

# Clinical Factors Associated with Intrapartum Presentation Change after Mechanical Cervical Ripening

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## Abstract

**Objective** The use of mechanical cervical ripening with balloon devices is common during induction of labor; however, there is risk for displacement of the fetal presenting part during its insertion. This study sought to investigate the clinical risk factors associated with an intrapartum presentation change from cephalic to noncephalic presentation after mechanical cervical ripening.

**Study Design** Data were obtained from the Consortium on Safe Labor, a multicenter retrospective study that abstracted detailed labor and delivery information from electronic medical records in 19 hospitals across the United States. All women with fetal cephalic confirmed position on admission undergoing induction of labor with mechanical cervical ripening were included. Women who had a cesarean delivery for noncephalic presentation were compared with women who had a vaginal delivery or cesarean delivery for other indications. Models were adjusted for nulliparity, multiple gestation, and gestational age.

**Results** A total of 3,462 women met inclusion criteria, with 1.3% ( $n = 46$ ) having an intrapartum presentation change from cephalic to noncephalic presentation after mechanical cervical ripening. Those who had a cesarean delivery for an intrapartum presentation change were more likely to be nulliparous (82.6 vs. 65.4%,  $p = 0.01$ ), less than 34 weeks' gestation (6.5 vs. 1.3%,  $p = 0.02$ ), and have twins (6.5 vs. 1.2%,  $p = 0.02$ ). In adjusted analysis, twins were associated with an increased odds of cesarean delivery for intrapartum presentation change (adjusted odds ratio [aOR]: 4.43; 95% confidence interval [CI]: 1.25–15.77), whereas multiparity reduced the odds (aOR: 0.38; 95% CI: 0.17–0.82).

**Conclusion** Nulliparity and multifetal gestation are associated with a cesarean delivery for an intrapartum presentation change after mechanical cervical ripening.

## Keywords

- ▶ intrapartum presentation change
- ▶ mechanical cervical ripening
- ▶ cervical balloon
- ▶ cesarean delivery

## Key Points

- Intrapartum presentation change after mechanical cervical ripening is low at 1.3%.
- Nulliparity and multifetal gestation are associated with a cesarean delivery for presentation change.
- There were no significant differences in neonatal morbidity by delivery status to delivery type.

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Induction of labor is common, with more than 22% of all gravid women undergoing induction of labor in the United States.<sup>1</sup> As induction of labor at 39 weeks becomes increasingly offered to patients, significant research has focused on optimal induction techniques for cervical ripening.<sup>2-6</sup> The use of mechanical ripening with a cervical foley balloon or double-balloon device is routinely used in the setting of an unfavorable cervix and is a recommended labor induction method.<sup>7</sup>

While the use of the mechanical ripening with a foley balloon has been shown to be safe and effective, there is a risk for displacement of the fetal presenting part from the pelvis during its placement.<sup>7-10</sup> Few studies have commented on the overall risk of intrapartum presentation change from cephalic to noncephalic after balloon placement, with rates of fetal position change between 0.5 and 5.4% based on small sample sizes.<sup>11,12</sup> Given the contribution of malpresentation to cesarean delivery and efforts to decrease cesarean delivery, further understanding of the frequency of intrapartum presentation change with mechanical cervical ripening and those at most risk of this complication is needed.<sup>13</sup>

Therefore, the objectives of this study were to determine the rate of intrapartum presentation change requiring cesarean delivery after mechanical cervical ripening, to investigate the clinical risk factors associated with noncephalic presentation after ripening, and to assess the associated maternal and neonatal morbidity related to cesarean delivery for intrapartum presentation change.

## Materials and Methods

This was a retrospective cohort study from a secondary analysis of deidentified data from the Consortium on Safe Labor (CSL) database obtained from the Eunice Kennedy Shriver National Institute of Child Health and Human Development. The CSL database is a publicly available and validated database, which collected detailed medical record information from 208,695 women across 12 clinical centers and 19 U.S. hospitals between 2002 and 2008. The database has been validated in previous literature, with most of the variables being highly accurate with greater than 95% accuracy.<sup>14</sup> All participating institutions had approval by their respective institutional review boards.

