

Evaluation of treatment for congestive heart failure in patients aged 60 years and older using generic measures of health status (SF-36 and COOP charts)

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Abstract

Objectives: to assess the functioning and well-being of older patients presenting with congestive heart failure (CHF) using established generic health status measures—the short form 36 health survey (SF-36) and Dartmouth COOP charts.

Methods: patients aged 60 or older with CHF were asked if they would take part. They were requested to complete interviewer-administered questionnaires before angiotensin converting enzyme (ACE) inhibitor treatment and at follow-up 4 weeks later. The interviewer administered the SF-36, COOP charts, the oxygen cost diagram and also asked patients to assess their health state overall and, after treatment, to assess changes, if any, in overall health.

Results: multi-dimensional health status measures indicate that patient's functioning and well-being is substantially compromised by CHF, especially in areas relating to physical functioning, and that treatment with ACE inhibitors has only limited effect in improving health-related quality of life. However, on simple single-item global assessments of health, patients report that their overall health-related quality of life is good and many report improvements in overall health status at follow-up.

Conclusions: ACE inhibitor treatment, whilst lengthening life, has a relatively limited impact on its quality. While multidimensional health status measures indicate CHF to be associated with poor health as measured by the SF-36 and COOP charts. However, when patients are asked simple single-item questions relating to their overall health state and the extent of change experienced after treatment, they report relatively good health and positive improvements as a consequence of therapy. Since elderly patients' expectations of improvement may be modest and their expectations of physical ability relatively limited, relatively small improvements, which may not appear large when reported in effect size statistics, may be important. Standardized questionnaires, and standardized statistical methods of assessing change, may not be appropriate for this patient group. A fuller understanding of their expectations and assessment of treatment outcomes is necessary.

Keywords: congestive heart failure, Dartmouth COOP charts, health status, SF-36

Introduction

An effective treatment for congestive heart failure (CHF) should not only reduce the risk of mortality but should also improve health status and, consequently, health-related quality of life. Assessments of quality of life in studies on this patient group have usually been limited to the classification of patients into one of four categories using the New York Heart Association criteria [1]. Despite the widespread use of this classification it has received criticism; there are, for

example, limited data concerning inter-observer validity [2], sensitivity to change or criterion validity [3]. Given such doubts, there has been a gradual shift away from this form of measurement and towards the inclusion of measures completed by patients themselves which assess health status and quality of life [4].

For example, the Department of Veterans Affairs Cooperative Vasodilator-Heart Failure Trial (V-HeFT II) utilized the Minnesota 'Living with Heart Failure Questionnaire' to assess outcomes in patients randomized to either enalapril or hydralazine plus isosorbide dinitrate.

However, data from disease-specific measures of outcome did not show any improvement in health-related quality of life for CHF patients treated with these drugs [4]. Three possible reasons have been suggested for such findings. Firstly, the questionnaires used had not been 'evaluated rigorously' and, consequently may not be sensitive to change in health status. Secondly, baseline measures of health-related quality of life indicated low levels of impairment, and so the impact of treatment could be limited at best. Thirdly, patients often report other illnesses: improvement of CHF may be masked by the presence of other ailments [4].

The purpose of the present study is to evaluate the health-related quality of life of CHF patients taking account of these criticisms. It will determine the impact of CHF on functioning and well-being using generic measures of outcome and the usefulness and appropriateness of generic health status measures in elderly people. It will also evaluate the impact of angiotensin converting enzyme (ACE) inhibitors in a newly diagnosed group of CHF patients using health status measures with established measurement properties and which are known to be sensitive to change [5, 6]; and assess change after ACE inhibitor therapy of those patients who report no other illnesses.

Methods

Patients and treatment

Consecutive patients referred by their general practitioner to the Department of Clinical Geratology at the Radcliffe Infirmary NHS Trust, Oxford, with a diagnosis of symptomatic CHF and who were aged 60 years or more, were asked to participate in the study. All patients approached during the study period (August 1994–October 1995) agreed to take part. They were assured that inclusion in the study would not alter their treatment in any way and would not subject them to extra examinations or medical tests. Patients were included in the study if they met the criteria which were used to establish a diagnosis of CHF in the Framingham study [7]. A medical history was taken by a research nurse to determine any co-morbidities.

