Current Cardiology Reports (2019) 21: 98
https://doi.org/10.1007/s11886-019-1194-9

NEW THERAPIES FOR CARDIOVASCULAR DISEASE (AA BAVRY, SECTION EDITOR)

Current Role of the CardioMEMS Device for Management of Patients with Heart Failure

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Published online: 27 July 2019
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Abstract

Purpose of Review Heart failure (HF) remains a significant burden to our healthcare system and a leading cause of hospitalizations. Current reactive strategies to treat and manage HF have failed to reduce hospitalizations and improve survival. The CardioMEMS device has recently been demonstrated to improve quality of life in HF and reduce HF-related hospitalizations. Current HF management strategies are reviewed with a particular emphasis on the current role of the CardioMEMS device.

Recent Findings The CHAMPION trial is the only randomized trial looking at the CardioMEMS device. Patients managed with targeted pulmonary artery pressures resulted in 28% reduction in the primary end-point of HF-related hospitalization at 6 months (HR 0.72, 95% CI 0.60–0.85, $p = 0.0002$) and 37% reduction during the entire follow-up period, which averaged 15 months (HR 0.63, 95% CI 0.52–0.77, $p < 0.0001$). The prospective open-label post-approval study recently presented a 58% reduction in HF hospitalizations per patient year (HR 0.42, 95% CI 0.38–0.47, $p < 0.0001$).

Summary Management of HF using the CardioMEMS device has been shown to reduce HF hospitalizations and improve quality of life regardless of ejection fraction. Patients best suited for this device are those with recurrent congestive symptoms despite optimal medical therapy.

Keywords CardioMEMS · Heart failure · Pulmonary artery pressure · Implantable hemodynamic monitor

Introduction

Heart failure (HF) affects around 6.2 million people in the United States (US) [1]. This figure is expected to increase to over 8 million people by 2030 [2]. The prognosis of HF remains poor—30% of patients will die within the first year of diagnosis [3–5] and 50% within 5 years [6, 7]. The medical costs from HF currently total around $20.9 billion and are projected to increase to $53.1 billion by 2030 [2]. Hospitalization continues to be the biggest contributor to this figure.

In the US, around 1 million hospitalizations per year are attributed to HF [8] with an average length of stay of 5 days for decompensation [9, 10]. A post hoc analysis shows that despite these somewhat long hospital stays, 48% of patients leave the hospital with continued congestive symptoms due to inadequate diuresis [11]. In the same study, of the remaining 52% of patients believed to be euvolemic upon discharge, up to 65% have return of congestive symptoms at 60-day follow-up. This helps to explain the high readmission rates for HF of 30% within 1 month and 50% within 6 months [12, 13]. High number of HF-related hospitalizations is also a strong predictor of mortality [14, 15].

Current HF management strategies have been inadequate at reducing readmissions and improving mortality. Care to date has been largely reactive, focusing on adjusting medications once the signs and symptoms of HF manifest. However, once HF symptoms present, patients quickly present to the hospital. A paradigm shift is needed in our management strategies utilizing better tools to identify and manage congestion early enough to prevent hospitalizations. Intracardiac and pulmonary artery (PA) pressures rise up to several weeks before the onset of symptoms [16, 17]. This information may give opportunity for earlier interventions before symptoms present, thereby preventing hospitalizations. Such a strategy would hopefully improve patient quality of life, reduce healthcare costs, and possibly improve survival.

This article is part of the Topical Collection on *New Therapies for Cardiovascular Disease*

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Ambulatory Monitoring of HF

The history and physical examination continue to be our most frequently used tool in the diagnosis and management of HF; however, this approach has significant limitations. Symptoms of shortness of breath, orthopnea, paroxysmal nocturnal dyspnea, edema along with signs of crackles, a third heart sound, and jugular venous distention have poor sensitivity and predictive value for decompensation [18]. Weight gain has also been demonstrated to be poorly sensitive for acute decompensation [19, 20]. The inaccuracy of these signs/symptoms and the limited frequency of our clinical interactions limit their usefulness to monitor for HF.

Tele-health increases the frequency of clinical interactions by monitoring weight and symptoms, but this strategy failed to reduce hospitalization or mortality [21, 22].

Natriuretic peptides have been used as a more objective means of assessing HF severity with good sensitivity, but only moderate specificity [23]. Using natriuretic peptides to monitor HF has been associated with a reduction in hospitalizations, but this strategy did not significantly alter all-cause mortality [24]. Subgroup analyses in this meta-analysis suggest that patients < 75 years of age and those with HF with reduced ejection fraction (HFrEF) may benefit the most from management guided by natriuretic peptide monitoring and also had improved survival. Older patients are more resistant to changes in natriuretic peptides and more likely to develop adverse events [25]. The use of natriuretic peptides to guide HF management is limited by a lack of an optimal target, an inability to attain goal levels in most, and a lack of a universal benefit in all patients with HF [26]. Patients with advanced age and preserved ejection fraction (HFpEF), who make up a large proportion of patients with HF, may not derive a benefit.

