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The Future of Electronic Fetal Monitoring

Philip Warrick PhD & Emily Hamilton, MDCM
PERIGEN, INC, MEDICAL RESEARCH & DEVELOPMENT

Summary

Starting from a description of the common practices in perinatal electronic fetal monitoring (EFM) in place today, this paper outlines promising new directions in EFM technologies and analysis that have the potential to improve detection of fetal distress during labour and delivery and thereby improve maternal and fetal outcomes.

Introduction

Electronic fetal monitoring (EFM) began with the early devices and seminal studies of Hon et al. in the early 1960s (1) that measured fetal heart rate (FHR) and uterine pressure (UP), a procedure also known as cardiotocography (CTG). EFM became commonplace in modern obstetrics in the 1970s and 1980s – despite lacking the evidence of randomized control studies that are required for the introduction of medical devices into clinical practice today. Nevertheless EFM use has become a mainstay of current perinatal obstetrics for the detection of fetal distress due to acute hypoxia. This paper highlights its benefits and limitations while proposing new directions available with modern computing, signal processing and machine learning that have the potential to improve how EFM acquires, analyzes and interprets data.

EFM Technologies

Standard fetal monitoring devices have changed little in recent decades. FHR is still calculated based on the identification of cardiac pulsation either non-invasively via an external Doppler ultrasound sensor or by means of a fetal ECG sensor on the fetal scalp. UP is measured directly with intrauterine pressure sensors or indirectly by using external sensors that measure abdominal wall tension.

Standard EFM Analysis

Approaches to EFM analysis are embodied in guidelines by the major obstetrical governing bodies: the American Congress of Obstetricians and Gynecology (ACOG), the Royal College of Obstetricians and Gynecology (RCOG) and the International Federation of Gynecology and Obstetrics (FIGO). The fetal heart rate (FHR) is described in terms of:

- Baseline level, which describes the effectiveness of the heart as a pump (the cardiac output)
- Baseline variability which describes autonomic neural control of the heart (and ultimately implicates brain function)
- Decelerations and their relationship to maternal contraction. These indicate the sensitivity of the fetus to episodes of fetal oxygen-supply interruption due to umbilical-cord compression by maternal contraction
- Accelerations (generally associated with fetal movement and well-being).

Thresholds of these FHR characteristics defined in the guidelines assess the normality or 'non-reassuring' (that is, possibly hypoxic) state of the fetus.

Historically, clinicians estimated each of these parameters manually by visual inspection of a paper tracing printout. However, information technology advances have made central monitoring and digital archiving common in modern obstetrical departments and the ability to automatically detect and display these features in real-time is possible in selected systems (e.g., PeriCalm Patterns).

Clinical implementation of these guidelines to have been successful in some important areas, notably, the reduction in of hypoxic ischemic encephalopathy (HIE) (2,3). However EFM use has been heavily debated due to inter- and intra-subject variation in its interpretation, and the view that high false-positive rates with EFM have contributed to the increase in cesarean section rates (4). Surprisingly, forty years after widespread introduction of EFM, very little is known about the real efficacy of FHR analysis based on guideline criteria. In fact, guideline features and thresholds have never been put to rigorous test to demonstrate that they are the most discriminating aspects of the FHR. Only recently have there been systematic studies using consistent, automated techniques that assess their performance in terms of sensitivity and specificity (11).

Innovative Approaches to EFM Analysis

While these recent studies that establish estimates of performance using current accumulated clinical knowledge are important, the possibility to analyze the UP and FHR signals with modern signal-processing techniques offers the potential to extract new discriminating information that has not been considered before. In addition, given an outcome criteria (such as fetal hypoxia), rapid developments in machine learning research have made it possible to select the most discriminating set of features from a larger set of correlated features. This will finally permit selecting features based on their information content rather than on clinical intuition and historical grounds.

Guideline-based FHR analysis focuses on features having direct correspondence to clinical understandings of FHR characteristics and clear visibility on the tracing. Signal-processing approaches that extract information from less-visible aspects of the FHR signal allow questions such as these to be addressed:

1) How is the fetus responding to uterine contractions?
2) Which is dominant--short-term or long-term variability (STV or LTV)?
3) Is the variability following simple cyclical patterns or it is less predictable?
4) What are the odds of a successful outcome if a ‘non-reassuring’ labour is allowed to continue naturally?

Clinicians’ informal answers to these questions are refined by experience and form their ongoing overall ‘situational-awareness’ during labor and delivery. Visual inspection, however, offers limited ability to quantify such assessments comprehensively and consistently. New signal-processing techniques provide indices with clinically relevant information, but do so in more consistently in mathematical, statistical and probabilistic terms. We describe a few of these approaches below.

System identification

PeriGen, a software company specializing in advanced obstetric decision-support, has recently proposed a new approach to FHR analysis, based on system-identification theory. It by-passes contraction and deceleration detection altogether and focuses directly on the dynamic relationship between uterine pressure (as an input) and the fetal heart rate (as an output). (17-18) Rather than delineating individual events, this mathematical method results in a succinct characterization of the overall response of the FHR to uterine pressure.

