The CardioMEMS™ HF System is the first and only FDA-approved heart failure monitor proven to significantly reduce heart failure hospital admissions and improve quality of life in NYHA Class III heart failure patients.¹

When used by clinicians to manage heart failure, the CardioMEMS HF System is:

- Safe and reliable — demonstrated 98.6% freedom from device- or system-related complications.¹
- Clinically proven — reduced heart failure admissions by 33%¹ and all-cause 30-day readmissions by 58%.²
- Proactive and personalized — patient management through direct monitoring of PA pressure and titration of medications.

Traditional physiologic markers in the development of acute decompensation in patients suffering from heart failure such as intrathoracic impedance, weight, blood pressure and symptoms are late and unreliable,³⁴ with only moderate sensitivity and specificity.¹⁷ Large, randomized, controlled studies using telemonitoring of these indirect markers have failed to demonstrate a reduction in heart failure hospitalizations.³⁴,⁸

This clinical compendium summarizes key studies demonstrating the safety and effectiveness of the CardioMEMS HF System.

What’s New since the Last Update of April 2019?


Pre-CHAMPION

VERDEJO HE, CASTRO PF, CONCEPCION R, FERRADA MA, ALFARO MA, ALCAINO ME, DECK CC, BOURGE RC. COMPARISON OF A RADIOFREQUENCY-BASED WIRELESS PRESSURE SENSOR TO SWAN-GANZ’ CATHETER AND ECHOCARDIOGRAPHY FOR AMBULATORY ASSESSMENT OF PULMONARY ARTERY PRESSURE IN HEART FAILURE


The CardioMEMS™ HF System monitors PA pressure measurements from a sensor implanted into the PA. The safety and accuracy of the CardioMEMS™ PA Sensor have been demonstrated in previous studies. Systolic and diastolic PA pressures were significantly correlated between the CardioMEMS Sensor and traditional Swan-Ganz catheter measurements and between the CardioMEMS PA Sensor and standard echocardiography.

CASTRO PF, CONCEPCION R, BOURGE RC, MARTINEZ A, ALCAINO M, DECK C, FERRADA M, ALFARO M, PERRONE S. A WIRELESS PRESSURE SENSOR FOR MONITORING PULMONARY ARTERY PRESSURE IN ADVANCED HEART FAILURE: INITIAL EXPERIENCE


Device implantation was simple and the sensor accurately measured PA pressure. No complications were observed and there was no evidence of PA thrombosis at 60 days. Diuretic and vasodilator doses were increased and the patient improved without further heart failure-related hospitalization.

ADAMSON PB, ABRAHAM WT, AARON M, ARANDA JM, BOURGE RC, SMITH A, STEVENSON LW, YADAV J. CHAMPION TRIAL RATIONALE AND DESIGN: THE LONG-TERM SAFETY AND CLINICAL EFFICACY OF A WIRELESS PULMONARY ARTERY PRESSURE MONITORING SYSTEM

*J Card Fail.* 2010;17:3-10.

The CHAMPION clinical trial investigated the safety and clinical efficacy of the CardioMEMS HF System and established this management strategy as a new paradigm for the medical management of patients with symptomatic heart failure.

ABRAHAM WT, ADAMSON PB, HASAN A, BOURGE RC, PAMBOKIAN SV, AARON MF, RAVAL NY. SAFETY AND ACCURACY OF A WIRELESS PULMONARY ARTERY PRESSURE MONITORING SYSTEM IN PATIENTS WITH HEART FAILURE


The safety and accuracy of the CardioMEMS PA Sensor have been demonstrated in previous studies. Systolic and diastolic PA pressures were significantly correlated between the CardioMEMS PA Sensor and traditional Swan-Ganz catheter measurements and between the CardioMEMS PA Sensor and standard echocardiography.

A feasibility study reported the safe and successful implantation of the CardioMEMS PA Sensor in a clinical setting with no serious device-related events (n = 17).

