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ECG alarms during left ventricular assist device (LVAD) therapy in the ICU

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ABSTRACT

Background: In hospitalized patients with left ventricular assist device (LVAD), electrical interference and low amplitude QRS complexes are common, which could impact the accuracy of electrocardiographic (ECG) arrhythmia detection and create technical alarms. This could contribute to provider alarm fatigue and threaten patient safety.
Objectives: We examined three LVAD patients in the cardiac intensive care unit (ICU) to determine: 1) the frequency and accuracy of audible arrhythmia alarms; 2) occurrence rates of technical alarms; and 3) alarm burden (# alarms/hour of monitoring)
Methods: Secondary analysis.
Results: During 593 h, there were 549 audible arrhythmia alarms and 98% were false. There were 25,232 technical alarms and 93% were for artifact, which was configured as an inaudible text alert.
Conclusion: False-arrhythmia and technical alarms are frequent in LVAD patients. Future studies are needed to identify both clinical and algorithm-based strategies to improve arrhythmia detection and reduce technical alarms in LVAD patients.

Introduction

Alarm safety is a Hospital Based National Patient Safety Goal established by The Joint Commission in 2014.[1] In the hospital setting, clinical alarm systems used in bedside monitors are designed to alert busy caregivers about a change in a patient's condition to avert adverse events. While this is the goal of clinical alarms, previous research shows that patients in the intensive care unit (ICU) yield high numbers of false and nonactionable alarms (i.e. true alarms but no action needed) creating an environment for alarm fatigue.[2-8] Nurses who experience alarm fatigue become desensitized to alarms, causing them to inadvertently ignore clinically relevant alarms, which could lead to missed true events and threaten patient safety.[8-15] In one large observational study, Drew et al. found that 90% of ICU audible arrhythmia alarms were false.[4] False alarms tend to be concentrated in patients with altered mental status, use of mechanical ventilation, and in patients with certain electrocardiographic (ECG) features (i.e., bundle branch block [BBB], ventricular paced rhythms, and low amplitude QRS complexes).[4,5,16]

Technical alarms (i.e., artifact, ECG leads fail/off, arrhythmia suspend) during continuous ECG monitoring, though not audible, can contribute to alarm fatigue. In the aforementioned study, over 30% of the 2.5 million alarms that occurred in the one month study period were identified as technical alarms.[4] Technical alarms occur when the signal quality is degraded due to patient movement and/or device interference, in the case of artifact; the ECG leads on the torso become detached, or the integrity of skin electrode(s) are compromised. These conditions impede the ability of the monitor's algorithm to perform accurate analysis of the ECG signal for arrhythmias. In the case of artifact, arrhythmia algorithms are still active, but their

Abbreviation: AVR, accelerated ventricular rhythm; BBB, bundle branch block; BLS, Basic Life Support; ECG, electrocardiogram; ICD, implantable cardioverter defibrillator; ICU, Intensive Care Unit; LVAD, left ventricular assist device; NBP, non-invasive blood pressure; V-brady, ventricular bradycardia; V-Fib, ventricular fibrillation; VT, ventricular tachycardia

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accuracy may be hindered by the short periods of artifact. However, if the artifact last for longer periods (i.e., 20 of the last 30 s), it will eventually trigger an "ARRHYTHMIA SUSPEND" alarm. This particular situation suspends all arrhythmia analysis, including analysis of lethal arrhythmias (i.e., asystole, ventricular fibrillation [V-fib], or ventricular tachycardia [VT]), placing patients in an unsafe situation because true alarms could go undetected.

Among patients undergoing LVAD therapy, the presence of increased electrical artifact and low amplitude QRS complexes are common,[17,18] which could significantly impact the accuracy of the arrhythmia detection and ultimately create more false arrhythmia and/or technical alarms. Some types of LVADs can create an electromagnetic field that interferes with pacemakers and ECG recordings causing 60-cycle interference.[19,20] An example of a 60-cycle type of technical alarm in a patient with an LVAD is shown in Fig. 1. Current Practice Standards for In-hospital ECG Monitoring in patients with mechanical circulatory support, including LVADs, identify ECG monitoring in the ICU as a Class I recommendation; hence, ECG monitoring is indicated.[21] Thus, while continuous ECG monitoring is standard practice in the ICU for LVAD patients, the occurrence of false arrhythmias and/or technical alarms may impact both arrhythmia detection accuracy and increase alarm fatigue in nurses.

