Electronic Fetal Monitoring: A Defense Lawyer's View

Thomas P. Sartwelle, BBA, LLB
Beirne, Maynard & Parsons, LLP, Houston, TX

Electronic fetal monitoring (EFM) has been used for four decades, after its introduction without clinical trials. EFM spawned a birth injury litigation crisis centered on the myth that it predicts cerebral palsy (CP). The myth has resulted in lottery-like judgments against physicians. The American Congress of Obstetricians and Gynecologists (ACOG) and sister organizations worldwide have the power to halt EFM's clinical proliferation and the undeserved litigation verdicts against physicians unjustly blamed for causing CP. This power has been unused. If ACOG and other organizations would declare EFM unreliable, it could change the clinical standard of care and alleviate the CP-EFM malpractice lottery.

[Rev Obstet Gynecol. *2012;5(3/4):e121-e125 doi: 10.3909/riog0191]*

KEY WORDS

Cerebral palsy • Electronic fetal monitoring • Litigation • Standard of care

Electronic fetal monitoring (EFM) has been in clinical use for four decades despite evidence suggesting it is ineffectual,[1-5] prone to interpretive errors,[6,7] has a 99% false-positive prediction of fetal distress,[8] has increased the incidence of cesarean delivery,[9-11] has not reduced the rate of cerebral palsy (CP),[4,5,10,11] and has not produced better perinatal outcomes.[4,5,11] Nevertheless, EFM remains the most common obstetrical procedure today.

Concomitant with EFM is the worldwide obstetrical malpractice litigation crisis centered around CP and neurologic birth injuries that EFM use can allegedly prevent.[4,5] This crisis was spawned by EFM courtroom experts specializing in courtroom

deliveries of neurologically perfect neonates, children thousands of defendant physicians could also have delivered if, according to the so-called experts, they had been more attentive or more educated. EFM propelled neurologic birth injury litigation to lottery-like payouts in which jury verdicts exceeded $100 million,[12] elevating "failure to diagnose and treat fetal asphyxia" into the most common claim in obstetrical malpractice litigation.

EFM is based on the 19th century myth that oxygen deprivation is the primary cause of CP and other perinatal brain abnormalities.[13,14] In Beller's words, EFM was "based on a catastrophic misunderstanding of fetal pathophysiology."[13] But most people, including many obstetricians, still believe Little's 1843 hypothesis on the cause of CP—oxygen deprivation at or before birth—even though there is almost no real knowledge concerning the length of time and degree of hypoxemia required to produce CP or any other neurologic injury in a previously healthy fetus.[15-17] This belief also ignores 40 years of CP-EFM research repeatedly proving that lack of oxygen causes only a small proportion of CP cases,[5] and that the common assumption that caregivers can prevent CP by actions taken during labor and delivery is based largely on erroneous assumptions and obsolete science.[5] That same research identified a multiplicity of antenatal and postnatal causative factors, a number of which are silent and impossible to recognize until years later.[4,5]

Equally surprising is physicians' tenacious use of EFM for every labor, a use based on belief in the myth that EFM use confers a magic protection from trial lawyers. The direct opposite is true, as pointed out in both the legal and medical literature.[4,18,19] Both myths are alive today and are the reason CP-EFM litigation continues unabated, turning physicians, in MacLennan's words, into "a de facto social welfare insurance scheme" and driving caretakers away from obstetrics.[4,5,20]

EFM Use in the Courtroom

EFM was introduced into clinical practice—without clinical trials—in the early 1970s. At the same time, US medical malpractice cases accelerated in frequency and claim severity, resulting in the first medical malpractice insurance crisis. Ironically, it was EFM that delivered to trial lawyers the CP litigation's crown jewel: a permanent computer-like tracing that courtroom experts could analyze, pinpointing for juries the exact time the fetus experienced asphyxia. Quick delivery by the courtroom experts delivered a child in unblemished health, as opposed to the child in the courtroom, strapped to a wheelchair, blind, deaf, or both, mentally challenged, and being fed through a plastic syringe connected to a stomach tube.

EFM is based on the 19th century myth that oxygen deprivation is the primary cause of CP and other perinatal brain abnormalities.

