Electrohysterography for uterine monitoring during term labour compared to external tocodynamometry and intra-uterine pressure catheter

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TITLE PAGE

Title: Electrohysterography for uterine monitoring during term labour compared to external
tocodynamometry and intra-uterine pressure catheter

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Condensation: Electrohysterography is an innovative technique for external uterine monitoring that performs better than external tocodynamometry during first stage of labour, and in obese women.
ABSTRACT

Title: Electrohysterography for uterine monitoring during term labour compared to external tocodynamometry and intra-uterine pressure catheter

Authors: Vlemminx MWC, Thijssen KMJ, Bajlekov GI, Dieleman JP, van der Hout–van der Jagt MB, Oei SG.

Objective: Current uterine monitoring techniques have major drawbacks that could be avoided when using electrohysterography for uterine monitoring. Recently, a new electrohysterography method has been developed, providing a real-time tocogram on standard cardiotocography monitors. The diagnostic characteristics of this novel method need to be determined and compared to conventional methods. We hypothesised that electrohysterography can perform better than external tocodynamometry due to the adhesive properties of the contact electrodes (less motion sensitive), and the improved signal acquisition through subcutaneous tissue (less obesity sensitive).

Study design: In this prospective diagnostic accuracy study, uterine contractions of labouring women were simultaneously monitored by three different monitoring techniques: electrohysterography, external tocodynamometry, and intra-uterine pressure catheter as method of reference. We performed a two-hour measurement during first and/or second stage of term labour. The contractions of each method were automatically detected by a computer-based algorithm. As the applied method had not been described in literature before, an interim analysis was performed to minimise exposure to the invasive pressure catheter. The main outcome parameter was the sensitivity of electrohysterography in comparison to external tocodynamometry for uterine contraction detection, tested by the Wilcoxon signed rank test.

Results: Uterine contractions of 48 term labouring women were simultaneously monitored by electrohysterography, external tocodynamometry, and intra-uterine pressure catheter. The
study was terminated after the interim analysis as the sensitivity of electrohysterography was significantly higher compared to external tocodynamometry: median 89.5% (interquartile range (IQR); 82-93) and 65.3% (IQR; 53-81) respectively, \( p<0.001 \). In a subgroup analysis of obese women \( (n=15) \), the sensitivity of electrohysterography was significantly higher than external tocodynamometry (median 88.4% (IQR; 79-95) and 45.8% (IQR; 38-61) respectively, \( p<0.001 \)). Whereas in a subanalysis of second stage of labour \( (n=8) \), electrohysterography did not perform better than external tocodynamometry (median 72.8% (IQR; 61-87) and 66.4% (IQR; 46-75) respectively, \( p=0.225 \)). Electrohysterography registered 0.4 more contractions per 10 minutes than the intra-uterine pressure measurement \( (p<0.001) \) and 0.5 more contractions per 10 minutes than external tocodynamometry \( (p<0.001) \).

**Conclusion:** Electrohysterography has a higher sensitivity for uterine contraction detection than external tocodynamometry during first stage of labour, in non-obese and obese women. Electrohysterography identifies more contractions than conventional techniques.

**Clinical trial registry:** W3-study, Dutch Trial Registry, NTR5894


**Key words:**

Cardiotocography (MeSH); Electrohysterography; External tocodynamometry; Intra-uterine pressure catheter; Uterine monitoring (MeSH)
Introduction

Uterine monitoring is one of the main intrapartum measurements. Recording of contractions is necessary to monitor labour progress, to evaluate the fetal heart rate pattern, and to detect excessive uterine activity (1-3). Unfortunately, current methods have major drawbacks.

External tocodynamometry (TOCO) is the present method of choice, being non-invasive and easy to apply. Although, its performance is hampered by obesity and maternal movements (4). Bakker et al. found good quality monitoring in only 2% of 41 external recordings during the last two hours of first stage, and in 34% of these recordings in the second stage (5). The current alternative to TOCO is an intra-uterine pressure catheter (IUPC), which provides quantitative information (6). However, this invasive method requires ruptured membranes and carries rare but serious risks such as placental and uterine perforation (7, 8). For these reasons, an accurate non-invasive alternative to enhance labour assessment is desired.

