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Predictors of successful defibrillation threshold test during CRT-D implantation

Andrzej Przybylski[1], Artur Oręziak[1], Zbigniew Lewandowski[2], Andrzej Hasiec[1], Michał Orczykowski[1], Franciszek Walczak[1]

[1]The Cardinal Stefan Wyszyński Institute of Cardiology, Warsaw, Poland
[2]Department of Epidemiology, Medical University of Warsaw, Warsaw, Poland

Abstract

Background: The assessment of defibrillation energy requirement (DER) is a standard practice during cardioverter-defibrillator (ICD) implantation. It is recommended to assure that the energy at least 10 J below the maximal energy deliverable by the implanted device successfully converts the induced ventricular fibrillation (VF). The cardiac resynchronisation therapy with defibrillator (CRT-D) recipients are at increased risk of developing serious complications due to repeated VF induction.

Aim: To define the prevalence of high DER among CRT-D recipients and to determine the factors which allow to obtain defibrillation safety margin.

Methods: We examined all patients who underwent CRT-D implantation between June 2006 and June 2009 in our institution. The verification of the DER required at least one termination of the induced VF with the energy at least 10 J below the maximal energy deliverable by the implanted device.

Results: The CRT-D was implanted in 65 patients. The first defibrillation test was successful in 57 (88%) patients. In the remaining 8 patients (12%), the defibrillation test was unsuccessful. These patients required system revision: reprogramming shocking polarity (2), reversing polarity and adjusting waveform (3), lead repositioning (1) and adding a subcutaneous lead (2). The use of high output devices (maximal energy > 30 J) and dual-coil leads was associated with a significantly ($p < 0.05$) lower rate of high DER, although high DER occurred in one patient implanted with the high output device. There was a correlation between the probability of successful defibrillation and renal function. It was less likely to obtain successful defibrillation safety margin in patients with creatinine > 175 μmol/L. During the follow up, ventricular tachyarrhythmia detected in the VF detection zone occurred in 13 (20%) patients, including two patients, who required system modification during implantation. In both cases, VF was terminated by the first defibrillation with the maximal energy of the implanted devices.

Conclusions: High DER occurred in a significant number of CRT-D recipients. There is a correlation between high DER and impaired renal function. The use of high output devices significantly decreases the number of patients who required system modification in order to obtain an adequate defibrillation safety margin.

Key words: cardiac resynchronisation therapy, implantable cardioverter defibrillators, defibrillation

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INTRODUCTION

The most important function of implantable cardioverter-defibrillators (ICD) is to stop life threatening ventricular arrhythmias, in particular ventricular fibrillation (VF) [1]. Defibrillation energy requirement (DER) during ICD implantation remains controversial due to the character of defibrillation and other important clinical conditions (degree of heart damage, medications) and the specificity of the equipment used (electrodes and maximal energy of ICD) [2–6]. Because it is impossible to assess the exact threshold of energy required for successful defibrillation, at least 10 J margin below the maximal energy deliverable by the implanted device, which successfully converts the induced VF, is recommended.

Address for correspondence:
dr n. med. Andrzej Przybylski, The Cardinal Stefan Wyszyński Institute of Cardiology, ul. Alpejska 42, 04–628 Warsaw, Poland, e-mail: aprzybylski@ikard.pl
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Induction of VF in patients with severe heart damage can cause hemodynamic decomposition or even pulseless electrical activity [2, 3, 7–9]. The group of patients in whom the VF induction (usually repeatable) causes substantial clinical problems are patients approved for the cardiac resynchronisation therapy with defibrillator (CRT-D).

The aim of our study is to assess the frequency and predisposing risk factors of increased DER in CRT-D patients.

METHODS

We examined all patients who underwent CRT-D implantation between June 2006 and June 2009 in our institution. The indications for CRT-D implantation were in accordance with current guidelines [1, 10]. All study patients signed the consent form prior to the enrolment to the study.

