Original Research

# Decision-to-Incision Times and Maternal and Infant Outcomes

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**OBJECTIVE:** To measure decision-to-incision intervals and related maternal and neonatal outcomes in a cohort of women undergoing emergency cesarean deliveries at multiple university-based hospitals comprising the National Institute of Child Health and Human Development Maternal–Fetal Medicine Units Network.

See related editorial on page 2.

* *For members of the National Institute of Child Health and Human Development Maternal–Fetal Medicine Units Network, see the Appendix.*

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**METHODS:** All women undergoing a primary cesarean delivery at a Network center during a 2-year time span were prospectively ascertained. Emergency procedures were defined as those performed for umbilical cord prolapse, placental abruption, placenta previa with hemorrhage, nonreassuring fetal heart rate pattern, or uterine rupture. Detailed information regarding maternal and neonatal outcomes, including the interval from the decision time to perform cesarean delivery to the actual skin incision, was collected.

**RESULTS:** Of the 11,481 primary cesarean deliveries, 2,808 were performed for an emergency indication. Of these, 1,814 (65%) began within 30 minutes of the decision to operate. Maternal complication rates, including endometritis, wound infection, and operative injury, were not related to the decision-to-incision interval. Measures of newborn compromise including umbilical artery pH less than 7 and intubation in the delivery room were significantly greater when the cesarean delivery was commenced within 30 minutes, likely attesting to the need for expedited delivery. Of the infants with indications for an emergency cesarean delivery who were delivered more than 30 minutes after the decision to operate, 95% did not experience a measure of newborn compromise.

**CONCLUSION:** Approximately one third of primary cesarean deliveries performed for emergency indications are commenced more than 30 minutes after the decision to operate, and the majority were for nonreassuring heart rate tracings. In these cases, adverse neonatal outcomes were not increased.

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**LEVEL OF EVIDENCE: II-2**

The American College of Obstetricians and Gynecologists (ACOG) Committee on Professional Standards established in 1989 that hospitals with obstetric services should have the capability to begin





a cesarean delivery within 30 minutes of the time that the decision is made to perform the procedure.[1] Examples of conditions cited by the American Academy of Pediatrics and ACOG that may require delivery within 30 minutes include hemorrhage from placenta previa, placental abruption, umbilical cord prolapse, and uterine rupture.[2] There is little published information, and no prospective studies, describing the relationship between cesarean response times for these emergencies and subsequent maternal and infant outcomes.[2] In spite of such limited data, the 30-minute response time has become a medical–legal benchmark for adequacy of obstetric care when cesarean delivery is indicated.[3]

Beginning in 1999, the Maternal–Fetal Medicine Units Network of the National Institute of Child Health and Human Development began a registry that included all cesarean births performed at the hospitals comprising the Network. This registry was designed to permit the study of several specific contemporary issues related to cesarean delivery. The main purpose of this analysis was to prospectively audit decision-to-incision intervals in a large cohort of women undergoing cesarean delivery for an emergency indication at multiple hospitals throughout the United States. In addition, we sought to measure maternal and infant outcomes potentially related to the cesarean delivery response time.

## MATERIALS AND METHODS

The Maternal-Fetal Medicine Units Network was established in 1986 by the National Institute of Child Health and Human Development (NICHD) to study clinical questions in obstetrics. Every 5 years university-based clinical centers compete to join the Maternal–Fetal Medicine Units Network, which at the time of this study was composed of 13 institutions and a data-coordinating center. These centers conducted research under a cooperative agreement with each other and the NICHD. Each center and the data coordinating center received Institutional Review Board approval for this study.

The cesarean delivery registry was a prospective observational study conducted between 1999 and 2002 and designed to assess several specific contemporary issues related to cesarean delivery. For the first two years, data were collected on all women undergoing a cesarean delivery or an attempted vaginal birth after a prior cesarean delivery at a participating center. During 2001 and 2002, data were collected only on repeat cesarean deliveries and attempted vaginal births after prior cesarean delivery. That is, data on primary cesarean deliveries were not collected during the last 2 years. For the purposes of this analysis, only data collected during the first 2 years were included.

