

Quality of life in patients undergoing cardiac resynchronisation therapy

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Abstract

Background: Cardiac resynchronisation therapy (CRT) is often recommended for the treatment of patients with severe heart failure and cardiac dyssynchrony. The procedure efficacy should be evaluated not only by objective criteria and clinical end points, but also by patients' subjective opinion of their everyday functioning.

Aim: To assess the quality of life (QoL) in patients treated with CRT.

Methods: The study comprised 26 CRT patients: 18 males and 8 females, aged 63.3±9.5 (34-75) years. The QoL was evaluated by NHP questionnaires twice: before CRT implantation and 15±4 months (mean) after the procedure.

Results: There was a significant improvement in the mean values of energy (2.9 vs. 2; $p < 0.01$), physical mobility (4.3 vs. 3; $p < 0.05$) and emotional reactions (5.2 vs. 3.7; $p < 0.05$) following CRT. However, some aspects of everyday functioning did not improve after CRT. They included looking after the home (66.7 vs. 66.7%) and sex life (54.2 vs. 70.8%). An improvement was observed in home life (33.3 vs. 20.8%) and social life (61.5 vs. 50%).

Conclusions: Cardiac resynchronisation therapy improves patients' QoL. The psycho-social condition of CRT patients needs further, larger studies and should be taken into account by attending health professionals.

Key words: cardiac resynchronisation therapy, chronic heart failure, quality of life

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Introduction

Cardiac resynchronisation therapy (CRT) is a commonly accepted method of treatment in the selected group of patients with advanced chronic heart failure (CHF). According to the Guidelines of the European Society of Cardiology from 2005, CRT is a class I recommendation in optimally treated patients with CHF in functional NYHA class III or IV with left ventricular ejection fraction <35% and contraction dyssynchrony [1]. These recommendations were based mainly on the results of the Companion [2] and Care-HF [3] trials where statistically significant survival benefits in patients treated with CRT vs. treated medically were found. The CHF progression leads to decreased quality of life (QoL). An expected result of treatment is an improvement or at least no deterioration in QoL [4, 5]. Quality of life was the subject of analysis in the studies on CRT. Improvements in the essential haemodynamic and clinical parameters, as well as in QoL, were documented in these studies [6-8].

The purpose of this study was to evaluate QoL of patients treated with CRT.

Methods

Patients

The study comprised 26 patients: 18 men and 8 women aged 63.3±9.5 (34-75) years.

The results of QoL of patients that met the following criteria were summarised: (a) qualification for CRT (examination performed prior to implantation), (b) orientation with respect to place, time and personal situation, and (c) successful procedure of permanent pacemaker or resynchronising defibrillator implantation (examination carried out after device implantation).

Assessment of QoL

The Life Quality Nottingham Health Profile Questionnaire (NHP) was applied to assess life quality

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[9]. It was shown that the results of accuracy, reliability and independence of the Polish NHP subscales version were comparable to the data derived from the studies using the original version and this fact justifies considering this method as accurate and reliable [10]. In part one of this questionnaire 6 aspects of life are evaluated. Three of them concern the physical sphere: E – energy, P – pain, PM – physical mobility; and three others the psychosocial sphere: ER – emotional reactions, S – sleep, SI – social isolation. The possible ranges of the results were as follows: E – 0-3 points, P – 0-8 points, PM – 0-8 points, ER – 0-9 points, S – 0-5 points, SI – 0-5 points.

Table I. Comparison of the quality of life in the examined group before and after introduction of resynchronising therapy (NHP, part I)

Parameter		Means±SD	Min-max	Median	p
Scales to assess physical sphere					
E	before	2.9±0.3	2-3	3	<0.005
	after	2.0±1.2	0-3	3	
P	before	2.9±2.6	0-8	2.5	NS
	after	2.5±2.3	0-7	2	
PM	before	4.3±2.3	1-8	4	<0.05
	after	3.0±2.0	0-7	3	
Scales concerning psychosocial sphere					
ER	before	5.2±1.8	1-9	5	<0.05
	after	3.7±2.6	0-8	3	
S	before	3.6±1.4	0-5	4	0.07
	after	3.1±1.6	0-5	4	
SI	before	1.6±1.7	0-5	1	NS
	after	0.9±1.1	0-3	0.5	

