

Comparison of defibrillation efficacy using implantable cardioverter-defibrillator with single- or dual-coil defibrillation leads and active can

Andrzej Lubiński, Ewa Lewicka-Nowak, Agnieszka Zienciuł, Tomasz Królak, Maciej Kempa, Anna Pazdyga, Grzegorz Raczak, Grażyna Świątecka

II Department of Cardiovascular Diseases, Institute of Cardiology, Medical Academy, Gdańsk, Poland

Abstract

Introduction: The reduction of defibrillation threshold (DFT) in patients treated with an implantable cardioverter-defibrillator increases patients' safety and prolongs ICD battery life.

Aim: To evaluate the possibility of reducing the defibrillation threshold in ICDs with an active can and an additional atrial defibrillation coil instead of the typical intracardiac single-coil lead.

Method: This study involved 138 patients (36 F and 102 M, mean age 54 ± 15 years) including 62 subjects with dual-coil defibrillation lead (group A) and 76 ones with single-coil defibrillation lead (group B). No statistically significant differences with respect to age, left ventricular function, main disease or exacerbation of heart failure according to the NYHA functional class were observed between groups. The defibrillation threshold was measured using the DFT+ protocol.

Results: No significant differences between groups were identified with respect to pacing and sensing parameters. The comparison of DFT values between the two studied groups revealed significant improvement (by 14% mean) of defibrillation efficacy in group A. In group A, the mean DFT was 9.8 ± 4.6 J (3-20 J) and mean defibrillation resistance – 45 ± 7 Ω (32-73 Ω), whereas in group B: 11.45 ± 5.25 J (3-28 J) and 72 ± 12.8 Ω (38-106 Ω), respectively. In 93% of patients from group A, DFT was below 15 J, in comparison to 81% of patients from group B ($p=0.046$). The odds ratio of a higher defibrillation threshold (≥ 15 J) in group A vs. group B was 0.3 (95% confidence interval: 0.09-0.98). The DFT reduction associated with modified ICD system use was independent of following clinical parameters: patient age, gender, main disease, end-diastolic left ventricular diameter, left ventricular ejection fraction, NYHA functional class and concomitant treatment with antiarrhythmic agents.

Conclusions: Modification of the electric field during defibrillation, achieved with the use of active-can ICDs with dual-coil defibrillation leads, allows a reduction of DFT by 14%. At the same time, it reduces the risk of a higher (≥ 15 J) DFT by three times compared to patients with a standard single-coil defibrillation lead.

Key words: implantable cardioverter-defibrillator, defibrillation threshold, two-coil and single-coil transvenous cardioverter defibrillator systems

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Introduction

The use of an implantable cardioverter-defibrillator (ICD) is the basic method of treatment for individuals who are at risk of sudden cardiac death due to malignant ventricular arrhythmias [1-3]. Intracardiac defibrillation with ICD systems is performed using transvenous right ventricular single- or dual-coil defibrillation leads. In the former, the current pathway

extends from the single-coil ventricular lead to the ICD shell, which acts as the other defibrillation pole and is referred to as an active can, while in the latter, the use of a defibrillation lead with an additional, atrial coil results in the current pathway between distal and proximal lead coils and the active ICD can. The pathway of defibrillation current is thus different, which may affect the defibrillation threshold.

Address for correspondence:

Dr. Andrzej Lubiński, II Klinika Chorób Serca, Instytut Kardiologii, Akademia Medyczna, ul. Dębinki 1, 80-211 Gdańsk, tel.: + 48 58 349 39 10, e-mail: alub@amg.gda.pl

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The safety of patients with malignant ventricular arrhythmias treated with ICD implantation depends on immediate and effective intracardiac defibrillation. The results of available studies on the effectiveness of defibrillation using ICD with an active can and single- or dual-coil defibrillation leads are divergent [4-8].

The aim of this study was to evaluate the possibility of reducing the defibrillation threshold in ICDs with an active can and an additional atrial defibrillation coil instead of the typical intracardiac single-coil lead.

