Does reducing capacitance have potential for further miniaturisation of implantable defibrillators?

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Abstract

***Objective*—To determine whether considerably smaller capacitors could replace 125 μF capacitors as the standard for use in implantable defibrillators.**

***Methods*—Measured energy, impedance, voltage, and current delivered were compared at defibrillation threshold in 10 mongrel dogs for defibrillation using 75 μF and 125 μF capacitors alternated randomly. Defibrillation was attempted with biphasic shocks of comparable tilt between an endocardial lead in the right ventricular apex and a "dummy" active can of an experimental implantable device placed in the subpectoral position.**

***Results*—A reduction of capacitor size of 40% was associated with an increase in voltage of 21% and in current of 22%. With a 65% tilt, no significant differences were found between the two capacitances with respect to the impedance or energy required for defibrillation.**

***Conclusions*—Multiple advances in electrode material, electrode configuration, shock morphology, and shock polarity have reduced defibrillation energy requirements. Smaller capacitors could be used in implantable cardioverter/defibrillators without a major decrease in effectiveness.**

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Keywords: capacitor size; defibrillation threshold; implantable defibrillator

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The use of implantable cardioverter-defibrillators (ICD) to prevent sustained ventricular tachycardia and sudden cardiac death has become widespread during the past few years.[1] Since the first implantation in 1980 by Mirowsky *et al*[2] major progress has been achieved and defibrillator size has been reduced dramatically. Further reductions are desired to reduce discomfort and morbidity following implantation. Energy requirements and therefore implant size could be reduced because of improvements in electrode configuration and material as well as shock morphology and polarity. At present, defibrillator volume is determined predominantly by battery and capacitor size. In currently used devices, 125 μF capacitors are used to guarantee a safety margin for defibrillation.[3] A reduction in capacitor size of only 50 μF could dramatically decrease implantable defibrillator volume, possibly below 50 ml.

The aim of this study was to compare in a canine model measured energy, impedance, voltage and current delivery at defibrillation threshold for defibrillators using 75 μF and 125 μF capacitors, both calculated to deliver a waveform with 65% tilt.

Methods

ANIMAL PREPARATION

The experiment was performed using 10 mongrel dogs (26·3 (SD 1·7) kg). First a venous line was set up in each foreleg. Through one of the venous lines 25–30 mg/kg body weight of pentobarbitone was given for anaesthesia. The dogs were intubated and ventilated with 30–40% oxygen on a Harvard ventilator. A femoral artery line was then placed percutaneously or through a stab incision. Blood gases and metabolic status were measured every 30–60 minutes and adjusted to maintain normal levels. The second venous line at the dog's

Energy, impedance, voltage, and current measured at defibrillation threshold using 125 μF and 75 μF capacitors. A single value is shown for each dog as well as mean value (MV) and standard deviation (SD) for each of the two capacitors

	Energy		*Impedance*		*Voltage*		*Current*	
Dog No	*75 μF (Joule)*	*125 μF (Joule)*	*75 μF (Ohm)*	*125 μF (Ohm)*	*75 μF (Volt)*	*125 μF (Volt)*	*75 μF (Ampere)*	*125 μF (Ampere)*
1	6·17	7·65	56·45	58·67	392·36	337·96	6·87	5·74
2	10·15	8·93	60·40	61·56	510·72	371·46	8·30	5·97
3	10·88	11·23	56·14	56·45	520·29	408·23	9·16	7·21
4	13·25	11·92	52·93	54·56	575·19	414·02	10·82	7·55
5	6·44	9·10	68·89	65·50	416·54	377·50	5·98	5·78
6	8·66	11·38	77·35	77·71	464·39	436·93	5·89	5·53
7	8·31	9·34	53·05	54·42	452·05	367·93	8·48	6·78
8	8·46	9·24	62·80	63·31	471·94	408·23	7·39	6·42
9	10·37	8·10	58·12	58·50	516·77	436·43	8·62	7·44
10	14·48	14·51	53·42	55·97	596·09	502·16	11·50	8·96
MV	9·72	10·14	59·95	60·66	491·63	406·08	8·25	6·74
SD	2·69	2·09	7·89	7·04	64·9	46·29	1·79	1·07

