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Evaluation of 3-tier and 5-tier FHR pattern classifications using umbilical blood pH and base excess at delivery

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Abstract

Objective

The relevance between time-series fetal heart rate (FHR) pattern changes during labor and outcomes such as arterial blood gas data at delivery has not been studied. Using 3-tier and 5-tier classification systems, we studied the relationship between time-series FHR pattern changes before delivery and umbilical artery blood gas data at delivery.

Methods

The subjects were 1,909 low-risk women with vaginal delivery (age: 29.1 ± 4.4 years, parity: 1.7 ± 0.8). FHR patterns were classified by a skilled obstetrician based on each 10 min-segment of the last 60 min before delivery from continuous CTG records in an obstetric clinic.

Results

The relationship between each 10 min-segment FHR pattern classification from 60 minutes before delivery and umbilical artery blood pH and base excess (BE) values at delivery changed with time. In the 3-tier classification, mean pH of Category I group in each 10 min-segment was significantly higher than that of Category II group. For Category I groups in each 10-minute segment, its number decreased and its average pH increased as the delivery time approached. In the 5-tier classification, there was the same tendency. About each level group in 10 min-segment, the higher the level, the lower the blood gas values, and mean pH of higher level groups decreased as the delivery time approached.

Conclusions

The relationship between classifications and outcomes was clear at any time from 60 min before delivery in 3- and 5-tier classifications, and the 5-tier classification was more relevant.

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Introduction

In cardiotocography (CTG), fetal conditions are monitored by continuous measurement of fetal heart rate (FHR) and uterine contractions. This monitoring provides nearly real-time fetal well-being from heart rate changes and is used in 89% of delivery cases in the United States (2004) [1], 91% in Canada (2009) [2], approximately 60% in the United Kingdom (UK) as National Institute for Health and Care Excellence (NICE) guidelines for fetal monitoring in the NHS detail explicit criteria for this monitoring (2018) [3]. In Japan, it is estimated to be almost 100%.

FHR waveforms are classified by four indicators: baseline, baseline variability, accelerations, and decelerations. Intrapartum guidelines using 3-tier and 5-tier classification systems to estimate fetal hypoxia and acidosis level have been proposed in many countries [4–8]. At present, the 3-tier classification based on FHR patterns is used in the United States, Canada, and UK. The classification in the United States is defined as Category I, II, III, and in Canada, as Normal, Atypical, and Abnormal [7]. In the UK, there is a 3-tier description classified as Reassuring, Non-reassuring, and Abnormal. The management categories for labor based on the 3-tier FHR pattern interpretations are defined as: Normal, Suspicious, Pathological, and Need for urgent interventions [4, 5]. A 5-tier classification was proposed in Japan [8] because the 3-tier classification was considered to be simple, with Category II covering too wide a range.

Three or five tier management guidelines based on the classification of FHR patterns are used in each country. At present, although there are many studies around the effectiveness of FHR pattern classification and outcomes [9–14], the effectiveness of continuous cardiotocography has not been sufficiently shown in comparison with intermittent auscultation [15, 16]. In these studies, the relevance between time-series changes in FHR pattern classification during labor and outcomes such as arterial blood gas data at delivery has not been studied. Therefore, we tried to analyze the relationship using the U.S. 3-tier and Japanese 5-tier guidelines between each 10 min-segment FHR pattern change from 60 minutes before delivery and umbilical artery blood gas data at delivery.

Materials and methods

The subjects in this study were 1,909 low-risk women with vaginal delivery (age: 29.1 ± 4.4 years, parity: 1.7 ± 0.8) from 2003 to 2006 at an obstetric clinic (Table 1). The data used in our study was fully anonymized before offered. A skilled obstetrician who was blinded to outcome retrospectively

Item	Mean ± SD (n = 1909)		
Gestational age	39 w 5 d ± 10 d		
Duration of labor	7 h 59 m ± 6 h 4 m		
instrumental delivery (%)	25		
Oxytocin administration (%)	5.6		
Maternal age (years)	28.9 ± 4.4		
Parity (time)	1.7 ± 0.8		
etal state			
Birth Weight (g)	3210 ± 85		
Gender (%)	Male: 52, Female: 48		
Apgar score 1 minute	9.24 ± 0.56		
Apgar score 5 minute	9.57 ± 0.56		

Table 1. Patient characteristics.