Detailed information regarding medical and obstetric history, intrapartum course, postpartum complications diagnosed before hospital discharge, and infant outcome were abstracted directly from maternal and infant charts by specially trained and certified research nurses. The prospective nature of this study allowed attending obstetricians to be contacted promptly to resolve any questions regarding diagnoses, treatment, or complications. To minimize potential confounding variables, including the effects of prematurity and prolonged surgical time on newborn outcome, the inclusion criteria for this analysis were restricted to only those women who delivered a singleton infant weighing 2,500 g or more by primary cesarean. The inclusion criteria were further restricted to include only those women who were in active labor, defined as reaching a minimum of 4 cm cervical dilatation, to ensure that all women studied had their emergency event occur in a labor and delivery unit, rather than a separate triage or observation unit. Emergency cesarean deliveries were defined to include those performed for umbilical cord prolapse, placental abruption, placenta previa with hemorrhage, nonreassuring fetal heart rate patterns, or uterine rupture.

Intervals, in minutes, from the decision time to perform cesarean delivery to the actual skin incision were calculated by trained research nurses for each procedure. The decision time was ascertained from either the physician or nurse progress notes and, if not available, the date and time the patient was prepped were used as a substitute. The skin incision times were ascertained from intraoperative records.

All infants admitted to a neonatal intensive care unit had further detailed data collected concerning their clinical course. A separate data collection form on the infant was completed for all cases of uterine rupture and for infants with the clinically assigned diagnosis of hypoxic ischemic encephalopathy as well as for infants with any of the following: seizures or cardiopulmonary resuscitation during the first 24 hours of life, head imaging, arterial or venous cord pH less than 7.0, or a 5-minute Apgar score of 3 or less.

Maternal complications possibly related to the rapidity with which cesarean delivery was undertaken were categorized as either infection-related morbidity or operative injury. Postoperative endometritis was defined as fever with abnormal uterine tenderness in the absence of other findings suggesting another source of infection. Wound complications included

seroma, hematoma, or infection. The diagnosis of wound infection required erythema of the incision accompanied by purulent drainage.

Data from the 13 centers were transmitted weekly by telecommunications link to the data coordinating center at The George Washington University Biostatistics Center where they were edited for missing, out of range, and inconsistent values. Edit reports were then transmitted to each center for correction or clarification. The study sample size was calculated based on the primary goal of the cesarean registry, which was to study uterine rupture after trial of labor.[4] For the purpose of that analysis, an estimated 12,000 women with prior cesarean deliveries undergoing a trial of labor were required. Statistical analyses were performed using SAS 8.2 (SAS Institute, Inc., Cary, NC). Categorical variables were compared using the Pearson $\chi^2$ or Fisher exact tests. Nominal two-sided $P$ values are reported with statistical significance defined as a $P < .05$ without adjustment for multiple comparisons.

## RESULTS

During 1999 and 2000, a total of 184,387 women delivered in the Maternal-Fetal Medicine Units Network, and 23,491 (12.7%) of these underwent a primary cesarean delivery. A total of 11,724 of these cesareans were performed in laboring women with singleton births weighing 2,500 g or greater. In 243 of these pregnancies, the response time could not be reliably established and were excluded, resulting in a total of 11,481 women available for analysis. The demographic characteristics of these women are shown in Table 1.

As shown in Figure 1, 2,808 (24%) of the 11,481 cesarean deliveries were performed for a primary emergency indication defined as a nonreassuring fetal heart rate, umbilical cord prolapse, placental abruption, placenta previa with hemorrhage, or uterine rupture. Overall, 1,814 (65%) of these emergency cesarean deliveries were commenced within 30 minutes of the decision to operate. Interestingly, 17% were commenced within 10 minutes and another 27% were commenced within 20 minutes. The most common indication for an emergency cesarean delivery was nonreassuring fetal heart rate. Of the 2,638 cesarean deliveries performed for this indication, 1,647 (62%) began within 30 minutes. Of the 170 cesarean deliveries performed for the other emergency indications, 98% were commenced within 30 minutes of the decision to operate.

Maternal complications potentially related to the rapidity of cesarean delivery are shown in Table 2 according to the decision–incision interval. There were no significant differences.

