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Combined cardiotocographic and ST event analysis: A review

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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.

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Introduction

Electronic fetal heart rate (FHR) monitoring is a widely used method for assessing fetal status during labor. It aims to enable clinicians to identify hypoxic fetuses at risk for deterioration and provide prerequisites for a decision to intervene, and to deliver either vaginally or by cesarean section, thereby avoiding neonatal and long-term injury due to intrapartum asphyxia. Although little evidence exists regarding its efficacy, monitoring through cardiotocography (CTG) continues to be the method of choice in modern labor and delivery units in developed countries [1]. Despite this, there has been no significant reduction in the incidence of long-term neurologic morbidity (including cerebral palsy) and research has been stimulated by the low true positive predictive value of CTG for metabolic acidosis, which often results in unnecessary interventions and a significant increase in the cesarean section rate during the last 40 years due to concerns during labor. The addition of fetal blood sampling (FBS) is believed to hamper this effect; however, systematic reviews report no evidence of benefit in reducing the operative interventions [2]. Furthermore, FBS has also been shown to have a poor positive predictive value for intrapartum hypoxia [3]. This is probably due to the fact that performance of FBS requires expertise, is invasive, and must be repeated with persisting CTG abnormalities, and thus is often not performed when indicated [4].

Other tools for fetal surveillance, for example, fetal pulse oximetry, have not been successful maybe due to the well-known challenge lying in developing new and emerging technologies, related not only to the need to provide basic physiology data but also to meet requirements of data acquisition, signal processing, and data presentation [5]. Furthermore, any method in the fetal monitoring area requires understanding and compliance to clinical guidelines as well as a positive attitude toward changes of practice, a truly challenging perspective in such a medico-legally loaded field. Other important aspects related to evaluating the effect of medical technology are the choice of outcome parameters, the study design, the clinical setting of a trial, the ownership of the technique, as well as financial support available for its development. Moreover necessary clinical trials are expected to meet evidentiary standards that were never applied to existing technologies.

ST-analysis of the fetal electrocardiogram (ECG; STAN®) was introduced in the labor wards in 2000, after many years of research, starting with experimental animal research. Early animal studies observed that changes in the ST-segment of the fetal ECG correlated with fetal hypoxia occurring during labor [6,7]. The ST analyzer (STAN® monitor; Neoventa Medical, Goteborg, Sweden) was developed to combine traditional CTG with automatic analysis of the ST-segment of the fetal ECG. Changes in the shape of the ST-segment are noted automatically and an ST event is generated for a significant ST-change (Fig. 1). Guidelines have been developed defining whether intervention is required according to changes occurring in the CTG in combination with ST-changes of the fetal ECG (Table 1) [8].

Protocols to guide the use of a medical device have to be assessed and approved by the company responsible for the technology as part of the CE-marking process and by the FDA before any use in the United States. This implies that a change of guideline is limited by regulations similarly to change of an indication in relation to drugs. The premarketing approval (PMA) process, required for any new methodology, is the most stringent process that requires full documentation, including basic pathophysiology, signal processing, data presentation, control of device design, production, and software and adequate clinical data to support its safe and efficient use. On the basis of all these data and years of efforts, marketing approval is granted based on specific indications and method of use, and is enforced by law. Thus, it is not just the availability of a specific technology that allows a clinician to apply it, but the limit up to which it is approved for use.

The technique

The STAN® concept is based on the association between changes of the ST-interval of the fetal ECG and the function of the fetal myocardium during hypoxia. The changes in fetal ECG associated with fetal distress are either an increase in T-wave amplitude, quantified by the ratio of T-wave amplitude to QRS-amplitude (T/QRS ratio), or a biphasic ST-segment. An increase in T-wave amplitude and subsequently