The inclusion criteria for the study were women with a viable gestation at 23 weeks' gestation or later undergoing induction of labor with mechanical ripening with foley balloon or double-balloon device with a confirmed vertex presentation at the start of the induction of labor. Women with a stillbirth or noncephalic presentation on admission were excluded from the study. We used the first pregnancy for women in the dataset with >1 pregnancy. The primary exposure of interest was mechanical cervical ripening with foley balloon or double-balloon device, and the primary outcome of interest was women with a cesarean delivery for malpresentation, who were classified as having an intrapartum presentation change compared with women with a vaginal delivery or a cesarean delivery for reasons other than presentation change.

Demographics and prenatal history information that were collected included maternal age, race, parity, insurance type, prepregnancy body mass index, history of prior cesarean section, history of an external cephalic version in the pregnancy, gestational age at induction of labor, presence of oligohydramnios or polyhydramnios, fetal growth restriction, and maternal history of preexisting diabetes, chronic hypertension, gestational diabetes, preeclampsia, or HELLP (hemolysis, elevated liver enzymes, and low platelets) syndrome. Twins were included and considered to have an intrapartum presentation change if the indication for cesarean delivery for twin A was malpresentation. We considered secondary outcomes including maternal and neonatal morbidity by intrapartum presentation change. An adverse maternal composite outcome was created including maternal death, intensive care unit admission, thrombosis, wound infection, wound separation, endometritis, pulmonary thromboembolism, hemorrhage, and blood transfusion. A neonatal composite morbidity outcome was also created encompassing neonatal death, sepsis, intraventricular hemorrhage, hypoxic ischemic encephalopathy, respiratory distress, pneumonia, and necrotizing enterocolitis.

Univariate analyses were conducted using the chi-square or the Fischer's exact tests for categorical variables and the Student's *t*-test or the Wilcoxon's rank-sum test for continuous variables. Statistical significance was defined with a two-tailed *p*-value  $\leq 0.05$ . Unadjusted and adjusted logistic regression was used to examine cesarean delivery for malpresentation with demographic and clinical characteristics. To identify clinically relevant factors, variables associated with a cesarean delivery for intrapartum presentation change with a *p*-value  $\leq 0.05$  were combined in a multivariable logistic regression model. These included parity, multigestation, and gestational age  $>34$ . Chi-square/Fisher's exact test and Wilcoxon rank-sum test were used to examine the maternal morbidity composite, neonatal morbidity composite, 5-minute Apgar score less than 7, neonatal intensive care unit (NICU) admission, NICU length of stay, and neonatal death with cesarean delivery for presentation change. All analysis was performed using Stata version 17 (StataCorp. 2021. Stata Statistical Software: Release 14. College Station, TX: StataCorp LLC).

## Results

A total of 3,462 women underwent induction of labor with cervical mechanical ripening during the study period, with 1.3% ( $n = 46$ ) of those women having an intrapartum presentation change leading to a cesarean delivery for noncephalic presentation.

Women with a cesarean delivery for intrapartum presentation change were more likely to be nulliparous (82.6 vs. 65.4%,  $p = 0.01$ ), have a twin pregnancy (6.5 vs. 1.2%,  $p = 0.02$ ), or be less than 34 weeks' gestation at delivery (6.5 vs. 1.3%,  $p = 0.02$ ). There were no other statistically significant differences in baseline demographic or clinical characteristics (**Table 1**).

