

Development and Testing of a New Measure of Health Status for Clinical Trials in Heart Failure

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The authors developed a new measure of subjective health status for patients with heart failure. Eighty-eight patients with heart failure were asked about the impact of their condition on 123 items related to physical and emotional function. The most frequently chosen and important items were included in a 16-item Chronic Heart Failure Questionnaire (CHQ) that examines dyspnea during daily activities, fatigue, and emotional function. The CHQ was tested in a controlled trial of digoxin in heart failure patients in sinus rhythm. When administered serially to 25 patients in the run-in phase of the trial, the CHQ proved reproducible. Subsequently, CHQ results distinguished those who reported improvement or deterioration from those who did not. The CHQ showed moderate correlations with patient global ratings, walk test scores, and clinical assessments of heart failure. The authors conclude that the CHQ may be useful for measuring health status in clinical trials in heart failure. Key words: Heart failure; quality of life; validity; responsiveness; clinimetrics. J GEN INTERN MED 1989;4:101-107.

WHILE INVESTIGATORS HAVE BEGUN to address the effects of treatment of heart failure on mortality,^{1,2} the impact on symptoms and patient function remains important. Because of the limited relations of cardiac function to exercise capacity³ and of laboratory exercise capacity to ability to undertake physically stressful activities of daily living,⁴ direct measurements of functional status are necessary. Up to now, investigators have relied on relatively unsophisticated instruments^{4,5} and ad hoc measures.⁶⁻⁹

These approaches may not capture all important elements of physical dysfunction, and they ignore emotional function altogether. Their reproducibility or precision, validity (ability to measure what they are designed to measure), and responsiveness (ability to detect all clinically important differences, even if the differences are small) remain untested.

In response to the need for a more sophisticated instrument for measuring subjective aspects of health status in clinical trials in heart failure, we developed the Chronic Heart Failure Questionnaire (CHQ). The

instrument examines three aspects of patients' lives: dyspnea, fatigue, and emotional function. In this report we describe how we developed the questionnaire, and demonstrate its reproducibility, validity, and responsiveness.

PRINCIPLES OF INSTRUMENT DEVELOPMENT

The Chronic Heart Failure Questionnaire is an evaluative instrument whose goal is to measure longitudinal change over time within persons.^{10,11} Our approach was guided by criteria that we deemed essential for the final questionnaire: 1) Both physical and emotional health should be measured. 2) Items must reflect areas of function that are important to patients with heart failure. 3) Summary scores amenable to statistical analysis must be provided. 4) Repetition in stable patients must yield similar results. 5) The questionnaire should be responsive to clinically important changes, even if those changes are small. 6) The questionnaire should be valid — that is, it should really be measuring subjective aspects of health status. 7) Considerations of cost and efficiency dictate that the questionnaire be relatively short.

INSTRUMENT DEVELOPMENT PHASE

Item Selection

We began by constructing a list of items likely to be important to patients with heart failure. The items were generated through a review of the literature,¹²⁻¹⁴ consultation with cardiac nurse specialists and cardiologists; and unstructured interviews with patients. The final item selection questionnaire contained 123 items, of which 61 dealt primarily with physical function, and 62 with emotional or social function. The item selection questionnaire was administered to 88 patients whose clinical diagnoses of heart failure were supported by echocardiographic, angiographic, or radionuclide angiographic evidence of cardiac dysfunction.

Of the 88 patients interviewed, 62 were men and 16 were women. Their mean age was 69.1 ± 10.7 (\pm SD) years. Nine were working outside the home. Twenty-six had stopped work because of their heart problems.

