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ORIGINAL ARTICLE - ADULT CARDIOLOGY

The effectiveness of home-based cardiac rehabilitation program on cardiovascular stress indices in men and women with myocardial infarction: a randomised controlled clinical trial

La efectividad del programa de rehabilitación cardíaca domiciliaria sobre los índices de estrés cardiovascular en hombres y mujeres con infarto de miocardio: un ensayo clínico controlado aleatorizado

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Abstract

Background: *cardiac rehabilitation is a structured program to prevent secondary cardiovascular diseases.* **Objective:** *to investigate and compare the effectiveness of home-based cardiac rehabilitation program (HBCRP) on improving cardiovascular stress indices in men and women who had experienced myocardial infarction (MI).* **Methods:** *in this randomized controlled clinical trial, 80 patients with MI were divided into two groups of intervention and control (n = 40 per group). Analyses were erformed separately in females and males in the both groups. The HBCRP included receiving routine medications along with walking for 8 weeks. The control group only received the routine care along with counseling about having adequate physical activity. Cardiovascular stress indicators including heart rate at rest (HR_{rest}), maximum heart rate (HR_{max}), recovery heart rate (RHR)at 1 and 2 minutes after the exercise test (i.e. RHR1 and RHR2), systolic and diastolic blood pressures at rest (SBPR and DBPR), and rate pressure product (RPP) were measured by a researcher blinded to the intervention before and after the test.* **Results:** *the results showed significant reductions in RHR1 ($p<0.001$), RHR2 ($p<0.01$), SBPR ($p<0.01$), DBPR ($p<0.01$), and RPP ($p<0.001$) in both males and females in the intervention group. A significant increase was also observed in HR_{max} ($p<0.001$) in the intervention group. However, there were no significant differences in HR_{max} and other variables comparing per- and post-experiment values in the control group.* **Conclusion:** *our results showed that 8 weeks of HBCRP sex-independently reduced cardiovascular stress indices in both men and women with MI.*

Key words: *Gender. Cardiac rehabilitation. Cardiovascular stress. Myocardial infarction.*

Resumen

Antecedentes: *la rehabilitación cardíaca es un programa estructurado para prevenir las enfermedades cardiovasculares secundarias.* **Objetivo:** *estudiar y comparar la efectividad de un programa de rehabilitación cardíaca en casa (HBCRP, por sus siglas en inglés) en la mejoría de los índices de estrés cardiovascular en hombres y mujeres que habían sufrido*

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un infarto de miocardio (IM). **Métodos:** *en este ensayo clínico controlado aleatorizado, 80 pacientes con IM se dividieron en dos grupos de intervención y control (n = 40 en cada grupo). Se realizaron análisis por separado en mujeres y hombres en ambos grupos. El HBCRP incluía la administración de medicamentos de rutina junto con caminatas por 8 semanas. El grupo de control solo recibió tratamiento de rutina junto con orientación acerca de la realización de actividad física adecuada. Un investigador cegado a la intervención midió los indicadores de estrés cardiovascular incluyendo frecuencia cardíaca en reposo (FC_{rep}), frecuencia cardíaca máxima (FC_{max}), recuperación de la frecuencia cardíaca (RFC) 1 y 2 minutos después de la prueba de ejercicio (i.e. RFC1 y RFC2), tensión arterial sistólica y diastólica en reposo (TASR y TADR) y producto frecuencia-presión (PFP), antes y después de la prueba.* **Resultados:** *los resultados mostraron una reducción significativa en RFC1 ($p<0.001$), RFC2 ($p<0.01$), TASR ($p<0.01$), TADR ($p<0.01$), y PFP ($p<0.001$), tanto en hombres como en mujeres del grupo de intervención. También se observó un aumento significativo en FC_{max} ($p<0.001$) en el grupo de intervención. Sin embargo, no hubo diferencias significativas en FC_{max} y otros variables al comparar los valores pre- y post-experimentales en el grupo control.* **Conclusión:** *nuestros resultados mostraron que 8 semanas de HBCRP redujeron los índices de estrés cardiovascular independientemente del sexo, tanto en hombres como en mujeres con IM.*

Palabras clave: *Género. Rehabilitación cardíaca. Estrés cardiovascular. Infarto de miocardio.*

