Original article

Kardiologia Polska
2011; 69, 3: 220–226
ISSN 0022–9032

Two models of early cardiac rehabilitation in male patients after myocardial infarction with preserved left ventricular function: comparison of standard out-patient *versus* hybrid training programmes

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Abstract

Background: The key to increase the percentage of cardiac patients undergoing cardiac rehabilitation is to follow a well-designed exercise programme at home. To maximise the benefits while minimising the risks of aggravating health status, home-based exercise should be tele-monitored.

Aim: To compare the effects on physical capacity and sympatho-vagal balance of two types of early cardiac rehabilitation in post-myocardial infarction (MI) male patients: the hybrid model, partly out-patient and partly home-based and tele-monitored *vs* standard rehabilitation performed only in the out-patient setting.

Methods: Sixty two male patients aged 54.7 ± 6.9 years, mean 27.3 ± 13.5 days after MI with preserved left ventricular systolic function (EF > 50%) underwent an eight-week training programme consisting of 24 training sessions. After performing the first ten interval trainings on a cycloergometer, 30 patients (the hybrid group) exercised at home while being monitored via TeleECG, while 32 patients (the out-patient group) continued their rehabilitation in the out-patient clinic. At entry and after completion of the rehabilitation programme, all patients underwent a symptom-limited treadmill stress test. The following parameters were analysed: maximal workload (METs), exercise duration (ED, min), heart rate (HR, bpm), blood pressure (BP, mm Hg), double product i.e. product of HR and systolic BP at rest and at peak exercise (DP, mm Hg/min, HR × systolic BP), and HR recovery (HRR) in the first and second minute of the recovery period.

Results: Maximal workload (out-patient: 7.3 ± 1.4 *vs* 7.8 ± 1.2, $p < 0.05$; hybrid: 8.5 ± 1.8 *vs* 9.9 ± 2.2, $p < 0.01$) and ED (out-patient: 10.1 ± 2.0 *vs* 13.5 ± 1.4, $p < 0.001$; hybrid: 10.9 ± 3.6 *vs* 12.5 ± 4.1, $p < 0.05$) increased significantly in both study groups. The remaining parameters did not change significantly, except for HRR_1 (22.1 ± 8.7 *vs* 29.5 ± 10.7, $p < 0.01$) and HRR_2 (37.9 ± 9.5 *vs* 43.8 ± 10.7, $p < 0.01$), which improved in the hybrid group only. Moreover, there were no significant differences between the study groups when comparing the training-induced percentage changes in the analysed parameters.

Conclusions: 1. Hybrid rehabilitation improved physical capacity and positively influenced the sympatho-vagal balance in post-MI male patients with preserved left ventricular systolic function. 2. The hybrid model was effective and comparable with standard out-patient-based programme.

Key words: home-based training, tele-monitored cardiac rehabilitation

Kardiol Pol 2011; 69, 3: 220–226

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Received: 06.10.2010 **Accepted:** 22.12.2010

INTRODUCTION

Comprehensive cardiac rehabilitation (CR) is a vital part of the contemporary care of patients who have suffered from myocardial infarction (MI) [1–5]. Although numerous studies showed that medications, appropriate diet and exercise improve the prognosis, adherence to these interventions is still suboptimal [6].

There are several factors responsible for poor adherence of post-MI patients to an early comprehensive CR programme in the out-patient setting. Firstly, chronic diseases limit mobility for all patients, regardless of where they live. Secondly, patients can lack motivation and physicians are often insufficiently involved in the management of chronic conditions. Finally, there are frequent difficulties in maintaining professional activity, with subsequent financial problems [7, 8].

A relatively new alternative for the care of post-MI patients is home-based tele-monitored CR. There have been only a few studies assessing the efficacy and safety of this model of CR [9, 10]. Therefore, we sought to compare the effects of two types of early CR on physical capacity and sympatho-vagal balance in post-MI male patients with preserved left ventricular (LV) systolic function: the hybrid model, partly out-patient and partly home-based and tele-monitored; and standard rehabilitation performed solely in the out-patient setting.

