



Published in final edited form as:

Am J Obstet Gynecol. 2013 January ; 208(1): 66.e1–66.e6. doi:10.1016/j.ajog.2012.10.873.

Monitoring uterine activity during labor: a comparison of three methods

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Abstract

Objective—Tocodynamometry (Toco—strain gauge technology) provides contraction frequency and approximate duration of labor contractions, but suffers frequent signal dropout necessitating re-positioning by a nurse, and may fail in obese patients. The alternative invasive intrauterine pressure catheter (IUPC) is more reliable and adds contraction pressure information, but requires ruptured membranes and introduces small risks of infection and abruption. Electrohysterography (EHG) reports the electrical activity of the uterus through electrodes placed on the maternal abdomen. This study compared all three methods of contraction detection simultaneously in laboring women.

Study Design—Upon consent, laboring women were monitored simultaneously with Toco, EHG, and IUPC. Contraction curves were generated in real-time for the EHG and all three curves were stored electronically. A contraction detection algorithm was used to compare frequency and timing between methods. Seventy-three subjects were enrolled in the study; 14 were excluded due to hardware failure of one or more of the devices (12) or inadequate data collection duration(2).

Results—In comparison with the gold-standard IUPC, EHG performed significantly better than Toco with regard to Contractions Consistency Index (CCI). The mean CCI for EHG was 0.88 ± 0.17 compared to 0.69 ± 0.27 for Toco ($p < .0001$). In contrast to Toco, EHG was not significantly affected by obesity.

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Conflict of interest: Dr. T. Euliano's husband is the President, and Dr. Darmanjian and Mr. Nguyen are employees, of Convergent Engineering. Dr. T. Euliano owns no stock nor holds any position in the company but is listed on patents filed for some of the technology described in this paper.

Conclusion—Toco 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.

Keywords

electrohysterography; electronic fetal monitoring; uterine activity monitoring

Introduction

Electronic fetal monitoring is used to assess both uterine activity (frequency of contractions) and fetal wellbeing (fetal heart rate pattern, especially in relation to contractions). The former is typically assessed non-invasively with a tocodynamometer (Toco): a strain gauge positioned over the maternal fundus which responds to changes in uterine tension transmitted to the abdomen. The device identifies the frequency of contractions, but not their intensity, and suffers both from misalignment following maternal movement and technical limitations in obese parturients. Currently the only alternative for Toco failure is the invasive intrauterine pressure catheter (IUPC), which carries inherent risks, most prominently infection.

In a comparison of Toco monitoring in obese (Body Mass Index (BMI) >35) and non-obese (BMI 20-25) women, Ray et al¹ describe a 30% rate of “difficult monitoring” in the obese group (vs 0% in the non-obese), requiring a 26% rate of internal monitoring (vs 0% in the non-obese). Vanner et al² similarly report poor quality Toco during more than one quarter of the monitoring time in 36% of obese parturients (compared with 16% in non-obese).

Even in the non-obese, Toco suffers frequent failures. Bakker et al³ 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. They also report “inadequate registration” in 60% of 151 patients monitored with IUPC, for 28% of stage one and 30% of stage two durations.

Electrohysterography (EHG), the uterine EMG, employs a different modality for monitoring uterine activity. Similar to observing an electrocardiograph rather than intracardiac pressures, EHG reports the electrical activity of the uterine muscle. This non-invasive monitor utilizes surface electrodes applied to the maternal abdomen and a high frequency, low noise amplifier. While prior studies have compared EHG to IUPC or Toco, to our knowledge this is the first study to compare EHG to both standard technologies real-time during active labor.

Materials and Methods

Adult patients admitted to Labor & Delivery in active labor with a singleton fetus in cephalic presentation and without bleeding, uterine scar, or contraindication to IUPC placement were eligible for inclusion. The study protocol was approved by our Institutional Review Board, and all subjects provided written, informed consent. Following rupture of membranes (either spontaneous or artificial by obstetric indication), the EHG monitor was applied. In addition, if an IUPC was not already present, one was placed by the obstetrician. Data from the IUPC, Toco (using a second electronic fetal monitoring unit), and EHG were collected simultaneously via a laptop computer. The patients’ nurses were blinded to all but the IUPC output for uterine activity monitoring and interventions.

A research data collector was available, and monitoring continued through vaginal delivery or movement to the operating room for cesarean delivery.

