Effect of implantable cardioverter/defibrillator lead placement in the right ventricle on defibrillation energy requirements. A combined experimental and clinical study

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Abstract

Objectives: The effect of implantable cardioverter/defibrillator (ICD) lead placement in the right ventricle (RV) on defibrillation efficacy has not been thoroughly investigated. Therefore, the goal of this combined experimental and clinical study was to evaluate the effect of a septal and a non-septal position of the right ventricular endocardial spring lead on defibrillation energy.

Methods: In 12 isoflurane-anaesthetized swine and subsequently in 8 patients who underwent ICD implantation, two different positions of the distal spring lead in the RV were investigated in randomized order: non-septal position (free wall of the RV) and septal position (interventricular septum). For each position, separate 50% probability determinations of energy (E50), peak voltage (V50) and peak current (A50) were calculated using the three reversal up/down defibrillation procedure. The E50, V50, A50 and impedance (I) were averaged and compared using the two-sided t-test for paired samples.

Results: Both the experimental study and the clinical study demonstrated that placing the distal defibrillation lead near the septum rather than near to the ventricular free wall resulted both in the swine and in the patients in significantly lower E50—31.6%—37.1%, V50—16.1%—20.9% and A50—10.0%—24.2%, respectively. Defibrillation impedances were significantly reduced only in the experimental study.

Conclusions: Defibrillation efficacy depends on the position of the distal spring electrode in the RV. A septal position significantly reduces the energy requirements compared to a non-septal position. The decrease in energy requirements might be explained by an increase in current flow through the septum and the posterolateral wall of the left ventricle. © 1998 Elsevier Science B.V. All rights reserved

Keywords: Implantable cardioverter/defibrillator; Endocardial lead placement; Defibrillation energy requirements; Electrode positions

1. Introduction

The first human implantation of the implantable cardioverter/defibrillator (ICD) in 1980 has revolutionized the overall approach to the management of life-threatening ventricular tachyarrhythmias [1]. The need for thoracotomy in usually high-risk patients with advanced cardiac disease was a major limitation in its routine clinical application. This risk was reduced by the introduction of the so-called non-thoracotomy lead systems implanted through either the cephalic or subclavian vein. However, as a consequence of the reduced surface area for delivering the defibrillating shock, it has generally been recommended to implant a subcutaneous/submuscular patch or array electrode in order to ensure an adequate magnitude of the electrical defibrillating field to parts of the left ventricle [2,3]. Initial clinical trials supported the suggestion that an accessory patch or array was necessary to achieve defibrillation...
thresholds (DFTs) at or below 20 J using monophasic shock waveforms [4–6]. Our experience with non-thoracotomy leads dates back to 1991. In the first twelve patients, we routinely implanted a submuscular patch electrode. The use of these patches was associated with early and late complications as patients discomfort, seroma, hematoma and infection. Therefore, we preferred the ‘lead alone’ approach. We tried to place the distal spring electrode of the endocardial lead system towards the interventricular septum to include this part of both ventricles into the electrical defibrillating field. In a first prospective study we achieved in nineteen consecutive patients a DFT of 20 J or less using monophasic shock waveforms [7]. To evaluate our clinical findings, the purpose of this prospective randomized combined experimental and clinical study was to compare the effect of a septal (Fig. 1) and a non-septal (Fig. 2) position of the right ventricular endocardial spring electrode on defibrillation energy.

2. Methods

2.1. Defibrillation lead description

The defibrillation lead system used in both studies was a tripolar, tined endocardial cardioversion/defibrillation and pacing lead (Endotak® C, Model 0092/0094, Cardiac Pacemakers Inc.; St. Paul, MN). The porous tip electrode served as the cathode for intracardiac right ventricular electrogram rate-sensing and pacing. The distal spring electrode (surface area = 405 mm²) served as an anode for rate-sensing and pacing and as a cathode for morphology-sensing and cardioversion/defibrillation shocks. The proximal spring electrode (surface area = 589 mm²) served as an anode for morphology-sensing and cardioversion/defibrillation shocks. Two different spacings (measured from the distal tip to distal end of the proximal spring electrode) were available to accommodate varying intracardiac proportions. Due to the smaller heart size in the swine compared to man, the Endotak® C Lead 0092 (spring electrode spacing = 15 cm) was chosen. In all patients, regardless of the heart size an Endotak® C Lead 0094 (spring electrode spacing = 18 cm) was implanted.

