Putting Life in the Years
Incorporating Quality of Life Into Left Ventricular Assist Devices Outcomes

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The important thing is not how many years in your life, but how much life in your years.

—Edward J. Stieglitz, MD

Durable left ventricular assist devices (LVADs) are now the most widely used surgical therapy for end-stage systolic heart failure. Current-generation LVADs have been proven in clinical trials to extend survival and improve quality of life, but these devices continue to be saddled with unacceptably high adverse events rates. Despite remarkable progress over the past decade, over two thirds of registered mechanical support recipients experience bleeding, infection, device malfunction, stroke, or death within the first year after implant. Anticipating which patients will experience an adverse event after LVAD remains challenging given the stochastic nature of device-related complications. Those patients in whom an LVAD would be lifelong destination therapy are the largest segment of the heart failure population undergoing consideration for mechanical support. Older LVAD recipients or those with a greater burden of comorbidities have no bailout option in the form of cardiac transplantation to rescue them from the complications of mechanical support. Some recipients may be left with residual frailty not responsive to mechanical support despite a successful implant. Given the potential for extended longevity after LVAD coupled with competing risks, lingering uncertainties, and the burden of living with mechanical support, a framework of patient-provider shared decision making has been encouraged to incorporate the patient’s perspectives, values, and priorities.

See Article by Arnold et al

Patients with heart failure have consistently indicated that quality of life is at least as important to them as survival when considering LVAD support. Systematic health-related quality of life (HRQOL) assessment is essential to defining more clearly the benefit of mechanical support and generating reasonable expectations for those considering LVAD therapy. The acknowledged importance of patient-centered outcome assessment is reflected in the requirement of serial HRQOL collection in a nationally audited registry to be certified as a destination therapy center by the Joint Commission. HRQOL can be measured either by generic instruments that provide a broad overview to allow comparison of chronic illness across populations or by disease-specific questionnaires with domains relevant for a given condition. Two instruments—the Kansas City Cardiomyopathy Questionnaire (KCCQ) and Minnesota Living with Heart Failure Questionnaire—target HRQOL relevant to the heart failure disease state and have been proven to be valid and reliable. These instruments are considered to be benchmarks for understanding HRQOL before and after LVAD implant given the absence of a HRQOL specific to mechanical circulatory support. Despite increasing sophistication and prevalence of HRQOL assessment, notable gaps remain in our ability to facilitate patient-centered shared decision making because of uncertainties about how best to use these HRQOL data. There has been vigorous debate about when and how to collect HRQOL, how to leverage this information to guide decision making, and how to integrate quality of life with other outcome measures.

The article by Arnold et al in this issue of Circulation: Heart Failure is a timely and important addition to the literature on HRQOL after mechanical support. The study cohort consisted of 1638 destination therapy LVAD recipients implanted in 2012 to 2013 and registered in the Interagency Registry for Mechanically Assisted Circulatory Support, a prospective observational registry of approved mechanical circulatory support devices in the United States. The primary outcome measure was the combined risk of death or persistently poor quality of life at 1 year, as defined by an average score of <45 on the 23-item self-administered KCCQ instrument assessed at 3, 6, and 12 months after implant. The KCCQ generates a score ranging from 0 to 100, with a lower score representing worse heart failure-specific HRQOL, and a score of <45 generally considered to be consistent with poor HRQOL. In this study, 29.7% of destination therapy LVAD recipients had a poor outcome 1 year after implant, with death in 22.4% and persistently poor HRQOL in another 7.3%. Factors associated with poor outcome included higher body mass index, anemia, previous cardiac surgery, cancer history, severe diabetes mellitus, and poor preimplant HRQOL. The authors took appropriate care to integrate serial HRQOL measurements over time given the potential for temporary dips in quality and took measures to reduce selection bias from missing KCCQ data. Of note, these findings should not be generalized to LVAD recipients in Interagency Registry for Mechanically Assisted Circulatory Support Profiles 5 to 7 or...
to those patients listed or likely to be listed for transplant. The frequency of poor combined outcome and prevalence of poor HRQOL also cannot be extrapolated beyond 1 year given the short time-horizon in the study, despite the anticipated need for lifelong LVAD support in this population.

