ORIGINAL ARTICLE

Fetal Pulse Oximetry and Cesarean Delivery

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ABSTRACT

BACKGROUND

Knowledge of fetal oxygen saturation, as an adjunct to electronic fetal monitoring, may be associated with a significant change in the rate of cesarean deliveries or the infant's condition at birth.

METHODS

We randomly assigned 5341 nulliparous women who were at term and in early labor to either "open" or "masked" fetal pulse oximetry. In the open group, fetal oxygen saturation values were displayed to the clinician. In the masked group, the fetal oxygen sensor was inserted and the values were recorded by computer, but the data were hidden. Labor complicated by a nonreassuring fetal heart rate before randomization was documented for subsequent analysis.

RESULTS

There was no significant difference in the overall rates of cesarean delivery between the open and masked groups (26.3% and 27.5%, respectively; P=0.31). The rates of cesarean delivery associated with the separate indications of a nonreassuring fetal heart rate (7.1% and 7.9%, respectively; P=0.30) and dystocia (18.6% and 19.2%, respectively; P=0.59) were similar between the two groups. Similar findings were observed in the subgroup of 2168 women in whom a nonreassuring fetal heart rate was detected before randomization. The condition of the infants at birth did not differ significantly between the two groups.

CONCLUSIONS

Knowledge of the fetal oxygen saturation is not associated with a reduction in the rate of cesarean delivery or with improvement in the condition of the newborn. (ClinicalTrials.gov number, NCT00098709.)

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In 2003, electronic fetal monitoring was used during approximately 3.2 million labors in the United States, accounting for 85% of all live births and making it the most common obstetrical procedure performed in this country.[1] Despite its widespread use, there is controversy about the interpretation and efficacy of electronic fetal monitoring.[2] For example, some people believe that the use of electronic fetal monitoring to detect a nonreassuring fetal heart rate is one of the many factors contributing to the escalating rate of cesarean delivery in the United States, which by 2004 had reached nearly 30%.[3]

In May 2000, the Food and Drug Administration (FDA) granted conditional approval of the OxiFirst Fetal Oxygen Saturation Monitoring System for use as an adjunct to electronic fetal monitoring.[4] This new technology was designed to improve knowledge of the fetal condition by continuously measuring fetal oxygen saturation in the presence of a nonreassuring fetal heart-rate pattern. With this technology, a specialized sensor is inserted through the dilated cervix after the membranes have ruptured and is positioned against the fetal face. Once in contact with the fetal skin, the device permits measurement of fetal oxygen saturation during labor.[5]

Conditional approval of the device was based primarily on the results of a trial[6] in which 1010 women with labors complicated by nonreassuring fetal heart-rate patterns were randomly assigned to either electronic fetal monitoring alone or electronic fetal monitoring plus continuous fetal pulse oximetry. The use of fetal oximetry was associated with a reduction in the rate of cesarean delivery for the indication of a nonreassuring fetal heart rate from 10.2 to 4.5% ($P=0.007$). However, the rate of cesarean delivery for the indication of dystocia in the oximetry group more than doubled, resulting in no overall difference in the rate of cesarean delivery between the two groups. The discrepancy in the effect of the oximeter between the two indications for cesarean delivery was unanticipated and not easily explained.[6,7]

Although the reduction in cesarean deliveries for the indication of a nonreassuring fetal heart rate was promising,[6] the results raised several questions. Was this discrepancy in the effect of the oximeter according to the indication for cesarean delivery reproducible? Was the sample size adequate to permit assessment of infant safety in instances when an obstetrician withholds cesarean delivery in the presence of an abnormal fetal heart rate because fetal oxygenation is deemed to be normal? Concerns such as these prompted the American College of Obstetricians and Gynecologists to withhold endorsement of the oximeter for use in clinical practice until additional studies were conducted.[8] Similarly, FDA approval was contingent on the results of postapproval studies.[4]

We designed a randomized trial to evaluate the effectiveness and safety of fetal oximetry. The primary objective was to determine whether fetal oximetry, as an adjunct to conventional electronic fetal monitoring, would result in a reduction in the overall rate of cesarean deliveries. We also assessed whether knowledge of fetal oxygen saturation changed the rate of cesarean delivery for the indications of nonreassuring fetal heart rate and dystocia and evaluated the potential side effects of such monitoring in both the mother and the neonate.

