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ORIGINAL RESEARCH ARTICLE

Effectiveness of ambulatory non-invasive fetal electrocardiography: impact of maternal and fetal characteristics

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Abstract

Introduction: Non-invasive fetal electrocardiography (NIFECG) has potential benefits over the computerized cardiotocography (cCTG) that may permit its development in remote fetal heart-rate monitoring. Our study aims to compare signal quality and heart-rate detection from a novel self-applicable NIFECG monitor against the cCTG, and evaluate the impact of maternal and fetal characteristics on both devices.

Material and methods: This prospective observational study took place in a university hospital in London. Women with a singleton pregnancy from 28 + 0 weeks' gestation presenting for cCTG were eligible. Concurrent monitoring with both NIFECG and cCTG were performed for up to 60 minutes. Post-processing of NIFECG produced signal loss, computed in both 0.25 (E240)- and 3.75 (E16)-second epochs, and fetal heart-rate and maternal heart-rate values. cCTG signal loss was calculated in 3.75-second epochs. Accuracy and precision analysis of 0.25-second epochal fetal heart-rate and maternal heart-rate were compared between the two devices. Multiple regression analyses were performed to assess the impact of maternal and fetal characteristics on signal loss. ClinicalTrials.gov Identifier: NCT04941534.

Results: 285 women underwent concurrent monitoring. For fetal heart-rate, mean bias, precision and 95% limits of agreement were 0.1 beats per minute (bpm), 4.5 bpm and −8.7 bpm to 8.8 bpm, respectively. For maternal heart-rate, these results were −0.4 bpm, 3.3 bpm and −7.0 to 6.2 bpm, respectively. Median NIFECG E240 and E16 signal loss was 32.0% (interquartile range [IQR] 6.5%–68.5%) and 17.3% (IQR 1.8%–49.0%), respectively. E16 cCTG signal loss was 1.0% (IQR 0.0%–3.0%). For NIFECG, gestational age was negatively associated with signal loss (beta = −2.91, 95% CI −3.69 to −2.12, $P < 0.001$). Increased body mass index, fetal movements and lower gestational age were all associated with cCTG signal loss (beta = 0.30, 95% CI

Abbreviations: BMI, body mass index; bpm, beats per minute; cCTG, computerized cardiotocography; CI, confidence interval; CTG, cardiotocography; E16, 16 per minute epochs (3.75 seconds); E240, 240 per minute epochs (0.25 seconds); ECG, electrocardiography; FHR, fetal heart rate; IQR, interquartile range; MHR, maternal heart rate; NIFECG, non-invasive fetal electrocardiography.

0.17–0.43, $P < 0.001$; beta = 0.03, 95% CI 0.01–0.05, $P = 0.014$; and beta = −0.28, 95% CI −0.51 to −0.05, $P = 0.017$, respectively).

Conclusions: Although NIFECG is complicated by higher signal loss, it does not appear to be influenced by increased body mass index or fetal movement. NIFECG signal loss varies according to method of computation, and standards of signal acceptability need to be defined according to the ability of the device to produce clinically reliable physiological indices. The high accuracy of heart-rate indices is promising for NIFECG usage in the remote setting.

KEYWORDS
ambulatory monitoring, computerized cardiotocography, fetal heart rate monitoring, non-invasive fetal electrocardiography, signal loss, signal quality

1 | INTRODUCTION

Cardiotocography (CTG) is one of the main modalities of antenatal assessment for pregnancies at risk of fetal hypoxemia. Limitations of inter- and intraobserver variation as well as clinical misinterpretation have weakened the intended aim to improve perinatal outcomes.[1] In contrast, the use of computerized CTG (cCTG) assessment confers a significant reduction in perinatal mortality compared with traditional visual CTG interpretation.[1] Built-in cCTG algorithms developed by Dawes and Redman allow numerical values for key fetal heart rate (FHR)-related indices to be generated.[2–4] Despite these advantages, cCTG use remains confined to the hospital environment and restricted by the number of available devices as well as availability of experienced practitioners. Furthermore, Doppler cCTG technology may sometimes not distinguish between maternal and fetal heart activity, emits energy which can be a safety issue especially with prolonged use, is limited by increased maternal habitus and may need frequent re-positioning of the transducer with fetal movements.[5,6]

