Evidence-Based Management of Category II EFM

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Disclosures
• No financial
• Vice-Chair of Committee for OB Practice for ACOG, Editor for Gabbe, Oral board examiner for ABOG

Primary Cesarean Indications

Barber et al. Obstet & Gynecol 2012
Evidence-Based Management of Category II

EFM, 2020

- Most commonly used instrument in obstetrics
  - 3.7 million births, 2018
- U.S. Preventative Services Task Force = D
  - Lack of evidence for benefit; potential harm
- Cesarean rates
  - 1970: 7%
  - 2018: 32%
- Cerebral palsy
- Stillbirth
- Perceived standard of care

EFM, 2020

- Most commonly used instrument in obstetrics
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**Speaking a Common Language**

The 2008 National Institute of Child Health and Human Development Workshop Report on Electronic Fetal Monitoring

Update on Definitions, Interpretation, and Research Guidelines

- 3 tier system
  - Category I; normal
  - Category II; indeterminate
  - Category III; abnormal

Macones et al, 2008, AJOG

Frey et al. BJOG 2018

**What we see**

- Category I
  - Incidence: 4.1 – 6.0%
  - 2 features: strongly associated with pH ≥ 7.20
- Category III
  - Incidence: 0.4 – 2.1%
  - 2 features: presence of both, pH ≤ 7.00
- Category II
  - The rest
  - No data

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### Effort Fetal Monitoring (EFM) Test Characteristics

<table>
<thead>
<tr>
<th>Category</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category I</td>
<td>0.0%</td>
<td>97.7%</td>
<td>0.0%</td>
<td>98.9%</td>
</tr>
<tr>
<td>Category II</td>
<td>100.0%</td>
<td>2.4%</td>
<td>1.1%</td>
<td>100.0%</td>
</tr>
<tr>
<td>Category III</td>
<td>0.0%</td>
<td>99.9%</td>
<td>0.0%</td>
<td>98.9%</td>
</tr>
</tbody>
</table>


### EFM Test Characteristics

<table>
<thead>
<tr>
<th>Type</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal Variability</td>
<td>8.8%</td>
<td>87.5%</td>
<td>0.7%</td>
<td>98.9%</td>
</tr>
<tr>
<td>Marked Variability</td>
<td>0.0%</td>
<td>99.2%</td>
<td>0.0%</td>
<td>98.9%</td>
</tr>
<tr>
<td>Repetitive late</td>
<td>7.0%</td>
<td>97.8%</td>
<td>3.2%</td>
<td>99.0%</td>
</tr>
<tr>
<td>Repetitive prolonged</td>
<td>7.0%</td>
<td>94.7%</td>
<td>1.4%</td>
<td>99.0%</td>
</tr>
<tr>
<td>Tachycardia</td>
<td>14.0%</td>
<td>95.7%</td>
<td>3.4%</td>
<td>98.3%</td>
</tr>
</tbody>
</table>


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### Learning More about Category II

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Other Ways to Look at Cat II

- All models are adjusted for nulliparity, fever, prolonged first stage, and obesity

AUC, area under the curve; EFM, electronic fetal monitoring


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Cat II – Myth Busting

Association of Atypical Decelerations With Acidemia

Alison G. Cahill, et al. Kindely A. Saul, am, Stanley 0. Olds, am, mce, and George A. Hanke, jn, 1972

- No association with acidemia
  - Shoulders
  - Over-shoots
  - Slow returns

Cahill AG, et al. Obstet & Gynecol 2012

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OBSTETRICS

Interpreting category II fetal heart rate tracings: does meconium matter?

Heather A. Frey, MS; Methodia C. Tsoul, MD, MPH, Anthony L. Shanko, MD; George A. Masones, MD, MSCJ; Allison G. Cahill, MD, MSCJ

- Prospective cohort, 5000 women
- Presence of meconium with Category II

- Greater likelihood of acidemia and morbidity
- Worse with thick meconium

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Electronic fetal monitoring patterns associated with respiratory morbidity in term neonates


• Prospective cohort, 5000 women, 37 weeks of after
• EFM pattern associated with respiratory morbidity
  ➢ Tachycardia
  ➢ Marked variability
  ➢ Prolonged decelerations