Following skin preparation by gentle rubbing with abrasive gel, six 3-cm² Ag/AgCl₂ electrodes (Ambu; Glen Burnie, Maryland, USA) were attached to the maternal abdomen (cf. Figure 1). The electrodes were connected to the amplifier in a monopolar fashion with common reference and common mode rejection leads on the left side of the patient's abdomen, to reduce 60Hz environmental noise. Electrode positions were modified slightly for each patient, as required by the location of the tocodynamometer and ultrasound fetal heart rate monitor. Impedance of each electrode was measured (as compared with the reference) (General Devices EIM-105 Prep-Check; Ridgefield, New Jersey, USA). Skin preparation was repeated as needed at each site until the measured impedance was below 10 kΩ where possible.

The recorded signals were fed to a 4-channel high-resolution, low-noise unipolar amplifier. All four signals were measured with respect to a reference electrode. The amplifier design employed driven right-leg (DRL) circuitry to reduce common mode noise between the patient and the amplifier common. The amplifier 3-dB bandwidth was 0.05 to 250 Hz.

Data from each patient included a uterine activity channel from two maternal-fetal monitors (Corometrics, GE Medical Systems; Waukesha, Wisconsin, USA) sampled at 8 Hz with 8-bit resolution. These cardiotocographs (CTG) reported the Toco- and IUPC-derived contraction curves. Data also included output from 4 abdominal EHG channels sampled at 500 Hz with 24-bit resolution.

To produce the EHG contraction curve, the 4 EHG signals were down-sampled at 20 Hz, band pass filtered between 0.2 Hz and 1 Hz to eliminate low and high frequency noise while preserving the main contraction power, and combined based on their signal-to-noise ratio. The output was then down-sampled at 8Hz and normalized to scale the signal from 0 to 100 units. All three uterine activity curves were displayed in real-time to the data collector and stored electronically for subsequent analysis.

Contraction location was statistically computed. Contractions were rejected if duration was <45s or >180s, amplitude <10 mmHg (IUPC) or <10 units (Toco and EHG), and amplitude <40% or >350% of median of the last 10 contractions. To evaluate contraction consistency, we used a modification of the Contractions Consistency Index (CCI) defined by Jezewski et al⁴ to compare EHG and Toco each to the gold standard, IUPC:

$$CCI = \frac{N_C}{\frac{1}{2}(N_T + N_E)}$$

where N_T is the number of contractions detected by IUPC, N_E is the number detected in the EHG or Toco signal, and N_C is the number of consistent contractions. Contractions were consistent when the peak of a contraction from the EHG or Toco signal was within ± 30 seconds of the peak of a contraction from the IUPC signal.

In addition to the overall CCI score, a running window CCI (15 minutes) was also computed for each combination of patient and device to determine the percentage of time CCI was below 0.75 during data collection. Recordings below that threshold were considered noisy with increased time of low contraction consistency between methods.

Descriptive statistics and graphical methods were used to summarize subject characteristics and examine variable distributions. Performance characteristics including CCI, positive

predictive value (PPV = true positives / (true positives + false positives)), and sensitivity (true positives / (true positives + false negatives)) were calculated for each participant. True positives are consistent contractions, false positives are contractions detected in Toco/EHG curve and not in IUPC curve, and false negatives are contractions detected in IUPC and not in Toco/EHG curve. EHG and Toco means were compared using two-sided paired t-tests. Contraction timing (peak, onset, offset, and duration) were also compared in the manner described above. Pearson correlation coefficient estimates were used to examine the relationship between BMI and CCI, positive predictive value (PPV), and sensitivity. We also used two-sided, two-sample t-tests to compare obese women (BMI > 35) to non-obese women for CCI, % CCI < 0.75, correlation, PPV, and sensitivity. With a sample size of 59, there is sufficient power (0.80) to detect a 0.37 s.d. unit difference between means and a correlation of 0.35 or larger. A p-value of less than 0.05 was considered statistically significant. Analyses were performed using SAS (version 9.1), and R (version 2.12.0).

