








ORIGINAL ARTICLE

PARAMETERIZATION OF RESPIRATORY RATE ALARMS IN MECHANICAL VENTILATORS OF PATIENTS DURING THE BATH

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ABSTRACT

Objective: to measure the effects of parameterizing the audible respiratory rate alarms of mechanical ventilators to reduce the number of alarms triggered during bed bath. **Method:** pragmatic clinical trial, to compare the number of alarms of the mechanical ventilator, in the groups: intervention - the Respiratory Rate alarms were parameterized at the beginning of the bath; control - no parameterization performed. Study registered on 27/08/2019 in the Brazilian Registry of Clinical Trials, RBR-6y6tyc, Rio de Janeiro, Brazil. **Results:** Regression models showed that parameterization, performed and maintained during and after bath in the intervention group, had the effect of increasing the average number of high respiratory rate alarm triggers by 12.5 and 6.4 times, respectively; and had no effect on low respiratory rate alarms. **Conclusion:** The contribution of this study is to assist health professionals in formulating protocols for individualized parameterization of alarms for Mechanical Ventilators.

DESCRIPTORS: Ventilators, Mechanical; Clinical Alarms; Nursing Care; Healthcare Personnel Alarm Fatigue; Baths.

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INTRODUCTION

Intensive Care Units (ICU) have a set of medical assistance equipment (MAE) used for patient treatment and monitoring. The MAEs have an audible and visual alarm system that can assist the interdisciplinary team professionals in caring for and solving the patients' problems⁽¹⁻³⁾.

For the safe and effective use of MAEs, it is necessary that users (components of the multidisciplinary team) develop skills and competencies necessary to master the use and operation of all their functions and resources, including alarm systems, to reduce unnecessary noise⁽⁴⁻⁶⁾. According to the International Electrotechnical Commission (IEC), in 2014, the functions of alarms are to alert and assist professionals in the early identification of aggravations, signaled by altered vital data or technical failures⁽⁷⁾.

The Emergency Care Research Institute (ECRI) in 2019 placed mechanical ventilator (MV) alarms among the top 10 health technology hazards, given the frequent reports of incidents related to improper parameterization of Mechanical Ventilators MV alarms, which can put patients at risk of brain injury due to hypoxia or death⁽⁸⁾.

The problem of this study is related to the risk caused by audible respiratory rate (RR) alarms of the MV sounding unnecessarily at certain times, such as when mobilizing the patient during bed bath; and the risk of the alarms not sounding when necessary. Both risks can be originated by inadequate parameterization of alarms, adjusted by the professionals of the interdisciplinary team, and can cause both alarm fatigue and concealment of relevant clinical alarms, negatively influencing patient safety. In this sense, the research hypothesis is that parameterization of MV alarms decreases the incidence of audible RR alarms in the bed bath.

Regarding the MAEs alarms, there are at least three factors that must be considered critical by the user (professional who operates the technology) to achieve the goals of using the equipment safely and effectively: the reliability of the data and information passed by the MAEs; clinical change, and consequently the patient's vital data at various times, such as during a bed bath; and the time for interpreting the information and making decisions, understood in this study as response stimulus time^(1,9-10).

Currently, it is paradoxical to think that alarms, the primary sources of information about changes in the patient's clinical condition and so essential to inform decisions and shorten the time for implementation of clinical procedures, may be obstacles in the ICU to achieve these goals⁽¹¹⁻¹²⁾.

Among the causes of this paradox, the alarm fatigue phenomenon is characterized by the delay and/or non-response to alarms in the ICU, due to desensitization of professionals to MAEs alarms⁽¹³⁻¹⁴⁾. The delay in response time to alarms triggered by the MAEs has been the subject of research in many studies, including in Brazil. However, there are few studies that have evaluated the effect size of other interventions, such as individualized parameterization of physiological variables monitored by the MAEs⁽¹⁵⁻¹⁷⁾.

From these reflections, the motivation for this study arose with the purpose of providing intensivists with real-world scientific evidence to support the development and incorporation of clinical protocols for the individualized parameterization of MV respiratory rate alarms, starting from the following research question: "Does parameterization of the MV Respiratory Rate alarms, immediately at the beginning of the bed bath, reduce the number of audible alarms triggered by the equipment, related to this vital sign, during the performance of the procedure?"

