Effect of partogram use on outcomes for women in spontaneous labour at term (Review)

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TABLE OF CONTENTS

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[Intervention Review]

Effect of partogram use on outcomes for women in spontaneous labour at term

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ABSTRACT

Background

The partogram (sometimes known as partograph) is usually a pre-printed paper form, on which labour observations are recorded. The aim of the partogram is to provide a pictorial overview of labour, to alert midwives and obstetricians to deviations in maternal or fetal wellbeing and labour progress. Charts often contain pre-printed alert and action lines. An alert line represents the slowest 10% of primigravid women's labour progress. An action line is placed a number of hours after the alert line (usually two or four hours) to prompt effective management of slow progress of labour.

Objectives

To determine the effect of use of partogram on perinatal and maternal morbidity and mortality.

To determine the effect of partogram design on perinatal and maternal morbidity and mortality.

Search strategy

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (March 2008) and CENTRAL (*The Cochrane Library,* Issue 3, 2007*).*

Selection criteria

Randomised and quasi-randomised controlled trials involving a comparison of partogram with no partogram, or comparison between different partogram designs.

Data collection and analysis

Three authors independently assessed eligibility, quality and extracted data. When one author was also the trial author, the two remaining authors assessed the studies independently.

Main results

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We have included five studies in this review, involving 6187 women; two studies assessed partogram versus no partogram and the remainder assessed different partogram designs. There was no evidence of any difference between partogram and no partogram in caesarean section (risk ratio (RR) 0.64, 95% confidence interval (CI) 0.24 to 1.70); instrumental vaginal delivery (RR 1.00, 95% CI 0.85 to 1.17) or Apgar score less than seven at five minutes (RR 0.77, 95% CI 0.29 to 2.06) between the groups. When compared to a four-hour action line, women in the two-hour action line group were more likely to require oxytocin augmentation (RR 1.14, 95% CI 1.05 to 1.22). When the three- and four-hour action line were compared, caesarean section rate was lowest in the four-hour action line group and this difference was statistically significant (RR 1.70, 95% CI 1.07 to 2.70, n = 613 , one trial).

Authors' conclusions

On the basis of the findings of this review, we cannot recommend routine use of the partogram as part of standard labour management and care. We do recommend that the evidence presented should be used as a basis for discussion between clinicians and women. Further trial evidence is required to establish the efficacy of partogram use.

PLAIN LANGUAGE SUMMARY

Effect of partogram use on outcomes for women in spontaneous labour at term

A partogram is a pre-printed form, the aim of which is to provide a pictorial overview of labour to plot progress in labour and to alert health professionals to any problems with the mother or baby. It has been unclear whether a partogram should be used and, if so, which design of partogram is better for women and babies. The review authors identified five randomised controlled trials involving 6187 women in spontaneous labour at term. Two studies, with 1590 women, assessed introducing the use of a partogram versus routine care without a partogram. Two studies involving 3601 women compared partograms with different placements of the action line. Overall, there was no evidence from this review that using a partogram reduced or increased caesarean section rates or had any effect on other aspects of care in labour. Where different types of partogram were compared, no design appeared better than others. It is possible that partograms may be useful in settings with poorer access to healthcare resources, as studies in Mexico and Africa showed some reduction in caesarean section rates with partogram use and early intervention for delayed progress in labour.

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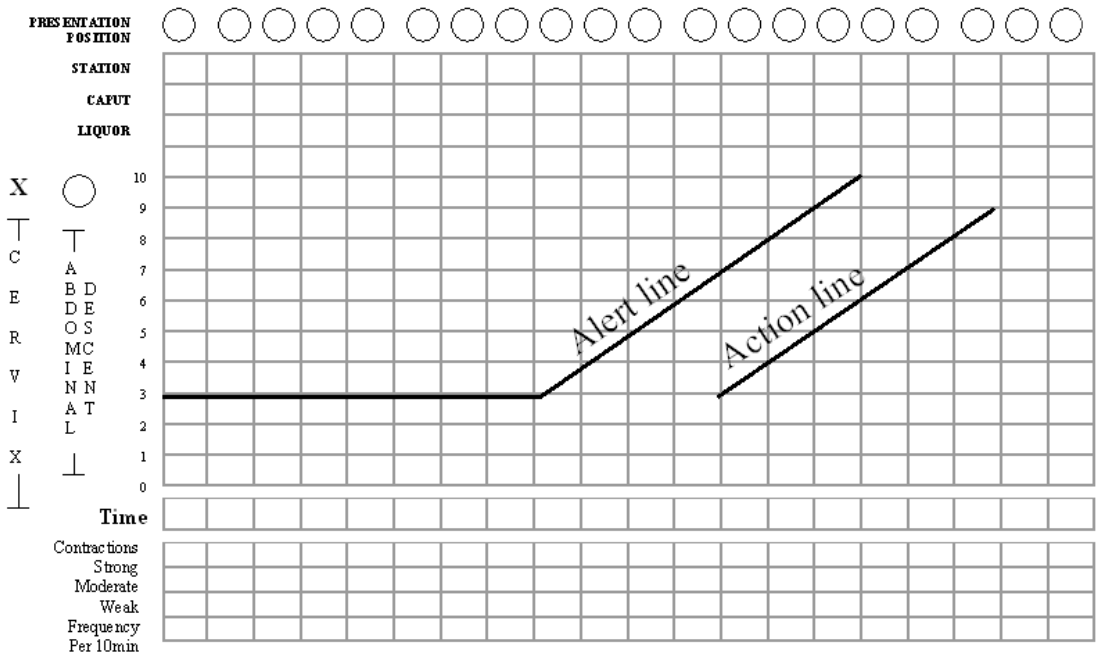
BACKGROUND

The partogram (or partograph) is a simple, inexpensive tool to provide a continuous pictorial overview of labour. The partogram is a pre-printed form, usually in paper version, on which midwives and obstetricians record labour observations. Most partograms have three distinct sections where observations are entered on maternal condition, fetal condition and labour progress; this last section assists in the detection of prolonged labour (Figure 1). Detection of prolonged labour is important as both postpartum haemorrhage and infection are more common in women with long labours (Neilson 2003). These risks are greater in developing countries with poorly resourced health services.

