Abstract

Introduction: The ARRIVE study found that induction of labor decreased the rates for cesarean section and was not associated with adverse neonatal outcomes. However, it is unclear if their study results are generalizable. Here, we aimed to analyze the perinatal and maternal outcomes of women undergoing elective induction of labor versus expectant management at a single center tertiary hospital.

Methods: We retrospectively investigated outcomes in 188 low risk nulliparous women who either underwent labor induction (n=66) or had spontaneous labor (n=122).

Results: There were no statistically significant outcomes between the two groups as it relates to the mother and neonate. The rate of cesarean delivery was 20% in the induction group versus 16% in the active labor group (p = 0.713). The woman who underwent induction had a relatively higher risk for morbidity including third degree laceration (p = 0.329), hypertensive disorders of pregnancy (p = 0.246), chorioamnionitis (p = 0.828), hemorrhage (p = 0.586) and infection (p = 0.586). Women in the induction group also spent more time in the labor (p < 0.001). Neonates in the induction group did have a relatively higher risk for meconium aspiration syndrome (p = 0.246), requiring respiratory support within 72 hours (p = 0.398), hyperbilirubinemia requiring phototherapy (p = 1.00), and shoulder dystocia (p = 0.732).

Conclusions: We provide evidence of higher rate of maternal and neonatal morbidity in women undergoing inductions, although not statistically significant. Thus, providers should have an informed discussion when deciding timing of delivery.

Introduction

The timing of delivery is an important discussion that obstetricians have with their patients. The risk of adverse outcomes have been shown to be significant in neonates delivered in the early-term period and include higher rates of respiratory distress syndrome, transient tachypnea, pneumonia, hypothermia and difficulties with feeding [1-4]. Additionally, women who undergo induction have been found to have unfavorable cervix, which carries a higher risk for uterine tachystole, fetal heart rate decelerations and cesarean delivery [5,6].

The generalized consensus that adverse neonatal and maternal outcomes are associated in women undergoing inductions of labor are primarily based on observational studies [7-10]. In fact, these assumptions have been challenged by varies studies, the largest of which was the Labor Induction versus Expectant Management in Low-Risk Nulliparous Women (ARRIVE) study by Grobman et al published in 2018. In this prospective study, 3,062 women were assigned to undergo elective induction of labor between 39 weeks 0 days to 39 weeks 4 days. Their maternal and neonatal outcomes were then compared to 3,044 women who underwent expectant management. They found that women in the induction group had significantly fewer rates of cesarean deliveries. Additionally, the neonates had no difference in adverse perinatal outcome [11].
The findings of the ARRIVE study were so compelling that in August 2018, practitioners at our hospital began scheduling patient’s for elective induction of labor in women at 39 weeks and 0 days or greater. To determine if our outcomes following institution of this practice were similar to the ARRIVE study, we elected to perform a comprehensive chart review on both maternal and fetal outcomes of low risk nulliparous women undergoing elective inductions as compared to women presenting in spontaneous labor. There were 3,337 deliveries at our single center tertiary hospital between August 2018 to August 2019. Of these, 188 patients met inclusion criteria. That is, low risk nulliparous women without maternal or fetal medical conditions that would preclude them from vaginal birth. The present pilot study investigated the neonatal and maternal outcomes of induction of labor versus spontaneous labor in low-risk nulliparous women taking place at Regional One Health.

Materials and Methods

We retrospectively investigated medical records of women who were seen and delivered at Regional One Health, a single center tertiary hospital in Memphis, Tennessee. The study was approved by the University of Tennessee Health Science Center and the Regional One Health institutional review board.

A total of 3,337 deliveries occurred at our institution between August 2018 and August 2019. We identified 188 patients who met the following inclusion criteria: low-risk nulliparous women who underwent induction of labor between 39 weeks 0 days of gestation to 40 weeks 6 days and low-risk nulliparous women who presented in labor between 39 weeks 0 days to 41 weeks gestation. Low risk is defined as no maternal or fetal medical conditions (e.g., hypertensive disorders of pregnancy or suspected fetal-growth restriction). The list that was generated and then verified by the Regional One Health Office of Medical Research and distributed by Health Information Management.