Non-invasive fetal electrocardiography (NIFECG) is a form of electrocardiography (ECG) which captures simultaneous maternal and fetal PQRST waves. NIFECG has the theoretical benefits of minimizing maternal-fetal heart activity confusion, not affected by maternal adiposity, and delivers no energy, permitting prolonged periods of fetal monitoring with safety.[7–9] In the booming era of telemedicine, remote FHR monitoring technology is both clinically and economically desirable, and due to the potential benefits of NIFECG, there is scope for this to be developed for use outside hospital setting. However, relatively small fetal QRS amplitudes pose technical challenges to FHR detection and analysis, as it can be masked by larger maternal QRS complexes as well as high frequency noise from electrical interference. To date, NIFECG has mostly been limited to research use due to low fetal signal to noise ratios.[10,11] Variable methods of signal processing and arbitrary criteria for signal acceptance have been used by researchers, precluding firm conclusions on the feasibility and utility of NIFECG in a clinical setting.[12–16] Moreover, NIFECG devices have required fitting and removal by trained healthcare professionals and therefore are not suitable for unassisted out-of-hospital remote use.[12–16]

Key message

Non-invasive fetal electrocardiography is more susceptible to signal loss than computerized cardiotocography but it is not hindered by maternal habitus or fetal movements. High accuracy of NIFECG-obtained heart-rate indices, together with its ability for self-application, may offer a promising step towards home fetal heart-rate monitoring.

Remote NIFECG monitoring with self-applied devices will need to be benchmarked against conventional cCTG assessment to identify potential areas for research and development as well as to explore the potential for clinical use. The objective of this study is to assess signal quality and heart rate correlation from a novel self-applicable NIFECG device and compare it with conventional cCTG, and to evaluate the impact of maternal and fetal characteristics on both NIFECG and cCTG signal quality.

2 | MATERIAL AND METHODS

This was a single-center pilot prospective cohort study conducted at St George's University Hospitals NHS Foundation Trust, London. Recruitment took place from June 2021 to June 2022. Women with a singleton pregnancy from 28 + 0 weeks' gestation who presented to the Day Assessment Unit requiring cCTG monitoring for any clinical indication were eligible. Details of the inclusion and exclusion criteria as well as study procedures are described in our protocol.[17]

Following written informed consent, concurrent monitoring using both cCTG and NIFECG was performed for a minimum of 40 minutes. Fetal movement count was recorded by the woman by pressing the fetal movement marker every time a fetal movement was perceived. Maternal and fetal characteristics such as body

mass index (BMI), self-reported ethnicity, gestation, placental site and pregnancy complications were recorded from pregnancy notes. cCTG outputs were extracted from the Dawes–Redman analysis using the Sonicaid FETALCARE3 software (Huntleigh Healthcare Ltd.).

2.1 | Signal acquisition

The femom™ device consists of a pod (for data acquisition, digitization and transmission) and a flexible polymer spreader which allows attachment of five removable wet-gel electrodes (Figure 1). It is designed to be placed and removed by women without medical assistance, and NIFECG signals are transmitted live via Bluetooth to a computer software. Skin preparation prior to NIFECG placement was performed using mild abrasive paper (3M SkinPrep 2236) to improve contact, and alcohol wipes in women with recent emollient application to optimize adherence. The NIFECG signals were displayed live as a raw NIFECG trace combining both fetal and maternal PQRST complexes, offering no interpretable information to the clinician or the women. Clinical decisions were made from cCTG traces in accordance with local guidelines.

