The Minnesota Living With Heart Failure Questionnaire

Sensitivity to Differences and Responsiveness to Intervention Intensity in a Clinical Population

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Background: The Minnesota Living With Heart Failure Questionnaire (LHFQ) is a commonly used measure of health-related quality of life in persons with heart failure. Researchers have questioned whether LHFQ is sensitive to subtle differences and sufficiently responsive to clinical interventions because the instrument has demonstrated variable performance in clinical trials.

Objectives: A secondary analysis was conducted to assess the LHFQ for sensitivity to different clinical states and responsiveness to varying intensities of clinical intervention.

Methods: A convenience sample of nine experimental or quasi-experimental studies from eight clinical sites in the United States yielded data from 1,136 patients with heart failure. Data in the studies had been collected at enrollment and one, three, and/or six months later. Data were analyzed using descriptive, univariate, and multivariate techniques.

Results: Total and subscale scores on LHFQ were poorer in those with worse New York Heart Association functional class, although there was no difference in LHFQ scores between classes III and IV. No difference in LHFQ scores was found when patients were classified by ejection fraction. Scores improved significantly following hospital discharge, even in those in the control group. Changes in LHFQ scores were greatest in those receiving high intensity interventions.

Conclusions: The LHFQ is sensitive to major differences in symptom severity but may not be sensitive to subtle differences. It is responsive to high intensity interventions. Investigators are cautioned against using this instrument without first maximizing intervention power or without a control group for comparison.

Key Words: clinical sensitivity • dose-response analysis • heart failure • instrument • measurement • responsiveness

Almost 5 million people in the United States suffer from heart failure (HF) (American Heart Association, 2001). Approximately one in every 100 elders has HF; it is the most common reason for hospital admission in the Medicare population. Further, the incidence of HF continues to rise and is anticipated to reach critical proportions as our population ages. As a result of this epidemic, the attention of the healthcare community has focused on reducing the cost and suffering associated with HF through enhanced therapy and disease management

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approaches. An outcome usually desired of these interventions is improved health-related quality of life (HRQL).

The Minnesota Living With Heart Failure Questionnaire (LHFQ), developed by Rector, Kubo, & Cohn (1987), is a disease-specific instrument used commonly in clinical trials and community programs to measure HRQL (Green, Porter, Bresnahan, & Spertus, 2000). Although the LHFQ has documented reliability and validity, including construct validity, its ability to discriminate among patient groups known to differ on variables contributing to HRQL has been unclear (Rector et al., 1987). Further, it has been noted to perform variably in response to clinical interventions. Sometimes improvement in HRQL will be evident following intervention, even in small samples (Rideout, 1992). In other studies, with similar sample sizes and characteristics, no effect is evident (Colucci et al., 1996). The interventions are possibly inadequate to consistently influence HRQL or the instrument is not sufficiently responsive to changes of the magnitude produced by the interventions. To add some clarity to these issues, a multisite investigation was conducted and aimed at further exploration of the psychometric properties of the LHFQ.

Approximately one in every 100 elders has heart failure, . . . the most common reason for hospital admission in the Medicare population

The purpose of this study was to assess sensitivity to clinical differences and responsiveness of the LHFQ to treatment intensity in a heterogeneous group of individuals being treated for HF. Sensitivity to clinical differences was defined as the ability to detect clinically important differences between patients. Responsiveness was defined as the improvement of scale scores after therapy of known efficacy (Deyo & Centor, 1986; Stewart & Archbold, 1992). To assess these characteristics, the following three questions were answered:

1. How well does the LHFQ differentiate a clinical population with differing levels of symptom and disease severity?
2. What is the natural history of change in LHFQ scores among patients receiving usual care rather than a special intervention?
3. How responsive is the LHFQ to interventions of varying intensity?

To answer these questions, data were analyzed from a sample of nine studies including 1,136 HF patients from across the United States.

Theoretical Framework

Lipsey (1990) argues the importance of using valid, reliable, and sensitive measures of dependent variables in research evaluating treatment effectiveness because data from such trials are used to calculate the effect size parameters for power analyses. A measure that is not sensitive to differences among participants or responsive to change due to treatment intensity will produce a small effect size, requiring a large sample size in clinical trials. An otherwise valid measure may not discriminate well among clinically different individuals. Validity and reliability of measures are not sufficient to assure that an instrument is responsive to changes produced by an intervention. "A measure can be a valid indicator of a characteristic but still not be a valid indicator of change on that characteristic" (Lipsey, 1990, p.100). This occurs when units of measurement are too gross (two response choices versus six response choices). In addition, anything that decreases variability in scores (e.g., floor or ceiling effects) can minimize sensitivity to differences and responsiveness to change. Alternately, too much subject heterogeneity can introduce error variance that can obscure treatment effects. Choosing an instrument with relatively little within-group variability, a sufficient number of response choices, and no evidence of a floor or ceiling effect can increase statistical power.

Background

The LHFQ is a disease-specific measure of HRQL that assesses patients' perceptions of the influence of HF on physical, socioeconomic, and psychologic aspects of life (Rector et al., 1987). Patients respond to 21 items using a 6-point response scale (0 to 5). The total summary score can range from 0 to 105; a lower score reflects better HRQL. Two subscale scores reflect physical (8 items) and emotional (5 items) impairment. The LHFQ is an appealing instrument because it is inexpensive, short, easily understood by ill and elderly individuals, self-administered, and easy to score. Further, it has face validity to the clinicians who use it.

The psychometric properties of the LHFQ have been assessed repeatedly (Gorkin, Norvell, Rosen, et al., 1993; Rector & Cohn, 1992). Internal consistency reliability of the instrument has been high, with Cronbach's alpha ranging from .73 to .93 in one study (Briancon et al., 1997). Test-retest reliability was high after a 7- to 21-day period (weighted kappa reliability coefficients .84) (Rector et al., 1987) and even higher after a one-week interval (r = .93 total, r = .89 physical dimension, r = .88 emotional dimension) (Rector & Cohn, 1992).

