Electronic fetal heart rate monitoring- Current Status

By
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You are more likely to die on the day of your birth than for the next 40 years of life combined

Ed Hon 1969

Early Hopes for Electronic Intrapartum FHR Monitoring

- In 1975 Paul and Quilligan predicted that Fetal Monitoring could decrease the incidence of mental retardation by 50%*
- Some believed that EFM could decrease the incidence of learning disabilities, antisocial behavior, deviant liberal thinking and could threaten the future of the Democratic Party.

*Quilligan EJ, Paul RH, 1975; Obstet Gynecol 45:96

Before 1975 It was commonly believed that most cerebral palsy was due to hypoxic events occurring during labor
Since then many studies have been done that would indicate that a minority of cases of cerebral palsy can be attributed to intrapartum hypoxia alone

51 years of electronic fetal heart rate monitoring (EFM) Where are we today?

While severe damaging fetal hypoxia during labor will always be detected with EFM, problems with EFM interpretation include:

- High inter and intra observer variation in interpretation
- Most abnormal EFM patterns do not result in significantly hypoxic fetuses

Inter and intra observer variation in EFM interpretation

- Inter observer agreement between paired observers 43% to 70%
- Intra observer agreement between 2 interpretations of the same EFM recording by the same observer on 2 different occasions 74% to 84%

Nielsen et al ACTA Ob Gyn 1987, Blix et al BJOG 2003, Beaulieu et al J CMA 1982, Devane et al J Adv Nursing 2005, Ayers-de-CamposBJOG 1999, Chauhan, et al AJOG 2008, Palmoaki et al, J Perinat Med 2006, Figueras et al J Perinat Med 2005

ACOG Practice Bulletin # 106 July 2009 (Reaffirmed 2015)

- EFM does not improve perinatal mortality
- EFM does not reduce the incidence of CP
- EFM has a 99% false positive rate in the prediction of CP
- EFM causes excess operative deliveries

Yet they recommend continuous EFM in all high risk patients

And amnioinfusion for variable deceleration

ACOG-EFM does not improve perinatal mortality

1979 1st NIH Consensus Development Conference on fetal monitoring

Non Randomized Historical Control Studies

11 reports from 1973 to 1978

Compared EFM patients to non-intensive auscultation patients for incidence of intrapartum fetal death (IFD)

No EFM	IFD	EFM	IFD	Ratio	P
99,842	176	38,785	21	3.26	<.01
Rate		1.76/1000		0.54/1000	

NIH Publication no.79-1073, Bethesda, Md. April 1979

Non Randomized EFM Trials

- High risk EFM fetuses had lower intrapartum fetal death rates after introduction of EFM than low risk auscultated fetuses from historical controls
- Benefit of EFM most pronounced with high risk patients

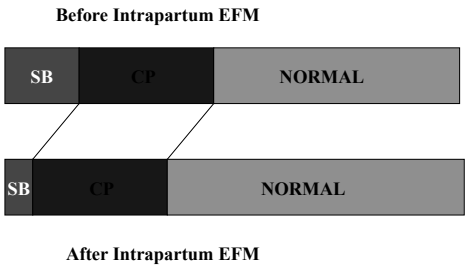
Randomized Controlled Trials of EFM v intensive auscultation showed:

- Fewer neonatal seizures in the EFM group but no difference in long term neurological abnormalities
- Higher cesarean section rate and more operative vaginal deliveries in the EFM group

ACOG: EFM does not reduce the incidence of CP

The reality is that while there has been a reduction in intrapartum fetal death,* there has been no reduction in the incidence of cerebral palsy since pre-fetal monitoring days. Prematurity accounts for the largest group of children with CP

*Antenatal Diagnosis. Report of a consensus development conference. NIH publication #79-1973, Bethesda Md, 1979



ACOG: There is a 99% false positive rate with EFM for prediction of CP

- From an epidemiologists vantage point, the role of EFM should be prediction of outcome*
- From the obstetrician's vantage point, EFM is a diagnostic modality and its role is to identify need for corrective intervention
- If EFM were perfect, there would be a 100% false positive rate in the prediction of CP because it would provide intervention that prevents all CP

* Nelson KB, et al, N Engl J Med 1996;334:613-8

Because of the problems with interpretation of intrapartum EFM and the uncertainty of basing clinical management on EFM, there have been 3 NICHD consensus conferences on the subject in 1979, 1997 and most recently in 2008. There is a continued recognition of the inconsistency of definitions, interpretation of the data, and how to use the data in clinical management

1997 NICHD Clinical Statement

- .."there was relatively little variation in opinion within the group about the definition of the normal fetal heart rate tracing.."
  1. Normal baseline rate
  2. Normal (moderate) FHR variability
  3. Presence of FHR accelerations
  4. Absence of FHR decelerations

"..there was agreement that .. Such a tracing confers an extremely high predictability of a normally oxygenated fetus…"

There was also agreement that recurrent late decelerations, recurrent severe variable decelerations or a prolonged deceleration with absent variability is consistent with hypoxia sufficient to cause damage or death.

