Original Research

Effects of the ARRIVE (A Randomized Trial of Induction Versus Expectant Management) Trial on Elective Induction and Obstetric Outcomes in Term Nulliparous Patients

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OBJECTIVE: To evaluate the effect of publication of the ARRIVE (A Randomized Trial of Induction Versus Expectant Management) trial on perinatal outcomes in singleton, term, nulliparous patients.

METHODS: An interrupted time series analysis was performed using clinical data for nulliparous singleton births at 39 weeks of gestation or later at 13 hospitals in the Northwest region of the United States (January 2016–December 2020). A modified Poisson regression was used to model time trends and changes after the ARRIVE trial (August 9, 2018). Outcomes of interest were elective induction, unplanned cesarean births, hypertensive disorders of pregnancy, a composite of perinatal adverse outcomes, and neonatal intensive care unit admissions.

RESULTS: The analysis included 28,256 births (15,208 pre-ARRIVE and 13,048 post-ARRIVE). The rate of elective labor induction was 3.6% during the pre-ARRIVE period (January 2016–July 2018) and 10.8% post-ARRIVE (August 2018–December 2020). In the interrupted time series analysis, elective induction increased by 42% (relative risk [RR] 1.42; 95% CI 1.18–1.71) immediately after the ARRIVE trial publication. Thereafter, the trend was unchanged compared with the pre-ARRIVE period. There was no statistically significant change in cesarean birth (RR 0.96; 95% CI 0.89–1.04) or hypertensive disorders of pregnancy (RR 0.91; 95% CI 0.79–1.06) immediately after the trial, and no change in trend. After the ARRIVE trial, there was no immediate change in adverse perinatal outcomes, but a statistically significant increase in trend of adverse perinatal events (1.03; 95% CI 1.01–1.05) when compared with a declining trend observed in the pre-ARRIVE period.

CONCLUSION: Publication of the ARRIVE trial was associated with an increase in elective induction, and no change in cesarean birth or hypertensive disorders of pregnancy in singleton nulliparous patients giving birth at 39 weeks or later. There was a flattening of the pre-ARRIVE decreasing trend in perinatal adverse events.

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In August 2018, the ARRIVE (A Randomized Trial of Induction Versus Expectant Management) trial reported that elective labor induction at 39 weeks of gestation in low-risk nulliparous pregnant people resulted in a 16% decrease in the risk of cesarean birth and a 36% decrease in the risk of hypertensive disor-

ders of pregnancy, which included either gestational hypertension or preeclampsia, compared with expectant management.[1] Despite national efforts to reduce cesarean births, particularly in the nulliparous term singleton vertex population, U.S. rates have remained high[2–4] and, consequently, the results of the trial received considerable interest. However, it was not clear how the trial findings would be implemented or whether the findings would be generalizable.[5,6] Concurrent with publication of the ARRIVE trial, the Society for Maternal-Fetal Medicine stated that it was, "…reasonable to offer elective induction of labor to low-risk nulliparous women ≥39 weeks…" and that, "…further research [should] be conducted to measure the impact of this practice in settings other than a clinical trial."[7]

We hypothesized that publication of the ARRIVE trial would result in a population-level increase in elective induction of labor in nulliparous patients at 39 weeks of gestation and a subsequent decrease in both cesarean birth and hypertensive disorders of pregnancy, with no increase in perinatal adverse events. To test our hypothesis, we performed an interrupted time series analysis in a large U.S. birth cohort to assess the effect of the ARRIVE trial on rates of elective induction of labor, cesarean birth, hypertensive disorders of pregnancy, and selected perinatal outcomes within a perinatal quality collaborative network.