Discriminant validity of the LHFQ has been tested by comparing LHFQ scores in various clinical groups. Rector and colleagues (1987) found a clear distinction in LHFQ scores between individuals in New York Heart Association (NYHA) functional class I and II but interquartile median scores overlapped between classes II (28–60) and III (34–64). Interestingly, investigation of the relationship between a time trade-off utility measure and scores on the LHFQ demonstrated a curvilinear relationship between the two measures, with a flattening of the relationship at the poorer levels of HRQL, suggesting that the LHFQ is not sensitive to subtle differences in poor HRQL (Havranek,

McGovern, Weinberger, et al., 1999). Instrument scores were not sensitive to differences in left ventricular ejection fraction (EF) (Gorkin, et al., 1993; Rector, et al., 1987), although only those with an EF ≤ 35% were included in most of the studies.

Some authors have noted that the LHFQ is insensitive to subjective reports of improved HRQL or clinical observations of improvement (Cohn, et al., U.S. Carvedilol Heart Failure Study group, 1997; Green, et al., 2000). Conversely, Rector and colleagues (1995) argue that the instrument is responsive to clinical improvement, with a change of 5 points in total score interpreted as clinically significant.

In spite of questions about sensitivity to differences and responsiveness of the LHFQ, it has been used in many clinical trials. Some authors have demonstrated an improvement in LHFQ scores in drug trials (Rector & Cohn, 1992) but others have not (Colucci, et al., 1996). Some exercise interventions have improved LHFQ scores (Tyni-Lenne, Gordon, Jensen-Urstad, et al., 1999) and others have failed to do so (Gottlieb, Fisher, Freudenberger, et al., 1999). Pacemaker therapy for refractory HF improved LHFQ scores sometimes (Gras, Mabo, Tang, et al., 1998) but not always (Brignole, et al., 1998). Educational interventions have produced mixed results as well (Rideout, 1992). Interestingly, investigators have noted that LHFQ scores improved similarly in both intervention and control groups over time (Cohn, et al., 1997).

Results of these trials have caused speculation that the treatments tested may be insufficient to influence HRQL (Reddy & Dunn, 2000). However, no studies have been done to measure the responsiveness of HRQL to intervention intensity. Dose-response analysis, in which the relationship between the amount of services received and outcomes achieved, could clarify whether variable results are due to insufficient treatment intensity. Dose-response analysis is typically used to assess medication efficacy, but the technique has been used to determine the effectiveness of clinical interventions, as was done in this study (Malone, Carter, Billups, et al., 2001; Velicer, Prochaska, Fava, Laforge, & Rossi, 1999).

Methods

A convenience sample of nine experimental or quasi-experimental studies from eight sites in the United States was used in this secondary analysis. Investigators were identified using a "Call for Contributors" published in the January 2000 issue of *The Journal of Cardiovascular Nursing* inviting investigators with existing LHFQ data to contribute data to this analysis. Each investigator was asked to contribute two or more data points (i.e., baseline and a subsequent measure) on 75 or more individuals with HF. Data on patient age, sex, marital status, income, education, EF, NYHA functional class, and the setting where the data were collected (e.g., home, hospital) were requested as well. The data were used to address three specific aims: (a) to assess sensitivity of the LHFQ to differences in symptom and disease severity, (b) to explore change in LHFQ scores in individuals assigned to the usual care group, and (c) to assess responsiveness of the LHFQ to interventions of varying intensity.

Sample

Longitudinal data were obtained on 1,136 patients from nine clinical trials conducted at eight sites representing the Southwest, Southeast, Northwest, Northeast, and Midwest sections of the United States (Armola & Dooley, 2001; Deaton, et al., 1999; Elliott & Sethares, 2001; Moser, Macko, & Worster, 2000; Riegel, Carlson, Glaser, & Hoagland, 2000; Riegel et al., 2002). Each study involved testing an intervention for HF patients and measuring HRQL with the LHFQ. The local Institutional Review Boards had approved the individual studies; the review committee at the primary author's institution approved this analysis of existing data. Each intervention was being tested in a formal clinical trial; all but one were externally funded. Five of the nine trials compared their intervention results to those of a randomly assigned control group, one used a matched control group, and three used a pretest/posttest outcomes research design. Seven of the trials employed a dedicated research associate. Data on NYHA functional class were collected by the research associate in five trials and by clinicians in four trials. The combined control group (n = 401) was comparable at baseline to the combined intervention group (n = 735) on all demographic characteristics.

The inclusion criteria were similar at all sites. Most (71.6 %) of the chronic HF patients were enrolled during a hospital visit and all spoke either English or Spanish. In two of the nine studies investigators specified an age, left ventricular EF, and/or NYHA functional class inclusion criterion, but most considered all patients with a documented diagnosis of HF. Patients with acute myocardial infarction, unstable angina, cognitive impairment, or severe psychiatric problems were excluded, as were those discharged to an extended care or skilled nursing facility or those who were homeless. Two investigative teams formally tested cognitive function with the Mini-Mental State Examination and others used clinical criteria to exclude patients who were unable to complete questionnaires and participate in interventions. One trial testing an exercise intervention excluded those with (a) orthopedic impediments to exercise, (b) severe obstructive pulmonary disease, (c) stenotic valvular disease, (d) history of uncontrolled ventricular tachyarrhythmias, or (e) sudden cardiac death.

Procedure

First Specific Aim: Symptom severity was measured using NYHA functional class (I to IV). The NYHA is a commonly used measure of the influence of symptoms on functioning of cardiac patients. Disease severity was measured by EF and grouped as systolic dysfunction (≤ 40%), diastolic dysfunction (≥ 50%), or an intermediate, mixed category (41–49%) (Kitzman, 2001).

