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Authors

Pelter, Michele M
Carey, Mary G
Al-Zaiti, Salah
et al.

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ORIGINAL ARTICLE

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An annotated ventricular tachycardia (VT) alarm database: Toward a uniform standard for optimizing automated VT identification in hospitalized patients

Michele M. Pelter RN, PhD[1] | Mary G. Carey RN, PhD[2] | Salah Al-Zaiti RN, PhD[3] | Jessica Zegre-Hemsey RN, PhD[4] | Claire Sommargren RN, PhD[1] | Lamberto Isola MS[5] | Priya Prasad PhD[6] | David Mortara PhD[1] | Fabio Badilini PhD[1]

[1]Department of Physiological Nursing, University of California San Francisco School of Nursing, San Francisco, California, USA

[2]School of Nursing, University of Rochester, Rochester, New York, USA

[3]Department of Acute & Tertiary Care Nursing, University of Pittsburgh, Pittsburgh, Pennsylvania, USA

[4]School of Nursing, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA

[5]AMPS-LLC, New York, New York, USA

[6]Department of Medicine, Division of Hospital Medicine, School of Medicine, University of California, San Francisco, California, USA

Correspondence
Michele M. Pelter, Department of Physiological Nursing, University of California San Francisco School of Nursing, San Francisco, California, USA.
Email: michele.pelter@ucsf.edu

Funding information
Center for Physiologic Research

Abstract

Background: False ventricular tachycardia (VT) alarms are common during in-hospital electrocardiographic (ECG) monitoring. Prior research shows that the majority of false VT can be attributed to algorithm deficiencies.

Purpose: The purpose of this study was: (1) to describe the creation of a VT database annotated by ECG experts and (2) to determine true vs. false VT using a new VT algorithm created by our group.

Methods: The VT algorithm was processed in 5320 consecutive ICU patients with 572,574 h of ECG and physiologic monitoring. A search algorithm identified potential VT, defined as: heart rate >100 beats/min, QRSs > 120 ms, and change in QRS morphology in >6 consecutive beats compared to the preceding native rhythm. Seven ECG channels, SpO_2, and arterial blood pressure waveforms were processed and loaded into a web-based annotation software program. Five PhD-prepared nurse scientists performed the annotations.

Results: Of the 5320 ICU patients, 858 (16.13%) had 22,325 VTs. After three levels of iterative annotations, a total of 11,970 (53.62%) were adjudicated as true, 6485 (29.05%) as false, and 3870 (17.33%) were unresolved. The unresolved VTs were concentrated in 17 patients (1.98%). Of the 3870 unresolved VTs, 85.7% ($n = 3281$) were confounded by ventricular paced rhythm, 10.8% ($n = 414$) by underlying BBB, and 3.5% ($n = 133$) had a combination of both.

Conclusions: The database described here represents the single largest human-annotated database to date. The database includes consecutive ICU patients, with true, false, and challenging VTs (unresolved) and could serve as a gold standard database to develop and test new VT algorithms.

KEYWORDS
alarm fatigue, algorithms, annotation protocol, electrocardiographic monitoring, intensive care unit, ventricular tachycardia

1 | INTRODUCTION

Despite alarm fatigue being recognized more than 10 years ago as a major patient safety hazard (Cvach, 2012; Drew et al., 2014; Harris et al., 2017; Sandelbach & Jepsen, 2013; Siebig et al., 2010; The Joint Commission, 2020), there have been very few advances made to solve this problem (Paine et al., 2016; Winters et al., 2017). The University of California San Francisco (UCSF) Alarm Study (Drew et al., 2014) represents the most comprehensive study to date that illustrates the magnitude of physiologic alarm burden in a cohort of consecutive intensive care unit (ICU) patients. During the 1-month study period, in 461 ICU patients (n = 77 beds), there were over 2.5 million audible and inaudible physiologic alarms. The audible alarm burden was 187 alarms/bed/day. A total of 12,671 audible arrhythmia alarms (i.e., asystole, ventricular fibrillation, ventricular tachycardia [VT], accelerated ventricular rhythm, ventricular bradycardia, and pause) were annotated and 90% were determined to be false positive. Hence, the vast majority of audible arrhythmia alarms are erroneous and likely contribute to alarm fatigue in clinicians.

Of the lethal arrhythmia alarm types (i.e., VT, asystole, and ventricular fibrillation), VT has been shown to be the most problematic, with as many as 80%–90% identified as false (Cvach et al., 2013; Drew et al., 2014; Nguyen et al., 2020; Pelter et al., 2020) compared to asystole (67%) and ventricular fibrillation (32%) (Drew et al., 2014). In several published secondary analyses using data from the UCSF Alarm Study, many of the false arrhythmia alarms occurred in patients with the following electrocardiographic (ECG) waveform features: bundle branch block (BBB); ventricular paced rhythms; and low amplitude QRS complexes (Drew et al., 2014; Harris et al., 2017; Nguyen et al., 2020; Pelter et al., 2016). Two studies found that a small proportion of true alarms (10%) often become buried within commonly occurring false alarms (Nguyen et al., 2020; Watanakeeree et al., 2021); thus, highlighting the risk to patient safety due to missed true events.

False arrhythmia alarms are largely due to deficiencies in current algorithms that do not account for the above-described ECG waveform abnormalities. For example, patients with a BBB (left or right) and a heart rate > 100 beats/min, which is common in acutely ill patients, can generate hundreds of VT alarms because current algorithms do not recognize the underlying wide QRSs associated with BBB (Nguyen et al., 2020). Importantly, VT alarms are configured as latching alarms, which means the nurse is required to physically silence the alarm(s), analyze whether the alarm is true or false, and determine if an action is required. Providers are equally impacted because they are contacted by nurses when alarms occur, which further contributes to alarm fatigue. Therefore, there is a need to improve VT algorithms to mitigate alarm fatigue among clinicians and reduce the risk of missed true events to improve patient safety.

As of today, three datasets have been used by monitoring manufacturers to develop and test arrhythmia algorithms when seeking approval from the Food and Drug Administration (FDA) (Hermes et al., 1980; Mark et al., 1982; Nolle et al., 1986). These data, however, are more than 30 years old, are from analog two-channel Holter recorders, and include small numbers of patients (i.e., 154 recordings [Hermes et al., 1980] and 47 patients [Mark et al., 1982]) with only a small number of critical arrhythmia events. In addition, the files are of short duration (i.e., 3 h to 30 min). While the *MIMIC III Waveform Database Matched Subset* collected in an ICU sample is publicly available to the research community, these data are incomplete as well (Clifford et al., 2015). For example, there are only a small number of recordings, (i.e., 750 training and 500 testing) and the recordings are "snippets" of 300 s around a potential VT event. A small number of VT events are available (i.e., 253 false and 90 true [training] and 176 false and 45 true [testing]). While two physiologic signals are included (SpO_2 and arterial BP), only two ECG leads are available, rather than the seven typically used in hospital-based ECG monitors. One positive aspect of these data was that the arrhythmias were annotated (Clifford et al., 2016).

Therefore, currently available databases used to develop and test arrhythmia algorithms to meet regulatory standards are extremely outdated and contain small numbers of both patients and arrhythmias. The one research database available, while more recent and annotated, too is rather small in size. Consequently, improvements to arrhythmia algorithms used in modern hospital-based ECG monitors have been stalled. To move the science in this field forward, there is a need for contemporary robust benchmark datasets from currently available bedside monitors. Such a dataset should also include other useful physiologic waveforms (i.e., SpO_2, arterial blood pressure [BP]) that are commonly acquired and have been shown to enhance arrhythmia algorithms (Aboukhalil et al., 2008; Baumgartner et al., 2012; Borowski et al., 2011; Desai et al., 2014; Li & Clifford, 2012; Salas-Boni et al., 2014). The annotation protocol described in this paper was designed to address this unmet need, which is made possible by an ongoing data acquisition effort at our hospital (Drew et al., 2014), which began in March 2013.

