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Post-ARRIVE Trial Update

June 8, 2023

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OBJECTIVES

1. To Review the Results from the ARRIVE trial
2. To Understand how this study may or may not apply to your labor floor
3. Too look at post ARRIVE trial national cesarean delivery rates

Disclosures

- I participated (as a clinician) in the ARRIVE trial

Questions

- Does your hospital allow 39wk week inductions in nulliparous patients with an unfavorable cervix?
- Do you think your hospital should be allowing elective inductions?

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ESTABLISHED IN 1812 AUGUST 9, 2018 VOL. 379 NO. 6

Labor Induction versus Expectant Management in Low-Risk Nulliparous Women

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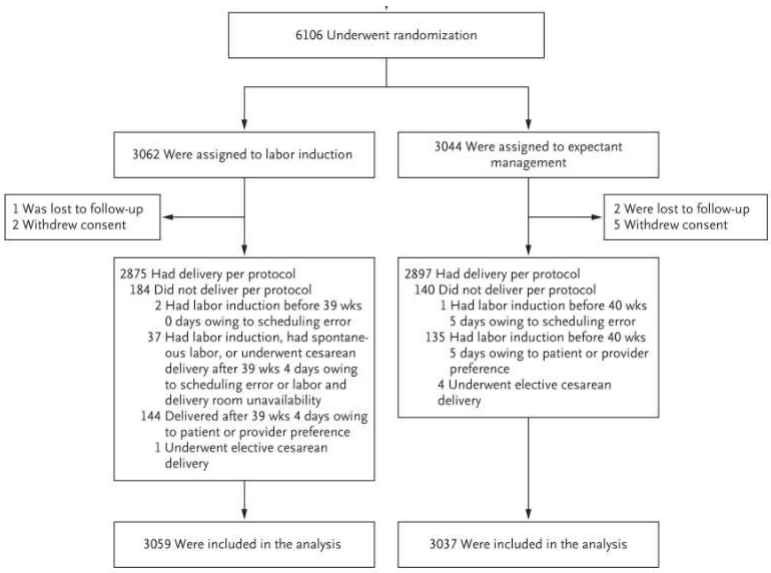
and Human Development

CONCLUSIONS

Induction of labor at 39 weeks in low-risk nulliparous women did not result in a significantly lower frequency of a composite adverse perinatal outcome, but it did result in a significantly lower frequency of cesarean delivery. (Funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development; ARRIVE ClinicalTrials.gov number, NCT01990612.)

Labor Induction versus Expectant Management in Low-Risk Nulliparous Women | NEJM



Labor Induction versus Expectant Management in Low-Risk Nulliparous Women | NEJM

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Table 2. Primary Perinatal Outcome and Components.*

Outcome	Induction Group (N=3059)	Expectant-Management Group (N=3037)	Relative Risk (95% CI)†	P Value‡
	no. (%)			
Primary composite outcome	132 (4.3)	164 (5.4)	0.80 (0.64–1.00)	0.049
Perinatal death	2 (0.1)	3 (0.1)	0.66 (0.12–3.33)	
Respiratory support	91 (3.0)	127 (4.2)	0.71 (0.55–0.93)	
Apgar score ≤3 at 5 min	12 (0.4)	18 (0.6)	0.66 (0.32–1.37)	
Hypoxic–ischemic encephalopathy	14 (0.5)	20 (0.7)	0.70 (0.35–1.37)	
Seizure	11 (0.4)	4 (0.1)	2.74 (0.91–8.12)	
Infection	9 (0.3)	12 (0.4)	0.74 (0.31–1.76)	
Meconium aspiration syndrome	17 (0.6)	26 (0.9)	0.65 (0.35–1.19)	
Birth trauma	14 (0.5)	18 (0.6)	0.77 (0.38–1.55)	
Intracranial or subgaleal hemorrhage	9 (0.3)	7 (0.2)	1.28 (0.48–3.42)	
Hypotension requiring vasopressor support	2 (0.1)	5 (0.2)	0.40 (0.06–1.79)	

* Details regarding the components of the primary perinatal outcome are provided in the Supplementary Appendix.
† Exact confidence intervals are provided for rare outcomes. The widths of the confidence intervals for components of the primary outcome have not been adjusted for multiplicity, so they should not be used to infer definitive effects of the management strategies.
‡ We used a group sequential method to control the type I error with the Lan–DeMets characterization of the O'Brien–Fleming boundary. One interim analysis was performed; in the final analysis of the primary outcome, a two-tailed P value of less than 0.046 was considered to indicate statistical significance. Since the adjustment is minimal, we report the 95% confidence interval for the relative risk.

