OBSTETRICS

# Novel uterine contraction monitoring to enable remote, self-administered nonstress testing

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**BACKGROUND:** The serial fetal monitoring recommended for women with high-risk pregnancies places a substantial burden on the patient, often disproportionately affecting underprivileged and rural populations. A telehealth solution that can empower pregnant women to obtain recommended fetal surveillance from the comfort of their own home has the potential to promote health equity and improve outcomes. We have previously validated a novel, wireless pregnancy monitor that can remotely capture fetal and maternal heart rates. However, such a device must also detect uterine contractions if it is to be used to robustly conduct remote nonstress tests.

**OBJECTIVE:** This study aimed to describe and validate a novel algorithm that uses biopotential and acoustic signals to noninvasively detect uterine contractions via a wireless pregnancy monitor.

**STUDY DESIGN:** A prospective, open-label, 2-center study evaluated simultaneous detection of uterine contractions by the wireless pregnancy monitor and an intrauterine pressure catheter in women carrying singleton pregnancies at ≥32 0/7 weeks' gestation who were in the first stage of labor (ClinicalTrials.gov Identifier: NCT03889405). The study consisted of a training phase and a validation phase. Simultaneous recordings from each device were passively acquired for 30 to 60 minutes. In a subset of the monitoring sessions in the validation phase, tocodynamometry was also deployed. Three maternal-fetal medicine specialists, blinded to the data source, identified and marked contractions in all modalities. The positive agreement and false-positive rates of both the wireless monitor and tocodynamometry were calculated and compared with that of the intrauterine pressure catheter.

**RESULTS:** A total of 118 participants were included, 40 in the training phase and 78 in the validation phase (of which 39 of 78 participants were monitored simultaneously by all 3 devices) at a mean gestational age of 38.6 weeks. In the training phase, the positive agreement for the wireless monitor was 88.4% (1440 of 1692 contractions), with a false-positive rate of 15.3% (260/1700). In the validation phase, using the refined and finalized algorithm, the positive agreement for the wireless pregnancy monitor was 84.8% (2722/3210), with a false-positive rate of 24.8% (897/3619). For the subgroup who were monitored only with the wireless monitor and intrauterine pressure catheter, the positive agreement was 89.0% (1191/1338), with a similar false-positive rate of 25.4% (406/1597). For the subgroup monitored by all 3 devices, the positive agreement for the wireless monitor was significantly better than for tocodynamometry ($P<.0001$), whereas the false-positive rate was significantly higher ($P<.0001$). Unlike tocodynamometry, whose positive agreement was significantly reduced in the group with obesity compared with the group with normal weight ($P=.024$), the positive agreement of the wireless monitor did not vary across the body mass index groups.

**CONCLUSION:** This novel method to noninvasively monitor uterine activity, via a wireless pregnancy monitoring device designed for self-administration at home, was more accurate than the commonly used tocodynamometry and unaffected by body mass index. Together with the previously reported remote fetal heart rate monitoring capabilities, this added ability to detect uterine contractions has created a complete telehealth solution for remote administration of nonstress tests.

**Key words:** contraction, intrauterine pressure catheter, nonstress test, remote pregnancy monitoring, telemedicine, tocodynamometry, uterine activity

## Introduction

The fetal nonstress test (NST) is the primary surveillance test used to reduce adverse pregnancy outcomes, such as stillbirth.[1] The conventional cardiotocography device used for NST monitoring uses a Doppler-based transducer to detect the fetal heart rate (FHR) and an abdominal pressure sensor or tocodynamometer (TOCO) to detect uterine contractions. Generally, the medical personnel are required to place these devices on the maternal abdomen and adjust their location to ensure continuous FHR recording and contraction monitoring, limiting the use to in-clinic situations. In addition, the TOCO suffers from low accuracy and sensitivity, as it is particularly dependent on accurate placement and is negatively impacted by a higher body mass index (BMI).[2–8]

Generally, it is recommended that at-risk pregnancies undergo NST monitoring 1 to 2 times per week in the final months of pregnancy, placing a substantial time burden on the pregnant woman.[9] Barriers to accessing recommended medical care have been identified as a social determinant of health that influences outcomes and can worsen health disparities among underprivileged and rural populations.[10,11] The importance of addressing barriers to care has been further highlighted by the COVID-19 pandemic.[12,13] Therefore, a telehealth solution that can empower pregnant women to obtain their recommended fetal surveillance from the comfort of their own home has the potential to promote health equity and improve outcomes.[14–19]

Toward this end, several remote monitoring systems have been

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## AJOG at a Glance

### Why was this study conducted?

Existing methods for monitoring uterine contractions require trained medical personnel, generally in a medical setting. There is an urgent need to develop telehealth tools enabling patients to remotely access care without the burdens of frequent in-office appointments.

### Key findings

A novel system using maternal electro- and phonocardiography successfully detected uterine contractions during labor, showing good agreement with an intrauterine pressure catheter and superior performance to tocodynamometry. Unlike tocodynamometry, the accuracy of this device was not affected by maternal obesity.

### What does this add to what is known?

The addition of this novel uterine contraction monitoring method to a previously validated wireless fetal heart rate monitoring device yielded a complete, telehealth solution for remote nonstress test monitoring that can significantly increase access to care and begin to address the social determinants that can affect health.

developed, some of which capture uterine activity using a TOCO[20,21] and some of which use electrohysterography (EHG) data from the maternal abdomen to overcome the aforementioned limitations of an external TOCO.[3,22,23] However, EHG-based devices often require single-use adhesive sensors and are currently approved only for term pregnancies (Food and Drug Administration (FDA) approved K140862 and K153262). To devise a telehealth solution to enable at-home fetal monitoring, we have developed, and previously validated,[24] a wireless, remote, FDA-cleared (K191401) pregnancy monitoring device, composed of a self-administered and wireless belt that uses biopotential and acoustic sensors to detect the FHR without the need for the skilled placement of the sensor. Here, we presented and validated a novel algorithm that uses the aforementioned biopotential and acoustic signals from the wireless pregnancy monitor (WPM) to reliably and noninvasively detect uterine contractions to extend the system capabilities to include all of the necessary components for conducting remote NSTs.

