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Fetal ECG Analysis for Intrapartum Electronic Fetal Monitoring: A Review

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Abstract: Computerized analysis of the fetal electrocardiogram has been developed during the past 40 years. A mature system for ST analysis (STAN) has resulted from a series of laboratory and clinical studies. The current STAN system provides adjunctive information to the standard interpretation of fetal heart rate (FHR) patterns. This monograph describes the basis for the STAN methodology, including the derivation of its basic measure, the T : QRS ratio. It summarizes the supporting research and clinical trials that have led to its adoption in obstetric practice. The STAN methodology is outlined according to current fetal heart rate classification and management guidelines. Recent clinical experiences with STAN systems in Europe and the United States are discussed. Finally, future directions for this technology are listed.
Key words: intrapartum fetal monitoring, fetal electrocardiography, ST segment analysis, fetal metabolic acidosis, STAN system

Introduction

Randomized controlled trials (RCTs) of electronic fetal monitoring (EFM) began to appear in the mid-1970s but failed to show benefits of EFM. Recent meta-analysis[1] showed that, when compared with fetal heart rate (FHR) auscultation, EFM led to higher operative delivery rates without significant lowering perinatal mortality. Adjunctive methods to improve the specificity of EFM, such as fetal scalp blood sampling for pH determination, were introduced in the mid-1970s. The addition of fetal scalp pH to standard EFM has been associated with the reduction of neonatal seizures but was largely abandoned in the United States 2 decades ago.[2] More recently, fetal pulse oximetry was introduced to improve the screening ability of EFM. A fetal pulse oximetry system was approved by the Federal Drug Administration on the basis of reduced cesarean delivery rates for ''nonreassuring'' FHR patterns but was not supported by a subsequent National Institute of Child Health and Human Development (NICHD) clinical trial.[3]

The shortcomings of EFM have been well outlined in the most recent American College of Obstetricians and Gynecologists

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Practice Bulletin[4] which has also shown that interpretation of a significant number of EFM tracings are problematic without additional data. Observations of the fetal electrocardiogram (fECG) stimulated research and development of a novel technology for automated fECG analysis.[5] The timeline for this system, known as ST analysis (STAN), is shown in Figure 1.

Background: Research and Development

Direct FHR recordings require the identification and capture of the fECG through a fetal scalp electrode. However, the critical elements in the fECG that could serve as markers for fetal myocardial status needed to be identified. In the early 1970s, Rosen et al[6] using a fetal guinea pig model showed that environmental hypoxia was associated with a significant elevation of the T-wave in the fECG. The biochemical alterations that accompanied this phenomenon included an increase in myocardial glycogenolysis and liberation of potassium. Elevations in T-wave height were shown to accompany increased local catecholamine concentrations associated with progressive, unrelieved hypoxemia.[7] The increase in T-wave height relative to the amplitude of the QRS complex was identified when the fetus transitions from aerobic to anaerobic metabolism in an environment of increased β-adrenergic release. Subsequently, a reliable measure of myocardial metabolic status, the T : QRS ratio (Fig. 2) was established. These findings led investigators to a focus on this modality in fetuses which were near term. Further observations identified other changes in the ST-segment, that is, biphasic or ST depression, which occurred when fetuses with chronic oxygen deprivation were subjected to acute hypoxic stress.

During the 1980s, the initial STAN systems were developed and refined in studies of human pregnancies (see Fig. 1). The important developments in this period were (1) improved signal processing allowing accurate recognition and capture of fECG; (2) computerized routines for calculating and displaying baseline T : QRS ratios and ST depression; and (3) establishment of clinical guidelines for applying these data to patient management.