While an LVAD provides some degree of continuous support of cardiac output during an arrhythmia event, identification of, and treatment for arrythmias is important. Studies show that while some LVAD patients are able to tolerate even lethal arrhythmias (i.e., asystole, V-fib, and/or VT) for a short period of time, if the arrhythmia is prolonged, intervention(s) are necessary.[19,21-24] Because LVAD patients often have the ECG features known to contribute to high numbers of false arrhythmia alarms (i.e., left BBB, ventricular pacemaker, low amplitude QRSs), these patients may also be susceptible to high rates of false alarms; thus, contributing to alarm fatigue.

Surprisingly, there are very few studies that have examined technical alarms in general, and to our knowledge, no study has examined this issue specifically in an LVAD patient group. One reason for the paucity of literature may exist because some technical alarms are inaudible; hence, many believe these types of alarms do not contribute to alarm fatigue. For example, technical alarms for artifact that last fewer than 20 of the last 30 s are typically configured as inaudible, rather a flashing text message alert is displayed on the monitor screen. While inaudible text messages may seem innocuous, one study reported that nurses are distracted by these alerts and wonder if an action is required.[25] Other types of technical alarms, however, are audible (i.e., ECG leads fail, respiratory leads fail) and will alarm until the nurse corrects the problem(s) (i.e., replace lead wires, or change skin electrodes). The last, and perhaps most significant type of technical alarm, is arrhythmia suspend, which creates an audible warning alarm that must be silenced by the user. The user is also required to fix the issue(s) causing the alarm. Therefore, technical alarms regardless of whether they are audible or inaudible, could have a significant impact on alarm fatigue.

The purpose of this study was to evaluate true and false ECG arrhythmias and technical alarms during LVAD therapy in the ICU. Our aims were threefold: 1) determine the frequency and accuracy of audible arrhythmia alarms for asystole, V-fib, VT, accelerated ventricular rhythm (AVR), V-brady, and pause; 2) determine the frequency and type of technical alarms for artifact, ECG/Respiratory leads fail, and arrhythmia suspend; and 3) calculate the alarm burden for both arrhythmia and technical alarms using the numbers of alarms/hour of ICU monitoring.

Methods

Setting and design

This is a secondary analysis from an alarm study, the methods of which have been previously published.[4] Briefly, the primary study was a prospective observational study designed to examine the number and type of alarms from bedside physiologic monitors at a large tertiary-quaternary academic medical center. The research infrastructure used in the study, captured *all* of the physiologic monitor data from each of the 77 ICU beds (16 cardiac, 32 medical/surgical, 29 neurological) over a one-month study period. The study was approved by the institution's Committee on Human Research with a waiver of signed patient consent since all ICU patients have physiologic monitoring as part of their routine care and our data was not

