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QUALITY OF LIFE IN PATIENTS WITH CHRONIC HEART FAILURE: A RANDOMIZED CONTROLLED TRIAL OF CHANGES INDUCED BY A REGULAR EXERCISE PROGRAM

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ABSTRACT. The aim of this study was to evaluate the impact of a three-month exercise program on the perception of quality of life in patients with severe chronic heart failure. In a randomized controlled setting, 27 patients with a left ventricular ejection fraction of 18.1 ± 8.0% were entered into the study. The training group performed aerobic exercises for three hours/week while the control group continued their usual activities of daily living. Quality of life was measured using the German version of the MOS SF-36. Two patients required a change in their drug regimen and were therefore withdrawn from the study. Twenty-five patients completed the study. In the exercise group the perception of quality of life improved significantly in the domains of vitality ($p = 0.0001$), physical role fulfilment ($p = 0.001$), physical ($p = 0.02$) and social ($p = 0.0002$) functioning. Exercise was effective in increasing peak oxygen uptake and exercise time ($p < 0.01$). Only weak correlations were registered between parameters of physical performance and quality of life domains. The results of the study indicate that aerobic exercise can improve the perception of quality of life in patients with severe chronic heart failure.

Key words: chronic heart failure; physical medicine; exercise; quality of life.

INTRODUCTION

Chronic heart failure is a complex syndrome manifested by haemodynamic disturbances, exercise intolerance, increased mortality and reduced quality of life. Besides impaired cardiac function, a variety of changes in peripheral skeletal muscles may contribute to the major and debilitating symptoms of chronic heart failure, dyspnoea and fatigue (3). Exercise therapy has been established as an adjunct to drug therapy in patients with chronic heart failure and has been found to increase functional capacity without major side-effects (25). The reported benefits of regular therapeutic exercise include improved exercise tolerance (9) and at least partial relief from symptoms and muscle weakness (21). However, the impact of exercise therapy on the patient's perception of quality of life (QL) is not well established. There is general concern about the correlation of physiological changes with QL in patients with heart disease. Different questionnaires exist to measure patients' perception of QL. Besides disease-specific questionnaires (15), assessment of QL with general questionnaires might also be useful to compare data concerning various chronic diseases (20). A widely accepted instrument for the assessment of QL is the Medical Outcome Study Short Form-36 (MOS SF-36) (12, 24). The MOS SF-36 is a generic instrument for the assessment of health-related QL. On the basis of a cross-cultural adaptation, the results of psychometric testing of the MOS SF-36 in healthy and diseased German-speaking populations were evaluated (1). It proved to be a psychometrically robust and practical instrument for outcome evaluation in rehabilitation medicine (1). The MOS SF-36 addresses the disabilities of cardiac patients and therefore seems well suited for the evaluation of QL in this group (10, 20).

The objective of this study was to assess QL in patients with chronic heart failure by correlating the domains of the MOS SF-36 with physiological variables and to evaluate the impact of regular aerobic exercise on their perception of QL.

MATERIAL AND METHODS

Patients

Twenty-seven patients aged 55.3 ± 8.6 years with established

Table I. *Baseline characteristics of the 25 study patients (mean ± SD)*

	Training ($n = 12$)	Control ($n = 13$)
Male/female	10/2	12/1
Age (years)	57 ± 10	54 ± 7
Weight (kg)	80.1 ± 15.6	78.6 ± 10.9
Height (cm)	176 ± 9	175 ± 7
LVEF (%)	17 ± 7	19 ± 9
Listed for HTX	5	6
NYHA functional class		
II	7	8
III	5	5
PeakVO_2 (ml/minute/kg)	15.9 ± 3.4	17.8 ± 2.4
Max. exercise time (seconds)	574 ± 128	592 ± 111
Medications (*n*)		
Digitalis	12	13
ACE inhibitors	12	12
Nitrates	9	6
Beta blockers	3	2
Diuretics	7	5
Cavedilol	3	1
Anti-arrhythmic agents	3	1

LVEF: left ventricular ejection fraction, HTX: heart transplantation, NYHA: New York Heart Association.

compensated chronic heart failure due to dilated idiopathic cardiomyopathy were enrolled into the study. The patients were recruited at the outpatient clinic of the University Hospital Department of Cardiology, University of Vienna, Austria. To exclude coronary artery disease as a cause of dilated cardiomyopathy, all patients underwent coronary angiography.

