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REVIEW

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Perinatal and Neonatal Outcomes Using Cardiotocography *Versus* STAN and Cardiotocography: a Systematic Review

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ABSTRACT

Objectives: *ST waveform analysis (STAN) was introduced to improve the interpretation of cardiotocography (CTG) resulting in reduction of unnecessary interventions and metabolic acidosis. A systematic review was conducted with the aim to evaluate the effect of STAN method compared with isolated CTG on perinatal and neonatal outcomes.*

Materials and methods: *A search of electronic databases (PubMed, Cochrane, Scopus) was conducted to identify randomized controlled trials (RCTs) in English language. Outcomes considered operative deliveries, fetal blood sampling (FBS), metabolic acidosis, perinatal and neonatal death, neonatal seizures, neonatal encephalopathy, transfer to the neonatal intensive care unit (NICU) and Apgar score.*

Results: *Seven RCTs were included in the present review. The first two RCTs showed that the combination of STAN and CTG was a better option than using CTG alone, because there was a documented reduction in the rate of operative deliveries due to fetal distress and metabolic acidosis. The following studies showed no statistically significant changes with the combination of methods, except from a reduction in FBS.*

Conclusions: *The findings from the RCTs were inconclusive. Most studies did not demonstrate a superiority of the combination regarding operative deliveries and neonatal outcomes but there were many methodological differences between the trials.*

Keywords: CTG, cardiotocography, STAN, ST waveform analysis, fetal ECG, fetal electrocardiography, operative deliveries, metabolic acidosis, fetal blood sampling, FBS, neonatal outcomes.

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INTRODUCTION AND OBJECTIVES

Electronic fetal monitoring (EFM) is a widely used method that is employed to identify preventable cases of fetal harm but there is still controversy over its value in clinical practice. Cardiotocography (CTG) was first introduced in the 1960s and the purpose of this method was to detect changes of the fetal heart rate (FHR) characteristics and to determine the fetuses who were at risk of hypoxia and may benefit from an early delivery (1, 2). Intrapartum hypoxia and subsequent metabolic acidosis are related to complications such as admission to neonatal intensive care unit (NICU), hypoxic ischemic encephalopathy (HIE), neonatal death, cerebral palsy, and learning difficulties (3, 4).

Cardiotocography is characterized by a high sensitivity, but it has only a limited specificity in predicting fetal hypoxia (5). To reduce false positive cases and unnecessary medical interventions, several adjunctive technologies have been developed to further estimate fetal oxygenation, such as fetal blood sampling (FBS), fetal stimulation, pulse oximetry and ST waveform analysis of fetal electrocardiogram (ECG) (6). Fetal blood sampling is an invasive procedure that requires appropriate laboratory equipment and provides intermittent information because it detects evidence of hypoxia in peripheral tissue (7). Other tools for fetal surveillance have not been proved to be more effective (8, 9).

ST waveform analysis (STAN), a relatively new method for continuous fetal monitoring, has been introduced after extensive experimental research (10). The fetal ECG (electrocardiogram), like the adult ECG, records electrical events of the heart in form of waves. Information can be evaluated about the amplitude of the T wave in relation to the QRS complex (T/QRS ratio) and the shape of ST segment (6, 7, 11). Fetal hypoxia is associated with changes in the ST waveform either a biphasic ST segment or an increase in the T/QRS ratio in combination with EFM abnormalities (12). To determine the benefits of the STAN method, many randomized controlled trials (RCTs) as well as numerous systematic reviews and meta-analyses have been performed. However, their outcomes were different and conflicting. In 2019, a new RCT providing information about late-term pregnancies was conducted (13).

The aim of the present systematic review was to evaluate the effect of the ST waveform analysis of fetal ECG as an adjunctive method to CTG compared with isolated CTG on perinatal and neonatal outcomes. ❑

MATERIAL AND METHODS

A systematic search of electronic databases (PubMed, Cochrane, Scopus) was performed in mid-2022 to identify studies that investigated perinatal and neonatal outcomes using CTG combined with ST waveform analysis compared to CTG. This review considered only RCTs published in English language without restriction on the year of publication. Randomized trials that analyzed the PR interval rather than the ST segment of the fetal ECG as well as non-randomized trials were excluded. Reference lists of included articles were also used as an additional search method.