2.2. Experimental study

2.2.1. Animals

Thirteen female Yorkshire swine were studied. Animal no. three died due to refractory ventricular fibrillation immediately after beginning of anesthesia. Data from the remaining 12 swine with an average body weight of 38.8 ± 1.4 kg (range 31–36 kg) and an average wet weight of both ventricles of 125.2 ± 15.1 g (range 99–143 g) were included in the final evaluation. Pre-operative and operative animal care were complied with the animal Welfare Act 1989 amended 1994 and the Guide to Care and Use of Animals, National Institutes of Health Publication #86–23.

2.2.2. Anesthesia

The swine were pre-anesthetized with xylozine (50.0 mg/kg i.m.) and ketamine HCl (40.0 mg/kg i.m.). About 15 min after administration of pre-anesthesia the swine were anesthetized with sodium pentothal (10–20 mg/kg i.v.) via a peripheral intravenous line, intubated and mechanically ventilated using a volume controlled ventilator, a tidal volume of 10–14 ml/kg at a rate of 10–15/min at FiO₂ 1.0. The isoflurane level was initially set at 1.5% and adjusted as needed to maintain anesthesia. Limb leads were attached for ECG monitoring. An arterial line was inserted via the left carotid artery. Arterial pressure, blood gases and pH were continuously monitored and maintained within acceptable physiological ranges.

2.2.3. Surgical procedure

An Endotak® C Lead 0092 was introduced through a left jugular venotomy and was positioned with the distal tip in the right ventricular apex. The distal coil was positioned either near the septum or the lateral free wall of the right ventricle according to a randomization protocol. Lead posi-
tion was verified using fluoroscopy. The lead was anchored at the venotomy site to prevent dislodgement. The animals were rotated in a right lateral position and maintained this position throughout the defibrillation episodes. Subcutaneous array wires were implanted in the left thorax between the fourth and eighth intercostal space and centered on the mid-axillary line. The array was only used in combination with the endocardial lead for backup rescue shocks.

2.2.4. Test protocol

A modified external cardioverter/defibrillator (Ventak ECD® 2815, Cardiac Pacemakers Inc.; St. Paul, MN) was used to determine 50% probability for delivered energy ($E_{50}$), peak voltage ($V_{50}$) and peak current ($A_{50}$) for each position. Data were collected using the three reversal up/down defibrillation procedure [8]. All shocks were delivered as a biphasic truncated exponential waveform with 80% fixed tilt. Fibrillation was induced using a 9 V DC signal through the proximal and distal coil of the endocardial lead. Fibrillation was confirmed by observing the lead II ECG and the absence of cardiac output, as judged by arterial pressure. After 10 s of fibrillation endocardial defibrillation was attempted. Starting with 610 V, the voltage step size was decreased and/or increased by 10% until a total of three reversals from success to failure or failure to success were encountered. A recovery period of three minutes was allowed between each induction of ventricular fibrillation. If an initial endocardial defibrillation attempt failed, a backup rescue shock (840 V ~ 40 J) was administered between the endocardial lead and the subcutaneous array. After each failed shock, the lead position was checked by fluoroscopy. After completion of the protocol the animals were sacrificed.

2.3. Clinical study

2.3.1. Study patients

The clinical study was approved by the local ethical committee, and all 8 patients gave their informed consent. Exclusion criterion was a left ventricular ejection fraction (LVEF) below 20%. Two women and six men (mean age 55 ± 18 years) were investigated at primary ICD implantation. Clinical cardiac function was classified as New York Heart Association (NYHA) Class I in one patient, Class II in five patients and Class III in two patients. Coronary artery disease was present in six patients. One of these patients suffered also from mitral and tricuspid valve insufficiency. In this patient coronary artery bypass grafting, mitral valve (Duran Ring Anuloplasty) and tricuspid valve anuloplasty (modified de Vega Anuloplasty) had been performed 2 years before ICD implantation. In the absence of detectable structural heart disease in two patients primary electrical disease was suggested. Each patient underwent cardiac catheterization with angiography and baseline electrophysiological study. The mean LVEF, measured by contrast ventriculography was 39 ± 14% (range 23–63%). Antiarrhythmic drugs were tested prior to implantation in all patients. The number of antiarrhythmic drugs ranged from 1 to 2 with a mean of 1.5 ± 0.5. Ventricular tachycardia (VT)/ventricular fibrillation (VF) could be induced in seven patients.

