OBSTETRICS

The limits of electronic fetal heart rate monitoring in the prevention of neonatal metabolic acidemia

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BACKGROUND: Despite intensive efforts directed at initial training in fetal heart rate interpretation, continuing medical education, board certification/recertification, team training, and the development of specific protocols for the management of abnormal fetal heart rate patterns, the goals of consistently preventing hypoxia-induced fetal metabolic acidemia and neurologic injury remain elusive.

OBJECTIVE: The purpose of this study was to validate a recently published algorithm for the management of category II fetal heart rate tracings, to examine reasons for the birth of infants with significant metabolic acidemia despite the use of electronic fetal heart rate monitoring, and to examine critically the limits of electronic fetal heart rate monitoring in the prevention of neonatal metabolic acidemia.

STUDY DESIGN: The potential performance of electronic fetal heart rate monitoring under ideal circumstances was evaluated in an outcomes-blinded examination fetal heart rate tracing of infants with metabolic acidemia at birth (base deficit, >12) and matched control infants (base deficit, <8) under the following conditions: (1) expert primary interpretation, (2) use of a published algorithm that was developed and endorsed by a large group of national experts, (3) assumption of a 30-minute period of evaluation for noncritical category II fetal heart rate tracings, followed by delivery within 30 minutes, (4) evaluation without the need to provide patient care simultaneously, and (5) comparison of results under these circumstances with those achieved in actual clinical practice.

RESULTS: During the study period, 120 infants were identified with an arterial cord blood base deficit of >12 mM/L. Matched control infants were not demographically different from subjects. In actual practice, operative intervention on the basis of an abnormal fetal heart rate tracings occurred in 36 of 120 fetuses (30.0%) with metabolic acidemia. Based on expert, algorithm-assisted reviews, 55 of 120 patients with acidemia (45.8%) were judged to need operative intervention for abnormal fetal heart rate tracings. This difference was significant (P=.016). In infants who were born with a base deficit of >12 mM/L in which blinded, algorithm-assisted expert review indicated the need for operative delivery, the decision for delivery would have been made an average of 131 minutes before the actual delivery. The rate of expert intervention for fetal heart rate concerns in the nonacidemic control group (22/120; 18.3%) was similar to the actual intervention rate (23/120; 19.2%; P=1.0) Expert review did not mandate earlier delivery in 65 of 120 patients with metabolic acidemia. The primary features of these 65 cases included the occurrence of sentinel events with prolonged deceleration just before delivery, the rapid deterioration of nonemergent category II fetal heart rate tracings before realistic time frames for recognition and intervention, and the failure of recognized fetal heart rate patterns such as variability to identify metabolic acidemia.

CONCLUSIONS: Expert, algorithm-assisted fetal heart rate interpretation has the potential to improve standard clinical performance by facilitating significantly earlier recognition of some tracings that are associated with metabolic acidemia without increasing the rate of operative intervention. However, this improvement is modest. Of infants who are born with metabolic acidemia, only approximately one-half potentially could be identified and have delivery expedited even under ideal circumstances, which are probably not realistic in current US practice. This represents the limits of electronic fetal heart rate monitoring performance. Additional technologies will be necessary if the goal of the prevention of neonatal metabolic acidemia is to be realized.

Key words: category II, fetal heart rate monitoring, metabolic acidemia

The impact of electronic fetal heart rate monitoring (EFHRM) on neonatal outcomes continues to be controversial. Although unexpected intrapartum fetal death has been largely eliminated with such monitoring, the goal of consistently preventing hypoxia-induced fetal metabolic acidemia, a condition with a well-defined relationship to neonatal encephalopathy, remains elusive.[1-5] Even less well-documented is the impact of EFHRM on long-term neonatal outcomes; because conditions such as cerebral palsy are multifactorial in origin, any potential impact of monitoring on such outcomes is so small as to never have been statistically demonstrated,[1-5] despite intensive efforts directed at initial training in fetal heart rate interpretation, continuing medical education, board certification/recertification, team training, and the development of specific protocols for the management of abnormal fetal heart rate patterns. We sought to examine reasons for the birth of infants with significant metabolic acidemia despite the use of EFHRM, to assess the potential impact of a previously published algorithm on these outcomes, and to examine critically the limits of EFHRM in the prevention of neonatal metabolic acidemia.