CRT-D implantation

All procedures were performed in a standard operating room meeting current recommendations [10]. All the electrodes were implanted using commonly used and approved methods [11]. The defibrillating electrode was positioned in the apex of the right ventricle (RV). We used dual-coil RV electrodes. Choice of the defibrillating lead (uni- or biphasic) was up to the operators' preference. The use of CRT-D (maximal energy ≤ or > 30 J) was up to the operators' decision and equipment availability.

VF induction

Induction of VF was performed under intravenous anaesthesia (propofol, fenthanyl). In four patient the endotracheal anaesthetic port of entry must have been used. The fast stimulation (burst) or synchronized with T wave shock (shock on T) was used to trigger VF. The energy of the first defibrillation test was programmed at least 10 J below the maximal energy deliverable. The second defibrillation test was performed using the maximal energy deliverable by the CRT-D. In case of unsuccessful both defibrillations, the external defibrillation was used. During the first VF induction the standard polarity and wave form of the ICD were used. The devices were programmed to deliver the maximal energy during follow-up.

Statistical analysis

Continuous variables are expressed as median ± standard deviation (SD), categorical variables are expressed as percentages (%). In order to assess the potential factors associated with defibrillation safety margin achievement we used logistic regression (gam function using S-Plus and LOGISTIC Procedure using SAS). We tested the association between variables for its linearity, and then we assessed the strength of predictability using odds ratios (OR). We also tested for categorical variables predicting achievement of the defibrillation safety margin or how much the likelihood changes with an adjustment of the continues variables by increasing them by one SD. A p value < 0.05 was considered significant.

RESULTS

The CRT-D was implanted in 65 patients. Baseline characteristics is displayed in Table 1. Information of implanted devices is enclosed in Table 2. The first defibrillation test was successful in 57 (88%) patients. In the remaining 8 patients (12%), the defibrillation test was unsuccessful and therefore these patients required the system to be modified (Table 3). Reprogramming shock polarity was required in 5 patients, 1 patient required lead repositioning and 2 other patients must have had a subcutaneous lead added. There were no complications associated with the VF induction process.

The chance of achieving successful defibrillation safety margin was 8 times higher in patients in whom the higher

Table 1. Baseline characteristics of the study group (n = 65)

Age [years]	59.3 ± 12.8
Males	54 (83%)
EF [%]	21.1 ± 7.5
LVEDD [mm]	72.4 ± 10.5
LVESD [mm]	63.7 ± 13.0
Creatinine [μmol/L]	113.8 ± 38.7
DCM/CAD	33 (51%)/32 (49%)
Primary prevention of sudden death	49 (75%)
History of AF	16 (25%)
History of cardiac surgery	10 (15%)
History of HTN	23 (36%)
Diabetes	16 (25%)
Amiodarone	13 (20%)
Beta-blockers	51 (78%)
CRT-D with energy ≤ 30 J/> 30 J	33 (51%)/32 (49%)
Single- or dual-coil lead	19 (29%)/46 (71%)

EF — ejection fraction; LVEDD — left ventricle end-diastolic dimension; LVESD — left ventricle end-systolic dimension; eGFR — estimated glomerular filtration rate; DCM — dilated cardiomyopathy; CAD — coronary artery disease (ischaemic cardiomyopathy); AF — arial fibrillation; HTN — hypertension; CRT-D — cardiac resynchronisation therapy with defibrillator

Table 2. List of CRT-D devices

Device	Number (%)
Cognis 100D (Guidant, Boston Scientific, USA)	1 (1)
EPIC HF (St. Jude Medical, USA)	5 (8)
INSync Protect (Medtronic, USA)	1 (1)
Kronos LV-T (Biotronik, Germany)	5 (8)
Lumax 300 HF-T (Biotronik, Germany)	22 (34)
INSync Maximo (Medtronic, USA)	15 (23)
INSync Sentry (Medtronic, USA)	16 (25)