The aim of the research, therefore, was to measure the effects of parameterizing the audible respiratory rate alarms of mechanical ventilators to reduce the number of alarms triggered during bed bath.

METHOD

Pragmatic, real world randomized unblinded clinical trial to compare the number of alarms of the MaquetR SERVO AIR Mechanical Ventilator model in the groups: intervention and control. The CONSORT (Extension for Pragmatic Trials Checklist)⁽¹⁸⁻¹⁹⁾ from the Equator network was used to assist in the construction of the manuscript.

Participant eligibility criteria were adults aged 18-100 years, intubated or tracheostomized; with at least one uninterrupted hour of Invasive Mechanical Ventilation (IMV). Exclusion criteria were patients presenting immediately before the bath with respiratory excursion per minute (RIPM) ≥ 36 or IRPM ≤ 11 ; patients in controlled mode and with Richmond Agitation Sedation Scale (RASS) ≤ -5 . Data collection was performed in a five-bed ICU of a state hospital in Rio de Janeiro.

The intervention group consisted of the observation periods (each observation period corresponded to one patient), in which alarms were parameterized only by the researcher, in the ICU of a State Hospital in Rio de Janeiro, between January and April 2019, immediately at the beginning of the bed bath of patients eligible for the intervention group.

The observation of both the intervention and control groups was performed only by the researcher, who stayed in the ICU, near the beds of the eligible patients, 30 minutes before the bed bath and 90 minutes after the beginning of the bath of the eligible patients.

Emphasizing the inexistence of guidelines for the incorporation of a parameterization protocol for audible alarms of MAEs and, at the same time, focusing on the importance of culture change in alarm parameterization in order to improve patient safety, the lower limit of the parameterization of RR alarms in this study followed the reference value of lower limit of RIPM of the Brazilian Recommendations for Mechanical Ventilation of the Brazilian Intensive Care Medicine Association (AMIB) (*Associação de Medicina Intensiva Brasileira*), whose value of an individual at rest must be at least 12 IRPM. For the upper limit of the parameterization, we followed the evidence that the parameterization can be made for the alarms to go off when the RIPM is higher than 35⁽²⁰⁻²¹⁾.

According to the above and the practical experience of the researchers of this study on the subject, the RR alarm limits in the patients of the intervention group were parameterized between 11 and 36 RIPM, for lower and upper limit, respectively, in the MV, immediately at the beginning of the bed bath.

The justification to parameterize this variable in the ventilators of all patients in the intervention group was the presence of the researcher close to these patients' beds during the data collection period, as well as the presence of the unit's team professionals to perform the bath. It should be noted that, if deemed necessary, the unit's team could change the borderline values of the parameterization previously determined in the research protocol, a fact that did not occur on any day of data collection.

It is noteworthy that the parameterization of High Respiratory Rate (HRR) and Low Respiratory Rate (LRR) alarms performed by ICU professionals was in all observation intervals in the control group and in the 20 minutes before bathing in the intervention group, with an upper limit greater than 36 and a lower limit less than 11.

The control group was composed of the observation periods in which there was no manipulation by the researcher in the parameterization of the alarms.

Regarding the sample, the minimum number of observation periods in each group was set to 35 periods, considering a margin of error of three alarms and a confidence level of 95%.

Random allocation of patients to each group on each observation day was simple with the aid of the WIN PEPPI computer program. Randomization resulted in 39 observation periods in the intervention group and 40 in the control group. Each patient, per observation, could be allocated either to the intervention group or to the control group, and the parameterization moment performed by the researcher coincided with the beginning of the bed bath.

Data regarding pathology, age, and weight of each patient were obtained from the medical records, and the MV variables were obtained from the records provided by the MV itself (extracted to a flash drive at the end of each patient's observation). First, the data from the medical records were noted in the data collection instrument on the day of observation of the eligible patients, and later, together with the MV records, were organized in a Microsoft Excel® spreadsheet, and analyzed in the statistical program R version 3.6. 1 to estimate the effects of covariates on the number of alarms, both in the intervention and control groups, where they were adjusted with Poisson Regression models and Negative Binomial Regression models from the R Commander (Rcmdr) and Generalized Linear Mixed Models using Template Model Builder (glmmTMB) libraries⁽²²⁾.

