A Prospective Evaluation of Two Defibrillation Safety Margin Techniques in Patients with Low Defibrillation Energy Requirements

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Low-Energy Defibrillation. ***Introduction:*** **In patients undergoing defibrillator implantation, an appropriate defibrillation safety margin has been considered to be either 10 J or an energy equal to the defibrillation energy requirement. However, a previous clinical report suggested that a larger safety margin may be required in patients with a low defibrillation energy requirement. Therefore, the purpose of this prospective study was to compare the defibrillation efficacy of the two safety margin techniques in patients with a low defibrillation energy requirement.**

Methods and Results: **Sixty patients who underwent implantation of a defibrillator and who had a low defibrillation energy requirement ($\leq$ 6 J) underwent six separate inductions of ventricular fibrillation, at least 5 minutes apart. For each of the first three inductions of ventricular fibrillation, the first two shocks were equal to either the defibrillation energy requirement plus 10 J (14.6 ± 1.0 J), or to twice the defibrillation energy requirement (9.9 ± 2.3 J). The alternate technique was used for the subsequent three inductions of ventricular fibrillation. For each induction of ventricular fibrillation, the first shock success rate was 99.5% ± 4.3% for shocks using the defibrillation energy requirement plus 10 J, compared to 95.0% ± 17.2% for shocks at twice the defibrillation energy requirement ($P = 0.02$). The charge time ($P < 0.0001$) and the total duration of ventricular fibrillation ($P < 0.0001$) were each approximately 1 second longer with the defibrillation energy requirement plus 10 J technique.**

Conclusion: **This study is the first to compare prospectively the defibrillation efficacy of two defibrillation safety margins. In patients with a defibrillation energy requirement $\leq$ 6 J, a higher rate of successful defibrillation is achieved with a safety margin of 10 J than with a safety margin equal to the defibrillation energy requirement.** *(J Cardiovasc Electrophysiol, Vol. 9, pp. 41-46, January 1998)*

ventricular fibrillation, ventricular defibrillation, probability of defibrillation, implantable cardioverter defibrillator

Introduction

At the time of defibrillator implantation, a variety of techniques are used to assess defibrillation efficacy and to program defibrillation safety margins.[1-4] Although implantable defibrillators can simply be programmed to deliver the maximum available energy, there are advantages to using the lowest energy consistently associated with successful defibrillation. In current clinical practice, an appropriate defibrillation safety margin in patients undergoing defibrillator implantation has been defined either as 10 J or as an energy equal to the defibrillation energy requirement. The results of a previous clinical study suggested that a larger safety margin may be required when the defibrillation energy requirement is $\leq$ 6 J than when it is > 6 J.[5] The purpose of this prospective study was to compare the defibrillation efficacy of a safety mar-

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gin of 10 J with that of a safety margin equal to the defibrillation energy requirement in patients with a low defibrillation energy requirement.

Methods

Patient Population

The study population consisted of 60 patients undergoing evaluation of a defibrillation energy requirement. The defibrillation energy requirement was determined prior to hospital discharge after implantation of an implantable defibrillator in 32 patients, 2 months after implantation of an implantable defibrillator in 15 patients, and 1 year after a defibrillator was implanted in 13 patients. The mean age of the patients was 62 ± 13 years, and 46 were men. Thirty-three patients had coronary artery disease, 20 had idiopathic cardiomyopathy, 3 had other forms of cardiomyopathy, and 4 had no structural heart disease. The mean left ventricular ejection fraction was 0.29 ± 0.13. The presenting symptom was cardiac arrest or syncope in 32 patients and ventricular tachycardia in 28 patients. Eight patients were being treated with amiodarone, and no patient was being treated with a Class I antiarrhythmic agent.

Defibrillator System

The patients provided informed consent under a protocol approved by the Human Research Committee at the University of Michigan. All patients came to the operating room in a postabsorptive state.

An endocardial defibrillation lead with a distal electrode of 295 mm^2 and a proximal electrode of 617 mm^2, separated by a distance of 11.5 cm, was used in this study (Endotak model 125, Cardiac Pacemakers, Inc., St. Paul, MN, USA). Under fluoroscopic guidance, the defibrillation lead was positioned in the right ventricular apex via a subclavian or cephalic vein. The distal shocking coil was placed in the right ventricular apex, and the proximal shocking coil was positioned in the right atrium or at the junction of the right atrium and the superior vena cava.