Patients were entered into this prospective, randomized controlled study if they met the following criteria: (i) an ejection fraction below 30% measured by radionuclide ventriculography; (ii) a maximum oxygen uptake of at least 12–15 ml/minute/kg in a prior exercise test; and (iii) clinical stability with unaltered medication for at least 12 weeks before the start of the training program.

Exclusion criteria were New York Heart Association (NYHA) functional class IV, atrial fibrillation or other severe arrhythmia, any acute disease within 30 days prior to commencement of the study, evidence of coronary or peripheral artery disease and any disease of the locomotor system which hindered participation in a regular exercise program. Patients who required more than minor assistance to complete the questionnaire were also excluded from the study.

All patients underwent symptom-limited exercise stress tests in the pre-study period. After approval of the local ethics committee the study was conducted at the Department of Physical Medicine and Rehabilitation. Informed consent was obtained from all patients. After inclusion into the study the patients were randomly allocated either to the exercise or the control group. Randomization was achieved with a computer generated randomization list (Lotus Symphony).

After 4 weeks of training one of the 27 patients showed signs of acute heart failure; his condition was reversed by modifying the drug regimen. Another patient assigned to the control group had a beta-blocking agent added to his drug regimen by his cardiologist. Both patients were withdrawn from the study. Twenty-five patients (22 males, 3 females) completed the study. Their mean age was 54.6 ± 9.2 years. Sixty percent of the patients had NYHA class II and 40%, NYHA class III.

The two groups were well balanced with respect to the majority of baseline characteristics such as anthropometric data, maximal oxygen uptake and medication. There were no statistically significant differences between the groups at baseline.

Apart from the two patients mentioned above, the subjects' medication remained unchanged throughout the study period.

The baseline characteristics of the patients are shown in Table I.

Intervention

Exercise. The aerobic exercise program consisted of a three-month bicycle ergometer training and step exercises. Each exercise session lasted for 1 hour. During the first month the patients attended the program twice weekly, from the fifth week on they did the exercises three times a week (total training time, 3 hours/week).The program consisted of a short warm-up period of 3–5 minutes and aerobic exercises of 2 × 25 minutes. The last 5 minutes were used for cooling down and stretching exercises. In order to control heart rate and blood pressure response to exercise, and to acclimatize patients to the exercise program, only the bicycle training was performed during the first two weeks. From the third week onwards, step exercises were added to the program. Exercise intensity was set at 50% of each patient's maximal functional capacity. In order to control this intensity of exercise, we used the heart rate corresponding to 50% of VO_{2max} of each patient. Heart rate was calculated using a modified version of Karvonen's formula (6) and was monitored continuously (Polar Electro OY, Kempele, Finland) throughout each exercise session. Patients performed the exercises within a range of ±5 beats of their individually prescribed training heart rate. The training was guided by a physiotherapist and regularly supervised by the authors.

The control group continued their activities of daily living without any additional exercise, but reported to the department at 2-week intervals.

Outcome measurements

Assessment of QL—the MOS SF-36. The health attributes addressed by the MOS SF-36 are functional status, well-being and overall health.

The questionnaire consists of 36 items related to 8 scales. These scales cover different aspects of health. For each of these 8 scales, the responses to the questions are summed and converted to a scale ranging from 0 to 100, with 100 indicating best function. These concepts are then reduced to three general health attributes: functional status, well-being and overall health.

The *functional status* includes four scales. It deals with limitations in physical functioning such as walking and climbing stairs (10 items), limitations in role functioning (due to physical limitations) such as duties at home or at work (4 items); limitations in role functioning due to emotional limitations (3 items) and the degree to which health interfered with social functioning and interactions with others (2 items). *Well-being* is addressed by three scales measuring mental health (5 items) addressing depression and mood state; energy/fatigue (4 items) and pain (2 items). Finally, *overall health* includes measurement of general health perception (5 items) and changes in health. This last item evaluates the patient's perception of change of health over the past year.

