



Cochrane
Library

Cochrane Database of Systematic Reviews

Amniotomy for shortening spontaneous labour (Review)

Smyth RMD, Markham C, Dowswell T

Smyth RMD, Markham C, Dowswell T.

Amniotomy for shortening spontaneous labour.

Cochrane Database of Systematic Reviews 2013, Issue 6. Art. No.: CD006167.

DOI: 10.1002/14651858.CD006167.pub4.

www.cochranelibrary.com

TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
BACKGROUND	2
OBJECTIVES	4
METHODS	4
RESULTS	7
Figure 1.	10
DISCUSSION	14
AUTHORS' CONCLUSIONS	16
ACKNOWLEDGEMENTS	17
REFERENCES	17
CHARACTERISTICS OF STUDIES	20
DATA AND ANALYSES	40
Analysis 1.1. Comparison 1 Amniotomy versus no amniotomy, Outcome 1 Length of first stage of labour.	44
Analysis 1.2. Comparison 1 Amniotomy versus no amniotomy, Outcome 2 Caesarean section.	45
Analysis 1.3. Comparison 1 Amniotomy versus no amniotomy, Outcome 3 Maternal satisfaction with childbirth experience.	46
Analysis 1.4. Comparison 1 Amniotomy versus no amniotomy, Outcome 4 Apgar score less than 7 at 5 minutes.	47
Analysis 1.5. Comparison 1 Amniotomy versus no amniotomy, Outcome 5 Length of second stage.	48
Analysis 1.6. Comparison 1 Amniotomy versus no amniotomy, Outcome 6 Dysfunctional labour.	49
Analysis 1.7. Comparison 1 Amniotomy versus no amniotomy, Outcome 7 Use of pain relief - epidural/narcotic.	50
Analysis 1.8. Comparison 1 Amniotomy versus no amniotomy, Outcome 8 Oxytocin augmentation.	51
Analysis 1.9. Comparison 1 Amniotomy versus no amniotomy, Outcome 9 Instrumental vaginal birth.	52
Analysis 1.10. Comparison 1 Amniotomy versus no amniotomy, Outcome 10 Caesarean section for fetal distress.	53
Analysis 1.11. Comparison 1 Amniotomy versus no amniotomy, Outcome 11 Caesarean section for prolonged labour.	54
Analysis 1.12. Comparison 1 Amniotomy versus no amniotomy, Outcome 12 Antepartum haemorrhage.	55
Analysis 1.13. Comparison 1 Amniotomy versus no amniotomy, Outcome 13 Postpartum haemorrhage.	56
Analysis 1.14. Comparison 1 Amniotomy versus no amniotomy, Outcome 14 Cord prolapse.	57
Analysis 1.15. Comparison 1 Amniotomy versus no amniotomy, Outcome 15 Maternal infection.	58
Analysis 1.16. Comparison 1 Amniotomy versus no amniotomy, Outcome 16 Maternal mortality.	59
Analysis 1.17. Comparison 1 Amniotomy versus no amniotomy, Outcome 17 Suboptimal or abnormal fetal heart trace (second stage of labour).	59
Analysis 1.18. Comparison 1 Amniotomy versus no amniotomy, Outcome 18 Admission to special care baby unit/neonatal intensive care unit.	60
Analysis 1.19. Comparison 1 Amniotomy versus no amniotomy, Outcome 19 Suboptimal or abnormal fetal heart trace (first stage of labour).	61
Analysis 1.20. Comparison 1 Amniotomy versus no amniotomy, Outcome 20 Meconium aspiration syndrome.	62
Analysis 1.21. Comparison 1 Amniotomy versus no amniotomy, Outcome 21 Acidosis as defined as a cord blood arterial pH of < 7.2.	63
Analysis 1.22. Comparison 1 Amniotomy versus no amniotomy, Outcome 22 Perinatal death.	64
Analysis 1.23. Comparison 1 Amniotomy versus no amniotomy, Outcome 23 Neonatal jaundice.	65
Analysis 1.24. Comparison 1 Amniotomy versus no amniotomy, Outcome 24 Seizures (neonate).	66
Analysis 1.25. Comparison 1 Amniotomy versus no amniotomy, Outcome 25 Respiratory distress syndrome.	67
Analysis 1.26. Comparison 1 Amniotomy versus no amniotomy, Outcome 26 Fracture.	68
Analysis 1.27. Comparison 1 Amniotomy versus no amniotomy, Outcome 27 Intracranial haemorrhage.	68
Analysis 1.28. Comparison 1 Amniotomy versus no amniotomy, Outcome 28 Cephalhaematoma.	69
Analysis 2.1. Comparison 2 Sensitivity analysis excluding trials with inadequate allocation concealment (c), Outcome 1 Length of first stage of labour.	70
Analysis 2.2. Comparison 2 Sensitivity analysis excluding trials with inadequate allocation concealment (c), Outcome 2 Caesarean section.	71

Analysis 2.3. Comparison 2 Sensitivity analysis excluding trials with inadequate allocation concealment (c), Outcome 3 Apgar score less than 7 at 5 minutes.	72
Analysis 3.1. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 1 Caesarean section.	73
Analysis 3.2. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 2 Maternal satisfaction with childbirth experience.	73
Analysis 3.3. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 3 Apgar score less than 7 at 5 minutes.	74
Analysis 3.4. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 4 Use of pain relief - epidural/narcotic.	74
Analysis 3.5. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 5 Oxytocin augmentation.	75
Analysis 3.6. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 6 Instrumental vaginal birth.	76
Analysis 3.7. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 7 Caesarean section for fetal distress.	76
Analysis 3.8. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 8 Caesarean section for prolonged labour.	77
Analysis 3.9. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 9 Maternal mortality.	78
Analysis 3.10. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 10 Admission to special care baby unit/neonatal intensive care unit.	78
APPENDICES	79
FEEDBACK	81
WHAT'S NEW	82
HISTORY	82
CONTRIBUTIONS OF AUTHORS	83
DECLARATIONS OF INTEREST	83
SOURCES OF SUPPORT	83
DIFFERENCES BETWEEN PROTOCOL AND REVIEW	84
NOTES	84
INDEX TERMS	84

Amniotomy for shortening spontaneous labour

Rebecca MD Smyth¹, Carolyn Markham², Therese Dowswell³

¹School of Nursing, Midwifery and Social Work, The University of Manchester, Manchester, UK. ²Northampton, UK. ³Cochrane Pregnancy and Childbirth Group, Department of Women's and Children's Health, The University of Liverpool, Liverpool, UK

Contact address: Rebecca MD Smyth, School of Nursing, Midwifery and Social Work, The University of Manchester, Jean McFarlane Building, Oxford Road, Manchester, M13 9PL, UK. rebecca.smyth@manchester.ac.uk.

Editorial group: Cochrane Pregnancy and Childbirth Group.

Publication status and date: New search for studies and content updated (no change to conclusions), published in Issue 6, 2013.

Review content assessed as up-to-date: 10 June 2013.

Citation: Smyth RMD, Markham C, Dowswell T. Amniotomy for shortening spontaneous labour. *Cochrane Database of Systematic Reviews* 2013, Issue 6. Art. No.: CD006167. DOI: 10.1002/14651858.CD006167.pub4.

Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

ABSTRACT

Background

Intentional artificial rupture of the amniotic membranes during labour, sometimes called amniotomy or 'breaking of the waters', is one of the most commonly performed procedures in modern obstetric and midwifery practice. The primary aim of amniotomy is to speed up contractions and, therefore, shorten the length of labour. However, there are concerns regarding unintended adverse effects on the woman and baby.

Objectives

To determine the effectiveness and safety of amniotomy alone for routinely shortening all labours that start spontaneously.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (30 April 2013).

Selection criteria

Randomised controlled trials comparing amniotomy alone versus intention to preserve the membranes. We excluded quasi-randomised trials.

Data collection and analysis

Two review authors assessed identified studies for inclusion, assessed risk of bias and extracted data. Primary analysis was by intention-to-treat.

Main results

We have included 15 studies in this updated review, involving 5583 women.

Amniotomy alone versus intention to preserve the membranes (no amniotomy) for spontaneous labour

There was no clear statistically significant difference between women in the amniotomy and control groups in length of the first stage of labour (mean difference (MD) -20.43 minutes, 95% confidence interval (CI) -95.93 to 55.06), caesarean section (risk ratio (RR) 1.27, 95% CI 0.99 to 1.63), maternal satisfaction with childbirth experience (MD -1.10, 95% CI -7.15 to 4.95) or Apgar score less than seven at five minutes (RR 0.53, 95% CI 0.28 to 1.00). There was no consistency between trials regarding the timing of amniotomy during labour in terms of cervical dilatation.

Amniotomy alone versus intention to preserve the membranes (no amniotomy) for spontaneous labours that have become prolonged

There was no clear statistically significant difference between women in the amniotomy and control group in caesarean section (RR 0.95, 95% CI 0.15 to 6.08), maternal satisfaction with childbirth experience (MD 22.00, 95% CI 2.74 to 41.26) or Apgar score less than seven at five minutes (RR 2.86, 95% CI 0.12 to 66.11).

Authors' conclusions

On the basis of the findings of this review, we cannot recommend that amniotomy should be introduced routinely as part of standard labour management and care. We recommend that the evidence presented in this review should be made available to women offered an amniotomy and may be useful as a foundation for discussion and any resulting decisions made between women and their caregivers.

PLAIN LANGUAGE SUMMARY

Amniotomy for shortening spontaneous labour

Evidence does not support routinely breaking the waters for women in normally progressing spontaneous labour or where labours have become prolonged.

The aim of breaking the waters (also known as artificial rupture of the membranes (ARM), or amniotomy), is to speed up and strengthen contractions, and thus shorten the length of labour. The membranes are punctured with a crochet-like long-handled hook during a vaginal examination, and the amniotic fluid floods out. Rupturing the membranes is thought to release chemicals and hormones that stimulate contractions. Amniotomy has been standard practice in recent years in many countries around the world. In some centres it is advocated and performed routinely in all women, and in many centres it is used for women whose labours have become prolonged. However, there is little evidence that a shorter labour has benefits for the mother or the baby. There are a number of potential important but rare risks associated with amniotomy, including problems with the umbilical cord or the baby's heart rate.

The review of studies assessed the use of amniotomy in all labours that started spontaneously. There were 15 studies identified, involving 5583 women, none of which assessed whether amniotomy increased women's pain in labour. The evidence showed no shortening of the length of first stage of labour and a possible increase in caesarean section. Routine amniotomy is not recommended as part of standard labour management and care.

BACKGROUND

Intentional artificial rupture of the amniotic membranes during labour, sometimes called amniotomy or 'breaking of the waters', is one of the most commonly performed procedures in modern obstetric and midwifery practice. It was introduced in the mid-eighteenth century, first being described in 1756 by an English obstetrician, Thomas Denman (Calder 1999). Whilst he emphasised reliance on the natural process of labour, he acknowledged that rupture of the membranes might be necessary in order to induce or accelerate labour (Dunn 1992). Since then, the popularity of amniotomy as a procedure has varied over time (Busowski 1995), more recently becoming common practice in many maternity units throughout the UK and Ireland (Downe 2001; Enkin 2000a; O'Driscoll 1993) and in parts of the developing world

(Camey 1996; Chanrachakul 2001; Rana 2003). The primary aim of amniotomy is to speed up contractions and, therefore, shorten the length of labour.

In order to carry out an amniotomy, the caregiver performs a vaginal examination to digitally identify the cervix and the amniotic membranes. The caregiver excludes the presence of blood vessels across the membranes (vasa praevia), and ensures the baby's head fits the pelvis well and is no higher than two stations above the ischial spines. The membranes are then punctured using a crochet-like, long-handled hook (commonly referred to as an amnihook) and the membranes are torn apart digitally. The mechanism by which amniotomy speeds up labour remains unclear. It is thought that when the membranes are ruptured, the production and release of prostaglandins and oxytocin increases, resulting in stronger

contractions and quicker cervical dilatation (Busowski 1995).

In the 1930s, Eastman suggested that the 'bag of water' surrounding the fetus played the principal role in the cervical dilatation and was therefore indispensable to normal labour (Busowski 1995). Since then this concept of a 'protective bag' around the baby buffering and protecting the infant from the immense forces of uterine contractions, as well as aiding cervical dilatation, has been supported by many (Caldeyro-Barcia 1972; Robertson 1997). Vincent 2005 advocated that the bulging membranes at the vaginal introitus serve to pre-stretch the perineum before the head has crowned. Pressure from intact membranes contributes to the ripening and effacement (softening and shortening) and dilatation of the cervix. The pressure exerted by the membranes stimulates oxytocin surges in much the same way as pressure from the fetal presenting part (Vincent 2005).

The membranes surrounding the fetus are composed of two layers: an inner amnion (nearest to the fetus) and an outer chorion (nearest to the lining of the pregnant womb, which is also known as the decidua). It is believed that softening and shortening of the cervix occurs in response to the prostaglandin PGE₂, which is produced by both the amnion during pregnancy and also by the cervix itself at term.

During pregnancy the chorion represents a protective barrier between the amnion and the cervix. The chorion produces an enzyme called prostaglandin dehydrogenase (PDHG), which breaks down PGE₂; thus preventing the cervix from ripening, and avoiding an inappropriate and premature labour.

There is a theory that in term pregnancies, the part of the chorion which is in direct contact with the opening of the cervix releases less PDHG. This allows the prostaglandins from the amnion to come into contact with the cervix, causing ripening and effacement (Van Meir 1997). If amniotomy is performed, the influence of these prostaglandins on the cervix is therefore lost. This may explain in part why, if amniotomy is performed too early (that is, when the woman is less than 3 cm dilated), it can be counterproductive and slow the process of labour down.

The converse has also been advocated: amniotomy use as a method of augmenting complicated and long labours (Enkin 2000b). Many caregivers promote amniotomy on the clinical assumption that it increases labour contractions and therefore improves labour progress (Frigoletto 1995), especially in those women with prolonged labour (Bohra 2003). Prolonged labour can be an important cause of maternal morbidity and contributes significantly to the half a million women who die annually as a result of childbirth (WHO 2004). Haemorrhage and infection, which are strongly associated with long labours, are also leading causes of maternal death (Neilson 2003). For this reason, amniotomy may be of particular importance for women in the developing world, who carry the greatest burden of morbidity and mortality associated with long labours.

As well as employing amniotomy as a method of shortening labour, many caregivers deem it valuable in order to introduce internal fetal monitoring devices, such as fetal scalp electrode or an intrauterine pressure catheter. It also allows visualisation of the amniotic fluid to detect meconium-stained liquor in order to identify factors, which may lead to fetal compromise (Clements 2001). There is some suggestion that the quality of the amniotic fluid can only provide limited information, as meconium-stained liquor may be seen in up to 20% of normal pregnancies at term (Gibb 1992).

In order to evaluate the use of amniotomy to accelerate spontaneous labour, it is important to identify what constitutes normal length of labour. Confirmation of the progress of labour is determined by the identification of increasing cervical dilatation and cervical effacement (Enkin 2000a; Neilson 2003). The definition provided by the World Health Organization for primiparous women is that more than 18 hours in labour is considered prolonged (Kwast 1994).

With the active management of labour protocol, introduced by O'Driscoll and Meagher over 30 years ago in Dublin, the use of amniotomy has been widely and readily accepted by some clinicians as part of a package ensuring that women are in labour for no longer than 12 hours (O'Driscoll 1993).

A study exploring the perceptions of duration of labour of traditional birth attendants in Mexico found that 29% of them thought labour of a primipara normally lasts 13 hours, and 74% of them said the labour of a multiparous woman could last between four and eight hours, but no longer than 10 hours (Camey 1996). Another developing country (Thailand) classified normal labour would not exceed 12 hours (Chanrachakul 2001).

As the definition of normality appears to be vague, with resulting variation in practice, no consensus has yet been reached amongst midwives and obstetricians to provide a definition of normality. For example, there is little agreement concerning the 'normality' of a labouring primigravida who has made slow but steady progress for 20 hours in the absence of maternal and fetal compromise (Neilson 2003). Very little is also known about how important length of labour is to most women (Impey 1999). Reducing length of labour might not be a desired effect for all women. There are arguments that the length and progress of labour should not be based on the premise that all labours are the same, but by the woman and baby's wellbeing (Jowitt 1993; Robertson 1997). Prolonged labour can ultimately be associated with delivery by caesarean section and low cord pH in the fetus. Amniotomy is employed with the assumption that shortening the length of labour is beneficial, with little apparent regard for any potential associated adverse effects. There is a lack of evidence to support or refute this assumption.

Although several theoretical hazards exist as a consequence of amniotomy, few studies show any substantial risks. Possible complications include umbilical cord prolapse, cord compression and

fetal heart rate decelerations, increased ascending infection rate, bleeding from fetal or placental vessels and discomfort of the actual procedure (Busowski 1995). Data from studies suggest that early amniotomy increases the hourly rate of severe variable fetal heart rate decelerations without evidence of an adverse effect on neonatal outcome (Fok 2005; Goffinet 1997). In areas of high HIV prevalence, it is considered prudent to leave the membranes intact for as long as possible to reduce perinatal transmission of HIV (WHO 2006). Under normal conditions, the membranes remain intact until full dilatation in 70% of the cases (Stewart 1995).

As well as the physical risks associated with amniotomy, psychological effects need to be considered (Clements 2001). The largest UK consumer-directed research investigating women's attitudes surrounding the procedure of amniotomy identified that some women worried more about removing the protective bag of fluid cushioning the baby's head than the pain or duration of their labours (NCT 1989). Some women complain that amniotomy causes them to lose control in labour (Robinson 2000). However, others (Impey 1999) have concluded that women prefer shorter labours and have little bias against the intervention (amniotomy) that helps achieve this.

Readers may wish to refer to the following Cochrane systematic reviews for further information about artificial rupture of the membranes: 'Package of care for active management in labour for reducing caesarean section rates in low-risk women' (Brown 2008), 'Amniotomy alone for induction of labour' (Bricker 2000), 'Amniotomy plus intravenous oxytocin for induction of labour' (Howarth 2001), 'Oestrogens alone or with amniotomy for cervical ripening or induction of labour' (Thomas 2001), and, 'Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care' (Wei 2012).

OBJECTIVES

To determine the effectiveness and safety of amniotomy alone for routinely shortening all labours that start spontaneously.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials comparing amniotomy alone versus intention to preserve the membranes. We excluded quasi-randomised trials.

Types of participants

Pregnant women with singleton pregnancies regardless of parity and gestation at trial entry in spontaneous labour.

Types of interventions

Amniotomy versus intention to preserve the membranes (no amniotomy).

Types of outcome measures

Primary outcomes

- (1) Length of first stage of labour (minutes);
- (2) caesarean section;
- (3) maternal satisfaction with childbirth experience;
- (4) low Apgar score (less than seven at five minutes or less than four at one minute).

Secondary outcomes

Maternal

- (5) Length of second stage of labour (minutes);
- (6) dysfunctional labour (no progress in cervical dilatation in two hours or ineffective uterine contractions (as defined by trial authors));
- (7) use of pain relief;
- (8) oxytocin augmentation and dosage used;
- (9) instrumental vaginal birth;
- (10) caesarean section for fetal distress;
- (11) caesarean section for prolonged labour;
- (12) antepartum haemorrhage (as defined by trial authors);
- (13) postpartum haemorrhage (as defined by trial authors);
- (14) perceived feeling of poor control in labour;
- (15) breastfeeding not established (as defined by trial authors);
- (16) adverse effects of amniotomy: umbilical cord prolapse, infection;
- (17) perineal trauma requiring suturing;
- (18) serious maternal morbidity or death;
- (19) uterine hyperstimulation;
- (20) postnatal depression (as defined by trial authors);
- (21) post-traumatic stress disorder (as defined by trial authors);
- (22) time interval between artificial rupture of membranes and birth of baby.

Fetal/infant

- (23) Admission to neonatal intensive care or special care nursery;
- (24) suboptimal or abnormal fetal heart trace;
- (25) meconium aspiration syndrome;
- (26) acidosis as defined as cord blood arterial pH less than 7.2;
- (27) serious neonatal morbidity or perinatal death (for example, infection, jaundice, seizures, respiratory distress syndrome, transmission of HIV, birth trauma (cephalhaematoma) disability in childhood).

Economic

- (28) Duration of postpartum hospital stay;
- (29) cost of hospital stay.

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 (30 April 2013).

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

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
 2. weekly searches of MEDLINE;
 3. weekly searches of EMBASE;
 4. handsearches of 30 journals and the proceedings of major conferences;
 5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.
- Details of the search strategies for CENTRAL, MEDLINE and EMBASE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the [Cochrane Pregnancy and Childbirth Group](#).
- Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.
- 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 trials identified by the updated search ([Garite 1993](#); [Mikki 2007](#); [Surichamorn 1998](#)).

Selection of studies

Two review authors independently assessed for inclusion all the potential studies we identified as a result of the search strategy. We resolved any disagreement through discussion or, if required, we consulted 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 resolved discrepancies through discussion or, if required, we consulted a third person. We entered data into Review Manager software ([RevMan 2011](#)) and checked for accuracy.

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

Assessment of risk of bias in included studies

Two review authors independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)). Any disagreement was resolved 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 could have produced comparable groups.

We assessed the method as:

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

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

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

We assessed the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);

- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

(3) 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. Studies were judged at low risk of bias if they were blinded, or if we judged that the lack of blinding could not have affected the results. Blinding was assessed separately for different outcomes or classes of outcomes.

We assessed the methods as:

- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel;
- low, high or unclear risk of bias 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 was supplied by the trial authors, we re-included missing data in the analyses which we carried out. We assessed methods as:

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

(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:

- low risk of bias (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other sources of bias

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

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

- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

(7) Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). 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 explored the impact of the level of bias through undertaking sensitivity analyses - see [Sensitivity analysis](#).

Measures of treatment effect

Dichotomous data

For dichotomous data, we presented results as summary risk ratio (RR) with 95% confidence intervals (CIs).

Continuous data

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

Unit of analysis issues

Cluster-randomised trials

We did not identify any cluster-randomised trials for inclusion.

Cross-over trials

We did not identify any cross-over trials for inclusion.

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; however, in this version of the review, none of the

included studies had high sample attrition or high levels of missing data.

For all outcomes analyses were carried out, as far as possible, on an intention-to-treat (ITT) basis, i.e. we attempted to include all participants randomised to each group in the analyses. 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 used the I^2 statistic to measure heterogeneity among the trials in each analysis. If we identified substantial heterogeneity, we explored it by pre-specified subgroup analysis. We regarded a heterogeneity level of above 50% as substantial.

Assessment of reporting biases

Where we suspected reporting bias (*see* 'Selective reporting bias' above), we attempted to contact study authors asking them to provide missing outcome data. Where this was not possible, and the missing data were thought to introduce serious bias, we planned to explore the impact of including such studies in the overall assessment of results by a sensitivity analysis.

Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2011). We used fixed-effect meta-analysis for combining data where trials were examining the same intervention, and the trials' populations and methods were judged sufficiently similar. Where we suspected clinical or methodological heterogeneity between studies sufficient to suggest that treatment effects may differ between trials, we used random-effects meta-analysis. If substantial heterogeneity was identified in a fixed-effect meta-analysis, this was noted and the analysis repeated using a random-effects method.

Subgroup analysis and investigation of heterogeneity

We planned to carry out the following subgroup analyses.

1. Parity: primigravid women compared with parous women.
2. Previous mode of delivery: caesarean section compared with vaginal delivery and no previous delivery.
3. Stage of labour: less than 3 cm dilated at the time of amniotomy compared with 3 cm or more.
4. Fetal surveillance: continuous fetal monitoring compared with intermittent.
5. Pain relief: pharmacological compared with non-pharmacological.
6. Position in labour: mobile versus restricted movement in women without an epidural.

We used the following outcomes in subgroup analysis.

1. Length of first stage of labour (minutes).
2. Caesarean section.
3. Low Apgar score less than seven at five minutes or less than four at one minute.
4. Length of second stage of labour (minutes).
5. Dysfunctional labour (no progress in cervical dilatation in two hours or ineffective uterine contractions (as defined by trial authors)).
6. Use of pain relief.
7. Oxytocin augmentation and dosage used.
8. Instrumental vaginal birth.
9. Caesarean section for fetal distress.
10. Caesarean section for prolonged labour.
11. Antepartum haemorrhage (as defined by trial authors).
12. Postpartum haemorrhage (as defined by trial authors).
13. Perceived feeling of poor control in labour.
14. Breastfeeding not established (as defined by trial authors).
15. Adverse effects of amniotomy: umbilical cord prolapse, infection.
16. Perineal trauma requiring suturing.
17. Uterine hyperstimulation.
18. Postnatal depression (as defined by trial authors).
19. Post-traumatic stress disorder (as defined by trial authors).
20. Time interval between artificial rupture of membranes and birth of baby.
21. Admission to neonatal intensive care or special care nursery.
22. Meconium aspiration syndrome.
23. Serious neonatal morbidity or perinatal death (for example, infection, jaundice, seizures, respiratory distress syndrome, transmission of HIV, birth trauma (cephalhaematoma) disability in childhood).

We conducted the planned subgroup analyses classifying whole trials by interaction tests as described by Deeks 2001.

Sensitivity analysis

We planned the following sensitivity analyses.

1. For primary outcomes, excluding trials where more than 30% of women did not receive the allocated treatment.
2. By trial quality, excluding trials with clearly inadequate concealment (high risk of bias).

RESULTS

Description of studies

Included studies

We included 15 trials (25 publications) in this review, totaling 5583 women. Of the three largest included trials, two were conducted in the UK (Johnson 1997; UK Amniotomy 1994; comprising, 940 and 1463 women respectively), and one in Canada (Fraser 1993, 925 women). Nine trials included both nulliparous and multiparous women, and six trials included nulliparous women only. In 14 trials, only women with a gestational age of at least 36 weeks were eligible for inclusion. The remaining trial (Garite 1993) used an estimated fetal weight of 2500 to 4000 grams. Thirteen trials compared amniotomy with intention to preserve the membranes (no amniotomy) only. Two trials (Barrett 1992; Stewart 1982) compared amniotomy with intention to preserve the membranes but if membranes were still intact at full dilatation, amniotomy was performed. Some eligibility criteria were notably different between studies, for example, cervical dilatation at randomisation, which ranged from immediate amniotomy regardless of cervical dilatation to amniotomy at full cervical dilatation. One trial (Blanch 1998) included women if their rate of progress in spontaneous labour crossed the action line of the partogram or they had made no progress over the previous two hours. One trial excluded women who did not achieve a spontaneous normal vaginal delivery without the use of oxytocin (Laros 1972).

None of the outcomes were consistently reported by all trials. The most commonly reported maternal outcomes pertained to mode of delivery (caesarean section and instrumental vaginal delivery), oxytocin use, analgesia use and length of second stage of labour. Maternal satisfaction with childbirth experience was only reported in two trials (Blanch 1998; Fraser 1991). The most frequently reported neonatal outcome was Apgar score less than seven at five minutes (five trials). None of the trials reported economic outcomes; however, one author (Mikki 2007) provided additional information on length of hospital stay, which was divided into blocks of hours up to 24 hours and then a group of women whose hospital stay was greater than 24 hours. There was no information provided about the number of days in total, and we were unable to calculate the mean length of hospital stay. We therefore felt that we were unable to present these data in a useful way. Studies were predominantly single centre ($n = 11$), and most were conducted in the UK, USA and Canada.

Excluded studies

There are nine excluded studies: eight were trials (Abdullah 2010; Garmi 2008; Levy 2002; Martell 1976; Nachum 2010; Schwarcz 1973; Schwarcz 1975; Surichamorn 1998) and one was a review article (Li 2006) which presented the results of a meta-analysis. Of the eight excluded trials: three were excluded on the basis of being quasi-randomised; two trials looked at amniotomy for induction or augmentation of labour; one trial looked at the effect of amniotomy on fetal heart rate tracing rather than on spontaneous labour; one trial compared amniotomy with oxytocin; and one trial did not provide enough information to determine whether it

was a randomised controlled trial.

Risk of bias in included studies

All studies included in the review were randomised. Methods of sequence generation were clear in eight studies and unclear in seven. Clear randomisation methods included tables of random numbers, random-number generators and randomisation by computer program (including random numbers) (Ajadi 2006; Blanch 1998; Franks 1990; Fraser 1993; Garite 1993; Johnson 1997; Laros 1972; UK Amniotomy 1994). In the remaining seven studies methods of sequence generation were not clearly described; one of these studies used non-stratified block randomisation (Zelen randomisation) (Fraser 1991).

Allocation concealment was adequate by description in six trials (Ajadi 2006; Barrett 1992; Blanch 1998; Fraser 1991; Fraser 1993; UK Amniotomy 1994). Two trials (Franks 1990; Garite 1993) used sealed envelopes that were not described as being opaque or sequentially numbered, and Mikki 2007 described using "simple randomisation with sealed envelopes". In four trials, information was not provided about allocation concealment and these were therefore classified as being unclear (Johnson 1997; Laros 1972; Shobeiri 2007; Stewart 1982). One trial (Wetrich 1970) used a blind draw to randomly assign patients, and in Guerresi 1981 participants were described as being divided into two equal subgroups.

Due to the nature of the intervention provided, it was not possible for the women or caregivers to be blinded. In one trial (Johnson 1997), the outcome assessor (statistician) was blinded to allocation. In two trials (Fraser 1991; Fraser 1993), outcome assessors were blinded to allocation only when looking at fetal heart rate outcomes. All trials reported 100% follow-up with the exception of Barrett 1992, which obtained 90% follow-up of its study population.

Overall the quality of included studies was variable. Several of the papers reported specific problems with recruitment and randomisation. Additionally, there was overlap of data between some of the included papers.

In two papers, a decision was made to stop the trial, one with only half the women recruited due to slow rate of recruitment (Blanch 1998), and one due to budget constraints (Mikki 2007).

In Barrett's paper (Barrett 1992), a number of randomisation cards were lost due to women being randomised before they were diagnosed as being in established labour. These women were discharged from hospital without their names being recorded and without any note of their allocated intervention being made, and thus on readmission did not receive their randomised treatment. It was impossible to comment on whether this was accidental or intentional. A more rigorous system was introduced, ensuring that a record was kept for each card drawn. As a result, women who were randomised before they were in established labour received their allocated intervention on readmission. The results were analysed

after the introduction of this system (120 women), and compared with the results for the whole study population (362 women). Findings noted in the comparison were that in the whole population there was a statistically significant difference between control and amniotomy groups for prevalence of fetal heart rate decelerations and epidural analgesia rate. In the group recruited after introduction of the new system there was no statistically significant difference between the groups for these outcomes, although the trend observed was the same.

