A WEARABLE HEALTH MONITORING SYSTEM DURING PREGNANCY

E.C. Karvounis[1,2], C. Papaloukas[1,3], K. Papanikolaou[1] and D.I. Fotiadis[1,4,*]

[1]*Unit of Medical Technology and Intelligent Information Systems, Dept. of Computer Science, University of Ioannina, GR 451 10 Ioannina, Greece*

[2]*Dept. of Material Science and Engineering, University of Ioannina, GR 451 10 Ioannina, Greece*

[3]*Dept. of Biological Applications and Technology, University of Ioannina, GR 451 10 Ioannina, Greece*

[4]*Michailideion Cardiology Center, GR 451 10 Ioannina, Greece*

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[*]Corresponding author

Unit of Medical Technology and Intelligent Information Systems,

Department of Computer Science, University of Ioannina,

PO Box 1186, GR 451 10 Ioannina, GREECE

tel.: +30 26510 98803, fax: +30 26510 98889

e-mail: fotiadis@cs.uoi.gr

Abstract

This paper describes an innovative, remote monitoring decision support system which is utilised in the early diagnosis of pregnancy complications, through the effective and non-invasive monitoring of fetal and maternal vital signs. We focus on the exploitation of abdominal fetal electrocardiogram as an alternative to Doppler ultrasound. The platform consists of two modules: the wearable device and a centralised system. The wearable device is responsible for the recording of the vital signs, pre-processing, extraction of preliminary diagnosis and transmission of the data wirelessly to a centralised system which is used for the storage and further analysis of the obtained data.

Introduction

Pregnant women living in remote areas work during pregnancy and face certain health problems (e.g. high blood pressure, kinetic problems requiring immobilization, kidney or heart diseases, multiple pregnancy). Usually they feel uncomfortable with frequent visits for prenatal monitoring. The inaccessibility of the fetus, the sensitivity of fetal and maternal health status and the susceptible psychological conditions pose significant difficulties in monitoring the progress of the pregnancy effectively. Furthermore, bulky or invasive equipment and long examinations in clinical settings affect both the mother and the fetus causing additional stress which influences their health condition. The use of a wearable platform able to monitor non-invasively fetal and maternal vital signs could improve significantly their living conditions.

In such a wearable system fetal electrocardiogram (fECG) must be processed. Various techniques have been used for fECG detection and extraction. The most recent ones include algorithms based on adaptive filtering (Mooney et al., 1995), FIR Neural Networks (Camps et al., 2001), fuzzy logic (Khandaker, 2000), IIR adaptive filtering combined with genetic algorithms (Kam & Cohen, 1999) and a wavelet-transform based method using a bi-orthogonal quadratic spline wavelet (Khamene & Negahdaripour, 2000). A statistical method has been used for simultaneous measurement of fetal and maternal heart rates in real-time for ambulatory monitoring (Ibahimy et al., 2003). Independent Component Analysis (ICA) for Blind Source Separation (BSS) techniques have been successfully applied (De Lathauwer et al., 2000). BSS is based on the assumption that the original (source) signals are linearly mixed and that these mixed signals are available. BSS finds in a blind manner a linear combination of the mixed signals and recovers the original source signals, possibly rescaled and randomly arranged in the output. ICA algorithms were tested and performed well. However, their main drawback is the need for both thoracic and abdominal recordings in order to provide accurate results. It should also be mentioned that ICA extracts the fetus waveform and not its heart rate (i.e. the position of the R wave peaks).

The proposed platform facilitates prenatal monitoring, focusing on both healthy and high-risk pregnant women, through the development of a transabdominal wearable monitoring device in the form of a comfortable elastic jacket, which is ideally suited for long-term ambulatory and domiciliary health monitoring. This is using both maternal and fetal vital signs and wireless telecommunications. Emphasis is placed on the recording of abdominal fECG, the development of innovative techniques for the extraction of fECG from the composite abdominal signal and the implementation of novel algorithms for the detection of possible health problems.

