OBSTETRICS

Computerized analysis of cardiotocograms and ST signals is associated with significant reductions in hypoxic-ischemic encephalopathy and cesarean delivery: an observational study in 38,466 deliveries

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BACKGROUND: Intrapartum cardiotocography is widely used in high-resource countries and remains at the center of fetal monitoring and the decision to intervene, but there is ample evidence of poor reliability in visual interpretation as well as limited accuracy in identifying fetal hypoxia. Combined monitoring of intrapartum cardiotocography and ST segment signals was developed to increase specificity, but analysis relies heavily on intrapartum cardiotocography interpretation and is therefore also affected by the previously referred problems. Computerized analysis was developed to overcome these limitations, aiding in the quantification of parameters that are difficult to evaluate visually, such as variability, integrating the complex guidelines of combined intrapartum cardiotocography and ST analysis, and using visual and sound alerts to prompt health care professionals to reevaluate features associated with fetal hypoxia.

OBJECTIVE: The objective of the study was to evaluate the effect of introducing a central fetal monitoring system with computerized analysis of intrapartum cardiotocography and ST signals into the labor ward of a tertiary care university hospital in which all women are continuously monitored with intrapartum cardiotocography. The incidence of adverse perinatal outcomes and intervention rates was evaluated over time.

STUDY DESIGN: In this retrospective cohort study, yearly rates of hypoxic-ischemic encephalopathy, instrumental vaginal delivery, overall cesarean delivery, and urgent cesarean delivery were obtained from the hospital's clinical databases. The rates occurring in the period from January 2001 to December 2003, before the introduction of the central monitoring system with computerized analysis of intrapartum cardiotocography and ST signals (Omniview-SisPorto), were compared with those occurring from January 2004 to December 2014, after the introduction of the system. All rates were calculated with 95% confidence intervals.

RESULTS: A total of 38,466 deliveries occurred during this period. After introduction of the system, there was a significant decrease in the number of hypoxic-ischemic encephalopathy cases per 1000 births (5.3%, 95% confidence interval [4.0—7.0] vs 2.2%, 95% confidence interval [1.7—2.8]; relative risk, 0.42, 95% confidence interval [0.29—0.61]), overall cesarean delivery rates (29.9%, 95% confidence interval [28.9—30.8] vs 28.3%, 95% confidence interval [27.8—28.8]; relative risk, 0.96, 95% confidence interval [0.92—0.99]), and urgent cesarean deliveries (21.6%, 95% confidence interval [20.7—22.4] vs 19.2%, 95% confidence interval [18.8—19.7]; relative risk, 0.91, 95% confidence interval [0.87—0.95]). The instrumental vaginal delivery rate increased (19.5%, 95% confidence interval [18.7—20.3] vs 21.4%, 95% confidence interval [21.0—21.9; relative risk, 1.07, 95% confidence interval 1.02—1.13].

CONCLUSION: Introduction of computerized analysis of intrapartum cardiotocography and ST signals in a tertiary care hospital was associated with a significant reduction in the incidence of hypoxic-ischemic encephalopathy and a modest reduction in cesarean deliveries.

Key words: central monitoring, electronic fetal monitoring, fetal distress, fetal heart rate, intrapartum surveillance, neonatal acidemia, neonatal asphyxia, neonatal encephalopathy, nonreassuring heart rate tracings, real-time alerts

Fifty years after being commercially available,[1] cardiotocography (CTG) maintains a solid place in the labor ward, remaining at the center of fetal monitoring and the decision to intervene. Several observational studies from the early years of the technology,[2–4] and 1 randomized controlled trial,[5] showed that its use was associated with decreased perinatal mortality when compared with intermittent auscultation. However, other trials conducted in the 1970s and 1980s failed to demonstrate similar effects,[6] and the technology's contribution to the reduction in perinatal mortality observed over the last decades is still a matter of debate.

On the other hand, rising cesarean delivery rates have become a motive of public concern in many countries because of their association with increased maternal morbidity,[7,8] and there is widespread belief that continuous intrapartum CTG monitoring has contributed to this.

