Testing a Published Model of Health-Related Quality of Life in Heart Failure

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ABSTRACT

Background: Health-related quality of life (HRQOL) in patients with heart failure is compromised and associated with increased mortality and rehospitalization. Inadequate conceptualization of variables related to HRQOL has hampered clinicians' efforts to enhance HRQOL. The purpose of this study was to test the Wilson and Cleary model (WCM) of HRQOL in patients with heart failure.

Methods and Results: Data from 293 patients with heart failure were analyzed to determine the best multivariate HRQOL model given variables derived from WCM. HRQOL was measured using the Minnesota Living with Heart Failure Questionnaire (MLHFQ). Health perception, symptom status, and age predicted the total MLHFQ ($P < .0001$) and the emotional scale ($P < .0001$), and health perception, symptom status, New York Heart Association predicted the physical scale ($P < .0001$). Health perception was a mediator of the effect of symptom status on HRQOL. Functional status was not a mediator of the effect of symptom status on health perception.

Conclusion: The most influential variables associated with HRQOL were the subjective variables: health perception and symptom status. Objective variables proposed by WCM to drive the model were not significant predictors. Mediator effects hypothesized in the WCM were not fully demonstrated in this sample. Thus modification of the WCM is warranted.

Key Words: Health perception, Minnesota Living with Heart Failure Questionnaire, symptom status, variable.

Health-related quality of life (HRQOL) is an outcome equally as important as mortality and rehospitalization, which traditionally have been the major clinical outcomes of interest in patients with heart failure.[1] Despite the high mortality among patients with heart failure,[2] at least 5 million Americans live with heart failure, and the number of patients and hospitalizations from heart failure is increasing every year.[3] HRQOL in these patients is substantially compromised,[4–6] and can change over time as a consequence of progression of heart failure or as the result of intervention.[7,8] Negative changes in HRQOL are related to poor clinical outcomes including rehospitalization and mortality.[9,10]

Because of the importance of HRQOL as an outcome and as a predictor of other clinical outcomes, full understanding of the variables associated with HRQOL in patients with heart failure is needed so that effective interventions to improve HRQOL can be developed. Several variables have been identified as potentially associated with HRQOL, including functional status,[4,11,12] symptom status,[13] biological/physiologic status,[4,14] demographic characteristics,[13,15] health perception,[16,17] and psychologic status.[18,19] However, the results of studies are not consistent and in no case has these variables been examined simultaneously based on a theoretical model of HRQOL.

In attempting to clarify the role of the many potential variables influencing HRQOL, a few models of HRQOL have been proposed,[20,21] but none have been validated in patients with heart failure. A model of variables influencing HRQOL could provide important information for clinicians and researchers attempting to develop effective interventions to enhance HRQOL in patients with heart failure. The model also could guide the direction and range of research on HRQOL. Accordingly, the purpose of this study was to test a published model of HRQOL, the Wilson and Cleary model, which has been suggested as an appropriate one for heart failure.[22] The specific aims of the study were to: (1) determine the bivariate relationships between HRQOL and health perception, symptom status, functional status, biological/physiologic

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Manuscript received June 14, 2004; revised manuscript received November 10, 2004; revised manuscript accepted December 10, 2004.

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1071-9164/$ - see front matter

doi:10.1016/j.cardfail.2004.12.001

status, individual characteristics, and environmental characteristics (variables suggested by the Wilson and Cleary model); (2) determine the best multivariate model of HRQOL based on these variables; and (3) test specific components of the Wilson and Cleary model of HRQOL.

