The Value of Non-invasive Electrocardiography in Assessing Fetal Status at Term Delivery

Anatoli Theodoridou¹, Zoi Koukou, Eleftheria Taousani¹, Angeliki Antonakou¹, Kleanthi Gourounti²

¹School of Health Sciences, Midwifery Department International Hellenic University
²Department of Midwifery, University of West Attica, Athens, Greece

ABSTRACT

Background: The electrocardiograph (ECG) is an efficient method for the accurate assessment of fetal heart rate. The barriers for accurate assessment are maternal heart rate, uterine contractions and abdominal muscles. Although previous monitoring methods have struggled to overcome these barriers, recent advances have led to a greater degree of success for listening and recording pulse-by-pulse fetal heart rate. Objectives: A prospective cohort study evaluating the use, reliability and safety of non-invasive electrocardiography, in conjunction with Fetal Heart Rate parameters such as, Short Term Variability (STV) together with umbilical cord pH and Apgar score, during the active phase of childbirth. Methods: A total of 41 women with single, normal, full-term pregnancies had systematic obstetric monitoring with Monica AN24. 20 had only monitoring and 21 also had and arterial blood flow measurements. pH was measured and correlated with neonatal Apgar score at 1 and 5 min. The study also included a questionnaire about the safety and usability of obstetric monitoring. Statistical analysis was done using IBM SPSS v. 26.0. Results: Mean age was 28.8 years, (SD ± 6.153). Electrocardiogram recordings (ECG) were classified as normal (71%) and suspicious (29%). Baseline between ECGs was different (p = 0.025) similarly for Short term variability (STV) (p <0.0001). BMI did not differentiate SVT rates. Only high acceleration (p <0.029) and small slowdowns had a statistically significant difference between normal and suspected cardiographs (p <0.029). APGAR score did not differ, whereas the umbilical cord pH was different in normal ECGs compared to the suspect (p = 0.012) and STV was also differentiated. A usability and safety survey was conducted after recording with MONIKA, and the response to whether they would accept recording with the device again, was positive for 96% of the 30 responders. Conclusion: The present study shows that the use of electrocardiography in obstetrics allows to draw conclusions about the fetal hematopoiesis and oxygenation status. This method could be clinically applied and be an important tool for further screening in embryos that may be hypoxic and to decide whether to continue with a vaginal or cesarean delivery, thereby achieving the goal of reducing perinatal morbidity and mortality.

Keywords: electrocardiography, electrocardiotocography, peripartum care, cardiotocography.

1. BACKGROUND

In recent years, efforts have been made to improve both the accuracy of FHR monitoring with advanced algorithmic processes and safety by emphasizing non-invasive technologies, (1). The electrocardiograph (ECG) is another efficient method for the accurate assessment of fetal heart rate. The barriers for accurate assessment are maternal heart rate, uterine contractions and abdominal muscles (2). Although previous monitoring methods have struggled to overcome these barriers, recent advances have led to a greater degree of success for listening and recording pulse-by-pulse fetal heart rate (3). The majority of the obstetric community has advocated fetal monitoring either by cardiotocography, electrocardiography or other methods as a key tool for effective fetal assessment during labor and delivery (4).

Although it is still unclear whether
continuous fetal monitoring during labor offers improvement or reduction in perinatal mortality, technology is leading to more normal deliveries and fewer cesarean deliveries (5). In terms of non-invasive monitoring, technology is making progress over invasive technology, but there are still problems with signal quality from “noise” resulting from fetal mobility, maternal movement and other nearby electrical devices. Cardiotocography (CT) and fetal heart rate (FHR) studies are the most common test in modern obstetrics. Electronic fetal monitoring has become an integral part of clinical practice (6). Studies have been conducted internationally to try to develop as objective a method as possible to find at-risk fetuses and to diagnose a high-risk pregnancy early (7), but the value of electronic monitoring has not been an easy and clear-cut assumption.

