Remote maternal and fetal health monitoring during pregnancy

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***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 maternal and fetal electrocardiograms. The main objective of our system is to extract the maternal and fetal ECG from thoracic and abdominal ECG recordings. Techniques like Principal Component Analysis and Independent Component Analysis were implemented in addition to techniques from the field of time-frequency analysis. After the separation of maternal and fetal ECGs, the maternal ECG is used for the detection of ischaemic and arrhythmic episodes. A four-stage procedure is used for ischemic episode detection. The four stages correspond to noise handling and ECG feature extraction, beat classification, window classification and identification of ischaemic episodes duration. Arrhythmia beat classification and arrhythmic episode detection was realized using the RR-interval signal. A set of rules is used for beat classification in four beat categories and a deterministic automato is used for the arrhythmic episode detection and classification into six categories. Monitoring of the fetus is implemented using patterns extracted from the fetal heart rate signal. The final decision is based on additional information such as maternal blood pressure, maternal SPO_2, maternal temperature and clinical reports which are combined with the above extracted patterns. The decision making procedure is based on a set of rules provided by experts. The system is evaluated using realistic and simulated data and the obtained diagnostic accuracy is high.**

I. Introduction

Electronic fetal heart rate (fHR) monitoring is commonly used to assess fetal well-being during labor. The motivation for monitoring the fetus during pregnancy is to recognize pathologic conditions, typically asphyxia, with sufficient warning to enable intervention by the clinician before irreversible changes set in. Although detection of fetal compromise is one benefit of fetal monitoring, there are also risks, including false-positive tests that may result in unnecessary surgical intervention. A systematic approach to interpreting the patterns of fHR is important. The fHR undergoes constant and minute adjustments in response to the fetal environment and stimuli. fHR patterns are classified as reassuring, non-reassuring or ominous. Non-reassuring patterns such as fetal tachycardia, bradycardia and late decelerations with good short-term variability require intervention to rule out fetal acidosis. Ominous patterns require emergency intrauterine fetal resuscitation and immediate delivery. Differentiation between a reassuring and non-reassuring fHR pattern is the essence of accurate interpretation, which is essential to guide appropriate decisions.

Various commercially available devices and systems (either stand-alone or interconnected to hospital centres) have already provided specific vital signs recording and monitoring. These refer mainly to portable devices accompanied with special visualisation and processing systems as well as health services targeted at pregnant women. All these systems make use of invasive techniques for fetal surveillance, like ultrasound and/or fetal scalp electrode [1-3].

In the field of fetal ECG (fECG) and fHR extraction, various research efforts have been carried out, including subtraction of an averaged pattern [4], matched filtering [5], adaptive filtering [6], orthogonal basis functions [7], fractals [8], FIR [9], dynamic neural networks [10], temporal structure [11], fuzzy logic [12], frequency tracking [13], polynomial networks [14], wavelets [15,16], and real-time signal processing [17]. The extraction of fECG from the complex signal (mother and fetus) can be reframed in a more efficient manner using Blind Source Separation (BSS) methods [18], such as Principal Component Analysis (PCA) [19, 20] and Independent Component Analysis (ICA) [6, 19, 21, 22]. The separation of the maternal and fetal signals from electrocardiograms acquired from skin electrodes located on a pregnant woman's body may be modeled as a Blind Signal Processing problem. The combination of wavelet analysis and BSS methods has also been proposed [23].

The proposed system facilitates the prenatal procedures for monitoring of the cardiac condition of both the mother

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and the fetus, by developing a transabdominal device for long-term health monitoring. Hospitals and obstetric clinics usually receive additional patients (most of them hypochondriacs) who might avoid their visit, reducing the hospitals' load. The hospitals' efficiency in that way can be increased as well as the quality of the provided services. Our system is also a valuable decision support tool for the obstetrician, who is enabled to monitor remotely patients, evaluate automated preliminary diagnosis of their condition based on collected and analysed vital signs, and most importantly be alerted when potential pregnancy complication require physical examination of the patient. Furthermore, the obstetricians are able to use mobile units and portable devices to access their patients' medical data anytime and anyplace, facilitating the organisation of their work and improving their efficiency.