Abbreviations: E – energy, P – pain, PM – physical mobility, ER – emotional reactions, S – sleep, SI – social isolation, SD – standard deviation, min-max – minimal and maximal value achieved by a patient in a given scale

The second part of this questionnaire contains questions concerning whether a given disease disturbs paid work (W), looking after the home (LaH), social life (SL), home life (HL), sex life (SxL), interest and hobbies (IH) and vacations (V) [9, 10].

A higher result in this questionnaire indicates worse subjective assessment of life quality. The examined individuals completed questionnaires twice: before device implantation and during the follow-up examination after the procedure (mean 15±4 months). After informing patients about the study as well as types of answers to the questionnaire questions, self-examination was performed without assistance of the treating physician.

Statistical analysis

Statistical analysis was performed with statistical software SAS version 8.e. The results are expressed as means and standard deviations or medians and ranges, respectively. Normal distribution of the analysed data was verified with the Kolmogorov-Smirnov test. Paired Student's t-test and nonparametric Wilcoxon tests were used.

The power of the linear correlations between results with respect to life quality and time of study follow-up after the procedure were calculated by means of Pearson's correlation index.

All tests were two-sided. Zero hypotheses were verified at the level of $p < 0.05$ statistical significance.

Results (Tables I-V)

Significant improvement in 3 examined aspects of life quality was found after the procedure: 2 of 3 regarding the physical sphere (energy – 2.9 vs. 2, $p < 0.005$; and physical mobility – 4.3 vs. 3, $p < 0.05$) and 1 of 3 concerning the psychosocial sphere (emotional reactions – 5.2 vs. 3.7, $p < 0.05$). Meanwhile, the results of the 'social separation' test were close to the statistical significance threshold (1.6 vs. 0.9, $p = 0.07$).

Table II. Summary of results of the used statistical tests (NHP, part I)

	Kolmogorov-Smirnov test				Non-parametric tests				Paired T-test	
	before		after		paired Wilcoxon test		Log-rank test		T	p
	D	Pr > D	D	Pr > D	Z	p	S	p		
Scales to assess physical sphere										
E	0.523	<0.0100	0.330	<0.0100	-2.8560	0.0043	45.5	0.0027	3.44	0.002
P	0.186	0.0203	0.203	<0.0100	-0.7186	0.4724	16.5	0.4827	0.85	0.405
PM	0.175	0.0391	0.157	0.0956	-2.4852	0.0129	71.5	0.0081	2.89	0.008
Scales concerning psychosocial sphere										
ER	0.146	>0.1500	0.159	0.0891	-2.1857	0.0288	76.5	0.0241	2.73	0.011
S	0.269	<0.0100	0.251	<0.0100	-1.4439	0.1488	23	0.1494	1.54	0.136
SI	0.221	<0.0100	0.296	<0.0100	-1.8098	0.0703	35	0.0731	1.97	0.060

Abbreviations: D, Pr, Z, p, S, T – statistical symbols (SAS v. 8.e package), others – see Table I

The vast majority of patients reported either improvement or a lack of depreciation in life quality after the procedure (from 70 to 92%). The most pronounced improvement concerned the following scales: emotional reaction and physical mobility. The fewest patients felt improvement in the scales regarding sleep disorders and pain.

Most patients experienced difficulties in various aspects of daily life both before and after the procedure. Before the procedure, most of all the underlying disease disturbed patients in home activities (66.7%) and social life (61.5%). The fewest problems expressed by patients regarded home life (33.3%) or interests and hobbies (41.7%). Following implantation, most patients stressed problems with sexual activity (70.8%) and still many of them manifested difficulties with daily activities at home (66.7%). The fewest, only 20.8%, noted difficulties in familial life resulting from the underlying disease. Thus, a slight improvement after the procedure was observed in the familial life sphere (33.3 vs. 20.8%) and social life (61.5 vs. 50%). More individuals expressed problems concerning sexual activity (54.2 vs. 70.8%). In the case of other indices, a comparable number of people indicated difficulties either before or after the procedure.

