

# Hybrid model of cardiac rehabilitation in men and women after myocardial infarction

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## **Abstract**

Background: A relatively new alternative for post-myocardial infarction (MI) patients' care is the hybrid cardiac rehabilitation (CR) consisting of ambulatory and home-based parts. The aim of the study was to compare the influence of CR on physical capacity, safety, adherence and return to work in post-MI male and female patients with preserved left ventricular systolic function, and to assess who benefited more from this model of trainings.

**Methods:** The study comprised 57 men aged  $54.5 \pm 7.5$  years and 30 women aged  $52.2 \pm 6.7$  years after MI. All subjects underwent an 8-week training program consisting of 24 interval trainings. The first 10 trainings were conducted in an out-patient clinic, then both groups did their training at home with TeleECG monitoring. At the beginning and after trainings all patients underwent a symptom-limited exercise stress test. Assessment included results of exercise tests. Moreover, a comparative analysis of adherence and returning to work in post MI female and male patients was performed.

**Results:** We found that trainings led to a significant improvement in physical capacity in all patients based on exercise test. When the training effects were compared between men and women, no significant differences were observed. The percentage of patients returning to work was higher in men than in women (78.9% vs. 50%, p < 0.01).

Conclusions: 1. Hybrid rehabilitation resulted in a comparable improvement in physical capacity in post-MI low-risk male and female patients. 2. Although hybrid rehabilitation facilitated patients' adherence to the training program, their return to work was significantly greater only in post-MI men. (Cardiol J 2015; 22, 2: 212–218)

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

## Introduction

Cardiac rehabilitation (CR) is an important and integral part of the contemporary cardiac care in patients after myocardial infarction (MI). Research data show that participating in CR improves physi-

cal capacity, endothelial and autonomic function, quality of life, return to work, and reduces total and cardiovascular mortality [1–6]. Despite the proven benefits, many patients after MI, especially women and older patients, are not referred to center-based CR programs.

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The causes why such an insufficient number of patients participate in the cardiac ambulatory rehabilitation include time-consuming commuting, difficulties in reconciling rehabilitation with professional activity, financial problems, patients' lack of motivation and physicians' insufficient involvement [7, 8]. A chance for more patients rehabilitated is home-based monitored rehabilitation. It is important for home-based trainings to be effective and comparable with those done in a health center setting. A relatively new alternative for post-MI patients' care is the hybrid model of training, performed partly at a center and partly at home with electrocardiogram telemonitoring (TeleECG). There are only few studies assessing the efficacy and safety of this model of CR and their authors did not evaluate who benefited more from this kind of rehabilitation - men or women [9–11]. Moreover, women in clinical studies are still largely underrepresented. The mean percentage of women enrolled in cardiovascular clinical trials since 2006 has been 30%, while only 50% of trials have reported results by gender analysis [12].

Therefore, we sought to compare the influence of hybrid CR consisting of ambulatory and home-based tele-monitored exercises on physical capacity, safety, adherence and return to work in post-MI male and female patients with preserved left ventricular systolic function, and to assess who benefited more from this model of trainings.

# **Methods**

We analyzed 87 consecutive male and female patients aged  $53.4 \pm 7.8$  years with stable angina pectoris (CCS class I or II), who were qualified for phase II of a comprehensive, post-MI, CR program.

Inclusion criteria included: age < 75 years, sinus rhythm, preserved left ventricular function (ejection fraction > 50%), and no evidence of right ventricular dysfunction on echocardiography, clinical stability for at least 2 weeks before the entry to the study and optimal stable medical treatment, no contraindications to stress test and patient's compliance to perform the proposed exercise program.

Patients were excluded if they had 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, impaired renal or hepatic function.

All patients underwent an 8-week training program consisting of 24 trainings. Before the inclusion and at the end of CR, all patients underwent a symptom-limited exercise stress test (EST).

Moreover, a comparative analysis of returning to work in our post-MI female and male patients was assessed.

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

#### Exercise stress test

The EST was performed on a treadmill according to a modified Bruce protocol using a computerized system CASE 8000 (Marquette Electronics, Milwaukee, Wisconsin). As described previously, a 3-lead ECG was monitored continuously before, during, and for 10 min after the test [10]. The test was discontinued in the 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. An EST 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 analyzed: 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, double product (DP, mm Hg/min  $\times$  100), e.g., the product of HR and systolic BP, at rest and at peak effort and HR recovery (HRR), i.e. the difference between HR at peak effort and in the 1st minute in the recovery period. Lack of HR drop by > 12 bpm in the 1st minute (HRR<sub>1</sub>) after ending EST is known to reflect diminished activity of the parasympathetic nervous system.

