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The Active Management of Risk in Multiparous Pregnancy at Term: association between a higher preventive labor induction rate and improved birth outcomes

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Abstract

Objective—To determine if exposure of multiparous women to a high rate of preventive labor induction was associated with a significantly lower cesarean delivery rate.

Study Design—Retrospective cohort study involving 123 multiparas, who were exposed to the frequent use of preventive labor induction, and 304 multiparas, who received standard management. Rates of cesarean delivery and other adverse birth outcomes were compared in the two groups. Logistic regression controlled for confounding covariates.

Results—The exposed group had a lower cesarean delivery rate (aOR 0.09, 0.8% vs. 9.9%, $p = 0.02$) and a higher uncomplicated vaginal delivery rate (OR 0.53, 78.9% vs. 66.4%, $p = 0.01$). Exposure was not associated with higher rates of other adverse birth outcomes.

Conclusion—Exposure of multiparas to a high rate of preventive labor induction was significantly associated with improved birth outcomes including a very low cesarean delivery rate. A prospective randomized trial is needed to determine causality.

Keywords

Active management of risk; Cesarean delivery; Neonatal intensive care unit admission; Preventive induction

Introduction

Cesarean delivery, as compared to simple vaginal delivery, is associated with higher rates of excessive blood loss, post-partum infection, and maternal mortality (1–4). Despite the risks associated with cesarean delivery, US national rates of cesarean delivery have steadily

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increased over the past decade (5–7). In 2006 the US national cesarean delivery rate reached an all time high of 31.1 %.

A recently described strategy for the reduction of group cesarean delivery rates involves the use of risk factors for cesarean delivery to guide the increased use of preventive labor induction (8–11). This strategy is called the Active Management of Risk in Pregnancy at Term (AMOR-IPAT). Within AMOR-IPAT, preventive labor induction is used to increase the likelihood that labor begins before conditions develop which make vaginal delivery less likely (e.g., a fetus that has grown too large to pass through the maternal pelvis and/or a placenta that is no longer able to adequately support the fetus during labor).

Multiparous women without a history of cesarean delivery (hereinafter called “multiparas”) are especially well-suited for AMOR-IPAT. Multiparas are more easily induced than nulliparous women (nulliparas) (12), and labor induction is safer in multiparas than in multiparous women with a prior history of cesarean delivery (hereinafter called “VBAC”) (13). In addition, problems encountered during previous deliveries, such as macrosomia and the need for assisted vaginal delivery, often provide useful information about the optimal timing of delivery in subsequent pregnancies. Finally, multiparas make up the largest of the three obstetric groups (5–7) and so a significant change of cesarean utilization among multiparas would have a proportionally larger impact on any population’s overall cesarean delivery rate. Accordingly, we performed a study to determine if there was a significant association between exposure of multiparas to AMOR-IPAT and a lower cesarean delivery rate.

Materials and Methods

A retrospective cohort study-design was used to compare 123 sequentially-delivered AMOR-IPAT-exposed multiparas to 304 randomly selected non-exposed multiparas. Of the exposed women, 60 were part of a previously published study involving women of mixed parity (study “A”) (8) and 58 were part of a second similar completed retrospective study involving women of mixed parity (study “B”) (11). Because no exposed multiparas in these two studies experienced a cesarean delivery, additional sequentially-delivered exposed multiparas (four) were considered until an exposed multipara was identified who had a cesarean delivery. Of the 304 randomly selected non-exposed women, 128 were part of study “A.” Study “A” randomly selected three non-exposed women for each exposed woman but did not match for parity group (nulliparas vs. multipara vs. VBAC) (8). In addition, 173 non-exposed women were part of study “B”. Study “B” randomly selected non-exposed women but matched exposed and non-exposed study subjects by maternal parity group (11). No additional non-exposed women were added to the study related to the inclusion of the final four exposed women. All women in this study delivered between 4/5/1998 and 11/18/02 at an urban academic medical center. All study subjects had a singleton pregnancy, at least one prenatal care visit with a hospital maternity care provider, and were a candidate for a trial of labor at 38 weeks gestation (i.e. no placenta previa, active HIV disease, or major fetal anomaly). All exposed women received their prenatal care and their labor management from family physicians. All non-exposed women received their prenatal care and their labor management from obstetricians. All cesarean deliveries were performed by obstetricians.

For women in the AMOR-IPAT exposed group, risk factors for cesarean delivery were identified and placed in one of two categories: 1) the utero-placental insufficiency (UPI) category (i.e., factors that accelerate placental aging), or 2) the cephalo-pelvic disproportion¹ (CPD) category (i.e., factors that accelerate fetal growth or limit pelvic diameter). The published odds ratio for cesarean delivery for each risk factor (14–17) was

converted into a number of risk-days using a previously published formula (8–10) (Appendix 1). The total number of risk-days that any given woman had in each risk category was then subtracted from 41 weeks 0 days gestation to estimate a category-specific upper limit of the optimal time of delivery (UL-OTD). The lower of the two category-specific UL-OTD's for each woman was identified as her final estimated UL-OTD, but the final UL-OTD was never less than 38 weeks 0 days gestation. If a woman had not developed spontaneous labor by one week before her UL-OTD, then labor induction was scheduled to ensure that she delivered on or before her UL-OTD. Furthermore, if a woman was scheduled for labor induction and had an unfavorable uterine cervix (modified Bishop's score < 6) (18), then she was offered pre-induction cervical ripening. For exposed women in this study, methods of pre-induction cervical ripening included dinoprostone (Prostaglandin E1), misoprostol (prostaglandin E2) and Foley bulb catheter with 60 cc's of fluid. . Occasionally, these methods of pre-induction cervical ripening were combined.

