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Short-term effects of a multi-disciplinary cardiac rehabilitation programme on psychological well-being, exercise capacity and weight in a sample of obese in-patients with coronary heart disease: A practice-level study

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Given that many patients referred to cardiac rehabilitation (CR) are obese, diet therapy, exercise training, nutritional and psychological counselling for both obesity and psychological distress should be included as important components in all CR programmes. In this practice-level, observational study we evaluated the short-term within-group effects of a four-week multi-factorial inpatient CR programme specifically addressed to weight loss, fitness improvement and psychological health increase on 176 obese in-patients with coronary heart disease (CHD). Outcome measures were exercise capacity measured with estimated metabolic equivalents (METs), body mass index (BMI) and psychological well-being (PGWBI). Results show statistically significant improvements in all the PGWBI sub-scales and total score, except in general health ($p = 0.393$). No moderation effects were found for BMI class, age, diabetes and ejection fraction (EF). METs significantly increased by 30.3% ($p < 0.001$) and BMI decreased by 1.37 points ($p < 0.001$). Significant correlations were found between BMI and weight reductions with PGWBI anxiety and total score improvements. This multi-disciplinary CR programme including diet therapy, exercise training and psychological counselling provides indication for short-term within-group effectiveness on functional exercise capacity, BMI and PGWBI in a sample of obese in-patients with CHD. However, controlled studies are needed to corroborate the results we found.

Keywords: cardiac rehabilitation; psychological well-being; exercise capacity; obesity; weight loss

Introduction

Over the last century the overweight and obese population expanded worldwide (WHO, 2006). Epidemiological evidence shows that obesity increases the risk of early death (Flegal, Graubard, Williamson, & Gail, 2005; Pischon et al., 2008;

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Whitlock et al., 2009) and leads to serious chronic diseases, such as diabetes, musculoskeletal disorders, some cancers and especially cardiovascular disease (CVD) (Lavie, Milani, & Ventura, 2009; WHO, 2006).

Obesity has a major negative impact on the cardiovascular system both through the proximal associations with several coronary risk factors (e.g. hypertension, hyperlipidaemia, insulin resistance, clotting abnormalities, sedentary life style, depression) and also through its adverse effects on the cardiovascular structure (Lavie, Milani, Artham, Patel, & Ventura, 2009; Savage & Ades, 2006; Vanhecke et al., 2009). Obesity is thus widely considered as a major risk factor for many CVDs such as heart failure (HF), coronary heart disease (CHD), sudden cardiac death and atrial fibrillation (Dela Cruz & Matthay, 2009; Lavie et al., 2009).

There is also increasing evidence that obesity is associated with poor health-related quality of life (HRQoL) (Kinge & Morris, 2010). In large part, the lower QoL perceived by obese individuals is due to worse physical functioning, role limitations due to physical problems and bodily pain (Kushner & Foster, 2000). However, obesity may create also a psychological burden on the individual and increase the risk of major psychopathological disorders, such as depression (Fabricatore & Wadden, 2004; Luppino et al., 2010). Indeed, psychological vulnerabilities among the obese are consistently reported in literature and data show that many obese individuals suffer from negative self-perceptions, low self-esteem, body-image disturbances, sexual problems, less interpersonal contact and poorer social skills, all which may increase the risk for psychological disorders (Davin & Taylor, 2009). In this regard, numerous studies indicate that psychological distress is a significant risk factor for CVD and adversely affects recovery following coronary events (Rozanski, Blumenthal, & Kaplan, 1999).