Initial human studies by Rosen and Lindecrantz[8] led to further prospective trials by Arulkumaran et al[9] in which the specificity of the T : QRS ratio (Fig. 2) was established for fetuses which had normal umbilical arterial buffering capacity. The parameters chosen for T : QRS ratio had a 99% specificity for normal fetuses and enabled the detection of hypoxia when the T : QRS ratio exceeded threshold. These clinical parameters were refined and validated in an observational study by Amer-Wahlin et al[10] which yielded a 100% sensitivity for metabolic acidemia (pH < 7.05 and base deficit > 12.0 mmol/L).

Mature technology for clinical usage appeared during the 1990s resulting in the development of the STAN S-21 model which has been superseded in the current decade by the STAN S-31 model (v. Fig. 3).

Description of STAN Systems

The STAN fetal monitoring system includes a conventional EFM system that displays standard fetal heart and uterine activity patterns with the addition of automated STAN. STAN usage is governed by a FHR classification matrix and a set of clinical guidelines which will be described later in this section. There is a comprehensive and mandatory education program to introduce new users to the STAN method.

Indications for clinical usage are shown in Table 1. ST-segment analysis parameters have been shown to be gestational

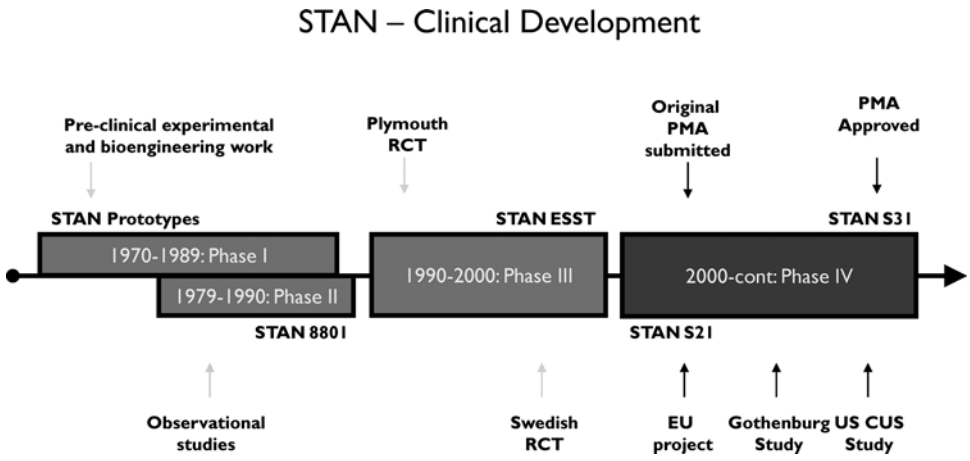


FIGURE 1. Developmental history of ST analysis (STAN) systems. For details see the text. EU indicates European Union; FDA, Federal Drug Administration; PMA, premarket approval; RCT, randomized controlled trial; US CUS, United States Clinical Usage Study.

age-dependent and deliberately limited to term fetuses considered at risk for intrapartum hypoxia. As the STAN method requires a fetal scalp electrode and ruptured membranes, so that any condition which contraindicates the use of invasive monitoring, for example, active maternal herpes simplex, human immunodeficiency virus, and hepatitis, would preclude its use. The STAN system must be allowed to collect fECG data in a relatively stable intrapartum environment so that accurate T : QRS baseline can be set for future comparisons. This necessitates initiation of STAN in the first stage of labor.

The key parameters for STAN are the status of the baseline T : QRS and the appearance of ST segment waveforms. The T : QRS ratio is derived from a train

