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Global Outcome in Patients with Left Ventricular Assist Devices

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Abstract

LVADs improve survival and quality of life (QOL) for most, but not all, patients with advanced heart failure. We described a broader definition of poor outcomes post-LVAD, using a novel composite of death, QOL, and other major adverse events. We evaluated the frequency of poor global outcome at 1 year post-LVAD among 164 patients (86% INTERMACS Profile 1-2; shock or declining despite inotropes) at a high-volume center. Poor global outcome (comprising death, poor QOL [KCCQ <45], recurrent heart failure [≥ 2 heart failure readmissions], or severe stroke) occurred in 58 (35%) patients: 37 died, 17 had poor QOL, 3 had recurrent heart failure, and 1 had a severe stroke. Patients with poor global outcomes were more likely designated for destination therapy (46% vs. 24%, $p=0.01$), spent more days hospitalized per month alive (median [IQR], 18.6[5.0-31.0] vs. 3.7[1.8-8.3], $p<0.001$), and had higher intracranial (12% vs. 2%, $p=0.031$) and gastrointestinal (44% vs. 28%, $p=0.056$) hemorrhage rates over the year post-implant. While LVADs often improve survival and QOL, ~1/3 of high acuity patients experienced a poor global outcome over the year post-LVAD. In conclusion, composite outcomes may better capture events

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DISCLOSURES

Dr. Joseph has received minimal speaking honorarium from Thoratec and serves on the advisory board for Heartware.

Dr. Silvestry has served as a consultant for Thoratec and Heartware.

Dr. Spertus owns the copyright to the Kansas City Cardiomyopathy Questionnaire and has served as a consultant to Novartis and Janssen Pharmaceuticals.

Dr. Arnold has served on an advisory board for Novartis.

All remaining authors report no relevant disclosure

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that matter to patients with LVADs and thus support informed decisions about pursuing LVAD therapy.

Keywords

Heart failure; left ventricular assist device (LVAD); quality of life; cardiovascular outcomes

INTRODUCTION

Risk prediction for poor outcomes in patients receiving left ventricular assist devices (LVADs) has proven to be difficult.¹ Furthermore, previous risk models have focused on mortality.²⁻⁴ While mortality is, of course, an important outcome, it does not encompass all outcomes that matter most to patients. Improved quality of life may be an equally or even more important treatment goal to some patients with advanced heart failure, compared with merely extending quantity of life.⁵ Therefore, we sought to define a composite poor global outcome consisting of not only death, but also quality of life and other determinants of poor health status (symptoms, function and quality of life), and to describe the incidence of this poor global outcome in a contemporary population of patients with advanced heart failure who received LVAD therapy. This broader definition of poor outcomes can enable clearer communication between patients and clinicians and more informed patient decisions regarding this therapy.

METHODS

We retrospectively identified a cohort of patients who underwent implantation of a continuous flow LVAD at Barnes Jewish Hospital in Saint Louis, Missouri between January 2012 and October 2013 and had at least one year of follow-up. We excluded patients under age 18, intra-operative deaths, and patients who transferred follow-up care to another institution. Patient characteristics prior to device implantation during the index admission and clinical outcomes were obtained through review of the medical records and chart abstraction. Severity of heart failure prior to LVAD implantation was assessed clinically using the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profile system, wherein profiles 1 or 2 indicate cardiogenic shock with multi-organ failure and declining clinical status despite inotropes, respectively, while profiles 3 through 7 indicate more stable heart failure.⁶

Health status was assessed at 3 months, 6 months, and 1 year after LVAD during in-person visits using the Kansas City Cardiomyopathy Questionnaire (KCCQ), a well-validated measure of disease-specific quality of life in patients with heart failure.⁷ The KCCQ is a 23-item self-administered questionnaire that yields an overall summary scale with scores that range from 0 to 100. Lower scores indicate greater symptom burden, more functional limitation, and worse quality of life and have been shown to be associated with increased risks of mortality and readmission in patients with heart failure⁸ and in patients after LVAD.⁹ All data were collected and managed using REDCap, an electronic data capture tool hosted by Barnes Jewish Hospital.¹⁰ The study was reviewed and approved by the Washington

University of Saint Louis Institutional Review Board, and a waiver of informed consent was granted.

