



# Do generic and disease-specific quality of life measures associate similarly in individuals with stable heart failure and individuals with stable COPD?

*As medidas de qualidade de vida genéricas e específicas para doença associam-se de forma semelhante em indivíduos com insuficiência cardíaca estável e indivíduos com DPOC estável?*

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## Abstract

**Background:** Individuals with heart failure (HF) present with chronic symptoms similar to those presented by individuals with chronic obstructive pulmonary disease (COPD). These symptoms can lead to worse health-related quality of life (HRQoL), which can be assessed through generic or disease-specific measures. **Aim:** To verify the association between generic and disease-specific measures of HRQoL in individuals with stable HF and those with stable COPD. **Methods:** Cross-sectional study which included two groups: 1) individuals with stable HF; 2) individuals with stable COPD. The Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) questionnaire was used as the generic measure of HRQoL answered by both groups. The disease-specific HRQoL instruments used in this study were the Minnesota Living with Heart Failure Questionnaire (MLHFQ) answered by individuals with HF, and the Saint George's Respiratory Questionnaire (SGRQ) answered by individuals with COPD. All instruments were applied during interviews by trained researchers. **Results:** In total, 122 participants were included (62 with HF, 57% were men with a mean age of  $55 \pm 14$  years; and 60 with COPD, 42% were men with a mean age of  $66 \pm 9$  years). Stronger correlations were observed between generic and disease-specific HRQoL instruments in individuals with HF ( $-0.71 \leq r \leq -0.48$ ) when compared to the correlations observed in individuals with COPD ( $-0.57 \leq r \leq -0.33$ ). Worse scores in the SF-36's component summaries were observed in individuals with worse HRQoL by the MLHFQ ( $p < 0.05$  for all analyses), but not in individuals with worse HRQoL by the SGRQ. **Conclusion:** There seems to be a stronger association between generic and disease-specific HRQoL measures in the group of individuals with stable HF compared to individuals with stable COPD.

**Keywords:** Quality of Life; Chronic Obstructive Pulmonary Disease; Heart Failure.

## Resumo

**Introdução:** A insuficiência cardíaca (IC) e a doença pulmonar obstrutiva crônica (DPOC) causam sintomas crônicos semelhantes e pior qualidade de vida relacionada com a saúde (QVRS), que pode ser avaliada através de medidas genéricas ou específicas para doença. **Objetivo:** Verificar a associação entre medidas genéricas e específicas para doença de QVRS em indivíduos com IC estável e com DPOC estável. **Métodos:** Estudo transversal que incluiu indivíduos com: 1) IC estável, e; 2) DPOC estável. O questionário Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) foi utilizado como medida genérica de QVRS respondida por ambos os grupos. Os instrumentos de QVRS específicos para doença utilizados neste estudo foram o Minnesota Living with Heart Failure Questionnaire (MLHFQ), respondido por indivíduos com IC, e o Saint George's Respiratory Questionnaire (SGRQ), respondido por indivíduos com DPOC. **Resultados:** Foram incluídos 122 participantes (62 com IC, 57% homens, idade média de  $55 \pm 14$  anos; e 60 com DPOC, 42% homens, idade média de  $66 \pm 9$  anos). Correlações mais fortes foram observadas entre instrumentos de QVRS genéricos e específicos para doença em indivíduos com IC ( $-0,71 \leq r \leq -0,48$ ) quando comparados às correlações observadas em indivíduos com DPOC ( $-0,57 \leq r \leq -0,33$ ). Piores escores nos componentes sumarizados do SF-36 foram observados em indivíduos com pior QVRS pelo MLHFQ ( $p < 0,05$  para todas as análises), mas não em indivíduos com pior QVRS pelo SGRQ. **Conclusão:** Parece haver uma associação mais forte entre medidas genéricas e específicas para doença de QVRS no grupo de indivíduos com IC estável em comparação com indivíduos com DPOC estável.

