the very low cost and high safety profile of aspirin, it hardly seems that any screening test is needed, particularly given the complexity and likely expense of using esoteric serum markers and rarely used uterine artery Doppler. At present, in this rapidly evolving field, I think the message for the provider is to keep measuring blood pressure and to recommend low-dose aspirin in women at risk of preeclampsia based on the American Congress of Obstetricians and Gynecologists or USPSTF guidelines. Routine employment of commercial tests or screening for uterine artery Doppler changes does not seem to add substantial benefit but does definitely add significant cost.—MEN

Computerised Interpretation of Fetal Heart Rate During Labour (INFANT): A Randomised Controlled Trial

The INFANT Collaborative Group, Peter Brocklehurst, David Field, Keith Greene, Ed Juszczak, Robert Keith, Sara Kenyon, Louise Linsell, Christopher Mabey, Mary Newburn, Rachel Plachcinski, Maria Quigley, Elizabeth Schroeder, and Philip Steer

Birmingham Clinical Trials Unit, Institute of Applied Health Research, College of Medical and Dental Sciences, University of Birmingham, Edgbaston, Birmingham, United Kingdom

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ABSTRACT

INFANT is a decision-support software that assesses fetal heart rate quality and contraction patterns alongside the Guardian electronic information capture system. INFANT color codes fetal heart rate patterns based on abnormalities (mild, moderate, severe), but does not make recommendations for clinical actions. This randomized controlled trial aimed to find whether the rate of poor neonatal outcomes would be affected by the assistance of decision-support software in the interpretation of cardiocographs.

The study took place at 24 sites in the United Kingdom and Ireland and included pregnant women 16 years or older, with a singleton or twin pregnancy, at 35 weeks' gestation or more, with no known gross fetal abnormality who were judged to require continuous electronic fetal heart rate monitoring (EFM) on the basis of their current practice. Participants were randomly assigned to either receive decision support using INFANT or no decision support. One primary outcome was poor neonatal outcome, which included intrapartum stillbirth or early neonatal death (excluding lethal congenital anomalies), neonatal encephalopathy, admission to the neonatal unit within 24 hours for 48 hours or more with evidence of respiratory illness, feeding difficulties, or encephalopathy with evidence of compromise at birth. Another primary outcome, within a subset of surviving children, was assessment of neurodevelopmental outcome at 2 years of age. Secondary outcomes included Apgar scores, duration of hospital stay, the need for neonatal resuscitation, and metabolic acidosis of cord blood samples, among others.

Of 47,062 recruited to the study between 2010 and 2013, 1020 women were excluded from analysis of the primary outcome. For the longer-term outcomes, follow-up data at 2 years were complete for 6707 children. Between the 2 groups, incidence of poor neonatal outcome did not differ significantly. In the decision-support group, 172 (0.07%) of 22,987 babies experienced poor neonatal outcome, and in the no-decision-support group, 171 (0.07%) of 23,055 babies experienced poor neonatal outcome (adjusted risk ratio, 1.01; 95% confidence interval, 0.82–1.25). No differences were noted between the groups in terms of components of the primary outcome or any of the secondary outcomes. In addition, no differences were noted in 2-year outcomes between the 2 groups. When a subset of the primary outcome cases was reviewed, it was found that a suboptimal response to the fetal heart rate abnormalities occurred 38% of the time, 14 of 35 in the study group and 13 of 36 in the control group.

There was no evidence supporting the hypothesis that decision-support software would affect the incidence of suboptimal care. The authors conclude that the opportunities for improving neonatal outcomes likely lie in guidance of how to clinically respond to fetal heart rate tracings as opposed to the interpretation of the fetal heart rate tracings themselves.
EDITORIAL COMMENT

(Wow! This was the trial that many of us were counting on to point the way forward in fetal heart rate monitoring. After the negative findings of the FOX trial (using fetal pulse oximetry) and the STAN trial (using sophisticated interpretation of the fetal ST segment on the electrocardiogram), fetal heart rate monitoring has lost steam. However, there are many individuals who still believe that with computer-aided decision support the consistency of interpretation would lead to better outcomes. This was the premise of the INFANT study, abstracted above, that randomized nearly 50,000 women to a decision support tool versus no tool. Unfortunately, as described previously, this study was also negative.

As we all know, EFM was developed in the 1960s and became widely adopted in the United States in the 1970s. In one of the largest randomized trials of EFM, there was a reduction in neonatal seizures, but an increase in the risk of cesarean deliveries in those women randomized to continuous EFM (Am J Obstet Gynecol 1985;152:524–539). Unfortunately, the follow-up data from this trial did not demonstrate a reduction in cerebral palsy in children whose mothers had been randomized to EFM (Lancet 1989;2(8674):1233–1236). By then, though, EFM had become adopted and benefits to nursing staffing by being able to follow the fetal heart rate tracing of multiple patients simultaneously and centrally were a large part of the tools entrenchment in labor and delivery units. But, why doesn’t the tool seem to lower the neonatal and long-term outcomes?

