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High spatial resolution measurements of specific absorption rate around ICD leads[☆]

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Abstract

Introduction—It has been shown that strong electric shocks can cause local refractoriness in the heart. This is of particular concern if the region of refractoriness is the area sensed by an implant to determine cardiac rhythm, as is the case with many Implantable Cardioverter Defibrillator (ICD) leads which use the same electrodes for shocking and sensing. Failure to sense the true cardiac rhythm can cause application of unnecessary shocks and potential induction of arrhythmias. We developed a system to accurately map the areas where local refractoriness is most probable. We measured the Specific Absorption Rate (SAR) around typical ICD leads. Current density (J), a parameter that determines defibrillation effectiveness, is proportional to the square root of SAR.

Methods and results—SAR measurements were performed in a homogeneous saline media using a variety of ICD leads. Gated 60 Hz shocks were used to produce heating, which was measured by thermistor probes. The temperature-rate-of-change is directly proportional to the SAR. Measurement techniques were developed that produced accurate SAR results at high spatial resolutions. Multiple polarities and configurations of ICD leads were tested.

Conclusions—We confirmed the spatial distribution of the SAR and corresponding current density possessed sharp peaks and were highly localized around the leads' electrodes. Scans with a resolution of 1 mm or less are required in the area of peak SAR in order to capture the peak's value.

Keywords

Defibrillation; Specific Absorption Rate (SAR); Measurement techniques

[☆]The opinions and conclusions stated in this article are those of the authors and do not represent the official position of the United States Food and Drug Administration.

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1. Introduction

Implantable Cardioverter Defibrillator (ICD) leads are used for the application of high voltage electric shocks to the interior of the heart. It has been shown that cardiac myocytes exhibit extended periods of refractoriness after strong electric shocks [1,2]. If the current density distribution around ICD leads is non-uniform this may cause regional refractoriness. This is of particular concern if the refractory region is sensed by an implant to determine cardiac rhythm, as is the case with many ICD leads which use the same electrodes for shocking and sensing. If the bulk of the heart was successfully defibrillated by an initial shock, while the region near the sensing electrodes takes longer to recover, the ICD may apply a second, unnecessary, shock. A shock applied at the wrong part of the cardiac cycle could generate secondary arrhythmias causing the ICD to apply additional shocks.

Before one can study the effects of local refractoriness caused by ICD shocks, one must be able to find and measure the spatial distribution of the current density and energy deposition reliably. To do this we developed a system to make high spatial resolution measurements around ICD leads of various configurations and geometries. Current density (J) has often been used to characterize defibrillation effectiveness [3–5]. In our study we measure Specific Absorption Rate (SAR) because it can be measured with greater spatial resolution and accuracy than J . SAR is related to J by Eq. (1), where σ is conductivity and ρ is density. The conductivity and density of the tissue-equivalent saline in our in vitro system is a constant.

$$J = (\sigma \rho (\text{SAR}))^{1/2} \quad (1)$$

2. Methods

The leads under test were suspended in a tank of normal saline. The test tank was placed below a three-axis positioning system having a spatial resolution of 0.126 mm in all three axes. The positioning system moved a thermistor probe through the saline to measure the thermal transients near the ICD lead during a shock. Fig. 1 is an overview of the experimental hardware setup.

The thermistor probes were constructed by inserting a miniature thermistor (0.3 mm diameter) in the tip of a glass capillary. The glass capillary was then inserted in the tip of a glass pipette. The entire assembly was sealed with epoxy. Testing showed the finished probes had a time constant of approximately 60 ms. All probes were calibrated to an accuracy of 0.01°C using a standard thermometer traceable to NIST calibration. It has been shown that inexpensive thermistor probes such as these can be used to make accurate high resolution SAR measurements in liquid media [6].

A custom software program, written in Asyst, handled all positioning and data acquisition. Complete automation was required due to the quantity of data and the total time needed to acquire it. For example, to map a planar region 2 cm wide by 20 cm long at 1.0 mm resolution requires 21 scan lines of 201 points, or 4221 measurements. At each measurement point, the program applied the shock; recorded current, voltage, and thermal response;

analyzed the data, stored raw and processed data; then moved the probe to the next sample point. To allow for complete decay of thermal transients between shocks, the software pauses at least 10 seconds or until the temperature rate of change falls below 0.001°C/s. Our example, 4221 samples at 10 s each, requires at least 11 h and 43 min to complete.

