

# Article/Artigo

# Health-related quality of life in patients with Chagas disease

Qualidade de vida relacionada à saúde na doença de Chagas

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#### ABSTRACT

Introduction: Chagas disease (ChD) is a chronic illness related to significant morbidity and mortality that can affect the quality of life (QoL) of infected patients. However, there are few studies regarding QoL in ChD. The objectives of this study are to construct a health-related QoL (HRQoL) profile of ChD patients and compare this with a non-ChD (NChD) group to identify factors associated with the worst HRQoL scores in ChD patients. Methods: HRQoL was investigated in 125 patients with ChD and 21 NChD individuals using the Medical Outcomes Study 36-item Short-Form (SF-36) and the Minnesota Living with Heart Failure Questionnaire (MLWHFQ). Patients were submitted to a standard protocol that included clinical examination, ECG, Holter monitoring, Doppler echocardiogram and autonomic function tests. Results: HRQoL scores were significantly worse among the ChD group compared to the NChD group in the SF-36 domains of physical functioning and role-emotional and in the MLWHFQ scale. For the ChD group, univariate analysis showed that HRQoL score quartiles were associated with level of education, sex, marital status, use of medication, functional classification and cardiovascular and gastrointestinal symptoms. In the multivariate analysis, female sex, fewer years of education, single status, worst functional classification, presence of cardiovascular and gastrointestinal symptoms, associated illnesses, Doppler echocardiographic abnormalities and ventricular arrhythmia detected during Holter monitoring were predictors of lower HRQoL scores. Conclusions: ChD patients showed worse HRQoL scores compared to NChD. For the ChD group, sociodemographic and clinical variables were associated with worst scores.

**Keywords:** Quality of life. Chagas disease. SF-36. Minnesota Living with Heart Failure Questionnaire.

#### RESUMO

Introdução: A doença de Chagas (DCh) é associada à morbidade e mortalidade significativas e que pode afetar a qualidade de vida (QV) dos pacientes infectados. Entretanto, encontramos poucos estudos sobre a QV na DCh. Os objetivos deste estudo são definir o perfil de qualidade de vida relacionada à saúde (QVRS) em pacientes com DCh, compará-lo com indivíduos sem a doença de Chagas (NDCh) e encontrar os fatores associados com os piores escores de QV para aqueles com DCh. Métodos: A QVRS foi investigada em 125 pacientes com DCh e 21 NDCh aplicando-se os questionários Medical Outcomes Study 36-item short-Form (SF36) e Minnesota Living With Heart Failure Questionanaire (MLWHFQ). Os pacientes foram submetidos a exame clínico, ECG, monitorização por Holter, Doppler ecocardiograma e testes de função autonômicas. Resultados: Os escores de QVRS nos domínios capacidade física e aspecto emocional do SF36 e na escala de MLWHFQ foram significativamente piores entre os pacientes com DCh. A análise univariada mostrou associação dos escores QVRS e nível de formação, gênero, situação conjugal, uso de medicamentos, classe funcional e sintomas cardiovasculares e gastrointestinais. Na análise multivariada, sexo feminino, poucos anos de estudos, situação conjugal de solteiro, pior classificação funcional, presença de sintomas cardiovasculares e gastrointestinais, doenças associadas, alteração ao Doppler ecocardiograma e arritmia ventricular ao Holter foram preditores de pior QVRS. Conclusões: Pacientes com DCh apresentaram piores escores de QVRS quando comparados com NDCh. Para o grupo com DCh, variáveis sociodemográficas e clínicas se associaram aos piores escores.

**Palavras-chaves**: Qualidade de vida. Doença de Chagas. SF-36. *Minnesota Living with Heart Failure Questionnaire.* 

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## INTRODUCTION

Evaluation of quality of life (QoL) has been increasingly used to monitor and manage care strategies, clinical investigations, allocation of resources and to monitor the integration of new technologies<sup>1-3</sup>. Focusing on clinical outcomes that have an impact on the patient's life is one of the principles of evidence-based medicine. Hence, QoL is not only a concern for patients, their families and doctors, but also for the health policy makers and the healthcare industry. Knowledge concerning the impact of diseases on the QoL of patients can improve planning and allocation of resources for research, training and health care<sup>4</sup>.

