HHS Public Access

Author manuscript

Am J Perinatol. Author manuscript; available in PMC 2021 August 25.

Published in final edited form as:

Am J Perinatol. 2019 December ; 36(14): 1431–1436. doi:10.1055/s-0039-1691766.

Is Foley Catheter Use during a Trial of Labor after Cesarean Associated with Uterine Rupture?

Jennifer L. Katz Eriksen, MD, MSc[1], **Suchitra Chandrasekaran, MD, MSCE**[1], **Shani S. Delaney, MD**[1]

[1]Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, University of Washington, Seattle, Washington

Abstract

Objective—We sought to assess the safety of transcervical Foley catheter (TCF) placement for cervical ripening in women undergoing induction of labor (IOL) after prior cesarean by evaluating the risk of uterine rupture.

Study Design—We performed a secondary analysis of the Maternal-Fetal Medicine Unit's Cesarean Section Registry, a prospective observational cohort study. We included women with a history of ≤2 low-transverse cesarean deliveries who underwent IOL at ≥24 weeks of gestational age with a live singleton fetus without major anomalies. We excluded those who received prostaglandins or laminaria. We performed multinomial logistic regression to calculate adjusted odds ratios (aORs) for uterine rupture and dehiscence. Relevant confounders included prior vaginal delivery, pregnancy-induced hypertension, chorioamnionitis, and cervical effacement and dilation on admission.

Results—A total of 2,564 women were eligible. Unadjusted analysis demonstrated no increased risk of uterine rupture with TCF (1.9 vs. 0.9%; $p = 0.10$) but an increased risk of uterine dehiscence (1.9 vs. 0.6%; $p = 0.02$). After adjustment, TCF was not associated with an increased risk of uterine rupture (aOR: 2.02; 95% confidence interval [CI]: 0.71–5.78) or uterine scar dehiscence (aOR: 1.32; 95% CI: 0.37–4.72).

Conclusion—Foley catheter is a safe tool for mechanical dilation in women undergoing IOL after prior cesarean.

Keywords

cervical ripening; induction of labor; TOLAC; VBAC

The overall cesarean delivery (CD) rate in the United States in 2015 was 32%, an increase of 55% over the previous two decades.[1] In response to this rise, there has been a renewed

Address for correspondence Jennifer L. Katz Eriksen, MD, MSc, Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, University of Washington, 1959 NE Pacific Street, Box 356460, Seattle, WA 98195-6460 (jenkatz@uw.edu).

Conflict of Interest

None declared.

The contents of this report represent the views of the authors and do not represent the views of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Maternal–Fetal Medicine Units Network or the National Institutes of Health.

effort on the part of physicians, public health officials, and other key stakeholders in the medical system to increase the proportion of deliveries that are vaginal births after cesareans (VBACs).[2–4]

The decision to undergo a trial of labor after cesarean (TOLAC) requires thoughtful consideration of the likelihood of success, plans for future fertility, and risks of neonatal and maternal morbidity, including the risk of uterine rupture, which is estimated to complicate approximately 0.5 to 0.9% of TOLACs in women with a prior low-transverse hysterotomy.[5] Studies on the safety and efficacy of TOLAC have been predominantly performed on women who labor spontaneously; however, nearly one quarter of women in the United States undergo induction of labor (IOL), which is associated with a more than twofold increased risk of uterine rupture for those with a scarred uterus.[1,6]

IOL can be performed with a variety of pharmacological and mechanical methods, and the risk of uterine rupture in women undergoing IOL has been shown to vary depending on the method used for induction.[7] While the safety associated with various pharmacological methods of IOL in this population has been well characterized, less is known about the risks of using a transcervical Foley catheter (TCF) for cervical ripening among women with a uterine scar. Several recent publications have aimed to characterize risks associated with this approach with mixed results. However, limitations posed by small sample size, retrospective data collection, and single-center study design challenge our ability to evaluate the results effectively.[8,9] A recent systematic review and meta-analysis that included 1,447 women undergoing TOLAC–IOL found a modest two- to threefold increase in the rate of uterine rupture with the use of balloon catheters, but this association was no longer demonstrated after excluding one single-institution study where practice was to perform single-layer hysterotomy closures, which are associated with an increased risk of rupture.[10] A recent Cochrane review found no high-quality trials on the subject and reported that there were insufficient data to advise on the best method of induction in women undergoing TOLAC–IOL.[10]

