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Vaginal Electrohysterography: The Design and Preliminary Evaluation of a Novel Device for Uterine Contraction Monitoring in an Ovine Model

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Abstract

Objective—Tocodynamometry is the most common method of labor evaluation but most clinicians would agree it has limited utility before 26 weeks gestation. The obesity epidemic has further reduced our ability to accurately detect uterine contractions using the tocodynamometer at any gestational age. We sought to design and test a novel contraction monitor that bypasses the maternal abdomen.

Methods—An optimized version of an intravaginal electrohysterographic ring device was tested in an ovine model. The device and its methodology as well as the tocodynamometer were validated against the current gold standard uterine activity monitor, the intrauterine pressure catheter in 6 sheep at varying gestational ages.

Results—Both the intravaginal ring device and the tocodynamometer correlated well with IUPC, r = 0.69 and 0.73 respectively ($p<0.001$). The number of contractions detected by each monitor remained similar even after accounting for confounders.

Conclusions—These results suggest that uterine activity can be monitored from the vaginal interface in an ovine model and offers an alternative clinical tool for the detection of contractions in situations in which tocodynamometry would be ineffective or intrauterine monitoring inappropriate.

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Declaration of Interest
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Keywords

contraction monitoring; electrohysterograph; preterm labor; tocodynamometry; uterine contraction

Introduction

In obstetrics, the most widely implemented apparatus for labor monitoring is the tocodynamometer (TOCO). The TOCO is a device applied to the maternal abdomen to measure displacement of the monitor by uterine contractions. Clinicians know that this device has many limitations but have very few options for non-invasive uterine monitoring. The greatest limitations to use of the TOCO are maternal obesity and early gestational age.[1] The known increased antepartum and intrapartum risks in obese women and the rising prevalence of obesity in pregnancy mandates optimal fetal and uterine assessment in these patients. The ability to detect labor early in gestation is fundamental to the obstetrician's ability to intervene and possibly delay early preterm birth, which is a leading cause of excessive health care expenditure.[2,3]

In recent years, in an effort to bypass these limitations, researchers have begun to develop and implement use of another technique, electrohysterography (EHG). Abdominal EHG, similar to electromyography, measures the electrical activity of muscle fibers of the uterus via electrodes placed across the maternal abdomen.[4-20] Effective labor depends on the presence of action potentials between muscle cells and these connections increase as labor becomes imminent. There have been many mathematical models proposed to show the accuracy of abdominal EHG compared to internal uterine pressure catheter (gold standard) monitoring but none of them has shown consistency, particularly at early gestational ages. The major limitation of abdominal EHG remains its reliability in detection of labor, particularly preterm labor.[21, 22]

This study was conducted to determine if the electrical activity of the pregnant uterus could be detected from the uterovaginal interface in an ovine model. This method was proposed so as to bypass the abdomen and remove gestational age and body habitus as potential limitations of contraction detection.

Materials and Methods

This study was conducted after approval of the Animal Care and Use committee at our institution. Six healthy pregnant sheep sourced from three farms based on availability (Archer Farms Inc., Darlington, MD; Robinson Services Inc., Mocksville, NC; Thomas D. Morris Inc., Reisterstown, MD) were studied over the course of five months at the Johns Hopkins Research Animal Resources (Johns Hopkins Medical Institutes, Baltimore, MD). Most sheep had two fetuses, but one was a singleton and another carried triplets. The weights of the Dorset ewes used in our experiments ranged from 115 to 210 pounds as measured on the morning of each experimental session (average size of a Dorset ewe is 150-200 pounds). Each sheep was tested more than once depending on their gestational age until they either gave birth, or had to be euthanized due to adverse reactions to general anesthesia. At least one week was allowed to pass between each experimental session on an

individual sheep in order to afford sufficient time to recover from anesthesia. Those sheep that were delivered were then adopted out to area farms. Gestational ages of the sheep on the days of experiments ranged from 90 to 141 days. On average, sheep have a 145 day gestational period (range 142-155 days).

