UNIVERSITÀ DEGLI STUDI DI TORINO

Title: **Evaluation of the Functional Status Questionnaire in heart failure: a sub-study of the second Cardiac Insufficiency Bisoprolol Survival study (CIBIS-II)**

Gallanagh: **Functional Status Questionnaire (FSQ) in Heart Failure**

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Abstract

Aims: We evaluated a generic quality of life (QoL) Functional Status Questionnaire (FSQ), in patients with chronic heart failure (CHF). The FSQ assesses the 3 main dimensions of QoL: physical functioning, mental health and social role. It also includes 6 single item questions about: work status, frequency of social interactions, satisfaction with sexual relationships, days in bed, days with restricted activity and overall satisfaction with health status. The FSQ was compared to the Minnesota Living with Heart Failure questionnaire (MLwHF).

Methods and Results: The FSQ was evaluated in a substudy (n=340) of the second Cardiac Insufficiency Bisoprolol Survival study (CIBIS-II), a placebo-controlled mortality trial. 265 patients (75%) patients completed both questionnaires at 6 months of follow-up. Both questionnaires indicated substantially impaired QoL. The FSQ demonstrated high internal consistency (Cronbach's $\alpha > 0.7$ for all items except "social activity" = 0.66) and construct and concurrent validity. After 6 months, the only item on either questionnaire to show a difference between the placebo- and bisoprolol-treatment groups was the single item FSQ question about "days in bed" ($p = 0.018$ in favour of bisoprolol).

Conclusions: The FSQ performed well in this study, provided additional information to the MLwHF questionnaire and allowed interesting comparisons with other chronic medical conditions. The FSQ may be a useful general QoL instrument for studies in CHF.

Key words: Heart failure, Quality of life, Functional Status Questionnaire, Minnesota Living with Heart Failure questionnaire.

Introduction

It is widely recognised that chronic heart failure (CHF) impairs quality of life (QoL) more than almost any other medical condition[1,2]. Reduced QoL in CHF is associated with a worse prognosis[3] and patients with advanced CHF may place more value on improving their QoL than they do on prolonging their life[4,5]. Therefore, improving QoL is a desirable objective of CHF treatments. There is however, uncertainty and debate about which instruments should be used to measure QoL in studies of CHF, although there is some consensus that both a 'disease-specific' and 'generic' QoL questionnaire should be employed[6].

The most widely used disease-specific instrument is the Minnesota Living with Heart Failure questionnaire (MLwHF)[7]. There has been far less agreement about the general QoL questionnaire used, with a variety of instruments employed in prior studies in CHF.

The Functional Status Questionnaire (FSQ)[8] is a generic questionnaire which has been used in other chronic incapacitating diseases such as chronic back pain[9], rheumatoid arthritis[10], chronic obstructive pulmonary disease[11], Parkinson's disease[12] and multiple sclerosis[13]. The FSQ was found to be more sensitive than the New York Heart Association (NYHA) functional classification in predicting subsequent clinical deterioration in elderly patients following percutaneous aortic balloon valvuloplasty[14]. Certain components of the FSQ, mainly 'physical functioning' and 'social role functioning' have been used previously in conjunction with other QoL measures in patients with CHF[3,15]. However, the FSQ in its entirety has not been validated in CHF.

The FSQ addresses the three main dimensions of QoL, namely physical functioning (including basic and intermediate activities of daily living), mental health and social role (including social activity, quality of social interaction and work performance). In addition, the questionnaire includes six single items that may be relevant in patients with CHF: work status, frequency of social interactions, satisfaction with sexual relationships, days in bed, days with restricted activity and overall satisfaction with health status.

The second Cardiac Insufficiency Bisoprolol Survival study (CIBIS-II)[16], a placebo-controlled mortality trial, provided an opportunity to evaluate the FSQ in patients with CHF.

Methods

Patients and Study Design

The design and principal findings of CIBIS-II have been described in detail elsewhere[16,17]. Briefly, this was a double blind, randomised, comparison of placebo and bisoprolol in 2647 ambulatory patients with CHF in NYHA functional class III (83%) or IV (17%) and with a left ventricular ejection fraction of ≤ 0.35. Eligible patients were commenced on bisoprolol 1.25 mg or placebo once daily and the dose increased progressively to 2.5 mg, 3.75 mg, 5.0 mg, 7.5 mg and 10.0 mg according to tolerance. The trial was stopped prematurely after a mean follow-up of 1.3 years because of a statistically significant reduction in the primary end-point of all-cause mortality, with a bisoprolol to placebo hazard ratio (and 95% confidence intervals) of 0.66 (0.54, 0.81), $p<0.0001$.