The UK amniotomy collaborative trial ([UK Amniotomy 1994](#)) and primiparous women included in Johnson's paper ([Johnson 1997](#)) are the same trial. Johnson's group, based at St James' in Leeds, also recruited multiparous women. To allow for completeness of data reporting on all the outcomes presented, we extracted data on primiparous women from the Johnson paper, as it was difficult to extract information on some reported outcomes for

multiparous women only. In order to prevent doubling up of data, we carefully checked this information against the data presented in the UK amniotomy paper to allow us to accurately derive information from the UK amniotomy paper, excluding the Johnson data.

It was noted in the trial reports [UK Amniotomy 1994](#) and [Johnson 1997](#), that at St James', the computer randomly allocated women to a 4:3 ratio (amniotomy:control). This disparity was due to a computer programming error. It was stated in Johnson's paper that this error would not affect the study conclusions and that the effect on the statistical power was small.

There was no information detailed in any of the other included study reports regarding quality issues.

We assessed the risk of bias for each study, as summarised in [Figure 1](#).

Figure 1. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Ajadi 2006	+	+	-	+	+	+
Barrett 1992	?	+	-	?	?	-
Blanch 1998	+	+	-	+	-	-
Franks 1990	+	?	?	+	-	?
Fraser 1991	?	+	-	+	?	-
Fraser 1993	+	+	-	+	-	-
Garite 1993	+	?	?	+	?	+
Guerresi 1981	?	-	?	+	+	+
Johnson 1997	+	?	+	+	?	-
Laros 1972	+	?	?	+	-	+
Mikki 2007	?	?	-	+	-	-
Shobeiri 2007	?	?	?	+	-	?
Stewart 1982	?	?	?	+	-	-
UK Amniotomy 1994	+	+	?	+	+	-
Wetrich 1970	?	-	-	+	+	-

Effects of interventions

We included 15 studies in this updated review, involving 5583 women. We have presented the data from one trial (involving 39 women) where women had spontaneous, but prolonged labour (Blanch 1998) separately.

Data were available for all primary outcomes. It should be noted that many of the women allocated to the control group (intention to preserve the membranes) did in fact receive an amniotomy at some stage in their labour.

Amniotomy alone versus intention to preserve the membranes (no amniotomy) for spontaneous labour

Primary outcomes

Length of first stage of labour (minutes)

Five trials involving 1127 women reported this outcome. High levels of heterogeneity (I^2 greater than 50%) were observed and there were no trials with inadequate allocation concealment. We therefore applied a random-effects model. There was no statistically significant reduction in the length of the first stage of labour (mean difference (MD) -20.43 minutes, 95% confidence interval (CI) -95.93 to 55.06). When examining subgroups of primiparous women only and multiparous women only, again, there were no statistically significant differences (primiparous MD -57.93 minutes, 95% CI -152.66 to 36.80; multiparous MD 23.10 minutes, 95% CI -50.89 to 97.09) and no evidence of subgroup differences.

Caesarean section

Nine trials involving 5021 women reported this outcome. Women in the amniotomy group had an increased risk of delivery by caesarean section compared with women in the control group. It should be noted that this difference was not statistically significant (risk ratio (RR) 1.27, 95% CI 0.99 to 1.63). When examining subgroups of primiparous women only and multiparous women only, this effect was observed in both groups, but again, was not statistically significant.

Maternal satisfaction with childbirth experience

One trial involving 84 women reported data on maternal satisfaction with childbirth experience. There was no statistically significant difference between the two groups (MD -1.10, 95% CI -7.15 to 4.95).

Low Apgar score (less than seven at five minutes or less than four at one minute)

Six trials involving 3598 women reported data on Apgar score of less than seven at five minutes. There were no trials that reported specific data for Apgar of less than four at one minute. Babies born to mothers in the control group were more likely to have an Apgar score of less than seven at five minutes, than those in the amniotomy group. It should be noted that this difference was not statistically significant (RR 0.53, 95% CI 0.28 to 1.00). We then analysed the results of studies which looked at primiparous women only and multiparous women only. In the primiparous subgroup, babies born to women who were randomised to the control group showed a statistically significant increase in the chance of an Apgar score of less than seven at five minutes (RR 0.42, 95% CI 0.20 to 0.88). In the multiparous subgroup, there was no difference between the amniotomy group and control group (RR 1.00, 95% CI 0.06 to 15.96).

Secondary outcomes

Maternal

Length of second stage of labour (minutes)

Eight trials involving 1927 women reported this outcome. High levels of heterogeneity (I^2 greater than 50%) were observed and explored by excluding trials with inadequate allocation concealment (Wetrich 1970). This did not affect the heterogeneity overall. We therefore applied a random-effects model. There was no statistically significant difference in the length of the second stage of labour between the two groups (MD -1.33, 95% CI -2.92 to 0.26). Subgroup analysis of primiparous women only showed a statistically significant reduction in the length of the second stage of labour in the amniotomy group (MD -5.43, 95% CI -9.98 to -0.89). Subgroup analysis of multiparous women only showed that there was no statistically significant reduction in the length of the second stage of labour in the amniotomy group (MD -1.19, 95% CI -2.92 to 0.53).

Dysfunctional labour (no progress in cervical dilatation in two hours or ineffective uterine contractions (as defined by trial authors))

Three trials involving 1695 women reported this outcome. High levels of heterogeneity (I^2 greater than 50%) were observed and explored by excluding trials with inadequate allocation concealment (Mikki 2007). Removing this study from the meta-analysis

on this basis showed that women in the amniotomy group had a significantly reduced risk of dysfunctional labour (RR 0.75, 95% CI 0.64 to 0.88). We then performed the meta-analysis including all studies reporting the outcome and applied a random-effects model. This showed that women in the amniotomy group had a significantly reduced risk of dysfunctional labour (average RR 0.60, 95% CI 0.44 to 0.82). We conducted subgroup analyses on primiparous women only and multiparous women only which showed similar statistically significant trends (RR 0.49, 95% CI 0.33 to 0.73 and RR 0.44, 95% CI 0.31 to 0.62 respectively). There was no information available in order to conduct further subgroup analyses.

Use of pain relief

Eight trials involving 3475 women reported this outcome. High levels of heterogeneity (I^2 greater than 50%) were observed and explored by excluding trials with inadequate allocation concealment (Franks 1990; Mikki 2007; Wetrich 1970). This did not affect the heterogeneity overall. We therefore applied a random-effects model. There was no statistically significant difference between the two groups in the use of pain relief (average RR 1.05, 95% CI 0.96 to 1.14).

Oxytocin augmentation and dosage used

Eight trials involving 4264 women reported information on the use of oxytocin. There were no data regarding the doses required in the two groups. High levels of heterogeneity (I^2 greater than 50%) were observed and explored by excluding trials with inadequate allocation concealment (Mikki 2007). This did not affect the heterogeneity overall. We therefore applied a random-effects model. There was a statistically significant reduction in the use of oxytocin augmentation in the amniotomy group (average RR 0.72, 95% CI 0.54 to 0.96). We conducted subgroup analyses on primiparous women only and multiparous women only. There was no statistically significant difference for primiparous women (average RR 0.79, 95% CI 0.56 to 1.11) however, there was a significant decrease in the use of oxytocin for multiparous women in the amniotomy group (RR 0.43, 95% CI 0.30 to 0.60).

Instrumental vaginal birth

Ten trials involving 5121 women reported this outcome. There was no statistically significant difference between the two groups in the incidence of instrumental vaginal birth (RR 0.99, 95% CI 0.87 to 1.13).

Caesarean section for fetal distress

One trial involving 690 women reported this outcome. There was no statistically significant difference between the two groups in

the incidence of caesarean section for fetal distress (RR 3.21, 95% CI 0.66 to 15.60).

Caesarean section for prolonged labour

One trial involving 690 women reported this outcome. There was no statistically significant difference between the two groups in the incidence of caesarean section for prolonged labour (RR 0.45, 95% CI 0.07 to 3.03).

Antepartum haemorrhage (as defined by trial authors)

One trial involving 690 women reported this outcome. There was no statistically significant difference between the two groups in the incidence of antepartum haemorrhage (RR 0.63, 95% CI 0.08 to 4.84).

Postpartum haemorrhage (as defined by trial authors)

Two trials involving 1822 women reported this outcome. There was no statistically significant difference between the two groups in the incidence of postpartum haemorrhage (RR 0.46, 95% CI 0.14 to 1.50).

Adverse effects of amniotomy: umbilical cord prolapse, infection

Two trials involving 1615 women reported on cord prolapse. There was no statistically significant difference between the two groups in the incidence of cord prolapse (RR 1.00, 95% CI 0.14 to 7.10).

Serious maternal morbidity or death

Three trials involving 1740 women reported information on maternal mortality. There was no statistically significant difference between the two groups (RR 3.01, 95% CI 0.12 to 73.61). Three trials involving 2150 women reported information on the incidence of maternal infection. There was no statistically significant difference between the two groups (RR 0.88, 95% CI 0.43 to 1.82).

Fetal/infant

Admission to neonatal intensive care or special care nursery

Five trials involving 2686 women reported this outcome. There was no statistically significant difference between the two groups in the risk of admission to a neonatal intensive care or special care nursery (RR 1.08, 95% CI 0.77 to 1.50).

Suboptimal or abnormal fetal heart trace in the first stage of labour

Four trials involving 1284 women reported this outcome. Women in the amniotomy group had an increased risk of a suboptimal or abnormal fetal heart trace; however, the difference was not statistically significant (RR 1.09, 95% CI 0.97 to 1.23).

Suboptimal or abnormal fetal heart trace in the second stage of labour

One trial involving 567 women reported this outcome. There was no statistically significant difference between the two groups in the risk of suboptimal or abnormal fetal heart trace in the second stage of labour (RR 1.15, 95% CI 0.89 to 1.48).

Meconium aspiration syndrome

Two trials involving 1615 women reported this outcome. There was no statistically significant difference between the two groups in the risk of meconium aspiration syndrome (RR 3.06, 95% CI 0.83 to 11.27).

Acidosis as defined as cord blood arterial pH less than 7.2

Two trials involving 1014 women reported this outcome. There was no statistically significant difference between the two groups (RR 1.18, 95% CI 0.80 to 1.73).

Serious neonatal morbidity or perinatal death (for example, infection, jaundice, seizures, respiratory distress syndrome, transmission of HIV, birth trauma (cephalhematoma) disability in childhood

Eight trials involving 3397 women reported information on perinatal death. There was one perinatal death in the amniotomy group, but there was no significant difference between the two groups for this outcome (RR 3.01, 95% CI 0.12 to 73.59). Five trials including 3202 women reported information on neonatal jaundice. There was no statistically significant difference between the two groups (RR 0.90, 95% CI 0.76 to 1.06). Five trials including 4069 women reported information on neonatal seizures. There was no statistically significant difference between the two groups (RR 0.88, 95% CI 0.15 to 5.35). One trial including 459 women reported information on intracranial haemorrhage. There were no intracranial haemorrhages in either group. The same trial, including 459 women reported information on respiratory distress. There were no cases of respiratory distress in either group. Three trials including 1712 women reported information on cephalhaematoma. There was no statistically significant difference between the two groups (RR 1.52, 95% CI 0.81 to 2.83). One trial involving 925 women reported information on neonatal fracture. There was no statistically significant difference between the two groups (RR 3.01, 95% CI 0.31 to 28.80).

Economic

No outcomes were reported.

Subgroup analysis

We were able to conduct subgroup analysis examining parity (*see above*). There was not enough information available in the trials to enable us to examine other prespecified subgroups.

Sensitivity analysis

We did not to carry out planned sensitivity analyses excluding trials where more than 30% of women did not receive their allocated treatment, as this would have resulted in all of the studies with the exception of [Stewart 1982](#) being excluded.

We were able to carry out sensitivity analyses excluding trials with clearly inadequate allocation of concealment (rated high risk of bias). No differences were observed in terms of statistical significance for any outcome.

Amniotomy alone versus intention to preserve the membranes (no amniotomy) for spontaneous labours that have become prolonged

Primary outcomes

Caesarean section

One trial involving 39 women reported this outcome. There was no statistically significant difference between the two groups in the incidence of caesarean section (RR 0.95, 95% CI 0.15 to 6.08).

Maternal satisfaction with childbirth experience

One trial involving 39 women reported data on maternal satisfaction with childbirth experience. Women in the amniotomy group were more satisfied with their childbirth experience (MD 22.00, 95% CI 2.74 to 41.26).

Apgar score less than seven at five minutes or less than four at one minute

One trial involving 39 women reported this outcome. There was no statistically significant difference between the two groups in the incidence of low Apgar score in the two groups (RR 2.86, 95% CI 0.12 to 66.11).

Secondary outcomes

Maternal

Use of pain relief

One trial involving 39 women reported this outcome. There was no statistically significant difference between the two groups in the incidence of use of pain relief (RR 1.48, 95% CI 0.85 to 2.57).

Oxytocin augmentation and dosage used

One trial involving 39 women reported this outcome. There was no statistically significant difference between the two groups in the incidence of use of oxytocin augmentation (RR 0.87, 95% CI 0.52 to 1.47).

Instrumental vaginal birth

One trial involving 39 women reported this outcome. There was no statistically significant difference between the two groups in the incidence of instrumental vaginal birth (RR 1.27, 95% CI 0.33 to 4.93).

Caesarean section for fetal distress

One trial involving 39 women reported this outcome. There was no statistically significant difference between the two groups in the incidence of caesarean section for fetal distress (RR 2.86, 95% CI 0.12 to 66.11).

Caesarean section for prolonged labour

One trial involving 39 women reported this outcome. There was no statistically significant difference between the two groups in the incidence of caesarean section for prolonged labour (RR 0.47, 95% CI 0.05 to 4.82).

Maternal death

One trial involving 39 women reported this outcome; there were no maternal deaths.

Fetal/infant

Admission to neonatal intensive care or special care nursery

One trial involving 39 women reported this outcome; there were no admissions to neonatal intensive care or special care nursery.

Economic

No outcomes were reported.

Subgroup analysis

We were able to conduct subgroup analysis.

Sensitivity analysis

We did not to carry out planned sensitivity analyses.

None of the included trials reported on the following outcomes; perceived feeling of poor control in labour; breastfeeding not established (as defined by trial authors); perineal trauma requiring suturing; post-traumatic stress disorder (as defined by trial authors); uterine hyperstimulation; postnatal depression (as defined by trial authors); time interval between artificial rupture of membranes and birth of baby; duration of postpartum hospital stay; cost of hospital stay

DISCUSSION

In this updated review, we examine the effectiveness and safety of amniotomy alone for routinely shortening all labours that start spontaneously, and those labours that have started spontaneously but become prolonged.

A total of 5583 women were recruited into 15 trials comparing amniotomy with intention to preserve the membranes.

There were no differences observed between the two groups in the length of the first stage of labour. However, this outcome may be influenced by the differences between the inclusion criteria pertaining to the cervical dilatation at which women were randomised. For example, there may be a large time interval between women randomised at 3 cm and women randomised at 6 cm, which is not accounted for in the analysis. It is difficult to make recommendations for this reason. It is of interest that only five trials presented this outcome, when a common clinical justification for using amniotomy is in order to reduce the length of the first stage of labour. There was no difference in the length of second stage of labour between the two groups. There was, however, a statistically significant reduction in the length of the second stage of labour in the amniotomy group in primiparous women alone (mean difference (MD) -5.43, 95% confidence interval (CI) -9.98 to -0.89). This small difference is unlikely to be of clinical significance and probably does not justify the routine use of amniotomy in primiparous women.

There were several findings which were not statistically significant. The results show a trend towards an increase in the risk of a caesarean section which neared significance, in women who have

had an amniotomy. It cannot be stated that there is no difference between the two groups on the basis that this finding nears statistical significance, and there are clinically significant implications and consequences of having a caesarean section. It should be noted that the indication for caesarean section was often unclear in the trial reports. There is a possibility that the method of fetal heart monitoring in labour may be a confounding variable affecting the indication for caesarean section, over and above whether a woman received an amniotomy or not. In a recent Cochrane review (Alfirevic 2006) looking at continuous cardiotocography (CTG) in labour, there was a significant increase in caesarean sections associated with continuous cardiotocography (risk ratio (RR) 1.66, 95% CI 1.30 to 2.13, $n = 18,761$, 10 trials). It was not clear from many of the trials included in our review whether women received continuous monitoring or not, and we were therefore unable to adjust for this. On these grounds, we would suggest that further research needs to be done looking specifically at this factor and allowing adjustment for potential confounding influences. From the four trials that did report on CTG abnormalities as an outcome, there was evidence nearing statistical significance that CTG abnormalities in the first stage of labour may be increased in those women randomised to the amniotomy group. There was no difference observed between the two groups for CTG abnormalities in the second stage of labour, although only one trial reported on this outcome.

There was a disappointing lack of information from most trials about maternal satisfaction with childbirth experience, especially given that 10 of the 14 trials were published from 1990 onwards. This outcome was reported in two trials involving a total of 123 women. Evidence presented in Blanch 1998 showed a statistically significant improvement in maternal satisfaction in those women randomised to amniotomy. However, this study examined amniotomy for dysfunctional labour. As the authors suggested (Blanch 1998), it could be argued that women's reported satisfaction regarding their allocated treatment may have been influenced by the caregivers' attitudes towards the allocated intervention, and women's own perceptions of dysfunctional labour requiring some sort of intervention such as amniotomy rather than a conservative approach. Fraser 1991 reports no significant difference in maternal satisfaction between the two groups.

There was evidence to suggest that there may be reduced risk of a five-minute Apgar score of less than seven in the amniotomy group, in women with normally progressing spontaneous labours. There were no data provided from any of the studies for Apgar scores at one minute. None of the studies reported raw Apgar scores and this may be a useful outcome measurement for future trialists to examine. Interestingly, few of the studies presenting data on Apgar scores provided information on cord pH. There was no evidence, from trials that reported on the risk of a cord pH of less than 7.2, of any difference between the two groups.

Evidence from this review suggests that the use of amniotomy as

an intervention may reduce the incidence of dysfunctional labour. It should be borne in mind that this meta-analysis is subject to significant heterogeneity and it is difficult to draw strong conclusions about this outcome as a result. It should be noted that this statistically significant finding is based on only three studies, one of which (Fraser 1993) did not present data on the length of the first and second stages of labour in their trial reports. The second of these studies (Mikki 2007) presented data on the length of the second stage of labour and did not suggest a significant difference between the two groups. The third of these studies (Shobeiri 2007) suggested that amniotomy reduces the length of the first and second stage of labour.

There was a statistically significant reduction in the number of women requiring oxytocin augmentation in the amniotomy group compared with the control group in women with normally progressing spontaneous labours. There was no information provided on the dosage of oxytocin required in the two groups, and this may be useful to know for drawing clinical conclusions about oxytocin use. It should be noted that some trials excluded women who required oxytocin following randomisation, and this may have influenced the overall result.

There was no statistically significant difference in the use of pain relief between the two groups. It was not possible to separate those women who had received epidurals from those who had received other forms of analgesia, or those women who had received several different forms of analgesia. It would therefore be difficult to comment, for example, on whether amniotomy has any effect on the requirement for epidural analgesia. There was no information provided in any of the studies about how pain was assessed. This may be worth considering in further trials.

There were no differences between the two groups in terms of maternal mortality. One author (Mikki 2007) provided unpublished information on their study group, stating that there was one perinatal death in the amniotomy group due to congenital cardiac disease and lactic acidosis, however, the difference was not statistically significant.

There were no differences found in any other outcomes examined in this review. However, many of the outcomes that fall into this category were only examined in single studies, and it would therefore be difficult to draw any meaningful conclusions.

The results presented above should be interpreted with caution. We noted that in nine out of 15 reports, more than 30% of women randomised to the control group (no amniotomy) received an amniotomy at some stage in their labour. The incidence of this observation ranged from 31% to 60%. One paper stated that the incidence was 20% and the remaining five papers provided no information. The reasons for amniotomy being performed were not always made clear. There are several explanations for why this may have happened. Few papers outlined specific criteria for deviating from the allocated intervention, with the majority of trials allow-

ing clinicians to perform an amniotomy at their own discretion. It is likely that in most cases an amniotomy was performed in a woman allocated to the control group for a clinical reason, such as fetal compromise or in order to assess the amniotic fluid. We cannot comment on whether some women in the control group received amniotomy based on the clinician's personal preference or because amniotomy was contemporary 'recognised practice'. All data in the review were presented by allocated group (intention-to-treat), and not by the intervention actually received. This may have influenced the results, and hence the conclusions drawn.

Due to unclear presentation of data in some published reports, we were unable to extract information for certain outcomes.

AUTHORS' CONCLUSIONS

Implications for practice

On the basis of the findings of this review, we do not recommend that amniotomy be introduced routinely as part of standard management and care for labour. In the current review, data for women with spontaneous labours that have become prolonged (Blanch 1998) have been examined separately.

We recommend that the evidence presented in this review should be made available to women offered an amniotomy and may be useful as a foundation for discussion and any resulting decisions made between women and their caregivers. It may be useful to provide information to women as part of their antenatal education.

Implications for research

We are unable to make any explicit recommendations regarding the use of amniotomy for the purposes of shortening spontaneous labour, when either progressing normally or becoming prolonged. We have identified that there is a need for large, well-designed multicentre randomised controlled trials with clear allocation concealment to be conducted, which will allow for robust conclusions to be drawn. It is of note that the largest trial included in this review, which was a multicentre trial, involved only 1463 women.

As a result of the findings of this Cochrane review, we make the following suggestions for the design and conduct of future trials investigating the use of amniotomy for shortening labour.

- Large multicentre trials are needed, which look at clinically relevant outcomes.
- Trials need clearly specified inclusion criteria, to allow for direct extrapolation to clinical populations. For example, results from a study looking at women who received amniotomy at 6 cm may not be applicable to a woman who is only 3 cm dilated, as the risks and benefits of amniotomy may be different. This

clarity would also allow for more accurate comparability, both clinically, and also between trials for the purposes of systematic review by meta-analysis, allowing for more robust conclusions and recommendations.

- There are several outcomes that were analysed that warrant further investigation, or require more detailed information to be collected. They include the length of first stage of labour, specifically looking at the cervical dilatation at the time of intervention and whether this impacts on the outcome measures in any way and allowing for adjustments to be made if this is the case; and the length of second stage of labour to evaluate further whether there are any clinically significant differences between the two groups. Maternal satisfaction is of crucial importance and should be investigated using recognised validated satisfaction scores in order to allow women to make informed choices about their care; cord pH is a less subjective measure than Apgar scoring and where feasible may be a more useful outcome. Caesarean section information should be presented alongside clear information about indications for caesarean section and timing in labour, adjusted for confounding factors such as continuous fetal monitoring; categorical information on the type and doses of analgesia used and pain-scoring methods and scores should be presented to allow for important pain-relief conclusions to be drawn, as outlined in the discussion, in order to allow women to make informed choices about their care; and more detailed information should be given on the need for oxytocin and the doses required in each of the two groups and may be more clinically useful than dichotomous data only.

- Data on economic outcomes should be obtained, to allow for allocation of resources and service planning.

- As detailed in the discussion, there was a considerable amount of deviation from allocated intervention, with many women in the control group receiving amniotomy. We were unable to draw any conclusions about why this may have happened and it may have affected the comparability of the included studies and the validity of the results. It may be useful to record detailed information in future studies regarding the reasons for the allocated intervention not being adhered to for completeness, and to allow for comparability.

- It is difficult to blind women and caregivers to their randomised allocation because of the invasive nature of the intervention. It is possible to blind the outcome assessor to treatment allocation, which is strongly recommended. Any blinding should be clearly stated in the trial report.

- Trial protocols should be made publicly available in order to allow comparison of the reported outcomes with prespecified outcomes. This will allow outcome reporting bias to be kept to a minimum.

- It is essential to involve consumers in any future trials at all stages, and most significantly during the planning stages, in order to identify those outcomes which are deemed of most relevance and importance.

- There was no information in any of the included trials regarding long-term outcomes for women and babies. We propose that future trialists should consider instituting some form of long-term follow-up which is feasible and appropriate for the study population in question.

ACKNOWLEDGEMENTS

The 2013 updated systematic review was financially supported by the UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP) and the Department of Reproductive Health and Research (RHR), World Health Organization. The named authors alone are responsible for the views expressed in this publication.

The National Institute for Health Research (NIHR) is the largest single funder of the Cochrane Pregnancy and Childbirth Group. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NIHR, NHS or the Department of Health.

We would like to thank Jon Barrett, William Fraser, Russell Laros and Nahed Mikki for providing additional information and for responding to queries.

We thank Tippawan Liabsuetrakul for translating [Surichamorn 1998](#).

REFERENCES

References to studies included in this review

Ajadi 2006 *{published data only}*

Ajada MA, Kuti O, Orji EO, Ogunniyi SO, Sule SS. The effect of amniotomy on the outcome of spontaneous labour in uncomplicated pregnancy. *Journal of Obstetrics and Gynaecology* 2006;**26**(7):631–4.

Barrett 1992 *{published and unpublished data}*

Barrett JFR, Phillips K, Savage J, Lilford RJ. Randomised trial of routine amniotomy in labour vs the intention to leave the membranes intact until the second stage. Proceedings of Silver Jubilee British Congress of Obstetrics and Gynaecology; 1989 July 4–7; London, UK. 1989:114.
* Barrett JFR, Savage J, Phillips K, Lilford RJ. Randomized trial of amniotomy in labour vs the intention to leave membranes intact until the second stage. *British Journal of Obstetrics and Gynaecology* 1992;**99**:5–10.

Blanch 1998 *{published and unpublished data}*

Blanch G, Lavender T, Walkinshaw S, Alfirevic Z. Dysfunctional labour: a randomised trial. *British Journal of Obstetrics and Gynaecology* 1998;**105**(1):117–20.

Franks 1990 *{published data only}*

Franks P. A randomized trial of amniotomy in active labor. *Journal of Family Practice* 1990;**30**:49–52.

Fraser 1991 *{published data only}*

Fraser WD. *A randomized controlled trial of the effect of amniotomy on labour duration [MSc thesis]*. Alberta, Canada: University of Calgary, 1988.
* Fraser WD, Sauve R, Parboosingh IJ, Fung T, Sokol R, Persaud D. A randomized controlled trial of early

amniotomy. *British Journal of Obstetrics and Gynaecology* 1991;**98**:84–91.

Fraser 1993 *{published data only}*

* Fraser WD, Marcoux S, Moutquin JM, Christen A. Effect of early amniotomy on the risk of dystocia in nulliparous women. *New England Journal of Medicine* 1993;**328**: 1145–9.
Fraser WD, Marcoux S, Moutquin JM, Christen A, Armson BA, Verreault JP, et al. The Canadian multicentre RCT of early amniotomy. *American Journal of Obstetrics and Gynecology* 1992;**166**:275.
Fraser WD, Marcoux S, Moutquin JM, Christen A, Armson BA, Verreault JP, et al. The Canadian multicentre RCT of early amniotomy. *Journal of Perinatal Medicine* 1991;**2**:93S.
Goffinet F, Fraser WD, Marcoux S, Breart G, Moutquin JM, Daris M, et al. Early amniotomy increases the frequency of fetal heart rate abnormalities. *British Journal of Obstetrics and Gynaecology* 1997;**104**:548–53.

Garite 1993 *{published data only}*

Garite TJ, Porto M, Carlson NJ, Rumney PJ, Reimbold PA. The influence of elective amniotomy on fetal heart rate patterns and the course of labor in term patients: a randomized study. *American Journal of Obstetrics and Gynecology* 1993;**168**:1827–32.

Guerresi 1981 *{published data only}*

Guerresi E, Gori G, Beccari A, Farro M, Mazzanti C. Influence of spasmolytic treatment and amniotomy on delivery times: a factorial clinical trial. *Clinical Therapeutics* 1981;**3**(5):382–8.

Johnson 1997 {published data only}

- * Johnson N, Lilford R, Guthrie K, Thornton J, Barker M, Kelly M. Randomised trial comparing a policy of early with selective amniotomy in uncomplicated labour at term. *British Journal of Obstetrics and Gynaecology* 1997;**104**:340–6.
- Peake K, O'Connor RA. Randomised trial comparing a policy of early with selective amniotomy and uncomplicated labour at term. [letter; comment]. *British Journal of Obstetrics and Gynaecology* 1997;**104**:1215–6.

Laros 1972 {published and unpublished data}

- Laros RK, Work BA, Witting WC. Amniotomy during the active phase of labor. *Obstetrics & Gynecology* 1972;**39**:702–4.

Mikki 2007 {published data only}

- Mikki N, Wick L, Abu-Asab N, Abu-Rmeileh NM. A trial of amniotomy in a Palestinian hospital. *Journal of Obstetrics and Gynaecology* 2007;**27**(4):368–73.

Shobeiri 2007 {published data only}

- Shobeiri F, Tehranian N, Nazari M. Amniotomy in labor. *International Journal of Gynecology & Obstetrics* 2007;**96**(3):197–8.

Stewart 1982 {published data only}

- Stewart P, Kennedy JH, Calder AA. Spontaneous labour: when should the membranes be ruptured?. *British Journal of Obstetrics and Gynaecology* 1982;**89**:39–43.

UK Amniotomy 1994 {published data only}

- Thornton JG. A multicentre randomised trial of early vs late amniotomy in spontaneous primiparous labour. *Journal of Perinatal Medicine* 1992;**20**(1):37.
- Thornton JG. A multicentre randomised trial of early vs late amniotomy in spontaneous primiparous labour. Proceedings of 26th British Congress of Obstetrics and Gynaecology; 1992 July 7–10; Manchester, UK. 1992:82.
- Thornton JG. The psychological effects of amniotomy. Proceedings of 26th British Congress of Obstetrics and Gynaecology; 1992 July 7–10; Manchester, UK. 1992:53.
- UK Amniotomy Group. A multicentre randomised trial of amniotomy in spontaneous first labour at term. *British Journal of Obstetrics and Gynaecology* 1994;**101**:307–9.
- * UK Amniotomy Group. Comparing routine vs delayed amniotomy in spontaneous first labor at term. A multicenter randomized trial. *Online Journal of Current Clinical Trials* 1994;**3**:122.

Wetrich 1970 {published data only}

- Wetrich DW. Effect of amniotomy upon labor. *Obstetrics & Gynecology* 1970;**35**:800–6.

