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Predictors of vaginal delivery after cervical priming using a double balloon catheter

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Objectives: To determine predictors of successful vaginal delivery after induction of labour using a double balloon catheter.
Methods: Medical records of women who underwent induction of labour using a double balloon catheter between 1 September 2017 and 31 August 2024 at a tertiary public hospital in Hong Kong were retrospectively reviewed.
Results: Of 111 women, 32 (28.8%) had a scarred uterus secondary to a previous Caesarean section or a myomectomy, 53 (47.7%) had failed pharmacological priming, and 26 (23.4%) had a contraindication for pharmacological priming. The latter group had lower body mass index and gestational age and comprised most cases of fetal growth restriction. In total, 106 (95.5%) women had successful cervical priming. Subsequently, 56 (50.5%) had vaginal deliveries and 55 (49.5%) underwent Caesarean sections. The rate of vaginal delivery was higher in women with a contraindication of pharmacological priming, compared with women with a scarred uterus and women who failed pharmacological priming (73.1% vs 50.0% vs 39.6%, p=0.02). Predictors of successful vaginal delivery after the use of a double balloon catheter were a body mass index of <30 kg/m^2 (adjusted odds ratio [aOR]=3.10, p=0.019), a history of vaginal delivery (aOR=4.08, p=0.026), and a cervix with an initial modified Bishop score of ≥4 (aOR=4.49, p=0.045). However, larger uterine or vaginal balloon volumes were not associated with higher vaginal delivery rates.
Conclusion: Predictors of vaginal delivery after induction of labour using a double balloon catheter were a non-obese status, a history of vaginal delivery, and a favourable cervical status.

Keywords: Labor, induced; Fetal growth retardation; Vaginal birth after cesarean

Introduction

Indications for induction of labour include hypertension, fetal growth restriction, and decreased fetal movements. When the cervix is unfavourable, cervical priming is required before oxytocin administration to increase the likelihood of a vaginal delivery. Cervical priming can be performed using pharmacological agents or mechanical devices. In a meta-analysis, mechanical priming is superior to pharmacological priming in terms of safety, but both are comparable at achieving vaginal delivery[1]. In women who received pharmacological priming, both the risks of uterine hyperstimulation (risk ratio=10.02) and neonatal intensive care unit admission (risk ratio=1.31) increase[1].

The Royal College of Obstetricians and Gynaecologists advocates the use of mechanical methods for induction of labour in women with a previous birth by Caesarean section, because of a lower risk of scar rupture when compared with the use of prostaglandins[2]. In pregnancies complicated by fetal growth restriction, mechanical methods are associated with a lower occurrence of adverse intrapartum outcomes, probably because of the lower risk of uterine hyperstimulation[3,4]. In addition, mechanical priming may be used as the second-line method when pharmacological priming has failed.

A double balloon catheter consists of a uterine balloon and a vaginal balloon. It ripens the cervix mechanically by exerting pressure to both parts and stimulates the local release of prostaglandins and oxytocin[5]. The Cook Cervical Ripening Balloon (Cook Medical, Bloomington [IN], United States) is approved by the Food and Drug Administration of the United States.

Successful cervical priming is correlated with women's acceptance of the double balloon catheter[6]. Therefore, knowledge about predictors of successful

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cervical priming and subsequent vaginal delivery can help clinicians counsel women on the use of a double balloon catheter and its acceptance. It is not clear whether the volumes of the uterine and vaginal balloons affect the vaginal delivery rate. In Hong Kong, a higher rate of vaginal delivery was associated with an occipital-anterior position of the fetal head at delivery and a lower birth weight[7]. However, these factors cannot be predicted or measured until advanced labour stage or after birth. This study aims to identify predictors of successful vaginal delivery after induction of labour using a double balloon catheter.

Methods

Medical records of women who underwent induction of labour using the Cook Cervical Ripening Balloon at Queen Elizabeth Hospital, Hong Kong between 1 September 2017 and 31 August 2024 were retrospectively reviewed. Women with or without pharmacological priming who had a singleton pregnancy, cephalic presentation, gestational age of ≥37 weeks, a normal cardiotocograph, and an initial cervical status of modified Bishop score (MBS) <6 were included. Those with any contraindication to vaginal delivery or incomplete documentation were excluded. Cervical priming was performed to women with (1) a scarred uterus secondary to a previous Caesarean section or myomectomy, (2) failed pharmacological priming (after two doses of 3 mg vaginal prostaglandin E2 or one dose of a 10-mg dinoprostone controlled-release tablet), or (3) a contraindication for pharmacological priming.

