

High defibrillation threshold in patients with implantable cardioverter-defibrillator. How to solve the problem, single-center experience

Michał Lewandowski, Andrzej Przybylski, Alicja Kraska and Hanna Szwed II Department of Coronary Artery Disease, National Institute of Cardiology, Warsaw, Poland

Abstract

Standard implantable cardioverter-defibrillator with transvenous leads systems have proven to be effective in terminating ventricular tachyarrhythmias in most patients (more then 90%) with sufficient safety margin, i.e. difference between maximal output energy of the ICD and defibrillation threshold. However in some clinical situation it is not possible, energy requirement is higher than normal, it is called high defibrillation threshold. We report clinical data of 3 patients with high defibrillation threshold among 415 ICD's implanted in our institution (cases of ischaemic cardiomyopathy, dilated cardiomyopathy and hypertrophic cardiomyopathy are presented). We summarize our experience, therapeutic options and literature review investigating factors which influence defibrillation threshold: related to underlying cardiac disease, therapy (drugs interactions) and ICD system(lead and pulse generator type). (Folia Cardiol. 2006; 13: 396–403)

Key words: implantable cardioverter-defibrillator (ICD), high defibrillation treshold

Introduction

The technological development of an implantable cardioverter-defibrillator (ICD) in the last decade has made the transvenous implantation of the device a fairly simple surgical procedure. ICD miniaturisation, the possibility of subcutaneous implantation, technically similar to that of cardiac pacemaker, together with low intraoperative mortality (according to some sources < 0.5%) [1] on the one hand, and a significant number of trials proving the efficiency of this method of therapy in

primary and secondary prevention on the other [2, 3] have caused a rapid increase in the number of implantations performed. Nonetheless this therapeutic method has its limitations like any other. The number of complications is increasing, both surgical and psychological, which are more difficult to evaluate and are often underesteemated [4, 5]. It seems that the greatest problems are still ahead of us since this branch of electrotherapy is still young and we do not have enough experience or long-term observations, for example in removing damaged leads or long-term consequences of implanting ICDs in children. Among many problems coming along with this method of treatment a high defibrillation threshold is one of the most difficult ones. It either renders the implantation impossible in accord with good clinical practice or leaves too narrow a safety margin after the procedure. In the latter case a procedure has sometimes to be repeated, it usually takes more time, is technically more complicated than standard implantation and it does not always end successfully. This article addresses the

Address for correspondence: Michał Lewandowski, MD, PhD

II Department of Coronary Artery Disease

National Institute of Cardiology Spartańska 1, 02–637 Warsaw, Poland

Fax: +48 22 844 95 10

e-mail: m.lewandowski@ikard.waw.pl

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very problem, as seen in our own observations. The definition of high defibrillation threshold has to be recalled here. Defibrillation threshold (DFT) is the simplest method of evaluating the efficacy of defibrillation impulse, defined as the lowest energy output that terminates arrhythmia. Historically it was stated that the difference between a given type ICD's maximum energy shock and DFT should not be less than 10 J. This value dates back to the period of developing the procedure in the 1990s. when epicardial leads were used. The most recent studies on endocardial leads recommend the safety margin of 1.9 DFT that guarantees a 95% efficiency probability [6].

Besides the above mentioned need to leave sufficient energy surplus in respect to maximum energy output of a given defibrillator the DFT value influences longevity of the battery. Low DFT values also eliminate the need to use additional leads during the ICD implantation which of course simplifies the procedure.

There are many factors influencing the defibrillation threshold. They can be divided with respect to the patient (underlying disease), treatment (the effect of the drugs) and the ICD system applied (the lead and the impulses' generator).

This article is a compilation of the experiences gathered in our centre together with the review of literature concerning the management of patients with high defibrillation threshold.

Methods

In the II Department of Coronary Artery Disease, Institute of Cardiology in Warsaw, 415 cardioverter-defibrillators were implanted.

In our centre the DFT is determined intraoperatively, by an orientational method, testing the DFT range from 10 J upward, so as to achieve successful defibrillation, leaving the surplus margin of 10 J in respect to the device's maximum energy output. Practically we routinely test 3 energy values: 10, 15 and 20 J.

