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Double-balloon catheter compared with single-balloon catheter for induction of labor with a scarred uterus

Yanping Xing^{*}, Na Li, Qiumei Ji, Lingling Hong, Xuezheng Wang, Baoheng Xing

The Second Department of Obstetrics, Cangzhou Central Hospital, NO.16, Xinhua Road, Yunhe District, Cangzhou 061000, Hebei, China

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ABSTRACT

Background: In obstetrics, labor induction is a common procedure. It has been proved that both single balloon catheters (Foley's catheter) and double balloon catheters (Cook cervical ripening balloon) are effective and relatively safe in cervical ripening and labor induction. This research aimed to compare the efficacy of single and double balloon catheter in the induction of labor with scarred uterus.

Methods: 120 pregnant women who had prior cesarean delivery participated in this research and were randomized into single-balloon catheter group (n = 60) and double-balloon catheter group (n = 60). The cervical ripening effect, security, and influence to the process of childbirth were analyzed in each group. **Results:** The validity of cervical ripening in single balloon group was better than double balloon group. Double balloon catheters increased the time between insertion and expulsion of the catheter and decreased spontaneous catheter expulsion rate. All the neonatal outcomes in these two groups were comparable.

Conclusion: Based on our data, the two different catheters both have their pros and cons in the labor induction of pregnant women with scarred uterus. The appropriate catheter used based on specific circumstance will improve the quality of labor induction.

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Introduction

In recent decades, the worldwide cesarean section incidence has elevated rapidly [1]. Based on the investigation by World Health Organization (WHO), the highest overall cesarean section incidence was observed in China [1]. The rate of cesarean section is still rising in all levels of hospitals in China [2]. With the increasing cesarean section rate, pregnancy in scarred uterus has become a common situation. The risk of uterine rupture and other complications during vaginal delivery was elevated by the presence of previous uterine scar [3]. Labor induction in women who had prior cesarean delivery has been an important clinical situation. The effective and relatively safe method for cervical ripening and labor induction in patients with scarred uterus is needed urgently.

In obstetrics, labor induction is a common procedure. Several different methods have been established for cervical ripening and can be divided into two parts, the pharmacological method and the mechanical methods [4]. Prostaglandin is widely used in the induction of labor. But for pregnant women with scarred uterus,

prostaglandin E1 treatment caused high uterine rupture incidence is unacceptable for the induction of labor [5]. Since the pharmacological method is not available for induction of labor with a scarred uterus, the mechanical methods should be tested.

Foley's single balloon catheter has been proved to be an effective and secure mechanical method in labor induction [6]. Compared to the treatment of prostaglandin, Foley's catheter has same induction efficiency, lower uterine tachysystole risk, lower cost, and better reversibility [7]. Foley's catheter induces labor through the pressure on lower uterine segment and cervix and the prostaglandins secretion [8]. Cook cervical ripening balloon is composed of cervico-vaginal balloon and uterine balloon [9]. Compared with the Foley's catheter, double-balloon catheter can apply pressure simultaneously on both external os and internal os [10]. Two different types of catheter have their own advantages and disadvantages in the induction of labor.

In this research, we aimed to demonstrate the efficacy and safety of single-balloon catheter and double-balloon catheter in the induction of labor with a scarred uterus.

Methods

This randomized controlled research was conducted in Cangzhou Central Hospital. Women in term pregnancy who had

^{*} Corresponding author.

E-mail address: xyp_2019xyp@163.com (Y. Xing).

a scarred uterus and were admitted between January 2017 and December 2018 to the department of obstetrics were recruited in this research. All the participants were given information about the labor induction by balloon catheter prior to the study. Informed consent was obtained from each participant. All the study complied with the Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects.

In this research, 120 participants were randomly divided into single-balloon catheter group (n = 60) and double-balloon catheter group (n = 60). In single-balloon catheter group, Foley's catheter was used. After being inserted above the internal cervical os, Foley's catheter was bloated with normal saline (120 mL). Cook cervical ripening balloon was used in double-balloon catheter group. After being inserted through the cervix, each balloon on external os or internal os was bloated with normal saline (80 mL). Except catheters, all the process in cervical ripening and administration in labor induction were exactly the same for these two groups. If the spontaneous expulsions of the catheter not happened 12 h after insertion, the catheter was removed artificially and Bishop score were assessed. In this research, cervical ripening was considered to be successful when Bishop score increased more than two points after the treatment of catheter.

Statistical analyze was performed by SPSS software version 17.0. Parametric data was shown as mean \pm standard deviation (SD) and the comparison between two groups was analyzed by Student's t test. Categorical variable was shown as number and percentage and differences were analyzed by χ^2 test. Statistical analysis was significant when P value <0.05.

