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ORIGINAL ARTICLE

Feasibility of Noninvasive Fetal Electrocardiographic Monitoring in a Clinical Setting

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Abstract Cardiac rhythm is an essential component of fetal cardiac evaluation. The Monica AN24 is a fetal heart rate monitor that may provide a quick, inexpensive modality for obtaining a noninvasive fetal electrocardiogram (fECG) in a clinical setting. The fECG device has the ability to acquire fECG signals and allow calculation of fetal cardiac time intervals between 16- and 42-week gestational age (GA). We aimed to demonstrate the feasibility of fECG acquisition in a busy fetal cardiology clinic using the Monica fetal heart rate monitor. This is a prospective observational pilot study of fECG acquired from fetuses referred for fetal echocardiography. Recordings were performed for 5–15 min. Maternal signals were attenuated and fECG averaged. fECG and fetal cardiac time intervals (PR, QRS, RR, and QT) were evaluated by two cardiologists independently and inter-observer reliability was assessed using intraclass coefficient (ICC). Sixty fECGs were collected from 50 mothers (mean GA 28.1 ± 6.1). Adequate signal-averaged waveforms were obtained in 20 studies with 259 cardiac cycles. Waveforms could not be obtained between 26 and 30 weeks. Fetal cardiac time intervals were measured and were reproducible for PR (ICC = 0.89; CI 0.77–0.94), QRS (ICC = 0.79; CI 0.51–0.91), and RR (ICC = 0.77; CI 0.53–0.88). QT ICC was poor due to suboptimal T-wave tracings. Acquisition of fECG and measurement of fetal cardiac time intervals is feasible in a clinical setting between 19- and 42-week GA, though tracings are difficult to obtain, especially between 26 and 30 weeks. There was high reliability in fetal cardiac time intervals measurements, except for QT. The device may be useful for assessing atrioventricular/intraventricular conduction in fetuses from 20 to 26 and >30 weeks. Techniques to improve signal acquisition, namely T-wave amplification, are ongoing.

Keywords Fetal cardiology · Fetal electrophysiology · Fetal electrocardiogram

Introduction

Antenatal evaluation of the fetal heart is an essential component for managing high-risk pregnancies, including maternal diabetes, maternal autoimmune disorders, congenital heart disease, and many other maternal and fetal pathophysiological conditions. Fetal cardiologists have largely focused on the accurate prenatal diagnosis of cardiac disease, including congenital heart defects, heart failure, and rhythm disturbances [16]. Assessment of the cardiac rhythm via ECG is standard for a comprehensive postnatal cardiac evaluation. In the current era, fetal cardiac evaluation of fetal rhythm is limited to fetal heart rate monitoring and echocardiographic Doppler and M-Mode techniques for assessing atrioventricular conduction [16]. Current modalities for visualizing ECG waveforms in the fetus include magnetocardiogram, intrapartum scalp monitoring, and the fetal electrocardiogram (fECG) [8]. Fetal scalp monitoring is invasive, limited to the perinatal period,

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and can only measure ST segments and heart rate variability [1]. The magnetocardiogram, though promising, is time consuming and expensive to use [18].

The potential utility of a noninvasive fECG for fetal evaluation is significant. Fetal electrocardiography utilizes signal-averaged electrical data obtained from a noninvasive fetal heart rate monitor to extract a standard electrocardiogram from the fetus by using algorithms similar to those used in fetal magnetocardiography. fECG offers the promise of a portable, inexpensive method for obtaining electrocardiograms on fetuses.

The Monica AN24 [Monica Healthcare Ltd, Nottingham, UK] is a small, wireless fetal heart rate device which is approved for use during labor and delivery by the US Food and Drug Administration (FDA). The device uses a wireless, noninvasive technology to collect real-time fetal electrical signal; skin electrodes are placed on the maternal abdomen to monitor and acquire the fECG, maternal ECG, and uterine contractions. A powerful internal processor extracts these variables individually in real time. The device utilizes complex algorithms to correctly identify signals related to the fetal heart rate and uterine contractions. It has been demonstrated that the fetal heart rate tracing derived by this noninvasive fECG device correlates well with the fetal scalp electrode method of obtaining fetal heart rate [6, 15]. Signals averaged from the device over several cardiac cycles have been used to create an ECG tracing. We aimed to demonstrate the feasibility of fECG acquisition in a busy fetal cardiology clinic using the noninvasive Monica fetal heart rate monitor.

