Effective evaluation of labor induction by modifier double balloon Foley catheter at 108 Military Central Hospital

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Summary

Objective: To evaluate the efficacy of labor induction by modifier double balloon Foley catheter (MDB) in pregnant women with the indication of vaginal delivery. *Subject and method:* Longitudinal prospective study on 82 pregnant women at Obtetricts Department of 108 Military Central Hospital from June 2020 to September 2021 with criteria: Pregnancy age was older than or equal to 37 weeks, singleton, vertex presentation, their cervical Bishop score < 6, cervix is unfavorable to detach the amnio membranes, intact membranes, to designate termination of pregnancy by vaginal delivery and consent to participate in the study. Labor induction was conducted by double balloon Foley modifier catheter. *Result:* With success criteria is defined as Bishop score after labor induction larger or equal 7, the success rate with MDB was 86.6%, the increase of Bishop scores averaged 5.63 points with p<0.001. 7.32% tiny fever was connected to Foley catheters. The cesarean section rate after induction was 14.6%. The vaginal birth rate after the succession of labor induction using combined MDBs was 88.7%. There was not any complication for the women and the newborn babies. *Conclusion:* Our findings suggest that MDB using labor induction was feasible and high effective procedure as well as without compromising maternal or fetal safety.

Keywords: Induction labor, Foley catheter, modified double balloon catheter.

1. Background

In obstetrics, labor induction is a common procedure that accounts for 9.6% to 23.3% of all pregnancies [5], [8], [10]. The goal of labor induction is to help women achieve vaginal delivery when the pregnancy has been ended, but still 25% of those underwent cesarean-section because labor induction is not effective and the main cause is unfavorable cervix [12]. Several different methods have been established for cervical ripening and can be divided into two parts, the pharmacological method and the mechanical methods [2]. WHO recognized both two methods are effective for cervical ripening but the mechanical method is less likely to cause trauma to mothers such as uterine rupture and fetal distress in comparison with the chemical method. Cook catheters have been used in many countries around the world with successful performance, however, it is rarely used due to costly price in Vietnam. Therefore, based on the Cook balloon model [1], specialists from 108 Military Central Hospital has used modified double balloon foley catheter making of two balloons from 20Fr foley catheter inserting in 30Fr foley catheter with an affordable price compared to the original cook balloon. *In this research, we aimed to demonstrate the efficacy and safety of modified double-balloon foley catheters in the induction of labor.*

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2. Subject and method

This longitudinal prospective descriptive study was conducted from June 2020 to September 2021 in the Department of Obstetrics, 108 Military Central Hospital, Viet Nam. The sample size is applicated by:

$$Z_{1}$$

With confidence degree of 95% ($\alpha = 0.05$, $Z_{1-\alpha/2}^{2} = 1.96$), selection bias of 10% ($d = 0.1$), success rate of cervical double balloon of 85.7% [1], $n = 48$. In this study, there were 82 participants.

Inclusion criteria in this study: Living singleton gestation, vertex presentation, gestational age ≥ 37 weeks, intact membranes, no vaginal infections caused by Streptococcus agalactiae, no signs of systemic infection: Women without fever (armpit temperature < 37.5°C), blood test WBC < 15G/l, no signs of labor: 30-minute obstetric monitoring found that contraction < 2 times/10 minutes and intensity < 20mmHg, the cervix is closing, Bishop score < 6 points, pregnant women agree to participate in the study.

Exclusion criteria consisted of any contraindication for vaginal delivery such as low-lying placenta, placenta previa, previous cesarean delivery of other uterine scars, fetal distress, excess birthweight (predictive pregnancy weight > = 4000gr), asymmetric fetus and mother's pelvis. In addition, history of allergy to oxytocin or rubber, or cases of severe systemic disease (severe preeclampsia, heart failure, liver failure, kidney failure...) were not included in the study.

All parturients enrolled in the study underwent abdominal and transvaginal ultrasound in order to exclude placenta previa, confirm vertex presentation, and measure cervical length. In addition, nonstress test, recording of temperature, complete blood count, pelvic examination, and determination of Bishop score were performed. MDB was inserted according to the technical protocol in which 108 Military Central Hospital was published. Based on the Cook balloon model, MDB was made of two balloons from 20Fr Foley catheter inserting in 30Fr foley catheter after be cut top of the 30Fr catheter near its balloon membrane (Figure 1 & 2). In MDB, there are two balloons - the intrauterine balloon is inflated first with 60 ml saline and gently retracted against the internal os while the proximal balloon outside the external os is inflated with 60ml saline. After the intersection, a tablet of augmentin 1g per 12h was administered to the women to prevent infections. A nonstress test was conducted after insertion and every 6h unless the clinical condition indicated otherwise. Balloon catheters of both types were withdrawn 12h after insertion if not spontaneously expelled previously due to cervical dilatation. At the time of catheter withdrawal, cultures were taken from the tip of the catheter in the women in which the catheter was not expelled spontaneously. A Bishop score was assessed by one of the obstetricians involved in the study after catheter withdrawal or expulsion occurred. The providers who were managing labor were blinded to the type of catheter previously used since this information was not mentioned in the medical file. After the balloon catheter was spontaneously expelled or removed after 12 hours, oxytocin was administered and amniotomy was performed. Oxytocin is infused at an initial rate of 5mIU/min, then every 15 minutes reassess and increase the dose once by 5mIU/15 minutes if the contraction is not adequate.