References to studies excluded from this review**Abdullah 2010 {published data only}**

- Abdullah A, Saboohi S, Hashami U. Effects of amniotomy versus spontaneous rupture of membrane on progress of labour and foetal outcome in primigravidae. *Journal of Liaquat University of Medical and Health Sciences* 2010;**9**(1):33–6.

Garmi 2008 {published data only}

- Garmi G, Salim R, Kadan I, Zafran N, Shalev E, Nachum Z. Augmentation of labour for prolonged latent phase at term: a randomized comparison between amniotomy, oxytocin or both. *American Journal of Obstetrics and Gynecology* 2008;**199**(6 Suppl 1):S58.

Levy 2002 {published data only}

- Levy R, Ben-Arie A, Paz B, Hazan I, Blickstein I, Hagay Z. Randomized clinical trial of early vs late amniotomy following cervical ripening with a foley catheter. *American Journal of Obstetrics and Gynecology* 2000;**182**(1 Pt 2):S136.
- * Levy R, Ferber A, Ben-Arie A, Paz B, Hazan Y, Blickstein I, et al. A randomised comparison of early versus late amniotomy following cervical ripening with a foley catheter. *BJOG: an international journal of obstetrics and gynaecology* 2002;**109**:168–72.

Li 2006 {published data only}

- Li N, Wang Y, Zhou H. Effects of routine early amniotomy on labor and health status of foetus and neonate: a meta-analysis. *Zhonghua fu chan ke za zhi* 2006;**41**(1):16–9.

Martell 1976 {published data only}

- Martell M, Belizan JM, Nieto F, Schwarcz R. Blood acid-base balance at birth in neonates from labors with early and late rupture of the membranes. *Journal of Pediatrics* 1976;**89**:963–7.

Nachum 2010 {published data only}

- Nachum Z, Garmi G, Kadan Y, Zafran N, Shalev E, Salim R. Comparison between amniotomy, oxytocin or both for augmentation of labor in prolonged latent phase: a randomized controlled trial. *Reproductive Biology and Endocrinology* 2010;**8**:136.

Schwarcz 1973 {published data only}

- Schwarcz R, Althabe O, Caldeyro-Barcia R, Belitsky R, Lanchares JL, Alvarez R, et al. Fetal heart rate patterns in labors with intact and with ruptured membranes. *Journal of Perinatal Medicine* 1973;**1**:153–65.

Schwarcz 1975 {published data only}

- * Caldeyro-Barcia R, Schwarcz R, Belizan JM, Martell M, Nieto F, Sabatino H, et al. Adverse perinatal effects of early amniotomy during labor. In: Gluck L editor(s). *Modern Perinatal Medicine*. Chicago: Yearbook Publishers, 1974: 431–49.
- Schwarcz R, Belizan JM, Nieto F, Tenzer SM. Latin American collaborative study about the effects of membrane rupture on labor and newborn. *Boletin de la Oficina Sanitaria Panamericana* 1975;**59**:1–80.

Surichamorn 1998 {published data only}

- Surichamorn P. Effect of artificial rupture of amniotic membranes and non-artificial rupture of amniotic membranes to labor time in normal labor women. *Chon Buri Hospital Journal* 1998;**24**(1):38–47.

Additional references**Alfirevic 2006**

- Alfirevic Z, Devane D, Gyte GML. Continuous cardiotocography (CTG) as a form of electronic fetal

- monitoring (EFM) for fetal assessment during labour. *Cochrane Database of Systematic Reviews* 2006, Issue 3. [DOI: 10.1002/14651858.CD006066]
- Bohra 2003**
Bohra U, Donnelly J, O'Connell MP, Geary MP, MacQuillan K, Keane DP. Active management of labour revisited: the first 1000 primiparous labours in 2000. *Journal of Obstetrics and Gynaecology* 2003;**23**(2):118–20.
- Bricker 2000**
Bricker L, Luckas M. Amniotomy alone for induction of labour. *Cochrane Database of Systematic Reviews* 2000, Issue 4. [DOI: 10.1002/14651858.CD002862]
- Brown 2008**
Brown HC, Paranjothy S, Dowswell T, Thomas J. Package of care for active management in labour for reducing caesarean section rates in low-risk women. *Cochrane Database of Systematic Reviews* 2008, Issue 4. [DOI: 10.1002/14651858.CD004907.pub2]
- Busowski 1995**
Busowski JD, Parsons MT. Amniotomy to induce labour. *Clinical Obstetrics and Gynecology* 1995;**38**(2):246–58.
- Calder 1999**
Calder AA. Chapter 20. Normal labour. In: Edmonds DK editor(s). *Dewhurst's Textbook of Obstetrics and Gynaecology for Postgraduates*. 6th Edition. Blackwell Science, 1999.
- Caldeyro-Barcia 1972**
Caldeyro-Barcia R. The effects of rupture of membranes on fetal heart rate patterns. *International Journal of Gynecology & Obstetrics* 1972;**10**:169–72.
- Camey 1996**
Camey XC, Barrios CG, Guerrero XR, Nunez-Urquiza RM, Hernandez DG, Glass AL. Traditional birth attendants in Mexico: advantages and inadequacies of care for normal deliveries. *Social Science and Medicine* 1996;**43**(2):199–207.
- Chanrachakul 2001**
Chanrachakul B, Herabutya Y, Panburana P. Active management of labor: is it suitable for a developing country? . *International Journal of Gynecology & Obstetrics* 2001;**72**: 229–34.
- Clements 2001**
Clements C. Amniotomy in spontaneous, uncomplicated labour at term. *British Journal of Midwifery* 2001;**9**(10): 629–34.
- Deeks 2001**
Deeks JJ, Altman DG, Bradburn MJ. Statistical methods for examining heterogeneity and combining results from several studies in meta-analysis. In: Egger M, Davey Smith G, Altman DG editor(s). *Systematic Reviews in Health Care: Meta-analysis in Context*. London: BMJ Books, 2001.
- Downe 2001**
Downe S, McCormick C, Lawrence Beech B. Labour interventions associated with normal birth. *British Journal of Midwifery* 2001;**9**(10):602–6.
- Dunn 1992**
Dunn PM. Dr Thomas Denman of London (1733-1815): rupture of the membranes and management of the cord. *Archives of Disease in Childhood* 1992;**67**(7 Spec No):882–4.
- Enkin 2000a**
Enkin M, Keirse MJNC, Neilson J, Crowther C, Duley L, Hodnett E, et al. Chapter 31. Monitoring the progress of labour. *A Guide to Effective Care in Pregnancy and Childbirth*. 3rd Edition. Oxford: Oxford University Press, 2000:281–8.
- Enkin 2000b**
Enkin M, Keirse MJNC, Neilson J, Crowther C, Duley L, Hodnett E, et al. Chapter 35. Prolonged labour. *A Guide to Effective Care in Pregnancy and Childbirth*. 3rd Edition. Oxford: Oxford University Press, 2000:332–40.
- Fok 2005**
Fok WY, Leung TY, Tsui MH, Leung TN, Lau TK. Fetal hemodynamic changes after amniotomy. *Acta Obstetrica et Gynecologica Scandinavica* 2005;**84**:166–9.
- Frigoletto 1995**
Frigoletto FD, Lieberman E, Lang JM, Cohen A, Barss V, Ringer S, et al. A clinical trial of active management in labour. *New England Journal of Medicine* 1995;**333**(12): 745–50.
- Gates 2005**
Gates S. Methodological Guidelines. The Editorial Team. Pregnancy and Childbirth Group. About The Cochrane Collaboration (Cochrane Review Groups (CRGs)) 2005, Issue 1.
- Gibb 1992**
Gibb D, Arulkumaran S. Chapter 8. Cardiotocograph interpretation: clinical scenarios. Meconium-stained amniotic fluid. *Fetal Monitoring in Practice*. Oxford: Butterworth-Heinemann, 1992:130.
- Goffinet 1997**
Goffinet F, Fraser W, Marcoux S. Early amniotomy increases the frequency of fetal heart rate abnormalities. *British Journal of Obstetrics and Gynaecology* 1997;**104**(5):548–53.
- Higgins 2005**
Higgins JPT, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions 4.2.5 [updated March 2005]. In: The Cochrane Library, Issue 3, 2005. Chichester, UK: John Wiley & Sons, Ltd. 2005.
- Higgins 2011**
Higgins JPT, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.
- Howarth 2001**
Howarth GR, Botha DJ. Amniotomy plus intravenous oxytocin for induction of labour. *Cochrane Database of Systematic Reviews* 2001, Issue 3. [DOI: 10.1002/14651858.CD003250]

Impey 1999

Impey L. Maternal attitudes to amniotomy and labour duration: a survey in early pregnancy. *Birth* 1999;**26**(4): 211–4.

Jowitt 1993

Jowitt M. Chapter 9. The cascade of intervention. *Childbirth Unmasked*. Wooller, 1993.

Kwast 1994

Kwast BE, Lennox CE, Farley TMM, Olayinka I. World Health Organization partograph in management of labour. *Lancet* 1994;**343**(8910):1399–404.

NCT 1989

National Childbirth Trust. *Rupture of the Membranes in Labour. A Survey Conducted by the National Childbirth Trust*. London: National Childbirth Trust Publications, 1989.

Neilson 2003

Neilson JP, Lavender T, Quenby S, Wray S. Obstructed labour. *British Medical Bulletin* 2003;**67**:191–204.

O'Driscoll 1993

O'Driscoll K, Meagher D, Boylan P. Chapter 4. Duration of labour. *Active Management of Labour*. 3rd Edition. London: Mosby, 1993.

Rana 2003

Rana TG, Rajopadhyaya R, Bajracharya B, Karmacharya M, Osrin D. Comparison of midwifery-led and consultant-led maternity care for low risk deliveries in Nepal. *Health Policy and Planning* 2003;**18**(3):330–7.

RevMan 2011 [Computer program]

The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). Version 5.1. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011.

Robertson 1997

Robertson A. Chapter 6. How can I help. *The Midwife Companion*. ACE Graphics, 1997.

Robinson 2000

Robinson J. Her master's voice? Amniotomy in Dublin. *British Journal of Midwifery* 2000;**8**(1):110.

Stewart 1995

Stewart P, Kennedy JH, Calder AA. Spontaneous labour: when should the membranes be ruptured?. *British Journal of Obstetrics and Gynaecology* 1995;**89**(1):39–43.

Thomas 2001

Thomas J, Kelly AJ, Kavanagh J. Oestrogens alone or with amniotomy for cervical ripening or induction of labour. *Cochrane Database of Systematic Reviews* 2001, Issue 4. [DOI: 10.1002/14651858.CD003393]

Van Meir 1997

Van Meir CA, Ramirez MM, Matthews SG, Calder AA, Keirse MJNC, Challis JRG. Chorionic prostaglandin catabolism is decreased in the lower uterine segment with term labour. *Placenta* 1997;**18**:109–14.

Vincent 2005

Vincent M. Amniotomy: to do or not to do?. *Midwifery* 2005;**8**(5):228–9.

Wei 2012

Wei S, Wo BL, Qi HP, Xu H, Luo ZC, Roy C, et al. Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care. *Cochrane Database of Systematic Reviews* 2012, Issue 9. [DOI: 10.1002/14651858.CD006794.pub3]

WHO 2004

WHO, UNICEF, UNFPA. Maternal Mortality in 2000: estimates developed by WHO, UNICEF and UNFPA, Geneva 2004. [http://www.who.int/reproductive-health/publications/maternal`mortality`2000/index.html](http://www.who.int/reproductive-health/publications/maternal%20mortality%202000/index.html) (accessed March 2006).

WHO 2006

WHO. Managing complications in pregnancy and childbirth - a guide for midwives and doctors. www.who.int/reproductive-health/impac/Procedures/Induction (accessed March 2006).

References to other published versions of this review**CDSR 2006**

Fraser WD, Turcot L, Krauss I, Brisson-Carrol G. Amniotomy for shortening spontaneous labour. *Cochrane Database of Systematic Reviews* 2006, Issue 3. [DOI: 10.1002/14651858.CD000015.pub2]

Smyth 2007a

Smyth R, Alldred SK, Markham C. Amniotomy for shortening spontaneous labour (Protocol). *Cochrane Database of Systematic Reviews* 2007, Issue 1. [DOI: 10.1002/14651858.CD006167]

Smyth 2007b

Smyth RMD, Alldred SK, Markham C. Amniotomy for shortening spontaneous labour. *Cochrane Database of Systematic Reviews* 2007, Issue 4. [DOI: 10.1002/14651858.CD006167.pub2]

Smyth 2013

Smyth RMD, Alldred SK, Markham C. Amniotomy for shortening spontaneous labour. *Cochrane Database of Systematic Reviews* 2013, Issue 1. [DOI: 10.1002/14651858.CD006167.pub3]

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Ajadi 2006

Methods	Randomisation: blocked randomisation technique using table of random numbers. Allocation concealment: sequentially-numbered, sealed opaque envelopes, eligible women. Blinding: woman and caregiver not blinded. Follow-up: 100%.
Participants	128 women were enrolled, 64 in experimental group and 64 in control group. Eligibility: spontaneous labour, 37-42 weeks' gestation, singleton pregnancies, cephalic presentation, cervical dilatation of at least 4 cm but less than 6 cm, multiparous and primiparous women. Exclusion: previous caesarean section, haemoglobinopathies, hypertension, malpresentation, multiple pregnancies APH, suspected IUGR, fetal distress. Mean cervical dilatation at entry to study: 4.6 ± 0.32 in the amniotomy group and 4.7 ± 0.30
Interventions	Experimental: amniotomy. Control: no amniotomy.
Outcomes	Women: mode of delivery, oxytocin, length of second stage of labour. Fetal/infant: Apgar score (no data given).
Notes	Multicentre/single centre: multicentre (2 sites). Setting: Nigeria. Additional outcomes: randomisation to delivery, randomisation to full cervical dilatation, Apgar score of less than 7 at 1 minute. In the amniotomy group 5 women had SROM after randomisation and in the intact group, 83 had amniotomy. Author contacted March 2007 for additional data, still awaiting response (30/03/07)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Blocked randomisation technique using table of random numbers
Allocation concealment (selection bias)	Low risk	Allocation concealment: sequentially-numbered, sealed opaque envelopes, eligible women
Blinding (performance bias and detection bias) All outcomes	High risk	Woman and caregiver not blinded. Outcome assessor - information not given about blinding

Ajadi 2006 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up 100%.
Selective reporting (reporting bias)	Low risk	All outcomes in the methods section have been reported on in the results section
Other bias	Low risk	No evidence of any other form of bias.

Barrett 1992

Methods	Randomisation: randomised controlled trial stratified by parity. Allocation concealment: numbered sealed opaque envelopes. Blinding: woman and caregiver not blinded. Follow-up: 90%.
Participants	362 women (does not include 36 women lost to follow-up), 183 in experimental group and 179 in control group. Eligibility: spontaneous labour, 37-42 weeks' gestation, singleton pregnancies, multiparous and primiparous women. Exclusion: none given in paper. Mean cervical dilatation at entry to study: 4 cm in ARM group and 4.1 in the control group
Interventions	Experimental: amniotomy. Control: no amniotomy, once full dilatation reached any membranes that had remained intact were ruptured
Outcomes	Women: length of first and second stage of labour, mode of delivery, pain relief - epidural, use of oxytocin. Fetal/infant: CTG abnormality.
Notes	Multicentre/single centre: single. Setting: Leeds UK. Additional outcomes: meconium-stained amniotic fluid, postpartum pyrexia > 38°C, umbilical vein lactate levels. In the amniotomy group 5 women had SROM after randomisation and in the control group, 83 women (46%) had amniotomy. Discrepancies in the number of cards drawn and the number of women entered into trial log. See text of review for further information. Author contacted, able to confirm singletons only, but does not hold data on other outcomes (Nov 2006)

Risk of bias

Bias	Authors' judgement	Support for judgement
------	--------------------	-----------------------

Barrett 1992 (Continued)

Random sequence generation (selection bias)	Unclear risk	Randomisation: randomised controlled trial stratified by parity
Allocation concealment (selection bias)	Low risk	Allocation concealment: numbered sealed opaque envelopes.
Blinding (performance bias and detection bias) All outcomes	High risk	Blinding: woman and caregiver not blinded. Outcome assessor - information not given about blinding
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Follow-up: 90%.
Selective reporting (reporting bias)	Unclear risk	Authors stated that they were unable to report on several pre-specified outcomes (pain scores in women without epidural) due to infrequency of measurement and problems with blinding. It is not clear what pain scoring system was in use, and whether blinding of the woman or the assessor was the issue Apparently free from other selective reporting bias.
Other bias	High risk	Discrepancies in the number of cards drawn and the number of women entered into trial log. Authors state in the text of the paper that they were unable to rule out the possibility of cheating. See text of review for further information

Blanch 1998

Methods	Randomisation: to 1 of 3 different interventions using a table of random numbers. Allocation concealment: consecutively-numbered, sealed opaque envelopes. Blinding: participant and caregiver not blinded. Paper does not state blinding of outcome assessor. Follow-up: 1 woman with a breech presentation was randomised in error and therefore excluded from analysis
Participants	61 women recruited, data available for 60. Eligibility: dysfunctional labour (spontaneous) where women have not progressed satisfactorily (diagnosed using a partogram), intact membranes, singleton fetus, cephalic presentation, gestation of at least 37 weeks, cervical dilatation of at least 3 cm, full cervical effacement, contractions at least every 5 minutes lasting 20 seconds, no evidence of fetal distress, primiparous and multiparous women. Exclusion: contraindications to oxytocin.

Interventions	Experimental: group 1 - oxytocin with amniotomy (not analysed in review), group 2 - amniotomy alone. Control: expectant management (no amniotomy).
Outcomes	Women: caesarean section, maternal satisfaction, Apgar score, epidural, oxytocin use, instrumental vaginal delivery. Fetal/infant: SCBU admission, cord pH.
Notes	Multicentre/single centre: single centre. Setting: Liverpool, UK. Due to slow rate of recruitment, a decision was made to stop the trial with only half the women recruited. Additional outcomes collected: dilatation rates, cord base excess, randomisation to delivery interval

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation: to 1 of 3 different interventions using a table of random numbers
Allocation concealment (selection bias)	Low risk	Allocation concealment: consecutively-numbered, sealed opaque envelopes
Blinding (performance bias and detection bias) All outcomes	High risk	Blinding: participant and caregiver not blinded. Paper does not state blinding of outcome assessor
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up: 1 woman with a breech presentation was randomised in error and therefore excluded from analysis
Selective reporting (reporting bias)	High risk	Additional outcomes reported in tables (oxytocin and epidural use) not specified in the methods section
Other bias	High risk	Due to slow rate of recruitment, a decision was made to stop the trial with only half the women recruited

Franks 1990

Methods	Randomisation: allocated randomly using a random-number generator. Allocation concealment: sealed envelopes. Blinding: paper does not state. Follow-up: 100%.
Participants	53 women, 26 in experimental group and 27 in control group. Eligibility: spontaneous labour, intact membranes, at least 36 weeks' gestation, nulliparous and multiparous women. Exclusion: multiple pregnancy, bleeding, conductive anaesthesia, premature labour, more than 6 cm dilated, contraindication to amniotomy, breech presentation
Interventions	Experimental: amniotomy. Control: no amniotomy.
Outcomes	Women: caesarean section, analgesia use, length of first stage, length of second stage. Fetal/infant: Apgar score.
Notes	Multicentre/single centre: single centre. Setting: New York, USA. In the control group, 16 (59%) women received an amniotomy before full dilatation, at clinician's discretion. Additional outcomes: weight of baby, time from randomisation to delivery

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation: allocated randomly using a random-number generator
Allocation concealment (selection bias)	Unclear risk	Allocation concealment: sealed envelopes.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding: paper does not state.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up: 100%.
Selective reporting (reporting bias)	High risk	All pre-specified outcomes reported
Other bias	Unclear risk	Papare suggests additional unspecified analyses performed (outliers excluded)

Fraser 1991

Methods	Randomisation: non-stratified block randomisation (Zelen randomisation). Allocation concealment: numbered sealed opaque envelopes. Blinding: woman and caregiver not blinded, outcome assessor blinded regarding fetal heart tracing assessment. Follow-up: 100%.
Participants	97 women recruited, 50 in control group, 47 in experimental group. Eligibility: nulliparous, spontaneous labour, single fetus, cephalic presentation, at least 38 weeks' pregnant, normal FHR tracing on admission, cervical dilatation of at least 5 cm. Exclusion: history of genital herpes, proteinuria or hypertension
Interventions	Experimental: amniotomy. Control: no amniotomy.
Outcomes	Women: oxytocin use, caesarean section, instrumental vaginal delivery, length of second stage of labour. Fetal/infant: suboptimal FHR tracing, Apgar score, cord pH, cephalhaematoma
Notes	Multicentre/single centre: single centre. Setting: Quebec, Canada. 19 out of 50 (38%) women in the control group had an amniotomy - 11 for augmentation and 8 for fetal distress. Additional outcomes: interval from randomisation to delivery, birthweight, blood transfusion, labour onset to rupture of membranes, ventilation of infant Women with cervical dilatation of less than 3 cm were randomised when the head was fixed in the pelvis and the cervix had undergone a change in dilatation after admission. Women with cervical dilatation of at least 3 cm were randomised when the fetal head was fixed in the pelvis

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation: non-stratified block randomisation (Zelen randomisation)
Allocation concealment (selection bias)	Low risk	Allocation concealment: numbered sealed opaque envelopes.
Blinding (performance bias and detection bias) All outcomes	High risk	Blinding: woman and caregiver not blinded, outcome assessor blinded regarding fetal heart tracing assessment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up: 100%.
Selective reporting (reporting bias)	Unclear risk	Difficult to extract planned outcomes from text.

Fraser 1991 (Continued)

Other bias	High risk	Additional subgroup analysis performed, not pre-specified in methodology regarding women who achieved vaginal delivery only
------------	-----------	-----------------------------------------------------------------------------------------------------------------------------

Fraser 1993

Methods	Randomisation: centralised and group assignment stratified according to medical centre and degree of cervical dilatation less than 3 cm vs at least 3 cm. Allocation concealment: telephone answering service. Blinding: woman and caregiver not blinded, outcome assessor blinded regarding fetal heart tracing assessment. Follow-up: 100%.
Participants	925 women, 462 in experimental group and 463 in control group. Eligibility: spontaneous labour, nulliparous, at least 38 weeks' gestation, single fetus, cephalic presentation, normal FHR. Exclusion: IUGR, severe pre-eclampsia, IDDM, cervical dilatation of more than 6 cm
Interventions	Experimental: amniotomy. Control: no amniotomy.
Outcomes	Women: analgesia, oxytocin use, caesarean section, instrumental vaginal delivery, death, length of second stage of labour, dysfunctional labour, cord prolapse. Fetal/infant: Apgar score, suboptimal FHR trace, cephalhaematoma, convulsions, fracture, meconium aspiration, perinatal death, SCBU
Notes	Multicentre/single centre: multicentre. Setting: 10 in Canada, 1 in USA. Additional outcome: birthweight, oxygen therapy and ventilation of neonate, antibiotic therapy of neonate, need for resuscitation, maternal intrapartum/postpartum fever, maternal antibiotic therapy, endometritis, wound infection, time of admission to randomisation, time of randomisation to rupture of membranes. 96% in the amniotomy group had an amniotomy in the first stage of labour compared with 51% in the control group (77% for failure to progress and 17% for fetal distress)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation: centralised and group assignment stratified according to medical centre and degree of cervical dilatation less than 3 cm vs at least 3 cm
Allocation concealment (selection bias)	Low risk	Allocation concealment: telephone answering service.

Fraser 1993 (Continued)

Blinding (performance bias and detection bias) All outcomes	High risk	Blinding: woman and caregiver not blinded, outcome assessor blinded regarding fetal heart tracing assessment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up: 100%.
Selective reporting (reporting bias)	High risk	Additional information on epidural use and narcotic analgesia not pre-specified in methods. There was no difference, however between the intervention and control groups for these outcomes
Other bias	High risk	Additional analysis of dystocia according to definition which had not been pre-specified (post-hoc analysis)

Garite 1993

Methods	Randomisation: randomisation by random-number computer program. Allocation concealment: consecutively-numbered, sealed envelopes. Blinding: no information provided. Follow-up: 100%.
Participants	459 women, 235 in amniotomy group, 224 in control group. Eligibility: singleton pregnancy, nulliparous and multiparous women, spontaneous labour, at least 36 weeks' pregnant, intact membranes, cervical dilatation of between 4 and 6 cm, vertex presentation at or below -2 station. Exclusion: fetal distress, chorioamnionitis on admission, previous caesarean section, pre-eclampsia, conditions making caesarean section likely, oligohydramnios, polyhydramnios
Interventions	Experimental: amniotomy. Control: no amniotomy.
Outcomes	Women: length of first and second stages of labour, instrumental vaginal delivery, caesarean section, oxytocin. Fetal/infant: suboptimal FHR, Apgar score, hyperbilirubinaemia, sepsis, intracranial haemorrhage, seizures, RDS
Notes	Multicentre/single centre: single centre. Setting: California, USA. Additional outcomes: presence of meconium. In the amniotomy group 12 women had SROM after randomisation and in the intact group, 55 had amniotomy had full dilatation or at delivery, 20 had amniotomy for internal fetal heart monitoring and 36 for dysfunctional labour and 13 for indeterminate reasons (31% of control group)

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation: randomisation by random-number computer program
Allocation concealment (selection bias)	Unclear risk	Allocation concealment: consecutively-numbered, sealed envelopes
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding: no information provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up: 100%.
Selective reporting (reporting bias)	Unclear risk	Pre-specified outcomes not documented in methods section.
Other bias	Low risk	None evident.

Guerresi 1981

Methods	Randomisation: multiparous and primiparous women separated into 2 groups, each was then randomly divided into 2 equal subgroups. Allocation concealment: not stated. Blinding: no information provided. Follow -up: 100%.
Participants	100 women, 50 experimental and 50 control. Eligibility: multiparous and primiparous women, 'term' gestation. Exclusion: women with anatomical or functional abnormalities likely to affect the course of delivery
Interventions	Experimental: amniotomy. Control: no amniotomy.
Outcomes	Women: length of first and second stage of labour. Fetal/infant: Apgar score.
Notes	Multicentre/single centre: single centre. Setting: Bologna, Italy. Study overall recruited 300 women, 200 of which received rociverone of butylscopolamine bromide and were therefore not analysed. Author (Prof Gori) contacted November 2007 for additional data, still awaiting response (30/03/07)

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation: multiparous and primiparous women separated into 2 groups, each was then randomly divided into 2 equal subgroups
Allocation concealment (selection bias)	High risk	Allocation concealment: "each of the groups was randomly divided"
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding: no information provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up: 100%.
Selective reporting (reporting bias)	Low risk	No evidence.
Other bias	Low risk	No evidence.

Johnson 1997

Methods	Randomisation: computer randomisation. Allocation concealment: unclear. Blinding: outcome assessor (statistician) unaware of allocation. Follow-up: 100%.
Participants	940 multiparous women (1550 overall, 600 nulliparous), 529 in experimental group, 411 in control group. Eligibility: intact membranes, uncomplicated spontaneous labour, at least 36 weeks, painful uterine contractions enough to cause descent of the presenting part and cervical dilatation. Exclusion: multiple pregnancy, non-vertex presentation, IUGR, pre-eclampsia
Interventions	Experimental: amniotomy. Control: no amniotomy.
Outcomes	Women: caesarean section, instrumental vaginal delivery, oxytocin. Fetal/infant: unable to extract without further info - Apgar score, morbidity
Notes	Multicentre/single centre: single centre. Setting: Leeds UK. Additional outcomes: third degree tear. Nulliparous women analysed in this trial were recruited as part of the UK amniotomy trial therefore only data from the multiparous women have been extracted from this

	<p>paper for the review.</p> <p>Ratio of randomisation is 4:3 amniotomy:no amniotomy due to computer programming error.</p> <p>54% of women in the control group received an amniotomy.</p> <p>Unable to locate and contact author (29/11/06) therefore unable to extract data for most outcomes, as no distinction between multiparous and primiparous women made.</p> <p>Primiparous women included in UK amniotomy study</p>
--	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation: computer randomisation.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment: unclear.
Blinding (performance bias and detection bias) All outcomes	Low risk	Blinding: outcome assessor (statistician) unaware of allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up: 100%.
Selective reporting (reporting bias)	Unclear risk	Unclear as to pre-specification of outcomes from text of review
Other bias	High risk	Computer programming error with randomisation - see paper.

Laros 1972

Methods	<p>Randomisation: table of random numbers.</p> <p>Allocation concealment: sealed envelopes.</p> <p>Blinding: no information given.</p> <p>Follow-up: 100%.</p>
Participants	<p>125 women were enrolled, 70 in experimental group and 55 in control group.</p> <p>Eligibility: spontaneous labour, intact membranes, vertex presentation, gestation 36-44 weeks, cervical dilatation of between 5 and 8 cm, multiparous and primiparous women.</p> <p>Exclusion: abnormal labours requiring oxytocin, caesarean section or operative vaginal delivery (possibly post-randomisation exclusions)</p>
Interventions	<p>Experimental: amniotomy.</p> <p>Control: no amniotomy.</p>
Outcomes	<p>Women: length of first stage of labour, length of second stage of labour, serious maternal morbidity and mortality.</p>

	Fetal/infant: Apgar score, perinatal morbidity and mortality	
Notes	Multicentre/single centre: single centre, air force hospital. Setting: USA. Additional outcomes: none reported. Additional information (unpublished) provided by the author suggests that there was post randomisation exclusion of women who did not achieve a normal delivery (<i>see</i> Participants).	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation: table of random numbers.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment: "randomly assigned".
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding: no information given.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up: 100%.
Selective reporting (reporting bias)	High risk	Reported outcomes that were not pre-specified - analysed with Chi ² showing no difference between the 2 groups
Other bias	Low risk	No evidence.

