Original article

Mortality in patients with heart failure treated with cardiac resynchronisation therapy. A long-term multi-centre follow-up study

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Abstract

Background: Benefits of cardiac resynchronisation therapy (CRT) for survival in selected congestive heart failure (CHF) patients have been acknowledged by the 2005 ESC guidelines.

Aim: To analyse mortality in CRT pacing only (CRT-P) patients during at least one-year follow-up.

Methods: This was a prospective, multi-site, at least one-year observational study on mortality and mode of death in patients who received CRT-P due to commonly accepted indications. One-year follow-up data (or earlier death) were available for 105 patients (19 females, 86 males) aged 60.6±9.8 years (35-78). Baseline NYHA class was 3.2±0.4 (3-4). Coronary artery disease (CAD) was the underlying aetiology of CHF in 57 (54%) patients and 48 (46%) patients had CHF due to non-coronary factors.

Results: Mean follow-up duration was 730 days (360-1780), median 625. There were 21 (20%) deaths: 5 (24%) sudden cardiac deaths (SCD), 13 (62%) deaths due to heart failure (HFD) and 3 (14%) other deaths. Thirteen (62%) patients died within the first year of observation. All SCD occurred in this period. Mean time to death was 303±277 days (19-960) to HFD – 339±313 days (19-960) and to SCD – 208±127 days (31-343). There were no significant differences between survivors and non-survivors with respect to left ventricular ejection fraction (LVEF) (25±10 vs. 20±8%), 6-minute walk test (6minWT) (276±166 vs. 285±163 m) and LV diastolic diameter (LVEDD) (71±9 vs. 78±10 mm) (all NS). The SCD and HFD patients had similar age (62.0±5.4 vs. 56.6±13.2 years), gender (80 vs. 83% males), NYHA class (3.1±0.2 vs. 3.5±0.3), LVEF (22±9 vs. 17±5%), LVEDD (86±10 vs. 79±9 mm), 6minWT (270±142 vs. 292±188 m) (NS). In 4 patients from the SCD group CHF was of non-coronary aetiology and only in 1 patient from the HFD group (p=0.003). The values of LVEF, LVEDD and NYHA class in HFD patients who died during the first year after implantation, compared with those who died later, were similar.

Conclusions: Sudden cardiac death probability in the studied CRT-P population was the highest during the first year after implantation. Afterwards, the risk of HFD started to increase. Thus, in all patients eligible for CRT prophylactic defibrillation function should be considered.

Key words: cardiac resynchronisation therapy, congestive heart failure, mortality

Kardiol Pol 2007; 65: 1287–1293

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Received: 27 February 2007. **Accepted:** 18 July 2007.
The study was partially supported by the research grant MNiSzW 3 P05C 00825.

Introduction

Cardiac resynchronisation therapy (CRT) was introduced to clinical practice in the 1990s. The European Society of Cardiology in 2005 recognised this method as class I indication in the treatment of patients refractory to medical therapy and with significant left ventricular (LV) dysfunction, chronic heart failure (CHF) assessed as functional NYHA classes III and IV, wide QRS complex ≥120 ms and ventricular asynchrony [1]. Current standards were based mainly on the results of COMPANION [2] and CARE-HF [3] trials where significant improvement in survival related to the use of either resynchronising systems equipped with cardioverter--defibrillator function (CRT-D) or CRT with pacing only (CRT-P) [2, 3] was shown. The CARE-HF study summarised in 2005 was dedicated to the use of CRT-P only. However, resynchronisation with defibrillator functionality as a primary prevention of sudden cardiac death (SCD) dominated throughout the world at that time [4]. Currently, a similar trend is seen also in Poland. It is obvious that isolated resynchronisation therapy due to increased risk of SCD in the recipient population is becoming a history and is being replaced quickly by CRT-D.

The aim of study was to assess the survival in patients treated with CRT-P for at least 12 months as well as to analyse death mode with respect to selected clinical data.

Methods

This analysis involved consecutive patients undergoing successful CRT-P implantation based on the recommendations valid since 2001. Since 2005 they have included symptomatic heart failure defined as NYHA class III or IV despite optimal medical therapy, depressed (≥35%) LV ejection fraction (LVEF) and wide QRS complexes ≥120 ms. In some patients enrolled in the recent years, the inter- and intraventricular asynchrony was evaluated by means of echocardiography. Patients with CRT-D were not included in this analysis. All selected patients treated with CRT-P received optimal CHF therapy according to the ESC recommendations. The end-point of follow-up was either the final visit, phone contact after at least one year or death at any time-point of the follow-up after implantation.

