Impact of labor induction at 39 weeks gestation compared with expectant management on maternal and perinatal morbidity among a cohort of low-risk women

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ABSTRACT

Objective: To determine maternal and perinatal outcomes after induction of labor (IOL) at 39 weeks compared with expectant management.

Methods: This is a retrospective national cohort study from the National Center for Health Statistics birth database. The study included singleton, low-risk pregnancies with a non-anomalous fetus delivered at 39–42 weeks gestation between 2015 and 2018. Maternal outcomes available included chorioamnionitis (Triple I), blood transfusion, intensive care unit (ICU) admission, uterine rupture, cesarean delivery (CD), and cesarean hysterectomy. Fetal and infant outcomes included stillbirth, 5-min Apgar ≤3, prolonged ventilation, seizures, ICU admission, and death within 28 days. We compared women undergoing IOL at 39 weeks to those managed expectantly. Non-adjusted and adjusted relative risks (aRRs) were estimated using multivariate log-binomial regression analysis.

Results: There were 15,900,956 births available for review of which 5,017,524 met inclusion and exclusion criteria. For the maternal outcomes, the IOL group was less likely to require a CD (aRR 0.880; 95% CI [0.874–0.886]; p value < .01) or develop Triple I (aRR 0.714; 95% CI [0.698–0.730]; p value < .01) but demonstrated a small increase in the cesarean hysterectomy rate (aRR 1.231; 95% CI [1.029–1.472]; p value < .01). Among perinatal outcomes, the stillbirth rate (aRR 0.195; 95% CI [0.153–0.249]; p value < .01), 5-min Apgar ≤3 (aRR 0.684; 95% CI [0.647–0.723]; p value < .01), prolonged ventilation (aRR 0.840; 95% CI [0.800–0.883]; p value < .01), neonatal intensive care (NICU) admission (aRR 0.862; 95% CI [0.849–0.875]; p value < .01) were lower after 39 week IOL compared with expectant management. There were no differences in risk for neonatal seizures (aRR 0.848; 95% CI [0.718–1.003]; p value 0.011) or death (aRR 1.070; 95% CI [0.722–1.586]; p value 0.660).

Conclusions: IOL at 39 weeks of gestation in a low-risk cohort is associated with a lower risk of CD and maternal infection, stillbirth, and lower neonatal morbidity. There was no effect on the risk for neonatal seizures or death.

Introduction

The decision to proceed with elective induction of labor (IOL) takes into consideration both maternal and perinatal risks. Retrospective cohort studies reported an increase in cesarean deliveries (CDs) in women undergoing IOL when compared with women who had spontaneous onset of labor (SOL) at term [1,2]. Subsequent observational and retrospective cohort studies found that women who underwent IOL prior to 41 weeks of gestation had an increased frequency of operative vaginal deliveries, adverse neonatal outcomes, and neonatal intensive care (NICU) admissions [3–8]. Thus, to mitigate these risks, recommendations were to avoid IOL among low-risk women.

More recent retrospective cohort studies challenged this previous standard by more appropriately comparing the maternal, perinatal, and neonatal consequences of IOL at 39 weeks with those managed expectantly past 39 weeks [9,10]. Analysis of data from the National Center for Health Statistics (NCHS) from 2005 and a population-based study from the State of California from 2006 found decreased maternal and...
neonatal risks associated with IOL compared with expectant management [11,12]. A meta-analysis of smaller randomized controlled trials reported that IOL at term was associated with lower CD rates as well as improved neonatal outcomes [13–16]. These meta-

analyses did not always specify the presence of maternal comorbidities or parity and often did not report on stillbirth rate [13,14]. No evidence for maternal or perinatal adverse effects was found in any of these studies [14].

