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Accuracy and reliability of fetal heart rate monitoring using maternal abdominal surface electrodes

WAYNE R. COHEN[1], SOPHIA OMMANI[1], SARMINA HASSAN[2], FADI G. MIRZA[3], MOLHAM SOLOMON[1], RAYMOND BROWN[2], BARRY S. SCHIFRIN[4], JOHN M. HIMSWORTH[5] & BARRIE R. HAYES-GILL[5]

Departments of Obstetrics and Gynecology, [1]Queens Hospital Center, New York, NY, [2]Temple University Hospital, Philadelphia, PA, [3]Columbia University Medical Center, New York, NY, [4]Kaiser Permanente Los Angeles Medical Center, Los Angeles, CA, USA, and [5]Department of Electrical and Electronic Engineering, University of Nottingham, Nottingham, UK

Key words
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Correspondence
Wayne R. Cohen, University Medical Center, Department of Obstetrics and Gynecology, 1501 N. Campbell Ave., Tucson, AZ 85724, USA. E-mail: waynercohen@me.com

Conflict of interest
The study was funded by *Monica Healthcare Ltd.,* which manufactured the study device and supplied it to the participating institutions for use in the study. *Wayne R. Cohen* and *Barry S. Schifrin* have been paid consultants to Monica Healthcare, Ltd. *Barry S. Schifrin* is a paid consultant to Philips Healthcare division of Koninklijke Philips Electronics N.V. *John M. Himsworth* was previously employed as a biomedical engineer by Monica Healthcare, Ltd. *Barrie Hayes-Gill*, a biomedical engineer, is an Executive Director and shareholder at Monica Healthcare, Ltd.

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Abstract

Objective. Compare the accuracy and reliability of fetal heart rate identification from maternal abdominal fetal electrocardiogram signals (ECG) and Doppler ultrasound with a fetal scalp electrode. *Design.* Prospective open method equivalence study. *Setting.* Three urban teaching hospitals in the Northeast United States. *Sample.* 75 women with normal pregnancies in labor at >37 weeks of gestation. *Methods.* Three fetal heart rate detection methods were used simultaneously in 75 parturients. The fetal scalp electrode was the standard against which abdominal fetal ECG and ultrasound were judged. *Main outcome measures.* The positive percent agreement with the fetal scalp electrode indicated reliability. Bland–Altman analysis determined accuracy. The confusion rate indicated how frequently the devices tracked the maternal heart rate. *Results.* Positive percent agreement was 81.7 and 73% for the abdominal fetal ECG and ultrasound, respectively ($p = 0.002$). The abdominal fetal ECG had a lower root mean square error than ultrasound (5.2 vs. 10.6 bpm, $p < 0.001$). The confusion rate for ultrasound was 20-fold higher than for abdominal ECG (8.9 vs. 0.4%, respectively, $p < 0.001$). *Conclusion.* Compared with the fetal scalp electrode, fetal heart rate detection using abdominal fetal ECG was more reliable and accurate than ultrasound, and abdominal fetal ECG was less likely than ultrasound to display the maternal heart rate in place of the fetal heart rate.

Abbreviations: afECG, abdominal wall-acquired fetal electrocardiogram technique; bpm, beats per minute; CI, confidence interval; ECG, electrocardiogram; FSE, fetal scalp electrode; FHR, fetal heart rate; MHR, maternal heart rate; PPA, positive percent agreement; RMS, root mean square.

Key Message

External methods for fetal heart rate identification were compared with monitoring with a standard scalp electrode. Intrapartum fetal heart rate determination using maternal skin surface electrodes was superior in accuracy and reliability to monitoring that relied on Doppler ultrasound technology, and was less likely to display the maternal heart rate in place of the fetal heart rate.

Introduction

Electronic monitoring of fetal heart rate (FHR) patterns is used in more than 85% of laboring women in the industrialized world (1–3). Two modes of monitoring are commonly used: internal and external.