# **Training program**

Patients were qualified for the program depending on the results of their initial EST.

The limit of training HR was calculated as the sum of resting HR and 60–80% of HR reserve, i.e. the difference between maximal HR at peak EST and HR at rest.

After performing the first 10 interval trainings on a cycloergometer in the ambulatory setting, patients were enrolled to a home-based telemonitored program.

# Interval training

All subjects underwent an interval training on a cycloergometer 3 times a week. Each session lasted 40 min and included a 4-min warm-up, six 4-min exercise bouts with 2-min rests in between,

Table 1. Baseline characteristics of patients studied.

	Women (n = 30)	Men (n = 57)	Р
Age	52.2 ± 6.7	54.5 ± 7.5	NS
History of myocardial infarction	30 (100%)	57 (100%)	NS
CCS I	9 (31%)	43 (83%)	< 0.01
CCS II	19 (66%)	7 (14%)	< 0.01
LVEF [%]	$60.2 \pm 8.3$	$54 \pm 7.2$	NS
Smoking	16 (56%)	25 (48%)	NS
Hypertension	15 (52%)	32 (62%)	NS
Diabetes	3 (10%)	10 (19%)	NS
Hypercholesterolemia	25 (86%)	47 (90%)	NS
Medication:			
Beta-blocker	25 (86%)	48 (92%)	NS
ACE-I	25 (86%)	45 (86%)	NS
Statins	30 (100%)	48 (92%)	NS
Aspirin	30 (100%)	57 (100%)	NS
Clopidogrel	28 (92%)	48 (92%)	NS

CCS — Canadian Cardiovascular Society; LVEF — left ventricular ejection fraction; ACE-I — angiotensin converting enzyme inhibitors

with gradually increased workload until the HR limit (established during the baseline EST) was reached, and a 10-min cool-down.

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

## Home-based training

After completing the ambulatory part of trainings, patients were enrolled to home-based trainings and underwent walking training applied in an interval manner. There were three 10-min walk exercises with 2-min rests in between. The first 10-min period was used as a warm-up, the second was the main part of the training, and the last 10-min stage was for relaxation.

All the patients were provided with EHO 3 devices by the PRO-PLUS company. As we described previously, each patient had to place 4 electrodes on the chest following a scheme in the instruction manual, which enabled a 3-channel ECG recording to be made [10].

The devices were pre-programmed for training sessions. The pre-programming included exercise duration and intervals. When the training started, the device automatically registered 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 such patient's symp-

toms as chest pain or palpitations to be verified. Once a training session was completed, patients transmitted the recorded ECG to the monitoring station via 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.

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

#### Statistical analysis

Statistical analysis was performed using SAS statistical software (version 8.2; Cary NC, USA). All data were expressed as mean  $\pm$  standard deviation. 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; or when it did, a non-parametric rank test was used. In order to assess the differences of categorized parameters in the two groups  $\chi^2$  test was used. A p value < 0.05 was considered statistically significant.

#### Results

Baseline clinical characteristics of the patients studied are presented in Table 1.

The majority of men were in the first class according to the Canadian Cardiovascular Society

Table 2. Exercise stress test results before and at the end of the study in men.

	Before (n = 57)	After (n = 57)	Р
Maximal workload [METs]	8.4 ± 1.6	9.9 ± 1.9	< 0.001
Duration [min]	11.5 ± 3.4	13.1 ± 3.8	< 0.001
HR rest [bpm]	$70.9 \pm 10.6$	$70.7 \pm 10.5$	NS
HR effort [bpm]	122.7 ± 15.7	$129.3 \pm 17.7$	< 0.001
SBP rest [mm Hg]	113.5 ± 14.1	113.2 ± 16.0	NS
DBP rest [mm Hg]	$76.6 \pm 18.0$	76.2 ± 17.6	NS
SBP effort [mm Hg]	166.2 ± 26.0	$175.4 \pm 29.7$	< 0.05
DBP effort [mm Hg]	84.1 ± 8.8	$86.4 \pm 9.8$	NS
DP rest [mm Hg/min]	81.2 ± 16.9	81.0 ± 17.4	NS
DP effort [mm Hg/min]	202.9 ± 47.4	$225.2 \pm 45.7$	< 0.05
HRR <sub>1</sub>	82.4 ± 13.8	86.4 ± 14.3	NS

MET — metabolic equivalent; HR — heart rate; SBP — systolic blood pressure; DBP — diastolic blood pressure; DP — double product; HRR — heart rate recovery in the 1st minute

Table 3. Exercise stress test results before and at the end of the study in women.