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classified each 10 min-segment of the last 60 min CTG data before delivery using the framework of Parer et al [17]. The outcomes were umbilical artery blood pH and base excess (BE) at delivery. The classified data were applied to the 3-tier classification used in the United States (Table 2) and the 5-tier classification used in Japan (Table 3). We analyzed the relationship between time-series changes of FHR patterns classification before delivery and outcomes at delivery. Another analysis was a grouping of outcomes, which was as follows: pH <7.0, $7.0 \le$ pH <7.1, $7.1 \le$ pH <7.2, $7.2 \le$ pH <7.3, $7.3 \le$ pH <7.4, pH \ge 7.4, and BE <-12, BE \ge -12.

Statistical analysis was performed by Friedman, Tukey's HSD, Wilcoxon signed-rank and Kruskal-Wallis test for these four respective indicators, using JMP (ver. 10, SAS) with a significance level of 0.05. The study was approved by the research ethics committee of the Graduate School of Applied Informatics, University of Hyogo.

Results

The frequency of the 3- and 5-tier classifications in each 10 min-segment of the last 60 min before delivery are shown in Table 4. In the 3-tier classification, Category I decreased as labor proceeded, while Category II significantly increased. The incidence of Category III, which may indicate fetal acidosis, was only 0.1% (n = 2) from 50 to 30 min before delivery. In the 5-tier classification, the incidences of Level 1 and 2, categorized as normal FHR pattern, significantly decreased as labor proceeded, whereas the incidences of Level 3 to 5, which may indicate fetal acidosis, significantly increased.

The relationship between the 3-tier classification in each 10 min-segment of the last 60 min before delivery and umbilical artery blood pH and BE at delivery are shown in Fig 1 and those for the 5-tier classification are shown in Fig 2. The horizontal axis of each figure shows 3- and 5-tier classifications in each 10 min-segment of the last 60 min before delivery. The vertical axis shows the mean and standard deviations of related outcome data. In the 3-tier classification, the relationship of Category I with umbilical artery blood pH at delivery was significantly higher than that of Category II, and the relationship of Category I with BE at delivery was significantly higher than that of Category II. There was no significant difference between Categories II and III because of the small number of cases in Category III (n = 2) from 50 to 30 min before delivery. In the 5-tier classification, pH showed a tendency to decrease as the level became higher at any 10 min-segment from 60 min before delivery, which showed the possibility of fetal acidosis. Significant differences in pH were found between Level 1 and 2 from 60 to 10 min before delivery. BE began to decrease at 20 min before delivery and there were significant differences in BE between Level 1 and 2, and Level 2 and 3.

Table 2. Summar	y of 3-tier FHR pattern	n classification.
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Category	FHR tracing		
Category I	Baseline rate: 110–160 beats per minute		
	Baseline variability: moderate		
	Late or variable decelerations: absent		
	Early decelerations: present or absent		
	Accelerations: present or absent		
Category II	Includes all tracings not categorized as Category I or III		
Category III	Absent baseline FHR variability and any of the following • Recurrent late decelerations • Recurrent variable decelerations • Bradycardia		
	Sinusoidal pattern		

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Baseline FHR		None	Early	Variable		Late		Prolonged	
				Mild	Severe	Mild	Severe	Mild	Severe
Moderate variability (amplitude 6–25 bpm)	110–160 bpm	1	2	2	3	3	3	3	4
	>160 bpm	2	2	3	3	3	4	3	4
	80–110 bpm	3	3	3	4	4	4	4	4
	<80 bpm	4	4		4	4	4		
Minimal variability (amplitude 3–5 bpm)	110–160 bpm	3	3	3	4	3	4	4	
	>160 bpm	3	3	4	4	4	5	4	
	80–110 bpm	4	4	4	5	5	5	5	5
	<80 bpm	5	5		5	5	5		
Undetectable variability (amplitude ≤2 bpm)		4	5	5	5	5	5	5	5
Marked variability (amplitude \geq 26 bpm)				3	3	3	4	3	4
Sinusoidal FHR pattern		4	4	4	4	5	5	5	5

Table 3. Summary of 5-tier FHR pattern classification.

