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REVIEW

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Intrapartum cardiotocography with and without computer analysis: a systematic review and meta-analysis of randomized controlled trials

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ABSTRACT

Objective: To evaluate whether intrapartum cardiotocography with computer analysis decreases the incidence of newborn metabolic acidosis or obstetric intervention when compared with visual analysis through a systematic review with meta-analysis of randomized controlled trials.

Methods: The research was conducted using Medline, Embase, Web of Science, Scopus, ClinicalTrial.gov, Ovid and Cochrane Library as electronic databases from the inception of each database to May 2018. Selection criteria included randomized trial evaluating women with cephalic presentation at term or late preterm term during labor who were randomized to electronic fetal heart rate monitoring with either computer analysis (i.e. intervention group) or standard visual analysis (i.e. control group). Trials evaluating antenatal fetal heart rate monitoring in women not in labor were excluded. The primary outcome was incidence of newborn metabolic acidosis, defined as pH less than 7.05 and base deficit greater than 12 mmol/L. Secondary outcomes were mode of delivery, admission to neonatal intensive care unit, hypoxic–ischemic encephalopathy, and perinatal death. The summary measures were reported as relative risk (RR) with 95% confidence interval (CI).

Results: Three randomized controlled trials (RCTs), including 54,492 participants, which met inclusion criteria for this meta-analysis, were analyzed. All the included trials enrolled women with cephalic presentation at term or late preterm. Women were randomized in the active first stage of labor and all of them received continuous cardiotocography (CTG) from randomization until delivery. Women who received continuous CTG during labor with computerized analysis had similar risk of newborn metabolic acidosis. No between group differences were found in the secondary outcomes.

Conclusions: Compared with visual analysis, use of computer analysis of fetal monitoring signals during labor did not significantly reduce the rate of metabolic acidosis or obstetric intervention.

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KEYWORDS
Acidosis; cardiotocography; fetal death; neonatal intensive care unit; perineal morbidity

Key message

Compared with visual analysis, computer analysis of fetal monitoring signals did not significantly reduce the rate of metabolic acidosis or obstetric intervention.

Introduction

Electronic fetal hear rate monitoring (EFM), or cardiotocography (CTG), records changes in fetal heart rate and their temporal relationship to uterine contraction. It has been developed with the aim of detecting fetal hypoxia during labor and hence to prevent metabolic acidosis. Despite being the standard for intrapartum management [1], this technique, significantly increase the operative delivery rate, and is associated only with less seizures as neonatal benefit [2]. Another concern is also the variability in the interpretation.

Several techniques have been studied in order to decrease the high false positive rate. Fetal ST

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waveform analysis (STAN) has been studied combined with CTG. A recent meta-analysis of randomized trials, however, showed that STAN during labor did not improve perinatal outcomes or decrease operative delivery rates, except for a 9% decrease in operative vaginal delivery [3,4]. Comparisons of visual and computerized interpretation of EFM have also been reported. However, whether or fetal monitoring with computer analysis improve perinatal outcomes is still subject of debate.

Thus, we aim to evaluate whether intrapartum fetal monitoring with computer analysis decreases the incidence of newborn metabolic acidosis or obstetric intervention when compared with visual analysis through a systematic review with meta-analysis of randomized controlled trials (RCTs).

Materials and methods

Search strategy

This review was performed according to a protocol designed *a priori* and recommended for systematic review [5]. Electronic databases (i.e. Medline, Scopus, ClinicalTrials.gov, Embase, ScienceDirect, the Cochrane Library at the CENTRAL Register of Controlled Trials, Scielo) were searched from their inception until May 2018. Search terms used were the following text words: cardiotocography, electronic fetal heart monitoring, quantitative, expert system, fetal assessment, labor, and labor. No restrictions for language or geographic location were applied. In addition, the reference lists of all identified articles were examined to identify studies not captured by electronic searches. The electronic search and the eligibility of the studies were independently assessed by two authors (G. S. and S. T.). Differences were discussed and consensus reached.

Selection criteria

Selection criteria included RCTs evaluating women with singleton or multiple gestations and cephalic presentation at term or late preterm during labor who were randomized to electronic fetal heart rate monitoring with either computer analysis (i.e. intervention group) or standard visual analysis (i.e. control group). Trials evaluating antenatal fetal heart rate monitoring in women not in labor were excluded. Quasi-randomized trials (i.e. trials in which allocation was done on the basis of a pseudorandom sequence, e.g. odd/even hospital number or date of birth, alternation) were also excluded.

