

Review Article

Quality-of-Life Measures for Cardiac Surgery Practice and Research: A Review and Primer

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Abstract: Declining mortality and major morbidity rates after cardiac surgery have led to increasing focus on patient quality of life (QOL). Beyond longevity, the impact of cardiac surgery on day-to-day functioning is incredibly salient to patients, their spouses, and families. As such, QOL measures are a welcome and sometimes necessary addition to clinical trials. However, how does one navigate the expansive market of QOL questionnaires, which QOL measures are applicable to cardiac surgery units, and how can they be used meaningfully in clinical practice? Because nearly two decades have passed since QOL measures were reviewed for relevance to cardiac surgery settings, an overview is provided of various generic (Short Form Health Survey

[SF-36], Sickness Impact Profile, Nottingham Health Profile) and disease-specific QOL measures (Duke Activity Status Index, Seattle Angina Questionnaire, MN Living with Heart Failure Questionnaire; Heart-QOL) with examples from cardiac surgery studies. Recommendations are provided for the application of QOL measures to clinical trials and the impact on clinical decision-making is discussed. The paucity of methodologically sound QOL studies highlights the necessity for further rigorous empirical data to better inform treatment efficacy studies and clinical decision-making. **Keywords:** quality of life, coronary artery bypass, coronary artery disease, evidence-based practice, review. *JECT. 2013;45:8–15*

With declining mortality and major morbidity rates after open heart and minimally invasive cardiac surgeries over the past four decades, a key indicator of surgical outcome is increasingly quantified in terms of the impact on functional status of patients and the ability and time patients can resume, or improve, their day-to-day lives. Beyond cardiac disease symptoms, self-report questionnaires offer a subjective, valid, consistent, and reliable way to measure the quality of life (QOL) of patients. Quality-of-life measures are a welcome and sometimes necessary addition to clinical trials for their relevance to patient day-to-day functioning in many facets of life. How-

ever, how does one navigate the expansive market of QOL questionnaires, which QOL measures are applicable to cardiac surgery units, and how can they be used meaningfully in clinical practice? Previous QOL reviews for cardiac surgery have addressed methodological design issues (1) and statistical analytic approaches (2); however, it has been nearly two decades since QOL measures have been reviewed as they apply to cardiac surgery settings. Therefore, the aims of this review are to overview QOL measurement tools used among patients undergoing cardiac surgery and to provide recommendations for implementing QOL measures in cardiac surgery units such as clinical trials.

Definition and Relevance of Quality of Life

Despite the nebulous term “quality of life” lacking consensus in definition, QOL can be broadly defined as a multidimensional construct comprised of physical, mental, and social facets and the ability to perform everyday activities including the social and occupational aspects of one’s

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life (3–5). Further subdivision of these categories is possible: physical condition includes mobility and abilities to self-care; social activities include family contact, perceived support, and aspects of intimacy; and psychological well-being includes stress, anxiety, and depression (6). When QOL is operationalized into a questionnaire format to elicit subjective responses about health or a particular chronic disease, questions tend to focus on the impact that one's (the patient, not physician) physical health has on the multifaceted functional domains that make up everyday life (e.g., social, emotional and occupational). Thus, QOL is sometimes referred to as health-related QOL and for parsimony is simply referred to here as QOL.

The extent to which patients subjectively rate their QOL in relation to the rigors of surgery or the effects of cardiac illness is complementary to clinical indices of disease severity. When QOL measures are applied to healthcare settings including cardiac surgery units, such outcome measures provide an important indicator of the relative success of the cardiac procedure, from the patient perspective at the very least. For example, serial follow-up assessment can delineate specific improvements and conversely deterioration in everyday function by comparison to presurgery. As Thompson and Yu (7) suggest, healthcare professionals tend to focus mostly on objective biological and physical indices (e.g., ejection fraction, coronary flow), yet the scope for QOL measures to tap into the broader impact of health (or surgery) makes these incredibly salient to patients' day-to-day lives, particularly in the longer term after a period of convalescence. Therefore, issues concerning QOL are central to management decisions regarding chronic diseases and may facilitate patient informed choice when making decisions about treatment such as invasive surgery. In a healthcare system in which total cures for chronic disease are rare, patients, their families, and caregivers are interested in a therapy that benefits their symptoms, physical function, and social roles.

