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Correlation of short-term variation derived from novel ambulatory fetal electrocardiography monitor with computerized cardiotocography

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KEYWORDS: ambulatory monitoring; computerized cardiotocography; fetal heart-rate monitoring; non-invasive fetal electrocardiography; short-term variation

CONTRIBUTION

What are the novel findings of this work?
Short-term variation (STV) captured by a self-applied non-invasive fetal electrocardiography (NIFECG) monitor is strongly correlated with STV obtained on computerized cardiotocography (cCTG). Inaccuracies caused by signal loss can be reduced or corrected, and fetal heart-rate monitoring regimes can be tailored to optimize signal quality and correlation.

What are the clinical implications of this work?
We identified key technological and algorithmic issues and developed strategies to mitigate disparities between cCTG and NIFECG. Together with evidence-based monitoring standards, these represent promising steps toward the realization of safe and effective remote fetal heart-rate monitoring.

ABSTRACT

Objectives *To compare short-term variation (STV) outputs from a novel self-applied non-invasive fetal electrocardiography (NIFECG) device with those obtained on computerized cardiotocography (cCTG). Technological and algorithmic limitations and mitigation strategies were also evaluated.*

Methods *This was a prospective cohort study of women with a singleton pregnancy over 28 + 0 weeks' gestation attending a tertiary London hospital for cCTG assessment between June 2021 and June 2022. Women underwent concurrent monitoring with both NIFECG and cCTG for up to 1 h. Postprocessing of NIFECG data using various filtering methods produced NIFECG-STV (eSTV) values, which were compared with cCTG-STV (cSTV) outputs. Linear correlation, mean bias, precision and limits of agreement were assessed for STV derived by the different methods of computation and mathematical correction.*

Results *Overall, 306 concurrent NIFECG and cCTG traces were collected from 285 women. Fully filtered eSTV was correlated very strongly with cSTV (*$r = 0.911$, $P < 0.001$*), but generated results only in 142/306 (46.4%) 1-h traces owing to the removal of traces with lower-quality signals. Partial filtering generated more eSTV data (98.4%), but with a weak correlation with cSTV (*$r = 0.337$, $P < 0.001$*). The difference in STV between the monitors (eSTV – cSTV) increased with signal loss; in traces with > 60% signal loss, the values became highly discrepant. Removal of traces with > 60% signal loss resulted in a stronger correlation with cSTV, while still generating eSTV results for 65% of traces. Correcting these remaining eSTV values for signal loss using linear regression analysis further improved correlation with cSTV (*$r = 0.839$, $P < 0.001$*).*

Conclusions *The discrepancy between STV computed by NIFECG and cCTG necessitates signal filtering, exclusion of poor-quality traces and eSTV correction. This study demonstrates that, with such correction, NIFECG is able to produce STV values that are strongly correlated with those of cCTG. This evidence base for NIFECG monitoring and interpretation is a promising step forward in the development of safe and effective at-home fetal heart-rate monitoring.* © *2023 The Authors. Ultrasound in Obstetrics & Gynecology published by John Wiley & Sons Ltd on behalf of International Society of Ultrasound in Obstetrics and Gynecology.*

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INTRODUCTION

Stillbirth is a devastating outcome of pregnancy, and efforts to reduce its prevalence are of significant public health interest[1]. Antenatal fetal surveillance to prevent demise is based largely on hospital-confined methods, such as ultrasound biometry, fetal Doppler assessment and cardiotocography (CTG). Despite considerable inter- and intraobserver variation and the potential for clinical misinterpretation, CTG remains widely used in hospitals around the world[2]. Computerized CTG (cCTG) overcomes these challenges via an in-built processing algorithm that generates numerical values for physiological fetal heart rate (FHR) parameters, thereby permitting standardized interpretation[3–7]. The use of cCTG has been shown to lead to a significant reduction in perinatal mortality compared with traditional CTG[2].