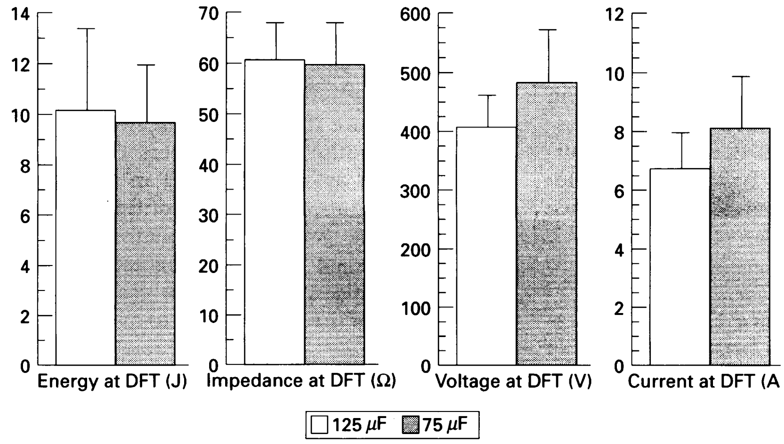


Figure 1 Comparison of defibrillation threshold (DFT) energy, impedance, voltage, and current. There is no significant difference between the 125 μF and 75 μF capacitor for energy requirement and impedance, but there is a significant difference for voltage and current. The 75 μF capacitor requires significantly (P < 0·001) higher voltage and current than the 125 μF capacitor.

forefoot was used for continuous anaesthesia with a pentobarbitone and saline infusion. For muscle relaxation 1 mg/kg succinylcholine was given intravenously. Three ECG electrodes were placed on the animal's skin in order to obtain the surface ECG (lead II) for continuous monitoring during the trials.

