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Laura Onderko Maine Medical Center

Et al.

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Maine Medical Center Experience with Explantation of Left Ventricular Assist Devices

Authors

Laura Onderko, Lauren Vickerson, and Andrew Schwartzman

RESEARCH AND QUALITY IMPROVEMENT BRIEF

Maine Medical Center Experience with Explantation of Left Ventricular Assist Devices

Laura L. Onderko, MD¹; Lauren Vickerson, APRN-FNP¹; Andrew Schwartzman, MD¹

¹ Department of Cardiology, MaineHealth, Portland, Maine

Keywords: heart failure, left ventricular function, heart assist devices, recovery of function

eft ventricular assist device (LVAD) therapy is approved for use as a bridge to transplantation and as a destination therapy for patients with advanced heart failure who are not candidates for heart transplantation. An LVAD is an implantable heart pump that provides hemodynamic support to the vital organs of the body. As experience with this technology has grown, a large body of evidence at the molecular, cellular, and organ level supports that LVAD therapy helps to reverse the pathology of heart failure. This phenomenon has been termed "reverse remodeling."1In certain instances, sufficient reverse remodeling occurs to allow for LVAD removal (i.e., bridge to recovery). The literature suggests that close to 10% of patients implanted with an LVAD could be explanted for recovery under optimal conditions.^{2,3} However, the actual rate of explantation is lower because many centers are reluctant to proceed due to the risk for recurrence of heart failure and non-standardized measurements of heart recovery. Therefore, it is imperative that the clinical course of patients after LVAD explantation be described to provide appropriate guidance for the decision on explantation. The literature on this topic is limited by the small sample sizes of singlecenter reports.4,5

The purpose of our study was to explore and document the characteristics and outcomes of patients who underwent LVAD explantation at Maine Medical Center, which has not been previously examined.

METHODS

We conducted a retrospective observational study by manual chart review of all patients who had undergone LVAD explantation at Maine Medical Center between December 1, 2012, and January 1, 2021. This study was deemed exempt by the MaineHealth Institutional Review Board.

We collected patient characteristics, including the level of support required, etiology of cardiomyopathy, and prior medical management, pre-LVAD implantation. We also collected data on long-term outcomes and medical management pre-LVAD implantation and post-LVAD explantation. We performed a descriptive analysis and reported the average hemodynamics collected by right heart catheterization, as well as echocardiogram parameters for pre-LVAD implantation, pre-LVAD explantation, and post-LVAD explantation.

Patient records were reviewed and divided into 3 time points for collecting relevant characteristics, including, but not limited to:

- 1. Pre-LVAD implantation: age, sex, race, etiology of cardiomyopathy, hemodynamics, echocardiographic data, medications, duration of heart failure, laboratory profiles.
- 2. Pre-LVAD explantation: echocardiographic and hemodynamic data, medications.
- 3. Post-LVAD explantation: longitudinal changes in left ventricular ejection fraction, heart-failure admissions, need for LVAD, heart transplant or death.

Correspondence: Laura L. Onderko, MD Department of Cardiology, MaineHealth Portland, Maine laura.onderko@mainehealth.org

RESULTS

A total of 5 patients were included in the study, and all received a HeartMate II device as destination therapy.⁶ Among these patients, the average age at LVAD implantation was 40.2 years, 80% were male and 20% were female with an average body mass index of 26.8 kg/m², and only 1 of 5 had hypertension or diabetes mellitus.

All patients were diagnosed with a non-ischemic cardiomyopathy with moderately to severely dilated left ventricular size (based on echocardiography). Three of the 5 patients underwent cardiac magnetic resonance imaging before implantation. Two patients had evidence of late gadolinium enhancement in the septal mid-wall consistent with a non-ischemic, idiopathic dilated cardiomyopathy. No patients required mechanical support before implantation (such as with an intra-aortic balloon pump or Impella device). Three of 5 patients were receiving guideline-directed medical therapy for heart failure at least 3 months before LVAD implantation. This therapy included beta-blockers, angiotensin converting enzyme inhibitors (ACEi), and spironolactone. The average time from diagnosis of congestive heart failure to LVAD implantation ranged from 1 to 21 months, with a 6.2-month average. The class of Interagency Registry for Mechanically Assisted Circulatory Support ranged from 2 to 4, with an average of 2.6.7

Table 1 outlines the filling pressures and hemodynamics measured by right heart catheterization before implantation, and Table 2 shows echocardiographic markers.

Explant

All patients underwent LVAD explantation due to myocardial recovery. The time from LVAD implantation to explantation ranged from 10 to 24 months, with a 16-month average. Table 1 displays the average filling pressures and hemodynamics evaluated by right heart catheterization immediately before LVAD explantation, and Table 2 displays the echocardiographic data collected immediately before LVAD explantation.

As described in Table 1 and Table 2, the filling pressures and hemodynamics no more than 3 months before LVAD implantation show evidence of high filling pressures. These high filling pressures indicated biventricular heart failure with an average pulmonary capillary wedge pressure of 18 mmHg (normal: 7-12 mmHg) and low cardiac output with an average of 1.12 L/min/m² (normal: > 2.5 L/min/ m²). Echocardiographic data indicates severely depressed left ventricular systolic function with an average ejection fraction of 15% (normal: >55%) and a moderately to severely dilated left ventricle. The same evaluation before LVAD explantation highlights significant improvement with normalized filling pressures and hemodynamics, as well as left ventricular ejection fraction and dimensions. These patients also tolerated guideline-directed medical therapy post-LVAD implantation. Among the patients, 4 of 5 received maximum beta-blocker dosages (defined as either 25 mg carvedilol twice daily or metoprolol succinate 200 mg daily), 3 received ACEi, 2 received Entresto, and 4 received spironolactone. Four patients completed cardiac rehab, attending 3 times per week to complete 36 sessions, before explantation.

