

Amniotomy for shortening spontaneous labour (Review)

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[Intervention review]

Amniotomy for shortening spontaneous labour

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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 (1) routinely shortening all labours that start spontaneously, and (2) shortening labours that have started spontaneously, but have become prolonged.

Search strategy

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (30 March 2007).

Selection criteria

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

Data collection and analysis

Two authors assessed identified studies for inclusion. Both authors extracted data. Primary analysis was by intention to treat.

Main results

We have included 14 studies in this review, involving 4893 women. There was no evidence of any statistical difference in length of first stage of labour (weighted mean difference -20.43 minutes, 95% confidence interval (CI) -95.93 to 55.06), maternal satisfaction with childbirth experience (standardised mean difference 0.27, 95% CI -0.49 to 1.04) or low Apgar score less than seven at five minutes (RR 0.55, 95% CI 0.29 to 1.05). Amniotomy was associated with an increased risk of delivery by caesarean section compared to women in the control group, although the difference was not statistically significant (RR 1.26, 95% CI 0.98 to 1.62).

There was no consistency between papers regarding the timing of amniotomy during labour in terms of cervical dilatation.

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 do 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 the routine breaking the waters for women in spontaneous labour.

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 routinely in all labours that started spontaneously. It also assessed the use of amniotomy in labours that started spontaneously but had become prolonged. There were 14 studies identified, involving 4893 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 for normally progressing labours or in labours which have become prolonged.

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 crotchet-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 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: '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).

OBJECTIVES

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.

METHODS

Criteria for considering studies for this review

Types of studies

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

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 (cephalhematoma) 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 March 2007).

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

1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. monthly searches of MEDLINE;
3. handsearches of 30 journals and the proceedings of major conferences;
4. weekly current awareness search of a further 36 journals plus monthly BioMed Central email alerts.

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

Trials identified through the searching activities described above are given a code (or codes) depending on the topic. The codes are linked to review topics. The Trials Search Co-ordinator searches the register for each review using these codes rather than keywords. We did not apply any language restrictions.

Data collection and analysis

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 2003) 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 2003. 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 have presented results as summary relative risk with 95% confidence intervals.

Continuous data

For continuous data, we have 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 intraclass 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 have applied tests of heterogeneity between trials, using the I-squared 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: primigravid 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).

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

We have included 14 trials (24 publications) in this review, totaling 4893 women. The three largest included trials ([Fraser 1993](#); [Johnson 1997](#); [UK Amniotomy 1994](#); comprising 925, 940 and 1463 women respectively), were conducted in the UK. Eight trials included both nulliparous and multiparous women, and six trials included nulliparous women only. In 13 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. Twelve 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 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. Studies were predominantly single centre (n = 11), and most were conducted in the UK, USA and Canada.

See table of 'Characteristics of included studies' and 'Characteristics of excluded studies' for details of the individual studies.

Risk of bias in included studies

We excluded four trials: two on the basis of being quasi-randomised, one trial looked at amniotomy for induction and one trial looked at the effect of amniotomy on fetal heart rate tracing, rather than on spontaneous labour.

All studies included in the review were randomised. Methods of randomisation were clear in eight studies and unclear in six. 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](#); [Garite 1993](#); [Johnson 1997](#); [Laros 1972](#); [UK Amniotomy 1994](#)). One of the eight 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](#)). Three trials ([Franks 1990](#); [Garite 1993](#); [Laros 1972](#)) used sealed envelopes that were not described as being opaque. One trial ([Wetrich 1970](#)) used a blind draw to randomly assign patients. In the remaining four trials, information was not provided about allocation concealment and these were therefore classified as being unclear. 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 one paper, a decision was made to stop the trial with only half the women recruited due to slow rate of recruitment (Blanch 1998).

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.

Effects of interventions

We have included 14 studies (24 publications) in this review, involving 4893 women. 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.

Primary outcomes

Length of first stage of labour (minutes)

Five trials involving 1127 women reported this outcome. High levels of heterogeneity ($I^2 > 50\%$) 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 (weighted mean difference (WMD) -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 WMD -57.93 minutes, 95% CI -152.66 to 36.80; multiparous WMD 23.10 minutes, 95% CI -50.89 to 97.09).

Caesarean section

Nine trials involving 4370 women reported this outcome. Women in the amniotomy group had an increased risk of delivery by caesarean section compared to women in the control group. It should be noted that this difference was not statistically significant (relative risk (RR) 1.26, 95% CI 0.98 to 1.62). 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

Two trials involving 123 women reported data on maternal satisfaction with childbirth experience. High levels of heterogeneity ($I^2 > 50\%$) were observed. We applied a random-effects model. There was no statistically significant difference between the two groups (standardised mean difference 0.27, 95% CI -0.49 to 1.04).

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

Six trials involving 2947 women reported data on low 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 0.55, 95% CI 0.29 to 1.05). We then analysed the results of studies which looked at primiparous women only. In the primiparous sub-group, 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). There were no data available for multiparous women only.

Secondary outcomes

Maternal

Length of second stage of labour (minutes)

Seven trials involving 1237 women reported this outcome. High levels of heterogeneity ($I^2 > 50\%$) 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 (WMD -2.38, 95% CI -5.27 to 0.50). Subgroup analysis of primiparous women only showed a statistically significant reduction in the length of the second stage of labour in the amniotomy group (WMD -6.59, 95% CI -12.34 to -0.84).

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

Two trials involving 1005 women reported this outcome. Women in the amniotomy group had a significantly reduced risk of dysfunctional labour (RR 0.75, 95% CI 0.64 to 0.88). There was no information available in order to conduct subgroup analyses.

Use of pain relief

Eight trials involving 2824 women reported this outcome. High levels of heterogeneity ($I^2 > 50\%$) were observed and explored by excluding trials with inadequate allocation concealment (Franks 1990; 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 (RR 1.01, 95% CI 0.94 to 1.09).

Oxytocin augmentation and dosage used

Eight trials involving 3613 women reported information on the use of oxytocin. There were no data regarding the doses required in the two groups. High levels of heterogeneity ($I^2 > 50\%$) were observed and there were no trials with inadequate allocation concealment. We therefore applied a random-effects model. There was no statistically significant difference between the two groups in the use of oxytocin augmentation (RR 0.83, 95% CI 0.64 to 1.09).

Instrumental vaginal birth

Ten trials involving 4470 women reported this outcome. There was no statistically significant difference between the two groups in the incidence of instrumental vaginal birth (RR 1.01, 95% CI 0.88 to 1.15).

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 0.48, 95% CI 0.05 to 4.82).

Postpartum haemorrhage (as defined by trial authors)

One trial involving 1132 women reported this outcome. There was no statistically significant difference between the two groups in the incidence of postpartum haemorrhage (RR 0.19, 95% CI 0.02 to 1.68).

Adverse effects of amniotomy: umbilical cord prolapse, infection

One trial involving 925 women reported on cord prolapse. There was no statistically significant difference between the two groups in the incidence of cord prolapse (RR 0.33, 95% CI 0.01 to 8.18).

Serious maternal morbidity or death

Three trials involving 1089 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). Two trials involving 1460 women reported information on the incidence of maternal infection. There was no statistically significant difference between the two groups (RR 0.81, 95% CI 0.38 to 1.72).

Fetal/infant

Admission to neonatal intensive care or special care nursery

Five trials involving 2035 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 1.12, 95% CI 0.79 to 1.57).

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

One trial involving 925 women reported this outcome. There was no statistically significant difference between the two groups in the risk of meconium aspiration syndrome (RR 3.01, 95% CI 0.61 to 14.82).

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)

Seven trials involving 2707 women reported information on perinatal death. There were no perinatal deaths in either group. Four trials including 2512 women reported information on neonatal jaundice. There was no statistically significant difference between the two groups (RR 1.17, 95% CI 0.75 to 1.82). Four trials including 3379 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. One trial including 459 women reported information on intracranial haemorrhage. There were no cases of respiratory distress in either group. Two trials including 1022 women reported information on cephalhaematoma. There was no statistically significant difference between the two groups (RR 1.63, 95% CI 0.86 to 3.10). 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.

None of the included trials reported on the following outcomes; antepartum haemorrhage (as defined by trial authors); 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.

Subgroup analysis

We were able to conduct subgroup analysis examining parity (*see figures*). 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 C). No differences were observed in terms of statistical significance for any outcome.

DISCUSSION

A total of 4893 women were recruited into 14 trials comparing amniotomy with intention to preserve the membranes.

Evidence from this review suggests that the use of amniotomy as an intervention may reduce the incidence of dysfunctional labour. It should be noted that this statistically significant finding is based on only two 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 ([Shobeiri 2007](#)) suggested that amniotomy reduces the length of the first and second stage of labour.

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 four 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 (WMD -6.59, 95% CI -12.34 to -0.84). 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 is often unclear from 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 (relative risk 1.66, 95% confidence interval 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. There was no significant difference in reported satisfaction between the two groups. The scoring systems used were different in each study, and taken individually each study showed almost opposite findings. 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 caregiver's 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, which nears statistical significance. 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.

There was no evidence to suggest that the need for oxytocin was increased in either group. 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 or perinatal mortality.

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 eight out of 14 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 allowing 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 labour

management and care. We do 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. 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 multi-centre 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 which 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 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.

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* 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%.
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Ajadi 2006

(Continued)

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

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

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 which 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.

Barrett 1992*(Continued)*

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

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

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

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

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

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

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.

Fraser 1991*(Continued)*

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

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

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

Item	Authors' judgement	Description
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Fraser 1993*(Continued)*

Allocation concealment? Yes

A - Adequate

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).

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Guerresi 1981

Methods	Randomisation: multips and primips 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.

Guerresi 1981*(Continued)*

	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 rocuronium of butylscopolamine bromide and were therefore not analysed. Author (Prof Gori) contacted November 2007 for additional data, still awaiting response (30/03/07).

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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 multips has been extracted from this paper for the review. Ratio of randomisation is 4:3 amniotomy:no amniotomy due to computer programming error. 54% of women in the control group received and amniotomy. Unable to locate and contact author (29/11/06) therefore unable to extract data for most outcomes, as no distinction between multips and primips made. Primips included in UK amniotomy study.

Risk of bias

Item	Authors' judgement	Description
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Allocation concealment? Unclear

B - Unclear

Laros 1972

Methods	Randomisation: table of random numbers. Allocation concealment: sealed envelopes. Blinding: no information given. Follow up: 100%.
Participants	125 women were enrolled, 70 in experimental group and 55 in control group. Eligibility: spontaneous labour, intact membranes, vertex presentation, gestation 36-44 weeks, cervical dilatation of between 5 and 8 cm, multiparous and primiparous women. Exclusion: abnormal labours requiring oxytocin, caesarean section or operative vaginal delivery (possibly post-randomisation exclusions).
Interventions	Experimental: amniotomy. Control: no amniotomy.
Outcomes	Women: length of first stage of labour, length of second stage of labour , serious maternal morbidity and mortality. 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 postrandomisation exclusion of women who did not achieve a normal delivery (see Participants).

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

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.

Shobeiri 2007*(Continued)*

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

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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 (Calder 1974) of more than 6. Exclusion: caesarean section postrandomisation.
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

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

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.

Wetrich 1970*(Continued)*

	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 two-thirds 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

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

^a APH: antipartum haemorrhage

ARM: artificial rupture of membranes

CTG: cardiotography

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
Levy 2002	IOL with foley catheter prior to amniotomy. Women not in spontaneous labour.
Martell 1976	Quasi-randomised.
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.
^a 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)	-18.01 [-67.54, 31.54]
2 Caesarean section	9	4370	Risk Ratio (M-H, Fixed, 95% CI)	1.26 [0.98, 1.62]
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	4	913	Risk Ratio (M-H, Fixed, 95% CI)	2.04 [0.94, 4.45]
3 Maternal satisfaction with childbirth experience	2	123	Std. Mean Difference (IV, Random, 95% CI)	0.27 [-0.49, 1.04]
4 Apgar score less than 7 at 5 minutes	6	2947	Risk Ratio (M-H, Fixed, 95% CI)	0.55 [0.29, 1.05]
4.1 Primiparous women	3	2385	Risk Ratio (M-H, Fixed, 95% CI)	0.42 [0.20, 0.88]
4.2 Primiparous and multiparous women	3	562	Risk Ratio (M-H, Fixed, 95% CI)	1.55 [0.38, 6.35]
5 Length of second stage	7	1237	Mean Difference (IV, Random, 95% CI)	-2.38 [-5.27, 0.50]
5.1 Primiparous women	6	496	Mean Difference (IV, Random, 95% CI)	-6.59 [-12.34, -0.84]
5.2 Multiparous women	3	386	Mean Difference (IV, Random, 95% CI)	-1.84 [-5.41, 1.73]
5.3 Primiparous and multiparous women	1	355	Mean Difference (IV, Random, 95% CI)	0.60 [-2.46, 3.66]
6 Dysfunctional labour	2	1005	Risk Ratio (M-H, Fixed, 95% CI)	0.75 [0.64, 0.88]
7 Use of pain relief - epidural/narcotic	8	2824	Risk Ratio (M-H, Random, 95% CI)	1.01 [0.94, 1.09]
7.1 Primiparous women	4	2306	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.93, 1.04]
7.3 Primiparous and multiparous women	4	518	Risk Ratio (M-H, Random, 95% CI)	1.21 [0.89, 1.65]
8 Oxytocin augmentation	8	3613	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.64, 1.09]
8.1 Primiparous women	2	1022	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.77, 1.05]
8.3 Primiparous and multiparous women	6	2591	Risk Ratio (M-H, Random, 95% CI)	0.79 [0.52, 1.20]
9 Instrumental vaginal birth	10	4470	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.88, 1.15]
9.1 Primiparous women	5	2507	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.88, 1.17]
9.2 Multiparous women	1	911	Risk Ratio (M-H, Fixed, 95% CI)	1.20 [0.66, 2.18]
9.3 Primiparous and multiparous women	5	1052	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.58, 1.31]
10 Caesarean section for fetal distress	1	39	Risk Ratio (M-H, Fixed, 95% CI)	2.86 [0.12, 66.11]

11 Caesarean section for prolonged labour	1	39	Risk Ratio (M-H, Fixed, 95% CI)	0.48 [0.05, 4.82]
13 Postpartum haemorrhage	1	1132	Risk Ratio (M-H, Fixed, 95% CI)	0.19 [0.02, 1.68]
13.1 Primiparous and multiparous women	1	1132	Risk Ratio (M-H, Fixed, 95% CI)	0.19 [0.02, 1.68]
16 Cord prolapse	1	925	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.01, 8.18]
17 Maternal infection	2	1460	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.38, 1.72]
17.1 Primiparous women	2	1460	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.38, 1.72]
18 Maternal mortality	3	1089	Risk Ratio (M-H, Fixed, 95% CI)	3.01 [0.12, 73.61]
22 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]
23 Admission to special care baby unit/neonatal intensive care unit	5	2035	Risk Ratio (M-H, Fixed, 95% CI)	1.12 [0.79, 1.57]
23.1 Primiparous women	4	1996	Risk Ratio (M-H, Fixed, 95% CI)	1.12 [0.79, 1.57]
23.2 Primiparous and multiparous women	1	39	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
24 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]
25 Meconium aspiration syndrome	1	925	Risk Ratio (M-H, Fixed, 95% CI)	3.01 [0.61, 14.82]
26 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]
27 Perinatal death	7	2707	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
27.1 Primiparous women	6	2576	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
27.2 Primiparous and multiparous women	1	64	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
27.3 Multiparous women	1	67	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
28 Neonatal jaundice	4	2512	Risk Ratio (M-H, Fixed, 95% CI)	1.17 [0.75, 1.82]
28.1 Primiparous women	2	1457	Risk Ratio (M-H, Fixed, 95% CI)	1.64 [0.74, 3.64]
28.2 Multiparous women	1	532	Risk Ratio (M-H, Fixed, 95% CI)	5.45 [0.68, 44.03]
28.3 Primiparous and multiparous women	2	523	Risk Ratio (M-H, Fixed, 95% CI)	0.76 [0.42, 1.36]
29 Seizures (neonate)	4	3379	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.15, 5.35]
29.1 Primiparous women	3	2388	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.15, 5.35]
29.2 Multiparous women	1	532	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
29.3 Primiparous and multiparous women	1	459	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
30 Respiratory distress syndrome	1	459	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
31 Fracture	1	925	Risk Ratio (M-H, Fixed, 95% CI)	3.01 [0.31, 28.80]
32 Intracranial haemorrhage	1	459	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
33 Cephalhaematoma	2	1022	Risk Ratio (M-H, Fixed, 95% CI)	1.63 [0.86, 3.10]

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

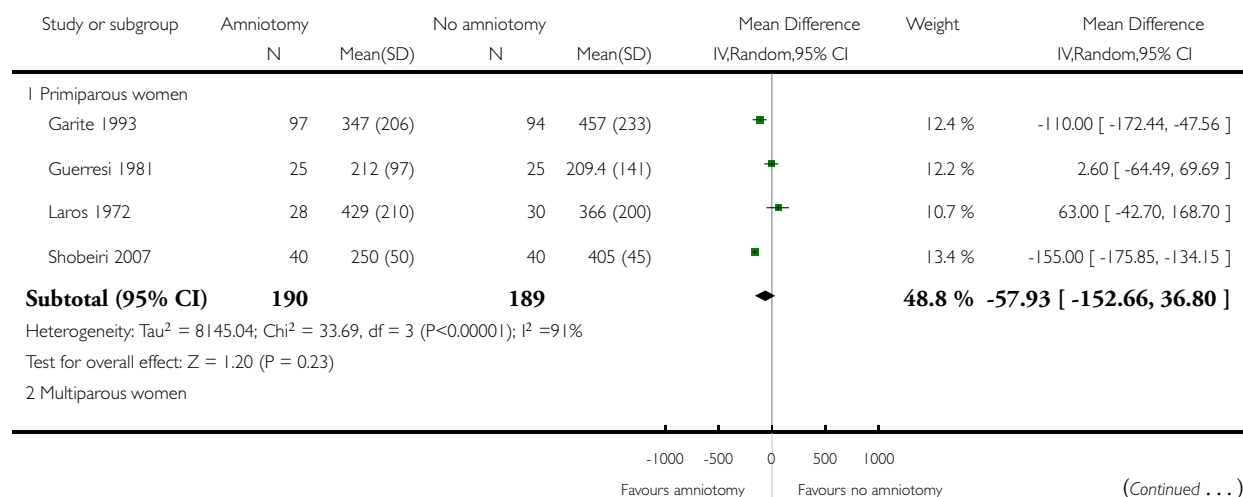
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Length of first stage of labour	5	1127	Mean Difference (IV, Random, 95% CI)	-21.73 [-53.36, 9.91]
1.1 Primiparous women	4	379	Mean Difference (IV, Random, 95% CI)	-54.62 [-161.77, 52.52]
1.2 Multiparous women	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	9	4370	Risk Ratio (M-H, Fixed, 95% CI)	1.26 [0.98, 1.62]
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	4	913	Risk Ratio (M-H, Fixed, 95% CI)	2.04 [0.94, 4.45]
4 Apgar score less than 7 at 5 minutes	6	2947	Risk Ratio (M-H, Fixed, 95% CI)	0.55 [0.29, 1.05]
4.1 Primiparous women	3	2385	Risk Ratio (M-H, Fixed, 95% CI)	0.42 [0.20, 0.88]
4.2 Primiparous and multiparous women	3	562	Risk Ratio (M-H, Fixed, 95% CI)	1.55 [0.38, 6.35]

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

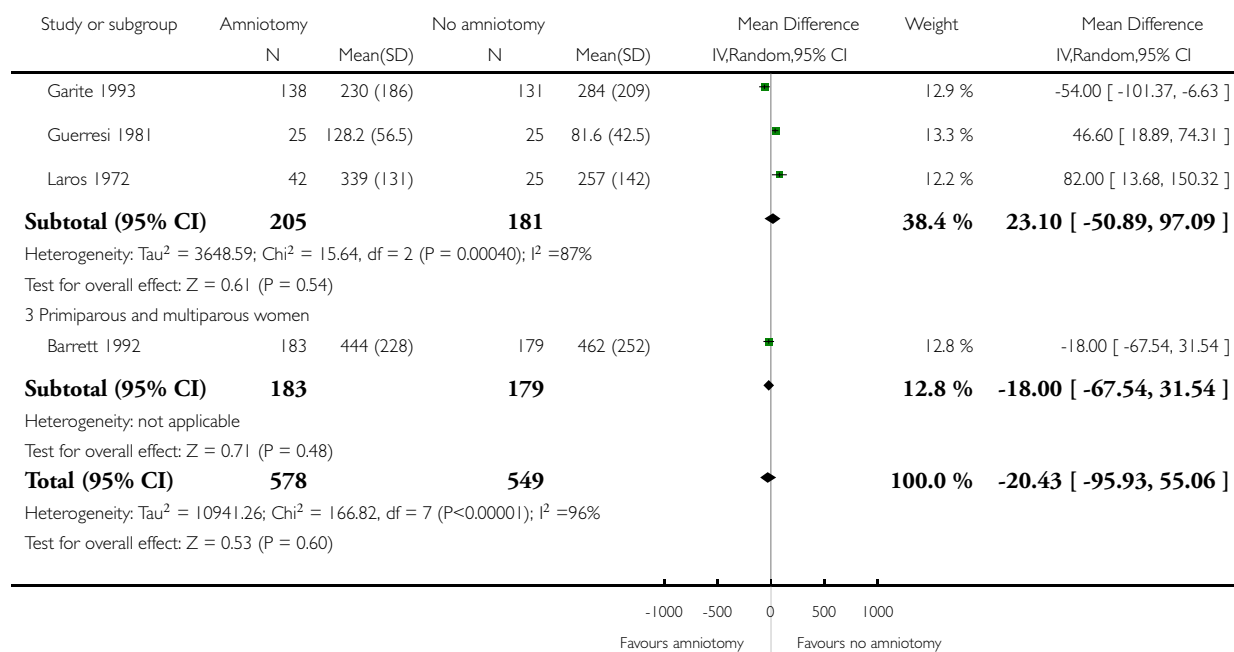
Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 1 Length of first stage of labour