METHODS

This is a cohort study of births from 13 hospitals (six hospitals with neonatal level III–IV and seven with neonatal level I–II) that participated in an ongoing perinatal quality collaborative (OB COAP [Obstetrical Care Outcomes Assessment Program]) based in the Pacific Northwest between January 2016 and December 2020. The OB COAP database captures clinical data abstracted from medical records for consecutive births (no sampling). Details of chart abstraction and data quality checks have been reported previously.[8] The Western-Copernicus Group IRB deemed research using deidentified OB COAP data as exempt from review by an institutional review board.

The analysis was restricted to singleton, cephalic-presenting, full-term births (39 weeks of gestation or later) to nulliparous patients. Scheduled cesarean births were excluded. Despite the coronavirus disease 2019 (COVID-19) pandemic in early 2020, which disrupted obstetric care, a prior analysis[9] did not show changes in perinatal outcomes; therefore, births in 2020 were included. The ARRIVE trial was published on August 9, 2018,[1] and professional obstetric associations published statements and practice advisories[7,10–12] on or near the publication date. The intervention time point in this analysis was August 9, 2018, and we included births from January 1, 2016, to August 8, 2018 (pre-ARRIVE), and from August 9, 2018, to December 31, 2020 (post-ARRIVE).

Patient characteristics (including age, self-reported race and ethnicity, most recently recorded body mass index (BMI, calculated as weight in kilograms divided by height in meters squared) at admission in labor, prepregnancy hypertension, prepregnancy diabetes, gestational diabetes, and socio-economic characteristics) were examined for the pre-ARRIVE and post-ARRIVE periods. Socioeconomic characteristics included health insurance type (public or commercial) and Distressed Communities Index quintiles (prosperous, comfortable, mid-tier, at risk, and distressed) from the Economic Innovation Group.[13] The Distressed Communities Index quintiles combine socioeconomic indicators into a measure of economic well-being based on area of residence.

The primary outcome of interest was elective induction of labor. *Elective induction of labor* was defined as labor induction that was recorded as "elective" or "non–medically indicated." Labor inductions with an indication of "suspected macrosomia" in the absence of diabetes or advanced maternal age and "postterm" inductions occurring before 41 0/7 weeks of gestation were classified as elective. Secondary outcomes were unscheduled cesarean birth, hypertensive disorders of pregnancy (preeclampsia or gestational hypertension), and two perinatal outcomes (neonatal intensive care unit [NICU] admission and a composite perinatal outcome). The composite perinatal outcome, modeled after the ARRIVE trial's outcome, included any of the following outcomes: perinatal death (stillbirth or neonatal death within 28 days of birth recorded by the hospital), 5-minute Apgar score lower than 4, seizure, septicemia or bacteremia, birth trauma (comprising brachial plexus injury, fracture of the skull, clavicle, or humerus; subgaleal hemorrhage; or intracranial hemorrhage), or resuscitation associated with the use of intubation, epinephrine, chest compressions, or umbilical line placement. Meconium aspiration syndrome and hypoxic–ischemic encephalopathy were also included when they were recorded in a free text "other complications" field. "Respiratory support within 72 hours," a neonatal outcome reported in the ARRIVE trial, was not available in the OB COAP data set.

The study used an interrupted time series analysis, which is a quasi-experimental design that can evaluate population-level interventions ("interruptions") at a

clearly defined time point.[14,15] Quasi-experimental studies[16] can estimate causal effects of an intervention or policy change when randomization is not feasible. Unlike before-and-after studies, an interrupted time series analysis establishes the underlying time trend in the outcome of interest and can be used to differentiate a level change, a trend change, or both.[17] The hypothetical scenario if the intervention had not taken place is referred to as the "counterfactual" and demonstrated graphically as the "expected" trend as if the intervention had not taken place. Because an interrupted time series provides a more robust evaluation of an intervention time point than a before-after comparison, statistical tests for the aggregate data pre-ARRIVE compared with post-ARRIVE were not appropriate. We examined all births occurring in 4-week time segments with a model[14] that specified a trend in the pre-ARRIVE period and assessed for both an immediate level change at the intervention time point (publication of the ARRIVE trial) and a change in the outcome's trend (ie, a change in slope) in the post-ARRIVE period. Outcomes were modeled using a modified Poisson regression approach with individual-level binomial data and CIs were calculated using robust standard errors.[18] Statistical significance was assessed by $P<.05$. Seasonality was considered (single sine and pairs of sine-cosines) but included in models only if model fit was improved (based on lowest Akaike's Information Criterion).[19] Because we used individual-level data, autocorrelation was not relevant.

