Peer-Reviewed Case Report

The Utility of Remote Hemodynamic Monitoring Devices in Patients with a Ventricular Assist Device

Bennet George, Amanda Hart, Sarah Branam, Maya Guglin

University of Kentucky, Gill Heart Institute, Lexington, KY

* Corresponding author: bennet.george@uky.edu

Abstract

Remote intracardiac hemodynamic monitoring is a growing area of interest to help aid in the management of patients with chronic congestive heart failure. The utility of remote hemodynamic monitoring has not previously been investigated with a ventricular assist device population. We present two cases of patients with ventricular assist devices in which we employed remote hemodynamic monitoring data to aid in patient management.

Key Words:
Heart failure, ventricular assist device, remote hemodynamic monitoring, CardioMEMS

Introduction

Congestive heart failure is a major public health concern with high economic burden on society and health care organizations. Heart failure is the leading cause of hospitalization in patients above 65 years of age and is also associated with a higher rate of readmissions[1]. Several strategies, both invasive and non-invasive, have been developed to predict the early signs of decompensation and optimize management. Remote hemodynamic monitor systems have gained momentum with enthusiasm intensifying after the results of the CardioMEMS™ (St. Jude Medical, Inc., St. Paul, MN) Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients

(CHAMPION) study, in which patients randomized to treatment guided by pulmonary artery pressure data from the CardioMEMS™ device reduced heart failure-related hospitalizations at six months[2]. Other devices, including implantable left atrial pressure sensors with a subcutaneous antenna coil have also been studied[3].

Readmission rates after left ventricular device (LVAD) implantation are high[4]. Hospital readmissions in LVAD patients occur at a rate of 1.5-2.5 per patient year of support with heart failure representing a leading cause[5-7]. Persistent heart failure early after LVAD implantation is common, occurring in up to 25% of patients[8]. The usefulness of remote hemodynamic monitoring in patients with LVAD is uncertain. It can theoretically aid in the management of patients with LVADs by optimizing medications and pump parameters, thereby reducing hospital readmissions. We present two cases of patients with LVADs whose volume status we were able to manage in an outpatient setting by relying on information made available by their respective implanted hemodynamic monitors.

Case 1

A 50-year-old, morbidly obese male with nonischemic, dilated cardiomyopathy with a left ventricular ejection fraction (LVEF) < 15% and left ventricular internal dimension in diastole of 9.1 cm was referred to our institution for management of heart failure. He had persistent heart failure symptoms and poor quality of life, despite optimal medical therapy including cardiac resynchronization therapy.

Evaluation for advanced heart failure therapy was initiated. Right ventricular size and function were grossly normal. Baseline right-sided intracardiac filling pressures were normal and mean pulmonary artery pressure measured 18 mmHg. The patient ultimately received a HeartWare® (HeartWare®, Framingham, MA) LVAD in late January of 2014 and after a relatively benign post-operative course, was discharged in two weeks. Pump speed was initially set at 2300 revolutions per minute (RPM) and changed to 2500 RPMs prior to discharge. Over the next 18 months, he had 15 admissions to our institution and 8 (53%) readmissions dealt with volume status, 5 for volume overload and 3 for dehydration. Three additional changes to pump speed were made during this period, ultimately maintained at 2900 RPMs.

Because of his body habitus, volume status was difficult to assess by physical exam. In light of his tenuous volume status and frequent admissions, he was referred for implantation of CardioMEMS™ performed in December of 2015. Figure 1 displays the changes in the patient's weights prior to implantation. Figures 2-5 display the pulmonary artery pressures, the patient weights, LVAD flows, and serum creatinine from December 2015 to March 2016 (after CardioMEMS™ implantation).