METHODS

Study population

We considered all consecutive male patients with stable angina pectoris (Canadian Cardiovascular Society class I or II) who during 2008–2009 were referred for the second phase of a comprehensive, post-MI, CR programme.

Inclusion criteria were: age < 75 years, sinus rhythm, preserved LV function (ejection fraction > 50%), and no evidence of right ventricular dysfunction on echocardiography, clinical stability for at least two weeks prior to entry to the study plus optimal stable medical treatment, no contraindications to exercise test (ET), and the patient's willingness to comply with the proposed exercise programme, either out-patient or at home.

Exclusion criteria were: unstable angina, congestive heart failure, uncontrolled hypertension (blood pressure > 180/ /120 mm Hg at rest), cardiac rhythm disturbances, valvular heart disease, left bundle branch block, and impaired renal or hepatic function. Of 93 patients referred to the Department of Cardiac Rehabilitation, 62 male patients, aged 36 to 72 (mean 54.7 ± 6.9 years), mean 27.3 ± 13.5 days after their MI, agreed to participate in the study. All patients underwent an eight-week training programme consisting of 24 sessions. Before inclusion and at the end of the rehabilitation, all patients underwent a symptom-limited electrocardiographic ET.

The study protocol was approved by the Institutional Ethics Committee on Human Research, and all participants gave their written informed consent.

Exercise stress test

Exercise stress test was performed on a treadmill according to a modified Bruce protocol using a computerised system CASE 8000 (Marquette Electronics, Milwaukee, Wisconsin, USA). A three-lead ECG was monitored continuously before, during, and for 10 min after, the test. The test was discontinued in case of fatigue, blood pressure increase over 230/120 mm Hg or a drop by more than 10 mm Hg compared to the baseline value, ST segment depression by at least 2 mm and/or anginal chest pain. The test was considered positive when ST segment depression of at least 1 mm was horizontal or downsloping, 80 ms beyond the J point.

The following parameters were analysed: maximal workload in metabolic equivalents (METs), exercise duration (ED, min), heart rate in beats per minute (HR, bpm) at rest and at peak effort, blood pressure (BP, mm Hg) at rest and at peak effort, and double product (DP, mm Hg/min × 100), i.e. the product of HR and systolic BP, at rest and at peak effort.

Moreover, HR recovery (HRR), i.e. the difference between HR at peak effort and in the first or second minute of the recovery period, was assessed.

A lack of HR drop by > 12 bpm in the first minute (HRR_1), and > 22 bpm in the second minute (HRR_2), after ET is known to reflect diminished activity of the parasympathetic nervous system.

Training programme

Patients were qualified for the programme depending on the results of their initial ET. The limit of training HR was calculated as the sum of resting HR and 80% of HR reserve, i.e. the difference between maximal HR at peak ET and HR at rest.

After performing the first ten interval trainings on a cycloergometer in the ambulatory setting, 30 patients gave up out-patient rehabilitation because of the inconvenience of commuting. They were enrolled on a home-based tele-monitored programme (hybrid group) while 32 patients (out-patient group) continued rehabilitation in the ambulatory setting.

Interval training

All subjects underwent interval training on a cycloergometer three times a week. Each session lasted 40 min and included a four-minute warm-up, six four-minute bouts of exercise with two-minute rests in between, with gradually increased workload until the HR limit (established during the baseline ET) was reached, and a ten-minute cool-down.

During each session, ECG, HR and BP were measured at baseline, at the end of each interval, and at recovery. The training was documented by a written protocol.

Home-based training

After completing interval training on a cycloergometer in the out-patient setting, patients with commuting problems were enrolled to the hybrid model and underwent walking training applied in an interval manner at home.

There were three ten-minute walk exercises with two--minute rests in between. The first ten-minute period was used as a warm-up, the second was the main part of the training, and the last ten-minute stage was for relaxation.

