Does the use of diagnostic technology reduce fetal mortality?

1 | COMMENTARY

1.1 | Overview

In this issue of Health Services Research, Grytten et al. examined the effect that the introduction of new diagnostic technologies of electronic fetal monitoring (EFM) and obstetrical ultrasound had on fetal death (stillbirth) in Norway. While both technologies have been studied widely since their introduction some four decades ago, there have been few well-designed studies on the effects of ultrasound and EFM on fetal death.

1.2 | Electronic fetal monitoring

Electronic fetal monitoring was introduced in the early 1970s as a tool to assess fetal well-being in the antepartum and intrapartum period with the focus on prevention of perinatal morbidity and mortality. The goal for antepartum surveillance was to prevent fetal death (stillbirth). The essential question that fetal monitoring is attempting to address is whether the fetus is well oxygenated in utero. The fetal heart rate response is modulated by the fetal brain through sympathetic and parasympathetic interplay. Diminished oxygenation and metabolic acidosis/acidemia are associated with defined abnormal fetal heart patterns that are potentially predictive of fetal brain injury and death. FHR monitoring has almost universal acceptance as an antepartum assessment tool for fetal well-being and for assessment of the fetus during the intrapartum management of labor. In the United States, FHR monitoring was used among 45 percent of laboring women in 1980, 62 percent in 1988, 74 percent in 1992, and 85 percent in 2002.

Despite this widespread use of EFM, particularly in the Western world, the efficacy of this technology remains controversial. This is particularly the case for our understanding of the impact of EFM on decreasing the risk of fetal death and fetal asphyxia. The impact of EFM on fetal outcomes is further challenged by the limitations of the science, and 63 percent of neonatal asphyxia cases have no known risk factors in term gestations. What is clear that the use of EFM has led to an increase in the cesarean delivery rate since being introduced as a tool to assess fetal status at any point in time.

Several tools have been introduced over the course of the last three decades to improve the accuracy of EFM in detecting fetal acidosis as indicated by fetal heart rate tracings that are judged to be abnormal during labor. Fetal scalp pH sampling was used in the decades of 1980s and 1990s. A fetal scalp blood pH level of less than 7.20 was considered abnormal and suggested the fetus was not getting enough oxygen. However, this technique was cumbersome and fell out of favor in 2000s and is rarely used today to evaluate the fetus for acidosis. Fetal scalp stimulation was introduced as another diagnostic test for fetal distress, but the interpretation of the fetal heart rate response was felt to be quite subjective. Fetal pulse oximetry was introduced in 2000s to assess fetal distress during labor. A Cochrane review compared fetal pulse oximetry plus EFM versus EFM alone based on clinical trials reporting on a total of 8013 pregnancies at 34 weeks and greater. There was evidence of a decrease in cesarean delivery for nonreassuring fetal status in the fetal pulse oximetry plus EFM group compared to EFM alone (RR 0.65, 95 percent CI 0.46 to 0.90, n = 4008). However, fetal pulse oximetry did not reduce the overall cesarean rates. Widespread use of this technology was never adopted as a better predictor for fetal acidosis.

In 2008, the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) partnered with the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) to sponsor a workshop focused on electronic FHR monitoring. The conference established rules for interpreting fetal heart rate (FHR) tracings from EFM: Category I (normal), Category II (indeterminate) which was not predictive of metabolic acidosis, and Category III (abnormal) which was associated with abnormal fetal acid-base status and the potential for metabolic acidemia. The group consensus was that EFM was a test of the current acid-base status of the fetus and was not predictive of adverse birth outcomes such as cerebral palsy. The false-positive rate of EFM predicting cerebral palsy was high, at greater than 99 percent. They also found that the use of EFM was associated with both increases in operative vaginal delivery and cesarean delivery for abnormal FHR patterns or acidosis or both, and that EFM use does not result in a reduction of cerebral palsy. However, the three-tiered system for categorization of FHR patterns is an improvement in clinical practice and has been accepted as the current standard.

1.3 | Fetal ultrasound

Fetal ultrasound was introduced in the mid-1970s as a tool for confirming gestational age and for fetal assessment and evaluation, particularly for congenital anomalies. The technology has greatly improved over the last several decades. Fetal diagnostic imaging is now a routine component in the care for nearly all pregnancies in the Western world. Ultrasound has great accuracy in gestational age assessment, detection of multiple gestation, and potentially lethal congenital anomalies. As a result, the expectation would
be that ultrasound would lead to the identification of those fetuses at greater risk for fetal and neonatal death. The earlier the ultrasound assessment is performed in the pregnancy, the more accurate the confirmation of gestational age. With early ultrasound confirmation of dates, women are less likely to progress to a postdate pregnancy that is associated with a greater risk for stillbirth. Another potential benefit of diagnostic ultrasound is for determination of placental location and detection of placenta previa and placental invasion abnormalities that impact fetal well-being. Fetal ultrasound assessment of well-being also includes the use of the ultrasound biophysical profile (breathing, tone, movement, amniotic fluid volume) when along with antenatal fetal heart monitoring nonstress testing (NST) serves as an adjunctive measure of fetal health.