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Parameter	Normal	Pre-LVAD implantation, mean (range)	Pre-LVAD explantation, mean (range)
Right atrial pressure, mmHg	0-5	11 (5-23)	5.5 (3-9)
Right ventricular pressure, mmHg	25/5	35/6 (25-48/4-11)	22/2.5 (17-27/1-5)
Pulmonary artery pressure, mmHg	25/10	42/21 (24-74/9-38)	22/7 (17-27/4-12)
Pulmonary artery mean pressure, mmHg	10-20	29 (16-50)	15 (12-17)
Pulmonary capillary wedge pressure, mmHg	7-12	18 (7-36)	7 (5-12)
Cardiac output, L/m²	4-8	3.96 (2.9-4.5)	4.8 (4.4-5.3)
Cardiac index*, L/min/m ²	2.5-4	1.12 (1.8-2.4)	2.5 (2.1-2.8)

Table 1. Average Hemodynamics by Right Heart Catheterization (n = 5)

Abbreviations: LVAD, left ventricular assist device.

* By Fick's Formula.

Table 2. Echocardiographic Evaluation (n = 5)

	Pre-LVAD	Pre-LVAD	Post-LVAD
Parameter	implantation	explantation	explantation*
Left ventricular ejection fraction, %, mean (range)	15 (10-24)	54.2 (50-56)	42 (35-50)
Left ventricular internal diameter at diastole, mm, mean (range) [†]	67 (58-82)	46 (41-53)	54 (48-57)
Left ventricular internal diameter at systole, mm, mean (range) [‡]	63 (52-77)	35 (32-42)	43 (35-46)
Degree of mitral regurgitation, %			
None	20	60	40
Mild	20	20	60
Moderate	60	40	0
Right ventricle function, %			
Normal	40	20	60
Mild	20	60	20
Moderate	20	0	20
Severe	20	20	0
Right ventricle size, %			
Normal	60	40	100
Mildly enlarged	20	20	0
Moderately enlarged	20	40	0
Degree of tricuspid regurgitation, %			
None	40	20	40
Mild	20	60	40
Moderate	20	0	0
Severe	20	0	0
Not reported	0	20	20

Abbreviations: LVAD, left ventricular assist device.

* 3 months post-LVAD explantation.

† Normal range: male, 42-58.4 mm; female, 37.8-52.2 mm.

‡ Normal range: male, 25-39.8 mm; female, 21.6-34.8 mm.

Following explantation, 1 patient died due to mixed cardiogenic and septic shock, and 1 patient had a cerebrovascular accident. Overall, patients went from class IV symptoms pre-LVAD implantation to class II/III symptoms post-LVAD implantation, and they were at least able to maintain this class after explantation. Notably, patients experienced a drop in left ventricular ejection fraction after explantation, and left ventricular dimensions increase slightly, though remained borderline normal. This decrease in left ventricular ejection fraction persisted with an average ejection fraction of 38% (range: 35%-45%) at 1-year follow-up and 47% (range: 34%-56%) at 2-year follow-up.

DISCUSSION

Prior studies showed that significant recovery to allow for explanation of LVAD only occurs in approximately 5% of patients with LVAD.⁸

Maine Medical Center's experience with LVAD explantation mirrors larger studies' findings overall in terms of characteristics of patients who recover left ventricular function. One such study involving more than 13000 patients found predictors of device explantation included age less than 50 years, non-ischemic etiology, less than 2 years between implant and initial heart-failure diagnosis, and able to tolerate higher doses of neurohormonal blockade while on LVAD support.³ In another retrospective study, patients receiving any neurohormonal blockade medications (defined by drugs classified as ACEi or angiotensin receptor blockers, betablockers, or mineralocorticoid antagonists) at 6 months post-implantation had improved survival rate at 4 years. Patients receiving all 3 medications had the lowest risk of death.9 As we develop better medical treatments for systolic heart failure, we may see more potential for myocardial recovery.

To better determine which patients could undergo explantation, further work will need to establish more standardized procedures. One prospective study looked at optimizing LVAD parameters in 40 patients with non-ischemic cardiomyopathy who underwent Heartmate II LVAD implantation.⁴ Ultimately, 50% of the patients underwent explantation within 18 months. At long-term follow-up (3 years), 77% of patients who underwent explantation were survival free from LVAD or transplantation. This study provides a model for standardized pharmacologic and cardiac monitoring that can result in a high rate of LVAD explantation.

One limitation of our study is the small sample size consisting of only 5 patients. Also, standardizing protocols for implantation and explantation may be useful with baseline cardiopulmonary exercise testing before and after LVAD implantation, as well as after explantation, would allow for more objective comparisons of cardiorespiratory fitness.

CONCLUSIONS

As the indications for LVAD implantation expand, determining patients who may be eligible for explant will become more important. These patients could also benefit from more specific treatment strategies that could optimize their recovery and candidacy for explantation. Monitoring outcomes post-explantation could also facilitate more targeted approaches that help to maintain and optimize recovery in this specific population of patients. With the small number of patients who undergo explantation at each center, there is a need to create larger registries across multiple centers to better characterize and follow this unique population.

Conflicts of Interest: None

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