II. Materials and Methods

Our automated diagnosis system targets the monitoring of the cardiac condition of both the mother and the fetus. For this purpose, two separate approaches have been developed (Fig. 1). In the first approach, all 8 leads are utilized and BSS techniques are employed, in order to separate the maternal ECG (mECG) and the fECG. In the second, only the abdominal leads (5 channels) are used and a methodology based on time-frequency analysis is applied in order to extract the maternal and fetal R–R interval signals, and thus the mHR and fHR. In the first case, the two signals are totally separated, but several limitations on the real-life conditions (limited number of leads) and on the BSS analysis

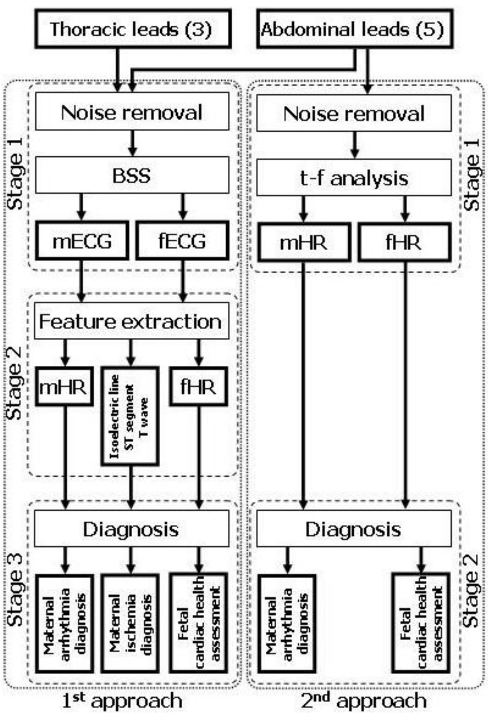

Fig. 1: The two approaches that are developed for the automated diagnosis subsystem.

(scale and permutation problems) lead us to develop the second approach, which only detects the maternal and fetal QRSs, without suffering from these limitations, since we are able to work with a small number of leads and having high accuracy. In both cases, noise removal techniques have been utilized, previous to the analysis, to improve the acquired recordings (leads).

Extensively tested algorithms and knowledge-based approaches were used to examine the maternal and fetal health status and detect potential risks for fetal hypoxia, pre-eclampsia, distress, intrauterine growth restriction, as well as maternal physical and psychological health problems (including congenital and other heart diseases). Cardiac arrhythmia detection and fetal cardiac health assessment are reached in both approaches, due to the fact that mHR and fHR, are available. However, cardiac ischemia diagnosis is based on several features extracted from the mECG and thus it can be reached only in the first approach.

A. First approach

In the first approach mECG and fECG are separated, using 8 lead recordings (3 thoracic bi-polar and 5 uni-polar on the abdomen). The thoracic signals contain primarily the mECG, 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 number of difficulties are associated with recording the abdominal ECG (abdECG). Electrical activity recorded from the maternal abdomen suppresses the fECG (the magnitude of the fECG signal at the maternal abdomen is of the order of several microvolts), which is a fraction of the mECG amplitude recorded at the maternal abdomen. Other sources of interference are also present, such as maternal muscle activity and electrical equipment contamination. These difficulties are compounded by the sensitivity of the abdECG signal amplitude to fetal position and to the normal reduction in fECG signal amplitude with gestational age. Techniques to improve fECG signal acquisition remain the subject of ongoing research.

Noise Removal: The presence of noise, such as power line interference (A/C), electromyographic contamination (EMG) and baseline wandering (BW), may lead to ambiguous results. To overcome it we developed a technique which manages to remove BW and noise in ECG recordings [24].

