

Omniview-Sisporto Published Papers' Highlights

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Prediction of neonatal acidemia by computer analysis of fetal heart rate and ST event signals

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OBJECTIVE: The objective of the study was to evaluate the accuracy of computer analysis of fetal heart rate (FHR) and ST event signals in prediction of neonatal acidemia.

STUDY DESIGN: One hundred forty-eight FHR tracings were evaluated to identify red alerts provided by the system, based on automated analysis of FHR and ST event signals, and compared with the occurrence of umbilical artery acidemia (pH \leq 7.05).

RESULTS: The presence of red alerts obtained sensitivity of 1.00 (95% confidence interval [CI], 0.56-1), specificity of 0.94 (95% CI, 0.89-0.97), positive predictive value (PPV) of 0.47 (95% CI, 0.22-0.72), negative predictive value (NPV) of 1 (95% CI, 0.96-1.00), positive likelihood ratio (PLR) of 17.6 (95% CI, 9.0-34.5), and negative likelihood ratio (NLR) of 0. When limiting analysis to red alerts that did not include ST data, sensitivity was 0.57 (95% CI, 0.20-0.88), specificity was 0.97 (95% CI, 0.92-0.99), PPV was 0.50 (95% CI, 0.17-0.82), NPV was 0.98 (95% CI, 0.93-0.99), PLR was 20.14 (95% CI, 6.3-64.2), and NLR was 0.44 (95% CI, 0.19-1.04).

CONCLUSION: Computer analysis of FHR and ST event signals provide higher accuracy in predicting neonatal acidemia.

Keywords: cardiotocography, computer assisted, electrocardiography, fetal hypoxia, fetal heart rate, fetal monitoring

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Omniview-SisPorto 3.5 – a central fetal monitoring station with online alerts based on computerized cardiotocogram & ST event analysis

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Abstract

Visual analysis of cardiotocograms is poorly reproducible and is currently recognized as the main weakness of the STAN methodology. The Omniview-SisPorto® 3.5 program is the most recent version of a central monitoring system that provides visual and sound alerts, based on computer analysis of cardiotocographic and ST event features. This paper describes the program's main characteristics and provides an overview of the system's online alerts. Omniview-SisPorto® 3.5 is the first central monitoring system to incorporate computerized analysis of cardiotocographic and ST event features, providing health professionals with online alerts for minor and major changes in monitored signals. The system is currently undergoing extensive clinical evaluation.

Keywords: cardiotocography; computer-assisted; electrocardiography; fetal; fetal hypoxia

Web link: <http://www.reference-global.com/doi/abs/10.1515/JPM.2008.030>

Fetal heart rate (FHR) monitoring remains widely used as a method for detecting changes in fetal oxygenation that can occur during labor. Yet deaths and long-term disablement from intrapartum hypoxia remain an important cause of suffering for parents and families, even in industrialized countries. Confidential inquiries in the United Kingdom have highlighted that as much as 50% of these deaths could have been avoided because they were caused by non recognition of abnormal FHR patterns, poor communication between staff, or delay in taking appropriate action.

Omniview-SisPorto aims to help decrease the number of Neonatal Encephalopathies related to intrapartum Hypoxia. It specifically aims to reduce human error in tracing interpretation and possible delays in taking appropriate actions by providing health professionals with visual and sound alerts to fetal heart rate changes.

The following articles are a description of 3 published papers and connect them to examples and existing commercial system features and benefits.

Prediction of neonatal acidemia by computer analysis of fetal heart rate and ST event signals

The aim of this study was to evaluate the predictive capacity of the Omniview-SisPorto 3.5 system, when analyzing the last hour of intrapartum STAN tracings to identify patients who went on to display umbilical artery acidemia at birth (ie, umbilical artery pH \leq 7.05).

MATERIALS AND METHODS

This prospective observational study was conducted in a tertiary care university hospital between May 2005 and September 2007. Consecutive cases were enrolled if they fulfilled the inclusion criteria. In all cases the umbilical cord was doubly clamped immediately after birth, and blood was aspirated from both artery and vein.

Computer analysis of cardiotocogram (CTG) plus ST tracings by the Omniview-SisPorto 3.5 system was performed off-line for this study but using a similar methodology to the one that is used when tracings are being acquired in real time (ie, only signals acquired until the present moment are available to elicit alarms). This was accomplished using a program feature, by which signals are processed from the start of the file, 1 minute at a time, only taking into account signals acquired until then, and a log of alarms elicited on a minute-by minute basis is recorded. Thus, no alerts that would be elicited during real tracing acquisition are lost or changed.

