

A MULTICENTER RANDOMIZED TRIAL OF FETAL PULSE OXIMETRY

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OBJECTIVE: Intrapartum fetal pulse oximetry (FPO) has the potential to overcome some of the disadvantages of electronic fetal monitoring (EFM). A prospective RCT was conducted in 9 centers to test the hypothesis that the addition of FPO to EFM lowers the cesarean delivery (CD) rate for non-reassuring fetal status (NRFS), without adversely affecting neonatal outcome.

STUDY DESIGN: Term patients who developed pre-defined abnormal EFM patterns were randomized to receive either EFM alone (Control Group = CG) or EFM plus FPO (Study Group = SG). In the CG, intervention by CD for NRFS was for defined abnormal EFM patterns, and in the SG intervention was for abnormal EFM patterns with an FSpO₂ < 30% for the entire interval between two contractions. Sample size provided adequate power to show a 50% reduction in CD for NRFS. All comparisons were for intent to treat.

RESULTS: 1010 patients were randomized, 502 in the CG and 508 in the SG. Pre-randomization variables were similar except for a higher rate of labor induction in the SG (56% vs 49%, $P = 0.03$). There was a > 50% reduction in CD for NRFS in the SG (4.5% vs 10.2%; OR = 0.42, 95% CI = 0.24 - 0.72, $P < 0.001$), however, there was a higher CD rate for dystocia in the SG (18.5% vs 8.6%; OR = 2.1, 95% CI = 1.6 - 2.4, $P < 0.001$) resulting in no overall difference in CD rate. There were no overall differences in neonatal outcomes between the two groups.

CONCLUSIONS: The addition of FPO to EFM in patients with abnormal EFM patterns resulted in a >50% reduction in CD for NRFS with no increase in adverse neonatal outcome. An unexpected increase in CD for dystocia offset the reduction in CD for NRFS, resulting in no overall reduction in CD. Nonetheless this new modality shows great promise for improving our ability to more accurately assess fetal status and intervene more appropriately for the fetus truly in distress.