Several key implications that may be helpful to clinicians emerge from this article. Based on this analysis, ≈1 in 13 destination therapy LVAD recipients are likely to face a persistently poor heart failure–specific HRQOL through 1 year after implant. This may be related to right heart dysfunction unaddressed by left-sided support, residual fraility, or poor HRQOL unrelated to heart failure but nevertheless captured by the KCCQ. At the time of shared decision making about LVAD, the risk of persistently poor quality of life should be emphasized to temper any unrealistic expectations. It is fair to say we do not yet know the optimum way to convey quality of life information to patients confronted with the decision to proceed with LVAD. Fortunately, varying modes of decision support, including decision aids that include quality of life, are undergoing active investigation in the multicentered DECIDE-LVAD study (Multicenter Trial of a Shared Decision Support Intervention for Patients and Their Caregivers Offered Destination Therapy for End-stage Heart Failure) of patients considering destination therapy.15 The study by Arnold et al16 promotes the use of a combined outcome incorporating both quality and survival, which was first explored in hospitalized patients with heart failure to identify those at risk for poor future HRQOL.17 A novel combined end point incorporating quality of life could help us better communicate prognosis and could even serve as end point for future studies.

What is the best tool for assessing overall quality of life after LVAD? KCCQ captures multiple dimensions of the patient experience including heart failure symptoms, functional and social limitations, satisfaction with therapy, and quality of life. The KCCQ has been robustly validated for heart failure–related HRQOL, yet may overestimate HRQOL after LVAD given the contribution of adverse events unrelated to heart failure to poor quality of life. The impact of infection, bleeding, device malfunction, or stroke on quality of life may not be captured with adequate fidelity by an instrument validated exclusively for heart failure. A generic HRQOL instrument such as the EuroQOL-5D encapsulates a wider view of HRQOL to enable comparisons before and after LVAD.18 The alignment of current and anticipated HRQOL with medical and device therapy—the central choice facing patients considering LVAD—may be more appropriate with a generic instrument such as the EuroQOL, which is also collected in Interagency Registry for Mechanically Assisted Circulatory Support.19 The EuroQOL-5D with visual analog scale is shorter to administer than KCCQ although there is now an abbreviated 13-item KCCQ instrument available.15 Generic HRQOL instruments, such as the EuroQOL-5D index score, can also facilitate time trade-off and cost-utility analyses, which will be critical in shaping health policy decisions for this expensive therapy.16 It should emphasized that generic instruments for HRQOL have important limitations. They may be less sensitive to change over time than disease-specific instruments and, in their simplicity, may fail to capture adequately the burden of symptoms most relevant to patients living with chronic heart failure, symptoms that dominate LVAD decisions. We urgently need additional robust comparisons of the performance characteristics of generic versus heart failure–specific HRQOL instruments in advanced heart failure to optimize these tools for use in LVAD decision making and in assessment of comparative effectiveness.

If promising improvements in device technology translate into lower adverse event rates and improved quality of life, thresholds for considering LVAD therapy in advanced heart failure will be lowered.17 Ambulatory patients with advanced systolic heart failure on oral medical therapy will increasingly be considered for elective LVAD therapy. As LVAD use expands into the less sick advanced heart failure population, the challenge and importance of integrating HRQOL into decision making will only grow. Current decisions surrounding LVAD deployment in ambulatory patients are seriously constrained by the lack of robust information on expected outcomes in terms of both survival and quality of life in patients on oral medical therapy. Indeed, poor HRQOL on medical therapy may itself be an important trigger for earlier ambulatory LVAD implant.18 For the less sick ambulatory population of patients with advanced heart failure in whom death is not imminent, shared decision making about LVAD will require a more measured and individualized consideration of risks and benefits. Novel decision aids will need to be assembled integrating anticipated downstream quality of life, adverse events, and survival based on a given patient’s level of illness and relevant comorbidities at the time LVAD is considered. Invaluable repositories like Interagency Registry for Mechanically Assisted Circulatory Support will make the derivation of these tailored decision tools possible. By incorporating the values, goals, and preferences of patients, the field of mechanical circulatory support is poised to realize the 21st century vision of patient-centered care. Together, we can harness the patient perspective to define more clearly and realistically those most likely to live long and prosper with mechanical circulatory support.

Disclosures

Dr Stewart is co-principal investigator of the REVIVAL study (Registry Evaluation for Vital Information for VADs in Ambulatory Life), sponsored by the National Heart Lung and Blood Institute.

References

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**Key Words:** Editorials ■ diabetes mellitus ■ heart failure ■ outcomes assessment ■ quality of life ■ stroke