Diagnostic Accuracy of Commercially Available Automated External Defibrillators

Takahiko Nishiyama, MD; Ako Nishiyama, ME; Masachika Negishi, ME; Shin Kashimura, MD; Yoshinori Katsumata, MD; Takehiro Kimura, MD; Nobuhiro Nishiyama, MD; Yoko Tanimoto, MD; Yoshiyasu Alazawa, MD; Hideo Mitamura, MD; Keiichi Fukuda, MD; Seiji Takatsuki, MD

Background—Although automated external defibrillators (AEDs) have contributed to a better survival of out-of-hospital cardiac arrests, there have been reports of their malfunctioning. We investigated the diagnostic accuracy of commercially available AEDs using surface ECGs of ventricular fibrillation (VF), ventricular tachycardia (VT), and supraventricular tachycardia (SVT).

Methods and Results—ECGs (VF 31, VT 48, SVT 97) were stored during electrophysiological studies and transmitted to 4 AEDs, the LifePak CR Plus (CR Plus), HeartStart FR3 (FR3), and CardioLife AED-2150 (CL2150) and -9231 (CL9231), through the pad electrode cables. For VF, the CL2150 and CL9231 advised shocks in all cases, and the CR Plus and FR3 advised shocks in all but one VF case. For VTs faster than 180 bpm, the ratios for advising shocks were 79%, 36%, 89%, and 96% for the CR Plus, FR3, CL2150, and CL9231, respectively. The FR3 and CR Plus did not advise shocks for narrow QRS SVTs, whereas the CL9231 tended to treat high-rate tachycardias faster than 180 bpm even with narrow QRS complexes. The characteristics of the shock advice for the FR3 differed from that for the CL9231 (kappa coefficient [κ]=0.479, P<0.001), and the CR Plus and CL2150 had characteristics somewhere between the 2 former AEDs (κ=0.818, P<0.001).

Conclusions—Commercially available AEDs diagnosed VF almost always correctly. For VT and SVT diagnoses, a discrepancy was evident among the 4 investigated AEDs. The differences in the arrhythmia diagnosis algorithms for differentiating SVT from VT were thought to account for these differences. (J Am Heart Assoc. 2015;4:e002465 doi: 10.1161/JAHA.115.002465)

Key Words: cardiopulmonary resuscitation • defibrillation • fibrillation • tachycardia

Out-of-hospital cardiac arrests are reported as having a poor outcome.1–4 Early defibrillation improves the survival of victims of sudden cardiac arrest.5–16 However, it is often difficult to shorten the time from the cardiac arrest to the defibrillation utilizing the emergency medical service. An automated external defibrillator (AED) allows bystander rescuers to defibrillate out-of-hospital ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT) before the emergency medical service arrives.17–25 In fact, nationwide dissemination of publicly accessible AEDs in Japan resulted in an earlier administration of shocks by bystanders and has improved the rate of survival.26,27 The AED effectiveness is dependent on the device’s ability to detect lethal arrhythmias and on the operator’s ability to use the device correctly,28 and errors associated with AED use have been identified as device dependent or operator dependent.29,30 There have been a few cases in which AEDs failed to recognize VF due to the presence of pacemaker spikes or artifact.31 AEDs are designed such that they have a very high specificity (>99%) and moderately high sensitivity (>90%) for VF detection in contrast to implantable cardioverter-defibrillators, which should be provided with a 100% sensitivity even at the cost of a decreased specificity. More precisely, implantable cardioverter-defibrillators automatically discharge electrical shocks to treat life-threatening VT/VF at the expense of some false (inappropriate) shocks, which are annoying but less critical for the patient. Therefore, a higher sensitivity for an implantable cardioverter-defibrillators to detect VF is crucial and respected as such. In contrast, giving a shock with an AED is unique in that it requires a layperson at the scene who may potentially be faced with a legal problem if he/she gives an inappropriate shock to a victim with no life-threatening arrhythmias. Accordingly, the specificity for an AED not to give inappropriate shocks for benign

From the Departments of Cardiology (T.N., S.K., Y.K., T.K., N.N., Y.T., Y.A., K.F., S.T.) and Medical Engineering (A.N., M.N.), Keio University School of Medicine, Tokyo, Japan; Cardiovascular Center, Tachikawa Hospital, Federation of National Public Service Personnel Mutual Aid Associations, Tokyo, Japan (H.M.).

