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CARDIAC PACING

An Effective and Adaptable Transvenous Defibrillation System Using The Coronary Sinus in Humans

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With use of a coronary sinus catheter electrode, a right ventricular catheter electrode and a chest wall patch electrode system, defibrillation threshold voltage, current and energy were measured with four distinct transvenous defibrillation techniques delivered in random sequence in each of 12 survivors of cardiac arrest immediately before implantation of a standard epicardial patch defibrillation system. The four transvenous defibrillation techniques were 1) single pathway monophasic pulsing, 2) single pathway biphasic pulsing, 3) dual pathway sequential pulsing, and 4) dual pathway simultaneous pulsing. A transvenous defibrillation method was considered to be potentially useful only if the defibrillation threshold was ≤500 V (≤15 J delivered energy). The 500 V value would allow a 2:1 defibrillation safety margin for a device with a maximal output of 30 J.

No single transvenous pulsing technique was uniformly superior in efficacy. However, by choosing the best pulsing technique for each patient, it was possible to obtain an average defibrillation threshold of 410 ± 135 V leading edge voltage, 7.2 ± 2.5 A leading edge current and 11.3 ± 7.4 J delivered energy for the group of 12 patients. With the ability to vary defibrillation technique, transvenous antiarrhythmic device implantation would have been possible in 10 (83%) of the 12 patients at or below a 15 J defibrillation threshold cutoff point. In contrast, if only one transvenous defibrillation method had been used, as few as 5 and at most 8 of the 12 patients would have been candidates for a transvenous defibrillation system given a 15 J defibrillation threshold cutoff point for insertion. The ability to vary defibrillation technique and current pathways not only increased the number of patients suitable for transvenous defibrillator implantation, but also improved the delivered energy safety margin from approximately 2:1 to 3:1 in comparison with that of any one of the four methods examined.

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The need for thoracic surgery to insert an automatic defibrillator to prevent sudden cardiac death limits the scope of application for such devices. A consistently effective transvenous defibrillation system with an acceptable defibrillation margin of safety could significantly alter the role of these devices. For example, an effective transvenous defibrillation system could be implanted for prevention of sudden death in high risk patients who have yet to manifest their first episode of ventricular tachycardia or ventricular fibrillation as well as in those patients who have had such episodes.

In the light of available data, it is unlikely, however, that any particular transvenous pulsing method or electrode position will result in uniformly acceptable defibrillation capabilities for all patients who might need an implantable automatic antiarrhythmic device. Although transvenous lead systems have already been employed in humans for defibrillation (1–9), the percent of patients for whom any particular transvenous approach is suitable is still unknown. Earlier work (9) has suggested that more patients might be candidates for a transvenous defibrillator if a right ventricular catheter electrode was employed in conjunction with a coronary sinus catheter electrode instead of a chest patch electrode. However, even with this method, defibrillation was successful in only 45% of patients with <500 V or 15 J, a value presumed safe for employment of transvenous defibrillation systems because it provides at least a 2:1 energy defibrillation safety margin (10). The purpose of this inves-

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Table 1. Clinical Data for 12 Survivors of Cardiac Arrest

Patient No.	Age (yr)/Gender	Underlying Heart Disease	Clinical Arrhythmia	LVEF	Antiarrhythmic Drugs Present During Defibrillation Testing	Therapeutic Procedure
1	72/F	IDC	VF ×2	0.28	None	AICD
2	45/F	CAD, DMI, S/P MVR	VF	0.49	None	AICD
3	57/M	CAD, AMI	VF	0.18	None	CABG, AICD
4	81/F	PED	VF	0.60	None	AICD
5	52/M	CAD, DMI	VF	0.42	None	CABG, AICD
6	46/F	IDC	VF	0.33	None	AICD
7	54/F	IDC	VF	0.20	None	AICD
8	47/F	CAD, AMI	VF	0.26	None	AICD
9	67/M	CAD, AMI, IDC	VT	0.18	None	CABG, AICD
10	30/M	HCM	VF	0.85	Disopyramide	AICD
11	49/F	Apical HCM	VF	0.49	None	AICD
12	52/M	PED	VF	0.60	None	AICD
Mean ± SD	54 ± 14			0.41 ± 0.21		

AICD = automatic implantable cardioverter-defibrillator; AMI = anterior myocardial infarction; CABG = coronary artery bypass grafting; CAD = coronary artery disease; DMI = diaphragmatic myocardial infarction; EF = ejection fraction; F = female; HCM = hypertrophic cardiomyopathy; IDC = idiopathic dilated cardiomyopathy; LV = left ventricular; M = male; MVR = mitral valve replacement; PED = primary electrical disease; S/P = status post; VF = ventricular fibrillation; VT = ventricular tachycardia.

tigation, therefore, was to develop an adaptable and effective transvenous defibrillation system that would increase the safety margin of defibrillation as well as the percent of patients suitable for transvenous antiarrhythmic devices.