Materials and Methods

This is a prospective observational pilot study between September 2012 and March 2013 of fECG acquired from fetuses (estimated GA 16 and 42 weeks) referred for fetal echocardiogram (all indications) in the Fetal Heart Program at Children's National Medical Center. The study protocol was approved by the Children's National Medical Center Institutional Review Board.

After obtaining informed consent, the noninvasive fECG device was placed on the maternal abdomen either before or after the fetal echocardiogram was performed. The skin was prepared for low impedance by gentle scrubbing of the surface skin cells. The five disposable electrodes were placed on the maternal abdomen in a standardized manner: Two electrodes were placed along the midline (at the side of the uterine fundus and above the symphysis), one at each side of the uterus, and the ground electrode on the left flank (Fig. 1). If the fundus was difficult to palpate, the position of the fetus was first demonstrated by quick ultrasound evaluation of fetal position in order to improve the positioning of the electrodes in the vicinity of the fetus. A Bluetooth feature allowed visualization of the fetal and maternal rhythm strip as it was recorded (Fig. 2) in order to determine adequacy of the signal. Recordings were performed for a minimum of 5 min after an adequate signal was obtained. Once the monitor demonstrated adequate signal, subjects were given the option to continue to wear the monitor for the duration of their clinical visit until they moved from a seated to standing position. In situations where an adequate signal could not be obtained initially, several steps were taken to troubleshoot. If despite these actions, a signal could not be obtained, the electrodes and monitor were removed when 15 min had lapsed from the onset of electrode placement. Subjects with follow-up fetal echocardiograms had fECG obtained at each visit.

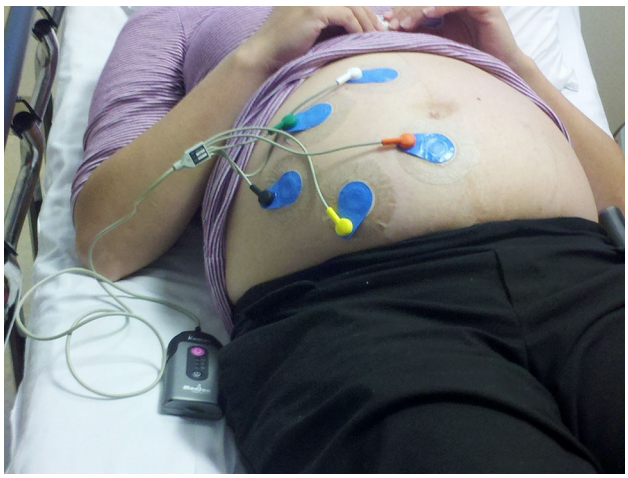

Fig. 1 Placement of electrodes on the maternal abdomen

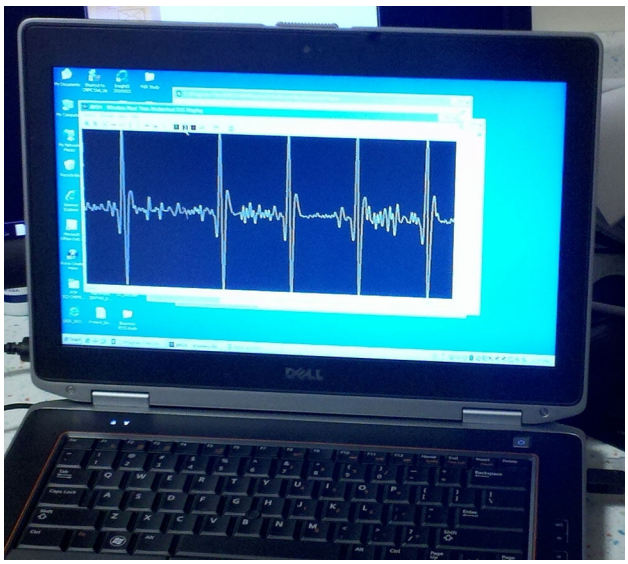

Fig. 2 Noninvasive fECG device Bluetooth allows for real time, crude determination of whether adequate acquisition settings have been obtained

