

Duration of double balloon catheter for patients with prior cesarean: a before and after study



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BACKGROUND: Previous studies that suggest a shorter time from cervical ripening balloon placement to delivery with shorter total balloon placement time have excluded patients with prior cesarean deliveries.

OBJECTIVE: To evaluate, in patients with a prior history of cesarean delivery undergoing cervical ripening with a double-balloon catheter, whether planned removal of device after 6 vs 12 hours would result in shorter time to vaginal delivery.

STUDY DESIGN: A before-and-after study was performed after a practice change occurred November 2020, shortening the planned time of double-balloon catheter placement for cervical ripening from 12 to 6 hours. Data were collected via retrospective electronic chart review. Primary outcome was time from balloon placement to vaginal delivery. Secondary outcomes included rates of cesarean delivery, maternal intraamniotic infection, and uterine rupture. Kaplan—Meier curves compared median times to delivery between the groups. A Cox proportional-hazards model was used to adjust for time of balloon placement, number of previous vaginal deliveries, and co-medications used.

RESULTS: From November 2018 to November 2022, 189 analyzable patients with a prior history of cesarean delivery received a double-balloon catheter for cervical ripening during their trial of labor. Patients were separated into pre- and postpolicy change groups ($n=91$ and 98 , respectively). The median time to vaginal delivery for the pregroup was 28 hours (95% CI: 26, 35) and 25 hours (95% CI: 23, 29) for those in the postgroup (P value .052). After adjusting for dilation at time of balloon placement, number of previous vaginal deliveries, and co-medication, the estimated hazard ratio for successful vaginal delivery postpolicy change was 1.89 (95% CI: 1.27, 2.81). There were no differences in rates of secondary outcomes.

CONCLUSION: In patients with prior cesarean delivery undergoing mechanical cervical ripening with a double-balloon catheter, planned removal at 6 hours compared to 12 hours may result in higher chances of successful vaginal delivery and possibly a shorter time to delivery, without increasing rates of cesarean delivery and intraamniotic infection.

Key words: cervical ripening, cervical ripening balloon, cesarean delivery, double-balloon catheter, duration, trial of labor after cesarean (TOLAC), vaginal birth after cesarean (VBAC)

Introduction

Cesarean delivery now accounts for about one-third of all deliveries in the United

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Tweetable statement: For patients with prior cesarean delivery undergoing cervical ripening with double-balloon catheter, shorter time to vaginal delivery may exist with planned 6 hours of placement compared to 12 hours.

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States, representing a 50% increase in rate since the late 1990s.¹ Although cesarean delivery can be a necessary measure to ensure the safety of both mother and fetus, the rapid increase in proportional deliveries without concomitant decrease in maternal and neonatal morbidity has raised concerns that it may be excessively employed.² In 2010, the National Institute of Health recognized trial of labor after cesarean delivery (TOLAC) as a reasonable option for patients with a prior cesarean delivery. As a result, there has been a concerted effort to increase vaginal birth rates in recent years,^{1,3} with the most recent vaginal birth after cesarean (VBAC) rate quoted by the CDC at 14.2%.⁴ This number consistently increases every year, constituting a growing population of birthing patients. Patients who experience a successful VBAC have been shown to have lower rates of birth-related morbidity, including

hemorrhage, thromboembolism, infection, unplanned hysterectomy, and ruptured uterus.³ Patients with a prior cesarean delivery are at an increased risk of requiring a repeat cesarean delivery and with each increasing cesarean, patients experience increased morbidity, including rates of hysterectomy, blood transfusions, adhesions, and surgical injury. Therefore, interventions that can increase success of vaginal delivery after cesarean, can help lower the rates of morbidity in this patient population.⁵

Induction of labor is an option for patients undergoing TOLAC⁶ and many will require cervical ripening.³ One option for cervical ripening during the induction process includes mechanical intervention with the use of a transcervical balloon catheter.⁷ Advantages to the use of this method vs prostaglandin-based methods of ripening include cost-effectiveness, reduced risk of

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Why was this study conducted?

Patients with prior cesarean delivery make up a growing percentage of vaginal deliveries. Our study aims to further characterize mechanical cervical ripening efficacy in patients with a prior cesarean delivery with hopes of improving clinical outcomes.