Methods

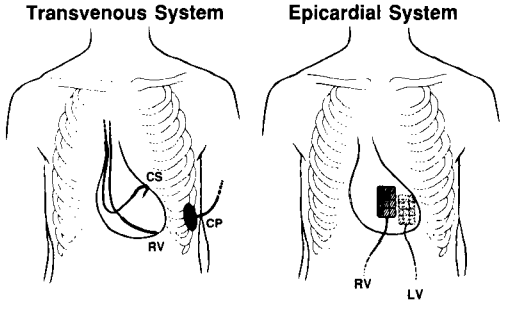
Study patients and lead systems. After giving informed consent, 12 survivors of cardiac arrest (Table 1) underwent defibrillation efficacy testing with a three lead transvenous defibrillation system (Fig. 1) immediately before receiving a standard epicardial lead system and an automatic implantable cardioverter-defibrillator. The three electrodes employed were a 6F coronary sinus (CS) catheter electrode, a 10.5F right ventricular (RV) catheter electrode and an 8 cm diameter chest patch (CP) electrode.

The right ventricular electrode (Medtronic model 10284) (Fig. 2) was inserted through the right internal jugular vein and positioned under fluoroscopic control in the right ventricular apex. An active fixation screw-in electrode ensured right ventricular lead stability during defibrillation testing. The screw-in electrode also was used as the cathode for bipolar sensing and pacing in conjunction with a more proximal anodal ring electrode. The defibrillation coil was immediately proximal to the pacing and sensing electrodes and extended 5 cm in length, typically to the tricuspid anulus.

The coronary sinus electrode (Medtronic model 10285) (Fig. 2) was 5 cm in length and positioned through the left subclavian vein into the distal coronary sinus. The coronary sinus electrode was always positioned such that the tip of the defibrillation electrode was near the left atrial appendage. The coronary sinus electrode also utilized two sensing electrodes proximal to the defibrillation coil as an aid in catheter positioning. Right and left anterior oblique fluoroscopic X-ray views of the coronary sinus electrode and right ventricular electrode were obtained in each patient to document lead location (Fig. 3).

The chest patch, an 8 cm diameter disc, was centered over the left lateral thorax in the anterior axillary line in the fifth intercostal space and simulated a subcutaneous patch electrode. Given the temporary nature of the transvenous component of the study, actual insertion of a subcutaneous patch could not be justified ethically. A cutaneous patch

Figure 1. Positions of the transvenous and epicardial defibrillation lead systems used in the study. For the transvenous system, the right ventricular (RV) catheter electrode was positioned in the right ventricular apex. The coronary sinus (CS) electrode was positioned in the lateral coronary sinus, with the tip located near the left atrial appendage. The chest patch (CP) electrode was placed at the anterior axillary line in the fifth intercostal space. For the epicardial system, two large patch electrodes were applied and positioned over the anterior right ventricle (RV) as the cathode and over the posterolateral left ventricle (LV) as the anode.



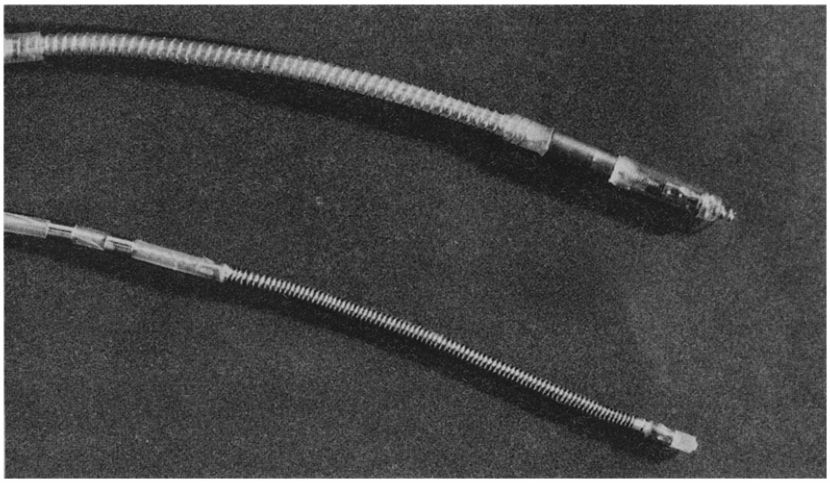


Figure 2. Photograph of the transvenous leads. The coronary sinus defibrillation electrode (**bottom**) is a 6F helical coil 5 cm in length. The right ventricular defibrillation electrode (**top**) is a 10.5F helical coil 5 cm in length. The right ventricular catheter also has a ring electrode and an active fixation screw-in electrode for pacing and sensing. The coronary sinus electrode has a pair of sensing electrodes proximal to the defibrillation coil. The coronary sinus electrogram provided by this pair of electrodes aided lead positioning.

approximates a subcutaneous patch for defibrillation testing purposes because the transdermal voltage decrease during defibrillation is insignificant (11).

