Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care (Review)

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[Intervention Review]

Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

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ABSTRACT

Background

Caesarean section rates are over 20% in many developed countries. The main diagnosis contributing to the high rate in nulliparae is dystocia or prolonged labour. The present review assesses the effects of a policy of early amniotomy with early oxytocin administration for the prevention of, or the therapy for, delay in labour progress.

Objectives

To estimate the effects of early augmentation with amniotomy and oxytocin for prevention of, or therapy for, delay in labour progress on the caesarean birth rate and on indicators of maternal and neonatal morbidity.

Search strategy

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (November 2008), MEDLINE (January 1970 to November 2008), EMBASE (1980 to November 2008), CINAHL (1982 to November 2008), MIDIRS (1985 to November 2008) and contacted authors for data from unpublished trials.

Selection criteria

Randomized and quasi-randomized controlled trials that compared oxytocin and amniotomy to expectant management.

Data collection and analysis

Three authors extracted data independently. We stratified the analyses into 'Prevention Trials' and 'Therapy Trials' according to the status of the woman at the time of randomization. Participants in the 'Prevention Trials' were unselected women, without slow progress in labour, who were randomized to a policy of early augmentation or to routine care. In 'Treatment Trials' women were eligible if they had an established delay in labour progress.

Main results

Twelve trials, including 7792 women, were included. The unstratified analysis found early intervention with amniotomy and oxytocin to be associated with a modest reduction in the risk of caesarean section; however, the confidence interval crossed unity and was compatible with no effect (risk ratio (RR) 0.89; 95% confidence interval (CI) 0.79 to 1.01). In Prevention trials, early augmentation was associated with a modest reduction in the number of caesarean births (RR 0.88; 95% CI 0.77 to 0.99). A policy of early amniotomy and early oxytocin was associated with a shortened duration of labour (mean difference - 1.11 hour). Sensitivity analyses excluding three trials with a full package of Active Management did not substantially affect the point estimate of the effect (RR 0.87; 95% CI 0.73 to 1.04). We found no other significant effects for the other indicators of maternal or neonatal morbidity.

Authors' conclusions

In prevention trials, early intervention with amniotomy and oxytocin appears to be associated with a modest reduction in the rate of caesarean section over standard care.

PLAIN LANGUAGE SUMMARY

Early amniotomy and early oxytocin for delay in first stage spontaneous labour compared with routine care

Caesarean section rates have increased substantially since the early 1970s; many women having their first babies are older and this may contribute to ineffective or difficult labor, most often because of inadequate uterine action (dystocia). The Active Management of Labor is a clinical protocol that includes early intervention with amniotomy and oxytocin to increase the frequency and intensity of uterine contractions (augmentation) when the progress of labor is delayed. Continued ineffective labor ('cervical arrest') can result in the decision to undertake a caesarian section. Early intervention also has risks that include uterine hyperstimulation and fetal heart rate abnormalities.

This review showed that a policy of early routine augmentation for mild delays in labor progress resulted in a modest reduction of the caesarean section rate compared with expectant management. The reduction in caesarian sections was most evident in the 10 trials looking at prevention of abnormal progression, rather than therapy (2 trials). The difference in caesarean risk was 1.47%. The number of women needed to treat (NNT) to prevent one caesarean section was approximately 68. This conclusion is based on 10 randomized controlled trials involving 7653 women. In these women, the time from admission to giving birth was also reduced (mean difference 1.1 hour).

The trials did not provide sufficient evidence on indicators of maternal or neonatal health, including women's satisfaction and views on the experience. Documentation of other aspects of care, such as continuous professional support, mobility and positions during labor, was limited as was the degree of contrast between groups. Women in the control group also received oxytocin but often later than in the intervention group. The severity of delay which was sufficient to justify interventions remains to be defined.

BACKGROUND

Caesarean section rates are over 20% in many developed countries (Betran 2007) and have increased nearly four-fold relative to the 5% rate observed in the early 1970s (NCCWCH 2004). The main diagnosis contributing to this increase is dystocia or prolonged labour (Anderson 1989; Liu 2004). Factors such as increasing maternal age appear to have contributed to the increase in the incidence of dystocia (Treacy 2006).

The 'active management' of labour is a clinical protocol that was designed to facilitate the organization of obstetric care in a busy labour ward. The active management of labour has been proposed as an alternative approach to the problem of dystocia, as well as a strategy to reduce the high rate of caesarean sections (O'Driscoll 1984). Active management includes: selective admission to the labour ward; selective use of electronic fetal monitoring; early intervention with amniotomy and oxytocin for delay in labour progress; routine use of a simplified 1 cm/hour partogram to guide clinical decision making; and continuous professional support. Classically, the protocol has included restricted use of epidural analgesia. Active management is based on the hypothesis that the most frequent cause of dystocia is inadequate uterine action: true cephalopelvic disproportion is assumed to be an infrequent cause of dystocia (O'Driscoll 1970). Amniotomy and oxytocin are performed with the purpose of increasing the frequency and intensity of contractions. Both the administration of oxytocin and amniotomy have been demonstrated to increase the frequency

and intensity of uterine contractions (Blanks 2003). As dystocia is primarily a problem of women who are in their first labour, active management focuses on nulliparous women. To date, there is no consensus with respect to the timing of amniotomy and oxytocin administration in the presence of a labour delay.

There are no universally accepted criteria for the diagnosis of dystocia. O'Driscoll proposed a partogram that includes, as a diagnostic criterion, a 1 cm/hour line originating at admission (O'Driscoll 1984). In contrast, Philpott suggested that the intervention threshold for dystocia should be based on an action line which is parallel to that proposed by O'Driscoll, but four hours to the right (Philpott 1982). Peisner noted that a high proportion of nulliparous women enter active phase dilatation only after 4 cm (Peisner 1986). This would argue against early intervention prior to 4 cm dilatation. The WHO has proposed a modified partogram that recommends that active phase be diagnosed only at 4 cm or more (WHO 2000). Clearly, the active management protocol proposes a low threshold for intervention for delay in labour progress. Early intervention is not without its risks. Uterine hyperstimulation and fetal heart rate abnormalities may result from oxytocin and amniotomy. The frequency of such complications needs to be better quantified.

Active management is a protocol that includes strict criteria for the diagnosis of labour, early amniotomy, prompt oxytocin with high-dose oxytocin in the event of inefficient uterine action, and continuous professional support during labour. A policy of combining early amniotomy with early oxytocin administration, which are applied sequentially in the active management of labour, are the key medical components of this approach to care. Several trials which have been labelled by the author as a trial of active management have only contrasted the used of early oxytocin and early amniotomy relative to routine care. Other studies of early amniotomy and early oxytocin, not labelled as active management trials, have been conducted. This review assessed the effects of early amniotomy and early oxytocin on the rate of caesarean section and maternal and neonatal morbidities.

Early amniotomy and oxytocin influence the overall organization of intrapartum obstetric care; therefore, this review is relevant to clinicians, consumers, and policy makers. For clinicians and consumers, the key issues are the effect of early augmentation in labour on indicators of morbidity and satisfaction with care. For policy makers, the key issues are the impact on the organization of care, including the appropriate settings and technical support required for routine obstetric care and their costs.

OBJECTIVES

1. To estimate the effects, among unselected women, of a policy of early augmentation with amniotomy and oxytocin (prevention) on the caesarean birth rate and on indicators of maternal and neonatal morbidity.
2. To evaluate the effects, among women with established delay in labour progress, of early augmentation with amniotomy plus oxytocin (therapy) on the caesarean birth rate and on indicators of maternal and neonatal morbidity.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized or quasi-randomized studies.

Types of participants

Pregnant women in spontaneous labour.
Types of participants are divided into two separate groups:
1. unselected pregnant women in spontaneous labour;
2. pregnant women in spontaneous labour where there is delay in the first stage;

Types of interventions

Early augmentation with amniotomy and oxytocin versus a more conservative form of management in the context of care. Trials where patients in both groups underwent amniotomy were excluded from this review.

Types of outcome measures

Primary outcomes

Caesarean section rate

Secondary outcomes

Maternal

Related to delivery method and labour duration
1. Spontaneous vaginal delivery
2. Instrumental vaginal delivery (forceps or vacuum, or both)
3. Length of first stage of labour
4. Duration of labour (duration in hours from admission in labour)
5. Satisfied with labour experience

Related to pain

1. Use of epidural analgesia

Potential adverse effects

1. Hyperstimulation of labour
2. Postpartum haemorrhage (greater than 500 ml)
3. Maternal blood transfusion
4. Postpartum fever or infection

Fetal/infant

1. Apgar score less than seven at five minutes
2. Acidosis as defined abnormal arterial cord pH (pH less than 7.10 or 7.20)
3. Suboptimal or abnormal fetal heart tracing
4. Fetal distress
5. Admission to special care nursery
6. Seizure/neurological abnormalities
7. Jaundice or hyperbilirubinaemia

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 (November 2008).

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

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

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

Trials identified through the searching activities described above were assigned to a review topic (or topics). The Trials Search Co-ordinator searched the register for each review using the topic list rather than keywords.

In addition, we searched MEDLINE (1966 to November 2008), EMBASE (1980 to November 2008), CINAHL (1982 to November 2008) and MIDIRS (1985 to November 2008) using the following search strategy, adapted for each database:

#1 Oxytocin/ OR oxytoc$
#2 amniotom$
#3 #1 AND #2

Searching other resources

We obtained data from any unpublished trials through direct communication with the authors.

We did not apply any language restrictions.

Data collection and analysis

Selection of studies

Two review authors (SQ Wei and BL Wo) independently assessed for inclusion all potential studies we identified as a result of the search strategy. We excluded studies where women in both treatment groups underwent amniotomy. We resolved any disagreement through discussion or consulted a third author (WD Fraser).

Data extraction and management

We designed a form to extract data. For eligible studies, at least two review authors (SQ Wei, BL Wo or ZC Luo) extracted the data independently. We resolved discrepancies through discussion or consulted a third author (WDF). We entered data into Review Manager software (RevMan 2008) and checked them for accuracy. When information regarding any of the above was unclear, we attempted to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors (SQ Wei and HR Xu) independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2008). Any disagreement was resolved by discussion or by involving a third author (WD Fraser).

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

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

We assessed the method as:

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

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

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

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

(3) Blinding (checking for possible performance bias)

We have described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We have noted where blinding was not possible or was not used (and this is likely to be the case in interventions where different styles of care were compared).
We assessed the methods as:
(1) adequate, inadequate or unclear for participants;
(2) adequate, inadequate or unclear for personnel;
(3) adequate, inadequate or unclear for outcome assessors.

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

We have described for each included study the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. We have stated whether attrition and exclusions were reported, the numbers (compared with the total randomised participants), reasons for attrition/exclusion where reported, and whether missing data were balanced across groups. Where sufficient information is reported, we re-included missing data in the analyses which we have undertaken.
We have assessed the methods as:

- adequate (e.g., where there was no missing data or low levels of missing data, and where reasons for missing data were balanced across groups);
- inadequate (e.g., where there were high levels of missing data or where attrition was not balanced across groups);
- unclear (e.g., where there was insufficient reporting of attrition or exclusions to permit a judgement to be made).

(For outcomes measured in labour, we would expect low levels of missing data to be no more than 10%.)

(5) Selective reporting bias

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

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

(6) Other sources of bias

We have described for each included study any important concerns we had about other possible sources of bias; for example, where there was a potential source of bias related to the specific study design; where the protocol changed part-way through; where there was extreme baseline imbalance; or where the study had been claimed to be fraudulent.
We assessed whether each study was free of other problems that could put it at risk of bias:

- yes;
- no;
- unclear.

(7) Overall risk of bias

We had made explicit judgements about risk of bias for important outcomes both within and across studies. With reference to (1) to (6) above, we have assessed the likely magnitude and direction of the bias and whether we considered it was likely to impact on findings.

Measures of treatment effect

Dichotomous data

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

Continuous data

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

Cluster-randomised trials

We did not identify any cluster-randomised trials on this topic.

Dealing with missing data

For included studies, we have noted levels of attrition.
We analyzed data on all participants with available data in the group to which they were allocated, regardless of whether or not they received the allocated intervention.

Assessment of heterogeneity

We applied tests of heterogeneity between trials, if appropriate, using the I^2 statistic. If we identified high levels of heterogeneity among the trials (exceeding 50%), a random-effects meta-analysis was used as an overall summary.

Assessment of reporting biases

Where we suspected reporting bias or where missing data were thought to introduce serious bias, this has been reported.

Data synthesis

We carried out statistical analysis using RevMan 2008. We used fixed-effect inverse variance meta-analysis for combining data where trials are examining the same intervention, and the trials' populations and methods were judged sufficiently similar. Where we suspected clinical or methodological heterogeneity between studies sufficient to suggest that treatment effects might differ between trials, we used random-effects meta-analysis.
If substantial heterogeneity was identified in a fixed effect meta-analysis, the analysis was repeated using a random-effects method.

Subgroup analysis and investigation of heterogeneity

We conducted the following subgroup analyses:

1. 'Prevention Trials' ,which were defined as trials that included unselected women in early spontaneous labour who were allocated to either early amniotomy and oxytocin in the case of delay in progress, or to usual care.
2. 'Therapy Trials' , which were defined as trials that only included women with an established delay in labour progress. In these trials, women had been allocated to either early amniotomy and oxytocin, or to routine care.

For fixed effect meta-analyses, we conducted planned subgroup analyses classifying whole trials by interaction tests as described by Deeks 2001. For random effects meta-analyses, we assessed differences between subgroups by inspection of the subgroups' confidence intervals; non-overlapping confidence intervals indicate a statistically significant difference in treatment effect between the subgroups.

