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Fetal Heart Rate Classification Proposed by the Perinatology Committee of the Japan Society of Obstetrics and Gynecology: Reproducibility and Clinical Usefulness

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Abstract

Aim: Intrapartum management guidelines based on fetal heart rate classification comprising a 5-tier system (Levels 1–5) was proposed by the Perinatology Committee of the Japan Society of Obstetrics and Gynecology (JSOG). This study aimed to assess the reproducibility and clinical usefulness of this classification.

Methods: For assessing intraobserver and interobserver reproducibility in the interpretation of fetal heart rate tracing, 2 obstetricians reviewed 247 fetal heart rate tracings using the JSOG classification (Level 1, normal; Level 2, benign variant; Level 3, mild variant; Level 4, moderate variant; and Level 5, severe variant) and a subjective 3-tier classification (normal, equivocal, and ominous). In a separate series, we investigated whether the JSOG classification is related to early neonatal outcome and the delivery mode in 96 deliveries.

Results: Weighted kappa coefficients of intraobserver and interobserver reproducibility in the interpretation of fetal heart rate tracings based on the JSOG classification were 0.73 to 0.77 and 0.70, respectively. In the subjective classification, these values were 0.69 to 0.72 and 0.59. There was a progressive increase in the rate of instrumental or cesarean deliveries across the 5 levels of the JSOG classification ($P<0.001$). Although, level 5 of the JSOG classification had a lower Apgar score and umbilical artery pH than did the other 4 levels ($p<0.05$), there were no significant differences among the other levels in regard to early neonatal outcome.

Conclusions: This study demonstrated that both intraobserver reproducibility and interobserver reproducibility of the JSOG classification for interpreting FHR tracings were clinically acceptable. The results also suggest that the intervention according to the JSOG classification is useful for avoiding worsening early neonatal outcomes.

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Key words: cardiotocography, classification, fetal heart rate, guideline, early neonatal outcome

Introduction

The combination of the various components of fetal heart rate (FHR) patterns (baseline variability, heart rate baseline, and decelerations) serves to estimate the degree of risk for such conditions as fetal hypoxemia, acidemia, and possible evolutional

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Table 1 JSOG classification§

FHR pattern classification levels	
FHR pattern levels	Designation
Level 1	Normal pattern
Level 2	Benign variant pattern
Level 3	Mild variant pattern
Level 4	Moderate variant pattern
Level 5	Severe variant pattern

§Five-tier fetal heart rate classification proposed by the Perinatology Committee of the Japan Society of Obstetrics and Gynecology

patterns to higher-risk conditions[1]. Therefore, the interpretation of FHR tracing is an important factor in managing deliveries. Over the past 4 decades, many studies have investigated the association between FHR and perinatal outcomes[2–5]. We have made management decisions for patients with nonstandardized patterns on the basis of these studies.

We believe that ubiquity of FHR monitoring emphasizes the need for standardized management relying on the best available evidence. Some studies have attempted to determine the severity of FHR patterns on the basis of the risk for fetal acidemia by referring to evidence in the literature[2,6]. This formed the basis for previous management recommendations.

Guidelines for the interpretation of interpartum FHR patterns, with or without management, were proposed in the United Kingdom (2001)[7], Canada (2007)[8], and the United States (2008)[9]. These guidelines used a 3-tier system for classifying FHR patterns according to "normal-suspicious-pathological," "normal-atypical-abnormal," and "Category I–III" classifications in the United Kingdom, Canada, and the United States, respectively. Furthermore the Perinatology Committee of the Japan Society of Obstetrics and Gynecology (JSOG) recently proposed intrapartum management guidelines based on classification of FHR patterns[1]. In these guidelines, FHR patterns have been classified into 5 levels (**Tables 1, 2**). On the basis of the JSOG classification, "nonreassuring fetal status" is defined as the risk for fetal acidemia, and the risk of FHR patterns evolving to higher-level risks, such as levels 3 to 5.