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Table 3. Secondary Outcomes.*

Outcome	Induction Group (N=3059)	Expectant-Management Group (N=3037)	Relative Risk (95% CI)	P Value
Neonatal				
Transfusion of blood products — no. (%)	4 (0.1)	5 (0.2)	0.79 (0.20–2.74)	0.75
Hyperbilirubinemia — no. (%)†	145 (4.7)	142 (4.7)	1.01 (0.81–1.27)	0.91
Hypoglycemia — no. (%)	37 (1.2)	35 (1.2)	1.05 (0.66–1.66)	0.84
Admission to neonatal intermediate or intensive care unit — no. (%)	358 (11.7)	394 (13.0)	0.90 (0.79–1.03)	0.13
Maternal				
Cesarean delivery — no. (%)	569 (18.6)	674 (22.2)	0.84 (0.76–0.93)	<0.001‡
Operative vaginal delivery — no. (%)	[illegible]	[illegible]	[illegible]	0.07
Hypertensive disorder of pregnancy — no. (%)	277 (9.1)	427 (14.1)	0.64 (0.56–0.74)	<0.001‡
Chorioamnionitis — no. (%)	407 (13.3)	429 (14.1)	0.94 (0.83–1.07)	0.35
Third-degree or fourth-degree perineal laceration — no. (%)	103 (3.4)	89 (2.9)	1.15 (0.87–1.52)	0.33
Postpartum hemorrhage — no. (%)	142 (4.6)	137 (4.5)	1.03 (0.82–1.29)	0.81
Postpartum infection — no. (%)	50 (1.6)	65 (2.1)	0.76 (0.53–1.10)	0.15
Admission to ICU — no. (%)	4 (0.1)	8 (0.3)	0.50 (0.13–1.55)	0.26
Death — no. (%)	0	0	NA	NA
Median duration of stay in labor and delivery unit (IQR) — hr§	20 (13–28)	14 (9–20)		<0.001‡
Postpartum hospital stay — no. (%)				0.01‡¶
<2 days	322 (10.5)	317 (10.4)		
2 days	2191 (71.6)	2084 (68.6)		
3 days	399 (13.0)	452 (14.9)		
4 days	130 (4.2)	166 (5.5)		
>4 days	17 (0.6)	18 (0.6)		
Median scores on Labor Agentry Scale (IQR)‖				
At 6–96 hr after delivery	168 (148–183)	164 (143–181)		<0.001‡
At 4–8 wk after delivery	176 (157–189)	174 (154–188)		0.01‡
Median labor pain scores (IQR)**				
Worst score	8 (7–10)	9 (8–10)		<0.001‡
Overall score	7 (5–8)	7 (5–9)		<0.001‡

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Is this data applicable to my labor unit?

1. What is your NTSV cesarean rate?
2. What criteria do you use for failed IOL/arrest of dilation and is it standardized across your unit?
3. Do you have the capacity and staffing to manage a large influx of IOL's and the added time on the labor floor?
4. Are you performing outpatient cervical ripening?

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Department / Program Name, Hospital / Member Name

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Table 3. Secondary Outcomes.*

