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Effect of a Passive Endocardial Electrode on Defibrillation Efficacy of a Nonthoracotomy Lead System

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Objectives. **We investigated the impact of an inactive endocardial lead on the 50% effective dose (ED50%) for successful ventricular defibrillation.**

Background. **The presence of abandoned epicardial mesh patch electrodes detrimentally affects the defibrillation efficacy of an endocardial lead system. It is not known whether abandoned endocardial electrodes produce a similar effect.**

Methods. **An endocardial lead system (ENDOTAK, model 0062, Cardiac Pacemakers, Inc.) was implanted in eight dogs (mean ±SD weight 23.7 ± 1.0 kg). The ED50% for each of seven lead configurations was determined by a three-reversal point protocol in a balanced-randomized order with and without a second electrically passive endocardial lead system in the right ventricle (power 0.97 to detect a 50-V difference). Biphasic shocks with 80% tilt were delivered 10 s after the induction of ventricular fibrillation. In one configuration the active electrode made contact with the passive electrode in the right ventricular (RV) apex. In another configuration the active electrode was placed in a more proximal position to avoid contact. Additionally, the ED50% was determined for the endocardial lead system with a passive pacing lead positioned in the RV apex.**

Results. **ED50% values for peak voltage, peak current and delivered energy were not significantly different with or without a passive RV electrode, and this was true whether or not the active electrode touched the passive electrode. However, ED50% values were significantly higher when the active electrode was slightly proximal than when it was positioned at the apex.**

Conclusions. **Physical contact between active and passive endocardial electrodes does not significantly alter defibrillation efficacy in this dog model. An increase in ED50% energy was caused by a slightly proximal position. Therefore, a good electrode position within the right ventricle is a more important determinant of defibrillation efficacy than is avoidance of the electrode touching a passive electrode.**

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Since the first implantation of an internal defibrillator 15 years ago (1), major changes and achievements have been made in this form of treatment for life-threatening ventricular arrhythmias (2,3). First-generation devices primarily used epicardial lead systems. Today, implantable cardioverter-defibrillator (ICD) devices utilize endocardial-based lead systems almost exclusively (4,5).

The nearly universal use of endocardial-based lead systems for first-time ICD implantation has created a dilemma for electrophysiologists and surgeons: When replacing early-model ICD pulse generators after battery depletion, or in the rare cases where epicardial lead systems have malfunctioned, should the epicardial leads be abandoned in favor of a new endocardial lead system? The results from two recent short-term animal studies (6,7) suggest that the presence of abandoned (electrically passive) epicardial electrodes significantly increases defibrillation energy requirements. A similar question needs to be answered for endocardial defibrillation lead systems as well. When endocardial defibrillation leads malfunction (8,9), should the old lead be abandoned without attempting extraction as pacing leads are often treated? (10). Epstein et al. (11) showed the presence of fibrous connective tissue and endocardial fibrosis around a transvenous electrode system. Therefore, defibrillation lead extraction may be contraindicated due to medical risk and procedural morbidity. In such cases, endocardial lead abandonment might be favored. However, the impact of an abandoned endocardial lead system on defibrillation efficacy has not been investigated systematically. Therefore, the purpose of the present study was to evaluate the impact of a passive endocardial defibrillation lead on the defibrillation energy requirements of an active endocardial defibrillation system. We also examined the impact of a

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Abbreviation and Acronyms

ECG = electrocardiogram, electrocardiographic
ED50% = effective dose for successful ventricular defibrillation
ICD = implantable cardioverter-defibrillator
RV = right ventricular
SVC = superior vena cava

conventional pacing lead on the active endocardial defibrillation configuration.

Methods

The study was approved by the Institutional Animal Care and Use Committee at the University of Alabama at Birmingham. It conforms to the "Guidelines of the American Heart Association on Research Animal Use" adopted November 11, 1984.

