A Comparative Study of Membrane Stripping and Nonstripping for Induction of Labor in Uncomplicated Term Pregnancy

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Abstract

A prospective, randomized controlled trial was undertaken at the Department of Obstetrics and Gynecology, Faculty of Medicine, Chulalongkorn Hospital to determine whether stripping of the fetal membranes is a safe and effective method for induction of labor in uncomplicated term pregnancy. Ninety-six women were included in this study; 16 were excluded; 41 were randomized to a study group and 39 to a control group. Both groups had pelvic examination performed under sterile technique and a Bishop score was assessed. In the study group, membrane stripping was performed. Gentle pelvic examination for Bishop scoring was continued weekly in both groups. Thirty five of 41 women (85.4%) in the study group delivered within 7 days as compared to 22 of 39 women (56.4%) in the control group, a statistically significant difference ($P = 0.004$). A statistically significant difference was also observed with respect to the mean number of days to delivery (5.3 ± 4.9 *versus* 9.5 ± 5.9 days, respectively; $P = 0.002$). No statistically significant differences were observed in both maternal and fetal complications. In conclusion, membrane stripping is a safe and effective method for induction of labor in uncomplicated term pregnancy.

Key word : Induction of Labor, Membrane Stripping, Nonstripping Uncomplicated Term Pregnancy

Digital separation of the fetal membranes from the lower uterine segment (stripping or sweeping the membranes) has been used for many years to induce labor at term, avoiding the need for either amniotomy or oxytocic drugs[1,2]. There are good theoretical reasons to suggest that it may be effective in that it stimulates intrauterine prostaglandin synthesis[3]. The formal attempts to assess the effects of digital stripping of the membranes at term have been marred by their large potential for bias[4,5]. They suggest that women who had the membranes stripped were more likely to go into

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labor within the next few days, and less likely to have postterm pregnancy, than were the women who served as controls. However, obstetricians in Thailand have condemned the procedure as harmful and useless. In addition, there is too little good evidence in this country to assess the effectiveness of the technique and the potential maternal and perinatal morbidity that it may entail[6]. We hypothesized that membrane stripping is clinically safe as well as efficacious and, as such, might be associated with earlier delivery.

MATERIAL AND METHOD

This trial was conducted at the antenatal clinic, Department of Obstetrics and Gynecology, Faculty of Medicine, Chulalongkorn Hospital. The protocol was approved by the ethical committee of the Faculty of Medicine, Chulalongkorn University. After documenting firm gestational dating criteria and obtaining informed consent, we prospectively assigned pregnant women whose gestational age was between 39 and 40 weeks' to a group that would undergo membrane stripping or one that would receive a weekly pelvic examination without membrane stripping. Both groups were low risk and intended to deliver at this hospital. Gestational age was ascertained with the known last normal menstrual period, early confirmation through size and ultrasound prior to 20 weeks' gestation and no size-date discrepancy during antenatal visits. Patients were excluded from the study if they had uncertain dates, abnormal fetal presentations, unengaged fetal heads, known medical complications of pregnancy, placenta previa (or low-lying placentas), known lower genital tract infections, previous cesarean sections or no desire to participate in the study.

After the patients were included into the study, They were assigned to one of two groups according to a table of random numbers. Baseline data were recorded on a standardized form. Sterile speculum and gentle pelvic examinations were performed in both groups to rule out local infections and to assess the status of the cervix by Bishop scoring[7]. In the study group, stripping of the membranes was done by digital separation of 2-3 cm of the membranes from the lower uterine segment using two circumferential passes of the examining finger under aseptic technique. In those patients with long and closed cervices randomized to the stripping group, the cervix was stretched digitally until membrane stripping could be accomplished. The patients were warned to expect a show and were allowed to go home.

Gentle pelvic examination for Bishop scoring was continued weekly in both groups. The patients were instructed to come to the delivery room immediately if they had rupture of the membranes, fever, heavy vaginal bleeding, or if they suspected the onset of labor. If gestational age reached 42 completed weeks (>294 days) without spontaneous onset of labor, the patients were admitted into the hospital for fetal monitoring and formal induction was performed with either prostaglandin E2 vaginal tablet or intravenous oxytocin drip. Only the authors performed all membrane stripping and assignment of Bishop scores after standardization of the technique.

The time from enrollment to delivery, week of gestation at birth, mode of delivery, maternal and neonatal complications were recorded for all patients.

The primary outcome measure was the proportion of patients who delivered within 7 days after enrollment in the study. Secondary outcome measures were as follows: 1) Bishop score among those who did not deliver by 1 week after the first pelvic examination; 2) the times from the first examination to delivery; 3) the incidence of postterm pregnancy in the two groups; and 4) maternal and fetal complications.