Next, a comprehensive chart review was performed and using variables similar to the ARRIVE study, data was recorded. Neonatal outcomes including perinatal death, the need for respiratory support within 72 hours after birth, Apgar score of 3 or less at 5 minutes, hypoxic-ischemic encephalopathy, seizure, infection (confirmed sepsis or pneumonia), meconium aspiration syndrome, birth trauma (bone fracture, neurologic injury, or retinal hemorrhage), intracranial or subgaleal hemorrhage, or hypotension requiring vasopressor support were analyzed. Additionally, birth weight, duration of respiratory support, cephalohematoma, and shoulder dystocia, transfusion of blood products, hyperbilirubinemia requiring phototherapy or exchange transfusion, hypoglycemia requiring intravenous therapy, admission to the neonatal intermediate or intensive care unit, and length of hospitalization were also analyzed.

Maternal outcomes included cesarean delivery, if the mother then developed hypertensive disorders of pregnancy (gestational hypertension or preeclampsia), chorioamnionitis, indication for cesarean delivery, indication for operative vaginal delivery, uterine incisional extensions during cesarean delivery, third-degree or fourth-degree perineal laceration, postpartum hemorrhage, postpartum infection, venous thromboembolism, number of hours in the labor and delivery unit, length of postpartum hospital stay, admission to the intensive care unit, and maternal death were recorded. Additionally, Maternal race or ethnic group as reported by the participant (Caucasian, African American, Asian, Hispanic, other, unknown, or more than one race), age of 35 years or older versus younger than 35 years and body-mass index (the weight in kilograms divided by the square of the height in meters) of 30 or more versus less than 30 were also recorded and analyzed.

The statistical analyses were conducted by the Biostatistics, Epidemiology, and Research Design (BERD) Clinic unit of The University of Tennessee Health Science Center. Categorical variables were summarized as counts and percentage and compared between the induction and active labor groups using chi-square test or Fisher exact test. Normally distributed variables were summarized as mean (Standard Deviation (SD)) and non-normally distributed variables were summarized as median (Interquartile Range (IQR)) and compared between treatment groups using Student’s t test or Wilcoxon rank sum test, respectively. The relative risk of an event was calculated by dividing the risk of event in those who underwent induction to the risk in those who underwent active (natural) labor. The primary perinatal composite outcome score was derived by first coding the need for respiratory support within 72 hours of birth, Apgar score ≤3 at 5 minutes after birth, hypoxic-ischemic encephalopathy, infection, meconium aspiration syndrome, and birth trauma as 0 (No) or 1 (Yes) and adding these values. Forest plot was used to present the Relative Risk (RR) and 95% confidence intervals (95%CIs) of primary perinatal composite outcome and cesarean delivery stratified by age (<35), BMI (<30 or ≥30 kg/m²), and race or ethnicity. All the statistical analyses were conducted in R statistical software (R version 3.5.3 (2019-03-11)). P-values ≤0.05 was considered statistically significant.

Results

One hundred and eighty-eight nulliparous low risk women met our inclusion criteria (Table 1). Of these, sixty-six underwent induction and remainder had active labor (n=122). The median age for women who underwent induction and active labor was 22 and 21, respectively (p=.884). Two women in the active labor group were > 35 years of age. Overall, there was no statistical difference in the race (p=.115) between women who underwent induction and those who had active labor. In the induction group, African American group made up 71% of the group, followed by 23% Caucasian, 2% Asian, 2% Hispanic, and 3% unknown. The average
body-mass index for both groups was 30. In both the induction group and active labor group, 58% and 57% respectively had had Body-Mass Index (BMI) greater than 30. The average gestational age in both groups was 40 weeks (p=.827).