Introduction

Coronary artery disease (CAD), angina pectoris, and myocardial infarction (MI) are among the main causes of death worldwide. According to the World Health Organization (WHO), mortalities due to CAD have risen from 7.1 million in 2002 to 11.1 million in 2020[1]. Evidence has shown that only one-third of all MI cases progress toward serious heart diseases leading to death[2]. Because of this, post-stroke managements have been focused on to investigate their therapeutic effectiveness in these patients. Among a variety of therapeutics interventions, supervised physical activity (PA) has been effective in preventing the relapse of cardiovascular diseases. Along with this, home-based cardiac rehabilitation programs (HBCRP) seem to be more effective than programs conducted in hospitals and health centers[3]. Besides, HBCRP can save time and expense making it more desirable to patients[3]. Researches indicate that only 10-20 % of patients with acute MI participate in secondary PA-based preventive programs[4]. The participation rate is even dramatically lower among women than men[5]. Considering the prevalence of CAD in women, their adherence to CR programs has been much less than expected[6]. Barriers to the enrollment of women into CR programs include both patient- and provider-oriented issues, as well as parameters related to the essence of the programs[7]. The fact that women are far less likely to refer to healthcare professionals for CR programs[8] may root in their beliefs or unawareness about the value of CR sessions, as well as their lower exercise capacity[9]. Although some have claimed poor outcomes of CR programs in women[10], these claims are not based on enough validated studies. Actually, Kaminsky et al., reported that pedometer-based PA interventions were more effective than time-based and pedometer-free programs in encouraging such activities in inactive women[11]. Despite poorer baseline risk parameters, the compliance and outcomes (exercise capacity and physical parameters) of PA programs in women have been comparable with men[12]. It seems that because of lower energy and exercise and functional capacities, CR programs may be of greater clinical benefit to improve these parameters in women[13]. Therefore, the purpose of the present study was to determine and compare the effectiveness of HBCRP to improve cardiovascular stress indices in men and women with MI.

Materials and methods

Participants

The study population consisted of all MI patients hospitalized in the cardiac intensive care unit and cardiology ward of Shahid Rahimi hospital, Khoramabad, Iran, from August to November 2017. The disease was diagnosed by experienced cardiologists and based on the New York Heart Association (NYHA) classification. All the subjects were diagnosed with heart failure and categorized as NYHA class II and III. Post-MI patients who had 'uncomplicated' and stable conditions and were at the phase-IV CR level were included. Overall, 120 patients were initially enrolled (fig. 1) of whom 85 fulfilled the inclusion criteria. Finally, 80 male and

