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Comparison of Single- and Dual-Coil Active Pectoral Defibrillation Lead Systems

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Objectives. **The purpose of this study was to compare defibrillation thresholds with lead systems consisting of an active left pectoral electrode and either single or dual transvenous coils.**

Background. **Lead systems that include an active pectoral pulse generator reduce defibrillation thresholds and permit transvenous defibrillation in nearly all patients. A further improvement in defibrillation efficacy is desirable to allow for smaller pulse generators with a reduced maximal output.**

Methods. **This prospective study was performed in 50 consecutive patients. Each patient was evaluated with two lead configurations with the order of testing randomized. Shocks were delivered between the right ventricular coil and either an active can alone (single coil) or an active can with the proximal atrial coil (dual coil). The right ventricular coil was the cathode for the first phase of the biphasic defibrillation waveform.**

Results. **Delivered energy at the defibrillation threshold was 10.1 ± 5.0 J for the single-coil configuration and 8.7 ± 4.0 J for the dual-coil configuration ($p < 0.02$). Moreover, 98% of patients had low (≤15 J) thresholds with the dual-coil lead system, compared with 88% of patients with the single-coil configuration ($p = 0.05$). Leading edge voltage ($p < 0.001$) and shock impedance ($p < 0.001$) were also decreased with the dual-coil configuration, although peak current was increased ($p < 0.001$).**

Conclusions. **A dual-coil, active pectoral lead system reduces defibrillation energy requirements compared with a single-coil, unipolar configuration.**

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Adequate defibrillation thresholds can be achieved routinely with transvenous lead systems because of improvements in lead design and shock waveforms (1–4). With downsizing of pulse generator size to allow for pectoral placement, the pulse generator shell can become part of the lead system (5). Such active pectoral lead systems reduce defibrillation thresholds further (6,7) and may simplify the implantation process (8,9).

Despite these advances, further improvement in defibrillation efficacy is desirable for several reasons. First, this would allow for smaller pulse generators with a lower maximal output. As the pulse generator size approaches that of pacemakers (10), it would permit subcutaneous pectoral implantation in all patients, while minimizing the risk of complications (11). Second, lowering biphasic defibrillation thresholds provides a greater safety margin, which may be important under conditions when thresholds rise, such as with ischemia, during antiarrhythmic drug therapy and possibly with lead maturation (12–14). Finally, improved defibrillation efficacy and uniformly low defibrillation thresholds will simplify the implantation procedure by minimizing lead positioning and acute defibrillation testing. To this end, identifying the optimal active can lead configuration is important. A single-coil, unipolar system is hypothesized to reduce defibrillation thresholds by providing an optimal vector for defibrillation (5), whereas a dual-coil, active can system (triad configuration) acts primarily by reducing shock impedance (6). The present study is a randomized, prospective comparison of these two active can lead configurations.

Methods

Patient group. This prospective study included 50 consecutive patients undergoing initial defibrillator implantation for standard clinical indications. Written informed consent was obtained from each patient, and the study was approved by the Institutional Review Board of the University of Maryland.

Defibrillation lead system implantation. The transvenous defibrillation lead (Endotak DSP, model 0125) was placed under fluoroscopic guidance. Briefly, venous access was obtained by either a left subclavian vein puncture or dissection to the cephalic vein, and the tip of the lead was positioned at the right ventricular apex. Adequate sensing and pacing characteristics were documented before securing the lead in place to the pectoral fascia. The Endotak DSP lead is a tripolar lead consisting of a distal electrode for sensing and pacing, a distal platinum coil (450 mm^2) in the right ventricle and a proximal platinum coil (660 mm^2) at the right atrial/superior vena caval

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junction. The distance from the lead tip to the proximal coil is 18 cm. The defibrillator emulator (model 6967), with a surface area of 78.4 cm^2, was placed in the subcutaneous prepectoral space. The pocket was kept moist with saline during testing to maintain electrical contact between the emulator and surrounding tissue. All lead components were manufactured by Cardiac Pacemakers, Inc. (Guidant Corp.).

