ORIGINAL ARTICLE

Comparison of a Newly-Designed and Conventional Strap Used for Cardiotocograph Recoding in Preterm Labor

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Objective: 1) To compare the outcomes of fetal heart rate monitoring using a newly-designed elastic cardiotocograph (CTG) bandage and a conventional ultrasound transducer bandage, and 2) to evaluate the satisfaction of the participants and labor staff using the newly-designed elastic CTG bandage compared to those using the conventional ultrasound transducer bandage.

Materials and Methods: The researchers invented the newly-designed elastic CTG bandage and conducted a quasi-experimental study with thirty-four pregnant women gestational age under 37 weeks using both the newly-designed elastic CTG bandage and the conventional ultrasound transducers. A comparison of the outcomes of fetal heart rate monitoring between the two methods was done using Wilcoxon signed-rank test. Then, two instruments (the CTG band satisfaction questionnaire for women, and the CTG band satisfaction questionnaire and fetal heart rate graph absence record for the labor staff) were administered to the respective participants. They were adapted for the study based on the diffusion of innovation model, which postulated that an innovation was generally adopted when five main factors (compatibility, complexity, trial-ability, observability, and relative advantage) were met.

Results: The median score of signals of fetal heart rate loss when solely using the newly-designed elastic CTG bandage was only 1.0 times and the conventional ultrasound transducer bandage was 3.0 times. There was a significant difference ($p<0.001$). Most members of the labor staff were satisfied with the suitability of the newly-designed elastic CTG bandage.

Conclusion: The newly-designed elastic CTG bandage improved the quality of fetal heart rate assessment compared to the conventional ultrasound transducer bandage, resulting in the reduction of errors during examinations and the labor staff's workloads while providing the ability to continuously assess the fetal heart rate.

Keywords: Cardiotocograph; Fetal heart rate; Intrapartum fetal monitoring

Received 15 November 2022 | Revised 10 April 2023 | Accepted 11 April 2023

J Med Assoc Thai 2023;106(5):549-55

Website: http://www.jmatonline.com

Preterm labor is a major public health issue and a leading cause of morbidity and mortality[1]. In the intrapartum period, complications during labor account for over a third of perinatal mortality and approximately one in three neonatal deaths are due to preterm birth complications[2,3]. The effective of surveillance fetal status during hospital admissions could reduce the perinatal mortality rate[2]. Fetal heart rate (FHR) monitoring is one method of checking a fetus's well-being[2]. A cardiotocograph (CTG) is an electronic instrument that continuously monitors the FHR and measures uterine contractions simultaneously for approximately 20 to 30 minutes[3]. The results are presented as a graph that shows the relationship between the FHR and uterine contractions[4]. One limitation of this process is the pregnant women must remain in the supine position during monitoring to interpret the CTG consistently[5]. Being supine causes the gravid uterus to compress the inferior vena cava which leads to diminished central venous return, which leads to symptoms of supine hypotension, such as pallor, dizziness, low blood pressure, sweating, and nausea. These symptoms can be relieved by changing the maternal position[6]. Thus, pregnant women who are unable to tolerate lying supine generally move into another position, leading to FHR signal loss during CTG monitoring. A study demonstrated that there was FHR signal loss during CTG monitoring in approximately 20% of term pregnancies. However, this signal loss could

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How to cite this article:

Disorntatiwat P, Liblub S, Prohm S, Chittacharoen A. Comparison of a Newly-Designed and Conventional Strap Used for Cardiotocograph Recoding in Preterm Labor. J Med Assoc Thai 2023;106:549-55.

DOI: 10.35755/jmedassocthai.2023.05.13850

be more frequent in preterm pregnancy due to the smaller size of the uterus[7].

The labor staff plays an important role in CTG monitoring of pregnant women and observing the graph that records the results of the examination. If there were abnormal signals, finding their cause, reporting the results to the physician, and promptly initiating treatment is a matter of great urgency[5]. Carefully avoiding the ultrasound transducer bandage head slip out of the correct position, which causes erroneous reporting, is necessary to prevent the signal loss. This is especially true for women with premature labor, who need continuous FHR monitoring. Labor staff must help pregnant women when they are uncomfortable and need to change their positions during CTG monitoring. Thus, when there are frequent signal losses during CTG monitoring, it increases the workload for the labor staff, as they have to constantly monitor the CTG's placement[3].

