OBSTETRICS

Clinically accurate fetal ECG parameters acquired from maternal abdominal sensors

Gari Clifford, PhD; Reza Sameni, PhD; Jay Ward; Julian Robinson, MBChB; Adam J. Wolfberg, MD

OBJECTIVE: We sought to evaluate the accuracy of a novel system for measuring fetal heart rate (FHR) and ST-segment changes using noninvasive electrodes on the maternal abdomen.

STUDY DESIGN: Fetal electrocardiograms were recorded using abdominal sensors from 32 term laboring women who had a fetal scalp electrode (FSE) placed for a clinical indication.

RESULTS: Good-quality data for FHR estimation were available in 91.2% of the FSE segments and 89.9% of the abdominal electrode segments. The root mean square error between the FHR data calculated by both methods over all processed segments was 0.36 beats per minute. ST deviation from the isoelectric point ranged from 0–14.2% of R-wave amplitude. The root mean square error between the ST change calculated by both methods averaged over all processed segments was 3.2%.

CONCLUSION: FHR and ST change acquired from the maternal abdomen is highly accurate and, on average, is clinically indistinguishable from FHR and ST change calculated using FSE data.

Key words: fetal electrocardiogram, fetal monitoring, labor

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Continuous fetal heart rate (FHR) monitoring during labor is utilized in >85% of labor episodes in the United States and represents the standard of care,[1] although there is scant evidence to demonstrate that the use of the technology improves newborn or maternal outcomes.[2] Encouraging data demonstrate that intrapartum fetal electrocardiogram (fECG) analysis can reduce newborn acidemia, hypoxic ischemic encephalopathy,[3] and cesarean deliveries.[4] However, the only clinically available device for fECG analysis—the STAN monitor from Neoventa (Moindal, Sweden)—requires an invasive fetal scalp electrode (FSE), limiting its use to a subset of pregnant women who are laboring with ruptured membranes and a dilated cervix.

The potential utility of noninvasive fECG for fetal evaluation is significant. However, to date, there has been no systematic study proving that fECG can be extracted noninvasively without distorting important clinical parameters, such as the ST segment. Prior reports have shown the capacity to measure FHR using electrodes on the maternal abdomen, but none have demonstrated the capacity to accurately record the fECG waveform with sufficient fidelity to evaluate the morphology.[5] Recently, we developed a novel real-time signal processing approach for extracting fECG that mitigates many of the issues involved in extracting an accurate and clinically relevant electrocardiogram (ECG). This study evaluates the performance of our technique in extracting FHR variations and ST levels from laboring patients and compares them to invasive scalp electrode data.

Materials and Methods

We recorded data from 32 term laboring women who had an FSE placed for a clinical indication and consented to participate in this study. Enrollment occurred sequentially, and there were no exclusion criteria. The study was conducted during the first and second stages of labor. Demographic information about the studied subjects is summarized in the Table.

Data were recorded using an E-TROLZ (North Andover, MA) physiologic monitoring platform, which samples 32 channels at 1 kHz. Standard gel-adhesive ECG electrodes (Red-Dot; 3M, St. Paul, MN) were used in a standard configuration developed to maximize the chances of having electrodes adjacent to the fetal heart. The general configuration of the abdominal

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TABLE
Demographic data of studied subjects

Demographics (n = 32)	Median	Range
Maternal age at delivery, y	32	19–40
Gestational age at delivery, wk	40	35–41
Nonwhite mother, %	41	
Multiparous, %	47	
Birthweight, g	3459	1840–4110
Female baby, %	50	
1-min Apgar score	8	2–9
5-min Apgar score	9	8–9
Body mass index	30.4	21.7–45.1
Epidural during study, %	97	
Pushing during study, %	9.4	