The interpretation of FHR patterns is subject to both interobserver variability and intraobserver variability. The reliability of the interpretation of these classifications should be carefully evaluated before the classifications gain widespread clinical acceptance[10–12]. However, no appropriate studies have examined the reliability and validity of the association between FHR patterns and fetal acidemia or cesarean delivery or both for the JSOG classification. Thus, to clarify the reliability and clinical usefulness of the JSOG classification, this retrospective study tested the following hypotheses: (1) classifying FHR according to the guidelines of JSOG classification increases intraobserver and interobserver reproducibility of the interpretation of FHR tracings compared with subjective classification and (2) use of these guidelines would allow us to accurately predict early neonatal outcomes, such as low Apgar scores and umbilical arterial pH.

Patients and Methods

Infants were delivered from 1,677 pregnant women from March 2008 through January 2010 at Tama-Nagayama Hospital of Nippon Medical School. When the women came to the hospital because of labor onset, electronic FHR monitoring was performed continuously until delivery, once the women progressed into active labor. The FHR monitoring was recorded with fetal actocardiograph (MT-516, Toitsu, Tokyo, Japan) at a paper speed of 3 cm/min and with an external ultrasonographic transducer. All patients were treated according to standard obstetric indications, including the interpretation of FHR tracings without the JSOG classification, with the route and timing of delivery at the discretion of the attending clinician. After delivery, all electronic FHR tracings were stored and were available for review.

To assess the intraobserver and interobserver reproducibility of the interpretation of FHR tracings, an obstetrician randomly selected tracings from those stored from March 2008 through January 2010 and included 107 deliveries. The inclusion criteria

Table 2-1 JSOG classification§: Normal baseline variability cases

deceleration / Heart rate baseline	None	Early	Variable		Late		Prolonged	
			Mild	Severe	Mild	Severe	Mild	Severe
Normocardia	1	2	2	3	3	3	3	4
Tachycardia	2	2	3	3	3	4	3	4
Mild bradycardia	3	3	3	4	4	4	4	4
Severe bradycardia	4	4		4	4	4		

Table 2-2 JSOG classification§: Decreased baseline variability cases

deceleration / Heart rate baseline	None	Early	Variable		Late		Prolonged	
			Mild	Severe	Mild	Severe	Mild	Severe
Normocardia	2	3	3	4	3†	4	4	5
Tachycardia	3	3	4	4	4	5	4	5
Mild bradycardia	4	4	4	5	5	5	5	5
Severe bradycardia	5	5		5	5	5		

†Normocardia and mild late deceleration are frequently observed in healthy fetuses, so level 3 is assigned. However, when there are background complications, such as placenta abnormalities and intrauterine growth restriction, then level 4 should be assigned.

Table 2-3 JSOG classification§: Undetectable baseline variability cases‡

deceleration	None	Early	Variable		Late		Prolonged	
			Mild	Severe	Mild	Severe	Mild	Severe
regardless of heart rate baseline	4	5	5	5	5	5	5	5

‡To be determined separately in the case with particular factors, such as presently receiving medication and cases with fetal abnormalities.

Table 2-4 JSOG classification§: Marked baseline variability cases

deceleration	None	Early	Variable		Late		Prolonged	
			Mild	Severe	Mild	Severe	Mild	Severe
regardless of heart rate baseline	2	2	3	3	3	4	3	4

Table 2-5 JSOG classification§: Sinusoidal pattern

deceleration	None	Early	Variable		Late		Prolonged	
			Mild	Severe	Mild	Severe	Mild	Severe
regardless of heart rate baseline	4	4	4	4	5	5	5	5

§Five-tier fetal heart rate classification proposed by the Perinatology Committee of the Japan Society of Obstetrics and Gynecology

were singleton pregnancy and tracings being recorded during active labor. Exclusion criteria were preterm birth (<34 weeks), fetal arrhythmia, fetal anomalies, and contraindications for vaginal delivery. The obstetrician selected the 247 segments (10–50 minutes in length) with diagnostic FHR patterns from these tracings. After all markings on the tracings were obscured, these 247 tracings were examined.

The FHR tracings were interpreted by the other 2 obstetricians: A.N. and M.H. with 28 and 9 years, respectively, of experience in the interpretation of FHR tracings. Both obstetricians had graduated from the same university and had similar scientific backgrounds. They determined the grade of FHR on the JSOG classification and detected baseline variability (normal, decreased, or undetectable), heart rate baseline (normocardia, tachycardia, mild bradycardia, or severe bradycardia), and decelerations (none, early, mild variable, severe variable, mild late, severe late, mild prolonged, or severe prolonged).