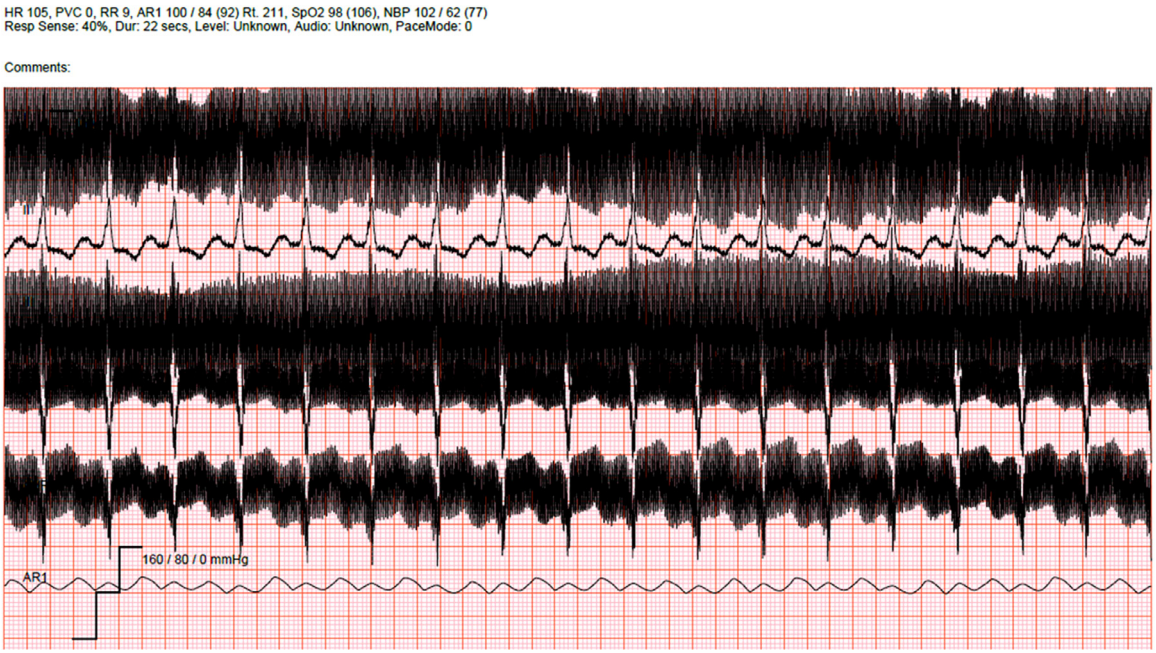

Fig. 1. Example of 60-cycle interference on an electrocardiogram (ECG) obtained from the bedside monitor in a patient with a left ventricular assist device. Note that a clean ECG signal is seen in lead II (heart rate 105 beats/minute), albeit the waveform is "fuzzy." A non-pulsatile arterial blood pressure waveform is present (AR1) at the bottom of the strip. The arterial blood pressure reading is 100/84 and the non-invasive blood pressure (NBP) is 102/62 (mean 77).

used for clinical care or decision-making, but rather examined retrospectively. Data were collected from 461 consecutive ICU patients. In this secondary analysis, we examine three LVAD patients who were admitted to the cardiac ICU. These three patients represent all of the patients who had an LVAD device during the study period.

ECG and physiologic data collection

Our research data-capture system acquires all physiologic (i.e., vital signs – waveform and numeric) and alarm data (audible and inaudible) from each bedside ICU monitor (Solar 8000i; version 5.4 software, GE Healthcare, Milwaukee, WI), using a specially designed CARESCAPE Gateway system (GE Healthcare, Milwaukee, WI). The data were exported to a secure external server (BedMasterEx; Excel Medical Electronics, Inc, Jupiter, FL) behind a firewall, which was then analyzed retrospectively. The bedside ECG monitor used the Mason-Likar 5-electrode lead configuration, resulting in seven ECG leads including leads: I, II, III, aVR, aVL, aVF and a V lead (V_1 at our hospital).

The focus of this paper is on two alarm categories: 1) true and false audible arrhythmia alarms; and 2) technical alarms (both inaudible and audible). The arrhythmia alarms were all configured as audible and included: asystole, V-fib, VT, AVR, V-brady and pause. The following technical alarms were analyzed: artifact, ECG/Respiratory leads off, and arrhythmia suspend. The technical alarms were configured in the following manner: (1) artifact = inaudible text message if $<$ 20 s of the last 30 s; (2) ECG/Respiratory leads fail = warning (continuous foghorn tone, must be silenced by the user); and (3) arrhythmia suspend due to artifact lasting $>$ 20 s of the last 30 s = warning (continuous foghorn tone, must be silenced by the user).

ECG arrhythmias and annotation of alarms

The annotation protocol (true vs. false) was performed by four PhD prepared nurse scientists using a standardized protocol. ECG competency for each annotator was ensured by a formal 10-week ECG course and a 3-hour alarm annotation certification course taught by the principal investigator of the primary study. Inter-rater reliability among the annotators was 95% (Cohen's Kappa score of 0.86).

