Folia Cardiologica 2015
tom 10, nr 2, strony 71–78
DOI: 10.5603/FC.2015.0016

ISSN 2353–7752

The evaluation of the number and adequacy of interventions, frequency of reprogramming of implantable cardioverters-defibrillators and pharmacotherapy changes in patients with dilated cardiomyopathy receiving primary sudden cardiac death prevention

Ocena liczby i adekwatności interwencji, częstości programowania kardiowerterów-defibrylatorów oraz zmian farmakoterapii u pacjentów z kardiomiopatią rozstrzeniową w prewencji pierwotnej nagłego zgonu sercowego

Joanna Pudło[1], Paulina Magda[2], Dominika Ochab[2], Tomasz Rajs[2], Maria Lelakowska-Pieła[3], Jacek Tadeusz Lelakowski[4]

[1]Department of Electrocardiology, John Paul II Hospital in Krakow
[2]Students' Scientific Group of Electrocardiology, Department of Electrocardiology, Institute of Cardiology, Jagiellonian University Medical College, Krakow
[3]The John Paul II Hospital in Kracow
[4]Department of Electrocardiology, Institute of Cardiology, Jagiellonian University Medical College, John Paul II Hospital in Krakow

Abstract

Introduction. Implantation of cardioverter-defibrillator (ICD) is an acknowledged strategy in primary prevention of sudden cardiac death (SCD). The aim of this study was to assess the number and adequacy of ICD interventions and occurrence of modifications of device parameters and pharmacotherapy changes, in patients with dilated cardiomyopathy receiving primary SCD prevention.

Material and methods. Retrospective analysis included 138 consecutive patients (123 males, 15 females) with ischaemic (IDCM) and non-ischaemic dilated cardiomyopathy (NIDCM), who underwent ICD implantation. The analysis comprised the number of ventricular tachyarrhythmia episodes, the number and appropriateness of ICD interventions, occurrence of ICD reprogramming and pharmacotherapy changes.

Results. ICD interventions occurred in 28% of subjects, pharmacotherapy changes in 27,5% and device parameters modifications in 55,8%. Patient's age and absence of atrial fibrillation appeared to be significant factors decreasing the risk of ICD interventions. AF presence was connected with high percentage of inadequate interventions. Ventricular arrhythmias presence and device parameters changes appeared to be more frequent in patients with NIDCM than with IDCM. NIDCM appeared to be an independent risk factor for ICD reprogramming.

Conclusions. ICD interventions are relatively rare in patients receiving primary SCD prevention. Patient's age and absence of atrial fibrillation appeared to be significant factors decreasing the risk of ICD interventions. Ventricular arrhythmias presence and device parameters changes appeared to be more frequent in patients with NIDCM than with IDCM.

Key words: cardioverter-defibrillator, dilated cardiomyopathy

(Folia Cardiologica 2015; 10, 2: 71–78)

Address for correspondence: prof. dr hab. n. med. Jacek Tadeusz Lelakowski, Klinika Elektrokardiologii, Instytut Kardiologii, *Collegium Medicum*, Uniwersytet Jagielloński, Krakowski Szpital Specjalistyczny im. Jana Pawła II, ul. Prądnicka 80, 31–202 Kraków, e-mail: jlelakow@szpitaljp2.krakow.pl

Introduction

Patients with implantable cardioverter-defibrillator (ICD) indications for primary prevention of sudden cardiac death (SCD) are a huge group of patients with an implanted device. Since the publication of the Guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death in 2006, their number is constantly growing. Interrogation of these devices, which should be done every 3–6 months [1] is a major burden for the health care system. During a routine follow-up visit (FUV), medical history since patient's last visit is taken, a physical examination is performed and the ICD's memory is read (interrogation), which shows i.a. interventions of the device due to recognition of life threatening ventricular tachyarrhythmias (AI, adequate interventions). According to various sources, the percentage of patients with an implanted device of the indications for primary prevention of sudden cardiac death, with ischaemic (IDCM) or non-ischaemic dilated cardiomyopathy (NIDCM), who experience a discharge from the ICD, varies between 20–35.5% [2–6], whereas 14.5–22.5% of which are inadequate (IAI, inadequate interventions) [4–7], that is, when the device mistakenly recognize the rhythm as requiring intervention — usually as a result of supraventricular tachyarrhythmias with rapid ventricular response [3]. Further activities performed during a FUV is checking of the other parameters of the device (battery status, bradycardia stimulation parameters — sensing and pacing, tachyarrhythmia detection and therapy settings), and then a decision is made whether to leave the previous settings or reprogram them. Sometimes during the FUV modification of pharmacotherapy (MOP) is done, but patients with ICDs are also under constant control of the clinical cardiologist, so MOP are rather rare during routine FUV. Using the recommended by the producers algorithms for discrimination between ventricular and supraventricular arrhythmias, optimal bradycardia pacing settings and optimal detection and therapy for ventricular arrhythmia settings reduces mistakes commited by the device and minimizes the need for changes.

When there are no episodes of ventricular arrhythmia recorded in the memory of ICD, none of the parameters of the device is changed and pharmacotherapy is regarded as optimal, the FUV boils down to simple interrogation of ICD with the conclusion that everything is in order, what is a burden for both patients (absence at work, a long journey to the department, sometimes the need for an accompanying person) and for outpatient department that from year to year must take care of a growing crowd of patients [8]. That is the reason, why remote monitoring of ICDs seems to be more and more interesting. The aim of the present study was to evaluate the number and adequacy of interventions, frequency of reprogramming of ICDs and MOP in patients with dilated cardiomyopathy (DCM) receiving primary SCD prevention.