In a sub-group of 351 patients (180 allocated to bisoprolol and 171 allocated to placebo) an ancillary QoL analysis was performed simultaneously with the main study. All patients in this sub-group were from France, the UK and Germany. The generic FSQ and disease-specific MLwHF self-administered questionnaires were completed by patients at baseline and every 6 months thereafter for up to 2.5 years. This analysis focused on the data collected up until 6 months because a high proportion of subsequent questionnaires were not completed.

QoL Instruments

The MLwHF is a validated 'disease-specific' questionnaire which measures the effects of CHF on QoL[7] (appendix 1). It assesses QoL in the past month. Briefly, the questionnaire evaluates two of the main dimensions of QoL: physical [8 items] and

emotional [5 items] health and provides summary scores for each of these dimensions. It is composed of 21 items in total, and in addition to physical and emotional dimensions it also assesses social and mental aspects of QoL. Each item is scored from 0-5, resulting in score ranges of 0-40 for the physical dimension and 0-25 for the emotional one. A total score is also provided and ranges from 0-105. In each case a lower score is indicative of a better QoL.

The FSQ, like the MLwHF questionnaire, is a short self-administered tool concerning the one month period prior to completion[8] (appendix 2). It includes two scales which assess physical function: basic activities of daily living (BADL) [3 items] and intermediate activities of daily living (IADL) [5 items]. Mental function is assessed by 5 items and social or role function is assessed by work performance (if patient is in employment) [6 items], social activity [3 items] and quality of social interaction [5 items].

The FSQ also contains six single items which ask questions about work status, days spent in bed due to illness, days where the patient had to curtail his/her routine activities because of illness, satisfaction with sexual activities, frequency of social interaction and a question about overall health satisfaction. There are 34 items in the FSQ in total. Using a simple algorithm, computer-generated scores are obtained for BADL, IADL, mental health, work performance, social activity and quality of interaction. Scores range from 0-100 and *a higher score is representative of a better QoL*, in contrast to the MLwHF questionnaire. A summary report is produced which displays each score on a scale and the answer to each of the single item questions. The developers of the FSQ described what they called “warning zones” or a range of scores they believed indicated when a patient had a problem requiring clinical

attention/investigation. The "warning zone" scores for BADL are 0-87, for IADL 0-77, for mental health 0-70, for work performance and social activities 0-78 and for quality of interactions 0-69.

Evaluation of the FSQ

The psychometric properties of the FSQ have previously been assessed and the instrument was found to be reliable and valid for use in the primary care setting[8]. Internal consistency (or internal reliability) is the extent to which questions within a domain assess the same characteristic. This was determined in the standard way using Cronbach's α. Construct validity seeks agreement between a theoretical concept and a specific measuring device and was assessed by examining correlations between related and unrelated dimensions. Concurrent validity can be assessed by comparing an instrument to another for which there is unequivocal evidence of its validity. We assessed this by comparing the FSQ scores in different NYHA functional classes and by examining correlations between the different dimensions of the FSQ and MLwHF questionnaire.

Statistical Analysis

Continuous variables are expressed as means and standard deviations, categorical variables are expressed with percentages and related sample size. Differences in baseline characteristics, QoL scores and improvements in QoL during follow-up between patients allocated to bisoprolol and placebo were assessed using χ^2 test for categorical variables and unpaired Wilcoxon rank sum test for continuous variables. Correlations within individual items of the FSQ and between FSQ items and MLwHF

dimensions were performed with the use of Pearson correlation coefficients. The level of significance was taken as two-tailed $p < 0.05$.

Results

Baseline characteristics

340 (97%) patients completed both questionnaires at baseline and 265 patients (75%) at 6 months of follow-up.

The mean age was 63, 81% of patients were male and the aetiology of CHF was ischaemic in almost half, similar to the whole CIBIS-II population[16]. The proportion of patients with NYHA class IV CHF was smaller in the QoL sub-study than in the whole population (8% versus 17%).

