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ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

Effects of outpatient followed by home-based telemonitored cardiac rehabilitation in patients with coronary artery disease

Dominika Szalewska[1], Piotr Zieliński[2], Jarosław Tomaszewski[1], Małgorzata Kusiak-Kaczmarek[3], Lidia Łepska[1], Katarzyna Gierat-Haponiuk[1], Piotr Niedoszytko[1]

[1]Department of Rehabilitation, Medical University of Gdansk, Gdansk, Poland
[2]Department of Sports Medicine, University of Physical Education and Sport, Gdansk, Poland
[3]Clinic of Rehabilitation, University Clinical Centre, Gdansk, Poland

Abstract

Background: Cardiac rehabilitation (CR) has been shown to reduce the cardiovascular mortality of patients with coronary artery disease (CAD) and help people to return to professional work. Unfortunately, limited accessibility and low participation levels present persistent challenges in almost all countries where CR is available. Applying telerehabilitation provides an opportunity to improve the implementation of and adherence to CR, and it seems that the hybrid form of training may be the optimal approach due to its cost–effectiveness and feasibility for patients referred by a social insurance institution.

Aim: To present the clinical characteristics and evaluate the effects of hybrid: outpatient followed by home-based cardiac telerehabilitation in patients with CAD in terms of exercise tolerance, safety, and adherence to the programme.

Methods: A total of 125 patients (112 men, 13 women) with CAD, aged 58.3 ± 4.5 years, underwent a five-week training programme (TP) consisting of 19–22 exercise training sessions. The first stage of TP was performed in the ambulatory form of CR in hospital; then, patients continued to be telemonitored TP at home (hybrid model of cardiac rehabilitation — HCR). Before and after completing CR, all patients underwent a symptom-limited treadmill exercise stress test. Adherence was reported by the number of dropouts from the TP.

Results: The number of days of absence in the HCR programme was 1.50 ± 4.07 days. There were significant improvements ($p < 0.05$) in some measured variables after HCR in the exercise test: max. workload: 7.86 ± 2.59 METs vs. 8.88 ± 2.67 METs; heart rate (HR) at rest: 77.59 ± 12.53 bpm vs. 73.01 ± 11.57 bpm; systolic blood pressure at rest: 136.69 ± 17.19 mm Hg vs. 130.92 ± 18.95 mm Hg; double product at rest: 10623.33 ± 2262.97 vs. 9567.50 ± 2116.81; HRR_1: 97.46 ± 18.27 bpm vs. 91.07 ± 19.19 bpm; and, NYHA class: 1.18 ± 0.48 vs. 1.12 ± 0.35.

Conclusions: In patients with documented CAD, HCR is feasible and safe, and adherence is good. Most patients were on social rehabilitation benefit, had a smoking history, and suffered from hypertension, obesity, or were overweight. A hybrid model of CR improved exercise tolerance.

Key words: cardiac rehabilitation, coronary artery disease, exercise training

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INTRODUCTION

Cardiac rehabilitation (CR) is widely recognised as playing a critical role during the recovery of cardiac patients, with meta-analyses demonstrating reduced cardiac and all-cause mortality, fewer cardiovascular-related events, less rehospitalisation, and shorter lengths of stay [1–3]. CR has also been shown to be a highly cost–effective form of secondary prevention [4–6]. Secondary prevention and CR are an integral part of the management strategy after revascularisation, because such measures reduce future morbidity and mortality in a cost–effective way [7]. Exercise training has been demonstrated to have the following effects: it improves exercise

Address for correspondence:
Dominika Szalewska, MD, PhD, Department of Rehabilitation, Medical University of Gdansk, Aleja Zwycięstwa 30, 80–219 Gdańsk, Poland, tel: +48 58 347 25 98, e-mail: dziel@gumed.edu.pl

