

ICD Patients with Elevated Defibrillation Threshold: Clinical Behavior and Therapeutic Alternatives

Carlos Eduardo Batista de Lima, Martino Martinelli Filho, Rodrigo Tavares Silva, Wagner Tetsuji Tamaki, Júlio Cesar de Oliveira, Daniela Cabral Martins, Silvana Angelina D'Orío Nishiôka, Anísio Alexandre Andrade Pedrosa, Sérgio Freitas Siqueira, Roberto Costa

Instituto do Coração do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo - Unidade de Estimulação Cardíaca Artificial, São Paulo, SP - Brazil

Summary

Background: The ideal programming of the implantable cardioverter defibrillator (ICD) shock energy should be at least 10J above the defibrillation threshold (DFT), requiring alternative techniques when the DFT is elevated.

Objective: To assess the clinical behavior of ICD patients with DFT > 25J and the efficacy of the chosen therapy.

Methods: Patients who had undergone ICD implantation between Jan/00 and Aug/04 (prospective database) and presented intraoperative DFT > 25J were selected. The analyzed variables were: clinical characteristics, LVEF, rescue of arrhythmic events from ICD and causes of deaths.

Results: among 476 patients, 16 (3.36%) presented DFT > 25J. The mean age was 56.5 years, and 13 patients (81%) were men. According to the baseline cardiomyopathy, 09 patients had Chagas' disease, 04 had ischemic cardiomyopathy and 03 had idiopathic cardiomyopathy. Mean LVEF was 0.37 and amiodarone was used by 94% of the patients. Mean follow-up (FU) period was 25.3 months. DFT was higher than maximum energy shock (MES) in 2 patients and it was necessary to implant an additional shock electrode (array). It was programmed MES in ventricular fibrillation zone of ICD therapy in the other patients. In the FU, 03 patients had 67 successful appropriate shock therapies (AST). There were 05 noncardiac and 02 heart failure deaths. The patients who died showed higher DFT levels ($p=0.044$) without correlation with death because there wasn't unsuccessful AST.

Conclusion: In this cohort of ICD patients, the occurrence of elevated DFT (>25J) was low, leading to alternative therapies. There was an association with severe ventricular dysfunction, although without correlation to the causes of death. (Arq Bras Cardiol 2008; 90(3):160-166)

Key words: Defibrillation threshold; defibrillators, implantable; death, sudden, cardiac.

Introduction

In 1960, Zoll¹ demonstrated that ventricular fibrillation (VF) could be reverted with the use of electricity and based on these principles, Mirowski et al² designed the implantable cardioverter defibrillator (ICD). After decades of studies carried out in dogs, they performed the first defibrillator implant in humans in 1980^{1,2}. Since then, several clinical studies have been performed, demonstrating the benefits of the ICD in reducing total and arrhythmic mortality in patients at high risk for sudden cardiac death (SCD)³⁻⁵. This benefit must be associated to a device-patient interaction, where the implanted system must be working perfectly with adequate Intraoperative electronic assessment measures^{6,7}.

During the ICD implantation, the defibrillation threshold (DFT) test is carried out through VF induction and shock

therapy release from the implanted device, evaluating the necessary energy for an effective defibrillation. Currently, the margin of safety considered adequate is that of 10J above the found DFT⁸. The capacity for energy storage and release of the current ICD devices varies from 30 to 39J, which does not allow an adequate margin of safety in some cases. The aim of this study was to analyze the clinical evolution and the procedures in patients with ICD and elevated DFT.