**Palavras-chave:** Qualidade de Vida; Doença Pulmonar Obstrutiva Crônica; Insuficiência Cardíaca.

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## INTRODUCTION

Chronic diseases place a great burden upon healthcare systems<sup>1</sup>. Heart failure (HF) and chronic obstructive pulmonary disease (COPD) are among the most common chronic diseases. These two health conditions are among the top 10 causes of death according to 2019 data from the World Health Organization (WHO): ischemic heart disease (the main cause of HF) is the world's biggest killer, responsible for 16% of the world's total deaths, while COPD is the third leading cause of death, responsible for approximately 6% of total deaths<sup>2</sup>. Both diseases have smoking as a common risk factor and similar signs and symptoms, such as dyspnea, peripheral muscle weakness, and exercise intolerance, which will lead to reduced quality of life (QoL)<sup>3,4</sup>.

The World Health Organization (WHO) defines QoL as "a human being's perception of his position in life by considering the context of the culture and value systems in which he lives and in relation to his goals, standards, and concerns"<sup>5</sup>. Health-related QoL (HRQoL), in turn, encompasses aspects of overall QoL that can be able to affect health, either physically or mentally<sup>6</sup>. Due to systemic manifestations caused by COPD and HF, the HRQoL of individuals with these conditions is significantly compromised, especially in the areas of bodily functioning and vitality<sup>7</sup>. In addition, HRQoL has been identified as an important predictor of clinical outcomes in these patient populations. For example, impaired HRQoL after hospital discharge was a powerful predictor of hospital readmission and mortality in HF<sup>8</sup>, and a predictor of mortality in COPD<sup>9</sup>.

HRQoL instruments have been classified as either generic, when they have generic questions that can be used with different patient populations, or disease-specific, when they have questions related to specific health conditions<sup>10</sup>. Examples of generic instruments include the Medical Outcomes Study 36-item Short-Form Health Survey (SF-36)<sup>11</sup> and the WHO QoL (WHOQOL)<sup>5</sup>, while examples of disease-specific instruments include the Minnesota Living with Heart Failure Questionnaire (MLHFQ) for individuals with HF<sup>12</sup>, and the Saint George's Respiratory Questionnaire (SGRQ) for individuals with respiratory diseases<sup>13</sup>. In fact, these two instruments have been identified as the most commonly used HRQoL instruments in these patient populations. In a systemic review including more than 100 randomized controlled trials that assessed QoL in HF, the MLHFQ was used in 87% of the studies, which was the most commonly used instrument<sup>14</sup>. Moreover, in a more recent systemic review of pulmonary rehabilitation outcomes in individuals with COPD, the SGRQ was identified as the most common HRQoL instrument (51% of the studies which investigated HRQoL)<sup>15</sup>.

In individuals with HF or COPD, generic and disease-specific HRQoL questionnaires may be differently associated with relevant clinical outcomes, such as exacerbations/decompensations and deaths<sup>8,9</sup>. However, it seems that no study so far has investigated the HRQoL of individuals with HF and COPD in-depth, as assessed by

generic and disease-specific instruments, to know whether these two types of instruments associate similarly in these two patient populations. It is relevant to compare HF and COPD populations in this study as these diseases are among the major causes of loss of QoL and disability, in addition to the important economic impact on individuals and their families. Moreover, by comparing the association between generic and disease-specific measures within each disease population, we might be able to suggest whether these two types of measures should be used in combination, or whether just one of them could be enough.

The objective of this study was to verify the association between generic and disease-specific measures of HRQoL in individuals with stable HF and in individuals with stable COPD. We hypothesize that the magnitude of the associations will be different between these two groups. As a secondary objective, we also aimed to compare generic measures of HRQoL between the two groups.

## METHODS

### Study design and sample

A cross-sectional study in which participants were recruited from the cardiac and pulmonary outpatient clinics from the Dr. Carlos Alberto Studart Gomes Messejana Hospital, in Fortaleza, Ceará, Brazil, from June to August 2015. The current study represents a sub-analysis of previous studies that aimed to investigate the association of HRQoL with clinical outcomes in individuals with COPD or HF. These previous studies were approved by the local ethics committee (approval numbers 1.107.111, 1.107.081, 1.086.364 and 1.064.300), and all participants provided written informed consent.

Inclusion criteria for individuals with HF were: Age  $\geq 18$  years old; HF diagnosis with functional class II, III, or IV according to the functional classification of the New York Heart Association – NYHA; clinical stability at the time of assessment; being under treatment of the disease for at least six months; absence of dementia or cognitive impairment that could compromise the assessments and; provided written informed consent. Inclusion criteria for individuals with COPD were: Age  $\geq 40$  years old; COPD diagnosis with moderate-to-severe airflow limitation; clinical stability at the time of assessment; being under treatment of the disease for at least six months; absence of dementia or cognitive impairment that could compromise the assessments and; provided written informed consent.