Results

Participants

At the beginning of this research, 168 pregnant women with scarred uterus were qualified for this research and were invited. 48 of them declined to participate in this research. So, 120 pregnant women with scarred uterus were randomized into single-balloon catheter group (n = 60) and double-balloon catheter group (n = 60). In single-balloon catheter group, cervical ripening was performed using Foley's catheter. In double-balloon catheter group, cervical ripening was performed using Cook cervical ripening balloon. 4 patients in single-balloon catheter group and 5 patients in double-balloon catheter group did not received catheter. After the insertion of catheter, 3 patients in single-balloon catheter group and 2 patients in double-balloon catheter group were excluded. At last, 106 pregnant women participated in this research, 53 in single-balloon catheter group and 53 in double-balloon catheter group (Fig. 1).

The baseline characteristics of patients in each group are shown in Table 1. Based on our statistical analysis, the maternal age, body mass index, weight gain, gestational age, gravidity, and parity in these two groups shown no significant differences. The incidence of pregnancy complications was also analyzed (Table 1). The incidence of these complications such as hypertension, diabetes, and thrombophilia in these two groups also had no significant differences. So, the baseline characteristics of patients in each group were comparable.

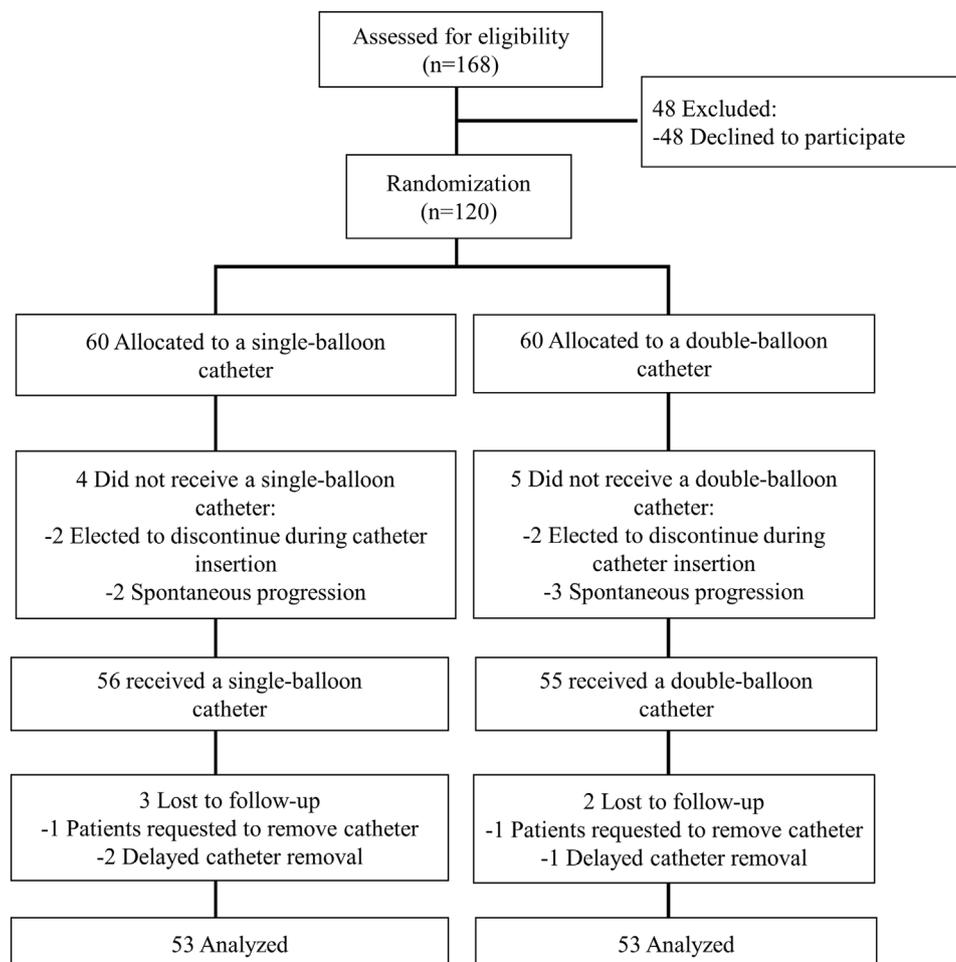


Fig. 1. Flow of patients through the study (enrollment, randomization, and analysis).

Table 1
Baseline characteristics of the two groups.

