The HeartQoL: Part II. Validation of a new core health-related quality of life questionnaire for patients with ischemic heart disease.

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ABSTRACT

Background

Evaluation of health-related quality of life is (HRQL) important in improving the quality of patient care. The aim of this study was to determine the psychometric properties of the HeartQoL in patients with ischemic heart disease (IHD), specifically angina, myocardial infarction (MI), or ischemic heart failure.

Methods

Data for the validation of the HeartQoL questionnaire were collected in 1) a cross-sectional survey and 2) a prospective substudy of patients undergoing either a percutaneous coronary intervention (PCI) or referred to cardiac rehabilitation (CR) were analyzed to determine the reliability, validity, and responsiveness of the HeartQoL questionnaire.

Results

We enrolled 6,380 patients (angina, n=2,110, 33.1%; MI, n=2,350, 36.8%; HF, n=1,920, 30.1%) across 22 countries speaking 15 languages. The HeartQoL questionnaire comprises 14-items with physical and emotional subscales and a global score (range 0 to 3 (poor to better HRQL). Cronbach's alpha consistently was ≥0.80; convergent validity correlations between similar HeartQoL and SF-36 subscales were significant ($r \geq 0.60$, $p<0.001$); discriminative validity was confirmed with predictor variables - health transition, anxiety, depression, and functional status. HeartQoL score changes following either PCI or CR were significant ($p<0.001$) with effect sizes from 0.37 to 0.64.

Conclusion

The HeartQoL questionnaire is reliable, valid, and responsive to change allowing clinicians and researchers to a) assess baseline HRQL, b) make between-diagnosis comparisons of HRQL, and c) evaluate change in HRQL in patients with angina, myocardial infarction, or heart failure with a single IHD-specific HRQL instrument.

Keywords: Ischemic heart disease; angina; myocardial infarction; heart failure; health-related quality of life; reliability; validity; responsiveness

INTRODUCTION

Ischaemic heart disease (IHD) accounts for approximately 15% of all deaths in Europe [1] and 16% in the USA [2]. With a wide range of health status deficits, treatment and therapeutic goals for patients with IHD include reduced mortality and an enhanced quality of the longer life. The Institute of Medicine has emphasized patient-centered care as one means to improve the quality of health care for patients [3]. Both the US Food and Drug Administration [4] and the European Medicines Agency [5] have provided guidance for selecting and using patient-reported outcome instruments. Further, the National Heart, Lung and Blood Institute has stressed the importance of patient-reported health status measures such as health-related quality of life (HRQL) in clinical care and relevant clinical trials for patients with IHD [6].

Patients with IHD present on a continuum of disease with angina, myocardial infarction (MI), and ischemic heart failure, the three most commonly reported IHD diagnoses. Between-diagnosis HRQL comparisons require the use of either generic HRQL questionnaires or disease-specific questionnaires which need validation in each of the diagnoses within a specific disease. Validated core disease-specific HRQL questionnaires have been available for about 20 years [7, 8] in oncology but not in cardiology. When the HeartQoL Project was initiated [9]; generic, rather than specific, HRQL tools were used [10], and continue to be used [11], for making between-diagnosis HRQL comparisons in patients with IHD. The HeartQoL Project was designed to develop a single reliable and valid core IHD-specific, HRQL questionnaire, to be called the HeartQoL, for comparing HRQL outcomes in patients with angina pectoris, MI, or ischemic heart failure with left ventricular systolic dysfunction [9].

With the trend toward globalization in health care, HRQL instruments need to be shown to be reliable and valid in an international setting. The development of the HeartQoL, which consists of 14-items with a 10-item physical and a 4-item emotional subscale scored from 0 (poor HRQL) to 3 (better HRQL) with a global score if needed, was based on data provided by an international cohort of 6,384 patients with angina, MI, or heart failure and is described elsewhere [12]. The purpose of this report is to

report on the psychometric properties of the HeartQoL.

