CE 2.1 ANCC Contact Hours

Abstract

Purpose: To compare two methods of securing external uterine tocodynamometer and fetal heart rate (FHR) ultrasound monitors to the abdomen.

Study Design and Methods: 100 women were enrolled in a prospective, randomized trial comparing the adhesive patch method to the circumferential belt method for securing electronic fetal monitoring (EFM) devices during labor. Device efficacies were compared by evaluating the EFM time lost due to monitor malpositioning. Investigator-developed nurse and patient questionnaires were used to assess satisfaction with each device.

Results: Data from 94 patients and 21 nurses were analyzed. There was no significant difference in efficacy between the two devices. There was a significant preference for the adhesive patch method in the nurses' assessment of EFM positioning, continuous assessment during epidural, and assessment during labor and birth, and in the patients' assessment of their mobility and comfort. This suggests that the adhesive patch method is equivalent to the circumferential method in its primary purpose (its ability to effectively position the EFM devices) and preferable over the circumferential method in terms of nurse and patient satisfaction.

Clinical Implications: The adhesive patch method of securing fetal-monitoring devices could be welcomed as a suitable alternate to the circumferential belt method during labor.

Key Words: Attitude of health personnel; Equipment design; Fetal monitoring/instrumentation; Patient satisfaction.

Adhesive patch attachment method

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COMPARING METHODS TO SECURE EXTERNAL FETAL-MONITORING DEVICES

Circumferential belt method

Many aspects of patient care during labor are centered on the heart rate tracing data obtained from electronic fetal monitoring (EFM) (Freeman, Garite, Nageotte, & Miller, 2012; Grivell, Alfirevic, Gyte, & Devane, 2012; Troiano, Harvey, & Chez, 2013). Cardiotocography, the graphical representation of the fetal heart rate (FHR) over time as delivered by EFM devices, is used to screen for fetal distress during labor. As current EFM devices rely on the Doppler shift principle and pattern recognition to determine fetal well-being, a poorly placed transducer could lower the accuracy of cardiotocography (Nurani, Chandraharan, Lowe, Ugwumadu, & Arulkumaran, 2012).

The elastic circumferential belt system has been widely accepted for EFM device positioning. However, there have been concerns regarding its positioning ability, its need for frequent readjustments, its difficulty with ambulation, and the discomfort reported by patients (Alfirevic, Devane, & Gyte, 2006; Lawrence, Lewis, Hofmeyr, Dowswell, & Styles, 2009; Selby et al., 2012; Sharma, 2012). The adhesive patch device was developed to address these concerns. A pilot study was conducted in 2011 on 43 patients in order to obtain a baseline assessment of the device's efficacy, to establish variables to examine, and to improve the quality of the study protocol. The pilot study was a randomized controlled trial comparing device adjustment frequency, minutes of EFM signal lost per labor hour, and satisfaction among patients and nurses. Two satisfaction questionnaires containing several 5-point Likert-like rating scales were designed and tested during this pilot study. Adjustment frequency and EFM minutes lost per hour demonstrated no significant difference in signal collection efficacy.

Our purpose in this second phase of the study was to compare the efficacy of the two methods of securing tocodynamometer and EFM ultrasound monitors to the abdomen and evaluate both patient comfort and nurse work burden. Our hypotheses were as follows:

1. Signal time lost would be equal or lower for the adhesive patch group.
2. The number of adjustments would be equal or lower for the adhesive patch method device, and that this adjustment frequency would correlate with nurse staff burden.
3. Nurse Satisfaction scores would be higher among the adhesive patch group than the circumferential belt group.
4. Patient Satisfaction scores would be higher among the adhesive patch group than for the circumferential belt group.

Methods

Sample

Using the EFM control results from the pilot study, a standard deviation of 2 minutes/hour on EFM, a power of 80%, and an alpha of 0.05 the sample size was determined to be 88; therefore, 100 women were enrolled.

We compared two methods of securing external fetal-monitoring devices; devices were similar in achieving continuous assessment of FHR and contraction monitoring.

Women satisfying all of the following eligibility requirements were asked to participate: (1) 18 years or older; (2) on continuous monitoring past 34 weeks gestation; (3) singleton pregnancy; (4) no known allergy to adhesives. Aside from those not meeting the above requirements, any woman meeting one or more of the following criteria was excluded: (1) high-risk/critically ill pregnancy; (2) patient declined consent; (3) BMI over 40; or (4) elective repeat cesarean birth.