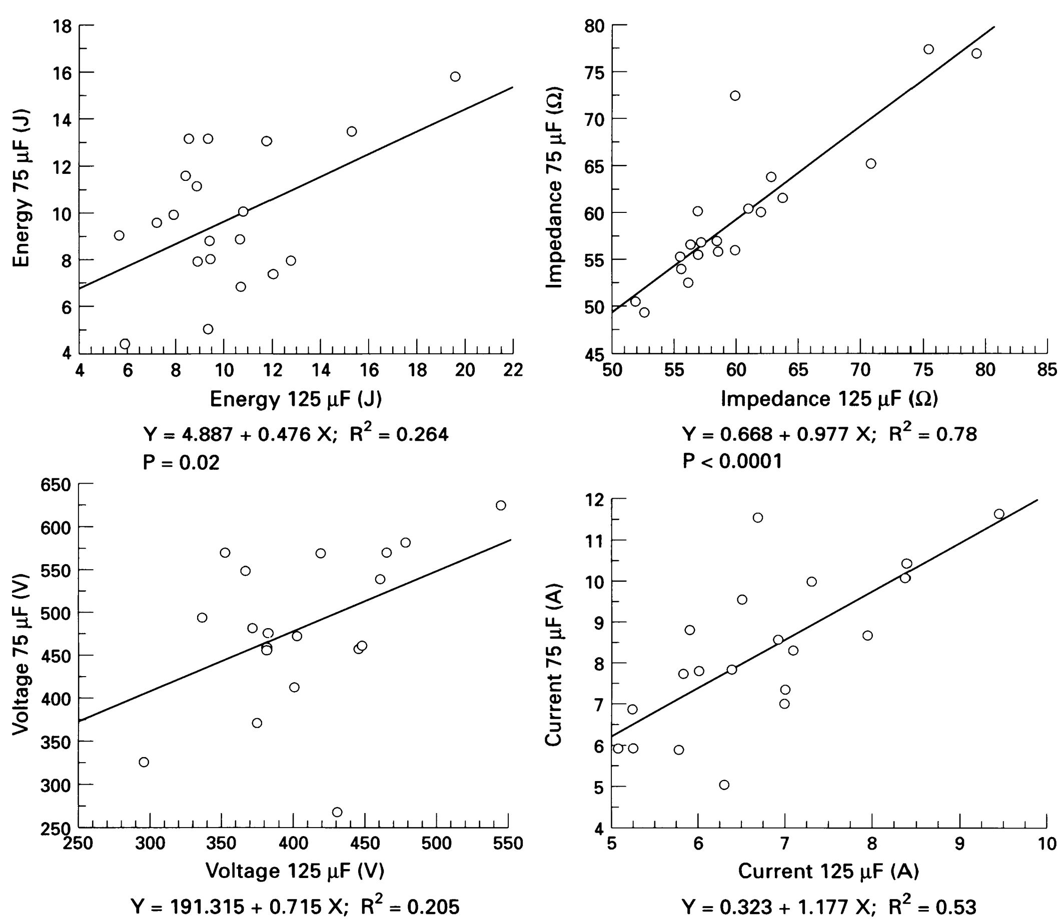
ELECTRODE POSITION

A standard Intermedics 293–05 titanium coil defibrillation lead with an electrode length of 5 cm was inserted through the external jugular vein and positioned in the apex of the right ventricle using fluoroscopy. Stable fixation of the lead was obtained by the myocardial screw at the tip of the electrode. This electrode allows stimulation, induction of fibrillation, and defibrillation. A dummy active can (volume 75 ml) was implanted in a subpectoral position. In case of internal defibrillation failure, two fast patch electrodes were attached on the animals' skin for external rescue shocks.

DEFIBRILLATION PROTOCOL

For induction of ventricular fibrillation a 60 Hz burst of current was delivered through the defibrillation electrode for one second. Defibrillation was attempted with a biphasic impulse between the RV coil serving as the cathode for the first phase of the defibrillation shock and the active can, using a custom defibrillator with a 125 μF or a 75 μF capacitor in random order. Assuming similar impedances for both waveforms, the impulse duration of the biphasic shock for both capacitors was calculated for 65% tilt for the first phase. Past experience has shown that a first phase of 6 ms and a second phase of 3·5 ms was appropriate for the 125 μF capacitor.[4] The first phase of the 75 μF capacitor was calculated to be 3·5 ms for 65% tilt and the second phase was set to 2·0 ms so as to correspond with the 125 μF capacitor. A step protocol was used for determining the defibrillation threshold. Defibrillation attempts were made starting with a leading edge voltage of

Figure 2 Regression graphs and statistics between energy, impedance, voltage and current at different capacitor sizes.



400 V. If a shock failed, the next attempts were made with increasing steps of 20 V until a shock succeeded. If the initial 400 V shock succeeded, subsequent attempts were made in steps 20 V lower, until a shock was unsuccessful.[5] The lowest successful defibrillation voltage was considered to be the threshold. Defibrillation threshold was determined twice for each animal.

DATA AQUISITION

During the trials the surface ECG and intracardiac signals, measured between the tip of the electrode and the subcutaneous dummy can, were recorded continuously on a data recorder and later digitised with a computer. Peak voltage, pulse duration, delivered energy, impedance, and exact shock waveform of the biphasic shock were all recorded by means of a custom built Macintosh based on-line data recording system with an A/D conversion rate of 250 kHz.

STATISTICS

Statistical analysis was performed using the Friedman test and Wilcoxon test for direct correlations between the two capacitor groups. A P value less than or equal to 0·05 was considered to be significant.

Results

The table shows the results for energy, impedance, voltage, and current for each dog at the defibrillation threshold and the mean values for all animals. There was no significant difference between the two capacitors with respect to the delivered energy (10·14 (SD 2·09) J for the 125 μF capacitor, 9·72 (2·69) J for the 75 μF capacitor) or impedance (60·66 (7·04) W for the 125 μF capacitor; 59·95 (7·89) W for the 75 μF capacitor). Voltage and current differed between the two capacitances ($P < 0{\cdot}01$). At defibrillation threshold, voltage was 21% higher with 75 μF (491·63 (64·9) V *v* 406·1 (46·3) V), and current was 22% higher with 75 μF (8·25 (1·79) A *v* 6·74 (1·07) A) (fig 1).