Generic and Disease-Specific Quality-of-Life Measures

Generic QOL measures are applicable to a range of health conditions other than heart disease (e.g., cancer, Parkinson's disease, arthritis, etc.). Such generic measures permit comparisons between groups of patients with certain conditions, undergoing particular procedures, and may advise health policy decisions and inform the distribution of resources and funding. Disease-specific measures on the other hand are more refined and designed to measure particular aspects of QOL affected by a specific condition (e.g., myocardial infarction [MI]). A potential advantage of disease-specific measures is that questions can be tailored to particular symptoms deemed important in clinical practice. As such, disease-specific QOL can be especially beneficial in elucidating benefits for particular treatments such as in randomized, control trials (RCTs).

An overview of several examples of generic and disease-specific measures might guide and direct researchers and clinicians toward the most appropriate measures in cardiac surgery.

Measures of Generic Quality of Life

Short Form Health Survey: Developed as part of the Medical Outcomes Study, this is arguably the most widely used, and thus validated, generic QOL measure (8). The questionnaire is self-administered and takes approximately 15 minutes to complete. Consisting of 36 individual items, the questionnaire is grouped into eight scales: physical functioning, social functioning, role limitations caused by physical problems, role limitations caused by emotional problems, mental health, energy/vitality, bodily pain, and general health and a single item concerning health change. The broad dimensions are consistent with the recommendations of the World Health Organization for a generic health-related QOL instrument (9). Collectively, the eight scales can be collated into two higher-order domains representing the Physical and Mental aspects of QOL (referred to as Physical Components Summary and Mental Components Summary).

The Short Form Health Survey (SF-36) has undergone an extensive validation and process to generate normative data including among coronary heart disease populations. Although each of the eight SF-36 scales have a mean of 50 and a standard deviation of 10, the role emotional and role physical scales have an ordinal, not linear, distribution and are thus not suitable for some statistical analysis (e.g., linear regression). Also, a caveat of ordinal data is proneness to floor and ceiling effects, and as such, these scales may not appear sensitive to change that occurs with improvement (and deterioration). Nevertheless, in heart disease samples, Dempster and Donnelly (10) identified the SF-36 as the most reliable, valid, and sensitive measure of ischemic heart disease patients' QOL, a statement corroborated by Al-Ruzzeh et al. among patients undergoing cardiac surgery (11). In the extant literature, Physical Components Summary scores were associated with 6-month mortality in 2480 patients undergoing cardiac surgery (12). Also, the physical functioning, pain, and general health subscales were associated with 12-month cardiac functional status (13). Importantly, the SF-36 has been used to document significant changes in QOL for octogenarians whom are not expected to receive excessive survival benefits from cardiac surgery alone (14). The Flinders Medical Center surgical unit has used the SF-36 to document consistent associations with depression (15) and also a comparative study of off- and on-pump coronary artery bypass graft (CABG) surgery (16).

Abbreviated versions of this scale have been developed (e.g., SF-12), taking less time to complete. The SF-12 was devised as a shortened version to predict the Physical

Components (PCS) and Mental Components Summary (MCS) scores. A study of 2441 cardiac rehabilitation attendees who completed both versions showed that the SF-12 closely approximated the SF-36 PCS and MCS summary scores and also a similar responsiveness to change was documented (17). Comparatively, the SF-36 will provide more detail in individual QOL domains; however, the SF-12 will suit clinicians and researchers requiring a valid but brief QOL measure.

Sickness Impact Profile: The Sickness Impact Profile (SIP) consists of 136 items, administered by the patient or an interviewer, taking approximately 30 minutes to complete (18). Originally consisting of 12 domains, statistical analyses (i.e., cluster and factor analyses) have led to refinement into three interpretable dimensions: physical (ambulation, mobility, body care), psychosocial (social interaction, communication, alertness, emotional behavior), and other (sleep/rest, eating, work, home management, recreational pastimes). It is recommended that either a total score be calculated or summary scores for the three domains of physical, psychosocial, and other. These broad domains produced favorable psychometric properties in angina patients for responsiveness to change in New York Heart Association class (19) and discriminant validity among patients with MI from control patients (20). Dempster and Donnelly (10) suggested that there is little information to support the internal consistency and discriminant validity of the SIP when used as 12 individual domains. As such, only the total SIP score was recommended for responsiveness in change to health status after surgery, thereby providing a single score estimate for generic QOL (10).

