

Infant Outcomes After Elective Early-Term Delivery Compared With Expectant Management

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OBJECTIVE: To compare the risk of neonatal morbidity and infant mortality between elective early-term deliveries and those expectantly managed and delivered at 39 weeks of gestation or greater.

METHODS: We conducted a population-based retrospective cohort study of 675,302 singleton infants born alive at 37–44 weeks of gestation from 2005 to 2009 in more than 125 birthing facilities in Florida. Data were collected from a validated, longitudinally linked maternal and infant database. The study population was categorized into exposure groups based on the timing and reason for delivery initiation—four subtypes of deliveries at 37–38 weeks of gestation and a comparison group of expectantly managed infants delivered at 39–40 weeks of gestation. Primary outcomes included neonatal respiratory morbidity, sepsis, feeding difficulties, admission to the neonatal intensive care unit (NICU), and infant mortality.

RESULTS: Neonatal outcome rates ranged from 6.0% for respiratory morbidities to 1.3% for both sepsis and feeding difficulties, and the infant mortality rate was 1.5 per 1,000 live births. When compared with infants expectantly managed and delivered at 39–40 weeks of

gestation, those delivered after elective induction at 37–38 weeks of gestation did not have increased odds of neonatal respiratory morbidity, sepsis, or NICU admission but did experience slightly higher odds of feeding difficulty (odds ratio 1.18, 99% confidence interval 1.02–1.36). In contrast, infants delivered by elective cesarean at 37–38 weeks of gestation had 13–66% increased odds of adverse outcomes. Survival experiences were similar when comparing early inductions and early cesarean deliveries with the expectant management group.

CONCLUSION: The issues that surround the timing and reasons for delivery initiation are complicated and each pregnancy unique. This study cautions against a general avoidance of all elective early-term deliveries.

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Although epidemiologic data support a beneficial effect of elective induction of labor for women at 41 weeks of gestation or greater,¹ the evidence regarding the effect of elective induction or cesarean delivery at earlier term gestations on the risk of neonatal morbidity and mortality has suggested an adverse effect. Several retrospective studies have reported poorer neonatal birth outcomes for early-term (37–38 weeks of gestation) compared with later term (39 weeks of gestation or greater) deliveries.^{2–7} However, many studies were conducted at a single institution or organization and do not reflect the variation across facilities regarding policies and procedures for scheduling inductions and cesarean deliveries. Most studies also lacked statistical power to investigate rare outcomes or to control adequately for confounders. More importantly, the increased risk conferred by elective early-term deliveries may be the result of an inappropriate choice of comparison group.^{8–10} By comparing elective early-term deliveries with later term spontaneous deliveries alone, studies may be overestimating adverse effects of elective early-term delivery. Because the clinical decision that

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must be made is a choice between elective early-term delivery and expectant management, in which the later delivery outcome remains unknown,^{9–12} the appropriate comparison group should consist of all infants who were candidates for elective early-term delivery but whose deliveries occurred at a later gestational age. We report the primary findings of a population-based study that defines a scientifically valid comparison group to investigate the association between elective early-term delivery and neonatal morbidity and infant mortality.

MATERIALS AND METHODS

We conducted a retrospective cohort study using data from a statewide maternal and infant longitudinally linked database.¹³ For each resident live birth in Florida from 1998 to 2009, we linked birth certificates to hospital discharge data and to death certificates from birth through December 31, 2010. We previously published an evaluation of the accuracy and reliability of our database.¹⁴ For this study, we considered singleton infants born alive at 37–44 weeks of gestation between January 1, 2005, and December 31, 2009 (Fig. 1). Births outside Florida, home births, and births in military hospitals were excluded. To focus on outcomes that occur at routine delivery hospitals, we also excluded facilities with less than 100 births per year. We then restricted to 675,302 infants who were candidates for the primary exposure by excluding those with a congenital anomaly diagnosed at birth and those whose mothers had medical or obstetric conditions that would justify delivery before 39 weeks of gestation¹⁵ or with documentation of drug or alcohol use during pregnancy.

The primary exposure in this study was elective early-term delivery, defined using information on both the timing and reason for delivery initiation. Although both the clinical estimate and date of last of menstrual period are susceptible to misclassification of gestational age, we used the clinical estimate as a result of its higher consistency with birth weight and better agreement with early ultrasound estimates.^{16–18} The reason for delivery initiation was based on information from birth certificates and discharge records. Because this study focuses on deliveries that either were or could have been electively delivered before 39 weeks of gestation, we first excluded women with a medical or obstetric condition existing before labor or delivery that would justify delivery at less than 39 weeks of gestation. Conditions were adapted from The Joint Commission's list, which is used in assessing national quality core measures for perinatal care (Appendix 1, available online at <http://links.lww.com/AOG/A780>).¹⁵ All other infants then were placed into one of three categories

(Appendix 2, available online at <http://links.lww.com/AOG/A780>). Spontaneous vaginal and cesarean deliveries after a noninduced trial of labor were classified as "spontaneous." Inductions and planned cesarean deliveries were first classified as "elective"; however, if a medical complication occurred only at delivery as opposed to being present before or during pregnancy (Appendix 3, available online at <http://links.lww.com/AOG/A780>), these were reclassified as "indicated." Deliveries in the "indicated" group were not excluded because their condition would not have been known until labor or delivery began; thus, they were still candidates for elective early-term delivery.¹⁹