Material and methods

Patients

We conducted a retrospective study, which included consecutive patients (n = 138, 15 females, 123 males, mean age 65 ± 12 [range 23–87] years) hospitalized in the Department of Electrocardiology in order to implant an ICD in 2010–2011 due to IDCM or NIDCM defined as reduced left ventricular ejection fraction (LVEF) that is 35% or less and heart failure in New York Heart Association (NYHA) class II or greater. Additional criteria were: optimal pharmacotherapy for heart failure, expected survival time of at least one year, state at least 40 days after myocardial infarction. Exclusion criteria were: hospitalization for replacement or up-grade of the system, the defibrillator with cardiac resynchronization therapy function (CRT-D), patient primarily planned for implantation of a CRT-D system, cardiac surgery other than coronary artery bypass graft, dual system (pacemaker at the contralateral side), history of cardiac arrest, the presence of congenital heart defects or genetically determined arrhythmias, loss of contact with the clinic. Of the 520 patients initially enrolled in the study, only 138 (26.54%) met the inclusion criteria. All participants were informed about the aim of the study and provided written consent of participation. The study protocol was approved by a local ethics committee (Komisja Bioetyczna, Okręgowa Izba Lekarska, Kraków).

Methods

Medical history from hospitalization and records from the in-office FUV were analysed. On admission, following variables were collected: age, gender, date of implantation, cause of cardiomyopathy (IDCM or NIDCM), LVEF, NYHA class and presence or history of atrial fibrillation (AF). All in-office FUV were registered. We analysed data printed from the programmer, plots of detected arrhythmias and comments written by the physician. We recorded dates of visits, number of interventions, type of intervention (anti-tachycardia pacing [ATP] or cardioversion [CV]), adequacy of intervention (AI and INAI), number of recorded ventricular fibrillations (VF), ventricular tachycardias (VT), nonsustained ventricular tachycardias (nsVT), supraventricular tachycardias (SVT), MOP (if any) and modification of device parameters (ROD, reprogramming of ICD device) defined as: changes in bradycardia pacing, changes in threshold or sensing settings, changes in detection of VT/VF, changes in therapy of VT/VF, changes in programming algorithms recommended by producer. VT zone was defined as 167–200 beats per minute (bpm), and VF zone was defined as 200 bpm or more. Additionally, fast ventricular

tachycardia zone (FVT) defined as ventricular tachycardia within the range of 200–240 bpm was activated in some cases, in order to treat slow episodes of VF by ATP first. nsVTs were ventricular tachyarrhythmias monitored and recorded by a device, but too short to be classified as VT (arrhythmias which did not dropped in detection zone) and provoke the intervention of ICD. SVTs were tachyarrhythmias classified by an ICD as supraventricular with the use of various discrimination algorithms.

Statistical analysis

Descriptive parameters of quantitative variables included arithmetic mean ± standard deviation (SD), median, maximum and minimum value, and sample size (*n*). Differences in quantitative variables between groups were tested using the Student t test for independent samples or the Mann-Whitney test, depending on the variable distribution.

Descriptive parameters of qualitative variables included numbers and percentages and were presented in the contingency tables. Differences in qualitative variables between groups were tested using the χ^2 test or the exact Fisher test. Kaplan-Meier survival curves were used to evaluate survival free from ICD intervention or modification of pharmacotherapy.

Dichotomy of variables: NYHA and LVEF were based on the mean and median across the base. The variables significantly affecting survival to the intervention or modification were included stepwise into a multivariate Cox proportional hazard model. The verification of the statistical significance of the regression coefficients was performed by the Wald test. Statistical hypotheses were verified at $\alpha = 0.05$. Calculations were performed using the STATISTICA 10.0 PL package (StatSoft, Inc.).

Results

During the observation period from the ICD implantation to the last documented visit in the clinic (mean value 616 days), interventions of the device occurred among 28% of patients. MOP was performed in 27.5% patients and ROD was implemented in 55.8% of subjects. Among patients who had ICD interventions during this time, 59% were treated by CV, and 74.4% by ATP. Specification of the other analysed qualitative and quantitative variables is contained in the Table 1 and 2. There were no statistically significant differences observed in terms of analysed variables (age, gender, NYHA class, LVEF, IDCM, AF) between separated groups of subjects — with and without: interventions, MOP and ROD respectively.

Kaplan-Meier curves for the probability of survival free from the first intervention, first MOP and first ROD are shown in Figure 1. Survival free form above-mentioned

Table 1. Description of quantitative variables

Variables	Number of patients	Mean	Standard deviation	Median	Minimum	Maximum
NYHA class (1, 2, 3, 4)	138	2	1	2	2	4
LVEF (%)	138	25	6	25	10	35
Time to 1st intervention	39	319	226	272	41	881
Time to 1st modification of pharmacotherapy	38	340	272	275	39	951
Time to 1st modification of parameters	77	353	297	251	19	1147
Total VF (from check-ups)	27	5	10	1	1	38
Total FVT (from check-ups)	6	3	4	1	1	11
Total VT (from check-ups)	27	4	5	2	1	21
Total nsVT (from check-ups)	66	1128	6743	12	1	54 539
Total SVT (from check-ups)	22	330	1293	9	1	6102
Total interventions from check-ups	39	1	1	1	1	3
Total adequate interventions from check-ups	34	1	1	1	1	3
Total CVs from check-ups	23	1	0	1	1	2
Total ATP from check-ups	29	1	0	1	1	2
Total modification of pharmacotherapy from check-ups	38	1	0	1	1	2
Total modification of parameters from check-ups	77	2	1	1	1	5