Interaction between the branches of the autonomic nervous system is reflected in FHR variability, and a reduction in the bandwidth of FHR variability can be indicative of its suppression in chronic hypoxemia[8–10]. Short-term variation (STV) is the numerical quantification of smoothed FHR variability, and the validation of cCTG-STV (cSTV) in detecting fetal hypoxemia has led to the development of widely-used standards in cCTG monitoring of high-risk women[8,9,11]. However, limitations in the number of cCTG platforms available, clinical expertise to apply monitors and availability of appointments hinder widespread monitoring of high-risk pregnancies.

Non-invasive fetal electrocardiography (NIFECG) captures fetal and maternal PQRST complexes through the maternal abdomen. Not only does it have the potential to detect true beat-to-beat variability, but it can also minimize fetal–maternal heart-rate confusion and is unaffected by fetal position or maternal habitus[12–16]. These theoretical benefits raise the possibility of its use outside hospital, with self-application by the patient, thereby increasing surveillance without increasing service demands. However, owing to technical challenges relating to small-amplitude fetal R-waves and susceptibility to interference and artifacts, this technology has been limited to research use[17,18]. In order to assess the potential for self-applied NIFECG devices to be used remotely, they will need to be benchmarked against cCTG to identify areas for research and development. The objective of this study was to compare STV outputs from a novel self-applicable NIFECG monitor with those of cCTG. Technological and algorithmic limitations and mitigation strategies were evaluated.

METHODS

This was a pilot prospective cohort study of patients attending St George's University Hospitals NHS Foundation Trust, London, UK, between June 2021 and June 2022. Women with a singleton pregnancy over 28 + 0 weeks' gestation, who presented to a day assessment unit requiring cCTG monitoring for any clinical indication, were eligible. Women unable to consent, those fitted with a pacemaker, those with a major fetal structural or genetic abnormality and those in labor were excluded. Study procedures adhered to a published protocol[19].

Signal acquisition

Concurrent monitoring with both cCTG and NIFECG was performed for up to 60 min. cCTG outputs were recorded using the Sonicaid FM800 Encore Fetal monitor (Huntleigh Healthcare Ltd, Cardiff, UK). NIFECG signals were captured using femom™ (Biorithm Pte Ltd, Singapore), a new self-applicable monitor consisting of a pod and a spreader, which allows easy attachment and removal of five gel electrodes for each monitoring session. This device is designed to be used in the remote setting, particularly by women requiring frequent monitoring, with the potential for self-application and production of automated FHR outputs. Through Bluetooth connection, raw ECG traces were displayed on four channels on an application installed on a mobile device. Data were extracted in BioCapture recording files which, following signal processing, were exported as comma separated value (csv) files, generating numerical FHR outputs per 0.25-s epoch. Comparative csv files were also derived from each concurrent cCTG trace. Researchers and clinicians received no information from the NIFECG device at the time of monitoring; management plans were devised based on cCTG outputs.

Signal processing

NIFECG postprocessing took place after monitoring, and the trace was sampled at a frequency of 500 Hz. Several steps including denoising, maternal signal enhancement, maternal R-peak detection, maternal signal removal, fetal signal enhancement and fetal R-peak detection were performed to derive FHR. FHR data were sampled at 4 Hz and expressed as an FHR value for each 0.25-s epoch. cCTG uses autocorrelation, which does not detect individual heart beats but generates a single representative periodicity value calculated over multiple beats. Therefore, smoothed FHR values were also produced at a frequency of 4 Hz[9].

cSTV values were produced automatically by the Dawes–Redman algorithm for each trace. This algorithm consisted firstly of removing minutes containing all or part of a deceleration or with > 50% signal loss. Pulse intervals (ms) were averaged within each 3.75-s epoch, and differences in averaged pulse interval between successive epochs were then averaged over each minute. These averaged minute epochal differences were in turn averaged over the entire trace to produce cSTV[4,9,20].