Despite the differences between patients with respect to timing of follow-up examinations (mean 15±4 months) and thus quality of life assessment after CRT, in the examined group no correlations between study timing and the results of the scale evaluating life quality were noted.

Discussion

Cardiac resynchronisation therapy improves survival of the patients. In order to confirm this thesis, it was mandatory to perform a properly designed long-term study comprising a large population [3]. In the Care-HF trial, analysis of the results of 813 patients showed a 36% reduction in mortality in the CRT group during 29-month follow-up. In the Companion study [2], which involved 1520 patients and lasted more than 3 years, the Kaplan-Meier curves for the composite end point (death plus hospitalisations due to CRF) after a period of statistically significant differences disclosed a trend to approximate to one another at the end of follow-up. One can conclude that each therapy and its effect have time limitations that in the case of CRT are seen in the third year after treatment application. An efficacy evaluation of a given medical procedure comprises not only objective criteria such as the results of the biochemical tests or physical capacity assessment but also the subjective opinion of the patient in terms of daily activity.

Advanced CHF associated with progressing disability and frequent hospitalisations is accompanied by markedly decreased daily life comfort, representing a significant problem in treatment of these patients.

Table III. Comparison of results evaluating life quality of particular patients recorded before and after resynchronisation (number of individuals n=26)

Parameter	Improvement	Results equal to baseline	Worse score after
Scales concerning physical sphere			
E	12 (46.15%)	12 (46.15%)	2 (7.69%)
P	10 (38.46%)	8 (30.77%)	8 (30.77%)
PM	16 (61.54%)	5 (19.23%)	5 (19.23%)
Scales regarding psychosocial sphere			
ER	17 (65.38%)	2 (7.69%)	7 (26.92%)
S	9 (34.62%)	12 (46.15%)	5 (19.23%)
SI	11 (42.31%)	10 (38.46%)	5 (19.23%)

Abbreviations: see Table I

Table IV. Quantitative and percentage assessment of patient function in the selected spheres before and after procedure (NHP, part II) (number of subjects n=24)

Parameter	Before	After
W	11 (45.8%)	11 (45.8%)
LaH	16 (66.7%)	16 (66.7%)
SL	14 (61.5%)	12 (50%)
HL	8 (33.3%)	5 (20.8%)
SxL	13 (54.2%)	17 (70.8%)
IH	10 (41.7%)	10 (41.7%)
V	12 (50%)	13 (54.2%)

Abbreviations: W – work, LaH – looking after the home, SL – social life, HL – home life, SxL – sex life, IH – interests and hobbies, V – vacations

Table V. Indices of the correlations between results regarding quality of life and timing of evaluation after the procedure

Parameter	r	p
Scales to assess physical sphere		
E	-0.04	0.83 (NS)
P	-0.06	0.79 (NS)
PM	-0.14	0.49 (NS)
Scales concerning psychosocial life		
ER	-0.13	0.54 (NS)
S	0.04	0.85 (NS)
SI	0.001	0.99 (NS)

Abbreviations: r – Pearson's correlation index, others – see Table I

Cardiac resynchronisation therapy, introduced to CHF treatment at the beginning of the 1990s, demonstrated a beneficial effect on the overall QoL of patients in the first clinical trials. The Care-HF trial showed an

improvement in life quality assessed by means of the Minnesota questionnaire (31 ± 22 vs. 40 ± 22 , $p < 0.001$) and according to the EuroQoL EQ-5D score protocol (0.7 ± 0.28 vs. 0.63 ± 0.29 , $p < 0.001$), respectively [3]. In the Companion study [2] application of electrotherapy (CRT equipped with cardioversion defibrillation function or CRT itself) improved QoL of patients compared with a control group (Minnesota questionnaire) – the difference was 26 ± 28 vs. 25 ± 26 vs. 12 ± 23 ($p < 0.001$) after 3 or 6 months of follow-up respectively. Statistically significant improvement in QoL was also noted in the MIRACLE ($n=500$, $p < 0.001$) [11] and MUSTIC SR ($n=67$, $p < 0.001$) studies [12]. So far the vast majority of published trials dealing with CRT have presented results for the overall QoL, although one should note that it consisted of many various factors. Areas that most commonly, additionally to overall life quality, are analysed involve somatic status and physical capacity or psychical general well-being and social relationship.