Our search strategy was as follows: "pregnant" OR "laboring women" AND "cardiotocography" OR "CTG" OR "electronic fetal monitoring" OR "EFM" OR "intrapartum fetal monitoring" AND "STAN" OR "ST analysis" OR "ST waveform analysis" OR "ST segment" OR "fetal electrocardiography" OR "fetal ECG" and related to the search in the title, abstract or keywords. Titles and abstracts were first screened to exclude apparently irrelevant studies. The full texts of the remaining articles were then reviewed to determine whether they met the inclusion criteria.

The following inclusion criteria were used: 1) population – laboring women with a fetus in cephalic presentation and continuous electronic fetal monitoring during labor; 2) intervention – CTG combined with STAN; 3) comparison – CTG; and 4) outcomes – perinatal outcomes such as operative deliveries (cesarean delivery, instrumental vaginal delivery) and fetal blood sampling, and neonatal outcomes such as metabolic acidosis, perinatal and neonatal death, neonatal seizures, neonatal encephalopathy, transfer to the NICU and Apgar score.

Data collection and analysis was simultaneously conducted by two authors. The initial database search resulted in 250 articles, of which 37 were duplicates (Figure 1). Titles and abstracts were then screened for relevance to the aim of the review. After evaluating the titles and abstracts, 206 articles were excluded because they were ir-

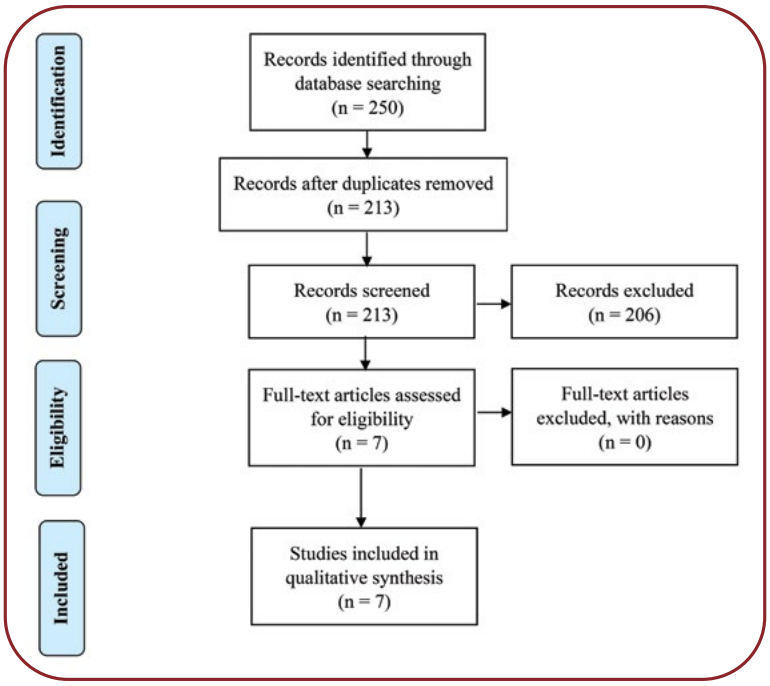

FIGURE 1. Flow chart

relevant to the aim of the study. Seven studies were fully reviewed and met all inclusion criteria. Data from the seven remaining studies were analyzed and assessed for methodological quality using the CONSORT checklist (14). ❑

RESULTS

A randomized clinical trial of pregnant women at more than 34 weeks of pregnancy with no known difficulties was conducted for one year at Plymouth General Hospital in the United Kingdom (15). The recordings were made with the use of the HP 8040A cardiotocogram recorder (Hewlett-Packard, Boblingen, Germany) or STAN 8801 recorder (Cinventa AB, Molndal, Sweden). During that year, 2400 deliveries were included in the trial: 1212 of them were monitored with the cardiotocogram arm and the remaining 1188 with the ST waveform analysis plus cardiotocogram arm. The results of the study demonstrated that fetal blood sampling was performed in more women in the CTG arm than the STAN arm. Also, more episodes of metabolic acidosis and low 5-minute Apgar scores were reported in the CTG arm. Regarding the operative deliveries, there was a highly significant reduction in total operative deliveries for fetal distress in the STAN arm, but there were no differences in the number of operative deliveries for failure to progress between the two arms.