Invasive Monitoring of HF

A rise in ventricular filling pressures is the underlying pathophysiology of acute decompensated HF. Right heart catheterization (RHC) to measure filling pressures is the gold standard to diagnose elevated cardiac filling pressures and has been used in decompensated HF to guide titration of diuretics to a hemodynamic goal. This can result in acute improvement in hemodynamics; however, this may not translate into sustained improvement [27]. In the ESCAPE trial, RHC was used in addition to routine HF therapy. Though the RHC group had improved exercise tolerance and quality of life, the use of RHC compared with routine HF therapy did not result in a difference in mortality and hospitalization [28]. The invasive nature of RHC limits its utility in an ambulatory setting. Several other devices have been used to continuously measure filling pressures in the heart.

Cardiac implanted electronic devices have been looked at to monitor HF. The widespread use of pacemakers and defibrillators in cardiac patients make them attractive targets for this purpose. Various parameters such as intrathoracic impedance and heart rate variability have been looked at to predict HF events with varying reported sensitivities ranging from 20 to 76% [20, 29–31]. Using this information in the DOT-HF trial resulted in no difference in survival and actually increased hospitalizations [32]. When patients in the impedance monitoring arm passed a threshold suggesting fluid retention, an audible alert was triggered that instructed patients to present to the hospital. This accounts for the increase in hospitalization and raises questions of how information should be made available to patients. Though thoracic impedance changes precede symptoms by days to weeks, these are further preceded by increases in pulmonary artery (PA) pressures by several days [17, 33].

The Heart POD (Abbott, Minneapolis, Minnesota) is a continuous left atrial pressure monitor studied in the LAPTOP-HF trial. The trial was terminated early due to safety concerns related to complications regarding the trans-septal implantation of the device, namely cardiac perforations. The trial results were overall negative demonstrating no reduction in a composite endpoint of recurrent HF hospitalization and complications of HF therapy. However, when using the endpoint of only recurrent HF hospitalizations, the results showed a reduction in HF hospitalizations of 43% [34].

The V-LAP system (Vectorious Medical Technologies, Tel Aviv, Israel) is an implantable left atrial pressure sensor implanted permanently in the septum using a trans-septal approach and is currently being studied. Another device being studied is the Titan LAP monitoring system (Integrated Sensing Systems, Inc., Ypsilanti, MI). This device is implanted surgically, thus limiting its use to patients undergoing cardiac surgery. It has been evaluated in first-in-man studies in patients undergoing implantation of a left ventricular assist device or other cardiac surgery [35].

The Chronicle IHM (Medtronic Inc., Minneapolis, Minnesota) right ventricular lead was looked at in the COMPASS-HF trial [36]. The device continuously monitored right ventricular systolic and diastolic pressures. There was a non-significant 21% reduction in HF events (hospitalizations and emergency or urgent care visits requiring intravenous therapy, $p = 0.33$), but did show a significant 36% relative risk reduction in HF-related hospitalizations (HR 0.64, 95% CI 0.42–0.96, $p = 0.03$) [16, 37]. Event rates in the control group were lower than expected making the study under-powered to detect differences in HF clinical events.

CardioMEMS Pulmonary Artery Pressure Monitoring System

The CardioMEMS device (Abbott Medical, Minneapolis, Minnesota) has been the most successful of implantable hemodynamic devices. The device is implanted into a branch of

the PA during RHC. It is a leadless and battery-free device consisting of three main components: the sensor, the home electronics system that simultaneously powers and interrogates the sensor relaying the information, and a secure website used by clinicians to review the data.

The CHAMPION trial was a randomized, single-blinded trial that enrolled 550 patients with class III HF regardless of left ventricular ejection fraction and had a hospitalization for HF within the preceding 12 months [38, 39]. Patients were randomized to management using daily measurement of pressures in addition to standard care versus standard care alone. Use of PA pressures resulted in 28% reduction ($p = 0.0002$) in the primary end point of HF-related hospitalization at 6 months. Over the entire single-blinded follow-up period, mean 15 months, PA pressure monitoring resulted in a 37% reduction in HF-related hospitalization. The numbers needed to treat to avoid a HF hospitalization were 8 at 6 months and 4 at 15 months. Overall freedom from system-related complications was 98.6% and freedom from pressure sensor failures was 100%. Patients in the treatment arm had lower mean PA pressures, improved Kansas City Cardiomyopathy Questionnaire scores, and improved 6-min walk tests [39].