Nottingham Health Profile: The Nottingham Health Profile (NHP) is divided into two parts. Part I consists of 38 statements of “problems people have in their daily lives” for six dimensions: physical mobility, energy, pain, sleep, social isolation, and emotional reactions (21). Responses are in a yes/no format and a weight is applied to each statement enabling a score, ranging from 0 to 100, to be calculated for each dimension. Part II consists of seven items concerning the “activities in your life which may be affected by health problems” for seven areas: work, looking after the home, social life, home life, sex life, interests and hobbies, and holidays. This scale is self-administered and takes approximately 10 minutes to complete. Many studies use Part 1 only of the NHP and so relatively little psychometric work has been done on Part 2.

Like with the SIP, the NHP also showed favorable responsiveness in angina patients according to changes in New York Heart Association class (19) and discriminant validity among patients with MI from the control group (20). In the extant literature, octogenarian cardiac patients were found to report similar NHP scores at 15-month and

8.2-year follow-up by comparison to NHP age- and sex-matched normative data, suggesting equivalent QOL can be achieved with cardiac surgery (22). Chocron et al. (23) showed that for 3 years after surgery, the trajectory of NHP scores was stable and that lower preoperative energy was associated with poorer survival. Chocron et al. (24) also suggested that patients undergoing aortic valve replacement experienced greater improvement in QOL by comparison to CABG surgery, although general improvements were evident in all domains (apart from social isolation) for both surgeries. Even among persons who experience an unexpected cardiac arrest in the postoperative period, survivors achieved an improvement in NHP QOL from cardiac surgery (25), suggesting postoperative in-hospital events do not preclude QOL benefits. Finally, Peric and colleagues (26) used the NHP to identify characteristics of persons reporting worse preoperative QOL and also ascertain those characteristics of persons whose QOL worsened with CABG surgery (27).

Comparison of Generic Quality-of-Life Measures: All three of the mentioned generic instruments cover the key areas of physical, social, and emotional functioning. However, the SF-36 and the NHP appear to have better content validity in the field of cardiac surgery because each covers energy/vitality and bodily pain, an appropriate if not essential aspect of cardiac surgery recovery for ischemic heart diseases and procedures involving sternotomy. A study among 299 patients undergoing cardiac surgery at baseline and 5 weeks postoperatively suggested that psychometric properties and sensitivity to change in angina and dyspnea were more favorable for the SF-36 than the NHP (28), supporting the SF-36 as a useful generic QOL measure.

Measures of Disease-Specific Quality of Life

The heterogeneity in etiology of heart diseases (e.g., ischemic, valvular stenosis, regurgitation, rheumatic, viral, congenital, alcoholic cardiomyopathy) opens up a broad scope of possible disease-specific QOL measures for application to patients undergoing cardiac surgery. However, in the absence of a QOL measure specific to cardiac surgery, subjectively meaningful aspects of QOL that are potentially deleteriously affected by cardiac surgery (e.g., cognitive function, sternotomy pain) would not be captured by cardiac disease-specific measures.

Duke Activity Status Index: The Duke Activity Status Index (DASI) 12-item scale (29) was developed from a study concerning peak oxygen uptake during exercise testing and therefore covers areas of functional capacity affected by heart disease. To obtain a total score, individual DASI items are weighted based on degree of physical exertion. Criterion validity was established whereby poorer functional capacity was associated with more

disease coronary vessels, heart failure, female sex, older age, lower left ventricular ejection fraction, and smoking history (30). The DASI was used in the original Bypass or Angioplasty Investigation (31) and diabetes trial (32) to support functional benefits to patients randomized to CABG surgery revascularization.

