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A conceptual definition of quality of life with a left ventricular assist device: Results from a qualitative study

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ABSTRACT

Objective: To develop a conceptual definition of quality of life (QoL) with a left ventricular assist device (LVAD).
Background: Conceptual and operational definitions of QoL with an LVAD are lacking.
Methods: A grounded theory method was used. Adult, outpatient LVAD recipients ($n = 11$) participated twice in individual or paired interviews.
Results: A conceptual definition of QoL while living with an LVAD was established as: "Being well enough to do and enjoy day-to-day activities that are important to me." Participants described 5 important life domains consistent with QoL literature: physical, emotional, social, cognitive, and spiritual/meaning. However, participants identified unique concerns not addressed by generic or heart failure disease specific measures typically used in the LVAD population.
Conclusion: Existing generic and heart-failure specific QoL measures are not adequate for understanding QoL among LVAD patients. Cognition and spiritual/meaning domains were significant; these need inclusion for comprehensive QoL assessment in the LVAD population.

Introduction

Despite advancements in clinical care, the number of people in the U.S. with heart failure has risen to 5.1 million.[1] As a result, increasing numbers of patients are receiving a left-ventricular assist device (LVAD). The LVAD has evolved since the 1980s to serve three types of patient groups with advanced heart failure (New York Heart Association Class III to IV):

- Bridge to transplant (BTT): patients awaiting a heart transplant
- Bridge to recovery (BTR): patients who regain myocardial function after LVAD
- Destination therapy (DT): patients who are not candidates for a transplant due to advanced age or other exclusion criteria.[2]

Patients who undergo LVAD placement may have very positive outcomes including improved breathing and increased activity tolerance.[3,4] However, adverse outcomes may include thrombosis, bleeding, infection, right heart failure, device malfunction and death. Additionally, patients with an LVAD experience significant life style modification including not being allowed to tub-bathe or swim.[5,6] Patients must learn to live with a controller device (microprocessor or computer) attached to their waistband and be connected to batteries. Thus, significant changes in quality of life (QoL) – potentially positive and negative – can be anticipated. QoL among patients with an LVAD is an emerging field that needs a valid conceptual definition and consistent terminology, both of which can contribute to improved validity and comprehensiveness in operational measurement.

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Review of literature

Defining and measuring quality of life among patients with LVADs

Phenomenal growth has occurred in the past three decades in recognizing the importance of evaluating QoL from the cardiovascular patient's perspective. However, studies measuring QoL are often reported without consistent terminology and are often lacking a conceptual definition of QoL. This is problematic, particularly when new cardiovascular patient populations are being studied, such as LVAD recipients. Researchers are often unaware of the conceptual underpinnings of the measurement tool they selected for use. This can result in poor validity as well as lack of comprehensiveness when measuring QoL in a new patient population.

The term patient reported outcomes (PROs) provides an umbrella category to encompass the various subjective measures being used in health care assessment. Because this term is available, the specific term QoL should be reserved for study outcomes in which at least three domains (major dimensions) of life have been evaluated (e.g., physical, social, emotional).[7] Alternatively, the more narrow term health-related quality of life (HRQL) is used to describe measurement of characteristics most likely to be affected by health status.[8] Recently, some researchers have used the term subjective health status interchangeably with HRQL, such as the authors of the Kansas City Cardiomyopathy Questionnaire (KCCQ).[9]

Because there is no disease-specific QoL measure for the LVAD population, investigators may take a combination of different approaches to measurement. Some investigators use generic health status measures (not designed specifically for heart failure population or LVAD patients). Two examples of generic health status measures used among LVAD patients are the EuroQol[10] and SF-36.[11] While generic health status instruments may lack sensitivity to detect changes in particular concerns, they are helpful in providing gross comparisons across patient populations.

