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## Original Article

# Performance of a condensed electrode patch compared to a diffuse electrode array for transabdominal fetal heart rate and uterine contraction monitoring: a preliminary report

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**Abstract:** Objective: Intrapartum monitoring of the fetal heart rate (FHR), maternal heart rate (MHR) and uterine activity (UA) can be done noninvasively via adhesive electrodes on the parturient's abdominal surface. This approach, requiring multiple electrodes placed at specific positions on the abdomen, performs at least as well as ultrasound and tocodynamometry-based monitoring. We tested whether a single adhesive electrode template (a "patch"), which would simplify use and obviate errors in electrode placement, would function as well as diffusely arrayed single electrodes. Methods: Seventeen healthy term parturients were monitored simultaneously with a diffuse electrode array and a condensed array patch, each connected to an identical electronic processor. Equivalence of the two electrode systems was determined by comparing their success rate, percent agreement and percent equivalence for FHR and MHR detection. UA monitoring was assessed by comparing the percent agreement and sensitivity of the systems. Results: The success rates of the multiple electrode array and the patch for FHR and MHR detection were above 96%. The reliability of the patch was statistically equivalent to the standard electrode array. The percent agreement for FHR was  $94.7 \pm 4.0\%$  and for MHR was  $92.8 \pm 5.3\%$ . These were not affected by maternal body mass index or whether it was early or late labor. The percent equivalence for both FHR and MHR was above 98% indicating equivalence of the patch with the diffuse electrode array in the accuracy of heart rate detection. The percent agreement of UA detection between the patch and the electrode array averaged 98% and was not influenced by whether it was early or late labor. The sensitivity of the patch for detecting individual contractions was 86.1%, equivalent to the standard electrode array. However, the sensitivity was lower in early compared to late labor ( $82.1 \pm 13.9$  vs.  $90.3 \pm 9.3\%$ ;  $P=0.052$ ). The lower 95% confidence limit in early labor (74.9%) fell below the 80% limit necessary for equivalence. Conclusion: The performance of an electrode patch template for intrapartum monitoring of fetal and maternal heart rate and uterine contractions was equivalent to that of a more diffuse electrode array in almost all respects.

**Keywords:** Electronic fetal monitoring, fetal monitoring, fetal heart rate monitoring, fetal electrocardiography, cardiotocography, uterine contractions

## Introduction

There is considerable evidence that noninvasive intrapartum monitoring of the fetal heart rate (FHR), uterine contractions (UC), and maternal heart rate (MHR) can be done successfully and reliably via adhesive electrodes placed on the parturient's abdominal wall [1-8]. The method requires multiple electrodes to be applied at discrete places on the abdomen to detect electrical signals from the fetal heart

and uterine smooth muscle. Placement of these individual electrodes is inconvenient and, more importantly, errors can occur in electrode location and skin preparation that can affect the quality of the data transferred from the electrode to the monitor. To address this problem, an electrode template to facilitate easy and accurate placement has been developed (Novii patch, Monica Healthcare, Ltd., Nottingham, UK). This device, designed to be centered over the umbilicus, incorporates four electrodes in

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**Figure 1.** Study patient showing the 5 standard disposable adhesive electrodes (blue) attached along with the condensed electrode patch in which the electrodes are integrated into a flat, flexible cabling assembly (white). Lead wires for each electrode system are attached to an AN24 monitor (not shown).

fixed positions and a fifth that can be moved to ensure its proper placement relative to the maternal symphysis pubis. An effective electrode template would simplify use of an abdominal surface monitoring system, obviate errors in skin preparation and electrode placement, and make the transabdominal approach to FHR and UC monitoring more efficient for staff and more comfortable for patients. To assess the performance of the new condensed electrode array template, or patch, we compared the FHR and UC data generated from it to the data obtained simultaneously from five diffusely arrayed single electrodes.

### Materials and methods

This single-center open prospective parallel equivalence trial was approved by the Institutional Review Board of the University of Arizona College of Medicine (protocol # 13-0197), and conformed to the guidelines of the Medical Association Declaration of Helsinki for human studies. It was done in partial requirement for US Food and Drug Administration clearance of the patch electrode system. A convenience sample of 17 patients who presented in labor or for induction of labor provided informed consent and participated in the study. All had term ( $\geq 37$  week) singleton pregnancies without known fetal or maternal complications.