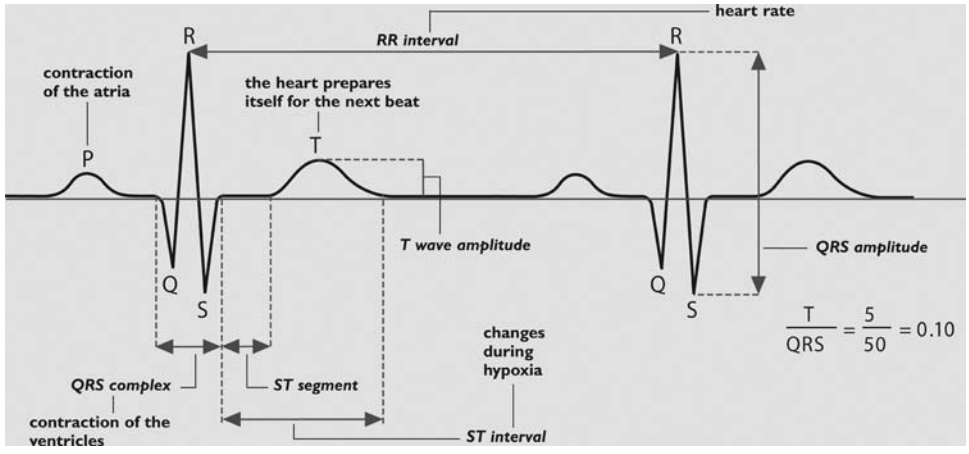


FIGURE 2. The basic electrocardiogram complex and derivation of T : QRS ratio. The T : QRS ratio is derived from the height of the T-wave (circled) divided by the amplitude of the QRS complex (circled) (Courtesy, Neoventa Medical).

FIGURE 3. ST analysis (STAN) Model S-31 Monitor System (Courtesy, Neoventa Medical).

of 30 consecutive valid cardiac cycles. The baseline T : QRS is determined over 20 T : QRS ratios and then tracked for changes over time. Figure 4 shows a typical tracing with baseline T : QRS noted by the cross-hatches in the second channel.

Alerting is performed by the STAN monitor when 1 of 3 situations occurs: (1) there is an episodic rise in T : QRS (greater than 0.10 for less than 10 min); (2) there is a baseline T : QRS rise (greater than 0.05 for more than 10 min); and (3) there are recurrent biphasic ST segments (Fig. 5). These alerts appear as flags on the top of the monitor display and are noted in the Event Log.

TABLE 1. STAN Clinical Guidelines

Before using STAN
> 36 + 0 gestational weeks
Ruptured membranes
No contraindication for scalp electrode or STAN
First stage, no active or involuntary pushing
At onset of STAN
Classify the FHR. Check for FHR reactivity and nondeteriorating fetal state
Check for normal ECG waveform with sufficient signal quality
Check for message indicating that baseline T/QRS is determined

ECG indicates electrocardiogram; FHR, fetal heart rate; STAN, ST analysis.

The combined use of FHR interpretation and STAN is based on an FHR classification scheme which resembles that of the recently published NICHD guidelines.[11] Figure 6 shows the classification matrix which defines 3 zones of FHR patterns—green, yellow, and red. Green zone tracings have a high likelihood of normal fetal oxygenation. Red zone tracings have the highest probability of fetal hypoxia and acidemia. Yellow zone tracings are indeterminate. Although most will be adequately oxygenated, a few will be academic.

The FHR classification is linked to a clinical management protocol shown in Figure 7. Regardless of the presence or absence of ST events, green zone FHR tracings require no intervention. Red zone tracings mandate urgent intervention such as resuscitation and/or delivery, with or without ST events. The management of yellow zone tracings is directly impacted by the presence of ST changes and stage of labor. Two examples of yellow zone tracings with and without ST event alerts are shown in Figures 8 and 9.