Figure 1. Section of partogram where labour progress is recorded



Historical background

The first obstetrician to describe the progress of labour graphically was Friedman (Friedman 1954) following his study of the cervical dilatation of 100 African primigravidae at term. The women were given frequent rectal examinations and their progress was recorded in centimetres of dilatation per hour, producing a slope resembling a sigmoid curve ('S' shaped). This became know as the cervicograph. In an attempt to utilise midwives efficiently in a hospital and clinic service in Zimbabwe (then Rhodesia), where doctors were in short supply, Philpott 1972a developed a partogram from this original cervicograph. This provided a practical tool for recording all intrapartum details, not just cervical dilatation. An 'alert line' was added following the results of a prospective study of 624 women (Philpott 1972b). The alert line was straight not curved and was a modification of the mean rate of cervical dilatation of the slowest 10% of primigravid women who were in the active phase of labour. This line represented a progress rate of 1 cm per hour. Should a woman's cervical dilatation progress more slowly, it would cross this alert line and arrangements were made to transfer her from a peripheral unit to a central unit where prolonged labour could be managed. The next stage of partogram development was the introduction of an 'action line', four hours to the right of the alert line (Philpott 1972c). This line was developed to identify primary inefficient uterine activity to prompt appropriate management. Correction of primary inefficient uterine activity would usually be with an intervention such as amniotomy or oxytocin infusion, or both.

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Use in obstetric practice

The partogram has been heralded as one of the most important advances in modern obstetric care (Safe Motherhood 1990); however, this was prior to any rigorous evaluation. Furthermore, the majority of early studies took place in hospital settings where most maternal deaths occur among women admitted with severe complications and often neglected labour (Lennox 1995). More than twenty years after its introduction, and using a partogram adapted from that formulated by Philpott and Castle (Philpott 1972b; Philpott 1972c) the World Health Organization (WHO 1994) conducted a prospective non-randomised study of 35,484 women in South East Asia and concluded that the partogram was a necessary tool in the management of labour and recommended its universal application. In this study, four pairs of hospitals participated (two pairs in Indonesia, one each in Thailand and Malaysia). A staged approach was adopted, whereby for the first five months of the study all eight centres collected baseline data; after five months the partogram was randomly introduced into one of each pair; in the remaining five months the partogram was introduced into all hospital sites. Introduction of the partogram, and agreed management protocol, reduced prolonged labour (from 6.4% to 3.4%), the proportion of labours requiring augmentation (20.7% to 9.1%), emergency caesarean section (from 9.9% to 8.3%) and stillbirths (from 0.5% to 0.3%).

A belief that partogram use is not affected by racial, cultural and socioeconomic differences, led to the approach finding favour in both high-income and low- to middle-income countries. However, in practice, it is conceivable that such variations in care between countries, and even units, may alter the use of the partogram and subsequent effectiveness, in terms of maternal and neonatal outcomes. As a consequence some practitioners have questioned its effectiveness, particularly when used in high-income countries (Groeschel 2001; Walsh 1994). Given that partograms were introduced to assist in rural settings with limited medical input or resources, or both, the transferability of such a tool for clinical practice needs consideration.

Evidence of benefit

There is some evidence to suggest that midwives find the partogram to have practical benefits in terms of ease of use, time resourcefulness, continuity of care and educational assistance (Lavender 1999). These positive aspects may contribute to improving maternal and fetal outcomes. On the other hand, it has also been reported that the partogram's status within some obstetric units is such that they may restrict clinical practice, reduce midwife autonomy and limit the flexibility to treat each woman as an individual (Lavender 1999), factors which could also impact on clinical and psychological outcomes.

Furthermore, there are worries that the use of the partogram can create unnecessary interference (Walraven 1994). This is because by assuming that all women will progress in labour at the same rate, partogram use could have adverse effects such as increased rates of artificial rupture of the membranes, oxytocin augmentation and use of analgesia resulting in a more negative labour experience.

Partogram designs

Different designs of partogram exist, and Cartmill 1992 hypothesised that the way a partograph is presented may affect an obstetrician's perception of the labour progress and thus influences decision-making. This hypothesis has received some support from others (Lavender 1998b; Tay 1996) who have suggested that the slope and position of the action line have an impact on caesarean section, intervention and maternal satisfaction.

The aim of this review is to assess the benefits and harms of partogram use on labouring women to enable women and clinicians to make informed evidence-based decisions.

OBJECTIVES

Objective 1: the primary objective of this review is to determine the effect of use of partogram on perinatal and maternal morbidity and mortality.

Objective 2: to determine the effect of partogram design on perinatal and maternal morbidity and mortality.

METHODS

Criteria for considering studies for this review

Types of studies

We included in this review all published, unpublished and ongoing randomised controlled trials that compare outcomes, as listed below, between partogram use and non-use. Randomised controlled trials of different designs of partogram were included for secondary analysis. We included trials that used quasi-random allocations (e.g. alternation). Studies reported in abstract form, without sufficient information on study methods or where results were not clear, were excluded only after an unsuccessful attempt to contact the author for further information.

Types of participants

All women with singleton pregnancies and cephalic presentations, in spontaneous labour at term.

Types of interventions

Labour management using a partogram was compared with labour management where no partogram was used. The two groups had to differ only in the partogram usage and not in other labour ward interventions, such as psychological support, early amniotomy or use of analgesia.

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To meet the second objective, studies reporting comparisons between different designs of partogram were included.
These are complex interventions. The partogram will be used in a way dictated by the accompanying guidelines and this may influence outcomes. Therefore, wherever possible, we have contextualised trial findings by describing the associated clinical guidelines.