Poor global outcome was defined as a composite outcome comprising the occurrence of any of the following: death, poor quality of life, recurrent heart failure readmissions, and severe stroke. Poor quality of life was defined as a KCCQ overall summary score of <45 at the most recent follow-up, which has been shown to roughly correspond to New York Heart Association class IV heart failure symptoms in patients with heart failure.¹¹ To account for patients with poor quality of life but with missing KCCQ assessments, we also included recurrent heart failure and severe stroke in the composite outcome. Recurrent heart failure was defined as 2 or more readmissions with an admitting diagnosis of heart failure and was considered a poor global outcome as it represented either device, refractory left or right heart failure, all of which are associated with poor prognosis.^{12,13} Severe stroke was defined as a modified Rankin score of 4 (inability to attend to bodily needs alone; bedridden, requiring constant care; or death).¹⁴

Patients were tracked for major adverse events post-LVAD. Major gastrointestinal bleeding included clinically evident or severe non-hemolytic anemia requiring admission, transfusion or endoscopy. Non-severe stroke was defined as 1) an acute neurological deficit persisting 24 hours that did not meet criteria for severe stroke (i.e. modified Rankin score 3), or 2) an intracranial hemorrhage or ischemic stroke based solely on imaging. Suspected pump thrombosis was determined by visualized thrombus post-explant or serum lactate dehydrogenase >1,000 mg/dl.¹⁵ A driveline infection was defined as pain, erythema, or drainage that required antimicrobial treatment for 14 days.

Baseline characteristics were compared between patients with vs. without a poor global outcome using chi-squared tests for categorical variables and *t*-tests for continuous variables. In addition, to explore the contribution of common post-implant adverse events to the development of a poor global outcome, we used univariate statistics to compare aggregate length of stay (days in hospital per month alive) and rates of major gastrointestinal bleeding, non-disabling stroke, pump thrombosis or hemolysis, and driveline infection between those with vs. without poor global outcome. All statistical analyses were conducted using SAS v9.3 (SAS Institute Inc., Cary, NC), and statistical significance was determined by a 2-sided *p*-value of <0.05. Due to the exploratory nature of these analyses, no adjustments were made for multiple comparisons.

RESULTS

There were 168 patients with advanced heart failure who received continuous flow LVADs at Barnes Jewish Hospital in St. Louis, Missouri from January 2012 through October 2013. We excluded 2 patients who were under age 18, 1 patient who died intra-operatively before LVAD implantation, and 1 patient who followed up at a different institution. Our final analytic cohort was comprised of 164 patients who received durable LVADs and were followed clinically for at least 1 year. Of note, KCCQ follow-up assessments were missing in 76 patients (46%); missingness was more common in patients with vs. without poor outcome (60% vs. 39%, *p*=0.007). Mean age ($\pm$ standard deviation, [SD]) of the cohort was

55.9±12.8 years, 79% were male, and 77% were white. Prior to implant, 86% were INTERMACS profiles 1 or 2, and 65% of patients received their LVAD as a planned bridge to heart transplant.

Of the 164 eligible patients who received an LVAD, 58 (35%) experienced poor global outcome over the following year. Death was the most frequent even among those with a poor outcome, in 37 patients (23%). Seventeen patients (10%) had poor quality of life, 3 (2%) experienced recurrent heart failure, and 1 (1%) had a severe stroke (Figure 1). Among the 37 patients who died, 8 patients (22%) had another component of poor global outcome before death (6 patients had severe stroke, 1 had poor quality of life, and 1 had recurrent heart failure).

The baseline characteristics of those with vs. without poor global outcome are shown in Table 1. In general, patients with poor global outcome were similar to those without poor global outcome in regard to demographics, pre-existing conditions and INTERMACS profiles. However, patients with a poor global outcome were more likely to have had their LVAD implanted as destination therapy (with vs. without poor outcome: 46% vs. 24%, $p=0.010$).