Key findings

Shorter time to vaginal delivery with shorter planned duration of double-balloon cervical catheter placement may exist in patients with prior cesarean delivery and can lead to a higher hazard ratio for vaginal delivery.

What does this add to what is known?

While prior work demonstrated shorter time to vaginal delivery with shorter planned duration of double-balloon cervical catheter placement, this study demonstrated these results for patients with a prior cesarean delivery, a group excluded from most prior studies.

uterine tachysystole, and fewer maternal side-effects.^{8,9} There are numerous variations among types of devices as well as protocols for balloon catheter placement, which make it difficult to compare studies. Because of this, there is a lack of consensus guidelines on balloon usage.

Understanding of the optimal use of balloon catheter for cervical ripening is evolving, and the most effective timing from insertion to removal may differ from the manufacturer's recommended time.¹⁰ Recent randomized controlled trials^{11,12} have attempted to assess this variable and noted that there may be a shorter time to vaginal delivery resulting from shorter planned duration of placement (6 vs 12 hours) of the balloon catheter. These studies^{11,12} have excluded patients with a prior cesarean delivery. Based on a PubMed search (using ((balloon[Title]) AND (cervical ripening[Title])) AND (cesarean [Title])), we are unaware of other studies to date assessing optimal duration of balloon catheter placement for patients with a prior cesarean delivery.

The objective of this study was to examine whether a shorter planned duration of double-balloon catheter placement (6 vs 12 hours) could result in a shorter time to vaginal delivery in patients with a prior cesarean delivery. We hypothesize that shorter time to vaginal delivery could be achieved with

shorter planned duration of balloon catheter placement in this population.

Materials and methods

This was a before-and-after study conducted at a Midwestern county hospital. The study was submitted to the local institutional review board and approved. A practice change occurred on November 15, 2020, at which time the standard duration of double-balloon catheter placement during induction of labor was changed from 12 hours (the manufacturer's recommendation) to 6 hours, based on published data that suggested improved time to vaginal delivery with 6 hours of balloon catheter placement.^{11,12} This practice was applied to all patients undergoing labor induction with a double-balloon catheter regardless of parity and prior cesarean history. Initial chart abstraction was conducted by Regenstrief Institute Data Services, the honest data broker for our electronic medical record system. Data were collected from November 2018 to November 2022 (2 years prior to and 2 years following the practice change) via retrospective electronic chart review and stored into a REDCap database. Additional variables were collected by manual chart abstraction. Inclusion criteria included singleton pregnancy regardless of gestational age, fetus in cephalic presentation upon admission, history of at least one prior cesarean delivery, and cervical ripening

accomplished with a double-balloon catheter. Patients with multiple gestation pregnancy, those with more than one balloon catheter placed during labor, and those being induced for fetal demise were excluded from the study.

Baseline characteristics collected included maternal age, race, BMI, marital status, and insurance coverage. In addition, number of prior cesarean deliveries, reason for prior cesarean, number of previous successful vaginal deliveries, gestational age at time of induction, cervical exam at time of balloon placement and removal, and whether oxytocin was used prior to and during balloon placement were collected. The primary outcome of this study was time from balloon placement to vaginal delivery. Secondary outcomes included rates of cesarean delivery and rates of maternal intraamniotic infection. The occurrence of uterine rupture was obtained as a safety outcome.

Summary statistics by time period (pre- and postpolicy change) were calculated for demographic and clinical variables of interest. Comparisons were made for the "intent to remove" groups (6 vs 12 hours), regardless of how long the catheter was actually left in before either spontaneous expulsion or provider removal. Differences in distribution of the variables between the two time periods were tested using Kruskal–Wallis rank sum tests for continuous variables and Fishers exact tests for categorical variables. Kaplan–Meier estimates of the time from balloon catheter placement to vaginal delivery were calculated and used to estimate the median time to delivery for patients induced in the two time periods. A log-rank test was employed to test for a difference in the median time to delivery. A Cox proportional hazards model was fit to adjust for potential confounders: dilation at time of placement, number of previous deliveries, and co-medication. These were chosen a priori based on their known importance to time to delivery. STROBE guidelines for cohort studies are followed throughout this manuscript.¹²

Results

From November 2018 to November 2022, 210 patients with a prior history of cesarean delivery received a double-balloon catheter during induction and met inclusion criteria for abstraction by the Regenstrief Institute. After chart review to evaluate for exclusion criteria, 189 patients were found to be eligible. Reasons for exclusion included patients who were found not to be eligible after additional retrospective chart review, for instance if they actually were not undergoing TOLAC, or received more than one balloon catheter during induction.