For NIFECG, two sets of STV (eSTV) data were produced, namely fully (F) filtered and partially (P) filtered eSTV, as outlined in Figure 1. Both sets of eSTV data incorporate the Dawes–Redman algorithm into their computation. The first step in both eSTV computations uses an outlier filter. Each trace time window was removed if the averaged pulse interval was outside the expected

range, similar to the initial step used by Dawes and Redman[4,9,20]. F-filtered eSTV then proceeded to use a further series of filters in which, firstly, epochs with > 50% of pulse intervals > 2000 ms or < 250 ms (FHR < 30 bpm or > 240 bpm) were discarded. Minutes in which > 50% of epochs were discarded were in turn removed, and traces in which > 50% of minutes were removed did not generate an eSTV result. Thus, F-filtered eSTV was generated only in traces with the least signal loss.

Signal loss was defined as FHR outliers < 30 bpm or > 240 bpm because FHR outside this range is mostly due to missed R-waves or artifacts that falsely inflate FHR, and thus is unlikely to be representative of true FHR. These values were therefore removed from eSTV analysis. The presence of an FHR outlier in each 0.25-s epoch was termed E240 signal loss (240 epochs per min), and the presence of FHR outliers for all samples in a 3.75-s epoch was termed E16 signal loss (16 epochs per min). This nomenclature aims to differentiate between signal loss according to the default processing method (E240) and the signal-loss processing method used by Dawes *et al.*[4] (E16). Both were calculated as the proportion of discarded epochs in the entire trace, expressed as a percentage.

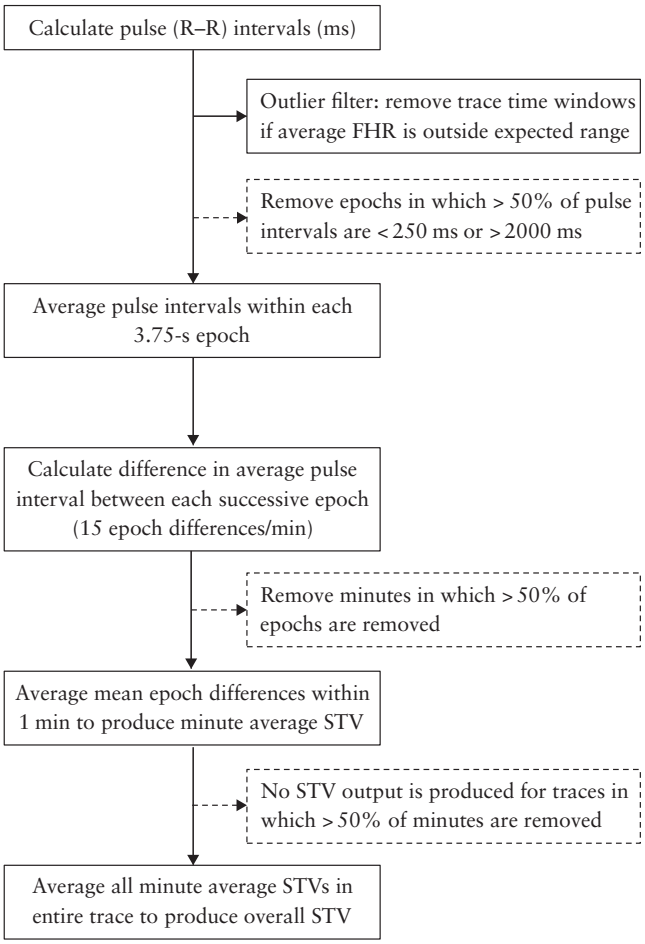

Figure 1 Flowchart summarizing computation of short-term variation (STV) by non-invasive fetal electrocardiography, using two different filtering strategies. Fully (F) filtered STV is produced by following all steps; calculation of partially (P) filtered STV excludes boxes with dashed outlines. FHR, fetal heart rate.

