Efficacy of a Single-Lead Unipolar Transvenous Defibrillator Compared With a System Employing an Additional Coronary Sinus Electrode 
A Prospective, Randomized Study

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**Background** Recent development of a prototype single-lead unipolar transvenous defibrillator offers the possibility of device implantation with the ease of a permanent pacemaker. Lowering defibrillation energy requirements would allow for a further reduction in defibrillator generator size and enhance the feasibility of pacemaker-like placement. However, if achieving a lower defibrillation energy requires placing additional intracardiac leads, the potential advantage of a smaller generator may be offset by the disadvantages of a more complex lead system. The purpose of this study was to compare defibrillation energy requirements of a single-lead unipolar defibrillator with a three-electrode system employing an additional lead in the coronary sinus.

**Methods and Results** Testing of a single-lead unipolar biphasic pulse defibrillation system versus a three-electrode system with an additional coronary sinus lead was performed in prospective, randomized fashion in 15 patients with a history of ventricular tachycardia or fibrillation. Ventricular fibrillation was induced with alternating current, and defibrillation threshold was measured by a pulse given 10 seconds after arrhythmia induction. The mean defibrillation threshold stored energy and mean leading edge voltage did not significantly differ between the two systems (11.3±5.9 J versus 9.9±5.2 J and 418±118 V versus 390±112 V, respectively; P>.4). Using either defibrillation system, all patients were successfully defibrillated by <24 J and over half of patients by <10 J.

**Conclusions** A unipolar transvenous biphasic defibrillation system is an effective means of treating ventricular fibrillation. The added complexity of additional leads is not offset by any significant improvement in defibrillation efficacy or energy requirements. Given the simplicity and effectiveness of a single-lead system coupled with a small generator, placement of defibrillation systems may now approach the ease of pacemaker implantation. (*Circulation. 1994;89:2641-2644.*)

**Key Words** • fibrillation • tachycardia • defibrillation

Transvenous defibrillation systems have proven to be effective in the treatment of patients with life-threatening ventricular tachyarrhythmias.¹⁻⁴ Recent development of a prototype single-lead unipolar transvenous defibrillator offers the possibility of device placement with the ease of permanent pacemaker implantation.² Efforts to reduce the size of the defibrillator generator by lowering defibrillation energy requirements would further facilitate its pacemaker-like implantation. However, if lower defibrillation energy requirements can only be met by placement of additional intracardiac leads, the potential advantage of a smaller generator may be offset by the disadvantages of a more complex lead system. Therefore, the purpose of this study was to compare the defibrillation energy requirements of a single-lead unipolar defibrillator with a three-electrode system that employs an additional defibrillation lead placed in the coronary sinus.

**Methods**

**Patients**

Fifteen consecutive patients with clinical ventricular tachycardia or fibrillation underwent testing of a prototype defibrillation system consisting of a unipolar single lead and pectorally implanted generator versus the addition of a coronary sinus lead to the identical system. Study patients included 12 men and 3 women with a mean age of 61±12 years (range, 39 to 79), all of whom subsequently received a transvenous defibrillator for clinical ventricular fibrillation (8 patients), ventricular tachycardia (4 patients), or both ventricular tachycardia and fibrillation (3 patients). All patients had structural heart disease: ischemic heart disease in 8 patients, idiopathic dilated cardiomyopathy in 3 patients, and 4 patients in whom the degree of left ventricular systolic dysfunction was out of proportion to the extent of their coronary artery disease. All patients underwent radionuclide ventriculography; the mean left ventricular ejection fraction was 0.38±0.18 (range, 0.13 to 0.71). This study was approved by the Human Subjects Review Committee of the University of Washington; all patients gave informed consent.

**Defibrillation System**

The prototype unipolar single-lead transvenous defibrillator consists of a tripolar 10.5F right ventricular endocardial lead incorporating a 5-cm-long coil anodal defibrillation electrode and standard bipolar pace/sense electrodes at the tip and a Medtronic model 7219C generator with a 108-cm² titanium shell.
(cathodal electrode) placed in the left infraclavicular region.2
The right ventricular electrode was placed via the left cephalic vein or the left subclavian vein and was used for testing the unipolar defibrillation system, the three-electrode system incorporating the coronary sinus lead, and subsequently, the permanently implanted transvenous defibrillator.1–3

The coronary sinus electrode consisted of a 6.5F transvenous catheter (Medtronic model 6963) with a 5-cm coil defibrillation electrode, which was placed into the coronary sinus via the left subclavian vein. Previous work suggested that the proximity of an electrode in the coronary sinus to the left ventricle may facilitate transvenous defibrillation.4 This lead was subsequently retained for the permanently implanted transvenous defibrillator either in the coronary sinus or in the superior vena cava.

The prototype pulse generator shell was positioned in the prepectoralis fascia, 2 to 3 cm inferior to the clavicle and 2 to 3 cm medial of the humeral head (Fig 1). The long axis of the generator was placed parallel to the long axis of the body. Skin edges at the incision site were approximated to ensure that the entire generator shell was encapsulated during testing.

Testing of Defibrillation Threshold

Testing of the single-lead unipolar defibrillation system versus the three-electrode system using the coronary sinus lead was performed in a prospective randomized fashion using a 120-μF capacitor biphasic pulse; each phase was delivered at 65% tilt and was of approximately equal duration (1.04:1) (see Fig 2).5–7 Ventricular fibrillation was induced with alternating current. The first defibrillation pulse of 10 J was given 10 seconds after induction of ventricular fibrillation (which included the period of alternating current application). For the single-lead unipolar defibrillation system, the bidirectional defibrillation pulse was delivered between the right ventricular coil electrode and generator can. For the three-electrode system, the bidirectional defibrillation pulse was delivered simultaneously between the right ventricular coil electrode plus coronary sinus electrode and generator can. A 100- to 200-J transthoracic anterior-posterior rescue pulse was immediately delivered (Physio-Control LifePak 6s) if the transvenous defibrillation pulse was unsuccessful.8,9 A rest period of at least 3 minutes transpired between separate inductions of ventricular fibrillation to allow for a complete return to baseline arterial blood pressure, heart rate, ST-T segment configuration, and QRS duration.