Patients with poor global outcome had a greater burden of aggregate days spent in the hospital in the year after LVAD implantation (with vs. without poor outcome: median [interquartile range], 18.6 [5.0, 31.0] vs. 3.7[1.8, 8.3], $p<0.001$; Table 2). Although the rates of non-severe stroke were similar between groups (12% vs. 5%, $p=0.125$), when broken into subtypes of stroke, patients with a poor global outcome had higher rates of non-severe intracranial hemorrhage (12% vs. 2%, $p=0.031$). There was a trend toward higher rates of major gastrointestinal bleeding among patients with a poor global outcome (44% vs. 28%, $p=0.056$), while rates of suspected pump thrombosis (17% vs. 17%, $p=0.991$) and driveline infection (19% vs. 23%, $p=0.583$) were similar between groups.

DISCUSSION

The goals of LVAD implantation for advanced heart failure are to improve patients' survival and health status. In a large, single center study of high acuity patients with advanced heart failure who received LVAD therapy, over one third experienced a poor clinical outcome in the year following implantation. Approximately two-thirds of these poor outcomes were due to death, with the remaining third reporting poor quality of life, having recurrent heart failure, or experiencing severe stroke. Patients who did and did not have a poor global outcome were similar at baseline, with the exception that those with a poor outcome were more likely to be designated for destination therapy. Importantly, patients experiencing a poor global outcome had more days in the hospital post-implant and more intracranial and gastrointestinal hemorrhages.

Our findings extend prior insights into LVAD outcomes. By combining several different outcomes, we have created a more complete picture with which to inform patients about potential treatment trajectories and appropriately calibrate their expectations. While this rate of poor global outcome may appear high, the reported rate of death is similar to previously

published estimates,⁶ despite the high acuity of patients in our cohort. Furthermore, the expected 1-year mortality for these patients would have been much higher without LVAD.¹⁶ Although some clinicians may argue that being alive is the only outcome of interest for patients facing death, prior work has shown that some patients with severe heart failure symptoms were willing to trade over half of their remaining life years to achieve a better quality of life.⁵ As such, simply extending a life without improving the quality of that life may not be an acceptable outcome to some patients with end-stage heart failure. Our definition of poor global outcome may thus better reflect the values, goals and preferences of patients considering LVADs.

This concept of composite endpoints, such as MACE (major adverse cardiac events), is not new in clinical research.^{17,18} While composite endpoints were originally conceived to increase statistical power in clinical trials, the reality is that patients do not consider only the risk of dying when making treatment decisions. Different patients assign different weight to survival, quality of life, and adverse events that may be impactful determinants of both.¹⁹ In one study, trialists predictably ranked death as the most important component of a composite outcome, but patients ranked heart attack and stroke as more important than death.²⁰ Physicians may underestimate the importance of a treatment's effect on quality of life.

The concept of a composite outcome is perhaps even more relevant in LVADs, because the its components each represent outcomes with substantial, lasting effects on quality of life, as opposed to those associated with only transient decrements that only serve to increase statistical power (e.g., repeat revascularization). LVADs most often prolong *and* improve life, but they also expose patients to a wide array of potential adverse events that could conversely impair quality of life. We attempted to include these events in our definition, namely refractory heart failure, severe stroke, and poor quality of life. Each of these factors both represents substantially impaired quality of life and has been associated with increased risk of mortality.^{12,13,21-24} Future studies are needed to assess patient time trade-off preferences for quality vs. quantity of life, as well as the importance of different major adverse events. Furthermore, it will be important to understand how such preferences differ between patients based on pre-LVAD severity of illness or device indication. These efforts will also require either validation of the KCCQ in patients with LVADs or creation of an LVAD-specific health status measure. Our work herein lays a foundation on which to build better models that accurately portray a patient's global risk for death and other life-altering outcomes, to better inform and equip patients with the knowledge to make value-concordant decisions regarding therapy.

