Prenatal Foetal Non-invasive ECG instead of Doppler CTG – A Better Alternative?

Antepartales fetales nicht invasives EKG statt CTG – Eine bessere Alternative zum CTG?

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Abstract

Introduction: This study aimed to evaluate foetal signal quality obtained using an antenatal foetal ECG system (Monica 24™) and compare it with Doppler ultrasound CTG monitoring (Corometrics® 250 series).

Material and Methods: Seventy pregnant women (gestational age: between 20 + 0 weeks and 40 + 0 weeks) were examined using the Monica AN24™ system and also underwent Doppler CTG. The signal quality of both methods was compared and correlated with gestational age and pre-pregnancy body mass index (BMI).

Results: Overall, ECG had a signal quality of 77.4% and CTG had a signal quality of 73.1% ($p > 0.05$). In gestational weeks (GW) 20–26, the signal quality of ECG was significantly better compared to that obtained with CTG (75.5 vs. 45.3%; $p = 0.003$), while in GW 27–36, the signal quality was better with CTG (72.3 vs. 83.0%, $p = 0.001$). No difference in signal quality was found between the two methods after the 37th GW (87.7 vs. 86.1%; $p > 0.05$). CTG showed a statistically significant correlation with BMI (rho 0.25, $p < 0.05$) while ECG showed no such correlation.

Conclusion: The use of non-invasive ECG is particularly indicated in the early weeks of pregnancy, while CTG offers superior results during the vernix period. There was no difference in signal quality after the vernix period. The signal quality with ECG was found to be independent of BMI, while the signal quality of CTG deteriorated with increasing BMI.

Zusammenfassung

Einleitung: In dieser Studie soll die Signalqualität einer antepartalen fetalen EKG- (Monica 24™) und CTG-Überwachung (Corometrics® 250 Series) verglichen werden.

Material und Methode: Bei 70 Schwangeren, die zwischen der 20 + 0 bis 40 + 0 Schwangerschaftswoche waren, wurde das Monica-AN24™-Überwachungssystem und CTG angeschlossen. Die Signalqualität beider Überwachungsmethoden wurde in Abhängigkeit von Schwangerschaftsalter und Body Mass Index (BMI) verglichen.

Ergebnisse: Ingesamt zeigt das EKG eine Signalqualität von 77,4%, wohingegen das CTG eine Signalqualität von 73,1% aufwies ($p > 0,05$). In der 20.–26. Schwangerschaftswoche zeigte das EKG eine statistisch signifikant bessere Signalqualität im Vergleich zum CTG (75,5 vs. 45,3%, $p = 0,003$), wohingegen in der 27.–36. SSW das CTG eine bessere Signalqualität zeigte (72,3 vs. 83,0%, $p = 0,001$). Ab der 37. SSW konnte kein Unterschied zwischen den Überwachungsmethoden gemessen werden (87,7 vs. 86,1%, $p > 0,05$). Das CTG zeigte eine statistisch signifikante Korrelation mit dem BMI (Rho 0,25, $p < 0,05$), jedoch zeigte sich keine Korrelation beim EKG.

Schlussfolgerung: Das nicht invasive EKG ist besonders in den frühen Schwangerschaftswochen indiziert, während in der Vernix-Periode das CTG überlegen ist. Nach der Vernix-Periode zeigt sich kein Unterschied in der Signalqualität. Die EKG-Signalqualität ist BMI-unabhängig, während das CTG bei erhöhtem BMI nur erschwert ableitbar ist.

Introduction

In the last 30 years cardiotocography (CTG) has become the most common method to monitor foetal health during birth [1,2]. The benefits of electronic foetal monitoring are still discussed [3–5]. To solve the problem of high inter- and intra-observer variability [1,6–8], guidelines and computer-assisted analysis pro-

grammes have been developed for the assessment CTG measurements [6–9].

In 2008 a non-invasive abdominal electrocardiogram (ECG) device was licensed for use in clinical practice [10]; however it was initially only licensed for *antenatal* use [11–13]. Neilson et al. [2] reported on the interference of maternal heart rate signals with foetal heart rate signals. This report together with a recent warning by the FDA (Food and Drug Administration Agency Med Watch) [14] about similar problems with CTG sensors indicates the necessity of improving foetal monitoring systems. A recently licensed non-invasive ECG system which monitors foetal heart rate while simultaneously monitoring maternal heart rate could be useful in this context. This method would allow episodes in which the maternal heart rate is mistaken for the foetal heart rate to be identified.