The STAN methodology differs from earlier EFM systems as it requires user

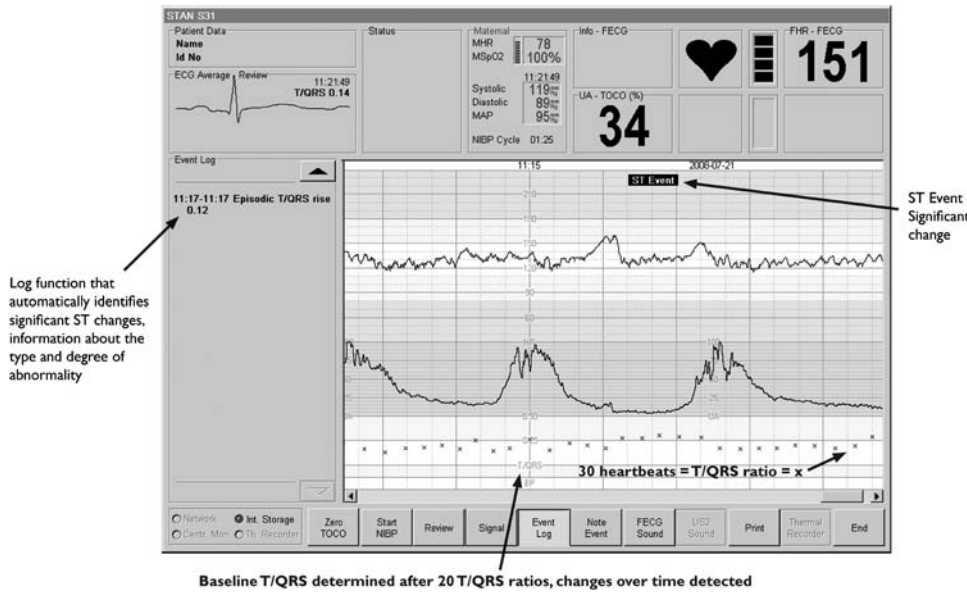


FIGURE 4. ST analysis (STAN) recording illustrating the actual fetal electrocardiogram, the ST event log, and ST alerts (Courtesy, Neoventa Medical).

certification and credentialing. All users must complete an educational tutorial, pass a written certifying examination, and then be credentialed on clinical usage by correctly applying the STAN Clinical Guidelines to real cases. The goal of this process is to ensure that the STAN method is being used properly and according to guidelines.

Clinical Trials of STAN

RCTs

After the development of functional STAN systems in the 1990s, 2 large RCTs were conducted, the first being a single center study in the United Kingdom[12] and the second, a multicenter study in Sweden.[13] The main outcome of interest was a reduction in cord artery metabolic acidosis (pH < 7.05 and base deficit > 12 mmol/L) with the addition of STAN data. The major outcomes of both studies are listed

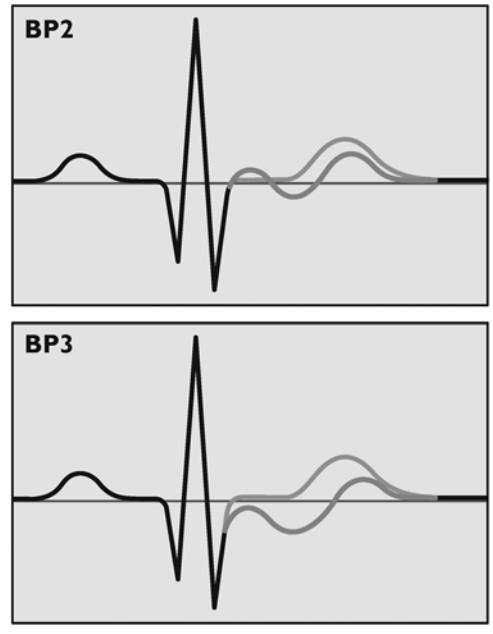
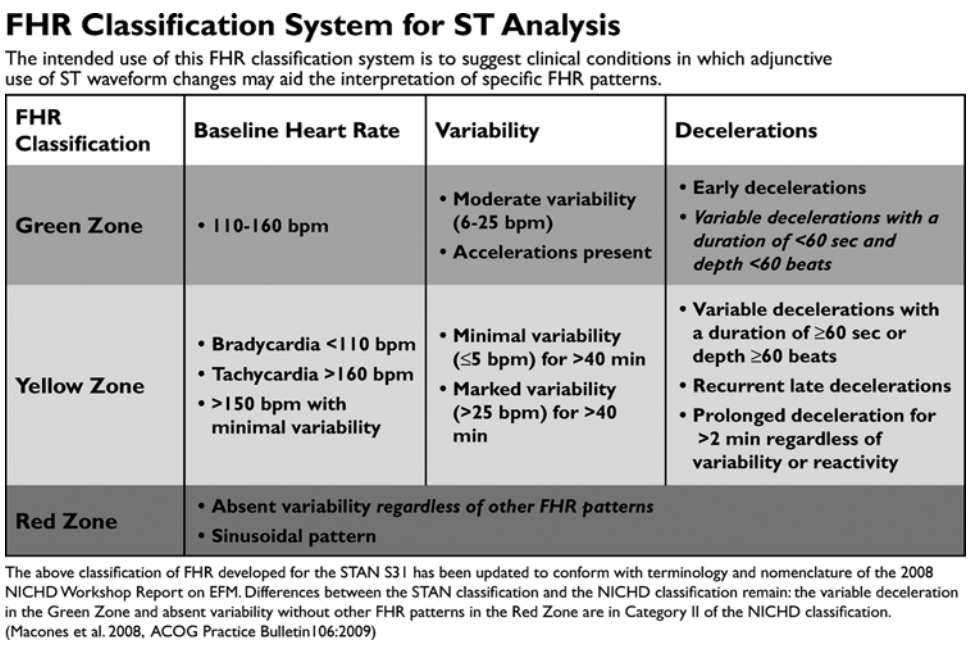


