Comparison of defibrillation thresholds using monodirectional electrical vector versus bidirectional electrical vector

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Key words:
Defibrillation threshold; Implantable cardioverter-defibrillator; Shock configuration.

Background. **Currently, two main lead configurations are used for implantable cardioverter-defibrillators (ICD). One generates a monodirectional electrical vector by using the can surface as an active part (hot can) together with a right ventricular defibrillation coil. The other one (TRIAD) produces a bidirectional electrical vector by adding a proximal defibrillation electrode on the same lead. The purpose of this prospective study was to determine whether there is a difference between these configurations in terms of the acute defibrillation threshold (DFT). The secondary objective was to evaluate the possible sequential effect of successive arrhythmia induction and defibrillation shocks on the final DFT value.**

Methods. **In 44 patients (37 males, 7 females, mean age 59.18 ± 12.05 years; mean ejection fraction 35.21 ± 11.69%), a Hot Can Ventak family ICD (Guidant, St. Paul, MN, USA) was implanted in a left pectoral pocket. During the implant procedure, step-down to failure DFT testing was performed twice in each patient using the two different above-mentioned configurations: the bidirectional and the monodirectional. The first configuration to be tested was determined by a 1:1 randomization by center.**

Results. **The step-down DFT protocol was followed in 35 patients. The average DFT was 8.6 ± 4.0 J for TRIAD and 10.4 ± 4.3 J for the monodirectional (p = 0.009) lead configuration; this represents a 16.3% decrease in the DFT using a bidirectional configuration. Furthermore, no relationship between the final DFT and the number of ventricular fibrillation inductions and shocks received was observed, confirming the secondary objective.**

Conclusions. **Compared to the monodirectional electrical vector, the bidirectional electrical vector is clearly more beneficial for the patient.**

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Introduction

During the past years, the energy required for internal defibrillation has been progressively and significantly reduced due to the improvement in lead performance and shock waveforms of the implantable cardioverter-defibrillator (ICD). After the year 1995, left pectoral implantation using an active ICD shell as an extra defibrillating electrode further contributed to improve this trend in defibrillation threshold (DFT) lowering independently of the surface or volume of the can[1-8].

The continuous tendency of downsizing ICDs to facilitate the implantation technique and reduce the discomfort to the patient requires a reduction in battery and/or capacitor size. With the currently available technologies, a reduction in capacitor size will probably have a negative impact on the maximal defibrillator output[8]; therefore this creates a further need for optimal configurations that eventually result in a lower DFT, and consequently allow for optimal safety margins.

Among the factors that can affect DFTs, defibrillation geometry[9] seems to be an important one to consider; this, especially since it has been made available to the physician and allows the selection of the best path for energy delivery within the heart. In order to determine the optimal geometry, this prospective, randomized study comparing the effects of two different defibrillating geometries on the final DFT for the same patient has been planned. One configuration generates a monodirectional electrical vector by using the distal coil electrode of the

ventricular defibrillating lead and the active can of the ICD. In this configuration the electrical vector, originating from the distal coil of the defibrillation lead (cathode) which is placed at the right ventricular apex travels through the heart and reaches the active surface area of the ICD (anode). The other configuration uses a bidirectional vector by using the ventricular distal coil as cathode and both the caval/atrial coil of the same lead and the active can of the ICD as anode. Thus, the defibrillation shock wave spreads out in two directions, apparently through an increased myocardial surface area (Fig. 1).