For data analysis, the frequency and proportions of prenatal and intra-partum co-variables present in the exposed and non-exposed groups were compared. Means and medians of continuous variables were calculated. Normal distributions were compared using the student's T-test, and non-normal distributions were compared using the Wilcoxon rank-sum test. Dichotomous and categorical variables were compared using chi-squared techniques (Fishers exact test). Relative risk was used as the measure of univariate association. Statistical significance for all tests was defined as a p-value ≤ 0.05 , and a statistical trend was defined as a p-value from 0.05 to 0.30, inclusive.

In order to compare the pre-38 weeks of gestation level of risk for cesarean delivery in the two groups, an indirect standardization procedure was performed (19,20). For this analysis, the larger non-exposed group was used as the reference group. Prenatal risk factors that at least trended toward different levels (p-value ≤ 0.30) in the two study groups, and that at least trended toward an association with increased or decreased cesarean delivery rate in the non-exposed group, were used as variables in this comparison. A standardized cesarean ratio (SCR) was calculated by dividing the expected cesarean delivery rate in the exposed group by the actual cesarean delivery rate in the non-exposed group.

An intention to treat approach was taken in the analysis of all outcomes. The primary outcome of the study was mode of delivery. Four secondary outcomes were identified prior to the start of the study: 1) major perineal injury (3rd or 4th degree), 2) one-minute APGAR score less than four, 3) five-minute APGAR scores less than seven, and 4) neonatal intensive care unit (NICU) admission. Univariate analyses using chi-squared methods were performed to evaluate the association between exposure to AMOR-IPAT and each of the five pre-identified outcomes. Multiple logistic regression was used to adjust for potential confounding in the association between AMOR-IPAT exposure and each of the five pre-identified outcomes. We also assessed the association between exposure to AMOR-IPAT and other birth outcomes using chi-squared techniques.

In order to evaluate overall birth health, we used two composite outcomes. The Adverse Outcomes Index (AOI) is a previously published score (21) that uses ten specific weighted outcomes to "assess not only the occurrence of deliveries with poor outcomes but also the number and relative severity of the outcomes" in any given group (Appendix 2). The AOI was calculated for each individual in each group and the outcomes of the two groups were then compared using Wilcoxon rank-sum analysis. In addition, we created a composite

¹We prefer to use the term cephalo-pelvic disproportion ("CPD") rather than failure to progress ("FTP") because CPD better captures the underlying etiology of preventable dystocia related to interactions that occur between maternal pelvic characteristics (diameter and soft tissue volume) and fetal morphology (weight, head circumference and shoulder girth).

outcome called “uncomplicated vaginal delivery” that identified a vaginal delivery not associated with the need for any of five other adverse outcomes: mechanical assistance (vacuum or forceps), major perineal injury (3rd or 4th degree tear), post partum hemorrhage (> 500 cc’s) or NICU admission (Appendix 3). The rate of uncomplicated vaginal delivery was determined for each group, and the rates were compared using chi-squared techniques (Fisher’s exact method).

A comparison of the distributions of gestational age at delivery in the two groups was performed using survival analysis techniques. We collapsed data related to gestational age at delivery, timing of induction and mode of delivery into half-week sub-strata and then encoded the data so as to enable graphic representation. The length of first and second stages of labor, the length of maternal hospital stay, and the length of neonatal hospital stay for each mom-baby pair within each study group were determined. Thereafter, comparisons of these time intervals between study groups were performed using Wilcoxon rank-sum testing. Data were analyzed using the STATA Statistical Program (version 8, College Station, TX). The IRB of the University of Pennsylvania approved this investigation.

Results

Table 1 identified levels of risk factors by study exposure group. Thirteen of 24 variables were present at statistically different levels between the exposure groups, and another four variables were present at levels that trended towards statistical significance. Within this group of seventeen variables, five were either significantly associated with cesarean delivery, or trended towards a significant association, in the non-exposed group. The five variables, with their respective relative risk for cesarean delivery, were: advanced maternal age (RR 1.95, $p=0.10$); African-American race (RR 2.24, $p=0.09$); alcohol use (RR 3.6, $p=0.003$); previous vacuum or forceps delivery (RR 2.77, $p=0.04$ and anemia in the first or second trimester (hemoglobin [hgb] ≤ 11 mg/dl) (RR 1.88, $p=0.003$). An indirect standardization procedure using these variables, and using the non-exposed group as the reference group, suggested that the AMOR-IPAT exposed group should have had a 10.6% cesarean delivery rate as compared to the 9.9% rate that occurred in the non-exposed group. The standardized cesarean delivery rate for the exposed group, as compared to the non-exposed group, was therefore 1.07. This indicates that the exposed group did not have a lower risk of cesarean delivery than the non-exposed group at the start of the term period of pregnancy.

