Review

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Antenatal Noninvasive Fetal Electrocardiography: A Literature Review

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Abstract

Fetal heart rate (FHR) monitoring is one of the central parts of obstetric care. Ultrasound-based technologies such as cardiotocography (CTG) remain the most common method for FHR monitoring. The CTG's limitations, including subjective interpretation, high interobserver variability, and the need for skilled professionals, led to the development of computerized CTG (cCTG). While cCTG demonstrated advantages, its superiority over visual interpretation remains inconclusive. This has prompted the exploration of alternatives like noninvasive fetal electrocardiography (NIFECG). This review explores the landscape of antenatal FHR monitoring and the need for remote FHR monitoring in a patient-centered care model. Additionally, FHR monitoring needs to evolve from the traditional approach to incorporate artificial intelligence and machine learning. The review underscores the importance of aligning fetal monitoring with modern healthcare, leveraging artificial intelligence algorithms for accurate assessments, and enhancing patient engagement. The physiology of FHR variability (FHRV) is explained emphasizing its significance in assessing fetal well-being. Other measures of FHRV and their relevance are described. It delves into the promising realm of NIFECG, detailing its history and recent technological advancements. The potential advantages of NIFECG are objective FHR assessment, beat-to-beat variability, patient comfort, remote prolonged use, and less signal loss with increased maternal body mass index. Despite its promise, challenges such as signal loss must be addressed. The clinical application of NIFECG, its correlation with cCTG measures, and ongoing technological advancements are discussed. In conclusion, this review explores the evolution of antenatal FHR monitoring, emphasizing the potential of NIFECG in providing reliable, home-based monitoring solutions. Future research directions are outlined, urging longitudinal studies and evidence generation to establish NIFECG's role in enhancing fetal well-being assessments during pregnancy.

Keywords: Ambulatory monitoring; Noninvasive fetal electrocardiography; Fetal heart-rate monitoring; Fetal heart rate variability

Introduction

Fetal heart rate (FHR) monitoring is a fundamental component of obstetric care,[1] guiding clinical decisions for antenatal interventions, timing of delivery, and intrapartum fetal surveillance.[2] The first documented FHR detection was in the 17th century and was undertaken by placing the ear directly to the mother's abdomen.[3,4] Fetal electrocardiogram (fECG) was first described by Cremner in 1906. However, challenges related to signal acquisition noninvasively and loss led to the adoption of cardiotocography (CTG) as the main method for FHR monitoring starting in the 1970s.[5] When CTG did not demonstrate a significant reduction in perinatal mortality and morbidity, interest in antenatal fetal ECG analysis was renewed.[2] Noninvasive fetal ECG (NIFECG) recorded through abdominal electrodes has seen an increasing body of research due to the advances made in signal processing and filtering techniques.[6] The recent COVID-19 pandemic highlighted the necessity for innovative, remote patient-friendly devices that allow for home monitoring of fetuses and enable clinicians to intervene and review results, thereby improving care for women with complex pregnancies.[7] NIFECG is the most promising technology for home antenatal fetal monitoring.

Over the last century, healthcare has undergone significant transformations, shifting from a physician-centric to a patient-centered and individualized care model.[8] Hathaliya *et al.*[8] describe four different phases in healthcare evolution, which are applicable to the advancements in fetal monitoring as illustrated in Figure 1.

Currently, FHR monitoring technology remains in the Healthcare 3.0 stage and has yet to advance to Healthcare 4.0. The COVID-19 pandemic highlighted the need to develop telemedicine and home-based remote monitoring solutions to ensure the safety and continuous engagement of women in their prenatal care. In the era of artificial intelligence (AI), it seems improbable that we would continue to rely on pattern recognition through visual interpretation rather than on computerized numerical measurements to establish reference standards for normality.

Fetal monitoring needs to align itself with the modernization and technological advances seen in the broader healthcare sector, particularly through the integration of AI and machine learning. The inclusion of AI algorithms into fetal ultrasound has demonstrated significant potential benefits, including the precise assessment of gestational age, fetal growth, and the detection of anomalies. The adoption of personal

