Neonatal Mortality for Primary Cesarean and Vaginal Births to Low-Risk Women: Application of an "Intention-to-Treat" Model

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ABSTRACT: Background: *The percentage of United States births delivered by cesarean section continues to increase, even for women considered to be at low risk for the procedure. The purpose of this study was to use an "intention-to-treat" methodology, as recommended by a National Institutes of Health conference, to examine neonatal mortality risk by method of delivery for low-risk women.* **Methods:** *Low-risk births were singleton, term (37–41 weeks' gestation), vertex births, with no reported medical risk factors or placenta previa and with no prior cesarean section. All U.S. live births and infant deaths for the 1999 to 2002 birth cohorts (8,026,415 births and 17,412 infant deaths) were examined. Using the intention-to-treat methodology, a "planned vaginal delivery" category was formed by combining vaginal births and cesareans with labor complications or procedures since the original intention in both cases was presumably a vaginal delivery. This group was compared with cesareans with no labor complications or procedures, which is the closest approximation to a "planned cesarean delivery" category possible, given data limitations. Multivariable logistic regression was used to model neonatal mortality as a function of delivery method, adjusting for sociodemographic and medical risk factors.* **Results:** *The unadjusted neonatal mortality rate for cesarean deliveries with no labor complications or procedures was 2.4 times that for planned vaginal deliveries. In the most conservative model, the adjusted odds ratio for neonatal mortality was 1.69 (95% CI 1.35–2.11) for cesareans with no labor complications or procedures, compared with planned vaginal deliveries.* **Conclusions:** *The finding that cesarean deliveries with no labor complications or procedures remained at a 69 percent higher risk of neonatal mortality than planned vaginal deliveries is important, given the rapid increase in the number of primary cesarean deliveries without a reported medical indication. (BIRTH 35:1 March 2008)*

Key words: *birth certificate, neonatal mortality, cesarean delivery, vaginal delivery, low-risk women*

The percentage of United States births delivered by cesarean section has increased substantially in recent years from 20.7 percent in 1996 to an all-time high of 31.1 percent in 2006 (1). Rates have increased rapidly even for women considered to be at low risk for a cesarean section (2,3). In March 2006, the National Institutes of Health held a State-of-the-Science Conference on "Cesarean Delivery on Maternal Request." The purpose of this conference was to "provide providers, patients, and the general public with

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a responsible assessment of currently available data on cesarean delivery on maternal request" (4). Although some thought that the premise of the conference erroneously implied that maternal request cesareans were a significant contributor to the rising cesarean rate (5–8), evidence was strong that the percentage of medically elective cesareans (i.e., those without a known medical reason) has been increasing in the U.S. (3,4,9,10).

The National Institutes of Health conference advocated comparing the outcomes of vaginal and cesarean deliveries using an "intention-to-treat" methodology (11), a methodology commonly used in medical research (12,13). Using this methodology, emergency cesarean sections performed after a woman was in labor would be combined with vaginal births to create a "planned vaginal delivery" category since the original intention of the physician and the mother in both cases was presumably to deliver the infant vaginally. The "planned cesarean delivery" group would include only those deliveries where a cesarean section was performed without labor (11).

In a previous study, we examined neonatal mortality for primary cesarean and vaginal births to low-risk mothers in the U.S. using data from 1998 to 2001 (14). Since the article was already in press at the time of the National Institutes of Health conference, it did not apply the National Institutes of Health recommended methodology. This article reanalyzes the data, applying the intention-to-treat framework to examine infant and neonatal mortality by method of delivery for women with no documented prenatal risk for cesarean delivery.

Methods

The 1999 to 2002 birth cohort national linked birth and infant death data sets were analyzed to examine infant and neonatal mortality by method of delivery. These data sets link the birth certificate to the infant death certificate for each infant who dies in the U.S. The purpose of the linkage is to use the many additional variables available from the birth certificate for more detailed infant mortality analysis (15,16).