Exposed women were characterized by two key findings: they presented to the hospital earlier in the term period than the non-exposed group, and they were more likely to deliver following induction of labor (61% vs. 16.4%, RR 3.71, 95% CI [2.77–4.96]) (Figure 1a and 1b). In addition, exposed women had an earlier median gestational age of delivery (38.7 weeks vs. 39.9 weeks, $p < 0.001$), and the pattern of the timing of delivery as a function of gestational age within the exposed group was regularly earlier than in the non-exposed group (Figure 2). The Cox Proportional Hazard ratio indicating earlier delivery in the exposed group was 2.19 (95% CI [1.77–2.72], $p<0.001$). The higher rate of labor induction in the exposed group was almost entirely due to the greater use of preventive induction (45.5% vs. 3.3%, RR 13.8, 95% CI [7.30–26.2]) (Table 3).

If labor was induced, then the median gestational age in the exposed group at the time of birth was 16 days earlier (38.7 weeks vs. 41.0 weeks, $p < 0.001$). If labor occurred spontaneously, then the median gestational age in the exposed group was 5 days earlier (39.3 weeks vs. 40.0 weeks, $p = 0.01$). In addition, exposed women had a lower median modified cervical Bishop’s score on admission (5 vs. 8, $p = 0.01$), and they were more likely to receive prostaglandins medication (PGE2 or PGE1) for cervical ripening (28.5% vs.

6.9%, RR 4.12, 95% CI [2.50–6.78]) (Table 2). While the median time from admission to delivery was longer in the exposed group (11.6 hours vs. 7.3 hours, $p < 0.001$), once labor started the median length for the both the first stage and the second stage was shorter in the exposed group as compared to the non-exposed group ([258 min vs. 280 min, $p=0.04$], [(14 min vs. 17 min., $p=0.05$], respectively). We did not censor women who had a cesarean delivery in our analysis of the duration of the various stages of labor. Hence, shorter first and second stages were noted in the exposed group even though twenty non-exposed women had a cesarean delivery prior to full cervical dilatation and ten non-exposed women had a cesarean delivery as the end point of their second stage of labor.

The cesarean delivery rate in the exposed group was 0.8%, as compared to 9.9% in the non-exposed group (OR 0.08, 95% CI [0.01–0.60]) (Table 3). AMOR-IPAT exposure was associated with a significantly lower rate of cesarean delivery rate for both utero-placental insufficiency (UPI) and cephalo-pelvic disproportion (CPD). The only cesarean delivery in the exposed group occurred due to excessive bleeding from a previously identified marginal placenta previa. Multiple logistic regression was used to adjust for covariates in the association between AMOR-IPAT exposure and cesarean delivery. Covariates in the final model included: AMOR-IPAT exposure (aOR 0.09, 95% CI [0.1–0.69], advanced maternal age (aOR 2.97, 95% CI [1.09–8.12]), African American race (aOR 3.53, 95% CI [1.11–11.2]), alcohol use (aOR 4.43, 95% CI [1.37–14.3]), and epidural analgesia (aOR 5.08, 95% CI [1.41–18.29]). The timing of cesarean delivery in each group, as a function of gestational age, is shown in Figure 1c.

The mean Adverse Outcome Index score was similar in the two groups (4.1 in the exposed group, as compared to 4.7 in the non-exposed group, $p = 0.23$) (Appendix 2). However, the uncomplicated vaginal delivery rate was significantly higher in the exposed group (78.9% vs. 66.4%, $p=0.01$) (Appendix 3). As noted in Table 4, AMOR-IPAT exposure was associated with a lower rate of 3rd or 4th degree perineal tear (0% vs. 4.3%, $p=0.04$). Because a case of major perineal trauma did not occur in the exposed group, adjustment for confounding could not be applied to this outcome. Women in the exposed group were also less likely to have either thick meconium at the time of amniotic membrane rupture (4.9% vs. 13.8%, RR 0.35, 95% CI 0.15–0.81), or fetal macrosomia (birth weight > 8lb 7oz) (5.7% vs. 17.4%, RR 0.33, 95% CI 0.15–0.70).

Rates of NICU admission (6.5% vs. 8.2%, $p=0.84$) and low APGAR scoring at one and five-minutes (6.5% vs. 11.8%, $p=0.15$; and 0.8% vs. 1.0%, $p=0.87$, respectively) were similar in the two groups, and multiple regression did not significantly alter the magnitude of these associations (data not shown). Rates of chorioamnionitis, assisted vaginal delivery and cephalo-hematoma were similar in the two groups. The two study groups had similar rates of low birth weight infants (3.2% vs. 2.3%, $p=0.57$), but the exposed group had more infants who weighted less than 6 lbs 8 oz (28.5% vs. 13.8%, $p < 0.001$). However, of the 32 infants in the exposed group who weighed less than 2950 grams at birth, only three required NICU admission, and of these, only one was delivered following induction of labor. This infant delivered at 38 weeks 5 days gestation, her labor was complicated by vaginal bleeding, and the reason for NICU admission was possible sepsis rather than respiratory insufficiency.

Discussion

This study finds a significant association in multiparas between exposure to a high rate of preventive labor induction (45.5% vs. 3.3%, $p < 0.001$) through AMOR-IPAT and a very low cesarean delivery rate (0.8% vs. 9.9%, $p < 0.001$). Rates of cesarean delivery in the exposed group were lower for both intolerance of labor and failure to progress. In addition, the group of women exposed to a higher rate of preventive labor induction had a

significantly higher uncomplicated vaginal delivery rate (78.9% vs. 66.4%, $p=0.01$) and significantly lower rates of major perineal injury, excessive blood loss and passage of thick meconium. No important birth outcomes occurred with increased frequency in the exposed group.