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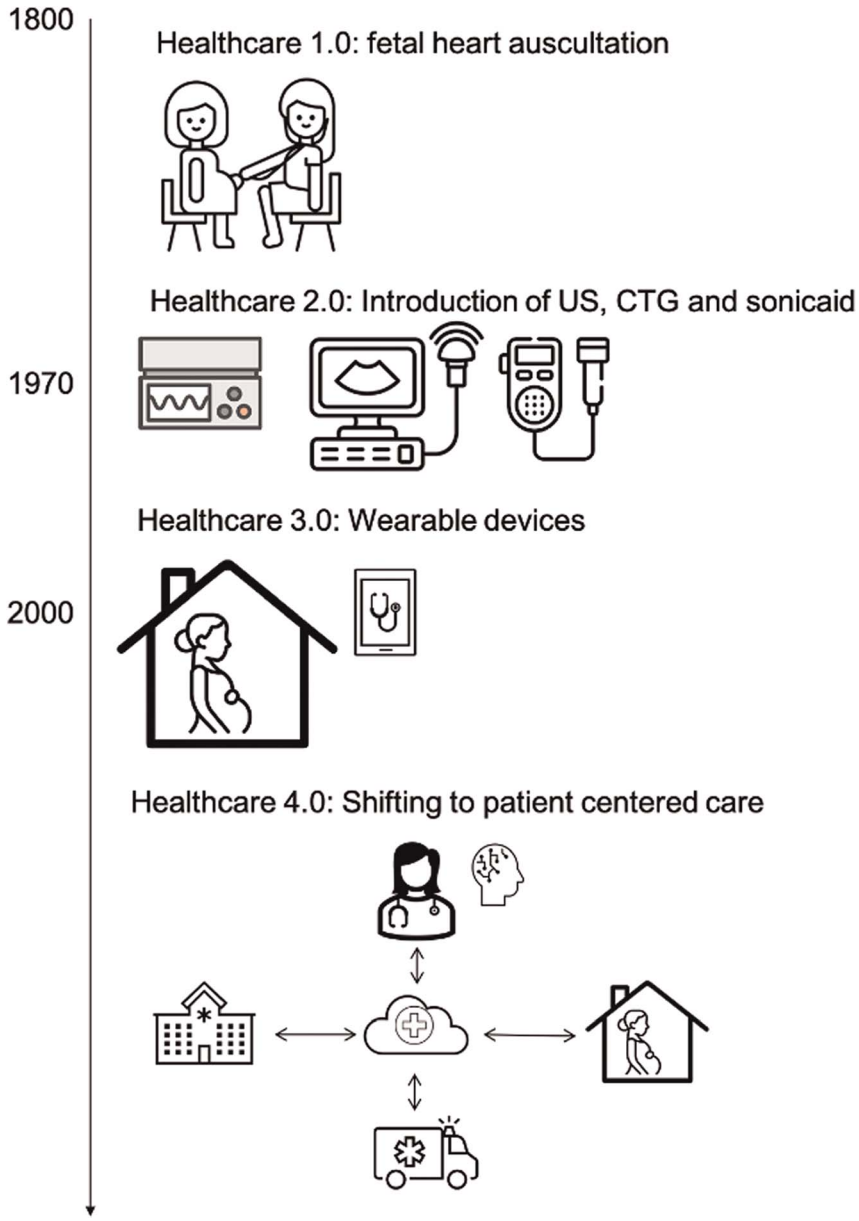


Figure 1. Timeline of major developments in healthcare and fetal monitoring. Icons from flaticon.com. Adapted from Pregnancy in the time of COVID-19: towards Fetal monitoring 4.0. BMC Pregnancy Childbirth 2023;23(1):33. doi: 10.1186/s12884-023-05349-3. © 2023 is licensed under CC BY 4.0. To view a copy of this license, visit https://creativecommons.org/licenses/by/4.0/

computer and smartphone-based applications has facilitated the introduction of safe and cost-effective remote monitoring solutions for the management of gestational diabetes and hypertension.[9,10] These tools not only engage women in their care by informing them when professional intervention is necessary, but they also provide context-specific decision support to healthcare professionals.[10]

Fetal heart rate variability

Physiology of fetal heart rate variability

Understanding FHR patterns is a key part of antenatal fetal monitoring to recognize behavioral states indicative of conditions such as hypoxia.[11] A thorough understanding of the mechanisms controlling FHR is therefore essential.[12] As depicted in Figure 2 the parasympathetic nervous system (PNS) and sympathetic nervous system (SNS) activity influence the HR baseline: the PNS slows the HR and the SNS increases it. As the PNS and SNS interact, the FHR constantly accelerates and decelerates. The baseline is therefore not a straight line and has obvious oscillations. The bandwidth of these oscillations is termed FHR variability (FHRV).[13] The parasympathetic branch of the autonomic nervous system (ANS) has been evidenced to develop more slowly than the sympathetic system. This difference is thought to be responsible for the gradual reduction of basal FHR with advancing gestation. [14]

It is well established that heart rate variability (HRV) is a marker for ANS function in adults[15] and is significantly

