Effects of a 12-week exercise-based program on the quality of life among myocardial revascularization subjects with normal and reduced left ventricular ejection fraction

Efectos de un programa de ejercicio de 12 semanas sobre la calidad de vida en sujetos con revascularización miocárdica con fracción de eyección ventricular izquierda normal y reducida.

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Abstract

Background/Aims/: Exercise-based cardiac rehabilitation is an effective and safe therapy to be used in the management of clinically stable patients following percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG).

Objectives: To determine if a 12-week physical exercise program (12-WPEP), after PCI or CABG with different left ventricular ejection fraction (LVEF) might improve the health-related quality of life (HRQOL).

Methods: A prospective, controlled before-after study was conducted in a cardiac rehabilitation service with a 12-WPEP. Each session had a duration between 40 to 60 minutes, three times per week. Before and after a 12-WPEP was evaluated HRQOL using the SF-36 questionnaire.

Results: The 12-WPEP improve the HRQOL but did not show differences among PCI (31 subjects) compared to CABG (18 subjects), regardless of whether the LVEF was normal or reduced (p<0.005).

Conclusion: 12-WPEP improved HRQOL in both PCI and CABG subjects regardless of LVEF.

Keywords: cardiac rehabilitation; coronary artery bypass graft; left ventricular ejection fraction; percutaneous coronary intervention; quality of life

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Resumen

Antecedentes: La rehabilitación cardíaca basada en el ejercicio es una terapia eficaz y segura que se utiliza en el tratamiento de pacientes clínicamente estables después de una intervención coronaria percutánea (ICP) o injerto de derivación de la arteria coronaria (OIDAC).

Objetivos: Determinar si un programa de ejercicio físico de 12 semanas (12-WPEP), después de la ICP o OIDAC con diferente fracción de eyección del ventrículo izquierdo (FEVI), podría mejorar la calidad de vida relacionada con la salud (CVRS).

Métodos: se realizó un estudio prospectivo, controlado antes y después en un servicio de rehabilitación cardíaca con un 12-WPEP. Cada sesión tuvo una duración de entre 40 y 60 minutos tres veces por semana. Antes y después se evaluó una CVRS de 12-WPEP mediante el cuestionario SF-36.

Resultados: El 12-WPEP mejoró la CVRS pero no mostró diferencias entre las ICP (31 sujetos) en comparación con OIDAC (18 sujetos), independientemente de si la FEVI era normal o reducida (p<0,005).

Conclusión: 12-WPEP mejoró la CVRS en ambos sujetos, ICP y OIDAC, independientemente de la FEVI.

Palabras clave: rehabilitación cardíaca; cirugía de revascularización coronaria; fracción de eyección del ventrículo izquierdo; intervención coronaria percutánea; calidad de vida. Número de registro en clinicaltrials.gov: NCT03643536

Introduction

Percutaneous coronary intervention (PCI) and coronary artery bypass graft surgery (CABG) are interventions that can reduce cardiovascular symptoms such as dyspnea and angina. The life quality and the functional capacity improved in the subjects who underwent surgery[1-4]. However, new cardiac events, death, and obstruction of the bypass placed can exist[5,6]. To diminish these risks, national and international guides recommend cardiac rehabilitation (CR) for people with coronary disease, who have suffered a myocardial infarction and are subjected to CABG and PCI. A 20-30% reduction of morbidity and mortality can be obtained with the use of CR[7-9]. According to the European Society of Cardiology (ESC), the American Heart Association (AHA) and the American College of Cardiology (ACC), CR is a recommendation Class Type I, in subjects treated with PCI and CABG[10]. This includes prescribed physical exercises, education, and counseling to modify the effects of coronary heart disease and improve long-term survival[11,12]. Exercise-based cardiac rehabilitation is an effective and safe therapy to be used in the management of clinically stable patients following PCI or CABG. The maximum oxygen uptake (VO2max) is improved by the exercise carried out during CR, optimizing the physical condition and health-related quality of life (HRQOL)[13].

The HRQOL is considered a very important criterion used to evaluate the effectiveness of different treatments in patients with coronary disease, and is defined by subjective evaluation regarding the current activities of health care and health promotion; it indicates the personal perception in various aspects such as the recovery of the functional, labor, sexual and social capabilities of the patient, factors that have great importance in the evolution of the patient; this perception is considered the best indicator of quality of life, and has become a key concept for the decision making[14-17]. In this study, we evaluated the effects of a physical exercise program in the health–related quality of life of subjects following CABG or PCI with normal and reduced left ventricular ejection fraction (LVEF).