The purpose of this study was twofold: (1) describe the creation of a large VT database annotated by clinical and ECG experts using a multi-tier protocol requiring three-person confirmation and (2) determine true vs. false VT events using a new VT algorithm created by our group. Existing data from 5320 consecutive ICU patients during a 19-month time period were used.

2 | MATERIALS AND METHODS

2.1 | Physiologic data capture infrastructure

All available physiologic data (described below) were collected using a sophisticated closed network system that connected all 77 bedside ICU monitors, including the central monitoring station, via a gateway system (Figure 1). The waveform data were sent to a secure server in our research laboratory for offline analysis. The following data were collected from each ICU monitor: (1) all available waveforms (e.g., ECG, invasive arterial BP, central venous pressure, intracranial pressure, and SpO_2); (2) vital signs (e.g., heart rate, non-invasive BP, and

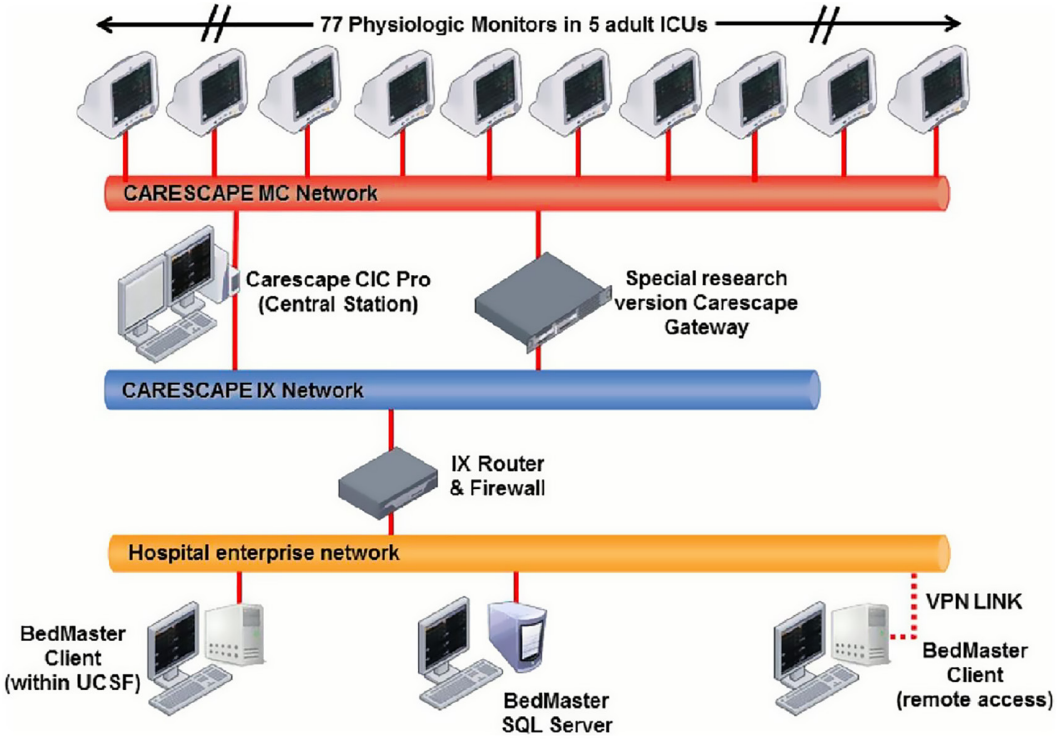

FIGURE 1 Data capture infrastructure was used to collect physiologic data from 77 intensive care unit beds. Permission to use figure granted by the open-access publisher [30]. https://doi.org/10.1371/journal.pone.0110274.g002.

respiratory rate); (3) alarm settings (i.e., crisis, warning, or advisory and message/technical); and (4) audible and inaudible alarms.

2.2 | Newly designed ventricular tachycardia algorithm

While all of the above signals and alarms were captured from the bedside monitor, for this study we used the seven available ECG leads (i.e., I, II, III, aVR, aVL, aVF, and a V lead [V1 is the hospital default]) as well as the plethysmograph (SpO_2), transthoracic impedance, and invasive arterial BP waveforms, which were processed with our new VT algorithm, called the UCSF VT algorithm. The UCSF VT algorithm was designed to decrease false alarms by addressing two major sources identified by our group: (1) ECG motion/noise artifact; and (2) ECG features associated with false alarms (i.e., BBB [left/right] and paced ventricular rhythms) (Drew et al., 2014; Harris et al., 2017; Nguyen et al., 2020; Suba et al., 2019; Watanakeeree et al., 2021). Below, we describe our algorithm approach.

Motion artifact is a common cause of false ECG alarms. Typically, the artifact source is a specific skin electrode on the body surface (i.e., right/left arm, right/left leg, chest lead), which causes pseudo-ectopic beats to be detected, thus triggering a false alarm(s). Often, only the ECG lead(s) used by a particular skin electrode is (are) affected while other leads that do not use this electrode are unaffected as shown in Figure 2. Our algorithm is designed to recognize the continuation of a normal rhythm in a lead(s) with a clean ECG signal, thus rejecting the pseudo-ectopic beats as VT.

The UCSF VT algorithm was also designed to reduce the problem of false VT in patients with BBB (left or right) and/or ventricular pacer. False VT can occur in patients with these ECG features (i.e., wide QRSs) when the heart rate exceeds 100 beats/min, which is the standard heart rate criteria used for VT. Because current algorithms do not automatically recognize these ECG features, sinus tachycardia in these patients can mimic VT. For patients with an underlying BBB (left or right) who have a sinus rhythm, our algorithm is designed to identify P waves to avoid labeling the wide QRSs associated with BBB as VT. With regard to ventricular paced rhythms, most current bedside monitors require the nurse to turn on the "pacer-mode" feature, which changes the filter settings and detects pacemaker stimuli (i.e., spikes). Failure to turn on the pacer-mode feature in patients with a pacemaker can cause false ventricular arrhythmia alarms (Figure 3). Our algorithm is designed to capture a "spike" time profile preceding each identified QRS. QRSs are determined to be "paced" when the QRS is >110 ms during the peak in the time profile when a spike occurs (i.e., 40–100 ms prior to the peak of the QRS complex), and within −40 to +20 ms of the QRS. Because current algorithms do not reliably identify pacer spikes before paced QRSs without activating the pacer-mode feature, our algorithm is able to overcome the problem of false VT due to ventricular pacing.

Finally, in addition to the above-mentioned strategies, our VT algorithm also used the SpO_2 and/or invasive arterial BP waveform(s) to recognize VT (e.g., VT coupled with a drop in SpO_2 and/or invasive arterial BP). This approach was useful because all of the patients included in this study had an SpO_2 signal and at least 25% had an invasive arterial BP signal. Of note, current hospital-based