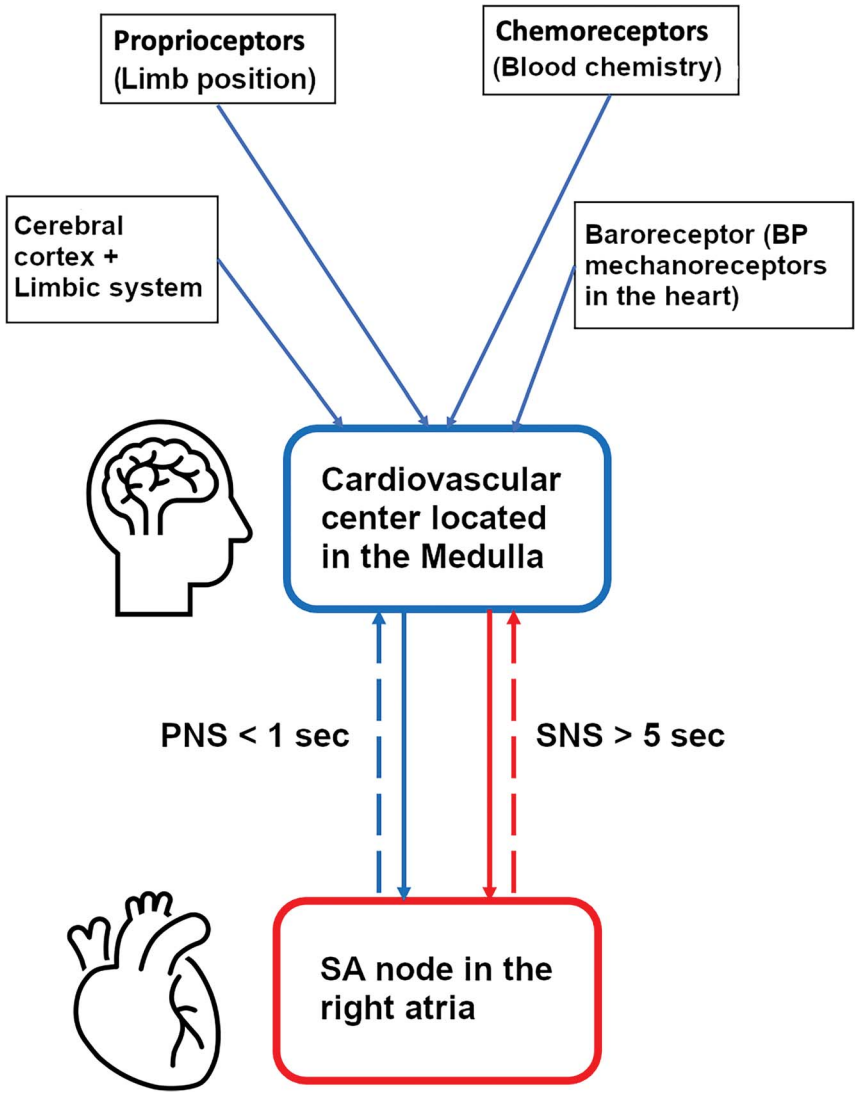


Figure 2. Regulation of heart rate variability. The heart has its intrinsic neurological system. The parasympathetic (vagal nerve) and sympathetic nervous system influence heart rate variability. Chemoreceptors, baroreceptors, proprioceptors, and the cerebral cortex govern this interaction. BP: Blood pressure; PNS: Parasympathetic nervous system; SNS: Sympathetic nervous system; SA node: Sinoatrial node.

reduced in patients with cardiac transplantation, indicating diminished autonomic function.[16] Similarly, in the fetus, FHRV is utilized to assess the functionality of the fetal ANS.[11]

Fetuses display two primary behavioral states (quiet and active sleep) that are distinguishable by specific heart rate patterns.[11,17] At term, the healthy fetus is expected to move between these states between 1 and 3 times an hour.[11] During active sleep, characterized by accelerations, fetal movements, and episodes of high variation, these features are typically interpreted as signs of fetal well-being.[17] Conversely, quiet sleep is marked by minimal fetal movements and reduced fetal HRV, which are also observed in compromised fetuses.[11] Distinguishing between these states based solely on FHRV can be challenging, with prolonged periods of low FHRV (over 50 minutes) often indicating potential pathology.[18] Particularly in pregnancies affected by fetal growth restriction (FGR), low FHRV is frequently associated with fetal metabolic acidosis due to hypoxemia.[11,19–21] The regulation of FHRV is governed by complex interactions among the ANS, blood pressure, gas exchange, cardiac function and vascular tone. Unlike many physiological processes described by homeostasis, the heart rate does not exhibit regularity.[22] Indeed, a low HRV is generally associated with pathology, and the complexity of this system often reflects the overall good health of the fetus.[23]

As FHR decreases with gestation, there is an increase in variability due to a rise in the interbeat interval.[24] This change correlates with the development of the autonomic system, which leads to more organized and predictable FHR patterns associated with different fetal behavioral states. Specific adaptation time points in the second half of pregnancy correspond to changes in FHRV.[25] Between 26 and 32 weeks, fetal cycles of activity and rest become more discernible,[25–27] with increased synchronization (up to 80%) of fetal body and eye movements with the FHRV

indices observed around 30–32 weeks.[25,28] Toward term, two further discernible FHR patterns appear: respiratory sinus arrythmia, associated with thoracic movement, and accelerations that coincide with fetal activity.[25]

Furthermore, factors such as maternal exercise,[29] maternal stress, and the use of opiate-based medications directly influence FHRV.[30] The first two are related to the catecholamine release in the mother which is thought to cross the placenta and therefore lead to increased variability.[31]

From biology to pathophysiology

The fetus adapts to cope with hypoxia.[12] The placental structure incorporates maternal lakes to increase the maternal oxygen supply. Fetal hemoglobin (Hb) has a higher affinity for oxygen, and the Hb concentration in the fetus is higher compared to adults.[1] Furthermore, fetuses have a highly efficient catecholamine-releasing system, enabling a rapid increase in HR through the release of adrenaline and noradrenaline. External stressors such as infections or drugs, as well as conduction abnormalities, like supraventricular tachycardia, can also elevate the FHR. Chronic hypoxemia, often resulting from placental dysfunction, reduces the volume of oxygenated blood returning to the fetus, triggering an adrenergic reaction that increases catecholamine release, thereby exerting an inotropic effect on the heart and enhancing the cardiac output through the umbilical arteries.[32] This reaction leads to centralization and avoids anaerobic metabolism, which produces lactic acidosis in the central organs: the heart, the brain, and the adrenals, while causing vasoconstriction in nonvital organs like the kidneys, gut, lungs, and limbs. This can present as a reduction in somatic (fetal) movements to conserve energy.[1]

Fetuses experiencing chronic hypoxia due to placental insufficiency are more likely to have a baseline FHR at the upper limit for their gestational age with reduced FHRV.[32] Reduced variability in intrauterine growth restriction (IUGR) pregnancies is speculated to stem from delayed maturation of the autonomic system in such pathologies. In animal models (sheep), partial embolization of the placenta stimulates placental insufficiency. Initially, HRV increases for nearly 24 hours but then stabilizes after a few days. Short-term variability (STV) and long-term variability (LTV) remain markedly reduced for the rest of the experiment (from 48 hours to 21 days).[33] In summary, baseline FHRV is the most consistent predictor of fetal well-being. In fetuses that maintain normal FHRV in the presence of decelerations, the risk of acidemia is very low. On the other hand, reduced variability is the strongest and most consistent predictor of neonatal acidemia.[34,35]

