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Implementation of A Randomized Trial of Induction Versus Expectant Management (ARRIVE) in a Community Hospital-Based Obstetric Practice

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Abstract

Background and aim

The randomized controlled trial titled A Randomized Trial of Induction Versus Expectant Management (ARRIVE) evaluated induction at 39 weeks in low-risk nulliparous patients and demonstrated a significant reduction in cesarean sections. The purpose of this study was to assess the maternal and neonatal outcomes before and after the ARRIVE trial implementation of induction at 39 weeks for low-risk nulliparous patients at our community hospital.

Methods

A retrospective chart review was completed comparing data one year prior to and after implementation of the ARRIVE trial 39-week induction. Categorical data were evaluated with a chi-square test. Continuous variables were analyzed using a two-sample independent t-test. Statistical significance was set at $p<0.05$.

Results

A total of 212 patients were included in the pre-ARRIVE trial cohort, and 189 patients were included in the post-ARRIVE trial cohort. Gestational age at which the elective inductions were performed was statistically lower ($p=0.0001$) post-ARRIVE. There was a statistically significant increase ($p=0.01$) in pre-delivery length of stay (LOS). The number of inductions also increased after the implementation of the ARRIVE trial ($p=0.0001$). The C-section rates were not statistically significantly different ($p=0.224$).

Conclusion

Our study found that induction rates increased and pre-delivery LOS increased after ARRIVE. Cesarean delivery rates, which increased post-ARRIVE for the whole population and the induction groups only, were not statistically significantly different. Compared to the ARRIVE trial, our results are mixed.

Categories: Obstetrics/Gynecology
Keywords: arrive trial, cesarean section, community hospital, induction, length of stay

Introduction

In 2022, the Centers for Disease Control and Prevention (CDC) reported that the total cesarean delivery rate in the United States was 32.1%, similar to 2021 [1]. In low-risk pregnancies, cesarean delivery is associated with increased maternal morbidity and mortality and greater financial cost relative to vaginal delivery [2]. In recent years, efforts have focused on avoiding a first cesarean, and the obstetric community has focused on the cesarean rate for nulliparа, term, singleton, vertex (NTSV) patients, with a goal of 24% [3,4]. Avoidance of the first cesarean delivery has immediate and downstream benefits to women in our care.

A randomized controlled trial (RCT) titled A Randomized Trial of Induction Versus Expectant Management (ARRIVE) of 6000 low-risk nulliparous patients demonstrated a statistically significant drop in cesarean section rate from 22.2% to 18.6% ($p<0.000$) when low-risk women were induced at 39 weeks compared to expectant management up to 42 weeks [5]. It had a profound impact on the care of term nulliparous patients and has also provoked some to question how much to believe in RCTs [6]. This study has been criticized for failing to meet its primary outcome, leading some to devalue its findings [7]. The primary outcome, adverse perinatal events, narrowly missed statistical significance with a p-value of 0.049, which required a predetermined p-value of 0.046. The confidence interval was 0.64-1.00, with prophylactic induction of labor (pIOL) neonatal subjects having fewer adverse events [8,9]. The trial participants were younger and more diverse than the general population, prompting questions about the generalizability of the findings [10]. An

excellent review by Grobman brings to light the paucity of high-quality evidence to guide clinicians for the optimal timing of deliveries. This review offers a number of large studies that support the ARRIVE findings [11].

The ARRIVE trial forces caregivers to confront their fundamental convictions regarding patient care - the duty to inform and patient autonomy. The ARRIVE trial can be easily summarized as allowing the patient to make an informed decision about pIOL [5]. If pIOL is accepted, the hospital and caregivers should respect the patient's decision; if pIOL is not desired, the pregnancy can proceed with proper surveillance without undue risk up to 42 weeks [5]. The purpose of this study was to assess the maternal and neonatal outcomes before and after the ARRIVE trial implementation of induction at 39 weeks for low-risk nulliparous patients at our hospital. It was expected to increase IOL for both medical and prophylactic (elective) indications. It also began the process of identifying the difficulties for a community hospital to accommodate women who prefer pIOL.