During each experiment, a sheep was monitored for uterine activity via three different modalities simultaneously. The electrical activity (electrohysterography or EHG) was recorded by our experimental system which consisted of a ring connected to a Biopac MP36R Data Acquisition system and its PC software, AcqKnowledge 4.1 (Biopac Systems Inc, Goleta, CA). The intrauterine pressure was assessed using Corometrics 120 Series Maternal/Fetal Monitor and its accompanying intrauterine pressure catheter (IUPC) (GE Healthcare, Little Chalfont, UK). The distortion of the abdomen caused by uterine contractions (tocodynamometry) was simultaneously recorded using Analogic FETALGARD Lite fetal monitor (Analogic Corporation, Peabody, MA).

Sheep have a bicornuate uterus with one uterine horn on each side of the sheep abdomen as opposed to a single cavity centrally located in humans. Sheep were selected as animal of choice due to their lack of fetal litters and their reduced cost compared to large primates. Due to their anatomy, each maternal animal was scanned using ultrasonography to determine if one or both uterine horns contained a lamb. Most of the sheep we used in this study carried one fetus in each horn; we elected to monitor the uterine horn on the left side of the sheep in these cases. In the event that the sheep carried a singleton or two fetuses within one uterine horn (for a total of three), the uterine horn with the single fetus was monitored.

EHG was recorded from two locations using two Ag/AgCl electrodes placed internally, on the cervix and at the vaginal fornix attached to a silicone ring. Reference and ground electrodes were placed exteriorly on the pubic bone lateral to the introitus. The external pelvic electrode sites were shorn and prepped with conductive gel prior to electrode placement.

After the electrodes were applied, the tocodynamometer (TOCO) was placed externally on the uterine horn of interest, and the IUPC was inserted through the vaginal canal and cervix and advanced into the space between the uterine wall and the amniotic sac (extracoelomic space). Typical electrode and monitor placement is depicted in Figure 1 presuming a singleton lamb is in the left uterine horn.

Signal Acquisition and preprocessing

Each experimental session required the subject sheep to be under anesthesia for the entire duration. Baseline recordings from all three devices (EHG, TOCO and IUPC) were obtained for at least 15 minutes at the beginning of each session. EHG as recorded at the two sites (cervix, vaginal) were acquired from AC-coupled electrodes at a sampling frequency of 1000 Hz, with an amplification factor of 1000, and an upper cut-off frequency of 200 Hz. Once the baseline recording was complete, oxytocin was infused intravenously to initiate contractions, adjusting the infusion rate gradually until the sheep was noted to have discrete contractions at 1-3 minute intervals. Oxytocin was infused via an intravenous line inserted into a vein on the sheep’s ear and the recordings from EHG, TOCO, and IUPC continued

uninterrupted for approximately 3-4 hours. Recordings were continued after discontinuation of the oxytocin infusion until either contractions abated or at least 30 minutes has elapsed.

A process of extracting a contraction curve from high-frequency EHG waveforms was previously described by Horoba et al.[23] Our signal processing method took a similar approach, and the EHG signals were low-pass filtered to 0.1 Hz and high-pass filtered to 0.002 Hz using fourth order Butterworth filters, which effectively eliminated low and high frequency noise. This yielded an envelope for each of the EHG signals, which were similar to those of TOCO and IUPC that clinicians are accustomed to. The processed EHG signals were then downsampled using MATLAB 2012b (MathWorks Inc., Natick, MA) to 4 samples per second to match those of TOCO and IUPC. The data from the TOCO and the IUPC were also filtered using fourth order Butterworth low pass filters with cutoff frequency at 0.1 Hz in order to smooth the data sets.

Data Analysis

All recordings were superimposed onto the same graph with time along the x axis. The units of the y axis differed for each device as IUPC measures in mmHg, TOCO measures in cm of water and EHG measures in millivolts (mV). The recordings of the IUPC were held as the "true" characteristic of the uterus at any given point in time. Due to the differing units of measurement, comparison of effectiveness between the TOCO or EHG and IUPC was limited to the total number of contractions (defined as gradual deflections from the baseline) noted by each device in 10-minute intervals along the total tracing.