All these patients were provided with EHO 3 devices by PRO-PLUS. Each patient had to place four electrodes on their chest adhering to the instruction manual, which enabled a three-channel ECG recording to be made.

The devices were pre-programmed for training sessions. The pre-programming included exercise duration and intervals. When the training started, the device automatically recorded resting ECG, and then, with light and sound signals, informed a patient about each training stage being started. Once each stage ended, the device recorded ECG. It was also possible to register ECG additionally during both exercise and rest. This enabled symptoms such as chest pain or palpitations to be verified. Once a training session was completed, patients transmitted the recorded ECG to the monitoring station by telephone. The monitors could assess ECG in terms of HR, arrhythmias, changes in ST segment, and verify if the training had been done properly according to the established training HR limits [10, 11].

During the home-based period, all patients were carefully monitored for complications such as unstable angina, MI, heart failure and/or serious cardiac rhythm disturbances.

Statistical analysis

Statistical analysis was performed using SAS statistical software (version 8.2; Cary, North Carolina, USA). All data are expressed as mean ± SD. Student's *t*-test for matched pairs was used to compare the parameters of a continuous type in the two groups studied when the distribution of variables did not differ significantly from the normal distribution. When it did, a non-parametric rank test was used. In order to assess the differences of categorised parameters in the two groups, a χ^2 test was used. A p value < 0.05 was considered statistically significant.

RESULTS

Baseline clinical characteristics of the studied patients are presented in Table 1. Mean time between MI and the start of the rehabilitation programme was 27.3 ± 13.5 days.

No significant differences were found in the demographic and clinical variables as well as social characteristics between the two groups. Most of the patients studied were in the first class according to the Canadian Cardiovascular Society Classification of Angina Severity (CCS) and had preserved LV function. Most enrolled patients had hypercholesterolaemia and hypertension. Moreover, all patients in both groups received

Table 1. Baseline characteristics of patients studied

	Out-patient group (n = 32)	Hybrid group (n = 30)	P
Age [years]	55.2 ± 7.7	55.5 ± 8.1	NS
History of MI	100% (32)	100% (30)	NS
CCS I	100% (32)	96.6% (29)	NS
CCS II		3.4% (1)	NS
LVEF [%]	59 ± 8.2	56 ± 7.2	NS
Smoking	46.9% (15)	43.3% (13)	NS
Arterial hypertension	68.8% (22)	66.6% (20)	NS
Diabetes	9.4% (3)	13.3% (4)	NS
Hypercholesterolaemia	100% (32)	87.5% (28)	NS
Medication:			
Beta-blocker	100% (32)	96.6% (29)	NS
ACE-I	87.5% (28)	93.3% (28)	NS
Statin	100% (32)	96.6% (29)	NS
Aspirin	96.8% (31)	100% (30)	NS
Clopidogrel	84.3% (27)	86.6% (26)	NS
Professional activity before MI:			
Active	84.4% (27)	86.7% (26)	NS
Retired	15.6% (5)	13.3% (4)	NS

MI — myocardial infarction; CCS — Canadian Cardiovascular Society Classification of Angina Severity; LVEF — left ventricular ejection fraction; ACE-I — angiotensin-converting enzyme inhibitors

Table 2. Exercise stress test results before and at the end of the study in patients rehabilitated according to the hybrid model

	Before (n = 30)	After (n = 30)	P
Maximal workload [MET]	8.5 ± 1.8	9.9 ± 2.2	< 0.01
Duration [min]	10.9 ± 3.6	12.5 ± 4.1	< 0.05
HR — rest [bpm]	72.6 ± 11.7	69.8 ± 8.1	NS
HR — effort [bpm]	123.6 ± 18.4	132.7 ± 15.3	NS
SBP — rest [mm Hg]	115.8 ± 15.3	116.7 ± 13.0	NS
DBP — rest [mm Hg]	75.3 ± 7.9	75.0 ± 6.3	NS
SBP — effort [mm Hg]	174.9 ± 29.3	184.4 ± 22.2	NS
DBP — effort [mm Hg]	84.2 ± 9.1	84.1 ± 9.0	NS
DP — rest [mm Hg/min]	84.2 ± 17.7	80.3 ± 11.9	NS
DP — effort [mm Hg/min]	217.9 ± 55.6	246.9 ± 45.7	< 0.01
HRR_1	22.1 ± 8.7	29.5 ± 10.7	< 0.01
HRR_2	37.9 ± 9.5	43.8 ± 10.7	< 0.01