	Before (n = 30)	After (n = 30)	Р
Maximal workload [METs]	7.2 ± 2.4	8.6 ± 1.7	< 0.01
Duration [min]	$7.4 \pm 3.6$	$8.6 \pm 4.0$	< 0.01
HR rest [bpm]	$79.9 \pm 16.3$	79.6 ± 13.1	NS
HR effort [bpm]	134.0 ± 19.2	135.8 ± 18.1	NS
SBP rest [mm Hg]	124.3 ± 17.2	122.1 ± 14.0	NS
DBP rest [mm Hg]	80.3 ± 10.3	79.6 ± 11.0	NS
SBP effort [mm Hg]	$166.2 \pm 24.4$	$169.8 \pm 24.6$	NS
DBP effort [mm Hg]	$89.7 \pm 9.3$	$87.5 \pm 9.6$	NS
DP rest [mm Hg/min]	$100.4 \pm 28.5$	97.0 ± 18.2	NS
DP effort [mm Hg/min]	224.4 ± 50.0	230.9 ± 45.2	NS
HRR <sub>1</sub>	90.6 ± 19.1	91.3 ± 16.9	NS

MET — metabolic equivalent; HR — heart rate; SBP — systolic blood pressure; DBP — diastolic blood pressure; DP — double product; HRR — heart rate recovery in the 1st minute

classification of angina severity but women were predominantly in the second class. All patients had preserved left ventricular systolic function. Most enrolled patients had hypercholesterolemia and hypertension. Moreover, all patients in both groups received standard medical therapy which was maintained throughout the study.

Tables 2 and 3 demonstrate EST results before and at the end of the study in both study groups. It should be emphasized that before the study EST duration and max workload were significantly greater in men than in women suggesting their better physical capacity (duration  $11.5 \pm 3.4$  vs.  $7.4 \pm 3.6$  min, p < 0.001, and max workload  $8.4 \pm 1.6$  vs.  $7.2 \pm 2.4$  METs, p < 0.001).

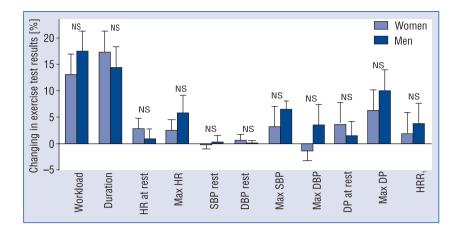
After CR was completed, maximal workload and EST duration increased significantly in both

groups. Of note, at the end of the study HR, systolic BP and DP measured at peak exercise increased significantly only in men. The remaining EST parameters did not change significantly. Yet, when the training effects were compared between men and women based on the  $\Delta\%$  increase of all the parameters analyzed, no significant differences were observed (Fig. 1).

Our study showed that patients accepted this model of trainings, including the need for interactive collaboration with the monitoring center. There were no dropouts during the study.

We did not observe any major adverse events or complications during the study.

During trainings we observed only single premature supraventricular and ventricular contractions in 13 (14.9%) patients (10 men and 3 women).



**Figure 1.** Changes in exercise stress test (EST) results in male and female patients who underwent a cardiac rehabilitation program. Percentage changes from the results of the baseline EST are plotted. See Table 1 for n in each group; NS — non significant; HR — heart rate; DBP — diastolic blood pressure; SBP — systolic blood pressure; DP — double product, that is, product of HR and SBP; HRR<sub>1</sub> — heart rate recovery in the 1<sup>st</sup> minute after ending EST.

Table 4. The percentage of men and women who returned to work after training program.

	Men	Women	Р
Professional work	45 (78.9%)	15 (50%)	< 0.01
Pension	9 (15.8%)	10 (33.3%)	NS
Mental work	35 (61.4%)	17 (56.7%)	NS
Physical work	13 (22.8%)	11 (36.7%)	NS
Inhabitants of a big city	36 (64.3%)	20 (66.7%)	NS
Inhabitants of a small town	20 (35.7%)	10 (33.3%)	NS

Our patients' return to work is presented in Table 4. We showed that a greater number of male patients than female returned to professional work after completing CR and their sickness benefits expired. The remaining parameters, such as the number of those receiving disability pension, type of professional work (physical vs. mental), the number of inhabitants living in a big city or small town, did not differ significantly between men and women.

