The Effect of Early Versus Late Amniotomy on The Course of Labor

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Objective: *Comparison effect of early versus late amniotomy on the duration time of first and second stage of labor, the cesarean section rate and analgesic use during labor.*

Study design: *Randomized control trial study.*

Setting: *Labor unit, Department of Obstetrics and Gynecology, Phramongkutklao Hospital.*

Subjects: *120 term singletons, nulliparous with cephalic presentation pregnant women who had spontaneous labor and came to labor room from June 1st, 2013 to October 31th, 2013.*

Material and Method: *After signed the consent form, the selected pregnant women were divided into two groups by random number table. The early amniotomy which performed when patients entered the active phase of labor (cervical dilatation 3-5 cm., n=60), and the late amniotomy which membrane was left intact and amniotomy was reserved for specific indications (n=60). The outcome of labor was recorded by the attending physicians.*

Main outcome measures: *Compare the duration of labor between two groups.*

Results: *The time of first stage of labor was not different between early and late amniotomy groups (560.0 vs. 637.5 min; p<1.0; time difference 77.5 minutes). There was statistically significant difference between women in the early amniotomy and control groups in cesarean section rate (43.3% vs. 20%; p = 0.006).*

Conclusion: *The amniotomy should not be introduced routinely as the standard labor management, because it was not proven to shorten the course of labor. The authors recommend that the women be informed about the results of the amniotomy, then the decisions were made between the women and their caregivers.*

Keywords: *Duration of labor, Amniotomy, Cesarean section rate*

J Med Assoc Thai 2017; 100 (2): 125-132
Full text. e-Journal : *http://www.jmatonline.com*

In the process of labor, the pregnant women usually has uterine contraction which may be inadequate to bring about demonstrable effacement and dilatation of the cervix. In 1970s, O' Driscoll[1] introduced the active managements of labor including oxytocin administration and amniotomy and believed it could reduce the duration of labor, dystocia and cesarean section rate[2-5]. The place of amniotomy as a non-pharmacological method of labor induction and augmentation is well-established, as possibly a result of natural prostaglandins[6]. The other benefit of amniotomy is earlier detection of meconium-stained amniotic fluid, and the opportunity to apply an electrode to the fetus or insert a pressure catheter into the uterine cavity for monitoring[6]. Many researches shown that amniotomy might reduce the duration of labor only 1-2 hours and possibly produced the complications such as chorioamnionitis, umbilical cord prolapsed[6-9] and abnormal fetal heart rate pattern[10-15]. Furthermore, the American College of Obstetricians and Gynecologists (ACOG)[16] did not suggest amniotomy for every woman who was in labor. They commented that amniotomy might reduce the duration of labor as the administration of oxytocin, but possibly increased the rate of chorioamnionitis. From the study of the Cochrane Pregnancy and Childbirth Group's Trials Register, there was evidence showed no shortening of the length of first stage of labor and a possible increased in caesarean section rate. They did not recommend routine amniotomy as part of standard labor management and care[17,18].

Amniotomy is a common procedure usually performed in the labor room of Phramongkutklao Hospital. The authors have concerned about the advan-

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tages and disadvantages of amniotomy. From all the above reasons, we conducted the present research to determine the influence of amniotomy on the outcome of labor, especially the duration of labor, in the early amniotomy group (done in early active phase who had cervical dilatation 3-5 cm.) compare to the late or selective amniotomy group (done in deceleration phase of active phase who had cervical dilatation 8-10 cm. or with other indications such as protraction of cervical dilatation, need to apply internal monitoring, etc.).

Material and Method

After the study protocol was approved by the Institutional Review Board Royal Thai Army, Medical Department, this randomized controlled trial study was conducted at labor room of Phramongkutklao Hospital from June to October, 2013. We assumed an alpha error of 0.05, a beta error of 0.1 (or 90% power); a sample size was calculated according to a study of Nachum Z et al[19] by used the first stage of labor interval of each group so 60 women per group was required. We enrolled 120 singleton term nulliparous pregnant women who had fetal cephalic presentation with spontaneous labor, cervical dilatation between 3-5 cm. and having no history of amniotic membrane ruptured considered as eligible participants. These women were counseled and after given full consent were eligible to be included in the present study. Women with medical illness, obstetrical complication, contraindications for amniotomy, having previous uterine scar, fetal anomaly, non-reassuring fetus and refusal to join the research were excluded.

