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Original Article

Designing the vocal alarm and improving medical ventilator

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Abstract

BACKGROUND: Today, as many as 1.5 million Americans use ventilators once in a year. .Response to mechanical ventilation alarms remains to be one of the most challenging tasks facing physicians, nurses or other medical personnel in the ICU. In the present study we aimed to compare the response times to "vocal alarms" and "visual or audible ones".

METHODS: In the present study we developed a system to evaluate the "Vocal Alarm" and improve the medical ventilator "Benet 7200 Alarms" with it. Ventilator generates the alarms when patient has any problem. The time of Activation & Deactivation is recorded. The survey was done in central ICU for six days, 3 days with vocal alarm, and 3days with "Beep" alarms and detected Alarm events then recorded seventy-two hours of data for each type of alarms. All of events information saved in the memory and SPSS was used to determine difference between two types of alarms.

RESULTS: On the average, the duration of the ventilator alarms activation were 33 ± 21 seconds for vocal alarms and 60 ± 46 for audible "Beep" alarms. The response times for vocal alarms were significantly lower (P = 0.001).

CONCLUSIONS: The response times for normal "Beep" alarms were longer than vocal alarms.

KEY WORDS: Medical ventilator, vocal alarm, equipment alarm system.

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A medical ventilator, an automatic machine that moves breathable air mechanically into and out of the lungs, would provide the mechanism of breathing for a patient, who is physically unable to breathe, or breath insufficiently.[1] Nowadays, as many as 1.5 million Americans per year use ventilators. Ventilators help premature infants breathe until their lungs are more developed and help patients recovering from the effects of anesthesia and sedatives given before and during surgery. Patients with heart disease, Chronic Obstructive lung disease, accident victims, and other emergency care may also require mechanical ventilators.[2] In hospital, alarm sounds are found everywhere; for example, there are about 50 alarms in the operating room and intensive care unit, not just in the clinical ward. Near to 20 years has become a greater attention to patient safety,[3] when alarms generated by medical equipments, fewer than half would be recognized by medical personal.[4] When we work in ICU and same area for a long term and find that alarms are used in many medical equipment applications, but they are often work less than optimal because their design and implementation do not always take the customer idea and needs.[3] Whereas all ventilators are equipped with alarms and detect critical events. Ventilator alarms are only audible beeps that are often difficult to hear outside of the patient's room. Moreover, the more number of false-positive alarms generated by medical equipment; this problem is because of that the ventilator alarms can blend in with other accustomed sounds of the intensive care unit (ICU) [5]. It is very important in patient management , As a

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result, some critical ventilator alarms go unrecognized for periods of time that result in permanent patient harm or death. In 2002, the Joint Commission on Accreditation of Healthcare Organizations published a new Sentinel Event guideline aimed at preventing ventilator-related deaths and injuries.

In 2002, Joint Committee for the Accreditation of Healthcare Organizations reviewed 23 reports of death or injury that were related to mechanical ventilation. Nineteen of those events resulted in death, and four resulted in coma; 65% were related to alarms. The issues included delayed or no response to the alarm; the alarm was off or set incorrectly; no alarms were present for certain types of ventilator disconnections; or the alarm was not audible in all areas of patient care.[6] Reports of ventilator alarm failures are continuing. It is interesting that in unstressed conditions humans do not easily learn and remember the significance of more than eight sounds, and in a study, the results were interesting in the sense that staff did not recognize all the alarms. The ICU nurses correctly identified only 39% of alarm sounds.[7] although , A few studies were done that detected response times to alarms in ICU healthcare workers but we reviewed previous studies to see anesthetists responses, that results showed , more quick response to visual or auditory alarms.[8] Likewise, another study found that only eight (0.5%) out of 1,455 alarms soundings in the ICU, indicated potentially life-endanger problems.[9] In fact, medical personnel were often the first line people to respond to the ventilator events. In some situations, the ventilator alarm is heard, but valuable time would be lost while the nurses try to determine which alarm is activated on the ventilator. There are many reported problems with auditory warnings in critical care areas such as the intensive care unit (ICU).[10]

Based on our previous experience, we needed to find a method to notify medical personnel of critical ventilator events that would be accurate, reliable, and instantly recognizable and also find a way that ventilator alarms would not blend in *with* other accustomed sounds of the intensive care unit (especially in multi chamber ICU type).

In the present study we aimed to compare the response times to “vocal alarms” and “visual or audible ones”. Since visual alarms required to be looking at the monitor in order to see, the alarm's cause and audible alarms can be blend in with other accustomed sounds of the intensive care unit.

