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

Results: We enrolled 6384 patients (angina, $n = 2111$, 33.1%; MI, $n = 2351$, 36.8%; heart failure, $n = 1922$, 30.1%) across 22 countries speaking 15 languages in the cross-sectional study and 730 patients with IHD in the prospective substudy. The HeartQoL questionnaire comprises 14-items with physical and emotional subscales and a global score (range 0–3 (poor to better HRQL). Cronbach's α was consistently ≥ 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 ranging from 0.37–0.64.

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, MI, 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

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Introduction

Ischemic 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 a means to improve the quality of health care for patients.[3] Both the US Food and Drug Administration[4] and the European

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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 (Table 1), was based on data provided by an international cohort of 6384 patients with angina, MI, or heart failure and is described elsewhere.[12] The purpose of this report is to report on the interim psychometric properties of the HeartQoL.

Methods

As intended, the international HeartQoL Project was conducted in two phrases[9] between 2002 and 2011 in 22 countries and 15 languages: (a) a cross-sectional survey phase to develop the HeartQoL questionnaire[12] and determine its reliability and validity using self-reported responses to the question of how much each patient was bothered by each of the 14 items identified in the

Table 1. The HeartQoL questionnaire (Physical subscale items, #1–8, 13, 14: Emotional subscale items, #9–12)

HeartQoL

Thank you for addressing these questions that will give us an understanding of how your heart problem has affected you.

We would like to know how your heart problem has bothered you and how you have been feeling **DURING THE LAST 4 WEEKS**.

Please circle one number

First, in the last 4 weeks, have you been bothered by having to:	No	A little	Some	A lot
1. Walk indoors on level ground?	3	2	1	0
2. Garden, vacuum, or carry groceries?	3	2	1	0
3. Climb a hill or a flight of stairs without stopping?	3	2	1	0
4. Walk more than 100 yards/metres at a brisk pace?	3	2	1	0
5. Lift or move heavy objects?	3	2	1	0

Now, in the last 4 weeks, have you been bothered by:	No	A little	Some	A lot
6. Feeling short of breath?	3	2	1	0
7. Being physically restricted?	3	2	1	0
8. Feeling tired, fatigued, low on energy?	3	2	1	0
9. Not feeling relaxed and free of tension?	3	2	1	0
10. Feeling depressed?	3	2	1	0
11. Being frustrated?	3	2	1	0
12. Being worried?	3	2	1	0
13. Being limited in doing sports or exercise?	3	2	1	0
14. Working around the house or yard?	3	2	1	0

HeartQoL questionnaire; and (b) 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 was designed as a two-phase study. The target in the international cross-sectional study was to enroll at least 315 patients (105 with angina, 105 with MI and 105 with heart failure).[9] The eligibility criteria are detailed elsewhere[12] and include patients with documented angina (Canadian Cardiovascular Society (CCS) functional status classification Class II, III, or IV),[13] MI, or ischemic heart failure (New York Heart Association (NYHA) functional status classification Class II, III, and IV),[14] of age $\geq$18 years old, and considered by the referring physician: (a) to be able to complete the self-administered battery of HRQL instruments, (b) not to have a serious psychiatric disorder, and (c) not be a current substance abuser.

The target in the prospective HeartQoL Responsiveness substudy was to enroll at least 200 patients with IHD in each of two arms: (a) patients with angina, non-ST elevation MI, or ischemic heart failure undergoing PCI and (b) patients with IHD referred to CR.[9]

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] As described in detail elsewhere,[12] each item in the item pool from which the HeartQoL was developed was from one of the three previously validated disease-specific questionnaires which were either (a) available in the 15 different languages (http://www.proqolid.org/) or (b) accepted linguistic translation techniques, such as forward-backward translation, were used to translate the questionnaires when language-specific translations were not available[20] 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

Based on each patient's response to how much they were bothered by each of the 14 HeartQoL items, the following psychometric properties of the HeartQoL were assessed using recommended criteria.[21]

Reliability. Internal consistency reliability (Cronbach's α) was assessed ($r \geq 0.70$ considered acceptable for group and $\geq$0.90 for individual comparisons).[22]

Validity. **Convergent validity:** Hypothesizing, a priori, strong correlations between similar SF-36 and HeartQoL constructs ($r \geq 0.50$)[22] 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.[23]

Discriminative validity: The 'known-groups' test for expected relationships[24] 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).

