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Health-Related Quality of Life Increases Similarly in Type 2 Diabetic versus Non-Diabetic Patients Following 7-12-Week Cardiac Rehabilitation

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Health-related quality of life increases similarly in type 2 diabetic versus non-diabetic patients following cardiac rehabilitation

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Structured Abstract

Purpose: Cardiovascular disease is the leading cause of death in the United States and results in substantial health-care expenditures. Health-related quality of life (HRQoL) is an important aspect in long-term recovery for cardiovascular disease patients. As such, improvement in HRQoL is a relevant outcome for determining cardiovascular rehabilitation (CR) program efficacy. Increasingly, diabetic patients are participating in CR and face additional challenges to HRQoL, yet there is a lack of research addressing program efficacy in this population. Here, we tested the hypothesis that CR would demonstrate a favorable change in HRQoL for both diabetic (D; n=37) and non-diabetic (N-D; n=58) patients. Further, we tested the hypothesis that the D group would demonstrate a greater overall change compared to the N-D group.

Methods: In this retrospective study, we reviewed the charts of 95 patients who completed a CR program and collected HRQoL measures using the COOP questionnaire, where lower scores indicate higher HRQoL.

Results: Following CR, COOP scores for both the N-D (pre: 20.39±0.79 *vs* post: 16.06±0.75; $p<0.05$) and D (pre: 20.92±0.88 *vs* post: 15.84±0.80; $p<0.05$) improved. HRQoL was not different between groups at the start of the program ($p=0.88$) nor at the end ($p=.58$) and thus, the improvement (Δ) in HRQoL was not different between groups ($p=0.44$).

Conclusions: These results suggest that D and N-D patients do not differ in their HRQoL at the start or end of CR, and that the two groups show similar improvements from attending the program.; larger sample studies are needed to confirm these findings.

Condensed Abstract

Health-related quality of life (HRQoL) was assessed in type 2 diabetics and non-diabetics before and after a cardiac rehabilitation program. HRQoL did not differ at baseline and improvements were similar in type 2 diabetic (n=37; ΔCOOP = -5.2±4.5) versus non-diabetic patients (n=58; ΔCOOP = -4.49±6.6).

Introduction

Cardiac rehabilitation (CR) is an essential post-cardiac event intervention[1]. The benefits of CR are myriad and include various physiological measures[2-4] along with quality-of-life measures[5]. Accordingly, CR programs align their goals with improving these variables[6]. As such, HRQoL is a vital criterion for evaluating the effectiveness of a CR program by indicating the personal perception of physical and emotional well-being in accordance with the patient's ideals and expectations[7]

Among the general population, supervised exercise improves both physical and emotional components of HRQoL[7-10]. With a CR population, increased HRQoL for both men and women who participate in the program as a result of various cardiac events has been reported in a number of investigations[5, 7-23]. These studies included all CR participants encompassing a range of cardiac events and comorbidities.

Recently, CR has seen an increase in the number of patients who have type II diabetes[24] and these patients are at the highest risk for new cardiovascular events[25, 26]. They demonstrate lower baseline HRQoL compared to non-diabetics and patients with comorbid diseases achieve poorer physical and psychosocial benefit from CR[25-27]. Underlying this discrepancy is a lack of physical exercise, increased obesity, decreased MET capacity, increased age, increased number of symptomatic complications of diabetes, and increased number of comorbidities among the diabetic population [28-31].

Supervised exercise and cardiac rehabilitation have been shown to improve factors that limit HRQoL, thus improving overall HRQoL of diabetic individuals[32-34]. However, we are unaware of any studies that have directly addressed the extent to which a CR program may improve HRQoL in diabetics vs non-diabetics. Accordingly, the purpose of the present study

was to test the hypothesis that both groups (type II diabetic and non-diabetic cardiac rehabilitation participants) will demonstrate a favorable change in HRQoL, and that the diabetic group will demonstrate a greater overall change compared to the non-diabetic group.