Analysis of alerts was carried out only in the last 60 minutes of the tracing because this was thought to bear the highest relationship with immediate newborn outcome. Additional alerts were present in a small number of patients before that period in both patients with and without umbilical artery acidemia. However, these were not included because they could have elicited an intervention that led to the reversion of what was only a temporary acidemia.

The last hour of the tracing was reviewed and the red alerts provided by the system during that period were compared with the occurrence of umbilical artery acidemia at birth, defined as a pH value 7.05 or less.

RESULTS

A total of 193 consecutive patients were enrolled, and 45 were subsequently excluded:

19 because of disconnection of the scalp electrode conditioning a large tracing-to-delivery interval and/or signal loss, 21 because of inadequate umbilical blood gases values, and five because of insufficient tracing duration. This resulted in a total of 148 cases available for analysis. 19 had maternal risk factors (8 hypertensive diseases, 8 diabetes, 1 anemia, 2 thrombophilias), 4 had fetal risk factors (2 hydramnios, 1 oligohydramnios, 1 fetal growth restriction), 9 had heavy meconium staining, 53 patients had an induced labor, and 16 patients had prolonged rupture of membranes (> 16 hours). The remaining patients were monitored internally because of poor FHRsignal quality with external acquisition methods.

The table below compares the appearance of red alerts in the last 60 minutes, with the occurrence of umbilical artery acidemia.

Variable	pH		Total
	≤ 7.05	> 7.05	
FHR plus ST red alerts			
Yes	7	8	15
No	0	133	133
Isolated FHR red alerts			
Yes	4	4	8
No	3	137	140
Total	7	141	148

There were 7 cases of umbilical artery pH of 7.05 or less, and these are displayed in detail in a table below.

No cases of neonatal hypoxic ischemic encephalopathy occurred in this series.

In the 148 studied cases, the occurrence of red alerts in the last hour of the tracing obtained a sensitivity of 1.00 (95% CI, 0.56-1), a specificity of 0.94 (95% CI, 0.89-0.97), a positive predictive value of 0.47 (95% CI, 0.22-0.72), a negative predictive value of 1.00 (95% CI, 0.96-1.00) in prediction of newborn acidemia.

When evaluating red alerts elicited exclusively by FHR analysis and not incorporating ST data, the obtained sensitivity was 0.57 (95% CI, 0.20-0.88), the specificity 0.97 (95% CI, 0.92-0.99), the positive predictive value 0.50 (95% CI, 0.17-0.82), the negative predictive value 0.98 (95% CI, 0.93-0.99).

COMMENT

This is the first study to evaluate the accuracy of intrapartum computerized analysis of FHR plus ST signals. Confidence intervals for sensitivity and positive predictive value are still wide because of the occurrence of a small number of patients with newborn acidemia. Further research is needed to confirm the high sensitivity found in this study. On the other hand, the small confidence intervals surrounding the high specificity and negative predictive values provide promising results for this technology.

Recent evidence using non computerized assessment has shown that the addition of ST segment analysis can enhance the accuracy of fetal monitoring, and our results also suggest this hypothesis. Using the system's red alerts that incorporate both FHR and ST event features, all 7 acidemic fetuses were identified, and there were 8 false-positive results. Six of these patients had an umbilical artery pH less than 7.20, suggesting that a milder degree of hypoxemia was occurring.

Patients displaying red alerts (including FHR plus ST signal features) and isolated FHR alert in the last hour of tracing, with their neonatal outcome values