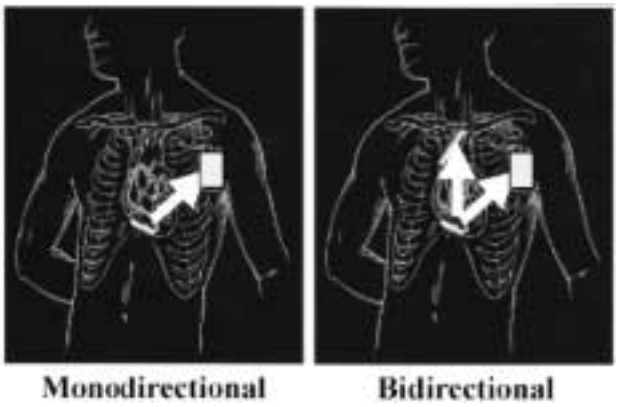

Figure 1. *Comparison of a monodirectional versus a bidirectional electrical vector configuration.* Left: *in the monodirectional configuration, the defibrillation shock wave travels from the distal electrode of the lead towards the active can of the implantable cardioverter-defibrillator.* Right: *in the bidirectional configuration, this wave is oriented towards the active can and towards the proximal electrode of the lead possibly spreading the defibrillation energy wave front through more myocardial cells.*

Methods

Population. Forty-four consecutive patients (37 males and 7 females, mean age 59.18 ± 12.05 years), candidates to receive a defibrillator for the accepted clinical indications, were enrolled in this multicenter randomized controlled single-blinded study. Each patient signed the informed consent before implant; the study was approved by the local Ethics Committees. Thirty-five patients completed the protocol (Table I).

The primary cardiac disease was: coronary artery disease or ischemic cardiomyopathy in 22 patients (63%), non-ischemic cardiomyopathy in 4 patients (11%), valvular disease in 5 patients (14%), long QT syndrome in 1 (3%) and arrhythmogenic right ventricular dysplasia in 1 (3%). In 2 patients (6%), no heart disease was diagnosed. The mean ejection fraction was 35.21 ± 11.69% (range 11-65%); the median NYHA functional class was II; no patient was in NYHA class IV.

The presenting arrhythmia was monomorphic ventricular tachycardia in 20 patients, polymorphic ventricular tachycardia in 2 patients, polymorphic ventricular tachycardia + ventricular fibrillation in 1 patient, monomorphic ventricular tachycardia + ventricular fibrillation in 4 patients and ventricular fibrillation in 7 patients; 1 patient had a prophylactic implant (MADIT indication[10]). Twenty patients (57%) were taking antiarrhythmic drugs (17 amiodarone, 1 mexiletine, 1 sotalol, and 1 atenolol).

Testing. After induction of general anesthesia and under continuous ECG and femoral arterial pressure monitoring, either via a surgical approach to the left cephalic vein or by means of left subclavian puncture, a defibrillation lead (Endotak DSP model 0125 for all the patients) was advanced and the tip was positioned at the right ventricular apex. A left subpectoral pocket was always obtained and, having checked for adequate sensing and pacing values, the lead was fixed to the pectoral fascia and connected to the ICD. Eleven patients were implanted with the single chamber Ventak Mini I, 24 with the Ventak Mini II, and 9 with the dual chamber Ventak AV I.

The Endotak DSP 0125 is a tripolar lead with an 8 mm^2 distal electrode as cathode for sensing and pacing and two defibrillating coils, the distal with a surface area of 450 mm^2 and the proximal with a surface area of 660 mm^2 as anode. The sizes of the ICDs (surface/volume) are respectively 103 mm^2/68 cm^3 for the Ventak Mini I, 88 cm^2/59 cm^3 for Ventak Mini II, and 116 cm^2/79 cm^3 for Ventak AV. All components are manufactured by Cardiac Pacemakers Inc. (CPI, St. Paul, MN, USA).

A paired comparison in the same patient between DFT values was obtained with two defibrillation configurations: one generating a bidirectional vector using the distal coil as cathode and both the proximal coil of the same lead and the active can of the ICD as anode (TRIAD) and the other generating a monodirectional electrical vector, using the distal coil of the lead and the hot can of the ICD. The first configuration to be attempted was determined by a 1:1 randomization. For the monodirectional configuration, both the positive defibrillating ports in the connector block of the device were closed with a DF-1 plug model 6996 and the proximal connector was insulated with a model 6054 lead cap. For the bidirectional configuration only one positive defibrillating port was closed with a DF-1 plug model 6996.