Sensitivity analysis

We carried out a sensitivity analysis to explore the effects of a policy of early amniotomy and oxytocin alone, without the full package of co-interventions that are usually considered as constituting active management: continuous professional care, selective admission at the labour ward. Three such studies of active management (Frigoletto 1995; Rogers 1997; Tabowei 2003) were excluded in the sensitivity analysis in order to assess the combined effect of early amniotomy and oxytocin on the primary outcome.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.
We identified 19 studies. Seven were excluded. The characteristics of the excluded studies are outlined in the 'Characteristics of excluded studies' table. In the study by Rouse (Rouse 1994), study groups differed only with respect to the use of amniotomy. The trial by Cardozo 1990 was excluded as the groups differed only in the use of oxytocin. In Hogston 1993, the method of allocation depended on the labour ward policies of the woman's treating physician. One study (Ruiz Ortiz 1991) was a non-randomized trial. There was no control group in two other studies (Cummiskey 1989; Xenakis 1995). Finally, in one study (Verkuyl 1986) there was no information on the inclusion or exclusion characteristics of the women.
Ten randomized control trials (Blanch 1998; Bréart 1992; Cammu 1996; Cluett 2004; Frigoletto 1995; Lopez-Zeno 1992; Rogers 1997; Sadler 2000; Somprasit 2005; Tabowei 2003) and two quasi-randomized trials (Cohen 1987; Serman 1995) were included in this review, *see* 'Characteristics of included studies'. In one study (Frigoletto 1995), randomisation was performed at the beginning of the third trimester and approximately one third of the women were excluded from the analysis after randomisation as they became ineligible for the intervention. Only caesarean section was reported by intention-to-treat. This study was only included for the 'caesarean section' outcome. Ten trials were 'prevention studies' (Bréart 1992; Cammu 1996; Cohen 1987; Frigoletto 1995; Lopez-Zeno 1992; Rogers 1997; Sadler 2000; Serman 1995; Somprasit 2005; Tabowei 2003) and two were 'therapy studies' (Blanch 1998; Cluett 2004). Eleven trials were conducted in nulliparous women (Bréart 1992; Cammu 1996; Cluett 2004; Cohen 1987; Frigoletto 1995; Lopez-Zeno 1992; Rogers 1997; Sadler 2000; Serman 1995; Somprasit 2005; Tabowei 2003). One trial was conducted in a mixed population of nulliparous and multiparous women (Blanch 1998). No studies were conducted solely in multiparous women. There were three trials of active management of labour (Frigoletto 1995; Rogers 1997; Tabowei 2003) which, in the experimental intervention, included strict criteria for the diagnosis of labour, early amniotomy, prompt oxytocin with high-dose oxytocin in the event of inefficient uterine action and continuous professional support.

Risk of bias in included studies

We independently considered 12 trials for randomisation method and attrition bias. Amniotomy is virtually impossible to mask, and oxytocin was not blinded in the trials. Randomization was blinded in 10 out of the 12 studies contributing data to the meta-analysis (Blanch 1998; Bréart 1992; Cammu 1996; Frigoletto 1995; Lopez-Zeno 1992; Rogers 1997; Sadler 2000; Serman 1995; Somprasit 2005; Tabowei 2003). In one study (Serman 1995) the method of allocation was based on the woman's medical file number (odd or even numbers). In another study (Cohen 1987), women were allocated by alternate assignment. Randomization blinding, when performed, was achieved by telephone in one trial (Frigoletto 1995), and by sealed envelopes in the remaining studies. In the Frigoletto 1995 trial, one third of the women became ineligible for the study between randomisation and the onset of labour because they developed medical complications or their labour was induced with oxytocin. Since post-randomisation attrition is likely to introduce bias, we only included the caesarean section data from this study as it was the only outcome that was reported in an intention-to-treat analysis. In one trial (Sadler 2000), the overall response rate to the maternal satisfaction questionnaire was 72% (28% attrition), but significantly more women with early intervention (76%) responded than those routinely managed (68%) which is likely to introduce outcome assessment bias.

Effects of interventions

Twelve trials including 7792 women in labour were analysed. The characteristics of the women at the time of admission to the studies are shown in Table 1. There were eleven trials (Bréart 1992; Cammu 1996; Cluett 2004; Cohen 1987; Frigoletto 1995; Lopez-Zeno 1992; Rogers 1997; Sadler 2000; Serman 1995; Somprasit 2005; Tabowei 2003) which included only nulliparous women. One trial was conducted in a mixed population of nulliparous and multiparous women (Blanch 1998). Ten trials enrolled women who were in normal spontaneous labour at randomisation, allocating them either to early amniotomy and oxytocin if slow progress in labour ensued or to expectant management. These studies were termed 'prevention' trials. Two trials (Blanch 1998; Cluett 2004) which included only women with an established abnormality in the progress of labour were grouped as 'therapy' trials.

Table 1. Baseline characteristics of the women

Trials	Maternal age (years)	Gestational age (weeks)	Cervical dilation (cm)
Blanch 1998	24.5	-	4.6
Bréart 1992	25.2	39.5	3.3
Cammu 1996	27.2	39.7	3.2
Cluett 2004	25.4	40.0	5.3
Cohen 1987	20.0	-	2.8
Frigoletto 1995	-	-	3.4
Lopez-Zeno 1992	27.0	39.8	3.2
Rogers 1997	20.6	39.5	2.9
Sadler 2000	25.7	39.7	4.5
Sermen 1995	23.6	39.1	-

Table 1. Baseline characteristics of the women (*Continued*)

Somprasit 2005	24.3	-	3.1
Tabowei 2003	23.8	40.1	-

In all studies, the more interventionist policy consisted of early amniotomy if membranes were intact and early oxytocin infusion. Oxytocin was used in women in the control group if a more marked delay in labour progress ensued. The severity of delay which justified oxytocin augmentation in the control group varied from usual care to an eight hour period of expectant management following randomisation. Care of the amniotic membranes for women in control groups also varied across trials.There was either an attempt to avoid amniotomy in control group women (Bréart 1992; Cammu 1996; Lopez-Zeno 1992; Rogers 1997; Sadler 2000; Serman 1995) or membranes were managed according to usual care 'no attempt to modify care from what is usually given on the service' (Cluett 2004; Cohen 1987; Frigoletto 1995; Somprasit 2005; Tabowei 2003). Studies varied in the degree of contrast achieved between groups with respect to the proportion undergoing the interventions (*see* the 'Characteristics of included studies' for details). In some trials, the proportion of women receiving oxytocin was similar in the two groups (Bréart 1992; Lopez-Zeno 1992; Rogers 1997; Serman 1995). However, in these studies, the groups contrast in respect of the time between randomisation and the initiation of oxytocin.

There was no evidence of statistical heterogeneity for any of the outcomes, with the exception of the length of the first stage of labour (I^2 = 81%), the overall duration of labour (I^2 = 94 %) ,and use of epidural analgesia in the therapy (I^2 = 62%).

In the unstratified analysis, the point estimate for caesarean section (CS) suggested a modest reduction with early amniotomy and oxytocin although the confidence interval crossed unity and were compatible with no effect (RR 0.89; 95% CI 0.79 to 1.01). In the stratified analysis, for prevention trials early augmentation was associated with a modest reduction in the CS rate (RR 0.88; 95% CI 0.77 to 0.99). In contrast, there was no statistical evidence of such an effect in therapy trials (RR 1.54; 95% CI 0.75 to 3.15). However, the number of therapy trials was small (2 trials involving 139 women). An interaction test (Breslow -Day test) between prevention and therapy groups for CS, showed a chi-squared value was 2.23, p = 0.136. Thus, there was no statistical evidence of an interaction between treatment effect and trial type (prevention versus therapy); however, the statistical power of this test was low. In a sensitivity analysis, we excluded the three prevention trials where the experimental intervention consisted of the full active management package. Results revealed that the effect estimate was not modified by excluding these three trials (unstratified analysis: RR 0.87; 95% CI 0.73 to 1.04; prevention trials: RR 0.84; 95% CI 0.70 to 1.01).

The length of first stage of labour was shortened in the early amniotomy and oxytocin group compared with the expectant management group (mean difference (MD) -1.43 hours; 95% CI -2.01 to -0.84). In the stratified analysis, the effect of the study group on the duration of the first stage of labour was most marked in the prevention trials (MD -1.57 hours; 95% CI -2.15 to -1.00). However, there was no statistical evidence of such an effect in the therapy trials (MD -0.21 hours; 95% CI -1.68 to 1.26).

Five trials reported duration of labour (admission to delivery interval). These trials were conducted in nulliparous women in therapy trials. Overall, early amniotomy and oxytocin was associated with a reduction in the duration of labour (MD - 1.11 hours; 95% CI -1.82 to - 0.41). One study (Sadler 2000) reported the median and range. However, there was significant heterogeneity across the studies, even when using standardised mean difference instead of mean difference (I^2 = 94%).

As for other maternal outcomes such as spontaneous delivery (RR 1.01; 95% CI 0.97 to 1.05), instrumental vaginal delivery (RR 1.01; 95% CI 0.92 to 1.11) and use of epidural analgesia (RR 1.05; 95% CI 0.99 to 1.12), there was no evidence of an effect on early amniotomy and oxytocin. Three trials (Bréart 1992; Cammu 1996; Lopez-Zeno 1992) reported on the frequency of requirement for maternal blood transfusion. A trend towards an increase in transfusion was noted (RR 2.41; 95% CI 0.85 to 6.83) in association with early intervention. This effect was mainly due to one study (Bréart 1992). There was no evidence of an effect of early intervention on a range of adverse maternal outcome indicators including hyperstimulation of labour, postpartum haemorrhage (greater than 500 ml), maternal blood transfusion, or postpartum fever or infection.

The relative risk for a number of indicators of fetal/infant morbidity and mortality (Apgar less than 7 at five minutes; abnormal arterial blood cord pH (pH less than 7.10 or 7.20); sub-optimal or abnormal fetal heart tracing; fetal distress; admission to special care nursery; seizure/neurological abnormalities; or jaundice or hyperbilirubinaemia) showed no evidence of differences between early amniotomy and oxytocin groups and control groups.

Three studies assessed the effects of the policy of early amniotomy and oxytocin on subjective indicators. Three trials (Bréart 1992; Cluett 2004; Sadler 2000) asked women about their overall satisfaction with the care they received. In one study (Bréart 1992), a majority of mothers rated their experience of delivery as sat-

isfactory or unsatisfactory, with similar levels of satisfaction reported in both groups (RR 1.01; 95% CI 0.99 to 1.04). In another trial (Cluett 2004), the proportion of women that indicated that they were satisfied with their labour experience was similar in two groups (RR 1.02; 95% CI 0.75 to 1.39). In the third trial (Sadler 2000), the proportion of women reporting that they were very satisfied was also similar in the two groups (RR 1.04; 95% CI 0.94 to 1.15). However, there was a higher proportion of non-responders in the control group. When results were summarized across trials, there was no difference between groups in the proportion who indicated that they were satisfied with their labour experience (RR 1.02; 95% CI 0.99 to 1.04).

DISCUSSION

The main finding of this systematic review suggests that a policy of early intervention with amniotomy and oxytocin, when applied in the context of a prevention strategy for women in normal spontaneous labour with mild delays in progress, may result in a clinically modest reduction in the rate of caesarean section. A labour shortening effect was observed consistently across trials. In prevention trials, there was estimated 70 minute reduction in the duration of labour. While labour shortening could be viewed as a desirable effect, little information is available concerning women's views on this effect. More information is required about women's perceptions of early intervention, and the effects of early intervention on pain during labour.

A major shortcoming of several of these studies was their difficulty in obtaining a contrast between treatment groups in the interventions provided. Obstetricians who have strong beliefs about the efficacy of routine methods of care may have difficulty in attaining the equipoise that is required to achieve the desired degree of contrast in the interventions administered (Klein 1995). With respect to outcomes, when a policy designed to reduce caesarean rates is implemented for women in the experimental arm of a trial, it is likely to impact on care providers attitudes concerning the use of caesarean in the control arm. Cluster-randomized designs, where centres are allocated either to the implementation of a new policy or to usual care, could provide a partial solution to these problems. This design would permit researchers to undertake efforts to optimise compliance while minimising contamination.

Active management of labour protocol (O'Driscoll 1970) consists of an accurate diagnosis of labour, early amniotomy, frequent vaginal examinations, high dose oxytocin augmentation for slow labour progress (cervical dilatation less than 1 cm/hour), and continuous professional social support. Early amniotomy and oxytocin are two key components of active management. This meta-analysis included three trials where the experimental intervention consisted of the full package of active management of labour (Frigoletto 1995; Rogers 1997; Tabowei 2003).

Concerning other indicators of maternal and neonatal morbidity, we found no evidence of an effect.

We wanted to assess whether the observed effect on caesarean section would be altered when we excluded studies of the active management of labour that included the full package of components making up this intervention. To this end, we conducted a sensitivity analysis by excluding three such trials. The direction and the magnitude of the effect of the point estimates were similar, irrespective of whether these three trials were included or not.

Over the past several years, a number of randomized clinical trials have assessed the effectiveness of the components of active management, either alone or in combination. A Cochrane review assessing the effects of early amniotomy as an isolated intervention has been published (Smyth 2007). It found that 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. Few randomized studies have been designed to assess oxytocin as an isolated intervention (Bidgood 1987; Hinshaw 2008). We are unaware of any systematic review assessing this specific component of active management. Other aspects of active management have also been studied separately: continuous support in labour has been found to be associated with a small but statistically significant reduction in caesarean risk (Hodnett 2007). A recent Cochrane review examines the effect of active management (as a package of care) on the rate of caesarean (Brown 2008). It found that active management is associated with modest reductions in the caesarean section rate. Our review, which assessed early augmentation with amniotomy and oxytocin for women in spontaneous labour, showed that early amniotomy and oxytocin applied in the context of a prevention strategy for women in normal spontaneous labour or with mild delays in progress, may result in a clinically modest reduction in the rate of caesarean section. It is of interest that when early amniotomy is performed alone, it seems to increase the risk of caesarean. When combined with oxytocin, it appears to have a protective effect. There is a need for better information about the effect of oxytocin alone.

In 1998, we published a systematic review of the effects of early augmentation of labour in nulliparous women (Fraser 1998). The direction and magnitude of the observed effect was similar to that in the current review: a small reduction in the risk of caesarean section was observed, but the 95% confidence interval included the null effect. The current review adds several new studies which results in narrower confidence intervals and a change in the conclusion of the meta-analysis. In the stratified analysis, for prevention trials, early augmentation was associated with a modest reduction in the caesarean section rate with the 95% confidence interval excluding the null effect. We believe that the stratified results can be considered separately from the overall results, in that we planned *a priori* to test our hypothesis in both the prevention and treatment strata. Furthermore, the context of care is somewhat different between prevention and treatment trials.

A limitation of this review is the lack of documentation from most trials relating to other aspects of care during childbirth, such as continuous professional support, mobility and positions during labour. It was difficult to determine how these co-interventions interact with the medical components of active management (early amniotomy and oxytocin) and their impact on clinical outcomes. Also, the degree of delay, that justified the use of oxytocin, varied across trials. Additionally, the criteria of 'treatment failure' (duration of cervical arrest following oxytocin treatment which justifies a caesarean section) were not standardized. It is highly plausible that standard diagnostic for 'treatment failure' could contribute to reducing the caesarean section rate.

In summary, data from the meta-analysis indicate that a policy of early routine augmentation for mild delay in labour progress results in a modest reduction of caesarean section rate. The severity of delay which is sufficient to justify intervention remains to be defined.

AUTHORS' CONCLUSIONS

Implications for practice

These data suggest that early labour augmentation, when used in a context similar to that seen in prevention trials, results in a modest reduction in caesarean section rate in nulliparous women. These interventions are the main medical interventions included in the active management of labour: a complex protocol that traditionally included, in addition to amniotomy and oxytocin, the prospective diagnosis of labour, continuous professional social support, limited use of epidural anaesthesia, maternal ambulation in early labour, and the selective use of electronic fetal monitoring. The approach to these co-interventions are likely to impact on the overall effects of such a program. Centres that opt to implement a policy of early labour augmentation should carefully consider their policies concerning these other aspects of labour management. Given widespread concerns regarding increasing caesarean section rates, women should be informed of the possible benefits of early intervention by amniotomy and oxytocin to reduce caesarean section, and of the apparent relative safety of the procedure.