Each patient in this study received a defibrillator with a truncated, fixed-tilt biphasic waveform with a first phase tilt of 60% and a second phase tilt of 50%. The generator functioned as a shocking electrode in 46 patients. Only one patient had a subcutaneous shocking electrode, and in this patient the generator did not function as a defibrillation electrode.

During the implantation procedure, a step-down defibrillation protocol was utilized to determine the defibrillation energy requirement. The defibrillation energy requirement was defined as the lowest energy that successfully converted ventricular fibrillation to sinus rhythm. A defibrillation energy requirement considered adequate for device implantation was at least 10 J less than the maximum output of the defibrillator. Shock energies of 20, 15, 10, 5, 3, and 1.0 J were delivered until ventricular fibrillation failed to convert to sinus rhythm. The shocks were delivered directly from the implantable defibrillator. Ventricular fibrillation was induced by ventricular pacing with a 15-V pulse with a duration of 1.1 msec delivered every 30 msec for 1 to 3 seconds. Shocks were delivered after ventricular fibrillation was sensed by the device. At least 5 minutes were allowed to elapse between each induction of ventricular fibrillation.

Study Protocol

At the time of the study protocol, the patients were brought to the electrophysiology laboratory in a postabsorptive state. All inductions and conversions of ventricular fibrillation were performed using the implanted defibrillator. At least 5 minutes were allowed to elapse between each induction of ventricular fibrillation. The delivered energies were 20, 15, 10, 6, 5, 4, 3, 2, and 1 J. The shock energy selected for the first defibrillation was the energy equal to the defibrillation energy requirement at the time of device implantation. The step-down defibrillation energy requirement was then determined using the decrements described above. The defibrillation energy requirement was defined as the lowest energy successful at converting ventricular fibrillation to sinus rhythm. If the defibrillation energy requirement was 6 J or less, the study protocol was performed. Twenty-six percent of the patients who underwent a defibrillator evaluation with a determination of the defibrillation energy requirement had a defibrillation energy requirement that allowed participation in the study protocol.

The study protocol required six inductions of ventricular fibrillation. The patients were randomly assigned to 1 of 2 safety margins for the first three inductions of ventricular fibrillation. The alternate technique was used for the subsequent three ventricular fibrillation inductions. One technique was designed to test the efficacy of a 10-J safety margin, and the shock energy was determined by

adding 10 J to the defibrillation energy requirement. A 10-J safety margin in patients with low defibrillation energy requirements will be associated with shock energies that are at least 2.5 times the defibrillation energy requirement. A safety margin equal to the defibrillation energy requirement was the second technique. The shock energy in this technique was determined by doubling the defibrillation energy requirement. The programmed shock energy for each of the first two shocks for each induction of ventricular fibrillation was either the defibrillation energy requirement plus 10 J, or the energy equal to twice the defibrillation energy requirement. At least 5 minutes were allowed to elapse between each induction of ventricular fibrillation. The success of each shock was noted. The total duration of ventricular fibrillation, the defibrillator charge time, and the shocking impedance were recorded for each induction of ventricular fibrillation.

Statistical Analysis

Continuous variables are expressed as mean ± 1 SD and were compared using a paired or unpaired *t*-test, as appropriate. Multiple continuous variables were compared by ANOVA, and nominal variables were compared by Chi-square analysis. A probability value less than 0.05 was considered statistically significant.

Results

First Shock Defibrillation Efficacy

The mean defibrillation energy requirement was 5.0 ± 1.1 J in the entire study population of 60 patients. The programmed energy for each of the first two shocks was 14.6 ± 1.0 J in the 10-J safety margin group. This was equivalent to a multiple of 3.1 ± 0.8 times the defibrillation energy requirement (range 2.5 to 6.0). When using a safety margin equal to the defibrillation energy requirement, the mean tested energy was 9.9 ± 2.3 J.

