

(In)security of multiparameter monitors in cardiac surgery: a diagnostic accuracy study**(In) segurança dos monitores multiparamétricos na cirurgia cardíaca: um estudo de acurácia diagnóstica****(In) seguridad de los monitores multiparamétricos en la cirugía cardíaca: un estudio de precisión diagnóstica****Received: 04/08/2019****Approved: 29/12/2019****Published: 17/02/2020****Andrezza Serpa Franco¹****Amanda Moreno Miranda²****Flavia Giron Camerini³****Vanessa Galdino de Paula⁴****Monica de Almeida Karam⁵****Roberto Carlos Lyra da Silva⁶**

This is a quantitative, descriptive study with quasi-experimental design, with the use of simulator, carried out in 2017 in the city of Rio de Janeiro, which aimed to evaluate the accuracy of the alarms of the multiparameter monitors related to the major arrhythmias in patients in the postoperative period of cardiac surgery. The first phase consisted of the characterization of the unit alarms and assessment of the accuracy of the rhythm and heart rate variables of multiparameter monitors caused by vital signs simulator. A total of 55 alarms were triggered: heart rate, saturation, hypotension, and hypothermia resulted in 84% (n=46). In the diagnostic accuracy, the monitors were 100% (n=7) sensitive to asystole, and pulseless ventricular tachycardia, while pulseless ventricular fibrillation and atrial fibrillation with rapid response caused the alarms to ring in only 43% (n=3). The technology evaluated has a high specificity; however, it is not quite sensitive to fatal rhythms, such as pulseless ventricular fibrillation or atrial fibrillation with rapid and slow response, making the equipments unsafe from the perspective of the alarms.

Descriptors: Clinical alarms; Data accuracy; Thoracic surgery; Arrhythmias, Cardiac; Monitoring, Physiologic.

Este é um estudo quantitativo, descritivo, com delineamento quase-experimental, com uso de simulador e, realizado em 2017 na cidade do Rio de Janeiro, e teve como objetivo avaliar a acurácia dos alarmes dos monitores multiparamétricos das principais arritmias nos pacientes em pós-operatório de cirurgia cardíaca. A primeira etapa constou da caracterização dos alarmes da unidade e avaliação da acurácia das variáveis de ritmo e frequência cardíaca dos monitores multiparamétricos provocadas pelo simulador de sinais vitais. Foram disparados 55 alarmes: frequência cardíaca, saturação, hipotensão e hipotermia somaram 84% (n=46). Na acurácia diagnóstica, os monitores foram 100% (n=7) sensíveis para assistolia e taquicardia ventricular sem pulso, enquanto a fibrilação ventricular sem pulso e a fibrilação atrial de alta resposta soaram alarmes em apenas 43% (n=3). A tecnologia avaliada tem alta especificidade; no entanto, não é completamente sensível a ritmos fatais, tais como fibrilação ventricular sem pulso ou fibrilação atrial de alta e de baixa resposta tornando os equipamentos pouco seguros na perspectiva dos alarmes.

Descritores: Alarmes clínicos; Confiabilidade dos dados; Cirurgia torácica; Arritmias cardíacas; Monitorização fisiológica.

Este es un estudio cuantitativo, descriptivo, con delineamiento casi experimental, con uso de simulador y, realizado en 2017 en la ciudad de Río de Janeiro y, tuvo como objetivo evaluar la exactitud de las alarmas de los monitores multiparamétricos de las principales arritmias en los pacientes postoperatorios de cirugía cardíaca. La primera etapa consistió en la caracterización de las alarmas de la unidad y la evaluación de la exactitud de las variables de ritmo y frecuencia cardíaca de los monitores multiparamétricos provocadas por el simulador de signos vitales. Se dispararon 55 alarmas: frecuencia cardíaca, saturación, hipotensión e hipotermia sumaron un 84% (n=46). En la agudeza diagnóstica, los monitores fueron 100% (n=7) sensibles para asistolia y taquicardia ventricular sin pulso, mientras que la fibrilación ventricular sin pulso y la fibrilación auricular de alta respuesta, sonaron alarmas en sólo 43% (n=3). La tecnología evaluada tiene alta especificidad, sin embargo, no es completamente sensible a ritmos fatales, tales como fibrilación ventricular sin pulso o fibrilación auricular de alta y baja respuesta, haciendo que los equipos sean inseguros desde la perspectiva de las alarmas.