METHODS

Per design, the international HeartQoL Project was conducted between 2002 and 2011 in 22 countries and 15 languages in two phases [9]: 1) a cross-sectional survey phase to develop the HeartQoL questionnaire [12] and determine it's reliability and validity; and 2) a prospective responsiveness phase with two study arms, percutaneous coronary intervention (PCI) and cardiac rehabilitation (CR), to determine it's responsiveness.

Patients

The HeartQoL Project target was to enroll at least 1) 315 patients (105 with angina, 105 with MI and 105 with heart failure) in an international cross-sectional study and 2) 150 patients with IHD in each of the two arms in the prospective study [9]. The eligibility criteria are detailed elsewhere [12] and include patients with documented angina (Canadian Cardiovascular Society (CCS) functional status classification Class II, II, or IV) [13], MI, or ischemic heart failure (New York Heart Association (NYHA) functional status classification Class II, III, and IV) [14], ≥18 years old, and considered by the referring physician 1) to be able to complete the self-administered battery of HRQL instruments, 2) not have serious psychiatric disorder, and 3) not be a current substance abuser.

Questionnaires

All patients in the cross-sectional survey completed a sociodemographic questionnaire, the Short-Form 36 (SF-36) [15], the Hospital Anxiety and Depression Scale (HADS) [16], and three IHD-specific questionnaires, the Seattle Angina Questionnaire (SAQ) [17], the MacNew Heart Disease Health-related Quality of Life Questionnaire (MacNew) [18], and the Minnesota Living With Heart Failure (MLHF) Questionnaire [19]. Face and content validity of the HeartQoL items are assumed as the psychometric properties of the three specific IHD questionnaires have been demonstrated. All patients undergoing PCI or referred to CR completed the HeartQoL, a sociodemographic questionnaire, the SF-

36, and the HADS at baseline and the HeartQoL, the SF-36, and the HADS 10-12 weeks after PCI and at the end of CR.

Psychometric properties

The following psychometric properties of the HeartQoL were assessed using recommended criteria [20].

Reliability

Internal consistency reliability (Cronbach's a) was assessed (r≥0.70 considered acceptable for group and ≥0.90 for individual comparisons) [21].

Validity

a. *Convergent validity*

Hypothesizing, *a priori*, strong correlations between similar SF-36 and HeartQoL constructs (r≥0.50 [21]) and lower correlations between dissimilar constructs, convergent validity of the HeartQoL was tested. The correlation coefficients between similar and dissimilar scales were tested for significant differences [22].

b. Discriminative validity

The "known-groups" test for expected relationships [23] was used to determine discriminative validity. Groups were defined as follows: HADS scores for anxiety and depressive symptoms (score ≤7= absent, >7= present); SF-36 health transition (deteriorated, no change, improved health); CCS and NYHA functional class (II, III/IV).

c. Evaluative validity

Paired t-tests were used to test for HeartQoL score changes. Responsiveness was reported as effect size (ES; small: ≥0.20, <0.50; moderate: 0.50, <0.80; and large: ≥0.80) using the standardized response mean [SRM] methodology (ES = A – B) / D) where A= time 2 mean, B= time 1 mean, and D= score change standard deviation [24].

RESULTS

Patients (Table 1)

A cohort of 6,384 patients, living in 5 different geographical regions with 54 sites in 22 countries (15 languages), was enrolled in the HeartQoL Project [12]. Patients with angina (n=2,110; 33.1%), MI (n=2,350; 36.8%), or heart failure (n=1,920; 30.1%) were referred. Women made up 25% (n=1,694) of the cohort whose mean age was 62.5 years (SD= 11.3). Specific clinical and sociodemographic details are provided elsewhere [12].

In the responsiveness substudy, 398 patients undergoing PCI in 10 countries speaking (eight languages) were enrolled (Danish, English [Ireland, USA], Flemish, French, German [Austria, Switzerland], Norwegian, Portuguese, and Spanish). In the CR arm, 383 patients from eight countries (six languages) were enrolled (Danish, English [Ireland, USA], Flemish, French, German [Austria, Switzerland], and Spanish).