Electrohysterography (EHG) is a promising non-invasive technique which measures the uterine electrical currents through contact electrodes at the maternal abdomen (9). Several EHG studies have demonstrated a high correlation with the intra-uterine pressure (IUP) (10, 11). Mathematical models and technical improvements of the 21st century have enabled EHG to be applied as a real-time method for uterine monitoring during term labour (12, 13).

The aim of this study is to evaluate the performance of a novel EHG method not described in literature before. It entails an innovative EHG technology that provides a real-time tocogram on standard cardiotocography monitors and is therefore ready for daily use. Our hypothesis is that EHG can perform better than TOCO due to the adhesive properties of the contact electrodes (less motion sensitive), and the improved signal acquisition through subcutaneous tissue (less obesity sensitive) (4, 14, 15).
Material and methods

In this diagnostic accuracy study, uterine contractions of pregnant women were simultaneously monitored using three tocographic techniques: 1) EHG, 2) TOCO, and 3) IUPC as the method of reference. Term labouring women carrying a singleton fetus in cephalic presentation were eligible to participate. Labour was defined as ≥3/10 min clinical contractions and ≥3 cm of dilation (2). Ruptured membranes and internal fetal monitoring were required to enable optimal placement of the external methods. Because of IUPC use, women at risk of infections were excluded: positive Group B streptococcus (urine or vagina), acute/chronic Hepatitis B or C, and HIV positive serology. Other exclusion criteria were: suspected placenta or vasa praevia, signs of intra-uterine infection or fetal distress, and abdominal dermatologic diseases.

Sensor-tipped IUPC’s were used (Koala, Clinical Innovations, Murray, Utah USA). Before insertion, an ultrasound was performed for placental localisation. Once placement in the amniotic cavity was established, both external methods were positioned.

EHG consisted of a single self-adhesive electrode patch connected to a translation module (Graphium and PUREtrace, Nemo Healthcare, Eindhoven, The Netherlands) (Figure 1). By manual palpation, we determined the optimal uterine interface (usually next to or above the umbilicus) and prepared the surface with abrasive sandpaper after which the patch was positioned. We measured the skin impedance (SIGGI II, MedCaT, Klazienaveen, Netherlands) and accepted values <5.0 kΩ. Next, data processing was performed by the translation module enclosing the following standard principles. Data from two independent electrodes were recorded at a 10 Hz sampling rate and combined into a single channel based on a physiological model of the myometrial conduction properties (12). The data were further processed by digital filtering techniques (which included a band pass filter between 0.3 and 0.8 Hz to suppress electrical activity from sources other than the uterus while preserving the
main contraction power) and converted into a measure for uterine activity correlating with the
IUP based on a mathematical model described by Rabotti et al. (12). The module sent the
processed signal to a cardiotocography (CTG) monitor as a ‘normal’ tocogram.

Finally, the attending nurse placed TOCO after manual palpation, to determine the
optimal position of the transducer at uterine fundus. The nurse wrapped the transducer tightly
around the abdomen with an elastic belt.

To record three tocograms, we installed two additional CTG-monitors (Avalon FM30,
Philips Healthcare, Eindhoven, The Netherlands). All monitors were connected to the
electronic patient record system for data storage and time synchronisation (EZIS, Chipsoft,
Amsterdam, the Netherlands, sampling frequency: 4Hz). The IUPC output was combined
with the fetal heart rate pattern and displayed to the obstetric team, while TOCO and EHG
were displayed on an extra monitor. During the two-hour measurement, relevant incidents
such as maternal movements, vaginal examinations or oxytocin modifications were annotated.
To simulate standard care, nurses checked TOCO recordings every 30 minutes and
repositioned if necessary. A registration of at least 30 minutes was sufficient. When two hours
were completed, only IUPC was continued until the delivery.