METHODS

The National Institute of Child Health and Human Development Maternal–Fetal Medicine Units Network conducted the trial. The network was established in 1986 to study clinical questions in obstetrics. At the time of this trial, the network consisted of 14 university-based clinical centers and an independent data-coordinating center. The study was approved by the institutional review board at each participating center and was conducted under an investigational-device exemption granted by the FDA. Written informed consent was obtained from all study participants.

TRAINING PHASE

Two centralized training sessions were conducted, which included didactic instruction as well as hands-on training with the study equipment. Additional training was performed at each site by educators from Nellcor Puritan Bennett, the manufacturer of the fetal pulse oximeter. The training included instruction on the recommended interpretation of values for fetal oxygen saturation.[6] Before a center was authorized to begin recruitment, attending physicians and research nurses had to pass both written and practical examinations for certification. Once they were trained

and certified, research nurse coordinators could train additional personnel at a later date, who in turn had to become certified to participate in the study. A mandated refresher training course was conducted after 2 years.

EQUIPMENT

Study equipment included an electronic fetal monitor (Corometrics Model 128 Basic Maternal Fetal Monitor, GE Healthcare), a fetal pulse oximeter (Nellcor OxiFirst N-400, Mallinckrodt), and a laptop computer. These components were customized to interface with one another and to permit masking of the values for fetal oxygen saturation in the control group. The equipment was also configured such that time-posted fetal heart rate, uterine contractions, and fetal oxygen saturation could be electronically archived. None of the manufacturers of these products provided financial support or had any role in the design, conduct, interpretation, or reporting of this study.

PROTOCOL

We screened nulliparous women presenting to a labor-and-delivery unit at any of the participating centers who had a singleton, cephalic, living fetus at or beyond 36 weeks of gestation. Exclusion criteria were a planned cesarean delivery, maternal fever (body temperature of at least 38°C), known human immunodeficiency virus or hepatitis virus infection, heart or renal disease, and diabetes mellitus. Women who were screened and whose examination showed cervical dilatation between 2 cm and 6 cm were eligible for randomization.

Data on fetal heart-rate patterns before randomization were collected to allow stratification of our study population into two groups — one group with nonreassuring fetal heart-rate patterns (the group for which the fetal oximeter was primarily intended) and the other without fetal heart-rate abnormalities before the time of randomization. Nonreassuring fetal heart-rate patterns were defined according to the following criteria, used by Garite and colleagues[6] in an earlier trial of fetal oximetry: severe variable decelerations (<70 beats per minute for at least 60 seconds), late decelerations, bradycardia (<110 beats per minute), tachycardia (>160 beats per minute), diminished heart-rate variability (<5 beats per minute over a period of at least 30 minutes), one or more variable decelerations in two consecutive 30-minute windows, increased heart-rate variability (>25 beats per minute over a period of 30 minutes), baseline rate of at least 100 to 120 beats per minute without accelerations, or suspected fetal arrhythmia. The principal investigator or an alternate investigator at each site reviewed all tracings.

After the placement of an internal electronic fetal heart-rate monitor and intrauterine pressure catheter, fetal oxygen sensors were applied by certified personnel. If three attempts at insertion were unsuccessful or if signal registration had not been accomplished after 15 minutes, the attempt at sensor insertion was declared to be unsuccessful, and the patient did not undergo randomization.

After successful placement of the sensors, randomization was performed by a research nurse through an encrypted program in the laptop computer. In the masked mode, no saturation values were displayed on the oximeter or printed on the paper tracing from the fetal heart-rate monitor. However, the signal strength was displayed on the oximeter so that the research nurse could adjust the sensor to maintain adequate contact with the fetus but could not see the actual saturation values. The status of the device — masked or not — was continuously recorded so that the integrity of the randomization assignment could be validated.

Intrapartum management in both groups was left to the discretion of the attending physician. A research nurse was present throughout labor to adjust the sensor as needed and at delivery to evaluate the newborn for facial marks from the sensor and to confirm the indication for cesarean delivery, if performed.

