A comparison between electrical uterine monitor, tocodynamometer and intra uterine pressure catheter for uterine activity in labor

Eran Hadar\textsuperscript{1,2}, Tal Biron-Shental\textsuperscript{2,3}, Oz Gavish\textsuperscript{1,2}, Oded Raban\textsuperscript{1,2}, and Yariv Yogev\textsuperscript{1,2}

\textsuperscript{1}Helen Schneider Hospital for Women, Rabin Medical Center, Petach Tikva, Israel, \textsuperscript{2}Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel, and \textsuperscript{3}Department of Obstetrics and Gynecology, Meir Medical Center, Kfar Saba, Israel

Abstract

Objective: We aimed to evaluate the performance of a non-invasive EMG electrical uterine monitor (EUM) versus tocodynamometry (TOCO) by comparing both to internal uterine pressure catheter (IUPC).

Study design: Prospective observational trial. Uterine activity was recorded continuously and simultaneously, in women during active term labor, with TOCO, EUM and IUPC. Uterine activity tracings were analyzed by three blinded physicians.

Results: Overall, 385 tracings from 43 women were analyzed. A similar rate of interpretable tracings between physicians was demonstrated for EUM (87%; 95% CI 80.9–92.7%) and IUPC (94.8%; 95% CI 83.4–96.3%), with a significantly lower rate for TOCO (67.5%; 95% CI 59.4–76.8%, \(p < 0.001\)). There is a significant difference in the contraction frequency for EUM versus IUPC (0.77 ± 2.3) compared to TOCO versus IUPC (\(\bar{C}0.34 ± 4.97\)). There is a high variability between the timing of TOCO contractions as compared to IUPC (4.74 ± 10.03 seconds), while a gap of 8.46 ± 4.24 seconds was detected for EUM. The sensitivity, positive predictive value and false positive rate for individual contraction identification by TOCO and EUM are 54.0%, 84.4%, 15.6% and 94.2%, 87.6%, 12.4%, respectively.

Conclusion: EUM is efficient as IUPC for uterine activity assessment and both techniques are superior in comparison to external tocodynamometry. Our results support the use of non-invasive EMG technology to monitor uterine activity.

Keywords

Contractions, EMG, electrical uterine monitor, internal uterine pressure catheter, labor, tocodynamometer

Introduction

Assessment of uterine activity is a key component in monitoring the process of active labor [1]. The common practice to evaluate uterine contractility is by external tocodynamometry (TOCO). It is non-invasive and can be carried throughout all stages of labor. However, it is limited by the lack of quantitative measurement of contraction intensity, and by providing only a single measure of global (rather than topographic) uterine pressure [2].

The gold standard for assessing uterine pressure is the intra-uterine pressure catheter (IUPC), which provides a quantitative measurement of intra-uterine pressure [3,4]. However, it is limited by being invasive and that it may be deployed only following rupture of membranes. Although some clinical guidelines [5,6] advocate for selective utilization of IUPC, its use has not been associated with improved pregnancy outcome [7,8] and rare complications have been reported [9].

An alternative method of assessing uterine activity is by measurement of uterine electrical activity via electromyography (EMG). This can be achieved invasively into the uterine muscle or non-invasively through the abdominal wall surface [10–19]. While most traditional EMG devices utilize only two electrodes, new multi-channel, non-invasive EMG devices have been recently introduced [20–24]. Such technology provides not only a quantitative measurement, but also a topographic characterization of uterine electrical activity. Recent data suggest that non-invasive multi-channel uterine electrical activity measurements are as good as IUPC for monitoring uterine contractility [20] and that it may be correlated to the risk of preterm labor [21,22].

We hypothesized that assessment of intrapartum uterine activity by EMG will be as good as an assessment by TOCO. Our aim was to evaluate the performance of the EUM-100 (a non-invasive multi channel EMG electrical uterine monitor, EUM) versus TOCO, by comparing both to IUPC, and to demonstrate that EUM technology in not inferior to TOCO.

Materials and methods

We conducted a prospective, multicenter, observational clinical trial, to show non-inferiority of the EUM-100
compared to TOCO by testing several performance parameters versus an IUPC as the gold standard. Uterine electrical activity was measured using the EUM-100 device (Electro-Uterine-Monitor-100, OB-Tools Ltd, Migdal Haemek, Israel), simultaneously with TOCO and IUPC measurements, during active labor. The study was approved by the institutional review board of all participating centers and all women provided written informed consent prior to participation in the study.

**Study population**

The study population included 43 parturients, admitted for labor and delivery, with a singleton pregnancy, at a gestational age of 37 + 0 to 41 + 6 weeks, during active phase of their labor. Eligibility for the study was limited to women in term active labor, reassuring fetal heart rate monitoring at enrollment with a clinical indication for IUPC insertion, for either arrested or protracted labor, as determined by the attending physician in the delivery ward.