FIGURE 5. Biphasic (depressed) ST segments 2 (above) and 3 (below) (Courtesy, Neoventa Medical).



FHR Classification System for ST Analysis

The intended use of this FHR classification system is to suggest clinical conditions in which adjunctive use of ST waveform changes may aid the interpretation of specific FHR patterns.

FHR Classification	Baseline Heart Rate	Variability	Decelerations
Green Zone	• 110-160 bpm	• Moderate variability (6-25 bpm) • Accelerations present	• Early decelerations • *Variable decelerations with a duration of <60 sec and depth <60 beats*
Yellow Zone	• Bradycardia <110 bpm • Tachycardia >160 bpm • >150 bpm with minimal variability	• Minimal variability (≤5 bpm) for >40 min • Marked variability (>25 bpm) for >40 min	• Variable decelerations with a duration of ≥60 sec or depth ≥60 beats • Recurrent late decelerations • Prolonged deceleration for >2 min regardless of variability or reactivity
Red Zone	• Absent variability *regardless of other FHR patterns* • Sinusoidal pattern		

The above classification of FHR developed for the STAN S31 has been updated to conform with terminology and nomenclature of the 2008 NICHD Workshop Report on EFM. Differences between the STAN classification and the NICHD classification remain: the variable deceleration in the Green Zone and absent variability without other FHR patterns in the Red Zone are in Category II of the NICHD classification. (Macones et al. 2008, ACOG Practice Bulletin106:2009)

FIGURE 6. ST analysis (STAN) classification guidelines for fetal heart rate (FHR) classification (Courtesy Neoventa Medical). ACOG indicates American College of Obstetricians and Gynecologists; EFM, electronic fetal monitoring; NICHD, National Institute of Child Health and Human Development.

in Table 2. The most important finding was a significant reduction in fetal metabolic acidosis and reduction in operative delivery. Follow-up studies of the neonates showed a significant reduction in neonatal encephalopathy although neither trial was powered for this outcome.[14]

The most recent Cochrane review[15] includes 2 more recent RCTs.[16,17] Table 3 includes all 4 trials considered by this review and 1 trial that concluded after its publication.[18] Although the overall meta-analysis suggested that the addition of STAN did not affect the outcomes of interest, that is, reduction in metabolic acidosis or operative vaginal delivery rates, these results should be interpreted cautiously because of the difference in design and powering of the additional studies. Interestingly, there was an overall reduction in neonatal encephalopathy seen in the groups enrolled in the ST arms in both newer RCTs.

