Uterine Activity Monitoring during Labour – A Multi-Centre, Blinded Two-Way Trial of External Tocodynamometry against Electrohysterography

Wehentätigkeit unter der Geburt – Eine Multicenter-Doppelblind-Studie: Vergleich des Tokogramms mit dem Elektrohystogramm

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Purpose: The aim of this study was to determine the quality of intrapartum uterine activity (UA) monitoring in daily practice during the first and second stages of labour. The total duration of inadequate UA monitoring is quantified in relation to the technique applied, namely, external tocodynamometry (TOCO) or electrohysterography (EHG).

Material and Methods: 144 UA recordings, collected from 1st September 2008 until 15th October 2009 from deliveries at the Marien-Hospital Witten, Germany, were analysed by obstetricians based at different centres. The included recordings were from singleton and simultaneously with external TOCO and EHG monitored pregnancies. External TOCO and EHG UA recordings were blinded.

Results: The percentages of "*adequate*" UA recordings in the first and second stages of labour were much higher for the external EHG than the external TOCO mode (p < 0.001). All doctors evaluated the UA assessment as "*easier*" (p < 0.001) using the EHG compared with TOCO.

Conclusion: Intrapartum UA monitoring in daily practice via the EHG mode provides a more recognisable UA trace than the TOCO.

Introduction

Standard obstetric care during labour is the assessment of uterine activity (UA). If UA is combined with the fetal heart rate (FHR) it gives valuable information on fetal condition [1]. In Germany external non-invasive tocodynamometry (TOCO) is currently the "gold standard" for recording uterine activity (UA) externally. However the TOCO is highly dependent on correct positioning of the sensor on the maternal abdomen as well as influenced by BMI and maternal movements [2–4].

Zusammenfassung

Fragestellung: Ziel dieser Studie ist die Qualitätsbeurteilung der Wehentätigkeitsaufzeichnung (UA) in der ersten und zweiten Geburtsphase. Die adäquate Aufzeichnungsperiode und Qualität wurde nach Aufzeichnungstechnik (Tokogramm (TOCO) vs. Elektrohystogramm (EHG)) evaluiert.

Material und Methodik: 144 UA-Aufzeichnungen, bei denen gleichzeitig TOCO und EHG abgeleitet wurden, wurden durch Gynäkologen/in bei unterschiedlichen Zentren beurteilt. Die Aufzeichnungen wurden verblindet ausgewertet.

Ergebnisse: Adäquate UA-Aufzeichnungen waren häufiger bei dem EHG im Vergleich zum TOCO (während der ersten und zweiten Geburtsphase; p < 0,001). Alle Ärzte beurteilten EHG-Qualität Wehentätigkeit als besser (p < 0,001).

Schlussfolgerung: Unter der Geburt zeigt das EHG mehr adäquate UA-Aufzeichnung und bessere Beurteilbarkeit als der "Goldstandard" TOCO.

During labour clinicians often focus on the FHR which is recommended by international guidelines [5–7]. However, for suspect and pathological FHR patterns a correct reading and interpretation of the cardiotocogram (CTG) is only possible with the additional monitoring of the UA trace. In oxytocin induced labour hyperstimulation tends to occur more often when UA is inadequate. Inadequate UA monitoring allows excessive UA to occur unrecognised, thus delaying appropriate response to reduce or discontinue oxytocin infusion. Legal claims have shown that the only effective strategy to prevent claims based on unrecognised oxytocin hyperstimulation is to reliably detect uterine contractions [8].

The intra-uterine pressure catheter (IUPC) provides a more recognizable UA trace than external tocodynamometry [3], but the IUPC is invasive and have been associated in rare cases with intra-uterine infection, uterus perforation and placental abruption [2,9].

Electrohysterography (EHG) has been known as a possible alternative method for the monitoring of contractions for more than 50 years [10–12]. Recent technical improvements in EHG acquisition and published reports [13–18] has created a renewed interest in EHG and raise the possibility that it may be feasible to discriminate between efficient and inefficient contractions. In the context of threatened preterm labour this is of course particularly relevant [14–18].

Several researchers have shown that the EHG signal agrees well with IUPC measurements using algorithms of varying complexity [19–24], especially Jezewski et al. evaluated in a good study TOCO and EHG [25].