**EUM, TOCO and IUPC devices**

Standard hospital equipment was used as either TOCO or IUPC monitor, including: GE/Corometrics 171, GE/Corometrics 172, GE/Corometrics 250-CX, HP-50, Philips/Avalon FM-30. A novel EMG device, the EUM-100 (Electro-Uterine-Monitor-100, OB-Tools Ltd, Migdal Haemek, Israel), was used to measure uterine electrical uterine activity. The system comprised of a multichannel surface EMG, a 3-dimensional position sensor and a personal computer providing data analysis and a graphical user interface. The surface EMG activity is acquired by 9 electrodes evenly placed on the patient’s abdomen and a tenth common ground electrode on the patient’s left thigh. The electrodes are placed at the level of the pubis, umbilicus and the uterine fundus with the patient in a supine position. After placement of the electrodes, their exact locations are determined using a three-dimensional position sensor (miniBird; Ascension Technology, Burlington, VT). The measurement of electrical signals together with their physical location provides an accurate estimation of the uterine activity in the three-dimensional space. The electrical signal from the myometrium is recorded and processed using a uterine contractility algorithm. All three devices – EUM, TOCO and IUPC – were wired to a recorder. Uterine activity data from all three devices was recorded at four samples per second using a Windows XP-based computer. Files were burned on a one-time recordable CD and sent for analysis and interpretation.

**Data interpretation**

From each woman’s tracings, three non-contiguous segments of 30 minutes were randomly selected. Randomization was done by computer software that randomly selected the starting point of each 30 minute segment for analysis, providing that two segments were taken during the first stage of labor and the third during the second stage of labor. Each segment included the concurrent measurements of the TOCO, IUPC and EUM. Tracings from each segment and each monitoring technology were printed as a single graph on a separate page. The printout was designed to follow standard tococardiogram paper, at a rate of 1 cm/minute. Fetal heart rate information was not presented on the graph pages. All graphs were masked as to technology which produced them, and the stage of labor at which it was recorded in. Physician printouts pack was shuffled before given for interpretation.

Each tracing was independently interpreted by 3 physicians that were blinded to the type of the tracing. All the physicians are board certified by the American Board of Obstetrics and Gynecology in maternal-fetal medicine and are experts practicing maternal-fetal medicine in the United States. The graph page included directed questions for each of the interpreting physicians: (1) Is the above 30-minute-trace interpretable, partially interpretable or un-interpretable? (2) Please mark the peak of all contractions in the above segment; (3) How many contractions were recorded in this segment? (Figure 1). After the physicians processed the tracings, they were collected, decoded and analyzed by a biomedical engineer and a quality assessment manager.

**Measurements**

The following quantitative data was extracted for each technology, per tracing, as evaluated by each of the 3 physicians: (1) Percent of interpretable tracings – how many of the tracings were defined by the physicians as interpretable: partially-interpretable or un-interpretable; (2) Frequency of contractions – the number of peak contractions identified by the physicians during 30 minutes, only in interpretable tracings; (3) Timing of contractions – the exact time of contraction peak.

**Data analysis**

Analysis included evaluation of the repeatability between the interpreting physicians for each method separately. To demonstrate repeatability, we calculated and compared the percentage of interpretable tracing and the agreement between physicians for percent of tracing interpretability.

Secondly, each technology was evaluated for several performance parameters, and we compared TOCO and EUM versus IUPC in terms of reliability, accuracy and agreement. To demonstrate reliability, we calculated the interpretability percent agreement of TOCO and EUM versus IUPC for interpretable, partially-interpretable and un-interpretable tracings. The Positive Percent Agreement (PPA) was calculated as the percent of the interpretable and partial interpretable tracings with EUM or TOCO out of interpretable and partially-interpretable tracings by IUPC. The Negative Percent Agreement (NPA) was calculated as the percent of un-interpretable tracings with EUM or TOCO out of un-interpretable tracings by IUPC. The Total Percent Agreement (TPA) was calculated as the percent of interpretable and un-interpretable tracings with EUM or TOCO out of total tracings. To demonstrate the accuracy of each technology we compared the contraction frequency (number of contraction count per each 30 minutes tracings, as detected by each physician) for TOCO, EUM and IUPC. We also calculated the delta (δ) in contraction frequency, between TOCO versus IUPC (Difference between TOCO contraction frequency to IUPC contraction frequency) and between EUM
versus IUPC (difference between EUM contraction frequency to IUPC contraction frequency). Delta ($\delta$) of up to one contraction was considered as an acceptable difference and was defined as the non-inferiority margin. Agreement was evaluated between TOCO and EUM versus IUPC for delta ($\delta$) in contraction frequency and timing of peak contractions using a Bland–Altman analysis and a linear regression model.