Design

In this prospective trial, the 100 women admitted to Labor and Delivery who met inclusion criteria and gave consent were randomized to either an experimental (adhesive patch) or control group (circumferential belt). Envelopes containing study versus control assignments as well as all necessary paperwork were prepared by a researcher, sealed, mixed, and then separated into two piles for bucket randomization. We used bucket randomization by cervical dilation stage to ensure that neither group received a disproportionate amount of stable, early labor patients or unstable, late labor patients. Labor stage was assessed at enrollment, at which time they were assigned to either the early labor (0–5 cm) or late labor (6–10 cm) category. The patient's nurse then selected the topmost envelope from the appropriate pile. A total of 21 nurses participated. Patients were enrolled in the morning and tracked in the study until they delivered or their nurse changed, whichever came first.

Adhesive Patch Patients

Patients assigned to the control group received standard care (circumferential belt). For patients assigned to the adhesive patch attachment group, the nurse or researcher placed the fetal heart monitors on the woman using the two single-sided adhesive anchors and two ribbed elastic straps that make up the adhesive patch device. The adhesive anchors were placed laterally on each side of the patient's abdomen approximately 4 to 6 inches from the umbilicus. The ribbed elastic straps contain notched holes and Velcro on each end that attach to these anchors and stretch across the abdomen between the two anchors. Each elastic strap holds one

transducer in place. The primary difference between the two attachment methods is how and where the straps are fastened; the adhesive patch secures the elastic straps via Velcro on the lateral surfaces of the abdomen, whereas the circumferential belts are wrapped around the back (Figure 1).

During labor, the nurse marked on the Nurse Satisfaction Survey tally sheet each time the monitors had to be readjusted. The same nurse completed the 5-point rating scales on the Nurse Satisfaction Survey form and tallied up the total number of readjustments at the end of his or her shift. The nurse also noted the time of study enrollment and cessation so that an average number of readjustments per hour enrolled could be recorded. At this time the patient was also given a researcher-generated Patient Satisfaction Survey that asked about comfort, ease of movement, and adhesive removal. The patient was able to choose whether she wanted to keep the adhesive patch method on after she and her nurse filled out the appropriate paperwork at shift change; if she chose to keep it on, she did so without being actively monitored in the study.

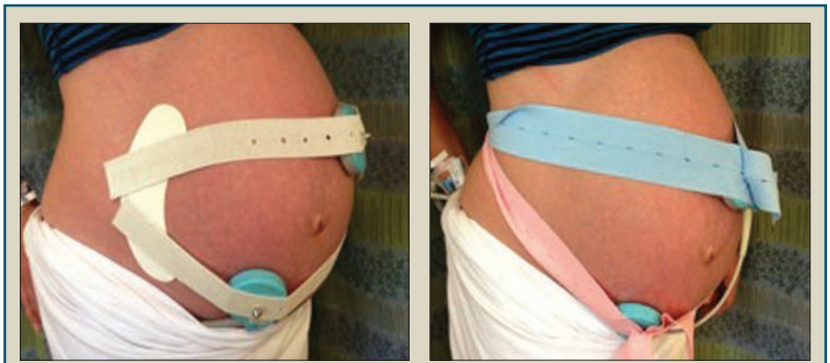
After birth, the FHR tracing strips were reviewed by a researcher, and the average time of signal loss per labor hour was calculated using the times noted by the nurse. The efficacy of each device was assessed by looking at the minutes of lost signal time per labor hour that the patient was tracked in the study. This included scrolling through each patient's FHR monitoring strips and tallying each time the heart rate was lost. The process was standardized so that losses of more than one half-minute "box" on the strip (30 seconds) were counted as a "lost minute," and losses of less than half of one "box" were not counted.

The total number of adjustments recorded by the patient's nurse was tallied and divided by the time the patient was monitored in the study. The survey data were coded and transferred into a spreadsheet.