Each obstetrician also determined the grade on the 3-tier subjective classification. The subjective classification was defined as follows: (1) normal: the FHR tracing was considered to indicate no risk for such conditions as fetal hypoxemia, acidemia, and possible evolutional patterns to higher risk conditions; (2) equivocal: the FHR tracing was considered to indicate nonreassuring fetal status but did not fulfill the definition of "ominous," and (3) ominous: the FHR tracing was considered to indicate a high risk of such conditions as fetal hypoxemia and acidemia and possible evolution to higher risk conditions and in urgent need of immediate delivery. To determine the subjective classification, the obstetricians interpreted the FHR tracing on the basis of the definition of the Perinatology Committee report[13], which is based on the research guidelines of interpretation established by the National Institute of Child Health and Human Development Research Planning Workshop in 1997. Decelerations were classified as early, variable, or late on the basis of specific characteristics. Early deceleration was defined as a visually apparent, usually symmetrical, gradual decrease and return of the FHR associated with a uterine contraction. A gradual FHR decrease in FHR was defined as a decrease lasting 30 seconds or more from onset to the FHR nadir. The nadir of the deceleration occurs at the same time as the peak of the contraction. Variable deceleration is a visually apparent abrupt decrease in FHR. An abrupt FHR decrease was defined as a decrease lasting 30 seconds or less from the onset of the deceleration to the beginning of the FHR nadir. The decrease in FHR was calculated from the onset to the nadir of the deceleration. The decrease in FHR was $\geq$15 beats per minute and lasted from $\geq$15 seconds to <2 minutes. Late deceleration was defined as a visually apparent, usually symmetrical gradual decrease and return of the FHR associated with a uterine contraction. A gradual FHR decrease in FHR was defined as a decrease lasting 30 seconds or more from the onset to the FHR nadir. The deceleration was delayed, with its nadir occurring after the peak of the contraction.

The 247 tracings were assessed at an interval of at least 4 weeks and in a different sequence by each obstetrician. Each obstetrician was blinded to the resuscitative measures followed, the maternal/neonatal outcomes, and the other obstetrician's interpretations.

After all responses had been analyzed, the data were entered into an Excel spreadsheet (Microsoft Corporation, Redmond, WA, USA). Intraobserver and interobserver reproducibility was assessed using both the JSOG classification and subjective classification. The worst grade of classification in each of the 247 records was investigated when various FHR patterns appeared. Interobserver variability was calculated between the initial interpretations of each observer.

In a separate series, we investigated whether the JSOG classification was related to the Apgar score, the umbilical arterial pH, and the delivery mode in 96 deliveries randomly selected by an obstetrician who does not included in interpretation of FHR tracings. The inclusion criteria were the same as described above. Subjects having records with inadequate quality in the final 10 minutes before delivery were excluded. All FHR tracings obtained after the women progressed into active labor until delivery were assessed in this series.

To assess the clinical usefulness of the FHR tracings, an obstetrician (A.N.) determined the grade of FHR tracings from 96 deliveries with the JSOG and subjective classifications in the same manner used for assessing intraobserver and interobserver reproducibility.

After all responses had been analyzed, the data were entered into an Excel spreadsheet. Maternal and neonatal data were obtained from medical records after the FHR tracings had been interpreted. Also recorded were maternal age, gestational age, gravidity, parity, Apgar score, and umbilical arterial pH. When several different levels of FHR pattern were obtained in a single FHR tracing, we adopted the worst level to examine.

