EDITORIALS

Obstetricians Still Await a Deus ex Machina

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Intrapartum electronic fetal heart-rate monitoring was introduced with great enthusiasm in the early 1970s. Most cases of cerebral palsy were thought to result from asphyxia during the intrapartum period, and it was hoped that the ability to recognize intrapartum fetal asphyxia and intervene with a timely delivery would reduce the incidence of fetal neurologic injury. During the years after the adoption of electronic fetal monitoring, numerous publications documented associations between various fetal heart-rate patterns and short-term outcome measures of neonatal well-being. These outcome measures were assumed to be reliable surrogates for the development of long-term neurologic handicaps. By the end of the 1970s, electronic fetal heart-rate monitoring had become a standard of care, despite the absence of randomized, controlled trials showing any reduction in the rate of long-term neurologic handicaps in the newborns.

When electronic fetal monitoring was rigorously assessed, however, the results provided little support for its use. Initial trials that showed no benefit from intrapartum monitoring were criticized for their small size. Larger trials that showed no benefit, including one involving almost 35,000 patients,[1] were criticized because they were conducted in term infants who were at low risk. A study reported in the *Journal* in 1990 showed no significant differences in the results of neurologic evaluations at 18 months of age among premature infants at high risk for intrapartum asphyxia who were randomly assigned to electronic monitoring and those assigned to intermittent auscultation during labor.[2] The accompanying editorial characterized intrapartum fetal monitoring as "a disappointing story."[3]

Where had we gone wrong? First, our basic premise was flawed. Only a small fraction of all cases of cerebral palsy arise from known causes, and a small fraction of those from intrapartum asphyxia.[4] Although electronic fetal heart-rate monitoring is technically easy to implement, interpretation of the data is subjective, difficult to standardize, and poorly reproducible. Experienced observers often disagree with one another's interpretations of monitoring records, and when asked to reexamine those same records months later, they frequently disagree with their own original interpretations.[5] Abnormal fetal heart-rate patterns observed during labor may reflect preexisting neurologic injury of the fetus that cannot be ameliorated by intrapartum interventions. Finally, a nonreassuring fetal heart-rate pattern should be seen as an imperfect screening test for fetal asphyxia, rather than as a diagnostic test for asphyxia.

After 25 years of use, electronic fetal heart-rate monitoring was associated with an unchanged rate of cerebral palsy in term infants but a soaring rate of cesarean deliveries.[6] Simultaneously, lawsuits alleging neonatal neurologic injury due to failure to diagnose and effectively treat intrapartum asphyxia were increasing. Although the precise fractional contributions to the rising rate of cesarean deliveries that were performed for presumed fetal asphyxia (as opposed to fear of potential litigation) are debatable and difficult to quantify, they are real and substantial.

Because of the limitations of fetal heart-rate monitoring, technology was developed for continuous measurement of fetal oxygen saturation during labor, with the goal of more accurately assessing fetal well-being and reducing the number of unnecessary cesarean deliveries. A randomized, controlled trial showed that the technical ability of fetal pulse oximetry to obtain data about fetal oxygen saturation safely, fairly reliably, and with minimal discomfort was acceptable to most women in labor.[7] Despite a reduction in the rate

of cesarean deliveries that were performed out of concern for intrapartum asphyxia, the overall rate of cesarean deliveries in the monitored group was undiminished, owing to an increase in the rate of cesarean deliveries performed for the indication of dystocia. Subsequently, other studies have replicated these findings but failed to provide any real insight into the association between nonreassuring fetal heart-rate patterns and dystocia.[8,9]

In this issue of the *Journal,* Bloom et al.[10] report the results of the largest trial to date of this relatively new technology. Salient entry criteria for study subjects were the presence of labor at term with an apparently normal singleton fetus in vertex presentation. All subjects underwent placement of the monitoring device, but the information from the device was hidden from care providers for half the subjects. The primary goal of monitoring with the use of fetal pulse oximetry was to reduce the overall rate of cesarean delivery. Unlike earlier studies,[7,8] study subjects were not required to have a nonreassuring fetal heart-rate pattern for enrollment, but a large, planned sample was expected to include enough patients with nonreassuring fetal heart-rate patterns to have a high probability of finding a difference in cesarean delivery rates in that subgroup if the intervention was efficacious. As with previous studies, application of the monitoring device was generally successful, was not associated with a high incidence of adverse effects, and was successful in obtaining the desired data about fetal oxygen saturation approximately 74% of the time the device was in place. Unfortunately, knowledge of this additional fetal physiological information did not change the rates of cesarean or operative vaginal delivery in either the general study population of 5341 women or the subgroup of 2168 women with nonreassuring fetal heart-rate patterns. The reduction in the rate of cesarean deliveries that were performed out of concern for intrapartum fetal asphyxia seen in previous studies was not observed in this trial, nor was there the enigmatic increase in cesarean deliveries for the indication of dystocia among women with nonreassuring fetal heart-rate patterns. The performance of electronic fetal heart-rate monitoring as a screening test for fetal oxygen desaturation was poor. Neonatal outcomes were not significantly different between the groups.

As noted by the authors in their discussion, fetal pulse oximetry, unlike electronic fetal heart-rate monitoring, has not been widely disseminated before appropriate trials were conducted to define the true usefulness of the new technology. This genie has not yet escaped from the bottle.[11] This case does offer the opportunity to discuss the appropriate role of the Food and Drug Administration (FDA) in approving new medical devices. Should the FDA's charge be minimalist and framed very narrowly, to approve a device that reliably does what it claims — in this case, accurately record fetal oxygen saturation — while not injuring people in the process? Or should the FDA's charge be more expansive, to approve a new device only after it demonstrates some medical value added to the current standard of care?

More than 30 years ago the new technology of electronic fetal heart-rate monitoring was introduced with the noble aspiration to eliminate cerebral palsy. We now find ourselves in the far less noble position of seeking new technology to mitigate the unintended and undesirable consequences of our last ineffective, but nonetheless persistent, technologic innovation.

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