Kardiologia Polska 2014; 72, 3: 269–274; DOI: 10.5603/KP.a2013.0283 ISSN 0022–9032

ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

Comparison between hybrid and standard centre-based cardiac rehabilitation in female patients after myocardial infarction: a pilot study

Iwona Korzeniowska-Kubacka[1], Maria Bilińska[2], Barbara Dobraszkiewicz-Wasilewska[1], Ryszard Piotrowicz[1]

[1]Department of Cardiac Rehabilitation and Noninvasive Electrocardiology, Institute of Cardiology, Warsaw, Poland
[2]Department of Arrhythmia, Institute of Cardiology, Warsaw, Poland

Abstract

Background: Despite the known benefits of cardiac rehabilitation (CR) for patients with stable coronary artery disease, it is neglected, especially in women. Home-based programmes may increase adherence to CR.

Aim: To compare the effectiveness of centre-based CR with a hybrid model of training, partly out-patient and partly home-based and tele-monitored, in terms of physical capacity and adherence in post-myocardial infarction (MI) women with preserved left ventricular function.

Methods: 53 post-MI female patients, aged 51.3 ± 7.6 years underwent an eight-week training programme (TP) consisting of 24 interval trainings. The first ten trainings were performed in a hospital, then 33 patients (Gruop A) continued them in the centre, the remaining 20 (Group B) did tele-monitored walking training at home (hybrid model). Before and after completing CR, all patients underwent a symptom-limited treadmill exercise stress test during which the analysis included: workload (METs), duration (min), heart rate (HR, bpm), double product (mm Hg/min) at rest and during effort, and HR recovery in the first minute after test. Adherence was reported as the number of trainings completed and the number of dropouts in two CR models.

Results: After CR, only workload (Group A: 6.5 ± 1.1 vs. 7.0 ± 1.4, $p < 0.05$; Group B: 7.4 ± 1.1 vs. 8.3 ± 1.4, $p < 0.01$) and duration (Group A: 4.7 ± 1.1 vs. 5.1 ± 1.2, $p < 0.01$; Group B: 8.1 ± 3.9 vs. 9.3 ± 4.2, $p < 0.01$) improved significantly in both groups. Comparing CR effects between both groups, no significant differences were observed. All patients completed TP.

Conclusions: In post-MI women, a hybrid model of training improved physical capacity and was a similarly effective form of CR as a centre-based approach. A home-based tele-monitored programme facilitated our patients' adherence to CR.

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

Kardiol Pol 2014; 72, 3: 269–274

INTRODUCTION

The benefits of comprehensive cardiac rehabilitation (CR) and supervised exercise training for patients with coronary artery disease (CAD) have been known for many years. The published studies have shown that CR reduces the rates of all-cause and cardiac mortality, incidence of acute cardiac events, hospital readmission and mitigates cardiovascular disease progression [1–3]. Despite the proven benefits, many patients who experience myocardial infarction (MI) or undergo coronary revascularisation, especially women and older patients, are not referred to centre-based CR programmes.

The factors contributing to the underuse of these programmes include poor patient motivation, comorbidities, time-consuming commuting, difficulties in reconciling rehabilitation with household chores and professional activities, financial and healthcare problems, and even overly conservative physicians [4, 5]. In addition, female patients are more frequently physically inactive, overweight and older than men [6, 7].

Address for correspondence:
Iwona Korzeniowska-Kubacka, MD, PhD, Institute of Cardiology, Department of Cardiac Rehabilitation and Noninvasive Electrocardiology, ul. Alpejska 42, 04–628 Warszawa, Poland, tel: +48 22 343 43 51, fax: +48 22 343 45 19, e-mail: drkubacka@wp.pl
Received: 27.06.2013 **Accepted:** 23.09.2013 **Available as AoP:** 27.09.2013

These problems can be overcome by conducting CR programmes at home.

It is important, though, that home-based trainings should be effective and comparable to those carried out in ambulatory settings. The way to make home-based exercise intensive enough is to perform it using the equipment for home-based training monitored with TeleECG system.

In the literature available, there are no reports assessing the effectiveness and safety of this model of home-based CR in a homogenous group of female patients after MI.

Therefore, the objective of this study was to compare the effects of supervised centre-based CR with a hybrid model of training, partly out-patient and partly home-based and tele-monitored, in terms of physical capacity and adherence in post MI women with preserved left ventricular (LV) function.

METHODS

The study comprised 53 consecutive post-MI female patients, aged 51.3 ± 7.6 years, who between 2008 and 2009 were referred to the second phase of comprehensive CR.

