Reducing Cesarean Delivery Rates: An Active Management Labor Program in a Setting with Limited Resources

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Objective: *To determine the effect of an active management of a labor program on the rate of cesarean section and labor outcomes in low-risk nulliparous pregnancies in a setting with limited resources.*
Material and Method: *Nine hundred and seventy-five low risk nulliparous pregnant women were randomized to receive either active management of a labor program (n = 325) or conventional management (n = 650). The rate of cesarean section and labor outcomes were compared between the two groups using Chi-square and t-tests.*
Results: *The subjects in the active management program had significantly shortened first stage of labor and total duration of labor compared with the conventional group (538.0 $\pm$ 242.9 min vs 589.4 $\pm$ 263.8 min, $p < 0.05$, 539.3 $\pm$ 261.4 min vs 610.3 $\pm$ 264.4 min, $p < 0.001$, respectively). There was no statistical difference found in the rate of cesarean section and other labor outcomes.*
Conclusion: *The active management program shortened the first stage and duration of labor in low-risk nulliparous pregnant women.*

Keywords: *Active management of labor, Cesarean section, Randomized controlled trial*

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Despite the fact that the World Health Organization (WHO) states that no region in the world is justified in having a cesarean section rate greater than 10 to 15 percent[1], rising cesarean section rates continue to be a problem in most countries. In the United States, for example, the total cesarean section birth rate climbed from 5.5% in 1970 to 24.4% in 2001[2,3]. In the United Kingdom and Brazil, the current rates are about 23.0% and 36.4%,respectively[4]. The most commonly described indication for primary cesarean section births worldwide is dystocia which contributed about one third[3]. Finding a means to decrease the incidence of dystocia would, therefore, imply a significant benefit to the reduction of cesarean section rates.

Active management of labor is a program that was introduced in 1969, with the purpose to lower the rate of primary cesarean deliveries by reducing the risk of dystocia[5].The program includes a selective criteria for nulliparous pregnant women, strict criteria for diagnosis of labor, early rupture of amniotic membranes, prompt intervention with high-dose oxytocin in the event of inefficient uterine contraction, continuous professional support and the use of electronic fetal monitoring.

Over the three decades, long-term use of this program at the National Maternal Hospital in Dublin led to a cesarean delivery incidence of 4.2%, similar to the original published percentage[6]. However, the efficacy of the program for reduction of cesarean section rates is still controversial and being investigated. Whereas some investigators found a reduction in the rate of cesarean sections from using an active management of labor program[7-9], others studies, including randomized controlled trials, showed no significant reduction[10-12]. In addition, maternal and neonatal

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safety has been questioned, despite reports that there are no increased complications[10,12].

Most studies take place in the setting of developed countries, where modern equipment and sufficient staff exist. In developing countries, however, there are frequently insufficient facilities and multiple economic problems. In these countries, there have been an inadequate number of studies regarding the efficacy of such a program.

Therefore, the present study was designed as a randomized controlled trial, to evaluate the efficacy of active management of labor in situations of limited resources, specifically in the setting of a developing country. This trial sought to test whether such a program could reduce both the rate of cesarean deliveries and the duration of labor in low-risk nulliparous pregnant women.

Material and Method

The authors conducted a randomized controlled trial of active management of labor program at Thammasat University Hospital, Thailand from May 2001 to December 2002. Thammasat University Hospital is a 500 bed teaching hospital complex. The trial was approved by the Thammasat University Research Review Committee and all participants signed the informed consent.

Consenting participants were assigned randomly to undergo either active management or conventional management of labor, with a ratio of one to two, respectively. Randomization was performed by opening sequentially numbered opaque envelopes. Each envelope contained an allocation that had been determined with the use of a random number table. The envelopes were kept in a locked drawer that was accessible only to the researchers. Each envelope was opened by an allocated midwife in the presence of the patient.

The inclusion criteria were nulliparous pregnant woman with the presence of a single live fetus; a normal fetal heart pattern at admission, cephalic presentation, gestational age $\geq$ 37 weeks, spontaneous labor without evidence of fetal distress such as abnormal external fetal heart monitoring or thick meconium-stained amniotic fluid at admission, no contraindications to vaginal delivery or oxytocin augmentation and no medical or surgical complications. Pregnant women who developed medical conditions or who did not want to participate during labor care were excluded. Patients with diabetes, cervical incompetence, and pregnancy-induced hypertension were ineligible for participation in the study.

