

Fetal Heart Rate Pattern Notification Guidelines and Suggested Management Algorithm for Intrapartum Electronic Fetal Heart Rate Monitoring

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Abstract

Context: Numerous randomized controlled trials have demonstrated limited efficacy of intrapartum fetal heart rate monitoring in improving fetal outcome. A potential reason is the wide variability in clinical decision making seen with its use. Standardizing management of variant intrapartum fetal heart rate tracings may reduce this variability and lead to improvement in fetal outcome.

Objective: We sought to develop notification guidelines and a management algorithm for variant intrapartum fetal heart rate tracings that improve fetal outcome and do not increase the operative delivery rate.

Design: Outcomes for cases involving the use of our notification guidelines and management algorithm over six months (1181 deliveries) were compared with outcomes for historical control subjects (2247 deliveries).

Main outcome measures: The main outcome measures were Apgar scores <7 and the operative delivery rate.

Results: We found no change in fetal outcome or operative delivery rate.

Conclusion: Our notification guidelines and management algorithm are safe and do not increase the operative delivery rate. A large multicenter trial is needed to demonstrate improvement in fetal outcome.

Introduction

When it was introduced in the 1960s, the rationale for intrapartum electronic fetal heart rate (FHR) monitoring was that it serves as a screening test for asphyxia severe enough to cause neurologic damage or fetal death. Uncontrolled trials in the 1970s demonstrated a reduction of more than threefold in intrapartum fetal death with use of FHR monitoring.¹ These positive results fueled clinical enthusiasm, allowing FHR monitoring to become common practice before it was critically evaluated. A number of randomized controlled trials followed in the 1970s and 1980s that failed to show significant benefit from FHR monitoring.²⁻⁸ The largest trial⁹ demonstrated a 55% reduction in transient neonatal seizures. However, there was no difference in the incidence of cerebral palsy at four-year follow-up evaluation.¹⁰ Along with questionable benefit, the randomized trials also demonstrated a two- to three-fold increase in the cesarean section rate.²⁻⁹

A potential reason FHR monitoring has not been proved efficacious is the wide variability in clinical decision making with its use.¹¹ Lack of standard definitions and a management algorithm for variant FHR tracings may have contributed

to this variability.¹¹ In the mid-1990s, the National Institute of Child Health and Human Development (NICHD) convened a research-planning workshop to develop standardized and unambiguous definitions for FHR tracings. It produced a standardized terminology that was published in 1997¹² and eventually endorsed by both the American College of Obstetricians and Gynecologists (ACOG)¹³ and the Association of Women's Health, Obstetric and Neonatal Nurses¹⁴ in 2005. The NICHD workshop also considered a management algorithm, but participants were unable to reach consensus.¹²

We believe a standardized terminology alone is not sufficient to significantly reduce the variability in clinical decision making with use of FHR monitoring. We introduce the Kaiser Permanente (KP) Vallejo Medical Center FHR Tracing Notification Guidelines and Suggested Algorithm for the Management of Variant Intrapartum FHR Tracings. The goal of our notification guidelines and management algorithm is delivery in the absence of significant fetal acidemia and/or in the presence of neonatal vigor, and without an increase in the operative delivery rate.

An umbilical arterial blood pH <7.0 has long been considered



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significant acidemia because it is associated with (but not predictive of) neurologic and other organ damage.^{15,16} We define significant acidemia as a pH <7.10. Although not associated with catastrophic outcomes, a pH between 7.0 and 7.1 is associated with costly and distressing morbidities requiring measures such as supplemental oxygen, intravenous lines, and admission to a neonatal intensive care nursery.^{11,17} We define neonatal vigor as a five-minute Apgar score ≥7, because a score <7 is associated with significant neonatal morbidity.¹⁸

