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The effect of wirelessly-enabled antepartum maternal-fetal monitoring on patient comfort, labor, and obstetric-neonatal outcomes: A prospective cohort study

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The study was approved by ethics committee of Amasya University (Date: July 8, 2021, Number: 122).
All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

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No conflict of interest was declared by the authors.

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Abstract

Background/Aim: More than half of perinatal deaths result from stillbirth, with one-third transpiring during the intrapartum period. Therefore, antepartum maternal-fetal monitoring is crucial. This study aims to evaluate the impact of wireless-enabled antepartum maternal-fetal monitoring during labor on enhancing patient comfort, labor duration, and obstetric-neonatal outcomes.

Methods: This study employed a prospective cohort methodology. From August 1st, 2021 to August 12th, 2023, 95 pregnant women who initiated active labor were followed using wireless-enabled antepartum maternal-fetal monitoring, and 95 women who used standard cardiotocography during labor. The study included pregnant women who were at least 37 weeks pregnant, had a dilation of 3–4 cm and 50% effacement, no ruptured membrane, and no risky pregnancy conditions (e.g., preeclampsia and HELLP syndrome), and did not use induction methods (e.g., oxytocin). Women who exhibited dilation and effacement beyond these parameters were not included in the study, but those with less were included when they reached these criteria. We compared demographic characteristics, labor duration, movement limitations due to cardiotocography, feelings of discomfort from the probe (assessed using a visual analog scale), and obstetric-neonatal outcomes between the two groups.

Results: The groups were homogeneous in terms of demographic characteristics ($P>0.05$). The average systolic blood pressure, measured every 2 h during childbirth, was higher in the control group ($P<0.001$). The visual analog scale value associated with continuous wear of the cardiotocography probe and movement restrictions was higher in the control group ($P<0.001$). Despite a significant difference in birth weeks between the groups ($P=0.043$), there was no significant difference in birth weights ($P=0.373$). The duration of labor was shorter in the study group ($P=0.011$). There was no significant difference in obstetric and neonatal outcomes ($P>0.05$).

Conclusion: Wirelessly-enabled antepartum maternal-fetal monitoring provides greater patient comfort and has a positive impact on labor duration.

Keywords: wirelessly-enabled antepartum maternal-fetal monitoring, patient comfort, labor duration, obstetric and neonatal outcomes

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Introduction

More than 6.3 million perinatal deaths occur annually worldwide. Over 60% of these entail deaths in the womb, with a third of them resulting from asphyxia in the intrapartum period [1]. The prevalence of such incidents is particularly higher in developing countries [2]. Because of this, antenatal surveillance is fundamentally important. Newly developed maternal-fetal monitoring devices, enhanced by wireless technology, have been introduced to help with antenatal monitoring, particularly in remote areas. In areas where maternal-fetal monitoring proves difficult, such devices usher ease for patients and ensure constant fetal monitoring.

Cardiotocography devices enable external monitoring of the fetus during non-stress testing, contraction stress testing, and labor. Studies have demonstrated that devices leveraging wireless, remote prototype technology can be effectively employed in external fetal monitoring [3]. The reliance on standard cardiotocographs to be used and interpreted by a specialized healthcare team can create strain during prenatal follow-up. Utilizing wireless devices personally also mitigates this pressure. This offers considerable benefits for patients with gestational hypertensive illnesses and gestational diabetes, or those with high-risk pregnancies. Its ease of use is also advantageous [4,5]. Some believe it could even decrease maternal and fetal morbidity and mortality associated with pregnancy complications [6].

During active labor, the fetus needs to be connected to cardiotocographs for regular monitoring. In high-risk pregnancies, this monitoring becomes continuous, necessitating the patient to remain bedridden. The constant requirement to lie down and limited mobility can make an already challenging labor process even more difficult. Wireless devices remove this restriction on patients' movements, allowing them the freedom to move as they wish, and studies have shown this to increase patient compliance [3].

Although the impact on fetal-maternal outcomes is generally considered positive, there are limited studies on this topic. Similarly, minimal research has been conducted to evaluate its effect on labor duration. This study was designed to assess patient discomfort related to the use of fetal monitors and restricted movement during labor, as well as to gauge the devices' influence on the length of labor and their implications for obstetric-neonatal outcomes.

This study was designed to assess the emotional discomfort associated with the attachment of cardiotocography probes and the resulting immobility in patients during labor. It also aimed to analyze the effects of these devices on labor duration and obstetric-neonatal outcomes.

Materials and methods

The study received approval from the ethics committee of Amasya University (Date: July 8, 2021, Number: 122) and was conducted following the principles of the Helsinki Declaration.