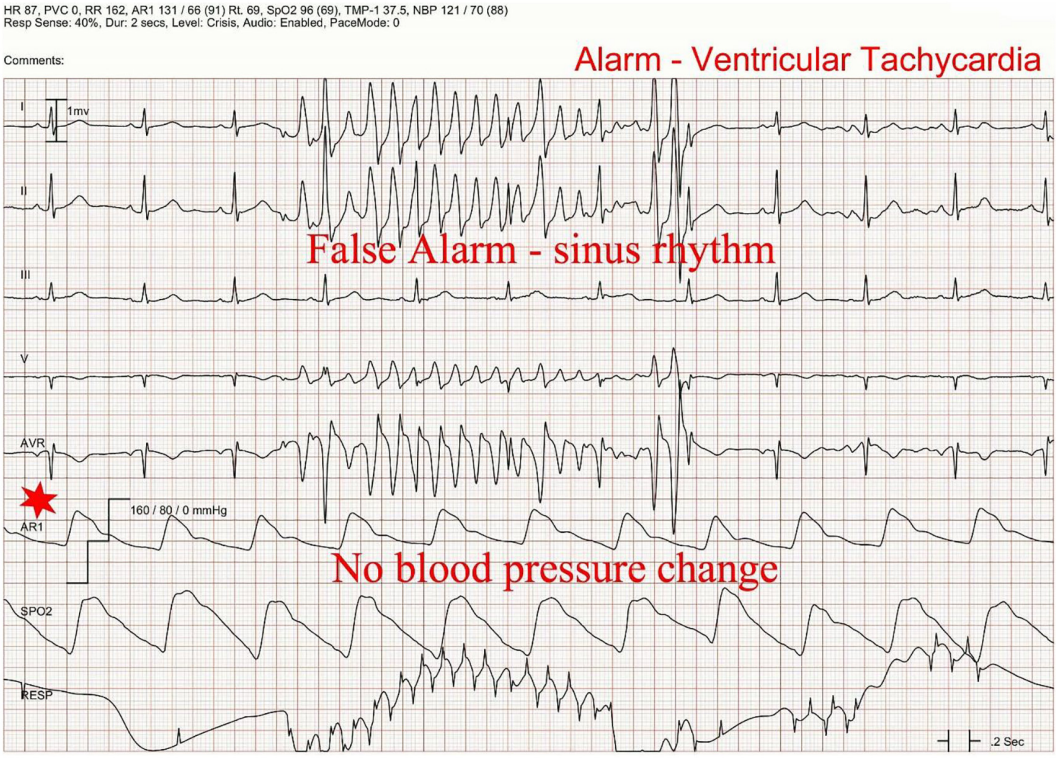

FIGURE 2 False ventricular tachycardia (VT) generated from a bedside physiologic monitor in an intensive care unit patient. Shown in order are electrocardiographic leads I, II, III, V1, aVR, invasive arterial blood pressure (AR1), oxygen saturation (SpO_2), and the impedance (IP) waveform used for respiratory rate assessment (RESP). Note that the artifact source causing the false VT alarm is the right arm skin electrode, which causes pseudo-ectopic beats to be detected as VT in all the leads that use this electrode as their signal source (I, II, and V1), as well as the IP signal (RESP) which used lead II. However, lead III, which uses the left arm skin electrode, is unaffected and sinus rhythm is seen. The invasive arterial blood pressure (noted by the star) and SpO_2 remain unchanged, which further supports that this alarm is false.

ECG monitor algorithms do not integrate these additional pulsatile signals; hence, our algorithm was enhanced considerably by their inclusion.

2.3 | Import process of ECG and physiologic data into the annotation software

A HIPAA-compliant patient de-identification procedure was applied to the files and each record was assigned a unique study ID number. In addition to demographic anonymization, a random date shift was applied to the start date, but not to the start time, for each recording. The de-identified data were loaded into the Continuous ECG Recording Suite (CER-S, AMPS-LLC; New York City, NY) platform for annotation. A customized version of the CER-S software was designed specifically for the VT annotation protocol. Figure 4 shows a screenshot of the CER-S annotation software program, which includes all available ECG and non-ECG waveforms (i.e., SpO2 and invasive arterial BP) and allows the annotator the ability to scroll forward and backward around an arrhythmia event. Each of the five annotators connected remotely to the UCSF network via a dedicated and secure research server (Figure 5).

2.4 | Study population

The sample included existing data from 5320 adult (>18 years of age) ICU patients during a 19-month time period (September 2013 to April 2015). There were a total of 572,574 h of ECG/ physiologic monitoring in the dataset. The ICU patients were admitted to one of three ICU types: (1) 16-bed Cardiac; (2) 32-bed Medical/Surgical; or (3) 29-bed Neurological (medical and surgical). The UCSF Committee on Human Research approved the study (IRB #: 12–09723) with waiver of patient consent because ECG and physiologic monitoring are a part of routine ICU care and we analyzed the data retrospectively; thus, did not influence clinical care. The data were collected from consecutive ICU patients.

2.5 | Annotation protocol

The VT annotation protocol was designed as a multi-tiered, multi-expert, ground truth, manual annotation, with three-person ascertainment of VT with disagreements resolved by a fourth expert. The annotation team (A-Team) was made up of five PhD-prepared nurse scientists (SA, MGC, MMP, CS, and JZH) with decades of experience as bedside and advanced practice nurses. All of the annotators are

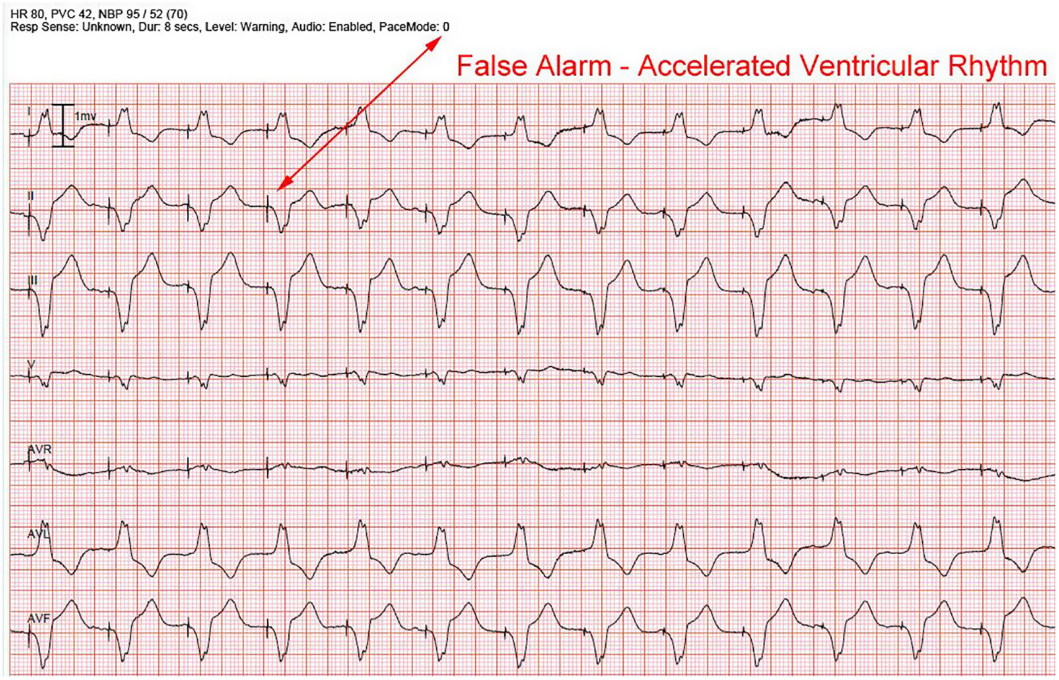

FIGURE 3 False alarm for accelerated ventricular rhythm (i.e., wide QRS rhythm <100 beats/min) in a patient with a ventricular pacer (start of the red arrow). Shown in order are electrocardiographic leads I, II, III, V1, aVR, aVL, and aVF. Note that the pacer mode feature has not been turned on (arrow), leading to non-stop alarms for accelerated ventricular rhythm. If the rate was >100 beats/min, alarms for ventricular tachycardia would be generated.

