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Non-medically indicated induction vs. expectant management in term nulliparas

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Abstract

Objective—To compare maternal and neonatal outcomes in nulliparous women with non-medically indicated inductions at term versus those expectantly managed.

Study Design—Data were obtained from maternal and neonatal charts for all deliveries on randomly selected days across 25 US hospitals over a three-year period. A low-risk subset of nulliparas with vertex non-anomalous singleton gestations who delivered 38 0/7 to 41 6/7 weeks were selected. Maternal and neonatal outcomes for non medically indicated induction within each

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week were compared with women who did not undergo non medically indicated induction during that week. Multivariable analysis was used to adjust for hospital, maternal age, race/ethnicity, body mass index, cigarette use and insurance status.

Results—31,169 women met criteria. Neonatal complications were either less frequent with non medically indicated induction or no different between groups. Non medically indicated induction was associated with less frequent peripartum infections (OR 0.39, 95%CI 0.16–0.98) at 38 weeks and less frequent third and fourth degree lacerations (OR 0.60, 95%CI 0.42–0.86) and less frequent peripartum infections (OR 0.66, 95% CI 0.49–0.90) at 39 weeks. Non medically indicated induction was associated with a longer admission-to-delivery time by approximately 3 to 4 hours and increased odds of cesarean delivery at 38 weeks (OR 1.50 95%CI 1.08–2.08) and 40 weeks (OR 1.30, 95%CI 1.15–1.46).

Conclusion—At 39 weeks, non medically indicated induction is associated with lower maternal and neonatal morbidity than women expectantly managed.

INTRODUCTION

Traditionally non-medically indicated induction of labor has been thought to increase cesarean delivery and thus maternal complications, especially in nulliparous patients.¹ However, many of the studies that have led to this conclusion have compared women undergoing induction with those in spontaneous labor.^{2–4} Unfortunately, spontaneous labor is not the actual alternative to induction that is available to physicians, and the appropriate comparison group should be composed of women undergoing expectant management.⁵

Previous studies comparing expectant management with non-medically indicated induction of labor have used administrative data or have been from single centers.^{5–7} The coding of labor induction indication is known to be inaccurate within administrative data,^{8,9} making these data sets suboptimal for these types of studies. Single center studies have been hampered by a sample size that is either too small to detect meaningful differences or a time frame that is so long that relevance to contemporary practice is uncertain.

The APEX (Assessment of Perinatal EXcellence) study, conducted by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Maternal-Fetal Medicine Units (MFMU) Network, utilized direct chart abstraction by trained research personnel to collect information on intrapartum care from 25 geographically dispersed hospitals. This database provides a resource that can provide the information necessary to help evaluate the consequence of non medically indicated induction. The present study is a secondary analysis of the APEX data that compares maternal and neonatal outcomes for nulliparas who undergo non medically indicated induction of labor with those of nulliparas who are expectantly managed.

METHODS

Between 2008 and 2011, we assembled a cohort of women and their neonates born in any of the 25 hospitals in the MFMU Network. This study, the Assessment of Perinatal EXcellence (APEX), was designed to develop quality measures for intrapartum obstetrical care. The

APEX study was approved by the Institutional Review Board at each participating institution under a waiver of informed consent. This manuscript is a planned secondary analysis of the data collected during APEX.

A full description of the methods of data collection has been described previously.¹⁰ In short, any patient who delivered at a hospital, was at least 23 weeks of gestation, and had a live fetus on admission was included. Data were collected on randomly selected days, chosen via computer-generated random selection, occurring over a three-year period (March 2008 to February 2011). The medical records for all eligible women and babies were abstracted by trained and certified research personnel and entered into a web-based data entry system. Data recorded included demographic characteristics, details of the medical and obstetrical history, information about intrapartum and postpartum events, and maternal and neonatal outcomes data. Maternal data were collected until discharge and neonatal data were collected up until discharge or until 120 days of age, whichever came first.

