



NON-INVASIVE FETAL ECG: METHOD REFINEMENT AND PILOT DATA

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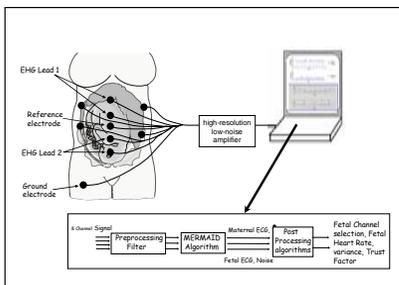
BACKGROUND

- Despite its limitations, fetal heart rate (FHR) tracing analysis is our best monitor of fetal well-being during labor.
- Transabdominal ultrasound (cardiotocography, CTG) has limitations: tracing loss during fetal movement, potential to confuse maternal for fetal heart rate, inability to monitor during cesarean delivery or abdominal surgery.
- The alternative, fetal scalp electrode monitoring, cannot be employed until the cervix is adequately dilated and the membranes are ruptured. It also entails risks including infection and hematoma.
- Preliminary evidence suggests the diagnosis of "fetal distress" can be enhanced with information acquired from the fetal electrocardiogram (FECG), reducing the operative delivery rate by 46% in one study.¹
- Non-invasive FECG extraction is a well-known problem of mixed signals - the FECG is hopelessly contaminated by the maternal ECG, maternal electromyograph (EMG), and noise.

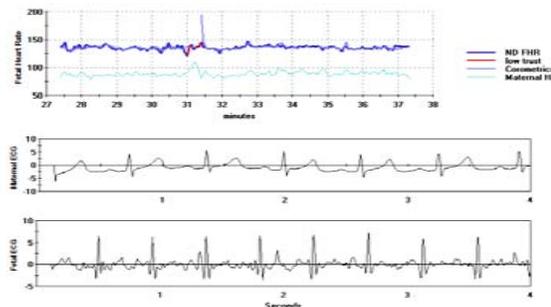
1. Westgate J, et al. Plymouth randomized trial of cardiotocogram only versus ST waveform plus cardiotocogram for intrapartum monitoring in 2400 cases. Am J Obstet Gynecol 169:1151-60, 1993

MATERIALS AND METHODS

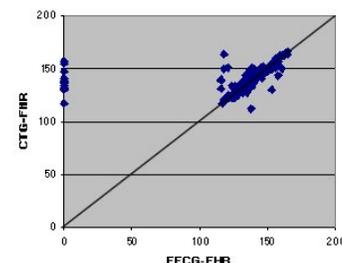
- Front-end signal processing hardware was designed to enhance the signal/noise ratio of conventional ECG equipment and improve the extraction of FECG.
- The newly developed Mermaid Algorithm (a Blind Source Separation (BSS) methodology based on Renyi's entropy) was tested and compared with other BSS methods and the more standard adaptive filtering method (MRANC).
- A reliability or "trust" factor, based on intrinsic properties of the FECG and FHR, quantifies the separation success from 0 (no separation) to 10.
- After written, informed consent, 28 laboring patients were enrolled in the study.
- Abrasive gel was used to reduce skin impedance. Electrode position was varied for the first 11 patients, until an optimal array was identified (Figure).
- Both FECG and CTG data were collected on each of the last 17 patients



Sample Data Screen



FHR signal comparison of FECG and CTG (4-second averages)



RESULTS

- CTG and FECG data were acquired for 12-51 minutes (median 45) on the 17 patients.
- The Mermaid algorithm outperformed existing BSS and adaptive filtering techniques in both computational requirements and FECG extraction quality.
- The FHR was successfully extracted by FECG for all patients, and correlated well with the CTG-determined rate (RMSE = 2.85 bpm)
- While prematurity ($GA < 37$ weeks) affected FECG extraction (RMSE 3.34 bpm), no consistent effect was identified for maternal weight (84 ± 17 kg), ruptured membranes (7/17), or electrode impedance (9.8 ± 6.9 k Ω)

DISCUSSION

- The authors have developed an improved technique for the extraction of FECG through the maternal abdomen.
- Current work is directed at refining the equipment and investigating the utility of this additional information, including quantification of FHR variability (an indicator of fetal well-being), extraction of features of the FECG, and detection and quantification of the electrohysterogram (from uterine contractions). Studies are ongoing on intrapartum monitoring, evaluation of preterm contractions, and interpretation of antepartum testing results.
- The eventual goal is a sophisticated maternal-fetal monitor with improved ability to predict both the progress of labor and the well-being of the fetus.
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Pursuant to federal guidelines, as stated under 42CFR50, three of the co-authors (TYE, DEM, NRE) of this publication are deemed to have a "significant financial interest" by virtue of their relationship to the company NeuroDimension, Inc.