Materials And Methods

This study was approved by the Ascension Providence Hospital Institutional Review Board (IRB) (#1424349-3). A retrospective chart review was completed comparing data from one year prior to the implementation of the ARRIVE trial into practice (January 2017-December 2017) with data from the following year after implementation (September 2018-September 2019). The period in between was when the preliminary presentation of the ARRIVE trial results was given in February 2018 at the Society of Maternal-Fetal Medicine annual meeting, and the publication occurred in August 2018. This period allowed physicians and nulliparous patients to be more fully informed about term prophylactic induction of labor (pIOL).

The inclusion criteria for this study were nulliparous patients, full term (>36, 6/7 weeks), singleton, vertex, spontaneous labor and induction regardless of indication for induction, and care provided by Women's Health Consultants (WHC). The exclusion criteria were multiparous patients, preterm (<37 weeks), multiple gestation, breech presentation, or patients managed outside WHC.

Patient data were collected from the Ascension Providence electronic medical record and cross-referenced with the WHC delivery and billing records in each of the designated time periods. WHC is a six-member obstetrical group whose practitioners have remained the same since September 2016. This group functions as residency faculty and works closely with residents on labor and delivery (L&D); however, they manage their patients privately in the outpatient setting. As a group, they have promoted the ARRIVE trial to their low-risk term nulliparous patients since September 1, 2018. Induction of labor was consistently offered to these women from September 2018 to August 2019. This sentinel event afforded the opportunity for a retrospective study using historical controls to assess the impact of offering induction to this group of women. As this is a single-institution study, we used convenience sampling to ensure we had a sufficient sample size.

The primary outcomes measured pre- and post-ARRIVE were the number of inductions prior to the sentinel event compared with the number of inductions after, length of stay pre-delivery, and C-section rates. We also performed subgroup analyses. We did not identify any confounding variables. Categorical data were evaluated with the chi-square test or Fisher's exact test when the expected cell count was less than five. Continuous variables were analyzed using an independent t-test. IBM SPSS version 26 (Armonk, NY: IBM Corp.) was used for analyses, and significance was set at $p<0.05$.

Results

A total of 212 patients were included in the pre-ARRIVE trial cohort, and 189 patients were included in the post-ARRIVE trial cohort. In this study, the pre-initiative and post-initiative patient demographics and newborn characteristics were comparable (Table *1*). The only difference was in the gestational age at which the elective inductions were performed, which was statistically different ($p=0.0001$), with the gestational age at the time of induction in the pre-ARRIVE trial being 39.3 weeks and in the post-ARRIVE trial being 38.9 weeks. This decrease was expected as an effect of the ARRIVE trial.

Variables	Pre-ARRIVE trial, mean (SD)	Post-ARRIVE trial, mean (SD)	Test statistic	p-Value*
Maternal age (years)	29.5 (4.8)	30.0 (4.7)	-1.1	0.267
BMI	31.0 (6.3)	31.9 (6.0)	-1.5	0.135
Gestational age at induction (weeks)	39.3 (1.0)	38.9 (0.9)	4.0	0.0001
Birth weight (g)	3293 (418.7)	3249 (396.9)	1.1	0.283

TABLE 1: Mean (SD) values of demographics of study participants and newborns.

*P<0.05 was considered statistically significant.

An independent t-test was performed.

The results of this study showed an increase in the number of inductions, including both medical and elective, being performed after the implementation of the ARRIVE trial in the Women's Health Consultants (WHC) practice in September 2018, as follows: 65.3% pre-ARRIVE trial vs. 88.3% post-ARRIVE trial (p=0.00001) (Table *2*). Table *3* shows the pre-delivery and post-delivery length of stay for the pre-ARRIVE vs. post-ARRIVE groups. There was a statistically significant increase (p=0.01) in pre-delivery length of stay (LOS). While the post-delivery LOS decreased, it was not statistically significant (p=0.101). In addition to these findings, as expected, the pre-delivery length of stay was similar between the induction groups: 23.2 h for the elective group vs. 23.5 h for the medical group (p=0.825) before the ARRIVE trial and 24.6 h for the elective group vs. 23.1 h for the medical group (p=0.504) after the ARRIVE trial. This is a reflection of the standardized induction methods utilized.