Participants were randomized into two groups by simple random sampling using the random number table into early amniotomy and late or selective amniotomy groups. The amniotomy was done in the early amniotomy group when cervical dilated between 3-5 cm. and Bishop scores more than 6. In the late amniotomy group, the amniotomy was preserved until spontaneous rupture of membrane or for other specific indications such as protracted of cervical dilatation, need of internal fetal monitoring to assess fetal heart rate or cervical dilatation at 8-10 cm. (deceleration phase of first stage of labor). However, in both groups, the participants were received the standard management that routinely practiced in Phramongkutklao Hospital. During labor, external fetal monitoring and analgesia were used individually, depended on the maternal and/or fetal conditions and the physicians' considerations. In cases of poor uterine contraction, the intravenous oxytocin infusion was administered. The cesarean section and any obstetrics procedures, such as vacuum and forceps extraction, were considered by using the standard criteria. The interpretation of the abnormal fetal monitoring was categorized into 3 categories according to Three-Tier Fetal Heart Interpretation system.

The data were collected in record form by attended physicians at that period. The main outcome was the first stage of labor interval, and the secondary

Table 1. Demographic data of all women by treatment group

Demographic data	Early amniotomy group n = 60	Late amniotomy group n = 60	*p*-value
Maternal age, years	25 (15 to 35)	23 (15 to 34)	0.384
Gestational age, weeks	39.4 (37.0 to 40.7)	39.4 (37.3 to 41.0)	0.433
Occupations			0.841
- Government	10 (16.6)	7 (11.7)	
- Employee	14 (23.3)	17 (28.3)	
- Private business	7 (11.7)	11 (18.3)	
- House wife	7 (11.7)	7 (11.7)	
- Student	22 (36.7)	18 (30.0)	
Weight, kg	64.5 (53.0 to 76.5)	65.9 (46.5 to 92.0)	0.508
Height, cm	160.0 (150.0 to 175.0)	158.0 (145.0 to 177.0)	0.087

Data are n (%) or median (min to max)

$p<0.05$ was statistical significant with Mann-Whitney U test

Table 2. Obstetric characteristic of all women by treatment group

Obstetric data	Early amniotomy group n = 60	Late amniotomy group n = 60	*p*-value
Gravida and parity			0.205
- G_1P_{0000}	48	43	
- G_2P_{0010}	12	12	
- G_3P_{0020}	0	3	
- G_4P_{0030}	0	2	
Bishop score	9 (7 to 13)	9 (7 to 13)	0.952
- Cervical dilatation, cm	3 (3 to 5)	3 (3 to 5)	0.094
- Station	-1(-2 to 0)	-1 (-2 to 0)	0.114
- Effacement	75 (50 to 100)	75 (50 to 100)	0.436
- Consistency			-
- Firm	0 (0.0)	0 (0.0)	
- Medium	0 (0.0)	0 (0.0)	
- Soft	60 (100)	60 (100)	
- Position			0.259
- Posterior	0 (0.0)	2 (3.33)	
- Middle	52 (86.67)	53 (88.33)	
- Anterior	8 (13.33)	5 (8.33)	
Oxytocin use	48 (80.0)	45 (75.0)	0.514
Amount of oxytocin use, mU/min-	1.99 (1.99 to 5.99)	2.16 (0 to 13.33)	0.451
Meconium-stained amniotic fluid	8 (13.33)	10 (16.67)	0.611
Analgesic use	42 (70.0)	30 (50.0)	0.025
Fetal heart rate			
- After amniotomy within 15 min			-
Category 1	60 (100.0)	60 (100.0)	
Category 2	0 (0.0)	0 (0.0)	
Category 3	0 (0.0)	0 (0.0)	
- After amniotomy more than 15 min			0.270
Category 1	54 (90.0)	60 (100.0)	
Category 2	4 (6.7)	0 (0.0)	
Category 3	2 (3.3)	0 (0.0)	

Data are n (%) or median (min to max)

p<0.05 was statistical significant with Mann-Whitney U test

results were the second stage of labor interval, rate of cesarean section, oxytocin use, analgesic use, abnormal fetal heart rate pattern from intrapartum fetal monitoring, incidence of fetal asphyxia by Apgar score, postpartum infection and chorioamnionitis.