Similarly, in another trial which was conducted in Sweden from 1998 to 2000, 4966 pregnant women at more than 36 completed weeks were monitored either with CTG alone or ST waveform analysis using the STAN S21 (Neoventa Medical) recorder, combined with cardiotocography (16). The study showed that ST waveform analysis with CTG reduces fetal hypoxia during labor as well as the number of operative deliveries for fetal distress. Specifically, 2447 women were monitored with CTG and 2519 with STAN. Metabolic acidosis, the first parameter considered by us, was defined as a cord-artery blood pH of less than 7.05 and BDecf of more than 12 mmol/L (17). The second parameter was the number of operative deliveries for fetal distress and the third one, neonatal morbidity based on Apgar scores at 1 and 5 min and admission to NICU, while fetal blood sampling was optional in both groups. Although, statistically significant differences were not observed between the two groups regarding the Apgar score, admission to NICU or neonatal encephalopathy, there was a significantly lower rate of cases with metabolic acidosis in the STAN group. In this group also, the number of operative deliveries for fetal distress was significantly lower, suggesting that ST waveform analysis combined with CTG led to a significantly improved perinatal result.

On the contrary, a randomized trial in which 1472 women at 36 or more weeks of pregnancy were enrolled showed that there were no statistically significant superior results in the STAN group (using the same recorder STAN S21 with Amer-Wahlin *et al*, 2001) compared to the CTG group (18). The trial was conducted in Finland for one year (2003-2004), with 733 women being included in the STAN group and 739 in the CTG group. There were no statistically significant differences in metabolic acidosis, neonatal outcomes or rate of operative deliveries between the two groups, which led to the conclusion that automatic ST waveform analysis may not contribute to an improvement of neonatal outcome. However, ST waveform analysis led to FBS reduction.

A study conducted in French hospitals investigated whether the ST-segment analysis (with STAN S21, Neoventa Medical) along with CTG could decrease the operative deliveries in women with abnormal cardiotocography in labor. In that

study, 399 out of 799 women with abnormal cardiotocography were placed in the STAN group and 400 women in the CTG group (19). Neonatal outcomes did not differ between the two groups and STAN did not lead to operative delivery rate reduction (cesarean or instrumental) for non-reassuring fetal status. The authors noticed an important reduction in the number of women whose fetus had at least one scalp blood pH measurement during labor in the STAN group.

The findings of the Dutch study with 5667 women in high-risk pregnancies over the 36 weeks showed that, although ST analysis combined with CTG decreased the metabolic acidosis, no changes in the Apgar scores and rate of operative deliveries were observed (20). Participants to that study were assigned to the index group (2827 women wearing a scalp electrode connected with a STAN S21 or S31) and the control group (2840 women wearing a scalp electrode connected to a conventional CTG). The incidence of metabolic acidosis calculated in the extracellular fluid was lower in the STAN group, but the incidence of metabolic acidosis calculated