Table 3. Methods of achieving the defibrillation safety margin

Description of methods	Number
Impulse polarity change	2
Impulse polarity change and 2nd phase length increase	3
Lead repositioning	1
Subcutaneous lead usage	2

output energy devices were used (OR = 8.35; $p < 0.05$; Figs. 1, 2A). There was a 5-fold increase in achieving successful defibrillation safety margin in those in whom the biphasic electrode was used (OR = 5.12; $p < 0.05$; Fig. 1, Fig. 2B). However, the chance of obtaining an adequate defibrillation safety margin was 2 times lower (in respect to one SD) in patients with impaired renal function (OR= 1/2.26 per 1 SD; $p < 0.03$; Fig. 1). In addition, the shape of the curve showing the association between the defibrillation safety margin and the creatinine levels was not linear ($p < 0.05$). It was less likely to obtain successful defibrillation safety margin in patients with creatinine > 175 μmol/L (approximately > > 2 mg/dL; Fig. 2C). The chance of obtaining successful defibrillation safety margin and estimated glomerular filtration rate (eGFR) have also a nonlinear relationship and increased with higher eGFR (Fig. 2D).

A comparison of the group with the successful first defibrillation and successful achievement of the defibrillation safety margin (group I, n = 57), and the group with unsuccessful first defibrillation (group II, n = 8) is shown in Table 4. The CRT-D with higher maximal energy deliverable and dual-coil lead was significantly more frequently used in patients in group I.

