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Women's experience of wearing a portable fetal-electrocardiogram device to monitor small-for-gestational age fetus in their home environment

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Abstract

Objective: To determine the acceptability, to women, of wearing a portable fetal electrocardiogram recording device at different stages of pregnancy and to gain insight into their experience of its use for long-periods of monitoring of small-for-gestational fetuses in the home environment.

Methods: A qualitative study using both a questionnaire and focus group involving women with singleton pregnancy >24 weeks gestation, no evidence of fetal malformation and an estimated fetal weight below 10th gestational centile on ultrasound scan. Fetal heart rate recordings were collected for up to 20h.

Results: In total, 59 questionnaires were completed; 35 after wearing the monitor for the first time and an additional 24 from the women who wore the device for a second time. Six women participated in the focus group; the principal theme identified related to the practicality of the fetal electrocardiogram device. Other themes identified were the discomfort that resulted from wearing the monitor and the reassurance provided in knowing that the baby's heart rate was being monitored.

Conclusion: Long-term ambulatory fetal electrocardiogram monitoring is an acceptable method of monitoring small-for-gestational fetuses. Overall, women concluded that benefits of wearing the device outweighed any discomfort it caused.

Keywords

fetal electrocardiogram, fetal heart rate, fetal monitoring, home monitoring, pregnancy, small-for-gestational age, women's experience

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Introduction

Despite significant improvements in antenatal care, the rate of stillbirth deliveries has remained static in the United Kingdom, at approximately 5 per 1000 births,¹ over the past two decades. In a meta-analysis published in 2011, the risk of stillbirth in high-income countries was demonstrated to be four times higher in fetuses measuring small-for-gestational (SGA) age compared with non-SGA fetuses, and SGA was noted to have the greatest population-attributable risk compared to other risks of stillbirth.^{2,3} Furthermore, a retrospective population study has shown that the antenatal detection of SGA could potentially halve the risk of stillbirth.^{4,5} Therefore, improving the identification and monitoring of

the SGA fetus could prevent stillbirth, likely through appropriate antenatal surveillance and timely delivery.^{2,6}

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There is no consensus as to the optimal timing of delivery in pregnancies complicated by SGA. Clinicians have to balance the risks of premature delivery, with the risk of stillbirth or survival, with the consequences of in-utero oxygen and nutrient deprivation. Given the impact of global stillbirth, it is important to identify antenatal fetal surveillance tests that optimize the timing of delivery for pregnancy complicated by SGA fetus, in order to prevent stillbirth.²

Current techniques for fetal surveillance employ different criteria for determining the timing of delivery but have made little impact on stillbirth rates⁷ because of their limitations. Ultrasound scans (for fetal biometry, quantification of amniotic fluid and Doppler assessments) and electronic fetal heart rate (FHR) monitoring by cardiotocography (CTG) are the most common investigations routinely performed for monitoring SGA fetuses.^{4,7,8} However, both techniques only provide a snap-shot of information on fetal well-being at regular intervals.⁹ They also restrict patient mobility and cannot be employed over long-time periods.^{10,11} It is plausible that newer ambulatory techniques that enable monitoring over a longer time period such as fetal electrocardiogram (ECG)-monitoring devices¹⁰ may improve the prediction of the risk of stillbirth and better inform decisions about the timing of delivery for women carrying SGA fetuses.

Although, previous studies have investigated the acceptability and feasibility of transabdominal fetal ECG monitoring during pregnancy and labor in the home and hospital environment, none of these studies recruited women to wear the monitor more than once.^{10,12-16} This study was therefore aimed to explore the acceptability of wearing the portable fetal ECG monitor on more than one occasion at different stages of pregnancy in the home environment using self-completed questionnaires followed by focus group discussion to allow in-depth exploration of the important issues raised from the woman's perspective.