Only when DFT ranges between 20–30 J we evaluate it very precisely. We believe that precise evaluation of DFT in most patients is not useful from the clinical point of view, it prolongs the procedure, requires multiple defibrillations (DF) and needlessly uses up the device's battery.

Using the technique described above, in 3 patients (0.72% of analysed group), we were not able to achieve the determined safety margin during the first procedure. We discuss these patients in the chronological order.

Patient 1

A 71-year old man with post-infarction cardiomyopathy was referred to our Department from a county hospital where he was admitted due to ventricular tachycardia with hypotension 90/50 mm Hg. These symptoms were well tolerated by the patient. Since pharmacotherapy was not effective, tachycardia was terminated by 100 J electric cardioversion, standard doses of amiodarone were administered and the patient was transferred into our Department for the ICD implantation. In the course of routine diagnostic procedures a post-infarction heart failure was diagnosed. Echocardiography and ventriculography findings demonstrated large dyskinetic aneurysm of the anterior heart wall, left ventricular ejection fraction (EF) about 20% and left ventricular end-diastolic diameter (LVEDD) 7.2 cm. Due to coronarography results the patient did not qualify for revascularisation treatment (left anterior descending artery (LAD) leading to the infarct zone was totally occluded). The indications for ICD implantation were determined. Intraoperatively, with the lead typically placed (SPS 75UP/BP, Biotronik) in the right ventricle's apex, the maximum output energy of the implanted ICD (Phylax 06, Biotronik) =30 I did not terminate ventricular fibrillation (VF). The lead was placed in different positions several times, even with the unorthodox placement on the interventricular septum. The successful intracardiac defibrillation was not achieved though. Naturally all possible programmable parameters modifications (impulse's shape and leads' polarity) were tried as well. In that case, after consulting with the manufacturer (no available subcutaneous net type lead able to lower DFT) an additional lead SVC type was implanted into superior vena cava. Unfortunately it did not help to achieve DFT < 30 J. Numerous unsuccessful internal defibrillations (12 tries overall) and successful termination of ventricular fibrillation only after an external defibrillation with maximum energy of 360 J delivered twice made the team drop the implantation procedure.

After the failed procedure it was stated that there are indications for buying a higher energy device, which at that time (1997) required a concession from the Ministry of Health. The patient had no symptoms, had no recorded clinically significant arrhythmias in repeated Holter ECG, serum amidarone level was in therapeutic range. Such being the case the patient was discharged but remained under Clinic's ambulatory surveillance (regular controls were performed every 2 months, including Holter ECG). Eight months after the hospitalisation the patient suddenly died at home.

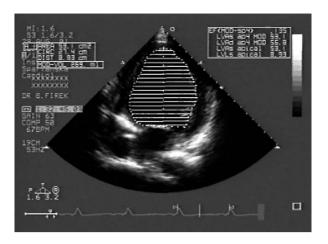


Figure 1. Echocardiogram of dilated cardiomyopathy demonstrating an enlarged left ventricle.

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Figure 2. Echocardiogram of hypertrophic cardiomyopathy demonstrating hypertrophy of the interventricular septum and left ventricle.

Patient 2

A 44-year old man with post-inflammatory cardiomyopathy, after sudden cardiac arrest caused by VF, successfully resuscitated by the family and later on by a medical emergency team. He was admitted into the Department for an ICD implantation as "a bridge therapy" while waiting for a planned heart transplant. He was diagnosed with congestive heart failure NYHA III/IV, EF was about 10%, LVEDD 9.1 cm (echocardiography's picture is presented on Fig. 1). Intraoperatively with the lead typically placed (KAINOX-SL 75/15 with two defibrillating coils) in the right ventricle's apex maximum energy output of implanted ICD (Mycrophylax plus, Biotronik) = 30 J was not sufficient to terminate VF. The lead was replaced several times, with different positions being checked out. A successful defibrillation was not achieved with satisfactory DFT after modifying and checking out all possible programmable parameters (impulse's shape and lead's polarity). Defibrillator was left in place since the maximum energy output was efficient at first try, although we were not able to reproduce this effect for the second time. Another attempt was undertaken 5 days after the first surgical procedure in the presence of manufacturer's representative who was a high DFT specialist. A successful internal DF was not achieved. Because of that the patient was placed on emergency Poltransplant's list, after consulting the case with the cooperating transplantology centre. He awaited the operation in Intensive Cardiac Care Unit for two months due to a rare blood type. The heart transplant with the ICD removal was uncomplicated. The patient stays asymptomatic in the Outpatients' Transplantology department.

