

Ambulatory pulmonary artery pressure monitoring in advanced heart failure patients

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Abstract

Heart failure (HF) is an emerging epidemic associate with significant morbidity, mortality, and health care expenditure. Although there were major advances in pharmacologic and device based therapies for the management of HF, mortality of this condition remains high. Accurate monitoring of HF patients for exacerbations is very important to reduce recurrent hospitalizations and its associated complications. With the failure of clinical signs, tele-monitoring, and laboratory bio-markers to function as early markers of HF exacerbations, more sophisticated techniques were sought to accurately predict the circulatory status in HF patients in order to execute timely pharmacological intervention to reduce frequent hospitalizations. CardioMEMS™ (St. Jude Medical, Inc., Saint Paul, Minnesota) is an implantable, wireless pulmonary arterial pressure (PAP) monitoring system which transmits the patient's continuous PAPs to the treating health care provider in the ambulatory setting. PAP-guided medical therapy modification has been shown to significantly reduce HF-related hospitalization and overall mortality. In advanced stages of HF, wireless access to hemodynamic information correlated with earlier left ventricular assist device implantation and shorter time to heart transplantation.

Key words: CardioMEMS; Heart failure; Remote heart failure monitoring; Pulmonary arterial pressure monitoring; Left ventricular assist device

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Core tip: Traditional heart failure monitoring methods have failed to accurately and timely identify worsening heart failure. Remote pulmonary artery pressure monitoring *via* CardioMEMS™ heart failure system identified heart failure exacerbations earlier and more accurately than clinical signs, and timely medical

interventions resulted in reduced hospitalizations and mortality. Remote pulmonary artery pressure monitoring appears to have positive clinical implications in patients with mechanical circulatory support.

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INTRODUCTION

Heart failure (HF) is a chronic debilitating condition which impairs the ability of the heart to effectively pump the blood to the body to meet its metabolic requirements. HF is an emerging epidemic with an estimated prevalence of 5.8 million in the United States, and over 23 million worldwide^[1]. Within the United States, the incidence of HF exceeds 650000 each year with an estimated annual financial burden of around 30.7 billion dollars^[2,3]. Although there were major advances in pharmacologic and device based therapies for the management of HF which improved the overall survival over time, mortality of this condition remains high. The estimated survival after the diagnosis of HF is 50% at 5 years and 10% at 10 years^[1]. Hospitalization for acute decompensated HF serves as a poor prognostic indicator with an approximate 30% and 50% readmission rates at 1-mo and 6-mo, respectively^[1,3]. With improved survival of patients after acute myocardial infarction, a growing elderly population, and frequent hospitalizations in the HF population owing to acute exacerbations, HF continues to be one of the leading causes of morbidity, mortality, and health care expenditures in the United States and worldwide.

Around 150000-250000 Americans suffer from advanced stage HF^[4]. Although cardiac transplantation is the gold standard treatment in such patients, limited organ availability restricts the number of heart transplants to around 2500 per year (https://www.unos.org/data/transplant-trends/#transplants_by_organ). More than 4000 patients are currently on the waiting list for a cardiac transplant (www.unos.org/data/transplant-trends/#waitlists_by_organ), a number which is expected to increase significantly because of the increasing number of patients living with advanced HF and an increasing elderly population. Left ventricle assist device (LVAD) has emerged as a life-saving option for these patients as either bridge to transplant, bridge to decision, bridge to recovery or as destination therapy. Around 15000 HF patients across the world are currently supported with LVADs^[5]. LVAD serves as destination therapy in more than 45% of the patients living with the device^[5].

PREVIOUSLY TESTED METHODS FOR MONITORING HF PATIENTS

Identification of physical manifestations such as weight gain, extremity edema, fatigue, shortness of breath, orthopnea, paroxysmal nocturnal dyspnea, jugular venous distention, third heart sounds, and rales, *etc.* have poor to moderate sensitivities and are often late manifestations of worsening HF, thereby, relying on these markers have limited impact on reducing HF hospitalizations^[6]. Also, such efforts largely employ patient self-management strategies, including diuretic dose adjustments based on clinical worsening, and are unsuccessful in patients with poor self-care skills and compliance^[6]. Two large trials which investigated the benefits of tele-monitoring in HF population failed to show any significant decrease in the all-cause mortality and HF hospitalizations in the tele-monitored group^[6]. A smart-phone based electrocardiographic monitoring of HF has been recently proposed, but there is not much data exploring this idea^[7].

Lainchbury *et al.*^[8] compared N-terminal pro-B-type natriuretic (NT-proBNP) guided titration of medical therapy in HF patients with intensive clinical management and with usual care in a randomized sample of 564 patients. There was a reduction in the 3-year mortality in the NT-proBNP-guided group compared to the clinically-guided group (30.9%; $P = 0.048$) and to those with usual care (31.3%; $P = 0.021$). These benefits were selectively seen in patients ≤ 75 years of age. However, there was no statistically significant difference in the overall hospitalizations for HF and the secondary outcomes among all the groups^[8]. Another study monitored plasma B-type natriuretic peptide (BNP) levels in up to 558 chronic stable HF patients in an ambulatory setting to predict imminent decompensation^[9]. The study showed that both symptomatic and asymptomatic HF patients had a wide range of plasma BNP levels. Interestingly, 21% of symptomatic decompensated HF patients had BNP levels below the diagnostic threshold of < 100 pg/mL^[9].