Measurement of heart rate variability

FHRV can be measured using time domains, frequency domains, or nonlinear domains as described in Table 1. Computerized CTG (cCTG) criteria,[36,42,43] employ computers to capture data from fetal monitors at 100 ms intervals using auto-correlation to estimate the accuracy of FHR, which is further checked by an error algorithm method. Pulse intervals are averaged every 3.75 seconds, which enables the baseline HR to be fitted. cCTG measures signal loss as the percentage of 3.75 ms epochs without any valid pulse intervals.[36] Cutoffs have been set to discern episodes of high and low variation, defined as a minute range exceeding 32 ms or falling below 30 ms, observable in at least five out of six consecutive minutes.

Current antenatal fetal heart rate monitoring

Cardiotocography

CTG uses a Doppler ultrasound transducer to monitor the FHR and a tocodynamometer for uterine activity. CTG received an enthusiastic welcome to obstetric care as early as the 1960s but, unfortunately, it lacked rigorous testing and validation before its clinical adoption. Despite initial optimism, it was apparent that perinatal mortality and morbidity did not reduce as anticipated.[2]

The principle of antenatal CTG relies on an appropriate FHR for gestational age and the presence of accelerations which are thought to be in response to fetal movements. FHR pattern interpretation from CTG traces is subjective and various systems have been developed to describe and categorize these traces to aid clinical decision making.[1] However, CTG is known for its high interobserver variability, and doubts remain as to its accuracy and reproducibility as a clinical test.[44]

Despite these challenges (Table 2), CTG is still widely used to assess fetal well-being in the antenatal and intrapartum periods.[2] Practically, CTGs are relatively expensive hospital-based devices to enable point-of-care assessment, requiring skilled healthcare professionals to apply the transducers and interpret the FHR traces visually. Furthermore, the acquisition of FHR signals by CTGs can be more difficult at earlier gestations, with increasing maternal body mass index (BMI) and during fetal movement.[45]

Computerized cardiotocography

cCTG was developed by Dawes and Redman in the early 1980s.[42,43] A computer algorithm enabled standardized interpretation of FHR patterns. It produced numerical values that measure FHR fluctuations that are not interpretable by the naked eye such as STV and LTV (Figure 3).[42]

Apart from eliminating interpreter bias, multiple cCTG indices have been shown to be correlated to fetal hypoxemia and adverse perinatal outcomes.[46] The TRUFFLE study, focusing on early FGR, employed both Doppler ultrasound waveforms of the ductus venosus and cCTG STV to determine the timing for delivery in FGR cases diagnosed before 32 weeks of gestation. The established thresholds are now in common use across the UK and Europe in the management of early-onset FGR pregnancies.[18] The main advantages of cCTG include reducing interobserver and intraobserver variability, thereby offering objective FHR assessments. It has been validated for use in FGR pregnancies and has been shown to shorten the duration of monitoring.[47] However, access to cCTG is limited, as it is not available in all countries or maternity units.[18] Like its noncomputerized counterpart, CTG requires the professional handling of transducers within a hospital setting.

Although the superiority of cCTG over visual interpretation in reducing perinatal mortality remains unproven,[48,49] initial findings from a 2015 Cochrane review stated that cCTG was more effective at predicting perinatal morbidity compared to visual CTG interpretation.[2] However, evidence from this review relies on two randomized controlled trials with less than 500 patients in total.[50,51] One study erroneously included four additional cases of perinatal mortality related to congenital anomalies. A more recent meta-analysis by Baker *et al.*[48] reported a nonsignificant reduction in perinatal mortality. Given the rare occurrence of perinatal

Table 1

Heart rate variability measures: Definitions and clinical relevance.

HRV	Definition	Clinical relevance in adults	Clinical relevance in fetuses
STV (ms)*	Mean variation of pulse interval epoch-to-epoch. Decelerations are excluded in the STV calculation.	Not used.	Best known indicator for fetal hypoxemia/acidosis (If the STV falls below 2.6 ms it is highly associated with fetal acidemia.[36])
LTV (ms)*	Minute range: difference between the highest and lowest value within that minute which is then averaged over the whole trace.	Not used.	LTV is validated against umbilical cord pH. STV and LTV are usually very closely correlated ($r = 0.91$) except in traces with sinusoidal features.[36]
SDNN (ms)†	Heart beats that occur outside of the SA node or are out of range are excluded. Lost or ectopic beats cause artificially long or short RR intervals which can falsely increase the SDNN.[37]	Gold standard for stratification of cardiac risk. SDNN >100 ms is associated with a five-times lower mortality risk than <50 ms.	Not used.
RMSSD (ms)†	Successive differences in R-R intervals are squared, then averaged before the square root is obtained.	A measure of respiratory sinus arrhythmia. Low RMSSD associated with a higher risk of sudden death in epilepsy.[38]	Not used.
HF (ms^2)‡	0.15–0.40 Hz (Requiring a recording of at least 1-minute)	Represents respiratory sinus arrhythmia.	Not used.
LF (ms^2)‡	0.04–0.15 Hz (Requiring a minimum of a 2-minute recording)	Reflects both the parasympathetic and the sympathetic nervous system.	Not used.
VLF (ms^2)‡	0.0033–0.0400 Hz (Requiring a minimum of 5-minute recording)	Strongest association with all-cause mortality compared to other frequency bands.[39]	Not used.
ULF (ms^2)‡	<0.003 Hz (Requiring a 24-hour recording)	Most likely driven by the circadian rhythm.[23]	Not used.
PRSA (ms)§	Crudely compared to complimentary halves of the STV as it separates the variability into the 'acceleration capacity' and the 'deceleration capacity'.	Best predictor for mortality after a myocardial infarct.[40]	Using PRSA could potentially be a better predictor for fetal deterioration compared to STV which is currently in use.[41]

*Computerized cardiotocography HRV measures.