Baseline characteristics are presented in [Table 1](#). There were no significant differences in age, race, ethnicity, or BMI in the pre- and postpolicy change groups. There was a statistically significant difference in the distribution of insurance coverage, mostly driven by an increase in uninsured patients in the postchange group (21.4% vs 6.6%; $P=.010$). Additionally, there were no significant differences in gestational age at time of induction, reason for prior cesarean, number of prior vaginal deliveries, as well as dilation, effacement, and station at the time of balloon insertion. There was a difference in dilation at the time of removal, with mean dilation of 4.6 cm in the pregroup and 4.0 cm in the postgroup ($P=.006$). There was a notable difference in reason for induction between groups, with more patients undergoing induction for elective reasons in the post group (57.1% vs 38.5%; $P=.005$). Finally, there were also no significant differences in use of oxytocin prior to and during use of the balloon.

The primary outcome, time from balloon insertion to vaginal delivery, is shown in [Table 2](#) and [Figure](#). Nonparametric tests (Kaplan–Meier) were used to compare pre- and postpolicy change delivery times. Out of 189 inductions, 112 (59.2%) resulted in a vaginal delivery. Of 91 patients prepolicy change, 51 (56%) resulted in a vaginal delivery. Of 98 patients in the postpolicy change group, 61 (62.2%) resulted in a vaginal delivery. The other 77 resulted in c-section and were considered censored at

time of delivery. There were no cases of uterine rupture diagnosed in either group. The estimated median time to vaginal delivery for patients undergoing TOLAC was 28 hours (95% CI: 26, 35) for patients induced prior to the policy change and 25 hours (95% CI: 23, 29) for those induced after (P value=.05). There was an expected difference in actual length time the balloon catheters were in place between pre- and postpolicy change groups (median 12.16 vs 7.16 hours; $P=.001$).

After checking the proportional hazards assumption, a Cox model was used to adjust for dilation at time of balloon placement, number of previous vaginal deliveries, and co-medication ([Table 2](#)). The sample size for this analysis was 181, as 8 observations were not included due to incomplete data. Of the 181 included, 108 (59.7%) resulted in vaginal delivery and 73 were censored due to c-section. After adjusting for the potential confounders, the estimated hazard ratio for vaginal delivery for patients induced postpolicy change was 1.89 (95% CI: 1.27, 2.81).

Secondary outcomes were additionally listed in [Table 2](#). There were no significant differences in cesarean rates as well as maternal intraamniotic infection. There was a statistically significant difference between groups in the distribution of cesarean indications, with more patients undergoing cesarean delivery in the prepolicy group for arrest indications (45.0% vs 40.5%; $P=.009$) and more patients in the postpolicy group undergoing cesarean for fetal indications (43.2% vs 35.0%; $P=.009$).

Comment

Principal findings

For patients undergoing induction of labor with a history of cesarean delivery, shorter planned duration of placement of balloon catheter for 6 hours compared to 12 hours may lead to a shorter time to vaginal delivery, with no significant differences in rates of cesarean or intraamniotic infection. In addition, adjusted analysis shows that there may be a greater chance for successful

vaginal delivery in patients with prior cesareans with shorter planned duration of balloon placement.

Results in the context of what is known

This is the first study to our knowledge to specifically look at outcomes related to duration of planned mechanical cervical ripening in patients with a history of cesarean delivery. However, there have been previous RCTs evaluating duration of balloon catheter placement in patients without a prior cesarean delivery. Bleicher et al.¹² compared cervical ripening with a double-balloon catheter for 6 vs 12 hours and found a shorter time-to-delivery interval with 6 hours of placement without change in cesarean rate. Similarly, Lassey et al.¹¹ compared cervical ripening but with a single balloon catheter for 6 vs 12 hours with concurrent administration of oxytocin and found a shorter induction times without a change in cesarean rate. Our study indicates that a shorter time to vaginal delivery may also exist in those who have had prior cesarean deliveries undergoing mechanical cervical ripening.