Methods

Recruitment

The prospective cohort study was conducted at Jessop Wing Hospital, Sheffield and approved by the North-West Preston NRES Research Ethics committee (15/NW/0278). The study group consisted of 35 non-laboring women with singleton pregnancies between 24 and 40 weeks gestation and an estimated fetal weight (EFW) of less than the 10th gestational centile on ultrasound scan.¹⁷ Patients with any fetal malformations were excluded from the study.

Informed written consent was obtained, and the fetal ECG monitor (Monica AN24; see Figure 1) was fitted by placing five skin electrodes in a standardized position on the maternal abdomen.¹⁰ When fully charged, the device is capable of obtaining recordings lasting up to 20h.¹⁸ Participants were allowed to go home and carry on with



Figure 1. Monica AN24 device.

their daily activities while wearing the monitor. They were advised to turn off and remove the monitor after 20h of use. However, they were at liberty to take off the monitor at any time if they experienced any discomfort. The monitor was either collected from patient's home by the research team or returned by the patient following the monitoring session. The fetal electrophysiological data recorded within the monitor were downloaded via a USB connection. All the data were analyzed when the study was completed, to ensure consistency in the analysis.

Questionnaire

Maternal experience for outpatient fetal monitoring was evaluated using a self-completed flexible data collection questionnaire.¹⁹ Participants who demonstrated interest in wearing the monitor again were contacted 2 weeks later and recruited for the second part of the study. The 2-week interval between monitoring sessions was designed to study gestational age-related changes in the FHR pattern. Similar instructions were given and participants were requested to fill in a questionnaire for the second time as well. The questionnaire explored the acceptability of wearing the monitor and any associated issues, such as the comfort of the device, if their sleep was affected, if it irritated their skin and if they were willing to wear the device again. These parameters were assessed on a scale of 1 to 10; where 1 represented the best outcome and 10 the worst (see appendix 1). There was also free text available for further explanation of the scores given, and this descriptive data were summarized.

To allow an in-depth understanding of the participants experience using the monitor and to enhance recruitment

Table 1. Maternal demographics, recording variables and delivery data.

Variables	Number of patients = 35	
Age (years)	28.9 (5.6)	
Body mass index, (kg/m ²)	23.6 (5.7)	
Ethnicity, n (%)	White British: 29 (82.9) Asian: 4 (11.4) Non-British European: 1 (2.9) Mixed ethnic group: 1 (2.9)	
Parity, n (%)	Nulliparity: 14 (40) Multiparous: 21 (60)	
Smoker, n (%)	Yes: 12 (34.3)	No: 23 (65.7)
Gestational age at recording, (weeks)	33.8 (3.37)	
Gestational age at birth, (weeks)	38.4 (1.81)	
Onset of labor, n (%)	Spontaneous: 10 (28.6) Induced: 17 (48.6) Did not labor: 8 (22.9)	
Mode of delivery, n (%)	Vaginal birth: 23 (65.7) Cesarean section: 12 (34.3)	
Gender of baby, n (%)	Male: 14 (40) Female: 21 (60)	
Birth weight (g)	2441.0 (2.81)	

The central tendency has been summarized using mean and standard deviation (SD).

to the main study through understanding women's perception of the acceptability of wearing the monitor, that is, their motivations or reluctance to wearing the monitor, a focus group was conducted. Focus groups can serve a useful function by setting data in context during the exploratory phase of a project.²⁰ This method is particularly useful for exploring people's experiences, examining not only what they think but how they think and why they think that way.²¹ In addition, they can also enable participants to bring forward issues of significance to them.²⁰ In this study, the focus group was conducted to provide women with an opportunity to discuss their experience of wearing the monitor twice at different stages of pregnancy or their reasons for declining to do so after wearing it once.

The optimum number of participants for a focus group is between 6 and 10, which is large enough to encourage discussion, but not too large to inhibit less vocal participants.²² To achieve the target number of participants for the focus group, we contacted 18 women by telephone, of whom nine had worn the monitor on two occasions and nine had declined to wear the monitor on a second occasion. Written informed consent was obtained from participants, a loose discussion guide was formulated and a guideline for the conduct of focus group and the maintenance of confidentiality was distributed for agreement before the discussion began.