Meta-analyses performed after 2018 reported similar results but were heavily influenced by the ARRIVE trial supporting IOL at 39 weeks for low-risk nulliparous women [16–18]. The results from the Walker et al. and the ARRIVE trial provide definitive evidence of potential advantages of IOL at 39 weeks, although there is limited evidence of benefit outside of a clinical trial [17,19]. Despite this limitation, these trials have led to a formal statement from the Society of Maternal-Fetal Medicine in support of IOL among low-risk nulliparous women at 39 weeks 0 days of gestation or beyond, although further research is still required [20,21].

It is with these published findings in mind, that we designed the current population-based retrospective cohort study that included all clinical settings, and which analyzed a low-risk birth cohort delivered prior to the publication of the ARRIVE trial [17]. Our hypothesis is that IOL in a contemporary low-risk cohort at 39 weeks, outside of a clinical research setting is associated with a decreased rate of CD and improved perinatal outcomes compared with women managed expectantly past 39 weeks up to 42 weeks.

**Methods**

This is a retrospective national cohort analysis using data abstracted from the NCHS and Centers for Disease Control and Prevention’s Division of Vital Statistics database from 2015 to 2018, which is de-identified and publicly available [22]. These years reflect outcomes prior to the formal statements supporting IOL at 39 weeks [21].

The intervention group consisted of low-risk women undergoing IOL at 39 weeks of gestation without an identifiable medical indication, irrespective of their final mode of delivery. The expectant management group consisted of women delivered between 40 and 42 weeks of gestation. Weeks were stated as completed weeks of gestation, which is how this variable is reported in the stillbirth or live birth databases.

We excluded women who delivered at <39 weeks or >42 weeks of gestation, multifetal gestations, known fetal congenital anomalies or aneuploidy, previous CD, and infant deaths at >28 days from analysis because of their association with perinatal complications often unrelated to the birth process [23,24]. Deliveries at >42 weeks of gestation were excluded because it is not common practice to continue expectant management given the inherent neonatal morbidities associated with post-date delivery [25,26]. We also excluded women with any form of diabetes or hypertension, as these conditions are considered high-risk with delivery usually recommended by 39 weeks [23–26]. Gestational hypertensive disorders care usually delivered by 37 weeks, but can present after 39 weeks. These women were excluded if they delivered during the 39th week, but not if they delivered afterwards [17,27]. The maternal outcomes of interest available in the databases included: CD, chorioamnionitis (Triple I), blood transfusion, intensive care unit (ICU) admission, uterine rupture, and cesarean hysterectomy.

The fetal death database was merged with the live birth database. This allowed us to calculate the stillbirth rate, which is the proportion of stillbirths to all births, including neonatal deaths in the denominator. Several maternal outcomes are not reported in the fetal death certificates such as maternal puerperal infection, blood transfusion, and cesarean hysterectomy. Rates for these outcomes reflect their incidence among live births. No imputations were performed and their absence is expected to produce an underestimate in the incidence of maternal outcomes. We included all stillbirths from 40 to 42 weeks, but at 39 weeks only those that occurred intrapartum [22]. We were able to identify this group by verifying whether the diagnosis was made pre-labor, intrapartum, or at an unknown time. This variable is reported for all jurisdictions, except: District of Columbia, Hawaii, Kansas, Missouri, Montana, Nevada, and New York.

All neonatal outcomes are derived from the live birth data. The neonatal outcomes of interest included: stillbirth, 5-min Apgar score ≤3, assisted ventilation for >6 h, NICU admission, and seizures. The neonatal death rates was the proportion of all deaths <28 days to all live births.

Maternal descriptive information was compared between the two management groups using the appropriate univariate statistical test. The unadjusted risk ratio was calculated comparing the risk for each
outcome among women undergoing IOL at 39 weeks to those managed expectantly.

Calculation of the risk ratio or relative risk (RR) is possible in cohort studies. Although the odds ratio provides a good estimate of the RR, with greater odds ratios the risk can be overestimated [28]. We calculated the RR and adjusted RR (aRR) to compare the effect of expectant management compared with IOL at 39 weeks. In a secondary analysis, we calculated RR and the aRR only for nulliparous women (women who had their first delivery). To evaluate the effect at each subsequent week, we compared the risk of fetal and neonatal death, neonatal seizures, and CD between women having IOL at 39 weeks to the risk of these outcomes for each subsequent week up to 42 weeks. This was also performed among the entire population and for nulliparas only.