A diagnosis of labor was made by using the following criteria: regular painful contractions occurring at least once every 5 minutes; contraction duration of at least 40 seconds; and either spontaneous rupture of membranes or bloody show with cervical dilatation and full effacement.

In the active management group, artificial rupture of membranes was performed within 1 hour of admission, two-hourly vaginal assessments and high doses of oxytocin augmentation were given if cervical dilatation was less than 1 cm/hr in the first stage of labor. Prolonged labor was defined as labor in excess of 12 hours.

The high dose oxytocin augmentation was defined as starting at 6 mU/min and increasing by 2 mU/min, every 30 minutes by infusion pump, titrating to 5 contractions in 10 minutes lasting at least 40 seconds. The maximum dose of oxytocin permitted was 40 mU /min.

In the particular setting of the present study, with limited facilities, the authors used external fetal heart monitoring at the time of admission and, otherwise, when the fetal heart rate was irregularly by intermittent auscultation. Fetal scalp blood sampling and internal fetal heart monitoring were not available at the facilities used for the present trial. Epidural anesthesia was also not available.

In the conventional management group, there was no standardized protocol for initiating or stopping oxytocin, nor was there a prescribed schedule for measuring dilatation of the cervix. Therefore, as in all institutions, there was variation in practice between the consultant obstetricians.

Dystocia was defined as a failure to progress in labor, either because of arrest of dilatation in the first stage of labor or as an arrest of descent in the second stage of labor. Continuous external fetal heart monitoring was performed if a fetal heart rate abnormality was detected. Fetal distress was defined as either repetitive late deceleration or repetitive severe variable deceleration of fetal heart rate, after attempts of intrauterine resuscitation (with hydration, uterine displacement, and oxygen administration) failed.

Fever was defined as at least 38 C any time from the onset of labor, through 24 hours after delivery.

Chorioamnionitis was determined if there were clinical symptoms and signs of chorioamnionitis any time from the onset of labor through delivery itself. Thick meconium stained amniotic fluid was recorded at the time of delivery.

Cesarean deliveries were performed as indicated for dystocia or fetal distress. Decisions were made by the consultant obstetrician on duty at the time. While the standard of care at Thammasat University Hospital is expected to include a laboring woman/midwife ratio of 1:1, the realistic limitations at the hospital resulted in an actual ratio closer to 2:1.

Statistical analysis was carried out with independent unpaired T-test for continuous variables and Chi-square test analysis for frequency data. Significance was set at a level of $p < 0.05$.

Results

From May 2001 to December 2002, 975 pregnant women were recruited for this study. Of that group, 15 post-randomizations were excluded because of severe preeclampsia, a misdiagnosis of breech presentation and participant choice to be discontinued from the trial. An unequal randomization (active and conventional management groups in a ratio of 1:2) was used to assign more participants to the conventional management group. 320 women were randomized to active management and 640 women to conventional management. The results are reported in Tables 1 below.

Table 1 shows the demographic features of the participants. There were no statistically significant differences in age, height, pre-pregnant BMI and weight gain between the active management and the conventional groups, except in the number of antenatal care visits. The average antenatal care visit in the active management group was significantly higher than those enrolled in the conventional group.

The labor characteristics are shown in Table 1. There was no difference statistically in cervical dilatation at admission between the two groups. The number of patients with oxytocin use in the active management group was significantly higher than in the conventional group, however the number of patients with meperidine use was not significantly different.

The first stage and the total length of labor in the active management group were significantly shorter than in the conventional group, although the length of the second stage showed no statistical difference. The total length of labor averaged 71 minutes shorter in the active management group.

The number of participants who had a vaginal delivery with prolonged labor was 72 out of 282 (25.5%) in the active management group and 195 out of 546 (35.7%) in the conventional group, which was different statistically.

Table 1 shows details of the modes of delivery and the indications for cesarean sections. There were no significant differences in the number of normal deliveries and operative obstetrics. There were 38 cesarean sections in the active management group (11.9%) and 94 in the conventional management group (14.7%), which was a reduction by 19% in the actively managed group.This was not statistically significant. Nevertheless, the incidence of dystocia was lower compared to the conventional management group. Cesarean sections performed for fetal distress were higher in the active management group.

