A mixed-methods evaluation of continuous electronic fetal monitoring for an extended period

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A mixed-methods evaluation of continuous electronic fetal monitoring for an extended period

Running Title – Womens’ experiences of fetal monitoring

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Conflict of Interest Statement:

There are no conflicts of interest associated with any of the authors involved in this work.
Abstract

Introduction: Continuous fetal monitoring (CFM) is used to objectively record the fetal heart rate and fetal activity over an extended period of time, however its feasibility and acceptability to women is currently unknown. The study addressed the hypothesis that continuous fetal monitoring is feasible and acceptable to pregnant women. Materials and Methods: Pregnant participants (n=22) were monitored using a continuous fetal electrocardiography device, the Monica AN24. Signal quality, duration of recording and cardiotocography findings were correlated with maternal and fetal factors. Participants’ change in anxiety before and after monitoring was assessed using validated questionnaires. Participants’ experiences were explored through a questionnaire (n=20) and semi-structured interview (n=13). Results: Recordings were successfully obtained in 19 of the 22 participants (86.3%). The mean recording quality of fetal heart rate was 69.0% (range 17.4-99.4%) and maternal heart rate was 99.0% (90.9-100.0%). Recording quality was positively correlated with gestational age. (p=0.05) and negatively correlated with uterine activity and maternal movement (p<0.001). Overall, participants were satisfied with their experience of CFM; 30% considered it preferable to intermittent monitoring. CFM did not significantly increase maternal anxiety, with a trend towards a reduction in Pregnancy Specific Anxiety score (p=0.07). Qualitative analysis grouped women’s responses into three themes, i) reassurance and anxiety, ii) the physical device and iii) future developments in CFM. Conclusions: CFM is a feasible and acceptable form of monitoring to pregnant women although further practical improvements could be incorporated. Further research is required to assess the ability of CFM to detect fetal compromise.

Keywords

Continuous fetal monitoring; pregnancy; patient experience; maternal anxiety; cardiotocography; feasibility study.
Abbreviations

BMI  Body mass index

CFM  Continuous fetal monitoring;

CTG  cardiotocograph;

fECG  fetal electrocardiogram;

FHR  Fetal heart rate

MHR  Maternal heart rate

PSA  Pregnancy specific anxiety score

STAI  State trait anxiety index

STV  Short term variability

Key Message

Continuous fetal heart rate monitoring is feasible and is not associated with an increase in maternal anxiety.
Introduction

Antepartum fetal monitoring aims to reduce perinatal mortality and morbidity rates by detecting signs of fetal compromise such as changes in: fetal growth, fetoplacental Doppler waveforms, fetal movements or fetal heart rate (1). However, many currently employed forms of fetal monitoring do not significantly reduce perinatal mortality or morbidity, especially in women who have a low risk of complications (2-4). One exception may be computerised analysis of the fetal heart rate trace; a meta-analysis of two trials including 469 participants found a significantly reduced relative risk of perinatal mortality (0.20 (95% CI 0.04-0.88) compared to manual interpretation of the fetal heart rate trace (2). A further criticism of current fetal monitoring methods is that they do not provide a longitudinal or objective view of fetal wellbeing and may not be sufficiently sensitive to detect signs of fetal compromise (5). Consequently, there has been increased interest in application of computerised analysis of the cardiotocograph (CTG) for extended periods.

Continuous fetal monitoring (CFM) describes technologies which can provide an objective view of fetal wellbeing and could be practically used over long periods of time. A systematic review of five studies including a total of 105 participants found a paucity of data about professionals’ and womens’ experiences of CFM (6). This review identified four main themes: practical limitations of the device, negative emotions, positive perceptions and device implementation. In these studies, CFM had high levels of participant satisfaction and was preferred to intermittent CTG. In addition to these studies of acceptability, recent studies have examined the feasibility of using CFM to measure components of the fetal ECG (fECG) (7, 8) and to determine factors (including gestation (9), maternal body mass index (BMI) (9), uterine contractions (10), diurnal variation and fetal gender (11, 12)) which affect fetal heart rate parameters and the quality of the CFM recording.