Implications for research

Further studies are required to assess the risks and benefits of active management. Standardization of diagnostic criteria regarding the degree of delay following treatment that is sufficient to justify a caesarean section needs further consideration. A period of two hours of observation after oxytocin, as reported in the Lopez-Zeno study (Lopez-Zeno 1992) may not be sufficient to judge treatment response, particularly in the low-dose oxytocin group. Limited information is available on the mothers' views of the two approaches to treatment.

Subsequent studies should focus on the effects of early labour augmentation versus expectant management among two specific contexts of increased caesarean rate: (1) where risk status is based on an established delay in labour progress, or on other characteristics which place the women at an increased risk (cervical status at admission) (Turcot 1997); (2) where risk status is based on the practice patterns of the care providers. We suggest that a cluster-randomization design may be the best methodology to assess the benefits of early augmentation in the latter context of increased risk.

In most adequately resourced centres, oxytocin augmentation is accompanied by continuous electronic fetal monitoring.This was the case in 8 of the 9 studies included in the review. One study (Tabowei 2003), conducted in Nigeria , did not report on the approach to fetal monitoring that was used. The results of this review cannot be generalized to settings where electronic fetal monitoring is not available.

It would be important to undertake an economic analysis in order to compare costs between active management of labour versus standard treatment. Early oxytocin use without rupture of membranes should be the subject of another Cochrane review. An additional key issue is the recommendation to avoid early artifical rupture of the membranes among patients who are HIV positive in order to prevent viral transmission. This is especially important in developing countries where a high proportion of women are HIV positive.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Blanch 1998

Methods	RCT.
Participants	40 women making slow progress in active phase of spontaneous labour with intact membranes (n = 21 in the amniotomy and oxytocin group, n = 19 in the control group). Inclusion criteria: cephalic presentation; gestation 37 or more weeks; full cervical effacement; cervical dilation 3 cm or more; regular uterine contractions at least every 5 minutes, lasting at least 20 seconds; no known contraindication to oxytocin; no evidence of fetal distress.
Interventions	Intervention group: amniotomy and oxytocin, oxytocin infusion was commenced immediately after amniotomy. The oxytocin infusion rate was doubled every 30 minutes, starting with 2 mU/minute; continuous electronic fetal monitoring was mandatory in this group. Control group: expectant management, intermittent auscultation was permitted.
Outcomes	Instrumental delivery; caesarean section; cord pH; Apgar score; satisfaction score.
Notes	Therapy trial. Mix of primiparous and multiparous women.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Random number table.
Allocation concealment?	Yes	Sealed opaque envelopes.
Blinding? All outcomes	No	Two different management groups.
Incomplete outcome data addressed? All outcomes	Yes	There were some missing data for the outcome of cord pH (10%).
Free of selective reporting?	Yes	
Free of other bias?	Unclear	The data on the number of women eligible for the trial were not available.The trial was stopped early with only half of the women recruited due to slow recruitment rate.

Bréart 1992

Methods	RCT.
Participants	1968 women (n = 989 in the early rupture group and n = 979 in the control group). Inclusion criteria: primiparous women, singleton birth, spontaneous labour,vertex presentation, full term, less than full dilatation, without conditions indicating a specific policy of management of labour, informed consent.
Interventions	Intervention group: early amniotomy and oxytocin; use oxytocin to induce a 1 cm/per hour dilatation; amniotomy had to take place as soon as possible and before 5 cm dilatation. Control group: conservative approach, amniotomy was to be done after 5 cm dilatation.
Outcomes	Mode of delivery; duration of labour; blood transfusion; Apgar scores; admission to special care unit; neurological anomalies; maternal perception; maternal characteristics; policies and type of rupture of membranes; economic consequences; jaundice; resuscitation.
Notes	Prevention trial. Nulliparous women. Only the data from France were included in the meta-analysis.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Computer-generated numbers.
Allocation concealment?	Yes	Sealed envelopes.
Blinding? All outcomes	No	
Incomplete outcome data addressed? All outcomes	Yes	No post-randomisation exclusions.
Free of selective reporting?	Yes	Main outcomes reported.
Free of other bias?	Unclear	No information on the number of eligible women.

Cammu 1996

Methods	RCT.
Participants	Study in a teaching hospital with mostly urban middle class women. 306 women in spontaneous labour (n = 152 in the active management group and n = 154 in the conservative management group).

Cammu 1996 (*Continued*)

	Inclusion criteria: nulliparous in spontaneous labour at or over 37 weeks of gestation, with a singleton fetus in cephalic presentation with a normal admission cardiotocogram and clear amniotic fluid on admission, being 150 cm or more in height and seen at least once antenatally in the outpatient clinic.
Interventions	Intervention group: early amniotomy and early oxytocin; amniotomy within 1 hour after admission; oxytocin augmentation when cervical dilation was less than 1 cm/hour; Initial oxytocin infusion at 2 mU/minute. Control group: selective management; no routine amniotomy, amniotomy only after arrest of dilatation; and use of oxytocin only if delay in progress > 2 hours.
Outcomes	Maternal characteristics; gestational age; cervical dilatation; intrapartum meconium; birthweight; breastfeeding; fetal scalp blood sampling; use of oxytocin and amniotomy; labour duration; instrumental and spontaneous vaginal deliveries; epidural; caesarean section; Apgar < 7 at 5 minutes; umbilical arterial pH = < 7.1; admission to neonatal intensive care.
Notes	Prevention trial. Nulliparous women.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	No information provided.
Allocation concealment?	Yes	Sealed opaque envelopes.
Blinding? All outcomes	No	Different treatment regimens compared.
Incomplete outcome data addressed? All outcomes	Yes	2% post-randomisation exclusions.
Free of selective reporting?	Yes	Main outcomes reported.
Free of other bias?	Unclear	No information on the number of eligible women.

Cluett 2004

Methods	RCT.
Participants	99 nulliparous women with dystocia (cervical dilation rate < 1 cm/hour in active labour) at low risk of complications; amniotomy and oxytocin group: n = 50; birth pool group: n = 49.

Cluett 2004 (*Continued*)

Interventions	Immersion in water in birth pool or standard augmentation for dystocia (amniotomy and intravenous oxytocin).
Outcomes	Epidural analgesia and operative delivery rates; augmentation rates with amniotomy and oxytocin; length of labour; maternal and neonatal morbidity including infections, maternal pain score, and maternal satisfaction with care.
Notes	Therapy trial. Nulliparous women.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Computer-generated randomisation schedule in balanced block of 20.
Allocation concealment?	Yes	Sequentially numbered, opaque, sealed envelopes.
Blinding? All outcomes	No	Different interventions.
Incomplete outcome data addressed? All outcomes	Yes	Post-randomisation exclusions in postpartum interview (4%).
Free of selective reporting?	Yes	Main outcomes reported.
Free of other bias?	Yes	

Cohen 1987

Methods	Randomization was accomplished by alternating women to aggressive management or control groups.
Participants	150 women (n = 75 in each group). Inclusion criteria: 37-42 weeks' gestation; uterine contractions accompanied by cervical dilatation of 3 cm or ruptured membranes; less than 3 contractions lasting 40 seconds each in a 10 minute time period.
Interventions	Early aggressive management: amniotomy if required, and oxytocin infusion. This was accomplished within 30 minutes of the admission. Initial oxytocin infusion rate:1 mU/minute and increased by 1 mU/minute every 30 minutes until adequate contraction pattern was achieved. Control group: usual care.

Cohen 1987 (*Continued*)

Outcomes	Maternal characteristics; cervical dilatation; effacement %; caesarean delivery; instrumental and spontaneous vaginal deliveries; duration of labour; Apgar score at 1 and 5 minutes; cord pH; birth weight.
Notes	Prevention trial. Nulliparous women.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	No	Quasi-randomisation by alternating women.
Allocation concealment?	No	inadequate allocation, alternation.
Blinding? All outcomes	No	Different treatment groups.
Incomplete outcome data addressed? All outcomes	Unclear	No information on numbers of postpartum women followed up.
Free of selective reporting?	Yes	Main outcomes reported.
Free of other bias?	Unclear	No information on eligible women.

Frigoletto 1995

Methods	RCT (group assignments, stratified according to site).
Participants	1915 women (n = 1009 in the active management group, n = 906 in the usual care group) from 17 prenatal care sites. Inclusion criteria: nulliparous; at least 18 years old; English-speaking. Exclusion criteria: women with conditions associated with an increased risk of preterm or caesarean delivery.
Interventions	Active management group: standardized criteria for the diagnosis of labour; amniotomy as soon as possible and oxytocin if cervical dilatation < 1 cm/hour. Initial oxytocin infusion rate at 4 mU/minute and increased by 4 mU/minute every 15 minutes to a maximum rate of 40 mU/minute unless uterine hyperstimulation or non reassuring fetal heart pattern; one-to-one nursing care. Control group: usual care. No standardized protocol.
Outcomes	Instrumental and spontaneous vaginal deliveries; caesarean section; epidural administration; duration of labour; cervical dilatation; complications and neonatal adverse events.

Frigoletto 1995 (*Continued*)

Notes	Prevention trial. Nulliparous women. One third of women were post-randomisation exclusions, outcome data for exclusions were only given for caesarean section but not for the other outcomes. (Attrition rates: less than 1% for the CS outcome, 35% attrition between randomisation and labour); this study has been included only for caesarean section outcome.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Random numbers in permuted blocks.
Allocation concealment?	Yes	Randomization was through telephone calls by recruiters to the co-ordinating centre; sealed opaque, sequentially numbered envelopes
Blinding? All outcomes	No	Active management and routine care.
Incomplete outcome data addressed? All outcomes	No	Large number of post-randomisation exclusions. Outcome data for exclusions were only given for CS in intention-to-treat analysis. (Attrition rates: CS: less than 1%; the other outcomes: 35%).
Free of selective reporting?	Unclear	Only CS reported for whole randomised sample.
Free of other bias?	Unclear	Changed protocol during study.

Lopez-Zeno 1992

Methods	RCT was based on a permuted-blocks design.
Participants	705 women (n = 351 in the active management group, n = 354 in the traditional management group). Inclusion criteria: nulliparous women in spontaneous labour after 37 weeks of gestation. Exclusion criteria: multiple gestation; non-cephalic presentation; previous uterine surgery; if amniotomy was performed or augmentation of labour with oxytocin was begun before labour diagnosis.
Interventions	Active management group: amniotomy within 1 hour of the diagnosis of labour; oxytocin if rate of cervical dilatation < 1 cm/hour. Initial oxytocin infusion rate was 6 mU/minute and increased by 6 mU/minute every 15 minutes until reaching 7 contractions per 15 minute or until maximum rate of 36 mU/minute. Traditional management group: care was left up to attending obstetrician, if cervical dilation was less than 1 cm per hour, oxytocin use at a lower dose.

Lopez-Zeno 1992 (*Continued*)

Outcomes	Caesarean section; instrumental and spontaneous vaginal deliveries; length of first and second stage of labour; epidural; maternal and neonatal morbidities.
Notes	Prevention trial. Nulliparous women.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Randomized assignment based on a permuted-block design.
Allocation concealment?	Yes	Sequentially numbered, opaque, sealed envelopes.
Blinding? All outcomes	No	Different intervention packages.
Incomplete outcome data addressed? All outcomes	Yes	Post-randomisation exclusion was 2%.
Free of selective reporting?	Yes	Main outcomes reported.
Free of other bias?	Yes	

Rogers 1997

Methods	RCT.
Participants	405 women (n = 200 for active management, n = 205 for usual care control protocol). Inclusion criteria: gestational age at or more than 37 weeks; low risk; term; nulliparous; cephalic presentation; no known maternal medical complications or fetal anomalies. Exclusion criteria: placenta praevia; abruptio placenta; twin gestation; prior uterine surgery; or any other obstetric or any medical complication of pregnancy.
Interventions	Active management group: strict diagnosis of labour, amniotomy was performed within 2 hours of admission, and augmentation of labour with oxytocin was initiated if cervical dilatation of 1 cm/hour in the first stage of labour or descent of 1 cm/hour in the second stage failed to occur. Initial oxytocin infusion rate at 6 mU/minute and increased every 15 minutes. Control group: usual care; oxytocin if progression in labour was not made, defined as cervical change of 1.25 cm/hour once the women was in the active phase of labour. Initial oxytocin infusion rate at 1 mU/minute and increased by 1 mU/minute every 30 to 40 minutes.

Rogers 1997 (*Continued*)

Outcomes	Maternal characteristics; cervical dilatation; thick meconium; internal fetal monitors; epidural; length of labour; instrumental and spontaneous vaginal deliveries; caesarean section; Apgar score < 7 at 5 minutes; cord pH < 7.1; admission to neonatal intensive care unit.
Notes	Prevention trial. Nulliparous women.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Computer-generated random numbers.
Allocation concealment?	Yes	Sealed, opaque envelopes.
Blinding? All outcomes	No	Different management.
Incomplete outcome data addressed? All outcomes	Yes	Low numbers of post-randomisation exclusions (0.5% attrition).
Free of selective reporting?	Yes	
Free of other bias?	Unclear	No information on the number of the eligible women.

Sadler 2000

Methods	RCT.
Participants	651 women (n = 320 in the active management group, n = 331 in the routine care group). Inclusion criteria: nulliparity; singleton pregnancy; cephalic presentation; spontaneous labour. Exclusion criteria: non-cephalic presentation; uterine scar; severe cardiac disease; contracted pelvis; gestation < 37 completed weeks; fetal distress on admission to the labour ward; elective caesarean section; intrauterine death; multiparity.
Interventions	Active management group: early amniotomy at diagnosis of labour,and early use of high-dose oxytocin for slow progress (less than 1 cm/hour cervical dilatation) in labour. Initial oxytocin infusion rate was 6 mU/minute and increased by 6 mU/minute every 15 minutes to a maximum rate of 36 mU/minute. Routine care: usual care. Initial oxytocin infusion rate was1 mU/minute and doubled the rate every 10 minutes to 8 mU/minutes, then increased by 2 mU/minutes to a maximum rate of 40 mU/minutes.

