Original Research

Central Fetal Monitoring With and Without Computer Analysis

A Randomized Controlled Trial

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OBJECTIVE: To evaluate whether intrapartum fetal monitoring with computer analysis and real-time alerts decreases the rate of newborn metabolic acidosis or obstetric intervention when compared with visual analysis.

METHODS: A randomized clinical trial carried out in five hospitals in the United Kingdom evaluated women with singleton, vertex fetuses of 36 weeks of gestation or greater during labor. Continuous central fetal monitoring by computer analysis and online alerts (experimental arm) was compared with visual analysis (control arm). Fetal blood sampling and electrocardiographic ST waveform analysis were available in both arms. The primary outcome was incidence of newborn metabolic acidosis (pH less than 7.05 and base deficit greater than 12 mmol/L). Prespecified secondary outcomes included operative delivery, use of fetal blood sampling, low 5-minute Apgar score, neonatal intensive care unit admission, hypoxic–ischemic encephalopathy, and perinatal death. A sample size of 3,660 per group (N=7,320) was planned to be able to detect a reduction in the rate of metabolic acidosis from 2.8% to 1.8% (two-tailed α of 0.05 with 80% power).

RESULTS: From August 2011 through July 2014, 32,306 women were assessed for eligibility and 7,730 were randomized: 3,961 to computer analysis and online alerts, and 3,769 to visual analysis. Baseline characteristics were similar in both groups. Metabolic acidosis occurred in 16 participants (0.40%) in the experimental arm and 22 participants (0.58%) in the control arm (relative risk 0.69 [0.36–1.31]). No statistically significant differences were found in the incidence of secondary outcomes.

CONCLUSION: Compared with visual analysis, computer analysis of fetal monitoring signals with real-time alerts did not significantly reduce the rate of metabolic acidosis or obstetric intervention. A lower-than-expected rate of newborn metabolic acidosis was observed in both arms of the trial.

**For a list of FM-ALERT study group members, see Appendix 1, available online at http://links.lww.com/AOG/A901.*

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Each author has indicated that he or she has met the journal's requirements for authorship.

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Dr. Ayres-de-Campos, Mr. Sousa, and Dr. Bernardes took part in the development of the Omniview-SisPorto system. They are employees of the University of Porto and have no involvement with the company that commercializes the system (Speculum, Lisbon). The University of Porto has a licensing agreement with Speculum for commercialization of the Omniview-SisPorto system, and the funds received from this agreement are totally reinvested in research. The other authors did not report any potential conflicts of interest.

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Reduced fetal oxygenation during labor remains an important cause of perinatal mortality and long-term neurologic morbidity[1,2] and is frequently attributed to suboptimal cardiotocographic monitoring and interpretation.[3] Because oxygen concentration in the fetal tissues cannot in practice be quantified, identifying metabolic acidosis in the umbilical cord or in the early neonatal circulation is the only objective way of documenting fetal hypoxia.[4]

Cardiotocography remains at the center of the decision-making process in intrapartum fetal monitoring, but tracing interpretation is subject to well-known interobserver disagreement,[5,6] and the technology has not been consistently shown to improve perinatal mortality and cerebral palsy.[7]

Computer analysis of cardiotocograms is a recent and promising alternative, allowing a reproducible and quantifiable interpretation of tracings. The Omniview-SisPorto program provides computer analysis of fetal monitoring signals: heart rate and toco combined with electrocardiographic ST analysis when the latter is available. The system elicits real-time visual and sound alerts for health care professionals in a central monitoring station when features associated with poor fetal oxygenation are detected[8] (eg, prolonged decelerations, repetitive decelerations with reduced variability). Data are fed to the system from conventional fetal monitors or STAN monitors using internally or externally acquired fetal heart rate and toco signals. Health care professionals visualize conventional tracings on multiple computer screens, and the color alert appears below each tracing. Detailed graphic analysis of cardiotocographic features (accelerations, decelerations, variability) is available on selection. The system has been shown to provide analysis that is in good agreement with a consensus of experts[9] and the program's alerts were shown to be accurate at identifying fetuses with severe acidemia.[10]

The primary aim of the study was to evaluate whether the use of computer analysis of cardiotocograms reduced the rate of newborn metabolic acidosis when compared with visual analysis. Secondary aims were to evaluate the effect of this technology on other measures of perinatal outcome and on obstetric intervention rates.