The investigator initiated the DFT testing by delivering 15 J as the starting energy value and lowered the energy according to a 12, 10, 8, 5 and 3 J scheme until the shock failed to convert the arrhythmia (Fig. 2). The lowest possible testing value was always 3 J. Rescue shocks were never used to determine the DFT. When the DFT was reached with the first configuration, the investigator switched to the second configuration, starting at the same initial quantity of energy (15 J).

If the lead was repositioned or the polarity was reversed during testing of the second configuration, the DFT testing had to be restarted with the initial configuration and beginning at 15 J, in order to truly compare the results of the two configurations.

Table I. Population and results.

Patient	Age (years)	Sex	Height (cm)	Weight (kg)	NYHA	LVEF (%)	Primary cardiac disease	Primary arrhythmia	AAD	Configuration	DFT	
											Bidirectional	Monodirectional
211	56	F	151	81	II	35	VD	MVT/VF	Amiodarone	Monodirectional	10	12
212	60	M	170	67.2	I	60	None	MVT		Bidirectional	8	12
213	52	M	167	74	I	35	CAD	MVT	Amiodarone	Monodirectional	12	10
216	75	M	170	70	II	40	CAD	MVT	Mexiletine	Bidirectional	8	20
218	61	M	170	65	II	30	VD	MVT	Amiodarone	Bidirectional	5	3
258	69	M	170	68	II	42	VD	MVT/VF	Amiodarone	Bidirectional	8	18
272	67	F	170	70	II	44	DCM	PVT/VF		Monodirectional	8	8
274	55	M	168	72	II	24	CAD	MVT		Bidirectional	5	8
278	75	M	154	67	II	42	CAD	MVT/VF		Monodirectional	3	8
280	NA	M	169	68	II	30	CAD	MVT		Bidirectional	8	5
281	49	M	175	85	I	40	CAD	VF		Monodirectional	3	5
284	39	M	170	60	I	45	CAD	VF	Amiodarone	Monodirectional	3	3
288	41	F	153	60	I	56	None	MVT	Sotalol	Monodirectional	8	15
292	76	M	162	76	II	NA	CAD	MVT	Amiodarone	Bidirectional	8	10
293	53	M	172	75	II	31	CAD	MVT	Amiodarone	Monodirectional	12	10
302	65	M	175	78	II	27	CAD	MVT		Bidirectional	15	12
310	49	M	170	85	I	35	CAD	MVT	Amiodarone	Monodirectional	15	15
312	77	M	185	101	II	30	CAD	PVT		Monodirectional	5	10
319	70	M	162	72	II	22	CAD	MVT	Amiodarone	Bidirectional	15	15
321	44	M	178	71	II	40	DCM	VF	Amiodarone	Bidirectional	10	8
327	46	F	158	84	I	65	Long QT syndrome	VF		Bidirectional	10	15
330	66	M	165	70	II	25	CAD	MVT	Amiodarone	Monodirectional	15	12
332	39	M	170	81	II	11	VD	MVT	Amiodarone	Monodirectional	20	20
333	55	M	173	76	II	30	CAD	Other		Monodirectional	5	10
334	65	M	162	82.6	II	38	CAD	MVT	Atenolol	Monodirectional	10	12
336	74	M	180	79	II	35	CAD	VF	Amiodarone	Bidirectional	10	8
337	61	M	174	79	III	30	VD	MVT	Amiodarone	Bidirectional	8	12
344	73	M	160	77	II	20	DCM	MVT		Bidirectional	10	8
345	67	M	160	59	II	39	CAD	MVT		Bidirectional	8	8
357	54	M	164	64	II	32	CAD	VF		Bidirectional	3	5
361	70	M	167	70	II	20	CAD	MVT	Amiodarone	Monodirectional	8	8
362	38	M	159	63	II	25	DCM	MVT	Amiodarone	Bidirectional	6	9
363	60	F	160	53	I	35	ARVD	MVT/VF	Amiodarone	Monodirectional	5	10
365	43	M	170	71.5	II	29	CAD	VF		Monodirectional	5	5
366	68	M	166	80.4	I	55	CAD	PVT		Bidirectional	10	12
Mean	59.18		167.11	72.99	1.77	35.21					8.63	10.31
SD	12.05		7.55	9.31	0.49	11.69					4.00	4.27
Min	38.00		151.00	53.00	1.00	11.00					3.00	3.00
Max	77.00		185.00	101.00	3.00	65.00					20.00	20.00