Exclusion criteria for both diseases were: orthopedic, cognitive limitations, or any condition that could compromise the results of the proposed assessments, or the presence of demyelinating neurological disease or any sequelae resulting from a stroke. This article was presented in accordance with the recommendations of the Strengthening the Communication of Observational Studies in Epidemiology (STROBE) initiative<sup>16</sup>.



## Assessments

Socio-demographic and clinical data were collected, such as age, sex, and comorbidities. Generic and disease-specific HRQoL questionnaires were administered by trained researchers during interviews. The generic HRQoL instrument used was the Portuguese-language version of the SF-36<sup>11</sup>. The SF-36 consists of 36 questions subdivided into eight domains: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. These domains can be aggregated into two component summaries: Physical Component Summary (PCS) and Mental Component Summary (MCS), which were used for analysis in the current study. The score for each component can range from 0 (worst) to 100 (best HRQoL)<sup>11</sup>. This instrument was answered by individuals with HF, as well as those with COPD.

Additionally, individuals with HF answered the MLHFQ, which has been validated for Brazilian Portuguese and consists of 21 questions, which evaluate the physical, socioeconomic, and emotional conditions<sup>12</sup>. Eight questions have a strong relationship with symptoms of illness and fatigue, and represent the physical domain of the instrument, while five other questions are strongly related to emotional issues, and represent the emotional domain; the other questions do not fit into any of these two domains. For each question participants were instructed to select a number from 0 to 5, where 0 indicates no limitation and 5 indicates a very important limitation. The final score for the MLHFQ can range from 0 to 105, with higher scores indicating worse HRQoL<sup>12</sup>. A cut-off of  $\geq 45$  points was used to indicate poor HRQoL, as this threshold proved to be valid when compared to other measures of disease severity<sup>17</sup>.

Individuals with COPD also answered the SGRQ<sup>18,19</sup>. The SGRQ has been translated and validated for Brazilian Portuguese<sup>13</sup> and consists of 50 items subdivided into three domains: symptoms (8 items), activities (16 items), and impact (26 items). The scores for each question are added together and a total score is referred to as a percentage of that maximum value (0-100); lower values indicate better HRQoL<sup>13</sup>. In addition, limitations in daily life caused by dyspnea in this patient population were assessed by the modified Medical Research Council scale, which was used to characterize the sample<sup>20</sup>.

## Statistical analysis

Data were presented as absolute and relative frequency, mean  $\pm$  standard deviation (parametric data), or median (interquartile range 25-75%) (nonparametric data). Correlations were assessed using the Spearman's correlation coefficient between generic and disease-specific HRQoL questionnaires, according to the normality in data distribution, which was assessed using the Shapiro-Wilk test. The strength of the correlations was classified as follows:  $r < 0.25$ , little or none;  $0.25 < r < 0.50$ , reasonable;  $0.50 < r < 0.75$ , moderate to good and;  $r > 0.75$ , good to excellent<sup>21</sup>.

In order to further investigate the association between generic and disease-specific instruments, the scores on the generic instrument were compared between subgroups of individuals defined according to the score on the disease-specific measure. For these between-group comparisons, the unpaired Student's t-test or Mann-Whitney test was used, depending on the normality in data distribution. Categorical variables were compared by the chi-square test. A value of  $p < 0.05$  was interpreted as statistically significant. The analyses were performed using SPSS 22.0 (IBM Corp., Armonk, NY, USA). GraphPad Prism 6 (GraphPad Software, La Jolla, California, USA) was used for graphical presentations.

## RESULTS

### Patient characteristics

Sociodemographic and clinical characteristics of the sample are described in Table 1. A total of 122 individuals were included (62 individuals with HF and 60 individuals with COPD). Comorbidities were present in 53% of the total sample, with high blood pressure and diabetes mellitus as the most frequent comorbidities. When the two patient groups were compared, we observed that individuals with HF were younger than those with COPD. Moreover, there was a relatively balanced sex distribution between the two groups (Table 1).

The scores for the HRQoL instruments in each group are also shown in Table 1. Individuals with HF had better SF-36's PCS scores (i.e. better HRQoL in the physical domain) than individuals with COPD, but no difference was observed for the MCS.