This study is a prospective cohort study. We included nulliparous and multiparous pregnant women aged between 19 and 40 years, whose active labor commenced between August 1st, 2021, and August 12th, 2023, and was beyond 37 weeks. The study aimed to evaluate the effect on labor duration, hence, it included pregnant women with 3–4 cm dilation and 50% or more effacement, irrespective of the status of the amniotic membrane.

Patients less dilated (less than 3–4 cm) or less effaced (less than 50%), who reached this stage without membrane rupture, were also included. However, those with ruptured membranes were excluded from the study. Individuals whose initial evaluation surpassed this cervical dilation and effacement were not considered for the study.

Additionally, we did not include patients who underwent labor induction procedures (e.g., with oxytocin and prostaglandin E2). Only patients with spontaneous labor progression were incorporated into the study.

To avoid impact on obstetric and neonatal outcomes, patients aged under 19 years or over 40 years, those diagnosed with hypertensive disease of pregnancy, diabetes history, preterm labor, intrauterine growth retardation, fetal anomalies, severe hyperemesis gravidarum, thrombophilia, impending abortion, hepatic, renal or autoimmune diseases, and those with a contraindication for normal vaginal birth (e.g., breech situs, large fetus) were excluded from the study. Pregnant women fulfilling these criteria were informed about the study and provided their consent. They were assigned to two groups based on their order of arrival. The first 95 patients made up the study group and were monitored with wirelessly-enabled antepartum maternal-fetal technology throughout labor. The following 95 patients were followed using standard cardiotocography. The patient's blood pressure was checked every 2 h, and vaginal examinations were also performed bi-hourly. Cardiotocography follow-up was maintained throughout labor. Routine hemogram, biochemistry, and full urinalysis were requested for patients. Pregnant women exhibiting abnormal values such as hemolysis, elevated liver enzymes, low platelets (indicative of HELLP syndrome), and preeclampsia were excluded from the study.

In the study, a Luckcome DS 2013 device was employed for standard cardiotocography, and a HwatimeT10 maternal/fetal integrated wireless monitor device (Product Code: 67402-K3493) was utilized.

The demographic characteristics of both groups (age, height, weight, body mass index [BMI], parity, obstetric history, known diseases, previous surgeries) were recorded. The initial vaginal examination, as well as subsequent examinations conducted every 2 h, were noted. Blood pressure measurements were also taken every 2 h. Other recorded data included the timing of the first vaginal examination, the time of birth, the week of gestation, the type of birth, the baby's weight, indications for a cesarean section, 1st and 5th Apgar scores of the baby, and whether the baby required intensive care. Half an hour after birth, the discomfort experienced by the patient due to the attachment of the cardiotocography probe and mobility restrictions related to the device was evaluated using the visual analog scale (VAS). The VAS is a scale that extends 10 cm, with values ranging from 0 to 10; with zero representing no pain and 10 indicating extreme pain [7].

Power analysis

G*Power version 3.1.9.7 was used to determine the sample size for this study. Calculations factored in Cohen's 1988 recommendation for medium or small effect size (medium effect d=0.5; small effect d=0.2) [8]. Accordingly, it was derived that the two independent groups' difference analysis necessitates a reach of 190 persons to maintain a medium effect size, 80% confidence interval, and 5% margin of error (study group 95, control group 95) [9]. A posthoc power analysis conducted after the study confirmed that the calculated power was achieved with the sample size of 190 individuals (1-β=0.80; Critical t=1.97, Df=188).

Statistical analysis

All statistical analyses were conducted using the SPSS software package (v. 23.0). We evaluated compliance with the normal distribution using Levene's test. For intergroup comparisons, we employed the Mann-Whitney U test and the independent sample t-test for variables that were non-normally and normally distributed, respectively. The Chi-square test was used to analyze the relationships between categorical variables. It was predetermined that $P<0.05$ would be considered statistically significant.

Results

The study group consisted of pregnant women monitored using wirelessly-enabled antepartum maternal-fetal monitoring (n=95), while those who were followed using standard cardiotocography made up the control group (n=95). There was no significant difference between the two groups in terms of demographic characteristics such as age, height, weight, BMI, parity, obstetric history, known disease, and previous surgery ($P>0.05$) (Table 1).

Table 1: Comparison of demographic characteristics of the groups.

