Heart Failure and Instruments for Measuring Quality of Life

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Heart failure is one of the most frequent and deadly diseases that clinicians have to deal with in clinical practice.[1] Between 1% and 2% of the population aged over 40 have heart failure and rises to 10% in those over 60-70 years old. Heart failure is also the most rapidly increasing cardiac disease.[2] It is the third leading cause of cardiovascular death in Spain, behind ischemic heart disease and stroke.[2] In 2005, heart failure was responsible for 4% of all deaths in males and for 10% of all deaths due to cardiovascular disease. In women, the corresponding percentages were 8% and 18%.[2,3] Recorded mortality for heart failure may nevertheless underestimate the disease's true impact on mortality, because it is the final stage of many illnesses affecting the heart. For example, when heart failure is due to ischemic heart disease or a hypertensive disease, the death certificate would record the death as being the result of those diseases and not of heart failure.

The increase in the prevalence of heart failure and the poor prognosis associated with the disease have driven research into its impact on health-related quality of life (HRQL).[4] In fact, heart failure is one of the most important chronic diseases affecting HRQL,[5] and although several clinical indicators are used to monitor evolution in patients' functional status (for example, the New York Heart Association—NYHA—classification system),[6] changes in patient perceptions of their health status may not be perceptible to the clinician. This another reason behind the increasing use of self-reported HRQL as an additional source of information about patients' health status.[7] In fact, many patients with advanced heart failure

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ascribe greater importance to HRQL than to the duration of life,[8] which is also limited by heart failure. For that reason, HRQL is an important end-point in clinical trials of interventions aimed at controlling heart failure such as medications and patient disease management programs.[9-11]

Heart failure is very incapacitating, with a large part of the impact on HRQL being due to the symptoms associated with the disease.[12] At the same time, HRQL has proved to be a predictor of rehospitalization in patients with heart failure.[13] This important, because heart failure is the leading cause of hospitalization in the population aged over 65 years and accounts for some 75 000 hospitalizations per year in Spain.[2,3] Lastly, elderly patients with heart failure more frequently present multi-comorbidity[14,15] which can also cause serious limitations in their daily activities and in physical and mental well-being, and therefore in their perceptions of their HRQL. For that reason, it is of particular importance to measure HRQL in elderly people with heart failure.

Generic and disease-specific instruments are available to measure HRQL in patients with heart failure. The quality of these instruments, as with any measurement instrument, can be assessed be evaluating their psychometric or clinimetric properties,[16] in particular, their reliability and validity. It is important to remember that several types of validity have been described including face, content, construct, and criterion validity. Among the generic instruments, the most notable, due to its frequent use in the context of heart failure is the Medical Outcomes Study (MOS) 36-item Short-Form Health Survey (SF-36).[17] The Spanish version of the instrument has been used previously to measure HRQL in the elderly[18] and has been shown to have good reproducibility and validity.[19] An important advantage of generic instruments is that they allow us to compare the HRQL of heart failure patients with that of other patient populations[5] as well as with samples of the general population with a similar age and sex distribution.[18] Disease-specific instruments for use in heart failure[17] only include those aspects of health which are affected by the condition, and should therefore in principle be more sensitive to clinical changes in heart failure.

A systematic review of 120 randomized heart failure clinical trials that evaluated HRQL between 1996 and 2005 found that the most frequently used disease-specific instrument was the Minnesota Living with Heart Failure Questionnaire (MLHFQ).[4] The psychometric properties of the MLHFQ, and particularly its reliability and validity, have been widely reported. In adult patients with heart failure, the instrument has been shown to have good internal consistency, with Cronbach's alpha values of >.80.[20] The MLHFQ also correlated with other HRQL measures and was able to distinguish between different degrees of severity of heart failure. Nevertheless, although the psychometric properties of the MLHFQ have been tested, the results do not provide conclusive evidence of the instrument's quality, especially as regards several items in the emotional sub-scale.[20] New studies are therefore necessary to better understand the performance of the MLHFQ emotional dimension, particularly in the elderly.

There has been some prior experience of using the MLHFQ in Spain, and some information is available on the validity of the Spanish version.[21] Parajón et al were the first to administer the MLHFQ in Spain to a general population of heart failure patients attending a specific, multidisciplinary heart failure unit in a tertiary level hospital. They used their own Castilian and Catalan translations of the questionnaire and found some evidence of construct validity for the MLHFQ. Construct validity refers to how far the results of measurement match theoretical concepts about the phenomenon studied. More specifically, Parajón et al found that a poor NYHA functional classification, presence of diabetes and anemia, the number of hospital admissions during the previous year, and having valve disease as a possible etiology for heart failure were associated with worse scores on the MLHFQ, ie, with worse HRQL.[21] More recently, Morcillo et al found that the MLHFQ correlated well with functional class and with the SF-36 in a small sample of patients with advanced heart failure included during a hospital stay.[22] The MLHFQ was also sensitive to changes in health status after an educational intervention and correlated with prognoses.[22] Sensitivity to change refers to an instrument's ability to detect changes in patients' health and improvements or deterioration in HRQL after treatment or other health care interventions, or because of changes due to the natural course of the disease.