Methods

Patients that had been submitted to ICD implant or change of generator (CG), and that presented elevated intraoperative DFT (>25J) in the absence of the margin of safety of 10J, were selected from the prospective database of the Service of Artificial Cardiac Stimulation of Instituto do Coração (The Heart Institute) of Hospital das Clínicas of the School of Medicine of the University of São Paulo. The patients with an ICD device presented Class I indication and level of evidence A established in the scientific literature

Mailing address: Carlos Eduardo Batista de Lima •
Rua Alves Guimarães, 408/122 - Pinheiros - 05410-000 - São Paulo, SP - Brazil
E-mail: carlos.lima@cardiol.br, carloseduardo_lima@yahoo.com.br
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as secondary prevention of SCD, i.e., those with episodes of syncopal ventricular tachycardia (VT), ventricular dysfunction and monomorphic sustained VT induced at the invasive electrophysiological study; spontaneous episodes of sustained VT with hemodynamic instability and recovered cardiac arrest due to VF or VT without a pulse⁹. The variables analyzed were: age, sex, base cardiopathy, heart failure functional class (New York Heart Association), LVEF at the echocardiogram, antiarrhythmic therapy and clinical evolution data including time of follow-up, arrhythmic event ICD rescue, deaths and procedures adopted to decrease the DFT.

Surgical procedure

The implants were preferably performed in the left pectoral region, with the objective of attaining a better shock axis due to the participation of an active generator shell as the shock pole, allowing a better chance of defibrillation. The used surgical implant technique was the transvenous one with the implantation of endocardic electrodes with venous access obtained through the subclavian vein puncture or dissection of the cephalic vein and implant of the ventricular electrode, preferably in a septal region of the right ventricle (RV). In some cases, an atrial electrode was implanted with a double-chamber ICD, to the discretion of the assistant physician. In cases of reoperations for optimization of the ICD artificial cardiac stimulation system in patients with prior pacemaker implant on the right pectoral or abdominal region, the previous site of implant was maintained, whenever possible, with the objective of re-using the old electrodes for the antibradycardia and sensitivity function. The intraoperative DFT test was performed according to the standard protocol of our institution (Fig. 1), with the first charge being half of the maximum energy of the implanted device, followed by a shock 10J below the maximum energy of the device to obtain an adequate margin of safety; if unsuccessful, a shock with the maximum energy of the device was applied and, if

necessary, an external 360J shock, according to the advanced life support guidelines in cardiology of the ACC/AHA¹⁰⁻¹².

Configurations and specifications of the generators and electrodes used

The generators used were manufactured by Biotronik Inc.: Belos VR (05) and Tachos DR (02); by Medtronic Inc., Minneapolis, MN, U.S.A.: GEM DR 7271 (01), GEM III 7275 (01); by Guidant Inc., St Paul, MN, U.S.A.: Ventak Prism 2 DR (01), Ventak Mini III 1786 (02) and Ventritex V 185C (02); by St. Jude Inc.: Photon DR V230HV (02). The characteristics of the implanted artificial cardiac stimulation system are described in Tables 1 and 2.

Statistical Analysis

In the group of patients with elevated DFT, the means of the DFT values were compared between patients who died and those who survived using Spearman's correlation coefficient. A *p* value < 0.05 was considered statistically significant.

Results

The data of procedures performed between January 2000 and August 2004 were analyzed, which constituted a cohort of 476 patients, of whom 16 (3.36%) were selected, as they presented elevated DFT (Fig. 2). The male sex was predominant (81%), with a mean age of 56.5 ± 9.33 years. Regarding the base cardiopathy, 09 patients (56%) presented chagasic etiology, 04 (19%) presented ischemic cardiopathy and 03 (25%) presented idiopathic dilated cardiomyopathy. The left ventricle ejection fraction (LVEF) was 0.37 ± 0.09 . The clinical characteristics of the patients with elevated DFT are described in Table 3.

Antiarrhythmic therapeutic

Most of the patients (94%) had used amiodarone (daily dose of 200 to 300 mg) for at least 2 months prior to the surgical procedure of the ICD implant or CG and no other isolated or associated antiarrhythmics were used during follow-up.

