

Implementation of the combined use of non-invasive fetal electrocardiography and electrohysterography during labor

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ORIGINAL RESEARCH ARTICLE

Implementation of the combined use of non-invasive fetal electrocardiography and electrohysterography during labor: A prospective clinical study

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Nemo Healthcare B.V. (Veldhoven, the Netherlands)

Abstract

Introduction: Fetal electrocardiography (NI-fECG) and electrohysterography (EHG) have been proven more accurate and reliable than conventional non-invasive methods (doppler ultrasound and tocodynamometry) and are less affected by maternal obesity. It is still unknown whether NI-fECG and EHG will eliminate the need for invasive methods, such as the intrauterine pressure catheter and fetal scalp electrode. We studied whether NI-fECG and EHG can be successfully used during labor.

Material and Methods: A prospective clinical pilot study was performed in a tertiary care teaching hospital. A total of 50 women were included with a singleton pregnancy with a gestational age between 36⁺⁰ and 42⁺⁰ weeks and had an indication for continuous intrapartum monitoring. The primary study outcome was the percentage of women with NI-fECG and EHG monitoring throughout the whole delivery. Secondary study outcomes were reason and timing of a switch to conventional monitoring methods (i.e., tocodynamometry and fetal scalp electrode or doppler ultrasound), repositioning of the abdominal electrode patch, success rates (i.e., the percentage of time with signal output), and obstetric and neonatal outcomes. Clinical trial registration: Dutch trial register (NL8024).

Results: In 45 women (90%), NI-fECG and EHG monitoring was used throughout the whole delivery. In the other five women (10%), there was a switch to conventional methods: in two women because of insufficient registration quality of uterine contractions and in three women because of insufficient registration quality of the fetal heart rate. In three out of five cases, the switch was after full dilation was reached. Repositioning of the abdominal electrode patch occurred in two women. The overall success rate was 94.5%. In 16% ($n=8$) of women, a cesarean delivery was performed due to non-progressing dilation ($n=7$) and due to suspicion of fetal distress ($n=1$).

Abbreviations: BMI, body mass index; CTG, cardiotocography; DU, Doppler ultrasound; EHG, electrohysterography; FHR, fetal heart rate; FSE, fetal scalp electrode; IUPC, intrauterine pressure catheter; NFMS, Nemo Fetal Monitoring system; NICU, neonatal intensive care unit; NI-fECG, non-invasive fetal electrocardiography; TOCO, external tocodynamometry.

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Neonatal metabolic acidosis did not occur. Two neonates (4%) were admitted to the neonatal intensive care unit for complications not related to intrapartum monitoring. **Conclusions:** NI-fECG and EHG can be successfully used during labor in 90% of women. Future research is needed to conclude whether implementation of electrophysiological monitoring can improve obstetric and neonatal outcomes.

KEYWORDS

cardiotocography, electrocardiography, electrohysterography, fetal heart rate, fetal monitoring, intrapartum monitoring, uterine contractions, uterine monitoring

1 | INTRODUCTION

During labor, obstetric caregivers act based on cardiotocography (CTG), a continuous registration of the fetal heart rate (FHR) and uterine activity, in order to avoid adverse maternal and perinatal outcomes.

Non-invasive intrapartum monitoring, using Doppler ultrasound (DU) and external tocodynamometry (TOCO), is commonly used, although it may have insufficient signal output due to maternal obesity or maternal and fetal movements.^{1,2} Invasive monitoring methods, fetal scalp electrode (FSE) and intrauterine pressure catheter (IUPC), perform better with regard to signal acquisition, accuracy and reliability, compared to non-invasive methods.³ To optimize registration quality, invasive monitoring is therefore considered to be the gold standard. However, both FSE and IUPC can only be used when the cervix is sufficiently dilated and membranes have ruptured. Furthermore, FSE is contraindicated in cases of very preterm labor, inheritable clotting diseases and maternal HIV or hepatitis infection.³ Also, FSE and IUPC are associated with risks of complications: FSE increases the risk for neonatal trauma to the scalp and wound infection, while IUPC increases the risk for uterine perforation, placental abruption and maternal infection.⁴⁻⁷ Routine use of IUPC is discouraged by the guideline of the Dutch Society of Obstetrics and Gynecology (NVOG) due to these risks and lack of evidence that its use improves obstetric outcomes.^{3,8-10}

To obtain better registration quality compared to conventional non-invasive methods (i.e., DU and TOCO), but without the aforementioned risk of complications, electrophysiological monitoring can be used.