HR — heart rate; SBP — systolic blood pressure; DBP — diastolic blood pressure; DP — double product, i.e. product of HR and SBP at rest and at peak exercise; HRR_1, HRR_2 — heart rate recovery in the first and second minute after ending exercise stress test

Table 3. Exercise stress test results before and at the end of the study in patients rehabilitated exclusively in the out-patient setting

	Before (n = 32)	After (n = 32)	P
Maximal workload [MET]	7.3 ± 1.4	7.8 ± 1.2	< 0.05
Duration [min]	10.1 ± 2.0	13.5 ± 1.4	< 0.001
HR — rest [bpm]	67.5 ± 9.6	67.1 ± 9.4	NS
HR — effort [bpm]	122.6 ± 15.2	126.6 ± 15.0	NS
SBP — rest [mm Hg]	120.5 ± 13.8	120.9 ± 12.3	NS
DBP — rest [mm Hg]	77.2 ± 6.1	77.3 ± 6.0	NS
SBP — effort [mm Hg]	168.8 ± 26.3	174.7 ± 26.9	NS
DBP — effort [mm Hg]	87.3 ± 8.7	87.7 ± 10.2	NS
DP — rest [mm Hg/min]	81.3 ± 15.2	80.9 ± 13.2	NS
DP — effort [mm Hg/min]	207.8 ± 45.3	221.7 ± 45.4	NS
HRR_1	23.3 ± 18.3	20.6 ± 20.9	NS
HRR_2	41.5 ± 16.9	42.5 ± 18.4	NS

Abbreviations as in Table 2

standard medical therapy which was maintained throughout the study.

The training HR limits did not differ significantly between the study groups (96.9 ± 11.1 *vs* 95.3 ± 11.9, NS). However, the percentage of training sessions performed with the HR limit was significantly higher in the hybrid group than in the out-patient group (26% *vs* 20%, $p < 0.001$).

Tables 2 and 3 demonstrate ET results before and at the end of the study in both study groups. Maximal workload and exercise duration increased significantly in both groups. However, HRR_1 and HRR_2 improved significantly after completing training programme only in patients rehabilitated according to the hybrid model.

The remaining ET parameters did not change significantly. Similarly, there were no significant differences between the training-induced changes (Δ%) in physical capacity and HRR in both study groups (Table 4). Only the percentage increase in HR at peak effort was significantly greater in the hybrid group after completion of the rehabilitation programme. There were no drop outs during the study, and no adverse effects of exercise training were observed.

DISCUSSION

We found that an eight-week training programme in stable post-MI male patients with preserved LV systolic function led to a significant improvement in physical capacity, regardless

Table 4. Comparison of the changes (%) in physical capacity and heart rate recovery after completion of post-myocardial infarction cardiac rehabilitation programme between study groups

	Δ% Out-patient group (n = 32)	Δ% Hybrid group (n = 30)	P
Maximal workload [MET]	11.5 ± 35.9	17.6 ± 16.1	NS
Duration [min]	15.5 ± 26.1	15.2 ± 12.1	NS
HR — rest [bpm]	0.2 ± 12.8	–2.4 ± 14	NS
HR — effort [bpm]	3.6 ± 7.9	8.2 ± 10.1	< 0.05
SBP — rest [mm Hg]	1.1 ± 11.1	1.8 ± 12.8	NS
DBP — rest [mm Hg]	0.6 ± 8.9	0.3 ± 10.6	NS
SBP — effort [mm Hg]	4.5 ± 14.2	7.0 ± 14.8	NS
DBP — effort [mm Hg]	1.0 ± 13.0	3.9 ± 10.2	NS
HRR_1	7.4 ± 11.8	2.9 ± 11.3	NS
HRR_2	4.2 ± 12.1	5.1 ± 12.7	NS