Materials and Methods

This study met criteria set forth in [45 CFR 46.101 (b), Category [4]] and was given exempt status by the Institutional Review Board of the MedStar Health Research Institute. We performed a case control study that compared 2 groups, a study group with fetal metabolic academia at birth and a group with normal cord gases.

Our study groups were drawn from all women who delivered from

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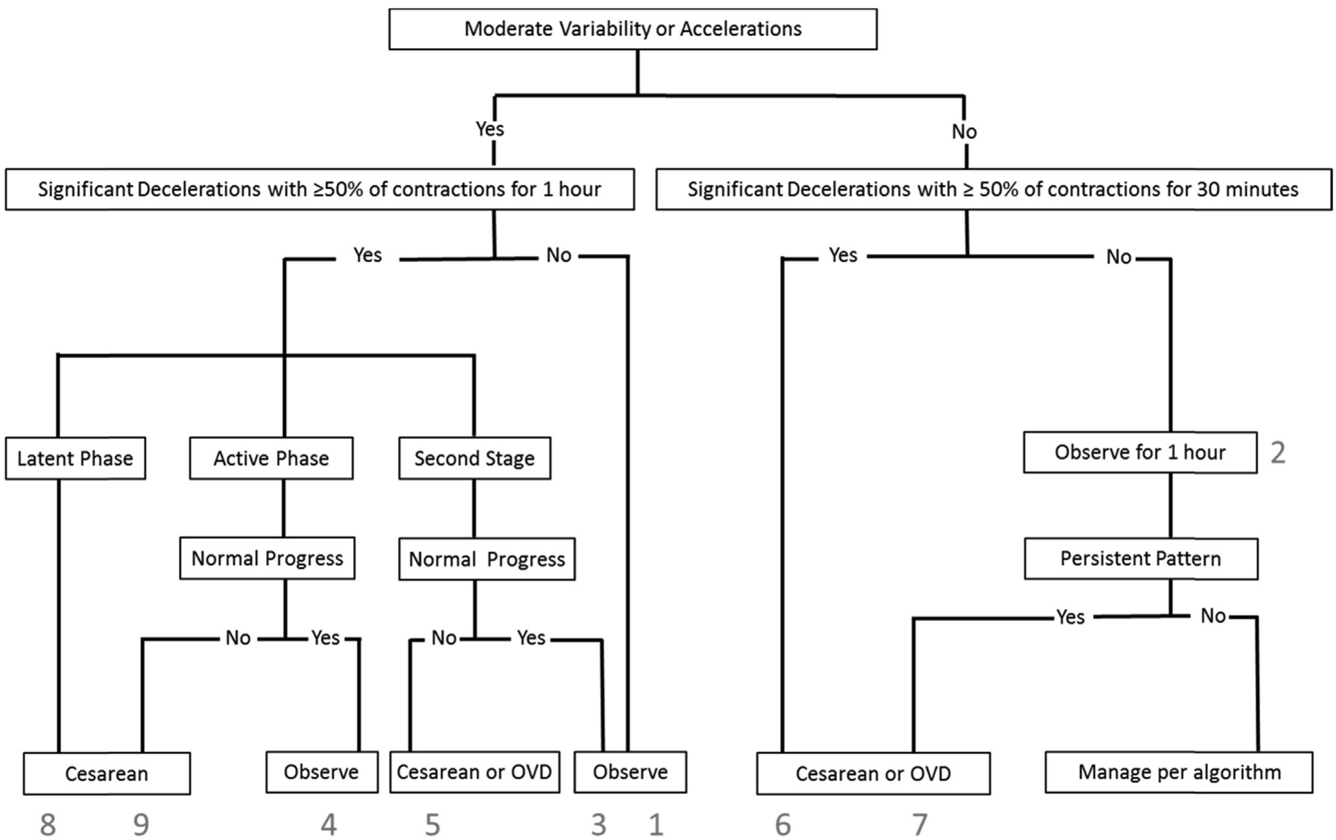
FIGURE 1
Algorithm for management of category II fetal heart rate tracing



OVD, operative vaginal delivery.

