



ORIGINAL CLINICAL SCIENCE

Development and validation of a patient-centered knowledge scale for left ventricular assist device placement

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BACKGROUND: A central tenet of patient-centered health care advocated by the Institute of Medicine and the American Medical Association is to enhance informed decision-making in a way that incorporates patient values, knowledge and beliefs. Achievement of this goal is constrained by a lack of validated measures of patients' knowledge needs.

METHODS: In this study we present a comprehensive and valid methodology for developing a clinically informed and patient-centered measure of knowledge about left ventricular assist device (LVAD) therapy to facilitate discussion and measure candidate understanding of treatment options. Using structured interviews with patients, caregivers, candidates for LVAD treatment (New York Heart Association Class III and IV) and expert clinicians ($n = 71$), we identified top patient decisional needs and perspectives on essential knowledge needs for informed decision-making. From this list, we generated 20 knowledge scale question items to refine in cognitive interviews ($n = 5$) with patients and patient consultants.

RESULTS: Good internal consistency and reliability of the knowledge scale (Cronbach's $\alpha = 0.81$) was seen in 30 LVAD patients and candidates. Knowledge was higher among patients currently with LVADs than candidates, regardless of receiving standard education (with education: 69.9 vs 50.1, adjusted $p = 0.02$; without education: 69.9 vs 37.6, adjusted $p < 0.001$).

CONCLUSION: The LVAD knowledge scale may be useful in clinical settings to identify gaps in knowledge among patient candidates considering LVAD treatment, and to better tailor education and discussion with patients and their caregivers, and to enhance informed decision-making before treatment decisions are made.

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Left ventricular assist devices (LVADs) have become an increasingly effective treatment for advanced heart failure (HF), with the number of potential LVAD candidates estimated at about 250,000 to 300,000 individuals per year in the United States alone.¹ Although LVAD treatment can be a promising option for improving longevity and quality

of life, many LVAD candidates have made decisions about their LVAD treatment quickly and reflexively, often before education is complete.^{2,3} Some even make decisions to decline LVAD treatment before receiving full education about potential lifestyle changes and complications.⁴ According to international mechanical circulatory support guidelines,⁵ patients should also be trained in proper self-care as part of their education. Nevertheless, a large percentage of patients receiving treatment for HF have no documentation of having received adequate education about factors affecting outcomes and risk for rehospitalization,⁶ showing a lack of emphasis on patient education. Perhaps of greater concern, patients report a lack of clarity about how LVADs impact (or do not impact) the likelihood of receiving a heart transplant, suggesting a lack of understanding or appreciation of key aspects related to LVAD decision-making.²

Although most LVAD programs have patient education programs in place during the time of consent, no standardized tools yet exist for ensuring informed decision-making among candidates for LVAD treatment.⁷ One noteworthy LVAD knowledge measure has been developed by Edlund et al⁸ to explore patients' understanding of LVAD therapy. However, their open-ended question format makes it difficult to unambiguously gauge the degree of knowledge comprehension necessary to make an informed decision about LVAD surgery.

Rizzieri et al⁷ called for more consistent discussions and assessments among LVAD candidates to ensure understanding of treatment options for advanced HF, including anticipated device-related complications and long-term health risks (e.g., bleeding, stroke, infection); lifestyle changes among patients and caregivers (drive-line maintenance behaviors, leisure and travel limitations, etc.); potential financial burdens; and alternative options, such as medical management, and comfort-directed therapies, such as palliative care. Greater knowledge about treatment options has been shown to reduce anxiety and improve decision-making.⁹ However, so far, no robust measures have been developed to facilitate discussion and measure LVAD candidate understanding, a key component of the informed consent process. We used a patient-centered approach with current LVAD patients and candidates for LVAD treatment to develop and refine a measure of patient knowledge about LVAD therapy. Patients may use this tool to gauge their understanding of treatment options, and health-care providers (e.g., cardiologists, cardiothoracic surgeons and clinic coordinators) may use this scale as a tool to help identify strengths and gaps in knowledge during the course of patient decision-making (pre-implant) about LVAD and alternative therapies. The scale can also help providers to tailor education and discussion with patients and their caregivers, and well to enhance informed consent before decisions for treatment are made.

Methods

Framework

Our methodology for scale development and validation is based on best practices outlined by Brod et al¹⁰ for inductive development of

scale items using qualitative methods that involves interview research, developing the interview discussion guide, reaching saturation, analysis of data, developing a theoretical model and generating question items. Based on these guidelines, we used the Ottawa Decision Support Framework (ODSF) as a guiding theoretical model, an evidence-based, mid-range theory for guiding patients to make health decisions, incorporating insights on decision-making from general psychology,¹¹ social psychology,¹² decision analysis,¹³ decisional conflict,¹⁴ social support^{15,16} and economic concepts of expectations and values.¹⁷ The framework emphasizes the centrality of assessing client and practitioner determinants of decisions to identify decision support needs, while providing decision support tailored to client needs. This model was used because of the importance of identifying decision support needs as a basis for constructing a knowledge measure. Our methodological approach combined inductive qualitative methods (open-ended interviews, free-listing and ranking exercises, described in what follows) with deductive quantitative validation of scale items through cognitive testing and psychometric analysis to assess content and face validity.

Sample and setting

Each phase of this research was conducted with a purposive sample of participants at a partnering site chosen to provide a wide range of variation and to reflect demographics of the larger LVAD population according to the latest data from the Interagency Registry for Mechanical Circulatory Support (INTERMACS).¹⁸ For all phases of this research, patient eligibility criteria included LVAD patients and candidates with advanced heart failure (New York Heart Association [NYHA] Class III and IV), age range of 30 to 80 years (this range was selected to enhance our ability to capture a wide range of patient perspectives), and intact decision-making capacity, with an acceptable surgical risk-benefit ratio for LVAD implantation. Patients were also screened by a transplant social worker for good psychosocial support, coping mechanisms and sufficient financial resources. Patients were also administered the Montreal Cognitive Assessment (MOCA)¹⁹ test as a screening measure to detect cognitive impairments, including "vascular dementia," or an overall lack in decision-making capacity that may interfere with individuals' ability to participate in the study. This scale has been validated for use among 30- to 80-year-olds, and has excellent reliability. For each of the phases, we took a separate subsample from the overall participant population described earlier.

In-depth interviews and ranking exercises to generate items

In-depth interviews were conducted with: LVAD patients; eligible candidates for LVAD treatment; caregivers; decliners of LVAD treatment; and leading LVAD clinical providers from 2 different hospitals, including cardiologists, cardiothoracic surgeons, LVAD (nurse and physician assistant) clinical coordinators, hospital financial advisors, lead clinical social workers and clinical bioethicists. Consistent with the definition provided by the Centers for Medicare and Medicaid Services, caregivers are defined as family members, friends or neighbors who provide unpaid assistance to a person with a chronic illness or disabling condition. We add that these caregivers are identified by the patient as a primary resource for daily, post-implant assistance with lifestyle changes and device management. Structured guides for in-depth interviews were developed from the authors' prior knowledge of domains and areas of interest, literature review of decisional needs

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