Methods

Inclusion Criteria

With Institutional Review Board approval of both Miami Valley Hospital and the University of Dayton, medical charts from July 2013-July 2014 were reviewed for the present study. A total of 200 medical charts were reviewed. Charts were eliminated if subjects did not complete at least 22 exercise sessions following referral to the CR program offered at Miami Valley Hospital. Program completion was defined as at least 22 sessions attended: required attendance for a minimum of 7 weeks of the program and related educational sessions (3 training sessions/week for 7 weeks plus a preliminary intake appointment). Fifty charts were eliminated due to non-completion. We included patients with history of MI, percutaneous transluminal coronary angioplasty (PTCA), and coronary artery bypass graft (CABG). In order to be included in the final analysis, charts had to be complete and contain pre- and post-program data for the variables described below. We excluded 55 charts for incomplete chart information. The remaining charts (n=95) were examined and included in the present study.

Cardiac Rehabilitation Protocol

The exercise sessions (3 times per week) consisted of 5 minutes warm-up, 30 minutes aerobic training (one or more of the following: treadmill, stationary bike, arm ergometer, elliptical machine, recumbent elliptical stepper, and rower), 5-10 minutes cool-down and

stretching, and 5 minutes recovery. The intensity of the initial aerobic training for all patients was targeted at resting heart rate+30 bpm. Subsequent sessions utilized target heart rate (40-70% HRmax) assessed by Karvonen method, RPE scale rating 11-13, and/or angina threshold to progress the exercise intensity on an individual basis in line with the recommendations of American Association of Cardiovascular and Pulmonary Rehab (AACVPR). Seven education classes (weekly) addressing cardiac risk factor modification were also offered. Additional diabetic education was provided on an individual basis by the patient's case manager and dietician. Diabetic education topics included but were not limited to types of diabetes, diabetes medications, diabetes-specific diets, exercise and diabetes, treatment of low/high blood glucose, and heart disease and diabetes.

The program was supervised by a staff consisting of cardiac nurses and exercise physiologists. Measurements collected during each exercise session for every patient included body weight, blood pressure readings (rest, exercise, recovery), HR (rest, exercise, recovery), and MET levels. Blood pressure was assessed (single measurement) by the staff using a manual sphygmomanometer. Heart rates and MET levels were monitored and calculated using a wireless telemetry (Scottcare). Within 30 minutes before and after exercise, blood glucose was assessed via finger stick whole blood samples and rapid glucometry. Non-insulin dependent diabetics were checked for a total of six sessions, while insulin dependent diabetics were checked at each session.

Before and after the CR program, patients self-reported HRQoL by completing the Dartmouth COOP questionnaire. This is a generic-type questionnaire developed by E. Nelson et al in the Dartmouth Primary Care Cooperative Information Project at the Dartmouth Medical School and has previously been used in cardiac rehabilitation settings[35]. It consists of nine

questions addressing nine sub-categories of HRQoL: feelings (F) physical fitness (PF), social support (SS), daily activities (DA), social activities (SA), pain (P), overall health (OH), quality of life (QL), and change in health (CH). Each question was scored using a 5-point Likert scale (1-5), with lower scores indicating a better HRQoL. Each score was added together for a total overall HRQoL score. The questionnaires were scored by the staff members.

Examined Variables

Data collection included pre-and post-cardiac rehabilitation Phase II program outcomes, diabetes status, patient cardiac diagnosis, cardiac risk level, number of sessions completed, and cardiac risk factors for each subject. Program outcomes included pre- and post- weight, height, BMI, resting systolic and diastolic blood pressures, MET levels, and Dartmouth COOP scores.