All patients received a test dose of 6.25 mg of captopril under close medical supervision in the Radcliffe Infirmary day hospital. No significant hypotensive events were encountered and it was possible to establish patients on a maintenance dose of 10–20 mg enalapril daily in 1–2 divided doses by the time of follow-up at approximately 1 month after the initial interview. Patients received additional conventional treatment in the form of diuretics and vasodilators at the discretion of their primary physician.

Outcome measures

Patients completed the short form health survey

(SF-36) and the Dartmouth COOP charts before treatment and then at follow-up approximately 1 month later. Both questionnaires are subjective health profiles, and provide data on a number of aspects of functioning and well-being. The domains of the SF-36 contain a number of items, whilst those of the COOP charts are each based on a single question accompanied by illustrative answers. The oxygen cost diagram (OCD), a visual analogue scale, was included to measure self-reported dyspnoea before and after treatment. Questionnaires were administered by interview.

SF-36

The SF-36 is a generic patient-completed health status questionnaire that has been proposed as an appropriate instrument for evaluating the differential impact of different illness conditions upon functioning and well-being and as an outcome measure for therapeutic interventions [8–10]. This US-developed questionnaire underwent minor modifications in wording to make it acceptable in the UK, and in this form was shown to have good measurement properties [11]. Evidence suggests that the measure can be used in the evaluation of health status in elderly people [12], especially when used in an interview setting [13].

The SF-36 is a short 36-item questionnaire which measures eight multi-item dimensions: physical functioning (10 items), social functioning (two items), role limitations due to physical problems (four items), role limitations due to emotional problems (three items), mental health (five items), energy/vitality (four items), pain (two items) and general health perception (five items). There is a further unscaled single item asking respondents about health change over the past year, data from which are not reported here.

Dartmouth COOP charts

The COOP charts [14] are another generic measure of functional status which have been suggested to be of potential value in the longitudinal assessment of outcomes in older patients [15]. This questionnaire is shorter than the SF-36, with each question accompanied by an illustration. They have been shown to be sensitive to changes detected by the longer SF-36 and are included here to determine whether such a brief measure could provide a similar picture of outcome [5].

There are eight questions which request patients to evaluate aspects of functioning and well-being in the areas of physical fitness, feelings, daily activities, social activities, pain, overall health, social support and quality of life. Each question has five response categories, with each response category being linked to a drawing intended to represent the health state. Each scale runs from 5 (worst possible health state measured by the questionnaire) to 1 (best possible health state). There is

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Table 1. Descriptive statistics for the SF-36 at baseline (A) and follow-up (B), together with 95% confidence intervals (CIs) and effect sizes ($n = 61$)

Domain	A/B	Mean	(SD)	95% CI	Effect size ^a
Physical	A	34.43	26.38	27.81-41.05	-0.18
	B	29.75	24.55	23.59-35.91	
Role Physical	A	30.74	39.63	20.79-40.69	0.31
	B	43.03	43.81	32.04-54.02	
Mental	A	54.64	48.7	42.42-66.86	0.26
	B	67.21	43.67	56.25-78.17	
Social	A	68.49	31.96	60.47-76.51	-0.05
	B	66.85	34.75	58.13-75.57	
Mental health	A	72.98	19.74	68.03-77.93	0.15
	B	75.93	21.29	70.59-81.27	
Energy	A	50.33	22.43	44.70-55.96	-0.22
	B	45.33	25.8	38.86-51.80	
Pain	A	71.77	28.15	64.71-78.83	-0.01
	B	71.58	28.73	64.37-78.79	
General health perception	A	60.84	20.35	55.73-65.95	-0.12
	B	58.38	21.34	53.02-63.74	

^a A positive effect size indicates improvement.

a further question asking patients to indicate on a five-point scale whether there has been any change in health in the past 4 weeks.

OCD

The OCD [16] is a measure initially designed for use in respiratory illness but which is regularly used both in research and clinical practice to evaluate the level of breathlessness experienced by CHF patients [17]. Patients mark on a 10 cm line the extent to which they are breathless. The scale runs from breathlessness at rest to breathlessness when walking briskly uphill.

Statistics

Descriptive statistics (means and standard deviations of scores) are used to present the data gained from the administration of the outcome measures. SF-36 scores are reported on a scale of zero (worst possible health state) to 100 (best possible health state) scale, whilst COOP carts are reported on a scale from 5 (worst health) to 1 (best possible health state). The OCD is reported on a scale of 0 (breathless at rest) to 10 (breathless when walking briskly uphill).