There were no significant differences in demographic and clinical baseline characteristics between patients allocated to bisoprolol compared to those allocated to placebo (tables 1 and 2).

MLWHF

The baseline MLwHF scores indicated moderately impaired QoL and were similar in patients randomized to bisoprolol compared to those randomized to placebo (table 2). After 6 months of follow-up, the scores relevant to physical and emotional dimensions as well as the total score decreased (i.e. improved) similarly in both the bisoprolol and placebo groups and there was no statistically significant difference between the treatment groups (table 2).

FSQ

At baseline the majority of items in the FSQ questionnaire also indicated moderately impaired QoL and there was no statistically significant difference between the two treatment groups (table 3). However, the single item ‘general health status’ identified a severe reduction in QoL.

After 6 months, all but two questionnaire items showed an improvement that was not statistically significantly different between treatment groups. The single item question about "days in bed" showed a larger increase in score (i.e. improvement) in patients receiving bisoprolol ($p = 0.018$) compared to those receiving placebo. The question about sexual relationships was answered by only about half of patients and decreased (i.e. deteriorated) over time (but the change was not different between the two treatment groups).

Evaluation of the FSQ and comparison with MLwHF

Internal consistency (reliability) among related FSQ items was high with Cronbach's Alpha values >0.7 for all items other than "social activity", where the value was 0.66 (table 4). Overall construct validity showed good correlations between related dimensions as presented in table 5 (e.g. "physical functioning" with "basic" and "intermediate activities" showed $r = 0.87$ and $r = 0.95$ respectively). Conversely, unrelated items were weakly correlated, demonstrating discriminant validity (e.g. "mental health" with "basic" and "intermediate activities" showed $r = 0.19$ and $r = 0.21$ respectively).

Related MLwHF dimensions and FSQ items presented moderate inverse correlations (table 6) whereas there was a weak correlation for unrelated sections of the questionnaires.

All the dimensions evaluated by the MLwHF questionnaire indicated significantly better QoL for patients in NYHA functional class III compared to patients in NYHA IV (table 7A). This was also generally true for the FSQ (table 7B) although the scores for the items related to "quality/frequency of interaction" and to "sexual relationship"

were not significantly higher (i.e. better). One item, work performance, could not be evaluated because only 2 patients in NYHA class IV completed this item.

Discussion

This is the first QoL analysis conducted in patients with moderate to severe CHF comparing the generic FSQ questionnaire with the most frequently used disease-specific MLwHF instrument. The FSQ performed similarly to the latter showing comparable accuracy but providing additional information to that obtained with the MLwHF. We did not detect any effect of bisoprolol on overall QoL, using either questionnaire, after 6 months of follow-up.

In our analysis the QoL scores generated by the MLwHF questionnaire (mean total score 40) were consistent with other CHF trials i.e. somewhere between the Valsartan Heart Failure Trial (Val-HeFT, mean 32.2) with a larger proportion of NYHA class II patients, the Cardiac Resynchronization in Heart Failure study (CARE-HF, mean 45) with only class III/IV patients and very similar to the Candesartan in Heart Failure: assessment of reduction in mortality and morbidity (CHARM) low LVEF patients (median 39), 72% of which were in NYHA class III or IV[18,19,20].

Treatment with bisoprolol did not lead to a significant improvement in overall QoL measured using the MLwHF after 6 months of follow-up. This finding is in keeping with the Metoprolol CR/XL Randomized International Trial in Congestive Heart Failure (MERIT-HF)[21] and US Carvedilol programme (USCP)[22].

Although the FSQ is a generic tool, the scores obtained using it were generally in close agreement with the MLwHF questionnaire highlighting a similar degree of impairment of QoL. The majority of scores fell within “warning zones”. Interestingly, the single item question in the FSQ about “general health status” gave the score indicating the most impaired QoL (mean score=50). While this might be a chance

finding, it may, alternatively, indicate that the MLwHF questionnaire and the other items in the FSQ fail to capture some important component of QoL in patients with CHF.