The data were analyzed with the software programs JMP 6.0 (SAS Institute Inc., Cary, NC, USA), SPSS Statistics 17.0 (International Business Machines Corp., Armonk, NY, USA), and Excel. To assess intraobserver and interobserver variability, weighted Kappa coefficients ($w\kappa$) with quadratic

Table 3 Clinical characteristics for assessing intraobserver and interobserver agreement (n=107)

Maternal age at delivery (mean ± SD)	32.3 ± 5.3 years
Gravidity, median (range)	0 (0–4)
Parity, median (range)	0 (0–2)
Primiparous	73 (68.2%)
Multiparous	34 (31.8%)
Gestational age (mean ± SD)	39.0 ± 1.3 weeks
Birth weight (mean ± SD)	2,938 ± 436 g
Delivery mode, number of patients (%)	
Spontaneous	72 (67.3%)
Instrumental	24 (22.5%)
Cesarean	11 (10.3%)

Table 4 Weighted kappa coefficient of interobserver and intraobserver interpretation

	Interobserver variability	Intraobserver variability	
		Observer 1	Observer 2
JSOG classification§	0.70	0.77	0.73
Subjective classification	0.59	0.69	0.72

§Five-tier fetal heart rate classification proposed by the Perinatology Committee of the Japan Society of Obstetrics and Gynecology

weights were calculated. This statistical analysis evaluates the level of reproducibility beyond that expected by chance[14,15]. This statistics cannot provide a simple substitute for clinical judgment, there are no absolutes that can be used to correlate the value of κ with strengths of reproducibility between the range of 0.00 and +1.00. Acceptable levels of reproducibility, therefore, depend on the clinical circumstances and variables under investigation. Weighted Kappa coefficients of 0.00 to 0.20, 0.21 to 0.40, 0.41 to 0.60, and ≥0.60 indicated poor, fair, moderate, and good reproducibility, respectively[16]. One-way analysis of variance (ANOVA) followed by Scheffé's F-test was used to compare the continuous variables, such as umbilical arterial blood gas pH, and the Kruskal-Wallis test was performed for categorical variables, such as the mode of delivery. A P value <0.05 indicated statistical significance.

Results

Intraobserver and Interobserver Reproducibility

Characteristics of the study population for assessing intraobserver and intraobserver reproducibility are listed in **Table 3**. The mean age was 32.3 ± 5.3 years, and 73 (68.2%) of the subjects were primiparous women (parity: 0–2). The rates of spontaneous delivery, instrumental delivery, and cesarean delivery were 67.3%, 22.5%, and 10.3%, respectively. The results of the intraobserver and interobserver reproducibility analyses are listed in **Table 4**. Both intraobserver reproducibility and interobserver reproducibility in the interpretation of FHR tracings based on the JSOG classification were "good" (wκ=0.73–0.77 and 0.70, respectively), and intraobserver reproducibility and interobserver reproducibility were "good" (wκ=0.69–0.72) and "moderate" (wκ=0.59), respectively, with the subjective classification.

Table 5 Clinical characteristics for assessing early neonatal outcome (n=96)

Maternal age at delivery (years, mean ± SD)	32.1 ± 5.3
Gravidity, median (range)	0 (0–4)
Parity, median (range)	0 (0–2)
Primiparous	64 (66.7%)
Multiparous	32 (33.3%)
Gestational age (mean ± SD)	38.9 ± 1.3 weeks
Birth weight (mean ± SD)	2,930 ± 414 g
Delivery mode, number of patients (%)	
Spontaneous	71 (74.0%)
Instrumental	21 (21.9%)
Cesarean	4 (4.2%)

Table 6 Delivery mode by JSOG and subjective classifications (n=96)

		Number	Delivery mode			P value
			spontaneous	instrumental vaginal delivery	cesarean section	
JSOG classification	Level 1	1	1 (100.0)	0 (0.0)	0 (0.0)	
	Level 2	4	4 (100.0)	0 (0.0)	0 (0.0)	
	Level 3	47	40 (85.1)	7 (14.9)	0 (0.0)	
	Level 4	37	24 (64.9)	9 (24.3)	4 (7.3)	
	Level 5	7	2 (28.6)	5 (71.4)	0 (0.0)	P<0.001*
Subjective classification	normal	4	3 (75.0)	1 (25.0)	0 (0.0)	
	equivocal	31	27 (87.1)	4 (12.9)	0 (0.0)	
	ominous	61	41 (67.2)	16 (26.2)	4 (6.6)	NS

Categorical variables are shown as number of patients (%).
The Kruskal-Wallis test was performed for categorical variables, such as the mode of delivery.
A P value <0.05 indicates statistical significance.