The results of HF hospitalization reduction were sustained over the long term. Following patients for mean of 18 months, rates of HF hospitalization were reduced in the treatment arm by 33% (HR 0.67, 95% CI 0.55–0.8, $p < 0.0001$) [40]. Additionally, following completion of the randomized access period, patients in the control arm were opened up, managed utilizing PA pressures, and followed longitudinally (mean 13 months). Armed now with this data, rates of hospitalizations for HF in the former control group were reduced by 48% ($p < 0.0001$) compared with rates of admissions during the randomized access. There was no significant difference in mortality [41•]. However, retrospective analysis of patients with HFrEF demonstrated not only a 28% lower hospitalization in the treatment group (HR 0.72; 95% CI 0.59 to 0.88; $p = 0.0013$), but also a strong trend for 32% lower mortality (HR 0.68; 95% CI 0.45 to 1.02; $p = 0.06$) [42]. In the same analysis, they looked at the effect of guideline-directed medical therapy (GDMT). Patients on at least 1 GDMT, angiotensin system blocker or beta-blocker, had 33% lower HF hospitalization (HR 0.67; 95% CI 0.54 to 0.82; $p = 0.0002$) and 47% lower mortality (HR 0.63; 95% CI 0.41 to 0.96, $p = 0.0293$). Patients on both optimal GDMT medications in the treatment arm had 43% lower HF hospitalizations (HR 0.57; 95% CI 0.45 to 0.74; $p < 0.0001$) and 57% lower mortality (HR 0.43; 95% CI 0.24 to 0.76; $p = 0.0026$) compared with controls. [42]. Another subgroup analysis of the 119 patients from CHAMPION with HFpEF (EF ≥ 40%) showed 46% reduction in HF hospitalization rate at 6 months in the treatment group ($p < 0.0001$) and 50% reduction after the blinded follow-up (mean 17.6 months) [40].

A retrospective cohort study using Medicare claims data was performed on 1114 patients who underwent CardioMEMs implantation [43]. Following implantation in this real-world cohort, there was a 34% reduction in HF hospitalizations and 23% reduction in all-cause hospitalizations sustained at 12 months.

Concern for the safety of the device was brought to light by the MAUDE database [44]. Of the original 575 implant attempts in the CHAMPION trial, it was reported there were 15 adjudicated serious adverse events (2.6%) with 1 case of PA injury and 2 deaths. Of the first 5500 real-world implants after FDA approval, there were 2.8% adverse events with 28 reports of PA injury/hemoptysis resulting in 14 intensive care unit stays, 7 intubations, and 6 deaths. There were 22 overall deaths (0.4%). There were also 46 cases of sensor failure, malfunction, or migration requiring 35 recalibrations, 13 re-implantations, and 11 hospitalizations (for re-intervention, HF, or over-diuresis), and 5 sensors could not be used despite recalibration. There were 18 reports of technical challenges with implantation with 14 implants aborted. There were 15 cases of access site-related bleeding or infection and 5 cases of pulmonary embolism or device thrombosis reported. Many of the adverse events including deaths and PA injury/hemoptysis seemed to be clustered shortly after FDA approval and appeared to level off after this, suggesting there may have been an early learning curve.

To look at the continued benefit and safety of the device, the CardioMEMS HF system post-approval study was started. It is a prospective, open-label trial that enrolled 1200 patients with CardioMEMS implants from 2014 to 2018 at 104 centers [45]. Compared with the CHAMPION cohort, patients enrolled in the post-approval study were older (mean age 69 years compared with 62), had more women (38% compared with 28%), and had more patients with HFpEF (47% compared with 22%). After implantation of the device, there was a 58% reduction in HF hospitalizations per patient year (HR 0.42, 95% CI 0.38–0.47, $p < 0.0001$). There was a 44% reduction in the combined endpoint of HF hospitalization and death (HR 0.56, 95% CI 0.51–0.62, $p < 0.0001$). All-cause hospitalization was also reduced by 28% (HR 0.72, 95% CI 0.67–0.77, $p < 0.0001$). Breaking patients up into three different stratum by ejection fraction showed similar reductions in HF hospitalizations (EF < 40% with 54% relative risk reduction, EF 41–50% with 6 3% relative risk reduction, EF > 50% with 61% relative risk reduction). Subgroup analyses demonstrated significant reduction in HF hospitalizations post-implant independent of gender, etiology of cardiomyopathy, device implantation (ICD or CRT-D), or race (White or African American). Freedom from device- or system-related complications at 1 year was 99.7%, and freedom from sensor failure was 99.9%.