Abbreviations as in Table 2

of the model implemented. Thus, the hybrid model was effective and comparable with a standard out-patient-based approach. It is noteworthy that the home-based part of the hybrid programme was monitored by a device with diode-emitted light and sound signals. This 'supervision' facilitated the achievement of the training limits of HR calculated during ET.

Although the percentage of training sessions performed with 80% HR limit was unsatisfactory in both study groups, it was significantly greater in the hybrid group. It should be emphasised that all our low-risk patients were in touch with a physician and a physical therapist, and were encouraged to train until target HR limits. There are several factors which might, at least partially, be responsible for these results.

Firstly, we studied previously untrained post-MI male patients who did not have enough strength in their legs to reach their HR limits. The majority of the training sessions came to an end because of fatigue. Secondly, exercise prescription using HR seems to be of limited value for patients taking beta-blockers. Previously published studies suggest that assessment of the anaerobic threshold is the most appropriate route to estimate training intensity in patients treated with beta-blockers [12, 13]. Although the majority of our patients trained below the upper limits for HR, they improved their physical capacity significantly.

To date, there have been only a few studies assessing the effects of home-based CR monitored using telemedicine equipment (TeleECG) on physical capacity in post-MI patients. Giallauria et al. [9] assessed the effects of exercise training in 45 patients after MI subdivided into three groups. Physical capacity improvement was comparable in patients trained in an out-patient centre and at home with TeleECG monitoring. However, it was significantly greater than in those trained at home without telemonitoring.

Similarly, Ades et al. [14] reported comparable improvements in exercise capacity and quality of life in patients with ischaemic heart disease trained either at their homes with TeleECG monitoring for three months or in an out-patient centre. Moreover, Jolly et al. [15] found no differences between the centre- and home-based training programme which was monitored only by telephone contact and nurse visit. Interestingly, the home-based CR was more costly to the health service.

It is noteworthy that most authors used various modes of monitoring during home-based rehabilitation in order to improve training safety and patient adherence [16–18]. In our study, the equipment used for monitoring home-based training provided not only information about cardiac events but was also useful for conducting each training session according to the established heart rate limit. In addition, HRR, which is thought to reflect the reactivation of the parasympathetic nervous system after effort, improved significantly only in patients rehabilitated according to the hybrid model. It should be emphasised that this improvement in the vagal tone in the hybrid group was achieved after an eight-week training programme.

On the other hand, Giallauria et al. [19] found that HRR in post-MI patients improved significantly after a three-month hospital-based training. Moreover, this beneficial effect could be maintained if the standard programme was followed by a three-month home-based unsupervised exercise training. Similarly, a three-month hospital-based training favourably modified HRR in elderly post-MI patients, and HRR response correlated with the improvement in cardiopulmonary ET parameters [20].

Taking into account that both physical capacity and HRR are known to have an impact on prognosis, individually programmed training sessions seem to be pivotal in improving the effectiveness of CR in post-MI patients [21]. Although a hospital-based approach is safe and effective, a home-based training programme with TeleECG monitoring could improve physical capacity and the sympathetic-parasympathetic balance in cardiac patients.

Limitations of the study

The results of this pilot study are aplicable to optimally treated group of male patients after MI, without LV systolic dysfunction. Women were excluded because they did not fulfill the inclusion criteria; they were older, had various comorbidities, or did not agree to participate in the rehabilitation programme. Moreover, the reliability of the stress test in women is lower than that in men.

CONCLUSIONS

1. Hybrid rehabilitation improved physical capacity and positively influenced the sympatho-vagal balance in post-MI male patients with preserved LV systolic function.
2. The hybrid model was effective and comparable with the out-patient-based approach.