Intraoperative Data

A total of 8 ICD implants and 8 ICD CG were carried out. The site of the generator was the right pectoral region in 02 cases, left pectoral region in 09 cases and abdominal region in 05 cases. The electronic parameters measured in the intraoperative period and the procedures for decreasing the DFT are shown in Table 4. The maximum programmable shock energy (SH) of the ICD devices varied from 30 to 39J and the mean DFT was $32.5 \text{ J} (\pm 6.5)$.

Alternative procedures as an attempt to decrease the DFT

The inversion of shock wave polarity (AX>B to B<AX, where AX corresponds to the active generator shell associated to proximal shock coil and B corresponds to the distal shock

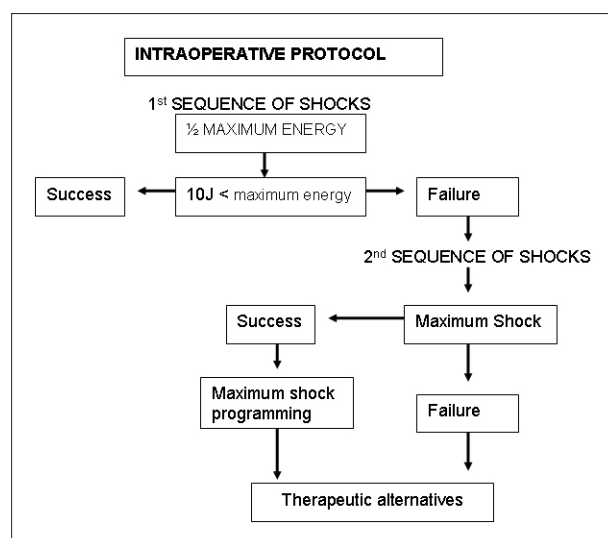


Fig. 1 - Standard protocol for the intraoperative DFT test.

Table 1 - Characteristics of the implantable heart stimulation system.

Patients	Device	Ventricular electrode	Active generator shell	Ventricular electrode – shock coil	Implantation sitesurgery (months)	Shock waveform
1	Belos VR	Kainox SL 75/16	Y	D	LP	B
2	Photon DR V230HV	Endotak 0072	Y	D	R Abd	B
3	Belos VR	Kainox SL 75/16	Y	D	LP	B
4	Gem DR 7271	Fidelis 6943	Y	S	LP	B
5	Ventak Prism 2 DR	Endotak 0072	Y	D	LP	B
6	Photon DR V 230HV	TelectronicsSPR	Y	S	LP	B
7	Belos VR	Kainox SL 75/16	Y	D	LP	B
8	Gem III DR 7275	Endotak 0072	Y	D	R Abd	B
9	Tachos DR	Kainox SL 75/16	Y	D	LP	B
10	Belos DR	Kainox SL 75/16	Y	D	RP	B
11	Ventak Mini III 1786	Endotak 0072	Y	D	R Abd	B
12	Ventritex V 185 C	Endotak 0072	Y	D	L Abd	B
13	Tachos DR	Kainox SL 75/16	Y	D	LP	B
14	Ventritex V158C	Endotak 0072	Y	D	LP	B
15	Belos VR	Kainox SL 75/16	Y	D	RP	B
16	Ventak Mini III 1786	Endotak 0072	Y	D	L Abd	B

Y - yes; N - no; S - single coil shock electrode; D - double coil shock electrode; LP - left pectoral; RP - right pectoral; Abd - abdominal; B - biphasic shock waveform.

Table 2- Defibrillator electrodes used.