Detailed information regarding the medical and obstetrical history, intrapartum course, postpartum complications diagnosed before hospital discharge, and the infant's condition was abstracted from maternal and infant charts by certified research nurses. In cases in which the initial maternal chart review indicated a diagnosis of placental abruption or prolonged fetal heart-rate decelerations at the time of sensor insertion, charts were reviewed by one of the investigators for confirmation. Similarly, neonatal charts were reviewed by an investigator for confirmation if any of the following was reported: death, a diag-

nosis of hypoxic–ischemic encephalopathy, seizure, cardiopulmonary resuscitation during the first 24 hours of life, head imaging, an umbilical-artery blood pH value below 7.0, the need for a ventilator, intubation at delivery, admission to the neonatal intensive care unit (NICU) for at least 14 days, or a 5-minute Apgar score of less than 4. Chart reviewers had no knowledge of the randomization assignment.

The composite outcome, defined to address fetal safety, consisted of any of the following: a 5-minute Apgar score of less than 4, an umbilical-artery blood pH value below 7.0, seizures, intubation in the delivery room, stillbirth, neonatal death, or admission to the NICU for more than 48 hours. Hypoxic–ischemic encephalopathy was diagnosed if the umbilical-artery blood pH was below 7.0, seizure occurred during the newborn period, and there was evidence of multiorgan dysfunction.

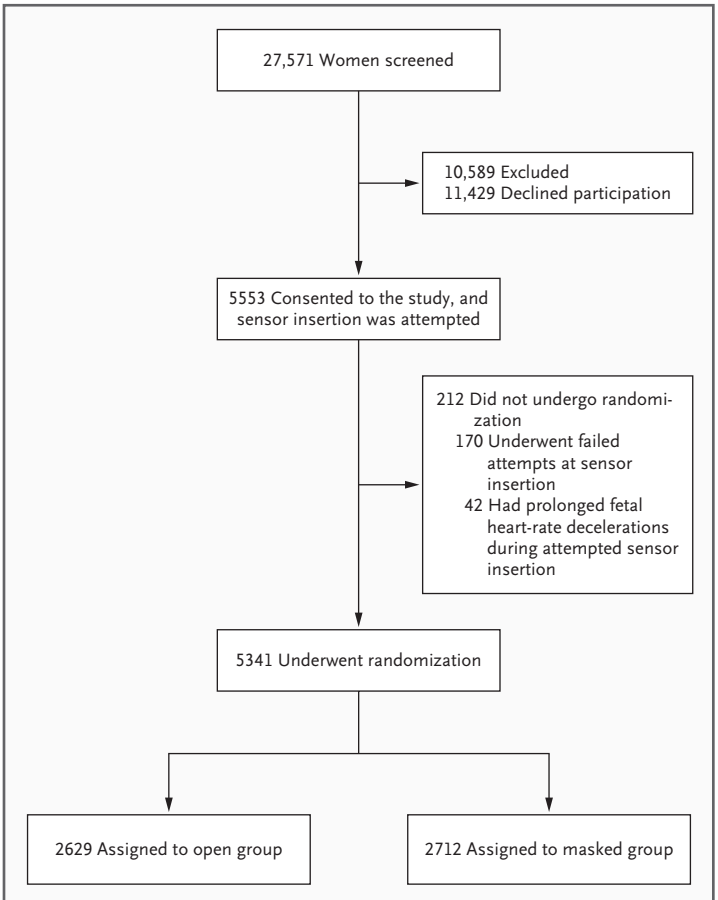

Figure 1. Screening, Enrollment, and Randomization.

STATISTICAL ANALYSIS

On the basis of data from one of the centers, we projected that the group in which values for fetal oxygen saturation were not displayed (the "masked" group) would have an overall rate of cesarean delivery of at least 15% and a 4% rate of cesarean delivery because of a nonreassuring fetal heart rate. Therefore, the enrollment of 10,000 patients was calculated to provide the study with a statistical power of almost 90% to detect a 15% reduction in cesarean delivery and to have 90% power to detect a 30% reduction in cesarean delivery because of a nonreassuring fetal heart rate, with a two-sided type I error rate of 5%. Moreover, it was expected that about one third of patients would have nonreassuring fetal heart-rate patterns at entry and that the enrollment of 10,000 would provide a statistical power of more than 90% to detect a 20% reduction in the overall rate of cesarean delivery in that group. This sample size resulted in similar power to detect a 50% increase in the composite neonatal outcome in the group in which values for fetal oxygen saturation were displayed (the "open" group).