CTG interpretation is prone to poor inter- and intraobserver agreement, particularly in the evaluation of variability and decelerations as well as in tracing classification.[9–11] Agreement is also dependent on the guidelines used for tracing analysis,[12] and it may be that the more objective guidelines recently published by leading scientific societies[13–15] will provide a more reproducible approach. CTG has also been shown to have limited specificity in the identification of hypoxic fetuses.[16–18]

Cite this article as: Lopes-Pereira J, Costa A, Ayres-De-Campos D, et al. Computerized analysis of cardiotocograms and ST signals is associated with significant reductions in hypoxic-ischemic encephalopathy and cesarean delivery: an observational study in 38,466 deliveries. Am J Obstet Gynecol 2019;220:269.e1-8.

0002-9378/$36.00

https://doi.org/10.1016/j.ajog.2018.12.037

AJOG at a Glance

Why was this study conducted?

To evaluate whether introducing a central fetal monitoring system with computerized analysis of cardiotocographic and ST signals into the labor ward of a tertiary care university hospital (in which all women are monitored continuously during labor) affected perinatal outcomes and intervention rates.

Key findings

In the years following introduction of the system, there was a 58% decrease in hypoxic-ischemic encephalopathy rates, a 4% decrease in overall cesarean delivery rates, and a 7% increase in instrumental vaginal delivery rates.

What does this add to what is known?

Introduction of central monitoring and computerized analysis of cardiotocographic and ST signals into a real-life setting was associated with an important reduction in the incidence of hypoxic-ischemic encephalopathy and modest changes in intervention rates.

Computerized analysis was developed to overcome the poor reliability of CTG interpretation and to increase its diagnostic accuracy.[19,20] All of these systems evolved to provide central fetal monitoring with real-time alerts based on computerized analysis of CTGs, allowing the display of multiple tracings on the same computer screen and producing visual and sound alerts to prompt tracing review and response from health care professionals.[21]

Omniview-SisPorto (Speculum, Lisbon, Portugal) is a system for the computerized analysis of CTG and ST signals, starting automatically after 10 minutes of tracing acquisition, and updated every minute (Figure 1).[22,23] No signal averaging or reduction is performed. Signals are analyzed by complex mathematical algorithms that identify uterine contractions, baseline fetal heart rate, accelerations, decelerations, and short- and long-term variability.

A series of additional algorithms integrate CTG and ST features, when these are available from STAN (ST analysis) monitors (Neoventa, Gothenburg, Sweden). Whether analyzing isolated CTG or combined CTG plus ST signals, the system elicits real-time visual and sound alerts for features associated with fetal hypoxia (see Figure 1 for examples of visual alerts and Table 1 for a description of all visual and sound alerts), which are updated every minute.

Detection of basic CTG features was found to be in high agreement with experts [24] and the system's red alerts showed a high sensitivity and specificity in the prediction of severe newborn acidemia, when evaluated in CTG tracings acquired just before birth.[25] The system is extensively described elsewhere.[22,23] The display of ST signals was incorporated in Omniview-SisPorto in 2006, and combined alerts for CTG plus ST data were introduced in 2007.

The aim of this study was to evaluate whether the introduction of Omniview-SisPorto into routine clinical practice of a tertiary care hospital affected the incidence of adverse fetal outcomes and intervention rates.

Material and Methods

In this retrospective cohort study, all women delivering at our institution between January 2001 and December 2014 were included. The number of deliveries, newborns with the diagnosis of hypoxic-ischemic encephalopathy (HIE), cesarean deliveries, nonelective cesarean deliveries, cesarean deliveries for a nonreassuring fetal state, and instrumental vaginal deliveries were obtained from the hospital's electronic patient record database (ObsCare; Virtualcare, Porto, Portugal) and administrative database (Sonho; ACSS, Lisbon, Portugal).

The yearly incidence of HIE was obtained by dividing the number of newborns with this diagnosis at hospital discharge by the number of births occurring after 24 completed weeks of gestation. The incidence of HIE in nonelective births was obtained by excluding all cases submitted to planned cesarean delivery and dividing the number of newborns with this diagnosis by the total number of newborns.