TABLE 1. Methodological characteristics of included studies

	Number of centers	Inclusion criteria	Sample size	Type of electronic fetal monitoring
Westgate, 1993, UK	Single center	All pregnancies of >34 weeks; with no gross fetal abnormality and with a decision to apply a scalp electrode	2.400	Internal or external
Amer-Wahlin, 2001, Sweden	Multicenter three centers	Laboring women; ≥36 weeks; singleton fetus; cephalic presentation; with a clinical decision of continuous internal CTG	4.966	Internal
Ojala, 2006, Finland	Single center	Laboring women; ≥36 weeks; singleton fetus; cephalic presentation; with a decision of amniotomy	1.472	Internal or external
Vayssiere, 2007, France	Multicenter two centers	Laboring women; ≥36 weeks; singleton fetus; cephalic presentation; with abnormal CTG or thick meconium-stained amniotic fluid	799	Internal or external (not specified)
Westerhuis, 2010, Netherlands	Multicenter nine centers	Laboring women aged ≥18 years; ≥36 weeks; singleton fetus; cephalic presentation; high risk pregnancy; with an indication for internal EFM	5.667	Internal
Belfort, 2015, USA	Multicenter 16 centers	Laboring women; ≥36 weeks; singleton fetus; with cervical dilation of 2 to 7 cm	11.108	Internal
Puertas, 2019, Spain	Single center	Laboring women; late term pregnancy (between 291 and 294 days); singleton fetus; cephalic presentation	200	External

continuation of Table 1

	STAN device	CTG device	Classification system	Randomization
Westgate, 1993, UK	STAN 8801 (Cinventa AB)	CTG (Hewlett-Packard 8040A)	4-tier system FIGO	Original randomization using sealed envelopes
Amer-Wahlin, 2001, Sweden	STAN S21 (Neoventa Medical)	Masked STAN S21	4-tier system FIGO	Allocation by STAN software at start-up (computer-generated table of random numbers)
Ojala, 2006, Finland	STAN S21 (Neoventa Medical)	CTG (Hewlett-Packard 8030A)	4-tier system FIGO	Opaque numbered sealed envelopes (randomization code generated by a computer program in blocks of 100)
Vayssiere, 2007, France	STAN S21 (Neoventa Medical)	CTG (Hewlett-Packard 8030A)	4-tier system FIGO	Opaque numbered sealed envelopes stratified by center (dilation at randomization (centimeters)
Westerhuis, 2010, Netherlands	STAN S21 or S31 (Neoventa Medical)	Conventional FHR monitor	4-tier system FIGO	Stratified randomization by center and parity (on a 1:1 basis through a web-based computer-generated randomization sequence with variable block size)
Belfort, 2015, USA	STAN S31 (Neoventa Medical)	Masked STAN S31	3-tier system FDA	Encrypted randomization installed on the S31 monitors (separate randomization sequence for each monitor)
Puertas, 2019, Spain	STAN S31 (Neoventa Medical)	CTG (Philips Avalon FM30)	4-tier system FIGO	Serially numbered opaque envelopes (allocation ratio 1:1)

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	Primary outcomes	Secondary outcomes
Westgate, 1993, UK	Operative delivery for fetal distress, metabolic acidosis in extracellular fluid	FBS, Apgar score, NICU admission
Amer-Wahlin, 2001, Sweden	Metabolic acidosis in extracellular fluid	Operative delivery for fetal distress, Apgar score, NICU admission, neonatal encephalopathy
Ojala, 2006, Finland	Neonatal acidemia (umbilical artery pH <7.10)	Operative intervention, FBS, umbilical artery pH <7.05, metabolic acidosis in blood
Vayssiere, 2007, France	Operative delivery for non-reassuring fetal status	Total rate of operative deliveries, FBS, metabolic acidosis in extracellular fluid, Apgar score, NICU admission, neonatal convulsions, neonatal death
Westerhuis, 2010, Netherlands	Metabolic acidosis in extracellular fluid	Operative delivery, FBS, metabolic acidosis in blood, Apgar score, total neonatal admissions, NICU admission, neonatal encephalopathy
Belfort, 2015, USA	Composite of neonatal outcomes	Maternal outcomes, neonatal outcomes
Puertas, 2019, Spain	Neonatal outcome (arterial blood pH for non-reassuring fetal status)	Maternal outcome (type of delivery and indications for each type)