Correspondence to: Seiji Takatsuki, MD, Department of Cardiology, Keio University School of Medicine, 35 Shinanomachi, Shinjuku-ku, Tokyo 160-8582, Japan. E-mail: seiji.takatsuki@gmail.com

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arrhythmias is important not only for the patient, but also for the rescuer.

AED manufacturers individually have developed arrhythmia analysis algorithms and collected data to investigate the AED performance. There are possible differences in the sensitivity and specificity for diagnosing tachyarrhythmias among the AEDs manufactured by different companies. However, little is known about the differences in the response to arrhythmias among each AED type. We investigated the diagnostic accuracy of the commercially available AEDs using surface electrocardiograms of VF, VT, and supraventricular tachycardias (SVTs) including atrial tachycardia, atrioventricular reentrant tachycardia, atrial flutter, and atrioventricular nodal reentrant tachycardia.

Methods

Extraction of the ECGs

This study was approved by Institutional Review Board of Keio University School of Medicine. We extracted the surface ECGs of tachyarrhythmias lasting >15 s without pacing spikes from the digital data stored in a lab system (Prucka, Cardiolab, GE, CT) with a recording rate of 1 ms during electrophysiological (EP) studies at our hospital. Lead II was selected, which had a QRS vector similar to that recorded by the AED patch electrodes. The extracted ECGs consisted of 31 VF, 48 VT, and 97 SVT episodes including 21 with aberrant conduction. Each patient who underwent EP study submitted written informed consent that the data obtained during EP study could be used for research purpose.

Investigating the Diagnostic Accuracy

The extracted data were transferred to a personal computer (Inspiron 570; Dell, TX) and converted to binary data by the EcgDataMaker (Nihon Kohden, Tokyo, Japan). The binary data were converted to analog ECG data by the DARepeat (Nihon Kohden) through a DA converter board (PCI-3338; Interface Corporation, Hiroshima, Japan). The ECG data were transmitted to 4 AEDs simultaneously through a 1/1000 scale resistor box and pad electrode cables. Four AEDs consisting of the LifePak CR Plus (CR Plus) (PhysioControl, WA), HeartStart FR3 (FR3) (Philips, Amsterdam, Netherland), CardioLife AED2150 (CL2150) (Nihon Kohden), and CardioLife AED9231 (CL9231) (Cardiac Science, WA) were investigated as to whether they advised delivering a shock for each of the ECGs (Figure 1).

According to the American Heart Association recommendations, VF and rapid VT were considered to be shockable rhythms. We analyzed the ECG data at 2-minute intervals.

Figure 1. AEDs studied. Four AEDs were investigated as to whether shocks were delivered for each arrhythmia. Recordings from each AED are shown analyzing the same ECG of VF. A, LifePak CR Plus, (B) HeartStart FR3, (C) CardioLife AED2150, and (D) CardioLife AED9231. AEDs indicates automated external defibrillators; VF, ventricular fibrillation.
and checked the reproducibility by performing 2 analyses for each ECG. The AED analysis data were transmitted to a personal computer via an infrared communication port for the CR Plus, SD card for the FR3, bluetooth for the CL2150, and serial communication (RS-232c) for the CL9231.

Data Analysis

The characteristics of the ECGs were analyzed using the digital data of the ECGs. The heart rate (HR) and QRS duration were measured during the VT and SVT. The parameters of the ECG were calculated as follows. The maximum amplitude was the maximum value of the absolute value of the amplitude of the ECG. The average amplitude was the mean of the absolute value of the amplitude of the ECG during the recording. The slopes of the ECGs, standardized by the differentials of the amplitude (dV/dt), were calculated by the voltage difference per 1 ms (Figure 2). The rate of change of the slope, that is, the secondary differential of the dV/dt (dV/dt²), was also calculated by the dV/dt difference per 1 ms (Figure 2). The maximum values of the dV/dt and dV/dt² were defined as the maximal values of the absolute values of the dV/dt and dV/dt². The ECG of the VT was considered irregular if it had fluctuations or beat-to-beat amplitude changes. Also, whether emergent cardioversion was applied for the recorded VT or not because of hemodynamic collapse during the EP study was examined.