**Contraction detection**

We used a computer-based algorithm for contraction detection developed by the Eindhoven
University of Technology (MatLab R2016B, MathWorks, Natick, Massachusetts, USA). The
algorithm (Figure 2), based on earlier literature (16-18), was tested before the beginning of
our study. In our original protocol we described a minimum contraction duration of 30 s (16).
While IUPC was our reference method, test measurements revealed non-detection of some
IUPC contractions. Therefore, the duration threshold in the protocol was adjusted to 25 s for
all three methods. Successive values of baseline tone were determined in a three-minute
window and shifted with one-minute steps. Samples were recoded from the lowest to the highest value in each step. Hence, the threshold for contraction detection varied along with the amplitude of analysed signals. From the lowest 10% of samples, a mean value was calculated. We defined the threshold value by the baseline tone plus the value equal to 25% of signal range (i.e. difference between highest and lowest value) in the analysed window. The amplitude had to be >2x the threshold value (=50%). Furthermore, a contraction was only recognised if enduring 25-180 s above the 25% range. The output is available in Figure 2.

**Study outcomes**

The primary outcome was the sensitivity of EHG and TOCO for contraction detection defined as: true positive contractions in EHG or TOCO / contractions in IUPC * 100. We considered contractions as true positive when the contraction top was within 30 s from IUPC. Secondary study outcomes were: contraction frequency (per 10 minutes), positive predictive value, false positive/negative contraction ratio, and the contraction consistency index adopted from Jezewski et al. (17). A low consistency index means that the method over- or underestimates the frequency. Furthermore, we performed secondary group comparisons of non-obese to obese women and a comparison of the first and second stage of labour. Obesity was defined as a Body Mass Index (BMI) of ≥ 30 kg/m2 before pregnancy and the second stage of labour as from full dilation.

**Statistical analysis**

The performance characteristics of the tested EHG method have not been evaluated before. The power analysis was therefore based on two prior studies that compared different EHG-technologies with both IUPC and TOCO: Euliano 2013 and Hayes-Gill 2012 (14, 19). As the novel EHG method was expected to perform equally or better, we decided to perform an
interim analysis to minimise the number of women being exposed to the invasive IUPC. The sample size was calculated on a mean difference in sensitivity between EHG and TOCO of 19% (87% and 68% respectively), with a standard deviation of 30% (14, 19, 20). To detect this difference with a power of 80% and a type I error of 2.5% (for the interim analysis), a sample size of 48 women was determined. An independent gynaecologist performed the interim analysis.

Normality was tested using the Kolmogorov-Smirnov test. All paired parameters were analysed using a paired two-sided t-test for normally distributed data or the Wilcoxon signed rank test for not-normally distributed data. Differences between unpaired groups have been examined using an unpaired two-sided t-test for normally distributed data and the Mann-Whitney U-test for not-normally distributed data. The contraction frequency difference between EHG/IUPC and TOCO/IUPC were visualised in histograms. Two-sided p-values <0.05 were considered statistically significant. Statistical evaluations were conducted in SPSS 20 statistics for Windows (IBM, New York, USA). Obstetric parameters have been extracted from the patient record. In case of missing data, we only analysed the available data.

Ethical considerations

The Institutional Review Board of Máxima Medical Centre approved the protocol on the 15th of July 2014 (NL48951.015.14) and the study was registered in the Dutch trial register (NTR5894). All women signed informed consent. Researchers MV and KT recruited women exclusively in our hospital and carried out all measurements.
Results

A total of 48 term pregnant women were enrolled between July 2014 and September 2015. The interim analysis was performed in January 2016 and resulted in a $p$-value of $<0.001$ regarding the difference in sensitivity between EHG and TOCO, allowing us to terminate the study.

About 400 women were eligible for inclusion. Common reasons for non-participation were: not willing to be confined to bed, anxiety for their first delivery, and the IUPC risks. Twelve women signed informed consent, but were not measured because: labour went too quick (5/12), women were only willing to participate after epidural (3/12), no researcher was available (1/12), a woman was in too much pain (1/12) and in two cases the reasons were unknown. Of the 49 started measurements, one participant was excluded because she gave birth within the first 30 minutes of recording. There were no dropouts due to technical problems, no women lost during follow-up, no adverse events and no skin reactions. Of three women, the body weight during labour was unknown. There were no other missing data. The baseline characteristics are available in Table 1. Of the 48 included women, 58.5% were nulliparous, 70.8% had induction of labour, and 75.0% had labour analgesia. Figure 3 shows the results of three tocograms in one participant.