The final exposure consisted of five levels: 1) electively induced delivery, 37–38 weeks of gestation; 2) elective cesarean delivery without a trial of labor, 37–38 weeks of gestation; 3) spontaneous delivery, 37–38 weeks of gestation; 4) medically indicated delivery, 37–38 weeks of gestation; and 5) delivery at 39–40 weeks of gestation after expectant management (full-term). The primary outcomes included respiratory morbidity, neonatal sepsis, feeding difficulties, and neonatal intensive care unit (NICU) admission captured using disease-specific indicators on the birth certificate and *International Classification of Diseases, 9th Revision, Clinical Modification* codes on the birth hospitalization discharge record (Appendix 4, available online at <http://links.lww.com/AOG/A780>), and infant mortality. In addition to diagnoses of respiratory conditions, infants requiring ventilation support were also considered to have respiratory morbidity. Neonatal sepsis included a specific diagnosis of septicemia or septic shock. Infants diagnosed with disorders of stomach function and feeding problems and those who were documented as having parenteral infusion of concentrated nutritional substances were considered to have feeding difficulties. Admission to the NICU was determined by a birth certificate indicator or the presence of financial charges attributable to intensive care or the level 3 nursery. Infant mortality was determined using both death certificates and discharge data. Survival time was calculated as the number of days from date of birth to the date of death for infants who died during the first 364 days of life and as 365 for infants who survived the first year.

The a priori identification of potential confounders was based on a review of the literature, an assessment of biologically plausible effects on the exposure–outcome associations, and whether the characteristic was captured in the study database. Maternal characteristics included age at delivery, race–ethnicity, nativity, marital status, education,



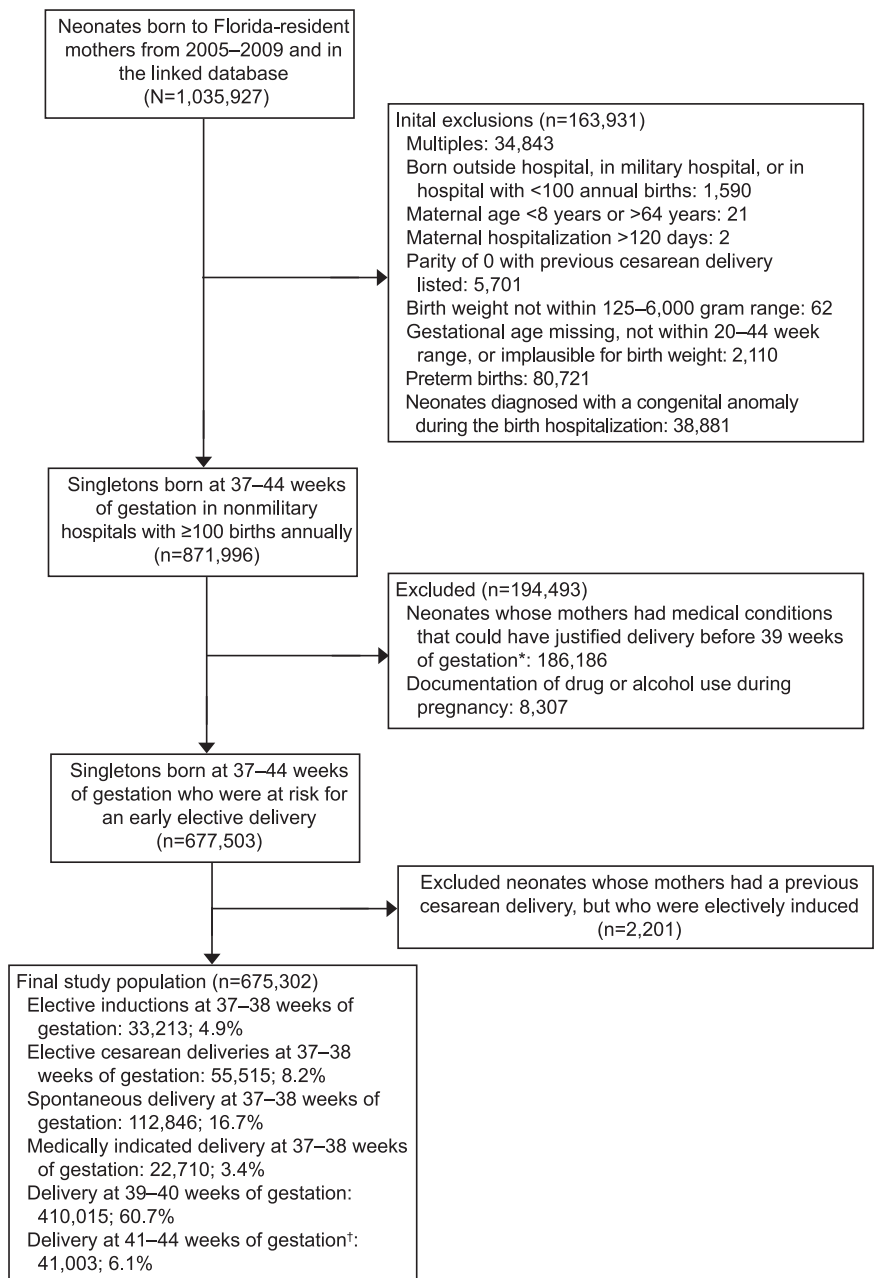


Fig. 1. Flow diagram of exclusion criteria, derivation of the final study population, and classification into exposure groups. *Deliveries at 41–44 weeks of gestation were not included in the reference exposure group during base-case analyses. However, during sensitivity analyses, the reference group included all deliveries at 39–44 weeks of gestation.