Statistical analysis

Mean and standard deviation were used for descriptive analysis. For comparison between two groups, Chi-square, Fisher's exact and Student *t* tests were used as appropriate. The results were considered statistically significant at $P < 0.05$.

RESULTS

From November 1994 through March 1995, 96 patients were enrolled. Although approximately 5,000 patients delivered during the time interval of this study, most of them did not meet our eligibility strict criteria. Sixteen of them (7 in the study group and 9 in the control group) subsequently were excluded (7 had lower genital tract infections, 4 delivered at another hospital, 3 could not perform membrane stripping, and 2 subsequently did not participate in the study), leaving 80 patients for analysis (41 in the membrane-stripping group and 39 in the control group).

The characteristics of the patients are shown in Table 1. The groups were matched for age, gravida, gestational age, and Bishop scores at recruitment. Table 2 shows the outcomes of the trial.

Significantly more patients in the membrane-stripping group delivered within 7 days of the initial examination (85.4% *versus* 56.4%; P = 0.004). In addition the study group delivered earlier than the control group in terms of days after the first pelvic examination (mean = 5.3 *versus* 9.5 days; P = 0.002). Although the change in Bishop scores among those who did not deliver within 1 week after the first examination was slightly more in the stripping group than in the control group, the difference did not reach statistical significance (1.8 ± 1.3 and 1.2 ± 1.3, respectively). The difference between the number of patients who advanced beyond 42 weeks' gestation (one in the stripping group and two in the control group) was not statistically significant between the groups. Neither chorioamnionitis nor accidental rupture of membranes occurred during stripping in any of our patients. The incidence of premature rupture of the membranes and the mode of delivery were similar in both groups.

Table 1. Patient characteristics.

	Stripping (n=41)	Control (n=39)
Maternal age (y)	26.0 ± 4.8	25.5 ± 4.4
Gravidity		
Primigravida	24 (58.5%)	24 (61.5%)
Multigravida	17 (41.5%)	15 (38.5%)
Gestational age	39.2 ± 0.6	39.0 ± 0.4
Bishop scores	6.6 ± 2.5	5.6 ± 2.7

Data are presented as mean ± standard deviation or N (%)

Table 2. Pregnancy outcomes.

	Stripping (n = 41)	Control (n = 39)	P
Delivery within 7 days	35 (85.4%)	22 (56.4%)	0.004
Days to delivery	5.3 ± 4.9	9.5 ± 5.9	0.002
Delivery ≥ 42 weeks	1 (2.4%)	2 (5.1%)	NS
PROM	1 (2.4%)	1 (2.5%)	NS
Mode of delivery			
Spontaneous	31 (75.6%)	23 (58.9%)	NS
Forceps	4 (9.8%)	9 (23.2%)	
Cesarean section	6 (14.6%)	7 (17.9%)	
Birth weight (grams)	3123.4 ± 380.5	3129.7 ± 338.4	NS
Apgar score			
1 minute	8.9 ± 0.1	8.9 ± 0.1	NS
5 minutes	9.9 ± 0.1	10.0 ± 0.0	NS
Puerperal morbidity*	2 (4.8%)	2 (5.1%)	NS
Postpartum hemorrhage**	1 (2.4%)	0	NS
Neonatal jaundice	5 (12.1%)	4 (10.3%)	NS

NS = not significance.
Data are presented as mean ± standard deviation or N (%).
PROM = premature rupture of the membranes.
* defined as a temperature of 38°C or higher on any two of the first 10 days postpartum, exclusive of the first 24 hours, and to be taken by mouth by a standard technique at least four times daily.
** defined as blood loss in excess of 500 ml by visual estimation during the first 24 hours after delivery.

There were no significant differences statistically in maternal or fetal complications in the two groups. There were four cases of postpartum febrile morbidity (two in the study group and two in the control group). All of them had cesarean section performed due to dystocia and the fever resolved spontaneously within 3 days after the surgery. One case of immediate postpartum hemorrhage occurred in the study group. This case had retained placenta and manual removal of the placenta was performed without any complication. There were nine cases of neonatal jaundice (five in the study group and four in the control group), all of whom responded to phototherapy without further treatment.

DISCUSSION

While stripping of the fetal membranes at term appears to have been a common practice in the obstetric community for many years, it has been poorly studied in Thailand. Theoretically stripping of the membranes should have a powerful effect in stimulating labor, since the procedure causes an increase in prostaglandin metabolites in the maternal circulation[3]. Furthermore the extent of this prostaglandin release is proportional to the area of membranes separated from the uterus[8]. We conducted this research in order to prove our hypothesis that this method for induction of labor is safe, efficacious and economically beneficial in this country. Since there is no report in Thailand on the treatment effect of membrane stripping in achieving delivery within 7 days, we conducted a pilot study to calculate the sample size. With a probability of type 1 error of 5 per cent and a probability of type

II error of 10 per cent, we calculated that at least 31 subjects were needed per group. To allow for a 20 per cent dropout rate, a minimum sample size of 74 subjected was projected. In our study, we recruited a total of 96 uncomplicated term pregnancies, and 16 of them were excluded. Therefore, eighty cases were included in the final analyses.

