Changes in Sleep Quality in Heart Disease Patients Following a Cardiac Rehabilitation Program

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Research Article

Keywords: Sleep disorder, cardiac rehabilitation program, Pittsburgh Sleep Quality Index

Posted Date: December 20th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-1143478/v1

Abstract

Sleep disorders are very common in patients with heart disease. The objective of this study has been to assess the effects of a cardiac rehabilitation program on sleep quality, quality of life, anxiety, depression and functional capacity in patients with heart disease.

A pre-test/post-test design study was carried out on the 240 patients included in the cardiac rehabilitation program at the “Virgen de la Victoria” hospital in Malaga; 50 patients (20.8%) were included in the program due to heart failure (HF) and the rest of them after having undergone a revascularization procedure or a surgery for valvular disease.

The patients underwent a cardiac rehabilitation program for 8 weeks, based on programmed physical training, health education and psychological treatment. At the end of the program, scores improved on the Pittsburgh Sleep Quality Index ($p = 0.008$), the SF-36 Quality of Life Questionnaire ($p < 0.001$), the Goldberg Anxiety and Depression Scale ($p < 0.001$) as well as in functional capacity ($p < 0.001$). When comparing patients with heart failure with those without, no differences were found in sleep quality, quality of life, anxiety or depression. In conclusion, the completion of an 8-week cardiac rehabilitation program may improve, in the short term, the quality of sleep in patients with heart disease.

1. Introduction

Sleep disorders are very common in patients who have suffered an episode of acute coronary syndrome[1], with angina pectoris[2] and/or heart failure[3,4], as well as in patients who underwent cardiac surgery[4]. Several meta-analyses show that insomnia is a significant risk factor for cardiovascular diseases[6,7,8], therefore interventions addressing sleep quality could in turn also positively affect the risk of developing cardiovascular conditions[9]. More in particular, evidence suggests that not only insomnia, but also an average sleep duration inferior to 6 hours/night may constitute an important risk factor for obesity, type 2 diabetes, hypertension as well as cardiovascular diseases[10].

Exercise improves the quality of sleep in healthy adults with sleep problems[11] and may reduce obstructive apneas during sleep[12]. Other works showed how exercise may increase sleep duration[13], efficiency, as well as sleep-associated breathing disorders[14] in patients with heart failure. In addition, sleep disorders appear to correlate with depressive symptoms in patients undergoing cardiac rehabilitation[15]; on the other hand, a program focusing on cardiac exercise may improve both aspects in these patients[16,17]. Particularly, physical exercise may improve sleep quality by the means of improving the mood, modulating the activity of sympathetic autonomic nervous system, and the release of cytokines as well as increasing the energy demand, which may lead to weight loss, thus improving the occurrence of sleep apneas[18].

Therefore, the main objective of this study was to assess the impact of a cardiac rehabilitation program on sleep quality. The secondary objectives of this study were to assess changes in quality of life, anxiety, depression and functional capacity; additionally, eventual differences in response to treatment between patients with heart failure and those without were also evaluated.

2. Methods

2.1_Study design

Single group pretest – post-test design study, without control group.

2.2_Population and Subject Selection

All the patients who joined the cardiac rehabilitation program at the “Virgen de la Victoria Hospital” in Malaga from January 2016 to January 2018 were considered eligible for this study.

The study protocol complied with the Declaration of Helsinki and the ICH E6 Guideline for Good Clinical Practice. It was reviewed and accepted by the Malaga Interprovincial Ethics Committee of the Andalusian Regional Ministry of Health (code: 1691-N-17) and met the requirements of the Andalusian Health System Order SAS 3470/2009 and with Organic Law 15/1999 of 13 December on the Protection of Personal Data. All patients signed and personally dated an approved Informed Consent Form, after receiving detailed written and verbal information.

Patients were selected according to the following inclusion criteria: (1) diagnosis of either (any) ischaemic heart disease re-vascularized by angioplasty or by-pass surgery, heart failure or need of cardiac valve surgery (repair or replacement); (2) clinical stability; (3) absence of contraindications to a physical training program.The following exclusion criteria were considered: (1) lack of motivation / collaboration from the patient; (2) patient’s refusal to sign the informed consent or participate; (3) comorbidities affecting the musculoskeletal system (eg, neuromuscular disease); (4) travel-time from patient’s residence to the hospital > 60’; (5) severe heart failure (NYHA Class IV: “Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.”[19]).

2.3_Sample Size

A sample size was calculated. To achieve a power of 90% to detect differences, therefore rejecting the null hypothesis, by means of a bilateral Student's T-test for two related samples and taking into account previous studies[20], the significance level was set to 5%. Considering the mean PSQI of the group was initially equal to 9.40 (SD 4.1), and to detect a difference after the intervention equal or greater than 3 units, considered as the minimum clinically significant difference [21], at least 47 pairs of subjects were deemed necessary for the scopes of this study.