Materials and methods

Study Design

A prospective controlled before-after study was conducted in patients admitted to the Cardiac Rehabilitation Center in Barranquilla, Colombia, from January to December of 2014, with CABG or post-PCI and agreed to participate by signing the informed consent form. This study, in accordance with the international and national ethical guidelines, was conducted and approved by the Simon Bolivar University Ethics Committee. Subjects with musculoskeletal limitations for physical exercise, untreated ventricular arrhythmias, with the presence of residual pericardial effusion, history of intermittent claudication or left ventricular ejection fraction <30% measured by 2D-echocardiography were excluded.

Outcome measures

This study collected social-demographic and clinical data. Cardiac rehabilitation program (CRP) starts with a review of the clinical history made by the cardiologist. For the evaluation of the health-related quality of life, SF-36 questionnaire was used. This questionnaire has 36 questions that address two major components based on 8 fields: a physical component which includes physical functioning, physical performance, pain, and general health, and the mental component which includes vitality, social function, emotional role and mental health[18,19]. To calculate the score, the items for each one of the eight dimensions are encoded, added and transformed into a scale from 0 (worst health status for this dimension) to 100 (best health status).

In the questionnaire, there were different response options depending on the question: three response question (0, 50 or 100), five response questions (0, 25, 50, 75 or 100) and six response question (0, 20, 40, 60, 80 or 100). Once the answers were obtained, they were averaged to create scores for each dimension and thus obtain the determined value of health-related quality of life for the 8 dimensions; the court point is 50, above and below which there are states of health positive or negative health[18,20].

Rehabilitation Program

Before 12-WPEP, subjects were divided into two groups, those with a LVEF by 2D-echocardiography between 30-54% and those with a LVEF ≥55% (control group). The CRP component of the physical exercise program was supervised and prescribed by a CR specialist. It was carried out in 3 sessions each 40 or 60 minutes with alternate days per week during 3 months, and with intensity between 40 to 80 percent of their VO2 max, as the AHA recommends[21]. Most patients received beta-blockers and the Borg scale modified from 0 to 10 was used[22,23]. It was composed by warm-up, stretching and aerobic exercises as well as strength training and cooling down exercises. The aerobic exercises varied between ergometer, treadmill, elliptical and dance; the total time was 30 minutes of aerobic exercise, 10 to 15 minutes of resistance training and cooling down exercises consisting of relaxation and 5-10 breathing exercise.

Statistical analysis

The data analyzed was collected using the software SPSS version 24 (June 2016). The Shapiro-Wilk test was used to verify the normality of the data of the group during before and after 12-WPEP. The Wilcoxon test was applied based on assigned rank for the median difference of before and after 12-WPEP. The Mann Whitney test was used to compare the difference between before and after 12-WPEP of CABG patients or patients with PCI in each group, and the median of these differences was compared.

49 patients with CABG (n=18) or PCI (n=31) were included. Of these, 32 (65.3%) had LVEF ≥ 55% (control group) and 17 (34.7%) had LVEF 30-54%. The characteristics of the patients included in the study are in Table 1.

Table 1. Characteristics of patients included in the study (n=49).

Characteristics	Frequency (%)
Sex (male/female)	30 (61.2)/19 (38.8)
Living as a couple	27 (55.1)
Low socio-economic stratum	29 (59.2)
CABG*/ PCI**	18 (36.7)/ 31 (63.3)
Body Mass Index	24.5±3.8 kg/m²
Waist circumference	93.6±10.6 cm
Medications	
Beta-blockers	41 (83.67)
Statins	46 (93.87)
Oral hypoglycemics	33 (67.4)
Insulin	4 (8.1)
Calcium antagonists	20 (40.8)
Angiotensin receptor blockers	16 (32.65)
Medical History	
Hypertension	41 (83.7)
Diabetes Mellitus	37 (75.5)
LVEF *** ≥55%	32(65.30)
LVEF*** 30-54%	17(34.70)
Age	**Mean (Standard Deviation)**
	63 ± (8.9) years

*CABG=Coronary Artery Bypass Graft; ** PCI= Percutaneous coronary intervention;

*** LVEF=Left ventricular ejection fraction by echocardiography 2D

The quality of life differences before and after 12-WPEP in all study subjects (n=49) using the SF-36 questionnaire showed that the dimensions: physical functioning, role physical, bodily pain, general health, physical component summary, vitality, social functioning, role emotional and mental component had a significant increase (p<0.001). The only component that had a significant decrease was mental health (p=0.001) (Table 2).