The researchers, therefore, created a newly-designed elastic CTG bandage to help holding the ultrasound transducer bandage in place with the aim of helping women in preterm labor to be more comfortable during CTG monitoring while being able to continuously assess the FHR to reduce errors while using the CTG. The present study was designed to evaluate whether the use of the newly-designed CTG band applied with an ultrasound transducer bandage improved FHR records, and the satisfaction of the women and labor staff with the newly-designed band during CTG monitoring.

The present study aimed to compare: 1) the outcomes of FHR monitoring using the newly-designed elastic CTG bandage and the conventional ultrasound transducer bandage, and 2) to evaluate the satisfaction of the pregnant women and the labor staff using the newly-designed elastic CTG bandage compared to those using a conventional ultrasound transducer bandage. The primary outcome was the number of failures to record the FHR, and the secondary outcome was the satisfaction of the pregnant women and the labor staff. The definition of labor staff was nurse-midwives for the purposes of the present study.

Materials and Methods

The researchers invented the newly-designed elastic CTG bandage which was designed and made using of a 10×90 cm piece of sheer elastic stretch fabric with three velcro straps on each end to allow adjustment to fit the pregnant women's abdomen properly. The newly-designed elastic CTG bandage

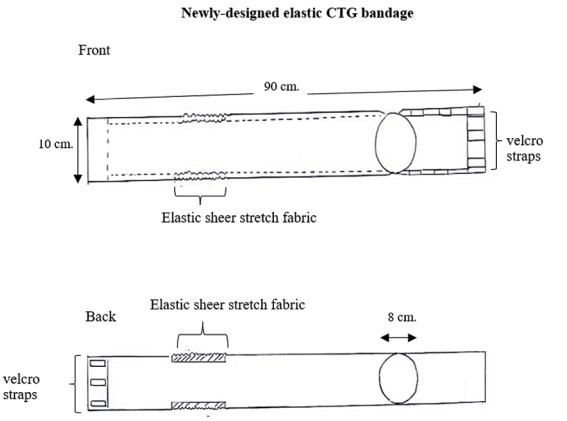

Figure 1. Design of the newly-designed elastic CTG bandage.

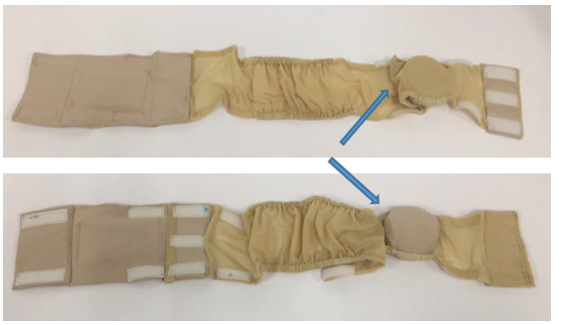

Figure 2. The hard, round, plastic disc to increase pressure on the ultrasound transducer head.

had a hard, round, eight-centimeter diameter plastic disc covered with fabric to increase the pressure on the ultrasound transducer head, as shown in Figure 1 and 2.

The present study was a quasi-experimental study conducted in the labor room at Ramathibodi Hospital in Bangkok, Thailand. The participants in the present study were pregnant women with a fetal gestational age of less than 37 weeks admitted to the labor room between April 2021 and February 2022. Women with multiple pregnancies were excluded. The sample sizes were determined using Cohen's formula[8]. The effect size was estimated based on a pilot study by calculating Cohen's d with the formula of the difference between the sample means/the standard deviation (SD). Cohen's d=0.65, Power of the test=0.80, and α (one-tailed)=0.05 were utilized to calculate the sample sizes. It was determined that 34 pregnant women and 19 labor staff would be required.

The intervention could be conveniently administered to pregnant women by the labor staff. The pregnant women would receive CTG monitoring using the conventional ultrasound transducer bandage

Figure 3. Applying the newly-designed elastic CTG bandage.

for 20 minutes. This was followed by using the newly-designed elastic CTG bandage on top of the ultrasound transducer bandage for 20 minutes, being sure to place the hard, round plastic disc in the newly-designed elastic CTG bandage on top of the ultrasound transducer head, wraped the stretchy fabric around the woman's abdomen, and used the velcro strips to adjust the size to properly fit the pregnant woman's abdomen (Figure 3). The labor staff observed and recorded the number of failures to record the FHR. The newly-designed elastic CTG bandage's satisfaction levels were measured by both the pregnant women and the labor staff.