MacNew Heart Disease Quality-of-Life Measure: The MacNew was developed from revisions to the Quality of life after myocardial infarction questionnaire (QLMI) (33,34). Reference data are available for this measure (35) ascertained from follow-up of patients with MI ($n = 346$), heart failure ($n = 201$), and ischemic heart disease ($n = 959$) surveyed 4–8 months after hospital discharge. The authors showed that QOL change was generally unrelated to diagnosis, age, and sex and that a minimal clinically important difference of .5 could be established. That said, other analyses have shown discordance in ways of scoring (36), possibly owing to inconsistencies in factor structure (33,37).

The Seattle Angina Questionnaire: The Seattle Angina Questionnaire (SAQ) (38) is a 19-item self-administered questionnaire consisting of five domains: physical limitations, angina stability, angina frequency, treatment satisfaction, and disease perception. Taking approximately 5 minutes to complete, summary scores can be tabulated for each subscale, but no total score can be derived according to the authors (38). The SAQ domains have been shown to improve after cardiac surgery among octogenarians (14,39). Other uses for the SAQ have included demonstrating the efficacy of robotic-assisted CABG (40), a study comparing the effects of radial artery and saphenous vein grafts (41), and the benefits for CABG over percutaneous coronary intervention with respect to angina (42,43).

Minnesota Living with Heart Failure Questionnaire: The Minnesota Living with Heart Failure Questionnaire (MLHF) (44) is one of the most commonly used QOL measures specific to heart failure and was originally designed for use in clinical trials. The 21 items tap into respondents' perceptions of how heart failure affects physical, socioeconomic, and psychological aspects of their life. Acceptable psychometrics and validity properties were established in patients undergoing valvular surgery for changes over time alongside the SF-36 (45). Criterion validity was supported in a study that reported changes in MLHF total and physical scores were related to changes in patients' ratings of dyspnea and fatigue (46). Superior sensitivity to change statistics was supported in a recent meta-analysis (pooled estimate), thus favoring the MLHF over other heart failure QOL measures (47). Other applications of the MLHF in cardiac surgery include reporting the symptomatic change after surgical or angioplasty interven-

tion for isolated narrowing of the proximal left anterior descending coronary artery (48). Finally, the MLHF was used to document the QOL benefit for symptomatic aortic valve stenosis surgery among high-risk patients whom had undergone previous CABG surgery (49).

The Heart-QOL Project: The objective of the Heart-QOL project was to reduce the MacNew, SAQ, and MLHF measures into a single set of heart disease-specific questions. A broader aim was to facilitate comparisons between cardiac diagnoses and outcomes. A total of 6384 patients were recruited (2351 MI, 2111 angina, 1922 heart failure) who had not been hospitalized in the previous 6 weeks from 22 countries (19 European countries plus Australia, Canada, the United States). A total of 49 items were reduced to a core set of 14; they were allocated across physical (10 items) and emotional (four items) domains. The psychometric data to date are encouraging with respect to internal consistency ($\alpha \geq .80$), convergent validity with comparable SF-36 subscales ($r \geq .60$), and sensitivity to change after percutaneous coronary intervention or cardiac rehabilitation (effect sizes .37–.64) (50). Between-diagnosis comparisons showed that patients with MI were found to experience poorer QOL than persons with angina and, surprisingly, heart failure (51). A clear advantage of the Heart-QOL's design, by comparison to other disease-specific measures, is that valid comparisons between etiologies can be made according to a set of items most relevant to cardiac disease states. This general characteristic combined with extensive normative data makes Heart-QOL the frontrunner in disease-specific QOL measures for diverse cardiac patients seen in cardiac surgery.

Application of Quality of Life in Research Trials

Having reviewed various generic and disease-specific QOL measures, their use in clinical trials allows quantification of the extent that a cardiac surgery intervention impacts on a patient's chronic disease or condition. However, a brief review of cardiac surgery trials (1) showed a paucity of published QOL research between 2004 and 2010. Discouragingly, major methodological limitations in the application of QOL measures were identified among retained studies. For example, many studies used a cross-sectional design without baseline QOL assessment, thereby precluding any demonstration of treatment efficacy, at least on QOL. As a consequence of the major limitations identified in their review, Noyez and colleagues (1) described a set of useful minimum recommendations for study design (Table 1). These methodological recommendations parallel some of the guidelines listed by Kelley et al. (52) for good practice in survey research. With respect to the particular use of QOL instruments and the resultant data, Chang et al. (53) adapted a set of criteria from cancer research to aid interpretation of

Table 1. Quality of life research design.