Patients were initially asked to volunteer physical and emotional problems they experienced as a result of their heart disease. They were then asked whether the 123 items represented ways in which their lives were affected by their heart disease. Items were scored ac-

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TABLE 1

Areas of Dysfunction in Heart Failure Reported by 88 Patients*

Dyspnea		Emotional	
Hurrying	187	Anxiety	
Walking upstairs	186	Restless	125
Going for a walk	179		
Carrying, such as groceries	156	Depression	
Being angry or upset	147	Discouraged	149
Bending	145	Down in the dumps	141
Walking uphill	131	Inadequate	115
		A burden on others	115
Fatigue		Embarrassment	
Worn out	218	Need to rest frequently because of fatigue or tiredness	164
Low in energy	213	Aching, tired legs	154
Generally tired	212	Need to rest frequently because of shortness of breath	122
Sluggish	190		
Exhausted	176	Frustration	
Not having enough energy to get through the day	143	Frustrated	147
Sleep disturbance		Impatient	115
Trouble getting to sleep	119		
Waking up during the night	117	Mastery	
Getting a good night's sleep	105	A feeling of fear or panic when you could not get your breath	129
Social		Feeling out of control of your breathing problems	122
Doing your usual social activities	108		
Cognitive			
Forgetful	133		
Difficulty in concentrating	105		

*Patients rated the importance of each affirmatively answered item on a five-point Likert scale (extremely important, quite important, . . . not very important). The score opposite each item represents the product of the number of people selecting the item and the mean importance they attributed to it (frequency-importance product). The maximum possible score, if all 88 subjects chose an item and rated it 5 in importance, would be 440.

cording to their importance on a five-point Likert scale. The highest-scoring items are presented in Table 1. The highest scores were given to items relating to fatigue and to dyspnea in day-to-day activities. Certain aspects of emotional function also received high scores: frustration, depression, and anxiety.

These results suggest three major dimensions of dysfunction: fatigue, dyspnea, and derangements of emotional function. To increase reproducibility, we stipulated that each of these dimensions should be represented by at least four items on the final questionnaire. The fatigue (four questions) and emotional function dimensions (four questions) were constructed by choosing the relevant items that obtained the highest products of frequency and importance on the item selection questionnaire. For the emotional function dimension we added three questions concerning positive affect, including feeling relaxed and happy (for a total of seven questions).

For the dyspnea dimension, we took a different approach. Reasoning that items associated with dyspnea would vary widely depending on the patient's sex, range of activities, and level of disability, we individualized the questions. Patients are asked to list activities associated with shortness of breath that they do frequently and that are important in their day-to-day lives. Twenty-three activities are offered as probes to aid recall. Patients are then asked to choose the five activities most important to them from among those they have listed. These five items constitute the dyspnea dimension for the individual patient for the duration of the study.

Item Presentation in the CHQ

Issues in item presentation include time specification and response option selection. Time specification refers to the fact that patients are asked to think about how they have been feeling over a well-defined time period; up to now, we have used two weeks, but this could be modified, depending on the study. The crucial issue in selecting response options for an evaluative instrument designed to measure change over time is ensuring item responsiveness: we chose a seven-point Likert scale to ensure that relatively fine gradations of change will be detected.

The CHQ that emerged from this process contains 16 items, which have been serially pretested to clarify issues of wording and item presentation. A summary of the questionnaire is included in the Appendix. Initial administration of the CHQ takes a maximum of 20 minutes (usually 10 to 15 minutes). Follow-up administration takes a maximum of 15 minutes (usually 5 to 10 minutes). Studies were undertaken to clarify the reproducibility, responsiveness, and validity of the CHQ.

TESTING THE CHQ

Methods

THE CONTROLLED TRIAL

Studies of CHQ measurement properties took place within a randomized controlled trial of digoxin in heart failure patients. Details of study design, patient recruitment, and primary outcomes in 20 patients eligible for the final analysis can be found in a separate report.¹⁵ In brief, patients in sinus rhythm with echocardiographic evidence of left ventricular dysfunction and significant functional disability were enrolled. A run-in period was conducted during which the CHQ was administered three times over a period of four to six weeks. Patients were then given digoxin and an identical placebo, each for seven weeks, the order determined by random allocation. Subjects, clinicians, and research staff were blind to the order of the treatments. Visits were planned for the end of the third, fifth, and

seventh weeks, but if a patient's condition deteriorated the period was terminated prematurely and outcome measures obtained.

Measures of outcome included the echocardiographic measurement of fractional shortening and end-diastolic left ventricular dimensions, a clinical heart-failure score (including findings from history, physical examination, and chest radiography),¹⁶ a six-minute walk test,¹⁷ the CHQ, global ratings of change in dyspnea, fatigue, and emotional function by patients and relatives, the Specific Activity Scale (SAS),⁵ and the New York Heart Association (NYHA) functional classification.

