Internal cardiac defibrillation in man: pronounced improvement with sequential pulse delivery to two different lead orientations

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ABSTRACT Wider applicability of an implantable automatic defibrillator depends on achieving internal cardiac defibrillation consistently with the lowest possible energy. In animal studies, we have found that the cardia defibrillation threshold could be reduced when sequential shocks separated in time and spacially arranged were delivered to the heart. We compared internal cardiac defibrillation using a single pulse shock delivered through an intravascular catheter with this new method for internal cardiac defibrillation in patients undergoing cardiac surgery for the correction of arrhythmias. For the single pulse shock and the first pulse of the sequential pulse shock, current was passed through an intravascular catheter with the catheter cathode at the apex of the right ventricle and the anode at the superior vena cava–atrial junction region. The second pulse of the sequential pulse countershock was delivered between the catheter cathode in the right ventricular apex and an oval plaque electrode secured on the laterobasal left ventricular epicardium as anode. With the single pulse alone for shock delivery, 12 patients could be defibrillated with an average of 20.1 ± 16.8 J, with a corresponding leading-edge peak voltage and current of 836 ± 319 V and 9.4 ± 4.5 A, respectively. However, two of the patients could not be defibrillated with energies below 50 J. With the sequential pulse shock delivery, a significant reduction in all values were recorded. Mean total energy for defibrillation averaged 7.7 ± 6.0 J. Leading-edge peak voltage and current from the catheter averaged 430 ± 148 V and 5.0 ± 2.8 A, respectively. In addition, all patients could be defibrillated with less than 23 J, and nine of the 12 patients (75%) could be defibrillated with less than 7.5 J. In contrast, only two of these same 12 patients (17%) could be defibrillated with less than 7.5 J using the single pulse alone (binomial exact test, p = .0156). We conclude that sequential pulse defibrillation provides a pronounced reduction in the total energy necessary for defibrillation compared with the single pulse delivered through a catheter alone. Furthermore, the sequential pulse system provides a reduction in the current density at the electrodes, potentially reducing myocardial damage. This system may be important in the design of a totally implantable automatic defibrillator.

Methods

Patients. Eighteen patients were volunteers, referred for surgical treatment of arrhythmias associated with the Wolff-Parkinson-White syndrome (16 total, 14 men and 2 women), ectopic atrial tachycardia (one woman), and ventricular tachycardia–ventricular fibrillation (VT-VF) caused by a ventricular aneurysm (one man) (table 1). Written and verbal informed consent were obtained from all patients in accordance with the regulations of the Health Sciences Standing Committee on Human Research of the University of Western Ontario. The mechanism for arrhythmia was established during an electrophysiologic study 24 to 48 hr before surgery. At the completion of the electrophysiologic study, the defibrillation catheter (Medtronic 6880) was substituted in place of one of the routinely used electrode catheters introduced percutaneously through the left subclavian vein. All patients but the man with VT-VF had normal left ventricular function with normal heart size. The patient with VT-VF had cardiomegaly with an ejection fraction of 33%.

Operative procedure. Patients were prepared for surgery, and the heart was exposed through a median sternotomy. Myocardial mapping verified the site of the accessory pathway or origin of VT. All patients underwent cannulation for institution of cardiopulmonary bypass. A silver-platinum plaque electrode (Medtronic TX-7 or TX-7a, surface area 2.5 and 5.0 cm², re-

TABLE 1
Characteristics of patient population

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Sex</th>
<th>Age (yr)</th>
<th>Arhythmia diagnosis</th>
<th>No. of induced VF (CD or SP)</th>
<th>Circulatory arrest (sec)</th>
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<td></td>
<td>18-63</td>
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<td>39</td>
<td>19</td>
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Total duration of circulatory arrest: Mean 31.4, 2.2 1 83.

CD = single pulse through the catheter alone; SP = sequential pulse; WPW = Wolff-Parkinson-White syndrome; EAT = ectopic atrial tachycardia.

aTechnical problems with lead connections.

bCatheter dislodged intraoperatively.

cCatheter dislodged preoperatively. All statistical analyses are based on the paired data from the remaining 12 patients.

