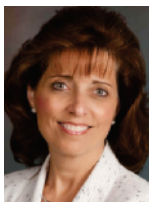
RESEARCH

Effect of Altering Alarm Settings: A Randomized Controlled Study

Maria Cvach, Kathleen J. Rothwell, Ann Marie Cullen, Mary Grace Nayden, Nicholas Cvach, and Julius Cuong Pham

About the Authors



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Abstract

Medical alarm signals are important for alerting clinicians to life-threatening conditions, but the high rate of false alarms can be problematic. Reduction in alarm signals may lead to increased staff responsiveness to alarms and create a quieter environment for patients. The effect of these changes on patient outcomes is uncertain.

Methods: We conducted a pilot, prospective, randomized, controlled trial in the cardiac care unit (CCU) to test a study protocol and data collection instruments and to examine the differences in alarms between usual care and altered settings. Subjects were randomized daily to either standard or altered CCU alarm settings. Secondary outcomes included the number of clinically significant events (CSEs) detected, event-triggered interventions (ETIs), frequency of alarms per monitored bed, and patient complications.

Results: Over the two-week study time frame, 22 unique patients were enrolled. There were 1,710 alarms over 163 hours of monitoring in the standard group and 1,165 alarms over 169 hours in the study group ($P < 0.001$). There were more CSEs detected (14 vs. 3) and ETIs (12 vs. 2) in the study group, but sample size was too small to determine efficacy. No cardiac arrests or adverse patient outcomes were observed in either group. All patients were discharged from the hospital. Study protocol and outcomes were feasible and lessons were learned.

Conclusion: This study demonstrated feasibility of a study protocol for conducting a randomized controlled trial to evaluate CSEs, ETIs, frequency of alarms, and adverse patient outcomes when altering default alarm settings. A longer study can be performed using a similar study design.

Introduction

Cardiac monitor alarms are intended to notify care providers of hazardous patient conditions or monitoring system problems requiring attention. Ideally, these alarms activate for true and actionable events. This is not always the case with current monitoring technology, which is designed for high sensitivity to avoid missing a true event. High sensitivity results in frequent false and nonactionable alarms. False alarms occur when the signal occurs in the absence of a valid alarm-triggering event.

Alarm fatigue occurs when care providers are overwhelmed by so many alarm signals, they become desensitized.

Nonactionable alarms correctly signal but do not require intervention. Research studies indicate the presence of false and/or nonactionable alarms ranges from 68% to 99%.[1–3]

False and nonactionable alarms often lead to alarm fatigue. Alarm fatigue occurs when care providers are overwhelmed by so many alarm signals that they become desensitized. The problem of alarm fatigue has been reported in the literature for many years.[1–7] It is multifactorial and related to the large number of alarm-enabled medical devices in use today, frequent false and nonactionable alarms, lack of alarm standardization across similar devices, unclear alarm accountability, and overuse of monitoring technology for conditions that don't require monitoring.

The frequency of alarm signals can be reduced considerably by altering alarm settings to reduce nonactionable and/or duplicative alarm signals and by individualizing alarms for patient need.[8–10] Reduction in alarm signals may lead to increased staff awareness of actionable alarms and create a quieter, healing environment for patients. Altering alarm settings to reduce low-priority alarm frequency and its effect on patient adverse events (an important outcome) has not been rigorously studied.

The purpose of the current study was to evaluate the feasibility of a study protocol and data collection tools to test the effect of an altered set of alarm parameters on the frequency of alarm signals and adverse patient events in a cardiac care unit (CCU). It was anticipated that altering monitor alarm parameters to minimize alarms would result in a decrease in audible alarm signals without increasing clinically significant adverse patient events.

Materials and Methods

The study was approved by the Institutional Review Board of Johns Hopkins Hospital (NA_00079765) and registered with clinicaltrials.gov (NCT02041858).

Study Design

We conducted a pilot, prospective, randomized, controlled trial. The study was conducted during a two-week time frame (from May 14 to May 31, 2013), Monday through Friday, from 9 a.m. to 5 p.m., in a 12-bed CCU at Johns Hopkins Hospital. Only English-speaking, adult patients who were able to give written consent were eligible to participate in the study.