In a questionnaire study of 125 clinicians, 45% of respondents felt that CFM would be beneficial (13). However, 64.3% of clinicians were concerned that CFM could increase levels of maternal anxiety and only 23.6% of clinicians felt that CFM would provide pregnant women with a sense of reassurance. Importantly, clinicians’ concerns and women’s experiences of CFM in combination with the technical feasibility of specific techniques of CFM are likely to impact upon the adoption of this novel technology into antenatal care. This study was conducted to evaluate the technical feasibility of CFM for extended periods and explore maternal experience in the same women. This study was not developed to determine the prognostic value of CFM in these
participants, rather this study sought to address clinicians’ concerns that CFM for extended periods would be associated with increased maternal anxiety.

Materials and methods

This study utilised a mixed-methods approach; by combining qualitative and quantitative methodologies we hoped to be able to increase the accuracy and scope of the research (14). In accordance with the “5 Ps” framework for mixed methods research, this study was conducted within a pragmatist paradigm (15). This study was approved by the Liverpool East Research Ethics Committee (REC: 16/NW/0287) and the Health Research Authority (IRAS201920). This study was registered on www.clinicaltrials.gov (NCT03370822).

This study was a single centre cohort study, potential participants were approached in a specialist clinic for women with a history of perinatal death at St. Mary’s Hospital, Manchester, between June 2016 and April 2017. All participants had undergone ultrasound scanning to confirm fetal wellbeing prior to the period of fetal monitoring. Eligible participants who met the inclusion were identified and approached by clinical staff. The inclusion criteria were: singleton pregnancy >24 weeks’ gestation, maternal age 18 or more years, fluent in English. Women who did not meet these criteria or who were in labour were excluded from the study. Participants gave written informed consent. Prior to CFM participants completed a questionnaire booklet recording maternal demographic characteristics and three validated measures of anxiety: Pregnancy Specific Anxiety (PSA) score, Generalised Anxiety Disorder-2 (GAD-2) and State-Trait Anxiety Index (STAI) (16-18).

CFM was performed using a portable fECG monitor, the Monica AN24 (Monica Healthcare Ltd, Nottingham, UK). Five cutaneous electrodes (AmbuBlue Sensor, VLC-00-S/25) were applied to specific areas of the participants’ abdomen as per the manufacturer’s instructions (Supplementary Figure 1). To reduce electrode impedance the participant’s skin was gently exfoliated prior to electrode application (3M Red Dot Trace Prep 2236). An initial 10 minute real-time recording was performed in a clinical research suite using a Bluetooth-enabled laptop. After confirming adequate electrode positioning the real-time monitoring was terminated and the device’s internal recording system was activated. Participants were then asked to wear the device for 24 hours or until the battery ran out, they were provided with a leaflet containing information on how to reattach the leads if they became detached from the electrodes. Participants returned to the research clinic the following day and fECG recordings were downloaded using the Monica VS software (Monica Healthcare Ltd, Nottingham, UK). All fECG traces were reviewed by a consultant obstetrician.
(AH, EJ) for clinically significant abnormalities. Following monitoring, women were asked to complete a second questionnaire booklet containing PSA, GAD-2, STAI and an acceptability questionnaire, which was adapted from a previously validated questionnaire (19). Data from the questionnaire booklets were extracted into Microsoft Excel 2010.

fECG recordings were exported from the device software as both a Microsoft Excel spreadsheet, with recording parameters broken down into 0.25 second epochs and as an automated analysis table containing recording quality (%) of maternal (MHR) and fetal heart rate (FHR) and interval analysis of the fECG as per the Dawes-Redman computerised CTG method. This calculates interval averages of measures of fetal heart rate variability, including short-term variability (STV), and accelerations/decelerations (20). Maternal variables which were analysed for any potential impact on recording quality included maternal BMI, gestational age, maternal heart rate, maternal movement and maternal uterine activity as determined by electrohysterography (EHG).