FIGURE 1. Artist’s conception of the location of the 6880 defibrillation catheter and TX-7 plaque electrodes in situ. The pair of electrodes on the catheter (A) were positioned at the atrial–superior vena caval junction and were the anode for the single shock and the first pulse of the sequential shock. The pair of electrodes at the tip of the catheter (B) was positioned in the right ventricular apex and was combined as the common cathode for the single shock and the first and second pulses of the sequential shock. The separate electrodes of B were also used to pace the ventricle with bipolar electrical stimuli. The mesh plaque electrode (C) on the epicardium of the laterobasal left ventricular free wall was the anode for the second pulse of the sequential shock.

Description of the electrode system. Current for the single pulse shock and the first pulse of the sequential shock was delivered through the catheter that had been implanted preoperatively during the electrophysiologic study. The electrode catheter (Medtronic 6880, 10F) has four electrode sleeves, each with a surface area of 1.25 cm², insulated with polyurethane (figure 1). The distal electrodes were positioned in the right ventricular apex and were the common cathode for all shocks. The proximal electrode pair was separated by 150 mm from the distal pair and rested at the atrial–superior vena caval junction. This was the anode for the single pulse shock and for the first pulse of the sequential pulse shock. The epicardial plaque electrode on the left ventricular free wall was the anode for the second pulse of the sequential pulse shock.

Exteriorized leads from the catheter and plaque electrodes were interfaced to two custom-designed defibrillators. The output from the defibrillators delivered trapezoidal pulses of preset incremental energies at 5 m sec total duration. Relay contact output of the defibrillators was connected in parallel to a VR12 recorder (Honeywell, Inc.) and a Medtronic 5325 stimulator. The stimulator was used to determine pacing threshold. Electrocardiographic leads were monitored to ensure that pacing QRS morphology was consistent with electrode placement in the right ventricular apex.
**Fibrillation and defibrillation.** An episode of VF was induced by passing a low-energy alternating current directly to the epicardium of the heart through the open chest. Defibrillation was attempted a minimum of 15 sec after the onset of fibrillation. The initial defibrillator setting was between 2.4 to 9.5 J (table 2). Higher initial settings were used for catheter defibrillation to reduce the number of shocks delivered. Energy was increased incrementally with each shock until defibrillation was achieved or the maximum energy setting was not successful. In the latter case, a rescue shock was applied with cardiac paddles. Increments for energy were 2.4, 3.3, 4.2, 6.5, 7.9, 9.5, 11.4, 13.6, 16.5, 19.0, 23.7, 30.7, 41.3, 58.7, and 70.9 J, calculated from discharge into a 110 ohm load. These correspond to stored energies of 2.5 to 75 J with increments of 1.25 J from 2.5 to 5 J, 2.5 J from 5 to 20 J, 5 J from 20 to 35 J, then 10 J and 15 J to 75 J. Smaller increments at the lower energy levels were accepted.

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Ei (J)</th>
<th>Method of energy delivery</th>
<th>Stored voltage increments of catheter (V)</th>
<th>Ef (J)</th>
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<tr>
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<td>SP</td>
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Ei = initial stored energy; CD = single pulse catheter shock; SP = sequential pulse shock; Ef = energy delivered for the successful shock of the episode.

*The “successful energy” used for calculation when two defibrillation episodes had the same lead orientation.*

For patient 8 it was noted that the patch electrode had been inadvertently sutured with the insulation side toward the heart during the first fibrillation episode with the sequential pulse. Therefore a second episode was allowed, with the electrode repositioned.