Internal monitoring detects fetal cardiac electrical activity through a fetal scalp electrode (FSE). That signal is used to calculate the heart rate from the R-R intervals of the fetal electrocardiogram (ECG). The external FHR monitoring technique employs an ultrasound transducer held against the parturient's abdomen by a belt. It detects movement of the fetal heart using the Doppler principle; sophisticated signal processing calculates the heart rate.

Internal monitoring is more reliable and accurate than external (4), being less affected by artifact, maternal obesity, and fetal and maternal movement. Internal monitoring requires the chorioamniotic membranes are ruptured and the cervix sufficiently dilated to permit introduction of the FSE. These factors limit its use, especially in early labor. Also, the presence of monitoring instrumentation in the uterine cavity penetrating the fetal skin risks infection and fetal injury (5,6).

A technique for FHR and uterine contraction monitoring that has the potential to combine the accuracy and freedom from artifact of internal monitoring and the applicability, convenience and safety of external monitoring has been introduced. The AN24 monitor (Monica Healthcare Ltd., Nottingham, UK) uses five ECG electrodes applied to the maternal abdominal wall (afECG). From the voltages detected on the abdomen, the device calculates the FHR and measures uterine contractility noninvasively.

We compared the relative accuracy and reliability of the afECG technique and traditional ultrasound FHR detection against internal monitoring when the three techniques were used simultaneously. Assessment of uterine contractility is described in a separate communication. We hypothesized that afECG-derived FHR data are at least as accurate and reliable as those obtained from ultrasound-based devices for the detection of the FHR during labor.

Material and methods

This prospective multicenter study compared the accuracy and reliability of two modes of FHR detection (afECG and ultrasound) with the FHR information obtained from a FSE. The latter was considered the 'gold standard', against which we compared the external techniques. This equivalence trial was carried out and its design approved as part of the application requirements for 510 k clearance of the AN24 monitor by the United States Food and Drug Administration.

The study was conducted in three teaching hospitals: Queens Hospital Center and Columbia University Medical Center (New York, NY), and Temple University Hospital (Philadelphia, PA). The protocol was approved by the Institutional Review Board at each institution and conformed to the guidelines of the World Medical Association Declaration of Helsinki. All hospitals used the Philips Healthcare Model 50XM fetal monitoring system (Philips Healthcare, Andover, MA) for internal scalp electrode and external Doppler ultrasound FHR monitoring.

Potential study participants had a singleton, term cephalic-presenting pregnancy, and arrived at the hospital early in, or prior to, labor. A patient was ineligible if her fetus had a known major anomaly, or a malpresentation, or if the mother had a medical problem such as an abdominal skin rash or history of adhesive sensitivity.

All patients were monitored initially with the ultrasound technique, and its tracing was available for decision-making. The transducer position was adjusted by the nurse if clinically required. The afECG electrodes were applied once it was determined that the ultrasound device was working appropriately. The data obtained by the afECG monitor were transmitted wirelessly to a bedside personal computer and stored for analysis. They were never available to the obstetric care team. During labor, the FSE was substituted for ultrasound in some patients. This change, made at the discretion of the supervising obstetrician, occurred in all cases because the external tracing was abnormal. If the patient was monitored only with the two external methods, she was excluded as a subject. When the FSE was attached, its data became the only FHR available to the clinicians, but we continued to obtain, manage and store the FHR information from the ultrasound and the afECG monitors. The maternal heart rate (MHR) was monitored using a pulse oximeter (Philips M1191A, Philips Healthcare) attached to the 50XM FHR monitor in 47 subjects. All subjects had FHR monitoring continuously throughout labor. None retracted her consent.

In total, 138 women consented to participate between December 2009 and June 2010. Of these, 35 were monitored solely by external techniques, four recordings were insufficient for meaningful analysis (<30 minutes), and in 18, data from one or more monitors were not stored by the computer because of a technical error. In six, only uterine contraction information was available. These exclusions left 75 women with simultaneously recorded FHR data from the three techniques during labor. Data from the three hospitals were analyzed in aggregate. Based on results from a previous study that compared ultrasound and afECG, a sample size of 50 would have a power of 0.9 to identify equivalence in success rate, reliability and accuracy within 10% of the standard with an alpha of 0.5 (7,8).