Our objective was to assess whether the use of TCF in women undergoing IOL after CD is associated with an increased risk of uterine rupture using this rich database, overcoming limitations faced in previous studies; we hypothesized that TCF would not be associated with an increased risk of rupture.

Materials and Methods

This is a secondary analysis of the Cesarean Section Registry study of the NICHD-MFMU (Eunice Kennedy Shriver National Institute of Child Health and Human Development – Maternal-Fetal Medicine Units) Network, an observational cohort study of 14,529 women with a history of prior CD undergoing TOLAC. The study was performed at 19 academic medical centers from 1999 through 2002 and approved by the human subjects committees at participating institutions. Inclusion criteria were (1) women with a singleton pregnancy at 20 weeks or more of gestation and (2) women who had an infant with a birthweight of at least 500 g, who had at least one prior CD. The details of the study have been previously published.[11]

In our analyses, we included women with a history of one or two prior CDs undergoing IOL with a live singleton fetus at ≥24 weeks' gestational age. We excluded women with prior vertical, T, J, unknown, or missing hysterotomy type, those who received prostaglandins or laminaria during IOL, and those who underwent IOL for premature rupture of membranes. We excluded women whose neonates were affected with major congenital anomalies.

Our primary outcome was the incidence of uterine rupture, which was defined as either a disruption/tear of the uterine muscle and visceral peritoneum or a separation of the uterine muscle with extension to the bladder or broad ligament. Our secondary outcome was the incidence of uterine dehiscence, which was defined as a disruption of the uterine muscle with intact serosa. All cases of uterine scar disruption were centrally reviewed to assure accuracy of the diagnosis.[12]

The exposure of interest was whether a Foley catheter was used as an induction agent; this was reported as a bivariate (yes/no) variable. The volume of inflation and duration of exposure were not recorded, and the variable was not centrally reviewed, as this was not a primary exposure of interest in the original study.[13]

Advanced maternal age was defined as age ≥35 years. Obesity was defined as prepregnancy body mass index ≥30 kg/m^2. Underlying maternal disease was defined as asthma, pregestational diabetes, chronic hypertension, seizure disorder, thyroid, and renal or connective tissue disease. Hypertensive disease of pregnancy was defined as gestational hypertension, preeclampsia, eclampsia, or HELLP (hemolysis, elevated liver enzymes, low platelets) syndrome. Chorioamnionitis was defined as a clinical diagnosis of puerperal infection in the absence of findings suggesting a nonuterine source of infection at any point during labor or in the postpartum period. A composite outcome variable of uterine infection was created for the diagnosis of either chorioamnionitis or endometritis. Prematurity was defined as gestational age < 37 weeks. A composite variable of rare maternal complications included uterine rupture, hysterectomy, thromboembolic disease, anesthetic complications, necrotizing fasciitis, peripartum seizure, cardiac arrest, maternal death, and other adverse events.

In the original analysis of the Cesarean Section Registry, investigators found that birthweight < 4,000 g and interval from prior CD > 2 years were associated with an increased likelihood of a successful VBAC; these cutoffs were then used in the analyses of the impact of these factors on the risk of uterine rupture.[14] To maintain consistency with the original analyses, we elected to use the same cutoffs in our analysis of the impact of birthweight and interdelivery interval on the risk of uterine rupture in our cohort.

Continuous variables were compared using the Wilcoxon rank-sum test, and categorical variables were compared using the χ^2 test. Multivariable logistic regression was performed to adjust for potential confounding factors for each type of scar disruption; we restricted the confounders to those characteristics that could plausibly be related to a causal pathway for uterine rupture or dehiscence and were significantly associated with the exposure of interest. Two-sided p values are reported with statistical significance defined as a $p < 0.05$ without

adjustment for multiple comparisons. Analysis was performed using Stata 14 (Stata-Corp LP, College Station, TX).