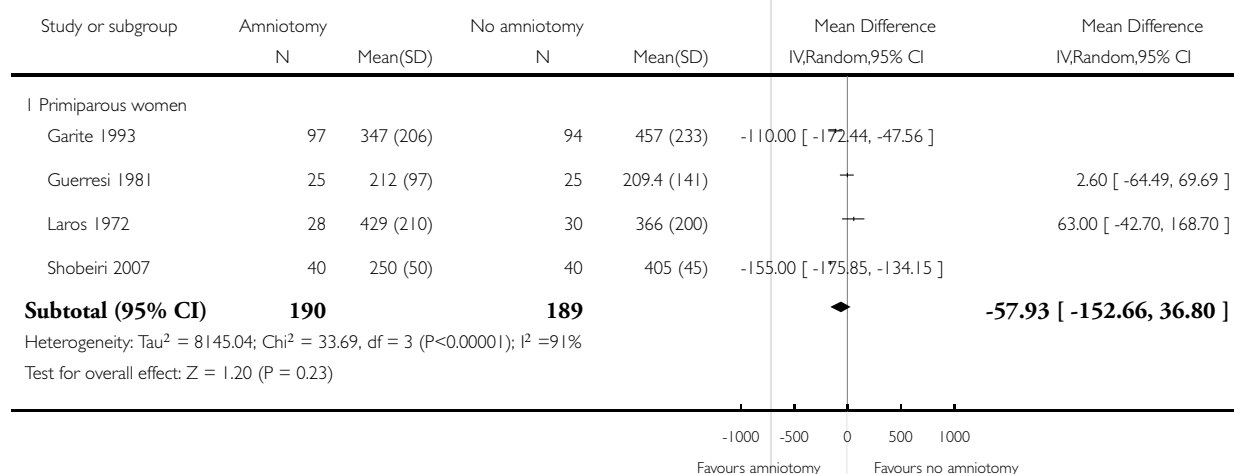
(... Continued)



Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

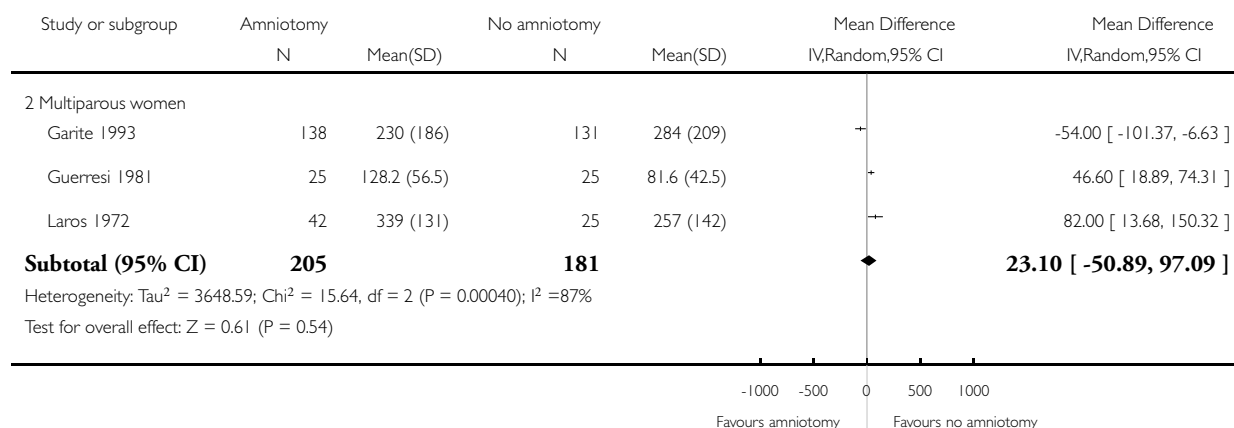
Outcome: I Length of first stage of labour



Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

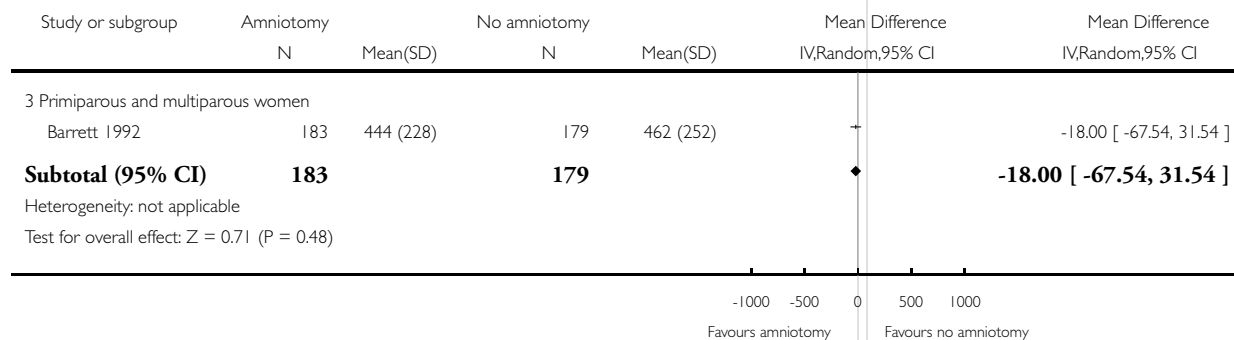
Outcome: I Length of first stage of labour



Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

Outcome: I Length of first stage of labour

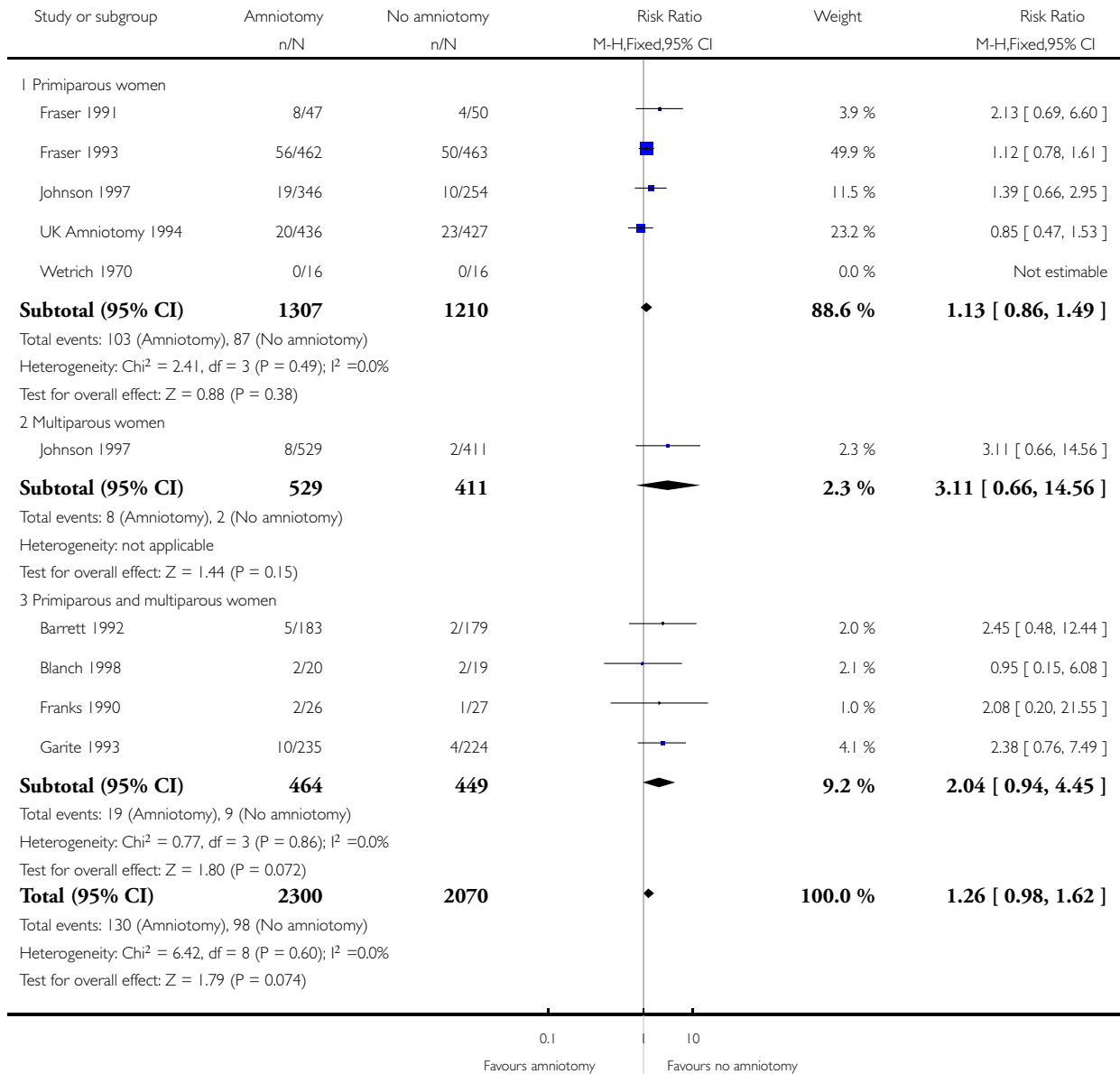


Analysis 1.2. Comparison 1 Amniotomy versus no amniotomy, Outcome 2 Caesarean section.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

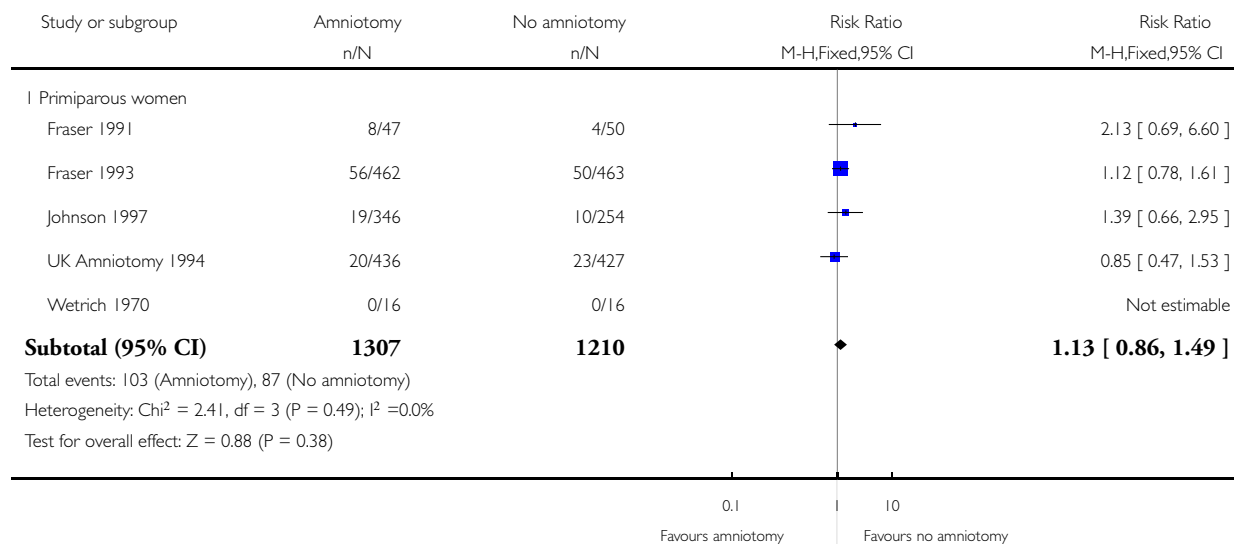
Outcome: 2 Caesarean section



Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

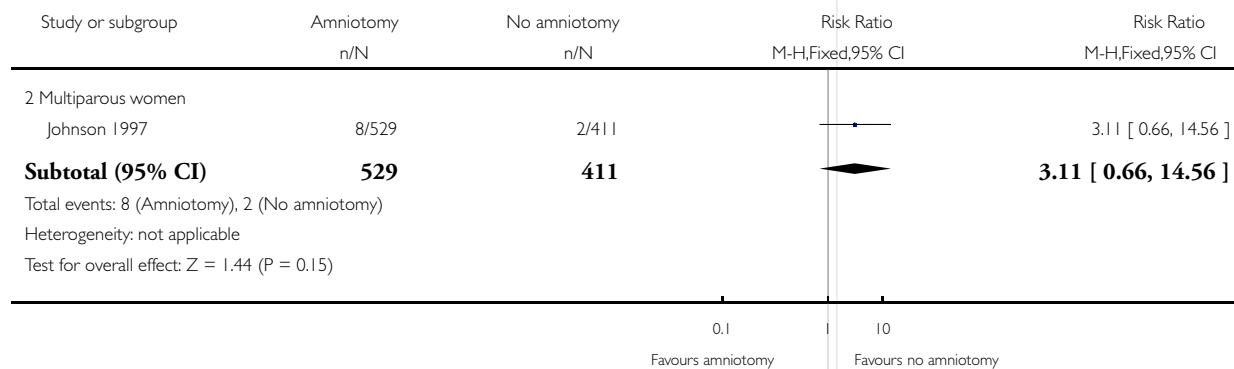
Outcome: 2 Caesarean section



Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

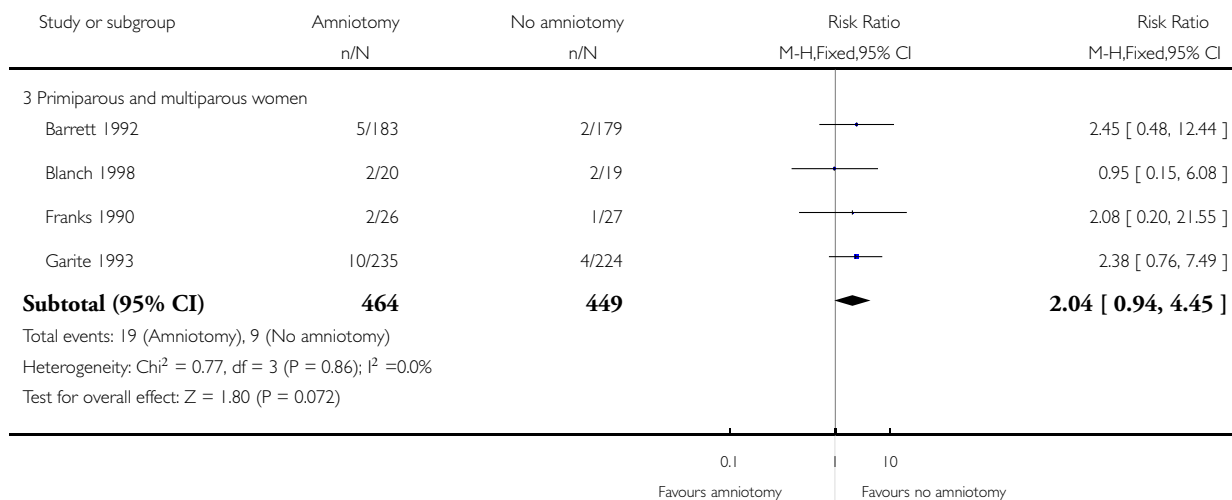
Outcome: 2 Caesarean section



Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 2 Caesarean section

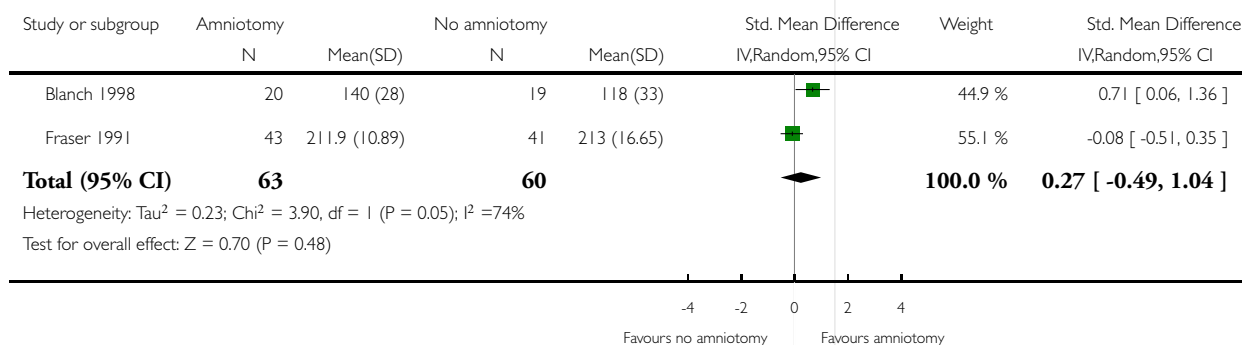


Analysis 1.3. Comparison 1 Amniotomy versus no amniotomy, Outcome 3 Maternal satisfaction with childbirth experience.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 3 Maternal satisfaction with childbirth experience

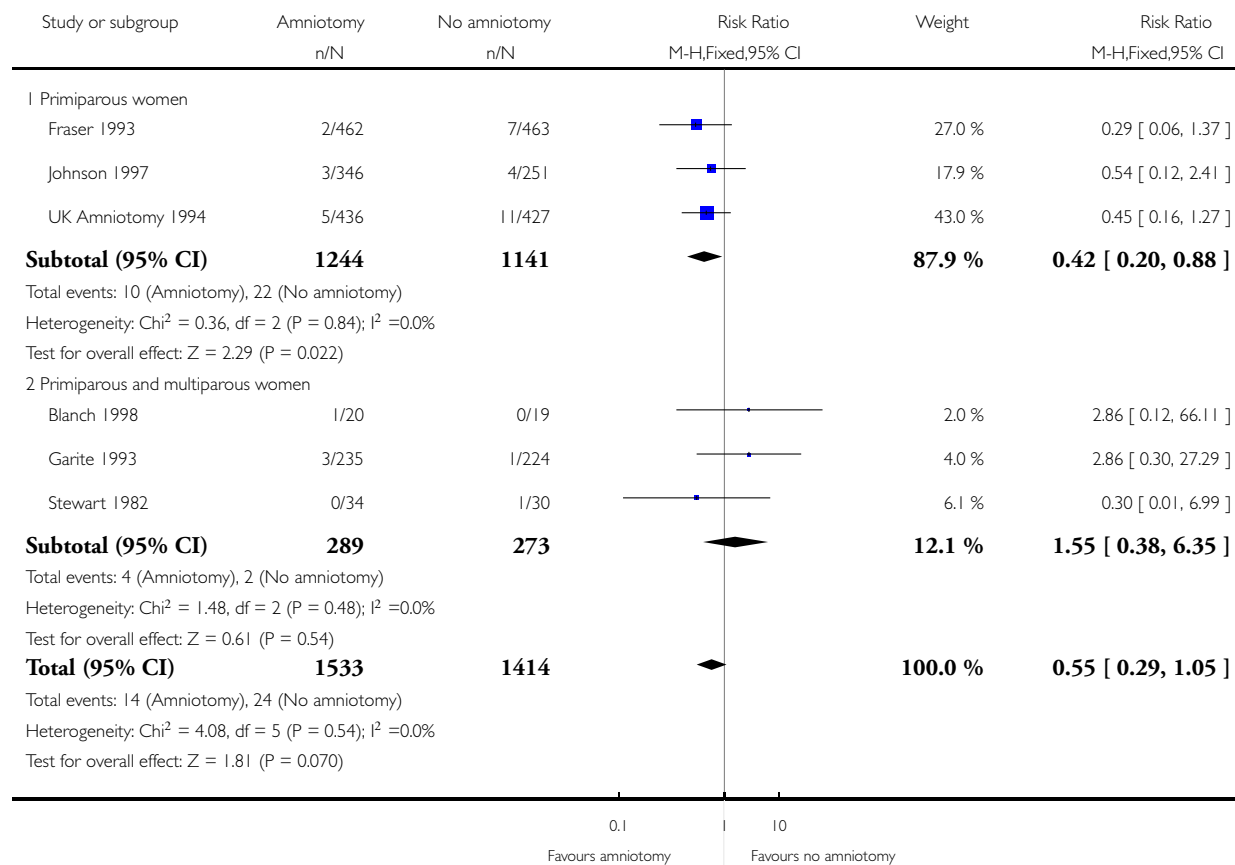


Analysis 1.4. Comparison 1 Amniotomy versus no amniotomy, Outcome 4 Apgar score less than 7 at 5 minutes.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