Method

This study focused on the alarms of mechanical ventilators in the Multi chamber ICU Type. The repeated vocal sounding of ventilator alarm was a major reason that causes nurses presented at the patient’s bedside. At the time of the study, Siemens and Bennett 7200 mechanical ventilators were used in ICU of ST. Alzahra hospital. The visual signal of these tools was a 15 mm diameter red light positioned on the top of the machine and the type of audible alarms used in this setting were beeps of the type incorporated into many medical devices. We selected Bennett 7200 mechanical ventilator with 12 visual or auditory alarms to determine patient's problems and 3 alarms for mechanical ventilator failures. these alarms include;High pressure limit, Low inspiratory pressure, Low PEEP/CPAP pressure, Low exhaled tidal volume, Low exhaled minute volume, High respiratory Rate, Inspiratory /Expiratory Ratio (I:E), Apnea, Low pressure O2 INLET, Low pressure Air INLET, Exhalation Valve Leak, Low Battery, safety valve open, ventilator inoperative and back up ventilator.

We developed a system to evaluate the “Vocal Alarms” and enhance the medical ventilator “Bennett 7200 Alarms” with it. Ventilator generated the alarm(s) when patient had any problem. The time of alarm Activation and Deactivation was recorded in EEPROMs (Electrical Erasable Programmable Read only Memory). Proposed system recognized the alarms by checking their relevant LEDs (Light Emitting Diode) status, and a laptop computer, which was connected to the system over the ventilator machine, and recorded the time. The visual signal was a 15 mm diameter red light positioned on the top of the machine. The audible "Beep" alarm had a sound like many other medical devices. The vocal alarms of our system were designed in Persian language and assigned priorities, by which the system chooses the most critical alarm to play. A pilot study was done in central ICU for six days (3 days with vocal alarms and 3 days with "Beep" alarms). Another issue is that sound alarms are often required to be self-checked when ventilator turns on. For example, during self-checking states of the equipment or when it is being checked by anesthetist or medical personnel, the new piece would perform self –check of the vocal sounds as well. During a four-month study (March 2007through June 2008), we designed and implemented the system which then was tested several times in medical equipment maintenance unit. Some of the alarms were generated manually to test the vocal alarms with different tones, voices, play speeds and loudness settings. On average, the ventilator vocal alarms length was between five to ten-seconds.

The vocal ventilator alarm system was initially tested in Central ICU of Alzahra Hospital from June through September 2008. This system checks the activation and deactivation events every one second. The ventilator also reports date and time (table 1).

This report was saved as an Excel file. The analysis of ventilator events information not only increased our knowledge about the number and duration of the events, but also allows respiratory care management to identify ventilator problems and showed the trend of the ventilator events during the past 3 days.

For trial, we determined the normal ventilator alarm settings and turned on the ventilator with our system (vocal alarm) and then it was connected to a patient. The monitor program on the system recorded the ventilator events information in its memory. After 3 days, the ventilator alarms returned to their original states (Beep mode). Then, we recorded the ventilator events for another 72h. (This system now collects this information for all types of ventilator events). Finally, the ventilator event information were analyzed by T student test to determine difference between two alarms type mean and drawing graph on Excel software too.

Table 1. A ventilator alarm report

Alarm Type	Activation and Deactivation (A/D)	Date	Time
15	A	2008-08-13	12:48:41
00	A	2008-08-13	12:48:47
02	A	2008-08-13	12:48:53
05	A	2008-08-13	12:49:02
06	A	2008-08-13	12:49:11
13	A	2008-08-13	12:49:11
15	D	2008-08-13	12:49:11
01	A	2008-08-13	12:49:17
03	A	2008-08-13	12:49:34
05	D	2008-08-13	12:49:44

Table 2. Statistics of response times to ventilator alarms in central ICU

Ventilator Alarm	N	Mean	Std. Deviation
Vocal	1734	0:00:46	0:00:21
Beep	563	0:00:33	0:01:00
p-value =0:001	T=4.945	df =2295	