Inclusion criteria were: age < 75 years, sinus rhythm, preserved LV function (ejection fraction > 50%), clinical stability for at least two weeks prior to entry to the study plus optimal and stable medical treatment, and the patient's willingness to comply with the proposed training programme (TP) performed either traditionally in the ambulatory setting (centre-based) or in the centre and at home (hybrid model).

Exclusion criteria were: unstable angina, congestive heart failure, uncontrolled hypertension, valvular heart disease, left bundle branch block, impaired renal or hepatic function.

All patients underwent an eight-week TP consisting of 24 interval trainings three times a week, started averagely three months after MI. Patients' adherence was measured as attendance in the TP programme, the number of all performed training sessions and the number of patients completing TP.

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

Exercise stress test

Details of the exercise stress test (ET) protocol have been described previously [8]. Briefly, all patients underwent a symptom-limited ET performed on a treadmill according to a modified Bruce protocol using a computerised CASE 8000 system (Marquette Electronics, Milwaukee, WI, USA).

A three-lead ECG was monitored continuously before, during and for 10 min after the test.

The test was discontinued in the case of fatigue, arterial blood pressure increase over 230/120 mm Hg, ST segment depression by at least 2 mm, and/or anginal 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 in at least two consecutive precordial leads and/or in at least two of the unipolar limb leads.

The following parameters were analysed: maximal workload in metabolic equivalents (METs), 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 × 100), e.g. the product of HR and systolic BP at rest and at peak effort.

In addition, HR in the first minute (HRR_1) after ET, which is known to reflect parasympathetic nervous system activity in the recovery period, was measured.

Training programme

Patients were qualified for TP on the basis of their ET results. The limit of training HR was calculated as the sum of resting HR and 80% of HR reserve, i.e. the difference between maximal and resting HR.

All women underwent interval training on a cycloergometer three times a week. The first ten interval trainings on the cycloergometer were performed in the ambulatory setting. Then, 33 women (Group A) continued them in the centre, and the remaining 20 women (due to very time-consuming commuting) continued TP in their homes being monitored with the TeleECG system (Group B).

Interval training

All patients underwent interval training on a cycloergometer three times a week. Each training session lasted 40 min and included a 2-min warm-up, followed by six 4-min exercise bouts separated by 2-min rests in between with gradually increased workload until HR limit achieved during ET was reached.

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 TP in the ambulatory setting, 20 women (Group B) who were unable to continue CR in the centre performed walking training at home in an interval manner according to the programme previously accomplished in male post-MI patients [8].

Each session consisted of three 10-min walks 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.

As described previously, all patients were provided with EHO 3 devices made by PRO-PLUS. The devices were pre-programmed for training sessions. This 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. 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 each training session whether it had been done properly according to the established training HR limits.

Statistical analysis

Statistical analysis was performed using SAS statistical software (version 8.2; Cary, NC, USA). All data was expressed as mean ± 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. 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

Table 1 presents the patients' characteristics. The two study groups were comparable at baseline in terms of age, history of MI, coronary risk factors such as body mass index, smoking, hypertension, diabetes and LV ejection fraction.

Table 1. Baseline characteristics of patients studied

	Group A (n = 33)	Group B (n = 20)
Age [years]	51.2 ± 3.1	51.5 ± 7.6
History of MI	100 (33%)	100 (20%)
Localisation of MI:		
Anterior	39 (13%)	30 (6%)
Inferior	36 (12%)	45 (9%)
Lateral	24 (8%)	25 (5%)
BMI [kg/m^2]	27.1 ± 4.6	27.7 ± 5.4
Smoking history	58 (19%)	65 (13%)
Hypertension	73 (24%)	55 (11%)
Diabetes	18 (6%)	10 (2%)
Hypercholesterolaemia	64 (21%)	70 (14%)
LVEF	54.1 ± 9.2	58.4 ± 8.6
Medication:		
β-blocker	82 (27%)	90 (18%)
ACE-I	52 (17%)	75 (15%)
Statins	91 (30%)	96 (29%)
Aspirin	96 (31%)	90 (18%)
Clopidogrel	91 (30%)	96 (29%)

Data are expressed as mean ± SD or percentages; ACE-I — angiotensin-converting enzyme inhibitor; BMI — body mass index; LVEF — left ventricular ejection fraction; MI — myocardial infarction; p = non significant

Moreover, all female patients in both groups received standard medical therapy which was maintained throughout the study. The training HR limits were comparable in Group A (109.56 ± 14.39 bpm) and Group B (106.61 ± 12.4 bpm). Similarly, the number of training sessions performed did not differ significantly between study groups. Women in the centre-based Group A participated in 650 sessions (82%), while patients performing hybrid TP (Group B) participated in 432 sessions (90%). No problems with patient scheduling or compliance were observed and there were no dropouts in either group. Although there were baseline differences in maximal workload and test duration between study groups, after ending TP, both groups showed similar improvements in maximal workload and test duration (Tables 2, 3).