Methods

Patients

The studies involved patients with life-threatening ventricular arrhythmias, approved for ICD treatment in the II Department of Cardiology of the Medical Academy in Gdańsk. Clinical characteristics of both groups are presented in Table I.

ICD implantation

The ICD implant procedure was performed in aseptic conditions in the operating room. The choice of a defibrillation lead (single- or dual-coil) was determined by the present availability of leads. A defibrillation lead was introduced transvenously and placed in the apex of the right ventricle, ensuring correct sensing during cardiac intrinsic rhythm and correct pacing parameters. In dual-coil defibrillation leads, a standard ventricular coil was placed apically in the right ventricle, while an additional defibrillation coil was placed in the high right atrium, at the junction of the superior vena cava. After stable lead positioning, the pacing threshold (U), R wave amplitude (R), intracardiac potential slew rate (S_{L-R}), and impedance of ICD leads (I) were measured with the ERA 400 analyser (Biotronik). The following sensing and pacing parameter values were regarded as acceptable: $U \leq 1.5$, $V/0.5$ ms, $R \geq 8.0$ mV, $S_{L-R} \geq 0.5$ V/s.

In ICD systems with a dual-coil defibrillation lead, the following passive fixation leads were implanted: Kainox SL (Biotronik) and Sprint 6942 (Medtronic). In systems with a single-coil defibrillation lead, the passive fixation leads used were SPS UP/BP and Kainox RV (Biotronik), as well as the following active fixation leads: Kainox RVS (Biotronik) and Sprint 6943 (Medtronic).

Adjustment of defibrillation threshold

The defibrillation threshold was measured using the DFT+ protocol [9-10], which was discussed in detail in our other study [11]. For this purpose, the ESA 400 external cardiac defibrillator and Biotronik Phylax Test Housing were used. Defibrillator test housing was implanted in the ICD pocket in the left subclavicular region.

After measuring the defibrillation threshold, the following active-can ICDs were implanted in all studied patients: Phylax 06/XM or Phylax AV (Biotronik), or Micro Jewel II or Jewel AF (Medtronic). In all patients the ICD was implanted subcutaneously in the left subclavicular area. Patients with prior pacemaker implantation, who had the ICD implanted on the opposite side of the chest for this reason, were excluded from the study.

Evaluated parameters

The following parameters were assessed in each subject: defibrillation threshold, defibrillation resistance, intracardiac potential amplitude and slew rate, as well as pacing impedance.

The results obtained in the group with a dual-coil defibrillation lead were compared with the group with the ICD and a single-coil defibrillation lead and the same study protocol was used. Additionally, the influence of the following factors on differences in study parameters was analysed: patient age, gender, main disease, end-diastolic left ventricular diameter, left ventricular ejection fraction, NYHA functional class and concomitant treatment with antiarrhythmic agents.

Statistical analysis

The data on defibrillation parameters, patient demographics and patients' clinical characteristics were expressed as a mean \pm standard deviation. Student's t-test and Fisher's test were used for single factor analysis of variance in the defibrillation threshold between groups. Interactions between analysed parameters were analysed using the multivariable logistic regression model.

Results

The study group consisted of 138 patients, including 36 females and 102 males, mean age 54 ± 15 years (15-80 years) approved for ICD implantation. Group A consisted of 62 patients who had an active-can ICD with a dual-coil defibrillation lead implanted in their left subclavicular region. The group included 11 females and 51 males, mean age 56 ± 16 years (15-80 years). Forty-five patients from this group had been implanted with Kainox SL (Biotronik), while in 17 cases the implanted lead was Sprint 6942 (Medtronic).