Patient 3

A 21-year old woman with hypertrophic cardiomyopathy diagnosed a few years before was referred into the Department for prophylactic implantation of an ICD, due to a high risk of sudden cardiac arrest (large heart hypertrophy, a significant blood pressure drop and signs of ischaemia in ECG during the ECG exercise test). She had had a cardiac pacemaker AAI implanted previously due to a sinus node's automatism insufficiency while treated with a beta-blocker.

Echocardiography performed before the operation (Fig. 2) demonstrated a monstrous heart's muscle hypertrophy (interventricular septum width = 4.5 cm, left ventricle free wall width = 5.0 cm) and a hairline narrowing of both ventricles' lumen. Intraoperatively using the defibrillating lead with two coils typically placed in the right ventricle's apex and a properly working pacing lead in the right atrium's aurix, maximum energy output of the implanted ICD (Photon DR) = 30 J did not terminate VF. The lead was replaced several times but even after changing the lead into a screw-type (TVL-ADX 1559, St. Jude Medical), repeating the placing procedure complete with "on the interventricular septum" position, a successful internal defibrillation was not achieved. All possible modifications of programmable parameters were of course checked out (impulse's shape and lead's polarity), (the placing of the lead on this stage of the procedure is shown on Fig. 3). The procedure was then ended and a re-operation with higher energy device implantation was planned. After asking for the delivery of the highest energy ICD available on the market = 36 J and a subcutaneous lead able to



Figure 3. Chest radiograph demonstrating position of the impulse generator (Photon DR) and leads in chambers of right heart.

decrease DFT by Medtronic, the date of the second surgical procedure was set. The second procedure took place 3 weeks after the first, in the presence of manufacturer's representative, a high DFT specialist. It started with trying to optimise the impulse's width according to a recommendation table sent with the device ATLAS DR (ICD alternative Defibrillation Bi-Phasic Waveform Pulse Width Recommendations). The efforts undertaken did not bring about the awaited DFT lowering. In this case the patient was re-operated, the lead was replaced into the right ventricle's apex and an additional lead was placed in left subclavian vein (TLV SV02 Ventritex, St. Jude Medical), so as to allow the defibrillation impulse to encompass the whole hypertrophied left ventricle. DFT was gauged with the leads so placed (Fig. 4) and a borderline value of 22.5 J was reached. Anticipating the progression of the disease (continued hypertrophy) an ATLAS DR device was implanted (it was the first procedure of this kind in Poland). Its maximum energy output 36 J provided a satisfactory safety margin. Post-operative period was uncomplicated. The device test 5 days after the operation was satisfactory — elicited ventricular fibrillation was successfully terminated by ICD (25 J). Six months after the operation the patient was asked to have another defibrillation threshold assessment test but she refused. She remains in ambulatory care and for 1.5 years she has had no ICD interventions.

In the cases presented the operation time and the X-ray radiation time were: 1) 188/20 min, 2) 120/6 min, 3) 210/6 min respectively and 150/12 min during the re-operation.

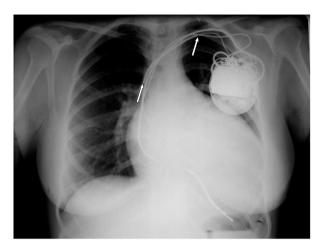


Figure 4. Chest radiograph demonstrating position of the impulse generator (Atlas DR) and leads in chambers of right heart and SVC electrode (arrows) in superior vena cava, left brachio-cephalic vein and left subclavian vein.