It is useful to compare the findings with the FSQ in patients in CIBIS-II and the findings with the FSQ in other studies. Scores are given for patients in other studies and patients in CIBIS-II respectively. Compared with ambulatory geriatric patients, our population showed worse QoL in terms of both "basic" (mean score 93.8 vs. 80.9) and "intermediate activities of daily living" (77.9 vs. 57.7), "mental health" (77.2 vs. 67.8), "social activity" (83.8 vs. 69.4) and "quality of interaction" (83.7 vs. 80.5)[23]. The FSQ demonstrated higher QoL in patients with Parkinson's disease (PD) than in our patients[24], although scores were lower for "basic" (71.5 vs. 80.9) but higher for "intermediate activities of daily living" (64.5 vs. 57.7) in patients with PD. Conversely, patients with pulmonary disease had a similar degree of impairment in their QoL to patients with CHF (e.g. 83.3 vs. 80.9 for BADL and 52.6 vs. 57.7 for IADL)[25].

The use of the FSQ in addition to the MLwHF questionnaire in a CHF population may confer several advantages. The FSQ asks about the number of days that the patient has been confined to bed and has reduced his or her daily activities as a result of illness. This was the only question from both questionnaires that identified a treatment effect of bisoprolol. Although this could be a chance finding, it is certainly consistent with the known effect of bisoprolol and other beta-blockers on hospital admission rates.

The FSQ also has more questions than the MLwHF questionnaire about frequency of interaction (how often individuals met with friends/relatives or spoke on the telephone) and about the quality of their interaction (how often they had been affectionate/irritable/isolated). These facets of the FSQ did not clearly correlate with either the physical activity or mental health items on the questionnaire and may address a new dimension of patient well-being, as well as provide additional information to the single MLwHF question which simply asks the extent to which CHF has made socialising difficult.

The FSQ also asks a question about the patient's ability to take care of others which may be a major factor contributing to QoL if he/she is responsible for children/grandchildren or a dependent partner.

Although the MLwHF does assess sexual relationships the answer is difficult to interpret because it is scored between 0-5; a score of 0 could indicate that the patient is not sexually active or that he/she is sexually active but dissatisfied with his/her sexual activity. The FSQ gives more specific options, including the option of stating that the patient did not have sexual relationships in the past month (time frame of the questionnaire). Despite this, few patients answered this question; perhaps due to the sensitive nature of the topic or because they felt that it was not applicable. This is a limitation of this specific item.

The FSQ assesses the impact of illness on the patient's mental health without explicitly stating the terms "anxiety" or "depression" which can have stigma attached to them and may make patients reluctant to answer questions with such labels.

Previously the Short Form-36 (SF-36) and Sickness Impact Profile (SIP) have been suggested as the best general QoL instruments for use in CHF. The FSQ offers several

potential advantages over both questionnaires in patients with CHF. The FSQ separates basic and intermediate activities of daily living, which is relevant as levels of physical functioning are impaired to different degrees in CHF: we found that intermediate activities of daily living (walking longer distances/climbing stairs/using transport/shopping) were more impaired than basic (washing/dressing/moving around at home). In addition the FSQ assesses areas that the SF-36 fails to capture, which are especially relevant to heart failure patients: days with restricted activities, days spent in bed, satisfaction with sexual relationships and quality of social interactions (in addition to frequency of interaction). The FSQ provides information about QoL over the past month as opposed to the SIP which assesses QoL only on the day the questionnaire is completed. As a result it may be less representative of patients' general QoL and more variable. Also the length of the SIP (136 items) makes it burdensome for patients and makes compliance and completeness of follow-up suspect.

Several factors could be responsible for the lack of change in QoL during treatment with bisoprolol. Neither questionnaire may have addressed determinants of health status influenced by beta-blockers or been sensitive enough to detect a change in QoL with the sample size studied. Alternatively, a positive effect of bisoprolol on some heart-failure related aspects of QoL might have been diluted by adverse effects on other determinants of QoL. Of course it is also possible that beta-blockers may not improve QoL or may take longer than 6 months to do so. However, some measures of patient reported overall wellbeing or change in overall wellbeing have identified an improvement during relatively short-term beta-blocker treatment. [26, 27, 28]

This sub-study has several limitations. The sample size was small and the majority of patients were NYHA class III. Content validity and the consistency of responses by means of test-retest reliability were not assessed. In addition to this, neither questionnaire assessed family members' or care-givers' QoL and the study was conducted in only 3 countries.