CHAMPION

WIRELESS PULMONARY ARTERY HAEMODYNAMIC MONITORING IN CHRONIC HEART FAILURE: A RANDOMISED CONTROLLED TRIAL


- The aim of this randomized, multicenter, single-blind, controlled study was to evaluate the safety of the system and the efficacy of PA pressure-guided therapy on heart failure hospitalizations:
  - NYHA Class III heart failure patients irrespective of left ventricular EF and who had been hospitalized for heart failure within the past 12 months were implanted with the CardioMEMS PA Sensor (n = 550); patients were randomized to either the treatment group (heart failure management guided by PA pressure measurements; n = 270) or the control group (SOC management; n = 280).
  - Mean follow-up time was 15 months.
  - Both primary safety and efficacy endpoints were met:
    - Patients had a 98.6% freedom from device- or system-related complications (95% CI 97.3 to 99.4) with no pressure-sensor failures (95% CI 99.3 to 100.0).
    - The rate of heart failure hospitalizations at six months was reduced by 28% in the treatment group (p = 0.0002).
  - During the first six months of follow-up, compared to the control group, the treatment group had:
    - A greater reduction in PA pressure (-156 vs. 33 mean AUC; p < 0.008).
    - Fewer patients admitted to the hospital for heart failure (20% treatment group vs. 29% control group; p < 0.03).
    - More days alive outside of the hospital (174.4 ± 31.1 vs. 172.1 ± 37.8 days; p < 0.02).
    - Better patient quality of life (45 ± 26 vs. 51 ± 25; p = 0.02 based on Minnesota Living with Heart Failure Questionnaire).
KEY TAKEAWAYS:

• The treatment group required < 1 medication change per patient per month compared to the control group (9.1 ± 7.4 vs. 3.8 ± 4.5 changes per patient during the first six months of follow-up; p < 0.0001).

• During the entire follow-up (mean 15 months), PA pressure-guided therapy (treatment group) significantly reduced heart failure hospitalizations by 37% compared to the control group (p < 0.0001; Figure 1).

• The treatment group had a lower risk of death or freedom from first heart failure hospitalization during the entire follow-up period compared to the control group (p = 0.0086).

SUSTAINED EFFICACY OF PULMONARY ARTERY PRESSURE TO GUIDE ADJUSTMENT OF CHRONIC HEART FAILURE THERAPY (CHAMPION): COMPLETE FOLLOW-UP RESULTS FROM THE CHAMPION RANDOMISED TRIAL


- This CHAMPION clinical trial analysis evaluated the impact on heart failure hospitalizations of the introduction of PA pressure monitoring in the control group (n = 170) of patients and continued PA monitoring in the treatment group (n = 177) during the open access phase of the trial.

- Following completion of the randomized access period (mean follow-up of 18 months), all patients were managed utilizing PA pressure monitoring with the CardioMEMS™ HF System (mean follow-up of 13 months) and evaluated in a longitudinal analysis.

NEW ACCESS TO PA PRESSURES IN THE CONTROL GROUP RESULTED IN A 48% REDUCTION IN HEART FAILURE HOSPITALIZATION RATES (0.36 vs. 0.68; HR 0.52; 95% CI 0.40 to 0.69; p < 0.0001; Figure 2).

- The low heart failure hospitalization rate in the treatment group during the randomized access period was maintained in the open access period (0.45 vs. 0.48; HR 0.93; 95% CI 0.70 to 1.22; p = 0.5838; Figure 2).

KEY TAKEAWAYS:

• The longitudinal analysis confirms the effectiveness of the CardioMEMS HF System and supports the findings from the randomized portion of the CHAMPION clinical trial.

• Even after adjustment for longitudinal confounders, new access to PA pressure monitoring for the formerly blinded control group resulted in a significant reduction in heart failure hospitalizations.

Preplanned (Prospective) CHAMPION Subgroup Analyses

**EFFECTS OF PA PRESSURE MONITORING ON HFpEF SUBGROUP**

**WIRELESS PULMONARY ARTERY PRESSURE MONITORING GUIDES MANAGEMENT TO REDUCE DЕСОМРЕNΣATΙΟΝ IN HEART FAILURE WITH PRESERVED EJECTION FRACTION**


- This subanalysis of the CHAMPION clinical trial evaluated the effect of PA pressure-guided therapy with the CardioMEMS™ HF System in NYHA Class III patients with preserved ejection fraction (HFpEF).
- Of the HFpEF patients (n = 119), 62 were randomized to the treatment group (PA pressure-guided therapy) and 57 to the control group (SOC).

**KEY TAKEAWAY:**

- PA pressure-guided therapy significantly reduced heart failure hospitalizations for HFpEF patients in the treatment group by 50% compared to those patients in the control group, with an average follow-up time of 30 months (p < 0.0001). Results were associated with a rate of 0.43 events/patient-year in the treatment group vs. 0.86 events/patient-year in the control group (Figure 3).

