OBSTETRICS

# The importance of the learning process in ST analysis interpretation and its impact in improving clinical and neonatal outcomes

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**BACKGROUND:** Intrapartum fetal heart rate monitoring was introduced with the goal to reduce fetal hypoxia and deaths. However, continuous fetal heart rate monitoring has been shown to have a high sensitivity but also a high false-positive rate. To improve specificity, adjunctive technologies have been developed to identify fetuses at risk for intrapartum asphyxia. Intensive research on the value of ST-segment analysis of the fetal electrocardiogram as an adjunct to standard electronic fetal monitoring in lowering the rates of fetal metabolic acidosis and operative deliveries has been ongoing. The conflicting results in randomized and observational studies may partly be due to differences in study design.

**OBJECTIVE:** This study aims to determine the significance of the learning process for the introduction of ST analysis into clinical practice and its impact on initial and subsequent obstetric outcomes.

**STUDY DESIGN:** This was a prospective observational study with the primary objective to evaluate the importance of the learning period on the rates of metabolic acidosis and operative deliveries after the implementation of ST analysis. The study was conducted at the Turku University Hospital, Turku, Finland, with 3400—4200 annual deliveries. The whole study population consisted of all 42,146 deliveries during the study period 2001 through 2011. The ST analysis usage rate was 18%. The data were collected prospectively from labors monitored with ST analysis as an adjunct to conventional intrapartum fetal heart rate monitoring. Primary endpoints were the rates of metabolic acidosis (cord artery pH <7.05 and an extracellular fluid compartment base deficit >12.0 mmol/L), fetal scalp blood sampling, and operative deliveries. Comparisons of these outcomes were made between the initiation period (the first 2 years) and the subsequent usage period (the next 9 years).

**RESULTS:** In the whole study population the prevalence of cord pH <7.05 decreased from 1.5—0.81% (relative risk, 0.54; 95% confidence interval, 0.43—0.67), the rate of cesarean deliveries from 17.2—14.1% (relative risk, 0.82; 95% confidence interval, 0.89—0.97), and the rate of fetal scalp blood sampling from 1.75—0.82% (relative risk, 0.47; 95% confidence interval, 0.38—0.58) when the 2 study periods were compared. In the ST analysis group, the frequency of cord metabolic acidosis rate was reduced from 1.0—0.25% (relative risk, 0.33; 95% confidence interval, 0.15—0.72).

**CONCLUSION:** We provide evidence that the results improve over time and there is a learning curve in the introduction of the ST analysis method. This was demonstrated by the lower rates of metabolic acidosis and operative deliveries after the initial implementation period.

**Key words:** acute operative delivery, cesarean delivery for fetal distress, fetal acidemia, fetal distress, fetal electrocardiogram analysis, fetal heart rate monitoring, fetal myocardial ischemia, forceps, intrapartum fetal monitoring, learning curve, nonreassuring fetal heart rate

## Introduction

Electronic fetal heart rate (FHR) monitoring was introduced with the goal to detect fetuses at increased risk for neonatal hypoxia. Continuous FHR monitoring has been shown to be superior to intermittent auscultation in detecting fetal compromise and preventing perinatal mortality.[1-4] However, the results have been conflicting and the benefits of FHR monitoring have not been conclusively established.[5-7] Even when experienced clinicians use accepted guidelines, FHR interpretation has a low specificity and a low positive predictive value in detecting metabolic acidemia.[8-13] To prevent neonatal hypoxia and avoid unnecessary operative deliveries, adjunctive technologies have been developed to further assess fetal oxygenation.