Relevant antepartum data regarding potential maternal risk factors were recorded, including maternal demographic information, comorbidities and chronic illnesses, as well as medication exposures. Fetal risk factors including genetic abnormalities, syndromes, and anatomical abnormalities were also noted. When available, neonatal data regarding heart rate and cardiac abnormalities noted on neonatal echocardiogram, neonatal ECG results, and clinically relevant lab test data were also documented.

The electrophysiological signal contained the fetal heart rate, fECG, maternal ECG, and uterine contractions. The fetal heart rate was extracted followed by the attenuation of maternal cardiac signal. The attenuation of maternal cardiac signal was performed using a combination of template matching and digital subtraction approach. fECG was exported as a wave file at a sample rate of 300 Hz and processing was done in MATLAB (Mathworks Inc., Natick, MA, USA). fECG was bandpass filtered between 0.5 and 70 Hz using Butterworth filter with zero-phase distortion. The filtered fECG was split into 1-min epochs, and the cardiogram was averaged using 0.4 s of data prior and 0.78 s of data post to each R-wave. This choice of pre- and post-duration of data around the R-wave was chosen to include the T-wave from the preceding cycle and the P and QRS complex of the subsequent cycle and allowed reliable identification of the onset of P-wave and the end of T-wave.

In each 1-min averaged cardiogram, the time points P_{onset}, P_{end}, Q, R, S, T_{onset}, and T_{end} were identified by two cardiologists (B.A. and A.K.) independently, as well as by a computer-based automatic identification algorithm [5]. Using these time points, P-, Q-, R-, S-, T-wave durations, the fetal cardiac time intervals, PR, QRS, RR, and QT intervals were calculated. To account for changes in heart rate, the QTc was derived from the QT interval using the Bazett's formula [12]. Inter-observer reliability between the two cardiologists readings were assessed using intraclass coefficient (ICC). The fECG time points (P_{onset}, P_{end}, Q, R, S, T_{onset}, and T_{end}) derived manually by the primary reading cardiologist (B.A.) were compared to the computer-based automatic identification of fetal cardiac time intervals (PR, QRS, RR, and QT) using Bland–Altman plots. fECG intervals were also compared to echocardiographic Doppler derived intervals and postnatal electrocardiogram when available. Relationships between fetal cardiac time intervals and variables such as GA and fetal heart rate were evaluated using Pearson's correlation coefficient.

Results

Fifty subjects consented to fECG monitoring; 60 studies were completed (mean GA 27.4 ± 5.3; range 17–39 weeks). The characteristics of the subjects and fetuses, including indication for fetal echocardiogram referral, fetal cardiac findings by echocardiogram, and maternal risk factors, are described in Table 1. Adequate signal-averaged waveforms (example shown in Fig. 3) were obtained in 20 studies (33 %) from 19 subjects, with a bimodal distribution for GA. No subjects between 25 and 30 weeks had interpretable data. The mean GA for the gestation was 22.6 ± 1.8 weeks and for late gestation was 33.6 ± 2.5 weeks. Thirteen fetuses had no cardiac disease, two had structural heart disease, two had supraventricular tachycardia, and two had genetically confirmed long QT syndrome. A total of 259 cardiac cycles were available for analysis, and fetal cardiac time intervals could be measured in all studies with waveforms. The mean fECG recording time was 12.59 ± 5.38 (range 5–30) min. Characteristics of each of these 19 subjects are detailed in Table 2. Of note, the manufacturer's fECG extraction program demonstrated adequate fECG signal in only 13 cases, and an additional seven subjects had adequate fECG extractable only through our specialized fECG extraction methods delineated above.