Study Assignment

Research assistants (RAs) randomly assigned subjects to one of two treatment arms from sealed envelopes for each study day. Thus, a patient who was in the CCU for several days could be on different treatment arms based on the daily randomization process. Once consented, patients remained in the study while in the CCU and participation ended upon transfer or discharge. A study nurse placed the patient on the randomly assigned settings, then placed the patient back on the unit standard settings at the end of each study day (5 p.m.).

Intervention: Alarm Settings

Subjects were randomly assigned to one of two sets of monitor alarm default parameter settings: standard CCU settings or altered CCU settings (Table 1). The altered CCU settings differed from the standard CCU settings in the following three ways: 1) ventricular tachycardia (VT) less than 2 (defined as a 3, 4, 5 beat run of VT) was a nonaudible, visual message appearing on the bedside monitor screen as opposed to an audible tone with visual message in the standard settings; 2) ST segment (ST) threshold breaches were nonaudible, visual messages appearing on the bedside monitor screen as opposed to an audible alarm tone with visual message; and 3) the peripheral oxygen saturation (SpO_2) alarm was readjusted to audibly alarm for an SpO_2 of 88% instead of 89%. Nurses were permitted to customize alarms based on identified patient need and using clinical judgment, as is routine practice in the CCU.

The primary objectives of this pilot study were to test a study protocol and data collection instruments and to examine the differences in alarms between usual care and altered settings.

Outcomes

The primary objectives of this pilot study were to test a study protocol and data collection instruments and to examine the differences in alarms between standard and altered settings. As such, the primary

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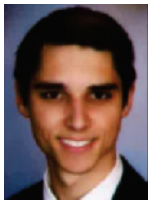

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Parameter	Manufacturer Alarm Settings	Standard Alarm Settings	Altered Alarm Settings
Asystole	Crisis	Crisis	Crisis
Ventricular Tachycardia/Fibrillation	Crisis	Crisis	Crisis
Ventricular Tachycardia	Crisis	Crisis	Crisis
Ventricular Tachycardia >2	Crisis	Advisory*	Message*
Ventricular Bradycardia	Crisis	Crisis	Crisis
Accelerated Idioventricular Rhythm	Message	Message	Message
Pause	Message	Crisis	Crisis
Tachycardia	Message	Message	Message
Bradycardia	Message	Message	Message
R wave on T wave	Message	Message	Message
Couplet	Message	Message	Message
Bigemeny	Message	Message	Message
Trigemeny	Message	Message	Message
Premature Ventricular Contraction	Message	Message	Message
Irregular	Message	Message	Message
Heart Rate	50/150 Warning	50/120 Warning	50/120 Warning
Premature Ventricular Contraction/min	6	10	10
Pulse Oximetry	90	89*	88*
ST Segment Abnormality	OFF	+2/–2 Advisory*	+2/–2 Message*

Table 1. Alarm Settings

Message: A visual message which appears on the monitor screen until the condition resolves
Advisory: An audible (continuous one-beep) alarm and visual message that appears on the monitor screen until the condition resolves
Warning: An audible (continuous two-beep) alarm and visual message that appears on the monitor screen until the condition resolves
Crisis: An audible (continuous three-beep) alarm and visual message that appears on the monitor screen until the alarm is silenced
*Parameter modified
R wave on T wave: A premature QRS complex interrupting the T wave of the preceding beat

outcome was the subjective success and lessons learned associated with the pilot test. Secondary outcomes included 1) detection of clinically significant events (CSEs), 2) event-triggered interventions (ETIs), 3) frequency of audible monitor alarm signals, and 4) patient complications.