Shown in Table 3 are selected infant outcomes for women who underwent a cesarean delivery for an emergency indication within 30 minutes of the decision to operate compared with greater than 30 minutes. Decision-to-incision intervals of 30 minutes or less were significantly associated with higher rates of fetal acidemia and need for intubation in the delivery room. Of the 538 infants with indications for emergency cesarean delivery who were delivered more than 30 minutes after the decision to operate and who had no missing outcome variables, 95% did not experience one of the adverse outcomes listed in Table 3.

As also shown in Table 3, the 2,808 emergency cesarean deliveries were complicated by a total of 8

**Table 1. Demographic Characteristics**

| Characteristic | Total Cohort (n = 11,481) | 30 Minutes or Less (n = 1,814) | 31 Minutes or More (n = 994) |
|---|---|---|---|
| Maternal age | 26.1 ± 6.4 (12–51) | 25.8 ± 6.7 (13–46) | 26.5 ± 6.7 (13–47) |
| 14 y or less | 55 (0.5) | 14 (0.8) | 5 (0.5) |
| 15–34 y | 10,109 (88.0) | 1,575 (86.8) | 848 (85.3) |
| ≥ 35 y or more | 1,317 (11.5) | 225 (12.4) | 141 (14.2) |
| Race | | | |
| White | 4,218 (36.7) | 558 (30.8) | 269 (27.1) |
| African American | 3,673 (32.0) | 788 (43.4) | 437 (44.0) |
| Hispanic | 2,914 (25.4) | 372 (20.5) | 219 (22.0) |
| Asian | 236 (2.1) | 29 (1.6) | 16 (1.6) |
| Other | 440 (3.8) | 67 (3.7) | 53 (5.3) |
| Nulliparous | 8,688 (75.9) | 1,115 (61.6) | 699 (70.5) |
| Education (y)* | 12.2 ± 2.9 (0–16) | 11.7 ± 2.9 | 12.2 ± 2.7 |
| Received prenatal care | 11,262 (98.1) | 1,778 (98.0) | 968 (97.4) |

All data are shown as number (%) or mean ± standard deviation (range).
* The maximum years of education that could be recorded was 16.

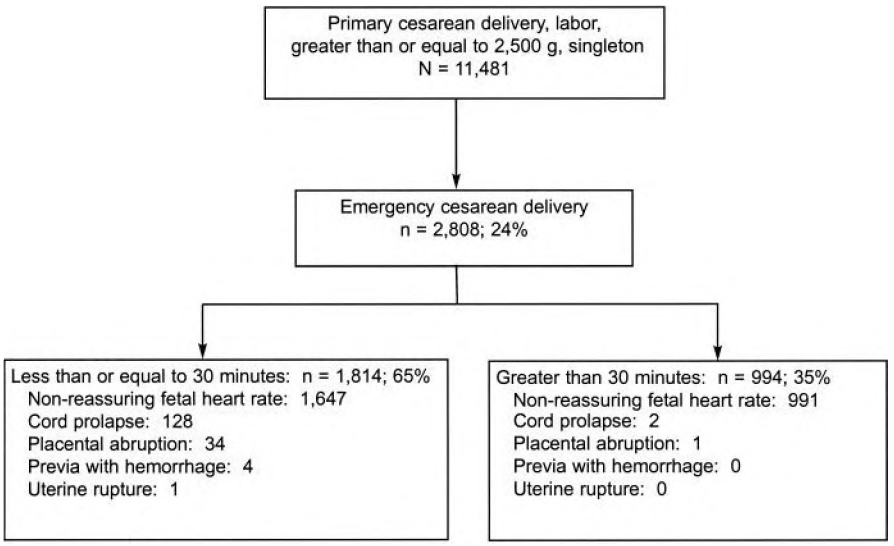


**Fig. 1.** Distribution of emergency and nonemergency primary cesarean deliveries according to decision–incision intervals.