The questionnaires were self-administered and could be completed within 10 minutes by each patient. Assistance by the examiners was offered upon request, but usually was not needed.

Exercise testing

Exercise studies were performed using a symptom-limited bicycle stress test (Ergoline 900S). We used an individualized ramp protocol providing an exercise time from 8 to 12 minutes for each patient. The pedalling rate was set at 60 to 70 rpm. Metabolic data were collected breath by breath, using a computer-based device (SensorMedics Metabolic System 2900c, Yoba Linda, LA, CA). The system reported 10-second averages for each parameter. The patients breathed through a mouthpiece connected to a mass flowmeter (SensorMedics, CA) which measured minute ventilation by the thermal conductivity technique. Oxygen uptake (VO_2) was measured with a fast response zirconium-oxide analyser (Servomex-Taylor, Sussex, GB). The pulse rate from a 12-lead electrocardiogram (Schiller AG, Switzerland) was recorded continuously at rest and throughout exercise. The test was terminated when the patient could not sustain the pedalling rate of 60–70 rpm due to exhaustion or dyspnoea, or when cardiac rhythm was severely disturbed. All patients had performed exercise tests prior to the study and were therefore familiar with the procedure.

Statistics

Demographic data are expressed as mean ± SD. For statistical evaluation, non-parametric tests (Mann–Whitney U test between groups, Wilcoxon signed-rank test before and after the study period) were used to avoid potential errors from exceptional distribution of data. The relationships between variables were analysed by simple linear regression (least square method) and multivariate analysis was performed. A co-variant analysis with baseline values as co-variable was used to compare the difference between baseline and three-month values between groups, using the SAS program (SAS Institute, Inc., SAS Campus Drive, Cary, NC 27513, USA). A p-value <0.05 was considered statistically significant.

Internal consistency was measured by item scale correlation and by correlation of general health perception with all other scales as suggested by the SF-36 health survey manual. Both correlations should exceed 0.30.

RESULTS

Physical performance

In the exercise group, peak oxygen uptake related to body weight increased significantly after the training period from 15.9 ± 3.4 to 18.5 ± 2.7 ml/minute/kg ($p < 0.01$). No statistically significant increase was seen in the control group (17.8 ± 2.4 vs 18.5 ± 3.5 ml/minute/kg). Exercising time increased significantly in the training group from 574 ± 128 to 748 ± 137 seconds ($p = 0.0015$); however, this was not observed in the control group (592 ± 111 to 627 ± 127 seconds; $p = 0.169$). Heart rate, blood pressure and blood lactate at maximal exercise were not different between the training and control group and before and after training. The gas exchange ratio also remained unchanged before and after training in both groups. Functionally, two patients improved from NYHA class III to class II in the exercise group; none of the patients improved beyond class II. In the control group all patients remained in their pre-training functional class.

Quality of life

At baseline, all patients were markedly impaired in certain QL domains (Table II). Patients with chronic heart failure scored low in the items physical functioning, physical role and general health perception. Compared with healthy individuals, our patients achieved only 65.8% in physical functioning, 64.5% in physical role and 64.5% in general health perception. Only a small impairment was registered in emotional role (87.2%), mental health (89.9%) and vitality (93.1%). Perception of pain did not appear to limit our patients, who scored higher than the average population (115.0%).

A comparison of the baseline values of the study population with published reference values of a healthy German-speaking population is given in Table III.

Changes after exercise training (Table IV)

The changes in QL after the study period are expressed as mean differences and compared between the two groups.

Functional status. The greatest improvement after training compared with the control group was seen in physical role (44.9 vs 4.4) and social competence (17.8

Table II. *Baseline of MOS SF-36 domains for both groups (mean ± SD)*

Domain	Training	Control	p-value
PFI	67.9 ± 16.2	53.3 ± 18.9	n.s.
ROLPH	62.5 ± 34.5	44.4 ± 36.8	n.s.
ROLEM	80.5 ± 33.2	61.1 ± 39.8	n.s.
SOCIAL	74.0 ± 24.2	78.1 ± 17.7	n.s.
MHI	65.2 ± 12.6	62.6 ± 12.9	n.s.
PAIN	91.7 ± 11.2	84.2 ± 18.8	n.s.
VITAL	58.5 ± 17.7	51.6 ± 12.6	n.s.
GHP	50.6 ± 22.4	44.2 ± 8.9	n.s.