The focus group addressed the following research questions:

- What are women's experiences of using the monitor?
- What motivates women to wear the monitor?

- Why do women decline a second use of the monitor after the first use?

The focus group was audio recorded and later transcribed verbatim. Analysis was conducted using content analysis,¹⁹ in which the research team independently read the transcripts before coming together to discuss their findings. The team searched for common patterns and themes emerging from the experiences of the women and their relative importance. Opposing views and areas of diversity were also considered. Emergent themes obtained by this process were explored by two researchers (H.K. and E.R.D.) independently and refined until final themes were agreed by both researchers as reflective of the data.

Results

The baseline characteristics of the participants and their fetuses are given in Table 1.

In total, 59 questionnaires were completed; 35 after wearing the monitor for the first time and an additional 24 from the women who wore the device for a second time. The quantitative results are summarized in Table 2.

Of the 18 women contacted for the focus group, 12 demonstrated interest; however, only six attended the meeting. Participants, who attended the meeting, wore the monitor on two occasions except for one woman who wore it twice but only during the day time. None of the participants who declined wearing the monitor second time, attended for the focus group meeting.

From the analysis, the principal theme identified related to the practicality of the fetal ECG device compared to

Table 2. Summary of questionnaire results.

Questionnaire results	Result*
Q1. How comfortable was the monitor?	3 (2–6)
Q2. Did wearing the monitor disturb your sleep?	2 (1–4)
Q3. Were you affected by a rash or marks on the skin under or around the sticky pads?	2 (1–6)

*Scores from 1 (best) to 10 (worst), with results displayed as median and interquartile range (IQR).

CTG. Other themes identified were: the discomfort that resulted from wearing the monitor and the reassurance provided in knowing that the baby's heart rate was being monitored. Overall, women concluded that the potential advantage of wearing the device outweighed the slight discomfort associated with its use. Direct quotations are used to contextualize the women's views and illustrate themes identified from the focus group discussions.

Practicality of the device

All six women described their perceived benefits of being able to be monitored at home rather than at the hospital:

It was a million times better; it's just nice to be able to get on with your everyday tasks. I went to work wearing it, and the children who I work with only noticed it towards the end of the day. (Patient C)

It is absolutely brilliant, after being strapped to a bed for six hours during my labour I needed to move around, so I do think it will benefit people massively. (Patient E)

I would have much preferred mobile monitoring. When you have two small kids, coming to the hospital and getting parked for an hour of monitoring is a lot of hassle, especially if you have to do it on a regular basis, which you do when you have a small baby. (Patient F)

Patient E further explained why she thought the mobile monitoring would be beneficial and how it would provide reassurance to the parents:

I think it is nice that it will be monitoring you doing your everyday activities rather than just being sat down. When you are monitored in hospital it is only getting a recording of what the baby's heart is doing then. However, I still took the dogs for a walk during pregnancy, so if that affected the heart rate of the baby then this new monitor would tell you and would reassure you that it is safe to be active during pregnancy. (Patient E)

Before taking part in the study, some women were concerned that the device might interfere with daily activities and prevent them from getting on with jobs. However, women at the focus group concluded that, for the majority of the time, the device was barely noticeable:

It was only really apparent when getting dressed and undressed, as I obviously had to reposition the device. (Patient D)

It did not prevent me from doing anything, in fact, I am sure I could have gone to the gym wearing it, or gone for a run! (Patient A)

Before it started itching I totally forgot about it, however, I am very sensitive to plasters and so when it started itching that was all I could think about and so had to remove it. (Patient E)

There were some concerns about the design of the device and opinions were divided. Some women felt that the wires from the monitor to the electrode pads were too long:

When going to the toilet you had to tuck all the wires back in, and there seemed to be quite a lot of excess. (Patient B)

As I only had the device on during the day, and so kept it around my neck, I did not need the wires to be as long as they were, it made it quite cumbersome. (Patient E)

I kept getting tangles in the wires because they were too long! (Patient C)

However, Patient A felt that the wires were not long enough:

The wires could have done with being a tiny bit longer. When laid in bed where do you put it? If you have a long top on then the leads have to go down the bottom and back up to the pillow, and this left little room for movement. (Patient A)

It appeared that there was a need for longer wires at night to allow movement when changing positions. However, during the day, the excess wires got in the way. Nonetheless, the discussion group did provide valuable feedback as to how other aspects of the device could be improved to make it more practical. For example, patients were given the option of wearing the device around their neck using the lanyard or putting it in a pocket. Some women found it heavy to wear round their neck for the whole day, but at the same time were nervous about putting it in their pockets, in case they accidentally pressed a button and interfered with the monitoring. It was suggested that a clip on the back of the device would be beneficial so that it could be attached to clothing to secure it. In addition, respondents felt that a clear case covering the monitor would prevent patients from accidentally pressing the buttons.

Discomfort caused by the device

The experience of wearing the device varied according to each individual, and this was particularly noticeable when the women were asked how wearing the device affected

their sleep. Some found that they barely noticed it, others found it so irritating that they had to remove it:

At night I would go to turn over having forgotten I was wearing the device and then I would feel something tug which reminded me that I had to move the device as well. (Patient B)

I didn't wear the device at night, I just wore it through the day as it caused me too much irritation. (Patient E)

I had a small bump and usually would sleep on my front as this was most comfortable, however, when wearing the monitor I was unable to do this and so it made it more difficult to get to sleep. (Patient A)

One of the major concerns of the device was the irritation that the electrode pads caused. Two women said that it was itchy to wear. Patient F explained why she felt itchy:

During pregnancy your belly contracts and expands, and so when the device was fitted it is loose, but then your belly goes really tight, and that is when you notice it and it starts to itch as the skin is stretched. (Patient F)

Patient C did not find the device irritating to wear, she said,

It did not cause any irritation while wearing the device; however, when I removed the pads the skin was a bit itchy where they had been and there was a slight redness, but this did not last very long at all. (Patient C)

The extent to which marks were left on the patients' skin varied. Patient E, who is sensitive to plasters, said it took a few days for the marks to fade completely after removing the device, whereas Patient D said it only took a few hours.

Reassurance provided by the monitoring

Ultimately the women felt that if wearing the monitor benefited their babies, then it was worth the slight discomfort:

The more that can be done to make sure you have a healthy baby at the end, the better. I think most mothers would do whatever needed doing to make sure the outcome is good. It does not matter if you have to wear a few wires for a week, or even for the whole pregnancy. (Patient A)

If it is helpful for your baby then you keep it on, but it was a relief to take it off. (Patient F)

Ultimately the positives of wearing it completely outweigh the negatives, knowing you are giving vital information is worth a little bit of discomfort. (Patient E)

The women were aware that their baby would not directly benefit from this study. However, during the focus group, it was explained to them that if the device was

approved for wider use then the information would be relayed to the hospital in real-time to be reviewed by staff. The women liked this concept and felt it would provide reassurance:

It would make me feel safer because if something was wrong the hospital staff would be straight on the phone to you. (Patient B)

It would be reassuring to know that someone is checking the heart rate, as long as technology works that is. (Patient D)

However Patient E also commented that wearing the device made her partner anxious:

My partner had more questions than I did, and at one point he said that seeing me wearing the device reminded him that there could be a problem. (Patient E)

When asked how they felt about being able to view feedback about their baby's heart rate directly via an application on their phone they were less approving:

I think only tell patients information on a need-to-know basis. The way you feel affects your pregnancy, and so you would not want to cause someone to feel more anxious than necessary. Even if your baby was not small, pregnancy is still a scary time as you do not know what is happening. No matter if it is a high or low risk pregnancy, less information is better. (Patient C)

I quite like the idea that the heart rate was being monitored and professional people were going to analyse it. If I could look at it I would be constantly wanting positive feedback, and if it was not there it could cause more anxiety than necessary. I think you can be given too much information sometimes but less can be better. Women with small babies are already anxious, and there is no need to add more. (Patient A)

Discussion

We report for the first time that the fetal ECG monitor is an acceptable method of long-term FHR monitoring even when repeat monitoring is required during the same pregnancy.

Rauf et al.¹³ assessed maternal views on telemetric fetal ECG monitoring in 51 women undergoing induction of labor at home using semi-structured diaries as well as a 4-point scales. The device was worn for a median time of 10 h and was acceptable to 46 out of 51 women (90%).

Comparing the results from our study to Rauf et al.,¹³ there may be alternative reasons to why 31.4% patients did not wear the monitoring device for the second time. In the home induction of labor study,¹³ women were directly benefiting from taking part in the research study and as a result, there was an incentive to participate in the future. However, in our study, the women were not informed of

the results of the FHR monitoring, and hence there was no incentive to wear the device again. Nevertheless, two-thirds of participants wore the monitor twice and completed the study, suggesting that the fetal ECG monitor is an acceptable method of long-term outpatient monitoring for SGA fetuses.

The quantitative data on a scale of 1 to 10 for the 59 completed questionnaires illustrated an average comfort level of three, sleep disturbance of two and rash severity of two. Given that numerical values are subject to personal interpretation and consequently are likely to be arbitrary, participants were asked to provide explanations for their numerical score after each scale. Such free-text annotations added richly to the quantitative data¹⁹ and, in this study, enabled a better interpretation of the numerical scores provided regarding the comfort of the monitoring device.

The most common comment in an additional free-text space on the questionnaire was the report of itching, which occurred as a result of the electrode pads on the abdomen. Our study used Ambu electrodes, as recommended in a previous study²³ which determined signal-to-noise ratio and compared the success rate of FHR recording using three different types of electrodes (Ambu, Covidien and Red dot). That study concluded that the success rate of acquiring FHR signals were higher with Ambu and Covidien compared to the Red dot. However, the study did not determine the degree of discomfort of irritation associated with either electrode pad. We employed the Ambu electrodes, as these had received regulatory approval (the CE Mark) in the United Kingdom. Further investigation is required to determine which of the electrodes was associated with the least irritation such as itching.

Women also commented on the practicality of wearing the device. While some found the device heavy to wear around the neck, others commented that the wires were too long and therefore made it impractical to wear. Suggestions as to how this could be improved included the addition of an elasticated belt or clip on the device to enable it to be better secured. There was a need for the device to be fixed during the day to prevent it disturbing daily activities and for it to be placed under the pillow at night to prevent it disturbing sleep.

The final question in the questionnaire asked patients to explain why they were, or were not, willing to wear the monitoring device again. Experiences varied and opinions were divided as a result. Some patients hardly noticed the device once they got used to wearing it; however, others found it very uncomfortable to wear. Despite this, overall, participants felt that if medically indicated, they would wear the monitoring device for the benefit of their babies.

Results from the focus group complimented those from the questionnaire. However, in the focus group, it was possible to obtain more detailed feedback on different aspects of wearing the device. Although, our focus group was

limited by the fact that none of the participant who declined wearing the monitor second time attended; it was impressive to hear both positives and negative comments from the ones who wore the monitor twice and attended the meeting. Nonetheless, the results should be interpreted with caution as the focus group comprised of women who wore the device on two occasion implying that they had a positive perception of fetal ECG monitoring in the home setting.