We plotted four weekly rates with model predicted time trends and the counterfactual expected time trends to visualize results from the analyses. Interrupted time series analyses are subject to confounding only if discontinuities in the potential confounders also occur at the time point of the intervention. Potential confounders (population changes in race and ethnicity, insurance type, BMI, Distressed Communities Index, and medical or obstetric risk) were plotted in time series; if we noted discontinuities at the time point of the intervention, this would have justified inclusion in the models. Potential confounders were considered if previously associated with changes in obstetric outcomes over time.

Because the ARRIVE trial study population was restricted to a lower risk nulliparous group, we repeated the analysis stratified by pregnancy risk status. Pregnancies with any of the following were assigned to the higher-risk group: any diabetes, prepregnancy hypertension, any other known medical comorbidities predating pregnancy, any known fetal anomaly, previous history of stillbirth, known fetal growth restriction, oligo or polyhydramnios, cervical cerclage in this pregnancy. If none were present, a pregnancy was classified as lower risk.

Because the effect of the ARRIVE trial may not have been instantaneous at the time point of publication, sensitivity analyses were performed using later interruption time points and excluding births in a washout period. These sensitivity analyses serve to evaluate whether there was an earlier or later inflection point for the effect of the ARRIVE trial. The first sensitivity analysis excluded a single 4-week interval with the intervention time point specified as September 9, 2018, and a second analysis excluded births from February to December 2018 to allow for a much longer implementation period post-ARRIVE. Some hospitals had low use of elective induction during the study period; therefore, we conducted a third sensitivity analysis restricted to hospitals that had at least a 10-percentage point increase in their crude elective induction rates pre-ARRIVE compared with post-ARRIVE. A fourth analysis restricted to a follow-up period ending in February 2020 before the onset of the COVID-19 pandemic. Interrupted time series models were replicated for all outcomes in the sensitivity analyses.

RESULTS

A total of 28,256 singleton nulliparous births at 39 weeks of gestation or later were included in the analysis: 15,208 pre-ARRIVE and 13,048 post-ARRIVE (Appendix 1, available online at http://links.lww.com/AOG/D205). Patient characteristics in the pre-ARRIVE and post-ARRIVE periods are shown in Table 1. Time series graphs for patient characteristics revealed that any apparent differences in aggregate data were due to gradual trends over time rather than abrupt changes at the time point of the ARRIVE trial; thus, no additional covariates were included in regression models (Appendix 2, available online at http://links.lww.com/AOG/D205).

The overall rate of labor induction (elective or medically indicated) in the study population was 38.5% (34.7% pre-ARRIVE and 43.0% post-ARRIVE) (Table 2). The rate of elective induction of labor was 7.0% (3.6% pre-ARRIVE and 10.8% post-ARRIVE). Elective labor inductions represented 10.5% of all inductions in the pre-ARRIVE period, compared with 25.2% of all inductions in the post-ARRIVE period. The rate of unscheduled cesarean birth was 27.0% pre-ARRIVE and 25.9% post-ARRIVE. Hypertensive disorders of pregnancy (preeclampsia or gestational hypertension) were recorded