2.2 | NIFECG signal processing and agreement with cCTG

Post-processing of the ECG signal took place after monitoring, consisting of removal of electrical noise, maternal signal removal, fetal signal enhancement and FHR derivation from RR interval calculation. This is expressed as an FHR value within each 0.25-second epoch, and an FHR trace is in turn generated using these data. Women who re-attended for cCTG monitoring at a later gestation were eligible for repeat concurrent NIFECG monitoring, and the trace with the lowest signal loss was used in the statistical analysis to reduce multicollinearity. Maternal heart rate (MHR) and FHR captured in each 0.25-second epoch were compared between the two devices in all traces for MHR and traces with <50% signal loss for FHR. Accuracy and precision analysis inclusive of mean bias, precision (standard deviation) and 95% upper and lower limits of agreement were calculated.

2.3 | Fetal ECG signal loss criteria and rates

An absence of identifiable R waves, or an artifact leading to a falsely high number of R waves, would result in an abnormally low or high FHR, respectively, between the perceived successive RR intervals. FHR outliers <30 or >240 beats per minute (bpm) are therefore defined as signal loss, where signal acquisition is defined as FHR within a valid range. This strategy is in keeping with that used by CTG and FECG (scalp electrode) monitors, where rates outside this range are considered not to be true FHR.[18,19] For cCTG, signal loss was defined by Dawes et al. as the percentage of 3.75-second epochs with no valid FHR computed.[4] For NIFECG, two methods of computation were used to calculate signal loss. E240 signal loss (240 epochs analyzed per minute) is defined as the presence of an FHR outlier (<30 or > 240 bpm) within each 0.25-second epoch (default method). To match the definition of signal loss set by Dawes et al., E16 signal loss (16 epochs analyzed per minute) defined by FHR outliers in a 3.75-second epoch, was also calculated.[4] Both are expressed as the percentage of epochs with signal loss in the entire trace. NIFECG traces with an E240 signal loss of >50% were further categorized depending on the cause for signal loss. Electrical interference was defined as high amplitude noise masking fetal R waves, where despite de-noising and processing, noise amplitude remained greater than fetal R waves. Loss of R waves pre-processing was defined as raw ECG clear of noise, but where no fetal R waves were detectable, and loss of R waves post-processing as clean ECGs produced after de-noising, but where fetal R waves were not detected.

FIGURE 1 The novel, self-applicable non-invasive fetal electrocardiography (femom) placed on the maternal abdomen.

2.4 | Statistical analyses

Descriptive data were presented as median and interquartile ranges (IQR) for continuous variables, and number and percentages for categorical variables. Comparisons between groups were performed using the χ^2 or Fisher's exact test for categorical variables. Multiple regression analyses were performed to assess the predictive values of maternal and fetal characteristics on signal loss from both devices, for both definitions of signal loss. This was carried out using signal loss from each device as the dependent variable, and maternal BMI, ethnicity, gestational age, placental site, estimated fetal weight centile and fetal movement count as explanatory variables. Statistical software package SPSS v28.0 (SPSS Inc.) was used for analysis.

2.5 | Ethics statement

Ethical approval was obtained from South-East Scotland Research Ethics Committee 02 on November 4, 2019 (REC reference 19/SS/0109, IRAS ID 260032), and MHRA on October 21, 2020 (CI/2020/0028).

3 | RESULTS

Concurrent NIFECG and cCTG monitoring was undertaken in 285 women. Demographic, maternal and pregnancy characteristics of the study population are shown in Table 1. Pregnancies were complicated by small-for-gestational-age (SGA) fetuses, hypertensive disorders or diabetes in 9.5%, 12.3% and 14.4% of cases, respectively. One woman reported a rash from a gel electrode contact, which resolved within 24 hours of disuse – no other reactions or safety issues were raised during the conduct of the study.

Figure 2 displays a clean raw NIFECG trace, combining both maternal and fetal electrical impulses, where fetal R waves are clearly seen. After standard signal processing, the mean bias for the clinically interpretable (traces with <50% E240 signal loss) FHR for NIFECG vs cCTG was 0.1 bpm, precision 4.5 bpm, and 95% upper and lower limits of agreement 8.8 bpm and −8.7 bpm, respectively. For MHR, mean bias, precision and 95% upper and lower limits of agreement were −0.4, 3.3, 6.2 and −7.0 bpm, respectively.

