

Thai Journal of Obstetrics and Gynaecology
January 2018, Vol. 26, pp. 27-33

OBSTETRICS

Membrane Stripping to Reduce Postdate Pregnancy: A Randomized Controlled Trial

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ABSTRACT

Objectives: To compare delivery before 40 weeks of gestation between the pregnant women who had membrane stripping and those with no intervention.

Materials and Methods: One hundred and seventy-eight pregnant women, gestational age of 38 weeks or more who attended antenatal care clinic at Khon Kaen Hospital from January to July, 2016 were randomized into two groups: membrane stripping group and no intervention group. The proportion of pregnant women who delivered before 40 weeks of gestation was analyzed.

Results: Baseline characteristics were similar between groups. The proportion of women who delivered before 40 weeks of gestation in membrane stripping group was significantly higher than no intervention group (69.3% VS 51.1%, $p=0.01$) (RR=0.6, 95% CI 0.4-0.9). There was no significant difference in cesarean section rate, maternal complications and neonatal outcomes between groups.

Conclusion: Membrane stripping can reduce postdate pregnancy.

Keywords: Postdate pregnancy, membrane stripping.

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การเลาะถุงน้ำคร่ำ เพื่อลดการตั้งครรภ์ที่อายุครรภ์มากกว่า 40 สัปดาห์: การควบคุมแบบสุ่ม

พริยา ทัดตินาพานิช, ฤทัยรัตน์ ตั่งมั่นสกุลชัย, มาลีชาติ ศรีพิพัฒนะกุล, ทูมวดี ตั่งศิริวัฒนา

บทคัดย่อ

วัตถุประสงค์: เปรียบเทียบสัดส่วนการคลอดก่อนอายุครรภ์ 40 สัปดาห์ ในสตรีตั้งครรภ์ที่ได้รับการเลาะถุงน้ำคร่ำเทียบกับสตรีตั้งครรภ์ที่ไม่ได้รับการเลาะถุงน้ำคร่ำ

วัสดุและวิธีการศึกษา: สตรีตั้งครรภ์ที่มีอายุครรภ์มากกว่าหรือเท่ากับ 38 สัปดาห์ ทั้งหมด 178 คน ที่มาฝากครรภ์ที่ห้องฝากครรภ์ รพ.ขอนแก่น ในช่วงเดือนมกราคม ถึง กรกฎาคม 2559 ได้รับการสุ่ม เป็น 2 กลุ่ม คือ กลุ่มที่ได้รับการเลาะถุงน้ำคร่ำ และกลุ่มที่ไม่ได้รับการเลาะถุงน้ำคร่ำ เปรียบเทียบการคลอดก่อนอายุครรภ์ 40 สัปดาห์ ในสตรีตั้งครรภ์ทั้งสองกลุ่มทั้งสองกลุ่ม

ผลการวิจัย: ลักษณะทางประชากรศาสตร์ไม่แตกต่างกันระหว่างทั้ง 2 กลุ่ม กลุ่มที่เลาะถุงน้ำคร่ำ คลอดก่อนอายุครรภ์ 40 สัปดาห์ ร้อยละ 69.3 ส่วนกลุ่มที่ไม่ได้รับการเลาะถุงน้ำคร่ำ คลอดก่อนอายุครรภ์ 40 สัปดาห์ ร้อยละ 51.1 ซึ่งมีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ อัตราการผ่าตัดคลอด ภาวะแทรกซ้อนต่อมารดาและทารกทั้งสองกลุ่ม ไม่มีความแตกต่างกัน

สรุป: การเลาะถุงน้ำคร่ำ สามารถลดการตั้งครรภ์ที่อายุครรภ์มากกว่า 40 สัปดาห์

คำสำคัญ: การเลาะถุงน้ำคร่ำ, อายุครรภ์มากกว่า 40 สัปดาห์

Introduction

The postdate pregnancy is gestational age (GA) more than 40 weeks to 41⁺⁶ weeks. The incidence of postdate pregnancy of Khon Kaen Hospital (KKH) is 17%. It is often associated with increased risk of perinatal morbidity and mortality⁽¹⁾. Fetal and neonatal mortality rates increase sharply after 40 weeks of gestation. It is believed that utero-placental insufficiency, meconium aspiration and intrauterine infection are the underlying causes of the increased perinatal mortality rates in these cases⁽²⁾. In 2006, Nicholson, et al found that the nadir of neonatal morbidity, including birth injuries, was around 38 weeks of gestation and then increase in a continuous fashion thereafter⁽³⁾.