Animal preparation. In eight mongrel dogs (mean ± SD weight 23.7 ± 1.0 kg), anesthesia was induced with intravenous pentobarbitol (30 to 35 mg/kg body weight) and maintained with a continuous infusion of pentobarbitol at a rate of ~0.05 mg/kg per min (12,13). Succinylcholine (1 mg/kg) was also given intravenously at the time of induction of anesthesia. Supplemental doses of succinylcholine (0.25 to 0.5 mg/kg) were given as needed to maintain muscle relaxation. The animals were intubated with a cuffed endotracheal tube and ventilated with room air and oxygen through a Harvard respirator (Harvard Apparatus Co.). A peripheral intravenous line was inserted, and normal saline was continuously infused. A femoral artery line was placed for hemodynamic monitoring as well as for arterial blood gas analysis and electrolyte measurements. Normal metabolic status was maintained throughout the study by taking blood samples every 30 to 60 min and correcting any abnormal values. Electrocardiographic (ECG) electrodes were applied for continuous monitoring of lead II. Body temperature was measured through an esophageal temperature probe and maintained at 36 to 38°C with a thermal mattress and heat lamp. At the end of the study, euthanasia was induced with a potassium chloride injection. The heart was removed and weighed.

Defibrillation lead configuration. One 11F defibrillation catheter (ENDOTAK, model 0062, Cardiac Pacemakers, Inc.) with a distal 3.4-cm right ventricular (RV) coil electrode, a 6.8-cm superior vena cava (SVC) coil electrode 9 cm proximal from the distal coil and a pacing electrode tip 6 mm distal from the RV coil was placed through a right jugular vein incision. Under fluoroscopic guidance, the distal coil was advanced in the RV apex, and the proximal coil was positioned in the SVC to serve as the anode for the first phase of the biphasic shock. A second, identical defibrillation catheter was placed through a left jugular vein incision to serve as a passive "bystander" in configurations 2 and 5 (described later).

Figure 1 shows a diagrammatic representation of the lead type (active or passive) and the approximate distal electrode position within the canine heart for the seven lead configurations that were tested. Each configuration was tested separately within each animal. The first three configurations were used to investigate whether a passive electrode in contact with the RV catheter electrode alters defibrillation efficacy. Configuration 1 consists of the active electrode in the RV apex with the passive electrode not present. Configuration 2 consists of the new, active electrode and the passive electrode in contact with it, mimicking the clinical scenario, where a new endocardial lead is implanted without removing the inactive old lead. In configuration 3, the passive electrode from configuration 2 has been removed. Configurations 4, 5 and 6 were used in a similar manner to determine whether a passive electrode affects defibrillation efficacy if it is present in the right ventricle but not in contact with the active electrode. Configuration 4 consists of the active electrode alone. Configuration 5 consists of a passive electrode positioned in the RV apex and an active electrode not touching it. The passive electrode was the same electrode that was active in configuration 4. Configuration 5 is intended to simulate the clinical scenario where an electrode that was placed in the normal position is now not functioning, and a new electrode has to be placed. To avoid physical contact between the apical passive lead and the new active lead, the active lead was placed in a more proximal position. In configuration 6, the passive electrode from configuration 5 has been removed. A seventh configuration was studied to investigate whether the presence of a conventional pacing lead (Irox tip, bipolar lead, 58-cm length, Intermedics, Inc.) near the distal electrode (floating electrode) of the defibrillation lead influences the effective dose for successful ventricular defibrillation (ED50%). The locations of the electrodes for each configuration were confirmed fluoroscopically.

