

Current methods of non-invasive fetal heart rate surveillance

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Summary

Introduction: As accurate fetal evaluation during labor is essential, there is a continuous need for better noninvasive ways of monitoring. Electronic fetal monitoring (EFM) is an essential tool towards effective fetal assessment during labor, with the invasive Intrapartum ST Segment Analyses (STAN) system an early favorite. There are very few non-invasive EFM devices worldwide, with only two having Food and Drug Administration (FDA) approval. **Methodology:** This state of the science review focuses on the most recent available scientific data regarding the role of non-invasive EFM and its effect on perinatal outcomes. **Results:** The Monica AN24 system, FDA approved and comparable to an external Doppler CTG, is independent of maternal BMI. The Mind child Meridian monitor, the second EFM device with FDA approval, is comparable to STAN, but with up to 32 electrodes for improved accuracy it can be difficult for medical professionals to master. The Nemo System, new to the market, was found to be highly acceptable as a 24-hour monitoring device by pregnant women in a single inaugural pilot study. **Discussion:** Non-invasive monitoring technology is making progress but there are still issues with signal acquisition and quality that stem from the newfound mobility of the monitored pregnant women. The two FDA approved devices are promising with a few caveats and there are also new devices that aim to improve on the shortcomings of the leaders with promising advances in signal acquisition and processing via additional electrodes and setups.

Key words: Electrocardiography; Electrocardiotocography; Peripartum care; Cardiotocography.

Introduction

The evaluation of fetal well-being during labor has been a significant consideration in obstetrics throughout the years. Therefore, considerable effort has been made towards developing evaluation methods that are both non-invasive and reliable and could help reduce perinatal morbidity and mortality [1]. A circadian interdependency between Maternal Heart Rate (MHR) and Fetal Heart Rate (FHR) [2], signal interference from the movement of both the fetus and the mother, further maternal noise from uterine contractions, respiration, abdominal muscle artifacts, as well as electrical noise from the device and power line are just some of the problems that these new devices are called to face [3]. The past few years have seen significant improvements in the accuracy of FHR monitoring, utilizing advanced signal processing techniques. There are numerous methods available with different clinical efficacy, due to variations in sensitivity, specificity, negative, and positive predictive value [4, 5] and not without their share of controversy [6-8].

Electronic fetal monitoring (EFM) by means of cardiotocography, electrocardiography, and other methods is an essential tool towards effective fetal assessment during labor [9, 10].

This state of the science review focuses on the most recent available scientific data regarding the role of non-invasive electrocardiographic monitoring and its effect on perinatal outcomes.

Early Research on Electronic Fetal Heart Rate Monitoring

Most of the monitoring techniques currently used in obstetric practice have been developed during the 20th century and have led to a significant reduction in perinatal mortality. The 1950s saw the development of phonocardiography by Hon [11], which quickly moved in the early 60s to cardiotocography (CTG), a non-invasive electronic monitoring system that allows the continuous recording of FHR by using Doppler Effect technology [12]. Uterine activity is simultaneously monitored by the use of a tocodynamometer, applied either intrauterine or, on the maternal abdomen. Its stated purpose was to reduce the incidence of fetal hypoxia [13]. It is a well-used method but not without serious shortcomings [1, 13-15]. The lack of real-time beat to beat data, frequent repositioning of the transducers causing up to 40% signal loss, the inability to always discriminate between MHR and FHR, and an array of well-documented artefacts have stigmatized this method [1, 13-15]. Also, it is not easily implemented even when upgraded with wireless parts, as it restricts mobility much more so than newer technologies [14, 16].

Initially, numerous studies were published showing that screening all pregnant women, both before and during labor with CTG, could contribute significantly to the reduction of perinatal morbidity and mortality. However, during the 1980s, a higher incidence of operative delivery and postnatal depression, negatively affecting breastfeeding and infant

