

Cardiotocography plus ST-analysis of the fetal electrocardiogram versus cardiotocography only for intrapartum monitoring: a Dutch randomized clinical trial (Chapter 6)

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Abstract

Context: Intrapartum surveillance with ST-analysis of the fetal electrocardiogram (ECG) potentially improves neonatal outcome.

Objective: To quantify the effectiveness of intrapartum fetal monitoring by cardiotocography (CTG) plus ST-analysis, using a strict protocol for performance of fetal blood sampling (FBS).

Design: Multicentre randomised clinical trial.

Setting: Three academic and six non-academic teaching hospitals in the Netherlands.

Participants: Labouring women with a high-risk singleton pregnancy in cephalic position beyond 36 weeks of gestation.

Interventions: Participants were randomly assigned to monitoring by CTG combined with ST-analysis (index) or CTG without ST-analysis (control). There were strict conditions for performance of FBS.

Main Outcome Measures: Primary outcome was neonatal metabolic acidosis defined as an umbilical cord-artery pH below 7.05 combined with a base deficit (BD) calculated in the extracellular fluid compartment above 12 mmol/L. Secondary outcome measures were metabolic acidosis in blood, operative deliveries, Apgar scores, neonatal admissions and moderate or severe hypoxic ischemic encephalopathy (HIE).

Results: We randomised 5681 women (2832 index; 2849 control). The FBS rate was 10.6% in the index group versus 20.4% in the control group (relative risk (RR) 0.52; 95% confidence interval (CI), 0.46 to 0.60). The incidence of the primary outcome was 0.7% in the index group versus 1.1% in the control group (RR 0.70; 95% CI 0.38 to 1.28). When metabolic acidosis was analyzed according to pH and BD calculated in blood, these rates were 1.6% and 2.6%, respectively (RR 0.63; 95% CI, 0.42 to 0.94). The number of operative deliveries, low Apgar scores, neonatal admissions and newborns with moderate or severe HIE was comparable in both groups.

Conclusion: Addition of ST-analysis of the fetal ECG to surveillance with CTG during labour does not significantly reduce the number of newborns with metabolic acidosis calculated in the extracellular fluid compartment of umbilical cord blood. However, it does reduce the number of newborns with metabolic acidosis calculated in blood and with severe acidosis. There is no effect of monitoring by ST-analysis of the fetal ECG on Apgar scores, neonatal admissions, moderate to severe HIE or operative deliveries.