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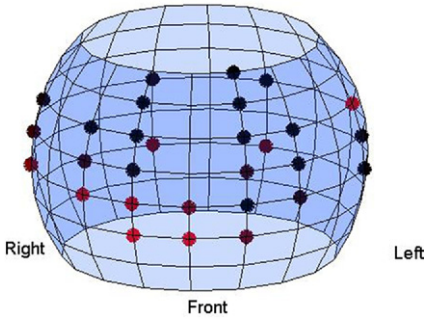
electrodes is illustrated in Figure 1. Electrodes were placed based on anatomic landmarks (the umbilicus, xyphoid process, pubic symphysis, axilla, and spine are used to locate electrodes), and as a consequence, the distance between electrodes varied with the maternal abdominal girth. The number of electrodes was arbitrarily chosen based on the capacity of the recording device, and allows for excellent coverage of the maternal abdomen, sides, and back. The specific location of the electrodes is unimportant, as the analysis is done based on the physiologic signal alone, without consideration to the location of each electrode. No patient skin preparation was done prior to electrode placement. Both the abdominal ECG data and the scalp ECG were preprocessed for removal of interference from maternal ECG (mECG), as well as power line contamination and other sources of background electrical noise, including maternal muscle artifact.

FIGURE 1
Abdominal electrode location



Locations of abdominal electrodes and corresponding signal quality on each electrode (*red* = high, *black* = low).

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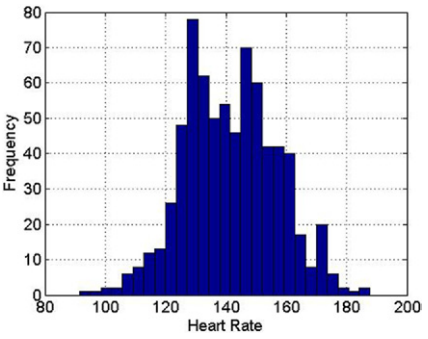
Our fetal extraction method was then applied to the abdominal data. For the extracted and filtered abdominal data, each beat was located using a standard QRS detector.[6] Each beat was segmented ±20 milliseconds around the fiducial point (R-peak). FHR was calculated from the reciprocal of the median RR interval scaled by a factor of 60. Median FHRs were calculated from 1012 10-second segments from the processed abdominal data and gold standard scalp fECG. Data were recorded for between 9–28 minutes from each subject, and we analyzed the first 10 seconds of every 30-second epoch of data for all 32 subjects. As a consequence, between 17–56 10-second segments were analyzed for each subject. Data were analyzed after delivery had occurred, and no research data were available to clinicians managing the subjects' labor.

We used a new method of extracting fECG from a mixture of mECG and fECG that uses a priori information concerning the cardiac signals, including their pseudoperiodic structure, to improve the performance of existing techniques and to design novel filtering techniques specific to fetal cardiac signal. By using a realistic model of an individual fetus' ECG,[7-9] which is tracked over time using a Kalman filter framework,[10] a low-distortion representation of the maternal beat could be extracted from the fECG/mECG mixture.[8-14] Although the Kalman filter and its extensions are now considered to be classic tools in the signal processing community, our approach involves customizing these techniques

FIGURE 2
Histogram of heart rates of studied fetal electrocardiograms



(1012 electrocardiograms segments used in histogram.)

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for fetal cardiac signals, to develop realistic dynamic models that are able to follow the temporal variations of the fECG in highly noisy environments. We have extended these frameworks and developed novel methods for tracking nonstationarities in both the noise and signal. Unlike other computational approaches, this method successfully cancels mECG, with minimal distortion (in the relevant clinical parameters) of the fECG.

The color coding in Figure 1 is an example that illustrates the signal quality from a given set of electrodes for 1 patient at a particular instant in time. The signal quality will vary across patients (and over time for a particular patient). This is often due to changes in maternal or fetal position and hence, not all sensors are used at any given point in time. However, it is difficult to predict which sensor locations are optimal in advance. We therefore, used an over-complete set of electrodes and a series of signal quality measures to determine automatically which sensors contribute most of the information at any given point in time.