Mikki 2007

Methods	<p>Randomisation: randomised controlled trial stratified by parity.</p> <p>Allocation concealment: sealed envelopes.</p> <p>Blinding: woman and caregiver not blinded, no information given regarding blinding of the outcome assessor</p> <p>Follow-up: 100%.</p>
Participants	<p>690 women were enrolled, 340 (74 nulliparous women, 266 multiparous women) in experimental group and 350 (83 nulliparous women, 267 multiparous women) in control group.</p> <p>Eligibility: low risk full-term pregnancy, singleton pregnancy, cephalic presentation, active labour, intact membranes, normal fetal heart rate.</p> <p>Exclusion: IUGR, induction of labour, suspected large for dates baby (>4.5 kg), pre-eclampsia, insulin dependent diabetes mellitus, more than 1 previous caesarean section, antepartum haemorrhage, advanced labour</p>

Interventions	Experimental: amniotomy. Control: no amniotomy.	
Outcomes	Women: caesarean section, length of second stage of labour (minutes), dysfunctional labour (no progress in cervical dilatation in 2 hours or ineffective uterine contractions (as defined by trial authors)), use of pain relief, oxytocin augmentation and dosage used; instrumental vaginal birth, postpartum haemorrhage (as defined by trial authors), perineal trauma irrespective of suturing Fetal/infant: low Apgar score less than seven at five minutes, admission to neonatal intensive care or special care nursery	
Notes	Multicentre/single centre: single centre. Setting: West Bank, Occupied Palestinian Territory. Additional outcomes: 60.2% (n = 50) of nulliparous women and 33.8% (n = 90) of multiparous women in the control group received an amniotomy It was calculated that the sample size required to detect a difference of 45 minutes in the duration of labour between the 2 arms required 533 women to be enrolled to both the intervention and control groups. This was not achieved as the trial was ended prematurely (after 1 year) due to budget constraints	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation: randomised controlled trial stratified by parity
Allocation concealment (selection bias)	Unclear risk	Allocation concealment: "simple randomisation with sealed envelopes"
Blinding (performance bias and detection bias) All outcomes	High risk	Blinding: woman and caregiver not blinded, no information given regarding blinding of the outcome assessor
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up: 100%.
Selective reporting (reporting bias)	High risk	Data on perinatal death not reported in the paper, however, data provided by the author through correspondence Outcomes not pre-specified in the methodology.
Other bias	High risk	Trial ended due to budget constraints.

Shobeiri 2007

Methods	Randomisation: randomised. Allocation concealment: no information given. Blinding: no information given. Follow-up: 100%.
Participants	80 women were enrolled, 40 in experimental group and 40 in control group. Eligibility: nulliparous, at least 38 weeks' gestation, singleton pregnancies, cephalic presentation, normal FHR, intact membranes, cervical dilatation of 3 cm or greater, painful uterine contractions every 5 minutes for at least an hour. Exclusion: none specified.
Interventions	Experimental: amniotomy. Control: no amniotomy.
Outcomes	Women: duration of first stage of labour, duration of second stage of labour, caesarean section, dystocia. Fetal/infant: FHR, Apgar scores at 1 min and 5 minutes.
Notes	Multicentre/single centre: single centre. Setting: Iran. Additional outcomes: duration of third stage of labour, interval between randomisation and membrane rupture, and randomisation and full dilatation

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation: randomised.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment: no information given.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding: no information given.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up: 100%.
Selective reporting (reporting bias)	High risk	Not all outcomes pre-specified in methodology.
Other bias	Unclear risk	Brief report.

Stewart 1982

Methods	Randomisation: randomly allocated. Allocation concealment: no information provided. Blinding: not stated. Follow-up: 100% (4 primiparous women of 68 women recruited, excluded on basis of delivery by caesarean section for cephalopelvic disproportion)
Participants	68 women recruited, 64 analysed. 34 women in intervention group and 30 women in control group. Eligibility: nulliparous (32) and multiparous women (32), 38 to 42 weeks' gestation, spontaneous labour, singleton fetus, intact membranes, cervical dilatation of no more than 4 cm and a cervical score of more than 6. Exclusion: caesarean section post randomisation.
Interventions	Experimental: amniotomy. Control: no amniotomy until full dilatation.
Outcomes	Women: oxytocin use, instrumental vaginal delivery, analgesia, amniotomy to delivery interval. Fetal/infant: Apgar score, meconium-stained liquor, perinatal death, suboptimal FHR, jaundice
Notes	Multicentre/single centre: single centre. Setting: UK - Glasgow, Scotland. Additional outcomes: umbilical artery pH of less than 7.15, SCBU admission for > 12 hours, mean birthweight CTG tracing - 33 women in amniotomy group had continuous monitoring, of which 30 traces were suitable for analysis. In the control group 26 women had continuous monitoring of which 21 traces were suitable for analysis

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation: randomly allocated.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment: no information provided.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding: not stated.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up: 100% (4 primiparous women of 68 women recruited, excluded on basis of delivery by caesarean section for cephalopelvic disproportion)

Selective reporting (reporting bias)	High risk	Outcomes not all pre-specified in methodology.
Other bias	High risk	Women who were delivered by caesarean section were excluded from analysis

UK Amniotomy 1994

Methods	Randomisation: random-number tables at 5 centres, computer randomisation (random-number generation) at 1 centre. Allocation concealment: numbered sealed opaque envelopes. Blinding: not stated. Follow-up: 100%.
Participants	1463 women entered 782 in experimental group and 681 in control group. Eligibility: women in first pregnancy (defined as no previous pregnancy of greater than 28 weeks' gestation), 37 to 42 weeks' gestation, spontaneous labour, singleton fetus, cephalic presentation, intact membranes. Exclusion: multiparous.
Interventions	Experimental: amniotomy. Control: no amniotomy.
Outcomes	Women: maternal satisfaction (unable to extract data), caesarean section, instrumental vaginal delivery, analgesia, infection requiring antibiotics. Fetal/infant: Apgar score, SCBU admission, jaundice, perinatal death, convulsions
Notes	Multicentre/single centre: multicentre. Setting: UK - Leeds, Shotley Bridge, Stoke-on-Trent, Tameside, Staffs, Glasgow. Additional outcomes: time from randomisation to delivery, intubation and ventilation of neonate, maternal blood transfusion. At St James, Leeds, ratio of randomisation is 4:3 amniotomy:no amniotomy due to computer programming error. Author contacted November 2006 and March 2007 for additional data, still awaiting response (30/03/07)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation: random-number tables at 5 centres, computer randomisation (random-number generation) at 1 centre
Allocation concealment (selection bias)	Low risk	Allocation concealment: numbered sealed opaque envelopes.

UK Amniotomy 1994 (Continued)

Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding: not stated.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up: 100%.
Selective reporting (reporting bias)	Low risk	No evidence.
Other bias	High risk	Computer programming error leading to imbalanced randomisation

Wetrich 1970

Methods	Randomisation: controlled randomised study. Allocation concealment: blind draw to randomly assign women. Blinding: woman and caregiver not blinded. Follow-up: 100%.	
Participants	32 women, 16 in experimental group and 16 in control group. Eligibility: normally progressive spontaneous labour prior to 6 cm dilatation, intact membranes at 6 cm dilatation, vertex fixed in pelvis and applied to cervix, singleton fetus, vertex presentation, EFW 2500-4000 g, cervical dilatation at time of ARM no greater and no less than 6 cm, participant followed personally throughout duration of labour. Exclusion: multiparous women, dysfunctional labour, severe pre-eclampsia, diabetes, placental abruption, rhesus isoimmunisation	
Interventions	Experimental: amniotomy. Control: no amniotomy.	
Outcomes	Women: length of second stage of labour, mode of delivery, pain relief. Fetal/infant: perinatal death.	
Notes	Multicentre/single centre: single centre. Setting: Iowa, USA. Additional outcomes: infant weight, time from 6 cm to full dilatation In control group, 5 women had amniotomy at full dilatation. It was noted approximately 2/3 of the way through the study that more women in the spontaneous rupture group had received caudal anaesthesia than the amniotomy group. In the terminal parts of the study the difference was evened up by arbitrary assignment of anaesthesia Unable to locate author through extensive Internet search.	
Risk of bias		
Bias	Authors' judgement	Support for judgement

Wetrich 1970 (Continued)

Random sequence generation (selection bias)	Unclear risk	Randomisation: controlled randomised study.
Allocation concealment (selection bias)	High risk	Allocation concealment: blind draw to randomly assign women.
Blinding (performance bias and detection bias) All outcomes	High risk	Blinding: woman and caregiver not blinded. No information reported for outcome assessor.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up: 100%.
Selective reporting (reporting bias)	Low risk	No evidence, but see below.
Other bias	High risk	Arbitrary assignment of anaesthesia used due to an observation 2/3 of the way through the study that more women in the control group required epidural anaesthesia, despite anaesthesia being specified as an outcome

APH: antepartum haemorrhage
 ARM: artificial rupture of membranes
 CTG: cardiotocography
 EFW: estimated fetal weight
 FHR: fetal heart rate
 IDDM: insulin dependent diabetes mellitus
 IUGR: intrauterine growth restriction
 RDS: respiratory distress syndrome
 SCBU: special care baby unit
 SROM: spontaneous rupture of membranes
 vs: versus

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Abdullah 2010	Quasi-randomised.
Garmi 2008	Study looking at effect of amniotomy for abnormally progressing labour
Levy 2002	IOL with Foley catheter prior to amniotomy. Women not in spontaneous labour

(Continued)

Li 2006	This is a review article (meta-analysis).
Martell 1976	Quasi-randomised.
Nachum 2010	Comparison groups included augmentation with oxytocin, amniotomy or a combination of both
Schwarcz 1975	Quasi-randomised.
Schwarcz 1973	Women in control group excluded if SROM before full dilatation. Paper looks at effect of amniotomy or no amniotomy on FHR only, and not on spontaneous labour outcomes. Author contacted for information about other outcomes not included
Surichamorn 1998	Unable to contact authors and unable to ascertain whether a randomised or quasi-randomised trial

FHR: fetal heart rate

IOL: induction of labour

SROM: spontaneous rupture of membranes

DATA AND ANALYSES

Comparison 1. Amniotomy versus no amniotomy

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Length of first stage of labour	5	1127	Mean Difference (IV, Random, 95% CI)	-20.43 [-95.93, 55.06]
1.1 Primiparous women	4	379	Mean Difference (IV, Random, 95% CI)	-57.93 [-152.66, 36.80]
1.2 Multiparous women	3	386	Mean Difference (IV, Random, 95% CI)	23.10 [-50.89, 97.09]
1.3 Primiparous and multiparous women	1	362	Mean Difference (IV, Random, 95% CI)	-18.0 [-67.54, 31.54]
2 Caesarean section	9	5021	Risk Ratio (M-H, Fixed, 95% CI)	1.27 [0.99, 1.63]
2.1 Primiparous women	6	2674	Risk Ratio (M-H, Fixed, 95% CI)	1.15 [0.88, 1.51]
2.2 Multiparous women	2	1473	Risk Ratio (M-H, Fixed, 95% CI)	1.76 [0.65, 4.76]
2.3 Primiparous and multiparous women	3	874	Risk Ratio (M-H, Fixed, 95% CI)	2.36 [0.99, 5.63]
3 Maternal satisfaction with childbirth experience	1	84	Mean Difference (IV, Fixed, 95% CI)	-1.10 [-7.15, 4.95]
4 Apgar score less than 7 at 5 minutes	6	3598	Risk Ratio (M-H, Fixed, 95% CI)	0.53 [0.28, 1.00]
4.1 Primiparous women	4	2542	Risk Ratio (M-H, Fixed, 95% CI)	0.42 [0.20, 0.88]
4.2 Primiparous and multiparous women	2	523	Risk Ratio (M-H, Fixed, 95% CI)	1.30 [0.26, 6.43]
4.3 Multiparous women	1	533	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.06, 15.96]
5 Length of second stage	8	1927	Mean Difference (IV, Random, 95% CI)	-1.33 [-2.92, 0.26]
5.1 Primiparous women	7	653	Mean Difference (IV, Random, 95% CI)	-5.43 [-9.98, -0.89]
5.2 Multiparous women	4	919	Mean Difference (IV, Random, 95% CI)	-1.19 [-2.92, 0.53]
5.3 Primiparous and multiparous women	1	355	Mean Difference (IV, Random, 95% CI)	0.60 [-2.46, 3.66]
6 Dysfunctional labour	3	1695	Risk Ratio (M-H, Random, 95% CI)	0.60 [0.44, 0.82]
6.1 Primiparous women	1	157	Risk Ratio (M-H, Random, 95% CI)	0.49 [0.33, 0.73]
6.2 Multiparous women	1	533	Risk Ratio (M-H, Random, 95% CI)	0.44 [0.31, 0.62]
6.3 Primiparous and multiparous women	2	1005	Risk Ratio (M-H, Random, 95% CI)	0.75 [0.64, 0.88]
7 Use of pain relief - epidural/narcotic	8	3475	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.96, 1.14]
7.1 Primiparous women	5	2463	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.94, 1.04]
7.2 Multiparous women	1	533	Risk Ratio (M-H, Random, 95% CI)	1.45 [1.16, 1.80]
7.3 Primiparous and multiparous women	3	479	Risk Ratio (M-H, Random, 95% CI)	1.15 [0.78, 1.68]
8 Oxytocin augmentation	8	4264	Risk Ratio (M-H, Random, 95% CI)	0.72 [0.54, 0.96]
8.1 Primiparous women	3	1179	Risk Ratio (M-H, Random, 95% CI)	0.79 [0.56, 1.11]
8.2 Multiparous women	1	533	Risk Ratio (M-H, Random, 95% CI)	0.43 [0.30, 0.60]
8.3 Primiparous and multiparous women	5	2552	Risk Ratio (M-H, Random, 95% CI)	0.77 [0.46, 1.28]

9 Instrumental vaginal birth	10	5121	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.87, 1.13]
9.1 Primiparous women	6	2664	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.87, 1.15]
9.2 Multiparous women	2	1444	Risk Ratio (M-H, Fixed, 95% CI)	1.12 [0.65, 1.95]
9.3 Primiparous and multiparous women	4	1013	Risk Ratio (M-H, Fixed, 95% CI)	0.84 [0.55, 1.29]
10 Caesarean section for fetal distress	1	690	Risk Ratio (M-H, Fixed, 95% CI)	3.21 [0.66, 15.60]
10.1 Primiparous women	1	157	Risk Ratio (M-H, Fixed, 95% CI)	4.49 [0.51, 39.25]
10.2 Multiparous women	1	533	Risk Ratio (M-H, Fixed, 95% CI)	2.01 [0.18, 22.01]
11 Caesarean section for prolonged labour	1	690	Risk Ratio (M-H, Fixed, 95% CI)	0.45 [0.07, 3.03]
11.1 Primiparous women	1	157	Risk Ratio (M-H, Fixed, 95% CI)	0.37 [0.02, 9.03]
11.2 Multiparous women	1	533	Risk Ratio (M-H, Fixed, 95% CI)	0.50 [0.05, 5.50]
12 Antepartum haemorrhage	1	690	Risk Ratio (M-H, Fixed, 95% CI)	0.63 [0.08, 4.84]
12.1 Primiparous women	1	157	Risk Ratio (M-H, Fixed, 95% CI)	0.37 [0.02, 9.03]
12.2 Multiparous women	1	533	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.06, 15.96]
13 Postpartum haemorrhage	2	1822	Risk Ratio (M-H, Fixed, 95% CI)	0.46 [0.14, 1.50]
13.1 Primiparous and multiparous women	1	1132	Risk Ratio (M-H, Fixed, 95% CI)	0.19 [0.02, 1.68]
13.2 Primiparous women	1	157	Risk Ratio (M-H, Fixed, 95% CI)	0.56 [0.05, 6.06]
13.3 Multiparous women	1	533	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.14, 7.07]
14 Cord prolapse	2	1615	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.14, 7.10]
14.1 Primiparous and multiparous women	1	925	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.01, 8.18]
14.2 Primiparous women	1	157	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
14.3 Multiparous women	1	533	Risk Ratio (M-H, Fixed, 95% CI)	3.01 [0.12, 73.59]
15 Maternal infection	3	2150	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.43, 1.82]
15.1 Primiparous women	3	1617	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.38, 1.72]
15.2 Multiparous women	1	533	Risk Ratio (M-H, Fixed, 95% CI)	3.01 [0.12, 73.59]
16 Maternal mortality	3	1740	Risk Ratio (M-H, Fixed, 95% CI)	3.01 [0.12, 73.61]
17 Suboptimal or abnormal fetal heart trace (second stage of labour)	1	567	Risk Ratio (M-H, Fixed, 95% CI)	1.15 [0.89, 1.48]
18 Admission to special care baby unit/neonatal intensive care unit	5	2686	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.77, 1.50]
18.1 Primiparous women	5	2153	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [0.78, 1.54]
18.2 Multiparous women	1	533	Risk Ratio (M-H, Fixed, 95% CI)	0.75 [0.17, 3.33]
19 Suboptimal or abnormal fetal heart trace (first stage of labour)	4	1284	Risk Ratio (M-H, Fixed, 95% CI)	1.09 [0.97, 1.23]
20 Meconium aspiration syndrome	2	1615	Risk Ratio (M-H, Fixed, 95% CI)	3.06 [0.83, 11.27]
20.1 Primiparous and multiparous women	1	925	Risk Ratio (M-H, Fixed, 95% CI)	3.01 [0.61, 14.82]
20.2 Primiparous women	1	157	Risk Ratio (M-H, Fixed, 95% CI)	3.36 [0.14, 81.24]
20.3 Multiparous women	1	533	Risk Ratio (M-H, Fixed, 95% CI)	3.01 [0.12, 73.59]
21 Acidosis as defined as a cord blood arterial pH of < 7.2	2	1014	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.80, 1.73]
22 Perinatal death	8	3397	Risk Ratio (M-H, Fixed, 95% CI)	3.01 [0.12, 73.59]
22.1 Primiparous women	7	2733	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
22.2 Primiparous and multiparous women	1	64	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
22.3 Multiparous women	2	600	Risk Ratio (M-H, Fixed, 95% CI)	3.01 [0.12, 73.59]

23 Neonatal jaundice	5	3202	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.76, 1.06]
23.1 Primiparous women	3	1614	Risk Ratio (M-H, Fixed, 95% CI)	1.16 [0.83, 1.62]
23.2 Multiparous women	2	1065	Risk Ratio (M-H, Fixed, 95% CI)	0.83 [0.67, 1.02]
23.3 Primiparous and multiparous women	2	523	Risk Ratio (M-H, Fixed, 95% CI)	0.76 [0.42, 1.36]
24 Seizures (neonate)	5	4069	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.15, 5.35]
24.1 Primiparous women	4	2545	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.15, 5.35]
24.2 Multiparous women	2	1065	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
24.3 Primiparous and multiparous women	1	459	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
25 Respiratory distress syndrome	2	1149	Risk Ratio (M-H, Fixed, 95% CI)	0.20 [0.01, 4.16]
25.1 Primiparous and multiparous women	1	459	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
25.2 Primiparous women	1	157	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
25.3 Multiparous women	1	533	Risk Ratio (M-H, Fixed, 95% CI)	0.20 [0.01, 4.16]
26 Fracture	1	925	Risk Ratio (M-H, Fixed, 95% CI)	3.01 [0.31, 28.80]
27 Intracranial haemorrhage	1	459	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
28 Cephalhaematoma	3	1712	Risk Ratio (M-H, Fixed, 95% CI)	1.52 [0.81, 2.83]
28.1 Primiparous and multiparous women	2	1022	Risk Ratio (M-H, Fixed, 95% CI)	1.63 [0.86, 3.10]
28.2 Primiparous women	1	157	Risk Ratio (M-H, Fixed, 95% CI)	0.37 [0.02, 9.03]
28.3 Multiparous women	1	533	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Comparison 2. Sensitivity analysis excluding trials with inadequate allocation concealment (c)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Length of first stage of labour	5	1127	Mean Difference (IV, Random, 95% CI)	-21.73 [-53.36, 9.91]
1.1 Primiparous women	4	379	Mean Difference (IV, Random, 95% CI)	-54.62 [-161.77, 52.52]
1.2 Multiparous women	3	386	Mean Difference (IV, Random, 95% CI)	23.47 [-46.14, 93.08]
1.3 Primiparous and multiparous women	1	362	Mean Difference (IV, Random, 95% CI)	-0.30 [-1.13, 0.53]
2 Caesarean section	8	4331	Risk Ratio (M-H, Fixed, 95% CI)	1.27 [0.98, 1.63]
2.1 Primiparous women	5	2517	Risk Ratio (M-H, Fixed, 95% CI)	1.13 [0.86, 1.49]
2.2 Multiparous women	1	940	Risk Ratio (M-H, Fixed, 95% CI)	3.11 [0.66, 14.56]
2.3 Primiparous and multiparous women	3	874	Risk Ratio (M-H, Fixed, 95% CI)	2.36 [0.99, 5.63]
3 Apgar score less than 7 at 5 minutes	5	2908	Risk Ratio (M-H, Fixed, 95% CI)	0.51 [0.26, 0.98]
3.1 Primiparous women	3	2385	Risk Ratio (M-H, Fixed, 95% CI)	0.42 [0.20, 0.88]
3.2 Primiparous and multiparous women	2	523	Risk Ratio (M-H, Fixed, 95% CI)	1.30 [0.26, 6.43]

Comparison 3. Amniotomy vs no amniotomy (dysfunctional labour)

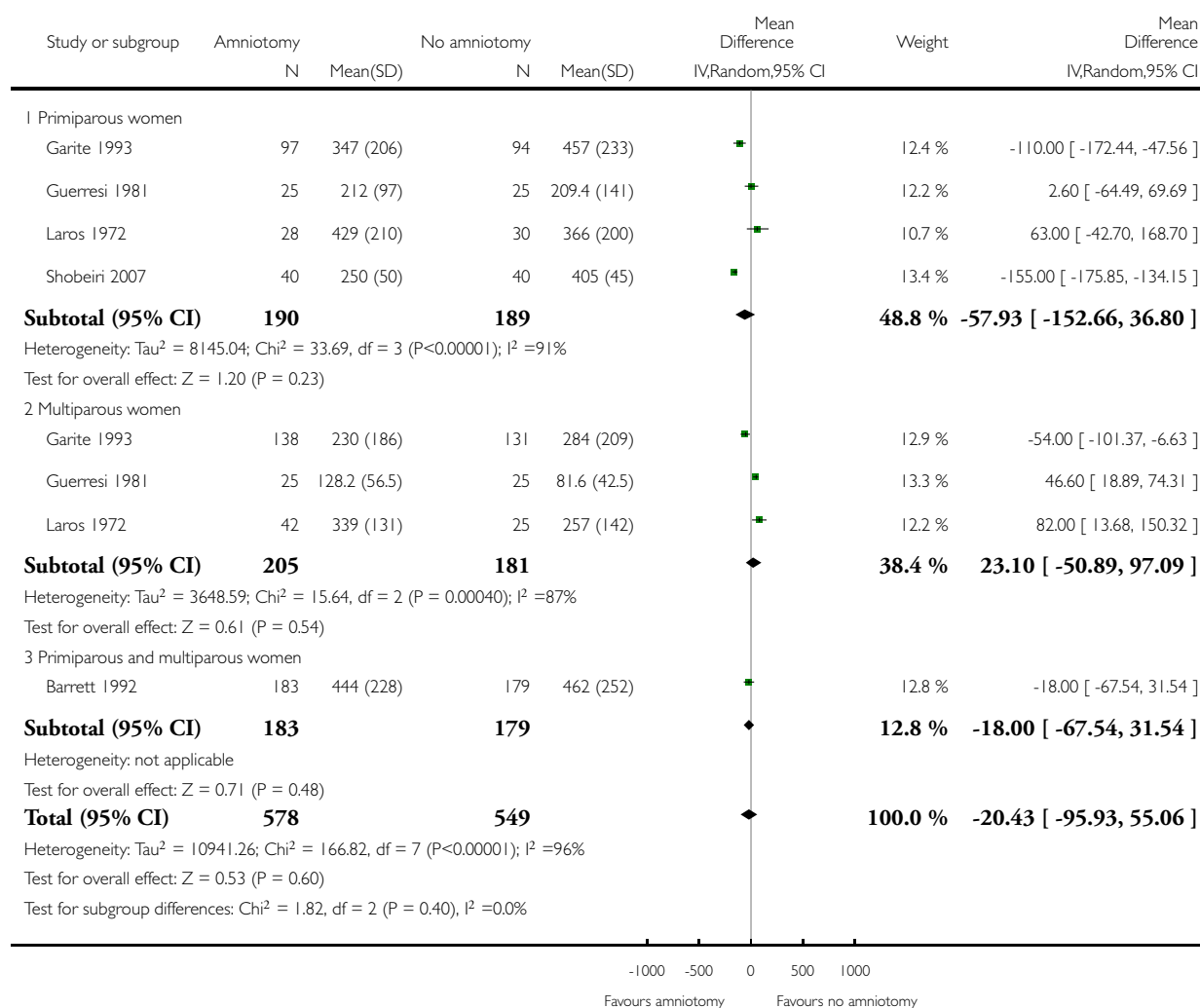
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	1	39	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.15, 6.08]
1.1 Primiparous and multiparous women	1	39	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.15, 6.08]
2 Maternal satisfaction with childbirth experience	1	39	Mean Difference (IV, Random, 95% CI)	22.0 [2.74, 41.26]
3 Apgar score less than 7 at 5 minutes	1	39	Risk Ratio (M-H, Fixed, 95% CI)	2.86 [0.12, 66.11]
3.1 Primiparous and multiparous women	1	39	Risk Ratio (M-H, Fixed, 95% CI)	2.86 [0.12, 66.11]
4 Use of pain relief - epidural/narcotic	1	39	Risk Ratio (M-H, Fixed, 95% CI)	1.48 [0.85, 2.57]
4.1 Primiparous and multiparous women	1	39	Risk Ratio (M-H, Fixed, 95% CI)	1.48 [0.85, 2.57]
5 Oxytocin augmentation	1	39	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.52, 1.47]
5.1 Primiparous and multiparous women	1	39	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.52, 1.47]
6 Instrumental vaginal birth	1	39	Risk Ratio (M-H, Fixed, 95% CI)	1.27 [0.33, 4.93]
6.1 Primiparous and multiparous women	1	39	Risk Ratio (M-H, Fixed, 95% CI)	1.27 [0.33, 4.93]
7 Caesarean section for fetal distress	1	39	Risk Ratio (M-H, Fixed, 95% CI)	2.86 [0.12, 66.11]
7.1 Primiparous and multiparous women	1	39	Risk Ratio (M-H, Fixed, 95% CI)	2.86 [0.12, 66.11]
8 Caesarean section for prolonged labour	1	39	Risk Ratio (M-H, Fixed, 95% CI)	0.48 [0.05, 4.82]
8.1 Primiparous and multiparous women	1	39	Risk Ratio (M-H, Fixed, 95% CI)	0.48 [0.05, 4.82]
9 Maternal mortality	1	39	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Admission to special care baby unit/neonatal intensive care unit	1	39	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10.1 Primiparous and multiparous women	1	39	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Analysis 1.1. Comparison 1 Amniotomy versus no amniotomy, Outcome 1 Length of first stage of labour.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 1 Length of first stage of labour

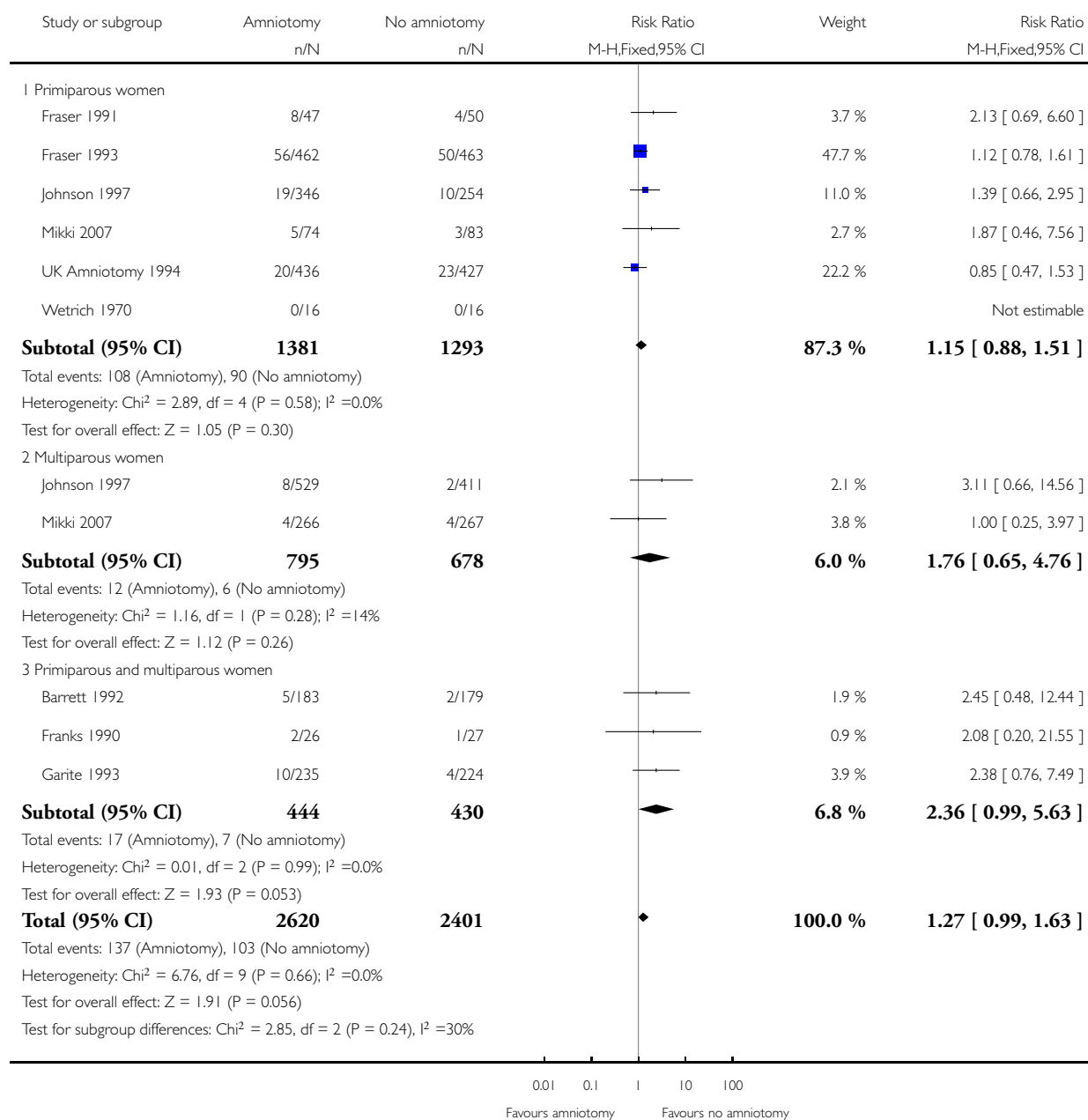


Analysis 1.2. Comparison 1 Amniotomy versus no amniotomy, Outcome 2 Caesarean section.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 2 Caesarean section