From the population of all mothers, we first identified mothers who would approach labor as candidates for a vaginal birth (Fig. 1). Consistent with the previous study, we also limited our analysis to those women with singleton, term (37–41 wk), vertex births and with none of the 16 medical risk factors (anemia, cardiac disease, acute or chronic lung disease, diabetes, genital herpes, hydramnios/oligohydramnios, hemoglobinopathy, chronic hypertension, pregnancy-associated hypertension, eclampsia, incompetent

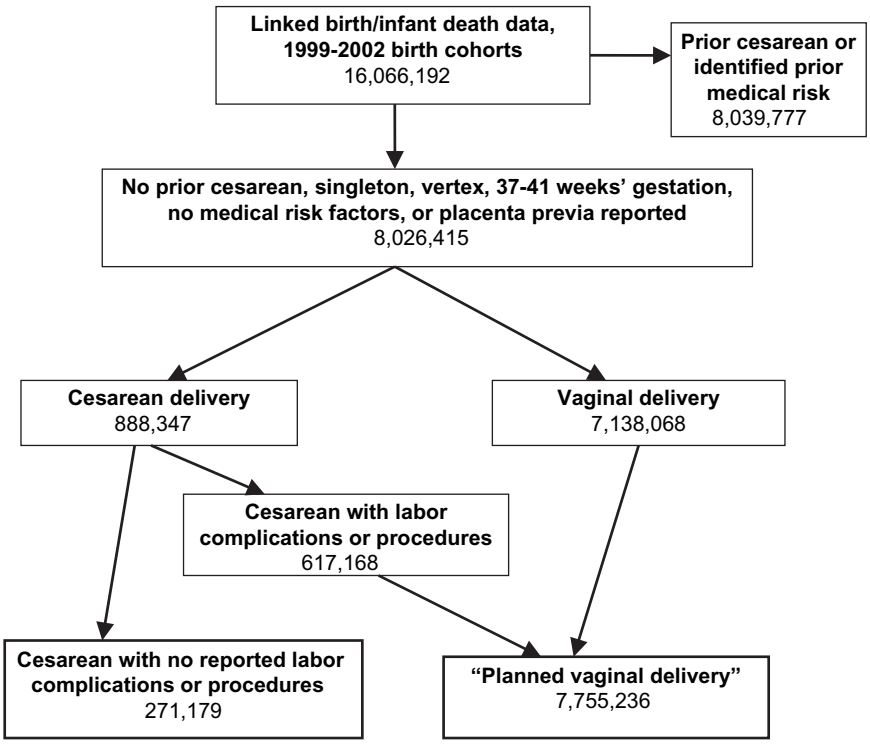

Fig. 1. Distinguishing between planned vaginal births and cesareans with no reported labor complications or procedures.

cervix, previous infant 4,000+ g, previous preterm or small-for-gestational-age infant, renal disease, Rh sensitization, uterine bleeding, and other) reported on the birth certificate and with no prior cesarean delivery and no placenta previa (which may be diagnosed prenatally).

For this study, 2002 data were added to update the study and to increase the number of births available for analysis; this addition made no substantive difference in the results. It resulted in an initial study population of 8,026,415 low-risk mothers likely to be eligible for a vaginal birth or a planned cesarean delivery.

In the prior analysis, births with complications of labor, delivery, or both were excluded, and only births, either vaginal or cesarean, with no prior risk and no complications were studied (14). However, for the current paper, the complications of labor or delivery (febrile, moderate/heavy meconium, premature rupture of membrane, abruptio placentae, other excessive bleeding, seizures during labor, precipitous labor, prolonged labor, dysfunctional labor, cephalopelvic disproportion, cord prolapse, anesthetic complication, fetal distress, and other) and the selected obstetric procedures indicating labor (induction of labor, stimulation of labor, and tocolysis) were used to separate the births into those with known labor and those without known labor applying the intention-to-treat conceptual framework (Fig. 1).

