Health-related Quality of Life Determinants in Outpatients

With Heart Failure¹

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This descriptive and exploratory study analyzed variables associated with health-related

quality of life among 130 outpatients. Health-related quality of life was measured through

the Minnesota Living with Heart Failure Questionnaire. Significant associations were found

between patients' health-related quality of life and their age (r=-0.177; p=0.044), vitality

(r=-0.625; p=<0.001) as well as mental health (r=-0.672; p=<0.001), which are both SF-

36 domains. The linear regression showed that heart failure symptom severity, vitality and

mental health explained 54% of HRQOL measurement variation. To control symptoms and

preserve good mental well-being are important to maintain health-related quality of life and

to deliver effective heart failure care.

Descriptors: Heart Failure; Quality of Life; Mental Health; Symptoms.

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Determinantes da qualidade de vida relacionada à saúde em pacientes ambulatoriais com insuficiência cardíaca

Trata-se de estudo descritivo e exploratório que analisou as variáveis associadas à qualidade de vida relacionada à saúde (QVRS), de 130 pacientes com insuficiência cardíaca, em seguimento ambulatorial. A QVRS foi avaliada pelo Minnesota Living with Heart Failure e realizada análise de regressão linear. A média da QVRS foi de 34,9 (dp=24,8; intervalo de 0 a 99). Foram encontradas associações significantes entre a medida da QVRS e idade (r=-0,177; p=0,044), vitalidade (r=-0,625; p=<0,001) e saúde mental (r=-0,672; p=<0,001), domínios do SF-36. A regressão linear mostrou que a gravidade dos sintomas da insuficiência cardíaca, e dois domínios do SF-36, vitalidade e saúde mental, explicaram 54% da variação da medida da QVRS. Controlar os sintomas e manter bem-estar mental é essencial para a manutenção da QVRS e são essenciais para o cuidado eficaz da insuficiência cardíaca.

Descritores: Insuficiência Cardíaca; Qualidade de Vida; Saúde Mental; Sintomas.

Determinantes de la calidad de vida relacionada a la salud en pacientes atendidos en ambulatorios con insuficiencia cardíaca

Se trata de un estudio descriptivo y exploratorio que analizó las variables asociadas a la calidad de vida relacionada a la salud (CVRS) de 130 pacientes con insuficiencia cardíaca en seguimiento en ambulatorio. La CVRS fue evaluada por el Minnesota Living with Heart Failure y realizado análisis de regresión linear. El promedio de la CVRS fue de 34,9 (DE = 24,8; intervalo de 0 a 99). Fueron encontradas asociaciones significantes entre la medida de la CVRS y edad (r=-0,177; p=0,044), vitalidad (r=-0,625; p=<0,001) y salud mental (r=-0,672; p=<0,001), dominios del SF-36. La regresión linear mostró que la gravedad de los síntomas de la Insuficiencia Cardíaca, y dos dominios del SF-36, vitalidad y salud mental, explicaron 54% de la variación de la medida de la CVRS. Controlar los síntomas y mantener el bienestar mental es esencial en la manutención de la CVRS y son esenciales para el cuidado eficaz de la Insuficiencia Cardíaca.

Descriptores: Insuficiencia Cardíaca; Calidad de Vida; Salud Mental; Síntomas.

Introduction

Heart Failure (HF) has been an increasing public health problem in developed countries. Its increase is usually associated with population age, the wide prevalence of cardiovascular risk factors and other diseases. HF is associated with complications like obesity and diabetes, and improved survival rates from myocardial infarction⁽¹⁾.

HF is also a growing concern in developing countries. In Brazil, HF affects over two million people, with 240,000 new diagnoses per year⁽²⁾. HF is present in one third of patients who are treated by the public health system in Brazil, which mostly attends the country's oldest and poorest people. HF is the main cause of heart-related

hospitalizations in the public health system (293,759 admissions in 2007), with an annual mortality rate of about 8% and approximately 23,442 deaths each year⁽²⁾.

Heart failure patients face a wide variety of symptoms that can adversely impact their quality of life. Physical and psychological symptoms are widely reported. Patients with heart failure face significant decreases in functional status, multiple hospital admissions, high mortality, multiple physical and psychological symptoms and a diminished quality of life⁽³⁾.

It is well known that HF significantly worsens healthrelated quality of life (HRQOL) by reducing patients' functional capacity and ability to perform activities of daily living. HRQOL encompasses various aspects of self-perceived well-being, which are related to or affected by the presence of a disease and/or treatment⁽³⁾.

The effects on HRQOL size are influenced by many factors, including patient age, gender, left ventricular dysfunction, New York Heart Association (NYHA) functional class, HF severity, mortality risk and mental health⁽³⁻⁴⁾. Heart failure patients face a wide variety of physical (dyspnea, fatigue, pain, edema, loss of appetite) and psychological (anxiety and depression) symptoms that can adversely impact their quality of life⁽³⁾. Female patients tend to report more physical limitations and depressive symptoms compared with male patients⁽⁵⁾.