Group B included patients who had an active-can ICD with a single-coil defibrillation lead implanted in the same location as the first group. The group consisted of 76 patients, including 25 females and 51 males, mean age 52 ± 14 years (18-78 years). In this group, patients had the following lead types implanted:

Table I. Clinical characteristics of studied population: Group A – patients with dual-coil defibrillation lead implantation. Group B – patients with single-coil defibrillation lead implantation

Parameter	Group A, n=62	Group B, n=76	p
MAIN DISEASE:			
Ischaemic heart disease	39 (63%)	46 (61%)	NS
Idiopathic dilated cardiomyopathy	10 (16%)	10 (13%)	NS
Idiopathic VF	7 (11.2%)	4 (5%)	NS
Hypertrophic cardiomyopathy	3 (5%)	6 (8%)	NS
Arrhythmogenic right ventricular dysplasia	1 (1.6%)	2 (3%)	NS
Long QT syndrome	1 (1.6%)	6 (8%)	NS
Prior myocarditis	1 (1.6%)	1 (1%)	NS
Others	(-)	1 (1%)	NS
ANTIARRHYTHMIC AGENTS:			
Amiodarone	33 (53%)	36 (47%)	
Sotalol	6 (9.7%)	15 (20%)	
β-blockers	16 (26%)	11 (15%)	
Calcium channel blockers	2 (3%)	2 (3%)	
No antiarrhythmic agents	5 (8%)	10 (13%)	
Left ventricular ejection fraction [%]	39±16 (15-87)	44±9 (15-80)	
Left ventricular end-diastolic diameter [mm]	59±10 (32-85)	58±12 (30-84)	

48 patients – UP/BP; 12 patients – Kainox RV; 15 patients – Kainox RVS (Biotronik); and 1 patient – Sprint 6943 (Medtronic). Clinical characteristics of studied patients are shown in Table I. No statistically significant differences with respect to age, left ventricular function, main disease or exacerbation of heart failure according to the NYHA functional class were observed between groups.

Each patient completed the full protocol of defibrillation threshold measurement. The comparison of defibrillation thresholds between the two studied groups revealed significant improvement (by 14% mean) of defibrillation efficacy in group A. Changes within the analysed parameters in both groups are shown in Table II.

Table II. Defibrillation threshold and defibrillation resistance in both groups of patients. Group A – patients with dual-coil defibrillation lead implantation. Group B – patients with single-coil defibrillation lead implantation

Parameter	Group A	Group B	p
Defibrillation threshold [J]	9.8±4.6 (3-20)	11.45±5.25 (3-28)	0.027
Defibrillation resistance [Ω]	45±7 (32-73)	72±12.8 (38-106)	0.0001

Moreover, in 93% of patients with a dual-coil defibrillation lead, the defibrillation threshold was below 15 J, in comparison to 81% of subjects with a single-coil defibrillation lead ($p=0.046$). The odds ratio of a higher defibrillation threshold (≥ 15 J) in patients with modified ICD systems vs patients with standard single-coil systems, analysed using multivariable logistic regression, was 0.3 (95% confidence interval 0.09-0.98). This is presented in Figure 1, whereas Figure 2 shows the relationship between the defibrillation threshold and defibrillation resistance. The analysis showed a weak positive correlation but without statistical significance.

The studied population was also evaluated in order to determine whether differences in defibrillation energies between groups were related to the analysed clinical factors. The multivariable logistic regression model was used for this purpose, including adequate interactions of variables in the analysis. No such relations were found with respect to age, gender, main disease, end-diastolic left ventricular diameter, left ventricular ejection fraction, NYHA functional class or antiarrhythmic agents used. The influence of analysed clinical factors on the defibrillation threshold for both types of leads is shown in Table III.

All patients also had their pacing and sensing parameters measured during implantation. No significant differences between groups were identified

with respect to the intracardiac potential amplitude (R wave), slew rate (S_{L-R}) and impedance of ICD pacing system (I) (Table IV).

In the population under study, implantation of an ICD was not associated with any complications, either during the procedure itself, or in the postoperative period.

Discussion

The introduction into therapy of ICD with a single-coil defibrillation lead and an active can implanted in the subclavicular area was a milestone in the development of this technique of treatment. It was possible owing to the use of biphasic defibrillating pulse waveforms [12-16]. The simplification of the implantation procedure and high effectiveness of such ICD systems resulted in their common use in clinical practice [17-20].