NYHA — New York Heart Association; LVEF — left ventricle ejection fraction; VF — ventricular fibrillation; FVT — fast ventricular tachycardia; VT — ventricular tachycardia; nsVT — non-sustained ventricular tachycardia; SVT — supraventricular tachycardia; CV — cardioversion; ATP — antitachycardia pacing

Table 2. Study group characteristics — description of qualitative variables

Variable		n	%
Occurrence of intervention	No	99	71.7
	Yes	39	28.3
Modification of pharmacotherapy	No	100	72.5
	Yes	38	27.5
Modification of parameters	No	61	44.2
	Yes	77	55.8
VF	No	111	80.4
	Yes	27	19.6
FVT	No	132	95.7
	Yes	6	4.3
VT	No	111	80.4
	Yes	27	19.6
nsVT	No	72	52.2
	Yes	66	47.8
SVT	No	116	84.1
	Yes	22	15.9
CV	No	115	83.3
	Yes	23	16.7
ATP	No	109	79.0
	Yes	29	21.0
Total		138	100.0

VF — ventricle fibrillation; FVT — fast ventricle tachycardia; VT — ventricular tachycardia; nsVT — non-sustained ventricular tachycardia; SVT — supraventricular tachycardia; CV — cardioversion; ATP — antitachycardia pacing

events was on average 550 ± 341 days [26–1301], 549 ± 344 days [26–1308], and 473 ± 372 days [19–1372] respectively.

The multivariate analysis performed using Cox regression model is presented in Table 3. It was revealed that the significant factors in reducing the risk of ICD intervention are: age (HR = 0.972, 95% CI: 0.948–0.997, p = 0.027) and an absence of AF (HR = 0.528, 95% CI: 0.277–1.004,

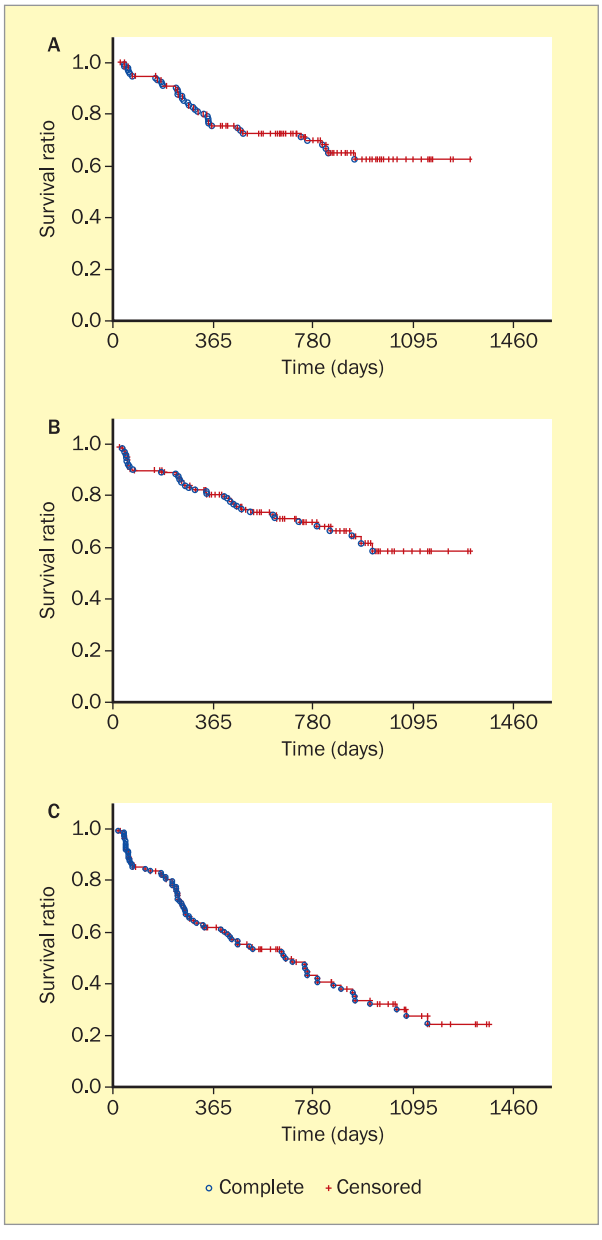

Figure 1. Kaplan-Meier curves for the probability of survival free from cardioverter-defibrillator (ICD) intervention (**A**), modification of pharmacotherapy (**B**) and reprogramming of ICDs (**C**)

Table 3. Multivariate analysis of the prognostic factors for intervention of ICD, modification of pharmacotherapy and modification of parameters of ICD respectively, using the Cox regression model

	Parameter	HR	95% CI	p value
Intervention	Age	0.972	0.948–0.997	0.027
	Atrial fibrillation (absence)	0.528	0.277–1.004	0.05
Modification of pharmacotherapy	LVEF (%)	0.948	0.897–1.002	0.061
	Atrial fibrillation (absence)	0.572	0.302–1.084	0.087
Modification of parameters	Non-ischaemic dilated cardiomyopathy	1.776	1.063–2.966	0.028

HR — hazard ratio; CI — confidence interval; LVEF — left ventricular ejection fraction

Table 4. Characteristics of patients with NIDCM and IDCM, occurrence of particular types of ventricular arrhythmias and types of intervention