ST waveform analysis of the fetal electrocardiogram (ECG) as an adjunct to standard electronic fetal monitoring (EFM) has been developed over the last 4 decades. ST segment elevation is a sign of myocardial infarction in adults.[14] An increase in the T wave height reflects metabolic adaptation to hypoxia also in fetuses.[15-17] Experimental studies with guinea pig and lamb fetuses have demonstrated that during acute hypoxia, a mature fetus reacts with an elevation of the ST segment and a progressive increase in T wave height.[18] ST analysis of the fetal ECG was introduced to clinical practice in the late 1990s. The STAN technology (Neoventa Medical AB, Mölndal, Sweden) adds analysis of the ST segment of the fetal ECG to the internal FHR monitoring and has been described in previous publications.[18,19] Six randomized controlled trials (RCTs) comparing the STAN methodology to standard FHR monitoring have shown differing results in fetal outcomes and obstetrical interventions due to fetal distress,[20-26] and subsequent meta-analyses have not been able to establish a consistent result.[27-34] While RCTs are the gold standard for assessing a new technology, they do not typically reflect everyday practice. Real-world evidence can provide complementary information on how a new technology influences the outcomes in regular clinical use and

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## AJOG at a Glance

### Why was this study conducted?

We sought to determine the importance of a learning process for the introduction of ST analysis as an adjunct to standard electronic fetal monitoring into clinical practice and its impact on obstetric outcomes.

### Key findings

When the first 2 years of ST analysis usage were compared to the subsequent 9 years there was a significant reduction in the rates of metabolic acidosis and operative deliveries.

### What does this add to what is known?

The benefits of ST analysis may not be evident in the early stages of adoption, since there is a learning period in the introduction and the results improve over time.

therefore the Food and Drug Administration is developing guidance on the use of real-world evidence—health care information to assess the safety and effectiveness of drugs and medical devices.[35-39] Thus, these RCTs should be complemented with observational studies conducted over much longer periods of time that are more consistent with standard obstetric practice.

Despite the controversies in RCTs, many European obstetric units are now using ST analysis in clinical practice and some have published observational studies that have demonstrated a reduction in adverse perinatal outcomes.[40-48] Implementation of a new methodology typically requires that clinical users change their practice patterns in accordance with a set of new guidelines. However, prior to a methodology's becoming common practice, there is often a so-called learning curve, or a period of time during which experience is gathered and proficiency is attained.[49-51] Because the identification of clinically significant ST events requires knowledge and repeated training, we believe that a learning curve exists in the incorporation of the method into routine clinical practice.

The objective of the present prospective observational study was to assess the learning process in using ST waveform analysis as an adjunct to standard EFM. We compared obstetric interventions and neonatal outcomes from the first 2 years of implementation of ST analysis with those observed subsequently during routine use of the method.

## Materials and Methods

Turku University Hospital, a tertiary referral center, has approximately 4000 deliveries per year. The current prospective observational study was conducted from 2001 through 2011. Over this time period, ST analysis was adopted as an adjunct to standard EFM. Complete patient demographic data, obstetric interventions, and neonatal outcomes were tracked as will be noted later. During the study period the number of deliveries per year increased but the proportion and profile of high-risk deliveries remained similar over the years. Adjunctive ST analysis was implemented during our participation in the European community multicenter trial[52] in the fall of 2000. Our labor and delivery unit was equipped with 3 STAN S21 devices from 2000 through 2002. One additional device was added in 2003 and 1 STAN S31 was acquired in 2007.

Implementation of ST analysis in clinical practice necessitates education, training, and certification for the whole obstetric staff and in our hospital all obstetricians and midwives were trained in the new method. The initial training included lectures and multimedia-based teaching with simulated cases. All staff members were certified with a test as ST analysis users with a formal credential prior to incorporating this methodology in clinical practice. For the first 2 years, a dedicated obstetrician and midwife were responsible for the continuing education. For the remainder of the period under observation, a physician superuser dedicated to the method and training (ST) provided the education for the obstetric staff. All new staff members went through the certification as they started to work at the delivery unit. We wanted to evaluate if a learning period of 2 years with intensive training was long enough to establish a new method and the same time frames (the first 2 and the subsequent 9 years) are used in analyzing the results.

The use of the ST analysis methodology and all cases were systematically reviewed as part of the European community trial. After the initiation of ST analysis into clinical practice, education, training, and case reviews of difficult or questionable cases continued. The training in FHR interpretation is part of standard practice and good interpretation skills are required in all deliveries independent of ST analysis usage.