In the centre-based Group A, maximal workload increased by 9.5% and duration by 9.1% ($p < 0.05$ and $p < 0.01$ compared to baseline, respectively) (Table 2). In Group B, maximal workload increased by 12.8% and duration by 17.5% (both $p < 0.01$ compared to baseline) (Table 3). The remaining parameters assessed during final ET did not change significantly in relation to baseline values in either study group.

When training effects were compared between Groups A and B based on Δ (%) increase of all ET parameters, no significant differences were observed (Fig. 1).

The health status was stable in all patients during the study, and in none were any adverse effects of TP observed.

DISCUSSION

To the best of our knowledge, our study, although pilot and observational, is the first to include only female patients referred to a hybrid CR programme after MI.

We tested the hypothesis that a hybrid model of exercise training, partly out-patient and partly home based and tele-monitored, is an effective alternative to an ambulatory-based programme for improving physical capacity and is able to increase the percentage of women participating in CR.

In our study, home-based walking training conducted in an interval manner and "supervised" by a device with diode-emitting light and sound signals resulted in an improvement in physical capacity. We observed a significant increase in maximum workload attained during final ET and significantly longer duration of the test. Moreover, the effects of hybrid training were comparable to those achieved in ambulatory settings.

To date, only a few publications have investigated the effects of home-based CR using a TeleECG system [9–14]. Moreover, previously published studies were conducted either in heterogeneous populations or only in male patients. Furthermore, the authors used various modes of training during home-based CR involving not only CAD patients but also those with symptomatic chronic heart failure and ejection fraction < 35%. In addition, some authors used tele-monitoring in order to register cardiac events, improve training safety,

Table 2. Results of exercise stress test before and after ending training programme (TP) in Group A

Group A: centre-based TP	Before TP (n = 33)	After TP (n = 33)	P
Maximal workload [METs]	6.5 ± 1.1	7.0 ± 1.4	< 0.05
Test duration [min]	4.7 ± 1.1	5.1 ± 1.2	< 0.01
Heart rate at rest [bpm]	78.7 ± 10.5	79.8 ± 10.2	NS
Maximal heart rate [bpm]	126.7 ± 16	129.0 ± 12	NS
Systolic BP at rest [mm Hg]	122.3 ± 15	122.1 ± 15.9	NS
Diastolic BP at rest [mm Hg]	78.2 ± 9.3	79.1 ± 8	NS
Maximal systolic BP [mm Hg]	171.8 ± 20.8	176.2 ± 21.7	NS
Maximal diastolic BP [mm Hg]	90.9 ± 11.2	90.0 ± 10.3	NS
DP at rest [mm Hg/min]	9,752.4 ± 2,228	9,775.6 ± 1,962	NS
Maximal DP [mm Hg/min]	21,954.1 ± 4,693	22,797.8 ± 3,850	NS
HRR_1	85.3 ± 14.8	85.1 ± 11.9	NS

BP — blood pressure; DP — double product, i.e. product of heart rate and systolic BP; HRR_1 — heart rate recovery in the 1st minute after ending exercise stress test; NS — non significant

Table 3. Results of exercise stress test before and after ending training programme (TP) in Group B

Group B: centre- plus home-based TP	Before TP (n = 20)	After TP (n = 20)	P
Maximal workload [METs]	7.4 ± 1.1	8.3 ± 1.4	< 0.01
Duration [min]	8.1 ± 3.9	9.3 ± 4.2	< 0.01
Heart rate at rest [bpm]	77.2 ± 11.72	80.8 ± 13.4	NS
Maximal heart rate [bpm]	136.2 ± 18.3	138.1 ± 17.8	NS
Systolic BP at rest [mm Hg]	118.3 ± 11.5	119.0 ± 12.1	NS
Diastolic BP at rest [mm Hg]	76.8 ± 7.9	75.8 ± 8.9	NS
Maximal systolic BP [mm Hg]	168.8 ± 20.8	174.8 ± 18.2	NS
Maximal diastolic BP [mm Hg]	87.3 ± 8.7	85.8 ± 8.8	NS
DP at rest [mm Hg/min]	9,173.0 ± 2,321	9,611.8 ± 1,923	NS
Maximal DP [mm Hg/min]	23,076.8 ± 4,729	24,067.3 ± 3,568	NS
HRR_1	90.6 ± 19.6	91.3 ± 17.3	NS

BP — blood pressure; DP — double product, i.e. product of heart rate and systolic BP; HRR_1 — heart rate recovery in the 1st minute after ending exercise stress test; NS — non significant

diagnose effort-related ischaemia and/or arrhythmia, and to modify the treatment [13].

