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Reducing False Alarm Rates and Workload in ICUs by Improving Arrhythmia Detection Algorithms of Patient Monitoring Systems

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Data Collection B

Statistical Analysis C

Data Interpretation D

Manuscript Preparation E

Literature Search F

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Conflict of interest:

None declared

Background:

Patient monitoring systems are widely used in intensive care units (ICUs) to monitor patient's conditions. A high false alarm rate can lead to alarm fatigue among nurses, increasing workload and stress. This study aimed to improve the accuracy of arrhythmia detection by enhancing the noise detection algorithm in patient monitoring systems and to determine whether false alarm rate and workload decreased through clinical trials.

Material/Methods:

Trials were conducted on adult patients in the ICU at Yongin Severance Hospital who required continuous electrocardiogram (ECG) monitoring for at least 2 days. After the first trial, the noise detection algorithm of the M50 (investigational device) was improved, and a second trial was conducted to evaluate its performance. Both trials followed the same study design. During the study period, M50 and MX700 (comparator device) were applied simultaneously for 3 days. Arrhythmia alarms were reviewed by an independent evaluator who assessed false alarms by comparing them with the ECG signals. False alarm rates were compared between trials using the chi-square (χ^2) test.

Results:

The clinical trial was conducted through 2 separate trials, with 17 and 11 participants, respectively. A comparative analysis of false alarm rates of the investigational device demonstrated a reduction from 71.75% to 27.61%. Statistical analysis using the chi-square test indicated a *P* value of 0.000 (<0.001), confirming a statistically significant difference.

Conclusions:

The results of 2 trials demonstrated reductions in false alarm rate and NASA-TLX score. These findings suggest that enhancing the noise detection algorithm in the patient monitoring system improved arrhythmia detection accuracy and helped reduce nurses' workload.

Keywords: **Arrhythmias, Cardiac • Electrocardiography • Intensive Care Units • Monitoring, Physiologic****Full-text PDF:** <https://www.medscimonit.com/abstract/index/idArt/949932> 2706 4 1 23

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Introduction

A patient monitoring system measures vital signs such as electrocardiogram (ECG), blood pressure, saturation of partial pressure oxygen (SpO₂), and temperature to monitor the patient's condition in emergency rooms, operating rooms, and intensive care units (ICUs) [1]. An alarm is triggered when a patient is in a critical condition, but most of these alarms are false [2]. According to a study on reducing the false alarm rate of arrhythmia in ICUs, expert labeling of 1250 arrhythmia alarms determined that the false alarm rate was 64.1% [3]. A study on patient characteristics related to false arrhythmia alarms in the ICU determined that 89.5% of 12671 arrhythmia alarms were false alarms [4]. A study on reducing false arrhythmia alarms using machine learning determined that 57.3% of 2829 arrhythmia alarms in the MIMIC II (Multiparameter Intelligent Monitoring in Intensive Care II) database were false, and 60.8% of 750 arrhythmia alarms in the PhysioNet/CinC public database were false [5]. The occurrence of numerous alarms can cause alarm fatigue, with staff becoming desensitized and ignoring or mismanaging alarms [6]. This can disrupt the work of medical staff and lead to adverse patient outcomes [7].

One of the main causes of the high false alarm rate in ICUs is the poor quality of electrocardiography (ECG) signals [8]. ECG records the electrical activity of the heart and is used to diagnose heart diseases. By detecting the QRS wave, the heart rate can be measured, and analyzing the waveform can help diagnose diseases. However, noise such as muscle noise, baseline wander, and power-line interference that occurs during ECG measurement can interfere with the analysis of ECG signals [9]. The muscle noise is caused by the activity of skeletal muscles [10]. Baseline wander is caused by breathing or patient movement, and power-line interference is caused by electromagnetic interference of the alternating supply [11,12]. Since various types of noise degrade the quality of ECG signals, effective noise removal is necessary for accurate ECG signal analysis.

These technical issues are closely related to the workload in ICUs [13]. ICU nurses are responsible for providing care to critically ill patients and making decisions in critical situations, resulting in higher workloads compared to nurses in other departments [14]. A demanding work environment and the quality of medical materials contribute to ICU nurses' occupational stress, which can negatively impact patient outcomes [15-17]. To address these challenges, previous studies have proposed various algorithmic approaches to improve the accuracy of arrhythmia alarms and reduce false alarms, including structured learning methods, AI models that emulate ICU expert decision-making, denoising techniques, and signal-based machine learning algorithms [18-21]. The present study aimed to improve the accuracy of arrhythmia detection by enhancing the noise detection algorithm in patient monitoring systems

and evaluating whether the enhanced algorithm reduces false alarm rate and nurses' workload.