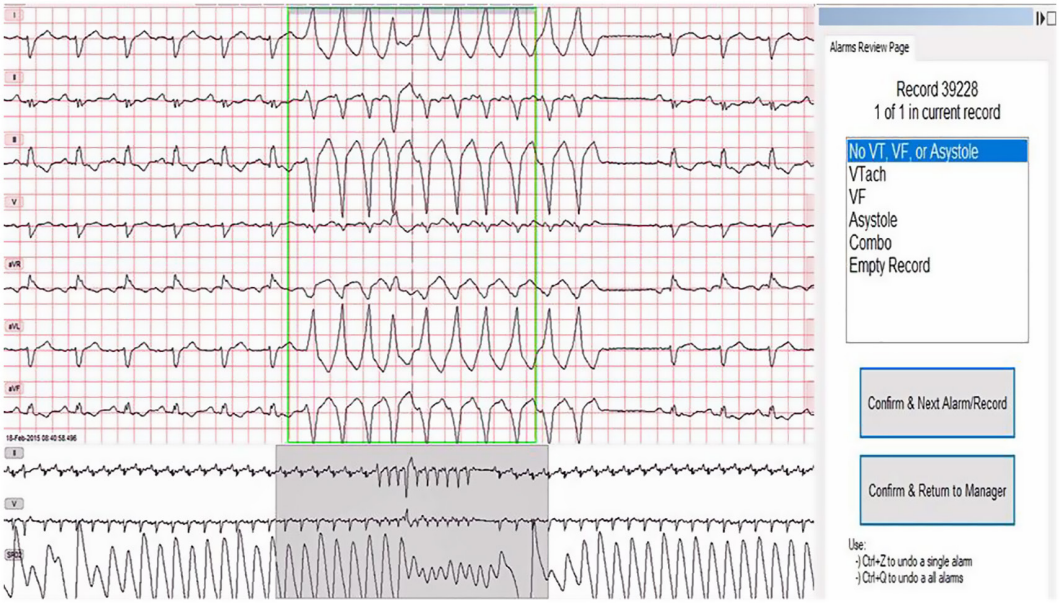

FIGURE 4 A true alarm for ventricular tachycardia (VT) in the Continuous ECG Recording Suite (CER-S) software program is illustrated. The context view (white area at the bottom) is a 30-s time window showing ECG leads II, III, V1, thoracic impedance respirations (Resp), and the SpO_2 waveform. The gray area in the context view outlines the 10-s window with the VT alarm. Note that the SpO_2 waveform in the context view dampens confirming the diagnosis of VT. Invasive arterial blood pressure (not shown) is also available if the patient has this device in place. The annotator selects a response located on the right-hand side of the figure (true, false, etc.) and then chooses "Next Alarm" to save and automatically move on to the next annotation.

highly skilled at interpreting hospital-based ECGs (i.e., bedside monitor and standard 12-lead ECGs).

Each VT was randomly assigned to each of the five annotators who independently performed the annotations. Three levels of annotation were used, including: (1) Level I – a VT was reviewed by three annotators. VTs with consensus (all three annotators agree) were finalized; (2) Level II – a VT for which only two annotators agreed in Level I, was re-assigned to a fourth annotator. If the

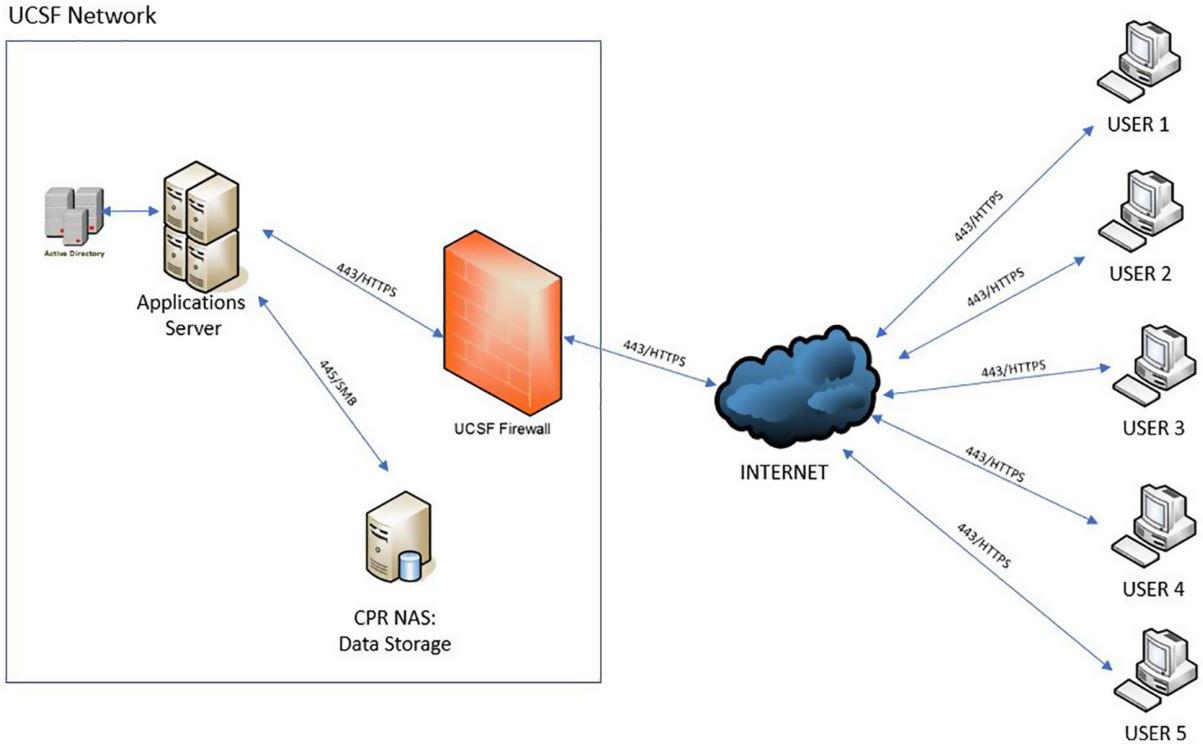

FIGURE 5 Infrastructure used for annotating true vs. false ventricular tachycardia alarms. Physiologic data stored in the active directory were accessed by the five annotators (USER) for annotation via the internet behind a Firewall.

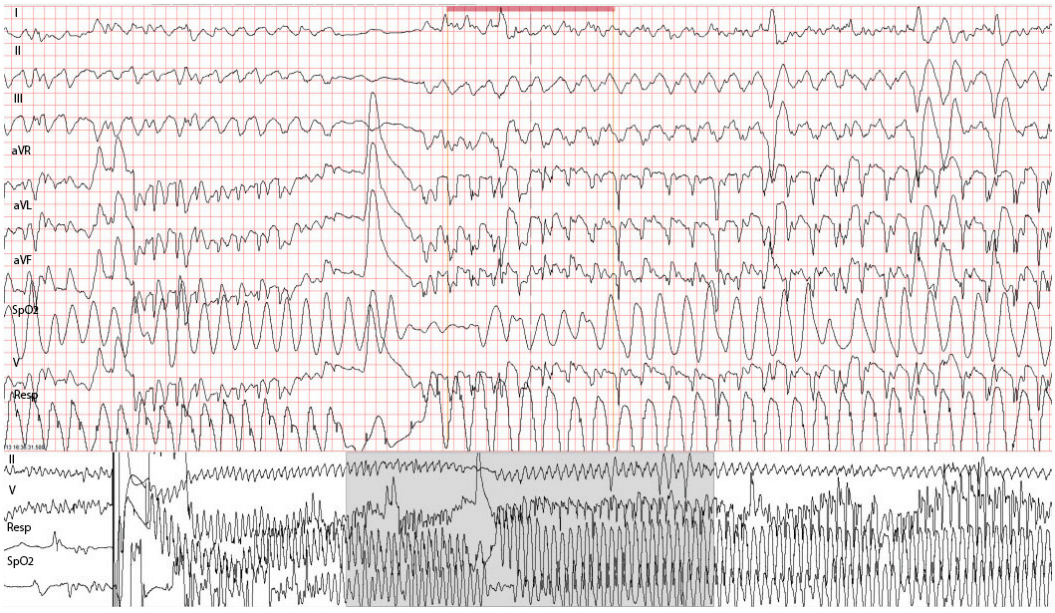

FIGURE 6 False ventricular tachycardia (VT) alarm during cardiopulmonary resuscitation (CPR). The pink area is a 60-s time window showing electrocardiographic (ECG) leads I, II, III, aVR, aVL, aVF, Sp02, V1, and thoracic impedance respirations (Resp). The context view (white area below pink) is a 2-min time window showing ECG leads II, V1, thoracic impedance respirations (Resp), and SpO_2. The gray shading represents the 60-s time window above. The heart rate (i.e., compression rate) can be seen in the thoracic impedance respiration waveform (Resp), presumably caused by true changes of thoracic impedance, and/or by pressure on the skin electrodes being used for thoracic impedance respiration detection (lead II is the default) typically at a rate of 120–150 compressions/min, which is our hospital's typical CPR compression rate. Note that when CPR is stopped briefly, the underlying rhythm is asystole (flat line in context view), then CPR resumes.

disagreement was resolved (i.e., fourth annotator concurred with the two initial annotators), the annotation was finalized; and (3) Level III – if the disagreement was not resolved after Level II annotation, the VT was reviewed by two independent reviewers with electrocardiology expertise (FB and DM) for a final decision.