Indication	Pre-ARRIVE trial		Post-ARRIVE trial		Test statistic	p-Value*
	Frequency	Percentage	Frequency	Percentage		
Elective inductions	54	27.10	62	33.00	28.9	0.00001
Medical inductions	76	38.20	104	55.30		
Labor	69	34.70	22	11.70		

TABLE 2: Indication for admission pre- and post-measured in frequencies and percentages.

*P<0.05 was considered statistically significant.

A chi-square test was performed.

Variables	Pre-ARRIVE trial, mean (SD)	Post-ARRIVE trial, mean (SD)	Test statistic	p-Value*
Pre-delivery (labor and delivery) (hours)	19.2 (11.4)	22.1 (10.9)	-2.6	0.01
Post-delivery (postpartum hours)	44.1 (16.4)	41.6 (14.1)	1.6	0.101

TABLE 3: Pre-delivery and post-delivery mean length of stay in hours for pre-ARRIVE vs. post-ARRIVE groups.

*P<0.05 was considered statistically significant.

An independent t-test was performed.

For each mode of delivery, there were no statistically significant differences between the pre-ARRIVE vs. post-ARRIVE groups for spontaneous vaginal delivery (SVD) (p=0.458), operative vaginal deliveries (OVD) (p=0.819), and cesarean delivery (CD) (p=0.224) (Table *4*). While not statistically significant, CD rates

increased from 19.8% to 24.9% post-ARRIVE. Table 5 shows the delivery mode of elective inductions only for pre-ARRIVE vs. post-ARRIVE groups. There were no statistically significant differences between the groups for spontaneous vaginal delivery (SVD) (p=0.881), operative vaginal deliveries (OVD) (p=0.051), and cesarean delivery (CD) (p=0.10). While not statistically significant, CD rates increased from 14.8% to 27.4% post-ARRIVE.

Mode of delivery	Response	Pre-ARRIVE trial		Post-ARRIVE trial		Test statistic	p-Value*
		Frequency	Percentage	Frequency	Percentage		
Spontaneous vaginal delivery (SVD)	Yes	153	72.2	130	68.8	0.6	0.458
	No	59	27.8	59	31.2		
Operative vaginal deliveries (OVD)	Yes	17	8.0	14	7.4	0.1	0.819
	No	195	92	175	92.6		
Cesarean delivery (CD)	Yes	42	19.8	47	24.9	1.5	0.224
	No	170	80.2	142	75.1		

TABLE 4: Mode of delivery for pre-ARRIVE vs. post-ARRIVE groups measured in frequencies and percentages.

*P<0.05 was considered statistically significant.

A chi-square test was performed.

Mode of delivery	Response	Pre-ARRIVE trial		Post-ARRIVE trial		Test statistic	p-Value*
		Frequency	Percentage	Frequency	Percentage		
SVD	Yes	39	72.2	44	71	0	0.881
	No	15	27.8	18	29		
Operative vaginal deliveries (OVD)	Yes	7	13	2	3.2	3.8	0.051
	No	47	87	60	96.8		
Cesarean delivery (CD)	Yes	8	14.8	17	27.4	2.2	0.1
	No	46	85.2	45	72.6		

TABLE 5: Delivery mode of elective inductions only for pre-ARRIVE vs. post-ARRIVE groups measured in frequencies and percentages.

*P<0.05 was considered statistically significant.

A chi-square test was performed.

Discussion

Our study found a statistically significant higher induction rate and longer pre-delivery LOS. CD rates, while increasing post-ARRIVE in the whole population and in the induction groups only, were not statistically significantly different. Gilroy et al. also found a higher induction rate but lower CD rates post-ARRIVE [12]. Similar to our study, a retrospective analysis of data from US hospitals also found an increase in elective induction, and no change in cesarean birth [13].

