Quality of Life and Clinical Indicators in Heart Failure: a Multivariate Analysis

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Summary

Background: In Heart Failure (HF), special attention must be given not only to objective or isolated aspects, but also to the patient's health self-perceptions. Subjective aspects can help healthcare providers understand and better treat HF.

Objective: The objective of this study was to evaluate the simultaneous effects of clinical indicators of HF on the Quality-of-Life (QOL).

Methods: We investigated, through a multivariate analysis, the QOL of 101 Brazilian HF outpatients using the Minnesota Living with Heart Failure Questionnaire (including subscales) and its correlation to clinical and physiological variables such as age, ethnicity, gender, echocardiogram parameters, body mass index, mean blood pressure at rest, time since diagnosis, Functional Classification according to the NYHA, functional capacity by a Specific Activity Scale, comorbidities, Framingham Score of Cardiac Risk (CR), Lung Function Test (spirometry) and Body Composition.

Results: QOL showed significant univariate correlations to the echocardiogram: ejection fraction (p=0.0415), left ventricular diastolic diameter (LVDD) (p=0.004), left ventricular systolic diameter (LVSD) (p=0.0001); comorbidities (p=0.002) and Lung Function Test: Forced Vital Capacity (FVC) (p<0.0001), Forced Expiratory Volume in the 1st second (FEV_1) (p<0.0001) and Maximal Voluntary Ventilation (MVV) (p=0.001). In the multivariate analysis, the backward stepwise protocol detected important simultaneous influent variables (r^2=0.60): gender (0.000178), ethnicity (p<0.00001), LVSD (P<0.00001), CR (p=0.000002), FVC (p=0.002027), FEV_1 (p<0.00001) and MVV (p=0.00001). (Arq Bras Cardiol 2009; 93(2):149-156)

Conclusion: Gender, ethnicity, LVSD, CR, FVC, FEV_1 and MVV are independent predictors of HF patients' QOL. Simultaneously, they are responsible for about 60% of the QOL variance. Biopsychosocial aspects could contribute to patient and health professional expectations and treatment results.

Key Words: Heart Failure; Quality of Life; Holistic Health; Multivariate Analysis.

Introduction

Assessing Quality of Life (QOL) has become indispensable when evaluating a patient in clinical practice. The World Health Organization defines QOL as "an individual's perception of their position in life, in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns"[1].

Heart Failure (HF) is a clinical syndrome resulting from a structural or functional cardiac disorder that impairs the capacity of the ventricle to fill with or eject enough blood according to the body demands, or when it does it with increased filling pressures. Its prevalence is estimated approximately as being 2.3% in general population[2] and 0.4% to 2.0% in the European population[3]; Approximately 5 million people in the United States have HF and it results in about 300,000 deaths each year. In Brazil, the largest country in South America, HF is the third cause of all hospitalizations[4]. HF is not just a specific population disease, but also a world epidemic.

Patients with HF have their lives impaired by the disease, and even with optimal treatment, the disease seems to have different degrees of impact on their QOL. Its management involves a multi-professional staff that must take care of the patient's clinical condition, dietary habits, weight management and non-pharmacological care (exercise, education, etc)[3].

Considering these points, the literature shows a significant gap between what health professionals consider to be important goals and what patients do[5], especially when simultaneous aspects of the disease are involved. Therefore, more studies are needed to understand the associations between the pathology of HF and symptoms and the effects of HF on patients' QOL[6]. Many efforts have been made by the scientific community to correlate the subjective and objective aspects of HF[5,7]. These considerations could help health professionals to outline strategies to manage this dysfunction, not only focused on objective goals, but also on the patients' expectations.

The present study was developed to investigate the association between the most commonly assessed clinical aspects of HF and

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Manuscript received on 03/16/08; revised manuscript received on 10/06/08; accepted on 10/24/08

the QOL of these patients, and how these aspects behave when they are analyzed in the presence of others.

Subjects and Methods

Population

One hundred-thirty seven ambulatory HF patients (functional class I-III), users of the Brazilian Public Health Care System were recruited, although only 101 were considered in the final analysis because the fully completed reports were returned.

The inclusion criteria were: stable patients with a clinical diagnosis of HF made by an experienced specialist associated with an ejection fraction ≤45% at the echocardiography (performed in the last 2 months), with no recent myocardial infarction, unstable angina, stroke, coronary revascularization procedure for at least 3 months before enrollment or pacemaker use. Patients with cachexia or difficulties to perform any of the tests were not included in the study.