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capacity and quality of life (QoL) of patients by reducing symptoms associated with the activities of daily living (ADL); it prevents deterioration of the left ventricular systolic function and left ventricular remodelling; it decreases the incidence of coronary events and the hospitalisation rate due to the exacerbation of ischaemic heart failure; it improves the prognosis in patients with ischaemic heart failure and coronary artery disease (CAD); it decreases systolic blood pressure and increases high-density lipoprotein (HDL) cholesterol levels; and it decreases triglyceride levels (level A of evidence) [8, 9]. In patients with chronic CAD, CR may be as effective as drug treatment and catheter intervention in terms of the improvement of prognosis. Hambrecht et al. [10] showed this effect after conducting a randomised trial that comprised 101 male patients with stable CAD, randomised to 12 months of exercise training or to percutaneous coronary intervention (PCI). In the conclusions the authors stated that, compared with PCI, the CR program resulted in superior event-free survival and exercise capacity at lower cost due to reduced rehospitalisation and repeat revascularisations. CR also plays a crucial role in the prevention of disability [11]. A novel and cheaper alternative for rehabilitation of outpatients with cardiovascular disease (CVD) is by following them with home-based telemonitored CR (hybrid cardiac rehabilitation — HCR). In Poland this approach has already been used for the rehabilitation of people with musculoskeletal system diseases, as well as in patients with hearing and speech disorders [11]. Introducing HCR may eliminate many of the factors currently causing low numbers of patients to be involved in outpatient-based rehabilitation programs, and it may also be more attractive for professionally active patients [12, 13]. Some studies have demonstrated the favourable effects of telemonitored CR in patients with stable CAD or heart failure in phase III of CR, in which the main goal is to strive for sustainable, beneficial lifestyle changes that will continue for the patient after completion of the programme, including education, assistance in quitting addictions, and returning to work [12, 13]. A randomised controlled prospective clinical trial comparing home-based training with telemonitoring guidance vs. centre-based training in patients with CAD in the maintenance phase (the Telerehabilitation in Coronary Heart disease study — TRiCH) is currently being conducted by Avila et al. [14]. Up-to-date meta-analyses showed that home-based CR is safe, has recently been used more frequently and widely, and is increasingly appreciated to promote patient self-efficacy for independent physical exercise [15, 16]. To our knowledge, the population assessed in this study was quite unique because it only comprised patients who did not work and were in receipt of disability payment or other forms of social benefits because of CVD.

The primary objective of the study was to evaluate the clinical characteristics of patients referred for hybrid form of CR. The secondary endpoint was the assessment of the effects of this kind of treatment.

METHODS

This was a retrospective single-institution cohort study, which comprised patients referred for home-based cardiac telerehabilitation by a social insurance institution.

Patient population

The study group consisted of 155 patients aged 57.31 ± 5.61 years, who had documented CVD and were referred by a social insurance institution for ambulatory CR followed by home-based cardiac telerehabilitation, phase III CR, from January 2010 to December 2013. Of this group, 125 patients with a mean age of 58.25 ± 4.48 years (112 men and 13 women) had CAD and were included in the study. The inclusion criteria were as follows: referral for HCR from a social insurance institution, documented CAD and no contraindications to exercise training, optimal medical treatment, and CR that commenced not sooner than 12 weeks following the cardiovascular event.

Exclusion criteria were: acute coronary syndromes or recent myocardial infarction (< three months), significant valvular heart disease, known severe ventricular arrhythmia with functional or prognostic significance, significant myocardial ischaemia, exercise-induced arrhythmia or haemodynamic deterioration at exercise test, and orthopaedic or other conditions that precluded regular exercise.

Study protocol

The study was designed as a retrospective non-randomised trial. Each patient gave written, informed consent for participation in the programme. The patients underwent the following assessments, both at entry and after completing HCR: physical examination, exercise treadmill test according to the Bruce protocol, and additional laboratory tests when needed to assess the clinical state. Adherence was reported as the number of dropouts during the whole HCR programme.