In combination, these factors place severe limitations on their daily living activities and have adverse effects on physical and mental health and perceived quality of life. For example, fatigue reduces autonomy and independence for daily activities⁽⁶⁾. However, though quality of life is measureable, it is also a complex and multi-faceted construct that is prone to cultural and social differences. To date, HRQOL during HF has been studied mostly in the United States⁽⁷⁻¹⁰⁾, Canada⁽¹¹⁾ Europe⁽¹²⁻¹⁴⁾ and Asia⁽¹⁵⁾. Due to a lack of studies, little is known about how HF influences HRQOL in South American populations⁽¹⁶⁻¹⁷⁾.

This study was guided by the question: "What are the associations among health-related quality of life, demographic and clinical variables in heart failure outpatients followed at a public hospital in Brazil?"

To address this knowledge gap, this study sought to identify the predictors of Health-related quality of life in heart failure patients followed at a public hospital in Brazil.

Method

Design, setting and subjects

A larger study that used an observational cross-sectional design was based at the University Hospital, Hospital das Clínicas in Ribeirão Preto, São Paulo state, which attends a mixed rural and urban population all over the Southeastern region of Brazil. Approval for the study was obtained from the Institutional Review Board at the School of Medicine. Participants were recruited from the Cardiology Division of the University Hospital. Eligible participants were recruited from a single specialty HF clinic in the hospital. Inclusion criteria included people aged 18 years or older, HF diagnosis based on clinical signs, radiological, and echocardiography findings,

and a medical visit at the Cardiomyopathy Specialized Clinic of the University Hospital during the study period. Exclusion criteria included the presence of neurological disorder, major psychiatric condition (such as dementia or schizophrenia), or cognitive impairment.

The enrollment period ranged from February 2005 to August 2006, 138 patients were invited to participate in the study. Two patients declined to participate and 6 patients could not participate due to their physical, psychological or cognitive conditions. Overall, a convenience sample of 130 patients was analyzed in the study.

Data collection and instruments

Data were collected immediately after the individual's medical visit. Other clinical data were obtained through a review of patients' medical records. To test comprehension and relevance of data collection instruments, a pilot test was performed on ten subjects. As no changes were necessary, those patients were included in the final sample.

The instruments used to measure the variables were the following:

- Health-related quality of life: it was measured using the total score of the Minnesota Living with Heart Failure Questionnaire (MLHFQ)⁽⁸⁾. The MLHFQ total scale ranged from zero to 105, with lower scores meaning better HRQOL. This measurement tool is reliable and valid⁽³⁾. The Portuguese version of the MLHFQ⁽¹⁷⁾ was used and the internal consistency for the total scale was 0.93 in the present study.
- Perceived mental health status: it was measured using the two domains from the Medical Outcomes Study SF-36: mental health (psychological distress and well-being) and vitality (energy and fatigue)⁽¹⁸⁾. In a possible range from zero to 100, higher scores reflect better health perception in both domains. The SF-36⁽¹⁹⁾ Portuguese translation was culturally adapted to Brazil and it was found reliable and valid in HF patients⁽¹⁶⁾. Hence, it was also used.
- Other Variables: Demographic data collected during the interview included age, gender, educational level (in years), marital status (married/have a partner versus not), and work status (having a paid job versus not). Clinical data were: HF etiology, length of follow-up for HF disease (in years). Left Ventricular Ejection Fraction (LVEF) echocardiography test was analyzed to measure left ventricular dysfunction, New York Heart Association Functional Class (NYHA-FC I, II, III e IV)

to measure HF symptoms, number of co-morbidities, number of medications prescribed, and artificial pacemaker presence or resynchronization therapy. Clinical variables were also grouped: LVEF (less than 30% and between 30% and 44%); and the NYHA-Functional Class (class I for asymptomatic HF and classes II to IV for symptomatic HF).

Data analysis

The data were analyzed using the statistical software SPSS (Statistical Package for Social Science version 15.0). Descriptive analysis was performed for all variables. To assess the association of demographic and clinical variables to HRQOL, univariate analyses based on Pearson's correlation was calculated for numerical variables. For categorical explanatory variables, Student's t test was performed to assess differences in mean MLHFQ total score among the categories. Pearson's correlations were calculated between the continuous variables (age, educational background, follow-up HF disease length of time, and Left Ventricular Ejection Fraction) and HRQOL (measured by MLHFQ total score). Linear regression analysis using a stepwise regression model was performed for multivariate investigation of the association between the HRQOL measure and demographic, clinical, and perceived mental health variables. Age and gender were considered factors that were a prior presence in HF and were controlled before clinical variables. The significance level was 0.05.