The improvement in the quality of life before and after 12-WPEP in CABG versus PCI are similar and statistically significant (p<0.05) in both groups (Table 3).

Table 4 shows that there are no significant differences among patients with CABG compared to PCI. As shown in Table 5, the quality of life before and after 12-WPEP in LVEF 30-54% versus LVEF 30-54% are similar and statistically significant (p<0.05) in each group. However, although some components of the SF-36 quality questionnaire were found to be higher in subjects with LVEF> 55%, no significant differences exist among patients with LVEF 30-54% or those with LVEF ≥55% (Table 5).

Table 2. Quality of life differences before and after 12-week physical exercise program in all study subjects (n=49)

SF-36 Score*	Before	After	P value
Physical Functioning	50 (40-60)	100 (100-100)	0.001
Role Physical	0 (0-25)	100 (100-100)	0.001
Bodily Pain	40 (20-75)	85 (75-100)	0.001
General health	29.2 (20-38.7)	50 (42.5-55)	0.001
Physical Component Summary	31.7 (21.5-45.9)	82.5 (73.1-87.5)	0.001
Vitality	27.5 (21.3-43.1)	51.3 (45-56.3)	0.001
Social Functioning	47.5 (35-60)	100 (85-100)	0.001
Role Emotional	0 (0.0-66.7)	100 (100-100)	0.001
Mental Health	36 (28-45)	28 (22-36)	0.001
Mental Component Summary	34.4 (23.1-48.6)	67.3 (64.3-71.2)	0.001

*Median (interquartile range)

Table 3. Quality of life before and after 12-week physical exercise program in CABG (n=18) vs. PCI*** patients (n=31).**

SF-36 Score*	CABG		PCI	
	12-Week exercise program		12-Week exercise program	
	Before	After	Before	After
Physical Functioning	50 (22.5-65)	100 (100-100)	50 (45-60)	100 (90-100)
Role Physical	0 (0-31.3)	100 (100-100)	0 (0-25)	100 (100-100)
Bodily Pain	30 (20-76.3)	80 (75-90)	50 (20-75)	85 (75-100)
General health	28.8 (19.2-35.2)	55 (38.8-55.1)	31.7 (20-40)	50 (45-55)
Physical Component Summary	30.2 (16.9-44)	83.1 (74.7-86.3)	34.2 (22.5-47.7)	82.5 (71.3-87.5)
Vitality	21.9 (15.9-49.1)	51.3 (50-56.3)	31.3 (21.3-42.5)	51.3 (41.3-56.3)
Social Functioning	37.5 (35-52.5)	85 (85-100)	50 (25-60)	100 (85-100)
Role Emotional	16.7 (0-100)	100 (100-100)	0 (0-66.7)	10 (100-100)
Mental Health	40 (28-55)	28 (24-40)	36 (28-44)	28 (20-36)
Mental Component Summary	37.9 (22.8-50.6)	68 (65.1-71.5)	29.1 (23.1-49.2)	67.3 (62-71.3)

*p<0.05 Median (interquartile range); **CABG=Coronary Artery Bypass Graft; ***PCI= Percutaneous coronary intervention

Table 4. Quality of life among patients with CABG ** compared to PCI* using SF-36 health questionnaire (n=49).**

SF-36 Score*		CABG	PCI	P value
SF- QUESTIONNARIE	Physical Functioning	-50 (-77.5/-32.5)	-45 (-50/-35)	0.9
	Role Physical	-100 (-100/-43.8)	-100 (-100/-75)	0.53
	Bodily Pain	-32.5 (-62.8/1.3)	-40 (-55/-10)	0.81
	General health	-16 (-30.5/-7)	-18 (-36/-10)	0.55
	Physical Component Summary	-52.5 (-62.5/-14.5)	-44 (-56/-26)	0.34
	Vitality	-29 (-40/0.8)	-15 (-29/0)	0.17
	Social Functioning	-48.5 (-60.5/-14.3)	-40 (-50/-25)	0.88
	Role Emotional	-83.5 (-100/0)	-67 (-100/-33)	0.80
	Mental Health	10.22 (-1/19.5)	4 (-2/16)	0.39
	Mental Component Summary	-29 (-43/-12.5)	-27 (-41/-15)	0.94