Data extraction and risk of bias assessment

The risk of bias in each included study was assessed by using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions*. Seven domains related to risk of bias were assessed in each included trial since there is evidence that these issues are associated with biased estimates of treatment effect: (1) random sequence generation; (2) allocation concealment; (3) blinding of participants and personnel; (4) blinding of outcome assessment; (5) incomplete outcome data; (6) selective reporting; and (7) other bias. Review authors' judgments were categorized as "low risk," "high risk," or "unclear risk" of bias [5].

Two authors (G.S. and S. T.) independently assessed inclusion criteria, risk of bias and data extraction. Disagreements were resolved by discussion.

All analyses were done using an intention-to-treat approach, evaluating women according to the treatment group to which they were randomly allocated in the original trials. Primary and secondary outcomes were defined before data extraction.

The primary outcome was incidence of newborn metabolic acidosis, defined as pH less than 7.05 and base deficit greater than 12 mmol/L. Secondary outcomes were mode of delivery, admission to neonatal intensive care unit, hypoxic–ischemic encephalopathy, and perinatal death.

Statistical analysis

The data analysis was completed independently by two authors (G. S. and S. T.) using Review Manager v. 5.3 (The Nordic Cochrane Centre, Cochrane Collaboration, 2014, Copenhagen, Denmark). The completed analyses were then compared, and any difference was resolved by discussion. The summary measures were reported as summary relative risk (RR) with 95% of confidence interval (CI) using the random effects model of DerSimonian and Laird. I-squared (Higgins I^2) greater than 0% was used to identify heterogeneity. Data from each eligible study were extracted without modification of original data onto custom-made data collection forms. A 2 by 2 table was assessed for RR. Data were extracted and imported into Review Manager v. 5.3 (The Nordic Cochrane Centre, Cochrane Collaboration, 2014, Copenhagen, Denmark).

Potential publication biases were assessed statistically by using Begg's and Egger's tests. p Value $< .05$ was considered statistically significant. The meta-analysis was reported following the Preferred Reporting

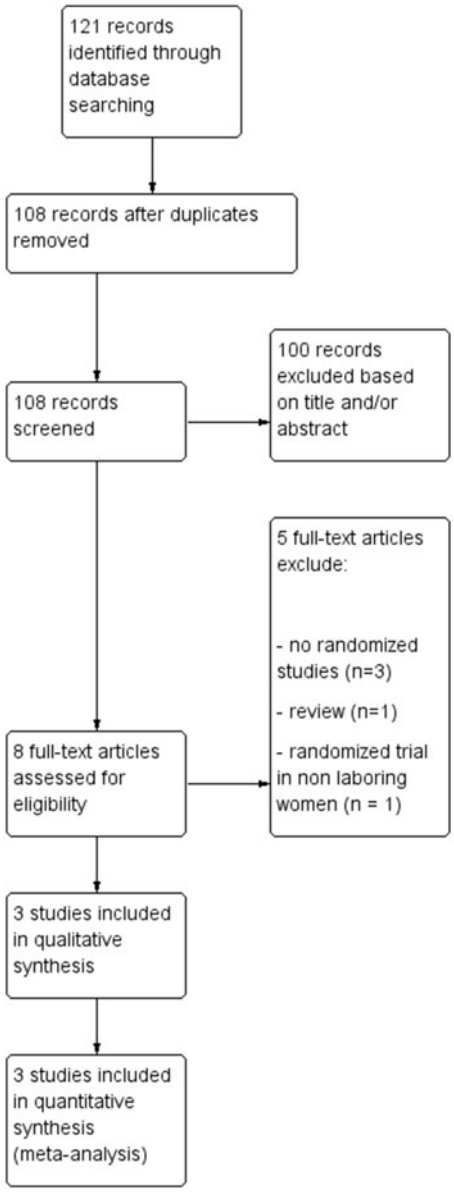

Figure 1. Flow diagram of studies identified in the systematic review. (Prisma template [Preferred Reporting Item for Systematic Reviews and Meta-analyses]).

Item for Systematic Reviews and Meta-analyses (PRISMA) statement [6].

Results

Study selection and study characteristics

Three RCTs, including 54,492 participants [7–9], which met inclusion criteria for this meta-analysis, were analyzed (Figure 1). The overall risk of bias was judged as low. Most studies had a low risk of bias in selective reporting and incomplete outcome data according with the Cochrane Collaboration's tool. No study was double blind because this was deemed difficult methodologically given the intervention (Figure 2). Statistically heterogeneity within the trials ranged from low to high with and $I^2 = 74\%$ for the primary outcome. Publication bias, assessed using Begg's and Egger's tests, was not significant ($p = .84$ and .80, respectively).