Materials and Methods

The proposed platform consists of the Wearable Device and the Centralised System (Figure 1). The Wearable Device consists of two components: the Sensing Module and the Handheld Device. The Sensing Module is a multi-sensor signal recorder jacket that uses two electric boards. These boards acquire in digital form the abdominal fECG and mECG, the maternal oxygen saturation (SpO_2), the temperature and the blood pressure. The chosen sensors are accurate, lightweight, and easy-to-use. As far as the ECG electrodes are concerned, these are disposable, pre-gelled, and simple to apply. CHEOPE (Chip for HEalth mOnitoring of PrEgnancy) is the ASIC chip used in the main board, which is able to acquire signals from different sensors and digitize them in order to transmit all the acquired measurements to the handheld device. A 16 bit microcontroller unit is used for data processing.

The Handheld Device is a Tablet PC where signal pre-processing & fECG extraction is implemented. It performs preliminary diagnosis based on medical knowledge and predefined thresholds. It checks the schedules of monitoring and commences the monitoring procedure holding all the necessary data for the operation of the modules running in the Tablet PC. In addition, it manages the communication with the centralised system.

The Centralised System includes the system repositories and the modules to perform other functions. The modules comprising the Centralised System fuse the individual measurements in order to provide a combined diagnosis on pregnancy status, manage the communication between the centralised system and the wearable devices and the algorithms for knowledge discovery and data mining in order to generate statistical anonymous data and trend identification. In addition, alerts and messages are generated.

The most crucial functions of the platform are signal processing and diagnosis. More specifically the following functions are provided: i) noise removal, ii) arrhythmia detection, iii) myocardial ischaemia diagnosis, iv) fECG extraction, and v) data fusion and diagnosis.

I. Noise removal

As far as myocardial ischaemia and arrhythmias are concerned, the QRS complex, the isoelectric line, the ST segment and the T wave must be correctly detected. However, the presence of noise (A/C, EMG and BW) in an ECG recording is unavoidable, thus making the detection process a difficult task. To overcome this problem we have developed a technique (Papaloukas et al., 2000) to remove BW and to accurately detect the isoelectric line and the J point in cases where the ECG is contaminated with A/C and/or EMG noise.

II. Arrhythmia detection

In the case of arrhythmia detection the heart rate variability (HRV) signal must be constructed. Thus, the exact location of the main QRS point (peak of the R or S wave) is needed. Our approach for arrhythmia diagnosis employs only the information from the R-R interval (Tsipouras et al., 2004). The procedure starts with the arrhythmic beat classification which is performed using a set of rules. The beat classification results are fed into a knowledge-based deterministic automato for arrhythmic episode detection and classification which is implemented for six rhythm types (ventricular bigeminy, ventricular trigeminy, ventricular couplet, ventricular tachycardia, ventricular flutter/fibrillation and 2^{o} heart block).

III. Myocardial ischaemia diagnosis

A four-stage procedure for ischaemic episode detection was developed (Papaloukas et al., 2001). In the first stage ECG feature extraction is realised, where the ST segment deviation and slope, as well as the T wave amplitude and polarity are estimated. In the second stage, each beat is classified as normal or ischemic using rules which take into account the ST segment and the T wave features. Then, window classification follows using a sliding adaptive window to examine whether a sequence of beats constitutes an ischaemic window (its duration is ~30s and contains ≥ 80% of ischaemic beats). In the last stage, the overall ischaemic episodes are identified, merging all the consecutive ischaemic windows.

IV. fECG extraction

fECG represents the electrical activity of the fetus generated by the heart muscle. Non-invasive fECG has proven to be a very interesting method for obtaining information about the state of the fetus and thus to assure its well-being during pregnancy. The main source of interference is maternal electrical activity, the amplitude of which is much higher than that of the fetus. Therefore, our system's main concern is to eliminate the mECG and extract the fetal waveform which is used for the monitoring of fetal heart rate (fHR) and detection of fHR variations. fECG is recorded using 9 leads (3 bi-polar for the mECG, 6 uni-polar for the fECG). The sampling frequency is 500 Hz and the resolution 12-bit. The thoracic signals contain primarily the maternal ECG, with little if any contribution from the fECG. On the contrary, the abdominal leads record a composite signal, consisting of the contributions from both the mECG and the fECG.

