Effective evaluation of two mechanical devices for cervical ripening: Modified double balloon foley catheter versus single balloon foley catheter

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Summary

Objective: To compare the effective of the modified double balloon Foley catheter (MDB) versus the single balloon foley catheter (SB) on labor induction. *Subject and method:* This prospective blind trial randomized 80 pregnant women were randomized to MDB group and 80 pregnant women to SB group. Primary outcomes were the rate of cervical ripening success, Bishop score increment, catheter withdrawal time, and cesarean section rate. *Result:* Cervical ripening success of MDB was 82.5% versus 67.5% of SB with p<0.01. Average Bishop score increment of MDB was 5.63 hour versus 5.02 hour of SB with p=0.033. Cesarean section rate was higher in SB group than MDB group (32.5% and 20.0%, respectively, p=0.048). *Conclusion:* Using the modified double balloon foley catheter to induce labor is a feasible and effective procedure.

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

1. Background

According to the World Health Organization (WHO), labor induction (LI) accounts for 9.6% to 23.3% of all pregnancies [3], [8], [9]. The goal of LI is to help women achieve vaginal delivery when the pregnancy has been ended, but still 25% of those underwent cesarean section because LI is not effective and the main cause is unfavorable cervix [11]. At present, two methods of cervical ripening in LI have been used including (1) Chemical methods (prostaglandin E1, E2) and (2) Mechanical methods (Foley catheter, Atad catheter double balloon, Cook balloon). WHO recognized the both two of methods are effective for cervical ripening but the mechanical method is less likely to cause trauma for mothers such as uterine rupture and fetal distress in comparison with the chemical method. In Vietnam, single balloon foley catheter is a widely used cervical ripening equipment. The benefits of Foley's catheter including easy operation, low price, reversibility, and nearly no side effects [7]. Cook balloon which is double balloon catheter has been used in many countries around the world with more successful performance is rarely used in Viet Nam due to its costly price. Based on the cook balloon model [1], specialists from 108 Military Central Hospital have used modified double balloon Foley catheter making of two available single balloon foley catheter (20Fr foley catheter inside 30Fr foley catheter) with an affordable price similar to the original cook balloon. To determine the performance of modified double balloon as the mechanical methods for cervical ripening in LI in Vietnam and less likely to cause complications for

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both mothers and fetuses in comparison with the chemical method. Thereby, we conduct research on the topic: "Effective evaluation of two mechanical devices for cervical ripening: Modified double versus single balloon Foley catheter" with two goals as the following: *1. To compare effects in cervical ripening of modified double balloon Foley catheter versus single balloon foley catheter in labor induction. 2. To analyze factors affecting the efficiency of modified double balloon foley catheter in labor induction.*

2. Subject and method

This comparative randomized clinical trial study was conducted from June 2020 to September 2021 in the Department of Obstetrics, 108 Military Central Hospital, Viet Nam, to compare the effectiveness of MDB versus SB in LI. Sample size is applicated by:

$$n_1 = n_2 = \frac{[Z_{(1-\alpha/2)}\sqrt{2p(1-p)} + Z_{1-\beta}\sqrt{[p_1(1-p_1)+p_2(1-p_2)}]^2}{(p_1-p_2)^2}$$

With confidence degree of 95% (α = 0.05), sample power of 80% (β = 0.2), success rate of single balloon of (p_1 = 69%) [7], success rate of MDB of (p_2 = 87.3%) [6], $n_1 = n_2 = 79$. In this study, there were 160 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 < 37.5ºC), 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, to 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.

We use stratified randomization for our study. 16 strata (2x2x2x2) are formed solely from maternal age (≤ 35 and > 35), level of total pregnancy weight gain (normal* and excessive**), number of births (parous and nulliparous women, and cervical length (≤ 28 and > 28mm). Randomization with 16 strata should be accomplished using 16 separate randomization processes. Based on participants' factors, after signing informed consent, participants were randomly computerized assignment to one of two groups in each stratum. The women who participated were blinded to the type of catheter used in their induction. The two intention-to-treat study groups were 80 participants randomized to MDB, 80 participants randomized to SB. All participants 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. The single balloon and MDB were inserted according to the technical protocol in which 108 Military Central Hospital was published. The balloon of SB was inserted through the internal cervical os and into the extra-amniotic space, this balloon is distended with 60ml saline. In MDB, there are two balloons, the intrauterine balloon is inflated first with 60ml 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 12h, oxytocin was administered and amniotomy was performed if the cervical conditions were adequate. 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.

The success criteria of this study were Bishop score ≥ 7 after removing the balloon or self-falling ball. 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, amniotomy - delivery time and the cesarean delivery rate. The secondary outcomes were to find some factors affecting the efficiency of MDB in LI as maternal ages, MBI, maternal parity, cervical length, infant weight.