### Correlations between generic and disease-specific HRQoL measures

Correlation coefficients between the scores on the SF-36 and the scores on the disease-specific questionnaires are shown in Tables 2 and 3. In the group of individuals with HF, a moderate and significant negative correlation was observed between the PCS of the SF-36 and the emotional domain of the MLHFQ (Table 2). There were also significant strong and negative correlations between the SF-36's PCS and the physical and total scores of the MLHFQ (Table 2). Regarding the MCS of the SF-36, moderate and significant negative correlations were observed with the physical, emotional, and total scores of the MLHFQ (Table 2).

Moderate and significant negative correlations were observed between the PCS of the SF-36 and the activities and impact domains of the SGRQ, as well as with its total score in the group of individuals with COPD (Table 3). Regarding the MCS of the SF-36, reasonable and significant negative correlations were observed with the symptoms and impact domains of the SGRQ (Table 3).



**Table 1.** Sociodemographic and clinical characteristics of individuals with heart failure and individuals with chronic obstructive pulmonary disease. Fortaleza, Ceará, Brazil, 2015. n = 122.

Characteristic	Total (n=122)	HF (n=62)	COPD (n=60)	p-value
Age, Years	62 (52 – 69)	55 ± 14	66 ± 9	<0.001
Male, n (%)	60 (49)	35 (57)	25 (42)	0.10
Literate, n (%)	95 (78)	58 (94)	37 (38)	<0.001
<b>Comorbidities, n (%)</b>				0.71
None	57 (47)	30 (48)	27 (45)	
Hypertension	49 (40)	21 (34)	28 (47)	
DM	24 (20)	12 (19)	12 (20)	
Others	16 (13)	15 (24)	1 (2)	
mMRC score	-	-	2 (1-3)	-
<b>Quality of life</b>				
SF-36 PCS	37 (30 – 46)	45 (39 – 51)	30 (25 – 36)	<0.001
MCS	49 (42 – 57)	48 (41 – 55)	50 (42 – 57)	0.65
SGRQ Symptoms	-	-	50 ± 21	-
Activity	-	-	73 (66 – 81)	-
Impact	-	-	45 ± 16	-
Total	-	-	54 ± 15	-
MLHFQ Physical	-	13 (7 – 27)	-	-
Emotional	-	7 (3 – 11)	-	-
Total	-	35 (18 – 56)	-	-

Data expressed as absolute and relative frequency, mean ± standard deviation or median (interquartile range 25-75%). COPD: chronic obstructive pulmonary disease; HF: heart failure; DM: diabetes mellitus; mMRC: modified Medical Research Council scale; SF-36: Medical Outcomes Study 36-item short-form health survey; PCS: physical component summary; MCS: mental component summary; SGRQ: Saint George's Respiratory Questionnaire; MLHFQ: Minnesota Living with Heart Failure Questionnaire.

**Table 2.** Coefficients of correlation between generic and disease-specific measures of health-related quality of life in individuals with heart failure. Fortaleza, Ceará, Brazil, 2015. n=62.

	SF-36's PCS	SF-36's MCS
MLHFQ-Physical	-0.71*	-0.63*
MLHFQ-Emotional	-0.48*	-0.66*
MLHFQ-Total	-0.71*	-0.67*

Data expressed as Spearman's correlation coefficient ( $r_s$ ). SF-36: Medical Outcomes Study 36-item short-form health survey; PCS: physical component summary; MCS: mental component summary; MLHFQ: Minnesota Living with Heart Failure Questionnaire. \*: p<0.05.

### Between-group comparisons of HRQoL with a generic measure

Figure 1 shows the comparison of SF-36's PCS and MCS scores between groups of individuals according to their scores on the disease-specific HRQoL questionnaires (i.e. total scores). It was observed that the PCS and MCS scores were lower, indicating worse HRQoL, in the group of individuals with HF and worse HRQoL by the MLHFQ. Regarding individuals with COPD, the PCS scores were worse