Finally, we calculated the sensitivity, positive predictive value (PPV) and false positive rate for individual contraction identification, between EUM and TOCO versus IUPC. Each detected contraction with a delay of up to $\pm 30$ seconds was recorded as detection of contraction, in all technologies. Sensitivity was defined as the percent of correct detections, as follows: TOCO sensitivity is the total number of contractions detected by EUM and IUPC divided by the number of contractions detected by IUPC. EUM sensitivity is the total number of contractions detected by EUM and I UPC divided by the number of contractions detected by IUPC. PPV for TOCO is defined as the total number of contractions detected by TOCO and IUPC divided by number of contractions detected by TOCO. PPV for EUM is defined as the total number of contractions detected by EUM and IUPC divided by number of contractions detected by EUM. False positive for EUM was calculated as the total number of undetected contractions in IUPC and detected number of contraction in EUM, divided by the number of detected contractions in EUM. False positive for TOCO was calculated as the total number of undetected contractions in IUPC and detected number of contraction in TOCO, divided by the number of detected contractions in TOCO.

### Statistical analysis

Data analysis was done with the SAS v9.3 software (Chicago, IL). Cochran test was used to compare the percentage of interpretable tracing. Frequency of contractions was compared by Friedman’s test followed by Dunn’s test. Wilcoxon’s test was used to compare differences in the contraction frequencies between EUM and TOCO versus IUPC. The Bland–Altman agreement plot and a linear regression model were used to compare the frequency of contraction and the timing of contractions between EUM and TOCO versus IUPC. Differences were considered significant when the $p$ value was less than 0.05. For demonstration of non-inferiority of EUM versus TOCO, in terms of difference from the gold standard, the non-inferiority margin was defined as $\delta = 5\%$; for the comparison of the difference in the number of contractions, the non-inferiority margin was defined as $\delta = 1$.

### Results

#### Population characteristics

A total of 45 women, aged 26–38, at gestational ages of 37–42 weeks, during active labor were enrolled to the study. Two patients decided to cancel their consent and were immediately disconnected from the EUM and TOCO devices. Therefore data from 43 women were available for final analysis – 129 segments per technology and a total of 385 half hour graphs, as one physician interpreted only 127 graphs.
Contraction frequency

The average contraction frequency was 7.4 ± 5.3, 11.5 ± 4.0 and 10.7 ± 4.5 contraction/30 min for TOCO, EUM and IUPC (Table 4). EUM demonstrated no significant differences in contraction frequency compared to IUPC, as measured by each physician separately (p value at least <0.129). TOCO tracings demonstrated a significantly lower contraction frequency than IUPC (p value at least <0.014) and EUM (p at least <0.001), as measured by each physician separately.

Timing of peak contraction

Both TOCO and EUM display a perfect fit (Slope = 1) to IUPC in the timing of peak contractions, suggesting a perfect agreement between methods. This was applied...
on 2178 out of 3753 (58%) interpretable or partial interpretable contractions by TOCO and on 3765 out of 3996 (94%) interpretable or partial interpretable contractions by EUM (Figure 4).

The Bland–Altman analysis of the delta ($\delta$) in timing of peak contractions (Figure 5) demonstrates high variability between the timing of TOCO contractions as compared to IUPC ($4.74 \pm 10.03$ seconds). A positive gap of $8.46 \pm 4.24$ seconds was detected for EUM, demonstrating an early onset of contractions by EUM versus IUPC, probably due to the fact that the electrical activity precedes the muscle mechanical activity.

### Individual contraction identification

To conclude, sensitivity and positive predictive value for individual contraction identification were calculated for individual contraction identification for TOCO and EUM, versus IUPC (Table 5).

### Discussion

This was a prospective three way observational study aimed to prove non-inferiority of the EUM versus TOCO, in comparison to an IUPC, in recording uterine activity. We analyzed 385 tracings from 43 women during active phase of labor. Our key findings demonstrate that: (1) There is similar rate of interpretable strips between physicians for EUM (87%; 95% CI 80.9–92.7%) and IUPC (94.8%; 95% CI 83.4–96.3%), while a significantly lower rate was demonstrated for TOCO (67.5%; 95% CI 59.4–76.8%, $p < 0.001$). The TPA for tracing interpretability is significantly higher for EUM versus IUPC (98.2%, 95% CI 96.9–99.5%) compared to TOCO versus IUPC (91.7%, 95% CI 89.0–94.5%, $p < 0.001$). (2) The average contraction frequency was $7.4 \pm 5.3$, $11.5 \pm 4.0$ and $10.7 \pm 4.5$ contraction/30 min for TOCO, EUM and IUPC. We found a significant delta ($\delta$) in the average contraction frequency for EUM versus IUPC ($0.77 \pm 2.3$) compared to contraction frequency detected by TOCO versus IUPC ($-3.34 \pm 4.97$).
Therefore, the TOCO misses on average more contractions than EUM as compared to IUPC. (3) For the timing of peak contractions, we demonstrated high variability between the timing of TOCO contractions as compared to IUPC (4.74 ± 10.03 seconds) and a gap of 8.46 ± 4.24 seconds for EUM. (4) For individual contraction identification the sensitivity, positive predictive value and false positive rate for TOCO and EUM are 54.0%, 84.4%, 15.6% and 94.2%, 87.6%, 12.4%, respectively.