Prior to the launch of the annotation protocol, a pilot annotation ($n = 193$ VT alarms/annotator) was completed. The pilot annotation served three purposes. First, to ensure that the VT events could be accessed by each annotator and that selected answers (i.e., true/false) were appropriately stored on the research server. Second, to confirm that the operational definitions were comprehensive and understandable by the annotation team. For example, we identified that a false VT alarm could occur during cardiopulmonary resuscitation as shown in Figure 6. As a result, the presence of cardiopulmonary resuscitation was added to the operational definitions (described below) as a false VT alarm. Thirdly, the pilot study allowed our team to determine the time required to annotate each alarm. On average, each annotation took approximately 1 min.

Following the pilot study, the annotation protocol was initiated. Each annotator was assigned an equivalent number of VT alarms, which were annotated independently. The annotation team met biweekly by video conference throughout the annotation protocol. A dedicated software engineer (LI) maintained the annotation software and resolved any questions and/or issues, which were infrequent, in a timely manner. The biweekly meetings were designed to ensure adherence to the study protocol, address questions and/or issues with the annotation software, and maintain the study timeline. Annotation outcomes (agreement, true vs. false) were not shared with the A-Team until the entire database was annotated. The annotation effort was completed in 7 months.

2.6 | Definition of ventricular tachycardia

The definitions used for true vs. false VT are shown in Table 1. We defined true VT using the commonly applied default settings in bedside hospital monitors, >6 consecutive ventricular beats (i.e., wide QRS complexes) at a rate >100 beats/min. VT that was monomorphic or polymorphic (Torsades des Pointe) was labeled as VT; thus, these VT types were not categorized differently. As stated above, false VT was based largely on our prior studies showing that artifact, bundle branch block (left/right), and ventricular paced rhythms are commonly associated with false VT alarms during in-hospital ECG monitoring. Knowing that algorithms can identify ventricular fibrillation (VF) as VT (and vice versa), we included the occurrence of VF as false VT (defined in Table 1). Following the pilot annotation as noted above, cardiopulmonary resuscitation was added to the false-positive criteria.

2.7 | Statistical analysis

Data quality checks were done throughout the annotation protocol by the Database Coordinator (FB) and a software engineer (LI).

TABLE 1 Operational definitions used to determine true vs. false ventricular tachycardia.

True Ventricular Tachycardia (VT)
Six consecutive ventricular beats are defined as wide QRS complexes with clearly abnormal conduction at a rate >100 beats/min.
The heart rate limit applies only to the average rate, not individual R-to-R intervals (i.e., 6 ventricular beats in <3.6 s).
A fusion beat at the onset of the VT counts as a ventricular beat.
The QRS morphology of the VT beats should be different from those of the preceding non-VT beats to avoid labeling bundle branch block (BBB) or ventricular-paced rhythms as VT.
False VT
Baseline noise or muscle artifact is present.
Periodic artifact simulating VT, which can be recognized by a heart rate too high to be "real" or a QRS width too narrow. Examine all available leads as well.
Single ECG lead.
Ventricular paced rhythm or bundle branch block—as stated above the QRS morphology of the VT beats should be different from those of the preceding non-VT beats.
Ventricular fibrillation—identified by course flutter waves without QRS complexes.
Presence of cardiopulmonary resuscitation. Heart rate waveform is similar to the thoracic impedance respiration waveform (Resp), presumably caused by true changes of thoracic impedance, or by pressure on one of the skin electrodes being used for impedance (lead II is the default lead). Typically, the pseudo-QRSs are >200 ms in width. Often an undisturbed lead allows for the recognition of the underlying rhythm typically at a rate of 120 to 150 compressions/min, which is our hospital's standard CPR rate.

Statistical analyses were done by an epidemiologist (PP). Descriptive statistics (frequencies, proportions, means, and standard deviations) were used to describe the sample (age, gender, and race), ICU type (i.e., cardiac, medical/surgical, neurological), ICU length of stay, and VT alarm rates. The same descriptive statistics were used to describe the annotated VTs as true vs. false and for the agreement among the annotators. The sample characteristics are described, but the VT alarms are the unit of analysis for this study. Data were analyzed using SPSS version 27.0 (IBM Corporation, 2021) (Mentorship)

3 | RESULTS

A total of 5320 ICU patients were processed using our developed VT algorithm and 858 (16.13%) had 22,325 VTs during the 19-month period. A total of 572,574 hours of physiologic monitoring data were processed. The 858 VT patients had a mean age of 62.8 ± 17.0 years and 40.8% ($n = 350$) were female. The sample included patients from varied age groups including: (1) 335 (39%) ≤59 years of age; (2) 300 (35%) between 60 and 74 years of age; and (3) 223 (26%) ≥75 years of age. Race was identified from the EHR and was as follows: 27 (0.5%) American Indian or Alaska Native; 745 (14.1%) Asian; 442 (8.3%)

TABLE 2 The number and percent of ventricular tachycardia events reviewed by each of the five annotators in both Level I and Level II annotations.

Level I annotation						Level II annotation				
Annotator	#1	#2	#3	#4	#5	#1	#2	#3	#4	#5
Number (%) of VT alarms annotated	13,348 (59.8%)	13,564 (60.8%)	13,406 (60.0%)	13,322 (59.7%)	13,346 (59.8%)	1379 (6.2%)	1882 (8.4%)	1732 (7.8%)	1958 (8.8%)	1978 (8.9%)

Abbreviations: VT, ventricular tachycardia; #, number; %, percent.

Black or African American; 63 (1.2%) Native Hawaiian or Other Pacific Islander; 40 (0.75%) Multi-race; 984 (18.5%) Other (unknown due to acute illness, declined to state); 3019 (56.7%) White. The ICU that the patient was treated in was as follows: 223 (26%) cardiac ICU alone (i.e., medical and/or surgical); 352 (41%) medical/surgical ICU alone; 215 (25%) neurological ICU alone (i.e., medical and/or surgical); and 60 (7%) in two ICU locations. The latter occurred typically in patients admitted to one type of ICU based on admitting diagnosis but were then transferred to another ICU based on the ultimate diagnosis (e.g., initial admission medical/surgical then transfer to neurological ICU after stroke diagnosis). The average ICU length of stay was 10.5 ± 14.5 days.

3.1 | Annotation agreement

Each of the five annotators performed an equivalent number of annotations in both Level I and Level II (Table 2). Figure 7 shows the level of agreement by annotation Level (i.e., I, II, and III), the number of true, false, and unresolved VTs (i.e., not true or false). In the Level I annotation (i.e., three annotators agreed), the level of agreement was 58.39% (13,036 of 22,325 total VT alarms). The discordant VTs (9289 VT alarms; 41.61%) were annotated in Level II (i.e., 4th annotator), where an additional 23.59% (5267 of 22,325 total VT alarms) were resolved. Following the level II annotation, we identified 17 (1.98%) unique patients who had 3828 VTs that remained unresolved (17.33% of total VTs). We examined the unresolved VTs and noted that the VTs were concentrated in patients with underlying ECG waveform abnormalities (described below); therefore, we decided not to move these VTs to the Level III annotation because an arbitrary decision could bias the results. However, an additional 194 VT alarms (0.87% of 22,325 total VT alarms) from the Level II annotated were evaluated in the Level III annotation (i.e., expert cardiology panel). Of the 194 VT alarms (0.87% of the total) annotated in Level III, 152 (0.68% of the total) were resolved and 42 (0.18%) remained unresolved. Therefore, the overall agreement (Levels I, II, and III) was 82.67% (18,455 of the 22,325 total VT alarms).