Informative minutes were defined as the number of minutes with accepted signal within the total monitoring duration. This was calculated using the formula: total minutes – (total minutes × % signal loss)/100. Informative minutes were compared against the difference in STV (eSTV – cSTV) between the two monitors.

Statistical analysis

Descriptive data are presented as median (interquartile range (IQR)) for continuous variables and *n* (%) for categorical variables. Linear regression analysis was performed using STV difference between the devices as the dependent variable and signal loss as the independent variable. Predicted STV differences (Y) were generated using regression equations, and corrected eSTV values were derived using the formula: eSTV – Y. The linearity of STV values derived from the two devices by various methods of computation was established using Pearson's correlation coefficient, after confirming normality using the Kolmogorov–Smirnov test. Accuracy and precision analysis was carried out to assess the mean bias, precision (expressed as SD) and 95% upper and lower limits of agreement (LoA) between each method of eSTV computation and cCTG. The statistical software package SPSS version 28.0 (SPSS Inc., Chicago, IL, USA) was used for analysis; $P < 0.05$ was considered to indicate statistical significance.

RESULTS

Concurrent NIFECG and cCTG monitoring was undertaken in 285 women, and 306 traces were collected from each machine. This study population was also used to investigate signal loss[21] and phase-rectified signal averaging (PRSA) in NIFECG traces[22]. Maternal and pregnancy characteristics are summarized in Table 1. No safety issues were reported during the study period.

Key outcome measures for the collected traces are presented in Table 2. Median eSTV in F-filtered and P-filtered NIFECG recordings were 9.2 ms (IQR, 7.6–11.4 ms) and 10.7 ms (IQR, 8.6–13.7 ms), respectively. For cCTG, median cSTV was 9.9 ms (IQR, 7.9–12.3 ms). eSTV outputs were generated in 142/306 (46.4%) traces using the F-filtered processing method and in 301/306 (98.4%) traces using the P-filtered processing method. cSTV values were generated for all cCTG traces. Linear correlation between P-filtered eSTV and cSTV was weak ($r = 0.337$, $P < 0.001$) (Table 3). Mean bias, precision and LoA were 1.57 ms, 4.86 ms and −7.96 to 11.1 ms, respectively. Conversely, a very strong linear correlation was observed between F-filtered eSTV and cSTV ($r = 0.911$, $P < 0.001$) (Figure 2, Table 3). Low mean bias, high precision and narrow LoA were also evident (−0.86 ms, 1.18 ms and −3.17 to 1.45 ms, respectively) (Figure 3, Table 3).

Despite the strong correlation, low outputs of eSTV using the F-filtered processing method (46.4%) prompted further analysis of the eSTV values produced using the P-filtered method. STV difference (eSTV – cSTV) for each

trace was compared against both E240 and E16 signal loss for the same trace. An increase in STV difference was observed when E240 signal loss rose above 60% (Figure 4), and a similar increase was seen when E16 signal loss rose above 50% (Figure 5). Of 306 NIFECG traces, 200 (65.4%) had ≤ 60% E240 signal loss. Removing all traces with > 60% E240 signal loss, linear correlation of the remaining P-filtered eSTV values with cSTV was improved ($r = 0.785$, $P < 0.001$). A higher proportion (225/306 (73.5%)) of NIFECG traces had ≤ 50% E16 signal loss. Removing traces with > 50% E16 signal loss also resulted in higher STV correlation ($r = 0.683$, $P < 0.001$) than that noted with the full dataset, but lower than that in traces with ≤ 60% E240 signal loss. Accuracy and precision analysis is shown in Table 3.

