Follow-up and characteristics of recipients of cardiac resynchronization therapy with and without a defibrillator

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ABSTRACT

Background: Cardiac resynchronization therapy defibrillator (CRT-D) and pacemaker (CRT-P) are treatment options for patients with advanced heart failure and electrical dyssynchrony. Current guidelines provide only factors favoring, not specific recommendations as to implant CRT-D or CRT-P. This analysis aimed to compare and contrast populations of CRT-D and CRT-P recipients.

Methods: Retrospective data were collected from medical records, including 231 patients treated with either CRT-D or CRT-P between 2015 and 2019. Following data were analyzed demographics, co-morbidities, pharmacotherapy, laboratory tests, and data related to the procedure of implantation. The primary endpoint of the study was all-cause mortality.

Results: A total of 231 patients were included (mean age [standard deviation, SD], 64.1 [12.3] years, 76% male), of these, 13.6% (n = 32) with CRT-P and 86.4% (n = 199) with CRT-D. Mean New York Heart Association (NYHA) class did not differ between the groups: 2.23 (0.9) in CRT-P and 2.35 (0.6) in CRT-D group ($P = 0.42$). Mean left ventricular ejection fraction was lower in patients eligible for CRT-D: 27.1% vs. 38% ($P < 0.001$). Patients were followed for a median (interquartile range [IQR]) of 29 (13–44) months and survival in the CRT-P group was 84%, in CRT-D — 82% ($P = 0.74$). Patients in the CRT-P group were older, and more often after atrioventricular node ablation. The CRT-P group had tendency towards higher Charlton Comorbidity Index, reaching a mean of 4.66 (1.5) points vs. 3.96 (1.5) points in CRT-D ($P = 0.06$).

Conclusions: Populations with CRT-P and CRT-D differ in terms of comorbidities; however, they have similar survival. Further studies are required to identify a group of patients, who derive a benefit from adding a defibrillator.

Key words: cardiac resynchronization therapy, outcomes research, population, follow-up

INTRODUCTION

Cardiac resynchronization therapy (CRT) is a well-established treatment of advanced heart failure with electrical dyssynchrony [1, 2]. Implantation of those devices is recommended for symptomatic patients with wide QRS complexes mainly of left bundle branch block (LBBB) morphology and reduced left ventricular ejection fraction (LVEF), although non-LBBB pattern recipients can also benefit from this therapy [3]. Resynchronization therapy has proven to improve survival, and LVEF, reduce the incidence of ventricular arrhythmia, and decrease heart failure symptoms [4]. CRT rather than a dual-chamber pacemaker is recommended in patients with reduced ejection fraction, who are expected to have a high proportion of right ventricular pacing, as the latter has been proven to increase mortality [1, 5].

An implantable cardioverter-defibrillator (ICD) is recommended for primary and secondary prevention of sudden cardiac death [6]. Secondary prevention involves patients with ventricular fibrillation or unstable ventricular tachycardia if none of reversible causes was diagnosed and expectation of survival with a good functional status is estimated at 1 year [6]. Implantation of ICD in primary prevention is recommended in patients with

WHAT'S NEW?

Our observations point out that populations with cardiac resynchronization therapy with defibrillators (CRT-D) and pacemakers (CRT-P)have similar survival, despite higher left ventricular ejection fraction in CRT-P group. This study showed some clinical differences between patients eligible for CRT-D and CRT-P, e.g. higher left ventricular ejection fraction, prior atrioventricular node ablation, age or Charlson comorbidity index score.

symptomatic heart failure and LVEF ≤35% after at least 3 months of optimal medical therapy, subject to estimated one-year survival [6, 7]. Since prophylactic implantation of those devices improves prognosis in mentioned groups of patients [7]. As a result, the majority of patients with heart failure, who meet the criteria for CRT, have also ICD-indications [4, 8].

According to European guidelines selection between cardiac resynchronization therapy defibrillator (CRT-D) and cardiac resynchronization therapy pacemaker (CRT-P) is ambiguous, the decision should be based on co-morbidities, life expectancy, general condition, and costs [1]. This choice is of crucial significance, but in many cases troublesome, causing discrepancies in practice across implantation centers [9]. This is the result of a lack of randomized controlled trials directly comparing the efficacy of CRT-D and CRT-P. This analysis aimed to compare CRT-D and CRT-P recipients taking into consideration clinical character and long-term mortality to dermine factors which favor addition of a defibrillator.

