A Novel Non Invasive Technology for Contraction Monitoring in Parturient Women—Can it Replace Invasive Intrauterine Pressure Catheter?

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Abstract

Introduction
Monitoring of uterine wall activity using tocometry is occasionally cumbersome. A non-invasive innovative device that uses Electrohysterography (EHG), to measure the specific electrical activity of the uterine muscle, was recently introduced. (PURE trace-Nemo Healthcare Inc.). We aimed to study the validity of this novel technology in comparison to the use of Intrauterine pressure catheter (IUPC).

Method
A prospective preliminary study including, women in active labor who had IUPC for assessment of labor progress. Uterine activity was depicted for each participant by both IUPC and EHG. Exclusion criteria included non-vertex presentation and abdominal skin irritation. Uterine activity detected by EHG was compared to IUPC by the use of a contractions consistency index calculation (CCI).

Results
Ten women at term were included in the analysis: four nulliparous and three multiparous women. All patients had labor augmentation with oxytocin after insertion of IUPC. Seven women had spontaneous vaginal delivery, two had vacuum extraction and one woman had an urgent cesarean delivery due to uterine rupture. In three women the EHG record keeping was not interpretable due to the mal alignment of the device to the patient's skin. Uterine activity recordings from all six remaining women well complied with IUPC tracings (CCI above 0.92). No inconvenience was reported by the patients.

Conclusions
Electrohysterography may provide a non-invasive and accurate means for assessment of uterine contractions. Optimal training of the operating team is needed for proper device assembly.

Keywords: Electrohysterography; Intrauterine pressure catheter; Tocometry; Uterine contractions

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Introduction

Tocometry measures contractions of the abdominal wall which indirectly represents the activity of the uterine muscle and thus is frequently inaccurate [1]. Tocometry needs to be allocated to the center of the maternal fundus. Frequent position change during labor or thick abdominal wall may cause Tocometry to be unreliable. The commonly used alternative is an invasive intrauterine pressure catheter monitor (IUPC). The IUPC may be applied into the uterine cavity only after rupture of the membranes. It is invasive and unpleasant to the woman and may carry rare but hazardous complications such as placental abruption and uterine rupture [2,3]. The need for a more accurate and non-invasive method to trace uterine activity led to the search for a modern technology that will assess contractions. Recently, an innovative electrohysterographic (EHG) abdominal wall device was introduced as an alternative to the standard intrauterine sensors [4,5]. Contraction s of the muscle create small changes in the electrical potential across the cell walls. During contractions, the electrical activity of the uterine muscle can be measured via the maternal abdominal wall. EHG has been developed to measure the specific electrical muscle activity of the uterus, and may offer highly accurate information that correlates with existing invasive measurement methods for uterine contractions; the IUPC. Vlemminx et al. [6], showed that EHG also appears to report a more detailed tocographic waveform, like hypertonia or unorganized electrical uterine activity.

The EHG uses a Graphium electrode patch applied to the abdominal skin and records electrical activity. Its' module amplifies and converts these signals to a recognized monitoring diagram for uterine activity, as commonly used in tocometry. This measurement is independent of the Body-Mass-Index, abdominal wall thickness or maternal position [7].

By using the Graphium electrode patch the patient comfort increases significantly when compared to other measurement methods. The patch does not require repositioning over time. It provides a safe and patient-friendly alternative for measuring uterine activity, and connects to the existing fetal monitoring infrastructure.

Nemo Healthcare is ISO 13485 certified. All products of Nemo Healthcare are CE-marked and comply with the stringent quality requirements for medical devices [8]. It is already marketed commercially in Europe and has been approved by, the committee for medical devices of the Israeli ministry of health [9].

We investigated the validity of the electrohysterographic device in comparison to the intrauterine pressure catheter in order to promote less invasive management protocols, for the detection of uterine function.

Materials and Methods

An own case control prospective study in a tertiary medical center during May 2015. Women in dysfunctional active labor, who met the local protocol criteria for insertion of intrauterine pressure catheter (previous uterine scar, multifetal pregnancy, or grand multiparity) were recruited. Exclusion criteria included non-cephalic presentation or abdominal skin irritation. Primary outcome measure was the validity of real-time electrohysterography to monitor uterine contractions in pregnant women during labor compared to the recordings of the IUPC. Final delivery mode (spontaneous, instrumental, caesarean) and fetal characteristics (Apgar score at 0, 5 minutes) were recorded and assessed as secondary outcomes.

Medical history and demographic parameters, including - maternal age, Body Mass Index(BMI), parity, gravity, past medical history, previous abdominal surgeries, estimation of fetal weight, amniotic fluid index, placental location, pelvic and cervical examinations during labor were recorded.
All women were connected to both IUPC and EHG, making their own control. Randomization, blinding and treatment allocation were not applicable. The devices were connected to two similar Tocometry monitors (AVALON FM 20 PHILIPS) that were synchronized before starting the script.