Labor inductions can be performed for varying reasons and at various gestational ages. These reasons include maternal reasons (preeclampsia, cardiac disease, etc.), fetal reasons (intrauterine growth restriction), and a combination of the two (uncontrolled gestational diabetes, post-term, etc.). Historically, IOL had been thought to increase the risk of cesarean section, but it was found that IOL was wrongly being

compared to women arriving at the same gestational age in spontaneous labor [14]. In recent years, proper comparisons of IOL versus expectant management have shown decreased or equivalent cesarean rates [5,15]. A meta-analysis of 157 randomized controlled trials found that the risk of cesarean delivery was 12% lower with labor induction than with expectant management [16].

The post-ARRIVE CD rate of 24.9% compares favorably with goals of many states of 23.9% [4]. However, while not significant, it was an increase in rate just the same. This underscores the need for additional large RCTs like the ARRIVE trial to improve generalizability. This study was helpful in defining the problems with implementing the ARRIVE trial in clinical practice. Not only pIOL but medical IOL increased dramatically. The ARRIVE trial results seem to have lowered the barriers for medical IOL of nulliparas, especially the patients with an unripe cervix.

From our experience, a consequence of the longer pre-delivery lengths of stay resulted in a decrease in available labor and delivery (L&D) rooms for medically indicated inductions and expectant mothers going into labor. This unavailability of resources to other patients is called a spillover and could affect the true benefit of an intervention [17]. Practitioners and L&D units need to find creative ways to accommodate our patients who want pIOL. This might include outpatient cervical ripening, prioritizing nulliparas ⩾35 years old over other IOLs, and requiring a favorable Bishop score [15]. Another idea, among other interventions, is to have patients on a standby induction list whereby they can be called in when the unit is slow.

The importance of a manageable L&D unit and buy-in by the nursing and resident staff cannot be overstated. Most importantly, the principles of patient autonomy, shared decision-making, and keeping patients informed of the latest research must be our top priority. The implementation of the ARRIVE trial challenges us to overcome these logistical barriers to deliver the care our patients expect and deserve. Our study has limitations. It was retrospective, small, and conducted at a single institution. We also did not collect race information, although our practice serves a high proportion of African Americans.

This retrospective analysis has few limitations. Although the two groups are comparable based on maternal characteristics, they come from a single institution. As well, the retrospective nature of the data is more limited compared with prospectively collected data. Certain breakthroughs change the course of medicine in historic ways. In obstetrics and gynecology, the HPV vaccine, the Women's Health Initiative, and now the ARRIVE trial will continue to have a huge impact on the care of women and their babies. While there will never be a perfect study, large RCTs are the best to guide us in all areas of medicine. This project was our first step to put this new knowledge into practice.

Conclusions

Compared to the ARRIVE trial, our results are mixed. The ARRIVE trial demonstrated major findings to guide the care of term nulliparous gravidas, including lower cesarean delivery and gestational hypertension. The large numbers and meticulous analysis help obstetrics practitioners and their patients with guidance at 39 weeks and beyond. Similarly, our study found that in addition to induction rates, pre-delivery LOS increased post-ARRIVE.

However, CD rates, which increased post-ARRIVE for the whole population and the induction groups only, were not statistically significantly different. This is in contrast to the ARRIVE trial's finding of a lower CD rate for pIOL at 39 weeks, which influenced the providers to more readily recommend pIOL for a wide variety of indications. Additionally, we experienced that the increased number of pIOLs caused a burden on the L&D unit, and it was necessary to restrict "elective" IOLs.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

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Disclosures

Human subjects: Informed consent for treatment and open access publication was obtained or waived by all participants in this study. Ascension Providence Hospital Institutional Review Board issued approval #1424349-3. **Animal subjects:** All authors have confirmed that this study did not involve animal subjects or tissue. **Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from any organization for the submitted work. **Financial relationships:** All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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