**Table 1** Demographics and clinical characteristics among women with mechanical cervical ripening

Demographics	Cesarean delivery for intrapartum presentation change (n = 46)	Vaginal or cesarean delivery for reasons other than presentation change (n = 3,416)	p-Value
Age	27.3 ± 5.6	27.2 ± 5.8	0.92
Race			
White	36 (80.0%)	2,389 (72.2%)	0.17
Black	1 (2.2%)	415 (12.5%)	
Hispanic	7 (15.6%)	366 (11.1%)	
Asian/Pacific Islander	1 (2.2%)	130 (3.9%)	
Other/Multiracial	0 (0.0%)	11 (0.3%)	
Parity			
Nulliparous	38 (82.6%)	2,233 (65.4%)	0.01
Multiparous	8 (17.4%)	1,183 (34.6%)	
Insurance type			
Private	39 (84.8%)	2,407 (70.5%)	0.12
Public	7 (15.2%)	980 (28.7%)	
Self-pay/other	0 (0.0%)	27 (0.8%)	
Multifetal twin gestation	3 (6.5%)	42 (1.2%)	0.02
History of prior cesarean section	0 (0.0%)	40 (1.4%)	0.99
Prepregnancy body mass index (kg/m <sup>2</sup> )	25.3 ± 6.0	26.8 ± 6.8	0.18
External cephalic version in pregnancy	0 (0.0%)	9 (0.3%)	0.99
Preexisting diabetes	2 (4.3%)	84 (2.5%)	0.32
Preexisting chronic hypertension	1 (2.2%)	82 (2.4%)	0.99
Gestational diabetes	1 (2.2%)	259 (7.6%)	0.26
Preeclampsia/HELLP	7 (17.1%)	269 (16.5%)	0.93
Gestational age less than 34 wk	3 (6.5%)	44 (1.3%)	0.02
Oligohydramnios	2 (4.9%)	141 (8.6%)	0.57
Polyhydramnios	3 (6.5%)	44 (1.3%)	0.24
Antenatal detection of fetal growth restriction	1 (2.2%)	111 (3.3%)	0.99

Abbreviation: HELLP: hemolysis, elevated liver enzymes, low platelets.  
Note: All data are presented as n (%) or mean ± standard deviation.

The final multivariate model included parity, twin gestation, and gestational age at delivery grouped as less than 34 weeks or greater than or equal to 34 weeks. No other variables were found to be cofounders. In the adjusted analysis, multiparity (adjusted odds ratio [OR]: 0.38; 95% confidence interval [CI]: 0.17–0.82) was associated with a decreased odds of cesarean delivery for intrapartum presentation change, whereas a twin gestation was associated with an increased odds of requiring a cesarean delivery for an intrapartum presentation change (adjusted OR: 4.43; 95% CI: 1.25–15.77). Gestational age greater than 34 weeks was no longer significant in adjusted analysis (adjusted OR: 0.91; 95% CI: 0.80–1.05; [Table 2](#)).

There were no significant differences in maternal or neonatal morbidity outcomes by cesarean delivery for intrapartum presentation change; however, this study was not

powered to detect differences in these secondary outcomes ([Table 3](#)).

## Discussion

This retrospective study highlights the overall low risk of intrapartum presentation change requiring cesarean delivery after mechanical cervical ripening with foley or double-balloon device. However, nulliparous patients and those with twin pregnancies may be at an increased risk for this occurrence.

There is no contemporary data describing the risk factors for clinically significant intrapartum presentation change leading to cesarean delivery after mechanical ripening. Nevertheless, the literature examining success of external cephalic version or intrapartum presentation change in twins is likely applicable in this situation as it includes maternal

**Table 2** Unadjusted and adjusted odds ratios for clinical risk factors for cesarean delivery for presentation change

Variables	OR (95% CI)	Adjusted OR (95% CI)
<b>Parity</b>		
Nulliparous	Reference (1.0)	Reference (1.0)
Multiparous	0.40 (0.18–0.85)	0.38 (0.17–0.82)
<b>Number of fetuses</b>		
Singleton gestation	Reference (1.0)	Reference (1.0)
Twin gestation	5.60 (1.67–18.78)	4.43 (1.25–15.77)
<b>Gestational age (wk)</b>		
< 34	Reference (1.0)	Reference (1.0)
≥34	0.91 (0.80–1.04)	0.91 (0.80–1.05)

Abbreviations: CI, confidence interval; OR, odds ratio.  
 Note: All data are presented as OR with 95% CI. Each adjusted model is simultaneously adjusted for each of the variables listed above.

