

Intrapartum Heart Rate Ambiguity: A Comparison of Cardiotocogram and Abdominal Fetal Electrocardiogram with Maternal Electrocardiogram

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Key Words

Fetal heart monitoring · Fetal heart rate · Maternal heart rate · Abdominal fetal electrocardiogram · Abdominal maternal electrocardiogram · Signal ambiguity and confusion

practice via the CTG modality provides significantly more 'MHR/FHR ambiguity' than abdominal fetal ECG, which also provides additional information on the MHR.

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Abstract

Objective/Aims: To investigate the presence of signal ambiguity of intrapartum fetal heart rate (FHR) monitoring during delivery by comparing simultaneous cardiotocogram (CTG), abdominal fetal electrocardiogram (ECG) with continuous maternal ECG. **Methods:** A total of 144 simultaneous CTG (Corometrics[®] 250 series), abdominal fetal ECG (Monica AN24[™]) and maternal ECG (Monica AN24[™]) recordings were evaluated. **Main Outcome Measures:** When the FHR is within 5 bpm of the maternal heart rate (MHR) acquired from the ECG, it is classified as 'MHR/FHR ambiguity'. Statistical analyses were performed with Fisher's exact test and the Wilcoxon signed-rank test. **Results:** Comparison of abdominal fetal ECG against CTG demonstrates significantly less 'MHR/FHR ambiguity' in both the first stage (mean 0.70 vs. 1.22%, $p < 0.001$) and second stage of labour (mean 3.30 vs. 6.20%, $p < 0.001$). **Conclusion:** Intrapartum FHR monitoring in daily

Introduction

In 1969, von Mosler [1] described a simple non-invasive method for fetal heart rate (FHR) monitoring using the principle of Doppler generated from ultrasound signals directed at the fetal heart through the maternal abdomen. The resulting Doppler shift in frequency allowed the FHR to be determined (cardio). By combining this technique with a tocodynamometer (i.e. a strain gauge) allowed the maternal contractions to be measured. The combination of both the cardio and toco signals in one instrument resulted in the well-known cardiotocogram (CTG) used extensively in obstetric practice. Since 1969, CTG monitoring has become commonplace and was established as the new gold standard for FHR determination even though no definitive evidence was presented that such technology would reduce neonatal morbidity [2].

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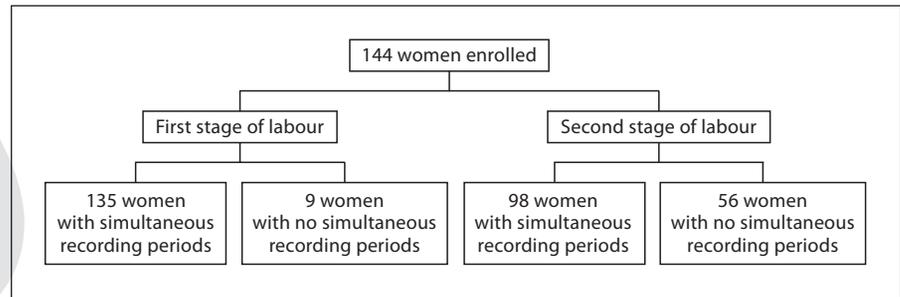


Fig. 1. Flow chart of enrolled patients.

CTG monitoring relies on the more artefact-prone ultrasound technology with reported signal loss from approximately 15% to almost 40% [3, 4]. Further, Neilson et al. [2] reported on confusing situations which may occur during fetal monitoring in which the fetal heart beat signal is replaced by an alternative heart beat signal from the mother. The stated occurrence of an unexpected adverse fetal outcome attributable to this signal ambiguity was 5 out of 10,000 deliveries; however, several more cases have occurred without adverse neonatal outcome, i.e. unnecessary interventions [2]. In addition, the USA Food and Drug Administration Agency MedWatch has recently reported on complaints from health professionals due to halving of the FHR, doubling of the FHR and switching between the FHR and maternal heart rate (MHR) when using CTG transducers [5].