The strong association between obesity and CVD is well depicted in the higher rates of overweight and obesity in the coronary population than the general non-clinical population (Savage, Lee, Harvey-Berino, Brochu, & Ades, 2002). Notably, among patients with CVD, 70% to 88% are overweight and 36% to 53% are obese (Bader, Maguire, Spahn, O'Malley, & Balady, 2001; Brochu, Poehlman, & Ades, 2000). Furthermore, nearly 80% of patients attending cardiac rehabilitation (CR) are overweight or obese (Bader et al., 2001; Brochu et al., 2000; Sierra-Johnson, Wright, Lopez-Jimenez, & Allison, 2005). Hence, CR programmes have recently begun to include interventions specifically addressed to weight loss, such as high caloric energy expenditure exercise training, diet therapy and cognitive-behavioural treatment (Ades et al., 2009; Harvey-Berino, 1998; Savage & Ades, 2006). However, the "obesity paradox" has created controversy regarding the benefit of weight reduction for patients with established CVD. Several studies have suggested that obese patients with CHD, HF and hypertension have a better prognosis than lean patients (Lavie, Milani, & Ventura, 2007, 2009) but some other studies have shown the safety and efficacy of weight loss for patients with CHD. For example, in a recent study of 530 patients, Lavie et al. noted significant improvements in cardiovascular risk factors and a trend of lower mortality among overweight and obese CHD patients who lost weight (Lavie et al., 2009).

Furthermore, the few studies that examined the effect of CR on weight and HRQoL have shown that decreases in percent body fat and BMI came also with significant improvements in QoL and psychological health (Gunstad et al., 2007; Lavie & Milani, 1997; Lavie, Morshedi-Meibodi, & Milani, 2008; Milani, Lavie, & Cassidy, 1996; Savage, et al., 2002; Yu, Li, Ho, & Lau, 2003). However, all these studies were done in America where CR generally lasts from two to four months and is outpatient (Jobin, 2005). Differently, in many European countries CR is done in short, intensive residential programmes (Benzer et al., 2007; Boesch et al., 2005). Furthermore, even if such studies investigated the effects of CR on weight, QoL and many other outcomes, data were examined separately and no correlations were studied between changes.

The primary aim of this observational study is thus to evaluate for the first time the short-term within-group effects of a four-week inpatient CR programme involving diet therapy, exercise training, nutritional and psychological counselling on weight, exercise capacity measured with estimated Metabolic Equivalents (METs) and psychological well-being (PGWBI) in a sample of obese in-patients with CHD. The second aim is to explore relationships between changes in PGWBI and changes in BMI, weight and METs.

Methods

This observational study has a pre-post design without control group. The local Institutional Review Board approved both the research aims and the informed consent form. Given that no experimental manipulation was planned, an ethical approval was not needed.

Procedure and participants

CHD patients referred to the CR unit do not pay for the treatment because the National Sanitary System in Italy covers all hospital charges. The CR programme lasts one month and patients live in the hospital for the whole period. Along with the standard informed consent all CHD patients who enter CR have to sign, patients who were admitted to the CR unit between March and September 2009 were also informed about the study protocol and those ones who gave their consent for anonymous data collection, analysis and publication were retained as eligible. According to inclusion and exclusion criteria 176 white in-patients (63 females – 30%) with obesity (defined as a body mass index (BMI) $\geq$30 kg/m^2) and CHD were selected and their data were collected from individual records stored in a secured digital database. CHD was defined as a history of at least one of the following: myocardial infarction, coronary artery by-pass grafting (CABG), coronary angioplasty (PTCA). Patients with recent (less than four weeks) myocardial infarction, CABG or PTCA were excluded. Time from cardiac disease onset was not recorded in the database and no attempt was made to get it from the medical records.

A full risk-factor and psychosocial assessment was conducted both at entry and at discharge from CR. Baseline body weight was measured at admission to CR in the morning after overnight fasting and after voiding. Weight was further measured weekly and at discharge from CR. For analytical purposes, patients were divided in three categories of BMI based on the WHO classification of obesity: Class I (BMI 30–34.9; $n = 64$), Class II (BMI 35–39.9; $n = 81$) and Class III (BMI $\geq$ 40; $n = 67$). They were also divided in tertiles of age: 50.6 $\pm$ 6.4 years (younger group), 60.9 $\pm$ 2.1 years (middle-aged group) and 70.8 $\pm$ 3.9 years (older group), with ranges 32–57, 58–65 and 66–85, respectively. Furthermore, patients were divided on the basis of ejection fraction (EF) in normal group (EF > 55%), mildly impaired group (EF 40–55%) and impaired group (EF < 40%). EF is defined by the ratio of the difference between the end-diastolic volume and the end-systolic volume to the end diastolic volume and represents a widely utilised index of left ventricular function.