Material and Methods

Patient Monitoring System

The 2 tested patient monitoring systems were the MX700 (Philips Medical Systems, USA) and M50 (Mediana Co, Republic of Korea). The MX700, a well-established device in ICUs, was utilized as a comparator device in this clinical trial. The M50, developed in Korea, was evaluated as the investigational device to compare its performance against the MX700. The M50 is a monitoring device that measures ECG, heart rate, noninvasive blood pressure (NIBP), arterial pressures, SpO₂, pulse rate, and respiration rate; the MX700 is a bed-side monitor of patient vital signs. This study involved 2 clinical trials, with the noise detection algorithm of the M50 improved after the first trial, and a second clinical trial was conducted to confirm whether the improved noise detection algorithm enhanced arrhythmia detection accuracy by analyzing false alarm rate and nurses' workload.

Study Population

This study was conducted on adult patients admitted to the ICU who required ECG monitoring for more than 2 days. Patients who met any of the following criteria were excluded from the clinical trial: patients with burn injuries, patients with a history of allergic reactions to patch components or those with sensitive skin, patients with fragile or compromised skin integrity, patients undergoing treatment for sternal wound infections or with an open sternum, patients with an artificial heart or receiving extracorporeal membrane oxygenation (ECMO) support, patients implanted with an implantable cardioverter-defibrillator (ICD), critically ill patients who have declined life-sustaining treatment, patients currently enrolled in another clinical trial, and patients deemed unsuitable for trial participation by the principal investigator or other researchers.

The workload associated with the use of M50 and MX700 was assessed among ICU nurses. ICU nurses are the main users of patient monitoring systems in the ICU and have clinical expertise, which qualifies them as participants for evaluating workload. All patients and nurses participating in the clinical trial voluntarily completed the informed consent form.

Ethics

This study was approved by the Institutional Review Board (IRB) of Yongin Severance Hospital (Approval No.: 9-2021-0080, approved on June 17, 2021; Approval No.: 92022-0087, approved

on August 12, 2022) and conducted 2 clinical trials in the ICU of the Department of Pulmonology and Allergy from June 2021 to January 2023. The clinical trials followed the ethical standards of the IRB and the Helsinki Declaration.

Study Procedures

To conduct ECG monitoring, the ECG leads of both the investigational device and the comparator device were simultaneously applied to the subjects, and ECG signals and arrhythmia alarms were monitored for 3 days. The ECG electrodes were attached to the RA (right arm), LA (left arm), and LL (left leg) positions on a single subject, with approximately 1-cm spacing between the 2 sets of electrodes. To prevent signal interference, electrodes were placed in distinct but adjacent positions and nearby electronic equipment was removed during monitoring. After the monitoring process was completed, the results were anonymized and sent to the evaluator. The evaluator examined the ECG waves, compared the arrhythmia alarm results with the ECG waves, and determined the occurrence and causes of false alarms. The assessment of false alarms was performed by an arrhythmia specialist from the Department of Cardiology at Severance Hospital. ICU nurses evaluated their workload using the NASA-TLX (National Aeronautics and Space Administration-Task Load Index) after their shifts.

Endpoints

The endpoints of this study are the false alarm rate and the NASA-TLX scores. Arrhythmia alarm results generated by the investigational device are compared to ECG wave results; if they match, they are classified as correct alarms, while non-matching results are classified as false alarms. The false alarm rate is defined as the proportion of alarms generated by each device that are identified as false alarms.

The NASA-TLX is one of the most reliable tools for assessing subjective workload and consists of 6 dimensions: mental demand, temporal demand, physical demand, performance, effort, and frustration [17,22]. The NASA-TLX survey scores range from 0 to 100, with higher scores indicating a higher level of workload [23].

Statistical Analysis

The analysis was performed using SPSS version 27 (IBM Corp., Armonk, NY, USA). The chi-square test was used to compare the false alarm rate observed during the clinical trial. The results presented include the frequency and proportion of alarms generated by the device, and chi-square statistic (χ^2). The difference was considered statistically significant when the P value was less than 0.05.

The Mann-Whitney U test was used to compare NASA-TLX scores. The results presented include descriptive statistics (mean, standard deviation) and the Mann-Whitney U statistic (U). The difference was considered statistically significant when the P value was less than 0.05.