The criteria used for the diagnosis of HIE did not change during the study period and were defined as the appearance of changes in muscle tone, feeding, state of conscience, or seizures during the first 48 hours of life, associated with evidence of hypoxia/acidemia in the umbilical cord blood or in newborn blood samples obtained during the first hours of life (ie, pH <7.05 and base deficit >12 mmol/L or lactate >10 mmol/L).[26–29]

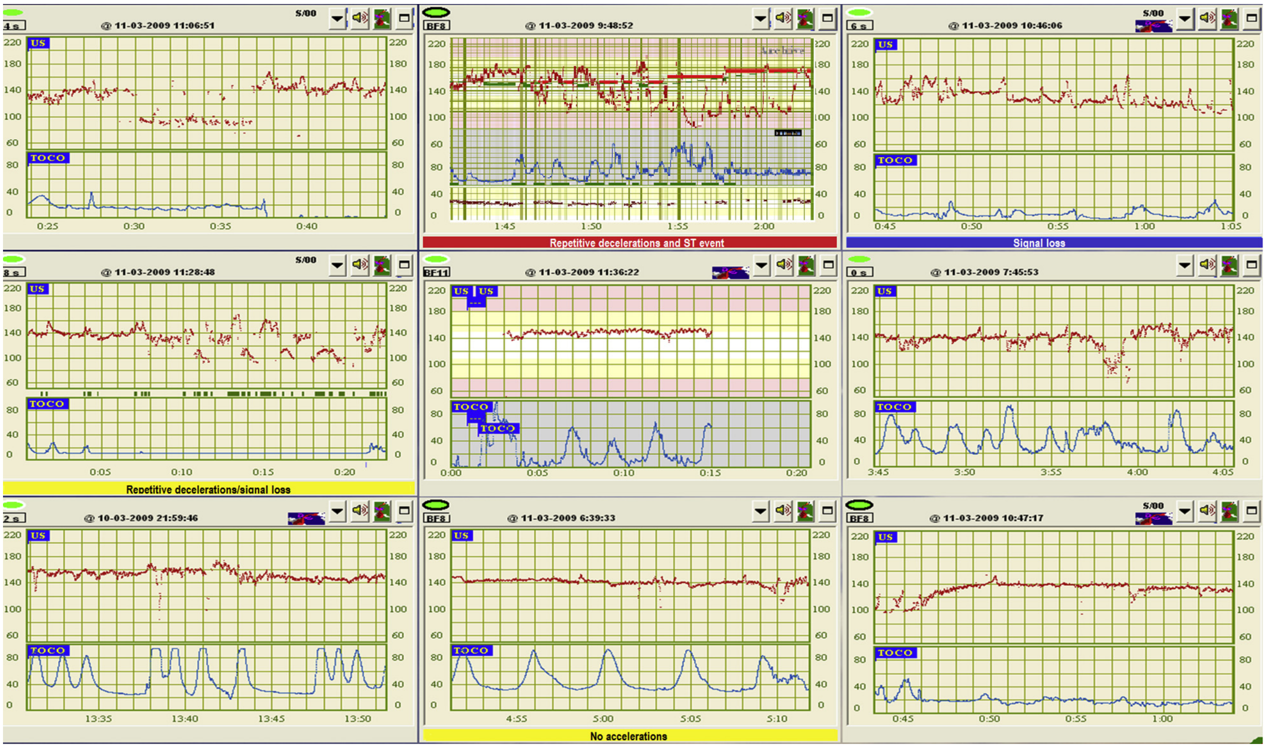
The overall cesarean delivery rate was obtained by dividing the total number of cesarean deliveries by the total number of births occurring after 24 completed weeks of gestation. Nonelective cesarean deliveries were defined as all those that were not programmed in previous days (ie, including all cases in which a cesarean delivery was performed within minutes to a few hours after the decision).