The presence or absence of a FHR for each 0.25 second epoch was coded as 1 or 0 respectively. The recording quality of each fECG trace was calculated as the percentage of present FHR within the total number of 0.25 second epochs. The average FHR and MHR were calculated using 0.25 second epochs for which a recording was present.

Statistical analysis

All raw data were reported as frequencies or the median (range). Anxiety scores were analysed using Wilcoxon matched pairs test. All statistical and graphical analyses were performed using STATA version 14 (STATACorp, Texas, USA) and GraphPad Prism 7.0. A p-value <0.05 was considered statistically significant. Sample size was planned to be a minimum of 20 participants which had 80% statistical power to detect a 20% difference in Pregnancy Specific Anxiety Score (α=0.05). There was no formal power calculation for the qualitative component.

Semi-structured interviews and Qualitative analysis

Following monitoring, participants were asked to partake in a one-to-one semi-structured interview. All interviews were conducted (by AC, ST or LS) in a quiet room using a topic guide which focused on 5 main areas: defining acceptability, practicalities of the device, the impact of the device on the participant before and after CFM and the potential clinical implementation of the device. All interviews were audio-recorded and transcribed verbatim. Identifiable information was removed and each participant was assigned a pseudonym. Transcripts were verified to check for transcription errors. Braun and Clarke’s six-step approach to inductive thematic analysis was
followed (21). Transcripts were subjected to line-by-line coding through iterative reading and re-reading. NVivo (Version 11, QSR International, MA, USA) was used to record, analyse and visualise themes. Peer debriefing was employed to ensure validity in themes (between AC, PA, HR and AH).

Results

Quantitative Data Analysis

Twenty two women agreed to participate in the study, participant demographics are shown in Table 1. Participant flow is shown in Figure 1. Two women did not have a recording of the trace due to technical problems with the device. In one further participant, CFM data could not be accessed by the device software, thus successful traces were obtained in 19 of 22 participants. Twelve women who had successfully recorded CFM traces participated in the interview.

Participants had a range of maternal ages and due to the nature of the research clinic all women were parous and had a history of perinatal death. The mean BMI was 28.4 kg/m², with 7 (31.8%) of participants having a BMI classified as obese. Although the greatest proportion of participants were White British (15/22, 68.2%), there were participants from a variety of ethnic groups. The majority of participants had no complications at the time of recording, 4 (18%) had maternal complications and 3 (13.6%) had reduced fetal movements. All participants had live births between 35-40 weeks with birthweights appropriate for gestational age.

Recordings were undertaken between 28-40 weeks of pregnancy and lasted a mean of 21.4 hours. The characteristics of the recordings are shown in Table 2. Maternal heart rate was more reliably recorded than fetal heart rate (99.0% of the duration of recording vs. 69.0%, p<0.0001 Mann-Whitney U-test). The recording quality of the fetal heart rate had a weak positive correlation with gestation at recording and a negative relationship with maternal movement and uterine activity (Figure 2A-C). There was no correlation between recording quality and BMI (Figure 2D), although one of the participants with an unsuccessful recording had a BMI of 48. To analyse fECG characteristics the Monica VS software breaks the CFM trace into frames of 60 minutes duration, which must have >60% signal present for analysis. A mean of 83.3% of frames were suitable for analysis (range 13.0-100%). All the baseline values were within the normal range, including STV. Interestingly, these CFM traces showed a total of just under three decelerations per hour (large + small decelerations), despite coming from babies with normal growth velocity and good neonatal outcome.
There was no statistically significant difference in the anxiety scores before or after using the CFM device (Figure 3A-D). The PSA showed a trend towards reduction (p=0.07). The majority of women in this study did not have a preference for CFM using the AN24 device or traditional intermittent CTG, with 30% stating a preference for the AN24 device. This was lower than previous reports (Figure 3E).

80% of the respondents found the device comfortable, although 55% reported irritation with skin electrodes. The majority of respondents felt that the device did not affect their activities of daily living, and the majority were satisfied with their experience of CFM (Table 3). There was a wide range of responses whether the device altered perception of fetal movements and whether participants enjoyed wearing the device with the largest group neither agreeing nor disagreeing with this statement. The majority of respondents felt that they could put the device on correctly without supervision and all respondents indicated that they would wear the device if advised to do so by a professional. A significant proportion (70%) of respondents felt that improvements could be made to the device, suggestions included: shorter wires, a means of wearing the device that was not around the neck, audible feedback to hear the heartbeat and a smaller box.