Outcome	Induction Group (N = 3059)	Expectant-Management Group (N = 3037)	Relative Risk (95% CI)	P Value
Neonatal				
Transfusion of blood products — no. (%)	4 (0.1)	5 (0.2)	0.79 (0.20–2.74)	0.75
Hyperbilirubinemia — no. (%)†	145 (4.7)	142 (4.7)	1.01 (0.81–1.27)	0.91
Hypoglycemia — no. (%)	37 (1.2)	35 (1.2)	1.05 (0.66–1.66)	0.84
Admission to neonatal intermediate or intensive care unit — no. (%)	358 (11.7)	394 (13.0)	0.90 (0.79–1.03)	0.13
Maternal				
Cesarean delivery — no. (%)	569 (18.6)	674 (22.2)	0.84 (0.76–0.93)	<0.001‡
Operative vaginal delivery — no. (%)	222 (7.3)	258 (8.5)	0.85 (0.72–1.01)	0.07
Hypertensive disorder of pregnancy — no. (%)	277 (9.1)	427 (14.1)	0.64 (0.56–0.74)	<0.001‡
Chorioamnionitis — no. (%)	407 (13.3)	429 (14.1)	0.94 (0.83–1.07)	0.35
Third-degree or fourth-degree perineal laceration — no. (%)	103 (3.4)	89 (2.9)	1.15 (0.87–1.52)	0.33
Postpartum hemorrhage — no. (%)	142 (4.6)	137 (4.5)	1.03 (0.82–1.29)	0.81
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Admission to ICU — no. (%)	4 (0.1)	8 (0.3)	0.50 (0.13–1.55)	0.26
Death — no. (%)	0	0	NA	NA
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Worst score	8 (7–10)	9 (8–10)		<0.001‡
Overall score	7 (5–8)	7 (5–9)		<0.001‡

1. What is your NTSV Cesarean Delivery Rate?

CMQCC
California Maternal
Quality Care Collaborative

FOR FAMILIES

Quality Care Collaborative

- QI INITIATIVES
- BIRTH EQUITY
- CARDIOVASCULAR DISEASE
- EARLY ELECTIVE DELIVERIES
- HYPERTENSIVE DISORDERS OF PREGNANCY

Original Investigation

April 27, 2021

Hospital Quality Improvement Interventions, Statewide Policy Initiatives, and Rates of Cesarean Delivery for Nulliparous, Term, Singleton, Vertex Births in California

Melissa G. Rosenstein, MD, MAS[1,2]; Shen-Chih Chang, MS, PhD[1,3]; Christa Sakowski, MSN[1]; et al

Author Affiliations

JAMA. 2021;325(16):1631-1639. doi:10.1001/jama.2021.3816

- **Findings** In this observational study of 7 574 889 NTSV births that compared the rates of cesarean delivery between 2014 and 2019, the rates in California had a statistically significant decrease from 26.0% to 22.8% (relative risk, 0.88). The cesarean delivery rate for NTSV births in the US (excluding California) was 26.0% in both 2014 and 2019.

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2. What criteria do you use for failed IOL/arrest of dilation and is it standardized across your unit?

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PRE-CESAREAN COMMUNICATION TOOL

Criteria for Arrest of Dilation in Active Labor
(all 3 should be met unless choosing the final option)
- ☐ Cervix ≥ 6cm dilation (active labor)
- ☐ Membranes ruptured
- ☐ No cervical change after at least 4 hours of adequate uterine activity (MVU ≥ 200, ideally with an IUPC in place) or at least 6 hours of oxytocin administration with inadequate uterine activity
- ☐ Although not fulfilling the above criteria, my clinical judgment deems this cesarean delivery indicated

Criteria for Failed Induction/Augmentation in Latent Labor
(all 3 should be met unless choosing the final option)
- ☐ Cervix < 6m dilation (latent labor)
- ☐ Membranes ruptured
- ☐ Oxytocin administered a minimum of 12 hours after membrane rupture without achieving active labor
  *Note: longer times may be appropriate based on individual considerations
- ☐ Although not fulfilling the above criteria, my clinical judgment deems this cesarean delivery indicated

Criteria for Arrest of Descent
(only 1 needed)
- ☐ At least 4 hours of pushing in nulliparous patient with epidural
- ☐ At least 3 hours of pushing in nulliparous patient without epidural
- ☐ At least 3 hours of pushing in multiparous patient with epidural
- ☐ At least 2 hours of pushing in multiparous patient without epidural
- ☐ Failed trial of operative vaginal delivery
- ☐ Although not fulfilling the above criteria, my clinical judgment deems this cesarean delivery indicated

Criteria for Non-Reassuring Fetal Status
(only 1 needed)
- ☐ Category III FHR
- ☐ Category II FHR remote from delivery that is not responsive to resuscitation efforts such as: maternal repositioning, fluid administration, maternal blood pressure support if hypotensive, scalp stimulation, correction of uterine tachysystole, amnioinfusion if repetitive variable decelerations
  *provider discretion regarding which category II tracings require delivery vs observation
- ☐ Although not fulfilling the above criteria, my clinical judgment deems this cesarean delivery indicated

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3. Do you have the capacity and staffing to manage a large influx of IOL's and the added time on the labor floor?

