

Implementation of new medical techniques: experience from the Swedish randomized controlled trial on fetal ECG during labor.

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BACKGROUND: In a large Swedish multicenter randomized controlled trial (RCT) on intra partum fetal monitoring with automatic analysis of fetal ECG waveform (STAN) in combination with cardiotocography (CTG) (4966 parturients, 300 obstetricians and midwives managing the patients), interim analysis revealed protocol violations. By a post hoc analysis of the results over time, factors affecting the acceptance of the new technique were analyzed.

METHODS: The rates of primary and secondary outcome measures (fetal outcome, operative deliveries) were compared in the two study groups (CTG + ST and CTG only). Changes over time were statistically evaluated using a test for homogeneity between the two periods.

RESULTS: After retraining, the CTG + ST group showed the lowest rates of operative delivery for fetal distress, fetal blood sampling and admissions to neonatal intensive care unit. Operative deliveries ($p = 0.02$) and the number of fetal blood sampling decreased significantly over time ($p = 0.001$).

CONCLUSIONS: Training and education probably predisposed the clinicians to a change and reinforced it when it occurred as a result of increased personal experience. The audit and feedback together with the influence of opinion leaders and inter-collegial interactions seem to have been of importance for the successively increasing acceptance of the new method during the RCT.