Characteristics		NIDCM		IDCM		Total		p value
		n	%	n	%	n	%	
Gender	Male	27	93.1	96	88.1	123	89.1	0.348
	Female	2	6.9	13	11.9	15	10.9	
Age	< 64 years	22	75.9	40	36.7	62	44.9	< 0.001
	≥ 64 years	7	24.1	69	63.3	76	55.1	
NYHA	II	16	55.2	80	73.4	96	69.6	0.058
	III + IV	13	44.8	29	26.6	42	30.4	
LVEF	< 25%	9	31.0	31	28.4	40	29.0	0.748
	≥ 25%	20	69.0	78	71.6	98	71.0	
AF	No	11	37.9	77	70.6	88	63.8	0.001
	Yes	18	62.1	32	29.4	50	36.2	
VF	No	21	72.4	90	82.6	111	80.4	0.220
	Yes	8	27.6	19	17.4	27	19.6	
FVT	No	29	100.0	103	94.5	132	95.7	0.236
	Yes	0	0.0	6	5.5	6	4.3	
VT	No	25	86.2	86	78.9	111	80.4	0.378
	Yes	4	13.8	23	21.1	27	19.6	
nsVT	No	12	41.4	60	55.0	72	52.2	0.190
	Yes	17	58.6	49	45.0	66	47.8	
CV	No	21	72.4	94	86.2	115	83.3	0.076
	Yes	8	27.6	15	13.8	23	16.7	
ATP	No	21	72.4	88	80.7	109	79.0	0.328
	Yes	8	27.6	21	19.3	29	21.0	
CV + ATP	No	26	89.7	104	95.4	130	94.2	0.221

NIDCM — non-ischaemic dilated cardiomyopathy; IDCM ischaemic dilated cardiomyopathy; NYHA — New York Heart Association; LVEF — left ventricular ejection fraction; AF — atrial fibrillation; FVT — fast ventricle tachycardia; VF — ventricle fibrillation; VT — ventricular tachycardia; nsVT — non-sustained ventricular tachycardia; CV — cardioversion; ATP — antitachycardia pacing

p = 0.05). Presence of NIDCM is a significant risk factor for the ROD (HR = 1.776, 95% CI: 1.063–2.966, p = 0.028). There were no predictors among analysed variables for MOP.

Among patients suffering from NIDCM, there was noticed a higher percentage of persons with AI and INAI, and lower of those remaining without any intervention (60% vs 23.3% vs 18.2% respectively). Interestingly, in this group of subjects the percentage of ROD was greater than in the group of patients suffering from IDCM (35.5% vs 14.8%, p < 0.057). Ventricular tachyarrhythmia occurrence was also more common in patients with NIDCM than with IDCM (25.9% vs 13.2%, p = 0.075). Among the subjects with AF, the percentage of patients with INAI was higher than of those without any interventions (67.7% vs 20%, p = 0.048). Main characteristics of patients with IDCM and NIDCM, particular types of ventricular arrhythmias and types of intervention are presented in Table 4.

Among patients suffering from ventricular arrhythmias, compared with those free of them, frequency of ICD interventions was significantly higher (43.5% vs 3.8%, p < 0.001), especially considering adequate ones (40% vs 0%, p < 0.001). Also the percentage of patients with MOP was higher (37.6% vs 11.3%, p < 0.001), than among group of patients without ventricular arrhythmias. Comparing groups of patients in terms of the presence of interventions, ROD was more frequent in group with interventions than without (17.6% vs 3.8%, p = 0.052).

A proportion of patients with ROD due to intervention in response to ventricular tachyarrhythmia was 31.4%, whereas when intervention was inadequate, this percentage was 3.8% (significant difference, p = 0.004). ROD was performed among all subjects with NIDCM, AF, NYHA class > 2 and LVEF < 25%. Among the other part of studied population, a proportion of ROD was 53,1% (100% vs 53.1%, p = 0.008).

Discussion

Primary prevention of SCD means i.a. supplying patients at high risk of cardiac arrest due to VT/VF with ICDs. On the basis of both the MADIT-II and SDC-HeFT studies, as well as DEFINITE study, there have been distinguished a group of people, which benefits most from ICD implantation for primary prevention of SCD, that is patients with IDCM and NIDCM [9–11]. Currently, the largest group of patients eligible for ICD implantation for primary prevention of SCD is patients with IDCM [10]. It was found that a low LVEF is the most important independent risk factor for SCD in patients after myocardial infarction (MI) [12]. Although it has been shown that patients with EF < 35% benefit from ICD implantation [10], it is known that the low fraction is neither sufficiently sensitive nor specific tool for estimating the risk of SCD [13]. Similarly, in our study, we observed no influence of LVEF on the occurrence of intervention and ventricular arrhythmias. For years, the SCD risk stratification factors have been searched in the above mentioned group of patients, but so far none of these methods obtained the rank of guidelines. Currently it is believed that the key issue is to look for arrhythmia substrate. In patients after MI the re-entry loop around the infarction scar is responsible for the formation and maintenance of life-threatening ventricular arrhythmias [14]. The mechanism of SCD in patients with NIDCM is less clear [15]. In our study, a higher percentage of patients with AI and INAI was observed in patients with NIDCM in comparison to IDCM. Similarly, the percentage of ROD as well as ventricular arrhythmias was higher in this group of patients. We found that the occurrence of NIDCM is an independent risk factor for ROD. Unfortunately, so far no good enough stratification factors of mortality in patients with NIDCM have been found. Our study suggests that among patients with an ICD, it is the patients with NIDCM that deserve special attention. This finding is particularly interesting because it was previously believed that patients with NIDCM are younger, possess fewer comorbidities and thus a lower mortality risk supporting their candidacy for ICD to reduce SCD.