Conclusion

This sub-study looking at QoL in CIBIS-II found the FSQ to be an interesting instrument with some promising psychometric properties. The content of the FSQ may be especially relevant to CHF patients and further study of it is merited. Despite the clear benefits of beta-blockers on survival and hospitalization in CHF, it was not possible to demonstrate an improved QoL with bisoprolol although this sub-study may have been underpowered.

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Table 1 Baseline characteristics

	CIBIS-2 overall study	CIBIS-2 Quality of Life Substudy			
	n=2647	Total n=351	Bisoprolol n=180	Placebo n=171	p value†
Demographics					
Age (years)	60.9 ± 10.5	63.2 ± 9.7	62.9 ± 10.2	63.6 ± 9.1	0.769
Height (cm)	170.9 ± 8.1	170 ± 8.5	169 ± 8.4	170 ± 8.5	0.366
Weight (kg)	78.5 ± 14.0	78.2 ± 14.4	77.4 ± 14.9	79.1 ± 13.9	0.144
Male sex, n (%)	2132 (81%)	284 (81%)	146 (81%)	138 (81%)	0.922
White, n (%)	2619 (99%)	347 (99%)	179 (>99%)	168 (98%)	
Black, n (%)	8 (<1%)	1 (<1%)	1 (<1%)	0	
Oriental, n (%)	16 (1%)	2 (<1%)	0	2 (1%)	0.174
Other, n (%)	4 (<1%)	1 (<1%)	0	1 (<1%)	
Smoking Habit*, n (%)					
Current smoker	439 (17%)	46 (13%)	27 (15%)	19 (11%)	
Ex-smoker	1204 (46%)	188 (54%)	98 (54%)	90 (53%)	0.383
Non-smoker	1001 (38%)	117 (33%)	55 (31%)	62 (36%)	
Medical History, n (%)					
Hypertension	1150 (44%)	133 (38%)	63 (35%)	70 (41%)	0.442
Coronary heart disease	1719 (65%)	203 (58%)	111 (62%)	92 (54%)	0.440
Myocardial infarction	1455 (55%)	175 (50%)	97 (54%)	78 (46%)	0.369
PCI	117 (4%)	34 (10%)	15 (8%)	19 (11%)	0.425
Cardiac surgery	377 (14%)	82 (23%)	46 (26%)	36 (21%)	0.432
Peripheral arterial disease	196 (7%)	28 (8%)	16 (9%)	12 (7%)	0.550
Mental health disorder	N/A	38 (11%)	18 (10%)	20 (12%)	0.647
NYHA class, n (%)					
III	2202 (83%)	323 (92%)	162 (90%)	161 (94%)	0.151
IV	445 (17%)	28 (8%)	18 (10%)	10 (6%)	

PCI = percutaneous coronary intervention

† Comparison of bisoprolol and placebo groups

***** available in only 2644 patients overall

N/A = not available

Table 2 **Baseline Minnesota Living With Heart Failure (MLwHF) questionnaire score and change between baseline and six months. A lower score represents better quality of life (and a decrease in score an improvement in quality of life).**

	Baseline Score		Difference between baseline and 6 months		p value
	Placebo	Bisoprolol	Placebo	Bisoprolol	
Physical dimension	20.4 (9.9) *(n = 164)*	21.4 (11.3) *(n = 174)*	-2.8 (8.9) *(n = 113)*	-3.2 (9.3) *(n = 122)*	0.709
Emotional dimension	7.9 (6.0) *(n = 165)*	8.5 (6.6) *(n = 174)*	-1.0 (3.8) *(n = 112)*	-1.3 (4.9) *(n = 120)*	1.000
Total score	39.6 (19.0) *(n = 165)*	42.0 (20.8) *(n = 174)*	-4.9 (16.4) *(n = 112)*	-6.4 (16.1) *(n = 119)*	0.455

Table 3 Functional Status Questionnaire score at baseline and change between baseline and six months. A higher score represents better quality of life (and an increase in score an improvement in quality of life).