The median sensitivity of EHG was 89.5% (interquartile range (IQR); 82-93), which was higher than the median sensitivity of TOCO, 65.3% (IQR; 53-81), $p<0.001$ (Table 2). The contraction consistency index, even as the false positive and false negative contraction ratio were significantly better in EHG (Table 2). The EHG peak was 2.0 s later than IUPC, while the TOCO peak was 0.6 s before IUPC (Table 2).

On average, IUPC registered 3.8 contractions per 10 minutes. The EHG method registered 0.4/10min more compared to IUPC ($p<0.001$) and 0.5/10min more than TOCO ($p<0.001$) (Table 1). These ‘additional’ contractions in EHG are considered false positive in
further analyses. In the histograms presenting the difference in contraction frequency of the
external methods per women, EHG revealed an overall overestimation whereas TOCO
showed both an over- and underestimation varying per measurement (Figure 4).

Moreover, the sensitivity differences were consistent in the obesity analyses. EHG
performed significantly better than TOCO in both non-obese (n=33) and obese women (n=15)
(Table 2). Additionally, both techniques showed a decrease of sensitivity in case of maternal
obesity, whereas only TOCO was significantly affected: EHG median -1.6%, p=0.374 and
TOCO median -27.2%, p=0.001 (Table 2 and Figure 5).

Finally, we compared EHG and TOCO measurements in the first and second stage
(n=8). The median sensitivity of EHG was significantly lower during the second stage (-
18.5%, p=0.025), while TOCO was not significantly affected (-3.0%, p=0.123).
Comment

EHG demonstrated a high sensitivity for contraction detection and performed better than TOCO during the first stage, in non-obese and obese women. Additionally, the contraction frequency was higher in EHG compared to both conventional techniques.

The main strength is the study design. We applied three techniques simultaneously, used a computerised analysis for contraction detection, and the women were continuously observed. Moreover, unlike earlier studies, our participants were included irrespective of the available monitoring technique, such as indication for IUPC use or whether TOCO was working properly (14, 19, 20). Additionally, we are the first to evaluate the performance of this real-time EHG method, that can be used on standard monitoring systems.

We are aware of some limitations. We included more women with induction of labour and epidural analgesia which could have increased the sensitivity results. Furthermore, the subanalyses were performed in small groups which could compromise the statistical power. Yet, post-hoc calculation of the obesity analysis revealed a power of 100% for detecting the difference in sensitivity between EHG and TOCO.

Our study results agree with previous EHG studies showing that EHG can improve external uterine monitoring compared to TOCO (sensitivity between 86.0% and 94.2% for EHG and between 46.0% and 73.6% for TOCO) (14, 19, 21, 22). However, each EHG technology entails numerous technical aspects such as the electrode configuration, the applied filtering technique, and the type of skin preparation. Therefore, previous studies are not directly applicable to this EHG method.

IUPC is currently being considered as the gold standard. However, IUPC is not 100% reliable due to inadequate positioning in the amniotic cavity or due to relocation (especially in the second stage) (23, 24). Furthermore, a randomised controlled trial comparing IUPC with TOCO revealed no difference in the operative delivery rate (28). Yet, there was a high
crossover from TOCO to IUPC, especially in obese women, and women with a previous uterine scar were excluded.

Our study reveals that EHG detects more contractions than IUPC. The first explanation regards electrical artefacts, due to maternal movements, electrode detachment, and pressure on the patch. The investigated method configures these ‘artefact-based contractions’ in a specific waveform, which can be recognised by experienced users (Figure 6). In our EHG monitoring strips, we identified 50 artefacts of which 68% could be explained by mechanical causes. Yet, these artefacts covered only 11% of all the additional EHG contractions. Additionally, this first hypothesis is supported by a decreasing EHG sensitivity during the second stage. However, with exception of the amplitude in some cases, the EHG contraction waveforms did not significantly change during maternal pushing (see Figure 7).