Statistical analysis

Data were analyzed using SPSS 27 (IBM Corporation, 2017). Descriptive statistics were used to examine frequencies for: 1) true versus false audible arrhythmia alarms; 2) number, type and duration of technical alarms; and 3) alarm burden, defined as the number of alarms (arrhythmia and technical) divided by the number hours of ECG monitoring in the ICU, as opposed to the ICU length of stay. For example, if a patient left the ICU for an exam or procedure, the time off of the unit was subtracted from the ICU length of stay since this value provides a more accurate description of alarm burden. The data are expressed as numeric values and percentages. To maintain privacy and confidentiality in this small sample, only ICU length of stay, total ECG monitoring time, presence of an implantable cardioverter defibrillator and/or pacemaker and the LVAD type are reported.

Results

All three patients included in the study had a continuous flow type LVAD. Table 1 outlines ICU length of stay, total ECG monitoring time, presence of an implantable cardioverter defibrillator and/or pacemaker and LVAD type in the three patients.

Frequency of Audible Arrhythmia Alarms: There were a total of 549 audible arrhythmia alarms, only nine (1.6%) were annotated as true. Table 2 shows the distribution of arrhythmia types and whether the alarm was true or false. The most common type of arrhythmia alarm was for pause (n = 307; 56%) and every pause alarm was false. Fig. 2 shows a false pause alarm due to low amplitude QRSs.

Frequency of Technical Alarms: A total of 25,232 technical alarms occurred and the duration was 65.9 h of ECG monitoring, which was 13% of the 593 total hours of monitoring. Technical alarms by type (i.e., artifact, ECG/Respiratory leads fail, and arrhythmia suspend), alarm configuration (inaudible versus audible) as well as the duration (hours) are shown in Table 3. Of the total number of technical alarms, 93% were inaudible text message alerts for artifact and 7% were audible warning alarms.

Alarm Burden: Table 4, shows the alarm burden for all of the arrhythmia and technical alarms. Patient #2, had half the alarm burden (26.57 alarms/hour of monitoring) as compared to patient # 1 (54.04 alarms/hour of monitoring) and patient #3 (49.16 alarms/hour of monitoring). For all three patients, the technical alarm burden far exceeded the audible arrhythmia alarm burden (technical 43 alarms/hours of monitoring; arrhythmia 0.93 alarms/hour of monitoring).

Discussion

This case-series appears to be the first to report on audible arrhythmia and technical alarms (both inaudible and audible) in LVAD patients. While we report on a very small number of patients, we examined nearly 600 h of continuous ECG data during the ICU admission. Our results illustrate the substantial alarm burden present in this specific patient population, particularly with regards to technical alarms. Surprisingly, a very small number of true arrhythmias occurred (n = 9; 2%). Importantly, none of the LVAD patients had a code blue event or died, suggesting cardiac output during these true arrhythmia events was likely supported by the LVAD device. Technical alarms were by far the most common type of alarm (98%) as compared to audible arrhythmia alarms. Artifact was the most common type of technical alarm. The overall alarm burden (arrhythmia and technical), was 43.48 alarms/monitored hour. This means there was nearly one alarm every minute in these three patients. While only 9% of all of the alarms were audible, these data demonstrate the magnitude of alarm burden faced by nurses, LVAD patients as well as their family and loved ones.

Of the nine true arrhythmias, eight were for VT, and one was for accelerated ventricular rhythm. All three patients had at least one true VT alarm and one false VT alarm, with patient #3 having the highest number of false VT alarms (105 alarms). A prior investigation

Table 1
Clinical Characteristics of Participants.

Variable of Interest	Patient #1	Patient #2	Patient #3
ICU Length of Stay (hours)	192	212	240
ECG Monitoring Time (hours)	182	189	222
ICD and/or Pacer	ICD	ICD	ICD/Pacer
Type of LVAD	KIT PUMP HeartWare HVAD Continuous flow centrifugal	HeartWare HVAD Continuous flow centrifugal	Thoratec Heartmate II Continuous flow axial-flow

ECG = electrocardiogram; ICD = implantable cardioverter defibrillator; ICU = intensive care unit; LVAD = left ventricular assist device.

Table 2
Audible arrhythmia alarms.