Defibrillation testing. Defibrillation testing was performed under conscious sedation with midazolam and fentanyl. Ventricular fibrillation was induced with high output ramp pacing through the defibrillation lead. Ventricular fibrillation was defined as irregular and chaotic activity on the surface electrocardiogram and intracardiac electrograms with a mean cycle length <200 ms. After 10 s, defibrillation was attempted with an external defibrillator (Cardiac Pacemakers, Inc., model 2815), which delivers fixed tilt, biphasic shocks through a 125-μF capacitance with 60% first-phase tilt and 50% second-phase tilt. The distal coil (right ventricle) was the shocking cathode for the first phase of the biphasic pulse. For the single-coil configuration, the emulator was the anode, and the proximal coil was disconnected from the shock pathway. For the dual-coil configuration, the proximal coil and emulator were connected electrically as the anode. The defibrillation threshold for one configuration was measured, followed by testing of the other configuration, with the order determined randomly.

The initial shock energy for testing was 15 J for each configuration. If successful, the energy was decreased to 10, 8, 5, 3 and 1 J in successive trials until defibrillation failed. If the initial 15-J shock failed, the energy was increased in 5-J steps in subsequent trials until defibrillation was successful. The defibrillation threshold was defined as the lowest initial shock energy that successfully terminated ventricular fibrillation. The defibrillation pulse characteristics measured included delivered energy, peak voltage, pulse width, impedance and peak current (15).

Statistical analysis. Paired *t* tests were used to compare continuous data between the two groups. Dichotomous variables were assessed with the chi-square test. All results are expressed as the mean value ± SD, and $p \leq 0.05$ was considered significant.

Results

Patient group. As expected for a cohort undergoing defibrillator implantation, most of the patients were men (74%) with a history of coronary artery disease and previous myocardial infarction (70%). The patients' mean age was 63 ± 14 years, and the mean left ventricular ejection fraction was 31 ± 13%. At the time of implantation, four patients (8%) were receiving amiodarone. No patients were receiving other type I or III antiarrhythmic drugs.

Defibrillation threshold variables. A summary of the measured data at the defibrillation threshold is shown in Table 1. Mean delivered energy was 10.1 ± 5.0 J for the single-coil configuration and 8.7 ± 4.0 J for the dual-coil configuration ($p < 0.02$). The paired results for each patient are presented in Figure 1. The dual-coil defibrillation threshold was lower in 24 patients, whereas the single-coil threshold was lower in eight patients. In the remaining 18 patients, the defibrillation thresholds were the same. As a result of this reduction in energy requirements, defibrillation thresholds were ≤15 J in 98% of patients with the dual-coil configuration, compared with only 88% of patients with the single-coil configuration ($p = 0.05$).

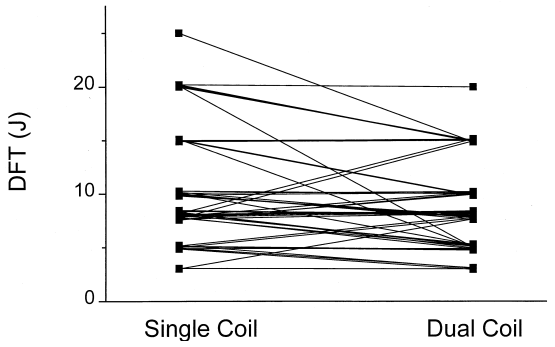
Table 1. Pulse Characteristics at Defibrillation Threshold

Configuration	Energy (J)	Voltage (V)	Current (A)	Impedance (ohms)
Single coil (mean ± SD)	10.1 ± 5.0	355 ± 87	6.5 ± 1.9	57 ± 11
Dual coil (mean ± SD)	8.7 ± 4.0	312 ± 71	8.4 ± 2.5	39 ± 7
p value	0.012	0.001	< 0.001	< 0.001

Leading edge voltage was also reduced significantly with the dual-coil configuration (Table 1). However, leading edge current was lower with the single-coil configuration. Paired currents at the defibrillation threshold for the 50 patients are shown in Figure 2. Current was lower in the single-coil configuration in 46 patients. In three patients current was lower with the dual-coil configuration, and in the remaining patient currents were equivalent. As expected, shock impedance was uniformly reduced with the addition of a second coil to the defibrillation pathway.