In clinical practice, controversy still exists of the value of continuous FHR monitoring [6–8]. High inter- and intraobserver variability of obstetricians is assumed to be the main cause [9–12], hence guidelines for interpreting FHR traces have been established and computer-generated evaluation systems have been introduced [13–17].

Using electrocardiography (ECG) analysis (ST changes) via fetal scalp electrodes provides an additional method for assessing the response of the fetus to hypoxia and in development of a metabolic acidosis [18]. In several randomized controlled trials it has been shown that fetal ECG can reduce the rate of neonatal encephalopathy and the rates of obstetric interventions [6, 18]. However, in order to apply a fetal scalp electrode, membranes must be ruptured, a cervix opening is necessary, and such a procedure can increase the chances of infection [19].

Recently a non-invasive abdominal fetal electrocardiogram (ECG) monitor, the Monica AN24™, has been approved for clinical practice, which has been demonstrated to be a reliable FHR and MHR monitor [20–22]. This device uses cutaneous electrodes applied to the maternal abdomen and detects the electrical signals from

both the fetus (fECG) and the mother (mECG) and extracts the FHR and MHR in real time.

The study reported here is designed to quantify the occurrence of ambiguous FHR in normal clinical usage. Fetal scalp electrodes were not used since it is not possible in very early labour (cervix dilatation <2 cm) and is an invasive procedure only used for special indications. Our pilot study showed good signal quality of the newly available abdominal fECG during the first stage of labour [22] and has been further improved in a more extended trial which also examines the second stage of labour. The latter results are currently in preparation for subsequent publication.

The purpose of this current study was to determine the level of ambiguous FHR recordings during the first and second stage of labour. Our study has quantified these levels of FHR ambiguity in relation to continuous MHR acquired via abdominal mECG. To perform this study, two FHR monitoring modalities were used, namely the traditional CTG instrument and non-invasive abdominal fECG, the results of which are shown in figures 1–7.

Materials and Methods

Power Calculation

Based on results from a previous study that compared ultrasound and abdominal fECG [22], a sample size of 50 with an α of 0.5 would have a power of 0.9 to identify equivalence in success rate, reliability and accuracy within 10% of the standard.

Study Samples

All patients who were admitted to Marien Hospital Witten for delivery and had a single pregnancy were eligible to participate in this study. Ethics approval was received from the Ethik-Kommission der Medizinischen Fakultät der Ruhr-Universität Bochum, Germany (ref. No. 3358-08 MPG).

Nearly all (144/147) women who were informed gave their written consent on the study and agreed to participate (fig. 1). The 144 women evaluated were admitted to hospital as a result of uterine contractions (36.2%), (premature) rupture of membranes (31.9%), or induction of labour (31.9%) in May to September 2009. With

Fig. 2. An example of CTG with possible MHR/FHR ambiguity (regions marked * and +), which is subdivided into 'true ambiguity' (see region marked *) and 'unknown' (see region marked +) (i.e. abdominal fECG surveillance modality missing data). Trace colours are: blue = FHR derived from abdominal ECG; red = FHR derived from CTG; black = MHR derived from abdominal ECG.