LVAD Patient	Asystole		V-fib		VT		V-brady		AVR		Pause		Total Alarms	
	True	False	True	False	True	False	True	False	True	False	True	False	True	False
#1	0	3	0	0	3	2	0	0	0	0	0	2	3	7
#2	0	11	0	0	2	27	0	0	0	1	0	69	2	108
#3	0	45	0	2	3	105	0	10	1	27	0	236	4	425
	0	59	0	2	8	134	0	10	1	28	0	307	9	540
													Total 549	

AVR = accelerated ventricular rhythm; LVAD = left ventricular assist device; V-brady = ventricular bradycardia; V-fib = ventricular fibrillation; VT = ventricular tachycardia.

identified VT as the most prevalent arrhythmia in LVAD patients, and nearly all were well tolerated.[23] Our study supports this finding in that none of the patients we examined had a code blue event or rapid response call during their ICU stay. In prior studies in non-LVAD patients (adults and pediatrics), VT was found to be a common false positive alarm[4,6,26-32] and is corroborated in our study of adult LVAD patients.

In our study, the most common audible arrhythmia alarm was for cardiac pause, accounting for 56% (n = 307) of the total number and all were false. We identified low amplitude QRS complexes as a common ECG feature. Previous studies have also identified this ECG feature as a common source of false alarms for not only pause but, asystole because the QRS algorithm for heart rate detection uses strict QRS amplitude criteria (i.e., unidirectional QRS > 5 mm in > two ECG leads).[4,5,16] Patient #3, who had over three-quarters of the total number of pause alarms, also has 45 false asystole alarms. Low amplitude QRSs was the likely source of both of these types of false alarms. This same patient (#3) also had a ventricular pacemaker. However, the "Pacer Mode" feature had not been active on the bedside monitor. This is important because Pacer Mode automatically adjusts the ECG filter settings to allow for improved identification of pacer spikes and subsequent QRS detection. This one monitoring modification could reduce false pause and asystole alarms among patients with a ventricular pacemaker.

The importance of activating the Pacer Mode feature during ECG monitoring has been previously described. In one study, when the Pacer Mode feature was not activated in patients with a ventricular pacemaker, a high number of false alarms for AVR were observed.[7] AVR is defined as a wide QRS complex rhythm < 100 beats/minute. While we had a small number of AVR alarms (n = 28), all but one of these types of alarms occurred in patient #3 who had a ventricular pacemaker. Our findings and those from other studies,[4,5,33] highlight the importance of education related to the Pacer Mode feature for in-hospital ECG monitoring.

Of the 593 total hours of monitoring in three LVAD patients, we found that technical alarms occurred for 66 h, or 11% of monitoring. The most common technical alarm was for artifact (93%) and lasted for a total of 23 h. Technical alarms have been cited as one of the most common occurring alarms in other studies.[4,34] While some technical alarms are configured as inaudible text message alerts, these flashing alerts can distract clinicians from patient care because they wonder if an action is required and thus, contribute to alarm fatigue.[25] Importantly, not all technical alarms are inaudible. In our study, technical alarms for ECG/Respiratory leads failure were configured as an audible warning alarm resulting in a continuous foghorn tone and occurred from 18 h for ECG leads fail, to 22 h for respiratory leads fail. This alarm tone not only distracts nurses and contributes to