Table 1 Maternal and fetal characteristics of 285 pregnancies that underwent fetal heart-rate monitoring

Characteristic	*Value*
Age (years)	32.0 (30.0–36.0)
Height (cm)	163.9 (160.0–169.0)
Weight (kg)	68.4 (60.2–81.6)
Body mass index (kg/m^2)	25.3 (22.6–29.5)
Ethnicity	
White	182 (63.9)
Black	34 (11.9)
Asian	51 (17.9)
Mixed/other	18 (6.3)
GA at presentation (weeks)	37 + 1 (34 + 5 to 39 + 3)
EFW centile	46.0 (25.0–67.0)
Small-for-gestational age	27 (9.5)
Hypertensive disorders of pregnancy	35 (12.3)
Diabetes mellitus	41 (14.4)

Data are given as median (interquartile range) or *n* (%). EFW, estimated fetal weight; GA, gestational age.

Table 2 Key outcome measures for 306 traces collected from 285 pregnancies using concurrent computerized cardiotocography (cCTG) and non-invasive fetal electrocardiography (NIFECG)

Outcome measure	*Value*
Monitoring duration (min)	60.0 (42.0–60.0)
STV	
cCTG (ms)*	9.9 (7.9–12.3)
NIFECG P-filtered (ms)†	10.7 (8.6–13.7)
NIFECG F-filtered (ms)‡	9.2 (7.6–11.4)
NIFECG signal loss	
E240 (%)§	34.0 (7.5–72.1)
E16 (%)¶	18.5 (2.1–52.9)

Data are given as median (interquartile range). *Short-term variation (STV) calculated in all 306 traces. †STV calculated in 301 partially (P) filtered traces. ‡STV calculated in 142 fully (F) filtered traces. §Defined as fetal heart rate (FHR) outliers (< 30 bpm or > 240 bpm) within a 0.25-s epoch. ¶Defined as 3.75-s epochs in which all FHR samples are outliers.

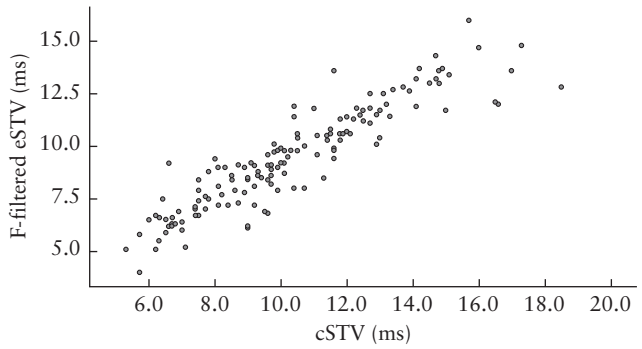

Figure 2 Scatterplot showing correlation between short-term variation obtained on fully (F) filtered non-invasive fetal electrocardiography (eSTV) and computerized cardiotocography (cSTV).

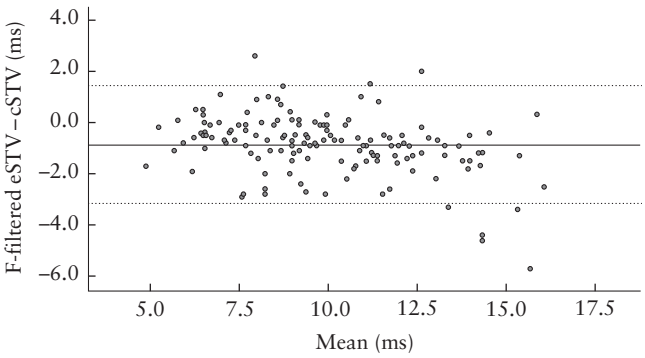

Figure 3 Bland–Altman plot showing agreement between short-term variation obtained on fully (F) filtered non-invasive fetal electrocardiography (eSTV) and computerized cardiotocography (cSTV). Mean difference (——) and 95% limits of agreement (·····) are displayed.