The finding that a high rate of preventive labor induction using AMOR-IPAT was associated with a lower cesarean delivery rate is consistent with the results of two recently published investigations. Specifically, a retrospective study from a rural secondary hospital (10) included 407 multiparous women exposed to a higher rate of preventive labor induction through AMOR-IPAT. The exposed group experienced a 1.2% cesarean delivery rate, while the non-exposed multiparous group experienced a 4.2% cesarean delivery rate (OR 0.42, $p=0.008$). Rates of other birth outcomes were not higher in the AMOR-IPAT exposed group. In addition, a 270 patient prospective trial from an urban setting (21) included 143 multiparous women. 71 were exposed to a higher rate of labor induction through AMOR-IPAT and experienced a 2.9% cesarean delivery rate, while 72 received usual care and experienced a 5.6% cesarean delivery rate (OR 0.51, $p=0.41$). In the randomized trial, rates of other birth outcomes were not higher in the AMOR-IPAT exposed group. While the randomized controlled trial failed to find statistical significance for the birth outcome “multiparous cesarean delivery,” the study was not powered to identify as statistically significant a 50% reduction of cesarean delivery in multiparous women. Taken collectively, both previous studies and the current study support the concept that AMOR-IPAT may be able to provide at least a 50% reduction in cesarean delivery risk in multiparous women.

In contrast to our findings, many previous studies of labor induction have linked labor induction in multiparous women to increased rates of both cesarean delivery and other adverse birth outcomes (22–25). However, these studies of multiparous labor induction focused on labor inductions for standard indications (26) or often did not consider the issue of cervical favorability (25). In retrospective investigations of multiparous induction that ensured adequate cervical ripening, higher rates of labor induction have not been associated with higher rates of cesarean delivery (27–31). Furthermore, the greatest source of potential concern in previous retrospective studies of labor induction is the issue of confounding by indication. If a retrospective study finds higher rates of cesarean delivery and other adverse birth outcomes in multiparous women having labor induction, are the adverse outcomes due to the induction procedure itself, or are they due to the reasons the induction procedure was initiated? We believe that the central research question should not be: “do multiparous women undergoing labor induction experience higher rates of cesarean delivery and other adverse outcomes than multiparous women who develop spontaneous labor” but rather: “how do the birth outcomes of one group of women (a group that experiences a relatively high rate of preventive labor induction) compare to the birth outcomes of another group of women (a group that experiences a more standard rate of labor induction for standard indications).” Although the practice-based perspective is not commonly used in the retrospective study of the association between labor induction and cesarean delivery, we believe that it is an appropriate and valid approach.

Rates of primary cesarean delivery are always lower in multiparas as compared to nulliparas (5,6). This is largely due to a simple selection issue: multiparas are women who have successfully delivered vaginally and have never required cesarean delivery, while nulliparas are women who have not yet had a successful trial of labor. However, because multiparas make up the largest of the three obstetric groups (e.g., nulliparas, multiparas and VBACs), a reduction of primary cesarean delivery rates in the multiparous group would have a proportionally larger impact on population-based cesarean delivery rates. For example, in an idealized population containing 30% nulliparas (with cesarean delivery rate of 24%), 55% multiparas (with a cesarean delivery rate of 9%), and 15% VBACs (with a cesarean delivery

rate of 80%), an eight-percentage point decrease in cesarean delivery rate in the multiparous group would have almost twice the impact on the overall population cesarean delivery rate as an eight percentage-point reduction in the nulliparous group, and almost four-times the impact of an eight-percentage-point reduction in the VBAC group. For this reason, we believe that there should be an increased emphasis on the study of methods of care that could lower cesarean delivery rates, and rates of other adverse birth outcomes, in multiparas.

As noted in this study, a group with a higher rate of preventive labor induction would be expected to have an average gestational age at delivery that is lower than a group exposed to a lower labor induction rate. Several recent studies reported increasing rates of adverse birth outcomes, including cesarean delivery, as a function of increasing gestational age during the term period of pregnancy (32–34). Progressive fetal growth is known to occur within the term period of pregnancy (35) and might explain the increasing likelihood of obstructed labor with increasing gestational age. In addition, multiparas, as compared to nulliparas, are more likely to have a high BMI at conception, develop gestational diabetes, and measure large-for-dates (36–37). These three factors would be expected to increase the weight of a fetus at any given gestational age in the late term period, thereby exacerbating the gestational age-related risk of cephalo-pelvic disproportion. In addition, progressive placental aging is also known to occur during the term period of pregnancy (35), and might explain the increasing likelihood of fetal intolerance of labor with increasing gestational age. Multiparas are also more likely to have chronic hypertension, advanced maternal age, and iron-deficiency anemia (38,39). These three risk factors would be expected to decrease the quality of placental function at any given gestational age in the late term period, thereby exacerbating the gestational age-related risk of utero-placental insufficiency. Hence, despite the link between multiparity and low cesarean delivery rate, the use of a more active management style, i.e., one that uses preventive labor induction to promote delivery relatively early in the term period, might lower even further the already reduced risk of cesarean delivery in multiparous women.

