

A Randomized Controlled Trial of a Bedside Partogram in the Active Management of Primiparous Labour

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Abstract

Objective: The partogram is a pictorial representation of the progress of labour, used in an effort to enhance early recognition of dystocia and help avoid Caesarean section (CS). The objective of this study was to evaluate the effect of partogram use on the CS and obstetric intervention rates.

Methods: We conducted a randomized controlled trial of use of the partogram in 1932 primiparous women with uncomplicated pregnancies at term. Patients were randomly assigned to one of two 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 in written notes. Outcomes were stratified according to whether labour was spontaneous or induced and whether membranes were initially intact or ruptured. The primary outcome was the rate of CS; secondary outcome measures were rates of obstetric intervention for dystocia.

Results: There was no significant difference between the groups in rates of CS (partogram 24%, standard notes 25%), rates of other interventions, amniotomy, oxytocin use, or the mean cervical dilatation in labour.

Conclusion: In this study, the use of a partogram without a mandatory management of labour protocol had no effect on rates of CS or other intrapartum interventions in healthy primiparous women at term.

Résumé

Objectif : Le partogramme est une représentation graphique du déroulement du travail qui est utilisée en vue d'améliorer le dépistage précoce de la dystocie et de contribuer à éviter le recours à la césarienne (CS). Cette étude avait pour objectif d'évaluer l'effet du recours au partogramme sur les taux de CS et d'intervention obstétricale.

Key Words: Partogram, Caesarean section, active management of labour (AML), oxytocin, amniotomy

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Méthodes : Nous avons mené un essai comparatif randomisé qui portait sur le recours au partogramme chez 1 932 femmes primipares présentant des grossesses sans complication à terme. Les patientes ont été affectées au hasard à l'un des deux groupes suivants : le groupe « standard », dans le cadre duquel le déroulement du travail a été documenté au moyen de notes manuscrites, ou le groupe « partogramme », dans le cadre duquel le déroulement du travail a été enregistré au moyen d'un partogramme installé au chevet des patientes, en plus d'être documenté au moyen de notes manuscrites. Les issues ont été stratifiées en fonction des critères suivants : « Le travail était-il spontané ou avait-il été déclenché? » et « Les membranes étaient-elles initialement intactes ou rompues? ». Le taux de CS constituait le critère d'évaluation principal de l'essai, tandis que les taux d'intervention obstétricale visant la dystocie en constituaient les critères d'évaluation secondaires.

Résultats : Nous n'avons constaté aucune différence significative entre les groupes en ce qui a trait aux taux de CS (partogramme : 24 %, notes standard : 25 %), aux taux de mise en œuvre d'autres interventions, d'exécution d'une amniotomie et de recours à l'oxytocine ou, encore, en ce qui a trait à la dilatation cervicale moyenne au cours du travail.

Conclusion : Dans le cadre de cette étude, le recours à un partogramme en l'absence d'un protocole obligatoire de prise en charge du travail n'a exercé aucun effet sur les taux de CS ou d'autres interventions intra-partum chez les femmes primipares en santé à terme.

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INTRODUCTION

A partogram is a graphical representation of a woman's progress in labour, plotting the duration of labour in hours against cervical dilatation in centimetres. Use of the partogram is based on the assumption that it facilitates earlier recognition of dystocia, thereby optimizing the timing of appropriate intervention, such as amniotomy, oxytocin augmentation, or, most importantly, Caesarean section (CS).

Over the past two decades, CS rates in North America have risen from 5% to a high of 29%.¹ Dystocia in women accounts for approximately one-half of all primary Caesarean sections.² Use of the partogram in the management of labour has been endorsed by the World Health Organization³ and the Society of Obstetricians and Gynaecologists of Canada (SOGC),² both of which cite the identification and management of dystocia as a major priority. In developing countries the focus of managing labour is on preventing maternal and fetal death related to prolonged labour, whereas in developed countries the focus is on earlier identification and management of dystocia in order to offer interventions and avoid CS. Reduction of the rate of primary CS for dystocia would then reduce the rate of repeat CS.