## Materials and Methods

### Study design

We conducted a prospective, open-label, 2-center study of a novel algorithm to noninvasively detect uterine contractions via a wireless remote pregnancy monitor (INVU; Nuvo Group Ltd, Tel Aviv-Yafo, Israel), comparing its detection of uterine activity with that of an intrauterine pressure catheter (IUPC), the standard of care for detecting uterine contractions during labor (ClinicalTrials.gov Identifier: NCT03889405). The study was conducted at the University of Arkansas for Medical Sciences (UAMS), Little Rock, Arkansas, and the University of Pennsylvania (UPenn), Philadelphia, Pennsylvania, following the principles outlined in the Declaration of Helsinki and in compliance with International Conference on Harmonisation-Good Clinical Practice standards. The local institutional review board at each study site approved the protocol (UAMS: protocol number 229056; approved March 25, 2019; UPenn: protocol number 832522; approved March 6, 2019). The first patient was enrolled in the study in April 2019, and the last patient completed the study in January 2020.

### Description of study device and algorithm

The WPM belt contains 8 biopotential and 4 acoustic sensors, which passively record abdominal signals (Figure 1).[24] Briefly, after the sensor data are acquired, they are digitized and sent wirelessly to cloud-based modules where the algorithm performs signal processing to identify maternal and fetal cardiac signals and uterine contractions by fusing the independent information gathered from the acoustic sensors (phonocardiogram [PCG]) and electrical sensors (electrocardiogram [ECG]). Uterine contractions lead to conformational changes in the tissue through which the maternal cardiac signals travel, resulting in a signal modulation that can be detected by the algorithm. A brief description of this methodology is included in Supplemental Figure 1. Processed data can be sent through a web-based application to the healthcare provider.

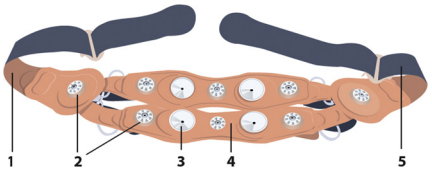
### Study population

Pregnant women between the ages of 18 and 50 years were eligible to participate in this study if they had a singleton pregnancy at $\geq$32 0/7 weeks' gestation, were in the first stage of labor, and had an IUPC already in place for labor management. The exclusion criteria included a prepregnancy BMI of $<$15 kg/m$^2$ or $>$50 kg/m$^2$, multiple gestation, known fetal anomaly, second stage of labor, uncontrolled hypertension, an implanted electronic device (eg, pacemaker or defibrillator), or an active abdominal skin condition (eg, wound or skin rash). Obstetrical providers were informed of the study and were asked to call the research team if they inserted an IUPC for clinical management and thought the patient would be amenable to participation. Trained research staff would approach the patient to confirm that they met the inclusion or exclusion criteria and consented to enrollment. All patients provided written informed consent to participate in the study.

### Training and validation phases

The study was divided into a training phase and a validation phase. In the training phase, patients in labor with an IUPC in place for clinical contraction monitoring had the monitoring belt simultaneously collect maternal signals and correlate them with the IUPC-detected contractions. The data from this phase were used to refine and finalize the algorithm.

FIGURE 1
**Wireless remote pregnancy monitor**




A wireless remote pregnancy monitor is shown detailing the (1 and 5) rear-closing buckle; (2) electrocardiogram sensors, 8 in total; (3) acoustic sensors, 4 in total; and (4) textile band.

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In the validation phase, the trained and locked algorithm was applied to a new group of participants in labor to assess the performance for identifying uterine contractions.

### Primary comparison: wireless pregnancy monitor vs intrauterine pressure catheter

The WPM belt was applied on the pregnant woman's abdomen. Before initiating the recording session, a 2-minute signal validation test was performed to confirm proper belt placement and sensor contact. Moreover, the IUPC baseline was recalibrated using standard procedures, and uterine contractions were recorded simultaneously from both devices for 30 to 60 minutes.

### Secondary comparison: wireless pregnancy monitor vs tocodynamometer vs intrauterine pressure catheter

To compare the WPM with the more commonly used external TOCO, a 3-way comparison was conducted in a subset of enrolled patients. Patients for this subset were selected by the medical staff in cases where the 3-way apparatus did not create a technical or clinical limitation. The placement of the TOCO was confirmed by the clinical nurse. In this substudy, uterine contractions were recorded simultaneously from all 3 devices (WPM, TOCO, and IUPC) for 30 to 60 minutes.

### Study outcomes

Three maternal-fetal medicine specialists, blinded to the data source, independently reviewed the uterine contraction recordings from each system and marked the start, peak, and end of each contraction that they identified. The tracing displays were identical, so that the blinded assessors could not identify the device type that produced the tracing. The assessors had no interaction with the patient, no information about the monitoring source of the recorded data, or the simultaneous recordings from the other devices. Following contraction marking, the blinded assessors evaluated the interpretability of the entire recording session: interpretable, noninterpretable, or partially interpretable.

For each assessor, the contraction data from the WPM and TOCO were referenced to the IUPC-identified contractions. Sessions of the WPM and TOCO that were marked as noninterpretable were analyzed as having no contractions, to conservatively err toward lower sensitivities for the study devices.

Positive agreement rates were calculated for both the WPM and TOCO as the percentage of the IUPC-identified contractions is correctly identified by the other devices. Contractions identified within ±30 seconds of IUPC contractions were considered to be in agreement, as reported in other studies.[5,25] The false-positive rate was defined as the percentage of contractions identified by the study device (WPM or TOCO) that did not correspond to a simultaneous contraction on the IUPC recording. The safe use of the WPM was assessed by reports of adverse events.

