Title:
Refinement of the LaborView Electronic Fetal Monitor

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Protocol

1. Project Title:

Refinement of the LaborView Electronic Fetal Monitor

2. Investigator(s):

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3. Abstract:

Despite its limitations, fetal heart rate (FHR) tracing analysis is our best monitor of fetal well-being during labor or preparation for cesarean delivery. Current monitoring methods: transabdominal ultrasound and fetal scalp electrodes have limitations (tracing loss during fetal movement, potential to confuse maternal for fetal heart rate, inability to monitor during cesarean section or abdominal surgery) and, in the latter case, risks (infection, hematoma). A reliable, non-invasive monitor of the fetal heart rate that can be used during labor, non-obstetric and obstetric surgery during pregnancy is needed. Recent developments in use of maternal abdominal electrodes for extraction of the FHR and contraction information inform this study.

LaborView®, developed by researchers at UF College of Medicine and OBMedical, is an FDA-approved non-invasive labor monitoring device. Refinement of the extraction algorithms continues, and that work is most effectively performed at UF, where the primary researchers and OBMedical are located.

LaborView monitoring will be recorded from 150 subjects admitted to Labor and Delivery at UFHealth. Data will be simultaneously obtained from the standard labor monitor. These signals will then be analyzed off-line for comparison and refinement of algorithms.

4. Background:

Despite its limitations, fetal heart rate (FHR) tracing analysis is our best monitor of fetal well being during labor. Typically, continuous electronic fetal monitoring is via transabdominal ultrasound (CTG: cardiotocograph). A transducer is strapped to the maternal abdomen and positioned in such a way to detect fetal rather than maternal heart rate. There are occasional periods of signal loss as the patient or her fetus moves, as well as times when the monitor incorrectly records the maternal signal. Maternal obesity presents particular challenges to non-invasive monitoring.

When there is particular concern regarding the fetal heart rate tracing the obstetrician may opt for a fetal scalp electrode (FSE). This is screwed into the fetal presenting part through the opening in the cervix (requires ruptured membranes and adequate dilation). This signal is usually more reliable, but entails risks of chorioamnionitis, fetal scalp infection, scalp hematoma, and potential vertical transmission of maternal viruses including HIV and hepatitis.

Recently, devices have come to market that extract the FHR and uterine electromyograph (EMG) from maternal abdominal electrodes. The proposed study will provide data for refinement of the LaborView device produced by OBMedical.

5. Specific Aims:

The goal of this research is to evaluate the LaborView device under various settings and test algorithm and device enhancements.

6. Research Plan:

All patients admitted to the Labor & Delivery Suite at UF Health, will be eligible for inclusion in the study except minors and those unable to consent for themselves.

Following written informed consent, the external monitors (tocodynamometer and ultrasound) may not be removed. Per LaborView directions, electrode application sites will be prepared to reduce skin impedance, electrodes will be applied to the maternal abdomen and data acquired for comparison with CTG data obtained through the traditional monitoring system. FHR, ECG, and uterine activity data from the existing fetal monitors will be collected via a laptop PC connected to the systems for comparison. The comparison will be performed off-line.

Evaluation of the externally obtained FECG will include (1) comparison of the calculated FHR with that of the CTG and/or fetal scalp electrode, (2) comparison of calculated short-term beat-to-beat variability between each source, (3) expert opinion comparison of the FHR tracings, and (4) morphologic and time interval analyses.

In addition, EMG data will be obtained via the electrodes. This will be analyzed real-time and compared with the toco and/or IUPC contraction information. When the toco signal fails (e.g., when the patient moves and the strap no longer overlies the uterus), the patient's nurse will be asked to reposition the strap. We may count the frequency with which nursing intervention is required. This intervention is always required when a patient is monitored with a toco, we are merely counting the frequency of required nursing intervention.

Nothing is required of the subjects. They will be non-invasively monitored for one to several hours. The information obtained will not be used for medical decision-making and there is no significant risk to the patient or her fetus. No longitudinal follow-up is planned or indicated.

7. Possible Discomforts and Risks:

Other than possible skin irritation from the electrodes, there are no health risks from this study.

8. Possible Benefits:

There are no health benefits directly for the subject. There are also no financial risks.

Patients will receive $50 in gift cards for participation in this protocol.

9. Conflict of Interest:

The PI is an unpaid consultant to OBMedical, the company that licenses the technology from UF. The PI is married to the CTO of OBMedical, Neil Euliano, PhD. The idea for the project came from both. Conflict of Interest management has been through the Office of Research Affairs under Gary Wimsett and a monitoring plan is in place. There is the potential for commercial application from which Neil Euliano and the University of Florida may benefit financially.