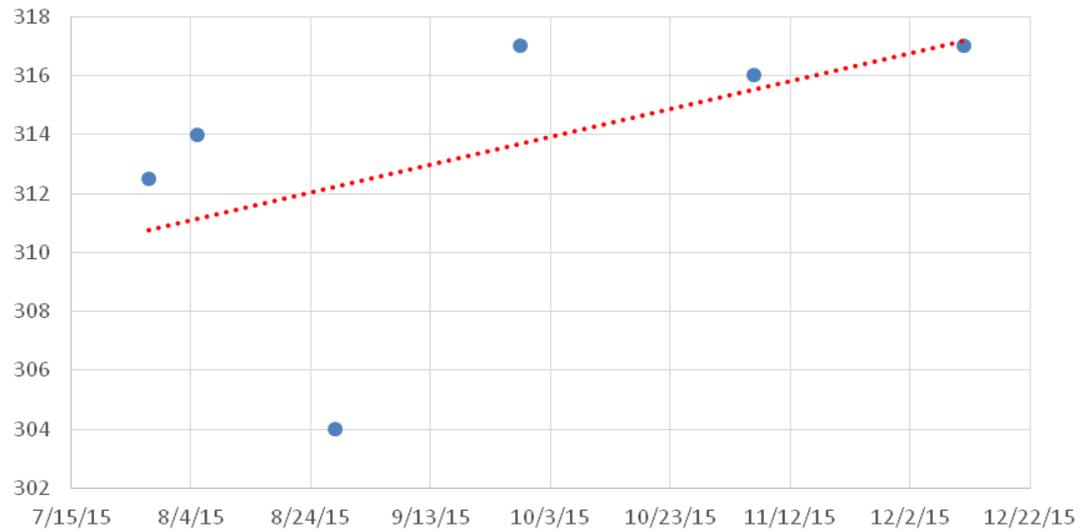**Figure 1:** Weight (lbs) in HeartWare® patient prior to CardioMEMS™ implantation

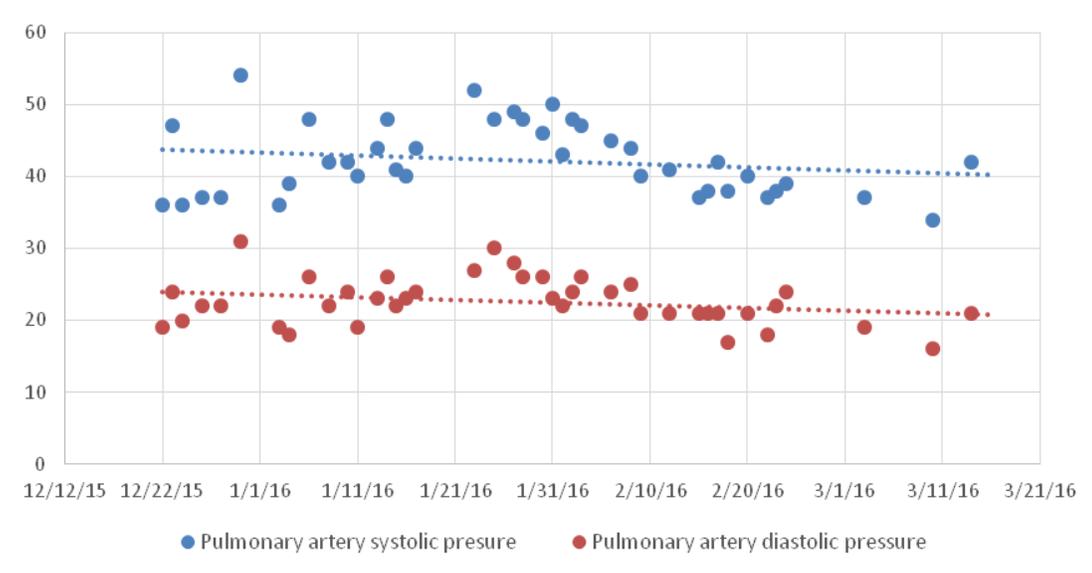**Figure 2:** Pulmonary artery pressures (mmHg) in HeartWare® patient with CardioMEMS™ device.