*Bloom. Cesarean Decision-to-Incision Time. Obstet Gynecol 2006.*

**Table 2. Selected Maternal Complications Associated With Emergency Cesarean Delivery According to Decision-to-Incision Interval**

| Outcome | 30 Minutes or Less (n = 1,814) | 31 Minutes or More (n = 994) | *P* |
|---|---|---|---|
| Endometritis | 212 (11.7) | 129 (13.0) | .32 |
| Wound complication | 23 (1.3) | 9 (0.9) | .39 |
| Operative injury | | | |
| Cystotomy | 2 (0.1) | 3 (0.3) | .35 |
| Bowel laceration | 1 (0.1) | 1 (0.1) | 1.00 |
| Ureteral injury | 2 (0.1) | 1 (0.1) | 1.00 |

All data are shown as number (%).

**Table 3. Selected Infant Outcomes in Relation to Emergency Cesarean Delivery Within 30 Minutes of the Decision Compared to Cesarean after 30 Minutes**

| Outcome | 30 Minutes or Less (n = 1,814) | 31 Minutes or More (n = 994) | *P* |
|---|---|---|---|
| 5-minute Apgar score | | | |
| 3 or less | 18 (1.0) | 9 (0.9) | .82 |
| Umbilical artery pH less than 7.0* | 52 (4.8) | 9 (1.6) | .001 |
| Intubation in delivery room | 56 (3.1) | 13 (1.3) | .004 |
| CPR | 32 (1.8) | 12 (1.2) | .26 |
| Hypoxic ischemic encephalopathy | 12 (0.7) | 5 (0.5) | .61 |
| Fetal death in labor | 3 (0.2) | 0 (0.0) | .31 |
| Neonatal death | | | |
| With no malformations | 7 (0.4) | 1 (0.1) | .27 |
| With malformations | 8 (0.4) | 3 (0.3) | .76 |
| None of the above† | 985 (92.6) | 513 (95.4) | .03 |

CPR, chest compression in the delivery room or cardiopulmonary resuscitation within 24 hours.

All data are shown as number (%).

* Umbilical artery pH was missing for 41% of the infants.

† Includes only those infants with no missing outcome variables: 1,064 in the 30-minutes-or-less group and 538 in the 31-minutes-or-more group

neonatal deaths not associated with congenital malformations. The one neonatal death in the 31-minutes-or-more group was a result of hypoxic ischemic encephalopathy. This infant was delivered 33 minutes after the decision was made to operate. Two of the neonatal deaths in the 30-minutes-or-less group were due to the same cause.

## DISCUSSION

Approximately two thirds of all primary cesarean deliveries performed in labor for an emergency indication were commenced within 30 minutes of the decision to operate in this multicenter study from university hospitals across the United States. Specifically, 62% of cesarean deliveries for nonreassuring fetal heart rate and 98% of cesarean deliveries for an obstetric accident–defined as umbilical cord prolapse, placental abruption or previa, or uterine rupture–met the 30-minutes-or-less guideline. The decision-to-incision interval appeared to have no impact on maternal complications. Infants delivered within 30 minutes for an emergency indication were more likely to be acidemic and to require intubation in the delivery room. It is important to note that two neonates who were delivered within 30 minutes also died as a result of asphyxial injury, thus emphasizing the reality that delivery within 30 minutes does not guarantee against an adverse outcome. Conversely, 95% of infants delivered for an emergency indication

beyond the 30-minute benchmark did not exhibit evidence of compromised condition at birth. Although this latter finding may seem reassuring at first glance, it might be argued that a 5% incidence of compromised infants is not acceptable considering that these infants were born at or near term. However, this position presumes that these 5% were preventable by shorter response times, which seems problematic given that similar outcomes occurred in births before the 30-minute time post. Such vagaries serve to underscore some of the clinical realities of the 30-minute dictum.

What exactly is the 30-minute dictum? According to the fifth Edition of Guidelines for Perinatal Care[2] published jointly by the American Academy of Pediatrics and ACOG: "Any hospital providing an obstetric service should have the capability of responding to an obstetric emergency. No data correlate the timing of intervention with outcome, and there is little likelihood that any will be obtained. However, in general, the consensus has been that hospitals should have the capability of beginning a cesarean within 30 minutes of the decision to operate." We emphasize that this guideline does not establish the 30-minute interval to be a *requirement* but rather a *capability*. The distinction between these two terms is important and we believe often overlooked. For example, not effecting cesarean delivery within 30 minutes is a common reason that obstetric malpractice claims are perceived to be indefensible.[3] The implication of such perception is that the 30-minute interval is a requirement or standard for acceptable obstetric practice. Intrinsic to this perception is the belief that delivering within 30 minutes necessarily would prevent untoward infant outcomes. We believe that our results should temper the notion that exceeding the 30-minute interval is necessarily an index of substandard obstetric care. We would argue that our results suggest that in the great majority of cases—but not all—obstetricians effectively triage emergency cesarean deliveries when given the capability to commence the operation within 30 minutes, which is likely what was intended when the guideline was promulgated. But, it also seems clear that delivering within 30 minutes by no means guarantees infant safety.

