DR NORWITZ: This roundtable is about the question of whether or not to induce labor in otherwise healthy, well-dated, low-risk singleton pregnancies. We will not debate issues surrounding induction in high-risk or multiple pregnancies.

Notably, we will discuss findings of the ARRIVE trial, which was designed, in part, to determine whether elective induction of labor at 39 weeks’ gestation in low-risk, nulliparous women with an uncomplicated pregnancy is associated with lower risk of perinatal death and severe neonatal complications, compared to expectant management. The findings of ARRIVE, published in 2018, demonstrated a statistically significant decrease in the rate of cesarean delivery (CD) in women who had elective induction. The investigators determined that 28 nulliparous women would need to undergo elective induction of labor to prevent 1 CD.

MATERIAL RISKS PAST 39 WEEKS
DR NORWITZ: My first question for the panel is: Are there risks to the mother of continuing a pregnancy beyond 39 weeks’ gestation? Let’s focus on singletons.

DR REPKE: There are certainly risks to the mother, and to the fetus. We know, from other perinatal network trials, that most cases of preeclampsia occur in the last trimester and after the 37th week. So, the longer a pregnancy goes beyond 39 weeks, the higher the probability of developing preeclampsia. Even women who have gestational hypertension may progress to preeclampsia.

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Is Routine 39-Week Induction of Labor in Healthy Pregnancy a Reasonable Course?  
A ROUNDTABLE DISCUSSION

**An indirect risk to the mother is that, the longer pregnancy progresses, the larger the fetus might become and the more difficult delivery will be. The risk of operative vaginal delivery and subsequent repair is greater for a macrosomic fetus.**

**DR NORWITZ:** Is postpartum hemorrhage an added risk of continuing pregnancy?

**DR CAUGHEY:** Postpartum hemorrhage is an indirect risk. As the risk of macrosomia increases—which it will with increasing gestational age—then outcomes of postpartum hemorrhage increase associatively. I do not think that, at a population level, it is an appreciative risk that you would counsel a patient about.

**RISKS TO THE FETUS AFTER 39 WEEKS**

**DR NORWITZ:** What about risks to the fetus?

**DR CAUGHEY:** From the fetus’ perspective, complications of a term pregnancy are progressive senescence of the placenta, which can lead to growth restriction; consequent oligohydramnios; and, in the worst case, stillbirth.

Even in a healthy environment in utero, the fetus continues to grow past term, increasing the risk that a fetus will become macrosomic and potentially experience a birth injury. But, as with postpartum hemorrhage, the risk is relatively small and not something I would counsel mothers about aggressively.

**DR SRINIVAS:** I would add that the risk of meconium aspiration syndrome increases after 38 weeks, and conditions such as chorioamnionitis increase with increasing gestational age. However, those absolute risks are small.

**DR NORWITZ:** Most short-term complications, such as respiratory problems, sepsis, intraventricular hemorrhage, and necrotizing enterocolitis, reach their nadir at 36 to 39 weeks in otherwise healthy pregnancies. After that, the risk of respiratory complications overall—although not specifically respiratory distress syndrome caused by surfactant deficiency—start to creep up.

There is also good evidence that, the longer a pregnancy, the greater the risk of neonatal encephalopathy—even independent of route of delivery. Whether that increased risk is due to placental senescence or complications at birth is hard to say.

**DR REPKE:** The ARRIVE trial does not really provide data on why the neonates in the expectant management group had an increased need for respiratory support. The composite results were not statistically significant (although they came close at \( P = .049 \)), but if you remove that respiratory support category, those results probably become even less significant, or at least the confidence interval would increase.

Dr Srinivas, as an ARRIVE investigator, can you explain why the ARRIVE expectant management group required more respiratory support? Was it all meconium related or were there other factors?

**DR SRINIVAS:** It was not all meconium aspiration. There was not a significant difference in rates of meconium aspiration between the 2 groups.

**DR CAUGHEY:** We used national data in a study about 10 years ago to look at respiratory complications. We found that respiratory distress syndrome reached its nadir at 39 weeks and then went up a little at 40 to 41 weeks—but barely so.