Current pathways and pulsing techniques. The transvenous lead system just described enabled many current pathways and waveforms to be tested. However, because of the clinical limitations inherent in repetitive ventricular fibrillation induction and termination in humans, we limited our investigation to four alternative transvenous defibrillation methods. In addition, the methods selected were in part chosen to maintain continuity with previous work; the coronary sinus electrode was used in each of the four methods tested and its polarity was always negative (9,12). The four methods are summarized in a visual format (Fig. 4) and below in greater detail:

I. $CS_M^- \rightarrow RV^+$ = monophasic waveform, single pulse.
II. $CS_B^- \rightarrow RV^+$ = biphasic waveform, single pulse.
III. $CS_M^- \rightarrow RV^+$, CP^+ = monophasic waveform, sequential pulse.
IV. $CS_M^- \rightarrow RV^+$ and CP^+ = monophasic waveform, simultaneous pulse.

Method I ($CS_M^- \rightarrow RV^+$) utilized a 65% tilt monophasic (M), truncated, exponentially decaying waveform delivered

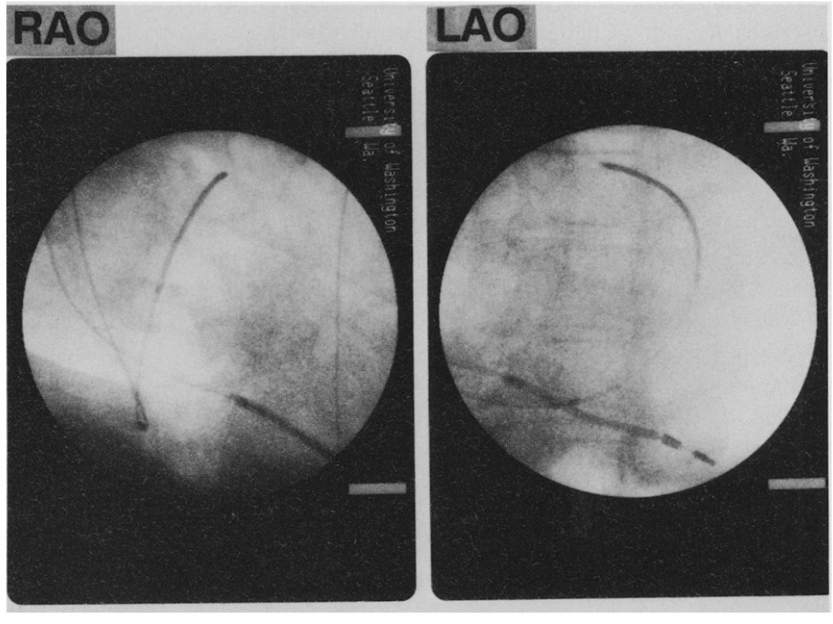


Figure 3. Right anterior oblique (RAO) and left anterior oblique (LAO) views of the right ventricular and coronary sinus electrodes in situ. The tip of the coronary sinus electrode (**upper electrode**) is positioned near the left atrial appendage. The tip of the right ventricular electrode (**lower electrode**) is in the right ventricular apex. The screw-in anchoring electrode of the right ventricular lead is visible in the left anterior oblique projection.

JACC Vol. 16, No. 4
October 1990:887-95

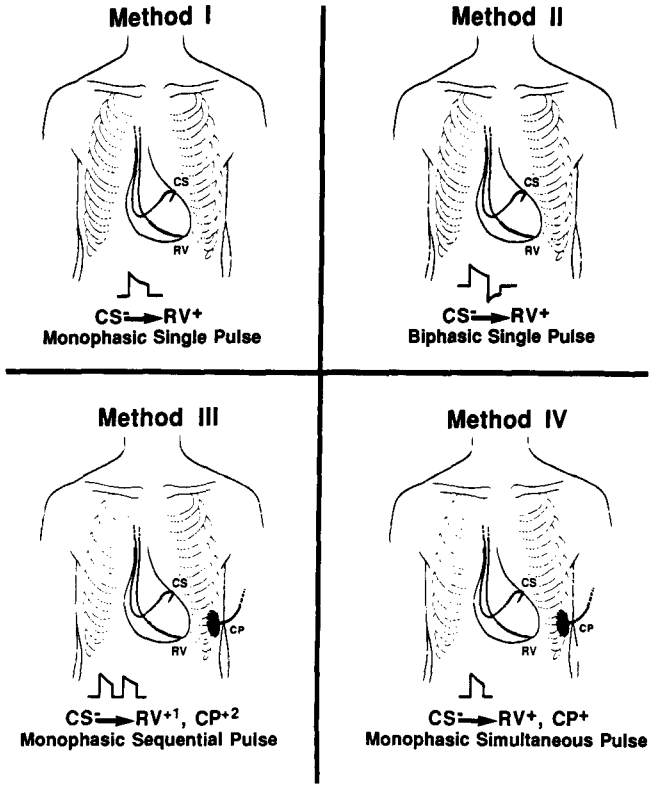


Figure 4. The four transvenous defibrillation methods used in the study. A full explanation of each pulsing technique is found in the Methods section. Abbreviations as in Figure 1.

between the coronary sinus (CS) coil electrode as the cathode and the right ventricular (RV) coil electrode as the anode (9).