Measurement of fetal cardiac time intervals were highly reproducible for PR (ICC = 0.89; CI 0.77–0.94), QRS (ICC = 0.79; CI 0.51–0.91), and RR (ICC = 0.77; CI 0.53–0.88) intervals between cardiologists. QT ICC was poor (ICC = 0.50; CI 0.01–0.075). The fECG value measurements obtained by computer-based identification demonstrated excellent agreement with the measurements made by the primary cardiologist, as demonstrated in Fig. 4.

Fetal cardiac time intervals (PR and RR) obtained by fECG were then compared to spectral Doppler derived PR and RR intervals from echocardiogram performed on the same day. There was good agreement between the two modalities for obtaining these intervals (Fig. 5). There were only four subjects with postnatal electrocardiograms available for review, and thus no correlations could be made to fECG intervals.

Looking at all 20 studies, there was no correlation between fetal cardiac time intervals measurements and GA. When subjects with cardiac findings, maternal risk factors, and family history of long QT were excluded ($n = 9$), there was still no relationship between any of the fetal cardiac time intervals measures and GA. Similarly, there was no significant relationship between fetal cardiac time intervals and changes in heart rate.

fECG in Subjects with Cardiac Findings

There were three fetuses with a parental history of long QT syndrome. One presented with fetal bradycardia to 100–110 beats per minute (Subject 49) and a second fetus with normal sinus rhythm was noted to have a QTc of 0.586 by magnetocardiogram (Subject 6). Both of these fetuses were presumed to have long QT syndrome, and

Table 1 Characteristics of subjects

Characteristic	Subjects with adequate FECG ($n = 19$)	Subject with inadequate fECG ($n = 31$)	p value
Maternal age	mean = 30.7 ± 6.4 years	mean = 31.27 ± 6.8 years	0.75
Gestational age at fECG	mean = 28.1 ± 6.1 weeks	mean = 26.9 ± 4.8 weeks	0.42
Fetal weight	mean = 1,406 ± 830 grams	mean = 1,150 ± 585 grams	0.36
Indication for fetal echocardiogram			
Fetal indication	$n = 10$	$n = 14$	
Maternal indication	$n = 4$	$n = 10$	
Family history	$n = 2$	$n = 7$	
Volunteer	$n = 3$	$n = 0$	
Fetal cardiac findings			
Normal fetal echo	$n = 14$	$n = 19$	
RVH/LVH/effusion	$n = 2$	$n = 6$	
Structural heart disease	$n = 1$	$n = 2$	
Arrhythmia	$n = 2$	$n = 4$	
Maternal risk factors			
No risk factors	$n = 14$	$n = 21$	
Gestational diabetes	$n = 1$	$n = 4$	
Pregestational diabetes	$n = 2$	$n = 4$	
Anti-SSA antibodies present	$n = 0$	$n = 2$	
Long QT syndrome	$n = 2$	$n = 0$	