Statistical analysis

Statistical analysis was performed with the intention to treat principle. Continuous outcomes were compared with the use of the Independent samples t-test or Mann-Whitney U test dependent on their distribution; dichotomous outcome was assessed with

Table 3. Duration of labor and mode of delivery of all women by treatment group

Duration and mode of delivery	Early amniotomy group (n = 60)	Late amniotomy group (n = 60)	*p*-value
Time from enrollment until fully cervical dilatation, min	205.0 (105.0 to 375.0)	215.0 (32.0 to 750.0)	0.713
Duration of first stage of labor, min	560.0 (202.0 to 1,380.0)	637.50 (180.0 to 1,350.0)	1.000
Duration of second stage of labor, min	26.0 (5.0 to 94.0)	19.00 (3.0 to 154.0)	0.073
Time from enrollment until delivery, min	241.5 (125.0 to 454.0)	244.50 (55.0 to 768.0)	0.763
Mode of delivery			
- Spontaneous vaginal	34 (56.7)	47 (78.3)	0.011
- Vacuum extraction	0 (0.0)	1 (1.67)	0.315
- Forceps extraction	0 (0.0)	0 (0.0)	-
- Cesarean section	26 (43.3)	12 (20.0)	0.006

Data are n (%) or median (min to max)

p<0.05 was statistical significant with Mann-Whitney U test

Table 4. Fetal outcome and obstetric complications of all women by treatment group

Fetal outcomes and obstetric complications	Early amniotomy group (n = 60)	Late amniotomy group (n = 60)	*p*-value
Fetal weight	3,240.00 (2,800.00 to 3760.00)	3,045.00(2,410.00 to 3,800.00)	0.123
APGAR score			
- At 1, min	9 (6 to 9)	9 (4 to 9)	0.557
- At 5, min	9 (8 to 9)	9 (8 to 9)	0.245
Fetal complications			
- Death	0 (0.0)	0 (0.0)	-
- Admission to ICU	2 (3.33)	0 (0.0)	0.150
- Cephalhematoma	9 (15.0)	12 (20.0)	0.470
- Meconium aspiration syndrome	0 (0.0)	0 (0.0)	-
- Intubation	0 (0.0)	0 (0.0)	-
Chorioamnionitis	0 (0.0)	0 (0.0)	-
Postpartum infection	0 (0.0)	0 (0.0)	-

Data are n (%) or median (min to max)

p<0.05 was statistical significant with Mann-Whitney U test

Chi-square test or Fisher's exact test where appropriate. Time to delivery was not normal distributed and was compared with the use of the Mann-Whitney U test. Relative risk by group and 95% confidence interval (CIs) were estimated. Statistical significant data were considered when *p*-value <0.05.

Results

A total of 120 pregnant women were divided into 60 in each group. For all of these studied population, all data were completely recorded and no missing subject through the study. The general information were asked for demographic data (Table 1). There was no statistically significant difference among the two groups in age, gestational age, occupation, weight and height.

Table 2 demonstrated obstetrical characteristics. There was no statistically significant difference between the early amniotomy and late amniotomy groups in Bishop Scores. The number of cases with oxytocin usage were 80% in early amniotomy group

and 75% in late amniotomy group, ($p = 0.514$), and the amount of oxytocin use were also not different. The meconium-stained amniotic fluid were found 13.33% in early amniotomy group and 16.67% in late amniotomy group, $p = 0.611$. The abnormal fetal heart rate (FHR) within 15 minutes after membrane ruptured were similar, however the abnormal FHR at more than 15 minutes after membrane ruptured were slightly higher in early amniotomy group (4 cases with FHR category II and 2 cases with FHR category III). However, there was no statistical significant difference between both groups (10.0% in early amniotomy group vs. 0% in late amniotomy group, $p = 0.27$). The statistical differences were found in number of analgesic useage with 70% in early amniotomy group and 50% in late amniotomy group, $p = 0.025$ (RR = 1.4, 95% CI 1.04 to 1.89).

For the primary outcome of the present study, in table 3 showed duration of labor and mode of delivery. There was no statistical significant difference among the two groups. Length of the duration from enrollment to fully cervical dilatation (differences of median -10 minutes, p-value = 0.731), duration of first stage of labor (differences of median -77.5 minutes, p-value = 1.000), second stage of labor (differences of median 7 minutes, p-value = 0.763) and the length of overall from enrollment until delivery (differences of median -3 minutes, p-value = 0.763). According to the route of delivery, the cesarean section in early amniotomy group was higher than late amniotomy group (43.33% vs. 20.00%, respectively, $p = 0.006$ and RR = 2.17, 95% CI 1.20 to 3.90).

There was no statistically significant in fetal birth weight, APGAR scores, fetal complications and postpartum infection or chorioamnionitis as showed in Table 4.