Before the trial began, we decided that the independent data and safety monitoring committee would use the group sequential method of Lan and DeMets,[9] with a spending function for the type I error corresponding to the O'Brien–Fleming boundary for interim monitoring. The final analysis was performed according to the intention-to-treat principle. Continuous variables were compared by means of the Wilcoxon rank-sum test, and categorical variables were compared by means of the chi-square or Fisher's exact test, as appropriate.

RESULTS

Recruitment began in May 2002. At the third interim analysis, on the basis of data from 5017 women, the data and safety monitoring committee concluded that an adequate number of subjects had already been enrolled to address the major study outcomes. This conclusion was based on the fact that the primary outcome, the rate of cesarean delivery, was higher than expected (27.4% instead of 15.0%), so that there was already 90% power to detect a 15% reduction in the primary outcome. The committee noted that secondary outcomes were also more frequent than projected and

that there was adequate power (86 to 92%) to detect the prespecified differences. An additional 324 women had been recruited by the time the decision was made to stop the study in February 2005.

A total of 27,571 women were screened, of whom 10,589 were excluded and 11,429 declined participation (Fig. 1). An additional 170 women underwent failed attempts at sensor insertion, and attempts were abandoned in another 42 women, who had prolonged fetal heart-rate decelerations during sensor insertion. Of the remaining 5341 women, 2629 were randomly assigned to the open group, and 2712 to the masked group.

Of the 5341 women in the final study cohort, 18 had no fetal oxygen-saturation values recorded after randomization (7 in the open group and 11 in the masked group). In another five women assigned to the masked group, fetal oxygen-saturation values were inadvertently displayed. The oxygen sensor was removed before completion of the study in 238 women in the open group and 267 women in the masked group for the following reasons: patient's request (244 women), physician's request (196), and technical problems (65). Discomfort accounted for 91.8% of the patients' requests for sensor removal, and interference with the cervical examination or management of late labor accounted for 66.8% of the physicians' requests.

Characteristics of the women who underwent randomization are summarized in Table 1. The median percentages of time that oxygen-saturation values were recorded in the open and masked groups were 75.2% and 72.9%, respectively.

Intrapartum outcomes for all women enrolled in the study are shown in Table 2. There were no significant differences between the two study groups in the overall rates of cesarean delivery or

Table 1. Characteristics of the 5341 Nulliparous Women Enrolled in the Study.*

Characteristic	Open Group (N=2629)	Masked Group (N=2712)	P Value
Age — yr	23.5±5.5	23.5±5.5	0.37
Race — no. (%)†			0.83
Black	817 (31.1)	838 (30.9)	
White	1348 (51.3)	1414 (52.1)	
Asian	39 (1.5)	34 (1.3)	
Other	425 (16.2)	426 (15.7)	
Ethnic group — no. (%)†			0.83
Hispanic or Latino	641 (24.4)	668 (24.6)	
Not Hispanic or Latino	1988 (75.6)	2044 (75.4)	
Years of education	12.4±2.8	12.4±2.7	0.77
Cervical dilatation at randomization — cm	4.7±1.0	4.7±1.0	0.34
Nonreassuring fetal heart rate before randomization — no. (%)‡	1055 (40.3)	1113 (41.1)	0.56
Type of labor — no. (%)			0.61
Spontaneous	1553 (59.1)	1570 (57.9)	
Indicated induction	870 (33.1)	932 (34.4)	
Elective induction	206 (7.8)	210 (7.7)	
Use of oxytocin — no. (%)	1859 (70.7)	1913 (70.5)	0.89
Use of regional analgesia — no. (%)	2266 (86.2)	2362 (87.1)	0.33
Hypertension during pregnancy — no. (%)§	328 (12.5)	331 (12.2)	0.76

* Plus–minus values are means ±SD. Percentages may not sum to 100 because of rounding.
† Information about race and ethnic group was self-reported when possible or was obtained from the patient's chart.
‡ Data were missing for 11 women in the open group and 3 in the masked group.
§ Hypertension during pregnancy was defined as either preeclampsia or gestational hypertension.