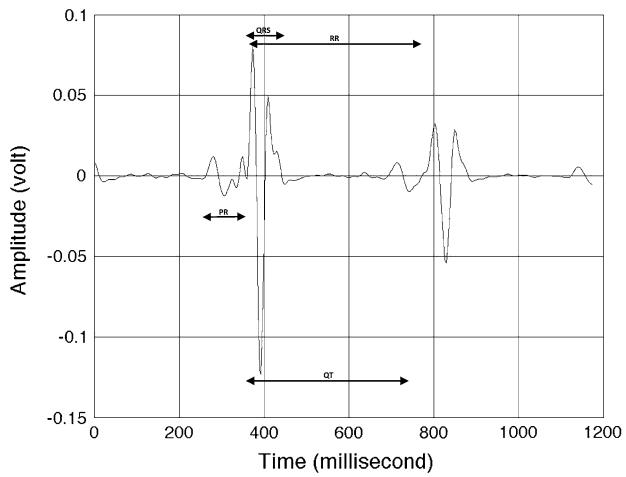

Fig. 3 Example of fECG signal-averaged waveform

postnatal ECG and genetic testing were confirmatory. The third fetus had normal sinus rhythm with no concerning findings on fetal studies and genetic testing was confirmatory for long QT. The QTc measured via fECG for the fetuses with confirmed long QT syndrome was significantly longer than fetuses without evidence of cardiac disease (QTc 0.514 vs. 0.494; $p = 0.041$). For Subject 6, the following fetal cardiac time intervals were obtained by magnetocardiogram PR 0.81, QRS 0.52, QTc 0.586, and RR 0.469 (for fECG derived intervals refer to Table 2).

Two fetuses were diagnosed with supraventricular tachycardia by fetal echocardiogram. At the time of fECG, one of the fetuses was undergoing treatment with maternal flecainide and was in normal sinus rhythm at the time of fECG (Subject 14). The second fetus remained in an irregularly irregular atrial rhythm at a rate of 220 beats per minute refractory to digoxin and flecainide. There was no difference in PR, QRS, or QTc in these two fetuses compared to fetuses without evidence of cardiac disease.

Finally, the fetal cardiac time intervals of the two fetuses with abnormal cardiac structure were compared to fetuses without evidence of cardiac disease. Several differences were noted. Fetuses with structural cardiac abnormalities (Subject 17 and 36) demonstrated significantly longer QRS (mean 0.112 ± 0.025 vs. 0.0911 ± 0.023) and QTc (mean 0.514 ± 0.016 vs. 0.488 ± 0.032) intervals. More specifically, the fetus with right ventricular hypertrophy and pericardial effusion (Subject 17) demonstrated a significantly longer QTc. The fetus with pulmonary atresia with intact ventricular septum (Subject 36) demonstrated significantly longer QRS and QTc.

Discussion

To date, there has been no systematic study to determine the feasibility of obtaining fECG in an outpatient fetal cardiology setting. Furthermore, there is limited literature

Table 2 Characteristics of subjects with adequate signal-averaged waveforms

Subject	Fetal echo indication	Cardiac finding	GA	Minutes of fECG data	Average RR	Average PR	Average QRS	Average QTc
6	Paternal long QT	Trivial pericardial effusion	35	16	0.455	0.134	0.081	0.513
8	Premature atrial contractions	Normal	34	8	0.432	0.142	0.078	0.474
11	Unclear images	Normal	32	9	0.451	0.104	0.067	0.503
12	Trisomy 21	Normal	23	11	0.450	0.177	0.086	0.470
14	SVT, maternal flecainide	Arrhythmia resolved	33	13	0.363	0.142	0.083	0.465
16	Neck/face mass	Normal	19	11	0.407	0.137	0.111	0.343
17	Neck teratoma	Right ventricular hypertrophy, trivial pericardial effusion	25	11	0.422	0.085	0.079	0.515
20	Paternal long QT	Normal	23	13	0.409	0.119	0.112	0.509
21	Right ventricle hypertrophy	Normal	23	9	0.404	0.116	0.069	0.465
26	Volunteer	Normal	23	30	0.410	0.140	0.130	0.528
34	Increased nuchal thickness	Normal	20	10	0.406	0.120	0.088	0.513
35	Gestational diabetes	Normal	32	13	0.405	0.150	0.112	0.509
36	Small right heart	Pulmonary atresia, intact ventricular septum (PAIVS)	30	11	0.447	0.142	0.119	0.517
36	PAIVS	PAIVS	32	15	0.443	0.136	0.134	0.512
37	Pregestational diabetes	Normal	25	14	0.433	0.155	0.081	0.487
38	SVT	Irregular atrial tachycardia	33	13	0.414	0.143	0.125	0.536
40	In vitro fertilization	Normal	21	5	0.439	0.115	0.084	0.498
45	Pregestational diabetes	Normal	23	14	0.395	0.164	0.120	0.504
49	Maternal long QT	Fetal bradycardia	36	15	0.408	0.115	0.073	0.488
50	Volunteer	Normal	39	22	0.350	0.135	0.076	0.456