Table 1. — *Pros and Cons of current fetal heart rate surveillance devices.*

Method	Main device	Type	Pros	Cons
Cardiotocography	Doppler	I	Most commonly used, Contraction monitoring, HR time series, Reduces incidence of fetal hypoxia [13]	Expert user required, No real-time beat to beat data, Signal loss, (MHR)/(FHR) discrimination issues [1, 13-15]. Restricts mobility [14, 16]. Higher incidence of operative delivery [17, 18]
	Ultrasound/toco dynamometer			
Magnetocardiography [19]	Superconducting Quantum Interference Device (SQUID) sensors	NI	Multichannel, Good SNR for fetal signals, Good results [20]	Expert user required. Specialist set up required. Short term monitoring only. Expensive, lack of mobility [21]
	STAN monitor [27]	I	Very good FHR, Reduces neonatal metabolic acidosis, [4, 18, 28-31]. Reduces the need for blood sampling [40]	Expert user required. Use only after the membranes have ruptured and cervical dilation has exceeded 2-3 cm [14, 18] Latest meta-analysis has concluded that STAN does not have a place in modern obstetrics [4, 18]
Non-invasive fetal electrocardiography	MERIDIAN Monitor* [23]	NI	FDA approved for Weeks of Gestation (WOG) ≥ 36 , Comparable to STAN [43]	No skin preparation, Number of electrodes [32] can be inconvenient for both staff and patient [42]
	NEMO System [41]	NI	Highly accepted by patients [41].	Minor skin preparation, New to the market, 2 studies only [41, 44]
	MONIKA AN24*/Novii	NI	FDA approved for WOG ≥ 36 weeks, Europe, WOG (≥ 20 weeks), Real-time FH, MHR EHG capable, Equal or even superiority in signal quality to the external Doppler, CTG independent of maternal BMI [54, 55] evaluate precise fetal cardiac time intervals (fCTIs) [57]	Skin preparation required, Success of beat-to-beat fHR detection, dependant strongly on location, timing, maternal activity levels, and maternal posture. Might have limited clinical utility if it is unsupervised with physical activity or posture shifts [58].
	KhAI-MEDICA [42]	NI	Only patent submitted	N/A

Abbreviations: I, invasive; NI, Non-invasive.

care, was reported with the use of this method [17, 18].

Fetal Electrocardiography

Magnetocardiography and non-invasive fetal electrocardiography are the other two current methods in use for EFM. Magnetocardiography [19] requires a magnetically shielded environment and high-end equipment. The restricted availability of this technology, as well as the lack of mobility for the patient [20], outweigh the benefits of this approach [21].

Fetal electrocardiography on the other hand allows for the interpretation of the electrical activity of the fetal heart and provides information regarding the physiological state of the fetus that can help clinicians to make appropriate and timely decisions during labor. The fetal cardiac electrical activity during each beat can be subdivided into P, QRS, and T waves. Each wave corresponds to a different phase in the cardiac cycle: P waves correspond to atrial contraction, QRS to ventricular contraction, and T waves to ventricular repolarization [22, 23]. Repolarization of myocardial

cells is very sensitive to metabolic dysfunction and may be reflected in changes in the ST waveform. Thus, in adults with myocardial infarction, the ST segment, the period that follows the QR complex and leads to the T wave, may be elevated [18, 23]. Similar findings can be observed in fetuses under conditions of moderate to severe hypoxemia [4, 24, 25]. This can be measured only after the membranes have ruptured and cervical dilation has exceeded 2-3 cm [14, 18]. Fetal electrocardiography is not as widely used in clinical practice as cardiotocography since many obstetricians are not familiar with the technology and consider it mostly an experimental technique [6, 8, 26]. One such method is the ST analysis (STAN) system, STAN monitor (Neovinta Medical, Mölndal, Sweden), an invasive technique most commonly used in Sweden, which measures ST segment deviation and T/R amplitude ratio by applying a scalp electrode to the fetal head during labor in high-risk pregnancies [27]. STAN was introduced to daily practice in 2000. Its use has shown promise in reducing neonatal metabolic acidosis, but not in reducing neonatal morbidity, thus it has not been widely adopted as a standard method

outside of Sweden [4, 18, 28-31].

To date, six randomized controlled trials utilizing STAN have been performed, five of which have published their results [32-37]. Furthermore, several related meta-analyses have been released. The meta-analyses showed that combined cardiotocography with STAN as compared to no monitoring reduces the risks of vaginal operative delivery by about 10% and of fetal blood sampling by 40% [38, 39].