continuation of Table 1

	Results
Westgate, 1993, UK	STAN group: significant reduction in operative deliveries for fetal distress, trend to less FBS, trend to less metabolic acidosis, trend to fewer low 5-minute Apgar score
Amer-Wahlin, 2001, Sweden	STAN group: significant reduction in operative deliveries for fetal distress, significant reduction in metabolic acidosis, no significant differences regarding Apgar score, NICU admission, neonatal encephalopathy
Ojala, 2006, Finland	STAN group: significant reduction in FBS, no reduction regarding umbilical artery pH <7.05, metabolic acidosis in blood, no differences regarding neonatal acidemia, operative intervention, Apgar score, NICU admission, neonatal encephalopathy
Vayssiere, 2007, France	STAN group: significant reduction in FBS, no differences regarding operative delivery for non-reassuring fetal status, total rate of operative deliveries, metabolic acidosis in extracellular fluid, Apgar score, NICU admission, neonatal convulsions, neonatal death
Westerhuis, 2010, Netherlands	STAN group: reduction in metabolic acidosis in extracellular fluid, significant reduction in metabolic acidosis in blood, reduction in FBS, operative deliveries were comparable between the groups, no differences regarding Apgar score, total neonatal admissions, NICU admission, neonatal encephalopathy
Belfort, 2015, USA	No differences regarding primary composite neonatal outcomes, maternal outcomes, secondary neonatal outcomes Increase to the frequency of the low 5-minute Apgar score in STAN group
Puertas, 2019, Spain	No statistically significant differences regarding neonatal and maternal outcomes between the groups

in the blood was significantly lower in this group. Also, the need for FBS was significantly lower in the STAN group than the CTG group.

After the European studies, an American study was also conducted, which concluded that ST waveform analysis combined with CTG did not improve perinatal outcomes or the number of operative deliveries (21). That multicenter randomized trial included 11108 women at 36 weeks (or more) with a singleton pregnancy, of whom 5576 subjects were assigned to the masked group, in which the STAN S31 device was utilized as a common electronic FHR monitor, and the remaining 5532 were assigned to the open group, in which the STAN S31 device was displayed ECG ST-segment information. The study claimed that there was no significant difference in the neonatal and maternal outcomes, except for the Apgar score of 3 or less at 5 minutes, which was more frequent in the open group.

More recently, a study based on a homogeneous population was conducted in Spain, in contrast to previous studies which have included both high and low risk population with disparate

inclusion criteria (13). The population sample included women with a singleton late-term pregnancy (about 291 to 294 days) because those pregnancies were at risk for FHR alterations during labor. This randomized study included 200 women, of whom 100 were enrolled to the CTG group and 100 to the STAN group (using the STAN S31, Neoventa Medical). The authors claimed that there were no differences in the number of operative deliveries, including the number of cesarean deliveries, or in neonatal outcomes between the two groups comprising of women in late-term pregnancies.

The results of the above studies are summarized in Table 1. ❑

DISCUSSION

The combination of an abnormal CTG and a progressive ST-wave elevation was associated with the group of fetuses in which metabolic acidosis was detected. The ST-wave elevation is possibly explained by glycogenolysis in the myocardium and activation of anaerobic metabolism through a wave of catecholamines, activation of adrenergic receptors, as the expected physiological response to hypoxemia (22). The occurrence of metabolic acidosis in fetuses can lead to perinatal complications up to birth asphyxia (23). Indeed, in the study by Westgate *et al* there was a 46% reduction in the occurrence of operative deliveries for fetal distress and a trend towards less metabolic acidosis ($p = 0.09$) (15). The authors highlighted that technological development of the STAN device would be necessary to identify an ST-segment depression. Towards this direction, the study by Amer-Wahlin *et al* used a new instrument that corrected the limitations of the earlier study (16). The device in this study, using digital signal processing, performed automatic evaluation of ST changes through a dedicated system. The data confirmed that the addition of ST wave analysis to conventional CTG improved the specificity of perinatal monitoring by reducing the rates of operative deliveries, fetal distress and metabolic acidosis.

