Prospective, Randomized Comparison in Humans of a Unipolar Defibrillation System With That Using an Additional Superior Vena Cava Electrode

Gust H. Bardy, MD; G. Lee Dolack, MD; Peter J. Kudenchuk, MD; Jeanne E. Poole, MD; Rahul Mehra, PhD; George Johnson, BSEE

Background A unipolar defibrillation system using a single right ventricular (RV) electrode and the active shell or “CAN” of the implantable cardioverter-defibrillator itself situated in a left infraclavicular pocket has been shown to be as efficient in defibrillation as an epicardial lead system. The purpose of this study was to determine whether defibrillation efficacy can be improved further by adding a superior vena cava (SVC) electrode to this already efficient defibrillation system.

Methods and Results We prospectively and randomly compared the defibrillation efficacy of a simplified unipolar defibrillation system, RV→CAN, with that of one incorporating a high SVC electrode, RV→SVC+CAN, in 15 consecutive cardiac arrest survivors undergoing implantation of a presently available transvenous defibrillation system. The RV defibrillation electrode was a 5-cm coil located on a 10.5F lead used as the anode in both lead configurations examined. The active CAN was a 108-cm² surface area of a titanium alloy pulse generator used as the cathode in both configurations and placed in a left infraclavicular pocket. The SVC electrode was a 6F 5-cm-long coil and was used as an additional cathode positioned at the junction of the SVC and the left innominate vein. The defibrillation pulse used was a 65% tilt, asymmetric biphasic waveform delivered from a 120-μF capacitor. The defibrillation threshold (DFT) stored energy, leading edge voltage, current, and pulsing resistance were measured for both lead systems. The single-lead unipolar system, RV→CAN, resulted in a stored energy DFT of 7.4±5.2 J, and the three-electrode dual pathway system, RV→SVC+CAN, resulted in a DFT of 6.0±3.4 J (P=.20). There was no difference in defibrillation efficacy with the more complicated three-electrode system over the unipolar system despite a decrease in pulsing resistance to 48.6±3.5 Ω compared with 61.2±5.9 Ω for the unipolar system (P<.0001) and a slight rise in delivered current to 6.3±1.8 A compared with 5.5±2.0 A for the unipolar system (P=.062).

Conclusions The unipolar single-lead transvenous defibrillation system provides defibrillation at energy levels comparable to that reported with present epicardial lead systems. Coupling of this lead system to a third SVC electrode increases system complexity but offers little defibrillation advantage despite a large decrease in pulsing resistance and a modest increase in delivered current. (Circulation. 1994;90:1090-1093.)

Key Words: death, sudden • fibrillation • tachycardia • cardioverter-defibrillators

Methods

Patient Population

After providing informed verbal and written consent, comparison of a prototype of a new unipolar single-lead, pectoral transvenous defibrillation system (Medtronic model 7219C) with that of the same system incorporating a third, superior vena cava (SVC) electrode was conducted in a randomized, prospective fashion in 15 consecutive patients with syncopal ventricular tachycardia (VT) and/or ventricular fibrillation (VF) before implantation of a standard transvenous defibrillator as previously described.

Defibrillation Lead Systems

The prototype unipolar transvenous defibrillation system has been described previously. Briefly, it consists of a single 10.5F anodal 5-cm-long endocardial right ventricular (RV) defibrillation electrode (Medtronic model 6966) and a 108-cm² surface area cathodal pulse generator titanium shell or “CAN” electrode (Medtronic model 7219C) that was placed in a left infraclavicular pocket (Fig 1A). The CAN electrode was used as the cathode for the first phase of the shock. The RV endocardial electrode was inserted into the left cephalic vein when possible; otherwise the left subclavian vein was cannulated. The endocardial RV lead also had standard bipolar pace/sense electrodes at the tip. This lead was used in defibrillation testing with the unipolar defibrillation system and with

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A new unipolar transvenous defibrillation system has been demonstrated to decrease defibrillation energy requirements into the range of presently implemented epicardial systems yet be nearly as easy to insert as a pacemaker. Although this is a promising new approach to defibrillation, any additional improvement in defibrillation efficacy offers the opportunity to decrease defibrillator size from the present 80-mL volume to significantly smaller sizes by allowing for devices with lower maximum output. Additional decreases in size would in turn decrease the mortality, morbidity, and costs of defibrillator surgery and potentially open the doors to prophylactic defibrillator use. Therefore, it was the purpose of this study to evaluate in a prospective, randomized fashion the value of adding a superior vena cava electrode to the unipolar single-lead defibrillation system in a consecutive population of cardiac arrest survivors.
the three-lead system in which the SVC and the CAN were the common cathode for the first phase of the shock that was delivered to the RV electrode. The RV lead ultimately was used as part of the permanently implanted standard transvenous defibrillation system described previously.13,14

The second transvenous lead used in simultaneous dual pathway pulsing from the SVC and active CAN electrode (Figure 1B) was a 6.5F catheter (Medtronic model 6963) that had a 5-cm-long coil electrode. This lead was inserted using Seldinger technique cannulation of the left subclavian vein. Like the RV lead, the SVC lead remained in situ for the permanent transvenous lead system used for patient care.13,14 The location of the SVC electrode was constant throughout the study, with the tip of this lead overlaying the midspine as the lead traversed the junction of the SVC and the left innominate vein. This location was chosen to direct more current toward the left ventricle as it passed from the RV electrode to the SVC electrode.