Thirteen women agreed to participate in the semi-structured interview (Figure 1). Interviews lasted between 4 and 23 minutes. Three themes emerged in thematic analysis: i) reassurance and anxiety, ii) the physical device and iii) future developments in CFM. Data saturation was deemed to have been reached as no new themes emerged in the final interview and all themes were mentioned to some extent in all interviews, quotations are used to illustrate themes.

Reassurance and anxiety

The majority of participants in the study found the Monica AN24 to be reassuring; although there were subtle differences as to why women were reassured, this was most frequently expressed as ‘peace of mind’. On the other hand, some participants’ anxiety increased as a result of using the Monica AN24, either through concerns that it had detected an abnormality or that they had disturbed the machine and affected the recording quality. For some women, the device was a ‘double-edged sword’, bringing aspects of both reassurance and anxiety: ‘It’s great to know that the baby’s alright, but when the baby’s not alright is that going to bring more anxiety and more stress, you know and make that situation even worse.’ (Jasmine). A number of participants reported the expectations from professionals and members of the public that using Monica AN24 would increase their anxiety: ‘A lot of people said to me, ‘Oh does it not make you anxious wearing that?’ You know, knowing that it’s on but actually I think it, it helps you calm down
because you know that, that during that period of time that it’s on you’re being monitored’ (Elizabeth)

The experience of using the device was also affected by women’s previous experiences of fetal monitoring or pregnancy complications especially if previous monitoring modalities had not detected fetal compromise: ‘My situation that brought me into [specialist clinic] nobody noticed what happened to the baby….it made me feel secure that whatever happens somebody is going to know the time or at some point what really happened.” (Alice)

The physical device

The second theme summarises the physical impact that the device had on the experience of participants in this study. Each woman had different physical experiences of wearing the device. The majority of women compared the device favourably to conventional monitoring, valuing the freedom to mobilise and ability to record fetal wellbeing during normal activities. In some cases some small negative impacts were reported: ‘It was just like having a heavy necklace on.’ (Nicola) and ‘I got home and everyone was laughing, they all thought I looked like Robocop or something’ (Abby). For some women, concern about the device altered activities of daily living, including sleep: ‘I was a bit anxious when I was asleep cos I didn’t want to pull the wires and disturb it or anything so I had to sleep with the Monica under my pillow and have the wires come down and just stayed in one position all night and not move.’ (Nicola)

In the interviews some women highlighted specific issues with the design of the device such as the length of the wires and lanyard: ‘I was trying to find something to wear where you can’t see all the wires ‘cos obviously you don’t want people asking why you’re wearing lots of wires.’ (Lisa) Participants reported they took measures to limit the impact of these problems by tucking wires into clothing. Some interviewees suggested how to improve the device for example: ‘I think it would be better if it was wireless.’ (Hannah). Although the physical aspects of the device could cause discomfort, women prioritised the reassurance it gave them: ‘It’d probably get really irritating then, but knowing the benefit it’s giving me, there’s no question. It wouldn’t even be a concern.’(Emma)

Future developments in CFM

Regarding wider implementation of the device all participants stated that the Monica AN24 could play an important role in monitoring, but they do not see this as a replacement for existing techniques such as ultrasound scanning or the maternal perception of fetal movements: ‘I was
comforted… However, if perhaps I didn’t have that same level of fetal movement, obviously I would have looked to come into hospital sooner for further investigation as I know that this [the Monica AN24] is not, you know, this is not a failsafe tool to monitor baby.’ (Lucy). Some participants wanted additional feedback from the device, particularly if they were not sure about fetal movements: ‘I can’t tell when the baby’s moving… I can’t tell till I look down at my stomach or when I put my hand on my belly and I can feel it. If that showed me that the baby is moving and that there is movement and things that would give me peace of mind, especially over a week period.’ (Jasmine). Other participants would gain reassurance from clinicians being able to continuously monitor the results in real-time so that action could be taken if necessary: ‘Real-time lessens the anxiety knowing that if there’s something wrong … someone is going to tell me in a minute because they can see it.’ (Katherine).