Types of outcome measures

Primary outcomes

Outcomes for mother

Short-term maternal outcomes

1. Caesarean section
2. Oxytocin augmentation
3. Duration of first stage of labour (length of labour greater than 18 hours, length of labour greater than 12 hours)
4. Negative experience of childbirth (as defined by trial authors)

Outcome for baby

5. Low Apgar score (less than seven at five minutes)

Secondary outcomes

Outcomes for mother

Short-term maternal outcomes

6. Serious maternal morbidity or death (e.g. admission to intensive care unit, septicaemia, organ failure)
7. Instrumental vaginal delivery
8. Vaginal birth not achieved within 24 hours, from onset of labour (as defined by trial authors)
9. Postpartum haemorrhage (as defined by the trial authors)
10. Blood transfusion
11. Regional analgesia
12. Opioid use
13. Duration of rupture of the membranes at the time of delivery
14. Performance of artificial rupture of the membranes during labour
15. Deep venous thrombosis
16. Pulmonary embolism
17. Antibiotic use
18. Duration of second stage of labour
19. Number of vaginal examinations in labour
20. Perception of labour as excessively long
21. Perception of labour as excessively painful
22. Episiotomy
23. Third and fourth degree tears
24. Shoulder dystocia

Long-term maternal outcomes

25. Postnatal depression (as defined by trial authors)
26. Breastfeeding failure (as defined by trial authors)
27. Fistulae
28. Perineal pain
29. Dyspareunia
30. Abdominal pain
31. Backache reported six weeks postnatal
32. Other pain
33. Prolapse or urinary incontinence
34. Faecal incontinence
35. Relationship with baby (as defined by trial authors)
36. Subsequent pregnancy complications
37. Postpartum rehospitalisation
38. Negative experience of childbirth (as defined by trial authors)

Outcomes for baby

39. Serious neonatal morbidity or perinatal death, excluding fatal malformations (e.g. seizures, birth asphyxia, neonatal encephalopathy, disability in childhood)
40. Admission to special care nursery
41. Need for intubation at delivery
42. Neonatal septicaemia
43. Intrapartum fetal death
44. Jaundice as defined by trial authors
45. Cord blood arterial pH less than 7.1
46. Birth trauma (e.g. Erb's palsy, fractured skull, cephalhaematoma, fractured clavicle)
47. Childhood disability (as defined by trial author)

Staff

48. Usability
49. Satisfaction (as defined by trial authors)
50. Ability to audit

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 (March 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;

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3. handsearches of 30 journals and the proceedings of major conferences;
4. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL and MEDLINE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the CochranePregnancyandChildbirth Group. The Cochrane Central Register of controlled trials draws on searches from Cinahl, Medline and other midwifery and obstetric databases.

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

In addition, we searched CENTRAL using the terms partogram or partogramme or partograph (*The Cochrane Library,* Issue 3, 2007). We did not apply any language restrictions.

Data collection and analysis

Selection of studies

We assessed for inclusion all potentially eligible studies. All authors independently evaluated trials for inclusion, without consideration of their results. However, trials to which an author (T Lavender) has contributed, were evaluated by the two other review authors. We were able to gain additional data from contacting one trial author (Windrim 2006), who provided subgroup data for women who met our eligibility criteria.

Assessment of study validity

We assessed the validity of each study using the criteria outlined in the Cochrane Handbook (Higgins 2008). We independently assessed the quality of included trials according to allocation of concealment, completeness to follow up and blinding in the assessment of outcomes. We resolved differences of opinion as to eligibility and quality by consensus.

(1) Allocation concealment

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

- adequate concealment of allocation, such as telephone randomisation, consecutively numbered sealed opaque envelopes;
- unclear whether there was adequate concealment of allocation; such as a list or table used, only specifying that sealed envelopes were used, or study does not report any concealment approach;
- inadequate concealment of allocation, such as use of case record numbers, dates of birth or days of the week, and any procedure that is entirely transparent before allocation such as open list of random numbers.

(2) Completeness to follow up

We assessed completeness to follow up and have noted levels of attrition; levels of attrition were assessed as adequate, unclear or inadequate. For outcomes measured in labour, we rated attrition levels as adequate if they were less than 20%.

(3) Blinding

We have noted where there had been any attempt to blind study participants, caregivers or outcome assessors to group allocation. With a complex intervention such as a partogram it is often not feasible to blind women or staff to group assignment.

(4) Data extraction

We designed a form to extract data. At least two authors extracted the data using the agreed form. We resolved minor discrepancies through discussion. We used the Review Manager software (RevMan 2008) to enter the data, and these were then independently double checked.

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

(5) Statistical analyses

We carried out statistical analysis using the Review Manager software (RevMan 2008). For those outcomes measured in labour, we only included trials with at least 80% complete follow up for the outcome measure of interest. We used fixed-effect meta-analysis for combining data when trials were sufficiently similar.

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

For continuous outcomes the mean difference is used if outcomes are measured in the same way between trials. We used the standardised mean difference to combine trials that measure the same outcome, but use different methods. We have reported where there was evidence of skewness.

We analysed data on an intention-to-treat basis. Therefore, all participants with available data were included in the analysis in the group to which they were allocated, regardless of whether or not they received the allocated intervention.

Measures of heterogeneity between trials were applied when appropriate using the I^2 statistic. When we identified high levels of heterogeneity among the trials (exceeding 50%), we used random-effects models. We did not carry out subgroup analyses because insufficient data on subgroups was provided.

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RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting assessment.

Our Search strategy identified 11 studies for potential inclusion. Of those, five studies with 6963 women participating were included (Lavender 1998a; Lavender 2006; Pattinson 2003; Walss Rodriguez 1987; Windrim 2006) and six were excluded (Cartmill 1992; Fahdhy 2005; Hamilton 2001; Kogovsek 2000; Mathews 2007; WHO 1994).

