CATEGORY II
FETAL MONITORING STRIPS:
SAFEGUARDING AGAINST INCORRECT
READINGS AND RESPONSES

BY

LUKE M. PITTONI, ESQ.
I. Background:

Today, the use of intrapartum fetal heart rate monitors is widespread. As of 2004, electronic fetal monitoring (EFM) was employed in an estimated 89% of live births.\(^1\) Like any technology, EFM has its limitations. An ACOG Practice Bulletin issued in December 2005 reviewed some of these limitations.

- The false positive rate of EFM for predicting adverse outcomes is high.
- The use of EFM is associated with an increase in the rate of operative interventions (vacuum, forceps, and cesarean delivery).
- The use of EFM does not result in a reduction of cerebral palsy case rates.

Interpretation of FHR tracings is subjective and not very reproducible. Studies have consistently shown that there is large inter- and intraobserver variability in interpretation of electronic FHR monitoring tracings. For this reason, the National Institutes of Child Health and Human Development convened a workshop to try to reach consensus, for research purposes, on definitions of FHR patterns.

In 2008, this group updated these recommendations by creating a three tier FHR interpretation system, in which Category I represents a normal tracing (predictive of normal fetal acid-base balance at the time of observation). Category II represents an indeterminate tracing. Category II tracings are not predictive of abnormal fetal acid-base status, but require continued surveillance and evaluation. Category III represents an abnormal tracing (predictive of abnormal fetal acid-base status at the time of observation). They recommended prompt evaluation of Category III tracings; most patients with these tracings require expeditious intervention, such as provision of maternal oxygen, change in maternal position, treatment of maternal hypotension, and discontinuation of any uterotonic drugs being administered.\(^2\)

In July of 2009, ACOG replaced its Practice Bulletin Number 70 from December 2005 with Practice Bulletin Number 106, Clinical Management Guidelines for Obstetrician-Gynecologists. In 2008, ACOG partnered with the Eunice Kennedy Shriver National Institute of Child Health and the Society for Maternal-Fetal Medicine to sponsor a workshop focused on EFM. The goal of the workshop was to review the categorizations from the prior workshops, assess existing classification systems for interpreting specific FHR patterns and to make recommendations for research priorities for EFM. Ultimately, ACOG arrived at the following:

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Summary of Recommendations and Conclusions:

The following recommendations and conclusions are based on good and consistent scientific evidence (Level A):

► The false-positive rate of EFM for predicting cerebral palsy is high, at greater than 99%.
► The use of EFM is associated with an increased rate of both vacuum and forceps operative vaginal delivery, and cesarean delivery for abnormal FHR patterns or acidosis or both.
► When the FHR tracing includes recurrent variable decelerations, amnioinfusion to relieve umbilical cord compression should be considered.
► Pulse Oximetry has not been demonstrated to be a clinically useful test in evaluating fetal status.

The following conclusions are based on limited or inconsistent scientific evidence (Level B):

► There is high interobserver and intraobserver variability in interpretation of FHR tracing.
► Reinterpretation of the FHR tracing, especially if the neonatal outcome is known, may not be reliable.
► The use of EFM does not result in a reduction of cerebral palsy.

The following recommendations are based on expert opinion (Level C):

► A three-tiered system for the categorization of FHR patterns is recommended.
► The labor of women with high-risk conditions should be monitored with continuous FHR monitoring.
► The terms hyperstimulation and hypercontractility should be abandoned.  

II. 3-Tier Fetal Heart Rate Interpretation System:

Category I - Normal

Include all of the following:

- Baseline rate: 110-160 bpm
- Baseline FHR variability: moderate
- Late or variable decelerations: absent
- Early decelerations: present or absent
- Accelerations: present or absent

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Category II - Indeterminate

Include all FHR tracings not categorized as Category I or III. Category II tracings may represent an appreciable fraction of those encountered in clinical care. Examples include any of the following:

Baseline Rate
- Bradycardia not accompanied by absent baseline variability
- Tachycardia

Baseline FHR variability
- Minimal baseline variability
- Absent baseline variability not accompanied by recurrent decelerations
- Marked baseline variability

Accelerations
- Absence of induced accelerations after fetal stimulations

Periodic or episodic decelerations
- Recurrent variability decelerations accompanied by minimal or moderate baseline variability
- Prolonged deceleration ≥ 2 min but ≤10 min
- Recurrent late decelerations with moderate baseline variability
- Variable decelerations with other characteristics, such as slow return to baseline, “overshoots,” or “shoulders”