However, studies are still being carried out on further improvement of intracardiac defibrillation efficacy. These trials focus on searching for optimal forms of defibrillation impulse, but also on the development of properties and placement of defibrillation leads [16-18]. According to the defibrillation critical mass theory [21-22], the improvement of defibrillation efficacy may be achieved by such adjustment of the defibrillation lead surface and position as allows more even distribution of the electric field over a wider surface of the myocardium. One method to reduce the defibrillation threshold may be a change of defibrillation field geometry to cover the maximum possible extent of the myocardium. For this reason, during ICD implantation large epicardial leads were initially used that almost totally covered the

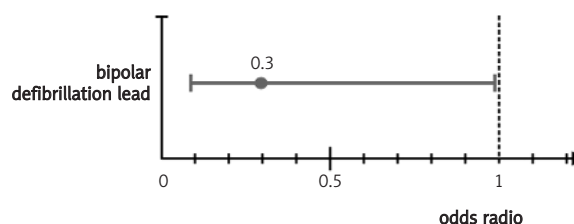


Figure 1. Odds ratio of high defibrillation threshold (≥ 15 J) in patients with modified ICD system with dual-coil defibrillation lead compared to patients with standard single-coil system. This means that risk of high (≥ 15 J) defibrillation threshold was 3-fold lower in patients with dual-coil defibrillation lead than in patients with standard single-coil defibrillation lead

pericardium. This solution enabled optimal distribution of the defibrillation current. The procedure, however, required thoracotomy and was thus associated with a great number of serious adverse events. Consequently, it was completely replaced by transvenous ICD systems.

This study assumed that in currently used active-can ICDs an increase of defibrillation effectiveness may be achieved by the use of leads with an extra defibrillation coil placed in the right atrium in addition to the standard ventricular defibrillation coil. This resulted in a favourable placement of defibrillation coils and increased the total surface of intracardiac

Table III. The influence of analysed clinical factors on defibrillation threshold (DFT) for both lead types: unipolar (UNI) and bipolar (BI). LVEDD – left ventricular end-diastolic diameter; LVEF – left ventricular ejection fraction

	No. of patients UNI	No. of patients BI	DFT [J] UNI	DFT [J] BI	p
Age <60 years	50	32	9 \pm 4.3	11.8 \pm 5.4	<0.005
Age \geq 60 years	26	30	8.1 \pm 4.3	10.3 \pm 5.4	<0.001
Females	25	11	10.1 \pm 4.3	8.9 \pm 4.7	<0.05
Males	51	51	12.1 \pm 5.3	10 \pm 2.6	<0.02
Ischaemic heart disease	43	39	12.2 \pm 5.4	10.1 \pm 4.5	<0.03
Idiopathic dilated cardiomyopathy	9	10	13.6 \pm 4.4	11.7 \pm 4.4	<0.05
Amiodarone	35	32	10.9 \pm 8.6	13.8 \pm 3.5	<0.05
No Vaughan-Williams group III antiarrhythmic agents	25	23	12.6 \pm 4.4	6.5 \pm 4.3	<0.03
LVEDD >5.8 cm	34	27	12.9 \pm 5.5	11.1 \pm 5.1	0.06
LVEF \geq 40%	39	26	8.3 \pm 3.8	9.8 \pm 4.2	<0.005
LVEF <40%	37	36	11.2 \pm 5	13.5 \pm 5.8	<0.001
NYHA class <III	49	51	9.3 \pm 4.7	10.9 \pm 5.4	<0.001
NYHA class \geq III	4	5	10.7 \pm 3.7	13.8 \pm 3.5	<0.01

Table IV. R wave amplitude, slew rate (SL-R) and ICD system impedance (I) in both groups of patients: Group A – patients with dual-coil defibrillation lead. Group B – patients with single-coil defibrillation lead

Parameter	Group A	Group B	p
R wave [mV]	8±4	8.7±32	0.7
SL-R [V/s]	1.2±0.4	1.0±0.7	0.6
pacing impedance [Ω]	452±134	492±92	0.2

electrodes, ensuring more even distribution of the electric field during defibrillation.