### Statistical analysis

A sample size of at least 50 subjects in the validation stage would have a power of more than 0.8 to identify uterine contractions, with a positive agreement having a half-width of 10%, using a 2-sided 95% exact binomial confidence interval. This power calculation assumed 2 contractions on average in a time interval of at least 30 minutes. However, we set out to recruit 80 subjects in the validation phase to increase the power of this study and leave an opportunity for subsequent unanticipated subanalyses. In addition, agreement and false-positive data were analyzed by subgroups for prepregnancy BMI: normal (BMI<25 kg/m$^2$), overweight (BMI, 25−29.9 kg/m$^2$), or obese (BMI≥30 kg/m$^2$). Data analysis was performed for each assessor separately and averaged across the assessors using SAS (version 9.4 or higher; SAS Institute Inc, Cary, NC).

## Results

A total of 118 participants were included in the performance analysis group, 40 in

TABLE 1
**Demographics and clinical characteristics of patients participating in the training and validation phases of the study**

| Phase | Maternal age (y) | Prepregnancy body mass index (kg/m$^2$) | Gestational age (wk) | Monitoring duration (min) | Cervical dilation at the start of the session (cm) | Participants receiving epidural analgesia (%) | Number of contractions per session |
|---|---|---|---|---|---|---|---|
| Training phase | 27.3 (5.0) | 29.7 (7.8) | 38.7 (2.4) | 38.4 (10.5) | 5.4 (1.4) | 97.5 | 13.6 (0.19) |
| Validation phase | 27.3 (5.1) | 29.8 (7.1) | 38.5 (2.0) | 37.6 (11.5) | 5.3 (1.6) | 91.0 | 13.7 (0.41) |

Data are presented as mean (standard deviation), unless otherwise indicated.

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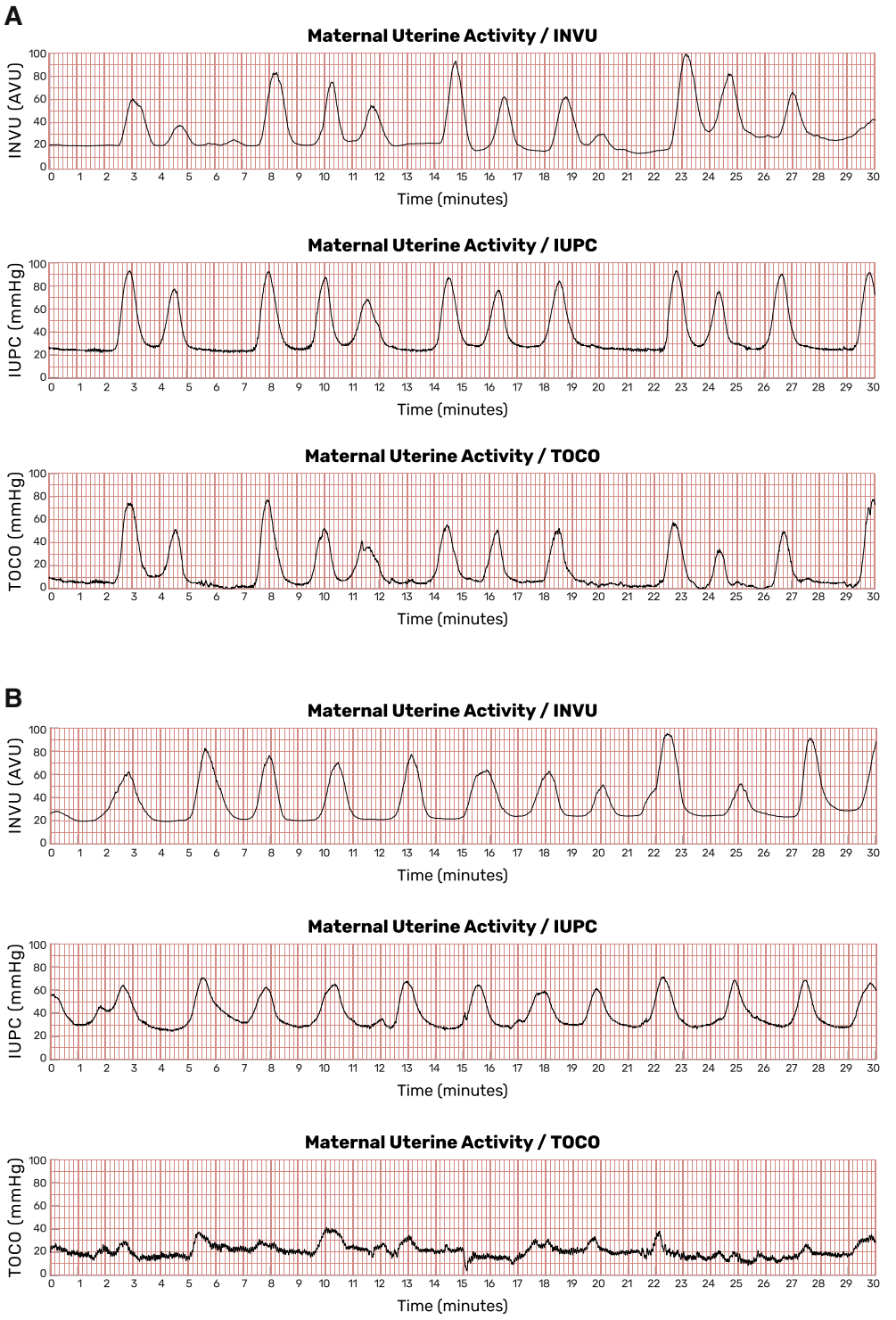
FIGURE 2
**Uterine contraction monitoring sessions showing recordings from the IUPC, TOCO, and WPM**




**A,** Both the WPM and TOCO recordings were followed closely with the IUPC recordings. **B,** In some monitoring sessions, the TOCO tracing, which is more sensitive to positioning, motion, and placement, failed to detect some of the IUPC contractions that were identified by the WPM.

*IUPC*, intrauterine pressure catheter; *TOCO*, tocodynamometer; *WPM*, wireless pregnancy monitor.