Defibrillation pulse voltage and current waveforms were measured on an oscilloscope. The defibrillation threshold was defined as the minimum energy that successfully terminated ventricular fibrillation 10 seconds after its induction, starting at a pulse amplitude of 10 J. Determination of this threshold was accomplished by changing pulse amplitude in increments of 5 J between energies of 10 to 30 J, decrements of 2.5 J between energies of 10 to 5 J, and 1.25 J for lower energies. After the defibrillation threshold was determined for one system, the alternate method was tested in like fashion. The defibrillation threshold was measured only once for each method, given concerns over repetitive fibrillation and defibrillation in subjects.

Statistics

A paired Student's t test (two-tailed) was used to compare defibrillation thresholds for the single-lead unipolar defibrillation system with the same system employing an additional coronary sinus electrode. Significance was defined as P<.05.

Results

Defibrillation Threshold

Defibrillation threshold data are displayed in the Table. The mean defibrillation threshold stored energy was 11.3±5.9 J and 9.9±5.2 J for the single-lead unipolar compared with the three-electrode system using the coronary sinus lead, respectively (P=.42) (Fig 3). Similarly, no significant difference was observed in mean leading edge voltage between the single-lead unipolar and the three-electrode system (418±118 versus 390±112 V, respectively). The measured leading edge current defibrillation threshold and resistance were significantly higher in the single-lead as opposed to the system using three electrodes (7±2.4 versus 4.6±1.6 Ω, P=.002, and 61.1±5.4 versus 46.3±4.8 Ω, P<.00001, Fig 4), most likely owing to the larger total electrode surface area of the three-electrode system. Using either defibrillation system, all patients were successfully defibrillated by less than 24 J and over half of patients (9 patients in both groups, 60%) by less than 10 J.
Discussion

A unipolar transvenous defibrillation system is an effective means of treating ventricular fibrillation. A more complicated system that employs the addition of a coronary sinus electrode or an electrode placed in the superior vena cava offers no significant advantage over a single lead in terms of defibrillation efficacy or energy requirements.

Defibrillation Threshold Data

<table>
<thead>
<tr>
<th>Parameter</th>
<th>RV+→CAN- (±SD)</th>
<th>RV+ + CS+→CAN- (±SD)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leading edge voltage, V</td>
<td>418±118 (323-618)</td>
<td>390±112 (215-519)</td>
<td>.43</td>
</tr>
<tr>
<td>Leading edge current, A</td>
<td>7±2.4 (2.6-11.3)</td>
<td>4.6±1.6 (2.3-6.7)</td>
<td>.002</td>
</tr>
<tr>
<td>Resistance, Ω</td>
<td>61.1±5.4 (53.2-72.1)</td>
<td>46.3±4.8 (38.3-55.1)</td>
<td>&lt;.00001</td>
</tr>
<tr>
<td>Stored energy, J</td>
<td>11.3±5.9 (1.7-22.9)</td>
<td>9.9±5.2 (2.8-16.6)</td>
<td>.42</td>
</tr>
</tbody>
</table>

RV+→CAN- indicates single-lead unipolar defibrillator system; RV+ + CS+→CAN-, three-electrode defibrillator system. Values are mean±SD (range).

The effectiveness of unipolar transvenous defibrillation may be related to use of the biphasic waveform and perhaps to electrode polarity (anodal versus cathodal electrode nearest the left ventricle). However, data from this study and those previously reported when testing an additional electrode in the superior vena cava position suggest that the direction of the current vector may also play a pivotal role in determin-
ning defibrillation efficacy.\textsuperscript{12,13} Despite the lower pathway resistance observed with the three-electrode system, this did not improve defibrillation efficacy. That is, any advantage in lowering pathway resistance afforded by an additional electrode (whether placed posteriorly in the coronary sinus or as reported previously in the superior vena cava) may have been compromised or negated by detracting from a more optimal current vector directed from the right ventricle to the left infraclavicular subcutaneous electrode.

**Study Limitations**

The size of the study group was small: only 15 patients. Although a larger population may have identified statistically significant differences in defibrillation efficacy of the tested systems, these data suggest that, in absolute numbers, such differences would be small and not clinically significant. It is also possible that different pulsing techniques, lead size, and design or subtle variations in lead placement may have altered these results. The observation that use of three electrodes was associated with a lower pathway resistance and in a few instances resulted in a lower defibrillation threshold suggests that in challenging circumstances (in which a simpler defibrillation system is ineffective), more innovative albeit complicated lead systems remain an option. These are potentially fruitful areas for future research.

**Implications**

The design of an optimal defibrillation system must take a number of considerations into account. These factors include defibrillation efficacy and reliability as well as technical considerations related to the size of the device, complexity of lead systems, and ease of implantation. Our data suggest that a single-lead unipolar transvenous defibrillation system is an effective treatment modality. The defibrillation energy requirements for such a device are modest and allow for reduced generator size, making subclavicular implantation feasible. The added complexity of additional leads is not offset by any significant improvement in defibrillation efficacy or energy requirements that might allow for use of a yet smaller, lower-energy-output generator. Given the simplicity and effectiveness of a single-lead system coupled with a small generator, placement of defibrillation systems may now approach the ease of pacemaker implantation.

**References**

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