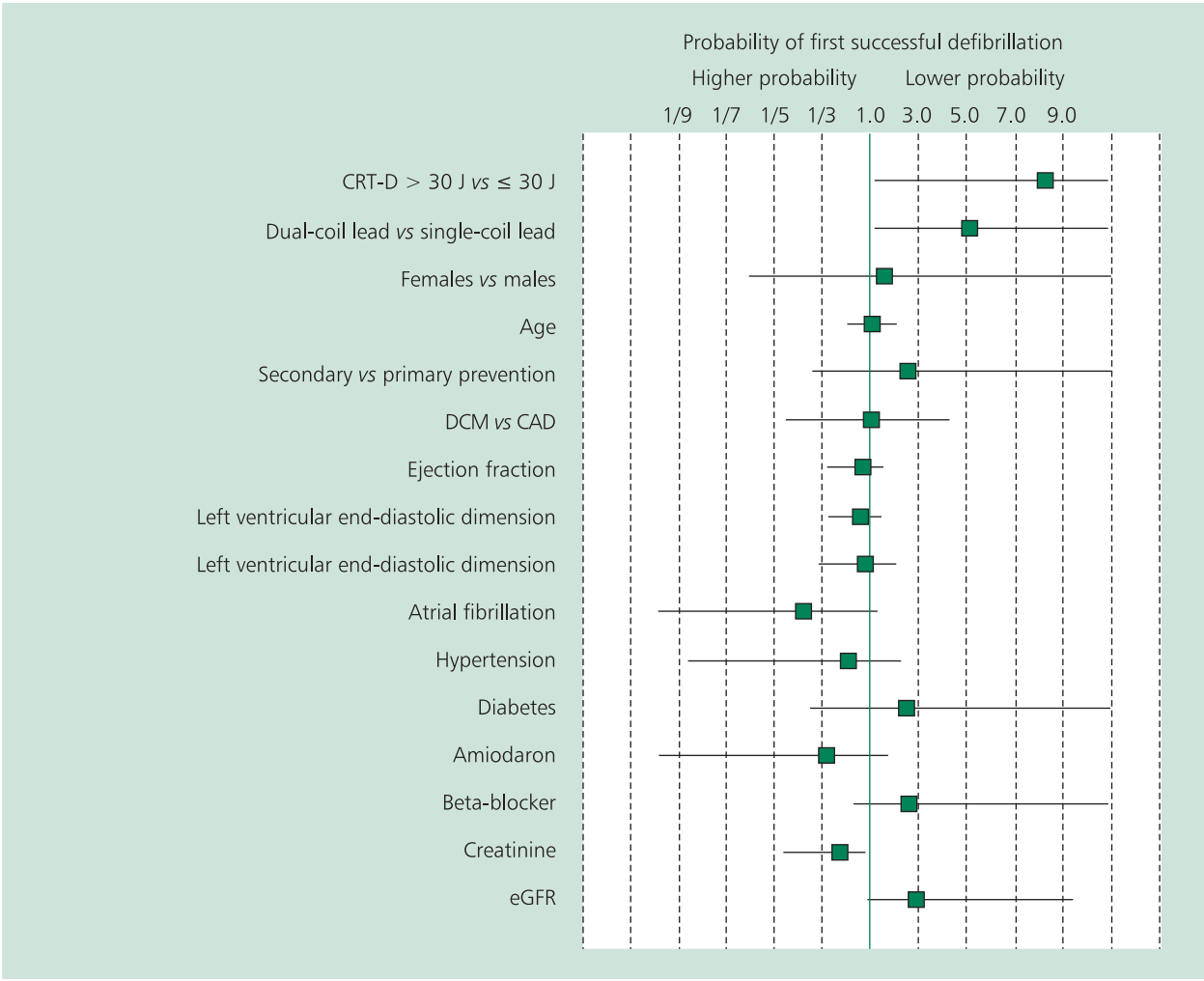

Figure 1. Quantitative assessment of the successful defibrillation according to different factors associated with the procedure. The chance of achieving first successful defibrillation according to categorical variables is represented by increased or decreased chance of successful procedure in the study group (e.g. dual-coil lead) *vs* control group (e.g. single-coil lead). Quantitative variables and their respective increased or decreased probability was calculated for group of patients with the difference of one standard deviation