Other Clinical Factors and Cat II

• Magnesium exposure
• Intrauterine growth restriction

Epplin KA et al. Am J Perinatol. 2015

PANORAMA

Cahill AG, et al. AJOG 2018

• Prospective cohort study, 8580 women, 37 weeks or beyond
• 2 hours of EFM prior to delivery
• Patterns predictive of acidemia and neonatal morbidity
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### Evidence

#### Figure 1.
- Participants
  - 14,450 Delivery Admissions
  - 10,997 Term singleton, non-anomalous deliveries
  - 9,492 Vaginal deliveries
  - Eligible participants
  - Excluded
    - 2,861 Preterm births
    - 298 Major anomalies
    - 294 Multiple gestations
    - Excluded
    - 1,505 Cesarean deliveries prior to labor
    - 530 Insufficient EFM
    - 373 No Umbilical cord gas
    - 9 Incarcerated patients
  - 149 Acidemia
  - 8,431 No Acidemia

Cahill AG, et al. AJOG 2018

#### Table: Predicting Acidemia

<table>
<thead>
<tr>
<th></th>
<th>AUC (95% CI)</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ever Category III</td>
<td>0.62 (0.57, 0.66)</td>
<td>69.1%</td>
<td>50.0%</td>
<td>2.4%</td>
<td>98.9%</td>
</tr>
<tr>
<td>Total deceleration area</td>
<td>0.76 (0.72, 0.80)</td>
<td>73.5%</td>
<td>67.2%</td>
<td>4.0%</td>
<td>99.3%</td>
</tr>
<tr>
<td>Total deceleration area &amp; ever tachycardic</td>
<td>0.77 (0.73, 0.80)</td>
<td>66.0%</td>
<td>76.2%</td>
<td>5.0%</td>
<td>99.2%</td>
</tr>
<tr>
<td>Total deceleration area &amp; ever moderate variability</td>
<td>0.77 (0.73, 0.81)</td>
<td>71.4%</td>
<td>68.3%</td>
<td>4.9%</td>
<td>99.2%</td>
</tr>
<tr>
<td>Ever Category III</td>
<td>0.63 (0.54, 0.63)</td>
<td>68.2%</td>
<td>58.8%</td>
<td>13.8%</td>
<td>95.0%</td>
</tr>
<tr>
<td>Total deceleration area</td>
<td>0.66 (0.64, 0.68)</td>
<td>74.8%</td>
<td>54.0%</td>
<td>13.4%</td>
<td>95.7%</td>
</tr>
<tr>
<td>Total deceleration area &amp; ever tachycardic</td>
<td>0.77 (0.75, 0.79)</td>
<td>57.5%</td>
<td>84.6%</td>
<td>26.2%</td>
<td>95.4%</td>
</tr>
<tr>
<td>Total deceleration area, ever moderate &amp; always moderate variability</td>
<td>0.77 (0.75, 0.79)</td>
<td>55.0%</td>
<td>85.7%</td>
<td>26.9%</td>
<td>95.2%</td>
</tr>
</tbody>
</table>

Cahill AG, et al. AJOG 2018

#### Figure 2.
- Comparisons for acidemia (A) and composite neonatal morbidity (B)
  - $P = .97$
  - $P = .01$
Clinical Translation

- Deceleration area threshold = 42,000 – 50,000
  - NNT = 5 (acidemia)
  - NNT = 6 (neonatal morbidity)
- Example:
  - Contracting q3 (~40 contractions in the last 120 min), 24-28 decelerations 60 beats below baseline

Cahill AG, et al. AJOG 2018

Clinical Opinion

OBSTETRICS

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

Steven L. Clark, MD; Michael P. Negrete, MD; Thomas J. Garite, MD; Roger K. Freeman, MD; David A. Miller, MD; Kathleen E. Simpson, RN; PhDs; Michael A. Bellott, MD; PhDs; Gary A. W iley, MD; Julian T. Perez, MD; Richard L. Redman, MD; Mary D’Aho, MD; Dwight J. Reese, MD; Larry C. Gister, MDs; Anthony M. Vintzileos, MD; J. Peter van Doornum, MD; Frank H. Bouch, MD; Lisa A. Miller, CNM; Dr. Gary D. V. Hawkins, MD


Problem: How we use the tool
Gain knowledge about the tool

- What do we do when we see this?

