ORIGINAL ARTICLE

UDC: 616.12
https://doi.org/10.2298/VSP171003010K

Implantable cardioverter defibrillator – powerful weapon in primary and secondary prevention of sudden cardiac death

Implantabilni kardioverter defibrilator – moćno oružje u primarnoj i sekundarnoj prevenciji iznenadne srčane smrti

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Abstract

Bacgraund/Aim. Sudden cardiac death (SCD) is one of the biggest problems of the contemporary medicine. Large studies showed that anti-arrhythmics, including amiodarone, are not effective in prevention of SCD in the patients with cardiac diseases who were on drug treatment. Those patients who received implantable cardioverter defibrillators (ICD) had better survival. The aim of this paper was to determine whether the patients receiving the ICD in the primary and secondary SCD prevention have longer survival than the patients treated exclusively with drug therapy. **Methods.** We included 1,260 patients with cardiac insufficiency and reduced left ventricular ejection fraction (LVEF < 35%) who were at high risk for malignant ventricular arrhythmias and SCD. Five hundred forty patients received ICD therapy. The cardiac resynchronization therapy – CRT/ICD group (n = 270) comprised the patients with cardiac insufficiency and CRT/ICD pacemaker at an optimal medical therapy. In the control group (n = 450), there were the patients with cardiac insufficiency (NYHA functional class 3–4, LVEF ≤ 35%, QRS duration ≥ 130 ms), at optimum drug therapy. **Results.** In the ICD group, there was a statistically significant increase in end-systolic volume (ESV) from 92.68 mL to 99.05 mL. In the group of patients with cardiac insufficiency who were on drug therapy, there was a significant decrease in LVEF (33.15% vs. 30.2%; $p = 0.017$), 6-minute walk distance (6 MWT distance) (216.55 m vs. 203.27 m, $p = 0.003$). In the same group, there was an increase in the values of ESV (90.19 mL vs. 95.41 mL; $p = 0.011$). An increase in the mortality rate in the group of patients with drug therapy compared to the CRT/ICD and ICD groups was statistically significant ($p < 0.05$). **Conclusions.** An ICD pacemaker implantation significantly reduces mortality compared to medical therapy only. In addition, the patients who have CRT in addition to ICD pacemaker, have a significantly better quality of life and increase in LVEF.

Key words:
death, sudden, cardiac; arrhythmias, cardiac; heart failure; defibrillators, implantable; drug therapy; pacemaker, artificial; mortality.

Apstrakt

Uvod/Cilj. Iznenadna srčana smrt (ISS) jedan je od najvećih problema savremene medicine. Velike studije pokazale su da antiaritmici, uključujući amiodaron, nisu efikasni u prevenciji ISS kod bolesnika sa srčanim oboljenjima koji su bili na medikamentnoj terapiji. Bolesnici kojima je ugrađen implantabilni kardioverter defibrilator (ICD) imali su bolje preživljavanje. Cilj ovog rada bio je da se utvrdi da li bolesnici kojima se ugrađuje ICD u primarnoj i sekundarnoj prevenciji ISS imaju duže preživljavanje u odnosu na one lečene isključivo lekovima. **Metode.** Uključili smo 1 260 bolesnika sa srčanom insuficijencijom i smanjenom ejekcionom frakcijom leve komore (LVEF < 35%) koji su imali povišeni rizik od maligne ventrikularne aritmije i ISS. Kod 540 bolesnika ugrađen je ICD pejsmejker. Terapija resinhronizacionim pejsmejkerom i ICD-om (CRT/ICD grupa) (n = 270) obuhvatila je bolesnike sa srčanom insuficijencijom i