MATERIALS AND METHODS

This was a multicenter randomized clinical trial (RCT) carried out in five hospitals in the United Kingdom: three tertiary care units and two district general hospitals, all managing high-risk women in labor.

The trial was registered at Current Controlled Trials with the number ISRCTN42314164, and the study protocol[11] was approved by the Cambridgeshire 1 Research Ethics Committee (reference number 09/H0304/61). An individual patient information sheet (see Appendix 2, available online at http://links.lww.com/AOG/A902) was provided to all participants and a consent form was signed by all women.

Women were eligible for participation in the study if they fulfilled the following inclusion criteria: singleton pregnancy with a cephalic presentation, 36 completed weeks of gestation or greater, no known major fetal malformations, in active labor but not in active second stage, no known contraindication to vaginal delivery, a clinical decision had been made to perform continuous cardiotocographic monitoring, 16 years of age or older, and able to provide written informed consent. Patients with risk factors for intrapartum hypoxia such as maternal diabetes, hypertension, and fetal growth restriction were also included in the trial. Patients were informed of the study by posters and leaflets distributed during antenatal appointments, labor education classes, and other hospital visits. The same information was available to women on arrival in the antenatal and labor wards.

Research or attending midwives approached eligible women if a decision was made to perform continuous cardiotocography during labor, because most women with low-risk labors elect to have intermittent auscultation. Midwives provided additional verbal and written information regarding the study and enquired about the woman's wish to participate. After giving written informed consent, women were enrolled in the trial by the selection of a randomization window in the Omniview-SisPorto program. Participants were asked at the time of recruitment if they wanted to know the final results of the study, and those who requested this, have been informed by email.

Women were randomized to one of two arms using a one-to-one computer-generated randomization sequence across all hospitals attributed by the Omniview-SisPorto program. Women randomized to the intervention arm received continuous cardiotocographic monitoring during labor with computer analysis and real-time alerts (Omniview-SisPorto[8]) in a central monitoring station located in one or more places in the labor ward, but not inside individual patient rooms. Women randomized to the control arm received continuous cardiotocographic monitoring during labor, displayed in the same central monitoring station but without computer analysis or alerts.

Patient enrollment was performed by a midwife who was not involved in study design or data analysis. Participants were unaware of the trial arm to which they were assigned, but the nature of the investigation prevented the blinding of health care professionals. Data collection and input were carried out by research midwives in each center who were not blinded to the intervention, but the statistician conducting data analysis was unaware of the allocation arm.

It was anticipated that cardiotocographic monitoring would be continued until the moment of birth or very close to it. Patients were allowed to opt out of the study at any time, for instance if there was a reason to discontinue monitoring. In the intervention arm, ultimate management decisions remained the responsibility of health care professionals, according to their best clinical judgment. However, nondirective guidelines were provided as posters in each center to help understand the meaning of the various alerts (Box 1).

In the control arm, women were managed according to the center's existing guidelines based on visual analysis of cardiotocographic tracings. The use of ST analysis and fetal blood sampling as adjunctive methods to cardiotocography was allowed in both arms. In the three centers where ST analysis was available, all health care providers were qualified in its interpretation. No formal training on cardiotocographic interpretation was put in place before the trial began.

Box 1. Guidelines Used to Help Understand the Meaning of the Various Alerts

Signal loss or maternal heart rate monitoring
Consider repositioning the Doppler probe, changing to internal FHR monitoring, reevaluating the scalp electrode connections, or changing the electrode.

ST signal loss
Consider reevaluating the scalp electrode connections or changing the electrode.

Tachysystole
Consider discontinuing or reducing oxytocin infusion or starting acute tocolysis.

Yellow alerts (tracing characteristics that do not fulfill the criteria of normality but are not usually associated with significant fetal hypoxia)
Consider maintaining close monitoring, starting ST analysis if available, or both.

