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Use of peripartum ST analysis of fetal electrocardiogram without blood sampling: a large prospective cohort study

Muriel Doret [a,b,*], Mona Massoud [a,b], Anne Constans [a,b], Pascal Gaucherand [a,b]

[a] Hospices Civils de Lyon, Hôpital Femme-Mère-Enfant, Department of Obstetrics and Gynaecology, Bron Cedex F-69677, France
[b] Université de Lyon, Faculté de Médecine Lyon Est, F-69622 Lyon, France

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ABSTRACT

Objective: Fetal peripartum surveillance with ST analysis of fetal electrocardiogram (STAN) alone or in combination with fetal blood sampling (FBS) is a worldwide debate. STAN monitoring without FBS support was implemented in 2000 in the authors' department when it took part in a European multicentre project. The aim of this study was to evaluate neonatal outcomes associated with peripartum STAN monitoring without FBS support in a large prospective cohort of patients at high risk of peripartum fetal asphyxia.

Study design: This prospective cohort study included all consecutive high-risk women monitored with STAN technology over a 77-month period, excluding fetuses with congenital anomalies. Outcome variables were fetal metabolic acidosis, umbilical pH $\leq$ 7.05 and normal extracellular base deficit, transfer to a neonatal intensive care unit, neonatal encephalopathy and neonatal death related to peripartum asphyxia. Cases with metabolic acidosis were reviewed by a referent midwife and referent obstetricians to check whether or not labour management was consistent with the STAN guidelines.

Results: In total, 3112 women were included in the study. The caesarean section rate for suspected fetal distress was 9.5% [95% confidence interval (CI) 8.5–10.5]. Acid–base status was available for 3067 (98.5%) neonates. There were 14 cases of fetal metabolic acidosis (0.45%; 95% CI 0.2–0.7), 62 cases with umbilical pH $\leq$ 7.05 and normal extracellular base deficit (2%; 95% CI 1.5–2.5), 27 neonates with 5-min Apgar scores $\leq$ 7 (0.87%; 95% CI 0.54–1.20) and 16 neonates were transferred to the neonatal intensive care unit (0.51%; 95% CI 0.26–0.76) due to peripartum asphyxia. No cases of neonatal encephalopathy, or fetal or neonatal death occurred. Out of the 14 cases of fetal metabolic acidosis, 11 were not managed in accordance with the STAN guidelines. Specificity was 80.5% and the negative predictive value was 99.9%. Sensitivity was highly affected by medical staff interpretation, varying from 9.1% in the authors' experience to 90.9% with appropriate labour management according to the STAN guidelines.

Conclusions: STAN monitoring without FBS support was associated with a low rate of fetal metabolic acidosis. Most cases of fetal metabolic acidosis were not managed in accordance with the STAN guidelines. This study not only supports STAN usage without FBS support, but also warns of possible guideline violations and subsequent adverse neonatal outcomes.

1. Introduction

Intrapartum fetal asphyxia is responsible for 30% of cases of cerebral palsy in term neonates [1]. Fetal surveillance during labour aims to reduce neonatal mortality and morbidity due to peripartum asphyxia. Continuous cardiotocography (CTG) has very good sensitivity for the detection of fetal metabolic acidosis and cerebral palsy due to peripartum asphyxia. It does not, however, help to reduce cerebral palsy or neonatal mortality [2–4]. Moreover, continuous CTG is associated with a significant increase in operative deliveries due to a high false-positive rate, and low specificity for fetal metabolic acidosis and cerebral palsy [2–4].

ST segment analysis of fetal electrocardiogram (STAN) has been developed over the last decade to reduce fetal metabolic acidosis and unnecessary operative deliveries for suspected fetal distress. Five randomized controlled trials (RCTs) comparing CTG with CTG + STAN monitoring, in association with fetal blood sampling (FBS), reached different conclusions [5–9]. Amer-Wahlin et al. reported a significant decrease in both fetal metabolic acidosis and operative deliveries for suspected fetal distress in a high-risk population [5]. Westgate et al. demonstrated a significant decrease in operative deliveries for suspected fetal distress with no change

* Corresponding author at: Hôpital Femme-Mère-Enfant, Service d'obstétrique, 59 Boulevard Pinel, 69677 Bron Cedex, France. Tel.: +33 4 27 85 51 70; fax: +33 4 27 86 92 61.
E-mail address: muriel.doret@chu-lyon.fr (M. Doret).

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in fetal acidosis [6]. The three most recent RCTs failed to demonstrate any influence of STAN monitoring on fetal metabolic acidosis in the extracellular fluid compartment or operative deliveries [7–9]. In a review based on the first three trials, Neilson concluded that a reduction in severe fetal metabolic acidosis and neonatal encephalopathy was associated with CTG + STAN monitoring combined with FBS, but this did not alter the operative delivery rate [10]. Additionally, many observational studies have reported patient cohorts monitored with STAN technology supported by FBS with promising results [11–15].

FBS support, however, is not systematically recommended in the STAN monitoring labour management guidelines [16]. Interestingly, four of the five RCTs reported a significant decrease in FBS with CTG + STAN monitoring compared with CTG alone, leading to intense debate on the use of FBS, even in countries where FBS is clinically used and recommended [6–9]. Moreover, Luttkus et al. demonstrated that STAN monitoring provides accurate information about intrapartum hypoxia similar to that provided by scalp pH, thus questioning the benefits of simultaneous fetal surveillance with STAN and FBS [17].