HeartQoL scores (Table 1)

The mean baseline HeartQoL global score in the group as a whole was 2.2±0.5. Global and physical subscale scores (better HRQL) were highest in patients with MI, intermediate with angina, and lowest with heart failure ($p<0.001$). Emotional subscale scores were highest in patients with MI and lower, but similar, in patients with angina and heart failure. Individual patient HeartQoL scores ranged from 0.0 to 3.0. Less than 1.0 % of the patients scored at the floor on any of the HeartQoL scales. Fewer than 9% of the patients scored at the ceiling on the HeartQoL global score, ≤14 % on the physical subscale, and ≤27 % on the emotional subscale.

Internal consistency reliability (Table 1)

Cronbach's α for the global score and each subscale was always between 0.80 and 0.91.

Convergent validity (Table2)

The correlations between similar HeartQoL and SF-36 subscales were ≥0.60 and always significant. As hypothesized, all correlations between dissimilar HeartQoL and SF-36 scales were lower (all r≤0.38, p<0.001).

Discriminative validity (Table 3)

Discriminative validity of the HeartQoL was confirmed in the group as a whole and each diagnosis. HeartQoL scores were always higher [better HRQL] in patients with 1) 'no change' or 'improved' vs. 'deteriorated' health status 2) 'without' vs. 'with' anxiety or depression, and 3) functional class 'II' vs. 'III/IV' in patients with angina or heart failure (p<0.001).

Responsiveness (Table 4)

The HeartQoL global, physical, and emotional subscale score changes improved with both interventions (p<0.001). The ES was 0.51 for the global, 0.49 for the physical, and 0.37 for the emotional subscale scores with PCI and 0.64, 0.59, and 0.47, respectively, with CR. The ES for the HeartQoL and SF-36 physical and emotional subscales were similar.

DISCUSSION

The HeartQoL questionnaire is a reliable and valid 14-item IHD-specific core HRQL questionnaire for patients with angina, MI, or ischemic heart failure. The HeartQoL questionnaire was developed and validated in a cohort of 6,384 patients with IHD who live in 22 countries and speak one of 15 languages; an independent cohort of 781 patients either undergoing PCI (n= 398) or referred to CR (n=383) from 10 countries speaking one of eight languages provided responsiveness data. Performing well on key psychometric attributes for HRQL instruments [20], the HeartQoL has potential as a core IHD-specific HRQL questionnaire and demonstrated that patients with MI have better HRQL than patients with angina who in turn have better HRQL than patients with heart failure.

The 14-items in the HeartQoL scale cluster as a 10-item physical and a 4-item emotional subscale providing both assessment and evaluation of how a patient with angina, MI, or heart failure perceives that he/she is bothered by their heart disease. Guidelines for key attributes of HRQL instruments include the conceptual and measurement model, reliability, validity, responsiveness, and respondent and administrative burden [20]. We assumed, a priori, face and content validity of the candidate item pool for the HeartQoL as the original three HRQL questionnaires had previously been validated in patients with angina (SAQ), MI (MacNew), or heart failure (MLHF).

Internal consistency reliability, i.e., freedom from random error, exceeded the recommended criterion for group HRQL comparisons with Cronbach's $\alpha > 0.70$ [20] on each HeartQoL scale in the total group and each diagnostic group. Examination of test-retest reproducibility was not possible as the HeartQoL questionnaire was developed in a cross-sectional survey study.

Using the "known groups" approach [23], discriminative validity of the HeartQoL was confirmed with a) SF-36 health transition, b) HADS anxiety and depression, and c) CCS and NYHA

functional status. Patients reporting their health as either “improved” or “no change” had significantly higher or better HRQL when compared to patients who reported “deteriorated” health. Patients without anxiety or depression had significantly higher HeartQoL scores than patients who were anxious or depressed. The same pattern applied to functional class with higher HRQL scores in patients with angina CCS or heart failure NYHA class II compared to class III/IV. The overall pattern with the HeartQoL is that patients with MI have a better HRQL than patients with angina who, in turn, have a better HRQL than patients with heart failure. This HRQL pattern is consistent with observations using generic HRQL instruments, specifically the SF-36 [15] and the EuroQoL EQ-5D [25], and with the MacNew, a core IHD-specific HRQL instrument which has been validated in patients with angina, MI, and heart failure since initiation of the HeartQoL Project [26-28].