One concern is that EFM interpretation is challenging and inconsistent. Concerns about this led to the National Institute of Child Health and Human Development consensus conference in 2008 that created 3 categories of tracings (Obstet Gynecol 2008;112:661–666). Category I tracings with moderate variability and without fetal heart rate decelerations are considered benign and are of no concern. Alternatively, category III tracings are almost always an indication for immediate delivery and rarely controversial. However, the vast majority of fetal heart rate tracings fall into the category II bucket. In a recent study, more than 90% of fetal heart rate tracings were category II during the second stage of labor (Am J Obstet Gynecol 2012;207:206e1–206e8). Thus, category II tracings, which are labeled indeterminate, are challenging and are not particularly predictive of neonatal acidemia (Obstet Gynecol 2012;120:1387–1393). While they have some features of concern such as fetal heart rate decelerations, they may have other reassuring features such as moderate variability. Unfortunately, because these categories are relatively simplistic, it is unclear that care can be improved with their use. Others have described more complex fetal heart tracing categories, and at least 1 has demonstrated improvements in outcomes (J Matern Fetal Neonatal Med 2013;26(1):71–74).

Thus, a software that provided EFM interpretation support was designed. This software, INFANT, categorized mild, moderate, and severe abnormalities and color coded them as blue, yellow, or red, respectively. The trial then randomized clinicians to receive this information or not on individual patients. Unfortunately, as described previously, there were no differences in the primary outcomes, nor any of the secondary outcome subcategories. Let’s consider the study design and whether there still may be hope for such programs.

First, the approach of creating categories of tracings and providing warnings about them seems to make sense. However, there may be specific types of tracings that are a smaller subset of these categories that clinicians actually need help identifying. For example, recurrent variable decelerations are relatively easy to identify, and it is unlikely that clinicians need help in their identification or interpretation. This is also true for a bradycardia. It may be, rather, that subtle changes in baseline or mild late decelerations are the types of tracings that such a support tool can help the clinician identify.

Another important issue in the design of this trial is that rather than conduct a cluster-randomized trial where some centers would use the INFANT tool and others would not, the study randomized tracings (individual patients). Thus, all clinicians knew they were part of the study, and it was conducted in an unblinded fashion. Thus, the clinicians could also learn as they used the tool how it would interpret fetal heart rate tracings over time and potentially improve the care even...
in the control group. The finding that both the overall perinatal mortality rate (0.3 per 1000 vs 1 per 1000) and the neonatal encephalopathy rate (0.8 per 1000 vs 1.3 per 1000) were significantly lower than previously estimated rates potentially signals that there may have been improvement, but the difference between the groups was not identified because of the nonclustered, nonblinded study design.

However, the final reason why a benefit may not have been seen is that in the process of improving neonatal outcomes from EFM there are several steps. First is the identification of a concerning fetal heart rate pattern. Next is the management that such a pattern should elicit. This study was focused on the first component, not the second. The fact that in both groups 38% of poor outcomes seemed to be the result of improper response to the fetal heart tracing suggests that there is a need for standardized response algorithms to fetal heart rate tracings and really should be the focus in improving neonatal outcomes. How we can create consistent, responsive teams on labor and delivery that will not fail to respond two-fifths of the time is truly the goal of optimizing labor and delivery management. Until we demonstrate that we can do that, I will not give up hope that we can use EFM to improve neonatal and long-term outcomes.—ABC

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Prime Time for Shared Decision Making

Erica S. Spatz, Harlan M. Krumholz, and Benjamin W. Moulton

Section of Cardiovascular Medicine, Yale School of Medicine (E.S.S., H.M.K.); Center for Outcomes Research and Evaluation, Yale–New Haven Hospital (E.S.S., H.M.K.), New Haven, CT; and Informed Medical Decisions Foundation, Healthwise Research and Advocacy, Boston, MA (B.W.M.)

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ABSTRACT

Washington State passed legislation in 2007 incentivizing shared decision making as an alternative option to traditional forms and procedures for informed consent for certain procedures. This requires patients to sign an attestation that they used a certified decision aid and discussed risks, benefits, and alternatives. These tools and processes could help protect clinicians from failure to inform litigation.

Certified patient decision aids have been used as a model for national certification standards developed by the National Quality Forum. However, the potential for shared decision making to create a more transparent, open process for patients may be hindered by clinicians' lack of experience with these decision aids. There is a need for well-defined standards to ensure policies on shared decision making are implemented without unnecessary burden on clinicians.

In order for shared decision making to be effective, the process needs to be clearly described. Shared decision making is defined as a process undertaken between a clinician and patient when there is more than 1 clinically appropriate intervention or management strategy available and through which the patient can decide which choice is best according to their values and preferences. Second, there should be incentives to evaluate and maintain certified decision aids. The National Quality Forum has issued criteria for the certification of patient decision aids. Third, clinician training in shared decision making, including using decision aids, should be promoted. Fourth, there is a need for an agreed-upon method of measurement in shared decision making. Finally, shared decision making should be integrated into clinical practice through positive incentives and while considering the workflow of routine clinical care.

Shared decision making has the potential to advance a more patient-centered, value-based health system and to engage patients and reduce costs. Common definitions, trusted certified decision aids, clinician engagement, strategies to enable seamless integration into practice, and a commitment to evaluation and improvement are needed, however, to achieve genuine shared decision making that is embraced by clinicians and patients alike.

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