Additionally, the risk of meconium aspiration syndrome does increase with increasing gestational age. When we looked at the need for respiratory support for 30 minutes or longer, we saw that need decrease until 39 weeks, then level off, and then go back up at 41 weeks. My guess would be that what drove this increase was the fact that, in the expectant management arm, a percentage of newborns had gone beyond 40 and 41 weeks’ gestation. Until the ARRIVE secondary analyses are done, we will not really know.

**DR NORWITZ:** Before we move on, I want to mention that, for me, one of the more compelling arguments for delivery at 39 weeks is stillbirth.

**DR REPKE:** That really is the problem foremost in our minds. Among healthy, low-risk, nulliparous women, the

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**KEY POINTS**

- Maternal risks in pregnancy after 39 weeks include higher probabilities of preeclampsia and fetal macrosomia.
- Risks to the fetus after 39 weeks’ gestation include progressive senescence of the placenta, meconium aspiration syndrome, neonatal encephalopathy, and stillbirth.
- Evidence from the ARRIVE trial suggests that induction of labor (IOL) at 39 weeks is a reasonable request from an otherwise healthy patient.
- However, there are practical and logistical challenges associated with large-scale IOL at 39 weeks. Labor and delivery units may not have the resources or capacity to accommodate the influx of patients.
- There is also the concern of “inevitable creep” where routine IOL at 39 weeks slowly gives way to IOL prior to 39 weeks.
expectation is that everything will be all right. I can’t think of anything worse than having a routine and otherwise normal obstetric appointment at 39 weeks and then finding absent fetal heart tones at 40 weeks. How do we counsel patients? What is the risk of stillbirth as pregnancy advances? The number I have heard bantered about is that, after about 38 weeks’ gestation, the stillbirth rate increases at about 1 for every 1000 pregnancies for every additional week. That might not seem like much of an increase—unless you are the one.

DR NORWITZ: This is where quoting relative risk and absolute risk really makes a difference. The data on absolute risk are not good. This goes back to a study¹ in 2000 in the United Kingdom—the absolute risk of stillbirth in the week after 38 weeks’ gestation is about 1 in 2000, which by week 40 goes up to about 1 in 1000 and then to 1 in 750 by week 41. Most of those stillbirths are unexplained in pregnancies with no risk factors.

The relative risk goes up to 1.5, even to 2.3 at 42 weeks, but the absolute risk is still relatively low—although if a hospital is doing 10,000 deliveries per year, a handful of term babies among that number, as you say, Dr Repke, will die each year.

DR SRINIVAS: The study you mention is probably the most interesting analysis of this question. But that study is almost 20 years old.

While there are unexplained stillbirths, when you think about some of the risks that Dr Caughey brought up earlier, such as oligohydramnios and growth restriction that also increase due to the placenta, screening for those conditions brings you to a fork in the road: The pregnancy that was being expectantly managed becomes an induction or signaling within their hypothalamic-pituitary-adrenal axis? And if you deliver them early, are you just making an obstetric problem a neonatal problem, and not affecting overall mortality?

DR REPKE: As a graphic presented in Dr Greene’s editorial⁴ on the ARRIVE study¹ makes clear, 28 to 32 weeks is the best time for a fetus to be delivered to yield the lowest fetal mortality. The tradeoff is going to be higher infant mortality, and that is not really what we want.

HOW RISKY IS ROUTINE INDUCTION AT 39 WEEKS?

DR NORWITZ: If we are moving toward earlier induction, what are the risks of routine induction of labor at 39 weeks’ gestation in otherwise well-dated, low-risk pregnancies?

DR REPKE: I have concerns, including ones that were noted in the 2013 study⁶ that Dr. Caughey conducted and that were discussed in Dr Green’s editorial accompanying the ARRIVE trial⁵ and subsequent letters to the editor for ARRIVE.⁷⁻⁹ First, even though ARRIVE comprised a mix of university and community hospitals, it was conducted under highly controlled circumstances that might not mirror real-world obstetric practice.