Table 2. Intrapartum Outcomes According to Study Group Assignment.

Outcome	Open Group (N=2629)	Masked Group (N=2712)	P Value	Relative Risk (95% CI)
Entire cohort — no. (%)				
Cesarean delivery				
Overall	692 (26.3)	747 (27.5)	0.31	0.96 (0.87–1.04)
Nonreassuring fetal heart rate	187 (7.1)	213 (7.9)	0.30	0.91 (0.75–1.09)
Dystocia	490 (18.6)	521 (19.2)	0.59	0.97 (0.87–1.08)
Forceps or vacuum-assisted delivery	380 (14.5)	400 (14.7)	0.76	0.98 (0.86–1.12)
Spontaneous delivery	1557 (59.2)	1565 (57.7)	0.26	1.03 (0.98–1.07)
Women with nonreassuring fetal heart rate before randomization who underwent cesarean delivery — no./total no. (%)				
Overall	327/1055 (31.0)	339/1113 (30.5)	0.79	1.02 (0.90–1.15)
Nonreassuring fetal heart rate	104/1055 (9.9)	123/1113 (11.1)	0.36	0.89 (0.70–1.14)
Dystocia	216/1055 (20.5)	210/1113 (18.9)	0.35	1.09 (0.92–1.29)

forceps or vacuum-assisted vaginal delivery. Specifically, the relative risk of cesarean delivery associated with knowledge of fetal oxygen saturation was 0.96 (95% confidence interval [CI], 0.87 to 1.04). These results were not materially changed when women in whom labor was induced were excluded (data not shown). The rates of cesarean delivery also did not differ significantly between the groups in an analysis limited to the 2168 women who had a nonreassuring fetal heart rate before randomization (Table 2).

Maternal and infant complications did not differ significantly between the study groups (Table 3). There was one neonatal death due to sepsis in the masked group. Similar proportions of infants in each group had facial marks from the sensor, and in 86.6% of these infants, the marks resolved by 24 hours of age. There was no significant difference in the time from randomization to delivery between the two groups. Among the 5553 women in whom sensor placement was attempted (Fig. 1), prolonged fetal heart-rate decelerations (less than 100 beats per minute for 2 or more minutes) during insertion developed in 54 women (12 who were randomly assigned to a study group and 42 who were not). Of these 54 women, 14 (25.9%) underwent immediate cesarean delivery and the fetuses of 28 (51.9%) had nuchal cords at birth. Uterine perforation or placental abruption, possibly associated with insertion of the sensor, did not occur.

The sensitivity, specificity, and positive and negative predictive values of nonreassuring fetal heart-rate patterns for low oxygen saturation (less than 30% for at least 2 consecutive minutes)[10] were 86.7%, 19.5%, 34.6%, and 74.9%, respectively (Table 4). Of note, 34.6% of the nonreassuring patterns, but also 25.1% of the normal patterns, were associated with low oxygen saturation.

DISCUSSION

In this study of more than 5000 women delivering at 14 university hospitals throughout the United States, knowledge of intrapartum fetal oxygen saturation had no significant effect on the rates of cesarean delivery overall or specifically for the indications of a nonreassuring fetal heart rate or dystocia. In addition, knowledge of fetal oxygen saturation did not significantly affect infant outcomes. Findings for the subgroup of women with fetal heart-rate abnormalities before randomization were similar to those for the overall cohort.

Low oxygen saturation, although common in women with fetal heart-rate abnormalities, was also quite frequent in women with normal fetal heart-rate patterns. These results may explain our finding that fetal oximetry was of no benefit as an adjunct for the interpretation of electronic fetal heart-rate patterns.

Prolonged fetal heart-rate decelerations during sensor insertion occurred in 54 women. We considered the possibility that this complication was provoked by direct impingement of the sensor

Table 3. Maternal and Infant Outcomes.