Measurement of CSEs and ETIs

Nurses in the CCU are responsible for patient monitoring. A nurse typically cares for two patients at a time. There is no centralized "monitor watcher." Nurses use multiple methods to alert them of audible alarm signals, including split-screen bedside monitor views, allowing the nurse to see both patients for which they are caring; "auto-view on alarm," which allows all nurses who are in patient rooms in the CCU to see and hear high-priority alarms (defined as alarms for patient care situations that may be life threatening and require immediate attention) identified by the monitor; hallway waveform screens strategically placed in the CCU to allow nurses to view patients when not near the central monitor located at the CCU nursing station or in a patient room; and acknowledgment pagers that alert the primary nurse of high-priority conditions using a middleware product and following an alarm escalation pathway to minimize sending nonactionable alarms to the nurse.

Each hour, the RA asked the nurse who was caring for a study patient to review a data collection tool (Figure 1) that listed both CSEs and ETIs. This tool was modified for adult

Effect of Enhanced Alarm Settings on Patient Adverse Events and Alarm Signal Frequency:
A Randomized Controlled Feasibility Study

Data Collection Sheet

Date: Study ID #: Bed #:

Profile: ☐ 1 ☐ 2 Consented by: ☐ Joy ☐ Ann Marie ☐ Grace

Observation	CSE Yes/No	Type of CSE_1	Type of CSE_2	Type of CSE_3	ETI Yes/No	ETI_1	ETI_2	ETI_3	Type of event that triggered intervention (i.e., Hi HR, Lo HR, Lo sat; Hi BP; Lo BP; Vent; A Fib)
9:00	☐Y ☐N				☐Y ☐N				
10:00	☐Y ☐N				☐Y ☐N				
11:00	☐Y ☐N				☐Y ☐N				
12:00	☐Y ☐N				☐Y ☐N				
13:00	☐Y ☐N				☐Y ☐N				
14:00	☐Y ☐N				☐Y ☐N				
15:00	☐Y ☐N				☐Y ☐N				
16:00	☐Y ☐N				☐Y ☐N				
17:00	☐Y ☐N				☐Y ☐N				

Other CSE: _____ **Other ETI:** _____
Comments: _____

Alarm customization: ☐ **N** ☐ **Y:** **List:** _____
☐ Patient placed back on CCU alarm defaults at end of **daily** data collection Signature _____

1

CSE – Clinically Significant Event ETI – Clinically Significant Event-Triggered Intervention

Effect of Enhanced Alarm Settings on Patient Adverse Events and Alarm Signal Frequency:
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Clinically Significant Event (CSE)
1. Hypotension (requiring call to prescriber)
2. Hypertension (requiring call to prescriber)
3. Apnea
4. Cyanosis
5. Hypoxia (requiring supplemental O2 or change in amount of supplemental O2)
6. Unintended extubation
7. Arrhythmia
8. Seizure
9. Change in LOC/Altered Mental Status
10. Combative Patient
11. Pain Crisis
12. Cardiopulmonary Arrest (Code)
13. Hypoglycemia
14. Other

Clinically Significant Event-Triggered Interventions (ETI)
a. Notified prescriber
b. Stimulated patient
c. Suctioned patient
d. Repositioned patient
e. Ambu-bagged patient
f. Administered oxygen or increased level of oxygen
g. Called a code/RRT
h. Administered a new medication/changed medication dose
i. Patient intubated
j. Implemented a new protocol
k. Changed patient diet
l. Other

Figure 1. Alarm Parameter Data Collection Tool For Manuscript

N = Study days	Standard CCU Alarm Settings n = 23	Altered CCU Alarm Settings n = 25
Age (Mean)	54	57
Male	9 (40%)	6 (24%)
ICU Admitting Diagnosis		
Cardiomyopathy (dilated/ischemic and nonischemic)	12 (52%)	11 (44%)
Chest Pain	1 (4%)	0
Myocardial Infarction		
(STEMI and NSTEMI)	7 (30%)	9 (36%)
Ventricular Tachycardia	0	1 (4%)
Congestive Heart Failure (decompensated)	1 (4%)	1 (4%)
Pericardial Effusion	2 (9%)	0
Marfan's Syndrome	0	2 (8%)
Ventricular Tachycardia/Fibrillation Cardiac Arrest	0	1 (4%)
Medical Comorbidities		
Coronary Artery Disease/Myocardial Infarction	4 (17%)	3(11%)
Pacemaker/Automatic Implantable Cardioverter Defibrillators	5 (22%)	5 (20%)
Aortic valve disease		2 (8%)
Hypertension	7 (30%)	8 (32%)
Diabetes	5 (22%)	2 (8%)
Hyperlipidemia	3 (13%)	3(11%)
Atrial Fibrillation	5 (22%)	5 (20%)
Congestive Heart Failure	5 (22%)	5 (20%)
Tachy/Brady Syndrome	2 (9%)	4 (16%)
Cardiomyopathy	2 (9%)	3(11%)
CREST Syndrome	0	3(11%)
Peripheral Vascular Disease	0	3(11%)
Pregnancy	2 (9%)	3(11%)
Obesity/Obstructive Sleep Apnea	4 (17%)	3(11%)
Graves' Disease	2 (9%)	4 (16%)
End-Stage Renal Disease	3 (13%)	0