1: Level 1, 2: Level 2, 3: Level 3, 4: Level 4, 5: Level 5.

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Of the 1,909 subjects, 2 (0.1%) had pH <7.0, and 3 (0.2%) had 7.0 \leq pH <7.1, and 36 (1.9%) had 7.1 \leq pH <7.2, and 372 (19.5%) had 7.2 \leq pH <7.3, 1080 (56.6%) had 7.3 \leq pH <7.4, and 416 (21.8%) had pH \geq 7.4. Regarding BE (mmol/L), BE <-12 was 21 (1.1%), and BE \geq -12 was 1888 (98.9%). Fig 3 shows the relationships of these groups with mean 3-tier (a) and mean 5-tier (b) classification values with pH groups at delivery in each 10 min-segment of the last 60 min before delivery. There was a significant difference among mean classification values with BE <-12 mmol/L and BE \geq -12 mmol/L groups at delivery in each 10 min-segment of the last 60 min before delivery. There was a 3-tier and 5-tier groups. However, in part, there was no difference among them. Table 5 shows mean 3-tier and mean 5-tier classification values with BE <-12 mmol/L and BE \geq -12 mmol/L groups at delivery in each 10 min-segment of the last 60 min before delivery. The mean 3-tier classification value of BE <-12 mmol/L group significantly for the delivery. The mean 5-tier classification value of BE <-12 mmol/L group always showed significantly higher than BE \geq -12 mmol/L group. The mean value of both groups tended to higher with time to delivery.

Discussion

The interpretation of FHR pattern in this study was performed by a single examiner with more than 20 years of clinical experience who was blinded to outcome. There are two factors contribute to the agreement level of FHR pattern interpretation by examiner: inter-observer agreement between multiple examiners, and intra-observer agreement with repeated examinations

Tim	e before delivery	60 min	50 min	40 min	30 min	20 min	10 min
3-tier	Category I	55.5%	50.6%	47.2%	36.7%	23.5%	1.9%
	Category II	44.5%	49.3%	52.6%	63.2%	76.5%	98.1%
	Category III	0.0%	0.1%	0.1%	0.1%	0.0%	0.0%
5-tier	Level 1	54.0%	49.3%	46.2%	35.9%	22.9%	1.9%
	Level 2	34.5%	38.0%	39.0%	46.0%	51.2%	35.7%
	Level 3	10.7%	11.6%	13.8%	16.3%	22.5%	44.5%
	Level 4	0.7%	1.0%	1.0%	1.7%	3.2%	17.5%
	Level 5	0.1%	0.0%	0.0%	0.1%	0.2%	0.4%

Table 4. The frequency of 3-tier (category) and 5-tier (level) classifications in each 10 min-segment of the last 60 min before delivery.

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Evaluation of FHR pattern classifications using umbilical blood pH and base excess at delivery

