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Hospital-based and telemonitoring guided home-based training programs: Effects on exercise tolerance and quality of life in patients with heart failure (NYHA class III) and cardiac resynchronization therapy. A randomized, prospective observation.

Edyta Smolis-Bąk [a,*], Rafał Dąbrowski [a], Ewa Piotrowicz [b], Tomasz Chwyczko [a], Barbara Dobraszkiewicz-Wasilewska [b], Ilona Kowalik [a], Barbara Kazimierska [a], Barbara Jędrzejczyk [a], Ryszard Smolis [b], Katarzyna Gepner [a], Aleksander Maciąg [a], Maciej Sterliński [a], Hanna Szwed [a]

[a] II Ischemic Heart Disease Department, Institute of Cardiology, Warsaw, Poland
[b] Department of Rehabilitation and Noninvasive Electrocardiology, Institute of Cardiology, Warsaw, Poland

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ABSTRACT

Cardiac resynchronization therapy with defibrillator function (CRT-D) along with an optimal medical therapy improves symptoms, cardiac efficiency, quality of life (QoL) and prognosis in patients with heart failure (CHF). The aim of the study was to assess effects of hospital-based and home-based/telemonitoring exercise training.

Methods: The prospective, randomized study was conducted in 52 patients (pts), aged 45–75 years (mean 62 ± 9.3), with CHF of ischemic or another etiology, NYHA class III and implanted CRT-D. Group CRT-Ex (n = 26) underwent initial exercise training in the hospital setting and continued training program at home with telemonitoring 5 times a week for 8 weeks. The CRT-control group (n = 26) consisted of patients who had hospital rehabilitation, but no training program after discharge.

Results: No differences between the groups in CHF etiology, comorbidities, medical therapy and in any of spiroergometry (CPX) parameters at baseline were observed. After 3–4 months the CRT-Ex group achieved better results in VO_2 peak, VCO_2 peak and treadmill test duration. But after 12 months the measurements returned to the baseline values. No significant differences were observed directly between two groups in distances of 6-MWT at baseline, at 3–4 months and at 12 months. Echocardiographic evaluation showed significant reduction of left ventricular dimensions and improvement in the left ventricular ejection fraction (EF), in both groups (25.3 ± 7.4% to 28.9 ± 9.1%, CRT-Ex group, p = 0.0213 and 24.9 ± 7.2% to 31.7 ± 10.6%, CRT-Control group, p = 0.0001). Significant improvement in all domains of QoL was observed in the CRT-Ex group, while the CRT-Control pts declared only higher energy levels and less pain. Intensity of telemonitoring guided home-based exercise training was low. In the 12- and 18-months follow-up there were no differences in the ICD-interventions, mortality or hospitalization rates between the groups.

Conclusions: A structured exercise training program in the hospital and home-based with telemonitoring was safe option of additional treatment and improved directly physical fitness and, quality of life in patients with NYHA III CHF and CRT-D. However these effects haven't been sustained in longer period of time and had no impact on prognosis.

1. Introduction

Chronic congestive heart failure (CHF) is a complex syndrome which requires comprehensive management. Cardiac resynchronization therapy with defibrillator function (CRT-D) combined with an optimal drug regimen improves symptoms, cardiac efficiency, quality of life (QoL) and prognosis in responders (approximately 30–40% of CHF patients) [1–5]. In CHF patients lack of regular exercise training and self-imposed limitations to exercise may play an important role. That is why targeted physical activity is a vital element of comprehensive CHF management [1,6,7]. Planning of exercise training in CHF patients is limited by their low exercise capacity, risk of arrhythmias, impact of more strenuous exercise on CRT function and difficulties in providing optimal rehabilitation in the hospital setting and at home. For these reasons, proper supervision of exercise training may be of key importance for patients with advanced CHF, especially due to potential adverse events. Special cardiac rehabilitation programs are developed to improve therapy in the hospital setting. Telemonitoring is an additional

* Corresponding author at: II Ischemic Heart Disease Department, Institute of Cardiology, Warsaw, Spartanska 1, 02-637 Warsaw.
E-mail address: esmolis@gmail.com (E. Smolis-Bąk).

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Table 1
Characteristics of the two studied groups: undergoing exercise training (CRT-Ex) and control (CRT-Control).