		Study group n=95	Control group n:95	P-value
		Mean (SD)	Mean (SD)	
Age (year)		27.49 (4.94)	27.69 (4.88)	0.634
Weight (kg)		76.86 (11.08)	74.64 (10.54)	0.159
Height (cm)		162.16 (4.97)	162.37 (5.45)	0.761
BMI (kg/m2)		29.19 (3.78)	28.31 (3.79)	0.118
		n (%)	n (%)	
Parity	Nulliparity	34 (35.8%)	33 (43.7%)	0.879
	Multiparity	61 (64.2%)	62 (65.3%)	
Education	Primary school	9 (9.5%)	13 (13.7%)	0.288
	Middle school	14 (14.7%)	8 (8.4%)	
	High school	42 (44.2%)	36 (37.9%)	
	University	30 (31.6%)	38 (40.0%)	
Previous surgery	Yes	6 (6.3%)	8 (8.4%)	0.579
	No	89 (93.7%)	87 (91.6%)	
Chronic disease	Yes	2 (2.1%)	4 (4.2%)	0.407
	No	93 (97.9%)	91 (95.8%)	

P-values were calculated with the independent t-test (maternal weight), Mann-Whitney U test, and Chi-Square Test (Parity, education, previous surgery, chronic disease).

The average blood pressure, measured every 2 h, was taken. The systolic blood pressure was higher in the control group ($P<0.001$).

There was no difference in terms of cervical dilatation and effacement in the vaginal examinations of the patients ($P=1.000$ and $P=0.134$; respectively) (Table 2).

The duration of labor was shorter in the study group compared to the control group ($P=0.011$) (Table 2).

The discomfort VAS values from the cardiotocography probe and the movement limitation for the patient were higher in the control group ($P<0.001$ and $P<0.001$, respectively) (Table 2).

Table 2: Comparison of the groups' average blood pressures, blood sugars, cervical examinations during hospitalization, duration of labor, and feeling uncomfortable with the NST probe inserted during labor and restriction of movement during labor.

	Study group n: 95	Control group n: 95	P-value
	Mean (SD)	Mean (SD)	
Systolic blood pressure (mm/Hg)	101.79 (10.91)	110.63 (8.96)	<0.001
Diastolic blood pressure (mm/Hg)	70.11 (7.64)	72.11 (8.86)	0.069
Cervical dilatation during hospitalization (cm)	4.00 (0.77)	4.00 (0. 72)	1.00
Cervical effacement during hospitalization (%)	61.47 (11.57)	58.95 (10.56)	0.134
Duration of labor (hour)	8.27 (1.86)	8.95 (1.90)	0.011
Feeling uncomfortable with the NST probe inserted during labor	2.61 (1.05)	9.14 (1.19)	<0.001
Restriction of movement during labor	3.14 (1.19)	9.18 (1.18)	<0.001
Serum glucose (mg/dl)	92.69 (18.74)	93.57 (15.56)	0.743

P-values were calculated with the independent t-test (maternal and infant weight), Mann-Whitney U test, and Chi-Square Test (Parity, education, previous surgery, chronic disease, delivery type, indications of cesarean, neonatal intensive care needs)

In comparing the obstetric and neonatal results of both groups, only the birth week was lower in the study group ($P=0.043$). No significant differences were observed in other results such as delivery type, indications of cesarean, infant weight, 1st-minute Apgar scores, 5th-minute Apgar scores, and neonatal intensive care needs ($P>0.05$) (Table 3).

Table 3: The results of obstetric and neonatal outcomes.

		Study group n: 95	Control group n: 95	P-value
		n (%)	n (%)	
Delivery type	Vaginal birth	84 (88.4%)	85 (89.5%)	0.817
	Cesarean	11 (11.6%)	10 (10.5%)	
Indications of cesarean	Vaginal birth	84 (88.4%)	85 (89.5%)	
	Fetal distress	6 (6.3%)	6 (6.3%)	
	Cephalopelvic disproportion	5 (5.3%)	3 (3.1%)	
	Prolonged action	0 (0.0%)	1 (1.1%)	
Neonatal intensive care needs	Yes	8 (8.4%)	15 (15.8%)	0.120
	No	87 (91.6%)	80 (84.2%)	
		Mean (SD)	Mean (SD)	
Birth week (week)		38.94 (1.36)	39.24 (1.55)	0.043
Infant weight (gram)		3254.26 (342.15)	3307.68 (471.65)	0.373
1st minute Apgar scores		8.62 (0.93)	8.54 (0.98)	0.322
5th minute Apgar scores		9.47 (0.72)	9.37 (0.81)	0.410

P-values were calculated with the independent t-test (infant weight), Mann-Whitney U test, and Chi-Square Test (Delivery type, indications of cesarean, neonatal intensive care needs)