This edition of *Revista Española de Cardiología* includes a study that evaluates for the first time some of the psychometric properties of the Spanish version of the MLHFQ in patients hospitalized with heart failure.[23] The authors report that the instrument's reliability and validity are satisfactory and recommend it for use in Spanish heart failure patients. The authors also point out that, due to its trans-cultural characteristics, the study will facilitate comparison with other countries. Certain other features of the study warrant comment.

The authors divided patients into 2 sub-groups based on changes in functional capacity between the 2 study visits (1 and 3 months after discharge). The first sub-group consisted of patients who remained unchanged between visits (reproducibility sub-group); the second sub-group consisted of patients who showed some change (sensitivity to change sub-group). Sensitivity to change in terms of improvement or deterioration in functional capacity between the first and second evaluation was only moderate (effect sizes up to 0.44). This may indicate that this aspect requires further testing, perhaps in patients in whom larger changes in clinical status are expected to occur. The representativeness of the results may also be somewhat limited as the study was based on heart failure patients enrolled consecutively on admission to hospital, and follow-up after discharge was performed in cardiology out-patient clinics. The findings may therefore not be applicable to patients who are largely treated at primary care level and who do not require hospitalization. Furthermore, there is no evidence that the 3 questions on functional status which were used to evaluate patients' functional capacity have been previously validated. This represents somewhat of a limitation in the standards used. The association with other, better indicators of clinical severity (or poor functional capacity) should be investigated in future studies. There is, furthermore, no evidence regarding the reproducibility of the NYHA classification or scale,[24] which was also used by the authors as the standard for functional capacity.

In spite of these limitations, the study represents an important contribution by showing that the psychometric properties of the Spanish version of the MLHFQ make it a reasonably valid and reliable instrument for use in research and in daily clinical practice. At the same time, it points the way to further research into other psychometric properties in heart failure patients and on which there is little data in the literature. These would include other types of validity, apart from construct validity. One such would be criterion validity, which consists in determining the degree of correlation between the instrument of interest and an external reference criterion or gold standard. In some studies, the criterion could be a generic or disease-specific HRQOL measure, but the question inevitably arises as to whether they can truly be considered a gold standard for comparison. Occasionally, the criterion variable may be a future event that we try to predict using our measurement instrument. In that case, the validity analyzed is termed predictive validity and it is perhaps the most important type of validity, particularly when it is of real clinical significance as is the case of rehospitalization or death. In an earlier study, we showed that simple instruments to measure HRQL such as the SF-36 and the MLHFQ could have a certain predictive validity in patients with heart failure.[13] More specficially, we observed that poorer HRQL, whether measured with the SF-36 or the

MLHFQ, was associated with rehospitalization and death in heart failure patients, independently of the other biomedical, psychosocial, and health care variables studied, and that it had a similar prognostic value to the drugs used.

Finally, validation is an on-going process which will, over time, produce new evidence regarding the MLHFQ's usefulness. Lines of useful future research would include determining whether the MLHFQ is equally valid in systolic and diastolic heart failure, and in the presence of certain types of co-morbidity (chronic obstructive pulmonary disease, diabetes mellitus, rheumatic disorders) which have a considerable impact on HRQL. When co-morbidity is present, it is possible that a generic questionnaire would function better than a disease-specific one, as the effect of the co-morbid condition on HRQL may be greater than that of heart failure and would not be adequately measured by the MLHFQ.