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January 1, 2012, to December 31, 2013, in 2 academically affiliated community teaching hospitals in the Baltimore-Washington corridor. One facility practiced universal umbilical cord gas analysis; the second facility encouraged the liberal use of such analysis but did not insist on it in all births. Inclusion criteria were singleton, vertex-presenting fetuses at ≥37 weeks gestation with EFHRM and umbilical artery blood gas measurements. Women with ≥1 previous cesarean deliveries were excluded. Fetal heart rate tracings (FHRTs) were archived electronically along with other data from the labor and delivery record with the use of the PeriCALM Tracings and PeriBirth data collection systems (PeriGen, Cranbury, NJ). Women who delivered infants with arterial cord blood metabolic acidemia (base deficit [BD], >12 mM/L) formed the index study group. Each index case was then inserted randomly back into a temporally ordered database of all patients, and the nearest patient who was matched for multiparous or nulliparous status who delivered an infant with BD < 8 mM/L was selected as a control.

For patients and controls, each FHRT was examined in its entirety by 1 of 3 authors (S.L.C., T.J.G., and A.T.) who applied to it a previously published algorithm for the management of category II FHRTs to determine when, if ever, the algorithm would have called for intervention (Figure 1).[3] The reviewers were blinded to cord gas values and whether any patient was included as a case or a control. To accomplish this blinding, 1 author (E.F.H.) organized and distributed the randomly combined set of normal and acidemic tracings but did not participate in the primary FHRT reviews.

After these blinded reviews of individual cases, a secondary review was performed by all reviewers for babies who were born with metabolic acidemia in which the initial reviewer did not recommend intervention (65 cases) based either on their clinical judgment or the use of the algorithm. Data regarding actual timing and the route of delivery, the indication for operative delivery, and newborn outcomes were also evaluated.

We then asked the following questions:

1. How did delivery decisions based on this algorithm-assisted review differ from those made in actual clinical practice? (A difference in cesarean rates for fetal indications in fetuses with and without metabolic acidemia between study and control groups would allow us to address this issue.)

2. What was the nature of the FHRTs in infants born with metabolic acidemia that were not predicted or potentially prevented even with FHRT interpretation by these experts? (This issue would be addressed by analysis of these individual tracings to identify common features of those fetuses who were born with metabolic acidemia despite monitoring.)
3. What are the limits of the ability of FHR monitoring to predict and prevent the occurrence of metabolic acidemia during labor? (This issue would be addressed by examination of the performance of an algorithm developed by a group of recognized experts and the structuring of the study to account for variables other than the intrinsic ability of FHR monitoring to demonstrate recognized abnormal FHR patterns.)

TABLE 1
Demographic features of control and metabolic acidemia groups

	Group		
Variable	Control (n=120)	Metabolic acidosis (n=120)	*P* value
Maternal age, median (interquartile range)	25.5 (20–30)	27 (21–32)	.11
Birthweight, median (interquartile range)	3293 (2989–3662)	3369 (3111–3686)	.46
Gestational age, median (interquartile range)	39.9 (39.0–40.5)	39.9 (39.1–40.6)	.89
Body mass index, median (interquartile range)	31.2 (27.7–35.4)	30.8 (27.6–37.1)	.63
Nulliparity, n (%)	96 (80.0)	96 (80.0)	1
Diabetes mellitus, n (%)	5 (4.2)	7 (5.8)	.76
Hypertension, n (%)	14 (11.7)	21 (17.5)	.27
Epidural, n (%)	60 (50.0)	40 (33.3)	.013

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Proportions were compared using chi-squared or Fisher's exact test or the Mann-Whitney test for nonnormal distributions, as appropriate. Normally distributed variables were compared with the use of the Student *t* test. All tests were 2-tailed, and a probability value of $<.05$ was considered to be significant.

Results

During the study period, 120 infants were identified with arterial cord blood BD > 12 mM/L, which represents 1.2% of the 9888 women who met the potential enrollment criteria and who delivered during this time frame and 2.2% of the 5510 infants with arterial cord blood gas sampling. Demographic characteristics for the study and control groups were similar (Table 1). The facilities that performed elective vs uniform blood gas analysis accounted for 9 and 111 of these cases, respectively.

The distribution of cases according to both cord arterial pH and BD are presented in Table 2. The median times from end of FHRT to delivery were 1.8 and 1.4 minutes for cases and control subjects, respectively. The 25th and 75th percentiles for these 2 groups were 0.4/0.5 and 9.2/8.4 minutes.