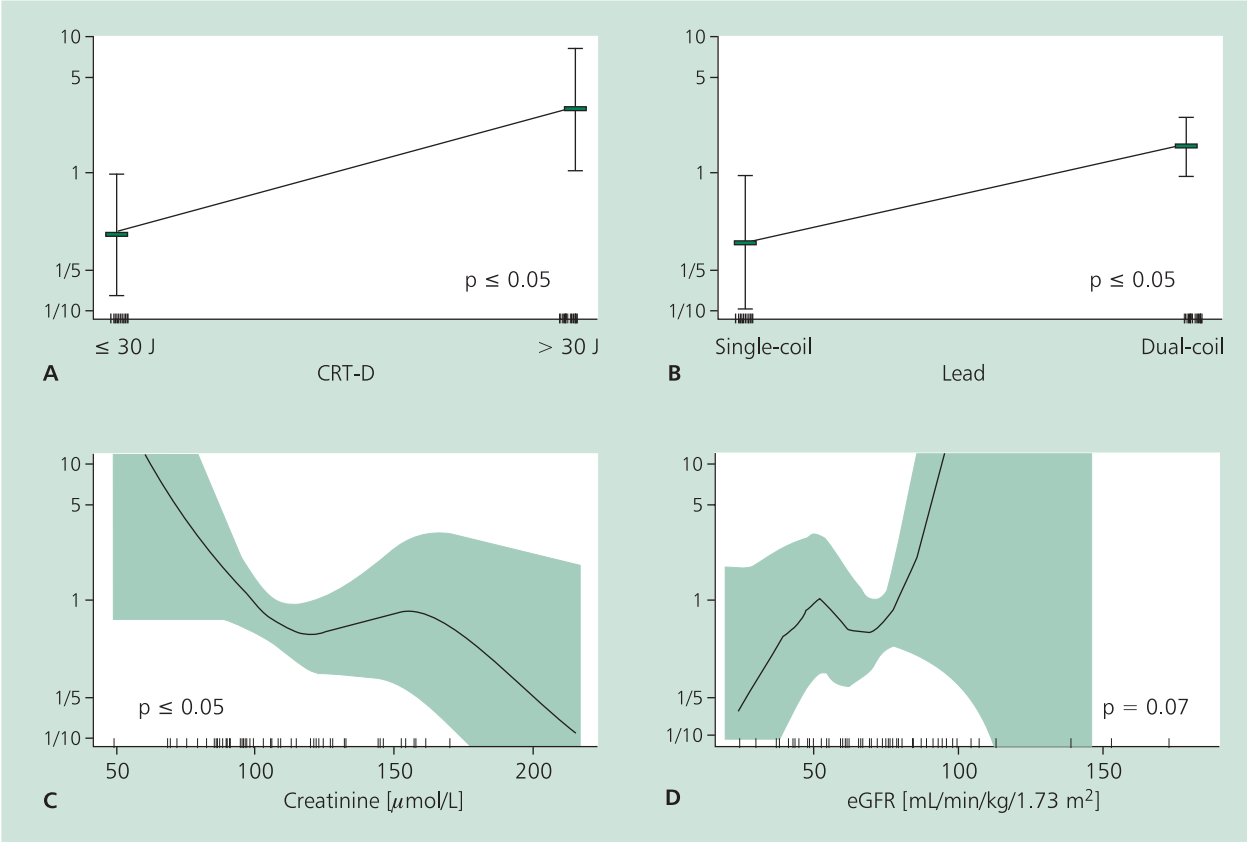

Figure 2. Probability of achieving (first) successful defibrillation according to: the use of devices with higher output energy (**A**); the use of dual-coil lead *vs* single-coil lead (**B**); creatinine levels (**C**); eGFR (**D**) as factors which significantly or border-line significantly associated with a positive defibrillation test. The curves were drawn using 95% confidence interval

Follow up

During a mean follow-up of 14.2 ± 9 months (range 3–33), four patients died and two underwent heart transplantation. The premature deaths were caused by heart failure. None of the deaths met the criteria of sudden death. The ICD intervention in VF zone (lower window of detection 180––200/min) occurred in 13 (20%) patients, among those 2 patients had higher DER and required some modifications to the system (1 patient had to have a subcutaneous electrode implanted and the other patient had to have an electrode polarity changed). In both patients, the first defibrillation was successful. In 2 patients the arrhythmia was stopped during the second or the third defibrillation test. In the remaining patients arrhythmias were stopped with the first defibrillation test.

DISCUSSION

Regardless many years of clinical experience and advanced technology, in some patients the problem with achieving an adequate defibrillation safety margin remains unsolved. Higher DER is more frequent with CRT-D implantation than with ICD and accounts for 3.9% to 6.2% of patients [9, 12]. In our group, in 8 (12.3%) patients the induced VF was not interrupted with the first defibrillation test with the energy set within the safety defibrillation margin. In the VENTAK CHF/CONTAK CD study (maximal energy used in the CRT-D-31 J study) an appropriate DER was achieved in 89% of all patients [13]. The 10 J defibrillation safety margin was either not achieved or an operator abandoned the VF induction, because of other concerning clinical conditions, in 11% of patients.

Higher DER predisposing factors

The following factors have been shown to be associated with an increased DER: low ejection fraction, left ventricular hypertrophy, New York Heart Association classification, and other than of ischaemic origin heart failure [7–9]. There are divergent results as to the amiodarone use, however the most recent study did not confirm amiodarone influence on DER [14]. We also failed to document such a relationship. In patients approved for the CRT-D implantation, increased DER was associated with prolonged implantations (> 257 min) and left ventricular end-diastolic dimension (64 mm) [13].

We have shown an association between successful defibrillation and renal function parameters (creatinine, eGFR). The probability of successful defibrillation decreases in patients with impaired renal function. The correlation between

Table 4. Comparison of patients with successful and unsuccessful first defibrillation

