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Review Article

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Fetal Electrocardiogram: St Waveform Analysis in Intrapartum Surveillance (Analisi Del Tratto St Dell'elettrocardiografia Fetale In Travaglio Di Parto)

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Abstract

ST-analysis of the fetal electrocardiogram (ECG) (STAN (®)) combined with cardiotocography (CTG) for intrapartum fetal monitoring has been developed following many years of animal research. Changes in the ST-segment of the fetal ECG correlated with fetal hypoxia occurring during labor. In 1993 the first randomized controlled trial (RCT), comparing CTG with CTG + ST-analysis was published. STAN (®) was introduced for daily practice in 2000. To date, six RCTs have been performed, out of which five have been published. Furthermore, there are six published meta-analyses. The meta-analyses showed that CTG + ST-analysis reduced the risks of vaginal operative delivery by about 10% and fetal blood sampling by 40%. There are conflicting results regarding the effect on metabolic acidosis, much because of controveries about which RCTs should be included in a meta-analysis, and because of differences in methodology, execution and quality of the meta-analyses. Several cohort studies have been published, some showing significant decrease of metabolic acidosis after the introduction of ST-analysis. In this review, we discuss not only the scientific evidence from the RCTs and meta-analyses, but also the limitations of these studies. In conclusion, ST-analysis is effective in reducing operative vaginal deliveries and fetal blood sampling but the effect on neonatal metabolic acidosis is still under debate. Further research is needed to determine the place of ST-analysis in the labor ward for daily practice.

Keywords: ST-Analysis; STAN; Cardiotocography; Fetal ECG; Intrapartum Fetal Monitoring.

1. Introduction

The cornerstone of intrapartum fetal well-being monitoring is cardiotocography (CTG), whose diagnostic accuracy has always been intensely debated in the scientific community. In fact, it is well known that there is a wide heterogeneity between institutions and different countries as regards the interpretation of cardiotocography, just as it has been demonstrated that the use of this technology leads to an increase in operations in the delivery room [1]. This last aspect has prompted the scientific community to question how to define non-reassuring CTG patterns in a more specific way. Some countries have responded by recommending intermittent auscultation in labor at low obstetric risk and thus reserving continuous cardiotocography for labor at high risk [2,3]. Similarly, to this trend, an effort has arisen over time to produce guidelines that make the interpretation of cardiotocographic monitoring easier. However, this effort was immediately limited by the existence of a wide variability in the interpretation of the tracings among different operators, even among cardiotocography experts [4].

Therefore, in an attempt to improve the diagnostic accuracy of cardiotocography, some ancillary methods have been explored.

Still today, some northern European centers use fetal scalp sampling to evaluate fetal oxygenation through pH or lactate in the event of a non-reassuring CTG tracing, in such a way as to limit the rate of unnecessary operative deliveries and caesarean sections [5,6]. The utility of fetal scalp harvesting has recently been questioned for various reasons [7]. First, only a few studies have demonstrated that scapula sampling correlates with perinatal hypoxia; secondly, it is not clear whether this method actually leads to a significant reduction in operating parts; finally, serious complications, albeit rare, have been attributed to the method, such as fetal haemorrhage, scalp abscess and CSF leakage [8-10]. These reasons have led some countries to abandon the use of this procedure.

A second ancillary method proposed is fetal scalp stimulation, which has recently been the subject of a Cochrane review. The latter included two randomized clinical trials for a total of 377 singleton and full-term pregnant women, failing to obtain definitive conclusions regarding the efficacy of this procedure [11].

The third ancillary method to CTG is represented by STAN, the analysis of the ST segment of fetal electrocardiography. With 6 randomized clinical trials, 10 meta-analyses, and over 20 published observational studies, the latter is one of the most studied and discussed, and therefore the most controversial, techniques for monitoring fetal well-being [12].

2. What is STAN?

STAN combines standard CTG monitoring with simultaneous assessment of fetal electrocardiography (ECG).