Table I. Clinical and demographic characteristics of the examined group

Parameter	Value
Number of patients	105
Female gender	19
Age [years]	60.6±9.8 (35-78)
Aetiology of CHF	
• CAD	57 (54%)
• idiopathic	45 (43%)
• prior valvular surgery	3 (3%)
Mean NYHA class	3.2±0.4 (3-4)
6minWT [m]	278±167
LVEF [%]	20±6
LVEDD [mm]	72±8

Abbreviations: CHF – chronic heart failure, CAD – coronary artery disease, 6minWT – 6-minute walk test, NYHA – New York Heart Association, LVEF – left ventricular ejection fraction, LVEDD – left ventricular end-diastolic dimension

Statistical analysis

Statistical software package SAS version 8.2 was used. Verification of null hypotheses was carried out by acceptance of statistical significance threshold at ≤0.05. After variation homogeneity and normality of continuous variables' distribution were verified, Student's t-test was used to evaluate differences between mean values of the analysed groups. These variables were expressed as means and standard deviations. Variables with a distribution not following the normal distribution (follow-up time) were compared by means of non-parametric tests and the findings were expressed as medians and ranges. Categorical variables were analysed using χ^2 test with Yates' correction or Fisher's exact test. The Kaplan-Meier survival curves were traced and survival probability was estimated for 3-month periods by means of hazard function.

Results

This analysis comprised patients treated in 6 Polish electrotherapy reference centres. The CRT-P systems were implanted in 105 patients. Clinical and echocardiographic characteristics of the examined group are outlined in Table I.

Mean follow-up time was 730 days (360-1780) and median 625 days. In the studied group, 21 (20%) deaths occured, including 5 SCD (24%), 13 deaths due to CHF progression (heart failure death – HFD) (62%) and 3 deaths caused by other or unknown reasons (14%). Thirteen (62%) patients died within the first year of follow-up and during this time all SCD-related deaths were noted. One-year mortality was 12.3% and two-year – 18% (Kaplan-Meier survival curve – Figure 1). Mean time to death of any cause was 303±277 (19-960) days, to HFD – 339±313 (19-960) days, and to SCD – 208±127 (31-343) days (NS). Mortality probability for 1000-day follow-up was calculated regarding all-cause mortality (Figure 2) and separately for SCD- and HFD-related mortality (Figure 3). In the aforementioned functions of death probability, there were seen 3 peaks of an increased risk of death in one-year follow-up estimated in 90-day periods: in the 1st, 3rd and 4th quarters (including two high peaks in the 1st and 3rd one) and gradually, exponentially increasing risk of death due to CHF as a function of follow-up time (Figure 3).

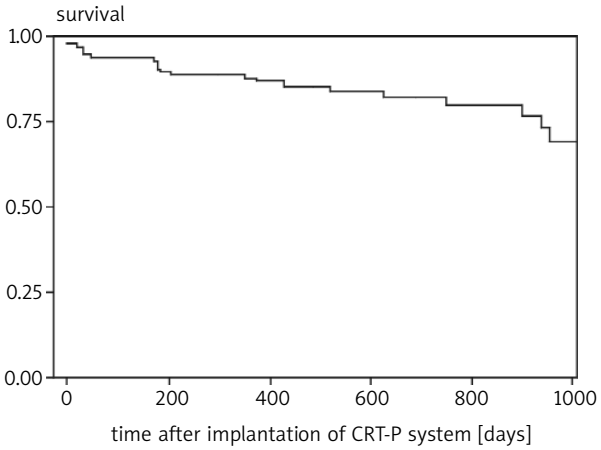

Figure 1. Kaplan-Meier survival curve of the examined group during 1000-day follow-up

No differences between survivors and those who died were found with respect to the baseline values of parameters such as LVEF, 6-minute walk test distance (6minWT) and LVEDD (Table II). The SCD and HFD patients did not differ with respect to age at baseline, gender, NYHA class, LVEF, LVEDD and 6minWT. Non-coronary CHF aetiology was noted in 4 of 5 SCD patients, but only in 1 of 12 individuals in the HFD group (p=0.003). The LVEF and LVEDD values were comparable in the group of patients who died within one-year follow-up due to progressive CHF and in the remainder of patients in the HFD group (Table II).