2.4_Intervention

The Multidisciplinary Cardiac Rehabilitation Program (MCRP) implemented was based on programmed physical training, health education and psychological counseling. The multidisciplinary team in charge of the MCRP included a cardiologist, two physical medicine and rehabilitation physician, a physiotherapist, a nurse

and a psychologist. Before starting the program, patients included underwent risk stratification (low, moderate and high) based on their level of ventricular dysfunction, onset of arrhythmias, signs and symptoms of ischaemia with exercise and METS achieved during the baseline cardiopulmonary exercise test (CPET), based on the guidelines of the Spanish Society of Cardiorespiratory Rehabilitation (SORECAR – Sociedad Española de Rehabilitación Cardiorespiratoria)[22]. Patients then underwent an adapted, individualized cardiac rehabilitation program for 8 weeks, with a frequency of 2 sessions/week for Low Risk patients and 3 sessions/week for Medium and High Risk ones.

Before each training session, the following variables were registered: blood pressure, heart rate, eventual presence of symptoms of chest pain, dyspnoea or discomfort preventing physical exercise. Each training session was structured as follows.

- Warm-up for 10', consisting in breathing exercises, gentle movements and stretching;
- Strength training exercises for 20', based on short-duration isometric and isotonic exercises. The resistance was set according to the 20 RM (repetition maximum) test; 3 sets of 10 repetitions were used for the upper limbs (biceps, deltoids, triceps and latissimus dorsi) and lower limbs (quadriceps). Rest intervals ranged 30” - 60” depending on the muscles trained and the individual physical condition.
- Aerobic training on a cycle ergometer or treadmill for 30'. The intensity was calculated according to the Karvonen formula (70% - 80% for the first and second month of the training regimen, respectively), based on the baseline data from the exercise test at the screening visit[23]. At the beginning, patients achieved 30’ at this intensity, dividing the session into 2 or more intervals, based on their individual tolerance, then gradually maintaining it for 30’ continuously.
- Relaxation for 10’, based on breathing exercises and stretching.

At the end of the training session, the same variables taken at the beginning were registered, thus verifying the return to the patient’s baseline status.

Health education was carried out 1/week by each professional of the team, to educate and motivate patients and caregivers in controlling the cardiovascular risk factors (CVRF). Groups focusing on nutrition and heart-healthy diet were implemented, as well as individualized advice for obese patients.

Psychotherapy was scheduled 1/week through group sessions, with the objective of improving the patient’s quality of life by controlling any emotional alteration secondary to the pathology and accepting the suffered pathological event.

2.5_Assessments

All patients were evaluated at the beginning and the end of the 2-month rehabilitation program by a specialist in Cardiology and one in Physical Medicine and Rehabilitation, who carried out a detailed anamnesis to verify their eventual comorbidities and CVRFs, physical examination, blood analyses, echocardiography (to assess ventricular function, according to the Left Ventricular Ejection Fraction, LVEF[24]) and Bruce protocol cycle-ergometer stress tests[25] (to assess patients’ functional capacity and individual

cardiovascular response to exercise). Sleep quality, quality of life, and presence of anxiety and/or depression were also enquired through validated questionnaires. The complete list of evaluations performed is detailed below.

2.5.1_Variables analyzed before the MCRP

- Demographic (age, sex).
- Body mass index (BMI).
- Systolic function (LVEF).
- Type of cardiac condition (revascularization, heart failure, heart valve surgery).
- Presence of other CVRFs (current or previously smoker, arterial hypertension, dyslipidemia, diabetes mellitus).

2.5.2_Variables analyzed before and after the MCRP

- *Sleep quality*. The Pittsburg Sleep Quality Index (PSQI) is a self-administered questionnaire assessessing the quality of sleep over a one-month interval. It contains a total of 19 items, grouped into 10 questions. The 19 items are combined in 7 areas with a corresponding score: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleep medication, daytime dysfunction. By adding up the scores of the different areas, a global score is obtained that allows discriminating "bad sleepers" (PSQI> 5) from "good sleepers" (PSQI $\leq$5)[26]. In our study we decided to consider a change of 3 or more points to indicate the minimum clinically significant difference, in accordance with Hughes[21].
- *Quality of life*. Quality of life was measured using the Spanish version of the Short Form Health Survey 36 (SF-36) Questionnaire, one of the most widely used instruments to measure health-related quality of life. It consists of 36 questions addressing different aspects of the daily life, grouped in 8 dimensions: physical function, physical role, bodily pain, general health, vitality, social function, emotional role, mental health. The SF-36 also includes a “transition item”, assessing change in general health status compared to the previous year; although not used to calculate any of the dimensions, it still provides useful information on the perceived change in recent health status[27].
- *Anxiety and depression*. The Goldberg Anxiety and Depression Scale (GADS), individually referred to as Goldberg Anxiety Scale (GAS) and Goldberg Depression Scale (GDS), is an 18-item self-report symptom inventory. Each subscale can give a maximum total of 9, with higher scores suggesting greater levels of symptomatology. Generally, anxiety score $\geq$ 5 or depression $\geq$2 shall be deemed as a 50% risk of a clinically important disturbance[28].
- *Functional capacity*. The functional capacity of the patient was expressed in metabolic equivalents of task (METS). A MET represents the amount of oxygen consumed while sitting at rest and is equal to 3.5 mL of oxygen per kilogram per minute. To obtain these values, the Bruce protocol with a cycle ergometer