Data Analysis and Statistical Approach

Data are presented as mean ± standard deviation. Paired student's t-tests were used to analyze pre-and post- data within each group. Unpaired student's t-tests were used to analyze pre-and post- data between the two groups. Step-wise multiple regression was used to examine potential contribution of cofactors for the prediction of improvements in HRQoL. Potential contributing factors were BMI, age, gender, MET levels, and number of exercise sessions. Significance was set a priori at $P<0.05$. Data were analyzed using Excel (Microsoft) and SPSS (IBM) software.

Results

Subject demographics

Subject characteristics are presented in table 1. Patients in the D group were older ($p<0.05$) and completed more sessions ($p<0.05$) compared to patients in the N-D group. The body weight between groups was not significantly different; however greater pre- and post- BMI for the D group compared to N-D approached significance ($p=0.07$, $p=0.08$, respectively).

Quality of Life

Both groups showed significant improvements in overall COOP scores ($p<0.05$) by the end of the program (Figure 1). Pre- and post- COOP scores, as well as the overall change in scores, were similar between the groups ($p=0.88$, $p=0.58$, $p=0.50$, respectively).

Regarding specific sub-scores of the COOP questionnaire, the N-D group made significant improvements (Figure 2; Δ = post - pre; $p<0.05$) in physical fitness, daily activities, social activities, and overall health; while the D group showed significant improvements ($p<0.05$) in physical fitness and change in health; however, no between group differences were detected. Additionally, there were no between-group differences observed in absolute pre-, post- scores of the sub-categories (Table 3). These results are displayed in Table 3.

Physiological Variables

Both groups significantly improved in exercise capacity as assessed by MET level (Table 1; $p<0.05$), resting systolic blood pressure (RSBP) ($p<0.05$), and resting diastolic blood pressure (RDBP) ($p<0.05$). MET levels and RDBP were similar between groups, while RSBP was lower in the N-D group ($p<0.05$) compared to the D group at the beginning of the program. RDBP ($p=0.13$) and exercise capacity ($p=0.07$) remained similar between the two groups; the N-D

group still demonstrated lower RSBP ($p<0.05$) at the program compared to the diabetic group. Overall, there was a weak correlation between the change in METS and the change in COOP scores ($r=-0.299$) for both groups (Figure 3).

Multiple regression

Based on the multiple regression results, there are no significant predictors of the change in COOP based on diabetic status, age, gender, pre- MET levels, or number of completed exercise sessions ($p=0.67$).

Discussion

In the present study our main findings were the following. First, we found both groups significantly improved their HRQoL, exercise capacity, and resting blood pressures by the end of the CR program. Second, we found these changes to be similar in both groups. Taken together it appears that this CR program had a comparable effect on these non-diabetic and diabetic patients in terms of HRQoL. This was in contrast to our hypothesis that the diabetic patients would have a lower initial HRQoL, but would demonstrate greater improvements by the end of the program. This may have been due to a healthier diabetic population with fewer complications compared to CR populations in general.

Cardiac Rehabilitation and HRQoL

In general, CR improves most aspects of HRQoL among men and women who have undergone varying types of cardiac events[5, 7-10, 12, 16, 20, 22] and we add to these previous studies. The overall magnitude of improvement in QoL due to CR is difficult to quantify. To our

knowledge, meta-analysis of randomized clinical trials has not been performed given the heterogeneity in outcome measures and varied reporting methods[36]. Our study demonstrated on average, a 22% increase in HRQoL for our total population (20% for N-D group, 24% for D group). In a non-statistical comparison to the previous studies, our results may demonstrate a greater change than those previously reported. We are unsure as to why this may be the case, as our CR program is similar in design (e.g. sessions, exercises, duration) as others, including those reported in the literature. Overall, these findings suggest that CR programs in general result in improvements in both physical and emotional components of HRQoL and the present study aligns with this conclusion.