Descritores: Alarmas clínicas; Exactitud de los datos; Cirugía torácica; Arritmias cardíacas; Monitoreo fisiológico.

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INTRODUCTION

This study has as subject the analysis of the effectiveness of the alarms of vital signs of the multiparameter monitors from the diagnostic accuracy test performed in real scenario of a surgical cardio intensive care unit. Alarms represent a protective barrier and when used properly, can contribute to a secure care, as they are sources of primary information.

Despite technological advances in health care, specifically as it relates to system alarms of the advanced life support equipment, there is discussion, today, whether they are really offering quality information in intensive care units (ICU), in view of the problems related to the misuse of this resource¹.

This questioning seems to gain more support in recent publications²⁻⁵ dealing with the patient safety subject and that allude to the abuse of alarms. Since 2011, through the Emergency Care Research Institute (ECRI - Institute in Pennsylvania - USA), a nonprofit institution that researches best practices for medical procedures, equipment, drugs and processes, annually publish a list that shows the 10 biggest dangers in health technology, in which alarms have been in the top².

In the latest release of the document with the top ten health technologies that present a danger for 2018, the ECRI keeps the alarms in the list, placing them in 4th place and highlights the failure of the alarms resulting from the devices and secondary reporting systems, improperly configured². The institute argues that the alarm cannot be just a tool for ensuring security, but the importance of reflecting on the risks related to alarm ring when not recognized the priority they deserve³.

One understands the importance and inclusion of the management of alarms in the patient safety goals, also highlighting the education of health professionals, who need to get to know better their medical care equipment (EMA), alarm systems, the reliability of these alarms and in particular to take over the management of the alarms to increase safety margin^{4,5}.

Cardiac surgery is an example of intervention that requires proper management of alarms, since arrhythmias are part of the major complications in the immediate postoperative period. It is a complex procedure that has important organic repercussions, changing in many ways the physiological mechanisms of patients, leading to postoperative critical condition, which implies the need for intensive care to establish good recovery of patients⁶.

Depending on the type of arrhythmia, the patient's clinical condition, underlying cardiopathy and heart rate during arrhythmia, the heart rhythm disturbances cause variable effects on cardiac output, oxygen consumption by the myocardium and coronary blood flow. The decrease in output is more intense when there is associated ventricular dysfunction, atrioventricular dissociation (as in cases of nonparoxysmal junctional tachycardia or ventricular tachycardia), absence of atrial contraction (as in atrial fibrillation) and presence of mitral regurgitation (as in ventricular tachycardia)⁷.

Given the risk of possible complications, the monitor, by shooting a consistent alarm, can enhance the sense of urgency and increase workforce reliability for quick response and prompt intervention, minimizing the adverse events that arrhythmia can cause for this type of patient. Even though, the alarm can be triggered when a device is not working properly and the problems in the devices or system include or loose connections or electrodes not adhered to skin, for example. Even if nothing is wrong with the patient, these conditions should be corrected immediately⁸.

However, when a large number of alarms overwhelms the team, a problem called alarm fatigue arises. The alarm fatigue phenomenon can be understood as the delay in the professional response time, and the alarms can be disabled, silenced or ignored, the team becomes insensitive to alarms, and decreases its alert state^{9,10}. It can be characterized by a delay in time or lack of response by the team to the alarms, due to an excessive number of alarms,

resulting in sensory overload and desensitization, with huge repercussions and negative impact on patient security¹⁰.

Given the size of this problem, the following research question arises: The multiparameter monitor is sensitive and specific enough to identify major arrhythmias, considering that these are the main complications of postoperative period following cardiac surgery? Therefore, this study aimed to evaluate the accuracy of the alarms of the multiparameter monitors regarding the major arrhythmias in patients after cardiac surgery.