The present analysis includes nulliparous women with singleton, vertex, non-anomalous gestations who delivered between 38 0/7 and 41 6/7 weeks. We excluded women delivering beyond 41 6/7 as they were post dates and by definition had an indication for induction. Additionally, women in our analysis did not have a scheduled non-medically indicated cesarean delivery. Additionally they did not have any of the following: pregestational or gestational diabetes mellitus, placenta accreta, placenta previa, placental abruption, use of anticoagulation, prior myomectomy, cocaine/methamphetamine use, chronic hypertension, or preeclampsia diagnosed before 38 weeks. This was done to insure that we had a low-risk cohort that was eligible for a non medically indicated induction as opposed to an indicated induction. Women were classified as having had a non medically indicated induction if they were coded as having had an “elective” induction or if an induction was performed without any other medical indication apparent in the chart. The study group assignment to non medically indicated vs. expectantly managed was assigned after the entire data set was collected.

Maternal outcomes chosen *a priori* were: postpartum hemorrhage, 3rd and 4th degree lacerations, peripartum infection, mode of delivery, time from admission to delivery, and delivery to discharge. Neonatal outcomes chosen *a priori* were: NICU admission, hyperbilirubinemia requiring treatment, an adverse respiratory outcome composite (respiratory distress syndrome, continuous positive airway pressure, or ventilator support started within 24 hours of birth on one or more days delivery), and an adverse neonatal outcome composite (5 minute Apgar score < 4, skeletal fracture other than of the clavicle, facial nerve palsy, brachial plexus palsy, subgaleal hemorrhage, ventilator support within 24 hours on two or more days, hypoxic ischemic encephalopathy, stillbirth after hospital admission or neonatal death).

Maternal and neonatal outcomes for women who underwent non medically indicated induction within each week of gestation were compared with those of women who reached that week and were expectantly managed (i.e., they did not undergo a non medically indicated induction). For example, women who underwent a non medically indicated induction at 38 weeks were compared with those who did not undergo a non medically

indicated induction at 38 weeks and thus were expectantly managed from 38 week on. Women in the expectantly managed group could go on to go into labor or to develop an indication for delivery. Women who developed an indication for induction and were delivered while in the expectant management group remained in the expectant management group. Multivariable regression was used to adjust for hospital, maternal age, race/ethnicity, body mass index, cigarette use and insurance status. Odds ratios, adjusted means and their 95% confidence intervals are presented. All tests were two-tailed and $P < .05$ was used to define statistical significance. No imputation for missing data was performed. Analyses were performed using SAS software (SAS Institute, Cary, NC).

RESULTS

Data were collected from 115,502 women, of whom 31,169 women met our inclusion criteria. The majority of eligible women were in their twenties, were non-Hispanic white, and were non-smokers. Most women had a BMI over 25 kg/m². Women undergoing non medically indicated induction were more likely to have private insurance, be of older maternal age, and obese. (Table 1)

Neonatal complications were either less frequent or not different in association with non medically indicated induction (Tables 2–4). In particular, NICU admission (OR 0.66, 95%CI 0.47–0.93) and the respiratory composite (OR 0.62, 95% CI 0.41–0.94) were lower among women who underwent non medically indicated induction at 39 and at 40 weeks, respectively.

Peripartum infections were less frequent in association with non medically indicated induction at 38 and 39 weeks of gestation. In addition, those women undergoing non medically indicated induction at 39 weeks were less likely to have a third and fourth degree laceration. Non medically indicated induction was associated with a significantly higher frequency of cesarean delivery at 38 and 40 weeks with an odds ratio of 1.50 (95% CI 1.08–2.08) and 1.30 (95% CI 1.15–1.46), respectively, but was not associated with an increased frequency of cesarean at 39 weeks of gestation. Admission-to-delivery time was longer for women undergoing non medically indicated induction by approximately 3 to 4 hours, but delivery to discharge time was no different between the groups.

Table 5 shows the reasons for delivery in the expectantly managed group. Spontaneous labor was the majority of cases with reaching post dates (41 0/7 weeks), preeclampsia, oligohydramnios and non reassuring fetal status or IUGR being the most common reasons for delivery.

COMMENT

Among our cohort of low-risk nulliparous women, those having non medically indicated induction were less likely to have several maternal and neonatal complications compared with those who were expectantly managed. In addition, there appeared to be no difference in the chance of cesarean when non medically indicated induction was performed at 39 weeks, although the chance of cesarean delivery was statistically higher when the non medically indicated induction was performed at either 38 or 40 weeks. The differences in maternal

outcomes are clinically significantly different as well as statistically significant, for example a difference of 2.4% to 10.6% for maternal infection at 38 weeks and 5.8% to 11.1% for maternal infection at 39 weeks.

