Original Article

Clinical Outcomes of High-risk Labours Monitored Using Fetal Electrocardiography

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Abstract

Objectives: The aim of the study was to review clinical and laboratory outcomes of a cohort of fetuses monitored during high-risk labours, simultaneously by fetal electrocardiography (FECG) and routine cardiotocography (CTG). Materials and Methods: Eighty-three parturients from the Department of Obstetrics and Gynecology of Medical University were included in the clinical study. Inclusive criteria to the study group were: (i) singleton pregnancy at term (between 37 and 42 weeks' gestation), (ii) longitudinal fetal lying, (iii) more than 2500 g of estimated fetal weight, (iv) meconium-stained liquor, and (v) induction of labour due to fetal indications. Fetal outcome parameters analysed included Apgar scores at 1st, 5th and 10th minute after birth, cord artery acid-base assessment and lactate concentrations analysis. FECG was performed during labour, until the neonate was born, with the use of single spiral scalp electrode connected to the STAN S21 heart monitor. Immediately after delivery, arterial cord blood gas and venous cord blood lactate's concentrations were analysed. Results: The sensitivity (100%), specificity (97%), negative predictive value (NPV) (100%) and positive predictive value (33%) were higher for FECG than for CTG. Moreover, several significant correlations between episodic/baseline T/QRS ratio rises and cord artery acid-base as well as lactate concentrations were demonstrated. Conclusions: Correlations between episodic/baseline T/QRS ratio rises and fetal outcome parameters indicate that observed changes in FECG reflect neonatal metabolic lactate acidosis. The high sensitivity, specificity and especially very high NPV are proof that FECG serves as a reliable method for electronic fetal monitoring during high-risk labours.

Ann Acad Med Singapore 2010;39:27-32

Key words: Fetal asphyxia, STAN system

Introduction

Intermittent auscultation (IA), cardiotocography (CTG), amniotic fluid colour and fetal scalp capillary blood gas analysis are currently accepted standards for intrapartum fetal monitoring.[1,2] According to the results of recent randomised clinical trials, intrapartum CTG monitoring is a very sensitive method; however, its very low specificity seems to be strongly disadvantageous.[3,4]

Fetal electrocardiographic (FECG) monitoring is a novel method for intrapartum examination of fetal status, in which analysis of ST-segment of the fetal electrocardiogram is performed. ST-segment and T-wave are associated with myocardial cells repolarisation and with their preparation for the next heart beat. The process of repolarisation is energy consuming, and elevation of the ST-segment and the T/QRS ratio, reflect "negative energy balance", which occurs when oxygen supply is insufficient to maintain oxygen-dependent energy supply.[5-7] STAN is currently used in more than 200 European hospitals.[8]

The aim of this study was to review clinical and laboratory outcomes [Apgar scores; pH, pCO_2, pO_2 and base deficit (BE) in arterial cord blood; lactate concentrations (LACT) in venous cord blood] of a cohort of fetuses monitored during high-risk labours, simultaneously by "STAN S21" fetal heart monitor and routine cardiotocography.

Material and Methods

The study protocol was approved by the Bioethics Committee of the Medical University (BN-001/27/03). Patients were informed about the methods of the study, its

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aim, indications and eventual complications before inclusion in the study. All patients gave written informed consent to participate in the study.

Eighty-three women in labour, hospitalised between 2002 and 2006, in the Department of Obstetrics, Gynaecology and Neonatology of Medical University, with implications for electronic intrapartum fetal status analysis, were included in the study. Inclusion criteria were meconium stained liquor (MSL) and/or occurrence of the following indications for labour induction:

1. Prolonged pregnancy, over 7 days after expected term (which was estimated on the basis of ultrasonographic examination that was performed between 11 and 14 weeks gestation), together with at least one of the following:

i) Ultrasonographic signs of oligoamnios, abnormal Manning's test result, disturbances in the umbilical artery or middle cerebral artery blood flow
ii) CTG signs of lowering of short- or long-term variability, and decelerations, that were not a direct indication for immediate obstetrical intervention

2. Lack of spontaneous uterine contraction after premature rupture of membranes for the first 6 hours.

Patients with obstetrical contraindications for delivery through natural passages, other than cephalic longitudinal lie of the fetus, earlier caesarean sections or presence of diseases, which may affect pregnancy i.e., pregnancy-induced hypertension, intrauterine fetal growth retardation, cholestasis of pregnancy, congenital fetal abnormalities, gestational diabetes mellitus or hyperthyroidism, were excluded from the study.