Sadler 2000 (*Continued*)

Outcomes	Caesarean section; operative vaginal delivery; fetal distress; maternal and neonatal complications; duration of labour; maternal satisfaction with care.
Notes	Prevention trial. Nulliparity. Some aspects of the active management protocol were not respected in 127 (40%) women. The majority of these related to failure to initiate or follow the high-dose oxytocin augmentation protocol. A meta-analysis is included in the article.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Computer-generated random numbers.
Allocation concealment?	Yes	Sealed envelopes.
Blinding? All outcomes	No	Active Management and routine care.
Incomplete outcome data addressed? All outcomes	No	Postpartum (breastfeeding and maternal satisfaction) attrition rates were 24% in the intervention group, and control group attrition rates were 32% (overall attrition rates were 28%).
Free of selective reporting?	Yes	
Free of other bias?	Unclear	No information for the eligible women. Postpartum data were missing.

Serman 1995

Methods	Randomization was based on the woman's medical file number (odd or even numbers).
Participants	145 women (n = 75 in the active labour management group, n = 70 in the traditional labour management (controls) group).
Interventions	Active management group: amniotomy was performed and oxytocin given as soon as cervical dilatation was less than 1 cm/hour for the first 3 hours of labour. Traditional management group: routine care. Initial oxytocin infusion rate in both groups: 5 mU/minute and increased every 15 minutes up to a maximum rate of 40 mU/minute. It was decreased if signs of fetal distress or uterine contractions < 2 minutes apart were present.

Serman 1995 (*Continued*)

Outcomes	Mode of delivery; epidural; Apgar < = 6 at 1 minute and 5 minutes; length of labour; meconium; neonatal and maternal morbidity.
Notes	Prevention trial. Nulliparous women. Article written in Spanish.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	No	Last digit hospital record number.
Allocation concealment?	No	
Blinding? All outcomes	No	Different management groups.
Incomplete outcome data addressed? All outcomes	Yes	No post-randomization exclusions.
Free of selective reporting?	Yes	
Free of other bias?	Unclear	No information on the number of eligible women.

Somprasit 2005

Methods	RCT.
Participants	960 women in Thailand. Inclusion criteria: nulliparous women at or more than 37 weeks' gestation; spontaneous labour; cephalic presentation; single fetus without fetal distress. Exclusion criteria: thick meconium-stained amniotic fluid at admission; contraindications to vaginal delivery or oxytocin augmentation; medical or surgical complications.
Interventions	Active management group: early amniotomy within one hour of admission, and high doses of oxytocin if cervical dilatation was less than 1 cm/hour in the first stage of labour. Initial oxytocin infusion rate was 6 mU/minute and increased by 2 mU/minute every 30 minutes to a maximum rate of 40 mU/minute. Routine care: usual care, no standard protocol, there was variation among obstetricians.
Outcomes	Caesarean section; duration of labour; maternal complications and neonatal outcomes.
Notes	Prevention trial. Nulliparous women.

Somprasit 2005 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Random number tables.
Allocation concealment?	Yes	Numbered, opaque, sealed envelopes.
Blinding? All outcomes	No	
Incomplete outcome data addressed? All outcomes	Yes	Some post-randomsation exclusions (1.5%), but analysis by intention to treat.
Free of selective reporting?	Yes	Reported on main outcomes.
Free of other bias?	Unclear	The management of the comparison group was not clearly described.

Tabowei 2003

Methods	RCT.
Participants	448 women in Nigeria. Inclusion criteria: nulliparous women in spontaneous labour, single fetus with cephalic presentation at term. Exclusion criteria: contraindications to vaginal delivery or oxytocin augmentation, pregnancy or medical complications.
Interventions	Active management group: early amniotomy was performed when labour was diagnosed, high doses of oxytocin if cervical dilatation was less than 1 cm/hour in the first stage of labour or descent was not demonstrated for 1 hour or more in second stage. Initial oxytocin infusion rate was 6 mU/minute and increased by 6 mU/minute every 15 minutes to a maximum rate of 36 mU/minutes, separate labour room cared for by a nurse-midwife. Routine care: Usual care, no standard protocol, there was variation among obstetricians.
Outcomes	Mode of delivery; duration of labour; maternal complications and neonatal outcomes.
Notes	Prevention trial. Nulliparous women.

Risk of bias		
Item	**Authors' judgement**	**Description**

Tabowei 2003 (*Continued*)

Adequate sequence generation?	Yes	Computer-generated random schedule.
Allocation concealment?	Yes	Opaque, sealed envelopes.
Blinding? All outcomes	No	Active management and routine labour management.
Incomplete outcome data addressed? All outcomes	Unclear	Some post-randomisation exclusions (11.7%).
Free of selective reporting?	Yes	
Free of other bias?	Unclear	Number of women eligible for recruitment were not shown.

CS - caesarean section.

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

Cardozo 1990	The trial was oxytocin only.
Cummiskey 1989	Data compare two methods of administration of the same medication. Women were randomized to the pulsatile-infusion group and the continuous-infusion group. No control group.
Hogston 1993	No randomisation. Treatment depending on labour ward of the treating consultant.
Rouse 1994	Two groups; one group was oxytocin and amniotomy, the other was oxytocin. There was no control group.
Ruiz Ortiz 1991	Method of distribution between experimental group and control group are not mentioned. No randomisation.
Verkuyl 1986	No information on inclusion or exclusion criteria.
Xenakis 1995	Low-dose versus high-dose oxytocin augmentation of labour. No control group.

DATA AND ANALYSES

Comparison 1. Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section rate	12	7792	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.79, 1.01]
1.1 Prevention	10	7653	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.77, 0.99]
1.2 Therapy	2	139	Risk Ratio (M-H, Fixed, 95% CI)	1.54 [0.75, 3.15]
2 Spontaneous vaginal delivery	11	5879	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.97, 1.05]
2.1 Prevention	9	5738	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.97, 1.05]
2.2 Therapy	2	141	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.71, 1.28]
3 Instrumental vaginal delivery (forceps or vacuum, or both)	11	5877	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.92, 1.11]
3.1 Prevention	9	5738	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.92, 1.11]
3.2 Therapy	2	139	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.35, 2.54]
4 Length of first stage of labour	5	2530	Mean Difference (IV, Random, 95% CI)	-1.43 [-2.01, -0.84]
4.1 Prevention	4	2431	Mean Difference (IV, Random, 95% CI)	-1.57 [-2.15, 1.00]
4.2 Therapy	1	99	Mean Difference (IV, Random, 95% CI)	-0.21 [-1.68, 1.26]
5 Duration of labour (duration in hours from admission in labour)	7	4675	Mean Difference (IV, Random, 95% CI)	-1.11 [-1.82, -0.41]
5.1 Prevention	7	4675	Mean Difference (IV, Random, 95% CI)	-1.11 [-1.82, -0.41]
5.2 Therapy	0	0	Mean Difference (IV, Random, 95% CI)	Not estimable
6 Use of epidural analgesia	8	4319	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.99, 1.12]
6.1 Prevention	6	4180	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.99, 1.10]
6.2 Therapy	2	139	Risk Ratio (M-H, Random, 95% CI)	1.08 [0.56, 2.10]
7 Hyperstimulation of labour	2	853	Risk Ratio (M-H, Random, 95% CI)	1.37 [0.76, 2.46]
7.1 Prevention	2	853	Risk Ratio (M-H, Random, 95% CI)	1.37 [0.76, 2.46]
7.2 Therapy	0	0	Risk Ratio (M-H, Random, 95% CI)	Not estimable
8 Postpartum hemorrhage (greater than 500 ml)	4	2674	Risk Ratio (M-H, Fixed, 95% CI)	0.83 [0.65, 1.08]
8.1 Prevention	4	2674	Risk Ratio (M-H, Fixed, 95% CI)	0.83 [0.65, 1.08]
8.2 Therapy	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
9 Maternal blood transfusion	3	2977	Risk Ratio (M-H, Fixed, 95% CI)	2.41 [0.85, 6.83]
9.1 Prevention	3	2977	Risk Ratio (M-H, Fixed, 95% CI)	2.41 [0.85, 6.83]
9.2 Therapy	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
10 Postpartum fever or infection	6	2923	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.69, 1.17]
10.1 Prevention	5	2824	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.66, 1.16]
10.2 Therapy	1	99	Risk Ratio (M-H, Random, 95% CI)	1.63 [0.41, 6.47]
11 Apgar score less than seven at five minutes	7	4519	Risk Ratio (M-H, Fixed, 95% CI)	1.11 [0.78, 1.57]
11.1 Prevention	6	4479	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [0.77, 1.55]
11.2 Therapy	1	40	Risk Ratio (M-H, Fixed, 95% CI)	2.73 [0.12, 63.19]
12 Acidosis as defined abnormal arterial cord pH (pH less than 7.10 or 7.20)	3	1416	Risk Ratio (M-H, Fixed, 95% CI)	1.11 [0.61, 2.02]
12.1 Prevention	3	1416	Risk Ratio (M-H, Fixed, 95% CI)	1.11 [0.61, 2.02]
12.2 Therapy	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

13 Suboptimal or abnormal fetal heart tracing	1	705	Risk Ratio (M-H, Random, 95% CI)	0.50 [0.13, 2.00]
13.1 Prevention	1	705	Risk Ratio (M-H, Random, 95% CI)	0.50 [0.13, 2.00]
13.2 Therapy	0	0	Risk Ratio (M-H, Random, 95% CI)	Not estimable
14 Fetal distress	2	1099	Risk Ratio (M-H, Fixed, 95% CI)	1.22 [0.55, 2.69]
14.1 Prevention	2	1099	Risk Ratio (M-H, Fixed, 95% CI)	1.22 [0.55, 2.69]
14.2 Therapy	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
15 Admission to special care nursery	7	4578	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [0.86, 1.33]
15.1 Prevention	6	4479	Risk Ratio (M-H, Fixed, 95% CI)	1.12 [0.90, 1.39]
15.2 Therapy	1	99	Risk Ratio (M-H, Fixed, 95% CI)	0.08 [0.00, 1.30]
16 Seizure/neurological abnormalities	2	2666	Risk Ratio (M-H, Fixed, 95% CI)	0.83 [0.25, 2.71]
16.1 Prevention	2	2666	Risk Ratio (M-H, Fixed, 95% CI)	0.83 [0.25, 2.71]
16.2 Therapy	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
17 Jaundice or hyperbilirubinemia	2	2219	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [0.68, 1.77]
17.1 Prevention	2	2219	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [0.68, 1.77]
17.2 Therapy	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
18 Satisfied with labour experience	3	2618	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.99, 1.04]
18.1 Prevention	3	2618	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.99, 1.04]
18.2 Therapy	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 2. Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Casarean section rate	9	5024	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.73, 1.04]
1.1 Prevention	7	4885	Risk Ratio (M-H, Fixed, 95% CI)	0.84 [0.70, 1.01]
1.2 Therapy	2	139	Risk Ratio (M-H, Fixed, 95% CI)	1.54 [0.75, 3.15]
2 Spontaneous vaginal delivery	9	5026	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.98, 1.06]
2.1 Prevention	7	4885	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.98, 1.06]
2.2 Therapy	2	141	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.71, 1.28]
3 Instrumental vaginal delivery (forceps or vacuum, or both)	9	5024	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.90, 1.11]
3.1 Prevention	7	4885	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.90, 1.11]
3.2 Therapy	2	139	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.35, 2.54]
4 Length of first stage of labour	3	1677	Mean Difference (IV, Fixed, 95% CI)	-1.25 [-1.61, -0.90]
4.1 Prevention	2	1578	Mean Difference (IV, Fixed, 95% CI)	-1.32 [-1.69, -0.95]
4.2 Therapy	1	99	Mean Difference (IV, Fixed, 95% CI)	-0.21 [-1.68, 1.26]
5 Duration of labour (duration in hours from admission in labor)	5	3822	Mean Difference (IV, Fixed, 95% CI)	-0.58 [-0.76, -0.40]
5.1 Prevention	5	3822	Mean Difference (IV, Fixed, 95% CI)	-0.58 [-0.76, -0.40]
5.2 Therapy	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
6 Use of epidural analgesia	7	3914	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [1.01, 1.11]
6.1 Prevention	5	3775	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [1.00, 1.11]
6.2 Therapy	2	139	Risk Ratio (M-H, Fixed, 95% CI)	1.20 [0.87, 1.66]

7 Postpartum hemorrhage (greater than 500ml)	2	1821	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.67, 1.15]
7.1 Prevention	2	1821	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.67, 1.15]
7.2 Therapy	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
8 Maternal blood transfusion	3	2977	Risk Ratio (M-H, Fixed, 95% CI)	2.41 [0.85, 6.83]
8.1 Prevention	3	2977	Risk Ratio (M-H, Fixed, 95% CI)	2.41 [0.85, 6.83]
8.2 Therapy	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
9 Postpartum fever or infection	4	2070	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.63, 1.27]
9.1 Prevention	3	1971	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.60, 1.23]
9.2 Therapy	1	99	Risk Ratio (M-H, Fixed, 95% CI)	1.63 [0.41, 6.47]
10 Apgar score less than seven after five minutes	5	3666	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.61, 2.29]
10.1 Prevention	4	3626	Risk Ratio (M-H, Fixed, 95% CI)	1.13 [0.57, 2.22]
10.2 Blanch	1	40	Risk Ratio (M-H, Fixed, 95% CI)	2.73 [0.12, 63.19]
11 Acidosis as defined abnormal arterial cord pH (pH less than 7.10 or 7.20)	2	1011	Risk Ratio (M-H, Fixed, 95% CI)	1.12 [0.60, 2.10]
11.1 Prevention	2	1011	Risk Ratio (M-H, Fixed, 95% CI)	1.12 [0.60, 2.10]
11.2 Therapy	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
12 Suboptimal or abdormal fetal heart	1	705	Risk Ratio (M-H, Fixed, 95% CI)	0.50 [0.13, 2.00]
13 Fetal distress	1	651	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.26, 4.10]
14 Admission to special care nursery	5	3725	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.83, 1.39]
14.1 Prevention	4	3626	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [0.88, 1.48]
14.2 Therapy	1	99	Risk Ratio (M-H, Fixed, 95% CI)	0.08 [0.00, 1.30]
15 Seizure/neurological abnormalities	2	2666	Risk Ratio (M-H, Fixed, 95% CI)	0.83 [0.25, 2.71]
16 Jaundice or hyperbilirubinemia	2	2219	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [0.68, 1.77]
17 Satisfied with labour experience	3	2618	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.99, 1.04]

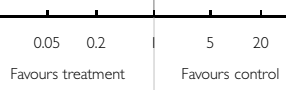
Analysis 1.1. Comparison 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour, Outcome 1 Caesarean section rate.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome: 1 Caesarean section rate