Pre-post PCI and CR HeartQoL score changes were significant ($p < 0.001$). While the t-test estimates the significance of observed pre-post-intervention changes, the effect size additionally provides a standardized measure of the magnitude of an effect to identify whether the observed differences matter, something that is important to clinicians. With PCI, the ES for the HeartQoL global score and each subscale ES was ‘weak’. On the other hand, the ES for the global score and physical subscale was ‘moderate’ with CR. The standard deviations in the physical and emotional subscale HeartQoL scores after PCI (0.8 to 0.9) suggest that a considerable number of patients in this study were still symptomatic 12 weeks after PCI. Patients undergoing PCI in our substudy were similar to the relatively low-risk patients in the COURAGE trial HRQL substudy where 47% of the patients were not angina-free three months after PCI [29]. This may, at least partially, be responsible for the smaller HeartQoL ES observed with PCI than CR in this study. While PCI is a procedure aimed at the alleviation of a single symptom, CR, on the other hand, entails "coordinated, multifaceted interventions designed to optimize a cardiac patient’s physical, psychological, and social functioning, in addition to stabilizing, slowing, or even reversing the progression of the underlying atherosclerotic processes, thereby reducing morbidity and mortality”

[30]. For these reasons, it should not be too surprising that the short-term impact of CR on HRQL is proportionately greater than with PCI which is consistent with the larger ES seen with CR in this study.

A "floor effect" occurs at the lowest possible score on an instrument indicating patients already have the lowest HRQL measurable and, conversely, a "ceiling effect" is the best HRQL measurable. With <1% of the patients at the floor in the HeartQoL and with <14% and <9% on the physical subscale and global scores at the ceiling, the questionnaire appears to be sensitive to positive and negative changes in HRQL. On the other hand, as 25% of the patients reported emotional subscale scores at the ceiling, assessing improvement in emotional HRQL may be somewhat more problematic. This potentially would be of concern in a trial where the instrument was being used to assess change, as no further increase in HRQL would be possible for 25% of the patients. However, the numbers of participants demonstrating "ceiling" effects in the present study is of less concern than might appear at first sight. All HRQL instruments applied to "routine care" patients are likely to have significant proportions scoring at or near the score indicating high HRQL. However, in any intervention trial in which HRQL is an endpoint, it is unlikely that the inclusion criteria will result in the inclusion of a substantial group where HRQL is already optimal, i.e., mean HeartQoL scores will be relatively low.

While respondent and administrative burden of the 14-item HeartQoL are low, the HeartQoL, as with any new HRQL instrument, will need continued extensive and rigorous examination of its psychometric properties before it can be considered as a standard for assessing and evaluating HRQL in patients with angina, MI, or heart failure. The HeartQoL will need to be validated other languages and will need head-to-head comparisons with the other available core IHD-specific HRQL instrument, the MacNew [26-28]. Further HeartQoL research needs include the establishment of test-retest reliability; further examination of floor and ceiling effects and establishment of responsiveness in patients who speak other languages; interpretability including

identification of the minimal clinical improvement of the instrument; and examination of the effect of low literacy, common among patients [31] but not frequently assessed with IHD-specific HRQL instruments [32].

CONCLUSIONS

The HeartQoL questionnaire, a new 14-item international core IHD-specific assessment and evaluation system on patient-reported HRQL is reliable, valid, and responsive in patients with a wide spectrum of IHD diagnoses, specifically angina, MI, and ischemic heart failure with the potential to have an impact on the quality of patient care. The HeartQoL questionnaire with two subscales and a global score will allow clinicians and researchers to a) assess baseline HRQL, b) make between-diagnosis comparisons of HRQL, and c) evaluate change in HRQL in patients with angina, MI, and heart failure undergoing interventions designed to improve patient HRQL and reduce the cardiovascular burden on patients and their families who live with heart disease.