FECG record was performed using "STAN S21" fetal heart monitor. A single spiral fetal scalp electrode was used for continuous monitoring throughout labour. Electrocardiographs were judged on the basis of an automatic assessment of ST changes, and T/QRS ratios. ST changes occurring during the last 3 hours of labour were identified and analysed specifically. These included:

i) episodic T/QRS ratio rise
ii) baseline T/QRS ratio rise
iii) biphasic ST-segment type 1, 2, 3 (BP I, BP II, BP III).

The electrocardiograms' abnormalities were interpreted according to the inventors' recommendations.[5] The indications for obstetrical interventions were assessed on the basis of electrocardiographic criteria.[6,7] The CTG was interpreted according to American College of Obstetrics and Gynecology (ACOG) criteria.[1] The intermediate (doubtful) CTG was diagnosed either when the baseline heart rate was 100 to 110 bpm or 150 to 170 bpm with or without bradycardia episodes. Additionally, situations when:

i) the variability of more than 25 bpm, however, without any accelerations was observed,
ii) reduced variability of less than 5 bpm for more than 40 minutes, but less than 60 minutes was stated, or
iii) uncomplicated variable decelerations with a loss of beats of more than 60 beats, and duration of less than 60 seconds occurred, were also interpreted as an intermediate CTG record.

An abnormal CTG record was diagnosed when the baseline heart rate exceeded 150 bpm in combination with reduced variability of less than 5 bpm. The same applies to tachycardia with a baseline heart rate of more than 170 bpm with abnormal less than 5 bpm variability. Persistent bradycardia with a baseline heart rate of less than 100 bpm, lasting for more than 10 minutes, classified also the CTG record as abnormal. If the reduced variability lasted for more than 60 minutes, or if there was an undulating, wave-like sinusoidal heart rate without signs of acceleration, these were also considered as abnormal CTG records. When complicated variable decelerations (longer than 60 sec, deeper than 60 bpm) or repeated late decelerations were observed, doubtful CTG was diagnosed. Additionally, with the exception of the ACOG citeria, the analysis of cardiotocograms included the number of decelerations during the last 3 hours of labour.

Immediately after delivery (not longer than 5 minutes), arterial cord blood samples were collected, and the acid-base status i.e., pH and base deficit (mmol/L) were measured using OMNI C gas analysis apparatus (Roche Diagnostic). pH values below 7.05 and base deficit below -12 mmol/L were considered abnormal. In order to estimate the intensity of fetal glycolysis, the lactate concentration (LACT-mmol/L) in the serum of umbilical venous blood was analysed. Immediately after delivery, fetal umbilical venous blood samples (10 mL) were collected in heparanized test tubes, and afterwards centrifuged (10 min; 5000 rev/min). The analysis was performed using enzymatic Lactate LS LOX-PAP method (ProDia International UAE. Korbach, Germany). LACT concentrations higher than 12 mmol/L were considered abnormal.[5] The clinical outcome of the fetus was evaluated in the 1st, 5th, and 10th minute after birth according to the Apgar score.

The statistical evaluation was performed using Statistica 7.0 PL software for Windows. The distribution of variables was done using non-parametric W Shapiro-Wilk's test, and according to its results, values were further analysed. $P < 0.05$ was considered significant. For the presentation of not normally distributed variables number of patients (N), values range (min-max), medians (Me), first and third quartile values (Q1-Q3) as well as dominants (D) were included in the descriptive statistics. However for normally distributed variables characteristics, the results are presented as number of patients (N), arithmetical mean

(X) and standard deviation (SD). For the statistical analysis of relationship between X and Y, correlations coefficients were estimated using Spearman's test. To determine the predictive value of biophysical tests, their sensitivity, specificity, positive and negative predictive values (PPV and NPV respectively) as well as precision were calculated.

Results

The characteristics of Apgar scores and biochemical parameters, measured in umbilical blood, is shown in Table 1. The analysis of correlations between neonates' clinical status in relation to type and number of decelerations is summarised in Table 2. Weak correlations between the number of early decelerations and lactate concentrations (R = 0.25; *P* = 0.02) as well as base deficit (R = -0,32; *P* = 0.003) were stated. Moreover, negative relationships between Apgar scores and occurrence of late decelerations during the 3 hours proceeding delivery were also demonstrated. In addition, a relationship was also observed between the number of late decelerations and pH (R = -0.296; *P* = 0.006), BE values (R= -0.336; *P* = 0.001), and lactate concentrations, measured in venous

Table 1. Characteristics of Apgar Scores, Acid-base Status and Lactate Concentrations