Second, I wish there were more data in the study.
about using the classic Bishop Score\textsuperscript{10} rather than the so-called modified Bishop Score [of cervical readiness for induction] because I believe that ignoring the Bishop Score makes a difference—and yet that was one of the conclusions of ARRIVE. If it is acceptable to induce at 39 weeks, obstetricians might start bringing in patients for induction who have a very low classic Bishop Score, not the modified Bishop Score, in which points are given for parity and preeclampsia. We are going to end up with issues that are not apparent in ARRIVE. This flies in the face of what most of us were taught: The Bishop Score does matter, and cervical favorability matters.

Third, do labor and delivery (L&D) units have the resources to handle a seismic shift in the approach to term pregnancy management if the number of elective inductions at 39 weeks suddenly increases by 50%, including the number of hours that those patients are going to stay in L&D?

**DR NORWITZ:** Those are legitimate concerns. We will come back to your third topic of resources later. As for your first 2 concerns, could the panel address whether the cervical examination matters, or does the routine use of cervical ripening agents make this less of an issue?

**DR CAUGHEY:** In my understanding, the Bishop Score was not designed to characterize who is going to have a successful induction but to determine who is going to go into labor in the next 1 or 2 weeks. If a woman is at 39 weeks and has an unfavorable Bishop Score, she is more likely to remain pregnant at 41 weeks. A woman who has a favorable Bishop Score, on the other hand—say, 7 or 8 at 39 weeks—is just the patient you do not need to induce. She is likely to go into labor on her own in the next few days; there is no reason to admit her and intervene.

That is contrary to what we have thought about this: We think, “Oh—favorable cervix, we can induce her.” But that is the patient that does not need our help. It is the other patient for whom we need better strategies for cervical ripening.

We can talk about resources later, but let me just say that there is no way we could start—at my institution and at many of the ones that I am familiar with—to induce a large percentage of the pregnant population. We would immediately be full, and patients who need to be in the hospital would not be able to get a bed.

**DO WE HAVE THE LARGE-SCALE CAPACITY TO INDUCE AT 39 WEEKS?**

**DR NORWITZ:** In light of the ARRIVE trial, do we start doing routine inductions in low-risk patients at 39 weeks? And do we have the capacity to do so?

**DR CAUGHEY:** Culture matters—that is, the local obstetrics culture. Dr Repke pointed out that ARRIVE was conducted at many different sites, but those sites generally adhere to protocols and stay close to the evidence. If induction at 39 weeks became routine practice, many institutions that have a much higher CD rate would not see the number of patients who need prolonged induction of labor. In those settings, induction would increase the risk of CD.

We know that there is a wide range in the CD rate across the United States. In Kozhimannil’s study,\textsuperscript{11} looking at all hospitals, the rate ranged from 7% to 70%; even if you looked at just the main hospitals, the CD rate is still 15% to 50%.

For a hospital that has a baseline CD rate of 40% or 50%, my concern is that introducing elective induction of labor would increase the CD rate because, in that setting, the threshold for pulling the trigger and performing a CD is so much lower than was likely the case in the ARRIVE trial.

**DR NORWITZ:** I think that the type of obstetric practice you are in makes a difference. Obstetricians in private practice need to get home or back to the office; they are likely to pull the trigger for a CD earlier than if they were in a different model, with adequate coverage and appropriately aligned incentives. So, if we do not risk-adjust, the data are somewhat meaningless.

I do think the weight of evidence—in ARRIVE and in a series of other studies—is that if you follow protocols closely, using cervical ripening agents in patients with an unfavorable cervix, the CD rate will not increase if you induce nulliparous patients at 39 weeks. In terms of outcome of CD, I am comfortable that we would not be increasing the CD rate, although that would vary from practice to practice.

**DR SRINIVAS:** ARRIVE,\textsuperscript{1} as well as other studies,\textsuperscript{12-15} is turning widely held ideas and practice on their head. The historic comparison of induction of labor to spontaneous labor has been totally erroneous and has set the stage for us to think that induction of labor is an inherently negative idea. Studies conducted before ARRIVE, such as HYPITAT\textsuperscript{16} (even though gestational hypertension was being studied) found a similar result: induction does not increase the CD rate. I agree that these findings will highlight interesting practice patterns, such as: When do you call a failed induction? How do you even define failed induction?

