Mechanism of reduction of newborn metabolic acidemia following application of a rule-based 5-category color-coded fetal heart rate management framework

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Abstracts
Objective: We have reported a 7-fold reduction in newborn umbilical arterial (UA) metabolic acidemia after adoption of a rule-based 5-category color-coded fetal heart rate (FHR) management framework. We sought evidence for the relationship being causal by detailed analysis of FHR characteristics and acid–base status before and after training.

Methods: Rates of UA pH and base excess (BE) were determined over a 5-year period in a single Japanese hospital, serving mainly low-risk patients, with 3907 deliveries. We compared results in the 2 years before and after a 6-month training period in the FHR management system. We used a previously published classification schema, which was linked to management guidelines.

Results: After the training period, there was an increase in the percentage of normal patterns (23%), and a decrease in variable decelerations (14%), late decelerations (8%) and prolonged decelerations (12%) in the last 60 min of labor compared to the pre-training period. There was also a significant reduction in mean UA pH and BE in the groups with decelerations after introduction of the FHR management framework.

Conclusions: The adoption of this FHR management system was associated with a reduction of decelerations and metabolic acidemia, without a change in cesarean or vacuum delivery rates. These results suggest that the obstetrical providers were able to better select for intervention those patients destined to develop more severe acidemia, demonstrating a possible causal relationship between the management system and reduced decelerations and metabolic acidemia.

Keywords
Fetal BE, fetal heart rate, fetal pH

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Introduction
There are currently major efforts to improve the effectiveness of FHR monitoring, particularly in Japan [1] and the United States [2], specifically with respect to the relationship between FHR patterns and metabolic acidemia, and clinical management approaches which will avoid this adverse outcome.

We have previously shown that following introduction of 5 category rule-based FHR management system, there was a 7-fold reduction in umbilical artery base excess less than −12mmol/L and pH less than 7.15 [3]. In this series of patients there was no significant change in cesarean delivery or vacuum extraction rates following introduction of the new system.

Against this background we sought evidence for the relationship being causal by detailed analysis of FHR characteristics and acid–base and blood gases at birth before and after the introduction of the training in this system. We hypothesized that if the reduction in metabolic acidemia were causal, there would be a reduction in those FHR patterns more closely associated with acidemia.

Methods
The study was carried out at Noda Clinic, Miyazaki, Japan. This hospital generally cares for low-risk patients. Data on vaginal delivery, cesarean delivery, use of vacuum extraction and umbilical cord blood gases were collected for a number of years for quality control purposes. We used the data in 2003 and 2004 as baseline. During 2005, a perinatologist (TI) carried out training for 6 months to educate the physicians and
nursing staff in the rule-based management of FHR patterns [4] and National Institute of Child Health and Human Development (NICHD) FHR pattern descriptions [5]. The current study was done before the most recent NICHD report [6] using 3-tiers, and we continue to use the 5-tier system for reasons already given [7].

The FHR framework categorizes 134 different possible combinations of baseline variability, baseline heart rate, and graded decelerations into 5 color-coded levels. A summary of the combinations of features defining the various colors is shown in Table 1. Findings within normal limits for all features were coded “green”. Progressively abnormal combinations of features result in classifications of “blue”, “yellow”, “orange” and “red” for each 10-min segment of the FHR tracing, with the most severe pattern encountered used for classification. Each FHR level has corresponding management maneuvers directed towards an operative intervention if required (Table 2). For “green”, no intervention is recommended. For “blue”, nurses inform the clinician of the FHR patterns and attempt amelioration through such conservative therapeutic maneuvers as position change, hyperoxia, correction of hypotension, assuring adequate intravascular volume and avoidance of excessive contractions (Table 2). For “yellow”, the clinician is required to be at the bedside for evaluation, confirmation of amelioration techniques and increased surveillance. For “orange”, preparation for urgent delivery is started by moving the patient to the operating room, checking the availability of personnel for anesthesia and newborn resuscitation, and continuing amelioration techniques. For persistent “red” patterns, urgent delivery is performed by Cesarean section or vacuum delivery.

The training period consisted of weekly attendance in the maternity unit by the perinatologist and included didactic sessions, interactive sessions, and attendance in the labor and delivery unit with physicians, midwives and obstetrical nurses. A booklet containing definitions of FHR patterns, the color grid classifying the patterns and guidelines for management of the patterns was produced for continuing education of staff. During the training period, the obstetrical and nursing staffs were all exposed to the guidelines, depending on their shifts. Pre- and post-training formal evaluation was not done.