REFERENCES

1. McMurray JJV, Pfeffer MA. Heart failure. Lancet. 2005;365:1877-89.
2. Banegas JR, Rodríguez-Artalejo F, Guallar P. Situación epidemiológica de la insuficiencia cardiaca en España. Rev Esp Cardiol Suppl. 2006;6:C4-9.
3. Villar F, Banegas JR, Donado JM, Rodríguez-Artalejo F. Las enfermedades cardiovasculares y sus factores de riesgo en España. Hechos y cifras. Informe SEA 2007. Madrid: Sociedad Española de Arteriosclerosis; 2007.
4. Morgan K, McGee H, Shelley E. Quality of life assessment in heart failure interventions: a 10-year (1996-2005) review. Eur J Cardiovasc Prev Rehabil. 2007;14:589-607.
5. Alonso J, Ferrer M, Gandek B, Ware JE Jr, Aaronson NK, Mosconi P, et al. IQOLA Project Group. Health-related quality of life associated with chronic conditions in eight countries: results from the International Quality of Life Assessment (IQOLA) Project. Qual Life Res. 2004;13:283-98.
6. Spertus J, Peterson E, Conard MW, Heidenreich PA, Krumholz HM, Jones P, et al. Monitoring clinical changes in patients with heart failure: a comparison of methods. Am Heart J. 2005;150:707-15.
7. Morris J, Perez D, McNoe B. The use of quality of life data in clinical practice. Qual Life Res. 1998;7:85-91.
8. Lewis EF, Johnson PA, Johnson W, Collins C, Griffin L, Stevenson LW. Preferences for quality of life or survival expressed by patients with heart failure. J Heart Lung Transplant. 2001;20:1016-24.
9. Leidy NK, Rentz AM, Zyczynski TM. Evaluating health-related quality-of-life outcomes in patients with congestive heart failure: a review of recent randomised controlled trials. Pharmacoeconomics. 1999;15:19-46.
10. Phillips CO, Wright SM, Kern DE, Singa RM, Shepperd S, Rubin HR. Comprehensive discharge planning with postdischarge support for older patients with congestive heart failure: a meta-analysis. JAMA. 2004;291:1358-67 [published correction appears in JAMA. 2004;292:1022].
11. Gonseth J, Guallar P, Banegas JR, Rodríguez-Artalejo F. The effectiveness of disease management programmes in reducing hospital re-admission in older patients with heart failure: a systematic review and meta-analysis of published reports. Eur Heart J. 2004;25:1570-95.
12. Rector TS, Anand IS, Cohn JN. Relationships between clinical assessments and patients' perceptions of the effects of heart failure on their quality of life. J Cardiac Failure. 2006;12:87-92.
13. Rodríguez-Artalejo F, Guallar P, Rodríguez C, Montoto C, Ortega A, Nieto A, et al. Health-related quality of life as a predictor of hospital readmission and death among patients with heart failure. Arch Intern Med. 2005;165:1274-9.
14. Havranek EP, Masoudi FA, Westfall KA, Wolfe P, Ordin DL, Krumholz HM. Spectrum of heart failure in older patients: Results from the National Heart Failure Project. Am Heart J. 2002;143:412-7.
15. Guallar-Castillón P, Magariños MM, Montoto C, Tabuenca AI, Rodríguez-Pascual C, Olcoz M, et al. Prevalencia de depresión, y factores biomédicos y psicosociales asociados, en ancianos hospitalizados con insuficiencia cardiaca en España. Rev Esp Cardiol. 2006;59:770-8.
16. Feinstein AR. Clinimetrics. New Haven: Yale University Press; 1987.
17. Johansson P, Agnebrink M, Dahlström U, Broström A. Measurement of health-related quality of life in chronic heart failure, from a nursing perspective — a review of the literature. Eur J Cardiovasc Nursing. 2004;3:7-20.
18. López-García E, Banegas JR, Graciani Pérez-Regadera A, Gutiérrez-Fisac JL, Alonso J, Rodríguez-Artalejo F. Valores de referencia de la versión española del Cuestionario de Salud SF-36 en población adulta mayor. Med Clin (Barc). 2003;120:568-73.
19. Alonso J, Prieto L, Antó JM. La versión española del SF-36 Health Survey (Cuestionario de Salud SF-36): un instrumento para la medida de los resultados clínicos. Med Clin (Barc). 1995;104:771-6.
20. Heo S, Moser DK, Riegel B, Hall LA, Christman N. Testing the psychometric properties of the Minnesota Living with Heart Failure questionnaire. Nurs Res. 2005;54:265-72.
21. Parajón T, Lupón J, González B, Urrutia A, Altimir S, Coll R, et al. Aplicación en España del cuestionario sobre calidad de vida «Minnesota Living With Heart Failure» para la insuficiencia cardíaca. Rev Esp Cardiol. 2004;57:155-60.
22. Morcillo C, Aguado O, Rosell F. Utilidad del Minnesota Living With Heart Failure Questionnaire en la evaluación de la calidad de vida en enfermos con insuficiencia cardiaca. Rev Esp Cardiol. 2007;60:1093-6.
23. Garin O, Soriano N, Ribera A, Ferrer M, Pont A, Alonso J, et al. Validación de la versión española del Minnesota Living with Heart Failure Questionnaire (MLHFQ). Rev Esp Cardiol. 2008;61:251-9.
24. Bennett JA, Riegel B, Bittner V, Nichols J. Validity and reliability of the NYHA classes for measuring research outcomes in patients with cardiac disease. Heart Lung. 2002;31:262-70.