

Short Communication

Reassessment of quality of life domains in patients with compensated Chagas heart failure after participating in a cardiac rehabilitation program

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Abstract

Introduction: We evaluated the effects of a cardiac rehabilitation program on quality of life. **Methods:** This secondary analysis of a single-arm study included 12 patients with Chagas heart failure. The cardiac rehabilitation program comprised exercise training and nutritional and pharmaceutical counseling. Quality of life was assessed using the SF-36 questionnaire. **Results:** The program promoted improved physical functioning ($\beta = +5.7$; $p = 0.003$), role-physical ($\beta = +1.9$; $p = 0.03$), and bodily pain ($\beta = +3.5$; $p = 0.02$) scores. Moreover, the summary physical health score ($\beta = +1.4$; $p = 0.001$) improved. **Conclusion:** The cardiac rehabilitation program significantly improved the physical quality of life of patients with Chagas heart failure.

Keywords: Chagas heart failure. Cardiac rehabilitation. Quality of life.

Chagas disease is a neglected parasitic infection caused by the protozoan, *Trypanosoma cruzi*, which affects a large number of individuals not only in Latin American but also in Europe, the United States, Asia, and Oceania¹. Heart failure is an important clinical manifestation of Chagas disease, and is associated with an increased mortality rate and decreased quality of life (QOL)^{2,3}.

Therapeutic approaches to Chagas heart failure are still based on the knowledge learned from other cardiomyopathies, and aim to improve symptoms, decrease mortality, and increase the patient's QOL^{4,5}. Cardiac rehabilitation has emerged as an important strategy to decrease mortality and improve QOL in patients with heart failure, mostly heart failure of ischemic etiology^{6,7}. However, the few trials that have evaluated the effects of cardiac rehabilitation on patients with Chagas heart failure have presented several methodological shortcomings^{8,9}.

A recent study conducted by our group demonstrated important clinical benefits of an 8-month cardiac rehabilitation program on patients with Chagas heart failure, mainly in terms of cardiac function and respiratory muscle strength, with no improvement on overall health-related QOL using a disease-specific instrument¹⁰. However, a comprehensive assessment

taking the different QOL domains into account was not performed. In the present study, we aimed to evaluate the effects of this cardiac rehabilitation program on different domains using a generic QOL instrument.

This is a secondary analysis of a single-arm pilot study that was designed to determine the safety and efficacy of a cardiac rehabilitation program in patients with Chagas heart failure. The full description and results of the primary analysis have been published¹⁰. In brief, 12 patients with Chagas cardiomyopathy stage C or D but with no history of clinical decompensations during the previous 3 months, were included in the study¹¹. Individuals who were not able to attend regular exercise training sessions, practitioners of regular exercise, and those with other associated non-Chagas cardiomyopathies or systemic/neuromuscular conditions that precluded exercise training, were excluded from the study.

The cardiac rehabilitation program comprised exercise training sessions, nutritional guidance, and pharmaceutical counseling. The exercise training protocol was performed three times per week for 60 min per session during an 8-month period. Each exercise session was divided into three different parts: i) aerobic exercise (30 minutes), performed on a treadmill or on a cycle ergometer at a moderate intensity (anaerobic threshold minus 10% in the first month of exercise protocol and the anaerobic threshold plus 10% in the following months); ii) 20 min of strength exercises comprising two sets of 12 repetitions for the major muscle groups (sit-ups, push-ups, and pull-ups); and iii) 10 min of stretching exercises for the major muscle

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groups (20–30 s for each position). Blood pressure, oxygen saturation levels, and heart rate were measured before, during aerobic exercise, and at the end of each training session in order to monitor intensity and guarantee patient safety. Training sessions were performed in the morning and were supervised by a cardiologist.

The nutritional guidance comprised general information about sodium consumption and water intake. The pharmaceutical counseling consisted of information regarding dosage of and adherence to prescribed medications. Patients received these interventions once a month during the follow-up period.

Quality of life was assessed using the Portuguese version of the SF-36 questionnaire¹², a generic instrument that includes 36 questions addressing eight different domains, categorized into two summary scores: physical health (physical functioning, role physical, bodily pain, and general health) and mental health (vitality, social functioning, role emotional, and mental health). Questions pertained to the four-week period prior to the interview. The final score (range: 0-100) was calculated according to the recommendations of the SF-36 creators, with higher scores representing a better QOL. Patients included in the study also underwent evaluations of functional capacity (maximal cardiopulmonary exercise test) and cardiac function (two-dimensional echocardiography), as previously described¹⁰. All assessments were performed at baseline and after 8 months of follow-up.

Data are expressed as the mean and standard deviation. Longitudinal changes over the time were evaluated using linear mixed models. The likelihood-ratio test was used

to choose the models that best fitted the data (random intercept or random slope models). Residual plots of all models were also examined and showed no major deviations from the regression assumptions.

A subgroup analysis was performed stratifying patients based on the presence of right ventricular (RV) dysfunction at baseline ($RVS' < 10\text{cm/s}$), an independent prognostic factor in patients with Chagas heart failure. The statistical analysis was performed using Stata statistical software: Release 13 (College Station, TX, StataCorp LP. 2013) and the significance level was set at 0.05.

The baseline characteristics of patients included in this pilot study were published in the primary paper¹⁰. In brief, the patients' mean age was 56.1 ± 13.8 years, most were women [$n = 9$ (75%)], and most self-reported their ethnicity as being mulatto [$n = 8$ (66.6%)]. The majority had stage C Chagas heart disease [$n = 10$ (83.3%)]. The mean left ventricular ejection fraction (Simpson) was $31.9 \pm 7.7\%$ and the VO_2 peak was $15.8 \pm 5.2\text{mL/kg/min}$. Six (50%) patients had baseline RV dysfunction. All patients were taking neurohormonal blockade therapy (beta-blockers or angiotensin-converting enzyme inhibitors/angiotensin II receptor blockers).

