UNIVERSITY OF WASHINGTON
COMMENT ON ARRIVE TRIAL PUBLICATION

On August 8, 2018, the New England Journal of Medicine published the highly anticipated results of the ARRIVE Trial (1). ARRIVE was a randomized trial of induction of labor versus expectant management in low-risk nulliparous women at 39 weeks of gestation. The trial included 6106 eligible women across 41 university and community hospitals. Greater than 60% of women had an unfavorable cervical exam with an initial Bishop score of <5 in both groups. This study demonstrated no statistical difference in the primary composite outcome of perinatal mortality and severe perinatal morbidity (Relative Risk [RR] 0.80, 95% Confidence Interval [95% CI] 0.64 to 1.00). Cesarean delivery rate was noted to be significantly lower in the induction of labor group (18.6% versus 22.2%, RR 0.84, 95% CI 0.76 to 0.93; *P* = < 0.001). The induction of labor group also demonstrated reductions in gestational hypertension and preeclampsia (9.1% versus 14.1%, RR 0.64, 95% CI 0.56 to 0.74, *P* = < 0.001), as well as need for neonatal respiratory support within the first 72 hours of life (3.0% versus 4.2%, RR 0.71, 95% CI 0.55 to 0.93). The authors suggest that policies aimed at the avoidance of elective labor induction among low-risk nulliparous women at 39 weeks of gestation are unlikely to reduce the rate of cesarean delivery on a population level (1).

The American College of Obstetricians and Gynecologists (ACOG), as well as the Society of Maternal Fetal Medicine (SMFM) published responses to the ARRIVE Trial (2,3,4). As stated by both ACOG and SMFM, based on the findings of the ARRIVE Trial, it is reasonable for obstetric providers to offer elective induction of labor to low-risk nulliparous women at 39 weeks gestation. However, both ACOG and SMFM emphasize that discussion of this labor intervention should include not only the ARRIVE Trial findings, but also the values and preferences of the pregnant woman. A shared decision making model is essential.

SMFM and ACOG highlight that if elective induction of labor is pursued, it is critical to adhere to current guidelines regarding definitions of failed labor induction and labor arrest in order to minimize the chance of a primary cesarean birth and perinatal morbidity. Current guidance from the American College of Obstetricians and Gynecologists and the Society for Maternal Fetal Medicine recommend that if the maternal and fetal status allow, cesarean births for failed induction of labor in the latent phase can be avoided by allowing longer durations of the latent phase (up to 24 hours or longer) and requiring that oxytocin be administered for at least 12–18 hours after membrane rupture before deeming the induction a failure (5).

It is unclear how generalizable these results are to the larger population, as women who enrolled in the trial were willing to be randomized to the induction arm and differed from the general population of women who delivered in the United States in 2016. Participants in the trial were younger, with a median age of 23 to 24 (vs. a mean age of 28.7 years for all U.S. mothers), and 4.1% were 35 years of age or older (vs. 17% for all U.S. mothers). Participants in this trial were less likely to be white and more likely to be black or Hispanic than women who delivered in the United States in 2016 (6).

As this trial was specifically regarding induction in nulliparous women, it is also unknown if these findings can be extrapolated to multiparous women. In addition, ACOG emphasizes that obstetric indications necessitating induction of labor should continue to be delivered at a time consistent with standard recommendations and guidelines for each condition. A non-medically indicated early term birth (<39+0 weeks of gestation) is not appropriate (7).

Cost information is not available at this time, and is a planned secondary analysis from this trial to provide more details on health care expenditures.

There is concern among many providers regarding how to accommodate nulliparous women who desire elective induction at 39 weeks gestation, given that induction slots are most commonly needed for other patients with medical or obstetric indications for delivery. During the counseling process with the patient's primary provider, it will be essential to discuss that elective induction availability will depend on the capacity, staffing and acuity of labor and delivery.

Despite many of the questions and issues raised above, the ARRIVE trial demonstrates that induction of labor in low-risk nulliparous women at 39 weeks gestation does not increase adverse maternal or neonatal outcomes, and results in decreased rates of cesarean delivery and hypertensive disease. Applied appropriately with consideration to individual institutional capabilities, this can be offered as a safe labor intervention.

Thus, in agreement with ACOG and SMFM, UW Medicine supports the following statement:

"ACOG and SMFM have reviewed the published results of the ARRIVE Trial and determined that it is reasonable for obstetric care providers to offer an induction of labor to low-risk women after discussing the options thoroughly, as shared decision making is a critical element. Women eligible for induction must meet the following criteria:

- Women who are planning their first delivery, are healthy and have no medical or obstetrical complications.
- Women who are 39 weeks pregnant with dating confirmed by ARRIVE trial criteria of last menstrual period consistent with an ultrasound performed before 21 weeks 0 days, or dated by ultrasound performed prior to 14 weeks 0 days for women with uncertain last menstrual period (1, 3)."

If the elective induction is not progressing with a persistent unfavorable cervix after 24 hours of cervical ripening, maternal and fetal status are reassuring, and membranes are intact, discharge home can be considered with the option to await spontaneous labor or return at a later date for repeat induction attempt.

These recommendations do not address multiparous patients as the ARRIVE trial included only nulliparous women. A shared decision making model should be used with multiparous patients who are interested in elective induction of labor ≥ 39 weeks, taking into account their pregnancy history, potential morbidities, values and preferences.

Specifically for scheduling at the University of Washington Medical Center Labor and Delivery unit, the procedure schedule will be adjusted to add 2 elective inductions per week. We will evaluate over time if there is adequate interest from patients to potentially add more than 2 elective spots per week, and if additional elective spots can be safely accommodated from patient census and nursing standpoints. Elective inductions should be scheduled only in the designated elective schedule spots; other induction spots should be reserved for medically indicated inductions only. Priority will be given to any medically indicated inductions. It is important to counsel patients regarding the possibility of their induction being delayed, depending on the acuity and staffing of Labor and Delivery.

References and Resources

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https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Advisories/Practice-Advisory-Clinical-guidance-for-integration-of-the-findings-of-The-ARRIVE-Trial

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