Predictors of change in defibrillation threshold. As noted earlier, the reduction in defibrillation threshold energy was not uniform. Figure 1 indicates that the reduction was most marked in those patients with high thresholds. In the 12 patients with a defibrillation threshold ≥15 J in the single-coil configuration, the threshold energy decreased by 28% from 17.9 ± 3.3 to 12.9 ± 4.5 J ($p < 0.01$) with the addition of the proximal coil to the active lead system. In contrast, in patients with low thresholds (<15 J) in the single-coil configuration, energy requirements decreased by only 4% with addition of the proximal coil (7.6 ± 1.9 vs. 7.3 ± 3.0 J, p = NS).

Figure 1. Delivered energy at defibrillation threshold (DFT). The results from each of the 50 patients are shown for the single- and dual-coil lead configurations. The order of testing was randomized for each patient.



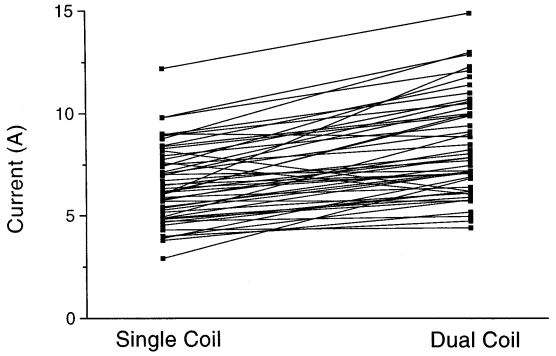


Figure 2. Peak current at defibrillation threshold. The results from each of the 50 patients are shown for the single- and dual-coil lead configurations. Note the consistent reduction in peak current with the single-coil configuration despite increased energy requirements.

Routine clinical variables and other defibrillation thresholds variables did not predict the difference of thresholds between the two configurations. Specifically, age, gender, ejection fraction and history of coronary artery disease or congestive heart failure did not differ between patients with lower dual-coil defibrillation thresholds and those with lower single-coil thresholds. Shock impedance was also not predictive of the change in defibrillation thresholds.

Discussion

The major finding of this study is that a dual-coil active lead system consisting of right ventricular and atrial coils with a pectoral electrode reduced defibrillation energy requirements compared with a single-coil configuration. Although the overall magnitude of the benefit of the dual-coil lead system was modest, the effect of incorporating the right atrial coil into the shock pathway was most marked in patients with high thresholds in the single-coil configuration. As a consequence of this effect, the percentage of patients with high thresholds was reduced from 12% to 2% with the dual-coil configuration. This indicates that with this lead system downsized pulse generators with reduced outputs (e.g., 25 J) can be routinely implanted with an adequate safety margin.

Our experimental design is deserving of comment. A dual-coil lead with fixed intercoil spacing was implanted in all patients. The dual- and single-coil configurations were evaluated by including or excluding the proximal right atrial coil in the defibrillation pathway. In the single-coil, unipolar configuration, the presence of a right atrial coil disconnected from the shock pathway will not shunt current because of the absence of a return pathway for current flow. Thus, this study allowed direct determination of the effect of adding a second coil to the active lead system, unconfounded by variabilities of coil size or position, which are inherent with multiple leads.