REMOTE HEMODYNAMIC MONITORING IN HF PATIENTS

With the failure of reliable clinical symptoms/signs, tele-monitoring, and laboratory bio-markers to help reduce the hospitalizations, and health care expenditure in the HF population, more sophisticated techniques were sought to accurately predict the circulatory status in HF patients in order to execute timely pharmacological intervention to prevent the primary onus of this disease, *i.e.*, hospitalizations. Echocardiography is being used as a monitoring system in the hospitalized and ambulatory population, but it is associated with significant costs, less accuracy, and observer variability. Traditionally, in hospitalized HF patients, right heart catheterization

(RHC) provides invaluable information regarding the volume status and filling pressures which can form the basis of successful medical management. However, RHC is not routinely recommended to aid in the management of hospitalized decompensated HF patients owing to its invasive nature and associated risks. We had no such accurate monitoring systems in the ambulatory setting until scientific advances led to the development of implantable hemodynamic monitors (IHMs) which provided hemodynamic information comparable to the information obtained from a RHC^[10]. The idea of IHM based monitoring and necessary interventions in HF patients was innovative and exiting.

Earlier trials of implantable hemodynamic monitoring in HF patients did not show significant clinical benefit or were unable to adequately assess clinical efficacy. The COMPASS-HF (Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure) trial using Chronicle (Medtronic Inc., Minneapolis, Minnesota) to estimate right ventricular pressures and guide medical therapy, did not show a significant reduction in HF-related events when compared to the control group^[11]. The Reducing Decompensation Events Utilizing Intracardiac Pressures in Patients With Chronic Heart Failure (REDUCEhf) study employed a device combining IHM and implantable cardioverter-defibrillator technology to measure right ventricular pressures and guide medical therapy^[12]. The REDUCEhf study was unable to test clinical efficacy end points adequately and findings from this study did not show a difference in the rate of HF-equivalents when medical therapy was guided based on the information obtained from the IHM^[12].

The Hemodynamically Guided Home Self-Therapy in Severe Heart Failure Patients (HOMEOSTASIS) trial is a small study of 40 patients in which the benefit of physician-directed patient self-management of left atrial pressures as measured with the implantable HeartPOD (St. Jude Medical Inc, Minneapolis, Minnesota) was investigated^[13]. Left atrial pressure guided medical therapy was associated with an improved event-free survival (death or hospitalization for acute decompensated HF), reduced mean daily left atrial pressures, improved New York Heart Association (NYHA) functional class, improved left ventricular ejection fraction, increased doses of neuro-hormonal antagonists, and reduced diuretic doses^[13]. Encouraging results from this smaller study formed the basis of the larger and currently ongoing LAPTOP-HF trial which will investigate the role of implantable left atrial pressure monitoring in conjunction with a new HF treatment paradigm across the spectrum of HF patients^[14].

CARDIOMEMS™ AND REMOTE PULMONARY ARTERIAL PRESSURE MONITORING

CardioMEMS™ (St. Jude Medical, Inc., Saint Paul, Minnesota) is a wireless pulmonary arterial (PA)

pressure monitoring system. It measures PA pressures from a battery free capacitive electromechanical sensor which is permanently implanted with a delivery system in the distal pulmonary artery with a RHC *via* transvenous access. An electronic system transmits the generated data to a secure network where it is readily available for interpretation by the treating clinician. Verdejo *et al*^[15] showed that wireless PA pressure monitoring using the CardioMEMS sensor correlated with Swan-Ganz catheter and echocardiographic PA pressure measurements. The outcomes of remote management of HF patients guided by wireless PA pressure monitoring was investigated in the landmark CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients) trial^[16].

The CHAMPION trial is a randomized, controlled, multi-center, single-blind trial in which 550 NYHA class III HF patients were implanted with the wireless CardioMEMS HF pressure sensor system^[16]. Physicians had access to the PA pressures of the patients in the treatment group only, in which medications were adjusted based on the generated data. The control group received traditional HF management. The primary efficacy endpoint was the rate of HF-related hospitalizations at 6 mo. In comparison to the control group, there was a remarkable 28% reduction in HF-related hospitalizations at 6 mo, and 37% at 15 mo in the treatment group (Hazard ratio 0.63, $P < 0.0001$)^[17]. There were no pressure sensor failures and 98.6% of the study population was free from device-related or system-related complications^[17]. A sub-analysis of the original trial in HF with preserved ejection fraction (HFpEF) patients showed that there was a 50% reduction ($P < 0.0001$) in HF-related hospitalizations at 17 mo in the treatment group^[18]. These landmark findings led to the Food and Drug Administration approval of the CardioMEMS™ HF system for ambulatory hemodynamic monitoring in NYHA class III HF with reduced ejection fraction (HFrEF) and HFpEF patients, who are on optimal medical therapy, and had a HF hospitalization in the previous year^[19]. In the 2016 European society of Cardiology guidelines, CardioMEMS received a Class IIb recommendation for directed therapy management and monitoring tool in HF patients^[20].