CR programme

The CR programme was multi-factorial in that it included many components such as exercise training, hypo-caloric diet, nutritional and psychological counselling, and CVD risk factors management.

Physical activity programme

The programme entailed daily sessions (six days a week) of aerobic activity that included 30-min sessions of cycloergometer and walking at low speed for about 45 min (3–4 METs). Every week the activity level was checked and the workload was redefined on the basis of the attained results.

Hypo-caloric diet

Diet was assigned after a personal interview with the patient. The caloric intake was set at approximately 80% of resting energy expenditure (REE). Each week, on the basis of the amount of weight loss, the diet was checked and adapted. The diet derived 50% of energy from carbohydrates, 30% from lipids, and 20% from proteins. In our population, dietary therapy provided 1579 Kcal/day on average.

Nutritional counselling

Nutritional programme consisted of both individual sessions (dietary assessment, evaluation of nutrient intake and adequacy, nutritional status, anthropometric, eating patterns, history of overweight) and hourly group sessions twice a week (10–20 participants) including: information on obesity and related health risks, healthy eating in general, general nutrition and core food groups.

Psychological counselling

The psychological intervention was cognitive-behavioural oriented and targeted both obesity and psychological distress. As regards the treatment of obesity, the intervention was mainly based on the principles of the new cognitive-behavioural approach for the treatment of obesity developed by Cooper and Fairburn (Cooper & Fairburn, 2001). Thus the goal was not only to teach the cognitive-behavioural techniques for weight loss but to encourage the acquisition of weight maintenance skills. The techniques taught included self-monitoring of eating and exercise behaviours, stimulus control, problem solving, assertiveness training, development of short- and long-term goals, development of cognitive strategies and relapse prevention. With respect to psychological distress such as depression and anxiety problems, the psychological intervention provided support and made use of counselling techniques for problem solving and crisis management.

The psychological sessions were both individual and group-based. The individual work consisted in bi-weekly psychological consultations scheduled along the four-week duration of CR (eight sessions in total). On the other hand, group sessions (10–20 participants) were scheduled hourly once a week (four in total) and provided impersonal education about psychosocial risk factors and specific training on assertive, motivational, coping and stress management skills, according to Italian and European guidelines for psychological interventions in CR (Graham et al., 2007; Sommaruga et al., 2003).

Instrumental evaluations

Exercise stress test was performed on the second day of hospital stay and was repeated again at the end of CR. Patients were taking their usual medications and had a light breakfast before the test. We utilised a Marquette series 2000 motorised treadmill together with a Marquette Max Personal ECG instrumentation. We used an individualised ramp protocol that has been described before (Ashley, Myers, & Froelicher, 2000). Reasons for test termination were limiting symptoms (fatigue, angina, dyspnoea, muscular pain), abnormal ECG, abnormal blood pressure. We measured the intensity of exercise using METs. 1 MET represents the amount of oxygen consumed at rest and is equal to approximately 3.5 ml O_2 kg^{-1} min^{-1}. We derived our estimate of METs from treadmill speed and grade.

All patients underwent an echocardiography examination for the calculation of EF. Two-dimensional and M-mode echocardiography parameters were obtained with a Vingmed System 5 instrument (GE Medical Systems, Milwaukee, WI, USA). Parasternal long- and short-axis views and apical 2- and 4-chamber views were used for evaluating left ventricular function. Depending on the quality of images, EF was calculated by two-dimensional method (i.e. Simpson) or M-mode method (i.e. Teichholtz) (Otterstad, Froeland, St John Sutton, & Holme, 1997; Sahn, DeMaria, Kisslo, & Weyman, 1978).