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the training phase and 78 in the validation phase. Supplemental Figure 2 shows a summary of the participant disposition. Overall, 62 subjects were recruited at UPenn and 56 at UAMS. At UPenn, 72 subjects were identified as potential participants but were not enrolled. Of these, 22 were close to delivery, 19 did not meet the inclusion or exclusion criteria, 6 were referred when research staff or the device were unavailable, and 25 declined to participate. Screening data for patients not enrolled were unavailable for the UAMS site. In the validation phase, 39 of 78 sessions included the TOCO as a third method for monitoring uterine activity.

The demographic and clinical characteristics of the study participants were similar for the training and validation phases of the study (Table 1). All participants were in the first stage of labor (cervical dilation of <10 cm), per protocol.

In some monitoring sessions, both the WPM and TOCO closely followed the contractions recorded by the IUPC (Figure 2, A); however, in other monitoring sessions, only the WPM matched the IUPC recorded contractions, whereas the TOCO did not record contractions (Figure 2, B).

As determined by the blinded assessors, the overall positive agreement for the WPM during the training phase was 88.4% (1440 contractions identified by the WPM of 1629 contractions identified by the IUPC) (Table 2). The overall false-positive rate for the WPM was 15.3% (260/1700).

For the validation phase with the refined and finalized algorithm, the overall positive agreement for the WPM was 84.8% (2722/3210), and the overall false-positive rate was 24.8% (897/3619) (Figure 3; Table 3). In those sessions using only the WPM and IUPC (39 participants), the overall positive agreement for the WPM was slightly higher at 89.0% (1191/1338; 95% confidence interval [CI], 86.0–92.0), with a similar false-positive rate of 25.4% (406/1597).

For the subgroup of the secondary analysis, including only those sessions using all 3 monitoring methods (39 participants), the positive agreement for the WPM was 81.8% (1531/1872; 95% CI, 76.9–86.6), which was significantly better than the positive agreement for the TOCO (37.5% [702/1872]; 95% CI, 28.2–46.8; $P<.0001$) (Figure 3; Table 4). The false-positive rate for the WPM in this 3-way setup was 24.3% (491/2022), whereas the false-positive rate for the TOCO was significantly lower at 10.7% (84/786; $P<.0001$).

The positive agreement of the WPM did not vary across BMI groups ($P=.13$) (Figure 4, A), whereas the positive agreement of the TOCO recordings was significantly reduced (30.3%, 255 of 842 contractions) in the group with obesity compared with the group with normal BMI (55.9%, 228 of 408 contractions; $P=.024$). The BMI category did not affect the false detection rates for either

**TABLE 2**
**Performance of the wireless pregnancy monitor in the training phase**

| | Positive agreement | | | | False detection rate | | | |
|---|---|---|---|---|---|---|---|---|
| Assessor | N | n | % | 95% CI | N | n | % | 95% CI |
| Assessor 1 | 553 | 518 | 93.7 | 90.9–96.5 | 673 | 155 | 23.0 | 17.1–29.0 |
| Assessor 2 | 542 | 462 | 85.2 | 80.6–89.9 | 500 | 38 | 7.6 | 4.4–10.9 |
| Assessor 3 | 534 | 460 | 86.1 | 81.3–91.0 | 527 | 67 | 12.7 | 8.2–17.3 |
| Total | 1629 | 1440 | 88.4 | 84.7–92.1 | 1700 | 260 | 15.3 | 10.7–19.9 |

*CI*, confidence interval.

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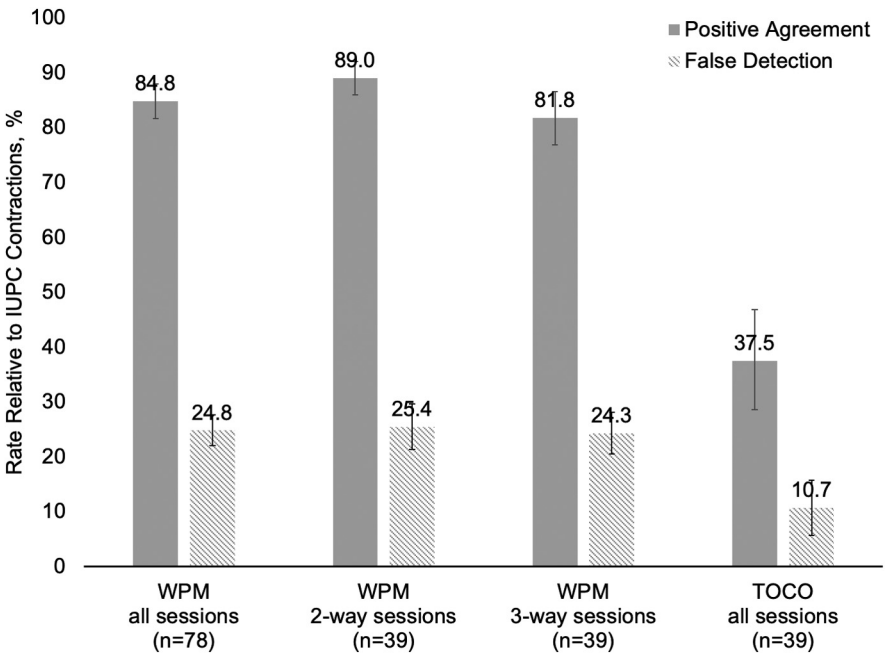
**FIGURE 3**
**Positive agreement and false detection rates for the validation phase**




*Error bars* show the 95% confidence interval. In the 3-way study, the positive agreement rate was significantly higher for the WPM than for the TOCO ($P<.0001$), whereas the false detection rate for the TOCO was significantly lower than that of the WPM ($P<.0001$).

*IUPC*, intrauterine pressure catheter; *TOCO*, tocodynamometer; *WPM*, wireless pregnancy monitor.