Effect sizes are used to indicate the extent of change detected by the measures. Effect sizes are calculated by dividing the mean change score by the baseline standard deviation. Kazis *et al.* [18] have demonstrated the use of effect sizes in identifying changes which are clinically meaningful in preference to the rather less discriminating criteria of statistical significance. An effect size of 1.00 is equivalent to a change of one standard deviation in the sample. As a benchmark for assessing the relative magnitude of a change, Cohen

[19] identified an effect size of 0.20 as small, 0.50 as moderate and of 0.80 as large. Effect size statistics have been cited as appropriate for multi-item scales, as well as single-item measures.

Results

Sixty-eight patients were recruited into the study, and complete data were available at both administrations for 61 of them. Incomplete data were a result of death ($n = 2$) or patients not completing sufficient items to calculate all scores on all the questionnaires at baseline and follow-up ($n = 5$). The mean age of patients was 81 years (range 60-92 years; 25th percentile, 78; median, 82; 75th percentile, 87). Eighteen of the patients were male and 43 were female.

Mean scores on the OCD were 4.33 cm [SD 2.67; 95% confidence interval (CI) 3.65-5.01] at baseline and 4.89 cm (SD 3.88; 95% CI 3.90-5.85) at follow-up. The OCD indicated little change from baseline (effect size = 0.21). Descriptive statistics and effect size statistics for the dimensions of the SF-36 and COOP charts for the sample at baseline and follow-up are reported in Tables 1 and 2. Effect sizes are small indicating little if any improvement in terms of health-related quality of life as measured by the domains of the two instruments.

It could be suggested that the level of improvement experienced by these patients was low due to comorbidities. Subsequently, patients who reported any other chronic illness were excluded from the data analysis. Table 3 reports descriptive statistics for the eight domains of the SF-36 for patients presenting with CHF and reporting no other illness either at baseline or

Table 2. Descriptive statistics for the Dartmouth COOP charts at baseline (A) and follow-up (B), together with 95% confidence intervals and effect sizes ($n = 61$)

Dimension	A/B	Mean	SD	95% CI	Effect size ^a
Physical	A	4.15	0.91	3.92-4.38	0.18
	B	4.31	0.81	4.10-4.52	
Feelings	A	2.16	1.20	1.85-2.47	-0.11
	B	2.03	1.40	1.94-2.66	
Daily activities	A	2.95	1.30	2.57-3.33	-0.40
	B	2.43	1.32	2.09-2.77	
Social activities	A	2.26	1.47	1.88-2.64	-0.14
	B	2.05	1.40	1.69-2.41	
Pain	A	2.39	1.28	2.06-2.72	0.22
	B	2.67	1.48	2.29-3.05	
Overall health	A	3.31	0.98	3.06-3.56	0.08
	B	3.39	0.99	3.14-3.64	
Social support	A	1.82	1.32	1.48-2.16	-0.17
	B	1.59	1.22	1.28-1.90	
Quality of life	A	2.41	0.78	2.21-2.61	0.00
	B	2.41	0.86	2.19-2.63	

^aA positive effect size indicates improvement.

Table 3. Congestive heart failure patients reporting no other illness at entry into the study (time 1) and follow-up (time 2); $n = 38$, compared with population data for elderly patients reporting no illnesses whatsoever ($n = 85$)

Test component	Mean no. of patients (and SD) reporting no other illness		
	Time 1	Time 2	Population with no chronic illness ^a
Physical	41.45 (25.01)	34.61 (24.09)	73.6
Role			
Physical	32.24 (40.65)	43.42 (44.15)	74.6
Emotional	67.54 (45.51)	74.56 (39.08)	90.7
Social	73.68 (28.58)	72.22 (31.93)	87.8
Mental health	77.37 (19.42)	80.74 (16.68)	83.7
Vitality/energy	51.45 (22.02)	48.29 (25.97)	67.1
Pain	78.65 (27.14)	76.02 (27.04)	80.5
General health perception	61.08 (20.67)	58.16 (18.56)	74.4

^aSource: Lyons *et al.*, 1994 [13].

