OBSTETRICS

Recognition and response to electronic fetal heart rate patterns: impact on newborn outcomes and primary cesarean delivery rate in women undergoing induction of labor

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OBJECTIVE: The objective of the study was to examine the clinical impact of specific fetal monitoring-related practices during induced labor.

STUDY DESIGN: This was a prospective, nonrandomized study.

RESULTS: We studied 14,398 women undergoing oxytocin induction of labor. A decrease in the infusion rate of oxytocin in the face of specified category II fetal heart rate tracings was associated with a significantly reduced rate of neonatal intensive care unit admission (3.8% vs 5.2%, P = .01) and Apgar score less than 7 at 1 and 5 minutes (4.9% vs 6.4%, P = .01, 0.6% vs 1.1%, P = .04). Compliance with an in-use checklist was associated with both a reduction in the rate of neonatal intensive care unit admission (2.9 vs 4.4, P = .00) and a reduction in the cesarean delivery rate (15.8% vs 18.8%, P = .00).

CONCLUSION: Electronic fetal heart rate monitoring improves neonatal outcomes when unambiguous definitions of abnormal fetal heart rate and tachysystole are coupled with specific interventions. Utilization of a checklist for oxytocin monitoring is associated with improved neonatal outcomes and a reduction in the cesarean delivery rate.

Key words: fetal heart rate monitoring, oxytocin, patient safety

Perhaps no subject in obstetrics has been associated with as much confusion and controversy as the value of electronic fetal heart rate monitoring (EHFHM). Despite well-designed basic science investigations into the physiology underlying standard fetal heart rate (FHR) patterns (variability, accelerations, and decelerations), these observations have not translated into measureable positive impacts on newborn outcomes but have contributed significantly to the cesarean delivery rate.1-4 Although agreement with this assessment is nearly universal, the origins of this disconnect remain obscure. If there is a subject that rivals EHFHM in controversy, it may be the use of oxytocin to stimulate labor. Although few would question the benefit of oxytocin to carefully selected patients when this drug is appropriately administered and monitored, ideal rates of infusion, definitions of hyperstimulation or tachysystole, and proper clinical endpoints for a reduction or discontinuation of oxytocin infusion based on fetal response to induced uterine contractions remain uncertain.5-9

We sought to investigate the impact of several areas of clinical assessment and practice related to oxytocin infusion and FHR monitoring on neonatal outcomes and the cesarean delivery rate.9 Our principal focus involved the impact of the identification and reaction to select category II FHR patterns and the uterine tachysystole in women undergoing the oxytocin induction of labor.

MATERIALS AND METHODS

The Hospital Corporation of America is the nation’s largest provider of inpatient health care, including deliveries. The 110 affiliated hospitals with obstetric and newborn services in 21 states have an annual delivery volume of approximately 207,000, representing 5-6% of all deliveries in the United States. Demographic representation (both ethnic and payer mix) has been shown to mirror that of the US population as a whole.10-12

The study population was singleton, term fetuses (gestation of ≥37 weeks) undergoing an induction of labor with oxytocin. Based on the annual delivery volume of each facility, we determined a sample size that would represent a statistically representative proportion of the entire population, using the Cochran’s sample size formula set for a 5% maximum error.13,14 All patient charts meeting the previously mentioned inclusion criteria were examined sequentially in a prospective manner beginning April 1, 2013, until the requisite sample

size was reached. All chart reviews were completed by Sept. 30, 2013.

Each chart was individually reviewed by a regional nurse who was certified as an FHRM instructor by the Association of Women’s Health, Obstetric, and Neonatal Nurses. For each 30 minute segment of fetal heart rate tracing (FHRT) in which oxytocin was being infused, the FHR tracing was examined and data concerning the practices specified in Table 1 were collected. A chart was considered compliant if practices 1-3 (Table 1) were documented for the labor in question prior to oxytocin infusion. Demonstration of practices 4-6 (Table 1) was required in each applicable 30 minute segment to qualify as compliant.

Each of these practices has been recognized in the existing literature as a potentially important contributor to safe peripartum care, although the quality of supporting evidence varies. Details of the checklists referred to in Tables 1 and 2 have been previously published. Of note, for items 5 and 6 (Table 1), it is suggested that unless each checklist element is present, the oxytocin dose should be reduced.