Table 2. Patient Demographics

patients from a prior similar study.[11] If the nurse stated that the patient had a CSE in the previous hour, they were asked to list the ETI that was performed. Hourly, the RA documented results on the data collection tool.

Complications monitored during this study included hospital length of stay (LOS), unit LOS, cardiopulmonary arrest, adverse events, and mortality. Hospital LOS, unit LOS, cardiopulmonary arrest, and mortality were extracted from medical chart review; reported adverse events were extracted from the hospital adverse event reporting system.

Measurement of alarm signals

Frequency and type of audible alarm signals were extracted directly from the physiologic monitor recorded database. Audible monitor alarms are differentiated by alarm priority. Low-priority "advisory" (one-beep, low-volume) and medium-priority "warning" (two-beep, medium-volume) patient alarms self-correct when the condition dissipates or is addressed by the nurse. High-priority "crisis" (three-beep, high-volume) alarms are life threatening and require someone to either silence them from the bedside or central monitor. Additionally, technical "system warning" (foghorn, low-volume) alarms are continuous sounding and relate to a technical issue. These audible alarms continue until the condition self-corrects or is addressed by the clinician. Nonaudible "message" alerts appearing on the monitor screen and audible "system advisory" low-priority alerts were not collected because they were unavailable in the physiologic monitor database.

Data analysis

The design of the study, in which the same patient was randomized each day and therefore contributed data on multiple study days and possibly to both arms, violated the independence assumption and necessitated the use of a multilevel regression analysis. To do this, two new variables were created: one unique for each study day and one unique for each patient. Using these two new variables, the alarm data were collapsed into study day–level data versus alarm-level data. A multilevel Poisson regression model was used with the unique patient variable as

a random intercept, and the coefficient for the profile status was estimated.

Results and Discussion

During the 10-day study period, a total of 22 unique patients were enrolled. Because patients could be in more than one arm of the study on different study days, patient demographics were recorded according to patient study day to account for the possibility that patients could cross over into the opposite arm of the study. There were 23 standard setting CCU study days and 25 altered setting CCU study days. Most patients were women and the average age was similar between groups (Table 2).

During the 10-day study period, a total of 22 unique patients were enrolled.

There were 1,710 alarms over 163 hours of monitoring using standard CCU settings compared with 1,165 alarms over 169 hours of monitoring using the altered CCU settings (Table 3). There were less alarm signals in the altered settings group (1,165 vs. 1,710, $P < 0.001$). There were less medium-priority (323 vs. 557, $P < 0.001$), low-priority (641 vs. 951, $P < 0.001$), and technical alarms (124 vs. 160, $P < 0.001$) for patients in the altered settings group but more high-priority alarms (77 vs. 42, $P = 0.003$). The most frequent alarm for both groups was high heart rate and low SpO_2 threshold breaches (not shown). As expected, the standard settings group had more audible VT greater than 2 and ST alarms compared with those in the altered settings group, which had these alarms set as a visual "message" alert (not shown).