Defibrillation protocol and data acquisition. The order in which each lead configuration was tested was defined by a block randomization scheme. On the basis of this randomization, group 1 (configurations 1 to 3) or group 2 (configurations 4 to 6) was tested first. Configuration 7 was tested randomly after configuration 3 or 6. ED50% testing was performed by following a modified three-reversal up–down protocol (13,14) starting with a leading edge voltage of 400 V. The initial step size was 40 V. If the first shock failed, incremental 40-V shocks were given until a defibrillation success occurred (first reversal). After a defibrillation success, the voltage was decreased by 40-V steps until the shock failed to defibrillate (second reversal). Then, the voltage was increased again by 40-V steps until a successful defibrillation occurred (third reversal). If the first shock succeeded, decremental 40-V shocks were performed until the shock failed (first reversal). After a failure, the voltage was increased by 40-V steps until the shock succeeded (second reversal). Then, the voltage was decreased again by 40-V steps until a failure occurred (third reversal). The ED50% for peak voltage was defined as the mean peak voltage of the three reversal points. Similarly, the ED50% for delivered energy and peak current was found by averaging the energy and peak current values for these three shocks.

Ventricular fibrillation was induced by 60-Hz alternating

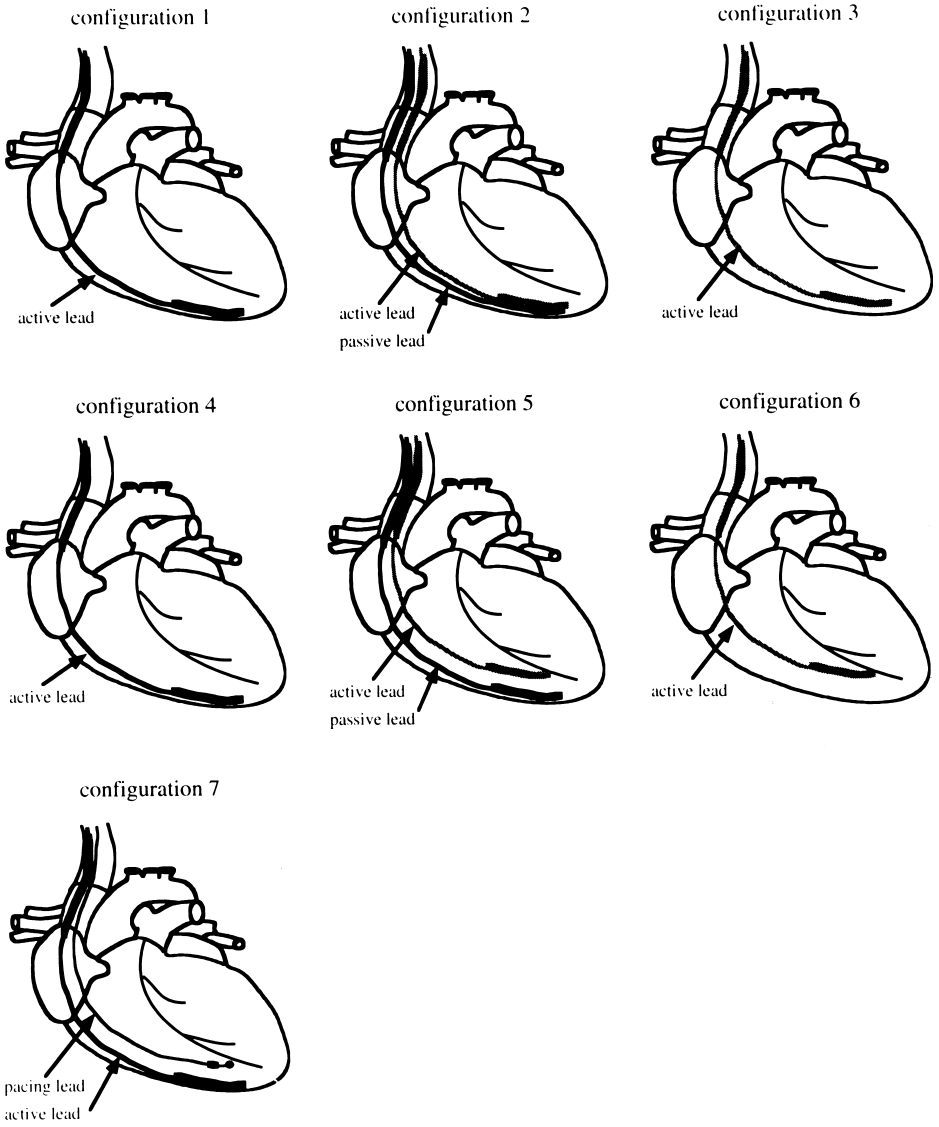


Figure 1. Defibrillation electrode configurations tested: an active RV defibrillation lead alone in the apex (configurations 1 and 4, active lead); an active apical defibrillation lead (configuration 2, active lead) in contact with a passive defibrillation lead (configuration 2, passive lead) in the apex; the newly placed active defibrillation lead alone in the apex (configuration 3, active lead); a passive defibrillation lead in the apex (configuration 5, passive lead) with an active lead with the tip proximal to the passive lead (configuration 5, active lead); an active lead alone at the proximal position (configuration 6, active lead); and an active defibrillation lead (configuration 7, active lead) in combination with a conventional pacing electrode (configuration 7, pacing lead).