Analysis

Uterine activity was obtained for PURE trace and IUPC separately. After alignment, tracings have been scanned and evaluated for each 45 minutes of script. Contractions were considered consistent when the peak of a contraction recorded by the EHG was within 30 seconds from the contraction depicted by the IUPC. The graphs were compared and analyzed for their frequency and intensity of contractions by Nemo healthcare staff in the Netherlands. A qualitative analysis was provided. Sensitivity was calculated as the percentage of correctly identified contractions by EHG that were simultaneously detected by an intrauterine pressure catheter. Positive predictive value was determined as: true positive / (true positives + false positives), while true positive contractions were consistent contractions elicited both by IUPC and EHG, and false positive contractions were contractions detected solely by EHG.

A modification of the Contractions Consistency Index was used, defined by Jezewski et al. [7], to compare EHG to the gold standard, IUPC. CCI=Nc/(0.5 (Nt + Ne)) (Nc=number of consistent contractions by both IUPC and EHG, Nt=number of contractions detected by IUPC and Ne=number of contractions detected by EHG). A low contraction consistency index means that EHG either over- or underestimates the number of contractions. Descriptive statistics was used to summarize subject characteristics and examine variable distributions.

Results

Ten women were included in the analysis: 4 nulliparous and 3 multiparous gravida. The median BMI was 28.05 kg/m² (Range 22.9-35.8), 4 patients were above 30 kg/m² and one with BMI 35.8 kg/m². The median gestational age was 39 (Range: 35.6-41.1) weeks. Demographic characteristics of the subjects are listed in Table 1. All patients were treated with oxytocin after insertion of IUPC and had epidural analgesia. The cumulative tracing recordings were 1800 min, with a median of 292.5 min per patient (Range: 180-450).

Seven women had spontaneous vaginal delivery, two had vacuum extraction due to non-reassuring fetal monitoring and one woman had an urgent cesarean delivery due to non-reassuring fetal monitoring and was found to have uterine rupture. Descriptive analysis found 99.1% sensitivity and 91.9% PPV. All six women with interpretable script, had CCI above 0.92 and 4 of them above 0.96 suggesting high validity and close approximation to the intrauterine pressure catheter signal (Table 2). One woman had an emergency cesarean delivery and was found to have uterine rupture. Both IUPC and EHG showed no uterine activity immediately prior to the urgent surgery.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Median</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Weight (Kg)</td>
<td>77.10</td>
<td>63-101</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>28.05</td>
<td>22.9-35.8</td>
</tr>
<tr>
<td>Gravidity</td>
<td>3</td>
<td>1-8</td>
</tr>
<tr>
<td>Parity</td>
<td>1</td>
<td>0-5</td>
</tr>
<tr>
<td>Birth Weight (grams)</td>
<td>3217</td>
<td>2340-3785</td>
</tr>
<tr>
<td>Apgar 1 min</td>
<td>9</td>
<td>8.9</td>
</tr>
<tr>
<td>Apgar 5 min</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Duration of monitoring (min)</td>
<td>292.5</td>
<td>180-450</td>
</tr>
<tr>
<td>IUPC contractions (n)</td>
<td>46</td>
<td>35-81</td>
</tr>
<tr>
<td>EHG contractions (n)</td>
<td>40</td>
<td>39-81</td>
</tr>
</tbody>
</table>

BMI-Body Mass Index, IUPC-Intra Uterine Catheter, EHG-Electrohysterography

**Table 1**: Subject Characteristics (n=10)
Table 2: Descriptive analysis comparing contractions detected by EHG to those detected by IUPC

<table>
<thead>
<tr>
<th>Patient no.</th>
<th>Contractions in IUPC (n)</th>
<th>Contractions in EHG (n)</th>
<th>a CCI</th>
<th>Sensitivity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-</td>
<td>-</td>
<td>NI</td>
<td>NI</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>-</td>
<td>-</td>
<td>NI</td>
<td>NI</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td>13</td>
<td>UR</td>
<td>UR</td>
<td>UR</td>
</tr>
<tr>
<td>4</td>
<td>81</td>
<td>81</td>
<td>1.00</td>
<td>100.00</td>
<td>100.0</td>
</tr>
<tr>
<td>5</td>
<td>-</td>
<td>-</td>
<td>NI</td>
<td>NI</td>
<td>-</td>
</tr>
<tr>
<td>6</td>
<td>43</td>
<td>40</td>
<td>0.96</td>
<td>93.00</td>
<td>100.00</td>
</tr>
<tr>
<td>7</td>
<td>35</td>
<td>40</td>
<td>0.93</td>
<td>100.00</td>
<td>87.50</td>
</tr>
<tr>
<td>8</td>
<td>74</td>
<td>79</td>
<td>0.96</td>
<td>100.00</td>
<td>93.70</td>
</tr>
<tr>
<td>9</td>
<td>49</td>
<td>52</td>
<td>0.97</td>
<td>100.00</td>
<td>94.20</td>
</tr>
<tr>
<td>10</td>
<td>37</td>
<td>39</td>
<td>0.92</td>
<td>100.00</td>
<td>94.90</td>
</tr>
<tr>
<td>Total</td>
<td>319</td>
<td>344</td>
<td>0.95</td>
<td>99.05</td>
<td>91.86</td>
</tr>
</tbody>
</table>

CCI=Nc / (0.5 (Nt + Ne))

Discussion

This study challenges the IUPC as the only modality that accurately detects uterine activity. We included 10 women who had cumulative tracing recordings for 1800 min with a median of 292.5 min per patient. We found that when recording was adequate, CCI was above 0.92 and for the majority above 0.96.

