**Factors associated with a failed induction in the setting of pre-eclampsia**

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**Background:** Induction is commonplace in the management of pre-eclampsia and delivery is often required preterm and prior to the onset of labor and/or cervical ripening. Which factors have the strongest associations with successful induction specifically in the setting of pre-eclampsia has not been delineated.

**Objective:**To determine which maternal, fetal and pre-eclampsia characteristics are associated with failed induction in women induced for pre-eclampsia, which may be useful for delivery management counseling.

**Study Design:** We performed a retrospective cohort study of all singleton, live-born, non-anomalous deliveries at the University of Cincinnati Medical Center over a five year study period. Patients were included in our study if they had a diagnosis of pre-eclampsia and underwent an induction of labor. Our primary outcome was failed induction. We evaluated multiple maternal, fetal, and pre-eclampsia characteristics: primiparity, obesity, excessive weight gain, severity of pre-eclampsia, major complications of pre-eclampsia, gestational age less than 34 weeks, cervical characteristics, fetal growth restriction and oligohydramnios. Logistic regression analysis was performed to determine strength of association.

**Results:** 801 patients were diagnosed with pre-eclampsia, of which 467 patients underwent an induction of labor. The factors most strongly associated with failed induction were primiparity (aOR 1.54 (95% CI 1.20-1.99) and an unfavorable cervix (aOR 1.38, 95% CI 1.09-1.75). Obesity (aOR 1.01, 95% CI 0.80-1.28), gestational age less than 34 weeks (aOR 1.27, 95% CI 0.95-1.68), severe disease (aOR 1.14, 95% CI 0.85-1.53), and fetal growth restriction (aOR 1.02, 95% CI 0.70-1.52) were not associated with a failed induction.

**Conclusions:** The factors most strongly associated with a failed induction in the setting of pre-eclampsia are primiparity and an unfavorable cervix. Although there are often maternal and fetal co-morbidities during induction in the setting of pre-eclampsia, the factors most associated with a failed induction of labor are similar to those associated with failed induction for other indications.

**Keywords:** pre-eclampsia, labor induction, cesarean section, primiparity, Bishops score, fetal growth restriction, oligohydramnios

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**Introduction:**

Pre-eclampsia is a common complication of pregnancy, occurring in 6-8% of pregnancies.1 The only known definitive management of pre-eclampsia is delivery. When not precluded by maternal instability, there has been documented benefit of expectant management to improve neonatal outcome. 2,3. However often maternal or fetal complications forgo the ability to await spontaneous labor. Thus, whether immediate delivery is indicated or expectant management is an option, patients with pre-eclampsia often require delivery prior to onset of spontaneous labor and therefore have high rates of induction.

Pre-eclampsia is the indication for 25-43% of all medically-indicated preterm births.4  While vaginal delivery may reduce morbidity for the mother, obstacles to induction are often present in pre-eclampsia such as primiparity, an unfavorable cervix, fetal growth restriction, and a sense of urgency to expedite delivery given maternal and/or fetal compromise, and this may lead to higher rates of unlabored cesarean section in the setting of pre-eclampsia. It has been demonstrated that patients with pre-eclampsia have higher rates of cesarean section after induction. 5,6 However, induction in the setting of pre-eclampsia, even in low birth weight infants, has not been shown to be harmful.7 Thus, unless there are other obstetrical contraindications to labor, induction does remain an option for patients with pre-eclampsia.

There are multiple obstacles to successful induction in the setting of pre-eclampsia. Obesity, a known risk factor for pre-eclampsia, has been shown to increase the rate of failed induction in the setting of pre-eclampsia.8 Primiparity, also a risk factor for pre-eclampsia, an unfavorable cervix, and concern for fetal compromise all can attribute to the increased cesarean rate in patients with pre-eclampsia. Lastly, maternal complications such as severe hypertension, hemolysis elevated liver enzymes and low platelet (HELLP) syndrome, eclampsia, renal failure, pulmonary edema, and others all require expedited delivery which can discourage providers from attempting an induction which will prolong the interval to delivery.

The maternal, fetal, and pre-eclampsia characteristics that are associated with a failed induction in the setting of pre-eclampsia, and the strengths of these associations, is an understudied area. The goal of our study was to evaluate several biologically plausible factors to determine which are associated with a failed induction, and the strengths of these associations. Our hypothesis is that certain maternal, fetal, and pre-eclampsia characteristics are more strongly associated with failed induction of labor, and knowledge regarding these associations may be valuable in devising delivery management strategies.