current through the pacing tip of the RV apex defibrillation lead, with the return electrode on the chest wall. Fibrillation was allowed to continue for 10 s before defibrillation was attempted. A failed shock was followed by a rescue shock of higher voltage delivered between the internal electrodes. If the first rescue shock failed, it was followed by external defibrillation with a Life-Pak 9 defibrillator (Physio-Control Corp.), given through the external defibrillator patches. A minimum of 4 min elapsed between each fibrillation–defibrillation attempt. Fibrillation was not reinitiated until blood pressure and heart rate had returned to normal.

The defibrillation electrodes were connected to a defibrillator (VENTAK, model 2805, Cardiac Pacemakers, Inc.). This defibrillator, modified for research, delivered a fixed-tilt (80%) single-capacitor biphasic shock from a 125-μF capacitor bank. The leading edge voltage and the tilt of the first phase were programmable. The truncated exponential biphasic shock utilized a second phase of opposite polarity to the first phase, with the second-phase leading edge voltage equal to 100% of the first-phase trailing edge voltage. The total duration depended on the impedance and ranged from 15.4 to 20.5 ms. The second phase duration was always 40% of the total duration. The current and voltage waveforms delivered to the animal were digitized at 20 kHz and recorded by a waveform analyzer (Data Precision 6100). Signal analysis software within the analyzer was used to obtain impedance and energy measurements. The data were transferred to a Macintosh computer for statistical analysis.

Statistical analysis. Results are expressed as the mean value ± SD of the ED50% for delivered energy, peak voltage, peak current and impedance for each configuration. Analysis of variance was adjusted for repeated measurements and was performed for the different configurations (SPSS, version 5.02, SPSS, Inc. and ISP version 3.3, Datavision AG, Switzerland). Statistical significance was defined as $p \leq 0.05$. The power of the study was 0.97, and 50-V difference was considered meaningful.

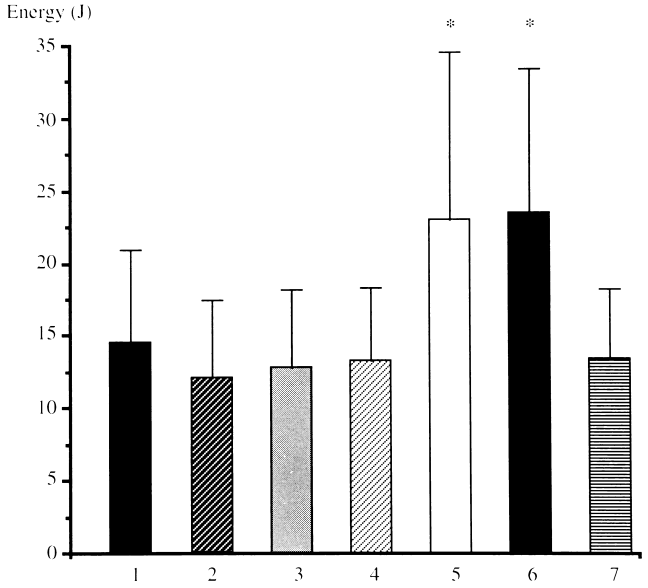


Figure 2. Mean ED50% and standard deviation for energy of both phases for all seven lead configurations. *p ≤ 0.05, configurations 5 and 6 versus configurations 1 to 4 and 7.