Table 3 Linear correlation of short-term variation obtained on non-invasive fetal electrocardiography (eSTV) by various methods of computation with short-term variation obtained on computerized cardiotocography

Parameter	*Traces with eSTV acquired (n (%))*	*Pearson's r coefficient*	P	*Mean bias (ms)*	*95% LoA (ms)*	*Precision (ms)*
P-filtered eSTV	301 (98.4)	0.337	< 0.001	1.57	−7.96 to 11.1	4.86
P-filtered eSTV with ≤ 60% E240 signal loss	200 (65.4)	0.785	< 0.001	0.05	−3.72 to 3.82	1.93
P-filtered eSTV with ≤ 60% E240 signal loss corrected	200 (65.4)	0.839	< 0.001	0.00	−3.22 to 3.22	1.64
P-filtered eSTV with ≤ 50% E16 signal loss	225 (73.5)	0.683	< 0.001	0.39	−4.34 to 5.12	2.42
P-filtered eSTV with ≤ 50% E16 signal loss corrected	225 (73.5)	0.748	< 0.001	0.00	−4.01 to 4.01	2.04
F-filtered eSTV	142 (46.4)	0.911	< 0.001	−0.86	−3.17 to 1.45	1.18

P-filtered traces are generated through partial filtering and F-filtered traces are generated through full filtering. E240 signal loss is defined as fetal heart rate (FHR) outliers (< 30 bpm or > 240 bpm) within a 0.25-s epoch and E16 signal loss is defined as 3.75-s epochs in which all FHR samples are outliers. Linear regression equations were used to correct eSTV for signal loss. LoA, limits of agreement.

Linear regression analysis using STV difference in the remaining P-filtered NIFECG traces as the dependent variable and signal loss as the independent variable was performed for both methods of signal-loss computation. Predicted STV differences were generated using regression equations in traces with ≤ 60% E240 signal loss ($r^2 = 0.272$, $P < 0.001$) and ≤ 50% E16 signal loss ($r^2 = 0.280$, $P < 0.001$). Corrected eSTV values were in turn formulated by subtracting the predicted differences from the original eSTV values. Linear correlation between corrected eSTV in traces with ≤ 60% E240 signal loss and cSTV ($r = 0.839$, $P < 0.001$) was stronger than that prior to correction. Similar findings were seen for the correlation between corrected eSTV in traces with ≤ 50% E16 signal loss and cSTV ($r = 0.748$, $P < 0.001$). Mean bias, precision and LoA were also improved following correction (Table 3).

The relationship between informative minutes and STV difference is shown in Figure 6. This shows that increasing the duration of monitoring, and hence increasing informative minutes, can reduce STV difference.

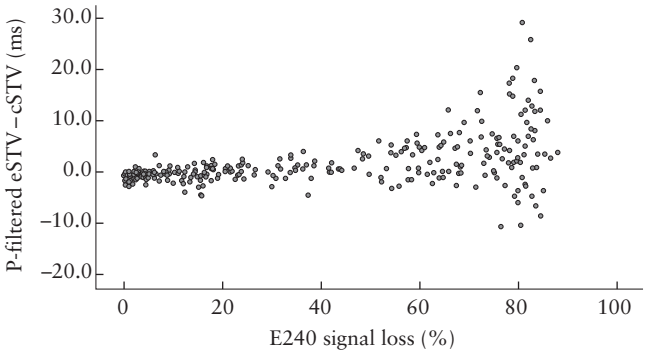

Figure 4 Scatterplot showing correlation between difference in short-term variation as determined by partially (P) filtered non-invasive fetal electrocardiography (eSTV) and computerized cardiotocography (cSTV) and E240 signal loss.

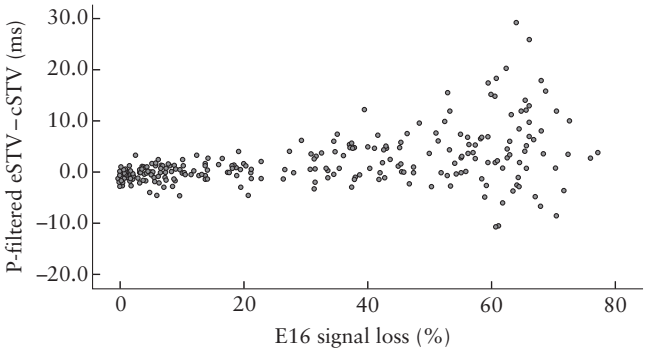

Figure 5 Scatterplot showing correlation between difference in short-term variation as determined by partially (P) filtered non-invasive fetal electrocardiography (eSTV) and computerized cardiotocography (cSTV) and E16 signal loss.