Results

A total of 73 patients were enrolled in the study. Of these, 14 were excluded because of the following: IUPC never functioned (5), Toco failed (2), the amplifier battery was problematic (2), practitioners failed to follow protocol with electrode selection/placement (2), duration of monitoring was inadequate (2), and a period in which both Toco and IUPC functioned simultaneously was lacking. The mean BMI of the excluded group was 34.4, similar to the included group. Demographic characteristics of the subjects are listed in Table 1. Thirty-nine of 59 delivered vaginally (66%). Table 2 displays the summary statistics for EHG and Toco, each compared to the gold standard, IUPC. Significant differences were identified between the two techniques for most of the variables under study. The EHG technique identified a higher number of consistent contractions and had a higher CCI (EHG mean 0.88 [95% CI 0.83-0.92]) than the Toco (mean of 0.69 [95% CI 0.61-0.76, $p < .0001$]). Correspondingly, the percent of time CCI was less than 0.75 differed significantly between the two methods, occurring an average of 17% (95% CI 10-24) with EHG compared to 46% (95% CI 37-55) with Toco ($p = .0001$). Waveform matching, as quantified by correlation, was superior with EHG, resulting in a mean correlation of 0.62 (95% CI 0.56-0.68) compared to 0.38 (95% CI 0.30-0.45) for Toco ($p < .0001$). PPV did not differ significantly for the two methods (EHG mean 0.89 (95% CI 0.85-0.92), Toco mean 0.86 (95% CI 0.81-0.92), $p = 0.37$). Sensitivity was significantly higher for EHG ($p < .0001$). Figure 2 shows the number of consistent contractions for each subject for EHG and Toco compared to number of contractions detected in IUPC. Points on or near the diagonal represent good correlation with the gold-standard.

Comparing contraction timing for women who had at least four consistent contractions with both non-invasive techniques ($n = 52$), toco detected contractions at nearly the same time as IUPC (contraction delay mean across patients of -1.2 ± 4.5 s) and EHG was slightly delayed (contraction delay mean across patients of 2.5 ± 2.6 s). A similar relationship was observed for detection of onset. Offset was nearly identical in all methods. Variability of offset detection (s.d.) was greater with Toco. As suggested by the reported differences, contraction duration was slightly less (4.5s) with EHG relative to IUPC and slightly greater using Toco (1.7s).

Pearson correlation coefficients were used to assess the relationship between BMI and performance characteristics (CCI, PPV, and sensitivity) of EHG and Toco. Results are displayed in Table 3. A significant negative correlation was detected for BMI and sensitivity as measured by Toco, indicating that higher BMI values correspond to less sensitive Toco results. A similar magnitude of correlation was estimated for EHG; however, this was of borderline statistical significance ($p = 0.07$). These relationships are illustrated in Figure 3,

including best linear fit lines for the two methods. It is important to note the negative slope for both, corresponding to the negative correlations and indicating that sensitivity falls when BMI is higher. Table 4 displays the comparison of obese to non-obese women. There were no statistically significant differences between these groups for EHG considering CCI, % CCI < 0.75, correlation, PPV, and sensitivity. This was not the case for Toco which indicated significantly lowered sensitivity in obese subjects.

Comment

This study documents the superiority of EHG to Toco in uterine activity monitoring. Normal, spontaneous labor generally proceeds without intervention. In this setting, external electronic fetal monitoring documenting contraction frequency and fetal response to labor, generally suffices and brief periods of signal drop-out are of little concern. When labor is induced or augmented, or fetal wellbeing is of concern (e.g. due to intrauterine growth restriction or maternal preeclampsia), signal quality rises in importance.⁵ The IUPC provides quantitative information regarding contraction intensity not available from the Toco. Use of EHG to infer intrauterine pressure remains an area of research with some promising results,^{6;7} but was not a goal of this study. In fact, the availability of IUPC data does not affect labor outcome.⁸⁻¹⁰

Recent EHG studies have documented the technology's utility in the diagnosis of preterm labor,¹¹⁻¹³ and have compared EHG with Toco^{10;14;15} and IUPC^{14;16} for term labor. The primary strength of the current study is the simultaneous comparison of all three technologies in the labor setting. Using IUPC as the gold standard, our results confirm the superiority of EHG over Toco for uterine activity monitoring in laboring women regardless of body habitus. CCI and sensitivity were higher for EHG compared to Toco, whereas PPV was similar. This suggests EHG is more reliable in terms of signal quality.