Moreover, taking into account the results of final EST, we found that only men who achieved greater workload (10.2 vs. 8.6 METs, p < 0.05) and longer exercise duration (13.8 vs. 10.5 min, p < 0.05) returned to work after CR.

### Discussion

The aim of this study was to compare the effects of a hybrid model of training consisting of ambulatory and home-based tele-monitored parts in post-MI men and women and to assess who benefited more from this CR also in the aspect

of returning to work. We found that an 8-week training program in stable coronary artery disease patients with preserved left ventricular systolic function led to a significant improvement in the physical capacity in all trained patients. When the training effects were compared between men and women, no significant differences were observed.

It is noteworthy that the home-based part of the hybrid program was monitored by a device with diode-emitted light and sound signals. This "supervision" facilitated patients to attain the training limits of HR calculated during EST. Importantly, all patients belonged to a low-risk group without left ventricular dysfunction and performed their training with intensity within 60–80% of the training HR limit. Moreover, all our patients were in touch with a physician and a physical therapist and were encouraged to train until target HR limit. Women achieved a similar increase in physical capacity as men did. It seems that the hybrid training should be dedicated to patients with a higher risk at training, e.g. heart failure patients. The low-risk post-MI patients with preserved left ventricular

function should undergo exclusively home-based rehabilitation. Such a solution might increase the number of patients rehabilitated.

To date, there are only few articles assessing the influence of home-based CR monitored using telemedicine equipment on physical capacity in post-MI patients. Previously published studies used various modes of training during home-based CR and included not only coronary artery disease patients but also those with symptomatic chronic heart failure. In addition, some authors used telemonitoring mainly in order to register cardiac events, improve training safety, diagnose effort-related ischemia and/or arrhythmia, and to modify the treatment [13].

Giallauria et al. [14] assessed the effects of exercise training in 45 patients, mainly men, after MI subdivided into 3 groups. Physical capacity improvement was comparable in patients trained in an out-patient center and at home with TeleECG monitoring, however, significantly greater than in those trained at home without telemonitoring.

Jolly et al. [15] found no differences between the center- and home-based training programs, which were monitored only by telephone contacts and nurse visits. In our papers published previously, we compared the hybrid model with the ambulatory CR separately in men and in women, and found a comparable increase in physical capacity after completing both modes of CR [10, 11]. Despite these proven benefits of CR, the adherence to the standard, supervised inhospital CR program remained suboptimal [16, 17]. Therefore, to improve adherence alternative models of care such as TeleECG home-based programs have been recommended. It should be emphasized that in our study all patients accepted this model of training, including the need for collaboration with the monitoring center, and completed CR. Moreover, there were no training-related complications in either group during the study.

The results of our study are consistent with an earlier report by Scane et al. [18] describing a heterogeneous group of patients rehabilitated at home and in a center. It is noteworthy that in our study the equipment was useful not only for conducting training according to the established HR limits but also provided information about cardiac events. Moreover, home-based trainings with TeleECG monitoring facilitated the attendance of a greater number of patients at CR programs.

The return to work is perceived by some authors as a marker of rehabilitation efficiency [19]. The reemployment rate in our study is consistent

with the previous report by Isaaz et al. [20] who showed that a greater number of men than women returned to work after CR (78% vs. 50%, p = 0.02). Moreover, similarly to previous study, patients who did not return to work were older and performed hard physical work before MI [19].

It should be emphasized that an improvement in physical capacity after CR was essential for returning to work in our male patients and in a study conducted by Farkas et al. [21].

In summary, the results of our study encouraged home-based CR to be applied in low-risk post-MI patients with preserved left ventricular function. These findings may have practical relevance in physical activity counselling.

# Limitations of the study

Ours was a non-randomized study, which focused primarily on the comparison of the effectiveness of hybrid models of exercise therapy: home- and center-based in consecutive male and female patients after MI. Furthermore, it was only an exercise study without any assessment of cardiovascular risk factors.

Despite the study limitations listed above, our study presents a new technology which allows us to increase the low rates of patients participating in CR programs and extend their benefits to higher risk patients.

## **Conclusions**

- 1. Hybrid rehabilitation resulted in a comparable improvement in physical capacity in post-MI low-risk male and female patients.
- 2. Although hybrid rehabilitation facilitated patients' adherence to CR, the return to work was significantly greater only in post-MI men.

# Conflict of interest: None declared

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