In our study the percentage of patients suffering from interventions (28%) is comparable to that reported in large trials. A major percentage of interventions was ATP (74.4%) comparing to CV (59%). ATP seems to be especially beneficial, due to reduction of painful discharges, which considerably worsens quality of life among ICD recipients in primary prevention [16]. What is interesting, in our study age reduced the risk of intervention. It may be explained by higher risk of death due to non-arrhythmic causes, but it has not been proven in literature [17]. In our study survival free from intervention, MOP and ROD was relatively long, contrary to literature, in which RODs were significantly less frequent, after 6 months after implant [18].

INAIs are a major problem among patients with ICDs and affect mainly patients with AF [3]. Experiencing repetitious interventions and fear of them, diminish the quality of life, may also lead to anxiety and depressive disorders [19, 20]. In our study, the lack of AF significantly reduced the risk of intervention. We conclude that despite the use of advanced algorithms of discrimination of supraventricular and ventricular arrhythmias, still too many patients suffer from inappropriate detection of supraventricular arrhythmia as VT or VF, and INAI as a consequence.

Managing patients with heart failure includes alleviation of signs and symptoms, prevention from hospitalization and improving survival [21]. Eligibility for ICD implantation occurs only in patients whose pharmacological treatment is optimal. During the post implantation period, beside regular ICD check-ups, all the patients are under control of clinical cardiologists and general practitioners, therefore the percentage of MOP in our study is relatively low (27%). During FUV, MOP, which is directly related to arrhythmia and is made to minimize the risk of inappropriate intervention or the occurrence of VT/VF, is necessary. Other MOPs made by a specialist during FUV, associated with other symptoms or comorbidities, could also be made by a general practitioner. In our study population, we have not found any factors predisposing to MOP among analysed features. In contrast, there were significantly more MOP in the group of patients with ventricular arrhythmia, in comparison to the group without.

The percentage of RODs in the observed group was 55.8%. According to literature, up to 78% interrogations of the ICD does not involve taking any action [22]. Considering that the number of patients with implantable devices is increasing, there are attempts being made to include these patients in remote monitoring systems (RM). The most debatable issue concerning RM is safety issue, especially in the case of ICDs and CRT-D. Guédon-Moreau et al. [23] in the ECOST trial confirmed the safety and effectiveness of RM of patients with ICDs. Moreover, patients controlled by RM had significantly lower incidence of NI and INAI and up to 72% less hospitalizations. In our study the percentage of RODs is relatively high. Probably it results from both the fact that to the RODs we also included changing the parameters of stimulation, but also because the stimulation pulse amplitude was adjusted to the threshold value during the FUV, not automatically. In all patients in the group with NIDCM, AF, NYHA > 2, and LVEF < 25% device parameters were modified, which indicates that these patients should

be taken under special care. ROD for obvious reasons was also more frequent in patients with interventions. In our study, NIDCM was the independent risk factor for modification of parameters ICD.

Limitations

Limitations of this study include its retrospective nature and small study sample, which may have prevented us from detecting statistical significance between analysed qualitative and quantitative variables. Small study sample is a result of strict inclusion criteria which let us exclude the majority of initially enrolled patients.

Conclusion

Patient's age and absence of atrial fibrillation appeared to be significant factors decreasing the risk of ICD interventions. Ventricular arrhythmias presence and device parameters changes appeared to be more frequent in patients with non-ischaemic than with ischaemic dilated cardiomyopathy.

Conflicts of interests

The authors declare no conflicts of interest.

Streszczenie

Wstęp. Implantacja kardiowerterów-defibrylatorów (ICD) jest uznaną strategią leczniczą w prewencji pierwotnej nagłego zgonu sercowego (SCD). Celem pracy była ocena liczby i adekwatności interwencji ICD oraz modyfikacji parametrów urządzenia i farmakoterapii u pacjentów z kardiomiopatią rozstrzeniową (DCM) w prewencji pierwotnej SCD.

Materiał i metody. Retrospektywnie przebadano 138 pacjentów z ICD (123 mężczyzn, 15 kobiet) wszczepionym z powodu niedokrwiennej (IDCM) i nieniedokrwiennej (NIDCM) DCM. Przeanalizowano liczbę epizodów tachyarytmii komorowej, liczbę i adekwatność interwencji ICD oraz modyfikacji parametrów urządzenia i farmakoterapii.

Wyniki. U 28% pacjentów zarejestrowano interwencje ICD, u 27,5% modyfikowano farmakoterapię, u 55,8% zaś zmieniano parametry urządzenia. Wiek chorych oraz brak napadów migotania przedsionków (AF) były istotnymi czynnikami zmniejszającymi liczbę interwencji. Obecność napadów AF była związana z istotnym pojawianiem się nieadekwatnych interwencji. Tachyarytmie komorowe i związaną z tym modyfikację parametrów urządzenia istotnie częściej zanotowano u osób z NIDCM niż z IDCM. Nieniedokrwienna DCM jest niezależnym istotnym czynnikiem determinującym liczbę modyfikacji parametrów urządzenia.

