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Patient-Centered Care for Left Ventricular Assist Device Therapy: Current Challenges and Future Directions

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Abstract

Purpose of review—Discuss the current status and obstacles that need to be overcome in the future to provide patient-centered care with left ventricular assist device (LVAD) therapy.

Recent findings—LVADs offer both longer survival and improvements in quality of life for carefully selected patients with inotrope-dependent heart failure (HF). Yet, this technology does not come without significant risk of adverse effects and burdens. Recent observational data comparing LVAD to medical therapy in ambulatory, non-inotrope dependent patients with advanced HF suggest that survival may be similar and changes in quality of life may depend on baseline status. As both LVAD technology and medical therapy continue to evolve, there are many unanswered questions regarding the benefits, risks, and burdens of LVAD therapies in less severe HF populations.

Summary—Further research is needed to ensure the optimal delivery of LVAD therapy including improved patient selection, implantation timing, device type, and decision support.

Keywords

Heart failure; LVAD; mechanical circulatory support; decision-making

Introduction

Left ventricular assist device (LVAD) therapy is an increasingly utilized treatment for select patients with end-stage heart failure (HF). While LVAD therapy has the potential to improve survival and quality of life, patients, and their families must weigh the trade-offs related to the numerous potential complications and burdens related to this therapy. The Institute of Medicine defines patient-centered care as “providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.”¹ Providing patient-centered care specifically in the realm of LVAD therapy requires that we 1) understand the short and long-term risks and benefits of LVAD therapy among broad populations of patients, 2) understand how to optimally deliver LVAD therapy including appropriate patient selection, implantation timing, choice of device type and settings, and concomitant medical therapy, and 3) individualize the risk/benefit profile of LVAD therapy to individual patients who are considering this treatment and can effectively

communicate the complexities of these individualized risks and benefits to patients and their caregivers. In this review, we highlight the current state of knowledge in each of these domains and comment on the key unanswered questions that are needed to allow the advanced HF community to provide truly patient-centered LVAD therapy.

Risks and Benefits of LVAD Therapy—Current Knowledge and Knowledge Gaps

Next generation LVADs are engineered with non-pulsatile, rotary designs that allow for smaller profiles with improved durability. Currently approved continuous-flow (CF) LVADs proved superior to pulsatile LVADs in terms of survival, durability, and rate of adverse events in both BTT and DT populations.^{2–4} However, the clinical trials that established the superiority of CF LVADs were limited to select patients with a limited follow-up time of approximately 2 years.^{4–8}

The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) registry has provided longer-term, real-world outcomes data. Since the approval of the first CF LVAD in April 2008, overall actuarial survival rates for CF LVADs have been 80% at 1 year, 70% at 2 years, 59% at 3 years, and 47% at 4 years.^{9,10} Recent data from INTERMACS suggest that the DT population has actuarial survival rates of 76% at 1 year and 57% at 3 years,¹⁰ but longer-term outcome data are needed. Current generation devices also improve functional status and quality of life metrics.^{7*}

However, individual patients must weigh these potential benefits against the potential for numerous adverse events and lifestyle changes. In a recent systematic review, adverse event rates in the year following DT LVAD implantation were 55% for rehospitalization, 30% for major bleeding, 10% for disabling stroke, 20% for device-related infection, 5% for device malfunction, and 18% for persistent HF requiring inotrope therapy or additional mechanical circulatory support. This cumulative 1 year risk/benefit profile is presented in a simplified pictogram to aid patients as they are facing the decision about DT LVAD (**Figure 1**).^{7*}

A major limitation in our current knowledge base regarding the complex trade-offs of LVAD therapy is that the long-term risks and benefits are rarely stratified by indication or other important patient factors. BTT and DT patients have been combined in studies with longer follow-up periods while the survival outcomes are likely different among these types of patients.^{10,11} In addition, many single center reports have small numbers of patients with incomplete baseline characteristics, inconsistent definitions of adverse events, and variable follow-up periods which make it impossible to pool data to get a more accurate estimate of rates of complications. In order to provide tailored estimates of risks and benefits, larger studies with longer follow-up periods, clearly defined baseline patient characteristics, and standardized definitions of adverse events are needed. For the DT population in particular—who are faced with life with a LVAD without the bailout of transplantation—we currently may be underestimating their individualized risks compared to benefits as most literature relies on data largely obtained from healthier BTT populations.¹²

The Who, What, When, Why, and How of Optimal Delivery of LVAD Therapy—More Questions Than Answers

Who and When—Patient Selection

The optimal delivery of LVAD therapy—including appropriate patient selection, implantation timing, device type and settings, and concomitant medical therapy—is largely unknown, but certainly has important implications for individual patients.