**Methods:**

We performed a retrospective cohort study of all singleton, live-born, non-anomalous deliveries at the University of Cincinnati Medical Center between January 2008 and January 2013. The study was approved by local Institutional Review Board. Patients were eligible for inclusion if they were diagnosed with pre-eclampsia prior to delivery and underwent an induction of labor.

The period included for the study was prior to the institution of the ACOG Task Force on Hypertension in Pregnancy9 guidelines for management. Thus, pre-eclampsia was defined as hypertension with the presence of new-onset proteinuria (over 0.3 gm of total urinary protein excretion over a 24-hour period). Patients with atypical pre-eclampsia, with any combination of hypertension, symptoms, HELLP, and/or fetal growth restriction but with the absence of proteinuria, were also included if the managing physician team made the diagnosis of pre-eclampsia based upon the clinical evaluation. Severe pre-eclampsia was defined as severe range blood pressures greater than 160/110, proteinuria over 5 gm in a 24 hour collection, neurological symptoms, epigastric pain, HELLP syndrome, pulmonary edema, renal failure, or oligouria.9  We used diagnoses at the time of care that was recorded in the medical record by the patient’s medical team to categorize and characterize study subjects. Patients were only included if they were induced, not if they presented with labor or premature rupture of membranes. Other exclusion criteria included indications for cesarean delivery such as breech, prior cesarean delivery and other maternal obstetrical or medical co-morbidities that were felt to contraindicate labor.

Inductions were per single institution protocol, which included cervical ripening with prostaglandins or a Foley bulb until the patient had a favorable cervix, followed by pitocin administration when indicated. The decision to stop induction and perform cesarean delivery for either maternal or fetal indications was at the discretion of the managing team of providers.

Our primary outcome was a failed induction which was defined as a cesarean section after attempted induction. Given the complex interplay between labor progression, fetal status assessment and the decision to abandon attempted induction we considered any cesarean after attempted induction as a failed induction. We evaluated multiple maternal, fetal, and pre-eclampsia characteristics that had biological plausibility at influencing the success of induction including: primiparity, maternal obesity (defined as pre-pregnancy body mass index, BMI, over 30), excessive weight gain as outlined by the Institute of Medicine10, prematurity, cervical characterization by using a calculated Bishops score11, severity of disease (mild versus severe pre-eclampsia), major complications of pre-eclampsia (including pulmonary edema, eclampsia, acute renal insufficiency, HELLP syndrome, neurological symptoms), need for intravenous anti-hypertensive medication, fetal growth restriction, oligohydramnios (defined as an amniotic fluid index less than 6 cm), and abnormal umbilical artery Doppler. Retrospective power analysis was performed to determine our power to make a negative conclusion.

The study data was collected and managed by REDCap (Research Electronic Data Capture) electronic data capture tools hosted at the University of Cincinnati.12 Categorical factors were evaluated using Chi- Square analysis. Continuous variables were analyzed using equal variance T test and presented as mean ± SD if the data was normally distributed or Wilcoxin-Rank sum analysis if non-normally distributed or ordinal and presented as median (95% CI). A p value of 0.05 was considered statistically significant. Logistic regression analysis was performed and crude odds ratios (OR) were calculated for each exposure variable being considered. Considering those results, a logistic regression model was created using variables that were found to have significance and/or those with strong biological plausibility which included: primiparity, obesity, excessive weight gain, delivery at less than 34 weeks, presence of severe disease, presence of a major complication, unfavorable cervix, fetal growth restriction, and oligohydramnios. Data are presented as adjusted OR with 95% confidence intervals. All data analysis was performed using NCSS 8 statistical software (Release 8. NCSS LLC, Kaysville, Utah).