Wnioski. Interwencje ICD serca rzadko się zdarzają w prewencji pierwotnej SCD. Wiek pacjentów oraz brak napadów AF są istotnymi czynnikami zmniejszającymi liczbę interwencji ICD. Tachyarytmie komorowe i modyfikacje parametrów urządzenia są szczególnie częste u pacjentów z NIDCM w porównaniu z osobami z IDCM.

Słowa kluczowe: kardiowerter-defibrylator, kardiomiopatia rozstrzeniowa

(Folia Cardiologica 2015; 10, 2: 71–78)

References

1. Epstein A.E., DiMarco J.P., Ellenbogen K.A. et al. 2012 ACCF/AHA/HRS Focused Update of the 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. Circulation 2013; 127: 283–352.
2. Buxton A.E., Fisher J.D., Josephson M.E. et al. Prevention of sudden death in patients with coronary artery disease: the Multicenter Unsustained Tachycardia Trial (MUSTT). Prog. Cardiovasc. Dis. 1993; 36: 215–226.
3. Daubert J.P., Zareba W., Cannom D.S. et al. Inappropriate implantable cardioverter-defibrillator shocks in MADIT II: frequency, mechanisms, predictors, and survival impact. J. Am. Coll. Cardiol. 2008; 51: 1357–1365.
4. Saxon L.A., Bristow M.R., Boehmer J. et al. Predictors of sudden cardiac death and appropriate shock in the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) Trial. Circulation 2006; 114: 2766–2772.
5. Poole J.E., Johnson G.W., Hellkamp A.S. et al. Prognostic importance of defibrillator shocks in patients with heart failure. N. Engl. J. Med. 2008; 359: 1009–1017.
6. Saxon L.A., Hayes D.L., Gilliam F.R. et al. Long-term outcome after ICD and CRT implantation and influence of remote device follow-up: the ALTITUDE survival study. Circulation 2010; 122: 2359–2367.

7. Kadish A., Schaechter A., Subacius H. et al. Patients with recently diagnosed nonischemic cardiomyopathy benefit from implantable cardioverter-defibrillators. J. Am. Coll. Cardiol. 2006; 47: 2477–2482.
8. Landolina M., Perego G.B., Lunati M. et al. Remote monitoring reduces healthcare use and improves quality of care in heart failure patients with implantable defibrillators: the evolution of management strategies of heart failure patients with implantable defibrillators (EVOLVO) study. Circulation 2012; 125: 2985–2992.
9. Bardy G.H., Lee K.L., Mark D.B. et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. N. Engl. J. Med. 2005; 352: 225–237.
10. Moss A.J., Zareba W., Hall W.J. et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N. Engl. J. Med. 2002; 346: 877–883.
11. Kadish A., Dyer A., Daubert J.P. et al Prophylactic defibrillator implantation in patients with nonischemic dilated cardiomyopathy. N. Engl. J. Med. 2004; 350: 2151–2158.
12. Yap Y.G., Duong T., Bland J.M. et al. Optimising the dichotomy limit for left ventricular ejection fraction in selecting patients for defibrillator therapy after myocardial infarction. Heart 2007; 93: 832–836.
13. Stecker E.C., Vickers C., Waltz J. et al. Population-based analysis of sudden cardiac death with and without left ventricular systolic dysfunction: two-year findings from the Oregon Sudden Unexpected Death Study. J. Am. Coll. Cardiol. 2006; 47: 1161–1166.
14. de Bakker J.M., van Capelle F.J., Janse M.J. et al. Reentry as a cause of ventricular tachycardia in patients with chronic ischemic heart disease: electrophysiologic and anatomic correlation. Circulation 1988; 77: 589–606.
15. Hsia H.H., Callans D.J., Marchlinski F.E. Characterization of endocardial electrophysiological substrate in patients with nonischemic cardiomyopathy and monomorphic ventricular tachycardia. Circulation 2003; 108: 704–710.
16. Groeneveld P.W., Matta M.A., Suh J.J. et al. Quality of life among implantable cardioverter-defibrillator recipients in the primary prevention therapeutic era. Pacing Clin. Electrophysiol. 2007; 30: 463–471.
17. Tsai V., Goldstein M.K., Hsia H.H. et al. Age differences in primary prevention implantable cardioverter-defibrillator use in U.S. individuals. J. Am. Geriatr. Soc. 2011; 59: 1589–1595.
18. Lunati M., Gasparini M., Santini M. et al. Follow-up of CRT-ICD: implications for the use of remote follow-up systems. Data from the InSync ICD Italian Registry. Pacing Clin. Electrophysiol. 2008; 31: 38–46.
19. Magyar-Russell G., Thombs B.D., Cai J.X. et al. The prevalence of anxiety and depression in adults with implantable cardioverter defibrillators: a systematic review. J. Psychosom. Res. 2011; 71: 223–231.
20. Jordan J., Titscher G., Peregrinova L. et al. Manual for the psychotherapeutic treatment of acute and post-traumatic stress disorders following multiple shocks from implantable cardioverter defibrillator (ICD). Psychosoc. Med. 2013 Dec 18; 10: Doc09. doi: 10.3205/psm000099. eCollection 2013.
21. McMurray J.J., Adamopoulos S., Anker S.D. et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012: The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC. Eur. Heart J. 2012; 33: 1787–1847.
22. Heidbüchel H., Lioen P., Foulon S. et al. Potential role of remote monitoring for scheduled and unscheduled evaluations of patients with an implantable defibrillator. Europace 2008; 10: 351–357.
23. Guédon-Moreau L., Lacroix D., Sadoul N. et al. A randomized study of remote follow-up of implantable cardioverter defibrillators: safety and efficacy report of the ECOST trial. Eur. Heart J. 2013; 34: 605–614.