In typical ICDs with an active can and a single-coil ventricular defibrillation lead, the current pathway extends from the apex of the right ventricle, where the lead is placed, to the left subclavicular region with the ICD housing, including particularly the intraventricular septum and the left ventricular myocardium. The modified lead system additionally ensures high defibrillation potential intensity within the right heart, from the right ventricle apex to the right atrium.

In this study, such electrode configuration in combination with an increased total electrode surface made it possible to reduce the defibrillation threshold according to the theoretical assumptions of the study (11.5±5.3 J vs 9.8±4.6 J; p=0.027).

A similar presumption has been made in a few studies presented so far. However, the findings of

available studies on the effectiveness of defibrillation with an active-can ICD with single- or dual-coil defibrillation leads are divergent [4-8]. Some authors note that the use of an additional defibrillation coil is not associated with the expected benefits [4, 7, 8]. Bardy et al. [4], who studied a group of 15 patients, found no differences in the defibrillation threshold between analysed ICD systems. It seems that this was due to a different position of the additional defibrillation coil. It was located on a separate lead introduced into the high superior vena cava, and not into the right atrium, as in our study. As a result, the geometry of the defibrillation field was found to be less favourable. Similarly, Manolis et al. [7] in their study performed on 94 patients reported no differences in the defibrillation threshold associated with the use of dual-coil defibrillation leads. However, a comparison of the results of the cited study with our data faces difficulties due to the range of evaluated ICD systems, as the analysis included patients without active-can ICDs, who had only two defibrillation electrodes instead of three.

Analogous results were obtained in the recent randomised, prospective clinical trial involving 18 sites and 76 participants. Rinaldi et al. [8] reported that the mean defibrillation threshold in patients with a single-coil lead was similar to patients after a dual-coil lead implantation. It is difficult to account for the discrepancies with our study. The fact that this was a multi-centre trial, in contrast to all other studies performed so far, may be of great importance.