Evaluative validity: Paired *t*-tests were used to test for HeartQoL score changes. Responsiveness was reported as effect size (ES) (small: $\geq$0.20, $<$0.50; moderate: $\geq$0.50, $<$0.80; and large: $\geq$0.80) using the standardized response mean (SRM) methodology ($ES = A - B)/D$) where A = time 2 mean, B = time 1 mean, and D = standard deviation of the change score.[25]

Results

HeartQoL questionnaire

The development of the 14-item, two-domain HeartQoL questionnaire is described in detail elsewhere[12] and the HeartQoL questionnaire itself is given in Table 1. In addition to English, the HeartQoL is available in the following languages: Danish, Dutch, Flemish, French, German, Hungarian, Italian, Norwegian, Polish, Portuguese, Russian, Spanish, Swedish, and Ukrainian (and will be available in Bulgarian, Croatian, Czech, Turkish, and Romanian).

Patients

A cohort of 6384 patients (Table 2), living in five different geographical regions with 67 sites in 22 countries (15 languages), was enrolled in the cross-sectional phase of the HeartQoL Project.[12] Patients with angina ($n = 2111$; 33.1%), MI ($n = 2351$; 36.8%), or heart failure ($n = 1922$; 30.1%) were referred.

Table 2. Patient characteristics and HeartQoL questionnaire mean (± SD) scores; ceiling (high HRQL) and floor (poor HRQL) effects; and internal consistency with Cronbach's α in the total group and in patients with angina, myocardial infarction (MI), or heart failure (HF)

	Total group ($n=6384$)	Angina ($n=2111$)	MI ($n=2351$)	HF ($n=1922$)	p-value*
Patient characteristics					
Age (years (±SD))	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 α	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 α	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 α	0.91	0.90	0.90	0.91	

HRQL: health-related quality of life; p-value between diagnosis with analysis of variance (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.

Women made up 25% ($n=1694$) of the cohort whose mean age was 62.5 years (SD = 11.3). Specific clinical and sociodemographic details are provided elsewhere.[12]

A total of 781 patients (25.1% female and mean age 64.6 (±11.2) years) undergoing PCI or referred to CR were enrolled in the HeartQoL Responsiveness substudy. We enrolled 398 patients undergoing PCI (26.9% female and mean age 65.4 (±11.6) years) in 11 countries (nine languages - Danish, English (Ireland, USA), Flemish, French, German (Austria, Switzerland), Norwegian, Portuguese, Russian, and Spanish; 73.1%. We also enrolled 383 patients in the CR arm (23.4% female and mean age 63.8 (±10.7) years) from eight countries (six languages: Danish, English (Ireland, USA), Flemish, French, German (Austria, Switzerland), and Spanish).

HeartQoL scores

The mean baseline HeartQoL global score in the group as a whole was 2.2 ± 0.5 (Table 2) based on each patient's self-reported response to how much they were bothered by each of the 14 HeartQol items. Global and physical subscale (items #1–8, 13, 14) scores (better HRQL) were highest in patients with MI, intermediate with angina, and lowest with heart failure ($p<0.001$). Emotional subscale (items #9–12)

Table 3. Convergent validity of the HeartQoL physical and emotional subscales with the Short Form-36 physical component scale (SF-36 PCS} and the Short Form-36 mental component scale (SF-36 MCS) in the total group of patients with ischemic heart disease (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 4. Discriminative validity of the HeartQoL global scale and physical and emotional subscales using (a) Short-Form 36 (SF-36) health transition, anxiety and depression (Hospital Anxiety and Depression Scale (HADS)) in the total group and in patients with angina, myocardial infarction (MI), or heart failure, (b) functional status with Canadian Cardiovascular Society (CCS) in patients with angina, and (c) New York Heart Association classification (NYHA) in patients with heart failure