A total of 3 CSEs affected one patient in the standard settings group, and 14 CSEs affected seven patients in the altered settings group (Table 4). Of note, 5 of the 14 CSEs were caused by one patient with "tachy/brady syndrome," and 2 of the 14 CSEs were caused by one patient who developed a hematoma postprocedure. There were two ETIs for patients in the standard settings group compared with 12 ETIs for patients in the altered settings group. Hospital LOS was

	Standard Alarm Settings N = 23 study days	Altered Alarm Settings N = 25 study days	*P*
Subject Days of Observation	10	10	—
Total Observation Hours	163	169	—
Total Alarm Signals	1710	1165	<0.001
High Priority	42	77	0.003
Medium Priority	557	323	<0.001
Low Priority	951	641	<0.001
Technical Alarm	160	124	<0.001

Table 3. Monitor Alarm Signal Frequency

High priority: Asystole, pause, ventricular tachycardia, ventricular fibrillation, ventricular bradycardia
Medium priority: High and low heart rate
Low priority: BP systolic, diastolic, and mean high and low; pulse oximetry saturation, ST alarms, VT >2
Technical alarm: Lead fail, arrhythmia suspend, RR lead fail, no telemetry, sensor, NBP max

N = Patient Study Day	Standard Alarm Settings N = 23	Altered Alarm Settings N = 25
Clinically Significant Events, Total	3	14
Arrhythmia (Ventricular Tachycardia, Tachycardia, Bradycardia)	0	7
Hypoxia (low peripheral O_2 saturation)	0	4
Hypotension	1	1
Tachypnea	2	0
Other: Hematoma	0	2
Event-Triggered Intervention, Total	2	12
Administer oxygen	0	3
Stimulate patient	1	1
Notify prescriber	1	3
Reposition patient	0	1
Obtain ECG/electrolytes	0	1
Electrodes changed	0	1
Administer new medication/change dose	0	1
Other	0	1
Complications		
Hospital length of stay, days (mean)	20.22	20.12
Unit length of stay, days (mean)	7. 96	11.56
Mortality	0	0
Adverse events	0	0
Cardiopulmonary arrest	0	0

Table 4. Detection of Clinically Significant Events, Event-Triggered Interventions, and Complications

similar for both groups. However, unit LOS was longer in the altered settings group (11.56 vs. 7.96 days). There were no cardiac arrests or adverse events in either group. No one died during the study time frame, and all patients were discharged from the hospital.

Discussion

For the past four years, alarm hazards have been listed by ECRI Institute as the number one health device technology hazard and have been among the top three medical device hazards since inception of the list in 2007 (ECRI, 2014; verbal communication with J. Keller, Vice President, ECRI Institute).

Failure to act due to silenced or ignored alarms has resulted in patient harm.[12] From 2005 through 2008, the U.S. Food and Drug Administration MAUDE (Manufacturer and User Facility Device Experience) database received 566 reports of patient deaths related to monitoring device alarms.[13] Between 2009 and 2012, The Joint Commission reported 98 significant patient events, 80 of which resulted in patient death, with the others resulting in serious harm. The Joint Commission issued a National Patient Safety Goal to be phased in between 2014 and 2016 and calls upon hospitals to understand its own alarm hazards and develop a systematic approach to alarm management.[14]

No research studies have determined, in a rigorous manner, the outcome of altering monitor alarm parameters and its effect on patient outcomes.

For the past four years, alarm hazards have been listed by ECRI (Emergency Care Research Institute) as the No. 1 health device technology hazard and has been among the top three medical device hazards since inception of the list in 2007

Cardiac monitor alarms are purposefully designed for high sensitivity, in order to not miss a true adverse event. These devices use single-parameter thresholds that alarm when the set limit is violated. Since there is a lack of research studies and standards regarding the best monitor default parameter settings, hospitals rely on manufacturer suggestions, staff consensus, and/or expert opinion.