AAD = antiarrhythmic drug; CAD = coronary artery disease/ischemic cardiomyopathy; DCM = dilated cardiomyopathy; DFT = defibrillation threshold; LVEF = left ventricular ejection fraction; MVT = monomorphic ventricular tachycardia; NA = not available; PVT = polymorphic ventricular tachycardia; VD = valvular disease; VF = ventricular fibrillation.

A minimum of two successful shocks at 15 J or less (successful conversions at or below an energy level which previously failed did not count) or two consecutive successes at 20 J (Mini) or 18 J (Mini II) in the final lead configuration were required for implant. The final configuration implanted was always the TRIAD configuration, since the purpose of this study was to evaluate the efficacy and safety of the Ventak Mini (Mini II) hot can + distal coil of the Endotak configuration in the acute condition. Results of this current study will be needed to determine guidelines regarding this new configuration. Still, the decision to choose the monodirectional vector as the final configuration if the difference in DFT was significantly high (> 10 J) with respect to the TRIAD was left to the discretion of the investigators. However, for all the patients participating in this study, this was not the case.

At least a 5 min delay was respected between two successive inductions, in order to allow for a complete return to baseline arterial blood pressure, heart rate, ST-T segment configuration and QRS duration. Besides the patient recovery, the objective of this delay was to avoid any possible effect of multiple inductions on the final DFT.

Ventricular fibrillation was induced by delivering a constant train of 30 ms pulses through the ventricular lead and maintaining the signal at least for 5 s. Ventricular fibrillation was defined as an irregular, rapid activity at the surface ECG, using at least three leads.

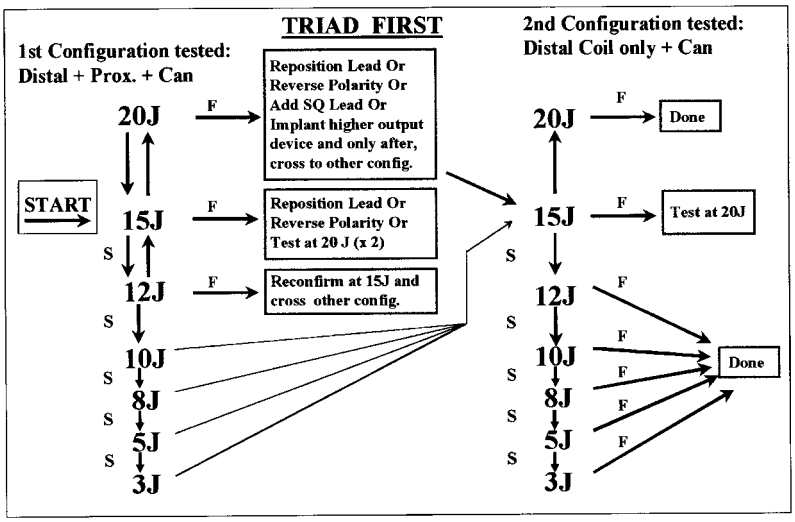

Figure 2. *Defibrillation threshold (DFT) scheme used during implant. The figure shows the scenario in which the first configuration to be tested is the TRIAD (bidirectional). Two successful defibrillations at 20 J were required in order to switch safely to the other configuration. If this was not possible, the lead was repositioned, a higher output device used or an SQ patch or array implanted in order to attain the correct safety margin. Once the DFT was obtained, the patient was switched to the other configuration. For those cases in which the monodirectional configuration was tested first, it was required that, having switched to the other (TRIAD) configuration, a minimum of two successful defibrillations at 20 J be achieved. If this was not the case, the lead was repositioned, a higher output device was chosen or an SQ patch or array was selected. In this case, the DFT was considered to be > 20 J. F = failure; S = success.*

The DFT was defined as the minimum energy required for successful termination of ventricular fibrillation. Successful termination was defined as a conversion to a rhythm that required no further ventricular antiarrhythmic therapy.