METHOD

This study is a quantitative, descriptive, quasi-experimental design, since the study aimed to analyze the technical field of equipment with direction from the perspective of patient safety. There was no experiment directly with patients, as the identification of arrhythmias was done through a simulator.

The study setting was a cardio intensive care unit, which receives adult patients in cardiac surgery postoperative period of a university hospital in the city of Rio de Janeiro. The unit has 13 beds, of which 7 are used exclusively for patients after cardiac surgery.

The collection took place in two distinct stages. In the first step the characterization of the unit alarm was made, with 60 hours of observation and recording in own instrument for data collection in table form. The choice of collection time has as reference the recent studies of characterization of ICU alarms^{11,12}. At this stage, all alarms of multiparameter monitors were activated and the alarms that rang most were registered, as well as the physiological variable responsible for the shooting.

In the second stage accuracy evaluation of the variables rhythm and heart rate (HR) was performed, through a simulator programmed by the researcher with the most frequent cardiac arrhythmia for the proposed clientele (ventricular tachycardia, pulseless ventricular fibrillation, atrial fibrillation with slow response, atrial fibrillation with rapid response). At this stage, the researcher recorded the positive sound or no sound of the alarm to the induction of arrhythmias and sinus rhythm to assess possible undue shots. This information fed the records of sensitivity and specificity.

The vital signs simulator used is called HS-30, RDMEDIQ® trademark. HS-30 is presented in five different versions, allowing the simulation of electrocardiogram (ECG), oximetry, respiration and temperature. This is a multifunctional patient simulator combined with ECG simulator with 10 terminals (cardiac pacemaker, arrhythmia, respiration, temperature and oximetry)¹³.

For data analysis, the choice was the application of contingency table called: 2x2 (two by two), used in diagnostic tests. The correct and early diagnosis, especially of serious illnesses, interfere decisively in the natural history of the disease, also determining appropriate conduct and consequently a greater chance of favorable outcomes with lower financial and social costs¹⁴.

The validity of the diagnostic test (ETD) is composed of two important properties: the sensitivity (SE) and specificity (SP). To analyze the sensitivity (SE) the following mathematical formula was applied: $SE = TP / (TP + FN)$ (True positive)/total monitors and to analyze the specificity (SP) it was applied: $SP = TN / (TN + FP)$ (True negative)/Total monitors.

RESULTS

The characterization data of alarms triggered by multiparameter monitors can be seen in Table 1. Changes in heart rate (tachycardia and bradycardia), saturation, hypotension, and hypothermia were approximately 84% (n=46). It is also possible to see that of the alarms triggered with no clinical relevance, one found: loose saturation cable, loose electrode, monitor

connected with no patient, absence of physiological changes and temperature cable misplaced, totaling 15% (n=8).

Table 1. Characterization of the alarms of multiparameter monitors in simulator. Rio de Janeiro-RJ, 2017.

Physiological variables	(n)	%
Tachycardia	16	29
Bradycardia	15	27
Low saturation	9	16
Hypothermia	4	7
Loose saturation cable	3	6
Hypotension	2	4
No physiological change	2	4
Monitor connected with no patient	1	2
Hypertension	1	2
Lloose electrode	1	2
Loose temperature cable	1	2
Total	55	100

In this study, it was found that of the alarms recorded, 49% (n=27) had some kind of interference by professionals. While in 51% (n=28) of the alarms triggered there was no intervention or did not arise any surveillance state by any professional category, as the alarm silenced by itself. The professional category that most evaluated and interfered during the sounding of the alarm was the nursing staff, composed of nurses, residents of nursing and nursing technicians, in a total of 85% (n=23) of the interventions performed.

The analysis of the diagnostic accuracy of the multiparameter monitors can be seen in Table 2.

It was found that arrhythmias, such as asystole and pulseless ventricular tachycardia were 100% (n=7) sensitive and 100% (n=7) specific. That is, if the patient had asystole or pulseless ventricular tachycardia, the unit monitors would be able to generate true alarms, that is, highly sensitive, also assuring that in the absence of these arrhythmias a false alarm is not generated, featuring that the monitor also has specificity.