Parameter	N	Me	min-max	Q_1	Q_3	D	X ± SD
pH	83	7.28	6.839-7.511	7.227	7.325	Multiple	-
pO_2 (mmHg)	83	13.80	2.50-71.90	9.70	20.50	Multiple	-
pCO_2 (mmHg)	83	49.50	6.90-85.60	41.90	55.80	Multiple	-
BE (mmol/L)	83	-4.90	-21.20-1.60	-7.40	-3.00	Multiple	-
LACT (mmol/L)	83	4.70	2.00-17.46	3.29	6.60	-	5.344 ± 2.741
Apgar 1	83	10	4-10	8	10	10 (52)	-
Apgar 5	83	10	6-10	9	10	10 (58)	-
Apgar 10	83	10	7-10	10	10	10 (65)	-

Apgar 1; 5; 10: Apgar scores during the 1st, 5th, 10th minute of neonates' life

BE : base deficit measured in arterial umbilical blood
D : dominant
LACT : lactate concentrations measured in venous umbilical blood
pH : pH values measured in arterial umbilical blood
pO_2 : partial oxygen pressure measured in arterial umbilical blood
pCO : partial carbon dioxide pressure measured in arterial umbilical blood

Table 2. Correlations Between Cardiotocographic Changes, Expressed in the Form of Early, Late or Variable Decelerations, and Biochemical Parameters as well as Apgar Scores in the Study Population (N = 83)

Type of deceleration	Early		Late		Variable	
	R	*P*	R	*P*	R	*P*
Number of decelerations vs pH	-0.171	NS	-0.296	0.006	-0.195	NS
Number of decelerations vs pO_2	0.114	NS	0.052	NS	-0.053	NS
Number of decelerations vs pCO_2	-0.084	NS	0.109	NS	0.029	NS
Number of decelerations vs BE	-0.317	0.003	-0.336	0.001	-0.099	NS
Number of decelerations vs LACT	0.254	0.020	0.283	0.009	0.133	NS
Number of decelerations vs Apg 1	-0.162	NS	-0.352	0.001	0.005	NS
Number of decelerations vs Apg 5	-0.122	NS	-0.350	0.001	-0.114	NS
Number of decelerations vs Apg 10	-0.113	NS	-0.292	0.007	-0.145	NS

Apg 1; 5; 10 : Apgar scores during the 1st, 5th, 10th minute of neonates' life
BE : base deficit measured in arterial umbilical blood
LACT : lactate concentrations measured in venous umbilical blood; NS: not significant
P : level of significance
pCO_2 : partial carbon dioxide pressure measured in arterial umbilical blood
pH : pH values measured in arterial umbilical blood
pO_2 : partial oxygen pressure measured in arterial umbilical blood
R : Spearman's correlation's coefficient

plasma samples (R = 0. 283; *P* = 0.009). However, no statistically significant correlations between the number of variable decelerations, clinical as well as biochemical parameters of fetal well being were stated. When the analysis of relationships between the changes in electrocardiogram record (highlighted as episodic T/QRS ratio rise), and clinical as well as biochemical status of neonates (Table 3) was performed, negative correlations (coefficients values higher than 0.4) between FECG changes and pH as well as base deficit values were stated (R = -0.46; *P* = 0.000). Additionally, a positive correlation between episodic T/QRS ratio rise and lactate concentrations was established (R = 0.419; *P* = 0.000). The analysis of relationship between the elevation of baseline T/QRS ratio's values and newborns' status (Table 3) revealed a negative correlation with pH values (R = -0.40; *P* = 0.000). The elevation of baseline T/QRS ratio values was accompanied by absolute base deficit values increase (R = -0.372; *P* = 0.001). The elevation of fetal FECG coefficient correlated also with an increase in venous lactate levels (R = 0.435; *P* = 0.000).

Analysing the relationship between the newborns' clinical status and the changes in fetal electrocardiograms, a weak negative correlation between the number of biphasic ST-segment type I and Apgar scores, estimated during the 10th minute after delivery (R = -0.243; *P* <0.05), was determined. Moreover, a weak negative correlation between biphasic ST-segment type II and Apgar scores, calculated during the 1st, 5th, and 10th minute of the newborns' life was stated (R = -0.302; *P* = 0.000). The observations of single changes in FECG record (biphasic ST-segment type III) did not correlate with the neonates' clinical status.

In our study, the sensitivity of fetal electrocardiography (abnormal FECG pattern) and its NPV almost reached 100%. The specificity of this test exceeded 90%, whereas its precision was 98%. An almost similar sensitivity was proven for cardiotocography (for doubtful CTG record); however, the specificity of this method was only 58.5%. The sensitivity of CTG in pathological record confirmation was 0%, as we did not observe any biochemical signs of fetal hypoxia among neonates with abnormal CTG record in our study (Table 4).