The ECG represents the electrical currents that are generated in the myocardium. The first wave, the P wave, corresponds to the contraction of the atria. Next comes the phase of contraction of the ventricles, which corresponds to the QRS complex. Finally, the last component is the T wave, which corresponds to the regeneration of membrane potentials, precisely because the heart prepares for the next beat. The QRS complex is robust and is ideal for recording heart rate, which can be obtained by taking the R-R interval into consideration. A cardiotocograph only takes into consideration this single part of the fetal ECG. The STAN system, on the other hand, associate's changes in the ST interval with the R-R interval measurement. The ratio of the height of the T wave to the amplitude of the QRS complex (T/QRS ratio) provides an accurate measure of the changes that can affect the T wave.

Graphically, a horizontal or above-baseline ST segment and a T wave with stable, non-increasing amplitude are characteristic of a normal ST segment. This indicates a positive energy balance, typical of an aerobic myocardial metabolism.

When subjected to hypoxia, myocardial cells exploit anaerobic metabolism to produce energy. Cardiac hypoxia and ischemia can lead to ST segment depression and T wave inversion, similar to what occurs in ischemic myocardial disease in adults [13,14].

For the purpose of the ST analysis, a special electrode with tips is placed on the fetal scalp spiral. The analysis comes from the automatic evaluation of 30 ECG complexes. From this set the calculation of the T/QRS ratio is performed; ST segment analysis is also performed with consequent identification of biphasic ST. If, for example, the heart rate is 120 bpm and the signal quality is good, the evaluation of 4 ST segments per minute is performed [13,14].

2.1 Types of STAN Events

The fetus usually shows a stable T/QRS ratio on the ECG during labor. Not usually there are marked ST elevations and no biphasic ST either. Under these circumstances the event diary it does not report any ST events. The absence of significant ST events indicates that the fetus has the situation under control, and its energy balance within the myocardium is positive. ST analysis offers us therefore the possibility of recording a situation in which the fetus is defending itself from hypoxia.

When significant ST segment changes occur, an "ST event" alarm appears on the screen (marked by a small black box indicating the moment of its appearance on the CTG trace). In the lateral space, the details of the ST event appear, i.e. type and entity.

There are three Types of ST Events

1. Episodic increase in T/QRS: this is given by the increase in the T/QRS ratio (which in turn indicates an increase in the amplitude of the T wave) lasting less than 10 minutes. It is possible to notice that the crosses at the base of the screen first tend to go up and then to go down. If the increase is greater than 0.11 it is identified as significant and recorded as an ST event. Physiologically, an episodic increase in T/QRS corresponds to short-term hypoxia, during which the fetus is forced to use anaerobic metabolism to maintain cardiac function.

2. Evento ST bifasico: esso è caratterizzato da una discesa del tratto ST. A differenza degli aumenti del T/QRS, non viene notificata l'entità della discesa del tratto ST. Al contrario, la depressione viene classificata in 3 gradi, in base al rapporto della curva con la linea di base. Avremo pertanto: a) il tipo 1, in cui il tratto ST tende a scendere ma si mantiene al di sopra della linea di base; b) il tipo 2 in cui il tratto ST tende a scendere e attraversa la linea di base ma non è mai completamente al di sotto di questa; c) il tipo 3, in cui il tratto ST è situato completamente al di sotto della linea di base (15).

Gli eventi ST bifasici generalmente indicano una situazione in cui l'ipossia si sta verificando ma il feto non può o non ha ancora avuto il tempo di rispondere con un metabolismo anaerobico.

3. Biphasic ST Event: it is characterized by a descent of the ST segment. Unlike T/QRS elevations, there is no notification of the extent of ST-segment descent. Conversely, depression is classified into 3 grades, based on the relationship of the curve to the baseline. We will therefore have: a) type 1, in which the ST segment tends to descend but remains above the baseline; b) type 2 in which the ST segment tends to descend and crosses the baseline but is never completely below it; c) type 3, in which the ST segment is completely below the baseline (15).

Biphasic ST events generally indicate a situation in which hypoxia is occurring but the fetus cannot or has not yet had time to respond with anaerobic metabolism.