There are very few electrocardiography devices and our up to date recent review focuses on them together with an overview of the available fetal monitoring methods available (8). The Monica AN24 -Novii Wireless Patch System, (9) is an established system of the very few readily available, used during labour, in the antenatal period, in women with an increased body mass index and for home birth that was reviewed previously by us (8). It has been approved for clinical use in Europe and the United States (9).

2. OBJECTIVE

This study aims to demonstrate the value of transabdominal electrocardiography using the Monica AN24 -Novii Wireless Patch System, (9) in terms of the use, reliability and safety of the method during the active phase of labour and to analyse and record the fetal heart rate and, in particular, the safety of the device during the active phase of labour with more than 3 cm dilatation who had singleton pregnancies, planned natural labor not caesarean section, full-term pregnancies without chromosomal or anatomical known issues of the fetus and all had systematic obstetric monitoring. In 21 of the subjects besides Monica AN24 monitoring during childbirth, blood gas analysis also took place, with blood taken with a heparinized syringe (1cc) following established procedure (12). The study took place at the Ippokration General Hospital of Thessaloniki, 2nd and 3rd Obstetric & Gynecology Clinics. All the participants gave written informed consent prior to the inclusion to the study, while the study has received the approval of the Scientific Committee of Ippokration General Hospital of Thessaloniki with protocol number 2/15/2/2012. pH was measured and correlated with neonatal Apgar score (13) at 1 and 5 min. A usability questionnaire about the discomfort caused by the application of the electrodes and the safety of the device during the hours it was connected was also completed by another 30 pregnant women who were hospitalized in the same clinics, in addition to the subjects, after spending 1 hour of Monica AN24 use, while giving written informed consent prior to the questionnaire.

Electrocardiograph procedure

Five high-quality electrodes are placed on the abdominal surface of the woman in a diamond shape, instruments instructions. Information on each pregnancy at the time of data recording as well as follow-up information was obtained from the subject medical records after their full written consent. Initial analyses as well as conversion from primary (“raw”) recordings to extracted data were performed using the analysis software, Monika DK1.4a, with pre-programmed Dawes-Redman criteria (14). Dawes-Redman criteria define a positive deviation from the fetal baseline of at least 10 bpm for at least 15 seconds as “minor acceleration” and a positive deviation from the fetal baseline greater than 15 bpm for at least 15 seconds as “major acceleration” in our analysis (14). Pathologically suspect cardiotocographs were defined as those that had at least one or more criteria as listed by the American College of Obstetricians and Gynecologists (15). Reduced variability of the fetal heart rate (pulse to pulse) variability of 5 to 10 beats per minute for more than 40 minutes. Presence of variable decelerations and or absence of accelerations, bradycardia (<100 beats per minute for at least 3 minutes), or tachycardia over 161-180 beats per minute (15).

Safety and discomfort assessment when using Monica ANS24 Questionnaire

During the removal of the Monica device from the subjects, information was collected by completing a questionnaire about the discomfort that the application of the electrodes might have caused and the safety of the device during the hours it was connected. The discomfort was linked to the number of electrodes the location where they were placed the pain or skin irritation from the stickers and even the care the women had to take to ensure the integrity and function of the device when changing position or movement. Safety information was recorded in a short questionnaire formulated for this study.

Statistical analysis

Descriptive statistics and statistical analysis of the findings were performed using IBM SPSS (Version 26.0, Armonk, NY) with non parametric statistical tests, as the data did not follow the normal distribution. For independent comparisons, the Mann-Whitney U Test was used, while the Kruskal-Wallis H non-parametric test, was used, with Bonferroni post hoc correction, to investigate the existence of a relationship between a quantitative variable and a categorical variable with more than two categorories.