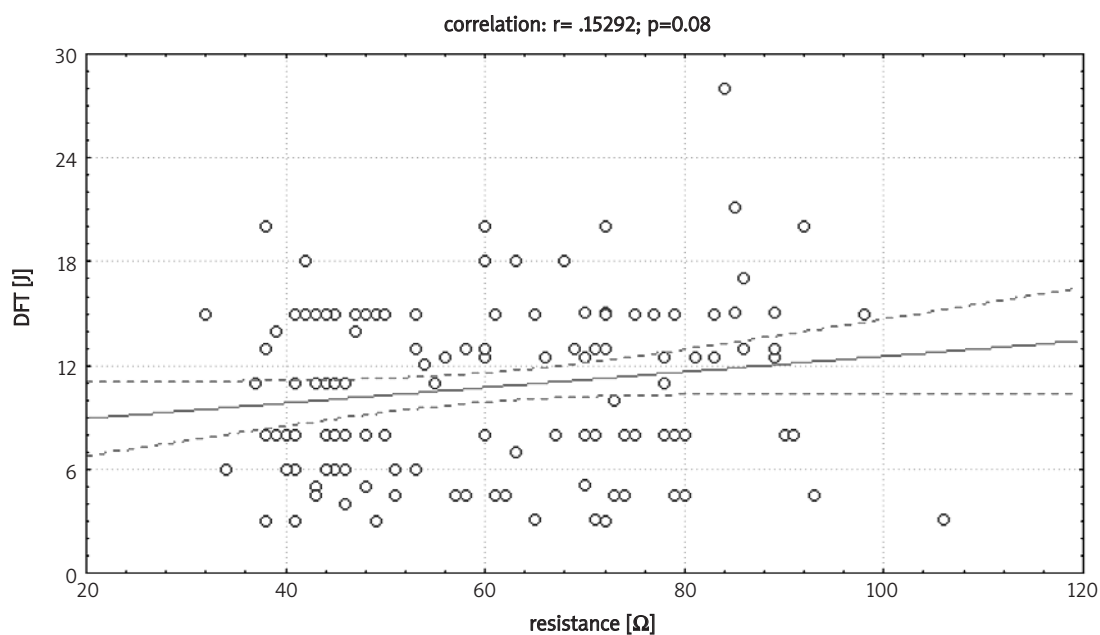


Figure 2. Correlation of defibrillation threshold and defibrillation resistance in studied population

Conducting a study simultaneously in several sites usually positively affects the results. However, in the cited study it cannot be excluded that the interpretation of arrhythmias triggered during defibrillation threshold measurement may vary between individual centres, especially as in some centres only single patients were enrolled in the study. This is strongly supported by the fact that the authors failed to provide any classification criteria for ventricular arrhythmias induced during implantation, often replacing their definitions: VF and *ventricular tachyarrhythmias* or *tachycardia*.

The results of our study are consistent with a previous study by Gold et al. [5], conducted on a population of 50 patients. The difference in the defibrillation threshold in favour of a system with a dual-coil lead was similar to that identified in our study (10.1 ± 5 J and 8.7 ± 4 J; $p < 0.02$). Additionally, 98% of patients with dual-coil defibrillation systems had low (< 15 J) values of the defibrillation threshold in comparison to 88% of subjects with a single-coil defibrillation lead ($p = 0.05$). Similar outcomes were observed in another study conducted in the same centre [6], in which the optimal position of the additional defibrillation coil was also evaluated.

This study was performed on the largest population so far. It showed that defibrillation energy required for the termination of VF was significantly reduced with defibrillation systems with an active-can ICD and a dual-coil defibrillation lead: ventricular and atrial, as compared to patients with a similar ICD implanted with a ventricular single-coil defibrillation lead. The average reduction of the required defibrillation energy was 14%. This beneficial effect was independent of any clinical parameters under study. It is remarkable that there were slight differences in concomitant antiarrhythmic treatment, which could act in favour of single-coil lead systems in terms of defibrillation efficacy. In this group of patients amiodarone was used less often than sotalol. These agents are known to potentially influence the defibrillation threshold, which may be increased with amiodarone and reduced with sotalol. Moreover, the analysis using multivariable logistic regression revealed that the implantation of modified ICD systems reduced the risk of increase of the defibrillation threshold by three times (i.e. ≥ 15 J). In patients with a dual-coil defibrillation lead, in 93% of cases the defibrillation threshold was < 15 J, as compared to 81% of patients with a single-coil lead ($p = 0.046$).

The use of a dual-coil defibrillation lead may provoke objections in terms of its larger diameter and rigidity. The available literature contains data indicating that the implantation of dual-coil leads is technically more difficult [23]. These doubts are, however, associated with

procedures in which an ICD was implanted in the right subclavicular pocket. Defibrillation lead implantation through the left side of the chest, as in our study, involves fewer technical problems owing to the milder curvature of the cephalic and subclavian veins than on the right side. The duration of the procedure was not compared between groups in the present study; however, no procedure termination due to technical problems was recorded.

The results of our study demonstrate significant clinical benefits associated with the use of a dual-coil lead with active-can ICD systems. Such defibrillation systems enable a reduction of the defibrillation threshold and, therefore, ensure further improvement of patients' safety and prolongation of battery longevity. On the basis of the results of our study, this method was accepted as a standard treatment in our department.

Conclusions

Modification of the electric field during defibrillation, achieved with the use of active-can ICDs with dual-coil defibrillation leads, allows a reduction of the defibrillation threshold by 14%. At the same time, it reduces the risk of a higher (≥ 15 J) defibrillation threshold by three times compared to patients with a standard single-coil defibrillation lead.