The rhythm detection criteria were defined for the following: (1) shockable rhythms: VF and rapid VT (HR ≥180 bpm); (2) nonshockable rhythms: SVT; and (3) intermediate rhythms: other VT (HR <180 bpm). As a whole, the sensitivity, specificity, and false positive rates were estimated for the performance of the AEDs. The sensitivity was demonstrated as a percentage of the number of shock advisories for VF and rapid VT. The specificity was expressed as a percentage of the number of nonshock advisories for VT.

Statistical Analysis

The data are expressed as the mean ± standard deviation. The ratios of the shocks for VTs and SVTs were compared using a χ² test. Interdevice agreement for the shock advice was analyzed for each pair of devices (a total of 6 combinations) by calculating the kappa coefficient (κ). The factors of the ECGs such as the HR, amplitude, QRS duration, dV/dt, and dV/dt² were compared with a parametric 2-sample t test or a nonparametric Mann–Whitney U test between the shock advice and nonshock advice given for each AED. A value of P<0.05 was considered significant. The analyses were performed with IBM SPSS software version 22.0 (IBM, Armonk, NY).

Figure 2. Representative cases of the ECGs, dV/dt and dV/dt². The ECG, dV/dt and dV/dt² of atrioventricular reentrant tachycardia, VT, and VF are shown, respectively. The slope of the ECG represented by the dV/dt was calculated by the voltage difference per 1 ms. The rate of change in the slope represented as the dV/dt² was calculated by the dV/dt difference per 1 ms. AVRT indicates atrioventricular reentrant tachycardia; VF, ventricular fibrillation; VT, ventricular tachycardia.
Results

Patient and ECG Characteristics

The records were obtained from stored recordings of EP studies at our hospital from 2008 to 2012. A total of 176 ECGs consisting of 31 VF, 48 VT, 54 atrial tachycardias, 23 atroventricular reentrant tachycardias, 2 atrial flutters, and 21 atroventricular nodal reentrant tachycardia episodes in 126 patients (85 males, 53±17 years) were utilized in this study. The ECGs of the VF episodes were recorded from a total of 24 VF patients that consisted of 5 with Brugada syndrome, 5 with other idiopathic VF, 4 with hypertrophic cardiomyopathy (HCM), 4 with dilated cardiomyopathy (DCM), 2 with congenital heart disease (CHD), 2 with coronary artery disease (CAD), 1 with cardiac sarcoidosis, and 1 with valvular heart disease (VHD). The ECGs of the 30 VTs were recorded from a total of 28 VT patients consisting of 7 with CAD, 4 with HCM, 4 with DCM, 5 with idiopathic VT, 3 with CHD, 2 with VHD, 2 with postmyocarditis, and 1 with arrhythmogenic right ventricular cardiomyopathy. SVTs consisting of atrial tachycardia, AVRT, atrial flutter, and atroventricular nodal reentrant tachycardia were classified into a narrow QRS (<120 ms) group and wide QRS (≥120 ms) group. The average HR, maximum HR, minimum HR, QRS width, amplitude, dV/dt, and dV/dt² are summarized in Table 1.

AED Performance Data for All Arrhythmias

VF

The ratio of shock advice of each AED for all ECGs is demonstrated in Figure 3, which was classified according to the types of arrhythmias including VF, VT, SVT, narrow QRS SVT, and wide QRS SVT. The diagnosis of the AEDs to advise to shock or not did not change when comparing the first and second attempts in all ECGs.

The average amplitude of VF was 0.36±0.18 mV. For VF, the CL2150 and CL9231 advised the need to shock in all 31 ECGs and the CR Plus and FR3 advised shocks in all cases except for 1. The ECGs for which shocks were not advised by the FR3 and CR Plus are demonstrated, respectively, in Figure 4. Regarding the characteristics, the average amplitude, maximum amplitude, maximum dV/dt, and maximum dV/dt² for both ECGs that the CR Plus and FR3 did not advise to shock were 0.25 mV, 1.32 mV, 0.073 mV/ms, and 0.022 mV/ms², and 0.15 mV, 0.57 mV, 0.033 mV/ms, and 0.018 mV/ms², respectively.