†Time domains.

‡The frequency domains.

§Nonlinear HRV measures.

HF: High frequency; HRV: Heart rate variability; Hz: Hertz; LF: Low frequency; LTV: Long-term variation; ms: Milliseconds; ms^2: Milliseconds squared; pH: Potential of hydrogen (indicating acidity or basicity); PRSA: Phase-rectified signal averaging; ULF: Ultra-low frequency; VLF: Very low frequency; r: correlation coefficient; RMSSD: Root mean square of successive differences in heart rate; RR: R peak-R peak; SA: Sinoatrial; SDNN: Standard deviation of the inter-beat interval of normal sinus beats; STV: Short-term variation.

Table 2

Benefits and limitations of antenatal fetal heart rate monitoring techniques.

FHR monitoring method	Benefit	Limitation	Remote use
CTG	• Readily available	• Highly subjective nature of visual interpretation • Professional interpretation required for healthcare • Potential for mother/fetal HR confusion • Signal strength negatively correlated with BMI	No
cCTG	• Computer algorithm • Validated • Reproducible • Objective	• Not available in all units • Only validated for antepartum • Potential for mother/fetal HR confusion • Signal strength negatively correlated with BMI	No
NIFECG	• True beat to beat variability • Safe for extended use of time • Potential for morphology and rhythm analysis • Objective analysis • Not affected by maternal BMI	• Gestation-dependent variability in signal acquisition	Yes
PCG	• Detecting extra heart sounds such as heart murmurs. • As an extra screening tool for congenital heart defects.	• Negatively correlated to maternal BMI	Yes
MCG	• High accuracy for beat-to-beat variability • Allows morphological analysis of the fetal heart	• Requiring a magnetically shielded room • Cost	NA

BMI: Body mass index; CTG: Cardiotocography; cCTG: Computerized CTG; HR: Heart rate; MCG: Magnetocardiography; NA: Not applicable; NIFECG: Noninvasive fetal electrocardiography; PCG: Phonocardiography.

mortality in clinical trials, these studies were likely underpowered to detect a significant decrease in perinatal death. Despite the latter, cCTG use resulted in an 87% reduction in perinatal mortality (relative risk: 0.23, 95% confidence interval: 0.04–1.30), justifying the continued investigation of cCTG use in both high- and low-risk pregnancies.[48]

The use of CTG Doppler technology is only recommended for medical indications and for the minimal time required—despite no direct adverse effects ever being documented.[52] For long-term prolonged home exposure, other forms of FHR monitoring are preferred such as NIFECG or phonocardiography. The advantages and disadvantages of current methods of antenatal fetal monitoring are summarized in Table 2.

Fetal electrocardiography

Fetal electrocardiography (fECG) records the electrical activity of the fetal heart. Invasive fECG is recorded using a fetal scalp electrode, which is attached to the fetal scalp through the cervix.[53] NIFECG is one of the most promising methods of FHR monitoring in the past few years.[54] Despite some devices being marketed for use, it is not commonly used in a clinical setting.

Noninvasive fetal electrocardiography

In NIFECG, electrodes are placed on the maternal abdomen, and sometimes the chest, to capture electric signals. The signal received is amplified, denoised, and enhanced. The maternal and fetal signals are superimposed: the fetal cardiac signal is indirect, and the size of the fetal heart is much smaller than that of the mother. Given that the maternal electrical signals are approximately 10 times stronger than those of the fetus, and that additional sources of electrical noise from maternal muscle activity, uterine contractions, and external electrical interference can further complicate signal clarity, rigorous denoising and maintaining an adequate signal-to-noise ratio are critical for accurately detecting fetal ECG R-peaks.[55]

The electrical signals are conducted through multiple feto-maternal interfaces including the amniotic fluid, fetal membranes, placenta, uterus, maternal peritoneal cavity, abdominal muscles, rectus sheath, subcutaneous fat, and skin.[54] It is possible to electronically subtract the maternal signal from the combined signal, thus leaving only the fetal signal for further analysis (Figure 4).[54]

Additionally, NIFECG is capable of recording uterine activity through electromyography. This can be compared to the tocodynamometer of the CTG measuring the length and the intensity of the uterine contractions with reported improved accuracy compared to the CTG.[56] Currently, a variety of types of NIFECG equipment, which have received regulatory approval for diverse gestational applications, are available for both clinical and research purposes (Table 3).[7,54]