Discussion

The three main factors that play role in regulation the duration of labor are the birth passage (the pelvis), the passenger (the fetus), and the power (uterine contractility & maternal expulsive effort)[6]. In these three factors, uterine contraction is the only one factor that can be adjusted and controlled. The common ways of controlling the appropriate uterine contractility are oxytocin infusion and amniotomy, which are usually practiced. For an intervention to be recommended as routine practice in obstetrics, the evidence of its benefit for mothers and babies must be convinced and also adverse event must be none or rare. On the other hand, there are many evidences and theories that suggest the adverse effect of amniotomy. Therefore, the amniotomy is queried about it's usefulness or not, especially when compared to its disadvantage.

Previous studies about early amniotomy and its shortening effect of labor were found the reduction of the first stage interval in various degrees[5,7,18-20], but it did not show in the present study, neither the length of first stage nor second stage of labor. However, the exactly started point of the first stage was difficult to know because the information usually got from participants' memories and estimation, so recall bias might be occurred. We tried to reduce these problems by comparing the duration from enrollment (cervix dilated 3-5 cm.) to fully cervical dilatation. There were also no difference in these durations between two groups. The result was similar to the recent systematic review studied by Smyth RMD[17] that included 15 studies in their updated review, involving 5,583 women to assess the use of amniotomy in all labor that started spontaneously, which revealed no clear statistically significant difference between women in the early amniotomy and control groups in length of the first stage of labor. This result showed that early amniotomy may not help to shorten duration of labor. The oxytocin use rate for augmentation of labor was increased in early amniotomy group of many studies, especially the studies of Barrett JF, et al[10] and Lee SM[21]. In our study, there was no different in the rate of oxytocin use and the dose of oxytocin. These results may possibly reflect that the natural process of labor with only supporting by oxytocin infusion is adequate for keeping good uterine contraction and early amniotomy may not be necessary. However, the data about oxytocin adverse effect such as uterine hyperstimulation were not recorded. They may had some differences between the two groups that may need further study.

Intrapartum fetal assessment had been done as standard procedures in both groups and there were slight higher incidence of abnormal FHR monitoring found in early amniotomy group than late amniotomy group but it was not statistically significant. These data suggested that amniotomy may possibly lead to greater pressure on the fetal head during uterine contraction and umbilical cord was also more likely to be compressed, leading to abnormal FHR monitoring. However, there were two fetuses diagnosed as non-re-

assuring fetuses indicated for emergency cesarean delivery in the early amniotomy group, while none were found in the late amniotomy group. Previous studies suggested a number of potential important but rare risks associated with amniotomy, including problems with the umbilical cord or the abnormal FHR with no significant increasing the FHR abnormality correspond to non-reassuring fetus[17-19].

In present study, the cesarean section rate was significantly higher in the early amniotomy group. The possible explanation may be in the early amniotomy group; we punctured the amniotic sac at first and adjusted for good uterine contraction. If there was no cervical progression within 2 hours, the arrest of dilatation was diagnosed. While in the late amniotomy group, when no cervical progression within 2 hours, we performed amniotomy and reevaluated in the next 2 hours. The study of Rouse DJ in 1999[22] had challenged that a longer time at least 4 hours, was necessary before concluding the active phase of labor failure. The subsequent vaginal delivery rate after 2 hours extension was 61% for these women. So the delayed diagnosis for 2 hours might reduced the cesarean section rate whether we punctured the amniotic sac at first or not. The systematic review studied by Smyth RMD, et al[17] also found that the results showed a trend towards an increased risk of a caesarean section, in women who had early amniotomy, though not enough to reach a statistical significant level. Similarly, the study of Lee SM[21] had higher cesarean rate in the early amniotomy group, especially due to failure to progress of labor than in the late amniotomy group. While the study of Ajadi MA[20] did not show significant different in cesarean section rate in both groups. These results showed that amniotomy possibly did not reduce cesarean section rate and incidence of dystocia. Chorioamnionitis and postpartum infection were not found in the present study. Differently, the study of Rose DJ[22] revealed that the amniotomy was associated with increased infectious morbidity. We also agreed that if amniotomy was performed too early during labor, it possibly increased the risk of chorioamnionitis, especially in those with prolonged labor.

The fetal outcome in the present study was similar to the findings of other researchers on these subjects. The incidence of low Apgar score (<7) at 1 and 5 minutes were similar in both groups[19,20]. It may be claimed that the early amniotomy did not have any adverse effects on fetus in the early lifetime.

Strength of the present study was a randomized control trial design and the power was 90%, but the limitation of the study was the data that were non-normal distribution that might be due to the small sample size. The further study with larger sample size might be corrected this limitation.