The double balloon catheter was put in place for up to 12 hours, unless it was spontaneously expelled or removed for indications such as prelabour rupture of membranes, spontaneous onset of labour, uterine hyperstimulation, abnormal cardiotocography, or at the woman's request. The uterine balloon was placed at the internal cervical os, whereas the cervicovaginal balloon was placed at the external cervical os. Both balloons were filled with 20 to 80 mL of saline, per the attending obstetrician's discretion and the woman's tolerance. A cut-off volume of 60 mL was used to classify low and high volumes[8].

After insertion, cardiotocography was performed for 1 hour and checked every 2 hours to ensure non-expulsion. Vital signs, uterine activity, vaginal bleeding, and the presence of rupture of membranes were monitored every 4 hours. The cervical favourability was reassessed after removal of the catheter. Those with a favourable cervix (an MBS ≥6) proceeded to induction of labour with amniotomy and oxytocin infusion. Those with an unfavourable cervix (an MBS <6) were offered a Caesarean section or further cervical priming per the attending obstetrician's discretion and the woman's preference.

Data retrieved included maternal age, height, body mass index, obstetric history, gestational age, gestational diabetes mellitus, indications for induction of labour, MBS before and after cervical priming, vaginal and uterine balloon volumes and duration of insertion, mode of delivery, indications for Caesarean section or operative vaginal delivery, neonatal outcomes, birthweight, and complications including heavy bleeding, uterine rupture, and fever (≥37.5°C[9]).

Statistical analysis was performed using the SPSS (Windows version 24; IBM Corp, Armonk [NY], United States). Comparisons of the three groups were made using the Chi-squared test for categorical variables or the Kruskal-Wallis test for continuous variables. Variables for success vaginal delivery after cervical priming were identified using univariate analysis. Variables with a p value of <0.2 were included in the multivariate analysis to identify predictors of vaginal delivery. A p value of <0.05 was considered statistically significant.

Results

Of 113 women identified, two were excluded owing to incomplete documentation of the double balloon catheter insertion procedure and the remaining 111 were included for analysis. Of these 111 women, 32 (28.8%) had a scarred uterus secondary to a previous lower segment Caesarean section (n=31) or a myomectomy (n=1), 53 (47.7%) had failed pharmacological priming, and 26 (23.4%) had a contraindication for pharmacological priming including fetal growth restriction (n=21), grand multiparity (n=2), allergy to prostaglandin (n=1), and personal preference (n=2). The three groups were comparable in terms of baseline characteristics, except that women with a contraindication for pharmacological priming had lower body mass index and gestational age and comprised most cases of fetal growth restriction (Table 1).

The double balloon catheter was put in place for a median duration of 12.0 (interquartile range, 11.0-12.0) hours. The volumes ranged from 30 to 80 mL for the uterine balloon and 20 to 80 mL for the vaginal balloon. The most common indication for induction of labour was fetal growth restriction (84.6%), followed by gestational or pre-existing diabetes mellitus (59.0%) and large-for-gestational age (44.6%) [Table 2].

Table 1. Baseline characteristics of participants

Characteristic	Scarred uterus (n=32)*	Failed pharmacological priming (n=53)*	Contraindicated for pharmacological priming (n=26)*	p Value
Maternal age, y	34 (31-36)	32 (29-35)	33 (30-35)	0.210
Maternal age ≥35 y	14 (43.8)	15 (28.3)	10 (38.5)	0.324
Maternal height, cm	158.0 (153.1-161.5)	158.5 (155.5-161.7)	157.3 (154.0-161.4)	0.575
Body mass index on admission, kg/m^2	28.7 (25.6-32.5)	29.3 (25.1-33.1)	26.6 (22.4-28.9)	0.025
Body mass index ≥30 kg/m^2	13 (40.6)	24 (45.3)	6 (23.1)	0.158
Prior vaginal delivery	5 (15.6)	11 (20.8)	6 (23.1)	0.757
Gestational age, wk	39 (39-41)	39 (38-39)	37 (37-38)	<0.001
Modified Bishop score prior to catheter insertion				0.312
<4	4 (12.5)	4 (7.5)	5 (19.2)	
≥4 to <6	28 (87.5)	49 (92.5)	21 (80.8)	