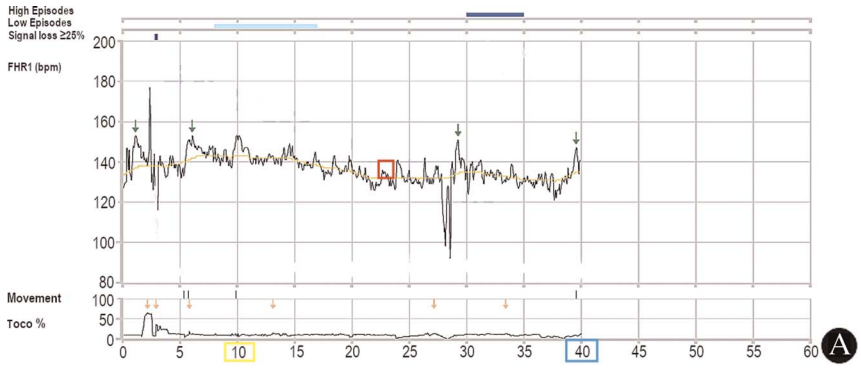
Advantages of noninvasive fetal electrocardiography

Signal acquisition

Signal acquisition with NIFECG is not affected by BMI, as demonstrated using the Femom device by BIORITHM in the study by Liu *et al.*[57] They showed that, unlike cCTG, NIFECG signal loss is unaffected by maternal BMI. Additionally, Graatsma *et al.*[58] conducted overnight NIFECG both at home and in the hospital, confirming that maternal BMI does not impact signal acquisition. One of the major challenges in obstetrics has been the rising incidence of obesity complicating fetal monitoring. NIFECG could offer a reliable alternative in cases where CTG fails to adequately monitor the fetus. Moreover, Liu *et al.*[57] also found that signal acquisition is also unaffected by fetal position, and other maternal characteristics such as body hair, or placental position. Another major benefit of NIFECG in signal acquisition is its capability to distinguish maternal heart rate from FHR, reducing the risk of confusion between the two.

Potential for remote monitoring

NIFECG is one of the few options that currently exists for home monitoring. Devices like INVU, Femom, Nemo



Dawes-Redman criteria for FHR1 first MET at 36 minutes, and MET at 40 minutes

Signal loss (%)	0.5	
Contractions	6	
Fetal movements (per hour)	6	*
Moves per min high	0.0	
Moves per min low	0.1	
Basal Heart Rate (bpm)	143	
Accelerations > 10 (bpm)	4	
All decelerations	1	
Significant decelerations >20 (lost beats)	0	
Area of largest deceleration (lost beats)	16	
Minor decelerations <=20 (lost beats)	1	
High episodes (mins)	6	
At 30 weeks gestation 6.16% of normal fetuses have less variation		
Low episodes (mins)	10	
STV overall (ms)	6.7	

B

Figure 3. Example of computerized CTG from Huntleigh Fetal Care. A Each minute is divided into 16 epochs of 3.75 ms each. Patient consent was obtained for reproducing this image. The FHR is averaged over each epoch and displayed in bpm. The red rectangle highlights the division of each minute into epochs. The yellow rectangle indicates the first analysis at 10 minutes, marking the minimum monitoring period. The blue rectangle shows that the recording can be stopped once criteria are met, here at 40 minutes. Green arrows denote accelerations, while orange arrows indicate uterine contractions. The light blue solid rectangle marks episodes of low variation, and the dark blue solid rectangle marks episodes of high variation. B The Dawes-Redman report displays variables and their units in the left column, with corresponding results in the right column (asterisk indicates analysis only includes maternally reported movements). CTG: Cardiotocography; FHR: Fetal heart rate; bpm: Beats per minute; FHR1: Fetal heart rate 1 (singleton); MET: Criteria met (appears as 'NOT MET' if criteria are not met); STV: Short-term variation; ms: Milliseconds; Toco %: Tocodynamometer.

Remote, and Avalon beltless are all designed to facilitate home monitoring.[59] Being a passive method for detecting fetal heart signals, NIFECG poses no safety risks, making it suitable for long-term monitoring overnight or for a prolonged time. Its electrodes are easily self-applied consistently in the same position and do not rely on fetal position, enhancing the feasibility of remote monitoring.

Enabling home monitoring could also be pivotal in offering women with complicated pregnancies, the possibility for closer monitoring, which could potentially be under the control of the patients. Currently, women with severe IUGR are monitored three times weekly. However, a reanalysis of the TRUFFLE data suggested that this frequency was insufficient and that more frequent monitoring could potentially reduce adverse outcomes.[60,61]

The benefit of having a more reliable heart rate variability analysis

Using R peak-R peak intervals to measure HR is one of the major breakthroughs for FHRV. Beat-to-beat variability is one of the main areas of research interest in adult cardiology. In the fetus, it is indicative of autonomic neural function, serving as a proxy for determining fetal oxygenation status. NIFECG allows for accurate analysis of true beat-to-beat variability, potentially advancing FHR analysis toward more extensive and objective measures. This could enhance smart telemedicine, providing caregivers and patients with precise tools and control in their care and that of their pregnancy. However, the superiority of this is yet to be proven.

Phase-rectified signal averaging (PRSA) is a relatively new technique that is particularly suited for the analysis of non-stationary signals. It can work despite the presence of electrical noise and detects quasi-periodicities (patterns which repeat themselves with an element of unpredictability) with a higher association with worsening of placental insufficiency. This was shown in the recent secondary analysis of the TRUFFLE data, where PRSA average acceleration capacity was shown to alter significantly earlier than the STV. This is potentially a better marker for fetal hypoxia and worsening placental insufficiency. PRSA was shown