Results

A total of 2,564 women were included in the cohort, of whom 12.6% ($n = 324$) underwent placement of a TCF. Demographic characteristics are presented in ► Table 1. Women who were induced with a Foley catheter were more likely to be obese (34.6 vs. 25.2%; $p = 0.002$), have underlying maternal disease (34.3 vs. 22%; $p < 0.001$) and hypertensive disease of pregnancy (27.5 vs. 10.8%; $p < 0.001$), and have different racial and ethnic demographics. They were less likely to have a prior successful vaginal delivery (32.6 vs. 57.1%; $p < 0.001$) or VBAC (20.4 vs. 41.8%; $p < 0.001$) and were more likely to have a less favorable cervical examination on admission. They were at an earlier gestational age at the time of delivery (38.8 vs. 39.4 weeks; $p < 0.001$) and were significantly more likely to be preterm (16.7 vs. 6.8%; $p < 0.001$).

► Table 2 shows delivery and neonatal outcomes by TCF use in our sample. The rates of uterine rupture and dehiscence were 1 and 0.8, respectively. Unadjusted analysis demonstrated no increased risk of uterine rupture with TCF (1.9 vs. 0.9%; $p = 0.10$) but an increased risk of uterine dehiscence (1.9 vs.0.6%; $p = 0.02$). Those induced with TCF had increased rates of chorioamnionitis (10.8 vs. 5%; $p < 0.001$), rare maternal complications (7.1vs.2.9%; $p < 0.001$), and significantly lower rates of successful VBAC (72.6 vs. 49.4%; $p < 0.001$). Neonates born to those induced with TCF were more likely to have a 5-minute Apgar score of <7 (4 vs. 1.5%; $p = 0.001$) and require neonatal intensive care unit (NICU) admission (17.9 vs. 11.5%; $p = 0.001$). After adjustment for history of prior vaginal delivery and VBAC, hypertensive disease of pregnancy, chorioamnionitis, and dilation and effacement on admission, Foley catheter was no longer significantly associated with an increased risk of uterine rupture (adjusted odds ratio [aOR] 2.01; 95% confidence interval [CI]: 0.70–5.76) or uterine dehiscence (aOR: 1.33; 95% CI: 0.37–4.76). Chorioamnionitis and hypertensive disease of pregnancy were significantly associated with an increased risk of uterine dehiscence but not uterine rupture (aOR: 7.40, 95% CI: 2.23–24.59 and aOR: 1.89, 95% CI: 1.13–3.14, respectively).

Comment

IOL is known to confer increased risk of uterine rupture for women attempting TOLAC, but it is yet to be elucidated whether of the use of a Foley catheter for cervical ripening contributes to this excess risk. We did not demonstrate a significant increase in the risk of uterine rupture or dehiscence in women undergoing TOLAC–IOL with TCF after controlling for relevant confounders. This is the largest study to date to demonstrate this finding regarding the potential safety of Foley catheter use in women attempting TOLAC–IOL.

Our findings contribute to a limited but growing body of literature in this area. A 2017 systematic review and meta-analysis of uterine rupture during TOLAC–IOL with Foley catheter found an odds ratio (OR) of 2.45 (95% CI: 1.34–4.47), which decreased in effect size and no longer achieved significance when excluding one study performed in

an institution where the practice was to perform single-layer closures, which are known to be associated with increased odds of uterine rupture (OR = 1.23; 95% CI: 0.48–3.14).[10] A single-institution cohort study of women with a history of prior CD in Finland found no difference in the rate of uterine rupture between those who received a TCF and those who labored spontaneously (0.3 vs. 0.8%; $p = 0.47$).[11] These findings are consistent with those from another single-institution retrospective cohort of women undergoing TOLAC, which found no difference in the rate of uterine rupture for those who received TCF when compared with those induced with amniotomy or oxytocin or those who labored spontaneously (1.6 vs. 1.2 vs. 1.1%; $p = 0.81$).[13] While the majority of the literature in this field does not support a finding of a significantly increased risk of uterine rupture after TOLAC–IOL with TCF, a retrospective cohort study analyzing a Swedish birth registry of all women attempting VBAC found that compared with those laboring spontaneously, women undergoing IOL with TCF had a nearly fourfold increase in the odds of uterine rupture (OR = 3.67; 95% CI: 1.46–9.23). Unfortunately, the authors did not report the odds of uterine rupture with TCF compared with other methods of IOL.[14]