Considerations for Diabetic Populations

Contrary to our initial prediction, the diabetic group did not display a lower HRQoL at the beginning of the program. These findings disagree with several studies that found diabetes has a negative effect on HRQoL among the general public indicated by generally lower rated HRQoL compared to non-diabetics[25, 26, 37]. In particular, Odili and colleagues (2008) found that multiple aspects of HRQoL including physical health, psychological health, and social relationships are significantly lower in diabetics in the general population compared to non-diabetics. Our study examined only CR diabetic participants who had recently undergone, in most cases, a traumatic cardiac event. This represents a small sub-set of the general diabetic population which most likely lead to the disparity in results of our study compared to other studies. Also, we may have examined an overall healthier diabetes population with more diabetes control and fewer complications compared to the general population which in turn may have led to the similar HRQoL scores. Because we lacked access to the patient's full medical

chart, we lacked knowledge of their diabetic status throughout the program. Therefore, we could not draw conclusions based on improvement in diabetes control or diabetes prognosis.

The diabetic population only showed significant improvements in the physical function and change in health sub-categories of HRQoL which may highlight a weakness in the CR program. Stronger psycho-social interventions may be necessary among diabetic patients especially and this would then increase overall improvements in COOP as well.

Interactions of Physiological and Psychological Factors

We found similar improvements in exercise capacity among the two groups which agrees with recent studies finding that increased physical activity and exercise capacity have a positive effect on HRQoL on both non-diabetics and diabetics[19, 38, 39]. More specifically, Rejeski et al reported a positive correlation between MET capacity and HRQoL independent of BMI among diabetic populations[40]. Our results however displayed only a weak correlation between MET levels and COOP scores, with no changes in BMI, thus we cannot assume that an increase in exercise capacity lead to an increase in HRQoL. Again, these varying results could be from situational factors relating to the distressing cardiac event and situation unique to a cardiac patient population. Within our CR program, we set a minimum goal of a 2 MET improvement over the course of the program, based on receommendations provided by the American College of Sports Medicine [41]. On average, the patients included in this study achieved this recommended MET level increase. However, it is possible that a potential relationship between MET levels and COOP scores may have been minimized given our modest gains in MET levels achieved. Additionally, of the variable examined, there were no significant predicting factors for the change in COOP score. This may have again been due the baseline characteristics of our

population, in that MET levels were not an overarching factor in the COOP scores for either group.

Limitations

This study has several limitations which deserve mention. First, the included subject population was recruited from a single-center and suffered from a lack of complete chart data and/or dropout from the program in a number of potential patients (~100). Along these lines, the generalizability of our data set may only extend to programs with a similar design and population. It is possible that with a greater number of subjects, particularly diabetic subjects, we may have observed our hypothesized disease-related differences. Second, we are limited in our follow-up of HRQoL changes in these patients. The COOP questionnaire was completed upon program completion, approximately 7-12 weeks following entry into the program. It would be of interest to follow these patients beyond their completion of the program to determine whether the improvements in HRQoL that we observe are maintained. Third, we lacked complete medical information on our subjects, and thus have no measure of what impact the CR program had on disease management (e.g. blood glucose levels, neuropathy, etc) in the diabetic group. It is reasonable to suppose these factors remained unchanged or improved; however, we cannot quantify these changes or attempt to relate them to the observed improvement in HRQoL in this group. Fourth, the physiological measurements reported in this study (e.g. blood pressure, METs) were collected for the purpose of program management and patient safety, rather than with an *a priori* research aim. Specifically, METs represent estimation rather than direct measurements of factors of interest (i.e. aerobic capacity). Additionally, blood pressure measurements may exhibit more variability than would occur in a prospective study.

Perspectives

The present findings suggest that this CR program is an effective intervention for improving the HRQoL and physical capabilities of both our non-diabetic and diabetic patients. The program may benefit from additional psycho-social interventions for both groups based on the lack of improvements made in these areas. It is evident from our results that in this population, the diabetics are fairly comparable to the non-diabetics upon arrival to the program, and as a whole is achieving similar results from the program. Therefore, it can be assumed that the program is equally valuable and effective for both groups of patients.