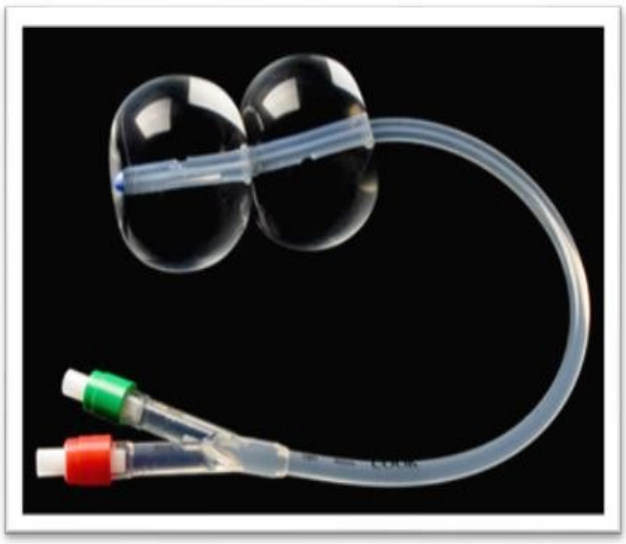

Figure 1. Original double ballon Cook catheter [1]

Figure 2. Modified double balloon Foley catheter

The success criteria of this study were Bishop score ≥ 7 after catheter's withdrawal or expulsion. Otherwise, the failure criteria were Bishop score < 7 after catheter's withdrawal or expulsion.

The primary outcomes of this study were the rate of cervical ripening success, the increment in the Bishop score from the time of catheter insertion until its withdrawal or expulsion, catheter withdrawal time, time to delivery after double-balloon device removal, the cesarean delivery rate and indication for cesarean delivery. Secondary outcomes included: Maternal adverse outcomes (fever, postpartum hemorrhage; third and fourth degree perineal lacerations), adverse neonatal outcomes (5-minute Apgar score less than 7, neonatal infection).

Statistical analysis was performed with the SPSS 26.0 packages. All reported results were based on observed data without imputation of missing data. Student's test was used for data with normal distribution. Results are presented as percentages or as medians and means ± SD. Differences were considered significant with $p<0.05$. For continuous outcomes, the effect size was the mean difference presented with 95% cis.

Research Ethics: Applying the modifier double balloon foley catheter for labor induction was approved by the 108 Military Central Hospital Technical Committee, and allowed for routine practice in the Department of Obstetrics and Gynecology with the aim of increasing the rate of vaginal delivery, reducing the rate of cesarean section. All parturients in the study were explained and signed a consent form to participate, the collected data is guaranteed to be confidential and only used for the study.

3. Result

In our study, there were 82 pregnant women were qualified for this research and were invited. The baseline characteristics of patients in each group are shown in Table 1.

Table 1. Baseline characteristics

Characteristic		MDB (n = 82)
Age		31.4 ± 9.8
BMI (kg/m^2)		27.8 ± 1.9
Gestational age (week)		38.9 ± 1.9
Indication for induction	Post-term	56 (68.29%)
	Oligohydramnios	13 (15.85%)

	Gestational diabetes	3 (3.66%)
	Gestational hypertension	10 (12.20%)
Preinduction cervical length (mm)		28.3 ± 7.8
Preinduction Bishop score		2.2 ± 0.9
Number of births		2 (1 - 3)
Ultrasound estimated gestational weight (gram)		3232 ± 256

Table 2. Rate of cervical ripening success

Outcome of cervical ripening	Number	Percentage (%)
Success	71	86.6
Failure	11	13.4

The rate of cervical ripening success by MDB was 86.6% (Table 2), including 21 cases of catheter's expulsion and 50 cases of catheter's withdrawal.

Table 3. Increment in the Bishop score (BS)

Mean Bishop score	Preinduction BS	Postcatheter BS	BS increment	p
Overall	2.20 ± 0.9	7.83 ± 1.15	5.63 ± 0.94	<0.001
Catheter's expulsion of success labor induction (n = 21)	2.30 ± 0.8	7.98 ± 1.9	5.68 ± 1.23	0.21
Catheter's withdrawal of success labor induction (n = 50)	2.10 ± 0.7	7.70 ± 1.06	5.60 ± 0.98	

The postcatheter Bishop scores was 7.83 ± 1.15, the Bishop score increment was 5.63 ± 0.94. The Bishop score increment differed significantly with p<0.001, but the Bishop score increment differed nonsignificantly between catheter's expulsion group and catheter's withdrawal in group of success labor induction (Table 3).