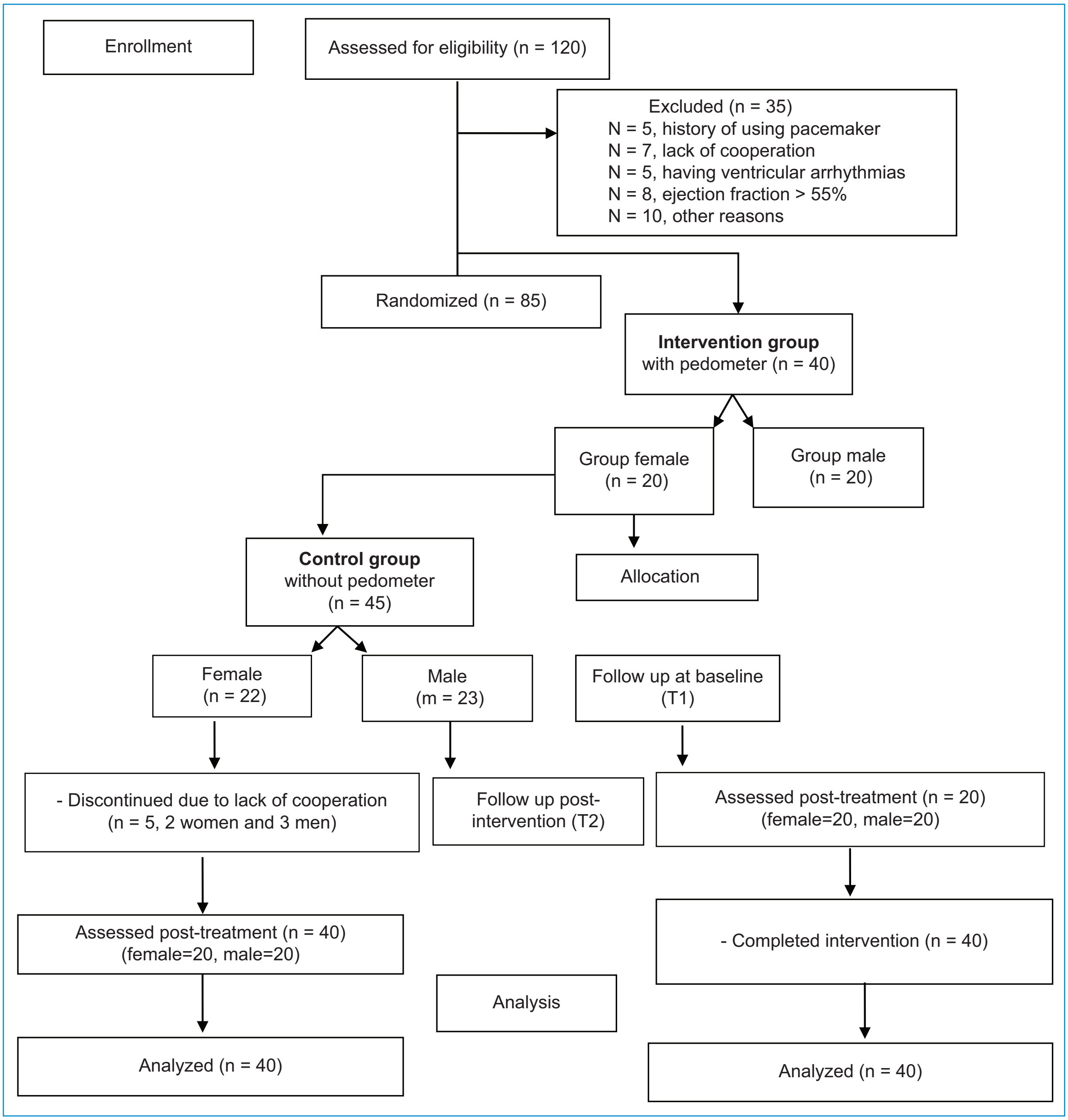

Figure 1. The CONSORT flowchart of the trial.

female patients with MI aged 45-60 years volunteered to participate in the study. After baseline assessments, the participants were randomly allocated to either intervention or control group.

The intervention group (with pedometer) included 40 patients who performed HBCRP as previously described[14]. Briefly, the cardiac rehabilitation walking program using waist-mounted pedometer (PA-S20, Switzerland) was instructed to be performed at 5 to 6 pm. The number of the steps seen on the step counter was recorded in a notebook. The patients were followed-up by phone calls every other day by the research team and consulted with a cardiologist during the study to receive appropriate treatments and recommendations. The patients in the control group only received counseling without offering any exercise educations. The patients did not attend any other therpaeutical or counsleing sessions during the study.

Inclusion and exclusion criteria

The inclusion criteria were history of angioplasty and/or angiography, diagnosis of mild-moderate CAD, elapsing at least eight weeks of MI, lack of regular physical activity within three months prior to the intervention, 40 % ≥ ejection fraction ≤ 55 %, and finally no history of using pacemakers.

The exclusion criteria were having ventricular arrhythmias or renal, respiratory, and endocrine diseases. The present study wass approved by the Ethics committee of Lorestan University of Medical Sciences (approval ID: IR.LUMS.REC.1397.105). The protocols were conducted according to the guidelines of Helsinki Declaration[15].

HBCRP

The HBCRP included walking at home for almost 45-60 min (5-min warming-up, 40-min walking, 5-min cooling-down, and stretching exercises). The rating of perceived exertion (RPE) was set as 11-13 on the Borg scale. The program was performed by the participants of the intervention group using a pedometer for 8 weeks and 5 sessions per week as noted previously[14]. From the week 2nd to 8th, the number of steps was gradually increased by 10 % per week (i.e. 100 steps/day to a total of 500 steps/week). A pilot study was conducted to standardize the way of performing the protocol and to determine the number of steps at the start of study (3,500 steps/day).