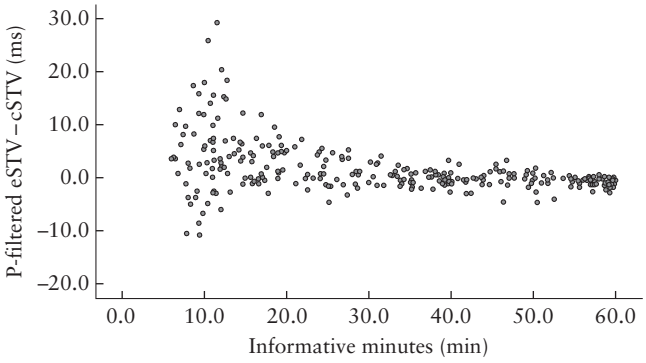

Figure 6 Scatterplot showing correlation between difference in short-term variation as determined by partially (P) filtered non-invasive fetal electrocardiography (eSTV) and computerized cardiotocography (cSTV) and informative minutes.

DISCUSSION

Summary of findings

This study found that STV correlation between NIFECG and cCTG was influenced significantly by methods of signal processing. Fully filtering NIFECG traces resulted in excellent correlation with cCTG but a lower yield of eSTV outputs, owing to rejection of a significant number of traces. Conversely, removal of filters led to a high eSTV yield from NIFECG but weak correlation with cSTV, as eSTV became increasingly discrepant from cSTV with increasing signal loss. Following the removal of poor-quality traces, correction for signal loss in the remaining NIFECG traces further improved the correlation, while also increasing eSTV yield relative to full filtration.

Comparison with the literature

Seliger *et al.*[12] evaluated STV correlation between Sonicaid cCTG (Huntleigh Healthcare Ltd) and Monica AN24 NIFECG (Monica Healthcare, Nottingham, UK) monitors in 26 pregnancies from 24 weeks' gestation. A threshold of > 50% signal loss was used to exclude traces unsuitable for analysis. Of 26 traces, 20 (76.9%) met the criteria for analysis, to which a similar filter was applied to remove 2-min windows containing > 50% signal loss. This led to a level of agreement comparable with that observed in the present study when filters were applied. The authors concluded that high-quality beat-to-beat signals are required to generate reliable data on FHR variability[12].

Another study compared STV derived from MONAKO (CTG) and KOMPOREL (NIFECG) systems using different computation methods in 67 term pregnancies[23]. Signal loss was defined as a FHR value of 0 bpm in a 0.25-s epoch, and traces with > 30% signal loss were excluded. A filter was also applied in which segments with > 80% signal loss were excluded. Multiple recordings were taken for each woman, and only the best were used for analysis. Very low signal loss of 1.8% was reported for NIFECG, after excluding seven women with uninterpretable traces. Despite filtering, postprocessed eSTV values were significantly higher compared with cSTV values, with a mean difference of 56%[23]. This is probably because of the definition of signal loss adopted, which meant that

spuriously high FHR values, probably caused by artifacts, were regarded as true FHR. Nonetheless, the authors concluded that NIFECG outputs were representative of true STV, while STV values were underestimated by CTG[23].

Limitations of signal processing

Although NIFECG has the potential advantage of producing data of superior temporal resolution with a high sampling frequency, it is also prone to artifacts and interference, giving rise to false fetal R-waves and thus fluctuations in FHR[12]. Low fetal signal-to-noise ratios resulting from poor conductivity through several fetal and maternal abdominal layers, in addition to artifacts from movement, conduction pathways and electrical surroundings, all play a role in limiting signal accuracy[17,18]. cCTG, on the other hand, is unable to sample at high frequencies, and therefore relies on autocorrelation to provide a more consistent rate[9,12]. The difference in technology will undoubtedly lead to discrepancies in the STV values generated.

