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A Simplified, Single-Lead Unipolar Transvenous Cardioversion-Defibrillation System

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Background. Transvenous implantable cardioverter-defibrillators provide significant advantages in the treatment of patients with life-threatening ventricular arrhythmias. However, present technology requires considerable electrophysiology expertise, multiple incisions, and long operative times for successful implementation.

Methods and Results. In this study, we present a prototype of a new, easy-to-insert unipolar transvenous defibrillation system that has the reliability of epicardial defibrillation but the ease of pacemaker insertion. This system incorporates a single anodal right ventricular defibrillation electrode using a 65% tilt biphasic pulse delivered to a 108-cm² surface area pulse generator titanium alloy shell as an active cathode placed in a left infraclavicular pocket. Testing of this system was performed before implantation of a standard nonthoracotomy-transvenous defibrillation system in 40 consecutive patients with a history of ventricular tachycardia or fibrillation. The simplified unipolar single-lead system resulted in a defibrillation threshold of 9.3 ± 6.0 J with 37 of 40 patients (93%) having a defibrillation threshold of less than 20 J. Moreover, the unipolar defibrillation system was efficiently used requiring only 3.4 ± 0.8 ventricular fibrillation inductions to measure the defibrillation threshold and 100 ± 28 minutes to implement.

Conclusions. This new unipolar transvenous defibrillation system is as simple to insert as a pacemaker, requires few ventricular fibrillation inductions, demands less technical expertise, and provides defibrillation at energy levels comparable to that reported with epicardial lead systems. It should substantially reduce the morbidity, time, and cost of defibrillator implantation. (*Circulation* 1993;88:543-547)

KEY WORDS • sudden death • ventricular fibrillation • ventricular tachycardia • defibrillation

Implantable cardioverter-defibrillators (ICDs) provide protection against sudden cardiac death in patients resuscitated from cardiac arrest.¹⁻¹⁰ Objections to the use of implantable antiarrhythmia devices continue, however, on several counts. First, despite their well-proven track record, ICDs with epicardial lead systems have been criticized because of problems with procedural morbidity and mortality.¹¹⁻¹⁸ Moreover, the cost of thoracic surgery and the prolonged inpatient hospitalization associated with epicardial implantation further reduce their appeal.¹⁹⁻²² Implantable defibrillators with transvenous lead systems have helped reduce some of the morbidity and mortality associated with defibrillator implantation, but they are limited in their scope of application. For example, such

devices often are less efficient at defibrillation, and fewer individuals satisfy implant defibrillation criteria than those receiving epicardial lead systems.^{10,23-30} In addition, transvenous defibrillation systems require substantial technical expertise to insert and still result in significant hospitalization and follow-up costs.²⁶⁻³³

This report describes our experience with a prototype unipolar single-lead, single-incision transvenous defibrillation system in a consecutive patient population of cardiac arrest survivors. This system is designed to be as efficient as epicardial lead systems, decrease surgical morbidity, minimize expertise required for use, limit the time and cost of defibrillator surgery, and potentially make the use of ICDs a more practical tool for prophylaxis against sudden cardiac death.

Methods

Patient Population

After informed verbal and written consent was provided, testing of a new unipolar single-lead transvenous defibrillation system was conducted in 40 consecutive patients with syncopal ventricular tachycardia, ventricular fibrillation, or both before implantation of a standard nonthoracotomy-transvenous defibrillator as described previously.²⁶

Unipolar Defibrillation Lead System

The unipolar transvenous defibrillation lead system consisted of a 10.5F anodal 5-cm-long endocardial right