Chauhan and colleagues[5] reviewed the literature on compliance with the 30-minute emergency cesarean delivery interval and found that approximately 60% of 446 such cesarean deliveries were performed within 30 minutes in the United States. Infant outcomes in relation to the decision–incision interval for emergency cesarean delivery were analyzed in three other studies comprising a total of 692 women.[6–8] One conclusion from all these studies was that newborn outcome was not necessarily disadvantaged when the decision–incision response time for cesarean delivery exceeded 30 minutes. Our results are concordant with these published experiences of others. Of note, our study is strengthened by the fact that it is a population-based study with ascertainment of all women delivering by primary cesarean during the study time period. In addition, all charts were reviewed by a dedicated team of research nurses who received specialized training for this study, and all data collected were subjected to a highly regimented process designed to reduce error.

Our analysis of indications for cesarean delivery, timing of the procedure, and associated infant outcome is limited because we cannot quantify the precise clinical perception of urgency by the obstetrician in those cesarean deliveries performed for nonreassuring fetal heart rate. Stated differently, cesarean delivery for nonreassuring fetal heart rate, the predominant reason for decision–incision times less than 30 minutes in our study, is known to include a wide spectrum of fetal compromise or lack thereof. Said yet another way, not all nonreassuring fetal heart patterns are equal, and clinicians understand this and inevitably prioritize the timing of emergency cesarean delivery. Clearly, clinical judgment plays a large role in the decision–incision times for primary cesarean deliveries done in labor for nonreassuring fetal heart rate.

It is important to emphasize that this study was observational in design. That is, the most definitive study design was not possible because patients obviously could not be randomly assigned to delivery before or after the 30-minute time point. In addition, our study was performed in university hospitals; thus, our results may not be readily generalizable to other health care environments. Therefore, we are forced to confront the fact that a benchmark has been established that can never be experimentally tested. Our observations are that obstetricians are prioritizing the timing of cesarean delivery such that those done within 30 minutes of the decision appear to have been necessary given that the infants were statistically at increased risk of compromise. Conversely, most infants delivered for emergency indications do not experience compromise whether delivered less than or greater than 30 minutes from the decision to operate.

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## APPENDIX

Other members of the Maternal–Fetal Medicine Units Network include University of Texas Southwestern Medical Center: J. McCampbell, D. Bradford; The Ohio State University: J. Iams, F. Johnson, S. Meadows, H. Walker; University of Alabama at Birmingham: D Rouse, A Northen, S Tate; University of Utah: M. Belfort, F. Porter, B. Oshiro, K. Anderson, A. Guzman; Thomas Jefferson University: A. Sciscione, M. DiVito, M. Talucci, M. Pollock; Wayne State University: M. Dombrowski, G. Norman, A. Millinder, C. Sudz, B. Steffy; University of Pittsburgh: K. Lain, M. Cotroneo, D. Fischer, M. Luce; Wake Forest University: P. Meis, M. Swain, C. Moorefield, K. Lanier, L. Steele; University of Miami: G. Burkett, J. Gilles, J. Potter, F. Doyle, S. Chandler; University of Cincinnati: T. Siddiqi, H. How, N. Elder; University of Tennessee: W. Mabie, R. Ramsey; University of Chicago: J. Hibbard, P. Jones, M. Ramos-Brinson, M. Moran, D. Scott; University of Texas Health Science Center at San Antonio: D. Conway, S. Barker, M. Rodriguez; George Washington University Biostatistics Center: E. Thom, H. Juliussen-Stevenson, M. Fischer; National Institute of Child Health and Human Development: D. McNellis, K. Howell, S. Pagliaro.