Recently, a monitoring device called Nemo Fetal Monitoring system (NFMS) (Nemo Healthcare B.V.) was developed which is based on electrophysiology. An abdominal patch is used which incorporates non-invasive fetal electrocardiography (NI-fECG), maternal electrocardiography and electrohysterography (EHG). NI-fECG uses multiple electrodes to monitor the FHR based on electrophysiological signals from which maternal electrocardiography signals are removed. EHG measures the electrical activity of the uterine muscle during contraction and relaxation. Both NI-fECG and EHG have been proven to be more accurate and reliable than conventional non-invasive methods (DU and TOCO) and are less affected by maternal obesity.¹¹⁻¹⁸

EHG has been studied in clinical practice and is considered a safe and promising method ready for further implementation.¹⁹ NI-fECG

Key message

Non-invasive fetal electrocardiography and electrohysterography outperform conventional non-invasive methods (i.e., Doppler ultrasound and external tocodynamometry), and are not accompanied by the disadvantages of invasive methods (i.e., fetal scalp electrode and intrauterine pressure catheter). Non-invasive fetal electrocardiography and electrohysterography monitoring was successful in 90% of women, with a high success rate.

has also previously been studied in a clinical setting, although often in a setting with simultaneous DU and FSE monitoring. In these studies, medical decisions were still based on conventional monitoring methods (i.e., DU or FSE).^{11,13,14} Studies in which medical decisions were based on NI-fECG monitoring, are still scarce.²⁰ In the current prospective clinical study, we aimed to investigate to what extent the combined use of NI-fECG and EHG could be successfully used during labor, without the necessity for invasive monitoring methods.

2 | MATERIAL AND METHODS

A prospective clinical study was performed in a tertiary care teaching hospital in the Netherlands from March 2021 until July 2021.

To be eligible for inclusion, women had to be at least 18 years old, pregnant with a singleton fetus in cephalic presentation with gestational age between 36⁺⁰ and 42⁺⁰ weeks, and have an indication for continuous intrapartum monitoring. Exclusion criteria were inability to understand the English or Dutch language, fetal cardiac arrhythmias, contraindications for the use of the electrophysiological monitoring device (i.e., maternal abdominal dermatological diseases, external or implanted electrical stimulators, and bathtub deliveries) and contraindications for the use of FSE (eg maternal infectious diseases and inheritable clotting diseases). Additionally, women could not participate in case of technical connection issues regarding the external set-up, which is used to communicate between the NFMS and the patient file and hospital alarm system, that precluded the generation of CTG alerts (Figure 1).