Orange alerts (tracing characteristics that may be associated with some degree of fetal hypoxia)
Consider reversal of hypoxic causes if possible, maintaining close monitoring, starting ST analysis if available, or performing FBS.

Red alerts (tracing characteristics that are likely to be associated with fetal hypoxia)
Consider immediate reversal of causes of hypoxia if possible or immediate delivery.

FHR, fetal heart rate; FBS, fetal blood sampling.

Both umbilical cord arterial and venous blood sampling were performed for the diagnosis of newborn metabolic acidosis. Sampling was carried out as soon as possible after birth using two preheparinized syringes, which were capped after removing air bubbles. Blood analysis was performed within 30 minutes of delivery.[12] Umbilical pH was recorded with three decimal places and later rounded off to two decimal places.

Data on basic demographic characteristics, pregnancy complications, course of labor, and neonatal outcome were obtained by the local research midwife from patient notes and electronic health records in the days after delivery and entered into the Omniview-SisPorto program. The research midwife transmitted these data automatically in an anonymized format to the coordinating center.

Participants with metabolic acidosis, 5-minute Apgar scores less than 7, or neonatal intensive care unit (NICU) admission were further investigated by the local research midwife (prompted by an automatic e-mail from the Omniview-SisPorto program) to evaluate whether: 1) neonatal blood analysis was performed in the first hour of life and its results, 2) neonatal encephalopathy of any grade had occurred in the first 72 hours of life, 3) death of the neonate had occurred in the first 28 days of life, 4) other important neonatal complications had occurred in the first 7 days of life, and 5) the results of brain ultrasonography or other imaging techniques performed in the first 7 days of life.

The primary outcome was the incidence of fetal metabolic acidosis, defined as an umbilical blood pH less than 7.05 and base deficit in the extracellular fluid greater than 12 mmol/L, either in the arterial or in the venous sample. If values from the two cord vessels were available and the difference between the two pCO_2 measurements was greater than 0.7 kPa and pCO_2 was greater than 2.9 kPa (the predefined quality criteria for pCO_2 values), base deficit in the extracellular fluid was recalculated according to the Sigaard-Anderson formula.[13] Otherwise, the base deficit in the extracellular fluid provided by the blood gas analyzer was used. The vessel with the lowest pH was used to determine the presence of metabolic acidosis. When values from only one vessel were available and pCO_2 was greater than 2.9 kPa, base deficit in the extracellular fluid was recalculated according to the Sigaard-Andersen

formula. Otherwise, the base deficit in the extracellular fluid provided by the blood gas analyzer was used.

If no cord blood acid-base data were available, the patient was still classified as having metabolic acidosis if a blood sample obtained from the neonate in the first hour of life showed the pH and base deficit in the extracellular fluid criteria defined for umbilical vessels or a lactate value greater than 10 mmol/L.

Secondary outcomes were overall rate of cesarean delivery, cesarean delivery for nonreassuring fetal state, instrumental vaginal delivery, instrumental vaginal delivery for nonreassuring fetal state, fetal blood sampling, 5-minute Apgar score less than 7, NICU admission, grade 2 or 3 neonatal hypoxic–ischemic encephalopathy, perinatal death, internal fetal heart rate monitoring, and signal loss.

Serious adverse events were defined as any of the following: severe metabolic acidosis (umbilical artery pH less than 7.00 and base deficit in the extracellular fluid greater than 12 mmol/L) with NICU admission, 5-minute Apgar score less than 7 with NICU admission, first available pH value after birth less than 7.05 or first available lactate value after birth greater than 10 mmol/L, grade 2 or 3 neonatal encephalopathy, and death in the first 28 days of life. All serious adverse events were reported by email to an independent Data Safety Monitoring Committee. This committee also received biannual reports on study progress with the incidence of primary and secondary outcomes in both arms.