Discussion

Chronologically presented clinical cases of various forms of cardiomyopathies show our centre's evolving views and experiences with respect to high DFT treatment. The first, tragically ended one, happened in the "pioneer" period in developing the method in our country. Undoubtedly amiodarone treatment, which does not prevent ventricular fibrillation, must have influenced DFT. Based on the observations published afterwards, we know now that the continuous amiodarone therapy increases the required defibrillation energy by 62% (DFT before the therapy 9.9 \pm 4.6 J vs. 13.7 \pm 5.6 J after reaching the therapeutic doses of the drug p = 0.004) [7]. The effect disappears 3 months after the discontinuation of the therapy. Some researchers postulate in case of treatment with III class antiarrhythmic agents, changing the length of DF impulse's second phase — shortening P2 from 5 to 2 ms [8].

It is known nowadays which of the anti-arrhythmic drugs can modify defibrillation threshold although the available data is a little vague. Different methodology and various clinical profile of the patients can yield opposing results. It is obvious when compared with statistics that 50–70% of patients with implanted ICD are treated with anti-arrhythmic drugs that each case requires an individualised assessment [9].

Among the DFT increasing drugs, apart from the already mentioned amiodarone there are: verapamil, class IB drugs (lidocaine, mexiletine) and class IC drugs (eg. propafenone). The list of drugs decreasing DFT is much shorter: class III drugs with the exclusion of amiodarone ("pure class III effect"). In clinical practice in means sotalol only, since other drugs have not been investigated in that respect [10]. Based on the above mentioned facts some researchers recommend checking DFT 3 weeks and 3 months after amidarone therapy has been initiated, especially since there can be interactions between ICD and anti-arrhythmic drugs other than DFT changes (such as changing arrhythmia cycle, pacing energy threshold or ATP efficacy) [9].

Apart from drugs' effects described above, there are other factors increasing DFT such as: primary disease progression, concomitant diseases, hyperkalemia, hypoxia, ischaemia, pericardial or pleural effusion, leads left in the heart or in the vessels and prolonged ICD implantation procedure with repeated defibrillations [10].

In clinical practice frequently chronic renal failure is a disease influencing DFT. In the course of the disease higher median values of DFT were observed: 15 J when creatinine level is > 1.5 mg% and 12.35 J when < 1.5 mg% [11].

The remaining safety margin is a crucial issue in the case of high DFT value. There are reports arguing that a threshold lower than historical 10 J is acceptable, although in such patients defibrillation efficacy tends to decrease after a year's observation. In one report 445 patients were divided into two groups: 1) 2–6 J safety margin with regard to DFT and 2) 6–12 J safety margin. Defibrillation efficacy was compared in these groups in a predischarge test and after a year. In the two points of time and in the group 2 as compared to 1 defibrillation efficacy was: 100% vs. 99% and 99.6% vs. 96.4% respectively, p = 0.01 [12].

Because of this some researchers postulate not only a pre-discharge test but a routine full test of the implanted ICD in a sedated patient two months after the implantation, to control DFT among other parameters [13]. In this trial 227 patients with a predischarge control test had another control test after 2 months. In 24 of them significant ICD abnormalities requiring correction were found, among others sensing disorders and lead displacement. Six of the patients (5%) required re-operation and in 8% of the patients DFT increase to > 25 J was detected. Some believe that DFT has to be controlled at least once a year, a fact that tends to be forgotten in the everyday practice [14]. The experience gathered up to date shows that 15% patients will have DFT increase > 10 J and 3% will need a re-operation because of that.

Lead's polarity is a well known programmable parameter influencing DFT. The system in which

a lead implanted into right ventricle's apex is an anode (+) is known to have lower DFT value compared to the one in which this lead is a katode.

There is a minority of patients (about 12%) in which the situation described above is reversed [15]. The manoeuvre commonly referred to as polarity reversal is therefore always worth trying since it requires only a programmer and an assessment of DFT in both situations [15].

