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MATERNAL-FETAL MEDICINE

Intrapartum signal quality with external fetal heart rate monitoring: a two way trial of external Doppler CTG ultrasound and the abdominal fetal electrocardiogram

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Abstract
Objective The objective of this study was to assess the fetal heart rate (FHR) signal quality of non-invasive abdominal fetal electrocardiogram (fECG) in comparison to the Doppler ultrasound cardiotocogram (CTG) during the first and second stage of labour.
Study design This was a prospective observational study of non-invasive fECG using five abdominally sited electrodes against the traditional Doppler ultrasound CTG probe on 144 patients. Data were analysed for signal quality before and after outlier removal.
Results Abdominal fECG signal quality was significantly better during the first stage of labour in comparison to Doppler CTG (median fECG reliability of 95.7 % vs. median 87.3 % for Doppler, $p < 0.001$), whereas during second stage of labour, equivalence was demonstrated ($p > 0.05$). For the first and second stage of labour, fECG showed 106/135 (78.5 %) and 46/98 (46.9 %) women having fetal signal loss below 20 %, respectively. Similarly, Doppler ultrasound demonstrated 104/135 (77.0 %) and 51/98 (52.0 %) women having fetal signal loss below 20 % during first and second stage of labour, respectively.
Conclusion The non-invasive abdominal fECG presents an improved FHR signal quality during the first stage of labour and an equivalent signal quality during the second stage.

Keywords Non-invasive fetal electrocardiogram (fECG) · Doppler ultrasound cardiotocogram (CTG) · Fetal heart rate (FHR) · First and second stage of labour · Signal quality

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Introduction

Electronic fetal monitoring (EFM) of the fetal heart rate (FHR) has been a readily accepted instrument for the monitoring of fetal wellbeing for the past 30 years. This has predominantly been implemented with an external Doppler ultrasound transducer having a relatively low signal loss [9] with an apparently accurate and reliable determination of the FHR. This usage of EFM during labour has essentially replaced auscultation, although there is little evidence that continuous EFM monitoring improves clinical outcome [1, 7]. Inter- and intra-observer variability of interpreting intrapartum cardiotocographic patterns by the obstetrician is assumed to be a limiting factor [2, 16, 19, 20]. In addition, earlier studies described average Doppler ultrasound FHR signal loss from approximately 15 % to almost 40 % [3, 4, 18], thereby affecting the accurate interpretation of such traces. Furthermore, both the FIGO and German Society of Obstetrics

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and Gynaecology (DGGG) guidelines describe an acceptable fetal signal loss of 20 and 15 %, respectively [5, 14].

Recently, a non-invasive abdominal fetal electrocardiogram (fECG) monitoring (the Monica AN24) has been approved for clinical practice that has demonstrated reliable FHR operation [10, 12, 13]. The purpose of the current study was to quantify the amount of FHR signal loss in relation to the method of monitoring: external Doppler ultrasound cardiotocogram (CTG) or non-invasive abdominal fECG.

Materials and methods

Study samples

All patients who were admitted to hospital for delivery and had a single 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 (31.9 %); or induction of labour (31.9 %). 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).

Study protocol

Five Ambu VLC-00-S electrodes were placed on the abdomen: one electrode was placed on the midline within a range of 3 cm above the navel, one was placed 6 cm above the symphysis, two were placed at the right and left lateral abdominal wall and finally one reference electrode was placed towards the back on the right lateral of the abdomen. This configuration allows three parallel abdominal fECG detection channels around the maternal abdomen. The skin was prepared for low impedance by gentle excoriation of the surface skin cells as described by the Monica protocol (using 3M Skinprep 2236). The electrodes were connected to the Monica AN24 recorder (Monica Healthcare, Nottingham, UK) with a sampling rate of 300 Hz. A 3.75 s moving window average FHR, updated every 0.25 s (i.e. 4 Hz) was generated to match the data format of the Doppler ultrasound CTG. All data were analysed offline after computer download. The cardiotocograph (CTG) data from the GE Corometrics 250 series were digitally stored for later analysis using the "CTG-Online®" software system with the 3.75 s average FHR data stored at 4 Hz intervals. As the two FHR modalities do not share a common time clock, synchronisation was achieved by cross correlating the two heart rate files and locating the peak correlation. All simultaneous external ultrasound and fECG recordings were subsequently evaluated for signal loss. The management of labour was solely on the basis of external Doppler ultrasound CTG recordings and all women had intermittent Doppler CTG recordings as described in the standard hospital protocol. The non-invasive abdominal FHR traces were only evaluated after delivery.