As noted in the introduction, several research groups, including our own,¹⁴ have identified obesity as a risk factor for failure of Toco monitoring. In the current study, CCI was affected by obesity for both non-invasive technologies, but for Toco it fell to 0.60 in this subgroup, compared to 0.82 for EHG (p=.03). Similarly, % Time CCI<0.75 increased to more than half the monitoring time (56.0%) for Toco in obese parturients, but remained less than one-quarter (24.2%) for EHG (p=.01). Adequate monitoring in the obese parturient has special importance considering their increased risk for labor complications.¹⁷ Ray et al¹ noted a 32% incidence of complications (postpartum hemorrhage, third degree tears and extension of episiotomy, and shoulder dystocia) in obese patients vs 6% in controls. Even without such complications, obese patients undergo a longer duration of labor and have a higher incidence of cesarean delivery.^{18;19} The combination of longer labor, which entails more cervical examinations, a high rate of induction/augmentation, and difficult non-invasive monitoring requiring the use of IUPC and/or fetal scalp electrode, places obese parturients at significantly greater risk of developing infection.¹⁷ Once infected, dysfunctional uterine contractility further prolongs labor and increases the cesarean risk.²⁰ Furthermore, chorioamnionitis is associated with increased risks for uterine atony, maternal blood transfusion, septic pelvic thrombophlebitis and pelvic abscess, as well as poor neonatal outcome.²¹ EHG monitoring for uterine activity may lessen these complications by reducing the need for intrauterine monitoring and by providing reliable contraction information early in labor that may reduce the need for repetitive cervical examinations and perhaps enhance the safe titration of oxytocin.

Though there is little reason to expect variable performance by location, a weakness of this study is its performance at a single site. Another potential weakness is that subjects underwent IUPC placement for "obstetric indication." Though not specifically documented

by the obstetricians, often this indication is an inadequate Toco tracing, thereby potentially biasing our results in favor of EHG, yet also confirming its superiority in these patients.

Important in all discussions of novel technology is the cost:benefit ratio. Benefits such as reduced nursing interventions for toco failures, improved patient comfort, and fewer IUPC-induced infectious complications are difficult to quantify. The recurring physical cost of toco is in the occasional replacement of the sensors and the inexpensive disposable belts. An IUPC certainly has increased per-patient acquisition costs. EHG sensors consist primarily of electrodes and therefore may be priced between the cost of the toco and IUPC. A design goal would include interacting directly with existing electronic fetal monitoring systems to ease the cost of adoption. Training for nurses should be minimal and consist only of appropriate skin preparation and electrode application. This study suggests that EHG is superior to Toco for non-invasive uterine activity monitoring. An ongoing study will evaluate whether this translates to superior clinical use: clinicians and nurses will evaluate fetal heart rate / uterine activity strips from all three technologies and compare interpretability.

Acknowledgments

This material is based upon work supported by the National Institutes of Health (R44 HD056606)

This work was presented in abstract form at the Annual Meeting of the American Society of Anesthesiologists, Chicago, Illinois, October 2011.

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Condensation

Using intrauterine pressure as the gold standard, electrohysterography out-performed tocodynamometry for uterine activity monitoring during active labor in 59 women of varying body habitus.

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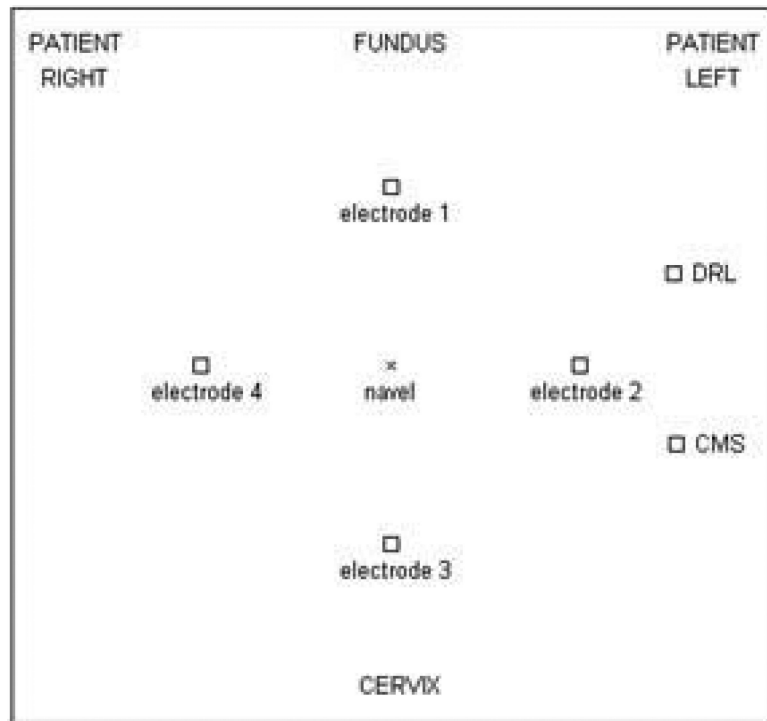