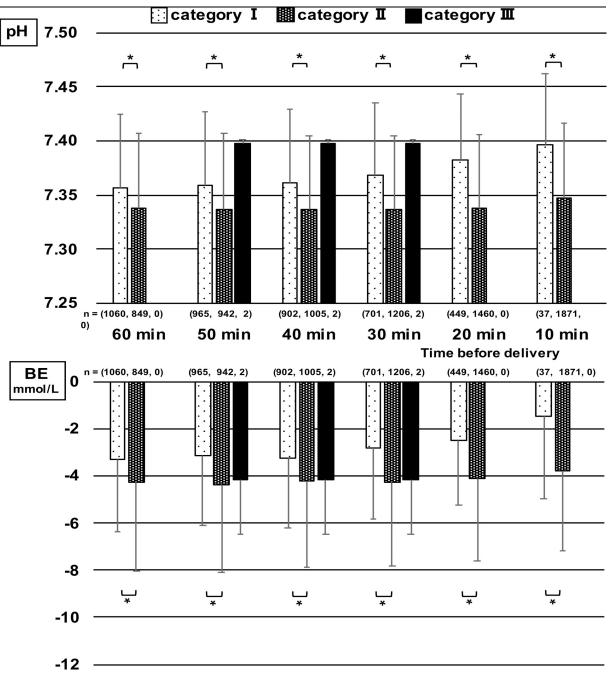
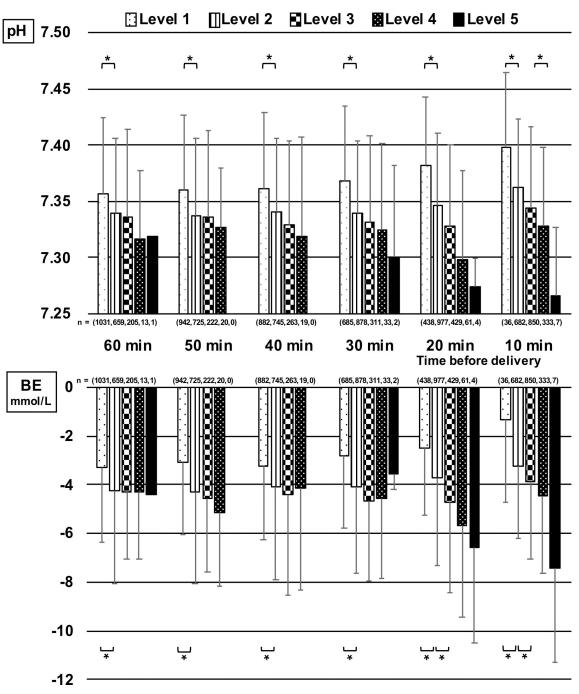


Fig 1. Relationships of umbilical artery blood pH and BE at delivery with 3-tier classification in each 10 min-segment of the last 60 min before delivery (mean + standard deviation). There were significant differences between category I and category II.

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by a single examiner. In addition, in the case of multiple examiners, the agreement level of repeat examinations is also involved. As for the agreement level in FHR pattern interpretations, the level of repeat examinations by a single examiner was higher than that among multiple examiners [18], and the agreement level among multiple examiners was widely dispersed [19]. Therefore, the interpretation of FHR patterns in this study was performed by a single examiner.

Guideline for FHR pattern interpretation in Japan uses a 5-tier classification [8], whereas a 3-tier classification is used in many other countries [4–7, 20]. From the results, the tendency of

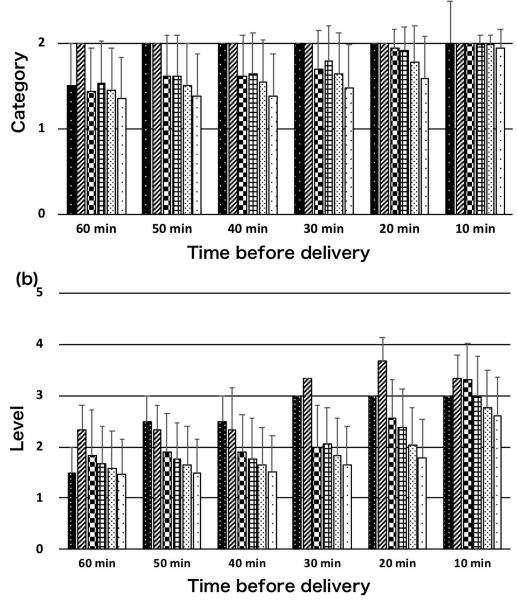


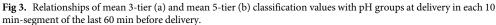


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the frequency in both 3- and 5-tire classifications in each 10 min-segment of the last 60 min before delivery showed that higher-level classifications increased and lower-level classifications decreased over time. With regard to the relationship between classification categories at each 10 min-segment from 60 min before delivery and umbilical artery blood gas data at delivery, one was the relationship between the 3- and 5-tier classification pattern and the outcome at each segment, and the other was the analysis of mean classification values among the groups