With regard to lethal rhythms, alarms of pulseless ventricular fibrillation presented 43% (n=3) sensitivity and 100% (n=7) specificity. When simulating an AF of rapid it was also demonstrated sensitivity of 43% (n=3) and a specificity of 100% (n=7). Whereas, if the patient presents AF of slow response, in the unit referred, the alarm monitor will not be able to shoot (0% sensitivity), reducing the possibility of identification and possible intervention of the health team. Although there is 100% specificity in this test, one must consider the seriousness of an arrhythmia as when it does not trigger the safeguard system to the health professional.

Table 2. Diagnostic accuracy of multiparameter monitors in simulator. Rio de Janeiro-RJ, 2017.

	Diagnostic accuracy	Asystole	Pulseless TV	Pulseless VF	AF of rapid response	AF of slow response
With Arrhythmia	TP	7	7	3	3	0
	FN	0	0	4	4	7
Sinus Rhythm	TN	7	7	7	7	7
	FP	0	0	0	0	0
Total (%)	Sensitivity	100%	100%	43%	43%	0%
	Specificity	100%	100%	100%	100%	100%

Legend: TP: true positive (induced arrhythmia and monitor sound); FN: false negative (induced arrhythmia and monitor did not sound); FP: false positive (sinus rhythm and monitor sound); TN: true negative (sinus rhythm and monitor did not sound); Mathematical formula of analysis, considering total of 7 monitors: Sensitivity=TP/Total monitors; Specificity=TN/Total monitors.

DISCUSSION

It is important to describe that the alarms of the unit are not routinely parameterized, nor are taken into account the peculiarities of the patient. Thus, all alarms were enabled prior to the collection, because some monitored variables were with the alarms disabled.

There were 7 multiparameter monitors available in the unit for patients in the postoperative period of cardiac surgery. From careful observation of the alarm sound, it is inferred that changes in heart rate (tachycardia and bradycardia), saturation, hypotension, and hypothermia occurred more frequently. These findings are relevant to assessing and preventing major complications in cardiac surgery including bleeding and arrhythmias, which directly affect cardiac output, leading to hemodynamic changes mentioned above¹⁵.

One has to consider that the team could only assess whether an alarm is relevant or not, assisting and evaluating the patient and the shot cause¹¹. It is known that clinical alarms alert when a patient's condition is worsening and/or when a device is not working as it should and problems of devices or system include loose connections. Therefore, even if nothing is wrong with the patient, these conditions should be corrected immediately⁸.

However, some studies presented evidence that the high number of clinically irrelevant or false alarms lead practitioners to a reduced alert state, which may result in delay time or lack of response to relevant or true alarms that cause the phenomenon of alarm fatigue, thereby compromising patient safety in intensive therapy^{1,2}.

A study showed that experienced care providers could not even identify half of the common alarms triggered at ICU, when reproduced⁹. The lack of training results in the misuse of the technology by the team and can justify the high incidence of false alarms, with the professional unprepared to handle the medical care equipment, creating difficulties in the setting of the various functions of these devices.

With regard to the alarms that sounded silent and by themselves, false alarms unnecessarily distract the attention of the staff and, therefore, are a nuisance. In most cases, these short alarms are self-correcting. Example of these alarms is the oxygen saturation and heart rate. Both cases occur frequently, with the vital alarm signal back to normal within a range of some seconds¹⁶. A similar case occurs when an intubated patient, to be aspirated, can trigger an alarm of cardiac monitoring and mechanical ventilation that do not require changes or alterations in schedules, but the alarm occurrence stimulates the environment and may trigger the professional, for a "false alarm", when running for a real alarm is triggered.

To meet the scientific test method of diagnostic accuracy, the findings were described in table type 2 x 2 contingency, but for better understanding one choses to present all the results found in the seven multiparameter monitors, as shown in Table 2.

The diagnostic accuracy studies aim to evaluate the ability of technology to accomplish diagnosis data. Thus, a reference test (gold standard) is employed, and accuracy of results (sensitivity and specificity) are directly given or are results that allow calculation of the measures. Thus, sensitivity is the ability the diagnostic test has to detect truly positive individuals, that is, to properly diagnose patients. Specificity is the ability the diagnostic test has to detect true negatives, that is, to properly diagnose healthy individuals¹⁷.