The development of the study complied with resolution 466/12 of the National Health Council and was approved by the Ethics and Research Committee of the proponent (opinion number 3,027,764) and coparticipant (opinion number 3,110,322) institutions. The study protocol is registered in the Brazilian Registry of Clinical Trials (ReBEC) under number RBR-6y6tyc. This study is a cutout of the first author's doctoral thesis, and was conducted in a five-bed ICU, which serves only patients with onco-hematologic diseases, in a state hospital in Rio de Janeiro. Data were collected between January and April 2019.

RESULTS

As described in Figure 1, the result of the allocation of study participants was 39 observation periods in the intervention group and 40 in the control group, with no exclusion in any group.

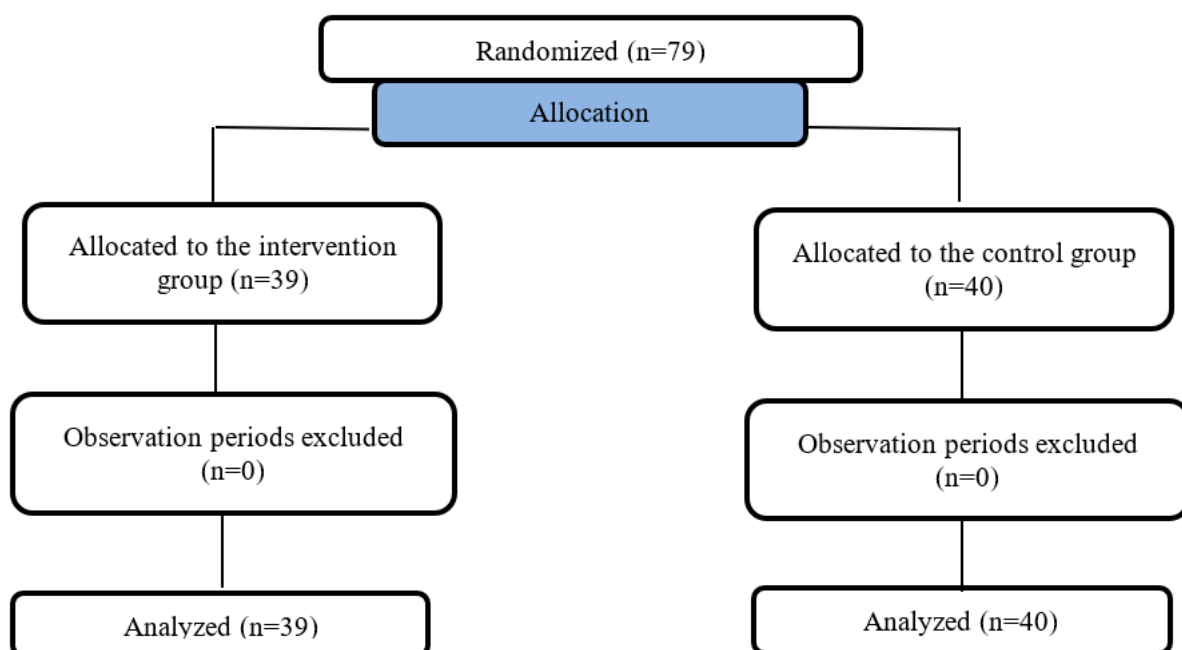


Figure 1 - Result of the allocation of study participants. Rio de Janeiro, RJ, Brazil, 2019. Source: Authors (2019).

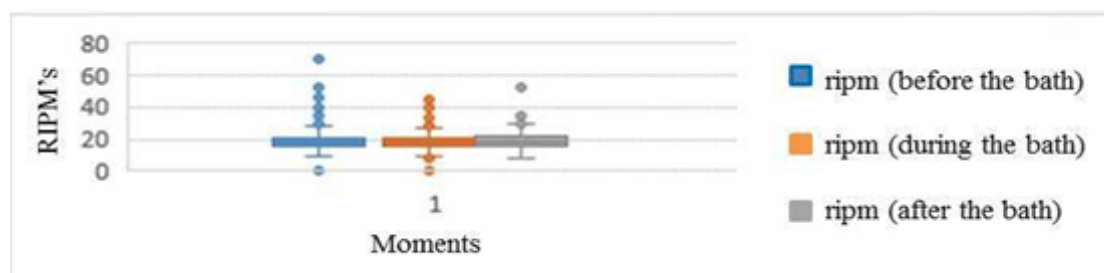
Each of the observation periods in the intervention and control groups lasted one hour (20 minutes before, during and after the bed bath), totaling 79 hours of observation. In Table 1, in both groups the sound alarms of HRR and LRR had low incidence.