No research studies have determined, in a rigorous manner, the outcome of altering monitor alarm parameters and its effect on patient outcomes. This study describes a protocol for collecting CSEs and ETIs using a data collection tool and randomized controlled design. Several lessons were learned from this pilot study. First, we learned that an RA was able to collect data on CSEs and ETIs through hourly rounding. Through partnering with the nurse caring for the patient, the RA could identify these events, even though the RA did not have actual clinical training. This has implications for the type of study personnel needed to conduct a larger, formal study. Second, we found that the burden of time and distraction on the nurse caring for the patient was minimal. Generally, it took less than five minutes for the RA to obtain necessary information from the nurse. We found that one RA might be able to assess outcomes on a larger unit (up to 32 beds), performing rounds every two hours instead of hourly. For the most part, nurses had a good recall of whether their patient had a CSE/ETI during the previous two hours. Third, our original vision was to compare manufacturer default settings with the altered CCU alarm settings. However, we realized that in our CCU, and perhaps other intensive care units around the country, the manufacturer default settings were not used. Therefore, both treatment arms would have been experimental compared with our standard practice. We therefore decided that the control arm should be the current practice in our CCU. While this may lead to variation in the impact of the altered CCU alarm settings, it would mirror potential real-world impact given the wide variety of monitor manufacturers and settings that could be in place. Given the very slight changes that were made to the altered CCU default settings compared with the standard CCU settings (Table 1), a significant reduction in the number of medium- and low-priority alarms occurred, which reduces alarm burden and unnecessary distraction of the nurse for nonactionable conditions. Fourth, our

original vision was to prevent individualization of alarm settings in both arms. This would lead to more standardization of the settings. However, our CCU encourages nurses to customize alarm settings based on patient need. This practice is recommended by several professional societies.[15,16] Therefore, taking this away would represent a deviation from standard of practice at some institutions. As a result, we decided to allow nurses to continue to customize the alarm settings in both the control and the intervention groups. While this may lead to variation in the effect of the altered alarm settings, it would mirror potential real-world impact of the altered alarm settings. Fifth, we found that early on, nursing staff sometimes confused clinically significant events with the mere fact of hearing an alarm. This emphasized the importance of using a script to clearly ask if the patient had a CSE compared with just hearing an alarm signal, which may have been a false alarm. Finally, collecting data on a paper form was difficult to manage and collate on a daily basis; thus, we recommend using an electronic tool to allow for easier capture and tabulation of data by the RA.

Our CCU encourages nurses to customize alarm settings based on patient need. This practice is recommended by several professional societies.

This study demonstrates a methodology for conducting a randomized-controlled study design to obtain outcome data related to altering patient monitor alarm settings.

Implications of the Study

This study demonstrates a methodology for conducting a randomized controlled study design to obtain outcome data related to altering patient monitor alarm settings. A similar study design can be conducted on a larger scale and over a longer time frame, which may help inform hospitals on the effects of altering monitor alarm settings on patient outcomes. This study was intended as a precursor to a larger multicenter study and to inform study coordinators of the study design, data collection tools, and data analysis process.

Limitations

This study had several potential limitations. First, the sample size was too small to draw conclusions about efficacy. This was not the intent of this study. Second, nurses were allowed to individualize alarms; therefore, deviation from study alarm parameters was possible. Nurses in the CCU typically customize alarms each shift, thus affecting one's ability to draw conclusions, but the current findings likely represent a more realistic assessment of the impact of altered alarm settings. Third, only English-speaking patients who were able to give consent were included in this study, thus excluding many critically ill patients who could have produced more alarms. Fourth, the study was performed on a single manufacturer's monitoring equipment. The question of whether the study protocol would work for all manufacturers, to collect alarm data, may be problematic, as alarms may signal for different reasons on different manufacturer's monitoring equipment and alarm algorithms may differ by manufacturer. Finally, these results came from patients in the CCU. It is unclear if this is generalizable to other populations, such as telemetry, pediatrics, surgical ICU, or medical ICU, which may yield different results.

Conclusion

This study demonstrated a process for conducting a randomized controlled trial to test the effect of altering alarm parameters on CSEs and ETIs. The current protocol is feasible to execute, and some suggestions are provided for modification. This protocol could serve as the basis for conducting a larger multicenter trial to test the effect of an altered set of alarm parameters on CSEs and ETIs.

This protocol can be the basis for conduct of a larger multicenter trial to test the effect of an altered set of alarm parameters on CSE and ETI.

Acknowledgments

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