The CARDIOMEMS device has been shown to be safe with low rates of complications and low rates of failure. Management of patients guided by PA pressures on top of standard treatment decreases PA pressures, HF hospitalizations, and all-cause hospitalizations.

Device Monitoring

Some infrastructure is required to monitor and manage patients with CardioMEMS. A member from the HF team needs to routinely check the website to review the data. It is helpful to have a protocol for up-titration and down-titration of medications. PA pressures are re-evaluated every few days and adjustments made. Data from the post-approval study showed that medication changes are front-loaded during the first 3 months after implant [46]. Initially averaging 2 medication changes per month, this number decreases to < 1 per month after 3 months from implant. PA pressures during the same period decrease rapidly during the first 2 months and level off and maintain. This suggests that after the first 3 months, many patients stabilize and management becomes less intense while still maintaining good results.

PA diastolic pressure goes along with pulmonary venous congestion and HF symptoms. The goal PA diastolic pressure is usually 8–20 mmHg. Patients can have low, normal, or high PA pressures. Patients with low or normal PA pressures are maintained on current therapy as long as there are no signs of poor perfusion, hypotension, or renal insufficiency. Patients with elevated PA pressures will have adjustments in diuretics and vasodilators until PA pressures are in goal or the patient develops an adverse reaction.

Cost/Value Analysis

An analysis of the potential cost/value of the device will give us insight into what patients may benefit from this technology. The cost of the sensor is priced at approximately $17,750. Utilizing clinical trial data on survival and hospitalizations, various models have looked at cost/value analyses comparing over 5 projected years with the device versus without. The lowest cost per quality-adjusted-life-year (QALY) was calculated from the CHAMPION group at $13,979 and the highest around $71,462 [39, 47, 48]. The model by the Institute for Clinical and Economic Review found a cost in the middle around $57,933 per QALY gained [47]. All of these models are highly dependent on the continued long-term benefits of the device lasting > 4.6 years. If there is not a sustained benefit, the cost to value would be considered high, in excess of $100,000 per QALY gained. The American College of Cardiology/American Heart Association Statement on Cost/Value Methodology assigns a cost of < $50,000 per QALY a high value, $50–150,000 is assigned intermediate value, and > $150,000 is assigned low value [49]. Thus, the cost/value of the CardioMEMS device is in the intermediate to possibly high value if its benefit sustains for 5 years.

Patients from CHAMPION trial were those with NYHA class III HF symptoms and a hospitalization in the past year for decompensation. With these same criteria, around 286,000 patients per year would be the candidate pool for potential device implantation. Assuming intermediate uptake of the device of 25% by year 5, the global cost has been estimated at 1 billion dollars per year [47]. If every potential candidate had the device implanted, the global cost would be enormous.

Patient Selection

Given that the CardioMEMS implantation is costly, it should be reserved for appropriately selected patients. GDMT in patients with chronic HFrEF has improved survival and reduced hospitalizations [13, 50, 51]. Despite the proven benefit of GDMT, it is clear that many patients admitted with HF are not on optimal GDMT. Even amongst patients followed in a real-world registry of patients with HFrEF, there remain significant gaps in the use of optimal GDMT [52]. In this registry, triple therapy with renin-angiotensin system blocker, beta-blockers, and aldosterone antagonist was used in clinical practice in < 10% of patients. The optimization of doses of these 3 classes of drugs occurred in < 5% of the patients. Given that most patients are not on GDMT, this is a huge target as an area for improvement in care for HF. There are guidelines on how to initiate and optimize medications and doses in HFrEF [53]. Patients with HFpEF continue to be a very difficult population to treat as few treatments have demonstrated improvement in clinical outcomes. However, recently pooled analyses from registries have demonstrated that patients with mid-range left ventricular systolic function (EF 40–49%) on beta-blocker and renin-angiotensin system blocker have demonstrated a reduction in all-cause mortality [54].

An independent panel of 10 experts, the California Technology Assessment Forum, highlighted the specific population that this technology may best be targeted for: high-risk patients with recurrent congestion despite optimal medical therapy, able to be compliant with device monitoring and medication adjustments, in centers of excellence with adequate resources to support the device [47]. In 2016, the European Society of Cardiology guidelines gave the CardioMEMS device a class IIb recommendation for directed therapy management and monitoring tool in HF patients [55•].