Table 1. Patient and Pregnancy Characteristics

Characteristic	Overall (N=28,256)	Pre-ARRIVE (January 2016–August 2018) (n=15,208)	Post-ARRIVE (September 2018–December 2020) (n=13,048)*
Age at delivery (y)	29.0 (25.0–32.0)	29.0 (24.0–32.0)	29.0 (25.0–33.0)
35 or older	3,739 (13.2)	1,845 (12.1)	1,894 (14.5)
Race and ethnicity of birthing person			
Additional races and ethnicities or mixed race	1,036 (3.7)	558 (3.7)	478 (3.7)
Asian or Pacific Islander	6,627 (23.5)	3,524 (23.2)	3,103 (23.8)
Hispanic or Latinx	3,735 (13.2)	1,929 (12.7)	1,806 (13.8)
Native American or Native Alaskan	281 (1.0)	151 (1.0)	130 (1.0)
Non-Hispanic Black	1,381 (4.9)	741 (4.9)	640 (4.9)
Non-Hispanic White	14,329 (50.7)	7,892 (51.9)	6,437 (49.3)
Missing data	867 (3.1)	413 (2.7)	454 (3.5)
Commercial insurance payer	19,190 (67.9)	9,854 (64.8)	9,336 (71.6)
Distressed Communities Index			
Prosperous	13,275 (47.5)	7,112 (47.4)	6,163 (47.7)
Comfortable	6,470 (23.2)	3,460 (23.1)	3,010 (23.3)
Mid-tier	3,174 (11.4)	1,729 (11.5)	1,445 (11.2)
At risk	3,984 (14.3)	2,178 (14.5)	1,806 (14.0)
Distressed	1,037 (3.7)	530 (3.5)	507 (3.9)
Any smoking during pregnancy	739 (2.6)	448 (2.9)	291 (2.2)
BMI (kg/m^2)			
At admission in labor	30.0 (27.0–34.0)	29.9 (26.9–33.8)	30.0 (27.0–34.1)
30 or higher	13,889 (50.1)	7,427 (49.8)	6,462 (50.5)
Prepregnancy hypertension	385 (1.5)	225 (1.6)	160 (1.3)
Prepregnancy diabetes	165 (0.6)	96 (0.6)	69 (0.5)
Gestational diabetes	2,281 (8.1)	1,205 (8.0)	1,076 (8.3)
Medical-obstetric pregnancy risk			
Lower	21,036 (74.4)	11,506 (75.7)	9,530 (73.0)
Higher	7,220 (25.6)	3,702 (24.3)	3,518 (27.0)
Hospital neonatal level of care			
I	2,506 (8.9)	1,286 (8.5)	1,220 (9.4)
II	2,951 (10.4)	1,568 (10.3)	1,383 (10.6)
III or IV	22,799 (80.7)	12,354 (81.2)	10,445 (80.1)

BMI, body mass index.
Data are median (interquartile range) or n (%).
* Interrupted time series models account for underlying time trends when comparing pre-ARRIVE with post-ARRIVE time periods; therefore, no statistical testing was performed to compare aggregate data between the two groups (see Appendix 2, available online at http://links.lww.com/AOG/D205).

in 8.3% of births pre-ARRIVE and 9.7% post-ARRIVE.

The interrupted time series analysis showed a 42% increase in the risk of elective Induction of labor in the 4-week period immediately after of publication of the ARRIVE trial (level change relative risk [RR] 1.42; 95% CI 1.18–1.71). There was no change in the slope trend (RR 1.01; 95% CI 1.00–1.01), which had been trending upward before the publication of the trial (Fig. 1, Table 3). Models for cesarean birth, hypertensive disorders of pregnancy, and NICU admission did not show any statistically significant change in level or slope after the publication of the ARRIVE trial (Fig. 1, Table 3). After the ARRIVE trial, there was no immediate change in adverse perinatal outcomes; however, there was a 3% change in the risk of adverse perinatal events over time (trend change RR 1.03; 95% CI 1.01–1.05) compared with the pre-ARRIVE period (0.98; 95% CI 0.96–0.99). Terms for seasonality did not improve model fit nor alter model estimates so final models were not adjusted for seasonality.