In the realm of patient selection, the INTERMACS patient profiles serve as a reference for categorizing patients. Lower (worse) INTERMACS profiles are associated with small increases in mortality after LVAD implantation, and large increases in mortality without LVAD. Specifically, for patients categorized as INTERMACS profile 1 (“crash and burn” with critical organ hypoperfusion), outcomes with medical therapy are abysmal but risk with chronic durable LVAD therapy is also relatively high, such that most centers have shifted towards temporary forms of MCS to first assess whether these patients can resolve multi-organ failure and recover to a lower INTERMACS profile prior to durable LVAD implantation.^{5,13,14} For patients categorized as INTERMACS profiles 2-3 (inotrope dependent) multiple studies have clearly demonstrated superior outcomes with chronic durable LVAD vs. medical therapy^{15–18}, and patients falling into these profiles currently account for the largest proportion of patients currently receiving LVAD therapy¹⁰.

By contrast, our current state of knowledge is considerably more limited for the large group of HF patients that fall into INTERMACS profiles 4-7 (ambulatory, non-inotrope dependent patients with advanced HF). The recently published Risk Assessment and Comparative Effectiveness of LVAD and Medical Management in Ambulatory HF Patients (ROADMAP) study was a non-randomized, prospective, observational study of patients in INTERMACS profiles 4-7 that illustrates the current clinical dilemma regarding the appropriate timing of LVAD therapy in this cohort of patients. Based on a composite primary endpoint of survival on original therapy with improvement in 6-minute walk distance of >75 meters at 12 months, the authors concluded that early LVAD implantation was superior to ongoing medical therapy. The early LVAD group also showed greater improvements in quality of life and depression scores. However, there were no differences in survival based on intention-to-treat analysis (mortality was 20% versus 21% at 12 months) and a substantially higher number of adverse events and hospitalizations occurred in the LVAD therapy arm.^{19**} Furthermore, the improvements in quality of life, walk distance, and depression were greater in the LVAD group at least in part because patients selecting early LVAD implantation started with lower scores for all of these measures and thus had more room for improvement. Overall, ROADMAP suggests that movement of current generation LVAD devices upstream in the HF disease process creates a highly preference sensitive medical decision, where survival appears to be more equivalent between early versus deferred LVAD therapy and patients must seriously consider whether their current quality of life is diminished enough to take on the risks of major surgery and possible device complications. Additional observational data defining the outcomes of ambulatory non-inotrope dependent patients that fall into INTERMACS profiles 4-7 is currently being collected in the ongoing Medical Arm of Mechanically Assisted Circulatory Support (MEDAMACS) registry and the Registry

Evaluation of Vital Information for VADs in Ambulatory Life (REVIVAL) study. Ultimately randomized, controlled data assessing a wide range of patient-centered outcomes is needed in the INTERMACS 4-7 population.

What, Why, and How—LVAD Type, Device Settings, and Role for Concomitant Medical Therapy

In order to improve durability and minimize complications, technological advances in LVAD pump design resulted in CF LVADs that have now completely replaced older pulsatile-flow LVADs. However, there may be unintended consequences of alterations in the flow patterns and differences between the types of LVAD related mechanical unloading that warrant further investigation.

Compared to first-generation pulsatile pumps, CF LVADS provide a lesser degree of left ventricular unloading as assessed by echocardiography, invasive hemodynamics, as well as circulating natriuretic peptide levels.²⁰ Compared to second-generation axial flow CF LVAD designs (HeartMate II), third-generation centrifugal CF LVADs (HeartWare HVAD and HeartMate III) are more sensitive to pump-head pressure (afterload minus preload) and thus will see lower flow rates and less left ventricular unloading if systemic vascular resistance and volume status are not optimized.