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**TABLE 3**
**Performance of the wireless, pregnancy monitor in the validation phase**

| | | WPM—all sessions | | | | WPM—with IUPC only | | | |
|---|---|---|---|---|---|---|---|---|---|
| Variable | Assessor | N | n | % | 95% CI | N | n | % | 95% CI |
| Positive agreement | Assessor 1 | 1106 | 1000 | 90.4 | 87.4–93.4 | 465 | 436 | 93.8 | 89.9–97.6 |
| | Assessor 2 | 1077 | 922 | 85.6 | 82.1–89.1 | 447 | 407 | 91.0 | 88.0–94.1 |
| | Assessor 3 | 1027 | 800 | 77.9 | 73.8–82.0 | 426 | 348 | 81.7 | 76.7–86.7 |
| | Total | 3210 | 2722 | 84.8 | 81.6–88.0 | 1,338 | 1,191 | 89.0 | 86.0–92.0 |
| False detection rate | Assessor 1 | 1501 | 501 | 33.4 | 30.1–36.6 | 660 | 224 | 33.9 | 29.1–38.8 |
| | Assessor 2 | 1133 | 211 | 18.6 | 15.6–21.7 | 504 | 97 | 19.3 | 14.9–23.6 |
| | Assessor 3 | 985 | 185 | 18.8 | 15.7–21.9 | 433 | 85 | 19.6 | 15.0–24.3 |
| | Total | 3619 | 897 | 24.8 | 22.0–27.6 | 1,597 | 406 | 25.4 | 21.3–29.6 |

*CI*, confidence interval; *IUPC*, intrauterine pressure catheter; *WPM*, wireless pregnancy monitor.
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the WPM ($P$=.9) or TOCO ($P$=.6) (Figure 4, B).

Each of the 3 blind assessors reported only 1.3% (1/78) of the overall WPM sessions as noninterpretable. For the TOCO sessions, the first assessor did not mark any session as noninterpretable (0/39), the second assessor found 15.4% (6/39) to be not interpretable, and the third assessor marked 5.1% (2/39). No device-related adverse events were reported.

## Comment

### Principal findings

A novel algorithm using maternal ECG and PCG signals successfully detected uterine contractions during labor, with a high positive agreement with the gold standard, IUPC. Moreover, in contrast to the TOCO, the performance of this innovative monitoring approach was not adversely affected by high BMI. As the device was designed as a self-applied and wireless pregnancy monitoring system, the added capability to detect uterine contractions outside the clinical setting raises the potential for this wireless device to perform remote NST and to serve as a novel telehealth tool for remote pregnancy monitoring. An earlier study demonstrated the WPM's ability to reliably detect maternal heart rates (MFRs) and FHRs.[24]

### Results

The WPM showed a high sensitivity for detecting uterine contractions during labor. In addition, in cases where only the IUPC and WPM were being used in the validation phase, the positive agreement was 89.0%, similar to the 88.4% agreement found during the training phase, potentially indicating that the addition of the TOCO sensors on the abdomen interfered with proper placement of the WPM belt. In direct comparison with the TOCO, the WPM showed a significantly higher contraction detection rate (81.78% vs 37.5%; $P$<.0001). Only 1 session (1.3%) with the WPM was deemed uninterpretable,

**TABLE 4**
**Performance of the wireless pregnancy monitor and tocodynamometer in the 3-way subgroup of the validation phase**

| | | WPM | | | | TOCO | | | |
|---|---|---|---|---|---|---|---|---|---|
| Variable | Assessor | N | n | % | 95% CI | N | n | % | 95% CI |
| Positive agreement | Assessor 1 | 641 | 564 | 88.0 | 83.8–92.2 | 641 | 308 | 48.1 | 36.9–59.2 |
| | Assessor 2 | 630 | 515 | 81.8 | 76.5–87.0 | 630 | 239 | 37.9 | 28.7–47.2 |
| | Assessor 3 | 601 | 452 | 75.2 | 69.3–81.2 | 601 | 155 | 25.8 | 16.6–34.9 |
| | Total | 1872 | 1,531 | 81.8 | 76.9–86.6 | 1872 | 702 | 37.5 | 28.2–46.8 |
| False detection rate | Assessor 1 | 841 | 277 | 32.9 | 28.5–37.4 | 345 | 37 | 10.7 | 5.9–15.6 |
| | Assessor 2 | 629 | 114 | 18.1 | 14.0–22.3 | 256 | 17 | 6.6 | 2.2–11.1 |
| | Assessor 3 | 552 | 100 | 18.1 | 13.9–22.3 | 185 | 30 | 16.2 | 8.1–24.4 |
| | Total | 2022 | 491 | 24.3 | 20.5–28.1 | 786 | 84 | 10.7 | 5.7–15.7 |

*CI*, confidence interval; *IUPC*, intrauterine pressure catheter; *TOCO*, tocodynamometer; *WPM*, wireless pregnancy monitor.
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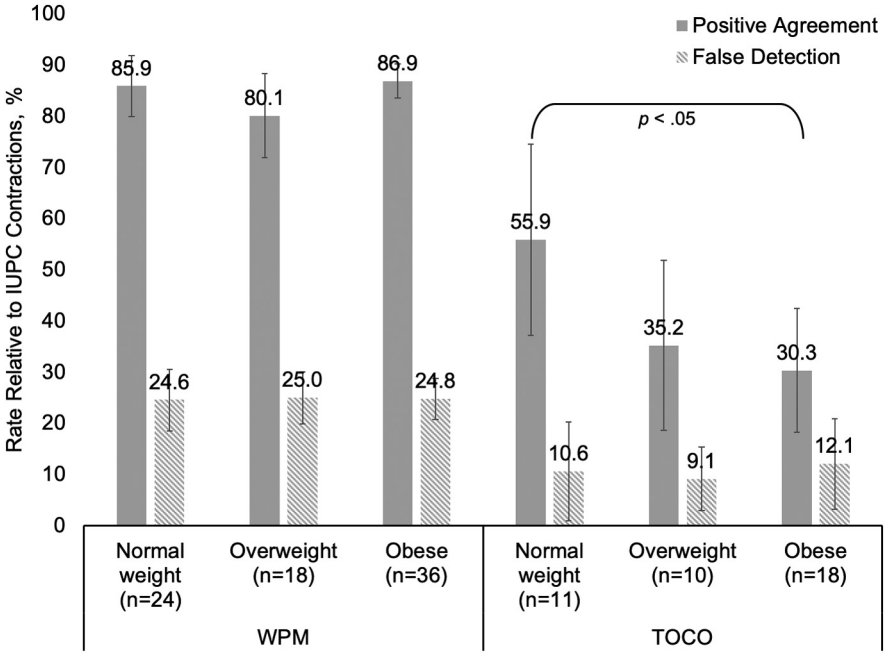
FIGURE 4
**BMI analysis**