For sample size calculation, an expected metabolic acidosis rate of 2.8% was assumed, because this had been previously reported in an observational study from one of the participating centers.[14] At the time the study protocol was elaborated, it was not possible to find any evidence of the effect of computer analysis of intrapartum fetal monitoring signals on perinatal outcome or an estimate of the expected degree of change. The closest available parallel was the evaluation of ST analysis compared with conventional cardiotocography during labor. A systematic review of the first four trials that studied this issue revealed an overall relative risk of metabolic acidosis for ST analysis of 0.64.[15] In the absence of a better alternative, this was the value used for the initial sample size calculation. Thus, assuming a reduction in metabolic acidosis from 2.8% to 1.8%, with an α of 0.05, a two-sided test, and a power of 0.80, 7,320 women needed to be randomized. Accounting for a 10% loss to follow-up, the study required the inclusion of 8,133 women to obtain 7,320 analyzable participants (3,660 per arm). A prespecified interim analysis was conducted after enrollment of the first 1,607 participants, in which the incidence of metabolic acidosis was found to be 0.6%, and there was a 27% reduction in the experimental arm. Sample size recalculation resulted in the need to enroll 48,788 participants. The steering committee took the decision to continue recruitment based on the trend toward a reduced incidence of the main outcome and some secondary outcomes (acidemia–pH less than 7.10 and 5-minute Apgar less than 7), because other trials had reported larger reductions in metabolic acidosis during the second half of the study (Schuit E. Reply: To PMID 23333546 [letter-reply]. Am J Obstet Gynecol 2013;209:394–5.),[16] and recruitment of additional centers was anticipated. In addition, differences found in secondary outcomes at the end of the trial could generate other research hypotheses.

Data analysis was carried out in the coordinating center and followed the intention-to-treat principle. The two arms were compared for the whole study population and for each participating center. Incidences were compared using relative risks with 95% confidence intervals.

To compare baseline and labor characteristics between the two arms, Student *t* test, Mann-Whitney test (for skewed continuous data), and χ^2 tests were used. To test the consistency of primary and secondary outcomes across centers, Mantel-Haenszel homogeneity tests were performed. The log-binomial model was used to compute an adjusted relative risk for outcomes with heterogeneity across centers. Statistical analysis was carried out with R 3.1.1 and IBM SPSS Statistics 21.

RESULTS

Figure 1 shows the trial profile. A total of 32,306 patients were assessed for eligibility between August 1, 2011, and July 31, 2014. Of these, 24,576 were considered ineligible or declined participation and 7,730 were enrolled in the trial. Because of the automatic nature of the randomization and allocation processes, all enrolled participants were randomized and all randomized participants received the allocated intervention–3,961 in the experimental arm and 3,769 in the control arm. There were 14 participants lost to follow-up (0.18%), and seven patients opted out of the study before delivery occurred because continuous cardiotocographic monitoring was stopped (0.09%). According to the intention-to-treat principle, all 7,730 randomized participants were included in the final analysis.

The distribution of recruited participants per center was as follows: 788 from St. George's Hospital, University of London (10%), 4,573 from the

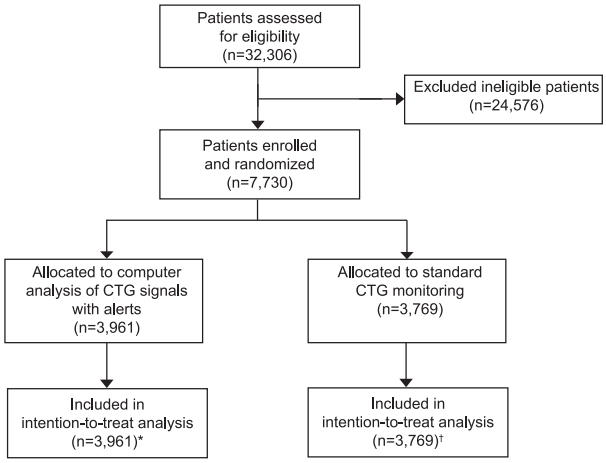

Fig. 1. Fetal Monitoring and Alert trial profile. *One patient opted out, and four were lost to follow-up; no outcome data were available for these patients. †Six patients opted out, and 10 were lost to follow-up; no outcome data were available for these patients. CTG, cardiotocogram.

Nunes. Computer vs. Visual Interpretation of Fetal Monitoring. Obstet Gynecol 2017.