Previous studies. The use of an active pectoral pulse generator for defibrillation has been demonstrated previously. Bardy et al. (5) first showed that a pulse generator in the left pectoral position could be used as part of an effective defibrillation lead system with a right ventricular coil (5). Defibrillation thresholds ≤24 J were observed with this unipolar configuration (8). Subsequently, the benefit of active lead systems was assessed quantitatively in two studies. We showed that a dual-coil, active pectoral lead system reduced defibrillation thresholds by 36% compared with the dual-coil, transvenous lead system alone (6). Also, Haffajee et al. (7) demonstrated that a single-coil, unipolar configuration reduced thresholds by 14% compared with a dual-coil, transvenous configuration (7). Thus, the 14% reduction in defibrillation thresholds observed in the present study, by adding a right atrial coil to a single-coil configuration, suggests that the use of an active pectoral electrode and the addition of a second transvenous coil both contribute to the overall benefit of a dual-coil, active can lead system. Moreover, the uniformly low thresholds obtained with this dual-coil, active can lead system is clinically important because of the significant reduction in the frequency of high thresholds.

The effect of adding a superior vena cava coil to a unipolar lead system was investigated previously by Bardy et al. (16). In that study, no significant benefit of adding a third electrode to the defibrillation system was observed. There were several differences between these studies, which may account for the discrepant conclusions. The second coil was smaller and positioned more proximally in the superior vena cava by Bardy et al. (16). In addition, a different biphasic waveform was evaluated. However, despite these differences, a 19% reduction in defibrillation threshold energy was noted, which is similar to the 14% reduction we observed. Thus, it seems plausible that the failure to achieve a significant benefit with a dual-coil lead system was due to the much smaller sample size (n = 15) in the study of Bardy et al. (16). Further studies are under way to help resolve this issue and to identify the factors that are important for minimizing active can defibrillation thresholds.

Understanding the mechanism for lowering defibrillation thresholds with the dual-coil lead configuration is important for continued improvement of defibrillation efficacy with future lead systems. Peak current at the defibrillation threshold was lower with the single-coil configuration. This indicates that this unipolar configuration is the optimal vector for defibrillation, because current is the critical determinant of defibrillation success (17,18). This is logical because the shock pathway from the right ventricular apex to the left shoulder directs current through more of the left ventricular muscle mass and interventricular septum (19). With the dual-coil configuration, the defibrillation vector is less optimal, so peak current at the defibrillation threshold is increased. However, the 32% reduction in shock impedance more than offsets the higher current requirement, so that the resultant mean defibrillation threshold energy is lessened. In other words, more current can be delivered at lower leading edge voltages or energies. Based on these observations, future studies should be directed toward minimizing shock impedance while maintaining an optimal defibrillation vector. Although the marked reduction in shock impedance appears to be an important cause of the reduction in defibrillation thresholds with the dual-coil configuration, we

cannot rule out that other unmeasured factors may have also contributed to this benefit, such as a change of current distribution.

Study limitations. Our results must be interpreted in the light of certain methodologic limitations. The fixed spacing between coils with the Endotak lead system does not permit evaluation of other electrode positions, and coil position can have significant effects on defibrillation efficacy (20). In addition, only a single shock polarity and tilt were evaluated. Although controversial, these variables may affect biphasic defibrillation thresholds (15,21–26). Finally, this study only evaluated defibrillation efficacy between single- and dual-coil leads. The clinical choice of lead systems also involves other characteristics such as handling and sensing. For instance, a more complex quadripolar lead with multiple coils would be larger and more prone to malfunction, and integrated bipolar sensing with dual coil leads may be associated with suboptimal sensing of ventricular fibrillation in some patients (27,28).

Conclusions. This prospective, randomized study demonstrates that a dual-coil, active lead system reduces defibrillation energy requirements compared with a single-coil, unipolar configuration. It is clinically important that defibrillation thresholds were uniformly low (≤15 J) in 98% of patients using the dual-coil lead. Peak current was higher with the dual-coil compared with the single-coil configuration, suggesting that a major mechanism in lowering defibrillation energy requirements is the marked reduction in shock impedance with the three-electrode system. It is noteworthy that not all patients had a reduction in defibrillation thresholds with the dual-coil lead. However, the only clinical predictor of such a reduction was a high threshold in the single-coil configuration.

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