was followed[25], roughly consisting in an exercise test in which the intensity is gradually increased at 3' intervals.

2.6_Data Analysis

Since all 240 patients who started the MCRP finished it, no missing data were registered.

Qualitative variables were described by frequency and percentages. The quantitative variables were represented by median, 25th percentile (p25) and 75th percentile (p75). The analyses were performed with RStudio v. 1.0.134. Non-parametric tests were used after verifying the normality and homoscedasticity criteria necessary to apply the parametric tests were not met. To assess the changes in the outcome measures median values before and after the treatment, the non-parametric Wilcoxon analysis was performed. To assess the correlation of the initial and final values of SF-36, GADS, and functional capacity with the PSQI, the Spearman Rho correlation coefficient was used. To assess which characteristics were independently correlated with the PSQI score, a linear regression model adjusted by the least squares method was performed. A comparison of baseline and final data, based on the presence or absence of heart failure, was made performing a bivariate analysis, using the Chi-square or the Mann-Whitney U test.

3. Results

3.1_Subjects included

A total of 240 patients were included in the study (male: female = 185:55, males = 77.1%), with a median age of 56 years [IQR: 51; 62] and a median BMI of 28.05 [IQR: 26.20; 31.34].

204 of them (85%) had undergone a revascularization procedure; of these, 174 (85.3%) had been treated with percutaneous transluminal coronary angioplasty (PTCA), 25 (12.3%) with aorto-coronary bypass and 5 (2.4%) with both. 50 patients (20.8%) were included in the program due to heart failure. 32 patients (13.3%) were included after having undergone surgery for valvular disease. **e-Table 1** shows the demographic and baseline characteristics of the participants.

91 patients (37.9%) carried out 2 sessions/week, while 149 (62.1%) managed to complete 3/week, based on risk stratification, as previously explained. As an exception, one patient with heart failure only participated twice a week due to logistic problems in granting his presence to the hospital for more than 2/week, despite his proven motivation in taking part to the program.

3.2_Characteristics of the patients at baseline and at the end of follow-up

Before starting the MCRP, 159 patients (66.2%) had poor sleep quality (PSQI > 5). 120 patients (50%) had anxiety disorder (GAS ≥ 5), while 168 (70.0%) had a depressive disorder (GDS ≥ 2). At the end of the

treatment, there were 135 patients with poor sleep quality (56.2%), those with an anxiety disorder were 85 (35.4%), and those with a depressive disorder were 143 (59.6%) (Figure 1).

Table 1 shows the baseline and post MCRP values for sleep quality (PSQI), quality of life (SF-36), anxiety and depression as well as functional capacity.

Table 1
Sleep quality, quality of life, anxiety, depression and functional capacity of subjects before and after the Multidisciplinary Cardiac Rehabilitation Program.

		PRE			POST				
	n	Median	p25	p75	Median	p25	p75	change	p
PSQI total	240	7.00	5.00	11.00	6.00	4.00	11.00	-1.00	**0.008**
PSQI Sleep quality	240	1.00	1.00	2.00	1.00	1.00	2.00	0.00	**0.023**
PSQI Latency	240	1.00	0.00	2.00	1.00	0.00	2.00	0.00	**0.023**
PSQI Sleep duration	240	1.00	0.00	2.00	1.00	0.00	2.00	0.00	0.403
PSQI Sleep efficiency	240	0.00	0.00	2.00	0.00	0.00	1.75	0.00	0.070
PSQI Sleep disturbancies	240	1.00	1.00	2.00	1.00	1.00	2.00	0.00	**0.033**
PSQI Sleep drug	240	0.00	0.00	1.00	0.00	0.00	2.00	0.00	0.499
PSQI Sleep dysfunction	240	1.00	0.00	1.00	1.00	0.00	1.00	0.00	**0.023**
SF-36 total	240	50.75	35.62	66.66	57.55	40.17	74.06	+6.75	**<0.001**
SF36 Physical function	240	67.50	46.25	83.75	70.00	50.00	85.00	+2.50	0.074
SF36 Physical role	240	0.00	0.00	75.00	25.00	0.00	100.00	+25.00	**0.003**
SF36 Bodily pain	240	57.50	32.50	80.00	67.50	36.87	90.00	+10.00	**0.008**
SF36 General health	240	45.00	35.00	55.00	45.00	35.00	60.00	0.00	0.709
SF36 Vitality	240	45.00	30.00	60.00	50.00	35.00	70.00	+5.00	**<0.001**
SF36 Social function	240	67.50	42.50	90.00	77.50	55.00	100.00	+10.00	**<0.001**
SF36 Emotional role	240	66.66	0.00	100.00	100.00	0.00	100.00	+33.34	**0.004**
SF36 Mental health	240	60.00	44.00	76.00	64.00	48.00	80.00	+4.00	**<0.001**