The graph shows the overall positive agreement and false detection rates (averaged across 3 assessors) for the WPM and TOCO by prepregnancy BMI. *Error bars* show the 95% confidence intervals. The positive agreement for the TOCO was significantly lower in participants with obesity than those with normal weight ($P<.05$). Normal weight: BMI<25 kg/m$^2$; overweight: BMI≥25 to <30 kg/m$^2$; and obese: BMI≥30 kg/m$^2$.

*BMI*, body mass index; *IUPC*, intrauterine pressure catheter; *TOCO*, tocodynamometer; *WPM*, wireless pregnancy monitor.

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whereas 6.8% of the TOCO sessions were uninterpretable. When the same analysis was performed that excluded the TOCO uninterpretable cases, the overall results remained similar (data not shown).

The standard external TOCO device relies on the uterine contraction being strong enough to transmit a pressure change to the maternal abdominal wall, which can be impeded by sensor placement, maternal obesity, and maternal position and movement, thereby affecting both sensitivity and false detection rates.[2–8] Novel monitoring technologies that have greater sensitivity for uterine contractions often have a higher "false" detection rate as well. For example, noninvasive EHG devices that measure uterine biopotentials from abdominal surface electrodes were reported to have false-positive contraction rates of 8.0% to 21.3% relative to IUPC.[3–5,7,23,26] Here, the number of falsely identified contractions by the WPM compared with the IUPC was 15.3% for the training phase and 24.8% for the validation phase, which was higher than the false-positive rate for the TOCO in this study but in line with historic data for the TOCO.[2,4–7]

Despite the IUPC being considered the gold standard, it may not detect all uterine activities. In some cases, myometrial activation leads to the generation of an isobaric contraction[27] that does not alter the intrauterine pressure[28,29] but still results in a structural change that can alter the propagation of electrical and acoustic signals through the tissue.[30–33] Such a change may be detected by the abdominal sensors of the WPM; however, as these mechanical changes do not induce pressure changes, this activity would not be detected by IUPC and could be reported as a "false positive" for the WPM. Moreover, a similar phenomenon could explain the reported false detection rate from EHG-based devices, which are triggered by the myometrial electrical signal, even if no significant muscle contraction ensues.[23]

As the WPM is a passive device with no energy transmitted into the body, there are no known or expected adverse events directly related to its use.[24] There are possible adverse events related to any devices that apply sensors to the skin, such as edema, erythema, or irritation; however, none of these were reported with the WPM.

## Clinical implications

The WPM provides an innovative method for noninvasively monitoring uterine contractions, which was more reliable than the TOCO. EHG has been recently appraised for its increased sensitivity in detecting uterine contractions; however, technical challenges of this method remain, including determining the optimal electrode configuration and interelectrode distance, filtering other bioelectric signals and movement artifacts and skin impedance.[22,34–37] As the monitor is designed as a self-applied belt and can operate completely remotely from the clinic or hospital, this platform could address several unmet needs in pregnancy healthcare. Previously, we have validated the ability for reliable and accurate detection of maternal and FHR using the WPM, even in patients with a BMI up to 50 kg/m$^2$.[24] Reliable measurements of patients with obesity using the WPM were also obtained in the current study, whereas the performance of the commonly used TOCO was significantly affected by high BMI. These results point to the potential advantage of the WPM in intrapartum monitoring in women with obesity.

The ability to detect uterine contractions using a wireless device designed for patient self-administration greatly expands the potential clinical impact of this device as a remote monitoring platform and may facilitate moving some pregnancy care out of medical offices and hospitals and into the home. For example, outpatient inductions of

labor have been shown to reduce cesarean delivery rates.[38,39] The ability to remotely monitor patients at home may provide the necessary reassurance for providers and patients to offer such a service. In addition, many high-risk patients require serial outpatient NSTs[9] and must travel to a medical facility for staff to monitor the pregnancy. This can be quite burdensome to patients, many of whom have structural barriers to care that lead to health inequities.[40–42] Having a device that allows providers to remotely administer NSTs could revolutionize prenatal care delivery and foster a patient-centered approach.

## Research implications

As calls continue to grow for solutions to enable virtual prenatal care paradigms,[16–19] novel technologies may play a role in safely reducing healthcare costs by supporting distributed care models.[43,44] Remote pregnancy surveillance could support home triage of patient concerns (eg, decreased fetal movement) or even support dehospitalization of select patients who may be safely managed from home. For example, preterm premature rupture of membranes can be safely managed in the outpatient setting.[45–47]

In addition, the WPM sensors collect a rich set of data from the maternal-fetal environment that extend beyond the MHR, FHR, and uterine activity traces extracted by the algorithm. For example, FHR variability is a clinical marker of fetal well-being that can be measured noninvasively during pregnancy[48–50] and could be quantified by a future version of the WPM algorithm.