These 10-minute intervals were then isolated by device and randomly presented to two independent reviewers who were blinded to the source device of each tracing. One reviewer was a former Labor and Delivery nurse with >25 years' experience and the other a board-certified perinatologist (MFM). The two reviewers were asked to count the number of contractions recorded on each tracing and record these numbers on a Microsoft Excel 2013 (Microsoft Corp, Redmond, WA) spreadsheet. The number of contractions that occurred during each interval for each device recorded by each reviewer was then averaged and the average contraction counts were used in final analysis. In addition, a Pearson correlation was assessed to determine the level of agreement between the reviewers.

Holding the number of contractions recorded by IUPC as "true", a mixed model analysis was performed. Using Stata 13 (StataCorp LP, College Station, TX) contractions were modeled as a continuous variable using linear mixed effects models. We used random intercepts for sheep, experiment and segment to account for the hierarchical structure of the data. The random effects were assumed to be normally distributed with respective variances. Device was modeled as a fixed effect represented by 2 indicator variables: vaginal vs. IUPC and TOCO vs. IUPC. Wald test was used to assess differences in average contraction counts between devices at 0.05 level of statistical significance.

Results

Twenty-three experiments were conducted in total. Data from 5 of these sessions (involving two of the 8 sheep used in this study) were excluded from analysis due to an inability to

record uterine activity with all three monitoring devices simultaneously. In all cases, this was due to an inability to advance the IUPC into the uterine cavity. Usually IUPC insertion was hindered by extremely tortuous cervical canals, but in one instance, insertion was precluded by torsion of the uterine horns due to a triplet gestation as revealed on necropsy. In no case was the data excluded due to insufficient recording by the intravaginal ring device.

After all experiments were completed, a total of 145 10-minute segments were generated during which all devices were recording properly. A portion of one such tracing is shown in Figure 2. Table 1 shows the total counts of contractions for each device as recorded by the nurse and the perinatologist. For the total number of contractions recorded by IUPC, TOCO and EHG devices, the Pearson correlations were 0.75, 0.93 and 0.69 ($p < 0.001$ for all three), respectively between the nurse and perinatologist. Due to the high correlation between providers, the average contraction count between providers was used for the remainder of analyses. Correlation between contractions recorded by TOCO compared to the gold standard (IUPC) yielded a correlation coefficient of 0.73 ($p< 0.001$). Between EHG and IUPC, this correlation was 0.69 ($p < 0.001$). To account for any confounding effects of repeated experiments on individual sheep, a mixed model regression analysis was then performed. This analysis confirmed that neither TOCO nor our ring device (EHG) differed from IUPC when the average provider contraction counts were analyzed.

Discussion

An accurate yet non-invasive method of labor detection remains an unmet clinical need in the field of obstetrics. Tocodynamometry has been in almost ubiquitous use despite unproven effectiveness. Tocodynamometry has many limitations, including poor correlation with IUPC, the dependence on proper placement on the maternal abdomen, and interference from maternal movement.[24-29] Abdominal EHG, while very promising, has yet to provide a reliable method of labor detection.[28,30,31] This study was undertaken to determine if EHG, as recorded from the cervical and vaginal surfaces offers a feasible means of detecting and recording uterine activity.

Although surgically speaking it is “non-invasive”, this ring device is placed intravaginally, like a pessary. Gravidae who present for an evaluation of preterm or term labor are subjected to vaginal exams in many forms. These women are generally able to tolerate a sterile vaginal examination, a sterile speculum examination, a transvaginal ultrasound or other interventions such as placement of a vaginal pessary very well. Monitoring via the intravaginal ring device described herein would likely also be well tolerated.