Early Neonatal Outcome

Characteristics of the study population are listed in **Table 5**. The distributions of the delivery mode across the levels of the JSOG and the subjective classifications are listed in **Table 6**. There was a progressive increase in the rate of instrumental or cesarean deliveries across the 5 levels of the JSOG classification (P<0.001). The subjective classification also showed the same pattern in the rate of instrumental or cesarean deliveries, but these changes did not reach significance.

The distributions of outcomes among the levels of the JSOG and subjective classifications are shown in **Table 7, Figure 1**. The median Apgar score at 1 minute was significantly lower in level 5 of the JSOG classification than in the other 4 levels. Among the other 4 levels, there were no significant differences. The Apgar score at 5 minutes showed the same pattern, but these changes did not reach significance except between levels 1 and 5. Level 5 of the JSOG classification was associated with lower umbilical artery pH values than were the other 4 levels ($p< 0.05$). Among the other 4 levels, there were no significant differences (**Table 7, Fig. 1**).

In the subjective classification, the "ominous" group showed lower umbilical artery pH values than did the equivocal group (p=0.001). Apgar scores did not differ significantly (**Table 7, Fig. 2**).

Table 7 Umbilical cord arterial blood gas pH values and Apgar scores by JSOG and subjective classifications (n=96)

		Number	1-minute Apgar score, median (range)	5-minute Apgar score, median (range)	umbilical cord arterial blood gas pH (mean ± SD)
JSOG classification	Level 1 or 2	5	9 (8–9)	9 (8–10)	7.285 ± 0.027
	Level 3	47	9 (7–10)	9 (8–10)	7.284 ± 0.065
	Level 4	37	9 (8–9)	9 (8–10)	7.273 ± 0.064
	Level 5	7	7 (2–9)*	9 (8–10)	7.145 ± 0.078**
Subjective classification	normal	4	8.5 (8–9)	8.5 (8–10)	7.297 ± 0.037
	equivocal	31	9 (7–10)	9 (8–10)	7.306 ± 0.068
	ominous	61	9 (2–10)	9 (8–10)	7.249 ± 0.070***

*p<0.05 against Level 3 and Level 4, the Kruskal-Wallis test followed by the Steel-Dwass test.
**p<0.05 against another level, ANOVA followed by Scheffé's F-test.
***p<0.05 against equivocal, ANOVA followed by Scheffé's F-test.

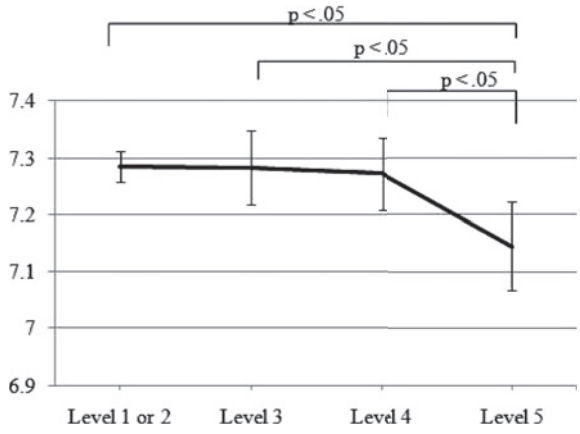

Fig. 1 Levels in the JSOG classification and umbilical artery pH.
Level 5 of the JSOG classification was associated with significantly lower umbilical arterial pH values than were Levels 1 to 4

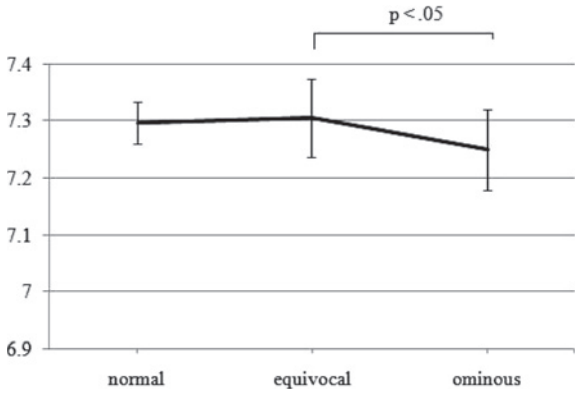

Fig. 2 The subjective classification and umbilical arterial pH.
Only the "ominous" group showed lower umbilical arterial pH values.