demonstrating that fECG can be extracted noninvasively without distortion of the ECG tracing due to interference from maternal ECG, maternal and abdominal contractions, and motion artifact. In 1906, Cremer recorded the first fECG using a string galvanometer; however, the forms of the P-, QRS-, and T-waves were not clear. In 1954, Davis and Meares became the first to demonstrate clear P-, QRS-, and T-wave morphologies on fECG [19]. The techniques were not standardized, and for half a century, attempts have been made to reproduce fECG noninvasively. A small number of recent studies have demonstrated the feasibility of fECG extraction from fetal heart rate monitors [3, 4, 6, 9, 15, 20, 21]. Unfortunately, the devices utilized in these studies are no longer manufactured. The device utilized in our study is small, inexpensive, and FDA approved for pregnancy and the early studies on fECG acquisition in a research setting have been promising. Furthermore, our specialized fECG extraction methods provided fECG signals, even when the manufacturer's techniques did not recognize a signal.

This is the first study to our knowledge to demonstrate the feasibility of fECG acquisition in an outpatient fetal cardiology clinic. An adequate fECG could be obtained as early as 19-week GA and with recordings as short as 5 min. Of the 60 studies performed, 33 % had adequate signal-averaged waveforms for evaluation. Although this is a small success rate, several of the major issues with signal acquisition can be improved with changes in technique and equipment. On several occasions, there was poor skin to electrode contact, which can be rectified with improved skin cleaning and exfoliation techniques, or improvement in the electrode itself. During our initial use of the noninvasive fECG device, the recommended manufacturer technique of placing the electrodes in a standard configuration (described above) was employed for all subjects, irrespective of fetal GA. We found that a quick visualization via ultrasound of the fetal position within the maternal pelvis or abdomen aided in appropriate positioning of the electrodes in the vicinity of the fetus. This resulted in improved signal acquisition in fetuses less than 30-week GA during the latter studies. The Bluetooth feature of the noninvasive fECG device allowed visualization of the maternal and fetal rhythm strip as it is being recorded. Utilization of this feature allowed us to determine whether the waveform quality was adequate and troubleshoot in real time. The 15 min allotted in this study were not always adequate to improve the signal quality. For optimization of the fECG, the manufacturers currently recommend placing