The second case described presents a patient in the last stages of post-inflammatory dilated cardiomyopathy but the high defibrillation threshold problem stems from the left ventricle dilatation, regardless of etiology either inflammatory or more often ischaemic. With left ventricular diastolic diameter so increased (LVEDD = 9.1; Fig. 1) and the whole heart enlargement, a lead typically placed in the right ventricle's apex and the device's active can might not be able between them to encompass the whole of the left ventricle mass with the delivered defibrillation impulse. A similar situation although caused by a different mechanism (hypertrophy instead of dilatation) occurred in the third case described. In such instances using a lead with two coils placed this way: distal in right ventricle, proximal in superior vena cava, left brachio-cephalic vein or left subclavian vein (Fig. 5) or adding a superior vena

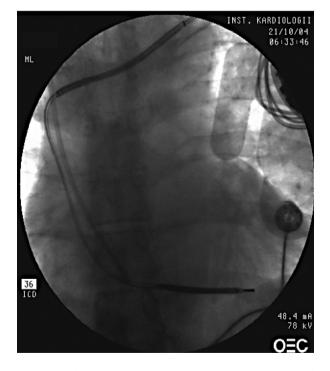


Figure 5. Chest radiograph demonstrating position of the two shocking coil lead: distal in the right ventricle apex and proximal in left brachio-cephalic vein and left subclavian vein.

cava type lead (the so-called floating lead (Fig. 4), lead marked with an arrow) to one-coid lead seems to be advantageous.

Placing the second (proximal) defibrillating spiral exactly in a way described above seems to be of crucial importance. There are some clinical trials proving that placing the lead in a lower part of the right atrium not only does not decrease DFT but tends to increase it, although not significantly [16]. As for the placement of the proximal lead in the superior vena cava the reports differ as to its influence on DFT. Some have shown its positive effect on lowering DFT [17, 18], others quite on the contrary [19]. There are reports of placing the additional lead in inferior vena cava, which according to the authors lowers DFT by 38% [20]. There are no randomised trials referring to additional lead placement in subclavian vein or left brachio-cephalic vein, though according to theoretical point of view such placement should be the most advantageous.

Due to the dynamic development of re-synchronizing therapy other unorthodox positions of leads in the heart's veins, designed to lower DFT were described [21, 22]. The latter of the called reports showed DFT lowering by 45–50%. The former's conclusions were more cautious: such a significant lowering of DFT was observed using a biventricular system (with the additional lead in anterior or posterior left coronary vein) as compared to the standard right ventricle system but medial DFT in both groups did not differ significantly and further investigation is needed.

Although the typical placement of defibrillating lead in the right ventricle's apex and the device's active can in left subclavian region is sufficient to obtain acceptable DFT values in the majority of patients (> 90%) [16, 23], some patients may require additional endocardial leads (mentioned above) or subcutaneous leads. The latter in the form of a subcutaneous net are available on all ICD manufacturers' offer. They are placed in the subcutaneous tissue or between the thoracic cage wall muscles in V intercostal space, on level with a nipple. This kind of solution makes the surgical procedure more extensive and more time-consuming, which increases the risk of complications, among others inflammatory. Lead type 6996 SQ (Medtronic) seems to be a promising solution in the cases of high DFT. It has a small diameter, can be placed in the intercostal space after tunnelling, reaching as far as the spine (the lead's end), in the posterior thoracic cage region. It is much easier to place it with surgical technique, compared to "patch" type leads. The system: a lead described above placed on thoracic cage's posterior wall, standard lead in the right ventricle's apex plus an impulse's generator active can guarantee optimum energy flow, encompassing the whole heart. The system described above can be modified by placing the additional lead in the superior vena cava.

The second patient's history also calls to mind a problem of protecting patients awaiting the heart transplant or the patients with contraindications for a standard operation (for example treated for an infection) or patients refusing to undergo ICD implantation, from sudden cardiac arrest. The results of two trials: WEARIT and BIROAD investigating the use of continuously worn external defibrillators have unanimously shown the effectiveness of this method in preventing sudden cardiac death [24, 25]. The devices of this kind currently manufactured can deliver a maximum energy output of 285 J for the monophasic impulse and 150 J for biphasic impulse. It seems that the latter function finds its use in cases of high defibrillation threshold, obviously after performing a provocation trial in each individual case [25]. The devices of this kind find their use in other clinical situations, such as: patients awaiting for an ICD implantation, previously implanted ICD's lead or defibrillator damage, potentially reversible cause of arrhythmia for a time needed for its removal (patients with ischaemia waiting for revascularisation procedure, with drug intoxication, in early post-operative period and so on). There is also a growing number of patients with contraindications to ICD implantation due to a poor health, concomitant diseases or predicted short survival period after the procedure.