There are some patients who are not good candidates. The device may not benefit those patients at end-stage HF headed to transplant, ventricular assist device, or palliative care. The device is unlikely to help patients with chronic kidney disease stage IV or V as they are resistant to diuretics. Patients with recurrent pulmonary emboli or deep vein thrombosis may not be good candidates for implant. Patients with body mass index > 35 kg/m^2 and chest circumference > 52 in. may not be good implant candidates as the device may have difficulty being sensed. Patients must also have a target implant PA diameter of at least 7 mm and must also tolerate anticoagulant or dual antiplatelet therapy for at least 1 month after implantation.

Conclusions and Further Research

The CardioMEMS device has demonstrated impressive results in the reduction in HF hospitalizations and improving quality of life above standard of care in patients with HFrEF and HFpEF. Despite the impressive results from a single industry-sponsored trial and real-world data across multiple subgroups, there remains a fairly low adoption rate of the device. Because of the current cost/value of the device, it appears to be best suited for patients with continued HF symptoms despite optimal GDMT. To address continuing concerns over the original study design and see if the results can be replicated, the MEMS-HF trial in Europe and GUIDE-HF trial in the US are ongoing [56, 57].

Compliance with Ethical Standards

Conflict of Interest Calvin C. Leung declares that he has no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

References

Papers of particular interest, published recently, have been highlighted as:
• Of importance
•• Of major importance

1. Benjamin EJ, Muntner P, Alonso A, Bittencourt MS, Callaway CW, Carson AP, et al. Heart disease and stroke statistics—2019 update: a report from the American Heart Association. Circulation. 2019;139(10):e56–e528. https://doi.org/10.1161/CIR.0000000000000659.
2. Heidenreich PA, Albert NM, Allen LA, Bluemke DA, Butler J, Fonarow GC, et al. Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. Circ Heart Fail. 2013;6(3):606–19. https://doi.org/10.1161/HHF.0b013e318291329a.
3. Barker WH, Mullooly JP, Getchell W. Changing incidence and survival for heart failure in a well-defined older population, 1970-1974 and 1990-1994. Circulation. 2006;113(6):799–805.
4. Loehr LR, Rosamond WD, Chang PP, Folsom AR, Chambless LE. Heart failure incidence and survival (from the Atherosclerosis Risk in Communities study). Am J Cardiol. 2008;101(7):1016–22. https://doi.org/10.1016/j.amjcard.2007.11.061.
5. Cowie MR, Fox KF, Wood DA, et al. Hospitalization of patients with heart failure: a population-based study. Eur Heart J. 2002;23(11):877–85.
6. Roger VL, Weston SA, Redfield MM, et al. Trends in heart failure incidence and survival in a community-based population. JAMA. 2004;292(3):344–50.
7. Curtis LH, Whellan DJ, Hammill BG, et al. Incidence and prevalence of heart failure in elderly persons, 1994-2003. Arch Intern Med. 2008;168(4):418–24. https://doi.org/10.1001/archinternmed.2007.80.
8. Hall MJ, Levant S, DeFrances CJ. Hospitalization for congestive heart failure: United States, 2000–2010. NCHS data brief, no 108. Hyattsville, MD: National Center for Health Statistics. NCHS Data Brief. 2012;(108):1–8.
9. Yancy CW, Lopatin M, Stevenson LW, de Marco T, Fonarow GC, ADHERE Scientific Advisory Committee and Investigators. Clinical presentation, management, and in-hospital outcomes of patients admitted with acute decompensated heart failure with preserved systolic function: a report from the Acute Decompensated Heart Failure National Registry (ADHERE) database. J Am Coll Cardiol. 2006 Jan 3;47(1):76–84.
10. Adams KF Jr, Fonarow GC, Emerman CL, LeJemtel TH, Costanzo MR, Abraham WT, et al. Characteristics and outcomes of patients hospitalized for heart failure in the United States: rationale, design, and preliminary observations from the first 100,000 cases in the Acute Decompensated Heart Failure National Registry (ADHERE). Am Heart J. 2005;149(2):209–16.
11. Lala A, McNulty SE, Mentz RJ, et al. Relief and recurrence of congestion during and after hospitalization for acute heart failure: insights from Diuretic Optimization Strategy Evaluation in Acute Decompensated Heart Failure (DOSE-AHF) and Cardiorenal Rescue Study in Acute Decompensated Heart Failure (CARESS-HF). Circ Heart Fail. 2015;8(4):741–8. https://doi.org/10.1161/CIRCHEARTFAILURE.114.001957.
12. Roger VL. Epidemiology of heart failure. Circ Res. 2013;113(6):646–59. https://doi.org/10.1161/CIRCRESAHA.113.300268.
13. Yancy CW, Jessup M, Bozkurt B, Butler J, Casey DE Jr, Drazner MH, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013;62(16):e147–239. https://doi.org/10.1016/j.jacc.2013.05.019.
14. Lee DS, Austin PC, Stukel TA, Alter DA, Chong A, Parker JD, et al. "Dose-dependent" impact of recurrent cardiac events on mortality in patients with heart failure. Am J Med. 2009;122(2):162–169.e1. https://doi.org/10.1016/j.amjmed.2008.08.026.
15. Setoguchi S, Stevenson LW, Schneeweiss S. Repeated hospitalizations predict mortality in the community population with heart failure. Am Heart J. 2007;154(2):260–6.
16. Zile MR, Bennett TD, St John Sutton M, et al. Transition from chronic compensated to acute decompensated heart failure: pathophysiological insights obtained from continuous monitoring of intracardiac pressures. Circulation. 2008;118(14):1433–41. https://doi.org/10.1161/CIRCULATIONAHA.108.783910.
17. Adamson PB. Pathophysiology of the transition from chronic compensated and acute decompensated heart failure: new insights from continuous monitoring devices. Curr Heart Fail Rep. 2009;6(4):287–92.
18. Capomolla S, Ceresa M, Pinna G, Maestri R, la Rovere MT, Febo O, et al. Echo-Doppler and clinical evaluations to define hemodynamic profile in patients with chronic heart failure: accuracy and influence on therapeutic management. Eur J Heart Fail. 2005;7(4):624–30.
19. Lewin J, Ledwidge M, O'Loughlin C, McNally C, McDonald K. Clinical deterioration in established heart failure: what is the value of BNP and weight gain in aiding diagnosis? Eur J Heart Fail. 2005;7(6):953–7.
20. Abraham WT, Compton S, Haas G, Foreman B, Canby RC, Fishel R, et al. Intrathoracic impedance vs. daily weight monitoring for predicting worsening heart failure events: results of the Fluid Accumulation Status Trial (FAST). Congest Heart Fail. 2011;17(2):51–5. https://doi.org/10.1111/j.1751-7133.2011.00220.x.
21. Chaudhry SI, Mattera JA, Curtis JP, Spertus JA, Herrin J, Lin Z, et al. Telemonitoring in patients with heart failure. N Engl J Med. 2010;363(24):2301–9. https://doi.org/10.1056/NEJMoa1010029.