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RT/ICD pejsmejkerom uz optimalnu medicinsku terapiju. U kontrolnoj grupi n = 450) bili su bolesnici sa srčanom insuficijencijom (NYHA funkcionalna klasa 3–4, LVEF ≤ 35%, QRS trajanje ≥ 130 ms, na optimalnoj terapiji lekovima). **Rezultati.** U ICD grupi postojalo je statistički značajno povecćanje ESV (end-sistolni volumen) od 92,68 mL do 99,05 mL. U grupi bolesnika sa srčanom insuficijencijom, koji su bili na terapiji lekovima, došlo je do značajnog smanjenja LVEF (33.15% vs. 30.2%; $p = 0{,}017$), distance nakon 6 minuta hodanja [6 MVT (216,55 m vs. 203,27 m; $p = 0{,}003$)]. U istoj grupi došlo je do povecanja vrednosti ESV (90,19 mL vs. 95,41 mL; $p = 0{,}011$). Povecćanje smrtnosti u grupi bolesnika sa terapijom samo lekovima u poređenju sa smrtnošću u CRT/ICD i ICD grupi bilo je statistički značajno ($p < 0.05$). **Zaključak.** Ugradnja ICD pejsmejkera značajno smanjuje smrtnost u poređenju sa lečenjem samo lekovima. Pored toga, bolesnici koji imaju CRT uz ICD pejsmejker, imaju znatno bolji kvalitet života i povecćanje LVEF.

Ključne reči:
smrt, iznenadna, srčana; srce, insuficijencija; defibrilacija srca; defibrilatori, implantabilni; lečenje lekovima; elektrostimulator srca; mortalitet.

Introduction

Sudden cardiac death (SCD) is one of the biggest problems of the contemporary medicine and its prevention is a challenge for every cardiologist. Most often, its occurrence presents the first and the last presentation of a cardiac disease. Many studies showed that the malignant arrhythmias are the main cause of the SCD. The secondary prevention of SCD is a treatment of the patients who survived cardiac arrest, or had the documented hemodynamically unstable ventricular arrhythmias. The primary prevention of SCD is a treatment of high-risk patients, but without documented previous cardiac arrest, or hemodynamically unstable ventricular arrhythmias. Ventricular tachycardia (VT) which degenerates in the ventricular fibrillation (VF) is the most often the cause of SCD. Practically, the effective management of VT is the prevention of SCD. Large multicentre studies showed that anti-arrhythmic, including amiodarone, are not effective in the prevention of SCD in the patients with cardiac diseases who were on drug treatment. Those patients who received implantable cardioverter defibrillators (ICD) had better survival.

Ventricular fibrillation and VT are the most common causes of SCD in the first 24 hours after an acute myocardial infarction (AMI). In the last 40 years, the in-hospital mortality had decreased from 30% to 10%–15% in AMI, mainly due to the prevention of a ventricular arrhythmias and conduction disorders. Ventricular fibrillation occurs most often during the first hour after AMI (80% of all cases occurs in the first 4 hours after AMI), and than its incidence rapidly decreases during 24–48 hours.

The epidemiological data show that the incidence of primary VF is significantly reduced, most probably, due to the correction of electrolyte disorders and other therapeutic measures that reduce the size of the myocardial infarction as well as due to the early use of beta-blockers. Unlike the primary VF caused by myocardial ischemia, which is the most frequent during the first hours after AMI, VF caused by a large necrosis, severe cardiac failure, left ventricular aneurysm and other severe AIM complications (secondary ventricular fibrillation) occurs later, after 48 hours, and has a poor prognosis [1].

Ventricular fibrillation and VT can only be stopped by the use of DC shock or defibrillators, and it is necessary to continuously apply the reanimation measures to maintain the vital functions, until its application. The occurrence of these vital threatening rhythm disorders does not depend on the size of the myocardial necrosis, and even very small AMI that otherwise have a good prognosis, could lead to the SCD.

Implantable cardioverter defibrillators (ICD) are devices that are designed primarily to perform the therapy of life threatening rhythm disorders. Today, the modern ICD devices have similar design and function as the standard bradycardic pacemakers. They use a lithium-vanadium battery due to the reliability of the energy source and the need to deliver a higher amount of energy in a short period of time.