Characterization data based on scientific reports and clinical practice, which take into account HF management such as gender, ethnicity, body mass index (BMI), mean blood pressure at rest (MBPR), Time since Diagnosis (TD) (up to 2 years or more than two years), Functional Classification according to the New York Heart Association (NYHA), Goldman's Specific Activities Scale (SAS)[8] for measuring functional capacity, comorbidities related to age (Charlson's Index)[9] and Framingham Score of Cardiac Risk (CR) according to the Brazilian Cardiology Society Guidelines[10,11] were assessed.

Lung Function Tests

A spirometric test was performed according to the American Thoracic Society and European Respiratory Society Standardization[12] (Pony Graphics Spirometer, Cosmed, Italy). Data such as Forced Vital Capacity (FVC), Forced Expiratory Volume in the first second (FEV_1), FEV_1/FVC% ratio and Maximal Voluntary Ventilation (MVV) were recorded. All values were expressed as percentages of the total values predicted for the Brazilian population[13].

Body Composition

Fat percent (Fat%), Fat-free mass (FFM) and Total Body Water (TBW) were measured by bioelectrical impedance (BF 907, Maltron International, UK). Resistance was measured in the supine position on the right side as described by Lukaski et al[14].

Quality of Life

QOL was measured using the Brazilian version of the Minnesota Living with Heart Failure Questionnaire (MLHF), a disease-specific measure that assesses patients' perceptions of the influence of HF on physical, socioeconomic, and psychological aspects of life[15]. Other important considerations about this instrument is the fact that it is a comprehensive, easy to apply tool and it has been validated for the Brazilian population[16]. Participants answered the 21 items using a 6-point response scale (0–5). The total summary score (Global Score) can vary from 0 to 105; a lower score reflects better QOL. Three subscale scores (dimensions) reflect physical (questions 2, 3, 4, 5, 6, 7, 12 and 13) and emotional (questions 17, 18, 19, 20 and 21) impairment and the other items are related to financial, medication side-effects, and lifestyle considerations (overall dimensions). This instrument is also suitable for older patients[17].

This study was approved by the Catholic University of Paraná Ethics Committee and all patients gave their formal consent for participation.

Statistical Analysis

Descriptive statistics were computed to characterize the sample through means ± standard deviations (Table 1). A bivariate correlation was performed for a first analysis of the most important association between QOL scores (physical, emotional, overall dimensions and global score) and continuous variables. Considering the bivariate correlation and clinical experience, the multiple regression analysis was performed by choosing as explanatory variables GENDER, ETHNICITY, NYHA, EF, LVDD, LVSD, CHARLSON, FVC%PRED, FEV1%PRE, MVV%PRED, CR and SAS. Colinearity among pulmonary function variables, particularly in FVC and FEV1, are known in normal situation, although studies have shown varied results in HF patients[18], ranging from normal values, to restrictive alterations, to combined restrictive and obstructive alterations[18-20]. Therefore, they were considered simultaneously in a multivariate model. In sequence, the backward stepwise regression for each dimension was performed in order to establish the most influential variables for this sample. All regressions were performed followed by an analysis of variance to test the power of dependent variable prediction. A $p < 0.05$ was considered significant in comparisons and correlations.

Gender (Female=0 and Male=1), ethnicity (White=0 and non-white=1), TD (0-2 years=0 and 2+ years=1), functional class (Class I = 0 and Class II / III= 1) were considered dummy variables to make the multiple regression possible.

Results

Of the 101 patients considered for this analysis, 74% were males (n=76) and 26% were females. Characterization of the sample is provided in Table 1.

QOL Differences in categorical variables

No differences were found in the QOL in relation to gender in all dimension scores as well as in the global score.

Non-Caucasian (n=39) patients seem to present a more affected QOL in Global Score (42.54±20.47) than Caucasian ones (n=62) (34.34±16.38) for p=0.02863. They also presented higher scores in the Overall dimension: non-Caucasian (10.12±6.2) *versus* Caucasian (7.0±5.3), p=0.008. The other dimensions did not show significant differences.

In relation to TD, the sample was divided in two groups (a 0 to 2 year group and a 2+ year group). Significant differences were found only in the Emotional dimension, where the 2+ year group had worse score values (16.07±5) when compared to the 0 to 2 year group (13.2±8.2). This shows a decrease in the psychological aspects of HF patients. In Table 2, the

Kruskall Wally's Test showed significant differences in QOL according to functional class (NYHA). Post-hoc Tukey's test showed that there was no difference between patients from Class II and III (p=ns), whereas Class I patients had better scores in all dimensions.