Psychological well-being measure

The Psychological General Well-Being Inventory (PGWBI) was the main outcome measure of the present study and was used to measure psychological health (Dupuy, 1984). The responses to 22 questions are arranged in six sub-scales: anxiety, depression, positive well-being, self-control, general health and vitality. Higher scores indicate better health. The questionnaire has already been used in cardiac patients in order to evaluate improvement in QoL during 10 years after CABG (Herlitz et al., 2003). The Italian version of the questionnaire has been recently validated (Grossi, Mosconi, & Groth, 2002). PGWBI was administered at admission and at discharge.

Statistical analysis

One-way ANOVA or the t-tests were used to identify baseline differences among sub-groups. Mann–Whitney test with Monte Carlo p estimation was used for gender and EF-groups given the unequal group sizes. Pair-wise t-tests were used to examine changes between baseline and completion of CR. One-way ANOVA was used to compare gain scores (post-pre) in PGWBI scales, functional work capacity (METs) and weight (BMI) across sub-groups. Non-parametric analysis with Monte Carlo p estimation was used when parametric assumptions were not met (i.e. homogeneity of variance) or group sizes were unequal (for gender and EF-groups). ANCOVA adjusting for baseline scores were used to compare gain scores across sub-groups when significant differences were found at baseline. Post hoc tests with Bonferroni adjustment were used to clarify all significant omnibus parametric tests. Exact chi-square was used for categorical variables. Cohen's d effect sizes were calculated for each PGWBI scale, taking baseline scores as the control group. Pearson correlations were calculated between changes in each PGWBI scales and changes in BMI and METs.

Data were analysed with SPSS 12 (SPSS, Chicago, IL, USA).

Results

Baseline characteristics

Demographic and clinical characteristics of participants are summarised in Table 1. Baseline comparisons showed that males had higher median scores on the PGWBI total score, depression, positive well-being and vitality ($p = 0.007$, $p = 0.028$, $p = 0.023$ $p = 0.003$ and $p = 0.013$, respectively). Furthermore, METs were lower in patients with higher BMI ($p < 0.001$), in older patients ($p < 0.001$) and in females ($p < 0.001$).

Changes in psychological well-being

Participants significantly improved from entry to discharge in all the PGWBI sub-scales and total score (all $p < 0.001$), except in general health ($p = 0.393$). Within-group effect sizes are significant and vary from small to medium according to Cohen's classification (Cohen, 1998) (Table 2). Unadjusted comparisons across sub-groups revealed no significant differences in gain scores.

Changes in METs

Exercise capacity significantly improved from entry to discharge. METs increased by 30.3% $\pm$ 44.4 ($p < 0.001$) (Table 3). Unadjusted comparisons across sub-groups revealed no significant difference in gain scores. Adjusting for baseline scores

Table 1. Demographic and medical characteristics.

Entry data	Total (N=176)
Females	52 (29.5%)
Age (years)	62.2 $\pm$ 9.4 (range 40.0–84.7)
Ejection fraction %	51 $\pm$ 10 (range 20–75)
$>$55%	82 (46.6%)
55–40%	58 (33%)
$<$40%	36 (20.5%)
Hypertension	150 (85.2%)
Diabetes	85 (48.3%)
Weight (kg)	106.2 $\pm$ 17.6 (range 66.7–167.5)
BMI	38.1 $\pm$ 5.1 (range 30.4–55.8)
Smoking	
Current smoker	23 (13.1%)
Ex-smoker	100 (56.8%)

Note: BMI, body mass index.

Table 2. Baseline and post-treatment means, standard deviations, gain scores and effect sizes for each PGWBI scale in cardiac rehabilitation participants.