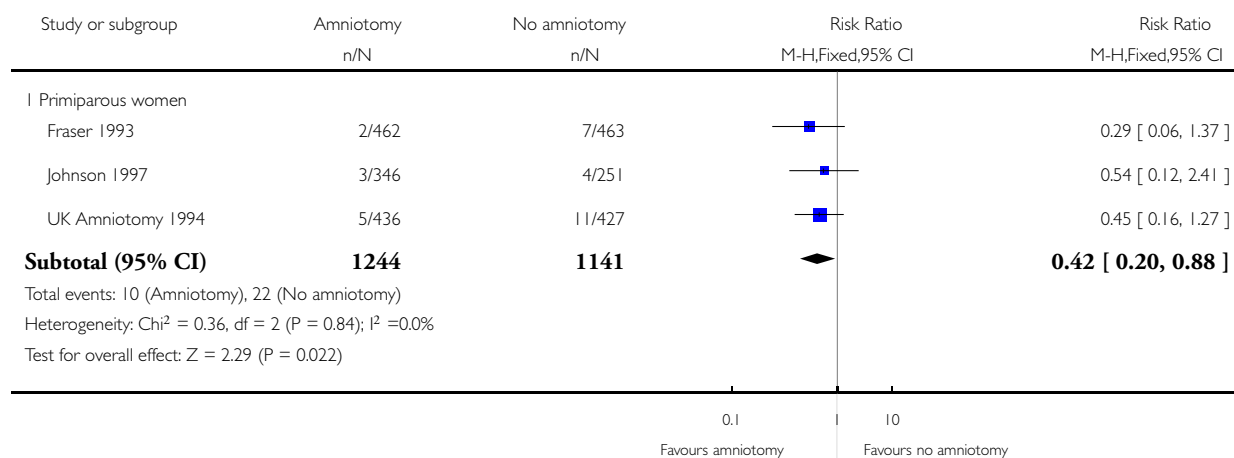
Outcome: 4 Apgar score less than 7 at 5 minutes



Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

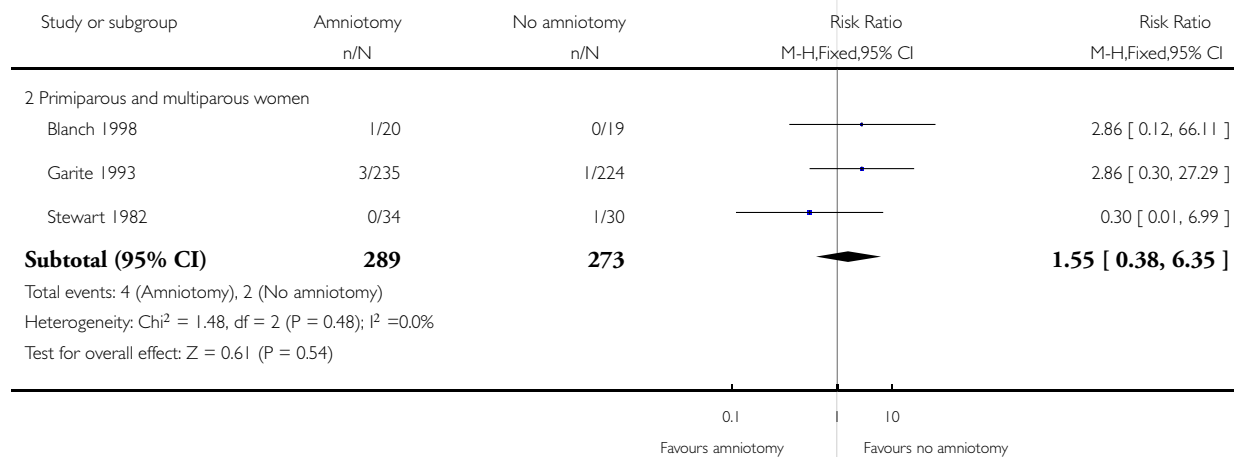
Outcome: 4 Apgar score less than 7 at 5 minutes



Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 4 Apgar score less than 7 at 5 minutes

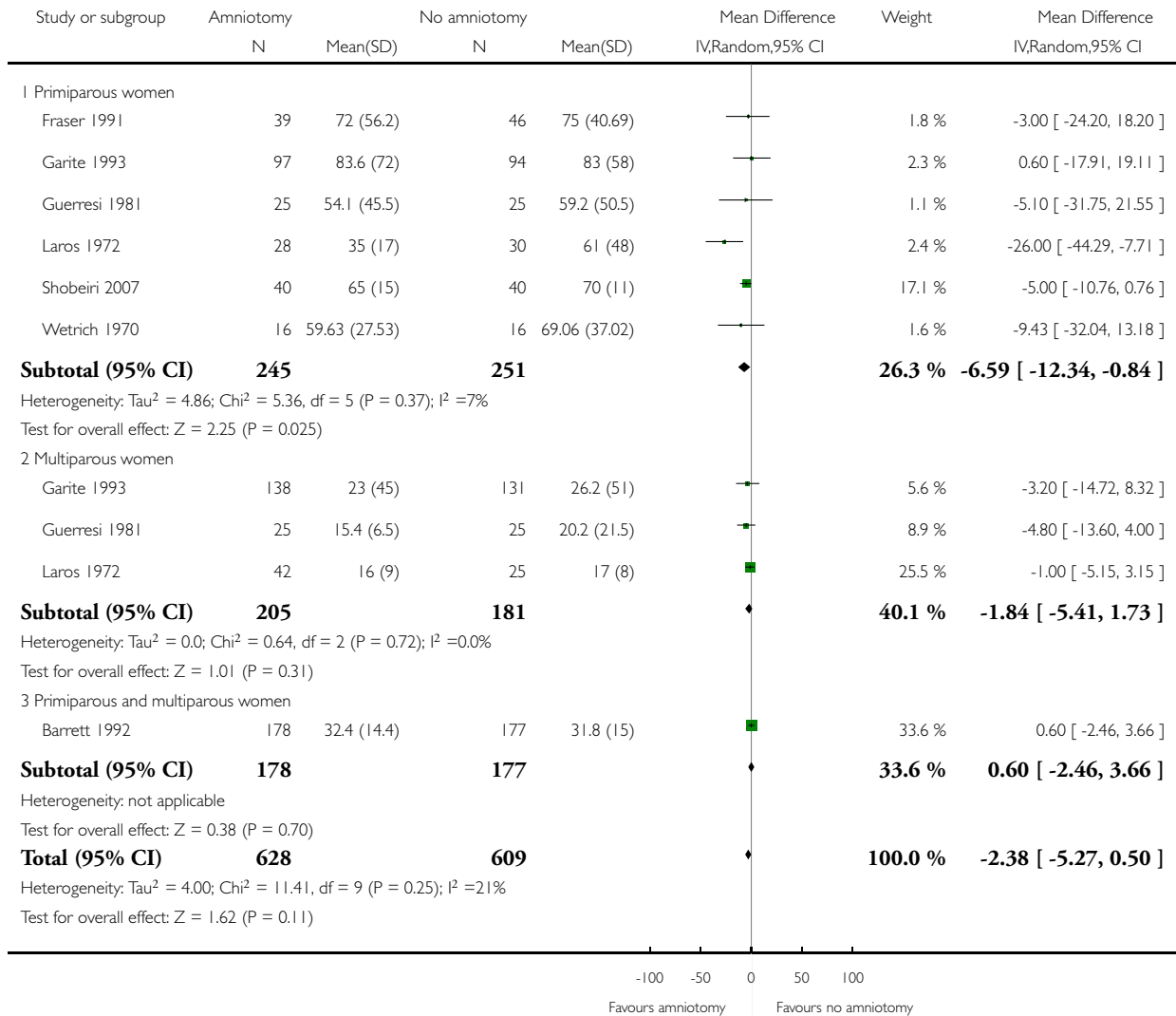


Analysis 1.5. Comparison 1 Amniotomy versus no amniotomy, Outcome 5 Length of second stage.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

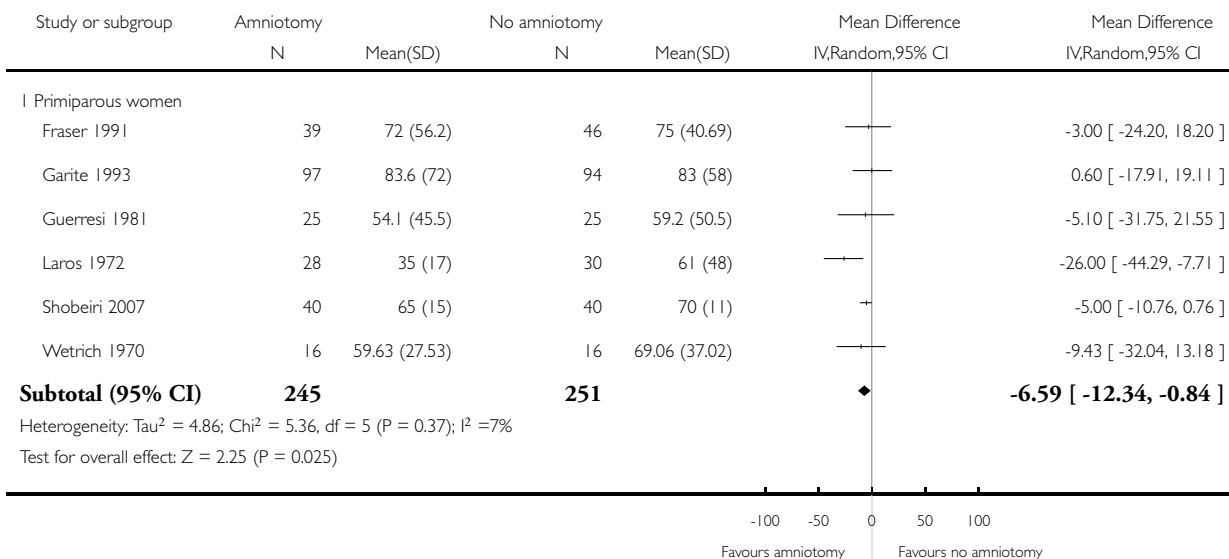
Outcome: 5 Length of second stage



Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

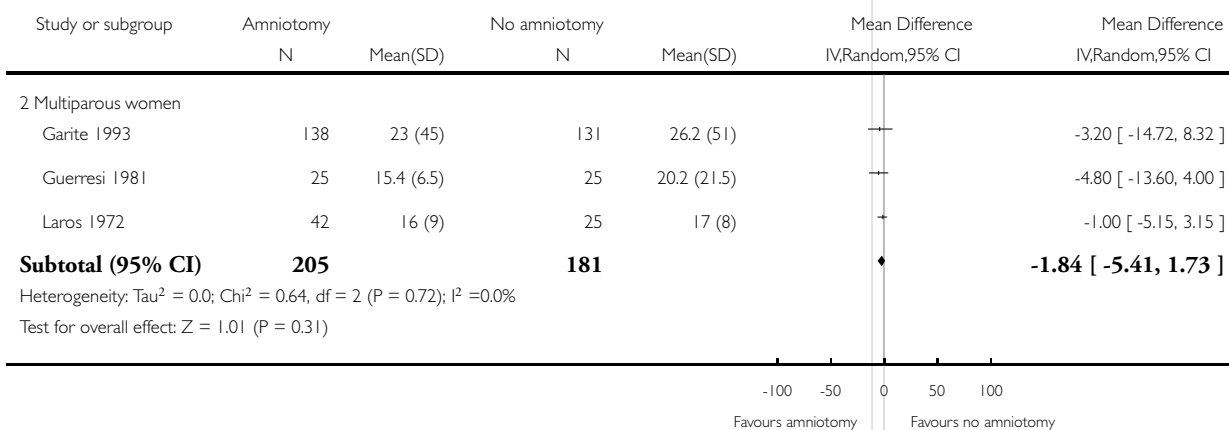
Outcome: 5 Length of second stage



Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

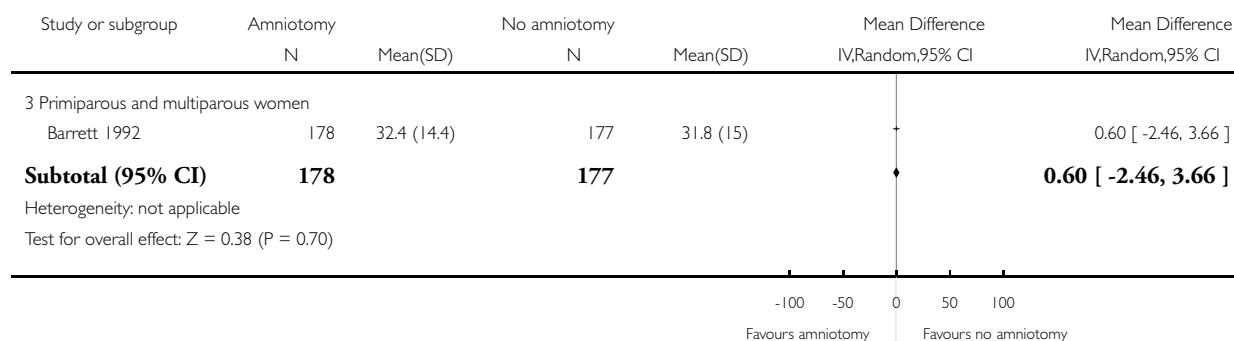
Outcome: 5 Length of second stage



Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

Outcome: 5 Length of second stage

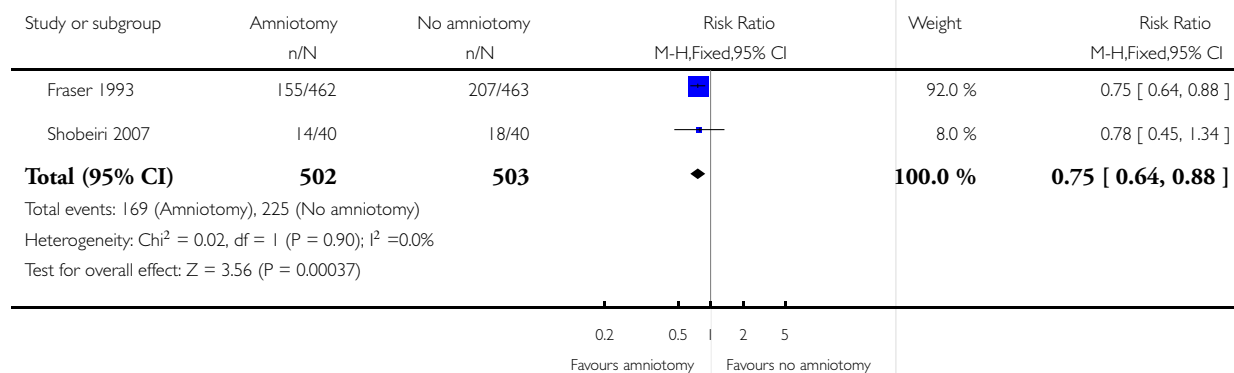


Analysis 1.6. Comparison I Amniotomy versus no amniotomy, Outcome 6 Dysfunctional labour.

Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

Outcome: 6 Dysfunctional labour

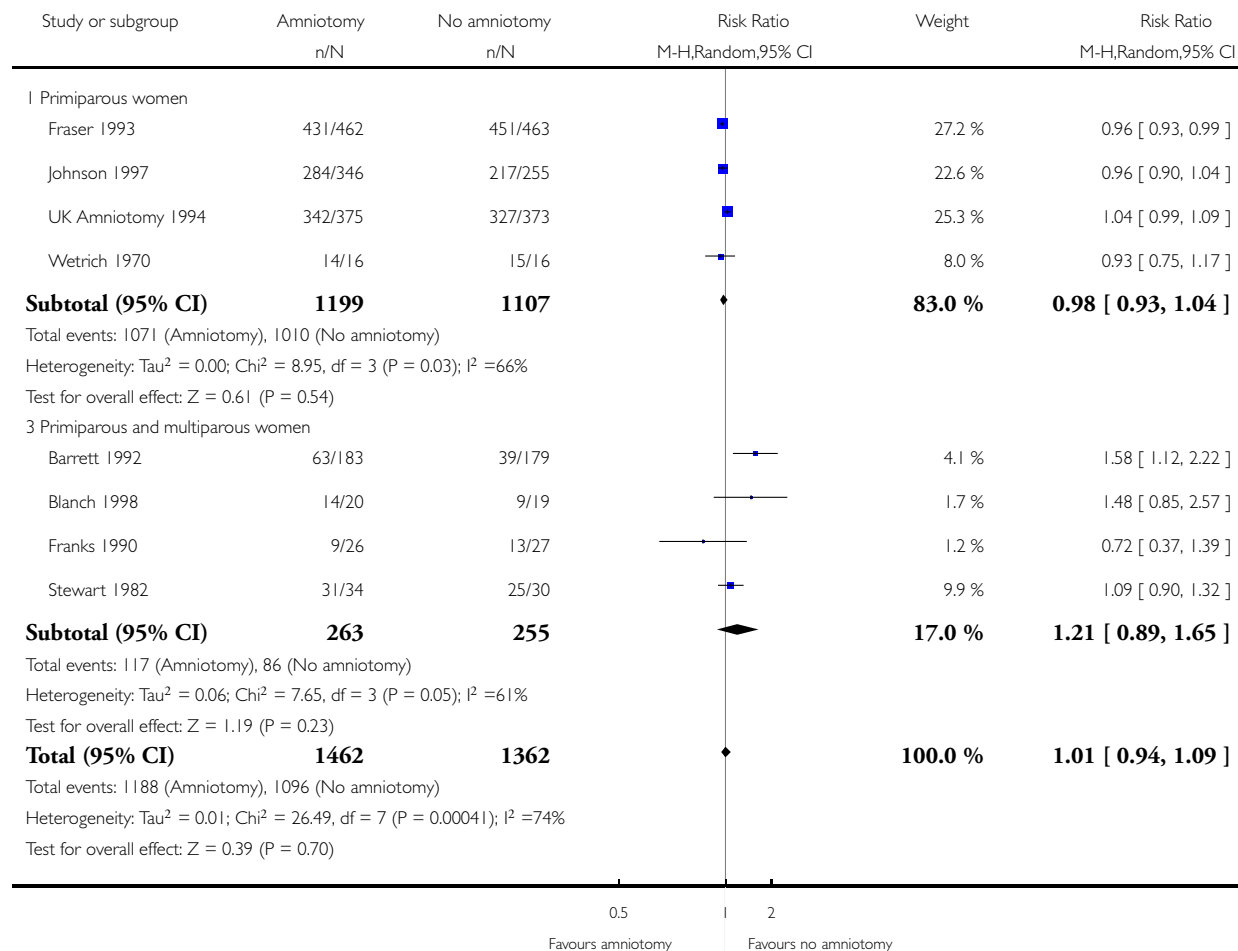


Analysis 1.7. Comparison 1 Amniotomy versus no amniotomy, Outcome 7 Use of pain relief - epidural/narcotic.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

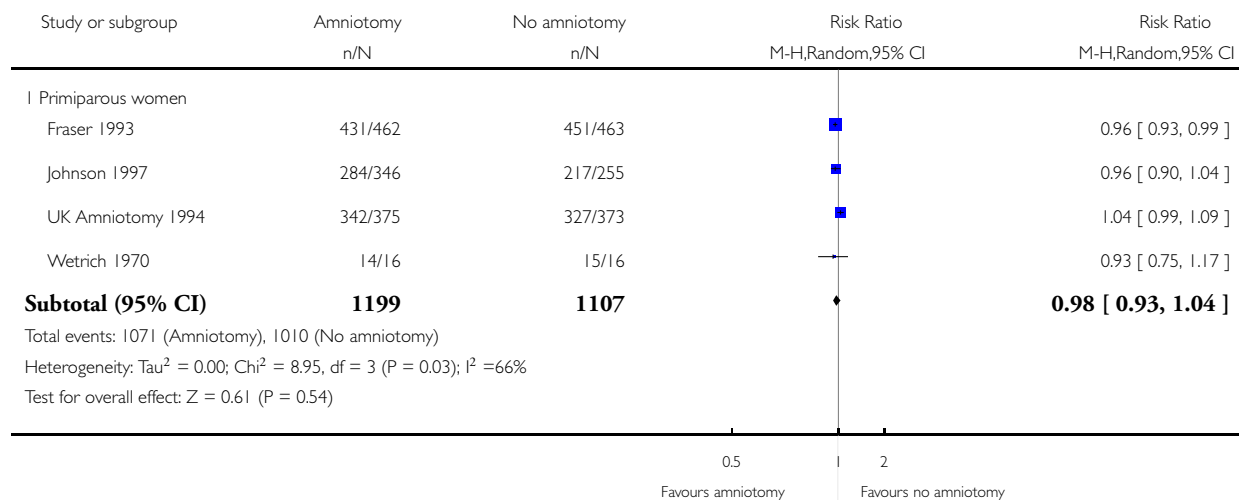
Outcome: 7 Use of pain relief - epidural/narcotic



Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

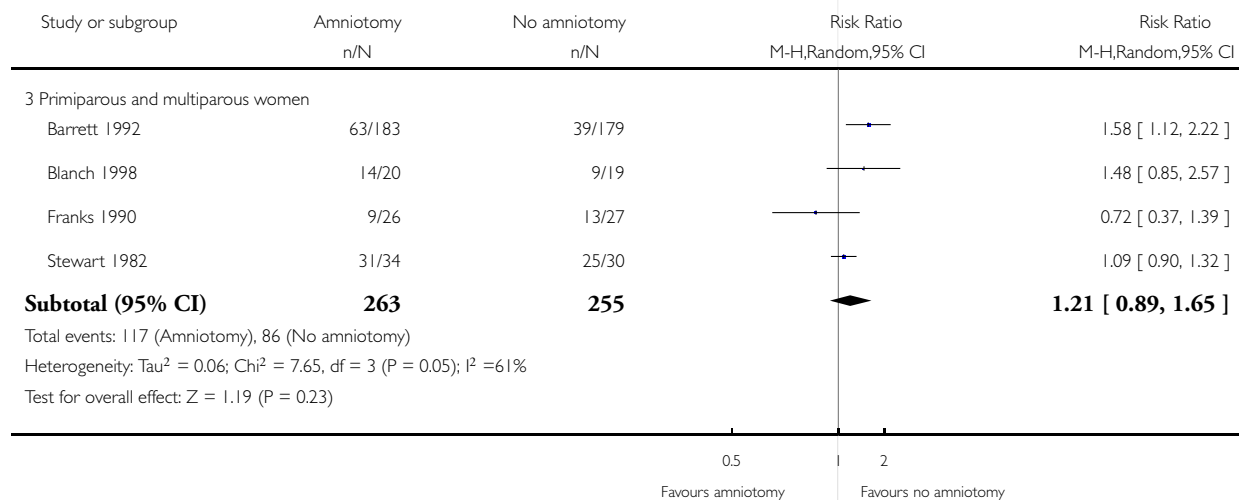
Outcome: 7 Use of pain relief - epidural/narcotic



Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 7 Use of pain relief - epidural/narcotic

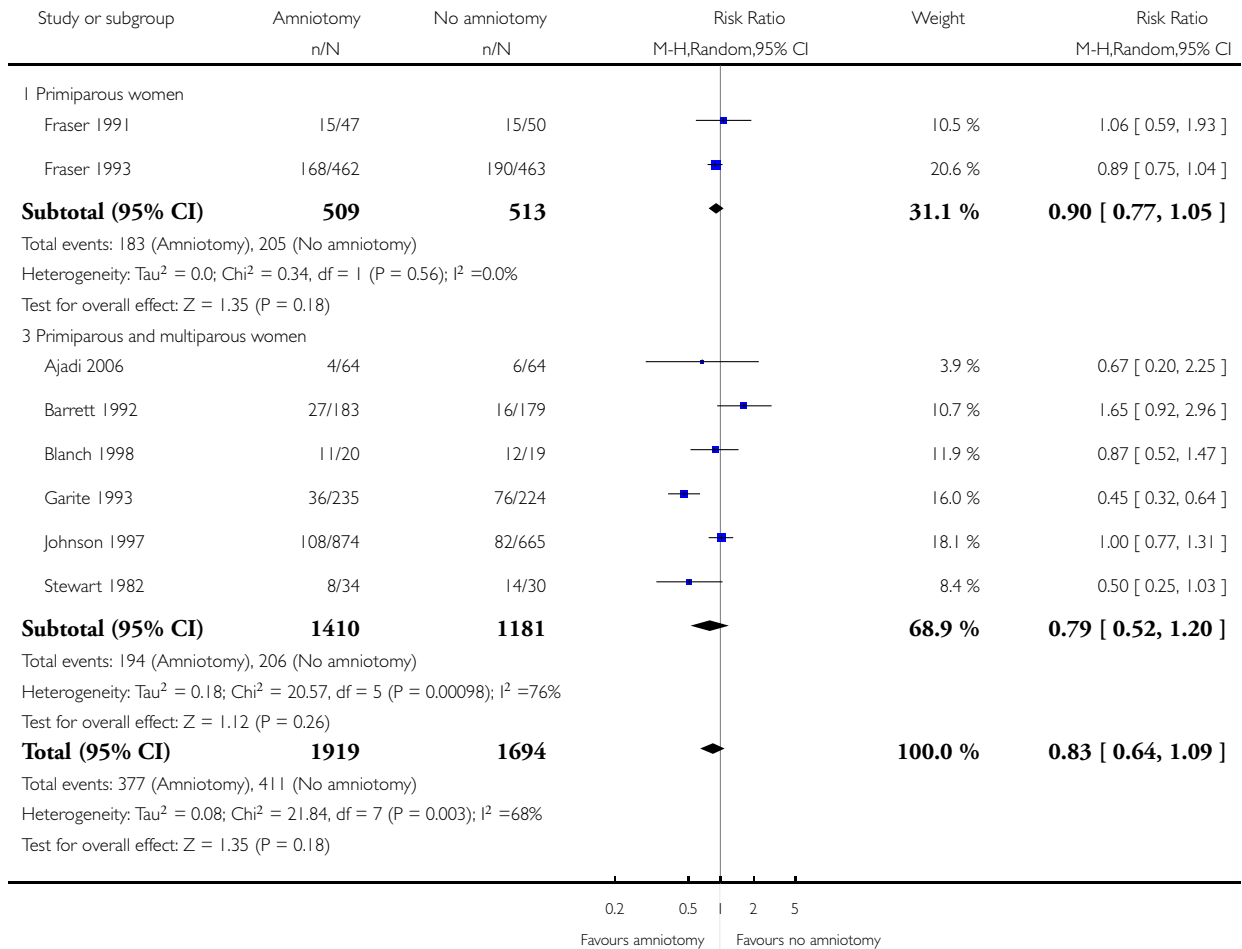


Analysis 1.8. Comparison 1 Amniotomy versus no amniotomy, Outcome 8 Oxytocin augmentation.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

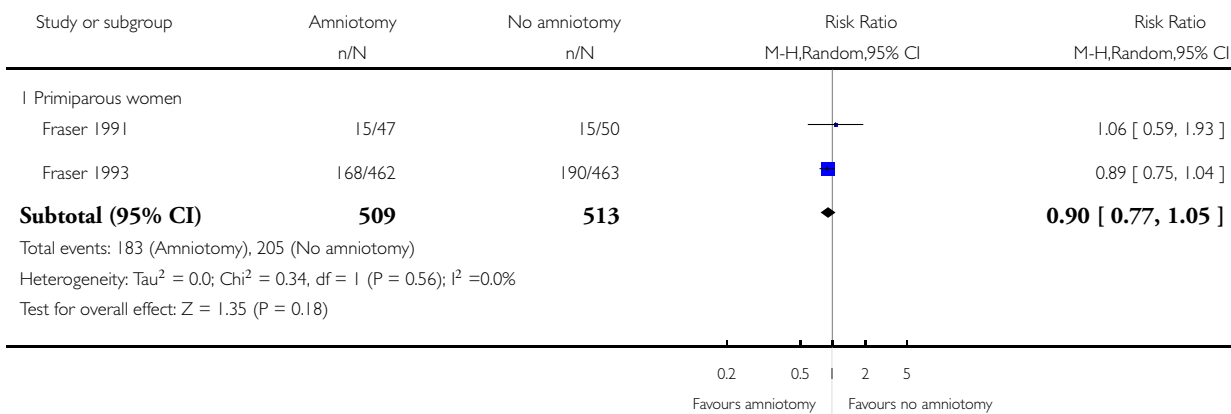
Outcome: 8 Oxytocin augmentation



Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

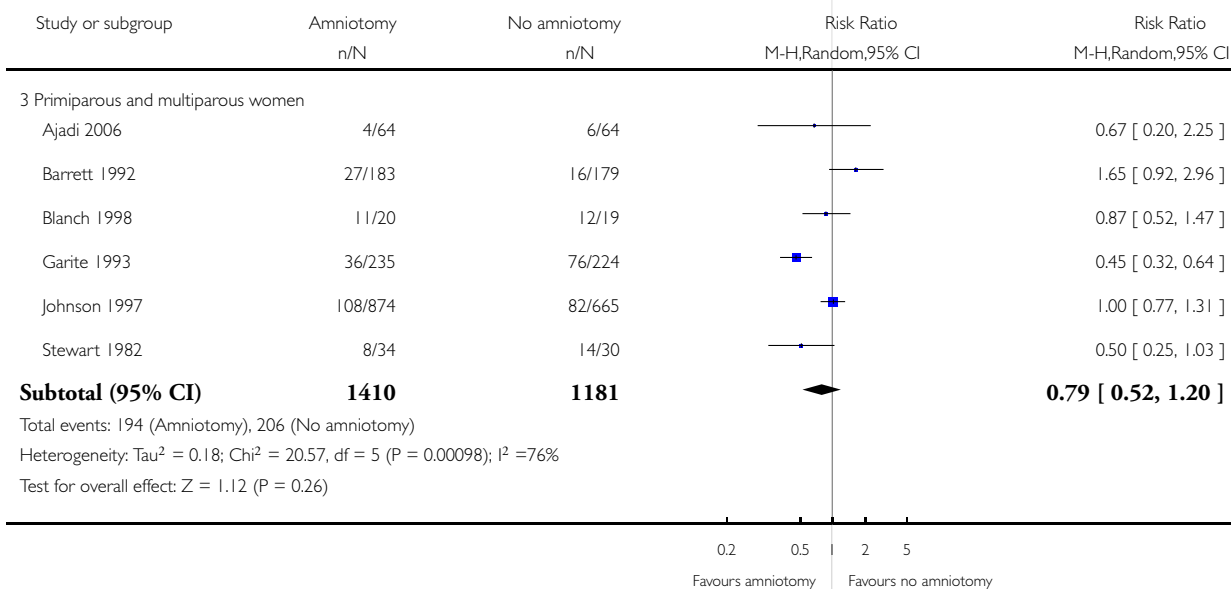
Outcome: 8 Oxytocin augmentation



Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

Outcome: 8 Oxytocin augmentation

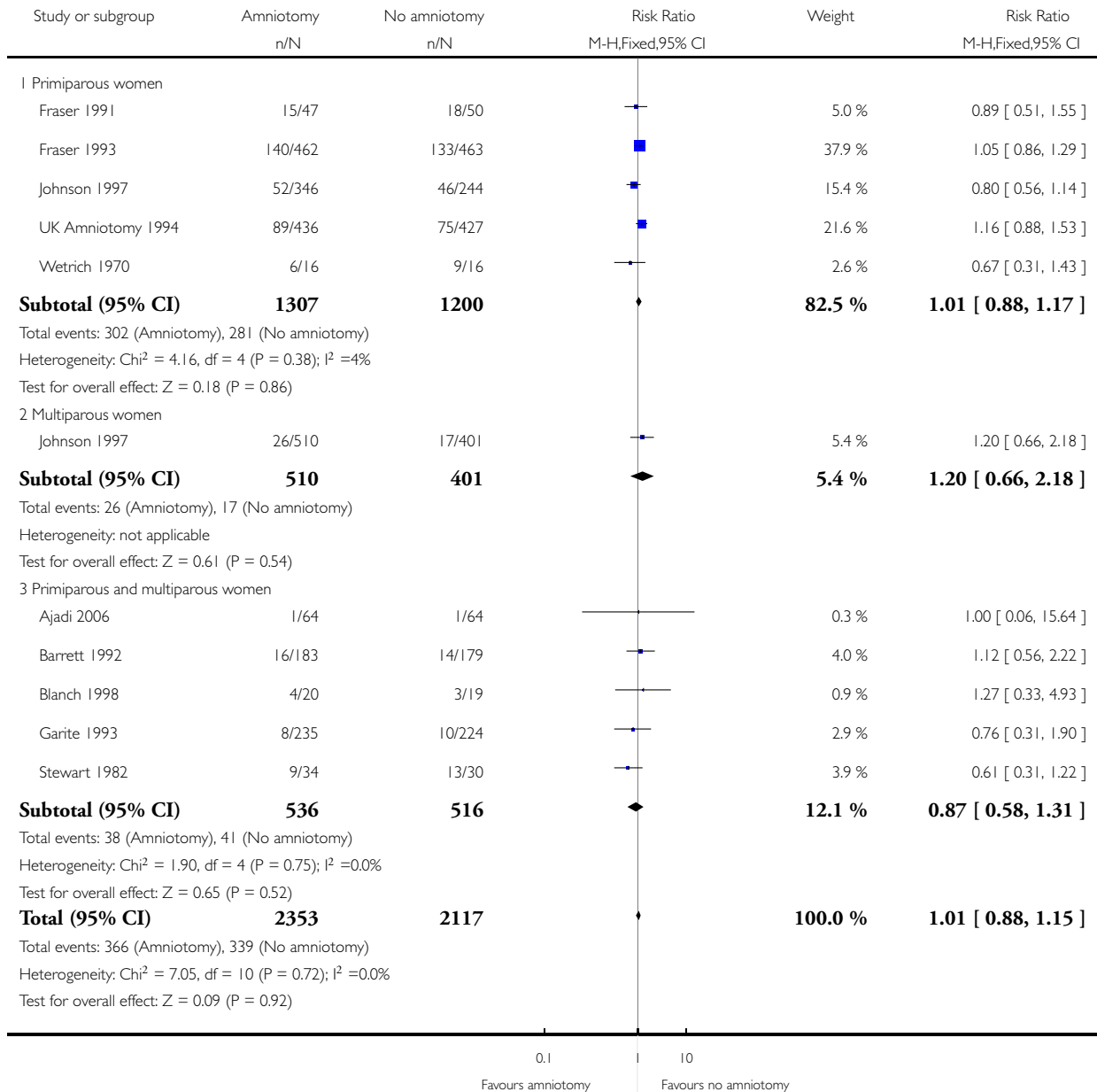


Analysis 1.9. Comparison 1 Amniotomy versus no amniotomy, Outcome 9 Instrumental vaginal birth.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

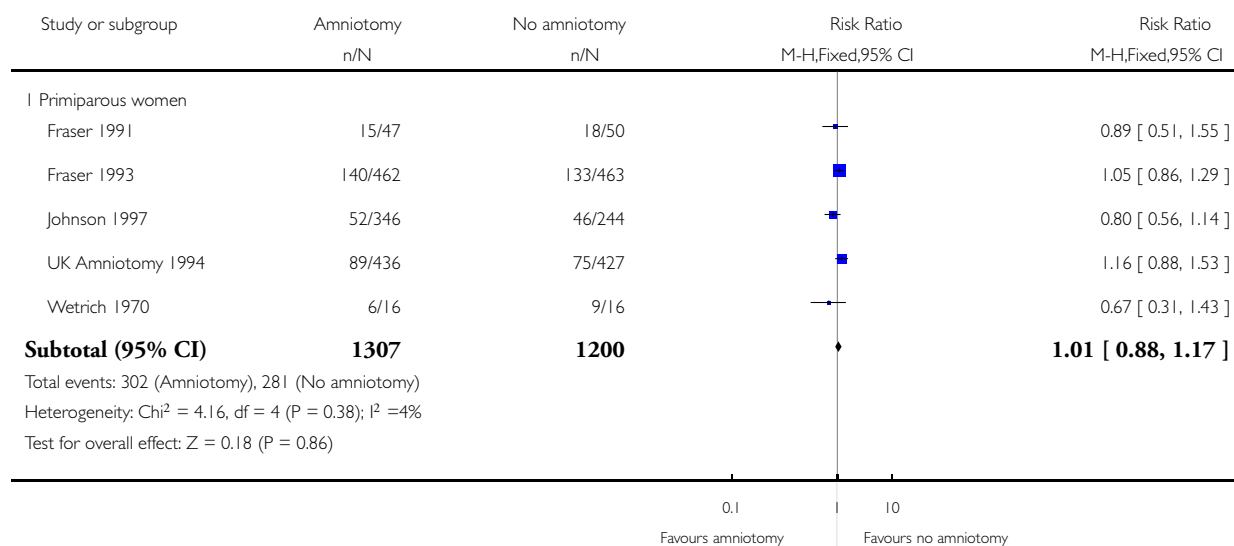
Outcome: 9 Instrumental vaginal birth



Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

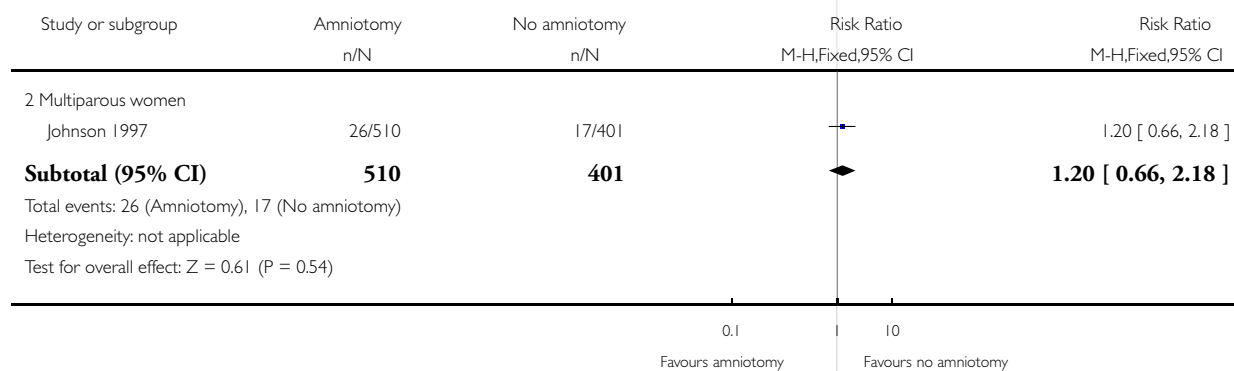
Outcome: 9 Instrumental vaginal birth



Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

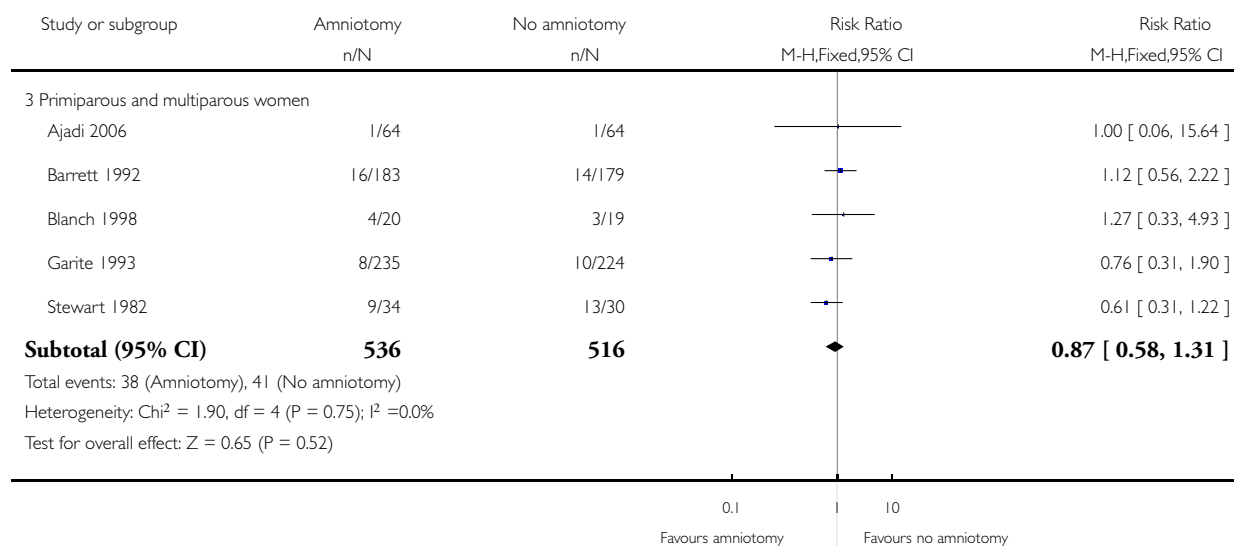
Outcome: 9 Instrumental vaginal birth



Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

Outcome: 9 Instrumental vaginal birth

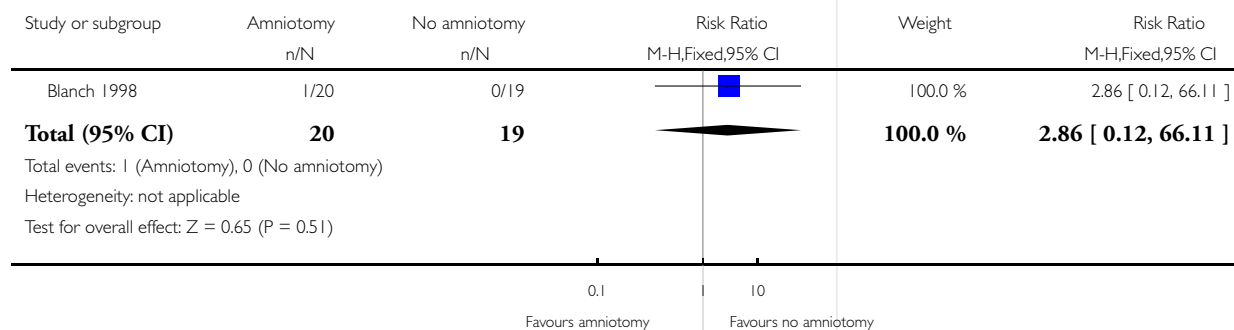


Analysis 1.10. Comparison I Amniotomy versus no amniotomy, Outcome 10 Caesarean section for fetal distress.

Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

Outcome: 10 Caesarean section for fetal distress

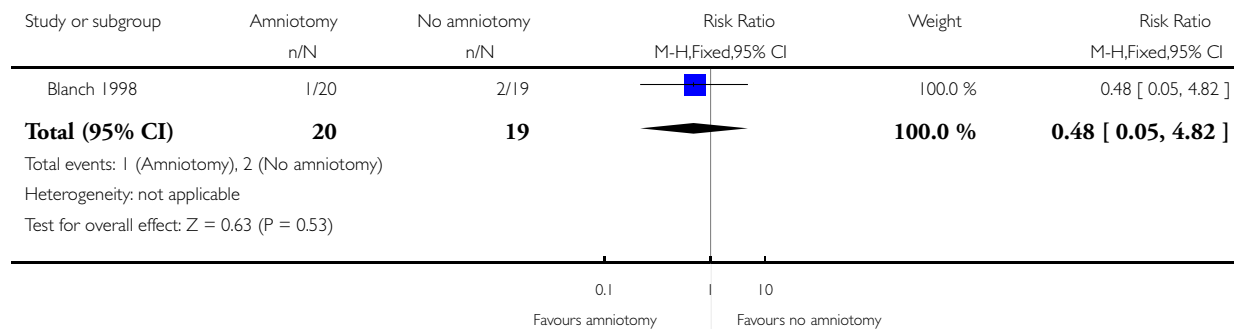


Analysis 1.11. Comparison 1 Amniotomy versus no amniotomy, Outcome 11 Caesarean section for prolonged labour.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 11 Caesarean section for prolonged labour

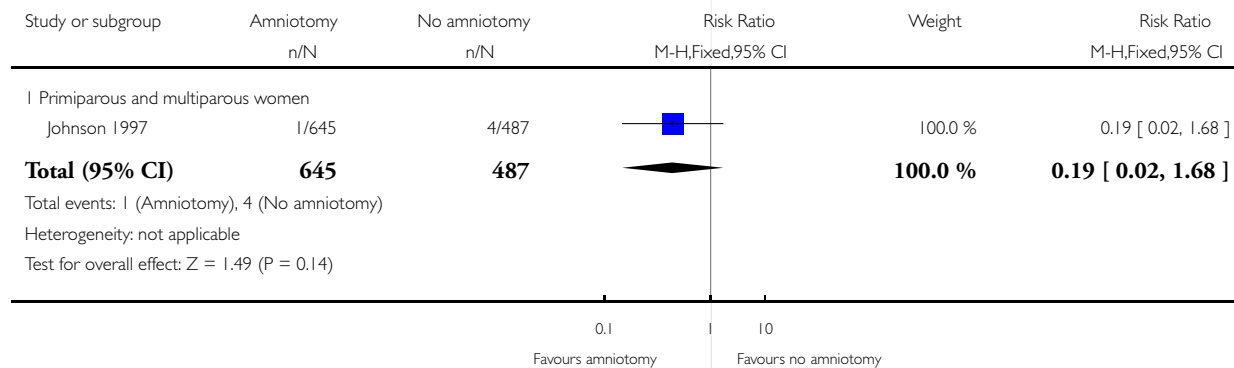


Analysis 1.13. Comparison 1 Amniotomy versus no amniotomy, Outcome 13 Postpartum haemorrhage.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

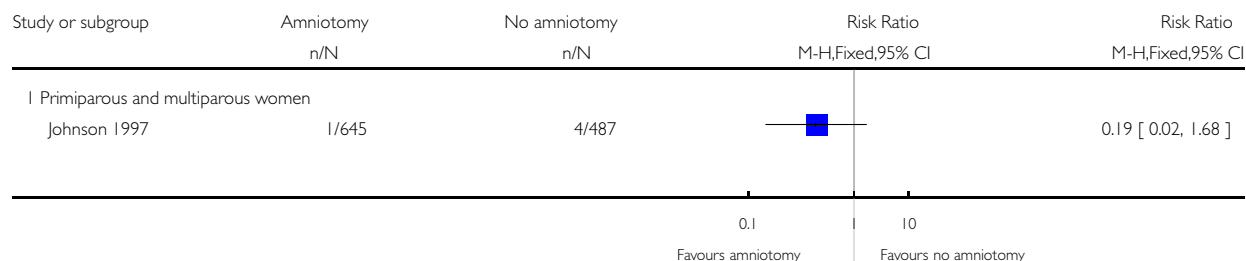
Outcome: 13 Postpartum haemorrhage



Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

Outcome: I 3 Postpartum haemorrhage

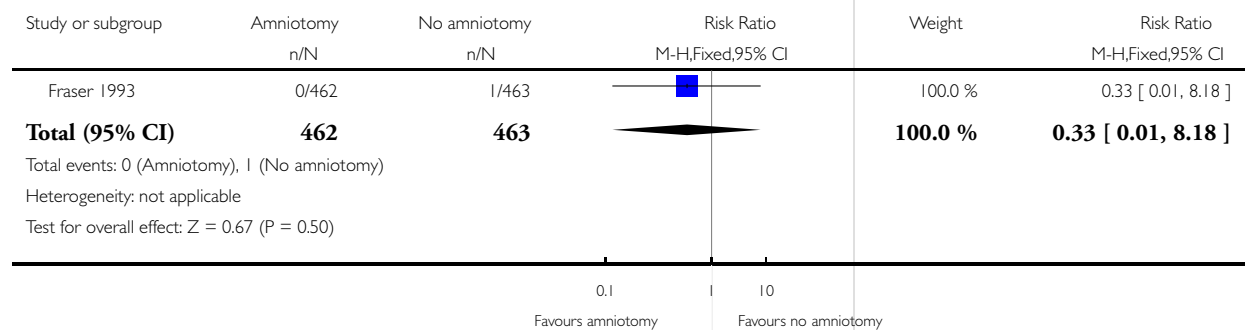


Analysis I.16. Comparison I Amniotomy versus no amniotomy, Outcome I 6 Cord prolapse.

Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

Outcome: I 6 Cord prolapse

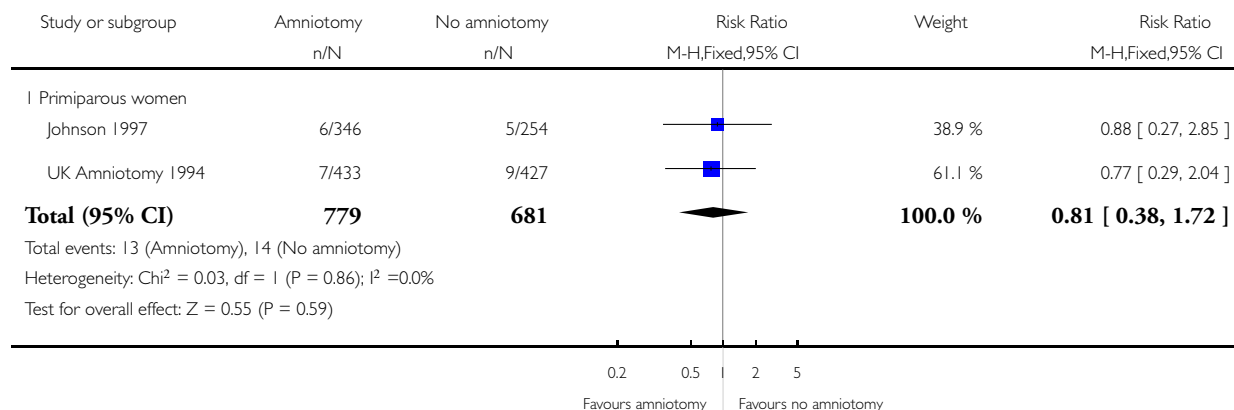


Analysis 1.17. Comparison 1 Amniotomy versus no amniotomy, Outcome 17 Maternal infection.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

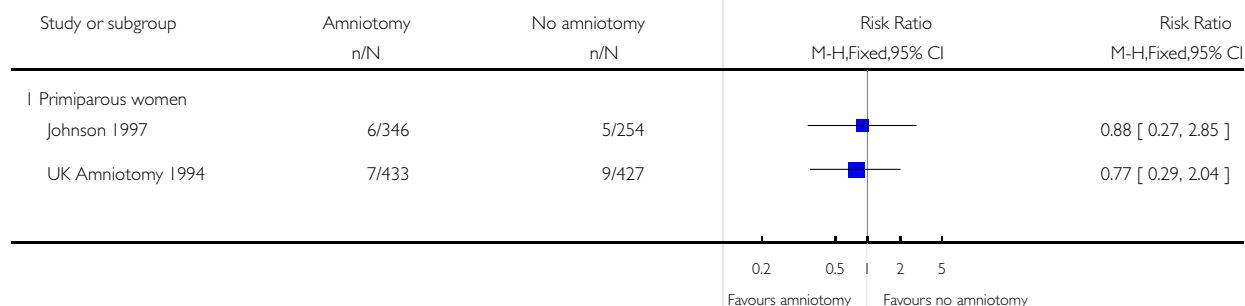
Outcome: 17 Maternal infection



Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 17 Maternal infection

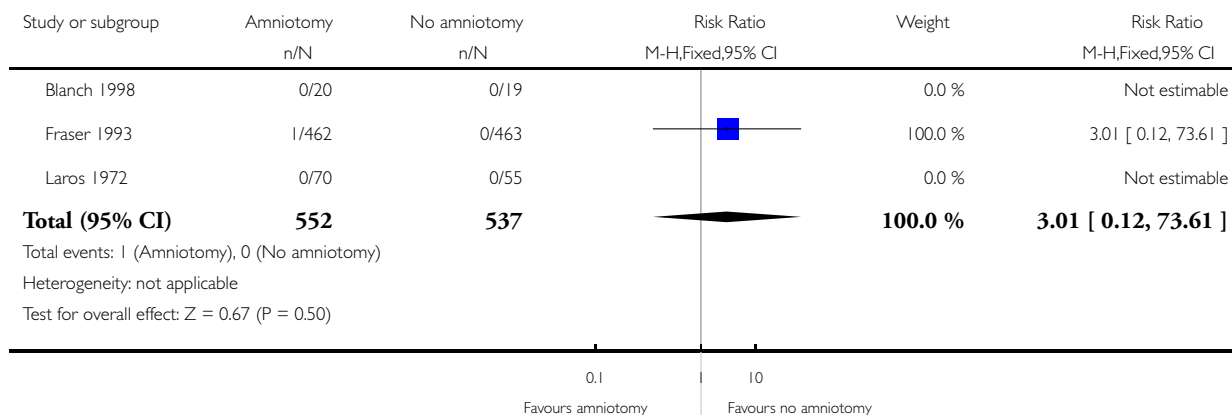


Analysis 1.18. Comparison 1 Amniotomy versus no amniotomy, Outcome 18 Maternal mortality.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 18 Maternal mortality

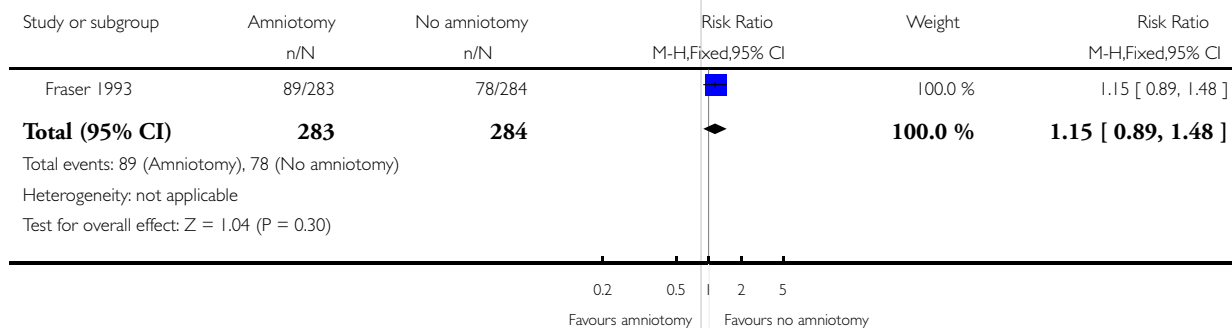


Analysis 1.22. Comparison 1 Amniotomy versus no amniotomy, Outcome 22 Suboptimal or abnormal fetal heart trace (second stage of labour).

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 22 Suboptimal or abnormal fetal heart trace (second stage of labour)

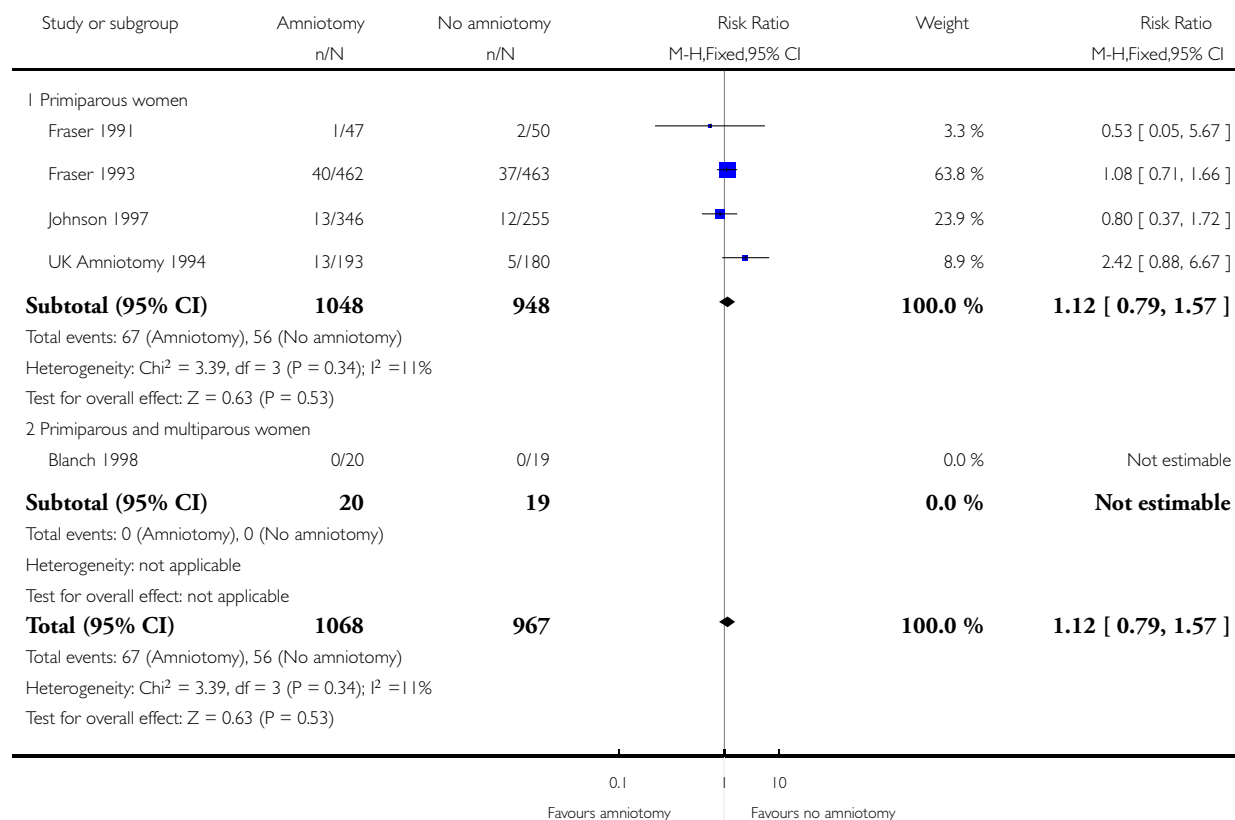


Analysis 1.23. Comparison 1 Amniotomy versus no amniotomy, Outcome 23 Admission to special care baby unit/neonatal intensive care unit.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

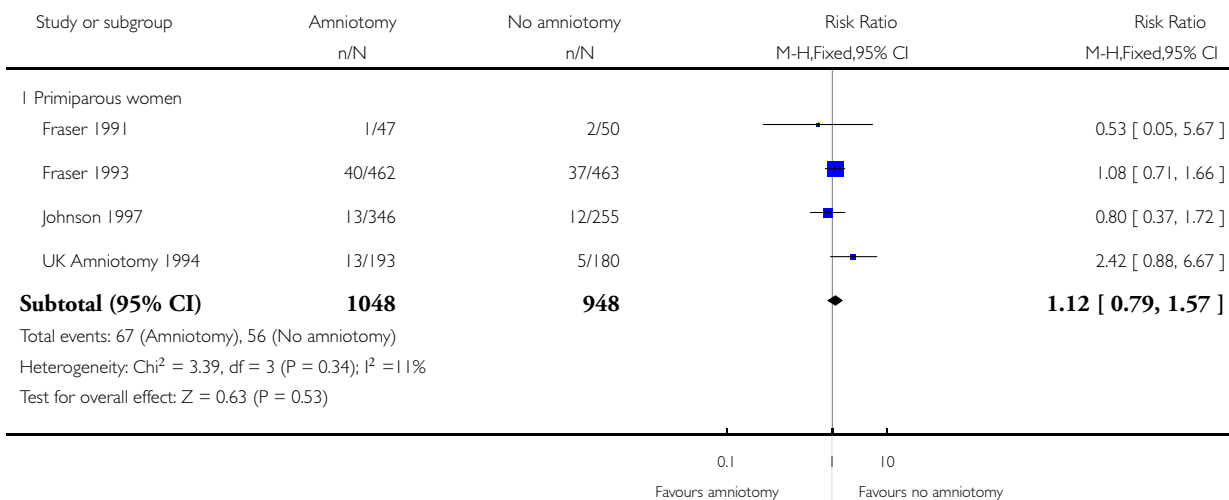
Outcome: 23 Admission to special care baby unit/neonatal intensive care unit



Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

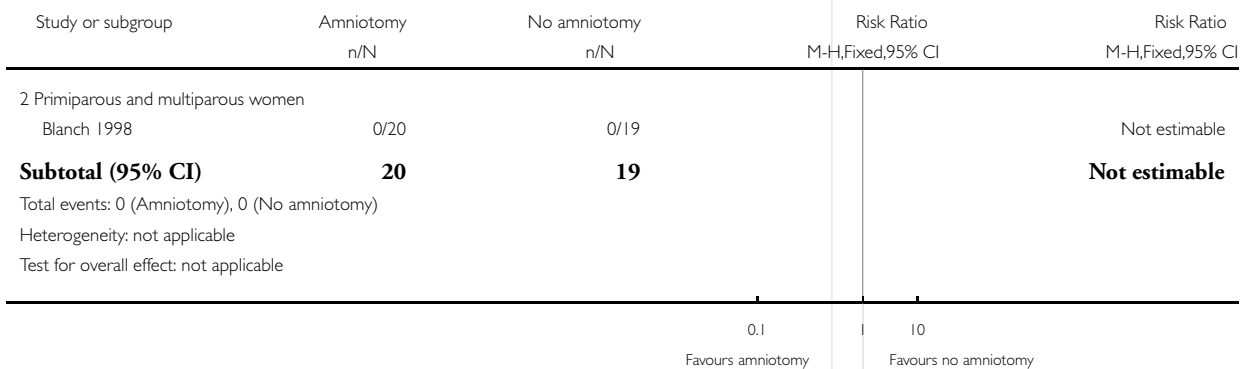
Outcome: 23 Admission to special care baby unit/neonatal intensive care unit



Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 23 Admission to special care baby unit/neonatal intensive care unit

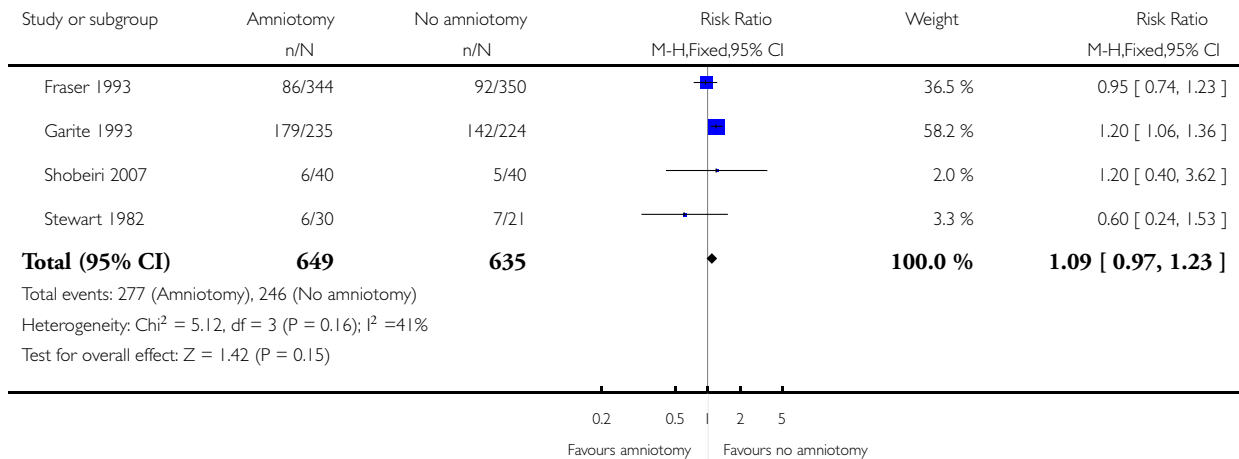


Analysis 1.24. Comparison 1 Amniotomy versus no amniotomy, Outcome 24 Suboptimal or abnormal fetal heart trace (first stage of labour).