The definition and scope of the term *quality of life* requires a thorough discussion. In this article, health-related QoL (HRQoL) is taken to be a measure that quantifies the patient's perception of the functional effects of the illness and treatment on different aspects of life, considering the subjectivity of the physical, emotional and social dimensions<sup>5,6</sup>.

Generic and specific measurement instruments can be used to evaluate HRQoL. The generic instruments, such as health profiles and utility measurements, are applicable to a large variety of populations and pathologies, allowing for comparison of different groups. They are most appropriate to epidemiological studies and to planning and evaluation in the healthcare system. The utility measurements are most widely used for cost analysis. In contrast, specific instruments are directed at evaluating individual and specific aspects of HRQoL following illness, injury or medical intervention<sup>7</sup>.

The generic Short-Form Health Survey (SF-36) was developed in the early 1990s<sup>8</sup> and has been translated into Portuguese and validated<sup>9</sup>. The SF-36 has proven to be very useful with general populations and specific subgroups for comparing the impact of diverse diseases and treatments. It is currently the most commonly used generic instrument in Brazilian and international studies. The MLWHFQ is a specific instrument for evaluating patients with heart failure developed by Rector et al<sup>10</sup> and translated into Portuguese and validated<sup>11,12</sup>.

Despite the recognized importance of using HRQoL instruments when evaluating the effects of diseases and their treatments, particularly chronic diseases<sup>4</sup>, very few studies exist in research databases involving HRQoL profiles of the ChD group.

Defined as the presence of infection from *Trypanosoma cruzi*, ChD is part of a group of diseases that affect vulnerable populations and is associated with underdevelopment and poverty. According to the report of the WHO Scientific Work Group, ChD still represented a health threat in Latin America in 2006. Considering the information from 21 countries where the disease is endemic, it is estimated that 7.7 million people are infected, presenting varying degrees of complications of medico-social significance<sup>13</sup>. ChD is one of the principal causes of death from infectious disease, with 10,000 deaths in 2008<sup>14</sup>.

In recent decades in Brazil, it is estimated that about 6,000 patients have died each year due to ChD-related causes, despite the effectiveness of public policy measures. This means that it is still a significant public health problem, with about 3.5 million chronic patients remaining, of which about 20% to 30% present cardiac impairment<sup>15</sup>. It is a chronic disease that mainly affects individuals of productive age and can be incapacitating and debilitating. It is one of the main causes of early retirement and has had a large social, economic and cultural impact<sup>16</sup>. The great variation in the clinical development of ChD, the lack of understanding of the mechanisms responsible for its progression and the wide spectrum of clinical, emotional and social manifestations<sup>17,18</sup> add to the importance of investigating the impact of ChD on the QoL of the patients.

The objectives of this study were evaluate the HRQoL profile of ChD patients and compare it with a control group without Chagas disease (NChD) to identify the factors associated with the worst scores and, consequently, poorer QoL.

## **METHODS**

This transversal study was conducted between 2004 and 2006 at the Clinical Hospital of the Federal University of Minas Gerais and the Infectious and Orestes Diniz Parasitic Disease Training and Reference Center (CTR-DIP). The patients studied were participants in a longitudinal prospective study begun in 1998 entitled: Autonomic dysfunction in ChD: mechanisms and prognostic implications, which primarily involves patients without systemic illnesses who are or have been treated at the abovementioned health facility. During the follow-up evaluation, 165 patients, of which 139 were ChD and 26 NChD, were invited and agreed to participate. No additional exclusion criteria were used. The group was composed of those who provided free, informed consent. Nineteen patients were excluded because of incomplete exams. The group evaluated consisted of 146 patients, 125 with ChD and 21 healthy controls (NChD group). A definite serological status for ChD was defined by the presence of two or more different positive reactions to Tripanossoma cruzi (indirect immunofluorescence, ELISA, indirect haemagglutination or complement fixation) in patients at risk of infection.