Detection of malignant ventricular arrhythmias is a specific and basic function of an ICD. The biggest advance in technology of those devices was the introduction of a gradual "tiered" therapy. This implies that the detected VT is treated with the least aggressive therapy applied through the antitachycardia burst stimulation with the different duration of the V-V stimulus. Contemporary devices use synchronous cardioversion with a low electrical power of a DC shock and finally defibrillation with the maximum DC shock strength current (30–40 J) in the case of VF [2, 3].

Several studies demonstrated the superiority of an ICD in comparison to a drug therapy in the primary SCD prevention. The MADIT study showed 54% reduction in overall mortality in the patients with a left ventricle ejection fraction (LVEF) < 35% who received ICD due to ischemic heart disease. In the MUSTT study, the patients with ICD and LVEF < 35% had a lower mortality rate due to arrhythmia by 75% and a reduction in overall mortality of 60%. The SCD-HEFT study showed that the patients with the congestive heart failure in New York Heart Academy (NYHA) class II and III, with LVEF<35% on the optimal drug therapy, who ICD, had mortality decreased by 23%. The MADIT II study examined the benefit of ICD implantation in the patients with coronary artery disease who had LVEF < 30% and at least one AMI. An absolute reduction in mortality rate by 31% was observed in the group of patients with ICD compared to those with conventional therapy [4, 5].

The largest studies which examined the efficacy of an ICD in a secondary SCD prevention were: AVID, CIDS, CASH and DUTCH CES. In each of the mentioned study, a significant and undoubtedly improved survival was registered in the patients with ICD compared to those who received anti-arrhythmic drugs (reduction of 20% in mortality

rate in the CIDS study, 38% and 39% in the CASH and AVID studies and of 73% in the DUTCH CES study) [6, 7].

The aim of this paper was to determine whether the patients receiving ICD in the primary and secondary SCD prevention have longer survival than the patients treated exclusively with drug therapy.

Methods

The study included the patients who were treated at the Clinic for Cardiovascular Diseases, Clinical Center Niš from 2007 to 2016 due to heart failure symptoms. The study was conducted according to the human rights and ethical principles for medical research from the Declaration of Helsinki, World Health Organization (WHO).

We included 1,260 patients with cardiac insufficiency and reduced ejection fraction (LVEF < 35%) who were at high risk for malignant ventricular arrhythmias and SCD.

Within the study, 540 patients received ICD therapy (ICD group) based on ICD compliance criteria. We included the patients with left ventricular dysfunction, at least 40 days after a large AMI infarction, and with LVEF ≤ 35% for the primary SCD prevention. For secondary SCD prevention, we included the patients who survived VF or haemodynamically unstable VT, who had non-ischemic dilated cardiomyopathy and a significant left ventricular dysfunction and life expectancy of at least a year. The cardiac resynchronization therapy (CRT/ICD) group (n = 270) comprised the patients with the cardiac insufficiency and cardiac resynchronization therapy CRT/ICD pacemaker (NYHA functional class III-IV, LVEF ≤ 35%, QRS duration ≥ 130 ms, dilated left ventricle (LV > 55 m), at optimal medical therapy for cardiac insufficiency with the fulfilled echocardiographic criteria for responsiveness to the CRT [pre-ejection period of LV (PEPLV) > 140 ms, difference between PEP LV and PEP RV period > 40 ms, SPWMD (septal to posterior wall motion delay > 135 ms). In the control group (n = 450), there were the patients with cardiac insufficiency (NYHA functional class III-IV, LVEF ≤ 35%, QRS duration ≥ 130 ms, at optimum drug therapy) who did not meet the criteria for ICD therapy as well as for CRT.