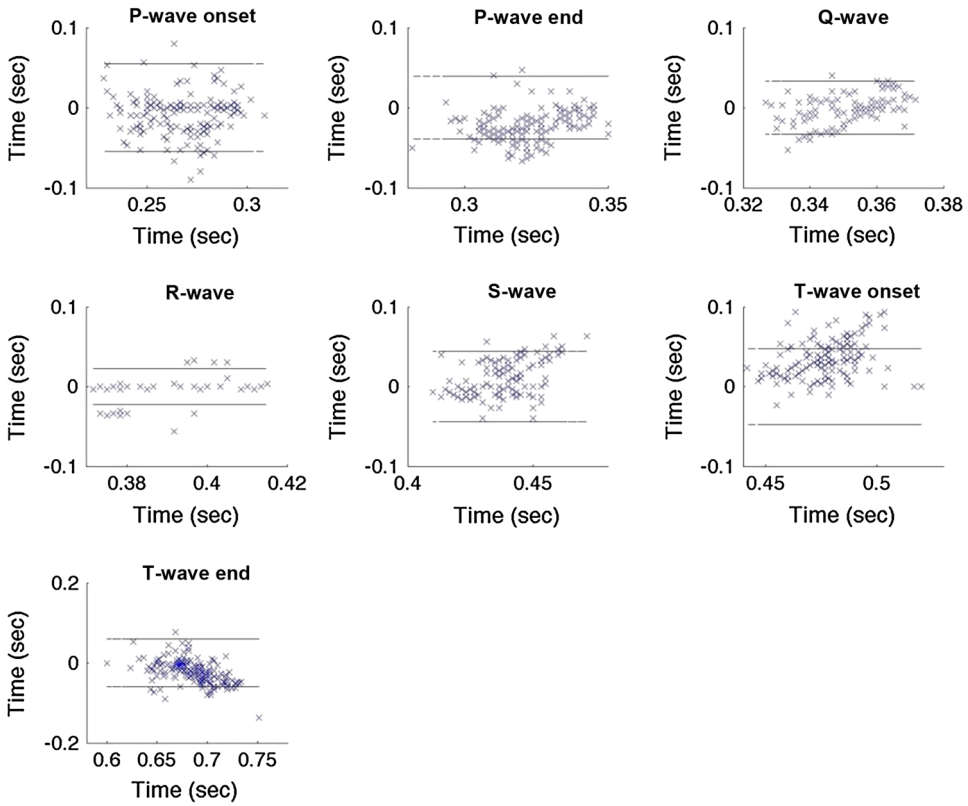

Fig. 4 Bland–Altman plot for cardiologist-derived fECG value measurements versus computer-based automatic identification software

the device for at least 30 min, preferably overnight, in order for the electrodes to stabilize and the mother to relax. This is, however, not feasible in the outpatient setting.

Our study demonstrated a gap in signal acquisition between 25- and 30-week GA. This has been theorized to be due to the increased fetal vernix during this time period resulting in poor amplification of fetal electrical signals [2, 13, 20]. In our experience, the utility of fECG in this time period is limited; however, we speculate that increasing the recording time may be useful for improving signal acquisition in this age group. In addition, technologies for stronger amplification of fetal signals across the maternal abdomen will be necessary to obtain data in this time period.

Measurements of PR, QRS, and RR intervals were highly reproducible by two cardiologists. Novel software that is able to identify the P_{onset}, P_{end}, Q, R, S, T_{onset}, and T_{end} also demonstrated strong agreement with manual measurements. The fECG, in conjunction with this software, may provide a fast and reliable method for evaluating specific fetal cardiac time intervals in a clinical setting, namely the noninvasive fECG device may be useful for evaluation of sinus node function as well as atrioventricular and intraventricular conduction. With improved post-processing, detailed identification of specific types of supraventricular tachycardias (reentrant vs. automatic vs. ectopic vs. flutter/fibrillation), diagnosis of varying degrees of congenital heart block, and visualization of ventricular conduction delays may be possible using this device.

In our experience, the QT measurements among cardiologists were not reproducible. This finding is similar to that of groups evaluating fetal cardiograms by magnetocardiography [10, 11, 14]. QT measurement is likely limited due to difficulty with accurate identification of the onset and endpoint of the T-wave. T-wave detection is believed to be challenging due to the low amplitude ventricular repolarization signal which makes it vulnerable to background noise [20]. In addition, subtle fetal movements may alter the acquisition of the T-wave, resulting in signal nullification from the averaging of multiple T-waves with opposing axes. Using the absolute value of the T-wave amplitude may be a technique for minimizing this limitation. Finally, even in adult and pediatric cardiology, the T-wave can be difficult to ascertain on a standard electrocardiogram, especially at high heart rates where the preceding T-wave and the proceeding P-wave coalesce [7]. Rapid heart rate is the norm, rather than the exception in the fetus and may be responsible for the difficulty with detecting the T-wave endpoint. It is possible that using a slower sweep speed could improve the ability to detect the T-wave.