Table 4. Effect size statistics for congestive heart failure patients reporting no other illness at entry into the study and follow-up ($n = 38$)

Domain	Effect size
Physical	-0.27
Role	
Physical	0.18
Mental	0.15
Social	-0.05
Mental health	0.04
Energy	-0.05
Pain	-0.10
General health perception	-0.14

at follow-up after treatment ($n = 38$). Table 4 reports effect sizes for this patient group, which again indicates very little change.

Table 3 also includes data gained from a postal survey in West Glamorgan (Wales) in which the SF-36 was completed by people aged 65 and over who reported no chronic illness [13]. The mean age of this group is 73.9 (range 65-89). The level of ill-health experienced by CHF patients is substantially higher than that reported by the group included in the postal survey, especially in the areas of physical functioning.

Table 5 provides a content-based interpretation of what the score differences may mean in terms of item response on one dimension of the SF-36, the physical functioning scale. Broadly speaking, scores of 75 and above indicate relatively good health. At both pre- and

Table 5. Content-based interpretation of the physical functioning score of the SF-36.

Score	Interpretation
100	No problems in physical function. Respondents perform all types of activities without limitations in health.
90	Very few problems in physical function. Respondents report minor limitations in a small number of areas, such as vigorous activities, walking more than a mile, or bending and kneeling.
80	Very few problems in physical function. Respondents report minor limitations in a number of areas, such as vigorous activities, walking more than a mile, or bending and kneeling.
75	Respondents <i>may</i> report severe physical limitation in one area of physical functioning, such as vigorous activities, and minor problems in a number of other such as walking more than a mile, or bending and kneeling.
70	Respondents are likely to report severe physical limitation in one area of physical functioning, such as vigorous activities, and minor problems in a number of other such as walking more than a mile, or bending and kneeling.
65	Respondents report severe limitations in one or two areas related to physical function, such as vigorous activities, walking a mile or more and climbing stairs. Respondents <i>may</i> also report minor limitations in other aspects of physical function, like bending and stooping.
60	Respondents report severe limitations in one or two areas related to physical function, such as vigorous activities, walking a mile or more and climbing stairs. Respondents also report minor limitations in other aspects of physical function, like bending and stooping.
55	Respondents report severe limitations in one or two areas related to physical function, such as vigorous activities, walking a mile or more and climbing stairs. They also report minor limitations in a number of other aspects of physical function, like bending and stooping.
50	Respondents report severe limitations in one or two areas related to physical function, such as vigorous activities, walking a mile or more and climbing stairs. They also report minor limitations in most other aspects of physical function, like bending and stooping.
40	Respondents report severe limitation in a number of areas related to physical function, such as being severely limited in both moderate and vigorous activities, walking half a mile and bending. They <i>may</i> also indicate some limitation in many other aspects of physical function such as bathing and dressing.
35	Respondents report severe limitation in a number of areas related to physical function, such as being severely limited in both moderate and vigorous activities, walking half a mile and bending. They also indicate some limitation in many other aspects of physical function such as bathing and dressing.
30	Respondents report severe limitation in a large number of areas related to physical function, such as being severely limited in both moderate and vigorous activities, walking half a mile and bending. They also indicate some limitation in many other aspects of physical function such as bathing and dressing.
25	Respondents report severe limitations in a large number of areas related to physical function. In a large number of areas in which they are not severely limited they will experience some limitation.
20	Respondents report severe limitations in a large number of areas related to physical function. In <i>nearly all</i> areas in which they are not severely limited they will experience some limitation.
10	Respondents report severe limitations in nearly all aspects related to physical function. In those areas in which they are not severely limited they will experience some limitation.
0	Respondents report severe limitations in all aspects of physical function, and are severely limited in both their mobility and daily routines.

post-treatment over 90% of respondents scored below 75 on this dimension, with 75% scoring 50 or below at both times.

One of the items of the COOP charts requests patients to assess change in health overall in the last 4 weeks (see Table 6). Twenty-six patients (42.6%)

Table 6. Assessment of change in health at follow-up

Assessment	n (%)
Much better	11 (18.0)
A little better	15 (24.6)
About the same	26 (42.6)
A little worse	6 (9.8)
Much worse	3 (4.9)

indicated that their health had improved in the last 4 weeks and, subsequently, since treatment. However, calculation of effect size statistics for this sub-group did not produce any larger than 0.35, once again indicating little change on any of the dimensions of the SF-36 or COOP charts. The item asking patients to assess their overall health-related quality of life on the COOP charts indicated, at both baseline and follow-up, little evidence that patients viewed their overall health-related quality of life as poor. Only four (6.6%) indicated their health as being pretty bad or very bad at baseline, and only six (9.8%) at follow-up.