Patients in the control group were only on optimal drug therapy that included β blocker, ACE inhibitor, diuretic, digitalis and anti-arrhythmic amiodarone (if refused to receive ICD in primary prevention). In all patients, we performed 12 channel electrocardiography (ECG), echocardiographic examination, and six-minute walking test (6MWT), examination of signs and symptoms of heart failure and drugs that were used. After an average follow-up period of one year from ICD or CRT/ICD implantation, ECG, echocardiographic examination, 6MWT distance, signs and symptoms of heart failure were compared together with the number of hospitalizations due to heart failure.

The procedures of pace-maker implantation were performed in sterile conditions, in the cardiac catheterisation laboratory using the Simens Axiom Artis fluoroscopy apparatus. The Pacemaker System Analyzer (PSA) (Figure 1) was also an integral part of the instrumentation used in implantation along with the sterile cables for the connection between the sterile pacemaker and non-sterile PSA. During the implantation, a sterile set of surgical instruments on a sterile stand was used (Figure 2).

Fig. 1 – Pacemaker programmer.

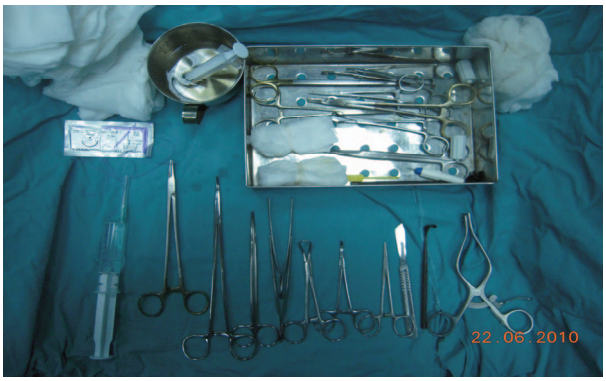

Fig. 2 – Surgical instruments for pacemaker implantation.

ICD pace-maker used for primary prevention was programmed for detection and therapy in the VF zone only (for heart rate mostly > 207/min). In the secondary prevention, in addition to the VF zone for detection and therapy, the VT zone was also activated. That included anti-tachycardia pacing (ATP) therapy options, and in case of its failure to interrupt the arrhythmia, an option to activate the DC shock.

Methods of descriptive and analytical statistics were used in the processing of the data obtained from the research. The selection of methodological procedures was adjusted to the aims of the study and to scientific hypotheses. All obtained parameters were statistically processed by the percentage ratio, mean values of numerical features, standard deviation, Student's *t*-test and χ^2 test, survival rate according to different therapy of cardiac insufficiency (Kaplan Meier curve), Cox regression model – risk factors for fatal outcome.

Results

The technical parameters obtained during the pacemaker implantation are given in Table 1. The gender and age structures of the examined groups are given in Table 2. By analyzing the parameters in Table 3, in the group of patients with CRT/ICD, we observed statistically significantly lower values of all parameters after the implantation of device compared to the same parameters before the implantation, (QRS 147.33 ms vs. 124.44 ms; LVEF 25.21% vs. 37.63%;

6-MWT distance 224.45 m vs. 289.9 m; EDV 286.89 mL vs. 181.22 mL; ESV 187.7 mL vs. 110.5 mL; PEP LV – 181.44 ms vs. 147.18 ms, PEP RV 114.3 ms vs. 96.21 ms; SPWMD 194.5 ms vs. 139.48 ms), $p < 0.001$. In the group of patients with ICD, there was a statistically significant increase in ESV (end-systolic volume) from 92.68 mL to 99.05 mL ($p < 0.001$), as well as an increase in PEP LV from 124.89 ms to 129.95 ms ($p = 0.003$). In the group of patients with cardiac insufficiency who were on drug therapy, there was a significant decrease in LVEF (33.15% vs. 30.2%; $p = 0.017$), 6 MWT distance (216.55 m vs. 203.27 m; $p = 0.003$). In the same group, there was an increase in the values of ESV (90.19 mL vs. 95.41 mL; $p = 0.011$) as well as in PEP LV parameters (122.75 ms vs. 128.56 ms; $p = 0.034$).