The aim of the current study is to determine which non-invasive method of UA monitoring (i.e. TOCO or EHG (with a newly CEcertified commercially available device)) is superior during the first and second stage of labour when used in daily obstetric practice.

Materials and Methods

Study samples

All patients who were admitted to hospital for delivery and had a singleton pregnancy were eligible to participate in this study. Nearly all (144/147) women who were informed and received written consent about the study agreed to participate. We evaluated 144 women, who were admitted to hospital as a result of uterine contractions (36.1%), (premature) rupture of membranes (32.3%) or induction of labour (31.6%). With written consent, the women underwent simultaneous abdominal ECG (using the Monica AN24) and intermittent Doppler ultrasound (using a GE Corometrics 250 series) recordings in established labour (mean gestation 39.2 weeks, range 35-42, SD 1.4), at a mean cervical dilatation of 2.2 cm (range 0-7, SD 1.4). 98/144 (67.7%) had intact amniotic membranes. 71.7% (104/144) had epidural anaesthesia, 68.8% (99/144) had a spontaneous vaginal delivery, 28.5% (41/144) had a lower Caesarean section and 2.8% (4/144) had a instrumental delivery. The body mass index (BMI) was in the range of 20.6-49.5 (mean 29.8, SD 4.7). The mean newborn weight was 3360g (SD 463.8, range 2240-4900) with an arterial pH value of 7.30 (SD 0.08, range 7.09 to 7.52). The 5 and 10 min Apgar score was in the range of 7-10 (mean 9.7, SD 0.6) and 8-10 (mean 10.0, SD 0.2), respectively.

Labour was purely managed using the current "gold standard" TOCO.

Study protocol

5 Ambu VLC-00-S electrodes were placed on the abdomen: 1 electrode was placed on the midline within a range of 3 cm above the navel; 1 was placed 6 cm above the symphysis, 2 were placed at the right and left lateral abdominal wall; and finally 1 reference electrode was placed towards the back on the right lateral of the abdomen. This configuration allows 3 parallel fECG detection channels around the maternal abdomen. The UA EHG channel was recorded using the left lateral electrode with re-

spect to the symphysis electrode (Monica AN24 recorder, Monica Healthcare, Nottingham, UK). The skin was prepared for low impedance by gentle excoriation of the surface skin cells as described by the Monica protocol (using 3 M Skinprep 2236). The resulting EHG data was stored in 4Hz intervals to match the TOCO data. Data were analysed off line after computer download. The TOCO data from the GE Corometrics 250 series was digitally stored for later analysis using the "CTG-Online[®]" software system with data stored at 4 Hz intervals.

The last 2 h of the first stage of labour (143 patients) where simultaneously EHG and TOCO data was available was evaluated as well as the whole second stage of labour (93 patients). These traces were blinded and randomly presented to 4 gynaecologists namely: 2 independent specialist registrar gynaecologists; 1 senior house officer; and 1 junior house officer. None of these gynaecologists were provided with any information as to whether the data presented was first or second stage of labour and which UA modality was being displayed. 5 random recordings during 1st stage and another 5 recordings during second stage of labour were assessed twice by each doctor. By repeating the assessment of these traces we were able to evaluate whether the same trace is assessed consistently by each obstetrician thereby demonstrating not only inter-observer variation but also assessing intra-observer variability.

The UA traces were assessed by the 4 obstetricians into 2 quality groups, namely: "*adequate*" or "*inadequate*" UA trace. "*Adequate*" UA recordings demonstrated a recognizable and reliable pattern with a baseline calibration at or below 20 mmHG (20%) (**•** Fig. 1). "*Inadequate*" UA recordings were divided into: no recognizable UA pattern, labelled as absent UA registration (**•** Fig. 2) or with a recognizable but unreliable pattern since "calibration" was not performed (**•** Fig. 3). Duration of absent UA or inadequate calibration of the contraction pattern could occur during part or the full length of the registration. The number of contractions was counted by each obstetrician for all "*adequate*" UA contraction traces. For each time period of UA recording, which was assessed as adequate by the analysing obstetrician, the average number of UA contractions were calculated for a 30 min period.

If the simultaneous EHG and TOCO time periods was below 20 min during first or 5 min during second stage of labour those patients were excluded from analysis.