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Porównanie skuteczności defibrylacji migotania komór przy zastosowaniu ICD z elektrodą z jednym lub dwoma biegunami defibrylującymi i aktywną obudową

Andrzej Lubiński, Ewa Lewicka-Nowak, Agnieszka Zienciuk, Tomasz Królak,
Maciej Kempa, Anna Pazdyga, Grzegorz Raczak, Grażyna Świątecka

II Klinika Chorób Serca, Instytut Kardiologii, Akademia Medyczna, Gdańsk

Streszczenie

Wstęp: Obniżenie progu defibrylacji migotania komór (DFT) u pacjentów leczonych przy pomocy ICD zwiększa bezpieczeństwo chorych, a zarazem wydłuża żywotność baterii ICD.

Cel: Badanie możliwości obniżenia DFT w obecnie stosowanych ICD z aktywną obudową poprzez zastosowanie, w miejsce typowej wewnętrzsercowej elektrody jednobiegunowej, elektrody z dodatkowym – przedsińkowym obwodem defibrylującym.

Metody: Badaniem objęto 138 chorych (36 K i 102 M, w średnim wieku 54 ± 15 lat), w tym 62 pacjentów z elektrodą z dwoma biegunami defibrylującymi (grupa A) oraz 76 chorych z elektrodą z jednym biegunem defibrylującym (grupa B). Obie grupy nie różniły się pod względem wieku chorych, funkcji lewej komory, rodzaju choroby podstawowej czy nasilenia objawów niewydolności serca, ocenianej wg klasyfikacji NYHA. Badanie progu defibrylacji przeprowadzano zgodnie z protokołem DFT+.

Wyniki: Nie stwierdzono istotnych różnic parametrów stymulacji i sterowania pomiędzy grupami. Porównanie wartości DFT wykazało znamienne wzrost skuteczności defibrylacji, średnio o 14%, w grupie A. W grupie A DFT wynosił średnio $9,8 \pm 4,6$ J ($3-20$ J), a opór układu defibrylującego $45 \pm 7 \Omega$ ($32-73 \Omega$), natomiast w grupie B, odpowiednio, $11,45 \pm 5,25$ J ($3-28$ J) i $72 \pm 12,8 \Omega$ ($38-106 \Omega$). U 93% pacjentów z grupy A DFT wynosił < 15 J, w porównaniu do 81% osób z grupy B ($p=0,046$). Iloraz szans (*odds ratio*) wystąpienia wysokiego DFT (≥ 15 J) u pacjentów z grupy A, w porównaniu do osób z grupy B, wynosił 0,3 (95% przedział ufności 0,09–0,98). Obniżenie DFT związane z zastosowaniem zmodyfikowanego układu ICD było niezależne od takich czynników klinicznych jak: wiek pacjenta, płeć, rodzaj choroby podstawowej, wymiar końcoworozkurczowy i frakcja wyrzutowa lewej komory, klasa czynnościowa wg NYHA oraz stosowane leki antyarytmiczne.

Wnioski: Modyfikacja przebiegu pola elektrycznego w czasie defibrylacji migotania komór, uzyskana poprzez zastosowanie w układach ICD z aktywną obudową elektrody z dwubiegunową elektrodą defibrylującą, umożliwia zmniejszenie DFT o 14%. Jednocześnie powoduje to 3-krotne zmniejszenie ryzyka wystąpienia wysokiego (≥ 15 J) DFT, w porównaniu do pacjentów z klasyczną elektrodą z jednym biegunem defibrylującym.

Słowa kluczowe: implantowany kardiowerter-defibrylator, próg defibrylacji, jedno- i dwubiegunowy układ defibrylujący

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Adres do korespondencji:

dr Andrzej Lubiński, II Klinika Chorób Serca, Instytut Kardiologii, Akademia Medyczna, ul. Dębinki 1, 80-211 Gdańsk,
tel.: + 48 58 349 39 10, e-mail: alub@amg.gda.pl