## Strengths and limitations

The study was strengthened by the 2-center design, the use of 3 independent and blinded assessors, and the use of a separate validation cohort to independently test the performance of the algorithm. Including only those women in labor who had an IUPC in place for monitoring contractions may be a limitation, as these patients are generally less mobile and their environment does not simulate the intended outpatient setting of remote monitoring. However, the IUPC is the gold standard for contraction monitoring. Furthermore, this cohort could have been skewed toward those whose contractions were not well traced by the TOCO, thereby necessitating the placement of an IUPC, which could underestimate the monitoring capability of the TOCO in this study. Another potential limitation was the need to simultaneously administer the WPM and TOCO for the 3-way analyses. Although TOCO placement was confirmed by a labor nurse, the placement of either (or both) devices could have been affected by the presence of the other. Such restriction may have contributed to the low sensitivity of the TOCO in this study and may explain the better sensitivity of the WPM in the 2-way group compared with the 3-way group.

## Conclusion

Uterine activity monitoring using the wireless noninvasive pregnancy monitoring device was more accurate than the commonly used TOCO and without the risks of an intrauterine sensor. Taken together with the existing FHR monitoring data, such wireless and remote capabilities may open the doors to much-needed telehealth solutions for pregnancy monitoring and management, offering novel healthcare protocols for both high- and low-risk pregnancies based on remotely administered NST. ■


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Data that underlie the results reported in this article will be considered for release for research purposes by the study sponsor on reasonable request through 2 years after publication of the manuscript. Requests for deidentified patient-level data may be submitted to amit.reches@nuvocares.com for review.

Portions of these data have been presented previously at the 41st annual meeting of the Society for Maternal and Fetal Medicine, held virtually, January 25—30, 2021.

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# Appendix

## Electrical uterine myography algorithm

A novel algorithm from the wireless remote pregnancy monitor (INVU, Nuvo Group Ltd, Tel Aviv-Yafo, Israel) detects uterine contractions based on the modulation of the maternal electrocardiogram (ECG) and phonocardiogram (PCG) signals captured by the 8 biopotential and 4 acoustic sensors of the pregnancy monitoring band. The electrical uterine myography (EUM) algorithm consists of 3 main stages. The first stage is performed on every 1-minute recording frame immediately after data collection, whereas the other 2 steps are accessed for the first time only after 10 full recording frames are completed, allowing a robust initial contraction detection considering the potential low occurrence rate of contractions. An overview of the algorithm is shown in Supplemental Figure 1.

## Algorithm steps

### Data preprocessing

Before converting them to a time series of peak modulation, both the ECG and PCG data go through the following processing steps: filtering, noise reduction, integrity check, and normalization. In addition, 5 distinct time series are created from each acoustic data channel by passing each channel through a set of high-pass filters with different cutoff frequencies, resulting in a set of 20 channels of acoustic data that differ in their spectral contents. The goal of this signal replication is to enable the search for uterine activity in data with more diverse characteristics, to improve weighting and selecting of the best surrogate EUM activity.

### Electrical uterine myography surrogate data preparation

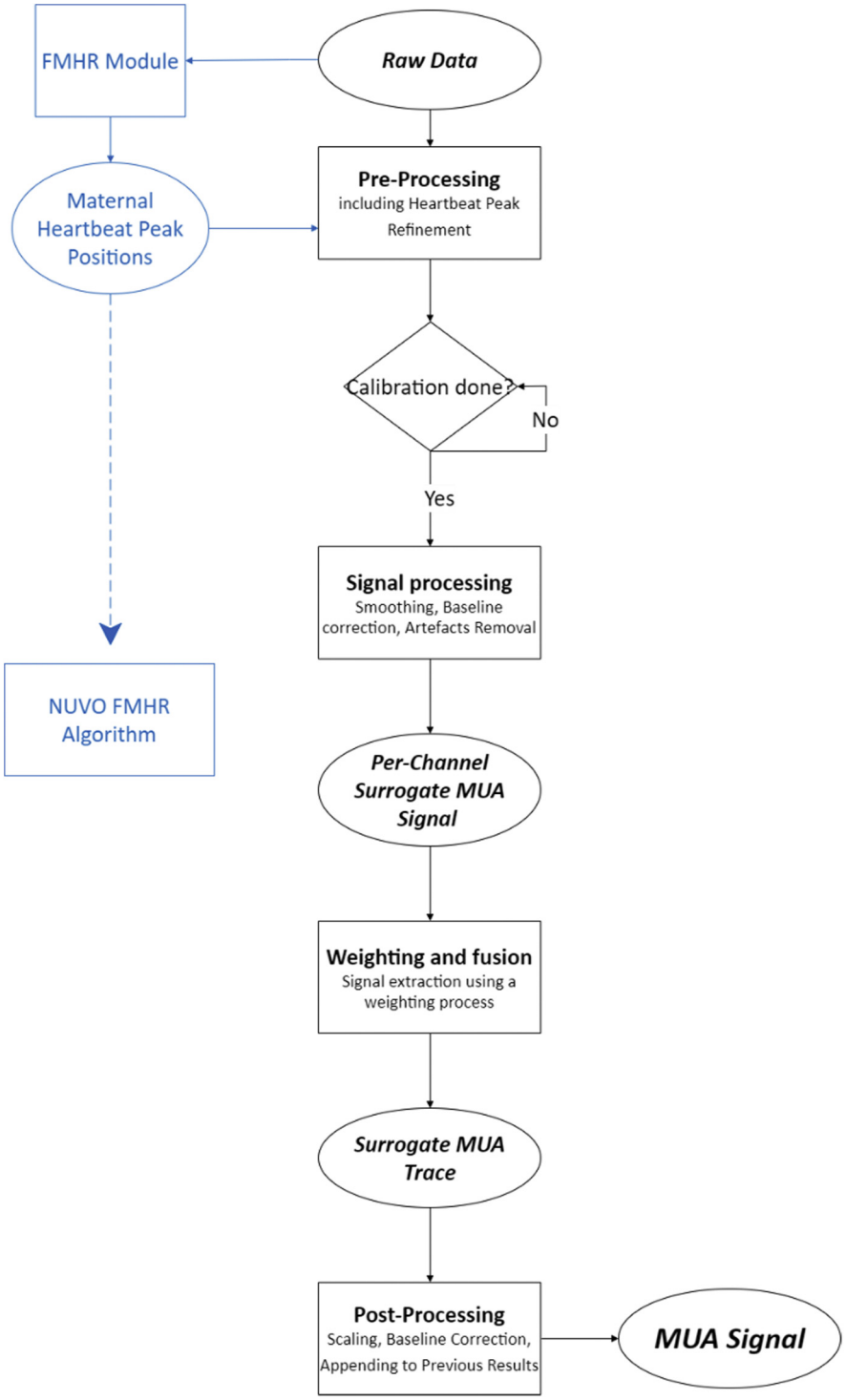
1. The timestamps of the heartbeat (HR) peaks (peaks related to both maternal QRS complexes and sound-based peaks from the lub-dub sounds of the PCG signal) are discrete and variable because of the natural HR variability. To process the peak data as a continuous time series, a cubic spline interpolation is performed on each channel's upward and downward peak values to produce a continuous time series of peak amplitude modulation. Moreover, for each channel, an initial surrogate EUM trace is produced by a simple addition of the interpolated time series of upward and downward pointing peaks and smoothing of this HR peak modulation signal using a moving root mean square filter.
2. For optimal contraction identification, channel data are fed into the contraction detector algorithm along with 2 supplementary versions of the signal, prepared ad hoc for the detection process: a smoothed version and an enhanced version. In this contraction identification module, the peaks are identified, outliers are marked, and small contractions are eliminated. Moreover, the remaining contractions are being enhanced.