Notification Guidelines and Management Algorithm

The notification guidelines and management algorithm are designed to work in tandem in a multidisciplinary approach. It was our intent that they promote use of NICHD terminology and further communication within the obstetric (OB) team. They are color coded in a manner similar to the familiar traffic light: green for FHR tracings that require attention but not urgently (indicated here by a dotted line box), yellow for tracings that require urgent attention (dashed line and a light grey box), and red for tracings that require emergent attention (solid line and dark grey box). They emphasize the significance of moderate FHR variability because it is strongly associated with a pH >7.15 or newborn vigor,¹⁹ and even with repetitive late or variable decelerations for one hour, its presence suggests a pH >7.10.²⁰ They both include tables that detail conservative measures, which are standard maneuvers that improve fetal status depending on the clinical situation.^{13,21} The wording in the tables differs slightly because the notification guidelines are geared to promote SBAR. (Adapted from the military, SBAR stands for situation,

background, assessment, and recommendation. It is succinct communication used between all members of the OB team when presenting patients. By allowing every member to make recommendations, SBAR flattens the labor and delivery (L&D) hierarchy, promoting the importance of multidisciplinary points of view and leading to greater patient safety.)

Finally, they are both designed to fit on a single sheet of 8.5"x11" paper and are laminated and posted at multiple areas in L&D.

The notification guidelines (Figure 1) are laid out with the presenting tracing on the left and the recommended time before notification on the right. There is no green-coded section (dotted line and box) as

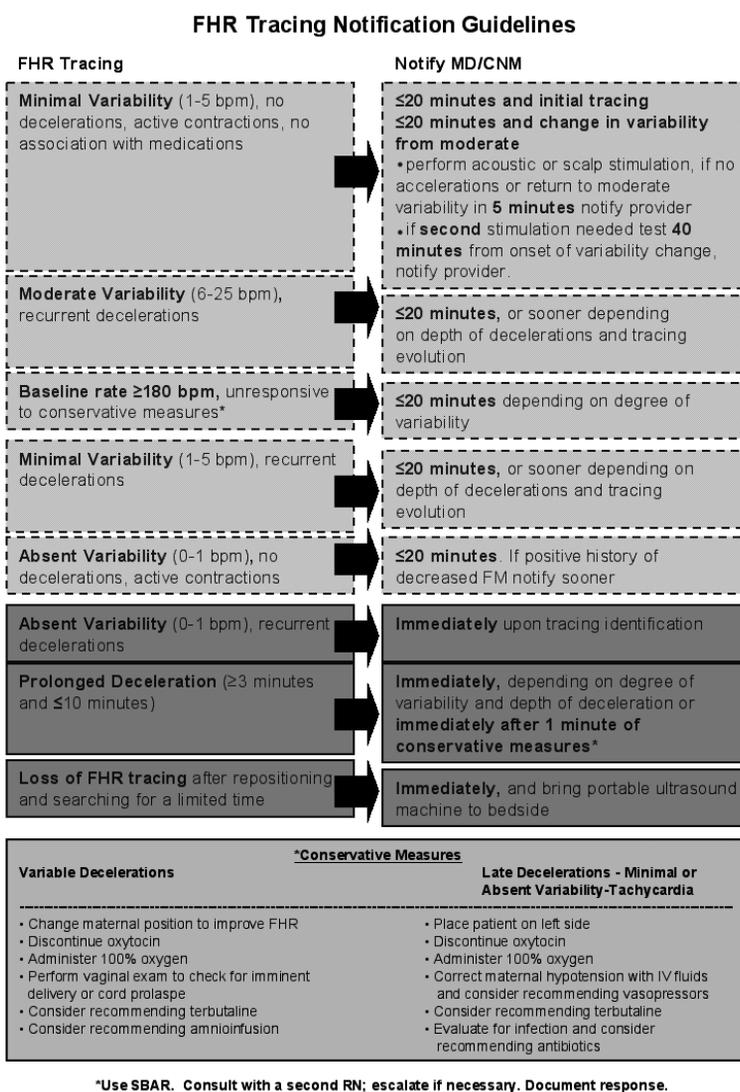


Figure 1. Fetal Heart Rate Tracing Notification Guidelines chart. (Color representations available from the authors upon request.)

bpm = beats per minute; CNM = certified nurse midwife; MD = physician; FHR = fetal heart rate; FM = fetal movement; IV = intravenous fluids; RN = registered nurse; SBAR = situation, background, assessment, and recommendation.