Second Specific Aim: In exploring changes in LHFQ scores over time, data from only those enrolled while in the hospital and assigned to a control group were used. Hospitalization is often a low point in HRQL and thus served as a rational starting point for the analysis of change over time. The control group was used to identify the amount and type of change in LHFQ scores that could be expected in

HF patients treated with usual care and not provided any of the special interventions offered by the investigators.

Third Specific Aim: To assess responsiveness of the LHFQ to intervention intensity, published research was used to develop a coding algorithm (Table 1). The algorithm was developed by the two lead authors, using the components common to successful HF programs (2000), and then reviewed by the co-investigators for validation. One to three points were allocated for each component of an intervention as a measure of its ability to influence HRQL in persons with HF. For example, pharmacologic therapy has been shown to influence survival and functional status but perceived HRQL, measured in a variety of ways, has not improved consistently with medications alone (Exner & Schron, 2001; Reddy & Dunn, 2000). Thus, programs including optimization of pharmacologic therapy were given only one point for that intervention component. Conversely, intense patient teaching and counseling can have a powerful influence on HRQL. Thus, up to four points were given for patient teaching and counseling, depending on the number of sessions and the environment in which it was provided (Moser, 2000; Rich, Beckham, Wittenberg, et al., 1995). The two lead authors coded and analyzed detailed descriptions of each intervention offered at the sites. The coding was submitted to each co-investigator for verification. A summed score of intervention intensity was computed from the number and type of intervention components provided. Raw scores for intervention intensity ranged from 2–9, but scores were grouped as low (2–3), moderate (4–6), and high (7–9) intensity interventions for the analysis.

Each investigator submitted baseline LHFQ data plus an additional measure from one or more of the following time

TABLE 1. Intensity Algorithm Used to Assign Points to Each Component of the Interventions Based on Predicted Effect on Health-Related Quality of Life

Intervention	Rationale
Inpatient education and counseling Yes = 1 point No = 0 points	Patient education/counseling improves HRQL but hospitalized patients are fatigued, overwhelmed, and disoriented at times which decreases the effect of inpatient education on HRQL (Jaarsma, Halfens, Huijer Abu-Saad, et al., 1999).
Outpatient education Intense = 3 points Moderately intense = 2 points Some = 1 point None = 0 point	The influence of patient education/counseling on HRQL is strengthened by repeated education and counseling sessions provided in a familiar environment (Moser, 2000; Rich et al., 1995; Riegel et al., 2002; Stewart, Pearson, & Horowitz, 1998).
Vigilant follow-up that is not otherwise captured in a category such as patient education (e.g., regular office visits) Intense = 3 points Moderate = 2 points More than routine = 1 point Routine = 0 points	Even without an educational component (covered above), vigilant follow-up probably provides some social support, which makes it a stronger influence on HRQL than might be expected (Riegel et al., 2002; Serxner, Miyaji, & Jeffords, 1998).
Optimal drug therapy Yes = 1 point No = 0 point	The data showing an improvement in HRQL with pharmaceutical therapy is weak (Exner & Schron, 2001). Some drugs improve symptoms and functional status while others cause patients to feel worse (Reddy & Dunn, 2000).
Interventions aimed at increasing patient control (e.g., patient-directed diuretic adjustment) Optimal control = 2 points Some control = 1 point None = 0 point	Perceived control has been shown to improve HRQL but not as significantly as repeated education and counseling (Moser & Dracup, 2001).
Exercise (home program or formal rehabilitation) Emphasized = 2 points Encouraged = 1 point None = 0 point	Exercise appears to have some effect on HRQL but not as much influence on HRQL as other interventions (Gottlieb et al., 1999; Tyni-Lenne et al., 1999).

Note. HRQL = health-related quality of life.

periods: four weeks, six weeks, three months, four months, and/or six months. Data collected at four and six weeks were combined (and labeled one month) and those collected at three and four months were combined (and labeled three months) based on the rationale that investigators typically allow two weeks on either side of the due date for data collection. In accordance with directions from the instrument authors, questionnaires with values missing for two or more items were not used in the analysis. All data were coded using a standardized scheme and submitted electronically in an Excel (Microsoft, Redmond, WA) format. As each data set was received, it was analyzed for both structure and content to achieve uniformity prior to combining the data sets.

Analysis

All analyses were done using SPSS version 9.0 (Chicago, IL). Demographic characteristics of the sample were assessed with descriptive statistics. Cronbach's coefficient alpha was calculated for total and subscale scores at each time period. Group LHFQ scores were compared using multivariate analysis of variance (MANOVA). When baseline LHFQ scores were compared by site, there were significant differences so baseline LHFQ scores were used as covariates in the analyses whenever possible. The interpretation of significance was adjusted using the Bonferroni statistic for multiple comparisons.

The first question tested for differences in LHFQ scores at baseline to determine if the instrument could discriminate among subjects based on symptom or disease severity. Physical subscale scores might be expected to respond to differences in symptom and disease severity more than emotional subscale scores. However, prior investigators (Gorkin, et al., 1993; Gras, et al., 1998; Rector, et al., 1987) used total and subscale scores; thus, all three scores were used in this analysis. Data from the full sample were used in this analysis, including those on whom no subsequent data were available because of subject death or study attrition.

In analyzing the second question, LHFQ scores from control group subjects enrolled during hospitalization with baseline, three-month, and six-month data were compared over time using repeated measures ANOVA. Only subjects with follow-up data were used for this analysis. This analysis was conducted both with and without covariates.

For the third question, MANOVA was used to assess responsiveness of the LHFQ to interventions of varying intensity. Total and subscale scores on the LHFQ were compared at one, three, and six months by intervention intensity, grouped as low, moderate, and high intensity. Only subjects with follow-up data were used in this analysis. Patients in the control group were assigned an intervention intensity score of zero and used in this analysis. Foster (2000) argues that dose-response studies are commonly compromised by failure to control for the fact that, in effectiveness or outcomes research, treatment dose can vary because patients choose different amounts of services or because different amounts are made available to them based on individual characteristics. That is, factors such as disease severity and age may influence the amount of services received by HF patients. Statistical control of potentially confounding variables is essential to minimize selection bias in dose-response studies. Therefore, baseline LHFQ scores, age, NYHA functional class, and EF were used as covariates in these analyses. All differences were evaluated statistically and clinically, using the instrument authors' five-point change in total scores as the clinical criterion (Rector et al, 1995). In addition, the grouping of scores into low, moderate, and high categories was varied as a check on the validity of the cut-points.