Blind Source Separation techniques: Three BSS techniques were evaluated: Principal Component Analysis (PCA) [19,20], Jade-ICA [21] and fixed-point ICA (Fast-ICA) [22]. BSS methods consist of extracting unknown signals (called sources), which are assumed to be statistically independent, from a few known mixtures of these signal. The main advantage of these techniques is that they do not require any a priori knowledge about the signals (contrary to filtering methods)

Feature extraction: From the obtained mECG and fECG signals, the QRS complexes of the mother and the fetus are detected, and thus, the mHR and fHR calculated. Also, the isoelectric line, ST segment and T wave of mECG are found.

Maternal ischemia diagnosis: The beginning of the ST segment (J point) and the peak of the T wave are used for maternal myocardial ischemia diagnosis, using the methodology described in [24]. The ischemic episode detection is performed by using a three-stage procedure [24]: beat classification, window classification and identification of ischemic episodes duration.

Maternal arrhythmia diagnosis: To diagnose cardiac arrhythmias of the mother, the time evolution of the R–R intervals is examined [16, 25, 26]. A set of knowledge-based rules [26] is used for beat classification in four beat categories: beats belonging to ventricular flutter/fibrillation episodes (VF), premature ventricular contractions (PVC), normal sinus rhythm (N) and beats belonging to 2^o heart block episodes. The arrhythmic episode diagnosis is performed classifying cardiac rhythms into seven categories: ventricular bigeminy, trigeminy, couplet, tachycardia and flutter/fibrillation, 2^o heart block and normal sinus rhythm, utilizing the beat classification and a deterministic automaton [26].

Fetal cardiac health assessment: The fHR varies for different reasons. In most cases, there is no connection to oxygen deficiency. Instead, the variations are signs of normal adaptation to changes in the environment. Some reasons include changes in placental blood flow, hypoxia, external stimuli, increases in temperature and drugs. When classifying a fECG, the baseline fHR, variability, reactivity and the appearance of decelerations have to be assessed. On the basis of these parameters, a fECG can be classified as normal, intermediate, abnormal or preterminal [27].

Baseline fHR is the mean fHR rounded to increments of 5 beats per minute during a 10-minute segment, excluding periodic changes and periods of marked fHR variability (segments of the baseline that differ by more than 25 beats per minute). Fetal tachycardia is defined as a baseline heart rate greater than 160 bpm and is considered a non-reassuring pattern. Tachycardia is considered mild if the heart rate is from 160-180 bpm and severe if it is greater than 180 bpm. Tachycardia greater than 200 bpm is usually due to fetal tachyarrhythmia or congenital anomalies rather than hypoxia alone. If the baseline fHR is less than 110 beats per minute, it is termed bradycardia. Fetal bradycardia is defined as a baseline heart rate less than 120 bpm. Bradycardia from 100-120 bpm with normal variability is not associated with fetal acidosis. Bradycardia less than 100 bpm occurs in fetuses with congenital heart abnormalities or myocardial conduction defects, such as those occurring in conjunction with maternal collagen vascular disease. Moderate bradycardia from 80-100 bpm is a non-reassuring pattern. Severe bradycardia, less than 80 bpm lasting for three minutes or longer, indicates severe hypoxia and is often a terminal event. If the cause cannot be identified and corrected, immediate delivery is recommended.

Variability has been defined as fHR fluctuations in the baseline fHR over 1 minute. These fluctuations vary in amplitude and frequency and are visually identified as the amplitude of the peak to trough in beats per minute. If the amplitude is not detectable, then it is described as absent fHR variability; if the amplitude is detectable, but less than 6 beats per minute, then it is defined as minimal fHR variability; if amplitude ranges from 6-25 bpm, then this is moderate fHR variability; if amplitude is greater than 25 bpm, then it is defined as marked fHR variability. In addition, a sinusoidal fHR pattern (i.e. smooth sine wave pattern of regular frequency and amplitude) is present.