With regards to the maternal outcomes, there were no maternal deaths, deep vein thrombosis or fourth degree perineal lacerations in either groups (Table 2). Cesarean delivery occurred in 20% (n=13) of the induction of labor group as compared to 16% in the active labor group. The relative risk was 1.20 and not statistically significant, p=.713. Most women required cesarean section in both groups for non-reassuring fetal heart tones; 58% (n=7) in induction group and 80% (n=16) in the active labor group. More women in the induction group required cesarean delivery for labor dystocia, 42% (n=5), as compared to the active labor group 20% (n=4). No subjects in the induction group developed uterine incisional extension during their cesarean section but 10% (n=2) in the active labor group did. Operative vaginal delivery in both groups was indicated in most cases for non-reassuring fetal heat tones; 71% (n=5) in the induction group and 78% (n=7) in the active labor group. Maternal exhaustion requiring operative delivery was more likely to occur in the induction group, 29% (n=2) as compared to the active labor group 11% (n=1) but this was not statistically significant (p=.487).

Intrapartum complications such as hypertensive disorders of pregnancy (i.e. gestational hypertension or preeclampsia) was higher in the induction group as compared to the active labor group; 5% (n=3) versus 1% (n=1), respectively. The relative risk was 5.54, not statistically significant (p=.29). Additionally, chorioamnionitis was higher in the induction group as compared to the active labor group; 12% (n=7) versus 10% (n=10), respectively. Relative risk 1.25, not statistically significant (p=.828). During delivery, third degree lacerations occurred more often in the induction of labor group, 10% (n=5) as compared to the active labor group 4% (n=4). The relative risk was 1.85, not statistically significant (p=.501). Also, postpartum hemorrhage more commonly occurred in the induction group 8% (n=5) as compared to the active labor group 4% (n=5). The relative risk was 1.85 and not statistically significant (p=.501). Postpartum infections (such as endometritis) more commonly occurred in the induction group, 3% (n=2) as compared to the active labor group 1% (n=1). This had a relative risk of 3.70 but not statistically significant, p=.586. Lastly, women in the induction group spent more time in labor; 36% delivered by 12 hours, 41% delivered by 24 hours, 11% delivered by 36 hours, 2% delivered by 48 hours and 5% delivered by 69 hours. In contrast, women who presented in labor primarily delivered in the first 12 hours (75%). The rest delivered by 24 hours (20%) and 36 hours (5%). This was statistically significant (p<0.001) (Table 2). On average a majority of patients from both groups were discharged by postpartum day two (p=.695).

With regards to the perinatal outcomes, there were no infants in either the induction of labor or the active labor group that had perinatal death, Apgar score less or equal to 3 at five minutes, hypoxic-ischemic encephalopathy, intracranial or subgaleal hemorrhage, hypotension requiring vasopressor support or transfusion of blood products (Table 3). Respiratory support within 72 hours of birth was required in 15% (n=10) of neonates in the induction group as compared to 10% (n=12) in the active labor group. The relative risk between the groups was 1.54 and this difference was not statistically significant, p=.398. Of these, 12% (n=8) of the neonates in the induction group required respiratory support less than 24 hours and 2% required respiratory support between 24 and 48 hours. Whereas 7% (n=9) of the neonates in the active labor group required respiratory support for less than 24 hours and 1% (n=1) required respiratory support between 24 to 48 hours. Meconium aspiration syndrome was observed in 5% (n=3) of the neonates in the induction group as compared to the 1% (n=1) of the neonates in the active labor group. The relative risk between the group was 5.55 and this difference was not statistically significant, p=.246. One of the neonates from the active labor group developed pneumonia. No neonates from the induction group developed pneumonia.