Table 1 - Numerical summary: alarm count. Rio de Janeiro, RJ, Brazil, 2019

Variable	Group	Moment	Average	SD	0%	25%	50%	75%	100%
HRR	Parameterized	Before (1st to 20th)	0,10	0,38	0	0	0	0	2
		During (21st to 40th)	0,28	0,79	0	0	0	0	4
		After (41st to 60th)	0,46	1,23	0	0	0	0	6
	Not Parameterized	Before (1st to 20th)	0,42	2,22	0	0	0	0	14
		During (21st to 40th)	0,10	0,37	0	0	0	0	2
		After (41st to 60th)	0,20	0,79	0	0	0	0	4
LRR	Parameterized	Before (1st to 20th)	0,20	0,92	0	0	0	0	5
		During (21st to 40th)	0,61	1,91	0	0	0	0	8
		After (41st to 60th)	1,43	3,81	0	0	0	0	15
	Not Parameterized	Before (1st to 20th)	0,02	0,15	0	0	0	0	1
		During (21st to 40th)	0,10	1,1	0	0	0	0	7
		After (41st to 60th)	0,10	0,9	0	0	0	0	6

Note: SD: standard deviation; HRR: high respiratory rate; LRR: low respiratory rate.

Source: authors (2019).



Note: RIPMs: respiratory incursions per minute.

Figure 2 - Boxplot of the respiratory incursions per minute of all observation periods, of both groups, in the 20 minutes before, 20 minutes during and 20 minutes after the parameterization of respiratory rate alarms. Rio de Janeiro, RJ, Brazil, 2019. Source: Authors (2019).

From the results of Poisson Regression with excess of zeros (regression indicated for results with an excess of periods without any event/outcome), described in Table 2, related to HRR alarms, it was found that in the multivariate model, where all covariates are controlled (p -value <0.05 was considered as statistical significance): the parameterized group had an 85% decrease in the average number of alarms considering all moments of each observation period compared to the non-parameterized group; and that, regardless

of the parameterization, the effect of the bath moment was to reduce by 80% (in the first 20 minutes) and by 45% (21st to 40th minute) the average number of alarms.

Table 2 - Poisson regression with zero inflation. Response variable: high respiratory rate alarms. Rio de Janeiro, RJ, Brazil, 2019

Variables	Univariate - exponential coefficient	p-value	Multiple - exponential coefficient	p-value
Non-Parameterized Group*	1			
Parameterized Group	0,61(0,34-1,07)	0,08	0,15 (0,04-0,52)	0,002870
1st to 20th minute before*	1			
1st to 20th minute during	0,39 (0,18-0,84)	0,0175	0,20 (0,05-0,74)	0,015793
	1			
21st to 40th minute after	0,72 (0,38-1,37)	0,3268	0,55 (0,20-1,45)	0,227913
Without sedation*	1			
With sedation	0,16 (0,06-0,41)	0,000124	0,18 (0,06-0,49)	0,000887
Non-Parameterized Group X 1st to 20th minute during* Interaction			1	
Interaction Parameterized Group X 1st to 20th minute during			13,58 (2,14-85,97)	0,005589
Non-Parameterized Group X 21st to 40th minute after* Interaction			1	
Interaction Parameterized group X 21st to 40th minute after			7,41 (1,52-35,98)	0,012924
Inflated Zero Model Intercept				0,0000002

Note: *Reference category.

Source: Authors (2019).

It was also found (Table 2) that the effect of sedation compared to patients not using sedation was to decrease the average number of alarm triggers by 82%; and the effect of the interaction group and time obtained a significant result, where the parameterized group at the time during and after the bath compared to the time before the bath had the effect of increasing the average number of alarm triggers by 12.5 and 6.4 times compared to the non-parameterized group at the same times.