Baseline and final values and statistical significance are shown.

Abbreviations - PSQI: Pittsburgh Sleep Quality Index; SF-36: 36-Item Short Form Survey; GAS: Goldberg Anxiety Scale; GDS: Goldberg Depression Scale; METS: Metabolic equivalents of task.

		PRE			POST				
SF36 Health transition	240	37.50	25.00	75.00	50.00	25.00	75.00	+12.50	**0.004**
GAS	240	4.50	0.00	7.00	3.00	0.00	6.00	-1.50	**<0.001**
GDS	240	3.00	1.00	5.00	2.00	0.00	4.75	-1.00	**<0.001**
METS	240	7.00	5.30	8.77	8.15	6.60	10.20	+1.15	**<0.001**
Baseline and final values and statistical significance are shown.									
Abbreviations - PSQI: Pittsburgh Sleep Quality Index; SF-36: 36-Item Short Form Survey; GAS: Goldberg Anxiety Scale; GDS: Goldberg Depression Scale; METS: Metabolic equivalents of task.									

3.3_Changes in sleep quality

At the end of the program, the median overall score on the PSQI scale was reduced from 7 points to 6 points ($p = 0.008$). In particular, the subscales that registered a change were sleep quality ($p = 0.023$), sleep latency ($p = 0.023$), sleep disturbance ($p = 0.033$) and sleep dysfunction ($p = 0.023$) (Table 1). These changes have been statistically significant, but the improvement could not be considered clinically significant, since < 3 points[21]. A quantitative analysis of the number of patients who showed a clinically significant improvement was performed: out of the 240, 60 patients registered a clinically significant improvement (25,0%), 163 did not show any clinically significant change (67.9%), while 17 presented a clinically significant worsening (7.1%).

3.4_Changes in quality of life, anxiety and depression levels

At the end of the program, the median overall score of the SF36 questionnaire increased from 50.75 points to 57.55 ($p < 0.001$). The subscales that registered a change were physical role ($p = 0.003$), bodily pain ($p = 0.008$), vitality ($p < 0.001$), social function ($p < 0.001$), emotional role ($p = 0.004$), mental health ($p < 0.001$) and health transition ($p = 0.004$) (Table 1).

To quantify the size of the changes in the different subscales, reference can be made to the hypothetical standard changes considered by Wyrwich and colleagues[29]. According to their work, the changes obtained in the physical role (+25 points: moderate effect) and emotional role (+33.33: moderate effect) subscales may be considered clinically significant.

At the end of the program, both the scores in the anxiety (-1.50, $p < 0.001$) and the depression subscale (-1.00, $p < 0.001$) were decreased (Table 1).

3.5_Changes in functional capacity

At the end of the program, the median functional capacity improved from 7.00 to 8.15 METS (p <0.001) (Table 1).

3.6_Relationship between quality of sleep, quality of life, anxiety, depression and functional capacity

After evaluating the correlation at baseline of quality of life, anxiety, depression and functional capacity with the PQSI score, we found a negative correlation with the quality of life score (p = 0.005) and a positive correlation with both Goldberg scales (p < 0.001). However, these correlations were weak (ρ < 0.55), as evidenced in Table 2.

Table 2
Correlation coefficients of the initial and final values of SF-36, Goldberg Anxiety Scale, Goldberg Depression Scale and functional capacity with the Pittsburgh Sleep Quality Index.

	SF-36		**GAS**		**GDS**		**METS**	
	Spearman's correlation coefficient	p	Spearman's correlation coefficient	p	Spearman's correlation coefficient	p	Spearman's correlation coefficient	p
PRE	-0,485	**0,005**	0,529	**<0,001**	0,468	**<0,001**	-0,086	0,187
POST	-0,526	**<0,001**	0,512	**<0,001**	0,486	**<0,001**	-0,161	0,012

Abbreviations - SF-36: 36-Item Short Form Survey; GAS: Goldberg Anxiety Scale; GDS: Goldberg Depression Scale; METS: Metabolic equivalents of task.