VT

The HR of the VT was 183±60 bpm and ranged from 75 to 300 bpm. With each AED, the average HR of the VT that was advised to be shocked was significantly higher than that for those that no shock was advised (CR Plus; 216±52 versus

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**Table 1.** ECG Characteristics

<table>
<thead>
<tr>
<th>Type</th>
<th>n</th>
<th>HR (bpm)</th>
<th>QRS Width (ms)</th>
<th>Average Amplitude (mV)</th>
<th>Maximum Amplitude (mV)</th>
<th>Maximum dV/dt (mV/ms)</th>
<th>Maximum dV/dt² (mV/ms²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VF</td>
<td>31</td>
<td>—</td>
<td>—</td>
<td>0.36±0.18</td>
<td>1.31±0.49</td>
<td>0.074±0.075</td>
<td>0.041±0.080</td>
</tr>
<tr>
<td>VT</td>
<td>48</td>
<td>183±60</td>
<td>158±38</td>
<td>0.41±0.25</td>
<td>1.31±0.76</td>
<td>0.069±0.049</td>
<td>0.033±0.042</td>
</tr>
<tr>
<td>SVT</td>
<td>97</td>
<td>153±46</td>
<td>104±37</td>
<td>0.23±0.21</td>
<td>1.12±0.63</td>
<td>0.090±0.062</td>
<td>0.046±0.068</td>
</tr>
<tr>
<td>Narrow</td>
<td>76</td>
<td>146±45</td>
<td>87±10</td>
<td>0.19±0.16</td>
<td>1.04±0.48</td>
<td>0.096±0.067</td>
<td>0.048±0.076</td>
</tr>
<tr>
<td>Wide</td>
<td>21</td>
<td>174±47</td>
<td>162±33</td>
<td>0.37±0.28</td>
<td>1.39±0.96</td>
<td>0.074±0.040</td>
<td>0.040±0.037</td>
</tr>
</tbody>
</table>

The characteristics of each arrhythmia such as the HR, amplitude, QRS duration, dV/dt, and dV/dt² are shown. HR indicates heart rate; SVT, supraventricular tachycardia; VF, ventricular fibrillation; VT, ventricular tachycardia.

Figure 3. Shock advice ratios. Shock advice ratios of each AED for VF, VT, and SVT are shown in the upper panel. In the lower panel, the shock advice ratios for a narrow QRS VT (<120 ms) and wide QRS VT (≥120 ms) are shown. AED indicates automated external defibrillator; SVT, supraventricular tachycardia; VF, ventricular fibrillation; VT, ventricular tachycardia.
145±46 bpm, P<0.01, FR3; 246±50 versus 169±53 bpm, P<0.01, CL2150; 223±45 versus 136±39 bpm, P<0.01, and CL9231; 220±44 versus 126±32 bpm, P<0.01, Figure 5). The median of the amplitude, maximum amplitude, and maximum dV/dt of the VTs advised to receive a shock were larger than those for the VTs not advised to be shocked (Table 2). Of those the FR3 delivered shocks for 8 VTs, and 6 VTs were considered irregular, whereas for the other AEDs the shocks were advised for all 8 VTs. The FR3 had the lowest rate of advising shocks for VT and did not respond to VTs with an HR of >250 bpm that had a stable interval and amplitude (Figure 6A and 6B). Whereas the FR3 advised shocks for VTs with an HR <200 bpm, in 1 that demonstrated fluctuations in the ECG baseline due to respirations and another that had a transient (actually 4 beat), HR acceleration (Figure 6C and 6D). For rapid VT and other VTs, the shock advice ratios were 22/28 (79%), 10/28 (36%), 25/28 (89%), and 27/28 (96%), and 5/20 (25%), 0/20 (0%), 2/20 (10%), and 3/20 (15%) for the CR Plus, FR3, CL2150, and CL9231, respectively.

Figure 4. Nonshock advised ventricular fibrillation (VF). A, A nonshock advised for VF by the CR Plus. B, A nonshock advised for VF by the FR3.

Figure 5. HR of shocked vs nonshocked VTs. The HRs of the shocked vs nonshocked VTs are plotted. All AEDs delivered shock therapy to the VTs with a significantly higher HR. AEDs indicates automated external defibrillators; HR, heart rate; VTs, ventricular tachycardias.
During the EP study, external electrical cardioversion was applied in 13 cases because of hemodynamic collapse during the VT. The mean blood pressure was 43±8 mm Hg in the cases with external cardioversion and 85±20 mm Hg in the cases without cardioversion. Regarding those VT ECGs, the ratios of the shock advice were 11/13 (85%), 5/13 (38%), 10/13 (77%), and 12/13 (92%) for the CR Plus, FR3, CL2150, and CL9231, respectively (P<0.05).