METHODS

To compare populations of CRT-P and CRT-D recipients, medical documentation was analyzed. We took into consideration records of patients, who received CRT between January 2015 and May 2019 at the 1st Department of Cardiology in University Hospital of Lord's Transfiguration of Poznan University of Medical Sciences, Poland. Included in the study were all *de novo* implants in addition to upgrades of pacemakers and ICDs to CRT-P or CRT-D. Revision interventions of CRT devices, pulse generator replacements, as well as upgrades from CRT-P to CRT-D, were excluded. Before the procedure, all patients were qualified for implantation of CRT and met current guidelines at the time of implant [10]. The evaluation took into consideration: history, cardiovascular physical examination, electrocardiography and echocardiography, blood tests, and pharmacological treatment. Patients provided written informed consent before all procedures of implantation/upgrade.

Analyzed data

The medical history of 231 patients was analyzed. Collected data included: basic demographic data (sex, age) and clinical data such as medical history, pharmacological treatment, especially treatment of heart failure and antiarrhythmic drugs. Furthermore: heart failure etiology, indication to device implantation, comorbidities including circulatory system diseases (coronary artery and valvular diseases), respiratory diseases, chronic kidney disease, diabetes mellitus, thyroid diseases, and malignancies. Moreover, before CRT implantation, more data were obtained: left ventricular ejection fraction from echocardiography and parameters from laboratory tests i.e.: peripheral blood smear, lipid panel, electrolytes, glycemia, creatinine for all patients. Following, natriuretic peptides were estimated at 70% of patients and glycated hemoglobin only for patients with diabetes mellitus. Data related to the procedure were: type of the device, type of the procedure i.e., upgrade or de novo implantation. Based on previous information the Carlson comorbidity index was calculated [11].

Follow-up

Patients were followed until August 2019. Mortality data were collected from the National Health Insurer, which provides information about alive citizens. Information of occurring deaths and dates were obtained from government records.

Statistical analyses

Statistical analyses were performed using STATISTICA 13, TIBCO Software Inc. Antromoteric measurements, and laboratory tests were compared using the Mann-Whitney and Student t-tests. The χ^2 and Fischer tests were used to analyze heart failure etiology, comorbidities, procedures data, and pharmacotherapy. Mortality rates were analyzed using a log-rank test and summarized by constructing Kaplan-Meier curves. Differences between variables were considered to be statistically significant if $P<0.05$. The study was approved by the Head of the local Ethical Committee.

RESULTS

Between January 2015 and May 2019, 231 implantations of CRT were performed, of which 32 (13.6%) were CRT-P. In both groups, CRT-P and CRT-D, male sex was more common: 75% (n = 24) and 77% (n = 153), respectively. CRT-D recipients were younger, of mean age (standard deviation [SD]) of 63.5 (12) vs. 67.8 (16) years in the CRT-P group ($P = 0.02$). In terms of body weight, height, and body mass index, both groups did not differ significantly (Table 1). When up-grade procedures were performed, implantation of CRT-P was more common than CRT-D (69% vs. 47%; $P = 0.02$).

Table 1. Basic characteristics of patients

	CRT-P (n = 32)	CRT-D (n = 199)	*P*-value
Age, years, mean (SD)	67.8 (16.5)	63.5 (11.9)	0.02
Male sex, n (%)	24 (75)	153 (77)	0.79
Weight, kg, mean (SD)	85.1 (16.2)	83.79 (16.1)	0.62
Height, m, mean (SD)	1.73 (0.1)	1.72 (0.1)	0.89
BMI, kg/m^2, mean (SD)	28.3 (4.2)	28.2 (4.7)	0.84
CCI, mean (SD)	4.66 (1.5)	3.96 (1.5)	0.03
NYHA class, mean (SD)	2.23 (0.77)	2.35 (0.56)	0.42

Abbreviations: BMI, body mass index; CCI, Charlson comorbidity index; CRT, cardiac resynchronization therapy; CRT-D, CRT with defibrillator; CRT-P, CRT with pacemaker; NYHA, New York Heart Association

Table 2. Indications for CRT implantation

	CRT-P (n = 32)	CRT-D (n = 199)	*P*-value
ICM, n (%)	14 (43.8)	104 (52.3)	0.37
DCM, n (%)	3 (9.4)	62 (31.2)	<0.01
High grade AV block, n (%)	4 (12.5)	3 (1.5)	<0.01
Valvular diseases, n (%)	2 (6.3)	10 (4.5)	0.52
HCM, n (%)	1 (3.1)	1 (0.5)	0.26
SSS, n (%)	1 (3.1)	0 (0)	0.14
AF, n (%)	1 (3.1)	0 (0)	0.14
Indeterminate, n (%)	5 (15.6)	11 (5.5)	0.04
Other, n (%)	1 (3.1)	8 (4)	0.64