**Results:**

A total of 7117 women delivered throughout the study period. A total of 801 patients were diagnosed with pre-eclampsia. Among those patients, 467 (58 %) were induced and 334 (42 %) were not induced (Figure 1). Of the 334 patients that were not induced, the most common indication was labor or premature rupture of membranes, n=84 (25%) followed by repeat cesarean section, n=94 (28%) and breech fetal presentation, n=19 (6%). Pre-eclampsia was the sole indication documented for not being induced in 31 (6%) of patients. Demographics of all patients with pre-eclampsia (n=801) are outlined in Table 1. With respect to decision to induce, those induced were slightly older statistically, and more likely to be black or Hispanic. Parity tended to be higher in the patients not induced, p<0.001. There were 248 patients less than 34 weeks gestation and 40% were induced, p< 0.001. The Bishop score between those not induced and induced was similar, median (IQR) of 1 (0, 3) in those not induced versus 2 (2, 2) in those induced, p=0.91. Patients with fetal growth restriction were less likely to be induced: there were 106 patients with known fetal growth restriction, 40% of those patients were induced, p<0.001.

Results of our primary analysis can be seen in Table 2. Maternal factors that were associated with a failed induction included: primiparity (OR 1.62, 95%CI 1.31-2.00), unfavorable Bishop score (OR 1.33, 95%CI 1.10-1.62), closed cervix (OR 1.57, 95%CI 1.29-1.92), uneffaced cervix (OR 1.63, 95%CI 1.32-2.01) gestational age less than 34 weeks (OR 1.40, 95%CI 1.11-1.75) and severe disease (OR 1.28, 95%CI 1.03-1.60). Patients with a major maternal complication of pre-eclampsia demonstrated a trend towards being associated with a failed induction (OR 1.21, 95%CI 0.98-1.47), however this was not statistically significant. Maternal factors such as obesity (OR 1.04, 95%CI 0.85-1.26) and excessive weight gain (OR 1.05, 95%CI 0.87-1.28) were not associated with a failed induction. Fetal growth restriction (OR 1.18, 95%CI 0.85-1.63), oligohydramnios (OR 0.96, 95%CI 0.67-1.38), and abnormal Doppler (OR 1.18, 95%CI 0.74-1.90) were not associated with a failed induction.

Post hoc analysis was performed to control for confounding variables and these results are presented in Table 3. Primiparity and unfavorable cervix remained most strongly associated with failed induction: aOR 1.54 (95%CI 1.20-1.99) and aOR (1.38 (95%CI 1.09-1.75) respectively (Figure 2). There was a trend toward an association between early preterm delivery less than 34 weeks and failed induction, aOR 1.27 (95%CI 0.95-1.68). The other variables did not seem to be associated with failed induction once data was controlled for confounding variables.

**Discussion:**

It has been reported that patients being induced with pre-eclampsia have a higher rate of cesarean section.5,6,13 Physician reluctance to induce likely contributes to the overall higher cesarean rate in these patients. In general, many factors may contribute to higher rates of failed induction including primiparity, obesity, unfavorable cervical characteristics, and underlying fetal compromise. Little is known about how certain characteristics of pre-eclampsia such as gestational age at indicated delivery, severity, presence of major complications, and fetal conditions such as growth restriction and oligohydramnios affect the ability to successfully induce patients with pre-eclampsia. Our study has demonstrated that the factors most associated with a failed induction in the setting of pre-eclampsia are similar to those that predict failed induction in the general obstetrical population.

We found the maternal factors with the strongest associations with a failed induction in the setting of pre-eclampsia were primiparity and an unfavorable cervix. It has been shown that an unfavorable Bishop score in general and in the setting of pre-eclampsia is associated with higher rates of failed induction.6,13 Our study supports that an unfavorable cervix in the setting of pre-eclampsia is one of the strongest risk factors for a failed induction; we found a 38% increase in cesarean delivery when the cervix was unfavorable, aOR 1.38 (95%CI 1.09-1.75). Another important maternal factor that is associated with failed induction is primiparity, which increased the risk for cesarean delivery by 54%, aOR 1.54 (95%CI 1.20-1.99). This is also consistent with data regarding failed induction in the general obstetrical population.6 Several maternal factors were not associated with failed labor induction including obesity and excessive weight gain. Our study did not find a significant association between obesity and failed labor in the setting of pre-eclampsia (aOR 1.01, 95%CI 0.80-1.28), however obesity has been previously reported to increase the risk for failed induction in pre-eclampsia, but with only a modest increase in risk (aOR 1.16, 95%CI 1.04-1.31).8 A key difference between our analysis and this study is that Robinson et al categorized obesity in five unit increasing increments, while we classified categorically as obese versus non-obese. We know of no prior studies looking at excessive weight gain and induction failure in the setting of pre-eclampsia.