The Omniview-SisPorto system was installed in the hospital's labor ward in January 2004, and STAN monitors were introduced in September 2003, followed by 2 months of staff training. Both have remained in routine clinical use since that time. The hospital has also maintained a policy of continuous CTG monitoring for all women in labor, CTG plus ST analysis according to STAN guidelines,[30] and no use of fetal blood sampling.

The periods before installation of the system and the start of STAN monitoring (January 2001 to December 2003) and after installation (January 2004 to December 2014) were compared, calculating the frequency of adverse outcomes and interventions rates, with 95% confidence intervals (CI). Relative risks for hypoxic-ischemic encephalopathy, overall cesarean delivery (CD), nonelective CD, and CD for nonreassuring fetal state were computed by the ratio between risk after and risk before the Jan. 1, 2004.

FIGURE 1

Screenshot of the labor ward's central monitoring station



Screenshot of the labor ward's central monitoring station (Omniview-SisPorto 4.0), displaying automated CTG analysis and visual real-time alerts of different colors.

CTG, cardiotocography.

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Because of the retrospective and noninterventional nature of the study and because data anonymity was guaranteed, the institutional review board considered it exempt from formal review (Comissão de Etica para a Saude do Hospital de S. Joao e da Faculdade de Medicina do Porto; letter signed on May 24, 2017).

Results

A total of 38,466 deliveries occurred between January 2001 and December 2014. Table 2 displays the evolution in yearly rates of the study outcomes, and Table 3 compares them for the 2 periods before and after introduction of the system.

The incidence of HIE between the 2 study periods decreased significantly, both in the overall population and in nonelective births (relative risk, 0.42, 95% CI, 0.29–0.61). Additionally, significant reductions were observed in overall cesarean delivery rates (relative risk, 0.96, 95% CI, 0.92–0.99) and nonelective cesarean delivery rates (relative risk, 0.91, 95% CI, 0.87–0.95). Conversely, the instrumental vaginal delivery rate increased (relative risk, 1.07, 95% CI, 1.02–1.13). No difference was observed in the rates of cesarean delivery for nonreassuring fetal state (relative risk, 0.90, 95% CI, 0.82–1.00). Evolution of the yearly rates of the main study outcomes is displayed in Figure 2.

Comment

Principal findings of the study

Introduction of computer analysis of CTG and ST signals was associated with a 58% reduction in the incidence of HIE, a 4% decrease in overall cesarean delivery rates, and a 6% increase in instrumental vaginal delivery rates.

Results in the context of other publications

To our knowledge, this is the first study to evaluate the effect of routine computerized analysis of CTGs and ST signals on outcomes and interventions. Other studies have evaluated central fetal monitoring stations without ST signals or computerized analysis,[31–33] and all reported disappointing results because no reductions in adverse outcomes were observed, and one study even found an increase in cesarean and operative vaginal deliveries.[32]

Evidence from randomized controlled trials (RCTs) evaluating computerized analysis of CTG signals is also inconclusive. The FM-Alert trial compared computerized analysis of CTG plus ST signals using Omniview-SisPorto with visual analysis in 7730 term pregnancies.[34]

TABLE 1
Description of SisPorto 4.0 visual and sound alerts, based on computer analysis of CTG plus ST signals

Variables	Description
Green alert	Normality criteria met
Blue alerts	Signal loss Tachysystole ST signal loss Monitoring of same twin?[a] Large signal loss[a] MHR monitoring?[a] No accelerations[a] Possible reduced variability (continue monitoring)[a]
Yellow alerts	Bradycardia Baseline shift Tachycardia Repetitive decelerations Late/prolonged decelerations[a] Very repetitive decelerations[a]
Red alerts	Bradycardia <100 bpm[a] Reduced variability (LTV)[a] Reduced variability (STV)[a] Sinusoidal pattern[a] Increased variability (saltatory)[a] Repetitive late/prolonged decelerations and reduced variability (STV)[a] Repetitive late/prolonged decelerations and reduced variability (LTV)[a] Repetitive late/prolonged decelerations[a] Deceleration >5 min[a] Deceleration >5 min and reduced variability[a] Repetitive decelerations and ST event[a] Late/prolonged decelerations and ST event[a]

LTV, long-term variability; *MHR*, maternal heart rate; *STV*, short-term variability.