Table 1

Parameters obtained during pace-maker implantation

Parameters	CRT-D (n = 270)	ICD (n = 540)
Pacing treshold A (volt, 0.5 ms), mean ± SD	1.17 ± 0.77	0.8 ± 0.47
Pacing treshold RV (volt, 0.5 ms), mean ± SD	0.67 ± 0.69	0. 7 ± 0.4
Pacing treshold LV (volt, 0.5 ms), mean ± SD	1.85 ± 0.8	–
Sensing A, mean ± SD	2 ± 0.75	1.8 ± 0.65
Sensing RV, mean ± SD	8 ± 3.8	11 ± 2.8
Sensing LV, mean ± SD	12 ± 4.6	–
Procedure duration (min), mean ± SD	91 ± 24.8	32 ± 17.6
Radiation exposure duration (min), mean ± SD	7.7 ± 4.9	2.1 ± 0.3
Received radiation dose (μGy/m^2), mean ± SD	1756 ± 321.1	217 ± 93
Complications (n)		
haemathoma	25	19
pneumothorax	0	0
infection	0	0
coronary sinus perforation	0	–
extracardiac stimulation	6	19

CRT-D – cardiac resynchronization therapy defibrillator; ICD – imeplantable cardioverter defibrillator; A – atrium; RV – right ventricle; LV – left ventricle; SD – standard deviation.

Table 2

Gender and age structure of the study groups

Parameters	Group		
	ICD (n = 540)	CRT/ICD (n = 270)	Drug therapy (n = 450)
Sex, n (%)			
male	386 (71.5)	224 (83.0)	350 (77.8)
famele	154 (28.5)	46 (17.0)	100 (22.2)
Age (year)			
mean	62.43	57.98	63.44
SD	8.93	14.35	6.96
min	33	23	44
max	75	73	76

For abbreviation see under Table 1.

Table 3

Investigated parameters at the beginning of the study and after follow-up period

Parameters	CRT/ICD		ICD		Drug therapy	
	Before mean ± SD	After mean ± SD	Before mean ± SD	After mean ± SD	Before mean ± SD	After mean ± SD
QRS (ms)	147.33(10.30)	124.44(10.66)*	113.16(5.58)	113.95(5.91)^{ns}	103.86(9.37)	104.32(8.90)^{ns}
LVEF (%)	25.21(5.08)	37.63(8.37)*	27.16(6.59)	27.00(5.89)^{ns}	33.15(6.26)	30.21(5.75)‡
6 MVT (m)	224.45(38.53)	289.90(67.63)*	209.89(28.18)	213.11(32.62)^{ns}	216.55(28.73)	203.27(30.22)†
EDV (mL)	286.89(55.81)	181.22(44.38)*	166.37(24.40)	164.11(23.97)^{ns}	156.36(33.13)	157.45(34.03)^{ns}
ESV (mL)	187.70(50.63)	110.50(22.33)*	92.68(21.19)	99.05(21.43)*	90.19(14.61)	95.41(18.67)‡
PEP LV (ms)	181.44(17.58)	147.18(8.57)*	124.89(6.93)	129.95(5.13)†	122.75(9.87)	128.56(6.13)‡
PEP RV (ms)	114.30(20.41)	96.21(17.31)*	110.68(13.76)	111.58(12.79)^{ns}	110.09(13.77)	111.50(12.39)^{ns}

EDV – end-diastolic volume; ESV – end-systolic volume; PEP – pre-ejection period; LV – left ventricle; RV – right ventricle; LVEF – left ventricle ejection fraction; GVT – six-minutes walking test; SPWDM – systolic delay of the posterior wall.
***$p < 0.001$; $^{†}p < 0.01$; $^{‡}p < 0.05$; ns – non significant.**
For other abbreviatons see under Table 1.