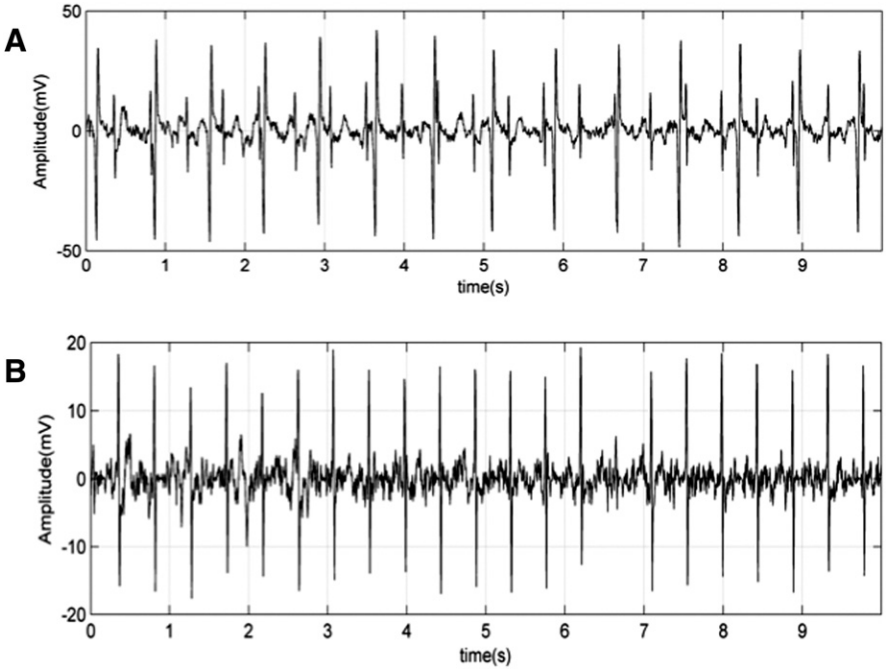
Isoelectric levels and ST levels were estimated from a subset of 271 10-second segments from the same data. Adult ST analysis was performed on an average window, rather than on individual beats,[15-17] and therefore, an average beat was calculated for each 10-second segment for use as an analysis template. Each beat was also cross correlated with

the template. Beats with a correlation with the template of <0.9 were rejected. If the number of beats left was <15 beats, or >40% of the beats were rejected, the segment was rejected. Otherwise, the remaining beats were reaveraged. ST analysis was then performed using techniques previously described,[16] except that the thresholds[15,17] were scaled to allow for differences between fetal and adult beats. These criteria were applied independently on each channel of data, so no information from the scalp electrode was used to alter the abdominal data or select abdominal data for comparison.

The ST-segment amplitude and the isoelectric level were computed as the median of signal segments of length 20 milliseconds surrounding the J-point and the isoelectric segment to avoid measurement jitter due to amplitude scatter of the original signal samples. To ensure objectivity in the analysis, the abdominal fetal separation algorithm was implemented by 1 author and the ST-segment analysis algorithms were developed and run independently by another author without collaboration.

This study was approved by the institutional review boards at our institutions.

