How to Do More With Less

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Heart failure (HF) management often seeks to improve on 3 key patient-focused axes: reduce the risk for mortality, reduce the chance for urgent events such as emergency department visits or hospitalization, and improve the quality of life.1 The latter of these goals is often of principal importance to patients: clinicians who care for patients with HF will commonly hear from their patients that they just want to feel better. Indeed, several studies demonstrated that the majority of patients with HF give more weight and importance to quality of life over longevity.2

The measurement of quality of life has gained traction in clinical research and clinical practice. Health-related quality of life (HRQL) entails eliciting symptoms, therapy-related effects, functionality in various dimensions of daily life and social wellbeing.3 It has become increasingly important to assess HRQL to gauge response to therapies instead of relying solely on health professional assessments, such as New York Heart Association functional class, which has poor inter-rater reliability.4 Hence, HRQL has become an important patient-reported outcome and end point for clinical trials in HF.

There are a multitude of generic and disease-specific HRQL instruments developed and used in the research environment: the Kansas City Cardiomyopathy Questionnaire (KCCQ) is now considered one of the key HF tools to assess patient-focused axes: reduce the risk for mortality, reduce the chance for urgent events such as emergency department visits or hospitalization, and improve the quality of life.1 The latter of these goals is often of principal importance to patients: clinicians who care for patients with HF will commonly hear from their patients that they just want to feel better. Indeed, several studies demonstrated that the majority of patients with HF give more weight and importance to quality of life over longevity.2

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There are a multitude of generic and disease-specific HRQL instruments developed and used in the research environment: the Kansas City Cardiomyopathy Questionnaire (KCCQ) is now considered one of the key HF tools to assess efficacy of new therapies. The KCCQ, developed in 2000, is a 23-item multidimensional self-administered questionnaire designed to evaluate the following 5 subscales: physical limitations, symptoms (frequency, severity, and changes over time), social limitations, self-efficacy, and quality of life.4 Its validity, reliability, responsiveness, and interpretability are well established in the setting of HF, and the questions asked mirror how patients and clinicians interact. Indeed, the KCCQ is the most highly rated instrument when assessed for validity, sensitivity to change and interpretability comparing the original full scales and KCCQ-12.5

Despite all the favorable qualities and scientific rigor in the development of the KCCQ instrument, its use was somewhat limited by its length—possibly too long for implementation into clinical practice. The respondent and administrative burden has been addressed in recent guidelines on the assessment of patient-reported outcome instruments.6 Thus, clinicians (and patients) wanting to implement this into clinical practice settings have not yet been able to do so on a mass scale, despite the direct relevance to clinical practice. In the current issue, Spertus7 has presented a shorter (12 items) version of Kansas City Cardiomyopathy Questionnaire, the KCCQ-12, which maintains the psychometric properties of the full (23 items) KCCQ. The authors validated the KCCQ-12 within 3 distinct clinical settings: (1) stable HF recovering from an acute myocardial infarction (from the Eplerenone’s Neurohormonal Efficacy and Survival Study [EPHESUS] trial), (2) outpatient HF clinic visits (KCCQ Interpretability study), and (3) acute HF recovery (1 week after hospitalization for decompensated HF, from the Efficacy of Vasopressin Antagonism in Heart Failure Outcome Study With Tolvaptan [EVEREST] trial). KCCQ-12 was shown to have high correlations with the original scales, high test–retest reliability and high responsiveness.7 Studies have suggested that a low KCCQ score may independently predict clinical outcomes in patients with HF, and it can provide some insights about their overall prognosis.12–14 KCCQ-12 was also shown to have comparable properties with the full KCCQ, in terms of prognostic and interpretability.7 However, it should be noted that the c-statistic was used to evaluate the prognostic value of KCCQ and KCCQ-12. C-statistics, despite being the most popular measure of model performance in the cardiovascular field, has some major drawbacks for being used in risk prediction models. For example, it is a rank-based measure (using ranks rather than the actual predicted probabilities), and it does not take the distribution of population risk into account—important in syndromes such as HF where a spectrum of risk is present. New measures such as net reclassification improvement or integrated discrimination improvement will be a better choice for future studies that examine prognosis and the KCCQ-12.5