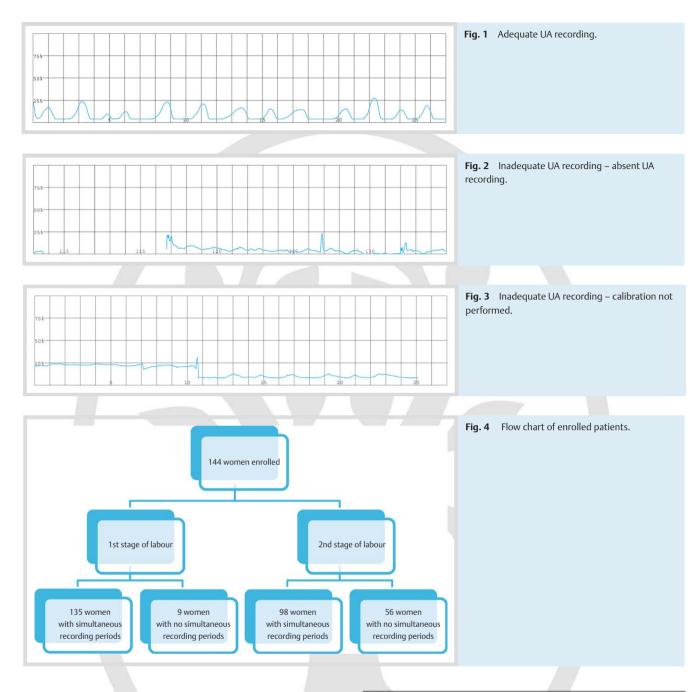
A grading scale was also used on all traces: a scale of '1' for easy, 2 for intermediate and 3 for difficult was employed.

Processing electrohysterography signal

From 1 pair of electrodes (left lateral and symphysis electrodes) the raw electrophysiological signal was processed by the Monica AN24 to extract the EHG signal containing the 0.2 Hz to 0.9 Hz low-frequency band. The signal was subsequently filtered using a low-pass filter (set at approximately 0.02 Hz) to provide the familiar envelope of a uterine activity signal comparable with the TOCO traces.

Data analysis

For statistical analyses the Wilcoxon signed rank test and Spearman's rho correlation coefficient were used. The analyses were carried out using the SPSS Statistics 17.0 software. The means and standard deviation (SD) were processed. P<0.05 for a twotailed test was considered statistically significant.



Results

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During the first stage of labour 135 women had simultaneous Doppler ultrasound CTG and abdominal FECG whilst in the second stage this number was 98 (**•** Fig. 4). The median simultaneous record length of TOCO and EHG were in the first stage of labour 194.2 min (mean 253.7 ±SD 244.0 min). The median second stage of labour simultaneous record length was 20.0 min (mean 48.1 ± 60.7 min).

The overall EHG signal showed significantly more "*adequate*" UA trace (average length of UA recordings mean $138.8\pm$ SD 110.9 min) when compared to the TOCO (mean 119.6 ± 99.6 min) [p<0.001]. EHG demonstrated no inadequate UA traces, i.e. were 100% reliable. However the TOCO' had a mean 8.1 (±SD 17.6) unreliable pattern due to "calibration", which was not performed, and 11.2 (±SD 15.6) min due to absent UA recording.

 Table 1
 Average number (min) of adequate UA recordings during 1st and 2nd stage of labour.

	Method	Mean	SD	Wilcoxon Signed Rank Test: p-value
1 st stage	ehg Toco	177,6 153,5	119,5 107,0	< 0,001
2 nd stage	ehg Toco	79,6 67,8	59,6 56,5	< 0,001

Similarly, during first stage and second stage of labour EHG showed significantly more "adequate" UA when compared to the TOCO (• Table 1).

All doctors identified more UA contractions (**• Table 2**, p < 0.001) with the EHG whilst the TOCO had a much larger variability (i.e. SD) in the number of contractions identified by the obstetricians – in other words using visual observation of contractions the

TOCO traces on some occasions severely overestimated the number of contractions whilst in other cases the number of contractions were grossly underestimated. Further, the assessment of UA was defined as "easier" (\circ Table 3; p < 0.001) using the EHG modality compared with TOCO. When the obstetricians repeated the evaluation of the traces there was no significant change in both the of number of contractions detected calculated for a 30 min time period of adequate recording and the ease of UA assessment of the EHG and TOCO recordings for stage 1 and 2 (\circ Table 4; p > 0.05).