3.2 | Unresolved ventricular tachycardia

As mentioned above, there were 3870 (17.33%) unresolved VTs. The unresolved VTs were concentrated in 17 (1.98%) unique patients. Of the unresolved VTs, 85.7% ($n = 3281$) were confounded by ventricular paced rhythm, 10.8% ($n = 414$) were confounded by underlying BBB (left $n = 1$ patient; right $n = 5$ patients), and 3.5% ($n = 133$) had a combination of both confounders. Figure 8a,b shows the examples of unresolved VT events. In A, the patient had a right BBB and atrial fibrillation at a heart rate just above 100 beats/min, which combined can mimic VT albeit at a slow rate. In B, the diagnosis of supraventricular tachycardia with aberrancy (right BBB type) vs. VT appears to be why this event was categorized as unresolved after four levels of annotation. Importantly,

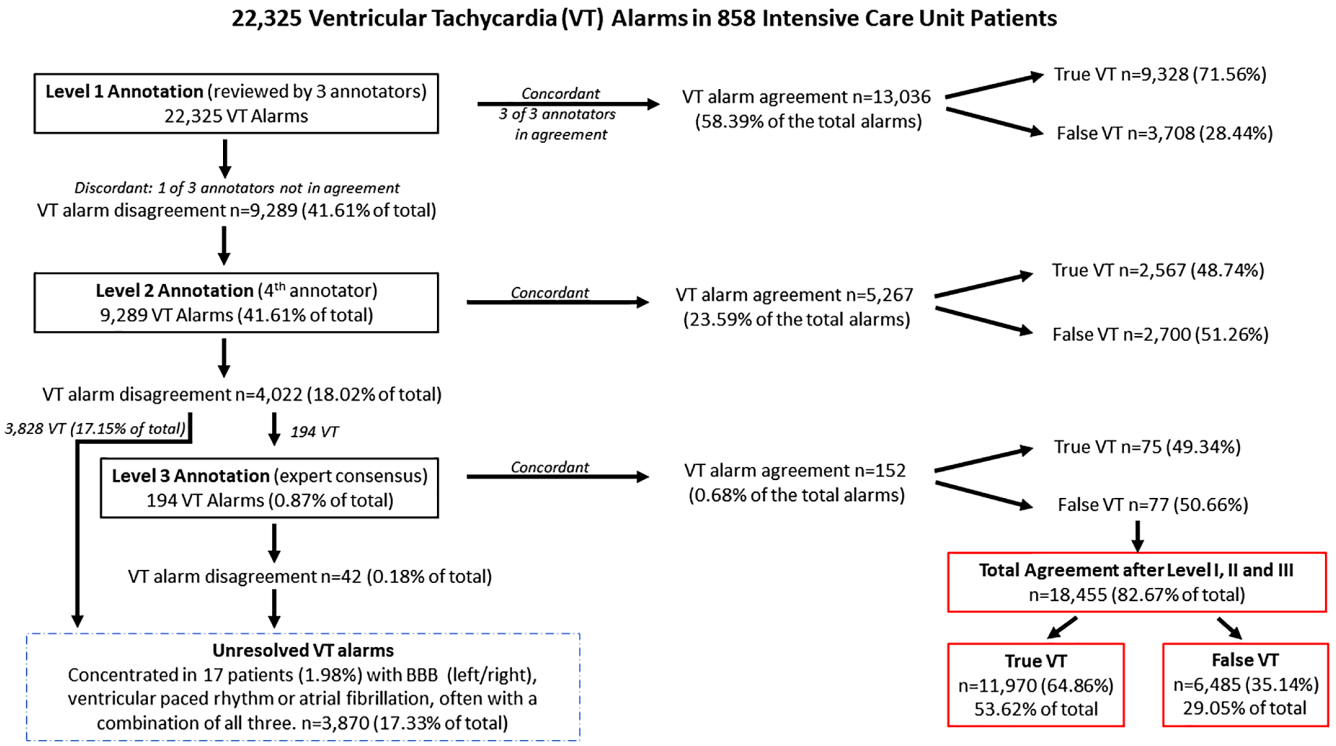

FIGURE 7 The annotation protocol outcomes from a total of 22,325 ventricular tachycardia (VT) alarms in 858 intensive care unit patients by agreement/disagreement and true/. Following annotation at all three levels, there were a total of 3870 (17.33%) VTs that remained unresolved and were concentered in 17 (1.98%) patients.

these 17 unique patients had a total of 16,045 VT alarms, which represents 71.87% of the 22,325 total VT alarms. Of note, in 12,217 (76.14% of 16,045) consensus was reached in Level I and Level II annotations. Figure 9 shows the level of agreement in the 17 unique patients.

4 | DISCUSSION

The VT annotation protocol described in this paper is the largest and most comprehensive human annotation effort done to date using contemporary ECG and physiologic monitor data in 5320 consecutively enrolled ICU patients. The validity of this annotation effort is strengthened by the protocol design used (i.e., multi-tier, manual annotation, three-person ascertainment). Of the 5320 total ICU patients included, 858 (16%) had a total of 22,325 VTs identified. The overall agreement was 83%, and 69% were true VT and 31% were false VT. Of the total VT alarms annotated, the consensus was not reached (i.e., unresolved) in 17% of the VTs and occurred in 2% of the sample. Using the VT event as the unit of analysis, 8 in 10 of the unresolved VTs were confounded by ventricular paced rhythm, 1 in 10 were confounded by underlying BBB (left or right), and <5% were confounded by both features.

One might assume that wide QRS complex tachyarrhythmias, VT in this study, are easy to diagnose. However, the findings from this annotation protocol suggest that diagnosing VT is complex. For example, 42% of the level I annotations went to a Level II annotation and the rate of true vs. false VT alarms decreased. This suggests that some VTs may not have the clearly distinguishable QRS patterns clinicians use to diagnose VT. It should be noted that all of the annotators were highly qualified (i.e., PhD-prepared nurses with decades of experience interpreting ECGs); yet, the diagnosis of VT was difficult in select VT events. This is an important point because bedside nurses, while trained in ECG interpretation, do not typically have a high level of expertise like that of the annotation team. An argument could be made that physicians, particularly those with ECG interpretation proficiency, would perform better; however, studies show that even experienced physicians have difficulty identifying VT (Baranchuk et al., 2009; Knight et al., 2001; Littmann, 2021). Therefore, in real-world clinical practice, the diagnosis of VT will be challenging in some cases, which has important treatment implications (i.e., under or over).

The software used for annotation allowed the annotators the ability to simultaneously view all seven ECG leads (including V1 – a key lead for diagnosing VT), SpO_2, and invasive arterial BP and the ability to scroll forward and backward around the VT. Therefore, the annotators had access to key data elements to make the diagnosis, which is superior to previously annotated datasets that included much smaller sample sizes (Clifford et al., 2012, 2015; Drew et al., 2014). Despite this, 17% of the VTs were unresolved. A future study that links patient responses (i.e., vital signs, symptoms) and/or outcomes associated with VT might aid in identifying actionable VT events, (Pelter et al., 2020) which could also enhance future algorithm development.