Statistical analysis: All statistical analyses were performed using SPSS software version 26. All reported results were based on observed data without imputation of missing data. All tests were performed and all reported values were two-sided unless otherwise indicated. A p-value less than 0.05 was considered significant. Student's test was used for data with normal distribution. The Mann-Whitney U test was used for data with non-normal distribution. Non-parametric values were analyzed using the chi-square test. Results are presented as percentages or as medians and means ± SD.

Research Ethics: Applying both the single balloon foley catheter and 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

Table 1. Characteristics of the two study groups

Characteristic		SB (n = 80)	MDB (n = 80)	p
Age		32.5 ± 9.1	31.4 ± 9.8	0.424
Pre-pregnancy BMI (kg/m^2)		22.7 ± 4.5	22.8 ± 4.2	0.513
Total pregnancy weight gain		13.5 ± 3.8	13.6 ± 3.9	0.32
Gestational age (week)		39.1 ± 1.3	38.9 ± 1.9	0.632
Indication for induction	Post-term pregnancy	55 (68.75%)	53 (66.25%)	0.321
	Oligohydramnios	13 (16.25%)	13 (16.25%)	
	Gestational diabetes	2 (2.5%)	3 (3.75%)	
	Gestational hypertension	10 (12.5%)	11 (13.75%)	
Preinduction cervical length (mm)		28.0 ± 8.4	28.3 ± 7.8	0.423
Preinduction bishop score		2.1 ± 0.9	2.2 ± 0.9	0.415
Number of births		2 (1 - 3)	2 (1 - 3)	0.513
Estimated gestational weight (gram)		3210 ± 126	3232 ± 256	0.562

There were no significant differences in maternal age, pre-pregnancy BMI, total pregnancy weight gain gestational age, indication for induction or ultrasound estimated gestational weight between those randomized to the SB and MDB groups. Neither there were significant differences in preinduction cervical length or Bishop score between two catheter groups.

Table 2. Induction parameters of the two study groups

Parameter		SB (n = 80)	MDB (n = 80)	p
Success induction labor rate n (%)		54 (67.5%)	66 (82.5%)	<0.01
Preinduction Bishop score		2.1 ± 0.9	2.2 ± 0.9	0.415
Postcatheter Bishop score		7.12 ± 0.64	7.83 ± 0.95	0.02
Bishop score increment		5.02 ± 0.56	5.63 ± 0.74	0.033
Catheter withdrawal time (h)		9.3 ± 3.5	7.6 ± 3.8	0.041
Amniotomy-delivery time (h)		5.1 ± 3.8	4.9 ± 3.2	0.11
Cesarean section (%)	Overall	26/80 (32.5%)	16/80 (20.0%)	0.048
	Nonprogressive labor	16/80 (20.0%)	7/80 (8.75%)	0.041
	Other causes	10/80 (12.5%)	9/80 (11.25%)	0.13
Newborn weight (gram)		3350 ± 326	3268 ± 348	0.45

Statistically significant differences in the outcome of induction between the two catheters were evident. The rate of cervical ripening success in the MDB group was higher than that of the SB (82.5% compared with 67.5%) with p<0.01. The Bishop score increment differed significantly between the SB and MDB (5.02 ± 0.56 and 5.63 ± 0.74, respectively, p=0.033).

In our study, mean amniotomy-delivery time differed nonsignificantly between the single balloon and the modified balloon (5.1 ± 3.8 and 4.9 ± 3.2, respectively, p=0.11). But there was statistically significant difference between SB and MDB in the mean catheter withdrawal times (9.3 ± 3.5 and 7.6 ± 3.8, respectively, p=0.041).

The overall cesarean section rate and the cesarean section rate in participants that were caused by nonprogressive labor, using SB versus MDB were 32.5% versus 20% and 20.0% versus 11.25%, respectively. These differences were statistically significant with p<0.05.

Our study shows that newborn weight differed nonsignificantly between the SB and MDB (3350 ± 326 gram and 3268 ± 348 gram, respectively, p=0.11), completely suitable with ultrasound estimated gestational weight.

Table 3. Relationship between maternal ages and results of two types of balloons

Maternal ages / Divices	≤ 35			> 35		
	Success	Failure	p	Success	Failure	p
SB	40	12	0.15	14	14	0.03
MDB	48	6		18	8	

There were no significant differences in the rate of success induction between the two catheters in women ≤ 35 years with p>0.05, but MDB had higher rate of success induction than SB in women > 35 years with p<0.05.

Table 4. Relationship between level of total pregnancy weight gain and the result of two types of balloon

	Normal*	Excessive**

Level of total pregnancy weight gain / Divices	Success	Failure	p	Success	Failure	p
SB	36	10	0.14	18	16	0.02
MDB	32	8		34	6	

**: Total pregnancy weight gain in the range of recommended pregnancy weight gain by prepregnancy BMI.*

***: Total pregnancy weight gain is more than recommended pregnancy weight gain by prepregnancy BMI.*

MDB and SB had no significant differences of the rate of success induction in cases of normal pregnancy weight gain, but MDB had higher rate of success induction than SB in cases of excessive pregnancy weight gain.