The Bruce Protocol and Termination Criteria

The protocol was implemented in the framework of a two-stage project (before and after an eight-week HBCRP). To determine the cardiovascular and respiratory functional indicators during the aerobic exhaustive exercise, the advanced treadmill test was used employing the modified Bruce protocol (3 km/hr increasing by 1.4 km/hr after 3 minutes followed by increasing the grade by 3 % at a constant speed) in each of the phases[16]. For this, the patients were primarily examined by a physician to determine their heights and weights (Seca 769 Scale, Germany) using standard methods with light clothes on and shoes off. The body mass index (BMI) was calculated as body weight/height^2. Each participant then sat on a chair calmly for 10 minutes, and blood pressure (Beurer BM-16 Blood Pressure Monitor made in Germany), heart rate (HR, bpm), and ECG-12 (aKenz Cardio 601, Suzuken Co., Japan) were measured.

The exercise test termination criteria in the current study included development of any unexpected heart abnormalities, BP exceeding of 180 mm Hg (systolic) and/or 100 mm Hg (diastolic), and HR_{rest}>100 bpm[17]. The subjective ratings of perceived exertion (RPEs) (Borg 6–20 scale)[18] were measured during the last minute of each phase. The researcher was blinded to the assignment of participants to study groups.

Assessment of cardiovascular stress indicators

These parameters included maximum heart rate (HR_{max}) immediately at the end of the test, recovery heart rate (RHR) at 1 and 2 minutes (i.e. RHR1 and RHR2) after the completion of the test (in seated position), and systolic and diastolic blood pressures at rest (SBPR and DBPR). These parameters were recorded at the beginning and end of the 8-week intervention. Myocardial oxygen consumption and the rate pressure product (RPP) were also determined. The recent was calculated based on the SBP and HR_{rest} as RPP=SBP HR_{rest}/100[19]. In addition, following an episode of aerobic exhaustive exercise, the HR_{max} was also measured during the activity on the treadmill.

Randomization

This study was a double-blinded clinical trial in which the patients and the researcher were unaware of the allocations. The eligible patients were assigned to the study groups through the stratified randomization method. They were first divided into two strata of control and intervention. Then the subjects were selected from the strata through the block randomization method and divided into the female and male subgroups according to the order of the numbers and internal arrangement of selected blocks. The block number was selected through lottery. To blind the researcher and prevent any prediction on the allocations, the sampling and the size of the blocks were hidden.

Statistical analysis

SPSS 22 (IBM Inc., New York, US) was used for statistical analysis. All the measured variables were checked for normal distribution of the data. Statistical significance (alpha level) was set at p<0.05. To determine any intragroup and intergroup variation in the measured variables before and after the HBCRP, the data was analyzed using both one-way ANOVA and

Table 1. Baseline demographic and clinical characteristics of participants

Variables	Sex					
	Male (n = 40)			Female (n = 40)		
	Experimentel group (n = 20)	Control group (n = 20)	P Value	Experimentel group (n = 20)	Control group (n = 20)	P Value
Age (y)	51.8 ± 7.35 52.1 ± 7.26		.59	52.5 ± 6.96 54 ± 7.33		.33
BMI (kg/m^2)	24.66±1.48 23.76±1.50		.43	24.44±1.12 24.25 ±1.33		.41
Smoking	2(10 %) 2(10 %)		.55	_1		.33
Unstable angina	1(5 %) 1(5 %)		.29	__		.38
Hypertension	3(15 %) 4(20 %)		.35	3(10 %) 2(10 %)		.24
Family history of heart disease	3(15 %) 3(15 %)		.38	3(15 %) 2(10 %)		.29
Diabetes mellitus	1(5 %) 2(5 %)		.56	1(10 %) 2(10 %)		.56
CABG	3(15 %) 3(10 %)		.30	2(10 %) 2(10 %)		.25
NSTEMI	1(5 %) 2(10 %)		.16	2(10 %) 2(10 %)		.24
STEMI	1(5 %) 1(5 %)		.22	2(10 %)2 (10 %)		.21
IDC	1(5 %)-		.42	1(5 %) 1(5 %)		.62

Values expressed as mean ± SD, number or percentage. CABG = coronary artery bypass grafting; NSTEMI = non-ST segment elevation myocardial infarction; STEMIZST-segment elevation myocardial infarction; IDM = idiopathic dilated cardiomyopathy. * Significant difference at p ≤ 0.05.

paired samples student *t*-test. Repeated measure ANOVA was utilized to compare the average heart rate at three separate times before and after the intervention.