As verdicts increased, studies revealed the interpretations of EFM experts disagreed with each other, and they sometimes disagreed with themselves.[6,7] Inter- and intraobserver variability was exactly the opposite of the experts' courtroom testimony. Decisions regarding cesarean delivery were no better, the experts advising immediate cesarean but days later, based on the same data, advising vaginal delivery.[9] EFM courtroom experts were also subject to hindsight bias. Knowing that there is a poor patient outcome renders experts much more likely to find evidence of fetal asphyxia on heart rate tracings.[21]

So what could the American Congress of Obstetricians and Gynecologists (ACOG) and others have done to dispel these myths and slow EFM proliferation in labor and delivery suites and courtrooms? Actually the solution was—and is—fairly simple. It will take time and effort, not because the solution to these myths is complicated, but rather because the belief in myth is so strong.[13,14]

The Solution

ACOG and other organizations only need to publish an official statement, a Practice Bulletin, declaring EFM useful as a nursing labor-saving device and also declaring that EFM is not the standard of care either in labor rooms or courtrooms. In short, the antidote to EFM clinical proliferation and as a courtroom sham is to call it what it is—unreliable.[22]

Standard of Care and the Courtroom

A physician is negligent—guilty of malpractice—when he or she does not do those things that the prudent physician would do taking into consideration the same or similar circumstances faced by the defendant physician. Negligence and what lawyers call *standard of care* are synonymous. Only physicians can testify as to what constitutes the standard of care and, therefore, in virtually every state and country with a blame system, medical malpractice claims do not proceed without a physician witness testifying the defendant practiced below the standard of care (ie, was negligent) and caused the patient's injury or death. Thus, a primary cause of medical malpractice lawsuits is the defendants' colleagues.[4,5]

A lay jury, the majority of whom have no medical training and even less scientific discernment, must choose whom to believe between the plaintiff's and defendant's experts. Essentially, a trial is a beauty contest between experts. How juries decide which witness to believe has been studied and, as it turns out, believability is minimally related to the soundness of the medical opinions.[23]

Pronouncements by recognized professional societies are strong evidence of the standard of care in virtually every courtroom and provide defendants a powerful weapon the other side lacks. This is especially true if those pronouncements are articulated in plain, declarative language understandable to jurors and judges. Is it a guarantee? No. But it is a powerful weapon. Such a pronouncement on EFM remains lacking today.

ACOG Practice Bulletins are some evidence of the standard of care and can influence clinical EFM use as well as outcomes of EFM-CP trials.

Practice Bulletin 106

ACOG Practice Bulletins are some evidence of the standard of care and can influence clinical EFM use as well as outcomes of EFM-CP trials. Until recently, these Bulletins did not acknowledge the clinical weaknesses of EFM. They have never labeled EFM unreliable for the courtroom. Practice Bulletin 106 (PB 106), *Intrapartum Fetal Heart Rate Monitoring*,[11] was published in 2009; it was, however, a lost opportunity to label EFM unreliable.

PB 106 is the last in a long line of national and international EFM conferences stretching back 40 years, meetings called to resolve continuing nomenclature differences, fetal distress criteria differences, and differing views on fetal heart rate interpretation and cesarean delivery indications. None have yet called for EFM's limited use or hinted at its unreliability. PB 106 also fails to make those calls. Only a very limited number of individual physicians have publicly recognized the futility and potential EFM dangers.[1,4,5,10]

PB 106 did, for the first time, acknowledge several EFM truisms, although the official ACOG verification of these truisms is decades late: (1) EFM has not reduced perinatal mortality, but has increased cesarean delivery rates along with increased risk of vacuum and forceps delivery; (2) EFM has not reduced the risk of CP; (3) EFM's false-positive rate for predicting CP is extremely high, at greater than 99%; and (4) inter- and intraobserver variability in EFM interpretation is high, especially when a poor outcome is known and such prior knowledge may alter the reinterpretation and such an opinion may not be reliable.[11]

PB 106 stopped short of unequivocally using the one word that would have changed the standard of care and provided a lifeboat for physicians facing EFM courtroom experts and their courtroom reinterpretations: *unreliable*.

What Should ACOG Do Now?

ACOG, and organizations like it, have two essential EFM missions: (1) to educate practicing obstetricians, and (2) to make a definitive, plain language, unequivocal statement that EFM is useful as a labor-saving device but is unreliable as it exists today, is not the standard of care except for limited pregnancies, and is unreliable as courtroom evidence.