Patients were subjected to an initial standardized consultation that was conducted by experienced cardiologists and trained personnel. The following information was gathered: I) demographic characteristics: sex, age, skin color, marital status and educational level; II) clinical features: systolic and diastolic arterial pressure, heart rate, weight, height and calculated body mass index, associated illnesses, use of continuous medication, the presence of cardiovascular and gastrointestinal ChD-related symptoms; III) functional classification: using the Goldman scale, from Class I (no limitation to physical activities and absence of symptoms) to Class IV (incapacity in physical activities with symptoms even at rest)<sup>19</sup>; IV) level of physical activity: subjects were classified into two groups according to the International Physical Activity Questionnaire (IPAQ) as insufficiently active (sedentary + irregularly active) and sufficiently active (regularly active + active, very active)<sup>20,21</sup>;

Complementary tests included: ECG, 24-hour Holter monitoring, Doppler echocardiogram and autonomic function evaluation, including short tests (Valsalva maneuver and respiratory sinus arrhythmia) and 24-hour heart rate variability analysis. The methodology used for these tests has been previously described by our research group<sup>22,23</sup>. The examinations were conducted and analyzed by experienced cardiologists who were blind to the serological profile of the patients and used the following classification parameters: I) electrocardiogram: abnormal in accordance with the ChD-specific Buenos Aires criterion<sup>24,25</sup>; II) ventricular arrhythmia detected during Holter monitoring: presence of nonsustained ventricular tachycardia or more than ten ventricular extrasystoles per hour<sup>25</sup>; III) abnormal Doppler echocardiogram considering the presence of one of the following abnormalities: left ventricular ejection fraction (LVEF) < 0.50, right ventricle (RV) > 56mm, left atrium (LA)> 40mm, presence of apical aneurysm or alteration in contractility; IV) abnormal autonomic function tests, considering the presence of one of the following abnormalities: heart rate variability with a standard deviation for normal cardiac intervals (SDNN) < 75ms on the 24h recordings, Valsalva ratio < 1.5 or respiratory sinus arrhythmia with a ratio of the greatest expiratory interval over the smallest inspiratory interval (mean of six respiratory cycles)  $< 1.1^{22,23}$ .

To evaluate HRQoL, interviews were conducted by trained professionals using the SF-36 generic multidimensional questionnaire<sup>8</sup> and the specific questionnaire MLWHFQ<sup>10</sup>.

The SF-36 is divided into eight domains: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health, as well as into two summary components: physical component summary (physical functioning, role-physical, bodily pain, general health, vitality) and mental component summary (mental health, role-emotional, social functioning, vitality, and general health). The result is expressed as a score varying from 0 (the most impaired) to 100 (no impairment)<sup>9</sup>.

The MLWHFQ consists of 21 questions covering physical, socioeconomic and psychological dimensions of life relative to the limitations frequently associated with the profile of cardiac insufficiency. The final score is the sum of the responses and varies from 0 (no impairment) to 105 (total impairment). The higher the score, the worse the quality of life<sup>12,26,27</sup>.

#### Statistical analysis

For the categorical variables, either the Chi square or Fisher exact tests were used to compare the demographic, clinical and complementary examination aspects of the NChD and ChD groups. For continuous variables, including the QoL scores, the Mann-Whitney test was used. In all analyses, a level of 5% was considered to be significant. Nonparametric tests were chosen because of the asymmetric nature of the variables tested. To evaluate the factors associated with QoL in the ChD group, five different outcome variables were used: physical and mental component summary and domains which showed significant differences in QoL between the ChD and NChD groups, the physical functioning and role-emotional from the SF-36 scale, and the MLWHFQ. For all of the variables, except the SF-36 role-emotional scale, the Qol scores were coded with an ordinal variable with four categories, which used the quartiles as cutoff points. The roleemotional scale was not recoded because it always produces a variable with four categories: scores 0, 33, 67, and 100. The explanatory variables were the clinical, sociodemographic and complementary examination characteristics.

The ordinal logistic regression model was used for the univariate and multivariate analysis and the proportional odds model was chosen. In the model for the role-emotional domain, due to the discrete distribution of data (scores of 0, 33, 66, and 100), the stereotype ordinal logistic regression model was also performed, but the results were similar to those of the proportional odds model, which was the one chosen<sup>28</sup>.