For NIFECG, the median E240 signal loss in all traces was 32.0% (IQR 6.5%–68.5%). When the same dataset was computed using the Dawes et al. definition, E16 signal loss decreased to a median of 17.3% (IQR 1.8%–49.0%). For cCTG, E16 median signal loss was 1.0% (IQR 0.0%–3.0%). Figure 3 demonstrates the raw NIFECG with high amplitude noise (due to electrical interference), masking the detection of fetal R waves. In traces with E240 signal loss >50%, 51/285 (18%) were due to electrical interference, 53/285 (19%) where no fetal R waves were detected post de-noising and processing, and 10/285 (4%) where despite a clean raw ECG trace, no fetal R waves were captured. During the course of recruitment, several flexible polymer spreaders for gel electrode attachment were used. A change to newly manufactured spreaders occurred in December 2021. Prior to the change, 24% (40/164) traces were rejected due to electrical interference, compared with 9% (11/121) after implementation of the new spreaders ($P < 0.001$). Loss of R waves (pre- and post-processing) led to trace rejection in 20% (33/164) of traces using the old spreaders, and 25% (30/121) of traces post-equipment change ($P = 0.387$).

The results of the multiple regression analysis are shown in Table 2 (NIFECG E16 vs cCTG) and Table S1 (NIFECG E240 vs cCTG). For NIFECG, gestational age showed a strong negative association with both E240 and E16 signal loss (beta = −3.65, 95% CI −4.62 to −2.67, $P < 0.001$, and beta = −2.91, 95% CI −3.69 to −2.12, $P < 0.001$, respectively), where an increase in gestation resulted in higher signal acquisition. In cCTG, gestational age was also negatively associated with signal loss (beta = −0.28, 95% CI −0.51 to −0.05, $P = 0.017$; Figure 4). The likelihood of cCTG signal loss increased with increasing maternal BMI (beta = 0.30, 95% CI 0.17–0.43 $P < 0.001$) as well with increased fetal movement (beta = 0.03, 95% CI 0.01–0.05, $P = 0.014$).

TABLE 1 Table demonstrating maternal and fetal characteristics of the study population. Data shown as median (IQR) or number (%).

Demographics	Study population ($n = 285$)
Age, years	32.0 (30.0–36.0)
Height, cm	163.9 (160.0–169.0)
Weight, kg	68.4 (60.2–81.6)
BMI	25.3 (22.6–29.5)
Ethnicity	
White	182 (63.9)
Black	34 (11.9%)
Asian	51 (17.9%)
Mixed/other	18 (6.3%)
Gestational age, weeks + days	37 + 1 (34 + 5 to 39 + 3)
Anterior placenta	151 (53.0%)
Estimated fetal weight centile	46.0 (25.0–67.0)
Small-for-gestational-age pregnancy	27 (9.5%)
Hypertensive disorders of pregnancy	35 (12.3%)
Diabetic pregnancy	41 (14.4%)
Indication for monitoring	
Reduced fetal movements	188 (66.0%)
Prelabor rupture of membranes	22 (7.7%)
Post-maturity	18 (6.3%)
Fetal growth restriction	12 (4.2%)
Hypertension	8 (2.8%)
Miscellaneous	37 (13.0%)