• Table 5 illustrates the difference in the number of contractions detected between each obstetrician. Here we can see that on only 1 occasion did 2 obstetricians show no significant difference during both stages of labour i.e. specialist registrar 1 and the junior house officer. The same specialist registrar showed no significantly different number of UA contraction when compared with the senior house officer during second stage of labour. In all other occasions there were statistically significant different numbers of UA using EHG.

When using comparing obstetricians the TOCO traces the same specialist registrar and junior house officer again showed no significant different UA contraction numbers during first and second stage of labour (**o Table 6**; p>0.05), whereas in all other

occasions the differences were statistically significant (**• Table 6**; p<0.001). Finally it should be noted that the contraction count difference amongst the TOCO group (**• Table 6**) was consistently higher than the EHG (**• Table 5**).

Finally with regards to BMI it was observed that using EHG only 1 obstetrician had a weak correlation of mean number of contractions in 30 min against BMI (Spearman's rho = -0.16, p = 0.03) whilst the other 3 obstetricians indicated no correlation with BMI when using EHG. However, with regards to TOCO, all obstetricians had a weak correlation of of mean number of contractions in 30 min against BMI (Spearman's rho range – 0.22 to – 0.29; p < 0.001)

Comments

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This study has shown that the EHG presents a more continuous uterine activity trace (classified as "adequate") when compared to TOCO and provides a trace that is much easier to be assessed. Further this evaluation showed that there was a high interobserver variability of both EHG and TOCO, however, this variability was higher for TOCO.

Table 2 Calculated mean number of contractions for a 30 min time period.								
	Stage of labour		EHG			ocogran	Wilcoxon Signed Rank Test: p-value	
		Mean	SD	Range	Mean	SD	Range	
Specialist registrar 1	1 st	12.9	1.9	4.9-17.6	9.1	7.2	0-24.0	< 0.001
	2 nd	14.8	2.6	11.4-27.3	11.2	5.1	0-27.9	< 0.001
Specialist registrar 2	1 st	11.2	2.4	0-17.6	5.7	6.1	0-14.0	< 0.001
	2 nd	13.6	2.9	5.1-27.3	6.8	5.5	0-21.3	< 0.001
Senior house officer	1 st	12.3	2.3	0-17.6	7.3	7.2	0-14.1	< 0.001
	2 nd	14.4	2.7	6.9-27.3	9.8	4.8	0-26.2	< 0.001
Junior house officer	1 st	12.9	1.8	7.0-17.6	8.8	7.1	0-8.2	< 0.001
	2 nd	14.9	2.8	10.9-28.6	11.5	4.9	2.7-28.7	< 0.001

Table 3 Mean number of ease of assessment of the EHG or tocogram (1 = easy. 2 = intermediate. 3 = difficult).

	Stage of labour	EHG Tocogram				Wilcoxon Signed Rank Test: p-value		
		Mean	SD	Range	Mean	SD	Range	
Specialist registrar 1	1 st	1.0	0.2	1–2	2.8	0.4	1–3	< 0.001
	2 nd	1.0	0.1	1–2	2.8	0.5	1–3	< 0.001
Specialist registrar 2	1 st	1.2	0.4	1–2	1.9	0.4	1–3	< 0.001
	2 nd	1.2	0.3	1–2	2.0	0.5	1–3	< 0.001
Senior house officer	1 st	1.4	0.5	1–3	2.6	0.5	1–3	< 0.001
	2 nd	1.2	0.4	1–3	2.7	0.5	1–3	< 0.001
Junior house officer	1 st	1.2	0.3	1–2	2.3	0.6	1–3	< 0.001
	2 nd	1.1	0.2	1–2	2.2	0.7	1–3	< 0.001

Table 4 Intraobserver variability of overall analysis of repeated evaluation for the mean number of contractions for a 30 min time period (mean ± SD) and ease of assessment (1 = easy to evaluate. 2 = intermediate. 3 = difficult to evaluate) for the EHG and tocogram traces (p > 0.05).