	HeartQoL Global	HeartQoL Physical	HeartQoL Emotional
Total group			
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[#]	<0.001[a,b]	<0.001[a,b]	<0.001[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 ($n = 1462$)	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 ($n = 1299$)	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)*
MI			
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[#]	<0.001[a,b]	<0.001[a,b]	<0.001[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)

(continued)

Table 4. Continued

	HeartQoL Global	HeartQoL Physical	HeartQoL Emotional
Deteriorate ($n = 746$)	1.8 (0.6)	1.7 (0.7)	2.2 (0.7)
p-value[#]	<0.001[a,b]	<0.001[a,b]	<0.001[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 ($n = 1024$)	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.

scores were highest in patients with MI and lower, but similar in patients with angina and heart failure. Individual patient HeartQoL scores ranged from 0.0–3.0. 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

Cronbach's α for the global score and each subscale was always between 0.80–0.91 (Table 2).

Convergent validity

The correlations between similar HeartQoL and SF-36 subscales were ≥0.60 and always significant (Table 3). As hypothesized, all correlations between dissimilar HeartQoL and SF-36 scales were lower (all $r \leq 0.38$, $p < 0.001$).

Discriminative validity

Discriminative validity of the HeartQoL was confirmed in the group as a whole and for each diagnosis (Table 4). HeartQoL scores were always higher (better HRQL) in patients with (a) 'no change' or 'improved' vs 'deteriorated' health status (b) 'without' vs 'with' anxiety or depression, and (c) functional class 'II' vs 'III/IV' in patients with angina or heart failure ($p < 0.001$).

Responsiveness (Table 5)

The HeartQoL global, physical, and emotional subscale scores were significantly improved with both interventions as were the SF-36 PCS and MCS scores ($p < 0.001$). The ES was 0.51 for the HeartQoL 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 HeartQoL physical and emotional subscale ES was larger than that observed for the corresponding SF-36 PCS and MCS with both PCI and 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 but, as the analyses are prelimnary, further psychometric testing is needed. The HeartQoL questionnaire was developed and validated in a cohort of 6384 patients with IHD who live in 22 countries and speak one of 15 languages; and an independent cohort of 730 patients either undergoing PCI ($n = 350$) or referred to CR ($n = 380$), from 10 countries speaking one of eight languages, provided responsiveness data. Performing well on key psychometric attributes for HRQL instruments,[21] the HeartQoL has potential as a core IHD-specific HRQL questionnaire and demonstrated that patients with MI have better HRQL scores than patients with angina who in turn have better HRQL scores than patients with heart failure.

The 14-items in the HeartQoL scale cluster as a 10-item physical subscale 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 the respondent and administrative burden.[21] We assumed, a priori, face and content

Table 5. HeartQoL Global and subscale mean scores (±SD), *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

MCS: mental component summary; PCS: physical component summary.

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 $\alpha > 0.70$[21] 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,[24] the 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 score 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. Per the patient eligibility criteria for the project, the HeartQoL questionnaire has been validated only in CCS and NHYA Class II, II, and IV patients. The overall pattern with the HeartQoL is that patients with MI have a better HRQL score than patients with angina who, in turn, have a better HRQL score than patients with heart failure. This HRQL pattern is consistent with observations using generic HRQL instruments, specifically the SF-36[1,5] and the EuroQoL EQ-5D,[26] 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.[27–29]

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 was 'moderate' and with each subscale it was 'small'. 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) 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.[30] 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'.[31] 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 that 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 an 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 score 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 the 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 in other languages and will need head-to-head comparisons with the other available core IHD-specific HRQL instrument, the MacNew.[27–29] Further HeartQoL research needs include the establishment of test-retest reliability; further examination of floor and ceiling effects and establishment of validity and 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[32] but not frequently assessed with IHD-specific HRQL instruments.[33]

Conclusions

Initial analysis of the HeartQoL questionnaire, a new 14-item international core IHD-specific assessment and evaluation system on patient-reported HRQL, suggests it 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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Conflicts of interest

The authors declare that there are no conflicts of interest.

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