*Median (interquartile range); **CABG=Coronary Artery Bypass Graft;

*** PCI= Percutaneous coronary intervention

Table 5. Quality of life differences among patients with ejection fraction (EF) 30-54% compared to patients with EF ≥ 55% measured by 2D-echocardiography before and after 12-week physical exercise program (n=49).

SF-36 Score*		Ejection fraction 30-54% n= 17			Ejection fraction ≥55% n= 32		
		12-Week exercise program			12-Week exercise program		
		Before	After	P value	Before	After	P value
SF-36 QUESTIONNARIE	Physical Functioning	50 (30.6-65)	100 (92.5-100)	0.001	50 (46.3-58.8)	100 (100-100)	0.001
	Role Physical	0 (0-25)	100 (100-100)	0.001	0 (0-25)	100 (100-100)	0.001
	Bodily Pain	50 (20-80)	85 (62.5-100)	0.03	40 20-75)	80 (75-100)	0.001
	General health	29.2(20-40.8)	50 (45-57.5)	0.001	30 (17.5-37.1)	52.5 (40-55)	0.001
	Physical Component Summary	29.4 (20.7-50.8)	80 (68.8-86)	0.001	31.8 (23.1-42.4)	83.1 (73.8-87.5)	0.001
	Vitality	37.5 (21.3-49.4)	56 (41.3-56.3)	0.03	26.3 (21.3-42.2)	51.3 (45-56.3)	0.001
	Social Functioning	37.5 (30-60)	85 (85-100)	0.001	50 (35-60)	100 (85-100)	0.001
	Role Emotional	0(0-66.7)	100 (100-100)	0.001	33.3 (0-66.6)	100 (100-100)	0.001
	Mental Health	36 (28-45)	36 (20-38)	0.04	36 (28-45.5)	28 (24-36)	0.007
	Mental Component Summary	29.1 (23.1-57)	68 (63-72.1)	0.001	35.1(23.1-48)	67.3 (64-71.1)	0.001

*Median (interquartile range).

Discussion

The effectiveness of CABG and PCI in the treatment of coronary artery disease is recognized[24]; therefore, CR has been shown to be a strategy that improves the results in terms of a higher quality of life, a decrease in mortality and a reduction of re-myocardial infarction[25]. Previous research indicates that the physical dimensions of the quality of life present a greater and a significant increase in comparison with different social dimensions[17,26]. This is consistent with the results of this study. Shepherd and While (2012) reported the bidirectional relationship between physical exercise and physical condition of the subject and their perception of increased performance and physical functioning during daily life activities[26]. In this regard, other authors' state that the physiological effects of physical exercise, including the increase of the VO2max, is the main mediator for increasing the individual's functional capacity and, therefore the ability to perform tasks, making possible a greater perception of well-being and health[10]. Health-related with quality of life becomes an indicator of optimal care because it allows patients to establish responses to the CR and predicts response to treatment.

The evaluation of the health-related quality of life in patients included in cardiac rehabilitation programs can be a useful tool to identify a greater risk of hospital readmission and mortality, allowing a closer follow-up with these patients and a greater control of the evolution of the effects of CRP and a better understanding of subjective areas of clinical condition of the patient. It also appears that the improvements in HRQOL obtained with CRP correlate with the observed gains in aerobic potential[11].

A decrease in median scores in the category of mental health was observed in this study. These findings differ from other studies that have found an increase in all categories of measured components of quality of life after exercise in subjects with CABG except for general health[16]. The above implies that the perception of discouragement and sadness persisted in patients despite the intervention.

On the other hand, other aspects such as feeling full of vitality and of energy, and greater participation in social activities contributed to the general mental health component and showed positive and significant changes. The results of our study are similar to an 8-week cardiac reha-

bilitation program in Japanese cardiac surgery patients, in which an improvement in all dimensions and components of the SF-36 questionnaire were reported[27].