Discussion

The use of CRT in CHF treatment is recommended when CHF is accompanied by a cluster of commonly recognised criteria, irrespectively of disease aetiology [1]. In the largest patient groups described in the literature, the predominant cause of LV impairment was coronary artery disease (CAD) (36 to 66% of patients), most often following myocardial infarction [2, 3, 5-9]. In the other patients – usually presented as one group of non--coronary aetiology or dilated cardiomyopathy – CHF was a result of valvular disease, pulmonary hypertension, history of myocarditis or was defined as idiopathic.

In the CARE-HF study where heart failure patients were randomised to CRT-P or to pharmacotherapy, 813 individuals were followed for 29.4 months. Events constituting study end-points were noted in 159 patients in the CRT-P group and in 224 patients in the control one – 39 vs. 55%, hazard ratio (HR) 0.63, 95% CI 0.51-0.77; p <0.001. There were 82 deaths in the CRT-P group and 120 in the pharmacotherapy one – 20 vs. 30%; HR 0.64; 95% CI 0.48-0.85; p <0.002. It was the first study showing significant (36%) mortality reduction with CRT, and also, as in several earlier reports, improvement in many secondary end-points regarding course of the

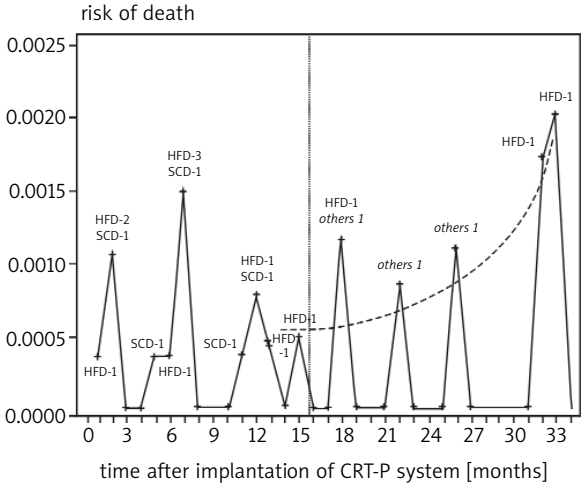

Figure 2. Death risk distribution in the examined population within 1000-day follow-up for all causes (SCD – sudden cardiac death, HFD – death due to heart failure, others – death due to other causes). Numbers of patients who died due to a given cause in a 90-day time period are presented near to discriminators. Attention should be paid to clear peaks of deaths within the first year of follow-up. Risk of death after one-year follow-up increases gradually as a function of time and is associated with deaths due to progressive heart failure and other causes

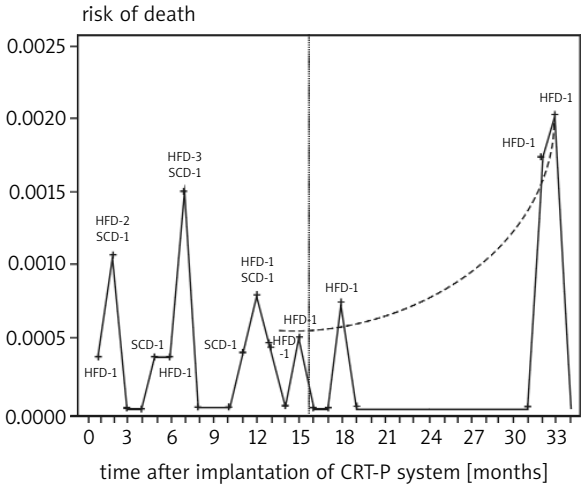

Figure 3. Death risk distribution in the examined population during 1000-day follow-up as sudden cardiac deaths (SCD) or due to progressive heart failure (HFD). Number of patients who died due to a given cause in a 90-day time period are presented near to discriminators. Attention should be paid to clear peaks of deaths within the first year of follow-up. Risk of death due to progressive heart failure after one-year follow-up increases exponentially (interrupted curve)

Table II. Comparisons of selected baseline demographic and clinical parameters between groups: patients who died during follow-up vs. survivors (A), patients who died due to sudden cardiac death vs. progressive chronic heart failure (B), patients who died due to chronic heart failure within the first year of follow-up vs. those who died later (C)