Patients	FHR alert	ST event	System red alert	Isolated FHR alert	Type of delivery	Interval tracing end to delivery (min)	Umb. artery pH	Umb. artery Bdecf (mmol/L)	Umb. vein pH	Umb. vein Bdecf (mmol/L)	Birthweight (g)	Appgar score at 1 and 5 mins
1	Repetitive decelerations	T/QRS rise	Yes	Orange	Inst	5	6.90	12	7.02	12	3160	7/8
2	Prolonged deceleration with reduced variability	T/QRS rise	Yes	Red	CS	4	6.94	14	7.04	14	2560	7/9
3	Repetitive decelerations	Biphasic ST	Yes	Orange	CS	10	6.97	10	7.05	8	2850	3/8
4	Repetitive decelerations with reduced variability	ST signal loss	Yes	Red	Inst	5	6.98	13	7.06	12	3474	7/8
5	Very prolonged deceleration	T/QRS rise	Yes	Red	Inst	4	6.98	8	7.01	11	3250	7/9
6	Repetitive decelerations	T/QRS rise	Yes	Orange	Vag	2	7.04	10	7.07	11	3270	7/9
7	Prolonged deceleration with reduced variability	ST signal loss	Yes	Red	Vag	0	7.05	10	7.17	11	2910	7/9
8	Prolonged deceleration with reduced variability	T/QRS rise	Yes	Red	Vag	0	7.06	9	7.11	8	2850	6/10
9	Repetitive decelerations	Biphasic ST	Yes	Yellow	CS	8	7.09	8	7.15	9	4430	7/9
10	Repetitive decelerations with reduced short-term variability	Biphasic ST	Yes	Red	CS	12	7.11	7	7.15	7	3500	9/10
11	Repetitive decelerations	T/QRS rise	Yes	Yellow	Vag	0	7.13	9	7.21	9	2586	9/10
12	Repetitive decelerations	T/QRS rise	Yes	Yellow	CS	17	7.13	7	7.25	11	2090	9/10
13	Repetitive decelerations	T/QRS rise	Yes	Yellow	Vag	0	7.16	6	7.27	2	3590	9/10
14	Repetitive decelerations	T/QRS rise	Yes	Yellow	Vag	0	7.28	7	7.40	7	3146	9/10
15	Repetitive decelerations	Biphasic ST	Yes	Yellow	Vag	0	7.28	1	7.32	2	3460	9/10
16	Reduced long-term variability	No	Yes	Red	CS	20	7.32	1	7.39	2	3830	9/10
17	Reduced short-term variability	No	Yes	Red	Vag	0	7.33	4	7.40	5	3390	8/9

CS, cesarean section; Inst, instrumental vaginal delivery; Umb, umbilical; Vag, normal vaginal delivery.

When ST event data were excluded, only 4 of the 7 acidemic cases were identified, and 4 false positives. Thus, 3 acidemic fetuses would not have displayed red alerts if isolated FHR monitoring had been performed. It can be seen from the table that all cases would have been detected if the orange alerts, the system's second most ominous alert, had also been included.

The appearance of this alert should prompt further investigation, including fetal blood sampling or STAN monitoring. However, inclusion of orange alerts for evaluation of the system's accuracy would also cause a sharp increase in the number of false positives. False positives are the main drawback of visual FHR analysis and also occur with the STAN technology. They may be caused by fetal adaptations to the challenges of labor rather than by noxious stimuli. The system appears to have reduced but not eliminated these cases, suggesting that further refinement of some alerts will be required.

In conclusion, computer analysis assures a robust approach to the issue of accuracy of FHR monitoring in prediction of neonatal outcome. The present study demonstrates that a high accuracy may be obtained with computer analysis of FHR plus ST signals in prediction of term fetuses that are born with umbilical artery acidemia. Although this was the largest sample size used to address this issue, confidence intervals for specificity and positive predictive values are still wide, and further studies are needed to confirm this finding.

The system's alerts, which appear together with a description of the criteria that were identified to evoke them, are expected to capture the health professional's attention and to provoke a reevaluation of the case under a new light, but they do not obviously guarantee a satisfactory outcome. The effect of introducing such a system into routine clinical practice requires the conduction of an adequately sized randomized controlled clinical trial, which is currently being prepared.

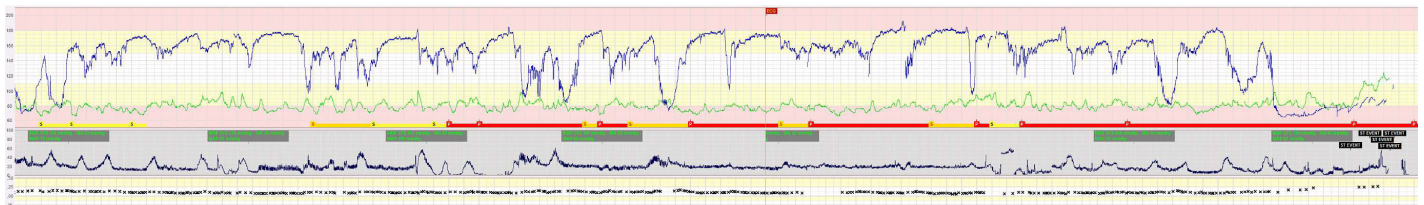


Fig. 1: Example of a tracing with red alerts since one hour before delivery. Artery pH was 6,94.