	Single-balloon catheter (n = 53)	Double-balloon catheter (n = 53)	p value
Maternal age (years)	27.4 ± 6.9	26.7 ± 7.6	NS
BMI before pregnancy (kg/m ²)	24.2 ± 5.76	24.9 ± 5.49	NS
Weight gain (kg)	12.8 ± 7.2	12.5 ± 6.8	NS
GA at time of insertion (week)	37.1 ± 6.4	36.4 ± 5.7	NS
Gravidity	3.6 ± 1.9	3.3 ± 2.2	NS
Parity	2.7 ± 1.8	2.9 ± 1.9	NS
Pregnancy complications			
Hypertension	5 (9.4 %)	2 (3.8 %)	NS
Diabetes	6 (11.3 %)	8 (15.1 %)	NS
Thrombophilia	1 (1.9 %)	2 (3.8 %)	NS
Oligohydramnios	14 (26.4 %)	17 (32.1 %)	NS
Polyhydramnios	0 (0.0 %)	3 (5.7 %)	NS
Previous prostaglandin use	15 (28.3 %)	12 (22.6 %)	NS

Data are presented as mean ± SD or n (percentage, %). BMI: body mass index, GA: gestational age. NS means no significant difference.

Baseline bishop score

To illustrate the cervical ripeness in each group during the labor induction, Bishop scores were assessed before catheter insertion and after catheter removal. The baseline Bishop score before balloon catheter insertion in two groups shown no significant difference (Table 2) (Fig. 2). After catheter expulsion or removal, Bishop score in both groups were significantly elevated when compared with the baseline Bishop score. But the Bishop score in single-balloon catheter group was significantly higher than in double-balloon catheter group after expulsion or removal of catheter (Table 2) (Fig. 2). This result indicated that single-balloon Foley’s catheter had a higher efficiency in cervical ripening during the labor induction of pregnant women with scarred uterus.

Intrapartum outcomes

We also analyzed several different intrapartum outcomes in these two groups (Table 3). The rate of spontaneous catheter expulsions was significantly higher in single-balloon catheter group than in double-balloon catheter group. In double-balloon catheter group, the time length from catheter insertion to expulsion was longer than in single-balloon catheter group. But different catheter did not influence the time from catheter insertion to delivery, rate of ripening success, or delivery mode in pregnant women with scarred uterus. Single-balloon Foley’s catheter had a higher pain score during catheter insertion than Cook cervical ripening balloon. The higher degree of pain caused by Foley’s catheter during the labor induction increased requirement of cesarean section. In single-balloon catheter group, Foley’s catheter generated higher incidence of laceration of the cervix and cord prolapse than double-balloon catheter in patients with scarred uterus.

Neonatal outcomes

To further investigate the differences between these two different catheters in labor induction of pregnant women with scarred uterus, the neonatal outcomes in these two groups (Table 4). The body weight, body length, and head circumference

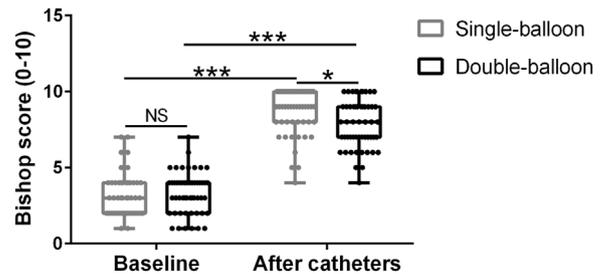


Fig. 2. Baseline Bishop score before balloon catheter insertion and after expulsion or removal of the balloon catheter in the two groups. *p < 0.05, ***p < 0.001, NS means no significant difference.

of newborn infants were not influenced by the use of different catheters. We also evaluated the neonatal complications by Apgar score and neonatal intensive care unit (ICU) admission in the two different group and no differences were found. In conclusion, no significant differences were found between single-balloon Foley’s catheter and Cook cervical ripening balloon in all neonatal outcomes.

Discussion

This research aimed to illustrate the security and efficacy of single-balloon catheter and double-balloon catheter for induction of labor with a scarred uterus. It is reported that China had the highest overall cesarean section incidence (46.2%) and the incidence dramatically elevated for women in all regions during the past years [11]. Medically justified cesarean section can efficiently decrease maternal and perinatal mortality and morbidity. But cesarean section has not shown any benefits for both pregnant women or their infants when the procedure is not necessary since it has been confirmed to has association with both short and long term of risk from current delivery to the future pregnant [12]. As a consequence of scarred uterus caused elevation in maternal and perinatal morbidity and uterine rupture incidence, the vaginal delivery proportion significantly declined after prior

Table 2
Baseline bishop score before balloon catheter insertion and after expulsion or removal of the balloon catheter in the two groups.