Some investigators have attempted to model multiple risk factors in order to predict cesarean risk (40,41). We believe that early models were only partially successful because they did not include gestational age as a covariate. More recently, gestational age has been used in modeling (42,43), but the purpose of this modeling was to predict increased risk of cesarean delivery at later gestational ages and to support the use of elective cesarean delivery during the late term period. In contrast, AMOR-IPAT uses predicted risk to guide the use of labor induction early in the term period of pregnancy so as to avoid the most common indications for cesarean delivery. With reference to planned delivery early in the term period, some critics have questioned the relationship between AMOR-IPAT and iatrogenic neonatal pulmonary problems. While one exposed infant developed respiratory insufficiency following an indicated induction for decreased fetal movement and a non-reactive NST, we did not encounter any neonates in this study that required NICU admission for pulmonary problems following early term preventive labor induction. However, it is important to emphasize that careful pregnancy dating, and the use of documented informed consent, are essential components of AMOR-IPAT (9).

Our study has several potential limitations. First, it is possible that factors other than AMOR-IPAT exposure may have accounted for some or all of the difference in outcomes between the exposed and non-exposed groups. However, an indirect standardization indicated similar levels of pre-38 week risk for cesarean risk in the two study groups. Second, exposed women came from three different family medicine offices and the non-exposed women came from six different obstetrics offices. Possible differences in charting styles may have led to information bias, and different styles of labor management may have affected the primary outcomes. It is well known that a variety of provider characteristics

have a significant impact on group cesarean delivery rates. However, most of the variables used in the logistic regression model were well defined and easily captured, e.g., standard demographic variables (age, insurance status, marital status), laboratory values (hemoglobin, Group B strep status), and clinical variables (height, substance abuse, type of analgesia). There was no evidence to suggest that the criteria for cesarean delivery were differentially applied by the two specialties, and all cesarean deliveries were performed by the obstetrics group. Finally, the study took place in an urban setting, was performed at an academic institution, and involved primarily African-American women. Hence, the generalizability of this study to other setting is unclear. However, the results of this paper are similar to those noted in the multiparas of a large retrospective study (n=1969) that involved rural Caucasian women from a non-academic setting(10).

Despite these limitations, this study found a strong association between AMOR-IPAT and two related outcomes in multiparous women: a very low cesarean delivery rate and a higher uncomplicated vaginal delivery rate. While the active intervention used in AMOR-IPAT, i.e. labor induction, is generally associated with higher levels of adverse birth outcomes, the impact of the increased use of preventive labor induction, with attention to pre-induction cervical ripening, and from a practice-based perspective rather than a mode-of-labor-onset perspective, has not been previously considered. The findings of this study describe a possible means to safely lower cesarean delivery utilization in multiparous women. An adequately-powered randomized controlled study involving the impact of AMOR-IPAT on cesarean delivery in multiparas is needed to further investigate these findings.

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Key:

Exp_spont = AMOR-IPAT exposed women who entered labor spontaneously

Exp_iol = AMOR-IPAT exposed women who entered labor following induction of labor

nonExp_spont = nonAMOR-IPAT exposed women who entered labor spontaneously

nonExp_iol = nonAMOR-IPAT-exposed women who entered labor following induction of labor

Key:

Exp_vag = AMOR-IPAT exposed women who delivered vaginally

Exp_cs = AMOR-IPAT exposed women who delivered by cesarean section

nonExp_vag = nonAMOR-IPAT exposed women who delivered vaginally

nonExp_cs = nonAMOR-IPAT-exposed women who delivered by cesarean section

Figure 1.

Figure 1a. Delivery of Study Groups as a function of gestational age—This is a figure that shows in bar-graph form the distribution of timing of delivery by gestational age in the two study groups.

Figure 1b. Mode of Onset of Labor of Study Groups as a function of gestational age—This is a figure that shows in bar-graph form the distribution of induction of labor by gestational age in the two study groups.

Figure 1c. Route of Delivery of Study Groups as a function of gestational age—This is a figure that shows in bar-graph form the distribution of cesarean delivery by gestational age in the two study groups.

A. Utero-placental Factors: Odds Ratio Time Units

Hx chronic hypertension	1.8	6 days	_____
Gestational Diabetes	1.8	6 days	_____
Insulin Dependent Diabetes	2.4	10 days	_____
Sickle Cell Trait	1.5	3 days	_____
Elevated AFP	1.4	3 days	_____
Cigarette Use	1.3	2 days	_____
Size < Dates (<= 3 cm)	1.6	4 days	_____
Advanced Age (>= 35 years at delivery)	1.8	6 days	_____
Anemia (1 st Trimester <= 10.0)	1.6	4 days	_____

TOTAL UPI Time Units _____

ULOTD-upi = (41 weeks – Total UPI Time Units) = _____

B. Cephalo-Pelvic Factors: Odds Ratio Time Units

Elevated BMI (>=30)	1.3	2 days	_____
Short stature (<= 62")	1.8	6 days	_____
Excess Weight gain (>= 30 lbs)	1.8	6 days	_____
Size > dates (>= 3 cm)	1.7	4 days	_____
Gestational Diabetes	1.8	6 days	_____
Type I Diabetes	2.4	10 days	_____
History vacuum/forceps	2.2	9 days	_____
Prev. macrosomia (>=4000 gm)	2.0	7 days	_____

TOTAL CPD Time Units _____

ULOTD-cpd = (41 weeks – Total CPD Time Units) = _____

FINAL ULOTD: Lower of the two ULOTD's (ULOTD-upi versus ULOTD-cpd), but the final ULOTD is always ≥ 38 weeks.