An early meta-analysis of five randomized controlled trials, which included 15,352 parturients, compared the combination of fetal electrocardiography with ST waveform analysis and CTG versus conventional CTG. The addition of STAN led to a non-significant reduction in metabolic acidosis (RR 0.72) but a significant decrease in fetal blood sampling (RR 0.59) and total operative deliveries (RR 0.94) [40]. A later systematic review [4] concluded that the use of an internal procedure to place an electrode on the fetal scalp is a serious risk for the fetus that cannot be negated by the modest, at best, results in reducing operational births.

A recent meta-analysis [18] of six RTCs was conclusive; STAN does not have a place in modern obstetrics since its only benefit is the reduction of metabolic acidosis but not operative deliveries, concluding that the benefits were insufficient to justify using ST waveform analysis as an intrapartum monitoring method.

Non-invasive Fetal Electrocardiography

Non-invasive fetal electrocardiography devices are limited in number as there are only three available worldwide, with only two having US Food and Drug Administration (FDA) approval. The available devices include the Monica AN24 monitor (Monica Healthcare, Nottingham, UK), the MERIDIAN monitor from MindChild Medical (North Andover, MA), and the recently introduced Nemo Fetal Monitoring System (Parides/Atlantis System, Nemo Healthcare, Veldhoven, The Netherlands) [41]. There is recent activity with small start-ups filing patents on non-invasive fetal ECG technology, but only the patent information is readily available. One of them, a yet unnamed device, is currently in trials from KhAI-MEDICA, Kharkiv, in Ukraine [42].

MindChild MERIDIAN Monitor

The MindChild MERIDIAN Monitor [23] is frequently used in preclinical signal processing related research to improve the related algorithms and has been cited as an example that non-invasive fetal electrocardiography devices are the way forward. The Meridian monitor was found comparable to STAN [43]. One benefit of this technique is that the Meridian monitor's abdominal electrodes can be applied without any prior skin preparation [43]. Researchers also are using the MindChild Medical monitor to evaluate fetal ECG waveform patterns that predict in-utero inflammation. Although the 32 abdominal electrodes allow for higher accuracy, the Meridian monitor can be very inconvenient both for the medical staff that have to ensure proper adhesion of up to 32 electrodes and also for the patient that has to endure monitoring for hours [42].

Nemo Fetal Monitoring System

The Nemo System (Parides/Atlantis System, Nemo Healthcare, Veldhoven, The Netherlands) is very new to the market and so far has an inaugural pilot study evaluating the acceptance and comfort of the system by pregnant women. The case-control cohort study for acceptance and potential use as a clinical device for fetal monitoring took place at the out-patient clinic of University Hospital Heidelberg, Department of Gynecology and Obstetrics, Germany in 2017 and demonstrated a high level of patient acceptance [41]. It requires a minor skin preparation with water soap and medical abrasive paper to lower skin impedance [41]. Nemo has been used in a study that showed that electrohysterogram (EHG) monitoring is a reliable and reasonable alternative to tocodynamometry and intra-uterine pressure catheters. The study, using Nemo for EHG, showed higher sensitivity for contraction detection and had a better performance than external tocodynamometry during the first stage of labor, regardless of the BMI of the women in labor [44].

Monica AN24

The Monica AN24 (Novii Wireless Patch System, Nottingham, UK) is a non-invasive device using five electrodes placed on the woman's abdomen, that has been approved by the FDA for monitoring fetal well-being. This device extracts the fetal and maternal electrocardiogram (ECG) and electrohysterogram (EHG) [27].

It has been shown to assess FHR using abdominal surface electrodes accurately. Monica AN24 can be used in a home monitoring setting [45, 46] for continuous telemetric trans-abdominal fetal ECG monitoring. The electrophysiological signals from the abdominal wall are used to measure FHR, MHR, and uterine contraction data [47, 48]. The device continuously monitors MHR which reduces the MHR/FHR ambiguity when compared with cardiotocography [48, 49]. In addition, the Monica AN24TM can accurately record the FHR from as early as 20 weeks' gestation [50]. It has been utilized in measuring MHR, FHR and uterine activity to help associate several distinct MHR patterns (such as periodic changes, variability, tachycardia, bradycardia) with uterine activity [49, 51] as well as fetal growth and birth weight [52].