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Brart 1992	45/989	47/979		9.9 %	0.95 [0.64, 1.41]
Cammu 1996	6/152	4/154		0.8 %	1.52 [0.44, 5.28]
Cohen 1987	10/75	11/75		2.3 %	0.91 [0.41, 2.01]
Frigoletto 1995	197/1009	176/906		39.0 %	1.01 [0.84, 1.21]
Lopez-Zeno 1992	37/351	50/354		10.5 %	0.75 [0.50, 1.11]
Rogers 1997	15/200	24/205		5.0 %	0.64 [0.35, 1.18]
Sadler 2000	30/320	32/331		6.6 %	0.97 [0.60, 1.56]
Serman 1995	7/75	14/70		3.0 %	0.47 [0.20, 1.09]
Somprasit 2005	38/320	94/640		13.2 %	0.81 [0.57, 1.15]
Tabowei 2003	20/221	36/227		7.5 %	0.57 [0.34, 0.95]
Subtotal (95% CI)	**3712**	**3941**		**97.9 %**	**0.88 [0.77, 0.99]**
Total events: 405 (Treatment), 488 (Control)					
Heterogeneity: Chi^2 = 9.87, df = 9 (P = 0.36); I^2 =9%					
Test for overall effect: Z = 2.09 (P = 0.036)					
2 Therapy					
Blanch 1998	5/21	2/19		0.4 %	2.26 [0.50, 10.32]
Cluett 2004	11/50	8/49		1.7 %	1.35 [0.59, 3.06]
Subtotal (95% CI)	**71**	**68**		**2.1 %**	**1.54 [0.75, 3.15]**
Total events: 16 (Treatment), 10 (Control)					
Heterogeneity: Chi^2 = 0.35, df = 1 (P = 0.56); I^2 =0.0%					
Test for overall effect: Z = 1.17 (P = 0.24)					
Total (95% CI)	**3783**	**4009**		**100.0 %**	**0.89 [0.79, 1.01]**
Total events: 421 (Treatment), 498 (Control)					
Heterogeneity: Chi^2 = 12.30, df = 11 (P = 0.34); I^2 =11%					
Test for overall effect: Z = 1.87 (P = 0.061)					



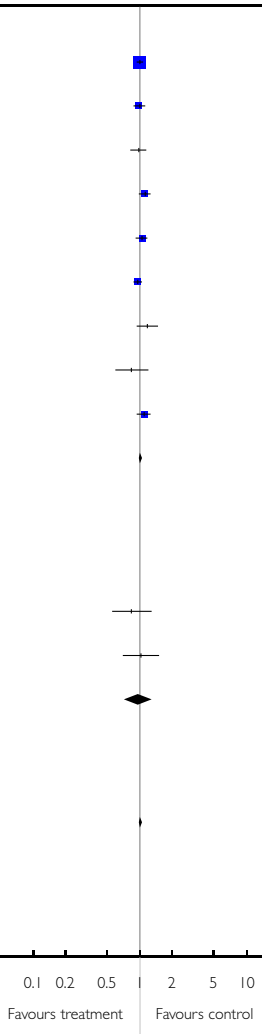
Analysis 1.2. Comparison 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour, Outcome 2 Spontaneous vaginal delivery.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome: 2 Spontaneous vaginal delivery

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Brart 1992	661/989	657/979		38.6 %	1.00 [0.94, 1.06]
Cammu 1996	119/152	122/154		7.1 %	0.99 [0.88, 1.11]
Cohen 1987	59/75	61/75		3.6 %	0.97 [0.82, 1.14]
Lopez-Zeno 1992	225/351	205/354		11.9 %	1.11 [0.98, 1.25]
Rogers 1997	150/200	148/205		8.5 %	1.04 [0.92, 1.17]
Sadler 2000	227/320	245/331		14.1 %	0.96 [0.87, 1.05]
Serman 1995	54/75	43/70		2.6 %	1.17 [0.93, 1.48]
Somprasit 2005	38/320	91/640		3.5 %	0.84 [0.59, 1.19]
Tabowei 2003	144/221	136/227		7.8 %	1.09 [0.94, 1.26]
Subtotal (95% CI)	**2703**	**3035**		**97.7 %**	**1.01 [0.97, 1.05]**
Total events: 1677 (Treatment), 1708 (Control)					
Heterogeneity: Chi^2 = 8.01, df = 8 (P = 0.43); I^2 =0%					
Test for overall effect: Z = 0.62 (P = 0.54)					
2 Therapy					
Blanch 1998	13/21	14/19		0.9 %	0.84 [0.55, 1.29]
Cluett 2004	25/50	25/51		1.4 %	1.02 [0.69, 1.51]
Subtotal (95% CI)	**71**	**70**		**2.3 %**	**0.95 [0.71, 1.28]**
Total events: 38 (Treatment), 39 (Control)					
Heterogeneity: Chi^2 = 0.44, df = 1 (P = 0.50); I^2 =0.0%					
Test for overall effect: Z = 0.32 (P = 0.75)					
Total (95% CI)	**2774**	**3105**		**100.0 %**	**1.01 [0.97, 1.05]**
Total events: 1715 (Treatment), 1747 (Control)					
Heterogeneity: Chi^2 = 8.72, df = 10 (P = 0.56); I^2 =0.0%					
Test for overall effect: Z = 0.56 (P = 0.58)					

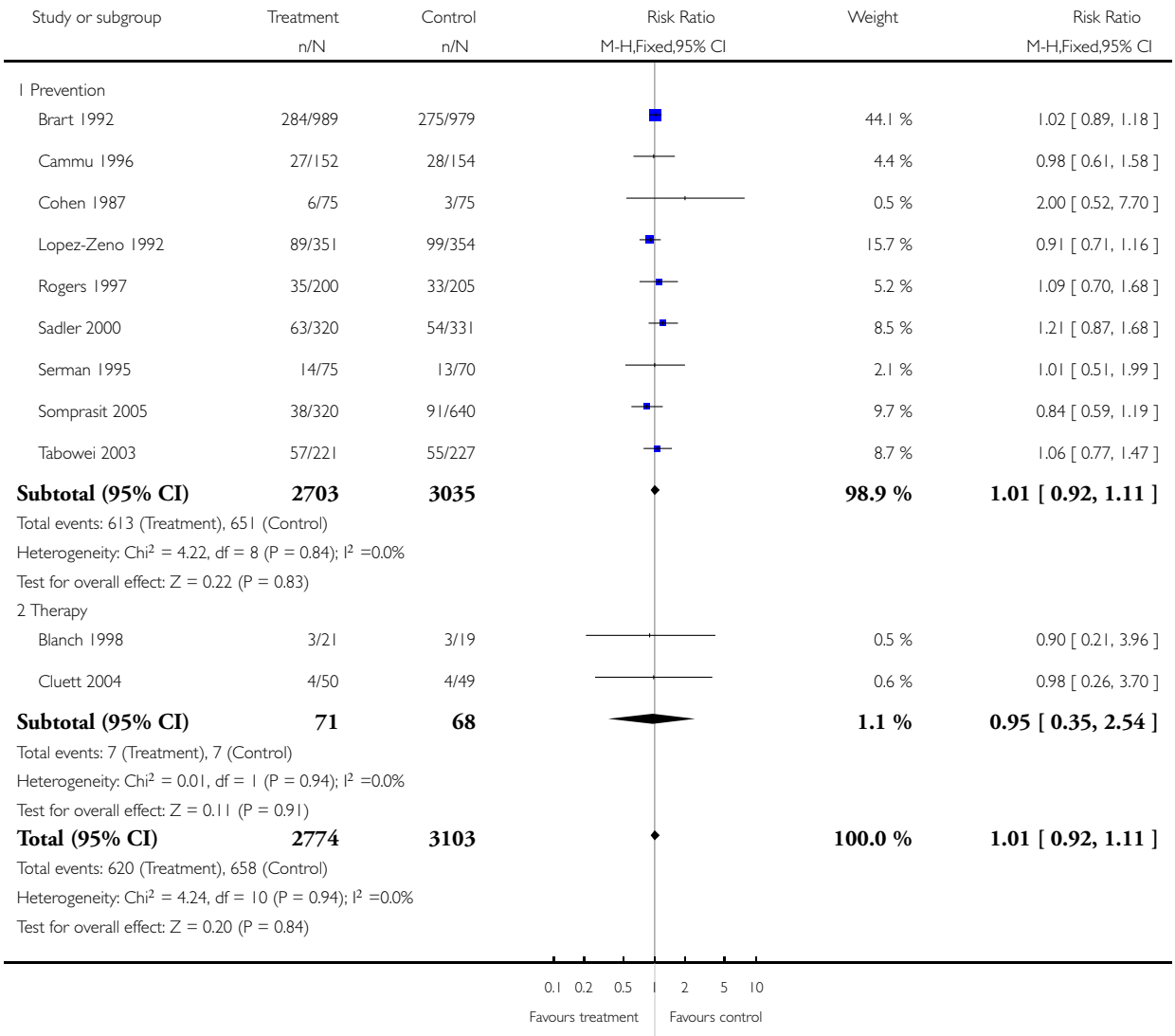


Analysis 1.3. Comparison 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour, Outcome 3 Instrumental vaginal delivery (forceps or vacuum, or both).

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome: 3 Instrumental vaginal delivery (forceps or vacuum, or both)



Analysis 1.4. Comparison 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour, Outcome 4 Length of first stage of labour.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome: 4 Length of first stage of labour

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Prevention							
Lopez-Zeno 1992	314	5.05 (2.33)	304	6.72 (3.64)		24.0 %	-1.67 [-2.15, -1.19]
Rogers 1997	200	8.5 (4.5)	205	10.1 (5.9)		15.4 %	-1.60 [-2.62, -0.58]
Somprasit 2005	320	8.97 (4.05)	640	9.82 (4.4)		22.7 %	-0.85 [-1.41, -0.29]
Tabowei 2003	221	4.52 (1.15)	227	6.57 (1.17)		27.6 %	-2.05 [-2.26, -1.84]
Subtotal (95% CI)	**1055**		**1376**			**89.7 %**	**-1.57 [-2.15, -1.00]**
Heterogeneity: $Tau^2 = 0.26$; $Chi^2 = 16.36$, df = 3 (P = 0.00096); $I^2 = 82\%$							
Test for overall effect: Z = 5.38 (P < 0.00001)							
2 Therapy							
Cluett 2004	50	10.26 (3.75)	49	10.47 (3.69)		10.3 %	-0.21 [-1.68, 1.26]
Subtotal (95% CI)	**50**		**49**			**10.3 %**	**-0.21 [-1.68, 1.26]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.28 (P = 0.78)							
Total (95% CI)	**1105**		**1425**			**100.0 %**	**-1.43 [-2.01, -0.84]**
Heterogeneity: $Tau^2 = 0.31$; $Chi^2 = 21.12$, df = 4 (P = 0.00030); $I^2 = 81\%$							
Test for overall effect: Z = 4.76 (P < 0.00001)							

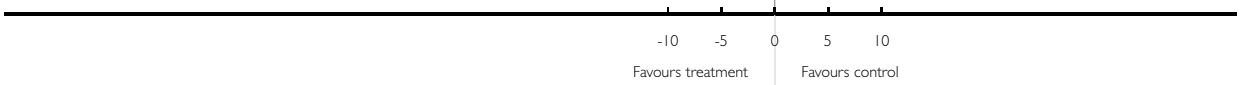
Analysis 1.5. Comparison 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour, Outcome 5 Duration of labour (duration in hours from admission in labour).

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome: 5 Duration of labour (duration in hours from admission in labour)

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Prevention							
Brart 1992	989	6.33 (2.7)	979	6.6 (2.8)		16.0 %	-0.27 [-0.51, -0.03]
Cohen 1987	66	7.8 (3.7)	65	8 (3.3)		11.1 %	-0.20 [-1.40, 1.00]
Lopez-Zeno 1992	314	6.49 (2.75)	304	8.15 (3.89)		14.9 %	-1.66 [-2.19, -1.13]
Rogers 1997	200	9.7 (4.9)	205	11.4 (5.4)		12.2 %	-1.70 [-2.70, -0.70]
Serman 1995	75	4.92 (1.17)	70	5.5 (1.35)		15.4 %	-0.58 [-0.99, -0.17]
Somprasit 2005	320	8.99 (4.36)	640	10.17 (4.41)		14.6 %	-1.18 [-1.77, -0.59]
Tabowei 2003	221	5.68 (1.48)	227	7.77 (1.65)		15.8 %	-2.09 [-2.38, -1.80]
Subtotal (95% CI)	**2185**		**2490**			**100.0 %**	**-1.11 [-1.82, -0.41]**
Heterogeneity: Tau^2 = 0.80; Chi^2 = 102.59, df = 6 (P<0.00001); I^2 =94%							
Test for overall effect: Z = 3.09 (P = 0.0020)							
2 Therapy							
Subtotal (95% CI)	**0**		**0**			**0.0 %**	**0.0 [0.0, 0.0]**
Heterogeneity: not applicable							
Test for overall effect: not applicable							
Total (95% CI)	**2185**		**2490**			**100.0 %**	**-1.11 [-1.82, -0.41]**
Heterogeneity: Tau^2 = 0.80; Chi^2 = 102.59, df = 6 (P<0.00001); I^2 =94%							
Test for overall effect: Z = 3.09 (P = 0.0020)							



Analysis 1.6. Comparison 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour, Outcome 6 Use of epidural analgesia.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome: 6 Use of epidural analgesia

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Prevention					
Brart 1992	665/989	611/979		34.7 %	1.08 [1.01, 1.15]
Cammu 1996	48/152	44/154		3.2 %	1.11 [0.78, 1.56]
Lopez-Zeno 1992	253/351	255/354		25.3 %	1.00 [0.91, 1.10]
Rogers 1997	118/200	105/205		10.3 %	1.15 [0.97, 1.37]
Sadler 2000	156/320	149/331		11.6 %	1.08 [0.92, 1.28]
Serman 1995	57/75	58/70		11.4 %	0.92 [0.78, 1.08]
Subtotal (95% CI)	**2087**	**2093**		**96.4 %**	**1.05 [0.99, 1.10]**
Total events: 1297 (Treatment), 1222 (Control)					
Heterogeneity: Tau^2 = 0.00; Chi^2 = 5.70, df = 5 (P = 0.34); I^2 =12%					
Test for overall effect: Z = 1.71 (P = 0.087)					
2 Therapy					
Blanch 1998	7/21	9/19		0.7 %	0.70 [0.33, 1.52]
Cluett 2004	33/50	23/49		2.9 %	1.41 [0.98, 2.01]
Subtotal (95% CI)	**71**	**68**		**3.6 %**	**1.08 [0.56, 2.10]**
Total events: 40 (Treatment), 32 (Control)					
Heterogeneity: Tau^2 = 0.15; Chi^2 = 2.60, df = 1 (P = 0.11); I^2 =62%					
Test for overall effect: Z = 0.24 (P = 0.81)					
Total (95% CI)	**2158**	**2161**		**100.0 %**	**1.05 [0.99, 1.12]**
Total events: 1337 (Treatment), 1254 (Control)					
Heterogeneity: Tau^2 = 0.00; Chi^2 = 9.28, df = 7 (P = 0.23); I^2 =25%					
Test for overall effect: Z = 1.59 (P = 0.11)					

Analysis 1.7. Comparison 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour, Outcome 7 Hyperstimulation of labour.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome: 7 Hyperstimulation of labour

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Prevention					
Rogers 1997	22/200	16/205		91.0 %	1.41 [0.76, 2.60]
Tabowei 2003	2/221	2/227		9.0 %	1.03 [0.15, 7.23]
Subtotal (95% CI)	**421**	**432**		**100.0 %**	**1.37 [0.76, 2.46]**
Total events: 24 (Treatment), 18 (Control)					
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.09$, df = 1 (P = 0.76); $I^2 = 0.0\%$					
Test for overall effect: Z = 1.05 (P = 0.29)					
2 Therapy					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**421**	**432**		**100.0 %**	**1.37 [0.76, 2.46]**
Total events: 24 (Treatment), 18 (Control)					
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.09$, df = 1 (P = 0.76); $I^2 = 0.0\%$					
Test for overall effect: Z = 1.05 (P = 0.29)					

Analysis 1.8. Comparison 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour, Outcome 8 Postpartum hemorrhage (greater than 500 ml).