Conceptual Framework: Wilson and Cleary's HRQOL Model

The model that guided the selection of variables potentially associated with HRQOL in this study was the Wilson and Cleary HRQOL model (WCM).[21] Wilson and Cleary proposed this model based on theory, clinical practice, and others' research findings to help clinicians or researchers begin to consider and test potential causal relationships to provide more effective interventions to improve patients' HRQOL.[21] Six categories of variables are proposed to be directly or indirectly related to HRQOL in the WCM: health perception, symptom status, functional status, biological/physiologic status, individual characteristics, and environmental characteristics. In the model as illustrated by Wilson and Cleary, the terms QOL and HRQOL are used interchangeably. To reduce confusion, our conceptualization includes only use of the term HRQOL. In the WCM, biological/physiologic status refers to the status of cells, organs, and organ systems. Symptom status refers to patients' subjective perceptions of abnormal physical, mental, and cognitive conditions. Functional status refers to patients' ability to perform several aspects of tasks or functions, such as physical, social, emotional, role, and cognitive functions. Health perception is defined as patients' global perceptions of their health. Individual characteristics are inferred (because they were not defined by Wilson and Cleary) to be demographic and psychologic characteristics of patients. Environmental characteristics are defined as support provided by family, friends, and others. In the WCM, biological/physiologic status affects symptom status; symptom status affects functional status; functional status affects health perception; and health perception affects HRQOL. Individual and environmental characteristics are thought to affect all categories except biological/physiologic status (Fig. 1). However, Wilson and Cleary acknowledged that the relationships between variables may be bidirectional, even though they did not illustrate them as such. In addition, they also acknowledged that the proposed relationships were tentative and testing was required to confirm them. To date, the variables making up the model remain to be tested in patients with heart failure.[21] In the current study, we examined the direct and indirect relationships among these variables.

Methods

Design

This study was a secondary analysis of data obtained from 2 randomized, controlled clinical trials of heart failure disease management interventions, 1 a multidisciplinary disease management intervention[23] and the other a home-based community case management education and counseling intervention.[24] Only baseline data from the enrolled patients were used in this analysis of the relationships between HRQOL and the following variables: (1) health perception, (2) symptom status, (3) functional status, (4) biological/physiologic status, (5) individual characteristics, and (6) environmental characteristics.

Patients were recruited during hospitalizations for heart failure exacerbations at community hospitals in Southern California and Central Ohio. The inclusion criteria of the 2 studies were similar. In both, patients enrolled had a confirmed heart failure diagnosis. Patients were excluded if they were discharged to an extended care facility, had unstable angina or acute myocardial infarction, cognitive impairments or severe psychiatric problems, and renal failure requiring dialysis.

Measures

HRQOL. HRQOL was defined as a patient's subjective perception of the impact of a medical condition or its treatment on various aspects of his or her daily life, including physical functioning, symptom status, psychologic status, and social interactions.[25] HRQOL was measured using the Minnesota Living with Heart Failure Questionnaire (MLHFQ).[26,27] This instrument is one of the most commonly used instruments to assess HRQOL in heart failure research.[11,28–30]

The MLHFQ consists of 21 items rated by patients using a 6-point Likert scale from 0 (no impact on HRQOL) to 5 (most severe impact on HRQOL). The instrument is scored by adding the item ratings. The total score can range from 0 to 105, with a lower score reflecting better HRQOL. The instrument consists of 3 separate scale scores: physical, emotional, and total. The strong internal consistency reliabilities of the total, physical, and emotional scales of this instrument have been found, with Cronbach's alphas ranging from .88 to .93.[26] Support for the construct validity of the MLHFQ has been reported in several studies.[11,26,27,31]

Health perception. Health perception was defined as a patient's global perception of his or her health. Health perception was measured using the 1 current health perception question from the Medical Outcomes Study SF-36.[32] A lower score reflects better health perception.

Symptom status. Symptom status was defined as a patient's subjective perception of the presence and severity of the 2 most common symptoms of heart failure: dyspnea and fatigue.[18,33] Although 2 separate instruments (ie, Dyspnea-Fatigue Index, a reliable and valid measure,[34] and an investigator-generated instrument[23]) were used to measure symptom burden in each of the studies from which data were derived, the measures were conceptually similar in that they asked patients to rate their perception of the severity and intensity of dyspnea and fatigue and to indicate their impact on daily life. They differed in the assignment of numerical ratings, thus a composite measure was derived for the purposes of the current analysis. In the current study, scores can range from 0 to 4. A score of 4 indicates no symptoms with ordinary activities and a score of 0 indicates the most extreme symptom burden. Thus lower scores indicate more burdensome symptoms.

Functional status. Functional status was defined as a patient's subjective perception of his or her ability to perform physical functions and was measured using New York Heart Association functional classification (NYHA). Despite known difficulties with reproducibility of this assessment,[35] it is used widely in clinical practice and research,[11,12] and for reasons of comparison with other