The addition of a bedside partogram as a tool to improve the effectiveness of intrapartum care has been studied in retrospective and cohort studies.^{4,5} These studies demonstrated that cervical dilatation of less than 1 cm per hour in the active phase of labour was associated with an increased risk of operative delivery. However, effectiveness of the partogram in reducing CS rates has never been examined in a randomized controlled trial (RCT), although differing designs of the partogram have been studied in RCTs.⁶⁻⁸

To address the lack of RCT evidence about the use of the partogram, and to evaluate its effectiveness in guiding interventions to avoid dystocia, we conducted a randomized controlled trial of use of the partogram in 1932 primiparous women. Because the use of a partogram was not an established part of intrapartum care at our centre but had been frequently employed by many of our caregivers earlier in their careers, we felt that we were in a unique position to study the effect, if any, of adding a partogram to our routine intrapartum care. The purpose of this study was to evaluate prospectively the use of the partogram as a bedside tool in the management of labour and for reducing rates of CS and obstetrical intervention. We chose change in CS rate as our primary outcome measure because we believe it is the most clinically important outcome of the management of progress in labour.

METHODS

The study was carried out between July 1997 and December 1999 at two sites of the Department of Obstetrics and Gynaecology at the University of Toronto (Mount Sinai Hospital and the Toronto General Hospital). The study was approved by the Research Ethics Board at each hospital. These two units, located in the same street, shared many caregivers and practice patterns and, at the time of the study, were responsible for a total of approximately 6500 deliveries per year. As the units were part of a tertiary care perinatal complex, approximately 50% of cases were

considered to have perinatal risk factors. The population served in the two sites consisted of women with at-risk pregnancies and normal pregnancy referrals from the local large multi-ethnic population. At the time of the study, the attending caregivers were obstetricians in 80% of cases, family physicians in 15%, and midwives in 5% of cases.

Women were invited to participate in the trial if they were nulliparous, at 36 to 42 weeks' gestation, and carrying a singleton pregnancy with a cephalic presentation. The exclusion criteria included non-cephalic presentation, known major fetal structural anomaly, previous uterine surgery, or an acute obstetric complication such as antepartum hemorrhage or severe hypertension. All women who agreed to participate gave informed consent before being enrolled in the study.

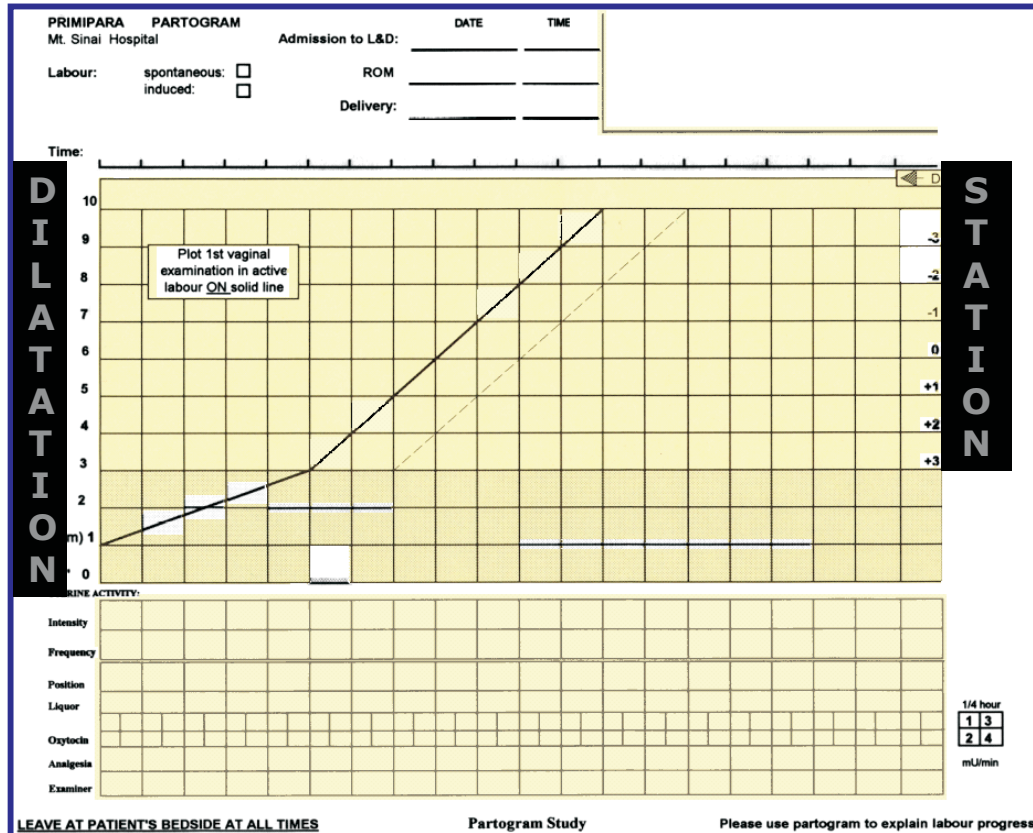
Eligible primiparous women in early labour were approached by research staff regarding enrolment in the study. We did not record data on ineligible or non-participating patients. Women who chose to join the study were randomly assigned to one of two groups: the standard group, whose progress in labour was recorded in written notes, or the partogram group, whose progress in labour was recorded on a bedside pictorial partogram as well as in the standard notes.