Paradoxically, obstetricians, the group most affected by CP-EFM litigation, are also among those needing the most education about the true causes of CP and the deficiencies of EFM. This need was highlighted 30 years ago[17] and was demonstrated by two recent ACOG member surveys.[24,25]

The Collaborative Perinatal Project data were published in 1985.[17] This massive study of pregnancy and childhood has never been matched in size, breadth, and depth before or since. The data exposed physicians' antiquated beliefs in the myths surrounding birth. Dr. John M. Freeman, the editor, vividly captured the need for re-education and presciently forecast the depth of that need, when he eloquently wrote in the introduction: "If we believe that we should teach only what we know to be true, as opposed to what we know to be myth, then much of what we 'know' about pre- and perinatal causes of CP, mental retardation (MR) and epilepsy should no longer be taught. Over the past two decades, few areas in medicine have changed as rapidly as those of obstetrics and neonatology. Yet, many of our assumptions about the factors associated with brain disorders, such as CP, MR and epilepsy, remain rooted in outdated knowledge."[17]

What followed the publication of the Project's data was a literal explosion of worldwide research on CP, MR, epilepsy, and associated subjects, including EFM—research that almost uniformly concluded that physicians' omissions and commissions rarely cause CP or other neurologic injuries. In 2003, ACOG surveyed practicing obstetricians' exposure to this published research by testing some of its members' neonatal encephalopathy and

CP causation knowledge, including knowledge about etiology and pathology.[24] Over half of the 643 respondents rated their knowledge as poor or deficient. The participants' test answers, the authors wrote, were "consistent with this pessimistic self assessment as . . . (65%) correctly answered less than half of the knowledge questions."[24] The conclusion: "issues of neonatal encephalopathy, pathogenesis and histopathology are not well understood by practicing obstetricians throughout the United States."[24]

In 2005, there was a similar member survey.[25] This survey followed the 2003 publication of ACOG and the American Academy of Pediatrics (AAP) definitive work on the causes of neonatal encephalopathy and cerebral palsy,[15] as well as the 1999 International Cerebral Palsy Task Force Consensus Statement.[16] The survey was designed in part to measure the impact of the ACOG-AAP statement on practicing obstetricians' subject matter knowledge. As expected, there was some improvement in knowledge base. Still, substantial knowledge gaps remained. More than one-third of those surveyed rated their knowledge regarding causation as poor or deficient.[25] Obviously, ACOG must direct much of its education effort at its own members if it expects to overcome the CP-EFM myths.

Finally, ACOG should issue a definitive statement that, based on years of clinical use and numerous clinical trials, EFM is not yet proven to accurately identify hypoxic events and therefore is unreliable for general clinical use and is not the standard of care for every pregnancy. It should plainly state that EFM use is acceptable because it is a proven labor-saving device, but that EFM is unreliable for courtroom use because of its false-positive profile, because reinterpretation has proven to be biased, and because prior knowledge of the outcome may alter the reinterpretation. Such a statement is not a call for EFM abandonment. It is only a call to recognize the reality of the legal climate in which physicians practice, where every untoward birth result will likely be scrutinized by an expert willing to ignore 40 years of evidence, testify EFM is reliable, and pinpoint the exact moment the child was neurologically devastated and should have been delivered earlier—testimony unsupported by reliable scientific scrutiny.[26]

…ACOG should issue a definitive statement that, based on years of clinical use and numerous clinical trials, EFM is not yet proven to accurately identify hypoxic events and therefore is unreliable for general clinical use and is not the standard of care for every pregnancy.

Conclusions

CP-EFM litigation is a huge waste of time and money better used researching the causes of CP and helping all children with CP and their families, not just the 10% lucky enough to succeed in the litigation lottery.[5] ACOG and other organizations could initiate the beginning of the end of CP litigation with an official pronouncement rather than waiting for tort reform or special CP courts, or any of the other political malpractice fixes. In the meantime, CP is not going away. But neither is the myth that EFM can predict the unknowable—the precise time that CP was reversible. And as long as there are expert witnesses willing to testify that EFM can prevent CP, CP-EFM litigation is also not going away.

MAIN POINTS

- Electronic fetal monitoring (EFM), the most common obstetrical procedure used today, is clinically ineffectual but primarily responsible for a worldwide birth injury litigation crisis centered around the myth that it predicts cerebral palsy (CP).
- Based on years of clinical use and numerous clinical trials, EFM has not yet proven to accurately identify hypoxic events.
- The American Congress of Obstetricians and Gynecologists needs to educate practicing obstetricians, and publish an official statement declaring EFM useful as a nursing labor-saving device but also stating that EFM is not the standard of care either in labor rooms or courtrooms.
- CP-EFM litigation is a huge waste of time and money better used researching the causes of CP and helping all children with CP and their families, not just the 10% lucky enough to win the litigation lottery.

The power to prevent the injustice and waste engendered by 40 years of useless CP lawsuits and trials is within the grasp of ACOG and similar groups. It is time for these groups to stop rearranging the Titanic's deck chairs, abandon the EFM ship, and alleviate the CP-EFM malpractice lottery. ■

For an in-depth review of EFM literature and history including the use and misuse of EFM in labor rooms and courtrooms see: Sartwelle TP. Electronic fetal monitoring: a bridge too far. J Legal Med. *2012;33:313-379.*

The author reports no real or apparent conflicts of interest.