22. Koehler F, Winkler S, Schieber M, Sechtem U, Stangl K, Böhm M, et al. Impact of remote telemedical management on mortality and hospitalizations in ambulatory patients with chronic heart failure: the telemedical interventional monitoring in heart failure study. Circulation. 2011;123(17):1873–80. https://doi.org/10.1161/CIRCULATIONAHA.111.018473.
23. Roberts E, Ludman A, Dworzynski K, et al. The diagnostic accuracy of the natriuretic peptides in heart failure: systematic review and diagnostic meta-analysis in the acute care setting. BMJ. 2015;350:h910. https://doi.org/10.1136/bmj.h910.
24. Pufulete M, Maishman R, Dabner L, Higgins JPT, Rogers CA, Dayer M, et al. B-type natriuretic peptide-guided therapy for heart failure: a systematic review and meta-analysis of individual participant data (IPD) and aggregate data. Syst Rev. 2018;7(1):112. https://doi.org/10.1186/s13643-018-0776-8.
25. Pfisterer M, Buser P, Rickli H, Gutmann M, Erne P, Rickenbacher P, et al. BNP-guided vs symptom-guided heart failure therapy: the Trial of Intensified vs Standard Medical Therapy in Elderly Patients With Congestive Heart Failure (TIME-CHF) randomized trial. JAMA. 2009;301(4):383–92. https://doi.org/10.1001/jama.2009.2.
26. Desai AS. Are serial BNP measurements useful in heart failure management? Serial natriuretic peptide measurements are not useful in heart failure management: the art of medicine remains long. Circulation. 2013;127(4):509–16; discussion 516. https://doi.org/10.1161/CIRCULATIONAHA.112.120493.
27. Steimle AE, Stevenson LW, Chelimsky-Fallick C, Fonarow GC, Hamilton MA, Moriguchi JD, et al. Sustained hemodynamic efficacy of therapy tailored to reduce filling pressures in survivors with advanced heart failure. Circulation. 1997;96:1165–72.
28. Binanay C, Califf RM, Hasselblad V, et al. Evaluation study of congestive heart failure and pulmonary artery catheterization effectiveness: the ESCAPE trial. JAMA. 2005;294(13):1625–33.
29. Conraads VM, Tavazzi L, Santini M, Oliva F, Gerritse B, Yu CM, et al. Sensitivity and positive predictive value of implantable intrathoracic impedance monitoring as a predictor of heart failure hospitalizations: the SENSE-HF trial. Eur Heart J. 2011;32(18):2266–73. https://doi.org/10.1093/eurheartj/ehr050.
30. Yu CM, Wang L, Chau E, Chan RHW, Kong SL, Tang MO, et al. Intrathoracic impedance monitoring in patients with heart failure: correlation with fluid status and feasibility of early warning preceding hospitalization. Circulation. 2005;112(6):841–8.
31. Whellan DJ, Ousdigian KT, Al-Khatib SM, et al. Combined heart failure device diagnostics identify patients at higher risk of subsequent heart failure hospitalizations: results from PARTNERS HF (Program to Access and Review Trending Information and Evaluate Correlation to Symptoms in Patients With Heart Failure) study. J Am Coll Cardiol. 2010;55(17):1803–10. https://doi.org/10.1016/j.jacc.2009.11.089.
32. van Veldhuisen DJ, Braunschweig F, Conraads V, Ford I, Cowie MR, Jondeau G, et al. Intrathoracic impedance monitoring, audible patient alerts, and outcome in patients with heart failure. Circulation. 2011;124(16):1719–26. https://doi.org/10.1161/CIRCULATIONAHA.111.043042.
33. Perego GB, Oldani M, Pellegrini D, Brasca FMA, Malfatto G, Villani A, et al. Correlation between pulmonary artery pressure and thoracic impedance: insights from daily monitoring through an implanted device in chronic heart failure. Int J Cardiol. 2017;245:196–200. https://doi.org/10.1016/j.ijcard.2017.07.042.
34. Abraham WT, Adamson PB, Costanzo MR, et al. Hemodynamic monitoring in advanced heart failure: results from the LAPTOP-HF trial. Late-Breaking Clinical Trials. Presented at HFSA 2016. Orlando, FL; J Card Fail. 2016;22(11): 940. DOI: https://doi.org/10.1016/j.cardfail.2016.09.012