Conflict of interest: *none declared*

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Porównanie dwóch modeli rehabilitacji kardiologicznej po zawale serca

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Streszczenie

Wstęp: Szansą na zwiększenie odsetka osób objętych rehabilitacją kardiologiczną (CR) jest jej realizacja w domu. Aby trening domowy był odpowiednio intensywny, musi być prowadzony z wykorzystaniem urządzeń do treningu w domu pod nadzorem TeleEKG.

Cel: Celem pracy była ocena wpływu dwóch modeli wczesnej CR u mężczyzn po zawale serca z zachowaną funkcją skurczową lewej komory: modelu hybrydowego składającego się z rehabilitacji ambulatoryjnej i domowej monitorowanej telemedycznie oraz rehabilitacji realizowanej wyłącznie w ambulatorium na wydolność fizyczną i równowagę współczulno-przywspółczulną.

Metody: Badaniami objęto 62 mężczyzn w wieku 54,7 ± 6,9 roku, po zawale serca z zachowaną funkcją skurczową lewej komory (EF > 50%). Wszyscy badani zostali objęci 8-tygodniowym programem treningowym, średnio 28 dni od zawału, zawierającym 24 treningi. Pierwsze 10 treningów interwałowych na cykloergometrze odbyli ambulatoryjnie, a następnie 32 chorych (Amb) kontynuowało je w ambulatorium, a pozostałych 30 (Hybrid) ćwiczyło w domu pod nadzorem TeleEKG. U wszystkich badanym na wstępie i po zakończeniu rehabilitacji wykonano ograniczoną objawami próbę wysiłkową na bieżni ruchomej. Ocenie poddano: maksymalne obciążenie (METs), czas trwania próby (min), częstotliwość rytmu serca (HR/min), ciśnienie tętnicze (BP, mm Hg), produkt podwójny (DP, mm Hg/min) w spoczynku i w czasie wysiłku oraz HR w 1. i 2. minucie po zakończeniu próby jako wyraz reaktywacji układu przywspółczulnego (HRR_1, HRR_2). W celu oceny efektywności rehabilitacji porównano wyniki próby wysiłkowej wstępnej i końcowej w obu badanych grupach.

Wyniki: W obu grupach istotnie wzrosło maksymalne obciążenie: w grupie Amb 7,3 ± 1,4 *v.* 7,8 ± 1,2 ($p < 0,05$) oraz w grupie Hybrid 8,5 ± 1,8 *v.* 9,9 ± 2,2 ($p < 0,01$), a także czas trwania próby: w grupie Amb 10,1 ± 2,0 *v.* 13,5 ± 1,4 ($p < 0,001$) oraz w grupie Hybrid 10,9 ± 3,6 *v.* 12,5 ± 4,1 ($p < 0,05$). Pozostałe parametry nie uległy zmianie, jedynie HRR_1 (22,1 ± 8,7 *v.* 29,5 ± 10,7; $p < 0,01$) i HRR_2 (37,9 ± 9,5 *v.* 43,8 ± 10,7; $p < 0,01$) wzrosły istotnie w grupie ćwiczącej pod nadzorem TeleEKG. Jednak gdy porównano efekty treningu między grupami, na podstawie przyrostu procentowego wszystkich badanych parametrów, to nie zaobserwowano istotnych zmian.

Wnioski: 1. Model hybrydowy wczesnej CR wpłynął korzystnie na poprawę wydolności fizycznej i równowagę współczulno-przywspółczulną u mężczyzn po zawale serca z zachowaną funkcją skurczową lewej komory. 2. Model hybrydowy jest porównywalnie efektywny z rehabilitacją ambulatoryjną u pacjentów po zawale serca.

Słowa kluczowe: rehabilitacja domowa monitorowana telemedycznie

Kardiol Pol 2011; 69, 3: 220–226

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Praca wpłynęła: 06.10.2010 r. **Zaakceptowana do druku:** 22.12.2010 r.