Results

The participants' demographic and clinical characteristics (at the time of hospitalization) including age, gender, waist circumference, BMI, type of CHD and its severity, blood pressure, history of taken medications, and smoking and alcohol drinking habits were recorded. Overall, 80 CHD patients were randomly divided into male and female subgroups within each of the control and intervention groups (n=20 per subgroup). There were no significant differences in the distributions or mean values of CHD types, age, BMI, smoking habits, blood pressure, family histories of heart diseases or diabetes, coronary artery bypass grafting (CABG), non-ST segment elevation myocardial infarction (NSTEMI) and/or STEMI between the groups and subgroups (table 1).

Table 2 shows intragroup and intergroup comparisons of HR_{rest}, HR_{max} at the Bruce Test, and RHR1 and 2 (i.e. 1 and 2 minutes after the test) between pre- and post-intervention in the intervention and control groups. While no significant differences were observed between pre- and post-experiment values of the mentioned parameters in neither females nor males in the control group ($p \geq 0.05$), significant improvements were seen in both genders in the intervention group after the HBCRP compared with the baseline values (table 2).

Discussion

Studies have revealed that many patients with CHDs do not attend to cardiac rehabilitation programs or

Table 2. Comparison of physiological markers at rest before and after cardiac rehabilitation in female and male patients with history of myocardial infraction

Physiological markers	Control groups		Experimentel groups	
	Pre (X ± SD)	Pos (X ± SD)	Pre (X ± SD)	Pos (X ± SD)
HR res (bpm)				
Female	77.5±4.3	77.4±4.5	80.8±2.04	72.1±2.99 ***
Male	78.2±=.39	77±3.05	79.9±2.51	71.4±3.06 ***
HR max (beat/minute)				
Female	147.9±6.75	147.5±7.36	140.4±5.31	150.7±6.12***
Male	137.1±5.27	136.8±5.8	145.1±4.77	155.5±6.55***
RHR1 (beat/minute)				
Female	130.7±5.92	131.3±6.2	125.4±4.57	125.2±5.39**
Male	121.3±5.2	121±5.51	129.2±6.14	125.6±7.79 **
RHR2 (beat/minute)				
Female	116.4±4.55	116.2±4.98	111.6±3.56	99±4.10 **
Male	107.8±5.41	107.7±6.88	114.7±6.32	97.1 ±4.04 **
SBP_{rest} (mm Hg)				
Female	132.8±10.65	131.1±11.43	134.5±10.95	129.5±11.5**
Male	130.2±13.43	130.1±13.11	132.8±10.65	126±11.66 **
DBP_{rest} (mm Hg)				
Female	9.28±92.6	10.93±90.4	6.72±97.8	8.14 **±89.4
Male	8.63±83.9	7.87±83.8	6.7±91.5	5.77 **±88.6
RPP (bpm_SBP mm Hg/100)				
Female	10.28±.97	10.23±.89	10.94±1.48	8.92±.8 ***
Male	10.09±.96	10.23±.89	10.67±.63	8.92±.8 ***

Values expressed as mean ±SD, HRrest = heart rate at rest; RHR1= recovery heart rate 1 min after test-exercise; RHR2= 2 min after test-exercise; SBPrest = systolic blood pressure at rest; DBPrest = diastolic blood pressure at rest; RPP = rate pressure product. * Significant difference comparing the pretest and posttest values. $p \leq 0.05$.
*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

adhere to physical activity recommendations[20]. Because of this, there is a need for using home-based pedometer rehabilitation programs more than ever before. Based on our information, a few studies have evaluated the effects of HBCRP on physiological indicators (HR_{rest}, HR_{max} during the Bruce test, RHR at post exercise, resting blood pressure (RBP), and myocardial oxygen consumption in MI patients. Our results showed that HBCRP significantly improved the mentioned indicators in both female and male MI patients.