Although most, but not all, of the complications provide a strong indication that labor has occurred, the exclusion of births with *any* reported labor complications or procedures from the cesarean section with no labor complications or procedures category was a conservative step to exclude as many cases as possible where labor was likely to have occurred. Although information on physician's intention for method of delivery is not reported on birth certificates, the "cesarean with no labor complications or procedures" category is the closest approximation to a "medically elective" or "planned" cesarean delivery category possible, given data limitations. The planned vaginal delivery category was created by combining vaginal births and cesarean sections with labor complications or procedures (Fig. 1). Primary cesarean sections with labor complications or procedures accounted for 617,168 (8.0 percent) of the total planned vaginal delivery category.

Neonatal mortality rates (per 1,000 live births) were computed for each method of delivery category. Previous studies examined demographic characteristics and leading causes of death (14,17). Logistic regression analysis was used to determine the risk of neonatal mortality by method of delivery while controlling for maternal age, parity, education, race or ethnicity, smoking, infant gestational age, and birthweight.

Three models were run. For model 1, total neonatal mortality was the dependent variable, with covariates for birthweight (< 2,500; 2,500–3,999; 4,000+ g); gestational age (37–39, 40, 41 wk); and maternal characteristics, such as age (< 20, 20–34, 35+ yr), race or ethnicity (non-Hispanic white, black, Asian or Pacific Islander, American Indian, Hispanic), parity (primipara, multipara), education (0–11, 12, 13+ yr), and smoking (yes or no). For model 2, neonatal mortality excluding congenital malformations was the dependent variable (since if congenital malformations were identified prenatally, this factor might affect the choice of delivery method), with the same covariates. Model 3 is identical to model 2, but infants with Apgar scores less than 4 or not stated were also excluded because intrapartum hypoxia might also be both a reason for performing a cesarean section and a contributor to infant death. Model 3 excluded data from California and Texas since neither state reports Apgar score on their birth certificates. To assess the possible effect of this exclusion, models 1 and 2 were run excluding data from California and Texas. Results were similar to those for the full models (data not shown), suggesting that excluding these two states did not have a substantial impact on the model 3 results.

Records with not stated responses for birthweight, maternal education, and parity were excluded from the models. The effect of these exclusions was small since each of these variables had 1 percent or less of records not stated. A separate covariate was constructed to represent missing smoking data since maternal smoking was not reported by South Dakota in 1999 and California in 1999 to 2002. Models that were run both including and excluding missing data on maternal smoking yielded similar results. The parameters in the logistic model were estimated by the maximum likelihood method using the LOGISTIC procedure of SAS, version 9.1.3 (18).

Results

Table 1 presents infant and neonatal mortality rates for births with no documented prenatal risk by method of delivery for the 1999 to 2002 birth cohorts. More than 8 million live births and 17,412 infant deaths were included in the analysis. Substantial differentials occurred in infant mortality rates by method of delivery; however, the subsequent discussion focuses primarily on neonatal mortality since the choice of method of delivery would be expected to be more strongly related to infant health in the period immediately following the delivery. Not surprisingly,

neonatal mortality rates were very low for this group of low-risk women, with a rate of 0.75 neonatal deaths per 1,000 live births compared with a neonatal mortality rate of 4.64 for the U.S. population as a whole for this time period.

When neonatal mortality rates were examined, the rate was 0.63 for vaginal deliveries and 1.69 for primary cesarean deliveries with labor complications or procedures, resulting in an overall rate of 0.72 for the planned vaginal delivery group. The neonatal mortality rate for primary cesareans with no reported labor complications or procedures was 1.73, or 2.4 times the rate for the planned vaginal delivery group.

Logistic regression was used to compute adjusted odds ratios for neonatal mortality by method of delivery (Table 2). This analysis compared the planned vaginal delivery group, which included all vaginal births plus cesarean sections with labor complications or procedures, with primary cesarean deliveries with no labor complications or procedures reported.

