Fetal Monitoring: Help or Hindrance?

2012
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Objectives

• Upon completion of this presentation the participant will be able to:
  • Understand the legal implications and liability with the use of electronic fetal monitoring
  • List the components of the NICHD nomenclature
  • Evaluate the system of EFM for consistency and challenges in interpretation and implementation
  • Describe new methods of assessing fetal well-being
Fetal Monitoring

• Is the most common obstetric procedure in the United States.
• As of 2002, 85% of approximately 4 million live births were evaluated with electronic fetal monitoring.
• Despite this widespread use, there has been no decrease in neonatal cerebral palsy and neurologic injury. (1)
One of the significant challenges in utilization of EFM is, its development has occurred over decades, in different countries, where different terms were used to describe some of the characteristics and patterns. (1 & 8)
Evolution of EFM

• 1958: Dr. Edward Hon: developed a method for continuous electronic fhr recording & described 3 patterns of decelerations: early, variable & late related to head compression, cord compression & utero-placental insufficiency.
• 1963: Dr. Hon: improved the recording with the scalp electrode.
• 1966: Caldeyro-Barcia: long/ short term variability & Hammacher identified that neonates with lates had lower Apgar scores and a higher stillbirth rate.
• 1969: Hammacher: accelerations= fetal well being.
As international interest grew

1971 International Conference for common nomenclature in New Jersey

1972 Second Conference in Amsterdam

General agreement was accepted for a common nomenclature for periodic changes (early, late and variable) \((11)\)
Continuous Data Display

• Should prevent fetal death and morbidity
• Thought to be superior in diagnosing fetal acidemia
• Assumption of efficacy. By the 1990’s meta-analyses clearly indicated that EFM increases cesarean deliveries and operative vaginal deliveries without improving outcomes in healthy, term pregnancies without risk factors. (15)
Common Areas of Litigation Related to EFM

- Failure to accurately assess maternal-fetal status
- Failure to appreciate a deteriorating fetal condition
- Failure to treat a nonreassuring FHR
- Failure to correctly communicate maternal/fetal status
- Failure of MD/CNM to respond appropriately when notified of a nonreassuring fetal status
- Failure to institute chain-of-command when there is a disagreement between clinicians
Malpractice claims

• The most frequent allegation in perinatal claims is delayed diagnosis of fetal distress.
• The most frequent allegation against obstetricians was “failure to perform a timely cesarean delivery”
• The issue in many of these cases was the providers failure to correctly interpret the monitor tracing as indicating a need for intervention.
Discrepancies

• In some cases the failure of the physician to perform the timely cesarean delivery was attributed, at least in part, to the nurses' misinterpretation of the monitor strip and the failure to convey a sense of urgency to the physician.
Misinterpretation of Strip

**Defendant Nurse**
- “Variables”
- “Accelerations”
- Unaware of likelihood of fetal compromise
- Increased oxytocin to comply with the plan for a vaginal delivery

**Defense Experts**
- “Late decelerations”
- “Overshoots”
- Tracing that appeared ominous for hours
- Increasing oxytocin likely compromised fetus further
Litigation Issues

• Failure to correctly communicate maternal/fetal status
Sentinel Event Alert No. 30

  - Institutions should develop clear guidelines for fetal monitoring of potential high-risk patients
  - Protocols for interpretation of fhr tracings
  - Educate nurses, residents, nurse midwives and physicians to use the terminology to communicate concerning abnormal fhr tracings. (16)
NICHD criteria: A Common Language!

- 1997: New nomenclature presented to clinicians
- Proposed to act as a foundation for future research.
- Needed to be tested for validity, reliability, and reproducibility.
- To improve the ability to interpret and compare studies scientifically and to generalize the results of clinical trials. (15)
NICHD Recommendations

• Three important components of fetal heart rate monitoring;
  – The development of standard definitions.
  – The description of FHR patterns that reflect an absence of asphyxia.
  – The description of FHR patterns that are predictive of current or impending asphyxia.
In 2008 NICHD, ACOG and the SMFM met to review the nomenclature, interpretation and research recommendations originally developed in 1997. (25)
Category I Normal: FHR patterns that correlate closely with a favorable neonatal outcome identified:

Category III / Abnormal FHR patterns associated with adverse neonatal outcomes.