To model the selected fetal, neonatal, and maternal outcomes, we applied multivariable logistic regression using a binomial distribution. For the aRR calculations, predictors were selected from the variables available in the fetal death and live birth certificates. For variable selection, we applied backward stepwise elimination. Multivariable log-binomial regression analysis was then performed to calculate aRR controlling for potential confounding variables based on historic significance and univariate analysis. We selected those variables included in both the certificate of live birth and stillbirth and included maternal age, race, parity, education, prenatal care, cigarette use, and body mass index (BMI). A backward stepwise elimination method was performed to arrive at the final regression model, which included maternal education, ethnicity, parity, BMI, and cigarette use.

We set the p value at .01 given the power from this large population-based study. Consequently, the confidence intervals were set at 99%. All calculations were performed using SAS version 9.4 (Cary, NC). We adhered to “Strengthening the Reporting of Observational Studies” (STROBE) guidelines for reporting cohort studies [29].

Results

There were 5,017,524 births included for review after exclusions. There were 1,178,430 women in the 39-week IOL group, with 520 neonatal deaths, and 120 intrapartum stillbirths. Among those managed expectantly, there were 3,839,094 births, among which there were 1659 subsequent neonatal deaths and 2250 stillbirths (Figure 1).

Maternal descriptive characteristics were similar between the two groups. In both groups, the mean maternal age was 28.0 years; the most common ethnicity among women was White followed by Black; the majority had a high school or greater level of education and the mean BMI was 26 kg/m² in both groups with approximately 6% of women reported as

![Flow diagram of the cohort selection from births and fetal deaths reported from 2015 to 2018.](Figure 1)
morbidly obese. Median parity was one in the IOL and zero in the expectantly managed group. Approximately one-third of women in the IOL and over half of the women in the expectantly managed group had a prior vaginal delivery. These findings were similar when only nulliparous women were included (Supplemental Tables 1 and 2).

Approximately 35% of women managed expectantly underwent IOL while 65% had SOL. Three percent of women managed expectantly developed gestational hypertension after 39 weeks. Women undergoing IOL at 39 weeks had a decreased aRR of CD (12%) and Triple I (28%). There was no difference in the aRR for transfusion, ICU admission, or uterine rupture. We did observe a significant increase in the aRR for cesarean hysterectomy (23%) although the absolute risk increase was small (1/10,000) (Table 1). The CD rates and Triple I rates were higher when we performed the analysis among nulliparous women compared with the entire population. The aRR for maternal outcomes were similar although the increased aRR for cesarean hysterectomy was no longer evident (Supplemental Table 3).

Although the absolute risk difference was small (5/10,000), intrapartum stillbirth rates were significantly lower (80%) among women delivered by IOL at 39 weeks compared with those managed expectantly (Table 1). Neonates in the IOL group were 30% less likely to have 5 min Apgar ≤3, over 15% less likely to require prolonged ventilation or necessitate NICU admission when compared with the expectant management group. There was no difference in the frequency or relative risk of neonatal deaths between the two groups (Table 1). The absolute risk for perinatal outcomes was higher, but the aRR between the two groups were similar to those reported for the entire cohort when we only included nulliparous women (Supplemental Table 3).

The risk at each week of gestation compared with IOL at 39 weeks demonstrates a gradual increase in the risk for CD (16–24%) and stillbirth (6–20/10,000) between 40 and 42 weeks. The risk for neonatal seizures was greater after 40 weeks (5–10/10,000) and the risk for neonatal death prior to 28 days did not increase significantly until 42 weeks (15/10,000). There was no difference in the risk for fetal or neonatal death whether we analyzed the entire cohort or nulliparous women (Supplemental Tables 4 and 5).

