Validation of the HeartQoL health-related quality of life questionnaire

Suggested validation synopsis

The 14-item questionnaire is designed to be used to assess and to evaluate health-related quality of life [HRQL] as a core heart disease specific questionnaire. The HeartQoL should be validated in each language in which it will be used.

The HeartQoL was developed [Oldridge N, Hofer S, McGee H, Conroy R, Doyle F, Saner H, et al. The HeartQoL: Part I. Development of a new core health-related quality of life questionnaire for patients with ischemic heart disease. Eur J Prev Cardiol. 2014;21:90-7] and validated in an international cohort of 6,380 patients with angina [n=], MI [n=], and heart failure [n=] living in 22 countries and speaking one of 15 different languages [Oldridge N, Hofer S, McGee H, Conroy R, Doyle F, Saner H, et al. The HeartQoL: Part II. Validation of a new core health-related quality of life questionnaire for patients with ischemic heart disease. Eur J Prev Cardiol. 2014;21:98-106].

The following is the process that we have used for validation studies in various languages.

Validation of health-related quality of life questionnaires like the HeartQoL heart disease specific HRQL questionnaires is carried out using the recommendations from the Scientific Advisory Committee of the Medical Outcomes Trust [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].

1. FACTOR STRUCTURE Principal component factor analysis [confirmatory or exploratory] with oblique or varimax rotation may be used to confirm or replicate the factor structure.

2. RELIABILITY [consistency with which the measurements yield similar results under varying conditions] and is examined with 2 strategies;

a] **internal consistency** [using Cronbach's alpha] which is typically a measure based on the correlations between different items on the same test [do several items that propose to measure the same general construct produce similar scores];

b] **test-retest reliability or reproducibility** [using intra-class correlation, ICC] is the variation in measurements taken by a patient under the same conditions but at different times [do stable patients give similar scores, for example, when tested two or four weeks apart ?]

3. VALIDITY [degree to which the instrument measures what it's supposed to measure] and is examined with 2 strategies:

a] **convergent validity** [using Pearson correlation coefficients with Steiger's test for comparisons] refers to the degree to which two measures of constructs that theoretically should be related, are in fact related [are physical scores similar in 2 different instruments measuring physical function ?];

b] **discriminant validity** [using "known groups approach] refers to the degree to which measurements that are supposed to be unrelated are, in fact, unrelated [are physical scores different in patients with CHD vs. no CHD ?]

3. **Sensitivity** [responsiveness] using t-test or effect size statistics to detect change

PATIENTS

Recruit patients with an ischemic heart disease diagnosis [e.g. angina, myocardial infarction [MI], or heart failure] who are optimally undergoing some form of treatment. We have found that approximately 100-125 patients with the specific diagnosis has typically been an adequate sample size but check the sample size table below for specific numbers.

In our validation studies we have asked each patient to complete at least:

1. The HeartQoL HRQL questionnaire;
2. A sociodemographic questionnaire;
3. a. Some comparative generic HRQL questionnaire [e.g., SF-12 or SF-36]; **OR**
   b. Some comparative IHD-specific HRQL questionnaire [e.g., MacNew];
4. A questionnaire for anxiety and depression [e.g., Hospital Anxiety and Depression Scale]

Validation Strategy Sample Sizes:

Reliability

Cronbach's Alpha:

Minimum (factorial Eigenvalue > 6)	Ideal (factorial Eigenvalue 3-6)
N=30	N=100

Test–retest Reliability (test stability):

Expected effect size: 0.7, α=0.05, β=0.08	Expected effect size: 0.9, α =0.05, β =0.08
N=11	N=5

Validity

Confirmatory Factorial Validity (CFA)

Minimum	Ideal
N=100	N=300

Convergent Validity (SF36 x I)

Expected effect size: 0.7, α=0.05, β=0.08	Expected effect size: 0.9, α =0.05, β =0.08
N=11	N=5

Discriminant Validity

Mean Group 1: 2.4 (0.5) Mean Group 2: 2.0 (0.6) Expected effect size: 0.9, a=0.05, b=0.08	Mean Group 1: 2.5 (0.6) Mean Group 2: 2.2 (0.7) Expected effect size: 0.5, a=0.05, b=0.08
N=21 per group	N=76 per group

Sensitivity (responsiveness)

Mean time 1: 1.7 (0.8) Mean time 2: 2.0 (0.7) Expected effect size: **0.4**, a=0.05, b=0.08	Mean time 1: 2.0 (0.6) Mean time 2: 2.4 (0.5) Expected effect size: **0.7**, a=0.05, b=0.08
N=100 per group	N=31 per group

Additional info: N is estimated for one particular group (i.e. PCI, cardiac rehabilitation or MI, AP or HF).

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