Our trial shows that stripping of the membranes is an effective method of induction of labor in uncomplicated term pregnancy. Eighty five per cent of the women in the study group delivered within 7 days compared to fifty six percent in the control group. In addition, the membrane-stripping group delivered earlier than the control group in terms of days after the initial examination. Thus, our results support previous studies showing that membrane stripping is an effective procedure to induce labor at term. The overall success rate for induction of labor within 7 days from previous studies ranged from 43.5 per cent to 92 per cent (4,5,9,10). Even though obstetric care providers were not blinded, there was no reason to believe that they would have been more likely to induce women who had been included in the study group.

One of the major concerns of membrane stripping is the possible introduction of infection into the extraamniotic space that could cause rupture of the membranes and chorioamnionitis, and it was the increase in maternal infections with stripping that led Swann to abandon the procedure(1). In our trial, the incidence of premature rupture of the membranes and maternal infections did not increase in the membrane-stripping group. In addition, we have not been able to detect other serious adverse effects.

In conclusion, membrane stripping in uncomplicated term pregnancy is a safe and effective method for induction of labor, without apparent harm to mother or baby. It is recommended as an alternative method for induction of labor in low-risk patients with certain gestational age, engaged fetal head, and in patients with no evidence of placenta previa or low-lying placenta and lower genital tract infections.

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การศึกษาเปรียบเทียบผลการเลาะแยกถุงน้ำคร่ำออกจากมดลูกส่วนล่างกับการตรวจภายในต่อการชักนำการเจ็บครรภ์คลอดในสตรีตั้งครรภ์ครบกำหนดที่ไม่มีภาวะแทรกซ้อน

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การวิจัยเชิงทดลองแบบสุ่มตัวอย่างไปข้างหน้าเปรียบเทียบผลการเลาะแยกถุงน้ำคร่ำออกจากมดลูกส่วนล่างกับการตรวจภายใน ในการชักนำการเจ็บครรภ์คลอดในสตรีตั้งครรภ์ครบกำหนดที่ไม่มีภาวะแทรกซ้อน ที่ภาควิชาสูติศาสตร์-นรีเวชวิทยา คณะแพทยศาสตร์ โรงพยาบาลจุฬาลงกรณ์ โดยแบ่งกลุ่มตัวอย่างแบบสุ่มเป็น 2 กลุ่ม จากจำนวนตัวอย่าง 96 ราย และคัดออกตามเกณฑ์ 16 ราย เหลือ 80 ราย แบ่งเป็นกลุ่มทดลอง 41 ราย และกลุ่มควบคุม 39 ราย ทั้งสองกลุ่มได้รับการตรวจภายในโดยวิธีปราศจากเชื้อและวัดค่าคะแนน Bishop ในกลุ่มทดลองทำการเลาะแยกถุงน้ำคร่ำออกจากมดลูกส่วนล่าง ผลการวิจัยพบว่า ในกลุ่มทดลองมีจำนวนสตรีตั้งครรภ์คลอดภายใน 7 วัน 35 คน จาก 41 คน คิดเป็นร้อยละ 85.4 กลุ่มควบคุมมีจำนวนสตรีตั้งครรภ์คลอดภายใน 7 วัน 22 คน จาก 39 คน คิดเป็นร้อยละ 56.4 ซึ่งแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($P = 0.004$) ระยะเวลาที่ใช้ตั้งแต่เข้ารับการศึกษาถึงทารกคลอดพบมีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ (ในกลุ่มทดลองเท่ากับ 5.3 ± 4.9 ในกลุ่มควบคุมเท่ากับ 9.5 ± 5.9 วัน, $P = 0.002$) ภาวะแทรกซ้อนที่เกิดกับมารดาและทารกในแต่ละกลุ่มไม่แตกต่างกัน โดยสรุปการเลาะแยกถุงน้ำคร่ำออกจากมดลูกส่วนล่างเป็นวิธีชักนำการเจ็บครรภ์คลอดวิธีหนึ่งที่มีความปลอดภัยและมีผลสำเร็จสูงในสตรีตั้งครรภ์ครบกำหนดที่ไม่มีภาวะแทรกซ้อน

คำสำคัญ : การเลาะแยกถุงน้ำคร่ำ, การชักนำการเจ็บครรภ์คลอด, ครรภ์ครบกำหนดที่ไม่มีภาวะแทรกซ้อน

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