Clinical implications

With cesarean delivery constituting a significant portion of annual deliveries, those who seek a VBAC delivery represent a consistently growing population of birthing patients. For those who undergo induction of labor, there is limited data published regarding optimal methods of induction for this patient population as well as paucity of resources available to these patients for use during the induction process. With increased morbidity associated with prolonged induction, continued efforts into studying efficient methods of induction remain important.¹³ Shortened time to delivery has been known to reduce maternal and perinatal morbidity, such as infection, hemorrhage, and cesarean delivery^{6,14} as well as conserve hospital resources and improve patient satisfaction.^{15,16}

Our study aimed to assess the impact of planned duration of mechanical cervical ripening in the TOLAC patient

TABLE 1
Baseline characteristics for study groups

Characteristic	Pre (N=91)	Post (N=98)	Total (N=189)	P value
Age				.35 ^a
Mean (SD)	31.0 (5.8)	30.2 (5.8)	30.6 (5.8)	
Race and ethnicity				.42 ^b
N-Miss	5	6	11	
Hispanic or Latino	35 (40.7%)	34 (37.0%)	69 (38.8%)	
Non-Hispanic Black	44 (51.2%)	43 (46.7%)	87 (48.9%)	
Non-Hispanic White	3 (3.5%)	8 (8.7%)	11 (6.2%)	
Non-Hispanic Other	4 (4.7%)	7 (7.6%)	11 (6.2%)	
Marital status				.008 ^b
N-Miss	3	1	4	
Divorced/separated/never married	52 (59.1%)	38 (39.2%)	90 (48.6%)	
Married/domestic partnership	36 (40.9%)	59 (60.8%)	95 (51.4%)	
Health insurance				.01 ^b
Medicare/Medicaid	78 (85.7%)	68 (69.4%)	146 (77.2%)	
Private insurance	7 (7.7%)	9 (9.2%)	16 (8.5%)	
Uninsured	6 (6.6%)	21 (21.4%)	27 (14.3%)	
BMI				.86 ^a
N-Miss	6	7	13	
Mean (SD)	33.4 (6.0)	33.1 (6.0)	33.3 (6.0)	
Gestational age (wk)				.74 ^a
Mean (SD)	39.1 (1.2)	39.0 (1.4)	39.1 (1.3)	
Reason for prior C-section				.64 ^b
Arrest of descent	6 (6.6%)	6 (6.1%)	12 (6.3%)	
Arrest of dilation	16 (17.6%)	12 (12.2%)	28 (14.8%)	
Malpresentation	8 (8.8%)	15 (15.3%)	23 (12.2%)	
NRFHT	32 (35.2%)	34 (34.7%)	66 (34.9%)	
Other	29 (31.9%)	31 (31.6%)	60 (31.7%)	
Reason for induction				.005 ^b
Diabetes	7 (7.7%)	6 (6.1%)	13 (6.9%)	
Elective	35 (38.5%)	56 (57.1%)	91 (48.1%)	
Hypertensive disorder	8 (8.8%)	16 (16.3%)	24 (12.7%)	
Late/postdate induction	10 (11.0%)	6 (6.1%)	16 (8.5%)	
Other	31 (34.1%)	14 (14.3%)	45 (23.8%)	
Prior vaginal deliveries				.30 ^a
Mean (SD)	0.9 (1.4)	0.7 (1.2)	0.8 (1.3)	
Prior C-sections				.017 ^a
Mean (SD)	1.0 (0.0)	1.1 (0.2)	1.0 (0.2)	
Prior VBACs				.54 ^a
Mean (SD)	0.4 (0.8)	0.3 (0.8)	0.3 (0.8)	
Months since last vaginal delivery				.71 ^a

(continued)

TABLE 1**Baseline characteristics for study groups** (continued)