The Minnesota questionnaire allows separate evaluation of the physical and psychical sphere, although in most published reports no information on these data is provided. The SF-36 and NHP are among questionnaires that examine several factors. Dorian et al. [13] assessed life quality of 72 patients (SF-36) after implantation of a resynchronising device, dividing them into groups with CRT switched on and off. This study at the end of 6-month follow-up showed that the group with switched-on CRT presented a statistically significant ($p < 0.05$) improvement in 4 of 8 indices. Favourable change concerned 2 scales describing the physical sphere – physical function and health problems – as well as 2 scales of the psychosocial sphere – social function and emotional problems. In the group with switched-off CRT, only the results of the health problems scale improved statistically significantly. Patients with switched-on CRT presented better results in 3 scales, 1 describing the physical sphere and 2 concerning the psychosocial sphere.

Skobel et al. [14] also evaluated QoL of patients with CRT by means of the SF-36 questionnaire [18 individuals with sleep apnoea (CSA) and 14 patients without sleep-related breathing disorders (SRBD)]. Patients after a period of approximately 4.5 months following device implantation found their life quality better than prior to the procedure [in the CSA group improvement was found in all scales concerning the physical sphere such as physical function, health problems, somatic symptoms and general health perception, and also 3 of 4 scales describing the psychosocial sphere – social activity, psychical health and emotional problems – while in the group without SRBD positive changes were much less pronounced and patients assessed better 3 of 4 indices concerning the physical sphere – physical activity, health problems and somatic symptoms – but only 1 (psychical health) of 4 scales of the psychosocial sphere]. The aforementioned studies showed that improvement in life

quality is not so obvious if assessed in more detail and if the analysis includes a higher number of variables rather than overall evaluation.

Our report is the first study carried out in Poland evaluating life quality of patients with CRT. We showed a statistically significant improvement in 3 of 6 analysed aspects of patient activity (NHP, part I), 2 of 3 mean results of the scales describing physical symptoms and 1 of 3 averaged results of the scales concerning psychosocial activity of the examined subjects (Tables I and II). The results of other examined determinants of life quality improved as well, including social separation, which decreased to a level of differences close to statistical significance ($p=0.07$). It is noteworthy that a patient completing the questionnaire has just two possible answers, 'yes' or 'no', so if changes regarding its function are subtle they are probably not noted. It may be that a broader spectrum of possible answers would disclose more significant differences regarding function before and after the procedure (for example, if the patient had a choice of answers on a five-degree scale). Analysing the results of tests performed for particular patients one may conclude that improvement or a lack of deterioration was manifested by the vast majority of the examined patients (Table III). These results are consistent with data of other studies carried out worldwide.

One can notice a high percentage of patients (around 50%) with problems concerning various aspects of daily life both before and after the procedure (see Table IV). These findings may be caused, as in the first part of the questionnaire, by the general character of the questions (the patient can choose between a positive or negative answer to questions concerning the issue of disease impact on a given sphere of function). This may result from the fact that CRT is not a method leading to complete recovery and in spite of the unquestioned advantages of its application, several difficulties remain significant.

The study of Krahn et al. [15] stressed that life quality of patients may change together with period of CRT. Better improvement in quality of life assessed by means of the Minnesota questionnaire was found at one month after CRT application (62 vs. 42 , $p < 0.001$), after three months patients manifested worsening QoL (55), after 6 months improvement with respect to this parameter was noted (48), and eventually after 1 year of follow-up worsening QoL was observed again (56). In our report, due to evaluation of QoL at various times after the procedure (mean 15 ± 4 months) caused by objective reasons but which could influence results, time itself was checked as to whether it was an independent variable with an impact on patients' results (Table V). Correlation indices neither statistically significant nor close to the significance threshold were found in our study. Thus, one can conclude that in the examined

group time did not have a significant influence on the results. This may have resulted from the fact that this report involved the group of selected patients with the most comparable timing of examination after CRT initiation.