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income, adequacy of prenatal care, reproductive history, prepregnancy body mass index, and tobacco use during pregnancy. Infant characteristics included sex and year of birth. We also considered hospital-level factors including obstetric volume, level of perinatal care, and the percentage of births to nurse midwives. Definitions of study variables are provided in Appendix 5, available online at <http://links.lww.com/AOG/A780>.

Descriptive statistics were used to describe the study population by exposure group; χ^2 tests were

used to determine statistically significant differences. We then calculated the crude frequency and rate of each outcome across exposure levels. For each binary outcome, generalized linear mixed models were used to estimate odds ratios (ORs) and 99% confidence intervals (CIs). Hospital-level random intercepts in the models permitted appropriate consideration of the correlation among infants born at the same facility, because hospital characteristics can be associated with both early-term delivery²⁰ and adverse birth outcomes.^{21–23} In addition to an



unadjusted model, two multivariable models were fit. The first included all maternal, infant, and hospital-level confounders. The second added an interaction term between the exposure and reproductive history to assess effect measure modification. For infant mortality, a multivariable marginal Cox model with a robust variance estimator was used to estimate hazard ratios and 99% CIs representing the association between exposure and infant survival. We used the same model-building strategy described but also tested the proportional hazards assumption by including interaction terms between time and each covariate into the model.

We also conducted two sensitivity analyses to determine the robustness of our findings to 1) the effect of gestational age misclassification; and 2) composition of the reference exposure group. Although there is increasing evidence that the clinical estimate has greater validity compared with last menstrual period–based data,¹⁸ we were unable to determine whether the clinical estimate was based on highly accurate prenatal measures (eg, early ultrasonography) or neonatal examination. Therefore, analyses were repeated among a subset of infants with the highest suspected accuracy, those in which the clinical estimate was in exact concordance with the last menstrual period-based estimate. Second, our reference group consists of infants who were candidates for elective early-term delivery but whose deliveries occurred at 39–40 weeks of gestation. However, it has been argued that deliveries at 41 weeks of gestation or greater should not be excluded because late or postterm delivery is a complication of expectant management.¹² Therefore, we repeated analyses using all deliveries at 39–44 weeks of gestation as the reference group. Statistical analyses were conducted using SAS 9.4 using a 1% type I error rate and two-sided hypothesis tests. The linked database was deidentified before use and approval was obtained from the institutional review boards of the Florida Department of Health, the University of South Florida, and Baylor College of Medicine.

RESULTS

The final study population consisted of 634,299 infants, with 224,284 (35.4%) delivered early term. Most infants (64.6%) were delivered at 39–40 weeks of gestation (Table 1). Among those delivered at 37–38 weeks of gestation, 50% were delivered after spontaneous labor onset and 40% after elective induction or by cesarean. The highest rates of early inductions were observed among infants born to

multiparous women (8.3%), women with adequate or intensive prenatal care (6.9%), non-Hispanic white women (6.4%), women who used tobacco during pregnancy (6.2%), women with private insurance (6.0%), and U.S.-born women (5.9%). Although many of these same characteristics were similarly associated with early cesarean deliveries, there were differences; infants born to women 35 years of age or older, to Hispanic women, and to foreign-born women experienced among the highest rates of early cesarean deliveries.

There were 51,846 (8.2%) infants who experienced an adverse outcome. Respiratory morbidity was the most prevalent outcome, affecting 1 in 16 infants (6.0%). Neonatal sepsis and feeding difficulties each occurred in 1.3% of infants, and the NICU admission rate was 2.6%. There were 928 infant deaths, an infant mortality rate of 1.5 per 1,000 live births. The unadjusted rate of each outcome varied considerably by exposure (Table 2). Across all morbidities, the early induced group had rates that were similar to the full-term group. Conversely, the early cesarean delivery group experienced higher rates of each outcome than the full-term group and, for respiratory morbidities and NICU admissions, approximately doubled the rate of the early induced group.

Compared with the full-term group, after adjusting for confounders, infants born after early induction did not have increased odds of respiratory morbidity, neonatal sepsis, or NICU admission (Fig. 2) but did experience slightly increased odds of feeding difficulty (OR 1.18, 99% CI 1.02–1.36). Infants in the early cesarean delivery group, on the other hand, were at higher odds of all four morbidity outcomes. Although the increased odds of neonatal sepsis relative to the full-term group was small (OR 1.13, 99% CI 1.01–1.27), they experienced a 66%, 51%, and 36% increased odds of respiratory morbidity, NICU admission, and feeding difficulties, respectively. There were few differences in first-year survival experiences among either of the early elective and full-term subgroups. However, the early spontaneous and early medical groups experienced a 31% (99% CI 1.05–1.63) and 51% (99% CI 1.06–2.15) increased risk of dying compared with the full-term group.