Results

Demographic Characteristics

The clinical trial was conducted in 2 phases. For the first clinical trial, 17 patients participated, with an average age of 78.2 years, and the second clinical trial, 11 patients participated, with an average age of 78.6 years.

The NASA-TLX was conducted among ICU nurses who cared for patients using the investigational device. For the first clinical trial, 29 nurses participated, with an average age of 30.8 years and an average work experience of 7.6 years. For the second clinical trial, 13 nurses participated, with an average age of 29.7 years and an average work experience of 6.7 years.

Improvement of Arrhythmia Detection Algorithm

Figure 1 shows the flow of the arrhythmia detection algorithm based on rhythm diagnostics. The algorithm simultaneously and continuously analyzes rhythm and noise using ECG signals.

After detecting QRS waves from the ECG signal, the rhythm is classified based on RR intervals. Then, the morphology of each QRS wave is analyzed to generate a template beat, which serves as the basis for rhythm diagnosis. If noise is detected in the ECG signal's baseline or QRS wave, a "noise signal" is displayed. Otherwise, an alert is triggered based on rhythm analysis.

Noise in the baseline can be detected based on the voltage distribution of the ECG wave over a given time interval. The ECG wave is sampled into multiple signals based on the time axis. The sampled signals are grouped based on time interval, and voltage ranges are determined based on the voltage distribution of ECG waves within each group. The noise judgment score is determined based on whether the voltage ranges of grouped sampled ECG waves exceed predetermined threshold levels. Additionally, the noise judgment score can be determined by evaluating whether the absolute values of the differences between grouped sampled signals surpass predefined threshold values. The noise state variable is determined based on the noise judgment score and temporal changes, and noise in the baseline is evaluated according to the noise state variable.

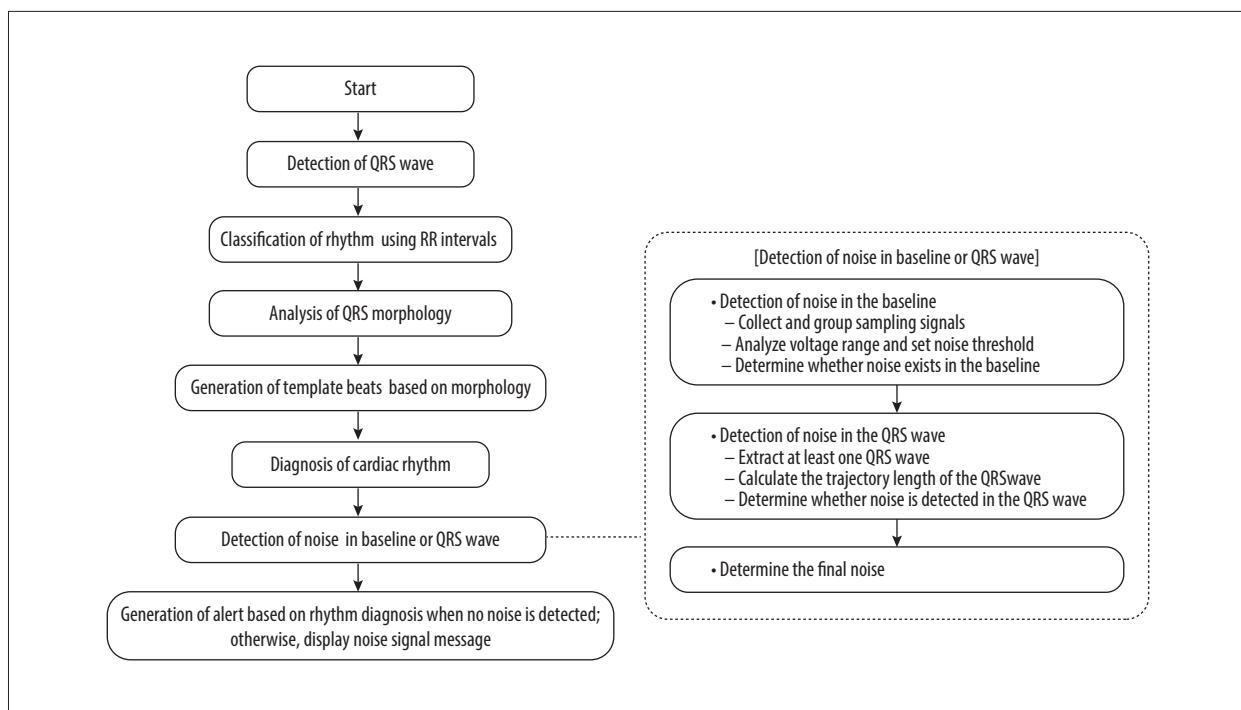


Figure 1. Improved algorithm for arrhythmia detection in patient monitoring system.