Conclusions

1. Application of cardiac resynchronising therapy improves quality of life.
2. Higher scores of life quality of patients treated with cardiac resynchronisation concerned selected aspects of their activity.
3. Furthermore, more detailed analysis and also special care of physicians or psychologists is required to achieve more pronounced improvement in life quality of the patients.

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Jakość życia chorych leczonych komorową stymulacją resynchronizującą

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Streszczenie

Wstęp: Komorowa stymulacja resynchronizująca (CRT) ma zastosowanie w leczeniu wybranych chorych z ciężką zastoinową niewydolnością serca. Prezentowana praca jest pierwszym w Polsce opracowaniem dotyczącym jakości życia chorych z CRT.

Cel: Ocena jakości życia chorych leczonych CRT.

Metody: Jakość życia oceniano kwestionariuszem NHP. Badani wypełniali go dwukrotnie – przed wszczęciem i podczas pierwszej odległej wizyty kontrolnej po zabiegu (średnio 15±4 mies.). Do badań włączono 26 chorych po udanym zabiegu – 18 mężczyzn i 8 kobiet w wieku 62,3±9,5 roku (34–75 lat).

Wyniki: Na podstawie przeprowadzonych badań stwierdzono, że:

1. Po zabiegu nastąpiła statystycznie istotna poprawa 3 ocenianych aspektów jakości życia; 2 z 3 dotyczących sfery fizycznej („Energia” – 2,9 vs 2; $p < 0,005$ i „Ograniczenia ruchowe” – 4,3 vs 3; $p < 0,05$) i 1 z 3 dotyczących sfery psychospołecznej („Reakcje emocjonalne” – 5,2 vs 3,7; $p < 0,05$). Bliskie istotności statystycznej są wyniki skali „Wyobcowanie społeczne” – 1,6 vs 0,9; $p = 0,07$.
2. Zdecydowana większość chorych odczuła poprawę lub brak pogorszenia jakości życia po zabiegu (70–92%). Największa poprawa dotyczyła skal: „Reakcje emocjonalne” i „Ograniczenia ruchowe”. Najmniej chorych odczuło poprawę w skalach: „Zaburzenia snu” i „Ból”.
3. Większość badanych osób odczuwało trudności w różnych aspektach codziennego życia, zarówno przed, jak i po zabiegu. Przed zabiegiem choroba najbardziej utrudniała wykonywanie prac domowych (66,7%) oraz życie towarzyskie (61,5%). Najmniej trudności zgłosili chorzy w sferach dotyczących życia rodzinnego (33,3%) oraz zainteresowań i hobby (41,7%). Po wszczęciu najwięcej chorych wskazało na trudności w życiu seksualnym (70,8%), nadal wiele osób miało też trudności z wykonywaniem prac domowych (66,7%). Najmniej, bo tylko 20,8% osób, zgłaszało utrudnienia w życiu rodzinnym wynikające z choroby. Niewielka poprawa po zabiegu nastąpiła w sferze życia rodzinnego (33,3 vs 20,8%) oraz życia towarzyskiego (61,5 vs 50%). Więcej osób zgłosiło problemy dotyczące życia seksualnego (54,2 vs 70,8%). Dla pozostałych wskaźników problemy przed zabiegiem i po zgłaszała podobna liczba chorych.

Wnioski:

1. Zastosowanie CRT poprawia jakość życia chorych.
2. Lepsza ocena komfortu życia chorych leczonych CRT dotyczyła wybranych aspektów ich funkcjonowania.
3. Uzyskanie większej poprawy jakości życia chorych wymaga dalszej, pogłębionej analizy, a także szczególnej troski lekarzy i psychologów.

Słowa kluczowe: komorowa stymulacja resynchronizująca, przewlekła niewydolność serca, jakość życia

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