Table 3. Correlations Between Episodic/baseline T/QRS Ratio's Rise and Biochemical as well as Apgar Scores in the Study Population (N = 83)

T/QRS ratio	Episodic rise		Baseline rise	
	R	*P*	R	*P*
T/QRS vs pH	-0.460	0.000	-0.400	0.000
T/QRS vs pO_2	-0.006	NS	-0.158	NS
T/QRS vs pCO_2	0.170	NS	0.252	0.021
T/QRS vs BE	-0.406	0.000	-0.372	0.001
T/QRS vs LACT	0.419	0.000	0.435	0.000
T/QRS vs Apg 1	-0.148	NS	-0.124	NS
T/QRS vs Apg 5	-0.137	NS	-0.104	NS
T/QRS vs Apg 10	-0.126	NS	-0.084	NS

Apg 1; 5; 10: Apgar scores during the 1st, 5th, 10th minute of neonates' life
BE : base deficit measured in arterial umbilical blood
LACT: lactate concentrations measured in venous umbilical blood
P : level of significance
pH : pH values measured in arterial umbilical blood
pO_2 : partial oxygen pressure measured in arterial umbilical blood
pCO_2 : partial carbon dioxide pressure measured in arterial umbilical blood
R : Spearman's correlation's coefficient

In this study, only 1 case of metabolic acidosis was observed. The patient was a 29-year-old primipara who was admitted to our department at 38 weeks' gestation due to premature rupture of membranes. Shortly after admission, CTG test was reactive and the amniotic fluid was evaluated as clear. Induction of labour with oxytocin was started 6 hours after the rupture of membranes as no uterine contractions was observed. Two hours later, FECG analysis was normal, without any T/QRS ratio rises, while in the repeated CTG record, early and uncomplicated variable decelerations had started to occur. Thirty minutes later, abnormal variability, higher then 25 bpm without accelerations, was found in the CTG record, and repeated variable uncomplicated decelerations were also observed. The CTG pattern was interpreted as intermediate; hence, fetal blood sampling was done, and the results showed pH = 7.29. The FECG signal was stable and no changes in T/QRS ratios were observed. At that time, the cervix was

Table 4. The Prognostic Value of Fetal Electrocardiography and Cardiotocography in the Prediction of Cord Artery Metabolic Acidosis (cord artery pH <7.05 and BE <-12 mmol/L)

Parameter	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Precision (%)
Abnormal FECG record	100.0	97.0	33.0	100.0	98.0
Pathological CTG record	0	96.0	0	98.7	95.0
Doubtful CTG record	100.0	58.5	2.9	100.0	59.0

CTG: cardiotocography; FECG: fetal electrocardiography; NPV: negative predictive value; PPV: positive predictive value

7 to 8 cm dilated, and the decision to continue with vaginal delivery was made. The second stage of labour started after 40 minutes. The CTG record was still interpreted as intermediate, FECG signal was stable, and no changes in FECG record were observed. After 90 minutes, baseline 0.06 rise in T/QRS ratio was observed, and 3 minutes later sharp 0.15 episodic rise in T/QRS appeared. A decision to proceed with vacuum delivery was made. In subsequent minutes, further 0.19 episodic rise in T/QRS and 0.17 baseline rise in T/QRS ratio were detected. The interval between the decision and completion of vacuum operation was around 6 minutes. The fetal weight was 2600 g, and the Apgar scores were 4, 6, and 9 points. The first neonatal breath was initiated after indirect cardiac massage; nevertheless, the next breaths were regular. Umbilical artery status: pH: 6.839, BE: -21.2 mmol/L, umbilical venous lactate concentration: 17.46 mmol/L. The newborn did not require admission to the intensive care unit, and his adaptative period was uncomplicated. The newborn was discharged 2 days after delivery.

Discussion

The aim of the study was to evaluate the relationship between the results of biophysical monitoring of fetus well being using the STAN method, biochemical as well as clinical newborns' parameters. Moreover, in our study we compared the predictive values of FECG and CTG monitoring for the detection of fetus asphyxia.