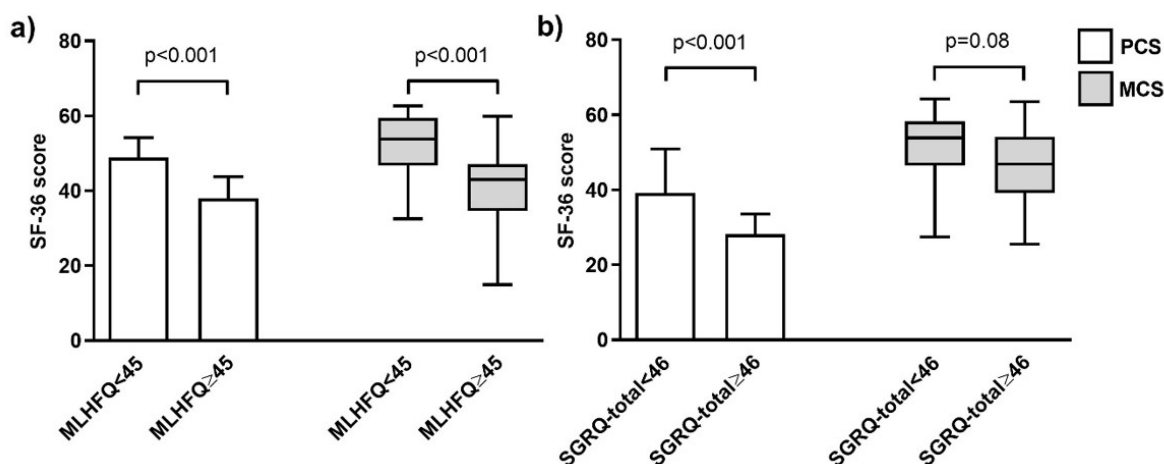
**Table 3.** Correlation coefficients between generic and disease-specific measures of health-related quality of life in individuals with chronic obstructive pulmonary disease. Fortaleza, Ceará, Brazil, 2015. n=60.

	SF-36's PCS	SF-36's MCS
SGRQ-Symptoms	-0.23	-0.44*
SGRQ-Activity	-0.57*	-0.23
SGRQ-Impact	-0.54*	-0.33*
SGRQ-Total	-0.54*	-0.36*

Data expressed as Spearman's correlation coefficient ( $r_s$ ). SF-36: Medical Outcomes Study 36-item short-form health survey; PCS: physical component summary; MCS: mental component summary; SGRQ: Saint George's Respiratory Questionnaire. \*: p<0.05.

in the subgroup of individuals with worse HRQoL by the SGRQ, but there was no significant difference for the MCS scores. The mean differences in the SF-36's PCS scores between subgroups stratified according to the disease-specific HRQoL measure were 11 points for the SGRQ, and 11 points for the MLHFQ, while the mean differences for the SF-36's MCS scores were 7 points for the SGRQ, and 11 points for the MLHFQ.





**Figure 1.** Comparisons (Student's t-test or Mann-Whitney test) of the PCS and MCS scores of the SF-36 between groups of individuals with HF (a) or COPD (b) separated according to their scores on the disease-specific HRQoL questionnaire. Fortaleza, Ceará, Brazil, 2015. n=122.

## DISCUSSION

The present study investigated the correlation between generic and disease-specific HRQoL measures in individuals with HF or COPD. Our results showed stronger correlations between generic and disease-specific HRQoL measures in individuals with HF, when compared to those observed in individuals with COPD. Moreover, the MLHFQ was better for discriminating generic HRQoL in HF, than the disease-specific HRQoL questionnaire for individuals with COPD. Previous studies have performed similar analyzes in samples of individuals with pulmonary or cardiac diseases (details in the following paragraphs), but never in the same study.

When investigating the correlation between generic and disease-specific HRQoL questionnaires in individuals with COPD, Wilke et al.<sup>22</sup> observed that the SF-36's PCS and MCS scores were significantly correlated with the SGRQ total score assessed at four different points in time: baseline, 4 months, 8 months, and 12 months ( $r=-0.679$  to  $-0.285$ ;  $p<0.01$ ). These correlation coefficients are slightly similar to the ones found in our study. Interestingly, in the study by Wilke et al.<sup>22</sup> the correlations between the SGRQ total score and SF-36's PCS scores in all time points were stronger than the correlations with SF-36's MCS scores; the same that was observed in our study with a cross-sectional design. Wilke et al.<sup>22</sup> also observed reasonable-to-good correlations between the SGRQ total score and other generic HRQoL instruments (i.e. EuroQol-5-Dimensions and Assessment of Quality of Life).