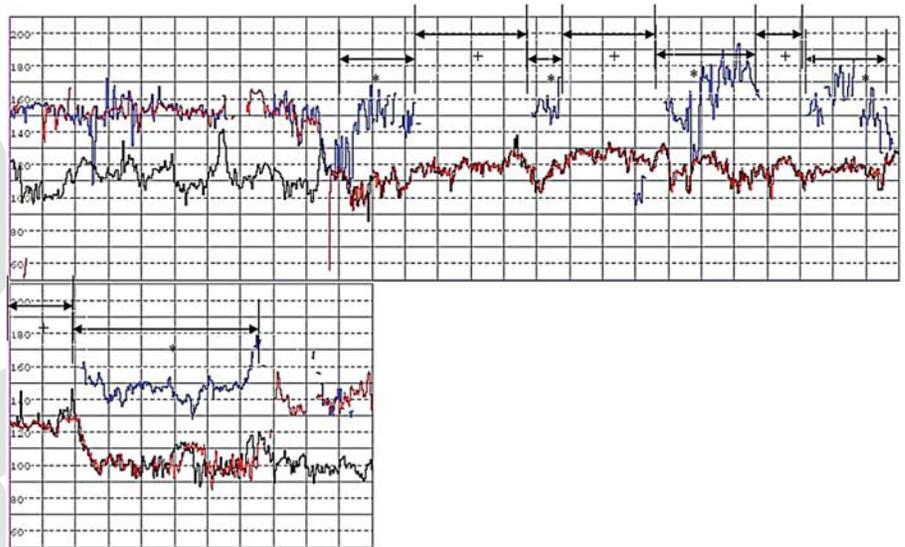


Fig. 3. An example of 'FHR/MHR confusion' (see region marked *) by the abdominal fECG modality. Trace colours are as described in figure 2.

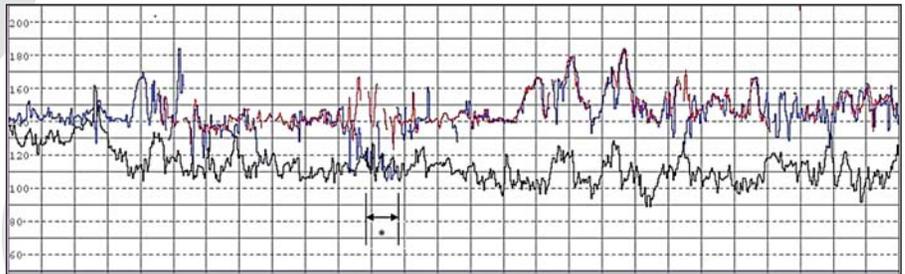


Fig. 4. An example of genuine FHR close to MHR during second stage of labour 'no ambiguity'. Trace colours are as described in figure 2.

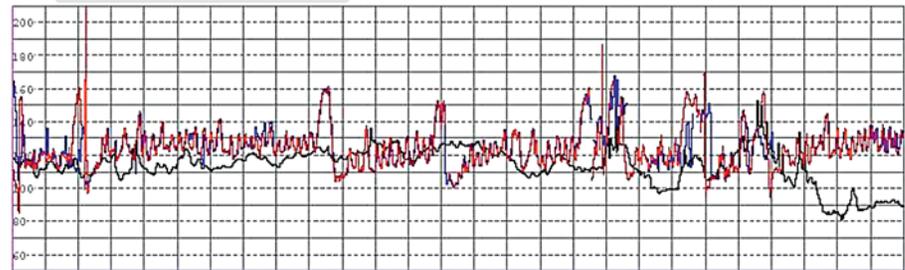
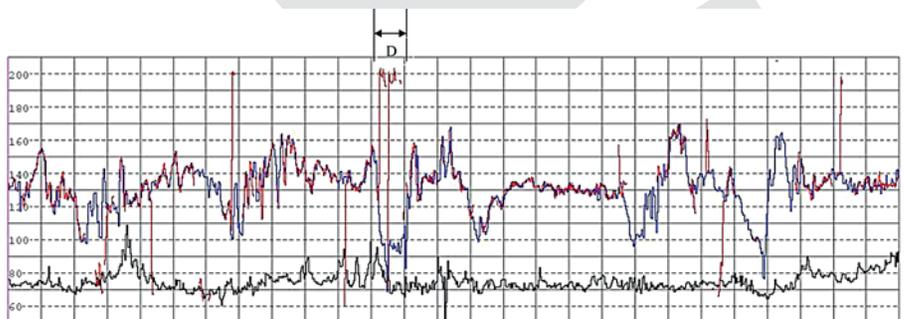


Fig. 5. An example of doubling (D) (see region marked 'D') of the FHR by the CTG. Trace colours are as described in figure 2.



Color illustration online only!