Category III - Abnormal

Include either:
- Absent baseline FHR variability and any of the following:
  - Recurrent late decelerations
  - Recurrent variable decelerations
  - Bradycardia
- Sinusoidal pattern

III. 5-Tier FHR Classification System:

Parer and Ikeda (2007) had previously proposed a color coded five-tier system for both FHR interpretation and management. Coletta and co-workers (2012) found that the five-tier system (Table I) had a better sensitivity than the three-tier system.\(^4\)

Coletta emphasized that although the EFM is often criticized for having a high false positive rate, as it is unable to predict cerebral palsy, this is not the intended goal. EFM is used to detect patterns that reflect significant hypoxia and allow intervention before fetal injury.\(^5\)

In 2013, Clark and colleagues stressed that there was no standard national approach to the management of Category II fetal heart rate (FHR) patterns, yet such patterns occur in the majority (≥80%) of fetuses in labor. Further, they noted that the management of Category II FHR patterns remain the most important and challenging issue in the field of FHR monitoring and is arguably second only to preterm birth as the most pressing issue in clinical obstetrics. In addition, the overall Caesarean delivery rate exceeded 32% in the United States in 2011, and exceeds 50% of all births in some hospitals.

Thereupon, the authors suggested an Algorithm for the management of Category II FHR patterns (Figure I) along with several important specific classifications (Table II).

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Algorithm for Management of Category II Fetal Heart Rate Tracings:

OVD, operative vaginal delivery.

*aThat have not resolved with appropriate conservative corrective measures, which may include supplemental oxygen, maternal position changes, intravenous fluid administration, correction of hypotension, reduction or discontinuation of uterine stimulation, administration of uterine relaxant, amnioinfusion, and/or changes in second stage breathing and pushing techniques.

TABLE II

Management of Category II Fetal Heart Rate Patterns: Clarifications for Use in Algorithm:

1. Variability refers to predominant baseline FHR pattern (marked, moderate, minimal, absent) during a 30-minute evaluation period, as defined by NICHD.
2. Marked variability is considered same as moderate variability for purposes of this algorithm.
3. Significant decelerations are defined as any of the following:
   - Variable decelerations lasting longer than 60 seconds and reaching a nadir more than 60 bpm below baseline.
   - Variable decelerations lasting longer than 60 seconds and reaching a nadir less than 60 bpm regardless of the baseline.
   - Any late decelerations of any depth.
   - Any prolonged deceleration, as defined by the NICHD. Due to the broad heterogeneity inherent in this definition, identification of a prolonged deceleration should prompt discontinuation of the algorithm until the deceleration is resolved.
4. Application of algorithm may be initially delayed for up to 30 minutes while attempts are made to alleviate category II pattern with conservative therapeutic interventions (e.g., correction of hypotension, position change, amnioinfusion, tocolytics, reduction or discontinuation of oxytocin).
5. Once a category II FHR pattern is identified, FHR is evaluated and algorithm applied every 30 minutes.
6. Any significant change in FHR parameters should result in reapplication of algorithm.
7. For category II FHR patterns in which algorithm suggests delivery is indicated, such delivery should ideally be initiated within 30 minutes of decision for cesarean.
8. If at any time tracing reverts to category I status, or deteriorates for even a short time to category III status, the algorithm no longer applies. However, algorithm should be reinitiated if category I pattern again reverts to category II.
9. In fetus with extreme prematurity, neither significance of certain FHR patterns of concern in more mature fetus (e.g., minimal variability) or ability of such fetuses to tolerate intrapartum events leading to certain types of category II patterns are well defined. This algorithm is not intended as guide to management of fetus with extreme prematurity.
10. Algorithm may be overridden at any time if, after evaluation of patient, physician believes it is in best interest of the fetus to intervene sooner.

FHR, fetal heart rate, NICHD, Eunice Kennedy Shriver National Institute of Child Health and Human Development.


The Algorithm relies strongly on the presence of moderate baseline variability or accelerations. They acknowledge that recent data suggests that Cesarean delivery based on classic definitions of protracted active phase, arrest of dilatation or arrest of second-stage descent alone may not be necessary, and that longer periods of observation may yield lower intervention rates. However, data demonstrating the safety of these more conservative approaches in the presence of persistent Category II FHR patterns are lacking. The authors emphasized that they are hesitant to recommend non-intervention for an arrest of active phase dilation of four (4) hours in the presence of recurrent late decelerations, even in the presence of moderate variability. Further intervention in patients with certain Category II patterns and slow, but technically adequate labor progression, may also be an appropriate option.