Table 1. Summary of the 5-tier color-coded FHR management system.

| Variable                      | No variability | Mild variability | Moderate variability | Severe variability |
|-------------------------------|----------------|------------------|----------------------|-------------------|
| Tachycardia                   |                |                  |                      |                   |
| Normal                        | B              | B                | Y                    | O                 |
| Mild bradycardia              | Y              | Y                | Y                    | Y                 |
| Severe bradycardia            | O              | O                | O                    | O                 |
| Minimal variability           |                |                  |                      |                   |
| Tachycardia                   | B              | Y                | Y                    | O                 |
| Normal                        | B              | B                | Y                    | O                 |
| Mild bradycardia              | O              | O                | R                    | R                 |
| Moderate bradycardia          | O              | R                | R                    | R                 |
| Severe bradycardia            | R              | R                | R                    | R                 |
| No variability                |                |                  |                      |                   |
| Tachycardia                   | R              | R                | R                    | R                 |
| Normal                        | O              | R                | R                    | R                 |
| Mild bradycardia              | R              | R                | R                    | R                 |
| Moderate bradycardia          | R              | R                | R                    | R                 |
| Severe bradycardia            | R              | R                | R                    | R                 |
| Sinusoidal                    | R              |                  |                      |                   |
| Marked variability            | Y              |                  |                      |                   |

G, green; B, blue; Y, yellow; O, orange; R, red; VD, variable deceleration; LD, late deceleration; PD, prolonged deceleration. Fetal heart rate risk categories for fetal acidemia related to variability, baseline rate, and presence of recurrent decelerations. Risk increases as colours progress from green through blue, yellow, orange and red. Management recommendations are linked to each category. Modified from ref. [4].

Table 2. Description of the activities associated with the five categories in the FHR management system.

| Category      | Therapeutic interventions | Operating room | Obstetrician | Anesthetist | Newborn infant resuscitator | Location of patient |
|---------------|----------------------------|-----------------|--------------|-------------|-----------------------------|---------------------|
| Green         | No                         | –               | –            | –           | –                           | –                   |
| Blue          | Yes                        | Available       | Informed     | –           | –                           | –                   |
| Yellow        | Yes                        | Available       | At bedside   | Informed    | Informed                    | Operating room      |
| Orange        | Yes                        | Immediately available | At bedside | Present | Immediately available | Operating room      |
| Red           | Yes                        | Open            | At bedside   | Present | Present | Operating room |

Modified from ref. [4].
obstetrical staff (except the perinatologist’s training noted above), in-house availability, management protocols, anesthesia coverage or referral patterns.

Baseline data (2003–2004) were compared with data in 2006 and 2007, after completion of the 6-month training period in 2005. All definitions were according to the NICHD statement on the nomenclature of FHR patterns [5]. In defining the degree of severity of decelerations, we used the classifications of Kubli et al. [8], in some cases with slight modifications.

Variable decelerations were defined by the NICHD guidelines, and quantified using the diagram proposed by Chao [9]. Severe variable decelerations are ≥60 s in duration and <70 beats/min or ≥2 min in duration and <80 beats/min. Moderate variable decelerations have a duration of 30–60 s and are <70 beats/min or ≥60 s in duration and <80 beats/min. All other variable decelerations are mild.

Late decelerations, as defined by NIH guidelines, are severe if the decrement of the deceleration is ≥45 beats/min below the baseline, moderate if the decrement is >15 beats/min and <45 beats/min below the baseline and mild if the decrement is no more than 15 beats/min below the baseline.

Early decelerations were not quantified because of their rarity and past disagreement about the definition.

Prolonged decelerations, as defined by NIH guidelines, require the FHR to be depressed for 2 minutes. Severe was defined as <70 beats/min, moderate as between 70 and 80 beats/min and mild as ≥80 beats/min. These are the criteria that are similar to those used for quantification of bradycardias.

For continuous variables, Student’s t-test or ANOVA were performed for the analysis of normally distributed data and Wilcoxon test was used for data that were not normally distributed. For categorical variables Fisher’s exact test and chi-square test were used. The Cochran–Armitage test for trend is used in categorical data analysis when the aim is to assess for the presence of an association between a variable with two categories and a variable with k categories. All statistical analyses were performed using JMP11 (SAS Institute, Cary, NC). A p value of <0.05 was considered statistically significant.