Fetal diagnostic imaging has also proved beneficial in fetal prenatal diagnosis including amniocentesis, chorionic villus sampling, and percutaneous umbilical blood sampling (PUBS) for fetal chromosomal karyotyping and for intrauterine fetal transfusion in instances of fetal isoimmunization. These procedures enabled by ultrasound could also result in a decrease in the risk of fetal death especially for potentially lethal conditions and for severe fetal isoimmunization (ie, Rh disease). Routine ultrasound also increased the number of pregnancy terminations for fetuses with congenital anomalies in one study. However, the RADIUS randomized trial from the United States did not show an increase in the number of fetal terminations.

Like EFM, ultrasound has been well studied as a tool for fetal assessment. Cochrane reviews encompass more than 1000 publications and the conclusions have been that using ultrasound as a screening tool has only a minimal effect on perinatal morbidity and mortality.

Fetal diagnostic imaging is typically performed and interpreted by experts. Certification for medical sonographers is through the American Registry Diagnostic Medical Sonographer (ARDMS). Certification is a voluntary process and documents that an individual has met specific requirements and has the knowledge, skills, and abilities to perform within a profession (ARDMS.org). The ultrasound practice receives an accreditation through the American Institute of Ultrasound in Medicine (AIUM). Both are important for demonstration of clinical competence in diagnostic fetal imaging.

Fetal heart rate interpretation modules have also been introduced and standardized over the last decade to assess an individual's competency and for institutional credentialing.

In the medical literature, there have only been a few well-designed studies evaluating the impact on EFM and ultrasound on fetal death. Most studies have had insufficient sample size to draw meaningful conclusions. In addition, both EFM and ultrasound have improved significantly over the last several decades as has clinical expertise in interpretation has improved, which may require temporal adjustment in evaluating the impact of these technologies on clinical outcomes. These studies also have a number of confounders giving diverse population demographics and level of maternal and fetal risk during pregnancy. Fetal death leading to stillbirth is a devastating outcome of pregnancy, and the incidence varies from 4 to 40 deaths per 1000 birth and depends on country and population factors.

This present study evaluates a large dataset collected in Norway covering the period from 1967 to 1995, which includes the first three decades of the introduction of EFM and ultrasound in the assessment of the fetus and antepartum and intrapartum evaluation of the fetus during labor. This was a period of rapid decline in fetal death in Western countries which occurred as both technologies became more commonly accepted as an integral component of routine obstetric practice. Over the last decade, the rates of stillbirth have remained fairly stable as obstetrical protocols and guidelines for assessment and interpretation of EFM and ultrasound have become embedded into clinical practice.

This source of these data was from the Medical Birth Registry of Norway. All maternity units are expected to report all births to the Registry. The introduction of EFM and diagnostic ultrasound at the hospital were collected using a questionnaire that was sent to all senior consultants in every maternity unit in the country at five-year intervals beginning in 1967-1969 and extending through 2004. By the end of 1980, 43 of 44 maternity units had ultrasound and most all adopted EFM.

The primary objective of the study was an assessment of fetal outcomes. For this study, a stillbirth was defined as a baby born at or after 28 completed weeks' gestation with no signs of life.

Known risk factors and confounders for stillbirth were including in the analysis. The study also included an additional analysis of congenital anomalies to test whether the introduction of routine fetal ultrasound assessment between 17 and 18 weeks' gestation led to a decrease in the prevalence of infant born with congenital anomalies.

Clinical data were collected from 1.2 million births at 44 maternity units. The results showed a marked decline in fetal death from 1.3 percent to 0.04 percent, and this decline was especially significant for post-term deliveries. EFM was not associated with any statistically significant effect on fetal death for term and post-term deliveries. EFM was not associated with any statistically significant effect on fetal death for term and post-term deliveries. EFM was not associated with any statistically significant effect on fetal death for term and post-term deliveries. EFM was not associated with any statistically significant effect on fetal death for term and post-term deliveries.

The contribution of routine ultrasound to the reduction of fetal death was nearly 20 percent overall. In an analysis of post-term outcomes (defined by a pregnancy greater than 41 weeks), ultrasound contributed to a 50 percent reduction in fetal death. For preterm deliveries, defined as less than 37 weeks, the use of ultrasound had no effect on fetal death. In the secondary analysis of congenital anomalies as a dependent variable, the regression coefficients for ultrasound and EFM were too small to reach statistical significance.

The strengths of this study are that it examines a large population where maternal care, EFM, and ultrasound were universally applied regardless of economic circumstances. The findings that ultrasound did play a role in the decrease in fetal death, particularly during the first two decades of observation, are confirmation of the benefits of ultrasound to improvement in obstetrical care and obstetrical outcomes. This result is consistent with the hypotheses about the potential impact of this technology on fetal outcomes. In contrast, EFM was not associated with the decline in stillbirth per 1000 birth and depends on country and population factors.
the same time period. However, this study just confirms the limitations of EFM in pattern recognition and interpretation with respect to preventing fetal death.

Antenatal fetal heart assessment using EFM for those at high risk for stillbirth has become the expected standard of care, combined with ultrasound assessment (biophysical profile and Doppler) for those at greatest risk for fetal death (eg, severe fetal growth restriction). As a result, antenatal fetal assessment with EFM has stood the test of time. The resulting concurrent temporal change in the standard of care is one of the limitations of this study. Another limitation is that the data were accumulated from a single country with a fairly homogenous population which might lead to a question of the findings not being generalizable to more diverse populations.

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