Characteristic	Pre (N=91)	Post (N=98)	Total (N=189)	P value
N-Miss	55	65	120	
Mean (SD)	88.9 (62.6)	78.9 (50.2)	84.1 (56.8)	
Dilation at balloon placement (cm)				.085 ^a
N-Miss	1	1	2	
Mean (SD)	0.9 (0.7)	0.7 (0.7)	0.8 (0.7)	
Effacement at balloon placement (%)				.43 ^b
N-Miss	0	1	1	
0	45 (49.5%)	58 (59.8%)	103 (54.8%)	
25	19 (20.9%)	19 (19.6%)	38 (20.2%)	
50	22 (24.2%)	17 (17.5%)	39 (20.7%)	
75	3 (3.3%)	3 (3.1%)	6 (3.2%)	
90	2 (2.2%)	0 (0.0%)	2 (1.1%)	
Station at balloon placement				.97 ^b
N-Miss	0	1	1	
0	1 (1.1%)	0 (0.0%)	1 (0.5%)	
-1	3 (3.3%)	3 (3.1%)	6 (3.2%)	
-2	15 (16.5%)	16 (16.5%)	31 (16.5%)	
-3	72 (79.1%)	78 (80.4%)	150 (79.8%)	
Pitocin prior to balloon Placement				.75 ^b
N-Miss	1	1	2	
No	86 (95.6%)	91 (93.8%)	177 (94.7%)	
Yes	4 (4.4%)	6 (6.2%)	10 (5.3%)	
Pitocin concurrent with balloon				.28 ^b
N-Miss	2	4	6	
No	37 (41.6%)	31 (33.0%)	68 (37.2%)	
Yes	52 (58.4%)	63 (67.0%)	115 (62.8%)	
Dilation at balloon removal (cm)				.009 ^a
N-Miss	1	3	4	
Mean (SD)	4.6 (1.4)	4.0 (1.5)	4.3 (1.4)	
Effacement at balloon removal (%)				.12 ^b
N-Miss	5	5	10	
0	2 (2.3%)	3 (3.2%)	5 (2.8%)	
25	10 (11.6%)	9 (9.7%)	19 (10.6%)	
50	37 (43.0%)	57 (61.3%)	94 (52.5%)	
75	26 (30.2%)	18 (19.4%)	44 (24.6%)	
90	11 (12.8%)	6 (6.5%)	17 (9.5%)	
Station at balloon removal				.14 ^b
N-Miss	1	4	5	
0	6 (6.7%)	4 (4.3%)	10 (5.4%)	
-1	26 (28.9%)	15 (16.0%)	41 (22.3%)	

(continued)

TABLE 1

Baseline characteristics for study groups (continued)

Characteristic	Pre (N=91)	Post (N=98)	Total (N=189)	P value
-2	30 (33.3%)	41 (43.6%)	71 (38.6%)	
-3	28 (31.1%)	34 (36.2%)	62 (33.7%)	

Data are represented as *n* (%) unless otherwise specified.

N-Miss, number of missing cases in each group.

^a Kruskal–Wallis rank sum test.; ^b Fisher's Exact test for count data.

population. While shorter planned duration of mechanical ripening did reveal a higher hazard ratio for successful VBAC, additional efforts will be needed in order to characterize this

further. Shorter duration of mechanical ripening was not shown to significantly change the overall rate of cesarean in our study. However, after adjusting for covariates, the chances of successful

vaginal birth were increased. For those who had a failed TOLAC and required subsequent cesarean delivery, there was a difference noted in reason for cesarean, with slightly fewer patients with