	Baseline Score		Difference between baseline and 6 months		p value
	Placebo	Bisoprolol	Placebo	Bisoprolol	
BADL	81.3 (17.6) *(n = 165)*	80.5 (18.5) *(n = 172)*	1.5 (18.4) *(n = 113)*	2.2 (12.2) *(n = 121)*	0.489
IADL	58.9 (22.1) *(n = 164)*	56.4 (24.1) (n = 171)	4.6 (18.3) *(n = 111)*	7.7 (17.7) *(n = 118)*	0.226
Physical functioning	68.9 (18.5) *(n = 164)*	67.1 (20.0) (n = 170)	3.3 (16.5) *(n = 111)*	5.2 (13.2) *(n = 117)*	0.341
Mental health	68.5 (19.3) *(n = 164)*	67.1 (19.2) *(n = 173)*	1.4 (14.3) *(n = 111)*	4.6 (16.6) *(n = 118)*	0.229
Social activity	71.4 (28.9) *(n = 151)*	67.3 (30.2) *(n = 161)*	6.9 (20.3) *(n = 97)*	10.4 (26.0) *(n = 106)*	0.430
Quality of interaction	80.2 (15.9) (n = 164)	80.7 (13.6) *(n = 172)*	2.2 (14.1) *(n = 112)*	-0.2 (12.4) *(n = 117)*	0.157
Work performance	72.9 (24.9) *(n = 23)*	67.8 (25.8) *(n = 19)*	0.0 (18.2) *(n = 12)*	15.3 (24.3) *(n = 12)*	0.116
Social role functioning	77.3 (15.9) *(n = 128)*	76.7 (14.6) *(n = 140)*	3.1 (11.7) *(n = 79)*	1.9 (11.2) *(n = 90)*	0.522
Frequency of interaction	63.1 (26.9) *(n = 161)*	65.8 (26.0) *(n = 169)*	0.0 (29.6) *(n = 107)*	-0.7(28.4) *(n = 115)*	0.814
Sexual relationships	47.8 (31.4) *(n = 68)*	52.7 (30.2) *(n = 83)*	-2.0 (24.6) *(n = 37)*	-1.4 (22.5) *(n = 54)*	0.883
Days in bed	91.9 (18.4) *(n = 161)*	89.1 (20.4) *(n = 173)*	-0.7 (20.5) *(n = 109)*	3.9 (16.8) *(n = 118)*	0.018
Days with restricted activities	70.9 (35.2) *(n = 158)*	67.5 (38.5) *(n = 167)*	8.8 (40.2) *(n = 106)*	13.6 (36.9) *(n = 113)*	0.438
General health status	42.7 (26.3) *(n = 161)*	42.4 (26.2) *(n = 172)*	15.9 (27.0) *(n = 110)*	16.0 (29.7) *(n = 120)*	0.935

BADL = Basic activities of daily living (see text). IADL = Intermediate activities of daily living (see text)

Table 4A Internal reliability of the Functional Status Questionnaire.

Dimensions and sub-dimensions	***N*=**	**Cronbach α**
Basic activities of daily living	*337*	0.776
Intermediate activities of daily living	*335*	0.793
Physical functioning	*334*	0.861
Mental health	*337*	0.779
Social activity	*312*	0.806
Social interaction	*336*	0.656
Work performance	*42*	0.799
Social role function (active)	*40*	0.783
Social role function (non active)	*268*	0.709

Table 4B Internal reliability of the Minnesota Living with Heart Failure Questionnaire

Dimensions and sub-dimensions	***N*=**	**Cronbach α**
Physical Dimension	*314*	0.898
Emotional Dimension	*333*	0.825
Total Score	*296*	0.892

Table 5 Pearson's correlations matrix at baseline for Functional Status Questionnaire (FSQ).

Scales	Basic activities	Intermed. activities	Physical function.	Mental Health	Social activity	Social interact.	Work perform.	Social/role function
Basic activities	1.00 *(n = 337)*							
Intermed. Activities	0.68 *(n = 334)*	1.00 *(n = 335)*						
Physical function.	0.87 *(n = 334)*	0.95 *(n = 334)*	1.00 *(n = 334)*					
Mental Health	0.19 *(n = 334)*	0.21 *(n = 332)*	0.22 *(n = 331)*	1.00 *(n =337)*				
Social activity	0.59 *(n = 312)*	0.76 *(n = 309)*	0.75 *(n = 309)*	0.29 *(n = 309)*	1.00 *(n = 312)*			
Quality of interaction	0.20 *(n = 333)*	0.23 *(n = 331)*	0.23 *(n = 330)*	0.54 *(n = 336)*	0.25 *(n = 308)*	1.00 *(n = 336)*		
Work perform.	0.13 *(n = 42)*	0.19 *(n = 42)*	0.19 *(n = 42)*	0.08 *(n = 42)*	0.09 *(n = 40)*	0.40 *(n = 42)*	1.00 *(n = 42)*	
Social/role function	0.45 *(n = 308)*	0.55 *(n = 305)*	0.56 *(n = 305)*	0.54 *(n = 308)*	0.68 *(n = 308)*	0.85 *(n = 308)*	0.85 *(n = 40)*	1.00 *(n = 308)*