The study was exempted from Committee on Human Research approval (National Cerebral and Cardiovascular Center) because there no longer exists a key or code sheet relating the individuals’ identities to their private health information.

Results

The overall annual birth rate increased by 25% from 609 to 809 during the 5-year period, with a total of 3907 deliveries. Of these, 310 (7.9%) were scheduled Cesarean deliveries, mostly for prior Cesarean delivery or non-vertex presentation.

In Figure 1(A) and (B) we show the relationship of the severity of the FHR categories at 10 min before delivery and umbilical arterial pH and BE, using the pre-training data. This confirms the relationship between the severity of the categories and decreasing umbilical arterial pH and BE. We also confirmed the relationship between the severity of the categories and a decrease in umbilical arterial PO2 and an increase in UA PCO2 (Figure1C and D).

Table 3 shows the acid–base and blood gas data before and after the introduction of the management system at 10 min before delivery with variable decelerations. There was an increase in umbilical arterial pH, BE and pO2, and there was a decrease in pCO2 following the introduction of the system of management.

Figure 1. The relationship between severity of FHR pattern categories and umbilical arterial pH, BE, PO2 and PCO2 using data from the pre-training period, at 10 min before delivery. G: green, B: blue, Y: yellow, O: orange, R: red. Student’s t-test. An asterisk means p < 0.05.
Figure 2 shows the changes of FHR patterns at 10 min intervals in the last hour before delivery, before (black bar) and after (gray bar) the introduction of 5-tier color-coded classification and standardized management system. Adoption of the management system was associated with significant decreases in variable decelerations before versus after the introduction of the management system at 60, 50, 40, 30, 20 and 10 min before vaginal delivery, respectively; (39.6%(2996/7566), 44.7%(3382/7566), 44.4%(3359/7566), 54.7%(4139/7566), 66.4%(5024/7566, 67.2%(5084/7566)) versus 30.1%(2277/9660), 33.2%(2512/9660), 39.7%(3004/9660), 47.1%(3564/9660), 56.9%(4305/9660), 65.5%(4956/9660), p<0.0001, and prolonged decelerations; (1.7%(129/7566), 1.5%(113/7566), 1.8%(136/7566), 3.6%(272/7566), 6.3%(477/7566, 28.4%(2149/7566)) versus 0.9%(68/9660), 1.3%(98/9660), 1.6%(121/9660), 2.2%(166/9660), 5.8%(318/9660), 23.8%(1801/9660), p<0.05, and a significant increase in normal patterns; (50.3%(38.3/7566), 45.4%(3437/7566), 44.3%(3351/7566), 32.1%(2427/7566), 19.9%(1503/7566, 1.3%(100/7566)) versus 59.5%(45.4/9660), 55.1%(4171/9660), 55.1%(4171/9660), 49.0%(3709/9660), 41.5%(3140/9660), 27.5%(2080/9660), 2.7%(206/9660), p<0.0001. There was also a decrease in late deceleration in the last hour before delivery before vaginal delivery; (5.2%(393/7566), 5.1%(386/7566), 5.0%(378/7566), 5.4%(409/7566), 4.3%(325/7566, 1.9%(144/7566)) versus 4.4%(333/9660), 4.7%(356/9660), 4.7%(356/9660), 3.9%(295/9660), 4.2%(318/9660), 0.9%(68/9660), p = 0.09, but this did not reach the statistical significance. The Cochran–Armitage test for trend is used.

After the introduction of the management system, the number patterns coded green was increased (73.83%(5586/7566) versus 76.07%(7348/9660)), and the number of blue (15.01%(1136/7566) versus 13.01%(985/9660)), yellow

Table 3. Umbilical arterial acid base and blood gas data in case of variable decelerations 10 min before delivery, before and after introduction of the management scheme.

|                      | Before training (n = 688) | After training (n = 744) | p value |
|----------------------|--------------------------|--------------------------|---------|
| pH                   | 7.29 ± 0.11              | 7.36 ± 0.13              | <0.05   |
| BE (mmol/L)          | -6.6 ± 1.2               | -2.8 ± 0.9               | <0.05   |
| pO2 (mmHg)           | 19.5 ± 2.1               | 21.92 ± 3.1              | <0.05   |
| pCO2 (mmHg)          | 43.33 ± 12.5             | 38.47 ± 9.6              | <0.05   |
| pH<7.15              | n = 11                   | n = 2                    |         |
| BE<−12 mmol/L        | n = 11                   | n = 2                    |         |

BE means base excess. Mean values illustrated are for cases with variable decelerations (mild, moderate, severe) 10 min before delivery. Data was analyzed by Student’s t-test.