STUDIES OF REPRODUCIBILITY

Reproducibility of the CHQ was estimated using data from 25 patients who completed the run-in period. A one-way analysis of variance was conducted, the factor of interest being time or repetition.

STUDIES OF RESPONSIVENESS

To study the responsiveness of the questionnaire, we examined patients' global ratings of change in shortness of breath, fatigue, and emotional function. We classified patients according to whether their global ratings suggested that their conditions had deteriorated, remained stable, or improved between adjacent visits. We compared individual patients' scores at the first visit during the study in which they reported an improvement with their scores at the preceding visits. For example, assume a patient reported, in the global rating of change made at the first follow-up visit, that his shortness of breath had abated. His or her CHQ score

from baseline would then be compared with his CHQ score at the first follow-up visit. We used the same strategy to investigate responsiveness to deterioration in function. We compared patients' scores at the first visits during the study in which they reported deterioration since their prior visits with their scores during those prior visits.

STUDIES OF VALIDITY

To study the validity of the CHQ we examined the relationship between changes in CHQ scores and changes in a number of key variables. Prior to analyzing the data, we made predictions concerning the variables in which one would expect strong relationships if the CHQ is really measuring disease-specific aspects of subjective health status.

Results

REPRODUCIBILITY

Examining data from the run-in period, no time effect was found, indicating that systematic changes in CHQ scores had not occurred. To calculate the coefficient of variation for the three dimensions, the square root of twice the mean square error ($\sqrt{2 \times \text{MSE}}$) from the analysis of variance was divided by the mean score across all three administrations. Coefficients of variation were 14% for shortness of breath, 18% for fatigue, and 18% for emotional function. These results compare favorably with most functional status and physiologic measures.⁴

RESPONSIVENESS

The study showed digoxin to be of benefit. Seven patients required shortened periods because of increasing heart failure; all seven treatment failures occurred while patients were taking placebo ($p = 0.016$). The CHQ showed that trends favoring digoxin were found in all three dimensions (Table 2). However, the digoxin-induced changes in dyspnea are small, and those in fatigue and emotional function are very small. Only for the dyspnea dimension does the difference between digoxin and placebo reach conventional levels of statistical significance (Table 2).

The performance of the CHQ is comparable to those of the other measures (Table 2). Echocardiographic measurement of fractional shortening showed a substantial digoxin effect which was highly statistically significant. The walk test showed a trend favoring digoxin that approached conventional levels of statistical significance. The NYHA functional classification showed a small but statistically significant effect. The SAS showed no difference between digoxin and placebo.

The results suggest two possible conclusions. Digoxin did not make any difference to fatigue and emotional function (and only a small difference in dysp-

TABLE 2
Mean Values in a Controlled Trial of Digoxin

	Digoxin	Placebo	p
CHQ* dyspnea score	21.2	19.5	0.044
CHQ fatigue score	16.4	16.1	0.37
CHQ emotional function score	37.3	36.2	0.09
Echocardiogram fractional shortening	20.7%	16.7%	0.004
Six-minute walk test	411 meters	392 meters	0.055
NYHA† classification	2.30	2.65	0.016
SAS‡ classification	2.60	2.60	0.5

*CHQ = Chronic Heart Failure Questionnaire. Higher CHQ scores denote better function.

†NYHA = New York Heart Association; SAS = Specific Activity Scale.⁵ Higher scores on the NYHA and SAS functional classifications denote worse function.

nea), or digoxin had an important effect that the CHQ failed to detect. We used two other methods of examining CHQ responsiveness in an attempt to elucidate this issue.