Based on the available data it is believed, that providing large centres treating patients with a high risk of sudden cardiac deth and heart transplant centres with external defibrillators of this kind is justified.

The use of automated external defibrillators (AED) becomes another solution to the problem of protecting high risk SDC patients (including patients with high DFT). Recently published European standards on this issue explicitly point out the importance of these devices in treating ventricular tachyarrhythmias [26]. Among indications to use the device in patient's house, protection of the high risk patients is quoted, in whom "ICD implantation is not indicated, is not possible or is not planned at present". The cost analysis of introducing the AED programme presented in these standards evaluates one year of life saved to be worth \$ 16.060. Medical's procedure costs presented like this and amounting to less than \$20.000 are considered very reasonable in American standards.

To sum up, the data about the factors influencing defibrillation threshold in patients with transvenously implanted ICD, an individual assessment of any given patient has to be made like in any other clinical situation. There are very few reports trying to define prognostic factors predicting the occurrence of high DFT [27], which might help in preparing beforehand for such difficult procedure, for example providing the hardware needed (such as special types of leads and high energy impulse's generator). The prospective analysis of 102 patients investigated in the report cited established that only 4 of 34 parameters (clinical, echocardiographic and electrophysiologic) are of any importance. They are: QRS width, intraventricular septum width, left ventricle mass and mass index. The significance of the left ventricular ejection fraction, LVEDD or concomitant amidarone therapy were not confirmed [27]. All previous investigations addressing this problem were conducted with monophasic, not biphasic impulse treatment — the latter being now a standard procedure (as in the investigation cited above) — and epicardial instead of endocardial leads. They confirmed male gender, amiodarone therapy [28] or male gender and low left ventricular ejection fraction [29] as significant prognostic factors. In investigations assessing endocardial systems high DFT risk factors were: male gender, amiodarone therapy, cardiomegaly, left ventricle dilatation, congestive heart failure, measured body surface [30-34], although in none of them left ventricular ejection fraction was confirmed as being significant, paradoxically.

Nowadays a single lead with two coils and a standard ICD are being most commonly used, as this system has the lowest DFT values.

The last of the presented patients in the end was given a higher energy class ICD compared to the standard device. Apart from the described model (Atlas VR and DR, St. Jude Medical: 36/42 J output energy/accumulated energy respectively) there are comparable high energy devices by other manufacturers, for example Ventak Prizm HE VR and DR, Guidant: 35/41 J, Gem SR and DR, Medtronic: 35/39 J. These devices are of a size comparable to the standard energy ICDs, unfortunately their price is much higher. However, when a satisfactory DFT cannot be achieved with an implantation of a standard device, using a high energy output defibrillator is to be considered.

Although in the case described changing the defibrillation impulse's form (tilt 50% instead of a standard 65% and changing I and II phase width as recommended by the manufacturer (DFT Management Kit, St. Jude Medical) did not bring about

the desired effect, optimising the programmable parameters of an ICD should be tried in each individual case.

There are situations when satisfactory DFT values cannot be achieved, even after exhausting every possible set of endocardial system, coupled with subcutaneous lead implantation. The chronologically oldest method is to be considered then — that is the implantation of a defibrillator with an epicardial lead in a heart surgery centre, although even this approach does not guarantee success.

Conclusions

- 1. In each patient with a high defibrillation threshold all possible potentially reversible causes should be considered.
- Unorthodox endocardial system: an additional lead and/or changing the lead's position or reversing lead's polarity may provide a solution to the problem. These procedures lower DFT in some of the patients (the so-called optimising the impulse's vector).
- 3. Currently available programmer's software allows for non-invasive modification of numerous ICD's parameters influencing DFT value, such as defibrillating impulse shape and width (the so-called optimising the impulse).
- 4. When all above mentioned methods of lowering DFT fail, the use of subcutaneous leads, implanting higher energy device or lastly implanting an epicardial electrode are to be considered.

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