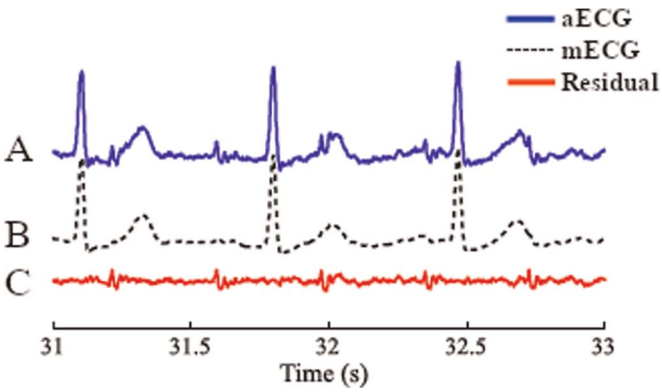


Figure 4. Kalman Filtering. A The abdominal ECG displaying both maternal and fetal ECG signals. B The maternal ECG component isolated from the abdominal ECG. C The residual signal after removing the maternal ECG, representing the fetal ECG with very low amplitude compared to the maternal ECG. aECG: Abdominal electrocardiogram; mECG: Maternal electrocardiogram; ECG: Electrocardiogram. Adapted from A review of signal processing techniques for non-invasive fetal electrocardiography. IEEE Rev Biomed Eng 2020;13:51–73. doi: 10.1109/RBME.2019.2938061. © 2020 is licensed under CC BY 4.0. To view a copy of this license, visit https://creativecommons.org/licenses/by/4.0/

to be a more sensitive parameter to distinguish between IUGR and normally grown fetuses when used in CTG.[62]

Fetal arrhythmias are currently only monitored through fetal echocardiography, but again NIFECG could be a promising new field for babies with heart block or supraventricular tachycardias diagnosed in utero. This would enable prenatal diagnosis and management of these cases if the signal acquisition is acceptable. Preliminary data, including findings by Behar *et al.*, indicate that NIFECG corresponds perfectly with echocardiography in diagnosing fetal cardiac arrhythmias, although one case was misclassified.[55,63]

Comfort for patients

Qualitative research indicates that NIFECG devices may be more acceptable to women compared to CTG for women in labor.[64,65] A systematic review of women using NIFECG and CTG in labor or antenatally suggests that fetal monitoring with NIFECG could be more acceptable to women for long periods of monitoring such as during induction.[66]

Disadvantages of noninvasive fetal electrocardiography

Signal loss

Currently, the inability to obtain a reliable fetal heart signal is the major drawback of NIFECG. This challenge is primarily due to the low amplitude of the fetal ECG compared to the maternal and general electrical noise captured by the device, resulting in larger signal loss than observed in cCTG. There are a multitude of factors that affect this phenomenon, and one of the larger studies observing the use of NIFECG in the antenatal period confirmed that signal loss is associated with gestation.[66,67] This study reports the relationship of gestation and signal loss as linear; however, other studies have shown that although there is a good level of signal acquisition toward the end of the second trimester, the principal time of signal loss is 26–34 weeks of gestation. This coincides with the presence of the vernix caseosa, which is hypothesized to decrease signal conductance.[68]

Unfortunately, there is a lack of standardization in defining signal loss in NIFECG. Different studies and different devices have used a variety of ways to define and measure signal loss. An FHR of <30 bpm or over 240-bpm is considered as a false reading due to the underdetection of fetal R-peaks or the erroneous overdetection of fetal R-peaks. Regarding the cCTG, signal loss is defined as the percentage of 3.75 second epochs in which the HR lies outside of the 30 and 240 bpm intervals.[43] A recent systematic review illustrated the difference in signal acceptance thresholds over different studies exploring the use of NIFECG.[67] This can vary from >34% of a trace being acceptable to >80% of being accepted as an interpretable trace.[66]

Increased anxiety

Remote FHR monitoring could be more acceptable to women due to increased control over monitoring and the ability to do this in their home setting. There is, however, a potential to bring increasing levels of anxiety if there are any problems with the technology. Brown *et al.*[69] estimated that nearly 65% of clinicians had concerns regarding

Table 3

Summary table of NIFECG devices with CE marking and those in development.

Name	Country	Technology	Gestation	Hardware/sampling rate	Remote use	Regulatory approvals
Avalon-Beltless	Netherlands	NIFECG	>37 weeks (intrapartum use)	4 electrodes	No	TGA for clinical use and CE marked
Femom	Singapore	NIFECG	>26 weeks	5 electrodes 500 Hz	Yes	None
Nemo Fetal Monitoring System	Netherlands	NIFECG	>21 weeks	6 electrodes 500–1000 Hz	Yes (Nemo Remote)	FDA cleared and CE marked
Meridian M110	United States	NIFECG	>37 weeks (intrapartum use)	>6 electrodes	No	FDA cleared
Novii	United States	NIFECG	>37 weeks (intrapartum use)	Previous Monica an24, 5 electrodes	Yes	FDA cleared and CE marked
Invu Cares	United States	NIFECG and fPCG	>32 weeks	4 electrodes and 1 fPCG	Yes	FDA cleared

CE: European Conformity; FDA: Food and Drug Association; fPCG; Fetal phonocardiography; Hz: Hertz; NIFECG: Noninvasive fetal electrocardiography; TGA: Therapeutic Goods Association.

maternal anxiety with continuous fetal monitoring at home. Crawford *et al.*[70] found that this was most likely an overestimation and that from the limited data available women preferred NIFECG to CTG and welcomed home monitoring.

