

# Standard External Doppler Fetal Heart Tracings versus External Fetal Electrocardiogram in Very **Preterm Gestation: A Pilot Study**

Jeffrey A. Gavard, PhD<sup>2</sup> Kristina McCormick, MD<sup>1</sup> Judy Wilson-Griffin, RN<sup>3</sup> Gary Fruhman, MD<sup>1</sup> Erol Amon, MD, ID<sup>1</sup> Gilad A. Gross, MD<sup>1</sup>

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Address for correspondence Gary Fruhman, MD, Saint Louis University School of Medicine, 6420 Clayton Road, Suite 6520, Saint Louis, MO 63117 (e-mail: fruhman@slu.edu).

#### Abstract

**Introduction** Very preterm babies can be difficult to monitor using standard external Doppler fetal heart tracings (eFHR). External fetal electrocardiogram (fECG) is a potential alternative.

Methods This was a prospective observational pilot study of hospitalized patients at 24 to 28 weeks' qestation. A total of 30 women were traced for up to 2 hours using eFHR followed by up to 2 hours using fECG. The percentage of time the fetal heart rate was traced during the 2-hour window for each modality was calculated. Differences of  $\geq$  60,  $\geq$  80, and  $\geq$  90% total time traced were compared between modalities using McNemar's test. Differences were also assessed for each method between nonobese (body mass index  $[BMI] < 30 \text{ kg/m}^2$ ) and obese  $(BMI \ge 30 \text{ kg/m}^2)$  women using chi-square and Fisher's exact tests.

## **Keywords**

- external heart rate tracing
- ► fetal ECG
- preterm
- obesity

**Results** Superior performance was found with eFHR at  $\geq$  60% (93.3 vs. 46.7%, p < 0.001),  $\geq 80\%$  (80.0 vs. 30.0%, p < 0.001), and  $\geq 90\%$  (60.0 vs. 23.3%, p < 0.01) total time traced. There was a statistically significant finding favoring nonobese women at  $\geq$  80% total time traced using fECG (7.1 vs. 50.0%, p = 0.017).

**Conclusion** With current technology fECG performance in very preterm qestation was worse than conventional eFHR, although fECG may have a role in nonobese patients.

External Doppler fetal heart rate (eFHR) monitoring and tocodynamometry are routinely employed to evaluate fetal wellbeing. At times it can be very difficult to continuously trace the fetal heart rate, especially at very preterm gestation due to the size of the fetus coupled with fetal movement and maternal habitus. To successfully trace these signals, nursing staff may need to frequently reposition the patient or transducers. Staff quite often resorts to buttressing monitors with towels or manually applying the transducers for prolonged periods of time. In addition, patients are frequently placed in restrictive positions that can be a source of frustration and discomfort. Furthermore, the flat recumbent position that is often employed to capture a heart tracing potentially compromises uteroplacental gas exchange.

Transabdominal fetal electrocardiogram (fECG) acquisition and electrohysterography are alternative approaches to fetal

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<sup>&</sup>lt;sup>1</sup>Division of Maternal Fetal Medicine, Department of Obstetrics, Gynecology, and Women's Health, Saint Louis University School of Medicine, Saint Louis, Missouri

<sup>&</sup>lt;sup>2</sup>Division of Research, Department of Obstetrics, Gynecology, and Women's Health, Saint Louis University School of Medicine, Saint Louis, Missouri

<sup>&</sup>lt;sup>3</sup>SSM Health–Saint Mary's Hospital, Saint Louis, Missouri

monitoring and it has been suggested in a prior study to be equivalent to external monitoring in the term population. <sup>1</sup> In 2012, the U.S. Food and Drug Administration approved the use of the AN24 fetal ECG (Monica Healthcare, Nottingham, United Kingdom) for fetal monitoring in labor at > 36 weeks' gestational age.<sup>2</sup> Four electrodes are placed on the abdomen in a diamond-shaped pattern. One is placed above the pubic bone in the midline, one is placed just below the umbilicus,