Uterine rupture is a rare outcome, and therefore despite our large numbers, it is possible that this study is underpowered to demonstrate a difference in such an infrequent outcome. Our analysis demonstrated a nonsignificant twofold increase in the risk of uterine rupture, consistent with the majority of other studies published on this topic. It is possible that a larger study would be able to achieve significance. To evaluate the feasibility of a prospective trial to address this question, we performed a power calculation to determine the sample size necessary to demonstrate a twofold increase in the risk of uterine rupture for women undergoing TOLAC–IOL with TCF. Assuming a twofold increase in uterine rupture from 1 to 2%, 80% power, and $\alpha = 0.05$, each group would require 1,237 women. Such a study would be challenging but would provide valuable information on this important clinical question.

The American College of Obstetricians and Gynecologists supports offering TOLAC to women with other clinical characteristics and maternal conditions that are associated with a similar increase in the risk of uterine rupture, including those with prior low vertical hysterotomy, two prior low-transverse hysterotomies, and maternal obesity.[2] As such, we believe that even if future studies were to demonstrate a significant similar twofold increased risk of uterine rupture, the magnitude of the effect estimated by our analysis suggests that this risk is in line with other clinical conditions that are not felt to preclude a TOLAC.

Our analysis demonstrated interesting associations between both chorioamnionitis and hypertensive disease of pregnancy with uterine dehiscence, but not frank uterine rupture. The relationship between chorioamnionitis and increased dehiscence may indicate that in the setting of infection and inflammation, poorly vascularized scar tissue is more susceptible to dehiscence. Similarly, in the setting of hypertensive disease, associated endothelial dysfunction may result in tissue edema in the relatively weaker scarred myometrium, increasing the risk of dehiscence. Additionally, the finding of increased dehiscence in these subgroups may reflect a lower threshold for physicians to discontinue labor induction in women with additional risk factors for adverse maternal and fetal outcomes, leading to

increased intraoperative diagnosis of dehiscence that may have either gone unrecognized or progressed to true rupture.

Women who received a TCF for their TOLAC–IOL had a lower rate of successful VBAC in our dataset (49.4 vs. 72.6%; $p < 0.001$). It is important to note that this secondary analysis does not prove a causal relationship between TCF use and lower probability of successful VBAC. Women who received a TCF for their IOL were more likely to have baseline maternal and obstetrical characteristics that are known risks factors CD. African-American race, obesity, underlying maternal disease, hypertensive disease of pregnancy, no prior vaginal delivery, and unfavorable cervical examination on admission—all characteristics that were more frequent in the TCF group—could potentially influence the ultimate mode of delivery. Efficacy of TCF for successful VBAC is an area with opportunity for further future research.

Similarly, our study identified an association between the use of TCF and increased risk of both NICU admission (17.9 vs. 11.5%; $p = 0.001$) and low APGAR score at 5 minutes of life (4.0 vs. 1.5%; $p = 0.001$). This increase may reflect the increased prevalence of other risk factors for NICU admission in those who received TCF for IOL (including prematurity, chorioamnionitis, and CD) and is an area for future study.

The strength of this study stems from the analysis of a large prospectively collected multicenter cohort. The size of the cohort allows for the exploration of the association of a relatively rare outcome. However, as discussed earlier, even the robust size of the cohort may not be sufficient to identify small but clinically meaningful differences in the risk of uterine rupture in our population of interest. Despite the large size of our cohort, there were only 26 cases of uterine rupture, and our model may have been subject to overadjustment. We attempted to minimize this possibility by adjusting only for those confounders that had a plausible connection to increased risk of uterine rupture and were associated with the use of TCF.