**Defibrillation Threshold Testing**

Defibrillation threshold testing was performed in a randomized fashion for the two systems under study. The waveform used for either system was a 65% tilt, 120-μF capacitor, asymmetric biphasic defibrillation pulse.15-17 The first transvenous defibrillation test began with a 10-J stored energy pulse delivered 10 seconds after VF onset, with the 10-second interval including the time period during which alternating current was applied.18 If the defibrillation pulse was unsuccessful, a 100- to 200-J transthoracic anterior-posterior rescue pulse was delivered immediately with a precharged external defibrillator (Physio-Control LifePak 6s).

After a minimum rest period of 3 minutes between VF inductions, pulse output was increased or decreased depending on transvenous shock failure or success. Between each induction and termination of VF, care was taken to ensure that ECG ST-T segments, QRS duration, and arterial pressure had returned to baseline values before VF was reintiated. Pulse energies were changed in 5-J steps between energies of 30 to 10 J, in 2.5-J steps for pulse energies between 10 to 5 J, and in 1.25-J steps below 5 J.

The defibrillation threshold was defined as the lowest pulse amplitude that could successfully terminate VF 10 seconds after its initiation.18 All defibrillation pulse characteristics were measured from oscilloscopic recordings of voltage and current waveforms, as previously described.19 For dual pathway pulsing, current and resistance were measured for each pathway. Because of the limitations of repetitive induction and termination of VF in humans, the defibrillation threshold was measured only once for each method examined.

**Statistical Analysis**

A two-tailed t test was used to compare defibrillation thresholds for the unipolar system with that of the system incorporating an SVC electrode. Comparisons were also made for percent efficacy at 10 J, an energy setting that was used in all patients for both methods.

**Results**

**Patient Clinical Characteristics**

Of the 15 patients studied, 13 were men (87%). The mean age was 61±10 years, with a range of 27 to 73 years of age. Coronary artery disease was the primary structural heart disease in nine, three had both coronary artery disease and dilated cardiomyopathy, one had dilated cardiomyopathy, one had right ventricular dysplasia, and one had long QT syndrome. The mean left ventricular ejection fraction was 0.44±0.15; range was 0.22 to 0.65. The index arrhythmia leading to device implantation was VF in five patients, VT in six patients, and both VT and VF in four patients.

**Defibrillation Efficacy**

The defibrillation threshold data are detailed in the Table. The defibrillation threshold stored energy for the single-lead unipolar defibrillation system was 7.4±5.2 J, with a range of 1.6 to 17.7 J (Fig 2). The measured leading edge voltage defibrillation threshold for the single-lead unipolar defibrillation system was 334±116 V, with a range of 164 to 543 V, and the measured
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leading edge current defibrillation threshold for the unipolar defibrillation system was 5.5±2.0 A, with a range of 2.6 to 9.7 A. The measured leading edge resistance at the defibrillation threshold with the two-electrode system was 61.2±5.9 Ω, with a range of 49.5 to 69.4 Ω (Fig 3). Of the 15 patients examined, 12 of 15 (80%) were defibrillated by less than 10 J, and all (100%) were defibrillated by less than 24 J using this system.

In the case of the three-electrode system, the mean defibrillation threshold stored energy was 6.0±3.4 J (range, 2.6 to 15.0 J) and was not statistically different than that with a two-electrode system (P=0.20). The measured leading edge voltage at the defibrillation threshold for the three-electrode pulsing method was 306±83 V (range, 209 to 500 V), and this was not statistically different than that for the two-electrode system (P=0.25). The measured combined leading edge current at the defibrillation threshold for the three-electrode system was 6.3±1.8 A (range, 4.1 to 11.0 A). The leading edge current at the defibrillation threshold for the three-electrode system was not statistically higher than for the two-lead system (P=0.062). The pulsing resistance for the three-electrode system at the defibrillation threshold was lower than for the unipolar system (48.6±3.5 Ω; range, 42.9 to 54.4 Ω; P<0.0001). Of the 15 patients examined, 14 (93%) were defibrillated by less than 10 J, and all (100%) were defibrillated by less than 24 J using this system.