Exercise stress tests

All participants underwent a symptom-limited exercise test performed according to the Bruce protocol on a Woodway treadmill using a computerised system (ECG Sun Tech Tango). A 12-lead electrocardiogram (ECG) was monitored continuously before, during and for 10 min after the test.

The test was discontinued in the case of reported anginal chest pain, maximal fatigue, an arterial blood pressure increase over 230/120 mm Hg, ST segment depression by at least 2 mm in ECG, or severe arrhythmia. The following parameters were analysed: maximal workload (measured in metabolic equivalents — METs), heart rate in beats per minute (HR, bpm) at rest and at maximal effort, blood pressure (BP, mm Hg) at rest and at maximal effort, and double product (DP, mm Hg/min × 100, i.e. the product of HR and systolic BP at rest and at peak effort). The measurement of heart rate recovery in the first minute (HRR_1) after the end of peak exercise was the method used to assess the reactivation of the parasympathetic nervous system.

Hybrid cardiac telerehabilitation

HCR consisted of two parts: training at the outpatient clinic under supervision of physicians and physiotherapists (8–10 days) and "home-based CR" (11–12 days). The patients trained five times a week. Each session in the clinic consisted of endurance training that comprised cycling and dynamic calisthenics followed by relaxation and other core components of CR according to recent guidelines [5]. The training HR corresponded to 60–80% of HR reserve and was calculated individually for every patient, based on data achieved in the exercise test [17]. Patients who gained 7.5 METs during exercise stress test or more were qualified to model A of CR, 6.0 METs or more to group B, and less than 6 METs to group C, accordingly [18]. After these sessions, patients received an individualised exercise prescription to be performed in the home environment. They exercised for at least 30 min a day, at an individually determined target HR zone corresponding to moderate intensity, i.e. 60–80% of HR reserve [19]. The "home-based CR" was performed under the supervision of the research group. It consisted of warming-up, aerobic endurance training based on cycling, walking, or Nordic Walking, followed by a cooling down period [12].

All subjects received remote-controlled equipment for tele-ECG (Pro Plus Company, Poland), which enabled the recording of ECGs and the transmission of results via a mobile phone network to the monitoring centre, which was located in the Department of Rehabilitation. Cellular phones were also used for voice communication between the patient and the physician. The telemonitoring system was programmed individually for each patient and contained data concerning exercise duration, resting intervals, and timing of ECG recording. Final decisions about exercise were taken by a physician before every training session. The technical details of the telemonitoring system are well described in the paper by Piotowicz et al. [12]

Statistical analysis

The collected data were analysed using IBM SPSS version 21. Student t-tests were performed to test the independent and dependent samples for normally distributed variables; the Mann–Whitney and Wilcoxon tests were used for variables not distributed normally. P-values of less than 0.05 were considered significant.

RESULTS

Baseline characteristics

Participant baseline clinical and demographic characteristics are summarised in Table 1. The mean age of the group was 58.25 ± 4.48 years; 10.4% were female (Table 1).

Table 1. Participants' baseline characteristics — hybrid cardiac telerehabilitation group (n = 125)

Males	112 (89.60%)
Kind of social benefit:	
Unemployed	1 (0.80%)
Disability payment	42 (33.60%)
Social rehabilitation benefit	64 (51.20%)
Sick leave	18 (14.40%)
Age [years]	58.25 ± 4.48
Body mass index [kg/m^2]	29.49 ± 4.70
Number of absence days in the rehabilitation programme	1.50 ± 4.07
Current smoker	22 (19.00%)
Smoking history	91 (79.80%)
Myocardial infarction	90 (72.00%)
Heart failure	15 (12.00%)
Percutaneous coronary intervention	88 (70.40%)
Coronary artery by-pass grafting	26 (20.80%)
Comorbidities:	
Arterial hypertension	103 (82.40%)
Diabetes	37 (29.60%)
Atrial fibrillation permanent or persistent	7 (5.60%)
Hyperlipidaemia	57 (45.60%)
Obesity	53 (42.70%)
Overweight	57 (45.60%)
Model of rehabilitation:	
A	66 (52.50%)
B	36 (28.80%)
C	23 (18.7%)
Treatment:	
Ca-blocker	26 (21.50%)
Beta-blocker	112 (93.30%)
Angiotensin converting enzyme inhibitors	87 (72.50%)
Clopidogrel/dabigatran	56 (46.70%)
Inhibitor PP	53 (44.50%)
Aspirin	105 (87.50%)
Statins	111 (92.50%)
Loop diuretics	9 (7.50%)
Oral anticoagulants	10 (8.30%)
Insulin	8 (6.60%)
Oral glucose-lowering agents	26 (21.70%)