The indication for using ST analysis was 36 completed gestational weeks and a decision to apply a scalp electrode when there is an identified maternal or fetal risk factor for fetal hypoxia. High-risk patients were eligible for monitoring with the ST analysis according to the decision of the attending staff and availability of equipment. Specific indications included modified International Federation of Gynecology and Obstetrics (FIGO) category intermediate or abnormal heart rate tracings, meconium-stained amniotic fluid, intrauterine growth restriction, maternal diabetes, hypertension and/or preeclampsia, postterm delivery, twins, breech presentation, and induction of labor. Due to the limited numbers of available STAN monitors, not all eligible patients could be assessed with STAN devices.

From 2001 forward, all data collected as described below were prospectively registered in a dedicated database provided by the European community trial. From November 2009 onward, data have been entered into a computerized delivery logbook. ST analysis recordings

are automatically given a unique identification number at the time of the recording associated with the patient's social security number. Approval for use of deidentified hospital register data was obtained from the Hospital District of Southwest Finland. No ethics committee approval was considered necessary.

EFM was used in all deliveries. FHR tracings were interpreted according to the modified FIGO 1985 4-tier classification system,[53] which is a part of the STAN clinical guidelines.[54] The additional information from ST analysis was used when the FHR pattern was interpreted as intermediary or abnormal. Intrapartum fetal scalp blood sampling (FBS) was performed at the discretion of the attending obstetrician irrespective of monitoring technique. Cord artery blood sampling was routinely obtained immediately after birth. In cases monitored with ST analysis, both artery and vein samples were obtained whereas routinely only 1 sample (artery pH) was obtained in the FHR only group. The same system was used throughout the study period. Measurements of pH and partial carbon dioxide were used to calculate extracellular fluid compartment base deficit (BDecf) using the Siggaard-Andersen[55] acid-base data chart algorithm. Metabolic acidosis was defined as cord artery pH <7.05 and a BDecf >12.0 mmol/L. Validation of the cord acid-base data was performed as previously described by Amer-Wåhlin et al.[26] This validation process requires both cord artery and vein samples with the cord artery sample showing a lower pH (difference at least 0.03) and higher $p_{CO2}$ (difference at least 1.0 kPa). In cases with only 1 available blood sample, metabolic acidosis was defined according to the same criteria as for the cord artery sample (pH <7.05 and BDecf >12.0 mmol/L).

Operative deliveries included both instrumental vaginal (vacuum and forceps) and all cesarean deliveries. FBS was registered on a per patient basis, as 1 patient can have >1 sampling procedure. FBS results were interpreted according to general guidelines: pH >7.25 normal, 7.20-7.25 needs to be checked again in 30 minutes, and pH <7.20 appoints for immediate delivery. If FBS was obtained to ensure fetal well-being in cases where FHR was abnormal in the beginning of ST analysis, a normal pH value ensured the reliability of ST analysis usage.

### Statistical analysis

The results were evaluated with software (SAS, version 9.2; SAS Institute Inc, Cary, NC). Fisher exact test was used to compare the time period 2001 through 2002 with the time period 2003 through 2011. Relative risk with 95% confidence intervals between the periods were calculated; $P$ values <.05 were considered significant.

## Results

From 2001 through 2011, our labor and delivery unit performed 42,146 deliveries. To establish the learning curve, we compared the first 2 years of ST analysis usage with the subsequent 9 years (Table). Because only umbilical cord arterial pH was routinely available for patients monitored with FHR alone, comparisons included those patients with pH <7.05, FBS use, and mode of delivery. In the whole study group the rate of arterial pH <7.05 decreased from 1.5−0.81% ($P < .0001$) and the rate of FBS usage from 1.75−0.82% ($P < .001$). During the study period there were 6142 cesarean deliveries, of which 57% were for suspected fetal distress during the first 2 years and 54% during the subsequent period. The rate of total operative deliveries decreased from 23.5−21.9% ($P = .0027$) and the rate of cesarean deliveries from 17.2−14.1% ($P < .0001$).