Having been a participant in ARRIVE, let me point out that we were not told how to manage labor or induction. The protocol was basic: before calling a failed induction, wait at least 12 hours, which is at the minimum end of current guidance—some guidelines suggest waiting as long as 24 hours.
The CD rate is so variable across institutions largely because of practice differences and to a smaller extent, demographic factors influence that rate. Having seen all the hospitals involved in ARRIVE, many of those included are representative of general obstetric practice; I am less concerned about the increase in CD rate but understand we need to be cognizant of variations in practice and its impact.

THE PROBLEM OF “INEVITABLE CREEP”

DR NORWITZ: With ARRIVE, we have a well-defined study and a defined population. If the recommendation is to move to routine 39-week induction, are some going to be done inappropriately? What populations should we be concerned about that need to be induced at 39 weeks?

DR SRINIVAS: For one, the pregnancy has to be well-dated. And it can be argued that you really should stick with the criteria of the trial, of a low-risk term pregnancy. ARRIVE adds insight into the shared-decision making conversation with a patient about what her values are regarding induction. Only about 30% of the women who were approached to participate in ARRIVE consented to do so. Many women may not want to have a 39th week induction. But given the results, it brings up the need for a conversation.

DR REPKE: It is so highly scrutinized now about delivering prior to 39 weeks, from scientific and economic perspectives, in Pennsylvania and, I am sure, in other states. If you are identified as having “electively induced” someone before 39 weeks, not only does that raise a red flag about the quality of your institution, you also may not get reimbursed. I am a little less concerned about “creep” in that regard—that obstetricians are going to say, “well, 38 plus 6 is the same as 39.” If you are short even a day of 39 weeks and your institution’s quality assurance reviewers identify that, you might be asked to account for that and, potentially, lose reimbursement for the entire hospitalization.

CROSSING A LINE? ELECTIVE INDUCTION BEFORE 39 WEEKS

DR NORWITZ: Are there circumstances under which you think it is acceptable to perform elective induction prior to 39 weeks?

DR REPKE: Sometimes we fight with insurers who say that delivery of placenta previa at 37 weeks is elective. It becomes important to define “elective”; a truly elective delivery prior to 39 weeks, however? I can’t think of a good justification.

DR CAUGHEY: There is one justification that I think is acceptable. In my state, we targeted 39 weeks and, of 52 hospitals that deliver babies, 49 eventually agreed to that date. The 3 that did not were small hospitals that have anesthesia coverage only on weekdays. Those hospitals said, “We’re going to do scheduled CDs at 38 weeks and 5 days on a Friday because if the patient comes in in labor over the weekend, it’s a disaster.” These are institutions that do 50 to 60 deliveries per year. Other than that, I cannot think of another medical reason to do a truly elective delivery earlier.

DR SRINIVAS: Are you talking about women with prior CD?

DR CAUGHEY: Yes.

DR SRINIVAS: For women with a prior CD, ACOG suggests a range of gestational age that is acceptable, and those deliveries with prior uterine scar are excluded from evaluation by The Joint Commission.

DR CAUGHEY: True.

DR SRINIVAS: At my institution we think of 39 weeks as optimal for patients with a prior CD (although many institutions deliver a couple of days earlier, for a variety of reasons, as mentioned).

DR CAUGHEY: True.

DR SRINIVAS: Right.

DR REPKE: When you look at the data that have been reported in studies of various levels of quality, the major reason for neonatal intensive care unit admission was transient tachypnea of the newborn.

DR REPKE: If you traded 30 cases of transient tachypnea for 1 stillbirth, would that be worth it? That is not a debate that will ever be resolved.

DR NORWITZ: Let us quickly address twins. When you have healthy, well-grown, diamniotic, dichorionic twins, do you wait until 39 weeks?

DR REPKE: No.
DR NORWITZ: We usually deliver at 38 weeks.

DR SRINIVAS: Agree—38 weeks.