2.2 How to Interpret STAN Events?

STAN technology is ancillary to cardiotocography, and as such depends on it. Therefore, when using this tool, the first step consists in interpreting the current CTG tracing according to the guidelines adopted by the technology itself (see table 1) (15).

The subsequent clinical behavior depends on the category of the CTG trace.

If the CTG trace is normal, any STAN event should be ignored, as this represents the result of an adrenal surge in a healthy fetus. Consequently, no action should be taken in this condition.

Even in the case of a preterminal CTG tracing, STAN events should not be considered, as the severity of the situation often dictates immediate delivery.

If, on the other hand, the CTG trace is of an intermediate category, then it is advisable to evaluate the type and extent of the STAN event. Intervention is recommended when the STAN event exceeds the threshold indicated in the guidelines (Table 2). The rationale behind this approach is the following: the more worrying the CTG monitoring is, the lower will be the entity of the STAN event necessary to determine the indication for intervention (15).

In the first stage of labor, the intervention consists in the use of intrauterine resuscitation maneuvers with the aim of removing the causes that could justify fetal suffering. If the measures taken

do not lead to an improvement in CTG monitoring and STAN events persist, then delivery should take place within a reasonable time (and without resorting to fetal scab sampling).

During the second stage of labor a STAN event should require operative delivery unless spontaneous birth is imminent.

2.3 Scientific Evidence on STAN Technology

The first randomized clinical trial comparing ST analysis plus CTG with CTG alone was published in 1993 in Plymouth, UK (16). This study included 2434 women with high-risk labor, in whom continuous CTG monitoring was indicated. The primary outcome was the operation rate for intrapartum fetal distress. The total operation rate for fetal distress was 5% (61/1219) in the CTG plus ST arm, i.e. significantly reduced compared to that observed in the CTG only arm, which was 9.1% (111/1215). In contrast, the rate of metabolic acidosis was not significantly different between the two groups. However, what distinguished this study was the fact that the technique employed was different from today, i.e. the identification of ST-segment changes did not happen automatically. Consequently, the technology did not include automatic alarms, but a careful eye on the part of the clinician. Therefore, this trial provided the opportunity and the stimulus to further develop the STAN technology.

Between 2000 and 2010, 4 more randomized clinical trials were performed in Europe (Sweden, Finland, France and the Netherlands) with a later version of STAN. As in the previous trial, patients monitored with CTG plus STAN were compared with patients monitored with CTG alone.

Between December 1998 and June 2000, the Swedish trial was conducted which included pregnant women with gestational age > 36 weeks, active labour, fetus in cephalic presentation and indication for continuous CTG monitoring (17). 4966 patients were enrolled. In this case the primary outcome was the rate of metabolic acidosis (defined by pH < 7.05 and base deficit > 12 mmol/L), which was 0.7% (15 of 2159) in the CTG plus STAN arm and 2 % (31 of 2079) in the CTG only arm. The operation rate for fetal distress was 8% (193 of 2519) in the CTG plus STAN arm and 9% (227 of 2447) in the CTG only arm. A subsequent analysis performed with an intention to treat approach confirmed the benefit obtained from monitoring with the STAN technique (18).

Two more RCTs were performed between 2003 and 2006, one in Finland in 2003 and the second in France between 2004 and 2006. The Finnish trial enrolled women with gestational age > 36 weeks, active labor, cephalic fetus and underwent amniorexi, while women in the second stage of labor were deliberately excluded. The purpose of the Finnish trial was to test whether the STAN technique could be able to modify the rate of metabolic acidosis (defined by a pH < 7.10), the operative rate and the need for sampling on the fetal scalp (19). The prevalence of metabolic acidosis was 0.7% in the CTG arm, furthermore the population included was found to be at lower risk than that enrolled in the Swedish trial. The French trial instead included women with singleton pregnancy, gestational age > 36 weeks, cephalic fetus and suspicious or abnormal CTG monitoring (20). The objective of the trial was to verify whether STAN technology was able to reduce the operation rate for non-reassuring fetal status. 799 patients were included, and the prevalence of metabolic acidosis was 1.3% in the CTG arm alone.