FIGURE 3
ECG waveforms extracted from abdomen



Segment of abdominal signals **A,** before and **B,** after maternal electrocardiogram subtraction.
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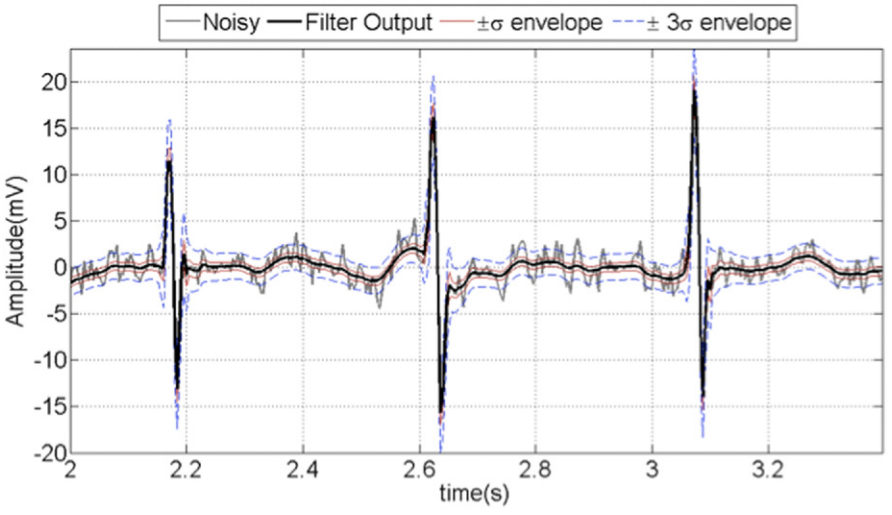
RESULTS

In Figure 2, the histogram of the average FHRs calculated from 1012, 10-second segments is shown. For these data, the minimum, maximum, and average FHR were 91.4 beats per minute (BPM), 187.8 BPM, and 141.6 BPM, respectively, with SD (σ) of 15.4 BPM. This range covers a broad range of typical FHRs.[5]

Data of sufficient quality for FHR estimation were available in 91.2% of the 10-second FSE segments, and 89.9% of the 10-second abdominal electrode segments. The average (root mean square) error between the FHR data calculated by both methods over all processed segments was 0.36 BPM. ST elevation from the isoelectric level ranged from 0–10.6% of R-wave amplitude. ST depression from the isoelectric level ranged from 0–14.2% of R-wave amplitude. The root mean square error between the ST change calculated by both methods averaged over all processed segments was 3.2% and the mean

FIGURE 4
Extracted fetal ECG waveforms



Several fetal electrocardiogram beats (from Figure 3, B), before (*gray lines*) and after (*black line*) postprocessing using our Kalman filter approach, together with 68% ($\pm\sigma$) and 99.7% ($\pm 3\sigma$) confidence intervals (*upper and lower dashed envelopes*).
ECG, electrocardiogram.
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FIGURE 5
Typical fetal ECG waveform

Typical fetal heart beat recorded from scalp electrode (*magenta*) and overlaid extracted abdominal fetal electrocardiogram (ECG) (*blue*).

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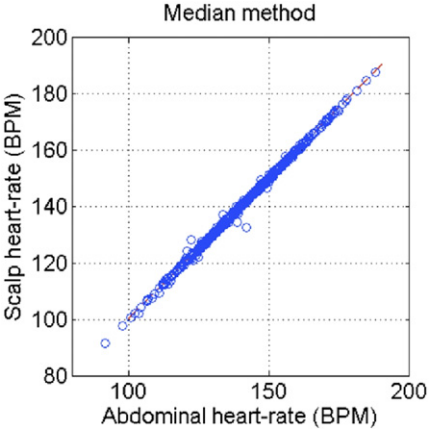
FIGURE 6
Extracted fetal heart rate



Comparison of median fetal heart rate calculated from scalp vs abdominal electrode for 10-second segments. (1012 electrocardiogram segments used in histogram.)

BPM, beats per minute.

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absolute difference was +0.4%, indicating a very small positive bias.

There was no relationship between the subjects' body mass index and the fidelity of the fECG waveform that was extracted.

A typical ECG waveform can be seen in Figure 3. Figure 4 illustrates the extracted fECG in Figure 3, B after postprocessing together with its 68% ($\pm\sigma$) and 99.7% ($\pm 3\sigma$) confidence intervals (signal envelopes). Figure 5 illustrates a comparison between 10-second averaged heartbeats from the invasive scalp electrode and the extracted fECG from the abdominal electrodes (without using the FSE). Note the similarity in morphology, including the isoelectric levels, the ST level, and the PR interval. The average correlation between the fECG extracted from the abdominal and scalp leads was 0.96 over a complete beat and 0.69 over the ST segment.