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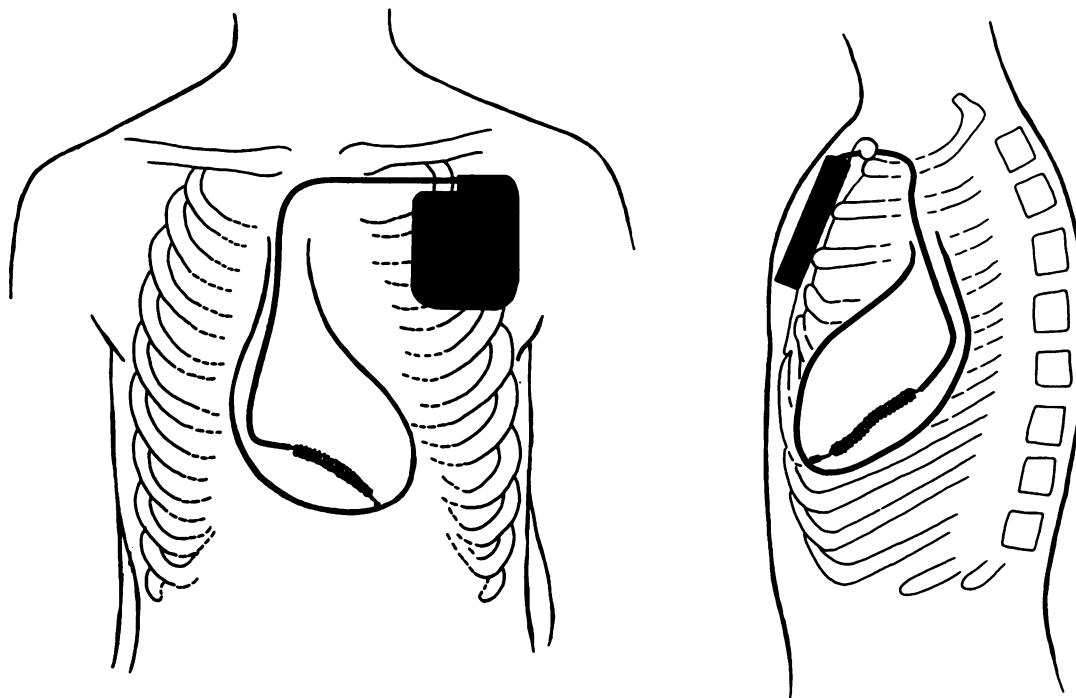


FIG 1. Illustration of the unipolar transvenous defibrillation system showing a single tripolar lead inserted into the right ventricular apex. Pace and sense electrodes are located at the tip. An anodal defibrillation coil electrode is positioned 2 cm proximal from the tip of the lead. The infraclavicular pulse generator shell serves as the cathode for defibrillation.

ventricular defibrillation electrode (model 6966, Medtronic) and a 108-cm² surface area cathodal pulse generator titanium shell electrode (model 7219C, Medtronic) that was placed in a left infraclavicular pocket (Fig 1). The right ventricular endocardial electrode was inserted into the left cephalic vein when possible; otherwise, the left subclavian vein was cannulated. The endocardial right ventricular lead also had standard bipolar pace and sense electrodes at the tip. This lead initially was used in testing the single-lead unipolar defibrillation system but subsequently was used as part of the permanently implanted standard nonthoracotomy-transvenous defibrillation system described below.

The 7219C pulse generator shell was positioned as shown in Fig 1 with the connector portal facing medially and the long axis of the cannister parallel to the long axis of the body. The cannister was seated on the pectoralis major muscle fascia and was positioned 2 to 3 cm beneath the left clavicle and 2 to 3 cm medial to the humeral head. The cannister's inferior margin was never positioned lower than the superior margin of the left areola.

Standard Nonthoracotomy-Transvenous Defibrillation Lead System

The nonthoracotomy-transvenous lead system defined as the "standard" lead system represents our standard clinical approach and has been described previously.²⁶ In summary, it consisted of three defibrillation electrodes and a pulse generator (model 7217B, Medtronic) positioned in the abdomen. The pulse generator shell was not electrically active in this system. One transvenous lead used in all of the standard defibrillation methods was the 110-cm 10.5F right ventricular tripolar pace, sense, and defibrillation lead (model 6966, Medtronic). A second transvenous lead, a 110-cm 6.5F catheter (model 6963,