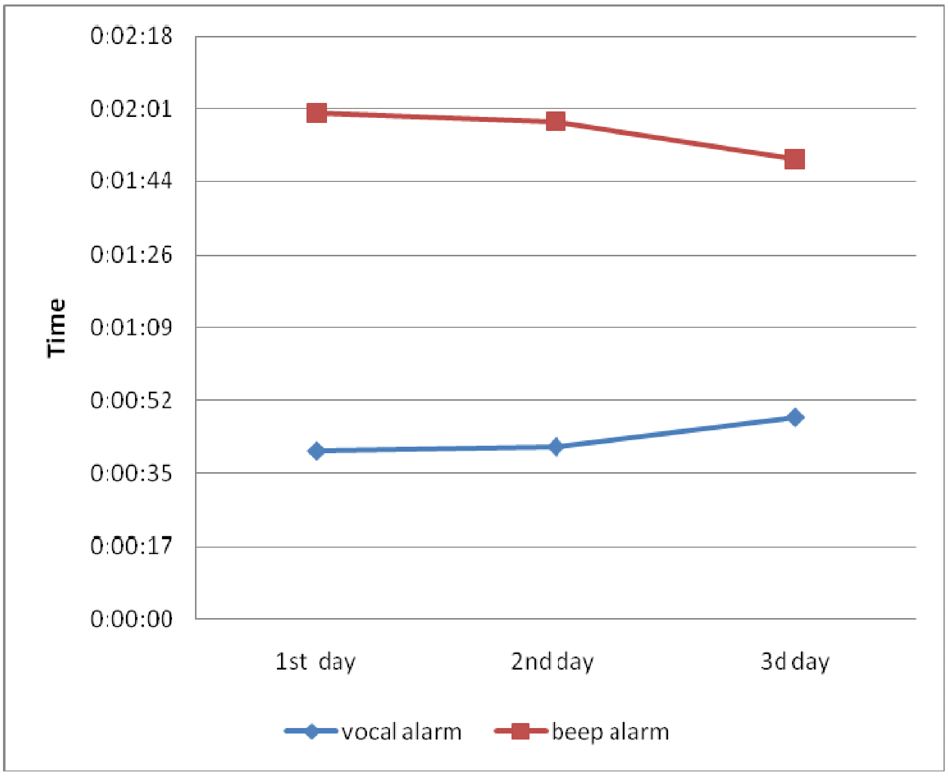

Figure 1. Comparison of the mean response times among beep and vocal ventilator alarms for alarm NO 13

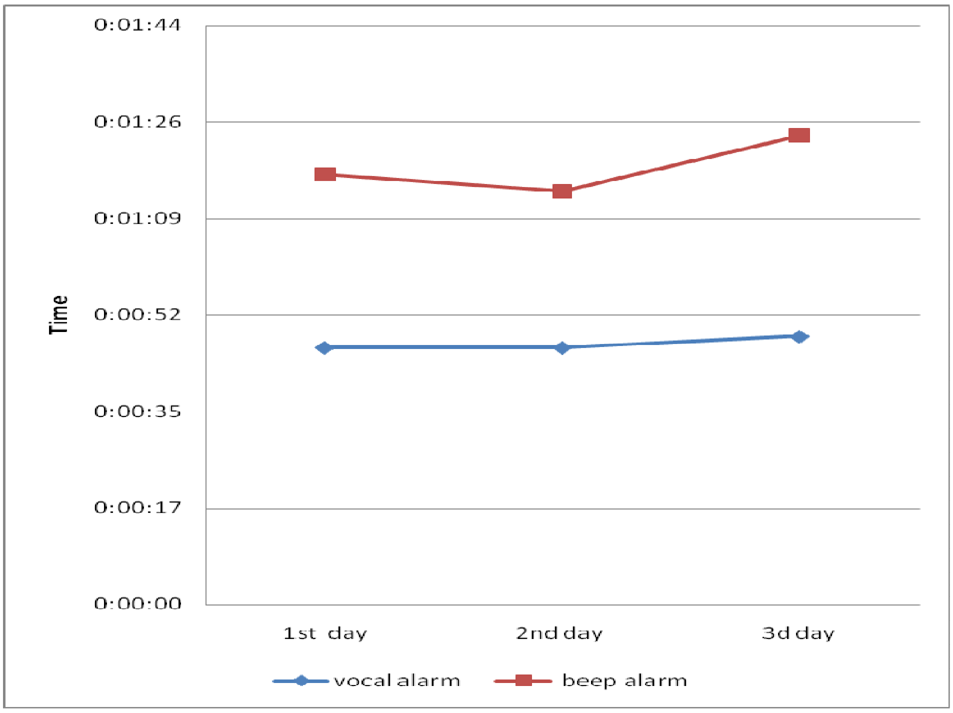

Figure 2. Comparison of the mean response times among beep and vocal ventilator alarms for all alarms