A			
Variable	**Patients who died**	**Survivors**	**p**
Age [years]	57.4±11.4	61.1±9.3	NS
NYHA class	3.2±0.5	3.2±0.4	NS
LVEF [%]	20±8	25±10	NS
LVEDD [mm]	78±10	71±9	NS
6minWT [m]	285±163	276±166	NS
B			
Variable	**Patients who died due to SCD**	**Patients who died due to CHF**	**p**
Age [years]	62.0±5.4	56.6±13.2	NS
Male gender [%]	80	83	NS
NYHA class	3.1±0.2	3.5±0.3	NS
LVEF [%]	22±9	17±5	NS
LVEDD [mm]	86±10	79±9	NS
6minWT [m]	270±142	292±188	NS
Non-CAD aetiology [%]	80	8	p=0.003
C			
Variable	**Patients who died due to CHF < one-year follow-up**	**Patients who died due to CHF > one-year follow-up**	**p**
NYHA class	3.8±0.4	3.4±0.3	NS
LVEF [%]	14±8	18±4%	NS
LVEDD [mm]	76±5	75±8	NS

Abbreviations: SCD – sudden cardiac death, others – see Table I

disease and quality of life. At the same time, a significant contribution to overall mortality was made by SCD, which in the CRT-P study arm accounted for 35% of fatal events [3]. The COMPANION trial showed 24% reduction in mortality associated with the use of CRT-P and 36% reduction, statistically significant, in mortality related to CRT-D application [2].

Guidelines on the CRT-D use recommend it as class IIa indication in all patients selected for CRT, also irrespectively of CHF aetiology [1]. The issue of SCD primary prevention was in the last decade studied extensively, particularly among patients with CAD treated with 'classic' ICD devices. Additional data suggesting an improvement in survival associated with ICD implantation among patients with dilated cardiomyopathy, irrespective of aetiology, were derived from the SCD-HeFT study. It dealt with primary death prevention in patients found in functional NYHA classes II and III, with LVEF ≤35%, randomised to a placebo group, to a group treated with amiodarone or with classical ICD implantation. This study involved a group of patients in whom some of the treated subjects met criteria for CRT. Annual mortality in the placebo and amiodarone groups did not differ and was 7.2%. Favourable impact of ICD implantation (with VVI of low basic pacing rate) on survival only was noted; mortality was reduced by 23% in this subgroup. The results were comparable in the group of CAD and non-CAD aetiology with a slight trend favouring the non-CAD group (HR 0.79 vs. 0.73, respectively). Independently analysed subgroups with QRS ≥120 ms, LVEF ≤30% and ICD implanted presented lower risk of death than the placebo group as well as subgroups with QRS <120 ms and LVEF >30%. It should be mentioned that advantages of ICD were not seen in patients found in NYHA class III in this study (HR 1.16) [10].

It is difficult to draw definite conclusions regarding indications for ICD in patients treated with CRT. However, together with the findings of ICD usage as primary prophylaxis of CAD with LV dysfunction (MUSTT, MADIT, MADIT II) [11-13] one may find additional arguments for application of defibrillation function in patients with CHF of various aetiology. Based on the enrolment criteria for the largest trials such as MUSTIC [5], InSync [6], MIRACLE [7], PATH-CHF [8], COMPANION [2] and CONTAK CD [9] regarding the use of CRT and CRT-D, clinical characteristics of 201 patients with idiopathic dilated cardiomyopathy were analysed as well as disease-related risk of death, CHF progression, heart transplantation, SCD or refractory ventricular tachyarrhythmia. The patients had to meet enrolment criteria for one of the aforementioned studies. During follow-up of 51±42 months the relative risk of CHF progression ranged from 3.14 (95% CI 1.41-6.99, p=0.005) to 4.63 (95% CI 1.76-12.2, p=0.0019) and arrhythmias were observed in 11-42% of all cardiac events. Analysing groups of criteria corresponding to the indications for the individual studies, less strict indications were associated with higher risk of arrhythmia while more serious symptoms of CHF at baseline were related to further CHF progression but without relative increase in arrhythmia events. However, in the examined group of patients natural disease course was analysed but possible modification of risk by means of CRT itself was not adjusted for [14].

It should be stressed that in spite of increasing absolute and relative numbers of system implantations, definite answers to questions on the impact of stimulation and defibrillation function in CRT-D systems on long-term outcome are not known yet. Mean follow-up in randomised trials is approximately 2 to 3 years. In the comparable period of follow-up in the COMPANION study, convergence of survival curves for patients treated pharmacologically and with CRT-P could be seen. It also holds true for the CRT-D group. Many authors, even from

countries with very high health care expenditures, believe that some patients with indications for CRT (elderly subjects, clinically severe heart failure assessed as NYHA class IV) do not benefit from prophylactic function of defibrillation.