In our dataset, high signal loss resulted in high eSTV values in our P-filtered traces, and hence greater STV differences between the two monitors. This shows that signal loss, defined as FHR outliers, creates discrepancy between epochs, thereby falsely increasing eSTV. By defining FHR outliers as < 30 bpm or > 240 bpm, in keeping with the definitions used by commercial monitor manufacturers, rates outside this range were considered not to represent true FHR[24,25]. To the best of our knowledge, the classification of outliers and the elimination process within the internal cCTG algorithm are not known. Although such outliers were not included in the epochal averaging of FHR, many FHR samples lay on the borders of the valid FHR range. The outlier filter removed trace time windows in which averaged FHR was found to be outside the expected range. Despite this step, many 30-s windows also lay on the borders of this range. Furthermore, by excluding outliers, very few data are left in traces with high signal loss with which to calculate eSTV, leading to additional discrepancies with cSTV.

Mitigating technical limitations and future research

Given the nature of NIFECG technology, eSTV should be generated only in high-quality traces ($\leq 60\%$ E240 signal loss), with a filtering method to eliminate outliers. As signal loss plays a major role in eSTV accuracy, mathematical correction for signal loss should also be considered. Although this raises the issue of no eSTV result being produced in poor-quality traces, a solution could be to prolong monitoring time. As NIFECG delivers no energy, extended monitoring can be performed safely; and as the aim of FHR monitoring is to establish the presence of an active fetal state, the detection of the latter within any period of time should be acceptable. The Dawes–Redman criteria use a minimum of 10 min of recording demonstrating normal FHR variability to indicate wellbeing[4,20]. A similar strategy could be used, in which normal eSTV obtained within any 10 min of high-quality signal may be accepted as confirmation of fetal wellbeing, regardless of the overall signal loss in the trace. Conversely, if more than 50 min of high-quality signal demonstrates low eSTV, it should be deemed a cause for concern[4,20].

Detailed analysis of signal quality, including the impact of fetal–maternal factors, has been described elsewhere[21]. Gestational age was associated negatively with signal loss (beta = −2.91 (95% CI, −3.69 to −2.12); $P < 0.001$), and a reduction in interference was observed upon changing the polymer spreader which attaches the electrodes ($P < 0.001$). Preliminary pilot data also suggest that signal acquisition outside the hospital environment results in less electrical noise/interference. Furthermore, in clinical use, application of the device at home on multiple occasions may allow improved signal acquisition. Further research into signal quality in the home environment together with device optimization will shed light on the potential utility of this technology.

Another method of fetal autonomic assessment is PRSA. This assesses quasiperiodic oscillations in non-stationary, noisy signals, thereby accounting for and eliminating artifacts as part of the signal-processing algorithm[26–28]. This method has been applied to both cCTG and NIFECG, and has shown possible superiority over STV in detecting evolving hypoxia[29]. PRSA may therefore be more appropriate for remote NIFECG monitoring, with less reliance on a high level of signal acquisition. Research comparing PRSA outputs from a self-applicable NIFECG monitor with those from cCTG should be performed to enable its use in clinical practice[22].

Conclusions

The systematic evaluation of eSTV acquisition using a self-applicable ambulatory NIFECG monitor has not only highlighted the potential utility of the device, but pinpointed the technical challenges that have to be overcome to permit clinical use. The discrepancy between STV computed by NIFECG and cCTG necessitates signal filtering, poor-quality trace exclusion and STV correction. The findings of this study indicate that, with such correction, the NIFECG device is able to produce eSTV values that are highly correlated with cSTV, and provide a rationale for thresholds used for trace exclusion. This study has established an evidence base for NIFECG monitoring and interpretation to facilitate the development of safe and effective at-home FHR monitoring strategies.

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