System identification analysis of FHR corresponds well to recognized fetal physiology. Many years ago the antepartum contraction stress test (CST) was used to unmask vulnerability for hypoxia by applying a controlled stress via contractions to determine if they induced decelerations, revealing a potentially compromised fetal-placental unit. (30-32) In many ways labor is the ultimate contraction stress test. Although the stress of contractions in labor is not controlled, uterine pressure can be measured. With system identification techniques it is possible to characterize the response of the fetal heart rate *relative* to the uterine contractions it experiences.

This novel approach is well-suited to current clinical practice. Although the fetal heart rate is subject to numerous influences, uterine pressure is the only input that is accessible by routinely used external monitoring; indeed, clinicians already interpret certain uterine pressure–fetal heart rate relationships (e.g., deceleration depth, shape and timing with respect to contraction) as indications of pathology. Accounting for measurement noise and artifact, we estimated linear system dynamics in terms of an impulse response function (IRF), a model that relates uterine pressure to very-low frequency FHR energy (below 0.03 Hz) , and is therefore complementary to other FHR components such as baseline and variability. From this IRF model we extracted two key parameters, *gain* and *delay,* that have direct clinical significan*ce.* *Gain* is an indication of the size of the FHR response, normally manifested as the depth of the deceleration relative to contraction amplitude. The *delay* is an indication of the timing of the response, normally observed as a lag between the on-set of the deceleration compared to the beginning of the contraction.

We have applied a machine learning method to consider the multiple factors including the IRF parameters, heart rate and variability parameters as well as trends over time in order to classify the tracing as normal or pathological. These statistical methods are well suited to biological systems where the relationships between the outcome state and many interrelated time dependent variables are not linear. In our study, the fetal heart rate response relative to uterine pressure response was very different in babies born with symptomatic metabolic acidosis compared to babies with normal gases at birth. This approach correctly classified more than half of the pathological cases, 1.5 hours before delivery with a false positive rate of 7.5%. Using the same dataset this method matched the sensitivity of a modern EFM feature-and-rule based approach and bettered its specificity by 15%. (18)

New measures of heart-rate variability

It is known that fetal heart-rate variability (fHRV) contains frequency components over a wide range of frequencies from 30mHz to 1Hz and beyond, with the lower frequency spectrum generally being a marker of sympathetic neural activity while the higher spectrum is mediated by the parasympathetic system (19,20). While some conventional measures of variability such as STV and LTV do account for some of these different frequency characteristics, linear power spectral analysis gives a more complete picture of the relative contributions of the two neural components, leading to use of the LF/HF power ratio of the fHRV, an index which is widely used in adult studies.

There is also much interest in non-linear fHRV measures, especially those addressing the regularity (or its opposite, the randomness or *entropy*) of the variability, also stemming from studies of adult HRV. These measures quantify the degree of steadiness or change of the variability over time. There have been numerous studies that show some discrimination of fetal distress cases using approximate entropy (ApEn), with non-healthy fetus showing more irregular patterns (20,21). Recent contributions using fractal analysis (22) or the scattering transform (23) generalize this analysis further. Fractal analysis measures in one parameter how the frequency spectrum is distributed, without use of an explicit frequency threshold to distinguish LF and HF. In a similar way, the scattering transform measures in a few succinct parameters the ‘burstiness’ or ‘intermittency’ of the fHRV with non-healthy fetus tending to be more intermittent.

Probabilistic Approaches

Timing and persistence of standard FHR parameters is assessed mentally by clinicians, but is difficult to model and quantify in automated systems. A recent work used Bayesian theory and sequences of FHR features to determine a probability of abnormality (29). In doing so, the short-term and long-term characteristics of the FHR are simultaneously assessed. The incorporation of timing in these probabilistic approaches, also called ‘generative’, distinguish themselves from ‘discriminative’ approaches which tend to make decisions sequentially and at one time scale without regard for the context of the decision time (i.e. the past history preceding the decision moment). These two approaches are not mutually exclusive and combining their strengths is the focus of considerable research (18).

Antenatal Monitoring

Fetal monitoring in the antenatal period is already routinely performed for certain high-risk pregnancies after the 26th week during the non-stress test (NST), which measures the FHR response to fetal movement during brief in-patient monitoring (20-40 min). Whereas perinatal monitoring is focussed on avoiding acute hypoxia, antenatal monitoring aims to detect more chronic hypoxia that may have fetal developmental repercussions during pregnancy. With more readily available in-patient access to antenatal EFM as well as the advent of wearable sensors, antenatal monitoring has implications for more informative developmental studies. This is currently being done for select patient groups such as those with reduced fetal movements after the 24th week. (28)

Innovative Developments in Monitoring

Fetal Electrocardiogram (fECG)

Electrodes placed on the surface of the maternal abdomen can detect changes in the electromagnetic field that arise from uterine contractions and from the fetal heart. The changes induced by the beating fetal heart are relatively weak given its size and are mixed with changes from maternal heart beats and other contracting muscles. It is therefore a challenging engineering problem to isolate the fetal cardiac signal and characterize the ECG—that is, detecting its morphology and critical electrical timing events (i.e., the PQRST complex). (5, 6)

The cardiac cycle time, or R-R interval, is not available from conventional fetal monitors. To improve signal-to-noise ratios with Doppler sensors, heart rate--the inverse of the cycle time—is averaged over several seconds and the R-R intervals are not retained. This is also true for scalp electrodes which acquire cleaner signals. Preserving this R-R information would be helpful to better characterize short-term fetal heart rate variability. Furthermore, detecting all the ECG complex events could provide features that help discriminate fetuses with significant hypoxia.