The second explanation is that EHG reports the origin of contractions (electrical activity) instead of the global effect (IUP). These ‘extra’ contractions might represent local electrical activity, which is not conducted throughout the whole myometrium and therefore does not change the IUP. During our observations, some women reported pain which was accompanied by EHG activity while the IUP did not change. If this theory is correct, then EHG could provide extra information which should be considered when interpreting EHG-tocograms.

The described EHG method can be easily connected to standard CTG-monitors and provides a real-time tocogram. The average peak delay is two seconds compared to IUPC and is potentially due to data calculation. We consider this delay clinically irrelevant as the average contraction duration is one minute and late decelerations start more than twenty seconds after the contraction onset (3, 25).

Our main concern is that the uterine activity awareness might have decreased over years by a habituation to inadequate tocograms. Until there is sufficient cervical dilation and
ruptured membranes for I UPC, TO CO is currently the only available modality. Nonetheless, uterine monitoring is a key measure for labour progress and interpretation of the fetal condition (1, 6). Improvement of uterine monitoring could be of clinical benefit (26, 27), yet the fetal heart rate patterns in regard to the EHG tocogram have not been assessed. Therefore, the effect on perinatal outcome needs to be further investigated (27, 28).

In conclusion, EHG is a promising non-invasive alternative for uterine monitoring during term labour.
Conflicts of interest notification: Máxima Medical Centre is a research partner of Nemo Healthcare. Author professor Oei is gynaecologist and head of the obstetric department of Máxima Medical Centre and leader of the fundamental perinatology research group from Eindhoven University of Technology, the scientific research from which the described EHG method and the company Nemo Healthcare has originated. Professor Oei has no affiliations with or involvement in Nemo Healthcare with any financial interest. During the study, authors M.V., K.T., and B.vd.H. were paid by a grant of the independent Dutch Foundation ‘De Weijerhorst’. From 2016, author K.T. is being paid by a grant from the European Framework Research and Innovation Program ‘Horizon 2020’ (Grant number 719500). Authors G.B. and J.D. have no conflicts of interest.

Acknowledgement:
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Abbreviations:
- BMI = body mass index
- CTG = cardiotocography
- EHG = electrohysterography
- IUP = intra-uterine pressure
- IUPC = intra-uterine pressure catheter
- IQR = interquartile range
- TOCO = external tocodynamometry
References:


26. Lucovnik M, Kuon RJ, Garfield RE. Assessment of parturition with cervical light-


Supporting information figures

Figure 1: The applied electrohysterography method.
1A: Abdominal electrode patch and EHG translation module.
1B: Positioning of the patch at the maternal abdomen, which can be below, next to, or above the umbilicus for proper interface with the uterine muscle.

Figure 2: The algorithm and output of the computer-based contraction detection.
The left figure shows the applied algorithm for contraction detection. From the lowest 10% of samples, a mean value was calculated. The threshold value was defined by the baseline tone plus the value equal to 25% of signal range (i.e. difference between highest and lowest value) in the analysed window. The amplitude had to be >2x the threshold value (=50%). Furthermore, a contraction was only recognised if enduring 25-180 s above the 25% range.
The output (right) represents 30 minutes of registration with intra-uterine pressure catheter (y-axis in millimetre of Mercury). The peaks are marked in seconds from the beginning of the measurement. Underneath the contractions are three rows of blocks. From top to bottom, these blocks represent: 1) actual contraction detection, 2) value equal to or more than 50% of signal range, and 3) value equal to or more than 25% of the signal range.

Figure 3: The result of real-time uterine monitoring with three different tocographic techniques in one pregnant woman.
The figure represents a measurement of 15 minutes. From top to bottom, the lines represent: fetal heart rate, intra-uterine pressure catheter, electrohysterography and external tocodynamometry.
Figure 4: Histograms showing the average differences in contraction frequency of electrohysterography and external tocodynamometry by comparison to the intra-uterine pressure catheter.

The vertical line (zero) represents a perfect correlation in number of contractions/10 minutes between the external methods and IUPC. On average, IUPC registered 3.8 contractions per 10 minutes. The EHG method registered 0.4 contractions per 10 minutes more compared to IUPC (p<0.001) and 0.5 per 10 minutes more than TOCO (p<0.001).