Table 4. Labor outcome

Parameter		Number	Percentage
Delivery in success group	Vaginal	63	88.7
	Cesarean section	8	11.3
Delivery in failure group	Vaginal	7	63.6
	Cesarean section	4	36.4
Delivery	Vaginal	70	85.4
	Cesarean section	12	14.6
Indication for cesarean delivery	Non-reassuring fetal heart rate	3	25
	Nonprogressive labor	4	33.3
	Maternal request	5	41.7
Catheter withdrawal time (h)		9.03 ± 2.84	
Time to delivery after double-balloon device removal (h)		4.9 ± 2.2	

The catheter withdrawal time was 9.03 ± 2.84 and the time to delivery after double-balloon device removal was 4.9 ± 2.2 (Table 4). The overall cesarean section rate after labor induction is 14.6%. The vaginal

birth rate after the succession of labor induction using combined MDBs was 88.7%. 7 cases of failure labor induction, which Bishop score after catheter's withdrawal was 6, were still vaginal delivery after performing amniotomy and administering oxytocin. When analyzing according to the results of labor induction, the rate of cesarean section in the successful labor induction group was higher than that in the failed induction group, this difference was statistically significant with $p<0.01$. In 12 cases of cesarean section, there were 3 cases of non-reassuring fetal heart rate, 4 cases of nonprogressive labor, and 5 cases of maternal request (Tablet 4).

Table 5. Maternal and neonatal adverse outcomes

Adverse outcome		Number	Percentage
Maternal	Fever	6	7.32
	Amniotic fluid infection	0	0
	Postpartum hemorrhage	0	0
	Third degree perineal lacerations	0	0
	Fourth degree perineal lacerations	0	0
Neonatal	5-min apgar score < 7	1	1.22
	Infection	0	0

In the study, there were no complications of postpartum hemorrhage, amniotic fluid infection. There were 6 pregnant women who had a slight fever after inserting the balloon. There were not cases of perineal lacerations after vaginal delivery.

Apgar rate for 5-minute under 7 accounts for 1.22%. There were no cases of neonatal infection.

4. Discussion

Single balloon foley catheter is a widely used cervical ripening equipment. The benefits of single balloon foley catheter including easy operation, low price, reversibility, and nearly no side effects [11]. The Foley catheter balloon may slide into the uterus in a fundal direction away from the cervical canal so that pressure is not maintained. Modified double balloon foley catheter is another cervical ripening equipment that has two balloons with similar principle of original double balloon cook catheter. Compared to foley's catheter, this equipment can generate pressure simultaneously on the external os and internal os. Furthermore, the cervical pressure of the internal uterine balloon in the cervical ripening double balloon may separate the membranes from the decidua, thus releasing endogenous prostaglandins from the adjacent deciduas [4]. Compared to cook catheter, our modified double balloon foley catheter is cheaper very much and available to apply. After more than 1 year of applying the modified double balloon foley's catheter for cervical ripening and labor induction, we found that this method gives the high successful might similar to the original cook catheter, and has almost no dangerous maternal and neonatal adverse outcomes.

Because there was no consensus of success criteria, the rate of cervical ripening success differed. In our study, with the success criteria of Bishop score ≥ 7 after catheter's withdrawal or expulsion, the rate of cervical ripening success was 86.6%. The Bishop score increment was significant (5.63 ± 0.74). In the study of Elad Mei-Dan, with the success criteria of Bishop score increment ≥ 2 or cervical dilatation ≥ 3cm, so the success rate was 99% [6], higher than our results. The results of our study are higher than the success rate in Camille's study (72%) [3], because the success criteria in this study were cervical dilatation ≥ 5cm, and the participants in this study included primiparous. In Policiano Catarina's study, with the success criteria of Bishop score increment

after catheter's withdrawal or expulsion were 3, the success rate reached 71% [9].

In our study, the catheter withdrawal time was 9.03 ± 2.84 and the time to delivery after double-balloon device removal was 4.9 ± 2.2, the overall cesarean section rate after labor induction was 14.6%, the vaginal birth rate after the succession of labor induction using combined MDBs was 88.7%. In another study, there was a similar cesarean section rate (20% in nulliparous and 6.7% in multiparous, respectively) and similar to cesarean section rate in participants using single balloon foley catheter [7].

In a prior meta-analysis of 30 RCTs [11], only one of which documented the CRDB, the authors concluded that maternal and neonatal infections are more likely to occur following induction of labor by intracervical catheters than by pharmacological agents. However, in the current study, there was 7.32% slight fever, no case of amniotic fluid infection, no case of neonatal infection, no case of perineal lacerations after vaginal delivery.

As above mentioned, there was no consensus of success criteria, the effective evaluation of labor induction might change depending on the study. This is a main limitation. In addition, the evaluation of Bishop score is a subjective factor, although we have tried to limit it, bias can still occur and affect research results.

5. Conclusion

Our findings suggest that the modifier double balloon Foley catheter using labor induction was feasible and high effective as well as without compromising maternal or fetal safety.

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