

Revised ITT analysis of Swedish RCT shows unchanged significant effect

The objective of this revision¹ was to compare the results of the current standard intention-to-treat (ITT) analysis with the results of the previously published Swedish randomised controlled trial² (RCT), and to perform a retrospective quality control and reanalysis of the data.

The revision included a renewed extraction of data from the original database, with the addition of 350 cases compared to the modified ITT analysis in the first publication. All cases with low Apgar score, low cord pH and/or admittance to neonatal care in the original database were checked with the aim of detecting any missing cases of asphyxia in the original analysis.

Main changes compared to original study results

Study arm	Current ITT (n=5049)	Original ITT (n=4699)	350 cases added
Neonatal metabolic acidosis - no cord data, but neonatal symptoms			
CTG + ST	7	5	2 cases added
CTG only	15	10	5 cases added
Cord metabolic acidosis only - verified cord data			
CTG + ST	10	10	2 cases added
CTG only	18	21	1 case added

In conclusion the authors state that when adding ST Analysis to CTG, the impact on adverse neonatal outcome remained significant regardless of the method for the ITT analysis.

Main results of the revised ITT

CTG + ST	CTG only	Relative risk (95% CI)	P-value
0.66% (17/2562)	1.33% (33/2484)	0.48 (0.27-0.86)	0.014

In the same issue of the journal, the difficulties and pitfalls involved in analysing data from randomised trials were commented by the Editor in Chief of the journal.

1. Amer-Wählin et al. 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. *Acta Obstet Gynecol Scand* 2011;90:990-996.
2. Amer-Wählin et al. Intrapartum fetal monitoring: Cardiotocography versus cardiotocography plus ST analysis of the fetal ECG. A Swedish randomized controlled trial. *Lancet*. 2001;358:534-8.

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.

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Abstract

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.

STUDY DESIGN:

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