Clinical application of noninvasive fetal electrocardiography

Technology in use

Despite NIFECG not routinely being used clinically, it has gained a huge amount of interest in the last few years. As mentioned, a multitude of devices have been developed and have been approved for use by the FDA and reached CE marking. In 2021, clinicians in Denmark started using the NEMO antenatal fetal ECG monitoring system remotely with patients.[71] Mostly at present, NIFECG is used to provide an FHR trace with visual interpretation. FHR obtained by NIFECG devices (to Femom, INVU, Novii, and Nemo) has been highly correlated to FHR obtained with CTG obtained using the conventional Doppler technology.[57,59] Despite signal loss being an issue across all NIFEG systems, Nemo reports a reliable FHR > 95% of the time with intrapartum use.[72] There has been a push in the last 10 years to make fetal ECG a reality in the clinical setting. The creation of large datasets of fetal ECG is one of the steps that has been taken to improve signal extraction and processing in the bioengineering world. This can enable the sharing of resources.

Interpretation of the signal

Measures of HRV with different NIFECG are highly correlated to those measured by conventional cCTG. STV calculated with Femom has been shown to be highly correlated to cCTG in a hospital-based on over 300 women in the UK[73] (Figure 5).

In the same cohort of patients, PRSA average acceleration capacity was found to be highly correlated to the STV measured on concomitant CTG monitoring.[74] Bester *et al.*[75] explored the Nemo monitor in 2021 using PRSA, observing changes in the AC and DC reference ranges throughout gestation. Stampalija *et al.* (2015), using the Monica monitor in 2014, employed PRSA and noted lower AC/DC values in FGR compared to normally grown fetuses, particularly in severe preterm cases.[76] van Laar *et al.*[77] conducted spectral analysis on the Nemo monitor, revealing an increase in absolute high-frequency and low-frequency power up to 30 weeks of gestation.

Incorporating AI analysis into FHR monitoring may further improve antenatal care.[78] Further work is needed to develop more intelligent algorithms to monitor pregnancies prior to the development of severe complications.[79] As done with DR in Computerized CTG, more precise HRV indices could lead to more information on the well-being of the fetus. With advances in machine learning, NIFECG offers a wearable, safe option for pregnant women with objective FHRV measures.

Conclusion

Antenatal fetal monitoring is widely used in clinical practice in many countries, particularly in Europe, even though unequivocal clinical evidence for its benefit is lacking. The computerized analysis of CTG recordings uses objective measures such as STV, which has established thresholds for intervention for pregnancies affected with FGR.[60] Further analysis of the TRUFFLE data suggests that PRSA, a novel measure of HRV which, by nature cancels the noise seen in an FHR trace, could be a better predictor of fetal compromise in FGR.[80] An increase in the frequency of monitoring of these pregnancies may improve outcomes in severe fetal growth restriction.

Doppler-based CTG is not suitable for prolonged repetitive home monitoring. By its nature, it also does not record true beat-to-beat variability or ECG morphology. NIFECG can do both, but the technology is still developing. FHR

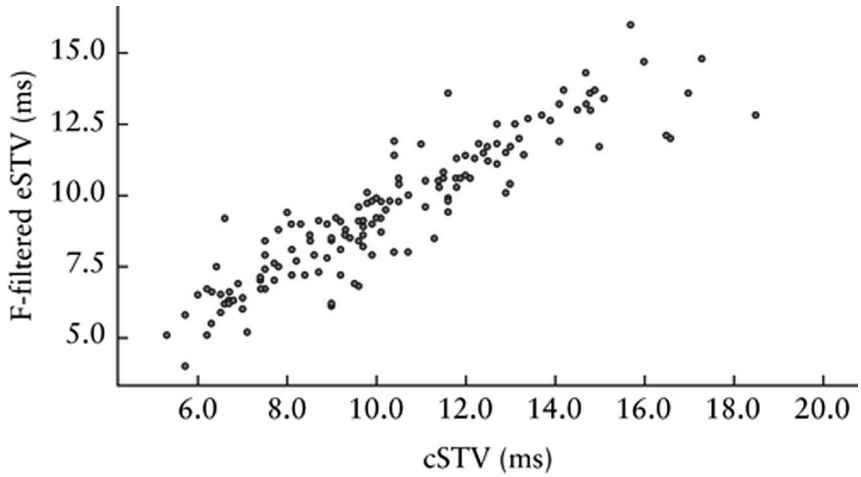


Figure 5. The scatter plot showing the correlation of eSTV (NIFECG STV) obtained through NIFECG using the Femom monitor (filtered) and cSTV obtained from computerized CTG using the Huntleigh machine. F-filtered: Fully filtered; CTG: Cardiotocography; cSTV: computerized short-term variation; ms: Milliseconds; NIFECG: Noninvasive fetal electrocardiogram; STV: Short-term variation. Adapted from Correlation of short-term variation derived from novel ambulatory fetal electrocardiography monitor with computerized cardiotocography by B. Liu, B. Thilaganathan, A. Bhide. © 2023 is licensed under CC BY 4.0. To view a copy of this license, visit https://creativecommons.org/licenses/by/4.0/

obtained using CTG and NIFECG is highly correlated. Other variability parameters such as STV and PRSA data acquired using NIFECG and CTG are also correlated. Signal loss remains one of the major issues for NIFECG, especially around the period of the vernix (28–34 weeks). Further work is needed to establish if women can use NIFECG remotely to obtain valid measures of FHRV. Reference standards need to be set for normal uncomplicated pregnancy for the quantification of FHRV. Work is necessary to generate evidence to support its continued use. Longitudinal repeated measurements are needed from pregnancies complicated by FGR as well as other pathologies such as insulin-dependent diabetes to observe how these differ from uncomplicated pregnancies.

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Conflicts of Interest

None.

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