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Randomized Comparison of a 90 uF Capacitor Three-electrode Defibrillation System with a 125 uF Two-electrode Defibrillation System

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Abstract. Introduction: **A variety of factors, including the number of defibrillation electrodes and shocking capacitance, may influence the defibrillation efficacy of an implantable defibrillator system. Therefore, the purpose of this study was to compare the defibrillation energy requirement using a 125 uF two-electrode defibrillation system and a 90 uF three-electrode defibrillation system.**

Methods and Results: **The defibrillation energy requirements measured with both systems were compared in 26 consecutive patients. The two-electrode system used a single transvenous lead with two defibrillation coils in conjunction with a biphasic waveform from a 125 uF capacitor. The three-electrode system used the same transvenous lead, utilized a pectoral implantable defibrillator generator shell as a third electrode, and delivered the identical biphasic waveform from a 90 uF capacitor. The two-electrode system was associated with a higher defibrillation energy requirement (10.8±5.5 J) than was the three-electrode system (8.9±6.7 J, $p < 0.05$), however, the leading edge voltage was not significantly different between systems (361±103 V vs. 397±123 V, $P = 0.07$). The two-electrode system also had a higher shocking resistance (49.0±9.0 ohms vs. 41.4±7.3 ohms, $p < 0.001$) and a lower peak current (7.7±2.6 A vs. 10.1±3.7 A, $p < 0.001$) than the three-electrode system.**

Conclusions: **A three-electrode defibrillation system that utilizes a dual coil transvenous lead and a subcutaneous pectoral electrode with lower capacitance is associated with a lower defibrillation energy requirement than is a dual coil defibrillation system with higher capacitance. This finding suggests that the utilization of a pectoral generator as a defibrillation electrode in conjunction with smaller capacitors is a more effective defibrillation system and may allow for additional miniaturization of implantable defibrillators.**

Key Words. **implantable cardioverter-defibrillator, defibrillation threshold, defibrillation energy requirement**

A variety of factors can influence the defibrillation efficacy of a non-thoracotomy defibrillation system. These factors include waveform, electrode configuration, capacitance and the number of defibrillation electrodes [1–4]. Incorporation of these variables into the design of a defibrillation system may improve defibrillation efficacy. Therefore, the purpose of this study was to compare, using a prospective randomized study design, the defibrillation energy requirement associated with a dual coil transvenous defibrillation system with a defibrillation system that utilizes smaller capacitance and three electrodes, including a pectoral generator defibrillator shell that functions as a shocking electrode.

Methods

Study design

Based on previous experience, the two-electrode defibrillation system was expected to have a defibrillation energy requirement of 12±5 J. To detect a 25% change in defibrillation energy requirement, i.e., 3 J, with 80% power, a prospective power calculation demonstrated that 24 patients were required. A prospective decision was made to enroll 30 patients in the event some patients were not able to complete the entire protocol.

Patient population

The mean age of the 30 patients included in this study was 65±12 years, the mean left ventricular ejection fraction was 0.32±0.17, and 28 of the patients were male. Coronary artery disease was present in 27 pa-

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tients, two patients had dilated nonischemic cardiomyopathy, and one patient had cardiac sarcoidosis. The presenting symptom or arrhythmia was aborted sudden death in thirteen patients, syncope in 12 patients, and monomorphic ventricular tachycardia in five patients. All patients underwent baseline electrophysiologic testing, and electropharmacologic testing with a mean of 0.5±0.6 antiarrhythmic drugs was unsuccessful before device implantation.

Of the 30 patients enrolled in this study, four did not complete the investigational protocol. The protocol was not completed in one patient who developed incessant ventricular tachycardia during defibrillator implantation, in two patients in whom the implantation procedure was prolonged due to technical difficulties which precluded additional defibrillation energy requirement testing, and in one patient who was inadvertently tested with an incorrect waveform. These four patients were similar to the remaining 26 patients who completed the defibrillation energy requirement testing in age, gender, ejection fraction, type of heart disease, or clinical presentation.

Implantation technique of defibrillation systems

All patients came to the operating room in a post-absorptive state. All antiarrhythmic drug therapy was stopped at least five half lives prior to device implantation, with the exception of 11 patients in whom amiodarone therapy had been ineffective. General anesthesia was induced with fentanyl or its derivatives and the patients were paralyzed with vecuronium bromide. Maintenance anesthesia was achieved with inhalational agents: nitrous oxide, halothane, isoflurane, or ethrane, in combination with intravenous fentanyl.

A transvenous lead with two coils (Endotak models 0074, 0075, and 0115, Cardiac Pacemakers Inc., St. Paul, MN) was implanted in each patient via the left subclavian vein. The lead is tined with a distal coil of 379 mm^2 and a proximal coil of 617 mm^2. The distal coil is 1.2 cm proximal from the end of the lead and is separated by a distance of 11.5 cm from the proximal coil. The distal coil was positioned in the right ventricular apex with the aid of fluoroscopy, which resulted in the proximal coil being positioned in the right atrium or at the right atrium superior vena cava border. A 50 cm^3 titanium generator shell was positioned subcutaneously in an infraclavicular prepectoral pocket.