Figure 2. Changes in the FHR patterns at 10 min intervals in the last hour before delivery, before (black bar) and after (gray bar) the introduction of the standardized management protocol. There was a significant reduction in variable, and prolonged decelerations. There was a significant increase in normal patterns. The Cochran–Armitage test for trend was used. An asterisk means p < 0.05. Double asterisk means p < 0.0001. Numbers of patients in each category are in the text.
and 18.1% (291/1610) in the 2 years after training (NS) was 21.2% (267/1261) of births 2 years before introduction, based system (NS). Vacuum-assisted vaginal delivery rate 6.0% (61/1610) in the 2 years after introduction of the rule-intended vaginal births in the 2 years before training, and scheduled cesarean delivery rate was 4.8% (61/1261) of below threshold were 1.11 and 1.31%. Cesarean deliveries below the pH threshold were 1.28 and 1.48%. Values of BE acidemia, except adoption of the structured management algorithm.

In order to support the contention that this relationship is causative, we would like to address the following three issues.

First, what else could have changed over the study period to explain the observed outcome? Potential factors could include improvements in obstetrical staffing, or improvements in technology, improvements in logistics and ability to intervene rapidly, or a change in patient demographics. None of these are likely, because before and after the introduction of the management, there were no concomitant changes in numbers or status of obstetrical staff, in-house availability, management protocols, anesthesia coverage or referral patterns. Regarding patient acuity, there were no changes in patient demographics, or ability to refer out more high risk patients. As noted, the Noda Clinic accepted only low-risk patients, those with complications or higher risk for poor fetal outcome being referred to tertiary centers in the antepartum period. Thus, we believe there were no obvious changes over the study period to explain the decrease in metabolic acidemia, except adoption of the structured management algorithm.

Second, were the outcomes (i.e. metabolic acidemia and operative delivery rates) stable before the introduction of the new system? As noted in our previous paper [3], analysis of pH < 7.15 and BE < –12 mmoL/L in 6 months period showed apparent random fluctuations before the interventions rather than a persistent trend downwards. Thus in 2004, the values below the pH threshold were 1.28 and 1.48%. Values of BE below threshold were 1.11 and 1.31%. Cesarean deliveries and vacuum-assisted vaginal deliveries showed no trend before the intervention. As previously reported [3], the non-scheduled cesarean delivery rate was 4.8% (61/1261) of intended vaginal births in the 2 years before training, and 6.0% (61/1610) in the 2 years after introduction of the rule-based system (NS). Vacuum-assisted vaginal delivery rate was 21.2% (267/1261) of births 2 years before introduction, and 18.1% (291/1610) in the 2 years after training (NS). The scheduled cesarean section rate was 7.9% (103/1303) of total births 2 years before training and 7.4% (125/1686) after introduction (NS). The overall cesarean section rate was thus not significantly different before and after training. Umbilical arterial pH < 7.15 occurred in 1.59% (20/1261) 2 years before introduction and 0.19% (3/1610) 2 years after introduction (p < 0.05). BE < –12 mmoL/L occurred in 1.75% (22/1261) of cases before introduction and 0.25% (4/1610) after introduction (p < 0.05). Although the mean values for the acid base and blood gas factors were within the normal ranges (Table 3), those below the threshold for unacceptable metabolic acidemia were reduced 7-fold.

Third, why would the structured classification system result in improved fetal outcomes without increased intervention? We believe our analysis supports the contention that earlier identification and intervention for tracings in the high end of the classification spectrum lead to fewer tracings deteriorating and hence less metabolic acidosis.

Although a cause and effect relationship is difficult to ascertain from our study design of “before and after” comparisons, we believe that it is plausible that the introduction of the standardized protocol resulted in the reduction in the incidence of metabolic acidemia. We believe it is likely that the color-coded system allowed the clinicians to better recognize those fetuses with FHR patterns more highly associated with metabolic acidemia and worsening evolution of patterns. With no change in operative delivery rates, this is consistent with better selection of those fetuses needing intervention during labor.

Furthermore, these observations, and those of others [10,11] support the potential clinical effectiveness of the 5-tier color-coded classification and management system.

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Declaration of interest
The authors report no decelerations of interest. The authors report no conflicts of interest. Funding was provided by institutional sources only.

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