Our data help contribute to the understanding of the consequences related to non medically indicated induction in nulliparous women. Prior studies that have documented an increase in cesarean with labor induction largely have compared women undergoing labor induction with those in spontaneous labor. Yet, when women undergoing labor induction have been compared with women undergoing the actual clinical alternative – that is, expectant management – that increase has not been documented, even for women with an unfavorable cervix.^{11–13} Our results support this finding for women at 39 weeks of gestation but not at 38 and 40 weeks. Studies have also suggested perinatal benefit from labor induction with regard to meconium aspiration syndrome and perinatal mortality, as well as improvement in outcomes when induction was done for hypertension/preeclampsia.^{14 15 16} Our work support and extend the evidence for perinatal benefit with regard to respiratory morbidity and NICU admission.

This study did not examine outcomes before 38 weeks because there were so few examples of non-medically indicated induction before this time. Furthermore, previous studies have examined neonatal outcomes^{17, 18} and demonstrated that perinatal outcomes are worse prior to 39 weeks. Nothing in this study would call into question the current recommendations to avoid non medically indicated induction deliveries before 39 weeks. We did not examine stillbirths because a live fetus on arrival was part of the entry criteria for the study and thus we did not have adequate data to study stillbirths. The lack of information about stillbirths would make expectant management seem to have fewer risks than it does in reality. We did not account for Bishop score because it was not collected in the parent study for women undergoing expectant management. The lack of Bishop score data could bias the study towards making non-medically indicated inductions seem more advantageous as this group may have had more women with favorable cervixes than the expectant management group.

While administrative data have the advantage of capturing a large number of hospitals and subjects for analysis, it has the disadvantage of lacking sensitivity and specificity when it comes to accurately determining non medically indicated induction.^{8, 9} The quality of the data used in our study is high in that data were abstracted by trained personnel and data entry was checked by edits and audits. In the context of observational studies, cohort analyses using high quality data will provide the best possible answer regarding the consequences of non medically indicated induction. Nevertheless, this study, as well as other observational studies before it, cannot eliminate the possibility of bias and unmeasured confounding. The suggestion, however, that non medically indicated induction may not be associated with worse perinatal outcomes and may improve maternal outcomes underscore the need for a randomized trial.¹⁹

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Appendix

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Table 1

Demographic characteristics, N (%)

	38 weeks		39 weeks		40 weeks	
	Non Medically Indicated Induction	Expectant Management	Non Medically Indicated Induction	Expectant Management	Non Medically Indicated Induction	Expectant Management
N	210	28468	815	23212	1676	14086
Maternal age, years						
< 20	25 (11.9)	5547 (19.5)	108 (13.3)	4421 (19.1)	208 (12.4)	2618 (18.6)
20–24.9	67 (31.9)	7607 (26.7)	262 (32.2)	6164 (26.6)	403 (24.1)	3674 (26.1)
25–29.9	72 (34.3)	7144 (25.1)	254 (31.2)	5850 (25.2)	499 (29.8)	3500 (24.9)
30–34.9	29 (13.8)	5914 (20.8)	132 (16.2)	4901 (21.1)	387 (23.1)	3079 (21.9)
> 35	17 (8.1)	2256 (7.9)	59 (7.2)	1876 (8.1)	179 (10.7)	1215 (8.6)
Race/ Ethnicity						
Non-Hispanic white	77 (36.7)	13518 (47.5)	516 (63.3)	11203 (48.3)	1018 (60.7)	7081 (50.3)
Non-Hispanic black	80 (38.1)	5785 (20.3)	133 (16.3)	4669 (20.1)	269 (16.1)	2782 (19.8)
Non-Hispanic Asian	9 (4.3)	1895 (6.7)	53 (6.5)	1505 (6.5)	100 (6.0)	798 (5.7)
Hispanic	35 (16.7)	5461 (19.2)	80 (9.8)	4363 (18.8)	219 (13.1)	2565 (18.2)
Other	9 (4.3)	1809 (6.4)	33 (4.1)	1472 (6.3)	70 (4.2)	860 (6.1)
Body mass index, kg/m ²						
<25	38 (18.1)	3962 (14.1)	128 (15.8)	3022 (13.2)	167 (10.0)	1620 (11.7)
25–29.9	65 (31.0)	11552 (41.2)	302 (37.3)	9512 (41.6)	632 (37.9)	5692 (41.0)
30–34.9	57 (27.1)	7680 (27.4)	231 (28.5)	6294 (27.5)	507 (30.4)	3966 (28.6)
35–39.9	30 (14.3)	3080 (11.0)	102 (12.6)	2545 (11.1)	202 (12.1)	1635 (11.8)
>=40	20 (9.5)	1772 (6.3)	47 (5.8)	1501 (6.6)	159 (9.5)	979 (7.1)
Smoking						
	14 (6.7)	2178 (7.7)	53 (6.5)	1803 (7.8)	143 (8.5)	1116 (7.9)
Private insurance	112 (53.3)	15540 (55.1)	580 (71.3)	12724 (55.3)	1160 (69.5)	7726 (55.4)