Among the limitations of this study is that there are important clinical differences between the group of women who were induced with a Foley catheter and those who were not; as such, this may limit the generalizability of our findings. However, given the high rates of indicated IOL in the United States, and recent data suggesting possible benefits of elective IOL in women desiring VBAC, we believe that there is a cohort of women in whom these findings are clearly relevant.[8]

In summary, we did not demonstrate an association between uterine rupture and the use of TCF for IOL in women with a history of prior CD. These findings potentially support the use of TCF for cervical ripening in women undergoing IOL with a history of prior CD and an unfavorable cervix and can be used to assist in counseling patients regarding the safety of a common clinical practice.

Acknowledgment

We would like to acknowledge the NICHD, the MFMU Network, and the Protocol Subcommittee for making this database publically available.

References

1. Martin JA, Hamilton BE, Osterman MJ, Driscoll AK, Mathews TJ. Births: Final Data for 2015. Natl Vital Stat Rep2017;66(01):1
2. Committee on Practice Bulletins-Obstetrics. Practice Bulletin No. 184: vaginal birth after cesarean delivery. Obstet Gynecol2017; 130(05):e217–e233 [PubMed: 29064970]
3. The Joint Commission. Specifications Manual for Joint Commission National Quality Core Measures (2010A1). Available at: https://manual.jointcommission.org/releases/Archive/TJC2010B/MIF0062.html.Accessed April 25, 2017
4. Office of Disease Prevention and Health Promotion. Maternal, infant and child health 7.2 Reduce cesarean births among low-risk women giving birth with a prior cesarean birth. Available at: https://www.healthypeople.gov/2020/topics-objectives/objective/mich-72.Accessed April 25, 2017
5. American College of Obstetricians and Gynecologists. ACOG Practice bulletin no. 115: Vaginal birth after previous cesarean delivery. Obstet Gynecol2010;116(2 Pt 1):450–463 [PubMed: 20664418]
6. Palatnik A, Grobman WA. Induction of labor versus expectant management for women with a prior cesarean delivery. Am J Obstet Gynecol2015;212(03):358.e1–358.e6
7. Lydon-Rochelle M, Holt VL, Easterling TR, Martin DP. Risk of uterine rupture during labor among women with a prior cesarean delivery. N Engl J Med2001;345(01):3–8 [PubMed: 11439945]
8. Kehl S, Weiss C, Rath W. Balloon catheters for induction of labor at term after previous cesarean section: a systematic review. Eur J Obstet Gynecol Reprod Biol2016;204:44–50 [PubMed: 27521597]
9. Kruit H, Wilkman H, Tekay A, Rahkonen L. Induction of labor by Foley catheter compared with spontaneous onset of labor after previous cesarean section: a cohort study. J Perinatol2017;37 (07):787–792 [PubMed: 28406484]
10. West HM, Jozwiak M, Dodd JM. Methods of term labour induction for women with a previous caesarean section. Cochrane Database Syst Rev2017;6(06):CD009792 [PubMed: 28599068]
11. Landon MB, Hauth JC, Leveno KJ, et al.; National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. Maternal and perinatal outcomes associated with a trial of labor after prior cesarean delivery. N Engl J Med2004;351(25): 2581–2589 [PubMed: 15598960]
12. Spong CY, Landon MB, Gilbert S, et al.; National Institute of Child Health and Human Development (NICHD) Maternal-Fetal Medicine Units (MFMU) Network. Risk of uterine rupture and adverse perinatal outcome at term after cesarean delivery. Obstet Gynecol2007;110(04):801–807 [PubMed: 17906012]
13. Bujold E, Blackwell SC, Gauthier RJ. Cervical ripening with transcervical Fauoley catheter and the risk of uterine rupture. Obstet Gynecol2004;103(01):18–23 [PubMed: 14704239]
14. Hoffman MK, Sciscione A, Srinivasana M, Shackelford DP, Ekbladh L. Uterine rupture in patients with a prior cesarean delivery: the impact of cervical ripening. Am J Perinatol2004;21 (04):217–222 [PubMed: 15168320]