Results

The 1,136 participants were, on average elderly, 68 years of age (± 13.96) and almost evenly divided by sex (Table 2). A majority (52%) were unmarried (single, divorced, separated, or widowed) and had at least a high school education. Some (28%) declined to provide income information, but many (46.8%) of those who did reported earning less than $20,000 annually. Most (66.7%) patients had systolic dysfunction; mean EF was 35.37 (± 17.49) but the values ranged from 10 to 90. The NYHA functional classifications spanned the full range, with the largest group of patients in functional class III (44.5%). A total of 168 participants (15% of total) provided only baseline data due to study attrition or death. Those subjects who dropped out of the studies were significantly more likely to have been assigned to the control group, be older, and have a lower EF and a poorer NYHA classification. Scores on the LHFQ were not significantly different in those providing only baseline data when compared to the others.

Alpha coefficients for total LHFQ scores at each time period ranged from .92 (baseline) to .96 (one month). Physical subscale alpha coefficients ranged from .92 (baseline) to .95 (one month). Emotional subscale alpha coefficients ranged from .87 (baseline) to .92 (one month). There was little evidence to suggest either a ceiling or floor effect in total LHFQ scores. Only 3% (n = 34) of subjects scored within the top 10% of the LHFQ scoring range and 5.4% (n = 61) scored within the bottom 10%.

Sensitivity to Differences in Symptom and Disease Severity

When baseline LHFQ scores were compared by symptom severity (measured by NYHA functional class) total scores were significantly different among the groups (F = 49.19, df = 3, 782, p< .001) as were each of the subscale scores (physical: F = 58.95, df = 3,782, p< .001; emotional: F = 28.59, df = 3, 782, p< .001). Health-related quality of life as measured by LHFQ worsened progressively in those with more symptoms, although no difference in total or subscale scores was evident between the functional classes III and IV on post hoc analysis (Figure 1). When LHFQ scores were compared by disease severity (measured by EF category [≤ 40%, 41–49 %, ≥ 50%]), no statistical or clinical differences were evident in total (F = .50, df = 2, p= .61) or subscale (physical: F = .24, df = 2, p = .78; emotional: F = .55, df = 2, p = .58) scores (Table 3).

Change in Control Group LHFQ Scores Over Time

A sample of 173 individuals enrolled in the hospital, assigned to the control group, and providing data at three intervals was available for this analysis; only 65 had a full

Table 1. Demographic Characteristics and Baseline Living With Heart Failure Questionnaire Scores by Site Number (*N* = 1,136)

Variable	Site 1, Study 1 *n* = 257	Site 1, Study 2 *n* = 280	Site 2 *n* = 147	Site 3 *n* = 125	Site 4 *n* = 67	Site 5 *n* = 77	Site 6 *n* = 75	Site 7 *n* = 74	Site 8 *n* = 34	Total *N* = 1,136
Age (years) (*SD*)	72.37 (11.6)	71.30 (12.9)	69.58 (12.8)	55.70 (13.5)	55.30 (13.0)	68.48 (12.1)	75.15 (12.8)	66.53 (10.7)	64 (14.9)	68.08 (13.9)
Female sex	131 (51%)	145 (51.8%)	76 (51.7%)	60 (48%)	52 (77.6%)	38 (49.4%)	39 (52%)	5 (6.8%)	13 (38.2%)	559 (49.2%)
Married	119 (46.3%)	123 (43.9%)	69 (47.9%)	30 (93.8%)	38 (63.3%)	27 (35.1%)	34 (45.3%)	35 (47.3%)	20 (60.6%)	495 (48%)
High school or higher	108 (42.5%)	204 (72.8%)	§	§	59 (100%)	48 (62.3%)	41 (56.2%)	67 (90.5%)	25 (78.1%)	552 (65%)
HF type										
EF ≤ 40%	47 (77%)	96 (52.2%)	88 (59.9%)	75 (78.9%)	65 (97%)	59 (76.6%)	44 (58.7%)	21 (55.3%)	24 (70.6%)	519 (66.7%)
EF 41–49%		18 (9.8%)	9 (6.1%)	2 (2.1%)	1 (1.5%)	4 (5.2%)	3 (4.0%)	9 (23.7%)		46 (5.9%)
EF ≤ 50%	14 (23%)	70 (38%)	41 (27.9%)	18 (18.9%)	1 (1.5%)	14 (18.2%)	25 (33.3%)	8 (21.1%)	10 (29.4%)	201 (25.8%)
NYHA										
I	§	0	2 (1.4%)	1 (1.2%)	1 (1.5%)	0	1 (1.3%)	25 (33.8%)	11 (32.4%)	41 (5.2%)
II		8 (3.4%)	43 (29.3%)	25 (30.1%)	17 (25.4%)	5 (6.5%)	28 (37.3%)	32 (43.2%)	8 (23.5%)	166 (20.9%)
III		99 (41.6%)	60 (40.8%)	41 (49.4%)	41 (61.2%)	43 (55.8%)	40 (53.3%)	17 (23%)	13 (38.2%)	354 (44.5%)
IV		131 (55%)	42 (28.6%)	16 (19.3%)	8 (11.9%)	29 (37.7%)	6 (8%)	0	2 (5.9%)	234 (29.4%)
EF	§	42.81 ± 8.3	35.25 ± 17.9	29.83 ± 17.9	27.69 ± 7.4	31.40 ± 14.7	38.56 ± 19.5	38.37 ± 14.0	31.68 ± 15.7	35.37 ± 17.5
LHFQ Total Scores	51.90 ± 25.4	50.28 ± 22.9	50.75 ± 23.0	53.23 ± 27.9	45.88 ± 21.9	75.96 ± 21.8	55.36 ± 18.4	38.81 ± 24.1	48.12 ± 27.5	52.04 ± 24.9
LHFQ Physical Subscale Scores	23.30 ± 11.4	22.83 ± 10.7	24.29 ± 10.3	23.63 ± 12.5	19.57 ± 10.2	35.36 ± 9.2	27.09 ± 8.8	17.90 ± 11.7	20.65 ± 12.9	23.77 ± 11.5
LHFQ Emotional Subscale Scores	11.75 ± 7.7	11.76 ± 7.5	10.90 ± 7.6	12.43 ± 8.1	10.69 ± 7.0	18.45 ± 7.2	12.15 ± 6.9	8.58 ± 7.3	10.59 ± 8.5	11.89 ± 7.8