Data collection and processing

The afECG device uses five ECG electrodes (Blue Sensor VLC-00S, Ambu, St. Ives, UK) (Figure 1) to record

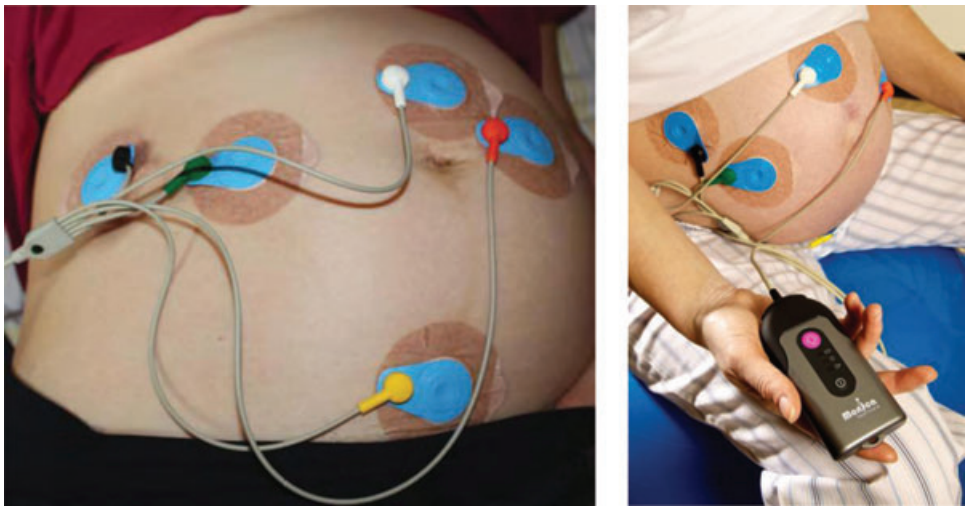

Figure 1. Arrangement of the five cutaneous electrodes on the mother's abdomen during labor and delivery and the abdominal fetal electrocardiogram device beside her.

electrophysiologic signals from the parturient's abdominal wall. From these are extracted the FHR, MHR and uterine contraction data. During the study, the FHR data were continuously collected from all three monitors and transmitted to the bedside computer. The FHR values from each device were updated every 0.25 seconds. Data from all three sources were synchronized to within 0.25 seconds by cross-correlating the FHR data from each source with the FSE-derived FHR.

Because each monitoring modality sometimes fails to generate clinically interpretable data, rules were applied to facilitate statistical analysis. The output from the FSE was considered valid if heart rate data were present, because this was the device we used as the standard against which the others were compared. Output from the afECG and the ultrasound methods was considered valid if an FHR value was present and was within 10% of the simultaneous FHR value recorded by the FSE. If FHR data from the FSE were absent, the simultaneous output from the afECG and Doppler devices was also considered invalid.

The requirement for the afECG value to be within 10% of the FSE value minimized the inclusion of inaccurate FHR data from both afECG and ultrasound when we assessed their reliability. Such inaccuracies can be due to periods of maternal–fetal heart rate confusion, and artifacts such as half- or double-counting that could give a false impression of a valid FHR figure.

Statistical methods

We compared the accuracy and reliability of two external FHR detection techniques to output from an FSE. We calculated two sets of results for each subject: one compared the afECG with the FSE; the other compared the ultrasound with the FSE. Subject results were combined to give an overall mean and two-sided 95% confidence interval for each accuracy and reliability statistic, in addition to the afECG/ultrasound accuracy and reliability ratios for each subject. Statistical software was Microsoft EXCEL (Microsoft Corporation). MATLAB (V7.5.0; The MathWorks) was used to create the Bland–Altman plots.

We assessed the *reliability* of the test devices by the positive percent agreement (PPA), i.e. the percentage of time the device generated a valid FHR within 10% of a valid simultaneous FHR from the FSE. Reliability expressed the ability of each test device to create a valid output concurrent with that of the FSE. As another reliability measure we calculated the proportion of recording during which the afECG or ultrasound reported a non-zero FHR value, i.e. the *success rate* of the device.