Appendix 1.

AMOR-IPAT-UL-OTD Calculation Sheet—this figure describes how the timing of preventive labor induction was determined in the AMOR-IPAT exposed group

Table 1

Levels of Risk Factors by Study Group

VARIABLE NAME	Exposed n=123	nonExposed n=304	Risk Ratio	95% CI	p value
DEMOGRAPHICS					
Age, median	25.7 years	27.3 yrs			0.005*
Advanced Age (>= 35 years at delivery)	8.9%	13.5%	0.66	0.35-1.25	0.25
African-American	85.4%	74.3%	1.14	1.04-2.27	0.015
Medicaid Insurance	69.1%	48.0%	1.44	1.22-1.70	< 0.001
Single Marital Status	80.5%	65.5%	1.23	1.09-1.39	0.002
PAST MEDICAL					
Previous TAB	34.2%	34.9%	0.98	0.73-1.31	0.91
Previous SAB	31.7%	26.6%	1.19	0.86-1.64	0.34
Chronic Hypertension	8.1%	3.6%	2.25	0.98-5.15	0.08
Asthma	18.7%	9.5%	1.96	1.18-3.25	0.01
Type I Diabetes	0%	0.3%	0.00	~	0.52
Sickle Cell Trait	1.6%	3.0%	0.55	0.12-2.51	0.74
Cigarette Use	28.5%	21.7%	1.31	0.92-1.86	0.17
Alcohol Use	11.4%	5.3%	2.16	1.09-4.29	0.04
PAST OB					
Previous Small Infant (<5lb 8oz)	28.5%	13.8%	2.06	1.39-3.06	<0.001
Previous Large Infant (>8lb 8oz)*	16.3%	10.5%	1.54	0.92-2.59	0.10
Previous vacuum or forceps delivery	10.6%	5.3%	2.16	1.00-4.05	0.05
LABORATORY					
1 hr Glucola > 135	10.6%	12.2%	0.74	0.47-1.58	0.74
Hemoglobin (1 st or 2 nd trimester <= 11)	26.0%	13.8%	1.88	1.25-2.84	0.003
Group B Strep culture positive	33.3%	29.0%	1.15	0.85-1.56	0.37
MATERNAL HABITUS					
Preconception weight, median	169.5 lbs	151.5 lbs			0.05
Preconception weight > 180 lbs	42.3%	29.3%	1.41	1.08-1.85	0.01

VARIABLE NAME	Exposed n=123	nonExposed n=304	Risk Ratio	95% CI	p value
Height, mean	65 in	65 in			1.00 *
Height < 62 inches	25.2%	19.1%	1.32	0.90–1.94	0.19
Preconception BMI, median (kg/m ² m)	28.3	25.9			0.05 *
Preconception BMI > 30	36.6	29.3%	1.25	0.93–1.67	0.14
INDEX PREGNANCY					
Weight Gain during pregnancy, median	23 lb	29 lb			< 0.001 *
Excess Weight Gain (>= 30 lbs)	28.5%	47.0%	0.60	0.45–0.82	< 0.001
Gestational Diabetes	3.25%	2.3%	1.41	0.42–4.74	0.54

* calculated with the Mann Whitney rank-sum test

Table 2

Levels of Intrapartum Variables/Factors by Study Group

VARIABLE NAME	Exposed n=123	non-Exposed n=304	Risk Ratio	95% CI	p value
SUBJECT STATUS ON ADMISSION					
Gestational age on admission, (median)	38.7 wks	39.9 wks			< 0.001
□□ Gestational age ≥ 41 weeks 0 days	4.9%	17.4%	0.28	0.12–0.63	< 0.001
□□ Gestational age ≥ 42 weeks 0 days	10.6%	27.3%	0.39	0.22–0.67	< 0.001
Ruptured Membranes on admission	10.6%	27.3%	0.39	0.22–0.67	< 0.001
Initial Bishop's Score, median	5	8	–	–	< 0.001
Initial Bishop's Score ≤ 5	50.4%	27.3%	1.85	1.43–2.78	< 0.001
Mean Arterial Pressure on admission (MAP–mmHg))	86.7	89.8			0.01
Mean Arterial Pressure (MAP) on admission ≥= 105	5.7%	8.2%	0.69	0.31–1.30	0.42
Mean Arterial Pressure at one hour (MAP–mmHg))	85.7	89.3			0.05
Mean Arterial Pressure (MAP) at one hour ≥= 105	8.1%	7.6%	1.07	0.53–2.19	0.84
Vertex Presentation	98.4%	98.7%	1.24	0.23–6.66	0.81
LABOR ONSET					
Spontaneous labor without augmentation	20.3%	40.1%	0.51	0.35–0.74	< 0.001
Induction of Labor Rate, all	61.0%	16.4%	3.71	2.77–4.96	< 0.001
-Induction with Prostaglandin (any)	28.5%	4.0%	7.21	3.87–13.4	< 0.001
-Induction with Prostaglandin E1 **	17.1%	3.3%	5.19	2.52–10.70	< 0.001
-Induction with Prostaglandin E2 **	13.0%	0.7%	19.77	4.61–84.7	< 0.001
Augmentation of labor ***	18.7%	42.1%	0.44	0.30–0.66	< 0.001
Elective Cesarean Delivery	0%	1.3%	0	–	0.20
INTRA-PARTUM EVENTS					
Use of Pitocin (any)	70.7%	50.7%	1.40	1.19 0 1.64	0.03
Use of Prostaglandins (any)	28.5%	6.9%	4.12	2.50–6.78	< 0.001
Artificial Rupture of Membranes	70.7%	54.9%	1.29	1.11–1.50	0.003
Epidural Analgesia	45.5%	74.3%	0.61	0.50–0.75	< 0.001
Placement of Internal Electrode	34.2%	26.6%	1.28	0.94–1.74	0.13