	Rehabilitation group (CRT-Ex)	Control group (CRT-Control)	p
Age (years)	60.0 ± 8.5	65.1 ± 8.2	**0.0192**
Males	25 (96.1%)	22 (84.6%)	0.1816
Body weight	86.7 ± 13.3	80.8 ± 17.2	0.1383
BMI (kg/m$_2$)	29.3 ± 4.1	27.4 ± 4.5	0.0944
Coronary heart disease, n (%)	13 (50.0%)	16 (61.5%)	0.3433
Myocardial infarction, n (%)	11 (42.6%)	12 (46.2%)	0.5480
Coronary angioplasty, n (%)	7 (26.9%)	9 (34.5%)	0.4174
Coronary artery bypass grafting, n (%)	4 (15.4%)	3 (11.5%)	1.0
Arterial hypertension, n (%)	12 (46.1%)	10 (38.5%)	0.8517
Diabetes mellitus, n (%)	7 (26.9%)	6 (23/1%)	0.9378
Hyperlipidemia, n (%)	20 (76.9%)	21 (80.1%)	0.7442
Stroke, n (%)	0 (0%)	0 (0%)	1.0
Transient ischemic attack (TIA), n (%)	1 (3.8%)	2 (7.7%)	0.6003
Heart failure etiology:			
Ischemic	11 (42.6%)	13 (50.0%)	0.1134
Other	9 (34.5%)	12 (46.2%)	
Unknown	6 (23.1%)	1 (3.8%)	
Atrial fibrillation: yes	17 (65.4%)	15 (57.7%)	0.2955

Statistical significance: $p < 0.05$.

option to prolong and make exercise training more effective and safer after discharge [6].

The aim of this study was to assess the effects of exercise training, both hospital-based and home-based with telemonitoring, on the exercise capacity and echocardiographic parameters in patients with advanced CHF (NYHA class III) and implanted CRT-D devices on optimal medical therapy. Additional assessments included the QoL and depressive symptoms. The study was conducted in the years 2008–2012 as a part of the Institute of Cardiology project (3.1/I/09) with the permission of the institutional Bioethics Committee (IK-NP-0021-73/1100/08).

2. Material and methods

All patients provided signed informed consent to participate in the study. The patients were consecutively recruited before implantation of CRT device using randomization pattern. The inclusion criteria were: CHF of ischemic origin or another etiology, NYHA class III, left ventricle ejection fraction <35% (LVEF), planned implantation of a CRT-D device (LBBB, QRS > 150 ms), controlled hypertension, diabetes and other metabolic disorders, capacity to perform treadmill exercise test, absence of complex arrhythmia. Exclusion criteria were: acute or uncontrolled disorders other than CHF and severe mobility impairment, severe musculoskeletal conditions which preclude physical rehabilitation (orthopedic, neurological), planned cardiac surgery or percutaneous coronary interventions, cardiac surgery or coronary angioplasty within last 3 months, acute coronary syndrome, stroke or TIA within last six months, venous thrombosis or pulmonary embolism in the past, significant valve and pulmonary diseases. The study patients were randomly allocated into two groups. Group CRT-Ex (n = 26) underwent initial exercise training at the hospital and continued their training program at home. The CRT-control (n = 26) consisted of patients who had no rehabilitation after discharge from hospital. The CRT-Ex patients initially trained in the Rehabilitation Unit (for 3 weeks on average) and then at home with telemonitoring 5 times a week for 8 weeks. Prior to CRT-D implantation and after 3–4 and 12 months, all patients had cardiopulmonary exercise testing (CPX) on a treadmill using the Naughton protocol. The following parameters were measured and analyzed: peak oxygen uptake (VO_2 peak), anaerobic threshold (AT), exercise tolerance (metabolic equivalents [METs] and treadmill test duration). Prior to and 12 months after CRT-D implantation standard echocardiography (2D Doppler) and a six-minute walk test (6-MWT) were performed according to the American Thoracic Society Guidelines [9]. Study patients were stratified using the Weber classification based on peak oxygen uptake: very severe CF (E): VO_2 peak < 6 ml/kg/min; severe CF (D): 6–10 ml/kg/min; moderate/severe CF (C): 10–16 ml/kg/min; mild/moderate CF (B): 16–20 ml/kg/min; mild/none (A): >20 ml/kg/min [10,11].