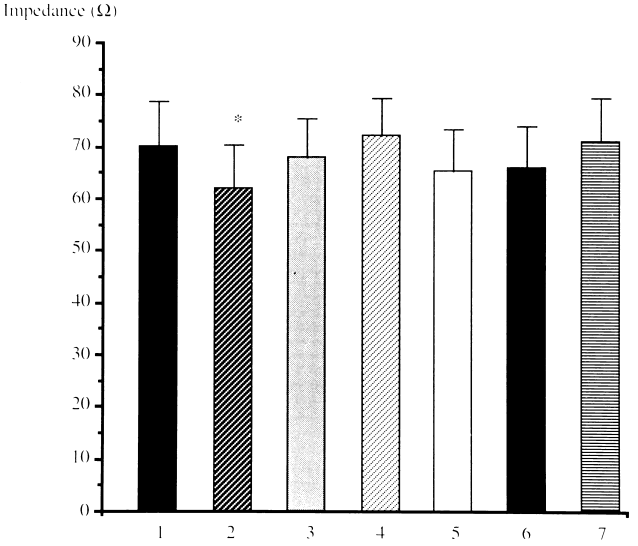


Figure 3. Mean ED50% and standard deviation for impedance for all seven lead configurations. *p ≤ 0.05, configuration 2 versus configuration 4.

Results

Figure 2 shows a bar graph for ED50% energy. There were no significant differences for peak voltage, peak current, energy delivered or impedance among configurations 1, 3 and 4. To isolate the impact of the passive lead, the ED50% values associated with configurations 1, 3 and 4 were compared with those for configurations 2, 5 and 6. No significant differences were found between configuration 2 and configuration 1, 3 or 4.

In contrast to configuration 2, in which the passive electrode was in contact with the active electrode in the RV apex, configuration 5, in which the active RV electrode was positioned proximal to the passive electrode, yielded different results. When the active lead was proximal to the RV apex, the ED50% was increased significantly, but impedance values were not different. To determine whether the significant increase was due to the lead position or to the passive lead, the passive lead was removed, and the active lead position was unchanged (configuration 6). There were no significant differences for ED50% values detected for configuration 5 versus configuration 6.

Impedance values are shown in Figure 3. The impedance for configuration 2 was lowest but was statistically significantly different from configuration 4 only.

In Table 1, the mean voltage of the three reversal points is shown for all eight dogs individually, demonstrating the wide range. No systematic reason was found to explain the increase or decrease in each individual animal.

Discussion

Today, the majority of patients who need an implantable defibrillator for the treatment of ventricular arrhythmias can be treated with an endocardial-based ICD system (5,15). On rare occasions, lead malfunction may necessitate implantation of a new endocardial lead for defibrillation. To our knowledge, no controlled study to determine the effect of "bystander" endocardial leads on defibrillation efficacy has been reported. Two previous studies (6,7) demonstrated that the presence of epicardial patch electrodes dramatically increases the shock strength required to defibrillate dogs using an endocardial-based lead system. Therefore, it was important to determine whether an electrically passive endocardial defibrillation lead might similarly impact defibrillation efficacy by providing a shunt path for the defibrillating current either when the passive electrode was in contact with the active electrode or when the active electrode was positioned at a slight distance from the passive electrode to avoid contact with it. We designed the present study to address both situations.