Neither the Finnish nor the French trials were able to demonstrate a significant difference between the groups in terms of metabolic acidosis at birth and functioning. However, both studies demonstrated a significant reduction in the use of fetal scalp sampling in the CTG plus STAN arm.

Finally, between 2006 and 2008, the Dutch trial was conducted which considered the difference in the rate of metabolic acidosis between the two groups as the main outcome. The women enrolled were adults, with single pregnancy at high obstetric risk, cephalic fetus, active labor and gestational age of at least 36 weeks (21). The prevalence of metabolic acidosis was 0.1% in the CTG arm (30/2840), not significantly different from the prevalence in the CTG plus STAN arm (0.7%, 20/2827).

From this overview of the first 5 randomized clinical trials, it is clear that there is no uniformity between the results. Only the Swedish trial demonstrated a significant reduction in the rate of metabolic acidosis in the CTG plus STAN arm compared to the CTG alone arm. However, it is also true that both the Finnish and the French trials were not developed with the aim of identifying whether there were significant differences between the groups regarding this outcome. Operation rates for nonreassuring fetal status or suspected fetal distress were significantly different in the STAN plus CTG arm in the English and Swedish trials only.

In 2015, the last randomized clinical trial was published involving 26 centers in the United States including 11108 women with singleton at term pregnancy (>36 weeks of gestation) and cephalic fetus (22). Unlike previous trials, this one also included patients with low obstetric-risk pregnancies. The primary outcome of the study was composite, and included: intrapartum fetal death, neonatal death, Apgar score < 3 to 5 minutes, neonatal seizures, metabolic acidosis, intubation for ventilation at delivery, and neonatal encephalopathy. Well, no significant difference was found between the two groups in relation to this composite outcome nor in relation to the operation rate in the delivery room. However, it must be said that this trial was characterized by important differences in methodology compared to previous trials (12):

1. The trial was performed in 26 centers taking over 3.5 years (41 months). The very low inclusion rate in some centers suggests a lack of adequate experience with STAN technology;

2. Recruitment was limited to weekdays from 8 to 14, and the population was predominantly made up of patients at low risk of fetal hypoxia. With 43,376 patients evaluated for eligibility and as many as 32,268 patients excluded because they were deemed ineligible, selection bias represents a real possibility.

3. The composite outcome chosen as the primary outcome of

the study turned out to be surprisingly low in both arms of the study: 0.94% in the CTG + STAN arm and 0.72% in the CTG arm, compared to the expected rate of 1.75%. This suggests the presence of the Hawthorne effect.

4. The STAN guidelines used in Europe were simplified in the United States, lowering the cut-off for interventionism. In detail, the American guidelines recommended a shorter wait (60 instead of 90 minutes) and smaller entities of the ST events before intervening. Furthermore, the guidelines also contained the suggestion not to rely only on STAN events to intervene, but also on clinical judgment. In case of cardiotocographic or clinical suspicion of fetal distress, the clinician could ignore the STAN and intervene as he thought best. It is therefore understandable how these recommendations could have had important consequences. First, it is likely that these suggestions may have led to an increase in the rate of unnecessary interventionism. Secondly, a study structured in this way could not really demonstrate whether the addition of ST analysis of the fetal ECG to cardiotocography could actually reduce the risk of fetal compromise.

In conclusion, the differences between the trials in terms of study protocols, inclusion criteria, enrollment rates, guidelines, use of fetal scalp harvesting and definition of critical outcomes make the interpretation of the results very difficult. The most recent meta-analysis using adjusted data from each clinical trial demonstrated that STAN technology is capable of reducing scalp puncture rate by 41%, operation rate by 8%, and metabolic acidosis rate by 8%. 36%. Similar benefits have not been described for other intrapartum fetal monitoring techniques (12).