It should be emphasised that despite these differences, home-based tele-monitored training was useful for improving physical capacity and quality of life and its effectiveness was comparable with standard centre-based CR. Giallauria et al. [9] evaluated the effects of a long-term exercise training in 45 post-MI mainly male patients subdivided into three groups. At the end of CR, physical capacity increased significantly in all patients, but a greater improvement was observed in patients who underwent supervised CR either in the centre or at home than in those trained at home without tele-monitoring. Similarly, Ades et al. [10], who trained 83 patients, men and women with CAD in their homes with TeleECG monitoring for three months, observed an improvement in exercise capacity and quality of life comparable with those seen in a group of 50 patients who trained in a centre. Despite these proven benefits of CR, the adherence to the standard, supervised in-hospital CR programme has remained suboptimal [15, 16].

Therefore, to improve adherence, alternative models of care such as TeleECG home-based programmes have been recommended. It should be emphasised that in our pilot and observational study all women participating in TP, either in the centre or at home, finished 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. [16] describing a heterogeneous group of patients rehabilitated at home and in a centre. It is noteworthy that the equipment used for monitoring home-based CR provided not only information about cardiac events but was also useful in conducting training according to the established HR limit. This made it comparable with centre-based training and promoted an improvement in physical capacity. Moreover, home-based

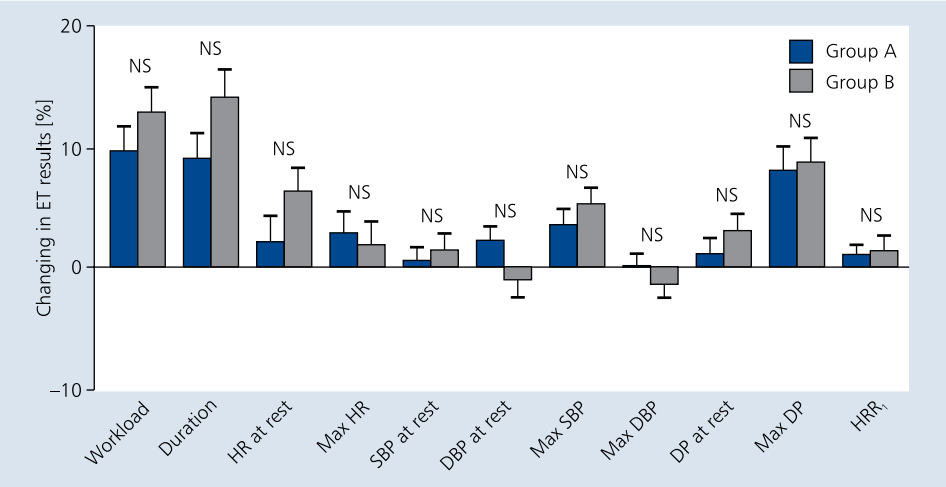

Figure 1. Changes in the exercise stress test (ET) results in female patients undergoing a cardiac rehabilitation programme. Percentage changes from the results of the baseline ET are plotted. See Table 1 for n in each group. All values are presented as mean ± standard deviation; NS — non significant; HR — heart rate; DP — double product, i.e. product of HR and systolic blood pressure; HRR_1 — heart rate recovery in the 1st minute after ending ET; DBP — diastolic blood pressure; SBP — sytolic blood pressure

TP with TeleECG monitoring facilitated a greater number of female patients' attendance at CR programmes.

Limitations of the study

This was a pilot and non-randomised study focused primarily on a comparison of the effectiveness of two models of exercise therapy, hybrid- and centre-based, in consecutive female patients after MI. Furthermore, it was only an exercise study without any assessment of cardiovascular risk factors. An acknowledged limitation of this study is the lack of a non-exercised control group. Nowadays however it is considered unethical to suggest that post-MI patients avoid physical activity.

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

CONCLUSIONS

In post-MI women, a hybrid model of training improved physical capacity and was a similarly effective form of CR as a centre-based approach. A home-based tele-monitored programme facilitated our patients' adherence to CR.