A strong relationship has been indicated between HR_{rest} and reduced sympathetic nervous activity and also the mortality rate in patients attending cardiac recovery programs[21]. On the other hand, physical activity during the cardiac rehabilitation program, as a non-pharmacologic strategy, can restore abnormal RHR in MI patients by affecting the vagal tone in these patients. Researchers have reported that regular rehabilitation programs can improve the function of autonomic nervous system[22]. This is important knowing that autonomic dysfunction (sympathetic/parasympathetic imbalance) is one of the main risk factors of heart diseases and sudden death[22]. In fact, sport activities augment the capacity of the cardiovascular system and baroreceptors to reverse and adapt to the stimulations by the autonomic nervous system (i.e. inhibition of sympathetic discharge)[23]. Furthermore, Heffernan et al. showed that through physical activities, it was possible to adjust RHR via both the sympathetic and the parasympathetic systems[24]. This was consistent with our findings as HBCRP significantly improved RHR1 and RHR2 indicating the impact of sport activities in regulation of the vagal tone in both male and female MI patients ($P \leq 0.05$). The effects of exercises on RHR1 and RHR2 can be attributed to the vagal reactivation through which autonomic nervous system and baroreceptors modulate cardiovascular stresses[25]. This finding conforms to the results reported by Julie et al.[26] demonstrating positive effects of aerobic exercises on reducing RHR. According to cardiovascular specialists and sport physiologists, HR and SBP can be used to determine energy requirement and the level of cardiovascular stress during sport activities. On the other hand, these are important variables for determining myocardial oxygen consumption and RPP during such activities. Generally, increased HR during exercise indicates that more blood and oxygen are sent to active muscles whereas high BP shows a high blood supply to the heart[27]. In the same vein, it was demonstrated that physical activity decreased RHR and RPP[28]. Moreover, Keyhani et al. noticed that an eight-week walking program improved the cardiac functional capacity in patients with congestive heart failure[28]. In line with another research[28], we also found that HR significantly decreased after the eight-week rehabilitation program in both males and females; however, there was no significant change in this parameter in the control group ($p \geq 0.05$). Furthermore, HR_{max} significantly increased in females and males in the HBCRP group. These results agree with those reported by Kraal et al.[29] who showed that HR_{max} significantly improved following home-based remote-monitored activities in patients with CAD. We further noted a significant decline in the values of RPP in males and females in the HBCRP group. This was while no significant improvement was observed in the control group ($p \geq 0.05$).

Evidence suggests that local vascular responses to physical activity can be due to the effects of vasodilators suh as histamine, nitric oxide, and prostaglandins, reduction in the sensitivity of alpha receptors, and/or decreased adrenergic activity. Considering that the heart needs sufficient oxygen to function properly, and the fact that inadequate oxygen supply weakens this organ leading to heart failure[30], regular exercises, depending on the intensity, duration, and mode, can reduce cardiac oxygen consumption and therefore the risk of cardiovascular events[31]. In the present study, an eight-week low- to moderate-intensity walking exercise reduced resting SBP in both males and females with MI. The positive effects of a home-based cardiac rehabilitation exercise program on the heart functional capacity and cadrivascular risk factors have also been noted in patients with acute coronary syndrome[32]. We also noticed a decline in resting DBP in patients of both genders in the HBCRP group after the intervention. This observation indicates that walking exercises can reduce HR_{max} and myocardial oxygen consumption and prevent elevation of blood pressure. This is while no significant alternations were observed in resting SBP and DBP in females and males in the control group ($p \geq 0.05$). These results agreed with the findings of Yazdi et al.[33] who reported positive effects of cardiac rehabilitation programs on the heart rate and blood pressure. In the present study, reduced RPP observed in MI patients after HBCRP was accompanied with improved cardiac functional capacity in both females and males ($P \leq 0.05$). Sharma and McLeod also showed that cardiac rehabilitation exercise significantly improved patients' physical tolerance[34].

Conclusions

This research showed that an eight-week HBCRP using pedometer improved heart rate, blood pressure, and RHR in men and women with a history of MI. These were accompanied with improvements in myocardial workload, oxygen consumption, and cardiovascular stress indicators in the patients. The changes were sex-independent and observed in both males and females. Accordingly, pedometers can be beneficial for patients with CADs who live far away from cardiac rehabilitation centers, and/or cannot go to sport centers for financial reasons, and/or lack free time to manage their walking exercise.

Limitations

Two potential limitations of our study must be considered when interpreting the results. First, we did not obtain a detailed history on medications used by the patients. Therefore, we cannot eliminate the possibility that some medications could confound the association between sports-related physical activity and the development of AMI by predisposing to the disease. Second, the results obtained here are specific to our patients and community; therefore, they should be extrapolated to other populations with caution.

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Conflicts of interest

The authors declare that does not exist an conflict of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained the written informed consent of the patients or subjects mentioned in the article. The corresponding author is in possession of this document.

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