Table 1 Demographic characteristics and medical/obstetrical history for 30 women

Characteristics	Value
Maternal age (y)	27.2 ± 6.2
Race	·
Caucasian	16 (53.3)
African American	14 (46.7)
Other	
Marital status	·
Single	12 (40.0)
Married	14 (46.7)
Divorced	4 (13.3)
Body mass index at admission (kg/m²)	31.0 ± 7.7
Body mass index categories	<u>.</u>
Nonobese (< 30.0)	16 (53.3)
Obese (≥ 30.0)	14 (46.7)
Gravidity	2 (1, 3)
Number of term births	1 (0, 2)
Number of preterm births	0 (0, 0)
Number of abortions	0 (0, 1)
Number of living children	1 (0, 2)
Gestational age at enrollment	26.8 (25.3, 27.5)
Placental location	<u> </u>
Anterior	13 (43.3)
Posterior	14 (46.7)
Lateral	3 (10)
Fetal orientation	<u> </u>
Vertex	25 (83.3)
Breech	4 (13.3)
Transverse	1 (3.3)
Preterm premature rupture of membranes	5 (16.7)
Amniotic fluid deepest vertical pocket (cm)	5.3 (3.5, 6.3)
Estimated fetal weight (g)	909 (637, 1,012)
Estimated fetal weight percentile	44 (31, 61)
Medical/obstetrical history	•
Chronic hypertension	4 (13.3)
Diabetes (type 1 or type 2)	3 (10.0)
Asthma	3 (10.0)
Vaginal bleeding	4 (13.3)
Preeclampsia	1 (3.3)
Preterm labor	4 (13.3)
Cervical insufficiency	10 (33.3)

Note: Data are shown as mean  $\pm$  standard deviation, median (interquartile range), or n (%).

and two are placed laterally, equidistant from the top and bottom electrodes. One electrode is placed lateral to the one on the right side and is used as a reference.<sup>3</sup> The electrodes are then attached to the AN24 fetal ECG device. The goal of the multiple electrodes is to transmit the fetal heart tracing irrespective of fetal and/or maternal movement. Further studies have shown that unlike eFHR, fECG is not affected by maternal body mass index (BMI) and hence may be more successful in tracing the fetal heart rate in an obese population.<sup>4,5</sup> Given these findings, we hypothesized that fECG may provide improved fetal monitoring in the very preterm population. Our study was designed to compare the success rates of fECG with those of eFHR in admitted antepartum gravidas between 24 and 28 weeks' gestational age.

### **Methods**

This was a prospective, observational pilot study that took place at a single urban academic-affiliated communitybased hospital between October 2014 and January 2016. The study was approved by the Institutional Review Board of Saint Louis University School of Medicine. Admitted antepartum patients between 24 and 28 weeks' gestation were eligible to participate in the study. Gestational age was determined based on last menstrual period and confirmed with or re-dated by ultrasound; if this information was unknown then ultrasound dating was used.<sup>6</sup> Exclusion criteria included multiple gestations, clinical instability, intrauterine fetal demise, and non-English speaking patients. Once a patient was deemed eligible for participation, she was approached and informed about the study. After informed consent was obtained, the patient was placed on the eFHR for up to 2 hours by the nursing staff, and was repositioned as necessary to maintain a continuous fetal heart tracing. The patient was then given a break for restroom use before being placed on the fECG for an additional 2 hours by one of the two authors (G. F. and J. W. G.). Per manufacturer instruction, before placement of the fECG electrodes, the abdomen was cleansed with soap and water and the skin was exfoliated to decrease impedance between the electrodes and the maternal abdomen. Upon completion of fECG monitoring, study participants were asked which method of fetal heart monitoring they preferred.

The percentage of time the fetal heart rate was traced during the 2-hour window for each modality was calculated as a percentage of the time. Continuous variables were compared using Wilcoxon signed rank tests. Differences of  $\geq 60$ ,  $\geq 80$ , and  $\geq 90\%$  total time traced were compared between modalities using McNemar's test. Differences also were assessed for each method between nonobese (BMI  $< 30 \text{ kg/m}^2$ ) and obese (BMI  $\geq 30 \text{ kg/m}^2$ ) patients using Kolmogorov–Smirnov tests for continuous variables and chi-square and Fisher's exact tests for categorical variables. A p value of < 0.05 was used to denote statistical significance. All analyses were performed using SPSS version 21.0 for Windows (SPSS, Inc., Chicago, IL). As this was a pilot study, a sample size was not calculated. This trial is registered with clinicaltrials.gov (NCT02546011).