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The Author(s) declare(s) that there is no conflict of interest

REFERENCES

1. Allender S, Scarborough P, Peto V and Rayner M. European Cardiovascular Disease Statistics 2008. Brussels: European Heart Network, 2008.

2. Kochanek K, Xu J, Murphy S, Minino A and Kung H. Deaths: preliminiary data for 2009. *Natl Vital Stat Rep*. 2011; 59: 1-51.

3. Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the Twenty-First Century*. Washington, DC: National Academy Press, 2001.

4. U.S. Department of Health and Human Services and Food and Drug Administration. Guidance for industry. Patient-reported outcome measures: Use in medical product development to support labeling claims. Washington, DC. 2009, p. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282.pdf.

5. Committee for Medicinal Products for Human Use. Reflection paper on the regulatory guidance for the use of health-related quality of life (HRQL) measures in the evaluation of medicinal products. European Medicines Agency, 2005, p. http://www.emea.europa.eu/pdfs/human/ewp/13939104en.pdf.

6. Krumholz HM, Peterson ED, Ayanian JZ, et al. Report of the National Heart, Lung, and Blood Institute working group on outcomes research in cardiovascular disease. *Circulation*. 2005; 111: 3158-66.

7. Aaronson NK, Ahmedzai S, Bergman B, et al. The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. *J Natl Cancer Inst*. 1993; 85: 365-76.

8. Cella DF, Tulsky DS, Gray G, et al. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. *J Clin Oncol*. 1993; 11: 570-9.

9. Oldridge N, Saner H and McGee HM. The Euro Cardio-QoL Project. An international study to develop a core heart disease health-related quality of life questionnaire, the HeartQoL. *Eur J Cardiovasc Prev Rehabil*. 2005; 12: 87-94.

10. Failde I and Ramos I. Validity and reliability of the SF-36 Health Survey Questionnaire in patients with coronary artery disease. *J Clin Epidemiol*. 2000; 53: 359-65.

11. Failde I, Medina P, Ramirez C and Arana R. Assessing health-related quality of life among coronary patients: SF-36 vs SF-12. *Public Health*. 2009; 123: 615-7.

12. Oldridge N, Höfer S, McGee H, et al. The HeartQoL: I. Development of a new core health-related quality of life questionnaire for patients with ischemic heart disease. *European Journal of Preventive Cardiology*. Submitted.

13. Campeau L. Grading of angina pectoris. *Circulation*. 1976; 54: 522-3.

14. Criteria Committee of the New York Heart Association. *Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels*. 9th ed. Boston: Little, Brown and Company, 1994: 253-256.

15. Ware J and Kosinski M. *The SF-36 Physical and Mental Health Summary Scales: A Manual for Users of Version 1, Second Edition.* Lincoln, Rhode Island: QualityMetric Incorporated, 2005.

16. Snaith RP. The Hospital Anxiety And Depression Scale. *Health Qual Life Outcomes*. 2003; 1: 29-32.

17. Spertus JA, Winder JA, Dewhurst TA, et al. Development and evaluation of the Seattle Angina Questionnaire: A new functional status measure for coronary artery disease. *J Am Coll Cardiol*. 1995; 25: 333-41.

18. Valenti L, Lim L, Heller RF and Knapp J. An improved questionnaire for assessing quality of life after myocardial infarction. *Qual Life Res*. 1996; 5: 151-61.

19. Rector TS, Kubo SH and Cohn JN. Patients' 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*. 1987; 3: 198-209.

20. Scientific Advisory Committee of Medical Outcomes Trust. Assessing health status and quality-of-life instruments: attributes and review criteria. *Qual Life Res*. 2002; 11: 193-205.

21. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. Hillsdale, NJ: Lawrence Erlbaum Assoc., 1988.