		Baseline		At completion				
Variables	*N*	Mean	S.D.	Mean	S.D.	p*	Gain score**	Effect size (C.I.)
Total	176	70.82	18.17	81.57	15.51	<0.001	10.75	0.64 (0.42–0.85)
Anxiety	176	17.71	4.77	20.20	4.02	<0.001	2.49	0.56 (0.35–0.78)
Depression	176	11.73	3.06	12.66	2.35	<0.001	0.93	0.34 (0.23–0.55)
Positive well-being	176	11.25	4.29	13.91	3.59	<0.001	2.66	0.67 (0.46–0.89)
Self-control	176	10.79	3.33	11.97	2.72	<0.001	1.18	0.39 (0.18–0.6)
General health	176	10.01	3.32	9.77	2.87	0.393	−0.24	−0.08 (−0.29 to 0.13)
Vitality	176	10.97	3.89	13.18	3.49	<0.001	2.20	0.60 (0.38–0.81)

Notes: *Pair-wise t-test on repeated measures.
**Post-treatment minus baseline scores.

Table 3. Baseline and post-treatment means, standard deviations, gain scores and effect sizes for attained METs and BMI in cardiac rehabilitation participants.

		Baseline		At completion				
Variables	*N*	Mean	S.D.	Mean	S.D.	p*	Gain score**	Effect size (C.I.)
METs	176	5.59	2.52	6.76	2.57	<0.001	1.17	0.46 (0.25–0.67)
BMI	176	38.07	5.11	36.69	0.37	<0.001	−1.38	−0.38 (−0.17 to −0.59)

Notes: METs, metabolic equivalent; BMI, body mass index.
*Pair-wise t-test
**Post-treatment minus baseline scores.

(only for comparisons across BMI classes and age-groups), we found that METs improvement was lower in the older patients (omnibus $p = 0.002$).

Weight loss

Participants lost 3.9 ± 1.8 kg ($p < 0.001$) and BMI decreased by 1.37 ± 0.63 points, i.e. by $3.6 \pm 1.6\%$. Unadjusted comparisons revealed a higher BMI reduction in BMI class III ($p = 0.001$), in the younger patients ($p = 0.016$) and in males ($p = 0.007$). Younger patients significantly lost more weight even after adjusting for baseline BMI scores ($p = 0.015$).

Correlations between changes

Statistically significant negative correlations were found between BMI and weight reductions with anxiety and total score improvements ($r = -0.14$, $p = 0.045$ and $r = -0.153$, $p = 0.042$, respectively). These correlations remained significant after controlling for BMI class, gender, age, diabetes and EF. In addition, patients who lost 5% or more of their baseline weight showed higher improvements in PGWBI total score at the end of CR ($p = 0.041$).

Discussion

We described the short-term effects of a four-week residential CR programme including exercise training, hypo-caloric diet, nutritional and psychological counselling on PGWBI, exercise capacity and weight in a sample of obese CHD inpatients. To the best of our knowledge, no previous study evaluated the effects of such a short, European-like residential and multi-factorial CR programme on the PGWBI of obese CHD patients. Furthermore, no previous study investigated any correlation between weight loss and psychological health improvement in such a population. Although it has been observed that weight loss from CR comes with positive changes in HRQoL (Lavie et al., 2008), no attempt was made to establish a correlation between the two outcomes. In this regard, we argue that observing a significant "mean" weight loss along with a significant "mean" improvement in HRQoL does not indicate that the two outcomes are related.

We observed small to medium improvements in almost all the PGWBI scales. The greatest effect sizes was found for the total score ($d = 0.64$) and this improvement is both statistically and clinically significant. Indeed, according to the staging scale suggested by the author (Dupuy, 1984), the baseline mean total score (70.8) was near the upper bound of the moderate distress stage, while the mean score we found at end of CR (81.6) was located in the "no distress" zone. With respect to the PGWBI sub-scales, the greatest effect sizes were found respectively for positive well-being ($d = 0.67$), vitality ($d = 0.60$) and anxiety ($d = 0.56$). The only PGWBI scale that did show a statistically significant improvement was general health. This result was expected because this scale was constructed to measure specifically the physical features of general health (Dupuy, 1984). Indeed, even if CR was effective in reducing weight and in increasing exercise capacity, CVD and obesity remained major concerns for our patients.