Results

One hundred and thirty patients were included. Their average age was 55.1 (s.d.=14.9) and most of them were less than 60 years old (78; 60%). The majority was male (n=77, 59.2%), married or living with a partner (80, 61.5%), they had a low education level (four years of formal study on average), and no paid employment (107, 82.3%) (Table 1).

The patients' length of inclusion into the specialty HF clinic was 1.5 years on average, ranging from zero (i.e. patients who were beginning the follow-up on the day of the interview) to 4.8 years. Most of the patients (80; 61.6%) were symptomatic in NYHA-Functional Class II-IV. The mean LVEF was 27% (s.d. = 29; range from 10% to 43%); 46.9% had severe LVEF and 32.3% had moderate LVEF dysfunction. Twenty-one patients (15.4%) had an artificial pacemaker due to

bradycardia and none of them had resynchronization therapy (Table 1).

Fifty-nine participants (44.3%) reported at least one comorbidity, and 86 (47%) participants showed associated diseases, such as: systemic arterial hypertension, chronic atrial fibrillation, arrhythmias, and hyperthyroidism. Among the participants, there was a large variation regarding medication uses, with subjects using from one to ten different classes of medication (mean= $5.8 \, {\rm e} \, s.d. = 1.8$). The most common medications used by the patients and reported in the medical records were diuretics, Angiotensin-converting enzyme, Betablockers and digitalis.

Table 1 - Characteristics of sample (n=130)

Characteristics Mean (s.d.) or n	
Age	55.1 (14.9%)
Less than 60	78 (60.0%)
60 or more	52 (40.0%)
Male	77 (59.2%)
Marital Status (married/partnered)	80 (61.5%)
Educational background (years)	3 (3.9%)
Work status (having no paid job)	107 (82.3%)
length of HF follow-up (in years)	1.5 (1.4%)
Functional Class (NYHA)	
I (asymptomatic)	49 (37.7%)
II/III or IV (symptomatic)	80 (61,6%)
not informed	1 (0.7%)
Left Ventricular Ejection Fraction	27% (29%)
less than 30% (severe dysfunction)	61 (46.9%)
from 30 to 40% (moderate)	42 (32.3%)
not informed	27 (20.8%)
Pacemaker presence (yes)	21(15.4%)

Regarding HRQOL, the mean MLHFQ was: 34.9 (s.d.=24.8; range from 0 to 99). The association between HRQOL and age was negative and weak (r=0.177; p=0.044), although statistically significant. Weak associations were found between HRQOL and length of HF follow-up (r=-0.233; p=0.015), as well as HRQOL and left ventricular ejection fraction (r=-0.236; p=0.017) (Table 2). No association was found between HRQOL and educational background (r=0.004; p=0.960). However, Perceived Mental Health, the exploratory variable of interest, measured by the vitality (r=-.625, p<0.001) and mental health domains (r=-0.672, p<0.001) of the SF-36, showed strong significant associations with HRQOL (Table 2).

Table 2 - Zero order correlation between HRQOL (MLHFQ total score) and explanatory variables

Explanatory variables	r*	p-value†
Age (years)	-0.177	.044
Educational background (years)	0.004	.960
Length of HF follow-up (years)	0213	.015
Left Ventricular Ejection Fraction	-0.236	.017
Vitality (SF-36 domain)	-0.625	<.001
Mental Health (SF-36 domain)	-0.672	<.001

^{*} Pearson's correlation; † p-value

No association was found between HRQOL and demographic variables. Although younger and female patients had higher MLHFQ Total scores (indicating perception of more negative HF effects on quality of life) than older and male patients, differences were not significant (p=0.092 and p=0.052, respectively). Nor did HRQOL vary based on marital status (Table 3). Health-related quality of life was significantly lower in patients with worse symptoms (NYHA Class II, III and IV; p<0.001) but non-significant differences were associated with severe left ventricular dysfunction (less than 30%; p=0.054) (Table 3).

The multivariate analysis was performed using a two-stepwise regression model, constructed first by entering NYHA Classification and then Mental Health and Vitality into the model. After entering the first step,

the adjusted r^2 was 0.204. Hence, the presence of HF symptoms explained, by itself, about 20% of variance in the HRQOL measure. When adding Mental Health and Vitality scales, R^2 increased to 0.496 (49% of the HRQOL variance) and this increase was statistically significant (p-values <0.001). The final model explained 54% of total MLHF scale variation and, also, vitality and mental health together with NYHA Functional Class explained 34% of variance (Table 4).