After applying the multivariate linear regression model, we saw that only the quality of life and the GAS independently correlated with the PSQI score (Table 3). These correlations were those maintained after the conclusion of the program (Tables 2 and 3**)**.

Table 3
Linear correlation of the initial and final values of Pittsburgh Sleep Quality Index with respect to the SF-36 and Goldberg scales

	Baseline			Post MCRP		
	β	**95% CI**	**p**	**β**	**95% CI**	**p**
SF-36	-0.055	-0.085/-0.025	**<0.001**	-0.068	-0.098/-0.037	**<0.001**
GAS	0.457	0.233/0.682	**<0.001**	0.342	0.100/0.584	**0.006**
GDS	0.190	-0.109/0.490	0.212	0.141	-0.165/0.448	0.364
constant	8.351	6.104/10.59	**<0.001**	9.759	7.378/12.141	**<0.001**
R2	0.333			0.340		

Abbreviations - CI: confidence interval; MCRP: Multidisciplinary Cardiac Rehabilitation Program; SF-36: 36-Item Short Form Survey; GAS: Goldberg Anxiety Scale; GDS: Goldberg Depression Scale;

3.7_Differences in response to treatment between patients with and without heart failure

To assess the baseline status of patients with and without heart failure, a bivariate analysis of all baseline characteristics was performed between the two groups of patients. Patients with heart failure had a higher prevalence of moderate to severe systolic dysfunction and a lower baseline functional capacity (5.27 vs 7.10, $p < 0.001$); compared to those without heart failure. On the contrary, no statistically significant differences were found in sleep quality ($p = 0.909$), quality of life ($p = 0.135$), anxiety ($p = 0.092$) or depression ($p = 0.281$) (Table 4).

Table 4
Comparison of baseline data based on heart failure

	without HF		with HF		p
	N = 190	79.2%	N = 50	20.8%	
Demographics					
Male N | %	148	77.9	37	74.0	0.560
Age median | IQR	56.00	10.00	58.00	13.00	0.394
BMI median | IQR	27.80	5.13	28.50	5.55	0.438
Pittsburgh Sleep Quality Index					
PSQI median | IQR	7.00	6.25	7.00	6.25	0.909
Short Form-36 questionnaire					
SF-36 total score median| IQR	49.96	33.93	54.10	23.52	0.135
Goldberg scales Median | IQR					
GAS median | IQR	5.00	5.00	3.00	7.00	0.092
GDS median | IQR	3.00	4.00	3.00	3.25	0.281
METS median | IQR	7.10	3.30	5.27	2.04	**< 0.001**
Systolic Function*					
Normal function n | %	110	57.9	7	14.0	**< 0.001**
Mild dysfunction n | %	56	29.5	6	12.0	
Moderate dysfunction n | %	17	8.9	16	32.0	
Severe dysfunction n | %	7	3.7	21	42.0	

Abbreviations - HF: heart failure; IQR: interquartile range; BMI: body mass index; PSQI: Pittsburgh Sleep Quality Index; SF-36: Short Form-36 questionnaire; GAS: Goldberg Anxiety Scale; GDS: Goldberg Depression Scale; METS: metabolic equivalents of task

*Systolic Function classification according to the Left Ventricular Ejection Fraction (LVEF), as reported in *Lang RM et al., 2015 – Normal: LVEF 50–70% (midpoint 60%); Mild dysfunction = LVEF 40–49% (midpoint 45%); Moderate dysfunction = LVEF 30–39% (midpoint 35%); Severe dysfunction = LVEF less than 30%*

Comparing the characteristics of the two groups at the end of program, patients with heart failure finished the program with a better score on the SF-36 questionnaire for quality of life (66.72 vs 54.94, p = 0.015). As for METS values, patients with heart failure had a lower score at the end of the program than patients without heart failure (5.68 vs 9.10, p < 0.001) (Table 5).

Table 5
Comparison of final data based on heart failure

	without HF		**with HF**		
	N = 190	79.2%	N = 50	20.8%	
	Median	**IQR**	**Median**	**IQR**	**p**
PSQI	6.00	7.00	6.00	4.25	0.288
SF 36 total score	54.94	32.43	66.72	24.24	**0.015**
SF36 Physical function	70.00	35.00	60.00	26.25	**0.032**
SF36 Physical role	0.00	75.00	50.00	100.00	**0.035**
SF36 Bodily pain	67.50	55.00	78.75	55.00	0.072
SF36 General health	47.50	25.00	45.00	20.00	0.518
SF36 Vitality	45.00	35.00	52.50	26.25	0.065
SF36 Social function	72.50	45.00	87.50	45.00	0.311
SF36 Emotional role	66.66	100.00	100.00	36.30	**0.002**
SF36 Mental health	64.00	32.00	76.00	37.00	**0.026**
SF36 Health transition	25.00	50.00	75.00	50.00	**<0.001**
GAS	3.00	6.00	2.50	4.00	0.085
GDS	2.00	5.00	1.50	3.25	0.061
METS	9.10	3.23	5.68	2.43	**<0.001**