An outlier removal process has been implemented to remove FHR data points that would naturally be ignored by a clinical reviewer's visual interpretation of an FHR trace. These consist of FHR data out of range, spikes on FHR data, and confusion with the maternal heart rate (MHR). The outlier removal process therefore comprises three steps as follows:

1. Discard any FHR data outside a 60–200 bpm range
2. Discard the FHR data when confused with MHR, defined as an FHR data point that lies within 5 bpm of the MHR
3. Discard 'isolated' FHR data points, defined as regions of FHR <10 s in duration and having an absolute FHR difference from the baseline of >15 bpm

Data analysis

The following data analysis was carried out with and without outlier removal:

- FHR success rate: defined as the percentage of time that an FHR value was reported divided by the total time.
- Percentage of patients with FHR signal loss <20 % (FIGO guidelines)
- Percentage of patients with FHR signal loss <15 % (DGGG guidelines)
- Correlation coefficients of FHR success rate versus stage of labour, BMI, birth weight and epidural, all after outlier removal

For statistical analyses, the Wilcoxon signed rank test and the Spearman's rho correlation coefficient were used. The analyses were carried out using the SPSS Statistics 17.0 software. The medians and range were determined for the FHR success rates. $P < 0.05$ for a two-tailed test was considered statistically significant.

Results

Fetal ECG signal quality after outlier removal was significantly better during first stage of labour in comparison to Doppler CTG (median 95.7 vs. 87.3 %, $p < 0.001$; Table 1; Fig. 1), whereas during second stage of labour no significant difference was demonstrated ($p > 0.05$) and the two devices were considered to be equivalent.

Table 1 also shows the subgroup analysis for percentage of patients having an FHR signal loss below both 20 and 15 %. Again, the abdominal fECG demonstrated a significantly improved FHR signal quality compared to Doppler CTG during first stage of labour ($p < 0.001$). However, no significant difference was found during second stage of labour ($p > 0.05$). For the first and second stage of labour, fECG (after outlier removal) showed 106/135 (i.e. 78.5 %) and 46/98 (i.e. 46.9 %) women with signal loss below 20 % compared to Doppler ultrasound CTG which demonstrated 104/135 (i.e. 77.0 %) and 51/98 (i.e. 52.0 %) women. For signal loss below 15 %, fECG showed 99/135 (i.e. 73.3 %) and 36/98 (i.e. 36.7 %) for first and second stage of labour compared to Doppler ultrasound CTG of 87/135 (i.e. 64.4 %) and 37/98 (i.e. 37.8 %) during first and second stage of labour, respectively.

The correlation of FHR success rate versus success rates at different stage of labour, BMI, birth weight and Epidural status was determined for the outlier removed data and this is illustrated in Table 2. Here it was found that:

1. During the first stage of labour, fECG FHR success rates had:
   - A strong positive correlation (0.68) with the fECG FHR success rates at the second stage of labour ($p < 0.001$).
   - A weak positive correlation with birth weight ($p = 0.009$) and first stage of labour Doppler CTG FHR success rates ($p < 0.001$) of 0.22 and 0.34, respectively.
   - No correlation demonstrated with the second stage of labour Doppler CTG FHR success rate, BMI and epidural anaesthesia ($p > 0.05$).
2. During the second stage of labour, fECG FHR success rates had:
   - A weak positive correlation (0.41) with the second stage of labour Doppler CTG FHR success rates ($p < 0.001$).
3. Second stage of labour Doppler CTG FHR success rates demonstrated:

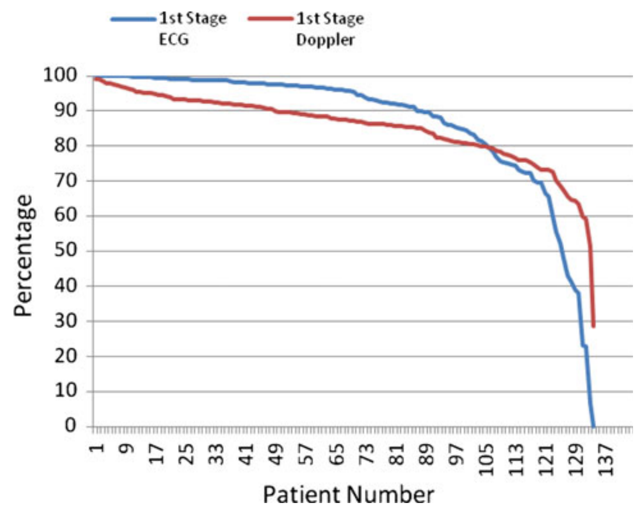

Fig. 1 Individual success rates for concurrent monitoring episodes (after outlier removal) plotted in descending order for both abdominal fetal ECG (*blue*) and Doppler ultrasound CTG (*red*) during the first stage of labour

Table 1 Median (range) of FHR success rate (%) and percentage of patients with signal loss below 20 and 15 % before and after outlier removal for first and second stage of labour

	Median FHR success rate (range) (%)	Percentage of patients with signal loss <20 % (%)	Percentage of patients with signal loss <15 % (%)
First stage ($n = 135$)			
Fetal ECG	97.7 (7.8–100)	81.5	77.8
Doppler CTG	85.5 (35.1–99.8)	89.6	80.7
Fetal ECG after outlier removal	95.7 (0–100)	78.5	73.3
Doppler CTG after outlier removal	87.3 (28.8–99.3)	77.0	64.4
Second stage ($n = 98$)			
Fetal ECG	85.5 (13.4–100)	54.1	48.0
Doppler CTG	92.3 (22.5–99.8)	76.5	64.3
Fetal ECG after outlier removal	80.2 (0.7–100)	46.9	36.7
Doppler CTG after outlier removal	82.2 (0–99.8)	52.0	37.8

