

More Evidence to Avoid Hospital Birth: A Critique of the Results of the ARRIVE Study by Judy Slome Cohain

A 2018 article by Grobman et al. in the *New England Journal of Medicine* has gotten a lot of press telling women that induction at 39 weeks is has better mother and baby outcomes compared to going into labor naturally. However, it is not as straightforward as the authors would have you believe.

The protocol to induce for postdates at 41 weeks was accepted by medical professionals about 10 years ago. The randomized controlled trials (RCT) for this protocol are based on poor quality studies that included births at high risk of perinatal death, such as premature births and those of diabetics, and entail high rates of noncompliance with protocol (Cohain 2015). There is no good evidence that induction for postdates among low-risk women results in better outcomes for mother or baby.

After a decade of inducing at 41 weeks, the ARRIVE study now supposedly provides RCT evidence to change the protocol again—to induction at 39 weeks. The excuse is not to improve neonatal outcomes—because it does not—but is supposedly to significantly reduce cesareans.

Most cesareans are done for non-medical reasons (Cohain 2009). Half of these surgical procedures are justified by the undefined term, “dystocia,” in which the cesarean is performed after an arbitrarily decided time limit has elapsed. The main reason not to perform a cesarean is because all major abdominal surgery results in the death of 1 in 10,000 women due to hemorrhaging or anesthesia complications.

The reason not to induce is also to avoid maternal death. Induction results in the death of about 1 in 10,000 women, caused by amniotic fluid embolism (AFE). Research shows that 50%–70% of AFE is “associated” with induction (Knight 2012; McDonnell 2015; Stolk 2012; Kramer 2013; Roberts 2010). In 1970, the AFI rate was 1 in 120,000, but now that we induce 25% of births and augment another 25% of births, the rate of AFE is up to 1 in 15,000 births. If the ARRIVE RCT trial, which promoted 39 week inductions, had told women before they signed up for the RCT of their risk of dying of AFE if they underwent induction, there would have been no trial because most women would not have agreed to join it. The danger of medical induction is comparable to driving to work five days a week for a year never wearing a seat belt or having airbags. Since the participating women were not informed of their risks, informed consent was not obtained. Yet the research received IRB approval. In addition, the study was approved despite the plan not to include enough women to pick up an increase in maternal deaths.

Low risk births have better outcomes when they are allowed to proceed with minimal medical intervention. The study clearly demonstrated this. Both groups underwent high rates of interventions and the outcomes were horrendous. At 5 minutes after birth, 15% of the babies were either not breathing at all or were weakly breathing; 1% needed respiratory support for a day or more; 12% were admitted to NICU; 0.6% suffered hypoxic ischemic encephalopathy (HIE) and 0.2% had seizures, both of which cause long term outcomes that are wide-ranging and may affect the babies’ motor, sensory, cognitive, and behavioural outcome; 0.3% had infections, which also often have long term sequelae like brain damage; 0.7% had meconium aspiration syndrome; 0.3% had intracranial hemorrhage; and 5% had hyperbilirubinemia.

Two percent of these babies suffered from shoulder dystocia, despite the lack of a single birth weight over 3560 g (7 lb 14 oz). Because the biggest baby in the study weighed 3560 g, one would not expect any cases of shoulder dystocia. It has been suggested that, in theory, inductions may cause shoulder dystocia due to Pitocin forcing the shoulder to get stuck above the pubic bone.

Maternal outcomes were also terrible: Five percent had severe postpartum hemorrhages (PPH) of >1500 cc, requiring blood, hysterectomy or blood products; 4% had third or fourth degree tears; and 2% had a postpartum infection.

The authors failed to report or address the effect of epidural analgesia on these labors. The title of the paper should have been: *Don't* induce your labor unless you want your baby to be brain-damaged.

Five percent, or 1 in every 20 births, did not comply with the assigned protocol. This means that for 5% of births, the doctor decided not to induce women in the induction group and 5% of participants in the expectant management group were induced. However, their outcomes were reported according to what

group the woman was originally randomized to be in. As a result, we don't actually know what cesarean rates each protocol resulted in. There might have been no difference between the two groups or induction might have had a higher cesarean rate.

Three perinatal deaths that were not stillbirths were reported, one in the “induction group” and two in the “expectant management group.” But because of the crossover, it is possible that all three resulted from overzealous inductions. There was no reason not to report the outcomes both by intention to treat and also according to what protocol the woman actually received. In any case, cesarean rates of 19% versus 22% are not different enough to change or direct a protocol, particularly in an unblinded study in which the doctors knew who was being induced.

Similar to the protocol to induce for postdates, Grobman et.al. reflects more evidence of research that uses bad methodology to make incorrect recommendations, once again, with the ultimate goal of medicalizing the birth process.

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