35. Hubbert L, Baranowski J, Delshad B, et al. Left atrial pressure monitoring with an implantable wireless pressure sensor after implantation of a left ventricular assist device. ASAIO J. 2017;63(5):e60–5. https://doi.org/10.1097/MAT.0000000000000451.
36. Bourge RC, Abraham WT, Adamson PB, Aaron MF, Aranda JM Jr, Magalski A, et al. Randomized controlled trial of an implantable continuous hemodynamic monitor in patients with advanced heart failure: the COMPASS-HF study. J Am Coll Cardiol. 2008;51(11):1073–9. https://doi.org/10.1016/j.jacc.2007.10.061.
37. Stevenson LW, Zile MR, Bennett TD, Kueffer FJ, Jessup ML, Adamson P, et al. Chronic ambulatory intracardiac pressures and future heart failure events. Circ Heart Fail. 2010;3:580–7.
38. Adamson PB, Abraham WT, Aaron M, et al. CHAMPION trial rationale and design: the long-term safety and clinical efficacy of a wireless pulmonary artery pressure monitoring system. J Card Fail. 2011;17(1):3–10. https://doi.org/10.1016/j.cardfail.2010.08.002.
39. Abraham WT, Adamson PB, Bourge RC, Aaron MF, Costanzo MR, Stevenson LW, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. Lancet. 2011;377(9766):658–66. https://doi.org/10.1016/S0140-6736(11)60101-3.
40. Adamson PB, Abraham WT, Bourge RC, Costanzo MR, Hasan A, Yadav C, et al. Wireless pulmonary artery pressure monitoring guides management to reduce decompensation in heart failure with preserved ejection fraction. Circ Heart Fail. 2014;7(6):935–44. https://doi.org/10.1161/CIRCHEARTFAILURE.113.001229.
41.• Abraham WT, Stevenson LW, Bourge RC, et al. Sustained efficacy of pulmonary artery pressure to guide adjustment of chronic heart failure therapy: complete follow-up results from the CHAMPION randomised trial. Lancet. 2016;387(10017):453–61. https://doi.org/10.1016/S0140-6736(15)00723-0 **This is the only current randomized trial looking at the CardioMEMS device**.
42. Givertz MM, Stevenson LW, Costanzo MR, Bourge RC, Bauman JG, Ginn G, et al. Pulmonary artery pressure-guided management of patients with heart failure and reduced ejection fraction. J Am Coll Cardiol. 2017;70(15):1875–86. https://doi.org/10.1016/j.jacc.2017.08.010.
43. Desai AS, Bhimaraj A, Bharmi R, Jermyn R, Bhatt K, Shavelle D, et al. Ambulatory hemodynamic monitoring reduces heart failure hospitalizations in "real-world" clinical practice. J Am Coll Cardiol. 2017;69(19):2357–65. https://doi.org/10.1016/j.jacc.2017.03.009.
44. Muthiah Vaduganathan M, Deflippis EM, Fonarow GC, et al. Postmarketing adverse events related to the CardioMEMS HF system. JAMA Cardiol. 2017;2(11):1277–9. https://doi.org/10.1001/jamacardio.2017.3791.
45. Shavelle DM. Pulmonary artery pressure-guided therapy for ambulatory heart failure patients in clinical practice: 1-year outcomes from the CardioMEMS post-approval study. Presented at: ACC 2019. New Orleans, LA; 2019.
46. Joly JM, Heywood JT, Shavelle D et al. Front-loaded intervention during first 90 days of pulmonary pressure guided management. Presented at HFSA 2017. Dallas, TX. J Card Fail. 2017;23 (8): Supplement S12–S13. https://doi.org/10.1016/j.cardfail.2017.07.030
47. Ollendorf DA, Sandhu AT, Chapman R, et al. CardioMEMS™ HF System (St. Jude Medical) and sacubitril/valsartan (Entresto™, Novartis) for management of congestive heart failure: effectiveness, value, and value-based price benchmarks. Institute for Clinical and Economic Review. https://icer-review.org/wp-content/uploads/2016/01/CHF_Final_Report_120115.pdf. Accessed 28 May 2019
48. Sandhu AT, Goldhaber-Fiebert JD, Owens DK, Turakhia MP, Kaiser DW, Heidenreich PA. Cost-effectiveness of implantable pulmonary artery pressure monitoring in chronic heart failure. JACC Heart Fail. 2016;4(5):368–75.
49. Anderson JL, Heidenreich PA, Barnett PG, Creager MA, Fonarow GC, Gibbons RJ, et al. ACC/AHA statement on cost/value