NICHD Research Planning Workshop AJOG 1997

April, 2008 – NICHD re-convened a workshop on EFM terminology

NICHD 2008- Terminology Uterine Contractions

- Normal: ≤5 contractions in 10 minutes averaged over a 30 minute window
- Tachysystole: >5 contractions in 10 minutes averaged over a 30 minute window.
  - Tachysystole should always be qualified as to the presence or absence of associated FHR decelerations
  - The term tachysystole applies to both spontaneous and stimulated labor
  - The terms hyperstimulation and hypercontractility are not defined and should be abandoned.

Evolution of FHR interpretation terminology

- Before 1997 – "Fetal Distress"
- 1997– Reassuring and Non-reassuring

2008 Reassuring and Non-reassuring terminology was excluded and EFM patterns were defined by category

NICHD 2008- Terminology
3-tier FHR Interpretation system
Category I
Normal FHR Pattern

- Baseline rate 110-160 bpm
- Baseline FHR variability: moderate (5-25 BPM)
- Late or variable decelerations: absent
- Early decelerations: present or absent
- Accelerations: present or absent

NICHD 2008- Terminology
3-tier FHR Interpretation system
Category II
Equivocal FHR Patterns
Baseline rate and variability

- Baseline rate: Bradycardia (<110 BPM) not accompanied by absent variability
- Tachycardia (>160 BPM)
- Variability: Minimal (≤5 BPM but present)
- Variability absent without recurrent decelerations
- Marked baseline variability (≥25 BPM)

NICHD 2008- Terminology
3-tier FHR Interpretation system
Category II
Equivocal FHR Patterns
Periodic changes

- Absence of induced accelerations after fetal stimulation
- Recurrent variable decelerations accompanied by minimal or moderate baseline variability
- Prolonged deceleration ≥2 but < 10 minutes
- Recurrent late decelerations with moderate baseline variability
- Variable decelerations with other characteristics such as slow return to baseline, or overshoots.

Am J Obstet Gynecol. 2013 Aug;209(2):89-97. doi: 10.1016/j.ajog.2013.04.030. Epub 2013 Apr 27.

Intrapartum management of category II fetal heart rate tracings: towards standardization of care.

Clark SL[1], Nageotte MP, Garite TJ, Freeman RK, Miller DA, Simpson KR, Belfort MA, Dildy GA, Parer JT, Berkowitz RL, D'Alton M, Rouse DJ, Gilstrap LC, Vintzileos AM, van Dorsten JP, Boehm FH, Miller LA, Hankins GD.

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Abstract

There is currently no standard national approach to the management of category II fetal heart rate (FHR) patterns, yet such patterns occur in the majority of fetuses in labor. Under such circumstances, it would be difficult to demonstrate the clinical efficacy of FHR monitoring even if this technique had immense intrinsic value, since there has never been a standard hypothesis to test dealing with interpretation and management of these abnormal patterns. We present an algorithm for the management of category II FHR patterns that reflects a synthesis of available evidence and current scientific thought. Use of this algorithm represents one way for the clinician to comply with the standard of care, and may enhance our overall ability to define the benefits of intrapartum FHR monitoring.

Prolonged decelerations

This algorithm does not address the issue of prolonged deceleration, as defined by the NICHD. This definition is too broad to be clinically useful in isolation.[20,21] A 121-second deceleration to 90 beats/min and a 9-minute and 59-second deceleration to 50 beats/min are, from a clinical standpoint, very different, yet both are, by definition, prolonged decelerations. The situations associated with prolonged decelerations also greatly impact the decision making—a prolonged deceleration following an epidural should give rise to a completely different set of management considerations than an identical pattern in a woman laboring with a scarred uterus.[40,42,43] Such variations are legion and cannot be adequately addressed with a single algorithm—indeed, their rarity and physiologic heterogeneity probably preclude meaningful study as a group. We can only comment that tolerance for such recurrent patterns remote from delivery ought to be small unless the etiology is apparent and can be promptly ameliorated.

PRE-EXISTING CNS ABN0RMALITY

Neonatal Encephalopathy and Neurologic Outcomes ACOG & American Acad. of Pediatrics 2nd edition March 2014

- Thus in a fetus exhibiting either moderate variability or accelerations of the FHR, damaging degrees of hypoxia induced metabolic acidemia can be reliably excluded.