Multiple regression analysis.

In order to identify important variables that presented a correlation with QOL, a bivariate test was initially performed with each continuous variable and the MLHF scores.

Those correlation results (r) are shown in Table 3.

Echocardiographic, spirometric and comorbidity parameters showed significant and repeated correlation indexes in most of QOL dimensions. In an isolate case, the emotional dimension had a significant correlation with age and SAS, showing a worse emotional status according to aging and the decrease of exercise capability. After identification of those important bivariate correlations, we proceeded with the multiple regression analysis, excluding those what were not significant. The scientific literature explains the importance of the union between the criterion of statistical and practical significance[21], so it has been decided to add some variables that were not significant in the univariate analysis of this sample to the multivariate design, respecting clinical experience, such as CR and the SAS. After several regression tests, the common selected variables for multivariate analyses were: GENDER, ETHNICITY, NYHA, EF, LVDD, LVSD, CHARLSON, FVC, FEV1, MVV, CR and SAS. All of those variables were simultaneously correlated to the MLHF dimensions, in this case considered as a dependent variable.

Table 4 shows the significance levels (p) according to multiple correlation levels (r and r^2) of each chosen variable. Non-significant (p) levels are indicated by *"ns"*.

Categorical variables were considered as dummy variables as explained in Methods. In order to verify the necessity of deleting any outlier observation, an analysis of residuals was performed and all cases were distributed in ±3.5 standards residuals so, there was no need for data exclusion.

Finally, a backward stepwise regression was carried out in order to identify the most influent variables that contributed with the multivariable model. Table 5 shows the results of the backward stepwise regression analysis of the MLHF dimensions.

It is possible to visualize R and R^2 values under each of the dimensions where R represents the correlation of variables (dependent *versus* independent) and R^2 represents a regression coefficient at a specific significance level for a specific sample size. In this study, the most important findings were associated with the MLHF Global Scores, where seven independent variables could consistently explain 60% of the results (gender, ethnicity, LVSD, CR, FVC, FEV_1, MVV). The other dimensions had weaker significant associations.

Table 1 - Baseline characteristics of the sample.

Characteristics	Means ± SD
Age (years)	63±13
Body Mass Index (Kg/m²)	27.6±4,6
Mean Blood Pressure at Rest (mmHg)	93.97±7.42
Ejection Fraction (%)	35±5
Left Ventricular Diastolic Diameter (mm)	64.24±7.74
Left Ventricular Systolic Diameter (mm)	55.12±6.12
Left Atrial Diameter (mm)	45.18±10
Comorbidity (points)	4.41±1.96
CR (points)	17.69±5.39
Fat (%)	28.86±7.77
FFM (%)	71.04±7.78
TBW (%)	51.3±6.56
SAS (Mets)	4.85±1.70
Minnesota Living with Heart Failure (points)	
Global Score	37.50±18.41
Physical dimension	14.2±8.8
Emotional dimension	15.1±6.4
Overall dimension	8.2±5.9
FVC (% predicted)	83.30±27.05
FEV_1 (% predicted)	80.79±25.03
FEV_1/CVF (% predicted)	100.31±14.88
MVV (% predicted)	97.87±30.46

CR– Cardiac Risk; FFM-Fat Free Mass; TBW– Total Body Water; SAS– Specific Activity Scale; FVC– Forced Vital Capacity; FEV_1– Forced Expiratory Volume in First Second; MVV– Maximal Voluntary Ventilation.

Table 2 – Differences in QOL according to functional classes (Kruskall Wallys Test)

	Functional Class (NYHA)			p
	I(n=21)	II (n=56)	III (n=24)	
Global Score	21.1±18.9	40.3±14.5	45.4±18.2	0.000004
Physical dimension	7.9±9	15.4±7.2	16.9±9.8	0.000672
Emotional dimension	9.2±6.9	15.7±4.9	18.9±5.9	<0.0000001
Overall dimension	4.0±5.3	9.2±5.5	9.6±5.6	0.000735

Post-hoc Tukey's test showed no difference between class II and III.

Table 3 – Bivariate Correlations (r) between the variables and QOL.