The instruments used in the present study were: 1) a demographic data form for both sample groups, 2) the CTG band satisfaction questionnaire for women, and 3) the CTG band satisfaction questionnaire and the FHR graph absence record for the labor staff. Both newly-designed elastic CTG bandage satisfaction questionnaires were developed by the researchers and were adapted based on the diffusion of innovation model, which demonstrated that innovations were generally adopted when five main factors, i.e., compatibility, complexity, trialability, observability, and relative advantage, were met[9]. The questionnaire's four answers ranged from very satisfied to very unsatisfied. The instruments' face and content validity were evaluated through consultation with a panel of three experts on maternal-newborn nursing and midwifery researchers of the Ramathibodi School of Nursing, Mahidol University, Thailand.

All data analyses were performed using the IBM SPSS Statistics, version 27.0.1.0 (IBM Corp., Armonk, NY, USA). Data were expressed as median and interquartile range (Q1, Q3) of the frequency of signal losses. The median of the two methods were evaluated for significance using Wilcoxon signed-rank test. A p-value of less than 0.05 was considered significant.

Table 1. Characteristics of the pregnant women (n=34) consist of age, gestational age, gravidity, parity, history of abortion, pre-pregnancy BMI, and antenatal complications

Demographic information	Data
Age (years); mean±SD	31.44±6.8
Gestation age; mean±SD	35.72±3.59
Pregnancy parity; n (%)	
Primigravida	18 (52.9)
Multigravida	16 (47.1)
History of abortion; n (%)	
No	28 (82.4)
Yes	6 (17.6)
Pre-pregnancy BMI; mean±SD	28.43±4.83
Complication during pregnancy; n (%)	
No complication	15 (44.1)
Complication	19 (55.9)
Gestational diabetes mellitus	7 (36.8)
Preterm Premature rupture of membranes	6 (31.6)
Gestational hypertension	1 (5.3)
Placenta previa	4 (21.1)
Incompetent cervix	1 (5.3)

BMI=body mass index; SD=standard deviation

Before collecting data, investigators submitted the study to the Committee on Human Subjects of the Faculty of Medicine Ramathibodi Hospital, Mahidol University for approval (COA. MURA2021/362). Data collection began after the study was approved. The present study lasted about one year and six months, included the process of designing the elastic CTG bandage, the ethical application process, the data collection, and the data analyses.

Results

A total of 34 pregnant women with a mean age of 31.44 years (SD 6.81) participated in the present study. The mean gestational age of the women at the time they completed the questionnaire was 35.72 weeks (SD 3.59). Over half of all respondents, 52.9%, were primigravida, while 47.1% of the respondents reported having had one birth before their current pregnancy (multigravida), and 17.6% of the participants had a history of spontaneous or induced abortion. The participants had a mean BMI of 28.43 kg/m² (SD 4.83) and 44.1% had no complications during pregnancy, although some had experienced gestational diabetes mellitus (36.8%), premature rupture of membranes (31.6%), or placenta

Table 2. Outcomes of number of heart rate signal losses comparison between two methods

The absence of fetal heart rate signal	n	Min-max	Median	IQR (Q1, Q3)	Z	p-value
Newly-designed elastic CTG bandage	34	0 to 4	1.0	3.5 (1.75, 5.25)	−4.258	<0.001
Conventional Ultrasound transducer bandage	34	0 to 12	3.0	1.0 (0.0, 2.0)	5.16	

CTG=cardiotocograph; IQR= interquartile range

Table 3. Outcomes of labor staff satisfaction related to compatibility, complexity, trial-ability, observability, and relative advantage