The most recent RCT was performed in the Netherlands[18] and showed a significant decrease in cord artery metabolic acidosis, as calculated in blood, when ST data were combined with FHR interpretation. It did not show significant differences in rates of operative deliveries or neonatal encephalopathy.

PROSPECTIVE COHORT STUDIES

Prospective cohort studies involving the use of STAN in clinical care have succeeded the original RCTs. Noren and Carlsson[19] conducted a 7-year follow-up of STAN use in routine clinical practice. During the period covered, STAN usage increased from 28% to 70% in the Gothenburg obstetric unit, metabolic acidosis declined from 0.76% to 0.06%, and rates of operative vaginal deliveries remained stable. These are important observations because they show the

ST Analysis

These guidelines indicate situations in which obstetric intervention is required. An intervention may include delivery or maternal-fetal resuscitation by alleviation of contributing problems such as tachysystole, maternal hypotension and hypoxia.

	No ST Event	ST Event Episodic, Baseline or 2 Biphasic** log messages
Green Zone	• Expectant management • Continued observation	• Expectant management • Continued observation
Yellow Zone	• Expectant management, closer observation • If >60 min (or earlier if FHR shows rapid deterioration of fetal condition), direct physician assessment of fetal state	• Direct physician assessment • Intrauterine resuscitation as appropriate • If no improvement in fetal condition, expeditious delivery • In second stage with active pushing, expeditious delivery
Red Zone	• Expeditious delivery regardless of any ST changes	• Expeditious delivery regardless of any ST changes

**The time span between the Biphasic messages should be related to the FHR pattern and the clinical situation.

FIGURE 7. ST analysis (STAN) clinical guidelines for management of fetal heart rate (FHR) + ST (Courtesy, Neoventa Medical).

impact of the STAN methodology in actual practice rather than in RCTs where study conditions are typically under tighter oversight.

A nonrandomized cohort study was conducted in 6 United States obstetric centers.[20] This study aimed to show that US physicians, trained in the STAN methodology, could use it effectively as intended. It showed that when yellow zone tracings occurred without ST events and no intervention was undertaken, the

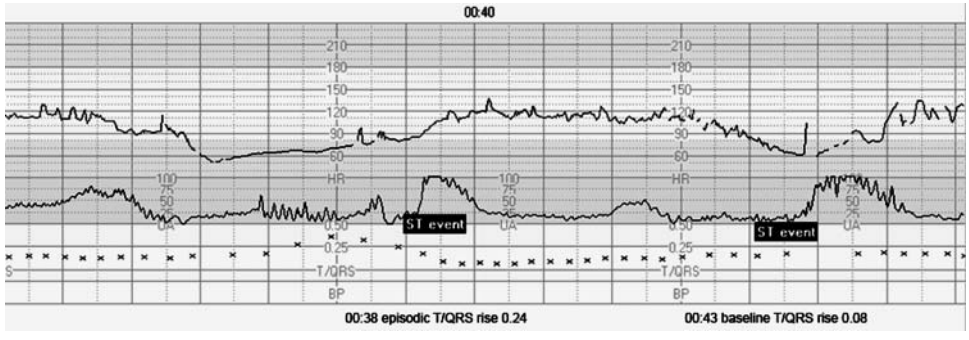


FIGURE 8. STAN tracing showing yellow zone elements (recurrent variable decelerations greater than 60 bpm amplitude) and STAN alerts (episodic and baseline rise in T : QRS ratios). This fetus was expeditiously delivered by cesarean section in good condition: Apgar scores of 8-9-10; Cord arterial blood gases were pH of 7.14, base deficit of 8.7 mmol/L (Case, Courtesy of Neoventa Medical). STAN indicates ST analysis.

