

ST analysis of the fetal ECG as an adjunct to fetal heart rate monitoring in labour
a clinical validation

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Avhandlingen baseras på följande delarbeten:

- I. **STAN in clinical practice – The outcome of 2 years of regular use in the city of Gothenburg.** Håkan Norén, Sofia Blad, Ann Carlsson, Anders Flisberg, Annika Gustavsson, Håkan Lilja, Margareta Wennergren, Henrik Hagberg. Am J Obstet Gynecol 2006;195:7-15
- II. **STAN, a clinical audit: the outcome of 2 years of regular use in the city of Varberg, Sweden.** Anna-Karin Welin, Håkan Norén, Anders Odeback, Mona Andersson, Gunnel Andersson, KG Rosén. Acta Obstet Gynecol Scand 2007; 86: 827-832
- III. **Fetal scalp pH and ST analysis of the fetal ECG as an adjunct to CTG. A multi-center, observational study.** Andreas Luttkus, Håkan Norén, Jens Stupin, Sofia Blad, Sabaratnam Arulkumaran, Rista Erkkola, Henrik Hagberg, Carsten Lenstrup, Gerard Visser, Onning Tamazian, Branka Yli, Karl Rosén, Joachim Dudenhausen. J. Perinat. Med 2004; 32: 486-494
- IV. **Fetal scalp pH and ST analysis of the fetal ECG as an adjunct to cardiotocography to predict fetal acidosis in labor.** Håkan Norén, Andreas Luttkus, Jens Stupin, Sofia Blad, Sabaratnam Arulkumaran, Risto Erkkola, Roberto Luzietti, Gerard Visser, Branka Yli, Karl Rosén. J Perinat. Med 2007; 35: 408-414

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ABSTRACT

ST analysis of the fetal ECG as an adjunct to FHR monitoring in labour –

a clinical validation. Norén Håkan 2008. Department of Obstetrics and Gynaecology, Sahlgrenska Academy at Göteborg University, Sahlgrenska University Hospital, S-413 45 Göteborg, Sweden.

The ability to make an accurate assessment of fetal well-being during labour is a great challenge. Animal and human studies have shown that fetal hypoxemia during labour can alter the shape of the fetal electrocardiogram (FECG) waveform, notable elevation of the T-wave and depression of the ST segment. A new medical device (STAN, Neoventa Medical, Mölndal, Sweden) has been developed to monitor the FECG during labour as an adjunct to continuous electronic FHR monitoring (CTG+ST analysis). Before a more general clinical use the technique has been the object of three randomised trials. The present thesis concerns the implementation of this new technique into clinical practice. At Sahlgren's hospital, Göteborg, Sweden, 4830 out of 14687 (32.9%) term deliveries were monitored between October 2000 and September 2002. While the number of monitored cases increased from 28.1% in the first year to 37.7% during the second year, the frequency of metabolic acidosis ($\text{pH} < 7.05$ and $\text{BD}_{\text{ecf}} > 12 \text{ mmol/L}$) decreased from 0.76% to 0.44% in all patients and from 1.12% to 0.56% in the CTG+ST monitored group assessed to be in need of close surveillance. The number of operative deliveries was unaltered (Paper I).

In a retrospective study at Varberg district hospital labour ward, covering the total population of deliveries during 2004 and 2005, 59% of the deliveries (1875/3193) were monitored with CTG+ST. The metabolic acidosis rate was 0.5%. Crash Caesarean sections (CS) were significantly reduced from 1.5% in the conventionally monitored (CTG) group to 0.3% in the CTG+ST group (Paper II). It was concluded that the frequency of metabolic acidosis in this large number of deliveries from Göteborg and Varberg is the same as noted in the CTG+ST group in a Swedish randomised trial on CTG+ST analysis.

Cases originating from a European Union commission supported multi centre study where CTG+ST had been used together with fetal blood sampling (FBS) were analysed. Of the 911 cases, 53 had cord artery $\text{pH} < 7.06$ and 44 had cord artery $\text{pH} 7.06 - 7.09$. These cases were analysed together with 97 control cases. CTG+ST clinical guidelines identified all adequately monitored cases with metabolic acidosis requiring special neonatal care. These cases were identified at least 19 minutes prior to delivery. In 22 cases, FBS was obtained 13 (7-24) minutes after CTG+ST guidelines had indicated abnormality and in eight no ST changes had occurred at time of FBS. The corresponding FBS data were $\text{pH} 7.10$ (7.01 – 7.15) and $\text{pH} 7.21$ (7.08 – 7.31), respectively, $p=0.01$. In cases of metabolic acidosis, scalp-pH fell 0.01 units per minute after a ST change rise had been recorded during second stage of labour. In 43 out of 53 cases with cord artery $\text{pH} < 7.06$ CTG + ST indicated intervention. In five cases no ST data existed and in the rest of the cases there were no ST indications. One of these newborn had metabolic acidosis but was clinically unaffected (Paper III and IV).

The time factor, i.e. the time between onset of significant ST events and delivery can be illustrated by the observation that of those with CTG+ST events recorded within 16 minutes of delivery, 61% had cord artery $\text{pH} \geq 7.20$. The corresponding figure for cases where CTG+ST indications occurred more than 16 minutes before delivery was 19% (OR 6.66, 2.29 – 19.86, $p < 0.001$).

In conclusion, these data indicate that ST analysis of the FECG identifies a term fetus exposed to hypoxia during labour in a reliable way. FBS has a role in fetal monitoring, e.g. when a CTG+ST recording starts late in labour with abnormal CTG.

Keywords: fetal ECG, ST analysis, electronic fetal monitoring, cardiotocography, fetal blood sampling, metabolic acidosis.

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