In addition, the outcomes data specified in Table 3 were collected for each patient. We then compared clinical outcomes among patients in whom each practice was followed with those among patients in whom the practices were not followed.

All data were submitted directly from the local site chart reviewer to an independent entity not affiliated with the Hospital Corporation of America (The Sullivan Group, Oakbrook Terrace, IL) for data compilation and statistical analysis. Composite system data and associated statistical evaluation were then made available to the authors and are presented here. Individual facility performance data were made available to local clinical and administrative leaders at these hospitals for quality improvement purposes.

Two-way contingency analysis was performed using a Fisher exact test, with a value of $P < .05$ considered significant. Number-needed-to-treat (NNT) calculations were performed using the standard formula of $NNT = 1/f_p - f_o$, where $f_p$ and $f_o$ represent the frequency of adverse outcome with or without a reduction in the dose of oxytocin.

Because this project involved only examination of deidentified aggregate data for quality improvement purposes, it was exempt from institutional review board approval based on 45CFR46.101(b)(2) and 46.102(f) as well as 45CFR164.514(a)-(c) of the Health Insurance Portability and Accountability Act.

**RESULTS**

During this study period, 14,398 charts were prospectively examined as outlined in the previous text. Data regarding each of the specific practices described in Table 1 and associated clinical outcomes described in Table 2 are presented in Table 2 and Figures 1 and 2. There was a significant correlation between a reduction in the dose of oxytocin based on the identification of specified abnormal FHR patterns (Table 1) and all indicators of improved newborn outcome (Table 2).

There was a similar significant reduction in neonatal intensive care unit (NICU) admissions when the oxytocin infusion rate was reduced in the face of uterine tachysystole. There was an inconsistent relationship between compliance with other individual practices and clinical outcomes (Table 2). Notably, however, compliance with all practices described in the in-use checklist was cumulatively associated with both a significant reduction in NICU admission and a reduction in the cesarean delivery rate in this population (Table 2).

**COMMENT**

Our data demonstrate several important points.

1. Patients in whom the specified abnormal fetal heart rate and/or uterine contraction patterns were identified and acted upon with a reduction in oxytocin dose experienced fewer low 1 and 5 minute Apgar scores and fewer newborn intensive care unit admissions than the control group. This represents the first presentation of data demonstrating improvement in neonatal outcomes with the use of EFHRM. These findings stand in contrast to several previous reports comparing EFHRM with intermittent auscultation.

A consideration of the differences in study design clarifies the reason for these different findings.

Most studies comparing EFHRM to intermittent auscultation were designed with the assumption that those clinicians interpreting and acting upon the information gleaned from EFHRM were interpreting and acting correctly. Yet no attempt was made to validate these assumptions; in fact, no unambiguous definition

### TABLE 1

**Clinical practices examined and current level of evidence**

| 1. | Estimated fetal weight prior to induction (level III). |
| 2. | Clinical assessment of pelvic adequacy prior to induction (level III). |
| 3. | Completion of a safety checklist prior to induction (level III). |
| 4. | Completion of a safety checklist every 30 minutes during induction (level III). |
| 5. | Number of 30 minute intervals in which specified FHRT elements were not present and oxytocin infusion rate was decreased (level III). |
| 6. | Number of 30 minute intervals in which specified uterine contraction elements were not present and oxytocin infusion rate was decreased (level II-2). |

**FHRT:** fetal heart rate tracing.

At least 1 acceleration of 15 bpm x 15 seconds in 30 minutes is observed, or adequate variability is present for 10 of the previous 30 minutes; no more than 1 late deceleration occurred in the previous 30 minutes; no more than 2 variable decelerations exceeding 60 seconds in duration and decreasing greater than 60 bpm from the baseline occurred within the previous 30 minutes; no no more than 5 uterine contractions in 10 minutes for any 20 minute interval; no 2 contractions greater than 120 seconds; duration; uterus palpates were soft between contractions; if intrauterine pressure catheter is in place, Montevideo units must calculate less than 300 mm Hg and the baseline resting tone must be less than 25 mm Hg.

of either correct interpretation or proper clinical response was provided. This assumption of uniform expertise and appropriate reaction to abnormal FHR tracings is especially surprising in light of the well-established inability even of individuals identified as experts to agree on FHR interpretation. In contrast, for purposes of this study we defined abnormal FHR patterns in a completely unambiguous manner and similarly defined a specific appropriate reaction when such patterns were observed (Table 1).