Stripping or sweeping the amniotic membrane is commonly practiced to induce labor. Digital separation of fetal membranes from the lower uterine segment is safe and easy to perform using circular movement of the examining fingers between the lower segment and the fetal membranes. It increases local release of prostaglandin F_{2α}, activity of phospholipase A₂, frequency of uterine contractions and also cause mechanical dilatation of the cervix. Moreover, it can promote the spontaneous onset of labor, reducing the duration of pregnancy and reducing induction of labor using oxytocin, prostaglandins or amniotomy. Although membrane stripping has been associated with an increase risk of premature rupture of membranes, discomfort from the procedure, other systematic review of 1,525 women reported no evidence of serious finding⁽⁴⁻⁶⁾.

Kashanian, et al., found that time to delivery was not different between membrane stripping group and no intervention group (7.7±6.9 and 7.1±5.6 days, p=0.61)⁽⁷⁾. In contrast, Boulvain and Ugwu, et al., reported that membrane stripping can reduce the incidence of postterm pregnancy^(6,8).

There was no study about the safety and efficacy of membrane stripping in prevention of postdate pregnancy. Despite many studies demonstrated the effectiveness of membrane stripping in postterm pregnancy but their findings are still inconclusive. Therefore, the present study was conducted to evaluate

whether membrane stripping could reduce postdate pregnancy.

Materials and Methods

This randomized controlled trial was conducted at Khon Kaen Hospital, Thailand from January to July, 2016. This study was approved by Khon Kaen Hospital Institute Review Board in Human Research. All participants were informed about the study and signed the consent form before enrollment.

We included pregnant women age 18 years old or more with gestational age 38 weeks or more, singleton pregnancy, cephalic presentation, no labor pain, and planned vaginal delivery. Pregnant women with HIV infection, placenta previa, rupture of membranes, previous uterine scar such as previous cesarean section, myomectomy, diabetes mellitus (overt or gestational type A₂), and pregnancy induced hypertension were excluded.

The pregnant women who had uncertain date, eg. had irregular period, wrong date, recent use of hormonal contraception, the gestational age was corrected using ultrasound⁽⁹⁾.

Eligible participants were randomized by computer generated with block of four and randomly assigned into two groups; membrane stripping and no intervention groups. The random numbers were put in the sequentially sealed, opaque envelopes. Pregnant women who were randomized to membrane stripping group, membrane stripping was performed by digital separation of fetal membranes from the lower uterine segment using two circular movements once a week until delivery by residents or staffs of Obstetrics and Gynecology. Routine ANC was similarly provided in both groups. Induction of labor using either vaginal misoprostol or intravenous oxytocin was provided after 40 weeks. Primary outcome was delivery before 40 weeks of gestation. Secondary outcome was cesarean section rate. Women who delivered in other hospital were interviewed by phone.

The sample size was calculated from a pilot study. We used formula for test of difference in two independence proportions with alpha of 0.05, power of

80% and 10% dropouts. The sample size in each group was 89 cases.

$$n/\text{group} = \left[\frac{z_{\alpha/2} \sqrt{2pq} + z_{\beta} \sqrt{p_1q_1 + p_2q_2}}{p_1 - p_2} \right]^2$$

Analyses were based on the intention to treat. Categorical variables were analyzed by Chi-square test or Fisher's exact test. Continuous variables were analyzed by Student t-test or Mann-Whitney U-test depends on data distribution. The primary outcome was presented as relative risk with 95% confidence interval. Other outcomes were presents as percentage, mean with standard deviation, and median with interquartile range. P value less than 0.05 was represented statistical significance. Statistical analysis was performed using SPSS 17.0 software.