Conclusion

The amniotomy should not be introduced routinely as a standard labor management because it was not proven to shorten the course of labor. We recommend that the women informed about the results of amniotomy then the decisions made between women and their caregivers.

What is already known on this topic?

Amniotomy might reduce the duration of labor and possibly produced the complications, the American College of Obstetricians and Gynecologists (ACOG) [16] did not suggest amniotomy for every woman who was in labor. The oxytocin use rate for augmentation of labor was increased in early amniotomy group of many studies, especially the studies of Barrett JF, et al[10] and Lee SM[21].

What this study adds?

The present study showed that early amniotomy may not help to shorten duration of labor. In our study, there was no different in the rate of oxytocin use and the dose of oxytocin. And the cesarean section rate is significantly higher in the early amniotomy group.

Acknowledgment

This study was supported by the Department of Obstetrics and Gynecology, Phramongkutklao Hospital. The authors wish to thank all the staffs of the Maternal-Fetal Medicine unit for their participation and thank all the colleagues for their cooperation in data collection in the present study.

Potential conflicts of interest

None.

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ผลของการเจาะถุงน้ำคร่ำเร็วเปรียบเทียบกับการเจาะถุงน้ำคร่ำช้าในระยะผู้ป่วยเจ็บครรภ์คลอด

ขชล รวมทรัพย์, ปริศนา พานิชกุล

วัตถุประสงค์: *เพื่อเปรียบเทียบระยะเวลาในการคลอดระหว่างกลุ่มผู้ป่วยเจ็บครรภ์คลอดที่ได้รับการการเจาะถุงน้ำคร่ำเร็ว เปรียบเทียบกับกลุ่มที่ได้รับการเจาะถุงน้ำคร่ำช้า*

ชนิดของการวิจัย: *การทดลองแบบสุ่มและมีกลุ่มควบคุม*

สถานที่ทำวิจัย: *ห้องคลอด กองสูตินรีเวชกรรม โรงพยาบาลพระมงกุฎเกล้า*

กลุ่มตัวอย่าง: *สตรีตั้งครรภ์เดี่ยว ครั้งแรก ที่มีส่วนนำของทารกเป็นศีรษะจำนวน 120 รายที่เข้าเกณฑ์ตามเกณฑ์การคัดเข้าที่ได้กำหนดไว้ที่มาห้องคลอดตั้งแต่วันที่ 1 มิถุนายน พ.ศ. 2556 ถึง 31 ตุลาคม พ.ศ. 2556*

วัสดุและวิธีการ: *หลังจากได้ลงชื่อยินยอมเข้าร่วมโครงการ จากนั้นแบ่งผู้เข้าร่วมโครงการเป็นสองกลุ่มโดยใช้ตารางเลขสุ่มได้แก่ กลุ่มที่เจาะถุงน้ำคร่ำทันทีเมื่อปากมดลูกเปิด 3-5 เซนติเมตร (ผู้เข้าร่วมวิจัย 60 คน) กับกลุ่มที่เจาะถุงน้ำคร่ำเมื่อมีข้อบ่งชี้ (ผู้เข้าร่วมวิจัย 60 คน) ข้อมูลการวิจัยจะถูกบันทึกโดยแพทย์ผู้ดูแลในขณะนั้นตามแบบบันทึกข้อมูล*

ตัวชี้วัดที่สำคัญ: *ระยะเวลาในการคลอด*

ผลการศึกษา: *ระยะเวลาที่ใช้ในช่วงเจ็บครรภ์คลอดจนถึงระยะเวลาที่ปากมดลูกเปิดเต็มที่ของทั้งสองกลุ่มไม่แตกต่างกันอย่างมีนัยสำคัญ (560.0 กับ 637.5 นาที; p<1.0; ความแตกต่างของเวลา 77.5 นาที) ในขณะที่ อัตราการผ่าคลอด (ร้อยละ 43.3 กับ ร้อยละ 20 ; p = 0.006) มีความแตกต่างกันอย่างมีนัยสำคัญ*

สรุป: *การเจาะถุงน้ำคร่ำไม่ควรใช้ปฏิบัติเป็นมาตรฐานในการดูแลผู้ป่วยเจ็บครรภ์คลอด เนื่องจากยังไม่พิสูจน์ได้ว่าสามารถลดระยะเวลาในการคลอดลงได้ แพทย์ผู้ดูแลควรให้ข้อมูลเกี่ยวกับผลของการเจาะถุงน้ำคร่ำให้ผู้ป่วยได้ทราบ และตัดสินใจร่วมกัน*