CHANGES IN PRACTICE: SHARED DECISION-MAKING PROTOCOLS

DR NORWITZ: Dr. Srinivas, you were an investigator for ARRIVE. Has the study changed your clinical practice at the Hospital of the University of Pennsylvania?

DR SRINIVAS: It has not, for some of the reasons mentioned regarding resources. We are thinking about how to operationalize having this conversation with patients and offering this.

Based on the findings of ARRIVE, and on the fact that there was a reduction in the CD rate and a significant reduction in hypertensive disorders, and certainly no neonatal harm or perinatal harm, I think we should be having a conversation with women about induction at 39 weeks, knowing that not all of them are interested. We have not done that in a systematic fashion yet because of resource issues around induction of labor and increased length of time on L&D.

DR NORWITZ: Earlier you mentioned shared decision making. Has that model changed the way you interact with patients? Do you bring up early induction? What if they bring it up?

DR SRINIVAS: I do bring it up. I talk to women about the findings of ARRIVE. I also bring it up when the situation is reversed, with women who do have to be induced for medical reasons, such as delivery for gestational hypertension at 37 or 38 weeks to discuss that many studies now have demonstrated that inductions do not seem to increase the CD rate.

DR CAUGHEY: We published the first paper on this idea of induced labor versus expectant management about 12 years ago. I practiced in San Francisco at the time; we could not convince women there to be induced at 41 weeks—they were not interested in being induced at all.

I have used the argument of induction of labor versus expectant management to explain to women who have preeclampsia or diabetes, or who are just at 41 weeks, that the risk of CD is not increased with induction of labor compared with expectant management. That is also why I mention the issue of institutional culture and practice style. At 12 hours, we may be barely getting started with induction. At other institutions, obstetricians are doing 8- or 9-hour inductions and calling it a day.

DR SRINIVAS: I agree. There was a large range of hospital types in ARRIVE, which debunked the notion that these are all academic centers that follow a specific protocol.

DR CAUGHEY: The idea that induction of labor is protocolized definitely needs to be debunked. The ARRIVE protocol was to induce labor as it usually occurs at those institutions. That being said, all participating institutions were affiliated with the Maternal-Fetal Medicine Units [MFMU] Network; they are not all academic centers, but they do have a higher volume of deliveries and have a culture that accepts research.

Recently I looked at variation in the CD rate across hospitals in Washington State. You have a CD rate of 9% at the low end and 40% at the high end. Again, I wonder what routine induction of labor does in a setting where the CD rate is 40%. You might think, “Maybe that will lower the rate.” Perhaps, but I am worried that, in such a culture where beliefs are already intense, the rate will increase.

Another point: If you have more crowding on labor floors, if you induce more women and you are therefore more crowded, then crowding kind of stresses everybody—such as “OK, who can we get delivered so we can get the next patient in?”

DR REPKE: Dr. Srinivas brought up the Bishop Score earlier. I want to add to what she said and describe the impact that ARRIVE might have had on my practice—full disclosure, I retired from clinical practice about 3 months before the findings of ARRIVE were published. We had a fairly strict policy that you could not electively induce at 39 or 40 weeks unless the patient had a classic Bishop Score of 7 or higher. ARRIVE potentially eliminates that restriction. Purely anecdotal, and unencumbered by data, when I started practice it was not uncommon to see women coming back for their third or fourth day on L&D to be induced. I worry about that; I do not think the Bishop Score is as irrelevant as ARRIVE data suggest.

DR NORWITZ: The ARRIVE trial has changed 2 things in my practice. First, we think it is reasonable for a patient to request induction after 39 weeks. We do not encourage it or initiate the discussion but, if they ask or request it we will review the data, describe the advantages/disadvantages and the implications of their decision, and work with the couple to decide on a plan of action that best fits their goals and expectations. Second, we engage the patients much more in terms of shared decision making. We let them know that they can change their mind at any time. If, after being informed and weighing the risks and benefits, they choose to proceed with elective induction of labor at 39 weeks, we will respect and honor this request, regardless of their parity or cervical status.
ARE THERE RESOURCES TO BROADLY PROVIDE EARLY INDUCTION?