After obtaining her informed consent for the study, each patient's abdominal wall was cleansed with soap and water, dried with a towel, and the condensed electrode self-adhesive patch was applied. In most cases, this was centered at the umbilicus. In patients with a large dependent abdominal panniculus, the patch was centered at the level of the iliac crests. The skin where its electrodes were to be attached was abraded lightly with ECG preparation tape (3M Red Dot Trace Prep; 3M Health Care, St. Paul, MN) to remove cornified surface cells and thereby reduce skin impedance. The lower electrode was attached 6-8 cm above the upper border of the symphysis pubis. The five individual electrodes (Blue Sensor R, Ambu A/S, Ballerup, DK) for the diffuse electrode version of the standard fetal/maternal monitor (Monica Healthcare, Ltd., Model AN24) were then attached in their usual designated places after similarly preparing the skin (**Figure 1**).

Each of the electrode systems was attached by wire leads to an individual AN24 monitor. We were thus able to monitor FHR, UC and MHR simultaneously in each patient using different electrode arrays, but identical electronic processors. The output from both monitors was stored in real time on an internal micro-flash SD memory card, and later downloaded to a PC for analysis in order to compare the performance of the diffuse electrode array and the condensed array of the electrode patch. The FHR, UC, and MHR tracings from the standard (diffuse) electrode array were available to the obstetric team for decision-making; they were blinded to the data from the condensed electrode patch.

For analysis the two FHR tracings were synchronized to within 0.25 seconds and then evaluated in serial 2-second intervals. Synchronization was accomplished by cross-correlating the FHR data from the two devices at differing time offsets. The peak in this correlation corresponded to alignment of the two data sets. Statistical analysis was performed using Microsoft Excel (Microsoft Corporation; Redmond, WA) and a commercial software package MATLAB (V8.1; The MathWorks, Inc.; Natick, MA, 2013).

To facilitate management of the large data set, we chose to analyze monitoring data from two time epochs: early in the first stage, and late in the first stage and second stage. The latter cat-

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egory included five cases of pure second stage and 12 cases in which the late first stage data were included with data from a very short second stage. We analyzed the first 30 minutes of simultaneous monitoring of each patient in the first stage of labor once we confirmed the patterns were synchronized. For the late labor recordings, delivery time was used as a reference and a 30-minute segment was assessed starting 60 minutes before delivery. Data were analyzed before and after stratification by early and late labor and by maternal BMI group ( $< 29$ ,  $29-34.9$ ,  $\geq 35$  kg/m<sup>2</sup>). The data collected from the two electrode arrays were used to compare their performance with respect to FHR, UC, and MHR determination. The standard diffuse 5-electrode array used in the FDA-cleared AN24 was, for purposes of the study, considered the standard against which the performance of the condensed electrode patch was compared.

Several measures of equivalence were used to determine whether data from the condensed electrode patch were equivalent to those from the diffuse array. We employed an approach analogous to that used in bioequivalence studies [9, 10]. We compared the 95% confidence interval (CI) for the mean of the data from the test device (the electrode patch) to that of the standard device (the diffuse electrode array). Because of the relatively small sample size we used a t-distribution rather than a traditional Gaussian distribution, with  $t=2.12$ . To be considered equivalent to the standard, the measurement's two-sided 95% CI had to fall within the prespecified range 0.8-1.25 of the t-distribution [9, 10].

As measures of FHR detection performance we determined the Success Rate (SR), defined as the proportion of 2-second intervals in which a FHR signal was present; the Percent Agreement (PA), the percent of intervals in which the mean condensed patch-derived FHR was within 10% of that of the diffuse standard array; and the Percent heart rate Equivalence (PE).

For the PE measure, in each 2-second interval we divided the mean FHR obtained from the patch by that from the standard array to create a "FHR ratio" and examined the distribution of the ratios for each patient and for the entire sample. The closer that such distributions cluster around unity, the greater the correspon-

dence between the FHR data from the two electrode systems. The percentage of ratios that fell between the two-sided t-distribution limits 0.8 and 1.25 was the PE. We required that at least 95% of the FHR ratios fell within this interval to demonstrate equivalence. The MHR data from the two devices were also compared and equivalence defined in the same way as for the FHR by using the measures SR, PA and PE.

To assess the concordance of UC detection between the two electrode systems we created a MATLAB program that scanned each patient data set to identify interpretable uterine activity data and the location of contractions [7]. Data were considered interpretable when there was no contraction and a stable well-defined baseline at or above 10% of full scale occurring for at least three minutes in a 10-minute period. A valid individual contraction was defined as a deflection of at least 10% of full scale above an interpretable baseline, lasting between 30 and 120 seconds.