These electrodes can also detect maternal uterine contraction and map its propagation, a measurement called electrohysterography (EHG). This is a different sensor than the strain-gauge approach used in the tocogram of conventional EFM. Euliano et al found that EHG propagated with less fundal dominance in mothers with active phase arrest of dilation compared to mothers with vaginal delivery (9). Lucovnik et al. have also used EHG to distinguish preterm labor from false labor. (10)

ST Segment Analysis (STAN)

The ST segment of the fECG has a particularly long history in the search for methods to detect fetal acidemia. Relying on ECG obtained from direct scalp electrodes, the STAN algorithm (Neoventa) defines an ST event as an elevation in the relative amplitudes of the T-wave and QRS complex (the T/QRS ratio) or as an ST segment morphology that is biphasic. (7)

To date there have been 6 country-specific prospective randomised clinical trials using ST segment technology and a number of observational studies. Results have not been consistent across the RCTs with respect to rates of operative delivery and reduction in measures of metabolic acidemia. In some studies (UK, Swedish) the operative interventions decreased in the STAN group and in others it did not (Finnish, French, Dutch, US). (8, 12-16) Outcomes related to metabolic acidosis were defined differently across the studies. Again an inconsistent pattern was seen, with reductions in metabolic acidosis related outcomes reported in some studies (Swedish, Dutch) but unchanged in others (Finnish, French and US) and borderline in another (UK). The largest and most recent US RCT with an enrollment of over 11,000 women concluded that ST segment analysis used as an adjunct to EFM did not improve perinatal outcomes or decrease operative-delivery rates.

The disparity in results may be partially explained by differing national clinical protocols in the studies that affect intervention, notably concerning fetal blood sampling and acceptable cesarean section rates. The former is the most definitive test of intrapartum acid base status and its use would strongly affect outcome irrespective of the method of fetal surveillance. Fetal blood sampling rates varied greatly across these studies--it is rarely performed in North America--and even within study arms. In addition, North American cesarean rates are much higher. Finally, adherence to an ST-segment specific protocol with focused educational efforts was part of the study protocol and the success of these critical aspects also affected study outcomes.

Fetal Magnetocardiogram (fMCG)

In the area of antenatal monitoring, an important problem during early development is that smaller fetal cardiac dimensions generate smaller-amplitude events that are more difficult to detect electrically (with fECG) or electroacoustically (with Doppler ultrasound). For this reason, fetal magnetocardiogram (fMCG), sensitive to minute changes in the electromagnetic field, is used in a few selected hospitals in the world to measure fetal cardiac development after the 24th week (26). First reported in 1974 (27), it can detect the lower amplitude R-waves of early fetal cardiology and do so with high temporal resolution (< 1ms), which make it an excellent choice for fHRV study. In addition, it can detect the cardiac time intervals including the systolic time intervals (STI). However, MCG devices are large and costly, requiring specialized installation including electromagnetic shielding for adequate signal quality and therefore even when available, applicability is generally limited to select high-risk pregnancy groups.

Cardiac-Valve Timing from Doppler

An innovative use of Doppler ultrasound technology, the same used for extracting the FHR in EFM, is to measure the timing of cardiac valve movement (24). Rather than only observing events associated with the propagation of the cardiac electrical fields, as with a typical ECG, these measure assess the electromechanical coupling of the heart. Four events during the cardiac cycles are detected with this technique, corresponding to the opening and closing of the mitral and aortic valves. Among these valve timing intervals, the STI during the early QRST complex are considered the most clinically relevant measures of myocardial function. For example, a prolonged pre-ejection period (PEP), the time between the onset of the Q wave and the opening of the aortic valve, has been correlated with early hypoxia and acidosis of the fetal myocardium (25). Assessment of the discriminating power of this information--and comparison with time-interval indices extracted from the fECG complex alone--will require larger clinical studies that include hypoxic cases.

Future directions

Introduction of these new methods will first require better quantitative estimates of current clinical performance using systematically interpreted classical FHR measures. From this reference point, it is possible to assess the value added by information from more subtle yet mathematically rich FHR features. The final step is to translate these indices into clinical terms with physiological significance, to enhance what the clinician already is doing, or to introduce novel information that pushes the state of the art in assessing perinatal fetal state. Automated-decision support systems that account for the best of current clinical knowledge and incorporate information from these new techniques are poised to enable richer and more consistent perinatal analysis--within hospitals and among hospitals--in ways that improve fetal and maternal outcomes.

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