We believe that encouraging the RN to make recommendations will foster communication and promote patient safety.

there is in the management algorithm because a complete listing of FHR tracings that do not require urgent provider (physician or certified nurse midwife [CNM]) notification would not be practical. The yellow-coded section (dashed line and light grey box) addresses tracings that require provider notification within 20 minutes. It includes tracings with decelerations or tachycardia because they are associated with fetal hypoxemia,²² which can progress to acidemia, and it includes tracings with minimal or absent variability because they are significantly associated with acidemia if they persist for more than an hour.^{19,20} As a general rule, FHR variability gradually diminishes over a period of 60 to 120 minutes in association with recurrent late or variable deceleration as significant fetal acidemia develops.^{19,20,23–25} The rapidity with which acidemia develops is influenced by the depth and length of the decelerations.^{19,23,25} We believe that 20 minutes is a reasonable interval before notification because it allows at least 40 minutes before the tracing is significantly associated with acidemia. However, the notification guidelines instruct the registered nurse (RN) to notify the provider before 20 minutes have passed if the evolution of the tracing suggests that acidemia is developing quickly.

For an FHR tracing that has minimal variability with no decelerations (and is not the initial 20 minutes of tracing), the notification guidelines instruct the RN to perform scalp stimulation or vibro-acoustic stimulation (VAS). A positive response to scalp stimulation or VAS is associated with a fetal pH >7.20.^{25–29} If there is no response or a second test is needed, the RN is instructed to notify the provider. Allowing the RN to perform a single test avoids

notification for tracings secondary to the fetal sleep cycle.³⁰

The red-coded section (solid line and dark grey box) of the notification guidelines addresses FHR tracings that require immediate provider notification. This includes a tracing with absent variability and recurrent decelerations, because it may be associated with significant acidemia; a prolonged deceleration ≥ 3 minutes, because notification at three minutes allows time for delivery within ten minutes (if necessary); and finally, loss of the FHR tracing so that a previously undetected deceleration can be recognized in a timely manner.

Along with calling for provider notification, the notification guidelines instruct the RN to institute simple conservative measures (change maternal position, discontinue oxytocin, administer oxygen, conduct a vaginal examination, administer fluids intravenously) and to recommend more interventional conservative measures (amnioinfusion or administration of terbutaline, vasopressors, or antibiotics) if deemed necessary. These are detailed in the table “Conservative Measures” in Figure 1. We believe that encouraging the RN to make recommendations will foster communication and promote patient safety. We also strongly encourage the use of SBAR.

The management algorithm (Figure 2) includes all three colors of the traffic light. The green-coded section (dotted line and box) addresses the management of a tracing showing marked or moderate variability with decelerations or tachycardia. Moderate variability is strongly associated with a nonacidemic fetus.^{19,20} However, because marked variability, decelerations, and tachycardia are associated with fetal hypoxemia,²¹ which may progress to acidemia,

the algorithm suggests that the provider consider the initiation of conservative measures.

The yellow-coded section (dashed line and light grey box) addresses the management of a tracing with minimal or absent variability for 20 or more minutes. If the tracing has recurrent variable decelerations (<90 beats per minute) or recurrent late decelerations with minimal or absent variability for 60 or more minutes, the management algorithm instructs the provider to deliver the infant because such a tracing is associated with significant acidemia. The table on the bottom right side of Figure 2 lists relatively common FHR tracings associated with significant acidemia.^{19,20,23,25} Such tracings should prompt the provider to proceed to delivery. If the tracing is not associated with significant acidemia, then the algorithm instructs the provider to initiate conservative measures and to assess fetal well-being with scalp stimulation or VAS. Fetal scalp blood sampling (for pH) has long been used to assess fetal well-being.²⁵ However, scalp stimulation and VAS are easier to perform and have been shown to be reliable alternatives.^{26–28} Scalp stimulation or VAS should be performed every 20 minutes if there is no return of moderate variability. If the tracing persists with minimal or absent variability and there is no response to scalp stimulation or VAS for 60 minutes, the algorithm instructs the provider to deliver the infant because such a tracing is associated with significant acidemia.