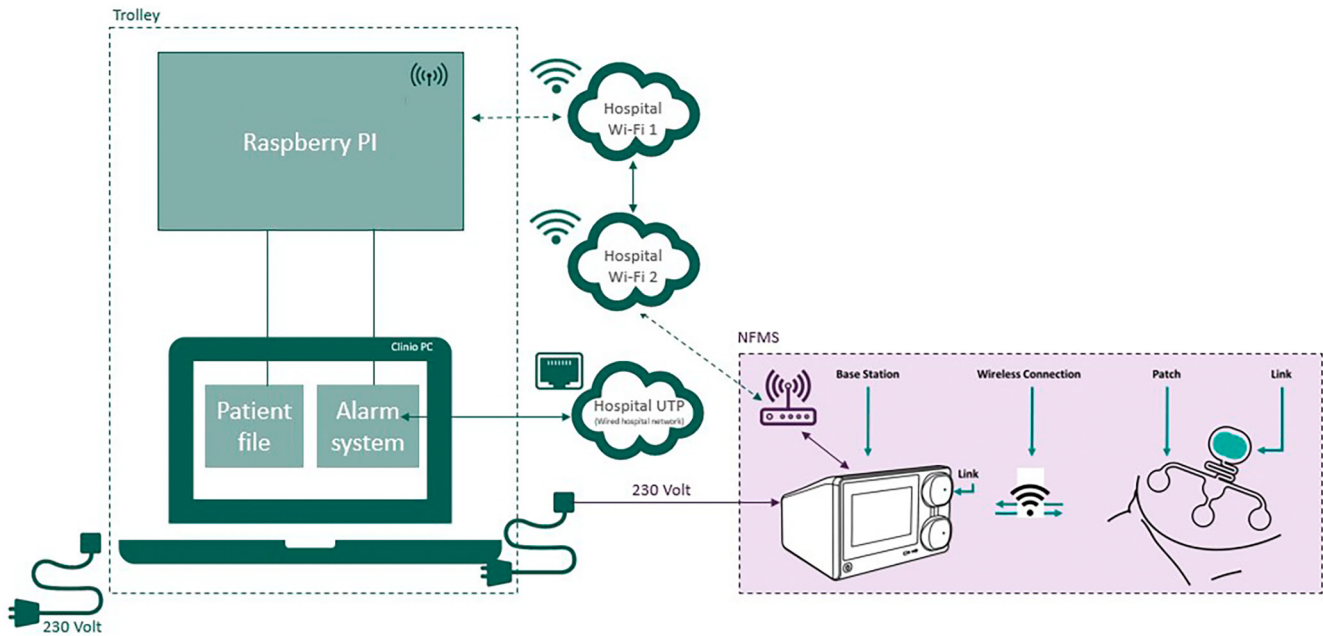


FIGURE 1 Connection of the Nemo Fetal monitoring system to the central monitoring system and patient files.

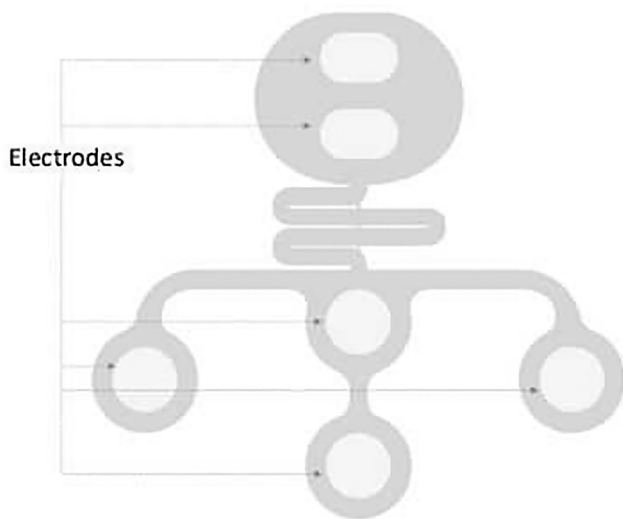


FIGURE 2 Patch comprising six self-adhesive electrodes.

For this study, CTG-data from the NFMS had to be transferred to both the electronic patient files and the hospital alarm system. To accomplish this, an external set-up was built specifically for the infrastructure in our hospital (Figure 1). In other hospitals, a direct connection between the NFMS and the hospital system can be acquired; however, in our hospital, data had to be sent to two systems (i.e., patient files and hospital alarm system) requiring a special set-up using a Raspberry Pi. Prior to study participation, the connection between the NFMS, Raspberry Pi and the two hospital systems (patient files and hospital alarm system) was tested to ensure CTG alerts could be generated.

All women received continuous intrapartum monitoring using the NFMS. NFMS consists of a base, amplifier and a disposable self-adhesive abdominal patch incorporating six electrodes (Figure 2).

The maternal abdominal skin was prepared in a standardized manner prior to application of the patch; the skin was washed with water and soap, after which it was abraded to optimize skin impedance. Skin impedance values of <2 , 2 – 5 and >5 k Ω were considered optimal, acceptable and undesirable, respectively. Impedance values were automatically measured by the NFMS. If the skin impedance was not optimal, the skin was abraded once more. If the skin impedance did not improve by this, the impedance values had to be accepted and monitoring was started. Abrading occurred only once to prevent skin damage. In addition, electrodes will get warmer over time due to body temperature and therefore the impedance values will probably improve. Obstetric caregivers were trained in the use and application of the NFMS prior to the study.

Monitoring using NFMS was started during the first stage of labor. Clinical decisions were made based on the CTG derived from the NFMS. Obstetric caregivers could reposition the abdominal patch or switch to conventional monitoring methods (i.e., FSE and TOCO or DU and TOCO) (Philips Avalon FM30 or Philips Avalon CL, Philips Healthcare) if deemed necessary by them. Switching to IUPC was not possible since the IUPC was not available for use in our hospital due to its risk of serious complications and lack of evidence on improvement of obstetric outcomes.^{3,8,9} When switched to conventional monitoring methods, medical decisions were based on the CTG derived from these conventional methods. Directly postpartum, obstetric caregivers were asked to fill out a questionnaire regarding the reason and timing of the switch.