Bishop score (0–10)	Single-balloon catheter (n = 53)	Double-balloon catheter (n = 53)	p value
Baseline bishop score	3.06 ± 1.39	3.36 ± 1.36	NS
Bishop score after expulsion or removal of the balloon catheters	8.72 ± 1.49	7.87 ± 1.58	<0.05
p value	<0.001	<0.001	

Data are presented as mean ± SD. NS means no significant difference.

Table 3
Intrapartum outcomes.

	Single-balloon catheter (n = 53)	Double-balloon catheter (n = 53)	p value
Spontaneous expulsions of the catheter	36 (67.9 %)	24 (45.3 %)	<0.01
Time from catheter insertion to expulsion (h)	8.4 ± 3.2	12.43 ± 3.9	<0.01
Time from catheter insertion to active labor (h)	15.3 ± 5.6	17.4 ± 4.8	NS
Time from catheter insertion to delivery (h)	17.4 ± 10.6	21.8 ± 9.8	NS
Time from catheter expulsion to delivery (h)	12.7 ± 7.5	9.7 ± 6.3	NS
Ripening success	50 (94.3 %)	51 (96.2 %)	NS
Mode of delivery			
Spontaneous vaginal delivery	19 (35.8 %)	24 (45.3 %)	NS
Instrumental delivery	12 (22.6 %)	14 (26.4 %)	NS
Cesarean section	20 (37.7 %)	14 (26.4 %)	NS
Indication for cesarean section			
Failure to progress	7 (13.2 %)	6 (11.3 %)	NS
Failed induction	3 (5.7 %)	2 (3.8 %)	NS
Non-reassuring fetal heart rate	5 (9.4 %)	5 (9.4 %)	NS
Maternal request	5 (9.4 %)	1 (1.9 %)	<0.05
Length of first stage of labor (h)	5.2 ± 2.6	4.3 ± 1.9	NS
Length of total labor (h)	6.3 ± 3.7	6.1 ± 4.5	NS
Vaginal delivery within 24 h from catheter insertion	24 (45.3 %)	28 (52.8 %)	NS
Vaginal delivery within 48 h from catheter insertion	28 (52.8 %)	34 (64.2 %)	NS
Patients requiring oxytocin administration	32 (60.4 %)	39 (73.6 %)	NS
Pain score during catheter insertion (1–10)	5.2 ± 1.5	4.1 ± 1.2	<0.05
Use of analgesia	48 (90.6 %)	45 (84.9 %)	NS
Composite adverse events			
Postpartum hemorrhage (>500 mL)	3 (5.7 %)	1 (1.9 %)	NS
Cord prolapse	4 (7.5 %)	0 (0.0 %)	<0.05
Laceration of the cervix	5 (9.4 %)	1 (1.9 %)	<0.05
Abruptio placenta	4 (7.5 %)	3 (5.7 %)	NS
Infection	2 (3.8 %)	2 (3.8 %)	NS
Hospital stay (d)	6.3 ± 1.7	5.9 ± 1.9	NS
Maternal satisfaction (1–10)	6.7 ± 2.4	7.4 ± 2.1	NS

Data are presented as mean ± SD or n (percentage, %). NS means no significant difference.

Table 4
Neonatal outcomes.

	Single-balloon catheter (n = 53)	Double-balloon catheter (n = 53)	p value
Birth weight (kg)	3.41 ± 0.46	3.38 ± 0.51	NS
Head circumference (cm)	33.51 ± 1.37	33.66 ± 1.48	NS
Body length (cm)	48.97 ± 1.87	49.24 ± 2.03	NS
Neonatal ICU admission	7 (13.2 %)	6 (11.3 %)	NS
Reason for ICU admission			
Asphyxia	0 (0.0 %)	1 (1.9 %)	NS
Meconium aspiration	4 (7.5 %)	3 (5.7 %)	NS
Suspected infection	2 (3.8 %)	2 (3.8 %)	NS
Dysmaturity	1 (1.9 %)	0 (0.0 %)	NS
Apgar score ≤7			
1 min	2 (3.8 %)	1 (1.9 %)	NS
5 min	0	1 (1.9 %)	NS

Data are presented as mean ± SD or n (percentage, %). ICU: intensive care unit. NS means no significant difference.

cesarean delivery [13]. Repeated cesarean section will increase the incidence of placental implantation and hysterectomy, and also is a big threat to the health of infants [14].