Patient 14 had an additional episode permitted after the experiment while on cardiopulmonary bypass.
as short recycle times were required. However, if defibrillation was not accomplished at lower settings, larger increments at higher settings were mandatory to achieve defibrillation while restricting the time of circulatory arrest, which could compromise patient safety. Average recycle charge time was 5 sec. Cardiopulmonary bypass was available on standby in the event of difficulty after achieving defibrillation. This precaution was for the safety of the patient. Patients were randomized as to whether the first fibrillation episode was defibrillated with the single pulse or the sequential pulse shock. A minimum of 10 min separated fibrillation episodes. The experimental protocol normally permitted only one fibrillation episode for each lead orientation. However, if the first shock of an episode defibrillated the arrhythmia, then an additional episode was permitted with the same defibrillation lead orientation, starting 1 to 3 J below the previous successful energy setting. A maximum of three fibrillation episodes were permitted in any patient. The duration of circulatory arrest for each episode was measured between the last normal systolic pressure tracing at the beginning of the onset of alternating current application and the return of normal pressure waves. The duration of circulatory arrest for a single episode did not exceed 70 sec and the total time for all the fibrillation episodes in a single patient did not exceed 120 sec (table 1). Defibrillation pulses were trapezoidal truncated wave forms of approximately 5 msec total duration for both the single and sequential pulse shocks. The two pulses of the sequential pulse shock were separated by 0.2 msec.

**Threshold energy determination.** Output lines from the defibrillators were connected to a Tektronix 5113 storage oscilloscope. Recorded discharge voltage and current waves from both defibrillators were photographed. For each lead orientation, defibrillation threshold was defined as the lowest energy that successfully defibrillated the heart. Energy was calculated from the following equation:

\[ J = d(E_o-I_o - E_f-I_f)/\ln(E_o-I_o/E_f-I_f) \]

where \( J \) = delivered energy in joules, \( d \) = pulse duration in seconds, \( E_o \) = leading-edge peak voltage, \( I_o \) = leading-edge peak current, \( E_f \) = final voltage at truncated cutoff, \( I_f \) = final current at truncated cutoff, and \( \ln \) = the natural logarithm to base e.

**Statistical analysis.** Analysis of the differences in the total energy, leading-edge peak voltages, and currents for each method was made by two-way analysis of variance (treatments by subjects design). Analysis of the values greater than or less than 7.5 J was done with binomial expansion and the exact test. Data are presented as the mean ± SD. A probability of .05 was considered significant.

**Results**

Six patients were not included in the statistical analysis because paired data were unavailable, two were excluded because of technical problems, three because of intraoperative manipulation of the heart resulting in the displacement of the catheter, and one because of preoperative displacement. Data from these patients was consistent with that of the paired data. With the catheter alone for delivery of shocks, the remaining 12 patients could be defibrillated with an average of 20.1 ± 16.8 J (figure 2), with a corresponding leading-edge peak voltage and current of 836 ± 319 V and 9.4 ± 4.5 A, respectively.

With sequential pulse shock delivery, a significant reduction in all values was recorded. Total energy for defibrillation averaged 7.7 ± 6.0 J. Leading-edge peak voltage and current from the catheter averaged 430 ± 148 V and 5.0 ± 2.8 A, respectively. Each of these values was significantly lower than the corresponding value for the single pulse shock (\( F = 6.48, 21.32, \) and 18.69 at 1 and 11 degrees of freedom for energy, leading-edge peak voltage, and current, respectively). In addition, all patients could be defibrillated with less than 23 J, and nine of the 12 patients (75%) could be defibrillated with less than 7.5 J. In contrast, only two of these same 12 patients (17%) could be defibrillated with less than 7.5 J with the catheter alone (\( p = .0156 \)). In addition, a patient who required more than 50 J with the single pulse for defibrillation was successfully defibrillated with 5.8 J when energy was delivered by the sequential pulse shock.

The patient with a ventricular aneurysm required 10.5 J with the sequential pulse shock and 20.3 J with the single pulse shock. Since completion of the study, two additional patients undergoing surgery for the correction of infarction-induced VT have also been defibrillated with less than 10 J with the sequential pulse shock.

Immediately after a successful single pulse shock, pacing threshold from the distal pair of electrodes on the catheter increased twofold to fourfold. However, two of the patients could not be defibrillated with energies below 50 J and pacing threshold was not measured. Postshock pacing threshold also increased with sequential pulse delivery but rarely exceeded a twofold increase.