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Post ARRIVE Labor and Delivery Bottleneck

An Operations Problem

Manifested as...

- Waitlist for 39wk IOLs
- Prolonged LOS on L&D
- Patients 'boarding' in OB triage or a full floor leads to cancelling inductions
- Unhappy providers and patients

Induction Working Group…

- Transparency/Communication
- Process Improvements
- What about Outpatient Cervical Ripening ?

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Baseline Data

Prentice Women's Hospital

- INDUCTION VOLUME
- 4,071 induction episodes over 1 calendar year (6/1/19 to 5/31/20)
- 2,741 (67%) had ≥ one documented cervical ripening agent
  - About 7.5 inductions per day require cervical ripening
  - Daily waitlist for induction slots of 3-19 patients

- L&D LENGTH of STAY
- Inductions undergoing **inpatient** cervical ripening:

  Average LOS of 22:13 hours

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Outpatient Process - Identify an Appropriate Patient

Northwestern Memorial Group Faculty OBGYN

Inclusion criteria

1) Patient undergoing induction between 37.0-40.6
2) Requires cervical ripening (Bishop score ≤6)

Exclusion criteria

- Any contraindication to vaginal delivery
- TOLAC
- Abnormal vitals on arrival
- Preeclampsia or uncontrolled hypertension
- Ruptured membranes
- Suspected fetal growth restriction
- Amniotic fluid volume abnormalities

Relative contraindications

- Presence of hardships (transportation issues, multiple no-shows, lack of support at home)
- Maternal anxiety (Consider number of telephone calls/messages sent during pregnancy)

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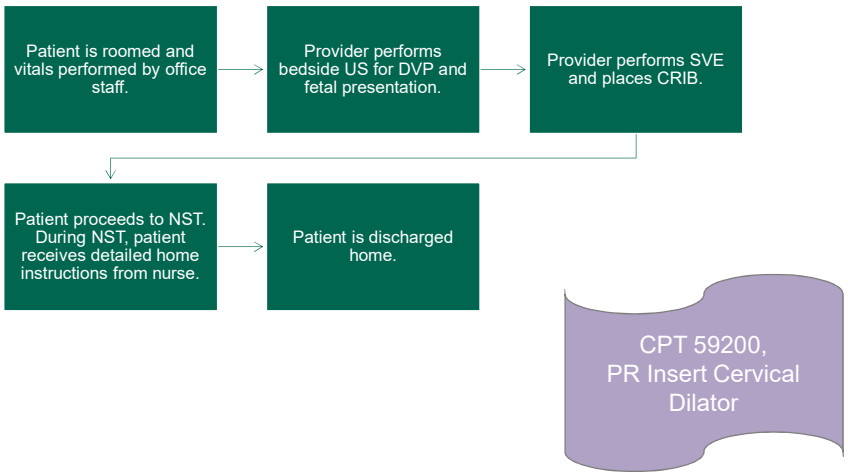
Outpatient Process – Cervical Ripening office visit