By using HS-30 simulator, the five different arrhythmias most present in cardiac surgery postoperative period were induced. It can be observed that whether the patient had asystole or pulseless ventricular tachycardia, the unit monitors would be able to generate true alarms, that is, highly sensitive and also ensure that, in the absence of these arrhythmias, a false alarm would not be generated, also featuring the monitor as having specificity.

Ventricular tachycardia usually appears within the first 48 hours to 7 days after cardiac surgery and although infrequent, it is potentially lethal. There are mortality reports of up to 44% of affected patients⁷. The causes reported in a retrospective study showed hypoxia, electrolyte disturbances (hypomagnesemia, hypokalemia) and acid-base balance (metabolic acidosis), acute myocardial infarct, occlusion of coronary grafts, ischemia, drugs (digital sympathomimetic drugs used for hemodynamic support, antiarrhythmic drugs used for the treatment of other arrhythmias such as atrial fibrillation) and clinical conditions that evolve with low cardiac output⁷.

From the point of view of being one of the most lethal and severe rhythms of cardiorrespiratory arrest (CRA), pulseless ventricular fibrillation it is an emergency and extremely worrying situation when the health professional is not triggered. In CRA, the time variable is very important, estimating that, every minute that the individual remains in CRA, 10% of survival probability are lost¹⁸.

Although there is 100% specificity in this test, one must consider the severity of an illness when this does not trigger the safeguard system to the health professional.

The main cause of CRA in adults, is ventricular fibrillation (VF). This heart rhythm disorder is caused by reentry mechanism, causing disordered and ineffective contractions of cardiac cells. It is the most common disorder of heart rate in the first two minutes of CRA in adults. It evolves rapidly to asystole, in case it is not established basic life support measures¹⁷.

In addition, the leading cause of VF, in cases of cardiac surgery postoperative period, are ischemic syndromes of unstable myocardial. The patients most prone to malignant tachyarrhythmias have a history of ventricular dysfunction, ventricular tachycardia or myocardial infarctation¹⁷.

The correct and early diagnosis, especially of serious illnesses, interfere decisively in the natural history of the disease, also determining appropriate conduct and consequently a greater chance of favorable outcomes with lower financial and social costs¹⁴.

In the accuracy analysis, the most present arrhythmias in the scenario presented and listed in this study were the data found in AF stimulus of slow response by the simulator.

In case the patient has AF of slow response in the unit referred, the monitor alarm will not be able to be triggered, decreasing the possibility of identification and possible intervention of the health team. It is a supraventricular tachyarrhythmia characterized by disorganized atrial activation with consequent deterioration of atrial function. Its incidence is estimated between 20 and 40% and its occurrence is more frequent between the 2nd and 5th days after cardiac surgery¹⁷.

The length of stay in ICU of patients who develop AF after surgery increases on average two to four days compared to those maintaining sinus rhythm. This complication is also the leading cause of hospital readmission after discharge from cardiac surgery. Cerebrovascular

accident (stroke), hypotension, acute pulmonary edema, increased length of stay in ICU and high additional costs are directly associated with postoperative AF, as well as increased morbidity and mortality¹⁷.

It is worth describing that although it has been used the terms AF of slow and rapid response referring to ventricular response that produces fine and coarse tracings, respectively, observed in the monitor, according to the last Brazilian Guidelines for Atrial Fibrillation 2016, the classification most commonly used in clinical practice refers to the clinical presentation of AF¹⁸. According to this guideline, it is defined as paroxysmal AF the one that is reversed spontaneously or with medical intervention within 7 days of onset. Persistent AF is when the episodes last longer than seven days. The terminology of long-standing persistent AF is used to denote cases lasting more than one year. Another denomination is permanent AF in the cases when attempts to restore the sinus rhythm will no longer be instituted. And finally, nonvalvular AF, recognized in the absence of rheumatic mitral stenosis, mechanical or biological valves or previous surgical repair of mitral valve¹⁸.