Conflict of interest: *none declared*

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Porównanie hybrydowego i ambulatoryjnego modelu rehabilitacji kardiologicznej u kobiet po zawale serca: badanie pilotażowe

Iwona Korzeniowska-Kubacka[1], Maria Bilińska[2], Barbara Dobraszkiewicz-Wasilewska[1], Ryszard Piotrowicz[1]

[1]Klinika i Zakład Rehabilitacji Kardiologicznej i Elektrokardiografii Nieinwazyjnej, Instytut Kardiologii, Warszawa
[2]Klinika Zaburzeń Rytmu Serca, Instytut Kardiologii, Warszawa

Streszczenie

Wstęp: Udział kobiet w programach rehabilitacji kardiologicznej (CR) jest znacząco mniejszy niż mężczyzn. Szansą na zwiększenie odsetka kobiet objętych CR jest jej realizacja w warunkach domowych. Sposobem na to, aby trening domowy był odpowiednio intensywny jest prowadzenie go pod nadzorem telemedycznym (TeleEKG).

Cel: Celem pracy było porównanie efektywności dwóch form CR, prowadzonej wyłącznie w ambulatorium i realizowanej zarówno w ambulatorium, jak i w warunkach domowych pod nadzorem TeleEKG (model hybrydowy).

Metody: Kobiety (n = 53) w wieku 51,3 ± 7,6 roku, po przebytym zawale serca (MI) zostały objęte 8-tygodniowym programem treningowym (TP), średnio 3 miesiące po MI, zawierającym 24 treningi. Pierwsze 10 treningów interwałowych na cykloergometrze realizowano w ambulatorium, a następnie 33 pacjentki (Grupa A) kontynuowały je w ośrodku, a pozostałe 20 (Grupa B) ćwiczyły w domu pod nadzorem TeleEKG. Przed i po zakończeniu TP u wszystkich chorych wykonano próbę wysiłkową na bieżni ruchomej ograniczoną objawami, w czasie której oceniano: maksymalne obciążenie (MET), czas trwania próby (min), tętno (HR/min), ciśnienie tętnicze (RR, mm Hg), produkt podwójny (DP, mm Hg/min) w spoczynku i w czasie wysiłku oraz HRR w pierwszej minucie po zakończeniu próby jako wyraz reaktywacji układu przywspólczulnego. Aby ocenić efektywność dwóch form CR, porównano przyrost procentowy parametrów badanych w czasie prób wysiłkowych wykonanych przed i po TP. Ponadto w obu grupach badanych oceniano liczbę treningów odbytych w czasie TP i liczbę kobiet uczestniczących w CR.

Wyniki: Po zakończeniu TP w obu grupach badanych uzyskano istotny wzrost obciążenia (Grupa A: 6,5 ± 1,1 *vs*. 7,0 ± 1,4; $p < 0,05$; Grupa: B: 7,4 ± 1,1 *vs*. 8,3 ± 1,4; $p < 0,01$) oraz wydłużenie czasu trwania próby (Grupa A: 4,7 ± 1,1 *vs*. 5,1 ± 1,2; $p < 0,01$; Grupa B: 8,1 ± 3,9 *vs*. 9,3 ± 4,2; $p < 0,01$). Pozostałe parametry nie uległy zmianie. Porównując efekty treningu na podstawie przyrostu badanych parametrów, nie zaobserwowano istotnych różnic między grupami A i B. Wszystkie kobiety zakończyły TP.

Wnioski: 1. Trening hybrydowy jest porównywalnie efektywną formą rehabilitacji jak trening w warunkach ambulatoryjnych. 2. Trening domowy monitorowany telemedycznie miał korzystny wpływ na udział kobiet w programie rehabilitacji kardiologicznej po przebytym zawale serca.

Słowa kluczowe: rehabilitacja kardiologiczna, trening domowy, monitorowanie telemedyczne

Kardiol Pol 2014; 72, 3: 269–274

Adres do korespondencji:
dr n. med. Iwona Korzeniowska-Kubacka, Klinika i Zakład Rehabilitacji Kardiologicznej i Elektrokardiografii Nieinwazyjnej, Instytut Kardiologii, ul. Alpejska 42, 04–628 Warszawa, tel: +48 22 343 43 51, faks: +48 22 343 45 19, e-mail: drkubacka@wp.pl
Praca wpłynęła: 27.06.2013 r. **Zaakceptowana do druku:** 23.09.2013 r. **Data publikacji AoP:** 27.09.2013 r.