### Discussion

This is a retrospective national cohort study analyzed births over 4 years prior to the publication of the ARRIVE trial results [17]. The population included was not limited to low-risk nulliparous women being delivered at large academic medical centers under a strict trial protocol, but considered all low-risk women regardless of parity, being delivered at centers providing different levels of care under different standards and with presumed differences regarding the decision to allow IOL at term among low-risk women.

Our data demonstrated an approximately 12% reduction in risk for CD, and 30% reduction in the risk for Triple I among presumed low-risk women who underwent IOL at 39 weeks of gestation compared with those managed expectantly. This small to moderate protective effect was also seen among nulliparous women. The decreased rate of CD is consistent with a decreased risk for puerperal infection [30]. Early work reported in the literature not only raised concerns

### Table 1. Maternal and Neonatal outcomes for induction of labor at 39 weeks compared with expectant management.

| Maternal outcomes                        | Induction of labor at 39 weeks N (%) | Expectant management (reference group) N (%) | Relative risk | Unadjusted | Adjusted a | p Value |
|------------------------------------------|-------------------------------------|---------------------------------------------|--------------|------------|------------|---------|
| Cesarean delivery                        | 145,974 (12.39)                     | 471,469 (16.35)                             | 0.693        | 0.880      | 0.874—0.886 | <.001   |
| Blood transfusion                        | 3,155 (0.27)                        | 10,780 (0.28)                               | 0.954        | 1.027      | 0.974—1.082 | .197    |
| Triple I                                 | 15,072 (1.28)                       | 93,633 (2.44)                               | 0.524        | 0.714      | 0.698—0.730 | <.001   |
| ICU admission                            | 837 (0.07)                          | 2,866 (0.07)                                | 0.951        | 1.032      | 0.931—1.143 | .436    |
| Uterine rupture                          | 164 (0.01)                          | 441 (0.01)                                  | 1.212        | 1.124      | 0.885—1.426 | .208    |
| C-hysterectomy                           | 299 (0.03)                          | 745 (0.02)                                  | 1.308        | 1.231      | 1.029—1.472 | .003    |

*Adjusted for maternal education less than high school, minority race, nulliparous status, body mass index less than 18 or greater than 25 kg/m², or smoking in the second and third trimesters.

ICU: Intensive care unit; Triple I: Intrauterine infection or inflammation; C-hysterectomy: cesarean hysterectomy; NICU: neonatal intensive care unit.
with IOL at term and increased risk for CD, but also reported complications directly related to the process of IOL [31,32]. Our results are consistent with the more recent ARRIVE trial that provided evidence to support IOL at 39 weeks among low-risk nulliparous women [17].

A novel and significant finding of our study is the 23% increase in the aRR for cesarean hysterectomy in the IOL group but not evident when nulliparous women were analyzed separately. This was likely able to be identified due to the large study population and may be related to parity. The increased rate of cesarean hysterectomy cannot be attributed to differences in the rates of uterine rupture or obstetrical hemorrhage, the two most common indications, as neither of these were different between groups. Furthermore, we excluded women with a prior CD, which can be associated with placental abnormalities in subsequent pregnancies. Induction agents, such as prostaglandins and oxytocin, have been associated with risk for uterine atony and rupture; however, we were unable to determine what agents were used for IOL [31–35]. Due to the nature of this study, the indication for cesarean hysterectomy could not be determined, however, the overall rate was lower (0.02%) than recent rates reported among nulliparous women undergoing IOL (0.11%) and history of CD [34]. Factors associated with risk for cesarean hysterectomy include high parity, maternal age, previous CD, placental pathology, uterine atony, and uterine rupture [35]. Although cause for uterine rupture is multifactorial, the factors that led to the increased risk for hysterectomy will require future analysis, especially for factors that we were unable to analyze, including methods used for cervical ripening and IOL, duration of labor, and indications for CD.