In actual practice, operative intervention on the basis of an abnormal FHRT occurred in 36 of 120 fetuses (30.0%) with metabolic acidemia. Based on the expert, algorithm- assisted reviews, 55 of these 120 patients with acidemia (45.8%) were judged as needing operative intervention for abnormal FHRT. This difference was significant (P=.016).[3] In infants born who were with BD >12 mM/L for whom the blinded, algorithm-assisted expert review indicated the need for operative delivery based on an abnormal FHRT, the decision for delivery would have been made an average of 131 minutes before the actual delivery. Among the 24 patients with metabolic acidemia who ultimately did deliver by cesarean section for an abnormal FHRT, such intervention was judged necessary by expert review in 20 patients and, on average, 80 minutes before actual birth. In the 68 patients with metabolic acidemia who delivered vaginally, earlier intervention was indicated, per expert review in 19 patients and, on average, 178 minutes before actual birth. The rate of expert intervention for FHR concerns in the nonacidemic control group (22/120; 18.3%) was similar to the actual intervention rate (23/120; 19.2%; P=1.0) Figure 2 shows the algorithm-assisted expert intervention rates according to both cord arterial pH and BD. There was a highly significant trend (P=.0001) toward greater rates of intervention with both falling pH and rising BD. Table 3 presents the relationship between BD and adverse newborn infant outcome. The trend toward increased rates of several adverse outcomes with rising BD was highly significant. However, even with BD values exceeding 15 mM/L,

TABLE 2
Distribution of cases: pH and base deficit

	Base deficit, n (%)		
pH	<8 mM/L (n=120)	12–15 mM/L (n=94)	>15 mM/L (n=26)
<7.10 (n=83)	0	58 (24.2)	25 (10.4)
7.10–7.15 (n=32)	11 (4.6)	20 (8.3)	1 (0.4)
>7.15 (n=125)	109 (45.4)	16 (6.7)	0

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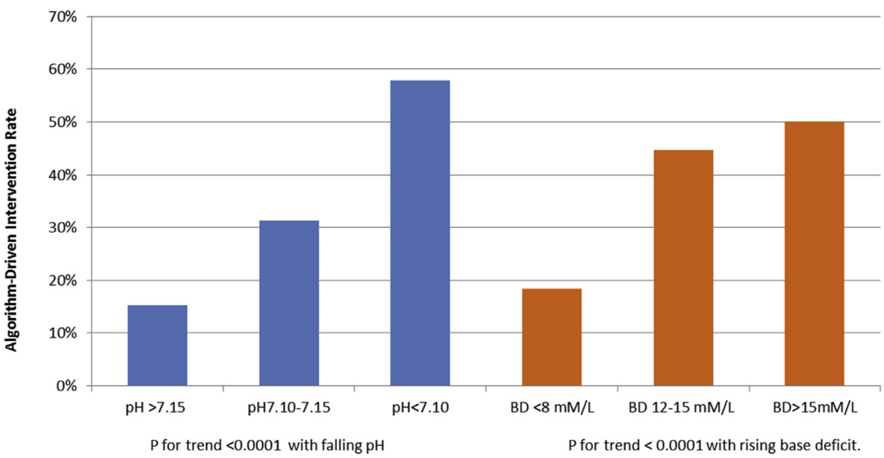
FIGURE 2
Algorithm-driven intervention rates according to pH and base deficit



As pH and base deficit deteriorate, the algorithm calls for increasing rates of intervention.

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adverse outcomes were present in only a few infants.

Expert consensus review did not mandate earlier delivery in 65 of 120 patients with metabolic acidemia. These 65 cases ("missed metabolic acidemia") were analyzed in detail and are categorized in Table 4. There was no difference in the rate of missed metabolic acidemia between the 3 primary reviewers (21, 22, and 22 cases each).

Comment

Principle findings

Expert, algorithm-assisted FHR interpretation has the potential to improve standard clinical performance in terms of significantly earlier recognition of a small number of tracings that are associated with metabolic acidemia.[3] This may be achieved without increasing the rate of operative intervention; although, as with any finding of no difference, it is possible that with a larger sample size, a statistically significant difference might be found. High-quality primary training, ongoing maintenance of expertise in FHR interpretation, and uniformity of interpretation and action are important.[3-7] However, our data also suggest that outcome improvements that are achieved by attention to these areas are limited, potentially impacting at most 15% of infants with acidemia.