Acceleration is defined as an abrupt increase in the fHR, 15 beats per minute above the baseline, lasting for at least 15 seconds and less than 10 minutes. Before 32 weeks' gestation, accelerations are defined as greater than 10 bpm above the baseline for more than 10 seconds. Prolonged acceleration is defined as an increase in the fHR for greater than 2 minutes, but less than 10 minutes (acceleration of ≥ 10 minutes is a baseline change). The presence of accelerations reveals fetal responsiveness and is considered a reassuring sign of fetal well-being.

Deceleration is defined as an abrupt decrease in the fHR and return to baseline usually of less than 30 seconds. The deceleration should be at least 15 beats below the baseline, lasting for at least 15 seconds, but less than 2 minutes in duration. These may either be normal or pathological. Early decelerations occur at the same time as uterine contractions and are usually due to fetal head compression and therefore occur in the first and second stage labor with decent of the head. They are normally perfectly benign. Late decelerations persist after the contraction has finished and suggest fetal distress. Variable decelerations vary in duration and shape with respect to each other and may be indicative of hypoxia or cord compression. Parallel recordings of the uterine contractions are necessary for identification of the three types of decelerations.

B. *Second approach*

The main disadvantage of the BSS-based approach is that it requires a large number of recorded ECG leads; the larger the number of the sources the better the results of the analysis. Furthermore, each electrode must record a different mixture of sources and thus the electrodes must be scattered on the mother's body and thoracic electrodes are required [28]. Therefore, the use of these methods is limited in cases of non-clinical environment systems (i.e. homecare devices) where, the recording of a large number of sources makes their application difficult and uncomfortable. Thus, a second approach is developed, which utilizes only the 5 uni-polar abdomen leads, while the methodology is designed and developed to be able to proceed with the analysis and extract mHR and fHR using even a single lead (if it carries sufficient fetal cardiac activity information).

Time-frequency analysis: A three-stage methodology for mHR and fHR extraction, from abdECG recordings, is used [25]. In the first stage the maternal R-peaks and fiducial points (QRS onset and offset) are detected, using time-frequency analysis, and the maternal QRS complexes are eliminated. Also, the maternal R–R interval signal is computed and the mHR is extracted from it. The second stage locates the positions of the candidate fetal R-peaks, using complex wavelets and pattern matching theory techniques. In the third stage, the fetal R-peaks which overlap with the maternal QRS complexes are found using a histogram based technique. The results from the second and the third stage are combined to form the fetal R–R interval signal and the fHR is extracted from it.

The mHR and fHR are utilized for maternal arrhythmia diagnosis and fetal cardiac health assessment, respectively, as it is descripted above.

C. *Data fusion and Overall Diagnosis*

Besides the above, some secondary systems, monitoring blood pressure, SPO_2 and temperature of the mother along with some supplemental information regarding textual reports and medical history, can be included in the monitoring system.

Maternal Blood Pressure: This system is responsible for assessing the recorded blood pressure values compared to stored medical thresholds. Normal blood pressure is below 140/90 mmHg (Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP)). SBP is the pressure in the arteries when the heart contracts while DBP is the pressure in the arteries when the heart rests (between heart beats). Categorization of the blood pressure is made as:

```
IF (140 mmHg≤SBP<160 mmHg)
OR (90 mmHg≤DBP<100 mmHg)
➔ Mild-to-moderate high blood pressure
ELSE IF (SBP≥160 mmHg)
OR (DBP≥100 mmHg)
➔ Mild-to-moderate high blood pressure
```

Maternal SPO_2: Arterial oxygen saturation monitoring in pregnant women is useful assessments of therapeutic interventions (ventilator changes, intravenous volume administration, oxygen therapy). The system responsible for SPO_2 diagnosis is based on the following rule related to digital oxymetry saturation values:

```
IF SPO2<96% ➔ Hypoxemia
```

Maternal Temperature: During pregnancy the maternal temperature is monitored and a corresponding diagnosis is produced according to the medical rules presented below:

```
IF Temperature>100.94°F  ➔ Severe Hyperthermia
ELSE IF Temperature>100.4°F  ➔ Hyperthermia
ELSE IF Temperature>99.5°F  ➔ Mild hyperthermia
```