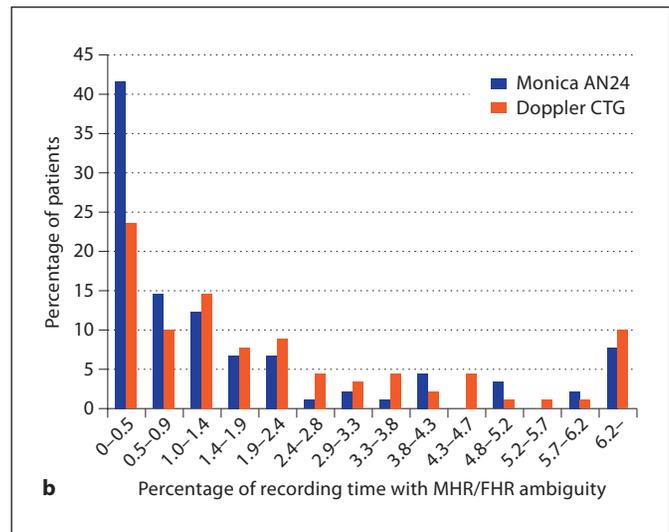
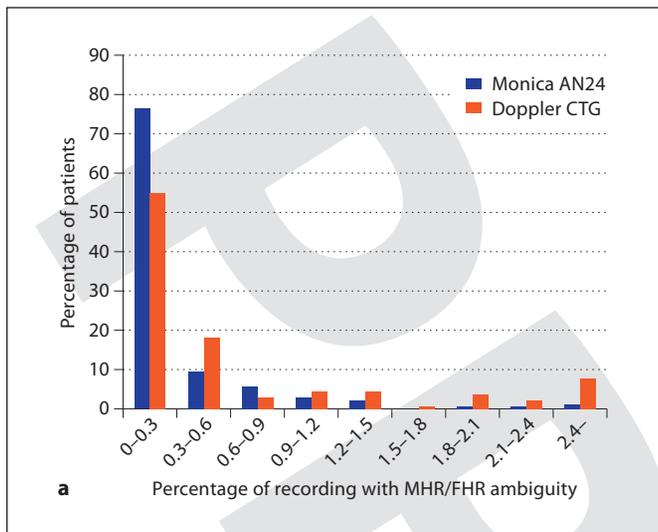


Fig. 6. Percentage of recording time of ‘true ambiguity’ during the first stage (a) and second stage (b) of labour.

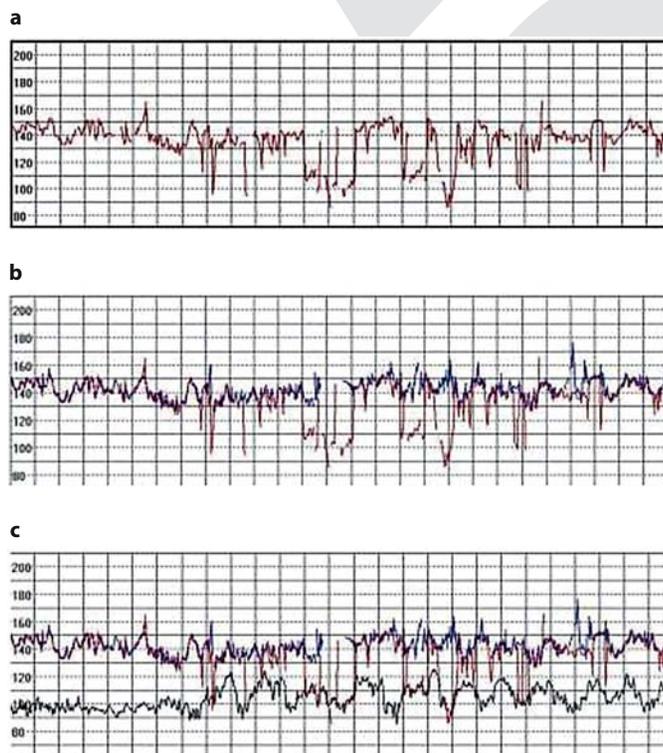


Fig. 7. a Red = FHR using Doppler ultrasound. b Red = FHR using Doppler ultrasound, blue = FHR using abdominal fECG. c Black = MHR; red = Doppler ultrasound; blue = abdominal fECG.