Results

One hundred and seventy-eight participants were randomly assigned into two groups, 89 cases in both groups. One participant in membrane stripping group dropped out due to birth before

admission and one in no intervention group dropped out due to delivery at district hospital and the data was not available. Therefore, the totally 88 participants left in each group were analyzed (Fig. 1).

Baseline characteristics including age, parity and gestational age were similar in both groups (Table 1). The proportion of delivery before 40 weeks in membrane stripping group was significant higher than no intervention group (69.3% versus 51.1%, $p=0.01$, $RR=0.6$, 95% CI 0.4-0.9) (Table 2). Time to delivery in membrane stripping group was significantly shorter than no intervention group 5(2-8) versus 7.5(4.5-12) days, $p<0.001$, route of delivery was similar in both groups (vaginal delivery 84.1% versus 77.3% and cesarean section 15.9% versus 22.7%, $p=0.25$ in membrane stripping group and no intervention group, respectively) (Table 2).

There were four women (4.6%) who had premature rupture of membranes only in membrane stripping group. There were no serious maternal complications and neonatal outcomes were similar in both groups (Table 3).

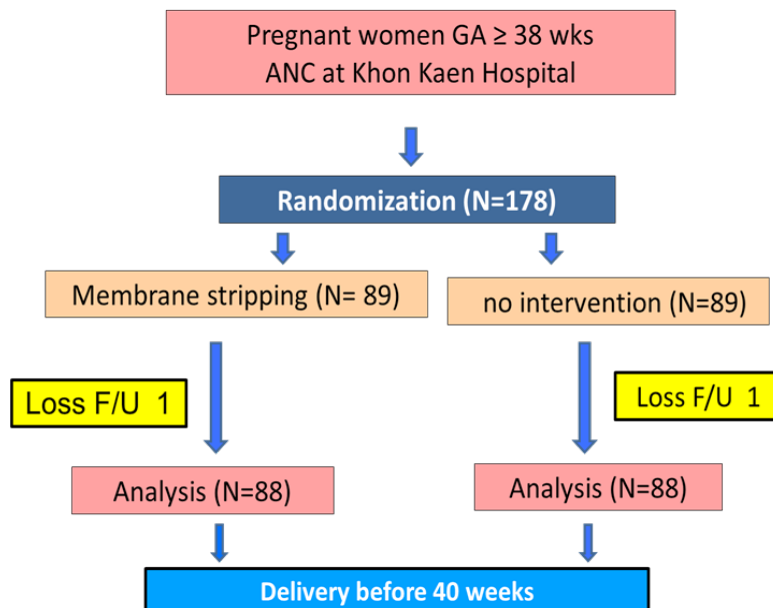


Fig. 1. Study flow chart.

Table 1. Baseline characteristics.

Characteristics	Membrane stripping (n= 88)	No intervention (n= 88)	p value
Age (yrs), median (IQR)	25 (21-30)	24.5 (21-29.5)	0.63
Parity			0.36
Nulliparous, no. (%)	53 (60.2)	47 (53.4)	0.975
Multiparous, no. (%)	35 (39.8)	41 (46.6)	0.944
Gestational age (weeks), median (IQR)	38 ⁺⁴ (38 ⁺² - 39 ⁺¹)	38 ⁺³ (38 ⁺¹ - 39 ⁺⁰)	0.08

Table 2. Primary outcome and secondary outcomes.

Duration of delivery	Membrane stripping (n= 88)	No intervention (n= 88)	RR	95%CI	p value
Primary outcome					
Delivery before GA 40 weeks, no. (%)	61 (69.3)	45 (51.1)	0.6	0.4-0.9	0.01
Nulliparous	36 (59)	23 (51.1)			
Multiparous	25 (41)	22 (48.9)			
Secondary outcomes					
Time to delivery (days), median (IQR)	5 (2-8)	7.5 (4.5-12)	-	-	< 0.001
Route of delivery					0.25
Vaginal delivery, no. (%)	74 (84.1)	68 (77.3)	-	-	
Cesarean section, no. (%)	14 (15.9)	20 (22.7)	-	-	

Table 3. Maternal complications and neonatal outcomes.