Using an approach analogous to that for heart rate, we assessed the reliability of the uterine activity output from the diffuse and condensed electrode arrays by the PA statistic. Reliability in this sense expresses the frequency with which the patch created an interpretable output in the presence of a simultaneous interpretable signal from the diffuse electrode system. Equivalence was established if the PA distribution fell above the lower limit of a two-sided 95% confidence interval using  $t=2.12$ .

In addition, we calculated the sensitivity of the patch electrode system for detection of individual contractions. This statistic indicates the percent of contractions identified by the diffuse array that were also detected by the patch array. One-way analysis of variance was used to compare measures of performance between labor epochs and among BMI subgroups. Data are presented as mean  $\pm$  standard deviation, unless otherwise stated.

### Results

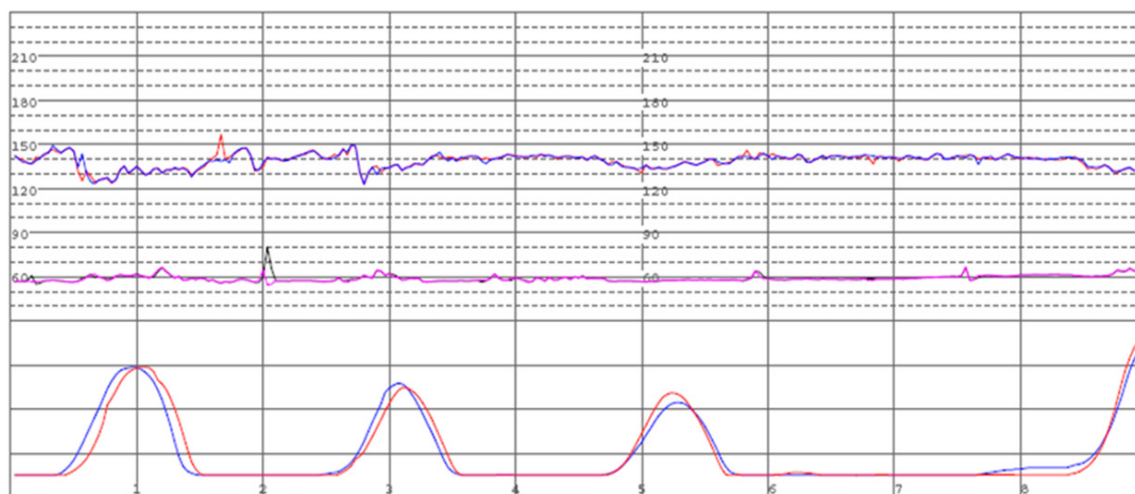
The study patients were  $27.5 \pm 6.5$  years old; gestational age was  $39.9 \pm 0.6$  weeks; and 41% were nulliparas. Their body mass index was  $33.8 \pm 5.8$  kg/m<sup>2</sup>. All babies were delivered in good condition. No patient withdrew from the study because of discomfort from the

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**Table 1.** Comparison of patch electrode to standard electrode array for detection of fetal heart rate and maternal heart rate

	Fetal Heart Rate	Maternal Heart Rate
Percent agreement		
Overall, mean $\pm$ SD (lower 95% CL)	94.7 $\pm$ 4.0 (92.6)	92.8 $\pm$ 5.3 (90.0)
Early labor, mean $\pm$ SD (lower 95% CL)	95.5 $\pm$ 4.6 (93.1)	93.2 $\pm$ 6.3 (90.0)
Late labor, mean $\pm$ SD (lower 95% CL)	93.8 $\pm$ 5.7 (90.8)	92.4 $\pm$ 5.5 (89.5)
Percent equivalence		
Overall, mean $\pm$ SD (95% CL)	98.7 $\pm$ 1.6 (97.9, 99.5)	98.2 $\pm$ 1.9 (97.2, 99.2)
Early labor, mean $\pm$ SD (95% CL)	99.3 $\pm$ 1.0 (98.8, 99.8)	97.9 $\pm$ 2.4 (96.7, 99.2)
Late labor, mean $\pm$ SD (95% CL)	98.2 $\pm$ 2.9 (96.7, 99.6)	98.5 $\pm$ 2.0 (97.4, 99.5)

CL, confidence limits; SD, standard deviation.