The relative percent success curves for the energy delivered are illustrated in figure 3. It was noted that successful defibrillation could be achieved with immediate return to sinus rhythm (arbitrarily called a “type I” break), or after 4 to 6 ventricular QRS complexes (arbitrarily called a “type II” break). Both patterns were observed after both the single pulse shock and the sequential pulse shock. Type II breaks occurred in four of 19 single pulse episodes and in nine of 20 sequential pulse episodes. However, in five patients type II breaks occurred only with sequential pulse shocks, whereas there were no patients in which it occurred only with single pulse shocks. This result was statistically different (\( p = .031 \)).

**Discussion**

These results demonstrated that defibrillation in man could be consistently achieved with less than 23 J and with a mean of 7.7 J with the sequential pulse shocks.
shock. This was a pronounced improvement over the energy necessary for defibrillation in the same patients with a single pulse shock delivered through the catheter alone. These results are consistent with our previous studies on animals, in which we found an improvement of a similar magnitude with sequential pulse energy delivery compared with a single pulse shock.5–8

Direct cardiac shock with single pulse energy delivery with either an intravascular catheter5, 10, 11 or an epicardial patch system4,4 has been used successfully in man at energies comparable to those for single pulse shock in this study. However, the methods differ for determining successful energy. Energies greater than 25 J require larger batteries and greater capacitor storage for an implantable device. In addition, such energy delivery has been shown to be associated with inability to sense and pace from the defibrillating catheter when this is part of the energy delivery system and, more importantly, it is painful.10–12 It is therefore highly relevant that the energy requirements in this study never exceeded 23 J for the sequential pulse shock and the mean for the 12 patients was 7.7 J. Also, it is noteworthy that 80% of the patients could be defibrillated with less than 10 J with the sequential pulse system, whereas over 30 J was necessary to achieve similar success with the single pulse shock. This narrow distribution of energy with the sequential pulse system is important as an index of interpatient variability for the design of an implantable automatic device. It is anticipated that any defibrillator system will encounter some patients who might require much more energy for defibrillation than the normal. Such a skewed distribution has been reported for defibrillation of patients at the time of surgery with direct cardiac single pulse shock delivery through paddles.13, 14 However, it is important to know how much additional energy a device would have to generate to ensure 100% success. In the present study, that upper maximum appeared to be 23 J with the sequential pulse and was over 60 J with the single pulse shock.

Since Wiggers15 first proposed in 1940 that multiple shocks might be more effective than a single shock in arresting defibrillation, there have been conflicting re-

FIGURE 2. Group means and SDs for the variables of defibrillation threshold for the 12 patients. A, Energy for the single shock (catheter) and sequential pulse shock (sequential pulse) total energy (total), that of the first pulse alone (6880), and the second pulse (TX-7). *Energy totals differ statistically (p < .05). **Energy for a particular lead orientation is reduced further yet (p < .01). B and C, Significant reductions in the peak voltage and current, respectively, were achieved for each pathway (p < .01).
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FIGURE 3. Cumulative percent successful defibrillation with single pulse shocks (triangles) and sequential pulse shocks (circles). It is noteworthy that 80% of the patients could be defibrillated with less than 10 J with the sequential pulse shock, whereas over 30 J was required with the single pulse shock to achieve 80% success.

tip to a left ventricular epicardial electrode was not found to improve defibrillation compared with the catheter alone. 8

Finally, the dual lead orientation of the present system would be expected to increase the volume of myocardium receiving higher current density and conversely reduce the volume of myocardium with lower current density. 6–8 This increase in effective distribution of current would be expected to enhance the ability of a shock to depolarize a sufficient volume of myocardium to extinguish fibrillation. Evidence that not all the myocardium may have been rendered refractory comes from the finding of the "type II" break, i.e., transient VT before normal sinus rhythm. For these shocks, some region of myocardium may not have been rendered refractory after the shock, but the mass of this tissue was clearly insufficient to sustain VT. This pattern (type II) was not restricted to the sequential pulse shock delivery but was seen in single pulse shocks in the present and previous 24 studies. We believe that it is likely the combination of at least these three factors that renders the sequential pulse advantageous over the single pulse.