Unlike the STAN system, the Monica AN24 can also be used during pregnancy, and not only intrapartum [53]. The Monica system is comparable to the signal quality of the external Doppler CTG independent of maternal BMI [53-55], and fetal presentation during delivery does not influence fetal signal success using the Monica AN24 system [55].

A recent study suggests a potential role for Monica AN24 in the monitoring of fetal arrhythmias as it provided high-quality tracings in 9 of 11 fetuses with gestational age < 26 or > 34 weeks [56]. Furthermore, it could be a useful tool to detect precise fetal cardiac time intervals (fCTIs) from 32 weeks' gestational age onwards as a very recent study indicated [57].

The success rate of beat to beat recording is an issue with

Monica AN24. Long-term Monica AN24 recordings have FHR signal dropouts due to movement of the woman, a clear limitation of abdominal fECG recording. Huhn *et al.* found differences in home and hospital-bound cases with better quality recordings in the home-based group during nighttime as opposed to daytime. They concluded that the success of beat-to-beat FHR detection depended strongly on whether the monitoring was done at home or at the hospital and was also dependent on the time of recording, maternal activity levels, and maternal posture. Thus they concluded that Monica AN24 might have limited clinical utility especially if it is an unsupervised recording with physical activity or posture shifts [58]. A very recent study from Hayes-Gill *et al.*, in 2020 [59], funded by Monica Healthcare Ltd, has assessed AN24's accuracy against ultrasound and abdominal electrocardiogram and found it conforms better with patterns derived using a direct fetal electrode [59]. They concluded that the AN24 is good enough to aid in the clinical interpretation of FHR patterns. Table 1 summarizes all current devices and their pros and cons.

Concluding Remarks

There has been a drive in the last few years for significant improvements in the accuracy of FHR monitoring, with advanced algorithmic processes and safety, and an investment in non-invasive technologies [4-8, 16, 21, 24, 41, 42, 46, 60] not without their share of controversies. The majority of the obstetrics community has embraced EFM as an essential tool towards effective fetal assessment during labor [9, 10]. Although it is still unclear if continuous intrapartum fetal monitoring does indeed offer an improvement on newborn outcomes such as a reduction in perinatal mortality, the technology does appear to lead to more operative vaginal deliveries and caesarean deliveries [61].

The STAN system uses a fetal scalp electrode and, consequently, can only be used in parturients with cervical dilation of at least 3-4 cm [27]. Furthermore, myometrial contractions are still recorded transabdominal, and the woman is not mobile.

Non-invasive fetal electrocardiography devices are very few with only two having FDA approval so far, Monica AN24 and MERIDIAN Nemo Fetal Monitoring System is the latest commercial addition [41].

As far as non-invasive monitoring is concerned, the technology is making progress as compared to invasive technologies, but there are still issues with signal acquisition and quality that stem from the newfound mobility of the monitored expecting women. True wireless devices are still in patent [62-64] or prototype stage [65-67], thus are not in any way directly comparable to the devices reviewed. The two FDA approved devices are promising, with a few caveats, and there are also new but unproven devices that target the shortcomings of the industry leaders by promising improvements in signal acquisition and processing via additional electrodes and setups [23, 41].

Focusing on improved algorithms for deciphering as

well as improving the signal acquisition process seems to be the way to improve the technology and the above-mentioned devices are moving in that direction [59]. An exhaustive review [68] of the current signal processing techniques argues that the way forward is the combination of different computational techniques as well as creating hybrid devices to be able to accurately capture FHR and the rest of the fetal modalities.

In conclusion, non-invasive monitoring devices appear to be trending and are considered almost as reliable, but certainly much safer than established methods. When used by trained personnel and in combination with other peripartum parameters, these devices can lead to improved outcomes but not in the reduction of caesarian births as originally promised. Finally, the main result of the current literature is that new methods of fetal echocardiography and electrohysterography could achieve a reduction in medical intervention and cesarean section, although this does not necessarily translate into reduced perinatal morbidity and fetal wellbeing.

Hopefully the new monitoring devices presented here will become the milestones on the road to the much-needed paradigm shift in FHM.

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Conflict of Interest

The authors have no conflicts of interest to disclose.

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