

Evaluation of Health-related Quality-of-Life in Cardiovascular Research : A Call for Action

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Summary

Ischemic heart disease (IHD) is the leading cause of morbidity and mortality in many countries around the world. With increasing survival after acute cardiac events, patient-reported outcome measures such as health status and health-related quality-of-life (HRQL) are becoming increasingly important. An IHD-specific HRQL questionnaire, called HeartQoL, has been designed, developed and validated with the support of the European Association for Preventive Cardiology and results have been published in 2014. The questionnaire has been designed to assess baseline HRQL, make between-diagnosis comparisons of HRQL and to evaluate changes in patients with angina, myocardial infarction, or heart failure with a single core IHD-specific HRQL instrument. The HeartQoL questionnaire contains 14 questions and is easy to use, and has been validated in patients with angina, myocardial infarction, heart failure, atrial fibrillation, implantable cardioverter defibrillator and heart surgery, has been translated into 32 languages and has been used in more than 50 published studies. However, HRQL is still not routinely assessed in cardiovascular research or clinical practice. In view of the importance of HRQL as outcome measure, researchers and clinicians are encouraged to consider the IHD-specific HeartQoL as patient-related outcome measure to assess HRQL in their research projects as well as in their clinical practice.

Key words: Ischemic heart disease, patient-reported outcome, outcome measure, health-related quality of life,

Universal health care goals include helping patients to live longer and better, that is, to optimize both survival and health. Both, the European Society of Cardiology ESC (1) and the American Heart Association (2) have recognized that they have a unique opportunity to advance initiatives aimed at increasing the prominence of patient-reported outcomes (PRO) in cardiovascular research and translating findings into clinical practice.

Patient health status includes 3 components: symptom burden, functional status, and health-related quality of life (HRQL). Symptom burden includes the types and frequency of symptoms a patient may have as a manifestation of disease or from medical treatment (e.g. symptoms from side-effects of medications). Functional status includes physical, mental/emotional, and social function. HRQL is the patient's perception of discrepancy between actual and desired functional status and overall impact of disease on well-being for a given patient (3) and is typically measured using one or both of two types of HRQL questionnaires: Generic HRQL instruments are widely applicable to persons with a variety of health conditions including the general population while disease-specific HRQL instruments focus on symptoms and functional impairments associated with a specific diagnostic group such as patients with ischemic heart disease.

Whereas the emphasis on improving cardiovascular health is laudable, it raises the question about how cardiovascular health is best measured. Therefore, the HeartQoL Project was launched in 2002 and later funded by the ESC in cooperation with the European Association for Cardiovascular Prevention and Rehabilitation, now known as the European Association for Preventive Cardiology (EAPC). The aim of the project was to develop and validate a core disease-specific health-related quality-of-life HRQL outcome measure in patients with ischemic heart disease (IHD), to be known as the HeartQoL, to allow within- and between-diagnosis comparisons following interventions that are routinely used in more than one IHD diagnosis.

The HeartQoL Project was conducted in two phases between 2002 and 2011 in five regions (Eastern, Northern, Southern, and West European regions and an English speaking region) with a total of 22 countries where 15 languages are spoken: Danish, Dutch, English (Australia, Canada, Ireland, United Kingdom, and the United States of America), French, Flemish, German (Austria, Germany, and Switzerland), Hungarian, Italian, Norwegian, Polish, Portuguese, Russian, Spanish (Cuba and Spain), Swedish, and Ukrainian. The project was conducted in two phases: a) an initial cross-sectional survey phase with the objective of developing the HeartQoL using Mokken scale analysis based on 26 physical, emotional and social items identified, and used with permission, from three validated IHD-specific HRQL questionnaires (4); and b) a second phase testing the HeartQoL questionnaire's psychometric properties (5).

Because patients with IHD present on a continuum of care, 6'384 patients with one of the three major IHD diagnoses were recruited (2'111 patients with angina, 2'351 patients with MI and 1'922 patients with heart failure). The conclusions of the first phase of the HeartQoL Project are that the HeartQoL questionnaire, with a global and physical and emotional subscale scores, has the potential to allow clinicians and researchers to a) assess baseline HRQL, b) make between-diagnosis comparison, and c) evaluate change in HRQL in patients with angina, myocardial infarction (MI), or heart failure with a single IHD-specific HRQL instrument (4). The conclusions of the second phase of the HeartQoL Project are that the HeartQoL is reliable, valid and responsive to change (5). The HeartQoL 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 based on the average of the 14 items (Figure 1).

Figure 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

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The HeartQoL questionnaire translations are available in a total of 32 languages: Azerbaijani, Bahasa Malaysia, Bulgarian, Chinese (Mandarin), Croatian, Czech, Danish, Dutch, English, Finnish, Flemish, French, German, Greek, Hmong, Hungarian, Icelandic, Italian, Korean, Latvian, Lithuanian, Norwegian, Persian, Polish, Portuguese, Romanian, Russian, Serbian, Spanish, Swedish, Turkish, and Ukrainian. Since the initial validation of the HeartQoL questionnaire in patients with angina, MI, or heart failure (5), the HeartQoL questionnaire has been validated in patients with stable coronary

disease (6), atrial fibrillation (7), angina or MI (8), implantable cardioverter defibrillator (9), heart valve surgery (10), acute MI (11), and angina, MI or heart failure (12). Validation manuscripts in Chinese [Mandarin] patients and Italian patients with angina, MI or heart failure are under review. As of 8 October 2020, 52 HeartQoL publications have been listed in PubMed.

The ESC and the AHA strategic goals focus primarily on ideal health behaviours (e.g. non-smoking, exercise), and ideal health factors (e.g. cholesterol and blood pressure control) as metrics of cardiovascular health. Although the importance of these factors is evident, they do not directly address the World Health Organization definition of health as “...a state of complete physical, mental and social well-being”(13). The definition of health and the concept of patient-centered health care support the measurement of patient health status as a key metric of cardiovascular health.

In sharp contrast to numerous calls for a stronger focus on outcomes that people notice and care about such as survival, function, symptoms and HRQL, the number of publications in the field of cardiovascular research and clinical trials which include an evaluation of patient-centered outcome such as HRQL are limited. This call for action by the HeartQoL Project Principal Investigators is therefore intended to reinforce not only the need to integrate patient-centered outcome measures into outcome research and clinical practice but also to emphasize that a main focus of research should be on values of health care and on improving patient’s HRQL by attending to the patient’s physical and emotional needs. The HeartQoL questionnaire is valid and reliable, easy to apply, and available to serve to get closer to patient-centered care.

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HeartQoL license

The use of HeartQoL is subject to a license provided by the ESC European Association for Preventive Cardiology. Requests for the use of the questionnaire can be made through the EAPC Website (<https://www.escardio.org/Education/Practice-Tools/CVD-prevention-toolbox/HeartQoL>). Licenses are valid for a single project with access to the HeartQoL in each language per request. No additional fees per additional site/location. EAPC Accredited centres get free access for audit / quality control purposes.