As the intravaginal ring device is placed circumferentially about the cervix, it would likely not remain in place once significant cervical effacement or dilatation occurs. Once these cervical changes are present however, whether or not the patient was in preterm or term labor would be obvious; other standard uterine activity monitors could be used and the need for our device would be forgone.

This study was conducted on sheep which allowed us to test our device in a large animal model that closely resembles human reproductive anatomy. The greatest advantage of this

model is that it allowed for simultaneous evaluation using IUPC, TOCO and our device. Excellent visual contemporaneous recording of uterine contractions was evident. The average count of contractions recorded by the intravaginal ring device as determined by two independent reviewers was not statistically different from the number of contractions recorded by IUPC. Ideally, this study would be carried out in a large primate model; however, at this stage of investigation, that undertaking was determined to be cost-prohibitive.

The presence of a bicornuate uterus in sheep may have been a cause for under-estimation of the level of correlation between IUPC and TOCO if the two devices were detecting contractions from opposite horns. Our device also may have under-recorded electrical activity from the level of the vagina as the extremely short cervical length of sheep may have allowed for incomplete contact of the electrodes with the vaginal fornices. Despite this potential limitation, the device performed well. Other disadvantages of our current animal model include the tortuous cervical canals that we encountered that, at times, precluded IUPC insertion. In addition, sheep are very resistant to oxytocin and prostaglandin administration and we often required much larger amounts of oxytocin than used in humans. Thus, in isolated cases, the time elapsed before a consistent uterine contraction pattern was established led to a prolonged duration under anesthesia and thus poor post-operative recovery necessitating euthanasia after our recording session.

The gap that this device is intended to fill in clinical obstetrics involves the diagnosis of preterm labor. When patients present early in gestation for preterm labor symptoms, the desire is to determine if their complaints are due to contractions. The TOCO oftentimes misses these contractions (especially if the woman is in the midtrimester or obese)[32] and thus falsely reassures both clinician and patient. At this time, the intravaginal ring device detects occurrence and not intensity of such contractions. Once there is cervical change, the diagnosis of preterm labor is no longer in question and an IUPC could then be placed as an alternative. This study was focused on the feasibility of EHG recording from the vaginal interface; however, further studies are underway to determine if the data recorded can be correlated to contraction intensity.

In order to address the limitations of external tocodynamometry in situations in which it is nonetheless important to detect uterine contractions, we have conducted a feasibility study using a device that bypasses the maternal abdomen. Our initial results show that a novel intravaginal ring device is able to detect uterine electrical activity that accurately reflects uterine contractions in an ovine model. This device has promise to address a current need in obstetrics today, that of uterine contraction detection at early gestational ages (22-28 weeks) and in obese gravidas, two clinical presentations in which the conventional tocodynamometer has a high failure rate. The false reassurance the TOCO may convey in these clinical scenarios, especially when accompanied by symptoms of preterm labor, moreover, can result in missed opportunities for antenatal intervention. Further studies will need to be conducted to determine if our device is affected by body habitus or gestational age. Confirmation of the utility of this intravaginal ring device awaits clinical trials.

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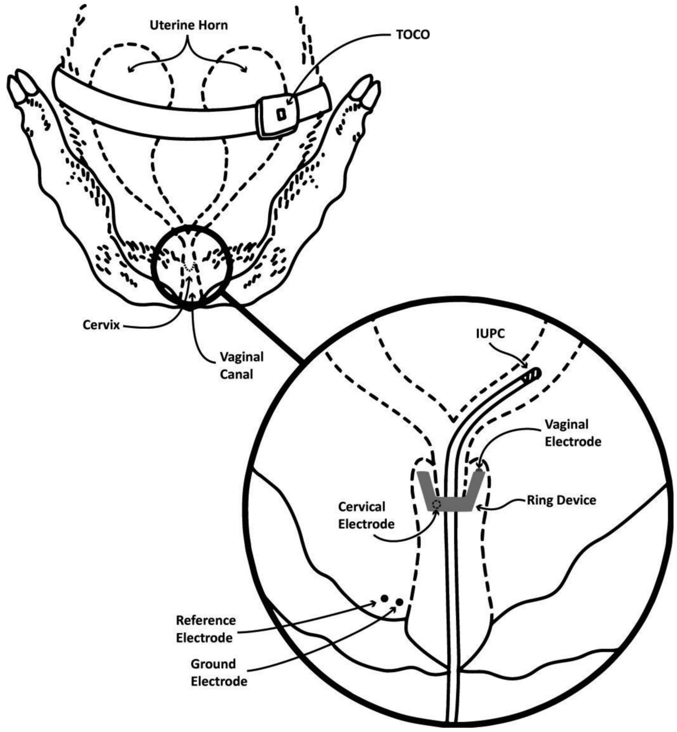