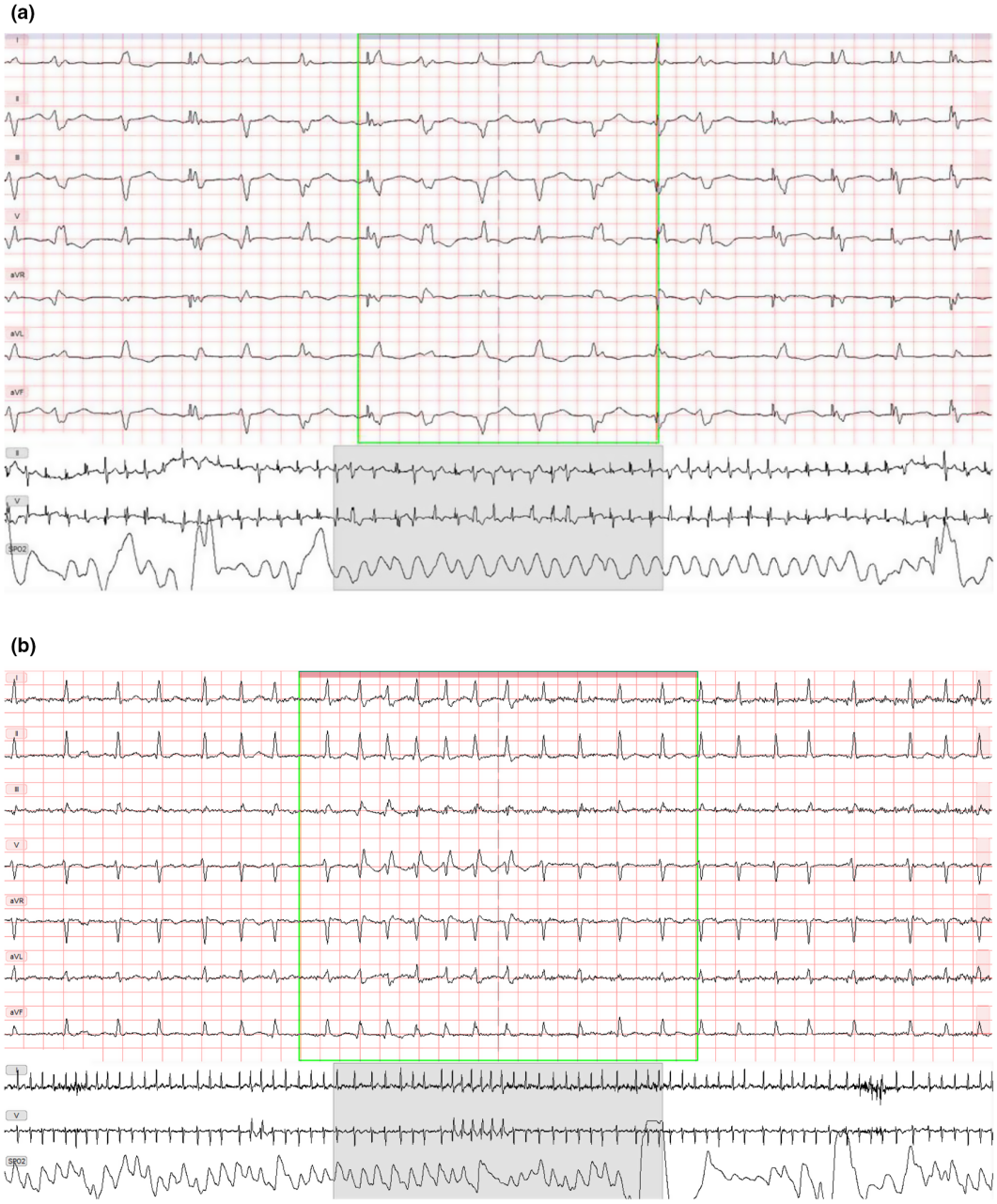

FIGURE 8 (a, b) Examples of two unresolved (not definitively true vs. false) ventricular tachycardia (VT) events. In both images, the top portion shows a 10-s snapshot (pink–green box surrounds possible VT event) in electrocardiographic (ECG) leads I, II, III, V1, aVR, aVL, and aVF. The context view (white area below pink) is a 30-s time window with ECG leads II (a) and I (b), V1, and the SpO_2 waveform. The gray area in the context view outlines the 10-s window with the VT event. (a) An intensive care unit patient with underlying right bundle branch block, intermittent atrial fibrillation, and ventricular pacing, interrupted by a six-beat run of possible VT. The heart rate is just above 100 beats/min. (b) An intensive care unit patient with atrial fibrillation and a six-beat run of possible VT.

The performance of our VT algorithm for identifying true VT (65%) appears to be higher than the bedside monitor used during this study. In a separate study that used the same bedside monitors, but in a much smaller sample, the rate of true VT was 13% (510 of 3861 VT alarms) (Drew et al., 2014). In that study, the VT alarms were adjudicated by one annotator using only a 10-s rhythm strip. While one could argue that the robust annotation used in the present study may have accounted for the proportional differences between the two studies a likely explanation is that our VT algorithm addresses two important problems associated with false VT, artifact and underlying wide QRS rhythms (i.e., BBB and ventricular paced rhythms). In addition, adding SpO_2 and/or invasive arterial BP, which are not used in current algorithms, likely enhanced our developed algorithm, which has been reported in other studies (Aboukhalil et al., 2008; Baumgartner et al., 2012; Borowski et al., 2011; Li & Clifford, 2012; Salas-Boni et al., 2014). While the VT algorithm tested in this study shows promise, a future study investigating the agreement between our identified VT

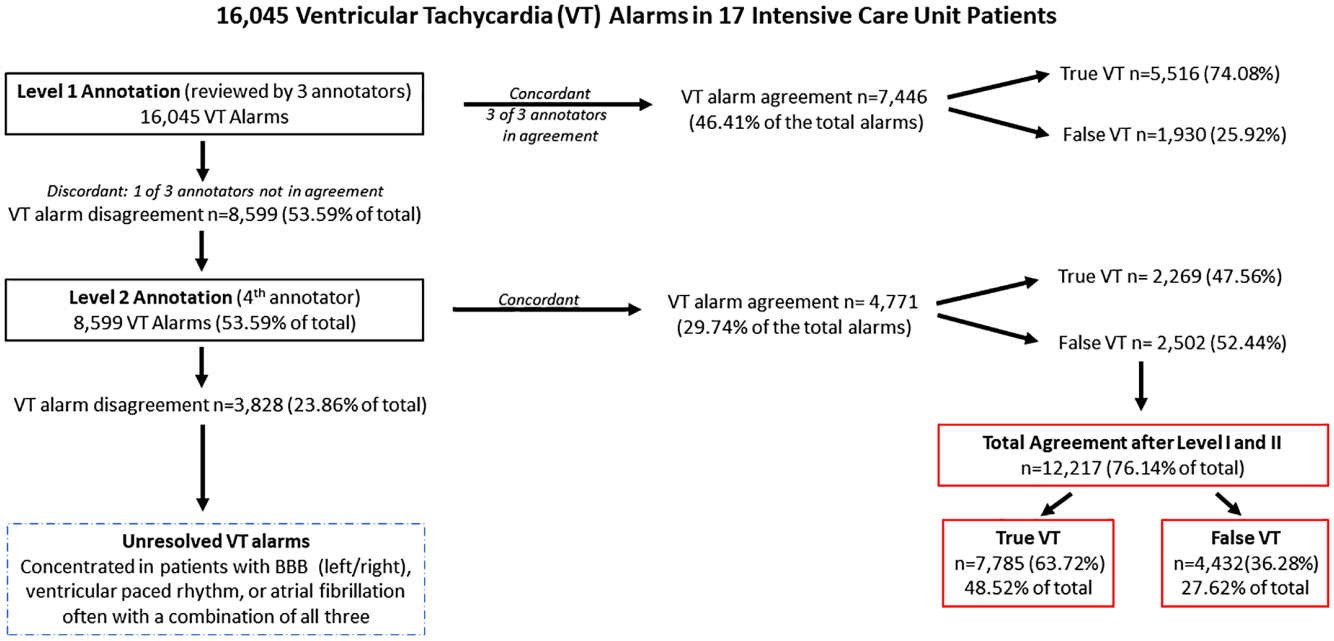

FIGURE 9 The annotation protocol outcomes from the 17 unique patients who had a total of 16,045 ventricular tachycardia (VT) alarms, or 71.87% of the total number of VT alarms. The 17 patients had 7785 true VT alarms (63.72%), 4432 false VT alarms (36.28%), and 3828 (23.86%) VT alarms that remained unresolved.

to that of the current bedside monitor, other vendors as well as the MIMIC III Database is warranted.