Several key features of this study deserve further consideration. First, the authors used 3 distinct clinical settings to derive and validate the short version of KCCQ to improve the generalizability. Second, instead of arbitrarily selecting items, they examined several scenarios for selecting the best possible subset of KCCQ items. They then tested each subset of items with calculating their correlation with the corresponding full-version score and noteworthy that item response variability, nonresponse rates, and clinical judgment were also involved in the process of item selection. Finally, they ensured that all psychometric properties (construct validity, predictive validity, reproducibility, responsiveness, and minimal clinically important differences) were maintained.

How were they able to eliminate questions and shorten the KCCQ? The original 23-item KCCQ is the only HF disease-specific instrument, which had a self-efficacy subscale—eliminated from the 12-item KCCQ. This was additionally supported by the study of Garin et al.,16 which showed only
a moderate internal consistency and a low reproducibility for the self-efficacy subscale of KCCQ. Similarly, Masterson et al.1 tested the KCCQ subscale structure and showed a weak item-to-total correlation, low Cronbach alpha, and only moderate test–retest reliability for the self-efficacy subscale items, raised some questions on usefulness of this subscale, and showed even a better internal consistency after deleting those items. Thus, deletion of the self-efficacy subscale improves the efficiency while maintaining the core features.

One of the important attributes of the 23-item KCCQ was its responsiveness to HF treatment,6 which facilitates its potential use in longitudinal studies or clinical practice. The findings of current study showed that despite excluding the symptom change scale from the 23-item KCCQ, the KCCQ-12 has responsiveness. Responsiveness and knowing what change is clinically relevant when testing the efficacy of a new therapy are attributes that are important.

Currently approved HF therapies that are in widespread use have taken advantage of the minimally clinically important difference of ≥5 points for the KCCQ, and this benchmark offers unique insight into clinical trial results.6,7,17,18 For example, in early clinical trials enrolling highly symptomatic patients with HF, cardiac resynchronization therapy demonstrated that quality of life improved, and easily hit the threshold of 5 points.19 However, later trials enrolling less symptomatic patients but otherwise similar features did not show a demonstrable improvement in HRQL, despite the benefits in other axes—all-cause mortality and HF hospitalizations. Thus, maintenance of this attribute, an established minimally clinically important difference, is important for any tool development. The KCCQ-12 has shown a performance comparable with KCCQ with an approximate KCCQ-12 summary score minimally clinically important difference of 3 to 5 points.

When will we start formally measuring quality of life in clinical practice? For HRQL tools to be adopted into routine practice, we will need to see acceptance by patients and clinicians, appropriate resources dedicated to the measurement of HRQL, wide-scale implementation of the KCCQ-12 into electronic medical records, and development of a mobile app for patients to use similar to blood glucose or blood pressure monitors. Integration into the day-to-day practice of caring for patients seems to be a worthy goal. This deserves exploration as to what effect the day-to-day, monthly, or yearly reporting or recording of HRQL could be useful in the care of patients.

One can imagine future HF practice where, similar to the diligence in reporting daily weight or periodic blood pressures and heart rates, the KCCQ score is a standard item on a patient or physician (or even a payor) dashboard. To get there, multiple steps need to be taken. Spertus et al.31 has derived a shorter version of the KCCQ that maintains the scientific rigor of the original KCCQ. This first critical step will allow for greater integration into clinical practice, but several steps remain before HRQL measurement is ubiquitous in clinical practice. This journey should be accelerated by recent developments in electronic health data and mobile health. A shorter but still valid instrument and a more feasible way of its administration could reduce the patient and administrative burden of HRQL instrument and ease their integration into clinical practice by addressing both the financial/human resources barrier and the acceptability among patients. Finally, patients, clinicians, payers, and policy makers need to recognize the importance of measuring and integrating HRQL into daily practice. Sometimes less quantity is equal to more quality.

Disclosures

J.A. Ezekowitz holds a Population Health Investigator award, and Dr Sepehrvand holds a Graduate Studentship award, both from Alberta Innovates: Health Solutions.

References


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