2.3.2. Anesthesia

The anesthetic regimen uniformly consisted of a fentanyl-enflurane (in oxygen/nitrous oxide)/pancuronium bromide-based technique. Continuous arterial pressure, central venous pressure, arterial blood gases, electrolyte balance and ECG were monitored throughout the implantation procedure. Immediately prior to and during fibrillation/defibrillation, nitrous oxide administration was discontinued and inspired enflurane concentration decreased to 0.2–0.8%, to increase arterial oxygen partial pressure and minimize potential myocardial depression.

2.3.3. Operative procedure

In all cases an Endotak® C lead was inserted into the left cephalic vein through a small incision over the deltopectoral groove. Under fluoroscopic guidance the tip of the endocardial lead was placed in the apex of the right ventricle. In randomized order the distal coil was positioned either next to the interventricular septum or the lateral free wall of the right ventricle.
2.3.4. Test protocol

For each position sensing and pacing threshold measurements were performed with a pacing system analyzer (PSA® Model 5312, Medtronic Inc.; Minneapolis, MN). Our study protocol required pacing thresholds of $<1.0$ V (0.5 ms pulse width), impedance 200–800 $\Omega$ (5 V/0.5 ms pulse width), R-wave amplitude $>5.0$ mV and slew rate (0.5 V/s, respectively, in sinus rhythm. Morphology sensing amplitude and shocking impedance (0.1 J) was measured with an external cardioverter/defibrillator (Ventak ECD® 2815, Cardiac Pacemakers Inc.; St. Paul, MN). A morphology sensing amplitude of $>3$ mV and a shocking impedance of 30–80 $\Omega$ was accepted. Fibrillation was induced via the endocardial lead system by brief application of 50 Hz alternating current (Unifib II; Unitek International, Sittard, BV, Netherlands). After 10 s fibrillation a biphasic shock (truncated exponential pulse waveform, 80% fixed tilt) with a start energy of 8 J was given. The energy step size was decreased ($\Rightarrow 5.1$, $\Rightarrow 3.1$, $\Rightarrow 2.1$, $\Rightarrow 1.1$, $\Rightarrow 0.5$ J) or increased ($\Rightarrow 10.1$, $\Rightarrow 15.1$, $\Rightarrow 20$ J) until a total of three reversals from success to failure or failure to success were encountered. For each position 50% probability determinations of delivered energy ($E_{50}$), peak voltage ($V_{50}$) and peak current ($A_{50}$) were calculated using the three reversal method. Each episode was separated by a minimum of 5 min until heart rate, arterial blood pressure and the ECG had returned to baseline parameters. In case of persisting VF a rescue shock of 40 J was delivered via the endocardial lead system. After each unsuccessful shock, the position of the lead was controlled by fluoroscopy. In addition an external cardiac defibrillator with external paddles and a maximum output of 340 J was maintained in a stand-by mode.

2.4. Statistical analysis

Delivered energy ($E_{50}$), peak voltage ($V_{50}$) and peak current ($A_{50}$) were defined as the average of the three reversals [8]. The $E_{50}$, $V_{50}$, $A_{50}$, impedance, pacing and sensing parameters were averaged and compared using the two-sided $t$-test for paired samples. $P$ values $<0.05$ were considered statistically significant. All data are expressed as mean ± standard error of the mean.

3. Results

In the experimental study 157 fibrillation/defibrillation sequences (mean ± SD: 13.08 ± 2.54, range: 9–17) were investigated. Placing the electrode from the right ventricular free wall towards the septum was associated with significant reductions ($P<0.05$) of the delivered energy ($E_{50}$ from 31.8 ± 1.2 to 21.9 ± 1.1 J), peak voltage ($V_{50}$ from

![Fig. 3. Effect of right ventricular spring lead position on $E_{50}$, $V_{50}$, $A_{50}$ and I mean normalized to the free wall position ( = non-septal position).](image)
645 ± 34 to 541 ± 30 V), peak current (I₀ from 11.7 ± 0.3 to 10.7 ± 0.3 A), and the shocking impedance (I from 55.6 ± 0.8 to 51.7 ± 0.7 Ω). The relative changes are presented in Fig. 3.

In the clinical study 88 fibrillation/defibrillation sequences (mean ± SD: 11.00 ± 1.60, range: 9–14) were required to complete the test protocol. No differences between the two electrode positions were observed, either for the pacing (pacing threshold 0.49 ± 0.05 V vs. 0.55 ± 0.07 V) and sensing parameters (R-wave 12.80 ± 5.57 mV vs. 16.50 ± 6.45 mV, slew rate 1.75 ± 0.21 V/s vs. 1.93 ± 0.57 V/s) or for the pacing impedance (647 ± 26.5 Ω vs. 648 ± 33.6 Ω).