4. RESULTS

Overall for the 41 women who participated in the study, mean age was 28.8 years, (SD ± 6.15) with the youngest being 17 and the oldest 42 years old. On their first birth were 61% of the participants while 27% were on the second. One participant had gestational diabetes with only 4 women having
minor birth complications. A sizable percentage (22%) were obese (BMI ≥30) while overweight (BMI ≥25) and normal weight (BMI 18.5–24.99) accounted for 39% of the total sample. Gestational age at delivery was less than 40 weeks at 53.7%. Electrocardiogram recordings (ECG) were classified as normal (29/41 70.7%) and suspicious (12/41, 29.3%), and statistical comparisons were made on the basis of this classification. Table 1 has the descriptive statistics of all categorical data measures depending on the EKG type of the participants. No statistical significance was evident between subjects of different ECG types.

**Baseline signal characteristics**

Baseline ECG signal should be between 110 and 160 beats per minute (bpm). Values below 110 bpm are classified as fetal bradycardia and above 160 bpm as tachycardia. There was a statistically significant difference between normal and suspected ECGs (p = 0.025). The values for suspected ECGs were higher with a mean of 142.39bmp (± 9.02SD) and a maximum of 155bpm in contrast to 134 (± 10.36SD) the mean of normal ECGs with 150bpm maximum (Figure 1a). No differences were observed in any of the measurements with regards to the BMI of the subjects.

**Short-term variation (STV)**

Variation is divided into short-term (or beat-to-beat) and long-term (long-term). The former cannot be reliably recorded and should be 2-6 beats, while the latter refers to the difference between the maximum and minimum recording during one minute and should be 5-25 beats. The fetal ECG measurement is the gold standard for short-term variation (STV). There was a statistically significant difference in STV (p < 0.001). The mean value in normal ECG was 12.18 (±4.93SD), respectively, for the suspect was 8.3 (± 2.33SD). In contrast, no difference was observed between normal weight and overweight or obese STV rates (Figure 1b). Periodic are those elements of the ECG that are related to uterine contractions and/or fetal movements. These are the accelerations and decelerations and are defined with the Dawes-Redman criteria (14). Small accelerations did not differ between normal and suspect ECGs.

In contrast, large accelerations were statistically significantly differentiated between the two ECG categories mean value in normal was 13.79 (±9.82SD) respectively for suspect was at 8.00 (±9.38SD) (p=0.029) (Figure 1c). Similarly, the small decelerations had a statistically significant difference between normal and suspicious ECGs (p <0.029) with the mean value in normal being 8.24 (± 8.19SD) and 4.5 (± 6.16SD) for suspects (Figure 1d).

The variability of the frequency and, above all, the range of variation of the ECG on the cardiotocography during delivery are also important evaluation criteria which, in combination with the other cardiotocographic findings, leads to conclusions regarding the oxygenation status of the fetus. Thus, low or absence of variability (<5 beats/minute) could be a relatively unfavourable prognostic indicator, as well as a higher variability (>15 beats/minute) when it lasts for a long time. The high variability rate had no statistically significant difference between normal and suspect ECGs.

In contrast, the low variability rate was different between the two categories (p<0.018). The mean value in normal was 3.01% (±6.3SD) respectively for suspect was at 16.6%
The Value of Non-invasive Electrocardiography in Assessing Fetal Status at Term Delivery

The Apgar score (at 1st and 5th minutes) did not differ, whereas the pH of the umbilical cord blood was different in normal ECGs compared to the suspects (p = 0.012). The mean in normal ECGs was 7.34 (± 0.08SD) and in suspicious 7.2 (± 0.07SD) (Figure 1f).

STV also showed a difference between subjects that had blood gas measurements, with mean STV for the normal ECGs being 11.06 while for the suspicious it was only 6.17. Table 2 has the descriptive statistics of all continuous data measurements depending on the EKG type of the participants. Figure 1 has all statistically important differences in the ECG measures.