Randomization was performed off-site at the central office of the University of Toronto Maternal Infant and Reproductive Health Research Unit. This computerized randomization service was accessed by touch-tone telephone 24 hours per day. Randomization was stratified by labour initiation (spontaneous versus induced) and by membrane status (ruptured or intact). There was no stratification by hospital site because the sites shared staff and practices, and we felt therefore that there was unlikely to be a large site-specific effect. Women randomized to the standard arm received routine intrapartum care and had their progress in labour documented by standard sequential notes. Caregivers referred to these notes when deciding whether or not to offer an intervention for slow progress in labour.

In the partogram group, caregivers documented progress in labour in the standard written notes in the same manner as the standard group. However, in these cases a partogram was added to the documentation of progress. The investigators designed the partogram used in the study specifically for primiparous labour. It incorporated a two-hour alert line, but no action line (Figure). The back of the partogram held guidelines for its use.

In a series of presentations, the study team educated obstetric caregivers at both sites about completion of the partogram and the potential role of the partogram in the recognition of dystocia. Intrapartum caregivers were asked not to begin charting on the partogram until clinical

Bedside partogram used in the study



assessment established that the woman was clearly in the first stage of labour, i.e., uterine contractions were occurring every three to five minutes, with cervical dilatation of at least 3 cm. Once charting had begun, we asked that the partogram be left on a clipboard at the bedside, updated as labour progressed, and reviewed with the patient. Where possible, we requested that the partogram be used as the primary caregiver tool for following progress in labour and for counselling women about this progress and any proposed interventions.

There were no mandatory actions if progress was slow enough to cross the alert line, but we advocated adherence to the SOGC guidelines for labour management² in all study participants, and copies of these guidelines were made available to all caregivers. Members of the study team maintained a strong presence in the labour and delivery units to ensure compliance with randomization allocation and to promote maximum use of the partogram by the caregivers and parturients in the partogram group.

Detailed records were obtained from the charts of all participants in the trial. These records included the timing of all

pelvic examinations and interventions, including amniotomy, oxytocin augmentation, and operative delivery. We also recorded the duration of each stage of labour and the length of time after either spontaneous or artificial rupture of membranes, in addition to all significant intrapartum complications, including non-reassuring fetal heart tracing, intrapartum hemorrhage, fever in labour, neonatal sepsis, and admission to the neonatal intensive care unit (NICU).

Data and Statistics

A poll of obstetric staff at our institutions indicated that a 25% reduction in the rate of CS in primiparous women would be considered to be a clinically significant effect. The database at our institutions showed an average primary CS rate of 17% over the preceding five years. Therefore, the primary CS rate in the partogram group would have to be 12.75% or lower. We chose an alpha of 0.05 and a beta of 0.2 (power of 80%) with one-tailed significance. We opted for a one-tailed statistic, as we felt that only a positive effect for the study group would support its addition to our charting. With these parameters, we calculated that a sample size

Table 1. Group demographics

	Partogram n = 970	Standard n = 962
Mean maternal age in years (SD)	30.1 (5)	30.0 (5)
Mean gestational age in weeks (SD)	39.9 (1.4)	39.9 (1.3)
Spontaneous labour	580 (60%)	576 (60%)
Induced labour	390 (40%)	386 (40%)
Postdates pregnancy	186 (19%)	175 (18%)
Hypertension	27 (3%)	26 (3%)
PROM	53 (5%)	63 (6%)
Oligohydramnios	27 (3%)	37 (4%)
Other	87 (9%)	70 (7%)
Uncertain	10 (1%)	15 (2%)
Partogram		
Complete	785 (81%)	NA
Incomplete	185 (19%)	NA

SD: Standard deviation; PROM: premature rupture of membranes; NA: not applicable.

of 1732 (866 per arm) would be required in order to demonstrate a 25% reduction in the rate of CS.