Maternal reproductive history was a significant effect measure modifier of exposure–outcome associations (Table 3). Among nulliparous women, the most notable differences from full sample analyses were statistically significant reductions in the odds of respiratory morbidity, NICU admission, and neonatal



Table 1. Characteristics of the Study Population by Timing of and Reason for Delivery

Characteristic	Total	Delivery at 37–38 Weeks of Gestation					P [†]
		Delivery at 39–40 Wk of Gestation*	Elective Induction*	Elective Cesarean*	Spontaneous*	Medically Indicated*	
Overall	634,299	410,015 (64.6)	33,213 (5.2)	55,515 (8.8)	112,846 (17.8)	22,710 (3.6)	
Maternal age (y)							<.001
Younger than 20	67,516	46,229 (68.5)	3,007 (4.5)	1,981 (2.9)	14,354 (21.3)	1,945 (2.9)	
20–34	483,463	313,299 (64.8)	25,755 (5.3)	41,369 (8.6)	86,360 (17.9)	16,680 (3.5)	
35 or older	83,320	50,487 (60.6)	4,451 (5.3)	12,165 (14.6)	12,132 (14.6)	4,085 (4.9)	
Maternal race–ethnicity							<.001
Non-Hispanic white	291,890	192,560 (66.0)	18,729 (6.4)	25,372 (8.7)	45,533 (15.6)	9,696 (3.3)	
Non-Hispanic black	131,223	82,094 (62.6)	5,795 (4.4)	10,478 (8.0)	28,377 (21.6)	4,479 (3.4)	
Hispanic	177,917	114,059 (64.1)	7,328 (4.1)	17,087 (9.6)	32,047 (18.0)	7,396 (4.2)	
Other	30,288	19,398 (64.0)	1,211 (4.0)	2,313 (7.6)	6,342 (20.9)	1,024 (3.4)	
Maternal country of birth							<.001
U.S.-born	440,755	284,025 (64.4)	26,057 (5.9)	37,424 (8.5)	78,076 (17.7)	15,173 (3.4)	
Foreign-born	193,544	125,990 (65.1)	7,156 (3.7)	18,091 (9.3)	34,770 (18.0)	7,537 (3.9)	
Marital status							<.001
Married	354,763	225,783 (63.6)	20,267 (5.7)	36,639 (10.3)	58,640 (16.5)	13,434 (3.8)	
Unmarried	279,536	184,232 (65.9)	12,946 (4.6)	18,876 (6.8)	54,206 (19.4)	9,276 (3.3)	
Adequacy of prenatal care							<.001
Adequate or intensive	265,709	154,632 (58.2)	18,215 (6.9)	28,896 (10.9)	52,192 (19.6)	11,774 (4.4)	
Intermediate	244,231	174,015 (71.3)	9,686 (4.0)	16,904 (6.9)	36,675 (15.0)	6,951 (2.8)	
Inadequate, none, or missing	124,359	81,368 (65.4)	5,312 (4.3)	9,715 (7.8)	23,979 (19.3)	3,985 (3.2)	
Reproductive history							<.001
Nulliparous	258,022	183,990 (71.3)	10,832 (4.2)	7,772 (3.0)	45,296 (17.6)	10,132 (3.9)	
Multiparous, no previous cesarean delivery	271,126	174,278 (64.3)	22,381 (8.3)	3,906 (1.4)	63,617 (23.5)	6,944 (2.6)	
Multiparous, previous cesarean delivery	105,151	51,747 (49.2)	*	43,837 (41.7)	3,933 (3.7)	5,634 (5.4)	
Maternal education							<.001
Less than high school	113,790	75,307 (66.2)	4,757 (4.2)	7,308 (6.4)	23,421 (20.6)	2,997 (2.6)	
High school diploma or high school equivalency diploma	199,585	129,032 (64.7)	10,271 (5.1)	16,764 (8.4)	36,793 (18.4)	6,725 (3.4)	
More than high school	317,568	203,376 (64.0)	18,079 (5.7)	31,222 (9.8)	52,080 (16.4)	12,811 (4.0)	
Principal source of payment							<.001
Private insurance	290,118	183,811 (63.4)	17,281 (6.0)	29,569 (10.2)	47,369 (16.3)	12,088 (4.2)	
Medicaid	285,135	185,758 (65.1)	14,132 (5.0)	21,997 (7.7)	54,031 (18.9)	9,217 (3.2)	
Self-pay	48,484	33,323 (68.7)	1,272 (2.6)	3,333 (6.9)	9,381 (19.3)	1,175 (2.4)	
Other	10,562	7,123 (67.4)	528 (5.0)	616 (5.8)	2,065 (19.6)	230 (2.2)	
Per-capita income							<.001
Less than \$20,000	186,642	119,846 (64.2)	9,002 (4.8)	15,885 (8.5)	35,332 (18.9)	6,577 (3.5)	
\$20,000–29,999	306,458	199,436 (65.1)	16,113 (5.3)	25,779 (8.4)	54,265 (17.7)	10,865 (3.5)	
\$30,000 or greater	138,823	89,172 (64.2)	7,980 (5.7)	13,663 (9.8)	22,808 (16.4)	5,200 (3.7)	
Prepregnancy BMI							<.001
Underweight	31,987	19,785 (61.9)	1,805 (5.6)	1,842 (5.8)	7,607 (23.8)	948 (3.0)	
Normal	319,620	207,577 (64.9)	16,964 (5.3)	24,376 (7.6)	60,013 (18.8)	10,690 (3.3)	
Overweight	142,635	92,981 (65.2)	7,446 (5.2)	13,625 (9.6)	23,320 (16.3)	5,263 (3.7)	
Obese I	62,942	40,717 (64.7)	3,340 (5.3)	6,950 (11.0)	9,354 (14.9)	2,581 (4.1)	
Obese II, III	38,977	24,865 (63.8)	2,079 (5.3)	5,253 (13.5)	5,054 (13.0)	1,726 (4.4)	
Missing	38,138	24,090 (63.2)	1,579 (4.1)	3,469 (9.1)	7,498 (19.7)	1,502 (3.9)	
Maternal tobacco use							<.001
Yes	48,887	31,077 (63.6)	3,039 (6.2)	4,102 (8.4)	9,142 (18.7)	1,527 (3.1)	
No	585,412	378,938 (64.7)	30,174 (5.2)	51,413 (8.8)	103,704 (17.7)	21,183 (3.6)	
Infant sex							
Male	322,149	206,402 (64.1)	16,948 (5.3)	28,360 (8.8)	58,398 (18.1)	12,041 (3.7)	
Female	312,148	203,611 (65.2)	16,265 (5.2)	27,155 (8.7)	54,448 (17.4)	10,669 (3.4)	