References

1. Grimes DA, Peipert JF. Electronic fetal monitoring as a public health screening program: the arithmetic of failure. *Obstet Gynecol*. 2010;116:1397-1400.
2. Gridell RM, Alfiredic Z, Gyte GM, Devane D. Antenatal cardiotocography for fetal assessment. *Cochrane Database Syst Rev.* 2010:CD007863.
3. Graham EM, Ruis KA, Hartman AL, et al. A systematic review of the role of intrapartum hypoxia-ischemia in the causation of neonatal encephalopathy. *Am J Obstet Gynecol*. 2008;199:587-595.
4. MacLennan A, Hankins G, Speer M. Only an expert witness can prevent cerebral palsy. *Obstet Gynecol*. 2006;8:28-30.
5. MacLennan A, Nelson KB, Hankins G, Speer M. Who will deliver our grandchildren? *JAMA*. 2005;294: 1688-1690.
6. Umstead MP, Permezel M, Pepperell RJ. Intrapartum cardiotocography and the expert witness. *Austr N Z J Obstet Gynecol*. 1994;34:20-23.
7. Gaffney G, Sellers S, Flavell V, et al. Case-controlled study of intrapartum care, cerebral palsy, and perinatal death. *Br Med J.* 1994; 308:743-750.
8. Nelson KB, Dambrosia JM, Ting TY, Grether JK. Uncertain value of electronic fetal monitoring in predicting cerebral palsy. *N Engl J Med*. 1996;334:613-618.
9. Barrett JF, Jarvis GJ, Macdonald HN, et al. Inconsistencies in clinical decisions in obstetrics. *Lancet*. 1990;336:549-551.
10. Clark SL, Hankins GD. Temporal and demographic trends in cerebral palsy—facts and fiction. *Am J Obstet Gynecol*. 2003;188:628-633.
11. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin No. 106: Intrapartum fetal heart rate monitoring: nomenclature, interpretation, and general management principles. *Obstet Gynecol*. 2009;114:192-202.
12. US Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation. *Confronting the New Health Care Crisis: Improving Health Care Quality and Lowering Costs by Fixing Our Medical Liability System*. Washington, DC: US Department of Health and Human Services; 2002.
13. Beller FK. The cerebral palsy story: a catastrophic misunderstanding in obstetrics. *Obstet Gynecol Surv*. 1995;50:83.
14. Obladen M. Lame from birth: early concepts of cerebral palsy. *J Child Neurol*. 2011; 26:248-256.
15. American College of Obstetricians and Gynecologists and American Academy of Pediatrics. *Neonatal Encephalopathy and Cerebral Palsy: Defining the Pathogenesis and Pathophysiology*. Washington, DC: American College of Obstetricians and Gynecologists; 2003.
16. MacLennan A. A template for defining a causal relation between acute intra partum events and cerebral palsy: international consensus statement. *Br Med J*. 1999;319:1054-1059.
17. *Prenatal and Perinatal Factors Associated with Brain Disorders*. Freeman JM, ed. Washington, DC: US Department of Health and Human Services; 1985.
18. Lent M. The medical and legal risk of the electronic fetal monitor. *Stan L Rev*. 1999;51:807-837.
19. Sartwelle TP. Defending a neurologic birth injury. Asphyxia neonatorum redux. *J Legal Med*. 2009;30:181-247.
20. Silvert M . Claim that events before birth caused cerebral palsy is disputed. *BM J*. 2000;320:1626.
21. Zain HA, Wright JW, Parrish GE, Diehl SJ. Interpreting the fetal heart rate tracing: the effect of knowledge of neonatal outcome. *J Reprod Med*. 1998;43:367-370.
22. *Daubert v Merrell Dow Pharmaceuticals, Inc*., 509 US 579 (1993).
23. Gordon R. The likeable witness: in litigation, as in life, likability is key. *For the Defense*. 2005;47:20-25.
24. Hankins GD, Erickson K, Zinberg S, Schulkin J. Neonatal encephalopathy and cerebral palsy: a knowledge survey of fellows of the American College of Obstetricians and Gynecologists. *Obstet Gynecol*. 2003;101:11-17.
25. Morgan MA, Hankins GD, Zinberg S, Schulkin J. Neonatal encephalopathy and cerebral palsy revisited: the current state of knowledge and the impact of American College of Obstetricians and Gynecologists task force report. *J Perinatol*. 2005;25:519-525.
26. Costantine MM, Saade GR. The first cesarean: role of "fetal distress" diagnosis. *Semin Perinatol*. 2012;36:379-383.