NFMS uses electrophysiology to generate a real-time CTG in a few consecutive steps: raw unipolar data obtained with NFMS was first processed using various signal processing methods to distinguish the electrical signals from the uterus, fetal heart and maternal heart. Electrical activity from other sources (eg maternal abdominal muscles) was also identified in order to suppress

these disturbing signals. Subsequently, EHG data was converted into a measure for uterine activity, which correlated with the intrauterine pressure based on a mathematical model.²¹ Fetal and maternal ECG data were converted into heart rate tracings. Processing and converting of data occurred real-time, allowing for intrapartum use.

The primary study outcome was the percentage of women with NFMS monitoring throughout the whole delivery. Secondary study outcomes were (1) reason and timing (i.e., stage of labor and number of centimeters dilation) of switches to conventional monitoring methods, (2) number of times the abdominal patch was repositioned, (3) success rate during the first and second stage of labor (defined as percentage of time during labor with concurrent signal output of both NI-fECG and EHG), (4) obstetric outcomes (i.e., mode of delivery, episiotomy rate and number of fetal blood samplings) and (5) neonatal outcomes (i.e., 5-min Apgar scores <7, neonatal metabolic acidosis and admissions to the neonatal intensive care unit (NICU)).

Neonatal metabolic acidosis was defined as umbilical artery pH < 7.05 and base deficit > 12.0 mmol/L or, when only one umbilical cord pH, probably the venous pH, was available, as pH < 7.10 and BD > 12.0 mmol/L.²²

The success rate was defined as the percentage of time during labor with concurrent output of both NI-fECG and EHG-signals. The success rate was based on the CTG-recordings available in the electronic patient files. In case of missing signals, we described the origin of missing output. For women in whom a switch was made to conventional methods, success rates were calculated based on the CTG-recordings until the moment of switch. Otherwise, the success rate was calculated from the time NFMS monitoring started, until childbirth.

2.1 | Statistical analyses

Based on data from our hospital, we calculated the use of conventional non-invasive monitoring using DU and TOCO to be approximately 30% in women with singleton deliveries between 36⁺⁰ and 42⁺⁰ weeks gestational age. We hypothesized that implementation of electrophysiological monitoring using NI-fECG and EHG could increase the percentage of non-invasive monitoring from approximately 30% with DU and TOCO to 55% with NI-fECG and EHG. Based on a one-sample exact test with a power of 90% and an alpha of 5%, we calculated inclusion of 35 women in this study. However, for a secondary study outcome (association of EHG parameters and blood loss postpartum) we calculated enrollment of 50 women. The results of the secondary study outcome will be described in a separate article.

Statistical analyses are descriptive and were conducted using SPSS software (version 26, IBM Corp.). Numbers and percentages are reported for categorical data. Mean with standard deviations or medians with interquartile ranges are reported for numerical data as appropriate.

3 | RESULTS

In total, 61 women agreed to study participation and were also considered eligible. Eleven women were excluded because of a connectivity issue between the NFMS and our central monitoring system.

We included 50 women who received intrapartum monitoring using NI-fECG and EHG. Table 1 shows the baseline characteristics of those included in the study.

In 90% ($n=45$) of the women, NI-fECG and EHG monitoring was used throughout the whole delivery. In 10% ($n=5$) of the women, a switch was made to conventional monitoring methods: in two women because EHG data was found to be inadequate, and in three women because of FHR signal loss. Table 2 shows additional information regarding the switches. The CTG-recordings of these five women are shown in Figure 3.

The abdominal electrode patch was repositioned during labor in two women to optimize FHR monitoring. In both women, NFMS monitoring was eventually discontinued. Both women had a body mass index (BMI) > 35 kg/m².

TABLE 1 Baseline characteristics of 50 women monitored by NI-fECG and EHG during labor.

