



# Does electronic fetal heart rate monitoring reduce the risk of neonatal death?

**IT'S UNCLEAR.** Although the authors of this retrospective analysis claim to have found evidence that electronic fetal heart rate monitoring lowers the risk of early neonatal death, that finding isn't supported by data from randomized, controlled trials.

*Chen H-Y, Chauhan SP, Ananth CV, Vintzileos AM, Abuhamad AZ. Electronic fetal heart rate monitoring and its relationship to neonatal and infant mortality in the United States. Am J Obstet Gynecol. 2011;204(6):491.e1-10.*

#### ►EXPERT COMMENTARY

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Obstetric care providers have two patients: the mother and the fetus. Although it is relatively easy to tell when the mother is unwell, determining the well-being of the fetus is far more difficult.

Several tests have been developed to confirm fetal well-being during labor. The most widely used is electronic fetal heart rate monitoring (EFM), also referred to as fetal cardiotocography. EFM was introduced by Hon and Lee in the 1960s, and is now the most common obstetric procedure in the United States.<sup>1,2</sup> It is noninvasive, simple to perform, inexpensive, and readily available in almost all obstetric units. However, despite our best efforts, we have little objective evidence that EFM has improved perinatal outcomes.

A 2006 Cochrane review of 12 randomized, controlled trials (RCTs) involving more than 37,000 women concluded that, compared with intermittent auscultation—the only acceptable control because randomization to no intrapartum monitoring would be unethical—the only benefit of intrapartum EFM was a reduction in the incidence

of seizures in the early neonatal period (the number needed to treat to prevent one event was 661). However, this finding did not translate into a diminished risk of seizures after the first week of life. There was otherwise no significant difference in perinatal outcomes, including no difference in the rates of cerebral palsy or death, although EFM was associated with an increased risk of obstetric intervention and operative delivery.<sup>3</sup>

It is this contradiction between the almost routine use of intrapartum EFM in the United States and the lack of evidence supporting its use that the authors hoped to address in their analysis.

#### What did Chen et al find?

In the lead-up to their analysis, the authors make a compelling argument that the existing data—including the 12 RCTs summarized in the Cochrane review<sup>3</sup>—are flawed. They raise specific concerns about such issues as “low-quality” study design, insufficient data in low-risk populations, and the use of pathologic antecedents (such as newborn encephalopathy) instead of cerebral palsy as a clinical endpoint. These are all reasonable and valid critiques.

So how did Chen and colleagues proceed? Did they design and execute a high-quality prospective study to address these issues? Did they reanalyze the existing RCTs using more sophisticated statistical methodology in an effort to correct for these deficiencies?

They did neither. They simply carried out another retrospective study using a large but

#### **FAST TRACK**

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poorly validated data set. In doing so, they transgressed and indeed aggravated all of the concerns they themselves raised about the existing literature. Specifically:

- Their retrospective analysis is a far inferior study design, compared with the RCTs they criticized
- Their efforts to distinguish between high-risk and low-risk pregnancies were rudimentary at best and relied on reported birth/death certificate data, which—as the authors themselves and the accompanying editorial concede<sup>4</sup>—is a notoriously unreliable source
- They made no effort to look at any medium- or long-term measures of neurologic injury.

The observation that EFM was associated with a decreased risk of neonatal seizures and 5-minute Apgar scores below 4 is not novel. Neither is the observation that EFM is associated with an increased risk of operative delivery—both cesarean and operative vaginal delivery. **The only novel observation in this study is that, in a cohort of 1.7 million singleton pregnancies, EFM appeared to be associated with a decrease in the risk of early neonatal death** (defined as death within the first 6 days of life), although no such association was noted for deaths in the late neonatal (7–27 days) or postneonatal (28–364 days) periods.

### Limitations of the study design

RCTs remain the gold standard for clinical trials, and for good reason. The **absence of randomization** in the current study poses significant limitations. It prevents us from understanding why some women received intrapartum EFM while others did not. This makes it impossible to determine if we are comparing two equal groups, a limitation that cannot be overcome even with the most elegant of statistical analyses.

More concerning, however, is the **lack of an adequate control group**. The authors conclude that “the use of electronic fetal heart rate monitoring was associated with a substantial decrease in early neonatal mortality and morbidity.” This begs the question:

### WHAT THIS EVIDENCE MEANS FOR PRACTICE

Not only does this analysis add little to the literature—it muddies the waters even further. In my opinion, the authors missed the boat entirely when it came to interpreting these data—but plaintiff’s attorneys won’t make the same mistake. I anticipate that, in the years ahead, this study will be quoted more by lawyers than by physicians. The study effectively seals the fate of any legal case in which EFM was not used in labor, despite the fact that the best available evidence shows no significant difference in perinatal morbidity and mortality between EFM and other standardized methods of intrapartum fetal monitoring, such as intermittent auscultation.

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compared with what? In the numerous RCTs on this topic, intrapartum EFM was compared head-to-head with a standardized protocol of intermittent auscultation, whereas the comparison group in the current study was women who did not receive EFM.<sup>3</sup> Stated differently, the absence of EFM is not equivalent to intermittent auscultation. An alternative and, in my opinion, far more likely explanation for the observed difference in mortality is that the current study compares women who received intrapartum EFM with those who simply had inadequate fetal monitoring in labor. And I am not aware of any report or, for that matter, any obstetric care provider who believes that it is unnecessary to monitor fetal well-being in labor.

**The conclusion of this study should have been that adequate monitoring of the fetus in labor can prevent early neonatal death, not that adequate monitoring of the fetus in labor with EFM can prevent early neonatal death.** Moreover, the authors’ attempt to deflect this issue by referring to the current study as an example of “reality-based medicine” as opposed to



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“evidence-based medicine” undermines the very foundation of scientific investigation.

### **More questions than answers**

The major conclusion of this study is that EFM protects against early neonatal death. So why is there no information about cause of death? These data should be readily available from a linked birth/death certificate data set. Such information might help to determine whether the excess early neonatal deaths were related to EFM or, more likely, to other variables surrounding or related to the delivery, such as the inability to perform an emergency cesarean, if indicated, or the lack of providers skilled in neonatal resuscitation. ❌

### **References**

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