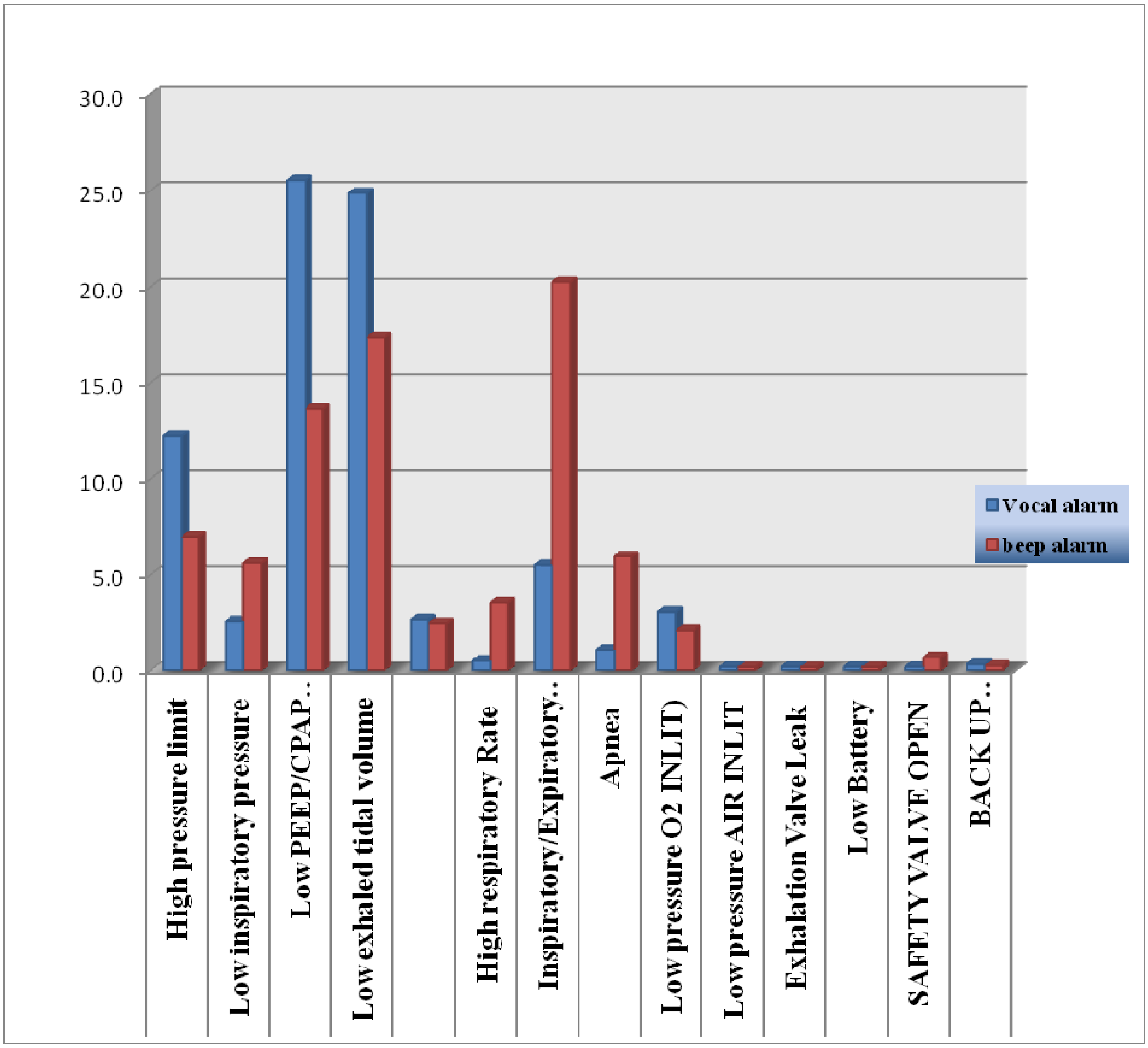

Figure 3. Frequency of ventilator alarms during the study

Results

The data included seventy-two hours recordings (1734 alarm events) for vocal alarms, and also seventy-two hours recording (563 alarm events) for audible "Beep" alarms. Then, we used T student test to compare the means of the response times to ventilator alarms in the beep and vocal ones in central ICU. On the average, the duration of the ventilator alarms activation were 33±21 seconds for vocal alarms and 60 ± 46 for audible "Beep" alarms (Table 2). Most ventilator alarms were responded within 25 to 35 seconds during the data analysis for this project, we observed that all of the alerts were activated and deactivated (responded) within one minute or less. Other data were composed the period time of ventilator events, and the comparisons of the mean response times among beep and vocal ventilator alarms for alarm number 13. Alarm number 13 represents a combination of all alarms together, which is shown in Figures 1, 2 and 3.