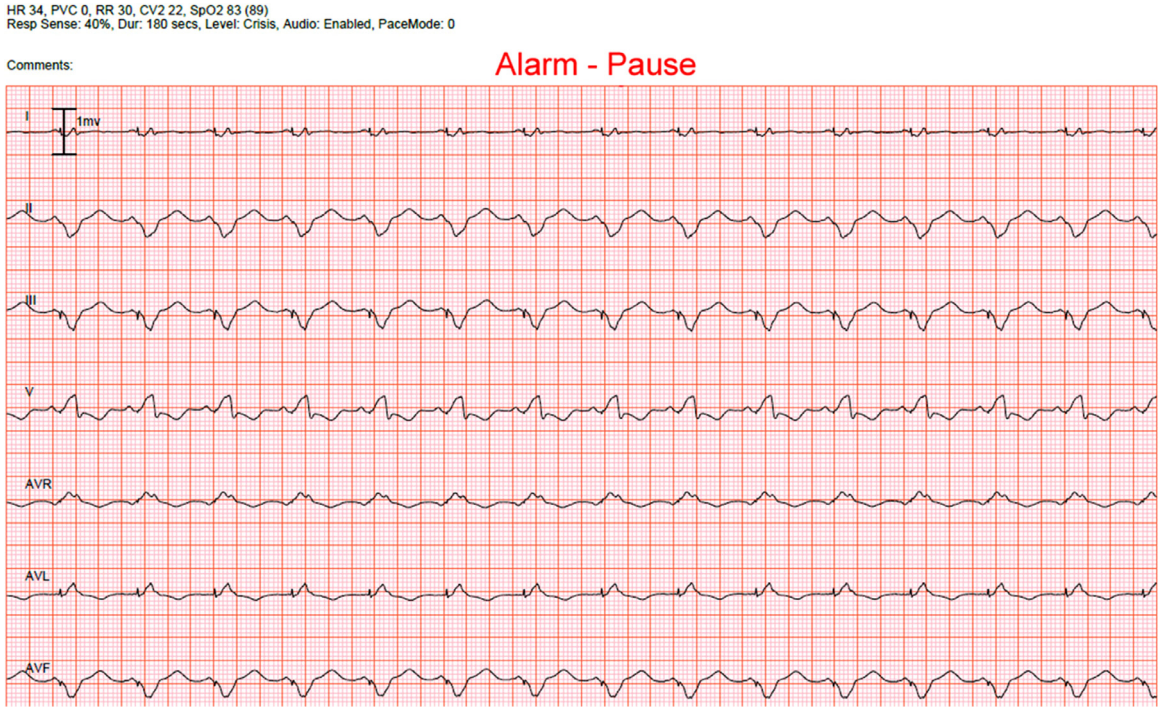

Fig. 2. False pause alarm in a patient with a left ventricular assist device. Shown from top to bottom are electrocardiographic leads I, II, III, V (V_1 default), aVR, aVL and aVF. Note that there are ventricular pacer spikes in front of every QRS, best seen in leads III, aVL and aVF. The cause of this alarm is low amplitude QRSs. The current algorithm requires a unidirectional (only positive or negative) QRS complex > 5 mm in two of the following leads, I, II, III or V. Note, that the pacer mode feature was not turned on (PaceMode 0 second line of text), which might have reduced these types of alarms.

Table 3
Technical alarms (audible and inaudible).

LVAD Patient	Artifact/ Duration (inaudible text message)		ECG Leads Fail/Duration (audible warning alarm - continuous foghorn tone)		Respiratory Leads Fail/Duration (audible warning alarm - continuous foghorn tone)		Arrhythmia Suspend/Duration (audible warning alarm - continuous foghorn tone)		Total Number and Duration of Alarms	
	Number	Duration (Hours)	Number	Duration (Hours)	Number	Duration (Hours)	Number	Duration (Hours)	Number	Duration (Hours)
#1	19,395	8.3	208	4	201	4	32	0.7	9836	16.8
#2	3925	3.2	483	2.3	461	5.7	43	1.7	4912	12.9
#3	10,107	11	163	12	159	12.1	55	1.1	10,484	36.3
Total	23,427	22.6	854	18.2	821	21.6	130	3.6	25,232	65.9

ECG = electrocardiogram; LVAD = left ventricular assist device.

alarm fatigue, but also can cause psychological anxiety to patients and/or families who are already in distress.

Notably, we found that there were nearly four hours of arrhythmia suspend, which means there was no arrhythmia detection as a result of sustained artifact. The problem created in this situation is that true arrhythmia events could be missed and highlights how persistent artifact could negatively impact patient safety. Based upon our findings and that of others, it is not surprising that interventions aimed at reducing false alarms, particularly technical alarms, have included educational interventions focused on proper ECG skin electrode placement, careful skin preparation and daily electrode changes.[8,31,33-37] While these interventions are likely to reduce false alarms in LVAD patients as well, there may be other interventions that should be examined in this particular patient population. For example, artifact due to the vibrations of the LVAD device may be unique in this patient group and require more thoughtful strategies including new algorithms, or filter settings in the monitor that can minimize this problem while ensuring accurate arrhythmia detection.