The current for each pathway of the dual pathway pulsing technique and the associated pathway resistance are as follows. For the RV-SVC component, the current was 2.7±0.8 A (range, 1.7 to 4.5 A) and the resistance was 115.3±9.8 Ω (range, 101.2 to 129.9 Ω). For the RV-CAN component, the current was 3.7±1.1 A (range, 2.0 to 6.5 A) and the resistance was 84.9±10.6 Ω (range, 64.7 to 104.4 Ω).

Discussion

This study has confirmed that the addition of a third transvenous electrode in the SVC position for purposes of dual pathway, simultaneous biphasic pulsing does not generally improve the defibrillation efficacy of a unipolar transvenous defibrillation system.

We postulate that the efficacy of the unipolar transvenous defibrillation system is related to several factors. First, the unipolar pulsing method uses a biphasic waveform, and this particular biphasic waveform has been shown to improve defibrillation efficacy in previous studies.15,17,20 Second, the current vector is directed from right to left and inferior to superior. Depending on the RV defibrillation coil location on the diaphragmatic surface of the right ventricle, the current also may be directed through the heart in a posterior to anterior direction. This is an advantageous combination of vectors.21 Third, an anodal configuration for the intracardiac electrode may be better than a cathodal one.22,23

The general failure of a third electrode in the high SVC–left innominate vein position to substantially improve upon the simpler unipolar defibrillation system may be a consequence of current drain away from the target tissues of the left ventricle.21 Our data suggest that the current delivered to the SVC is about 43% of the total current delivered with the dual pathway system. The diversion of a substantial amount of current from the pathway that would otherwise go to the subcutaneous CAN appears to be disadvantageous for most patients. By inference, the subcutaneous location of the CAN appears to provide a better current path toward the fibrillating ventricles than when used with the SVC lead, offsetting the advantage of lower resistance and higher currents observed with dual pathway pulsing.

The limitations of this study relate to the type of pulsing technique and lead system used to examine the relative efficacy of an SVC electrode added to the unipolar configuration. It is conceivable that a different biphasic pulse, a different SVC location, a different SVC lead design, or a different electrode polarity could have resulted in an alternative conclusion to that found in our study. We must be cognizant of the multiple

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**Pulse Measurements at the Defibrillation Threshold**

<table>
<thead>
<tr>
<th>Lead System</th>
<th>Leading Edge Voltage, V</th>
<th>Leading Edge Current, A</th>
<th>Resistance, Ω</th>
<th>Stored Energy, J</th>
</tr>
</thead>
<tbody>
<tr>
<td>RV→CAN</td>
<td>334±116</td>
<td>5.5±2.0</td>
<td>61.2±5.9</td>
<td>7.4±5.2</td>
</tr>
<tr>
<td>RV→SVC+CAN</td>
<td>306±83</td>
<td>6.3±1.8</td>
<td>48.6±3.5</td>
<td>6.0±3.4</td>
</tr>
<tr>
<td>P</td>
<td>.25</td>
<td>.062</td>
<td>&lt;.0001</td>
<td>.20</td>
</tr>
</tbody>
</table>

RV→CAN indicates simplified unipolar defibrillation system; RV→SVC+CAN, defibrillation system incorporating a high superior vena cava electrode.

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![Graph of paired defibrillation threshold data for stored energy for the unipolar single-lead defibrillation system (RV→CAN⁻) and for the three-lead defibrillation system (RV⁺→SVC⁻+CAN⁻).](image)

![Graph of paired pulse resistance data for the unipolar single-lead defibrillation system (RV⁺→CAN⁻) and for the three-lead defibrillation system (RV⁺→SVC⁻+CAN⁻) at defibrillation.](image)
subtleties affecting defibrillation and not extend our conclusions substantially beyond the present methodologies. In addition, our data do not cancel the value of an SVC lead in any individual patient, as was the case in this study, where patient-specific needs may differ from that of a larger population. Finally, the population studied was relatively small. It is reasonable, however, to conclude at the end of studying 15 patients that a very large number of patients would need to be examined in order to find any statistically significant difference, if it were to occur. Thus, we believe that these findings suggest that more fruitful efforts at improving defibrillation efficacy with the unipolar active CAN system lie elsewhere. Any decrease in defibrillation energy requirements from that achievable with the unipolar defibrillator as currently configured probably will need to derive from other approaches, perhaps from leads in other locations, from alternate waveforms, or from different materials.

It is also relevant to comment on the relatively low defibrillation threshold values found in this study compared with earlier studies of the unipolar defibrillation system. The mean unipolar defibrillation threshold was 7.4 J. This value is lower than the 8- to 10-J range previously reported.1 The difference is probably one of sample size. The lower defibrillation threshold values do not, however, negate the value of the comparison in this study, which was prospective and randomized and therefore valid for comparative purposes.

Acknowledgments

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