Alternatively, there are also CTG devices available which are used to monitor twin pregnancies. They give an acoustic warning signal when the heart rates of the twins coincide. It would be theoretically possible to use such a twin CTG device so that maternal and foetal heart rates could be recorded simultaneously, with a warning signal appearing when the heart rates coincide. Other proposals include the use of pulse oximetry or more frequent monitoring of the maternal pulse rate by the midwife as well as more attention to be focused on capturing the "typical" acoustic sounds of the foetal heart.

This study aimed to investigate which monitoring method offers a better foetal signal quality in gestational weeks 20 + 0 to 40 + 0 before carrying out a larger study which will analyse the risk of misidentifying the foetal heart rate.

Material and Methods

The Monica AN24™ system is a small, portable, battery-operated, electrophysiological monitoring system which detects foetal and maternal heart rates using abdominal electrodes.

In our study, all 70 pregnant women gave their informed consent to participate in the study after receiving detailed (written and oral) information. Placing of the 5 abdominal electrodes of the Monica AN24™ system was done by a physician trained in the use of the Monica AN24™. After positioning the Monica AN24™, the sensors for the CTG (GE Corometrics 250 series) were placed. Sensors and electrodes were positioned with the pregnant woman lying either in a right or a left lateral position. The signal quality was analysed separately for each monitoring method for the time during which the foetal heart rate recorded. Signal quality and pre-pregnancy BMI were calculated.

Evaluation of the foetal ECG was done using the programme Monica DK™ Version 1.7; CTG data was stored using the Trium system.

To directly compare foetal ECG and CTG, simultaneous CTG and ECG recordings from the pregnant women were evaluated. Current heart rates at intervals of 250 ms were used for CTG measurement. ECG used heart rate duration (RR intervals) with a resolution of 3.3 ms.

Data were imported into SPSS, which was used to calculate mean values, standard deviation, Spearman's rho coefficient, and Wilcoxon signed-rank test. A sub-group analysis of signal quality was done for the following gestational ages: Group 1 = gestational week (GW) 20–26, Group 2 = GW 27–36, Group 3 = GW 37–40. This study only analysed the heart rates calculated using the two methods. In the one method, the ECG potential, or part of it, is the trigger, while the other method is based on heart wall movements which are registered by ultrasound measurement.

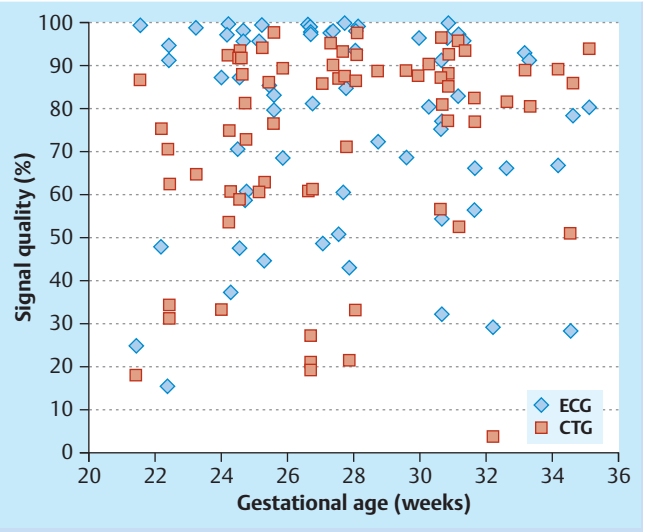

Fig. 1 Signal quality correlated with gestational week (GW).

Results

Overall, ECG signal quality was 77.4%, and signal quality with CTG was 73.1% ($p > 0.05$; **Table 1**; **Fig. 1**). In GW 20–26 the signal quality obtained using ECG was significantly better compared to the signal quality with CTG (75.5 vs. 45.3%, $p = 0.003$), while in GW 27–36 the signal quality using CTG was better (72.3 vs. 83.0%, $p = 0.001$). After the 37th GW no difference in signal quality could be detected between the two monitoring methods (87.7 vs. 86.1%, $p > 0.05$).