Northwestern Memorial Group Faculty OBGYN



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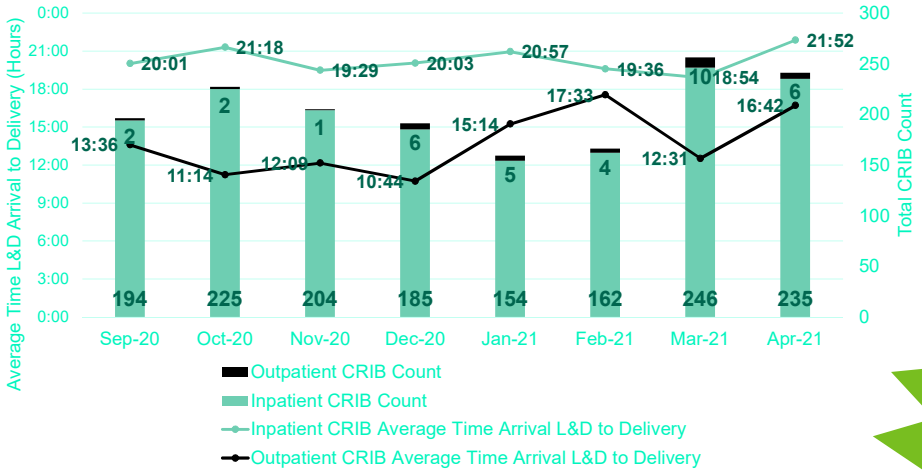
Average Time L&D Arrival to Delivery

Comparison of Outpatient vs. Inpatient cervical ripening balloon placement



Average LOS savings: 7 hours per patient!

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MAKE SURE TO TRACK YOUR OWN DATA CLOSELY

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What about on a national level?

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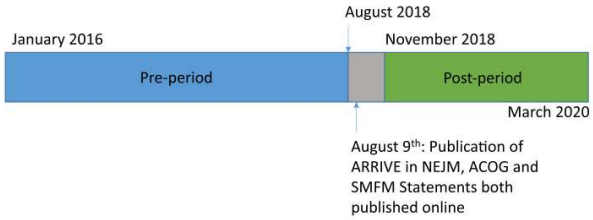
BRIGHAM AND WOMEN'S HOSPITAL
HARVARD MEDICAL SCHOOL TEACHING HOSPITAL
Mass General Brigham

Interrupted Time Series Analysis



- Primary exposure: ARRIVE trial publication and dissemination
- Primary outcomes: 39-week induction of labor, cesarean delivery, and ≥ 41-week birth

Wood, R, Freret, T, Clapp, M, Little, S. Changes in induction of labor and cesarean delivery post ARRIVE trial: A quasi-experimental analysis. sMFM Oral Plenary Session. Feb 9, 2023.

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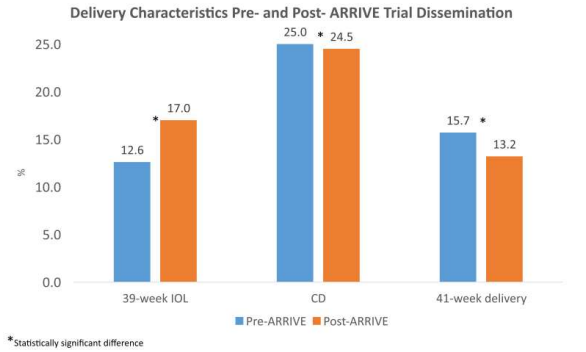
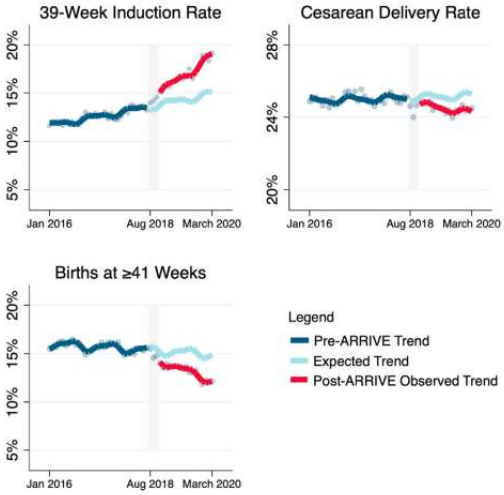


*Statistically significant difference



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Thank you.

References

Grobman WA, Rice MM, Reddy UM, Tita ATN, Silver RM, Mallett G, et al. Labor induction versus expectant management in low-risk nulliparous women. N Engl J Med 2018;379:513–23. DOI: 10.1056/NEJMoa1800566.

Rosenstein et al. Hospital Quality Improvement Interventions, Statewide Policy Initiatives, and Rates of Cesarean Delivery for Nulliparous, Term, Singleton, Vertex Births in California. JAMA 2021

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