Satisfaction	Little; n (%)	Moderate; n (%)	Very satisfy; n (%)	Most satisfy; n (%)
Compatibility				
Design		7 (36.8)	11 (57.9)	1 (5.3)
Size and length	1 (5.3)	7 (36.8)	8 (42.1)	3 (15.8)
Beauty/appearance	1 (5.3)	9 (47.7)	9 (47.7)	-
Fabric used		4 (21.1)	13 (68.4)	2 (10.5)
Complexity				
Easy-to-use		4 (21.1)	12 (63.2)	3 (15.8)
Non slippage		2 (10.5)	13 (68.4)	4 (21.1)
Easy to disassemble		6 (31.6)	9 (47.4)	4 (21.1)
Easy to clean	2 (10.5)	5 (26.3)	10 (52.6)	2 (10.5)
Trial-ability				
Accuracy of FHS detection during examination		2 (10.5)	14 (73.7)	3 (15.8)
Lack of signal loss/interruption		2 (10.5)	13 (68.4)	4 (21.1)
Placing the device on pregnant women's abdomens		4 (21.1)	13 (68.4)	2 (10.5)
Observability				
Satisfaction with the newly-designed elastic CTG bandage score		5 (26.3)	12 (63.2)	2 (10.5)
Relative advantage				
Satisfaction score for using the newly-designed elastic CTG bandage compared to only using a conventional ultrasound transducer bandage		5 (26.3)	13 (68.4)	1 (5.3)

FHS=fetal heart sound; CTG=cardiotocograph

previa (21.1%). The demographic data were shown in Table 1.

The number of FHR signal absences by using newly-designed elastic CTG bandage and the conventional ultrasound transducer bandage was tested for normality distribution using the Shapiro-Wilk. There were not normally distributed. So, Wilcoxon signed-rank test was used to test statistically differences. The number of FHR signal absences using the conventional ultrasound transducer bandage had a median score of 3.0 occurrences with 0 to 12 occurrences greater, compared to a median of 1.0 occurrences with 0 to 4 occurrences when using the newly-designed elastic CTG bandage with the ultrasound bandage. The results of Wilcoxon signed-rank test showed that the number of fetal heart signal absences between the two methods was statistically significantly different ($p<0.001$), as presented in Table 2.

There were no significant differences in the pregnant women's satisfaction regarding feeling comfortable when using the conventional ultrasound transducer bandage or the newly-designed elastic CTG bandage. The satisfaction rating for comfort when using the conventional ultrasound transducer bandage had a mean score of 3.68 (SD 0.77), while using the newly-designed elastic CTG bandage had a mean score of 3.76 (SD 0.74). However, having a sensation of tightness when using only the conventional ultrasound transducer bandage (mean 3.50, SD 1.05) received a higher score than when using the newly-designed elastic CTG bandage (mean 3.26, SD 1.16).

A total of 19 labor staff ranging in age from 23 to 56 years with a mean age of 35.72 years (SD 11.0) and having between 1 and 34 years of work experience (SD 10.75) participated in the present study. The majority of the labor staff were satisfied with the suitability of the newly-designed elastic CTG bandage (design 57.9%, size and length 42.1%, and fabric used 68.4%). Additionally, almost half of the labor staff were satisfied with the appearance of

the band (47.4%) and reported that they were very satisfied with the easy-to-use features [non-slippage (63.2%), ease of disassembly (68.4%), and the ease of cleaning (52.6%)]. Regarding the trial-ability, most of the labor staff reported they were very satisfied with the accuracy of fetal heart sound (FHS) detection during the examination (73.7%), lack of signal loss/interruption (68.4%), and with the process of placing the newly-designed elastic CTG bandage on the pregnant women's abdomens (68.4%). With regard to observability while using the CTG band, 63.2% of the labor staff reported they were very satisfied, which was similar to their overall satisfaction with using the newly-designed elastic CTG bandage (Table 3).

Discussion

The development of innovations in nursing is a new concept in the nursing process for developing, improving, and adapting products or procedures to significantly benefit outcomes[10]. Results of the present study showed the clinical usefulness of the newly-designed elastic CTG bandage in assisting with the assessment of the FHR. The absence of the FHR on the graph when using the newly-designed elastic CTG bandage was statistically significantly less than when using only a conventional bandage with the ultrasound transducer. This significant reduction in the signal loss while using the newly-designed elastic CTG bandage helps continuously assess the FHR and prevent errors. The performance of the newly-designed elastic CTG bandage allows early identification of FHR changes associated with hypoxia and, subsequently, allows early intervention, which leads to improved outcomes[11].

Similar to the another innovative technologies, such as the use of wireless fetal monitoring, which represents an improvement in the quality of the FHR tracings[12,13], the newly-designed elastic CTG bandage was reported to reduce signal loss, which was clearly displayed on the FHR graphs, meaning more consistent and accurate FHR information provided for assessment. This is because the newly-designed elastic CTG bandage can fit well with the ultrasound transducer head and the flexibility of the stretch fabric helps the newly-designed elastic CTG bandage attach to the ultrasound transducer bandage more securely. The newly-designed elastic CTG bandage seemed to be a non-technological innovation that has the potential to produce a significant improvement in the quality of fetal wellbeing assessment.