Inconsistent interpretation and clinical response may obscure the value of any diagnostic test, regardless of its intrinsic value. It is clear that in these previous investigations, the study group should have been patients in whom specific action resulted from the detection of specific FHR and uterine contractions (UC) patterns rather than patients who simply wore monitor belts during labor. Our study demonstrates that with the use of unambiguous definitions of abnormal tracings and a uniform, defined clinical response, the use of EFHRM does improve neonatal outcomes. These data also provide support for previously published recommendations with respect to the general management of category II FHRTs.

2. A reduction in oxytocin dose in reaction to the defined abnormal FHR or UC patterns resulted in increased rates of cesarean delivery, albeit with improved neonatal outcomes when viewed as isolated, individual parts of overall care (Table 2). This is not surprising and simply represents a restatement of a well-recognized truth: excessive use of oxytocin can result in fewer cesarean deliveries but is detrimental to newborn outcomes. However, the incorporation of the multiple patient safety practices contained in the in-use checklist (including the

<table>
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<th>Variable</th>
<th>NICU admission</th>
<th>1 minute Apgar &lt;7</th>
<th>5 minute Apgar &lt;7</th>
<th>Primary cesarean</th>
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<td>Adverse cases</td>
<td>Adverse, %</td>
<td>P value</td>
<td>Adverse cases</td>
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<td>Estimated fetal weight reviewed prior to oxytocin</td>
<td>Yes 396</td>
<td>10,672 3.7</td>
<td>0.58240</td>
<td>495 10,628 4.7</td>
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<td>Adequacy of pelvis reviewed prior to oxytocin</td>
<td>Yes 378</td>
<td>10,786 3.5</td>
<td>0.00544</td>
<td>464 10,745 4.3</td>
</tr>
<tr>
<td>Used preoxytocin checklist</td>
<td>Yes 435</td>
<td>11,653 3.7</td>
<td>0.69638</td>
<td>528 11,604 4.6</td>
</tr>
<tr>
<td>Used in-use oxytocin checklist</td>
<td>Yes 170</td>
<td>5868 2.9</td>
<td>0.0001</td>
<td>242 5846 4.1</td>
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<tr>
<td>Oxytocin stopped or decreased, abnormal UC</td>
<td>Yes 44</td>
<td>1398 3.1</td>
<td>0.01194</td>
<td>67 1395 4.8</td>
</tr>
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<td>Oxytocin stopped or decreased, abnormal FHR</td>
<td>Yes 91</td>
<td>2364 3.8</td>
<td>0.00913</td>
<td>115 2352 4.9</td>
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</table>

FHR, fetal heart rate; NICU, neonatal intensive care unit; UC, uterine contractions.

specified reactions to abnormal FHR or UC patterns) resulted in a synergistic improvement in the rate of NICU admissions and low Apgar scores and a significant reduction in rate of cesarean delivery (Table 2 and Figures 1 and 2). These findings support the proposal that an appropriate reduction in the rate of cesarean delivery is best approached by disciplined adherence to multiple individual components of labor management. With such an approach, a trade-off between cesarean delivery rates and neonatal outcomes may not be necessary.

3. We observed a significantly decreased rate of NICU admission when the oxytocin infusion rate was reduced in the face of uterine tachysystole, even with a normal FHRT (Table 2). These data support previous observations regarding the impact of uterine tachysystole on newborn outcomes and suggests that detection of tachysystole should generally lead to a reduction in oxytocin dose, regardless of the current FHR pattern.

4. This prospective study was not randomized and might on that basis be open to criticism. Although randomization is a desirable feature of any clinical investigation, we note that nonrandomization of these patients would potentially have an impact on our conclusions only if patients at higher risk for adverse pregnancy outcomes were disproportionately assigned to nurses who systematically provided less skillful care. However, standard nursing practice in our system, as well as

the broader US system, generally includes the assignment of higher risk patients to more experienced nurses. Unless greater experience is associated with diminished ability to properly interpret FHR patterns, recognize tachysystole, and implement other recognized patient safety practices, true randomization would probably serve to strengthen our conclusions because the patients regularly receiving these components of care were likely at higher risk for adverse events yet experienced fewer adverse outcomes.