VARIABLE NAME	Exposed n=123	non-Exposed n=304	Risk Ratio	95% CI	p value
Placement of IUPC	8.1%	23.4%	0.35	0.19–0.65	<0.001
Use of Vacuum or Forceps	9.8%	9.9%	0.99	0.52–1.87	1.00
INTRAPARTUM FINDINGS					
Thick Meconium at ROM	4.9%	13.8%	0.35	0.15–0.81	0.007
Fetal Intolerance to Labor (repetitive late decelerations)	3.3%	10.3%	0.32	0.11–0.88	0.02
Maternal Fever (Temp > 101)	0.8%	1.6%	0.49	0.06–4.19	0.68
Labor Timing **					
Admission-delivery	11.6 hours	7.3 hours			<0.001 *
1 st stage–median ****	258 min	280 min			0.04 *
1 st stage > 8 hr *****	22.0%	10.9%	2.02	1.27–3.21	0.005
2 nd stage–median	14 min	17 min			0.05 *
2 nd stage > 1 hr	8.1%	11.8%	0.69	0.35–1.34	0.30

* Mann Whitney rank-sum test

** Some inductions in the exposed group involved both types of prostaglandins

*** Augmented labor includes both slow labor and premature rupture of membranes without labor

***** Onset of labor in this study was defined by objective documentation of cervical change, so women in this study who presented the hospital after cervical change had begun had a truncation of their actual duration of the first stage of labor.

Table 3

Induction of Labor and Cesarean Delivery Information: Overall Rates and Indications*

VARIABLES:	Exposed n=123	nonExposed n=304	Risk Ratio	95% CI	p value
INDUCTION OF LABOR INFORMATION:					
Induction of Labor Rate, overall	61.0% (75)	15.8% (48)	3.86	2.87–5.19	<0.001
Indicated Induction	15.4% (18)	12.5% (38)	1.23	0.74–2.06	0.42
Elective Induction	45.5% (57)	3.3% (10)	13.8	7.30–26.2	<0.001
Reasons for Indicated Induction					
PreEclampsia	3.3% (4)	2.6% (8)	1.24	0.38–4.03	0.73
> 41 weeks	2.4% (3)	4.3% (16)	0.23	0.07–0.80	0.01
Oligohydramnios/TUGR	5.7% (7)	3.3% (10)	1.73	0.67–4.44	0.25
Gestational Diabetes	0% (0)	1.0% (3)	–	–	0.26
Non-reassuring Antenatal Testing	1.6% (2)	0.3% (1)	4.94	0.45–54.0	0.15
History of rapid labor	1.6% (2)	0.7% (2)	2.47	(0.35–17.3)	0.35
History of term stillbirth	0% (0)	0.3% (1)	–	–	0.52
Reasons for Elective Induction					
Impending PreEclampsia	2.4% (3)	1.3% (4)	1.85	0.42–8.16	<0.001
Impending Cephalo-Pelvic Disproportion	29.2% (36)	0% (0)	–	–	<0.001
Impending Utero-Placental Insufficiency	8.1% (10)	0.0% (0)	–	–	<0.001
Risk of precipitous labor	3.3% (4)	0.3% (1)	9.89	1.12–87.6	0.01
Unstable Lie	1.6% (2)	0% (0)	–	–	0.03
Social/Miscellaneous	1.6% (2)	1.6% (5)	0.99	0.19–5.02	0.99
CESAREAN DELIVERY INFORMATION:					
Cesarean deliveryRate	0.8% (1/123)	9.9% (30/304)	0.08	0.01–0.60	<0.001
Indications for C-section:					
Fetal Intolerance	0%	4.0%	–	–	0.02
Failure to Progress	0%	3.6%	–	–	0.04
Malpresentation (breech)	0%	1.3%	–	–	0.58
Active Herpes	0%	1.0%	–	–	0.56
Hemorrhage due to Marginal Placenta Previa	0.3%	0%	–	–	0.28

VARIABLES:	Exposed n=123	nonExposed n=304	Risk Ratio	95% CI	p value
Occurance of Cesarean Delivery by Mode of Labor Onset					
Spontaneous labor	0% (0/48)**	7.2% (22/234)**	–	–	0.002
Indicated Induction of Labor	0.8% (1/18)**	2.6% (8/38)**	0.31	0.04–2.44	0.24
NICU INFORMATION					
NICU Admission (overall)	7.3%	8.6%	0.86	0.41–1.77	0.84
Sepsis-suspect or actual	2.4%	2.3%	1.35	0.51–3.56	0.59
Respiratory–persistent TTN, pneumonia, or amniotic fluid/meconium aspiration	2.4%	2.3%			
Hypoglycemia	0.8%	1.0%			
Cardiac arrhythmia	0.8%	0.8%			
GI problem	0%	0%			
Significant congenital problem	0.8%	0.3%			
Severe hyperbilirubinemia	0%	0.3%			
COMPOSITE OUTCOMES					
Adverse Outcome Index	4.1	4.7	–	–	0.23
Uncomplicated Vaginal Birth	78.9%	66.4%	1.19	1.05–1.34	0.01

* when not specified, rates are based on entire study group

** percentages reflect proportion of all infant in each study group delivered by cesarean delivery as a function of mode of onset of labor; fractions represent proportion of infants delivered by cesarean delivery within each mode of labor onset group.