A limitation of our study was the fact that non-homogeneous protocols for late follow-up were adopted in the participating centres. Thus, some data were lost for the analysis. However, this does not change the main study conclusions. During the follow-up, most cases of SCD were noted in patients with non-CAD CHF aetiology. All SCD events occurred within the first year of follow-up and they significantly contributed to the increased risk of death in this period of time (Figure 3). Due to the observational nature of this analysis and the low number of study participants, it is difficult to draw definite conclusions. However, this fact seems to confirm the opinion that CHF aetiology is of less importance when primary SCD prophylaxis is considered in patients with CRT. It is also known that in patients selected for CRT, SCD as the leading cause of death is 'promoted' by milder clinical CHF course at baseline or significant clinical improvement [14, 15].

In our patients due to a lack of homogeneous data it was not possible to analyse these correlations objectively. However, subjective observations consistent with previous reports suggest that SCD was observed predominantly in patients with good response to CRT; most of them were found after the procedure in functional NYHA class II. Death due to CHF progression was associated with the problem of natural CRT limitations. Mean follow-up time in this report was 24 months; the longest was 5 years. Mortality due to CHF was, like SCD, related to increased death risk in the first year of follow-up (Figure 3). It was noted in patients at high risk at baseline and then refractory to applied treatment. The small numbers in subgroups of patients who died due to CHF blunted this correlation despite the presence of a discernible trend in baseline LVEF, LVEDD and NYHA class. After one-year follow-up, mortality linked to progressive CHF was associated with gradually increasing risk of death as a function of follow-up time (Figure 3). This may be related to a several-month period of improvement followed by exhaustion of contractility reserves that were mobilised by resynchronisation.

Characteristics of the whole group presented here and treatment method were the most consistent with criteria of the CRT arm of the CARE-HF study. Comparison of the Kaplan-Meier survival curves in the analysed population with the results of this trial showed in general a comparable course of the curves for patients treated with CRT. However, after 400 days of follow-up the curve derived from our study crosses and then moves away from the curve of patients treated medically in the CARE-HF trial (Figure 4). The two CRT populations did not differ with respect to age but in the CARE-HF population mean LVEF was slightly higher (25 vs. 20%) and baseline NYHA class slightly lower (3.04 vs. 3.2, respectively). Overall mortality in our group was 20% during 24 months of follow-up and was equal to that observed in the CRT arm of the CARE-HF trial within 29 months of follow-up. Annual and two-year mortality were 12.3 and 17 vs. 9.7 and 18%, respectively. Sudden death in our group was observed in 24% of cases compared to 35% in the CARE-HF study population. It should be pointed out that these data are not comparable in every detail since follow-up time in our study was a mean for the observed patient group while in the CARE-HF trial it was the real time achieved by all alive participants. In spite of the similar criteria for CRT application in the comparable groups, this fact may suggest the interpretation that lower access to this method in Poland caused, at least in the first years of clinical use, selection of a higher number of patients with end-stage CHF. This might have had an impact on increased mortality, including those who died due to CHF progression during the first year of follow-up.

Increasing availability of CRT and its natural evolution means that more CHF patients improve to NYHA class II. This trend seems to increase the role of CRT-D systems. Implantation resynchronising therapy devices with cardioversion/defibrillation function account for an increasing percentage of all electrotherapeutic procedures worldwide. In Poland, in spite of increasing CRT usage, only 9 CRT devices (including CRT-D) per 1 million of inhabitants were implanted in 2005. This number is several times lower than the European average. Actions towards popularisation and better availability of CRT, especially CRT-D, are becoming an increasingly important task for Polish cardiologists.

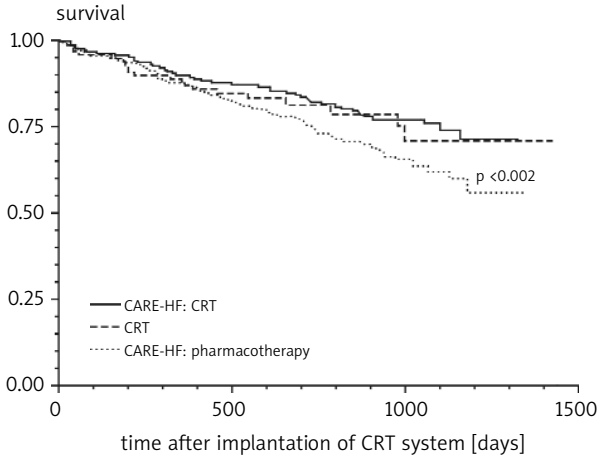

Figure 4. Kaplan-Meier survival curve in the studied group (CRT) referred to findings concerning survival in the CARE-HF trial [3]

Conclusions

1. In the first year of follow-up of CRT, the risk of sudden cardiac death is the highest and then the risk of death due to heart failure increases exponentially.
2. In all patients selected for CRT, preventive addition of cardioversion/defibrillation function should be considered.