Manufacturer	Models
Biotronik	Kainox SL 75/16
CPI – Guidant	Endotak C 0072
Medtronic	Sprint Fidelis 6943, SQ 6996, VCS 6937
St Jude Medical	Telectronics SPR

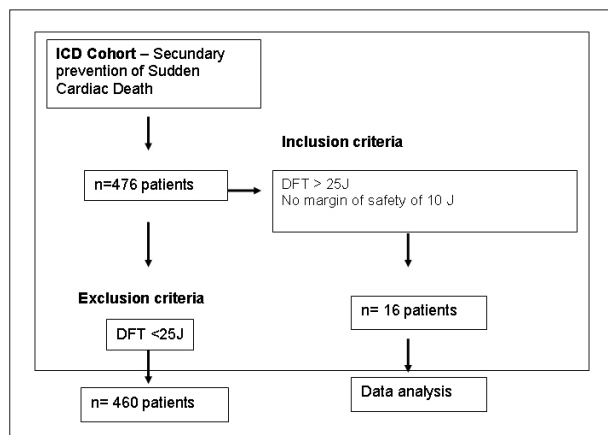


Fig. 2 - Study protocol plan.

coil of the RV electrode) was performed in 4 cases without success in reducing DFT.

The shock electrode in the RV was repositioned in 4

cases, of which 1 was successful, presenting DFT reduction from 30 to 20J, thus attaining an adequate margin of safety. An additional shock electrode was implanted in the superior vena cava (SVC) in 1 case, with reduction in DFT from 30 to 20J and the electrode implant failed in another case due to SVC thrombosis. An additional shock electrode (array) implant was necessary in two cases where the DFT was higher than the maximum energy of the implanted device. These electrodes were implanted in a second surgical time by left lateral thoracotomy in one case and by videothoracoscopy in another; in both cases, the electrodes had been initially implanted in a subcutaneous region without adequate DFT reduction. The posterior epicardial implant were successful, with a decrease > 10J in the DFT, with no additional surgical complications.

Evolution Data

The mean follow-up period was 25.3±17.7 months. All patients' programming was maintained at maximum shock in the fast tachyarrhythmia zone (>182 bpm). The appropriate therapy was successful in 100% of the cases, with 3 patients presenting shock therapy with 1 shock in 1 patient, 2 shocks in another and 64 shocks in another analyzed during the entire follow-up. The frequency of appropriate shock therapies was 18%. There were 7 deaths, with 5 being of non-cardiac cause, including liver failure due to hepatocarcinoma, multiple-organ failure, septic shock and O2 due to advanced heart failure evolution. One patient had been submitted to heart transplant and the data prior to the transplant were analyzed.

Table 3- Patients with elevated defibrillation threshold (DFT): clinical characteristics.

	Elevated DFT
Total of patients (n)	16
Age (yrs) (SD)	56.5 ± 9.33
Male sex % (n)	81 (13)
Time of follow-up (months) (SD)	25.3± 17.7
Mean DFT (J) (SD)	32.5 ± 3.5
Underlying cardiopathy % (n)	
Ischemic	25 (3)
Chagasic	56 (9)
Idiopathic	19 (4)
HF Functional Class (NYHA) % (n)	
I / II	63 (10)
III / IV	37(6)
LVEF (SD)	0.37±0.09
Amiodarone use % (n)	94 (15)

SD - standard deviation; elevated DFT - elevated defibrillation threshold; HF - heart failure; NYHA - New York Heart Association; LVEF - left ventricular ejection fraction.

Discussion

The incidence of elevated intraoperative DFT during the ICD implant is quite variable in the literature, with values between 0 and 24% having been reported¹³. One explanation for the varied results is that the cardiac stimulation systems used were also varied and with the technological improvement of the devices, which currently have smaller generators that allow the implant in the pectoral region, an active generator shell, transvenous electrodes with double coil and biphasic shock waveform, the finding of an elevated DFT has been less frequent¹⁴.

The incidence of this problem in our study was low (3.36%), maybe because most of the devices used for these patients had the aforementioned characteristics. The term “defibrillation threshold” has been questioned by some authors, considering that the actual DFT measurement is not currently performed. During the DFT test, the attainment of the margin of safety is enough for the successful ICD implant, thus the term “energy necessary for defibrillation” (END) is considered more adequate¹³. The stringent DFT attainment would require a series of successive shocks for the defibrillation, which could induce the deterioration of the patient’s hemodynamic state¹³.