Discussion

This study demonstrates that CFM for extended periods using a Monica AN24 monitor is feasible and does not have significant negative impact upon mother’s experience or anxiety. Importantly, the proportion of successful traces and the proportion of FHR trace recorded are similar to published data (69% vs 73.1% (10)). In addition, the lack of relationship between the quality of FHR trace and maternal BMI, and a weakly positive relationship with gestation have also been consistently seen (8, 9). This suggests that the technical performance of CFM using the Monica AN24 is consistent between study populations. As well as the quantitative measurements, the qualitative data obtained was consistent with a meta-analysis of five published studies (6), identifying practical limitations of the device, high levels of satisfaction and maternal reassurance, but anxiety as to whether the FHR trace was normal.

Another feature in common with other studies was technical difficulties meaning that CFM was not successful in all cases, as with other reports this improved with practical experience of the device (22). However, some technical aspects (most notably the physical characteristics of the device) negatively impacted upon women’s experience, with a lower proportion expressing a preference for the Monica AN24 compared to conventional CTG than in other studies (23, 24). Therefore, technical developments, specifically to improve the detection of the FHR trace, are required to improve the reliability of the device. Other improvements, such as incorporation of wireless technology are required to improve its usability and women’s experience.

This study was strengthened by the mixed methods approach which gives a holistic evaluation of the technical performance of the device and a detailed view of the impact and experience of
wearing the Monica AN24 device. Furthermore, the use of validated anxiety scores allows the
findings to be compared to other populations. However, the study is limited by recruiting from a
single high-risk clinic in a tertiary maternity unit and by the sample size (although this was
comparable to similar cohorts). Although the sample size for qualitative interviews was small
(n=13), the absence of novel themes arising from the interviews indicated that data saturation had
been reached, this is consistent with the findings of Guest et al. who found that data saturation
occurred within the first 12 interviews with elements of themes being present within the first 6
interviews (25). Critically, women’s prior experience of pregnancy loss may have influenced their
views and experiences. As CFM would not be routinely indicated in such pregnancies, this study
merits repeating in other populations, in which CFM may be employed more frequently, such as
women with fetal growth restriction or reduced fetal movements.

Importantly, women perceived CFM as an additional form of monitoring rather than a
replacement for ultrasound assessment of fetal wellbeing or maternal perception of fetal
movements. This is important when planning future studies implementing CFM, such that
participants may be unwilling to use CFM as a sole form of fetal monitoring. Participants also
suggested potential areas for technological development of CFM, in particular real-time
monitoring and feedback to women that their baby is well.

There is growing interest in using CFM to interpret features of the fECG to either detect cardiac
rhythm abnormalities or identify fetal compromise (7, 8, 12). Given that CFM can record the
fECG with adequate quality for interpretation in a large number of cases, the interest in this
methodology is likely to increase. However, in addition to technological developments studies
need to consider how normal or deviations from normal are defined and how the potential
relationship with pregnancy outcome is explored. For example, decelerations, which are non-
reassuring or abnormal features on intrapartum FHR traces were evident in all antepartum FHR
traces in this study despite all participants’ pregnancies having no evidence of fetal compromise.
Consequently, prognostic accuracy studies of CFM should be performed, where the recording is
not revealed, so that fECG features can be accurately correlated to fetal outcome. One such study
found that a single episode of STV<4ms had a positive predictive value for fetal compromise of
39%, which rose to 80% if there were 3 episodes of STV <4ms (12). In addition, studies of CFM
should focus on populations most likely to benefit such as women with suspected fetal
compromise (e.g. small for gestational age infants and reduced fetal movements).

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References


Legends

Table 1 - Participant demographics and pregnancy outcome

Table 2 – Recording characteristics (bpm = beats per minute, ms = milliseconds)

Table 3 – Questionnaire responses from participants. Numbers of respondents shown with proportion in parentheses.