(continued)



Table 1. Characteristics of the Study Population by Timing of and Reason for Delivery (continued)

Characteristic	Total	Delivery at 37–38 Weeks of Gestation					P [†]
		Delivery at 39–40 Wk of Gestation*	Elective Induction*	Elective Cesarean*	Spontaneous*	Medically Indicated*	
Infant year of birth							<.001
2005	125,501	80,471 (64.1)	7,290 (5.8)	10,949 (8.7)	22,735 (18.1)	4,056 (3.2)	
2006	127,132	81,600 (64.2)	7,016 (5.5)	11,519 (9.1)	22,706 (17.9)	4,291 (3.4)	
2007	129,110	82,906 (64.2)	6,884 (5.3)	11,900 (9.2)	22,653 (17.5)	4,767 (3.7)	
2008	127,954	82,178 (64.2)	6,618 (5.2)	11,537 (9.0)	22,851 (17.9)	4,770 (3.7)	
2009	124,602	82,860 (66.5)	5,405 (4.3)	9,610 (7.7)	21,901 (17.6)	4,826 (3.9)	
Hospital annual birth volume							<.001
100–499	10,492	6,439 (61.4)	1,363 (13.0)	963 (9.2)	1,425 (13.6)	302 (2.9)	
500–999	54,516	36,703 (67.3)	3,164 (5.8)	4,180 (7.7)	9,187 (16.9)	1,282 (2.4)	
1,000–1,999	157,624	103,343 (65.6)	7,869 (5.0)	14,543 (9.2)	26,926 (17.1)	4,943 (3.1)	
2,000 or greater	411,667	263,530 (64.0)	20,817 (5.1)	35,829 (8.7)	75,308 (18.3)	16,183 (3.9)	
Hospital perinatal care level							<.001
0, 1	179,712	120,631 (67.1)	9,529 (5.3)	13,432 (7.5)	30,672 (17.1)	5,448 (3.0)	
2	202,078	131,583 (65.1)	11,158 (5.5)	18,368 (9.1)	33,590 (16.6)	7,379 (3.7)	
3	252,509	157,801 (62.5)	12,526 (5.0)	23,715 (9.4)	48,584 (19.2)	9,883 (3.9)	
Hospital nurse-midwife births (%)							<.001
Less than 20	481,189	306,454 (63.7)	26,087 (5.4)	44,257 (9.2)	85,623 (17.8)	18,768 (3.9)	
20–29	84,880	57,290 (67.5)	4,064 (4.8)	6,200 (7.3)	15,050 (17.7)	2,276 (2.7)	
30 or greater	68,230	46,271 (67.8)	3,062 (4.5)	5,058 (7.4)	12,173 (17.8)	1,666 (2.4)	

BMI, body mass index.

Data are n or n (%) unless otherwise specified.

* Percentages displayed are row percentages; numbers may not sum to group totals and percentages may not total 100 as a result of missing data.

† P values are based on the χ^2 test for statistical independence.

* Elective inductions among women with a previous cesarean delivery were extremely rare and thus excluded from the study.

sepsis for the early induced group and a reversal in the direction of association (from increased to decreased odds) of neonatal sepsis for early cesarean deliveries. Among multiparous women without a previous cesarean delivery, the magnitude of the adjusted ORs for each early-term exposure group compared with full-term increased relative to the full sample for all outcomes. Among this subset, in addition to the slightly increase odds of feeding difficulties for early inductions compared with full-term infants, there was also a 23% increased odds of NICU admissions (99% CI 1.06–1.42).