Figure 6 presents the results of the median FHR estimations from the scalp and abdominal electrodes. When plotted as a function of each other, they clearly demonstrate a strong correlation, with almost every point lying on the line of identity. To quantify this observation, the Kolmogorov-Smirnov goodness-of-fit hypothesis test was performed on the scalp and abdominal heart rate time series. The null hypothesis, ie, the hypothesis that the scalp and abdominal heart rate time series of 10-second segments have identical distributions, was rejected in only 5.5% of the study segments ($P < .01$).

Comment

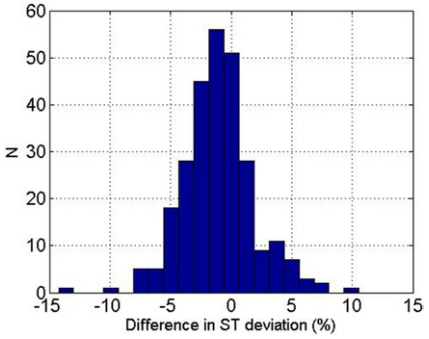
Our results indicate that extraction of noninvasive fECG without distorting clinical parameters is possible using a novel signal processing approach. FHR variability and ST deviation from ECG acquired from the maternal abdomen can be estimated, which are clinically indistinguishable from FHR variability and ST deviation derived from the FSE in our patient population.

This report is the first to compare the fECG waveform measured using noninvasive electrodes to the ECG waveform measured using FSE. To the extent that the FSE represents the gold standard in fetal monitoring, both for fECG and for FHR monitoring, this is an important evaluation of our technique's accuracy.

In 10.1% of abdominal ECG segments evaluated, we failed to extract a useful ECG waveform. However, the current study was conducted on data recorded during labor but analyzed after delivery. Therefore, human errors, such as sensor misplacements, sensor detachments, or loose connections, have been accumulated in the 10% figure. In the future, real-time analysis of data, with immediate display of signal quality and ECG waveform, will allow for the clinician to make minor adjustments that will increase accuracy of the technology over the 89.9% rate reported here.

Due to the small number of patients studied and the fortunate absence of intrapartum hypoxic or ischemic events, we were unable to watch the change in the ST segment during periods of fetal ischemia. Because of this, we do not demonstrate that our algorithm maintains ST-segment fidelity between the FSE and the abdominal leads during conditions of hypoxia or ischemia. Larger clinical studies or animal research will be needed to confirm the fidelity of our algorithms under all clinical circumstances.

FIGURE 7
Fetal ST deviation



Empirical distribution of differences in ST deviation estimated from extracted abdominal and scalp electrodes. (271 electrocardiogram segments used in histogram.)

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There are no guidelines as to exactly how much of an elevation or depression would be clinically significant in a fetal population. Figure 7 presents the distribution of the differences in ST elevation or depression between the scalp and abdominal extracted data. Note that the largest difference was <14.5%. This difference can be explained due to the morphological difference of the fECG extracted from the scalp and abdominal leads, similar to different adult ECG morphologies. Moreover, considering that ST-segment elevation requires a continued elevation for several epochs, the actual ST-level sensitivities are expected to be better than the results presented in this study.

Future research will extend these analyses to larger samples of patients at high risk for ischemia, as well as to animal models where fetal oxygen content and umbilical vascular flow can be modulated.

Although our methods performed well in the second stage of labor and among obese women, additional studies that include larger numbers of women in these clinical situations that challenge conventional monitoring technology, will be needed to extend our results.