**PROSPECTIVE SUBGROUP ANALYSIS: HFpEF PATIENTS MANAGED WITH THE CARDIOMEMS™ HF SYSTEM SHOW SIGNIFICANT REDUCTION IN HEART FAILURE HOSPITALIZATION**

![Cumulative Heart Failure Hospitalizations](image1)

Days after Implant

<table>
<thead>
<tr>
<th>Days after Implant</th>
<th>Control Group, HFpEF</th>
<th>Treatment Group, HFpEF</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>180</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>360</td>
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<td>40</td>
<td>20</td>
</tr>
<tr>
<td>900</td>
<td>50</td>
<td>25</td>
</tr>
</tbody>
</table>

Average 18 months of follow-up 50% RRR, p < 0.0001

**EFFECTS OF PA PRESSURE MONITORING ON HFrEF SUBGROUP, HFrEF SUBGROUP ALREADY ON GDMT**

**PULMONARY ARTERY PRESSURE-GUIDED MANAGEMENT OF PATIENTS WITH HEART FAILURE AND REDUCED EJECTION FRACTION**


Initiation of a PA pressure-guided heart failure management strategy, even in HFrEF patients receiving optimal background medical and device therapy, was able to achieve large, consistent reductions in heart failure hospitalization and mortality in HFrEF patients enrolled in the CHAMPION trial.

**KEY RESULTS:**

**Prospective Study Results**

- In the CHAMPION HFrEF cohort, heart failure hospitalization rates were 28% lower (p = 0.0013); mortality was 32% lower, trending toward significance (p = 0.06) at 18 months (Figure 4 and Figure 5).

**PROSPECTIVE SUBGROUP ANALYSIS: HFrEF PATIENTS SHOW SIGNIFICANT REDUCTION IN HEART FAILURE HOSPITALIZATION AND STRONG TREND TOWARD IMPROVED SURVIVAL**

![Clinical outcomes](image2)

![Survival probability](image3)

<table>
<thead>
<tr>
<th>Time (Days)</th>
<th>Control</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>100</td>
<td>100</td>
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<tr>
<td>360</td>
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<td>80</td>
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<td>720</td>
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<td>900</td>
<td>60</td>
<td>50</td>
</tr>
<tr>
<td>1080</td>
<td>50</td>
<td>40</td>
</tr>
</tbody>
</table>

Kaplan-Meier Survival Analysis

<table>
<thead>
<tr>
<th>No. at Risk</th>
<th>Control</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>234</td>
<td>209</td>
</tr>
<tr>
<td>Treatment</td>
<td>222</td>
<td>202</td>
</tr>
</tbody>
</table>

HR 0.68 (95% CI 0.45-1.02) p = 0.06
KEY RESULTS:

- In the CHAMPION HFrEF population (prospective subgroup analysis), heart failure hospitalization rates were 28% lower than control (p = 0.0013) and mortality was 32% lower, trending toward significance (p = 0.06).
- Because there was such a strong signal for improved survival in the prospective study, a retrospective study was done on the CHAMPION HFrEF subgroup, splitting them into groups based on the ability to tolerate GDMT:
  - **Group 1** (n = 485): tolerated at least one ACEI/ARB and/or BB.
  - **Group 2** (n = 337): tolerated both ACEI/ARB and BB.

Heart failure hospitalization in Group 1 was 33% lower than control (p = 0.0002) (left panel, left points).

Heart failure hospitalization in Group 2 was 43% lower than control (p < 0.0002) (left panel, right points).

Mortality in Group 1 was 37% lower than control (p = 0.0293) (right panel, left points).

Mortality in Group 2 was 57% lower than control (p = 0.0052) (right panel, right points).

CONCLUSION:

- PA pressure-guided heart failure management strategy resulted in significant reductions in hospitalizations and mortality in patients receiving prior optimal GDMT.

- Maximally tolerated GDMT at target doses is very important to control heart failure disease progression. There is apparent synergy between GDMT and hemodynamic monitoring in the control of heart failure disease progression.

- This retrospective analysis suggests the impact of GDMT on mortality and heart failure progression is significantly enhanced by avoiding decompensation events using guidance from the CardioMEMS™ HF System.
Retrospective Subanalyses

CARDIOMEMS™ HF SYSTEM-GUIDED PA PRESSURE MONITORING PROVIDED ACTIONABLE INFORMATION AND A MORE PERSONALIZED PHARMACOLOGICAL APPROACH, SO CLINICIANS COULD BETTER MANAGE HF

EFFECT OF CRT ON HEART FAILURE RELATED HOSPITALIZATIONS IN PATIENTS WITH REDUCED EF UTILIZING REMOTE PULMONARY ARTERY PRESSURES IN THE CHAMPION TRIAL


- This subanalysis of the CHAMPION clinical trial evaluated the effect of PA pressure-guided therapy with the CardioMEMS™ HF System in patients with rEF (rEF < 40%; n = 430) with and without a CRT device.
- 40% (171 of 430) of rEF patients had CRT devices; of this cohort, 82 patients were in the treatment group and 89 in the control group.
- 60% (259 of 430) of rEF patients did not have CRT devices; of this cohort, 126 patients were in the treatment group and 42 in the control group.