As FBS has not been performed in the authors' department for many years and the STAN guidelines do not recommend FBS support, STAN technology was implemented in the department without FBS support. The aim of this study was to evaluate neonatal outcomes associated with peripartum fetal monitoring with CTG + STAN without FBS support in a large prospective cohort of patients at high risk of peripartum fetal asphyxia.

2. Materials and methods

The Hospital Edouard Herriot (Lyon, France), which recently moved to the Hospital Femme-Mère-Enfant (Bron, France), is a tertiary referral centre for high-risk pregnancies, fetal medicine and neonatology, with approximately 3000 deliveries per year. This prospective cohort study was exempted from institutional review board review as no intervention was performed. All patients delivering at this institution are informed that, unless they object, all medical data are collected for further research.

STAN technology (Neoventa, Medical AB, Molndal, Sweden) was implemented at the hospital in 2000 when it participated in a European multicentre project on peripartum fetal monitoring, coordinated by Neoventa Medical, Goteborg [18]. The maternity unit was equipped with two S21 STAN devices between 2000 and 2005 and three S31 STAN devices since 2005. All obstetricians and midwives received initial training, which included lectures, written information and multimedia-based teaching with simulator cases provided by the manufacturer (STAN, Neoventa Medical, Moelndal, Sweden). For the first two years of the project, a referent midwife was present five days/week in the labour and delivery room to provide help and supervise STAN use. Additionally, all cases were systematically reviewed during the daily departmental meeting. Monthly training sessions based on selected cases were organized from 2000 to December 2004 by two referent midwifes and one referent obstetrician.

Since 2000, indication for STAN monitoring and relevant information about the ante- and peripartum periods, labour management and neonatal outcomes have been collected prospectively in a dedicated database. Data from the learning curve have been published in part elsewhere [19].

Patients at high risk of fetal asphyxia were eligible for routine monitoring with STAN technology, according to the decision of the attending medical staff and equipment availability. Selection criteria for STAN monitoring were: gestational age over 36 weeks, cephalic presentation, high risk of peripartum fetal acidosis (suspicious or abnormal CTG, thick meconium-stained amniotic fluid, postdate delivery, labour induction, suspicion of intrauterine growth restriction and any other at-risk situation according to the medical staff). All patients were eligible for inclusion in the study, excluding fetuses with major malformations or chromosomal anomalies.

CTG analysis was performed in accordance with the International Federation of Gynecology and Obstetrics guidelines [20]. Labour management and ST event interpretation were performed according to the manufacturer's guidelines [5,20]. Umbilical cord arterial and venous pH and partial pressure of CO_2 were measured for all deliveries, and extracellular fluid compartment base deficit was calculated using the Siggaard-Andersen acid–base chart algorithm [21]. Quality control of acid–base status was performed in accordance with Kro et al. [22].

The main outcome variable was fetal metabolic acidosis, defined as umbilical artery pH $\leq$ 7.05 or, if arterial pH was missing, umbilical venous pH $\leq$ 7.05, associated with extracellular base deficit $\geq$ 12 mmol/l.

The secondary outcome variables were fetal acidosis, defined as umbilical artery pH and/or venous pH $\leq$ 7.05 with normal extracellular base deficit (<12 mmol/l); 5- and 10-min Apgar scores $\leq$ 7, transfer to the neonatal intensive care unit, neonatal encephalopathy, and fetal or neonatal death related to peripartum asphyxia. Case notes of patients with fetal metabolic acidosis were reviewed systematically to check for adherence to the initial STAN management labour guidelines by two referent obstetricians and one referent midwife [5,12]. A consensus was obtained to classify each case. Violations of the STAN guidelines included: delay in taking action when a significant ST event recommended delivery (>20 min during first stage of labour and 10 min during active second stage of labour), ST event misinterpretation leading to inappropriate intervention and/or delayed intervention, delay in taking intervention with preterminal CTG and prolonged bradycardia > 10 min which indicate immediate delivery, and no indication for STAN monitoring (initiation of STAN monitoring with a preterminal CTG or with a pathological CTG without previous fetal wellbeing assessment by digital scalp stimulation).

Qualitative data are expressed as percentages and quantitative data are expressed as means with 95% confidence intervals (95% CI).

3. Results

All consecutive women monitored with CTG + STAN from 1 July 2000 to 31 December 2007 were eligible for inclusion in the study. During these 77 months, 3195 women at high risk of peripartum fetal asphyxia were monitored with a S21 or S31 STAN device. Eighty-three patients were excluded from the study due to fetal malformations or chromosomal anomalies; the remaining 3112 women were included in the study. The main obstetric and neonatal characteristics and indications for STAN monitoring are shown in Tables 1 and 2.

In total, 1044 women had an operative delivery (43.2%; 95% CI 41.4–44.9). Of these, 614 operative deliveries were performed for suspected fetal distress (19.7%; 95% CI 18.5–21.3): 298 caesarean sections (9.5%; 95% CI 8.5–10.5) and 316 vaginal operative deliveries (10.1%; 95% CI 9.–11.2).

3.1. Neonatal outcomes

Umbilical acid–base data were available for 3067 (98.5%) neonates. Both umbilical arterial and venous pH were available for 2926 (94%) neonates, and at least one umbilical pH was available for 141 (4.5%) neonates. The percentage of reliable acid–base status was 71.8% according to the diagram proposed by Kro et al. [22]. Data for both umbilical arterial and venous pH were missing in 45 cases (1.4%).

Out of the 3112 patients, there were 14 cases of fetal metabolic acidosis (0.45%; 95% CI 0.2–0.7) (Tables 3 and 4). In the 2169