All data were obtained by the study research nurses and entered onto data sheets and scanned off-site at the data managing centre in the University of Toronto Maternal Infant and Reproductive Health Research Unit. For symmetrically distributed continuous variables, the mean and the standard deviations were used. Frequency distributions were used for discrete data and tested by the chi-square test. We used the Microsoft Access data management software (Microsoft Corp., Redmond, WA) for data entry and management, and SPSS 10 (SPSS Inc., Chicago, IL) for analysis.

RESULTS

Between July 1997 and December 1999, we recruited 1932 women to the study, 1374 from Mount Sinai Hospital and 558 from Toronto General Hospital. We randomized 962 patients to receive standard care and 970 to care utilizing the partogram. We did not record data related to women who declined to participate in the trial. In all cases, patients complied with their group assignments. We received entry and outcome data on all participants. Baseline demographic characteristics were similar in both groups and are presented in Table 1.

There was no significant difference between the two groups in the primary outcome measure, with 25% of women in the standard group and 24% in the partogram group delivering by Caesarean section (See Table 2). There were also no

significant differences in spontaneous or operative vaginal delivery between the two groups. In the partogram group, the rate of completion of the partogram was 81%. The other 19% of partograms had a variable number of omissions (Table 1). Rates of intrapartum interventions (vaginal examination, amniotomy, and oxytocin augmentation) were the same in each group and were initiated at the same mean cervical dilatation (Table 3). Evaluation by staff for non-reassuring tracings occurred with equal frequency (41%) in each group. In addition, there were no differences between the groups with respect to significant neonatal or maternal morbidity (Table 4). The rates of maternal fever and neonatal sepsis, intact perineum, and minimal (first degree) tearing were equivalent in each group. Data related to higher degrees of perineal morbidity were not recorded.

DISCUSSION

Since 1954, when Friedman first reported graphic representation of progress in labour,⁹ obstetric caregivers have used the concept of a “partogram” to aid intrapartum care. Friedman’s curves were based on observations of cervical dilatation and fetal station graphed against time in hours from the onset of labour. An S-shaped curve of typical cervical dilatation plotted against time was described, and normal durations of labour were defined.

Philpott developed the first formal partogram in Zimbabwe in 1972.¹⁰ His aim was to promote early recognition of dystocia and referral of women from remote areas into hospitals with CS facilities. His partogram combined the

Table 2. Delivery outcomes

	Partogram n = 970	Standard n = 962	P
Mean birth weight in grams (SD)	3460 (479.7)	3440 (489.8)	NS
Caesarean section*			
Overall	240 (24%)	244 (25%)	NS
In spontaneous labour	125 (13%)	121 (13%)	
In induced labour	115 (12%)	123 (13%)	
First stage of labour	177 (18%)	191 (20%)	
Second stage of labour	63 (6%)	53 (6%)	
Operative vaginal delivery			NS
Spontaneous labour	173 (30%)	178 (31%)	
Induced labour	121 (31%)	89 (23%)	
Spontaneous vaginal delivery			NS
Spontaneous labour	282 (49%)	277 (48%)	
Induced labour	154 (40%)	174 (45%)	

SD: Standard deviation; NS: not statistically significant, $P > 0.05$.

*Categories for Caesarean section are not mutually exclusive.

graphic details of labour progress, developed by Friedman in 1954, with Hendricks' concept of a carefully defined starting time¹¹ and added information about fetal and maternal condition. Beazley and Kurjak modified the partogram to commence at the first vaginal examination and end at delivery.¹²

In England, Studd et al.¹³ studied 741 consecutive spontaneous labours to identify high-risk labours that needed oxytocin stimulation. Uterine contractions were augmented if progress extended two hours past the limit indicated by the nomogram. This resulted in shorter labours, fewer instrumental deliveries and Caesarean sections, and higher neonatal Apgar scores than in those labours that were not stimulated. This study, building on the reports of Philpott and Castle,¹⁴ was followed by increased use of the partogram in the United Kingdom, and its use subsequently spread throughout the world.