KEY TAKEAWAY:

- Remote PA pressure data in the treatment group resulted in similar reductions in heart failure hospitalization in patients with and without a CRT device, suggesting that heart failure management guided by PA pressures may provide additive benefits to CRT therapy:
  - For patients in the rEF-CRT group, those who received PA pressure-guided therapy had significantly fewer heart failure hospitalizations (RRR = 24%; p = 0.0264).
  - For patients in the rEF-no CRT group, PA pressure-guided therapy resulted in a RRR = 23%.

THE UTILITY OF REMOTE WIRELESS PULMONARY ARTERY PRESSURE MONITORING IN PATIENTS WITH OR WITHOUT A HISTORY OF MYOCARDIAL INFARCTION: EXPERIENCE FROM THE CHAMPION TRIAL

Strickland WL, et al. JACC. 2011.¹⁵

- This subanalysis of the CHAMPION clinical trial determined whether PA pressure monitoring affected the clinical outcomes of patients with and without a history of MI.
- 271 of the 550 NYHA Class III heart failure patients enrolled in the CHAMPION clinical trial had a history of MI and were randomized to either the control (n = 137) or treatment (n = 134) groups.
- At six months, there was a 2.2-day benefit of days alive outside the hospital for patients in the treatment group; at 15 months, this increased to 30.1 days.

KEY TAKEAWAYS:

- AF patients in the treatment group had a significantly lower heart failure hospitalization rate than those in the control group at six months (37%; p = 0.0004) and 15 months (41%; p < 0.0001).
- AF patients had a 57% higher heart failure hospitalization rate vs. non-AF patients (0.47 vs. 0.30 events/patient; p < 0.0001).

IMPACT OF REMOTE, WIRELESS PULMONARY ARTERY HEMODYNAMIC MONITORING IN PATIENTS WITH ATRIAL FIBRILLATION AND CHRONIC HEART FAILURE: INSIGHTS FROM THE CHAMPION TRIAL

Miller, et al. JACC. 2012.¹⁶

- This CHAMPION clinical trial subanalysis compared the baseline characteristics and impact of PA pressure-guided therapy on hospitalization rates in patients with a history of AF (n = 255) compared to those with normal sinus rhythm (n = 200).
- The AF cohort had significant baseline differences compared to the sinus rhythm cohort (older: 65 vs. 59; more often male): 80% vs. 66%, more frequently had CRT or CRT-D devices.
- 44% vs. 27%, higher mean PA pressures: 30.2 vs. 28.5 mmHg, etc.

KEY TAKEAWAYS:

- AF patients in the treatment group had a significantly lower heart failure hospitalization rate than those in the control group at six months (37%; p = 0.0004) and 15 months (41%; p < 0.0001).

TARGETING PULMONARY ARTERY PRESSURES IN THE TREATMENT OF CHRONIC HEART FAILURE: INSIGHTS FROM THE CHAMPION TRIAL


- This CHAMPION clinical trial subanalysis determined whether remote access to PA pressure data may provide a method to identify and treat high filling pressures in heart failure patients at increased risk for decompensation (n = 550).
- At implant, the mean PA pressure was similar in both control and treatment groups (31.8 ± 10.7 mmHg and 31.3 ± 11.1 mmHg, respectively).

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Table 1. RRR of heart failure hospitalizations

<table>
<thead>
<tr>
<th>History of MI</th>
<th>RRR at 6 Months for Treatment Group</th>
<th>RRR at 15 Months for Treatment Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of MI</td>
<td>30% (p &lt; 0.0039 vs. control)</td>
<td>46% (p &lt; 0.0001 vs. control)</td>
</tr>
<tr>
<td>No MI</td>
<td>25% (p = 0.016 vs. control)</td>
<td>23% (p = 0.021 vs. control)</td>
</tr>
</tbody>
</table>

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¹⁶ Miller, et al. JACC. 2012.
• Average PA pressures increased during the six weeks prior to heart failure hospitalizations in both groups (p < 0.0001) and decreased significantly after successful in-hospital decongestion (p < 0.0001).