Previous studies have compared uterine EMG to IUPC, and found good parameters of correlation [23–26] between technologies. However, these studies were limited by small numbers, utilizing mostly invasive measurements with only single or dual channel EMG devices. Recently,
Haran et al. [20] directly compared the EUM-100 device to IUPC, in 47 laboring patients. They concluded that the performance of the EUM is strongly correlated (r value = 0.0808–1, p < 0.0001) to IUPC with regard to onset, time to peak, duration and intensity of contractions.

We expected that the percent of interpretable strips will be, as previously published, approximately 70% [27]. Indeed, our results show that EUM is not only non-inferior to TOCO but also has a good performance above the expected 70%, as does the IUPC. These results were previously demonstrated in several studies that have compared TOCO to EMG with or without IUPC as a reference [28,29]. In the study by Haran et al. [20] 14.85% of IUPC tracings were of poor quality due to problems with determination of baseline uterine activity and catheter displacement, kinking and blocking. Similar reports come from earlier studies [30] as do our results demonstrate that 13.0% of IUPC reading cannot be fully interpreted, and are either partially interpretable or un-interpretable.

Contraction frequency is one of the quantitative parameters that TOCO monitoring can provide. Our results indicate that the difference in contraction frequency assessment for the EUM versus IUPC is approximately 0.77 ± 2.3, which is lower than the predefined non-inferiority margin of 1. In contrast, the frequency difference between TOCO and IUPC is −3.34 ± 4.97, which is higher than the non-inferiority cutoff. This indicates that TOCO misses more contractions than does the EUM, as compared to IUPC. These results demonstrate that EUM is not inferior to TOCO in regard to contraction frequency, and may even be superior to it, performing similarly to IUPC.

Timing of peak contraction is another quantitative measurement that TOCO can provide. When we analyzed the timing of peak contractions, we found that there is high variability between the timing of TOCO contractions as compared to IUPC (4.74 ± 10.03 seconds), implying that this quantitative assessment by TOCO is of poor quality. Interestingly, we found a positive gap of 8.46 ± 4.24 seconds between EUM and IUPC, demonstrating an early onset of contractions by EUM versus IUPC. This is probably due to the fact that the electrical activity precedes the muscle mechanical activity.

The evaluation of uterine activity is an important aspect of labor monitoring. It may aid in detection of non-reassuring fetal heart rate (as decelerations are defined in relation to contractions), evaluation of power in scenarios of protracted or arrested labor and diagnosis of true preterm labor. The currently available methods lack key elements of uterine activity monitoring. The use of EUM rather than TOCO or IUPC allows overcoming their disadvantages of invasive monitoring by IUPC and semi quantitative monitoring by TOCO, while ascertaining the ability to quantify uterine activity for frequency, duration and intensity of contractions in a safe, non-invasive and accurate method that can be preformed thought pregnancy and during all stages of labor.

| Table 5. Sensitivity, positive predictive value and false positive rate for individual contraction identification. |
|---|---|---|---|---|---|---|
| | TOCO | EUM | TOCO | EUM | TOCO | EUM |
| Physician 1 | 72.7% | 95.1% | 85.4% | 90.6% | 14.6% | 9.4% |
| Physician 2 | 42.2% | 92.9% | 83.5% | 85.6% | 16.5% | 14.4% |
| Physician 3 | 57.6% | 94.4% | 83.7% | 86.3% | 16.3% | 13.7% |
| Total | 54.0% | 94.2% | 84.4% | 87.6% | 15.6% | 12.4% |

Figure 5. Bland–Altman agreement plot of differences (delta, δ) in contraction timing (Seconds), between (A) EUM versus IUPC and (B) TOCO versus IUPC. IUPC – intra uterine pressure catheter, EUM – electro uterine monitor, TOCO – tocodynamometry.

DOI: 10.3109/14767058.2014.954539

Assessment of uterine activity in labor by a novel technology
and delivery, unrelated to gestational age, prior and after rupture of membranes.

To conclude, our study demonstrates non-inferiority of the EUM versus TOCO in the following parameters: interpretability of tracings, frequency of contractions and timing of contraction. The results support the use of non-invasive EMG technology to monitor uterine activity, and the exact conditions, definitions and indications warrant further study.

**Declaration of interest**

The authors report no conflict of interest.

**References**