**Figure 2.** Typical FHR and UC tracing of the condensed patch electrodes (red) and the standard diffusely arrayed electrodes (blue) demonstrating close correspondence for FHR, MHR and UC detection.

electrodes, and none reported skin irritation from them. The total length of monitoring was 9348 minutes in the first stage and 1000 minutes in the second stage. We found very close correspondence between the data from the two kinds of electrode arrays in almost all of our performance measures (**Table 1; Figure 2**).

The success rate of both the patch and the standard electrode array was high, and nearly identical, for FHR (96.5  $\pm$  4.3% vs. 95.0  $\pm$  5.8%, respectively;  $P=0.879$ ) and MHR (98.8  $\pm$  3.4% vs. 99.9  $\pm$  0.2%;  $P=0.192$ ). The SR of the patch did not differ significantly according to the labor epoch or maternal BMI for either FHR or MHR.

The PA and PE data for maternal and fetal heart rate detection are presented in **Table 1**. The PA indicates how reliably the electrode patch identified the heart rate in comparison to the stan-

dard electrodes. For both FHR and MHR the PA exceeded 90 percent, and fell above the lower limit of a two-sided 95% confidence interval derived for 17 subjects when  $t=2.12$ . (Only the lower confidence limit is relevant in this measurement because the PA cannot exceed 100%). In other words, the reliability of the patch electrode was statistically equivalent to that of the standard array to which it was compared. The overall PA of the patch electrode with the standard array for FHR was 94.7  $\pm$  4.0% and for MHR was 92.8  $\pm$  5.3%. The PA during early labor did not differ from that in later labor for FHR ( $P=0.352$ ) or MHR ( $P=0.701$ ), and the PA for FHR and MHR was not influenced by the subject's BMI (**Table 2**).

The PE (**Table 1**) for FHR and MHR was above 98% and similar in value (98.7  $\pm$  1.6 and 98.2  $\pm$  1.9%, respectively). In each case the PE fell



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**Table 2.** Overall percent agreement and percent equivalence of patch electrode with standard electrode array according to maternal body mass index for fetal and maternal heart rate

	Body Mass Index			P-value
	< 29 kg/m <sup>2</sup> n=5	29-34.9 kg/m <sup>2</sup> n=7	≥ 35 kg/m <sup>2</sup> n=5	
Percent agreement, FHR	95.6 ± 2.8	95.1 ± 4.1	93.2 ± 5.0	0.620
Percent equivalence, FHR	99.2 ± 0.8	98.6 ± 1.7	98.5 ± 2.2	0.771
Percent agreement, MHR	93.0 ± 4.8	92.3 ± 5.3	93.2 ± 7.0	0.959
Percent equivalence, MHR	98.5 ± 1.7	97.6 ± 2.5	98.6 ± 1.2	0.630

FHR, fetal heart rate; MHR, maternal heart rate.

**Table 3.** Comparison of electrode patch to standard electrode array for detection of uterine activity in terms of percent agreement and sensitivity

Percent agreement	
Overall, mean ± SD	98.0 ± 2.8
(lower 95% CL)	(96.6)
Early labor, mean ± SD	98.7 ± 3.6
(lower 95% CL)	(96.9)
Late labor, mean ± SD	97.3 ± 4.8
(lower 95% CL)	(94.8)
Sensitivity	
Overall, mean % ± SD	86.1 ± 8.0
(lower 95%CL)	(81.9)
Early labor, mean % ± SD	82.1 ± 13.9
(lower 95% CL)	(74.9)
Late labor, mean % ± SD	90.3 ± 9.3
(lower 95% CL)	(85.5)

CL, confidence limit; SD, standard deviation.

within the 95% confidence limits for the t-distribution, indicating equivalence of the patch electrode system with the standard diffuse electrode array in the accuracy of FHR and MHR detection.

The PA of the uterine activity from the electrode patch and the standard electrode array was high, averaging 98 percent, and statistically equivalent (**Tables 3** and **4**). The PA was not influenced significantly by whether the parturient was in early or later labor. The PA was slightly and significantly better in the highest BMI group compared to leaner cases ( $P=0.017$ ). The sensitivity of the patch-derived data for detecting individual contractions was overall 86.1%, confirming the equivalence of the performance of the two electrode arrays in detecting individual uterine contractions. However, the sensitivity was lower in early compared to late labor ( $82.1 \pm 13.9$  vs.  $90.3 \pm 9.3\%$ ;

$P=0.052$ ), and the lower 95% CL in early labor (74.9%) fell below the limit of 80% necessary to declare equivalence.