Complications unique to pre-eclampsia, such as severity of disease, need for intravenous anti-hypertensives for severe hypertension, and major complications such as eclampsia, renal failure, HELLP syndrome, pulmonary edema, may also influence the rate of successful induction. Some patients with these co-morbidities were not induced at the discretion of their managing provider, however our analysis only included those that initiated the induction process. It also should be noted out of the patients who were not induced, pre-eclampsia was the sole indication for only 9% of these patients, indicating a high rate of attempted induction regardless of severity of disease. We did not find the presence of severe pre-eclampsia or major complications of pre-eclampsia to increase the rate of failed induction significantly. Severity of disease demonstrated significance OR 1.28 (95%CI 1.03-1.60) until post hoc analysis controlling for confounding variables negated this trend aOR 1.14 (95%CI 0.85-1.53). A similar effect was found with major complications of pre-eclampsia such as those listed above.

Another obstacle in inducing patients with pre-eclampsia is often the premature gestational age at the time delivery is indicated. Nassar et al demonstrated that 48% of patients at less than 34 weeks being induced for pre-eclampsia had a successful vaginal delivery, and that a favorable Bishop score was best predictor of success.15 Our study demonstrated that preterm delivery (<37 weeks) and early preterm delivery (<34 weeks) were not associated with a higher rate of failed induction. Blackwell et al found a 68% rate of successful inductions in preterm patients from 32-34 weeks gestation, with higher rates of failure at earlier gestational ages.16 Our data are similar, with a 54% rate of successful induction in all patients delivered at less than 34 weeks, however this rate was not statistically significant when compared to those over 34 weeks, aOR 1.27 (95% CI 0.95-1.68).

Fetal complications of pre-eclampsia such as growth restriction, abnormal Doppler, oligohydramnios, and a non-reassuring fetal status can also hinder induction success. Fetal growth restriction and oligohydramnios are secondary to placental insufficiency in the setting of pre-eclampsia.2 During induction, placental hypoperfusion likely contributes to a non-reassuring fetal status or fetal intolerance of labor, thus increasing the cesarean section rate in patients with pre-eclampsia. Surprisingly, we did not find an association with failed induction in patients with fetal growth restriction, oligohydramnios, or abnormal Doppler. The rate of failed induction was approximately 31% in patients with oligohydramnios and 40.5% in patients with fetal growth restriction, which is similar to the overall rate of failed induction in this cohort. It has been shown that low birth weight secondary to extreme prematurity is associated with higher rates of cesarean section7,16, however these studies do not typically compare growth restricted fetuses to appropriately grown fetuses at the same gestational age. Our study demonstrates that fetal growth restriction in the setting of pre-eclampsia does not increase the risk of failed induction, nor does the presence of oligohydramnios.

Strengths of our study include a single center institution that is protocol-driven by ACOG guidelines. While many studies investigate management of pre-eclampsia in labor, it is often difficult to standardize management as individual practice patterns may vary based on personal experience. Another strength to our study is the large number of patients in the study population and the low rate of planned cesarean section solely for pre-eclampsia. Finally, while many studies look at individual factors and the cesarean section rate, we considered multiple likely factors in one analysis. To our knowledge, this is the first study that looks at maternal, fetal, and pre-eclampsia characteristics in the same patient population and the subsequent risk of failed induction.

There are several limitations to our study. Some of our patients had incomplete records, most notably with respect to presence of fetal growth restriction, oligohydramnios and Doppler evaluation as all did not all undergo an ultrasound immediately prior to delivery. Many variables assessed were somewhat subjective such as cervical scoring, categorization of the fetal tracing, and neurological symptoms and we relied on the interpretations and diagnosis made by the team caring for each individual patient. Finally, not all patients that were candidates for vaginal delivery underwent an attempt at labor induction, 9% of women underwent cesarean section solely for pre-eclampsia, and inclusion of these patients with the most severe disease would likely alter our results to some degree. Ideally a prospective study in which all women without contraindications to labor undergo attempted induction would more accurately quantitate any association between these characteristics and failed induction.