Analysis 1.3. Comparison 1 Amniotomy versus no amniotomy, Outcome 3 Maternal satisfaction with childbirth experience.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 3 Maternal satisfaction with childbirth experience

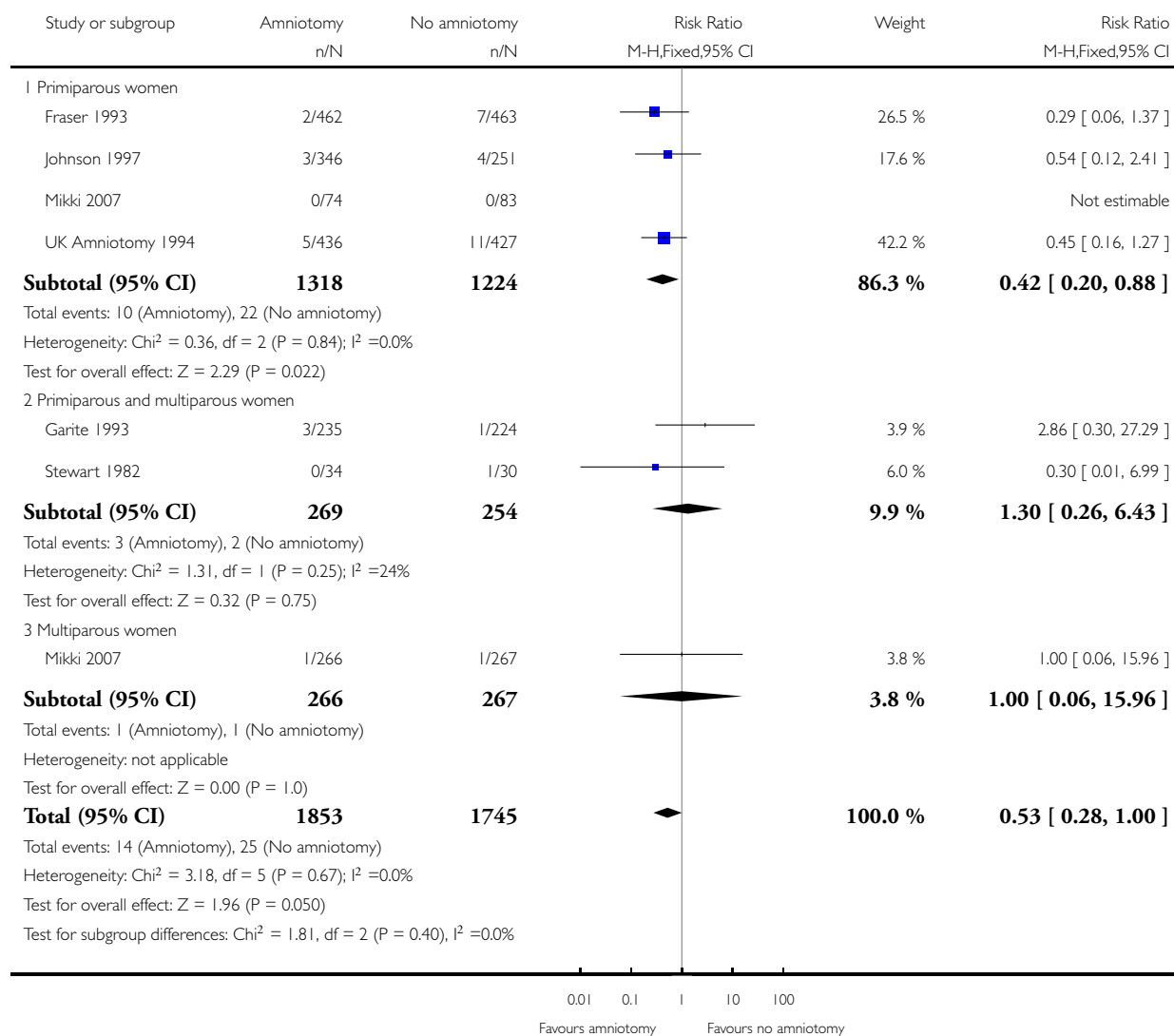


Analysis 1.4. Comparison 1 Amniotomy versus no amniotomy, Outcome 4 Apgar score less than 7 at 5 minutes.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 4 Apgar score less than 7 at 5 minutes

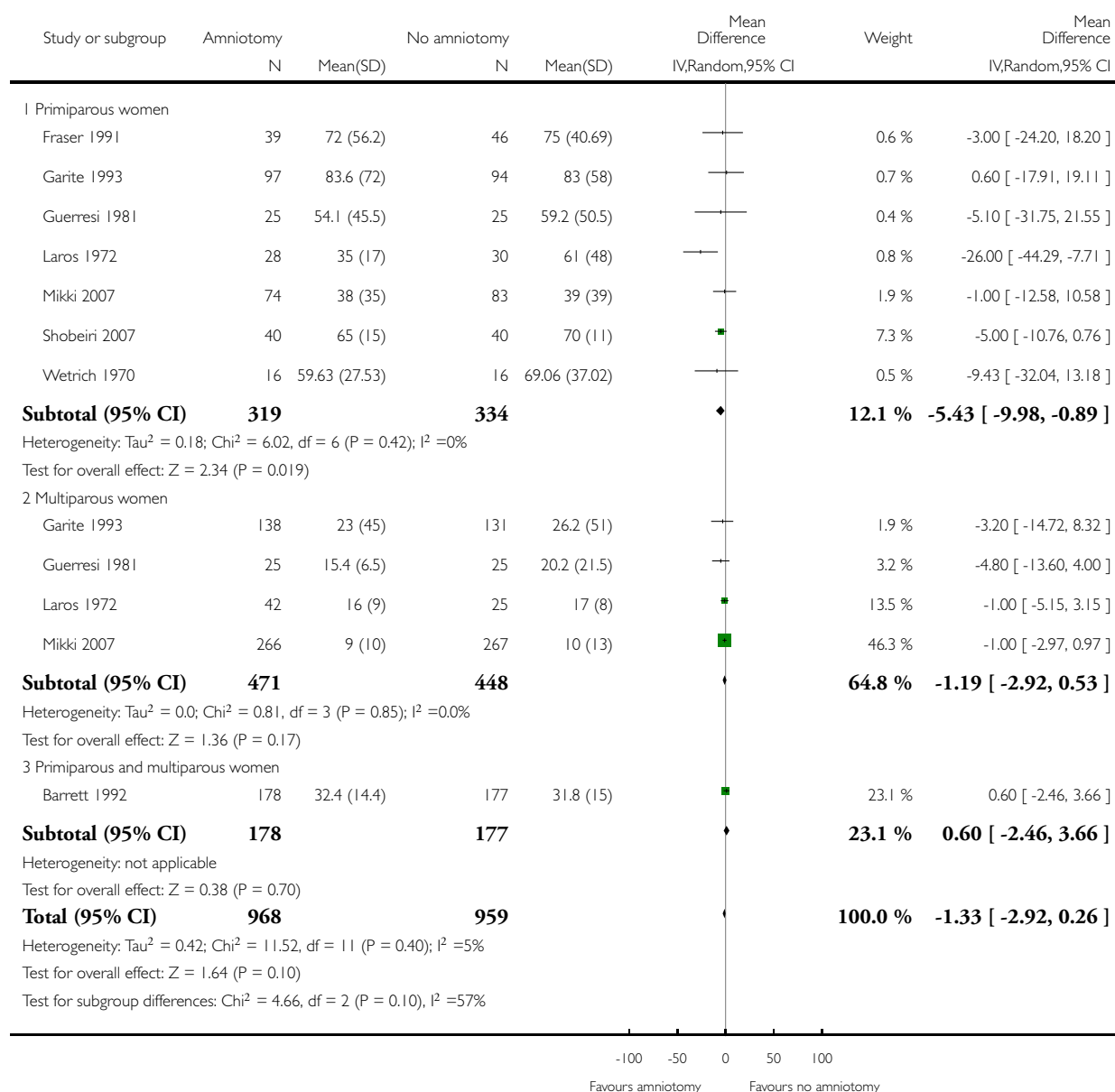


Analysis 1.5. Comparison 1 Amniotomy versus no amniotomy, Outcome 5 Length of second stage.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 5 Length of second stage

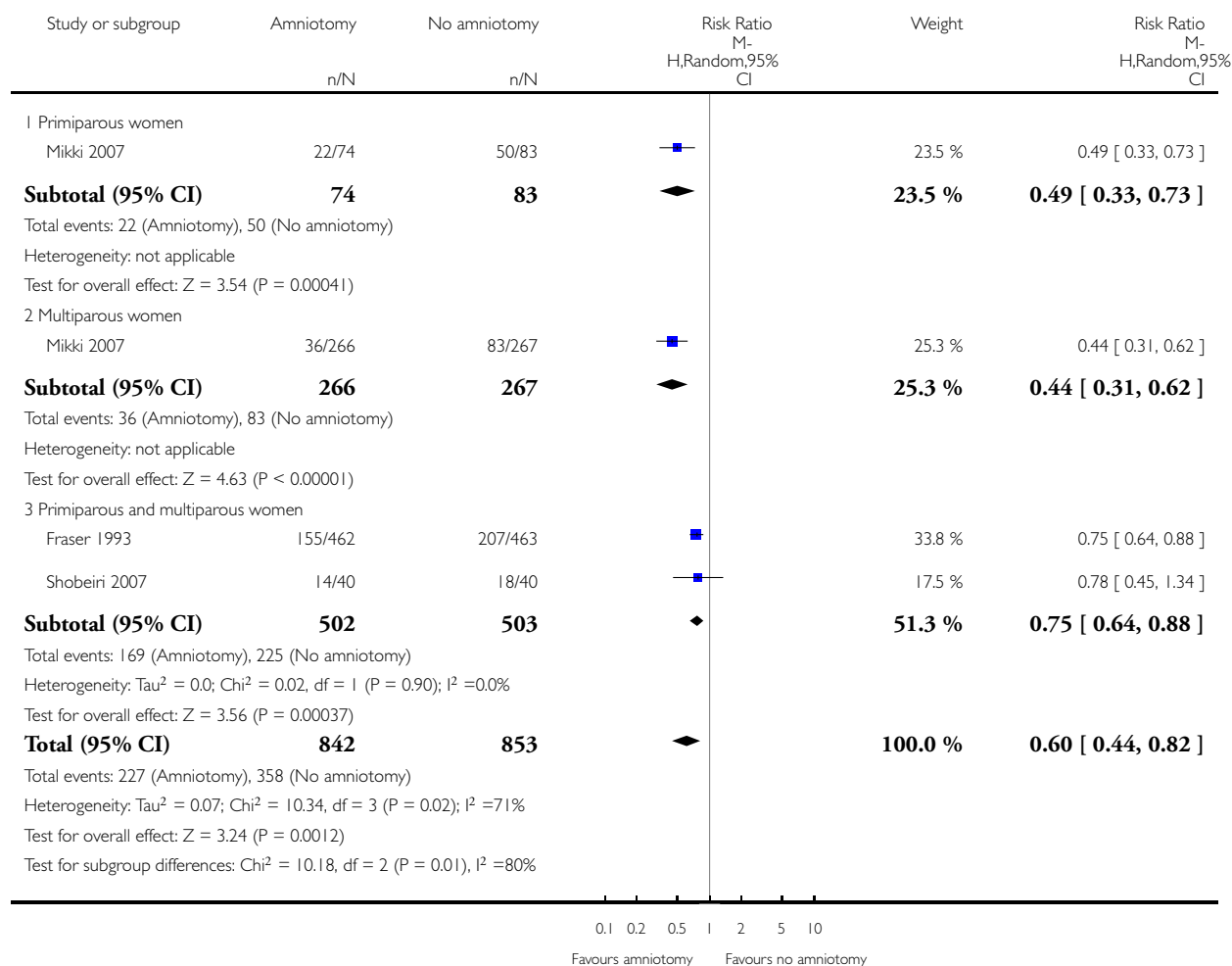


Analysis 1.6. Comparison 1 Amniotomy versus no amniotomy, Outcome 6 Dysfunctional labour.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 6 Dysfunctional labour

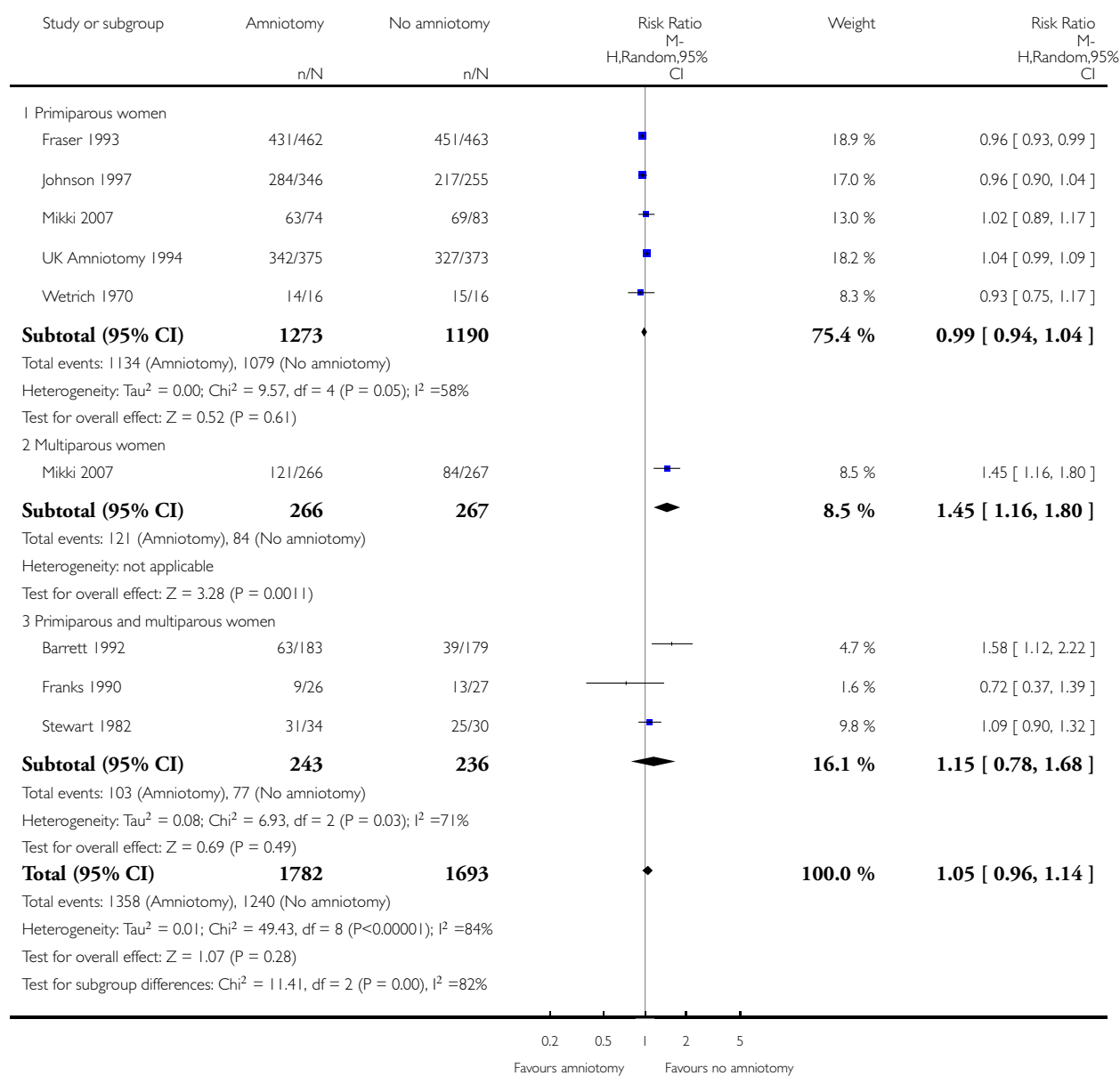


Analysis 1.7. Comparison 1 Amniotomy versus no amniotomy, Outcome 7 Use of pain relief - epidural/narcotic.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 7 Use of pain relief - epidural/narcotic

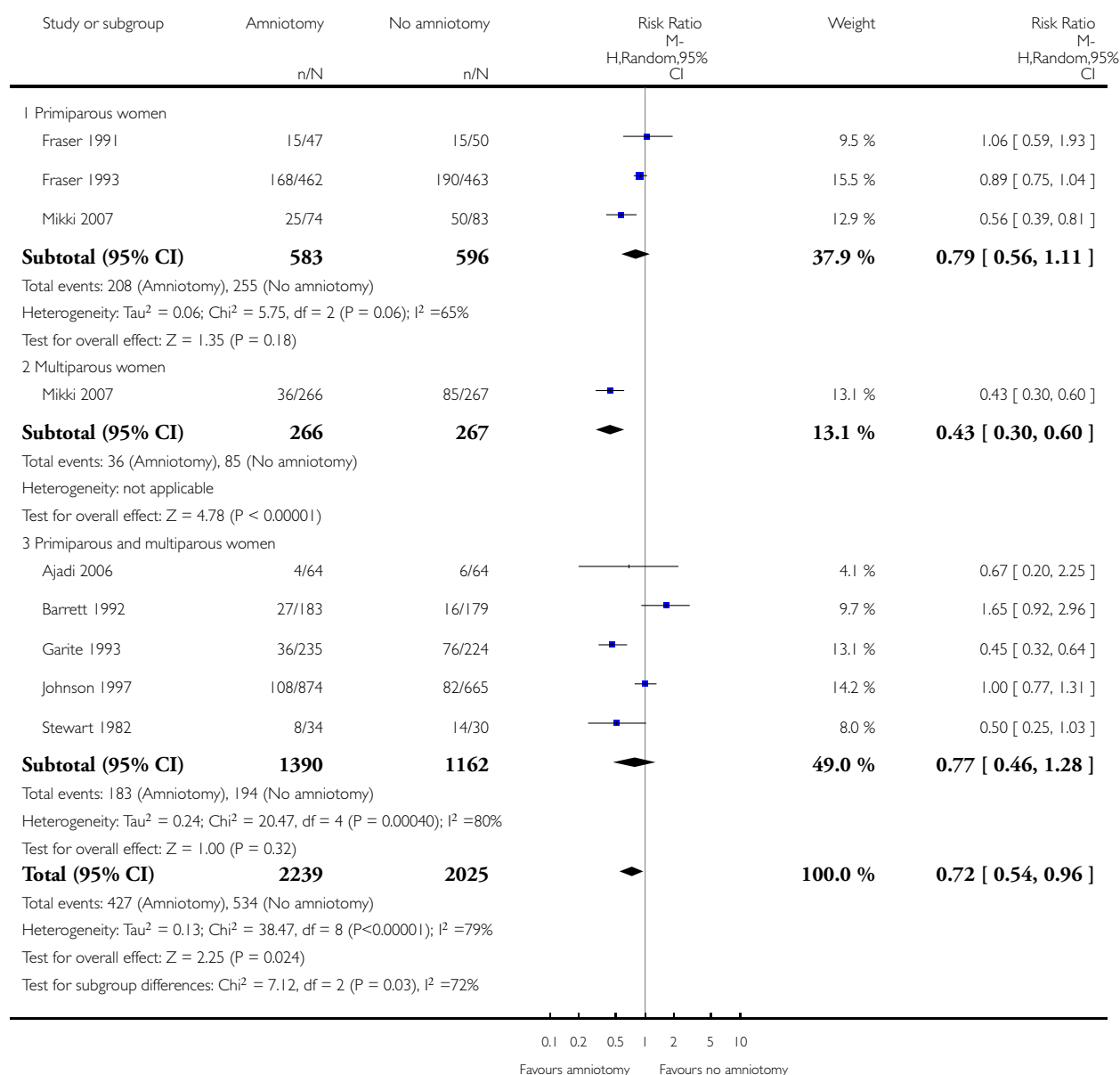


Analysis 1.8. Comparison 1 Amniotomy versus no amniotomy, Outcome 8 Oxytocin augmentation.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 8 Oxytocin augmentation

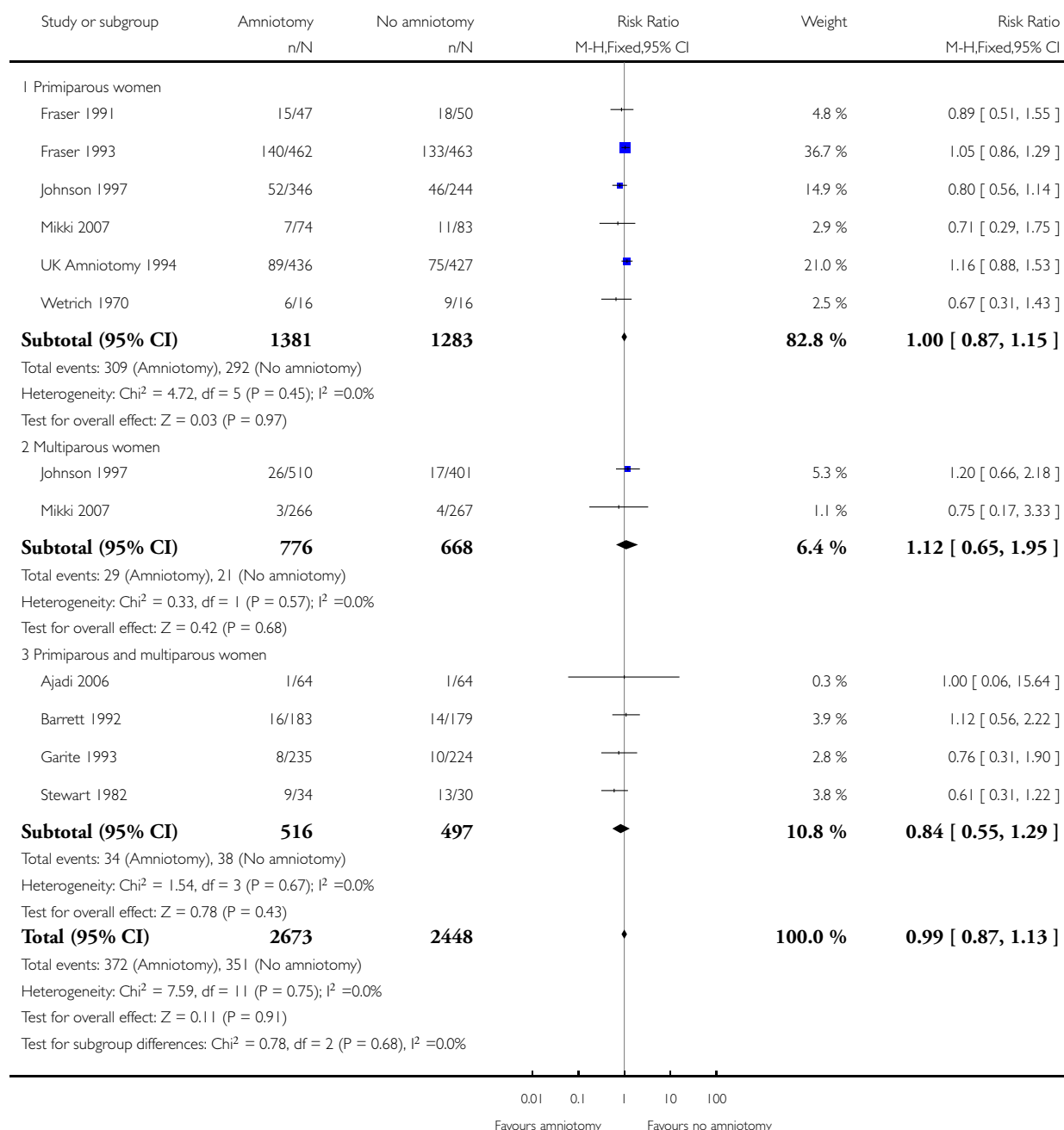


Analysis 1.9. Comparison 1 Amniotomy versus no amniotomy, Outcome 9 Instrumental vaginal birth.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 9 Instrumental vaginal birth

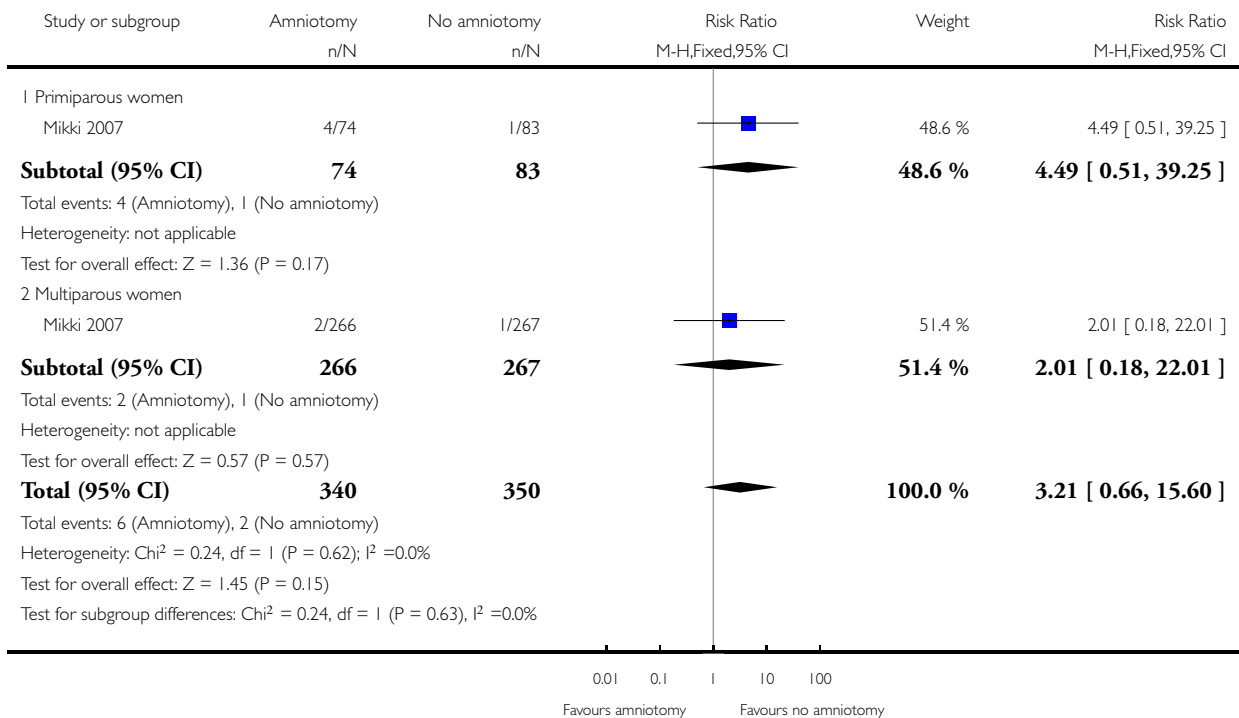


Analysis 1.10. Comparison 1 Amniotomy versus no amniotomy, Outcome 10 Caesarean section for fetal distress.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 10 Caesarean section for fetal distress

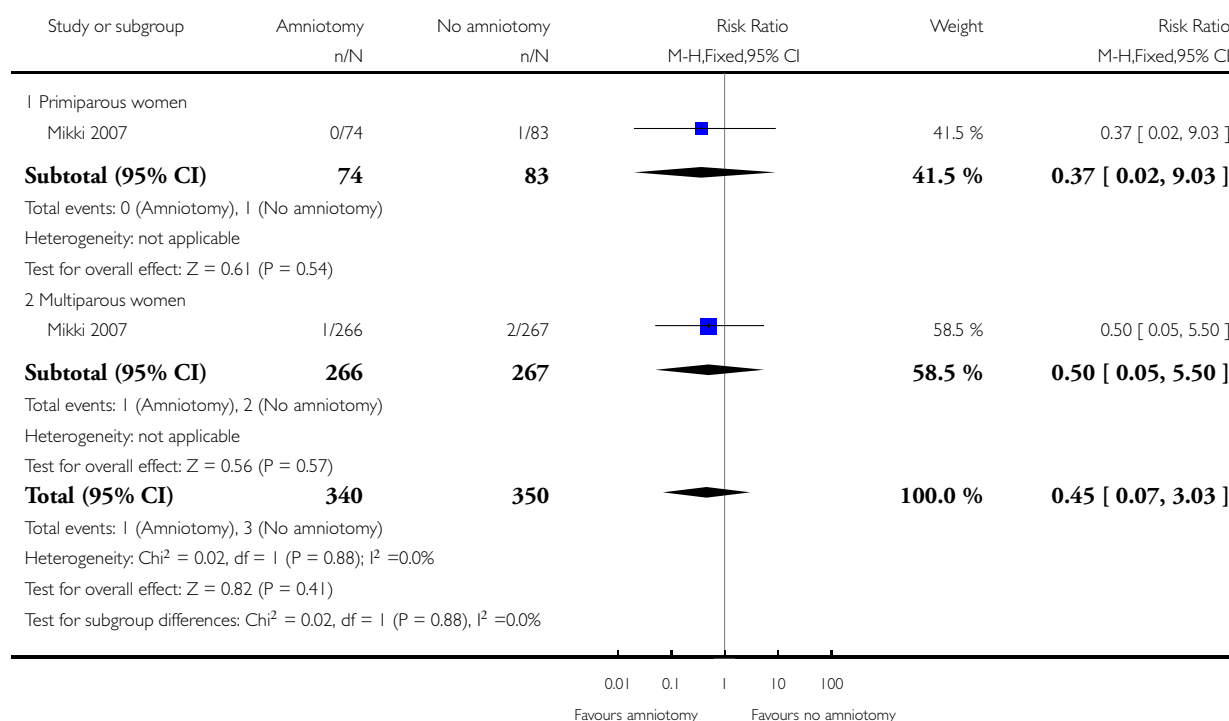


Analysis 1.11. Comparison 1 Amniotomy versus no amniotomy, Outcome 11 Caesarean section for prolonged labour.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 11 Caesarean section for prolonged labour

