

ECG WAVEFORM ANALYSIS- THE FINAL RESULTS

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Despite encouraging observational and retrospective data, the prospective multicentre trial of the addition of PR-FHR time parameters to conventional EFM failed to show a significant benefit over conventional EFM in either reducing the incidence of acidaemia or the intervention for presumed fetal distress. The question remains as to whether this RCT measured efficacy (the intrinsic value of new monitoring technique in preventing adverse neonatal outcomes under optimal clinical conditions) or effectiveness (the effect of this technology in routine clinical practice). The favourable interim analysis by Van Wijngaarden et al ¹ excluded violations of the trial protocol from analysis, making the efficacy of time interval analysis likely. The full results ² were reported as intention to treat; a 'warts and all' approach which should mimic the non-trial environment more closely. This suggested that time interval analysis in day to day practice would not be effective. Future studies are being conducted to address the issues of long-term neurodevelopmental follow up in the trial babies.

Other trials introducing new technology to the realm of fetal monitoring have had similar problems in proving effectiveness. They test not only the monitoring technology but also the human response and their intervention. With adverse neonatal outcome in labour a rare event, further prospective randomised trials need to be massive and are unlikely to prove significant benefits easily. A randomised trial is the gold standard for assessing new therapy, but is it the appropriate tool to assess a new monitor or test? Labour remains the most dangerous of journeys for some babies. Our current methods of monitoring the fetus during this time remain unsophisticated. The challenge for the future is to vigorously test new developments, with the recognition that we assess both the new monitors and the interventions they should trigger.

1. van Wijngaarden WJ. Sahota DS. James DK. Farrell T. Mires GJ. Wilcox M. Chang A. Improved intrapartum surveillance with PR interval analysis of the fetal electrocardiogram: a randomized trial showing a reduction in fetal blood sampling. American Journal of Obstetrics & Gynecology. 174(4):1295-9, 1996 Apr.
2. Strachan BK. van Wijngaarden WJ. Sahota D. Chang A. James DK. Cardiotocography only versus cardiotocography plus PR-interval analysis in intrapartum surveillance: a randomised, multicentre trial. FECG Study Group. Lancet. 355(9202):456-9, 2000 Feb 5.