Results

One hundred patients were enrolled in this study. The data for two subjects were discarded due to not meeting enrollment criteria. Of the remaining 98 subjects, 4 consent forms were either not signed or not retained with the paperwork and so were also discarded. The data for the remaining 94 subjects who were appropriately enrolled and had retained, signed consent forms were analyzed in this study. The continuous data did not follow a normal distribution; therefore, a Mann–Whitney *U* was used as a nonparametric test. Categorical data points were analyzed with a chi-squared test. SPSS and Statistica were used for data analysis.

FIGURE 1. Adhesive Patch Method and Circumferential Method



Adhesive Patch Attachment Method | Circumferential Belt Method

Patient Characteristics

A chi-squared test was used to compare subject characteristics as recorded on the Nurse and Patient Satisfaction Questionnaires (Table 1). These data points were limited in number due to the variability of nurse and patient survey completion. It should be noted that the mean BMIs for the adhesive patch and circumferential belt groups differed significantly (adhesive patch method BMI 30.19 vs. circumferential belt BMI 32.41, $p = 0.032$). Other statistically significant differences were birthing method and patient walking during the study (See Table 1).

Signal Time Lost

The two methods of attaching EFM devices demonstrated no significant difference in signal ("time off monitor"), with a median frequency of 6.47 minutes of monitoring lost per hour for the circumferential belts and 4.72 minutes lost per hour for the adhesive patch device ($p = 0.25$, Figure 2).

Need for Adjustment

Adjustment frequency was used as a measure of nurse burden. There was no significant difference between the two methods in adjustment frequency. The circumferential belt adjustment frequency was 1.08 adjustments per hour and the adhesive patch method device adjustment frequency was 1.05 adjustments per hour ($p = 0.63$).

Nurse Satisfaction

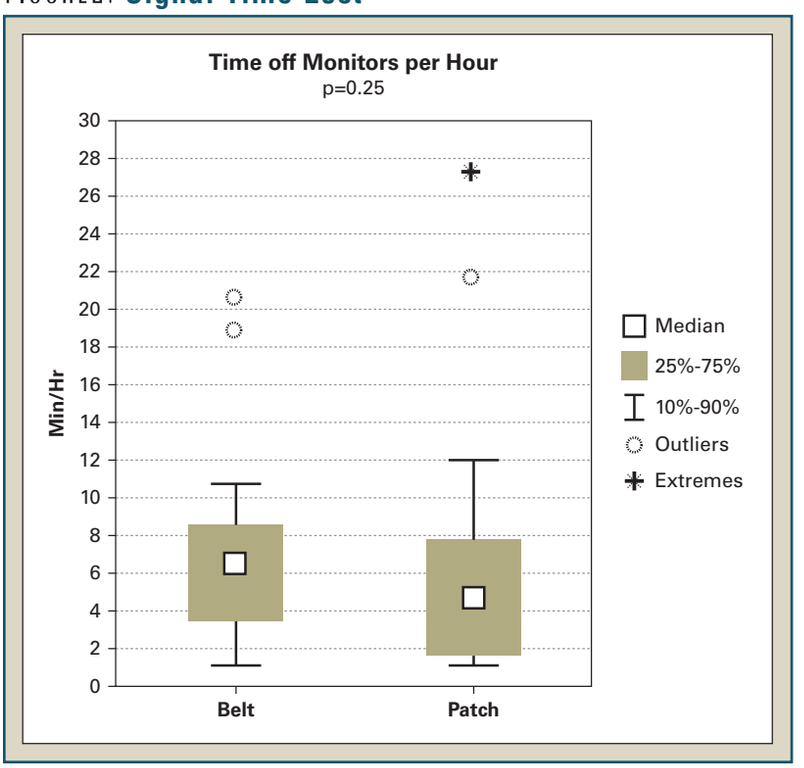
The Nurse Satisfaction questionnaire assessed the device efficacy, patient comfort, and patient mobility. These subjective data demonstrated a significant trend in favor of the adhesive patch method in terms of monitoring accuracy, ease of adjustment, patient comfort, and patient mobility. Comments made by the nurses on the survey forms included suggestions to increase the size of the notched holes on the straps, complaints about adhesive quality during times of excessive sweating, and reports of pain and erythema upon removal. However, analysis of Likert responses to the survey questions about removal experiences demon-

TABLE 1. Descriptive Statistics of Patient Sample (*n* = 94)