Medtronic) had a 5-cm-long coil electrode that could be positioned in either the superior vena cava or the coronary sinus as needed. This lead was inserted using the Seldinger technique of cannulation of the left subclavian vein. The third electrode that was used was a 56-cm² subcutaneous chest patch electrode (model 6921L, Medtronic) positioned over the anterolateral left thorax for use in bidirectional shocks.²⁶ The defibrillation pulsing techniques available with this system used a monophasic 65% tilt dual-pathway pulse delivered simultaneously or sequentially across the two pathways.^{10,25,26,33}

Defibrillation Threshold Testing

Defibrillation threshold testing always began with the unipolar lead system. It was not possible to randomize testing of the unipolar, single-lead defibrillation system because the standard (ie, permanent) nonthoracotomy-transvenous lead system could not be removed once it was placed.

The waveform used with the unipolar defibrillation method was a 65% tilt asymmetric biphasic defibrillation pulse delivered between the anodal right ventricular endocardial electrode and the cathodal pulse generator titanium shell electrode.^{24,34,35} The first transvenous defibrillation test began with a 10-J stored energy pulse delivered 10 seconds after ventricular fibrillation onset, including the time period during which alternating current was applied.³⁶ If the transvenous pulse was unsuccessful, a 100- to 200-J transthoracic rescue pulse was delivered immediately via a precharged external defibrillator (Physio-Control LifePak 6s).³⁷

After a minimum rest period of 3 minutes between ventricular fibrillation inductions, pulse output was increased or decreased, depending on transvenous shock failure or success. Pulse energies were changed in 5-J steps between energies of 30 to 10 J, in 2.5-J steps for

pulsing energies of 10 to 5 J, and in 1.25-J steps at less than 5 J. Between each induction and termination of ventricular fibrillation, care was taken to ensure that ECG ST-T segments, QRS duration, and arterial pressure had returned to baseline values before ventricular fibrillation was reinitiated.

The defibrillation threshold was defined as the lowest pulse amplitude that could successfully terminate ventricular fibrillation 10 seconds after its initiation.^{36,38} All defibrillation pulse characteristics were measured from oscilloscopic recordings of voltage and current waveforms as previously described.³⁸ Because of the limitations of repetitive induction and termination of ventricular fibrillation in humans, the defibrillation threshold was measured only once for each method examined.

Defibrillation threshold measurements for the clinically implemented nonthoracotomy-transvenous lead system were determined similarly, although pulsing methods and waveforms were those available with the commercially available implantable pulse generator described above.^{10,25,26,33,38}

Statistical Analysis

A two-tailed *t* test was used to compare defibrillation thresholds for the unipolar system with that finally implanted in the patient. Comparisons also were made for the number of inductions of ventricular fibrillation needed to find a method capable of defibrillating under 20 J and for the time to implement the system. The time dedicated to lead insertion and to defibrillation threshold testing to achieve a satisfactory implant was determined in the last 11 patients.

Results

Patient Clinical Characteristics

Of the 40 patients studied, 31 (78%) were men. Mean age was 57 ± 13 years with a range of 27 to 73 years. Coronary artery disease was the primary structural heart disease in 20 patients, 7 had a dilated cardiomyopathy, 6 had both coronary artery disease and a dilated cardiomyopathy, 3 had primary electrical disease, 2 had long QT syndrome, 1 had right ventricular dysplasia, and 1 had hypertrophic cardiomyopathy. Mean ejection fraction was 0.39 ± 0.16 , with a range of 0.10 to 0.70. The index arrhythmia leading to device implantation was ventricular fibrillation in 16 patients, ventricular tachycardia in 15 patients, and both ventricular tachycardia and ventricular fibrillation in 9 patients.

Defibrillation Efficacy

The defibrillation threshold stored energy for the single-lead, single-incision unipolar defibrillation system was 9.3 ± 6.0 J, with a range of 1.6 to 29.4 J. The measured leading edge voltage defibrillation threshold for the unipolar defibrillation system was 376 ± 119 V, with a range of 164 to 700 V. The measured leading edge resistance at the defibrillation threshold was 58 ± 7 Ω , with a range of 46 to 74 Ω . Of the 40 patients examined, 37 of 40 (93%) were defibrillated by less than 20 J using this system (Fig 2) and 39 of 40 (98%) by less than 24 J.