Given the findings, the information acquired do reflect on the importance of proper management of hard technologies in healthcare to optimize patient safety, avoiding problems like lack of maintenance, improper maintenance, buying incompatible parts, lack of purchasing planning, among others. Management of them in health facilities has become a requirement regulated by the National Sanitary Surveillance Agency (ANVISA) by RDC No. 02 of January 25, 2010 and RDC No. 20 of March 26, 2012^{19,20}. In addition, it is worth noting that while one of the prerequisites for this management is higher education, the resolution does not specify the professional category to exercise this function in article number 8, which can be of great benefit to users, whether nursing becomes part of the specialized groups in this technological segment.

Health Technology Assessment (HTA) worldwide, has predominantly been focused on drugs, therapeutic medical devices and procedures, especially surgical ones. Therefore, understanding the HTA instruments in this context is fundamental for the clinical reasoning, direct professionals to good health practices that result in benefit and safety to patients, as well as reduce costs for health systems and assist health managers in decision making based on understandable and reliable information¹⁴.

In this sense, it is understood that the Clinical Engineering sector is of fundamental importance in the hospital because it prevents damage to the high amount of corrective maintenance or incomplete or mistaken utilization of medical care equipment that can reflect damage to the patient, as well as increased care costs. Moreover, it can contribute to the production of other researches that contribute to the HTA, whose theme has been greatly encouraged by both public and private sectors, emerging as a public health policy since 2010. It is noteworthy that the Clinical Engineering of the unit in this study it was informed about the occurrences found in monitors after the findings in this study in order to generate a service order and possible monitor evaluation.

CONCLUSION

Through this study in the setting addressed, it is clear that the heart rate was the major cause of alarms during the observation period. However, the evaluated technology has high specificity. However, is not quite sensitive to fatal rhythms such as pulseless VF, AF of rapid response and AF of slow response, because it does not meet the accuracy criteria used in this work for the recognition of arrhythmias simulated, which makes it uncertain as safeguard system during the postoperative period and, sometimes, in transport and perioperative period.

The analysis of heart rate and cardiac rhythm are important allies to assess the clinical condition of critically ill patients, since its variations can cause serious hemodynamic effects. However, the alarm of such variables, such as safeguard systems, need to be effective. In this regard, the alarm must be clinically relevant for a problem that, in fact, alert to the needs of the

patient, and the team should act in resolute manner as the origin and meaning of the alarm, fixing the problem before an adverse event occurs.

In this context, the nursing staff has increased participation to identify important hemodynamic changes, and situations with no clinical relevance and even false alarms, probably due to the long time next to the bed and the constant evaluations. Thus, patient safety depends on a properly sized team, trained and prepared to optimize early interventions as the event can be avoided, but also in situations of emergency nature.

It is clear, therefore, that despite its unquestionable importance in the natural history of a large number of diseases and economic impact associated with its use, the diagnostic tests, considering their qualities and consequently the accuracy, has been little used, especially in technologies.

Although it is important to train the staff on the management of alarms and parameterization, there are no application if the alarm does not ring. In addition, there is a clear lack of studies evaluating diagnostic tests, both from a clinical point of view and safety for the patient, as the economic. Despite numerous studies on the alarm fatigue phenomenon, little is known about the reliability of the technology park in intensive care units, contributing to improvement in teaching and research in nursing.

From these results, this study also allowed the reflection that the intervention strategy most appropriate and safe appears to be the involvement of clinical engineering in the prevention and, in particular, corrective maintenance of monitors that showed lack accuracy, providing uncertainty for patients. Moreover, the involvement of managers in HTA studies can contribute significantly to the possible incorporation of safer technologies from the point of view of cardiovascular surgery.

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CONTRIBUTIONS

Andrezza Serpa Franco and **Amanda Moreno Miranda** contributed to study design, data collection and analysis, writing and review. **Flavia Giron Camerini** participated in the study design, writing and approval of the final version. **Roberto Carlos Lyra da Silva**, **Vanessa Galdino de Paula** and **Monica de Almeida Karam** contributed to the critical review of the final version.

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