§ Missing data

Note. Valid percentages calculated to account for missing data. HF = heart failure; EF = ejection fraction; NYHA = New York Heart Association; LHFQ = Living With Heart Failure.

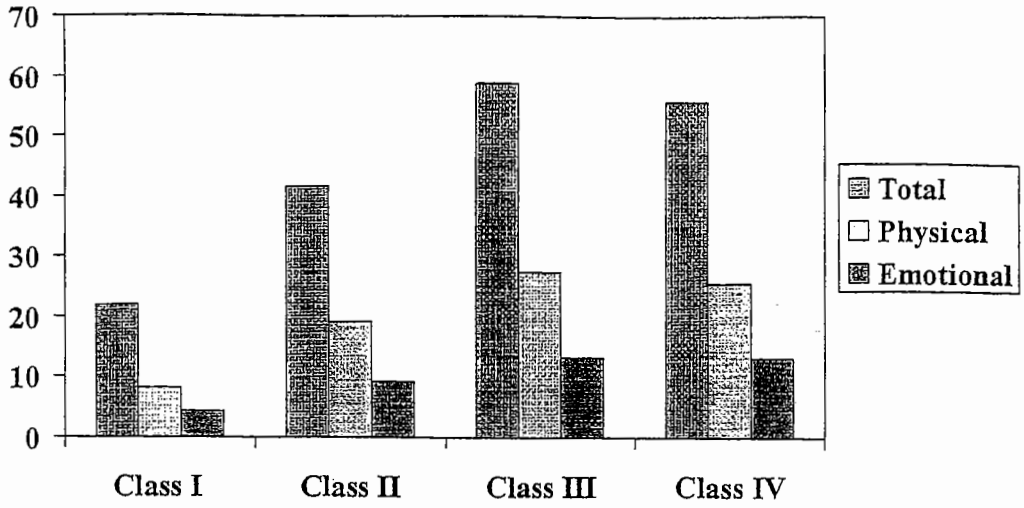

FIGURE 1. Baseline Minnesota Living With Heart Failure Questionnaire scores separated by New York Heart Association functional class.

complement of covariates. When analyzed without the covariates, total LHFQ scores improved 13.3 points (26.6%) in the first three months and 2.2 points (5.9%) in the subsequent three months after hospitalization (F = 43.69, df = 2,171, $p < .001$). Physical (F = 35.14, df = 2,171, $p < .001$) and emotional (F = 20.54, df = 2,171, $p < .001$) subscale scores improved significantly as well. When the analysis was repeated using age, NYHA class, and EF as covariates, total and subscale score improvements were comparable but the improvement over time was no longer statistically significant. Specifically, total LHFQ scores improved by 16.5 points (34%) in the first three months and 5.9 points (18.4%) in the subsequent three months after hospitalization (Figure 2). According to Rector and colleagues' (1995) criterion of a five-point change in total scores, the improvement in LHFQ scores between baseline and three months was clearly clinically important, regardless of the sample used.

Responsiveness to Intervention Intensity

When raw scores were grouped into low (2–3), moderate (4–6), and high (7–9) intensity interventions, an examination of group mean LHFQ scores demonstrated differential responsiveness based on the intensity of the intervention provided (Table 4). Significant differences were evident among the treatment dose groups at one (F = 3.60, df = 9,579, $p < .001$), three (F = 8.85, df = 9,1029, $p < .001$), and six (F = 5.07, df = 9,768, $p < .001$) months. When the raw scores were regrouped as low (2–4), moderate (5–7), and high (8–9) intensity, the findings remained the same. That is, there were significant differences among the treatment dose groups at one (F = 3.43, df = 9,579, $p < .001$), three (F = 7.45, df = 9,1029, $p < .001$), and six (F = 4.86, df = 9,768, $p < .001$) months.

At each time interval, mean scores for each intensity group (low, moderate, high) were contrasted against control group scores (see Table 4). At one month, none of the scores differed significantly from those of the control group. At three months, total and subscale scores were all significantly better in the high intensity intervention group compared to the control group ($p < .001$). At six months, total (p = .001) and physical (p = .008) subscale scores were significantly worse than controls in the low intervention group. None of these interpretations changed when the scores were regrouped.

Discussion

The most important finding of this study was that LHFQ differentiated only between subjects receiving a high intensity intervention compared to those in the control group. Factors influencing both the intervention received (e.g., EF,

TABLE 3. Minnesota Living With Heart Failure Questionnaire Scores by Baseline Ejection Fraction Category (N = 759)

Variable	Ejection Fraction <40% (n = 514)	41–49% (n = 45)	>50% (n = 200)
Total LHFQ scores	53.42 ± 24.8	55.58 ± 24.3	51.97 ± 22.6
Physical subscale	24.27 ± 11.6	25.18 ± 10.9	24.77 ± 10.2
Emotional subscale	12.18 ± 7.8	12.16 ± 7.5	11.51 ± 7.9

Note. LHFQ = Living With Heart Failure Questionnaire; multivariate analysis of variance used to compare mean total and subscale LHFQ scores at baseline in each of the ejection fraction categories.
$p > .05$