Table 2 Spearman's rho correlation coefficients for fetal ECG success rate, Doppler CTG success rate, BMI, birth weight and epidural anaesthesia

	Fetal ECG stage1 success rate	Fetal ECG stage2 success rate	Doppler stage1 success rate	Doppler stage2 success rate	BMI	Birth weight	Epidural
Fetal ECG stage 1 success rate	N/A	0.68*	0.34*	0.15	0.00	0.22*	0.10
Fetal ECG stage 2 success rate	0.68*	N/A	0.15	0.41*	−0.14	0.19	−0.03
Doppler stage 1 success rate	0.34*	0.15	N/A	0.20	−0.10	−0.09	0.07
Doppler stage 2 success rate	0.15	0.41*	0.20	N/A	−0.35*	0.16	−0.28*
BMI	0.00	−0.14	−0.10	−0.35*	N/A	0.14	−0.01
Birth weight	0.22*	0.19	−0.09	0.16	0.14	N/A	0.06
Epidural	0.10	−0.03	0.07	−0.28*	−0.01	0.06	N/A

* Correlation is significant at the 0.01 level (two-tailed)

- A weak negative correlation with BMI (−0.35 at $p = 0.001$)
- A weak negative correlation with epidural anaesthesia (−0.28 at $p = 0.009$).

Nine women and 46 women had no simultaneous abdominal fetal ECG and Doppler CTG recordings in the first and second stage of labour, respectively. The median simultaneous record length of Doppler CTG and fECG was 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 ± SD 60.7 min). The median birth weight was 3,350 g (mean 3,390.8 ± SD 484.3 g).

The median correlation coefficient of the time varying Doppler ultrasound CTG FHR data file versus abdominal fetal ECG FHR data file for all patients was 0.94 (range −0.11 to 0.99) for first stage of labour and for the second stage of labour it was 0.85 (range −0.73 to 0.99).

Discussion

This study uniquely demonstrates the superior FHR signal detection rate of non-invasive abdominal fECG compared to the currently accepted standard Doppler Ultrasound CTG during the first stage of labour. No inferiority was found during the second stage of labour.

Though the often required signal detection rates of above 80 [15] or 85 % [5] is not based on any detailed research [14, 17], these criteria detection rates are significantly less for Doppler ultrasound CTG when compared to abdominal fECG. For the 20 % threshold after outlier removal, abdominal fECG in the first stage of labour showed 78.5 % of patients achieved the criteria, whilst for Doppler CTG, only 77 % of patients achieved the criteria. For the 15 % threshold, the situation was considerably worse with the abdominal fECG having a patient success rate of 73.3 %, but Doppler CTG patient success rate fell to 64.4 %. Other studies have linked signal loss with movements of the mother or the baby [4]. In addition, if the FHR changes quickly as in cardiac arrhythmias, loss of signal may also occur [8].

In agreement to the study of Solum in second stage of labour Doppler ultrasound, FHR signal success rate was negatively correlated (albeit weakly) with BMI [18], i.e. an increase in BMI resulted in a lower Doppler FHR success rate. However, abdominal fECG FHR success rate showed neither a negative nor a positive correlation with BMI.

The inadvertent detection of MHR can occur with both recording techniques. For example, this can occur if the ultrasound transducer is wrongly directed towards the maternal blood flow in a maternal vessel, or if MHR meets typical fetal characteristics and the FHR is not typical. It is also possible for abdominal fECG to do this if the fECG signal quality is poor and the algorithm is not able to detect the fECG complexes. A detailed FHR data analysis of MHR/FHR ambiguity using the two FHR modalities is presented in J Perinat Med [11].

When the signal detection rate is low, improvement of FHR detection can be accomplished using a scalp ECG electrode clip once rupture of membranes has occurred. It has been shown that signal detection rate here is significantly better when compared to external ultrasound detection. However, regularly achieving an FHR success rate above 80 % for scalp ECG can also not be guaranteed [3]. The scalp ECG also provides the opportunity to analyse both the T/QRS ratio and the ST segment within the fECG morphological complex [2]. Even though certain contraindications exist and early rupture of membranes might also increase the rate of caesarean section [6], the direct ECG with a scalp electrode is the method of choice in the surveillance of high-risk deliveries or women with low FHR signal detection rate in many countries [2, 3].

We conclude that the presented results could potentially lead to a change of current FHR surveillance in clinical practise as the non-invasive abdominal fECG has a proven superiority to the more traditional Doppler ultrasound during the first stage of labour (and is equivalent during the second stage). Finally, non-invasive abdominal fECG opens up the possibility of FHR beat to beat and morphological analysis only currently possible with the highly invasive fetal scalp ECG.

Conclusions

This study demonstrates the increased signal quality during the first stage of labour and an equivalent signal quality during the second stage of labour of a new commercially available non-invasive abdominal fECG device (the Monica AN24^{TM}) when compared to Doppler ultrasound CTG.

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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.

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

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