FM-ALERT: a randomised clinical trial of intrapartum fetal monitoring with computer analysis and alerts versus previously available monitoring.

Inês Nunes[1], Diogo Ayres-de-Campos[1], Austin Ugwumadu[2], Pina Amin[3], Philip Banfield[4], Antony Nicoll[5], Simon Cunningham[6], Paulo Sousa[1], Cristina Costa-Santos[7], João Bernardes[1], for the FM-ALERT study group

1Department of Obstetrics and Gynecology – School of Medicine, S. Joao Hospital, University of Porto; Instituto de Investigação e Inovação em Saúde – INEB: Institute of Biomedical Engineering, University of Porto, Porto, Portugal.

2 Department of Obstetrics and Gynecology, St George's Hospital and University of London, London, UK

3 Department of Obstetrics and Gynecology, University Hospital of Wales, Cardiff, Wales, UK

4 Department of Obstetrics and Gynecology, Glan Clwyd Hospital, Rhyl, Wales, UK

5 Department of Obstetrics and Gynecology, Ninewells Hospital, Dundee, Scotland, UK

6 Department of Obstetrics and Gynaecology, Leighton Hospital, Mid Cheshire Hospitals, Crewe, Cheshire, UK

7 Department of Health Information and Decision Sciences, School of Medicine, University of Porto, Porto, Portugal.

Introduction: Cardiotocography (CTG) is widely used for intrapartum fetal monitoring, but its interpretation has limited interobserver agreement and the technology has not been shown to improve clinically important outcomes. Computer analysis incorporating real-time alerts for healthcare professionals has recently been developed as a reproducible alternative. This study was conducted to determine whether the use of this technology resulted in improved perinatal outcomes or reduced intervention rates.

Materials and Methods: This multicentre randomised clinical trial was carried out in five hospitals in the United Kingdom. Inclusion criteria were: women aged ≥16 years, able to provide written informed consent, singleton pregnancies ≥36 weeks, cephalic presentation, no known major fetal malformations, in labour but excluding active second stage, planned for continuous CTG monitoring, and no known contra-indication for vaginal delivery. Eligible women were randomised using a computer-generated sequence to one of two arms: computer analysis of fetal monitoring signals with real-time alerts using the Omniview-SisPorto® 3.5 system (Speculum®, Lisbon, Portugal) or CTG monitoring as previously performed (control arm). ST analysis and fetal scalp blood sampling were available in both arms. The primary outcome was the incidence of newborn metabolic acidosis (valid paired samples with umbilical artery pH < 7.05 and BDecf >12 mmol/L). Secondary outcomes were cesarean section rates, instrumental vaginal delivery rates, use of fetal blood sampling, 5-minute Apgar score < 7, neonatal intensive care unit admission, moderate and severe neonatal hypoxic-ischemic encephalopathy and perinatal death. Analysis followed an *intention to treat* principle.

Results: A total of 7730 cases were enrolled, 3961 were randomised to the experimental arm and 3769 to the control arm. Fourteen cases were lost to follow-up (0.18%) and 7 patients opted out of the study before birth (0.09%). Cord blood gas values were available in 87.0% of cases. No significant differences in baseline characteristics occurred between the two groups. Newborn metabolic acidosis occurred in 0.40% of cases in the experimental arm and 0.58% of those in the control arm (RR=0.69 [0.36-1.31]). No significant differences between the groups were found in cesarean section rates (20.4% vs. 20.5%, RR=1.00 [0.91,1.09]), instrumental vaginal delivery rates (31.6% vs. 29.5%, RR=1.07 [1.00-1.14], random effects model RR=1.02

[0.84-1.24]), use of fetal blood sampling (6.1% vs. 5.6%, RR=1.09 [0.91-1.30]), 5-minute Apgar score < 7 (1.2% vs. 1.4%, RR=0.86 [0.58-1.27]), neonatal intensive care unit admission (3.5% vs. 3.8%, RR=0.91 [0.72-1.15]), moderate and severe neonatal hypoxic-ischemic encephalopathy (0.13% vs. 0.03%, RR=4.76 [0.56-40.70]), or perinatal death (0.025% vs. 0%).

Conclusion: Access to computer analysis of CTGs resulted in the lowest incidence of newborn metabolic acidosis ever reported in randomised controlled trials, but the difference was not statistically significant. The incidence of the primary outcome was much lower than expected, suggesting that the study was underpowered to detect such differences. Intervention rates were similar in both arms.

Key-words: cardiotocographic (CTG) monitoring; intrapartum monitoring; computer analysis; real-time alerts; fetal metabolic acidosis; adverse perinatal outcomes; intrapartum interventions.