Baseline variable	N (%), mean \pm SD or median (IQR)
Maternal age (years)	32.5 (5.0)
Body mass index (kg/m ²)	24.8 (7.0)
Body mass index (kg/m ²)	
BMI \leq 20	1 (2.0)
BMI 20–25	27 (54.0)
BMI 25–30	10 (20.0)
BMI 30–35	5 (10.0)
BMI 35–40	5 (10.0)
BMI 40–50	1 (2.0)
BMI \geq 50	1 (2.0)
Gestational age at delivery (weeks ^{+days})	39 ⁺¹ \pm 1 ⁺²
Nulliparous women	25 (50.0)
Previous cesarean delivery	4 (8.0)
Induction of labor	41 (82.0)
Meconium stained amniotic fluid	7 (14.0)
Labor analgesia	
None	11 (22.0)
Epidural analgesia	36 (72.0)
Opioids	3 (6.0)
Intrapartum fever (>38.0°C)	4 (8.0)
Oxytocin augmentation during labor	42 (84.0)
First stage labor duration (h:min)	07:05 (08:04)
Second stage labor duration (h:min)	00:16 (00:35)
Neonatal birthweight <10th percentile	5 (10.0)

Abbreviations: EHG, electrohysterography; NI-fECG, non-invasive fetal electrocardiography.

The average time of NFMS monitoring was 10h and 3min. The mean success rate of NFMS was 94.5% (Table 3). Of the 5.5% with missing NFMS output, 1.1% involved missing NI-fECG output only, whereas in 4.4%, there was no CTG-recording in the electronic patient file at all due to technical problems with either the NFMS itself (eg battery empty, incorrect link placement) or the connection between NFMS and the electronic patient files (eg problems with wireless data connection, temporary disconnection after transferring women to the recovery room for epidural analgesia). There were no cases of missing EHG output only.

The overall success rate was high in both the first stage of labor ($n=50$) and the second stage of labor ($n=42$) (94.3% and 97.1%, respectively) (Table 3). For women in whom a switch was made from monitoring methods based on inadequate NI-fECG signals or EHG signals, the success rates before and after switch are described in Table 2.

The obstetric and neonatal outcomes are described in Table 4. In 16% ($n=8$) of women, a cesarean delivery was performed because of non-progressing dilation ($n=7$) or suspicion of fetal distress ($n=1$). Neonatal metabolic acidosis did not occur in the study population. Two neonates (4%) were admitted to the NICU. One neonate due to secondary perinatal asphyxia based on a sudden unexpected post-natal collapse. This neonate had a 5-min Apgar score of 10 and arterial umbilical pH of 7.27. Approximately 30min postpartum, during breastfeeding, the neonate did not breathe and was hypotonic and pale. The neonate was admitted to the NICU. Ultrasound and magnetic resonance imaging of the brain and heart did not show any abnormalities. After 6 days, the neonate was transferred to the medium care unit. The other neonate admitted to the NICU was born at a gestational age of 36 weeks and 5 days and admitted because of respiratory distress, which was considered a transition problem. Based on two risk factors for infection (premature delivery and hypothermia) the neonate was treated with antibiotics. After one day of admission, the neonate was transferred to the medium care unit and the antibiotics were stopped within 48h. The blood cultures were negative.

4 | DISCUSSION

This study shows that NI-fECG and EHG can be successfully used for intrapartum monitoring in 90% of women. In three women, a switch was made based on inadequate NI-fECG signals and in two women based on inadequate EHG signals. A switch to the invasive FSE was only deemed necessary in two women. This study showed a high success rate of NFMS monitoring.

In 90% of women, the obstetric caregiver decided a switch to conventional monitoring methods was not necessary and thus the CTG was considered adequate and reliable from a clinical point of view. This is in line with the results of previous studies which showed a good accuracy and reliability of NI-fECG.^{11,17} The percentage of women with a need to switch when using DU and TOCO is not completely known, although the use of FSE is estimated at 71% of all deliveries in the Netherlands.²³ Monson et al.²⁰ reported that 39% of women with DU and TOCO monitoring switch to internal monitoring during labor. With non-invasive electrophysiological monitoring, we were able to demonstrate a lower rate of switches to internal monitoring methods.

In the women with a switch to conventional monitoring methods, a possible contributing factor for inadequate signal acquisition with the NFMS was maternal pushing. Two out of five women were in the second stage of labor. Pushing may cause short-term signal disturbances caused by the electrical activity of the abdominal muscles, which can hinder the identification of the electrical activity of the relatively small fetal heart. Previous studies also describe lower success rates of NI-fECG during the second stage of labor as compared to the first stage of labor.^{11,13}

In the other three women with a switch, maternal obesity was present (BMI of 39, 36 and 33 kg/m²). However, it is unclear whether maternal obesity contributed to the need to switch, especially since previous studies showed that both NI-fECG and EHG are less influenced by maternal BMI as compared to conventional non-invasive methods (DU and TOCO).^{11,16} Therefore, when switching from NFMS to DU and TOCO, signal improvement is not

TABLE 2 Information regarding switches to conventional monitoring methods.