Two studies compared partogram versus no partogram (Walss Rodriguez 1987; Windrim 2006). The Windrim 2006 study took place in Canada and the Walss Rodriguez 1987 study in Mexico; therefore they were from two very different settings. The Windrim 2006 study and Walss Rodriguez 1987 study both compared their usual descriptive, sequential, recording of intrapartum details, with an experimental arm, i.e. the partogram. In the Windrim 2006 study the partogram used incorporated a two-hour alert line, but no action line. In the Walss Rodriguez 1987 study, a 'Friedman' (Friedman 1954) partogram was used. The partogram was not currently in use in either unit. Two studies compared partograms with different placement of action lines (Lavender 1998a; Lavender 2006). Lavender 2006 was a two-arm trial and Lavender 1998a was a three-arm trial. Other than the placement of the action line, labour management remained consistent. If progress crossed the action line, diagnosis of prolonged labour was made and managed according to standard protocol; this involved clinical assessment and augmentation, as appropriate. Both studies took place in a single hospital in England. One study, in South Africa, compared a partogram with an alert and action line with one which contained an alert line only (Pattinson 2003). In this study, the group that received a partogram with only an alert line received more aggressive intrapartum management; a vaginal examination was carried out every two hours and oxytocin infusion advocated when progress crossed the line. Those with an alert and action line had more expectant management; vaginal examinations every four hours and commencement of oxytocin if progress crossed the four hour action line.

Only two outcomes were reported by all trials; caesarean section rates and Apgar score. Other outcomes were not consistently reported.

Risk of bias in included studies

Included studies were assessed for methodological quality on the basis of sequence generation, allocation concealment, blinding, attrition and other concerns about bias (*see* 'Methods of the review' above). Sequence generation and allocation concealment were graded as adequate in four trials (Lavender 1998a; Lavender 2006; Pattinson 2003; Windrim 2006) and were unclear in one trial (Walss Rodriguez 1987). Attempts to contact the trial author, for clarification, failed. This paper generally lacked detail, making assessment of quality and contextualisation of the results difficult. Attrition was low, with less than 5% of participants excluded or lost to follow up in all five trials. In one trial (Lavender 1998a) there were higher levels of missing data (13.5%) for the maternal satisfaction outcome. In this study, maternal satisfaction was only assessed in a sub-set of women (n = 615); this comprised all women recruited over a prespecified 12 month period of whom 519 responded.

Effects of interventions

1. Partogram versus no partogram

Two randomised trials have been included in this comparison with 1590 women participating (Walss Rodriguez 1987; Windrim 2006). The Walss Rodriguez 1987 study reported only three outcomes, relevant to this review, therefore results were only pooled for these outcomes. There was no significant differences between groups in caesarean section (Analysis 1.1: risk ratio (RR) 0.64, 95% confidence interval (CI) 0.24 to 1.70, n = 1590, two trials); instrumental vaginal delivery (Analysis 1.4: RR 1.00, 95% CI 0.85 to 1.17, n = 1590, two trials) or Apgar score less than seven at five minutes (Analysis 1.2: RR 0.77, 95% CI 0.29 to 2.06). (For the result relating to caesarean section there were high levels of heterogeneity (I^2 = 93%) so this result should be interpreted with caution.) There was insufficient evidence of benefit or harm in any of the other maternal or neonatal outcomes, reported by Windrim 2006. The results for caesarean section rate were different in the two studies. In the study carried out in a low-resource setting (Walss Rodriguez 1987), the caesarean section rate was lower in the partogram group (RR 0.38, 95% CI 0.24 to 0.61). In the high-resource setting (Windrim 2006), there was no difference between groups (RR 1.03, 95% CI 0.82 to 1.28).

Sensitivity analysis

The Walss Rodriguez 1987 study had poor allocation concealment and provided very little information on study methods. In view of the high risk of bias associated with this study, we carried out a sensitivity analysis excluding it from the analysis. There were no significant differences between groups when this study was removed.

2. Partogram with two-hour action line versus partogram with four-hour action line

Two randomised trials have been included in this comparison with 3601 women participating (Lavender 1998a; Lavender 2006). Both studies were carried out in the same high-resource setting. There was no significant difference in caesarean section between the groups (Analysis 2.1: RR 1.06, 95% CI 0.85 to 1.32, n = 3601,

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two trials). Women in the two-hour action line group were more likely to receive oxytocin augmentation (Analysis 2.10: RR 1.14, 95% CI 1.05 to 1.22, n = 3601, two trials). There were no statistically significant differences in any of the remaining maternal or neonatal outcomes.

3. Partogram with two-hour action line versus partogram with three-hour action line

Only one randomised trial (carried out in a high-resource setting) compared a two-hour versus a three-hour action line with 617 women participating (Lavender 1998a). There was no difference in caesarean section (Analysis 3.1: RR 0.78, 95% CI 0.51 to 1.18, n = 617, one trial) or any other clinical maternal outcomes. However, women in the two-hour action line group were less likely to report a negative childbirth experience than those in the three-hour action line group (Analysis 3.6: RR 0.49, 95% CI 0.27 to 0.90, n = 348, one trial). There was no difference in neonatal outcomes.

4. Partogram with three-hour action line versus partogram with four-hour action line

Only one randomised trial, again carried out in a high-resource setting, compared a three-hour versus a four-hour action line with 613 women participating (Lavender 1998a). Caesarean section rate was lowest in the four-hour action line group and this difference was statistically significant (outcome 04.01: RR 1.70, 95% CI 1.07 to 2.70, n = 613 , one trial). There were no differences in any of the remaining clinical maternal outcomes or any neonatal outcomes.

5. Partogram with alert line versus partogram with alert and action line

Only one randomised trial compared a partogram with an alert line only versus a partogram with an alert and action line, with 694 women participating (Pattinson 2003). This trial was carried out in a low-resource setting. The caesarean section rate was lower in the alert line only group (outcome 05:01: RR 0.68, 95% CI 0.50 to 0.93, n = 694, one trial). More oxytocin was used when labour was managed aggressively, with the use of a single line, but the evidence was not significant. There was no difference in any of the remaining maternal or neonatal outcomes.

6. Earlier versus later intervention: pooled results for trials in high- and low-resourced settings

To examine the effect of early or late intervention in high- and low-resource settings, we pooled results from three studies. Two studies examined two- and four-hour action lines (Lavender 1998a; Lavender 2006) in a high-resource setting and one study examined alert line only versus alert and action line in a low resource setting (Pattinson 2003). When results were pooled, there were no differences between the groups for caesarean section rate, Apgar score or instrumental delivery. However, as stated above, in the low-risk setting, the early intervention had a positive effect on the caesarean section rate.