At least 2% of the neonates in both the induction and active labor groups (n=1 and 2, respectively) were treated for a blood infection secondary to maternal chorioamnionitis. Birth trauma (bone fracture) occurred in 3% (n=2) of the neonates in the induction group similar to the active labor group, 3% (n=4). Of the neonates from the induction group, 6% (n=4) required phototherapy for hyperbilirubinemia whereas only 3% (n=4) required it in the active labor group. The relative risk between the groups was 1.85 and this difference was not statistically significant, p=.601. Additionally, 2% (n=1) of the neonates from the induction group and 3% (n=3) of the active labor group had hypoglycemia requiring intravenous therapy. The relative risk was not significant between these findings; 0.62 (p=1.0). The neonates in the induction group tended to weigh more with mean weight of 3310 grams whereas the neonates in the active labor group mean weight was 3172 grams. This difference was not statistically significant (p=.732). At least 5% (n=3) of the neonates from the induction group had shoulder dystocia versus 3% (n=3) in the active labor group. The relative risk was 1.85 but not statistically significant (p=.732). Approximately 30% (n=20) of the neonates from the active labor group were admitted to the Neonatal Intermediate Care Unit (NICU) while only 22% (n=27) of the neonates from the active labor group required admission to the NICU. The relative risk was 1.37 and not statistically significant (p=.29). On average, the neonates stayed in the hospital for 2 days in both groups. Overall, when comparing neonates delivered in women who underwent active induction compared to those who had spontaneous induction, no difference in outcome was observed.
Table 1: Maternal demographic information. No difference was observed between the induction and active labor group as it related to age, race, BMI, and gestations age. Race was reported by the participants. Body-mass index (BMI) is the weight in kilograms divided by the square of the height in meters.
Table 2: Maternal outcomes. No statistically significant difference was noted in overall outcomes. Cesarean delivery was relatively higher in the induction group as compared to the spontaneous labor group (20% vs. 16%; relative risk 1.20; 95% CI, 0.64 to 2.26). Women in the induction of labor group had higher relative risk for 3rd degree laceration (relative risk 2.33; 95% CI, 0.65 to 8.27), hypertensive disorders of pregnancy (relative risk 5.54; 95% CI, 0.59 to 52.18), chorioamnionitis (relative risk 1.25; 95% CI, 0.50 to 3.11), hemorrhage (relative risk 1.85; 95% CI, 0.45 to 6.15) and post-partum infection (relative risk 1.85; 95% CI, 0.55 to 6.15). Women in the induction group spent more time in the labor and delivery unit (relative risk 3.70; 95% CI, 0.56 to 40.01; P<0.001).

| Hours in labor (%) | Induction | Active Labor | Relative Risk (95%CI) | P-value |
|--------------------|-----------|--------------|-----------------------|---------|
| 12 hours           | 24 (36%)  | 92 (75%)     | <0.001                |         |
| 24 hours           | 27 (41%)  | 24 (20%)     |                       |         |
| 36 hours           | 11 (17%)  | 6 (5%)       |                       |         |
| 48 hours           | 1 (2%)    | 0            |                       |         |
| 60 hours or more   | 3 (5%)    | 0            |                       |         |

| Length of postpartum hospital stay (%) | Induction | Active Labor | Relative Risk (95%CI) | P-value |
|----------------------------------------|-----------|--------------|-----------------------|---------|
| One day                                | 21 (32%)  | 32 (26%)     |                       | 0.695   |
| Two days                               | 39 (60%)  | 79 (65%)     |                       |         |
| Three days                             | 6 (9%)    | 10 (8%)      |                       |         |