University Hospital of Wales, Cardiff (59%), 1,156 from Ninewells Hospital, Dundee (15%), 1,007 from the Glan Clwyd Hospital, Rhyl (13%), and 206 from Leighton Hospital, Crewe (3%).

The main demographic and obstetric characteristics of the population were similar in both groups (Table 1). Umbilical cord blood gas values were available in 87.0% of the 7,730 analyzed participants. One patient in whom cord blood gas values were unavailable was still considered to have metabolic acidosis, because a lactate value greater than 10 mmol/L was documented in the neonatal circulation during the first hour of life.

The incidence of primary and secondary outcomes in both arms is displayed in Table 2. No difference was found in the incidence of metabolic acidosis: 0.404% in the experimental arm, 0.583% in the control arm (relative risk 0.69, 95% confidence interval 0.36–1.31). To test for the consistency of primary and secondary outcomes across centers, Mantel-Haenszel homogeneity tests were performed. Heterogeneity across centers was found only for overall instrumental vaginal delivery rate. Consequently, a log-binomial model was computed to recalculate this outcome. On adjusted relative risk, intervention rates and adverse outcomes were similar in the two arms of the trial.

In a subgroup analysis of laboring women with pre-existing medical conditions or complications occurring during the current pregnancy, a significantly lower incidence of newborn acidemia (pH less than 7.10) was observed in the experimental arm. No differences between groups were seen in the subgroup of patients monitored with ST analysis (Appendix 3, available online at http://links.lww.com/AOG/A903).

DISCUSSION

In this large multicenter RCT of computer analysis of cardiotocography with real-time alerts compared with visual analysis, no differences were observed in the rate of neonatal metabolic acidosis or obstetric intervention. Metabolic acidosis rates were 30% lower in the experimental arm, but the difference was not statistically significant. Similarly to what has been reported in other recent fetal monitoring trials,[17,18] an unexpectedly low rate of newborn metabolic acidosis was observed, resulting in the study being underpowered to detect the predefined difference.

Among the strengths of this study are the large number of participants and the multiple centers involved. On the other hand, the complex nature of the response to computer alarms makes clinical outcomes very dependent on staff performance. The heterogeneity of clinical experiences in the different centers therefore tends to produce similar results in both arms of the study. Differences in clinical management and in the risk characteristics of the study population could also be responsible for the observed intervention rates, which are higher than those reported in other trials evaluating intrapartum fetal monitoring technologies.[17–19]

To ensure recruitment during night hours, where less attention to cardiotocography may occur, midwives who enrolled patients could also be involved in labor management. It is therefore possible that midwives with different equipoise to the intervention enrolled at different paces.

Enrollment at the time a decision was taken to perform continuous intrapartum cardiotocography was expected to result in a population at high risk for metabolic acidosis, because it includes patients with induced or augmented labor as well as those with abnormalities detected on intermittent auscultation. On the other hand, patients with serious pregnancy complications or with cardiotocographic abnormalities diagnosed before labor were likely to be excluded, because they are more frequently delivered by elective cesarean. Likewise, acute intrapartum complications occurring while the patient was under intermittent auscultation (major placental abruption, cord prolapse, fetal hemorrhage, uterine rupture) were unlikely to be enrolled. The results cannot

Table 1. Main Demographic, Gestational, and Labor Characteristics of the Study Population*