Numerous sub-analyses supported the encouraging results obtained from the original CHAMPION trial. The reduced HF-related hospitalization rate was postulated to be from physician controlled effective changes in diuretic dosing in the treatment group ($P < 0.0001$ for more frequent diuretic dose changes in treatment group compared to control)^[21]. Wireless PA pressure-guided HF management was superior to clinical signs-guided management with a 67% relative risk reduction ($P = 0.0007$) in HF hospitalizations when diuretic doses were adjusted based on PA pressure alone vs clinical signs alone^[22]. At 6 mo, the target group experienced a higher frequency of medication adjustments with significant increases in the doses of diuretics, vasodilators, and

neuro-hormonal antagonists with preserved renal function despite intensification of diuretic therapy^[23]. Remote PA pressure-guided treatment resulted in similar reductions in HF hospitalization in HFrEF patients with and without a cardiac resynchronization therapy (CRT) device, suggesting that HF management guided by PA pressures may provide additive benefits to CRT^[24].

Wireless PA-pressure monitoring on top of guideline-directed medical therapy and CRT or ICD, had an additive effect in improving HF hospitalizations and mortality^[25]. There were significant reductions in all-cause hospitalization ($P < 0.0032$), and in the number of deaths or all-cause hospitalization in the treatment group ($P = 0.0017$)^[26]. Interestingly, it was observed that measurement of PA pressures using RHC alone may result in under-diagnosing pulmonary hypertension related to HF. Of the 217 patients who did not meet criteria for pulmonary hypertension during implantation RHC, 49% met criteria for pulmonary hypertension based in the first week IHM data^[27]. Alam *et al*^[28] compared 34 HF patients who had an implanted CardioMEMS HF system with 32 HF patients without an IHM, and reported a three-fold improvement in the Kansas City Cardiomyopathy Questionnaire scores ($P < 0.001$) and increased 6-min walk distance ($P < 0.001$) in the CardioMEMS group. These findings represent improved quality of life and exercise capacity. Results from the CHAMPION trial and subsequent sub-analysis confirmed that early and appropriate medical interventions following early detection of elevated PA pressures resulted in a significant reduction of HF-related hospitalizations, readmission rates and mortality.

There is an increasing trend in the number of HF patients living with LVADs and an increasing use of LVAD as destination therapy for advanced HF patients. Feldman *et al*^[29] conducted a sub-analysis of the CHAMPION trial to determine the validity of remote PA pressure directed therapy on optimization of medications, pump parameters, and timing of heart transplantation in patients receiving a LVAD. Of the 27 patients who received an LVAD, 15 patients were assigned to the treatment group where their medical therapy was modified based on PA pressures and 12 patients in the control group received standard care. The data obtained from CardioMEMS HF system led to significantly more medication changes in the treatment arm ($P = 0.025$). Wireless access to hemodynamic information correlated with earlier LVAD implantation ($P = 0.001$) and shorter time to transplantation ($P = 0.001$) in the treatment arm^[29].

Over the last few decades, efforts have been directed at reducing recurrent hospitalizations for worsening HF in this patient population. A variety of markers varying from clinical symptoms and signs to laboratory testing have been investigated to identify acute decompensated HF early enough to prevent hospitalizations, subsequent morbidity, and health care expenditure. Daily weight monitoring is a cornerstone for managing HF patients. It has been shown that increases in body weight begin at

least 1 week before a HF hospitalization^[30]. However, less than a half of the HF patients including those recently discharged after a hospitalization for HF exacerbation check their weight on a daily basis^[31]. Daily electronic body weight transmission to a HF clinic in patients with severe HF who had a recent HF hospitalization did not show any benefit in reducing HF re-hospitalization or death^[32].

CONCLUSION

HF continues to be a major public health problem with a significant financial burden. As more and more people are living with HF, it is important have a simple, reliable, and valid monitoring system to aid in the early identification and appropriate management of worsening HF in the ambulatory setting. IHM is an innovative and exciting monitoring system for HF management. CardioMEMS has steered HF research into a new direction which will serve as the gateway to future therapies and innovations in the management of chronic HF patients. Also with increasing number of people living with LVADs and LVAD being used as destination therapy in a large percentage of the LVAD population, CardioMEMS will be a promising monitoring system to better manage HF as well as the LVAD device in this population. However, given the small number of participants involved in many of the available trials, large multicenter randomized clinical trials are needed to make valid recommendations in an effort to lower mortality and improve quality of life in the chronically sick HF population. Wireless left atrial pressure-guided and PA pressure-guided management of HF can have a substantial positive effect on reducing the financial burden of HF and improving the overall morbidity and mortality in this population.

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