The red-coded section (solid line and dark grey box) of the algorithm addresses the management of a prolonged deceleration ≤ 60 beats per minute (or ≤ 80 beats per minute if remote from delivery). At severely reduced heart rates, particularly ≤ 60 beats per minute, fetal cardiac

output cannot be sufficiently maintained, and acidemia can develop quickly.^{24,25,31} When there is cessation of oxygen delivery, it is likely that neuronal cell damage or death begins at approximately ten minutes.³² In patients with prolonged decelerations after uterine rupture, significant neonatal morbidity was avoided if delivery was accomplished within ten minutes.³³ The red-coded section (solid line and dark grey box) of the algorithm is based on a goal of accomplishing

delivery within ten minutes from the time the prolonged deceleration reaches its nadir. Fortunately, most prolonged decelerations resolve with little or no intervention; however, there are no reliable indicators that distinguish a transient deceleration from a bradycardia. The algorithm instructs the provider to prepare to move the patient to the operating room (OR) for delivery if the deceleration does not resolve by three minutes. If the deceleration has resolved after transport to

the OR, the decision to deliver the infant should be reevaluated. The choice of three minutes as a threshold for moving the patient is based on recommendations by the KP National Risk Management Perinatal Patient Safety Transfer Project (PPSP).³⁴

Methods

The notification guidelines and management algorithm were approved by the Vallejo Medical Center PPSP committee. They were

Kaiser Vallejo Medical Center Suggested Algorithm for the Management of Variant Intrapartum Fetal Heart Rate Tracings (≥ 32 weeks EGA) *