DISCUSSION

A total of 6187 women were recruited from five trials comparing partogram use; two trials comparing partogram versus no partogram and three trials comparing different partogram formats. Four of the five trials were of good quality. In the remaining trial (Walss Rodriguez 1987), the method of allocation concealment and the method of randomisation was unclear.

Our primary objective was to compare partogram versus no partogram for women in spontaneous labour. Evidence from this review is inconclusive. Evidence from trials comparing partogram versus no partogram was limited to only two trials with 1590 women (Walss Rodriguez 1987; Windrim 2006) of differing methodological quality. The strongest study, in terms of quality, was that conducted by Windrim 2006 which showed no differences in any clinical outcomes measured (caesarean section, duration of labour, oxytocin augmentation, amniotomy, epidural use, use of antibiotics in labour, Apgar scores, or admissions to neonatal intensive care unit) following introduction of the partogram. However, as acknowledged by the study authors, the findings may have been influenced by the relatively high percentage of non compliance in completing the partogram (20%) or the cross contamination of care by staff, or both. In both studies (Walss Rodriguez 1987; Windrim 2006) the partogram was the experimental arm. These findings can not be extrapolated to units where the partogram is currently in use; removing the partogram as opposed to introducing it may produce different findings.

Based on the limited evidence from the two trials included in this review, we cannot advocate the introduction of routine use of the partogram. However, we acknowledge that many units, in high- and low-income settings, currently use a partogram and have reported benefits in terms of ease of recording, provision of pictorial overview of progress, training of clinicians and transferring of care (Lavender 1999; Lavender 2007). In such settings, where the partogram is currently in use, there would be resistance to the removal of this tool. One cannot therefore advocate for the non-use or removal of this tool. We therefore believe that, until robust trial evidence is available, the use of the partograph should be determined by clinician and maternal preference.

Our secondary objective was to compare the use of different designs of partogram for women in spontaneous labour. Combined evidence from trials comparing the different placement of action lines (Lavender 1998a; Lavender 2006) showed little difference in caesarean section rates and few differences in other maternal outcomes (instrumental vaginal delivery, serious maternal morbidity

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or death, performance of artificial rupture of membranes, blood loss less than 500 mls, epidural use, number of vaginal examinations). When the two-hour action line was compared with the four-hour action line, the only difference found was an increase in oxytocin augmentation in the two-hour arm (Analysis 2.10: RR 1.14, 95% CI 1.05 to 1.22, n = 3601, two trials). This is unsurprising given that the associated guidelines advocated earlier use of oxytocin. When the two-hour action line and three-hour action line were compared, differences were found in the self-reported maternal experience with less women in the two-hour arm reporting a negative experience (Analysis 3.6: RR 0.49, 95% CI 0.27 to 0.90, n = 348, one trial). The relevance of these findings are uncertain, especially as the comparison between the two-hour versus four-hour arm and three-hour versus four-hour arm revealed no differences. It may be that women in the two-hour arm perceived their labours to be shorter, as the three-hour action line was current local policy. Alternatively, it may be that because those women whose labours were managed with the two-hour action line received more intervention, they also received more labour support. There were no differences in any neonatal outcomes (cord pH less than 7.1, Apgar score less than seven at five minutes, admission to special care nursery, serious morbidity or perinatal death). Although the findings of these studies were fairly consistent, both studies were from the same setting, and therefore their generalisability needs consideration.

The remaining trial included in this review (Pattinson 2003) was not combined with the previous trials, as this was a trial which compared a partogram with an alert line and aggressive management versus one with an alert and action line, with more conservative management. This trial described a package of care for labour management alongside the partogram use, which advocated more frequent vaginal examinations (two-hourly) for women in the aggressive management group, thereby suggesting a more complex intervention. This study was the only one which compared different partogram designs that clearly demonstrated a difference in caesarean section rates; the more aggressive arm having the lower rate (Analysis 5.1: RR 0.68, 95% CI 0.50 to 0.93, n = 694, one trial). Given that the partogram is a complex intervention, used in conjunction with labour guidelines, the approach used in this study may be more appropriate. Utilising a reductionist approach, to what is in essence a complex intervention, may produce less meaningful findings.

AUTHORS' CONCLUSIONS

Implications for practice

Given the limited number of trials in this area and the heterogeneity, it is difficult to offer any recommendations for the routine use of the partogram or the use of specific types of partogram. However, given the fact that the partogram is currently in widespread use, it appears reasonable, until stronger evidence is available, to enable women and clinicians to make their own decisions.

Implications for research

The maximum number of trials in any of the comparisons was two. None of these trials was multi-centred and all study units had different labour ward guidelines. Given the limitations of the studies included and the potential impact of organisational issues, e.g. guidelines on partogram use, a large cluster-randomised trial is recommended to compare partogram versus no partogram. Although the World Health Organization (WHO 1994) compared partogram use between sites, the partogram was introduced in stages and published data were not available on the randomised phase of the study; this study is therefore awaiting assessment until unpublished data have been made available to us.

Interestingly, both studies from low-income countries (Pattinson 2003; Walss Rodriguez 1987) showed a statistically significant difference in caesarean section rates; an area that warrants further exploration. Any future trials should stratify participants according to parity, services with low (20 or less per 1000) and high perinatal mortality (more than 20) and low versus high intervention rates in the first stage of labour. We had intended to carry out a subgroup analysis but data were not available. There is also a need to take into account management and organisational issues, such as hospital policies, when designing future studies. Divergent policies with respect to partogram use should then be subjected to post-hoc subgroup analysis.