[a] Sound alerts are identified. See reference 20 for a more detailed description.

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Metabolic acidosis rates were lower in the computerized analysis arm, but the difference was not statistically significant (0.40% vs 0.58%, relative risk, 0.69, 95% CI, 0.36−1.31). Umbilical blood acidemia (pH <7.10) was significantly reduced in the computer arm in a subgroup of high-risk pregnancies (4.05% vs 5.85%, relative risk, 0.69, 95%CI 0.50−0-96).

Another RCT compared the INFANT system (K2 Medical, Plymouth, UK) for computer analysis of CTG tracings with visual analysis in 46,042 women.[35] Poor neonatal outcome was similar in both groups (defined as intrapartum stillbirth, early neonatal death excluding malformations, neonatal encephalopathy, early neonatal intensive care unit admission for more than 48 hours with encephalopathy or respiratory illness).

Visual analysis of CTG plus ST is widely used in western European countries such as Norway, Denmark, Finland, The Netherlands, France, and Portugal. A few published cohorts have evaluated the association between increased use of CTG plus ST and frequency of adverse outcomes and interventions. Norén and Carlsson[36] reported a 92% reduction in metabolic acidosis over a period of 7 years (from 0.72% to 0.06%), while CTG plus ST use increased from 26% to 69%. At the same time, cesarean deliveries decreased from 17.9% to 14.8%.

Kessler et al[37] reported a decrease in metabolic acidosis rates (1.4% vs 0.3%, odds ratio, 0.2, 95% CI, 0.1−0.7) over the course of 5 years in patients monitored with CTG plus ST, with an overall decrease in cesarean deliveries from 10.1% to 8.8%. Timonen and Holmberg[38] compared metabolic acidosis and operative delivery rates between the first 2 years after implementation of ST analysis (2001−2002) and the subsequent 9 years (2003−2011). The frequency of metabolic acidosis fell from 1.0% to 0.25% (relative risk, 0.33, 95% CI, 0.15−0.72), and cesarean deliveries decreased from 17.2% to 14.1% (relative risk, 0.82, 95% CI, 0.89−0.97).

Three large European RCTs comparing visual analysis of CTG plus ST signals with isolated CTGs showed that the former resulted in decreased metabolic acidosis and intervention rates, but 2 smaller trials reported contradictory findings.[39,40] A more recent RCT from the United States failed to find any significant differences between the 2 methods in a composite outcome that included intrapartum fetal death, neonatal death, low 5 minute Apgar, neonatal seizures, metabolic acidosis, ventilation, and neonatal encephalopathy.[41] Meta-analysis of all these trials found moderate reductions in operative vaginal delivery and metabolic acidosis rates with CTG plus ST.[42,43]

Clinical implications

There are several possible explanations for the reduction in HIE and cesarean deliveries rates observed in the present study. Sound and visual alerts provided by the system may have prompted reevaluation of tracings by health care professionals and a faster response, thus reducing the occurrence of severe fetal hypoxia and HIE. The quantifiable analysis provided by the computer may have helped in the interpretation of cases with borderline CTG findings, (such as borderline variability), providing reassurance to staff and thus avoiding unnecessary intervention.[44]

On the other hand, introduction of the combined CTG plus ST technology may have been the most relevant factor, increasing specificity in the diagnosis of fetal hypoxemia.[45] There are now several reports from centers in high-resource countries showing that it is possible to

TABLE 2
Yearly number of deliveries, rates of HIE, overall CD, nonelective CD, and CD for NRFS for the study period