The characteristics of the three included trials are summarized in Table 1. All the included trials enrolled women with cephalic presentation at term or late preterm. Two studies included only singleton gestations, while one study included both singletons and twins. Women were randomized in the active first stage of labor and all of them received continuous CTG from randomization until delivery. Two trials had newborn metabolic acidosis, defined as pH less than 7.05 and base deficit greater than 12 mmol/L, as primary outcome [7, 8], while the INFANT trial [9] had a composite of perinatal outcome as primary outcome.

Synthesis of results

Women who received continuous CTG during labor with computerized analysis had similar risk of newborn metabolic acidosis (RR = 0.72, 95% CI = 0.37–1.40; Figure 3). No between group differences were found in the secondary outcomes, including mode of delivery, admission to neonatal intensive care unit, hypoxic–ischemic encephalopathy, and perinatal death (Table 2).

Discussion

Principal findings

This meta-analysis of pooled data from three RCTs showed that intrapartum fetal monitoring with computer analysis did not decrease the incidence of newborn metabolic acidosis or obstetric intervention when compared with visual analysis.

Our meta-analysis represented level-1 data and included appropriately powered, large-scale, multicenter, well-designed RCTs. Test of heterogeneity points to the non-efficacy of computerized CTG as studied so far. This may be the first meta-analysis analyzing the efficacy of computerized analysis of CTG during labor. Limitations of our study are inherent to the limitations of the included RCTs. Only three trials were included, and none of them were double-blind. The three included trials had different inclusion criteria, and used different system for CTG analysis. The vast majority of the included women came from one large trial [9], which therefore drives the statistics.

Notably, the RCTs did not validate the clinical use aspect fully. Studies should be complemented with observational studies conducted over much longer