In the early years of the study period there was a significant increase in the usage of the ST analysis due to the staff becoming more familiar with the new method. During the whole study period ST analysis was used in 7723 (18%) deliveries. The indications for using ST analysis, clinical practice, and baseline characteristics of the patients were not altered during the study period. There were 27 newborns with cord artery metabolic acidosis among the cases monitored with ST analysis; 10 (37%) occurred during the initial 2 years. When all deliveries monitored with ST analysis in the period from 2001 through 2002 were compared to the period from 2003 through 2011, there was a significant decrease in the prevalence of metabolic acidosis (1.0% vs 0.25%, $P = .0035$). Figures 1 and 2 show the annual rates of obstetric interventions, outcomes, and ST analysis usage for 2001 through 2011.

## Comment

### Principal findings of this study

In the whole study population after the introduction of ST analysis as an adjunct to standard EFM there was a significant reduction in: (1) the prevalence of cord pH <7.05 (1.5% vs 0.81%); (2) the rate of operative deliveries (23.5% vs 21.9%); (3) the rate of cesarean deliveries (17.2% vs 14.1%); and (4) the need of FBS usage (1.75% vs 0.82%) when the first 2 years of ST analysis usage were compared to the subsequent 9 years. Also, in the ST analysis group the rate of metabolic acidosis was reduced from 1.0−0.25%. We found that after the adoption of ST analysis in obstetric practice, there is a learning curve after which the benefits of the method are achieved.

Our 11-year prospective observational study represents one of the longest continuous clinical experiences with an EFM system that incorporates adjunctive analysis of the fetal ST segment. A follow-up time of several years makes it possible to evaluate the clinical benefits of this new method in everyday obstetric practice and the impact of a learning curve.

### Previous studies

The use of EFM is controversial, hence the method has a high sensitivity but only a limited specificity in predicting fetal hypoxia. Meta-analysis of the RCTs have failed to show conclusively that EFM during labor reduces cerebral palsy, infant mortality, or other standard measures of neonatal well-being.[7] Continuous EFM often leads to unnecessary interventions due to the high false-positive rate of the method.[7] Several adjunctive technologies have been developed to further assess fetal oxygenation.

The debate of the usefulness of EFM with additional ST segment analysis continues, although several RCTs,

**TABLE**
**Obstetric interventions, outcomes, and ST analysis usage 2001 through 2002 compared to 2003 through 2011**

| | 2001 through 2002 | 2003 through 2011 | | |
|---|---|---|---|---|
| | n = 6867 | n = 35,279 | *P* value | RR (95% CI) |
| Total operative deliveries | 1614 (23.5%) | 7712 (21.9%) | .0030 | 0.93 (0.89–0.97) |
| Cesarean delivery | 1178 (17.2%) | 4964 (14.1%) | <.0001 | 0.82 (0.77–0.87) |
| Operative vaginal delivery | 436 (6.3%) | 2748 (7.8%) | <.0001 | 1.23 (1.11–1.35) |
| ST analysis usage | 1001 (14.6%) | 6722 (19.1%) | <.0001 | 1.31 (1.23–1.39) |
| Fetal blood sampling | 120 (1.75%) | 291 (0.82%) | <.0001 | 0.47 (0.38–0.58) |
| Metabolic acidosis in ST cases | 10 (1.0%) | 17 (0.25%) | .0151 | 0.33 (0.15–0.72) |
| pH <7.05 in all deliveries incl. ST cases | 104 (1.5%) | 286 (0.81%) | <.0001 | 0.54 (0.43–0.67) |