methodology in clinical practice guidelines and performance measures: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and Task Force on Practice Guidelines. J Am Coll Cardiol. 2014;63:2304–22.

50. Fonarow GC, Albert NM, Curtis AB, Gheorghiade M, Liu Y, Mehra MR, et al. Incremental reduction in risk of death associated with use of guideline-recommended therapies in patients with heart failure: a nested case-control analysis of IMPROVE HF. J Am Heart Assoc. 2012;1(1):16–26. https://doi.org/10.1161/JAHA.111.000018.
51. Tran RH, Aldemerdash A, Chang P, Sueta CA, Kaufman B, Asafu-adjei J, et al. Guideline-directed medical therapy and survival following hospitalization in patients with heart failure. Pharmacotherapy. 2018;38(4):406–16. https://doi.org/10.1002/phar.2091.
52. Greene SJ, Butler J, Albert NM, DeVore AD, Sharma PP, Duffy CI, et al. Medical therapy for HF with reduced ejection fraction: the CHAMP-HF registry. J Am Coll Cardiol. 2018;72:351–66.
53. Yancy CW, Januzzi JL, Allen LA, et al. 2017 ACC expert consensus decision pathway for optimization of heart failure treatment: answers to 10 pivotal issues about heart failure with reduced ejection fraction. J Am Coll Cardiol. 2018;l 71:201–30.
54. Choi KH, Choi JO, Jeon ES, et al. Guideline-directed medical therapy for patients with heart failure with midrange ejection fraction: a patient-pooled analysis from the KorHF and KorAHF registries. J Am Heart Assoc. 2018;7(21). https://doi.org/10.1161/JAHA.118.
55.• Ponikowski P, Voors AA, Anker SD, et al. 2016 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure: the task force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC). Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. Eur J Heart Fail. 2016;18:891–975 **This is the first guideline to incorporate the use of CardioMEMS in the management of HF.**
56. Angermann CE, Assmus B, Anker SD, Brachmann J, Ertl G, Köhler F, et al. Safety and feasibility of pulmonary artery pressure-guided heart failure therapy: rationale and design of the prospective CardioMEMS Monitoring Study for Heart Failure (MEMS-HF). Clin Res Cardiol. 2018;107(11):991–1002. https://doi.org/10.1007/s00392-018-1281-8.
57. Lindenfeld J, Abraham WT, Maisel A, Zile M, Smart F, Costanzo MR, et al. Hemodynamic-GUIDEd management of Heart Failure (GUIDE-HF). Am Heart J. 2019;214:18–27. https://doi.org/10.1016/j.ahj.2019.04.014.

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