In this study, 17% of the VTs were unresolved and were concentrated in 2% of the sample. The vast majority of the unresolved events were confounded by ventricular-paced rhythm, followed by underlying BBB. Less than 5% of the events had a combination of both confounders. Tachyarrhythmias (sinus or atrial) at a rate >100 beats/min in patients with these confounders can mimic VT. Importantly, these 17 patients had nearly three-quarters of the total number of VTs. These confounders have been identified as a source of false VT in other studies (Aboukhalil et al., 2008; Drew et al., 2014; Harris et al., 2017; Nguyen et al., 2020; Pelter et al., 2020; Watanakeeree et al., 2021). Importantly, these ECG confounders are common in adult hospitalized patients. In one study with 4739 community-based participants (mean age 62 + 6.2 years), 31.8% had ECG abnormalities, including BBB (right and left), atrial fibrillation; and left ventricular hypertrophy and occurrence rates increased with age (Ioannou et al., 2018). In a hospital-based study of 148 patients >60 years of age, 17% had atrial fibrillation, 39% repolarization abnormalities and 5% BBB (right or left) (Rojas et al., 2019). Finally, in another hospital-based study in 292 cardiac ICU patients, 63% had baseline ECG abnormalities including left ventricular hypertrophy, BBB (right/left), or drug-induced ECG waveform abnormalities (Drew et al., 1998). Given that 61% of our sample was older than 60 years of age, these ECG abnormalities are expected to be common in ICU patients, which could increase false VTs. This is problematic given that these ECG abnormalities are associated with structural heart disease, which places these select patients at risk for true VT (Al-Khatib et al., 2018). Of note, while the unresolved VTs were concentrated in a small cohort of unique patients, these ECG confounders were commonly seen in our entire sample. This suggests that our algorithm was able to differentiate VT in a large number of cases, but still needs refinements to overcome this problem. In summary, the diagnosis of true VT is very complex among select patients with underlying ECG waveform abnormalities and co-occurring tachy arrhythmias highlighting the need for further algorithm enhancements to improve the detection of true VT while minimizing false alarms.

New and improved arrhythmia algorithm development for use in commercially available ECG devices has remained stagnant for decades. This is largely due to the fact that only three benchmark datasets (i.e., AHA-ECRI, the CUBD, and the MIT/BIH Databases) (Hermes et al., 1980; Mark et al., 1982; Nolle et al., 1986), which were developed in the 1970s, are available for testing and developing VT algorithms when seeking approval from the FDA. There are fundamental flaws in these datasets, including analog signals, two-channel Holter recordings, small numbers of patients, insufficient numbers of critical arrhythmias, and short recording times (i.e., 3 h to 30 min). While the MIMIC III Waveform Database Matched Subset collected in an ICU sample is publicly available to the research community, these data are incomplete as well (Clifford et al., 2015). For example, there are only a small number of recordings, (i.e., 750 training and 500 testing) and the recordings are "snippets" of 300 s around a potential VT event. A small number of VT are available (i.e., 253 false and 90 true [training] and 176 false and 45 true VTs [testing]). While two physiologic signals are included (SpO_2 and invasive arterial BP), only two ECG leads are available, rather than the seven typically used in hospital-based ECG monitors. One positive aspect of these data was that the arrhythmias were annotated; however, details about

the annotation team were not described (i.e., clinical experts vs. engineers). Several investigators tested new VT algorithms using these data and showed promising results; however, a consistent finding was that VT was the most difficult to accurately classify (Clifford et al., 2015). Given these limitations, it is not surprising that very few advances have been made in this field of study.

The human annotation protocol outlined in this paper represents the most comprehensive study done to date in an ICU population using data from modern-day bedside monitors. These data offer significant opportunities for other researchers to develop and test new and improved arrhythmia algorithms and enhance predictive analytic algorithms that integrate arrhythmias. In addition, these data could raise the standards used by regulators (i.e., FDA) when approving hospital-based ECG monitoring devices with the ultimate goal of improving the accuracy of arrhythmia detection.

There is a need to do similar annotation efforts examining other important arrhythmias (i.e., asystole, ventricular fibrillation, atrial fibrillation, and ventricular bradycardia), which our group is undertaking now. Despite the improved performance of our algorithm for identifying true VT, the present study also shows the complexity of classifying VT among select patients with underlying ventricular-paced rhythms and BBB.

5 | LIMITATIONS AND FUTURE RESEARCH

While our dataset included a large cohort of over 5300 patients, 16% of whom had ≥1 VT event(s), we included only ICU patients. Future studies are needed that examine VT in non-ICU environments where ECG monitoring is used (i.e., telemetry unit, medical/surgical, emergency department, etc.). ICU patients are often immobile and unconscious, which could reduce the noise and artifact associated with false VT. In addition, our algorithm incorporated SpO_2, which all the ICU patients had available, and/or the arterial blood pressure waveform, which ~10% of the ICU patients had available. Because non-ICU unit may have only SpO_2 available and none would have arterial blood pressure waveforms, the performance of our algorithm in this setting is likely to be impacted. Thus, the performance of our algorithm in these populations/settings is unknown and requires additional evaluation. We examined only one vendor's ECG data. The performance of our VT algorithm as compared to other vendors is warranted to augment the generalizability of our findings. In addition, the performance of our algorithm to that of the current bedside monitor is needed to determine agreement/disagreement and missed VT events. We did not differentiate monomorphic vs. polymorphic (Torsades des Pointe) VT during the annotation, which could be useful for developing and testing new algorithms. Antidotally, we found that polymorphic VT was rare; hence, only a small proportion of the total number of VT events in our database are polymorphic in nature. We examined only VT in this paper, evaluation and annotation of other clinically important arrhythmias are needed. While we defined VT using the criteria currently used in clinical practice (i.e., >6 wide QRSs >100 beats/min), these rather strict criteria may be too sensitive and result in unnecessary (i.e., non-actionable) true VT. For example, in a prior study, we showed that actionable true VT (i.e., new/adjust medications or electrolytes, defibrillation, and in-hospital cardiac arrest) was of longer duration and much faster than non-actionable VT. [16] Additional studies are warranted to identify clinically important VT criteria that are associated with untoward patient outcomes (i.e., cardiac arrest, acute symptoms, and/or vital sign changes), which could further reduce unnecessary alarms while identifying high-risk patients who would benefit from available therapies. While our designed VT algorithm resulted in fewer false VT events (35%) when compared to the current bedside monitor at our institution (87%), [5] this rate is still unacceptably high. We also identified a small subgroup of 17 unique patients who had nearly 4000 unresolved VT events (neither true nor false). These patients often exhibited underlying ventricular pacer and/or BBB (right/left), and co-occurring tachycardia (i.e., sinus, or atrial fibrillation/flutter). Therefore, future algorithm development aimed at improving VT detection in patients with these confounders is needed. In addition, incorporating other ECG features including QRS morphology and other features in specific leads, including aVR (Vereckei et al., 2008) and lead II (Pava et al., 2010) should also be explored in future algorithms. Lastly, the number of missed VT event (false negatives) using our VT algorithm was not explored. However, our group is undertaking this endeavor now.

6 | CONCLUSIONS

The VT alarm annotation protocol described in the paper is the single largest and most comprehensive human annotation effort done to date. The protocol design used (i.e., ground truth, multi-tier, manual annotation, confirmed by three-experts) using currently available bedside ECG monitors should serve as a gold standard database used to develop and test not only current but new VT algorithms. The UCSF VT database includes a rich sampling of real-world ICU patients with not only true and false VT events, but less definitive VT events, which has implications for clinical practice and researchers developing VT algorithms. Our carefully annotated database could also be used to test artificial intelligence (AI) approaches (i.e., machine learning) used to identify VT. Given that we had a much higher rate of true VT using our developed algorithm, our data are likely to substantially enhance AI techniques. The next step in this line of inquiry is to annotate the rate of false-negative VT (i.e., missed VT) using our algorithm and compare our identified VTs to those used in several currently available bedside monitors.

AUTHOR CONTRIBUTIONS

Conception and design: Pelter MM, Mortara DW, Badilini F; Collection and assembly of data: Badilini F, Isola L; Data analysis: Prasad PA; Interpretation: Pelter MM, Carey MG, Al-Zaiti S, Zegre-Hemsey J, Sommargren C; Manuscript writing: All authors; All authors approved the final version of manuscript.

CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to report.

DATA AVAILABILITY STATEMENT

Research data are not shared.

ETHICAL STATEMENT

This study was approved by our institutions Committee on Human Research (IRB #:12-09723) with waiver of patient consent because ECG and physiologic monitoring is part of routine ICU care and we analyzed the data retrospectively.

ORCID

Michele M. Pelter https://orcid.org/0000-0001-9456-228X
Salah Al-Zaiti https://orcid.org/0000-0002-6862-0658
Lamberto Isola https://orcid.org/0000-0002-2595-1959

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