The maintenance of the prior surgical site in patients with

Table 4- Intraoperative electronic assessment and procedures for decreasing the elevated DFT

Patients	RV stimulation threshold (V)	Ventricular sensitivity (mV)	Ventricular impedance (Ohms)	Shock Impedance (Ohms)	DFT 1(J)	Alternative procedure	DFT 2 (J)
1	0.7	15	569	39	30	RE	20
2	1.9	8.5	526	40	33	MS	33
3	0.3	20	770	41	30	MS	30
4	1.5	22	984		30	RE and RP N/ SUC. SVC	20
5	0.7	VSD	450	62	26	MS	26
6	1.7	9.0	600	30	33	MS	33
7	0.3	20	740	38	30	RP and RE N/ SUC. ARRAY	20
8	2.0	11	773	32	30	RP and SVC N/SUC - thrombosis. ARRAY	20
9	0.8	20	800	66	30	MS	30
10	0.8	26	550	43	30	MS	30
11	1.5	10.7	480	41	31	MS	31
12	1.3	5.5	440	50	39	MS	39
13	0.6	VSD	590	39	30	MS	30
14	1.4	7.4	420	30	38	MS	38
15	0.3	20	530	30	>30	RE and RP N/SUC. MS	30
16	1.5	8.0	410	34	31	MS	31

RE - repositioning of the right ventricle shock electrode; RP - reversal of shock polarity; SVC - additional shock electrode positioned at superior vena cava; MS - shock therapy programming at the site of fast tachyarrhythmia in maximum shock; ARRAY - additional shock electrode (array type); N/SUC - no success; DFT 1 - DFT at the 1st test; DFT 2 - DFT after alternative procedures. VSD - ventricular-stimulation dependent, without escape rhythm.

previous pacemaker implant is an adequate procedure in some cases; however, it can increase the chance of finding an elevated DFT, considering that the placement of the active generator shell in the right pectoral or abdominal regions makes the shock axis (generator-SVC-RV) unfavorable, not encompassing a large myocardial area during the defibrillator shock therapy (Fig. 3)¹⁵. Some devices have a new programming that allows the inversion of shock wave polarity, with the distal shock coil in the right ventricle being the positive pole (anode) and the proximal coil in the SVC, together with the active generator shell, being the negative pole (cathode) and vice-versa. The DFT decrease with the inversion of shock wave polarity was described in some studies and no pattern of polarity is considered to be the best one, considering that the distal shock coil as the anode can promote a lower DFT in some cases and a higher one in others; thus, it is necessary to repeat the DFT test after any alteration in shock wave polarity^{13,16}. Another limitation is that the programming of the inversion of shock wave polarity is not available in all the used devices. In our study, the inversion of polarity was carried out in three cases; however, this method was not successful.

When facing an elevated DFT, the repositioning of the ventricular electrode must be attempted in case of failure after the inversion of polarity; the best shock axis must be observed, with the preference for the implant in the septal region of the RV. When the ICD generator change is necessary (reoperations), it is not usually possible to reposition the ventricular electrode due to the chronic healing and electrode impaction processes, which make electrode removal difficult, especially in cases with more than one year of electrode implant. The repositioning of the ventricular electrode was performed in 04 cases, although the procedure was successful in only one of them, with a reduction of 10J in the DFT and attainment of an adequate margin of safety. Despite the low success rate obtained with this procedure in the present cohort, we consider it must

be performed, if necessary, as it is a simple procedure that has shown satisfactory results as reported in some studies in the literature¹⁷.