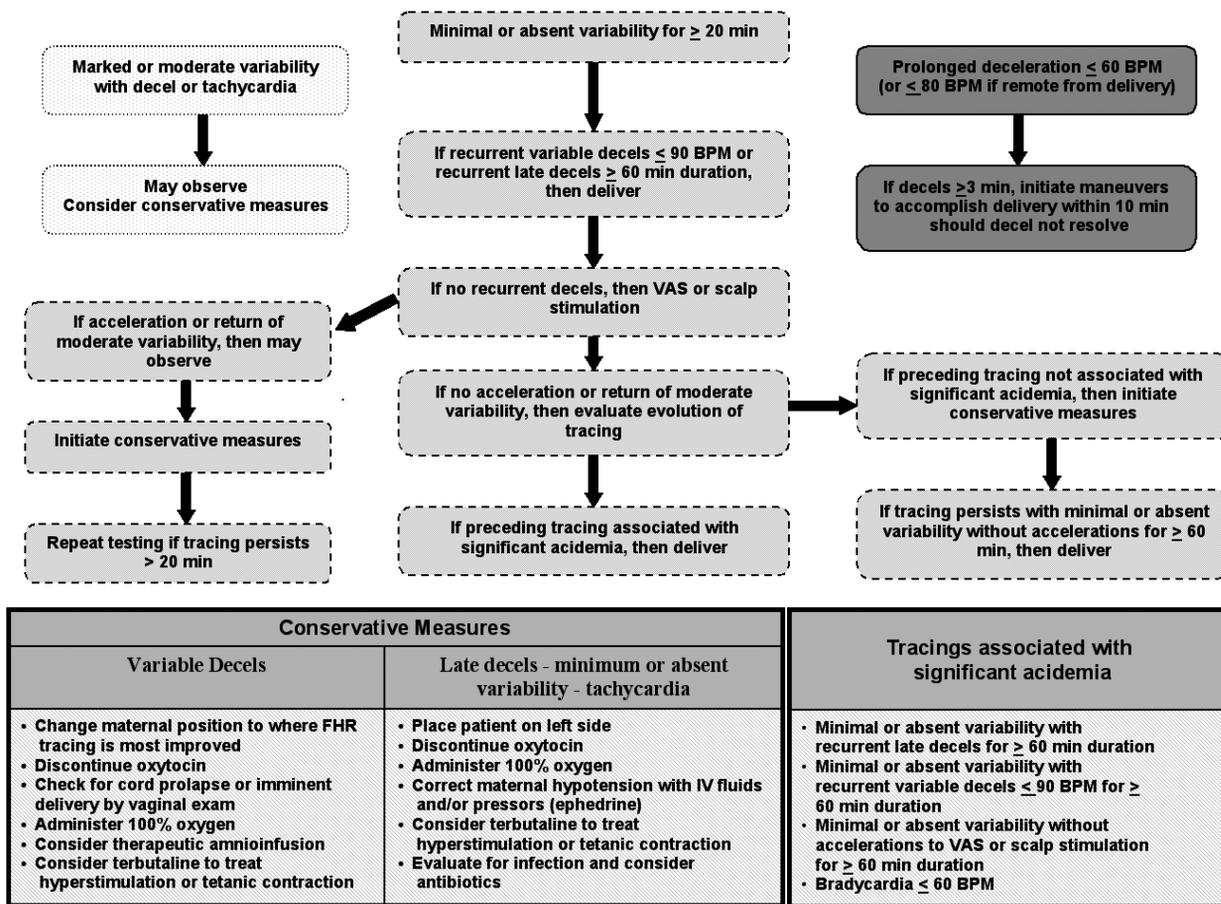


Figure 2. Kaiser Permanente Vallejo Medical Center suggested algorithm for the management of variant intrapartum fetal heart rate tracings (≥32 weeks estimated gestational age) chart. This document is intended to assist the provider in the management of variant intrapartum fetal heart rate tracings.

(Color representations available from the authors upon request.)

bpm = beats per minute; decel = deceleration; FHR = fetal heart rate; IV = intravenous; min = minutes; VAS = vibro-acoustic stimulation.

introduced to all Vallejo medical and RN staff in November 2005 in a four-hour tutorial in combination with four training DVDs.³⁴ The objective of the DVDs was to facilitate the adoption of NICHD terminology as the standard language for all KP facilities and assist in the development of collaborative practice agreements that will establish a more consistent exchange of information among OB team members.³⁴ A “strip review” for all laboring patients was established at morning rounds in which the RN presents the patient to the OB team and describes the FHR tracing using NICHD terminology. (We have found the paper copy of the FHR tracing superior to the monitor screen for this purpose). The entire OB team then agrees on a management plan with the help of the management algorithm.

Data were obtained directly from the delivery logs from January 1, 2006 to June 30, 2006 (beginning approximately one month after introduction of the algorithm and guidelines) and from the same six-month period in 2005 and 2004. The mean monthly incidence of five-minute Apgar scores <7, cesarean section rate, and surgical vaginal delivery rate were calculated. A *t*-test was used to compare data. Statistical software used for analysis was Excel 2003 (Microsoft, Seattle, WA). All significance tests were two-tailed, with an α value of 0.05.

We conducted a survey of our staff. Providers and RNs were asked to answer “never, 25%, 50%, 75%, or always” to the following four questions: 1) How often do you use the management algorithm? 2) Does the management algorithm support your decision making? 3) Does the management algorithm simplify your decision making? 4) How often have you observed the RNs using the notification guidelines? The RNs were

asked to answer in a similar fashion the following four questions: 1) How often do you use the notification guidelines? 2) Do the notification guidelines support your decision making? 3) Do the notification guidelines simplify your decision making? 4) How often have you observed the doctors or CNMs using the management algorithm? All staff members were also asked their age, sex, and years of experience.

Results

We compared 1181 deliveries (from January 1, 2006 to June 30, 2006) to 2247 deliveries (from the same six-month period in 2005 and 2004). We found no difference in the rate of five-minute Apgar scores <7, cesarean section rate, or operative delivery rate after introduction of our notification guidelines and management algorithm.

The survey revealed several trends. Individual staff members tended to give the same answer to all four questions they were asked. Physicians with more than ten years of experience consistently answered all four questions with either “never” or “25%.” Physicians with less than ten years of experience tended to answer all four questions with either “50%” or “75%.” No physician answered “always.” CNMs tended to answer all four questions with either “50%” or “75%” no matter how many years of experience they had. RNs with more than ten years of experience tended to answer all four questions with either “50%” or “75%.” RNs with less than ten years of experience tended to answer all four questions with “75%” or “always.” No RN answered “never.” During the dates the trial was conducted, staff members were evenly divided, such that approximately 50% of the physician and CNM staff and 50% of the RN staff had more

than ten years of experience, and 50% of each group had less than ten years of experience.