Abbreviations - HF: heart failure; IQR: interquartile range; PSQI: Pittsburgh Sleep Quality Index; SF-36: Short Form-36 questionnaire; GAS: Goldberg Anxiety Scale; GDS: Goldberg Depression Scale; METS: metabolic equivalents of task

Evaluating the response to treatment between patients with and without heart failure heart failure, differences in the improvement in funcional capacity could also be observed, greater in patients without heart failure (1.00 vs 0.25, p = 0.005). As for the median changes in sleep quality, quality of life, anxiety and depression, no statistically significant differences could be observed (Table 6).

Table 6
Comparison of differences between baseline and final values based on heart failure

	Without HF		With HF		
	N = 190	79.2%	N = 50	20.8%	
	Median	**IQR**	**Median**	**IQR**	**p**
PSQI	0.00	4.00	-1.00	4.00	0.183
SF 36 total	3.39	15.07	4.84	20.02	0.427
GAS	0.00	2.00	0.00	2.25	0.430
GDS	0.00	1.00	0.00	2.00	0.986
METS	1.00	2.60	0.25	1.97	**0.005**

Abbreviations - HF: heart failure; IQR: interquartile range; PSQI: Pittsburgh Sleep Quality Index; SF-36: Short Form-36 questionnaire; GAS: Goldberg Anxiety Scale; GDS: Goldberg Depression Scale; METS: metabolic equivalents of task

3.8_Differences in response to treatment between patients who have undergone 2/week sessions and those who have undergone 3/week sessions

In our study, low-risk patients underwent 2 sessions/week, while medium and high-risk patients had 3 sessions/week. The only exception was represented by a patient from the heart failure group who followed the 2/week program due to problems getting to the hospital. To verify whether this may bias the analysis, the results in median changes obtained for all the variables have been compared, showing no differences when performing 2 or 3 weekly treatments ($p > 0.05$).

3.9_Monitoring for complications

During the treatment sessions, no major complications of traumatic, orthopedic or cardiovascular nature have been observed, that would imply a suspension of the training program. 13 patients experienced an episode of angina pectoris and 1 an episode of supraventricular tachycardia. These complications were resolved after medical evaluation, without the need of suspending the cardiac rehabilitation program.

4. Discussion

The prevalence of poor sleep quality in our sample of patients at the beginning of the MCRP was equal to 66.2%, confirming the high frequency of this finding among patients who attend a cardiac rehabilitation program. Our observations are in agreement with those of other authors. Duarte et al. observed a 76% prevalence of poor sleep quality in a sample of 101 patients included in a cardiac rehabilitation program[15,20].

Banack et al., in a sample of 259 patients, detected poor sleep quality in 52% of the subjects, with a higher prevalence in subjects with depressive symptoms than in those without (77% vs 31%)[15]. Our study suggests that carrying out an 8-week cardiac rehabilitation program may improve the quality of sleep in patients with heart disease in the short term, but these changes are not clinically relevant. These results are consistent with those obtained by other authors in previous studies. Duarte and colleagues observed an improvement in the PSQI of 2.4 points after an intensive cardiac rehabilitation program (3 hours /day, 5 or 6 days a week) carried out in patients admitted for 4 weeks[20]. The fact that the change obtained by these authors was greater than the one obtained in our sample could depend on the higher volumes and frequencies the training program was implemented at; however, neither in this study the magnitude of the changes reached the minimum clinically significant difference. Similarly, Suna and colleagues, in a sample of 44 patients recently treated for acute heart failure, showed that a physical exercise program carried out twice a week for a total of 12 weeks can improve the quality of sleep in these patients, but neither in this case the changes in the PSQI reached the minimum significant difference[16].

The results obtained appear similar to those obtained in healthy subjects in whom it has been shown that an aerobic activity program can improve the quality of sleep. However, while in some studies the improvement in the PSQI has been equal to or greater than 3 points[30,31], in others the minimum clinically significant difference was not reached[32,33,34,35]. These differences may be due to the heterogeneity of the populations studied and the chosen exercise modalities and caution should therefore be paid when interpreting and comparing the results obtained in different studies.

Our study demonstrated the positive impact of a cardiac rehabilitation program on the quality of life perceived by the participant patients and measured through the SF-36, with particular focus on the physical and emotional role dimensions. These results confirm those obtained by Duarte et al. who observed an improvement in all the 8 dimensions of the SF-36 as well as in the global score[20]. Additionally, our study evidenced a weak positive correlation between quality of sleep and quality of life.