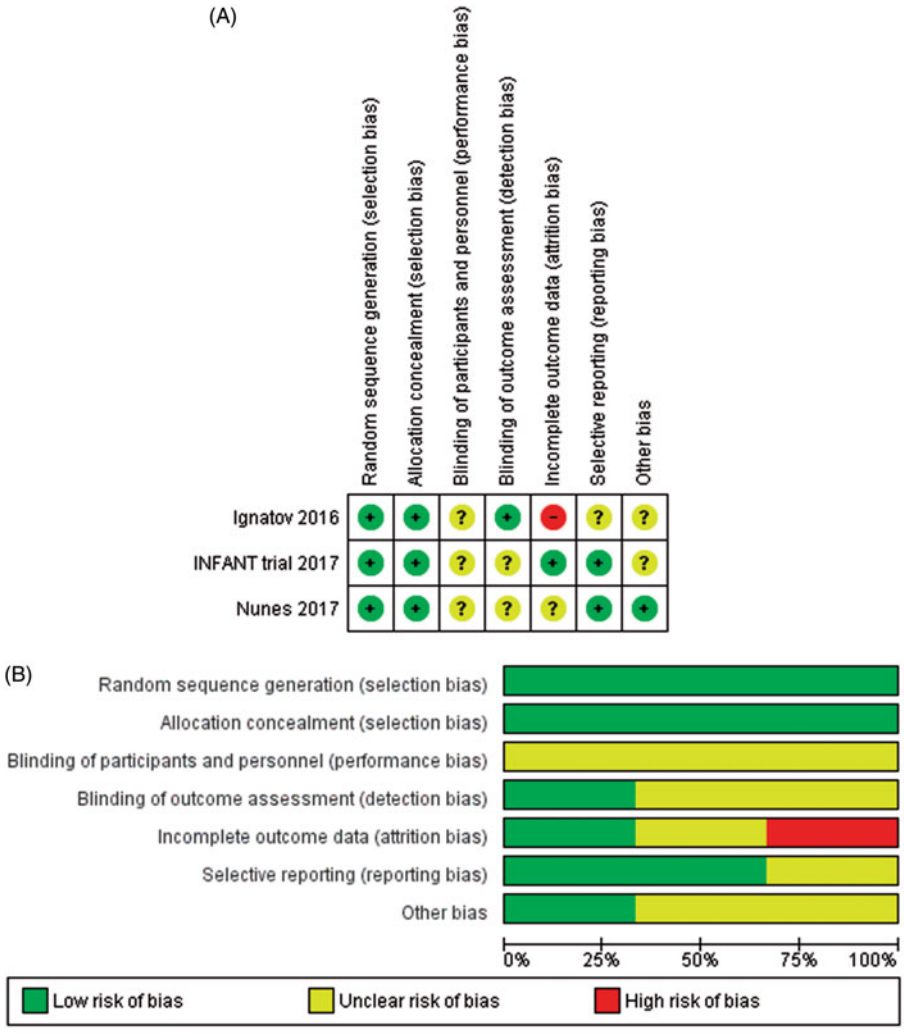

Figure 2. Assessment of risk of bias. (A) Summary of risk of bias for each trial; Plus sign: low risk of bias; minus sign: high risk of bias; question mark: unclear risk of bias. (B) Risk of bias graph about each risk of bias item presented as percentages across all included studies.

periods that were more consistent with standard obstetric practice. Another issue is the complementary technology of education and coherent management of the CTG based information that is included in both arms of a study. In this type of study, there is also the need to analyze the attitude towards a new technology and the ability to follow clinical guidelines. Another shortcoming is the lack of definition of method of calculating base deficit for cord metabolic acidosis. The very low incidence of metabolic acidosis, moreover, limits the power of the analysis.

Interpretation

Different techniques have been studied to improve delivery outcomes of pregnant women [10–20]. Given the limitations of the standard CTG, authors focused on alternatives which could decrease the false positive rate of EFM [3,4]. In 1977, Dawes and Redman at Oxford University in UK, started to investigate the association between outcomes and numerical analysis of the fetal heart rate parameters, in pregnancy. Dawes and Redman were able to quantifying parameters that are difficult to assess by the human eye, such as short- and long-term variability. Specifically they demonstrated that the short-term variability (STV), parameter that is very closed to the beat to beat variation, correlates well with the development of metabolic acidemia and intrauterine death. The system is today named Sonicaid FetalCare, and is based on a database with more than 73,500 traces [21]. The computerized CTG represent a more objective method for the analysis of the fetal heart rate than the visual CTG in pregnancy [22]. Such methodic has been introduced to overcoming the problems related to the analysis and interpretation of the cardiotocographic traces

Table 1. Characteristics of the included studies.

	Ignatov 2016 [7]	Nunes 2017 [8]	INFANT trial 2017 [9]
Study location	Bulgaria	UK	UK and Ireland
Number of centers	1	5	24
Number of patients included[a]	720 (360 versus 360)	7730 (3961 versus 3769)	46,042 (22,987 versus 23,055)
Inclusion criteria	Maternal age >18 y/o; singleton pregnancy, vertex presentation >36 weeks; no major fetal malformation; active first stage of labor; continuous EFMMaternal age ≥16 y/o; singleton pregnancy, vertex presentation >36 weeks; no major fetal malformation; active first stage of labor; continuous EFM	Maternal age ≥16 y/o; singleton or twin pregnancy, vertex presentation >35 weeks; no major fetal malformation; active first stage of labor; continuous EFM	
Computerized system used	NEXUS/OBSTETRICS system (Nexus GMT, Frankfurt, Germany)	Omniview-SisPorto program	Infant system
Characteristics of the computerized analysis	Microfluctuations analysis in fetal heart rate (OSZ), fetal 48 heart rate (FRQ) and DEC scored on a scale ranging between 0 (normal measure) and 6 (highly abnormal measure) and summated for an overall CTG score	Analysis of fetal heart rate and toco combined with electrocardiographic ST analysis, where available	Analysis of fetal heart signals: baseline heart rate; heart-rate variability; accelerations and type and timing of decelerations; quality of the signal; and contraction pattern

[a]Data are presented as total number (number in the intervention group versus number in the control group).
DEC: decelerations; CTG: cardiotocography; EFM: electronic fetal monitoring.

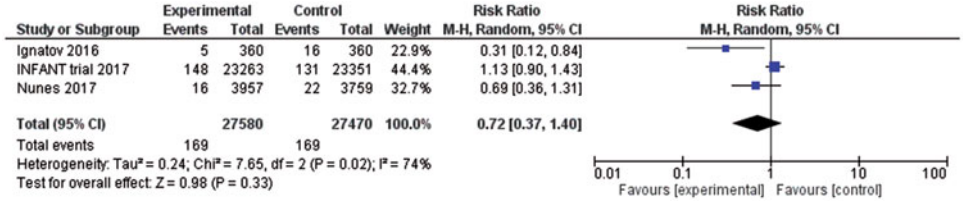

Figure 3. Forest plot for the risk of newborn metabolic acidosis, defined as pH less than 7.05 and base deficit greater than 12 mmol/L.

during pregnancy, the so-called "Non stress test," subjected to inter- and intraoperator variability, and to identify fetuses at risk of fetal acidosis. Computerized CTG, based mostly on Dawes/Redman criteria, is now the standard non-stress test for antepartum management of high-risk pregnancies, including those complicated by intrauterine fetal growth restriction, in Europe [23,24].