The defibrillation characteristics (E₀, V₀, and A₀) in patients were considerably lower than in the swine. Placing the electrode from the free wall to the septal position again resulted in significantly reduced E₀ (10.5 ± 1.9 to 6.6 ± 1.4 J), V₀ (359 ± 40 to 283 ± 35 V), A₀ (6.3 ± 0.8 to 4.7 ± 0.7 A), whereas the shocking impedance remained unchanged (59.3 ± 2.3 vs. 60.9 ± 1.9 Ω). It is remarkable that in spite of the different control levels of the E₀, the required energy with the septal electrode position was roughly reduced by one-third, both for the experimental and the clinical study (Fig. 3).

4. Discussion

The challenge of defibrillation using a totally endocardial lead system is to provide adequate voltage density or potential gradients to most of the fibrillating myocardium [9,10]. In context with the ‘critical mass theory’, successful defibrillation requires a minimum of potential gradients (about 6–7 V/cm) within the major part of the heart (~90%). A low potential gradient in only approximately 10% of the ventricular mass has been shown to cause failure of defibrillation [11,12]. As the left myocardium represents most of the myocardial mass, the electrical defibrillating field should incorporate this part of the heart. However, the location of the endocardial leads is limited to the right heart.

The most common endocardial lead configuration consists of a proximal electrode, which usually serves as anode, located at the junction of the high atrium (RA) and superior vena cava (SVC) and a distal electrode serving as cathode, located in the right ventricle (RV). A shock is delivered between these electrodes and generates a potential gradient field. Despite the lack of an electrode near to the left ventricle experimental studies have shown that this technique is successful [3,13]. An early acute human feasibility study by Mirowski et al. [14] demonstrated that endocardial defibrillation of VF was possible with energies ranging from 5 to 15 J.

In order to reduce the defibrillation energy, different positions of the proximal electrode (anode) were investigated: left subclavian vein, brachiocephalic vein, mid-RA, RA/SVC junction and coronary sinus. In general Block et al. [15] found no improvement by positioning the anode horizontally high in the left brachiocephalic vein instead of vertically low in the SVC. Only individual patients had a benefit from a change of the position. Trappe et al. [16] tested three different positions of the proximal electrode: the brachiocephalic vein, the mid-RA and the RA/SVC junction. The mean energy requirements of the three positions were neither statistically different, nor was any lead position consistently associated with lower defibrillation energies. However, an optimal electrode position was identified in 83% of all patients. In contrast the studies of Stajduhar et al. [17] and Markewitz et al. [18] demonstrated the advantage of a subclavian/inominate vein position over the SVC position in the majority of their patients.

The advantage of a coronary sinus lead in combination with a right ventricular lead is to apply a higher transmyocardial voltage gradient to the lateral and basal left ventricle. Despite these theoretical advantages, two clinical studies using entirely endocardial lead systems including the coronary sinus failed to show a success rate exceeding 50% at an energy level of 18 J or less [19,20]. Bardy et al. [19] had to exclude three out of 23 patients from their acute study because of the inability to cannulate the coronary sinus. Lead dislodgement from coronary sinus position was the most frequently reported complication in the European Transvene™ lead system study [21]. The coronary sinus was the initial lead position finally used in only five out of 103 patients. In 96% of the patients the investigators preferred the easier accessible lead placement in the SVC.

The effect of lead placement in the RV has been less well investigated. Schuder et al. [22] concluded from their early experimental studies that the position of the electrode within the RV is critical. Failure to position the tip of the electrode in the apex caused a definite decrease in system effectiveness. These results were later confirmed by Heil et al. [23] and Usui et al. [24]. Both studies showed, that placement of the right ventricular electrode 2 cm distant from the apex increased the defibrillation energy requirements for entirely endocardial lead systems. In addition, mapping studies have demonstrated that low post-shock voltage gradients in the apex and the posterolateral wall of the left ventricle are the cause of failed shocks [9].

As a result of our early clinical study not only was apical positioning important, but also maintaining close contact between the electrode and the interventricular septum was a key factor to achieve low defibrillation energies. Mapping studies during the defibrillation shocks between RV and SVC electrodes have shown, that the highest potential gradients are close to the electrodes and the lowest are along the posterolateral and basal left ventricular free wall. Furthermore the electrical defibrillating fields are not uniform and shock strength must be high enough to create potential gradients about 6–7 V/cm even distant from the electrodes [9]. Based on these observations and our clinical results it seems to be logical to place an electrode in the RV as close as possible to the interventricular septum, which represents
about 30% of the left myocardial mass [7,25]. It appears that the optimal positioning of the Endotak® C lead is with a pronounced ‘S’ curve, with the distal coil lying against the septum and the tip fixed in the apex (Fig. 1).