Table 6 Pearson's correlations matrix at baseline for Functional Status Questionnaire (FSQ) and Minnesota Living With Heart Failure (MLWHF) questionnaire.

	MLWHF	
FSQ	**Physical dimension**	**Emotional dimension**
BADL	-0.58 *(n =334)*	-0.36 *(n = 335)*
IADL	-0.66 *(n =332)*	-0.38 *(n = 333)*
Physical functioning	-0.68 *(n = 331)*	-0.41 *(n = 332)*
Mental Health	-0.28 *(n = 334)*	-0.61 *(n = 335)*
Social Activity	-0.58 *(n = 311)*	-0.41 *(n = 311)*
Quality of interaction	-0.24 *(n = 333)*	-0.47 *(n = 334)*
Work performance	-0.27 *(n = 41)*	-0.33 *(n = 42)*
Social role function	-0.48 *(n = 307)*	-0.57 *(n = 307)*

BADL = Basic activities of daily living (see text). IADL = Intermediate activities of daily living (see text)

Table 7A Minnesota Living With Heart Failure (MLwHF) questionnaire scores by New York Heart Association (NYHA) functional classification at baseline.

	NYHA III	NYHA IV	p value
Physical dimension of MLwHF	20.1 (10.3) *(n = 310)*	29.6 (10.1) *(n = 28)*	< 0.0001
Emotional dimension of MLwHF	8.0 (6.1) *(n = 311)*	11.1 (7.7) *(n = 28)*	0.0473
Total score of MLwHF	39.6 (19.6) *(n = 311)*	54.6 (19.2) *(n = 28)*	0.0004

Table 7B Functional Status Questionnaire (FSQ) scores by New York Heart Association (NYHA) functional classification at baseline.

	NYHA III	NYHA IV	p value
BADL	82.5 (16.5) *(n = 309)*	63.8 (24.7) *(n = 28)*	0.0004
IADL	59.4 (22.4) *(n = 307)*	38.6 (22.7) *(n = 28)*	0.0001
Physical functioning	69.7 (18.1) *(n = 306)*	49.8 (21.7) *(n = 28)*	0.0001
Mental health	68.7 (18.6) *(n = 310)*	57.0 (23.1) *(n = 27)*	0.0159
Social activity	71.3 (28.8) *(n = 284)*	48.4 (30.1) *(n = 28)*	0.0005
Quality of interaction	80.7 (15.0) *(n = 309)*	77.3 (11.9) *(n = 27)*	0.1711
Work performance	69.5 (25.3) *(n = 40)*	91.7 (3.9) *(n = 2)*	N/A
Social role functioning	77.9 (15.1) *(n = 243)*	68.9 (14.1) *(n = 25)*	0.0051
Frequency of interaction	65.5 (25.8) *(n = 303)*	53.3 (30.9) *(n = 27)*	0.0531
Sexual relationships	50.7 (30.8) *(n = 143)*	46.9 (31.2) *(n = 8)*	0.7425
Days in bed	91.9 (17.3) *(n = 307)*	74.1 (32.3) *(n = 27)*	0.0079
Days with restricted activities	71.2 (36.1) *(n = 300)*	44.0 (38.2) *(n = 25)*	0.0007
General health status	44.1 (26.0) *(n = 307)*	25.0 (22.4) *(n = 26)*	0.0003

BADL = Basic activities of daily living (see text). IADL = Intermediate activities of daily living (see text)
N/A = statistical comparison not appropriate

Figure 1: Histogram showing baseline Functional Status Questionnaire (FSQ) scores and "warning zones" – the score below which there is a clinically important reduction in quality of life for that domain.