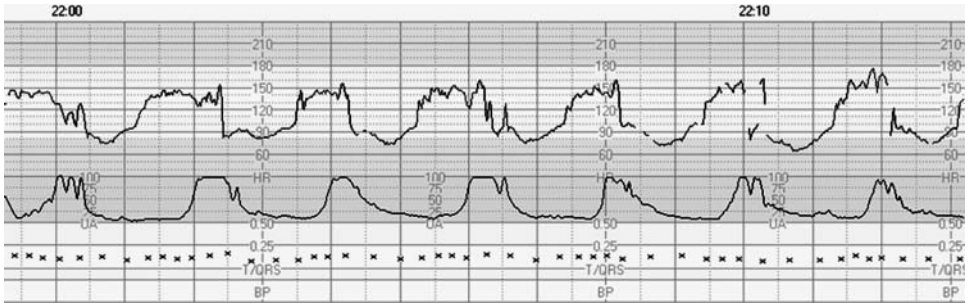


FIGURE 9. STAN tracing showing yellow zone elements (recurrent variable decelerations greater than 60 bpm amplitude) without STAN alerts in the second stage of labor. Spontaneous vaginal delivery occurred within 30 minutes with Apgar scores of 9-9-10. Cord arterial blood gases were pH of 7.19 with a base deficit of 6.3 mmol/L (Case, Courtesy of Neoventa Medical). STAN indicates ST analysis.

likelihood of that the likelihood that fetal metabolic acidosis was absent exceeded 95%. More importantly, the level of agreement between the US clinicians and STAN experts for clinical management decisions was 90%.

Future Status of STAN for Intrapartum Care

In the current and anticipated healthcare environment, increasing attention has focused on cost-benefit analysis of medical interventions. Heintz et al[21] performed a study on long-term health effects of using EFM with and without STAN in the reduction in cerebral palsy. Assumptions were based on Swedish healthcare data and modeled the connection between metabolic acidosis and cerebral palsy. Their decision tree model predicted that, when compared with standard EFM, EFM plus STAN would reduce the occurrence of cerebral palsy, and would increase lifetime cost-savings, and quality-adjusted life years. Although this is a single study, it indicates that improved detection of at-risk fetuses and reduction of metabolic acidosis can be an important first step in eliminating preventable life-long handicaps.

STAN monitoring systems have continued to migrate into routine usage in the labor and delivery units of many European countries. After Federal Drug Administration Approval in 2005, STAN systems are also being introduced gradually in United States obstetric units. As this monograph is being written, the Maternal-Fetal Medicine Unit Network of the NICHD is initiating a multicenter randomized trial of the STAN methodology in the United States. This trial will

TABLE 2. Combined Perinatal Outcomes of UK and Swedish Randomized Trials[12–14]

	FHR	**FHR + ST**		
Outcomes	**n = 3662**	**n = 3738**	**Odds Ratio**	***P***
Operative delivery for nonreassuring fetal status	9.2%	6.8%	0.72	< 0.001
Cord artery metabolic acidosis	1.46%	0.65%	0.44	0.003
Moderate/severe neonatal encephalopathy	n = 12 0.33%	n = 2 0.05%	0.16	0.01

FHR indicates fetal heart rate.

TABLE 3. Randomized Controlled Trials of STAN

Study	Number Enrolled	FHR Only	FHR + STAN	Metabolic Acidosis	Operative Delivery Rate	Encephalopathy
Westgate et al[12]	2434	1215	1219	Decreased	Decreased	Decreased
Amer-Wahlin et al[13]	4966	2477	2519	Decreased	Decreased	Decreased
Ojala et al[17]	1483	739	733	No difference	No difference	Decreased
Vayssiere et al[16]	799	400	399	No difference	No difference	No difference
Westerhuis et al[18]	5681	2849	2832	Decreased	No difference	No difference

FHR indicates fetal heart rate; STAN, ST analysis.

be similar to that of the Swedish RCT[13] described earlier. Although it will be a few years before all of the patients are enrolled and the data collected and analyzed, this study has the potential to affect significant change in intrapartum care in North America, should its results be similar to those of its predecessor.

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