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome: 8 Postpartum hemorrhage (greater than 500 ml)

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Brart 1992	43/649	48/521		46.2 %	0.72 [0.48, 1.07]
Rogers 1997	8/200	14/205		12.0 %	0.59 [0.25, 1.37]
Sadler 2000	48/320	47/331		40.1 %	1.06 [0.73, 1.53]
Tabowei 2003	1/221	2/227		1.7 %	0.51 [0.05, 5.62]
Subtotal (95% CI)	**1390**	**1284**		**100.0 %**	**0.83 [0.65, 1.08]**
Total events: 100 (Treatment), 111 (Control)					
Heterogeneity: Chi^2 = 2.92, df = 3 (P = 0.40); I^2 =0.0%					
Test for overall effect: Z = 1.39 (P = 0.17)					
2 Therapy					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**1390**	**1284**		**100.0 %**	**0.83 [0.65, 1.08]**
Total events: 100 (Treatment), 111 (Control)					
Heterogeneity: Chi^2 = 2.92, df = 3 (P = 0.40); I^2 =0.0%					
Test for overall effect: Z = 1.39 (P = 0.17)					

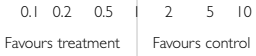
Analysis 1.9. Comparison 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour, Outcome 9 Maternal blood transfusion.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome: 9 Maternal blood transfusion

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Brart 1992	9/987	1/979		20.2 %	8.93 [1.13, 70.33]
Cammu 1996	2/152	3/154		59.8 %	0.68 [0.11, 3.99]
Lopez-Zeno 1992	1/351	1/354		20.0 %	1.01 [0.06, 16.06]
Subtotal (95% CI)	**1490**	**1487**		**100.0 %**	**2.41 [0.85, 6.83]**
Total events: 12 (Treatment), 5 (Control)					
Heterogeneity: Chi^2 = 3.90, df = 2 (P = 0.14); I^2 =49%					
Test for overall effect: Z = 1.65 (P = 0.099)					
2 Therapy					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**1490**	**1487**		**100.0 %**	**2.41 [0.85, 6.83]**
Total events: 12 (Treatment), 5 (Control)					
Heterogeneity: Chi^2 = 3.90, df = 2 (P = 0.14); I^2 =49%					
Test for overall effect: Z = 1.65 (P = 0.099)					



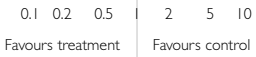
Analysis 1.10. Comparison 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour, Outcome 10 Postpartum fever or infection.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome: 10 Postpartum fever or infection

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Prevention					
Cammu 1996	8/152	4/154		4.9 %	2.03 [0.62, 6.59]
Lopez-Zeno 1992	8/351	16/354		9.6 %	0.50 [0.22, 1.16]
Rogers 1997	28/200	27/205		25.6 %	1.06 [0.65, 1.74]
Somprasit 2005	26/320	59/640		30.8 %	0.88 [0.57, 1.37]
Tabowei 2003	24/221	33/227		25.5 %	0.75 [0.46, 1.22]
Subtotal (95% CI)	**1244**	**1580**		**96.4 %**	**0.88 [0.66, 1.16]**
Total events: 94 (Treatment), 139 (Control)					
Heterogeneity: $Tau^2 = 0.01$; $Chi^2 = 4.62$, df = 4 (P = 0.33); $I^2 = 13\%$					
Test for overall effect: Z = 0.94 (P = 0.35)					
2 Therapy					
Cluett 2004	5/50	3/49		3.6 %	1.63 [0.41, 6.47]
Subtotal (95% CI)	**50**	**49**		**3.6 %**	**1.63 [0.41, 6.47]**
Total events: 5 (Treatment), 3 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.70 (P = 0.48)					
Total (95% CI)	**1294**	**1629**		**100.0 %**	**0.90 [0.69, 1.17]**
Total events: 99 (Treatment), 142 (Control)					
Heterogeneity: $Tau^2 = 0.01$; $Chi^2 = 5.38$, df = 5 (P = 0.37); $I^2 = 7\%$					
Test for overall effect: Z = 0.82 (P = 0.41)					



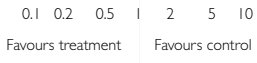
Analysis 1.11. Comparison 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour, Outcome 11 Apgar score less than seven at five minutes.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome: 11 Apgar score less than seven at five minutes

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Brart 1992	10/987	10/977		18.8 %	0.99 [0.41, 2.37]
Cammu 1996	5/152	4/154		7.4 %	1.27 [0.35, 4.63]
Lopez-Zeno 1992	1/351	1/354		1.9 %	1.01 [0.06, 16.06]
Rogers 1997	2/200	2/205		3.7 %	1.03 [0.15, 7.21]
Sadler 2000	1/320	0/331		0.9 %	3.10 [0.13, 75.89]
Tabowei 2003	38/221	36/227		66.4 %	1.08 [0.71, 1.64]
Subtotal (95% CI)	**2231**	**2248**		**99.0 %**	**1.10 [0.77, 1.55]**
Total events: 57 (Treatment), 53 (Control)					
Heterogeneity: Chi^2 = 0.52, df = 5 (P = 0.99); I^2 =0.0%					
Test for overall effect: Z = 0.51 (P = 0.61)					
2 Therapy					
Blanch 1998	1/21	0/19		1.0 %	2.73 [0.12, 63.19]
Subtotal (95% CI)	**21**	**19**		**1.0 %**	**2.73 [0.12, 63.19]**
Total events: 1 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.63 (P = 0.53)					
Total (95% CI)	**2252**	**2267**		**100.0 %**	**1.11 [0.78, 1.57]**
Total events: 58 (Treatment), 53 (Control)					
Heterogeneity: Chi^2 = 0.84, df = 6 (P = 0.99); I^2 =0.0%					
Test for overall effect: Z = 0.59 (P = 0.55)					



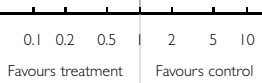
Analysis 1.12. Comparison 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour, Outcome 12 Acidosis as defined abnormal arterial cord pH (pH less than 7.10 or 7.20).

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome: 12 Acidosis as defined abnormal arterial cord pH (pH less than 7.10 or 7.20)

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Cammu 1996	7/152	7/154		35.0 %	1.01 [0.36, 2.82]
Lopez-Zeno 1992	13/351	11/354		55.1 %	1.19 [0.54, 2.62]
Rogers 1997	2/200	2/205		9.9 %	1.03 [0.15, 7.21]
Subtotal (95% CI)	**703**	**713**		**100.0 %**	**1.11 [0.61, 2.02]**
Total events: 22 (Treatment), 20 (Control)					
Heterogeneity: Chi^2 = 0.07, df = 2 (P = 0.97); I^2 =0.0%					
Test for overall effect: Z = 0.35 (P = 0.72)					
2 Therapy					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**703**	**713**		**100.0 %**	**1.11 [0.61, 2.02]**
Total events: 22 (Treatment), 20 (Control)					
Heterogeneity: Chi^2 = 0.07, df = 2 (P = 0.97); I^2 =0.0%					
Test for overall effect: Z = 0.35 (P = 0.72)					



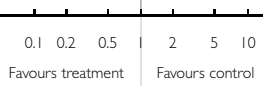
Analysis 1.13. Comparison 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour, Outcome 13 Suboptimal or abnormal fetal heart tracing.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome: 13 Suboptimal or abnormal fetal heart tracing

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Prevention					
Lopez-Zeno 1992	3/351	6/354		100.0 %	0.50 [0.13, 2.00]
Subtotal (95% CI)	**351**	**354**		**100.0 %**	**0.50 [0.13, 2.00]**
Total events: 3 (Treatment), 6 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.97 (P = 0.33)					
2 Therapy					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**351**	**354**		**100.0 %**	**0.50 [0.13, 2.00]**
Total events: 3 (Treatment), 6 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.97 (P = 0.33)					



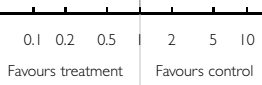
Analysis 1.14. Comparison 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour, Outcome 14 Fetal distress.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome: 14 Fetal distress

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Sadler 2000	4/320	4/331		36.3 %	1.03 [0.26, 4.10]
Tabowei 2003	9/221	7/227		63.7 %	1.32 [0.50, 3.48]
Subtotal (95% CI)	**541**	**558**		**100.0 %**	**1.22 [0.55, 2.69]**
Total events: 13 (Treatment), 11 (Control)					
Heterogeneity: Chi^2 = 0.08, df = 1 (P = 0.78); I^2 =0.0%					
Test for overall effect: Z = 0.49 (P = 0.63)					
2 Therapy					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**541**	**558**		**100.0 %**	**1.22 [0.55, 2.69]**
Total events: 13 (Treatment), 11 (Control)					
Heterogeneity: Chi^2 = 0.08, df = 1 (P = 0.78); I^2 =0.0%					
Test for overall effect: Z = 0.49 (P = 0.63)					



Analysis 1.15. Comparison 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour, Outcome 15 Admission to special care nursery.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome: 15 Admission to special care nursery

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Brart 1992	79/987	64/977		44.4 %	1.22 [0.89, 1.68]
Cammu 1996	3/152	8/154		5.5 %	0.38 [0.10, 1.41]
Lopez-Zeno 1992	14/351	11/354		7.6 %	1.28 [0.59, 2.79]
Rogers 1997	1/200	4/205		2.7 %	0.26 [0.03, 2.27]
Sadler 2000	17/320	16/331		10.8 %	1.10 [0.57, 2.14]
Tabowei 2003	40/221	36/227		24.5 %	1.14 [0.76, 1.72]
Subtotal (95% CI)	**2231**	**2248**		**95.5 %**	**1.12 [0.90, 1.39]**
Total events: 154 (Treatment), 139 (Control)					
Heterogeneity: Chi^2 = 4.80, df = 5 (P = 0.44); I^2 =0.0%					
Test for overall effect: Z = 0.98 (P = 0.33)					
2 Therapy					
Cluett 2004	0/50	6/49		4.5 %	0.08 [0.00, 1.30]
Subtotal (95% CI)	**50**	**49**		**4.5 %**	**0.08 [0.00, 1.30]**
Total events: 0 (Treatment), 6 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.78 (P = 0.075)					
Total (95% CI)	**2281**	**2297**		**100.0 %**	**1.07 [0.86, 1.33]**
Total events: 154 (Treatment), 145 (Control)					
Heterogeneity: Chi^2 = 8.37, df = 6 (P = 0.21); I^2 =28%					
Test for overall effect: Z = 0.61 (P = 0.54)					

Analysis 1.16. Comparison 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour, Outcome 16 Seizure/neurological abnormalities.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome: 16 Seizure/neurological abnormalities

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Brart 1992	4/985	5/976		83.5 %	0.79 [0.21, 2.94]
Lopez-Zeno 1992	1/351	1/354		16.5 %	1.01 [0.06, 16.06]
Subtotal (95% CI)	**1336**	**1330**		**100.0 %**	**0.83 [0.25, 2.71]**
Total events: 5 (Treatment), 6 (Control)					
Heterogeneity: Chi^2 = 0.02, df = 1 (P = 0.88); I^2 =0.0%					
Test for overall effect: Z = 0.31 (P = 0.76)					
2 Therapy					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**1336**	**1330**		**100.0 %**	**0.83 [0.25, 2.71]**
Total events: 5 (Treatment), 6 (Control)					
Heterogeneity: Chi^2 = 0.02, df = 1 (P = 0.88); I^2 =0.0%					
Test for overall effect: Z = 0.31 (P = 0.76)					

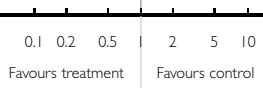
Analysis 1.17. Comparison 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour, Outcome 17 Jaundice or hyperbilirubinemia.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome: 17 Jaundice or hyperbilirubinemia

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Brart 1992	32/956	28/957		90.4 %	1.14 [0.69, 1.88]
Cammu 1996	2/152	3/154		9.6 %	0.68 [0.11, 3.99]
Subtotal (95% CI)	**1108**	**1111**		**100.0 %**	**1.10 [0.68, 1.77]**
Total events: 34 (Treatment), 31 (Control)					
Heterogeneity: Chi^2 = 0.31, df = 1 (P = 0.58); I^2 =0.0%					
Test for overall effect: Z = 0.39 (P = 0.70)					
2 Therapy					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**1108**	**1111**		**100.0 %**	**1.10 [0.68, 1.77]**
Total events: 34 (Treatment), 31 (Control)					
Heterogeneity: Chi^2 = 0.31, df = 1 (P = 0.58); I^2 =0.0%					
Test for overall effect: Z = 0.39 (P = 0.70)					



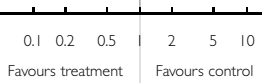
Analysis 1.18. Comparison 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour, Outcome 18 Satisfied with labour experience.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 1 Early amniotomy and early oxytocin versus routine care on spontaneous labour

Outcome: 18 Satisfied with labour experience

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Brart 1992	930/989	910/979		80.7 %	1.01 [0.99, 1.04]
Cluett 2004	42/88	44/94		3.8 %	1.02 [0.75, 1.39]
Sadler 2000	190/243	169/225		15.5 %	1.04 [0.94, 1.15]
Subtotal (95% CI)	**1320**	**1298**		**100.0 %**	**1.02 [0.99, 1.04]**
Total events: 1162 (Treatment), 1123 (Control)					
Heterogeneity: Chi^2 = 0.38, df = 2 (P = 0.83); I^2 =0.0%					
Test for overall effect: Z = 1.18 (P = 0.24)					
2 Therapy					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**1320**	**1298**		**100.0 %**	**1.02 [0.99, 1.04]**
Total events: 1162 (Treatment), 1123 (Control)					
Heterogeneity: Chi^2 = 0.38, df = 2 (P = 0.83); I^2 =0.0%					
Test for overall effect: Z = 1.18 (P = 0.24)					