● Pulmonary artery systolic pressure ● Pulmonary artery diastolic pressure

Figure 3: Weight (lbs) in HeartWare® patient after CardioMEMS™ implantation
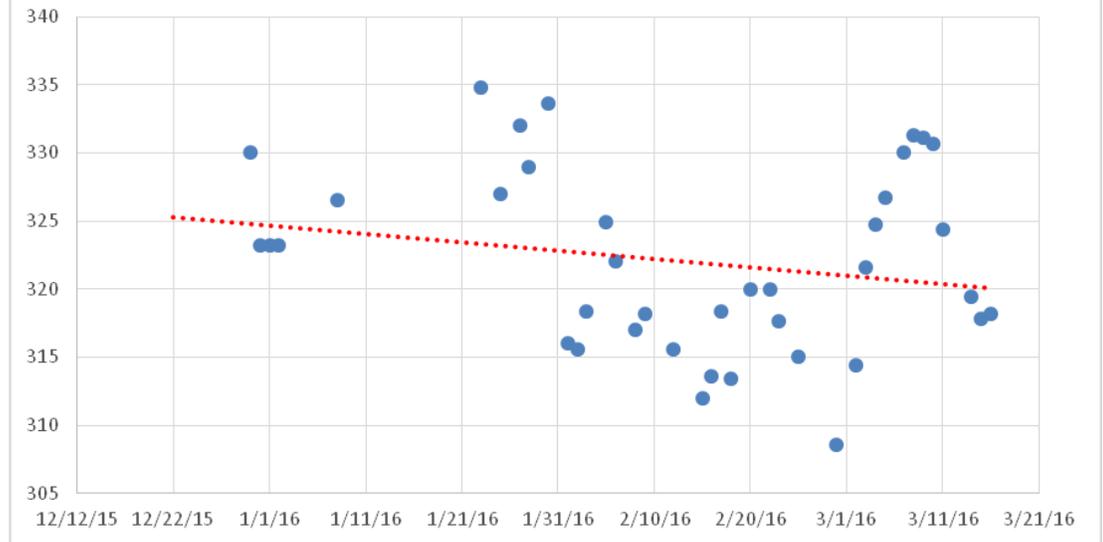
Figure 4: Flows (Liters/minute) in HeartWare® patient after CardioMEMS™ implantation
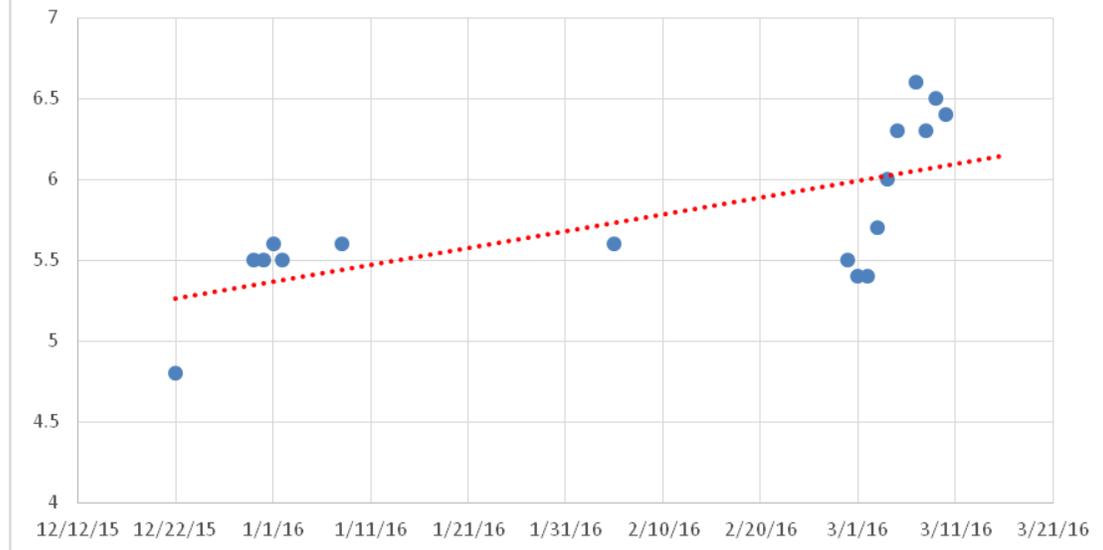
During this 3-month window, the medical regimen was adjusted as was the pump speed based on hemodynamic data obtained. A total of eight occurrences of medication changes were noted all of which involved adjustments to diuretic dose. Exactly half the adjustments involved increasing the dose and half decreasing the dose. Pump speed was increased to 3000 RPMs during this period. The patient only had two admissions to our institution during this time,