The training program included active exercises of small and subsequently larger muscle groups of the lower and upper limbs (isometric exercises with normal inspiration/expiration), respiratory exercises, range-of-motion exercises of the shoulder joint on the implantation side (passive, active-passive, self-assisted, active). The CRT-Ex patients while in hospital received instruction in self-assessment of their health status, operation of the telemonitoring equipment and correct performance of exercises within their planned training program. At home, the patients performed dynamic exercises of small and larger muscle groups, isometric exercises of small muscle groups, coordination and respiratory exercises. Before starting exercising, the patients sent their ECG recording at rest to the monitoring center and by telephone answered questions concerning their subjective health, blood pressure, body weight and medications. After the monitoring center approval, they started a training session. Automated ECG recording was coordinated with the exercise cycle. The patient was transmitting the ECG recordings by a cell phone to the monitoring center where the staff assessed the safety, effectiveness and correctness of the exercises.

The depressive symptoms were measured using the Beck Depression Inventory (BDI) and the QoL was assessed with the Nottingham Health Profile (NHP) prior to CRT-D implantation and after 3–4 and 12 months [12–14]. Patients were in a Heart Failure Disease Management Program. They had constant contact with physiotherapist, doctor and nurse. Patients from both groups were under close surveillance in addition to elective cardiac clinic visits (CRT-D control, a visit to a cardiologist). In case of need telephone calls, cardiologist consultations and hospital admissions were provided.

3. Statistical analysis

After assessment of the distribution characteristics of continuous variables (for conformity with a Gaussian distribution), measurable variables with a normal distribution were presented as the arithmetic mean and standard deviation. The paired Student's *t*-test was used to assess the significance of differences between the means in two related groups. The differences between the means in two unrelated groups were assessed with the *t*-test or the Cochran's Q-test. The measurable variables with an irregular distribution or variables measured using ordinal scales were characterized by the median and lower and upper quartiles. The following nonparametric tests of significance were used: the Wilcoxon signed-rank test for related measurements and the Mann–Whitney tests for unrelated groups. The nominal variables were presented as absolute and relative frequencies of unrelated units. To assess the significance between fraction differences in two groups the chi-squared test incorporating Yates correction for continuity or the exact test were used. The significance of differences between related binary variables was assessed with the McNemar's test. The two-sided hypotheses were verified at the statistical significance level of $p \le 0.05$. The SAS 9.2 software was used in the analysis.

Table 2
Spiroergometric parameters prior to exercise training, after exercise training and at 12 months of follow-up.

	CRT-Ex			CRT-Control			p CRT-Ex vs CRT-Control		
	At baseline	At 3–4 months	At 12 months	At baseline	At 3–4 months	At 12 months.	At baseline	At 3–4 months	At 12 months
VO_2 peak [ml/kg/min]	13.0 ± 2.3	17.2 ± 3.9	13.1 ± 4.1	10.7 ± 3.2	13.4 ± 4.2	14.2 ± 3.1	0.4149	**0.0324**	0.9427
VO_2 [%]	48.9 ± 10.0	62.7 ± 14.5	50.8 ± 18.5	45.9 ± 15.1	57.5 ± 16.8	61.9 ± 15.1	0.9931	0.9175	0.3013
VCO_2 peak [l/min]	1.04 ± 0.25	1.44 ± 0.37	1.07 ± 0.45	0.82 ± 0.26	1.01 ± 0.23	1.05 ± 0.29	0.3870	**0.0059**	0.9999
VO_2 AT [ml/kg/min]	12.1 ± 1.8	17.5 ± 8.7	10.9 ± 3.5	10.5 ± 1.8	12.6 ± 2.3	14.7 ± 4.3	0.9955	0.6481	0.8443
Time [min]	5.88 ± 2.74	7.98 ± 2.80	7.34 ± 3.07	3.59 ± 2.36	5.22 ± 2.70	5.42 ± 3.09	0.2011	**0.0076**	0.3826
METs	4.15 ± 1.41	5.47 ± 1.76	5.74 ± 2.22	3.06 ± 1.70	4.13 ± 1.80	4.62 ± 2.38	0.6466	0.4178	0.6117
%HR max	66.1 ± 10.4	65.2 ± 18.7	70.2 ± 15.9	70.6 ± 18.4	72.4 ± 18.9	70.5 ± 15.4	0.9725	0.8243	1.0000

VO_2 peak = peak oxygen uptake, VCO_2 peak = peak carbon dioxide elimination; AT = anaerobic threshold; METs = metabolic equivalents; HR = heart rate, statistical significance: $p < 0.05$.