ACOG and AWONN

- Maternal lateral repositioning
- Intravenous fluid bolus
- Decrease oxytocin and/or administer tocolytic
- Amnioinfusion
- Maternal oxygen administration

Maternal Positioning

- In theory...
Enter maternal position → improve placental perfusion → improve fetal oxygenation
- 20% resolution of decelerations with maternal repositioning
- Data from 15 laboring women:

<table>
<thead>
<tr>
<th>Maternal Position</th>
<th>Left lateral</th>
<th>Supine</th>
<th>Right lateral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean systolic blood pressure</td>
<td>95 ± 10</td>
<td>96 ± 10</td>
<td>95 ± 10</td>
</tr>
<tr>
<td>Mean diastolic blood pressure</td>
<td>60 ± 10</td>
<td>60 ± 10</td>
<td>60 ± 10</td>
</tr>
<tr>
<td>Baseline fetal heart rate (bpm)</td>
<td>124 ± 15</td>
<td>125 ± 15</td>
<td>124 ± 15</td>
</tr>
</tbody>
</table>
ACOG and AWONN

- Maternal lateral repositioning
- Intravenous fluid bolus
- Decrease oxytocin and/or administer tocolytic
- Amnioinfusion
- Maternal oxygen administration

Intravenous fluid bolus

At time of epidural?

- 10-14% incidence of hypotension after neuraxial analgesia
- RCT of 1.5L IV fluid preload vs no fluid preload at time of epidural
  - No difference in incidence of hypotension
- May be beneficial in volume depleted patients
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Unanswered Questions
- Amount of fluid
- Type of fluid
- Impact on fetal heart tracings
- Impact on uterine contractility

ACOG and AWONN
- Maternal lateral repositioning
- Intravenous fluid bolus
- Decrease oxytocin and/or administer tocolytic
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Tachysystole
- Average of >5 contractions in 10 min over 30 min period
- 11% of all deliveries, 32% with associated FHR changes
- Inadequate relaxation
- Associated with neonatal acidemia and cesarean for non-reassuring fetal status
Evidence-Based Management of Category II
EFM

Benefit to Uterine Relaxation?

- Decrease or discontinue oxytocin
- Betamimetics associated with improvement in fetal heart rate abnormalities (RR 0.26, 95% CI 0.13-0.53)
- Cardiovascular adverse effects

Unanswered questions

- Useful for Category II without tachysystole?
- Nitroglycerine?
- Neonatal outcomes?
- Oxidative stress?

ACOG and AWONN

- Maternal lateral repositioning
- Intravenous fluid bolus
- Decrease oxytocin and/or administer tocolytic
- Amnioinfusion
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Amnioinfusion

- Alleviating cord compression by infusion of fluid

<table>
<thead>
<tr>
<th>Benefit</th>
<th>No benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>↓ Occurrence of variable decelerations</td>
<td>Prophylactic amnioinfusion</td>
</tr>
<tr>
<td>↓ Cesarean for NRFS</td>
<td>Chorioamnionitis</td>
</tr>
<tr>
<td></td>
<td>Meconium</td>
</tr>
</tbody>
</table>

- 60% reduction in FHR abnormalities compared with controls
- Reduction in cesarean for nonreassuring fetal status (RR 0.46, 95% CI 0.31-0.68)

Unanswered Questions

- Type of fluid (LR vs NS)
- Temperature of fluid
- Rate (Intermittent vs Continuous)
- Effect on labor/contractility
- Effect on neonatal outcomes
ACOG and AWONN

- Maternal lateral repositioning
- Intravenous fluid bolus
- Decrease oxytocin and/or administer tocolytic
- Amnioinfusion
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Maternal Oxygen (O₂) Supplementation

Fetal hypoxia → Anaerobic metabolism → Metabolic acidosis (↓pH ↑Lactate)

Oxygen
Hyperoxygenation is harmful

- Neonate
  - Bronchopulmonary dysplasia, retinopathy, abnormal neurodevelopment
- Adult
  - AVOID trial: Increased size of myocardial infarct
  - Oxygen-ICU trial: Increased ICU mortality with liberal O₂ supplementation

