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Implanted Hemodynamic Monitoring in Management of Significant Right Heart Failure before and after Left Ventricular Assist Device Implantation: Creation and Maintenance of Fontan Physiology in Severe Right Ventricular Dysfunction

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# Abstract

In the left ventricular assist device (LVAD) population, right ventricular (RV) failure represents a significant cause of morbidity and mortality. It is unclear whether hemodynamic monitoring with the implantable CardioMEMS system can improve outcomes within this population. This case report highlights two patients in our clinic who had CardioMEMS implanted after LVAD, enabling us to modify their medical regimens remotely and more frequently in the management of their RV failure.

**Keywords**: LVAD, left ventricular assist device, CardioMEMs, hemodynamic monitoring



### Introduction

LVADs remain an important therapy for end stage heart failure, exceeding the number of transplants performed annually in the US (1). However, despite the excellent results, early and/or progressive decline of right ventricular function after LVAD implant remain as major problems. These conditions have been shown to be associated with increased morbidity and mortality within the high-risk LVAD population (2).

Previous studies have shown that CardioMEMS (St. Jude Medical, Inc.) hemodynamic monitoring affords several advantages in LVAD patients, reducing the number and duration of hospitalizations (3-5). This case report highlights the role of CardioMEMS in the management of patients who developed severe right heart failure after LVAD implantation. Both of these patients met the criteria for LVAD implantation, with severe symptoms despite optimal medical therapy.

## Case Study 1:

The patient is a 75 year-old male aerospace engineer who presented with shortness of breath on exertion, ankle swelling, atrial fibrillation, low ejection fraction, Stage D heart failure status post biventricular implantable cardioverter defibrillator (ICD). His past medical history included ischemic heart disease, coronary artery bypass graft (CABG) and percutaneous coronary intervention (PCI). His symptoms gradually progressed to syncopal episodes, ventricular fibrillation requiring pacing, and New York Heart Association (NYHA) Class IV heart failure. In October 2016, a right heart catheterization demonstrated a low cardiac output of 2.2 L/min. The patient was admitted, placed on inotropic support, and evaluated for LVAD placement. Echocardiogram showed severe left ventricular dilatation with ejection fraction less than 20%, right ventricular dilatation, severe mitral regurgitation, severe aortic regurgitation, and mild tricuspid regurgitation. (Video 1. Echo of patient 1. <a href="https://imgur.com/a/uArwoFH">https://imgur.com/a/uArwoFH</a>).

During his hospital stay, the patient was selected for LVAD destination therapy and a HeartMate II LVAD was implanted with aortic valve closure on November 16, 2016. His hospitalization was complicated by aspiration pneumonitis as well as episodes of ventricular tachycardia, possibly due to dual inotropic support. He underwent extensive physical and occupational therapy, and was discharged on December 2, 2016 with LVAD pump speed 8600 rotations per minute (rpm), bumetanide 1.5mg daily and spironolactone 50mg daily.

The patient developed worsening right heart failure symptoms in the following weeks, including dyspnea on exertion, lower extremity edema and weight gain. Patient was readmitted to the hospital on April 12, 2017 and was considered as a candidate for CardioMEMS hemodynamic monitoring. The CardioMEMS was implanted on May 1, 2017. He was admitted to the ICU after developing post-procedural hemoptysis due to pulmonary artery perforation and left lung collapse requiring intubation. The procedure required stiffer wires during intervention due to complex anatomy, which may have prompted the hemoptysis. The patient was



also on aspirin 325 mg daily and Plavix 75 mg. He was discharged on May 11, 2017 with LVAD pump speed 9000 rpm, bumetanide 1mg daily and spironolactone 25mg daily based on hemodynamic monitoring.

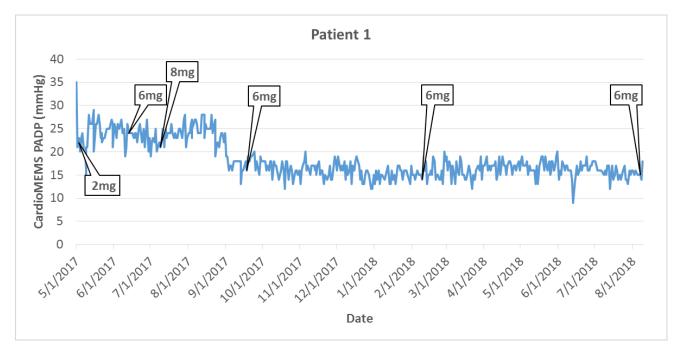


Figure 1. Patient 1 CardioMEMS Data with Bumetanide Dosage

CardioMEMS measurements were transmitted three times a week to the cardiology team to monitor pulmonary artery diastolic pressure (PADP) (Figure 1). Bumetanide dosage adjustments based on CardioMEMS were communicated to the patient over telephone with the goal of lowering PADP. On September 1, 2017, a follow-up right heart catheterization was performed and showed continued volume overload with pulmonary capillary wedge pressure (PCWP) 23 mmHg (Table 1). LVAD pump speed was increased from 9000rpm to 9400rpm in order to increase cardiac index.