After the development of the Sonicaid system, others computerized systems, where developed in order to overcome the poor reproducibility of visual analysis [25]. SisPort, for example, is a program for automated analysis of tracing during labor developed at the University of Porto by Ayres-de-Campos [26], to perform the automated analysis of cardiotocograms. Nexius and INFANT (K2 Medical System) are the two decision support software used respectively in the trials by Nunes [8] and in the Infant trial [9]. Both centralizes viewing of fetal signals during labor, allowing simultaneous monitoring of multiple tracings in one or more locations. Both display the cardiotocograph on a computer screen alongside other clinical data collected as part of routine of clinical care.While, computerized CTG has been proven to improve perinatal outcomes when used antepartum as nonstress test in high-risk pregnancies [23,24], the efficacy during labor, is still subject of debate [27]. This review with meta-analysis showed that, when used in laboring women, in clinical trials, compared with visual analysis, computer analysis of fetal monitoring signals that do not include the new guidelines interpretation of CTG, did not significantly reduce the rate of metabolic acidosis or obstetric intervention.

Table 2. Primary and secondary outcomes.

	Ignatov 2016 [7]	Nunes 2017 [8]	INFANT trial 2017 [9]	Total	I^2	RR (95% CI)
Metabolic acidosis	5/360 (1.4%) versus 16/360 (4.4%)	16/3957 (0.40%) versus 22/3759 (0.58%)	148/23,263 (0.64%) 131/23,351 (0.56%)	169/27,580 (0.6%) versus 169/ 27,470 (0.6%)	74%	0.72 [0.37–1.40]
Spontaneous vaginal delivery	N/A	1896/3957 (48%) versus 1874/ 3759 (50%)	11,896/23,263 (51.1%) versus 12,031/23,351 (51.5%)	13,792/27,220 (50.7%) versus 13,905/ 27,110 (51.3%)	40%	0.98 [0.96–1.01]
Operative vaginal delivery	2/360 (0.6%) versus 4/360 (1.1%)	1252/3957 (32%) versus 1113/ 3759 (30%)	5698/23,263 (24.5%) versus 5765/ 23,351 (24.7%)	6952/27,580 (25.2%) versus 6882/ 27,470 (25.0%)	55%	1.02 [0.95–1.09]
Cesarean delivery	50/360 (13.9%) versus 81/360 (22.5%)	809/3957 (20%) versus 772/ 3759 (20%)	5669/23,263 (24.4%) versus 5555/ 23,351 (23.8%)	6528/27,580 (23.7%) versus 6408/ 27,470 (23.3%)	79%	0.95 [0.84–1.08]
Admission to NICU	7/360 (1.9%) versus 21/360 (5.8%)	137/3,957 (3.5%) versus 143/ 3759 (3.8%)	Not reported	144/4,317 (3.3%) versus 164/4119 (4.0%)	80%	0.60 [0.23–1.58]
Hypoxic-ischemic encephalopathy	3/360 (0.8%) versus 5/360 (1.4%)	7/3957 (0.18%) versus 8/ 3759 (0.21%)	18/23,263 (0.1%) versus 21/23,351 (0.1%)	28/27,580 (0.1%) versus 34/27,470 (0.1%)	0%	0.82 [0.49–1.35]
Perinatal death	0/360 (0%) versus 0/360 (0%)	1/3957 (0.025%) versus 0/3759 (0.000%)	6/23,263 (0%) versus 4/23,351 (0%)	7/27,580 (0.02%) versus 4/27,470 (0.01%)	Not applicable	1.64 [0.51–5.32]

Data are presented as number in the intervention group versus number in the control group. NICU: neonatal intensive care unit; RR: relative risk.

Conclusions

In summary, compared with visual analysis, use of computer analysis of fetal monitoring signals during labor at term or late preterm did not significantly reduce the rate of metabolic acidosis or obstetric intervention.

Disclosure statement

No potential conflict of interest was reported by the authors.

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