	Experimental Arm (n=3,957)	Control Arm (n=3,759)	Total (N=7,716)
Baseline characteristics			
Maternal age (y)	28±6	29±6	28±6
Maternal height (cm)	164±9	163±11	163±10
Last maternal weight (kg)	75±19	75±19	75±19
No. of previous pregnancies			
0	1,864 (47)	1,784 (48)	3,648 (47)
1	1,053 (27)	995 (26)	2,048 (27)
2	517 (13)	500 (13)	1,017 (13)
3 or more	523 (13)	480 (13)	1,002 (13)
3rd-trimester GBS carrier status			
Negative	267 (7)	234 (6)	501 (7)
Positive	120 (3)	109 (3)	229 (3)
Undetermined	3,570 (90)	3,416 (91)	6,986 (90)
Labor characteristics			
Gestational age (wk)	40±2	40±2	40±2
Beginning of labor			
Induced	2,036 (51)	1,924 (51)	3,960 (51)
Spontaneous	1,921 (49)	1,835 (49)	3,756 (49)
Augmented labor	2,225 (56)	2,129 (57)	4,354 (56)
Meconium staining during labor			
Heavy or with particles	315 (8)	303 (8)	618 (8)
Light	394 (10)	366 (10)	760 (10)
None	3,248 (82)	3,090 (82)	6,338 (82)
Intrapartum bleeding	137 (3)	115 (3)	252 (3)
Temperature greater than 38°C intrapartum	162 (4)	135 (4)	297 (4)
No analgesia	67 (2)	49 (1)	116 (1)
Epidural analgesia	2,661 (67)	2,520 (67)	5,181 (67)
Parenteral analgesia	1,262 (32)	1,216 (32)	2,478 (32)
Inhaled analgesia	3,446 (87)	3,304 (88)	6,750 (87)
Interval between tracing end and birth	2 (0–720)	2 (0–444)	2 (0–720)
Type of delivery			
Cesarean	809 (20)	772 (20)	1,581 (20)
Instrumental	1,252 (32)	1,113 (30)	2,365 (31)
Normal	1,896 (48)	1,874 (50)	3,770 (49)

SD, standard deviation; GBS, group B streptococci.
Data are mean±standard deviation, n (%), or median (minimum–maximum).
* Fourteen participants were lost to follow-up.

therefore be immediately generalized to centers where continuous cardiotocographic monitoring is performed in all labors. Subgroup analysis suggests that computer analysis may only confer benefit in the higher risk group of women with pre-existing or pregnancy complications.

It is also recognized that some complications occurring after fetal monitoring has finished but before the fetus is extracted such as shoulder dystocia, anesthetic complications at cesarean delivery, or difficulties in fetal extraction can also result in metabolic acidosis, and these cannot be avoided by continuous cardiotocographic monitoring. However, as a result of the randomized nature of the study, they should be evenly distributed between the two arms. Metabolic acidosis is an objective measure of intrapartum hypoxia and is commonly used as a primary outcome in trials evaluating intrapartum fetal monitoring,[17,18] but incorrect or failed sampling can occur, and although evenly distributed between the two arms, the 13% of participants with absent results is a limitation of this study.

This is one of two large RCTs to evaluate computer analysis of intrapartum cardiotocography. Another trial evaluating the Guardian system (K2 Medical, Plymouth, United Kingdom) has been completed, but only a preliminary evaluation is published.[20] A smaller study (n=720) evaluated the Nexus system and reported significant reductions in hypoxia, acidemia, cesarean delivery, and NICU admission rate in the computer arm.[21]

There are several hypotheses for the absence of statistically significant differences in outcomes. First and foremost is that the trial was underpowered to

Table 2. Incidence of Primary and Secondary Outcomes in the Two Study Arms (Intention-to-Treat Analysis)