Figure 1. Electrode location. Abbreviations: DRL (Driven Right Leg); CMS (Common Mode Signal)

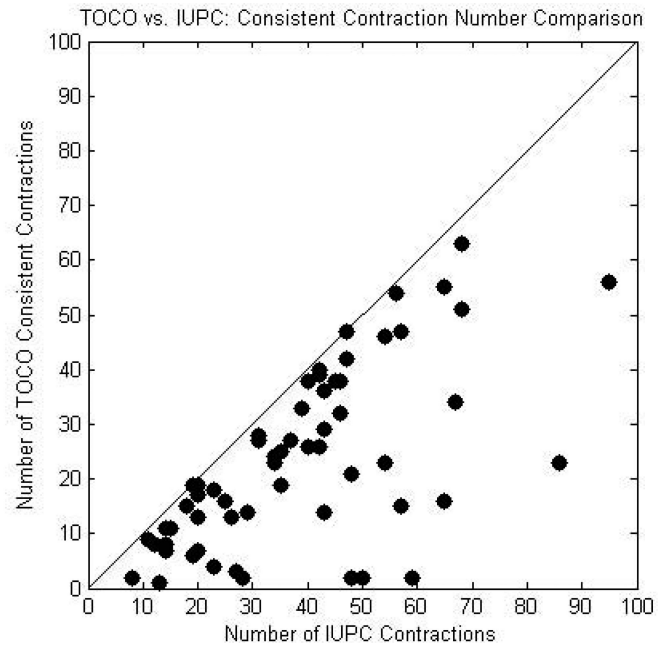
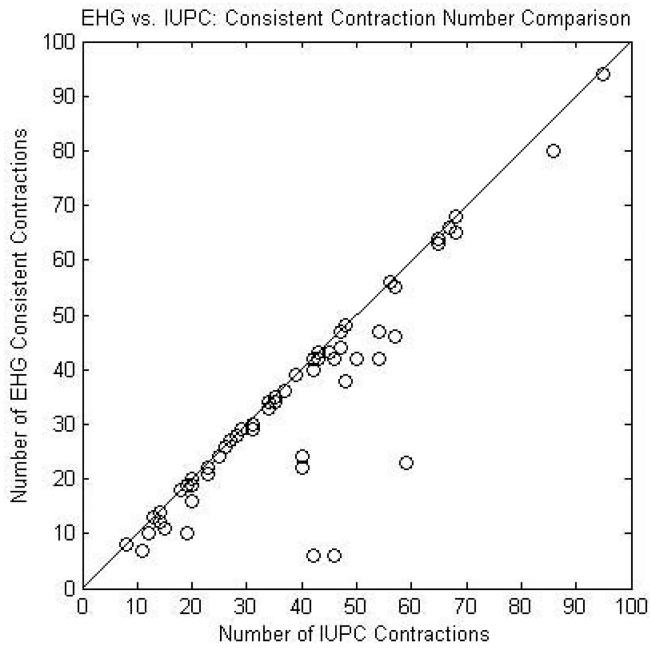


Figure 2. Plot of consistent contractions per patient for both methodologies EHG vs. IUPC and Toco vs. IUPC. Each dot corresponds to one subject. Those near the diagonal indicate the non-invasive method is equivalent to IUPC; those below the diagonal indicate superiority of IUPC.