Category II / Indeterminate: The field continues to struggle with the area between these two extremes. Lack of uniform terminology, differing opinions in interpretation, and wide variations in definition and management of nonreassuring patterns. (25)
Category II

- Category II is the largest of the 3 categories and does not meet either Category I or Category III criteria. As such it is referred to as “indeterminate” because it is inconsistently associated with fetal acidemia.
- The problem? Approximately 80% of the strips we encounter are Category II.\(^{(25)}\)
FHR Patterns NOT defined

- Undefined concepts in 1997 & 2008
  - Wandering baseline
  - Lambda pattern
  - Shoulders
  - Overshoot
  - Variable decelerations with a late component
  - Mild, moderate, and severe variables
  - Pseudosinusoidal patterns
  - Reassuring and nonreassuring patterns
Clinical Management

• 30 years of trying to come to a consensus on definitions and classifications.
• We still have the challenge inherent in interobserver variability.
Human Factors

• Agreement between observers is reasonably high for
  – Baseline rate
  – Accelerations
  – Decelerations
• But low for variable decelerations and lower still for variability.
• Computers have been investigated for standardizing EFM interpretation.
Reproducibility

• Clinicians disagree with each other in their evaluation of FHR about 80% of the time.
• Even when reviewing the same FHR pattern several months later, a clinician disagrees with his or her own initial interpretation about 20% of the time. (3)
Inter-rater reliability

• Chauhan: 5 clinicians, 100 parturients
• Traditional intrapartum evaluation: reassuring vs. nonreassuring
• 46% of these patients had an emergent C/S
• 2% had a fetal pH less than 7.0
• Study found poor inter-rater reliability and they could not predict which parturient had an emergency C/S or low pH! (3)
Computer Based Assessment

• NICHD Nomenclature designed for both visual assessment and computer based assessment
• Utilize the accuracy of the computer to assist the subjective assessment of the clinician (15)
• Improve consistency of documentation and help eliminate interobserver variation.
OBIX Perinatal Data System
E-Tools: Baseline
E-Tools: 10x10 Accelerations
E-Tools: 15x15 Accelerations
E-Tools: Minimal Variability
E-Tools: Moderate Variability
E-Tools: Deceleration Tool
Litigation Issue

• Failure of MD/CNM to respond appropriately when notified of a nonreassuring fetal status

• Failure to institute chain-of-command when there is a disagreement between clinicians
Air Strip: There’s an App for that!
Speak up…

• Perinatal nurses need to be so secure in their own interpretation of fetal heart rate tracings that they feel free to question the interpretation of a nursing or medical colleague.

• Only then will many ob malpractice cases have a fair chance at a successful defense. (29)
Litigation Issue

• Failure to adequately monitor fetal heart rate
• Failure to identify maternal vs. fetal heart rate
• Failure to adequately monitor uterine contractions
Recommendations

• If continuous EFM is ordered, monitoring of the FHR and uterine activity via EFM should be continuous until birth.
• Issues commonly seen with incomplete or poor quality EFM recording:
  – Patient is obese
  – Patient wants to ambulate
  – Patient moves, causing signal loss
  – Maternal heart rate displayed as fhr.
Traditional Way
Monica Monitoring System
Recording of Monica Strip
Doppler Ultrasound Recording
Feather-Lite Toco
• Failure to appreciate deterioration of the fetal condition...
Competency

• Adopt & universally use one common language for FHR patterns via electronic fetal monitoring. NICHD nomenclature.
• Establish joint nurse/nurse-midwife/physician EFM educational programs. HCA
• Ensure and document all providers are competent to interpret EFM data. HCA
• Establish a clear & agreed upon definition of fetal well-being & document assessment on admission. (10)
Competency of Physicians and Nurses

• 43 Ob/Gyn training programs
  – 79% use clinical experience, & 87% include structured lectures to train residents and fellows.

• Perinatal morbidity and mortality conferences used by 85% through clinical experience and case studies.

• RN’s typically undergo bi-annual competency training (AWHONN).