Only the Lavender studies (Lavender 1998a; Lavender 2006) reported measures of maternal childbirth experience. Future studies should also include assessment of women's views; however, mixed method approaches, including qualitative inquiry, may reveal more meaningful results.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Lavender 1998a

Methods	Prospective randomised clinical trial. Random allocation by sealed, opaque envelopes.
Participants	928 primigravid women from the North West of England, with uncomplicated pregnancies who presented in spontaneous labour at term.
Interventions	Women were randomised to have their progress of labour recorded on a partogram with an action line 2, 3 or 4 hours to the right of the alert line.
Outcomes	Caesarean section rate, maternal satisfaction, instrumental delivery rate, need for augmentation, randomisation to delivery interval, use of epidural, cord blood gas analysis, blood loss > 500 ml, number of vaginal examinations, Apgar score, admission to special care baby unit.
Notes	Maternal satisfaction was only assessed in a sub-set of women, i.e. all women recruited over a prespecified 12 month period (n = 615). .

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Table of random numbers.
Allocation concealment?	Yes	Consecutively numbered, sealed, opaque envelopes.

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Lavender 1998a (*Continued*)

Blinding? Clinical Staff	No	Not feasible.
Blinding? Women	No	
Blinding? Oucome assessors	No	
Incomplete outcome data addressed? All outcomes	Yes	Small loss to follow up after randomisation (less than 1% attrition) for outcomes measured in labour. There were higher attrition for the maternal satisfaction outcomes measured in the postnatal period.
Free of other bias?	Unclear	10% (who were otherwise eligible) were not approached (overall, 57% of eligible women were randomised).

Lavender 2006

Methods	Prospective randomised clinical trial. Random allocation by sealed, opaque envelopes.
Participants	2975 primigravid women from the North West of England, with uncomplicated pregnancies, in spontaneous labour at term.
Interventions	Women were randomised to have their progress of labour recorded on a partogram with an action line 2 or 4 hours to the right of the alert line.
Outcomes	Outcomes were stratified according to intended place of birth (midwife led unit or obstetric unit). Caesarean section rate, maternal satisfaction, instrumental delivery rate, need for augmentation, randomisation to delivery interval, use of epidural, cord blood gas analysis, blood loss > 500 ml, number of vaginal examinations, Apgar score, admission to special care baby unit.
Notes	

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Table of random numbers. Randomisation stratified by intended place of birth (2 participating units).
Allocation concealment?	Yes	Consecutively numbered, sealed, opaque envelopes.

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Lavender 2006 (*Continued*)

Blinding? Clinical Staff	No	Not feasible.
Blinding? Women	No	
Blinding? Oucome assessors	No	
Incomplete outcome data addressed? All outcomes	Yes	Less than 1% attrition after randomisation.
Free of other bias?	Unclear	Large numbers of women who were otherwise eligible were not approached to participate. The numbers not approached varied depending on the recruiting unit, 26% not approached in the midwifery and 61% in the delivery unit.

Pattinson 2003

Methods	Prospective randomised clinical trial. Random allocation by sealed, opaque envelopes.
Participants	694 healthy nulliparous women from South Africa, who were in active spontaneous labour, at term, with a healthy singleton pregnancy and cephalic presentation.
Interventions	Women were randomised to either aggressive or expectant management protocols. Aggressive management entailed using a single line partogram, a vaginal examination every 2 hours and use of oxytocin if the line was crossed. Expectant management entailed using a 2-line partogram, with the alert line and a parallel action line 4 hours to the right, with a vaginal examination every 4 hours. If the action line was reached, oxytocin was started.
Outcomes	Caesarean section rate, operative deliveries, oxytocin use, received analgesia, Apgar score, perinatal death.
Notes	

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Computer-generated list of random numbers.
Allocation concealment?	Yes	Sealed, opaque envelopes.
Blinding? Clinical Staff	No	

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Pattinson 2003 (*Continued*)

Blinding? Women	No	
Blinding? Oucome assessors	No	
Incomplete outcome data addressed? All outcomes	Yes	Low attrition after randomisation (less than 1%). Where women did not receive the allocated intervention, there was intention-to-treat analyses.
Free of other bias?	Yes	Recruitment stopped early due to funding constraints.

Walss Rodriguez 1987

Methods	Prospective study in which women 'at random' were distributed in 1 of 2 groups.
Participants	434 women in Mexico, with term pregnancies who presented in labour (cervix 2 cm or more dilated) with live, singleton, cephalic presentation.
Interventions	One group had their labour managed according to the Friedman partogram and the other had labour managed using a non-graphic, descriptive record.
Outcomes	Caesarean section, forceps delivery, normal delivery, Apgar score.
Notes	This study was translated into English.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Quasi-randomised study. No information on how randomisation was achieved.
Allocation concealment?	Unclear	No information on how women were allocated to groups, not clear that group allocation was truly random.
Blinding? Clinical Staff	No	
Blinding? Women	No	
Blinding? Oucome assessors	No	

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Walss Rodriguez 1987 (*Continued*)

Incomplete outcome data addressed? All outcomes	Yes	No apparent loss to follow up.
Free of other bias?	Unclear	Very little information on study methods was provided.

Windrim 2006

Methods	Prospective randomised clinical trial. Computerised allocation, by telephone.
Participants	1932 primiparous women, with uncomplicated pregnancies at term, with contractions every 3-5 minutes and cervix at least 3 cm dilated, in Toronto, Canada. Outcomes were stratified according to whether labour was spontaneous or induced. Only data from women not induced were included (n = 1156).
Interventions	Women were randomised to 1 of 2 groups: the standard group, who had the progress of labour charted in written notes, or the partogram group, whose progress in labour was recorded using a bedside graphical partogram as well as written notes.
Outcomes	Rate of caesarean section, operative vaginal delivery, spontaneous vaginal delivery, duration of first stage of labour, duration of second stage of labour, number of vaginal examinations, epidural analgesia use, artificial rupture of membranes, oxytocin augmentation, evaluation for non-reassuring fetal heart tracing, maternal and neonatal morbidity.
Notes	Only data from those in spontaneous labour are included in the review.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Stratified randomisation by off-site computerised randomisation service.
Allocation concealment?	Yes	By telephone to off-site service.
Blinding? Clinical Staff	No	Not feasible. Bedside charts.
Blinding? Women	No	
Blinding? Oucome assessors	No	
Incomplete outcome data addressed? All outcomes	Yes	No missing data apparent.