CardioMEMS-directed management was continued and bumetanide dosage was reduced to 3mg twice per day (bid). Patient showed clinical improvement in physical stamina and quality of life without dyspnea on exertion or lower extremity edema despite echocardiogram showing continued severe right ventricular systolic dysfunction. (Video 2. Patient 1. Severe right ventricular dysfunction. https://imgur.com/TazuX9N) Patient's visits have decreased in frequency to less than once per month, he has had no hospitalizations, and he continues to work.



	Before LVAD	After LVAD	After CardioMEMS
Date	10/31/2016	5/1/2017	9/1/2017
RAP (mmHg)	21	19	10
PAP (mmHg) Systolic/Diastolic (Mean)	65/34 (44)	55/28 (38)	41/15 (26)
PCWP (mmHg)	35	32	23
CI	1.1	1.78	1.90

Table 1. Patient	Cardiac	<b>Catheterization Data</b>
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RAP right atrial pressure PAP pulmonary arterial pressure PCWP – pulmonary capillary wedge pressure CI – cardiac index

#### Case Study 2:

The patient is a 76 year-old male who presented to the clinic with shortness of breath on exertion, bilateral leg edema, orthopnea, paroxysmal nocturnal dyspnea, and fatigue. His history was significant for Stage C, NYHA Class III to IV non-ischemic cardiomyopathy with ejection fraction of 25%. He also had hypertension, hyperlipidemia, diabetes mellitus, paroxysmal atrial fibrillation with biventricular ICD, and chronic renal insufficiency. His symptoms progressed despite optimal medical therapy and he was therefore considered a candidate for LVAD placement. Echocardiogram showed severe left ventricular dilatation with ejection fraction less than 20%, right ventricle dilatation, mild to moderate mitral regurgitation, and mild tricuspid regurgitation.

The patient was selected for LVAD destination therapy and a HeartMate II LVAD was implanted on June 17, 2015. He underwent physical therapy and was discharged with LVAD pump speed 9000 rpm, bumetanide 1mg daily and spironolactone 25mg daily.

His first year post-LVAD was mostly uneventful despite several falls without cardiac complications leading to distal fractures that required hospital admission for follow-up. However, symptoms gradually worsened with increased PI events, low-flow alarms on LVAD, declining right heart function, and 20 pounds of weight gain over 3 weeks in January 2017. Patient was admitted to the hospital for volume overload, renal dysfunction and worsening right side dysfunction on January 26, 2017 and considered as a candidate for CardioMEMS placement to optimize management of his treatment. The patient had CardioMEMS implanted on January 31, 2017 with an uneventful post-operative period.



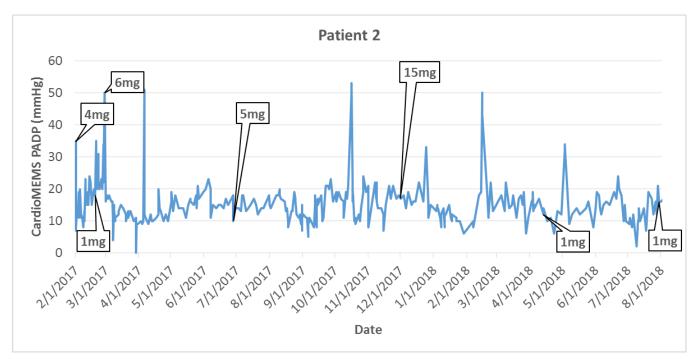


Figure 2. Patient 2 CardioMEMS Data with Bumetanide Dosage

CardioMEMS measurements were transmitted three times a week to the cardiology team and treatment adjustments were communicated to the patient over telephone. The patient became more symptomatic with shortness of breath, dyspnea on exertion, as well as weight gain despite the use of diuretics and dosing per his CardioMEMS reading. Therefore, the patient was scheduled for right heart catheterization on March 7, 2017 and admitted to the hospital following his catheterization due to significant volume overload. The patient had multiple ramp studies performed as well as RV pacing changed to LV pacing to help with septal wall motion due to concerns that the LVAD cannula may have been dislodged or moved towards the septum due to mechanical falls. He was discharged on March 14, 2017 with LVAD pump speed 8600 rpm, bumetanide 2mg daily, spironolactone 12.5mg every 48 hours.

CardioMEMS-directed management was continued and bumetanide dosage was adjusted accordingly, decreasing from 7.5mg bid in October 2017 to 0.5mg daily in July 2018. Most recent catheterization showed RAP 3 mmHg, mean PAP 13 mmHg, and CI 3.6 despite ongoing right ventricular dysfunction (Video 3. Ongoing right ventricular dysfunction in Case 2. https://imgur.com/a/f1p2j30). Patient continues to follow up at our clinic regularly for all recommended visits. His hemodynamics is shown in Table 2.