• Physician competency is not formally evaluated. (19)
HealthStream

• The Advanced Fetal Monitoring & Assessment Program
• Developed by HCA in collaboration with Advanced Practice Strategies (APS)
• Online learning program focused on best practices in EFM
• Consists of seven modules by recognized EFM experts
• ACOG accredited for 12 CME cognates and HealthStream for 14 contact hours for nurses
Currently

- There is no single way of ensuring competency in the interpretation of fetal heart rate tracings
- The National Certification Corporation does offer certification in electronic fetal monitoring for nurses.
• Failure to treat a nonreassuring fetal heart rate.
Fetal Acidemia/ EFM

- Relationships between FHR variability
- Depth of decelerations
- Fetal acidemia
- Fetal vigor (5 minute Apgar score $\geq 5$)
- Duration of pattern to degree of acidemia $^{(20)}$
Results

• Moderate FHR variability was strongly associated (98%) with an umbilical cord pH > 7.15 or newborn vigor (Apgar score ≥ 7)

• Undetectable or minimal variability in the presence of late or variable decelerations was the most consistent predictor of newborn acidemia, though the association was only 23%. (20)
Results

• There was a positive relationship between degree of acidemia and the depth of the deceleration or bradycardia.
• Except for bradycardia, newborn acidemia with decreasing FHR variability in combination with decelerations develops over a period of time approximating one hour. (20)
Five Gradations of Fetal Anemia

• No acidemia
• No central fetal acidemia (oxygenation)
• No central fetal acidemia but FHR pattern suggests intermittent reductions in O2 which may result in fetal O2 debt
• Fetus potentially on verge of decompensation
• Evidence of actual or impending damaging fetal asphyxia (8)
<table>
<thead>
<tr>
<th>Variable</th>
<th>Risk of Acidemia</th>
<th>Risk Evolution</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green</td>
<td>O</td>
<td>Very low</td>
<td>None</td>
</tr>
<tr>
<td>Blue</td>
<td>O</td>
<td>Low</td>
<td>Conservative tech/begin preparation</td>
</tr>
<tr>
<td>Yellow</td>
<td>O</td>
<td>Moderate</td>
<td>Conservative tech/increased surveillance</td>
</tr>
<tr>
<td>Orange</td>
<td>Borderline/ acceptably low</td>
<td>High</td>
<td>Conservative tech/prepare for urgent delivery</td>
</tr>
<tr>
<td>Red</td>
<td>Unacceptably high</td>
<td>Not a consideration</td>
<td>Deliver</td>
</tr>
</tbody>
</table>
Conservative Techniques

• For modification of variant FHR patterns
  – Position change
  – Hyperoxia
  – Adequate intravascular volume
  – Correct excessive contractions
  – Avoid constant pushing
  – Tocolysis
  – Amnioinfusion to correct amniotic fluid deficit
# Management of Categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Techniques</th>
<th>OR</th>
<th>OB</th>
<th>Anesthesia</th>
<th>NRP</th>
<th>Location</th>
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<tr>
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<td>Available</td>
<td>Informed</td>
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<tr>
<td>Orange</td>
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<td>@ bedside</td>
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<td>OR</td>
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<tr>
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<td>Open</td>
<td>@ bedside</td>
<td>Present</td>
<td>Present</td>
<td>OR</td>
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### TABLE 5
Risk categories for fetal acidemia related to FHRV, baseline rate, and presence of recurrent decelerations

<table>
<thead>
<tr>
<th>Variable</th>
<th>No</th>
<th>Early</th>
<th>Mild VD</th>
<th>Moderate VD</th>
<th>Severe VD</th>
<th>Mild LD</th>
<th>Moderate LD</th>
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<th>Mild PD</th>
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<td>Tachycardia</td>
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<td>B</td>
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<td>Normal</td>
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<td>Y</td>
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<tr>
<td>Mild bradycardia</td>
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<td>Moderate bradycardia</td>
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<td>Severe bradycardia</td>
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<td>Sinusoidal</td>
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</tbody>
</table>

* R, blue; G, green; L.D, late decelerations; O, orange; P.D, prolonged decelerations; R, red; V.D, variable decelerations; Y, yellow.*
## Color Coded Chart