Method II ($CS_B^- \rightarrow RV^+$) utilized all aspects of method I except that the waveform was biphasic (B). The nature of this biphasic waveform, an asymmetric 65% tilt pulse capable of being generated with a single capacitor, has been described in earlier studies (13) on epicardial patch-patch defibrillation. It was possible to generate such a waveform with one capacitor by inverting the trailing edge voltage of the first phase of the pulse and utilizing it as the leading edge voltage of the second phase of the pulse.

Method III ($CS_M^- \rightarrow RV^+, CP^+$) utilized two monophasic (M) 65% tilt waveforms in a sequential pulse technique in which the coronary sinus (CS) electrode served as a common cathode. The first pulse was delivered to the right ventricular (RV) electrode as the first anode, and 0.2 ms later the second pulse was delivered to the chest patch (CP) electrode as the second anode.

Method IV ($CS_M^- \rightarrow RV^+$ and CP^+) utilized the same waveform, current pathways and electrode polarity used in method III. However, in method IV, both anodes, the right ventricular (RV) and chest patch (CP) electrodes, were interconnected and a single shock was delivered simultaneously between this electrode pair and the common cathode.

The pulse waveform used for all methods, including the negative phase of the biphasic pulse, was a truncated exponentially decaying 120 μF capacitor discharge with a tilt of 65%. This waveform tilt and capacitance were chosen to keep the trial referable to the pulsing methods employed with the standard automatic implantable cardioverter-defibrillator. Total capacitance and tilt were held constant at 120 μF for each of the four methods examined in accord with previous observations (14) suggesting that capacitance as well as tilt affect defibrillation efficacy. In the case of the sequential pulse technique of method III, capacitance was maintained at 120 μF by employing a 60 μF capacitor for each pulse. For methods I, II and IV, a single 120 μF capacitor was utilized.

Defibrillation methods. To begin defibrillation efficacy testing, one of the four transvenous defibrillation methods was randomly selected to be tested first. Alternating current (60 Hz) was used to initiate ventricular fibrillation through the right ventricular bipolar pacing electrodes and defibrillation was attempted at 10 s after the onset of ventricular fibrillation (9,15). Both the voltage and current waveforms were recorded during pulsing using methods previously reported (16). Briefly, two Tektronix AM502 differential amplifiers and two Tektronix 2230 digitizing oscilloscopes in combination with an IBM-AT computer enabled on-line waveform storage and analysis for determination of resistance and integration of waveforms to measure delivered energy. The external defibrillator used for the study was a Medtronic model 2394. Because defibrillator voltage settings did not necessarily correlate with actual measured voltage values (secondary to variable voltage decreases across the internal resistance of the external defibrillator), all defibrillation threshold voltage values stated are derived from measured variables rather than defibrillator settings.

Defibrillation efficacy trials were begun with a voltage setting of 600 V. Between episodes of fibrillation and defibrillation, ≥3 min was allowed to elapse. The electrocardiographic QRS and ST-T waves, arterial pressure and pulmonary pressures were required to return to baseline values before ventricular fibrillation was reinduced. If the initial 600 V defibrillation pulse was successful, ventricular fibrillation was reinduced and defibrillation was attempted with a 500 V pulse. If the 500 V test was successful, a 400 V pulse was attempted on refibrillation. If the 400 V test was successful, subsequent decrements in leading edge voltage were made in 50 V steps. This process was repeated until the lowest amplitude pulse failed to terminate ventricular fibrillation and the patient required defibrillation with a 200 J transthoracic rescue pulse.

If defibrillation was unsuccessful at 600 V, a transthoracic rescue pulse was immediately delivered. Subsequently, on reinduction of ventricular fibrillation, defibrillation was attempted at 700 V. If this test was unsuccessful, a voltage setting of 800 V was chosen for the next episode of ventric-