Parameter	Successful defibrillation (n = 57)	Unsuccessful defibrillation (n = 8)
Age [years]	59.4 ± 12.7	59.0 ± 14.0
Males	47 (82%)	7 (87%)
EF [%]	20.8 ± 7.3	23.4 ± 8.4
LVEDD [mm]	71.9 ± 10.1	75.9 ± 13.0
LVESD [mm]	63.5 ± 12.4	64.7 ± 17.0
Creatinine [μmol/L]	108.8 ± 31.2	146.5 ± 64.0
eGFR [mL/min/kg/1.73 m^2]	82.0 ± 43.3	57.5 ± 21.2
DCM/CAD	29 (51%)/28 (49%)	4 (50%)/4 (50%)
Primary prevention	42 (74%)	7 (87%)
History of AF	12 (21%)	4 (50%)
History of cardiac surgery	10 (18%)	0
History of HTN	19 (33%)	4 (50%)
Diabetes	15 (26%)	1 (13%)
Amiodarone	10 (18%)	3 (38%)
Beta-blockers	46 (81%)	5 (63%)
CRT-D with energy ≤ 30 J/> 30 J	26 (46%)/31 (54%)	7 (87%)/1 (13%)*
Single- or dual-coil lead	14 (25%)/43 (75%)	5 (62%)/3 (38%)*

*statistically significant, $p \leq 0.05$; abbreviations the same as those in Table 1

renal function and DER has been described previously in 95 patients with ICD implantation. The defibrillation threshold was proportionally higher in patients with renal impairment. The total mortality and sudden death rate were higher in patients with eGFR < 60 mL/min, compared to the patients with normal renal function [15]. The paradigm of worse outcomes in patients ICD and with renal insufficiency have been documented previously [16, 17]. Among many, renal insufficiency was the strongest predictor of worse outcomes in the MADIT study [18]. We can nor rule out the possibility that the unsuccessful defibrillation was due to the progression of renal insufficiency, which can also be one of the confounders causing death in this group of patients.

How to decrease DER

There are many methods decreasing DER [2, 9, 11]. It is difficult to assess their importance due to unpredictable character of defibrillation, and other ethical and clinical problems associated with repeatable VF inductions. The most commonly used methods include the following: (1) using higher output energy devices, (2) changing polarity or the impulse waveform, (3) implanting subcutaneous leads, (4) repositioning the lead, (5) delaying the VF induction process in sick patients or in patients with complications (pneumothorax, substantial blood loss).

Every method has its limitations. In our study we showed that the use of CRT-D with higher output energy is associated with the 8 times higher probability of successful defibrillation. However, an implantation of higher output energy device does not guarantee an achievement of the defibrillation safety margin. In our study, the use of subcutaneous lead was necessary in one patient who received the high output energy CRT-D. Russo et al. [9] reported that in 48% of patients with higher DER, the replacement of ICD with the device of higher output energy did not solve the problem, and the additional modification of the system was required. The high cost of the CRT-D with higher output energy limits significantly its clinical applicability. Due to the difficulty in identyfing a patient with high DER prior to the device implantation, it is very difficult to decide before starting the procedure who will receive such a device.

Our study showed that the dual-coil lead use is associated with the 5 times higher probability of achieving the defibrillation safety margin. We should interpret this fact with caution, because the dual-coil leads were used in patients with the higher output energy devices (caused by the withdrawal of single-coil lead by one of the manufactures).

According to the published reports, the change of waveform or polarity decreases the defibrillation energy by 4–6 J on average. Thus, when maximal high output energy CRT-D defibrillation is not successful, a 10 J safety margin may not be achieved [19–22]. Therefore, we implemented the change of the waveform or polarity of the impulse in situations when we were unable to achieve the safety margin but the defibrillation with maximal energy was successful. However, the change of the waveform is not possible in some devices. In all patients with the unsuccessful defibrillation test while using maximal energy, we decided to use a subcutaneous lead, which lowers the DER by, as much as, 10 J [23].

Limitations of the study

The major limitation of the study was the lack of patient randomisation to the CRT-D (higher or lower output energy) and defibrillation lead (single- or dual-coil). Due to the medical and ethical concerns, it is impossible to compare different methods of overcoming higher DER, because of the repeatable VF inductions. Furthermore, there were different standard settings and variable availability of the devices used in the study.