Reason	Conventional method used	Timing	Dilation	BMI (kg/m ²)	Success rate 60 min before switch (%)	Success rate 60 min after switch (%)	
Case 1	Inadequate EHG data	DU + TOCO	First stage of labor	3 cm	32.5	98.3	79.2
Case 2	Inadequate EHG data	DU + TOCO	Second stage of labor	10 cm	22.8	86.9	77.5 ^a
Case 3	Inadequate NI-fECG signal	FSE + TOCO	First stage of labor	2 cm	39.2	79.2	99.6
Case 4	Inadequate NI-fECG signal	DU + TOCO	First stage of labor (delayed pushing)	10 cm	36.1	46.7	9.4 ^b
		FSE + TOCO					100.0
Case 5	Inadequate NI-fECG signal	DU + TOCO	Second stage of labor	10 cm	20.8	85.0	80.0 ^c

Abbreviations: DU, doppler ultrasound; EHG, electrohysterography; FSE, fetal scalp electrode; NI-fECG, non-invasive fetal electrocardiography; TOCO, external tocodynamometry.

^aBased on a recording of 5–6 min between time of switch and childbirth.

^bBased on a recording of 16 min between switch from NFMS to DU + TOCO and switch from DU + TOCO to FSE + TOCO.

^cBased on a recording of 5 min between time of switch and childbirth.