Parameter for Mann–Whitney *U*-Test	Circumferential Belt Group (Control)				Adhesive Patch Group (Study)				Mann–Whitney *U* *p*-Value
	n	Mean	Median	SD	*n*	Mean	Median	SD	
Gestational age	46	39w1d	39w6d	7.2w	41	39w2d	39w1d	1.5w	0.741
BMI (kg/m²)	41	32.41	31.58	5.39	48	30.19	28.81	5.40	0.032*
Dilation at enrollment	43	4.05	4.00	2.29	45	3.70	3.00	2.56	0.555
Duration of study monitoring (hrs)	45	5.80	6.00	2.68	48	6.28	6.35	2.96	0.484
Parameter for Chi Square	***n***	**Survey Answer by % of Responders**			***n***	**Survey Answer by % of Responders**			**Fisher's Exact *p*-Value**
Prior birth	40	62.8% nulliparous 37.2% with ≥1 prior			42	55.6% nulliparous 44.4% with ≥1 prior			0.585
Birthing method	28	64.3% vaginal 30.7% C-section			36	88.9% vaginal 11.1% C-section			0.020*
Patient walked during study	37	13.5% yes			44	29.6% yes			0.071*
Patient received an epidural	37	86.5% yes			44	84.1% yes			0.5

n = Total number of survey responders for each question. Not all survey forms were entirely filled out, and some nurses skipped questions because they were not applicable. Each percentage references this *n*.
*Statistically significant difference.

FIGURE 2. Signal Time Lost



strated that the majority of nurses and patients agreed/strongly agreed that removal did not cause irritation.

Patient Satisfaction

Fifty-five percent of adhesive patch attachment patients versus 7% of circumferential belt patients strongly agreed that their device was comfortable. Circumferential belt users disagreed (24%) and strongly disagreed (6%) with the statement that "The device was comfortable." In regard to mobility, 56% of adhesive patch users and 6% of circumferential belt users strongly agreed with the statement "It allowed for ease of movement during the labor process" (Table 2).

Nurse and patient opinions regarding adhesion and adhesive quality are shown in Table 3. The patient survey data demonstrated a significant preference for the adhesive patch method in terms of comfort and mobility. Even when the removal caused pain or irritation, many subjects reported that they "still loved" the adhesive patch

TABLE 2. Nurse and Patient Satisfaction Results

Survey Parameter	Circumferential Belt Group				Adhesive Patch Attachment Group				
	n	Rank Sum	Strongly Agree (%)	Agree (%)	*n*	Rank Sum	Strongly Agree (%)	Agree (%)	Rank Sum Exact *p*-Value
Nurse Survey									
The device was effective in positioning the FHR monitor	34	1103.5	11.8	58.8	42	1822.5	35.7	50.0	0.031*
The device allowed for ease of adjustment of the FHR monitor	31	966.0	12.9	54.8	38	1449.0	31.6	44.7	0.154
We were able to achieve a continuous FHR assessment during the placement of the epidural	26	528.5	7.7	30.8	25	797.5	28.0	52.0	0.005*
We were able to achieve a continuous FHR assessment during the labor and birth	30	765.0	10.0	40.0	34	1315.0	38.2	41.2	0.004*
The device allowed the patient to move comfortably without compromising the heart rate monitoring process	33	966.5	6.1	51.5	38	1589.5	26.3	57.9	0.010*
Patient Survey									
The device was comfortable	34	1103.5	5.9	52.9	44	2159.0	54.6	36.4	<0.001*
Device allowed for ease of movement during the labor process	35	954.5	5.7	60.0	43	2126.5	55.8	37.2	<0.001*

* = statistically significant difference

method because the others were "too tight." When adhesive patch devices fell off due to excessive sweating, some patients requested they be reapplied rather than switching to circumferential belts and indicated so in the comment section of the survey form. Many control patients complained that the circumferential belts were itchy and that the straps felt too tight around the abdomen, whereas adhesive patch patients claimed adhesive was not as itchy and even relieved some of their back pain during labor.