These results should be analyzed in view of certain limitations. First, patients are unlikely to weigh all components of the composite equally, based on varying individual characteristics. While we believe that the outcomes selected for our composite represent important outcomes to most patients, there is a lack of objective evidence to dictate what adverse events should be included and how they should be weighted. Second, nearly half of our cohort had missing follow-up KCCQ assessments, more often in patients with a poor global outcome, so the rate of poor global outcome due to poor quality of life may be underestimated. The reasons for missing follow-up data in our cohort are not known. Also, while the KCCQ has been the most commonly used health status measure for quality of life

in LVAD studies,^{25,26} it has not been fully validated in patients with LVADs. Finally, as this was a single-center study, it is unclear whether the rate of observed poor global outcome is reflective of national practice. Our analytic cohort represented particularly high acuity patients (86% INTERMACS profiles 1 or 2), given the regional referral nature of the hospital, and these profiles have been associated with higher risk for mortality and adverse events.^{27,28} As the mortality rates in this cohort were consistent with published national estimates for patients at all levels of disease severity, we suspect these results are likely generalizable. However, given that there has been movement away from implanting such severely ill patients with LVADs,²⁸ whether these results translate to patients in lower risk groups requires further study. Additionally, this small sample size did not provide us the power for multivariable, predictive modeling to identify patients at high risk for poor outcomes.

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Figure 1. Frequency and Causes of Poor Global Outcome in Patients with LVADs

¹Of those who died, prior to death: 6 had severe strokes, 1 had poor quality of life, and 1 had recurrent heart failure.

Table 1

Baseline Characteristics of Patients with vs. without Poor Global Outcome

Variable	Outcome		P-value
	Poor (n = 58)	Favorable (n = 106)	
Age (years)	55.9 ± 13.5	56.0 ± 12.4	0.956
White	42 (72%)	84 (79%)	0.569
Men	42 (72%)	88 (83%)	0.116
Body mass index (kg/m ²)	30.0 ± 5.6	29.7 ± 6.2	0.787
INTERMACS Profile			0.263
1	21 (37%)	46 (43%)	
2	28 (49%)	42 (40%)	
3	6 (10%)	15 (14%)	
4	2 (3%)	2 (2%)	
5	1 (1%)	2 (2%)	
Atrial fibrillation	28 (48%)	41 (39%)	0.234
Chronic obstructive pulmonary disease	6 (10%)	10 (10%)	0.866
Depression	14 (24%)	26 (25%)	0.943
Diabetes mellitus	24 (41%)	50 (47%)	0.516
History of gastrointestinal bleeding	6 (10%)	5 (5%)	0.201
Coronary artery disease	35 (60%)	56 (53%)	0.88
Current smoker	4 (7%)	10 (10%)	0.772
Prior smoking	34 (59%)	63 (59%)	0.958
Hypertension	28 (49%)	52 (49%)	0.992
History of intracardiac thrombus	3 (5%)	14 (13%)	0.103
Device strategy			0.010
Bridge to transplant	30 (52%)	76 (72%)	
Destination therapy	27 (46%)	25 (24%)	
Bridge to decision	1 (2%)	5 (5%)	

All data are presented as mean ± SD or %

Table 2

Association of Poor Global Outcome with Post-LVAD Events

Variable	Outcome		P-value
	Poor (n = 58)	Favorable (n = 106)	
Days in hospital per months alive			
Mean $\pm$ SD	17.0 $\pm$ 11.6	6.8 $\pm$ 8.3	<0.001
Median (IQR)	18.6 (5.0, 31.0)	3.7 (1.8, 8.3)	<0.001
Major gastrointestinal bleeding	26 (44%)	29 (28%)	0.056
Non-disabling stroke	6 (10%)	6 (6%)	0.348
Hemorrhagic	7 (12%)	2 (2%)	0.031
Ischemic	5 (9%)	5 (4%)	0.259
Suspected pump thrombosis	10 (17%)	18 (17%)	0.991
Driveline infection	11 (19%)	24 (23)%	0.583