Tocometry is the most commonly used device to monitor uterine contractions, however, it is considered unreliable and inaccurate. It identifies the frequency of contractions, but not their intensity, and suffers both from misalignment following maternal movement and technical limitations in obese parturients [7]. Bakker et al. [1] describe some period of “inadequate registration” (no tracing or unreliable pattern due to inadequate calibration) in 98% of 41 labors, for an average of 35% of stage-one duration and 33% of stage-two.

Few studies comparing EHG with tocometry already demonstrated the superiority of electrohysterography for uterine contraction detection during active labor [10,11]. Euliano et al. [7] conducted the first study that compared EHG with standard technologies, external tocometry and intrauterine pressure catheter, during active labor (n=59). EHG performed significantly better than external tocometry with regard to the Contractions Consistency Index [7] 0.88 ± 0.17 and 0.69 ± 0.27, (p<0. 0001), respectively. Sensitivity was significantly increased with the use of EHG compared with external tocometry: 89% and 62%. They concluded that tocometry does not correlate well with the gold-standard IUPC and fails more frequently in obese patients. EHG provides a reliable non-invasive alternative regardless of body habitus. These findings are important in the obese parturient where adequate monitoring has special importance considering their increased risk for labor complications [12-15]. Today, the only possible management in these patients is using the gold standard treatment and inserting IUPC. However, according to our findings EHG could serve a comparable alternative.

Studies evaluating the accuracy of the
Electrohysterography in comparison to IUPC are limited. Jacob et al. conducted a prospective study including 32 women at labor and examined the validation of EHG compared to IUPC recordings. EHG detected uterine contractions accurately with sensitivity of 94.5%, PPV 88.3% compared to IUPC [16]. These findings correlates well with our findings of superior sensitivity and PPV [15,16].

Patient number 3, was indicated for IUPC insertion according to local protocol due to trial of labor after cesarean (TOLAC). She previously had three successful vaginal births after cesarean (VBAC). During labor both methods did not show any activity of the uterine muscle. Following this observation and the concern of the medical staff for uterine rupture, the woman had urgent cesarean delivery and uterine rupture was diagnosed.

The EHG technology is operator dependent. Before connecting the Graphium patch, the skin should be gently brushed with a delicate abrasive paper, removing the superficial layer from the epidermis to conceive a more accurate electrical signal. The preparation of the skin is crucial for getting an adequate script. The tracings of three patients in this study were not adequate for interpretation, due to improper preparation of the skin before connecting the Graphium patch. Following the study, a team from Nemo Healthcare trained our personnel using measurements of skin impedance in order to achieve better quality of monitoring.

The major weakness of EHG is the inability to quantify uterine activity by the use of Montevideo units (MVU) as measured by IUPC. In cases where delivery is augmented, calculating the total MVU of uterine contraction supports the proper titration of oxytocin augmentation. Nevertheless, studies show no correlation between MVU and delivery outcome. Mol et al. [17] compared monitoring uterine contractions with an intrauterine pressure catheter (IUPC) versus external monitoring and demonstrated that use of an IUPC did not improve the outcome of labor. In the lack of a positive effect, they evaluated level of IUP in Montevideo units (MVU) in correlation with dysfunctional labor and adverse neonatal outcome and found no improvement in birth outcomes. Lately, Maggio et al. [18] showed no correlation between MVU and the risk for uterine rupture in women treated with oxytocin for trial of labor after cesarean section.

We concluded that Electrohysterography may provide non-invasive and safe means of assessing uterine contractions, comparable with IUPC. However, further studies should be done to strengthen these observations and to learn how to quantify contraction intensity that is lacking today in this modality. Optimal training of the operating team is crucial for high quality monitoring. This will allow better assessment of EHG accuracy hopefully leading to less invasive procedures in delivery room and minimizing potential complications. The use of EHG may be found beneficial in the diagnosis of uterine rupture during labor.

Compliance with Ethical Standards
All authors declare that they have no conflict of interest. Kirsten Thijssen is employees of Nemo health care. All procedures performed in this study were in accordance with the ethical standards of the institutional research ethical committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Material is based upon work supported by the National Institutes of Health (NCT02374151). Informed consent was obtained from all individual participants included in the study.

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References


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