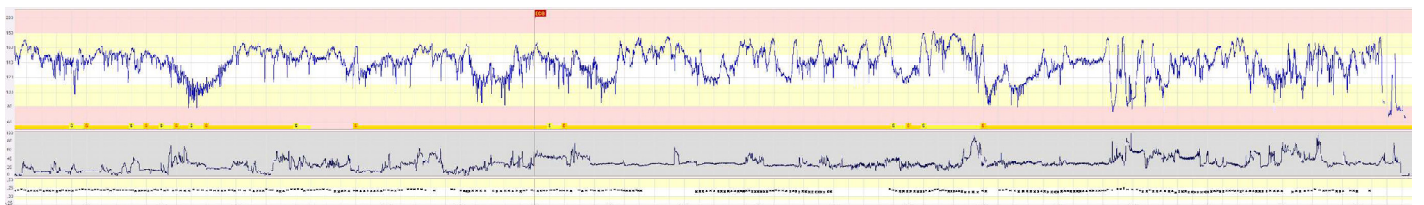


Fig. 2: Example of a non-reassuring tracing but without red alerts. Artery pH was 7,19.

Omniview-SisPorto 3.5 – a central fetal monitoring station with online alerts based on computerized cardiocotogram & ST event analysis

This gives a brief description of the Omniview-SisPorto system, a program for automated analysis of CTGs, and provides an overview of the system's online alerts.

Description of the system

The Omniview-SisPorto system was designed as a central monitoring station, allowing the combined display of up to 16 CTG and/or STAN tracings on the same computer screen – the main program window (Figure 3).

Computer processing of CTG features starts automatically after 11 min of tracing acquisition, and is updated every minute. This includes estimation of fetal heart rate (FHR) baseline, identification of accelerations and decelerations, and quantification of

short- and long-term variability. A detailed display of the results can be accessed by maximizing a single tracing window. A combination of CTG analysis with ST event features is used to provide online alerts, which are displayed in the main program window, as well as in maximized tracing windows.

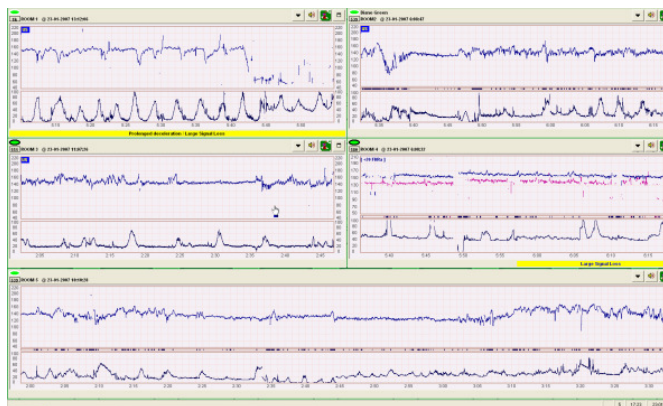


Fig. 3: Window displaying 5 tracings

Tracing acquisition, display and storage is handled automatically by the program, as it continuously detects the connection and disconnection of fetal monitors transmitting appropriate signal features.

External input is only required for identification of patients. A multi-client-server architecture ensures that a practically unlimited number of computers can be connected via a local intranet to display tracings. Exams can be printed automatically on tracing end or at the user's request, with or without the results of automated analysis. Previously acquired tracings can be processed as a whole, or analyzed as if they were being acquired online, at normal or higher speeds.

Processing of information to produce online alerts starts automatically after 11 min of acquisition, and is updated every minute. Definitions used for alerts were inspired on published consensus guidelines for interpretation of CTG and combined CTG+ST signals, but were adapted according to the results of previous optimization and validation studies.

Alerts Description

The **Normality criteria met** alert was designed for tracings for antepartum or as labour admission tests. When all normality criteria regarding baseline, accelerations, decelerations and variability are present it produces a green alert without sound.

Attention alerts occur with changes that are not commonly associated with fetal hypoxia, such as signal loss, excessive uterine contractions, and maternal heart rate monitoring. They produce a blue visual alert.

Non-reassuring alerts occur with changes in the FHR that are usually not associated with fetal hypoxia, but may require continued monitoring and, occasionally, further investigation: fetal tachycardia; absent accelerations; repetitive but short-lasting decelerations. They produce a yellow alert without sound.

Very non-reassuring alerts occur with more worrying changes in the FHR, which are usually associated with a considerable risk of impending fetal hypoxia: repetitive and moderate-lasting decelerations; prolonged decelerations. Careful monitoring and further measures are usually required to avoid progress to relevant degrees of hypoxia. They produce a blinking orange visual alert with sound.

Pre-terminal alerts occur with signal changes that are commonly associated with moderate-to-severe fetal hypoxia: reduced long-term and short-term variability; very prolonged deceleration or related to ST events. Rapid measures are required in these cases to avoid an abnormal fetal outcome, which may include rapid reversal of the underlying cause or immediate delivery.