The logistic regression procedure began with the selection of

TABLE 1 - Sociodemographic and clinical features and complementary test characteristics of non-Chagas
disease (NChD) and Chagas disease (ChD) patients.

	NChD (n=21)		С	ChD (n=125)	
Variables	n	%	n	%	p-value
Sociodemographics					
sex					
male	13	62.0	72	58.0	0.711 <sup>a</sup>
skin color					
white	9	43.0	28	22.0	0.135 <sup>a</sup>
brown	7	33.0	54	43.0	
black	5	24.0	43	34.0	
marital status					
with partner	15	71.0	95	76.0	0.653ª
education level					
up to 2 years	11	52.0	89	71.0	0.019 <sup>b</sup>
elementary school	2	10.0	21	17.0	
secondary school or more	8	38.0	15	12.0	
age (years)		46 (28-71)		29 (25-68)	
Clinical condition					
functional classification					
Ι	21	100.0	102	82.0	0.392 <sup>b</sup>
II or more	0	0.0	23	18.0	
BMI					
normal	3	25.0	29	44.0	0.022 <sup>b</sup>
overweight	4	33.0	31	47.0	
obese	5	42.0	6	9.0	
IPAC					
sedentary	0	0.0	5	4.0	0.552 <sup>b</sup>
irregularly active	19	100.0	100	88.0	
regularly active	0	0.0	9	8.0	
continued use of medicine	0	0.0	55	44.0	< 0.001
associated illness	5	24.0	47	38.0	0.222 <sup>a</sup>
cardiovascular symptoms	4	19.0	59	47.0	0.016
gastrointestinal symptoms	4	19.0	24	19.0	0.999 <sup>t</sup>
heart rate (bpm)		68 (56-80)		64 (46-98)	< 0.001
systolic arterial pressure (mmHg)		126 (100-160)		126(100-180)	0.001
diastolic arterial pressure (mmHg)		80 (70-90)		84 (60-130)	< 0.001
Complementary tests	_				
abnormal ecg	0	0.0	73	58.0	<0.001 <sup>b</sup>
abnormal doppler echo	3	16.0	61	56.0	0.001 <sup>b</sup>
ventricular arrhythmia (holter)	2	10.0	48	43.0	0.005 <sup>b</sup>
abnormal autonomic function	5	24.0	63	55.0	0.009 <sup>a</sup>

Data are absolute numbers (percentage) or median values (minimum-maximum). NChD: non-Chagas disease, ChD: Chagas disease, BMI: body mass index, IPAC: International Physical Activity Questionnaire, ECG: electrocardiogram, Doppler Echo: Doppler echocardiogram. <sup>a</sup>Chi square test, <sup>b</sup>Fisher test, <sup>c</sup>Mann-Whitney test. variables that had a p-value of  $\leq 0.20$  in the univariate analysis and later was adjusted by eliminating individual variables. The criterion for the variables to remain in the final model was a p value  $\leq 0.05$  (Wald test). The *odds ratio* (OR) and confidence interval (CI) was estimated for each covariable. This model provides a single OR estimate for all of the categories compared, due to the proportional odds assumption, which was tested for all of the variables individually and for the final model. A deviance test was used to evaluate the model's goodness-of-fit<sup>29</sup>.

#### **Ethical considerations**

This study involved reciprocal agreement between the researcher and the research line coordinator and was assessed and approved by the COEP UFMG (Research Ethics Committee of the Federal University of Minas Gerais). All of the study participants signed the informed consent forms and received written examination results, as well as the recommendations and appropriate referrals, while being treated as usual in the specialized health unit.

The WHO's recommendations and the Helsinki Declaration of 1975 were taken into consideration, along with Resolution 196/96 of the Ministry of Health on Research involving Human Beings, to ensure that the rights and well-being of the subjects were respected.