Discussion

This study has demonstrated that both intraobserver reproducibility and interobserver reproducibility of the JSOG classification for interpreting FHR tracings were clinically acceptable. The results also suggest that the choosing treatment on the basis of the JSOG classification is useful for avoiding worsening early neonatal outcomes.

Electronic FHR monitoring was introduced in clinical practice from the 1960s to the 1980s[17] to allow early detection of abnormal FHR patterns thought to be associated with hypoxia, thus facilitating earlier intervention to prevent fetal neurological damage or death or both[3]. In Japan FHR monitoring is used in nearly all delivery suites.

Sameshima et al have reported that intrapartum FHR monitoring was useful for detecting fetal acidemia in low-risk pregnancies[5]. On the other hand, several studies have suggested that electronic FHR monitoring has not yielded its anticipated benefits. Except for reducing the rate of neonatal seizures, its routine use, particularly in low-risk pregnancies, has not had a measurable effect on morbidity and mortality and has increased the rates of cesarean section and instrumental delivery[18]. In addition to the low specificity of FHR monitoring for indicating fetal compromise, the low reproducibility of observers' visual interpretation and the classification of FHR

tracings have been suggested[19].

The present study has demonstrated clinically acceptable levels of intraobserver reproducibility in the interpretation of FHR using the JSOG (wκ=0.73–0.77) and subjective (wκ=0.69–0.72) classifications. These results are in good agreement with those of previous studies. Lotgering et al.[12] investigated intraobserver reproducibility in the interpretation of 100 antepartum FHR tracings with subjective means. To determine intraobserver reproducibility, one observer assessed the same 100 recordings. The overall intraobserver reproducibility was high, with κ=0.70 to 0.80. Devane et al.[10] also demonstrated high intraobserver reproducibility among 28 midwives using a 3-tiered subjective classification. These studies, together with the present study, suggest that intraobserver reproducibility for the interpretation of FHR tracings is clinically acceptable, even for subjective classification.

Previous studies have shown low interobserver reproducibility in the interpretation of FHR tracings. Lotgering et al.[12] investigated interobserver reproducibility in the interpretation of 100 antepartum FHR tracings by 5 observers. The reproducibility was low (κ=0.09–0.69). In another study, Donker et al.[11] investigated interobserver reproducibility among 21 experienced obstetricians in 13 obstetric cases. The overall kappa demonstrated fair reproducibility (κ=0.48). The present study showed moderate interobserver reproducibility with the subjective classification (wκ=0.59), a finding consistent with those of previous studies. In contrast, interobserver reproducibility with the JSOG classification was high (wκ=0.70) and clinically acceptable. This finding suggests that the JSOG classification may improve interobserver reproducibility in the interpretation of FHR.

Previous studies have suggested that a reassuring FHR pattern is a good predictor of a favorable outcome, but the reverse is not always true[5]. Consistent with these studies, our results suggest that levels 1 and 2 of the JSOG classification are good predictors of a favorable early neonatal outcome, because none of the subjects with these levels underwent instrumental or cesarean delivery, and there was no worsening of neonatal outcomes. In addition, although no levels, except level 5, of the JSOG classification showed significant differences in Apgar scores or umbilical artery pH, there was a progressive increase in the rate of instrumental or cesarean deliveries across all levels of the JSOG classification. Thus, the results suggest that the intervention according to the JSOG classification is useful for avoiding worsening early neonatal outcomes.

A limitation of this survey was its small size. The association between specific FHR patterns and fetal acidemia should be examined in an appropriate study, such as a prospective series of unselected cases which includes a full range of different FHR patterns recorded until the time of birth, measurements of umbilical cord arterial blood gas pH, and other measures of newborn outcome. The goal of developing guidelines is to allow the predictive value of monitoring to be assessed more meaningfully and to allow evidence-based clinical management of intrapartum fetal compromise, with the ultimate aim of minimizing acidemia in newborns without excessive obstetric intervention. Further studies are needed to validate the effectiveness of these guidelines.

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