Abbreviations: AV, atrioventricular; AF, atrial fibrillation; DCM, dilated cardiomyopathy; ICM, ischemic cardiomyopathy; HCM, hypertrophic cardiomyopathy; SSS, sick sinus syndrome; other — see Table 1

Table 3. Comorbidities

	CRT-P (n = 32)	CRT-D (n = 199)	*P*-value
AF, n (%)	18 (56.3)	78 (39.1)	0.07
Hypertension, n (%)	20 (62.5)	119 (59.9)	0.78
CAD, n (%)	17 (53.1)	111 (55.8)	0.78
Post PCI, n (%)	9 (28.1)	91 (45.6)	0.06
Post CABG, n (%)	9 (28.1)	34 (17.3)	0.15
Valvular diseases, n (%)	10 (31.3)	33 (16.8)	0.05
Post valvular surgery, n (%)	8 (25.0)	29 (14.3)	0.15
Post TAVI, n (%)[a]	1 (3.1)	0 (0)	0.14
Thyroid diseases, n (%)	5 (15.6)	29 (14.7)	0.90
DM, n (%)	10 (31.3)	56 (28.1)	0.71
CKD, n (%)[a]	3 (9.4)	45 (22.8)	0.06
COPD, n (%)	5 (15.6)	27 (13.7)	0.77
Malignancy in the past or during therapy, n (%)	1 (3.1)	12 (6.1)	0.44
Ventricular arrhythmia, n (%)	4 (12.5)	51 (25.4)	0.11

[a]Too low number of cases for designations of the analysis

Abbreviations: AF, atrial fibrillation; CABG, coronary artery bypass graft; CAD, coronary artery disease; ChF, chronic heart failure; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; PCI, percutaneous coronary intervention; TAVI, Transcatheter Aortic Valve Implantation; other — see Table 1

Comorbidities

The frequency of heart failure of ischemic etiology did not differ in both groups (CRT-P, 43.75% vs. CRT-D, 52.26%; $P = 0.37$). Other indications for CRT implantation are given in Table 2. Secondary prevention was indication for CRT-D implantation in 16.1% (n = 46). In terms of other comorbidities, differences were not statistically significant, exact numbers and P-values are given in Table 3.

CRT-P implantation was more common after atrioventricular (AV) node ablation or when this procedure was planned (Table 4).

Blood tests and echocardiography

In terms of blood tests, both groups were similar. No significant differences were noticed in analyses of peripheral blood smear, electrolytes, glycemia, natriuretic peptides, and glycated hemoglobin. Mean LVEF was lower in patients eligible for CRT-D implantation: 27.1% vs. 38%. In the CRT-P group, 47% (n = 15) o patients had LVEF lower than 35%. Further data are given in Table 5.

Pharmacotherapy

Medications used in CRT recipients were different in both groups. Pharmacotherapy of patients with CRT-D

Table 4. Implantation procedures data

	CRT-P (n = 32)	CRT-D (n = 199)	*P*-value
Up-grade, n (%)	22 (68.8)	94 (47.2)	0.02
Planned or past AV node ablation, n (%)	5 (15.7)	5 (2.5)	<0.01

Abbreviation: AV, atrioventricular; other — see Table 1

Table 5. Results of blood tests and echocardiography

	CRT-P (n = 32)	CRT-D (n = 199)	*P*-value
RBC, 10^{12}/l, mean (SD)	4.6 (0.5)	4.6 (0.5)	0.79
WBC, 10^{9}/l, mean (SD)	7.6 (1.9)	7.5 (1.9)	0.61
PLT, 10^{9}/l, mean (SD)	211.3 (69.7)	197.7 (65.2)	0.29
Na, mmol/l, mean (SD)	139.4 (3.5)	139.3 (3.3)	0.84
K, mmol/l, mean (SD)	4.4 (0.5)	4.9 (5.3)	0.23
Glycemia, mmol/l, mean (SD)	6.8 (2.2)	6.7 (2.8)	0.70
Creatinine, µmol/l, mean (SD)	98.1 (22.7)	118.2 (67.1)	0.05
LDL, mmol/l, mean (SD)	1.9 (0.8)	2.4 (1.0)	0.05
HDL-C, mmol/l, mean (SD)	1.4 (0.4)	1.4 (0.5)	0.96
TG, mmol/l, mean (SD)	1.2 (0.5)	1.3 (0.7)	0.31
TCh, mmol/l, mean (SD)	4.0 (0.9)	4.3 (1.1)	0.17
NT-proBNP, pg/ml, median (IQR)	1740 (917–2450)	1449 (936–3207)	0.89
BNP, pg/ml, median (IQR)	205 (122–373)	348 (151–551)	0.18
LVEF, %, mean (SD)	38.0 (9.7)	27.1 (7.0)	<0.01