Conclusion

In conclusion, the results of our study suggest that a comprehensive CR program improves HRQoL and exercise capacity of non-diabetic and diabetic patients to the same extent regardless of diabetes status. Due to the retrospective nature of this study, we were unable to control for certain factors beyond the existing CR sessions. More specifically, we could not control exercise type (aerobic versus strength training), dietary habits, etc. Our study included limited exclusion criteria with the intention that our results would be an accurate representative of the CR population in general. However, this leads our study to lack specific results pertaining to differences between genders, age, cardiac diagnosis, etc. Future studies may examine the differences between certain sub-groups aside from diabetes status.

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Figure Legends

Figure 1. Health-related quality of life scores in diabetic and non-diabetic participants
Cardiac rehabilitation (CR) significantly reduced COOP scores for both non-diabetics (n=58; black bars) and diabetics (n=37; grey bars), indicating a positive change in this measure of health-related quality of life. No significant differences were observed between the two groups at program intake or after completion of the 17 week program. Data are means ± std dev; * P <0.05 vs Pre.

Figure 2. Change in health-related quality of life subscores
Changes in individual subscores of the COOP questionnaire are presented for both non-diabetics (black bars) and diabetics (grey bars). Both groups had significant reductions (improvement) in physical fitness, whereas only non-diabetics significantly improved daily activities, social activities, and overall health. Diabetics saw significant improvement in their change in health. * p<0.05 pre vs post, there were no significant differences between N-D and D; F: feelings, PF: physical fitness, SS: social support, DA: daily activities, SA: social activities, P: pain, OV: overall health, QL: quality of life, CH: change in health

Figure 3. Change in health-related quality of life as a function of the change in aerobic fitness
Changes in MET achieved during rehabilitation sessions from intake to program completion were plotted against changes in the COOP measure of health-related quality of life. No significant correlation was observed and no differences in correlation were demonstrated between the non-diabetics (black circles) and diabetics (grey circles).

Table 1. Subject demographics

Characteristic	***Non-diabetic*** (n=58)	***Diabetic*** (n=37)
Male	34 (59%)	28 (76%)
Female	24 (41%)	9 (24%)
Age (years)	62.0±11.6	66.8±10.5†
Height (m)	1.7±0.1	1.7±0.1
Weight (kg)		
Pre	85.6±18.1	94.3±18.1
Post	84.8±18.0	93.5±17.4
BMI (kg/m^2)		
Pre	29.5±5.8	31.6±5.2
Post	29.2±5.8	31.3±5.0
METs		
Pre	4.2±1.4	3.8±0.8
Post	7.0±3.0*	5.9±0.3*
RSBP (mmHg)		
Pre	115±8	119±12†
Post	110±8*	115±10*†
RDBP (mmHg)		
Pre	67±8	67±8
Post	64±5*	63±7*

BMI: body mass index; METs: metabolic equivalents (1 MET = 3.5 ml/kg/min); RSBP: Resting systolic blood pressure; RDBP: resting diastolic blood pressure.

Data are n (%) or mean±st dev; * $p<0.05$ vs Pre, † $p<0.05$ vs N-D,

Table 2. Cardiac characteristics of studied population

Characteristic	*Non-diabetic (n=58)*	*Diabetic (n=37)*
Disease		
MI	8 (14%)	2 (5%)
PTCA	9 (16%)	7 (19%)
MI/PTCA	28 (48%)	16 (43%)
CABG	13 (22%)	12 (33%)
Risk stratification		
Low	12 (21%)	7 (19%)
Moderate	39 (67%)	27 (73%)
High	11 (19%)	3 (8%)
Cardiac risk factors		
Obesity	20 (35%)	27 (73%)
Hypertension	24 (41%)	34 (92%)
Smoker	8 (14%)	2 (5%)
Psychosocial	3 (5%)	5 (14%)
Sedentary	17 (29%)	24 (65%)
Family history	24 (41%)	20 (54%)
Stress	23 (40%)	19 (51%)
Hyperlipidemia	37 (64%)	36 (97%)
Ejection fraction	45.5±13.5	50.7±11.0
Total CR sessions	26.2±3.6	27.9±2.2†