When the defibrillator is not capable of reverting the induced arrhythmia (VF) with the maximum shock, i.e., when the DFT is higher than the maximum energy of the implanted ICD shock therapy, the implant of the additional shock electrode positioned in the SVC, as well as a patch or array electrode, can decrease the DFT, as they encompass a larger area of myocardial mass, thus optimizing the shock axis^{18,19}. In the present study, satisfactory results were obtained with the implant of an additional shock electrode positioned in the SVC, with a successful outcome in 01 case, with a decrease of 10J in DFT and no success in another case due to the difficulties in the venous access. The DFT was higher than the energy of the implanted device in 02 cases and the implant of an additional shock electrode (array) was successfully carried out, with a decrease of 10J in DFT in these cases. In the cases that presented VF reversion only when the maximum shock therapy of the implanted device was applied and considering the difficulties of obtaining a more stringent DFT due to the possible worsening of the hemodynamic state in patients with borderline pressure levels after the anesthetic induction or other clinical reasons, we considered the DFT as being the maximum energy of the implanted device. In these cases, a maximum energy shock therapy programming in the zone of fast tachyarrhythmia (>182bpm) was chosen as well as a more stringent outpatient follow-up, with the programming of the implant of an additional shock electrode (array) in a second surgical time to obtain the adequate margin of safety, hence offering a better protection to these patients.

Rattes et al²⁰ have reported that the percentage of successful defibrillations is, on average, 76.4% at the level of the actual DFT and that 100% of the successful defibrillations were attained with shock therapy release 1.2 to 1.4 times the DFT in animal studies²⁰. Some studies consider 5J to be an adequate

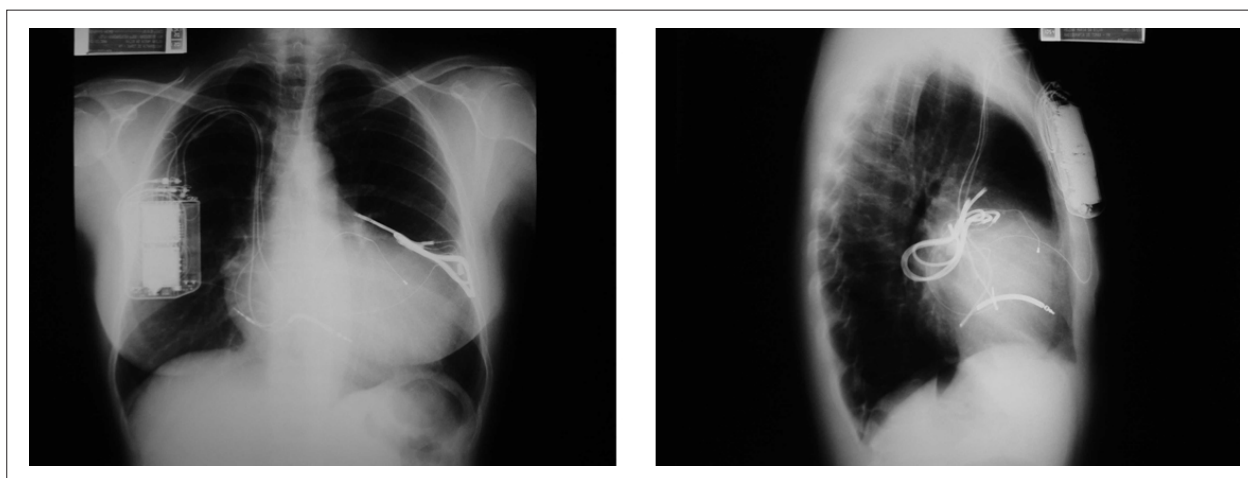


Fig. 3 - Chest x-ray in AP and side views. Patient with ICD on the right side due to previous pacemaker implant, thus maintaining the prior surgical site. The patient presented DFT above the maximum shock energy of the implanted device and needed external defibrillation. Additional shock electrode (array) implant in the epicardial region with decrease in DFT by 10J.

margin of safety in the DFT and some authors even consider it unnecessary to perform the defibrillation test²¹⁻²⁵.