Abbreviations: NT-proBNP, pro-B-type natriuretic peptide; HDL, high-density lipoprotein; K, potassium; LDL, low-density lipoprotein cholesterol; LVEF, left ventricular ejection fraction; Na, sodium; PLT, platelets; RBC, red blood cell count; WBC, white blood cell count; TCh, total cholesterol; TG, triglycerides; other — see Table 1

Table 6. Pharmacotherapy

	CRT-P (n = 32)	CRT-D (n = 199)	*P*-value
Anticoagulants, n (%)	19 (60)	98 (49.2)	0.27
VKA, n (%)	14 (43.3)	56 (28.2)	0.09
NOAC, n (%)	5(16.7)	42 (21)	0.58
antiplatelets, n (%)	11 (33.3)	80 (40.5)	0.46
DAPT, n (%)	2 (6.7)	21 (10.8)	0.35
ACEI/ARB, n (%)	27 (83.3)	180 (90.3)	0.25
β-blockers, n (%)	27 (83.3)	189 (94.9)	0.02
Aldosterone antagonists, n (%)	18 (56.7)	164 (82.7)	0.01
Statin, n (%)	24 (73.3)	144 (72.4)	0.92
Diuretics, n (%)	24 (73.3)	170 (85.2)	0.10
Amiodarone, n (%)	2 (6.7)	58 (29.1)	<0.01

Abbreviations: ACEI, angiotensin-converting-enzyme inhibitors; ARB, angiotensin receptor blockers; DAPT, dual antiplatelet therapy; NOAC, non-vitamin K antagonist oral anticoagulants; VKA, vitamin K antagonists; other — see Table 1

contained, in more than 85%, ACE inhibitors or ARBs, *β*-blockers, and diuretics, which were more common than in the CRT-P group for the last two. Moreover, in the first mentioned group, antiarrhythmics were more often given, especially amiodarone. Detailed data are given in Table 6.

Survival

Median (interquartile range [IQR]) follow up for all patients was 29 (13–44) months (35.5 [21–44] months, 29 [13–45] months in the CRT-P and CRT-D groups, respectively; $P = 0.42$). In that period, all-cause mortality did not differ significantly between the groups. Survival in the CRT-P group was 84% (n = 27), whereas in the CRT-D group 82% (n = 163); $P = 0.74$ (Figure 1). Those data did not correlate with the calculated mean Charlson comorbidity index (CCI), which was significantly higher for patients with CRT-P by 0.6. Consequently, in this group mean CCI score was 4.66 (1.5), however, in the CRT-D group 3.96 (1.5) ($P = 0.03$). Factors associated with higher mortality in the whole group included higher red blood cell distribution width, white blood cells, C-reactive protein, creatinine, and natriuretic peptides.

Primary prevention CRT-D vs. CRT-P

CRT-D was implanted in primary prevention in 147 patients. Like in the whole group, those patients were older than the CRT-P group: CRT-D, 63.5 (12.5) vs. CRT-P, 67.8 (16.5) years ($P = 0.03$). In terms of body weight, height, and body mass index, both groups did not differ significantly. Concerning individual comorbidities, the number of comorbidities in both groups did not differ significantly.

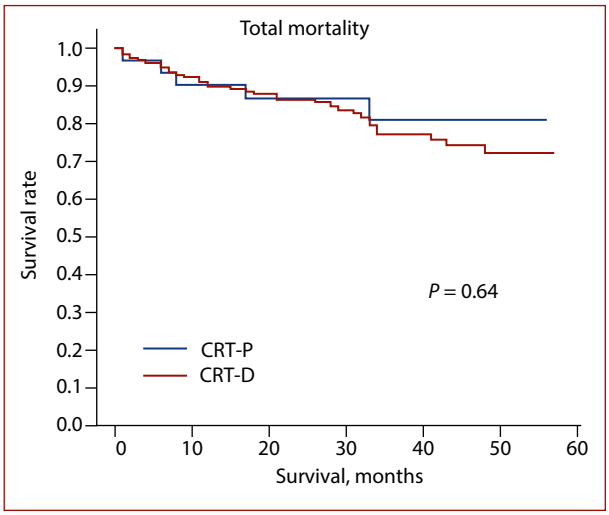

Figure 1. Kaplan-Meier survival curves for the CRT-P and CRT-D groups. Survival did not differ significantly