CF LVADs, which rotate at thousands of rounds per minute, are associated with alterations in hematologic properties that may contribute to the adverse events of hemolysis, bleeding, and thrombosis.²¹ In addition, the long-term effects of non-pulsatile blood flow on end-organ and vascular function are unknown, but may contribute to patient outcomes while on chronic LVAD support. For example, CF LVADs have been found to alter cerebral auto-regulation of blood flow²², increase aortic vascular stiffness via alterations in vessel collagen and elastin content²³, and increase sympathetic nervous system activity²⁴. All of these findings in theory could contribute to the pathophysiology of CF LVAD related complications such as gastrointestinal bleeding, hypertension, and stroke. In addition, the effects of modulating the degree of pulsatility by adjusting pump settings or restoring intermittent pulsatility in LVAD pump technology warrants further investigation. The HeartMate III device is programmed to ramp up the rotor speed by 2000 rotations per minute (rpm) then down by 4000 rpm then back up 2000 rpm to the set speed over 0.3 seconds every 2 seconds, creating an artificial pulse pressure 30 times per minute. Whether partial restoration of hemodynamic pulsatility will decrease CF LVAD complications and improve patient outcomes will be assessed in the Multi-center Study of MagLev Technology in Patients Undergoing MCS Therapy With HeartMate 3 (MOMENTUM 3), which plans to randomize 514 patients to the newer device versus 514 patients to Heart Mate II, and complete data collection in November 2018.²⁵

Finally, little is known about the role of concomitant medical therapy in LVAD patients. For example, it is unknown if LVAD patients should receive neurohormonal blockade to preserve right ventricular function, beta-blockers to limit arrhythmias, and renin-angiotensin-aldosterone system blockade to reduce vascular stiffness. Additional systematic studies looking at different devices, settings, and concomitant medical therapy are necessary to refine the optimal delivery of LVAD therapy.

Individualizing Risks and Benefits of LVAD Therapy

A major challenge to HF clinicians and patients contemplating LVAD therapy is trying to apply the risks and benefits from clinical trials and registries to an individual patient's unique characteristics and condition. Many of the large registries that report long-term outcomes have combined BTT and DT patients, making it difficult to apply this data to patients with extremes of age, varying comorbidity, and disparate social support.^{11,26,27} Similarly, current HF risk models predicting survival for patients on medical therapy, such as the Seattle HF Model and HF Survival Score, have limitations and should be interpreted cautiously in the patient considering advanced HF therapies.^{13,14,28} Furthermore, the majority of LVAD clinical trial and HF risk score data is derived from study population's made up of mostly Caucasian men with a significant under-representation from minorities and women.^{6,11,17} This may explain in part why the Seattle HF Model underestimates risks in African-Americans.²⁹ Larger clinical studies and registries that include and characterize a wide spectrum of patients including older patients with multi-morbidity, women, and patients with racial and ethnic diversity are needed to provide better point estimates of individual risk for all patients considering LVAD therapy. This can be inherently challenging in the face of rapidly evolving device technology, where long-term outcomes from large numbers of patients are outdated by the time such data can be accrued.

Finally, HF clinicians must take a serious look at whether LVAD therapy is being considered equitably. Women and racial/ethnic minorities have a high prevalence of HF³⁰, yet receive a disparagingly low percentage of LVADs.^{31,32} This has been hypothesized to be secondary to several issues including differing etiologies of HF, reduced referrals for advanced therapies, poor access to care, patient choice, provider bias, and poor candidacy for advanced therapies such as body size, comorbidities, insurance, and social support.^{28,32-35} Providers and policy makers should monitor practice patterns to ensure that equitable access and evaluation for advanced therapies is provided.