The maintenance of the amiodarone therapy was chosen in these cases aiming at offering additional protection in the prevention of sudden arrhythmic death, reduction of arrhythmias and, consequently, defibrillator shock therapy²⁶. Some authors suggest, as an adequate procedure, the withdrawal of antiarrhythmic drugs, especially amiodarone, due to the characteristic of defibrillation threshold increase attributable to this drug^{27,28}. The small incidence of shock therapy occurrence in the present study hinders the analysis of safety in these patients; however, the 03 patients who received shocks presented a DFT equal to the maximum shock energy of the device and used amiodarone with shock therapy programming at maximum shock energy, with 100% of therapy success.

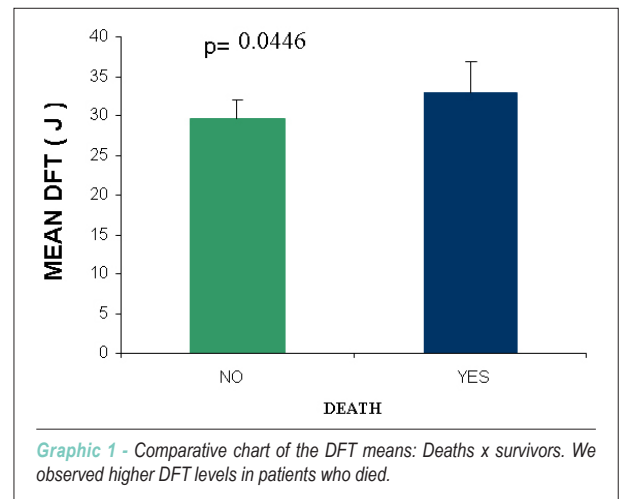
In these cases, where the VF reversion was possible only with the ICD maximum shock energy, the margin of safety can be 1 to 9J and the additional shock electrode implant (array type) is necessary.

There was a long-term follow-up (> 2 years) and despite the elevated mortality (43.75%) in this group of patients with elevated DFT, there were no deaths due to arrhythmia or unsuccessful appropriate shock therapies. When Spearman's correlation coefficient is used to compare the patients with elevated DFT who died with those who survived, we observed that the DFT was higher among those who died ($p=0.044$), identifying patients with higher mortality (Graph. 1).

We suggest a sequence of procedures that must be followed, which can be adapted, whenever possible, on an individual basis: 1- reversion of shock polarity; 2- repositioning of the shock electrode; 3- additional shock electrode positioned in the SVC or additional shock electrode (array type); 4- maximum shock programming while in surgical programming for array electrode implant (if the DFT is lower than the maximum shock energy of the implanted ICD, but without the adequate margin of safety).

There are several mechanisms for the occurrence of an elevated DFT and it is difficult to predict its onset; however, the influence of some associated factors such as age, male sex, LV dysfunction and the use of antiarrhythmic drugs (especially amiodarone) on the DFT of patients with ICD has been described in other clinical studies²⁹⁻³².

The presence of an elevated DFT or the elevated energy necessary for the defibrillation (END) constitutes a challenge for the physician who is performing the procedure, considering that the success of the defibrillator implant depends on



an adequate margin of safety; there are some therapeutic alternatives for decreasing DFT, but they must be adapted on an individual basis.

Conclusion

There was a low incidence of elevated DFT in this cohort of patients with ICD. Additionally, there was an association between elevated DFT and severe ventricular dysfunction, male sex, amiodarone use and positioning of the generator on the right pectoral or abdominal regions. The alternative procedures of repositioning the ventricular electrode, reversion of shock polarity and the implant of additional electrode in the SVC or an additional shock electrode (array type), when individually adapted, are therapeutic options in cases with an elevated defibrillation threshold with no margin of safety, providing the benefit of the ICD in the prevention of sudden cardiac death in these patients.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

Sources of Funding

There were no external funding sources for this study.

Study Association

This study is not associated with any graduation program.

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