Table 1 demonstrates that there was no significant difference in the number of maternal complications between the two groups. There was no chorioamnionitis in the active management group. The birth weights were comparable. Despite the fact that the number of neonates with thick meconium stained amniotic fluid and whose APGAR scores at one minute were less than 7, were lower in the active management group, there was no statistical difference.

Discussion

The authors conducted a randomized trial to evaluate whether a program for active management of labor could lower the rate of cesarean sections among women delivering their first babies, in a setting with limited resources. While the decreased rate was not statistically significant, there was a trend toward a decreased rate with a 19% risk reduction.

The cesarean section rate in the active management group was 11.9%, which was obviously high when compared to the original report[5]. However, it was difficult to compare the cesarean section rate between the present study and other studies from different countries, due to many factors, including different patient populations and resources.

Until the present study, there have been no randomized trials with this particular setting and logistical situation. Only a related historical cohort study in Thailand was performed by Chanrachakul et al[13]. In several countries including Thailand, the concept of 'once cesarean section, always cesarean section' is still generally accepted as the standard policy. The consequence of this acceptance brought the overall cesarean section rate up to 22% in Thailand[14]. Therefore, the implementation of active management of labor in the present study to reduce unnecessary primary cesarean sections might have a major impact on the cesarean delivery incidence.

Table 1. Characteristics between Active management group and Conventional management group

	Active management (n = 320)	Conventional management (n = 640)	p value
Demographic characteristics			
Age (years)	24.4±4.5	24.2±4.5	NS
ANC	7.7±2.9	7.1±3.4	<0.05
Height (cm)	156.9±4.8	156.6±5.5	NS
Pre-pregnant BMI (kg/m^2)	20.2±2.9	20.5±3.0	NS
Weight gain (kg)	13.6±4.7	13.3±5.2	NS
Labor characteristics and length of labor			
Cervical dilatation at admission (cm)	3.1±1.2	3.1±1.4	NS
Oxytocin use	178 (55.6%)	305 (47.7%)	<0.05
Meperidine use	86 (26.9%)	163 (25.5%)	NS
Length of labor ($\bar{x}$ ± SD) (minutes)			
First stage	538.0±242.9	589.4±263.8	<0.05
Second stage	24.4±20.4	26.6±26.3	NS
Total	539.3±261.4	610.3±264.4	<0.001
Prolong labor ≥ 12 h	72/282 (25.5%)	195/546 (35.7%)	<0.01
Mode of delivery and indication for cesarean section			
Mode of delivery			
Normal labor	244 (76.3%)	455 (71.1%)	NS
F/E or V/E	38 (11.9%)	91 (14.2%)	NS
C/S	38 (11.9%)	94 (14.7%)	NS
Indication for C/S			
Dystocia	30 (78.9%)	83 (88.3%)	NS
Fetal compromise	8 (21.1%)	11 (11.7%)	NS
Maternal complications and neonatal outcomes			
Maternal complications			
Fever	26 (8.1%)	53 (8.3%)	NS
Chorioamnionitis	0 (0.0%)	6 (0.9%)	NS
Neonatal outcomes			
Birth weight (g)	3025.3±382.7	3026.5±382.8	NS
Thick meconium AF	12 (3.8%)	30 (4.7%)	NS
APGAR at 1 min < 7	6 (1.9%)	15 (2.3%)	NS

ANC = The number of antenatal care visits, BMI = Body Mass Index,
C/S = cesarean section, F/E = forceps extraction, V/E = vacuum extraction, AF = Amniotic fluid

The percentage of fetal distress was almost two times higher in the active management group. Similar findings were reported by Tabowei et al[9], Chanrachakul et al[13] and Rogers et al[15]. The reason for these results could be that the criteria for diagnosis of fetal distress used in the present study, was based on external fetal heart monitoring. Nevertheless, the present study showed no adverse effects in perinatal mortality or lower APGAR scores of the newborn.