They emphasized that some well-defined features of Category II patterns (e.g. fetal tachycardia or marked variability) were not included in the Algorithm. It is not because they considered these patterns innocuous, but that it was their expectation that other concerning patterns included in the Algorithm will appear prior to the need for intervention. They also indicated that the Algorithm does not address the issue of prolonged decelerations. They felt that this definition is too broad to be clinically useful in isolation.

They stressed that this Algorithm, nor any other management approach to labor, will ever predict or prevent, unexpected sentinel events that may occur without warning and rapidly change a FHR pattern from Category II to Category III. Even the most expeditious response may be insufficient to avoid neonatal encephalopathy and its sequelae.
However, there are two clinical situations that exist with category II patterns, that while they exclude ongoing hypoxia/acidemia, they may be harbingers of sentinel events that may rapidly lead to profound hypoxia namely vaginal bleeding sufficient to suggest a possible placental abruption and any woman undergoing a trial of labor often a Cesarean section.

Their most vexing issue was the issue of decreased or absent variability. They accept the accuracy of data concluding that FHR variability must be absent to reliably reflect a high degree of correlation with severe fetal acidemia. However, they caution against delaying delivery of a deteriorating FHR pattern because criteria indicating probable severe metabolic acidemia has not yet been met.\(^6\)

Soncini and colleagues demonstrated that the interpretation of fetal heart rate tracings based on a strictly standardized system is closely associated with umbilical artery acid-base status at delivery. The authors assigned tracings with moderate FHR variability or FHR acceleration to Category IIA and tracings with minimal/absent baseline FHR variability and no FHR accelerations to Category IIB.

Their results confirmed that the neonatal outcome for Category II tracings was varied, especially in terms of acid-base values of the fetal umbilical artery blood at birth. However, Category IIB correlated with neonatal outcome deterioration in terms of acid-base balance -1 minute Apgar score, NICU admission and development of neonatal encephalopathy. On the other hand, the presence of moderate HFR variability and accelerations (Category IIA) correlated with a high negative predictive value of severe metabolic, reaching 100%. Their results confirmed that the presence of moderate FHR variability and/or accelerations generally ensure that the fetus is not hypoxic.\(^7\)

IV. Fetal Heart Rate Monitoring Patterns Consistent with an Acute Peripartum or Intrapartum Event:

1. A Category I or Category II fetal heart rate tracing when associated with Apgar scores of 7 or higher at 5 minutes, normal umbilical cord arterial blood (± 1 standard deviation), or both is not consistent with an acute hypoxic-ischemic event.

2. There is a great distinction to be made between a patient who initially presents with an abnormal fetal heart rate pattern and one who develops an abnormal fetal heart rate pattern during labor.


a. A Category II fetal heart rate pattern lasting 60 minutes or more that was identified on initial presentation with persistently minimal or absent variability and lacking accelerations, even in the absence of decelerations, is suggestive of a previously compromised or injured fetus. If fetal well-being cannot be established by appropriate response to scalp stimulation or biophysical testing, the patient should be evaluated for the method and timing of delivery. An emergency Caesarean delivery may not benefit a fetus with previous severe compromise.

b. The patient who presents with a Category I fetal heart rate pattern that converts to Category III as defined by the Eunice Kennedy Shriver National Institute of Child Health and Human Development guidelines is suggestive of a hypoxic-ischemic event.

c. Additional fetal heart rate patterns that develop after a Category I fetal heart rate pattern on presentation, which may suggest intrapartum timing of a hypoxic-ischemic event, include tachycardia with recurrent decelerations and persistent minimal variability with recurrent decelerations.⁸

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Tachycardia
Bradycardia
Variability

Absent
Undetectable from baseline

Minimal
Undetectable from baseline - ≤ 5 bpm

Moderate
6 – 25 bpm
Accelerations
Early Decelerations
Variable Decelerations
Late Decelerations
Category I

Criteria: Baseline rate 110 to 160 beats per minute; baseline variability moderate; late or variable decelerations absent; early decelerations present or absent
Category II

Criteria: Minimal variability
Category II

Criteria: Marked variability
Category II

Criteria: Absent variability without recurrent decelerations
Category II

Criteria: Absence of induced accelerations after fetal stimulation
Category II

Criteria: Recurrent late decelerations with moderate variability
Category II

Prolonged deceleration
Category II

Criteria: Recurrent variable decelerations with moderate variability
Category II

Criteria: Variable decelerations with “slow return to baseline”, “overshoots” or “shoulders”
Category III

Category III (Abnormal) Tracings

Absent variability and recurrent variable decelerations
Category III

Sinusoidal pattern