22. Steiger JH. Tests for comparing elements of a correlation matrix. *Psychol Bull*. 1980; 87: 245-51.

23. Hays RD, Anderson RT and Revicki D. Assessing reliability and validity of measurement in clinical trials. In: Staquet MJ, Hays RD and Fayers P, (eds.). *Quality of Life Assessment in Clinical Trials: Methods and Practice*. New York: Oxford University Press, 1998, p. 169-82.

24. Liang MH, Fossel AH and Larson MG. Comparisons of five health status instruments for orthopedic evaluation. *Med Care*. 1990; 28: 632-42.

25. Dyer MT, Goldsmith KA, Sharples LS and Buxton MJ. A review of health utilities using the EQ-5D in studies of cardiovascular disease. *Health Qual Life Outcomes*. 2010; 8: 13.

26. Yu DS, Thompson DR, Yu CM and Oldridge NB. Validation of the Chinese version of the MacNew heart disease health-related quality of life questionnaire. *J Eval Clin Pract*. 2008; 14: 326-35.

27. Höfer S, Saleem A, Stone J, Thomas RJ, Tulloch H and Oldridge N. The MacNew Heart Disease Health-related Quality of Life questionnaire in patients with angina amd patients with ischemic heart failure. *Value in Health*. In press; doi:10.1016/j.jval.2011.07.003.

28. Vandereyt F, Dendale P, Vanhees L, Roosen J, Höfer S and Oldridge N. Psychometric properties of the Flemish version of the MacNew Heart Disease Health-related Quality of Life questionnaire. *Acta Cardiol*. In press.

29. Weintraub WS, Spertus JA, Kolm P, et al. Effect of PCI on quality of life in patients with stable coronary disease. *N Engl J Med*. 2008; 359: 677-87.

30. Taylor RS, Brown A, Ebrahim S, et al. Exercise-based rehabilitation for patients with coronary heart disease: systematic review and meta-analysis of randomized controlled trials. *Am J Med*. 2004; 116: 682-92.

31. Kutner M, Greenberg E, Jin Y and Paulsen C. *The Health Literacy of America's Adults: Results From the 2003 National Assessment of Adult Literacy [NCES 2006–483]*. Washington, DC: National Center for Education Statistics, 2006.

32. Gromoske A, Oldridge N and Brondino MJ. Readability of three heart disease health-related quality of life questionnaires. *J Cardiopulm Rehabil Prevent*. 2011; 31: 245-8.

Table 1. Patient characteristics and HeartQoL questionnaire mean (± standard deviation) scores; ceiling (high HRQL) and floor (poor HRQL) effects; and internal consistency with Cronbach's a in the total group and in patients with angina, myocardial infarction (MI), or heart failure

	Total Group (n=6,384)	**Angina** (n=2,111)	**MI** (n=2,351)	**Heart failure** (n=1,922)	**p-value ***
Patient characteristics					
Age (years	62.5 (11.3)	63.1 (10.2)	59.7 (11.4)	65.1 (11.5)	<0.001[a,b,c]
Gender (male)	75.2%	72.4%	75.9%	77.2%	<0.001[a,c]
HeartQoL:					
Physical score	2.2 (0.7)	2.2 (0.6)	2.4 (0.6)	2.0 (0.7)	<0.001 [a,b,c]
Ceiling effect	8.1%	6.2%	13.4%	3.8%	
Floor effect	0.2%	0.1%	0.1%	0.4%	
Cronbach's a	0.90	0.89	0.90	0.90	
Emotional score	2.4 (0.6)	2.3 (0.6)	2.4 (0.6)	2.3 (0.7)	=0.003 [a,b]
Ceiling effect	25.2%	23.9%	26.3	25.4 %	
Floor effect	0.6%	0.6%	0.4%	0.9%	
Cronbach's a	0.81	0.80	0.81	0.82	
Global score	2.2 (0.5)	2.2 (0.6)	2.4 (0.5)	2.1 (0.6)	<0.001 [a,b,c]
Ceiling effect	5.2%	4.0%	8.3%	2.8%	
Floor effect	0.1%	0.1%	0.0%	0.1%	
Cronbach's a	0.91	0.90	0.90	0.91	