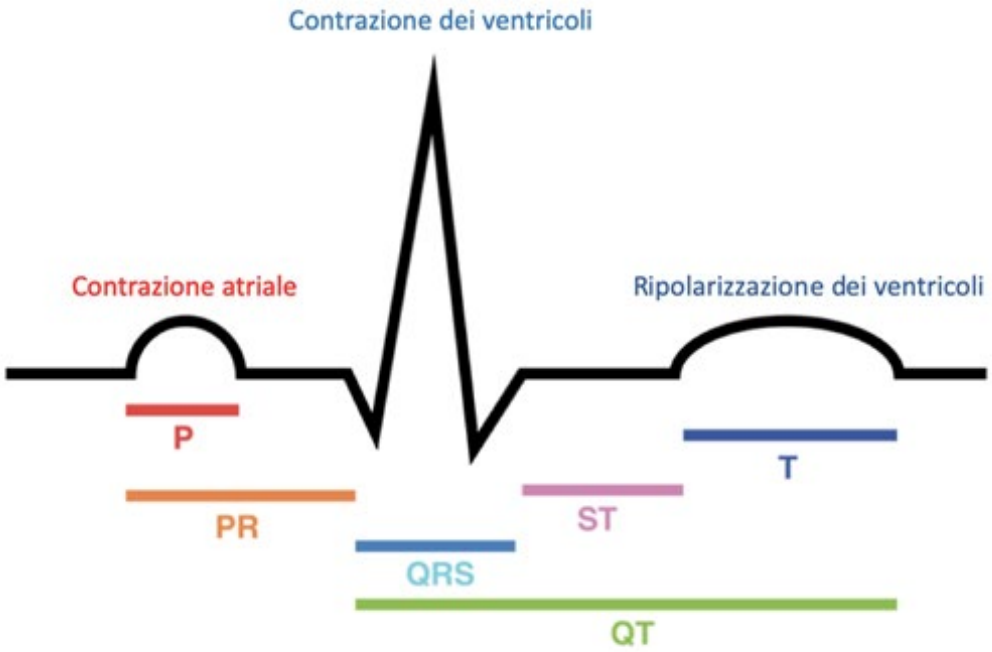

Figure 1: Schematic representation of a normal ECG complex. The P wave represents atrial contraction, the QRS complex represents contraction of the ventricles, and the T wave indicates repolarization of the ventricles.

	Linea di base	Variabilità	Decelerazioni
CTG normale	110-150 bpm	Accelerazioni 5-25 bpm	• Decelerazioni uniformi precoci • Decelerazioni variabili non complicata (durata < 60 sec, < 60 bpm perdita)
CTG intermedio	• 100-110 bpm • 150-170 bpm • Episodio breve di bradicardia (<100 bpm per ≤ 3 min)	• 25 bpm (pattern saltatorio) • < 5 bpm > 40 min con assenza di accelerazioni	Decelerazioni variabili non complicata (durata < 60 sec, > 60 bpm perdita)
• **CTG anormale**	• 150-170 bpm e ridotta variabilità • >170 bpm • Bradicardia persistente (<100 bpm per > 3 min)	• < 5 bpm per > 60 min • Pattern sinusoidale	Decelerazioni variabili complicate con durata > 60 sec Decelerazioni uniformi tardive ripetitive
CTG preterminale	Totale assenza di variabilità (2 bpm) e reattività con o senza decelerazioni o bradicardia		

Table 1: Cardiotocography classification system to be used with STAN technology. The goal is to increase the specificity of the interpretative ability of cardiotocography, in situations in which the fetal state is considered not reassuring.

Evento ST	Aumento T/QRS episodico	Aumento linea di base T/QRS	ST bifasici
CTG normale	Management d'attesa e sorveglianza continua		
CTG intermedio	> 0.15	> 0.10	3 eventi bifasici **
CTG anormale	> 0.10	> 0.05	2 eventi bifasici **
CTG preterminale	Parto immediato		

Table 2: ST analysis and situations where intervention* is required

*The intervention could include delivery or maternal-fetal resuscitation by removing the possible causes of fetal distress (for example uterine hyperstimulation by oxytocin infusion, maternal hypotension, etc.)

**Duration between biphasic ST events should be related to CTG pattern and clinical situation.

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