TABLE 2

Main outcomes for the comparison between study groups

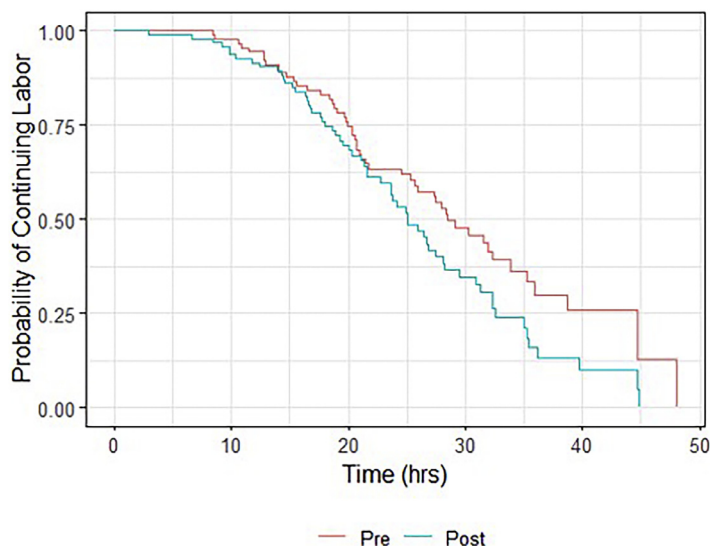
Outcome	Pre (N=91)	Post (N=98)	Total (N=189)	P value
Length of balloon placement (min)				<.001 ^a
Mean (SD)	699.8 (205.3)	509.3 (208.2)	601.0 (227.3)	
Median (Q1, Q3)	730.0 (685.0, 769.5)	430.0 (373.2, 723.0)	711.0 (397.0, 745.0)	
Mode of delivery				.46 ^b
C-Section	40 (44.0%)	37 (37.8%)	77 (40.7%)	
Vaginal	(56.0%)	61 (62.2%)	112 (59.3%)	
Chorioamnionitis				.59 ^b
No	85 (93.4%)	89 (90.8%)	174 (92.1%)	
Yes	6 (6.6%)	9 (9.2%)	15 (7.9%)	
	Pre (N=40)	Post (N=37)	Total (N=77)	
Primary reason for C-section				.009 ^b
Arrest disorders	18 (45.0%)	15 (40.5%)	33 (42.9%)	
Fetal indications	14 (35.0%)	16 (43.2%)	30 (39%)	
Placental abruption/bleeding	0 (0.0%)	1 (2.7%)	1 (1.3%)	
Other	8 (20.0%)	5 (13.5%)	13 (16.9%)	
	Pre (N=51)	Post (N=61)	Event (N=112)	
Time to delivery (h)				.05 ^c
Median (95% CI)	28 (26, 35)	25 (23, 29)		
Hazard ratio (95% CI) for successful vaginal delivery	N=108	P		
Being in the postpractice change group	1.89 (1.27, 2.81)	0.002 ^d		
Dilation at CRB Placement	1.80 (1.30, 2.49)	<0.001 ^d		
Number of prior vaginal deliveries	1.28 (1.14, 1.44)	<0.001 ^d		
Co-medication	1.38 (0.92, 2.05)	0.12 ^d		

Data are represented as *n* (%) unless otherwise specified.

^a Kruskal–Wallis rank sum test.; ^b Fisher's exact test for count data.; ^c Log-rank test (Kaplan–Meier analysis).; ^d Cox proportional hazards, adjusted for dilation at time of placement, number of previous deliveries, and co-medication.

FIGURE

Kaplan–Meier estimates for time to delivery. Kaplan–Meier estimates of time to delivery for the pre- and postimplementation groups. Red line represents the preimplementation group (routinely leaving balloon in for 12 hours) and the blue line represents the postimplementation group (routinely leaving the balloon in for 6 hours.) *P* value for difference = .05.



arrest indications (ie, arrest of dilation, descent) and slightly more with fetal indications (ie, nonreassuring fetal heart rate) in the post group. While these numbers were statistically significant, they were small and therefore difficult to interpret conclusively. In addition, there were no significant differences in maternal intraamniotic infection and no cases of uterine rupture, although the cohort was relatively small. We are unsure of any mechanistic reason why a shorter balloon duration would lead to a change in cesarean indications like this. While it is likely a function of a small number of cesareans, such that a few cases can significantly impact the category rates, we will explore this in future quality improvement work being planned on labor induction protocols.

Research implications

The results of our study demonstrate the need for further research regarding the duration of mechanical cervical ripening in patients undergoing TOLAC, and future efforts could be best conducted with a prospective study. This

would allow standardization of balloon use, including insertion protocol, as well as control for exposures such as addition of oxytocin during the induction process. By standardizing the study, we would aim to reduce observer bias in assessment of outcomes.