List of system alerts

Reassuring (for antepartum)
Normality criteria met

Attention
Signal loss
Excessive uterine
Maternal heart rate monitoring?
ST signal loss

Attention extra (sound)
Large signal loss
Maternal heart rate monitoring?

Non-reassuring
Basal bradycardia
Baseline shift
Fetal tachycardia Basal
No accelerations
Decelerations
Repetitive decelerations

Very non-reassuring (sound)
Very repetitive decelerations
Prolonged deceleration
Repetitive decelerations and ST event

Pre terminal (sound)
Reduced long-term variability
Repetitive decelerations and reduced long-term variability
Tachycardia, decelerations and ST event
Repetitive decelerations and ST event
Decelerations and ST event
Very repetitive decelerations and ST event
Prolonged decelerations and ST event
Reduced short-term variability
Repetitive decelerations and reduced short-term variability
Very prolonged deceleration
Prolonged deceleration with reduced variability

Discussion

The Omniview-SisPorto system was designed to incorporate the concepts of central monitoring, computerized CTG analysis, and online alerts using combined CTG+ST event data. The main aim of this technology is to alert health professionals to situations that may be associated with fetal hypoxia, thus preventing that such occurrences are overlooked in busy labor ward settings.

It is also intended as an adjunct to clinical decision, especially regarding CTG changes that are poorly assessed by the human eye or when complex integration of CTG and ST information is needed.

It is hoped that this technology, when associated with appropriate training of health professionals on signal interpretation, clinical decision, and adequate management, will contribute to reduce perinatal morbidity and mortality consequent to intrapartum events.

Computer quantification of short-term variability as an adjunct to fetal electrocardiographic monitoring

Omniview-SisPorto is also intended as an adjunct to clinical decision, especially regarding CTG changes that are poorly assessed by the human eye or when complex integration of CTG and ST information is needed. One example that addresses to this issue was published in a response to the paper of Westerhuis et al. Limitations of ST analysis in clinical practice: three cases of intrapartum metabolic acidosis (BJOG 2007;114:1194–1201).

Results

The paper by Westerhuis et al. illustrates three cases of intrapartum fetal metabolic acidosis that were missed or alerted to very late by STAN analysis. The authors note the marked reduction in variability occurring in the final segments of each tracing.

We were interested to quantify these changes, so we obtained the original fetal heart rate files from the authors. With their permission, we have quantified changes in variability over time in each of these cases and detected episodes of reduced variability in each of the cases.

The example depicted below is one of those cases as it if was acquired and analyzed in real time in the labour ward with the current version of Omniview-SisPorto.

The short-term variability, which is poorly assessed by the human eye, degrades over the last 1 and a half hour of the tracing. The system would issue a first red alert for reduced short-term variability 1h20m before the delivery and continuously during the last hour.

This is an example that illustrates the difficulties of CTG interpretation. In this case the newborn was resuscitated and at 8 months had cerebral palsy.

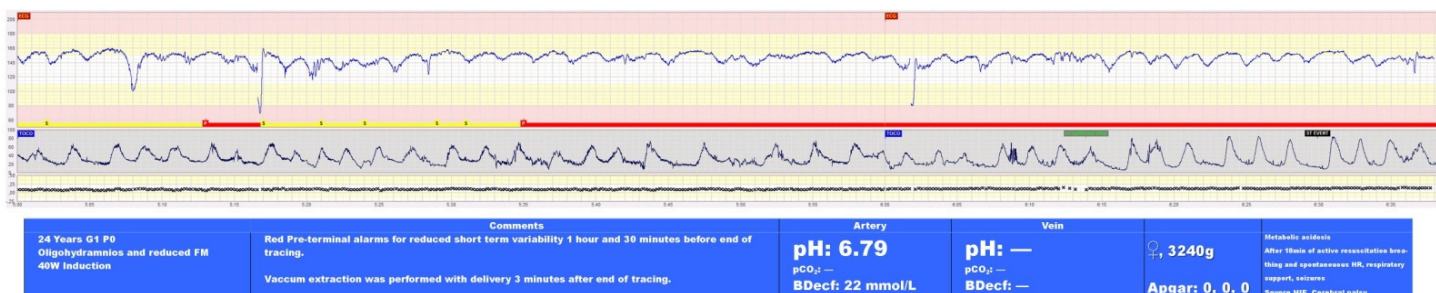


Fig. 4:Example of a tracing with red alerts since one 1h 20 min before delivery. Artery pH was 6,79.

List of other international peer reviewed papers published and using the Sisporto system:

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