| Induction                      | Active Labor | Relative Risk (95%CI) | P-value |
|-------------------------------|--------------|-----------------------|---------|
| Perinatal death (%)           | 0            | 0                     | NA      |
| Respiratory Support Within 72 Hours of Birth (%) | 10 (15%) | 12 (10%) | 1.54(0.70, 3.37) | 0.398 |
| Duration of respiratory support (%) | <24 hours | 8 (12%) | 9 (7%) | 0.496 |
|                               | 24 to 48 hours | 1 (2%) | 1 (1%) |         |
| Apgar score less or equal to 3 at 5 min (%) | 0 | 0 | NA |
| Hypoxic–ischemic encephalopathy (%) | 0 | 0 | NA |
| Infection (%)                  | Pneumonia    | 0                     | 1 (1%)   | 0.76 |
|                               | Unknown      | 1 (2%)                | 2 (2%)   | |
| Meconium aspiration syndrome (%) | 3 (5%)      | 1 (1%)                | 5.55(0.59, 52.26) | 0.246 |
| Birth trauma (bone fracture, neurologic injury, or retinal hemorrhage) (%) | 2 (3%) | 4 (3%) | 0.92(0.17, 4.91) | 1 |
| Intracranial or Subgaleal hemorrhage (%) | 0 | 0 | NA |
| Hypotension requiring vasopressor support (%) | 0 | 0 | NA |
| Birth weight (mean (SD))       | 3310.53 (510.04) | 3172.11 (380.53) | 0.037 |
| Shoulder dystocia (%)          | 3 (5%)      | 3 (3%)                | 1.85 (0.38, 8.90) | 0.732 |
| Transfusion of blood products (%) | 0           | 0                     | NA       | |
| Hyperbilirubinemia requiring phototherapy (%) | 4 (6%) | 4 (3%) | 1.85(0.48, 7.15) | 0.601 |
| Hypoglycemia requiring intravenous therapy (%) | 1 (2%) | 3 (3%) | 0.62(0.07, 5.81) | 1 |
Perinatal outcomes. No significant findings between the two groups were noted. Neonates in the induction group did have a relatively higher risk of requiring respiratory support within 72 hours of birth as compared to the spontaneous labor group (relative risk, 1.54; 95% CI, 0.70 to 3.37). Neonates in the induction group had a higher relative risk of meconium aspiration syndrome (relative risk, 5.55; 95% CI, 0.59 to 52.26). Additionally, hyperbilirubinemia requiring phototherapy was relatively higher in the neonates from the induction group (relative risk 1.85; 95% CI, 0.38 to 8.90). Although the gestational ages of both groups were similar (39 weeks), infants born in the induction group tended to weigh more (3310.53 grams in the induction group vs. 3172.11 grams in spontaneous labor group). Shoulder dystocia were also more common in the induction of labor group (1.85; 95% CI, 0.38 to 9.90).

Table 3: Perinatal outcomes. No significant findings between the two groups were noted. Neonates in the induction group did have a relatively higher risk of requiring respiratory support within 72 hours of birth as compared to the spontaneous labor group (relative risk, 1.54; 95% CI, 0.70 to 3.37). Neonates in the induction group had a higher relative risk of meconium aspiration syndrome (relative risk, 5.55; 95% CI, 0.59 to 52.26). Additionally, hyperbilirubinemia requiring phototherapy was relatively higher in the neonates from the induction group (relative risk 1.85; 95% CI, 0.38 to 8.90). Although the gestational ages of both groups were similar (39 weeks), infants born in the induction group tended to weigh more (3310.53 grams in the induction group vs. 3172.11 grams in spontaneous labor group). Shoulder dystocia were also more common in the induction of labor group (1.85; 95% CI, 0.38 to 9.90).

Discussion

The consensus that induction of labor results in increased adverse outcomes in both the mother and fetus is primarily based on observational studies [8-10]. These studies have recently been challenged by the findings in the prospective ARRIVE study which found fewer rates of cesarean deliveries in those undergoing induction of labor as compared to those who were expectantly managed. Additionally, there were no differences in adverse neonatal outcomes5. It is the premise of this controversy which prompted the basis of this research investigation. We aimed to investigate the maternal and neonatal outcomes of nulliparous low-risk women at a single center tertiary hospital.

With regards to the maternal outcome, there was no maternal deaths, admissions to the ICU or maternal complications such as 4th degree tears or development of deep vein thrombosis in either group. There was a trend towards increased rate of cesarean delivery in the induction group compared to the spontaneous labor group, 20 % vs. 16 %, but not statistically significant. The most common indication for both cesarean delivery and operative vaginal delivery in both groups was non-reassuring fetal heart tones. Still, the induction of labor group tended to have higher rate of cesarean section for “labor dystocia” and operative vaginal delivery due to “maternal exhaustion.” Collectively, no statistical difference in maternal outcomes was shown, suggesting induction of labor can be done safely.