The present study clearly demonstrates that the left ventricular septal mass encompassed by the electrical defibrillating field is more important than that of the free wall of the RV. The benefit of the septal position might be explained by two mechanisms. First, as a result of a change of the voltage vector, peak voltage at the defibrillation energy was lower with the septal position. This indicates that the septal position creates a more optimal vector, because voltage is one of the critical determinants of the defibrillation success. Second, placing the distal coil close to the septum which is a part of both ventricles should decrease the defibrillation energy by directing more current to both sides of the heart. The decrease in energy, peak current and peak voltage for the septal position might be due to the increased gradient fields with this position in major parts of the left ventricle. Our last hypothesis remains speculative at this time, and mapping studies are necessary to explain the true mechanism.

5. Limitations of the study

Some limitations of the study should be addressed. First, the data were obtained using only an endocardial dual coil lead system. Therefore these results may not be applicable to other defibrillation lead systems especially to those including an active pectoral pulse generator. Second, only one waveform and shock polarity were investigated, so the optimal combination of these parameters may not have been used. Finally, clinical follow up of these patients to assess the stability of the lead position was not performed. Since 1991 we have implanted more than 250 endocardial ICD-leads. In all these cases we placed the distal coil as close as possible to the septum. During follow-up, X-ray revealed lead dislodgement in only four patients. Therefore we conclude, that the septal position remains stable over time in the majority of the patients.

6. Conclusion

As demonstrated in the present study, defibrillation efficacy depends on the position of the distal spring electrode in the right ventricle. Comparing the septal position to the non-septal position, there was a significant decrease in the energy requirements both in the animal experiments (−31%) and in the human implantations (−37%). Proximity of the distal spring electrode to the interventricular septum is a key factor to reduce the defibrillation energy. Possible mechanisms are that the septal position creates a favorable change in the voltage vector and higher voltage gradients across the septum and the posterolateral wall of the left ventricle. However, mapping studies are necessary to verify these hypothesis. Understanding of the mechanism for lowering the defibrillation energy with the septal position seems to be important for current implantation techniques and the development of future endocardial lead systems.

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References

Appendix A. Conference discussion

Dr J. Melo (Carnaxide, Portugal): Can you elaborate, is it difficult to get the stable position on the septal position?

Dr Winter: No I think it’s very simple. But in some rare cases it may be a time-consuming procedure. Since 1991 we have implanted more than 250 endocardial leads using this technique. In only four patients additional subcutaneous electrodes were necessary to achieve defibrillation thresholds at or below 20 J.

Dr F. Wellens (Aalst, Belgium): Indeed the position of the electrode near the septum is lowering the DFTs in a considerable manner. Over the last year, we are positioning the electrode under TEE control. In some cases we don’t even use any more radioscopic control. It is a very short procedure and it’s much more easy than trying to reposition the electrode under radioscopic control.

Dr Winter: Yes. In our first cases we controlled the position of the right ventricular lead by fluoroscopy and in addition by transesophageal echocardiography. Now I think fluoroscopy is completely sufficient for positioning the lead in the right ventricle.

Dr T. Kaul (Birmingham, AL, USA): Have you got any clinical data on displacement of the lead?

Dr Winter: We observed four lead dislodgements. (Slide) In 1995 we presented this study at the 16th Annual Scientific Sessions of the North American Society of Pacing and Electrophysiology in Boston. In 86 out of 100 patients induced ventricular fibrillation was successfully terminated with 15 J or less using the initial lead position. Repositioning of the lead was necessary in 14 patients, whose defibrillation thresholds were above 15 J. In 11 patients repositioning was successful within a 15 J energy level. Despite multiple repositioning of the lead in three patients the obtained defibrillation thresholds were 20 J in two patients and 40 J in one patient. Optimal placement of the endocardial lead in the right ventricle is critical to low defibrillation energy requirements.

Dr Kaul: Under normal circumstances, would you prefer an endocardial system or an epicardial system of equal efficacy? I know both systems of almost equal efficacy are available at the moment.

Dr Winter: Of course endocardial lead systems. Since biphasic shock waveforms are available, there is only a small group of patients, who may not be candidates for an endocardial lead system.

Dr Kaul: I agree with you in this respect, because the endocardial system is more physiological and it doesn’t cause any problem at the reoperations, if you need.