Statistical analysis. Means, SD and ranges were used to represent continuous variables. Comparison between the DFTs of the two configurations was made using the two-sided paired Student's t-test.

Results

All patients underwent ICD implant without complications in terms of morbidity or mortality. Thirty-five out of 44 patients completed the protocol; 9 patients were excluded from the protocol since testing was not fully completed, mainly due to the impossibility of performing one limb of the testing procedure. The deviations were: failure to reach a true DFT (n = 5), uncertainties with respect to the ventricular fibrillation conversion (n = 2), and the worsening in the patient's conditions (n = 2). The dropouts were uniformly distributed whether the first approach was the monodirectional or the bidirectional one.

No changes of the polarity were necessary to complete the DFT testing. The mean DFT for the bidirectional configuration was much lower than that of the monodirectional configuration (Fig. 3). The mean DFT for the bidirectional vector configuration was 8.6 ± 4.0 J whereas that for the monodirectional vector configuration was 10.4 ± 4.3 J. This represents a 16.3% reduction in the DFT when a TRIAD configuration is employed. The p value was 0.009 making it highly significant. The associated shock impedances were 43.5 ± 7.1 Ω in the bidirectional configuration and 60.1 ± 8.0 Ω for the monodirectional configuration (Fig. 4). Even this difference was highly significant ($p < 0.001$).

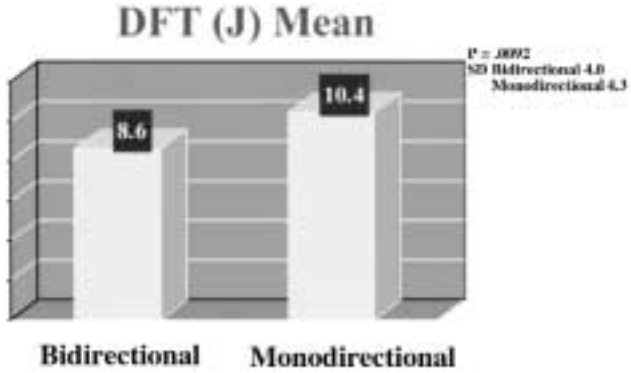

Figure 3. *Defibrillation threshold (DFT) results for both configurations. The final DFT for the bidirectional vector configuration was 8.6 ± 4.0 J whereas that for the monodirectional configuration was 10.4 ± 4.3 J (p = 0.0092). This represents a 16.3% reduction in the DFT when using a TRIAD configuration.*

In terms of the possible effect of multiple testing on the final DFT values it can be seen in figure 5 that the order of testing did not affect the results. In the figure the first couple of columns represents the DFT obtained during the first limb of the study. The second couple shows the DFT obtained during the second limb of the study. No difference was present in terms of DFT regardless of the temporal sequence employed in testing the two configurations. These results show that there is no significant change in the electrical pattern of the patient if many inductions and shocks are delivered, provided there is a sufficient resting period to allow for patient recovery between inductions.