The distributions of maternal age, race/ethnicity and body mass index were significantly different between non medically indicated induction and expectant groups at 38, 39 and 40 weeks. Insurance status was significantly different at 39 and 40 weeks only.

Table 2

Adjusted* odds ratios, adjusted* means and 95% confidence intervals for non-medically indicated induction at 38 weeks vs. expectant management and outcomes

	Non Medically Indicated Induction N (%)	Expectant Management N (%)	OR	95%CI
Neonatal outcomes:				
Neonatal intensive care unit admission	12 (5.7)	2201 (7.7)	1.17	0.63–2.20
Respiratory composite	3 (1.4)	574 (2.0)	1.62	0.48–5.49
Hyperbilirubinemia requiring treatment	9 (4.3)	1288 (4.5)	1.09	0.53–2.24
Neonatal composite	0 (0.0)	220 (0.8)	-	-
Maternal Outcomes:				
Postpartum hemorrhage	0 (0.0)	519 (1.9)	-	-
Third and fourth degree lacerations	8 (3.8)	1710 (6.0)	0.54	0.26–1.13
Peripartum infection	5 (2.4)	3009 (10.6)	0.39	0.16–0.98
Mode of delivery				
Spontaneous vaginal	124 (59.1)	19246 (67.6)		
Operative vaginal	15 (7.1)	2797 (9.8)	0.88	0.50–1.55
Cesarean	71 (33.8)	6425 (22.6)	1.50	1.08–2.08
	Non Medically Indicated Induction		Expectant Management	
	Median (interquartile range)	Adjusted mean (95%CI)	Median (interquartile range)	Adjusted mean (95%CI)
Time from labor and delivery admission to delivery in hours	16 (14–20)	17.85 (16.67–19.03) [†]	11 (7–16)	13.93 (13.70–14.16)
Time from delivery to discharge days	2 (2–3)	2.81 (2.51–3.11)	2 (2–3)	2.70 (2.64–2.75)

* Adjusted for maternal age, race/ethnicity, body mass index, cigarette use, insurance status and hospital

[†] P<0.05 in the generalized linear model

Table 3

Adjusted* odds ratios, adjusted* means and 95% confidence intervals for non-medically indicated induction at 39 weeks vs. expectant management and outcomes

	Non Medically Indicated Induction N (%)	Expectant Management N (%)	OR	95%CI
Neonatal outcomes:				
Neonatal intensive care unit admission	41 (5.0)	1809 (7.8)	0.66	0.47–0.93
Respiratory composite	14 (1.7)	482 (2.1)	0.69	0.39–1.20
Hyperbilirubinemia requiring treatment	47 (5.8)	1004 (4.3)	1.01	0.73–1.40
Neonatal composite	7 (0.9)	178 (0.8)	1.51	0.68–3.35
Maternal Outcomes:				
Postpartum hemorrhage	9 (1.2)	442 (2.0)	0.79	0.39–1.58
Third and fourth degree lacerations	35 (4.3)	1451 (6.3)	0.60	0.42–0.86
Peripartum infection	47 (5.8)	2576 (11.1)	0.66	0.49–0.90
Mode of delivery				
Spontaneous vaginal	511 (62.7)	15366 (66.2)		
Operative vaginal	94 (11.5)	2314 (10.0)	1.10	0.87–1.40
Cesarean	210 (25.8)	5532 (23.8)	1.13	0.94–1.36
	Non Medically Indicated Induction		Expectant Management	
	Median (interquartile range)	Adjusted mean (95%CI)	Median (interquartile range)	Adjusted mean (95%CI)
Time from labor and delivery admission to delivery in hours	14 (10–19)	17.28 (16.66–17.91) [†]	11 (7–17)	14.20 (13.95–14.45)
Time from delivery to discharge days	2 (2–3)	2.78 (2.62–2.94)	2 (2–3)	2.71 (2.64–2.77)