#### Results

Of the 36 patients recruited to participate, 30 patients were able to be analyzed. Of the six patients not included in the analysis, two were discharged before the study could be performed, two had a malfunctioning fECG, one required a higher level of obstetrical care before fECG monitoring, and one patient was determined to be 31 weeks' gestation following ultrasound evaluation. Demographic data and medical/obstetrical history of the 30 women are shown in -Table 1. -Table 2 demonstrates the results when the two modalities are compared. Standard eFHR monitoring yielded superior results at all time percentage points. These included:  $\geq$  60% time traced ( $n = 28 \ [93.3\%] \ vs. <math>n = 14$ [46.7%], p < 0.001),  $\geq 80\%$  time traced (80.0 vs. 30.0%, p < 0.001), and  $\geq 90\%$  time traced (60.0 vs. 23.3%, p < 0.01). The 30 patients were then divided into obese and nonobese groups (>Table 3). A total of 14 women had a BMI  $\geq$  30 kg/m<sup>2</sup>. There were no differences in demographics, medical/obstetrical histories or the percentage of time traced by eFHR between the obese and nonobese groups. fECG, however, was superior in the nonobese patient group. The median percentage of time the fECG was detected was 8% in the obese group compared with 83% in the nonobese patients (p = 0.048). In the obese group, an 80% tracing time was seen in only one patient (7.1%) compared with eight patients (50.0%) in the nonobese group (p = 0.017).

All patients preferred the comfort of fECG over eFHR. An additional finding of fECG monitoring was an increased amount of traced uterine activity from the electrohysterography lead, determined to be an artifact from patient movement. This finding was not systematically evaluated.

## **Comment**

To our knowledge, this is the first study to compare eFHR to fECG for preterm gestation. We hypothesized that fECG would be better at recording the fetal heart tracing compared with eFHR. However, that was not the case for any of the cutoffs that we used. In 2008, Graatsma et al<sup>7</sup> published a study of 150 women between 20 and 40 weeks' gestation who had 15 hours of fetal tracing using fECG. Out of the 150 recordings, 123 recordings (82%) were considered to be of sufficient quality, which was defined as  $\geq$  60% time traced. In 2013, Hofmeyr et al<sup>8</sup> published a study of 411 women between 20 and 24 weeks' gestation who used fECG to record the fetal heart tracing for at least 30 minutes. A total of 130 women (31.6%) were excluded from analysis; 19 (4.6%) were excluded because fECG did not detect the fetal heartbeat > 50% of the time. Of the 281 women analyzed, the mean signal loss as a percentage of recording time was 4% with a range of 0 to 46.3%.

Quantifying what constitutes a fetal heart tracing of sufficient quality can be difficult and challenging to standardize. Many physicians order continuous monitoring for fetuses at preterm gestation at risk for adverse fetal events. Under these circumstances, the percentage of recorded and interpretable fetal heart tracing should be as high as possible. In our study,

**Table 2** Fetal heart tracing times and percentages for 30 women

Characteristics	Standard tracing	Fetal electrocardiogram	p Value
Recording time (min)	120 (120, 120)	120 (97, 120)	< 0.005
Time tracings were detected (min)	112 (95, 118)	59 (3, 108)	< 0.001
Percentage of time tracings detected	93 (82, 99)	49 (6, 90)	< 0.001
Tracings detected $\geq 60\%$	28 (93.3)	14 (46.7)	< 0.001
Tracings detected < 60%	2 (6.7)	16 (53.3)	
Tracings detected $\geq 80\%$	24 (80.0)	9 (30.0)	< 0.001
Tracings detected < 80%	6 (20.0)	21 (70.0)	
Tracings detected $\geq 90\%$	18 (60.0)	7 (23.3)	< 0.01
Tracings detected < 90%	12 (40.0)	23 (76.7)	

Note: Data are shown as median (interquartile range) or n (%).

Table 3 Characteristics and fetal heart tracings of 14 obese and 16 nonobese women

Characteristics	Obese (N = 14)	Nonobese (N = 16)	p Value
Maternal age (y)	28 (22, 35)	28 (20, 31)	0.395
Race			
Caucasian	7 (50)	9 (56)	0.732
African American	7 (50)	7 (44)	
Other			
Marital status			
Single	6 (42.9)	6 (37.5)	0.926
Married	6 (42.9)	8 (50.0)	
Divorced	2 (14.3)	2 (12.5)	
Body mass index at admission (kg/m²)	37.4 (34.2, 42.2)	25.9 (21.3, 27.9)	< 0.001
Gravidity	2 (1, 4)	3 (1, 3)	1
Number of term births	1 (0, 2)	1 (0, 2)	0.995
Number of preterm births	0 (0, 0)	0 (0, 1)	1
Number of abortions	0 (0, 1)	0 (0, 1)	1
Number of living children	1 (0, 2)	1 (0, 2)	0.751
Gestational age at enrollment	26.8 (25.4, 27.4)	26.5 (25.0, 27.6)	0.971
Placental location			•
Anterior	7 (50)	6 (37.5)	0.49
Posterior	5 (35.7)	9 (56.3)	
Lateral	2 (14.3)	1 (6.3)	
Fetal orientation			
Vertex	10 (71.4)	15 (93.8)	0.237
Breech	3 (21.4)	1 (6.3)	
Transverse	1 (7.1)	0 (0.0)	
Preterm premature rupture of membranes	1 (7.1)	4 (25.0)	0.336
Amniotic fluid deepest vertical pocket (cm)	5.3 (3.6, 6.3)	5.3 (3.7, 6.2)	0.936
Estimated fetal weight (g)	901 (628, 1004)	942 (610, 1094)	0.659
Estimated fetal weight percentile	45 (28, 66)	43 (28, 47)	0.778