Table 2. Electrical Variables at the Defibrillation Threshold Determinations

Defibrillation Method	Voltage (V)	Current (A)	Resistance (Ω)	Delivered Energy (J)
I) $CS_M^- \rightarrow RV^+$	502 ± 130 (p = 0.0017)	9.1 ± 3.0 (p = 0.0096)	57 ± 6 (p = 0.6610)	16.1 ± 8.2 (p = 0.0063)
II) $CS_B^- \rightarrow RV^+$	504 ± 155 (p = 0.0089)	9.1 ± 3.6 (p = 0.0295)	57 ± 6 (p = 0.6464)	18.6 ± 11.6 (p = 0.0188)
III) $CS_M^- \rightarrow RV^+$, CP^+	469 ± 180 (p = 0.0352)	7.2 ± 3.3 (p = 0.9760)	68 ± 12 (p = 0.0060)	14.8 ± 10.9 (p = 0.0428)
IV) $CS_M^- \rightarrow RV^+$ and CP^+	515 ± 178 (p = 0.0025)	11.0 ± 4.6 (p = 0.0012)	48 ± 7 (p = 0.0009)	18.0 ± 10.8 (p = 0.0067)
Best transvenous	410 ± 135	7.2 ± 2.5	57 ± 5	11.3 ± 7.4
Epicardial	272 ± 93 (p = 0.0013)	6.8 ± 3.1 (p = 0.6473)	43 ± 12 (p = 0.0038)	4.9 ± 3.0 (p = 0.0047)

All p values are in reference to the "best transvenous" defibrillation method. B = biphasic; CP = chest patch; CS = coronary sinus; M = monophasic; RV = right ventricle.

ular fibrillation. The value of 800 V was the maximal transvenous voltage employed. A value of 800 V was chosen as our maximal voltage setting because higher voltages may have promoted tissue injury. Thus, if defibrillation was not possible at 800 V, the defibrillation threshold was arbitrarily and conservatively designated to be 900 V.

At the end of the randomized protocol for evaluating each of the four transvenous defibrillation systems, the patient underwent a sternotomy for implantation of a standard automatic internal cardioverter-defibrillator. In each patient, a uniform defibrillation lead system was applied using two large patch electrodes (CPI model 0041), one over the anterior right ventricle (cathode) and one over the posterolateral left ventricle (anode) (12). Defibrillation thresholds for the epicardial lead system were then determined with use of a 65% tilt, monophasic, 120 μF single pulse waveform. Epicardial defibrillation was then compared with the best transvenous defibrillation technique possible for each patient from the four systems examined. In addition, percent efficacy curves were constructed for delivered energy for the best method in each patient and for the epicardial defibrillation method. The BMDP program, version 2, was employed for analysis of variance and covariance, including repeated measures, followed by paired two-tailed *t* tests between the best transvenous system and each of the alternative defibrillation methods for determination of statistical significance.

Results

Clinical characteristics. The clinical data for the 12 patients studied are summarized in Table 1; the group included 5 men and 7 women (mean age 54 ± 14 years). Five patients had coronary artery disease, five had a cardiomyopathy and two had primary electrical disease. The average ejection fraction was 0.41 ± 0.21. One patient (Case 10) was receiving disopyramide at the time of defibrillation testing. No complications were observed in any patient during the study.

Defibrillation threshold data. The mean defibrillation threshold data for leading edge voltage, leading edge current, resistance and delivered energy are detailed in Table 2 for each transvenous defibrillation method studied, for the best transvenous defibrillation method and for the standard epicardial defibrillation method. Individual defibrillation threshold values for each patient and for each method can be found in Table 3 for delivered energy.

The mean defibrillation threshold leading edge voltage

Table 3. Defibrillation Threshold Delivered Energy (joules) for Each Method in 12 Patients

Patient No.	Method I $CS_M^- \rightarrow RV^+$	Method II $CS_B^- \rightarrow RV^+$	Method III $CS_M^- \rightarrow RV^+$, CP^+	Method IV $CS_M^- \rightarrow RV^+$ and CP^+	Best Transvenous	Epicardial
1	26.1	46.7	13.1	26.1	13.1	5.1
2	8.2	15.8	8.5	18.8	8.2	10.3
3	18.7	21.0	19.2	29.6	18.7	7.2
4	14.0	9.3	13.9	7.9	7.9	3.9
5	13.7	21.9	27.8	18.6	13.7	7.7
6	13.3	15.0	6.6	12.8	6.6	1.8
7	6.8	3.8	2.2	4.6	2.2	3.7
8	30.7	29.5	40.2	33.7	29.5	8.0
9	26.5	20.9	13.8	18.3	13.8	6.2
10	6.9	7.7	3.3	3.3	3.3	2.0
11	8.7	22.4	8.9	8.8	8.8	0.9
12	19.8	9.5	20.5	33.4	9.5	2.0
Mean ± SD	16.1 ± 8.2	18.6 ± 11.6	14.8 ± 10.9	18.0 ± 10.8	11.3 ± 7.4	4.9 ± 3.0

Abbreviations as in Table 3.