Communication of Individualized Risks and Benefits of LVAD Therapy

Advanced HF patients who are considering LVAD therapy are forced to confront a complex technology that has the potential to improve survival and quality of life but also comes with risks for numerous complications and burdens. Determination of the outcomes that matter most to patients may help direct individualized therapy since survival may not be the most important outcome for all patients.²⁸ Patients place differing value on quality of life (symptoms, physical function, mental, emotional, and social facets of life), avoidance of major surgery, and burdens of therapy (lifestyle changes, lost opportunities, dependence on an electric machine, direct medical costs, indirect costs, and caregiver burden).^{28,36,37} As LVAD therapy is increasingly considered for INTERMACS 4-7 patients, where early implantation of an LVAD does not appear to significantly change survival, sorting through the complex trade-offs of therapy becomes even more important for all patients. HF clinicians therefore must be able to 1) effectively inform patients and their families of the expected benefits, risks, and burdens of LVAD therapy compared to other management options (often including palliative care), 2) recognize the wide uncertainty for an individual

patient, 3) solicit patient values, goals, and preferences, and then 4) facilitate shared decision-making.

Family caregivers are particularly involved in LVAD therapy.^{14,28} The 2013 ISHLT Guidelines for MCS recommend that a caregiver and his/her burden be assessed during the selection process.¹⁴ Patient caregivers post LVAD often experience anxiety, guilt, depression, and increased sense of intimacy with the patient.^{38–40} It is the responsibility of clinicians to share the full spectrum of potential outcomes with the patient and caregiver(s).

Unfortunately, the most commonly utilized materials to inform patients about the risks and benefits of LVAD therapy have significant shortcomings.^{7*,41} Educational materials developed by industry tend to focus on the benefits of therapy while minimizing or omitting risks.⁴¹ Patient advocates currently supported with an LVAD have a tendency to be biased towards the benefits of LVAD therapy since patients with negative outcomes such as death or stroke are not available to communicate with patients considering LVAD therapy.⁴¹

Decision support tools that utilize pictographs and other novel formats to convey complex statistics can help clinicians provide patients with less biased risks/benefit profiles, clearly compare treatment options, and facilitate values clarification, all of which help lead to a well-informed decision (**Figure 2**).^{7*,28,42} One such multimedia LVAD decision support tool that follows the International Patient Decision Aid Standards is available for use for free at <https://patientdecisionaid.org>.⁴³ Its ability to enhance patient and caregiver knowledge, improve decision quality, and integrate into routine clinical care is currently being studied in the multi-center Trial of a Decision Support Intervention for Patients and Caregivers Offered Destination Therapy Heart Assist Device (DECIDE-LVAD).⁴⁴

Conclusions

Improvements in pump technology have resulted in better outcomes for advanced HF patients requiring LVAD therapy; however the potential for serious adverse events remains significant—necessitating a renewed focus on providing patient-centered care with this therapy. In order to achieve this goal, we must better understand the long-term risks and benefits of LVAD therapy in a broad population of patients including older patients who may not be candidates for transplant, women, minorities, and those with comorbidities. Furthermore, better information is needed regarding the optimal patient, timing, and type of LVAD on patient-centered outcomes such as survival, quality of life, hospitalizations, and adverse events. Finally, we must develop effective methods of tailoring and communicating the outcomes with LVAD therapy to individual patients and their families in a non-biased way that allows for informed and shared decision-making.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Key Points

- Left ventricular assist device (LVAD) therapy has the potential to improve survival and quality of life for patients with advanced heart failure (HF), but comes with a risk of numerous potential complications.
- There is a clear survival benefit of continuous flow (CF) LVAD therapy compared to optimal medical therapy among patients with inotrope-dependent advanced HF.
- There are unanswered questions regarding the role of LVAD therapy compared to medical therapy in ambulatory, non-inotrope dependent patients with advanced HF and this is a topic under active clinical investigation.
- Further research is needed to ensure the optimal delivery of LVAD therapy including appropriate patient selection, timing of implant, type of device and settings (CF vs. intermittently pulsatile), and the role of concomitant medical therapy.
- Decision support aids may help facilitate informed shared decision-making in LVAD therapy

Figure 1.
One-Year Benefits and Risks of LVAD Therapy
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Figure 2.

Development of LVAD decision aid materials that can help clinicians facilitate shared decision making between clinicians, patients, and their family caregivers.

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