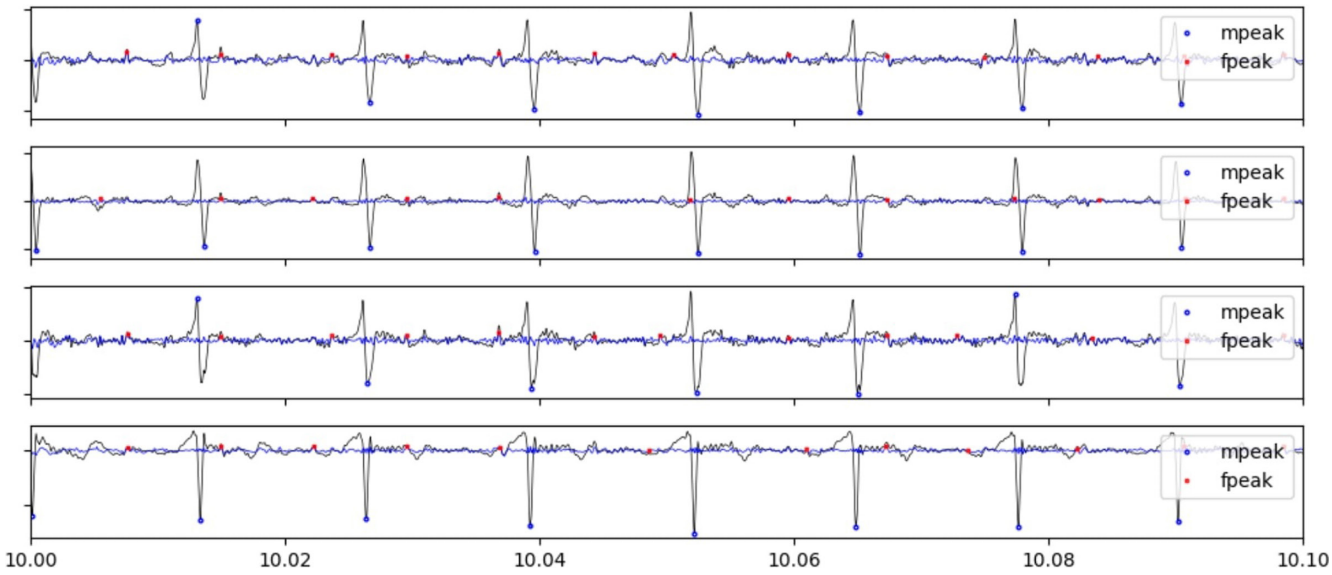

FIGURE 2 Raw non-invasive fetal electrocardiography trace after noise filtering and processing, displayed on the four channels as derived from PC-based software. Maternal (mpeak) and fetal (fpeak) R waves are marked by blue and red dots, respectively.