Adherence to the programme and safety

Out of the 125 patients with CAD, 119 patients completed the whole programme. The reasons for discontinuation of the programme were as follows: low back pain, depression and reported fainting with no identified reason, urological disorders, personal obligations, and upper respiratory tract infection. A further three patients completed CR, but did not undergo

Table 2. Results of exercise stress test before and after ending hybrid cardiac telerehabilitation

Characteristic	T1 (mean ± SD)	T2 (mean ± SD)	P
Maximal workload [METs]	7.86 ± 2.59	8.88 ± 2.67	< 0.001
HR rest [bpm]	77.59 ± 12.53	73.01 ± 11.57	< 0.001
HR max [bpm]	127.53 ± 19.54	126.48 ± 19.99	0.526
SBP at rest [mm Hg]	136.69 ± 17.19	130.92 ± 18.95	0.001
DBP at rest [mm Hg]	84.46 ± 12.86	83.64 ± 11.33	0.508
SBP max [mm Hg]	168.53 ± 26.13	168.60 ± 26.71	0.977
DBP max [mm Hg]	85.93 ± 14.28	87.44 ± 13.06	0.303
DP at rest [mm Hg/min]	10623.33 ± 2262.97	9567.50 ± 2116.81	< 0.001
DP max [mm Hg/min]	21682.47 ± 5488.51	21544.56 ± 5720.79	0.781
HRR_1	97.46 ± 18.27	91.07 ± 19.19	< 0.001
NYHA	1.18 ± 0.48	1.12 ± 0.35	0.008

T1 — beginning of hybrid cardiac rehabilitation (HCR); T2 — end of HCR; SD — standard deviation; HR — heart rate; SBP — systolic blood pressure; DBP — diastolic blood pressure; DP — double product, i.e. product of HR and SBP; HRR_1 — heart rate recovery in the first minute after ending exercise stress test; NYHA — classification of New York Heart Association

examination after HCR due to: (1) complete atrioventricular block in the ECG before the examination; (2) paroxysm of atrial fibrillation, and; (3) planned, elective coronarography on the day of the final examination. The mean number of absence days in the HCR program was 1.50 ± 4.07 days. None of the tested patients were excluded from home-based training or finished the training earlier for cardiovascular reasons.

Physical capacity

Exercise capacity after rehabilitation, measured in METs on a treadmill, improved significantly ($p < 0.001$). The following parameters decreased significantly by the end of the HCR programme: resting HR, systolic BP, DP at rest, HRR, and New York Heart Association (NYHA) functional class. The results are shown in the Table 2. Changes in resting DP are presented in Figure 1.

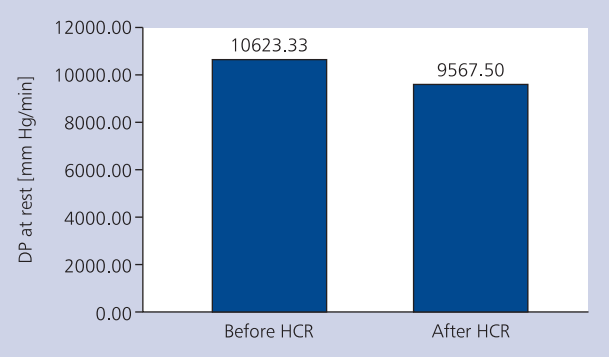

Figure 1. Changes in double product (DP) at rest before and after hybrid cardiac telerehabilitation (HCR)