Limitations of this study include the relatively small number of adequate signal-averaged waveforms obtained for fECG evaluation. As a result of these small numbers, no

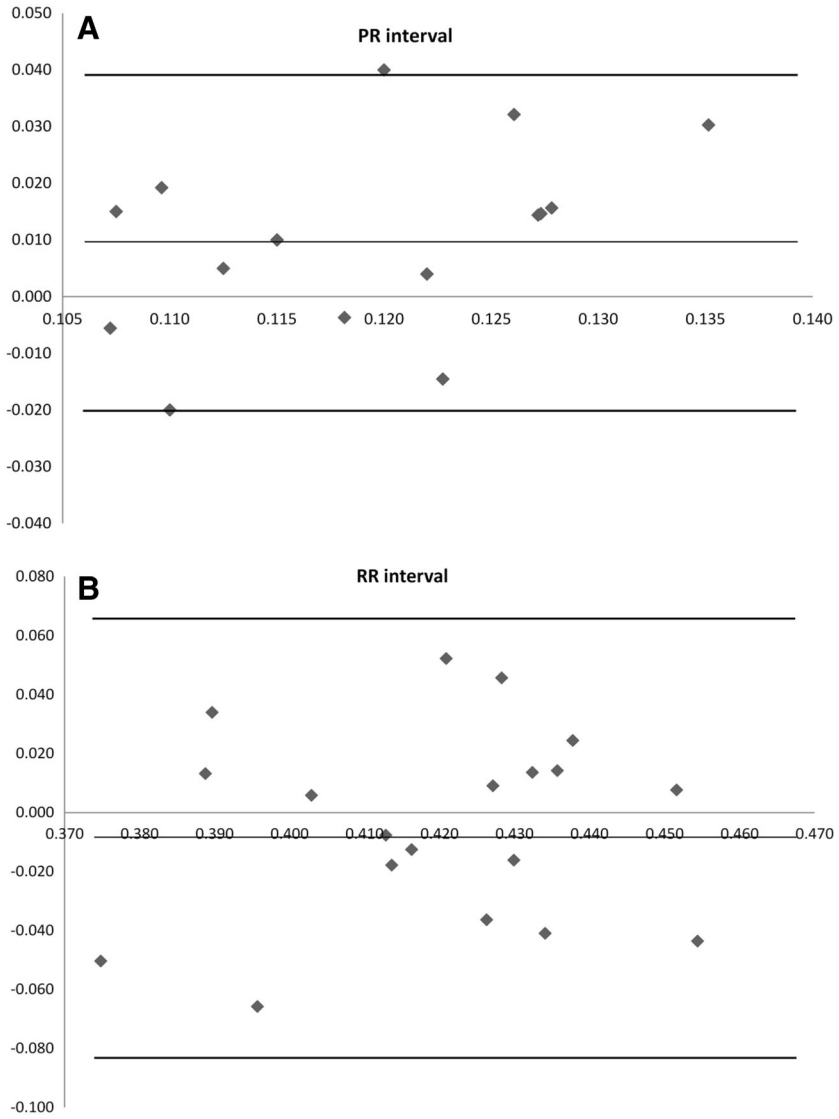

Fig. 5 Bland–Altman plot for noninvasive fECG versus echocardiographic spectral Doppler derived **a** PR and **b** RR intervals

significant comparisons or correlations could be made based on variables such as GA and heart rate, as described previously [17, 20], maternal or fetal risk factors, or cardiac disease processes. The feasibility of acquiring fECG from the noninvasive fECG device is evident; however, adequate user training and time for optimizing signal transmission is essential for its success. Studies are ongoing for prospective acquisition of fECG data from normal and abnormal fetuses at various gestational ages. Techniques to improve the amplification of fetal cardiac electrical signals are under development as well.

Conclusion

Acquisition of fECG tracings and measurement of fetal cardiac time intervals is feasible in a clinical setting with the noninvasive fECG device between 19- and 42-week GA, though tracings are difficult to obtain, particularly between 26- and 30-week GA. There was high reliability in PR, QRS, and RR, but not in QT measures. The device may be used for assessing atrioventricular and intraventricular conduction; however, currently there is limited utility for QT assessment. Techniques to improve signal-averaged waveforms, namely T-wave amplification, are ongoing.

Conflict of interest The authors declare they have no conflict of interest.

Ethical standard All procedures performed in the studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors.

Informed consent Informed consent was obtained from all individual participants included in the study.

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