As in the previous study (14), three models were computed; covariates for all models were birthweight, gestational age, age of mother, race or ethnicity,

Table 1. Infant and Neonatal Deaths and Mortality Rates for Vaginal and Primary Cesarean Births to Women with No Documented Prior Risks[a] with and without Reported Labor Complications and Procedures, United States, 1999–2002 Birth Cohorts (Rates per 1,000 Live Births)

		Deliveries with Labor (Planned Vaginal Delivery)				
Rates and Deaths	*Total Deliveries to Low-Risk Women*	*Total*	*Vaginal*	*Primary Cesarean with Labor Complications or Procedures*	*Primary Cesarean with No Labor Complications or Procedures*	*Ratio of Primary Cesarean with No Labor Complications or Procedures to Planned Vaginal Delivery*
Rates						
Infant	2.17	2.12	2.03	3.20	3.49	1.64
Total neonatal	0.75	0.72	0.63	1.69	1.73	2.42
Early neonatal	0.41	0.39	0.33	1.09	1.08	2.77
Late neonatal	0.34	0.33	0.30	0.60	0.65	1.99
Postneonatal	1.42	1.41	1.40	1.50	1.76	1.25
Number of deaths						
Infant	17,412	16,466	14,493	1,973	946	
Total neonatal	6,014	5,546	4,500	1,046	469	
Early neonatal	3,314	3,022	2,348	674	293	
Late neonatal	2,700	2,524	2,152	372	176	
Postneonatal	11,395	10,920	9,993	927	477	
Births	8,026,415	7,755,236	7,138,068	617,168	271,179	

[a]*Births to women with singleton, full-term (37–41 weeks' gestation), vertex presentation infants with no medical risk factors or placenta previa reported on the birth certificate who have not had a previous cesarean.*

Table 2. Adjusted Odds Ratios and 95% Confidence Intervals for Neonatal Mortality for Women with No Documented Prior Risks[a] by Method of Delivery: United States, 1999–2002 Birth Cohorts

Logistic Regression Model	*Method of Delivery*	*Adjusted OR[b] (95% CI)*
Model 1—Dependent variable = total neonatal mortality	Planned vaginal deliveries[c]	1.00
	Primary cesareans with no labor complications or procedures	2.34 (2.13–2.58)
Model 2—Dependent variable = neonatal mortality excluding congenital anomalies	Planned vaginal deliveries[c]	1.00
	Primary cesareans with no labor complications or procedures	1.93 (1.67–2.24)
Model 3—Dependent variable = neonatal mortality excluding congenital anomalies and events with Apgar score < 4[d]	Planned vaginal deliveries[c]	1.00
	Primary cesareans with no labor complications or procedures	1.69 (1.35–2.11)

[a]*Births to women with singleton, full-term (37–41 weeks' gestation), vertex presentation infants with no medical risk factors or placenta previa reported on the birth certificate who have not had a previous cesarean;* [b]*all models adjusted for maternal age, race/ethnicity, education, parity, and smoking, and for infant birthweight and gestational age;* [c]*includes vaginal and cesarean deliveries with labor-related codes;* [d]*data from California and Texas are excluded from model 3 because they do not report Apgar score on the birth certificate.*

parity, mother's education, and smoking. For model 1, the dependent variable was total neonatal mortality, and the adjusted odds ratio for neonatal mortality associated with cesarean delivery with no reported labor complications or procedures compared with planned vaginal delivery was 2.34 (95% CI 2.13–2.58) (Table 2). In model 2, the dependent variable was neonatal mortality excluding congenital anomalies (since if a congenital malformation was diagnosed prenatally, this factor might affect the choice of delivery method), and the adjusted odds ratio was 1.93 (95% CI 1.67–2.24). In model 3, the dependent variable was the same as that in model 2, but it also excluded events with Apgar scores less than 4 (since intrapartum hypoxia might be both a reason for performing a cesarean and a contributor to neonatal death), and the adjusted odds ratio was 1.69 (95% CI 1.35–2.11).