The responsiveness of the questionnaire can be examined by comparing the within-subject variability, quantitated by $\sqrt{2 \times \text{MSE}}$, with the minimal clinically important difference.¹⁸ Clinical experience with the questionnaire has revealed that a minimal clinically important difference is approximately 0.5 per question. That is, patients whose conditions improve or deteriorate by scores of 2 or more in fatigue, 2 to 3 in dyspnea, and 3 to 4 in emotional function tend to report that their conditions have changed, and the changes are important to them in their day-to-day lives. The ratios of the minimal clinically important differences to within-subject variability are 0.75, 0.68, and 0.84 for the three dimensions. This indicates that (choosing conventional values for alpha error and beta error of 0.05 and 0.10, respectively) it could be anticipated that a cross-over study would require no more than 25 subjects per group for detection of a minimal clinically important difference, while a parallel-groups design would require no more than 46 per group.¹⁸ This suggests the CHQ is likely to be responsive, in that it will be able to detect clinically important changes in function with feasible sample sizes.

The second strategy was to examine changes in scores of subjects whose global ratings of change suggested improvement or deterioration between study visits, irrespective of what treatment they were receiving. Assuming that the CHQ is responsive, one would anticipate an improvement in score which, across all subjects who improved between visits, would exceed the minimal clinically important difference (0.5 per question) and would be statistically significant. For example, 11 of the 20 subjects reported improvements in their global ratings of dyspnea at some time during the study (Table 3). Scores in the CHQ dyspnea dimension improved over these visits, and a paired t-test showed the differences to be statistically significant (Table 3). The findings for all three dimensions were similar, de-

spite the small numbers of subjects who reported improvements (particularly in emotional function) at some time during the study. However, the change in emotional function was less than 0.5 per question, raising questions about the responsiveness of the emotional function dimension.

These results suggest the CHQ is responsive to improvement in health status. The findings in subjects whose conditions deteriorated also show substantial statistically significant differences, but once again, the change in emotional function is less than 0.5 per question (Table 3).

VALIDITY

Evidence for the validity of the CHQ can be gleaned from the data already presented: questionnaire scores remain stable in patients deemed clinically stable, and improve in groups in which clinical improvement is anticipated. Further evidence comes from the accuracy with which we predicted correlations between changes in CHQ dimensions and changes in other variables. Our predictions, and the results observed, were: 1) Changes in the three CHQ dimensions would bear a close relation ($r \geq 0.5$) to changes in patients' corresponding global ratings of change.* The correlation between change in the CHQ dyspnea score and the global rating of change in dyspnea was 0.65 ($p < 0.001$); that between change in the CHQ fatigue score and the global rating of change in fatigue was 0.62 ($p < 0.001$); and that between change in the CHQ emotional function score and the global rating of change in emotional function was 0.34 ($p < 0.001$). 2) Change in the CHQ dyspnea score should relate closely ($r \geq 0.5$) to change in the walk test score. The correlation observed was 0.60. 3) Change in the CHQ

*Pearson's correlations are reported. These assume independence of observations. Individual subjects contributed multiple data points to the correlations, violating this assumption. A definitive method for establishing a correlation in this situation has not been established. However, we repeated the analysis with several methods that yielded results comparable to those obtained with Pearson's correlation. Details are available on request.

TABLE 3

Chronic Heart Failure Questionnaire (CHQ) Responsiveness: Changes in CHQ Scores* of Patients Whose Global Ratings Showed Changes in Function over Two Consecutive Visits

Dimension	Patients Whose Condition Improved			Patients Whose Condition Deteriorated		
	Number	Mean Change in CHQ per Item	p	Number	Mean Change in CHQ per Item	p
Dyspnea	11	0.80	0.004	15	0.53	0.001
Fatigue	9	1.11	0.002	11	0.91	0.002
Emotional function	9	0.43	0.006	11	0.42	0.004

*Higher CHQ scores denote better function.

dyspnea score should bear a moderate correlation ($r > 0.4$) with change in heart-failure classification. The correlation observed was 0.42.

It would be worthwhile knowing how other functional status measures used in heart failure patients compare with the CHQ. Since the NYHA and SAS are measures of dyspnea on daily activity in patients with heart failure, the appropriate comparison is with the CHQ dyspnea score, and if these other instruments are valid, then predictions based on the CHQ dyspnea score should also apply. Correlations between changes in the CHQ dyspnea score, the NYHA functional classification, and the SAS, on the one hand, and global rating of change in dyspnea, change in the walk-test score, and change in heart failure classification on the other hand, are shown in Table 4. The correlations are consistently higher with the CHQ dyspnea score than with the other instruments, suggesting the CHQ is a more valid measure of changes in shortness of breath in heart failure patients.