Up to 10% of neonatal metabolic acidemia is linked to FHR tracings, which is inadequate for interpretation, or stopped well before delivery (Table 4). However, only a fraction of these are potentially amenable to prevention, because factors such as maternal habitus may interfere with even the most diligent efforts at monitoring. In 8% of cases, metabolic acidemia resulted from sudden, unpredictable sentinel events (persistent prolonged decelerations with prompt delivery) and would not be prevented by more careful monitoring, more expert analysis, or enhanced team functioning (Table 4). Of the cases of metabolic acidemia, 18% were associated with the onset of less severe category II FHR patterns not suggestive of a sentinel event or obstetric emergency, with onset <1 hour before birth (Table 4). We believe that a 30-minute window of observation and attempts at in utero resuscitation before a decision for intervention in these category II patterns and an additional 30 minutes to initiate an urgent cesarean delivery in these cases reflects both acceptable standards of care and the realities of current obstetric practice.[3,8] Thus, a significant reduction in this category of infants with metabolic acidemia is unlikely even under ideal circumstances.

Eighteen percent of infants with acidemia had FHRTs that simply did not suggest the presence of metabolic acidemia, either according to expert interpretation or the use of an algorithm that had been developed by many of the nation's leading authorities in fetal monitoring (Table 4).[3] All had moderate variability, and none had persistent repetitive late or severe variable decelerations. These tracings were not materially different from those commonly seen during labor in infants who were born without an elevated BD.[3-5] The greater use of epidural anesthesia in the control group (Table 1) and the lack of significant FHR changes of any type in these 18% of fetuses with acidemia suggests that epidural use did not play a role in these findings.

Meaning of the findings

Elevated levels of umbilical artery base deficit have been linked to adverse neonatal outcomes.[9-12] There are several possible explanations for the failure of EFHRM to eliminate the birth of infants with such metabolic acidemia. First, it is possible that errors in FHR pattern recognition are common and might be remedied by more intensive efforts at training and certification and more diligent efforts to record an interpretable FHRT consistently.[4-6] Second, it may be that nonuniform application of standard interpretative techniques is to blame and that the solution lies in the use of standardized algorithms for interpretation and management of abnormal FHR patterns.[3,7] Third, the ability of obstetric teams to react with sufficient speed once an abnormal FHRT is identified may be insufficient and might be addressed with enhanced team training or a reorganization of surgical services.[8] Finally, the technology itself may be lacking; it may be unrealistic to expect near-perfect sensitivities and positive predictive values for the detection of metabolic acidemia with the use of heart rate alone.

We sought to design a single study in which each of these theories might be tested to explore the limits of current technology and scientific understanding of FHR patterns in preventing the birth of infants with metabolic acidemia. The

TABLE 3
Base deficit and neonatal outcome

		Neonatal outcome, %					
Base deficit	N	5-Min Apgar score ≤6	Intubation	Bag and mask ventilation	Neonatal intensive care unit transfer	Shoulder dystocia	CPR
<8 mM/L	120	0.8	1.7	2.5	8.3	0.8	1.7
12-15 mM/L	94	8.5	9.6	10.6	25.5	2.1	3.2
>15 mM/L	26	19.2	15.4	19.2	42.3	3.8	7.7
P for trend		.0005	.0075	.0045	.0001	.5	.25

CPR, cardiopulmonary resuscitation.
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contributions of interpretive expertise and uniform clinical application of expert pattern interpretation was addressed with tracing interpretation by the listed authors, assisted by an algorithm that was developed and endorsed by 13 of the most widely published investigators in the fields of fetal monitoring and acid-base analysis.[3,5-7] The potential impact of ideal team performance after the identification of a concerning pattern was addressed by the assumption of a 30-minute period of observation of a nonemergent category II FHR pattern followed by delivery within an additional 30 minutes.[3,7,8,12] In addition, the entire analysis was completed in a highly artificial environment in which attention to detail was unhampered by the need to provide actual patient care simultaneously. Put simply, in terms of FHRT identification and timely delivery of fetuses who are at risk for metabolic acidemia, this is likely as good as it is going to get. Residual deficiencies are appropriately attributed to the limitations of the technology itself.