The first studies showed that the combination of fetal ECG with CTG was a better option than using CTG alone (15, 16). Unlike the studies mentioned above, the Finnish trial recognized only one positive result regarding the needs of obtaining fetal blood (FBS), which were significantly lower in the STAN method (18). Subsequent studies had similar results with the Finnish trial. For example, the French trial, that included women with abnormal CTG, showed a significant reduction in FBS and no difference in terms of operative deliveries or metabolic acidosis (19). The Dutch trial also showed a reduction in FBS and no difference in operative deliveries with the STAN method but there was a significant reduction in metabolic acidosis calculated in blood and a reduction (not significant) in metabolic acidosis calculated in the extracellular fluid (20). In the US trial, where ST-wave analysis was combined with continuous fetal monitoring by CTG, no statistically significant changes were found to show superiority of the combination of methods (21). Also, the results of the Spanish trial, which included a homogeneous population, showed no change or statistically significant benefit from the combination of methods in terms of perinatal or neonatal complications (13).

Many RCTs and systematic reviews have been performed, but their outcomes were different and conflicting. Methodological differences between studies can explain these findings. For example, the Finnish trial was used a different base deficit (BD) algorithm from the other RCTs (18). In all studies, metabolic acidosis was defined as an umbilical cord artery blood pH < 7.05 and a BD in the extracellular fluid (BDecf) > 12.0 mmol/L, except for the Finnish trial, in which BD was calculated in the blood (BDblood), leading to a falsely elevated rate of metabolic acidosis (24). The US trial was used a three-category CTG classification (FDA guidelines) in contrast to the European trials, which used four-category CTG classification (FIGO guidelines), and this affected the clinical behavior (20, 25, 26). Another important difference was that the French RCT included women with abnormal CTG, which is a violation of STAN clinical guidelines as alerts for changes in the ST segment occur when the fetus is still well oxygenated (18, 24).

It is evident that, apart from the first two studies (14, 15), the remaining ones included in the present paper showed no significant differences between the use of STAN method combined with CTG and CTG alone (13, 18-21). A meta-analysis comparing STAN method with CTG, which was conducted by Blix *et al*, showed that STAN surveillance of the fetus could lead to less metabolic acidosis and less need for FBS (27). Another re-

view and meta-analysis by Saccone *et al* highlighted that STAN did not offer a better clinical choice when combined with CTG as it reduced perinatal outcomes and operative delivery rates in the same way the CTG did alone (28). One recent meta-analysis by Al Wattar *et al* collected data from the literature and compared studies based on the different fetal surveillance methods. Among them, STAN method and the combination with CTG were assessed for perinatal outcomes and no significant differences were evident (29).

The present review has some strengths, the literature was searched in a systematic manner and the inclusion criteria did not restrict to the year of publication. This increases the validity of the results as all available studies written in English were reviewed. The generalizability of the results was limited by the methodological differences between studies, such as heterogeneity in inclusion criteria of sample, different sample sizes, different management protocols, violations of STAN guidelines, differences in the CTG classification system and definition of metabolic acidosis. Future studies need a larger sample size and similar protocols to be able to generalize the results. ❑

CONCLUSIONS

Seven studies were included in the present paper after a detailed review of the literature to compare fetal monitoring methods about perinatal and neonatal outcomes. The methods compared included fetal electrocardiography with ST-wave analysis and cardiotocography, combined to isolated CTG. Most studies did not recognize a superiority of the combination in operative deliveries and neonatal outcomes. Cardiotocography is an essential method of monitoring the fetus with positive results. Analysis by STAN method is also a good choice but requires training in recognizing and interpreting the results. Both methods can be combined with fetal blood sampling when deemed necessary to identify complications of hypoxemia or metabolic acidosis. Overall, both methods are used in clinical practice with positive results, but their combination is controversial regarding the benefit of perinatal or neonatal outcomes.

The introduction of STAN was implemented to improve the interpretation of CTG and in turn reduce unnecessary interventions. To determine the benefits of STAN method, many RCTs as well as numerous systematic reviews and meta-analyses have been performed. However, the outcomes remain inconclusive. Although some studies suggested that the combined methods provided several benefits over the CTG alone, including lower rate of operative deliveries, a decrease in fetal metabolic acidosis and markedly improved neonatal outcomes, some studies failed to confirm the same outcomes. Thus, there is an indisputable need for improved methods as well as more randomized studies to evaluate fetal health during labor. ❑

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