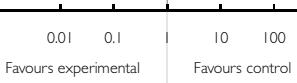
Analysis 2.1. Comparison 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded), Outcome 1 Casarean section rate.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded)

Outcome: 1 Casarean section rate

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Brart 1992	45/989	47/979		20.5 %	0.95 [0.64, 1.41]
Cammu 1996	6/152	4/154		1.7 %	1.52 [0.44, 5.28]
Cohen 1987	10/75	11/75		4.8 %	0.91 [0.41, 2.01]
Lopez-Zeno 1992	37/351	50/354		21.6 %	0.75 [0.50, 1.11]
Sadler 2000	30/320	32/331		13.6 %	0.97 [0.60, 1.56]
Serman 1995	7/75	14/70		6.3 %	0.47 [0.20, 1.09]
Somprasit 2005	38/320	94/640		27.2 %	0.81 [0.57, 1.15]
Subtotal (95% CI)	**2282**	**2603**		**95.6 %**	**0.84 [0.70, 1.01]**
Total events: 173 (Experimental), 252 (Control)					
Heterogeneity: Chi^2 = 3.85, df = 6 (P = 0.70); I^2 =0.0%					
Test for overall effect: Z = 1.81 (P = 0.071)					
2 Therapy					
Blanch 1998	5/21	2/19		0.9 %	2.26 [0.50, 10.32]
Cluett 2004	11/50	8/49		3.5 %	1.35 [0.59, 3.06]
Subtotal (95% CI)	**71**	**68**		**4.4 %**	**1.54 [0.75, 3.15]**
Total events: 16 (Experimental), 10 (Control)					
Heterogeneity: Chi^2 = 0.35, df = 1 (P = 0.56); I^2 =0.0%					
Test for overall effect: Z = 1.17 (P = 0.24)					
Total (95% CI)	**2353**	**2671**		**100.0 %**	**0.87 [0.73, 1.04]**
Total events: 189 (Experimental), 262 (Control)					
Heterogeneity: Chi^2 = 6.59, df = 8 (P = 0.58); I^2 =0.0%					
Test for overall effect: Z = 1.48 (P = 0.14)					



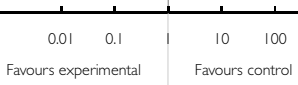
Analysis 2.2. Comparison 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded), Outcome 2 Spontaneous vaginal delivery.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded)

Outcome: 2 Spontaneous vaginal delivery

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Brart 1992	661/989	657/979		39.4 %	1.00 [0.94, 1.06]
Cammu 1996	119/152	122/154		7.2 %	0.99 [0.88, 1.11]
Cohen 1987	59/75	61/75		3.6 %	0.97 [0.82, 1.14]
Lopez-Zeno 1992	225/351	205/354		12.2 %	1.11 [0.98, 1.25]
Sadler 2000	227/320	245/331		14.4 %	0.96 [0.87, 1.05]
Serman 1995	54/75	43/70		2.7 %	1.17 [0.93, 1.48]
Somprasit 2005	244/320	455/640		18.1 %	1.07 [0.99, 1.16]
Subtotal (95% CI)	**2282**	**2603**		**97.6 %**	**1.02 [0.98, 1.06]**
Total events: 1589 (Experimental), 1788 (Control)					
Heterogeneity: Chi^2 = 7.72, df = 6 (P = 0.26); I^2 =22%					
Test for overall effect: Z = 1.12 (P = 0.26)					
2 Therapy					
Blanch 1998	13/21	14/19		0.9 %	0.84 [0.55, 1.29]
Cluett 2004	25/50	25/51		1.5 %	1.02 [0.69, 1.51]
Subtotal (95% CI)	**71**	**70**		**2.4 %**	**0.95 [0.71, 1.28]**
Total events: 38 (Experimental), 39 (Control)					
Heterogeneity: Chi^2 = 0.44, df = 1 (P = 0.50); I^2 =0.0%					
Test for overall effect: Z = 0.32 (P = 0.75)					
Total (95% CI)	**2353**	**2673**		**100.0 %**	**1.02 [0.98, 1.06]**
Total events: 1627 (Experimental), 1827 (Control)					
Heterogeneity: Chi^2 = 8.48, df = 8 (P = 0.39); I^2 =6%					
Test for overall effect: Z = 1.04 (P = 0.30)					



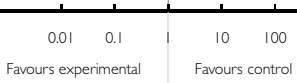
Analysis 2.3. Comparison 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded), Outcome 3 Instrumental vaginal delivery (forceps or vacuum, or both).

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded)

Outcome: 3 Instrumental vaginal delivery (forceps or vacuum, or both)

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Brart 1992	284/989	275/979		51.2 %	1.02 [0.89, 1.18]
Cammu 1996	27/152	28/154		5.1 %	0.98 [0.61, 1.58]
Cohen 1987	6/75	3/75		0.6 %	2.00 [0.52, 7.70]
Lopez-Zeno 1992	89/351	99/354		18.2 %	0.91 [0.71, 1.16]
Sadler 2000	63/320	54/331		9.8 %	1.21 [0.87, 1.68]
Serman 1995	14/75	13/70		2.5 %	1.01 [0.51, 1.99]
Somprasit 2005	38/320	91/640		11.2 %	0.84 [0.59, 1.19]
Subtotal (95% CI)	**2282**	**2603**		**98.7 %**	**1.00 [0.90, 1.11]**
Total events: 521 (Experimental), 563 (Control)					
Heterogeneity: Chi^2 = 3.98, df = 6 (P = 0.68); I^2 =0.0%					
Test for overall effect: Z = 0.01 (P = 0.99)					
2 Therapy					
Blanch 1998	3/21	3/19		0.6 %	0.90 [0.21, 3.96]
Cluett 2004	4/50	4/49		0.7 %	0.98 [0.26, 3.70]
Subtotal (95% CI)	**71**	**68**		**1.3 %**	**0.95 [0.35, 2.54]**
Total events: 7 (Experimental), 7 (Control)					
Heterogeneity: Chi^2 = 0.01, df = 1 (P = 0.94); I^2 =0.0%					
Test for overall effect: Z = 0.11 (P = 0.91)					
Total (95% CI)	**2353**	**2671**		**100.0 %**	**1.00 [0.90, 1.11]**
Total events: 528 (Experimental), 570 (Control)					
Heterogeneity: Chi^2 = 4.00, df = 8 (P = 0.86); I^2 =0.0%					
Test for overall effect: Z = 0.00 (P = 1.0)					



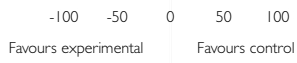
Analysis 2.4. Comparison 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded), Outcome 4 Length of first stage of labour.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded)

Outcome: 4 Length of first stage of labour

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Prevention							
Lopez-Zeno 1992	314	5.05 (2.33)	304	6.72 (3.64)		53.9 %	-1.67 [-2.15, -1.19]
Somprasit 2005	320	8.97 (4.05)	640	9.82 (4.4)		40.2 %	-0.85 [-1.41, -0.29]
Subtotal (95% CI)	**634**		**944**			**94.1 %**	**-1.32 [-1.69, -0.95]**
Heterogeneity: Chi^2 = 4.72, df = 1 (P = 0.03); I^2 =79%							
Test for overall effect: Z = 7.07 (P < 0.00001)							
2 Therapy							
Cluett 2004	50	10.26 (3.75)	49	10.47 (3.69)		5.9 %	-0.21 [-1.68, 1.26]
Subtotal (95% CI)	**50**		**49**			**5.9 %**	**-0.21 [-1.68, 1.26]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.28 (P = 0.78)							
Total (95% CI)	**684**		**993**			**100.0 %**	**-1.25 [-1.61, -0.90]**
Heterogeneity: Chi^2 = 6.79, df = 2 (P = 0.03); I^2 =71%							
Test for overall effect: Z = 6.93 (P < 0.00001)							
Test for subgroup differences: Chi^2 = 2.07, df = 1 (P = 0.15), I^2 =52%							



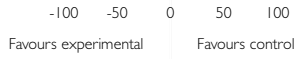
Analysis 2.5. Comparison 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded), Outcome 5 Duration of labour (duration in hours from admission in labor).

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded)

Outcome: 5 Duration of labour (duration in hours from admission in labor)

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Prevention							
Brart 1992	989	6.33 (2.7)	979	6.6 (2.8)		56.6 %	-0.27 [-0.51, -0.03]
Cohen 1987	66	7.8 (3.7)	65	8 (3.3)		2.3 %	-0.20 [-1.40, 1.00]
Lopez-Zeno 1992	314	6.49 (2.75)	304	8.15 (3.89)		11.8 %	-1.66 [-2.19, -1.13]
Serman 1995	75	4.92 (1.17)	70	5.5 (1.35)		19.6 %	-0.58 [-0.99, -0.17]
Somprasit 2005	320	8.99 (4.36)	640	10.17 (4.41)		9.7 %	-1.18 [-1.77, -0.59]
Subtotal (95% CI)	**1764**		**2058**			**100.0 %**	**-0.58 [-0.76, -0.40]**
Heterogeneity: Chi^2 = 26.43, df = 4 (P = 0.00003); I^2 =85%							
Test for overall effect: Z = 6.23 (P < 0.00001)							
2 Therapy							
Subtotal (95% CI)	**0**		**0**			**0.0 %**	**0.0 [0.0, 0.0]**
Heterogeneity: not applicable							
Test for overall effect: not applicable							
Total (95% CI)	**1764**		**2058**			**100.0 %**	**-0.58 [-0.76, -0.40]**
Heterogeneity: Chi^2 = 26.43, df = 4 (P = 0.00003); I^2 =85%							
Test for overall effect: Z = 6.23 (P < 0.00001)							



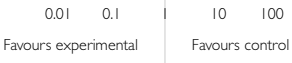
Analysis 2.6. Comparison 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded), Outcome 6 Use of epidural analgesia.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded)

Outcome: 6 Use of epidural analgesia

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Brart 1992	665/989	611/979		53.4 %	1.08 [1.01, 1.15]
Cammu 1996	48/152	44/154		3.8 %	1.11 [0.78, 1.56]
Lopez-Zeno 1992	253/351	255/354		22.1 %	1.00 [0.91, 1.10]
Sadler 2000	156/320	149/331		12.7 %	1.08 [0.92, 1.28]
Serman 1995	57/75	58/70		5.2 %	0.92 [0.78, 1.08]
Subtotal (95% CI)	**1887**	**1888**		**97.2 %**	**1.05 [1.00, 1.11]**
Total events: 1179 (Experimental), 1117 (Control)					
Heterogeneity: Chi² = 4.51, df = 4 (P = 0.34); I² =11%					
Test for overall effect: Z = 2.05 (P = 0.040)					
2 Therapy					
Blanch 1998	7/21	9/19		0.8 %	0.70 [0.33, 1.52]
Cluett 2004	33/50	23/49		2.0 %	1.41 [0.98, 2.01]
Subtotal (95% CI)	**71**	**68**		**2.8 %**	**1.20 [0.87, 1.66]**
Total events: 40 (Experimental), 32 (Control)					
Heterogeneity: Chi² = 2.60, df = 1 (P = 0.11); I² =62%					
Test for overall effect: Z = 1.12 (P = 0.26)					
Total (95% CI)	**1958**	**1956**		**100.0 %**	**1.06 [1.01, 1.11]**
Total events: 1219 (Experimental), 1149 (Control)					
Heterogeneity: Chi² = 8.18, df = 6 (P = 0.23); I² =27%					
Test for overall effect: Z = 2.23 (P = 0.026)					



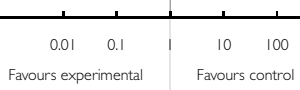
Analysis 2.7. Comparison 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded), Outcome 7 Postpartum hemorrhage (greater than 500ml).

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded)

Outcome: 7 Postpartum hemorrhage (greater than 500ml)

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Brart 1992	43/649	48/521		53.5 %	0.72 [0.48, 1.07]
Sadler 2000	48/320	47/331		46.5 %	1.06 [0.73, 1.53]
Subtotal (95% CI)	**969**	**852**		**100.0 %**	**0.88 [0.67, 1.15]**
Total events: 91 (Experimental), 95 (Control)					
Heterogeneity: Chi^2 = 1.93, df = 1 (P = 0.16); I^2 =48%					
Test for overall effect: Z = 0.96 (P = 0.34)					
2 Therapy					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Experimental), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**969**	**852**		**100.0 %**	**0.88 [0.67, 1.15]**
Total events: 91 (Experimental), 95 (Control)					
Heterogeneity: Chi^2 = 1.93, df = 1 (P = 0.16); I^2 =48%					
Test for overall effect: Z = 0.96 (P = 0.34)					



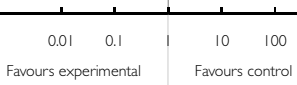
Analysis 2.8. Comparison 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded), Outcome 8 Maternal blood transfusion.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded)

Outcome: 8 Maternal blood transfusion

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Brart 1992	9/987	1/979		20.2 %	8.93 [1.13, 70.33]
Cammu 1996	2/152	3/154		59.8 %	0.68 [0.11, 3.99]
Lopez-Zeno 1992	1/351	1/354		20.0 %	1.01 [0.06, 16.06]
Subtotal (95% CI)	**1490**	**1487**		**100.0 %**	**2.41 [0.85, 6.83]**
Total events: 12 (Experimental), 5 (Control)					
Heterogeneity: Chi^2 = 3.90, df = 2 (P = 0.14); I^2 =49%					
Test for overall effect: Z = 1.65 (P = 0.099)					
2 Therapy					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Experimental), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**1490**	**1487**		**100.0 %**	**2.41 [0.85, 6.83]**
Total events: 12 (Experimental), 5 (Control)					
Heterogeneity: Chi^2 = 3.90, df = 2 (P = 0.14); I^2 =49%					
Test for overall effect: Z = 1.65 (P = 0.099)					



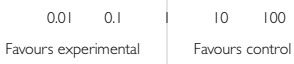
Analysis 2.9. Comparison 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded), Outcome 9 Postpartum fever or infection.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded)

Outcome: 9 Postpartum fever or infection

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Cammu 1996	8/152	4/154		6.4 %	2.03 [0.62, 6.59]
Lopez-Zeno 1992	8/351	16/354		25.6 %	0.50 [0.22, 1.16]
Somprasit 2005	26/320	59/640		63.2 %	0.88 [0.57, 1.37]
Subtotal (95% CI)	**823**	**1148**		**95.1 %**	**0.86 [0.60, 1.23]**
Total events: 42 (Experimental), 79 (Control)					
Heterogeneity: Chi^2 = 3.61, df = 2 (P = 0.16); I^2 =45%					
Test for overall effect: Z = 0.83 (P = 0.41)					
2 Therapy					
Cluett 2004	5/50	3/49		4.9 %	1.63 [0.41, 6.47]
Subtotal (95% CI)	**50**	**49**		**4.9 %**	**1.63 [0.41, 6.47]**
Total events: 5 (Experimental), 3 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.70 (P = 0.48)					
Total (95% CI)	**873**	**1197**		**100.0 %**	**0.89 [0.63, 1.27]**
Total events: 47 (Experimental), 82 (Control)					
Heterogeneity: Chi^2 = 4.39, df = 3 (P = 0.22); I^2 =32%					
Test for overall effect: Z = 0.62 (P = 0.53)					