JACC Vol. 16, No. 4
October 1990:887–95

data for methods I through IV, respectively, were 502 ± 130, 504 ± 155, 469 ± 180 and 515 ± 178 V. For delivered energy the mean defibrillation threshold data for transvenous methods I through IV, respectively, were 16.1 ± 8.2, 18.6 ± 11.6, 14.8 ± 10.9 and 18.0 ± 10.8 J. There was no statistical difference for defibrillation threshold data among any two of the four transvenous methods when compared with each other with respect to voltage or delivered energy. However, the best transvenous method in each patient yielded mean defibrillation threshold values for both voltage and energy significantly less than any individual pulsing method ($p \leq 0.05$ for any comparison between transvenous methods) (see Table 2 for more precise statistical comparison data). The best transvenous defibrillation threshold voltage was 410 ± 135 V and the best transvenous defibrillation threshold delivered energy was 11.3 ± 7.4 J. Epicardial defibrillation threshold values of 272 ± 93 V and 4.7 ± 3.0 J were, not surprisingly, substantially less than those in any of the transvenous methods, including the best transvenous method ($p = 0.0013$ and $p = 0.0047$, respectively).

Among the 12 patients, the best transvenous method was method I, the single pulse monophasic technique, in 3 patients; method II, the single pulse biphasic technique, in 2 patients; method III, the sequential pulse technique, in 4 patients; and method IV, the simultaneous pulse technique, in 3 patients. Thus, with respect to providing the optimal means of inducing defibrillation in the most patients, no method proved significantly more effective than any other.

Defibrillation safety margin and percent efficacy. The ability to choose the best of the four possible defibrillation methods provided a 24% improvement in defibrillation delivered energy requirements (11.3 ± 7.4 J) when compared with the overall most effective method examined (method III, 14.8 ± 10.9 J) and a 39% improvement in defibrillation delivered energy when compared with the overall worst method examined (method II, 18.6 ± 11.6 J). In addition, this system flexibility allowed the average safety margin for defibrillation to improve to 2.7:1 from 2.0:1 (for the single most effective method, method III) and from 1.6:1 (for the single least effective method, method II) with respect to delivered energy values, assuming a 30 J output device. In individual patients, the flexibility in defibrillation techniques could account for as much as a 33.6 J difference in efficacy (Fig. 5, Table 3).

The percent efficacy for delivered energy of epicardial patch defibrillation is shown with reference to the best transvenous method in Figure 6. At 15 J, defibrillation was successful in 100% of patients with epicardial patch electrodes and in 83% with the best transvenous system available. This 83% efficacy for defibrillation at ≤15 J with the adaptable system compared favorably with the 42% to 67% defibrillation efficacy possible with any of the four individual methods (Fig. 7).

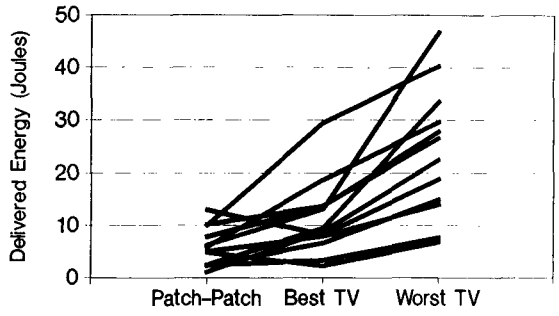


Figure 5. Delivered energy defibrillation threshold values for epicardial patch-patch, best transvenous (TV) and worst transvenous methods in the 12 patients.

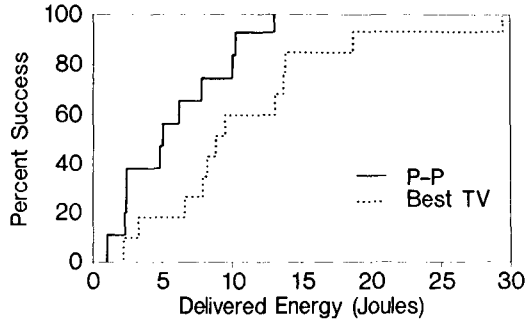
Safety of lead systems. As in earlier studies (9), no cardiac injuries were evident as a result of the transvenous defibrillation methods employed. In particular, there was no evidence of coronary sinus thrombosis, coronary sinus perforation or injury on visual inspection of the coronary sinus and atrioventricular groove structures after performance of the sternotomy.

Discussion

Defibrillation safety margins. In this study, we demonstrated the utility of an adaptable, variable waveform three electrode coronary sinus, right ventricular, chest patch transvenous defibrillation system. Flexibility in the use of waveform and current pathway had two distinct advantages: 1) more patients could have utilized transvenous antiarrhythmia devices if these devices were in fact available at the time of the study, and 2) the safety margin between the defibrillation threshold and the maximal possible output of the device improved.

We based our investigation on the assumption that effective and safe application of transvenous defibrillation systems requires the defibrillation threshold to be ≤15 J (or 500 V) given a 30 J maximal output antiarrhythmia device.

Figure 6. Percent successful defibrillation at delivered energy values for the best transvenous (TV) method and the standard epicardial large patch–large patch (P-P) method of defibrillation.