written consent, the women underwent continuous abdominal ECG (using the Monica AN24) and intermittent CTG (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). All deliveries were managed using only the Corometrics CTG. The attendant care team were blinded to the abdominal ECG (fetal and maternal) and this was only viewed and evaluated *after* delivery and had no influence on the management of labour. Of the 144 women who consented, 98 (67.7%) had intact amniotic membranes, 104 (71.7%) had epidural anaesthesia, 99 (68.8%) had a spontaneous vaginal delivery, 41 (28.5%) had a lower uterine segment caesarean section, and 4 (2.8%) had an instrumental delivery. Indication for caesarean section was in all of the 41 cases a result of failure to progression of labour. The time length of simultaneous recording of all patients during the first stage of labour was median 240 min (mean 295 ± 254 min (SD)) and during the second stage of labour was median 162 min (mean 158 ± 54 min). The body mass index was in the range of 20.6–49.5 (median 28.9, mean 29.8, SD 4.7). The mean newborn weight was 3,390 g (median 3,365 g, SD 463.8, range 2,240–4,900) with an arterial pH value of 7.30 (SD 0.08, range 7.09–7.52). 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.

Study Protocol

Five Ambu VLC-00-S electrodes were placed on the maternal 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 exfoliation of the surface skin cells as described by the Monica

protocol (using 3M SkinPrep 2236). The electrodes were connected to the Monica AN24 recorder and data was downloaded to a computer for subsequent analysis. The CTG data from the GE Corometrics 250 series (paper velocity 1 cm/min) was also digitally stored for later analysis. In both the CTG and abdominal ECG systems, the heart rate data was stored at 0.25 s intervals. The heart rate data from both sources were then synchronized to within 0.25 s by cross-correlating the FHR data from each source, with the highest correlation showing correct synchronization.

The resulting synchronised heart rate files from the CTG and the abdominal fECG (including the mECG) were imported into Microsoft Excel (Microsoft Office 2007) where the heart rate data was compared and analysed. All simultaneous CTG and abdominal fECG recordings were evaluated for 'possible MHR/FHR ambiguity' if the FHR lay within ± 5 bpm of the MHR measured via the use of the mECG acquired with the Monica AN24 recorder. Since the duration of recordings varied from patient to patient (range 0.13–22.32 h, median 3.99 h), the percentage of 'possible MHR/FHR ambiguity' with respect to the total recording time was calculated and evaluated. For each 'possible MHR/FHR ambiguity' period the other fetal surveillance modality was checked and subdivided into three groups: (i) if the other fetal surveillance modality had a FHR 5 bpm outside of the MHR it was classified as 'true ambiguity' (fig. 2), or (ii) if the other fetal surveillance modality also had its FHR within 5 bpm of the MHR it was then classified as 'no ambiguity' (fig. 4), or (iii) if the other fetal surveillance modality had no FHR data it was then classified as 'unknown' (fig. 2). Similarly, a percentage calculation of those subdivisions was carried out. All comparisons were carried out using Microsoft Excel (Microsoft Office 2007), which evaluated the difference in maternal and FHR in both the first and second stage of labour were evaluated. In each case the signal reliability for both modalities was also evaluated as the percentage of available FHR and MHR in the recorded time period.

Finally, for severe cases of FHR ambiguity where the 'possible MHR/FHR ambiguity' exceeded 4%, these cases were evaluated separately. The 4% cut-off was derived in a panel discussion of two consultants and eight specialist registrars at which level a clinical impact (for example a fetal blood sample) is expected to occur for a patient. The discussion was based on a signal ambiguity case for which repeated dips would have given an indication for fetal blood sampling. For this subgroup the number of erroneous decelerations (deceleration of FHR >15 bpm for >15 s and <3 min) and number of erroneous bradycardia events (deceleration of FHR >15 bpm for >3 min) were evaluated when in fact the FHR was incorrectly presenting the MHR data.