### Risk of Acidemia Related to Variability, Baseline Heart Rate and Recurrent Decelerations

<table>
<thead>
<tr>
<th>Category</th>
<th>Risk of Acidemia</th>
<th>Risk of Evolution</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green</td>
<td>0</td>
<td>very low</td>
<td>None. Indoor MJC. Increased surveillance.</td>
</tr>
<tr>
<td>Blue</td>
<td>0</td>
<td>low</td>
<td>If necessary, allow MJC.</td>
</tr>
<tr>
<td>Yellow</td>
<td>0</td>
<td>moderate</td>
<td>If necessary, allow MJC.</td>
</tr>
<tr>
<td>Orange</td>
<td>acceptably low</td>
<td>high</td>
<td>Prepare for possible urgent delivery.</td>
</tr>
<tr>
<td>Red</td>
<td>unacceptably low</td>
<td>not a consideration</td>
<td>Deliver</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Decelerations</th>
<th>Recurrent variables</th>
<th>Recurrent late</th>
<th>Prolonged</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Early</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>Early</td>
<td>(last 30 s-6 mm)</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
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</table>

### Moderate variability (normal)

<table>
<thead>
<tr>
<th>FHR</th>
<th>Tachycardia</th>
<th>Normal</th>
<th>Mild Bradycardia</th>
<th>Moderate Bradycardia</th>
<th>Severe Bradycardia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(&lt;100 BPM)</td>
<td>(10-160 BPM)</td>
<td>(&gt;60 BPM)</td>
<td>(&gt;80 BPM)</td>
<td>(&gt;80 BPM)</td>
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### Minimal variability

<table>
<thead>
<tr>
<th>FHR</th>
<th>Tachycardia</th>
<th>Normal</th>
<th>Mild Bradycardia</th>
<th>Moderate Bradycardia</th>
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</thead>
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<td></td>
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<td>(10-160 BPM)</td>
<td>(&gt;60 BPM)</td>
<td>(&gt;80 BPM)</td>
<td>(&gt;80 BPM)</td>
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</table>

### Absent variability

<table>
<thead>
<tr>
<th>FHR</th>
<th>Tachycardia</th>
<th>Normal</th>
<th>Mild Bradycardia</th>
<th>Moderate Bradycardia</th>
<th>Severe Bradycardia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>(10-160 BPM)</td>
<td>(&gt;60 BPM)</td>
<td>(&gt;80 BPM)</td>
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</tbody>
</table>

### Sinusoidal

<table>
<thead>
<tr>
<th>Marked variability</th>
</tr>
</thead>
</table>

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**REFERENCE:**
Preliminary Approach

• Guideline is a first step in optimal pattern management.
• Selective approaches to each individual FHR pattern with guidelines for risk of fetal acidemia.
• Must be individualized to institutions and modified at different times of day as logistics change.
• An alternative approach to identify fetal hypoxia and need for intervention that should be available soon is...
ST Segment Analysis

• STAN was approved in 2005 by the FDA as an adjunct to electronic fetal monitoring
• Available in Europe for some time
• Decreased need for operative vaginal delivery and emergency cesarean birth.
• Large RCT currently underway.
• Comparison under US conditions with standard EFM alone with results expected in 2013. 
  (21)
ECG Analysis

Analysis of segments of the fetal ECG to determine the presence of myocardial ischemia.

Only the gold scalp lead is used.
STAN

• Based upon the ability to detect changes in the ST interval when the fetus mobilizes its compensatory mechanisms against hypoxia.
• An already hypoxic fetus or one with a decreased capacity to mount a response may not show a change in T-wave amplitude with further hypoxia.
• STAN is only useful as an adjunct system to be used on a fetus still capable of mounting a response.
FDA Approval

• Singleton pregnancies
• Fetus is more than 36-0/7 weeks gestation
• Membranes are ruptured
• First stage of labor
• No active or involuntary pushing
• No contraindication to scalp electrode
• Established a baseline T/QRS ratio
Baseline Requirements

- Fetal ECG electrode
- Maternal skin reference electrode
- Microprocessor-based monitor to ID the fetal ST segment & T-wave changes.
- Compares the changes to a baseline reading of 500 consecutive heart-beats or 4-5 minutes of monitoring.
- Creates the baseline for subsequent comparison
ST Events