SVT
The FR3 did not advise shocks for any of the SVTs. The SVT ECGs included 21 cases with a wide QRS morphology. In order to assess the differences in the device response to different QRS morphologies, we divided the SVTs into a narrow QRS group and wide QRS group. The mean HR of the wide QRS group was 174±47 bpm, which was significantly higher than that of the narrow QRS group (146±45 bpm, P<0.01). The CL9231 advised shocks most frequently for narrow QRS SVT and exclusively for SVTs with an HR faster than 180 bpm (Figure 7). All AEDs except for the FR3 treated at least 1 ECG with a wide QRS SVT.

Diagnostic Accuracy
The performance data are summarized for each AED. The sensitivity for shockable rhythms was 88%, 68%, 89%, and 98% for the CR Plus, FR3, CL2150, and CL9231, respectively (P<0.01). The specificity for nonshockable rhythms was 95%, 100%, 87%, and 74%, respectively (P<0.01). The false positive rate was 5%, 0%, 13%, and 26%, respectively (P<0.01).

Correlation of the Shock Advice
We compared the interdevice agreement for the shocks among each of the AEDs by calculating the kappa coefficient (κ). The FR3 had a different characteristic of the shock advice than the CL9231 (κ=0.479, P<0.01). Although the FR3 did not advise shocks for SVTs and most VTs, the CL9231 treated tachycardias faster than 180 bpm. The CR Plus and CL2150 demonstrated characteristics between the above 2 AEDs (κ=0.818, P<0.01).

Discussion
Early defibrillation is critical for survival from sudden cardiac arrest because the most frequent initial rhythm is VF. To treat VF, rescuers must be able to rapidly integrate the use of an AED with cardiopulmonary resuscitation (CPR). AEDs are reliable computerized devices that use voice and visual monitors to guide rescuers to defibrillate VF and pulseless VT. In this study, we investigated the differences in the patterns
of the shock advice for VF, VT, and SVT by commercially available AEDs. For VF, all AEDs advised shocks in almost all cases. It is impossible for both the sensitivity and specificity to reach 100% with any system. To avoid any false detection causing an inappropriate shock, designing algorithms for a 100% specificity at the expense of a lower sensitivity seems sensible for AEDs. The international standards advocate that AEDs have a sensitivity of >90% for detecting coarse VF of at least 200 μV in amplitude, and an overall specificity of >95% so that laypersons can operate them safely. In fact, a previous study reported that the sensitivity and specificity for all shockable rhythms (VF or VT) were 81.0% and 99.9%, respectively. The amplitude was one of the most important factors for detecting VF. For fine VF with an amplitude of <200 μV, the sensitivity was reported to be only 67.3%. In our study, the VF ECGs had an amplitude of 1.31 mV and did not include low amplitude fine VF, because the VF was able to be defibrillated within 30 s during the EP study. Although information on the detailed algorithms has not been published, each cutoff amplitude is considered to be 80, 100, and 150 μV for Medtronic, Philips, and Nihon Kohden. In addition, the HR and waveforms were analyzed according to the individual algorithms.

In contrast to the response for VF, the ratio of shock advice for VT and SVT varied depending on the type of AED, and the FR3 had the lowest ratio of shock advice among the 4 AEDs. The performance goals for the arrhythmia analysis algorithms advocated by the American Heart Association showed a >75% sensitivity for rapid VT. The task force did not specify a minimum rate above which VT should be shocked, because the tolerance to VT varies widely among patients. The 3 AEDs, excluding the FR3, demonstrated a sensitivity higher than 75% for VT with an HR of >180 bpm, and the FR3 had a sensitivity of only 36%.