Table 5. Relationship between maternal parity and the result of two kind balloons

Maternal parity / Divices	Nulliparous women			Multiparous women		
	Success	Failure	p	Success	Failure	p
SB	30	20	0.04	24	6	0.48
MDB	32	6		34	8	

The rate of success induction in nulliparous women of MDB was also higher than the group using SB with $p<0.05$. There were no significant differences of the rate of success induction between the two catheters in multiparous women with $p>0.05$.

Table 6. Relationship between cervical length before LI with cervical softening result of two types of balloon

Cervical length / Divices	Cervical length ≤ 28mm			Cervical length > 28mm		
	Success	Failure	p	Success	Failure	p
SB	37	18	0.12	17	8	0.03
MDB	31	9		35	5	

For cervical length > 28mm, the rate of successful induction of MDB was also higher than the group using SB with $p<0.05$. There were no significant differences of the rate of success induction between the two catheters for cervical length ≤ 28mm with $p>0.05$.

Table 7. Relationship between infant weight and successful effect of two types of balloon

Groups of successful / Birth weight	SB	MDB	p
> 3500gram	9	14	1
2500 - 3500gram	32	37	0.3
< 2500gram	13	15	0.4

Pregnancy weight did not affect the success of the two types of balloons with $p>0.05$.

4. Discussion

4.1. Similarity of characteristics of women participating in the study

In our study, the characteristics of women participating in research in the two research groups

are similar of the subjects: Age, BMI of pregnant women, maternal parity, gestational age, indications of labor, initial Bishop score, estimated gestational weight, preinduction cervical length, preinduction Bishop score. This is an important factor to ensure the results of scientific research in practice.

4.2. Discussion on effects in cervical ripening of two catheters

Our research results in Table 2 show that the cervical ripening success was successful in SB compared to MDB with the difference of $p<0.01$, in which SB was lower than MDB group (67.5% compared to 82.5%, respectively). The Bishop score increment differed significantly between SB and the modified balloon (5.02 ± 0.56 and 5.63 ± 0.74, respectively, p=0.033). And there were differences between SB and the modified balloon catheters in the mean catheter withdrawal times were statistically significant (9.3 ± 3.5 and 7.6 ± 3.8, respectively, p=0.041). A possible reason for the advantage of the cervical ripening double balloon catheter is that its internal balloon covers the internal os and anchors the device in place, while the external balloon maintains the pressure of both balloons on both sides of the cervix. In contrast, the Foley catheter balloon may slide into the uterus in a fundal direction away from the cervical canal so that pressure is not maintained. 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 [2].

In our study, mean time from amniotomy to delivery differed nonsignificantly between SB and the modified balloon. In another study, a systematic review and meta-analysis that compared double-balloon to single balloon catheter for cervical ripening and LI, there were no differences in the meantime from intervention to delivery [12]. Also in discordance with our results, a recently published meta-analysis that included five randomized trials (996 women, 491 with single-balloon and 505 with cervical ripening double balloon) found that time from catheter insertion to delivery did not differ between the two types of catheter [10].

In our study, we found an increased cesarean section rate in participants using SB versus MDB. In another study, there was also an increased cesarean section rate in participants using Foley catheter versus the cervical ripening double balloon catheter (47.5 versus 20% in nulliparous and 12.5 versus 6.7% in multiparous, respectively) [5]. In contrast to our results, a recently published meta-analysis that included five randomized trials found that the incidence of cesarean delivery did not differ between the two types of catheter [10] but this meta-analysis lacked parity stratification of their results.

4.3. Discussion on some factors affecting the efficiency of MDB in LI

In our study shows that MDB had significantly higher result of successful cervical ripening in women > 35 years and nonsignificant different result of successful cervical ripening in women ≤ 35 years than SB. In Dunn Liam's study, advanced maternal age is a risk factor for failure induction, the rate of cesarean section following labor induction for women > 35 years of age is higher than for women < 35 years old [4]. Thus, MDB is an effective suggestion for induction of labor for pregnant women who have advanced maternal age.

The results of our study show that MDB is significantly more successful than SB for cases of excessive pregnancy weight gain. Thus, if women with excessive pregnancy weight gain are indicated to open the cervix during labor, they should be advised to use MDB.

Our research results show that MDB is significantly more successful than SB for nulliparous women, and for multiparous women, there was no difference in the rates of success between the two catheters. Thus, nulliparous women who should be recommended are indicated the cervical ripening by MDB.

The results of our study show that MDB was significantly more successful than SB for pregnant women that had cervical length > 28mm and nonsignificant different result for pregnant women who had cervical length ≤ 28mm. Thus, MDB should

be recommended for pregnant women with cervical lengths more than 28mm.

Our research results show that infant weight does not affect the success of two catheters with p>0.05.

5. Conclusion

Based on the findings of the present study, cervical ripening by MDB might be more effective than induction by the SB, especially for pregnant women which have advanced maternal age, excessive pregnancy weight gain, long cervical lengths and nulliparous women.

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