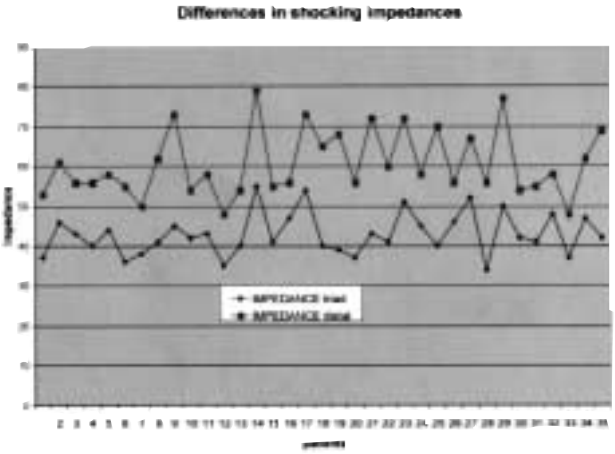

Figure 4. *Difference in impedance between the TRIAD and distal coil only configurations. The shock impedances for all patients clearly show a significant decrease in impedance for the TRIAD configuration with respect to the distal coil only.*

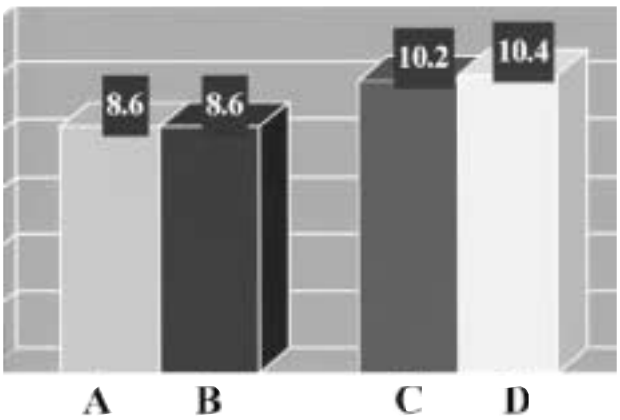

Figure 5. *Sequential effect of multiple defibrillation shocks on the final defibrillation threshold (DFT).* Column A *represents the DFT obtained in those patients whose first testing choice fell on the bidirectional configuration.* Column B *shows those patients whose DFT results in the bidirectional configuration were obtained after having performed DFT testing in the monodirectional configuration.* Column C *shows patients who underwent DFT testing in the monodirectional configuration first while the data in* column D *are the DFTs obtained after testing in the bidirectional configuration. There was no significant difference between them, suggesting that if a good resting period between successive inductions was observed, there were no sequential effects on the final DFT.*

Finally, the shock impedances within one configuration did not resolve into any statistical difference supporting a direct correlation between the impedance and the final DFT. Within the same group, there was no relationship between the final DFT and the shock impedances ($r = 0.28$ for the TRIAD group and $r = 0.22$ for the distal coil group).

Seventeen patients out of 35 were on amiodarone. In this group there was no correlation between drug therapy and the final DFT in both configurations (5 patients had an equal DFT, 6 patients had a bidirectional DFT < monodirectional DFT and 6 had a bidirectional DFT > monodirectional DFT). Very few patients were on beta-blockers (2 out of 35).

Discussion

The reduction of the ICD size and the use of low defibrillation energies with good safety margins has been the objective of the last years. New defibrillation waveforms and the use of biphasic waves[2] greatly contributed to reduce the amount of energy necessary for defibrillation. Furthermore, the development of leads with shunt resistors that allow for a better distribution of the energy has been documented[3,4]. The use of the ICD device as an active electrode (TRIAD) has contributed to lower the measured DFTs[5-7]. The ability to interchange the number of active electrodes and their positions has permitted physicians to control the outcome of the results. The change in defibrillation geometry has allowed placement of the electrical vector in positions where more cardiac mass could be affected.

Previous studies by Bardy et al.[5] demonstrated the usefulness of the active can for defibrillation with a single coil lead and the absence, in a small group of patients, of a significant benefit in spite of a system rendered more complex by the addition of a second coil in the superior vena cava[11].

Recently Gold et al.[12,13] published two papers on this issue: in the first[12] they compared, in a small population, three different configurations for shock delivery and, in the second[13] they performed, in a greater number of patients, only monodirectional and bidirectional vectors. In both they concluded that the bidirectional configuration was better than the monodirectional one.