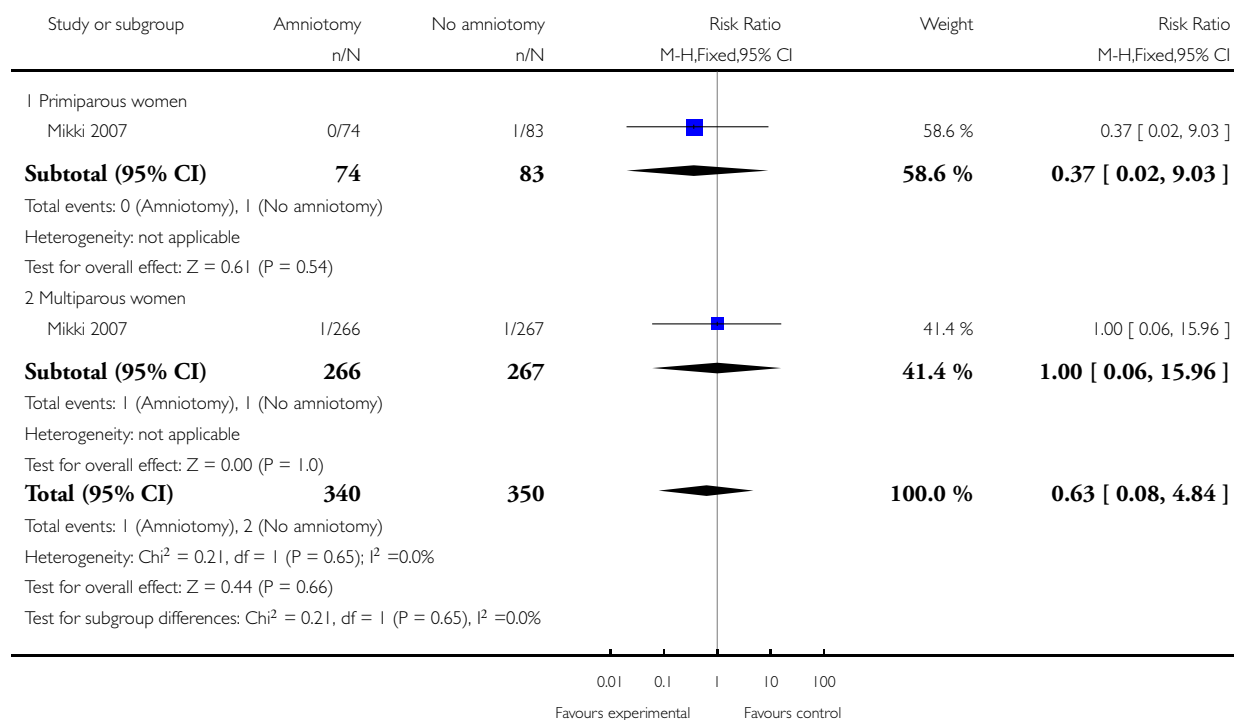


Analysis 1.12. Comparison 1 Amniotomy versus no amniotomy, Outcome 12 Antepartum haemorrhage.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 12 Antepartum haemorrhage

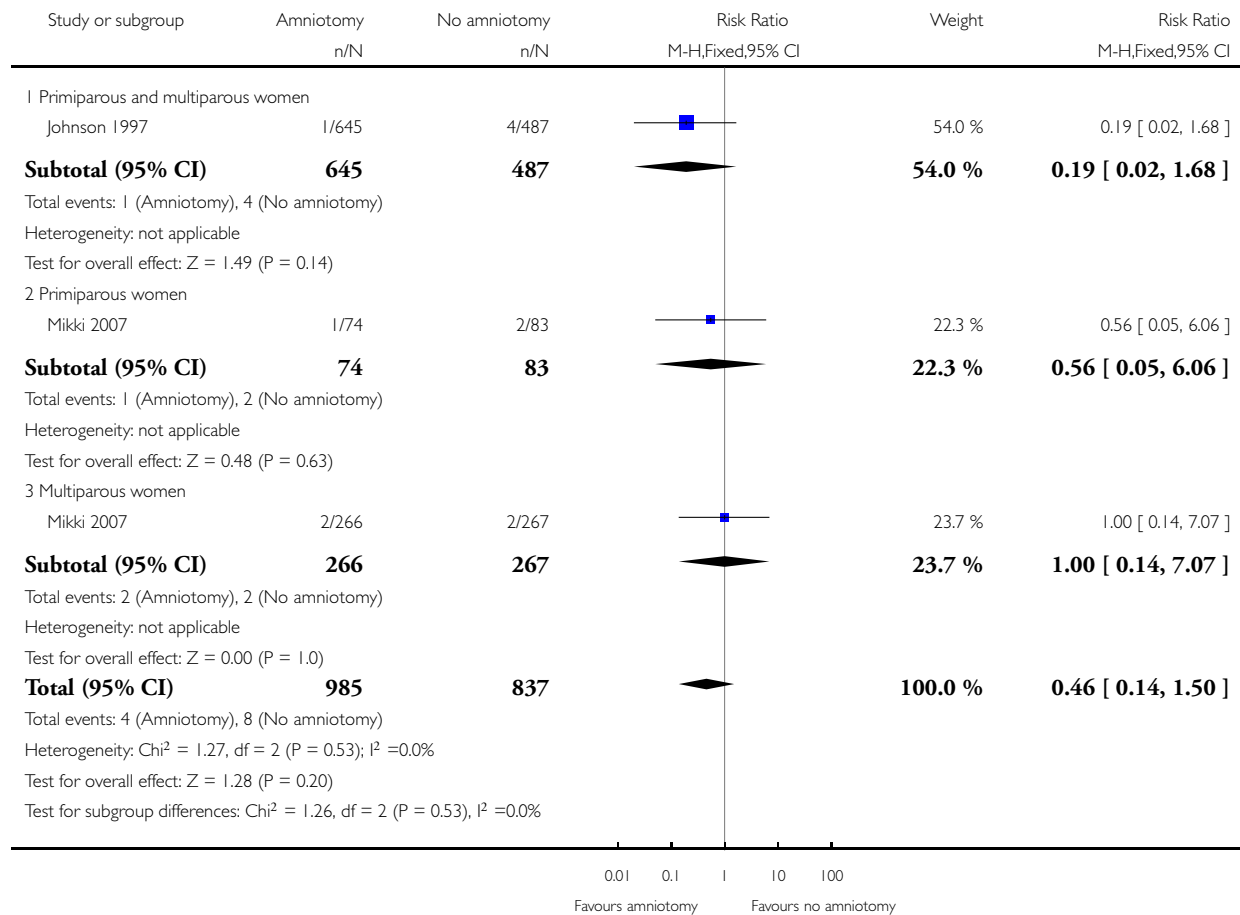


Analysis 1.13. Comparison 1 Amniotomy versus no amniotomy, Outcome 13 Postpartum haemorrhage.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 13 Postpartum haemorrhage

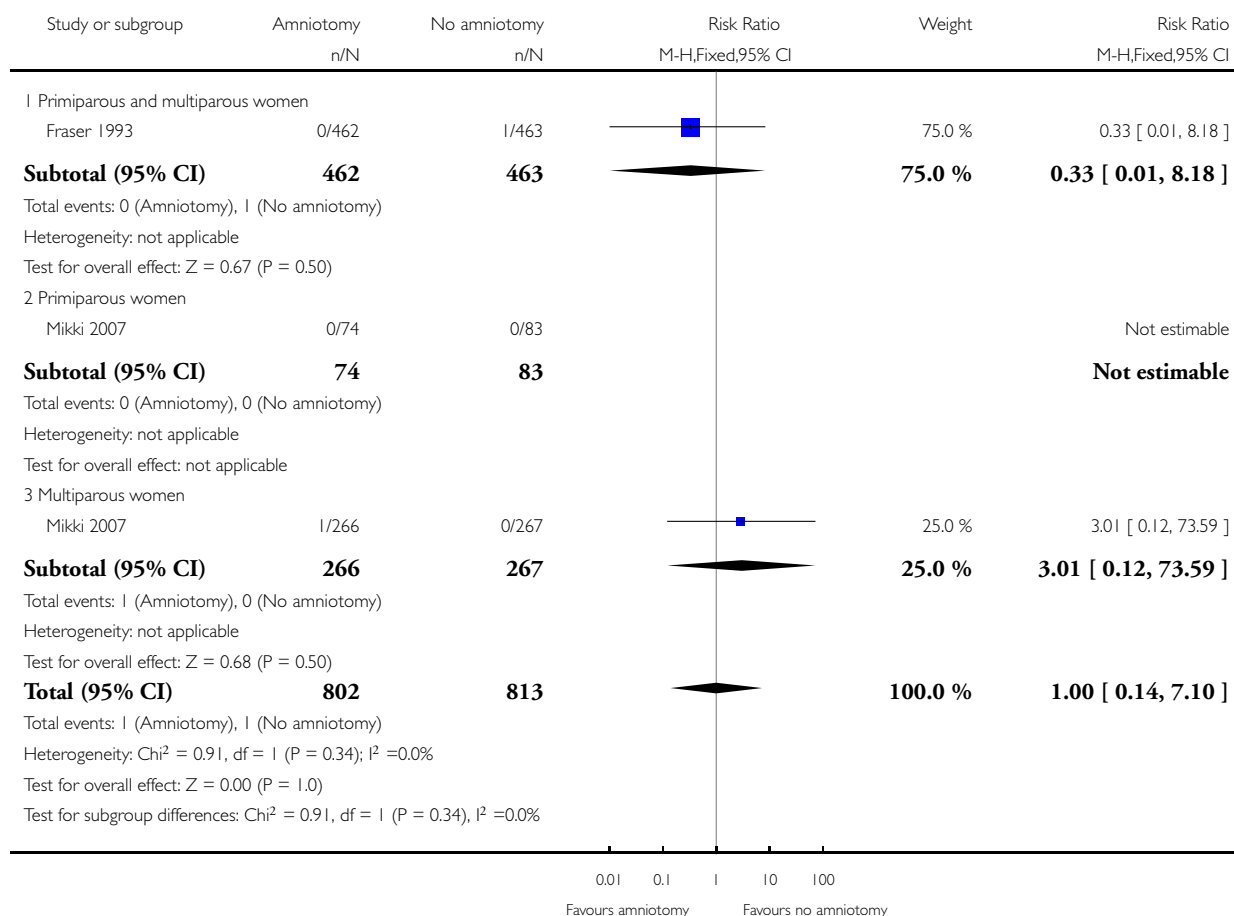


Analysis 1.14. Comparison 1 Amniotomy versus no amniotomy, Outcome 14 Cord prolapse.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 14 Cord prolapse

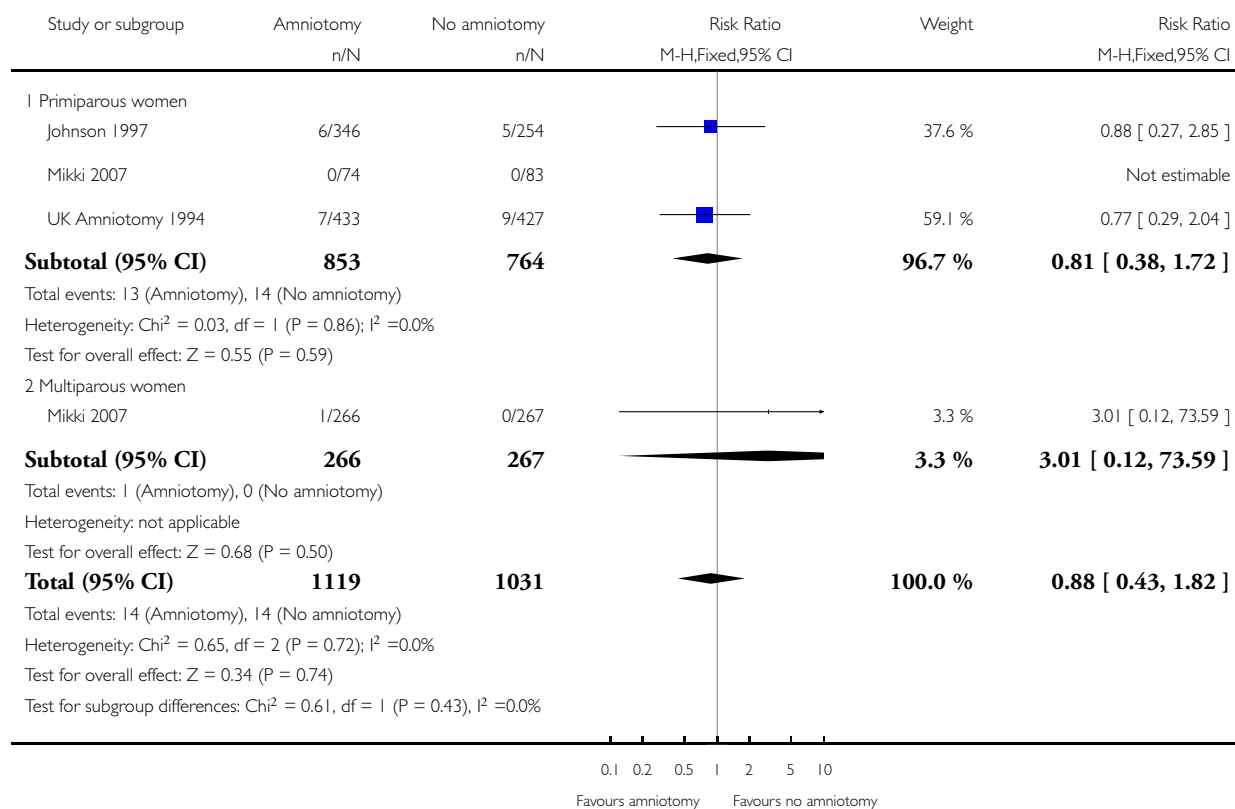


Analysis 1.15. Comparison 1 Amniotomy versus no amniotomy, Outcome 15 Maternal infection.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 15 Maternal infection

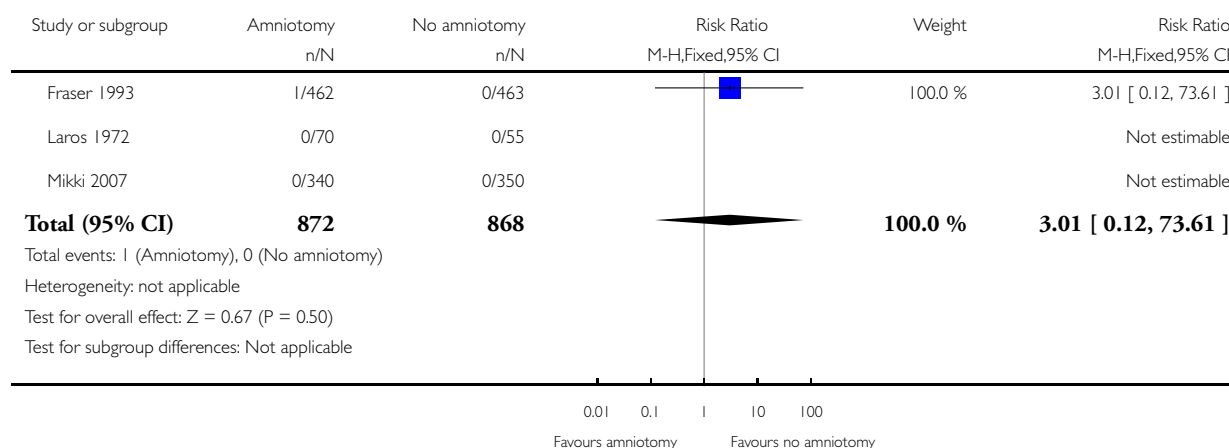


Analysis 1.16. Comparison 1 Amniotomy versus no amniotomy, Outcome 16 Maternal mortality.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 16 Maternal mortality

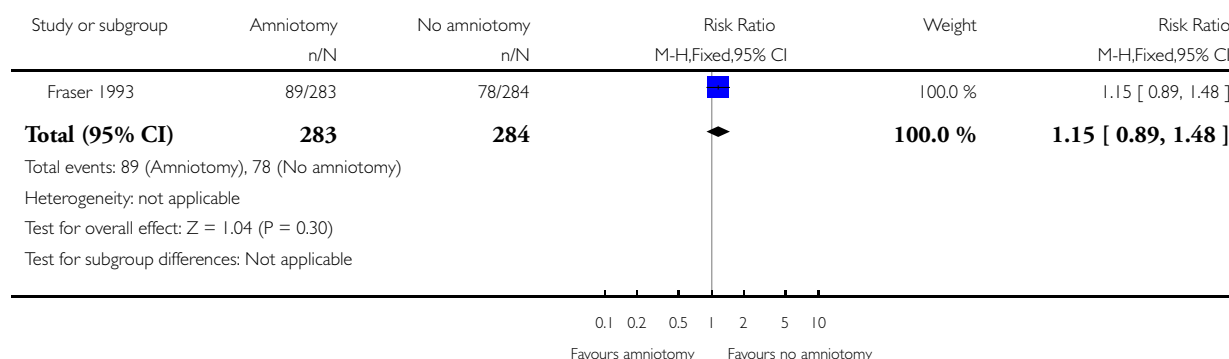


Analysis 1.17. Comparison 1 Amniotomy versus no amniotomy, Outcome 17 Suboptimal or abnormal fetal heart trace (second stage of labour).

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 17 Suboptimal or abnormal fetal heart trace (second stage of labour)

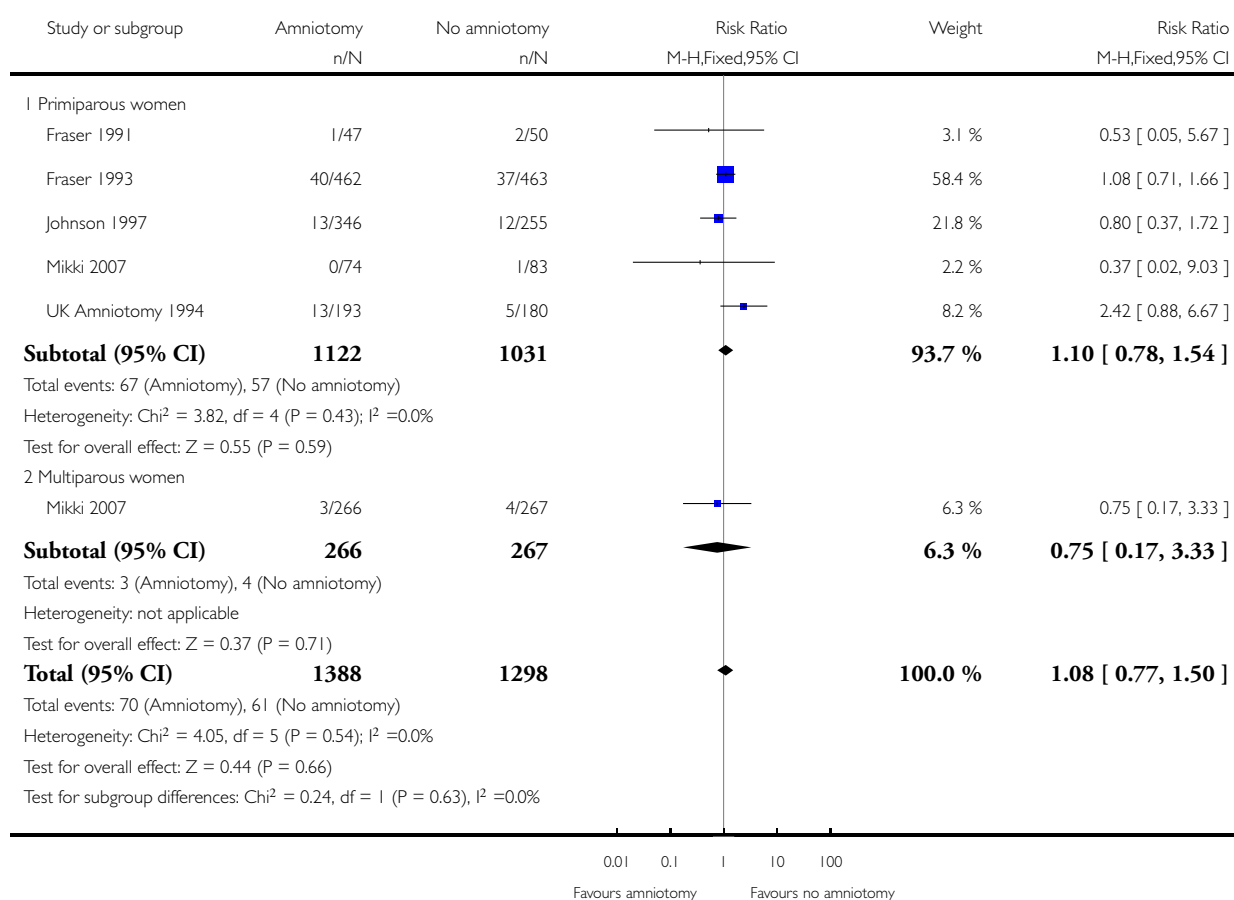


Analysis 1.18. Comparison 1 Amniotomy versus no amniotomy, Outcome 18 Admission to special care baby unit/neonatal intensive care unit.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 18 Admission to special care baby unit/neonatal intensive care unit

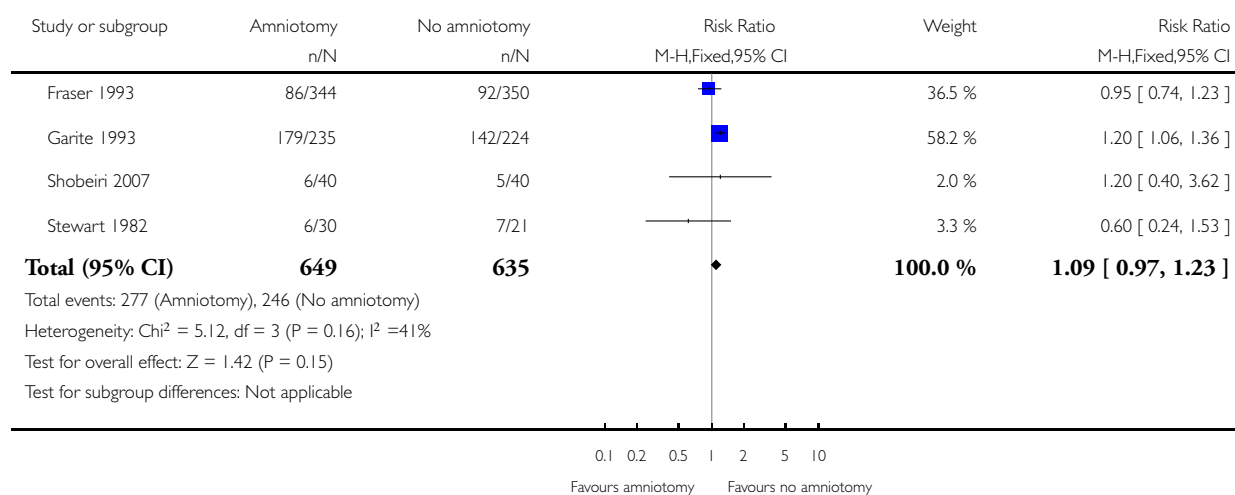


Analysis 1.19. Comparison 1 Amniotomy versus no amniotomy, Outcome 19 Suboptimal or abnormal fetal heart trace (first stage of labour).

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 19 Suboptimal or abnormal fetal heart trace (first stage of labour)

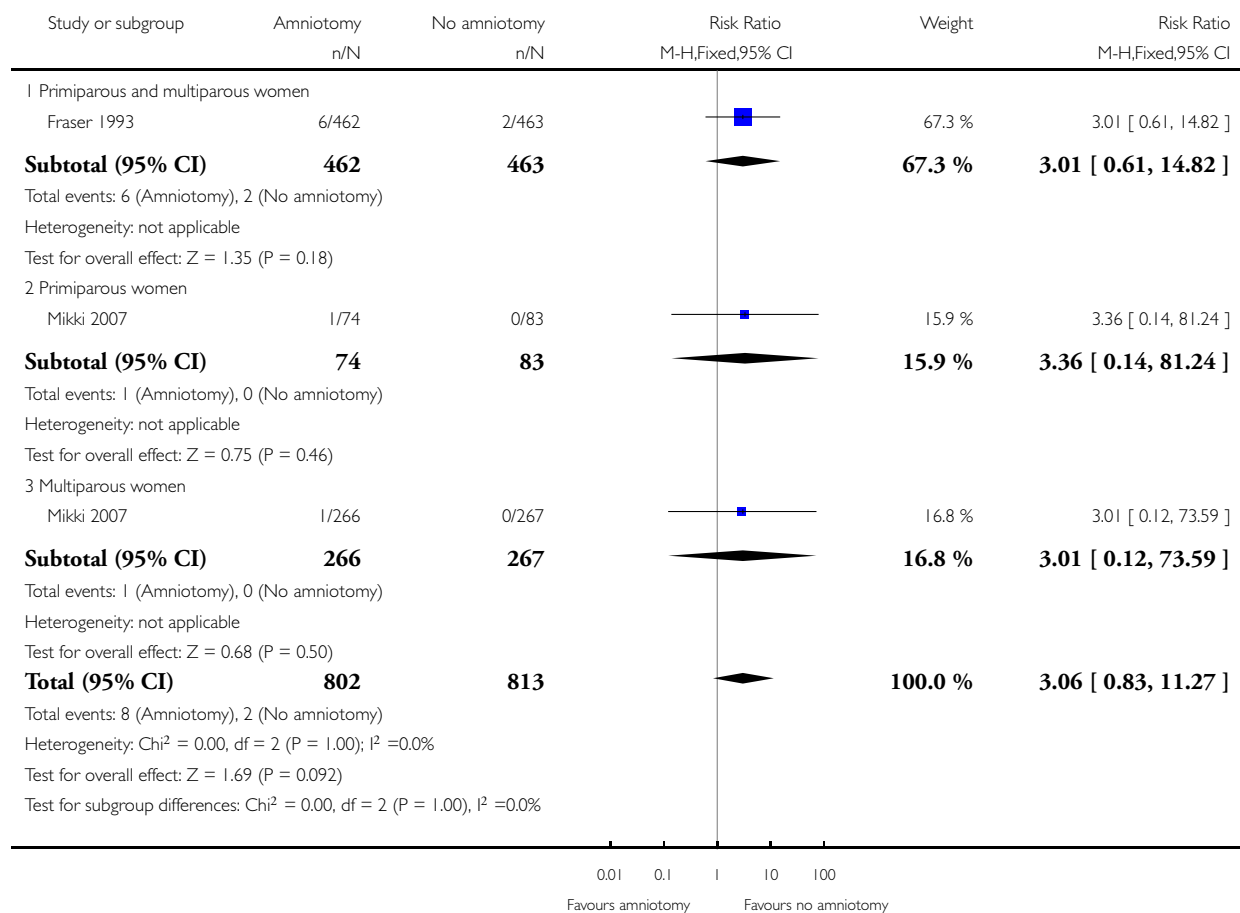


Analysis 1.20. Comparison 1 Amniotomy versus no amniotomy, Outcome 20 Meconium aspiration syndrome.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 20 Meconium aspiration syndrome

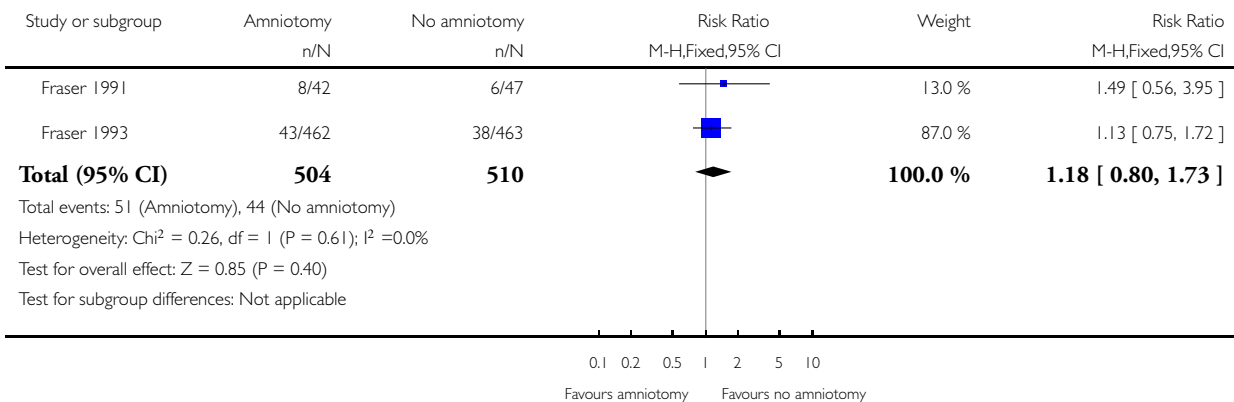


Analysis 1.21. Comparison 1 Amniotomy versus no amniotomy, Outcome 21 Acidosis as defined as a cord blood arterial pH of < 7.2.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 21 Acidosis as defined as a cord blood arterial pH of < 7.2