There are many obstacles that obstetricians face when deciding how to proceed forth with delivery in patients with pre-eclampsia. Concerns for both maternal safety and fetal ability to tolerate labor especially in the setting of premature gestation and growth restriction may lead some to advocate for primary cesarean section in these patients. Our study has demonstrated that while obstetricians tend to view patients with pre-eclampsia as a challenging cohort of patients because of maternal, fetal, and pre-eclampsia characteristics, this may not be the case. In fact, we found that factors most associated with a failed induction in the setting of pre-eclampsia are similar to those that predict a failed induction in the general obstetrical population. Our evidence supports that predictors of a failed induction in pre-eclampsia are similar to those reported in the general population and that factors specifically related to pre-eclampsia do not have significant influence on the rate of success.

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Study data were collected and managed with REDCap software (Research Electronic Data Capture) which is hosted at Cincinnati Children’s Hospital Medical Center under the Center for Clinical and Translational Science and Training grant support (UL1-RR026314-01 NCRR/NIH). REDCap is a secure, web-based application that was designed to support data capture for research studies to provide (1) an intuitive interface for validated data entry, (2) audit trails for tracking data manipulation and export procedures, (3) automated export procedures for seamless data downloads to common statistical packages, and (4) procedures for importing data from external sources.

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**Table 1:** Demographic characteristics, select delivery and fetal outcomes compared in women with pre-eclampsia induced and not induced. BMI-body mass index, GA-gestational age, NICU-neonatal intensive care unit, LOS-length of stay. For fetal growth restriction, 672 patients included in analysis as had ultrasound assessment of growth prior to delivery. For cord pH, 561 included in analysis.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Not induced** | **Induced** | **p value** |
|  | N= 334 | N= 467 |  |
| **Demographics:** |  |  |  |
| Age (years), mean ± SD | 27 ± 6.6 | 25.6 ± 6.4 | <.001 |
| Race, n (%) |  |  |  |
| White | 137 (51.1) | 131 (48.9) |  |
| Black | 168 (36.8) | 289 (63.2) |  |
| Hispanic | 22 (39.3) | 34 (60.7) |  |
| Other | 8 (38.1) | 13(61.9) |  |
| Parity, median(95%CI) | 1 (1,1) | 0 (0,0) | <0.001 |
| BMI pre-pregnancy, mean ± SD | 31.4 ± 9.7 | 30.5 ± 9.4 | 0.18 |
| Tobacco use, n (%) | 85 (25.4) | 90 (19.5) | 0.04 |
|  |  |  |  |
| **Delivery Management:** |  |  |  |
| GA at delivery (weeks), median (95%CI) | 35 (34,36) | 37 (37,37) | < 0.001 |
| Delivery less than 34 weeks, n (%) | 149 (44.6) | 99 (21.2) |  |
| Bishop score, median (95%CI) | 1 (0,2) | 2 (2,2) | 0.11 |
| Cervical dilation, median (95%CI) | 1 (0.5,1.5) | 1 (1,1) | 0.09 |
| Effacement, median (95%CI) | 40 (20,50) | 40 (30,50) | 0.11 |
| Fetal growth restriction, n (%) | 64 (22.1) | 42 (11.0) | <0.001 |
|  |  |  |  |
| **Fetal Complications** |  |  |  |
| Birth weight, mean ± SD | 2216 ± 1067 | 2737 ± 776 | <0.001 |
| Apgar at 5 minutes, median (95%CL) | 9 (9,9) | 9 (9,9) | 0.006 |
| cord pH | 7.25 ± 0.08 | 7.26 ± 0.08 | 0.30 |
| NICU admission | 165 (49.8) | 121 (26.1) | <0.001 |
| Newborn LOS (d), mean(95%CL) | 4 (3,5) | 2 (2,3) | <0.001 |