Furthermore, the women in the induction group also had a relatively higher risk of developing hypertension disorders of pregnancy, chorioamnionitis, third degree laceration, hemorrhage and postpartum infections (Table 2), findings consistent with the previous observational studies [8-10]. Finally, similar to the ARRIVE study, women in the induction group spent more time in the labor and delivery unit (P<0.001) (Table 3). Our findings and what are reported in the literature is not alarming as elective inductions generally result in a longer labor course, necessitating multiple cervical exams, contributing to the maternal complications listed above. The extended labor period also requires highly skilled nurses and staff which may result in 25% increase in overall costs [12]. Thus, induction of labor may result in more adverse events in women compared to those who undergo spontaneous labor.

When evaluating the outcomes in neonates, our study did not demonstrate difference between neonates born to mothers who underwent induction compared to women who presented in active labor. More specifically we did not observe any perinatal deaths, Apgar scores less or equal to 3 at five minutes), hypoxic-ischemic encephalopathy, intra-cranial or subgaleal hemorrhage, hypotension requiring vasopressor support or transfusion of blood products. We did find that neonates in the induction group were more likely to develop meconium aspiration syndrome and require respiratory support within 72 hours. They were also more likely to require phototherapy for hyperbilirubinemia (Table 2). These findings are in contrast with those in the ARRIVE study but not necessarily surprising. Early term deliveries are associated with these complications [3,13]. Still, induction of labor should not be discouraged for patients due to the lack of statistically significant adverse neonatal outcomes.

Interestingly, in comparison to the ARRIVE study, most of our patient population identified themselves with the African American (Table 1). Researchers at the Centers for Disease Control and Prevention (CDC) have shown that African American women are up to three times as likely to suffer pregnancy related complications as compared to Caucasian women [14]. Factors such as higher prevalence of comorbidities, lower socioeconomic status, less access to prenatal care can contribute but do not fully explain the observed health disparity. It is reasonable to consider the relatively higher maternal and neonatal adverse outcomes observed in the women undergoing induction in our study may be causality of this complex national problem and that the results of the ARRIVE study is not generalizable to all patient populations [15].

There are several limitations in this study. First, there is potential for selection bias as this is a retrospective study. In future work, more stringent patient selection based on good dating and clear medical history can be used to reduce the number of variables that can lead to confounding effects. Second, Bishop Scores were not obtained from our chart reviews. This is partly because not all the components of the Bishop score were consistently documented.
Nulliparous patients with an unfavorable cervix undergoing induction of labor may carry a higher rate of cesarean delivery [8]. It is valuable then to include this variable in data analysis in future work. Lastly, the sample size ultimately was under-powered to detect any significant differences. Extending the project would allow further participants to be enrolled.

In conclusion, this study demonstrated no statistically significant findings between the nulliparous low risk women undergoing induction of labor as compared to women delivering spontaneously. However, neonates in the induction group did have a relatively higher risk for adverse events including meconium aspiration syndrome, respiratory compromise requiring respiratory support within 72 hours, hyperbilirubinemia requiring phototherapy, and shoulder dystocia. Additionally, women in the induction group tended to have relatively higher risk for cesarean delivery, third degree laceration, developing gestational hypertension or preeclampsia, chorioamnionitis, post-partum hemorrhage and post-partum infection. Lastly, women in the induction group spent more time in the labor and delivery unit (P<0.001). When discussing the timing of delivery with patients, it is important to communicate these potential adverse neonatal and maternal risks. It is also important for the healthcare provider to consider the healthcare costs of elective inductions. Nevertheless, both the American College of Obstetrics and Gynecology and Society for Maternal-Fetal Medicine (SMFM) consider elective inductions after 39 weeks and 0 day reasonable and the option should be made available when patients request.

Data Availability

The patient data used to support the findings of this study are restricted by HIPAA in order to protect patient privacy. Requests for data, [6-12 months] after publication of this article for researchers who meet the criteria for access to confidential data can be made to Caitlin Witt, chamm7@uthsc.edu.

Conflicts of Interest

There are no conflicts of interest.

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