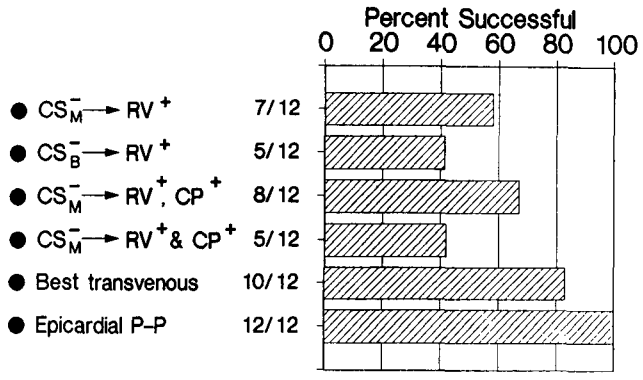


Figure 7. Percent of the 12 patients for whom defibrillation was possible at ≤15 J for each of the transvenous and epicardial methods tested. Abbreviations as in Figures 1 and 6.

However, there are no data, animal or human, to guide us in selecting a safe value for the defibrillation threshold implant criterion for transvenous systems despite implant guidelines for epicardial systems (10,17). In epicardial defibrillation, the concept of a defibrillation threshold safety margin is usually not a clinical concern because defibrillation thresholds are in the 5 to 10 J range (250 to 300 V) for monophasic waveform 65% tilt truncated pulses delivered across two large patch electrodes (9,12,13,15,16,18,19). Few patients with an epicardial electrode system appear to undergo sudden death from failure to defibrillate during long-term follow-up. This finding may relate to the large defibrillation safety margins provided by an epicardial lead system for most patients. Nevertheless, sudden death has been reported (20) in patients with an implantable defibrillator, but it remains unclear whether these patients had similarly large safety margins. In our experience, sudden death after hospital discharge as a result of failure to defibrillate occurred in one patient whose defibrillation threshold at the time of implantation was >500 V or 15 J. Thus, we extrapolated from personal experience and from the limited data available on defibrillation threshold safety margins for epicardial electrode systems to suggest an implant criterion for transvenous systems of 500 V or 15 J.

Factors that may reduce defibrillation threshold. Although we expect the 500 V or 15 J limit to be safe for transvenous systems, the long-term implant situation may be sufficiently unpredictable to warrant every effort to reduce the defibrillation threshold further if possible. Multiple factors are known to alter defibrillation efficacy, especially antiarrhythmic drug administration (21–23). In addition, the transvenous electrode-tissue interface may evolve with time and alter long-term defibrillation efficacy. Furthermore, the defibrillation threshold value used in clinical decision making is not a firm number. On any given occasion, the pulse strength necessary to defibrillate may be more as well as less than the "defibrillation threshold" determined at implantation. Therefore, a screening defibrillation threshold limit of 15 J or 500 V might be considered a reasonable "go–no go" dividing line for implantation of a transvenous system. Given the relatively low mortality experienced in most patients undergoing an open surgical procedure for defibrillator implantation, we recommend the use of an epicardial system if the transvenous defibrillation threshold is >15 J.

Different groups of patients may require different implantation criteria. The patients selected for this study were generally healthier than most patients previously reported. One reason is that most were survivors of out of hospital ventricular fibrillation rather than patients with ventricular tachycardia. Patients with ventricular fibrillation have better cardiac function than do patients with ventricular tachycardia (24). The second reason is that we skewed our patient selection to those able to tolerate the rigors of the protocol. Thus, our data are likely to be better than what might be anticipated for the population at large.

Role of coronary sinus lead. To achieve adequate defibrillation thresholds with a transvenous system, we believe the use of a coronary sinus electrode facilitates success. An earlier study (9) using monophasic single pulses demonstrated a 32% improvement in defibrillation efficacy if a transvenous right ventricular catheter electrode was combined with a coronary sinus catheter electrode rather than with a chest wall electrode (17.5 ± 7.9 versus 25.6 ± 11.4 J, respectively; $p = 0.0016$). Thus, we attempted to build on the apparent utility of a coronary sinus electrode by using it as the cornerstone of the more adaptable system described in this study.

The selection of the coronary sinus electrode as the cathode in this study was made for two reasons: 1) to maintain continuity with our earlier monophasic study (9) where the coronary sinus was selected as the cathode, and 2) to utilize the concept that the dual pathway sequential and simultaneous pulsing methods (methods III and IV) would yield higher current densities to the posterior, basilar and lateral regions of the left ventricle if the common cathode was the coronary sinus rather than the right ventricular or chest patch electrode. It is our hypothesis (Fig. 8) that if the right ventricular or chest patch electrode was the common cathode instead of the coronary sinus electrode, the pulsing vectors would influence less myocardial tissue.