Abbreviations: see Table 1

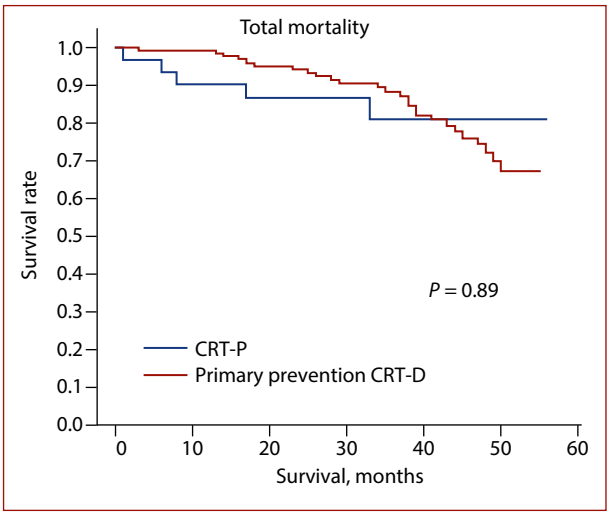

Figure 2. Kaplan-Meier survival curves for the CRT-P and primary prevention CRT-D groups. Survival did not differ significantly

Abbreviations: see Table 1

In terms of pharmacotherapy, patients in the CRT-D group in comparison to the CRT-P group more often used β-blockers (95.2%, n = 140 vs. 78.1% n = 25; P <0.01, respectively), ACE inhibitors (91.1%, n = 134 vs. 78.1% n = 25; P <0.05, respectively), diuretics (86.4%, n = 127 vs. 68.8%, n = 22; P = 0.02, respectively) and aldosterone antagonists (82.3%, n = 121% vs. 53.1%, n = 17; P <0.01, respectively). Regarding blood tests, both groups were similar, the only significant difference was the mean low density lipoprotein level (LDL), which was higher in the CRT-D group 2.4 (1.0), CRT-P 1.9 (0.8), P = 0.02. Like in the whole population, mean LVEF was lower in patients eligible for CRT-D implantation: 27.5% vs. 38%, in the CRT-P group (P <0.01). Median follow-up for primary prevention CRT-D was 37 (25–47.5) months, for CRT-P 35.5 (21–44) months (P = 0.31); in this time all-cause mortality did not differ significantly between the groups (P = 0.71) (Figure 2).

DISCUSSION

During the study period of 4.5 years, 231 CRT devices were implanted, of which only 13% were CRT-P. Implantation of CRT-P rather than CRT-D was favored by i.a. a higher Charlson Comorbidity Index or higher LVEF. Survival in the CRT-P and CRT-D groups was similar, which was rarely reported in previous studies.

In other studies, which included a much larger number of patients, the percentage of CRT-P recipients ranged between 13% and 16%, which is similar to our findings [12–15]. However, some authors noted a higher proportion of CRT-P devices of 20%–45%, but those studies usually included older participants: over 75 years old [16–19]. Those differences are not unexpected, as older age favors implantation of CRT-P devices according to the Guidelines [1]. Despite similar recommendations in Europe and the United States, patterns of selecting CRT devices vary through countries and years of implantation, reaching an even higher percentage of CRT-P than CRT-D in some studies [14, 20, 21]. However, our results, in terms of the percentage of CRT-P, are similar to tendencies in Poland [9].

Current European trends regarding CRT implantation were analyzed in the European Society of Cardiology (ESC) CRT Survey II. Our findings are similar in terms of CRT-P implantations in older patients and patients with higher LVEF. Factors favoring CRT-P implantation elicited from the ESC survey were *inter alia* female sex, New York Heart Association (NYHA) class III and IV, and implantation in a university hospital [9]. This study did not show those differences, probably because of high differences in sex percentage (75% male in both groups), a low number of NYHA class IV patients, and data from a single center only.