PFI: physical functioning, ROLPH: physical role, ROLEM: emotional role, SOCIAL: social competence, MHI: mental health, PAIN: pain, VITAL: vitality, GHP: general health perception.

Table III. *Comparison of the MOS SF-36 baseline scores of all study patients with a healthy German population (1) (mean ± 95% CI)*

Domain	Baseline	Healthy German population Absolute values
PFI	60.6 ± 7.52	92.1 ± 1.7
ROLPH	53.5 ± 17.44	82.9 ± 3.33
ROLEM	70.8 ± 14.88	81.2 ± 4.25
SOCIAL	76.0 ± 8.4	85.2 ± 2.52
MHI	64.0 ± 5.00	71.2 ± 1.94
PAIN	88.1 ± 6.2	76.6 ± 1.94
VITAL	55.2 ± 6.24	59.3 ± 1.89
GHP	47.4 ± 6.88	73.6 ± 2.08

PFI: physical functioning, ROLPH: physical role, ROLEM: emotional role, SOCIAL: social competence, MHI: mental health, PAIN: pain, VITAL: vitality, GHP: general health perception.

vs −0.6). Physical functioning increased by 21.4 in the training group and by 9.4 in the control group. Emotional role functioning increased in both groups, the increase being more pronounced in the training group (27.5 vs 15.4).

Well-being. The largest increase after training was observed in the perception of vitality (17.6 vs −2.9) and to a smaller extent in mental health (12.4 vs 3.2). No change was seen in the perception of pain: 5.3 vs 2.5.

Overall health. General health perception was markedly impaired at baseline compared with normative data and significantly improved after training (19.0 vs 6.9).

Analysis of variance with baseline values as co-factor revealed lower *p*-values, indicating that patients with low baseline values had the maximum benefit from the exercise program.

Table IV. *Differences between baseline and three months for both groups (adjusted mean)*

Domain	Training	Control	*p*-value
PFI	21.4	9.4	0.02
ROLPH	44.9	4.4	0.001
ROLEM	27.5	15.4	0.07
SOCIAL	17.8	−0.6	0.0002
MHI	12.4	3.2	0.02
PAIN	5.3	2.5	0.3
VITAL	17.6	−2.9	0.0001
GHP	19.0	6.9	0.01

PFI: physical functioning, ROLPH: physical role, ROLEM: emotional role, SOCIAL: social competence, MHI: mental health, PAIN: pain, VITAL: vitality, GHP: general health perception.

Table V. *Correlation between the health domains of the MOS SF-36 and peak oxygen uptake (ml/minute/kg) and maximal exercise time (seconds) at baseline (*n = *25)*

	Peak oxygen uptake		Maximal exercise time	
Domain	R	*p*-value	R	*p*-value
PFI	−0.17	n.s.	0.15	n.s.
ROLPH	0.24	n.s.	0.18	n.s.
ROLEM	0.20	n.s.	0.30	n.s.
SOCIAL	0.5	0.01	0.65	0.001
MHI	0.25	n.s.	0.14	n.s.
PAIN	0.03	n.s.	0.20	n.s.
VITAL	0.18	n.s.	0.13	n.s.
GHP	0.55	0.007	0.38	0.07

PFI: physical functioning, ROLPH: physical role, ROLEM: emotional role, SOCIAL: social competence, MHI: mental health, PAIN: pain, VITAL: vitality, GHP: general health perception.

Correlations of MOS SF-36 with parameters of physical performance (Table V)

At baseline, the total patient population showed significant positive correlations between peak oxygen uptake and the social competence ($r = 0.5$, $p = 0.01$) and general health perception ($r = 0.55$, $p = 0.007$) subscales. Similar correlations were found between the two MOS subscales and exercising time (social competence: $r = 0.65$, $p = 0.001$, general health perception: $r = 0.38$, $p = 0.07$).