<table>
<thead>
<tr>
<th>EKG type</th>
<th>Normal (N=29)</th>
<th>Suspect (N=12)</th>
<th>Mann – Whitney test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>Age (years)</td>
<td>28.72</td>
<td>5.92</td>
<td>29.00</td>
</tr>
<tr>
<td>BMI</td>
<td>26.67</td>
<td>3.72</td>
<td>25.44</td>
</tr>
<tr>
<td>Signal Loss (%)</td>
<td>11.31</td>
<td>14.74</td>
<td>3.06</td>
</tr>
<tr>
<td>ECG FHR Mean</td>
<td>137.10</td>
<td>8.53</td>
<td>143.67</td>
</tr>
<tr>
<td>ECG FHR Basal</td>
<td>133.77</td>
<td>10.36</td>
<td>142.39</td>
</tr>
<tr>
<td>Small accelerations</td>
<td>23.10</td>
<td>14.03</td>
<td>14.42</td>
</tr>
<tr>
<td>Large accelerations</td>
<td>13.79</td>
<td>9.82</td>
<td>8.00</td>
</tr>
<tr>
<td>Small decelerations</td>
<td>8.24</td>
<td>8.19</td>
<td>4.50</td>
</tr>
<tr>
<td>Large decelerations</td>
<td>2.52</td>
<td>6.77</td>
<td>0.25</td>
</tr>
<tr>
<td>STV</td>
<td>12.18</td>
<td>4.94</td>
<td>8.30</td>
</tr>
<tr>
<td>High variability rate (%)</td>
<td>47.41</td>
<td>23.25</td>
<td>42.47</td>
</tr>
<tr>
<td>Low variability rate (%)</td>
<td>3.01</td>
<td>6.33</td>
<td>16.98</td>
</tr>
<tr>
<td>Apcar 1min</td>
<td>8.00</td>
<td>0.00</td>
<td>7.92</td>
</tr>
<tr>
<td>Apcar 5mins</td>
<td>8.97</td>
<td>0.19</td>
<td>9.29</td>
</tr>
<tr>
<td>Blood Gass pH</td>
<td>7.342</td>
<td>0.085</td>
<td>7.203</td>
</tr>
</tbody>
</table>

Table 2. Descriptive statistics for continues measurements per ECG type. ECG=electrocardiography, FHR =Fetal Heart rate, min = minute, SD= Standard Deviation.

Figure 1. Box plots of ECG quality measures per ECG type. a) basal ECG fetal heart rate (FHR), b) Short-term variation (STV) c) Large accelerations in the ECG d) Small decelerations e)Low variability and f) Blood gas pH. f) has a logarithmic y axis.

Finally a usability and safety survey was conducted after recording with MONIKA AN24 using a questionnaire created for the purpose of this research. The median age was 29 years and 34 weeks was the median week of pregnancy with most being in higher education. No one considered that the electrode placement process was inconvenient.

Correspondingly only 4% responded that the electrodes caused some discomfort. Also only 8% showed bruises or scars on the skin. To the final question of whether they would accept recording with the device again, 96% answered yes.
5. DISCUSSION

Most of the monitoring techniques used in everyday obstetric practice were developed in the late 20th century, resulting in a reduction in perinatal mortality. The main cause of perinatal mortality and morbidity is fetal hypoxia which, regardless of the aetiology, eventually leads to tissue hypoxia and loss of physiological functions (16). Cardiotocography (CT) and fetal heart rate (FHR) study are the most common test in modern obstetrics (8).

Fetal hear rate was monitored using electrocardiograms using the MONICA AN24 instrument (external electrocardiographic monitoring using wireless technology) (9). Only 3 participants in our study had losses greater than 30% due to detachment of an electrode. In the present study the average loss rate was generally very low. In other words the recording was very reliable as the lowest signal recording success rate recorded in our study was 85.37% in obese, 95.23% for normal and a very good 98.75% for overweight demonstrating the suitability of the method for above normal weight epistopes. The procedure was well received as shown by the questionarre answered with 96% of them recommending the procedure.