Over a number of years in Dublin, O'Driscoll introduced an intrapartum care program known as the Active Management of Labour (AML).¹⁵ In addition to strict adherence to use of the partogram, the care of women in the AML consisted of (a) accurate diagnosis of labour, (b) early amniotomy, (c) high-dose oxytocin for poor progress, and (d) one-to-one labour support. With adherence to this program, O'Driscoll's group reported that the incidence of prolonged labour in spontaneously labouring primiparous women could be reduced, while maintaining CS rates as low as 5%.¹⁶

Since the 1970s, efforts have been made in many countries to reduce rising rates of CS. In addition to peer review committees and support for vaginal birth after CS (VBAC), interventions to reduce primary CS for dystocia have also been studied. The various components described by O'Driscoll in his program have been studied, both collectively and separately. To date there have been two RCTs of the overall AML program. Frigoletto et al. found that strict adherence to AML guidelines did not reduce CS rates but was associated with a shorter duration of labour and less maternal fever.¹⁷ Lopez-Zeno et al. reported a CS rate of 10.5% in their AML group, compared with 14.1% in the traditional management group, without increasing maternal or neonatal morbidity.¹⁸ This 26% reduction in the CS rate was due primarily to a decrease in dystocia.

There have also been RCTs of some of the individual components of AML. Fraser et al., in an RCT of early amniotomy, demonstrated a shorter duration of the first stage of labour but no difference in CS rate.¹⁹ One-to-one continuous intrapartum support has been associated with a reduced need for intrapartum analgesia, fewer operative births and less reporting of dissatisfaction with childbirth experiences.²⁰ However, a large North American trial of continuous support by nurses found no effect on CS rates in hospitals characterized by high rates of intrapartum interventions.²¹

Proponents of the use of a partogram suggest that it facilitates early diagnosis of dystocia and, therefore, more timely

Table 3. Intrapartum duration and interventions

	Partogram n = 970	Standard n = 962	P
Duration of first stage: mean in hours (SD)			NS
Spontaneous labour	16.8 (7.3)	16.0 (7.6)	
Induced labour	14.0 (6.8)	13.9 (7.0)	
Duration of second stage: mean in hours (SD)			
Spontaneous labour	2.4 (1.8)	2.4 (1.9)	
Induced labour	2.7 (1.9)	2.5 (1.9)	
Number of vaginal examinations after 2 cm (mean)	4	4	
Epidural analgesia	902 (93%)	879 (91%)	
Cervical dilatation at insertion of epidural (mean)	3 cm	3 cm	
Artificial rupture of membranes (ARM)	521 (53.7%)	520 (54.1%)	NS
Cervical dilatation at ARM (mean)	4 cm	4 cm	
Oxytocin augmentation	757 (78%)	755 (78%)	NS
Cervical dilatation when oxytocin begun (mean)	3 cm	3 cm	
Maximum oxytocin dose (mU/min) mean (SD)	11.9 (7.8)	12.4 (8.3)	NS
Evaluation for non-reassuring fetal heart tracing	399 (41%)	391 (41%)	

SD: standard deviation; NS: not statistically significant, $P > 0.05$.

Table 4. Maternal and neonatal morbidity

	Partogram n = 970	Standard n = 962	P
Maternal morbidity			
Intact perineum, or 1st degree tear	424 (44%)	444 (46%)	NS
Intrapartum temperature $> 38^{\circ}\text{C}$	114 (12%)	78 (8%)	NS
Postpartum temperature $> 38^{\circ}\text{C}$	32 (3%)	24 (2%)	NS
Neonatal morbidity			
1-minute Apgar < 7	113 (11.6%)	99 (10.2%)	NS
5-minute Apgar < 7	12 (1.2%)	10 (1.0%)	NS
NICU admission	33 (3.4%)	37 (3.9%)	NS
Received antibiotics	115 (11.9%)	97 (10.1%)	NS

NS: not statistically significant, $P > 0.05$; NICU: neonatal intensive care unit.