In order to determine the impact of the increase in physical performance on quality of life parameters, we looked for correlations between the subscales of the questionnaire and increases in physical performance. In the training group, increase in physical performance correlated positively with increase in social competence ($r = 0.69$, $p = 0.017$) and with improvement in general health perception ($r = 0.57$, $p = 0.06$). All other domains were not significantly related to changes in performance data.

The item total correlation coefficients for the 35 items within the eight health scales ranged from 0.35 to 0.92, thus indicating satisfactory internal consistency. In accordance with the recommendations of the MOS handbook, correlation coefficients of the scales with general health perception ranged from 0.38 to 0.66.

DISCUSSION

Two major findings emerge from our study. First, patients with chronic heart failure are severely impaired

in many domains of their quality of life compared with healthy individuals. In particular, the perception of physical functioning, the ability to fulfil their physical role and general health perception are far below normative values. Our results are in agreement with previous data using various QL measuring instruments. Dracup et al. (4) reported poor perception of QL in patients with chronic heart failure. Data from the MOS using the MOS 20-item questionnaire demonstrated low values for the scales of general health perception, physical functioning and physical role functioning among patients with chronic heart failure (8). In that study, a subgroup of patients with dyspnoea at rest even scored much lower. This may be due to the fact that patients with functional class NYHA IV were excluded from our study. Another survey of QL perception in chronically ill patients exhibited poor role and social functioning in patients with chronic heart failure (20). Similar results were demonstrated in another study, showing least satisfaction with health and physical functioning (5). Perception of pain does not appear to limit the QL of patients in this study. None of them had dilative cardiomyopathy due to coronary artery disease. Therefore anginal pain was of no importance in our patients.

The second finding of our study is that regular hospital-based outpatient exercise training results in a significant improvement of QL. In particular, domains related to physical activity such as physical functioning, role limitation caused by physical problems and social competence were markedly improved. Our exercise training program was successful in increasing physical performance. This is expressed by the significant increase in maximal oxygen uptake.

Therefore, we first assumed that improvement of physical performance influences perception of QL. Studies concerning changes in QL after coronary artery bypass surgery showed an inverse relationship with poor preoperative exercise capacity (18). However, we did not find a positive correlation between certain domains and increased peak VO_2 in the training group. This is in concurrence with previous findings that showed that so far, no simple exercise end-point has met the goal of serving as a surrogate for the determination of QL (19). Also Wielenga and co-workers demonstrated a significant improvement in well-being after an exercise program despite only moderate increase in exercise capacity (26). Other studies stress the fact that patients with chronic heart failure maintain positive attitudes towards healthcare and treatment (5, 13). Interventions by the therapeutic team were found to contribute to a positive perception of QL (5).

Improvement in social functioning was also reported with drug therapy (16). This emphasizes the notion that the therapeutic aim for many patients is to achieve a more "effective" lifestyle (11) and to preserve their functioning and well-being (17).

A short-term exercise program in patients after myocardial infarction, including psychological counselling, revealed a significant improvement in QL, especially in the presence of anxiety and depression (14). A non-randomized long-term study concerning the impact of regular physical exercise in patients with chronic heart failure demonstrated improvements in fatigue and emotional function after an aerobic walking program. It is noteworthy that the major gains in these items were achieved within the first four weeks of the training period (7). A recent controlled study with a strength training-based intervention demonstrated only a small impact on QL (2). On the contrary, an endurance-type training of the knee extensor muscles was found to be effective not only in increasing the functional ability of patients with moderate chronic heart failure but also in improving physical and psychosocial health-related quality of life (22, 23). These effects were shown for both sexes (23) as well as for a group of female patients only (22).

The patients' improvement in the NYHA classification after the training period was of no statistical significance. Previously, only weak correlations between the physician's NYHA classification and the patient's perception of his QL were found (19).

We conclude that a three-month aerobic exercise program results in a significant and clinically important improvement in QL in patients with severe stable chronic heart failure. Further investigation should be directed towards the impact of the different components of the rehabilitation process upon QL improvement in patients with severe chronic heart failure.

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