Our results show that the improvement in the quality of life before and after 12-WPEP in CABG versus PCI was similar, however in each group the quality of life was increased statistically. Contrasting previous studies where it is reported that the effectiveness of cardiac rehabilitation is influenced by the type of intervention (CABG or PCI) and by the duration and the number of sessions of the exercise program[28].

This research showed a higher quality of life perception in both groups; however, at the beginning of the CR, the median scores of the dimensions of physical health were lower in patients with CABG. On the same issue, the dimension of pain in the population studied had lower values in subjects with CABG unlike those one operated with PCI due to the presence of a postoperative pain in CABG that leads to higher morbidity and a longer recovery period.

Recently it was shown that both, PCI and CABG, demonstrated a significant improvement in LVEF compared to baseline at the 6 and 12-month time points. Patients with severely reduced LV function undergoing multivessel PCI had a statistically significant increase in LVEF over time, but patients undergoing CABG demonstrated greater gains in LVEF over the same time period. This data suggest that surgical revascularization with CABG may be a procedure of choice in patients with depressed LV function and multivessel CAD; however, PCI also demonstrates a significant, if more modest, increase in LVEF and may be considered in patients who either refuse CABG or are deemed unsuitable for surgery[29].

In a previous study it was assessed the effectiveness in improving exercise capacity (6MWT), cardiorespiratory function (peakVO_2), and autonomic function (HRV) following either CABG or PCI. Showing that a 6-weeks CR program benefits both patient groups in terms of exercise capacity, cardiorespiratory function and autonomic nervous system modulation of heart rate, with CABG patients showing the most improvement. As heart rate variability (HRV) was used as a measure of the autonomic function it is suggested that this can be a useful additional variable to gauge cardiac function following cardiac rehabilitation with exercise. In addition, the study indicates that the effect of CR is of benefit to patients with reduced parasympathetic tone prior to the start of CR and that CR has a greater effect in post-CABG compared to post-PCI. Moreover, HRV is independent of 6 minutes' Walk Test (SMWT) and peak VO2, suggesting that HRV is a useful additional measure to employ for CR[30].

The physical exercise program implemented in our study had a duration of 12 weeks, which was enough to achieve the positive effects on the increase of the quality of life. In this regard, in Europe[31], the United States[32], and South America[33] was found great variability regarding the duration of the exercise program and the sessions held.

When assessing the impact of diet and exercise on long term CABG operated subjects the evidence indicates a limited number of studies based on this kind of intervention with positive results, considering differences in relation to age and gender. Since those studies the interventions are evaluated in a short term is needed a greater patient follow-up time to see the impact of the plan of long-term physical exercise in this kind of studies[34]. Cano et al. (2012) drew attention to the importance of a physical exercise program, in the prognosis of a post coronary revascularization patients, the improvement of patient's functional capacity and quality of life-related to the health with a reduction in ejection fraction[10]. The left ventricular ejection fraction (LVEF) is clinically used as a predictor of long-term prognosis in coronary artery disease (CAD) patients, there is a scarcity of data on the effectiveness of exercise-based cardiac rehabilitation on LVEF. A clinical trial using 12-week early (within 1-month post-discharge) structured individually tailored exercise showed significantly improves LVEF in post-event CAD patients[35]. The same has been demonstrated in a 6-week exercise program in subjects with reduced and preserved left ventricular ejection fraction[36]. The Cochrane systematic review and meta-analysis showed a significant reduction in the risk of hospitalization with CR but not in the risk of myocardial infarction or revascularization. It was identified further evidence supporting improved HRQOL with exercise-based CR[37]. It is important in the design and implementation of CR programs to always include quality assessment particularly because the perception of the evaluator and the subject examined is different[38].

Conclusions

The 12-WPEP had a positive impact on the quality of life-related to health both in patients with CABG and PCI. Regardless of the previous value of left ventricular ejection fraction, the subjects presented a significant improvement in the quality of life dimensions which means that the results obtained on quality of life are independent of the LVEF values found before the exercise program. Our results confirm the concept that short exercise programs can obtain the same benefits on quality of life as prolonged exercise programs.

More researches are needed to evaluate the long-term effects that physical exercise programs have on the quality of life of the PCI and CABG subjects. The obvious limitations of this study are the small sample size and the fact that represent a single-center experience.

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