Stratifying by pregnancy risk status (lower or higher), there was a 44% increase in the risk of elective induction of labor in the 4-week period after the trial's publication (level change RR 1.44; 95% CI

Table 2. Pregnancy and Neonatal Outcomes

Outcome	Overall (N=28,256)	Pre-ARRIVE (January 2016–August 2018) (n=15,208)	Post-ARRIVE (September 2018–December 2020) (n=13,048)*
Induction of labor	10,881 (38.5)	5,276 (34.7)	5,605 (43.0)
Elective induction	1,964 (7.0)	552 (3.6)	1,412 (10.8)
Cesarean, unscheduled	7,475 (26.5)	4,102 (27.0)	3,373 (25.9)
HDP	2,536 (9.0)	1,269 (8.3)	1,267 (9.7)
NICU admission	1,988 (7.0)	1,125 (7.4)	863 (6.6)
Perinatal adverse composite outcome†	582 (2.1)	348 (2.3)	234 (1.8)

HDP, hypertensive disorders of pregnancy; NICU, neonatal intensive care unit.
Data are n (%).
* Interrupted time series models account for underlying time trends when comparing pre-ARRIVE with post-ARRIVE time periods; therefore, no statistical testing was performed to compare aggregate data between the two groups.
† Detailed obstetric and neonatal outcomes are shown in Appendix 12, available online at http://links.lww.com/AOG/D205.

1.18–1.77) in the lower-risk group (Table 4). In the higher-risk group, there was no immediate change in the rate of induction, but there was a 3% increase in the risk over time (trend change RR 1.03; 95% CI 1.003–1.06) (Table 4) (Appendix 3, available online at http://links.lww.com/AOG/D205). Models showed no changes in unplanned cesarean birth or hypertensive disorders of pregnancy in either the lower-risk or higher-risk groups (Table 4). Models for the perinatal composite outcome in the lower-risk group showed a trend change only after the ARRIVE trial (trend change RR 1.03; 95% CI 1.004–1.05) compared with the previously decreasing trend (Table 4) (Appendices 4 and 5, available online at http://links.lww.com/AOG/D205). Admissions to NICU in the higher-risk group only revealed a similar pattern, with a pre-ARRIVE time trend increasing in the post-ARRIVE period (trend change RR 1.02; 95% CI 1.01–1.04).

Four of the 13 hospitals in the study cohort had an increase of 10 percentage points or more in the rate of elective induction (n=15,128) (Appendix 6, available online at http://links.lww.com/AOG/D205). Restricting to these four hospitals, models showed an increase in elective induction (1.54; 95% CI 1.21–1.95) but no statistically significant changes for other outcomes (Appendices 7 and 8, available online at http://links.lww.com/AOG/D205). Sensitivity analyses with different lag periods and a shorter follow-up period (excluding the COVID-19 pandemic) resulted in no changes in statistical significance for the level or trend change terms in the overall results as compared with the primary analyses (Appendices 9–11, available online at http://links.lww.com/AOG/D205). The one exception was that with the shorter follow-up period, the change in trend of perinatal adverse findings after ARRIVE did not reach statistical significance.

DISCUSSION

Using a robust quasi-experimental study design that controlled for underlying time trends,[20] our study found a 42% increase in elective inductions (RR 1.42; 95% CI 1.17–1.73) immediately after the publication of the ARRIVE trial but no change in the overall trend of elective induction use in a contemporary obstetric cohort of nulliparous births at 39 weeks of gestation or later. This analysis did not find a decrease in either unplanned cesarean birth or hypertensive disorders of pregnancy after publication of the ARRIVE trial; reassuringly, there was no increase in cesarean birth. There was no immediate change in adverse perinatal events; however, there was a statistically significant increase in the time trend of adverse perinatal events.