When restricting to infants with exact agreement on gestational age measures, results were similar to the base-case analysis, although there was a trend for measures of association to move toward the null (Appendix 6, available online at <http://links.lww.com/AOG/A780>). The only difference among the early induced and early cesarean delivery groups was that early inductions no longer had increased odds of feeding difficulties compared with the full-term group. Infants born at 39–40 weeks of gestation constituted 91% of all deliveries between 39 and 44

weeks of gestation (Appendix 7, available online at <http://links.lww.com/AOG/A780>). When the full-term group was expanded to also include 41- to 44-week infants, results were nearly identical to the base-case analyses (Appendix 8, available online at <http://links.lww.com/AOG/A780>).

DISCUSSION

Many studies have suggested that elective inductions and cesarean deliveries at 37–38 weeks of gestation increase risk of adverse birth outcomes. However, most studies failed to choose a comparison group that incorporates the risk associated with the clinical decision to expectantly manage a pregnancy beyond the early-term period. Therefore, increases in risk for elective early-term deliveries were likely exaggerated. In this population-based cohort, infants delivered after early induction experienced odds of respiratory morbidities, neonatal sepsis, and NICU admission that were comparable with infants expectantly managed and delivered at 39–40 weeks of gestation. After stratifying by reproductive history, we found reduced odds of several adverse birth outcomes for early



Table 2. Unadjusted Rates* of Adverse Infant Outcomes by Timing of and Reason for Delivery

Adverse Infant Outcome	Overall	Delivery at 37–38 Weeks of Gestation				
		Delivery at 39–40 Wk of Gestation	Elective Induction	Elective Cesarean	Spontaneous	Medically Indicated
No. of births	634,299	410,015	33,213	55,515	112,846	22,710
Any respiratory morbidity						
No. of cases	37,931	22,350	1,611	5,744	6,175	2,051
Rate (%)	5.98 (5.92–6.04)	5.45 (5.38–5.52)	4.85 (4.62–5.09)	10.35 (10.09–10.60)	5.47 (5.34–5.61)	9.03 (8.66–9.41)
NICU admission						
No. of cases	16,575	9,747	649	2,123	2,883	1,173
Rate (%)	2.61 (2.57–2.65)	2.38 (2.33–2.42)	1.95 (1.81–2.11)	3.82 (3.67–3.99)	2.55 (2.46–2.65)	5.17 (4.88–5.46)
Neonatal sepsis						
No. of cases	8,505	5,206	327	762	1,635	575
Rate (%)	1.34 (1.31–1.37)	1.27 (1.24–1.30)	0.98 (0.88–1.10)	1.37 (1.28–1.47)	1.45 (1.38–1.52)	2.53 (2.33–2.74)
Feeding difficulties						
No. of cases	7,996	4,764	394	890	1,499	449
Rate (%)	1.26 (1.23–1.29)	1.16 (1.13–1.20)	1.19 (1.07–1.31)	1.60 (1.50–1.71)	1.33 (1.26–1.40)	1.98 (1.80–2.17)
Infant mortality						
No. of cases	928	539	51	85	214	39
Rate (per 1,000)	1.46 (1.37–1.56)	1.31 (1.21–1.43)	1.54 (1.14–2.02)	1.53 (1.22–1.89)	1.90 (1.65–2.17)	1.72 (1.22–2.35)

NICU, neonatal intensive care unit.

* For each rate, exact (Clopper-Pearson) 95% confidence limits are constructed by inverting the equal-tailed test based on the binomial distribution.

inductions among nulliparous women but observed a slight increase in odds of NICU admissions and feeding difficulties for early inductions among multiparous women without a previous cesarean delivery. In contrast to early inductions, infants delivered after early cesarean delivery had increased odds of several adverse outcomes, ranging from a 13% to 66% increase. There were no differences in survival when comparing either early inductions or early cesarean deliveries with the full-term group. Although our findings of no difference in the odds of several adverse outcomes among early inductions contradict much of the published literature, our results are in general agreement with the few studies that have used a methodologically appropriate comparison group.^{9–11,24} There is a paucity of information from large studies on the risk of these outcomes for early cesarean deliveries compared with an expectant management group; however, our findings for early cesarean deliveries are similar to other studies comparing early and late term cesarean deliveries, particularly among repeat cesarean deliveries.^{7,25}

A number of health care delivery systems have implemented strategies to decrease all elective deliveries before 39 weeks of gestation; many have been

successful in significant reductions.^{3,26,27} The results of this study raise the concern that these efforts may be based largely on biased or misleading evidence. In contrast to the current dogma, we found that when a methodologically appropriate comparison group was used, elective induction before 39 weeks of gestation was not associated with an increased likelihood of adverse outcomes. The consistency of findings among this large study and previous, smaller studies that have accurately reflected the decision clinicians and patients face contribute to ongoing discussions as to whether our actions concerning elective early-term induction of labor are patient-centered and evidence-based.^{9,11,24}

The results of this study do support the avoidance of purely elective cesarean deliveries before 39 weeks of gestation in lieu of expectant management. Infants in the early cesarean delivery group born to nulliparous women experienced a 59% increased odds of respiratory morbidities. Among infants born to multiparous women with no prior cesarean delivery, early cesarean delivery was associated with a near threefold increased odds of respiratory morbidities and NICU admission. Although the prevalence of early cesarean delivery was rare among nulliparous (3.0%) and