DISCUSSION

In the present investigation the CHQ proved less responsive to the effects of digoxin than did echocardiographic measurement of fractional shortening and clinical assessment of heart failure. However, comparisons of scores across time periods when, irrespective of treatment status, patients made global ratings of improvement or deterioration, suggest the CHQ can detect change in dyspnea and fatigue when it occurs. While some support for the responsiveness of the emotional function dimension was also obtained, the results were not as strong. These findings suggest that digoxin had only a small impact on dyspnea, fatigue, and emotional function.

An alternative explanation for the apparent differences between responsiveness of the dyspnea versus the fatigue and emotional function dimensions lies in their structures. The dyspnea questions are individualized, in the sense that the subject chooses five important and frequently performed activities and is questioned about the degree of dyspnea in performing these activities. A more standard approach is used for the fatigue and emotional function dimensions. It is possible that the individualized approach enhanced the responsiveness of the dyspnea dimension.

It is important to compare the CHQ with existing disease-specific measures of health status. The NYHA functional classification is very widely used, while it has been suggested that the SAS is more reproducible.⁵ Both instruments are far briefer, and thus more efficient, than the CHQ. However, both deal only with exertional dyspnea, while the CHQ also measures fatigue and emotional function. In the present investigation the SAS was less responsive than either the CHQ or the NYHA classification. The correlations between the

TABLE 4

Correlations Between Congestive Heart Failure Questionnaire (CHQ) Dyspnea Dimension, NYHA* Functional Classification, and SAS† Classification‡

	Global Rating of Change in Shortness of Breath	Change in Walk Test Score	Change in Heart Failure Score
CHQ dyspnea score	0.65	0.60	0.42
NYHA functional classification	0.20	0.24	0.10
SAS classification	0.34	0.11	0.04

*NYHA = New York Heart Association.

†SAS = Specific Activity Scale.⁵

‡In natural units, correlations between NYHA and SAS and other measures are negative; sign has been reversed for comparison purposes. All correlations greater than or equal to 0.20 are statistically significant at the 0.05 level.

change in CHQ and global ratings of change in dyspnea, changes in walk-test score, and changes in clinical assessment of heart failure were strikingly higher than correlations between changes in NYHA classification and SAS and these measures (Table 4). These data strongly suggest that the CHQ dyspnea dimension is a more valid measure of change in exertional dyspnea on daily activities than the older and more efficient instruments.

The results reported here require confirmation in the hands of other investigators. Nevertheless, we believe the evidence suggests that the CHQ is ready for use in other clinical trials in heart failure in which investigators wish to determine the effects of their interventions on aspects of health status of direct relevance to patients.

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APPENDIX

Summary of the Chronic Heart Failure Questionnaire

The questionnaire begins by eliciting five activities in which the patient experiences dyspnea during day-to-day activities:

1. I would like you to think of the activities that you have done during the last two weeks that have made you feel short of breath. These should be activities which you do frequently and which are important in your day-to-day life. Please list as many activities as you can that you have done during the last two weeks that have made you feel short of breath.

[CIRCLE THE NUMBER ON THE ANSWER SHEET LIST ADJACENT TO EACH ACTIVITY MENTIONED. IF AN ACTIVITY MENTIONED IS NOT ON THE LIST, WRITE IT IN, IN THE RESPONDENT'S OWN WORDS, IN THE SPACE PROVIDED]

Can you think of any other activities you have done during the last two weeks that have made you feel short of breath?

[RECORD ADDITIONAL ITEMS]

2. I will now read a list of activities that make some people with lung problems feel short of breath. I will pause after each item long enough for you to tell me if you have felt short of breath doing that activity during the last two weeks. If you haven't done the activity

during the last two weeks, just answer "no." The activities are:

[READ ITEMS, OMITTING THOSE WHICH RESPONDENT HAS VOLUNTEERED SPONTANEOUSLY. PAUSE AFTER EACH ITEM TO GIVE RESPONDENT A CHANCE TO INDICATE WHETHER HE/SHE HAS BEEN SHORT OF BREATH WHILE PERFORMING THAT ACTIVITY DURING THE LAST TWO WEEKS. CIRCLE THE NUMBERS ADJACENT TO APPROPRIATE ITEMS ON THE ANSWER SHEET]