Discussion

This study used an intention-to-treat model as recommended by a National Institutes of Health conference (4) to compare neonatal mortality for cesarean deliveries to low-risk women with no reported labor complications or procedures with planned vaginal births, the latter category including unplanned cesarean sections. The overall neonatal mortality rate was 2.4 times higher among cesarean deliveries with no labor complications or procedures, compared with planned vaginal births. After controlling for all confounders available on the birth certificate, in the most conservative model, neonatal mortality was 69 percent higher for cesarean deliveries with no labor complications or procedures, compared with planned vaginal deliveries.

Earlier studies comparing the results of cesarean and vaginal births were criticized because they did not sufficiently risk adjust for the likelihood that the clinical factors that led to the decision to perform the cesarean section also contributed to the poorer outcomes associated with cesarean births (19). Our previous study corrected for that by limiting the analysis to the lowest risk group possible from the birth certificate and then comparing neonatal mortality by method of delivery, finding neonatal mortality 102 percent higher for cesarean deliveries even when controlling for all variables available on the birth certificate (14). The National Institutes of Health conference suggested another approach—the use of an intention-to-treat model, since a portion of the mothers who approached birth anticipating a vaginal delivery could experience complications in labor that led to an unplanned cesarean section and since it was these cesareans that posed the greatest risk for neonatal mortality (11,20). We applied the National Institutes of Health recommended framework to the 1999 to 2002 U.S. data and found that cesarean deliveries with no labor complications or procedures remained at 69 percent higher risk of neonatal mortality than planned vaginal births.

The strength of the study remains the comprehensive population-based nature of the data set, which includes all births and more than 98 percent of infant deaths in the U.S. from 1999 to 2002, together with the large number of sociodemographic and medical variables available for analysis. Limitations of the study include concerns about the accuracy of reporting specific data items on the birth certificate. Reporting for the major variables in this study (neonatal mortality and method of delivery) is generally considered to be excellent; however, underreporting of individual medical risk factors and complications of labor and delivery on birth certificates has been documented (21–23). Notably, our study does not focus on the reporting of individual medical risk factors but only includes births with *none* of 16 medical risk factors reported and with the "no medical risk factors" checkbox checked. Similarly, births are grouped by whether any of 14 complications of labor or delivery (including "other") are reported or whether none are reported and the "no complications" checkbox has been checked. Nonetheless, it is possible, based on either poor reporting or because the risks involved items not recorded on the birth certificate, that the group including cesarean delivery with no labor complications or procedures was still an inherently higher risk group, and those risks accounted for both the decision to perform a cesarean section and the subsequent neonatal death.

It is also important to note that birth certificate data cannot be used to infer the intentions of either mothers or their practitioners, so these data do not address "maternal request" cesareans. Birth certificate data also cannot account for widely varying cesarean delivery rates (both with and without labor) and for differences in practice patterns between clinicians with relatively similar patient populations (24,25).

Conclusions

This reanalysis of the best national data currently available using the intention-to-treat algorithm advocated by the National Institutes of Health State-of-the-Science Conference on Cesarean Delivery on Maternal Request reconfirms the higher rate of neonatal mortality associated with planned cesarean deliveries. It must again be stressed that cesareans with no reported labor complications or procedures make up a small proportion (3.4%) of low-risk births.

Nevertheless, we are still unable to explain away the increased risk for neonatal mortality associated with primary cesarean delivery among these low-risk women. The finding that cesarean deliveries with no labor complications or procedures remained at a 69 percent higher risk of neonatal mortality than planned vaginal deliveries is important, given the rapid increase in the number of primary cesarean deliveries without a reported medical indication.

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