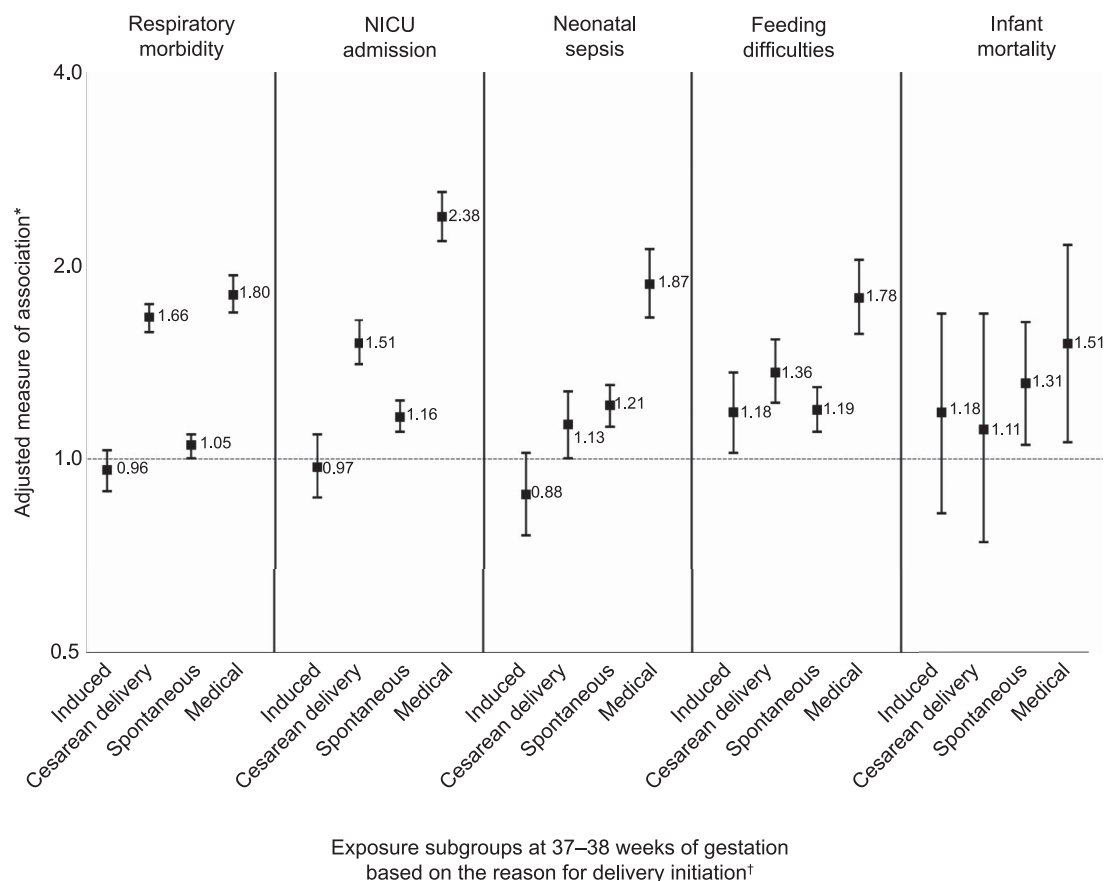


Fig. 2. Adjusted measures of relative risk and 99% confidence intervals representing the associations between the timing and reason for delivery and infant outcomes. *For each outcome except infant mortality, adjusted odds ratios were generated from a multivariable generalized linear mixed model with a binary distribution and logit link. For infant mortality, adjusted hazard ratios were generated from a multivariable marginal Cox model. †The reference exposure subgroup in all models consists of full-term deliveries at 39–40 weeks of gestation. Models were adjusted for maternal age, race or ethnicity, nativity, marital status, adequacy of prenatal care, reproductive history, education, principal source of payment, per-capita income, prepregnancy body mass index, tobacco use during pregnancy, infant sex, year of birth, hospital annual birth volume, perinatal care level, and the percentage of births to nurse-midwives. Induced includes elective inductions, 37–38 weeks of gestation. Cesarean delivery includes elective cesarean deliveries, 37–38 weeks of gestation. Spontaneous includes spontaneous deliveries, 37–38 weeks of gestation. Medical includes medically indicated deliveries, 37–38 weeks of gestation. NICU, neonatal intensive care unit.

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multiparous women without a prior cesarean delivery (1.4%) in our study population, it was common (41.7%) among women with a prior cesarean delivery despite the data supporting an 35–55% increased odds of neonatal morbidities compared with continuing the pregnancy to 39–40 weeks of gestation.

Study limitations include potential misclassification of gestational age, the reasons for delivery initiation, and pregnancy outcomes, which were identified using birth certificate and hospital discharge data. All are subject to omissions and other errors. However, because all infants were born at 37 weeks of gestation or greater, we do not expect under- or overdiagnosis of outcomes to be different

across exposure levels. Therefore, the anticipated effect of misclassification would be to conservatively bias measures of association toward the null. Furthermore, our sensitivity analyses provided confidence that misclassification of gestational age was unlikely to change our main findings. Our database did not capture information on fetal deaths and stillbirths that may have occurred while expectantly managing pregnancies at 37–38 weeks of gestation until 39 weeks of gestation or greater. However, based on stillbirth rates at 37 and 38 weeks of gestation,²⁸ we would only have expected 19 stillbirths among the early induction and early cesarean delivery groups during our study if those pregnancies had