Komentarz. Opieka nad chorymi z wszczepionym kardiowerterem-defibrylatorem — równanie z wieloma zmiennymi

dr hab. n. med. Maciej Sterliński
Instytut Kardiologii w Warszawie

W pracy oryginalnej Joanny Pudło i wsp. przedstawiono jednoośrodkowe wyniki obserwacji średnioterminowej w grupie chorych z profilaktycznie wszczepionym kardiowerterem-defibrylatorem (ICD) w wyniku istotnego uszkodzenia lewej komory o różnej etiologii, czyli w subpopulacji obecnie najczęściej leczonej tą metodą [1].

Odsetek chorych z interwencjami ICD, sięgający 28% — zwłaszcza w średnim okresie obserwacji nieprzekraczającym 2 lat — jest odsetkiem istotnym i wynikiem porównywalnym z podawanym w dostępnych doniesieniach. W badaniu SCD-HeFT, które najlepiej przystaje do komentowanej pracy, interwencje wystąpiły u 31% chorych podczas 5 lat obserwacji, czyli rocznie średnio u 7,5% [2]. Natomiast w badaniach obserwacyjnych częstotliwość interwencji w podobnych populacjach ocenia się na 20–30% w czasie 1–2 lat, a w populacji niewyselekcjonowanej — nawet na ponad 40% [3, 4]. Okres kilkunastu miesięcy po wszczepieniu ICD jest związany z najwyższym zagrożeniem interwencjami [3] i podobny trend widać na rycinie 1 w komentowanym artykule. W obserwacjach średnioterminowych chorych z ICD wszczepionym profilaktycznie prawdopodobieństwo pierwszej interwencji określano na 11–15% dla interwencji adekwatnych i około 10% dla interwencji nieadekwatnych, niezależnie od etiologii [5, 6]. Ciekawy jest fakt, że interwencje urządzeń częściej dotyczyły chorych z etiologią pozawieńcową.

Liczba chorych z adekwatnymi interwencjami ICD zależy nie tylko od obecności tachyarytmii komorowych ale i od sposobu programowania [7, 8]. Różne strategie ustalania stref detekcji i sekwencji terapii mogą mieć wpływ nie tylko na możliwość eliminacji bolesnych wyładowań ICD, ale nawet na rokowanie długoterminowe [9]. W populacji z chorobą wieńcową i ICD wszczepionym w ramach profilaktyki pierwotnej stwierdziliśmy ostatnio skuteczność przynajmniej jednej terapii niskonapięciowej (ATP) u 85% pacjentów [4]. Dominujące wykorzystanie ATP w badanej grupie — u 75% chorych z interwencjami ICD jako zjawisko samodzielne lub w skojarzeniu z terapią wysokoenergetyczną — pośrednio potwierdza zastosowanie optymalnych strategii doboru programowania urządzeń przez Autorów, choć brak dokładnych danych na ten temat pozostawia pewien niedosyt. W tym miejscu w pracy brakuje też wyraźnego rozgraniczenia analizy na interwencje adekwatne i nieadekwatne. Interwencje nieadekwatne mogą wystąpić u aż 1/4 chorych z ICD, co jest szczególnie obciążające dla pacjentów bez terapii adekwatnych [3, 10]. Migotanie przedsionków (AF) to jeden z najistotniejszych czynników ryzyka nieadekwatnych interwencji ICD i sytuacja taka znalazła swoje odzwierciedlenie w wynikach prezentowanej pracy [9]. Autorzy nie podają, czy część spośród zanotowanych w badanej grupie nieadekwatnych interwencji była spowodowana uszkodzeniem elektrody. Wynika to zapewne ze zbyt krótkiego okresu obserwacji; problem ten może narastać w dalszych latach. W starszych doniesieniach uszkodzenie elektrody występowało aż u 25% chorych z ICD w 10-letniej obserwacji, a nieadekwatna interwencja urządzenia jest często pierwszym objawem dysfunkcji elektrody. Nowsze typy urządzeń zawierają algorytmy różnicujące szumy uszkodzeń i pozwalają na redukcję nieadekwatnych interwencji z tego powodu, co nie zmienia faktu, że problem uszkodzenia elektrod jest jedną z ważniejszych „ciemnych stron" terapii za pomocą ICD.

Trudny do skomentowania jest fakt, że istotnie częściej zmieniano farmakoterapię u chorych z arytmiami komorowymi i interwencjami urządzenia. Niestety nic nie wiadomo o tych zmianach; czy dotyczyły one strategii *up-stream,* czy leczenia o potencjalnym efekcie antyarytmicznym? Natomiast próba rozwiązania problemu poprzez zmiany w programie urządzenia u tylko 3,8% chorych z nieadekwatnymi interwencjami jest zaskakująco niska. Co prawda samo wystąpienie AF nie korelowało z częstszymi wskazaniami do modyfikacji terapii farmakologicznej, ale — być może — w wymienionej wyżej podgrupie było to postępowanie z wyboru, jeśli założy się, że większości przypadków za nieadekwatne interwencje odpowiadało AF. Temu z kolei wydaje się intuicyjnie przeczyć fakt, że zmiany w programie dotyczyły wszystkich chorych z AF, pozawieńcową etiologią niewydolności serca w klasie NYHA wyższej niż II i frakcją wyrzutową poniżej 25%, czyli potencjalnie „idealnych kandydatów" do nieadekwatnych interwencji ICD. Z tych wątpliwości wynika moje skojarzenie z równaniem z wieloma zmiennymi zawarte w tytule komentarza. W celu uporządkowania rozważań warto podkreślić wzrastające zastosowanie ablacji przeznaczyniowej, zwłaszcza w przypadku problemów związanych z napadami AF, jako metody wspierającej efekty opieki nad chorymi z ICD lub poddawanych terapii resynchronizującej [11].