Weight decreased by 3.6% and METs improved by 30.3% in our sample. Weight loss, despite being statistically significant, might be considered modest in relation to current clinical guidelines (NIH, 1998). However, as already argued by Bader et al. (2001) and Gondoni et al. (2008), improvement in exercise capacity may be considered of greater importance.

We investigated also the moderating effect of some demographic and clinical factors such as gender, age, BMI classes, diabetes and EF on baseline and gain scores. We found that obese males reported better scores than obese females in many PGWBI scales. This result is in accordance with previous findings on the significant predictors of psychological distress in the obese, among which being female is the most important (Fabricatore & Wadden, 2004), but it is also in contrast with a recent study that did not find any significant difference between CHD women and men on psychological measures at baseline of CR (Barth et al., 2009). However, in this latter study, the obesity rate was very low (23% in both groups) and results are thus not comparable. We found also that severity of obesity, age, diabetes and EF had no differential influence on baseline PGWBI and that psychological health improvements observed at discharge were not moderated by any of them. Furthermore, in baseline adjusted analyses BMI-class moderated neither weight reduction nor METs improvement. Differently, in the same adjusted analyses, age-groups moderated both weight reduction and METs improvement, with the younger patients showing better results. Similar results were found also in a previous study whose primary aim was to compare the benefits of CR between young and old CHD patients (Lavie & Milani, 2006). Notably, the CR programme evaluated in that study is very different from the one described in this article in that the former was outpatient and lasted for a longer period (12 weeks).

The structure and delivery of CR programmes varies widely between Western countries (Benzer et al., 2007). In Italy, the common CR structure and delivery system is a three–four-week inpatient residential programme. The fact that CHD patients referred to this kind of CR live at the rehabilitation centre virtually ensures 100% compliance with exercise, diet and counselling sessions, in addition to providing an environment of clinical, social and peer group support (Boesch et al., 2005). It is thus not known whether the present results are comparable to more traditional, outpatient programmes in the United States and elsewhere.

Finally, an interesting statistically significant correlation emerged between weight loss and psychological health improvement and this relation resulted statistically significant independently of gender, BMI, age, diabetes and EF. However, no causal relationship can be established because there was no experimental manipulation in the present study. Furthermore, CR included individual and group-based psychological interventions that directly addressed psychological distress. This means that many factors could explain the significant association between weight loss and PGWBI improvement, even an increased physical activity and a reduced disease severity. However, we did not find any statistically significant correlation between METs increase and mental health improvement, and no significant change in perceived general health was evident.

No previous study evaluated the effects of CR delivered to CHD obese patients on their psychological health measured with the PGWBI. Furthermore, few studies have assessed the impact of CR on obese patients' psychological health and none of them has investigated any process of change. In their paper, Michie, O'Connor, Bath, Giles, and Earll (2005) acknowledged the paucity of research examining the mechanisms that improve mental health in CHD patients during CR. In our practice-level study, we explored the hypothesis that weight loss from CR may contribute to PGWBI improvement in obese CHD patients. The relationship we found is intriguing but it must be viewed cautiously given that no experimental design was employed.

Some study limitations deserve attention. First, this study has no control group. As previously suggested by Bjarnason-Wehrens et al. (2007), it is very difficult to randomise patients to a control group when there are ethical reasons which guarantees effective treatment to every patient. Furthermore, this study has no follow-up assessments, making thus impossible to know if observed short-term improvements were maintained after discharge and in the long-term.

In conclusion, this multi-factorial residential CR programme has shown to provide indications for effectiveness in a sample of CHD obese in-patients. Besides weight reduction and METs improvement, we observed positive changes also in the PGWBI scales measuring psychological and emotional well-being and a significant correlation between PGWBI improvement and weight loss was evident. Our findings warrant future studies designed to disentangle the single effects that are active and interact in this multi-factorial CR programme for obese patients with CHD. Furthermore, controlled studies are needed to corroborate the results we found.

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