The same conclusions were reached in other studies using the same instrument (17, 18). The conclusions show that the recording quality of both fetal ECG and uterine contractions remained stable during delivery, thus demonstrating the reliability and efficacy of the Monica An24 system compared to conventional ECG (17) in both the 2nd and 3rd trimesters of pregnancy (18). In the data set there was no significant difference between participants with different BMI between measurements in agreement with the international literature (20, 21).

The study by Glass et al. at the University Hospital Frankfurt came to a similar conclusion that the use of the MONICA AN24 is not influenced by the position or projection of the fetus in terms of reliable ECG recording. This non-invasive monitoring method has the potential to provide ease of use and better recording in cases where the mother is obese or wants to move (19).

The success rate of pulse-to-pulse logging is an issue with the MONICA AN24. Long-term recordings with the MONICA AN24 show interruptions of the received ECP signal due to maternal movements, a clear limitation of fetal electrocardiography. Huhn and colleagues found differences in the home with gas measurements was very small (N=3), they should be interpreted with caution.

The use of fetal ECG is the gold standard for the assessment of short-term variability (STV) (10, 22). The presence of good short-term variability (STV) is a reassuring feature regardless of how short the recording is, as it is a sign of intact neurological modulation of the ECG and normal cardiac response. There is also a clear correlation between poor STV and metabolic acidosis in labour (10, 22).

There was a statistically significant difference in our STV results with the mean value in normal deliveries being at 12.18 while for suspect deliveries it was at 8.3, (p<0.0001), irrespective of BMI, as there was no difference between normal weight and overweight or obese infants in STV. The same conclusion was reached in an early prospective study (17) where no correlation was found between maternal and fetal ECG and, noise and BMI did not affect recording.

Appgar score (1st & 5th minute measurements) did not show any difference, but the pH of the umbilical cord was different in normal ECGs compared to suspect ECGs. During delivery, there is a normal decrease in pH. The mean pH of umbilical artery blood at birth is 7.25 and the 10th percentile is approximately 7.15 (23). The mean value for suspect ECGs was at 7.2 very close to 7.15 of acidosis (23, 24). The acid-base balance of the fetus is also affected by the delivery process. Thus, the pH value of fetal blood in the e.g. ejection phase should be assumed to be lower than that measured (3, 24).

STV also showed a differentiation between the pregnancies that had gas measurements, as for normal cardiotograms, the mean STV value was 11.06 while for suspect ones it was only 6.17. Of course as the number of suspect cardiotocographs with gas measurements was very small (N=3), they should be interpreted with caution.

In conclusion, the present study shows that the use of electrocardiography in obstetrics allows to draw conclusions about the fetal hematopoiesis and oxygenation status. A key...
indicator of the fetus’s well-being is the recording of short-term variability (STV) as a reassuring feature as it is a sign of intact neurological configuration of the FHR and normal cardiac response that cannot be measured with a classic cardiotocogram. The system has many advantages over its use and most importantly, while non-invasive it has high accuracy in recording even in women with high body mass index due to the different way of detecting ECG compared to conventional cardiological devices.

Electronic fetal heart rate monitoring and the diagnostic information obtained is crucial for the management of any condition and should be made available in clinical practice with the ultimate aim of reducing obstetric perinatal and neonatal complications. No single method of electronic monitoring can give us sufficient information to fully assess the actual fetal status, either because of the high rate of false positives but mainly because it is not enough to simply apply each method without the possibility of a correct assessment. In practice, this means that no method can be better than the professional applying it.

- **Acknowledgments:** The authors would like to acknowledge all the women who participated in this study.
- **Declaration of patient consent:** The authors certify that they have obtained all appropriate patient consent forms.
- **Author’s contribution:** A.T. gave a substantial contribution to the conception and design of the work. AT, ZK, ET collected the data. AT, ZK, AA analysed the data. AT, ZK, ET wrote the article, while AA and KG revised it critically for important intellectual content. All authors read and corrected the manuscript and gave final approval of the version to be published.
- **Conflicts of interest:** There are no conflicts of interest.
- **Financial support and sponsorship:** Nil.

**REFERENCES**