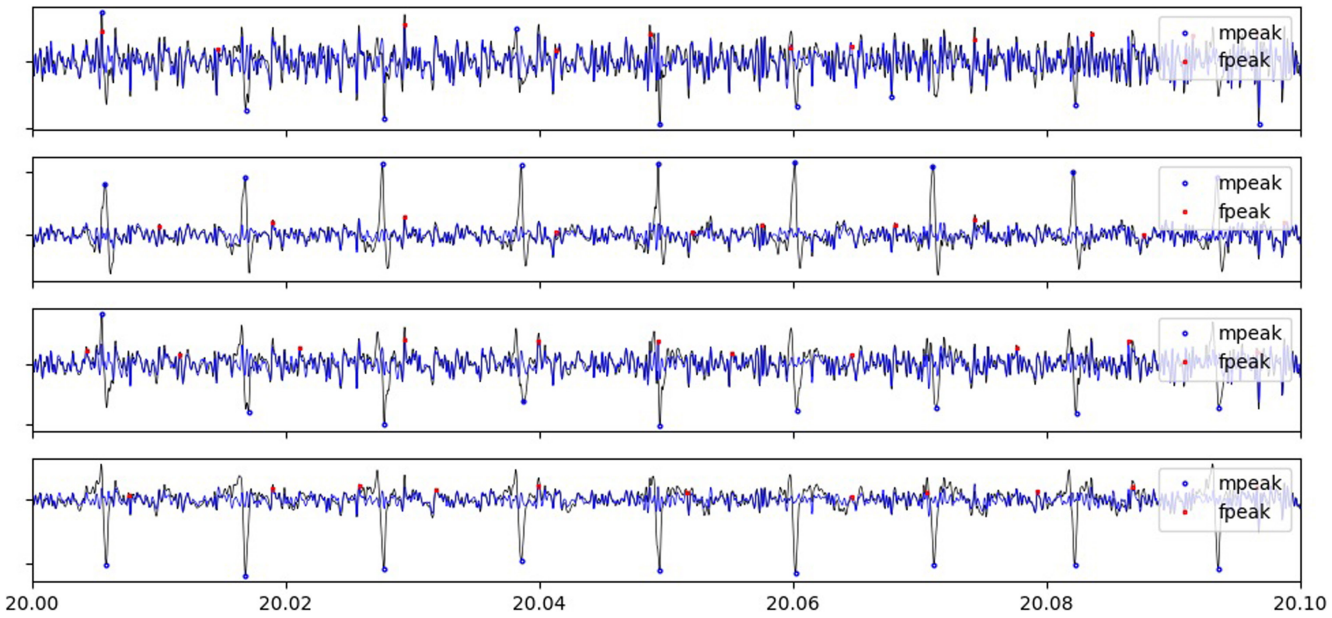

FIGURE 3 Raw non-invasive fetal electrocardiography trace with high amplitude noise (electrical interference). Maternal (mpeak) and fetal (fpeak) R waves are marked by blue and red dots, respectively, but fetal R waves are evidently difficult to identify as masked by noise.

4 | DISCUSSION

Our study demonstrates the benefits as well as the challenges of NIFECG in comparison with conventional cCTG monitoring. FHR and MHR outputs from NIFECG showed minimal bias and high levels of precision when compared with cCTG. Signal acquisition in NIFECG generally faces more technical difficulties than in cCTG principally at early gestations, but appears to be unhindered in women with higher BMI or with fetal movements. Signal acquisition using the criteria defined by Dawes et al. resulted in a halving of signal loss, demonstrating the arbitrary nature of various signal processing thresholds, explaining the variability of reported comparative success of methods used.

NIFECG was first discovered in 1906 as a means of detecting FHR; by 1957, methods using this technology to detect fetal hypoxemia were proposed.[20] Small amplitude fetal R waves are masked not only by the larger maternal QRS complexes but also by electrical noise. The latter could be due to surrounding electrical interference, poor electrode contact, conduction pathways through equipment as well as other interference from myographic and biological artifacts.[7,10,11] Our data suggest that change in the flexible polymer spreaders resulted in lower rates of electrical interference in women

TABLE 2 Multiple regression analysis of the influence of maternal and fetal characteristics on non-invasive fetal electrocardiography (NIFECG) E16 and computerized cardiotocography (cCTG) signal loss, using the same computation method. Dependent variable was set as signal loss (%) from each device, and maternal and fetal characteristics were set as independent variables.

	NIFECG E16 signal loss				cCTG signal loss			
Maternal/fetal characteristics	*B* coefficient	SE	*P*-value	95% CI	*B* coefficient	SE	*P*-value	95% CI
Intercept	128.20	16.00	<0.001	96.72–159.68	3.69	4.69	0.433	−5.55 to 12.93
BMI	0.17	0.22	0.460	−0.28 to 0.61	0.30	0.07	**<0.001**	0.17–0.43
Ethnicity								
White	Reference				Reference			
Black	4.24	4.36	0.331	−4.34 to 12.82	−0.52	1.28	0.684	−3.04 to 2.00
Asian	1.31	3.70	0.724	−5.98 to 8.60	−0.17	1.09	0.874	−2.31 to 1.97
Mixed/other	−5.38	5.59	0.337	−16.39 to 5.64	−1.00	1.64	0.544	−4.23 to 2.23
Gestational age	−2.91	0.40	**<0.001**	−3.69 to −2.12	−0.28	0.12	**0.017**	−0.51 to −0.05
Anterior placenta	5.17	2.71	0.057	−0.16 to 10.51	0.95	0.80	0.233	−0.62 to 2.52
EFW centile	−0.10	0.06	0.072	−0.21 to 0.01	0.01	0.02	0.462	−0.02 to 0.05
Fetal movement count	0.02	0.04	0.579	−0.05 to 0.09	0.03	0.01	**0.014**	0.01–0.05

Bold values depict statistically significant findings ($P < 0.05$).

Abbreviations: BMI, body mass index; EFW, estimated fetal weight.