Textual Reports: A Pregnancy Report is a part of information whose validity is relatively short-lived, and frequently updated, such as the daily measurements, contact with a health care professional, psychological and physiological status, etc. The information included in a textual report is essential for the assessment of maternal and fetal health status. Two indicative cases from the 19 questions that compose the textual report are presented below:

- `Have you noticed blooding from down below?`
- `Do you have nausea or want to vomit?`

Medical History: It contains all data needed for the constitution of a comprehensive medical record providing information on general medical history, obstetrics history, previous pregnancies, and family history in order to determine predisposition, blood transfusion and operation, heart diseases and allergies.

Apart from the alerts provided the preliminary diagnosis module (e.g. appearance of arrhythmic episodes, increase in blood pressure or body temperature, etc.) the results of the primary diagnosis are combined with the textual reports and her medical history to provide useful diagnostic data about the maternal and fetal health condition and the pregnancy progress.

In order to maximize the useful information content to produce information of tactical value to the responsible obstetrician and improve the system's reliability, data from different sources should be collected and combined. The application of data fusion in our system is perceived as essential due to the fact that pregnancy assessment is one of these areas in which the required output of the analysis may not be measured directly. The fusion is the stage where the measured data, with (mECG, fECG, Blood Pressure) or without (Temperature, SPO_2) pre-processing, is combined with other data (previous measurements, textual reports, medical history, demographic data) and a priori knowledge (medical rules and thresholds) in order to generate a global assessment and suggestions for other monitoring parameters.

III. Results

Experimental results were obtained using datasets of real and simulated recordings. All results were evaluated by expert cardiologists. It should be noted that the current employed dataset was composed by real abdominal recordings extracted from the database of the University of Nottingham [5]. This database consists only of abdominal recordings; so simulated signals were also generated using a dynamical model for generating synthetic electrocardiogram signals called *ecgsyn* [29]. In addition, two widely used standard reference databases [30, 31] were employed for the evaluation of the algorithms for the diagnosis of maternal ischemia and arrhythmia.

mECG and fECG separation: One real recording [32] and 30 simulated were used for the evaluation of the proposed BSS approaches. Each recording consists of 8 channels, 5 abdominal and 3 thoracic. The real recording has 1 min duration while the simulated 6 min. After the BSS application, several channels are produced; so a detection algorithm is applied for the location of the channels of interest (the mECG and fECG). The obtained sensitivity (Se) and positive predictive accuracy (PPA) for PCA was 98.44% and 99.99%, respectively. ICA methods (fast-ICA and

JADE) presented the best results (100% for both Se and PPA).

In the case of time-frequency analysis, additional abdominal signals were used, obtained from the fECG database of the University of Nottingham [5]. Specifically, 4 long recordings of 15 min duration with three measurement locations for improved signal acquisition were used. The three channels of raw ECG data were recorded between the 20^{th} and 41^{th} weeks of gestation. The sampling frequency was 300Hz and 12-bit resolution was employed. The system uses three pairs of electrodes placed around the mother's abdomen. In our case we didn't use thoracic signals but only abdominal recordings. Table 1 presents the results obtained from the evaluation of the proposed method. The average Se is 98.18% and the average PPA is 97.88%, while the average Acc is 96.11%. The dataset includes totally 7402 fetal R-peaks from which 150 were not detected (2.06%), while 139 artefacts are detected as fetal R-peaks (1.91%).

TABLE 1
EVALUATION RESULTS

Record	TP	FP	FN	Se (%)	PPA (%)	Acc (%)
w24	1935	10	82	95.93	99.49	95.46
w28	1915	0	10	99.48	100	99.48
w32	1789	33	30	98.35	98.19	96.60
w34	1624	107	17	98.96	93.82	92.91
Total	**7263**	**150**	**139**	**98.18**	**97.88**	**96.11**

Table 2 presents several methods proposed in the literature for the extraction of the fHR. Due to the fact that there is no benchmark database, each approach is evaluated using different dataset. Therefore, a direct comparison between the results is not feasible. All the methods were validated using real records (no simulated signals were involved) while all leads are placed on the abdomen of the mother (no thoracic leads were used). The proposed method provide comparable results with the other methods.