Quality of Life in Cardiac Surgery (1)	
Number of patients	The total number of patients that could be included in the study, inclusion and/or exclusion criteria, and the total sample reported in the study The number of patients with and without complete preoperative and postoperative quality-of-life information How missing data was handled (e.g., imputation)
Differences in study and nonstudy patients	Accounting for missing preoperative quality-of-life data and a comparison of groups with and without preoperative quality-of-life data (e.g., demographics, comorbidity)

Also see CONSORT Statement (63): 4a, 13a, 13b, 15. STROBE statement (64): 6, 8, 9, 11, 12, 13, 14, 15, 16, 17.

heart failure clinical trials, and these are applicable to cardiac surgery (Table 2). Nevertheless, a Consolidated Standards of Reporting Trials (CONSORT) statement is in development to standardize QOL assessments across clinical trials (54). It is anticipated that adherence to the CONSORT QOL reporting guidelines will be mandatory in clinical trials using QOL measures, at least for those wishing to publish their work. In deciding between a generic and disease-specific QOL measure, concomitant use of both is optimal and highly recommended (10). However, if only one measure can be used, disease-specific QOL measures appear more sensitive to change in RCTs (55).

Application of Quality of Life in Clinical Practice

It is reasonable that the clinical decision-making surrounding emergency and critically ill cardiac surgery cases would not be materially affected by having individual patients QOL score. Empirical findings have led to recommendations that those with an already subjectively rated favorable preoperative QOL should have CABG surgery mainly to increase survival rather than material change in QOL (56). Conversely, the greatest potential for improvement in QOL is among those with the lowest QOL. This suggests that application of QOL questionnaires can particularly abet the clinical decision-making when QOL is subjectively reported as poor and perhaps when the anticipated survival from surgical intervention is unclear or low. Importantly, an individual patient can be given a percentile rank for their current QOL according to appropriate age- and sex-matched normative data. In these cases, QOL measures will offer insight into day-to-day functioning (e.g., for generic QOL measures) and open up patient-practitioner discussions surrounding limitations imposed by specific cardiovascular diseases and their characteristic symptoms (e.g., disease-specific QOL measure). Indeed, interpretation of normative data is contingent on whether a disease vs. generic QOL measure was applied, because the former permits comparisons by age

Table 2. Quality-of-life measure reporting guidelines (53).

Conceptual	
A priori hypothesis stated	Assessed whether authors had a predefined HRQOL end point and/or stated expected changes because of the specific treatment
Rationale for instrument reported	Assessed whether authors gave a rationale for using a specific HRQOL measure
Measurement	
Psychometric properties reported	Assessed whether a previously validated measure was used or psychometric properties were reported or referenced in the article
Cultural validity verified	Assessed whether the measure was validated for the specific study population
Adequacy of domains covered	Assessed whether the measure covered, at least, the main HRQOL dimensions relevant for a generic HF population, and/or according to the specific research question
Methodology	
Instrument administration reported	Assessed whether authors specified who and/or in which clinical setting the HRQOL instrument was administered
Baseline compliance reported	Assessed whether authors reported the number of patients providing an HRQOL assessment before the start of treatment
Timing of assessment documented	Assessed whether authors specified the HRQOL timing of assessment during the trial
Missing data documented	Assessed whether authors gave some details on HRQOL missing data during the trial
Interpretation	
Clinical significance addressed	This refers to the discussion of HRQOL data being clinically significant from a patient's perspective and not simply statistically significant
Presentation of results in general	Assessed whether authors discussed the HRQOL outcomes, giving any comments regardless of the results (either expected or not)

Also see Kelley (52).