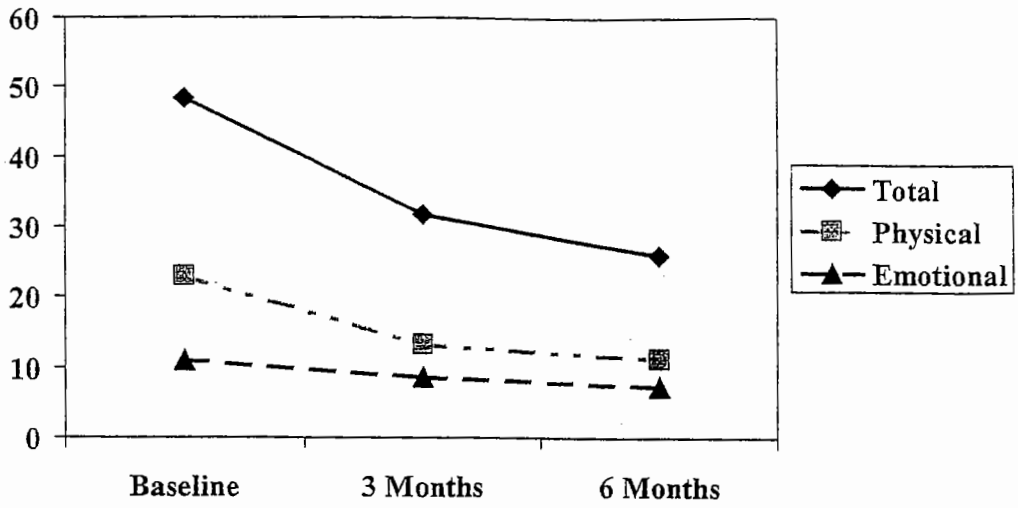

FIGURE 2. Minnesota Living With Heart Failure (LHFQ) Scores in Persons Enrolled in the Hospital, Assigned to the Control Group, and Followed at 3 and 6 Months (n = 65).

age, NYHA) and the resulting outcome (e.g., baseline LHFQ scores) were controlled in the analysis. These findings suggest that the variability in response noted in prior trials results from lack of responsiveness of the instrument. Alternately, the interventions provided may not be sufficiently intense to influence HRQL in a general HF population. It has been noted previously that a common error in healthcare research is failure to attend to the intensity of the intervention (Lipsey, 1990). Instead, investigators often concern themselves with increasing power by maximizing sample size rather than strengthening the intensity of the intervention. The findings of this study underscore the importance of delivering an intervention to HF patients that is sufficiently intense to influence HRQL.

It is interesting to note that individuals assigned to a low intensity intervention had worse HRQL at six months when compared to the control group. This result could be attributable to pooling of a nonsystematic sample of datasets from studies with heterogenous designs and slightly different inclusion and exclusion criteria. It could also be due to problems with the dose algorithm used to assign subjects to groups or an artifact of differences in the numbers of subjects receiving different intensity interventions. If, however, this finding is true, it may be that low intensity interventions are only sufficient to bring the diagnosis into consciousness (i.e., decrease denial) without providing enough support to offset the resulting decline in HRQL. Further research is needed to replicate and explain this interesting observation.

TABLE 4. Minnesota Living With Heart Failure Questionnaire Scores Separated by Intensity of the Intervention Provided

Intervention	LHFQ Scores	1 Month (SD)	3 Months (SD)	6 Months (SD)
Intensity		(n = 203)	(n = 353)	(n = 266)
No intervention control group	Total	26.31 (27.1)	33.78 (23.8)	26.97 (23.9)
	Emotional	6.73 (8.5)	8.53 (7.1)	7.51 (7.1)
	Physical	12.04 (12.6)	14.32 (10.8)	11.52 (11.0)
Low intensity intervention (raw score 2–3)	Total	28.30 (25.2)	44.50 (22.7)	47.87 (22.9)*
	Emotional	7.07 (7.3)	10.08 (7.5)	10.65 (6.2)
	Physical	13.39 (12.2)	20.19 (10.8)	23.87 (10.7)*
Moderate intensity intervention (raw score 4–6)	Total	55.09 (26.9)	35.77 (25.7)	27.56 (23.5)
	Emotional	14.73 (7.8)	8.76 (7.5)	6.22 (7.1)
	Physical	21.91 (11.8)	15.18 (11.6)	12.65 (10.7)
High intensity intervention (raw score 7–9)	Total	44.98 (28.6)	30.40 (24.0)*	32.07 (23.8)
	Emotional	12.65 (8.7)	9.02 (8.3)*	9.33 (7.9)
	Physical	17.86 (12.6)	10.55 (9.5)*	12.15 (10.7)

Note. LHFQ = Living With Heart Failure Questionnaire; NYHA = New York Heart Association.

*$p < .05$ for comparisons of total and subscale scores at each time period (e.g., six months) contrasted against the control group. Multivariate analyses conducted using baseline LHFQ scores, ejection fraction, age, and NYHA functional class as covariates in the analysis.

An important finding was the pattern of LHFQ scores over time in patients enrolled during hospitalization and assigned to the control group. As suspected, hospitalization is a low-point in HRQL. This fact should be acknowledged in any study measuring HRQL. However, the improvement in the early months after hospital discharge, even without a special intervention, was not anticipated. This trajectory has important implications for clinicians and investigators who test HRQL before and after an intervention without a comparison group. If LHFQ is used to measure HRQL, the LHFQ score may improve after discharge, regardless of the intervention provided.