		E	HG			Tocogram			
	Con-	Repeat Con-	Assess-	Repeat	Con-	Repeat Con-	Assess-	Repeat	
	traction	traction Count	ment	assessment	traction	traction Count	ment	assessment	
Specialist registrar 1	13.3±1.0	13.7±0.9	1.1±0.2	1.0 ± 0.0	9.1±5.0	9.2±5	2.8 ± 0.4	2.8±0.4	
Specialist registrar 2	11.7±2.1	12.2±1.4	1.3±0.3	1.3 ± 0.3	6.1 ± 4.6	5.9±4.8	2.0 ± 0.4	2.0 ± 0.4	
Senior house officer	13.2±1.4	13.2±1.1	1.3±0.4	1.6 ± 0.5	7.4 ± 4.2	7.5±5.0	2.6±0.5	2.6±0.5	
Junior house officer	13.5±1.2	13.4±1.0	1.1±0.3	1.0 ± 0.0	9.3 ± 4.9	8.4±5.0	2.2 ± 0.6	2.1±0.7	

Table 5Wilcoxon Signed Ranks Test (Z-value; $* = p = 0.001$; $** = p < 0.001$) of interobserver variability for the EHG between obstetricians.								
	Stage of labor	Specialist registrar 1	Specialist registrar 2	Senior house officer	Junior house officer			
Specialist registrar 1	1 st 2 nd	-	8.6** 6.1**	5.1** 1.6	1.2 1.4			
Specialist registrar 2	2 1 st	- 8.6**	-	8.4**	9.0**			
	2 nd	6.1**	-	6.2**	6.9**			
Senior house officer	1 st 2 nd	5.1**	8.4**	-	4.3**			
Junior house officer	2 nd 1 st	1.7 1.2	6.2** 9.0**	- 4.3**	3.4*			
junior nouse officer	2 nd	1.4	6.9**	3.4*	-			

Table 6 Wilcoxon Signed Ranks Test (Z-value; ** = p<0.001) of interobserver variability for the tocogram between obstetricians.

	Stage of labor	Specialist registrar 1	Specialist registrar 2	Senior house officer	Junior house officer
Specialist registrar 1	1 st	-	9.3**	7.4**	0.9
	2 nd	-	7.2**	4.7**	0.6
Specialist registrar 2	1 st	9.3**	-	7.9**	9.4**
	2 nd	7.2**	-	6.4**	7.1**
Senior house officer	1 st	7.4**	7.9**	-	8.1**
	2 nd	4.7**	6.4**	-	5.9**
Junior house officer	1 st	0.9	9.4**	8.1**	-
	2 nd	0.6	7.1**	5.9 **	-

The tocogram has been suggested by many to be the best monitoring system available since it is non-invasive with an inherent limitation in that it cannot quantify uterine activity [3,26]. No difference in spontaneous vaginal deliveries or obstetric outcome has been shown when comparing TOCO with internal monitoring [27,28] and hence it has become the currently accepted modality for recording UA.

Even though our study results showed higher rates of adequate tocogram recordings than previously reported [3] we found that the regions of inadequate TOCO traces marked varied differently from obstetricians to obstetricians. We have demonstrated however, a considerably higher percentage of adequate EHG trace was identified compared to TOCO. Recent studies by Jacod and Euliano [19,29]. demonstrated accurate detection of uterine contractions using EHG when compared with internal intrauterine pressure catheter recordings. The increased number of uterine contractions compared to TOCO could be explained due to the increased sensitivity of this method.

The cause of the poor quality tracing of the TOCO are due to incorrect positioning of the tocodynamometer, insufficient tension of the strap holding the transducers as well as obese patient which is not in the supine position [26, 30]. All of these reasons result in increased midwife attendance being necessary for contraction monitoring using the TOCO.

Finally, after more than 50 years of research and promise the technology of electrohysterography is now a feasible alternative to the tocogram for the monitoring of uterine activity during labour.

Conclusion for clinical practise

Intrapartum UA monitoring in daily practice via the EHG mode provides a more recognizable UA trace than the TOCO.

Contribution to authorship

All authors contributed to the study protocol, reviewed the results and wrote the article. The first author performed the statistical analysis and collected clinical data. The first, third, fourth and fifth authors analysed the UA contraction curves.

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Details of Ethics Approval

We received the positive ethics approval from the "Ethik-Kommission der Medizinischen Fakultät der Ruhr-Unversität Bochum, Germany" reference No. 3358-08 MPG.

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Conflict of interest

Professor Hayes-Gill is employed by the University of Nottingham and is also a Director of Monica Healthcare Ltd.

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