Figure 2 compares the corresponding energy, voltage, impedance, and current data points for each of the two capacitors at defibrillation threshold in the individual dogs. Although the difference was not statistically significant, the regression line for energy implies a tendency for the 125 μF capacitor to require more energy for successful defibrillation than the 75 μF capacitor. For impedance, the regression line is nearly 45°, illustrating the similarity between the two capacitors with respect to impedance. As expected, higher voltage is required for defibrillation with the 75 μF capacitor, and current showed the same behaviour.

Discussion

The aim of defibrillation is to synchronise repolarisation of the myocardium so that the majority of myocardial cells are in the refractory period when the fibrillation wave arrives, thus ending fibrillation.[6] Past experience has shown that defibrillation requires a certain critical mass of participating myocardium, otherwise fibrillation persists. Defibrillation does not require the entire myocardium to be depolarised; rather, the numbers of myocardial cells that are participating in fibrillation need to be reduced below the critical value.[6,7] Therefore, the goal of defibrillator development is to create as homogeneous a voltage field as possible with a voltage gradient near the myocardial threshold value to avoid energy waste.[8,9]

Along with optimal electrode configuration[10,11] and position, shock morphology is important for low energy termination of fibrillation.[8] It has been known for a few years that biphasic waveforms are more effective than monophasic.[12] Several studies have shown that 65% tilt is the best phase duration with 125 μF capacitors.[4,13] This study assumed that 65% tilt would be appropriate for 75 μF capacitors also, but the optimal tilt for small capacitors has yet to be determined. It is possible that 75 μF capacitors with optimal tilt might yield even better results.

With epicardial defibrillation using monophasic shocks it has been postulated that smaller capacitors match the heart's chronaxie more closely and deliver a more homogeneous field, thus lowering defibrillation threshold energy and allowing more successful shocks per battery.[13,14] These conclusions should apply equally well to endocardial lead systems using biphasic shocks. It follows that smaller capacitors should be more efficient for use in ICDs for both size and battery life reasons, as long as the capacitor can deliver enough energy to provide a safety margin for defibrillation.

Capacitor size determines the maximum energy that can be delivered as a function of time and voltage. For a 75 μF device, a shorter duration is required to achieve 65% tilt, so more voltage is needed to deliver the same energy as the 125 μF device. Using the formula $E = 0{\cdot}5 \times C \times V^2$ for the delivered energy from a capacitor, with a 125 μF capacitor a 600 V shock will deliver 22·5 J, while with a 75 μF capacitor the same voltage would deliver only 13·5 J. In order to give a full shock of 22 J, the capacitor has to be charged to 770 V. Since the maximum voltage attainable with present hybrid and capacitor technology is 750–780 V,[15] higher defibrillation thresholds leave insufficient margin of safety. This is especially true if pathway impedance is high, which would allow the voltage to be delivered but would have considerable impact on current. With smaller capacitors it is therefore mandatory that the pathway impedance remains low in order to allow sufficient current flow with a given charge voltage.

Recent advances in electrode material, configuration, shock morphology, and shock polarity have shown in clinical practice that defibrillation thresholds of 12 J or less can be achieved.[16–18] Since energy delivered depends strongly on the current flow, and current flow is determined by pathway impedance, in clinical practice ICDs using smaller capacitors might be used only in conjunction with low impedance lead systems.

Conclusions

Our results indicate that the use of smaller capacitors, as low as 75 μF, in ICDs should be pursued if the pathway impedance of systems used in conjunction with the smaller capacitors is low enough to guarantee enough current flow and energy delivery. The use of these smaller capacitors would allow the construction of defibrillators with low size and weight, possibly allowing subcutaneous implantation similar to current VVI pacemakers.

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