Discussion

The study results indicate that the vocal alarms were noted and recognized better from the outset. The vocal alarms would be easy to localize, resistant to masking by other sounds and therefore, they would not easily miss and interfere with other communications. In addition, at the critical moments, when it is necessary, they would be easy to distinguish from other alarms, and easy to retain. Another advantage of the vocal alarms is clear detection of the problems without necessity of any pre-learning. This is because of that the system of the Bennett 7200 mechanical ventilators were developed to distinguish among different types of alarms generated by the ventilator. Our result showed that the mean of the response times reduced for vocal alarms.

While, other studies reported that audible alarms recognized 39% of the time by nurses and 40% of the time by anesthetists and operating-room technicians correctly,[3] this study showed that not only people learn and remember vocal alarms better than the other audible sounds, but also, they would respond more quickly to them. This study additionally identified that the majority of problems announced by ventilator alarms (27%), were caused by low PEEP/CPAP or Low exhaled tidal volume and they were showed as disconnection.

Another problem the staffs that have the experience working in ICU account for is the number of false alarms that sound. These alarms activate when the patient moves, during respiratory tract suction or when electrodes are loosen; they do not necessarily signal a change or deterioration in the condition of the patient. An Australian study of 2,000 incident reports identified only 317 incidents responsible for problems with ventilators and disconnections caused the majorities (47%).[11] another study to determine the predictive value of alarms from pulse oximeters, end-tidal PCO_2 monitors, ventilators, and electrocardiographs in a pediatric ICU found that 68% were false and the positive predictive value for ventilator alarms was only 3%.[12]

A study in the department of Anesthesia, St George Hospital, Sydney, measured and compared the response times to audibly or visually presented alarms in the operating theatre. The response times by the anesthetists to cancel randomly generated visual and audible false alarms were measured during maintenance of routine anesthesia. Alarms were generated and times were recorded by a laptop computer on the anesthetic machine. The visual signal was a 15 mm diameter red light positioned next to the physiological monitor mounted on the top of the machine. The audible alarm was a Sonalert buzzer of the type incorporated into many medical devices. Their result indicated that nineteen anesthetists provided a total of seventy-two hours of data (887 alarm events). The response times to visual alarms were significantly longer than the response times to audible alarms (it is not necessary to be reported).[13] The research data suggested that vocal alarms appear to be much better in the hospital environment. This study suggests that it is safer to rely on speech alarms when time-critical information such as oxygenation percentage, apnea, and ventilator disconnection is happened. Audible alarms would appear to be more appropriate for conveying less urgent information. On the other hand, researchers initially proposed using melodic alarms for medical environments. Those alarms were consisting of a sequence of notes of different pitches in a distinctive rhythm and the urgency would be indicated by playing the notes more rapidly. Their approach to alarm design was using, single all-purpose alarms, priority based alarms, equipment-based alarms, risk-based alarms, and risk-and-response based alarms. Selecting the latter, Kerr proposed alarms for hypoxia, ventilator problems, cardiovascular problems, interruption to perfusion, drug administration problems, and thermal risk, each in a low and high level of alarm and distinguished by melodic changes. There have been several evaluations of the melodic alarm recommendations. They have found that the responses to the medium-priority alarms were faster and more accurate than responses to the high-priority alarms. One would expect that a response to the high-priority alarms is faster and more accurate than those to the medium-priority alarms, but this was not the way the fact was.[14]

In our study, anesthetists or medical personnel suggested that it is better for sounds to vary in their patterns, number of tones in each alarm, and to increase the sounds tone after several repetitions.

Sobieraj et al study of the audibility of patient clinical alarms to nursing personnel was done during the first shift on a medical/surgical in-patient ward at William Beaumont Army Medical Center. The study was conducted during normal hospital operations, to determine whether patient alarms could sufficiently compete against environmental background noises. Patient clinical alarms were audible at distances of 95 feet or more with the room doors open, but they were not sufficiently audible to hospital staff members when the room doors were close or during floor-buffing activities. They suggest that, under these circumstances, hospitals may not meet Joint Commission on Accreditation of Healthcare Organizations 2004 National Patient Safety Goal, Section 6b. Because the audibility of patient clinical alarms directly affects patient safety, satisfaction, and quality of care. They provide recommendations for engineering controls and modifications to work routines.[15] Also, at the end of this research, medical personnel suggested that, infant large leaks around the endotracheal tube can be problematic due to the difficulty of maintaining tidal volume (patient cycling) of the ventilator causing frequent alarming. This issue needs further survey in the future. The new vocal /audio ventilator alerts were very distinct from any other type of alarms in the ICU and were virtually impossible to ignore. This will serve the design purpose to prevent prolonged duration of critical ventilator events. Although the Speech was not send to the nursing stations, but it could heard in the patient's room even if the door was close. Ventilator alarms generated during patient procedures may also represent patient discomfort.

The authors declare no conflict of interest in this study.

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