A novel algorithm was developed for fECG extraction based on the complex continuous wavelet transform and a heuristic approach. The algorithm can be divided into four stages. First, preprocessing is realised through signal averaging in order to enhance the fetal QRS complexes. Then, the mother heart beats are recognised by applying the complex frequency B-spline wavelet. In the next stage, the candidate fetal QRSs are detected using the same wavelet with different parameters. In the last stage a heuristic algorithm is applied to identify the overlapped (with the maternal QRSs) fetal QRS points and discards the misdetected (false positive) QRS points. Having extracted the fECG, we proceed with fHR monitoring which is an established means for assessing fetal health during the antenatal period. The goal of monitoring is to detect fetal stress and distress so that appropriate assistance can be taken to alleviate the cause(s) of these complications. The fluctuations of the heart beating or heart rate variability (HRV) is a useful tool for assessing non-invasively the status of the autonomic nervous system (ANS) or detecting eventual cardiac malfunctions.

V. Data fusion and overall diagnosis

Our system combines data and knowledge from different sources aiming at maximising the information content, producing information of tactical value to the responsible obstetrician and improving the system's reliability. This takes place in the decision fusion stage where the incoming results of the preliminary diagnosis are combined with other data (previous measurements, textual reports, medical history, demographic data, etc.) and a priori knowledge (medical rules and thresholds) in order to generate the assessment.

As far as the fetal diagnosis is concerned, it should be mentioned that the normal range for the fetal heart rate is 120–160 beats/minute. This normal range or baseline rate is the average fetal heart rate obtained between uterine contractions, changes and movements. The baseline can be affected by several factors such as hypoxia, catecholamine production and certain medications. Table 1 shows possible cause(s) concluded by tracing the fetal heart rate. Based on this set of medical rules the proposed system is able to monitor the health condition of the fetus and extract the diagnosis.

Results

So far we have employed abdominal signals to evaluate the system's performance in fECG extraction. They were obtained from the University of Nottingham (Pieri et al., 2001). More specifically, 8 short recordings of 1 min duration with three measurement locations for improved signal acquisition were used. The three channels of raw ECG data were recorded between the 20 and 41 gestational week. The sampling frequency was 300Hz and 12-bit resolution was employed. The acquisition system uses three pairs of electrodes placed around the mother's abdomen. When we applied our algorithm in the dataset of the 8 different recordings, both the sensitivity (Se) and the positive predictive accuracy (PPA) reached almost 100% in fetal R-wave detection. As it is shown in Table 2, where the algorithm's performance is depicted for each recording, only in one case (recording of week 29) a fetal beat was missed. Furthermore, in Table 3 the performance of the system in fHR extraction is compared with those of other similar approaches. It should be mentioned that most of the techniques presented in Table 3 were evaluated using either simulated signals or a small dataset of real recordings.

Discussion

A wearable system is presented for the monitoring of the health status of the fetus and pregnant mother. The proposed platform acquires several vital signs, such as fetal and maternal heart rate, blood pressure, temperature and respiration, and processes them in order to provide diagnosis. The data are transmitted to a centralised hospital system where among other tasks the diagnosis is generated. The main algorithm which supports the system is fECG extraction. It uses ECG recordings from the mother's abdomen and it is based on the theory of complex continuous wavelet transform.

We tested this algorithm using real data incorporating records from almost all gestation period, from the 20th to 41st week. The proposed algorithm has been proven to be very efficient. The results cannot be compared directly with those of other similar approaches since there is no standard database with MECG recordings. Moreover, most of the detection systems been proposed so far evaluate their performance using either simulated signals or a small amount of real recordings.