	MLHF	Physical	Emotional	Overall
AGE	0.14	0.03	0.27*	0.09
BMI	0.01	0.05	-0.02	-0.01
MBPR	-0.08	0.00	-0.13	-0.12
EF	-0.20*	-0.24*	-0.23*	-0.03
LVDD	0.28**	0.29**	0.26**	0.17
LVSD	0.37***	0.34***	0.38*	0.24*
LAD	-0.02	-0.03	-0.03	0.02
COMORBIDITY	0.30**	0.26**	0.38***	0.12
CR	0.12	0.10	0.12	0.10
%FAT	0.04	0.01	0.09	0.01
%FFM	-0.03	-0.01	-0.08	-0.00
%TBW	-0.10	-0.10	-0.09	-0.07
SAS	-0.15	-0.09	-0.23*	-0.09
FVC	-0.45***	-0.47***	-0.35***	-0.32***
FEV_1	-0.48***	-0.48***	-0.39***	-0.34***
FEV_1/FVC	0.06	0.09	-0.01	0.06
MVV	-0.32***	-0.30**	-0.31***	-0.22*

**p≤0.05; **p≤0.01; ***p≤0.001*
BMI– Body Mass Index; MBPR– Mean Blood Pressure at Rest; EF– Ejection Fraction; LVDD– Left Ventricular Diastolic Diameter; LVSD– Left Ventricular Systolic Diameter; LAD– Left Atrial Diameter; CR– Cardiac Risk; FFM– Fat Free Mass; TBW– Total Body Water; SAS– Specific Activity Scale; FVC– Forced Vital Capacity; FEV1– Forced Expiratory Volume in the First Second; MVV– Maximal Voluntary Ventilation.

Table 4 - Significance levels (p) according to the correlation coefficient (r) and the coefficient of determination (r2).

	Global score	Physical Dimension	Emotional dimension	Overall dimension
	(R=0.80; R^2=0.64)	(R=0.73; R^2=0.54)	(R=0.76; R^2=0.58)	(R=0.65; R^2=0.42)
GENDER	<0.01	<0.01	NS	NS
ETHNICITY	<0.01	<0.01	<0.01	<0.01
NYHA	0.03	NS	0.01	0.02
EF	NS	NS	NS	NS
LVDD	NS	NS	NS	NS
LVSD	<0.01	NS	<0.01	0.01
COMORBIDITY	NS	NS	0.01	NS
CR	0.01	<0.01	NS	NS
SAS	NS	NS	NS	NS
FVC	<0.01	0.02	<0.01	0.03
FEV_1	<0.01	<0.01	<0.01	<0.01
MVV	<0.01	<0.01	<0.01	<0.01

NYHA– Functional Class according to New York Heart Association; EF– Ejection Fraction; LVDD– Left Ventricular Diastolic Diameter; LVSD– Left Ventricular Systolic Diameter; CR– Cardiac Risk; SAS– Specific Activity Scale; FVC– Forced Vital Capacity; FEV_1– Forced Expiratory Volume in the First Second; MVV– Maximal Voluntary Ventilation; NS– Non-significant.

Table 5 – Backward stepwise regression of the MLHF questionnaire dimensions.

Dimension		Beta	Std.Err.	B	Std.Err.	t(93)	p-level
Global Score	Intercept			-27.817	13.839	-2.010	0.047
(R=0.77; R^2=0.60)	GENDER	-0.281	0.072	-11.934	3.055	-3.906	<0.001
	ETHNICITY	0.409	0.074	15.381	2.784	5.525	<0.001
	LVSD	0.621	0.082	12.768	1.687	7.568	<0.001
	FVC	0.632	0.199	0.431	0.136	3.176	0.002
	FEV_1	-1.456	0.255	-1.071	0.187	-5.717	<0.001
	MVV	0.628	0.134	0.393	0.084	4.671	<0.001
	CR	0.397	0.079	1.355	0.270	5.022	<0.001
Physical Dimension	Intercept			27.951	2.631	10.626	<0.001
(R=0.48;R^2=0.23)	FEV_1	-0.482	0.088	-0.170	0.031	-5.479	<0.001
Emotional Dimensions	Intercept			0.447	2.798	0.160	0.873
(R=0.55; R^2=0.30)	NYHA	0.413	0.086	6.520	1.354	4.815	<0.001
	LVSD	0.297	0.086	2.137	0.616	3.467	<0.001
Overall Dimension	Intercept			14.589	1.876	7.776	<0.001
(R=0.33; R^2=0.11)	FEV_1	-0.337	0.095	-0.079	0.022	-3.559	0.001

LVSD– Left Ventricular Systolic Diameter; FVC– Forced Vital Capacity; FEV_1– Forced Expiratory Volume in the First Second; MVV– Maximal Voluntary Ventilation; CR– Cardiac Risk; NYHA– Functional Class according to New York Heart Association.

