Acta Obstet Gynecol Scand. 2011 Sep;90(9):990-6. doi: 10.1111/j.1600-0412.2011.01203.x. Epub 2011 Jun 27.

Swedish randomized controlled trial of cardiotocography only versus cardiotocography plus ST analysis of fetal electrocardiogram revisited: analysis of data according to standard versus modified intention-to-treat principle.

Amer-Wåhlin I, Kjellmer I, Maršál K, Olofsson P, Rosén KG.

Department of Women and Child Health, Karolinska Institute, Stockholm

OBJECTIVE: To undertake a renewed analysis of data from the previously published Swedish randomized controlled trial on intrapartum fetal monitoring with cardiotocography (CTG-only) vs. CTG plus ST analysis of fetal electrocardiogram (CTG+ST), using current standards of intention-to-treat (ITT) analysis and to compare the results with those of the modified ITT (mITT) and per protocol analyses.

METHODS: Renewed extraction of data from the original database including all cases randomized according to primary case allocation (n=5 049).

MAIN OUTCOME MEASURES: Metabolic acidosis in umbilical artery at birth (pH <7.05, base deficit in extracellular fluid >12.0mmol/l) including samples of umbilical vein blood or neonatal blood if umbilical artery blood was missing.

RESULTS: The metabolic acidosis rates were 0.66% (17 of 2 565) and 1.33% (33 of 2 484) in the CTG+ST and CTG-only groups, respectively [relative risk (RR) 0.50; 95% confidence interval (CI) 0.28-0.88; p=0.019]. The original mITT gave RR 0.47, 95%CI 0.25-0.86 (p=0.015), mITT with correction for 10 previously misclassified cases RR 0.48, 95%CI 0.24-0.96 (p=0.038) and per protocol analysis RR 0.40, 95%CI 0.20-0.80 (p=0.009). The level of significance of the difference in metabolic acidosis rates between the two groups remained unchanged in all analyses.

CONCLUSION: Re-analysis of data according to the ITT principle showed that regardless of the method of analysis, the Swedish randomized controlled trial maintained its ability to demonstrate a significant reduction in metabolic acidosis rate when using CTG+ST analysis for fetal surveillance in labor