* Data are presented as median (interquartile range) or No. (%) of participants

Table 2. Indications for induction of labour

Indication	Scarred uterus (n=32)*	Failed pharmacological priming (n=53)*	Contraindicated for pharmacological priming (n=26)*
Current or history of antepartum haemorrhage	2 (6.3)	3 (5.7)	0
Decreased fetal movements	1 (3.1)	3 (5.7)	1 (3.8)
Fetal growth restriction	0	0	21 (80.8)
Gestational or pre-existing diabetes mellitus	11 (34.4)	11 (20.8)	1 (3.8)
Hypertensive disorder	1 (3.1)	3 (5.7)	0
Large-for-gestational age (estimated fetal weight or abdominal circumference >90th percentile)	4 (12.5)	17 (32.1)	0
Oligohydramnios	1 (3.1)	3 (5.7)	2 (7.7)
Past term	10 (31.3)	2 (3.8)	0
Small-for-gestational age (estimated fetal weight or abdominal circumference <10th percentile)	2 (6.3)	10 (18.9)	1 (3.8)
Others	0	1 (1.9)	0

* Data are presented as No. (%) of participants

The time interval from catheter insertion to vaginal delivery ranged from 9 to 29.5 hours. The rate of successful vaginal delivery was higher among women with a contraindication for pharmacological priming, compared with women with a previous Caesarean section or myomectomy and women who failed pharmacological priming (73.1% vs 50.0% vs 39.6%, p=0.02, Table 3). The rate of non-emergency Caesarean section was highest in women who failed pharmacological priming, compared with women with a previous Caesarean section or myomectomy and women with a contraindication of pharmacological priming (58.5% vs 43.8% vs 23.1%, p=0.012); the most common indication was failed induction of labour (Table 3).

Independent predictors of vaginal delivery after the use of a double balloon catheter were a body mass index of <30 kg/m^2 (adjusted odds ratio [aOR]=3.10, p=0.019), a history of vaginal delivery (aOR=4.08, p=0.026), and an initial cervical status of MBS of ≥4 (aOR=4.49,

Table 3. Outcomes of induction of labour using a double balloon catheter

Outcome	Scarred uterus (n=32)	Failed pharmacological priming (n=53)	Contraindicated for pharmacological priming (n=26)	p Value
Balloon expulsion	1 (3.1)	3 (5.7)	2 (7.7)	0.742
Successful priming	32 (100)	50 (94.3)	24 (92.3)	0.397
Labour without amniotomy or oxytocin	1 (3.1)	2 (3.8)	1 (3.8)	0.663
Mode of delivery				
Vaginal	16 (50.0)	21 (39.6)	19 (73.1)	0.020
Operative vaginal	1 (3.1)	3 (5.7)	0	0.441
Caesarean section	16 (50.0)	32 (60.4)	7 (26.9)	0.020
Emergency for fetal distress	2 (6.3)	1 (1.9)	1 (3.8)	0.577
Non-emergency	14 (43.8)	31 (58.5)	6 (23.1)	0.012
Cephalopelvic disproportion	0	1	0	
Failed induction of labour	9	27	4	
Suspicious cardiotocography	2	0	0	
Malpresentation after catheter removal	0	2	1	
Suspected scar dehiscence	3	0	0	
Unfavourable cervix	0	1	1	
Prior delivery	n=5	n=11	n=6	0.387
Vaginal	4 (80.0)	6 (54.5)	5 (83.3)	
Caesarean section	1 (20.0)	5 (45.5)	1 (16.7)	
No prior delivery	n=27	n=42	n=20	0.040
Vaginal	12 (44.4)	15 (35.7)	14 (70.0)	
Caesarean section	15 (55.6)	27 (64.3)	6 (30.0)	
Time from catheter insertion to vaginal delivery, h	20 (14.5-23.75)	23.0 (21.0-25.0)	20.0 (18.0-24.5)	0.959
Birthweight, g	3292.5 (2985.0-3482.5)	3250.0 (2835.0-3470.0)	2400.0 (2242.5-2607.5)	<0.001
Birthweight >4000 g	1 (3.1)	1 (1.9)	0	0.672

* Data are presented as median (interquartile range), No. (%) of participants, or No. of participants

p=0.045) [Table 4]. The area under the receiver operating characteristic curve was 0.647 (Figure), which was within the range of inadequate discrimination (0.5-0.7).

Fourteen women developed primary postpartum haemorrhage, with blood loss ranging from 550 to 1900 mL (Table 5). One woman with a scarred uterus presented with fetal distress necessitating vacuum extraction, which was complicated with postpartum haemorrhage secondary to uterine scar rupture, which was repaired using laparotomy. The neonate developed severe hypoxic-ischaemic encephalopathy and died on day 13 of life. Three women with a scarred uterus complained of Caesarean scar pain and were suspected of having scar dehiscence, but this subsequently was not confirmed during the Caesarean section. One woman with a scarred uterus had uterine hyperstimulation without oxytocin infusion. Nine women developed transient intrapartum fever; one woman had maternal sepsis and four neonates had perinatal sepsis.