Discussion

Giving birth is a challenging process for women. This period often restricts the women's free movement, as they are typically bedridden and tethered to standard cardiotocography devices used for fetal heartbeat monitoring. Such restrictions can make the process even more daunting and uncomfortable. Thus, it is crucial to employ new technological devices that can make the birth process easier. Research indicates that wireless cardiotocography devices, which eliminate the movement restriction experienced by expectant mothers due to the probes attached to their abdomens during labor, enhance patient compliance [3]. These devices are also expected to decrease maternal and fetal morbidity and mortality from pregnancy complications [6]. However, assessing the impact of these novel devices in this context is currently in the research stage. Among the potential benefits of these devices is their possible influence on labor duration and obstetric and neonatal outcomes, as a result of improved patient compliance and the mobility they offer throughout the childbirth process. In light of this, the current study compares labor duration and obstetric and neonatal

outcomes of patients who used these devices against those who were subjected to standard cardiotocography, the routine practice.

The aim of wireless antepartum fetal monitoring is to track pregnant women in rural places where access to gynecologists and obstetricians may be challenging. It is particularly effective in remote and economically disadvantaged areas for identifying high-risk pregnancies. Furthermore, this method enables the appropriate antenatal follow-up of these women in suitable medical facilities.

In this respect, the plan aimed to achieve more favorable results with high-risk pregnancies, enhance the standard of health services, and decrease their costs. Evaluations from studies conducted have confirmed the successful usage of wireless antepartum fetal monitors. However, it was observed that these monitors have no impact on obstetric and neonatal outcomes [3,10]. In a research carried out by Mhajna et al. [11], several different wireless devices were utilized to assess both fetal and maternal heart rates, showing results comparable to pre-existing standard methods. Nevertheless, neither obstetric nor neonatal outcomes were evaluated.

Similarly, the study conducted by Mugyenyi et al. [6] found that wireless devices functioned comparably to standard methods, proving comfortable for use by both pregnant women and physicians. They emphasized the need for additional studies to evaluate these devices' effects on perinatal outcomes and costs.

To understand this, we assessed the discomfort caused by the device's probe and the discomfort resulting from movement restriction using a VAS. In both scenarios, the VAS values were consistently higher with the standard device. From this, we can infer that patient compliance and comfort were superior with the wireless antepartum fetal monitor. In the study, pregnant women's blood pressure in both groups was measured on a bi-hourly basis. The mean systolic blood pressure was significantly lower in those monitored with a wireless antepartum fetal monitor. This leads us to question if a higher VAS score, that is, less comfort, might affect blood pressure. Further studies are required for a better evaluation of these findings.

The study evaluated obstetric (delivery type, indications for cesarean, week of birth, and infant weight) and neonatal outcomes (1st and 5th minute Apgar scores, and neonatal intensive care needs). The birth week was significantly higher in the control group, but there was no significant difference seen between the groups in terms of the other outcomes.

The study also evaluated the duration of labor effects from each device. Pregnant women monitored with a wireless antepartum fetal monitor had significantly shorter labor compared to those using standard devices. Even though the groups showed similar cervical effacement/dilatation during hospitalization, and the birth weeks were significantly higher in the control group, the parity and infant weights remained similar. This implies that the effect of shorter labor duration in the study group on its significance was minimal. In other words, it suggests that other factors potentially affecting birth duration were equal between the groups.

Limitations and strengths

The study does have certain limitations that need consideration. The scope of the study could have been expanded if patients were monitored with these devices throughout the pregnancy as well as during labor, offering a more comprehensive evaluation of obstetric and neonatal outcomes. The power of the study could also have been enhanced with a larger number of subjects. Still, the study's strength lies in that it assesses obstetric and neonatal outcomes along with labor duration, a topic on which there is little research available. Variables that could influence the study's results, including patient parity and infant weight, require consideration, especially for determining birth duration. Fortunately, these parameters did not differ between the study groups. To best assess patient mobility limitations due to cardiotocography and the discomfort of being attached to the probe, evaluations were conducted after a half-hour rest period post-birth, utilizing the VAS.

Conclusions

The study indicates that patients monitored with wirelessly-enabled antepartum maternal-fetal monitoring during childbirth experienced enhanced comfort. Other findings showed lower systolic blood pressure and shorter delivery time with the use of this wireless monitoring. These results may be attributed to the comfort provided by the device. Specifically, the diminished pain duration, afforded by these devices, can be viewed as an additional benefit and source of comfort for women enduring childbirth. Lower blood pressure might also signal reduced anxiety levels during birth. However, these devices did not influence obstetric and neonatal outcomes, according to our study. Owing to the paucity of research on wireless-enabled antepartum maternal-fetal monitoring, there is not enough data to compare our study results. Comprehensive studies with larger sample sizes are required to gather substantial information on this subject, especially to evaluate obstetric and neonatal outcomes more effectively.

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