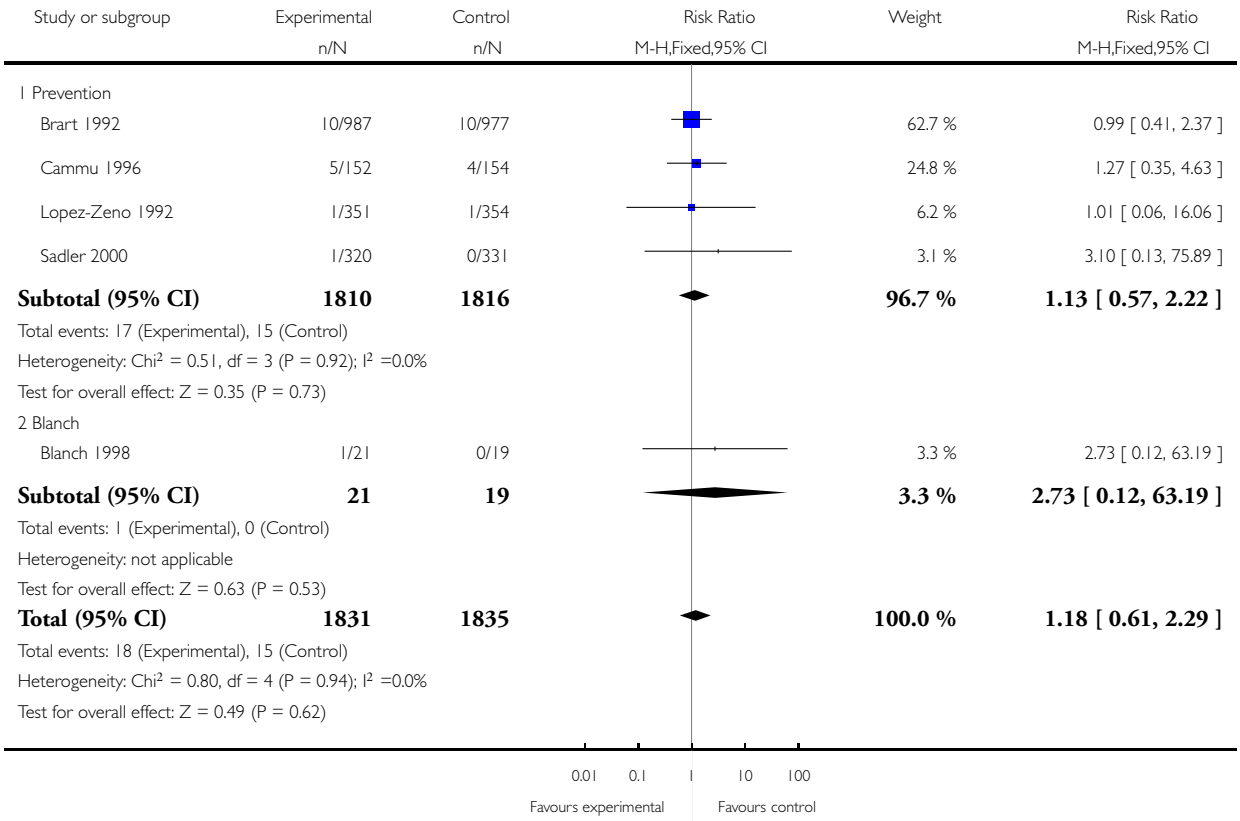


Analysis 2.10. Comparison 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded), Outcome 10 Apgar score less than seven after five minutes.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded)

Outcome: 10 Apgar score less than seven after five minutes



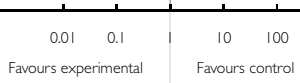
Analysis 2.11. Comparison 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded), Outcome 11 Acidosis as defined abnormal arterial cord pH (pH less than 7.10 or 7.20).

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded)

Outcome: 11 Acidosis as defined abnormal arterial cord pH (pH less than 7.10 or 7.20)

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Cammu 1996	7/152	7/154		38.8 %	1.01 [0.36, 2.82]
Lopez-Zeno 1992	13/351	11/354		61.2 %	1.19 [0.54, 2.62]
Subtotal (95% CI)	**503**	**508**		**100.0 %**	**1.12 [0.60, 2.10]**
Total events: 20 (Experimental), 18 (Control)					
Heterogeneity: Chi^2 = 0.06, df = 1 (P = 0.81); I^2 =0.0%					
Test for overall effect: Z = 0.36 (P = 0.72)					
2 Therapy					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Experimental), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**503**	**508**		**100.0 %**	**1.12 [0.60, 2.10]**
Total events: 20 (Experimental), 18 (Control)					
Heterogeneity: Chi^2 = 0.06, df = 1 (P = 0.81); I^2 =0.0%					
Test for overall effect: Z = 0.36 (P = 0.72)					



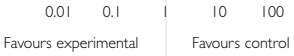
Analysis 2.12. Comparison 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded), Outcome 12 Suboptimal or abdormal fetal heart.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded)

Outcome: 12 Suboptimal or abdormal fetal heart

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Lopez-Zeno 1992	3/351	6/354		100.0 %	0.50 [0.13, 2.00]
Total (95% CI)	**351**	**354**		**100.0 %**	**0.50 [0.13, 2.00]**
Total events: 3 (Experimental), 6 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.97 (P = 0.33)					



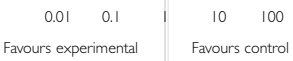
Analysis 2.13. Comparison 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded), Outcome 13 Fetal distress.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded)

Outcome: 13 Fetal distress

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Sadler 2000	4/320	4/331		100.0 %	1.03 [0.26, 4.10]
Total (95% CI)	**320**	**331**		**100.0 %**	**1.03 [0.26, 4.10]**
Total events: 4 (Experimental), 4 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.05 (P = 0.96)					



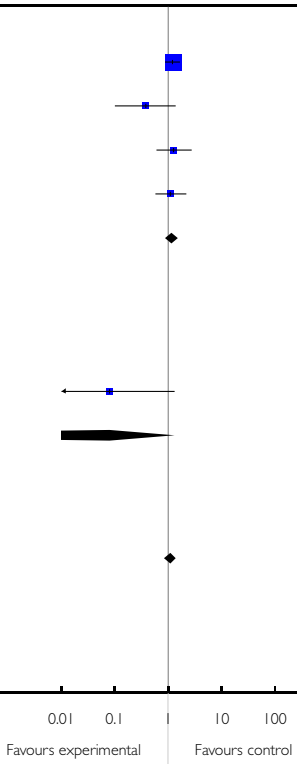
Analysis 2.14. Comparison 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded), Outcome 14 Admission to special care nursery.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded)

Outcome: 14 Admission to special care nursery

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Prevention					
Brart 1992	79/987	64/977		61.0 %	1.22 [0.89, 1.68]
Cammu 1996	3/152	8/154		7.5 %	0.38 [0.10, 1.41]
Lopez-Zeno 1992	14/351	11/354		10.4 %	1.28 [0.59, 2.79]
Sadler 2000	17/320	16/331		14.9 %	1.10 [0.57, 2.14]
Subtotal (95% CI)	**1810**	**1816**		**93.8 %**	**1.14 [0.88, 1.48]**
Total events: 113 (Experimental), 99 (Control)					
Heterogeneity: Chi^2 = 2.99, df = 3 (P = 0.39); I^2 =0.0%					
Test for overall effect: Z = 0.99 (P = 0.32)					
2 Therapy					
Cluett 2004	0/50	6/49		6.2 %	0.08 [0.00, 1.30]
Subtotal (95% CI)	**50**	**49**		**6.2 %**	**0.08 [0.00, 1.30]**
Total events: 0 (Experimental), 6 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.78 (P = 0.075)					
Total (95% CI)	**1860**	**1865**		**100.0 %**	**1.08 [0.83, 1.39]**
Total events: 113 (Experimental), 105 (Control)					
Heterogeneity: Chi^2 = 6.60, df = 4 (P = 0.16); I^2 =39%					
Test for overall effect: Z = 0.55 (P = 0.58)					

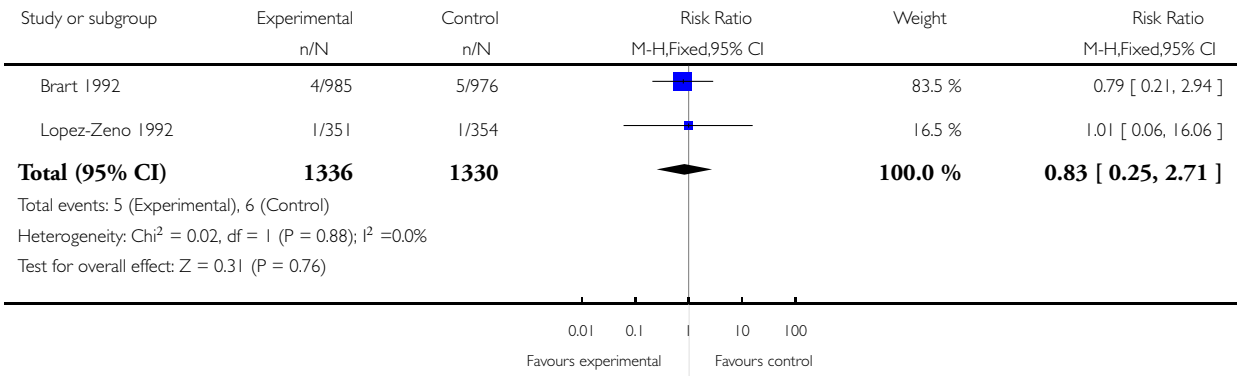


Analysis 2.15. Comparison 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded), Outcome 15 Seizure/neurological abnormalities.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded)

Outcome: 15 Seizure/neurological abnormalities

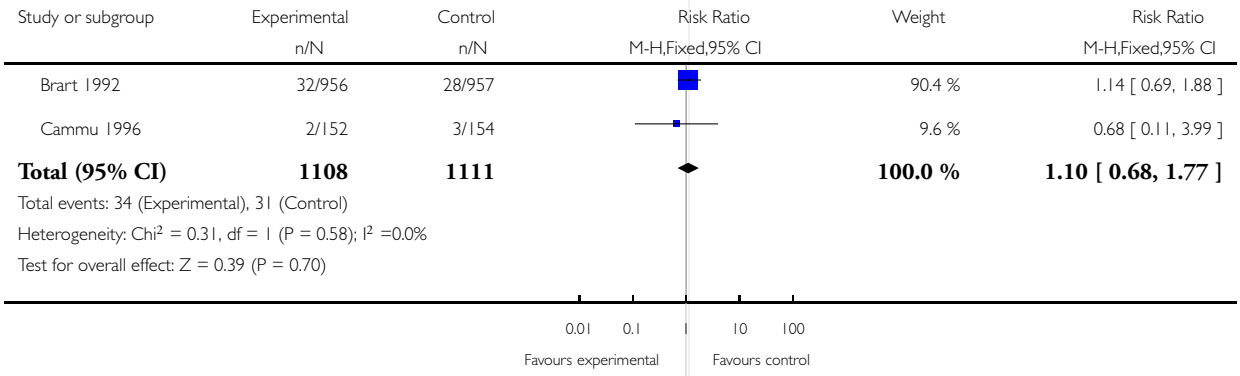


Analysis 2.16. Comparison 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded), Outcome 16 Jaundice or hyperbilirubinemia.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded)

Outcome: 16 Jaundice or hyperbilirubinemia



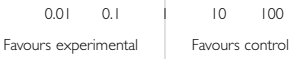
Analysis 2.17. Comparison 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded), Outcome 17 Satisfied with labour experience.

Review: Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care

Comparison: 2 Early amniotomy and early oxytocin versus routine care on spontaneous labour (Sensitivity analyses:Active management trials excluded)

Outcome: 17 Satisfied with labour experience

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Brart 1992	930/989	910/979		80.7 %	1.01 [0.99, 1.04]
Cluett 2004	42/88	44/94		3.8 %	1.02 [0.75, 1.39]
Sadler 2000	190/243	169/225		15.5 %	1.04 [0.94, 1.15]
Total (95% CI)	**1320**	**1298**		**100.0 %**	**1.02 [0.99, 1.04]**
Total events: 1162 (Experimental), 1123 (Control)					
Heterogeneity: Chi^2 = 0.38, df = 2 (P = 0.83); I^2 =0.0%					
Test for overall effect: Z = 1.18 (P = 0.24)					



HISTORY

Protocol first published: Issue 4, 2007

Review first published: Issue 2, 2009

12 November 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Shuqin Wei: assessed the studies for inclusion; evaluated the study quality; extracted the data; wrote the review; co-ordinated the review; finalized the review in response to the feedback.

Bilan Wo: assessed the studies for inclusion; extracted the data;and partially wrote the review.

Hairong Xu: assessed the studies for inclusion and evaluated the study quality.

Zhong-Cheng Luo: evaluated the study quality, extracted the data and revised the review.

Chantal Roy: collected the relevant publications on this subject and assessed the studies for inclusion.

William D Fraser: conceived the idea for the review; assessed the studies for inclusion; evaluated the study quality; revised the meta-analysis; and is the guarantor for this review.

DECLARATIONS OF INTEREST

William D Fraser is the principal investigator of one of the papers in the meta-analysis.

SOURCES OF SUPPORT

Internal sources

- University of Montreal, Canada.

External sources

- Canadian Institutes of Health Research (CIHR), Canada.
  Dr Fraser is supported by a Canada Research Chair in Perinatal Epidemiology, from the CIHR.
- CIHR Strategic Training Initiative in Research in Reproductive Health Sciences (STIRRHS), Canada.
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- Quebec Foundation of Health Research (FRSQ), Canada.
  Dr. Luo is supported by a Junior Scholar award.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Some outcomes proposed in the protocol were not included in the review because there were no data available in the included trials. Future updates of this review will included these outcomes if data become available. These outcomes are: women's use of non-epidural analgesia; level of pain; perineal trauma; antepartum haemorrhage; serious maternal morbidity or death; maternal health service utilization (cost); infant health service utilization (cost). Future clinical trials are needed for these effects.

INDEX TERMS

Medical Subject Headings (MeSH)

Labor Stage, First; Amnion [surgery]; Cesarean Section [utilization]; Obstetric Labor Complications [prevention & control; * therapy]; Oxytocics [*administration & dosage]; Oxytocin [*administration & dosage]; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans; Pregnancy