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EDITORIAL

Importance of patient-reported outcomes in cardiovascular illnesses

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Abstract

Patient-reported outcomes (PROs) are increasingly recognized as pivotal tools in understanding health status, treatment impact, and quality of life (QoL) in patients, particularly those with chronic cardiovascular diseases. These standardized and validated tools capture the patient's perspective on physical, emotional, and social health dimensions, bridging gaps often missed by clinical evaluations. Despite their growing adoption in research, the use of PROs in new drug approvals has declined, from 30% between 1997-2002 to 16.5% between 2011-2015, raising concerns about their underutilization in real-world settings. However, their role in clinical care and research continues to expand, with the proportion of clinical trials incorporating PROs increasing from 14% between 2004-2007 to 27% between 2007-2013. PRO measures (PROMs) span multiple domains, including overall health, such as EQ-5D, SF-36, and PROMIS Profile-29 to evaluate health-related quality of life (HRQoL), psychological health, evaluated by instruments like the Patient Health Questionnaire-9 (PHQ-9), specific symptoms, such as pain and fatigue, functional status, and disease-specific outcomes such as the Kansas City Cardiomyopathy Questionnaire (KCCQ-12). The clinical impact of PROs is evident in their association with prognostic outcomes. Each 5-point decrease in the KCCQ score correlates with a 6–9% higher risk of cardiovascular death or heart failure hospitalization. Meta-analyses reveal that higher HRQoL reduces mortality risk by 37% (HR 0.633, 95% CI: 0.514-0.780). Additionally, in pre-terminal cancer patients, self-reported abilities to walk 4 meters and wash oneself independently predicted survival, hazard ratios of 0.63 (p=0.015) and 0.67 (p=0.024), respectively. Moreover, in chronic obstructive pulmonary disease, pain and discomfort predicted re-hospitalization and HRQoL predicted 180-day survival. These findings underscore the critical role of PROs in enhancing patient care, guiding therapeutic decisions, and shaping healthcare policies.

Key words: heart failure; patient-reported outcomes.

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Role of patient-reported outcomes

Over the past two decades, patient-centered care has gained recognition for improving outcomes, satisfaction, and alignment with patient values. Evidence links patient-centered communication to better recovery, improved health status, and reduced diagnostic tests and referrals through fostering common ground between patients and providers.[1] Patient-reported outcomes (PROs) play a critical role in this framework of joint decision-making and therapeutic alliance. PROs are standardized and validated tools designed to capture the patient's perception of their health, the burden of disease, and the effects of treatment. Unlike clinical evaluations, these instruments produce structured, quantitative data directly from patients without interpretation by clinicians or caregivers. PROs encompass a broad range of information, including disease symptoms, treatment side effects (*e.g.*, pain, fatigue, anxiety), functional abilities (physical, emotional, social, or cognitive functioning), and multidimensional constructs like health-related quality of life (HRQOL).[2,3] With increasing life expectancy, there is increasing prevalence of chronic diseases such as cancer and heart failure, along with substantial overlap and comorbidities.[4] The longitudinal use of PROs, particularly in chronic diseases, can provide valuable insights into a patient's perspective, including aspects such as disease progression, functional abilities, quality of life, and mental health, throughout the course of an illness or in response to changes in treatment.[2,3] A substudy of the Clinical Impact of Routine Assessment of Patient-Reported Health Status in Heart Failure Clinic (PRO-HF) Trial revealed that in the intervention arm, where participants shared their Kansas City Cardiomyopathy Questionnaire-12 (KCCQ-12) results with clinicians, the use of the KCCQ-12 significantly improved clinicians' ability to accurately evaluate patients' health status. Additionally, patients were more than twice as likely to report that their symptoms were better understood by their healthcare providers.[5]

Initially, PROs were mainly utilized in the setting of research. Clinical trials are increasingly expected to incorporate the patient's perspective into study outcomes and this has resulted in a rise in the use of patient-reported outcome (PRO) measures in clinical trials- from 14% between 2004 and 2007 to 27% between 2007-2013.[6,7] However, despite this growing incorporation of PROs in research, the use of PROs in new drug approvals has steadily declined. Between 1997 and 2002, 30% of new drugs included PRO labeling; this dropped to 24% between 2006 and 2010 and further declined to only 16.5% between 2011 and 2015.[8] This trend is concerning, as PRO assessments offer a closer reflection of routine clinical care. This decline may be due to methodological challenges in developing validated PROMs, difficulty in demonstrating clinically meaningful changes, and regulatory agencies' preference for hard clinical endpoints. Effectiveness studies, particularly in real-world settings, are often better suited than traditional randomized controlled trials (RCTs) for conducting comprehensive PRO assessments, allowing for a clearer understanding of how therapy impacts symptoms and daily life.