There was no difference in defibrillation efficacy between men and women with this system. The defibrillation threshold for the men was 9.4 ± 6.3 J (range, 2.7 to 29.4 J), and the defibrillation threshold for the women was 8.8 ± 5.0 J (range, 1.6 to 16.8 J) ($P = .77$).

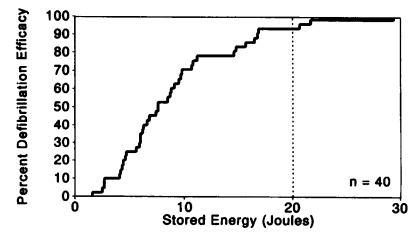


FIG 2. Plot of percent efficacy of stored energy at the defibrillation threshold for the unipolar single-lead, single-incision defibrillation system. At less than 20 J, 93% of patients could be defibrillated.

The data on the single-lead, single-incision unipolar defibrillation system compared favorably with our currently available standard nonthoracotomy-transvenous approach. Of the several methods tested with our standard system, even the best of the various lead systems tested did not outperform the single-lead system. In the case of the best of the standard nonthoracotomy-transvenous pulsing methods studied for each patient, the mean defibrillation threshold stored energy was 11.3 ± 4.9 J, with a range of 1.7 to 23.4 J ($P = .01$). The measured leading edge voltage at the defibrillation threshold for the best standard nonthoracotomy-transvenous pulsing method studied was 424 ± 95 V, with a range of 166 to 622 V ($P = .003$). Pulsing resistance at the defibrillation threshold was 62 ± 14 Ω , with a range of 39 to 95 Ω ($P = .04$).

To achieve defibrillation efficacy with the standard system comparable to that possible with the new single-lead, single-incision unipolar defibrillation system (both 93% at less than 20 J), an average of 4.0 ± 2.2 pulsing methods had to be tested to find a suitable nonthoracotomy-transvenous defibrillation system that would satisfy the implant criterion of less than 20 J. To identify the best pulsing method and measure the defibrillation threshold, an average of 7.4 ± 3.2 ventricular fibrillation inductions were required compared with 3.4 ± 0.8 ventricular fibrillation inductions for the single-lead unipolar system ($P < .00001$).

The time dedicated to lead insertion and to defibrillation threshold testing to achieve a satisfactory implant was 100 ± 28 (range, 66 to 137) minutes for the single-lead, single-incision unipolar defibrillation system and 183 ± 19 (range, 153 to 213) minutes for our currently available nonthoracotomy-transvenous approach ($P < .00001$).

Discussion

The present study has demonstrated that implantable defibrillators can be as simple to insert as a pacemaker, require few ventricular fibrillation inductions for confirmation of efficacy, demand less technical expertise to implement, and provide defibrillation at energy levels comparable to that reported with epicardial lead systems while being superior to present nonthoracotomy-transvenous lead systems.

The defibrillating efficiency of the new pulsing method evaluated in this study is related to several factors. One factor facilitating low defibrillation thresholds is the use of a biphasic waveform, demonstrated to be superior to monophasic waveform defibrillation in earlier clinical studies.^{34,35} A second component of the unipolar defibrillation system that facilitates defibrillation is the nature of the current vector. As shown in Fig 1, the impulse is

directed from right to left and inferior to superior. In some individuals, depending on the right ventricular defibrillation coil location on the diaphragmatic surface of the right ventricle, the current also may be directed posterior to anterior. A third factor favoring efficient defibrillation with the unipolar lead system may be electrode polarity. Although an evaluation of polarity on defibrillation thresholds was not formally examined for this lead system, earlier data suggest that the electrode closest to the left ventricle should be anodal for optimal defibrillation.^{39,40} Finally, it is likely that the use of a continuous surface area electrode of low resistance—the titanium casing of the defibrillator itself—makes defibrillation more efficient by decreasing pulsing resistance and, in turn, increasing current density.