intervention. These trials have largely focused on the design of the partogram.⁶⁻⁸ Cartmill and Thornton found that changing the ratio of the units on the x- and y-axes, thereby changing the gradient of the graph, affected obstetric decision-making.⁶ Lavender et al. reported that variation in placement of an “action” line at two, three, or four hours resulted in clinically significant changes in CS rates and significant differences in maternal satisfaction.⁷ More recently, in a prospective cohort study of 1413 women, Sizer et al. evaluated the role of the partogram in the second stage of labour and found that it represents an objective basis for management of the second stage of labour.⁸

These authors, and others, have stated that the role of the partogram in the first stage of labour has been established. To date, however, there have been no published randomized trials on the effectiveness of the partogram alone to change intrapartum outcomes. Completion of a partogram was not a standard part of intrapartum care at hospitals in our centre. Our presumption was that addition of a partogram would improve care and reduce the CS rate, and we decided to test this in an RCT prior to introducing the partogram as a standard part of our intrapartum care. The presumption was not supported by the study results: there were no differences in obstetric outcomes between the two groups.

There are a number of possible reasons why the outcome of this trial was negative. The first is that the study result represents a true negative: that there is no benefit to the addition of a partogram and that a graphic depiction of labour does not add to carefully compiled caregiver notes. However, other factors must be considered before stating that there is no effect from the addition of a partogram.

First, given the very close level of monitoring and care administered to all women in both groups, and the absence of mandatory interventions in either group, it would be difficult for any one intervention to cause a large effect on outcomes in either group. Moreover, as in any study, the possibility of a Hawthorne effect exists; that is, the trial itself might have changed the intensity of care given to the women in labour.

Another possibility is that rates of intervention were already appropriate in our patient population and did not need extra guidance from a partogram. However, the primary CS rate in our study was higher than we expected, reflecting, in part, an increase in CS rates across Canada and worldwide. Our rate was also higher than those found in other trials of the active management of labour. This may be because, unlike other trials, we did not limit enrolment in the trial to women with very low-risk, normal pregnancies. O'Driscoll commented that the rate of CS in the second stage of labour was much greater in the trials of AML reported by Frigolletto et al. (a rate of 4%) and by Lopez-Zena et al. (a rate of 3%) than in the Dublin experience (0.2%).²² In both groups in our trial, the rate of second stage CS was higher again (approximately 6%).

There is a risk of a selection bias regarding subjects, as we did not record outcomes data for women who were not randomized. Many women were randomized after the diagnosis of labour (unlike most active management trials), thereby possibly excluding women whose labour was faster or who were in too much pain to discuss recruitment. Hence, study patients potentially represented a group at higher risk for requiring CS. It is possible, therefore, that use of a partogram might be more effective if applied to *all* women in labour rather than to selected women.

The absence of effect might also be explained by non-compliance with the trial. Although the study employed the best randomization available and there were no randomization violations, there remained an ongoing risk of non-compliance after randomization. There was an 81% completion rate; 19% of partograms were not completed fully. This 19% incomplete compliance rate may have been responsible for some of the lack of difference between the groups.

A significant concern of the investigators was that inadequate use of the partogram in the intrapartum care of the

partogram group patients could reduce effect size between groups. We attempted to minimize this risk by providing multiple information sessions for caregivers before and during the trial. The investigators and a full-time research nurse spent as much time as possible encouraging use of the partogram at the bedside in patients randomized to the partogram arm. It remained possible, however, that caregivers complied with the requirement to complete the partogram but did not embrace it as being central to intrapartum decision-making. This risk was exacerbated by there being some overlap among staff, so caregivers might simultaneously care for patients in both groups. A study design that randomized partogram use between hospital units rather than between individual patients might be more successful in changing the culture of the labour ward and demonstrating any true effect from the use of a partogram.

It is also possible that the use of a partogram is effective only as part of a rigorously applied management protocol, in which inadequate progress in labour is routinely managed by appropriate interventions. By encouraging rather than mandating adherence to the SOGC guidelines for management of labour, we may not have provided the circumstances for an adequate comparison of the two groups.

CONCLUSION

This trial demonstrated that use of the partogram did not reduce the rate of Caesarean section in primiparous women. The addition of an intrapartum partogram did not result in any measurable difference in the incidence of intrapartum interventions or the duration of labour. A pragmatic interpretation of these findings might be that addition of a partogram to intrapartum care in units where it was not previously used is unlikely to have a major effect on rates of CS or obstetric intervention.

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