Variables	Years 2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Number of deliveries	3009	2954	2828	2777	2587	2555	2604	2840	2839	3042	2852	2614	2464	2501
Number of births	3031	2975	2869	2818	2620	2600	2642	2892	2906	3092	2917	**2677**	2528	2566
Overall CD rate, %	30.51	27.59	32.50	29.13	30.19	27.51	27.80	29.82	28.95	28.07	30.79	28.27	27.80	28.35
Nonelective CD rate, %	22.10	20.45	22.81	20.42	20.60	18.32	18.70	16.20	20.18	20.15	21.84	19.66	19.64	19.63
CD for NRFS rate, %	6.04	6.26	4.21	4.03	5.14	3.72	4.11	3.91	4.76	7.13	8.52	4.63	4.46	4.28
HIE cases per 1000 births	5.6	5.4	4.9	4.3	3.1	3.8	3.8	2.8	0.7	0.3	1.7	1.9	2.0	0.4
HIE cases per 1000 nonelective births	6.1	5.8	5.4	4.6	3.4	4.2	4.2	3.1	0.8	0.4	1.9	2.0	2.1	0.4

CD cesarean deliver; *HIE*, hypoxic-ischemic encephalopathy; *NRFS* nonreassuring fetal state.

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achieve metabolic acidosis rates as low as 0.4–0.7%.

In the present study, an HIE rate was 2.2%, and all of these are much lower numbers than previously reported.[46] The demonstration of causality is difficult, but it seems that important adverse outcomes can be reduced in centers using modern intrapartum fetal monitoring technologies without the need to increase cesarean deliveries. The reported reduction in our institution's CD rates contrasted with a sharp increase taking place at the national level between the years 2001 and 2012.[47]

Research implications

Further research is needed to evaluate whether these results can be generalized to other centers using computerized analysis of CTG and ST signals. Studies are also needed to distinguish which are the most effective components of these monitoring and management strategies and to elucidate whether they are associated with a recently reported reduction in cerebral palsy rates[48] as well as with the continued decrease in perinatal mortality reported in several high-resource countries.

TABLE 3
Number of deliveries, rates of HIE, overall CD, nonelective CD, and CD for NRFS in the periods before and after introduction of the Omniview-SisPorto system and ST analysis at the end of 2003 (95% CI, 95% confidence intervals)

Variables analyzed	2001–2003	2004–2014	RR
Number of deliveries	8791	29,675	—
Number of births	8875	30,258	—
HIE cases per 1000 births	5.3 (95% CI, 4.0–7.0)	2.2 (95% CI, 1.7–2.8)	0.42 (95% CI, 0.29–0.61)
HIE cases per 1000 nonelective births	5.8 (95% CI, 4.4–7.7)	2.4 (95% CI, 1.9–3.1)	0.42 (95% CI, 0.29–0.61)
Overall CD rate, %	29.9% (95% CI, 28.9–30.8)	28.3% (95% CI, 27.8–28.8)	0.96 (95% CI, 0.92–0.99)
Nonelective CD rate, %	21.6% (95% CI, 20.7–22.4)	19.2 (95% CI, 18.8–19.7)	0.91 (95% CI, 0.87–0.95)
CD for NRFS rate, %	5.5% (95% CI, 5.0–6.0)	4.9% (95% CI, 4.7–5.2)	0.90 (95% CI, 0.82–1.00)
Instrumental vaginal delivery, %	19.3% (95% CI, 18.5–20.1)	21.0% (95% CI, 20.6–21.5)	1.07 (95% CI, 1.02–1.13)

CD cesarean deliver; *HIE*, hypoxic-ischemic encephalopathy; *NRFS* nonreassuring fetal state; *RR*, relative risk.