### Fusion of the surrogate electrical uterine myography data from all channels into a finalized electrical uterine myography trace

1. The weighting process is designed to construct an optimal channel weights vector, by which the processed channels are then averaged to produce a single EUM trace. This weights vector is achieved by creating several sets of weights for different subsets of channels (with possible overlap) and selecting the best set of weights for the data matrix.
2. For each subset of channels, the process of weight construction starts with 2 series of initial weights (an all-equal weights vector and a vector of weights constructed according to scores given to each contraction by other traces) that will independently undergo optimization using gradient descent and enhancement.
3. After optimization, the 2 weight vectors will compete against each other (based on several signal measurements), and the set of weights selected to "represent" the channel subset will compete with the weights of the other channel subsets toward a selection of the final weighting vector.

After the EUM for the current 1-minute frame is extracted, it is appended to the previously extracted EUMs, to build a continuous EUM signal, except for the first 10 minutes used for calibration.

**SUPPLEMENTAL FIGURE 1**
**Maternal uterine contraction and FMHR algorithms**




Maternal uterine contraction algorithm (*black*) and FMHR algorithm (*blue*) components of the wireless remote pregnancy monitor are shown. *Rectangles* represent processes, *ovals* represent start or endpoints, and *diamonds* represent decision nodes. Details of the heart rate algorithm have been presented previously.[24]

*FMHR*, fetal and maternal heart rate; *MUA*, maternal uterine activity.

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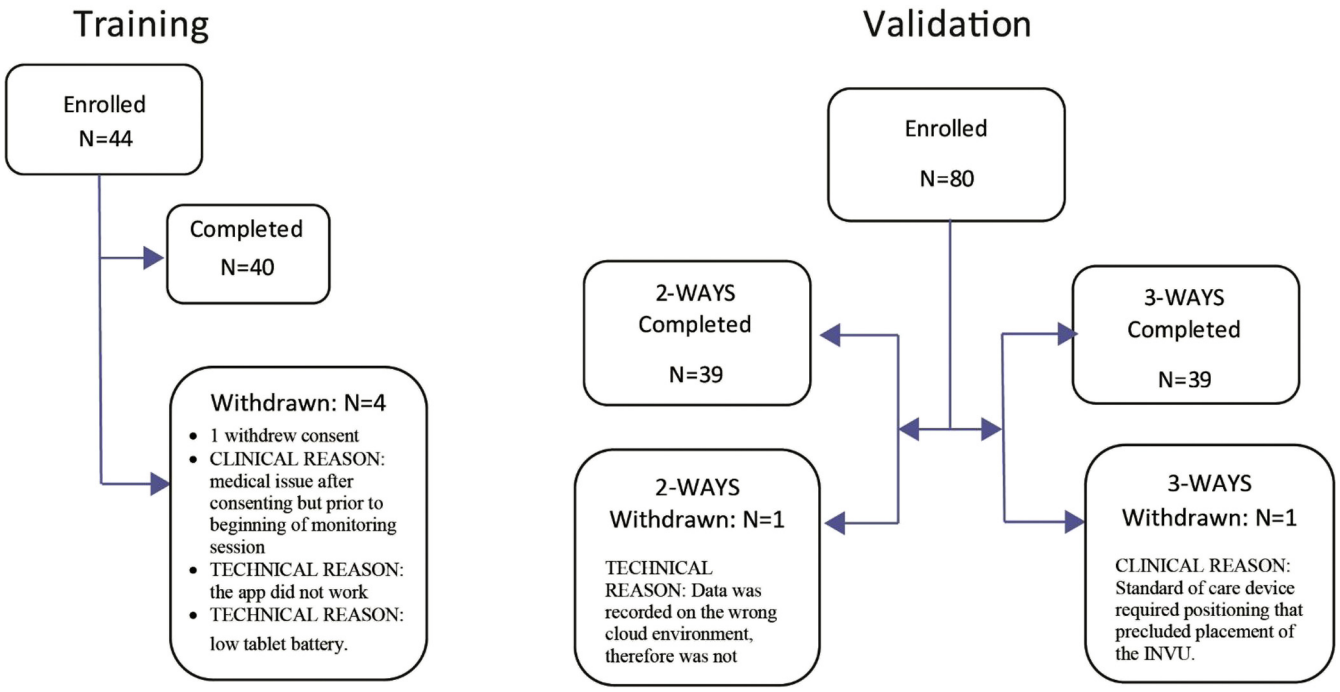
**SUPPLEMENTAL FIGURE 2**
**Disposition of subjects in the training and validation phases**

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