DISCUSSION

Telerehabilitation programmes for cardiology patients are very important alternatives to traditional forms of rehabilitation, or residential or ambulatory care, and are especially appreciated by social insurance institutions due to being cost–effective. Secondary prevention of CVD realised in the form of CR is highly recommended (class IB) by the European Society of Cardiology (ESC), the American Heart Association (AHA), and the American College of Cardiology (ACC) [6, 20]. As recommended by the ESC and the AHA, CR includes a combination of core components: physical activity, behavioural change, risk factors modification, nutritional counselling, and psychosocial wellbeing to optimise its impact on the cardiac patient, but physical activity is considered the most important treatment, as reported by the Kenniscentrum-Centre d'Expertise [21]. The main result of this study is that HCR is effective, feasible, and safe, and that compliance is good.

The most recent and relevant literature concerning telerehabilitation for cardiac patients is presented in a review article published online by Frederix et al. [21].

The management of stable CAD patients comprises lifestyle modification, control of CAD risk factors, evidence-based pharmacological therapy, and patient education [22], all elements of which are provided by comprehensive CR, whether ambulatory, stationary, or home-based.

Other important goals of CR are returning to work after illness and preventing disability. In our study, patients took part in phase III of the CR not earlier than 12 weeks after the cardiovascular event. Korzeniowska-Kubacka et al. [23] have already described this form of rehabilitation in detail, and showed that the hybrid model of training, comprising outpatients being followed by home-based CR, improved physical capacity, and its effectiveness was similar to that of a centre-based CR approach. Moreover, a home-based telemonitored program facilitated patients' adherence to CR [23] and improved physical capacity. In heart failure patients,

adherence to CR seems to be even better for home-based telemonitored CR than for standard CR [24]. In our study group, more patients were close to the NYHA I class, they had more-or-less asymptomatic cardiac disease, which could have an impact on the conclusion that HCR is safe in CAD patients. Worringham et al. [3] developed a system to enable walking-based CR, in which the patient's single-lead ECG, HR, GPS-based speed and location were transmitted by a programmed smartphone to a secure server for real-time monitoring [3]. Information about the recent status of telerehabilitation in terms of its feasibility, efficacy, safety, and cost–effectiveness was presented exhaustively in a recent review article by Frederix et al. [21]. They stated explicitly that this form of treatment proves to be a feasible and effective alternative to in-hospital CR, but multi-disciplinary evaluations of telemonitored rehabilitation programs that assessed patients' safety and health economics are lacking.

Limitations of the study

In our study, ECG was not monitored during real-time exercise, but ECGs were sent before starting exercise and at peak exercise, which could be regarded as a study limitation. Another limitation is that there was no control group (complete in-hospital or outpatient programme), which could make it impossible to do a direct comparison other than to say that HCR is feasible and safe, that adherence by patients is good, and that participants improved their exercise tolerance. Perhaps it would be of interest to look specifically at the home telemonitored part of the study separately, but the purpose of our study was to assess the effectiveness of the hybrid form of rehabilitation, which is used, apart of stationary forms of rehabilitation, by social insurance institutions as a form of pension prevention.

It seems that this form of treatment, together with technological progress in medicine, will be increasingly available for patients with CAD in the future, lowering not only the risk of subsequent cardiovascular events, but also the risk of disability and permanent incapacity for carrying out professional work as well.

CONCLUSIONS

1. For patients with documented CAD referred for HCR by a social insurance institution, this form of rehabilitation is feasible and safe, and adherence is good.
2. Most patients were on social rehabilitation benefit, had a smoking history, and suffered from hypertension or obesity, or were overweight.
3. A hybrid model of CR improved exercise tolerance.