Outcomes	Membrane stripping (n= 88)	No intervention (n= 88)	p value
Maternal complications			
Premature rupture of membrane (PROM), no. (%)	4 (4.6)	0	0.12
Vaginal bleeding, no. (%)	0	0	-
Chorioamnionitis, no. (%)	1 (1.1)	0	0.99
Neonatal outcomes			
Birth weight (g), mean (SD)	3,114.1 (373.2)	3,184.1 (389.2)	0.25
Meconium stain amniotic fluid	22 (25)	11 (12.5)	0.03
Birth asphyxia (APGAR ≤ 7)			
At 1 min, no. (%)	12 (13.6)	5 (5.7)	0.07
At 5 min, no. (%)	3 (3.4)	0 (0)	0.25
Admission to NICU, no. (%)	4 (4.6)	3 (3.4)	0.99

Discussion

Our findings supported the effectiveness of membrane stripping for induction of labor. Although, most of the previous studies performed membrane stripping in pregnant women gestational age more than 40 weeks and meta-analysis of 14 randomized controlled trials⁽⁶⁾ found that membrane stripping in pregnant women with gestational age 38 weeks had no benefit, but the present study demonstrated that membrane stripping in pregnant women GA 38 weeks or more could successfully induce labor and had delivery before 40 weeks more than control group. The present study included pregnant women who were 38 weeks or more, then followed up until 40 weeks and induced labor after 40 weeks while other studies followed up until 42 weeks. The reason of conducting study in women with gestational age of 38 weeks or more was due to increase perinatal risk index, neonatal morbidity and mortality rate due to meconium aspiration syndrome, uteroplacental insufficiency induced intrauterine growth restriction, fetal distress and fetal macrosomia, and increase cesarean section rate⁽¹⁻³⁾. The present study showed that membrane stripping reduced postdate pregnancy as high as 40% or every five women who had membrane stripping could reduce postdate pregnancy in one woman (NNT=5). Approximately 60% of primigravida women in membrane stripping group delivered before 40 weeks. The other potential benefit of membrane stripping founded in the present study was significantly shorter time to delivery when compared to no intervention. The participants who had membrane stripping experienced spontaneous labor within 5 days after the procedure. Cesarean section rate in membrane stripping group was not increase which was comparable to other studies^(6-8,10). Premature rupture of membrane (PROM) occurred in membrane stripping but the difference was not statistically significant^(7,9) which was consistent with our finding. Even though four participants in the membrane stripping group had premature rupture of membranes, however, none of them developed chorioamnionitis. Other complications of membrane stripping such as vaginal bleeding, which was reported

in the previous study^(6, 8, 11), was not found in the present study. Neonatal outcomes (birth asphyxia at 1 minute, 5 minutes, rate of admission NICU) were not different in both groups, which was similar to previous studies^(6,8,11). The present study showed more birth asphyxia at 1 minute in membrane stripping group compare to no intervention group, this might be due to the higher incidence of meconium stain in membrane stripping group (25% VS 12.5%).

The strength of the present study was randomized controlled trial and low dropout rate (1.1%) and limitation in the present study was patient satisfaction, especially in terms of maternal discomfort or pain during membrane stripping was not evaluated.

Membrane stripping is a useful procedure in low resource setting and help reducing postdate pregnancy. Other aspects should be assessed such as patient satisfaction, physicians satisfaction, and cost effectiveness of the procedure.

Conclusion

This study supported that membrane stripping can reduce postdate pregnancy without any maternal and neonatal complications.

Acknowledgements

The authors would like to thank nurses and staffs of Department of Obstetrics and Gynecology, Khon Kaen Hospital for their helps and supports.

Potential conflicts of interest

The authors declare no conflict of interest.

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