Among neonates, we have demonstrated that IOL at 39 weeks of gestation resulted in a significantly lower frequency of 5-min Apgar ≤3, requirement for prolonged ventilation, or NICU admission compared with the expectant management group. Although not significant, we observed a trend toward decreased risk of seizures among women who were induced at 39 weeks. Additionally, expectant management was not associated with an increase in the risk for neonatal deaths up to 28 days after delivery. When we compared the effect by week, an increased risk for neonatal death was not observed until 42 weeks. These findings were maintained even after limiting analysis to nulliparous women.

A substantial finding was the decrease in the aRR for stillbirth associated with IOL at 39 weeks. This was not evident in the ARRIVE trial due to the small absolute risk [17,21]. The 80% decrease we observed is most likely related to factors such as estimated fetal weight prior to birth, stillborn weight, congenital infection, or structural abnormalities that are unreliable or not available for analysis in the fetal death certificate [36]. Future research that includes additional information will allow us to analyze some of these factors.

The strength of this study is the heterogeneous nature and large sample size of pregnancies analyzed in both the IOL at 39 weeks of gestation group and the expectant management group. We were able to analyze data proceeding from sundry clinical settings, which broadens the applicability of the findings compared to the populations reported for prior trials [17,19,37,38]. It was important to include stillbirths that occurred during IOL of labor at 39 weeks in order to compare with the risk for stillbirth with expectant management. We were able to do this by using the variable that is included in the certificate of stillbirth describing the timing at which the death occurred although not reported consistently for all jurisdictions. An additional strength of this study is the quality of the data for the variables we have included which have been shown to provide reliable responses [36].

The large number of delivery information included in this cohort also allowed us to analyze outcomes week to week after 39 weeks. This is significant as the mean gestational age in the expectantly managed arm of the ARRIVE trial was 40 weeks and does not allow a detailed assessment of how each additional week can affect risk among women being managed expectantly [17]. The primary neonatal outcome in the ARRIVE trial was a composite of perinatal death or severe morbidity which was lower but not significant [17]. This cohort study not only allowed us to analyze these outcomes but we were able to separate the various components of perinatal morbidity and mortality, which were significantly improved with IOL for most outcomes except for neonatal mortality at less than 28 d.

An important limitation regarding this study cohort is that we have identified a low-risk population that underwent IOL. The data available in the birth certificates do not allow us to specify why the IOL was performed. We feel that although this is significant, it does not detract from the fact that IOL at 39 weeks among low-risk women may be safer than expectant management past 39 weeks. Although we were able to include clinically relevant confounders available in the birth certificates that could have caused bias, we cannot be certain that other variables or practice
patterns may also affect the risk. Another limitation is the inability to determine methods utilized for IOL, Bishop score, fetal monitoring, severity of bleeding requiring transfusion, severity of uterine rupture versus dehiscence, and/or indications for intervention such as CD. However, it is assumed that there is enough similarity in practice as recommended by ACOG that this would not directly affect the results. The data for the variables analyzed met NCHS standards of reliability and precision with a high degree of completeness and accuracy [39].

Our findings are consistent with the most recently published studies and meta-analysis regarding IOL at 39 weeks among nulliparous women or those of advanced maternal age [11,14,17,18,21,38,40,41].

**Conclusions**

In conclusion, our study demonstrates that in low-risk women IOL at 39 weeks gestation benefits maternal and perinatal outcomes with lower maternal and neonatal morbidity when compared with expectant management through 42 weeks. We have also shown in secondary analysis that the risk for both maternal and fetal complications increases with each additional week of gestation. Based on our study and supported by a growing body of literature, clinical protocols aimed at the avoidance of IOL at 39 weeks gestation in low-risk women seem unwarranted. Discussions should address the significant improvement in maternal and perinatal outcomes. The finding of increased rate of cesarean hysterectomy should be further investigated, particularly those factors that may potentially contribute to this complication among multiparous women undergoing IOL.

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