and fetal factors that allow for fetal position change. Parity has been shown to impact external cephalic version success as well as second twin intrapartum presentation.<sup>15–18</sup> It is possible that the multiparous uterus is more accommodating, and therefore, patients that did have an intrapartum presentation change were more likely to have an attempt at an intrapartum external cephalic version and be successful; however, we cannot comment on this from our current data. Twins also lead to greater uterine distention that may allow for greater mobility of the fetus leading to intrapartum presentation change. It is also possible that nulliparous women may also have a fetal head that is less engaged in the pelvis and thereby have a higher chance of presentation change with balloon displacement.<sup>19</sup>

The use of the foley balloon or double-balloon device was not protocolized in the participating study centers, and there may be variation in the amount of inflation of the balloon that may also change the risk of intrapartum presentation change. A large volume instilled in the balloon has been shown to be more effective in reaching greater cervical dilation and increasing labor speed,<sup>20</sup> but there have been no studies to our knowledge examining the rate of intrapartum presentation change with varying levels of instilled fluid. The authors would hypothesize that a larger volume of instilled fluid would increase displacement of the fetal head from the pelvis and thereby increase the risk of intrapartum presentation change, but further investigation is needed to answer this question.

Future studies should aim to characterize practices by providers regarding offering of external cephalic version after intrapartum presentation change. A large prospective study that can also comment on the use of dual-balloon devices versus foley balloon devices as well as the amount of liquid inflated into the balloon would be helpful in interpreting the results to clinical practice.

**Strengths and Limitations**

There are numerous strengths of our study. We aimed to identify and study a rare outcome, intrapartum presentation

**Table 3** Maternal and neonatal outcomes according to delivery type/presentation change

	Cesarean delivery for presentation change (n = 46)	Vaginal or cesarean delivery for reasons other than presentation change (n = 3,416)	p-Value
<b>Maternal outcomes</b>			
Maternal composite morbidity <sup>a</sup>	7 (15.2%)	383 (11.2%)	0.40
<b>Neonatal outcomes</b>			
5-min Apgar score <7	2 (4.3%)	54 (1.6%)	0.17
NICU admission	7 (15.2%)	464 (13.6%)	0.75
NICU length of stay	43.0 (3.0–43.5)	4.7 (2.9–8.0)	0.16
Neonatal death	0 (0.0%)	3 (0.1%)	0.99
Composite neonatal morbidity <sup>b</sup>	3 (6.5%)	122 (3.6%)	0.23

Abbreviations: NICU, neonatal intensive care unit.  
 Note: All data are reported as median (interquartile range) or n (%).  
<sup>a</sup>Composite maternal morbidity includes maternal death, intensive care unit admission, thrombosis, wound infection, wound separation, endometritis, pulmonary thromboembolism, hemorrhage, and blood transfusion  
<sup>b</sup>Composite neonatal morbidity includes neonatal death, sepsis, intraventricular hemorrhage, hypoxic ischemic encephalopathy, respiratory distress, pneumonia, and necrotizing enterocolitis.

change after mechanical ripening, which requires large numbers of study participants as seen in the CSL database. The validated CSL database also provides a large sample of women from throughout the United States improving the generalizability of our results and reducing confounding factors. Our study also examines novel clinical factors associated with intrapartum presentation change after mechanical ripening, which has not been previously discussed in the literature.

While our study is clinically relevant, it is not without limitation. We are unable to determine if patients had an intrapartum presentation change and were offered an external cephalic version in labor and/or if it was successful. While this may be important, the focus on patients with cesarean delivery for malpresentation highlights the patients that required major obstetrical intervention and are of most clinical significance. Retrospective medical record review studies are also inherently limited by the dataset source.

**Conclusion**

In conclusion, the rate of intrapartum presentation change after mechanical ripening with a foley balloon or double-balloon device is low at 1.3%; however, nulliparous women with multifetal gestations may be at increased risk of requiring a cesarean delivery for an intrapartum presentation change.

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**Conflict of Interest**

None declared.

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