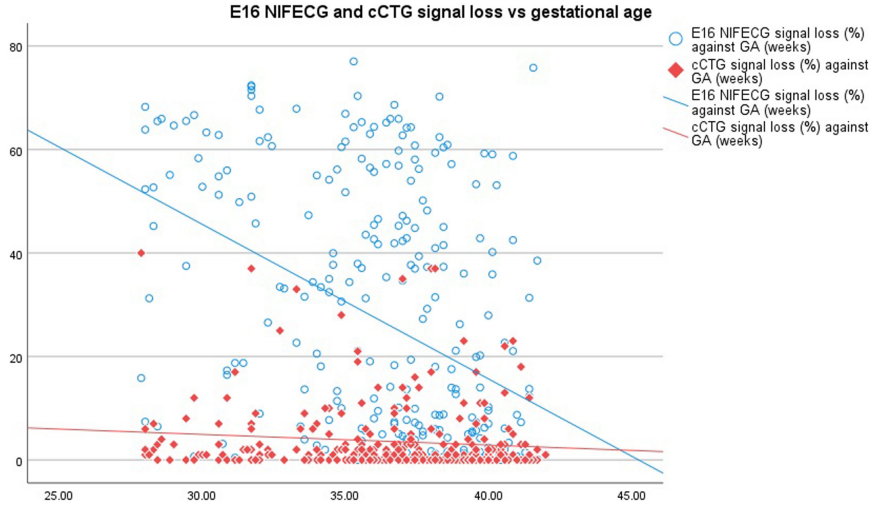

FIGURE 4 Scattergram showing signal loss (%) on the *Y*-axis, against gestational age (GA) (weeks) on the *X*-axis, in both non-invasive fetal electrocardiography (NIFECG) (E16 signal loss) and cCTG. Empty blue circles depict overall NIFECG signal loss, and filled red diamonds are cCTG signal loss. The line of best fit in the NIFECG group has a stronger negative correlation with gestational age compared with the cCTG group.

recruited after December 2021. Material and wiring used in the initial spreaders may have interfered with electrical conductivity but this sort of variance is expected during device development. It may be that with equipment optimization and monitoring carried out in environments with less electrical interference, signal loss due to this factor could be reduced. Nevertheless, as a result of the frequency of maternal QRS complexes and electrical noise, signal loss has a bigger impact on NIFECG than cCTG and, consequently, several different methods for computation of signal loss have been proposed. Cohen et al. defined signal loss as the percentage of 0.25-second epochs where FHR was zero, leading to a lower reported mean signal loss of 16.6%.[21] This differed from Huhn et al., who classified this as the percentage of seconds with detectable FHR within each minute epoch, resulting in a reported signal loss of 23.9% in the routine care home-monitored group, and 54.5% in the high-risk hospitalized group.[16]

Many researchers have set pre-defined signal acceptance criteria for NIFECG, where traces with less than an arbitrarily set percentage of signal loss are deemed successful.[12–15,22,23] Graatsma et al. used the same NIFECG signal loss computation as defined by Dawes et al. in 150 women from 20 weeks, and deemed traces with <40% signal loss to be of sufficient quality. Using this criterion, they reported successful traces in 82% of their study cohort compared with 68% in the current study. This may be attributed to their prolonged monitoring time of 15 hours (as compared with 1 hour in the current study), which mostly took place during maternal sleep.[15] Fuchs et al. studied 773 women from 28 weeks and defined signal acceptance as <20% signal loss, in line with the FIGO intrapartum CTG guidelines, to assess antenatal NIFECG signals. Only 46% of traces fulfilled this criterion.[23] Furthermore, we believe that the approach of using intrapartum guidelines to assess antenatal FHR is potentially flawed. Acute or subacute fetal hypoxic events are unlikely to occur antenatally in the absence of

uterine activity antenatally and thus a high intrapartum threshold for signal acceptance offers little clinical benefit in the antenatal context.