In this process the estimation including the effect of patients (random effect) was verified and the difference was minimal compared to the estimation without the patient effect.

The results of the fit of the multivariate negative binomial regression model (also indicated for results with excess periods without any event/outcome) for the number of alarms of the LRR are presented in Table 3 (p-value <0.05 was considered as statistical significance). These results show that: a) the observations of the parameterized group compared to the non-parameterized had 4.07 times more alarms triggered; b) after the beginning of the bath (21st to 40th minute), compared to before, there were 2.6 times

more alarms triggered; c) patients in the assisted-controlled ventilatory mode had a 90% decrease in the mean number of alarms triggered compared to the controlled mode.

Table 3 - Negative binomial regression without inflation of zeros. Response variable: low respiratory rate alarms. Rio de Janeiro, RJ, Brazil, 2019

	Univariate - exponential coefficient	p-value	Multiple - exponential coefficient	p-value
Non-Parameterized Group*	1			
Parameterized Group	5,48 (1,58- 18,94)	0,00712	5,07 (1,46- 17,53)	0,010307
1st to 20th minute before*	1			
1st to 20th minute during	2,06 (0,51- 8,26)	0,3041	2,18 (0,54- 8,70)	0,267949
	1			
21st to 40th minute after	3,18 (0,86- 11,75)	0,0824	3,65 (0,99- 13,45)	0,051269
Controlled Mode*	1			
Assisted-Controlled Mode	0,09 (0,02- 0,34)	0,000254	0,10 (0,02- 0,35)	0,000327

Note: *Reference category.

Source: Authors (2019).

DISCUSSION

Nursing care by nurses to patients requiring mechanical ventilation, as well as the developments related to the use of MV in the ICU, are currently inserted in the advanced practice nursing (APN). APN involves a specialized knowledge base, acquisition of skills such as critical thinking, ability to make complex decisions, and technical skills. The attributes of this concept involve clinical expertise, leadership, autonomy, and role development⁽²³⁾.

Nursing surveillance of patients in the ICU includes assessment, interpretation of data, recognition of a problem and meaningful response. Thus, alarms assist in identifying and responding to the first signs of disturbances in the patient's organ systems, which are usually preceded by changes in vital signs monitored in the MAEs by the nursing team⁽²⁴⁾.

Alarm fatigue leads to different forms of alternative and unsafe solutions, including a delayed response, disabling alarms, making the volume inaudible, or adjusting alarm settings to dangerous limits, all of which can result in lethal alarm loss⁽¹⁾.

Therefore, if alarms are parameterized in an individualized way, with reviews of these settings whenever necessary, professionals will incorporate an important method for improving patient safety, preventing serious adverse events such as cardiac arrest.

The clinical moment and peculiarity of each patient must be considered, and thus, increase the chance of avoiding that a certain clinical alteration worsens, therefore, avoid complications resulting from the exponential evolution of the organic disorder, from the signaling to the interdisciplinary team by sound alarms. Thus, by signaling the alarms, the healthcare team will have a subsidy for the early incorporation of immediate nursing actions to solve the altered vital signs and, consequently, the patient's health problems,

avoiding clinical complications, which could also lead to an increase in hospitalization time and hospital costs⁽²⁵⁾.

To guide the individualized parameterization of MV alarms, it must be taken into account the junction of the previous evaluation of the patient's baseline clinical data; the presence or absence of professionals from the interdisciplinary team at the patient's bedside; and the patient's mobilization related to bed bath, diagnostic imaging and laboratory tests, physical examination, change of decubitus, procedures such as orotracheal suctioning, insertion of indwelling urinary catheter and nasogastric tube, dressings, among others. The availability by the MAEs of retrospective electronic records of vital data may contribute to research that aims to help nurses in performing the parameterization of alarms.

The management of the use of MAEs alarms in the ICU makes it necessary to train professionals to perform individualized parameterization of the MAEs alarms, helping them to master the use of technology and enabling care to occur with the least possible obstacles. Professional commitment is also fundamental for the optimization of the management service.