For SVT, the FR3 did not advise shocks regardless of whether it had a wide or narrow QRS morphology. In contrast, the CL9231 had the highest ratio of shock advice for VT, and its ratio of shock advice for SVT with a narrow QRS morphology was 18%. These results revealed the differences in the individual arrhythmia analysis algorithms according to each AED manufacturer. The American Heart Association task force designated SVT, including sinus tachycardia, bundle branch block, and Wolff-Parkinson-White syndrome, as a nonshockable rhythm and required a specificity of >95% for SVT. Among the 4 AEDs we investigated in this study, only the FR3 was able to attain that performance goal. For the CR Plus and FR3, it is speculated that the algorithm is dependent on the recognition of the ECG morphology rather than the HR. The FR3 was less sensitive to VT and advised no shocks for SVT, whereas the CL9231 treated high rate SVTs despite them having a narrow QRS morphology for SVTs with an HR faster than 180 bpm. If the priority had been placed on the HR as a parameter, the FR3 would have had an improved ratio of delivering shocks for VT. However, in that case the benefit of the FR3 of being able to only advise no shocks for SVTs may have disappeared.
The CR Plus and CL2150 had characteristics between the above 2 AEDs. AEDs analyze multiple features of the surface ECG signals, including the frequency, amplitude, and some integration of factors, such as the slope and morphology. In comparing wide QRS SVTs with VT, the ratio of the shock advice for a wide QRS SVT was lower than the latter. This implies that the algorithm was designed to recognize the upstroke of the QRS complex. The same tendency to advise shocks for VT and SVT was shown. The algorithm that highly recommended shocks for VT also highly recommended shocks for SVT and vice versa. We could not describe the algorithms of each AED; however, an HR >180 was a dominant factor for judging shockable rhythms with the CL9231. AEDs are meant to be used for unconscious people, and hence, treating VT should be encouraged. However, if the AED is used for conscious people, advertent shocks for SVT should be avoided. Although an accuracy of diagnosing VT of >70% is required, it is not recommended to treat SVT with shocks. In this regard, the concept for the manufacturers to determine whether or not to treat regular tachycardias with shocks is reflected, and we could not conclude which algorithm was superior since no AEDs could attain a >75% sensitivity for rapid VT and a >95% specificity for SVT at the same time.

The diagnostic accuracy of commercially available AEDs has been reported; however, the differences among the manufacturers remain unknown. This study demonstrated that the AEDs advised shocks for VF in almost all cases. For VT and SVT, it also verified that the ratios of the shock advice differed for each AED. The accuracy of the ECG rhythm analysis was elucidated for each AED. This study revealed that AEDs could advise to deliver shocks for SVTs, especially those with a wide QRS complex. Furthermore, what percentage of these false actions is acceptable remains an open question, and requires further evaluation. It is unreasonable to expect AEDs to be 100% accurate in recognizing and treating all lethal arrhythmias requiring defibrillation. Actually, the FR3 had a lower shock advice ratio for VT than the other AEDs, which might provoke concern for its clinical use. However, our VT ECGs did not consist of fatal VTs recorded during cardiopulmonary resuscitation. For the VF ECGs, the FR3 had satisfactory results and that was the only AED that did not advise the delivery of shocks for any SVTs including wide QRS complex SVTs. Hence, it is too early to recommend

**Figure 7.** HR of shocked vs nonshocked SVTs. The HR of the shocked or nonshocked narrow QRS SVTs and wide QRS SVTs is plotted. The FR3 did not deliver shocks for any SVTs. The CR Plus delivered shocks for a few cases of wide QRS SVTs. The CL2150 advised shocks in a few cases. The CL9231 had a tendency to respond to narrow QRS SVTs with an HR higher than 180 bpm. HR indicates heart rate; SVTs, supraventricular tachycardias.
Referring from using the FR3 based on the results of our study, and further evaluation is needed. Regardless, it is critically important for bystanders to not only be able to properly use AEDs, but also to perform continuous CPR. In the future, the adoption of such functions as detecting respirations or the pulse by the surface pad electrodes may help recognize pulselessness more objectively and subsequently provide appropriate shock advice for both VT and SVT.

**Study Limitations**

This study was not performed with ECGs obtained by AED patch electrodes during CPR, but instead was with lead II ECGs recorded during EP studies in patients who did not undergo CPR. Hence, the differences in the patch electrodes among the AEDs and appropriateness of the use of the patch electrodes were not taken into account. VF was immediately defibrillated by shocks in the EP lab, hence traces of end-stage VF, so-called fine VF, were not obtained or tested. It is unknown whether the VTs in this study would have caused a loss of consciousness because the patients were sedated during the EP study. Therefore, the data do not necessarily reflect clinically relevant “pulseless VT”.

**Conclusions**

This study revealed that commercially available AEDs correctly defibrillated by shocks in the EP lab, hence traces of end-stage VF, so-called fine VF, were not obtained or tested. It is unknown whether the VTs in this study would have caused a loss of consciousness because the patients were sedated during the EP study. Therefore, the data do not necessarily reflect clinically relevant “pulseless VT”.

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None.

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