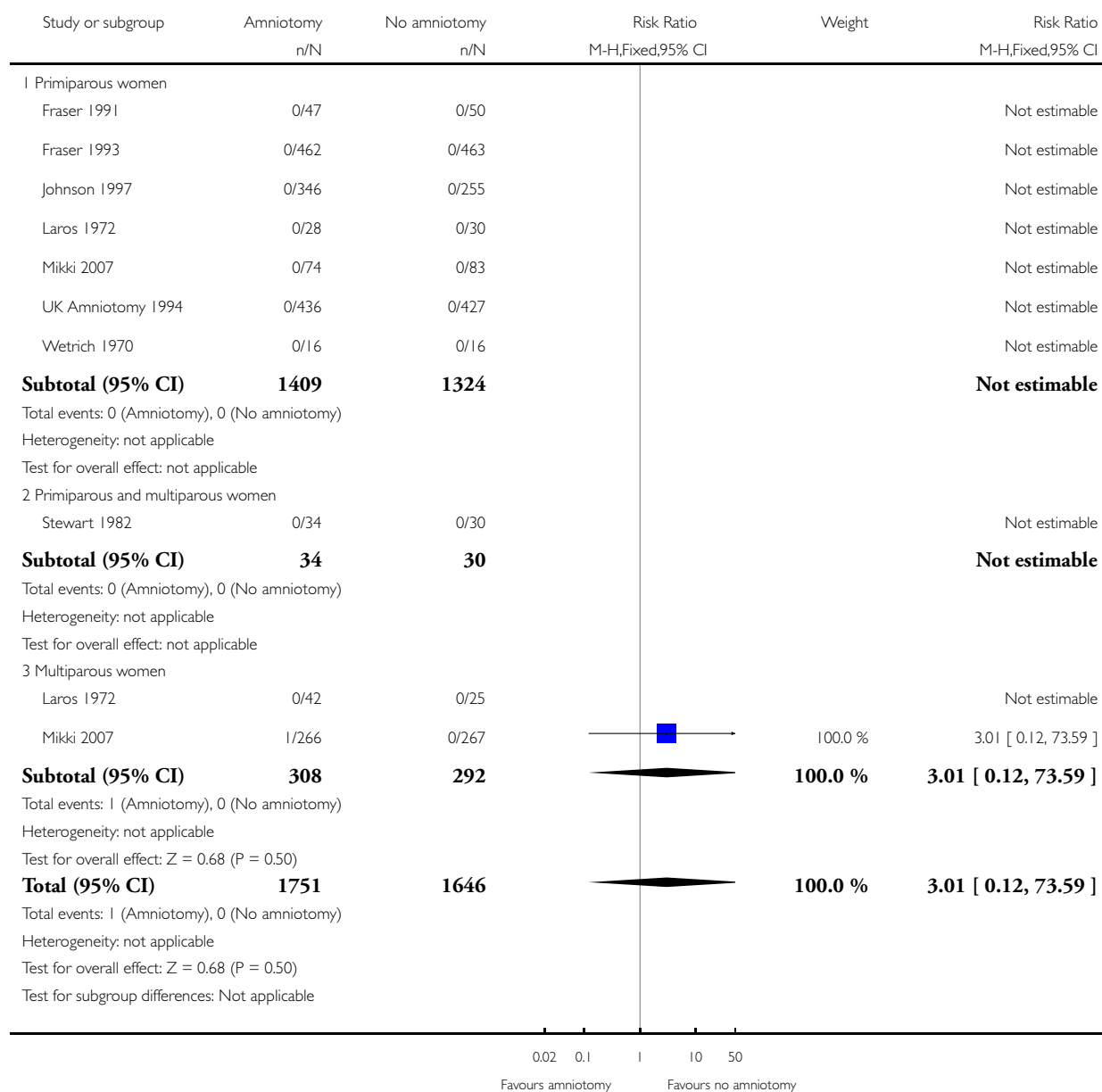


Analysis 1.22. Comparison 1 Amniotomy versus no amniotomy, Outcome 22 Perinatal death.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 22 Perinatal death

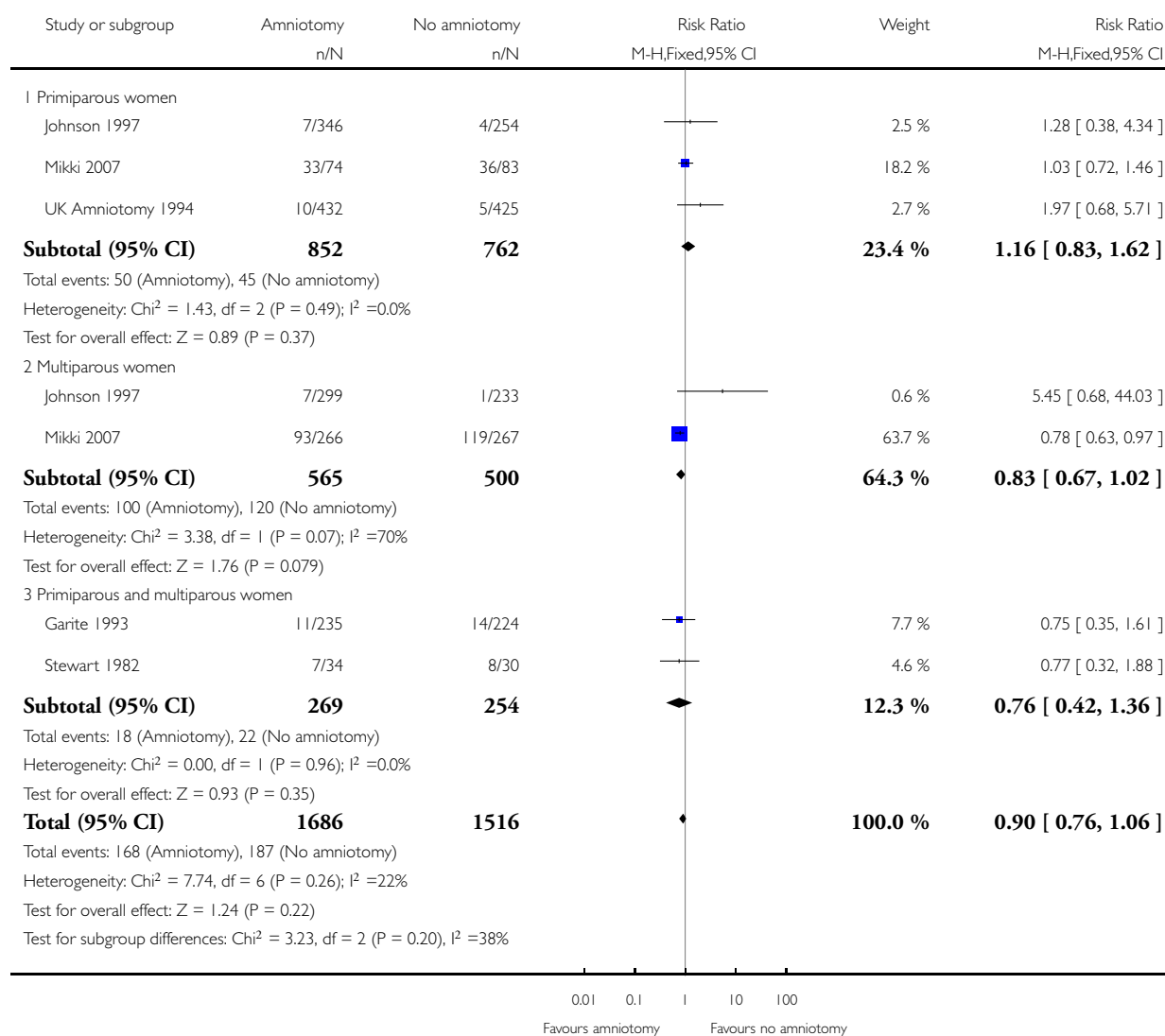


Analysis 1.23. Comparison 1 Amniotomy versus no amniotomy, Outcome 23 Neonatal jaundice.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 23 Neonatal jaundice

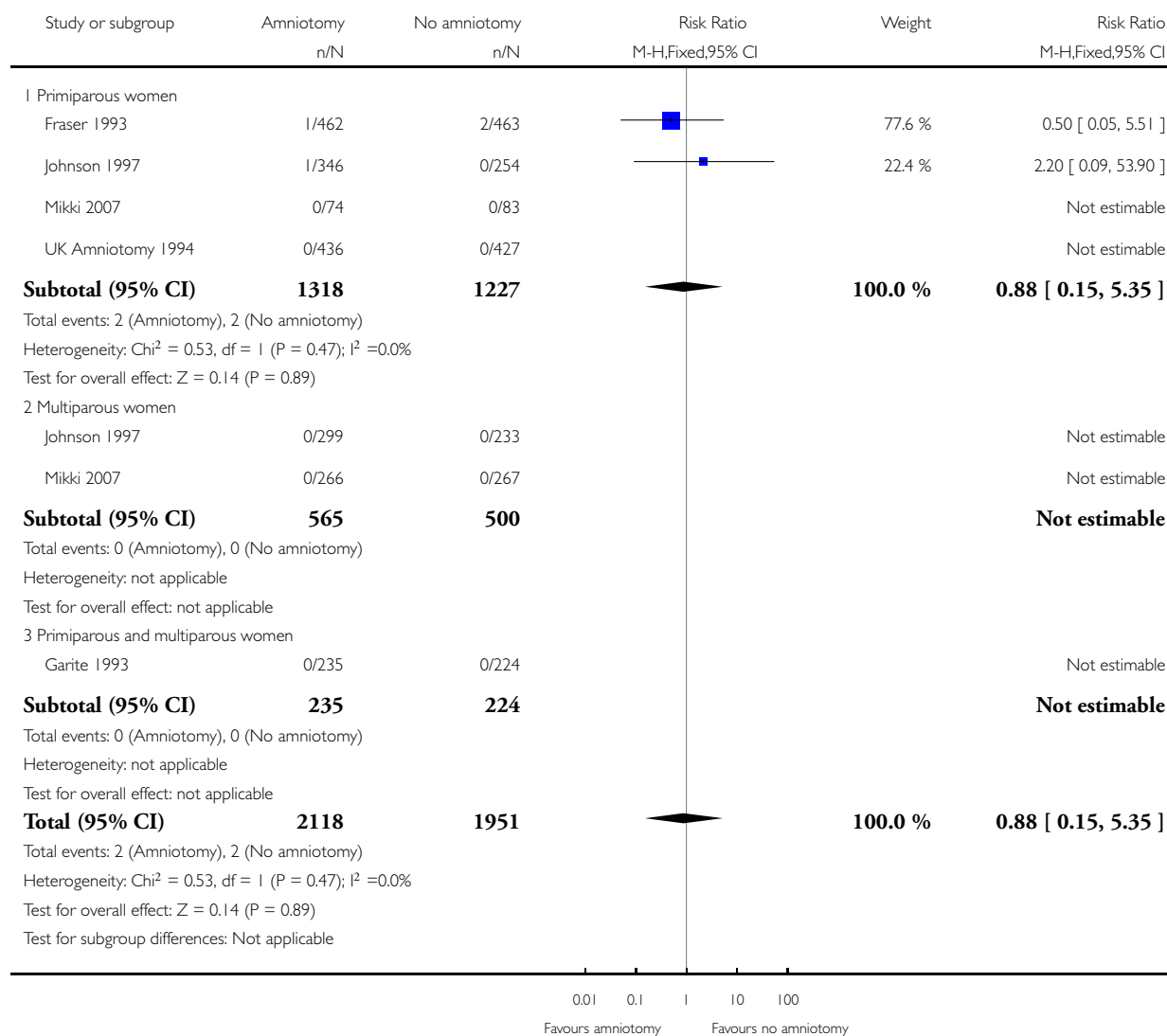


Analysis 1.24. Comparison 1 Amniotomy versus no amniotomy, Outcome 24 Seizures (neonate).

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 24 Seizures (neonate)

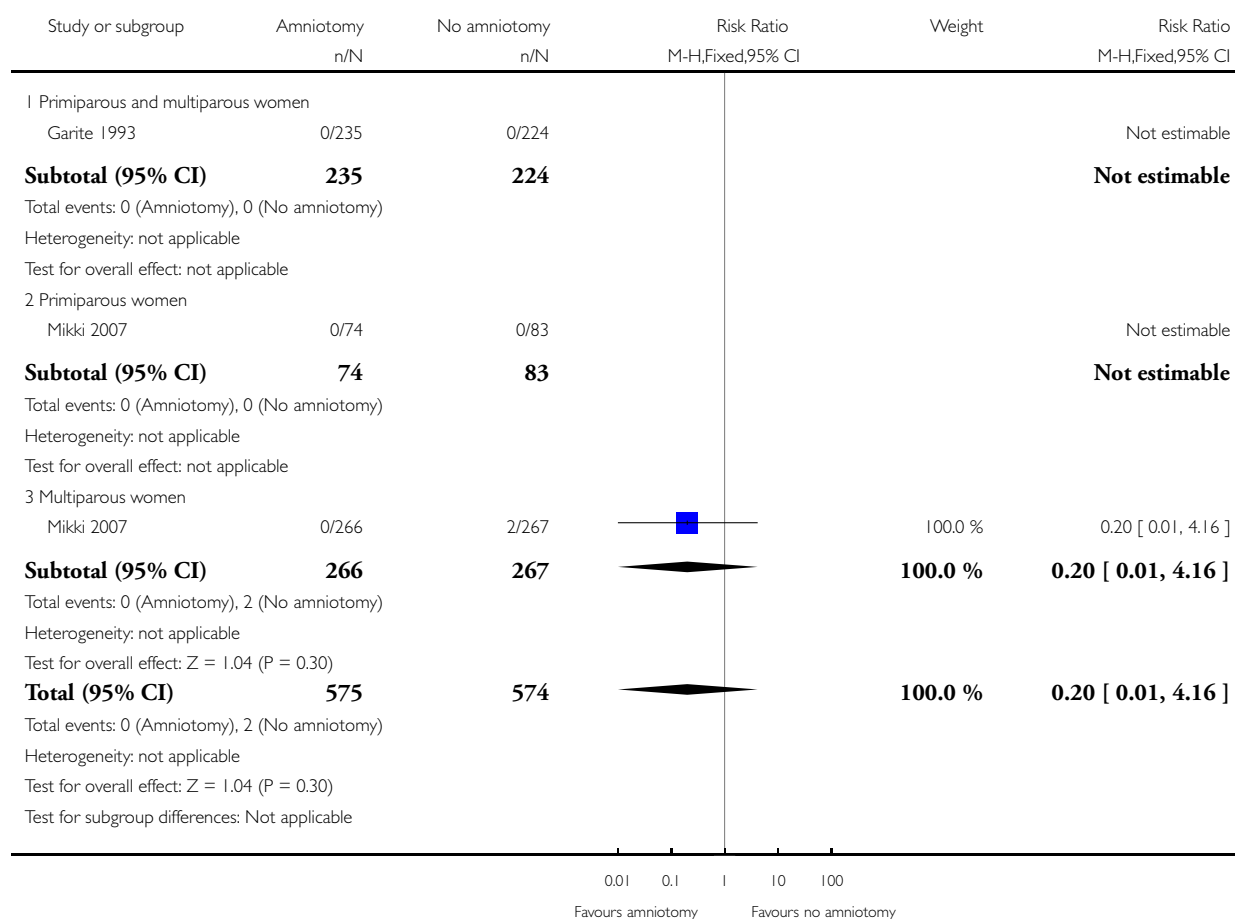


Analysis 1.25. Comparison 1 Amniotomy versus no amniotomy, Outcome 25 Respiratory distress syndrome.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 25 Respiratory distress syndrome

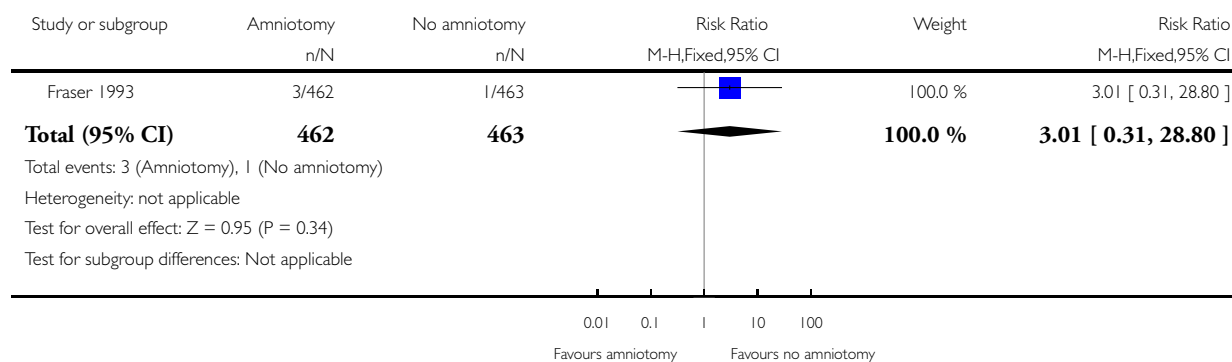


Analysis 1.26. Comparison 1 Amniotomy versus no amniotomy, Outcome 26 Fracture.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 26 Fracture

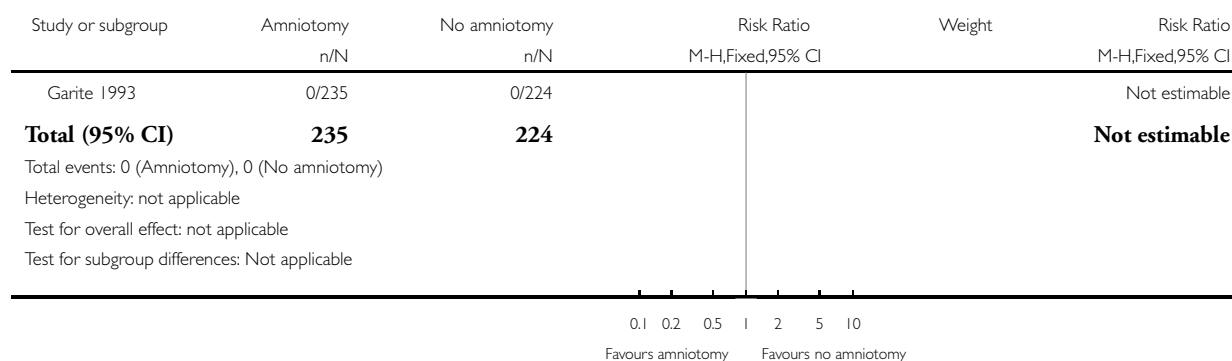


Analysis 1.27. Comparison 1 Amniotomy versus no amniotomy, Outcome 27 Intracranial haemorrhage.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 27 Intracranial haemorrhage

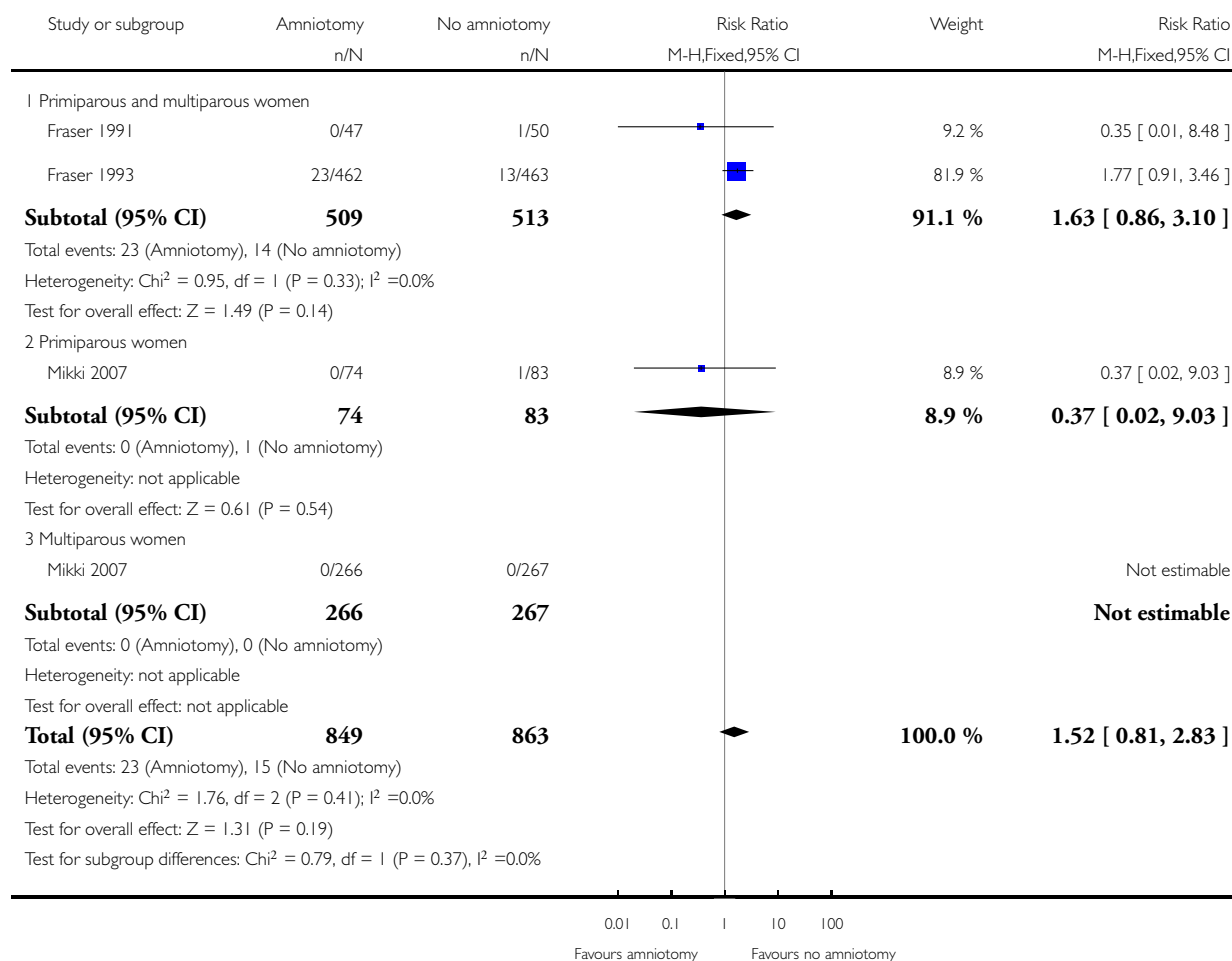


Analysis 1.28. Comparison 1 Amniotomy versus no amniotomy, Outcome 28 Cephalhaematoma.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 28 Cephalhaematoma

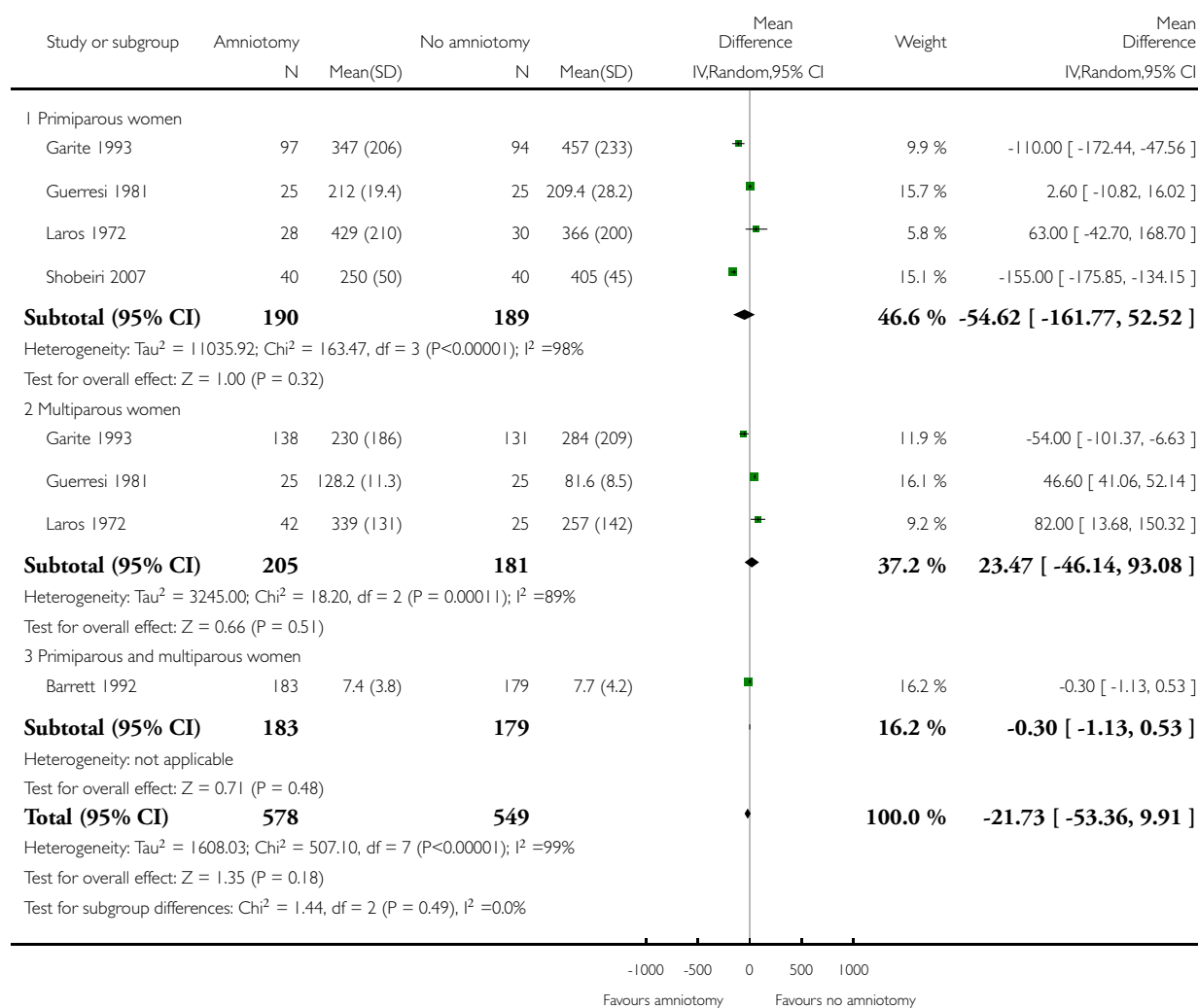


Analysis 2.1. Comparison 2 Sensitivity analysis excluding trials with inadequate allocation concealment (c), Outcome 1 Length of first stage of labour.

Review: Amniotomy for shortening spontaneous labour

Comparison: 2 Sensitivity analysis excluding trials with inadequate allocation concealment (c)

Outcome: 1 Length of first stage of labour

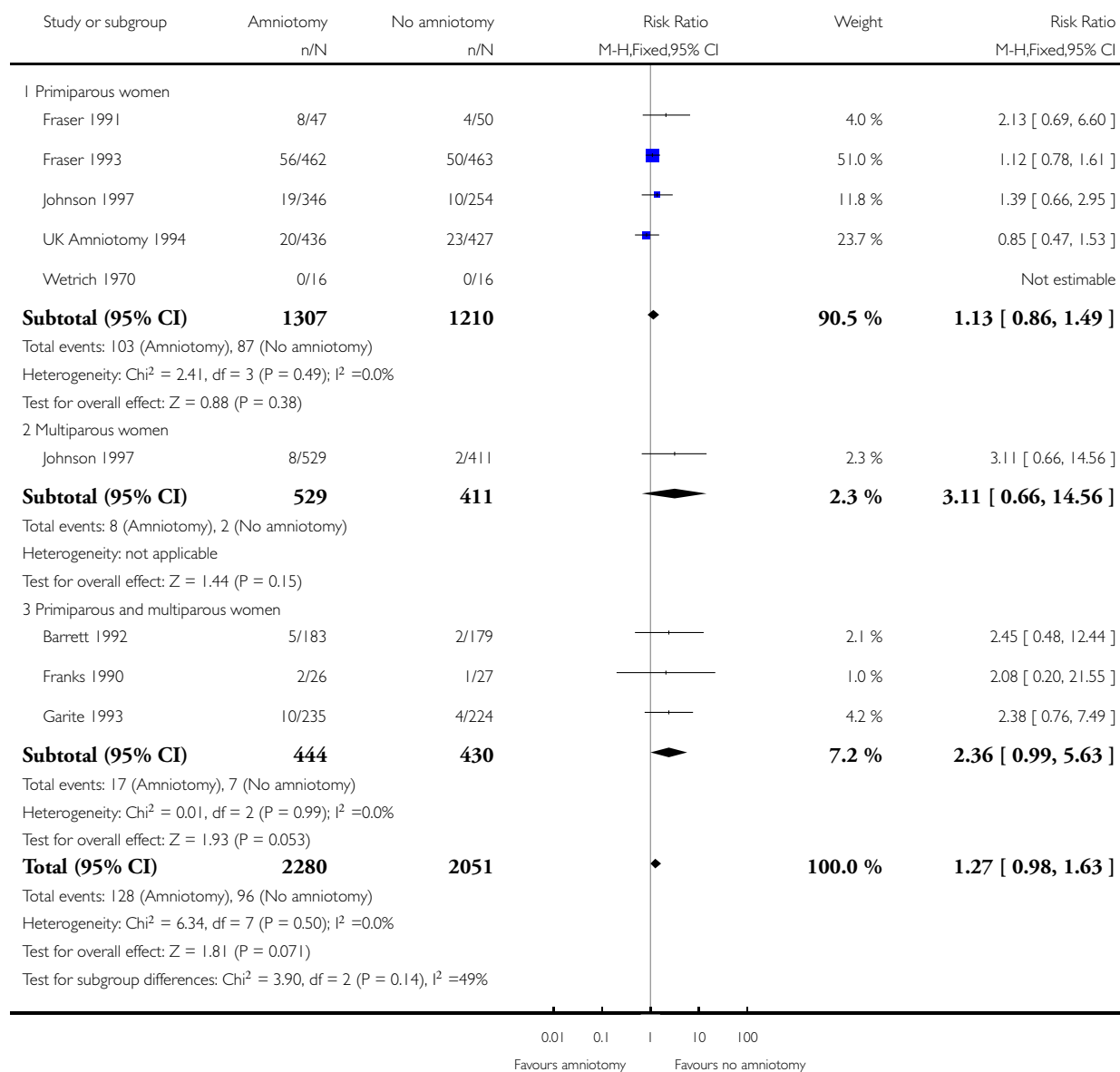


Analysis 2.2. Comparison 2 Sensitivity analysis excluding trials with inadequate allocation concealment (c), Outcome 2 Caesarean section.