The shock waveform used was a 60 Hz sinewave burst, 800 ms in duration. The sinewave was generated by the computer then applied to the ICD leads via an audio power amplifier. Power spectral density analysis, performed by the authors, showed both monophasic and biphasic ICD waveforms have more than 90% of all energy below 2 kHz. This indicates heating from an ICD shock is due to conduction and not dielectric heating. The choice of a sinusoidal waveform, rather than the typical biphasic defibrillation waveform, has no effect on the shape of the SAR pattern. Sixty Hertz was chosen as the stimulus frequency for several reasons. At 60 Hz, heating is caused by conduction just as it is with a typical ICD shock waveform. All our data acquisition inputs were already filtered against 60 Hz interference. Further, if any 60 Hz artifact was present in the temperature signal it could easily be filtered since 60 Hz is well above the maximum thermal response frequency. We confirmed that the 60 Hz electric field from the shock did not produce any artifact in our temperature data. Sequential measurements, with the thermistor tip in the same location, but with the probe's wires oriented parallel or perpendicular to the lead's axis, showed no significant difference in the $\Delta T/t$ sensed. Since orientations favorable to, and unfavorable to, electric field coupling of the wires attached to the thermistor produced the same result, we concluded that any coupling to the wires was insignificant.

The voltage, current, and temperature inputs were each sampled at 250 Hz by a 16-bit converter from one second before the application of a shock to one second after the application.

The SAR (W/kg) was calculated using Eq. (2), where C_H is the specific heat capacity of the saline (kcal/kg/°C), 4186 is the conversion factor from kcal to joule, and $\Delta T/t$ is the change in temperature per unit time.

$$\text{SAR} \cong 4186 C_H \frac{\Delta T}{t} \quad (2)$$

When measuring the change in temperature per time, care must be taken to ensure one is measuring the slope due to power deposited at the point of measurement [7]. The actual temperature rise can be corrupted by thermal response time, instrument response time, conduction, and convection. We calculated the slope of temperature rise from a least squares linear fit for the central 400 ms of each 800 ms shock. This portion of the temperature history, illustrated in Fig. 2, was found to be very linear even when the total temperature rise was small.

Each calculated SAR value was normalized by the applied RMS power of the shock used to make the measurement; thus, all our results have the dimensions of (W/kg)/W. This was done to remove any variance caused by drift in the amplifier's gain over the course of the

experiment and to allow extrapolation of our results over a wide range of shock powers. Extrapolation of SAR over a range of applied powers is only valid if our measurements of T/t are linear over that range. Fig. 3 shows that our measurements are linear over a wide range of applied power. For our test setup, linearity began to deteriorate at powers less than 10W because the T became too low to measure reliably. At powers greater than 65 W electrolysis began to produce bubbles which moved the fluid during the measurements. All our data was taken at power levels in the linear range.

3. Results

Many geometries, combinations of leads, and electrical configurations were tested. These permutations were suggested by manufacturers' publications and clinical reports. The resultant volume of data is very large, too large to present in one paper. The results presented here are representative samples.

Fig. 4 illustrates the orientation and SAR of an endocardial integrated ICD lead. Fig. 4(b) shows the SAR measured along an endocardial integrated ICD lead, normally introduced into the right heart via the left subclavian vein. The lead was held straight in the test tank such that the distal and proximal electrode coils were on a common central axis [Fig. 4(a)]. Other experiments and computer simulations were done to assess the change in SAR as the angle between the distal and proximal electrode coils decreased from this 180° case. The shock current passed between the distal (surface area of 3.79 cm²) and proximal (6.17 cm²) electrode coils, no ground-plate or third electrode was used for these measurements. Each shock was approximately 50 W into a total impedance of 16 Ω.