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Windrim 2006 (*Continued*)

Free of other bias?	Unclear	No information on the number of women approached or the numbers of eligible women declining participation.

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

Cartmill 1992	A report of a hypothetical study. No research conducted and no data presented.
Fahdhy 2005	This was a cluster-randomised trial in which midwives were randomised to receive training, alongside using the partogram. The intervention was therefore the training and not the partogram. There is no description of what midwives in the control group received.
Hamilton 2001	This study was presented in abstract form only and lacked detail. It was particularly unclear whether participants were in spontaneous labour and whether they were at term. Attempts were made to contact the trial author, without success.
Kogovsek 2000	It was unclear from the presentation of data which outcome data were from women in spontaneous labour. We were unable to contact any of the authors.
Mathews 2007	This was a crossover trial comparing two partographs, one which included a latent phase and one which did not. In this study all physicians posted to the labour ward used the first partograph (composite or simplified depending on the random allocation) for 10 days. After one weeks break, all physicians used the second partograph. Study participants were therefore physicians and not women.

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

Hamilton 2004

Methods	This was an RCT and a before and after trial, comparing routine recording of cervical dilatation over time versus an experimental group where individualized reference ranges were superimposed.
Participants	4812 participants (nulliparous, with live singleton cephalic presenting babies of at least 35 weeks gestation) in 7 centres.
Interventions	Computerised labour curve with individualised reference range.
Outcomes	Caesarean section rate.
Notes	This study was identified when the review was nearing completion and will be assessed for inclusion when the review is updated.

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WHO 1994

Methods	This study was not designed as an RCT. However, part of the study, i.e. the 5 month period where centres where randomised either to the first 5 months of partogram use or the same 5 month period pre-implementation, is essentially equivalent to a cluster RCT. Published data relating to this part of the trial were not available. Despite contacting two members of the original research team, we have not, so far, been able to obtain such data.
Participants	35,484 women in South East Asia. All labours over 34 weeks gestation, including inductions, malpresentations, and multiple pregnancies were included.
Interventions	Partogram, intensive teaching of midwives and medical staff, presence of WHO consultant
Outcomes	Caesarean section, labour > 18 hours, duration of labour, labour augmented, postpartum sepsis.
Notes	

RCT: randomised controlled trial

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DATA AND ANALYSES

Comparison 1. Partogram versus no partogram (studies carried out in high- and low-resource settings)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Casearean section (overall)	2	1590	Risk Ratio (M-H, Random, 95% CI)	0.64 [0.24, 1.70]
1.1 Low-resource setting	1	434	Risk Ratio (M-H, Random, 95% CI)	0.38 [0.24, 0.61]
1.2 High-resource setting	1	1156	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.82, 1.28]
2 Apgar score less than 7 at 5 minutes	2	1596	Risk Ratio (M-H, Random, 95% CI)	0.77 [0.29, 2.06]
2.1 Low-resource setting	1	440	Risk Ratio (M-H, Random, 95% CI)	0.46 [0.04, 5.00]
2.2 High-resource setting	1	1156	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.29, 2.52]
3 Epidural analgesia	1	1156	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.98, 1.05]
3.1 High-resource setting	1	1156	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.98, 1.05]
4 Instrumental vaginal delivery	2	1590	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.85, 1.17]
4.1 Low-resource setting	1	434	Risk Ratio (M-H, Fixed, 95% CI)	1.17 [0.79, 1.74]
4.2 High-resource setting	1	1156	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.81, 1.15]
5 Duration of first stage of labour	1	1156	Mean Difference (IV, Fixed, 95% CI)	Not estimable
5.1 High-resource setting	1	1156	Mean Difference (IV, Fixed, 95% CI)	Not estimable
6 Duration of second stage of labour	1	1156	Mean Difference (IV, Fixed, 95% CI)	Not estimable
6.1 High-resource setting	1	1156	Mean Difference (IV, Fixed, 95% CI)	Not estimable
7 Number of vaginal examinations	1	1156	Mean Difference (IV, Fixed, 95% CI)	Not estimable
7.1 High-resource setting	1	1156	Mean Difference (IV, Fixed, 95% CI)	Not estimable
8 Admission to special care nursery	1	1156	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.51, 1.75]
8.1 High-resource setting	1	1156	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.51, 1.75]
9 Oxytocin augmentation	1	1156	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.95, 1.10]
9.1 High-resource setting	1	1156	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.95, 1.10]
10 Performance of artificial rupture of membranes during labour	1	1156	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.88, 1.11]
10.1 High-resource setting	1	1156	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.88, 1.11]
11 Antibiotic use	1	1156	Risk Ratio (M-H, Fixed, 95% CI)	1.23 [0.88, 1.73]
11.1 High-resource setting	1	1156	Risk Ratio (M-H, Fixed, 95% CI)	1.23 [0.88, 1.73]

Comparison 2. Partogram with 2-hour action line versus partogram with 4-hour action line (studies carried out in a high-resource setting)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section (overall)	2	3601	Risk Ratio (M-H, Random, 95% CI)	1.06 [0.85, 1.32]
2 Caesarean section (distress)	2	3601	Risk Ratio (M-H, Fixed, 95% CI)	1.30 [0.86, 1.96]
3 Caesarean section (delay)	2	3601	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.77, 1.25]
4 Instrumental vaginal delivery	2	3601	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.80, 1.03]

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5 Serious maternal morbidity or death	2	3601	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
6 Negative childbirth experience	2	2269	Risk Ratio (M-H, Random, 95% CI)	0.61 [0.28, 1.35]
7 Cord pH less than 7.1	2	3601	Risk Ratio (M-H, Fixed, 95% CI)	0.73 [0.44, 1.22]
8 Apgar score less than 7 at 5 minutes	2	3601	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.50, 1.35]
9 Admission to special care nursery	2	3601	Risk Ratio (M-H, Fixed, 95% CI)	0.78 [0.46, 1.31]
10 Oxytocin augmentation	2	3601	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [1.05, 1.22]
11 Performance of artificial rupture of the membranes during labour	2	3601	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [0.99, 1.15]
12 Serious neonatal morbidity or perinatal death	2	3601	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
13 Blood loss > 500 ml	2	3601	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [0.90, 1.26]
14 Epidural use	2	3601	Risk Ratio (M-H, Fixed, 95% CI)	1.04 [0.95, 1.14]
15 Vaginal examinations	2	3601	Mean Difference (IV, Fixed, 95% CI)	-0.14 [-0.27, -0.02]