A high prevalence of anxiety and depressive disorders was observed in our population, together with their association with poor sleep quality. This has previously been described in patients with heart disease[20]. Other works[15,16] also evidenced how poor sleep quality may have a strong correlation with depressive symptoms in a cohort of patients included in a Cardiac Rehabilitation program. As regards our study, an improvement in these very aspects was observed in patients who attended our MCRP. These results confirm those obtained in previous studies[20,36,37,38]. Also, Abdelbasset and colleagues have recently shown how aerobic exercise may improve depressive symptoms in patients with heart failure [39].

Although the high prevalence of sleep disorders in patients with heart failure is well documented and studied, in our sample no differences were observed between patients with heart failure and those without. This may be due to the fact that patients with NYHA stage IV heart failure were not included in our study. In fact, as Suna and colleagues previously pointed out[16], patients with severe heart failure (NIHA IV) have a much higher prevalence of poor sleep quality when compared to class I-III.

Evaluating the response to treatment between patients with and without heart failure, no differences emerged as regards the changes in quality of sleep, quality of life, anxiety and depression; as for the functional capacity, patients with heart failure had a lower baseline value, which did not improve as much as that of patients without heart failure. This result may be due to the fact that patients with heart failure exhibit a decrease in cardiac output during exercise and, as long as cardiac dysfunction associated with heart failure persists, it is not possible to have a normalization of maximum oxygen consumption[40].

5. Limitations

The first methodological limitation of this study is the single group pretest-posttest design, together with the absence of a control group. From our point of view, the existing evidence[41,42] of the benefits that a cardiac rehabilitation program would carry for every patient included in the study, would make ethically unacceptable to refrain from providing an adequate intervention to all of the participants. Secondly, the number of sessions carried out was different among the patients in our study, since low-risk patients had 2 sessions a week, while medium to high-risk patients had 3 sessions a week. This adjustment of the treatment, based on individual patient's risk, allowed us to increase the number of participants to our cardiac rehabilitation program. On the other hand, to avoid this choice could introduce some bias in the analyses, the results obtained for all the variables have been compared, showing no differences could be observed in said changes, either when performing 2 or 3 weekly treatments.

6. Conclusion

Patients who attend a cardiac rehabilitation program tend to have a high prevalence of poor sleep quality, which in turn may have a weak association with quality of life, anxiety and depression. Performing an 8-week cardiac rehabilitation program can improve the quality of sleep and quality of life in patients with heart disease in the short term, while decreasing their levels of anxiety and depression. However, the changes obtained in sleep quality were not clinically relevant. Also, no statistically significant differences were found in sleep quality when comparing patients with heart failure (NYHA stages I-III) with those without it. Likewise, the response to treatment in patients with sleep problems, was no different when stratifying between patients with and without heart failure.

In our opinion, the fact the changes obtained were not clinically relevant is not surprising, as the poor quality of sleep can depend on a combination of predisposing, precipitating and perpetuating factors that should be evaluated in each patient, in order to propose an individualized treatment plan[43]. The importance of these factors could explain the lack of significant differences found when comparing the quality of sleep in patients with and without heart failure. In fact, the results of our study suggest that, despite patients with heart failure may frequently present specific symptoms related to poor sleep quality (like cough, orthopnea, paroxysmal nocturnal dyspnea and nocturia)[44], in patients with NYHA I-III the impact of these factors does not represent the major determinant to explain the high prevalence of sleep disorders, the etiology of which must necessarily be considered multifactorial. Therefore, current clinical practice guides accordingly suggest that an "ideal" treatment plan for sleep disorders should include the assessment and treatment of those comorbidities currently considered to be related to poor sleep quality, this in association with cognitive-

behavioral therapy and the optimization of pharmacological therapy[45]. Further studies will be needed to evaluate the differences in sleep quality between patients with heart disease with and without heart failure, possibly including patients with NIHA-IV, and to determine what would be the best treatment to improve sleep quality in these patients

Abbreviations

BMI: Body mass index

CPET: Cardiopulmonary Exercise Test

CVRF: Cardiovascular Risk Factors
GAS: Goldberg Anxiety Scale

GADS: Goldberg Anxiety and Depression Scale

GDS: Goldberg Depression Scale

IQR: Interquartile Range

LVEF: Left Ventricular Ejection Fraction

MCRP: Multidisciplinary Cardiac Rehabilitation Program

METS: metabolic equivalents of task

NYHA: New York Heart Association

PSQI: Pittsburgh Sleep Quality Index

PTCA: percutaneous transluminal coronary angioplasty

p25: 25th percentile

p75: 75th percentile

RM: repetition maximum

SD: standard deviation

SF-36: Short Form Health Survey 36

SORECAR: Sociedad Española de Rehabilitación Cardiorrespiratoria

Declarations

Author Contributions:

F.L.R. - Conceptualization, investigation, original draft writing.