The labor induction is an ordinary obstetric procedure with a high incidence which can promote vaginal birth in patients who has an unfavorable cervix through the changing of cervix characteristics [15]. Labor induction in women with prior cesarean delivery is considered to be an important clinical situation. The effective and relatively safe method for cervical ripening in pregnant women with prior cesarean delivery is needed urgently. Several different methods for labor induction have been used and are divided into pharmacological method and the mechanical methods. Based on previous studies, the pharmacological agent is not suggested for the labor induction in patients with scarred uterus [16]. So mechanical methods have become the option to perform labor induction in women with prior cesarean delivery. It has been proved that mechanical methods for cervical ripening

show a lower uterine rupture incidence in patients who had a scarred uterus [17].

Foley's catheter is a widely used cervical ripening equipment which has single balloon. The benefits of Foley's catheter including easy operation, low price, reversibility, and nearly no side effects [18]. Cook cervical ripening balloon is another cervical ripening equipment which has two balloons. Compared to Foley's catheter, this equipment can generate pressure simultaneously on external os and internal os. In this research, we compared the safety and efficacy of Foley's catheter with Cook cervical ripening balloon for induction of labor with a scarred uterus.

120 patients who had scarred uterus participated in this research and were randomized into single-balloon catheter group (n = 60) and double-balloon catheter group (n = 60). The baseline characteristics of the two groups were analyzed before the treatment of different catheters. No differences were found in the maternal age, body mass index, weight gain, gestational age,

gravidity, or parity between the patients in each group before the labor induction. The incidence of pregnancy complications such as hypertension, diabetes, thrombophilia, oligohydramnios, and polyhydramnios also had no difference between these two groups.

Foley's catheter triggers cervical ripening through the pressure on lower uterine segment and cervix and the prostaglandins secretion stimulated by membranes separation [19]. Cook cervical ripening balloon applies pressure on both the external and internal os of unripe cervix which can be held in place and avoid the need for traction [10]. According to the data of this research, both single- and double-balloon catheter significantly increased the Bishop score in pregnant women with scarred uterus. But the Bishop score in double-balloon catheter group was significantly lower than in single-balloon catheter group after catheter removal which shown a higher cervical ripening efficacy. The volume of normal saline in Foley's catheter was larger than in each balloon of Cook cervical ripening balloon. Larger volume of balloon in Foley's catheter generated higher pressure on unripe cervix and had a higher cervical ripening efficacy. However, the higher pressure generated by Foley's catheter increased the pain and discomfort in patients during the process of labor induction. Pain score during catheter insertion in double-balloon catheter group was significantly lower than in single-balloon catheter group. There were five patients who required for catheter removal during labor induction in single-balloon catheter group but only one patient in double-balloon catheter group. These data indicated that Cook cervical ripening balloon was more comfortable and better accepted by pregnant women with scarred uterus during the labor induction.

In this research, Cook cervical ripening balloon and Foley's catheter had comparable rates in labor induction. The time from catheter insertion to active labor and the time from catheter insertion to delivery in these two groups were also comparable. It has been confirmed that the two balloons of Cook cervical ripening balloon can keep it in place [20]. Spontaneous catheter expulsion rate of single balloon catheter was significantly higher than double balloon catheter. Meanwhile, Cook cervical ripening balloon had a longer time from catheter insertion to expulsion than Foley's catheter. The differences in the rate of spontaneous expulsion and time from insertion to expulsion between these two groups were also caused by the differences of the balloon volume between Foley's catheter and Cook cervical ripening balloon. Single-balloon catheter group had higher incidence of laceration of the cervix and cord prolapse when compared with double-balloon catheter group. According to differences in incidence of these two composite adverse events, in terms of safety, Cook cervical ripening balloon was better than Foley's catheter in induction of labor with a scarred uterus.

Based on the results in this research, the delivery mode and indications for cesarean section shown no differences between single-balloon catheter group and double-balloon catheter group. All the neonatal outcomes in these two groups were also comparable.

The limitations of this research also should be mentioned. First, the number of patients participated in this research was restricted to women with scarred uterus. This research will be more clinically applicable when more participants are involved in study. Second, pregnant women with two or more previous uterine scars should be involved in this research.

In conclusion, both Foley's catheter and Cook cervical ripening balloon are effective and safe in the cervical ripening of pregnant women with scarred uterus. Both catheters of labor induction have their own advantages and disadvantages. The choose of different type of catheter in labor induction should be based on the specific

characteristics of pregnant women. The current findings could be verified in a bigger population of participants, as a relatively small number of patients were observed in the current study.

Conflicts of interest

The authors declare that they have no conflict of interest.

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