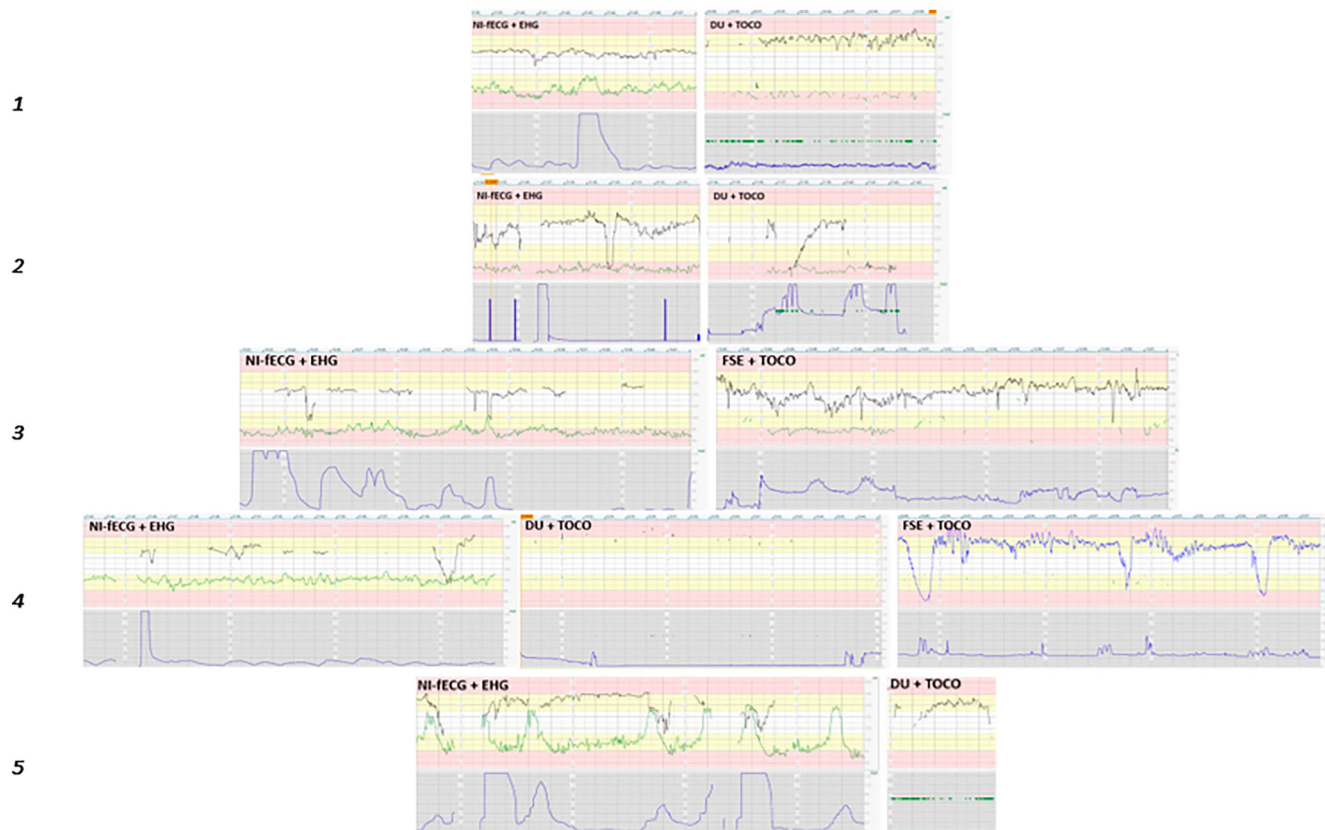


FIGURE 3 CTG-recordings of women before (left) and after (right) a switch to conventional monitoring methods. Case 1 and 2 were switched due to inadequate EHG-signals, whereas case 3 to 5 were switched due to inadequate fECG-signals. The EHG-recording of case 2 shows repeated modified scaling of uterine activity, visible as single straight lines on the tocogram. To obtain a correct interpretable tocogram, this should be prevented. Modified scaling should be a learning objective for correct implementation of the NFMS.

TABLE 3 Success rates of the Nemo Fetal Monitoring system (combined use of NI-fECG and EHG).

	NI-fECG, maternal ECG and EHG	
	Mean \pm SD	95% CI
Overall	94.5 \pm 7.0	92.5–96.5
First stage of labor (n=50)	94.3 \pm 7.2	92.2–96.3
Second stage of labor (n=42)	97.1 \pm 7.2	94.9–99.4

Abbreviations: EHG, electrohysterography; NI-fECG, non-invasive fetal electrocardiography.

always expected. In literature, FSE still outperforms NI-fECG in women with obesity¹¹ and therefore, improvement in signal quality can be expected in these cases with a switch to FSE. These effects were also reflected in our results: regardless of women's BMI, when switching from NFMS to DU and TOCO, success rates dropped, whereas they improved when switching to FSE and TOCO.

Interestingly, two women had a switch based on inadequate EHG signals while success rates were high before the switch (98.3% and 86.9%, respectively) and dropped after switching to conventional methods (79.2% and 77.5%, respectively). In these two cases, a switch was deemed necessary based on difficulties interpreting the EHG signals. This might be explained by the limited exposure of obstetric caregivers to EHG.

Currently, clinical studies are very limited in which medical decisions were made based on NI-fECG. One study is available which describes the clinical use of NI-fECG using the Monica Novii device.²⁰ They reported a switch from NI-fECG to conventional monitoring methods in 51% of women (21% switched to DU and 30% switched to FSE), while our reported percentage of switches is significantly lower (10%). This difference may be explained by the different technology used in the Monica Novii device as compared to the NFMS device, resulting in different success rates. This hypothesis is supported by the fact that most of the women in the study by Monson et al. switched to conventional monitoring methods due to gapping or loss of FHR signal while this was the reason to switch for only 2 out of 50 women in our study (4%).

We found higher success rates of combined use of NI-fECG and EHG than Lempersz et al reported for NI-fECG (94.5% and 89.5%, respectively), confirming the beneficial effect of the recently made technical improvements concerning the suppression of signal disturbances.^{11,17,24} FSE still has the highest success rate (97.7%), although NI-fECG approaches this (94.5%), and is higher as compared to the success rate of DU (82.8%).¹¹

The cesarean delivery rate in our study was comparable to the one reported by Bakker et al. who investigated outcomes after internal and external tocodynamometry.⁹ The reported cesarean delivery rate for singleton, low-risk term pregnancies in the Netherlands in 2020 was

TABLE 4 Obstetric and neonatal outcomes of 50 women monitored by NI-fECG and EHG during labor.

Obstetric and neonatal outcome	N (%)
Deliveries with fetal blood sampling during labor	6 (12.0)
Mode of delivery	
Spontaneous	40 (80.0)
Assisted vaginal delivery	2 (4.0)
Cesarean delivery	8 (16.0)
Failure to progress	7 (87.5)
Suspicion of fetal distress	1 (12.5)
Episiotomy	8 (16.0)
5-min Apgar score <7	3 (6.0)
Neonatal metabolic acidosis ^a	0 (0.0)
NICU admission	2 (4.0)

Abbreviations: EHG, electrohysterography; NI-fECG, non-invasive fetal electrocardiography.

^aNo umbilical cord pH available from two neonates; however, 5-min Apgar scores were 10 for both children.