Clinical implications

Our data suggest that, of infants who are born with metabolic acidemia, only approximately one-half could be identified potentially and have delivery expedited, even under ideal circumstances, which are probably not realistic in current US practice. This is not to diminish the importance of the optimization of training in FHR pattern recognition and the use of a standardized approach to interpretation and intervention to improve patient care. However, the occurrence of unpredictable sentinel events during labor, the inability to monitor some fetuses adequately on a continuous basis, and the occasional more rapid than expected deterioration in base excess that is seen in some fetuses with nonemergent category II FHR tracings, all render EFHRM a valuable but imperfect tool. In addition, almost 20% of fetuses who are born with significant metabolic acidemia do not, even in retrospect and with knowledge of the outcome, have an FHRT with diminished variability or any other feature that would be considered as an indication for intervention in standard US practice. This represents the limits of the technology.

Although the poor positive predictive value of FHR for neonatal metabolic acidemia has long been recognized, these findings challenge our decades-old assumptions regarding the sensitivity of this technology, the importance of variability in excluding metabolic acidemia, and the utility of base excess measurement as an arbiter of fetal tolerance of labor.[12-16] An assumption that, with expert FHRT interpretation, nothing short of an unpredictable sentinel event will result in the birth of an infant with significant metabolic acidemia is invalid.

Research implications

Research groups actively are investigating novel adjunctive methods to examine aspects of the electronic fetal monitoring tracing that are not readily discernable by the naked eye and novel area-under-the curve approaches to FHRT analysis. More discriminating signal processing algorithms such as heart rate variability at various frequencies, subtle heart rate responses relative to contractions, or fractal analysis of variability are also under investigation.[17-19]

Strengths and weaknesses

Strengths of this study include it being 1 of the largest series to date of infants who

TABLE 4
Fetal heart rate tracing interpretation in 120 cases of metabolic acidemia

	Cases	
Variable	N	%
Operative delivery recommended	55	46
Sentinel event	10	8
Fetal heart rate tracing inadequate for interpretation or stopped >15 minutes before delivery	12	10
Fetal heart rate tracing of concern, but delivery within 60 minutes of initial appearance	22	18
No abnormal fetal heart rate features that suggested need for delivery	21	18

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were born with arterial metabolic acidemia and our inclusion of 26 infants with BD of >15, a level which classically signifies severe metabolic acidemia. Because most acidemia is of a benign, respiratory nature reports based on pH alone are of extremely limited value. In addition, our examination of the FHRT throughout the entire course of labor and a median end of tracing to delivery interval of <2 minutes makes this study unique. Our blinding of the reviewers to the metabolic status of the infant at birth is also a strength of this study; "expert" retrospective FHRT interpretation with foreknowledge of the outcome is always scientifically suspect. Finally, our presentation of a statistically significant trend analysis that demonstrates increased algorithm-based intervention as pH falls and BD rises and a demonstration of significant relationship between algorithm-based FHRT interpretation and adverse clinical newborn infant outcomes significantly enhances the credibility of our binary conclusions regarding algorithm-assisted vs actual clinician performance (Figure 2).

A potential weakness of this study involves the possibility of inappropriate, retrospective application of our data to individual cases and equally inappropriate extrapolation of our data beyond its justified conclusions. These data cannot be used to support a conclusion that, in any individual case of neonatal metabolic acidemia, application of the algorithm would have resulted in a different outcome. In a similar manner, rejection of electronic monitoring as a diagnostic tool on the basis of its inability to delivery perfect outcomes consistently would be unwise. Finally, although our data document the imperfections of fetal heart rate variability in the prediction of normal acid-base status at birth, reliance on this and other standard features of FHR interpretation remains the standard of care; other than universal cesarean delivery, this is currently the best we can do in reducing intrapartum metabolic acidemia. Both patient and physician expectations must be adjusted accordingly.[20]

Next steps in research

The prevention of intrapartum fetal death and the detection of a large fraction of fetuses that experience metabolic acidemia during labor represent major contributions to medicine by the technology of EFHRM. Ultimately, however, additional approaches to the detection of fetal central nervous system hypoxia during labor that does not involve fetal heart rate will be necessary to close the gap between current and desired intrapartum outcomes. ■

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