Finally, we examined alarm burden using the number of alarms per hour of ECG monitoring. This is different from other investigators who have used the number of alarms/bed/day, which distributes the alarms across the entire unit.[4,5,27,28,30,31,34,38,39] In our analysis, we found that there was one arrhythmia alarm/hour of monitoring among the three LVAD patients. However, the alarm burden from technical alarms was much higher. There were 44 technical alarms/hour of monitoring. Patient #3 was an outlier with regards to alarm frequency for both arrhythmia and technical alarms. This one patient had over three-quarters of the 549 arrhythmia alarms and only 4 were true. This one patient also had 42% of the overall number of technical alarms. This particular patient had low amplitude QRSs and a wide QRS due to a ventricular paced rhythm. As mentioned previously, these ECG features (i.e., ventricular pacemaker, low amplitude QRSs, and BBB), while present in only a small number of ICU patients are associated with high rates of false alarms.[3–5] In one study, the researchers found that only 2% of the ICU patients in their study, generated 70% of 12,671 arrhythmia alarms,[4] a finding corroborated by others.[3,27,31,40] However, all patients on a unit are impacted by these alarms because nursing care is diverted from others in critical need. Therefore, alarm reduction strategies tailored to individual patients has the potential to decrease alarm fatigue related patient events and improve care for all patients on the unit because nurses would not be constantly assessing false alarms.

Limitations

In this study we reported on three patients with LVAD admitted to our cardiac ICU. While this is a small sample size, it should be noted that LVADs are relatively uncommon, thus, a large sampling of LVAD patients is challenging. Despite our small sample, we had access to nearly 600 h of continuous ECG recordings. In addition, all of the arrhythmias for asystole, V-fib, VT, accelerated ventricular rhythm (AVR), ventricular bradycardia (V-brady) and pause were carefully annotated by five nurse scientists. Hence, we had the ability to comprehensively examine both arrhythmias and technical alarms for this study.

Also, it should be noted that our data came from one ECG vendor, so how these types of alarms might occur in a monitor from a different manufacturer is not known. Lastly, because this was a secondary analysis, we were not able to explore the consequences of alarm fatigue on nurses (i.e., prevalence or threshold level), patients and/or families (i.e., psychological, physiological) or potential impact on patient outcomes directly. Despite these limitations, this secondary analysis of three LVAD patients with continuous ECG data, documents the high number of audible arrhythmia alarms that can occur, most of which are false, and the extreme number of technical alarms caregivers are exposed to.

Table 4
Alarm burden.

LVAD Patient	ECG Monitoring Hours	Audible Arrhythmia Alarms		Technical Alarms (inaudible and audible)		Total # of all Alarms	
		# Arrhythmia Alarms	# Alarms/hour Monitoring	# Technical Alarms	# Alarms/hour Monitoring	All Alarm Types	# Alarms/hour Monitoring
#1	182	10	0.04	9836	54	9844	54.04
#2	189	110	0.58	4912	25.98	5022	26.57
#3	222	429	1.93	10,484	47.23	10,913	49.16
Total	593	549	0.93	25,232	42.55	25,781	43.48

ECG = electrocardiogram; LVAD = left ventricular assist device.

Conclusion

Audible arrhythmia alarms are frequent in LVAD patients, and the vast majority are false. None of the three patients included in our study had a rapid response, code blue event, or died during hospitalization. While an LVAD device supports cardiac output, these critically-ill patients are at risk for lethal arrhythmias, and thus, accurate and timely identification of arrhythmia events with continuous ECG monitoring remains very important. Because resuscitation efforts differ significantly in patients with an LVAD when compared to standard BLS protocols, education about these differences is important to highlight.[41] This study illustrates the significant number of both audible arrhythmia and technical alarms (both inaudible and audible) in LVAD patients. A better understanding of both false arrhythmia and technical alarms could help guide future recommendations for industry and/or clinical strategies to mitigate false alarms. Given our findings, there is a need to develop and test specific strategies aimed at reducing both false arrhythmia and technical alarms in this specific patient group.

This paper calls for the attention of patient safety leaders, clinicians, and practitioners to be mindful of the arrhythmia and technical alarms that can occur in LVAD patients. Because the use of LVADs is ever expanding, specific strategies to reduce or eliminate these issues in this special population should be the focus of future research. These efforts should be both clinical in focus as well as algorithm-based with the goal of improving identification of true arrhythmias while minimizing technical alarms.

Declaration of Competing Interest

None.

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