For any implantable automatic defibrillation device, two other factors are important: (1) myocardial damage and (2) perception of pain. It is reasonable to expect a relationship between the amount of energy delivered at any electrode and both of the latter. It is important to realize that not only was total energy reduced with the sequential pulse shock but that two separate pulses were delivered, each comprising approximately 50% of the total energy. Therefore, even if the total energy was equal to that for the single pulse, the leading edge peak voltages and currents at any electrode would still be 30% lower than that needed for the single pulse shock. (It should be remembered that energy is the product of voltage times current. A reduction of each factor by 30%, to 0.7, thus reduces the resultant product to 0.5, i.e., 0.7 × 0.7 = 0.5.) Thus the damage and pain associated with damage caused by current density would be reduced further.

Mirowski and colleagues 25, 26 pioneered the concept of an automatic implantable defibrillator, initially with a right ventricular chamber lead coupled to a subcutaneous plate. Defibrillation has also been achieved with a transvenous catheter system. 10, 11, 19, 24, 28 In the latter, some dislodging of leads was evident, 27 although this was not a consistent finding. 10 Catheter displacement in the present study was a minor problem, primarily caused by the extensive intraoperative manipulation of the heart during cannulation for bypass preparation and elevation of the heart to allow visual localization of the

ports in the literature regarding such advantages. 16–21

What then are the reasons for the pronounced reductions in energy obtained in the present study? We believe that there are at least three critical determinants of energy necessary for defibrillation that could explain these improvements: (1) pulse separation time, (2) the use of energy delivery by intracavitary to epicardial patch, and (3) spacial orientation of the lead.

Previous studies with double or multiple pulses delivered over a single pathway examined intervals over the range of 10 to 200 msec. 16–18 We have found in animal preparations that sequential pulse shock results in a reduction in defibrillation threshold, 5, 7 which is dependent on separation time. The lowest energy was found with separations of 0.2 and 1.0 msec. 7, 8, 22 A separation of 0.2 msec was used in the present study.

Because muscle has a higher impedance than blood or body fluid, 23 electrode systems that use electrodes contained exclusively in the vascular space or on the epicardium could be less effective due to the shunting of some current preferentially away from the higher-impedance muscle. Thus the energy necessary for defibrillation would be increased. The second pulse of the sequential pulse shock had to traverse muscle because the cathode was in the right ventricular chamber and the anode was on the left ventricular epicardium, resulting in a potential reduction in energy necessary for defibrillation. This reduction in energy is not simply due to a lead orientation that uses the left ventricular free wall, since a single pulse passed from the catheter
hand-held roving electrode on the posterior epicardium during electrophysiologic assessment. The use of tines on the distal tip of the intracavitary electrode in implantable devices alleviates this problem.28

One potential limitation of this study is that the majority of the patients had normal ventricular myocardium, while the potential candidates for an implantable defibrillator would usually have diseased myocardium. From our previous experience with single pulse defibrillation10 and the one patient in this study and two in subsequent study, there does not appear to be a major effect of myopathy on the defibrillation threshold. However, further study is necessary to determine what, if any, alterations in defibrillation threshold occur in the energy necessary for defibrillation with major myopathy.

The system as described may yet be improved further: (1) In animal studies, increasing the surface area of the patch has been found to reduce defibrillation threshold.29, 30 (2) The details of the pulse may not be optimal. In this study we investigated one wave form that was selected to be similar to one of the wave forms capable of being generated by an automatic internal device. (3) It may also become possible to make both lead systems intracavitary,31 thereby eliminating the requirement for a thoracotomy. (4) Although the sequential pulse shock system has shown impressive efficacy, alternative and perhaps more convenient electrode placements that use a sequential pulse delivery system may well provide further reductions in the energy necessary for defibrillation threshold.

We conclude that the sequential pulse shock provides a pronounced reduction in the total energy necessary for defibrillation compared with the single pulse shock delivered through a catheter alone. Furthermore, the sequential pulse system, by reducing the energy content of each of the pulses to approximately one-half of the total energy delivered, provides a reduction in leading-edge peak voltage and current at the electrodes for each energy shock. This in turn would be expected to reduce myocardial damage and pain. This system provides a substantial improvement over use of a single pulse shock for defibrillation and will be important for the design of a totally implantable automatic device.

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