Limitations of this study include the potential for selection bias. Only women who had an FSE placed for a clinical indication were included in the study, and only women who consented to participate in the study were included. Additionally, nearly all women in the study had an epidural in place when data were collected. It may be that the epidural diminished patient activity and made it easier to extract the fECG signal. Additional research will be needed to determine whether our technique performs as well in a group of women without regional anesthesia as it does in the group of subjects presented here.

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REFERENCES

1. American College of Obstetricians and Gynecologists. ACOG practice bulletin no. 106: intrapartum fetal heart rate monitoring: nomenclature, interpretation, and general management principles. Obstet Gynecol 2009; 114:192-202.

2. Vintzileos AM, Nochimson DJ, Guzman ER, Knuppel RA, Lake M, Schifrin BS. Intrapartum electronic fetal heart rate monitoring versus intermittent auscultation: a meta-analysis. Obstet Gynecol 1995;85:149-55.

3. Amer-Wahlin I, Bordahl P, Eikeland T, et al. ST analysis of the fetal electrocardiogram during labor: Nordic observational multicenter study. J Matern Fetal Neonatal Med 2002;12:260-6.

4. Noren H, Blad S, Carlsson A, et al. STAN in clinical practice—the outcome of 2 years of regular use in the city of Gothenburg. Am J Obstet Gynecol 2006;195:7-15.

5. Sameni R, Clifford GD. A review of fetal ECG signal processing; issues and promising directions. Open Pacing Electrophysiol Ther J 2010;3:4-20.

6. Hamilton PS, Tompkins WJ. Quantitative investigation of QRS detection rules using the MIT/BIH arrhythmia database. IEEE Trans Biomed Eng 1986;33:1157-65.

7. McSharry PE, Clifford GD, Tarassenko L, Smith LA. A dynamical model for generating synthetic electrocardiogram signals. IEEE Trans Biomed Eng 2003;50:289-94.

8. Clifford GD. A novel framework for signal representation and source separation: applications to filtering and segmentation of biosignals. J Biol Syst 2006;14:169-83.

9. Clifford GD, Shoeb A, McSharry PE, Janz BA. Model-based filtering, compression and classification of the ECG. Int J Bioelectromagn 2005;7:158-61.

10. Sameni R, Shamsollahi MB, Jutten C, Clifford GD. A nonlinear Bayesian filtering framework for ECG denoising. IEEE Trans Biomed Eng 2007;54:2172-85.

11. Sameni R, Vrins F, Parmentier F, et al. Electrode selection for noninvasive fetal electrocardiogram extraction using mutual information criteria. Proceedings of the 26th International Workshop on Bayesian Inference and Maximum Entropy Methods in Science and Engineering (MaxEnt 2006). Vol 872. Paris, France: CNRS; 2006.

12. Sameni R, Jutten C, Shamsollahi MB. Multichannel electrocardiogram decomposition using periodic component analysis. IEEE Trans Biomed Eng 2008;55:1935-40.

13. Sameni R, Clifford GD, Jutten C, Shamsollahi M. Multichannel ECG and noise modeling: application to maternal and fetal ECG signals. EURASIP J Adv Signal Process 2006;2007:1-14.

14. Sameni R. Extraction of fetal cardiac signals from an array of maternal abdominal recordings [doctoral thesis]. Grenoble, France: Electrical Engineering and Computer Science, Institut National Polytechnique; 2008.

15. Jager F. Automated detection of transient ST-segment changes during ambulatory ECG monitoring [doctoral dissertation]. Ljubljana, Slovenia: Faculty of Electrical and Computer Engineering, University of Ljubljana; 1994.

16. Jager F, Moody GB, Mark RG. Detection of transient ST-segment episodes during ambulatory ECG monitoring. Comput Biomed Res 1998; 31:305-22.

17. Jager F, Taddei A, Moody GB, et al. Long-term ST database: a reference for the development and evaluation of automated ischemia detectors and for the study of the dynamics of myocardial ischemia. Med Biol Eng Comp 2003;41:172-82.