p-value between diagnosis with ANOVA (post-hoc Bonferroni correction; in case of inhomogeneous variances, Welch's F-statistic and post-hoc Games Howell correction) and with Chi-square for proportions

a, AP vs. MI; b, MI vs. HF; c, AP vs. HF

Table 2. Convergent validity of the HeartQoL physical and emotional subscales with the Short Form-36 physical (SF-36 PCS} and the Short Form-36 mental component scale (SF-36 MCS) in the total group of patients with IHD and in patients with angina, myocardial infarction (MI), or heart failure

IHD	**SF-36 PCS (r)**	**SF-36 MCS (r)**	**p-value***
HeartQoL Physical	0.68**	0.36**	<0.001
HeartQoL Emotional	0.28**	0.60**	<0.001
p-value#	<0.001	<0.001	
ANGINA			
HeartQoL Physical	0.64**	0.38**	<0.001
HeartQoL Emotional	0.28**	0.65**	<0.001
p-value#	<0.001	<0.001	
MI			
HeartQoL Physical	0.64**	0.37**	<0.001
HeartQoL Emotional	0.25**	0.62**	<0.001
p-value#	<0.001	<0.001	
HEART FAILURE			
HeartQoL Physical	0.67**	0.34**	<0.001
HeartQoL Emotional	0.31**	0.60**	<0.001
p-value#	<0.001	<0.001	

\# Steiger's test for comparing Pearson correlation coefficients

** *p*-value for correlation coefficients always < 0.001

Table 3. Discriminative validity of the HeartQoL global scale and physical and emotional subscales using 1) SF-36 health transition, anxiety and depression (Hospital Anxiety and Depression Scale) in the total group and in patients with angina, myocardial infarction, or heart failure, 2) functional status with Canadian Cardiovascular Society (CCS) in patients with angina, and 3) New York Heart Association classification (NYHA) in patients with heart failure

Total group		**HeartQoL Global**	**HeartQoL Physical**	**HeartQoL Emotional**
SF-36 health transition				
Improve (n= 1572)		2.4 (0.5)	2.4 (0.6)	2.5 (0.6)
No change (n=1821)		2.4 (0.5)	2.3 (0.6)	2.5 (0.6)
Deteriorate (n= 2653)		2.0 (0.6)	2.0 (0.7)	2.2 (0.7)
	p-value [#]	<0.001 [a,b]	<0.001 [a,b]	<0.001 [a,b]
Anxiety (HADS)				
No (n=3973)		2.4 (0.5)	2.3 (0.6)	2.6 (0.5)
Yes (n=2042)		1.9 (0.6) *	2.0 (0.7) *	1.9 (0.7) *
Depression (HADS)				
No (n=4500)		2.4 (0.5)	2.3 (0.6)	2.5 (0.5)
Yes (n=1510)		1.8 (0.6) *	1.8 (0.7) *	1.9 (0.7) *
Angina				
SF-36 health transition				
Improve (n= 513)		2.4 (0.5)	2.3 (0.6)	2.5 (0.6)
No change (n=635)		2.3 (0.5)	2.3 (0.6)	2.4 (0.6)
Deteriorate (n= 835)		2.0 (0.6)	1.9 (0.6)	2.2 (0.7)
	p-value [#]	<.001 [a,b]	<.001 [a,b]	<.001 [a,b]
Anxiety (HADS)				
No (n=1225)		2.4 (0.5)	2.3 (0.5)	2.6 (0.5)
Yes (n=747)		1.9 (0.6) *	1.9 (0.7) *	2.0 (0.6) *
Depression (HADS)				
No (n=1,462)		2.3 (0.5)	2.3 (0.6)	2.5 (0.5)
Yes (n=508)		1.9 (0.6) *	1.8 (0.7) *	1.9 (0.7) *
CCS functional status				
II (n=1,299)		2.3 (0.5)	2.2 (0.6)	2.4 (0.6)
III/IV (n=584)		2.1 (0.6) *	2.0 (0.7) *	2.3 (0.6) *
Myocardial infarction				
SF-36 health transition				
Improve (n= 551)		2.5 (0.5)	2.6 (0.5)	2.5 (0.6)
No change (n=590)		2.6 (0.4)	2.6 (0.5)	2.5 (0.5)

