ARRIVE Trial: Talking Points for Members

There have been numerous studies demonstrating a correlation between elective induction of labor, adverse maternal outcomes, and cesarean birth. The ARRIVE Trial, recently published in the New England Journal of Medicine, was initiated in response to concerns raised regarding the risks and benefits of elective induction of labor. Prior studies used designs such as observational cohorts and comparisons of labor induction to spontaneous labor onset, instead of comparing the perinatal outcomes of women who had labor induction to women who were managed expectantly. This trial was designed to answer questions about whether elective induction of labor at 39 weeks was associated with a lower risk of perinatal death or severe neonatal complications than expectant management.

The low-risk, nulliparous women who participated in this study had reliable estimated due dates and carried a live, singleton fetus in vertex presentation. The study recruited women who were planning to give birth in one of 41 large hospitals that participate in the Maternal-Fetal Medicine Network Unit. Although there were 22,533 women eligible for this study, only 27% (6106) agreed to participate, which can signal that the study sample may be different from the target population.

The women were randomized to induction of labor at 39 weeks versus expectant management. Of those 6106 randomized, 5772 (94.5%) delivered within the research guidelines. These guidelines included women in the induction group undergoing induction at 39 0/7-39 4/7 weeks. Women participating within the expectant management group were not induced until at least 40 5/7-42 2/7 weeks, unless they had a medical indication.

The median gestational age at birth was 4 days shorter (39.3 weeks) for the induction group when compared with the expectant management group (40 weeks), a difference of only 4 days. The median maternal age for the induction group was 24 years, and the median maternal age for the expectant management group was 23 years. Of note--the mean maternal age in the United States was 26.6 years in 2016, so the women in this study were slightly younger than the general population of women giving birth today. (**https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_01.pdf**) The study publication did not include mean age for comparison to the US mean age.

There were several outcomes reported from this study. These include the following:

- The primary outcome being investigated was a composite measurement of adverse perinatal outcomes (perinatal death or severe neonatal complications) (4.3% elective induction group vs. 5.4% in the expectant management group; relative risk, 0.80; 95% CI, 0.64 to 1.0, P=0.049). This difference was not statistically significant, as an interim analysis had been performed, and a lower p value had been assigned.

- A secondary outcome was the rate of cesarean birth between the two groups. Results demonstrated a statistically significant decrease in the rate of cesarean section in the women who had elective induction vs. the expectant management (18.6% vs. 22.2%; relative risk 0.84, 95% CI, 0.76 to 0.93; P<0.001).

- There was a significant decrease in the rate of hypertensive disorders of pregnancy in the women in the elective induction group vs. the expectant management group (9.1% vs. 14.1%; relative risk, 0.64; 95% CI, 0.56-0.74; P<0.001).

Here are some additional details to be aware of regarding the ARRIVE Trial:

1. Based upon the results of this study, the authors reported that 28 nulliparous women would need to undergo elective IOL in order to prevent 1 cesarean. Other studies have shown other care practices that decrease the cesarean rate. These include:

   a. One cesarean may be avoided with 14 women being cared for by doulas (Bohren et al, 2017).
   b. One cesarean may be avoided by 11 women using intermittent auscultation rather than usual care (Alfirevic, Devane, Gyte, & Cuthbert, 2017).
   c. One cesarean may be avoided by 23 low-risk women delivering at home (Wax, et al, 2010).
   d. One cesarean may be avoided by 42 women being upright and moving in labor vs. being in bed. (Lawrence, Lewis, Hofmeyr, & Styles, 2013).

   These non-induction options noted are less costly and do not disrupt the potential advantages of spontaneous labor when compared with routine induction (**http://www.birthtools.org/Hormonally-Mediated-Physiologic-Childbirth**).

2. The authors reported that the length of stay in labor and delivery was longer for those in the induction group, but they had a shorter postpartum stay. Due to staffing and acuity differences among departments, this shorter postpartum stay would not offset the resources expended for the additional time in labor and delivery. Nurse-to-patient staffing ratios are higher during labor and when performing an induction of labor than when providing postpartum care. The maintenance of safe staffing ratios is essential to quality patient care (AWHONN, 2010).

3. The management approaches were outlined and included cervical ripening for a woman whose Bishop's score was less than 5. This step in the induction of labor process is not universally available across all health care settings.

4. It was suggested that there be at least 12 hours of latent phase between cervical ripening, use of Pitocin, or rupture of membranes before an induction was considered to have "failed". This management approach is consistent with the recommendations of ACOG and SMFM for expanding the time to achieve active labor before making the decision to perform a cesarean. This suggestion for extended time may have led to variations in management, which in turn could affect the results.

5. The authors recommended that the cost-effectiveness of labor induction in this population would need further study. There are numerous negative operational effects that may occur within health care organizations and facilities as a result of routine induction at 39 weeks.

When interpreting the results of the ARRIVE trial, caution is necessary. Based upon selection criteria for the trial, these results are not generalizable to all low-risk women at term. For example:

- All participants consented to enter a study of induction of labor. Women who did not have favorable attitudes toward induction declined to participate, resulting in only 27% of eligible women agreeing to participate.
- The median ages of women reported in this study are 2-3 years younger than the average age of nulliparous women in the United States today.
- At the time they entered the study, participants did not have any complications of pregnancy necessitating labor and birth prior to 40 5/7 weeks.

- The participants' EDCs were reliable. Participants either knew their last menstrual period (LMP) AND gestational age was confirmed with ultrasound before 21 weeks, or if LMP was uncertain, the EDC was determined by ultrasound prior to 14 weeks of gestation.

Response:

For the reasons outlined above, the results of the ARRIVE trial will not be applicable to all women at 39 weeks gestation. These participants were low-risk, nulliparous young women with reliable EDCs experiencing uncomplicated pregnancies. Misinterpretation and incorrect application of the ARRIVE Trial findings could have unintended adverse consequences for women who do not have the same demographic or obstetric characteristics.

Implementation of practice changes to offer 39 week induction of labor should proceed cautiously after thoughtful consideration of available research and not based solely on the findings of one study. All decisions regarding maternity care should incorporate the woman's personal preferences and medical needs as paramount. Research related to the longer-term effects of induction of labor is still insufficient to determine its full impact.

ACNM is committed to supporting informed decisions regarding maternity care and safeguarding women's opportunity to have a healthy physiologic birth and avoiding unnecessary procedures (**http://www.midwife.org/acnm-healthy-birth-initiative**). We have several robust programs available to decrease the risk of cesarean birth including **www.birthtools.org**and **www.birthtools.org/HBI-Reducing-Primary-Cesareans**, and are committed to supporting woman-centered, evidence-based maternity care.

Read the ACNM Statement

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