Problems with Category II management

- Repetitive prolonged decelerations
- Absent variability with normal baseline rate and no periodic FHR changes
- Cannot use variability during decelerations to rule out damaging metabolic acidosis

Current management recommendations

- Category I (Normal pattern) no intervention indicated
- Category III Abnormal patterns demand successful correction or delivery
- Category II Equivocal Patterns
  - May continue to observe if moderate FHR variability and or accelerations spontaneous or induced
  - Unclear how to manage category II patterns with minimal variability and absence of accelerations

Maternal heart rate coincidence on the fetal monitor

Problem Cases

- 12 cases of misleading MHR
- All had maternal tachycardia
- All occurred in the 2nd stage of labor
- 4 began in the late first stage of labor
- 3 recognized with good outcome
- 6 with pH <7.0
- 6 with Cerebral Palsy
- 2 stillbirths

#	MHR	Stage	pH	Outcome
2	Tachy	1&2	n/a	**Stillborn**
3	Tachy	2	6.9	Apgar 2-6. Normal outcome
4	Tachy	2	n/a	Evolving fetal sepsis
5	Tachy	2	n/a	FSE Severe VD, Stat C/S Nl
6	Tachy	1&2	6.8	Apgar 0-1, BE -20, HIE, Now **CP**
7	Tachy	2	7.3	Sinusoidal, F-M Hem, HIE,**CP**
8	Tachy	2	6.84	Apgar 5-7, BE -17, HIE, Now **CP**
9	Tachy	2	n/a	**Stillborn**
10	Tachy	1&2	n/a	FSE->I.D, VAVD, OK
11	Tachy	2	6.71	Apgars 1-3, BE-23, HIE, Now **CP**
12	Tachy	1&2	6.74	Apgars 2-3, BE -15, HIE, Now **CP**
13	Tachy	2	6.76	Apgars 3-6, BE -20, HIE, Now **CP**

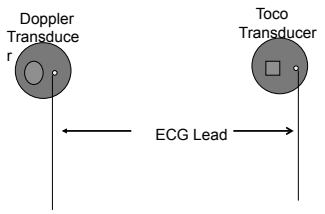
When MHR is recorded from maternal abdominal Doppler Transducer

- There is software in both Corometrics and Philips monitors that will compare the signal derived from the maternal abdominal Doppler transducer to a MHR signal obtained from maternal ECG or pulse oximeter.
- In the Corometrics monitor this logic must be turned on (enabled). With coincidence it shows overlapping hearts
- In the Philips monitor this logic is always operating if there is a maternal signal available for comparison. The new Philips monitors always have a maternal signal source. With coincidence it shows question marks

Requirements for automatic coincidence detection

- **There must be either a maternal ECG hookup or a maternal SPO2 signal hookup to provide the MHR signal for comparison to the signal being traced by the Doppler external transducer**
- **On HP-Philips monitor, after 30 seconds of coincidence the monitor prints a ?**
- **On GE-Corometrics the heartbeat coincidence (HBC) detection must be enabled. When HBC is enabled it prints "HBC" on the center margin of the tracing. It will indicate coincidence when a detected phase relationship occurs for => 60% of detected beats for about 60 seconds. It will print overlapping hearts when coincidence is detected and when coincidence is resolved it will print side by side hearts.**

Maternal ECG signal from face of external transducers



Maternal Pulse integrated in TOCO Transducer, means automatic measurement of MHR and differentiation to FHR without applying any additional sensors or electrodes. #

- Current Customer clinical situation = all vendors
  - As described very often in medical OB literature coincidence of FHR / MHR is one major reason for Incidents when not realized and resulting litigation.
  - Cross Channel Verification (CCV), the Philips Coincidence Detection is already standard Feature for all Avalon Fetal Monitors, similar although less effective solutions also exist with other vendors such as GE.
  - Today CCV* between Mother and Baby requires MSpO2 or MECG Monitoring
  - Additional parameters add Effort for the Clinicians and add Discomfort for the Mother
  - Maternal Monitoring via SpO2 or MECG is not consistently utilized in majority of monitoring situations
- Additional Safety with **Philips** *Smart Pulse*
  - Safety = CCV* is always active as a Safety Net
  - Comfortable for Mom – no additional Transducers placed
  - Easy to use = not possible to forget for clinician
  - Unique to Philips - Patent protected !

*CCV = Cross Channel Verification, Philips specific functionality
 # not yet available in USA

Confidential 37

BvB

Received Ampicillin 2 hr before delivery
Delivered by C/S at 1047
Apgars 1^{1},3^{5},4^{10}
Cord Blood gases:
Art pH 7.11, pCO_2 62, HCO_3 20
Vein pH 7.30, $pCO_2$42, HCO_3 21
Placenta-chorioamnionitis and funisitis
All neonatal cultures negative
Dx HIE with cerebral edema, elevated creatinine, and MAS
Now spastic quad

Because the neonatologist made a diagnosis of hypoxic, ischemic encephalopathy, all care providing physicians that saw the neonate-child carried forth the same diagnosis. The case went to trial and was settled by the defense because of the mis-diagnosis of H.I.E.