The data for Fig. 5 were obtained using the same endocardial integrated ICD lead plus a subcutaneous patch electrode, normally placed submuscularly next to the rib cage on the left chest. As shown in Fig. 5(a), the integrated lead was held straight in the test tank with the patch suspended approximately 5 cm from the lead's central axis. Both of the integrated lead's electrode coils (total surface area of 9.96 cm²) were connected to the same polarity, the patch electrode (28 cm²) was connected to the opposite polarity of the amplifier's output. The data in Fig. 5(b) are the SAR in an XY-plane passing through the axis of the integrated ICD lead and perpendicular to the face of the patch electrode. Each shock was approximately 50 W into a total impedance of 8 Ω. The electrical connections were changed as shown in Fig. 5(c); this connected the integrated lead's proximal electrode coil and patch electrode (total surface area of 34.17 cm²) to one polarity, while the integrated lead's distal electrode coil (3.79 cm²) was connected to the opposite polarity. Fig. 5(d) is the SAR measured in the same location as that for Fig. 5(b). Each shock was approximately 35 W into a total impedance of 13 Ω.

The data for Fig. 6 were collected using the same experimental setup shown in Fig. 5(a). The data was acquired in the XZ-plane, rather than the XY-plane, to show the SAR approximately 2 mm above the face of the patch electrode.

Fig. 7(a) shows the normalized SAR patterns from experimental measurements of an endocardial integrated ICD lead held straight in the test tank. Fig. 7(b) shows the results of a

finite element analysis simulation of the same lead as modeled using a commercial software package (Cosmos by Structural Research and Analysis Corp.). Both data sets represent the SAR in an axisymmetric plane starting 1 mm from the surface of the ICD lead.

4. Discussion

The data indicate that spatial distribution of current density, as evidenced by SAR patterns, are highly localized. The SAR drops rapidly with distance from the electrodes. All patterns exhibited high narrow peaks at the edges of the electrodes. Our data demonstrates that bringing electrodes of opposite polarity as close as 2 cm has little effect on the peaks and overall shape of SAR patterns. At 2 cm the only noticeable effect was a raising of the SAR floor between the electrodes.

Our data shows that the maximum SAR is found near the edges of electrodes. These SAR peaks can easily be missed with low spatial resolution scans. For typical ICD leads, the spacing between measurement points should be 1mm or less to reliably capture the peak SAR values. Where the SAR's spatial rate of change is less, lower resolution can be used. Since our computer models show SAR patterns similar to experimental results, those models can be used to predict the areas where high spatial resolution scanning is needed.

These data provide new information on the spatial distribution of current densities induced near ICD leads. This information can be used to study the issues of the induction of local refractoriness in stimulated heart tissues.

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Fig. 1.
Block diagram overview of instrumentation system.

Fig. 2.
Example of temperature vs time for a single shock, including one second pre- and one second post-shock.

Fig. 3. Linearity of $1/T$ with applied power. The squares are the measured data while the line is the least squares linear fit ($r^2=0.9991$).

Fig. 4. SAR measured on a 1 mm square grid in an axisymmetric plane along an endocardial integrated ICD lead stretched straight. Distal and proximal coils were opposite polarities. (a) Shows the orientation of the lead; (b) is a surface plot of the SAR.

Fig. 5.

SAR measured on a 1 mm square grid in a plane passing through the axis of an endocardial integrated ICD lead and perpendicular to a subcutaneous patch electrode. (a) Shows the experimental setup for the SAR surface plot shown in (b); both electrode coils of the integrated lead were at the same polarity while the patch electrode was at the opposite polarity. (c) Shows the experimental setup for the SAR surface plot shown in (d) the distal electrode coil was at one polarity while the proximal electrode coil and patch electrode were at the opposite polarity.

Fig. 6.

SAR measured on a 1 mm square grid, 1 to 2 mm above the surface of the subcutaneous patch electrode. (a) Is a diagram of the patch electrode showing the 12 conductive windows on the active face of the patch; the opposite face of the patch is a solid sheet of silicone. Each of the conductive windows is a square 15.2 mm on a side. (b) Is an intensity image of the SAR clearly showing the conductive windows.

Fig. 7. Normalized SAR results from computer model (a) of endocardial integrated ICD lead compared to actual measurements (b).