(EHG, electrohysterography; TOCO, external tocodynamometry; IUPC, intra-uterine pressure catheter)

Figure 5: Sensitivity of electrohysterography and external tocodynamometry in pregnant women with and without maternal obesity.

The box plots represent the interquartile range from the 25th till the 75th quartile and the horizontal line in the box shows the median. Each box is lined by the minimum and maximum. The circles are cases with outlying values, whereas the asterisk is a case with an extreme outlying value. In case of maternal obesity, both techniques showed a decrease in median sensitivity, EHG -1.6%, p=0.374 and TOCO -27.2%, p=0.001.

(EHG, electrohysterography; TOCO, external tocodynamometry)

Figure 6: Artefact in an electrohysterography tocogram.

An artefact can be recognised by a small and steep contraction with a horizontal flat top. In this electrohysterography tocogram, the middle contraction represents an artefact.

Figure 7: Electrohysterography during the second stage of labour.
The figure represents a study measurement of 30 minutes. The labouring woman started pushing in the middle of this cardiotocogram, after which no significant change of the tocogram was observed. The lines from top to bottom represent: fetal heart rate, intra-uterine pressure catheter, electrohysterography, and external tocodynamometry.
Table 1. Overview of the sociodemographic and clinical characteristics of the pregnant women that were simultaneously monitored with electrohysterography, external tocodynamometry and intra-uterine pressure catheter.

<table>
<thead>
<tr>
<th>Patient characteristic</th>
<th>Pregnant women n=48</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age (y)</td>
<td>31.9±4.1</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>45 (93.8)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (6.3)</td>
</tr>
<tr>
<td>Body mass index (kg/m2)</td>
<td></td>
</tr>
<tr>
<td>Before pregnancy</td>
<td>28.5±8.0</td>
</tr>
<tr>
<td>During measurement</td>
<td>32.8±6.8</td>
</tr>
<tr>
<td>Parity</td>
<td></td>
</tr>
<tr>
<td>Nulliparous</td>
<td>28 (58.3)</td>
</tr>
<tr>
<td>Multiparous</td>
<td>20 (41.7)</td>
</tr>
<tr>
<td>Gestational age (weeks+days)</td>
<td>39±3 (37+1 - 41+6)</td>
</tr>
<tr>
<td>Start of labour</td>
<td></td>
</tr>
<tr>
<td>Spontaneous onset</td>
<td>14 (29.2)</td>
</tr>
<tr>
<td>Induction of labour</td>
<td>34 (70.8)</td>
</tr>
<tr>
<td>Oxytocin usage</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>12 (25.0)</td>
</tr>
<tr>
<td>Yes</td>
<td>36 (75.0)</td>
</tr>
<tr>
<td>Labour analgesia</td>
<td></td>
</tr>
<tr>
<td>No analgesia</td>
<td>12 (25.0)</td>
</tr>
<tr>
<td>Epidural analgesia</td>
<td>33 (68.8)</td>
</tr>
<tr>
<td>Remifentanil</td>
<td>3 (6.3)</td>
</tr>
<tr>
<td>Duration measurement (min)</td>
<td>105.1 (30-150)</td>
</tr>
<tr>
<td>Cervical dilatation (cm)</td>
<td></td>
</tr>
<tr>
<td>Start measurement</td>
<td>4.9 (3-10)</td>
</tr>
<tr>
<td>Stop measurement</td>
<td>7.6 (3-10)</td>
</tr>
<tr>
<td>Mode of delivery</td>
<td></td>
</tr>
<tr>
<td>Spontaneous vaginal delivery</td>
<td>32 (66.7)</td>
</tr>
<tr>
<td>Vacuum delivery</td>
<td>7 (14.6)</td>
</tr>
<tr>
<td>Caesarean delivery</td>
<td>9 (18.8)</td>
</tr>
<tr>
<td>Neonatal birthweight (g)</td>
<td>3 550.2±503.5</td>
</tr>
<tr>
<td>Detected contractions (number total)</td>
<td></td>
</tr>
<tr>
<td>Intra-uterine pressure catheter</td>
<td>1 902</td>
</tr>
<tr>
<td>Method</td>
<td>Mean Frequency (cesation/10min)</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Electrohysterography</td>
<td>4.2 ± 0.5&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Intra-uterine pressure catheter</td>
<td>3.8 ± 0.7</td>
</tr>
<tr>
<td>Electrohysterography</td>
<td></td>
</tr>
<tr>
<td>External tocodynamometry</td>
<td></td>
</tr>
</tbody>
</table>

