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SPECIAL REPORT

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Nicole S. Carlson and Sharon L. Leslie Q2 Q1

Correspondence
Nicole S. Carlson, CNM, PhD, 229 Warren Street, NE, Atlanta, GA 30317.
nicole.carlson@emory.edu

Nicole S. Carlson, CNM, PhD, is an assistant professor in the Nell Hodgson Woodruff School of Nursing, Emory University, Atlanta, GA.

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How Will Results From ARRIVE Change Birth for Women in Your Community?

A Randomized Trial of Induction Versus Expectant Management (ARRIVE) was a federally-funded, multi-site, clinical trial to compare elective induction of labor at 39 weeks gestation to expectant management until 40 5/7 weeks gestation for low-risk, nulliparous women (U.S. National Library of Medicine, 2013). Initial results for ARRIVE were announced on February 1, 2018 at the annual meeting of the Society for Maternal Fetal Medicine, which prompted a flurry of reactions from clinicians, researchers, and the public. Readers of this column may remember past discussions of ARRIVE and its potential to serve as rationale for a nationwide shift toward labor induction (Carlson, 2015; Woeber & Carlson, 2018).

The trial of 6,106 nulliparous women is now complete, and initial results include significant reductions in the following: cesarean birth (18.6% in the induction group vs. 22.2% expectant management group, Risk Ratio [RR] 0.84, 95% Confidence Interval [CI] [0.76, 0.93]), maternal admission to intensive care unit (0.1% in the induction group vs. 0.3% in the expectant management group RR 0.50, 95% CI [0.13, 1.55]), neonatal respiratory support in first 72 hours following birth (3.0% in the induction group vs. 4.2% in the expectant management group RR 0.71, 95% CI [0.55, 0.93]), and diagnosis of preeclampsia or gestational hypertension (9.1% in the induction group vs. 14.1% in the expectant management group RR 0.64, 95% CI [0.56, 0.74]; Grobman, 2018). Many people are asking what these results could mean for the future of labor and birth in the United States. Are we on the precipice of a new age in which almost all women will have their labors induced? Is physiologic labor to become a higher risk option that requires informed consent? Before we jump to any dire predictions, let's first review some key points about ARRIVE.

First, the results of ARRIVE have not yet been published in a peer-reviewed journal. To date, only the conference abstract and clinical trial guidelines have been made public (Grobman, 2018; U.S. National Library of Medicine, 2013). Until we can examine the full report of the study results after peer-review, we do not know critical details necessary to interpret the findings.

Second, it is not appropriate for ARRIVE results to be translated into practice at this time, and clinicians should not use preliminary findings to justify increased use of labor induction or to counsel women to consider elective induction at 39 weeks gestation. In statements released directly after the ARRIVE results were presented in an abstract, the Society for Maternal-Fetal Medicine (2018) and the American College of Nurse-Midwives (ACNM, 2018) urged patience for maternity care providers; elective induction of labor at less than 41 0/7 weeks in women with unfavorable cervices should still be avoided. In addition, Lisa Kane Low, President of ACNM, encouraged maternity care providers to continue the process of shared decision-making with individual women who may not desire the multiple interventions involved in labor induction (ACNM, 2018).

Third, several issues with the design of ARRIVE limit its clinical relevance. Although the trial is interpreted by many as a comparison of labor induction at 39 weeks gestation to spontaneous labor at later gestational ages, ARRIVE may also be interpreted as a comparison of elective induction at 39 weeks to elective induction *at later gestational ages*. Women who agreed to

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participate in ARRIVE clearly did not object to elective induction; they consented to be randomized to study groups. It is therefore possible that many women who were randomized to the expectant management group and did not go into labor spontaneously before 40 5/7 weeks asked for inductions soon after. Although the abstract did not include details on the type of labor onset for women in the expectant management group, the median gestational age at birth of newborns for these women was only 40.0 weeks (interquartile range 39.3–40.7 weeks) despite the fact that they could have waited until 42 2/7 weeks before having their labors induced according to the study protocol (Grobman, 2018; U.S. National Library of Medicine, 2013).

Nulliparous women whose labors were induced at later gestational ages were less likely to have vaginal births than women whose labors were induced at earlier gestational ages according to investigators of a recent secondary analysis of the Consortium on Safe Labor data (Kawakita et al., 2017). In that study, which included a large group of nulliparous women whose labors were induced at multiple sites across the United States ($N = 10{,}591$), for every additional week of gestational age past 37 weeks, women had an 18% decreased chance of achieving vaginal birth compared to the previous gestational week (adjusted Odds Ratio 0.82, 95% CI [0.79, 0.86]). Whether this finding is a result of variations in clinical decision making or in women's responses to induction as gestation advances could not be determined by the data. Thus, it would not be surprising for women in ARRIVE who had inductions at later gestational ages to have a greater chance of cesarean than women in the induction group. The full report of ARRIVE is needed to better understand differences in cesarean birth rates between groups.

Fourth, ARRIVE is not generalizable to most maternity care providers, women, and hospitals in the United States. Maternity care providers in ARRIVE used labor induction protocols that resulted in very low rates of cesarean birth: 18.6% in the ARRIVE induction group compared to 25.7% among similar, low-risk women nationally (Martin, Hamilton, Osterman, Driscoll, & Drake, 2018) and 32% to 60% among similar women who labored at 240 California hospitals (Main, 2018). Women in ARRIVE were given plenty of time and received the best combinations of induction agents to achieve successful vaginal births. Although evidence-based guidelines for inducing labor to prevent the first cesarean birth exist (Spong, Berghella, Wenstrom, Mercer, & Saade, 2012), failed labor induction before 6 cm cervical dilation was the indication for 53% of cesarean births among nulliparous women in the large study from the Consortium on Safe Labor (Zhang et al., 2010). This finding clearly indicates that many providers move prematurely to cesarean during labor induction. Further, the settings of ARRIVE were academic medical centers with 24/7 in-house surgical and anesthesia providers, which makes them significantly different than hospital settings in which most U.S. women give birth.

Earlier this year, Grobman et al. (2018) published the results of a study to determine the frequency of adverse maternal and perinatal outcomes as a function of the duration of the latent phase of labor among nulliparous women who undergo labor induction. The researchers concluded that it is safe for providers to wait up to 15 hours following oxytocin administration and rupture of the membranes before preforming cesarean (Grobman et al., 2018). On behalf of the California Maternal Quality Care Collaborative, Elliot Main (2018) referred to these results and stressed, "If a hospital's induction guidelines are to be changed to allow for elective inductions at 39 weeks, strict guidelines for defining failed induction … and for management of active phase and fetal monitoring abnormalities need to be adopted simultaneously" (p. 1).

The women in ARRIVE were also not like most women in United States in that they represented a select group of low-risk women who were willing to have highly medicalized labors and births in academic medical centers (Grobman, 2018; U.S. National Library of Medicine, 2013). In addition, their maternity care providers were aware that these women were ARRIVE participants and that one of the important outcomes of the study was the rate of cesarean birth (U.S. Library of Medicine, 2013). Oversight of labor management and decision-making regarding cesarean (second opinion or audit and feedback) are proven methods to lower cesarean rates (Chaillet & Dumont, 2007). How much did oversight of providers' clinical decisions serve to decrease the cesarean rate among all women in the study and specifically those whose labors were induced at 39 weeks gestation? We do not know. However, we do know that most U.S. women do not labor in hospitals at which audit and feedback on cesarean decisions are used.

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