Defibrillation energy requirement testing

Thirty patients undergoing defibrillator implantation were enrolled in this study after written informed consent was obtained under a protocol approved by the Committee for Human Research at the University of Michigan. The two-electrode system used a biphasic defibrillation pulse from a 125 uF capacitor, delivered between the proximal and distal coils of the transvenous lead. The biphasic waveform had a first phase tilt of 60% and a second phase tilt of 50%, and the leading-edge voltage of the second phase was equal to the trailing-edge voltage of the first phase. The three-electrode system used an identical biphasic waveform which was delivered from a 90 uF capacitor. In this defibrillation system, the distal coil served as one electrode, and the proximal coil and the 50 cm^3 titanium shell functioned together as the second electrode.

The defibrillation energy requirement was determined for the two-electrode system and for the three-electrode system in random order. Ventricular fibrillation was induced using one to three seconds of alternating current. Using an external defibrillator, the appropriate shock was delivered 10 seconds after the initiation of ventricular fibrillation. A step-down protocol was utilized to determine the defibrillation energy requirement. The delivered energy was given in the following order until the shock failed to convert ventricular fibrillation to sinus rhythm: 20, 15, 10, 8, 5, and 3 J. The defibrillation energy requirement was defined as the lowest energy that converted ventricular fibrillation to the normal rhythm. When defibrillation was successful at 3 J, the defibrillation energy requirement was defined as 3 J. At least five minutes were allowed to elapse between each induction of ventricular fibrillation. The amount of delivered energy, peak voltage, peak current, system impedance and waveform duration for each defibrillation was measured and recorded from the external defibrillator. Only the 26 patients that completed defibrillation energy requirement testing with both defibrillation systems were included in the analysis.

Statistical analysis

Continuous variables are expressed as the mean ± 1 SD. Paired and unpaired tests were used as appropriate. A chi square analysis was used to compare nominal variables. A relationship between continuous variables was assessed using linear regression analysis. Probability values less than 0.05 was considered statistically significant.

Results

The defibrillation energy requirement was 10.8±5.5 J for the two-electrode system and was 8.9±6.7 J for the three-electrode system ($p < 0.05$; Figure 1). However, the leading edge voltages were not significantly different (361±103 V vs. 397±123 V, $p = 0.07$). The defibrillation resistance (49.0±9.0 ohms) and the pulse duration (14.1±1.8 ms) were greater for the two-electrode system as opposed to the three-electrode system (41.4±7.3 ohms, $p < 0.001$; 7.8±1.1 ms, $p < 0.001$, respectively). The current for the two-electrode system was lower than the current for the three-electrode system (7.7±2.6 A, vs. 10.1±3.7 A, $p < 0.001$). A defibrillation energy requirement less than or equal to 5 J was achieved in 4 patients with the two-electrode system

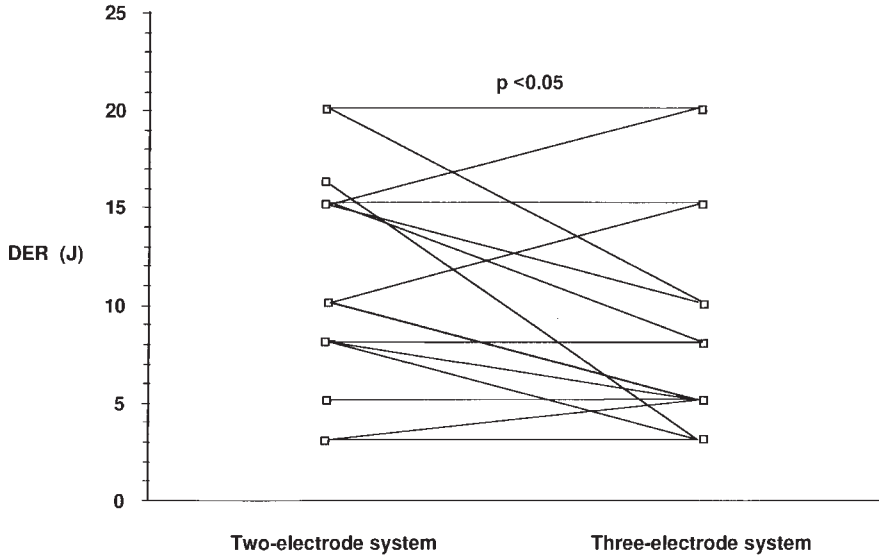

Fig. 1. *This figure shows individual defibrillation energy requirement data for the two-electrode system (left) and the three-electrode system (right). Abbreviations: DER = defibrillation energy requirement, J = Joules.*

and in 13 patients with the three-electrode system ($p < 0.001$).