In addition to the ability of extracting accurately the fHR signal, the current monitoring system was also designed to be applied non-invasively. This feature is highly desirable from both the doctors' and patients' point of view. Moreover, the non-invasive nature of system combined with its wearability makes the system appropriate for healthcare support at remote settings. The system proposes a major shift from a pregnancy information system based on the hospital setting to one which can always be carried by the pregnant woman and used at any time and any place.

It is not only a stand-alone wearable monitoring device but a set of innovative sub-systems which incorporate state of the art technologies.

The main problem in designing such wearable platforms is the elimination of noise of the vital signals. This is performed by the Sensing Module. Especially in the case of ECG acquisition, we observed that the signal is affected moderately by A/C interference, so better filtering modules could also be used to handle this drawback. In addition, other vital signs (like uterine contractions) can be acquired and tested. Furthermore, the overall system must be evaluated through a series of clinical trials in order to fully examine its potential.

Obstetricians usually utilize Doppler Ultrasound as the main tool for assessing the wellbeing of a pregnancy. We propose a wearable platform, which does not replace Doppler but it complements for accurate monitoring and diagnosis. The system combines several techniques for signal processing, analysis and data fusion. It is easy to use it and preliminary results indicate high performance.

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Tables & Figures

Table 1: Medical rules used in fetal health diagnosis.

Tracing	Pattern	Possible Cause(s)
Elevation in rate over 160 beats/min for more than 10 min	Baseline tachycardia	Maternal fever; fetal anemia; fetal tachyarrhythmia; dehydration; idiopathic maternal anxiety
Rate below 120 beats/min for 10 min	Fetal or baseline bradycardia	Medication; maternal systemic lupus; hypoxia
Fluctuations or oscillations in FHR for about 1 min	Long term variability	Responsiveness of fetus' behavioral/wake state
Rate counted from 1 R wave to the next in each cardiac cycle	Beat-to-beat or short-term variability	When variability is present, the fetus is thought to have an intact nervous system. Loss of variability causes a flat baseline and signals a compromised situation
FHR is higher than 150 beats/min, for more than 15 sec	Accelerations	Partial cord compression; may be non-specific
Slowing of FHR in a pattern	Early decelerations	Head compression, commonly observed 4-6 cm in mirror image of contractions
"U" "V" or "W" shaped heart rate	Variable decelerations	Oligohydramnios; cord compression; nucal cord
30 beats/min less than regular for up to 10 min	Prolonged decelerations	Maternal hypotension; abruption placenta; uterine hyperstimulation; uterine rupture; cord compression; rapid fetal descent
Repetitive undulation of baseline	Sinusoidal	RH isoimmunization; fetomaternal hemorrhage
Slowing of FHR in a pattern- begins to fall after onset	Late decelerations	Hypoxia; IUGR; maternal hypotension; uterine hypertonus; uteroplacental insufficiencies

Table 2: Results for fECG extraction in eight different recordings.

	TP	**FP**	**FN**	**Se[1](%)**	**PPA[2](%)**
Week 24	143	0	0	100	100
Week 26	139	0	0	100	100
Week 29	137	0	1	99	100
Week 35	128	0	0	100	100
Week 37	134	0	0	100	100
Week 39	143	0	0	100	100
Week 40	141	0	0	100	100
Week 41	121	0	0	100	100
TOTAL	**1086**	**0**	**1**	**100**	**100**

[1]Se: Sensitivity, [2]PPA: Positive Predictive Accuracy

Table 3: Performance in fECG extraction for various approaches.

Author	Description	Accuracy (%)
Mooney et al., 1995	Adaptive algorithm	100
Khamene & Negahdaripour, 2000	Bi-orthogonal quadratic spline wavelet	100
Khandaker, 2000	Fuzzy Approach	89
Camps et al., 2001	FIR Neural Networks	91
Ibahimy et al., 2003	Statistical Analysis	88
Current Work	Complex Continuous Wavelet Transform	100

Figure 1: The system's architecture.