TOCO, ***tocodynamometer***; **IUPC**, ***intrauterine pressure catheter***

Figure 1.

Diagram of the top-down view of supine sheep depicting monitor placement assuming a single lamb is in the left uterine horn.

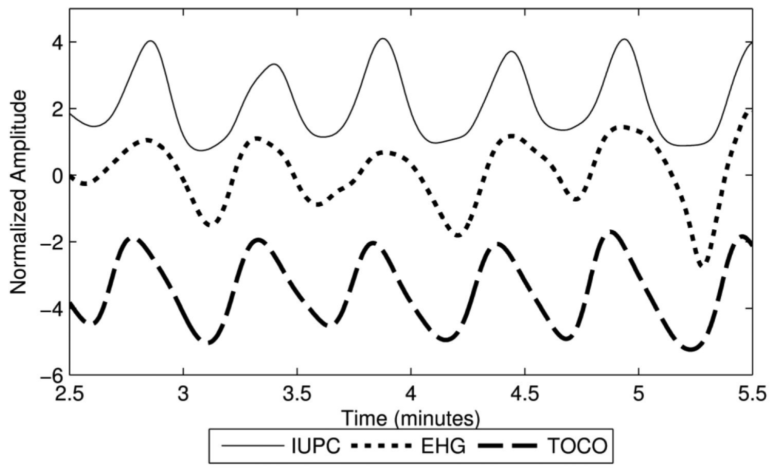

Figure 2.

A graph of EHG, TOCO, and IUPC recordings.

EHG, intravaginal electrohysterography; TOCO, tocodynamometry; IUPC, intrauterine pressure catheter

Table 1

Summary of the characteristics of each sheep experiment as analyzed by two independent providers

	Sheep Weight (lbs)	Sheep GA (days)	Total contractions on IUPC		Total contractions on TOCO		Total contractions on EHG		Correlation IUPC to TOCO		Correlation IUPC to EHG	
			Nurse	MFM	Nurse	MFM	Nurse	MFM	Nurse	MFM	Nurse	MFM
Experiment #1	115	107	137	155	155	161	159	135				
Experiment #2	115	115	186	141	166	171	191	111				
Experiment #3	125	117	92	74	70	72	80	63				
Experiment #4	115	128	160	147	153	158	158	144				
Experiment #5	125	141	39	32	45	44	51	31				
Experiment #6	115	90	109	102	105	111	100	77				
Experiment #7	115	93	87	68	97	77	92	73				
Experiment #8	115	98	68	55	76	73	91	56				
Experiment #9	115	100	139	114	118	118	143	106	0.71*	0.65*	0.69*	0.57*
Experiment #10	115	103	87	76	94	88	95	83	p= 0.94		p=0.89	
Experiment #11	115	111	98	85	93	93	95	76				
Experiment #12	115	131	34	36	37	36	29	29				
Experiment #13	190	120	84	30	91	86	102	72				
Experiment #14	190	125	67	49	57	53	69	52				
Experiment #15	210	127	98	67	110	105	134	75				
Experiment #16	190	128	31	27	42	25	30	22				
Experiment #17	210	129	11	10	14	9	14	14				
Experiment #18	190	135	41	44	7	2	46	43				

* correlation significant at the 0.01 level