Primary and Secondary Outcomes	Experimental Arm (n=3,961)	Control Arm (n=3,769)	RR (95% CI)	Homogeneity Test* (*P*)	Adjusted RR (95% CI)
Metabolic acidosis	16 (0.404)	22 (0.583)	0.69 (0.36–1.31)	.424	—
Umbilical blood pH less than 7.10†	152 (3.8)	158 (4.2)	0.91 (0.74–1.14)	.793	—
Umbilical blood pH less than 7.15†	367 (9.3)	372 (9.9)	0.94 (0.82–1.08)	.905	—
Umbilical blood gas data	3,464 (87.5)	3,248 (86.2)	0.91 (0.81–1.02)	.372	—
5-min Apgar less than 7‡	47 (1.2)	52 (1.4)	0.86 (0.58–1.28)	.434	—
Perinatal death	1 (0.025)	0 (0.000)	2.85 (0.12–70.06)	—	—
HIE of any grade	7 (0.177)	8 (0.212)	0.83 (0.30–2.29)	—	—
Grade 2 or 3 HIE	5 (0.126)	1 (0.027)	4.76 (0.56–40.70)	.219	—
Cesarean delivery	809 (20.4)	772 (20.5)	1.00 (0.91–1.09)	.525	—
Cesarean delivery for NRFS	258 (6.3)	239 (6.3)	1.03 (0.87–1.22)	.476	—
Instrumental VD	1,252 (31.6)	1,112 (29.5)	1.07 (1.00–1.14)	.026	1.028 (0.99–1.06)
Instrumental VD for NRFS	483 (12.2)	431 (11.4)	1.07 (0.94–1.20)	.170	—
NICU admission	137 (3.5)	143 (3.8)	0.91 (0.72–1.15)	.777	—
FBS during labor	240 (6.1)	210 (5.6)	1.09 (0.91–1.30)	.205	—
ST analysis during labor§	2,763 (70)	2,584 (69)	1.02 (0.99–1.05)	.364	—
Signal loss§	4.61 (0–90.1)	4.75 (0–100)	0.087‖	—	—
Signal quality§	95.54 (0–99.95)	95.38 (0–99.98)	0.104‖	—	—

RR, relative risk; CI, confidence interval; HIE, hypoxic–ischemic encephalopathy; NRFS, nonreassuring fetal state; VD, vaginal delivery; NICU, neonatal intensive care unit; FBS, fetal blood sampling.

Data are n (%) or median (minimum–maximum) unless otherwise specified.

* Mantel-Haenszel homogeneity tests were performed to test for the consistency of primary and secondary outcomes across centers.

† Umbilical blood pH values not available in 497 patients (12.5%) in the experimental arm and 521 patients (13.8%) in the control arm.

‡ Apgar score not available in four patients (0.1%) in the experimental arm and one patient (0.02%) in the control arm.

§ Data for ST analysis not available 32 patients (0.8%) in the experimental arm and 35 patients (0.9%) in the control arm.

‖ *P* values from Mann-Whitney test.

show this difference. A lower than expected incidence of metabolic acidosis was observed in the control arm, suggesting the occurrence of a Hawthorne effect–an increased attention to fetal monitoring and subsequent management motivated by the knowledge that a study is being undertaken. A similar effect has been suggested in other trials on intrapartum fetal monitoring.[17–19] It would be interesting to know the rate of metabolic acidosis in participating centers before the trial began and in nonenrolled women while the trial was underway, but cord blood sampling is not routinely performed on all women in these centers, so these data are unavailable. The control group could have been contaminated from the training and experience gained in the experimental arm. The systematic analysis provided by the computer, together with clear instructions on how to deal with the different alerts, could have influenced clinical management in the control group. Over the course of the study period, a significant decrease in the rate of cesarean delivery, cesarean delivery for nonreassuring fetal state, and instrumental vaginal delivery for nonreassuring fetal state was observed, but no differences in primary and secondary outcomes were found in the first or the second part of the study (Appendix 4, available online at http://links.lww.com/AOG/A904).

Another hypothesis for the mainly negative results is that health care professionals were not close to the system or ignored the alerts when these occurred. The latter effect was not possible to document because the system does not register acknowledgment of alerts. An unlimited number of viewing posts is possible with Omniview-SisPorto, but some participating centers only used one central monitor, so it is possible that some alerts were not seen by health care professionals. Clinicians from two participating centers organize regular training courses in cardiotocographic interpretation in the United Kingdom, so overall experience in these two centers is likely to be high.

It is likely that central monitoring stations with computer analysis of cardiotocograms will continue to be widely used in high-resource countries, but like occurs with other intrapartum fetal monitoring technologies, it is difficult to demonstrate their benefit in RCTs.[17–21] This study provides evidence that continuous monitoring of cardiotocograms with computer analysis and real-time alerts is associated with a low

incidence of newborn metabolic acidosis and does not increase intervention rates, but there is no clear demonstration of benefit when compared with visual analysis. The inclusion of a larger sample size or the conduction of similar trials in centers with less experienced staff may provide different results. Similarly, continued refinement of interpretation algorithms may be required in the future.

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