one for a concern of his implantable cardiac defibrillator firing and another for evaluation of atypical chest pain. At present time, five months after CardioMEMS™ implantation, he is doing well and has not had any futher readmissions.

Figure 5: Serum creatinine (mg/dL) in HeartWare® patient after CardioMEMS™ implantation
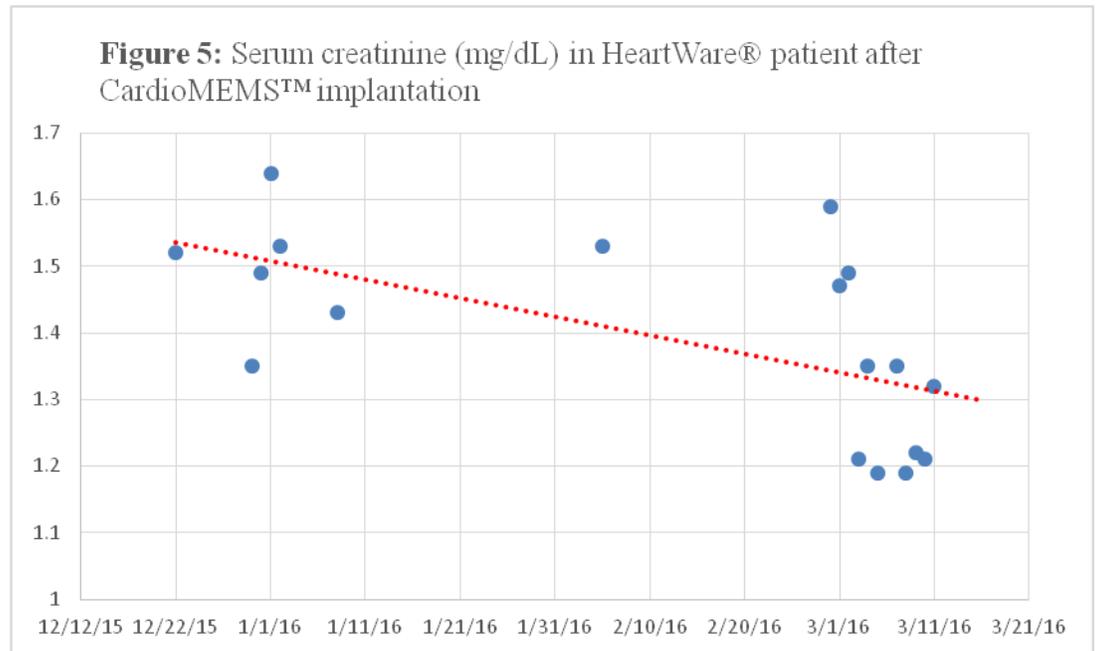
Case 2