In addition, we would also aim to expand out secondary outcome analysis to include postpartum hemorrhage rates and more comprehensive neonatal outcomes including NICU admission, APGAR scores, length of stay, etc.

Strengths and limitations

Strengths of our study include capitalizing on a practice change to include patients undergoing TOLAC, a group previously excluded from similar studies. We utilized a robust medical record system and had trained clinicians verifying all data. This study had several limitations. First, because this was a before-and-after study design, we were unable to control for certain variables including balloon insertion protocol and amount of saline filled in each balloon. At our institution, balloon

insertion protocol was left to the discretion of the practitioners. Second, we were unable to capture the reason for balloon removal, whether it was by spontaneous expulsion, adequate ripening at the clinical endpoint, or protocol endpoint. We speculate that spontaneous expulsion and/or adequate ripening are associated with the establishment of labor, which is known to be more favorable for a vaginal delivery. In that same vein, we could not characterize further induction medications that were used with and after balloon removal, specifically oxytocin titration dosage and protocol. We presume based on standard of practice at our institution, that if oxytocin was started with balloon placement, then it was continually titrated after removal until delivery. It is difficult to conclude therefore whether improved time to delivery was due to shorter balloon placement or whether more expeditious initiation of oxytocin could have contributed. The addition of another intervention, oxytocin in the case of our study, limited the assessment of the exposure we sought to study. However, in prior studies,^{17,18} there has not been a clear advantage of one method over the other. We adjusted for factors selected a priori but there may have been other factors that were unaccounted for in our hazard ratio analysis. Finally, as institutional policies often take time to adopt and change practices, there was a possibility of selection bias, and some patients receiving balloon placement for 12 hours even postpolicy change which could have attributed to median duration of balloon placement of 7.16 hours.

Conclusions

In conclusion, for patients with prior cesarean delivery undergoing mechanical cervical ripening with a double-balloon catheter, planned removal at 6 hours compared to 12 hours may result in higher chances of successful vaginal delivery and possibly a shorter time to delivery, without increasing rates of cesarean delivery and intraamniotic infection.

Patient consent

Patient Consent is not required because no personal information or details are included.

This study was accepted and presented at the Central Association of Obstetricians and Gynecologists 90th Annual Meeting in Nashville, TN on October 25 to 28, 2023. ■

Conflicts of interest

The authors report no conflict of interest. ■

CRedit authorship contribution statement

Rachel J. Tang: Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Data curation, Conceptualization. **Leah M. Bode:** Writing – review & editing, Data curation. **Kyle M. Baugh:** Writing – review & editing, Data curation. **Kelly M. Mosesso:** Methodology, Formal analysis. **Joanne K. Daggy:** Methodology, Formal analysis. **David M. Guise:** Data curation. **Evgenia Teal:** Software, Formal analysis, Data curation. **Megan A. Christman:** Writing – review & editing, Conceptualization. **Britney N. Tuskan:** Writing – review & editing, Conceptualization. **David M. Haas:** Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Methodology, Investigation, Formal analysis, Conceptualization.

REFERENCES

1. National Institutes of Health Consensus Development conference statement: vaginal birth after

cesarean: new insights. *Obstet Gynecol.* 2010;115(6):1279–95. <https://doi.org/10.1097/AOG.0b013e3181e459e5>. PMID: 20502301.

2. Caughey AB, Cahill AG, Guise J-M, et al. Safe prevention of the primary cesarean delivery. *ACOG* 2014;210(3):179–93. <https://doi.org/10.1016/j.ajog.2014.01.026>.

3. ACOG Practice Bulletin No. 205: Vaginal birth after cesarean delivery. *Obstet Gynecol* 2019;133(2):110–27. <https://doi.org/10.1097/aog.0000000000003078>.

4. Martin JA, Hamilton BE, Osterman MJK. Births in the United States, 2021. NCHS data brief, no 442. Hyattsville, MD: National Center for Health Statistics; 2022. <https://doi.org/10.15620/cdc:119632>.