Table 3. Adjusted Associations* Between the Timing of and Reason for Delivery and Infant Outcomes Stratified by Maternal Reproductive History

	Nulliparous Women*	Multiparous Women, No Previous Cesarean Delivery*	Women With a Previous Cesarean Delivery*
No. of infants	258,022	271,126	105,151
Any respiratory morbidity			
Delivery at 39–40 wk of gestation	1.00 (reference)	1.00 (reference)	1.00 (reference)
Delivery at 37–38 wk of gestation			
Elective induction	0.88 (0.78–0.98)	1.09 (0.99–1.20)	†
Elective cesarean	1.59 (1.42–1.77)	2.94 (2.53–3.41)	1.46 (1.37–1.56)
Spontaneous	0.94 (0.88–1.00)	1.18 (1.11–1.25)	1.29 (1.09–1.52)
Medically indicated	1.65 (1.50–1.82)	2.16 (1.91–2.44)	1.76 (1.52–2.04)
NICU admission			
Delivery at 39–40 wk of gestation	1.00 (reference)	1.00 (reference)	1.00 (reference)
Delivery at 37–38 wk of gestation			
Elective induction	0.78 (0.66–0.93)	1.23 (1.06–1.42)	†
Elective cesarean	1.04 (0.87–1.24)	2.82 (2.27–3.51)	1.55 (1.40–1.72)
Spontaneous	1.03 (0.95–1.11)	1.35 (1.24–1.48)	1.40 (1.08–1.80)
Medically indicated	2.03 (1.80–2.29)	3.22 (2.74–3.78)	2.62 (2.16–3.18)
Neonatal sepsis			
Delivery at 39–40 wk of gestation	1.00 (reference)	1.00 (reference)	1.00 (reference)
Delivery at 37–38 wk of gestation			
Elective induction	0.78 (0.63–0.97)	1.04 (0.84–1.29)	†
Elective cesarean	0.60 (0.46–0.79)	1.69 (1.19–2.40)	1.39 (1.18–1.65)
Spontaneous	1.04 (0.93–1.15)	1.43 (1.27–1.62)	1.88 (1.31–2.69)
Medically indicated	1.73 (1.48–2.03)	2.53 (1.99–3.23)	1.71 (1.25–2.35)
Feeding difficulties			
Delivery at 39–40 wk of gestation	1.00 (reference)	1.00 (reference)	1.00 (reference)
Delivery at 37–38 wk of gestation			
Elective induction	1.10 (0.88–1.37)	1.28 (1.06–1.55)	†
Elective cesarean	1.18 (0.93–1.51)	1.82 (1.28–2.60)	1.35 (1.16–1.57)
Spontaneous	1.16 (1.04–1.30)	1.22 (1.08–1.38)	1.29 (0.89–1.87)
Medically indicated	1.61 (1.34–1.95)	2.26 (1.78–2.88)	1.68 (1.23–2.30)
Infant mortality			
Delivery at 39–40 wk of gestation	1.00 (reference)	1.00 (reference)	1.00 (reference)
Delivery at 37–38 wk of gestation			
Elective induction	1.24 (0.64–2.41)	1.17 (0.76–1.80)	†
Elective cesarean	1.41 (0.60–3.28)	1.31 (0.47–3.65)	1.03 (0.64–1.65)
Spontaneous	1.35 (0.94–1.93)	1.29 (0.95–1.75)	1.30 (0.51–3.35)
Medically indicated	1.68 (0.91–3.10)	1.24 (0.57–2.68)	1.58 (0.79–3.19)

NICU, neonatal intensive care unit.

Data are estimate (99% confidence interval).

Bold indicates that the reported measure of association is statistically significantly different from 1.

* For each outcome except infant mortality, adjusted odds ratios were generated from a multivariable generalized linear mixed model with a binary distribution and logit link. For infant mortality, adjusted hazard ratios were generated from a multivariable marginal Cox model. Models were adjusted for maternal age, race–ethnicity, nativity, marital status, adequacy of prenatal care, education, principal source of payment, per-capita income, prepregnancy body mass index, tobacco use during pregnancy, infant sex and year of birth, and hospital annual birth volume, perinatal care level, and the percentage of births to nurse-midwives. Models also included an interaction term between timing and reason for delivery initiation and reproductive history; estimates were calculated separately for 1) nulliparous women only; 2) multiparous women without a prior cesarean delivery only; and 3) women with a prior cesarean delivery only.

† Elective inductions among women with a previous cesarean delivery were extremely rare and thus excluded from the analysis.

been expectantly managed to 39 weeks of gestation or greater. Our study did not capture the entire scope of neonatal outcomes, did not consider maternal outcomes, and was unable to adjust for patient preferences and health behaviors; therefore, our conclusions should be interpreted cautiously. Last, although our results are based on a large, statewide database, the racial–ethnic breakdown of our Florida

cohort, particularly the high proportion of Hispanics, and the high percentage of foreign-born gravidas may not be generalizable to other areas of the United States.

The issues that surround the timing and reasons for delivery initiation are complicated and each pregnancy unique. This study adds to a small but growing body of literature that cautions against



a general avoidance of all elective early-term deliveries and fosters support for continued research, based on better data, in this still relatively new arena.

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