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Śmiertelność wśród chorych z niewydolnością serca leczonych komorową stymulacją resynchronizującą. Wieloośrodkowa obserwacja długoterminowa

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Streszczenie

Wstęp: Udowodniony korzystny wpływ stymulacji resynchronizującej (CRT) na przeżywalność wśród chorych z niewydolnością serca (CHF) znalazł swoje odbicie w standardach ESC 2005.

Cel: Analiza śmiertelności wśród chorych zakwalifikowanych wyłącznie do CRT w okresie co najmniej rocznej obserwacji odległej w świetle wzrastającej roli zastosowania CRT z funkcją defibrylacji (CRT-D).

Metodyka: Prospektywna wieloośrodkowa analiza kliniczna, w co najmniej rocznym okresie obserwacji, śmiertelności i mechanizmów zgonu wśród chorych z CRT wszczepionym w wyniku powszechnie uznanych wskazań. Roczną obserwację lub rejestrację wcześniejszego zgonu uzyskano u 105 chorych (19 kobiet, 86 mężczyzn) w wieku 60,6±9,8 roku (35–78). Wyjściowa klasa wg NYHA wynosiła 3,2±0,4 (3–4). Niewydolność serca miała etiologię wieńcową u 57 (54%) chorych i pozawieńcową u 48 (46%).

Wyniki: Średni czas obserwacji wyniósł 730 dni (360–1780), mediana 625. Zanotowano łącznie 21 (20%) zgonów: 5 (24%) nagłych zgonów sercowych (SCD), 13 (62%) zgonów z powodu progresji niewydolności serca (HFD) i 3 (14%) zgony z innych przyczyn. W pierwszym roku obserwacji zmarło 13 (62%) chorych i w okresie tym wystąpiły wszystkie SCD. Średni czas do zgonu wynosił 303±277 dni (19–960), do HFD – 339±313 dni (19–960), a do SCD – 208±127 dni (31–343). Pomiędzy pozostałymi chorymi a tymi, którzy zmarli, nie zanotowano różnic w wyjściowych wartościach frakcji wyrzutowej lewej komory (LVEF) (25±10 *vs* 20±8%), wynikach testu 6-minutowego marszu korytarzowego (276±166 *vs* 285±163 m). Różnica na granicy istotności statystycznej wystąpiła jedynie w wyjściowym wymiarze późnorozkurczowym lewej komory (LVEDD) (71±9 *vs* 78±10 mm, p=0,05). Grupy SCD i HFD nie różniły się wiekiem (62,0±5,4 *vs* 56,6±13,2 roku); płcią (mężczyźni 80 *vs* 83%), klasą wg NYHA (3,1±0,2 *vs* 3,5±0,3), LVEF (22±9 *vs* 17±5%), LVEDD (86±10 *vs* 79±9 mm), testem 6-minutowego marszu korytarzowego (270±142 *vs* 292±188 m). Pozawieńcową etiologię CHF stwierdzono u 4 spośród 5 zmarłych z powodu SCD i tylko u 1 osoby z grupy 12 chorych zmarłych z powodu z HFD (p=0,003). U chorych zmarłych z powodu HFD w pierwszym roku obserwacji i pozostałych kolejne parametry wynosiły odpowiednio: LVEF – 14±8% (7–25, mediana 13) *vs* 18±4% (12–22, mediana 20), LVEDD – 76±5 (72–79) *vs* 75±8 mm (62–82) oraz klasa NYHA – 3,8±04 (3–4) *vs* 3,4±0,3 (3–4); wszystkie różnice NS.

Wnioski: W pierwszym roku po implantacji u chorych z CRT największe jest ryzyko nagłego zgonu sercowego, a następnie wykładniczo wzrasta ryzyko zgonu z powodu niewydolności serca. U chorych kwalifikowanych do stymulacji resynchronizującej powinno się rozważyć profilaktyczne dodanie funkcji kardiowersji/defibrylacji.

Słowa kluczowe: stymulacja resynchronizująca, niewydolność serca, śmiertelność

Kardiol Pol 2007; 65: 1287–1293

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Praca wpłynęła: 27.02.2007. **Zaakceptowana do druku:** 18.07.2007.

Praca zrealizowana częściowo ze środków grantu MNiSzW 3 P05C 00825.