Alternatively, investigators may use disease-specific measures originally designed for patients with heart failure, such as the Minnesota Living with Heart Failure (MLHFQ)[12] and the Kansas City Cardiomyopathy Questionnaire (KCCQ)[9]; both are well-published and validated measures for patients with heart failure. The MLHFQ provides a global measure that strives to provide a more comprehensive summary of overall QoL (including concerns such as finances and intimacy). In contrast, the KCCQ provides a subjective health status pertaining to areas most likely to be affected by heart failure (focused more on physical and role functioning); it is referred to by the authors as HRQL or subjective health status.[9] While these measures are sound PROs for patients with heart failure, without being supplemented or replaced by LVAD-specific measures, they cannot be expected to address LVAD patient concerns such as reliance on batteries to survive, a drive-line exiting from the abdomen, and regular dressing changes.

Patients with an LVAD have unique QoL concerns that, to date, have received relatively little study; it is important to understand QoL from the perspective of the patients' themselves before assuming that an operationalized measure for heart failure provides valid and comprehensive reflection. By first clarifying the conceptual definition of QoL for a specific patient group, investigators can increase validity for the method of operationalized measurement in their research.

Not all researchers reporting PRO outcomes among LVAD patients cite their conceptual definition, as noted in recent LVAD studies[13,14] requiring readers to deduce the concept from the measurement tools used.[15] This may not be an easy feat as the tools themselves may lack a succinct conceptual definition, requiring the reader to explicate one by reading the categories of questions asked in the measure.

Past studies on quality of life in patients with VADs

Initial studies of patients with an LVAD focused on morbidity and mortality.[16,17] As evolving technology and care contributed to better outcomes, investigators have included PROs[18,19] such as subjective health status or QoL.[3,4,20,21]

Recently, two systematic reviews identified studies of QoL among LVAD patients and identified several measurement gaps. MacIver and Ross[22] reported that while overall QoL was reported as improved, several aspects have not received adequate assessment including emotional distress, cognitive function, sleep disruption, sexual activity, driving restrictions, and end of life issues. Brouwers et al[23] reviewed PROs among LVAD patients and concluded there was a paucity of studies from the patient perspective and that further study was needed to identify the psychosocial impact of LVAD therapy. Increased understanding from patient perspective can help clinicians identify whether LVAD therapy is concurrent with patient specific goals. Further, Brouwers et al[23] advocated for clinicians to increase their focus on the coping abilities and health status of LVAD patients rather than focusing primarily on survival and stabilization after LVAD placement.

Thus, while heart failure and generic measures have demonstrated post-operative improvements in heart failure symptoms, use of these measures alone may miss aspects of life uniquely experienced by a patient with an LVAD. Therefore, it is important in QoL research to provide both conceptual and operational definitions for QoL and validate measures when used in a new patient population[24]; this foundational work has received very little attention in the LVAD population and can help the researcher decide on the appropriate measure or combination of measures.

Purpose

This paper reports findings from adult outpatients ($n = 11$) who participated twice in individual or paired interviews in order to describe QoL in the context of living with an LVAD. Thus, the present study presents findings including a conceptual definition of QoL, identification, and development of five domains important to this unique population.

Methods

Design

A qualitative methodology was most appropriate due to lack of a conceptual definition and few related studies. Qualitative research in health care a) is important to facilitate a deeper understanding of day-to-day living with illness,[25] b) has been used among heart transplant patients to yield information unobserved by quantitative instruments,[26] and c) can provide baseline validity for development of quantitative measures.[27] Grounded theory methodology was the most appropriate means to fulfill the study's goal.[28,29]

Sampling and recruitment

In order to identify participants believed to be best suited for conceptualization of QoL in the LVAD population, a purposeful, theoretical sampling of LVAD outpatients from a large heart center in the Midwest was utilized. Inclusion criteria were broad: all adult outpatients with an LVAD were invited to participate. Exclusion criteria included those who could not speak, or could not speak English. To facilitate recruitment, LVAD clinicians from the heart center used informational flyers and personal invitations. Participants were added until data saturation occurred, meaning that no new data or themes were obtained and redundancy was achieved.