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divided by outcome level. These were complementary to each other. The results showed that poor FHR pattern group had a poor outcome, and on the contrary, poor outcome group had a poor FHR pattern. This tendency continued from 60min before delivery. The relation between the outcome pH groups and the average classification values with each group showed that the groups with lower pH values in both 3-tier and 5-tier had significantly higher classification values over time, and the mean values also tended to increase over time. The BE group divided into two groups had the same tendency and this is more clear in the 5-tier classification.

	Level	BE<-12mmol/L	BE≧-12mmol/L	Wilcoxon p-value
	n	21	1888	
3-tier	60min	1.71	1.44	0.0125
	50min	1.86	1.49	0.0009
	40min	1.81	1.53	0.0095
	30min	1.81	1.63	0.0931
	20min	1.95	1.76	0.0416
	10min	2.00	1.98	0.5274
5-tier	60min	2.05	1.58	0.0039
	50min	2.19	1.64	0.0003
	40min	2.14	1.69	0.0070
	30min	2.33	1.84	0.0047
	20min	2.71	2.06	0.0004
	10min	3.20	2.78	0.0222

Table 5. Relationships of mean 3-tier and mean 5-tier classification values with BE	groups at delivery in each 10 min-segment of the last 60 min before delivery.

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No literature has been found about the relationship between changes in FHR pattern over time and outcomes. A similar study [21] of the relationship between FHR classification and pH at delivery showed that the sensitivity to fetal acidosis in the 5-tier classification was higher than that in the 3-tier classification. This tendency was confirmed in the current study from 60 min before delivery, with BE showing a similar tendency. These results suggest that the 5-tier classification at any time from 60 min before delivery have a closer relationship with umbilical artery blood gas data at delivery, compared to the 3-tier classification. As in Coletta et al [21, 22], comparing fetus groups with pH <7.0 and pH >7.2, the result of 3-tier and 5-tier classifications showed that the group with higher pH gathered in the lower levels, and those with lower pH gathered in the higher categories. However, this is the result of cumulative time course of FHR classification, because the concept of time course essential for finding the tendency is sparse. In our analysis, we could clarify the relationship between changes in 3- or 5-tier classification along the time-series analysis from 60 minutes before delivery and the outcomes.

The purpose of analyzing the characteristics of FHR waveform pattern is to find evidence of prognostic signs in the process from hypoxemia to metabolic acidosis occurred during labor. The 3-tier or 5-tier classification for continuous FHR monitoring is considered an integrated method for that purpose in which the presence of acceleration and moderate FHR variability can predict the absence of metabolic acidosis [23]. However, there is little concept of time course in the current classifications. In this study, we have analyzed under the concept of time-series FHR classification. The results showed that poor FHR classification group had a poor outcome, and on the contrary, poor outcome group had a poor FHR pattern from 1 hour before delivery. The 5-tier classification became clearer than the 3-tier classification using time-series analysis. Although this result is from normal cases, we expect to find characteristic signs that lead to early detection of fetal acidosis from the time-series changes in FHR data.

Conclusion

The result from the analysis between time-series changes of FHR pattern classification before delivery and outcomes at delivery showed that the relationship between classifications and outcomes was clear at any time from 60 min before delivery in 3- and 5-tier classifications, and that the 5-tier classification was more relevant.

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Conceptualization: Shinji Katsuragi.

Data curation: Shunichi Noda.

Formal analysis: Hitomi Kikuchi.

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Validation: Tomoaki Ikeda.

Writing - original draft: Hitomi Kikuchi.

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