TABLE 2
COMPARISON OF METHODS

Author	Description	Dataset	Acc (%)
Pieri *et al.*, [5]	matched filter	400 records 5-10 min	65
Azad [12]	fuzzy approach	5 records	89[1]
Ibahimy *et al.*, [17]	statistical analysis	5 records 20 min	89[2]
Karvounis *et al.*, [16]	complex wavelets	15 records 1 min	98
Karvounis *et al.*, [26]	**time-frequency methods**	**4 long records 15 min**	**96**

[1]Defined as: $performance = 100\left(TP - \left(FP + FN\right)\right)/TP\,\%$.

[2]Correlation coefficient between the simultaneous fHR measured from Doppler ultrasound and the method.

Pieri et al. [5] uses the larger dataset among all the methods presented on Table 2 (400 records of 5-10 min each), but the results are rather poor (65%). The fuzzy-based approach by Azad [12] performed very well with 89% average performance, but there is no reference about the exact number and duration of abdECG records that were used for the evaluation. The study by Ibahimy *et al.* [17] is evaluated using the correlation coefficient between the simultaneous fHR measured from Doppler ultrasound and the method (89%).

Maternal ischemia diagnosis: The method [24] was tested on the ESC ST-T database [30] and high scores were obtained for both Se and PPA (93.75% and 78.50%, respectively, using aggregate gross statistics and 90.68% and 80.66%, respectively using aggregate average statistics).

Maternal arrhythmia diagnosis: The method [26] is evaluated using the MIT-BIH arrhythmia database [31]. The achieved scores indicate high performance: 98% accuracy for arrhythmic beat classification and 94% accuracy for arrhythmic episode detection and classification.

IV. DISCUSSION

A system is presented for the monitoring the health status of the pregnant mother and the fetus. The proposed system acquires several vital signs, such as fetal and maternal electrocardiograms, blood pressure, temperature and respiration, and processes them in order to provide diagnosis. The data are transmitted to a centralised system where among other tasks the diagnosis is generated. The system is based on the separation of maternal and fetal electrocardiograms obtained from the mother's thorax and abdomen. The system was evaluated using several real and simulated multichannel recordings and the proposed algorithms have been proven to be very efficient.

The system is non-invasive, which 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 that is based on the hospital setting to one which can always be carried by the pregnant woman and used anywhere.

The BSS based approach, besides presenting very good results; it also automatically locates the signals of interest among the resulted signals of the BSS analysis. This is a major advantage compared to most of the BSS based approaches proposed in the literature; no procedure that locates the signals of interest or quantitative criterion that measures its quality exists [6,8-11,13,14,19-22].

The time-frequency method is based on the analysis of abdominal leads; thoracic leads are not necessary. Also, the number of the leads is not important; the analysis can be carried out with even with a single lead, if it carries substantial fECG information. Both these features are major advantages of the proposed methodology due to the fact that the placement of a large number of electrodes on the mother is difficult and impossible to be performed under non-clinical or mobile settings.

The main problem in designing such a system is the elimination of noise of the vital signals. Especially in the case of ECG acquisition, we observed that the signal is affected moderately by A/C interference, muscle contractions, respiration, in addition to electromyogram (EMG) and electrohysterogram (EHG) due to uterine contractions [6]. So, better filtering modules could also be used to overcome these drawbacks. Also, the shape of the fECG signal depends on the position of the electrodes (there is no standard electrode positioning for optimal fECG acquisition [28]), on the gestational age and the position of the fetus [33]. All of the aforementioned constraints make the fECG extraction a difficult process. Furthermore, the overall system must be evaluated through a series of clinical trials in order to fully examine its potential.

Another limitation of the proposed system is the lack of a uterine contraction recording. The incorporation of an external transducer for recordings of the uterine contractions is essential for detection of all types of periodic fHR changes.

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