A management strategy used in some hospitals is central monitoring (alarm towers), where the alarm noise is diverted from the patients' bedside to this tower, to provide more comfort and optimize the patients' sleep. Studies show that professionals working in the ICU have difficulty in adequately defining the settings of the MAEs alarms, due to lack of knowledge about the appropriate limits⁽²⁵⁾.

The Joint Commission assists, accredits, and certifies healthcare organizations and programs in the United States. This body guides that safety in alarm settings must be a priority in ICUs and attributed incidents and deaths related to alarms and alarm fatigue⁽²⁶⁾. In Brazil, AMIB recommends that MV alarm settings be made in an individualized manner, using specificity and sensitivity criteria appropriate for the patient's clinical status⁽²⁰⁾.

In one study, during 40 hours of observation, 227 alarms from the multiparameter monitor were recorded (mean of 5.7 alarms/hour) and 199 alarms from infusion pumps, hemodialysis, mechanical ventilators, and Intra-Aortic Balloon (IAB) (mean of 4.9 alarms/hour), totaling 426 alarms, a total mean of 10.6 alarms/hour. Multiparametric monitors have been shown to generate more alarms when compared to other MAEs⁽⁴⁾. Unlike alarms from multiparameter monitors, MV alarms behaved differently in the ICU, as identified in this study. The excessive silence may also reflect the alarm fatigue phenomenon.

The ECRI Institute, which addresses patient safety, has ranked improper parameterization of MV alarms as the fourth greatest danger to patients for 2019, as it can put them at risk of hypoxic brain injury or death. Leaks, disconnections, and other failures associated with MV components are common and can quickly lead to patient harm if the condition is not identified and corrected promptly. Properly parameterized alarms can prevent such consequences. In 2018, the Institute initiated investigations into deaths resulting from MV circuit disconnections during which alarms were not activated and silence prevailed. In two cases since the beginning of 2018, MV alarms were not parameterized properly. ECRI Institute reaffirms that healthcare institutions need to insert policies on individualized parameterization of MV alarms in patient care practices, parameterized by ICU multidisciplinary team professionals, and incorporation of protocols to verify that policies are being followed⁽⁸⁾.

In the service studied, the use of an alarm management program was not evidenced. A study showed that the incorporation of an alarm management program in a healthcare institution improved clinical results in patient care⁽²⁷⁾. The improvement may be justified by the professionals' appropriation of the MAEs usability, an extremely important factor for alarm management in ICUs⁽²⁸⁾.

It is noteworthy that in both types of RR alarm triggers and in both groups, the incidence of alarms was low, considering each observation period, because in most cases,

the RIPM of the patients did not exceed the limits established in the parameterization used in this study, nor in the conventional parameterization used in the researched unit, both at the lower and upper limits of the RF alarm settings, as observed in the boxplot related to the variations of the RIPM.

However, the variables "sedation" and "mode" influenced the average number of alarm triggers, leading to the reflection that these ventilatory conditions should be considered when performing individualized parameterization of the MV alarms.

As to the limitations of the study, we highlight the fact that only the sound alarms of the MV RR were parameterized, and that data collection was carried out in an ICU with five beds. It is also noteworthy that a gap was evidenced in the literature of publications of studies specifically about parameterization of respiratory rate alarms of mechanical ventilators.

CONCLUSION

The parameterization of HRR and LRR sound alarms immediately at the beginning of the bed bath did not have the effect of reducing triggers, according to the effect measures described in the results of this study. For better patient care safety and quality, among other strategies, healthcare institutions should implement alarm management in the sectors that use the EMAs, and the multidisciplinary team professionals should change the culture in the parameterization of RR alarms and other variables, conducting periodic training on the usability and individualized parameterization of the EMAs alarms. The studied service does not have this management.

The contributions of this study to ICU practice can be delimited, according to the estimates made, of the magnitude of the effect and influence of alarm parameterization and other explanatory variables, such as the use of sedation, in the incidence of sound alarms, which may guide the nursing and multidisciplinary professionals to the importance of individualized parameterization of RR alarms in the ICU, improving patient safety. It may also contribute to help health professionals who work in the ICU, for the formulation of protocols for parameterization of alarms of the MV RR. Other studies may continue the theme, addressing other alarms and scenarios.

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