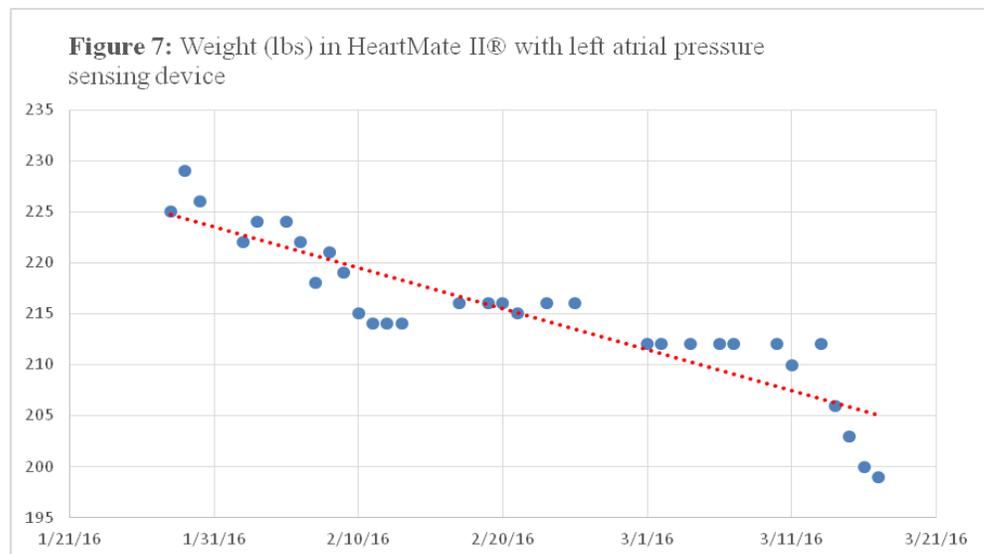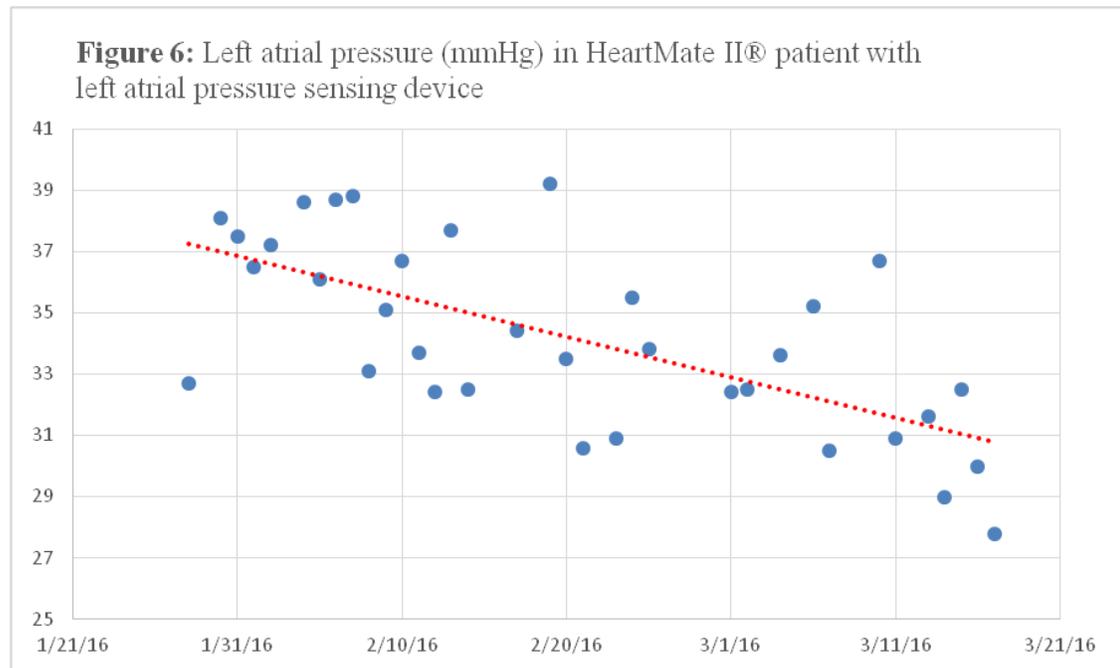A 66-year-old male with coronary artery disease status post 3-vessel coronary artery bypass grafting and resultant ischemic cardiomyopathy with an LVEF < 15% was referred to our institution for advanced heart failure options. He had recurrent hospitalizations for decompensated heart failure in the prior year. In April of 2014, his pacemaker was upgraded to a CRT/BiV ICD and a left atrial pressure-sensing device was implanted simultaneously as part of the Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy (LAPTOP-HF) study. He developed progressively worsening heart failure with New York Heart Association Class IV symptoms. Between September and December of 2015, he was admitted for acutely decompensated heart failure 4 times with an average hospital length of stay of 5 days. Given his end-stage ischemic cardiomyopathy, a HeartMate II® (Thoractec) was implanted in late December of 2015.