Figure 1: Flow diagram reporting the numbers of women participating in the study, participants who had an unsuccessful recording, those included in the final analysis and those who participated in the qualitative interview.

Figure 2: Graphs demonstrating relationship of the proportion of fetal heart rate recording with maternal or pregnancy characteristics, A) Gestational age, B) Maternal movement, C) Uterine activity as measured by electrohysterogram (EHG) (plotted as individual results, each colour represents values from a different participant) and D) Uterine activity as measured by EHG plotted as mean results demonstrating a negative correlation with recording quality and E) Maternal BMI. *=p<0.05, **p<0.01, **** p<0.0001.

Figure 3: Graphs reporting analysis of maternal anxiety as assessed by A) Pregnancy Specific Anxiety (PSA) Score, B) GAD-2 score, C) State Anxiety Score, D) Trait Anxiety Score, all of which demonstrate no statistically significant difference between scores before and after wearing the AN24 device. E) Patient preference for form of fetal monitoring in this study compared to that reported in Philippe et al. and Reinhardt et al. [20,21].

Supplementary Figure 1: The Monica AN24 device for CFM showing adhesive electrodes applied to the maternal abdomen connected by wires to a storage device which produces a recording of the fetal heart rate trace and uterine activity. Photograph used with permission of Monica Healthcare Limited.
Table 1 - Participant demographics and pregnancy outcome

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<td>Obese</td>
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<td>Birthweight (g)</td>
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Table 2 – Recording characteristics (bpm = beats per minute, ms = milliseconds)

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</tr>
<tr>
<td>Recording Fetal Heart Rate at night at rest (%)</td>
<td>81.3 (0 – 100.0)</td>
</tr>
<tr>
<td>Frames analysed</td>
<td>15.5 (12 - 24)</td>
</tr>
<tr>
<td>Proportion of frames analysed (%)</td>
<td>72.7 (13.0 – 100)</td>
</tr>
<tr>
<td>Mean Baseline (bpm)</td>
<td>137.7 (126.9 – 149.4)</td>
</tr>
<tr>
<td>Decelerations per hour</td>
<td>2.9 (1.0 – 5.3)</td>
</tr>
<tr>
<td>Accelerations per hour</td>
<td>14.2 (1.6 – 27.9)</td>
</tr>
<tr>
<td>Short term variability (ms)</td>
<td>11.0 (4.4-17.0)</td>
</tr>
<tr>
<td>High variation (%)</td>
<td>36.3 (3.3 – 73.4)</td>
</tr>
<tr>
<td>Low variation (%)</td>
<td>6.5 (0 – 61.7)</td>
</tr>
<tr>
<td>Maximum minute variation (ms)</td>
<td>60.3 (24.5 – 91.6)</td>
</tr>
</tbody>
</table>
Table 3 – Questionnaire responses from participants. Numbers of respondents shown with proportion in parentheses.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree nor disagree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>The device affected the activities of my daily life</td>
<td>0 (0)</td>
<td>2 (10)</td>
<td>1 (5)</td>
<td>6 (30)</td>
<td>11 (55)</td>
</tr>
<tr>
<td>Whilst wearing the device I felt more aware of my baby’s movements</td>
<td>6 (30)</td>
<td>2 (10)</td>
<td>8 (40)</td>
<td>3 (15)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>I enjoyed wearing the device</td>
<td>2 (10)</td>
<td>4 (20)</td>
<td>9 (45)</td>
<td>4 (20)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>I was satisfied with my experience of continuous fetal monitoring</td>
<td>9 (45)</td>
<td>4 (20)</td>
<td>2 (10)</td>
<td>2 (10)</td>
<td>3 (15)</td>
</tr>
</tbody>
</table>
Women agreed to participate in study (n=22)

Women who completed CFM (n=22)

Attempted recording unsuccessful (n=2)

Women who had successful recording (n=20)

Women who had successful recording (n=20)

Women who had CFM suitable for analysis (n=19)

CFM not correctly downloaded by software (n=1)

Participants who had an interview (n=12)