It should be noted that the management of labour was purely on the basis of CTG recordings and all women had intermittent CTG recordings as specified by the local hospital protocol. The non-invasive FHR and MHR traces derived from abdominal fECG were only evaluated after delivery.

Data Analysis

The following exclusion criteria were applied: simultaneous Doppler ultrasound and abdominal ECG <20 min during first stage of labour or <5 min during second stage of labour.

For statistical analyses the Wilcoxon signed-rank test and Fisher's exact test were used. The analyses (i.e. means and SDs) were carried out using SPSS Statistics 17.0 software. $p < 0.05$ for a two-tailed test was considered statistically significant.

Table 1. Mean \pm SD (percentages) and Wilcoxon signed-rank test for first and second stage of labour

	Fetal ECG, %	Doppler CTG, %	Wilcoxon
<i>First stage of labour (n = 135)</i>			
Possible MHR/FHR ambiguity	0.70 \pm 1.2	1.22 \pm 1.9	<0.001
True ambiguity	0.29 \pm 0.7	0.72 \pm 1.1	<0.001
No ambiguity	0.28 \pm 0.6	0.29 \pm 0.7	0.004
Unknown	0.13 \pm 0.3	0.21 \pm 0.7	n.s.
FHR reliability	87.09 \pm 19.1	85.21 \pm 10.4	<0.001
MHR reliability	99.93 \pm 0.36		–
<i>Second stage of labour (n = 98)</i>			
Possible MHR/FHR ambiguity	3.30 \pm 4.4	6.20 \pm 9.0	<0.001
True ambiguity	1.5 \pm 2.1	2.9 \pm 6.1	0.001
No ambiguity	1.07 \pm 1.8	0.93 \pm 1.8	0.005
Unknown	0.73 \pm 1.7	2.37 \pm 3.3	<0.001
FHR reliability	70.51 \pm 27.9	76.46 \pm 20.0	n.s.
MHR reliability	99.90 \pm 0.54		–

Results

CTG and non-invasive fECG had both possible MHR/FHR ambiguity. Our study results demonstrated that significantly less 'possible MHR/FHR ambiguity' occurs with the abdominal fECG modality compared to the CTG for both the first stage (fECG 0.70% vs. CTG 1.22%, $p < 0.001$) and second stage of labour (fECG 3.30% vs. CTG 6.20%, $p < 0.001$). Similarly, the abdominal fECG showed significantly less 'true ambiguity' (i.e. first stage fECG 0.29% vs. CTG 0.72%, $p < 0.001$, and second stage fECG 1.50% vs. CTG 2.90%, $p = 0.001$). The 'true ambiguity' data of table 1 has been presented in an alternative form as PDF histograms in figure 6a, b. These plots show the distribution of patients as a function of the percentage of recording time where 'true ambiguity' occurs. The CTG presents many more instances of increased true ambiguity. In particular, during stage 2 the CTG shows 10 patients (compared to 2 for abdominal fECG) when there was greater than 6.2% of true ambiguity.

Table 1 illustrates the comparison of CTG versus abdominal fECG in terms of the percentage (mean and SD) of possible ambiguous MHR/FHR data, etc. The data has been separated into first and second stage of labour. During the first stage of labour, 135 women had simultaneous CTG and abdominal fECG whilst in the second stage this number was 98 (fig. 1). The median length of recording times for simultaneous CTG and abdominal fECG were in the first and second stage of labour 194 and 20 min,

respectively (mean \pm SD; first stage 253.7 \pm 244.0 min; second stage 48.1 \pm 60.7 min).