To our knowledge, no other focus groups have been conducted to learn more about the experience of wearing the fetal ECG-monitoring device (Monica AN24) during pregnancy. A qualitative study using semi-structured individual interviews on 15 women who participated in the trial of home induction of labor using the Monica AN24 device demonstrated willingness to undertake the same experience again if invited to do so for induction of labor in future pregnancies.¹⁴ The analysis identified three main themes based on the women's feedback: "the need for women to labor within their comfort zone," "a desire to achieve the next best thing to a normal labor" and "the importance of a virtual presence to offer remote reassurance."¹⁴ Similarly, participants in our study commented on the practicality of being able to wear the device at home. They felt it was beneficial to be monitored in their comfort zone in order to obtain a realistic recording of how the baby responded to daily activities. They also commented on the reassurance provided in knowing that their baby was being monitored and that someone else would be viewing the results. All participants in the focus group felt that despite the discomfort caused by the monitoring device, they would be willing to wear the device again for the benefit of their unborn child.

A further limitation is related to an informal assessment of maternal anxiety. We did not use validated questionnaire which raises a question on the reliability of results and limits the generalization of findings. However, a recent systematic review of maternal anxiety scores in pregnancy²⁴ has demonstrated that none of these are completely reliable, and therefore, the use of these would not have significantly affected the reliability of the results obtained.

Practical limitations of the device predominantly focused on the number of cables. Although, manufacturers of Monica AN24 appear to be responding to these concerns, as the most recent model of Monica AN24, the Monica Novii, has a cable-free design.²⁵ Suggestions made by the study participants can help manufacturers in further refining the design of the monitoring device.

Conclusion

In conclusion, we have shown that women would consider ambulatory FHR monitoring at home when indicated. Overall, the study approved the concept of long-term home monitoring, identified the portable fetal ECG monitor as a promising method of monitoring SGA fetuses and has

highlighted the facilitators and barriers to wearing the monitor in clinical care or research. These observations can be used to undertake robust research to assess the use of the portable fetal ECG monitor for optimizing the timing of delivery for SGA fetuses to prevent stillbirth.

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Author contributions

All authors contributed significantly to the manuscript and approved the final version. H.K. analyzed the data and wrote the report. E.R.D. recruited patients and analyzed the data. D.A. provided input, oversaw the process, edited the report and supported throughout.

Declaration of conflicting interests

The authors report no conflicts of interest in this work. H.K. certify that the manuscript is being submitted by her on behalf of all the authors. Written, informed consent was taken from the patient for reporting this work. The manuscript is original work of all authors. All authors made a significant contribution to this study. This manuscript has not been submitted for publication; it has not been accepted for publication and has not been published in any other journal. All authors have read and approved the final version of the manuscript.

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Appendix I

Questionnaire

Q1a) **How comfortable was the monitor?** Please rate comfort from 1 to 10, where 1 means the monitor was extremely comfortable and 10 means it was extremely uncomfortable.

Level of comfort									
→									
1	2	3	4	5	6	7	8	9	10

Q1b) **If you found wearing the monitor uncomfortable in any way, please explain why?**

Q2a) **Did wearing the monitor disturb your sleep?** Please rate disturbance from 1 to 10, where 1 means your sleep was not disturbed at all and 10 means the monitor made it extremely difficult to sleep.

Amount of sleep disturbed									
→									
1	2	3	4	5	6	7	8	9	10

Q2b) **If your sleep was disturbed in any way, please explain why?**

Q3a) **Were you affected by a rash or marks on the skin under or around the sticky pads?** Please rate how you were affected from 1 to 10, where 1 means you had no rash or marks and 10 means you were severely affected by a rash, marks or both.

Amount of rashes/mark									
→									
1	2	3	4	5	6	7	8	9	10

Q3b) **If you had a rash, marks or both, please describe what happened and how long they lasted?**

Q4a) **Are you still prepared to wear the monitor for a second 16 hour period?**

Yes	Not sure	No

Q4b) **Please explain your answer.**

Thank you for completing the questionnaire.