Prior to implantation, the patient had significantly elevated right- and left-sided filling pressures with a pulmonary capillary wedge pressure of 35 mmHg as well as moderate pulmonary hypertension with a mean pulmonary artery pressure of 40 mmHg and a pulmonary vascular resistance of 2.8 Wood units despite inotrope therapy. His post-operative course was complicated by respiratory insufficiency requiring tracheostomy, healthcare associated pneumonia, ventricular tachycardia, acute kidney injury, and blood-loss anemia. He slowly

recovered and was subsequently discharged home with physical therapy. Left atrial pressure readings from his previously implanted device were used to aid in outpatient medications adjustments. Figures 6-7 display the left atrial pressure readings and patient weights from January 2016 to March 2016.

Figure 6: Left atrial pressure (mmHg) in HeartMate II® patient with left atrial pressure sensing device

Figure 7: Weight (lbs) in HeartMate II® with left atrial pressure sensing device

During this brief 7-week period, the patient's diuretic regimen was changed twice. The initial change was an increase in the dose of his loop diuretic and the second was the addition of a thiazide diuretic. During this period, device speed was

changed and RPMs were increased from 8800 to 9400. Although the left atrial pressure remains elevated, he is feeling well and has not have any hospitalizations since the implantation of LVAD.

Discussion

Fluid retention remains a significant clinical concern in patients with end-stage heart failure even after LVAD implantation. While an LVAD can provide full mechanical support with systemic flows close to normal at rest, adjuvant diuretic therapy is often still required. Decompensated heart failure while on a ventricular assist support device is a known clinical entity[9]. This is likely related to the fact that the LVAD is preload dependent and afterload sensitive[10, 11].

Traditional noninvasive remote monitoring of heart failure patients requires patients to comply with a stringent fluid restriction, daily weight monitoring, and self-assessment of edema. Many patients lack self-care skills and literacy, which makes it difficult for them to carry out these tasks. Compliance rates for even the relatively simple task of weighing one's self on a daily basis is poor[12, 13].   As a result, many system practices rely on telemonitoring strategies. The National Institute of Health TELE-HF study randomized 1,653 patients to standard care versus telemonitoring using an automated telephone based system to collect information. No significant difference between either group was found in terms of all-cause mortality or heart failure-related readmissions[14]. The failure of similar telemonitoring strategies has been replicated but studies do conflict[15-17].

Noninvasive monitoring can be utilized in LVAD patients to monitor hemodynamics and guide therapy to address fluid retention and symptoms of decompensation. There is currently no data on the utility of these devices in patients with durable circulatory support devices. The pitfalls of relying on patient self-assessment or telemonitoring could be extrapolated to an LVAD patient population although given the careful candidate selection and the need for close, frequent follow-up, one would expect this group to be able to comply more readily. It has been our experience that symptomatic fluid retention may persist after LVAD implantation.   Management based on intracardiac monitoring devices is very promising in optimizing hemodynamics, improving quality of life, and reducing hospitalizations.

