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Determinants of Subcutaneous Implantable Cardioverter-Defibrillator Efficacy

A Computer Modeling Study

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ABSTRACT

OBJECTIVES This study determined the impact of subcutaneous implantable cardioverter-defibrillator (S-ICD) coil and generator position on defibrillation threshold (DFT).

BACKGROUND S-ICD implantation can occasionally result in unacceptably high DFT. Implant position characteristics associated with high DFTs in S-ICD patients have not been fully elucidated.

METHODS A 3.8-million-element computer model built from magnetic resonance images was used to simulate the electric fields that occur during defibrillation. Generator positions were tested from posterior to anterior in 4-cm increments. The left parasternal coil was tested with 0, 5, and 10 mm of underlying subcutaneous fat and the generator with 20 mm of underlying fat. The estimated DFT for the S-ICD was defined as the energy delivered when producing an electric field of 4 volts/cm in at least 95% of the ventricular myocardium.

RESULTS Estimated DFTs were 22, 29, 64, and 135 joules for posterior, standard (lateral), mid-anterior, and anterior generator locations, respectively. Defibrillation thresholds were 29, 58, and 95 joules with 0, 5, and 10 mm subcoil fat, respectively, and 45 joules with 20 mm subgenerator fat. Combining anterior generator position with subcoil fat resulted in a very high DFT (379 joules). Shock impedance increased with both subcoil and subgenerator fat but was minimally affected by anterior/posterior generator position.

CONCLUSIONS The model suggests that an S-ICD implantation strategy involving posterior generator location and coil and generator directly over the fascia without underlying fat is likely to markedly lower DFTs with the S-ICD and assist in troubleshooting of patients with unacceptably high DFTs. (J Am Coll Cardiol EP 2017;■:■–■) © 2017 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

The subcutaneous implantable cardioverter-defibrillator (S-ICD) is now widely used for the treatment of life-threatening ventricular arrhythmias as an alternative to the transvenous ICD (T-ICD) (1,2). Studies demonstrate that most S-ICD shocks are successful in terminating ventricular tachycardia (VT) and ventricular fibrillation (VF) (1). The rate of successful S-ICD defibrillation is comparable to that of T-ICD, with the caveat that the S-ICD requires higher energy shocks than the T-ICD (3). In

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ABBREVIATIONS AND ACRONYMS

DFT = defibrillation threshold

LV = left ventricular

MRI = magnetic resonance imaging

S-ICD = subcutaneous implantable cardioverter-defibrillator

T-ICD = transvenous implantable cardioverter-defibrillator

VF = ventricular fibrillation

VT = ventricular tachycardia

the IDE (Investigational Device Exemption) study of the S-ICD, at the time of implantation, 82.8% of patients had successful consecutive conversion of the initial 2 induced VF episodes after final device positioning, and all patients ultimately had successful defibrillation according to the testing protocol (requiring 2 successive successful conversions at 65 J) (4). An analysis of 111 clinical VT/VF events treated by the S-ICD demonstrated that 90.1% were successfully converted by the first shock (1), comparable to a T-ICD rate of 89.6% with dual coil leads in the MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy) study (5). Furthermore, 98.2% of the 111 events were successfully converted by the 5 available S-ICD shocks. Factors associated with the defibrillation threshold (DFT) of the T-ICD, including lead and generator positions, have been described previously (6). Implant factors associated with DFT of the S-ICD have not yet been fully elucidated, however.

In this study, we used a computer model to simulate defibrillation with the S-ICD to explore the impact of position of both the S-ICD coil and generator implants on DFT.

METHODS

THE MODEL. Computer modeling of defibrillation is a well-established technique representing the thorax anatomy by a 3-dimensional (3D) matrix of small circuit elements with appropriate tissue resistivities. Electrodes are applied that introduce currents. A numerical solution is obtained, resulting in voltages and gradients that can be measured anywhere in the thorax. Similar computer models have been described (7-14), including some focused on S-ICD simulation (8,9). The particular model we used has been described previously (7,15).

The computer model and magnetic resonance imaging (MRI) data set were licensed from an academic research laboratory (Bakken MIND Laboratory, University of Minnesota, Minneapolis, Minnesota). MRI data were de-identified. The subject was a 63-year-old male, 100 kg, 180 cm tall, with 80% stenosis in the left anterior descending coronary artery and normal ventricular size and function. A 1.5-T scanner (Sonata, Siemens, Malvern, Pennsylvania) was used. Images were obtained from abdomen to neck, and those at end-diastole represented the arrested heart. The images were manually segmented at the axial resolution of the MRI (1.5 mm), yielding a model with 3.8 million elements and 1.5 × 1.5 × 5 mm thoracic resolution (**Figure 1**). Each tissue was assigned an electrical resistivity value according to published studies (16-19) as follows: muscle was 225 ohms-cm, lung was 1,400 ohms-cm, blood was 150 ohms-cm, myocardium was 250 ohms-cm, liver and kidneys were 600 ohms-cm, and bone and fat were 2,000 ohms-cm. Resistivities were assumed to be isotropic, including myocardial fibers (20-22). Homogenous resistivity was used for each tissue type, as in similar studies (7-14). However, the model has sufficient resolution to allow a highly heterogeneous thorax, with distinction among tissues including lateral thoracic arteries, azygous vein, esophagus, parasternal cartilage, ribs, epicardial fat, mediastinal and retrosternal fat, and pulmonary vessels, among others (**Figure 1**). Other assumptions included a passive monodomain representation of the heart and thorax, with negligible capacitance. The latter assumption was based on the widely cited reference of Gabriel et al. (16). They surveyed and measured tissue resistance and capacitance properties (i.e., the permittivity which determines polarization and capacitance) across a large frequency range. After tabulating resistive and reactive parts of the complex impedance of tissues in our model at defibrillation modeling frequencies, we found that the electric field magnitude errors incurred by neglecting permittivity were <5%. In this manner, the resistive-only representation of the thorax was justified.

Validation of the model centered on thoracic electric field accuracy and not on determining a DFT, which when measured clinically, is a probabilistic variable and not a fixed number. As with other investigators using similar models, our bridge from an electric field to a DFT estimation was the critical mass concept, experimentally developed by Zipes et al. (23), Zhou et al. (24), and Witkowski et al. (25), discussed below. To confirm electric field accuracy, a comparison to actual measurements in the source subject with skin and esophageal electrodes was conducted. The subject swallowed 2 pairs of tethered bipolar electrodes (Arzco, Chicago, Illinois) to position behind the left atrium, using atrial electrogram guidance. The pair was then separated by pulling one tether 4 cm. A second pair of electrodes was placed on the skin at various positions on the thorax, and currents were injected into it. This allowed verification that near-cardiac electric fields caused by extrathoracic currents were simulated with less than 10% error. Additional tests in saline-filled elliptical tanks with actual S-ICD generators and coils (Boston Scientific, St. Paul, Minnesota) further ensured the accuracy of electric field simulations, errors were less than 2%. In addition, the model's conventional structure and its history (7,15),