Although a systematic review has recommended the use of the SGRQ as a disease-specific instrument with good sensitivity for individuals with COPD<sup>23</sup>, a recent study suggested that the SGRQ may not be an appropriate instrument to measure symptom severity or activity limitations in individuals with COPD<sup>24</sup>. Other studies claim that disease-specific and generic HRQoL questionnaires should be used in combination to obtain a more complete picture of the health status of individuals with COPD<sup>22,24</sup>.

HRQoL in subjects with HF has been extensively studied in previous studies. Garin et al.<sup>25</sup> performed a systematic review to evaluate and compare data on the conceptual model and metric properties of HF-specific HRQoL instruments. The authors observed that the MLHFQ is by far the most used disease-specific HRQoL instrument, which was reported in 81 articles (out of 94), followed by the Chronic Heart Failure Questionnaire, which was reported in only 9 articles<sup>25</sup>. The results of a prospective study with a large sample of 1211 individuals with HF provided new information on the responsiveness of the MLHFQ, showing that this questionnaire is highly responsive as it captured changes in HRQoL 6 months after discharge, revealing that all MLHFQ domains have good sensitivity to change in HF<sup>26</sup>. The SF-36, however, does not quantify the burden of symptoms or limitations caused by the disease, which makes it less sensitive to clinical changes, either over time or after therapeutic intervention. Its clinical interpretation is more difficult than with a disease-specific instrument, making the MLHFQ more responsive to changes over time than the SF-36 in patients with HF<sup>27</sup>.

In a recent study by Gallagher and coworkers<sup>28</sup>, the authors investigated the acceptability and feasibility of implementing different HRQoL instruments (mostly disease-specific) into HF clinics and observed a correlation coefficient of 0.68 between the MLHFQ total score and the EQ-5D health score, a generic HRQoL measure. Interestingly, in the review by Garin et al.<sup>25</sup> the authors reported a correlation coefficient of 0.74 between the MLHFQ total score and the physical functioning domain of the SF-36, which is a value similar to the one found in our study for the correlation with the SF-36's PCS (i.e.  $r_s=-0.71$ ). In fact, the correlations between the MLHFQ and the SF-36 were stronger than the ones between the latter and the SGRQ scores in subjects with COPD. Combined with the fact that the MLHFQ was better for discriminating between subjects with different scores on the SF-36, we understand that in HF, both the generic and the disease-specific



questionnaires used in this study seem to reflect in a more similar way the individuals' HRQoL, and can be used in isolation. In individuals with COPD, the use of the generic and disease-specific questionnaire may be necessary in combination to allow a better picture of the HRQoL of these individuals.

Besides the relevant results of our study, ideas for new investigations can be drawn from the current one. It would be important to investigate how the different HRQoL instruments associate with each other in groups of individuals with COPD or HF, in comparison with individuals with the combination of both diseases. Moreover, it would be relevant to verify whether the associations between generic and disease-specific instruments remain stable as the diseases progress.

### Study limitations

This study has some limitations that must be considered when interpreting the results. As the study used a convenience sample, generalization of the results may be compromised. Another limitation is the lack of data that would allow a better characterization of the samples, such as cardiac or lung function. Moreover, our study could have investigated more HRQoL instruments, in order to have a better picture of the association between generic and disease-specific instruments. Finally, the association between these two types of instruments was investigated in one point in time, i.e. we do not know whether this association changes over time.

### CONCLUSION

We conclude that there seems to be a stronger association between generic and disease-specific HRQoL measures in individuals with HF when compared to the association in individuals with COPD. This is supported by stronger correlations between generic and disease-specific HRQoL measures in people with HF, and by the fact that the disease-specific HRQoL questionnaire used with this group appears to discriminate better groups with different scores in the physical and mental component summaries of the generic HRQoL questionnaire. Future studies should consider this information when choosing the HRQoL instrument to be used in individuals with COPD or HF, or when comparing the results from different studies.

### How can the results of this study be used in clinical practice?

- In HF, both generic and disease-specific HRQoL questionnaires seem to reflect in a more similar way the individual's HRQoL and can be used in isolation.
- In COPD, the use of generic and disease-specific HRQoL instruments should be used jointly to reflect more comprehensively the HRQoL of individuals with this condition.

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The authors have reported that no funding was received for this study.

### CONFLICT OF INTEREST

None.

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