• When the monitor detects a significant change in the ST interval, it displays an “ST event” on the main screen in an event log.
• 3 types of events are indentified by STAN
  – Episodic T/QRS ratio increase
  – Baseline T/QRS ratio increase
  – Biphasic ST
During labor fetuses essentially fall into 3 categories

- Tolerating labor without any issue = category I
- Clearly in trouble with abnormal fetal acid-base balance who need urgent intervention or delivery = category III
- Category II: where we evaluate, continue surveillance and reevaluate all the clinical circumstances
Category II Meet STAN

- This is the area where it is believed that STAN may be potentially helpful.
- Initial assessment of FHR monitoring strip and categorization into one of three zones.
  - Green: no intervention, watch expectantly
  - Red: need expeditious delivery
  - Regardless of ST changes
## FHR Classification System for ST Analysis

<table>
<thead>
<tr>
<th>FHR Classification</th>
<th>Baseline FHR</th>
<th>Variability</th>
<th>Decelerations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Green Zone</strong></td>
<td>• 110-160 bpm</td>
<td>• Moderate variability (6-25) • Accelerations present</td>
<td>• Early decelerations • <em>Variable deceleration with a duration of &lt; 60 sec and depth &lt; 60 beats</em></td>
</tr>
<tr>
<td><strong>Yellow Zone</strong></td>
<td>• Bradycardia &lt; 110 bpm • Tachycardia &gt; 160 bpm • &gt; 150 bpm with minimal variability</td>
<td>• Minimal variability (&lt; 5 bpm) for &gt; 40 min • Marked variability (&gt; 25 bpm) for &gt; 40 min</td>
<td>• Variable decelerations with a duration of ≥ 60 sec or depth ≥ 60 beats • Recurrent late decelerations • Prolonged deceleration for ≥ 2 min regardless of variability</td>
</tr>
<tr>
<td><strong>Red Zone</strong></td>
<td></td>
<td>• Absent variability—regardless of other FHR patterns</td>
<td>• Sinusoidal pattern</td>
</tr>
</tbody>
</table>
## ST Analysis: Management

<table>
<thead>
<tr>
<th>Zone</th>
<th>No ST Event</th>
<th>ST Event</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Expectant management</td>
<td>• Expectant management</td>
</tr>
<tr>
<td></td>
<td>• Continued observation</td>
<td>• Continued observation</td>
</tr>
<tr>
<td>Green zone</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Expectant management, closer observation</td>
<td>• Direct physician assessment</td>
</tr>
<tr>
<td></td>
<td>• If &gt; 60 min (or earlier if FHR shows rapid deterioration of fetal condition), direct physician assessment of fetal state</td>
<td>• Intrauterine resuscitation as appropriate</td>
</tr>
<tr>
<td>Yellow Zone</td>
<td></td>
<td>• If no improvement in fetal condition, expeditious delivery</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• In second stage with active pushing, expeditious delivery</td>
</tr>
<tr>
<td>Red Zone</td>
<td>• Expeditious delivery regardless of an ST changes</td>
<td>• Expeditious delivery regardless of an ST changes</td>
</tr>
<tr>
<td></td>
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</tr>
</tbody>
</table>
Utility of STAN

• Comes in the management of those patients classified in the yellow zone because ST changes in this zone become an important indicator of progressive hypoxia, and the initiation of anaerobic metabolism, with its potential for metabolic acidosis.
Implication

• This presentation is not meant to be a comprehensive scientific explanation of STAN monitoring.
• Approved training, certification, and credentialing are all mandated by the FDA.
• There is also a learning curve to the use of the system.
Help or Hindrance?

• Recommendations
  – Continued use of EFM in the U.S. in light of medico-legal climate
  – Adoption of the NICHD criteria by all specialties to enhance communication
  – Interdisciplinary training in fetal monitoring
  – Computer enhanced pattern recognition to supplement clinicians interpretation & communication
  – Continued evaluation of supplemental technologies
Why we keep caring...


26. HealthStream: on line @ www.HealthStream.com

27. OBIX Perinatal Data System: on line at [www.obix.com](http://www.obix.com)