The current study's findings resonate with the previous studies showing that innovations can help solve problems or enhance services that meet patient needs, resulting in a more positive outcome for patients and health care providers[10]. Participants valued the newly-designed elastic CTG bandage and felt satisfied and comfortable with it. This is because the patients were not restricted by having to lying still and only being allowed to sleep on their back, but were able to move around or lie on their sides during the monitoring. Although, there is another current innovation (wireless fetal monitoring) that helps to improve signal quality and has been reported to improve women's mobility during monitoring[12,13], it is a fact that the alternative innovation is currently widely available only in high-resource settings, such as developed countries, and is still unavailable in lower resource settings[13]. With its low-cost design and easy-to-use features, the newly-designed elastic CTG bandage could overcome resource availability challenges while satisfying the needs of patients.

Most of the labor staff was very satisfied with the trial-ability, explaining that the newly-designed elastic CTG bandage helped to ensure the accuracy and consistency of FHS detection during the monitoring and prevented signal loss. Additionally, the newly-designed elastic CTG bandage helped to reduce the labor staff's workload because they did not have to hold the head of ultrasound transducer in place manually all the time to prevent the transducer from slipping out of position during the monitoring. This means that they could provide more effective care for the pregnant women. For these reasons, the labor staff was very satisfied with the newly-designed elastic CTG bandage and requested to continue using them after the completion of the study. This was relevant to observability in the innovation model, which is related the results of an innovation being visible to others, leading to its adoption being more likely[9,10,14].

In respect to the suitability of the equipment, the gestational ages of the participants were between 24 and 36 weeks, leading to the participants having different abdominal sizes. Therefore, the newly-designed elastic CTG bandage was designed to be adjustable, using stretch fabric and velcro attached to the ends of the band, so that it could be adjusted for different gestational belly sizes. Although there were velcro strips attached to the ends of the newly-designed elastic CTG bandage, it was still unable to be tightened enough for pregnant women who had a small belly size, resulting in the need to tighten the band with clips. Labor staff, therefore, suggested creating the CTG bands in different sizes so they

could choose a suitable size according to the pregnant woman's belly size. Additionally, the present study reports showed that the velcro fastenings allowed the strap to adjusted and removed easily.

However, cleaning the CTG after each use with a pregnant woman is required and the labor staff reported moderate scores with regard to this aspect. Although cleaning the newly-designed CTG bandage is relatively simple, they would prefer it to be single-use, so there would be no need to clean it. This is something that needs to be considered in the future development of the newly-designed elastic CTG bandage.

The present research, however, is subject to several limitations. The first is its nonrandom design, which means that confounding factors were not controlled for and might limit the inferences that can be made based on the research results. The second limitation concerning the present study is that it was limited to only preterm pregnancies, which may make it difficult to generalize specific findings to other groups in different stages of pregnancy. Since the present study did not evaluate full-term pregnancies, a future study should investigate whether differences in gestational ages, including full-term pregnancies influence the study's outcomes.

Conclusion

The development of innovations in labor care is a new concept in the process of developing, improving, and adapting products or procedures to significantly improve outcomes, reduce time consumption, lower workloads, and respond directly to patient needs. The newly-designed elastic CTG bandage contributes to more efficient FHR assessment by reducing the frequency of the loss of FHR signal compared to using a conventional ultrasound transducer bandage by itself. This results in a reduction in errors during examinations and the labor staff's workload, and improves the ability to continuously assess the FHR.

What is already known on this topic?

The CTG is widely used for continuously monitoring the FHR and measuring uterine contractions simultaneously; however, signal loss during FHR monitoring can occur due to the pregnant women change positions, making it challenging to interpret the CTG's results.

What this study adds?

Compared to conventional ultrasound transducer bandages, the newly-designed elastic CTG bandage contributes to more efficient FHR assessment by reducing the frequency of FHR signal losses, resulting in a reduction in errors during the examinations and enabling more continuous FHR monitoring.

Acknowledgement

The authors would like to gratefully thank the Faculty of Medicine, Ramathibodi Hospital, Mahidol University for their support grant and all of the participants who took part in the present study.

Conflicts of interest

The authors declare no conflict of interest.

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