Table 1 shows the overall scores of the QOL domains and their summary components. Patients with baseline RV dysfunction presented lower scores for all QOL domains and summary scores than those with preserved RV function.

The longitudinal effects of the cardiac rehabilitation program on QOL during the study are also depicted in **Table 1**. There were significant improvements in the physical functioning ($\beta = +5.7$; $p = 0.003$), role-physical ($\beta = +1.9$; $p = 0.03$), and

TABLE 1
Quality of life domains and summary scores at baseline and at follow-up.

QOL domain	Baseline	8-month	β^*	p-value*
Physical functioning	18.8 ± 38.6	64.3 ± 45.3	+5.73	0.003
Role-physical	49.6 ± 24.4	65.0 ± 18.7	+1.89	0.03
Bodily pain	49.8 ± 29.9	77.6 ± 21.2	+3.46	0.02
General health	45.3 ± 15.4	57.1 ± 12.2	+1.49	0.07
Vitality	54.6 ± 26.9	67.9 ± 23.6	+1.66	0.25
Social functioning	67.7 ± 34.7	75.0 ± 26.0	+0.68	0.65
Role-emotional	41.7 ± 47.4	57.1 ± 46.0	+1.84	0.29
Mental health	62.3 ± 28.3	69.7 ± 21.5	+1.14	0.25
Physical health score	33.9 ± 7.8	45.2 ± 7.1	+1.42	0.001
Mental health score	46.3 ± 13.5	47.8 ± 11.2	+0.12	0.80

QOL: Quality of life. *Linear mixed model analysis. Data are presented as the mean ± standard deviation.

bodily pain ($\beta = +3.5$; $p = 0.02$) domains, as well as in the summary physical health score ($\beta = +1.4$; $p = 0.001$). These changes remained statistically significant even after adjustment for changes in maximal oxygen consumption during follow-up. No significant changes in the other QOL domains or the summary score of mental health ($p > 0.05$) were observed at the end of follow-up. Patients with RV dysfunction at baseline demonstrated significant improvements in the domains of physical functioning ($\beta = +8.3$; $p = 0.001$), bodily pain ($\beta = +3.8$; $p = 0.02$), vitality ($\beta = +4.1$; $p = 0.03$), and in the summary physical health score ($\beta = +2.1$; $p > 0.001$) whereas those with preserved RV function showed significant enhancements only in the summary physical health score ($\beta = +0.9$; $p = 0.002$).

The major findings of the present study were improvements in some physical-related QOL domains (physical functioning, role-physical, and bodily pain) and in the physical summary score of patients with Chagas heart failure after completing an 8-month cardiac rehabilitation program. These results are particularly important since studies have demonstrated that cardiac symptoms exert an important negative influence on QOL in patients with Chagas disease¹³. A previous analysis of the same dataset using a disease-specific questionnaire (Minnesota Living with Heart Failure) showed no overall improvement in health-related QOL, except among those with the greatest severity of cardiac impairment at baseline, reinforcing the deleterious impact of cardiac symptoms on health-related QOL¹⁰.

Chagas heart failure is characterized by the presence of fatigue and dyspnea. These symptoms may contribute to progressive reduction of functional capacity and impaired ability to perform activities of daily living, negatively impacting QOL¹⁴. In this context, a recent systematic review published by Sousa et al.¹⁵ (that included 12 studies evaluating different aspects of QOL among patients with Chagas disease) demonstrated that cardiac derangements are associated with a worse perception of QOL. In addition, they found a positive association between functional capacity and QOL. Therefore, it is speculated that strategies aimed at decreasing symptoms and increasing functional capacity could also improve the perception of QOL in patients with Chagas disease.

The only study evaluating the effects of exercise training on physical and psychosocial QOL aspects in individuals with Chagas cardiomyopathy was conducted by Lima et al.⁹. After 12 weeks of follow-up, they found that exercise training had significant effects on the psychosocial aspects of QOL but did not improve the physical domains. These results could be explained by the low frequency of patients with complaints of functional limitation [63% were New York Heart Association (NYHA) class I]. In contrast, our study included patients with more severe cardiac dysfunction and functional limitations (75% were NYHA class II or III); we found significant improvements in all physical QOL domains. RV dysfunction at baseline is an important surrogate of disease severity and is an independent prognostic factor in patients with Chagas heart failure. Individuals with RV dysfunction at baseline obtained the greatest enhancements in QOL, including in the physical and

psychosocial domains. The changes observed in the physical QOL domains in the present study were independent of the changes in maximal oxygen consumption observed during follow-up, reinforcing the results of Costa et al.¹⁴, that a patient's QOL is more strongly associated with submaximal activities than with maximal efforts.

The lack of a control group, the small sample size, and the inclusion of a wide age-range of patients are the major limitations of the present study. However, these limitations appear to be non-differential and would move the findings towards the null hypothesis.

To conclude, a cardiac rehabilitation program resulted in significant improvements in the physical aspects of QOL in a small cohort of patients with severe Chagas heart failure. Individuals with RV dysfunction at baseline obtained the greatest benefit, both in terms of improved functional capacity (as previously demonstrated in the primary study¹⁰) and QOL.

Ethical considerations

All participants were advised about the goals and procedures of the study and signed an informed consent form. The study was approved by the Institutional Review Board (CAAE: 0055.0.009.000-11) and was registered at Clinicaltrials.gov (NCT02516293).

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Conflicts of interest

The authors declare that have no conflicts of interest.

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