## RESULTS

#### Demographic, clinical, and complementary examination characteristics

The sociodemographic and clinical features and complementary test results of the ChD and NChD subjects are presented in **Table 1**. Significant differences were observed in the level of education, percentage of obese participants, frequency of use of medication, reports of cardiovascular symptoms, median cardiac frequency, systolic and diastolic arterial pressure, abnormal ECG, abnormal Doppler echocardiogram, ventricular arrhythmia detected during Holter monitoring and abnormality in the autonomic function tests.

### Quality of life

**Table 2** shows that the QoL scores were significantly worse amongst the ChD group compared to the NChD group in the SF-36 domains of physical functioning and role-emotional. Poor QoL was also observed in the ChD group with the MLWHFQ scale. The SF-36 item evaluating the patient's perception of the development of their state of health over the past year did not show statistically significant differences between the groups, 9.6% of the ChD group considered that their state of health was worse or much worse compared to 0% of the NChD group. About 30% of the NChD considered that their health was better or much better, in contrast to 21.6% in the ChD group. In the two groups, the most common response was no change, as reported by 68.8% of the ChD and 61.9% of the NChD group.

Multivariate analyses using the ordinal logistic regression model are presented in Table 3. The models were well fitted, considering the Deviance test and the supposition of proportional *odds*; i.e., the single OR for all of the QoL categories compared were valid for all of the constructed models. The abnormal echo variable (p = 0.063) was kept in the model for the SF-36 physical summary score because of its clinical importance. The covariables associated with a poor QoL according to the final logistic regression model were: I) Medical Outcomes Study 36-item Short-Form (SF-36): a) physical component summary: poorer functional classification (OR = 8.02, 95% CI = 2.63–24.41), presence of cardiovascular symptoms (OR = 4.12, 95%CI = 1.78-9.55), and Doppler echocardiogram examination abnormalities (OR = 2.05, 95% CI = 0.96-4.36; b) mental component summary: presence of cardiovascular symptoms (OR = 2.69, 95%CI = 1.26–5.78), female sex (OR = 2.49, 95%CI = 4.31–20.66) poorer physical functioning (OR = 2.49, 95%CI = 1.12-5.52); c) physical functioning: less than two years of education (OR = 16.82, 95%CI = 4.10-

TABLE 2 - Quality of life scores of non-Chagas disease (NChD) and Chagas disease (ChD) groups.

Quality of life variables	NChD (n=21)	ChD (n=125)	p-value <sup>a</sup>
SF-36			
physical summary	52 (48 - 55)	48 (38 - 54)	0.078
mental summary	55 (51 - 57)	53 (43 - 58)	0.446
physical functioning	95 (85 - 100)	85 (65 - 95)	0.011
role-physical	100 (63 - 100)	100 (50 - 100)	0.249
bodily pain	72 (57 - 100)	62 (42 - 96)	0.154
general health	72 (62 - 85)	67 (50 - 82)	0.108
vitality	80 (60 - 83)	75 (55 - 85)	0.490
social functioning	100 (75 - 100)	88 (63 - 100)	0.596
role-emotional	100 (100 - 100)	100 (33 - 100)	0.020
mental health	80 (66 - 88)	76 (60 - 88)	0.454
MLWHFQ scale	0 (0 - 10)	5 (0 - 14)	0.028

NChD: non-Chagas disease, ChD: Chagas disease, SF-36: Medical Outcomes Study 36-item Short-Form, MLWHFQ: Minnesota Living with Heart Failure Questionnaire. Data are median (Q1-Q3). <sup>a</sup>Mann-Whitney test.

68.97), female sex (OR = 3.36, 95%CI = 1.51–8.72), presence of cardiovascular symptoms (OR = 4.6, 95%CI = 1.93–11.30), presence of gastrointestinal symptoms (OR = 3.7, 95%CI = 1.19–6.37), associated illness (OR = 2.75, 95%CI = 1.19–6.37), and ventricular arrhythmia detected during Holter monitoring (OR = 2.47, 95% CI=1.12–5.45); d) role-emotional: presence of cardiovascular symptoms (OR = 8.6, 95%CI = 3.60–20.59) and female sex (OR = 7.04, 95% CI = 3.4–16.32). II) Minnesota Living with Heart Failure Questionnaire (MLWHFQ): marital status (single) (OR = 2.30, 95% CI=1.02-5.15), fewer years of education (OR=4.39, 95%CI=1.37-14.13), poorer functional classification (OR = 3.30, 95%CI = 1.54–7.05), presence of cardiovascular symptoms (OR = 9.11, 95%CI = 3.93–21.12).