The overall first shock success rate with the defibrillator programmed to the defibrillation energy requirement plus 10 J was 99.5% ± 4.3%, compared to 95.0% ± 17.2% for a first shock programmed to twice the defibrillation energy requirement (P = 0.02). There was only one failed first shock defibrillation attempt with a safety margin of 10 J, whereas nine failed attempts were noted in six patients in whom the safety margin was equal to the defibrillation energy requirement (Table 1).

First and Second Shock Defibrillation Efficacy

The probability that an episode of ventricular fibrillation would be successfully defibrillated with either the first or the second shock was not significantly different between the defibrillation energy requirement plus 10 J (100% ± 0%) and the defibrillation energy requirement × 2 (98.8% ± 6.0%; P = 0.2) groups. There were two patients in whom the second shock with a safety margin of twice the defibrillation energy requirement was not effective (Table 1).

Failed Defibrillation Attempts

The defibrillation energy requirement in patients who had at least one failed defibrillation attempt was 4.5 ± 1.9 J, and was 5.0 ± 1.2 J in patients with 100% successful defibrillation (P = 0.3). The likelihood of a failed shock did not cor-

TABLE 1

Pt. No.	DER (J)	Efficacy of DER + 10 J Success		Efficacy of DER × 2 Success	
		First Shock	Second Shock	First Shock	Second Shock
1	5	3/3	—	2/3	1/1*
2	2	3/3	—	2/3	1/1
3	5	3/3	—	2/3	1/1
4	4	3/3	—	2/3	0/1
5	6	2/3	1/1	0/3	3/3
6	5	3/3	—	1/3	1/2

DER = defibrillation energy requirement; DER + 10 J Success = successful defibrillations with defibrillation energy requirement plus 10 J shocks; DER × 2 Success = successful defibrillations with an energy of twice the defibrillation energy requirement.

*Second shock successful, but shock energy inadvertently programmed to 27 J instead of 10 J.

Note: In each instance, the numerator represents the number of successful defibrillations, and the denominator represents the number of defibrillation attempts.

relate with age (P = 0.3), gender (P = 0.3), ejection fraction (P = 0.9), type of structural heart disease (P = 0.7), presentation with cardiac arrest (P = 0.3), concurrent therapy with amiodarone (P = 0.6), the use of a defibrillator can as a shocking electrode (P = 0.1), or the defibrillation energy requirement determined during defibrillator implantation (P = 0.3).

Charge Times and Duration of Ventricular Fibrillation

The charge time (4.2 ± 0.5 sec) and the total duration of ventricular fibrillation (8.6 ± 1.0 sec) associated with a 10-J safety margin were significantly longer than the charge time (2.9 ± 0.8 sec, $P < 0.0001$) and the total duration of ventricular fibrillation (7.7 ± 1.7 sec, P = 0.0002) associated with a safety margin equal to the defibrillation energy requirement. The total duration of ventricular fibrillation before a successful first shock was 8.6 ± 1.0 seconds when the 10-J safety margin technique was utilized, compared to 7.3 ± 1.0 seconds ($P < 0.0001$) when a safety margin equal to the defibrillation energy requirement was used. The shock impedance was similar for each of the two groups (42.2 ± 8.2 Ω vs 42.5 ± 8.3 Ω, P = 0.2).

Discussion

Major Findings

This study is the first to prospectively compare the efficacy of two defibrillation safety margins in patients with a defibrillation energy requirement ≤ 6 J. The results demonstrate that a higher rate of successful defibrillation is achieved with a safety margin of 10 J than with a safety margin equal to the defibrillation energy requirement. The higher probability of successful defibrillation with a 10-J safety margin is associated with an approximately 1-second longer duration of ventricular fibrillation. If the defibrillation energy had been the maximum available energy, i.e., 27 to 29 J, then the charge time and the total duration of ventricular fibrillation would have been 3 to 4 seconds longer. Currently, approximately 25% of patients have defibrillation energy requirements ≤ 6 J. Hence, these observations are of clinical importance because an objective approach to programming safety margins in patients with a defibrillation energy requirement ≤ 6 J is critical as advances in defibrillation result in improved low-energy defibrillation efficacy.

