Abdominal fetal ECG: A non-invasive screening for fetal cardiac malformations

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Background

The prevalence of major malformation in the newborn population is 2-3%. 25% of these malformations are cardiac pathologies, i.e. 0.5-0.75%. Some of the pathologies cannot be detected during pregnancy (either they are undetectable or they are normal for the fetus but regarded as pathology in a newborn). We assume that approximately 0.3% of the fetal population have detectable cardiac pathologies.

By looking at the FECG waveform and measuring the intra-beat intervals durations such as QRS width, P-R segment or P-R interval during mid-pregnancy, a high risk group for congenital cardiac malformation can be defined. This may serve as a mid trimester screening modality, selecting patients for further evaluation by means of fetal echocardiography.

Objectives

- Expanding the database all along the project (at least 500 cases). The objective is to conduct measurements on a weekly basis (starting from week 18 and till the end of gestation). “Normal” cases - for which no cardiac pathology is found up to the time of our data acquisition will be examined, as well as cases in which pathology has been identified with the aid of echocardiography.
- Uncover new information about fetal cardiac morphology and functioning by defining the normal features of FECG, in particular the intra-beat intervals in the average FECG complex, from 18 weeks of gestation until delivery.
- Analyze the FECG waveform features in fetuses with suspected congenital cardiac malformation in order to develop adequate parameters to detect the related abnormalities.

  We intend to examine a large amount of pathological cases (100-150 cases). This might allow us to assess the intra-beat intervals and wave durations, at least for the most common pathological cases.
- Developing algorithms to identify the S-T segment and the T/QRS ratio on-line, from the time-dependent average FECG waveform. The aim is to examine the algorithm on cases of acute hypoxemia during birth or ischemia during the pregnancy.

Methodology

Study Population: Cases where cardiac pathology is ruled out (by Echocardiography checkup examination) provide the control group. We predict needing to recruit at least 400 patients for the control group. In these cases of the control group, postnatal clarification will be conducted regarding: the week of delivery, the method of delivery, the neonatal birth weight, whether any

signs of fetal distress were noted, and so on. The control cases will be divided into groups according to the week of gestation, starting from the 18th week and up to the end of gestation.

The cases where echocardiography detects pathology comprise the research group. We expect a research group of 100-150 patients to expose various types of cardiac malformation. These might allow us to create a sub-division of the research group by the type of the cardiac pathology.

Data Acquisition: The recordings are conducted with the aid of a FECG and Heart Rate Monitor (FEMO) system. This device is based on the algorithm developed by the Tel Aviv University Medical Physics group. The FEMO is a rapid computer based non-invasive system which detects the superimposed maternal and fetal ECG signal from the mother's abdomen, and then separates and processes the two signals independently. The application requires only a single lead with three electrodes, and runs on-line on a PC with A/D converter. The electrodes are placed in the form of a triangle with its base upwards.

The FEMO algorithm provides an on-line series of fetal R-R intervals. By using the detected fetal R-wave as a trigger, an average fetal ECG complex is obtained, displaying intra-beat features of possible diagnostic importance.

Preliminary results

During the last year a group of more than 100 cases which were classified as normal pregnancies was tested. The average FECG complex was obtained from the maternal abdominal ECG signal, and intra-beat durations and intervals such as: QRS complex duration, P-R interval, P-R segment, P wave duration, Q-T interval, S-T segment and S-T interval were calculated for each case. In 12 cases the echocardiography test detected fetal cardiac malformations. According to our preliminary analysis, in 9 out of 12 cases there are significant differences in the calculated intra-beat intervals compared to the control (normal) group.

In conclusion, we believe that the device that we have developed for fetal ECG monitoring has considerable clinical research potential. This is a mobile low cost system, which provides reliable results in real time. The final goal of our study is to upgrade the system and to add additional applications to it, such as: to indicate possible cardiac pathologies in cases in which the calculated intra-beat parameters of the average ECG complex deviate from the normal values. Or, to enable detection of high risk group with suspicion of fetal hypoxia, and so forth.

We hope that in the future the system will be considered as a clinical device that will immediately provide a warning regarding medical problems, and will assist in reaching decisions regarding whether to send the examinee for farther evaluation.