* Adjusted for maternal age, race/ethnicity, body mass index, cigarette use, insurance status and hospital

[†] P<0.05 in the generalized linear model

Table 4

Adjusted* odds ratios, adjusted* means and 95% confidence intervals for non-medically indicated induction at 40 weeks vs. expectant management and outcomes

	Non Medically Indicated Induction N (%)	Expectant Management N (%)	OR	95%CI
Neonatal outcomes:				
Neonatal intensive care unit admission	126 (7.5)	1172 (8.3)	0.87	0.71–1.06
Respiratory composite	26 (1.6)	321 (2.3)	0.62	0.41–0.94
Hyperbilirubinemia requiring treatment	95 (5.7)	578 (4.1)	1.02	0.80–1.30
Neonatal composite	8 (0.5)	125 (0.9)	0.55	0.26–1.15
Maternal Outcomes:				
Postpartum hemorrhage	35 (2.2)	297 (2.2)	1.09	0.75–1.60
Third and fourth degree lacerations	99 (5.9)	938 (6.7)	0.82	0.66–1.03
Peripartum infection	143 (8.5)	1724 (12.2)	0.87	0.72–1.05
Mode of delivery				
Spontaneous vaginal	930 (55.5)	8861 (62.9)		
Operative vaginal	176 (10.5)	1453 (10.3)	1.05	0.88–1.26
Cesarean	570 (34.0)	3772 (26.8)	1.30	1.15–1.46
Non Medically Indicated Induction				
	Median (interquartile range)	Adjusted mean (95%CI)	Expectant Management	
			Median (interquartile range)	Adjusted mean (95%CI)
Time from labor and delivery admission to delivery in hours	17 (12–22)	18.86 (18.36–19.36) [†]	12 (8–18)	15.28 (14.96–15.60)
Time from delivery to discharge days	2 (2–3)	2.70 (2.59–2.81)	2 (2–3)	2.70 (2.63–2.77)

* Adjusted for maternal age, race/ethnicity, body mass index, cigarette use, insurance status and hospital

[†] P<0.05 in the generalized linear model

Table 5

Reasons for delivery in patients expectantly managed, N (%)

	Expectantly managed at 38 weeks n=28,468	Expectantly managed at 39 weeks N=23,212	Expectantly managed at 40 weeks 14,086
Spontaneous labor and/or premature rupture of membranes	22,072 (77.5)	17,619 (75.9)	9709 (68.9)
Reasons for indicated delivery			
Patient reached postterm (41 0/7 weeks)	2602 (9.1)	2602 (11.2)	2602 (18.5)
Preeclampsia/gestational hypertension	1530 (5.4)	1120 (4.8)	519 (3.7)
Oligohydramnios	1075 (3.8)	938 (4.0)	701 (5.0)
Non-reassuring fetal status or intrauterine growth restriction	811 (2.8)	621 (2.7)	371 (2.6)
Macrosomia	105 (0.4)	105 (0.5)	55 (0.4)
Cholestasis	48 (0.2)	24 (0.1)	5 (0.0)
Prior stillbirth	1 (0.0)	0 (0.0)	0 (0.0)
Infection	7 (0.0)	5 (0.0)	2 (0.0)
Injury/trauma	10 (0.0)	7 (0.0)	3 (0.0)
Other maternal medical condition (non-obstetrical)	110 (0.4)	77 (0.3)	28 (0.2)
Elective	97 (0.3)	94 (0.4)	91 (0.6)