*CI*, confidence interval; *RR*, relative risk.
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meta-analysis, and observational studies have been published. The effectiveness of ST analysis in the prevention of metabolic acidosis, unnecessary operative deliveries, and fetal blood sampling has been studied in 6 RCTs.[20-25] The designs of the trials have varied considerably and the results have been conflicting. The duration of the studies has varied from 14–41 months; recruitments per center and month have differed; and, importantly, the trials have been performed in the beginning of the use of this new method after a short prestudy training. In the study by Amer-Wåhlin et al[26] a clear learning effect was found in the second part of trial. This was confirmed in the meta-analysis by Schuit et al,[28] whereas the recent US trial[25] did not find any significant differences between the study periods. RCTs have their place in developing scientific evidence about the efficacy and safety of new methods, but their information should be completed with real-world evidence.[39] Some observational studies have investigated the effects of long-term use of ST analysis. In the Swedish study the outcomes were monitored over a period of 7 years and the rate of metabolic acidosis fell from 0.72–0.06%.[47] In the study by Kessler et al[43] the study period was 5 years and the rate of metabolic acidosis decreased from 1.4–0.3%. The study by Chandraharan et al[46] also lasted 5 years and the rate of metabolic acidosis decreased from 1.35–0.76%. The rate of operative deliveries decreased slightly or remained unchanged in these studies. In our study the cord metabolic acidosis rate was reduced from 1.0–0.25% between the study periods and the rate of total operative deliveries also decreased significantly.

Fetal blood sampling as an additional test for fetal well-being has been used mainly in Central and Northern Europe. After the implementation of adjunctive ST analysis a reduction in the use of FBS has been shown in several studies.[22-24] Our study confirmed these results. It seems logical that when the confidence in the new technology increased the use of this conventional and more invasive method decreased.

## The learning curve

Previously, other authors have noted the importance of the learning curve when introducing a new medical technology.[43,47,56,57] Our study supports this notion and suggests that a learning curve may have a rather long duration when there is an initiative to introduce knowledge (education and training), validation of knowledge and training (certification and credentialing), and assessment of proficiency (clinical audit) for an entire obstetric staff (physicians, midwives, and nurses).

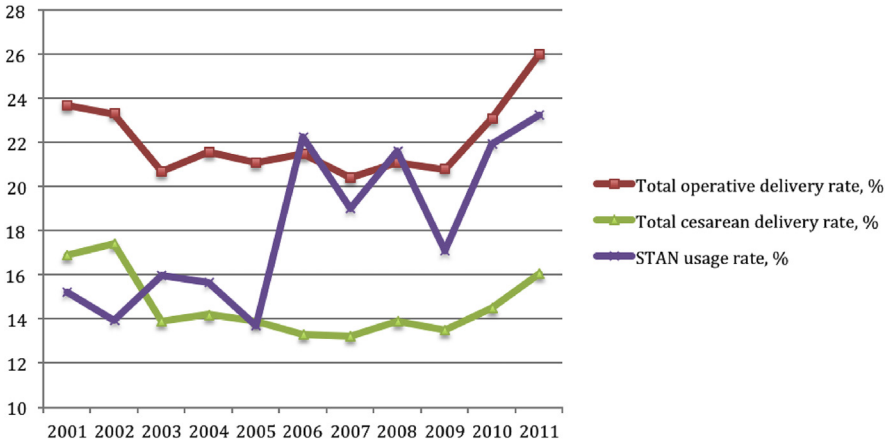
Such a gradual and thorough approach to the introduction and use of new technology, as was undertaken at our institution, would appear to be justified by the outcomes that we observed.

## Strengths and limitations

In an observational study with a follow-up period of several years a confounding bias is a threat to validity of the research.[58] A slight limitation of this study is that we were not able to make complete comparisons of baseline characteristics in patients between the 2 study periods. However, as the number of STAN machines was a limiting factor it is not likely that the number of low-risk patients monitored with ST analysis would increase significantly over time. In Finland, the high-risk patient population has increased slightly during the study period,[59] as it has in most Western countries.