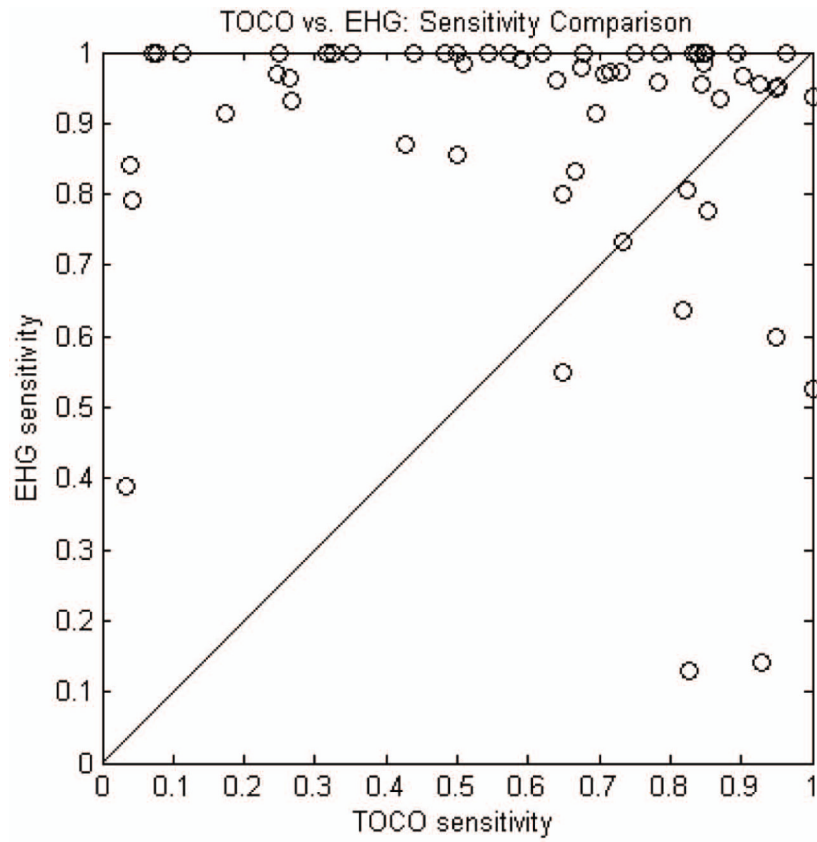


Figure 3. Plot of sensitivity versus BMI. Open dots and dashed line (best linear fit) represent EHG observations; filled dots and solid line represent Toco observations. As BMI increases, sensitivity decreases for both technologies, however the relationship is steeper for Toco.

Table 1

Subject characteristics (n=59)

Variable	Mean	S.D.	Range
Body weight (lbs)	204.6	57.6	122 – 384
BMI	34.3	8.6	23.1 – 61.4
Gestational age	39	1.7	33 – 42
Duration of monitoring (min)	137	65.8	48.6 – 345.9
IUPC contractions	38.3	19.2	8 – 95
EHG contractions	37.7	19.6	8 – 94
Toco contractions	26.4	16.0	1 – 64

Table 2

Comparison of operating characteristics for contraction detection comparing EHG to IUPC and Toco versus IUPC (n=59)

Variable	EHG vs. IUPC		Toco vs. IUPC		Difference		P-value*
	mean	s.d.	mean	s.d.	mean	s.d.	
Consistent CTX	33.8	19.4	23.5	16.2	10.4	16.3	<.0001
CCI	0.88	0.17	0.69	0.27	0.19	0.33	<.0001
% CCI < 0.75	16.7	26.7	46.1	34.0	-29.4	44.2	.0001
Correlation	0.62	0.24	0.38	0.28	0.25	0.35	<.0001
PPV	0.89	0.14	0.86	0.19	0.03	0.24	0.37
Sensitivity	0.89	0.20	0.62	0.29	0.27	0.37	<.0001

* two-sided paired t-test

Table 3

Pearson correlation coefficient estimates (and p-value of test for significant correlation) of BMI with CCI, PPV, and sensitivity (n=59)

	EHG	Toco
CCI	-0.20 (0.13)	-0.23 (0.09)
PPV	-0.10 (0.44)	0.10 (0.43)
Sensitivity	-0.23 (0.07)	-0.26 (0.04)

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Table 4

Comparison of obese and non-obese women. Listed are mean (s.d.) and two-sample two-sided t-test p-value.

	Toco		EHG	
	Non obese (n=38)	Obese (n=21)	Non obese (n=38)	Obese (n=21)
		P-value		P-value
CCI	0.74 (0.25)	0.60 (0.30)	0.91 (0.11)	0.82 (0.24)
% CCI < 0.75	40.7 (32.2)	56.0 (35.6)	12.6 (19.1)	24.2 (36.1)
Correlation	0.41 (0.28)	0.32 (0.29)	0.65 (0.22)	0.57 (0.26)
PPV	0.85 (0.20)	0.88 (0.18)	0.91 (0.11)	0.85 (0.19)
Sensitivity	0.67 (0.26)	0.51 (0.30)	0.93 (0.13)	0.82 (0.27)