The major finding of this study is that the presence of an electrically passive endocardial defibrillation lead having a distal electrode either in contact with or not in contact with the active RV electrode does not significantly alter defibrillation efficacy. A possible explanation for this finding is that the current shunting caused by the passive electrode affects an area with a high potential gradient near the active electrode. The current shunting would not be expected to lower this strong gradient sufficiently to decrease it below the level needed to defibrillate because it would be in an area where the potential gradient is already weak. In fact, there was a nonsignificant trend suggesting that ED50% values were lower when both passive and active leads were present and their distal electrodes were in contact in the RV apex (configuration 2). The mechanism for this observed behavior may be related to the shock impedance. The slightly lower impedance for configuration 2 could have been caused by the larger effective surface area when the passive and active electrodes were in contact.

Table 1. Individual Defibrillation Thresholds

	Dog 1	Dog 2	Dog 3	Dog 4	Dog 5	Dog 6	Dog 7	Dog 8
Conf. 1	524.8 ± 76.6	464.8 ± 84.4	493.2 ± 26.1	385.6 ± 44.1	361.0 ± 88.6	476.1 ± 65.8	297.9 ± 43.2	348.6 ± 24.1
Conf. 2	496.4 ± 21.8	474.2 ± 66.9	408.6 ± 41.1	409.3 ± 49.2	313.8 ± 24.0	297.3 ± 28.0	305.2 ± 24.0	329.5 ± 43.7
Conf. 3	403.3 ± 24.8	521.7 ± 63.8	444.1 ± 24.3	423.9 ± 43.7	345.6 ± 45.2	404.6 ± 49.6	254.6 ± 42.0	349.0 ± 23.7
Conf. 4	340.7 ± 42.6	459.3 ± 99.3	413.8 ± 41.7	460.0 ± 27.6	299.0 ± 43.9	459.2 ± 25.6	316.0 ± 23.8	364.1 ± 64.6
Conf. 5	571.7 ± 22.5	618.9 ± 23.5	688.3 ± 23.8	402.5 ± 23.9	354.6 ± 25.4	671.6 ± 22.1	379.8 ± 41.9	440.2 ± 20.8
Conf. 6	519.8 ± 88.1	619.7 ± 86.3	654.1 ± 40.8	403.2 ± 27.3	372.1 ± 67.5	623.7 ± 69.2	498.7 ± 23.5	509.3 ± 48.9
Conf. 7	319.2 ± 49.6	394.8 ± 22.5	409.8 ± 41.0	394.0 ± 25.7	370.8 ± 65.2	432.5 ± 46.3	374.0 ± 49.1	379.4 ± 62.5

Data presented are mean voltage ± SD of the three reversal points in each dog for each lead configuration (Conf.)