DR NORWITZ: Last, let us address an important topic that came up earlier: logistics. If early induction is the right thing to do, if a patient requests it, how can the system cope with all of these patients being “electively induced” at 39 weeks?

Let me reframe the question: Do we have to bring women scheduled for early induction onto L&D? After all, doing that is just going to clog up L&D. Is there an option for cervical ripening off L&D?

DR REPKE: My concern might be unfounded scientifically but it is definitely founded in real-world events: It will take just 1 case of somebody undergoing cervical ripening at home who returns with a stillbirth before that institution’s policy changes.

There is going to be a fairly high threshold for hospitals and obstetricians to be comfortable with having patients undergo pharmacologic cervical ripening at home. Maybe this would work in states where the medicolegal situation is different than where I have previously practiced. Regardless, I do not think that this is going to be a significant option.

I am also concerned about the resources. If we were to start bringing in women routinely for induction, or even increase the rate by 50%, I do not think we have the resources right now to manage that increased volume on L&D.

DR NORWITZ: As I talk about this topic at meetings, I find that outpatient cervical ripening is already being performed across the country, routinely, in many places. Some hospitals are using a transcervical Foley catheter, sometimes inserted in the office; the patient is then sent home and instructed to return when the catheter falls out. This is happening a lot, and has been going on for a long time—and, yes, I wonder what the safety record is. I am sure adverse events occur, but those might have happened anyway.

DR REPKE: I would probably be less concerned about nonpharmacological cervical ripening.

DR SRINIVAS: Studies have looked at the use of outpatient cervical Foley catheter for the induction process out of the hospital.18 If some of that clock could be started at home, before the patient is in the hospital, the obstetrician would have less hospital time in latent, which may help with some of the latent labor decision making regarding performing a CD.

Hospitals are already using a technique of inserting cervical Foley alone; from a safety perspective, the studies that have been published—although they are of mixed quality—have not shown any adverse events.19 There is a need for larger studies to demonstrate safety, the ones we have were not sufficiently powered, because the prevalence of adverse events would be relatively low.

Another alternative is having institutions perform cervical ripening, or start induction, in their antenatal units or other locations that do not include licensed L&D beds; I think that many institutions are doing this as well.

An abstract recently presented at the 2019 Society for Maternal-Fetal Medicine Pregnancy Meeting20 shows gains with induction at 39 weeks on the outpatient side, including less testing and fewer sonograms. Those gains may vary by practice setting, of course.

DR CAUGHEY: It boils down to what Dr Repke said: If we increase our induction rate by as much as 50%, we are not going to have the resources to handle that volume. Either we widely expand our L&D units or figure out a more strategic way to handle the load.

I like how it is being done at Dr Norwitz’s institution, because I am concerned that, in our field, 1 large trial is published and all of a sudden we are changing our practice. With a trial such as ALPS,21 for example, I think that the variability in practice of giving an injection of betamethasone is small, institution to institution. For early induction, however, where there could be a lot of variability of practice, it makes me nervous to think that we would widely expand our L&D units or figure out a more strategic way to handle the load.

However, we should also honor women’s preferences; if a patient says, “I’d really like this with this pregnancy,” then offering them a share in decision making makes sense. Then, any change in practice would not happen so rapidly, and we would likely be able to figure out what works best. If we move the “front end” of induction into a triage environment, not unlike an outpatient environment, we would lighten the load on L&D.

DR NORWITZ: I think that where we are heading is in the direction of outpatient cervical ripening. We would likely perform the initial intervention on hospital premises close to an operating room; I do not think we are yet ready to do this in our outlying clinics. We would perform the initial intervention—either pharmaceutical cervical ripening or placement of a transcervical Foley catheter—monitor for 1 to 2 hours, and then send the patient home for follow-up in 12 to 24 hours. I think that is where we are heading—a downstream consequence of ARRIVE.

CONSENSUS: WILL EARLY INDUCTION (SOMEDAY) BE PART OF ROUTINE PRACTICE?

DR NORWITZ: So, are we moving toward recommending elective induction at 39 weeks for all patients?
REFERENCES