### Discussion

In this study we demonstrated the feasibility of using a simple maternal abdominal electrode patch for intrapartum FHR, UC, and MHR monitoring. In almost all respects the performance of the patch was equivalent to that of a standard array of five single electrodes currently used for transabdominal monitoring in several countries [6, 7]. We attached each electrode system to an identical electronic fetal monitor so as to study the discrete function of the different electrode arrays.

In order for an electrode pair to obtain a reproducible high quality signal from the fetal heart, the electrode dipole's axis must be optimally oriented in relation to the main cardiac vector. Similarly, uterine electromyography requires electrodes ideally oriented to detect myometrial depolarization. In both cases the need to separate the fetal and maternal ECG signals and to minimize competing electrical noise from noncardiac and nonuterine events is of considerable importance. To address these challenges, an electrode grid has been used by several investigators to reliably detect the fetal ECG and the electrohysterogram (EHG), with the number of electrodes ranging from just a few to dozens [2, 3, 11-13].

The FDA-cleared monitor we used as a standard in this study uses five standard ECG electrodes placed on the maternal abdomen at specific assigned locations. While this system has proved useful for clinical monitoring [6-8], it requires close attention during application to ensure that the correct electrodes are attached in their designated positions. To simplify placement and minimize the risk of electrode mislo-

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**Table 4.** Overall percent agreement and sensitivity of patch electrode patch with standard electrode array for uterine activity according to maternal body mass index

	Body Mass Index			P-value
	< 29 kg/m <sup>2</sup> n=5	29-34.9 kg/m <sup>2</sup> n=8	≥ 35 kg/m <sup>2</sup> n=4	
Percent agreement	95.5 ± 2.5	98.6 ± 2.6	99.9 ± 0.24	0.017
Sensitivity	85.7 ± 10.3	86.4 ± 7.0	85.9 ± 9.3	0.990

cation an electrode patch was developed. This links all five electrodes via a short flexible ribbon cable in a standard template. This simplified application obviated the chance of incorrect electrode location.

Even though the electrodes in the template were located more centrally on the abdomen than the comparison standard array, FHR and MHR detection was not degraded. In fact, the two electrode arrays produced statistically equivalent results. Of importance, there was no difference in the performance of the electrode patch for FHR or MHR detection between the two labor epochs studied. During the late first stage and the second stage of labor maternal movement and skeletal muscle activity have the potential to interfere with identification of the ECG and EHG signals detected at the abdominal wall. However in this study, performance of the patch electrode system for FHR and MHR detection, as measured by PA and PE, was not affected by progression into late labor.

The PA for UA was best in the highest BMI group, and sensitivity was unaffected by maternal obesity. The single exception to equivalence of the two electrode techniques was the 8.2% lower sensitivity for uterine contraction detection in early compared to late labor. The cause of this is under investigation, and may well relate to the previously reported [7] high false positive rate of electrohysterography using the diffuse electrode array compared to intrauterine pressure recording during the early portion of labor. The patch electrode's uterine contraction detection capabilities will need to be determined by comparing its performance to that of an intrauterine pressure-recording system.

We demonstrated previously that the accuracy and reliability of the standard electrode array was not affected adversely by maternal obesity [8]. The same can be said of the electrode

patch for heart rate detection, as its relative equivalence with the standard array in this study was not affected adversely by increasing maternal BMI. Our conclusions regarding BMI must, however, be tentative because the number of cases in each BMI group was small.

We have demonstrated that an electrode patch template works well in intrapartum monitoring of FHR, MHR and UC. The performance of the electrode patch was equivalent to that of a standard more diffuse electrode array in almost all respects, and was for the most part unaffected by the period of labor or the mother's BMI, with the exception of a somewhat lower sensitivity for contraction detection in early labor. Using the patch resulted in no demonstrable loss of signal quality. Its use may enhance patient and provider convenience and acceptability, and reduce the chance of improper electrode placement when transabdominal cardiotocography is indicated.

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### Disclosure of conflict of interest

The study was funded by Monica Healthcare, Ltd., which manufactured the monitoring equipment used in the study, and provided it to the study institution. Dr. Cohen has served as a paid consultant to Monica Healthcare Ltd., where Dr. Hayes-Gill is a director and shareholder and Mr. Anyaegbunam has been an employee.

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