Discussion

Our trial has several obvious limitations. First of all, it was not randomized. However, we believe that a randomized trial would not be practical. As previously stated, our notification guidelines and management algorithm were introduced to our OB staff during a four-hour tutorial along with PPSP training DVDs that encourage the use of SBAR and NICHD terminology. These interventions, along with the “strip review” at morning rounds involving the entire OB team, promote and develop a collaborative practice style in an L&D unit. Randomizing individual members of the OB team to either use or not use these interventions would require dividing L&D into two isolated units. Randomizing patients alone would require providers to develop two different practice styles.

Our trial failed to assess an effect on the incidence of umbilical artery pH <7.10 because our facility does not currently have a reliable method of recording and tracking cord pH. We hope this will change in 2007 when the KP HealthConnect program is instituted at the Vallejo Medical Center.

Finally, our trial was limited by its relative small size. It had insufficient power to demonstrate a significant effect on the incidence of five-minute Apgar scores <7. Because the incidence is only in the 2.5th percentile at the Vallejo Medical Center and the incidence of umbilical artery pH <7.10 is only in the 2.5th percentile at tertiary centers,³⁵ it would take a very large trial to demonstrate a significant effect on either. If we choose 0.05 as the type I error, 80% as the power, and 20% as the

... our trial was limited by its relative small size.

amount our notification guidelines and management algorithm will reduce the incidence, we would need close to 14,000 study subjects to prove an effect on either Apgar score or cord pH. Such a large trial would be practical only if it were done at multiple centers.

Although we were unable to demonstrate a decrease in the incidence of five-minute Apgar scores <7, we were encouraged to see that our notification guidelines and management algorithm did not increase the incidence, suggesting they do not negatively affect perinatal outcome. We were also encouraged to see that they did not affect the operative delivery rate; an effective strategy to improve the efficacy of intrapartum FHR monitoring should not increase the rate of unnecessary obstetric intervention. Given the small size of our trial, we believe that these results are the best we could hope for and that they allow us to propose a larger multicenter trial to test the efficacy of our guidelines and algorithm to improve perinatal outcome.

Our staff survey was likely biased by multiple factors, so conclusions from these data are difficult to extrapolate. Staff members might have been influenced by a past event (such as a failure of intrapartum FHR monitoring to prevent a bad outcome) or by a steadfast belief that they already know all there is to know about monitoring. They might have been influenced by legal concerns (even past litigation). They might have been influenced by particular staff members with whom they commonly work and their ability to form a cohesive team. However, despite these and numerous other potential biases, the survey did reveal two obvious trends: 1) RNs were more likely to use the notification guidelines than physicians or CNMs were to use the

algorithm and 2) younger staff were more likely than older staff to use either the guidelines or the algorithm. The first trend supports our belief that only a multidisciplinary approach will have a reasonable chance of success. RN involvement is crucial; a strategy that includes only physicians is likely to fail because of low compliance. The second trend suggests that facilities with younger staff members, such as teaching hospitals or residency programs, are more likely to accept strategies that change their style of practice and are therefore better places to evaluate such strategies.

Conclusion

The future of FHR monitoring is uncertain. The randomized trials done to date have shown little benefit and demonstrate a two- to threefold increase in the cesarean section rate when FHR monitoring is used.²⁻⁹ A potential reason that FHR monitoring has not proven efficacious is the wide variability in clinical decision making with its use. Universally accepted evidenced-based standardized practice guidelines are needed to reduce this variability.¹¹ Six months after their introduction, our notification guidelines and management algorithm appear to be safe and do not increase obstetric intervention. We propose that a large trial including multiple KP facilities (especially teaching hospitals) be conducted to evaluate the efficacy of our notification guidelines and management algorithm to improve perinatal outcome. ❖

Acknowledgment

Katharine O'Moore-Klop of KOK Edit provided editorial assistance.

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The future of FHR monitoring is uncertain.

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Hope

While there's life, there's hope.

—Terence, 190-158 BC, Roman comic dramatist