Table 3 - Mean of MLHFQ total scale by Categorical Explanatory Variables

Explanatory variables	Mean (s.d.)	p-value*
Gender		
Female	39.3 (23.3)	0.092
Male	31.8 (25.4)	
Age (years)		
Less than 60	38.3 (25.6)	0.052
60 or more	29.7 (22.7)	
Marital status		0.869
Married/living with significant other	35.4 (25.7)	0.009
Widowed/Divorced/Separated/Single	34.6 (23.5)	
Functional Class (NYHA)		
I (asymptomatic)	21.0 (16.7)	<0.001
II/III or IV (symptomatic)	42.7 (23.9)	
Left Ventricular Ejection Fraction		
Less than 30% (severe dysfunction)	39.6 (26.6)	0.054
From 30 to 40% (moderate)	29.8 (22.2)	

^{*} p-value from Student's t test

Table 4 - Regression Analysis MLHFQ total score as the Outcome

Explanatory Variable	Coefficient	St. Error	p-value*	r2†	p-value‡
STEP 1					
NYHA Functional Class (ref.: Class I)					
Classes II, III, IV	0.460	4.537	0.00	0.204	0.00
STEP 2:					
NYHA Functional Class	0.300	3.764	0.00		
Mental Health	-0.566	.78	0.00	0.496	0.00
STEP 3:					
NYHA Functional Class	0.208	3.725	0.00		
Mental Health	-0.477	.096	0.00		
Vitality	-0.195	.104	0.33	0.541	0.00

^{*} p-value from Student's t test; † Pearson's correlation; ‡ p-value

Discussion

The contribution of perceived mental health (measured by Vitality and Mental Health SF-36 subscales) to explain the variance in HRQOL was high (31%) after adjusting for demographic and clinical variables. This is consistent with results usually obtained from observational studies in clinical research⁽¹⁴⁾. These results support the hypothesis that symptom severity and psychological factors (such as mood, depression

and anxiety) significantly contribute to HRQOL in HF patients $^{(9-10,20)}$. The levels of HRQOL in our study were similar to those found in other patients with HF in Brazil $^{(16,19,21)}$ and in the USA $^{(5,10,14)}$.

The participants in this study were predominantly less than 60 years old, male, married, with low educational level and without paid employment. Most of the patients were symptomatic, and they were classified

as having severe LVEF or moderate LVEF dysfunction. Among the participants, lower HRQOL was associated with severity of HF symptoms (NYHA functional Classes II, III e IV), and severe left ventricular dysfunction. These findings are consistent with studies undertaken in the United Kingdom⁽¹⁴⁾ and the United States^(4,7-8). In line with other studies, younger patients and women had lower HRQOL⁽³⁻⁴⁾, but there was no association with marital status. Physical symptom status was the most powerful predictor of HRQOL in patients with heart failure⁽²²⁾.

The patients in this study primarily had a lower socio-economic status and showed high levels of low literacy, but this is typical for patients treated in Brazilian public hospitals^(16,19,21-23). The HF sample was also similar to populations from other studies in Brazil^(16,21,24). Although samples used in other studies from the USA^(8,25) and Spain⁽²⁰⁾ showed similar characteristics, most of the samples have considerably higher socio-economic and educational levels. In the future, we propose including this kind of population in a new study in order to improve our knowledge about that population's health.

The impact of HF symptoms is both physical and psychosocial and how to manage these symptoms effectively is a cornerstone of HF management success and self-care^(3,10). Given the importance of HRQOL to patients, the adaptation of disease management interventions to support effective self-care of HF in Brazil is a priority^(16-17,24). Programs to support self-care should include both patients and partners and examine ways to ensure that the many facets of these interventions are accessible and beneficial to patients with very low socioeconomic and educational levels^(9,24-25).

These results suggest that the development and provision of interventions to improve psychological status may improve physical symptom status and HRQOL in HF patients⁽²²⁾. Those most at risk for diminished quality of life are those of younger age, worse functional status, increased symptom prevalence and increased symptom burden⁽³⁾. Though provision of these therapies to the larger population with depressive symptoms will be costly, this may be offset via reduced re-hospitalization rates, which are also common in HF patients from Brazil.

Conclusion

Regarding the effects of HF on HRQoL, there was a weak association between HRQoL and the length of HF follow-up, as well as between HRQoL and the left ventricular ejection fraction. However, Perceived Mental

Health, the exploratory variable of interest, measured by the vitality and mental health domains of the SF-36, was significantly associated with HRQoL. The contribution of perceived mental health to explain the variance in HRQoL was higher after adjusting for demographic and clinical variables. These results support the hypothesis that symptom severity and psychological factors significantly contribute to improve HRQoL in HF patients. Our findings indicated the importance of keeping control of HF symptoms and mental health improvement.

The study is limited by its cross-sectional design and limitations regarding the number of variables that could be measured. Further, longitudinal studies are needed to examine the influence of clinical and psychosocial dimensions on HRQoL across the HF trajectory. Our results suggest that interventions tailored to improve self-perceived vitality and mental health may be worth it to maintain a high level of HRQoL in chronic HF conditions.

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