Many studies have shown a clearly significant reduction in the length of labor, including the present study[7-12]. The total length of labor was reduced by 71 minutes in the present study. Prolonged labor (more than 12 hours) was also significantly decreased in the present study. Most studies have shown similar findings in that active management program requires more oxytocin, either in frequency or amount. However, using high-dose oxytocin showed no statistically significant adverse effects to the fetus either in perinatal morbidity or in APGAR score[16-18]. These findings were consistent with the results found in the present study.

The present study showed a low rate of maternal and fetal complications in both groups, most likely because the program to only enroll low-risk pregnant women was strictly followed. These findings represent the safety of this program in such a situation. However, careful monitoring of fetal heart rate

should be considered when using this program. Moreover, the cost of a full package active management of labor should outweigh the cost of performing cesarean sections and, also, the lower maternal morbidity from less cesarean deliveries should be weighed with the possibility of more fetal distress in using this program.

In the setting of the present trial, epidural analgesia was not available, and meperidine was chosen as an alternative efficient analgesic agent[19]. There were no significant differences between the two groups using meperidine. Although, epidural analgesia is an ideal method to reduce labor pain, many studies have shown that it may prolong the duration of labor and increase the incidence of cesarean deliveries for nulliparous pregnant women[20-22].

There are a couple of key limitations in the present study. Firstly, the duration of follow up of participants may be too short to evaluate long-term complications. Secondly, the sample size of the active management group is too small to reach statistical significance for efficacy evaluation.

In conclusion, the present study demonstrated a reduction in the length of labor and the number of pregnant women with prolonged labor, by using an active management program in low-risk nulliparous pregnant women in a setting with limited resources. However, this program reduced the rate of cesarean sections non-significantly, there was a trend toward a decreased rate.

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การศึกษาการลดอัตราการผ่าตัดคลอดในกลุ่มสตรีตั้งครรภ์ที่ได้รับการดูแลการคลอดแบบตื่นตัว

จรินทร์ทิพย์ สมประสิทธิ์, ชำนาญ แท่นประเสริฐกุล, อติวุทธ กมุทมาศ

วัตถุประสงค์*: เพื่อศึกษาเปรียบเทียบอัตราการผ่าตัดคลอดและผลของการคลอด ในสตรีตั้งครรภ์แรกที่ไม่มีภาวะแทรกซ้อน ที่ได้รับการดูแลการคลอดแบบตื่นตัว (Active management) กับการดูแลโดยทั่วไป (Conventional management)*

รูปแบบการวิจัย*: การวิจัยแบบทดลองสุ่มตัวอย่างแบบอัตรา 1:2 กลุ่มตัวอย่าง 2 กลุ่ม*

การดำเนินการวิจัย*: สตรีตั้งครรภ์แรกที่ไม่มีภาวะแทรกซ้อนของการตั้งครรภ์ จำนวน 975 ราย ที่มาคลอดบุตรในโรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ ได้รับการเลือกโดยการสุ่ม 1:2 เพื่อรับการดูแลแบบการคลอดแบบตื่นตัว จำนวน 325 ราย และได้รับการดูแลแบบทั่วไป จำนวน 650 ราย และเปรียบเทียบอัตราการผ่าตัดคลอดและระยะการคลอดระหว่าง 2 กลุ่ม โดยใช้ Chi-square และ t-tests*

ผลการวิจัย*: อัตราการผ่าตัดคลอดและผลของการคลอดต่อมารดาและทารกไม่มีความแตกต่างกัน อย่างมีนัยสำคัญทางสถิติ แต่พบว่าในกลุ่มที่ได้รับการดูแลการคลอดแบบตื่นตัว มีการดำเนินการคลอดในระยะที่ 1 และระยะเวลาการคลอดโดยรวม สั้นกว่าในกลุ่มที่ได้รับการดูแลแบบทั่วไปอย่างมีนัยสำคัญทางสถิติ (538.0 $\pm$ 242.9 นาที, 589.4 $\pm$ 263.8 นาที, $p < 0.05$ และ 539.3 $\pm$ 261.4 นาที, 610.3 $\pm$ 264.4 นาที, $p < 0.001$ ตามลำดับ)*

สรุป*: การดูแลการคลอดแบบตื่นตัวช่วยลดระยะเวลาตั้งแต่เจ็บครรภ์จนกระทั่งคลอด ในสตรีตั้งครรภ์แรกที่ไม่มีภาวะแทรกซ้อนของการตั้งครรภ์*