In the group of patients with resynchronization therapy before CRT/ICD pacemaker implantation, 207 (76.6%) patients had NYHA functional class III and 54 (20.1%) patients had NYHA functional class IV (Table 4). After the implantation of abovementioned device, 18 patients had NYHA class 4, 72 (26.6%) patients were in NYHA 2 class, and 180 (66.6%) patients had NYHA class III of heart failure.

In the group of patients before ICD was implanted, 225 (41.6%) had NYHA II functional class, and after its implantation 270 (50%) patients were in NYHA class II. In the group of patients with drug therapy, 171 (38%) patients were in the NYHA class II, and after the follow-up period, 153 (34%) patients were in the same functional class. After the follow-up period, in the group of patients treated with medicaments, the percentage of those with NYHA class IV increased from 2% to 6%.

In the group of patients with ICD, 27 patients, or 5% died after the follow-up period of at least a year (Table 5). In the group of patients with CRT/ICD device, 18 patients, or 6.7% had a fatal outcome, while in the drug therapy group, this number was 108, or 24% deaths during the follow-up. An increase in a mortality rate in the group of patients with drug therapy compared to the CRT/ICD and ICD groups was statistically significant ($p < 0.05$). There was no significant difference in mortality between the ICD and CRT/ICD groups.

In the group of patients with CRT/ICD, 72 (26.6%) patients had the pacemaker activation/switch on [anti-tachycardia pacing (ATP) or DC shock], while in the ICD group, 21 (35%) patients had the pace-maker activation.

Observing the length of survival in the analyzed groups, it was detected that the patients in the CRT/ICD group had the longest survival [391.7 days with statistical error (SE) = 7.913 days], statistically significantly longer than the subjects in the group of patients with the drug therapy, whose survival was 329.892 ± SE = 10.11 days (Log Rank χ^2 = 9.728; $p < 0.01$) (Figure 3). The patients with implanted ICD had an average survival of 351.6 days with SE = 9.01 and also a significantly longer survival than the patients with the drug therapy (Log Rank $\chi^2 = 7.623$; $p < 0.05$).

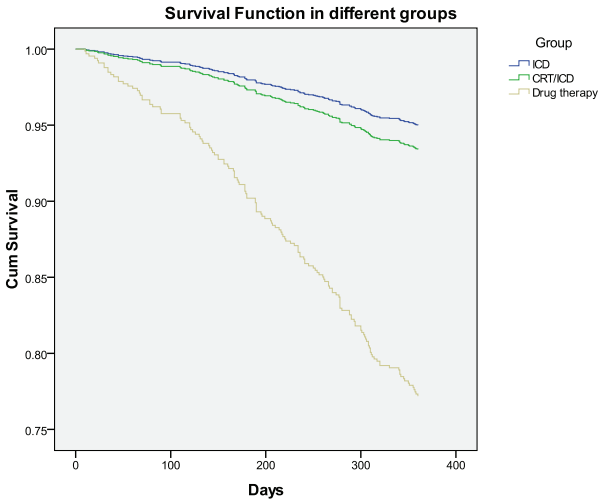

Fig. 3 – Kaplan-Meier curves in the study groups. For abbreviations see under Table 1.

Sudden cardiac death is defined by the WHO as a death related to any cardiac disease that occurs outside the hospital, in an emergency department, or immediately upon arrival to the hospital, or within an hour. It is thought that in the USA, for over 45% of all patients who dies of cardiac disease, the immediate reason is SCD [8–10]. The greatest number of SCD is caused by arrhythmias.

Table 4

NYHA class at the beginning and at the end of study

NYHA class	ICD n (%)	CRT/ICD n (%)	Drug therapy n (%)
Before			
II	225 (41.6)	9 (3.3)	171 (38)
III	225 (41.6	207 (76.6)	270 (60)
IV	90 (16.8)	54 (20.1)	9 (2)
After			
II	270 (50.0)	72 (26.6)	153 (34)
III	225 (41.6)	180 (66.6)	270 (60)
IV	45 (8.4)	18 (6.8)	27 (6)

NYHA – New York Heart Association.
For other abbreviations see under Table 1.