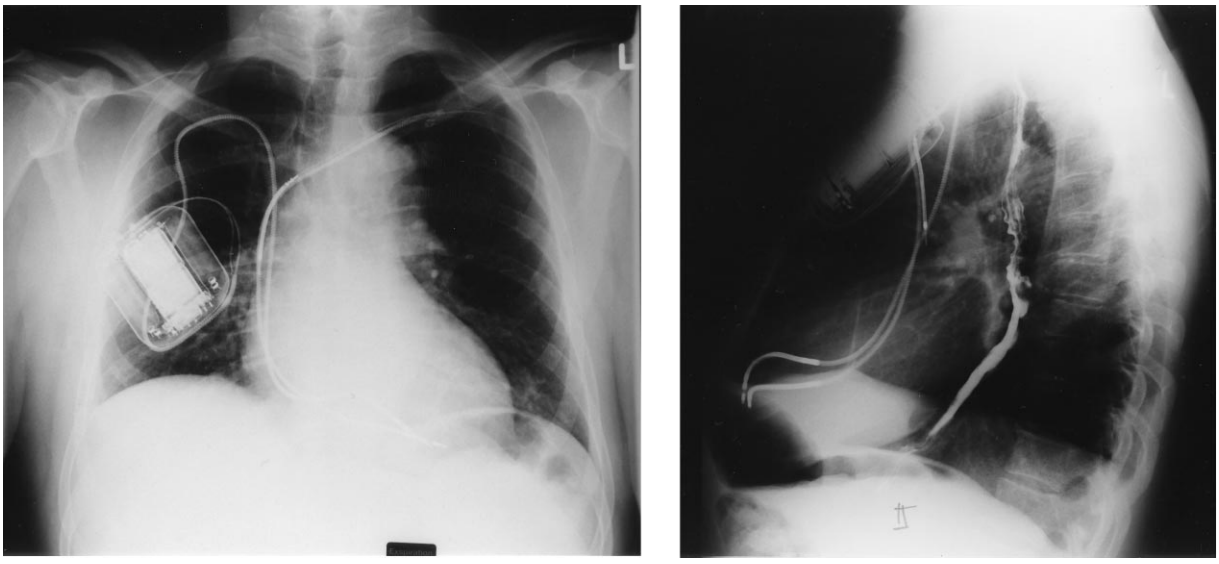
This lower impedance would allow a higher current to flow at a given shock voltage.

By comparing the difference in ED50% between configurations 2 and 3 and the difference between configurations 5 and 6, we were able to infer that the increase in ED50% for configuration 5 compared with configuration 1 or 4 was due to the position of the active RV electrode relative to the RV apex and not to the presence of the passive electrode. The ED50% increases as the distal tip of the RV electrode is drawn out of the apex (16). The same holds true for the pacing lead. The pacing lead does not affect the ED50% but might prevent good placement of the defibrillation lead (17). Therefore, obtaining a good position for the RV electrode in the RV apex is much more important than attempting to place the RV electrode to avoid an old passive defibrillation electrode.

Clinical implications. These findings have important clinical implications because in the future it is likely that decisions concerning endocardial defibrillation lead abandonment or extraction will need to be made. The X ray images shown in Figure 4 are from a patient with malfunctioning endocardial leads that could not be removed due to fibrous tissue at the superior cava/right atrial junction. On the basis of data from this animal study, we abandoned the inactive electrode system and implanted a second electrically active system, as shown in Figure 4. According to the previous rationale, the second lead was placed as far as possible into the right apex. In the present canine study, we did not investigate whether the sensing characteristics of the active lead were changed by the presence of the passive defibrillation or pacing lead or the long-term effect on mechanical integrity of implanted defibrillation leads in contact with another. For this reason, any mechanical contact of the two electrodes was avoided in this patient, resulting in a fully functioning lead system, including a defibrillation threshold of 15 J. This scenario is not a general recommendation for the abandonment of all leads, but in the situation shown in Figure 4, abandoning inactive endocardial electrodes is a possible alternative to cardiocthoracic surgical removal. In these selected patients, careful intraoperative testing is mandatory.

Conclusions. Within the limitations of a canine model, our results suggest that defibrillation efficacy of endocardial lead systems will not be detrimentally affected by the presence of a passive "bystander" electrode in the right ventricle. However, if the abandoned lead physically prevents the new lead from being implanted with its distal tip in the RV apex, the defibrillation strength requirements would be expected to

Figure 4. Anteroposterior **(left)** and lateral **(right)** X-ray views in a patient with an abandoned and an active endocardial electrode system.



increase. On the basis of the present animal model data, the important factor for the ED50% defibrillation requirements when using an active endocardial-based system together with an inactive endocardial lead system seems to be the lead position. Although the presence of a passive endocardial defibrillation lead did not detrimentally affect defibrillation efficacy in the present study, these results alone are not sufficient to recommend abandonment of defibrillation leads. The decisions for implanting a second lead should include careful and complete testing of sensing characteristics during normal rhythms and during ventricular fibrillation to ensure that the ICD system functions properly.

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