There are a number of possible explanations for our findings. First, although the elective induction rate more than doubled in nulliparous patients at 39 weeks of gestation or later post-ARRIVE, elective induction remained relatively uncommon (10.8% aggregate rate across all post-ARRIVE time points) and a higher uptake of elective induction may be needed to produce a statistically significant difference in cesarean birth or pregnancy-related hypertensive disorders at a population level. The low rate of elective induction may reflect reluctance on the part of clinicians to offer elective term induction, inability of labor and delivery units to accommodate elective inductions, or low uptake from pregnant people,[21] which may not be surprising given that 71.5% of eligible pregnant people approached about the ARRIVE trial declined to participate.[1] However, in sensitivity analyses among hospitals with high uptake of elective induction or when allowing for an extended lag period for uptake of elective induction practices, we still did not detect a significant change in either maternal outcome.

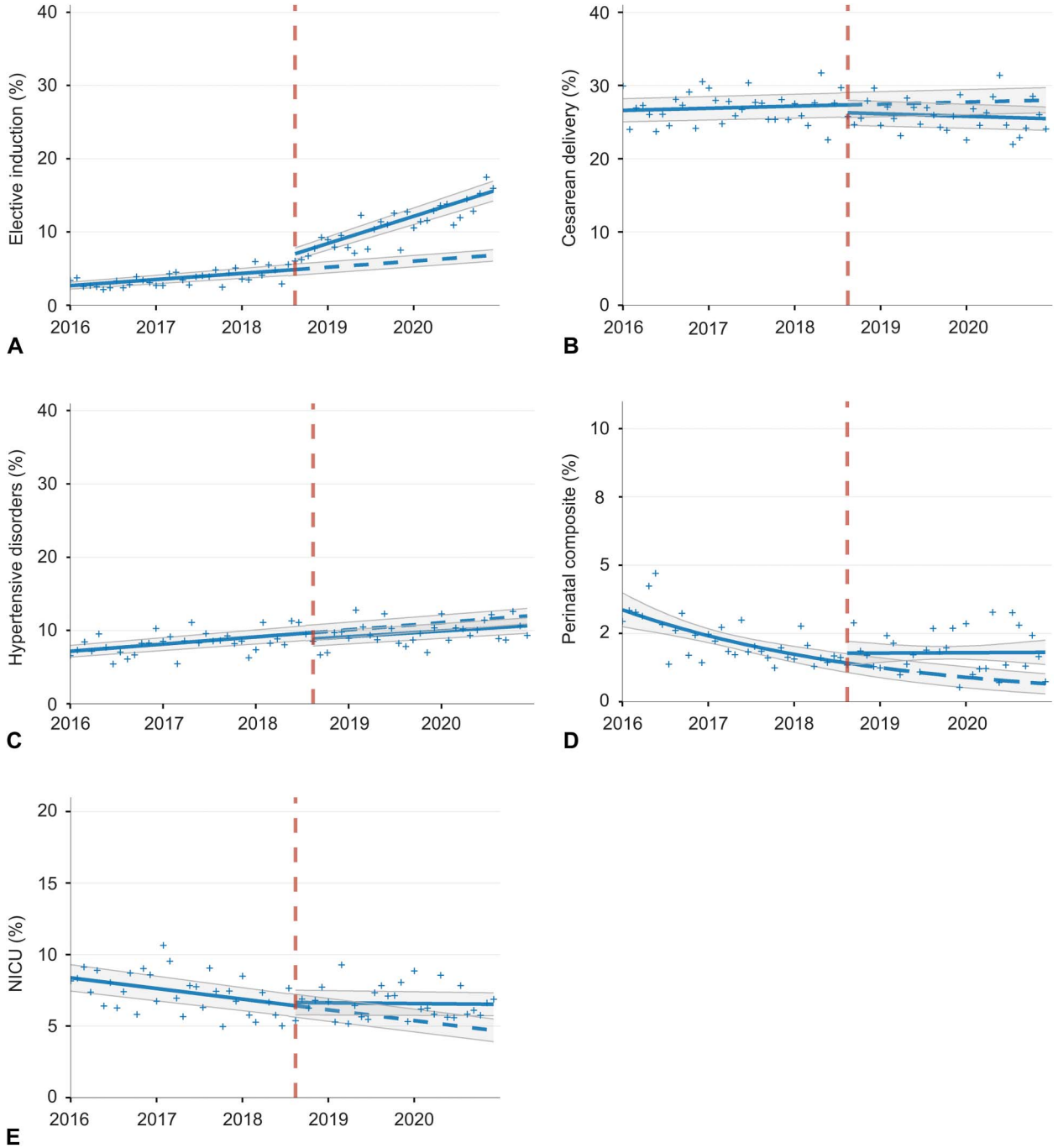

Fig. 1. Interrupted time series analysis graphs for elective induction (**A**) and secondary outcomes (**B**–**E**). Modeled trendlines shown in *blue,* counterfactual shown with *dashed blue line,* 95% CIs shown in *grey,* mean rate in four weekly intervals shown by *point,* intervention time point (ARRIVE [A Randomized Trial of Induction Versus Expectant Management] trial publication) shown by *dashed red line*. Cesarean delivery (**B**), hypertensive disorders of pregnancy (**C**), perinatal composite (**D**), and neonatal intensive care unit admission (NICU) (**E**).

Nethery. Effects of the ARRIVE Trial in Clinical Practice. Obstet Gynecol 2023.

Second, the effect of elective induction on outcomes may vary among different populations. This is supported by a randomized trial from the United Kingdom of women aged 35 years or older that found no difference in cesarean birth rate in those undergoing term elective induction compared with those managed

Table 3. Model Estimates of Level and Trend Change Using Interrupted Time Series Analyses for the Primary Outcomes

Outcome	Time Trend/4-wk Interval*	Level Change	Trend Change/4-wk Interval
Elective induction	1.02 (1.01–1.03)†	1.42 (1.18–1.71)†	1.01 (1.00–1.02)
Cesarean birth	1.00 (1.00–1.00)	0.96 (0.89–1.04)	1.00 (0.99–1.00)
HDP	1.01 (1.004–1.01)†	0.91 (0.79–1.06)	1.00 (0.99–1.01)