Probability of Successful Defibrillation

Theoretically, uniformly successful defibrillation should occur with shock energies high on the slowly ascending portion of the probability of successful defibrillation curve.[6-10] This part of the defibrillation energy requirement curve is commonly referred to as the "plateau." The term plateau, however, is a misnomer because the probability of successful defibrillation does not achieve a constant value.[6-10] The results of animal and clinical studies suggest that the slowly ascending portion of the defibrillation energy requirement curve begins at a multiple of approximately 1.3 times the defibrillation energy requirement.[5-10] In most patients, close to 100% successful defibrillation is expected with a shock energy of twice the defibrillation energy requirement.[5] However, a shock energy greater than twice the defibrillation energy requirement may be required to achieve uniformly successful defibrillation in patients with a low defibrillation energy requirement.[5] In the present study, a 10-J safety margin in patients with a low defibrillation energy requirement was associated with shock energies of 2.5 to 6.0 times the defibrillation energy requirement. The use of shock energies equal to larger multiples of the defibrillation energy requirement likely explains the increased probability of successful defibrillation observed with the 10-J safety margin. In patients with higher defibrillation energy requirements, the probability of successful defibrillation with a 10-J safety margin will likely decrease according to the multiple of the defibrillation energy requirement.[5,9,10]

Previous Studies

A number of animal studies and a single human study have addressed the issue of defibrillation energy requirement curves and safety margins.[5-10] In humans, a step-down defibrillation energy requirement identifies the energy associated with 70% probability of successful defibrillation.[5] The results of previous experimental and clinical trials suggest that essentially uniformly successful defibrillation is achieved with an energy of twice the defibrillation energy requirement, although the defibrillation energy requirement curve for an animal or a patient with a low defibrillation energy requirement is narrower and has a greater slope than for an animal or a patient with a higher defibrillation energy requirement.[5,9,10] Therefore, doubling a low defibrillation energy requirement that is slightly underestimated could result in a significantly reduced probability of successful defi-

brillation at that shock energy. This is probably the explanation for why patients with low defibrillation energy requirements occasionally require a larger defibrillation safety margin than patients with higher defibrillation energy requirements.

The data that support the use of a 10-J safety margin are limited. In patients at high risk for lethal ventricular arrhythmias, implantable defibrillator therapy has been shown to reduce the risk of sudden cardiac death if an empiric safety margin of 10 J is achieved.[11-15] Neither clinical nor experimental studies have directly addressed the issue of absolute energy margins; however, the probability of successful defibrillation can be estimated based on a multiple of the defibrillation energy requirement. Assuming a defibrillation energy requirement $\leq$ 25 J, the conventional 10-J safety margin provides a safety margin energy equal to 0.4 times the defibrillation energy requirement with a 35-J output defibrillator, and in humans is associated with a high probability of successful defibrillation.[5] The risk of sudden death and total mortality is higher in patients in whom a 10-J safety margin, or a shock energy less than 1.2 times the defibrillation energy requirement, cannot be achieved.[16,17] This implies that shock energies of a multiple greater than this are required for appropriate clinical efficacy.[16,17]

Limitations

A limitation of this study is that the data were obtained using the same endocardial lead and biphasic waveform. Therefore, these data may not be applicable to defibrillation using other lead systems and waveforms.

Clinical Implications

A rational approach to defibrillator programming in patients with a low defibrillation energy requirement is to program the first shock energy equal to the defibrillation energy requirement plus 10 J. Confirmation of defibrillation efficacy is probably not required with a 10-J safety margin because of the probability of nearly universally successful defibrillation observed with this safety margin technique in patients with low defibrillation energy requirements. Alternatively, one could program the device to an energy equal to twice the defibrillation energy requirement; however, with this lower safety margin technique it may be important to confirm defibrillation efficacy. Programming the shock energy to the maximum available energy irrespective of the defibrillation energy requirement results in several additional seconds of ventricular fibrillation and is probably not necessary. Using the lowest effective defibrillation safety margin will allow therapy to be delivered more quickly, may prevent syncope, may prolong device longevity, and may be hemodynamically beneficial for patients with a biphasic defibrillator.[18-23]

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