Several studies have suggested that the vernix caseosa may act as insulation to electrical conduction in the early third trimester.[7,10,11,15,16,24–26] Vernix production peaks in the early third trimester but as the fetus grows, the distribution of vernix is reduced with increasing skin surface area, along with continued shedding into the amniotic fluid cavity.[26,27] This is consistent with our finding that a lower gestational age is a significant predictor of increased signal loss in NIFECG. Although our data did not include pregnancies in the second trimester, studies recruiting pregnancies from as early as 15 weeks have reported that signal acquisition was higher in the second trimester and lowest in the early third trimester (27–36 weeks), with an improvement in the late third trimester.[15,16,25,26] Fuchs et al.'s findings, however, contradicted this, as in a cohort of 773 pregnancies from 28 to 42 weeks, they observed no linear correlation between signal loss and gestational age ($R = 0.059$, $P = 0.096$).[23] It is possible that non-linear analysis of the data could have elicited an association between these variables, or perhaps that the vernix theory still requires further evaluation.

Over 80% of NIFECG traces in this study were interpretable, suggesting that NIFECG may still have clinical potential in home FHR monitoring where women may be able to self-apply the monitor on multiple occasions. Without consensus or a firm evidence-base, previous studies have not only used various methods of signal loss computation, but set a signal acceptance criterion ranging from 20% to 66% of signal loss to define a successful trace.[12,13,15,22,28] As the aim of FHR monitoring is to establish the presence of an active fetal state, the presence of this within any period of time should be acceptable. The Dawes–Redman criteria uses a minimum of 10 minutes demonstrating normal FHR variability to establish fetal wellbeing.[3,4] We suggest that, regardless of signal loss, a trace where at least 10 minutes of fetal R waves are captured that demonstrate physiological FHR indices by displaying normal key FHR parameters such as short-term variation (STV), should be sufficient to demonstrate fetal wellbeing.[3,4] An alternative approach is to increase the length of NIFECG monitoring, as the device delivers no energy and women can wear the monitor for longer durations without safety concerns.[15] Further research is required to define the range of normality of FHR indices by comparing a self-applied NIFECG with the cCTG STV to establish its correlation and limits of agreement.

Doppler technology used in cCTG is dependent on proximity to the fetal heart to allow detection of cardiac movement.[5] Not surprisingly, increased maternal habitus and fetal movements would cause difficulties in sound penetration and disruption of contact, leading to signal loss, as supported by our findings.[9] In contrast, NIFECG does not require physical proximity to the fetal heart. This is demonstrated in studies where despite standardized electrode placement, signal loss was not associated with fetal presentation.[15,16] Self-applied FHR monitoring using Doppler technology is highly likely to cause fetal-maternal HR confusion, whereas this is virtually eradicated in NIFECG.[8,21] To the best of our knowledge, internal processing algorithms, outlier definitions and methods of exclusion within cCTG are not in the public domain, giving rise to further differences in signal loss from NIFECG.

5 | CONCLUSION

This study systematically evaluates signal quality of a self-applicable NIFECG monitor and compares this with the cCTG. The data demonstrate that non-standardized signal loss computation and signal acceptance criteria explain the heterogeneity seen in the published literature. By setting comparable computational models and identical analysis thresholds, it is possible to achieve acceptable (>80%) levels of interpretable fetal ECG signals within a short monitoring period. Using these NIFECG traces, high levels of FHR accuracy and precision were evident compared with cCTG. Despite technical challenges, NIFECG may be the most promising method of ambulatory self-applied FHR monitoring. Electrical interference may be mitigated through equipment optimization and environment change. Standards of signal acceptability need to be defined according to the device's ability to produce clinically reliable physiological indices, rather than previously defined arbitrary thresholds, to allow accurate assessments of fetal wellbeing.

AUTHOR CONTRIBUTIONS

Conceptualization: BT, AB, BL. Methodology: BL, AB, BT. Data collection and processing: BL. Statistical analysis: BL. Data interpretation: BL, AB, BT. Draft: BL. Review & editing: BL, AB, BT.

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CONFLICT OF INTEREST STATEMENT

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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