Perinatal adverse composite outcome	0.98 (0.96–0.99)†	1.22 (0.86–1.73)	1.03 (1.01–1.05)‡
NICU admission	0.99 (0.99–0.998)‡	1.03 (0.86–1.22)	1.01 (1.00–1.02)

HDP, hypertensive disorders of pregnancy; NICU, neonatal intensive care unit.
Data are relative risk (95% CI).
* In interrupted time series models, the time trend represents the underlying slope (change per 4-weekly interval) for the outcome variable, the level change represents an immediate effect of the intervention (publication of the ARRIVE trial), and the trend change represents the change in the slope of the outcome after publication of the ARRIVE trial.
† $P<.001$.
‡ $P<.05$.

expectantly.[22] Interestingly, although the ARRIVE trial population included only low-risk pregnancies, we observed an increase in elective induction across both risk subgroups, which suggests that elective induction is being offered on a widespread basis.

Third, in our study, cesarean birth was observed in 27.0% of the pre-ARRIVE study population, hypertensive disorders of pregnancy were observed in 8.3% of the pre-ARRIVE study population, NICU admission was observed in 7.4% of the pre-ARRIVE study population, and the composite perinatal outcome was observed in 2.3% of the pre-ARRIVE study population. In the ARRIVE trial, cesarean birth was observed in 22.0% of the expectant management group; hypertensive disorders of pregnancy were observed in 14.1% of the expectant management group, admission to NICU or intermediate care was observed in 13.0% of the expectant management group, and the composite perinatal outcome was observed in 5.4% of the expectant management group. These differences could potentially be explained by the trial's inclusion criteria or patient self-selection for participation in the trial. In contrast, our study included all pregnant people who attempted vaginal birth at 39 weeks of gestation or later during the study period. Similarly, differences in the characteristics of the pregnant population in our study compared with those in the ARRIVE trial may have contributed to the outcomes observed in our study. Our study population had a higher median maternal age (29 years vs 23 years in ARRIVE), a higher rate of commercial health insurance (64.8% vs 43.9%), and a different racial and ethnic distribution. Previous research has demonstrated that underlying characteristics of the study population (including BMI, age, socioeconomic factors, and race and ethnicity) are associated with differences in risk of both cesarean birth and hypertensive disorders of pregnancy.[23,24]