Discussion

Predictors of vaginal delivery after induction of labour using a double balloon catheter were a maternal body mass index of <30 kg/m^2, a history of vaginal delivery, and a cervix with an initial MBS of ≥4, all of which are well recognised[10-13]. The rates of successful cervical priming ranged from 92.3% to 100%, but the rates of vaginal delivery ranged from 39.6% to 73.1%, similar to a previous study[14]. The rate of vaginal delivery was highest in women with a contraindication of pharmacological

Table 4. Predictors of vaginal delivery after induction of labour using a double balloon catheter

Variable	Univariable analysis			Multivariate analysis	
	Vaginal delivery (n=56)*	Caesarean section (n=55)*	p Value	Adjusted odds ratio (95% confidence interval)	p Value
Maternal age ≥35 y	22 (39.3)	17 (30.9)	0.468	-	-
Body mass index ≥30 kg/m^2	14 (25.0)	29 (52.7)	0.005	3.10 (1.20-8.02)	0.019
Maternal height, cm	159.0 (156.0-162.9)	157.0 (153.3-160.0)	0.290	-	-
Birthweight >4000 g	1 (1.8)	1 (1.8)	>0.99	-	-
Large-for-gestational age	7 (12.5)	14 (25.5)	0.134	0.51 (0.15-1.69)	0.268
History of vaginal delivery	15 (26.8)	7 (12.7)	0.105	4.08 (1.19-14.06)	0.026
Scarred uterus	16 (28.6)	16 (29.1)	>0.99	-	-
Gestational diabetes mellitus	9 (16.1)	17 (30.9)	0.105	0.47 (0.15-1.46)	0.192
History of pharmacological priming	21 (37.5)	32 (58.2)	0.046	0.43 (0.17-1.08)	0.072
Modified Bishop score			0.071		
<4	3 (5.4)	10 (18.2)		-	-
≥4	53 (94.6)	45 (81.8)		4.49 (1.03-19.49)	0.045
Uterine balloon volume, mL			0.105		
<60	9 (16.1)	17 (30.9)		-	-
≥60	47 (83.9)	38 (69.1)		2.10 (0.74-5.96)	0.166
Vaginal balloon volume, mL			0.636		
<60	16 (28.6)	19 (34.5)		-	-
≥60	40 (71.4)	36 (65.5)		-	-

* Data are presented as median (interquartile range) or No. (%) of participants

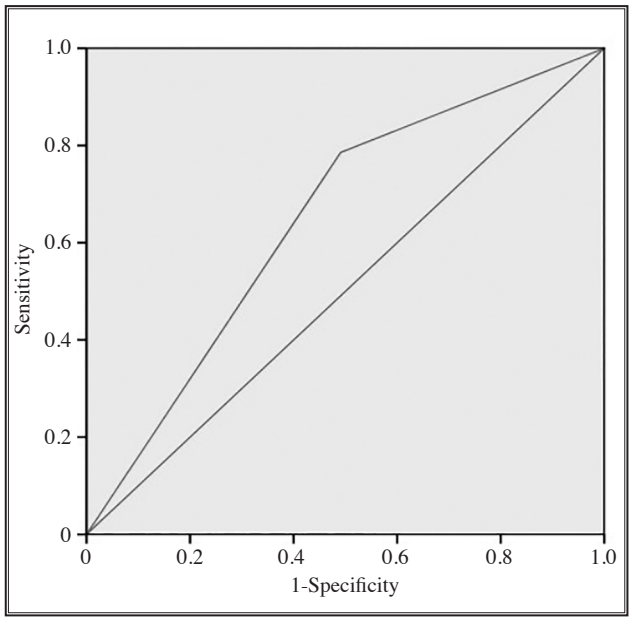

Figure. Receiver operating characteristic curve of successful vaginal delivery after induction of labour using a double balloon catheter.

priming, probably because of their lower body mass index. The higher rate of non-emergency Caesarean section in women with failed pharmacological priming was expected, given the low success rate of induction of labour by double balloon catheters as a second-line method after administration of dinoprostone[7].

Obesity (body mass index of ≥30 kg/m^2) was associated with a higher rate of Caesarean section, consistent with other studies[10,11]. Balloon catheters are more successful than misoprostol at achieving cervical ripening in women with obesity[15]. Therefore, the double balloon catheter remains an acceptable choice for cervical priming in women with obesity. Nonetheless, they should be advised on the lower-than-average successful vaginal delivery rate.