An analysis of variance after the initial multivariate model and after the backward stepwise method was employed showed that the independent variables could explain the MLHF dimension scores ($p<0.05$). We also performed the F-test for each regression in order to test the significance of R, which is the same as testing the significance of R^2. All analyses showed significant values for R and R^2.

Specifically for Global Scores, the stepwise regression method is used in the exploratory phase of research or for purposes of pure prediction; we demonstrate this association in Figure 1.

Discussion

HF is a multifactorial dysfunction that decreases functional status; it requires frequent hospitalizations and affects patients' life expectancy. Nearly 5 million Americans are currently living with HF, and 550,000 new cases are diagnosed each year[22]. Specifically in Brazil, it results in a large amount of expenses for the patients and the public health system[4,23]. When analyzing the clinical causes that have resulted in the highest numbers of hospital admissions in 2002, under the Brazilian Public health System responsibility, HF was ranked third (372,604), after pneumonia (794,260) and asthma (376,447)[4]. Strategies to improve outcomes that focus not only on objective and physiological outcomes are primordial for its management, aiming at wider results[24,25].

QOL in HF is still a complex object of study and it has not been well established to date. Many aspects can influence its assessment (biopsychosocial aspects), and these point stimulate its investigation.

The present study suggests that QOL in HF has to be analyzed in a multiple-angle view. That was observed in Global Score associations, where seven distinct independent variables explained about 60% percent of the sample QOL results when analyzed simultaneously.

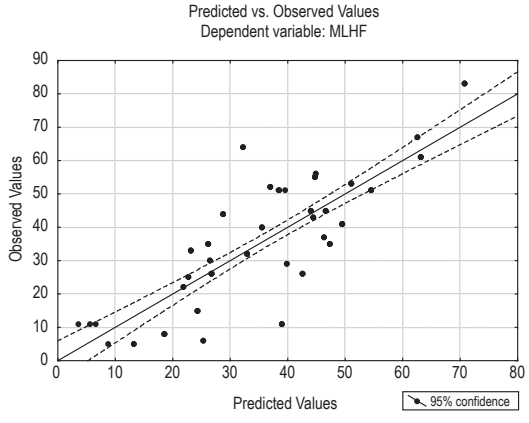

Figure 1 – Predicted versus Observed QOL Values.

Ethnicity is one of the factors to be considered in our study. Non-Caucasian patients have a poorer QOL when compared to Caucasian ones. Literature explains that there are differences among ethnicities regarding the prevalence, etiology, and outcomes of HF[26]. As cited by Taylor et al[27], compared to Caucasians, African-Americans are diagnosed with HF at a markedly higher rate, are more likely to have hypertension than coronary artery disease, die more quickly, and are more often hospitalized due to HF. Even with the advances of cardiac therapy in the United States, they do not benefit equally; for instance, African-American patients do not respond as well as Caucasians to the angiotensin-converting enzyme inhibitor[28]. There have been no studies carried out with the African-Brazilian population, but the same mechanism seems to be involved. Moreover, ethnic differences might be related not only to HF management or physiopathology, but also to the Brazilian health and social systems, where African descendants have less access to prevention and treatment of several diseases[29,30].

The NYHA Functional Classification is a widely used general (4 categories), provider-derived classification scheme to categorize patients in terms of symptoms associated with daily activities.

Our study, similarly to others, showed significant differences in NYHA functional classes when their QOL were compared. Bennet et al[31], found differences in QOL except in classes III and IV. The present report did not take into consideration class IV because of the technical difficulties in the performance of some tests such as spirometry, which causes extreme dyspnea to class IV patients. It was observed that as in NYHA classes, class I patients have less evident impairment of their QOL. The multivariate analysis showed NYHA Functional Classification as an important influence variable in the patients' QOL, specifically in Global Scores and Emotional Dimension. NYHA Functional Classification showed a significant association with vitality and mental health in a study using SF-36[5], suggesting that NYHA Classes must be assessed taking into consideration not only the physical aspects, but also the subjective ones.