It is crucial that in our study population of women in high-risk labours, a strong correlation between most important biochemical parameters of newborns' status i.e. pH, BE, LACT, and episodic/baseline T/QRS ratios values rise was stated, as it confirms that T/QRS ratios changes reflect the acid-base status of the fetus. It is also essential to highlight that FECG sensitivity in the detection of fetal asphyxia (according to our criteria: pH <7.05; BE <-12 mmol/L) was 100% whereas specificity was 97%. The reliability of this method was further confirmed by its very high NPV (100%). Interestingly, comparable sensitivity was proven for CTG monitoring (100%); however, much lower specificity was additionally observed (58.5%). Surprisingly, CTG monitoring was not able to detect severe fetal metabolic acidosis. Therefore, comparing the obtained results as well as parameters of predictive value, we concluded that fetal electrocardiography monitoring with automatic ST-segment analysis (ST FECG) may serve as a method of choice for fetal status monitoring during high-risk labours.

The metabolic acidosis is diagnosed when umbilical arterial pH values decrease below 7.05 and base deficit exceeds -12 mmol/L.[11] In this study, only 1 case of metabolic acidosis was observed. Our case of metabolic acidosis was recognised using FECG analysis. It was probably caused by acute umbilical fetal distress; however, the period of acidosis was very short. Unfortunately, the changes in FECG record occurred a little too late to end the delivery before changes in fetal blood gases occurred. The adaptation of the newborn was uncomplicated. In this case in our opinion, the new STAN method allowed the diagnosis of fetal distress but metabolic acidosis was not avoided. However, the CTG pattern was intermediate and the fetal blood sampling analysis was normal; hence, if the labour would be monitored only by CTG, the neonatal metabolic acidosis would probably be much more intensified.

Although our results are in agreement with various other studies, several authors have highlighted that the usefulness of FECG monitoring may be controversial.[9-12] Dervaitis et al[13] analysed 105 women in labour and they decided that the criterion of fetal asphyxia would be pH values below 7.15. In their study, no relationship between biochemical parameters, measured in the umbilical blood, and fetal ST-segment's changes, was observed on electrocardiograms. At the same time, the STAN method was estimated to be sensitive and specific in 50% and 66%, respectively. Due to this, authors concluded that FECG was a method of high NPV, but its sensitivity, specificity and PPV are disadvantageous.

Interestingly, an opposite observation was reported by Kwee et al[14] who examined 637 women during high-risk labour. They reported that the STAN method detected all cases of severe fetal metabolic acidosis (pH <7.0). The evaluated NPV and PPV exceeded 90%, and the high sensitivity, compared to classic cardiotocography, seemed to be advantageous. Moreover, a linear correlation between T/QRS ratio and pH as well as BE values, measured in arterial umbilical blood, was determined. Analogical results, obtained in a multicentre study, were also reported by Luzietti et al.[15] In their study of 618 women in labour, 5 cases of baseline T/QRS ratio values rise were observed, and all of these changes were associated with occurrence of severe fetal metabolic acidosis. Additionally, the specificity and NPV of this method exceeded 90%.

Surprising results were obtained by Nordstrom and colleagues,[16] as they could not demonstrate a correlation between T/QRS ratio values (during expulsive stage of labour) and LACT levels. In our view, it may be caused by the fact that only 46 women were included in their study. Moreover, no information about the number of changes in electrocardiograms records were presented.

A direct confirmation of the fact that changes in FECG record and fetal acid-base status are correlated can only be found in the results of multicentre randomised clinical trials, reported by various authors.[9-11] However, a recent randomised study conducted in France does not fully support previous observations. Vaysierre et al[17] examined

799 women during high-risk labour (MSL and/or abnormal CTG pattern) and did not demonstrate any decrease in the frequency of both obstetrical interventions because of operative delivery for fetal distress (ODFD) and severe metabolic acidosis occurrence. Quite comparable results were also reported by Ojala et al,[18] who examined 1483 women in labour from Finland.

In summary, it is important to highlight that our results are in agreement with previous studies. Undoubtedly, there is a correlation between changes in fetal electrocardiogram records and biochemical parameters.[9-20] The clinical predictive value of FECG in the detection of fetal asphyxia seems to be dependent only on diagnostic criteria of this severe fetal status. Nevertheless, the fact that FECG NPV and its specificity is always higher compared to CTG is irrefutable. New results in current literature, which report false negative FECG record, clearly justifies the need for further examination of the clinical usefulness of FECG in fetal status monitoring during labour.[8,21]

Conclusions

We conclude that: (i) The correlations between episodic/baseline T/QRS ratio values rises and clinical parameters of newborns' outcome indicate that fetal electrocardiography reflects the severity of fetal lactatic acidosis. (ii) Higher sensitivity, specificity, and most importantly NPV of FECG compared to CTG indicate that FECG is a much more reliable method for fetal well being monitoring during high-risk labours and, therefore, improves the safety of perinatal care.

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