Table 4

Major Other Adverse Outcomes based on AMOR-IPAT exposure status

VARIABLE	Exposed n=123	Non-Exposed n=304	Risk Ratio	95% CI	p-value
MATERNAL-Delivery					
3 rd or 4 th Degree Perineal Injury	0%	4.3%	-	-	0.04
Severe Shoulder Dystocia	3.2%	4.0%	0.73	0.27-2.50	0.73
Estimated Blood Loss, all	326cc ± 192	423cc ± 236	-	-	< 0.001*
Excess Blood Loss (>500 cc), all	8.9%	13.5%	0.66	0.35-1.25	0.19
Excess Blood Loss (>500 cc), vag only	4.1%	5.5%	0.75	0.28-2.01	0.56
MATERNAL-Post-Partum					
Maternal fever (>100.4)	0.8%	4.0%	0.21	0.03-1.57	0.12
Post Partum hemoglobin, median	9.9 ± 1.6	10.3 ± 1.4	-	-	0.02
Post Partum anemia (Hgb<8)	10.6%	6.6%	1.61	0.83-3.13	0.17
Flux in hemoglobin with delivery	0.92 gms±1.03	1.16 gms±1.12	-	-	0.08*
NEONATAL					
Thick Meconium at Rupture of Membranes	4.9%	13.8%	0.35	0.15-0.81	0.01
Cephalo-hematoma	0.8%	3.6%	0.22	0.03-1.72	0.11
Erb's Palsy	0.8%	1.0%	0.82	0.09-7.84	0.87
Pulmonary Hypertension	0.8%	0.3%	2.47	0.09-39.2	0.51
Clavicle Fracture	0.8%	0.0%	2.47	0.09-39.2	0.51
Humeral Fracture	0%	0.3%	2.47	0.09-39.2	0.51
Birth weight	3213 gm ± 419	3427 gm ± 485	-	-	< 0.001*
Low Birth Weight (< 2500 grams)	3.2%	2.3%	1.4	0.42-4.74	0.57
Small (< 6lb 8oz)	28.5%	13.8%	2.06	1.39-3.06	< 0.001
Large (> 8lb 7oz)	5.7%	17.4%	0.33	0.15-0.70	0.001
Head circumference	33.4 cm ± 2.0	34.1 cm ± 1.6	-	-	< 0.001*
□□ Venous Cord Blood pH ≤ 7.2	0%	2.3%	-	-	0.20
APGAR@ 5 min < 7	0.8%	1.0%	0.82	0.09-7.84	0.87
APGAR@ 5 min < 4	0%	0.3%	-	-	1.00

* calculated with the Mann Whitney rank-sum test

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Appendix 2

Development of Adverse Outcome Index by Group

VARIABLE NAME	Exposed, n=123 number (rate)	NonExp, n= 304 number (rate)	Weights
1. Maternal Death	0 (0%)	0 (0%)	750
2. Intrapartum or neonatal death	0 (0%)	0 (0%)	400
3. Uterine rupture	0 (0%)	0 (0%)	100
4. Maternal ICU admission	0 (0%)	1 (0.3%)	65
5. Infant Birth Trauma (Erbs palsy, vacuum or forceps injury)	3 (2.4%)	5 (1.6%)	60
6. Return to operating room of labor and delivery unit	0 (0%)	0 (0%)	40
7. Admission to NICU	8 (6.6%)	25 (8.2%)	35
8. Apgar score less than 7 at 5 minutes	1 (.8%)	3 (1.0%)	25
9. Maternal blood transfusion	1 (.8%)	2 (0.67%)	20
10. Third-or fourth-degree perineal tear	0 (0%)	13 (4.3%)	5
Adverse Outcome Score (mean)	4.1	4.7	P=0.23
Overall Frequency of at least one adverse outcome	11 (8.9%)	41 (13.5%)	P=0.19

Appendix 3

Development of the Uncomplicated Vaginal Delivery Rate by Study Group

VARIABLE NAME	Exposed, n=123 number (rate)	NonExp, n= 304 number (rate)	p-value
Cesarean Delivery	1 (0.8%)	30 (9.9%)	0.001
Assisted Vaginal Delivery (vacuum or forceps)	12 (9.8%)	30 (9.9%)	0.97
Shoulder dystocia (severe)	4 (3.2%)	12 (4.0%)	0.73
Major perineal trauma (3 rd -or 4 th -degree injury)	0 (0%)	13 (4.3%)	0.02
Post-partum hemorrhage (vaginal delivery, EBL > 500 cc's)	6 (4.9%)	42 (13.8%)	0.008
NICU Admission	8 (6.5%)	25 (8.2%)	0.55
Overall frequency of complicated vaginal delivery (at least one complication)	26 (21.1%)	102 (33.6 %)	0.01
Overall frequency of uncomplicated vaginal delivery (none of the five identified adverse outcomes)	97 (78.9%)	202 (66.4%)	0.01