Data are mean ± standard deviation, mean (range), n, or n (%) unless otherwise specified.

<sup>a</sup> p<0.001 electrohysterography compared to intra-uterine pressure catheter and external tocodynamometry, two-sided paired student t-test
Table 2. The diagnostic characteristics of electrohysterography for uterine contraction detection during term labour in comparison to external tocodynamometry, with the intra-uterine pressure catheter as method of reference.

<table>
<thead>
<tr>
<th>Diagnostic characteristic</th>
<th>EHG</th>
<th>TOCO</th>
<th>Difference</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity overall (n = 48) (%)</td>
<td>89.5 (82-93)</td>
<td>65.3 (53-81)</td>
<td>24.2</td>
<td>&lt;0.001a</td>
</tr>
<tr>
<td>-- Sensitivity non-obese women (n = 33) (%)</td>
<td>90.0 (86-93)</td>
<td>73.0 (59-87)</td>
<td>17.0</td>
<td>&lt;0.001a</td>
</tr>
<tr>
<td>-- Sensitivity obese women* (n = 15) (%)</td>
<td>88.4 (79-95)</td>
<td>45.8 (38-61)</td>
<td>42.6</td>
<td>0.001a</td>
</tr>
<tr>
<td>-- Sensitivity first stage (n = 8) (%)</td>
<td>91.3 (88-98)</td>
<td>69.4 (63-89)</td>
<td>21.9</td>
<td>0.018a</td>
</tr>
<tr>
<td>-- Sensitivity second stage** (n = 8) (%)</td>
<td>72.8 (61-87)</td>
<td>66.4 (46-75)</td>
<td>6.4</td>
<td>0.225a</td>
</tr>
<tr>
<td>Contraction consistency index† (n = 48) (%)</td>
<td>85.9 (73-90)</td>
<td>65.1 (52-84)</td>
<td>20.8</td>
<td>&lt;0.001a</td>
</tr>
<tr>
<td>Positive predictive value (n = 48) (%)</td>
<td>80.8 (64-90)</td>
<td>67.2 (52-86)</td>
<td>13.6</td>
<td>&lt;0.001a</td>
</tr>
<tr>
<td>False positive contraction ratio‡ (n = 48) (%)</td>
<td>19.2 (10-36)</td>
<td>32.8 (14-48)</td>
<td>13.6</td>
<td>&lt;0.001a</td>
</tr>
<tr>
<td>False negative contraction ratio‡ (n = 48) (%)</td>
<td>9.8 (6-15)</td>
<td>33.6 (18-52)</td>
<td>23.8</td>
<td>&lt;0.001a</td>
</tr>
<tr>
<td>Top of contraction (n = 48) (sec)</td>
<td>2.0±4.0</td>
<td>-0.6±4.7</td>
<td>2.6</td>
<td>0.002b</td>
</tr>
</tbody>
</table>

* Maternal obesity was defined as BMI > 30 kg/m² before pregnancy.
** Second stage was defined as from full dilation.
† Contraction consistency index = true positive contractions in EHG or TOCO / (0.5*(contractions in IUPC + contractions EHG or TOCO).
‡ False positive and false negative contraction ratios = false positive or false negative contractions respectively / total contractions in EHG or TOCO *100.

EHG, electrohysterography; TOCO, external tocodynamometry

Data are median with (interquartile range) or mean with ± standard deviation (outliers included).

Wilcoxon Signed rank test. Two-sided paired student t-test.
Contraction frequency difference of TOCO in comparison to IUPC (per 10 minutes)