HRQOL, health-related quality of life; HF, heart failure.

and the latter by disease. Beyond case-by-case decision-making, interestingly, empirical work on QOL has been demonstrated to alter clinical decision-making and practices concerning surgical intervention. Specifically, in a meta-analysis of heterogeneous surgeries, the QOL results from 10 RCT studies were deemed important enough to affect change in clinical decision-making (57). The potential for relevance of QOL research to inform clinical practice and case-by-case decisions at the bedside underscores the importance of accurate QOL data for clinician and patient alike to thereby balance the tradeoff between longevity and QOL, among other factors. Indeed, the paucity of data from methodologically sound studies (1) emphasizes that further empirical work is required to inform the clinical practices and decision-making process.

The clinical application of QOL measures in the period after cardiac surgery inevitably relates to convalescence. Prior knowledge of patient QOL recovery trajectories can inform patients and caregivers to develop realistic expectations about recovery and can be provided at the time of discharge planning. For example, a degree of pain, fatigue, sleep difficulties, low mood, activity restriction, and decreased social activity is common from the rigors of surgery in the immediate postoperative period. Moreover, in the short term, perception of QOL is influenced more by physical functioning than emotional functioning (58), whereas physical QOL typically improves steadily in linear fashion over time, whereas mental QOL shows early improvements that abate over time (59). Detractions from these common QOL recovery trajectories could inform follow-up procedures and cardiology management. Notwithstanding standard cardiology investigations, failure to make gains in QOL could prompt psychological evaluation given the known detrimental influence of psychological depression on QOL after cardiac surgery (15) and the importance of depression management in the patient undergoing cardiac surgery postoperatively (60,61).

Quality-of-Life Assessment in Cardiac Surgery: The Flinders Medical Center Experience

This section outlines recent experiences with routine administration of the SF-12 to all cardiothoracic patients at the Flinders Medical Center, South Australia. Selection of a generic QOL measure has ensured that comparisons between heterogeneous cardiothoracic surgeries are valid. The SF-12 was selected for optimal balance between brevity and clinician time constraints with psychometric validity and sensitivity. The roll-out phase occurred in February 2010 and consisted of paper-pen administration of the SF-12 in the preadmission clinic the week before surgery. By 6 months postoperatively, patients are telephoned and complete the questions over the phone with data entered instantaneously; alternatively, questionnaires are sent with a reply paid envelope for convenience. Data at each time point are entered on a secure database managed at weekly database meetings. The specific database requirements are analogous to those used by The Perfusion Downunder Collaborative Database Project and the reader is referred elsewhere for information on such software requirements (62). Currently, Flinders Medical Center has more than 600 cardiothoracic cases with preoperative SF-12 QOL scores (>340 have completed the 6-month follow-up) that will inform normative data requirements in addition to clinical decisions. Barriers to date have included patient loss-to-follow-up, time demands of clinical staff, and poor compliance. A follow-up procedure tailored to patient preference for either paper-pen vs. telephone administration has improved compliance. Currently, culturally sensitive adaptations are being developed for SF-12 use with

Indigenous Australian peoples whom comprise approximately 10% of all cardiothoracic surgeries.

Limitations of Quality of Life

Without a definitive consensus in definition, readers should prudently interpret QOL research paying attention to how QOL was defined and measured. General limitations impinging on the validity of self-reported QOL research include the effects of social desirability, memory recall bias, adaptive physical and psychosocial adjustments over time to illness, and therefore changes in the manner illness is perceived over time (e.g., successful aging). Accurately quantifying changes in QOL and extrapolating the impact of surgical intervention (improvement, deterioration) beyond these limitations is therefore challenging.

CONCLUSION

The use of generic and disease-specific QOL measures is a promising research field with many applications to RCTs and clinical practice in cardiac surgery. The concomitant use of generic and disease-specific QOL measures provides optimal information; however, disease-specific measures appear more sensitive to change. There is no correct QOL measure to administer, whether generic or disease-specific, and thus readers are encouraged to tailor this review to their specific needs. The paucity of methodologically sound QOL studies highlights the necessity for further rigorous empirical data to better inform treatment efficacy studies and clinical decision-making. In anticipation of the CONSORT statement for QOL measures (54), and validity data for the Heart-QOL (50,51), it is an opportune time for QOL research in cardiac surgery. In the future, identifying normative QOL profiles of cardiac surgery recovery might better inform anticipated trajectories of recovery for patients.

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