**Table 2:** Select maternal, pre-eclampsia and fetal characteristics and their association with failed labor. Data derived from all patients induced (n= 467) with following exceptions: Unfavorable Bishop score (n=467), fetal growth restriction (n= 382), oligohydramnios (n=380), and umbilical artery Doppler (n=164) given lack of documented Bishop score or sonogram markers documented prior to induction.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Successful induction** | **Failed induction** | **OR** | **95% CI** |
|  | n= 312 (67%) | n= 155 (33%) |  |  |
| **Maternal characteristics, n (%)** |  |  |  |  |
| Primiparous | 158 (58.3) | 113 (41.7) | 1.62 | 1.31-2.00 |
| Obese | 130 (64.7) | 71 (35.3) | 1.04 | 0.85-1.26 |
| Excessive weight gain | 153 (65.4) | 81 (34.6) | 1.05 | 0.87-1.28 |
|  |  |  |  |  |
| **Obstetrical characteristics, n (%)** |  |  |  |  |
| Delivery less than 37 weeks | 104 (61.2) | 66 (38.8) | 1.23 | 1.00-1.48 |
| Delivery less than 34 weeks | 54 (54.5) | 45 (45.5) | 1.40 | 1.11-1.75 |
| Unfavorable Bishop | 138 (60.3) | 91 (39.7) | 1.33 | 1.10-1.62 |
| Cervix closed | 94 (54.0) | 80 (46.0) | 1.57 | 1.29-1.92 |
| Cervix uneffaced | 68 (50.7) | 66 (49.3) | 1.63 | 1.32-2.01 |
|  |  |  |  |  |
| **Pre-eclampsia characteristics, n (%)** |  |  |  |  |
| Severe pre-eclampsia | 199 (63.0) | 117 (37.0) | 1.28 | 1.03-1.60 |
| Major complication | 105 (61.4) | 66 (38.6) | 1.21 | 0.98-1.47 |
| Need for IV medication | 85 (62.5) | 51 (37.5) | 1.14 | 0.92-1.41 |
| Fetal growth restriction | 25 (59.5) | 17 (40.5) | 1.18 | 0.85-1.63 |
| Oligohydramnios | 26 (68.4) | 12 (31.6) | 0.96 | 0.67-1.38 |
| Abnormal Doppler exam | 11 (55.0) | 9 (45.0) | 1.18 | 0.74-1.90 |
|  |  |  |  |  |

**Table 3:** Post hoc analysis assessing the association between maternal, pre-eclampsia and fetal characteristics and the rate of failed induction. Data presented as adjusted OR and 95% CI.

|  |  |  |
| --- | --- | --- |
| **Characteristic** | **aOR** | **95% CI** |
| Delivery less than 34 weeks | 1.27 | 0.95-1.68 |
| Excessive weight gain | 1.03 | 0.81-1.30 |
| Fetal growth restriction | 1.02 | 0.70-1.50 |
| Major complication of pre-eclampsia | 1.07 | 0.82-1.40 |
| Obesity | 1.01 | 0.80-1.28 |
| Primiparity | 1.54 | 1.20-1.99 |
| Severe pre-eclampsia | 1.14 | 0.85-1.53 |
| Unfavorable cervix | 1.38 | 1.09-1.75 |

Figure 1:

Flowchart of subjects included/excluded from analysis.

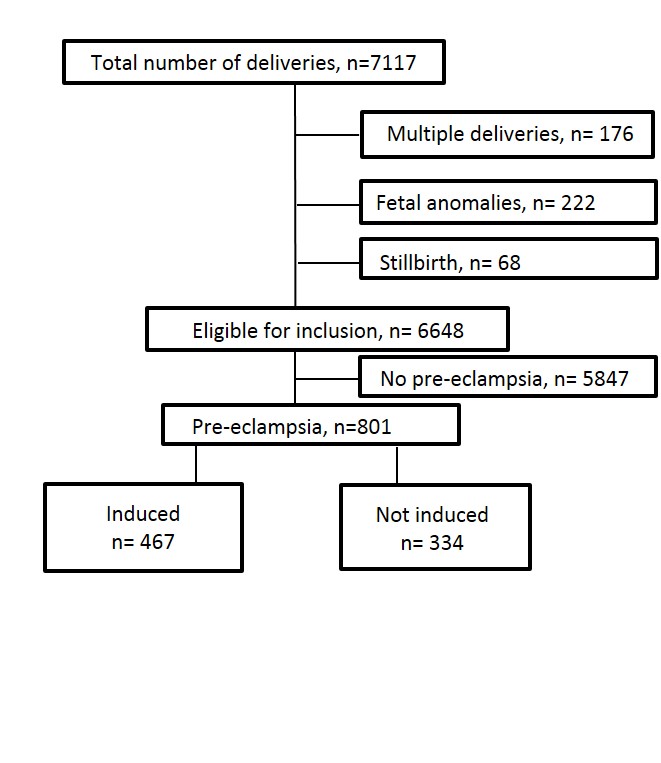


Figure 2: Adjusted OR and 95% CI for most significant factors associated with failed induction in the setting of preeclampsia.