TABLE 3 - Model of multivariate analyses: associated factors with quality of life domain: physical and mental summaries, physical functioning and role-emotional of the SF-36 and Minnesota Living with Heart Failure Questionnaire (MLWHFQ) scales.

	Physical	Mental summary	SF-36	SF-36 Role-	MLWHFQ
Variables	summary SF-36	SF-36	physical function	emotional	
Female		9.43[4.31-0.66]	3.63 [1.51-8.72]	7.04 [3.4-16.32]	
Marital status (single)					2.30 [1.0215]
Education			16.82 [4.10-68.97]		4.39 [1.37-14.13]
<2 years					
Poorest functional classification	8.02 [2.63-24.41]	2.49 [1.12-5.52]			3.30 [1.54-7.05]
CVS	4.12 [1.78-9.55]	2.69 [1.26-5.78]	4.67 [1.93-11.30]	8.61 [3.60-20.59]	9.11 [3.93-21.12]
GIS			3.76 [1.17-12.11]		
Associated illnesses			2.75 [1.19-6.37]		
Abnormal Doppler Echo	2.05 [0.96-4.36]				
Ventricular arrhythmias (Holter)		<u> </u>	2.47 [1.12-5.45]		<u> </u>
Goodness-of-fit test	0.74	0.73	0.99	0.10	0.93
Supposition proportional odds	0.55	0.44	0.99	0.20	0.44

Data are *odds ratio* with 95% confidence interval. MLWHFQ: Minnesota Living with Heart Failure Questionnaire, SF-36: Medical Outcomes Study 36-item Short-Form, CVS: cardiovascular symptoms, GIS: gastrointestinal symptoms, Doppler Echo: Doppler echocardiogram, OR: *odds ratio*, CI: confidence interval. A p-value deviance score.

## DISCUSSION

### Differences in the clinical, demographic and complementary examination characteristics of the Chagas disease and non-Chagas disease groups and their association with quality of life

Considering the demographic and clinical differences found between the ChD and NChD groups and the results of complementary tests, a lower level of education, lower percentage of obesity and lower median functional class was verified in the ChD group. The same group showed greater rates of continuous use of medication, presence of cardiovascular symptoms, abnormalities in ECG and Doppler echocardiogram tests and autonomic function tests, greater ventricular arrhythmia detected during Holter monitoring, as well as greater median systolic and diastolic pressure. According to the relevant literature, the differences observed are related, either directly or indirectly, to the ChD profile and the potential development of cardiac disease. An exception was the smaller percentage of obesity in the group, since no specific data exists in the literature regarding this condition in Ch<sup>16,18,30-34</sup>.

The known vulnerability associated with underdevelopment and poverty, observed in the majority of the population affected by ChD<sup>35</sup>, was expressed in this study by the lower level of education verified in the ChD group. In the literature, this condition is highlighted as predictive of mortality from cardiovascular diseases<sup>26,36</sup>, and in this study, it was predictive of poorer HRQoL in the ChD group for the SF-36 physical functioning domain and the MLWHFQ scale.

Features identified in the ChD group, including a lower level of education, greater frequency of continuous medication use and greater presence of cardiovascular symptoms, were associated with poorer HRQoL scores. Such findings suggest that, in addition to the relevance of further study, a multidisciplinary health team is important in the development of a care model, as highlighted in the literature for patients suffering from chronic diseases<sup>4</sup>.

#### Health-related quality of life of Chagas disease

Reports in the literature indicate poorer HRQoL scores for individuals with chronic diseases, mainly in the case of diseases that are more symptomatic and cause greater incapacity<sup>3</sup>. Studies concerning QoL in ChD are scarce and most articles addressed this QoL issue in a generic sense, without using validated instruments. Some papers deal with specific conditions, such as those of pacemaker users, heart failure, or pre- and posttreatment evaluations, and do not describe the profile of QoL in ChD patients. Furthermore, some authors suggest that the putative relation between ChD and depression deserves to be elucidated<sup>37</sup>.