All CRT devices were implanted in patients with heart failure, which is not surprising, as it is well-established treatment for symptomatic heart failure [2, 3]. Ischemic heart disease was the most common etiology of heart failure in this study with a similar percentage in both groups. Those findings contradict some trials, in which ischemic heart disease favored implantation of CRT-D rather than CRT-P [9, 12, 22, 23]. The decision of CRT-P implantation in ischemic patients was justified by other factors, like age or ejection fraction, which caused similarities in heart failure etiology.

An incidence of native atrioventricular block was similar in both groups, which is contrary to the results of the ESC Survey [9]. It is noteworthy that CRT-P was implanted more often before or after AV node ablation, and so was artificial AV block, which was also seen in the American trial of Hatfield [14]. In this view, a more frequent incidence of atrial fibrillation in the CRT-P group is not surprising, as in the CeRtiTuDe study and findings from the ESC CRT Survey II [9, 23]. It is a consequence of implantation of CRT-P in patients with tachycardiomyopathy in the course of persistent atrial

fibrillation. Those procedures are justified by the outcomes of the DAVID trial and the current guidelines [24, 25].

Patients included in this study differ significantly in terms of mean LVEF reaching higher values in the CRT-P group, with a mean value of over 35%. Similar outcomes were noted in a Japanese registry, with mean LVEF of over 30% [26]. The reason for those differences is CRT-P implantation in the following indications: (1) heart failure due to a high percentage of right ventricular pacing; (2) AV node ablation in patients with tachycardiomyopathy in the course of persistent atrial fibrillation. In terms of the type of procedures, our results are similar to the Euro CRT Survey II registry, in which up-grade procedures were favored in CRT-P recipients; the reasons for that are similar to the ones mentioned above [27, 28].

Significant differences were noted in the studied groups in medical therapy: beta-blockers, aldosterone antagonists, and antiarrhythmic drugs were more commonly used in the CRT-D group. Beta-blockers and aldosterone antagonists were previously found to be less common among CRT-P recipients [14, 23]. This tendency is the result of qualification of patients with impaired AV conduction and inefficient sinus node. In most cases, β-blockers are withdrawn in those patients. In the case of aldosterone antagonists, differences may result from higher LVEF in the CRT-P group, thus not all patients take those drugs. Trends toward more common use of antiarrhythmics in the CRT-D group were previously noted and resulted from previous ventricular arrhythmia [18, 29].

In terms of the Charlson Comorbidity Index, the findings of our study are similar to some previous studies, with a significantly higher burden of CCI in CRT-P recipients, with precise numbers particularly comparable to those noted by Munir [17, 18]. Consequently, CRT-P recipients have been previously proven to have more comorbidities in comparison to CRT-D [12].

Survival of patients in our center was similar to this noted in the study of Christie et al. as well as in the Japanese registry, with no significant difference between CRT-D and CRT-P recipients [17, 26]. Previous analyses evaluating the prognosis of patients with heart failure and CRT present ambiguous results. The Italian registry showed that CRT-D recipients have longer survival, on the other hand, in the DANISH trial, prophylactic ICD implantation was not associated with longer survival. However, this trial included patients with non-ischemic cardiomyopathy [30, 31]. Similar survival in our study may be a consequence of dissimilarity of populations, especially significantly higher ejection fraction in the CRT-P group. Therefore those patients had less advanced heart failure, and consequently a better prognosis. A previous Polish study proved the ischemic etiology of heart failure to be a strong predictor of mortality; however, that study did not notice any dependency of prognosis on the etiology of heart failure, regardless of the type of the device [32].

There are several limitations of this study. First, the CRT-P group was relatively small, which is a consequence of tendencies in our country favoring implantation of CRT-D rather than CRT-P, and it included implantations from one center only. Also, this is a single-center, nonrandomized study, that results in significant differences in populations (e.g., in LVEF). Third, this study is a retrospective analysis, and as a result, it included some incomplete databases (e.g., pharmacotherapy, blood tests), which limited the ability to utilize some variables.

CONCLUSIONS

CRT-P, rather than CRT-D, was chosen in older patients with higher LVEF. The CRT-P population was prone to be after AV node ablation, and patients qualified for CRT-P had lower concentrations of creatinine and LDL-cholesterol, but a higher number of comorbidities. Despite the above differences, survival in CRT-P and CRT-D subgroups was similar, reaching over 80% in long-term follow-up. Similar survival in both groups demonstrates that the mentioned-above factors should be taken into consideration during qualification to CRT and decision-making about adding a function of a defibrillator. Appropriate qualification for CRT-P is essential, as properly qualified patients with those devices have similar survival to patients with CRT-D.

Article information

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