Accuracy of the FHR output of the external monitoring modes was estimated by Bland–Altman analysis (9). The FHR values from each test device were compared with the average of the test FHR and the FSE. The *root-mean-square (RMS) error*, a measure of precision, was determined between the actual FHR differences and the regression line of the Bland–Altman plot. This provided individual subject RMS error values, and the characteristics of the regression line.

We performed Bland–Altman analysis for each subject and each modality, producing subject-level error statistics and corresponding ratio means. In addition, the FHR data were combined graphically across all subjects to produce a Bland–Altman plot of all FHR values. This provided bias and limit of agreement values for the entire dataset.

FHR monitors sometimes display the MHR rather than the FHR, a potential cause of clinical errors. To analyze our data

for the presence of fetal–maternal heart rate confusion (the confusion rate, CR), we calculated the percentage of FHR determinations for which each external device calculated a FHR value that was both more than 5% different from that of the FSE and within 5% of the MHR.

Differences in the sample characteristics among the participating institutions were sought using one-way analysis of variance (ANOVA) for continuous variables and the Fisher exact test for categorical variables. When the ANOVA was significant, the Student–Newman–Keuls test was used to identify differences between institutions.

Results

The gestational age and body mass index did not differ among study patients from the three hospitals (Table 1). Cases at one hospital were about five years older than the average from the other two. There was a significant difference in epidural anesthesia use among sites, ranging from 66 to 98%. FHR data were collected from the three simultaneous techniques for a total of 19 166 minutes: 15 574 minutes in the first stage, and 3 592 minutes in the second stage of labor.

The aggregate FHR PPA reliability results for the 75 participants (Table 2) were calculated from each individual PPA (i.e. one value per patient, equally weighted). Overall FHR PPA values were 81.7% for the afECG and 73.0% for the ultrasound method ($p = 0.002$). This differential reliability was present in the first and the second stages of labor. Both test devices were significantly more reliable in the first stage. In the second stage, the afECG method had a higher PPA than did ultrasound (71.9 vs. 61.7%; $p = .045$).

We determined the ratios of the afECG to the ultrasound PPA values for each subject. These were combined, resulting in an overall mean ratio of 1.75, reflecting superior reliability of the afECG over ultrasound when each was compared with FSE performance. Moreover, the fall in reliability of the ultrasound recordings between first and second stage was significantly greater ($p < 0.002$) than that seen for the afECG.

The overall FHR success rates for the afECG and ultrasound methods were similar (83.4 and 82.5%; Table 3). By contrast, those for FSE were 97.8 and 94.7% in the first and second stages. The success rate for afECG was not significantly different from its PPA (83.4 vs. 81.7%). Ultrasound, however, had a higher overall success rate than PPA (82.5 vs. 73%; $p = 0.012$), particularly in the second stage (77.8 vs. 61.7%; $p < 0.001$). The differences between overall success and PPA occurred primarily because both test devices sometimes reported FHR values that were more than 10% different from the FSE. Given that the FSE has a success rate of 95–98%, the ultrasound technique data indicate that for about 10% of the time in the first stage and 15% of the time in

Table 2. Fetal heart rate (FHR) reliability, expressed as positive percent agreement.

Subjects, *n*	Overall 75	Stage 1 72	Stage 2 41
afECG *	81.7 ± 20.5%	84.9 ± 21.5%	71.9 ± 20.4%
CI	77.1; 86.4%	80.0; 89.8%	65.7; 78.1%
US*	73.0 ± 24.6%	74.7 ± 28.2%	61.7 ± 24.8%
CI	67.4; 78.5%	68.2; 81.2%	54.2; 69.2%
Ratio*	1.75 ± 4.2	1.81 ± 4.2	2.21 ± 6.2
CI	1.0; 1.4	1.0; 1.4	1.0; 1.5
p-value**	<0.01	<0.01	<0.01

*Expressed as mean ± standard deviation.