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 24 Suboptimal or abnormal fetal heart trace (first stage of labour)

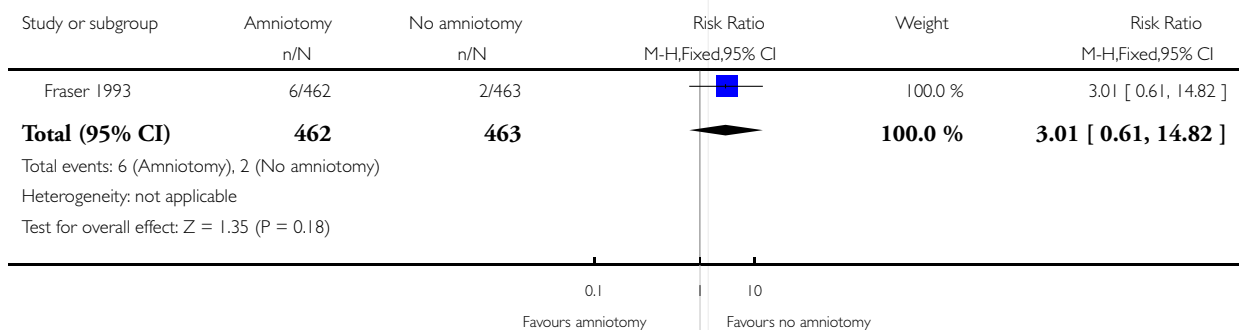


Analysis 1.25. Comparison 1 Amniotomy versus no amniotomy, Outcome 25 Meconium aspiration syndrome.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 25 Meconium aspiration syndrome

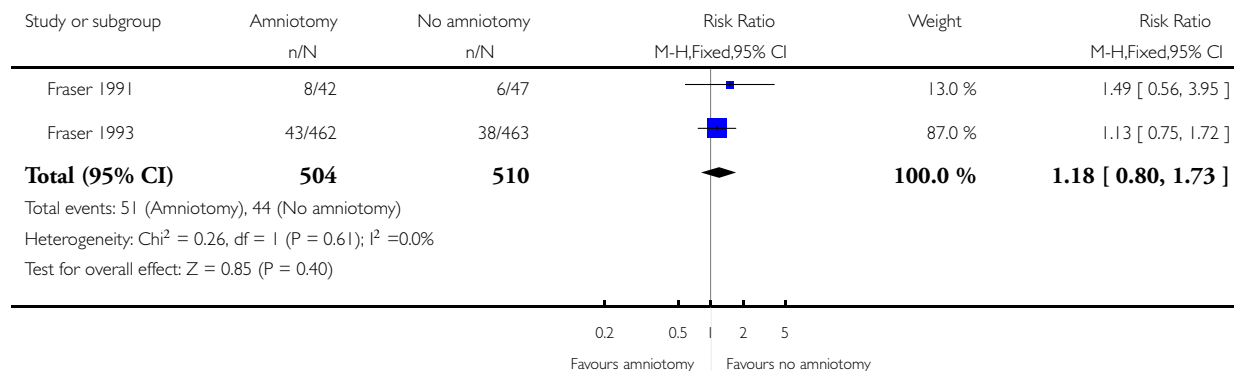


Analysis 1.26. Comparison 1 Amniotomy versus no amniotomy, Outcome 26 Acidosis as defined as a cord blood arterial pH of < 7.2.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 26 Acidosis as defined as a cord blood arterial pH of < 7.2

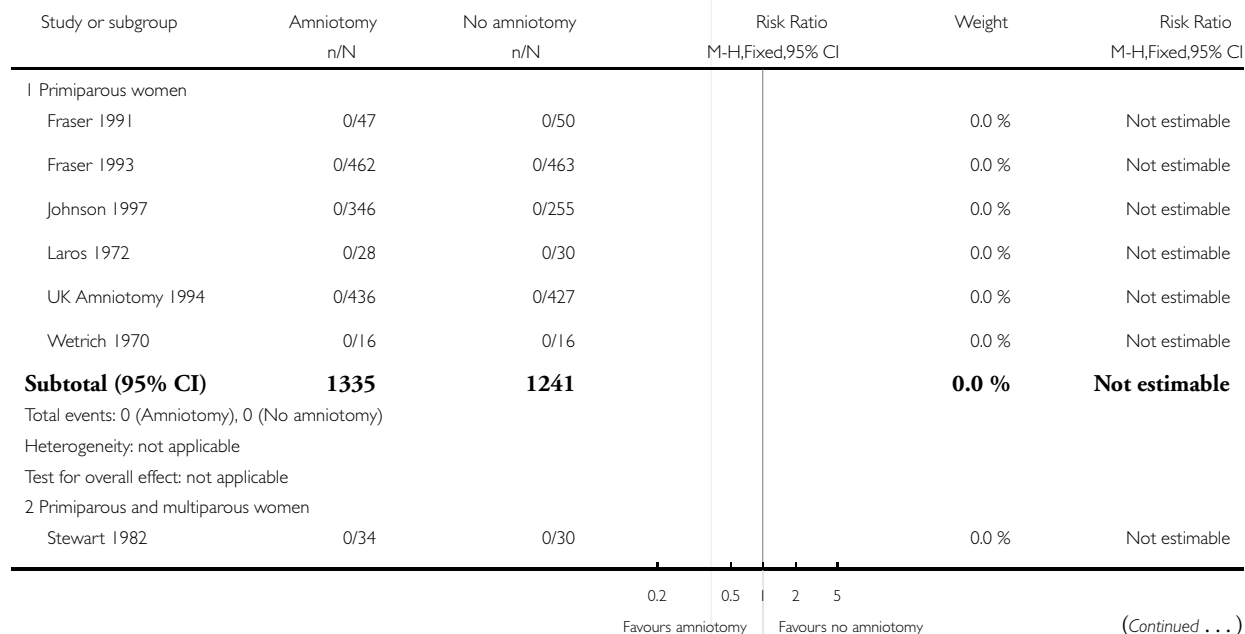


Analysis 1.27. Comparison 1 Amniotomy versus no amniotomy, Outcome 27 Perinatal death.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 27 Perinatal death



(... Continued)

Study or subgroup	Amniotomy n/N	No amniotomy n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Subtotal (95% CI)	34	30		0.0 %	Not estimable
Total events: 0 (Amniotomy), 0 (No amniotomy)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
3 Multiparous women					
Laros 1972	0/42	0/25		0.0 %	Not estimable
Subtotal (95% CI)	42	25		0.0 %	Not estimable
Total events: 0 (Amniotomy), 0 (No amniotomy)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	1411	1296		0.0 %	Not estimable
Total events: 0 (Amniotomy), 0 (No amniotomy)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					

0.2 0.5 2 5
Favours amniotomy Favours no amniotomy

Review: Amniotomy for shortening spontaneous labour
Comparison: I Amniotomy versus no amniotomy
Outcome: 27 Perinatal death

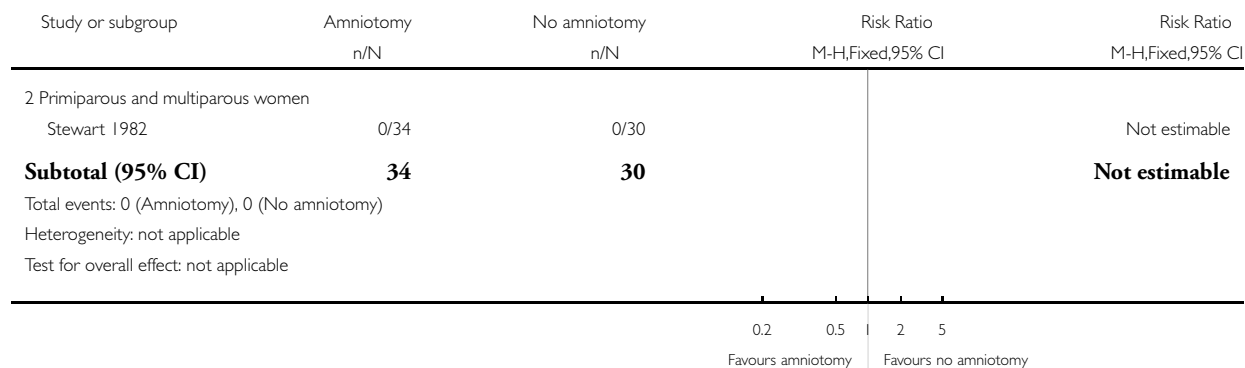
Study or subgroup	Amniotomy n/N	No amniotomy n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
I Primiparous women				
Fraser 1991	0/47	0/50		Not estimable
Fraser 1993	0/462	0/463		Not estimable
Johnson 1997	0/346	0/255		Not estimable
Laros 1972	0/28	0/30		Not estimable
UK Amniotomy 1994	0/436	0/427		Not estimable
Wetrich 1970	0/16	0/16		Not estimable
Subtotal (95% CI)	1335	1241		Not estimable
Total events: 0 (Amniotomy), 0 (No amniotomy)				
Heterogeneity: not applicable				
Test for overall effect: not applicable				

0.2 0.5 2 5
Favours amniotomy Favours no amniotomy

Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

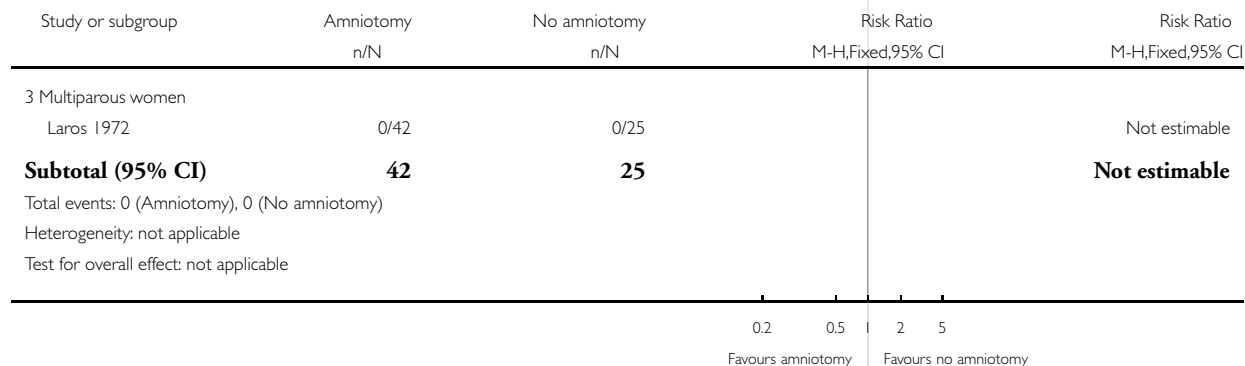
Outcome: 27 Perinatal death



Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

Outcome: 27 Perinatal death

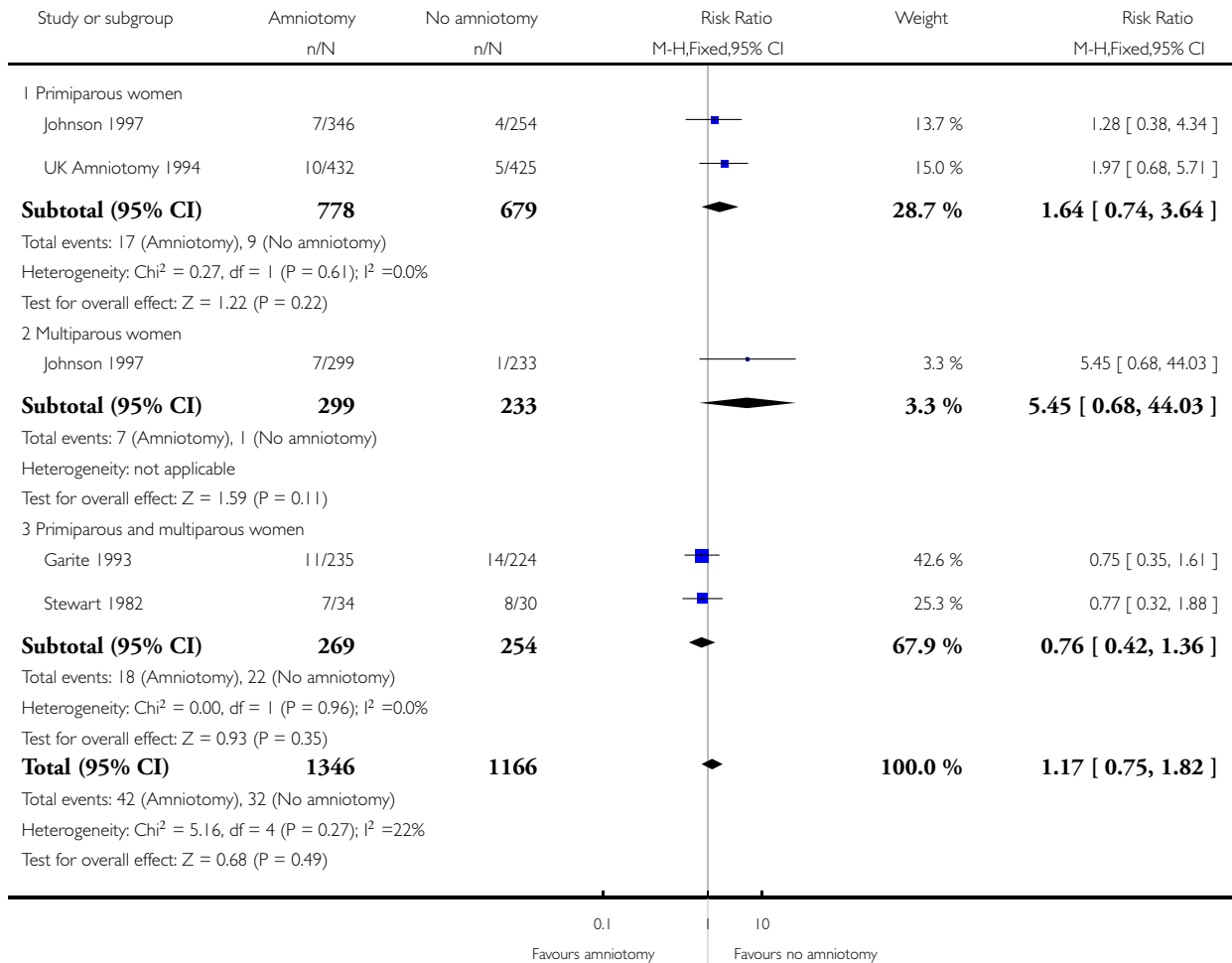


Analysis 1.28. Comparison 1 Amniotomy versus no amniotomy, Outcome 28 Neonatal jaundice.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

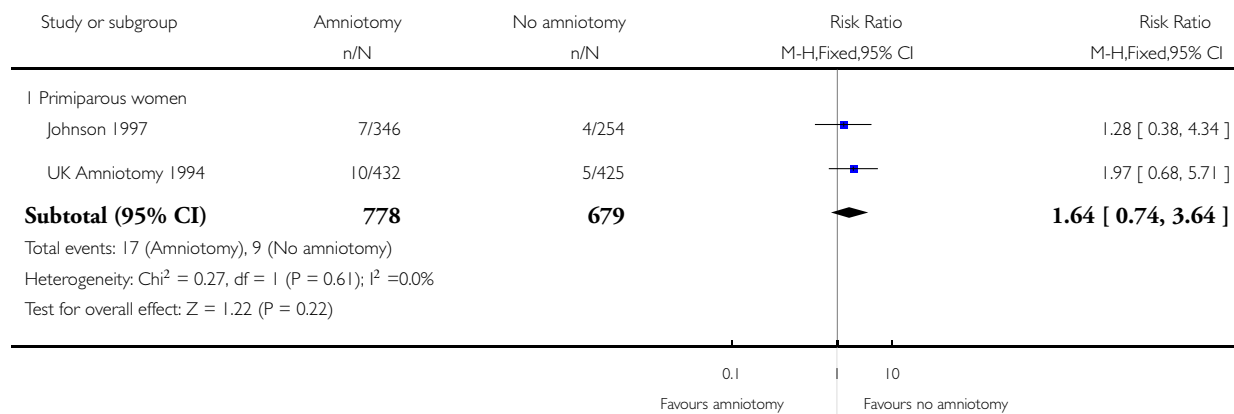
Outcome: 28 Neonatal jaundice



Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

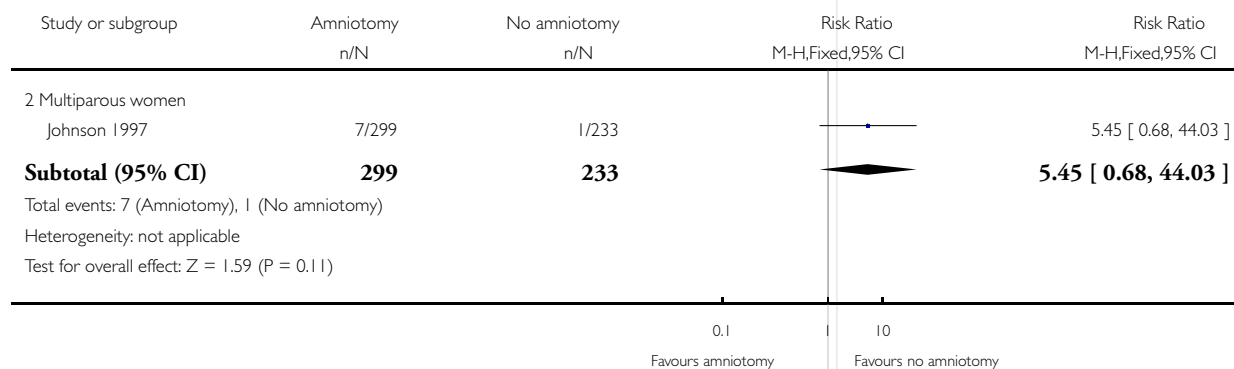
Outcome: 28 Neonatal jaundice



Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

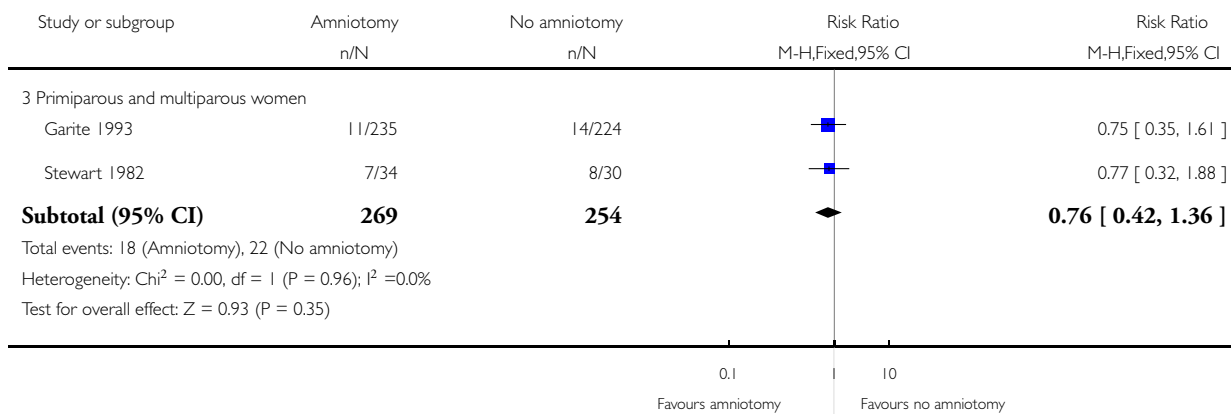
Outcome: 28 Neonatal jaundice



Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

Outcome: 28 Neonatal jaundice

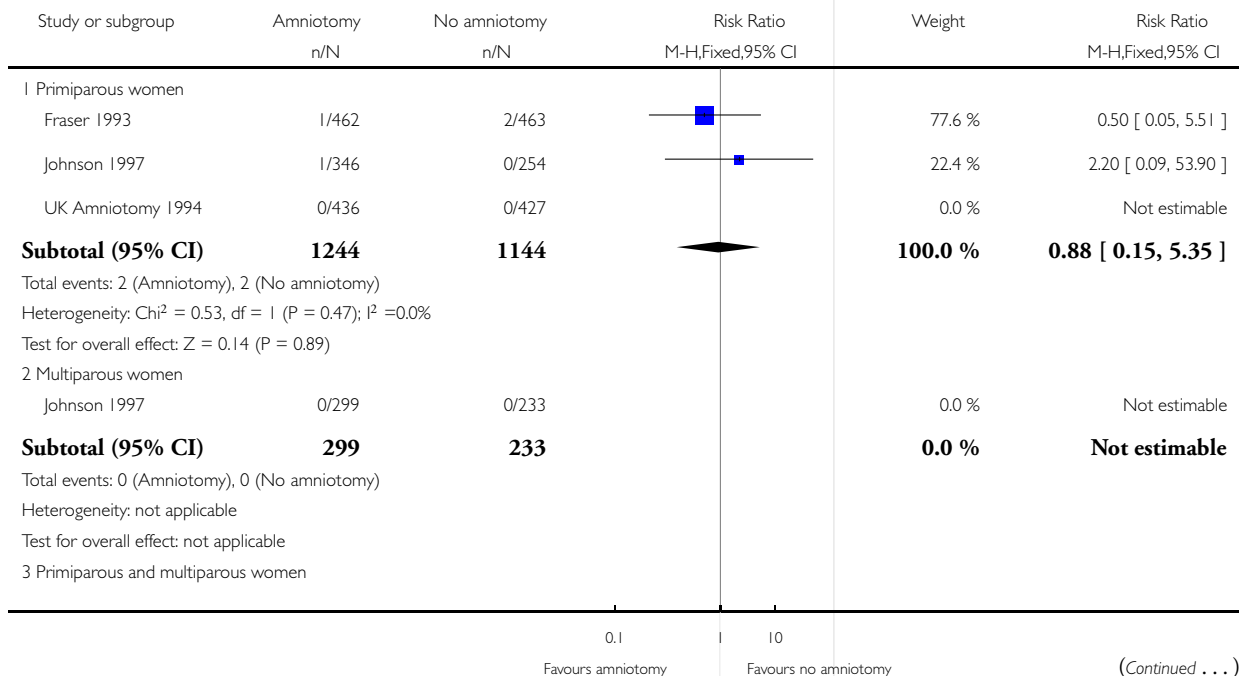


Analysis I.29. Comparison I Amniotomy versus no amniotomy, Outcome 29 Seizures (neonate).