	Before LVAD	After LVAD	After CardioMEMS
Date	6/9/2015	1/31/2017	10/18/2017
RAP (mmHg)	10	12	18
PAP (mmHg) Sys/Dia (Mean)	48/22 (32)	44/16 (33)	42/20 (31)
PCWP (mmHg)	17	20	20
CI	1.72	1.87	3.3

#### Table 2. Patient 2 Cardiac Catheterization Data

### Discussion:

Right heart failure (RHF) is a frequent complication following LVAD implantation with an incidence of 20-50% of cases. RHF may lead to impaired LVAD flow, decreased tissue perfusion and multi-organ failure, which are associated with increased morbidity and mortality. Despite the fact that many risk factors contributing to the development of RHF after LVAD implantation have been identified, management of right ventricular dysfunction still remains a challenge. The functions of the left and right ventricles are intimately linked through systolic ventricular interaction due to sharing of oblique fibers in the interventricular septum (6). The oblique fibers determine shortening and lengthening that produces 80% of RV systolic function (7). Both ventricles are dependent on one another, thus any change in compliance, shape, or size of one ventricle can affect the other (8).

After LVAD implantation, there is often loss of the septal contribution to overall RV function with postoperative paradoxical septal motion. Acute hypoxemia perioperatively can also result in pulmonary vasoconstriction, worsening pulmonary vascular resistance, and associated RV dysfunction. Over time, there is increased flow from the LV/LVAD and increased venous return to the RV, resulting in an increase in RV preload. These factors lead to worsening of right heart function both in early stages after LVAD implantation and progressively over months or years.

The CardioMEMS pulmonary artery (PA) pressure monitor is a small implantable wireless sensor that is placed in a branch pulmonary artery for continuous monitoring of PA pressures. It has been shown to be safe, reliable and clinically effective in reducing HF associated hospitalizations for New York Heart Association (NYHA) Class III patients as described in the CHAMPION trial (9,10). CardioMEMS monitoring enables optimization of the balance between PA pressures and LV filling through controlling volume status with the use of diuretics in order to achieve required cardiac output. Keeping PA pressures low preserves RV function and helps prevent unfavorable irreversible cardiac remodeling (11). In a sense, keeping PA pressure low, but not too low, may mimic Fontan physiology



so that RV dysfunction becomes less important. If the pressures are too low, then LV filling may be insufficient to meet the demands of the LVAD pump. Thus diuretic dosing and LVAD pump speed are two key components of managing volume status in LVAD patients to avoid symptoms of heart failure and enable patients to attain better quality of life.

In our first patient, we observe a dramatic decline in right atrial pressure, pulmonary artery pressure, and pulmonary capillary wedge pressure after CardioMEMS implant (Table 1). CardioMEMS pulmonary arterial diastolic pressure (PADP) trend data confirms our observations, particularly after LVAD pump speed increase to achieve higher cardiac index in September 2017 (Figure 1). Patient 1 has had no additional hospitalizations since his implant, whether cardiac or non-cardiac related (Table 3). He is currently achieving our goal PADP of 17mmHg through CardioMEMS-guided diuretic management and not experiencing any heart failure symptoms.

Patient and Device	Months between LVAD implantation and CardioMEMS	Months of data collection with CardioMEMS	Number of HF- related hospitalizations before CardioMEMS	Number of HF- related hospitalizations after CardioMEMS	Number of diuretic adjustments with CardioMEMS
Patient 1 – Heartmate II	5	15	2	0	16
Patient 2 – Heartmate II	18	18	3	3	54

Table 3	. Patient	Data wit	h CardioMEI	MS after	LVAD	Implantation
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Our second patient has unfortunately had multiple hospitalizations due to noncardiac related mechanical falls which have complicated our management strategy. However, we have been able to manage his right heart failure on an outpatient basis despite significant RV dysfunction. He had not yet shown a decline in right heart pressures at the time of his most recent catheterization (Table 2), but his most recent echocardiogram showed significant improvement with RAP 3 mmHg and mean PAP 13 mmHg. His cardiac index has increased from 1.87 to 3.6 and CardioMEMS monitoring has enabled us to make 54 diuretic adjustments since implant (Table 3), which would have been unfeasible without remote monitoring. He is currently taking 1.5mg bumetanide per day, compared to his dosage of 7.5mg bumetanide bid approximately 1 year ago, and achieving our goal PADP of 12mmHg (Figure 2).



## Conclusion

The benefit of CardioMEMS has not been adequately investigated in patients with LVAD and RV failure, a population which carries a high readmission rate after implantation. Review of our cases supports the use of CardioMEMS in management of right-sided heart failure with LVAD. Further work will be needed to definitively establish guidelines regarding the use of this dual device therapy.



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