**from paired t-test comparing afECG and US.

Positive percent agreement : % success rate compared with valid FSE FHR value.

afECG, abdominal fetal ECG detection; US, Doppler ultrasound FHR detection technique; CI, 95% confidence interval.

Table 1. Characteristics of the study sample.

	All sites $n = 75$	Queens Hospital Center $n = 36$	Temple University Hospital $n = 31$	New York Presbyterian Hospital $n = 8$	*p*-Value
Gestational age, weeks	39.6 ± 1.1	39.4 ± 1.1	39.7 ± 1.0	39.3 ± 1.1	0.432
Maternal age, yr	25.5 ± 5.1	25.9 ± 4.4	23.8 ± 5.0	29.8 ± 6.2*	0.008
Maternal BMI, kg/m^2	32.6 ± 7.6	32.1 ± 8.3	33.5 ± 6.8	31.6 ± 7.6	0.699
Epidural analgesia, %	82	66	97	88	0.006
Duration of monitoring, minutes	255.5 ± 181.3	291 ± 210	186 ± 109*	367 ± 187	0.010
Duration Stage 1 monitoring, minutes	216.3 ± 168.6	230 ± 194	170 ± 112**	339 ± 189	0.033
Duration Stage 2 monitoring, minutes	85.5 ± 69.3	107 ± 76	40 ± 26***	75 ± 26	<0.001

Data presented as mean ± standard deviation, unless otherwise specified.

*Significantly different from other two groups (ANOVA, Student–Newman–Keuls).

**Significantly different from New York Presbyterian Hospital (ANOVA, Student–Newman–Keuls).

***Significantly different from Queens Hospital Center.

BMI, Body Mass Index.

Table 3. Fetal heart rate (FHR) reliability, overall success rate.

FHR success rate	Subjects, *n*	Overall 75	Stage 1 72	Stage 2 41
	afECG	83.4 ± 20.1%	86.4 ± 21.1%	75.2 ± 19.2%
	CI	78.8; 87.9%	81.56; 91.2%	69.43; 81.1%
	US	82.5 ± 21.1%	82.6 ± 24.4%	77.8 ± 21.1%
	CI	77.8; 87.3%	77.0; 88.2%	71.4; 84.1%
	Ratio	1.2 ± 1.7	1.3 ± 2.1	1.2 ± 1.6
	CI	0.9; 1.1	0.9; 1.2	0.8; 1.1
	p-value	0.38	0.12	0.25

Overall success rate expressed as the percentage of time the afECG and Doppler US monitor techniques recorded a fetal heart rate.
afECG, abdominal fetal ECG detection; US, Doppler ultrasound FHR detection technique; CI, 95% confidence interval.

Table 4. Fetal heart rate (FHR) accuracy of abdominal fetal ECG detection (afECG) and Doppler ultrasound (US) monitors compared with fetal scalp electrode (FSE).

Accuracy*	Subjects, *n*	Overall 75	Stage 1 72	Stage 2 41
	afECG**	5.3 ± 2.4	4.5 ± 2.4	7.9 ± 4.2
	CI	4.7; 5.8	3.9; 5.0	6.6; 9.2
	US**	10.9 ± 5.8	8.7 ± 5.7	16.1 ± 7.6
	CI	9.6; 12.2	7.4; 10.0	13.8; 18.5
	Ratio** afECG/US	0.7 ± 0.6	0.7 ± 0.6	0.5 ± 0.3
	Ratio CI	0.5; 0.6	0.5; 0.7	0.4; 0.6
	p-value	<0.0001	<0.0001	<0.0001
	afECG slope	0.01 ± 0.2	0.02 ± 0.2	−0.13 ± 0.2
	afECG y-intercept at x-axis mean (bpm)	−0.07 ± 0.5	−0.1 ± 0.6	0.7 ± 2.0
	US slope	0.4 ± 0.5	0.4 ± 0.5	0.3 ± 0.6
	US y-intercept (bpm)	2.8 ± 7.0	−2.9 ± 6.9	−1.7 ± 10.1

*Expressed as the root mean square error from Bland–Altman analysis of FHR in bpm, and as slope and y-intercept from regression analysis.
**Expressed as mean ± standard deviation.
afECG, abdominal fetal ECG fetal heart rate detection technique; bpm, beats per minute; CI, 95% confidence interval; US, Doppler ultrasound fetal heart rate detection technique.

the second stage, ultrasound was likely reporting an incorrect FHR.