Discussion

This adhesive patch nursing research study stimulated interest among nurses to look for ways to improve patient comfort while maintaining accuracy of external FHR monitoring during labor. Signal and adjustment frequency results suggest that the adhesive patch attachment device is as effective as the circumferential belt in securing monitors during labor. Though the difference was not statistically significant, the trend demonstrated less signal time lost with adhesive attachment device use than with circumferential belt use. The survey data demonstrate a clear preference by nurses and patients for the adhesive patch device over the circumferential belt in terms of comfort and mobility. Overall, the data suggest that the adhesive patch method performs as well as the standard circumferential belt and is favored by both nurses and patients.

Limitations

Allocation concealment was not possible as nurses were aware of which device was the standard of care and which the experimental. Nurses may have already had biases about either attachment method.

Although care was taken to standardize adjustment frequency data, data collection by nurses remained in-

Nurses reported higher satisfaction with the adhesive patch method due to ease of positioning and adjustment. Patients reported higher satisfaction with the adhesive patch method due to increased comfort and mobility.

consistent. Some nurses included marks for strap readjustments during patient repositioning, whereas others only marked the tally sheet when the monitor(s) fell off. In addition, some nurses lost the tally sheets after birth and had to estimate how many adjustments were made. There was also considerable variability in the sample sizes across different data points collected, a fact that was especially prominent in the Nurse Satisfaction Survey data. Also, the nursing comments regarding patch irritation were inconsistent with the scores demonstrating no irritation. There is a possibility that this result underestimates the true incidence of irritation after removal due to nurse inconsistencies in filling out surveys and lack of patient follow-up after birth. There were several nurse surveys that were not completely filled out, a fault possibly attributable to time limitations, nurse training related to the study protocol, nurse shift changes, or misplacement of paperwork at shift change. Some nurses had to be called the next day for their survey input. In addition, some nurses either chose to or were only able to answer some of the questions on the survey.

An issue that was considered during the study design period was the fact that only women in the adhesive patch attachment group were able to directly compare the two devices being studied. A crossover study was considered that included a switch between the devices halfway through the monitoring period. The independent sample design was chosen instead due to the potential nurse burden in switching the devices at certain times, the inherent variability in labor duration across different subjects, and the inability for a research team member to always be present to ensure that the switch protocol was enforced. However, the fact remains that only one group was able to weigh the comparison on the survey form and comment on the difference between the two devices. It is unclear whether the control group

TABLE 3. Nurse and Patient Device Quality

Survey Parameter	*n*	Mean	SD	Strongly Agree (%)	Agree (%)	Undecided (%)	Disagree (%)	Strongly Disagree (%)
Nurse Survey								
The adhesive on lateral attachment effectively adhered to the patient's body during the entire monitoring period	40	3.5	1.4	30.0	37.5	0.0	20.0	12.5
The length of the circumferential belt was adequate for the effective use of the FHR monitor	40	4.2	1.1	37.5	55.0	2.5	2.5	2.5
The removal of the adhesive did not cause the patient significant skin irritation	40	2.9	1.7	17.5	30.0	10.0	17.5	15.0
Patient Survey								
The removal of the adhesive did not cause significant skin irritation	43	3.23	1.4	20.9	30.2	16.3	20.9	7.0

Clinical Nursing Implications

- The adhesive patch attachment device was equivalent in this study to the circumferential belt device in its primary purpose of efficiently holding EFM monitors in place during labor so as to secure accurate fetal and uterine data.
- There were statistically significant differences in favor of the adhesive patch attachment device in terms of monitoring accuracy, ease of adjustment, patient comfort, and patient mobility.
- The majority of subjects agreed or strongly agreed that adhesive patch attachment device removal did not cause irritation.
- In light of the higher nurse and patient satisfaction rates, the adhesive patch attachment device could be welcomed as a suitable alternative to the circumferential belts for use during labor.
- Determine cost effectiveness when product is available to purchase.

participants would have altered their survey scores had they been able to compare the circumferential belts to another device.

Recommendations for Future Research

This project was developed to look at patient comfort and nurse burden with EFM monitors during labor. We encourage study replication to include psychometric testing and refinement of the survey instruments. With regard to the adhesive patch device, future research could include looking at options for different strap lengths, adhesive removal techniques, and patient follow-up to assess overall impressions and lasting thoughts on experiences with adhesive removal. ✣

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www.google.com/patents/US7789836

Cutting Edge Medical Device Consulting—Pumpkin Patch Monitoring System.

http://www.pumpkinpatchkit.com

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