9%. We included more high-risk women with the majority having an induction of labor (82%). When we compared our cesarean delivery rate (16%) with the cesarean delivery rate in the Netherlands for women with induced labor (15%), the rate was comparable.²⁵ The two neonates admitted to the NICU were not admitted for reasons that can be related to intrapartum monitoring. Due to the small sample size, no further conclusions can be drawn regarding obstetric and neonatal outcomes.

Implementing NI-fECG and EHG during labor almost completely eliminated the need for invasive monitoring. This may be partly explained by the Hawthorne effect. Since blinding was not possible, no clinical decision protocol was used, and the primary outcome was known to caregivers prior to the study, they might have been inclined to continue NFMS-monitoring, so that this was beneficial for the study.²⁶ However, the opposite could also be true: the increased attention for adequate and interpretable CTG-output may have contributed to a more strict assessment of the CTG and therefore have led to a decision to switch. Moreover, the overall success rate was also high, confirming that there was no need to switch to conventional methods due to loss of signal output.

According to the International Federation of Obstetrics and Gynecology, CTG signal loss should not exceed 20%. When assessing the individual rates of signal loss of the women without a switch to conventional monitoring methods ($n=45$), only one woman had signal loss >20% during labor. It could therefore be argued that a switch based on inadequate FHR monitoring would have been recommended for this woman. However, good signal output of the CTG-recording was visible in the data directly derived from the NFMS, although this data was not saved in the electronic patient file. Occasionally, the CTG was not displayed in the electronic patient file when, for example, the obstetric caregiver did not link the CTG-data properly. Since we determined the success rates using the electronic patient files, instead of the CTG-data directly derived from the NFMS, the success rates were falsely influenced in a negative manner.

The success rate of the second stage of labor may be slightly overestimated as three NFMS-recordings were discontinued prior to or during the second stage of labor due to inadequate signal acquisition of the FHR. These CTG-recordings were thus shorter or not available for analysis in the second stage of labor, while success rates would probably have decreased further as the second stage of labor is typically the stage with more signal disturbances from abdominal muscles.

In our hospital, a separate alarm system is used, instead of one incorporated in the electronic patient files. Therefore, a special set-up (Figure 1) had to be built to send NFMS-data to both systems. Unfortunately, this set-up was susceptible to technical connection issues, which led to the exclusion of 11 women and negatively affected the success rate of the remaining 50 women. For future studies, we recommend a direct connection with both systems to prevent these issues.

Since NI-fECG and EHG are less affected by maternal BMI compared to DU and TOCO,^{11,14-16} the combined use of NI-fECG and EHG would be ideal for women with obesity. The prevalence of obesity has nearly tripled since 1975, according to the World Health Organization. With the rising incidence of obesity, the clinical applicability of electrophysiological monitoring will continue to increase.

Furthermore, NI-fECG and EHG are proven more patient-friendly²⁷ and will offer future possibilities to extract additional parameters which might distinguish between physiology and pathology in the future: with regard to NI-fECG, one could think of fECG waveform analysis or spectral analysis on the beat-to-beat FHR to differentiate between healthy and hypoxic fetuses.²⁸ With regard to EHG, speed, vector and entropy can be investigated for their diagnostic potential regarding the onset of true labor or effective uterine activity during labor.²⁹

A larger prospective study comparing electrophysiological and conventional monitoring is needed to conclude whether electrophysiological monitoring can improve obstetric and neonatal outcomes. Its cost-effectiveness should also be subject of future research.

5 | CONCLUSION

NI-fECG and EHG can be used for intrapartum monitoring with a high success rate and without a need to switch to conventional monitoring methods in 90% of women.

AUTHOR CONTRIBUTIONS

MF was responsible for conception, planning, carrying out, analyzing and writing the manuscript. RV was responsible for writing the manuscript. DW, JL and GO were responsible for conception, planning and writing of the manuscript.

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CONFLICT OF INTEREST STATEMENT

Swan G. Oei initiated the scientific research from which Nemo Healthcare B.V. and the described Nemo Fetal Monitoring system device have originated. Rik Vullings was one of the founders of Nemo Healthcare B.V. and is shareholder.

ETHICS STATEMENT

The study was prospectively registered in the Dutch trial register (NL8024). The Medical Ethics Committee of the Máxima Medical Center, Veldhoven, The Netherlands, approved the study (W19.077) on December 2, 2019. Oral and written informed consent was obtained from all women included in the study.

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