Types of patient-reported outcome measures

Patient-reported outcome measures (PROMs) refer to measurement tools such as standardized questionnaires that are used to evaluate PROs, such as in clinical trials. These validated tools are utilized instead of open-ended questions to ensure consistency in the wording, response options, and assessment approach across all participants. This standardization allows researchers to attribute variations in responses to genuine differences in patient perceptions rather than methodological inconsistencies or biases. The development of PROMs typically involves collaboration among clinicians, patients, and experts in psychometrics to ensure that the tools effectively capture clinically significant issues that hold meaningful relevance for patients.

PROMs can be classified into several categories, each assessing different dimensions of a patient's health. Overall health measures provide a broad evaluation of a patient's well-being across physical, emotional, and social domains. Common examples include the EQ-5D, Short-Form Health Surveys (SF-36, SF-12), and PROMIS Profile-29, which assess health-related quality of life (HRQoL). ([9]) Psychological health PROMs focus on mental health aspects, such as anxiety, depression, and emotional distress. Instruments like the Hospital Anxiety and Depression Scale (HADS), Patient Health Questionnaire-9 (PHQ-9), and Generalized Anxiety Disorder-7 (GAD-7) are widely used to assess mental status.[10] Symptom-specific PROMs target individual symptoms experienced by the patient, such as pain or fatigue, with tools like the Brief Pain Inventory (BPI) and Fatigue Severity Scale (FSS) providing insight into symptom severity. Functional status PROMs evaluate how a disease affects a patient's ability to perform daily activities, with assessments focusing on specific tasks like the ability to wash oneself or the ability to walk 4 meters.[11] Finally, disease-specific PROMs are tailored to assess the impact of particular conditions on a patient's life. Examples include the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) for heart failure, the Minnesota Living with Heart Failure Questionnaire (MLHFQ), each providing a targeted evaluation of disease impact. Together, these PROMs offer a comprehensive view of a patient's health, guiding clinical decisions and improving patient-centered care. PROMs are summarized in Figure 1 and Table 1.

Clinical impact of quality of life assessment

The assessment of patient-reported outcomes (PROs) has enhanced our understanding of the factors influencing quality of life (QoL) in individuals living with chronic diseases. A study examining QoL in patients with adult congenital heart disease in Malta revealed that mood disorders, anxiety, and other psychiatric conditions significantly decrease these patients' QoL. ([12]) Such findings offer valuable insights, highlighting aspects of health that may have previously been underrecognized, and providing opportunities to address these factors in clinical care. Although widely utilized in research, there is increased interest in incorporating PROs into clinical practice, which can help inform policies and reimbursement. In clinical practice, PROs are increasingly utilized in heart failure clinics to track symptom burden and guide medication titration. Similarly, following myocardial infarction, PROMs such as the Seattle Angina Questionnaire help monitor recovery and identify residual angina symptoms that may warrant further intervention.

Moreover, evidence suggests that PRO may be play a prognostic role in healthcare outcomes, including hospitalizations and survival. Pokharel *et al.* found that each 5 point decrease in KCCQ overall summary score was associated with a 6-9% lower risk of cardiovascular death or heart failure hospitalization in heart failure patients from the Treatment of Preserved Cardiac Function Heart Failure With an Aldosterone Antagonist (TOPCAT) trial, irrespective of left ventricular ejection fraction or prior myocardial infarction.[13] Patient-reported health status has demonstrated greater sensitivity in detecting significant changes in clinical practice and a superior ability to predict future clinical events in heart failure patients compared to the NYHA classification.[5] A meta-analysis of 43 studies indicated that higher HRQoL was associated with a reduced risk of death, with a hazard ratio of 0.633 (95% CI:

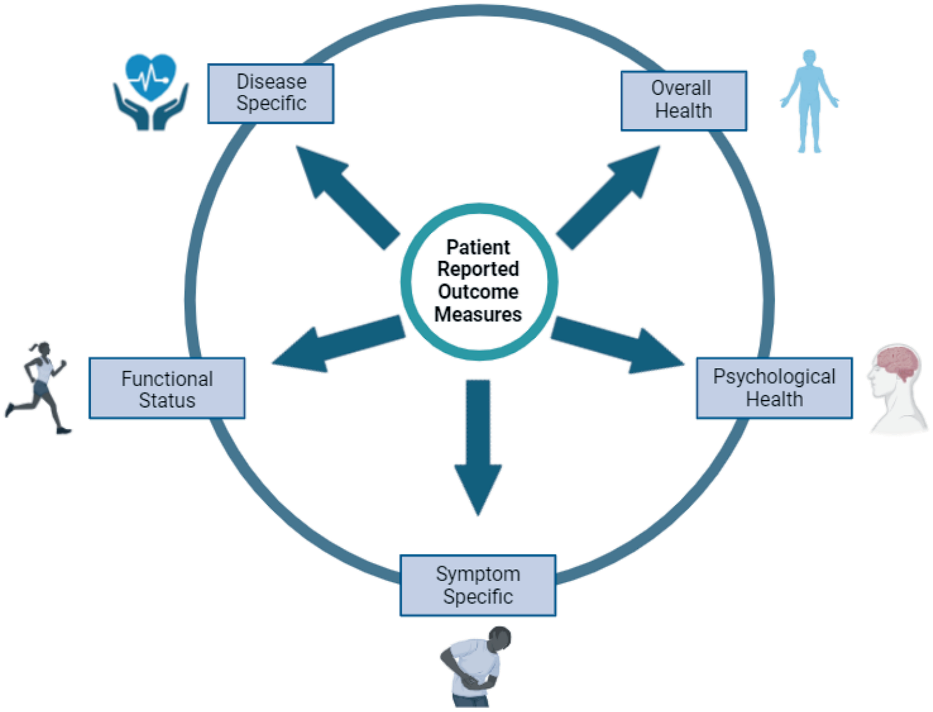

Figure 1. Categories of patient reported outcome measures. Patient reported outcome measures (PROMs) can be classified into those that assess overall health, psychological health, functional status and those that are symptom-specific or disease-specific. Specific examples for each category are listed in Table 1.

Table 1. Types of patient reported outcome measures.

Category of PROM	Description	Examples
Overall health	Overall assessment of health, capturing the broad impact of disease across physical, emotional, and social domains (*i.e.* Health related quality of life; HRQoL)	EQ-5D Short-Form Health Survey (SF-36) Short-Form Survey 12 (SF-12) PROMIS Profile-29
Psychological health	Focuses on the psychological aspects of health, such as anxiety, depression, or emotional distress.	Hospital anxiety and depression scale (HADS) Patient health questionnaire-9 (PHQ-9) Satisfaction with life scale (SWLS) Generalized anxiety disorder-7 (GAD-7)
Symptom specific	Focuses on specific symptoms experienced by the patient, such as pain or fatigue.	Brief pain inventory (BPI) Fatigue severity scale (FSS)
Functional status	Assesses the impact of a disease on a patient's ability to perform everyday activities.	Ability to wash oneself Ability to walk 4 meters
Disease specific	Measures designed to assess the impact of a specific disease on a patient's health and daily life.	Heart failure - Kansas City cardiomyopathy questionnaire (KCCQ-12) - Minnesota living with heart failure questionnaire (MLHFQ) Coronary artery disease - Seattle angina questionnaire Cancer - BREAST-Q - Functional assessment of cancer therapy–general (FACT-G) Chronic kidney disease - 36-item kidney disease quality of Life (KDQOL-36) Asthma - Asthma control test (ACT) Neurological diseases - Quality of life in neurological disorders (Neuro-QoL)

PROM, patient reported outcome.

0.514 to 0.780).[1] In patients with pre-terminal cancer, the self-reported ability to walk 4 meters and wash oneself were independent predictors of survival, with a hazards ratio of 0.63 (p=0.015) and 0.67 (p=0.024) respectively.[11] Another study found that pain or discomfort significantly predicted rehospitalization in patients with chronic obstructive pulmonary disease who had been hospitalized for pneumonia.[15] Furthermore, patients in the middle and highest tertiles of health-related quality of life (HRQoL) exhibited a reduced 180-day mortality risk compared to those in the lowest tertile, further underscoring the strong correlation between patient-reported outcomes (PROs) and survival in chronic diseases, particularly cardiovascular disease.

Hence, PROs play a significant role in assessing health status, promoting patient-centered care, and improving health outcomes in patients with cardiovascular diseases. Hence, these metrics should be prioritized during both clinical trial design and therapeutic strategies in the management of these patients.

Contributions

All authors made a substantive intellectual contribution, read and approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

Conflict of interest

The authors have no conflict of interest to report.

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