An effective and easily insertable transvenous defibrillator has substantial implications for the treatment of patients with ventricular tachycardia and ventricular fibrillation. As concerns mount over the safety and efficacy of antiarrhythmic drugs for the treatment of ventricular arrhythmias,⁴¹⁻⁴⁶ device therapy holds increasing promise. However, defibrillator use also has limitations.¹¹⁻¹⁸ If defibrillators can be applied easily without significant procedural costs, there is a possibility that overall therapeutic costs for such patients could be reduced close to that for patients requiring pacemakers.

A broader consequence of an easily inserted and effective defibrillator is its role in sudden death prevention. Sudden cardiac death remains a major cause of mortality in the United States. Any practical, reasonably priced approach to the problem that can be widely implemented will have significant public health consequences. Certain high-risk subgroups, such as those with hypertrophic cardiomyopathy or long QT syndrome or those awaiting cardiac transplantation, would be reasonable candidates.

The practical procedural advantages to this simplified, unipolar transvenous lead system are several. First, only one standard infraclavicular incision would be required. Currently, two and sometimes three incisions are needed to position the patches and pulse generator. Second, a standard lead length is used. Present transvenous lead systems are more than 100 cm long and require tunneling procedures under thoracic skin to an abdominal pocket. With this unipolar system, the pulse generator is small enough to be placed in an infraclavicular pocket, and therefore the lead length need be only approximately 50 cm, which is standard pacemaker lead length. There are several implications related to the use of a standard lead length. One is ease of handling. Long leads are relatively difficult to manipulate. Another advantage is that tunneling would no longer be required. In addition, shorter leads will be easier to exchange should lead fractures occur, as is likely in younger patients who may have an implantable defibrillator for many years.

A third advantage of the unipolar defibrillation system is that implantation will be possible using local anesthesia rather than general anesthesia. Although some institutions do implant standard nonthoracotomy-transvenous defibrillation systems using local anesthesia, most do not. There are two reasons for the common use of general anesthesia. One is the multiple incisions and tunneling of electrodes required with present lead systems. Another is the usual need for intubation to maintain ventilation during repetitive inductions of ven-

tricular fibrillation. Both of these requirements fade with the unipolar system. As mentioned above, only one incision is needed, and tunneling is avoided by the short lead length. Reliable defibrillation at low defibrillation thresholds also makes extensive testing unnecessary. Consequently, it may prove possible to anesthetize the patient transiently with ultrashort-acting agents to perform one or two inductions of ventricular fibrillation. This would be similar to what might be done during an outpatient cardioversion procedure.

The ability to insert defibrillators under local anesthesia in turn means that the procedure can be performed in the catheterization or electrophysiology laboratory routinely rather than in the operating room, as is usually done. Personnel requirements, time requirements, and costs consequently should decrease. In addition, the procedure may be performed on an outpatient basis if there are no other indications for hospitalization.

The simplicity of the technology also is advantageous. With present transvenous lead systems, the implanting electrophysiologist and surgeon must be skilled in bioengineering principles. Care must be demonstrated in dealing with electrical connections, signal monitoring, waveform configurations, pulsing systems, electric field distribution, and so on. The unipolar defibrillation system obviates many of these concerns and allows physicians who are only modestly skilled in these issues to address the clinical problem of preventing sudden death.

A limitation of this study is that the standard nonthoracotomy-transvenous defibrillation system may have appeared less effective than it otherwise would have by virtue of the fact that it was always tested after the unipolar defibrillation system was tested. This consideration does not alter the fact that the unipolar system proved effective irrespective of whether the standard system was effective. Furthermore, the mean defibrillation threshold with the standard nonthoracotomy-transvenous defibrillation system in this study of 11.3 ± 4.9 J does not differ from that observed in our general population of patients.²⁶ This indicates that the testing of the unipolar transvenous defibrillation system probably did not affect the outcome of the standard system in any significant way.

In conclusion, the present study has demonstrated that implantable defibrillators can be as simple to insert as a pacemaker, require few ventricular fibrillation inductions for testing of efficacy, demand less technical expertise to implement, and provide defibrillation at energy levels comparable to that reported with epicardial lead systems.

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