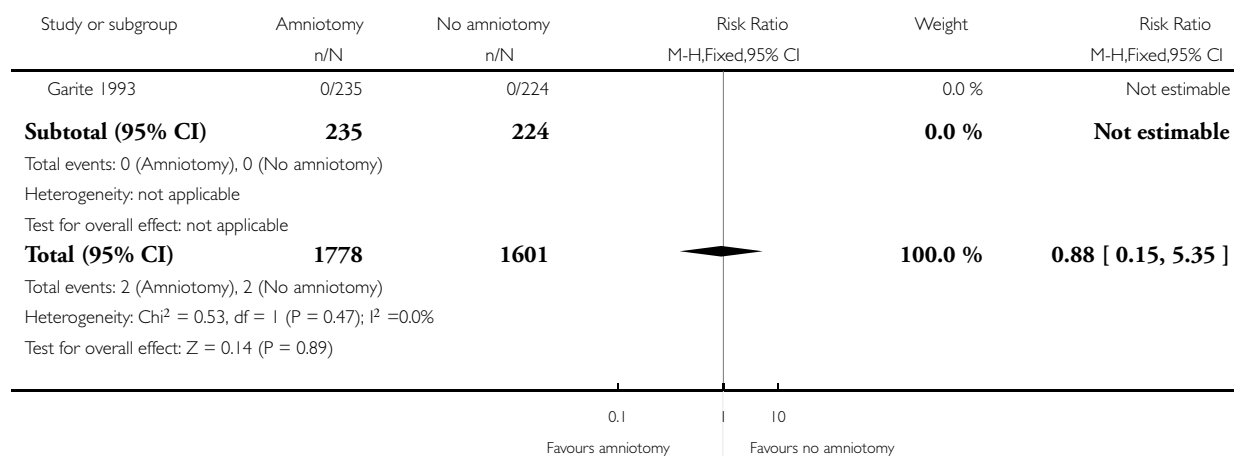
Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

Outcome: 29 Seizures (neonate)



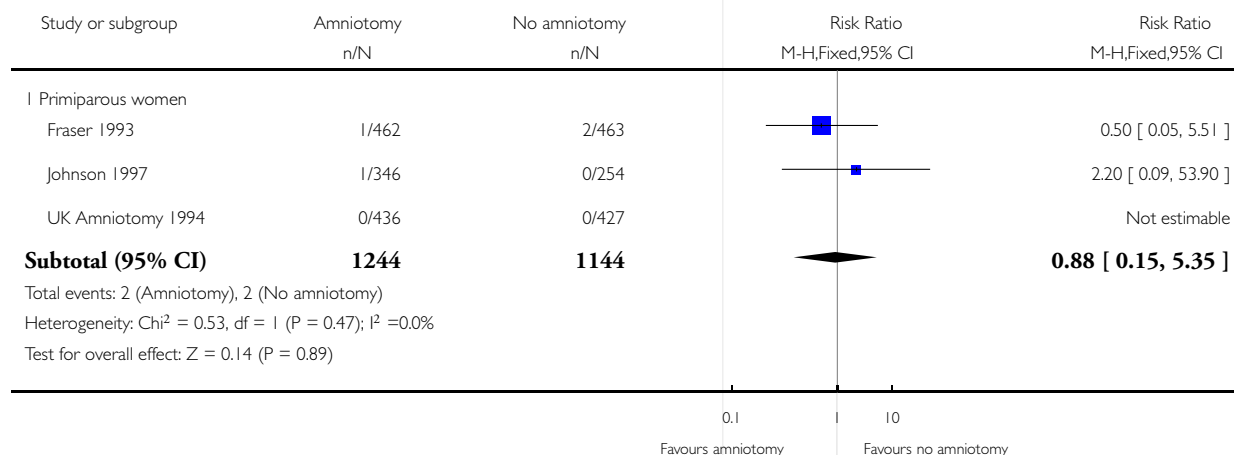
(... Continued)



Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 29 Seizures (neonate)



Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

Outcome: 29 Seizures (neonate)

Study or subgroup	Amniotomy n/N	No amniotomy n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
2 Multiparous women				
Johnson 1997	0/299	0/233		Not estimable
Subtotal (95% CI)	299	233		Not estimable
Total events: 0 (Amniotomy), 0 (No amniotomy)				
Heterogeneity: not applicable				
Test for overall effect: not applicable				
			0.1 Favours amniotomy	10 Favours no amniotomy

Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

Outcome: 29 Seizures (neonate)

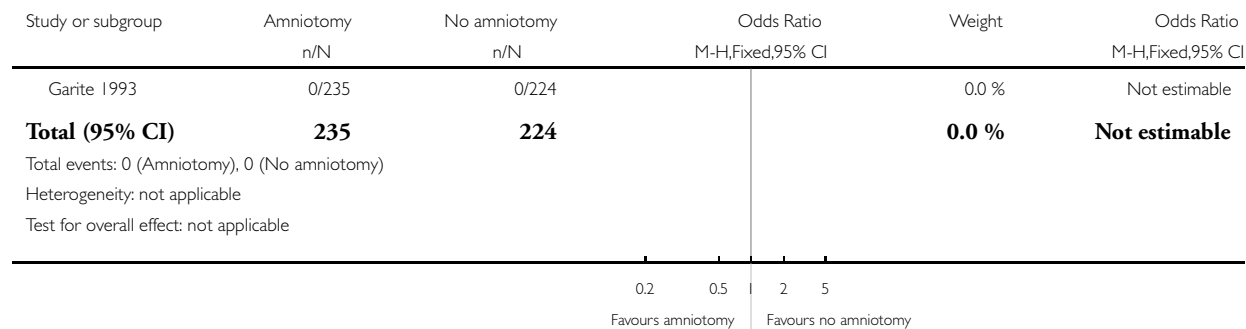
Study or subgroup	Amniotomy n/N	No amniotomy n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
3 Primiparous and multiparous women				
Garite 1993	0/235	0/224		Not estimable
Subtotal (95% CI)	235	224		Not estimable
Total events: 0 (Amniotomy), 0 (No amniotomy)				
Heterogeneity: not applicable				
Test for overall effect: not applicable				
			0.1 Favours amniotomy	10 Favours no amniotomy

Analysis I.30. Comparison I Amniotomy versus no amniotomy, Outcome 30 Respiratory distress syndrome.

Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

Outcome: 30 Respiratory distress syndrome

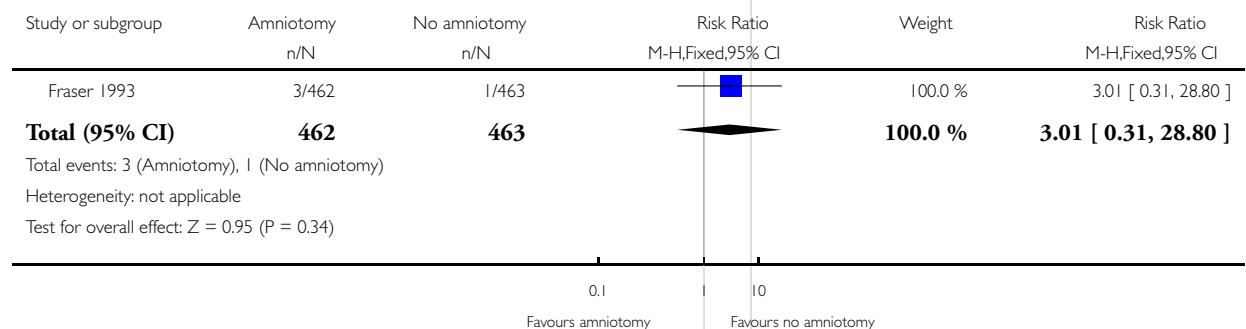


Analysis I.31. Comparison I Amniotomy versus no amniotomy, Outcome 31 Fracture.

Review: Amniotomy for shortening spontaneous labour

Comparison: I Amniotomy versus no amniotomy

Outcome: 31 Fracture

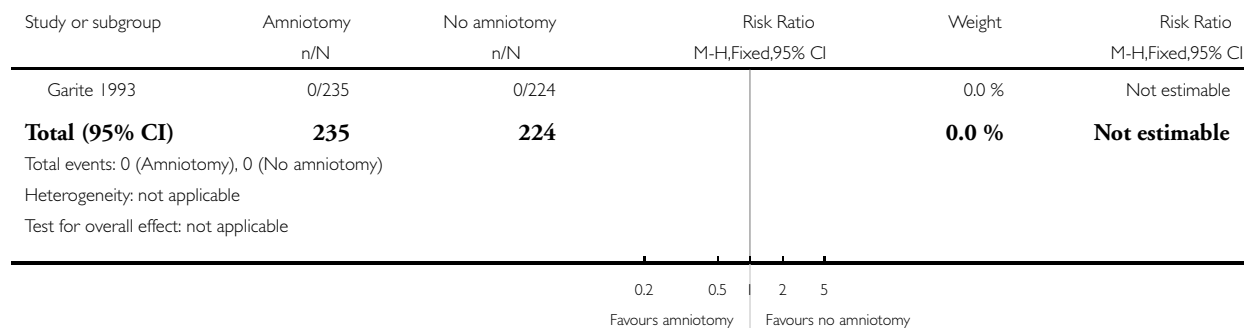


Analysis 1.32. Comparison 1 Amniotomy versus no amniotomy, Outcome 32 Intracranial haemorrhage.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 32 Intracranial haemorrhage

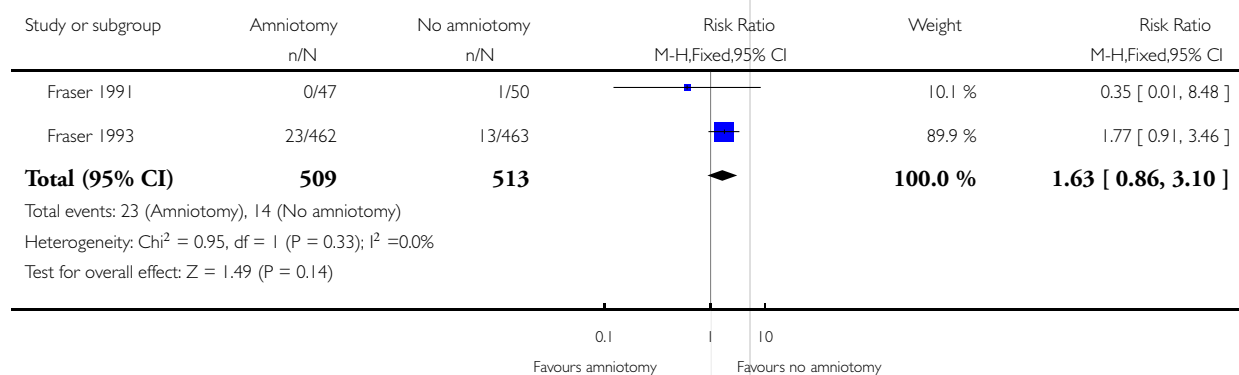


Analysis 1.33. Comparison 1 Amniotomy versus no amniotomy, Outcome 33 Cephalhaematoma.

Review: Amniotomy for shortening spontaneous labour

Comparison: 1 Amniotomy versus no amniotomy

Outcome: 33 Cephalhaematoma

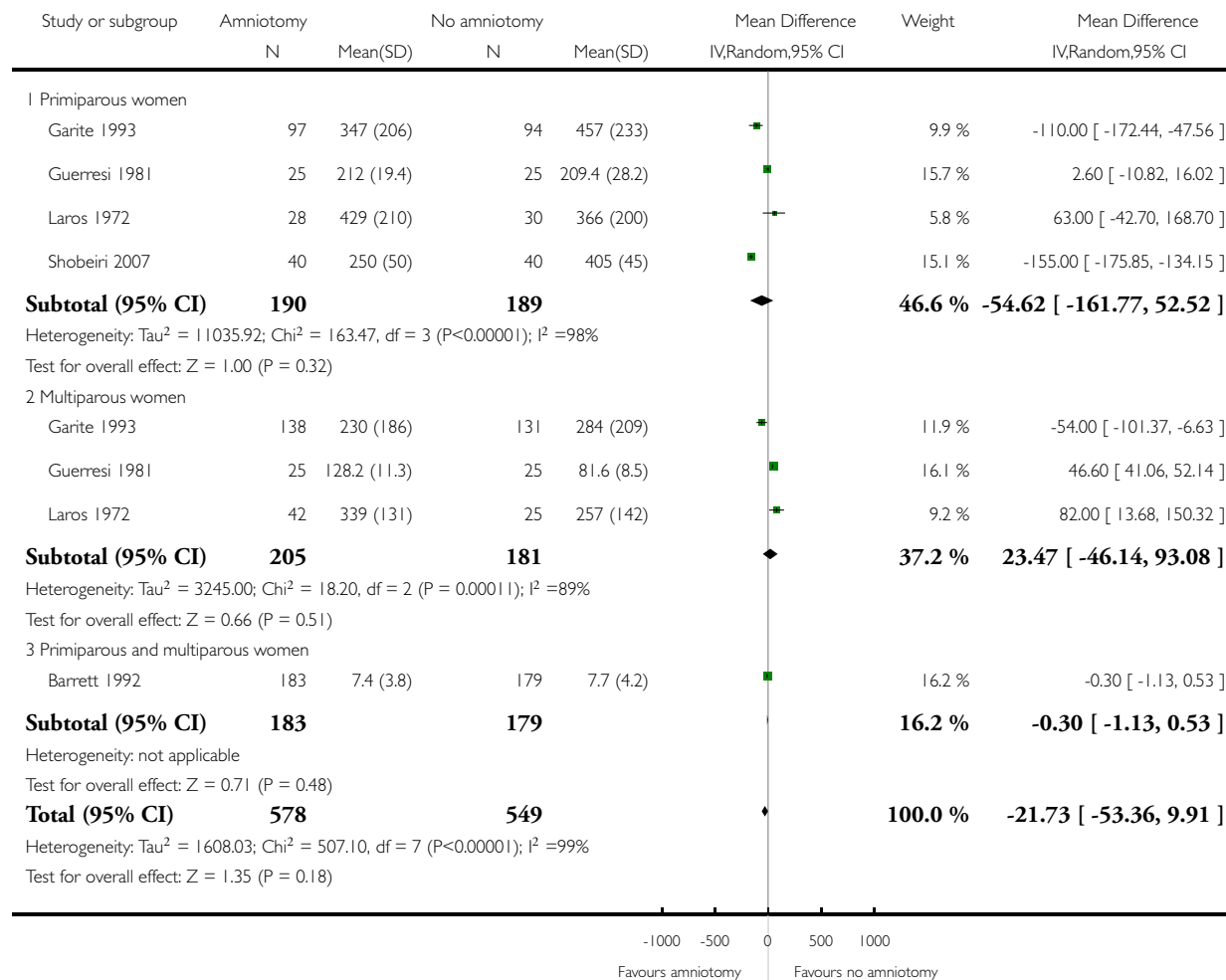


Analysis 2.1. Comparison 2 Sensitivity analysis excluding trials with inadequate allocation concealment (c), Outcome 1 Length of first stage of labour.

Review: Amniotomy for shortening spontaneous labour

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

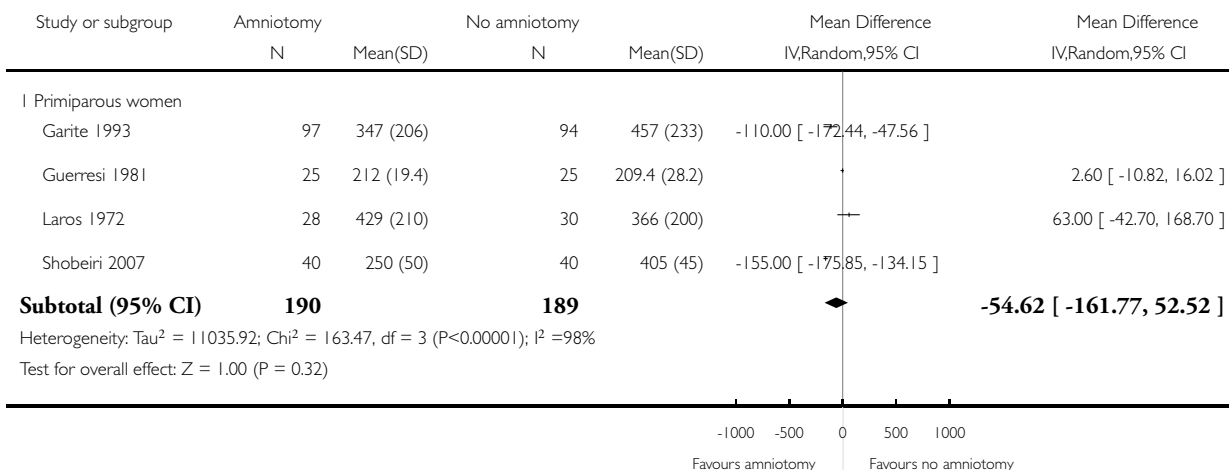
Outcome: 1 Length of first stage of labour



Review: Amniotomy for shortening spontaneous labour

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

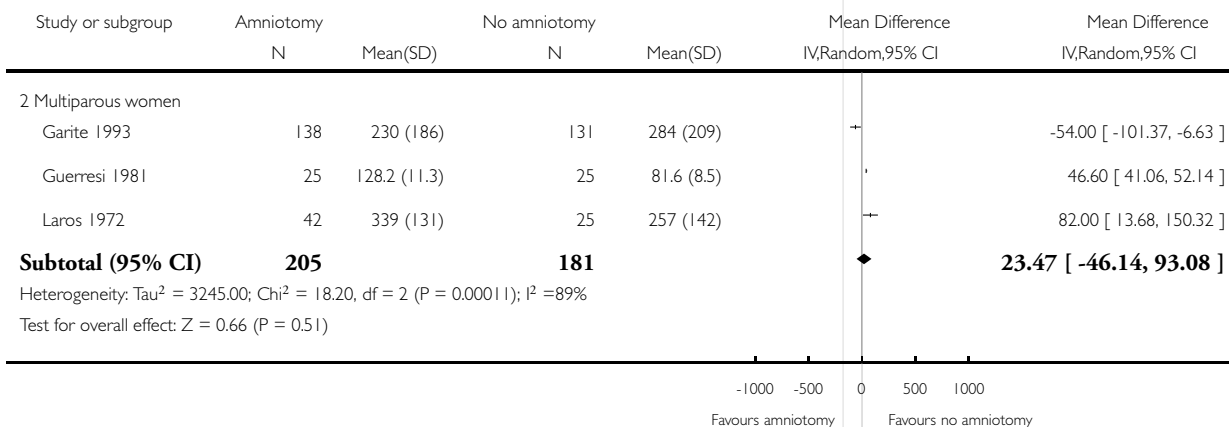
Outcome: 1 Length of first stage of labour