Patients with poor physiological function cannot be assumed to have a correspondingly poor health-related quality of life

In this population, the LHFQ was sensitive to differences in symptom severity, except in the most compromised patient groups (i.e., NYHA class III and IV). This finding may reflect a restriction in variability in this sample, because most patients were functional class III or IV. Or, it may reflect problems with the NYHA classification method (Bennett, Riegel, Bittner & Nichols, in press). Others have found this same lack of sensitivity to differences at poorer levels of HRQL (Gorkin, et al., 1993; Havranek, et al., 1999; Rector, et al., 1987). However, Bennett, Oldridge, et al. (in press) found that LHFQ physical subscale scores could differentiate NYHA functional class III and IV patients. More research is needed to determine if the LHFQ can distinguish among patients who are severely compromised by symptom severity. In the meantime, researchers testing interventions intended to differentially improve HRQL in HF patients who are extremely symptomatic may want to use a different measure, multiple measures of HRQL, or a finer-grained criterion for functional status than the NYHA classification.

The LHFQ was not sensitive to differences in disease severity, even when a full range of EF values was used. This finding was not entirely unexpected, considering that prior investigators have documented that even HF patients with a low EF may be asymptomatic (Marantz, Tobin, Wassertheil-Smoller, et al., 1988). Clearly, patients with poor physiological function cannot be assumed to have a correspondingly poor HRQL.

Major limitations of this study included use of an algorithm for scoring intervention intensity that had only content validity based on the published literature. It was validated and revised with input from the seven clinical co-investigators, but further validation of this algorithm is needed before others use it. Grouping of the intervention intensity scores into low, moderate, and high had only face validity but credence was provided by reanalyzing the data with a different grouping that yielded almost identical results. Other limitations were the varying samples used for the comparison of responsiveness to intervention intensity. Data were not available on every subject at all intervals, so comparisons cannot be made across time. Further, patients were not randomly assigned to interventions of differing intensity, so these data must be interpreted as hypothesis-generating in nature. A strength of this study was the large, heterogeneous sample that reflects the general HF patient population.

Future research should explore the clinical importance of total and subscale scores further. Although Rector et al. (1995) argue that a five-point change in total LHFQ score is clinically significant, further research is needed to validate this and to identify what change in subscale scores is clinically important. The LHFQ is commonly used in both clinical trials and in clinical programs, so this information could produce a criterion that best discriminates patients who have improved from those who have not (Deyo & Centor, 1986).

In summary, the LHFQ was shown to be sensitive to differences in symptom severity except in individuals who were severely symptomatic. Lack of sufficient intervention intensity appears to be partially responsible for the variable results seen in the clinical trials that used the LHFQ. Investigators are encouraged to compare results to a control group and follow patients for at least 6 months to evaluate the true effect of their interventions on HRQL because LHFQ scores improve immediately after hospital discharge, even in those assigned to a control group and some differences between high intensity intervention group scores and those of patients assigned to the control group were statistically significant at three months and stable at six months. A decline in HRQL in the low intensity intervention group was evident at six months. Further research exploring responsiveness of the LHFQ is needed.

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References

American Heart Association. (2001). Heart and stroke facts: 2001 statistical update. American Heart Association. Available: *www.americanheart.*org [2001, September 17].

Armola, R. R., & Dooley, J. (2001). *Assessment of quality of life and cost-effectiveness of patients enrolled in a heart failure disease management program.* Presented at the Heart Failure Summit VI, Cleveland Clinic, Cleveland, OH.

Bennett, J.A., Riegel, B., Bittner, V., & Nichols, J. (in press). Validity and reliability of the NYHA classes for measuring research outcomes in patients with cardiac disease. *Heart & Lung.*

Bennett, S., Oldridge, N., Eckert, G., et al. (in press). Discriminant properties of commonly used quality of life measures in heart failure. *Quality of Life Research.*

Briancon, S., Alla, F., Mejat, E., et al. (1997). Mesure de l'incapacite fonctionnelle et de la qualite de vie dans l'insuffisance cardiue. Adaptation transculturelle et validation des questionnaires de Goldman, de Minnesota et de Duke. [Measurement

of functional inability and quality of life in cardiac failure. Transcultural adaptation and validation of the Goldman, Minnesota and Duke questionnaires.] *Archives des Maladies du Coeur et des Vaisseaux, 90*, 1577-1585.

Brignole, M., Menozzi, C., Gianfranchi, L., et al. (1998). Assessment of atrioventricular junction ablation and VVIR pacemaker versus pharmacological treatment in patients with heart failure and chronic atrial fibrillation: A randomized, controlled study. *Circulation, 98*(10), 953-960.

Cohn, J. N., Fowler, M., Bristow, MR, & the US Carvedilol Heart Failure Study Group. (1997). Safety and efficacy of carvedilol in severe heart failure. *Journal of Cardiac Failure, 3*(3), 173-179.

Colucci, W., Bristow, M., & the US Carvedilol Heart Failure Study Group. (1996). Carvedilol inhibits clinical progression in patients with mild symptoms of heart failure. *Circulation, 94*, 2800-2806.

Deaton, C., Jacobson, L., Causey, R. L., et al. (1999). Reversing the trend: Improvement in resource utilization, quality of life, and self-care in patients referred to an advanced heart failure clinic. *Circulation, 100*:18 [Supplement]), I-100.

Deyo, R., & Centor, R. (1986). Assessing the responsiveness of functional scales to clinical change: An analogy to diagnostic test performance. *Journal Chronic Diseases, 11*, 897-906.

Elliott, K., & Sethares, K. (2001). Improving clinical outcomes in heart failure. *American Journal of Critical Care, 10*(3), 211.

Exner, D. V., & Schron, E. B. (2001). Impact of pharmacologic therapy on health-related quality of life in heart failure: Findings from clinical trials. In D. K. Moser & B. Riegel (Eds.), *Improving outcomes in heart failure: An interdisciplinary approach*. Gaithersburg, MD: Aspen.

Foster, E. M. (2000). Is more better than less? An analysis of children's mental health services. *Health Services Research, 35*(5 Pt 2), 1135-1158.

Gorkin, L., Norvell, N. K., Rosen, R. C., et al. (1993). Assessment of quality of life as observed from the baseline data of the Studies of Left Ventricular Dysfunction (SOLVD) trial quality-of-life substudy. *American Journal of Cardiology, 71*(1069-73).