Conflict of interest: *none declared*

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KAMPANIA „ZASTAWKA TO ŻYCIE” („*VALVE FOR LIFE*”)

ZASTAWKA TO ŻYCIE

Inicjatywa *European Association of Percutaneous Cardiovascular Interventions* (EAPCI), *European Society of Cardiology* (ESC), Polskiego Towarzystwa Kardiologicznego (PTK) i Asocjacji Interwencji Sercowo-Naczyniowych PTK

Mimo poprawy spadku umieralności w Polsce w dalszym ciągu choroby układu sercowo-naczyniowego są główną przyczyną zgonów. Jeżeli ta sytuacja nadal się utrzyma, liczba zgonów w 2020 r. przekroczy 200 tysięcy.

Choć polska kardiologia plasuje się w czołówce najlepszych w Europie, zgony z powodu chorób układu sercowo-naczyniowego dotyczą prawie połowy naszego społeczeństwa. Posiadamy obecnie jeden z najwyższych w Europie i na świecie odsetek leczenia ostrych zespołów wieńcowych za pomocą zabiegów przezskórnej angioplastyki wieńcowej (PCI) na milion mieszkańców. W ciągu kilku lat wzbogaciliśmy się o kolejne kardiologiczne placówki (160 ośrodków, w tym 148 dyżurujących w systemie 24/7) oraz nowych specjalistów. Nadal jednak pojawiają się obszary, które choć mają duże możliwości terapii, to zastosowanie nowych metod leczenia w naszym kraju jest zbyt małe. Mowa tu m.in. o metodach terapii osób cierpiących na ciężkie zwężenia zastawki aortalnej, u których zabieg chirurgiczny wiąże się z wysokim ryzykiem. Ocenia się, że 30–40% pacjentów z ciasnym zwężeniem zastawki aortalnej nie kwalifikuje się do leczenia chirurgicznego. Rozwiązaniem dla tych chorych jest zabieg TAVI, czyli przezcewnikowa implantacja zastawki aortalnej.

Niestety ta metoda leczenia nie należy do powszechnych w Polsce. W 2013 r. wykonano 381 zabiegów TAVI, a w 2014 r. już 453, co stanowi zaledwie 11,7 zabiegów na milion osób. Średnia w krajach „starej unii” to 50 na milion osób, w Niemczech ponad 100. Aby osiągnąć średnią unijną w naszym kraju, powinno się wykonywać 2000 zabiegów TAVI rocznie. Choć dochód narodowy na mieszkańca w Niemczech jest wyższy 3,6-krotnie w porównaniu z Polską, liczba zabiegów TAVI jest tam aż 22 razy większa. Przy czym Polska w ostatnich latach rozwija się bardzo dynamicznie, notując realny dodatni wzrost PKB, przekraczający ten obserwowany w wielu państwach Europy Zachodniej. Tak słabe wyniki w naszym kraju potwierdzają fakt, że możliwości, jakie posiadamy, nie są adekwatne do znanych nam realiów życia. Bez odpowiednich środków wsparcia niektórych metod leczenia i poszerzania świadomości społecznej wśród osób chorych oraz ich bliskich polska medycyna nie może liczyć na większe zmiany w obszarze zwalczania chorób układu sercowo-naczyniowego.

Europejska inicjatywa “*Valve For Life*” jest w Polsce koordynowana przez prof. Dariusza Dudka i prof. Adama Witkowskiego, przy współpracy prof. Zbigniewa Kalarusa, Prezesa PTK oraz prof. Jarosława Kazimierczaka, konsultanta krajowego w dziedzinie kardiologii. Więcej szczegółów znajdziecie Państwo na oficjalnej internetowej stronie kampanii: **www.zastawkatozycie.pl**.