Four studies evaluated ChD patients using a validated QoL instrument (WHOQoL-bref), although with different methodologies. Hueb, using self-evaluations, reported that ChD subjects were significantly dissatisfied with their QoL, general health and daily activity performance in general<sup>38</sup>. Ozaki demonstrated that worse QoL scores correlated with a greater intensity of depression symptoms<sup>39</sup>. Dias verified the lowest score in the environment domain in ChD. The worst perception of QoL in the physical domain was related to a greater number of associated diseases and cardiac and gastric forms of ChD. The psychological and social relation domains were related to cardiac and gastric forms of ChD, while the environment domain correlated with women<sup>40</sup>. Gontijo et al<sup>41</sup> analyzed the QoL in ChD and verified that the cardiac

form of the disease is associated with greater psychological suffering compared to the absence of cardiopathy and that faith helped to deal with the day-to-day difficulties.

In this study, the ChD group presented significantly worse scores for the SF-36 physical functioning and role-emotional domains and for the MLWHFQ. Studying pacemaker patients, Oliveira also reported that the SF-36 physical functioning scores were lower in the ChD group compared to a NChD group<sup>42</sup>. Hidden fear of the impossibility of stopping the disease and its possible malign development<sup>43</sup> are perhaps expressed by the worse role-emotional score verified for the ChD group in this study.

Significant differences were observed in the HRQoL scores between the ChD and NChD groups only in the SF-36 domains of physical functionality and role-emotional and in the MLWHFQ. However, **Table 2** shows that the medians of the scores in the ChD group were lower in all of the valid aspects, as also reported by Hueb<sup>38</sup>.

#### Factors associated with the worst scores

In the present study, it is noteworthy that being female appears to be a risk for over nine-fold poorer QoL for the mental components summary, seven-fold for the role-emotional domain and over threefold for the physical functioning domain, in agreement with data in the literature for other clinical conditions. It is interesting that the ChD literature indicates being male as a risk factor for more severe myocardial damage<sup>44</sup>. In addition, an abnormal ECG, which is recognized as a factor associated with an increased risk of events amongst ChD patients, did not correlate with poorer QoL. Such findings demonstrate the complementary nature of the HRQoL evaluation and that it adds valuable information to routine clinical methods by considering other aspects related to patient well-being.

It is also noteworthy that the presence of factors subject to intervention, such as associated illness and gastrointestinal and cardiovascular symptoms, negatively influenced the QoL of ChD. The presence of cardiovascular symptoms, for example, impacted on five of the HRQoL aspects evaluated and the MLWHFQ score, indicating the great effect of this factor on the well-being of patients.

An abnormal Doppler echocardiogram, the presence of ventricular arrhythmia and poorer functional classification, indicated by Rassi et al<sup>32</sup> as risk factors for sudden cardiac death due to cardiovascular causes, also appeared in this study as risk factors for poorer HRQoL in the ChD group. It is noteworthy that poorer functional classification increased the odds of poorer QoL eight-fold in the physical components summary and 17-fold in the physical functioning domain.

#### Limitations

Some limitations of this study should be considered. The main limitation is the small available sample of NChD subjects. This study was conducted in patients followed in a longitudinal prospective study and it was not possible to recruit new patients, since all of them had been selected almost ten years before. It was not possible to retrieve some potentially significant information, because of the duration of residence in the rural area and of exposure to reinfection. The absence of SF-36 reference scores for the Brazilian population is also an important issue, since it prevents further comparison between ChD patients and other populations.

#### Conclusions

Chagas disease is related to the poorest QoL scores in the physical functioning and role-emotional domains of the SF-36

generic questionnaire and the MLWHFQ specific questionnaire. The factors which stand out among those related to the worst scores in the ChD are being female, cardiovascular symptoms and poor functional classification. Although further studies are required in order to define SF-36 reference values for the Brazilian population, the data strongly suggest that the evaluation of HRQoL should be incorporated into clinical studies involving ChD.

## **CONFLICT OF INTEREST**

The authors declare that there is no conflict of interest.

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