The data of table 1 has also been divided into one main category and three subcategories as defined earlier, namely 'possible MHR/FHR ambiguity', 'true ambiguity', 'no ambiguity', and 'unknown', respectively. An example of extensive 'true ambiguity' and 'unknown' using the CTG modality is shown in figure 2. Figure 3 shows an example of 'true ambiguity' by the abdominal fECG modality. Figure 4 illustrates an example of a genuine FHR trace which is close (i.e. within \pm 5 bpm) to the MHR during the second stage of labour – this example represents 'no ambiguity'. Finally, figure 5 presents an example of a typically occurring artefact with CTG, i.e. the doubling (D) of FHR. In this case only when the FHR data lies within 5 bpm of the mother will it be classified as 'possible MHR/FHR ambiguity'.

For completeness, table 1 illustrates the percentage of time when for both surveillance modalities the FHR was within 5 bpm of MHR (i.e. 'no ambiguity') and when it was not possible to analyse the data since the other modality was missing (i.e. 'unknown').

This work also evaluated the reliability of both EFM surveillance modalities in terms of the percentage success rates of recording FHR data. During the first stage of labour the FHR percentage reliability of the abdominal fECG was significantly better than the CTG (fECG 87.1% vs. CTG 85.2%, $p < 0.001$); no significant difference however, was found during the second stage (fECG 70.5% vs. CTG 76.5%, $p > 0.05$).

A subgroup analysis of the patients with a high level of 'possible MHR/FHR ambiguity' in either CTG or abdominal fECG has been presented in table 2. This data illustrates the *number* of recordings with over 4% of 'possible MHR/FHR ambiguity' in either CTG or abdominal fECG. It can be seen from table 2 that the CTG modality had significantly more 'possible MHR/FHR ambiguity' recordings than fECG during the first (abdominal fECG 5 patients (3.7%) versus CTG 16 patients (11.9%) recordings, $p = 0.02$) and second stage of labour (abdominal fECG 25 patients (25.5%) versus CTG 46 patients (46.9%) recordings, $p = 0.002$). Significantly, in this subgroup, abdominal fECG again demonstrated less 'true ambiguity' in both the first and second stage of labour (first stage abdominal fECG 1.28% versus CTG 2.81%, $p = 0.006$; second stage fECG 2.30% versus CTG 4.73%, $p = 0.013$).

In this 4% subgroup the number of erroneous decelerations (>15 bpm between 15 s and 3 min) were counted for each patient. In stage 1 for abdominal fECG the count was zero whilst for CTG the average count per patient was

Table 2. Subgroup analysis of the *number* of recordings with over 4% of 'possible MHR/FHR ambiguity' in either abdominal ECG or Doppler ultrasound CTG recording

	fECG, %	Doppler CTG, %	Statistical test
<i>First stage of labour (n = 135)</i>			
Patients >4% ambiguity	3.7 (n = 5)	11.9 (n = 16)	0.02 ^a
True ambiguity	1.28 \pm 1.6	2.81 \pm 1.5	0.006 ^b
No ambiguity	1.48 \pm 1.1	1.54 \pm 1.2	NS ^b
Unknown	0.40 \pm 0.5	0.93 \pm 1.8	NS ^b
FHR reliability	81.12 \pm 22.7	78.46 \pm 10.3	NS ^b
<i>Second stage of labour (n = 98)</i>			
Patients >4% ambiguity	25.5 (n = 25)	46.9 (n = 46)	0.002 ^a
True ambiguity	2.30 \pm 2.6	4.73 \pm 7.7	0.013 ^b
No ambiguity	1.76 \pm 2.2	1.52 \pm 2.2	0.006 ^b
Unknown	1.00 \pm 0	3.63 \pm 4	<0.001 ^b
FHR reliability	66.57 \pm 29.9	69.15 \pm 22.0	NS ^b

^a Fisher's test. ^b Wilcoxon test.

1.87 with a range of 0–12. As can be seen on occasions, a patient can have >5 erroneous decelerations. This result was also demonstrated during second stage of labour where for abdominal fECG the average erroneous deceleration count was 0.04 (i.e. 1 count in 28 patients) whilst for CTG the average was significantly higher at 2.00 counts – here the study results showed that 5 patients had >5 erroneous decelerations.