Ocena przydatności hybrydowej rehabilitacji kardiologicznej u pacjentów z chorobą wieńcową

Dominika Szalewska[1], Piotr Zieliński[2], Jarosław Tomaszewski[1], Małgorzata Kusiak-Kaczmarek[3], Lidia Łepska[1], Katarzyna Gierat-Haponiuk[1], Piotr Niedoszytko[1]

[1]Katedra i Klinika Rehabilitacji, Gdański Uniwersytet Medyczny, Gdańsk
[2]Pracownia Medycyny Sportowej, Akademia Wychowania Fizycznego i Sportu, Gdańsk
[3]Klinika Rehabilitacji, Uniwersyteckie Centrum Kliniczne, Gdańsk

Streszczenie

Wstęp: Rehabilitacja kardiologiczna (CR) obniża śmiertelność z przyczyn sercowo-naczyniowych i ułatwia powrót do pracy zawodowej pacjentom z chorobą wieńcową. Niestety, w większości krajów europejskich odsetek osób korzystających z tej formy leczenia jest niski. Zastosowanie telerehabilitacji umożliwia poprawę w zakresie dostępności do CR, a hybrydowa forma rehabilitacji wydaje się rozwiązaniem optymalnym ze względu na jej wysoką efektywność kosztową u pacjentów kierowanych przez zakład ubezpieczeń społecznych.

Cel: Głównym celem pracy było przedstawienie charakterystyki klinicznej pacjentów i ocena efektów hybrydowej rehabilitacji kardiologicznej (HCR), prowadzonej w warunkach domowych, po wstępnej rehabilitacji w warunkach ambulatoryjnych.

Metody: Grupę 125 pacjentów (112 mężczyzn, 13 kobiet) z chorobą wieńcową, w wieku 58,3 ± 4,5 roku poddano 5-tygodniowej CR złożonej z 19–22 sesji treningowych. Pierwszy etap prowadzono w formie ambulatoryjnej CR, następnie pacjenci kontynuowali program usprawniania w warunkach domowych. Przed rozpoczęciem programu oraz po jego zakończeniu u wszystkich osób wykonano test wysiłkowy na bieżni ruchomej. Uczestnictwo w programie było oceniane poprzez liczbę dni absencji.

Wyniki: Średnia liczba dni absencji w programie HCR wyniosła 1,50 ± 4,07. Zaobserwowano istotną ($p < 0,005$) poprawę niektórych wskaźników w teście wysiłkowym po HCR w stosunku do parametrów sprzed rehabilitacji: maks. obciążenie: 7,86 ± 2,59 METs *vs*. 8,88 ± 2,67 METs; częstość rytmu serca (HR) w spoczynku: 77,59 ± 12,53/min *vs*. 73,01 ± 11,57/min; skurczowe ciśnienie tętnicze w spoczynku: 136,69 ± 17,19 mm Hg *vs*. 130,92 ± 18,95 mm Hg; produkt podwójny w spoczynku: 10623,33 ± 2262,97 *vs*. 9567,50 ± 2116,81; HRR_1: 97,46 ± 18,27/min *vs*. 91,07 ± 19,19/min; klasa NYHA: 1,18 ± 0,48 *vs*. 1,12 ± 0,35.

Wnioski: U pacjentów z udokumentowaną chorobą wieńcową HCR jest bezpieczna i możliwa do przeprowadzenia przy wysokim poziomie uczestnictwa w programie. Większość pacjentów korzystało ze świadczenia rehabilitacyjnego, było aktywnymi palaczami, palaczami w przeszłości, leczyło się z powodu nadciśnienia tętniczego, było otyłych lub miało nadwagę. Dzięki HCR w badanej populacji uzyskano poprawę tolerancji wysiłku fizycznego.

Słowa kluczowe: rehabilitacja kardiologiczna, choroba wieńcowa, trening fizyczny

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Adres do korespondencji:
dr n. med. Dominika Szalewska, Katedra i Klinika Rehabilitacji, Gdański Uniwersytet Medyczny, Aleja Zwycięstwa 30, 80–219 Gdańsk, tel: +48 58 347 25 98, e-mail: dziel@gumed.edu.pl
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