A comprehensive educational program with user certification and credentialing is a crucial part of the implementation of ST analysis. It is possible that better understanding of fetal physiology improves FHR interpretation skills and perinatal outcomes even without ST analysis. However, EFM has been used for decades and despite intensive efforts directed at training, certification, and the development of specific protocols for the management of abnormal FHR patterns, the results have been controversial.[8] Our results show that even in a high-risk population it is possible to achieve very low rates of metabolic

**FIGURE 1**
**Percentage of operative deliveries in total population and STAN usage rate**

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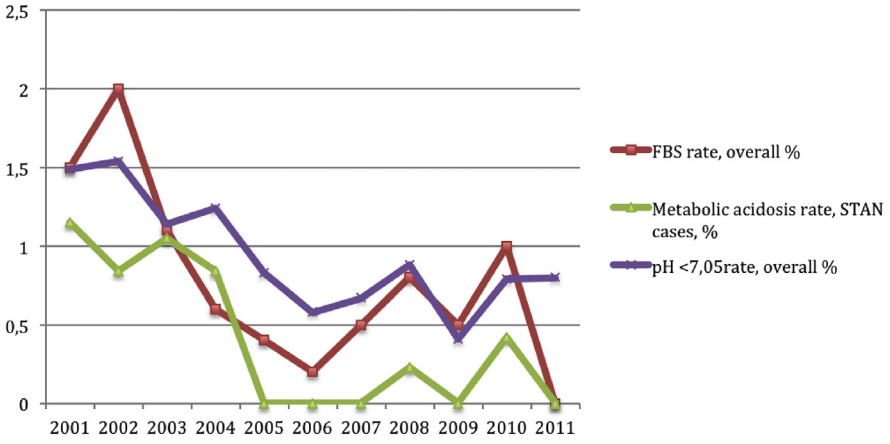
acidosis once the staff becomes familiar with a new technology and to maintain improved outcomes over several years.

## Implications for practice

A good intrapartum decision-support tool should be associated with a reduction in unneeded interventions coupled with improved perinatal outcomes. In our study, the former is reflected by a decrease in cesarean delivery rates and use of FBS, and the latter by a reduction in cord artery metabolic acidosis. A slight increase in the number of operative vaginal deliveries might be due to the fact that during active phase of the labor the fetus is in increased risk for hypoxia and therefore the STAN alerts more frequently than during the first stage of labor. The appropriate intervention during the active phase is usually an operative vaginal delivery.

The success of ST analysis in regular clinical use depends on correct interpretation and appropriate intervention. This study adds more support to the clinical benefits of ST analysis in everyday obstetric practice. Review of this study's findings demonstrates that use of ST analysis achieves some of the very same goals that were pursued by the original RCTs. While the RCTs showed that obstetric outcomes were *usually* improved by use of ST analysis, when compared to the use of standard FHR monitoring alone, our study suggests that, in regular clinical use, such improvements may not be evident in the early stages of adoption. Therefore, clinicians and hospitals considering the adoption of the ST analysis system should recognize not only that a learning curve exists, but also that its duration may be quite long. Finally, as intended in its original and current clinical protocols, the incorporation of ST analysis into routine clinical practice mandates that regular case audits be performed to insure continued proficiency after the learning period has been completed.

**FIGURE 2**
**Percentage of metabolic acidosis, overall pH <7.05 and fetal scalp blood sampling (FBS) usage**

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## Implications for research

A properly designed RCT with a follow-up period of several years is needed to determine the efficacy of ST analysis in preventing adverse pregnancy outcomes. The results should be analyzed in shorter time periods to determine the effect of the learning curve. Education, training, and case reviews are important when introducing a new medical technology to obstetric practice and this should be noticed also in further studies.

The ability of ST analysis to provide early detection of fetal acidemia in special high-risk groups (eg, patients with intrauterine growth restriction, macrosomia, or postterm pregnancies) deserves further investigation. The alterations in ST segments may be different in special high-risk pregnancies and with a subgroup analysis it might be possible to identify fetuses deriving a larger benefit from the use of the method.

## Conclusion

In conclusion, our data suggest that in real-life practice the use of intrapartum ST analysis as an adjunct to standard EFM reduces the rates of metabolic

acidosis and operative deliveries. The benefits of the method may not be evident in the early stages of adoption, since there is a learning period in the introduction and the results improve over time. ■


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