Gottlieb, S. S., Fisher, M. L., Freudenberger, R., et al. (1999). Effects of exercise training on peak performance and quality of life in congestive heart failure patients. *Journal of Cardiac Failure, 5*(3), 188-194.

Grady, K., Dracup, K., Kennedy, G., et al. (2000). Team management of patients with heart failure: A statement for healthcare professionals from the Cardiovascular Nursing Council of the American Heart Association. *Circulation, 102*, 2443-2456.

Gras, D., Mabo, P., Tang, T., et al. (1998). Multisite pacing as a supplemental treatment of congestive heart failure: Preliminary results of the Medtronic Inc. InSync Study. *Pacing & Clinical Electrophysiology, 21*(11 Pt 2), 2249-2255.

Green, C. P., Porter, C. B., Bresnahan, D. R., & Spertus, J. A. (2000). Development and evaluation of the Kansas City Cardiomyopathy Questionnaire: A new health status measure for heart failure. *Journal of the American College of Cardiology, 35*(5), 1245-1255.

Havranek, E. P., McGovern, K. M., Weinberger, J., Brocato, A., Lowes, B. D., & Abraham, W. T. (1999). Patient preferences for heart failure treatment: Utilities are valid measures of health-related quality of life in heart failure. *Journal of Cardiac Failure, 5*(2), 85-91.

Jaarsma, T., Halfens, R., Huijer Abu-Saad, H., et al. (1999). Effects of education and support on self-care and resource utilization in patients with heart failure. *European Heart Journal, 20*(9), 673-682.

Lipsey, M. W. (1990). *Design sensitivity: Statistical power for experimental research*. Newbury Park, CA: Sage Publishers.

Malone, D. C., Carter, B. L., Billups, S. J., et al. (2001). Can clinical pharmacists affect SF-36 scores in veterans at high risk for medication-related problems? [see comments]. *Medical Care, 39*(2), 113-122.

Marantz, P. R., Tobin, J. N., Wassertheil-Smoller, S., et al. (1988). The relationship between left ventricular systolic function and congestive heart failure diagnosed by clinical criteria. *Circulation, 77*(3), 607-612.

Moser, D. K. (2000). Heart failure management: Optimal healthcare delivery programs. *Annual Review of Nursing Research, 18*, 19-126.

Moser, D. K., & Dracup, K. (2001). Impact of nonpharmacologic therapy on quality of life in heart failure. In D. Moser & B. Riegel (Eds.), *Improving outcomes in heart failure: An interdisciplinary approach*. Gaithersburg, MD: Aspen.

Moser, D. K., Macko, M. J., & Worster, P. (2000). Community case management decreases rehospitalization rates and costs, and improves quality of life in heart failure patients with preserved and non-preserved left ventricular function: A randomized controlled trial. *Circulation, 102*(18 [Supplement]), 11-740.

Rector, T., & Cohn, J. (1992). Assessment of patient outcome with the Minnesota Living with Heart Failure questionnaire: reliability and validity during a randomized, double-blinded, placebo-controlled trial of pimobendan. Pimobendan Multicenter Research Group. *American Heart Journal, 124*, 1017-1025.

Rector, T., Kubo, S., & Cohn, J. (1987). Patient's self-assessment of their congestive heart failure. Part 2: content, reliability and validity of a new measure, The Minnesota Living with Heart Failure Questionnaire. *Heart Failure, 1*, 198-209.

Rector, T., Tschumperlin, L., Kubo, S., et al. (1995). Use of the Living With Heart Failure questionnaire to ascertain patients' perspectives on improvement in quality of life versus risk of drug-induced death. *Journal of Cardiac Failure, 1*(3), 201-206.

Reddy, P., & Dunn, A. B. (2000). The effect of beta-blockers on health-related quality of life in patients with heart failure. *Pharmacotherapy, 20*(6), 679-689.

Rich, M. W., Beckham, V., Wittenberg, C., Leven, C. L., Freedland, K. E., & Carney, R. M. (1995). A multidisciplinary intervention to prevent the readmission of elderly patients with congestive heart failure. *New England Journal of Medicine, 333*, 1190-1195.

Rideout, E. (1992). Chronic heart failure and quality of life: The impact of nursing. *Canadian Journal of Cardiovascular Nursing, 3*(1), 4-8.

Riegel, B., Carlson, B., Glaser, D., & Hoagland, P. (2000). Which patients with heart failure respond best to multidisciplinary disease management? *Journal of Cardiac Failure, 6*(4), 290-299.

Riegel, B., Carlson, B., Kopp, Z., LePetri, B., Unger, A., & Glaser, D. (2002). Effect of a standardized nurse case management telephone intervention on resource use in chronic heart failure patients. *Archives of Internal Medicine, 162*(6), 705-712.

Serxner, S., Miyaji, M., & Jeffords, J. (1998). Congestive heart failure disease management study: A patient education intervention. *Congestive Heart Failure, 4*(June), 23-28.

Stewart, B., & Archbold, P. (1992). Nursing intervention studies require outcome measures that are sensitive to change: Part one. *Research in Nursing & Health, 15*, 477-481.

Stewart, S., Pearson, S., & Horowitz, J. D. (1998). Effects of a home-based intervention among patients with congestive heart failure discharged from acute hospital care. *Archives of Internal Medicine, 158*, 1067-1072.

Tyni-Lenne, R., Gordon, A., Jensen-Urstad, M., Dencker, K., Jansson, E., & Sylven, C. (1999). Aerobic training involving a minor muscle mass shows greater efficiency than training involving a major muscle mass in chronic heart failure patients. *Journal of Cardiac Failure, 5*(4), 300-307.

Velicer, W. F., Prochaska, J. O., Fava, J. L., Laforge, R. G., & Rossi, J. S. (1999). Interactive versus noninteractive interventions and dose-response relationships for stage-matched smoking cessation programs in a managed care setting. *Health Psychology, 18*(1), 21-28.