There was no significant relationship between the defibrillation energy requirement, leading edge voltage, current, or resistance and with patients characteristics including age, gender, type of heart disease, mode of presentation, or recent use of amiodarone.

Discussion

Major findings

This study demonstrates that a defibrillation system which utilizes a short-duration biphasic waveform from a 90 uF capacitor and which incorporates the implantable defibrillator generator as a third electrode decreases the defibrillation energy requirement by approximately 20% compared to a two-electrode transvenous lead system used in conjunction with a 125 uF capacitor. Additionally, the likelihood of achieving a defibrillation energy requirement of 5 J or less is significantly greater with the three-electrode defibrillation system. This decrease in defibrillation energy requirement is associated with a decrease in defibrillation resistance and waveform duration, while the current increases and the leading edge voltage does not change significantly.

Low defibrillation energy requirements

The 20% reduction in the defibrillation energy requirement with the 3-electrode defibrillation system translates into approximately a 2 J improvement in the defibrillation energy requirement. This may appear to be a small and insignificant improvement relative to previous improvements. Early attempts at implantation of non-thoracotomy defibrillation systems failed in up to 30% of patients because of high defibrillation energy requirements [5–7]. The use of biphasic waveforms lowered defibrillation energy requirement, which improved implantation success, and also eliminated the routine need for additional electrodes [8–10]. Now that a defibrillation energy requirement of 10 to 12 J is frequently obtained, further reductions of the defibrillation energy requirement obtained with modifications of the defibrillation system will likely be in the range of 10 to 25%. This represents a 1 to 2.5 J reduction of the defibrillation energy requirement, similar to that seen in the present study. Therefore, achieving a 20% reduction in defibrillation energy requirement is clinically relevant, and obtaining a defibrillation energy requirement of less than or equal to 5 J in many of the patients represents a new benchmark.

If a defibrillation energy requirement of $\leq$5 J can be achieved in most patients, as was observed in the present study, then it may be possible to safely decrease the maximum energy in a defibrillator. Traditionally, a 10 J safety margin has been considered adequate. However, previous animal experiments and a recent clinical study suggests that defibrillation at twice the defibrillation energy requirement is highly effective [11–14]. Another clinical study suggests that safety margins greater than twice the defibrillation energy requirement may be required in patients with low defibrillation energy requirements [10]. Although additional data are required to fully address this issue, a defibrillator with a maximum output of approximately 20 J may be reasonable for patients with defibrillation energy requirements less than or equal to 5 J.

Mechanisms

There were two significant differences between the two-electrode and the three-electrode defibrillation systems which were compared in the present study. The three-electrode defibrillation system included the generator shall as a shocking electrode, and utilized lower capacitance which resulted in a shorter pulse duration. These factors, either independently or in combination, can affect the energy, voltage, resistance, and current associated with the defibrillation energy requirement [1,2,8,12,15,18,19]. Because two factors were simultaneously changed, it is difficult to determine the relative contribution of each factor.

The improved defibrillation efficacy noted when the generator shell is used as a defibrillation electrode could be secondary to a more efficient defibrillation vector [8,9,15,20]. With the use of an additional electrode in the left pectoral area, a greater portion of the left ventricle is in the path of the defibrillation current. Furthermore, a third electrode decreases the defibrillation impedance by increasing the defibrillation surface area. A lower impedance generates a greater defibrillation current which may improve defibrillation efficacy.

In previous studies, a decrease in capacitance has consistently been shown to result in a significant rise in leading edge voltage and current, while having no effect on resistance. The results of the present study are consistent with these previous reports [1,2,15,18,19]. Lastly, the effect of lower capacitance on defibrillation efficacy has been variable [1,2,15,18,19]. Nonetheless, a decrease in capacitor size is advantageous because it results in a smaller defibrillator. In the present study, improved defibrillation efficacy was achieved despite a decrease in capacitance. This allows for a reduction in defibrillator size through the simultaneous benefit of improved defibrillation efficacy and smaller capacitance.

Study limitations

A limitation of this study is that a defibrillation threshold curve was not constructed. The defibrillation threshold is not an absolute number but is a statistical phenomenon which is affected by the technique used to determine it [16]. Also, only an acute defibrillation energy requirement was determined, and therefore these data may not be applicable in the chronic setting. In addition, these results may not apply to other defibrillation systems.

Clinical implications

These data are the first to demonstrate a decrease in the defibrillation energy requirement with a three-electrode defibrillation system that utilizes a transvenous lead with dual coils and a prepectoral defibrillation electrode in conjunction with a 90 uF capacitor. This three-electrode system allowed for significantly more patients to obtain a low defibrillation energy requirement, i.e., of less than or equal to 5 J. This may allow for smaller implantable defibrillators to be developed by combining lower maximum defibrillator output with smaller capacitors.

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