Discussion

The SF-36 data provided in this survey indicate the very severe impact CHF has upon self-reported functioning

and well-being of patients aged 60 and over. When compared with data gained from respondents aged 65 and over who report no chronic illness, the scores on all dimensions of the SF-36 are considerably compromised in the patient group. This is the case whether patients report with CHF alone or with other chronic illnesses. It must be borne in mind, however, that the population data were gained from a sample with a mean age lower than that of the CHF patients in this study.

The data from this study support findings reported elsewhere that treatment for CHF has only limited impact upon self-reported health-related quality of life *as measured by standardized instruments* [4, 20]. It has been suggested that such a finding may reflect the fact that CHF is more prevalent in older persons who may also have other illnesses [4, 20]. However, in this study care was taken to determine whether other long-term illnesses were present, and data from those patients with no other illnesses were analysed separately as a sub group. Nonetheless, scores at both times were severely compromised in the areas of physical functioning and little change was detected as a function of treatment.

Both the SF-36 and the COOP measures of functional status, as well as the OCD, indicated very limited improvement in this patient group as a function of therapy. This finding echoes that of the V-HeFT II trial, which used illness-specific measures of health status to evaluate outcomes of treatment. The authors of that report suggested that there was a need for reliable and valid measures of outcome that would detect the impact of CHF on health status and would be sensitive to treatment effects [4]. This report has adopted two well validated generic measures. These measures have suggested that the health status of CHF patients, especially in areas relating to physical functioning, is severely compromised, and yet that treatment, at least in the short term, has limited effect. SF-36 scores were substantially lower than scores gained from those without any chronic illness and, even in the short term, improvements were modest. Previous research has indicated that the use of the ACE inhibitor enalapril leads to a significant improvement in terms of mortality [21]. The evidence of data from trials such as V-HeFT II [4], CONSENSUS [23] and the research reported here would, however, suggest that such treatment, whilst lengthening life, has a relatively limited impact on its quality. However, what is striking in both the data reported here and in the V-HeFT II trial is that patients, for the most part, do not assess their overall health-related quality of life as bad, and many claim an overall health improvement after treatment when asked to assess change directly. The authors of V-HeFT II suggest that such a finding may be misleading as these data are based upon single item questions of health which, they claim, are notoriously unreliable. Furthermore, patients may claim improvements in

health in order to please their clinicians. However, these interpretations may be an over-simplistic account for this finding. Firstly, there is evidence that appropriately phrased single item questions can be accurate [22], especially in the evaluation of change over time [23] and, secondly, the patients in this report were told that their responses would not be fed back to their clinicians.

Elderly patients' expectations of improvement may be modest and their expectations of physical ability relatively limited [24]. As such, relatively small improvements, which may not appear large when reported in effect size statistics may be viewed as important in this patient group. Standardized questionnaires—and, indeed, standardized statistical methods of assessing change—may therefore be quite inappropriate. Undeniably, such measures present a useful picture of the impact of CHF on elderly patients, but it may be unreasonable to assume that treatment will dramatically influence their overall health status scores on such standardized measures. However, given the evidence that substantial numbers claim to benefit from treatment it is important that a fuller understanding of their expectations and assessment of treatment outcomes is gained. Standardized forms alone may not provide a full picture of treatment effects.

Key points

- Results on the multi-dimensional SF-36 and COOP charts health status measures indicate that patient's functioning and well-being is substantially compromised by congestive heart failure.
 - The SF-36 and COOP charts indicated that ACE inhibitors had only limited effects in terms of improvement in health-related quality of life as measured on these forms.
 - Results from simple single item global assessments of health did indicate that patients believed therapy improved their health status overall.
 - Before standardized multi-dimensional measures of outcome are adopted for use in elderly people their operating characteristics need to be more fully understood. Generic measures may not truly represent the health state of elderly patients as they may not cover aspects of health regarded as important by this age group.
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Acknowledgements

We wish to thank Joanna Gordon for helping to collect the data, and Anglia and Oxford Regional Health Authority for funding this study.

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Received in revised form 16 August 1996



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