Table 5

Mortality in the study groups

Mortality	CRT/ICD n (%)	ICD n (%)	Drug therapy n (%)	Total n (%)
No	252 (93.3)	513 (95)	342 (76)	999 (79.2)
Yes	18 (6.7)	27 (5)	108 (24)*	261 (20.8)
Total	270 (100.0)	540 (100.0)	450 (100.0)	1,260 (100.0)

For abbreviations see under Table 1.
***$p < 0.05$ (vs. CRT/ICD and ICD groups).**

Discussion

Among them, the cause are the ventricular tachycardia and fibrillation in over 80%, and for the rest of patients bradyarrhythmias and asystole. The coronary artery disease is responsible for arrhythmias in at least 80% of these patients, and dilated idiopathic cardiomyopathy and hypertrophic cardiomyopathy are the next most common cause. A survival after cardiac arrest varies from less than 5% to 60% depending on the characteristics of the cardiac arrest (e.g., cardiac ethiology or not, the presence of other people or not at that moment, VF or not) [11–14]. The results of cardiopulmonary resuscitation (CPR) do not depend only on the quality of the reanimation, but also on the patient's condition before the start of CPR. It is now generally accepted that the time of electrical defibrillation is the most important determinant of survival after a cardiac arrest. The introduction of automatic external defibrillators is allowed for use by even less-trained users to deliver electric shock in cases of out-of-hospital VF or VT, often several minutes before the arrival of the medical emergency medical team. The strategy is also known as the "first defibrillator response" [15–17].

Prevalence of cardiac insufficiency is an increasing problem in modern cardiology. Cardiac insufficiency as a diagnosis is in the expansion and more and more patients have this diagnosis. In our study, there were 1,290 patients with this diagnosis. There were no statistically significant differences regarding the gender and age between investigated groups. Sudden cardiac death is the most common cause of death in the patients with cardiac insufficiency. The patients with NYHA class II have 1-year mortality of 5%–15%, while the patients with NYHA class III have an annual mortality of 20%–50%, and the most vulnerable patients in NYHA class IV have an annual mortality of 30%–70% [16–18]. The patients with a higher NYHA class die of cardiac insufficiency and its repercussions on other organs while the patients with a lower NYHA class die more often from SCD. In the group of patients with CRT/ICD device, 76.6% had NYHA class III, and 20.1% had NYHA class IV. After the implantation of CRT/ICD pacemaker, 26.6% of patients were in NYHA class II and 66.6% in NYHA class III [15, 17, 19].

In the group of patients with CRT/ICD, the percentage of patients with NYHA functional class II had increased from 41.6% to 50% after the follow-up period. In the group with the drug therapy, the percentage of patients with NYHA class II decreased during the follow-up from 38% to 34%, but the percentage of patients with NYHA functional class IV increased from 2% to 6%.

Dilated cardiomyopathy is frequently the final result of ischemic heart disease. In our study, the highest percentage of patients had an ischemic heart disease as the cause of dilated cardiomyopathy, and the rest of patients had idiopathic dilated cardiomyopathy. Implantation of an ICD pacemaker is the only effective therapy for SCD prevention. It is known that the highest risk of SCD have patients with previous cardiac arrest, sustained VT, family history of SCD, extreme left ventricular hypertrophy, etc. Also, presyncope in the anamnesis could represent a strong predictor of high risk of SCD [18–20].

In our research, there was also a group of patients who survived VT or VF, and found no organic substrate on the myocardium, probably because we were unable to perform an endomyocardial biopsy. Therefore, we were not able to clarify the cause of arrhythmias in these patients.