Reasons for methods chosen. The transvenous defibrillation methods chosen for testing in this study also derived from an attempt to employ useful pulsing methods and waveforms examined in earlier studies (7–10,12,13,16,19,25–28). The four defibrillation methods chosen for study were representative techniques from the many defibrillation methods available. Given considerations of polarity, current pathway, pulsing technique and pulse waveform, it became necessary to constrain the number of defibrillation methods examined. Clinical limitations imposed on repetitive induction and termination of ventricular fibrillation led us to select

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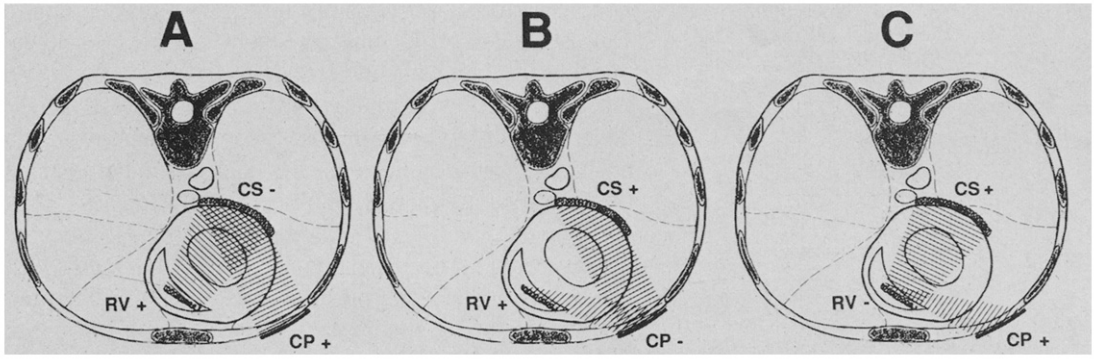

Figure 8. A stylized horizontal cross section through the chest illustrates expected differences in current vectors with a three electrode system for dual pathway techniques if either the right ventricular (RV) or chest patch (CP) electrode is the cathode instead of the coronary sinus (CS) electrode. In **panel A**, the coronary sinus electrode is the cathode; in **panel B**, the chest patch electrode is the cathode; in **panel C**, the right ventricular electrode is the cathode. The **cross-hatched areas** represent hypothetic current pathways. When the coronary sinus electrode is the cathode, more ventricular muscle may be subjected to high current densities than with either the chest patch or right ventricular electrodes as the cathode. Also, when the coronary sinus electrode is the cathode, more ventricular mass may be subjected to double the current in the sequential pulse defibrillation technique.

one pulsing method from each of the typical techniques examined in humans in the past: standard single pathway monophasic waveform pulsing (method I), single pathway biphasic waveform pulsing (method II), dual pathway monophasic waveform sequential pulsing (method III) and dual pathway monophasic waveform simultaneous pulsing (method IV).

Alternative transvenous lead systems. In an effort to demonstrate the feasibility of transvenous defibrillation systems, other clinical investigators have explored pulsing methods considerably different from ours. The Endotak lead system by Cardiac Pacemakers has been implanted in patients by several investigators (29–31). The pulsing techniques in these studies utilized a three electrode system: a right ventricular (RV) electrode, a chest patch (CP) electrode and a superior vena cava (SVC) electrode. Monophasic waveform 65% tilt pulses were delivered in one of four configurations: $RV^- \rightarrow CP^+$; $RV^- \rightarrow SVC^+$; $SVC^- \rightarrow CP^+$; $RV^- \rightarrow SVC^+$ and CP^+ simultaneously. The only method of these to yield an acceptable defibrillation threshold was the simultaneous pulsing technique of $RV^- \rightarrow SVC^+$ and CP^+, with which defibrillation at <15 J was reported (31) in the majority of patients. Therefore, this approach apparently provides another useful alternative transvenous defibrillation method.

Yee et al. (32) also endeavored to improve the efficacy of transvenous defibrillation with yet another alternative pulsing method. In their study, sequential pulse defibrillation with monophasic pulses of 3 ms duration was conducted between a right ventricular catheter electrode as the common cathode and a superior vena cava electrode as the first anode and a coronary sinus catheter electrode as the second anode. This sequential pulse method was effective in terminating 13 of 18 ventricular fibrillation episodes with voltages of 500 to 700 V, making it a potentially suitable method for use with a transvenous antiarrhythmia device. Thus, the method of Yee et al. (32) may represent still another alternative approach to the problem.

Conclusions. Our results and those of other investigators support the need for adaptability in defibrillation technique. Our data demonstrate that no single method examined is sufficiently superior to another to warrant uniform application in all patients. It appears that patient to patient diversity in disease process, cardiothoracic anatomy and arrhythmogenic substrate makes a universally superior defibrillation method unlikely. Thus, we find that a variable waveform pulsing system that incorporates a coronary sinus electrode should improve the likelihood that a transvenous defibrillation system can be utilized in any individual patient as well as provide for a significantly lower defibrillation threshold and a wider defibrillation safety margin.

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