5. The clinical improvements demonstrated with the specific approaches to the FHR pattern recognition and reaction defined in this study were statistically and clinically significant; when all components of the in-use checklist were utilized, the rate of NICU admissions was reduced by one third, and the cesarean rate was reduced from 18.8% to 15.8% (Table 2 and Figures 1 and 2). However, in an absolute sense, these reductions affected only a minority of the entire population of women delivering babies. Indeed, a sample size
of more than 14,000 was necessary to demonstrate statistical benefit, even in a study population of women who, by virtue of labor induction, were at an increased risk of adverse outcomes. This observation emphasizes the importance of sample size and power calculations in the assessment of any study involving FHR monitoring when a conclusion of no difference is reached.

An NNT calculation was performed on the data involving the effect of oxytocin dose reduction on NICU admissions in the face of the defined abnormal FHR and uterine contraction patterns. This analysis suggests that oxytocin reduction would be necessary in 64 cases of uterine tachysystole and 72 cases of the defined category II FHR patterns to avoid 1 NICU admission; to avoid 1 infant with a 5 minute Apgar score less than 7, these numbers are 895 and 204, respectively. These numbers reflect both the resiliency of the term fetus and the poor positive predictive value of an abnormal FHR or UC pattern. More importantly, these numbers provide an explanation of the common clinical error described by the term, normalization of deviation, in which the memory of individual adverse events (“I’ve never had a problem continuing the oxytocin with a tracing like this”) is at odds with outcomes-based data.

6. Although the achievement of the improved short-term neonatal outcomes demonstrated in this study are desirable, there is a weak correlation between the abnormal outcomes we examined and neonatal encephalopathy or other demonstrable long-term adverse sequelae of labor. Thus, the data presented in this study cannot be interpreted as directly supporting a link between better recognition of subtle intrapartum FHR patterns and improvement in long-term neurological outcomes in any individual case.

7. Table 2 demonstrates that in a significant number of cases, abnormal FHR and uterine contraction patterns were not uniformly recognized and acted upon in actual practice, although the bar we set for compliance with pattern recognition (correct interpretation and action taken on every abnormal 30 minute FHR segments during oxytocin infusion) was very high. These data suggest that, even among highly trained individuals who have undergone standard testing for proficiency in FHR interpretation, the realities of human ability to consistently interpret FHR patterns with perfect accuracy while simultaneously caring for an actual mother and baby in labor differs significantly from the performance achievable with an isolated, retrospective FHRT analysis with a known neonatal outcome. This recognition of a limited ability of humans to consistently interpret complex waveforms in various disciplines is reflected in a large volume of literature dealing with computer-assisted waveform analysis. In a number of areas of medicine, the computer interpretation of electrocardiogram waveforms is largely replacing primary human interpretation.

An FHRT/UC pattern represents not only a more complex waveform than an electrocardiogram but must be interpreted continuously over hours, rather than as a single, minutes-long event. We anticipate that computer interpretation of FHR/UC patterns may have to replace or augment primary human interpretation if the improved outcomes that we have demonstrated to be achievable in our investigation are to be realized in the general obstetric population.

8. Our study examined the value of EFHRM only in that subpopulation of laboring women undergoing oxytocin induction of labor at term with respect to a single treatment variable, continuing or reducing the rate of oxytocin infusion. Thus, the direct extrapolation of these observations to other patient populations or interventions using our definitions would be unjustified at this time. However, we anticipate that similar unambiguous approaches to FHR interpretation and management, perhaps utilizing computer-assisted waveform analysis, will ultimately prove to yield similar results in other clinical situations as well.

We also believe that alternative but equally unambiguous definitions of an abnormal FHRT may in the future prove to be as valid as that utilized in this study. As with other areas of patient safety improvement, standardization of practice per se is of immense value and should not be ignored while awaiting development of the perfect protocol.

9. Each of the management practices examined had previously been suggested to be important in the provision of clinical care. However, as demonstrated in Table 1, evidence to support these suggestions was not generally of the highest quality and thus could not reasonably be considered as standard or mandated. Our data significantly strengthen many of these recommendations (Table 2), particularly those related to oxytocin dosing in the face of certain category II FHR patterns and the cumulative benefit of a comprehensive program incorporating all specified elements of care. We suggest that adoption of a protocol or checklist incorporating these care elements would be a reasonable next step that may both improve neonatal outcomes and reduce the rate of cesarean delivery.

ACKNOWLEDGMENT
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REFERENCES