Review: Amniotomy for shortening spontaneous labour

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

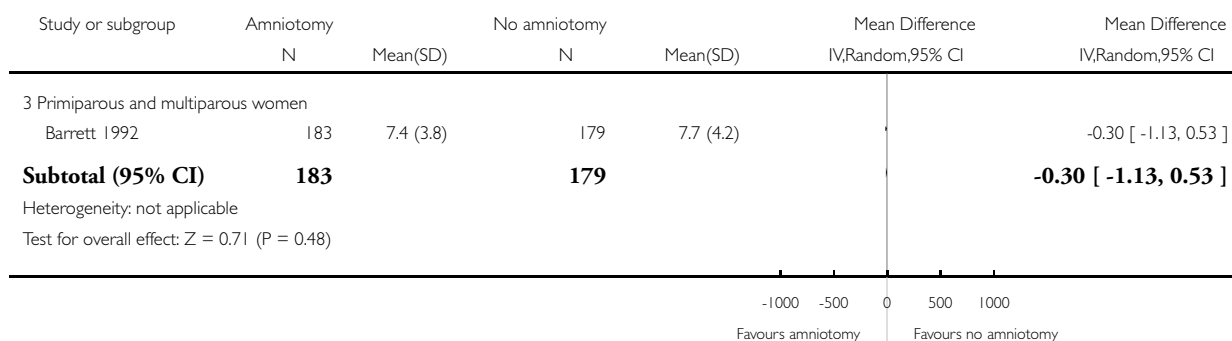
Outcome: 1 Length of first stage of labour



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

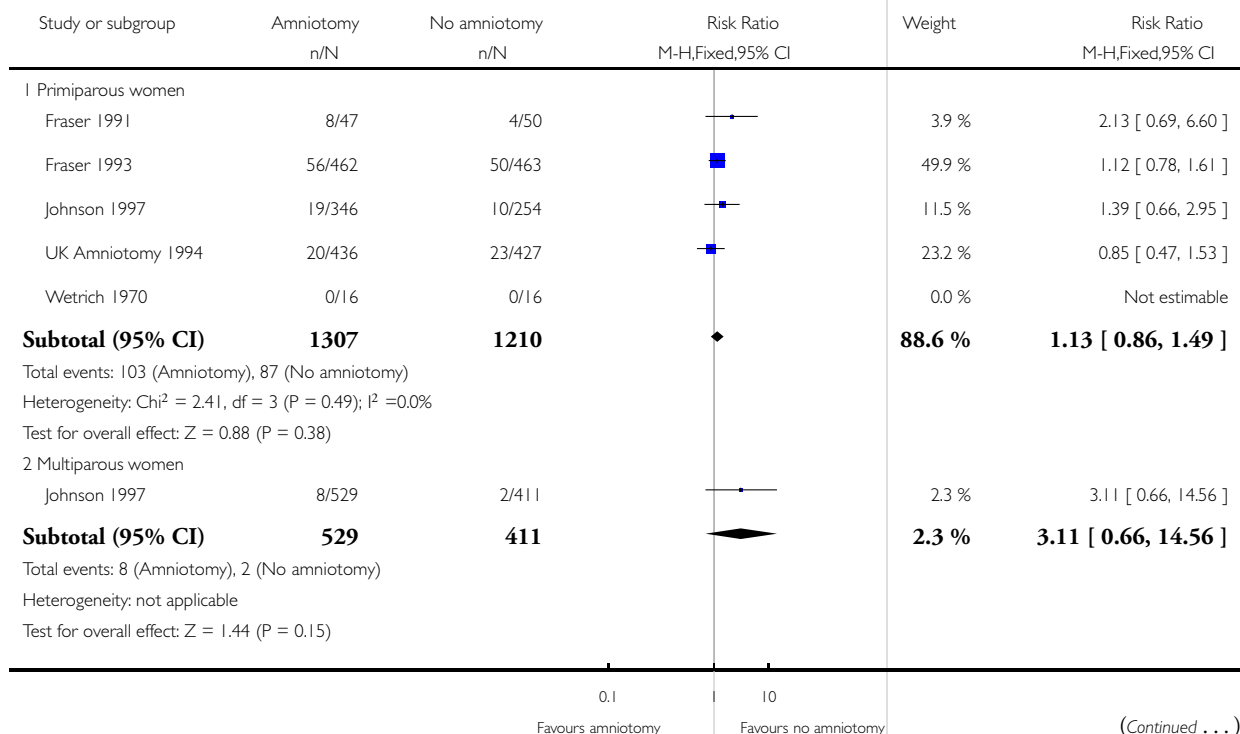


Analysis 2.2. Comparison 2 Sensitivity analysis excluding trials with inadequate allocation concealment (c), Outcome 2 Caesarean section.

Review: Amniotomy for shortening spontaneous labour

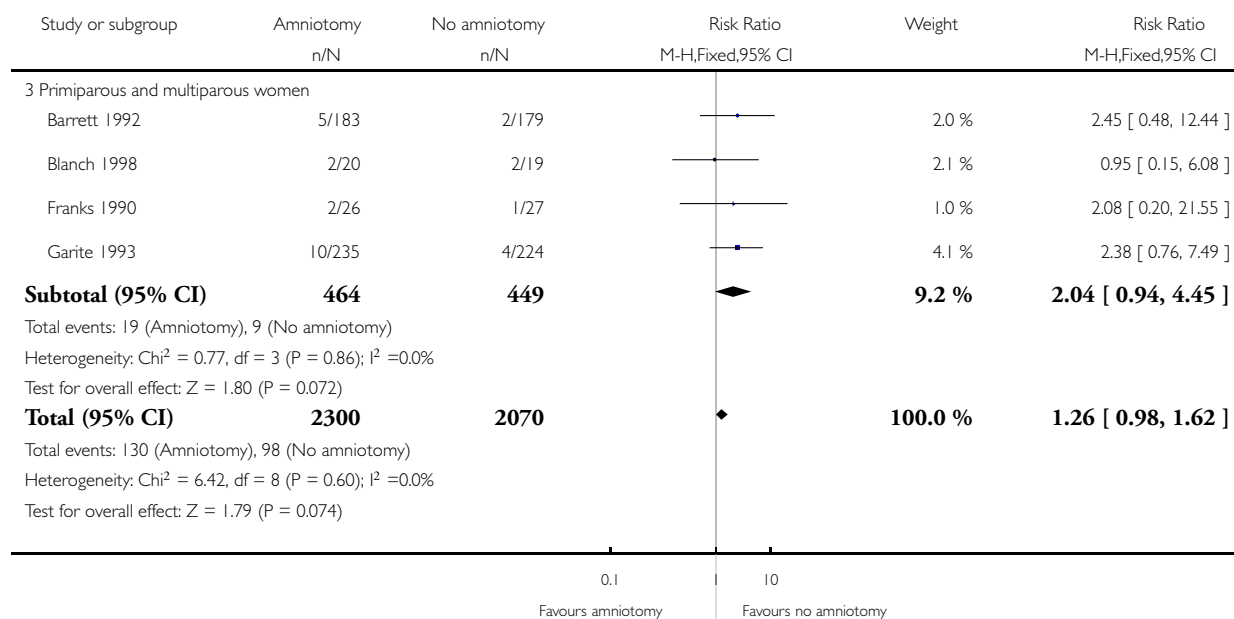
Comparison: 2 Sensitivity analysis excluding trials with inadequate allocation concealment (c)

Outcome: 2 Caesarean section



(Continued ...)

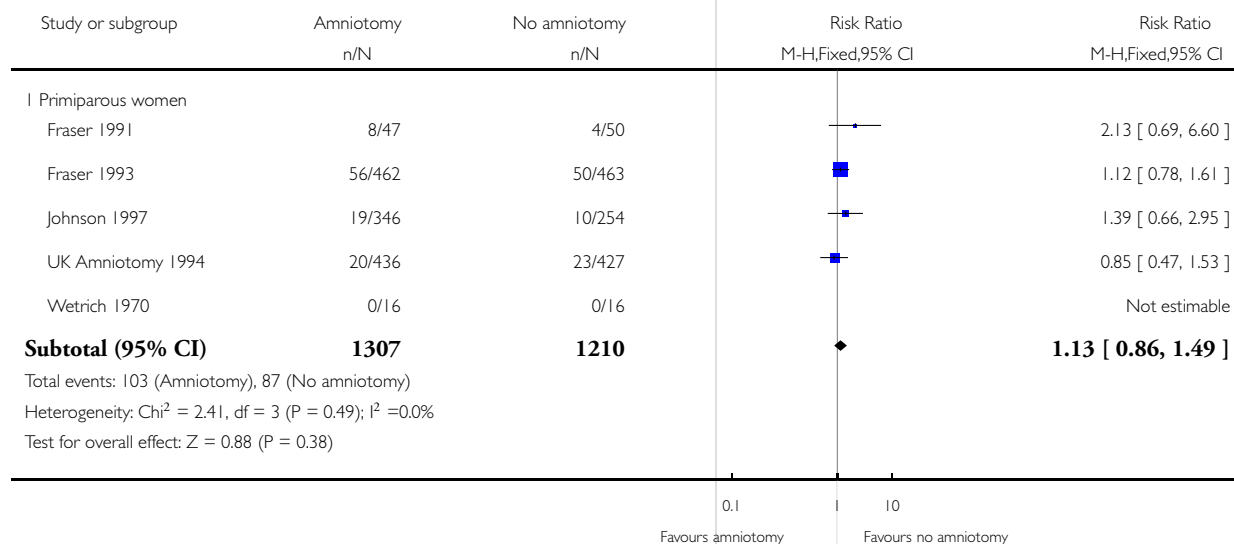
(... Continued)



Review: Amniotomy for shortening spontaneous labour

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

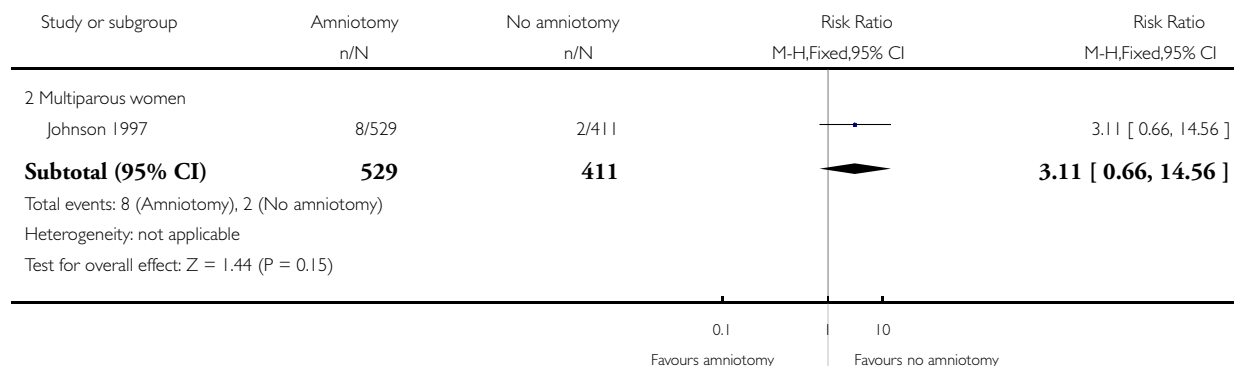
Outcome: 2 Caesarean section



Review: Amniotomy for shortening spontaneous labour

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

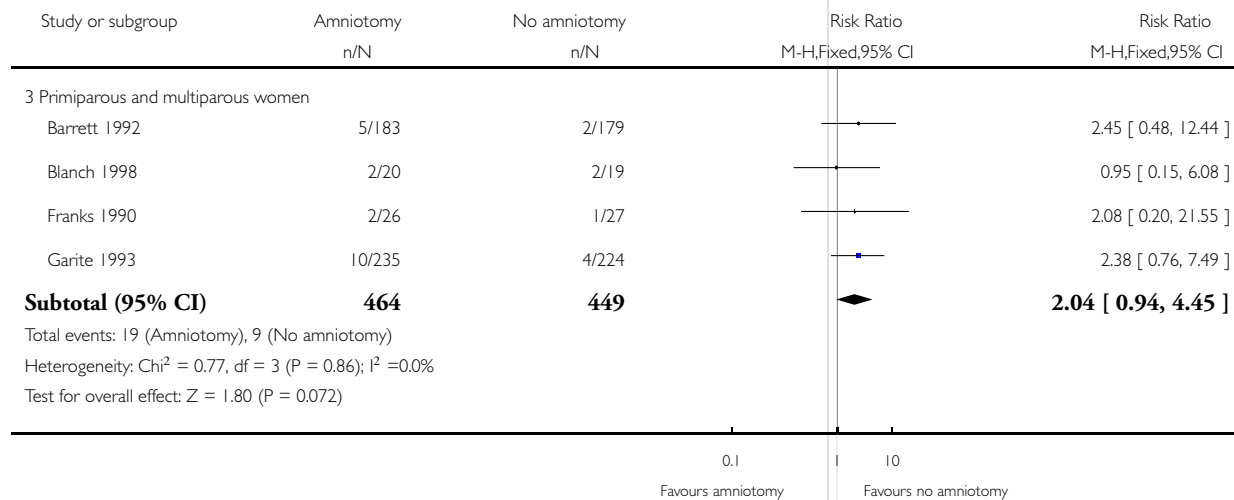
Outcome: 2 Caesarean section



Review: Amniotomy for shortening spontaneous labour

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

Outcome: 2 Caesarean section

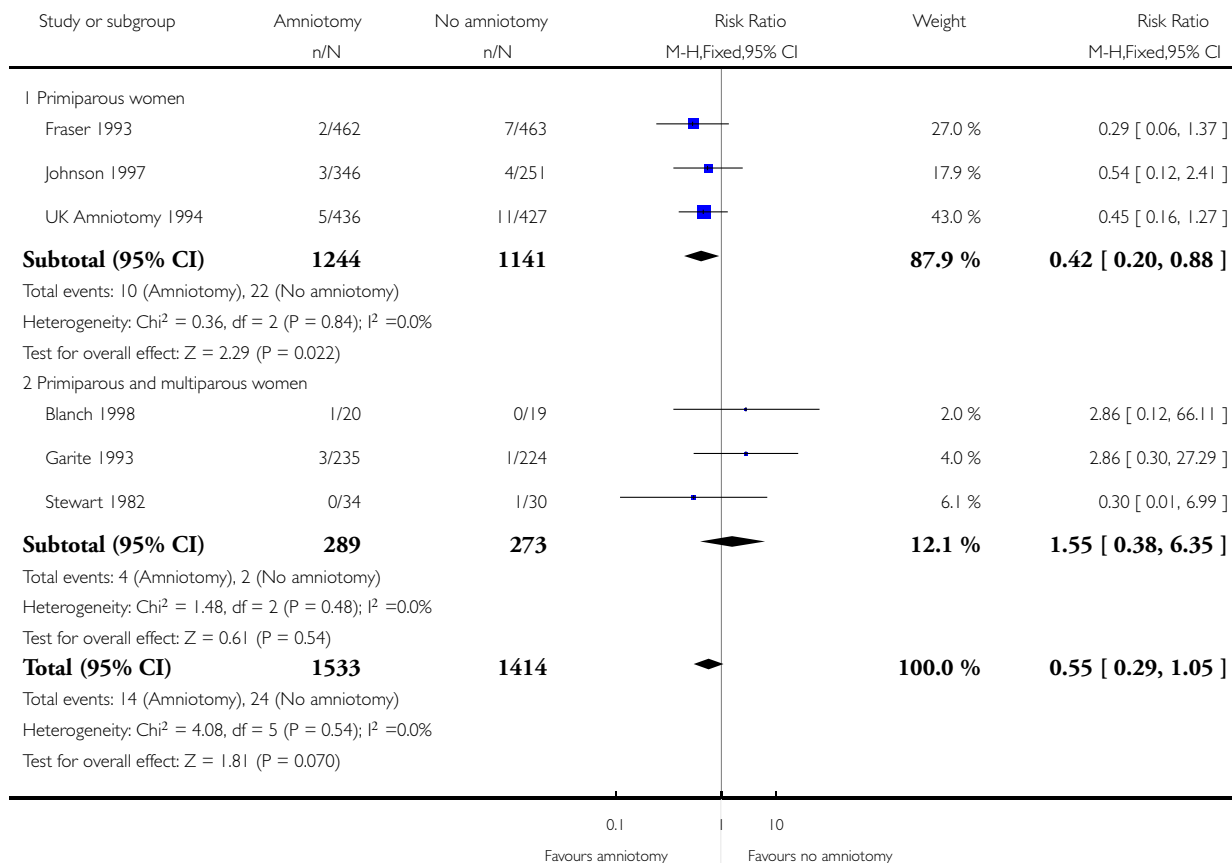


Analysis 2.4. Comparison 2 Sensitivity analysis excluding trials with inadequate allocation concealment (c), Outcome 4 Apgar score less than 7 at 5 minutes.

Review: Amniotomy for shortening spontaneous labour

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

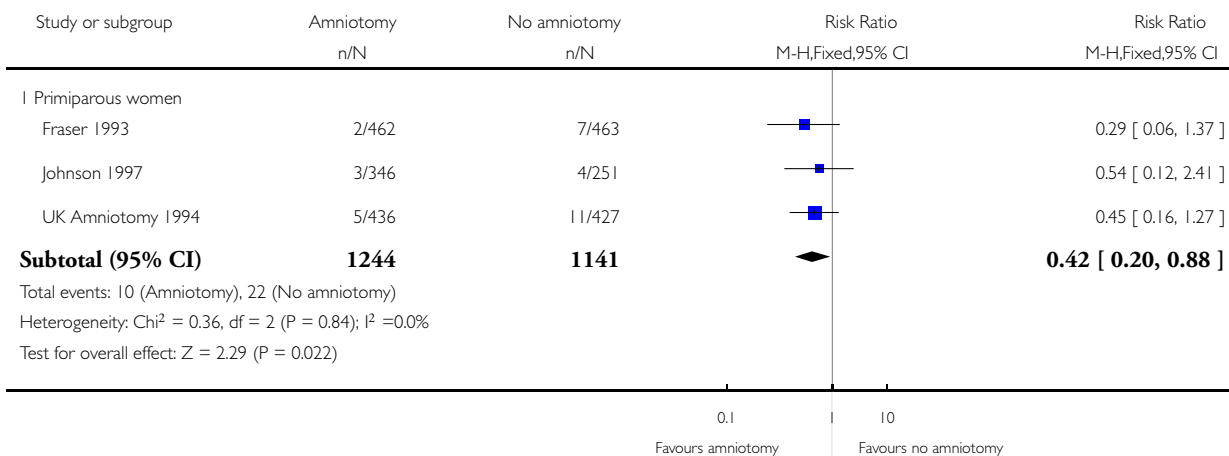
Outcome: 4 Apgar score less than 7 at 5 minutes



Review: Amniotomy for shortening spontaneous labour

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

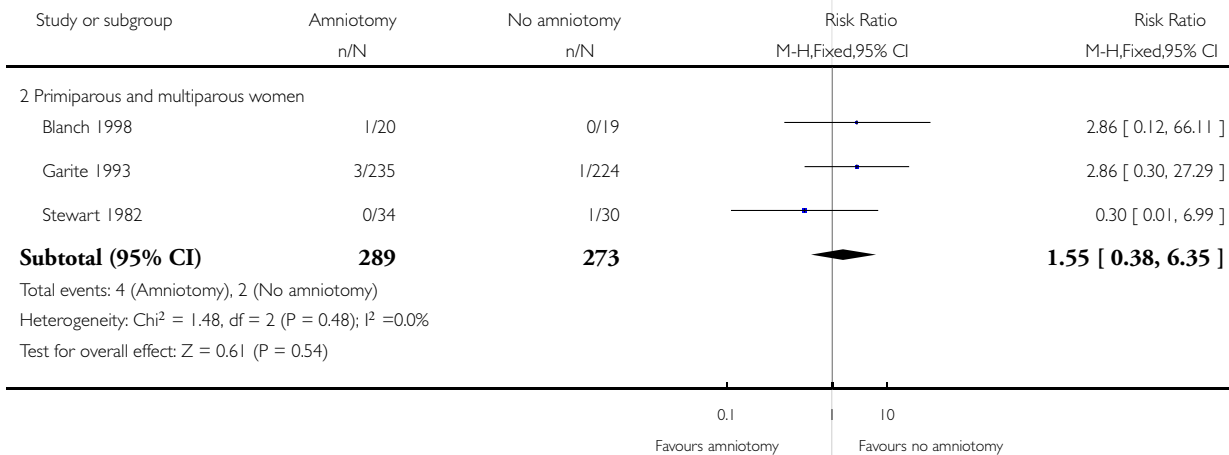
Outcome: 4 Apgar score less than 7 at 5 minutes



Review: Amniotomy for shortening spontaneous labour

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

Outcome: 4 Apgar score less than 7 at 5 minutes



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 randomized 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

A reply from the authors will be published as soon as it is available.

Contributors

Peter Wein

WHAT'S NEW

Last assessed as up-to-date: 12 July 2007

Date	Event	Description
25 June 2008	Feedback has been incorporated	Feedback from Peter Wein added.
21 April 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 4, 2006

Review first published: Issue 4, 2007

Date	Event	Description
30 November 2007	Feedback has been incorporated	Feedback from Jim Thornton and reply from authors added.

CONTRIBUTIONS OF AUTHORS

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

Rebecca Smyth and Sarah K Alldred assessed new studies for inclusion independently and extracted all the data. Data were double entered into Review Manager. Rebecca Smyth and Sarah K Alldred interpreted the results individually and together wrote the Results, Discussion and Conclusions. Carolyn Markham read the review and was satisfied with its content.

DECLARATIONS OF INTEREST

None known.

INDEX TERMS

Medical Subject Headings (MeSH)

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

MeSH check words

Female; Humans; Pregnancy