Noise in the QRS wave can be detected based on the trajectory length of the ECG wave. The QRS wave is extracted from the ECG wave, and the trajectory length is calculated using the differences between inflection points within the QRS wave. If the calculated trajectory length is significantly longer than the normal trajectory length of QRS waves, the QRS wave is determined to contain noise.

Final noise can be determined based on the frequency of noise detection in the baseline and the presence of noise in the QRS wave. Final noise is identified when noise is detected twice consecutively in the baseline or when noise is detected in the QRS wave. When final noise is identified, the related ECG wave is excluded from the analysis, and a “noise signal” notification is displayed to indicate degraded signal quality. This approach contributes to reducing false alarms and enhancing arrhythmia detection accuracy.

False Alarm Rate

Table 1 shows the results of the chi-square test for the false alarm rates observed in M50 and MX700. In the first clinical trial, the false alarm rate was 71.75% (160) for M50, and 29.54% (135) for MX700. The false alarm rate caused by noise was 65.63% (105) for M50 and 10.37% (14) for MX700. The chi-square test results indicated that both the overall false alarm rate ($\chi^2=108.704$, $P<0.001$) and the false alarms caused by noise ($\chi^2=92.887$, $P<0.001$) were significantly higher for M50 compared to MX700.

In the second clinical trial, the false alarm rate was 27.61% (37) for M50, and 15.54% (30) for MX700. The false alarm rate caused by noise was 35.14% (13) for M50 and 36.67% (11) for MX700. The chi-square test results indicated that the false alarm rate of the M50 was significantly higher than that of the MX700 ($\chi^2=7.070$, $P=0.008$). However, there was no significant difference in the false alarm rate caused by noise between M50 and MX700 ($\chi^2=0.017$, $P=0.897$).

Table 2 shows the results of the chi-square test for the false alarm rates observed in the M50 during 2 separate clinical trials. The false alarm rate for M50 was 71.75% (160) in the first clinical trial, and 27.61% (37) in the second clinical trial. The false alarm rate caused by noise was 65.63% (105) in the first trial and 35.14% (13) in the second trial. The chi-square test results indicated that both the overall false alarm rate ($\chi^2=65.932$, $P<0.001$) and the false alarm rate caused by noise ($\chi^2=11.630$, $P=0.001$) were significantly reduced in the second clinical trial.

NASA-TLX

Table 3 shows the results of the Mann-Whitney U test comparing the NASA-TLX scores between the M50 and MX700 groups. The Mann-Whitney U test results indicate no significant differences were found in the overall NASA-TLX scores during the first clinical trial ($P=0.903$) and the second clinical trial ($P=0.967$). Furthermore, no significant differences were found in the subscales of NASA-TLX, including mental

Table 1. False alarm rates and comparison results for M50 and MX700.

	M50		MX700		χ^2	<i>P</i> value		
	Observed frequency	Ratio (%)	Observed frequency	Ratio (%)				
1st clinical trial (n=17)								
False alarms								
Noise	105	65.63	14	10.37	92.887	0.000		
Not noise	55	34.38	121	89.63				
Total alarms								
Correct alarm	63	28.25	322	70.46	108.704	0.000		
False alarm	160	71.75	135	29.54				
2nd clinical trial (n=11)								
False alarms								
Noise	13	35.14	11	36.67	0.017	0.897		
Not noise	24	64.86	19	63.33				
Total alarms								
Correct alarm	97	72.39	163	84.46	7.070	0.008		
False alarm	37	27.61	30	15.54				

Table 2. False alarm rates and comparison results for M50 used in 2 clinical trials.

	1 st clinical trial (n=17)		2 nd clinical trial (n=11)		χ^2	<i>P</i> value
	Observed frequency	Ratio (%)	Observed frequency	Ratio (%)		
False alarms						
Noise	105	65.63	13	35.14	11.630	0.001
Not noise	55	34.38	24	64.86		
Total alarms						
Correct alarm	63	28.25	97	72.39	65.932	0.000
False alarm	160	71.75	37	27.61		

demand, temporal demand, physical demand, performance, effort, and frustration.