Review: Amniotomy for shortening spontaneous labour

Comparison: 2 Sensitivity analysis excluding trials with inadequate allocation concealment (c)

Outcome: 2 Caesarean section

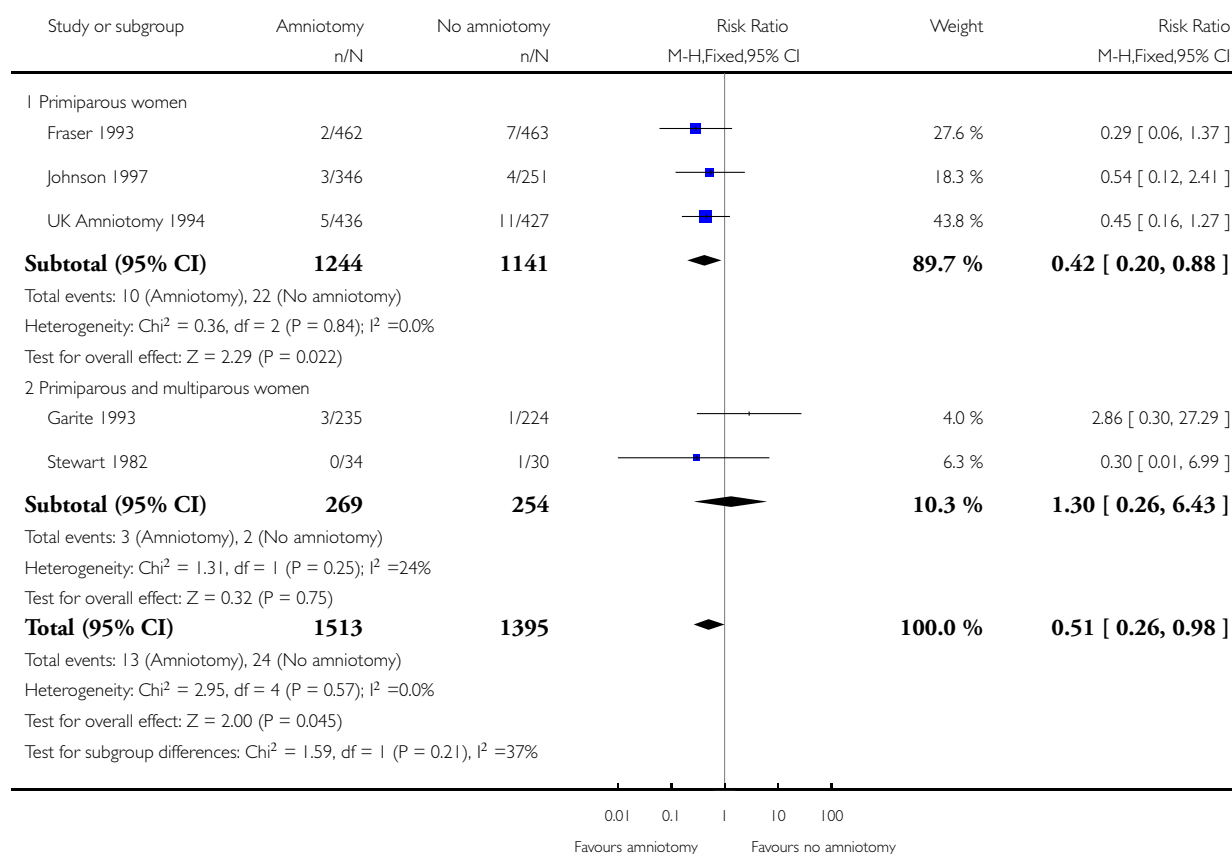


Analysis 2.3. Comparison 2 Sensitivity analysis excluding trials with inadequate allocation concealment (c), Outcome 3 Apgar score less than 7 at 5 minutes.

Review: Amniotomy for shortening spontaneous labour

Comparison: 2 Sensitivity analysis excluding trials with inadequate allocation concealment (c)

Outcome: 3 Apgar score less than 7 at 5 minutes

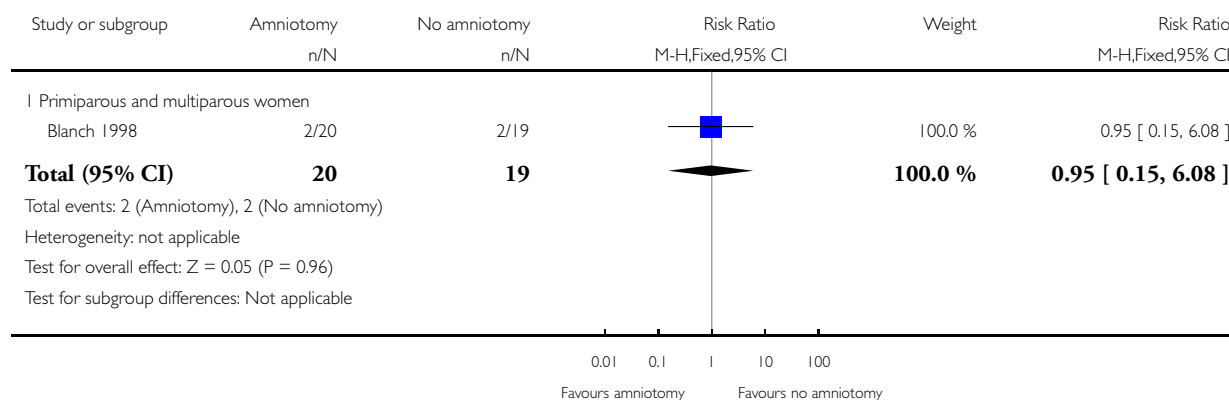


Analysis 3.1. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 1 Caesarean section.

Review: Amniotomy for shortening spontaneous labour

Comparison: 3 Amniotomy vs no amniotomy (dysfunctional labour)

Outcome: 1 Caesarean section

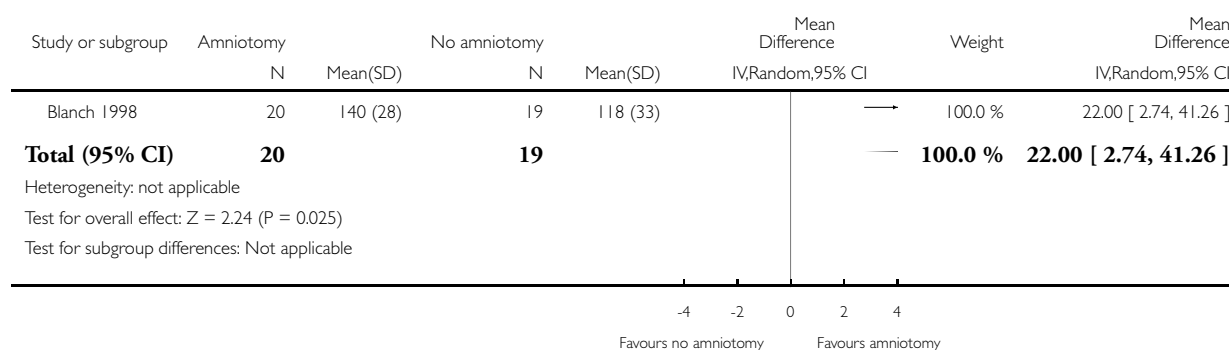


Analysis 3.2. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 2 Maternal satisfaction with childbirth experience.

Review: Amniotomy for shortening spontaneous labour

Comparison: 3 Amniotomy vs no amniotomy (dysfunctional labour)

Outcome: 2 Maternal satisfaction with childbirth experience

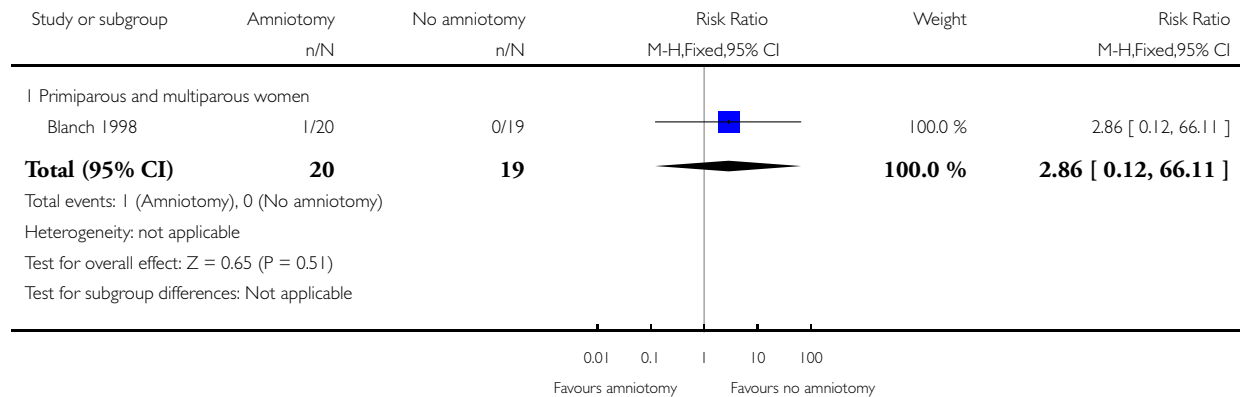


Analysis 3.3. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 3 Apgar score less than 7 at 5 minutes.

Review: Amniotomy for shortening spontaneous labour

Comparison: 3 Amniotomy vs no amniotomy (dysfunctional labour)

Outcome: 3 Apgar score less than 7 at 5 minutes

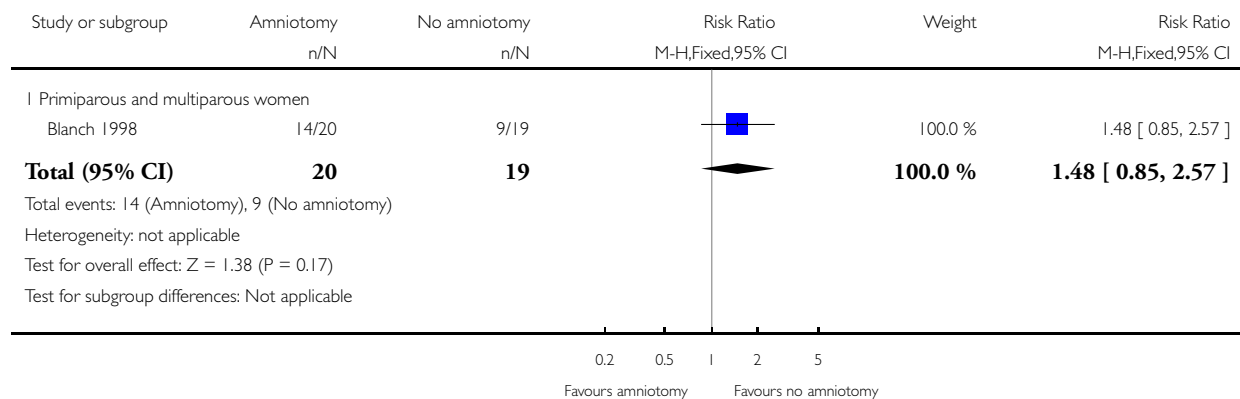


Analysis 3.4. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 4 Use of pain relief - epidural/narcotic.

Review: Amniotomy for shortening spontaneous labour

Comparison: 3 Amniotomy vs no amniotomy (dysfunctional labour)

Outcome: 4 Use of pain relief - epidural/narcotic

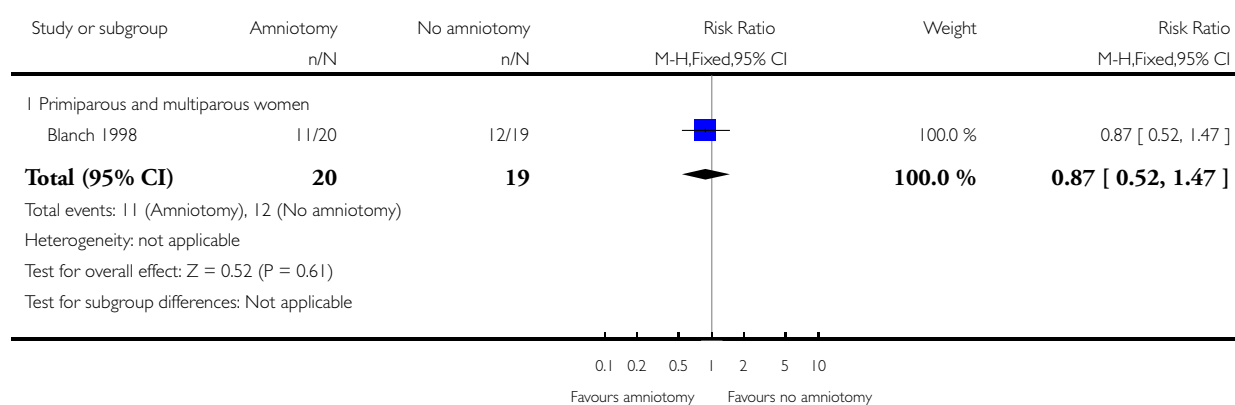


Analysis 3.5. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 5 Oxytocin augmentation.

Review: Amniotomy for shortening spontaneous labour

Comparison: 3 Amniotomy vs no amniotomy (dysfunctional labour)

Outcome: 5 Oxytocin augmentation

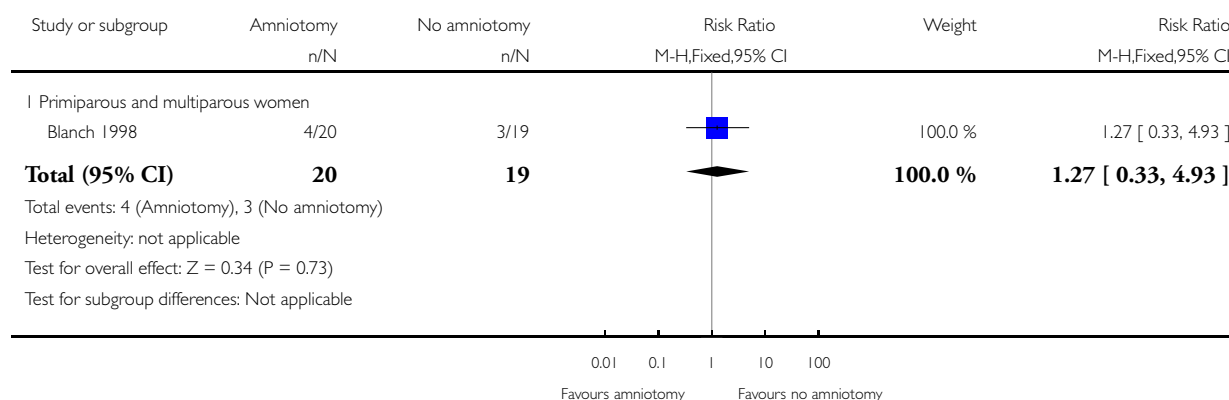


Analysis 3.6. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 6 Instrumental vaginal birth.

Review: Amniotomy for shortening spontaneous labour

Comparison: 3 Amniotomy vs no amniotomy (dysfunctional labour)

Outcome: 6 Instrumental vaginal birth

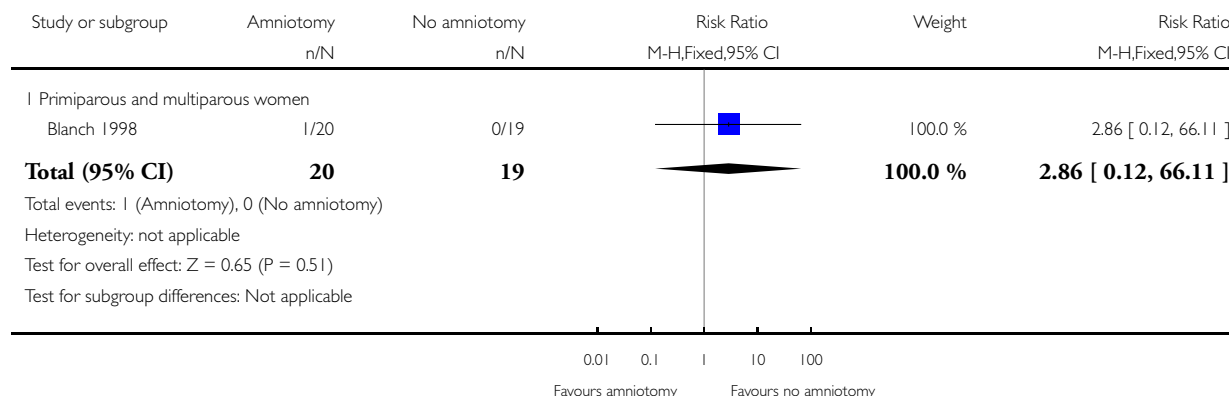


Analysis 3.7. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 7 Caesarean section for fetal distress.

Review: Amniotomy for shortening spontaneous labour

Comparison: 3 Amniotomy vs no amniotomy (dysfunctional labour)

Outcome: 7 Caesarean section for fetal distress

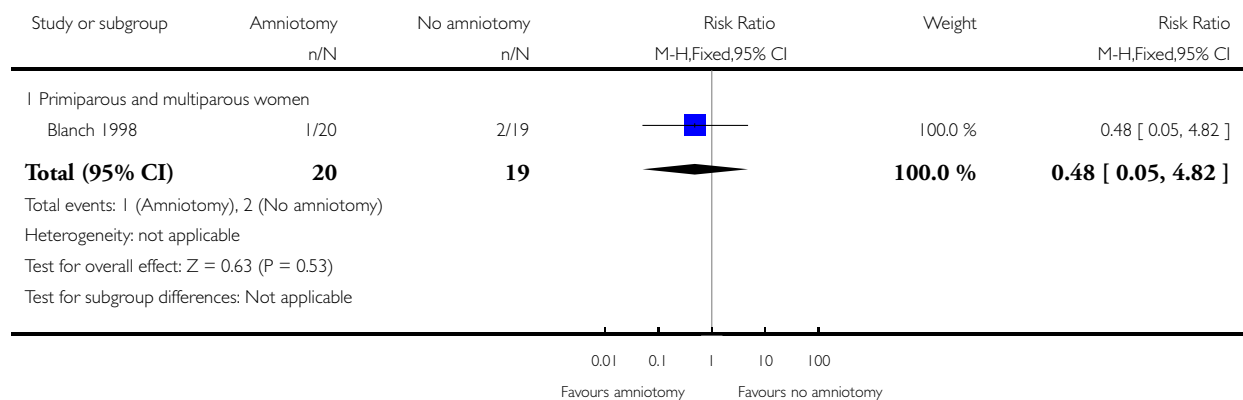


Analysis 3.8. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 8 Caesarean section for prolonged labour.

Review: Amniotomy for shortening spontaneous labour

Comparison: 3 Amniotomy vs no amniotomy (dysfunctional labour)

Outcome: 8 Caesarean section for prolonged labour

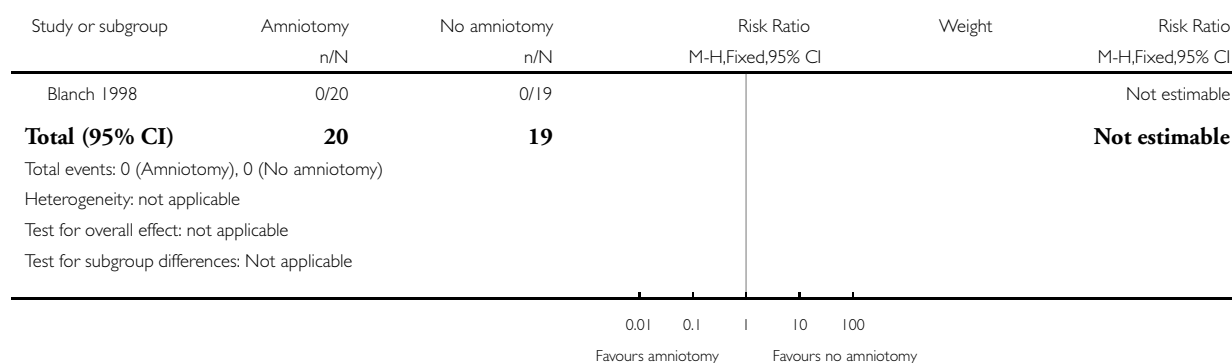


Analysis 3.9. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 9 Maternal mortality.

Review: Amniotomy for shortening spontaneous labour

Comparison: 3 Amniotomy vs no amniotomy (dysfunctional labour)

Outcome: 9 Maternal mortality

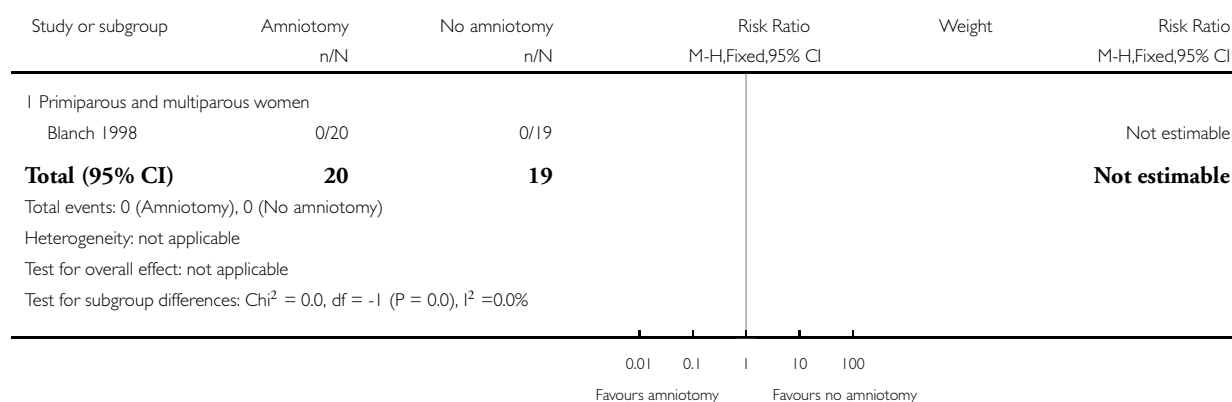


Analysis 3.10. Comparison 3 Amniotomy vs no amniotomy (dysfunctional labour), Outcome 10 Admission to special care baby unit/neonatal intensive care unit.

Review: Amniotomy for shortening spontaneous labour

Comparison: 3 Amniotomy vs no amniotomy (dysfunctional labour)

Outcome: 10 Admission to special care baby unit/neonatal intensive care unit



APPENDICES

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

The following methods were used to assess [Ajadi 2006](#); [Barrett 1992](#); [Blanch 1998](#); [Franks 1990](#); [Fraser 1991](#); [Fraser 1993](#); [Garite 1993](#); [Guerresi 1981](#); [Johnson 1997](#); [Laros 1972](#); [Mikki 2007](#); [Shobeiri 2007](#); [Stewart 1982](#); [UK Amniotomy 1994](#); and [Wetrich 1970](#).

Selection of studies

Two review authors (Rebecca Smyth (RS), Sarah K Alldred (SKA)) assessed for inclusion all potential studies identified as a result of the search strategy. We resolved any disagreement through discussion and joint review of the data in the original article and discussion.

Assessment of methodological quality of included studies

We assessed the validity of each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2005](#)). Methods used for generation of the randomisation sequence are described for each trial.

(1) Selection bias (allocation concealment)

We assigned a quality score for each trial, using the following criteria:

- (A) adequate concealment of allocation: such as telephone randomisation, consecutively-numbered, sealed opaque envelopes;
- (B) unclear whether adequate concealment of allocation: such as list or table used, sealed envelopes, or study does not report any concealment approach;
- (C) inadequate concealment of allocation: such as open list of random-number tables, use of case record numbers, dates of birth or days of the week.

(2) Performance bias (blinding of participants, researchers and outcome assessment)

We assessed blinding using the following criteria:

- (A) blinding of participants (yes/no/unclear);
- (B) blinding of caregiver (yes/no/unclear);
- (C) blinding of outcome assessment (yes/no/unclear).

(3) Attrition bias (loss of participants, for example, withdrawals, dropouts, protocol deviations)

We assessed completeness to follow-up using the following criteria:

- (A) less than 5% loss of participants;
- (B) 5% to 9.9% loss of participants;
- (C) 10% to 19.9% loss of participants;
- (D) more than 20% loss of participants.

Data extraction and management

We designed a form to extract data. Two review authors (RS, SKA) extracted the data using the agreed form. We resolved discrepancies through discussion. We used the Review Manager software ([RevMan 2011](#)) to double enter all the data.

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

Measures of treatment effect

We carried out statistical analysis using [RevMan 2011](#). We used fixed-effect meta-analysis for combining data in the absence of significant heterogeneity if trials were sufficiently similar.

Dichotomous data

For dichotomous data, we presented results as summary relative risk with 95% confidence intervals.

Continuous data

For continuous data, we used the weighted mean difference for outcomes measured in the same way between trials. We used the standardised mean difference to combine trials that measured the same outcome, but use different methods. If there had been evidence of skewness, we would have reported this.

Dealing with missing data

We analysed data on an intention-to-treat basis. Therefore, we included all participants with available data in the analysis in the group to which they were allocated, regardless of whether or not they received the allocated intervention. If in the original reports participants had not been analysed in the group to which they were randomised, and there was sufficient information in the trial report, we would have restored them to the correct group.

Unit of analysis issues

Cluster-randomised trials

For future updates we will include cluster-randomised trials in the analyses along with individually-randomised trials if they are identified. Their sample sizes will be adjusted using the methods described in [Gates 2005](#) using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), or from another source. If ICCs from other sources are used, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.

We will also acknowledge heterogeneity in the randomisation unit and perform a separate meta-analysis. Therefore, we will perform the meta-analysis in two parts as well.

Assessment of heterogeneity

We applied tests of heterogeneity between trials, using the I^2 statistic. We identified high levels of heterogeneity among the trials (exceeding 50%), and explored it by prespecified subgroup analysis and performed sensitivity analysis. We used a random-effects meta-analysis as an overall summary when considered appropriate.

Subgroup analyses

We planned to conduct the following subgroup analyses:

- parity: primigravida women compared with parous women;
- previous mode of delivery: caesarean section compared with vaginal delivery and no previous delivery;
- stage of labour: less than 3 cm dilated at time of amniotomy compared with 3 cm or more;
- fetal surveillance: continuous fetal heart monitoring compared with intermittent;
- pain relief: pharmacological compared with non-pharmacological;
- indication for intervention: dysfunctional labour versus routine use or fetal compromise;
- position in labour: mobile versus restricted movement in women without an epidural.

Sensitivity analyses

We planned to conduct the following sensitivity analysis:

- for primary outcomes, excluding trials where more than 30% of women did not receive their allocated treatment;
- by trial quality, excluding trials with clearly inadequate allocation of concealment (rated C).

FEEDBACK

Thornton, October 2007

Summary

This is a lovely review. However it was a pity that the authors decided not to include the randomisation to delivery interval as an outcome variable. This is the only measure of labour duration that can be collected without significant risk of bias, and also the one that is most important to women.

Length of the first and the second stage of labour, measured separately, are both susceptible to bias. The time of onset of the first stage is difficult to determine objectively, and although full dilatation is a relatively objective measure, it requires a vaginal examination to make the diagnosis. The timing of vaginal examinations after early amniotomy might differ compared with women not undergoing amniotomy.

In designing the UK amniotomy trial I was very aware of this problem and put a lot of effort into ensuring that the time of randomisation and time of delivery were both recorded. This allowed us to report cumulative randomisation to delivery intervals, and it was clear that there was a modest reduction in the group allocated to early amniotomy.

I remain no fan of early amniotomy, but in fairness I think there is some evidence that it has a modest effect on shortening the overall randomisation to delivery interval.

(Summary of comment from Jim Thornton, October 2007)

Reply

The outcome 'randomisation to birth of baby interval' was included in the initial draft of our protocol for this review. Following peer review it was removed however, as the consumer panel commented that women might not find this information helpful, as the outcome has no meaning outside the context of a randomised trial. Also, although we agree that measurement of the duration of the first and second stage of labour is subject to bias and to variation between observers, these measurements are relevant as they are used in everyday midwifery and obstetric practice, and are the basis for clinical decisions.

We will reconsider whether to include 'randomisation to birth of baby interval' as an outcome when the review is updated.

(Summary of response from Rebecca Smyth, November 2007)

Contributors

Feedback: Jim Thornton

Response: Rebecca Smyth

Wein, 8 November 2007

Summary

The abstract suggest bias by the review authors. They refer to the 26% increase in the relative risk of Caesarean section associated with amniotomy rather than control as a 'not statistically significant' difference, but call a 55% reduction in the relative risk of an Apgar score <7 at 5 minutes 'no evidence of any statistical difference'. Furthermore, for primiparous women the difference in Apgar scores was statistically significant.

(Summary of feedback received from Peter Wein)

Reply

We agree the wording of the abstract appears biased. This was an oversight on our part, and not intentional. The abstract has been revised so that the wording is consistent.

The analysis of Apgar score by parity was not included in the abstract as it was a subgroup, and reporting of results in the abstract is restricted to the main analyses. These data are however presented in the results text.

Contributors

Feedback: Peter Wein

Response: Rebecca Smyth and S Kate Alldred

WHAT'S NEW

Last assessed as up-to-date: 10 June 2013.

Date	Event	Description
15 May 2013	New search has been performed	A new review author helped to prepare this update. An updated search identified three new reports (Abdullah 2010 ; Li 2006 ; Nachum 2010); all have been excluded. There are no new included studies in this update. We now analyse separately data presented by Blanch 1998 for women with prolonged labour. Conclusions remain unchanged.
15 May 2013	New citation required but conclusions have not changed	Review updated.

HISTORY

Protocol first published: Issue 4, 2006

Review first published: Issue 4, 2007

Date	Event	Description
29 November 2012	New citation required but conclusions have not changed	Error corrected.
29 November 2012	Amended	Edits have been made to clarify that this review examines the effectiveness and safety of amniotomy alone for routinely shortening all labours that start spontaneously. In the current review, data for women with spontaneous normal labour have been pooled with data from one trial where women had spontaneous, but prolonged labour (Blanch 1998). However, in the next update, the review authors will examine the effectiveness and safety of amniotomy for this subgroup of women

(Continued)

30 November 2010	New search has been performed	Search updated. Three new trial reports identified. One has been included (Mikki 2007) and two excluded (Garmi 2008 ; Surichamorn 1998). The conclusions have not changed.
6 December 2008	Feedback has been incorporated	Authors replied to feedback from Peter Wein and edited the Results section of the Abstract in response to the feedback
25 June 2008	Feedback has been incorporated	Feedback from Peter Wein added.
21 April 2008	Amended	Converted to new review format.
30 November 2007	Feedback has been incorporated	Feedback from Jim Thornton and reply from authors added.

CONTRIBUTIONS OF AUTHORS

Rebecca Smyth (RS) drafted and finalised the text of the protocol. Sarah K Alldred (SKA) contributed significantly to the content. Carolyn Markham (CM) (consumer representative author) commented on the final draft.

For the first version of the review, RS and SKA assessed new studies for inclusion independently and extracted all the data. Data were double entered into [RevMan 2011](#). RS and SKA interpreted the results individually and together wrote the [Results](#), [Discussion](#) and [Authors' conclusions](#). CM read the review and was satisfied with its content.

RS and SKA contributed equally to the 2011 update, with CM approving the final version for publication.

RS and TD contributed to the 2013 update, with CM approving the final version for publication.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- The University of Liverpool, UK.

External sources

- UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP) and the Department of Reproductive Health and Research (RHR), World Health Organization, Switzerland.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In the protocol the objectives were: To determine the effectiveness and safety of amniotomy alone for (1) routinely shortening all labours that start spontaneously, and (2) shortening labours that have started spontaneously, but have become prolonged.

We revised the objectives to read: To determine the effectiveness and safety of amniotomy alone for routinely shortening all labours that start spontaneously (see [Published notes](#)).

NOTES

In the earlier versions of this review, data for women with spontaneous normal labour were pooled with data for women with spontaneous labour that had become prolonged ([Blanch 1998](#)). In this 2013 update, we have presented data separately for women with prolonged labour.

INDEX TERMS

Medical Subject Headings (MeSH)

Amnion [*surgery]; Labor Stage, First [*physiology]; Labor, Induced [methods]; Randomized Controlled Trials as Topic; Time Factors

MeSH check words

Female; Humans; Pregnancy