1. Being **angry** or upset
2. Having a **bath** or shower
3. **Bending**
4. **Carrying**, such as carrying groceries
5. **Dressing**
6. **Eating**
7. **Going** for a walk
8. Doing your **housework**
9. **Hurrying**
10. **Lying** flat
11. **Making** a bed
12. **Mopping** or scrubbing the floor
13. **Moving** furniture
14. **Playing** with children or grandchildren
15. **Playing** sports
16. **Reaching** over your head
17. **Running**, such as for a bus
18. **Shopping**
19. **Talking**
20. **Vacuuming**
21. **Walking** around your own home
22. **Walking** uphill
23. **Walking** upstairs
24. **Walking** with others on level ground
25. **Preparing** meals
26. Trying to **sleep**

If more than five items have been listed, the interviewer then helps the subject determine the five activities that are most important in the subject's day-to-day life.

3. Of the items you have listed, which is the most important to you in your day-to-day life? I will read through the items, and when I am finished, I would like you to tell me which is the most important.

[READ THROUGH ALL ITEMS SPONTANEOUSLY VOLUNTEERED AND THOSE FROM THE LIST THAT THE PATIENT MENTIONED]

Which of these items is most important to you in your day-to-day life?

[LIST ITEM ON RESPONSE SHEET]

This process is continued until the five most important activities are determined. The interviewer then proceeds to find out how much shortness of breath the subject has experienced during the preceding two weeks. Throughout the questionnaire, response options are printed on cards of different colors, which are given to the subject.

4. I would now like you to describe how much shortness of breath you have experienced during the last two weeks while doing the five most important activities you have selected. Please indicate how much

shortness of breath you have had during the last two weeks while [INTERVIEWER: INSERT ACTIVITY LIST IN 3a] by choosing one of the following options from the card in front of you: [GREEN CARD]

1. Extremely short of breath
2. Very short of breath
3. Quite a bit short of breath
4. Moderate shortness of breath
5. Some shortness of breath
6. A little shortness of breath
7. Not at all short of breath

This process continues until the subject's degrees of dyspnea on all five of his or her most important activities has been determined. The remainder of the questionnaire asks 11 standard questions that are the same for all subjects. The wording is deliberately repetitious, experience having taught us that the repetition ensures subjects' understanding. Response options are consistently presented as seven-point scales. An example of the way the questions are structured follows:

5. In general, how much of the time during the last two weeks have you felt frustrated or impatient? Please indicate how often during the last two weeks you have felt frustrated or impatient by choosing one of the following options from the card in front of you: [BLUE CARD]

1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. Hardly any of the time
7. None of the time

The wording structures of the other questions are identical, and appropriate seven-point scales are offered for each question. The content of the remaining ten questions is as follows:

6. What about fatigue? How tired have you felt over the last two weeks?

7. How often during the past two weeks have you felt inadequate, worthless, or as if you were a burden on others?
8. How much energy have you had in the last two weeks?
9. In general, how much of the time did you feel upset, worried, or depressed during the last two weeks?
10. How much of the time during the last two weeks did you feel relaxed and free of tension?
11. How often during the last two weeks have you felt low in energy?
12. In general, how often during the last two weeks have you felt discouraged or down in the dumps?
13. How often during the last two weeks have you felt worn out or sluggish?
14. How happy, satisfied, or pleased have you been with your personal life during the last two weeks?
15. In general, how often during the last two weeks have you felt restless, tense, or uptight?

Scoring of the CHQ

The questions are divided into three areas, or dimensions:

Dyspnea (questions 4a-4e)

Fatigue (question 6, 8, 11, 13)

Emotional function (question 5, 7, 9, 10, 12, 14, 15)

The scores for all questions in each dimension are simply added together. Thus, using a seven-point scale for the responses, the minimum and maximum scores for each dimension would be:

<i>Dimension</i>	<i>Minimum Score (Worst Function)</i>	<i>Maximum Score (Best Function)</i>
Dyspnea	5	35
Fatigue	4	28
Emotional function	7	49