Bivariate correlations demonstrated weak but significant associations between echocardiogram parameters such as EF, LVDD and LVSD, showing that a poor output capacity and an enlarged systolic and diastolic diameter of the left ventricle caused by overload can impair QOL. Myers et al[32], using another QOL instrument, demonstrated weak but significant correlations between EF and QOL[32]. Mitani et al[5], using a generic instrument (SF-36)[33], found no associations among these parameters. In an important study for this area, Grigioni et al[24], using the MLHF questionnaire, also found no association between echocardiogram and QOL parameters; however, they considered NYHA classes I to IV. Interestingly, when we performed the multivariate analysis, only LVSD remained as an overall influential factor for QOL. Additional studies would be important to clarify these points.

The Chalson Comorbidity Index[9,34] shows the prognosis based on age and comorbid conditions and with each increased level of the comorbidity index, the cumulative mortality attributable to comorbid diseases increases in a step-wise fashion. In our study, comorbidities had a significant bivariate correlation with QOL and although the multivariate model did not show statistically important significance, we could observe a tendency ($p=0.082518$) in it. Comorbidity in HF patients can contribute to diagnosis difficulties in older patients[35] and is directly associated with prognosis when considering mortality[36]. There is a scarcity of previous specific studies correlating QOL in HF with comorbidities.

CR showed to be an important aspect to be considered when assessing QOL in HF, as its multiple score takes into consideration not only the impact of specific variables as age, cholesterol levels, blood pressure and smoking, but also their synergism[11]. Its presence in the backward stepwise model showed the importance of clinical experience when evaluating HF patients.

This research showed that pulmonary function is impaired and had a significant association with the patients' QOL. The bivariate correlation showed that higher MLHF scores had worse results at the spirometry. Decreased FVC and FEV_1 and a normal FEV_1/CVF were observed in the sample and this is corroborated by Johnson et al[18] and Forgiarini et al[19]; however, other studies did not correlate pulmonary dysfunction and QOL in HF. Another important aspect to consider is that at least one pulmonary function parameter was associated with QOL (dimensions). Abnormal respiratory values could be attributed to muscular factors[19,37-39], which explains breathlessness and reduced exercise capacity beyond the diaphragm position; this is altered in HF, causing a mechanical disadvantage in respiratory efficacy as a result of an adaptive response to a change in the cardio-thoracic ratio by the direct mechanical displacement of the diaphragm due to an increase in heart size[40].

The most important finding of this work is related to the simultaneous effects of the variables and the patient's QOL in the multivariate analysis. Considering all bivariate correlations related to QOL variables plus practical experience-based variables, it was demonstrated that $R^2= 0.64$ and after the backward stepwise method, $R^2= 0.60$. The backward stepwise model is a sequential search method that starts with all variables and eliminating independents one at a time until the elimination of one makes a significant difference in R-squared. In our case, we selected explanatory variables that provided good predictors of QOL such as gender, ethnicity, LVSD, CR, FVC, FEV_1, MVV (Table 4).

The limitations of this study include the fact that the studied variables still failed in determining about forty percent of QOL variance and this could be related not only to the objective variables, but to other disease aspects that were not found in the present study; yet, this work is a first step in an attempt to correlate a very important and misunderstood aspect of HF assessment and we believe that further studies with larger sample sizes and the inclusion of other independent variables such as smoking exercise practice and leisure, psychological support and others might explain larger variations of QOL.

In conclusion, gender, ethnicity, LVSD, CR. FVC, FEV_1 and MVV can be considered independent predictors of HF patients' QOL; together, they represent about 60% of the QOL variance. This study showed that QOL is affected in HF patients and it is important to be considered in the disease management. Other aspects in addition to the objective ones are also fundamental in the HF patient daily living. This reminds health care professionals to emphasize not only the physiological results, but also to be aware of holistic aspects such as cultural and social life, psychological influences and functionality that could affect the patient's global status.

Acknowledgements

The study was carried out with the support of University of Paraná (Brazil) and Health Sciences Doctoral Program of the Catholic University of Paraná (Brazil).

Special thanks to Prof. Dr. Roberto Pecoits Filho and Dr. Fabiane Nascimento for their helpful suggestions during this study pre-design.

The authors are indebted to Prof. Marcia Olandoski for statistical help.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

Sources of Funding

This study was partially funded by UNIPAR.

Study Association

This article is part of the doctoral thesis submitted by Jefferson J. Amaral dos Santos, from Pontífica Universidade Católica do Paraná.

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