CONCLUSIONS

High DER occurred in a significant number of CTR-D recipients. There is a strong correlation between higher DER and impaired renal function. The use of CRT-D with higher output energy decreases the probability of necessary modifications of the implantable system in order to obtain the defibrillation safety margin.

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Czynniki wpływające na skuteczny test defibrylacji podczas implantacji kardiowertera-defibrylatora z możliwością terapii resynchronizującej

Andrzej Przybylski[1], Artur Oręziak[1], Zbigniew Lewandowski[2], Andrzej Hasiec[1], Michał Orczykowski[1], Franciszek Walczak[1]

[1]Instytut Kardiologii im. Prymasa Tysiąclecia Stefana Kardynała Wyszyńskiego, Warszawa
[2]Zakład Epidemiologii, Warszawski Uniwersytet Medyczny, Warszawa

Streszczenie

Wstęp: Test skuteczności defibrylacji (DER, *defibrillation energy requirement*) jest standardową częścią implantacji kardiowertera-defibrylatora. Zalecane jest wykazanie, że energia mniejsza o co najmniej 10 J od maksymalnej energii wszczepianego urządzenia przerywa wywołane migotaniem komór (VF, *ventricular fibrillation*). Chorzy kwalifikowani do implantacji układu resynchronizującego z defibrylatorem (CRT-D, *cardiac resynchronisation therapy with defibrillator)* są szczególnie narażeni na powikłania związane z wielokrotną indukcją VF, a także istnieje u nich duże ryzyko wystąpienia podwyższonego DER.

Cel: Celem pracy była ocena częstości i czynników predysponujących do wystąpienia podwyższonego DER w trakcie implantacji CRT-D.

Metody. Badaniem objęto wszystkich chorych, którym implantowano układ CRT-D w okresie od czerwca 2006 do czerwca 2009 roku. W czasie testu DER stosowano energię co najmniej o 10 J mniejszą niż maksymalna energia implantowanego CRT-D.

Wyniki: Układ CRT-D wszczepiono u 65 chorych. Pierwszy test defibrylacji był skuteczny u 57 (88%) osób. U 8 (12%) pacjentów pierwsza defibrylacja była nieskuteczna i w celu uzyskania marginesu bezpieczeństwa konieczna była modyfikacja układu: zmiana polarności defibrylacji (2), zmiana polarności i kształtu impulsu (3), repozycja elektrody (1) oraz implantacja elektrody podskórnej (2). Zastosowanie CRT-D o podwyższonej energii (>30 J) oraz elektrod dwuzwojowych było związane z istotnie rzadszym występowaniem podwyższonego DER ($p \leq 0,05$), chociaż problem ten wystąpił u chorego, któremu implantowano urządzenie o podwyższonej energii. W prezentowanym badaniu wykazano związek prawdopodobieństwa uzyskania DER w zależności od stopnia upośledzenia wydolności nerek (od stopnia filtracji kłębuszkowej). W czasie obserwacji odległej interwencje CRT-D spowodowane arytmiami wykrytymi w strefie rozpoznania VF wystąpiły u 13 (20%) pacjentów, w tym u 2 chorych, którzy mieli w czasie zabiegu podwyższony DER i wymagali modyfikacji układu. U obu tych osób skuteczna była pierwsza defibrylacja.

Wnioski: Podwyższone DER występuje w stosunkowo dużym odsetku implantacji CRT-D. Istnieje zależność pomiędzy podwyższonym DER i parametrami uszkodzenia nerek. Zastosowanie CRT-D o podwyższonej energii istotnie zmniejsza odsetek chorych, u których konieczna jest modyfikacja układu w celu uzyskania marginesu bezpieczeństwa defibrylacji.

Słowa kluczowe: terapia resynchronizująca, implantowane kardiowertery-defibrylatory, defibrylacja

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Adres do korespondencji:
dr n. med. Andrzej Przybylski, Instytut Kardiologii im. Prymasa Tysiąclecia Stefana Kardynała Wyszyńskiego, ul. Alpejska 42, 04–628 Warszawa, e-mail: aprzybylski@ikard.pl
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