In the FHR accuracy analysis (Table 4) the afECG technique showed a lower overall RMS error relative to the FSE compared with ultrasound (5.2 vs. 10.6 bpm, $p < 0.0001$). This halving of the RMS error with afECG was true in both labor stages. The higher accuracy of the afECG method is supported by the wide gap between the upper confidence limit of the afECG error and the lower confidence limit of the ultrasound error. The error of both devices increased in the second stage, but the increase was larger for ultrasound; hence, the error ratio (afECG error/ultrasound error) fell in the second stage.

To illustrate further the accuracy of both devices tested against the internal electrode, we made Bland–Altman plots of the FHR data from the afECG and ultrasound monitors against the average of the test FHR and the FSE FHR for the first (Figure 2) and second (Figure 3) labor stages. The plots, which utilize data combined from all subjects, illustrate the relative accuracy of the two test devices. The afECG FHR values were closer to the FSE determinations than were those of the ultrasound technique. This is visually evident in the plots, and confirmed by analysis, with closer limits of agreement in both labor stages for the afECG ($p < 0.001$).

We determined the CR in the 47 cases in which continuous MHR monitoring was done (Table 5). The mean CR for ultrasound FHR detection was 20-fold higher than for the afECG (8.9 vs. 0.4%, $p = 0.0002$). The CR for both devices increased in the second stage, but remained much greater for the ultrasound-derived measurements than for the afECG (11 vs. 0.7%, $p < 0.001$).

Discussion

Doppler ultrasound technology is widely used for FHR monitoring, although its potential problems of reliability, accuracy, influence by fetal or maternal movement, and insertion of the MHR are recognized. The use of afECG-based FHR monitoring was proposed several decades ago (10,11) but its use was compromised by a limited ability to extract the fetal signal reliably.

Better transabdominal access to the fetal ECG is now possible (7,12–15). New electronics and signal processing software allow the afECG monitor used in this study to reliably isolate the fetal ECG signals from competing electrical activity. The noninvasive technique carries no risk of infection or trauma, can be used before cervical dilatation has occurred and, because it analyzes ECG signals rather than heart movement, it in principle provides accurate representation of rate and variability. The afECG approach was at least equal in accuracy and reliability to the ultrasound technique; in many respects, afECG monitoring proved superior to the ultrasound method.

To estimate the relative accuracy and reliability of the study monitors we used individual patient statistics. The nature of the recordings gives the impression of requiring a repeated measures analysis, as each trace is made up of a large number of individual data points obtained serially from each patient. However, the statistics used at the patient level are derived by combining all of these readings over a single recording (i.e. success rate, RMS error, etc.) and cannot be applied meaningfully to an individual data point as required in repeated measures. Our method of analysis based on patient-level statistics does, however, take proper account