Praca jednoośrodkowa zawsze pozostaje pod wpływem schematów postępowania i zasad przyjętych w tymże ośrodku. Dlatego przedstawione w artykule Joanny Pudło i wsp. krzywe przeżycia bez punktów końcowych, takich jakich jak interwencja w zakresie farmakoterapii czy reprogramowania, odzwierciedlają też częstotliwość rutynowych lub ponadplanowych wizyt pacjentów. Nie znamy dokładnych powodów ani schematów decyzji związanych z punktami końcowymi — mogą wynikać z indywidualnych przekonań lekarza kontrolującego. Moim zdaniem komentarza wymaga nieco arbitralne stwierdzenie, że w przypadku braku interwencji czy braku arytmii zazwyczaj nie przeprogramowuje się urządzenia. To zazwyczaj prawda, ale chciałbym zwrócić uwagę na konieczność weryfikacji aktywnego programu urządzenia. Mimo że programowanie urządzeń wciąż nie jest przedmiotem jednoznacznych rekomendacji, to uprzednio wprowadzony program może znacznie odbiegać od aktualnej wiedzy medycznej lub nawet zawierać groźne dla życia chorego błędy.

Każda praca — niezależnie od swoich ograniczeń — dotycząca problematyki obserwacji odległej chorych z ICD, zwłaszcza pochodząca z dużego ośrodka z tradycjami, rozszerza naszą wiedzę lub budzi twórcze wątpliwości. Na podstawie wyników przedstawionych przez Autorów widać wyraźnie, że wszczepialne urządzenia zapewne długo jeszcze nie będą autonomicznym bytem typu *implant and forget*, a nieunikniony rozwój telemedycyny, technologii urządzeń i algorytmów programowania nie zastąpią trudnych decyzji klinicznych podejmowanych ostatecznie przez zespół opiekujący się pacjentami.

Piśmiennictwo

1. Raatikainen M.J., Arnar D.O., Zeppenfeld K. i wsp. Statistics on the use of cardiac electronic devices and electrophysiological procedures in the European Society of Cardiology countries: 2014 report from the European Heart Rhythm Association. Europace 2015; (supl. 1): i1–i75. doi: 10.1093/europace/euu300.
2. Bardy G.H., Lee K.L., Mark D.B. i wsp. Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) Investigators. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. N. Engl. J. Med. 2005; 352: 225–237.
3. Reichlin T., Kühne M., Sticherling C. i wsp. Characterization and financial impact of implantable cardioverter-defibrillator patients without interventions 5 years after implantation. QJM 2011; 104: 849–857.
4. Maciąg A., Przybylski A., Sterliński M. i wsp. Effectiveness of antitachycardia pacing therapy after primary prophylaxis implantation of implantable defibrillators in coronary artery disease patients. Adv. Med. Sci. 2014; 59: 161–165. doi: 10.1016/j.advms.2013.12.004.
5. Kreuz J., Balta O., Liliegren N. i wsp. Incidence and characteristics of appropriate and inappropriate therapies in recipients of ICD implanted for primary prevention of sudden cardiac death. Pacing Clin. Electrophysiol. 2007; 30 (supl. 1): S125–S127.
6. Sedláček K., Ruwald A.C., Kutyifa V. i wsp.; for the MADIT-RIT Investigators. The effect of ICD programming on inappropriate and appropriate ICD therapies in ischemic and nonischemic cardiomyopathy: the MADIT-RIT trial. J. Cardiovasc. Electrophysiol. 2015; 26: 424–433. doi: 10.1111/jce.12605.
7. Sweeney M.O., Wathen M.S., Volosin K. i wsp. Appropriate and inappropriate ventricular therapies, quality of life, and mortality among primary and secondary prevention implantable cardioverter defibrillator patients: results from the Pacing Fast VT REduces Shock ThErapies (PainFREE Rx II) trial. Circulation 2005; 111: 2898–2905.
8. Tan V.H., Wilton S.B., Kuriachan V. i wsp. Impact of programming strategies aimed at reducing nonessential implantable cardioverter defibrillator therapies on mortality: a systematic review and meta-analysis. Circ. Arrhythm. Electrophysiol. 2014; 7: 164–170. doi: 10.1161/CIRCEP.113.001217.
9. Moss A.J., Schuger C., Beck C.A. i wsp.; MADIT-RIT Trial Investigators. Reduction in inappropriate therapy and mortality through ICD programming. N. Engl. J. Med. 2012; 367: 2275–2283. doi: 10.1056/NEJMoa1211107.
10. Poole J.E., Johnson G.W., Hellkamp A.S. i wsp. Prognostic importance of defibrillator shocks in patients with heart failure. N. Engl. J. Med. 2008; 359: 1009–1017.
11. Kosiuk J., Nedios S., Darma A. i wsp. Impact of single atrial fibrillation catheter ablation on implantable cardioverter defibrillator therapies in patients with ischaemic and non-ischaemic cardiomyopathies. Europace 2014; 16: 1322–1326.