Data are n (%) or mean ± st dev. * $p<0.05$ vs Pre, † $p<0.05$ vs N-D,

PTCA: Percutaneous transluminal coronary angioplasty, MI: Myocardial infarction, CABG: Coronary artery bypass graft

Table 3. HRQoL sub-scores pre- and post- CR program

Sub-category	*Non-diabetic*	*Diabetic*
Feelings		
Pre	2.3±1.1	1.7±1.1
Post	2.0±1.0	1.6±0.8
Physical fitness		
Pre	3.3±0.7	3.6±1.1
Post	2.7±0.7*	2.8±0.6*
Social Support		
Pre	1.9±1.2	1.5±0.9
Post	1.5±1.0	1.3±0.8
Daily activities		
Pre	2.8±1.0	2.5±1.6
Post	1.7±0.8*	2.0±1.3
Social activities		
Pre	2.0±1.2	1.6±1.1
Post	1.4±0.8*	1.5±0.6
Pain		
Pre	2.7±.9	2.3±1.4
Post	2.6±1.1	2.3±1.0
Overall health		
Pre	2.7±.8	2.9±1.6
Post	2.6±1.1*	2.6±1.0
Quality of life		
Pre	2.1±.8	2.0±0.9
Post	1.9±0.8	1.7±0.7
Change in health		
Pre	1.8±1.0	2.0±1.1
Post	1.5±0.8	1.3±0.6*

Data are mean ± st dev; * $p<.05$ vs Pre; † $p<0.05$ vs N-D

Figure 1
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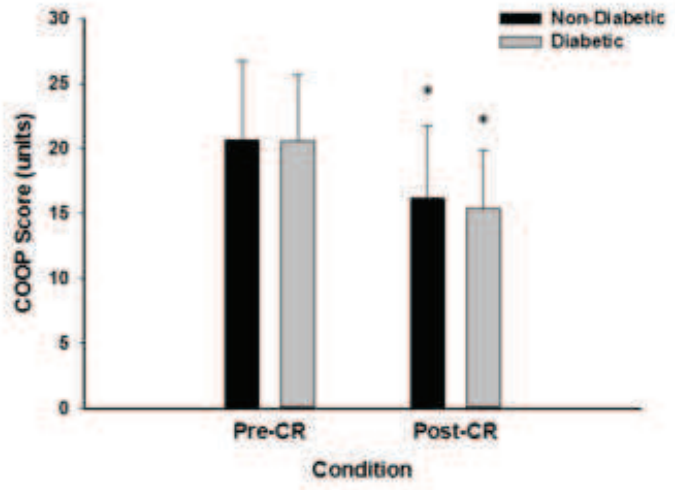

Figure 2
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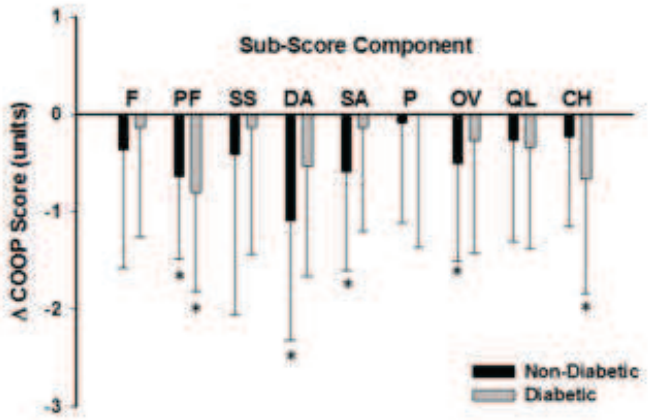

Figure 3
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