Comparison 3. Partogram with 2-hour action line versus partogram with 3-hour action line (study carried out in a high-resource setting)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section (overall)	1	617	Risk Ratio (M-H, Fixed, 95% CI)	0.78 [0.51, 1.18]
2 Caesarean section (distress)	1	617	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.44, 2.10]
3 Caesarean section (delay)	1	617	Risk Ratio (M-H, Fixed, 95% CI)	0.71 [0.42, 1.19]
4 Instrumental vaginal delivery	1	617	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.69, 1.26]
5 Serious maternal morbidity or death	1	617	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
6 Negative childbirth experience	1	348	Risk Ratio (M-H, Fixed, 95% CI)	0.49 [0.27, 0.90]
7 Cord pH less than 7.1	1	617	Risk Ratio (M-H, Fixed, 95% CI)	0.38 [0.07, 1.96]
8 Apgar score less than 7 at 5 minutes	1	617	Risk Ratio (M-H, Fixed, 95% CI)	1.44 [0.41, 5.05]
9 Admission to special care nursery	1	617	Risk Ratio (M-H, Fixed, 95% CI)	3.83 [0.43, 34.12]
10 Oxytocin augmentation	1	617	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.85, 1.21]
11 Performance of artificial rupture of membranes during labour	1	617	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.77, 1.15]
12 Serious neonatal morbidity or perinatal death	1	617	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
13 Blood loss > 500 ml	1	617	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.63, 1.45]
14 Epidural use	1	617	Risk Ratio (M-H, Fixed, 95% CI)	1.16 [0.94, 1.44]
15 Vaginal examinations	1	617	Mean Difference (IV, Fixed, 95% CI)	Not estimable

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Comparison 4. Partogram with 3-hour action line versus partogram with 4-hour action line (study carried out in a high-resource setting)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section (overall)	1	613	Risk Ratio (M-H, Fixed, 95% CI)	1.70 [1.07, 2.70]
2 Caesarean section (distress)	1	613	Risk Ratio (M-H, Fixed, 95% CI)	1.77 [0.70, 4.42]
3 Caesarean section (delay)	1	613	Risk Ratio (M-H, Fixed, 95% CI)	1.68 [0.97, 2.91]
4 Instrumental vaginal delivery	1	613	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.72, 1.28]
5 Serious maternal morbidity or death	1	613	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
6 Negative childbirth experience	1	340	Risk Ratio (M-H, Fixed, 95% CI)	0.80 [0.51, 1.27]
7 Cord pH less than 7.1	1	613	Risk Ratio (M-H, Fixed, 95% CI)	2.57 [0.50, 13.17]
8 Apgar score less than 7 at 5 minutes	1	613	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.22, 3.04]
9 Admission to special care nursery	1	613	Risk Ratio (M-H, Fixed, 95% CI)	0.51 [0.05, 5.65]
10 Oxytocin augmentation	1	613	Risk Ratio (M-H, Fixed, 95% CI)	1.09 [0.91, 1.30]
11 Performance of artificial rupture of membranes during labour	1	613	Risk Ratio (M-H, Fixed, 95% CI)	1.04 [0.85, 1.26]
12 Serious neonatal morbidity or perinatal death	1	613	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
13 Blood loss > 500 ml	1	613	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.68, 1.56]
14 Epidural use	1	613	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.80, 1.27]
15 Number of vaginal examinations in labour	1	613	Mean Difference (IV, Fixed, 95% CI)	0.10 [-0.19, 0.39]

Comparison 5. Partogram with alert line only versus partogram with alert and action line (study carried out in a low-resource setting)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section (overall)	1	694	Risk Ratio (M-H, Fixed, 95% CI)	0.68 [0.50, 0.93]
2 Instrumental vaginal delivery	1	694	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.66, 1.15]
3 Oxytocin augmentation	1	694	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.62, 1.05]
4 Low Apgar Score (less than 7 at 5 minutes)	1	2	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5 Perinatal death	1	694	Risk Ratio (M-H, Fixed, 95% CI)	7.12 [0.37, 137.36]

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Comparison 6. Earlier versus later intervention: combined analysis for trials in high- and low-resource settings

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section (overall) (New Outcome)	3	4295	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.67, 1.31]
1.1 Low-resource setting	1	694	Risk Ratio (M-H, Random, 95% CI)	0.68 [0.50, 0.93]
1.2 High-resource setting	2	3601	Risk Ratio (M-H, Random, 95% CI)	1.06 [0.85, 1.32]
2 Apgar score low at 5 or 10 minutes	3	4295	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.48, 1.86]
2.1 Low-resource setting	1	694	Risk Ratio (M-H, Random, 95% CI)	7.12 [0.37, 137.36]
2.2 High-resource setting	2	3601	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.50, 1.35]
3 Instrumental delivery	3	4295	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.80, 1.02]
3.1 Low-resource setting	1	694	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.66, 1.15]
3.2 High-resource setting	2	3601	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.80, 1.03]

WHAT'S NEW

Last assessed as up-to-date: 30 March 2008.

10 November 2008	Amended	Contact details edited.

HISTORY

Protocol first published: Issue 3, 2005

Review first published: Issue 4, 2008

29 April 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Tina Lavender, Anna Hart and Rebecca Smyth assessed studies for inclusion independently and extracted all the data. All three authors interpreted the results individually. Tina Lavender drafted and finalised the text of the review. Anna Hart and Rebecca Smyth contributed to the content.

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DECLARATIONS OF INTEREST

Tina Lavender was investigator of two trials included in this review; therefore she was not involved with evaluating these studies.

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