Deteriorate (n= 1072)		2.2 (0.6)	2.2 (0.6)	2.3 (0.5)
	p-value #	<.001 a,b	<.001 a,b	<.001 a,b
Anxiety (HADS)				
No (n=1546)		2.5 (0.4)	2.5 (0.5)	2.6 (0.5)
Yes (n=65)		2.1 (0.6) *	2.1 (0.7) *	1.9 (0.7)
Depression (HADS)				
No (n=1783)		2.5 (0.4)	2.5 (0.5)	2.5 (0.5)
Yes (n=415)		1.9 (0.6) *	2.0 (0.7) *	1.9 (0.7) *
Heart failure				
SF-36 health transition				
Improve (n= 508)		2.3 (0.6)	2.2 (0.7)	2.5 (0.6)
No change (n=596)		2.2 (0.6)	2.1 (0.7)	2.4 (0.6)
Deteriorate (n= 746)		1.8 (0.6)	1.7 (0.7)	2.2 (0.7)
	p-value #	<.001 a,b	<.001 a,b	<.001 a,b
Anxiety (HADS)				
No (n=1202)		2.2 (0.6)	2.1 (0.7)	2.6 (0.5)
Yes (n=641)		1.8 (0.7) *	1.7 (0.7) *	1.9 (0.7) *
Depression (HADS)				
No (n=1255)		2.3 (0.5)	2.1 (0.6)	2.5 (0.5)
Yes (n=587)		1.7 (0.6) *	1.6 (0.7) *	1.9 (0.7) *
NYHA functional status				
II (n= 1,024)		2.2 (0.6)	2.1 (0.6)	2.4 (0.6)
III & IV (n=744)		1.9 (0.7) *	1.7 (0.7) *	2.2 (0.7) *

p-value between-diagnosis with ANOVA (post-hoc Bonferroni correction; with non-homogeneous variances, Welch's F-statistic and post-hoc Games Howell correction)

a: improve vs. deteriorate. b: no change vs. deteriorate

* p-value <0.001

Table 4 HeartQoL global and subscale p-values and effect sizes using the standardized response mean (SRM) for percutaneous coronary intervention [PCI] and cardiac rehabilitation [CR] in patients with ischemic heart disease

	PCI [n=398]	CR [n= 383]
HeartQoL		
Physical subscale		
Baseline	1.6 [0.8]	2.0 [0.7]
Follow- up	2.0 [0.8]	2.3 [0.6]
p-value for change	<0.001	<0.001
effect size (SRM)	0.49	0.59
Emotional subscale		
Baseline	1.9 [0.9]	2.2 [0.7]
Follow- up	2.2 [0.8]	2.5[0.6]
p-value for change	<0.001	<0.001
effect size (SRM)	0.37	0.47
Global scale		
Baseline	1.7 [0.8]	2.0 [0.6]
Follow- up	2.0 [0.7]	2.4 [0.5]
p-value	<0.001	<0.001
effect size (SRM)	0.51	0.64
	PCI [n=339]	**CR [n= 345]**
SF-36		
PCS		
Baseline	38.8 [9.9]	42.4 [9.3]
Follow- up	43.0 [10.3]	46.5 [9.3]
p-value for change	<0.001	<0.001
effect size (SRM)	0.46	0.54
MCS		
Baseline	46.5 [11.6]	48.1 [11.1]
Follow- up	49.6 [10.6]	51.8 [9.4]
p-value for change	<0.001	<0.001
effect size (SRM)	0.30	0.45