A recent study used U.S. national birth certificate data (2.5 million births) for low-risk nulliparous patients at 39 weeks of gestation or later[25] to assess the effect of ARRIVE. This analysis used a prestudy and poststudy design and compared annual data for 2015–2017 with data for 2019. This study reported time trends based on three time points pre-ARRIVE;

Table 4. Model Estimates of Level and Trend Change Using Interrupted Time Series Analyses for the Primary Outcomes in Subgroups by Pregnancy Risk Status

	Lower Risk		Higher Risk	
Outcome	Level Change	Trend Change	Level Change	Trend Change
Elective induction	1.44 (1.18–1.77)*	1.01 (0.995–1.02)	1.26 (0.76–2.10)	1.03 (1.003–1.06)†
Cesarean birth	0.97 (0.88–1.07)	1.00 (0.99–1.01)	0.97 (0.86–1.10)	1.00 (0.99–1.003)
HDP	0.94 (0.79–1.12)	1.00 (0.99–1.01)	0.86 (0.65–1.12)	1.00 (0.99–1.02)
Perinatal adverse composite outcome	1.52 (0.97–2.37)	1.03 (1.004–1.05)†	0.82 (0.47–1.43)	1.02 (0.995–1.05)
NICU admission	1.03 (0.83–1.28)	1.00 (0.99–1.01)	1.07 (0.80–1.43)	1.02 (1.01–1.04)†

HDP, hypertensive disorders of pregnancy; NICU, neonatal intensive care unit.
Data are relative risk (95% CI).
* $P<.001$.
† $P<.05$.

but this analytic approach does not statistically control for underlying time trends. Interestingly, their cesarean birth rate in 2019 (27.3%) was lower than expected based on a 3-year trend from 2015 to 2017 (27.8–27.9%). Although this is an interesting finding, prestudy and poststudy designs cannot infer causality, and assessing time trends using three time points is limited. In our population, the absolute cesarean birth rate was also decreasing using aggregate pre-ARRIVE and post-ARRIVE data; however, using a robust study design, we found no significant change in cesarean births after the publication of the ARRIVE trial.

Strengths of our study are the use of clinical rather than administrative data and a robust interrupted time series analysis. Results were consistent using multiple sensitivity analyses. Limitations include absence of a control group for the interrupted time series analysis, which was unavoidable given the widespread dissemination of the ARRIVE trial, and the lack of information about patient experience and acceptability of elective induction. Results may differ in populations with different characteristics or different rates of elective induction. Detailed data for elective induction protocols and cervical status on induction were not available; therefore, we could not consider how criteria or practice for elective induction may have altered our findings. Additionally, no simulation studies or power estimations were performed. Thus, it remains possible that there may not be adequate power to detect small differences, especially in subgroup analyses, and outcomes with nonsignificant results should be interpreted with these limitations.

The ARRIVE trial, a single randomized controlled trial, rapidly changed clinical practice in our study population. Despite an increase in elective inductions among nulliparous patients of 39 weeks of gestation or later, we did not observe changes in cesarean birth or hypertensive disorders of pregnancy. Our study raises questions about the generalizability of the randomized controlled trial results to other populations and their effect on clinical practice and outcomes.[26] This highlights the need for implementation studies to assess the effects of proposed guideline and practice changes on obstetric care and outcomes outside of the setting of randomized clinical trials.[27]

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