Outcome	Open Group (N=2629)	Masked Group (N=2712)	P Value
Maternal — no. (%)			
Chorioamnionitis*	282 (10.7)	291 (10.7)	1.00
Postpartum endometritis†	114 (4.3)	120 (4.4)	0.87
Wound complication‡	4 (0.2)	3 (0.1)	0.72
Infant — no. (%)			
5-minute Apgar score <4	6 (0.2)	3 (0.1)	0.34
Umbilical-artery blood pH value <7.0§	13 (0.6)	12 (0.5)	0.79
Intubation at birth	19 (0.7)	19 (0.7)	0.92
Neonatal intensive care	126 (4.8)	147 (5.4)	0.30
Sepsis	9 (0.3)	8 (0.3)	0.76
Hypoxic–ischemic encephalopathy	0	1 (<0.1)	1.00
Stillbirth	0	0	—
Neonatal death	0	1 (<0.1)	1.00
Facial marks from the sensor	152 (5.8)	155 (5.7)	0.92
Composite outcome¶	84 (3.2)	91 (3.4)	0.74

* Chorioamnionitis was diagnosed in women with a body temperature of 38°C or higher during labor who had no other apparent source of infection and who had at least one of the following: uterine tenderness, foul-smelling vaginal discharge or amniotic fluid, or maternal or fetal tachycardia.
† Postpartum endometritis was diagnosed in women who had a body temperature of 38°C or higher and uterine tenderness without another source of infection.
‡ Wound complications included seroma, hematoma, and cellulitis.
§ Data were missing for 361 infants in the open group and 385 in the masked group.
¶ The composite outcome includes one or more of the following: 5-minute Apgar score of less than 4, umbilical-artery blood pH value of less than 7.0, seizures, intubation in the delivery room, stillbirth, neonatal death, and admission to the neonatal intensive care unit for more than 48 hours.

on the umbilical cord or by manipulation of the fetal head during insertion of the sensor. Indeed, 52% of the cases were associated with a nuchal cord. This rate is approximately double the expected incidence among all babies delivered.[11] Other than the unusual case of an abnormal fetal heart rate temporally related to sensor insertion, measuring fetal oxygen saturation and providing this information to clinicians had no discernible beneficial or harmful effects.

There are both similarities and differences between our findings and those previously reported by Garite and colleagues.[6] Neither study showed any significant change in the overall rate of cesarean delivery when fetal oximetry was used as an adjunct to electronic fetal monitoring. However, Garite and colleagues found an unexplained shift in the particular indications for cesarean deliveries when fetal oximetry was used. Specifically, fetal oximetry was associated with a significant reduction in the rate of cesarean delivery among patients with a nonreassuring fetal heart rate and a concomitant increase in cesarean delivery for a diagnosis of dystocia. One proposed explanation for these results was that fetal oximetry permitted the continuation of labor complicated by a nonreassuring fetal heart rate such that dystocia could later emerge as the indication for cesarean delivery.[7] This hypothesis suggests that a nonreassuring fetal heart rate in a normally oxygenated fetus can be a harbinger of impending dystocia. We did not reproduce the finding of a reduced rate of cesarean delivery in association with a nonreassuring fetal heart rate or an increased rate of cesarean delivery in association with dystocia.

Often, new technology is adopted in practice without the controlled observation necessary for objective assessment of its efficacy. The widespread adoption of intrapartum electronic fetal monitoring in the early 1970s has been cited as an example of the incorporation of technology without proof of benefit.[12-14] The development of

Table 4. Relationship between Nonreassuring Fetal Heart-Rate Tracings and Low Oxygen Saturation.

Fetal Heart Rate	Total Patients* (N=3877)	Low Oxygen Saturation (N=1278)	Normal Oxygen Saturation (N=2599)
Nonreassuring	3199		
No. (%)		1108 (86.7)	2091 (80.5)
% of Total		34.6	65.4
Reassuring	678		
No. (%)		170 (13.3)	508 (19.5)
% of Total		25.1	74.9

* Only patients with fetal oximetry data for at least 60% of the time between randomization and delivery are included.

fetal oximetry held out the promise that knowledge of fetal oxygen saturation might improve understanding of fetal well-being during labor and thus reduce the rate of cesarean delivery for the indication of abnormal fetal heart rate. Our trial confirms the value of rigorous assessment of new forms of technology by showing that knowledge of fetal oxygen saturation does not lead to a significant reduction in cesarean births overall or for the indication of a nonreassuring fetal heart rate.

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APPENDIX

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