The advantage of remote hemodynamic monitoring is the ability to identify increases in intracardiac and pulmonary pressures before the development of heart failure symptoms, sometimes days to weeks earlier[14]. The core question of implantable hemodynamic monitoring systems is to determine whether frequent assessment of intracardiac filling is better at reducing hospitalizations compared to traditional tools. Adamson contends that understanding the pathophysiology of the congestive cascade would aid in maintaining euvolemia, by highlighting that increases in filling pressures precede the autonomic adaption to such increases, and are subsequently followed by changes in weight and the development of symptoms such as dyspnea and edema[18].

This principle is evidenced in both our cases. In case 1, the patient went from 8 volume status related admissions over an 18-month period to zero volume status related admissions over a 5-month window. The second patient with a left atrial pressure-sensing device had recently undergone LVAD implantation thus any success of avoiding hospitalization for decompensated heart failure is confounded. Despite this, we were still able to make adjustments to his medication regimen. Figures 3 and 6 highlight the weight changes in both of our patients during remote monitoring. Although the immediate impact from adjustments to diuretic changes to weight is difficult to assess, we believe the general downward trend in weight was related to our ability to make frequent adjustments based on the remote intracardiac data available. Interestingly, the scatter of data appreciable in Figure 2 would suggest that weight was not the driver between medications adjustments.

There are several other potential advantages of remote hemodynamic monitoring specific to the LVAD patient population. In pump thrombosis, increases in pulmonary arterial pressures correlate with a rise in serum lactate dehydrogenase (LDH)[19]. The potential to suspect the diagnosis of device thrombosis remotely, before LDH is checked (which requires a clinic visit), or more importantly, before the patient develops significant symptoms would be invaluable.

Additionally, as LVADs are preload sensitive, remote intracardiac pressure monitoring could allow for more accurate pump speed modifications and help optimize the unloading of the left ventricle. In both our patients, we were able to increase pump speed successfully while making changes to diuretic regimens. A total of four changes to pump speed were made in the patient from case one (including one prior to discharge of the recently placed LVAD) without the use of remote hemodynamic monitoring while one change was made after implantation. The use of invasive hemodynamics for guidance of the LVAD speed adjustment was shown to be superior to a traditional echo-guided ramp test[20].

Our second patient had pre-LVAD implantation pulmonary hypertension related to intracardiac congestion. Secondary pulmonary hypertension, if severe enough, is a contraindication for cardiac transplantation. The ability to monitor pulmonary artery pressures and adjust medications accordingly would be more comfortable for patients and help avoid exposing them to the risks of repeated right heart catheterizations. This approach, in fact, may accelerate the normalization of pulmonary vascular resistance, highlighting yet another advantage of remote hemodynamic monitoring. In addition to recording pulmonary artery pressures, the CardioMEMS™ system monitors heart rate and dysrhythmias that could compromise LVAD function[2]. This was not an issue with our patient. Given the multiple, distinct advantages of remote hemodynamic monitoring, perhaps the trend of future LVAD models will include the ability to measure left ventricular end diastolic pressures remotely. The idea of a "smart" pump which can self-adjust pump speed based on built-in hemodynamic pressure sensors has already started to circulate in the literature[21].

The ability of remote hemodynamic monitoring devices to accurately detect elevated intracardiac filling pressures is unknown. Furthermore, the presence of continuous-flow, mechanical support device within the left side of the heart may reduce the sensitivity of pulmonary artery diastolic pressures. Nevertheless, the potential advantages of remote hemodynamic monitoring the LVAD patient population merits focus for future investigations.

In summary, decompensated heart failure and associated congestion remains problematic for LVAD patients. Where traditional methods for assessing volume status have proven unreliable, the utility and success of remote invasive hemodynamic monitoring systems are clear and should have similar utility and success in an LVAD patient. In our small cohort, such systems have proven beneficial. Further studies including larger cases series and randomized control data are needed to validate this claim.

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