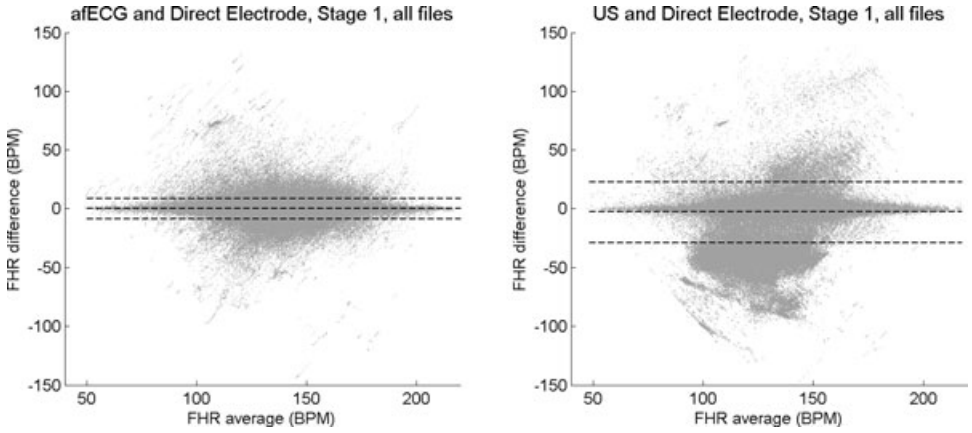

Figure 2. Bland–Altman plot of fetal heart rate differences, for all subjects, during the first stage of labor. Difference is plotted between abdominal fetal electrocardiogram and fetal scalp electrode (left), and between ultrasound and the fetal scalp electrode (right) in subjects monitored simultaneously with all three modalities. For the AN24, the bias is −0.16, and the limits of agreement (± 1.96 SD) 8.40; −8.72. For the Doppler ultrasound technique the bias is significantly greater, −2.87, with limits of agreement of 22.65, −28.39.

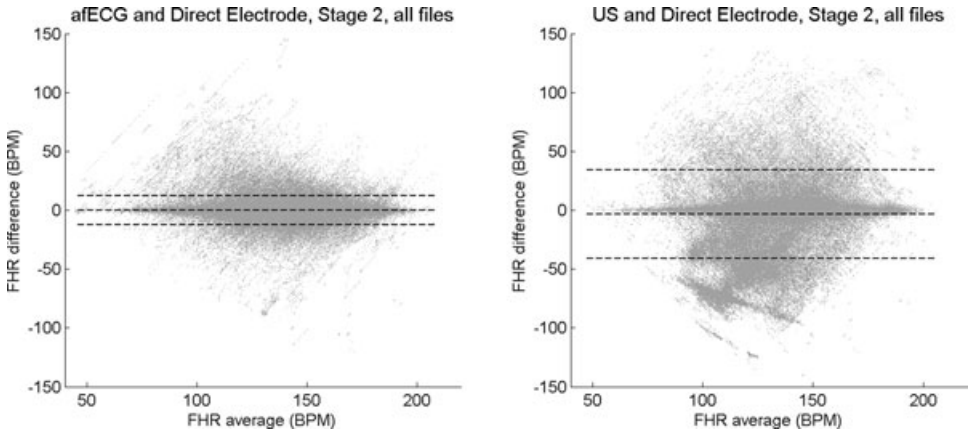

Figure 3. Bland–Altman plot of fetal heart rate differences, for all subjects, during the second stage of labor. Difference is plotted between abdominal fetal electrocardiogram and fetal scalp electrode (left), and between ultrasound and the fetal scalp electrode (right). For the abdominal fetal electrocardiogram, the bias is −0.08, and the limits of agreement (±1.96 SD) of 12.42, −12.27. For Doppler ultrasound technique, the bias is significantly greater, −3.44, with limits of agreement of 34.01, −40.89.

of repeated measures, as each individual patient-level value would include an error contribution from within-patient variation.

Both external devices were less successful overall in displaying an FHR pattern than the FSE-based technique. The test devices were both about 83% successful in displaying an apparently valid heart rate (irrespective of its accuracy), compared with the approximately 98% success of the FSE. While the afECG was not inferior to ultrasound in its ability to generate a FHR pattern, this overall equivalence should not distract from the fact that the afECG technique generally provided more accurate and reliable FHR recordings than did the Doppler ultrasound approach. This was especially true during the second stage of labor, when maternal bearing-down activity and other movements predispose to artifactual and potentially misleading ultrasound signals. This distinction between the two external monitoring techniques is emphasized by the differences in the success rate and the PPA for each external device. For the afECG these values were not significantly different, consistent with a previous report (16); for ultrasound the success rate was significantly higher than the PPA, particularly during the second stage. This indicates that the ultrasound method displayed erroneous FHR information (i.e. heart rates that were not within 10% of the scalp electrode-derived value) much more often than the afECG. During the second stage, ultrasound reported an incorrect

Table 5. Fetal and maternal heart rate confusion.