The MADIT study showed a 54% reduction in the overall mortality in the patients with an LVEF < 35% and ICD implanted, due to ischemic heart disease. The MUSTT study in the patients with LVEF < 35% showed that the reduction in mortality due to arrhythmia in the patients who received ICD pacemaker was 75%, and a reduction in the overall mortality was 60%. These two studies were the first which investigated ICD pacemaker implantation for primary prevention in the high-risk patients. They showed that the left ventricle dysfunction is the strongest predictor of SCD. The decrease in LVEF after AMI by 5% increased the risk of SCD by 21% in the first month. The SCD-HEFT study was designed to show whether amiodarone, or ICD reduce total mortality in the patients with coronary artery disease, or non-ischemic cardiomyopathy, classified as NYHA class II or III, and those who had LVEF less than 35%. The patients were randomized to 3 cohorts: 847 with placebo, 845 with amiodarone, and 829 with ICD. The main conclusion of the study was that the patients with a congestive heart failure in NYHA class II or III, with LVEF < 35%, with an optimal drug therapy, had a mortality in the controlled placebo group of 7.2% per year for 5 years. A simple ICD, programmed only for the detection zone of 188/min, and for therapy only with the maximal DC shock, reduces mortality by 23%. Amiodarone, when taken as a primary prevention does not increase survival and it has the same effect as placebo in the primary prevention. The MADIT II study examined the prophylactic benefit of ICD in the patients with coronary artery disease, LVEF < 30%, who had at least one myocardial infarction [4–7]. The patients with ICD had 31% of mortality reduction compared to the group of patients with the conventional therapy. Both groups of patients had equivalent and necessary doses of beta-blockers, ACE inhibitors, diuretics, digitalis and aspirin. The conclusions of the MADIT II study showed that in patients with a previous myocardial infarction and left ventricular dysfunction, the prophylactic ICD pacemaker significantly increased survival.

The patients with the greatest benefit of ICD implantation are those who are prone to malignant arrhythmias: congenital heart disease, hypertrophic cardiomyopathy, Brugada syndrome, idiopathic VT/VF, left ventricular noncompaction cardiomyopathy, long and short QT syndromes, arrhythmogenic right ventricular dysplasia, infiltrative cardiomyopathy [4, 5].

Secondary prevention is indicated in the patients who survived a cardiac arrest or sustained VT. Numerous randomized studies showed that the use of ICD is associated with a reduction in mortality compared to the patients treated with any type of drug therapy. The most important of these are the AVID, CIDS, and CASH studies. In each of the ICD studies, significant and undoubtedly improved the survival compared to anti-arrhythmic drugs was demonstrated (from 20% in the CIDS study, more than 38% and 39% in the CASH and AVID studies to as much as 73% in the Dutch DUTCH CES study). In our study we found a statistically significant difference in survival of patients with primary and secondary prevention (received ICD pace-

maker) compared to the patients who were on the drug therapy (24% vs. 5%, respectively) [6, 7]. Also, the patients who had resynchronization therapy (CRT pacemaker implanted) together with ICD had better quality of life, a statistically significant increase in LVEF compared to other groups of patients (36.27% vs. 24.63%, respectively), as well as the improvement of other echocardiographic parameters.

Conclusion

Based on the results of this study, it can be concluded that ICD pacemaker implantation significantly reduces mortality, both in primary and secondary prevention, compared to medical therapy only. In addition, the patients who have CRT in addition to ICD pacemaker, have a significantly better quality of life, an increase in LVEF and the echocardiographic parameters which are indices of left ventricular function. Also, the use of medication therapy in the patients with the implanted pacemakers reduces the frequency of DC shock delivery which preserves the myocardial function and reduces the damage that occurs during electrical current passes through the heart muscle. In the end, it was shown that the patients who have received the resynchronization therapy have the highest benefit from the implantation of the pacemaker system in terms of survival.

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Received on October 3, 2017.
Accepted on January 9, 2018.
Online First January, 2018.