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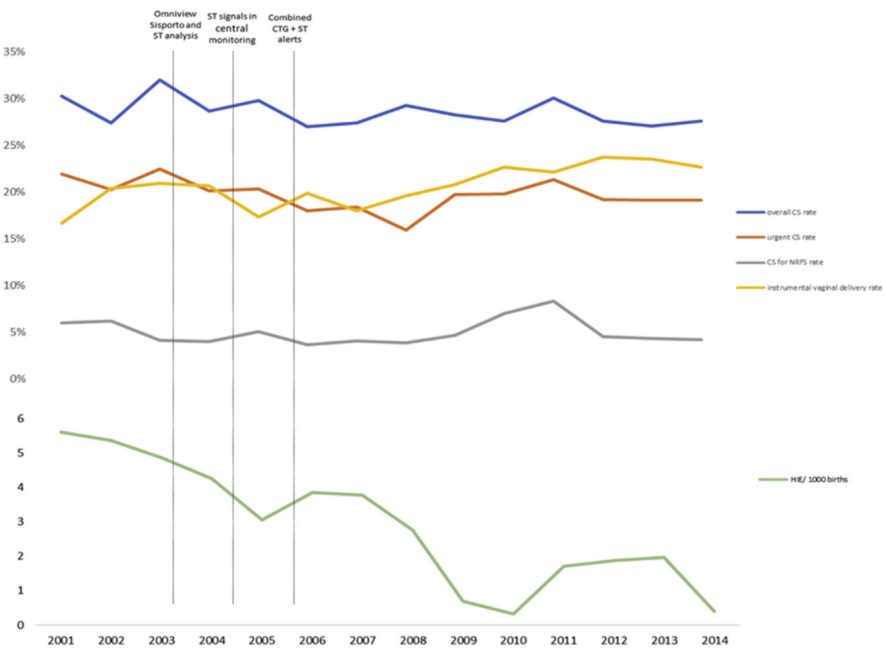
FIGURE 2
Yearly rates of overall conditions



Yearly rates of overall cesarean deliveries, urgent cesarean deliveries, cesarean deliveries for nonreassuring fetal state, and hypoxic-ischemic encephalopathy. Time of introduction of the different components of Omniview-SisPorto and ST analysis (*top*).

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Strengths and limitations

Among the strengths of the study are the large number of cases evaluated and the rigorous nature of the data because they were extracted directly from electronic patient records. It translates a real-life setting, rather than the somewhat artificial nature of an RCT,[49] in which recruitment may occur preferentially during the day, and there may be increased attention in both arms of the trial (Hawthorn effect), leading to improved outcomes in the whole trial population.[50–52]

The limitations are mostly related to the observational nature of the study, the lack of available demographic data on the study population, and the consequent difficulty in determining confounders and establishing causality. Because all women delivering at the hospital were included in the study and reference criteria remained the same, it is unlikely that there were major changes in population characteristics and that these were in a direction that would justify the observed improvements.

Other aspects of intrapartum care also changed during the study period, in addition to the introduction of ST analysis and related training, such as a regular audit of intrapartum cesarean deliveries starting in January 2002, and the organization of in-house simulation-based training of obstetric emergencies in 2006. Both could have affected adverse outcomes and intervention rates.

There was constant renovation of labor ward and neonatal intensive care unit staff over the years and experiences naturally varied, but it is impossible to determine the direction and magnitude of bias introduced by these changes.

We were unable to report the incidence of metabolic acidosis because this was not routinely incorporated in the hospital database before 2010. However, HIE is a more robust measure of outcome related to poor intrapartum oxygenation, as has a stronger association with long-term neurological outcomes.[26–28] Unfortunately, we could not obtain information on the different subgrades of HIE for the initial years of the study period, nor were we able to quantify the percentage of cases that had CTG plus ST monitoring during labor, precluding further comparisons.

The generalizability of the observed results to other settings depends on local practices, including the use of specific interpretation guidelines[12] and staff training modalities. Results need to be confirmed in other centers and are not generalizable to those that do not monitor all women continuously during labor.

Conclusions

The present study documents a significant reduction in HIE and cesarean delivery rates after introduction of a system for computerized analysis of CTG and ST signals in the labor ward of a tertiary care university hospital. Further research is required to demonstrate whether there is causality between these associations and whether these results can be generalized to other settings. ■

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Received May 20, 2018; revised Nov. 29, 2018; accepted Dec. 20, 2018.

Drs Ayres-de-Campos and Bernardes are coinventors of the Omniview-SisPorto system. The Institute of Biomedical Engineering receives royalties from the commercialization of the system. The other authors report no conflict of interest.

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