Table 1

Characteristics by Foley catheter use in women undergoing labor induction with a history of prior cesarean delivery

	No Foley, *N* = 2,240		Foley, *N* = 324		*p*-Value
	N	*%*	*N*	*%*	
Maternal characteristics					
Advanced maternal age	510	22.8	77	23.8	0.69
Race/ Ethnicity					
Caucasian	1,294	57.8	154	47.5	<0.001
African-American	579	25.8	136	42	
Hispanic	260	11.6	28	8.6	
Asian	30	1.3	4	1.2	
Native American	4	0.2	0	0	
Other/unknown	73	3.3	2	0.6	
Prepregnancy obesity	442	25.2	83	34.6	0.002
Underlying maternal disease	492	22	111	34.3	<0.001
Obstetrical history					
Prior vaginal delivery	1,275	57.1	105	32.6	<0.001
Prior VBAC	907	41.8	65	20.4	<0.001
Number of prior cesareans					
1	2,164	96.6	317	97.8	0.24
2	76	3.4	7	2.2	
Interdelivery interval < 2 years	139	6.4	26	8.1	0.26
Labor characteristics					
Initial dilation (centimeters)					
0–2	1,288	62.6	270	96.1	<.001
3–5	763	37.1	11	3.9	
> 6	6	0.3	0	0	
Initial effacement					
< 50%	427	21.4	141	54	<.001
≥ 50%	1,572	78.6	120	46	

Am J Perinatol. Author manuscript; available in PMC 2021 August 25.

	No Foley, *N* = 2,240		Foley, *N* = 324		*p*-Value
	N	%	*N*	%	
Oxytocin	2,159	96.4	320	98.8	0.025
Amniotomy	1,106	49.4	139	42.9	0.029
Analgesia	2,140	95.5	321	99.1	0.002
Infant characteristics					
Gestational age at delivery (weeks)					
< 28	3	0.1	1	0.3	<0.001
≥ 28 to <34	36	1.6	16	4.9	
≥ 34 to <37	114	5.1	37	11.4	
≥ 37 to <42	1,995	89.1	258	79.6	
≥ 42	92	4.1	12	3.7	
Birthweight > 4,000 g	272	12.1	24	7.4	0.13

Abbreviation: VBAC, vaginal birth after cesarean.

Table 2

Delivery and neonatal outcomes by Foley catheter use in women undergoing induction of labor with a history of prior cesarean delivery

	No Foley, *N* = 2,240		**Foley, *N* = 324**		***p*-Value**
	N	***%***	***N***	***%***	
Unadjusted delivery outcomes					
Uterine scar disruption	34	1.5	12	3.8	0.02
Uterine rupture	20	0.9	6	1.9	0.10
Uterine dehiscence	14	0.6	6	1.9	0.03
Uterine infection	112	5	35	10.8	<0.001
Rare complications	66	2.9	23	7.1	<0.001
Successful VBAC	1,626	72.6	160	49.4	<0.001
Transfusion	35	1.6	9	2.8	0.12
Wound infection	5	0.2	2	0.6	0.20
Unadjusted neonatal outcomes					
5-minute Apgar score < 7	33	1.5	13	4	0.001
NICU admission	258	11.5	58	17.9	0.001
Seizures requiring treatment	6	0.3	0	0	0.35
Ventilator support within 24 hours of birth	49	2.2	9	2.8	0.50
aOR	**No Foley**		**Foley**		
Uterine rupture	-		aOR: 2.01 (95% CI: 0.70–5.76)		
Uterine dehiscence	-		aOR: 1.33 (95% CI: 0.37–4.76)		

Abbreviations: aOR, adjusted odds ratio; CI, confidence interval; NICU, neonatal intensive care unit; VBAC, vaginal birth after cesarean.