Again for completeness, table 2 illustrates the percentage of time when for both surveillance modalities the FHR was within 5 bpm of MHR (i.e. 'no ambiguity') and when it was not possible to analyse the data since the other FHR modality was missing (i.e. 'unknown'). Finally, for the first and second stage of labour the FHR signal reliability demonstrated no statistical difference between the two EFM modalities.

Discussion and Conclusions

This study has compared two non-invasive surveillance modalities for FHR monitoring. These results demonstrate that MHR/FHR ambiguity is significantly higher with the use of the CTG mode in both the first and second stage of labour. This study has quantified the level of such signal ambiguity and reinforces the work by Neilson [2] and the concerns of Nageotte [23]. The findings of this study demonstrate the advantages of using the

abdominal ECG modality to detect such FHR/MHR ambiguity.

In labour we have encountered instances where the transition of the fetal trace to the maternal trace occurred imperceptibly monitoring the MHR in the 'normal fetal heart range' (fig. 2). Therefore, clinical staff are not alerted to the possibility of misleading data, and hence the potential for unnecessary fetal blood sampling, emergency caesarean section or even worse, undetected prolonged fetal bradycardia in combination with maternal tachycardia could occur. During labour, MHR is sometimes in the 'normal fetal heart range' and can be successfully differentiated with both surveillance methods (fig. 4).

Abdominal fECG and CTG methods can both incorrectly confuse MHR with FHR. Abdominal fECG can do this if the abdominal signal is of poor quality or excessive maternal movement and hence excessive abdominal electromyogram noise develops. However, abdominal fECG recordings provided by the Monica AN24 always provide a simultaneous and visible MHR trace. As a result, MHR/FHR ambiguity in these rare cases is easily identified by the obstetrician. Alternatively, CTG detects MHR if the transducer is inadequately directed at the maternal heart and if the MHR matches typical fetal characteristics. In addition, CTG machines often are not used to display the MHR and hence the gradual transition of the FHR into a MHR state passes unnoticed. A frequently used alternative for FHR registration is obtained from the fetus using a scalp electrode. In comparison to CTG, the scalp modality has reduced FHR signal loss [24] and can be used in conjunction with ST analysis to improve fetal outcome [6–8]. However, this method is invasive and has contraindications [25]. In the case of fetal mortality in utero and hence there is no fECG signal, the amplifier can increase its gain until a recognisable ECG R-wave is identified. Under such circumstances it is possible that the R-wave of the mECG complex can masquerade as the fECG [25, 26].

All patients were in an intention to deliver vaginally, however the caesarean section rate was high at 28.5%. This was not due to CTG changes. The indication for caesarean section was in all cases failure to progress of labour.

In conclusion, the real danger is mistaking the maternal for the FHR at a time when the FHR, if properly registered, would be non-reassuring or outright bad. This is the blind spot in our fetal surveillance.

The midwife could check the maternal pulse at regular intervals and make sure it is not synchronous with the FHR. More attention could be paid on the acoustics of fetal and maternal sound in the CTG loudspeakers. Ma-

ternal pulse oximetry can help to differentiate the risk of confusion; however pulse rate recordings are affected by maternal movement and other factors [2, 9]. Our results show that the MHR can be reliably obtained through abdominal ECG tracing; hence continuous FHR/MHR comparison can be made. It should be pointed out that this functionality is already available on some twin CTG monitors, which generates an alarm when the same twin is being monitored on both channels. Hence one channel can be used for the FHR whilst the other could be 'off-label' used for the MHR and appropriate alarms would indicate when the MHR is being recorded on the fetal channel. Real-time ultrasonography is recommended if there is any doubt whether the detected signals originate from the fetus or mother [25, 26].

Conclusion

Intrapartum FHR monitoring via the abdominal ECG offers reduced 'ambiguous fetal heart rate' traces when compared to CTG.

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Disclosure Statement

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

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