The aim of this paper was to test the results, in terms of a lowered DFT, of two defibrillation configurations. In the first one, called the bidirectional vector or TRIAD configuration, the energy is delivered from the proximal coil of the lead and canalized towards two active positive electrodes, the proximal electrode being situated in the lead itself proximal to the superior vena cava, and the second being the ICD itself. This allows for a bifurcation of the defibrillation energy vector towards the area of the right atrium and towards the left pectoral area. This configuration seems geometrically better since most of the cardiac mass will be affected by the electrical wave energy. In the second, monodirectional configuration, the proximal electrode is suppressed allowing for only one energy vector, that is to say, distal coil to active can of the device. Our results are consistent with those reported by Gold et al. Some methodological differences in our study (multicenter study, more detailed step down DFT search including a 12 J test) could render these findings more powerful.

The reason why the second configuration was tested was its simplicity. If the final DFTs were to be lower than the bidirectional configuration, we could have a system consisting of less parts since the proximal coil of the lead would not be necessary. Therefore, the diameter of the lead would be reduced.

As was stated in the Results section, the bidirectional configuration gave a significantly lower DFT value

than the monodirectional vector. This could be a consequence of the increased number of cardiac cells that are somewhat affected by the defibrillation waveform as opposed to that of the monodirectional configuration[9]. The analysis of the shock impedances has shown a significantly lower impedance in the bidirectional configuration as opposed to the other one. This implies that the current circulating in the TRIAD configuration, with a low impedance compared to the monodirectional configuration, is higher and therefore more cells could be affected. Unfortunately, using the implanted device for DFT testing, it is not possible to measure the actual intensity of current. For this reason, we can only hypothesize an increase in current as a result of the drop in impedance in the bidirectional configuration. Even though the current intensity in a lower impedance system is higher, the energy used for each shock is determined only by the programmed level. Thus, the device longevity is not affected by the low impedance.

The impedance values within the same group were subsequently analyzed. The linear correlation between impedances and the final DFT was analyzed and no significant relationship was found. These results are opposed to the difference between configurations since these differences in impedance were mainly due to the nature of the vectorial configuration of the shock wave and to the amount of myocardial cells affected.

With respect to the possible effect of several inductions and shocks on the final DFT, further analysis of the data revealed that the final DFT obtained was independent of the number of shocks received. This is surely due to the fact that, between two successive inductions, a time lapse sufficient to allow recovery of the patient was required. Furthermore, it could be said that the anesthetic drugs given do not affect the final DFT.

This finding could allow the accurate determination of a true DFT regardless of the number of ventricular fibrillation inductions.

In conclusion, the acute results comparing two defibrillating configurations have shown that a bidirectional electrical vector produces a lower DFT than a single vector configuration. The bidirectional configuration, also known as TRIAD, uses both coils of the defibrillation lead together with the active can of the ICD. The monodirectional configuration uses the distal coil of the lead and the active can of the defibrillator.

These results confirm the need of an electrical vector that covers as much of the cardiac surface as possible whilst at the same time decreasing the shock impedance and therefore increasing the shock current. Although the two groups of findings were significantly different, this aspect would not have a big impact on clinical practice since this difference would not particularly influence the final amount of energy delivered by the device. Anyway, these results may be considered as preliminary findings which may lead to improvements in the device.

As a secondary result, it has been observed that the number of inductions has no sequential effect on the final DFT, provided that a sufficiently long time is allowed between inductions to permit patient recovery and a return to baseline values.

Study limitations. It has to be pointed out that these are short-term results and that at present long-term studies cannot be carried out since it is not possible to switch configurations unless the patient is resubmitted to surgery. Old studies showed that the DFT tended to rise both with monophasic and biphasic waveforms[14,15]; based on more recent investigations (including newer electrode systems such as those used in the present study)[16,17], it seems that the DFT tends to remain constant with time, once the chronic stage has been reached. Therefore it could be extrapolated that the bidirectional electrical vector will still be the therapy of choice unless otherwise proven.

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