(Continued)

Table 3 (Continued)

Characteristics	Obese (N = 14)	Nonobese (N = 16)	p Value
Medical/obstetrical history	·	·	·
Chronic hypertension	3 (21.4)	1 (6.3)	0.315
Diabetes (type 1 or type 2)	3 (21.4)	0 (0.0)	0.09
Asthma	3 (21.4)	0 (0.0)	0.09
Vaginal bleeding	1 (7.1)	3 (18.8)	0.602
Preeclampsia	1 (7.1)	0 (0.0)	0.467
Preterm labor	0 (0.0)	4 (25.0)	0.103
Cervical insufficiency	5 (35.7)	5 (31.3)	1
External Doppler fetal heart tracing			
Recording time (min)	120 (120, 120)	120 (120, 120)	1
Time tracings were detected (min)	106 (83, 120)	112 (99, 116)	0.851
Percentage of time tracings detected	88 (69, 100)	94 (85, 99)	0.699
Tracings detected $\geq$ 60%	13 (92.9)	15 (93.8)	1
Tracings detected < 60%	1 (7.1)	1 (6.3)	
Tracings detected $\geq 80\%$	10 (71.4)	14 (87.5)	0.378
Tracings detected < 80%	4 (28.6)	2 (12.5)	
Tracings detected $\geq$ 90%	7 (50)	11 (68.8)	0.296
Tracings detected < 90%	7 (50)	5 (31.3)	
Fetal electrocardiogram			
Recording time (min)	119 (35, 120)	120 (120, 120)	0.244
Time tracings were detected (min)	9 (0, 80)	100 (23, 120)	0.021
Percentage of time tracings detected	8 (0, 69)	83 (19, 100)	0.048
Tracings detected $\geq$ 60%	4 (28.6)	10 (62.5)	0.063
Tracings detected < 60%	10 (71.4)	6 (37.5)	
Tracings detected $\geq 80\%$	1 (7.1)	8 (50.0)	0.017
Tracings detected < 80%	13 (92.9)	8 (50.0)	
Tracings detected $\geq$ 90%	1 (7.1)	6 (37.5)	0.086
Tracings detected < 90%	13 (92.9)	10 (62.5)	

Note: Data are shown as median (interquartile range) or n (%).

we used three different percentages as cutoffs to define tracings of sufficient quality, and eFHR uniformly performed better than fECG.

The maternal BMI has been previously shown to not interfere with fECG tracings in term gestations.  $^{4,5}$  This finding was not consistent in our study when the modality was applied to preterm gestation. fECG was more likely to provide tracings of sufficient quality in patients with a BMI  $<30\ kg/m^2$  for all three cutoff points, but did not perform as well as eFHR.

Strengths of this study include its prospective design, and that each patient served as her own control. There are limitations that warrant discussion. Because this is a pilot study, the sample size is small. eFHR and fECG tracings were performed sequentially, not contemporaneously, which is technically not feasible. In addition, we initially started the study with patients receiving continuous fetal monitoring

due to concern over fetal wellbeing. After 10 patients were recruited, we decided to perform the study on patients who did not require continuous fetal monitoring because some fECG tracings were not of sufficient quality to provide reassurance of fetal status. These patients were not on the fECG for a full 2 hours. Furthermore, there is a significant learning curve to applying and using the fECG. The patient's skin requires exfoliation with a certain amount of pressure before placing the electrodes to reduce skin impedance. Suboptimal exfoliation will result in increased noise and may hinder the quality of tracings.

In conclusion, eFHR performed better than fECG in recording fetal heart tracings in singleton gestations between 24 and 28 weeks. However, 100% of patients preferred the comfort of fECG over eFHR and thus fECG may have clinical utility in preterm gravidas with a BMI  $< 30 \text{ kg/m}^2$ . There is a newer version of the AN24 monitor (Monica Healthcare Ltd.,

Nottingham, United Kingdom), which was designed to reduce noise from the maternal heart rate as well as more accurately record uterine activity. Further studies are needed to optimize this technology in the preterm population.

#### Conflict of Interest

The authors report no conflict of interest.

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