Confusion rate*	Patient Count	Overall 47	Stage 1 43	Stage 2 26
	afECG**	0.4 ± 0.6%	0.3 ± 0.6%	0.7 ± 0.8%
	CI	0.24; 0.6%	0.15; 0.5%	0.41; 1.0%
	US**	8.9 ± 15.2%	9.5 ± 17.8%	11.0 ± 15.4%
	CI	4.58; 13.3%	4.2; 14.7%	5.32; 16.7%
	afECG/US ratio**	0.5 ± 2.2	1.2 ± 4.7	0.1 ± 0.2
	Ratio CI	0.04; 0.1	0.05; 0.3	0.03; 0.1
	p-value	0.0002	0.0007	0.0007

*Expressed as the percentage of fetal heart rate (FHR) determinations for which each external device calculated a FHR value that was more than 5% different from that of the fetal scalp electrode (FSE), and within 5% of the maternal heart rate determined by pulse oximetry.

**Expressed as mean ± standard deviation.

afECG, abdominal fetal ECG fetal heart rate detection technique; CI, 95% confidence interval; US, Doppler ultrasound abdominal fetal heart rate detection technique.

FHR about 16% of the time (77.8 vs. 61.7%), compared with about 3% of the time by afECG (75.2 vs. 71.9%).

The mean overall afECG/ultrasound ratio of the PPAs was 1.75, demonstrating a higher reliability of afECG-derived compared with ultrasound-derived FHR information. In other words, when a FHR pattern was obtained from the FSE, afECG was more likely than ultrasound to display a FHR. The superior reliability (i.e. the ability to obtain and display the FHR) of the afECG technique over ultrasound was evident throughout labor, and was most marked during the second stage despite some deterioration in both signals.

The accuracy (i.e. correctness of the FHR information) of afECG monitoring also exceeded that of ultrasound. The afECG had half the RMS error of ultrasound, and Bland–Altman analysis confirmed that afECG FHR values were significantly closer to those of the FSE values than those obtained from ultrasound monitoring.

An insidious problem with ultrasound-based monitoring techniques is their propensity to occasionally display the MHR rather than the FHR. This is not always clinically apparent and has led to serious misinterpretations of fetal status, with either unnecessary interventions or failure to timely intervene (17,18). We determined the frequency of maternal–fetal heart rate confusion using data from the 47 women in whom continuous MHR data were available from the pulse oximeter. The confusion rate was dramatically lower for afECG than for ultrasound in both the first (20-fold) and second (15-fold) stages of labor. It averaged about 8.9% for ultrasound and only about 0.4% for afECG. The afECG technique was therefore substantially less likely to display MHR information that could lead to erroneous interpretation. Our calculation of the relative CR is possibly an underestimate. The pulse oximeter is not particularly accurate or reliable in determining the MHR (RMS error of ± 3 bpm), and it averages the heart rate. The maternal ECG was present continuously in all cases from the afECG monitor; however, we used the oximeter data because it is currently the standard approach used to determine MHR during FHR monitoring.

A potential weakness of the study relates to how ultrasound monitoring was used. Prior to the introduction of the FSE, clinicians used the ultrasound monitor data to make clinical decisions. After the FSE was in place, the team was blinded to the ultrasound recording. However, a member of the research team had to check the ultrasound transducer every 20–30 minutes to ensure its proper functioning. It is therefore possible that the ultrasound technique was not used optimally during the study and that we have underestimated its accuracy and reliability. We believe that this explanation is unlikely, as visual inspection of the heart rate patterns revealed no deterioration of the ultrasound tracings after the ultrasound information was withdrawn from clinical view.

In summary, we found that FHR detection using afECG was more reliable and accurate than ultrasound when both were compared with the FSE. Ultrasound provided incorrect heart rate information about 10% of the time in the first stage and 15% in the second stage. Moreover, the afECG was less likely than ultrasound to display the MHR in place of the FHR. These findings may have significant implications for clinical care. Studies to assess the accuracy of afECG data in identifying FHR decelerations, variability and other basic elements of clinical interpretation are underway.

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