5. Marshall NE, Fu R, Guise JM. Impact of multiple cesarean deliveries on maternal morbidity: a systematic review. *Am J Obstet Gynecol* 2011;205(3):262.e1–8. <https://doi.org/10.1016/j.ajog.2011.06.035>. Epub 2011 Jun 15. PMID: 22071057.

6. Rouse DJ, Owen J, Hauth JC. Criteria for failed labor induction: prospective evaluation of a standardized protocol. *Obstet Gynecol* 2000;96(5 Pt 1):671–7. [https://doi.org/10.1016/s0029-7844\(00\)01010-3](https://doi.org/10.1016/s0029-7844(00)01010-3). PMID: 11042299.

7. Induction of labor. *ACOG Practice Bulletin No. 107. American College of Obstetricians and Gynecologists.* *Obstet Gynecol* 2009;114:386–97.

8. Cook® Cervical Ripening Balloon with Stylet | Cook Medical, https://www.cookmedical.com/products/wh_crbs_webds/. Accessed 2 Aug 2024.

9. Jozwiak M, Bloemenkamp KW, Kelly AJ, Mol BW, Irion O, Bouvain M. Mechanical methods for induction of labour. *Cochrane Database Syst Rev* 2012(3):CD001233. <https://doi.org/10.1002/14651858.CD001233.pub2>. Accessed 2 Aug 2024.

10. Cromi A, Ghezzi F, Agosti M, et al. Is transcervical Foley catheter actually slower than prostaglandins in ripening the cervix? A randomized study. *Am J Obstet Gynecol* 2011;204(4):338.e1–7. <https://doi.org/10.1016/j.ajog.2010.11.029>. Epub 2011 Jan 26. PMID: 21272849.

11. Lassey SC, Haber HR, Kanbergs A, Robinson JN, Little SE. Six versus twelve hours of single-balloon catheter placement with oxytocin administration for labor induction: a randomized controlled trial. *Am J Obstet Gynecol* 2021;224(6):P611.E1–8. <https://doi.org/10.1016/j.ajog.2021.03.021>.

12. Bleicher I, Dikopolitsev E, Kadour-Ferro E, et al. Double-balloon device for 6 compared with 12 hours for cervical ripening. *Obstet Gynecol* 2020;135(5):1153–60. <https://doi.org/10.1097/aog.0000000000003804>.

13. Triebwasser JE, VanArtsdalen J, Kobemik EK, Seiler K, Langen ES. Assessing maternal and fetal risks associated with prolonged induction of labor. *Am J Perinatol* 2019;36(5):455–9. <https://doi.org/10.1055/s-0038-1675642>. Epub 2018 Nov 10. PMID: 30414603.

14. Grobman WA, Bailit J, Lai Y, et al. Defining failed induction of labor. *Am J Obstet Gynecol* 2018;218(1):122.e1–8. <https://doi.org/10.1016/j.ajog.2017.11.556>. Epub 2017 Nov 11. PMID: 29138035; PMCID: PMC5819749.

15. Shetty A, Burt R, Rice P, Templeton A. Women's perceptions, expectations and satisfaction with induced labour—a questionnaire-based study. *Eur J Obstet Gynecol Reprod Biol* 2005;123(1):56–61. <https://doi.org/10.1016/j.ejogrb.2005.03.004>. PMID: 15905017.

16. Sherman DJ, Frenkel E, Tovbin J, Arieli S, Caspi E, Bukovsky I. Ripening of the unfavorable cervix with extraamniotic catheter balloon: clinical experience and review. *Obstet Gynecol Surv* 1996;51(10):621–7. <https://doi.org/10.1097/00006254-199610000-00022>. PMID: 8888040.

17. West HM, Jozwiak M, Dodd JM. Methods of term labour induction for women with a previous caesarean section. *Cochrane Database Syst Rev.* 2017;6(6):CD009792. <https://doi.org/10.1002/14651858.CD009792.pub3>. PMID: 28599068; PMCID: PMC6481365.

18. Ralph JA, Leftwich HK, Leung K, Zaki MN, Torre MD, Hibbard JU. Morbidity associated with the use of Foley balloon for cervical ripening in women with prior cesarean delivery. *J Matern Fetal Neonatal Med* 2022;35(20):3937–42. <https://doi.org/10.1080/14767058.2020.1844653>.