A.M.G.G. - Conceptualization, investigation, review and editing.

R.C.C. - Investigation.

M.J.R.B. - Investigation.

A.M.B. - Investigation.

P.S.S. - Review and editing.

M.J.N. - Review and editing.

All authors have read and agreed to the published version of the manuscript.

Additional information

Funding: This research received no external funding.

Conflicts of Interest: The authors declare no conflict of interest.

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Figures

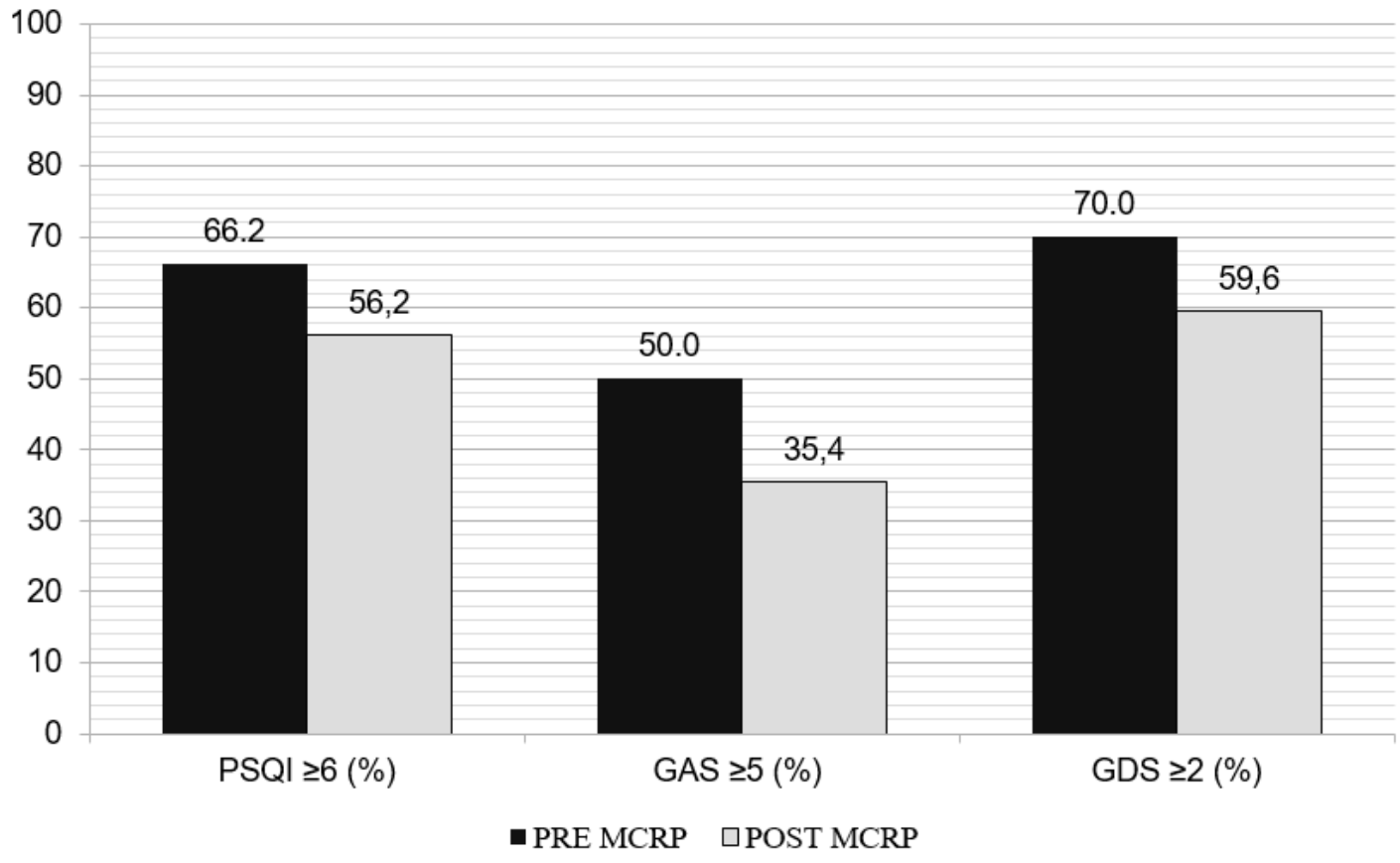

Figure 1

Prevalence (%) of poor sleep quality (PSQI ≥6), anxiety (GAS ≥5), and depression (GDS ≥ 2) before and after the Multidisciplinary Cardiac Rehabilitation Program *Abbreviations - PSQI: Pittsburgh Sleep Quality Index;*

GAS: Goldberg Anxiety Scale; GDS: Goldberg Depression Scale; MCRP: Multidisciplinary Cardiac Rehabilitation Program

Supplementary Files

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