- Randomized controlled noninferiority trial
- Inclusion: Term, singleton pregnancies admitted for spontaneous labor or induction of labor
- Exclusion: Fetal anomaly, maternal hypoxia
- Primary outcome: Umbilical artery lactate

References:
- Hamel et al. AJOG 2013
- Raghuraman et al. Obstet Gynecol 2017
- Hansmann et al. Lancet 2004
- Girardis et al. JAMA 2016
- Vento et al. Pediatrics 2001
- Stub et al. Circulation 2015
- Hamel MS, et al. AJOG 2014
Results

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Room air</th>
<th>Oxygen</th>
<th>P-value</th>
<th>Relative Risk</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Umbilical artery gas pH</td>
<td>7.26 (7.24, 7.28)</td>
<td>7.25 (7.23, 7.27)</td>
<td>0.55</td>
<td>--</td>
<td></td>
</tr>
<tr>
<td>Base excess</td>
<td>-3.62 (-4.3, -2.9)</td>
<td>-3.4 (-4.3, -2.9)</td>
<td>0.99</td>
<td>--</td>
<td></td>
</tr>
<tr>
<td>pCO2 (mmHg)</td>
<td>19.7 (17.7, 23.2)</td>
<td>24.4 (20.8, 28.8)</td>
<td>0.06</td>
<td>--</td>
<td></td>
</tr>
<tr>
<td>pO2 (mmHg)</td>
<td>35.6 (33.5, 38.2)</td>
<td>37.4 (34.2, 39.6)</td>
<td>0.44</td>
<td>--</td>
<td></td>
</tr>
<tr>
<td>Cesarean delivery</td>
<td>2 (3.9)</td>
<td>6 (12.5)</td>
<td>0.14</td>
<td>0.32 (0.07, 1.48)</td>
<td></td>
</tr>
<tr>
<td>Cesarean delivery for NIPPS</td>
<td>0 (0.0)</td>
<td>2 (4.2)</td>
<td>--</td>
<td>--</td>
<td></td>
</tr>
<tr>
<td>Operative vaginal delivery</td>
<td>6 (11.8)</td>
<td>1 (2.1)</td>
<td>0.10</td>
<td>5.65 (0.71, 45.20)</td>
<td></td>
</tr>
</tbody>
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What happens to electronic fetal monitoring?

Resolution of recurrent decelerations within 30 minutes of administration

<table>
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<th>Room air</th>
<th>Oxygen</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resolution of recurrent decelerations</td>
<td>49 (73.6)</td>
<td>49 (88.0)</td>
<td>0.15</td>
</tr>
</tbody>
</table>
Unanswered Questions

1. Does this work?
2. At what dose? For how long?
3. On whom?
4. Are there harms/risks?

Cat II Management

- Cesarean = no more things to do

Summary

- Learning more about Cat II tracings
- Clinical factors to consider in interpretation
- Almost no evidence for the elements of 'conservative management'
- Open to new evidence
Thank you

O₂C₂ Trial

Enrollment
- Admission to L&D
- Active labor and Category II FHT necessitating resuscitation

Randomization
- O₂ 10L/min facemask
- RA No facemask

Summary of RCTs

<table>
<thead>
<tr>
<th>Source</th>
<th>n</th>
<th>Findings in O₂ group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thorp et al, 1995</td>
<td>85</td>
<td>↓ Umbilical artery pH↑ Neonatal acidemia</td>
</tr>
<tr>
<td>Nesterenko et al, 2012</td>
<td>56</td>
<td>↑ Oxidative stress↑ Delivery room resuscitation</td>
</tr>
<tr>
<td>Khaw et al, 2002</td>
<td>44</td>
<td>↑ Maternal and fetal free radical activity</td>
</tr>
<tr>
<td>Qian et al, 2017</td>
<td>443</td>
<td>↔ Umbilical artery pH</td>
</tr>
</tbody>
</table>
Cochrane: Oxygen

- "There is not enough evidence to support the use of prophylactic oxygen therapy for women in labor, nor to evaluate its effectiveness for fetal distress"
- "In view of the widespread use of oxygen administration during labor and the possibility that it may be ineffective or harmful, there is an urgent need for randomized trials to assess its effects"