Neither a higher uterine balloon volume nor a higher vaginal balloon volume was associated with a higher vaginal delivery rate, consistent with a study of

Table 5. Complications after induction of labour using a double balloon catheter

Complication	Scarred uterus (n=32)*	Failed pharmacological priming (n=53)*	Contraindicated for pharmacological priming (n=26)*	p Value
Composite adverse intrapartum outcome	10 (31.3)	14 (26.4)	4 (15.4)	0.370
Primary postpartum haemorrhage ≥500 mL	5 (15.6)	8 (15.1)	1 (3.8)	0.305
Primary postpartum haemorrhage ≥1000 mL	3 (9.4)	1 (1.9)	0	0.106
Intrapartum fever	3 (9.4)	4 (7.5)	2 (7.7)	0.958
Maternal sepsis	0	0	1 (3.8)	0.192
Malpresentation after removal of catheter	0	2 (3.8)	1 (3.8)	0.535
Scar rupture	1 (3.1)	0	0	0.288
Uterine hyperstimulation	1 (3.1)	0	0	0.288
Apgar score <7 at 5 min	1 (3.1)	1 (1.9)	0	0.441
Perinatal sepsis	1 (3.1)	2 (3.8)	1 (3.8)	0.985
Neonatal death	1 (3.1)	0	0	0.288

* Data are presented as No. (%) of participants or No. of participants

single balloon catheters that the overall Caesarean section rate did not differ significantly between those using a high-volume (≥60 mL) Foley catheter and those using a low-volume (≤30 mL) Foley catheter[8].

One (0.9%) woman with a scarred uterus had uterine rupture, consistent with the 1% in previous studies[15,16]; the uterine and vaginal balloons were filled with 80 mL of saline. Additionally, one woman with a scarred uterus had uterine hyperstimulation without oxytocin infusion, although the double balloon catheter is associated with a lower risk of uterine hyperstimulation compared with pharmacological priming[17]. We hypothesise that the cervical priming effect of a double balloon catheter was brought about more by the release of endogenous prostaglandins than by the actual pressure exerted. Therefore, women should be advised about the risk of uterine hyperstimulation, and their uterine contractions should be monitored.

Pain is often the reason women decline the use of the double balloon catheter. Nonetheless, there was no report of premature removal of the balloon due to pain or discomfort. The double balloon catheter is considered well tolerated[18]. However, in single balloon catheters larger balloon volumes of 70 mL are associated with higher pain scores at the time of expulsion[19].

There were three cases of fetal malpresentation after removal of the double balloon catheter. We hypothesise that these fetuses were at high stations when the catheter was inserted[20]. All three cases used a large-volume (60-80 mL) uterine balloon. In women using a single balloon catheter, higher volumes (180-250 mL) are associated with a higher risk of cord presentation, compared with lower volumes (70-150 mL)[21]. Smaller uterine balloon volumes may decrease the risk without lowering the vaginal delivery rate. Larger balloon volumes are not associated with a higher vaginal delivery rate but can cause discomfort, malpresentation, and other complications. It is suggested that the balloons be filled to a volume that is tolerable by the woman, up to 80 mL. The volume should be reduced if the woman experiences discomfort.

There were limitations to the present study. The study was retrospective and the sample size was small and from a single hospital. The hospital's protocol on induction of labour may not be generalisable to other settings. The area under the curve was considered inadequate discrimination; the successful vaginal delivery rate after the use of a double balloon catheter may have been affected by intrapartum or other factors that were not investigated. Nonetheless, the knowledge about predictors of successful vaginal delivery after the use of a double ballon catheter enables evidence-based counselling of women and empowers them to make informed decisions about their labour and delivery. Women at higher risk of hyperstimulation or with a contraindication for pharmacological priming were included in the analysis, in addition to the more commonly studied groups of women with a previous Caesarean section or failed pharmacological priming.

Conclusion

Predictors of vaginal delivery after the use a double balloon catheter were a non-obese status, a history of vaginal delivery, and a favourable cervical status. Although the overall successful vaginal delivery rate was about 50%, the successful cervical priming rate was ≥90%.

Contributors

All authors designed the study, acquired the data, analysed the data, drafted the manuscript, and critically revised the manuscript for important intellectual content. The authors had full access to the data, contributed to the study, approved the final version for publication, and take responsibility for its accuracy and integrity.

Conflicts of interest

As an executive editor of the journal, KYL was not involved in the peer review process. Other authors have no conflict of interest to disclose.

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Data availability

All data generated or analysed during the present study are available from the corresponding author upon reasonable request.

Ethics approval

This study was approved by the Central Institution Review Board of Hospital Authority, Hong Kong (reference: CIRB-2024-097-1). All patients were treated in accordance with the tenets of the Declaration of Helsinki. The patients provided informed consent for all treatments and procedures and for publication.

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