The difference in signal quality was not statistically significant in the BMI groups ($p > 0.05$; **Table 2**; **Fig. 2**). However, while the CTG signal quality was found to be significantly correlated with the BMI (rho 0.25, $p < 0.05$), there was no correlation between ECG signal quality and BMI.

The mean duration of synchronous monitoring using both methods was 197.6 minutes (standard deviation ± 33.2 minutes; range 116–351 minutes).

Table 1 Signal quality correlated with gestational week (GW).

Signal quality	Total	GW 21–26	GW 27–36	GW ≥ 37
No. of patients	70	20	31	19
ECG (%)	77.4	75.5	72.3	87.7
ECG SD (%)	23.5	30.2	21.4	15.3
CTG (%)	73.1	45.3	83.0	86.1
CTG SD (%)	23.7	24.0	11.5	10.9
p-value*	0.21	0.003	0.001	0.51

SD: standard deviation; *: comparison of ECG vs. CTG (Wilcoxon signed-rank test)

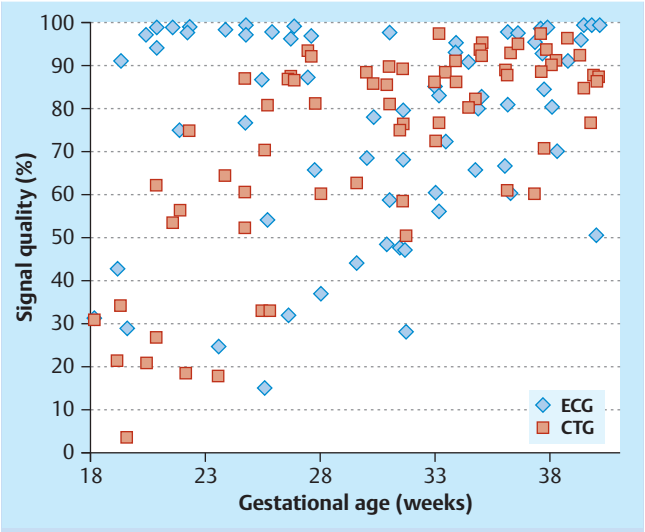

Fig. 2 Signal quality correlated with body mass index (BMI).

Table 2 Signal quality correlated with body mass index (BMI).

Signal quality	BMI < 25	BMI ≥ 25, < 30	BMI ≥ 30
No. of patients	20	27	23
ECG (%)	72.1	82.9	75.6
ECG SD (%)	29.0	19.0	22.7
CTG (%)	66.8	72.7	79.0
CTG SD (%)	22.9	26.0	20.8
p-value*	0.46	0.20	0.38

SD: standard deviation; *: comparison of ECG vs. CTG (Wilcoxon signed-rank test)

Discussion

This study showed that signal capture of the foetal heart rate was particularly good in GW 20–26. In the vernix period, however, the signal quality was better with CTG. After the vernix period, no difference in signal quality was found between CTG and ECG. ECG signal quality was not correlated with BMI, while a correlation was found between CTG signal quality and BMI. This is particularly important because a distinct increase in maternal BMI has been noted in the past few decades [15].

The limitations of this study include the limited numbers of patients and the use of a CTG device from only a single manufacturer. Further studies will be needed to show whether this trend for foetal signal quality can be confirmed.

In a multi-centre study, an electrohysterogram (Monica AN24™) was found to be easier to use to measure maternal contractions compared to a tocogram [16]. Spectral analysis using an electrohysterogram could potentially be used to diagnose preterm labour [17], but unambiguous studies on this point are lacking.

Conclusion

The use of non-invasive ECG is particularly indicated in the early weeks of pregnancy when signal capture is more difficult using CTG. In the vernix period, signal capture proved to be better using the CTG. After the vernix period, no difference in signal quality was found between ECG and CTG. ECG signal quality is not dependent on maternal BMI, while signal capture using the CTG is more difficult in women with a higher BMI.

Ethics Committee Approval

This study was approved by the Ethics Commission of the Medical Faculty of Ruhr University Bochum.

Conflict of Interest

Professor Hayes-Gill is professor at the University of Nottingham and a director of Monica Healthcare Ltd. Monica Healthcare Ltd, United Kingdom, supported this study with 15 000 Euros.

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