Table 4 shows the results of the Mann-Whitney U test conducted on the NASA-TLX scores of the M50 used in the 2 clinical trials. The Mann-Whitney U test results indicate a statistically significant reduction in NASA-TLX scores for the M50 used in the second clinical trial ($P=0.000 <0.001$). Specifically, scores for temporal demand ($P=0.021$), physical demand ($P=0.000 <0.001$), and performance ($P=0.000 <0.001$) showed significant

decreases, and the effort score exhibited a statistically significant increase ($P=0.002$).

Discussion

This study aimed to enhance the noise detection algorithm of the patient monitoring device and evaluate its performance through 2 clinical trials. During ECG wave monitoring, various types of noise – such as muscle noise, baseline wander, and

Table 3. NASA-TLX scores and comparison results for M50 and MX700.

	M50	MX700	U	P value
1st clinical trial (n=29)				
Mental demand	26.00±16.25	28.16±15.29	546.5	0.444
Temporal demand	61.52±22.07	64.74±19.61	573.0	0.567
Physical demand	23.52±14.87	27.11±12.17	490.5	0.199
Performance	51.89±23.10	51.32±24.54	607.0	0.832
Effort	31.69±18.12	28.68±12.68	571.5	0.619
Frustration	29.74±23.57	30.53±16.24	478.0	0.444
Overall	38.32±14.44	38.42±7.50	615.5	0.903
2nd clinical trial (n=13)				
Mental demand	19.67±16.85	19.00±20.72	104.0	0.721
Temporal demand	15.33±19.13	14.33±18.41	108.5	0.864
Physical demand	15.00±16.26	14.33±13.35	109.0	0.882
Performance	16.67±19.79	13.67±11.87	104.5	0.730
Effort	16.00±12.98	24.00±18.44	83.5	0.218
Frustration	23.33±23.88	19.33±21.12	105.0	0.751
Overall	17.67±14.40	17.44±13.46	111.5	0.967

Table 4. NASA-TLX scores and comparison results for M50 used in 2 clinical trials.

	1 st clinical trial (n=29)	2 nd clinical trial (n=13)	U	P value
Mental demand	26.00±16.25	19.67±16.85	361.5	0.118
Temporal demand	61.52±22.07	15.33±19.13	73.5	0.000
Physical demand	23.52±14.87	15.00±16.26	297.0	0.021
Performance	51.89±23.10	16.67±19.79	124.5	0.000
Effort	31.69±18.12	16.00±12.98	236.5	0.002
Frustration	29.74±23.57	23.33±23.88	337.5	0.372
Overall	38.32±14.44	17.67±14.40	149.5	0.000

power-line interference – can occur, potentially leading to errors in QRS wave detection and subsequent analysis inaccuracies. The noise detection algorithm of the M50 detects noise in the baseline and noise in the QRS wave. It then determines the presence of noise in ECG waves and supports the exclusion of noise-contaminated signals during ECG wave analysis, improving the accuracy of arrhythmia detection.

In the 2 clinical trials, the false alarm rate of the M50 decreased from 71.75% to 27.61%, and the false alarm rate caused by noise reduced from 65.63% to 35.14%. Previous studies on

arrhythmia false alarms in the ICU have indicated that the typical false alarm rate of patient monitoring systems ranges from 50% to 80% [3-5]. In the first clinical trial, the false alarm rate of the M50 fell within the typical range of false alarm rates observed in patient monitoring systems. In the second clinical trial, the false alarm rate of the M50 decreased due to improvements in the arrhythmia detection algorithm, and it was confirmed to be lower than the typical false alarm rate in patient monitoring devices.

The NASA-TLX score for the M50 system decreased from 38.32 to 17.67. Studies on nurses' responses to alarms and alarm fatigue have identified frequent false alarms as one of the most disruptive factors in their work [24]. The high number of false alarms can reduce the alertness of ICU nurses, potentially leading to delayed responses to alarms and causing stress to patient hospitalized in the ICU [25]. Therefore, reducing the false alarm rate is essential to reduce the workload and stress of ICU nurses. The NASA-TLX results indicated that workload decreased when using patient monitoring systems with improved arrhythmia detection algorithms. The improvement in the noise detection algorithm has positively contributed to reducing the false alarm rate and the workload of ICU nurses and also enhances the accuracy of arrhythmia detection. This advancement supports the enhancement of patient monitoring systems and the efficiency of ICU nursing care.

In this study, the comparison between the existing algorithm and the improved algorithm was conducted using data from different subjects. As a result, the different approaches were not the only variable, and the false alarm rate may have been influenced by other factors. It is anticipated that a comparative study using ECG data from the same subjects would enable a more objective and credible assessment of their performance.

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