• Treatment patients with heart failure hospitalizations had lower pressures compared to control patients with heart failure hospitalizations at all time points prior to hospitalization:
  – Treatment patients also had lower PA pressures compared to the control patients regardless of hospitalization type (heart failure related or non-heart failure related).

**KEY TAKEAWAYS:**

• Higher PA pressures and increases in PA pressure were both associated with increased risk for heart failure hospitalizations.

• Heart failure treatment strategies that target both high PA pressure and increases in PA pressures may be effective strategies for lowering the risk of decompensation in chronic heart failure patients.

**BENEFITS OF PULMONARY ARTERY PRESSURE MONITORING IN PATIENTS WITH NYHA CLASS III HEART FAILURE AND CHRONIC KIDNEY DISEASE: RESULTS FROM THE CHAMPION TRIAL**


This subgroup data analysis from the CHAMPION clinical trial compared heart failure hospitalizations between NYHA Class III heart failure patients with CKD monitored (mean follow-up of 18 months) with PA pressure (n = 150) to those managed with SOC (n = 147):

• When CKD patients were managed with PA pressures, heart failure hospitalization rates were significantly reduced (42%) compared to patients with CKD managed according to SOC (0.48 vs. 0.83; HR 0.58; p < 0.001).

• Changes in CKD indicators (creatinine and glomerular filtration rates) were not adversely affected in the PA pressure-monitored group.

**KEY TAKEAWAYS:**

• CKD in patients with heart failure is a frequent comorbidity that is associated with worse clinical outcomes, including higher heart failure hospitalization rates.

• For heart failure patients with CKD, PA pressure monitoring reduced heart failure hospitalizations by 42% compared to SOC heart failure management.

• Intensified heart failure medical therapy as a result of PA pressure monitoring was safe and did not adversely affect renal function.

**PULMONARY HYPERTENSION RELATED TO LEFT HEART DISEASE: INSIGHT FROM A WIRELESS IMPLANTABLE HEMODYNAMIC MONITOR**


This CHAMPION clinical trial subanalysis evaluated the effect of PA pressure monitoring in heart failure patients with comorbid PH (mean PA pressure > 25 mmHg):

• Data were obtained for 314 patients (59%) who had WHO Group II PH. Patients in the PH cohort were further stratified by TPG and pulmonary vascular resistance.

• 67% (213 out of 314) of PH patients had a TPG ≤ 15.

• Patients without PH were at significantly lower risk for mortality than PH patients (HR 0.31; 95% CI 0.19 to 0.52; p < 0.0001).

• PH patients had higher heart failure hospitalization rates than non-PH patients (0.77/year vs. 0.37/year; HR 0.49; 95% CI 0.39 to 0.61; p < 0.001).

• In patients with and without PH, ongoing knowledge of hemodynamic data resulted in a reduction in heart failure hospitalization for PH patients (HR 0.64; 95% CI 0.51 to 0.81; p = 0.002) and for non-PH patients (HR 0.60; 95% CI 0.41 to 0.89; p = 0.01).

• Among PH patients, there was a reduction in the composite endpoint of death and heart failure hospitalization with ongoing knowledge of hemodynamics (HR 0.74; 95% CI 0.55 to 0.99; p = 0.04), but no difference in survival (HR 0.78; 95% CI 0.50 to 1.22; p = 0.28).

**KEY TAKEAWAY:**

• PH patients are at a high risk for adverse outcomes. Ongoing knowledge of hemodynamic variables may allow more effective treatment strategies to reduce the morbidity of the disease.

**HEART FAILURE AND RESPIRATORY HOSPITALIZATIONS ARE REDUCED IN HEART FAILURE SUBJECTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE USING AN IMPLANTABLE PULMONARY ARTERY PRESSURE MONITORING DEVICE**


The purpose of this CHAMPION clinical trial subanalysis was to evaluate whether PA pressure-guided therapy reduced heart failure hospitalizations and REHs in a cohort of patients with comorbid COPD (n = 187).

**KEY TAKEAWAYS:**

• There was an overall reduction in PA pressures; patients in the treatment group (n = 91) had an average AUC reduction of 202 mmHg days compared to the increase of 107 mmHg days in the control group (n = 96; p = 0.03).

• At 15 months, there was a 41% reduction in heart failure hospitalization rates in the treatment group vs. the control group (0.55 vs. 0.99; HR 0.59; 95% CI 0.44 to 0.81; p = 0.0009).

• At 15 months, patients in the treatment group (n = 91) had a 62% reduction in REH (0.12 vs. 0.31; HR 0.38; 95% CI 0.21 to 0.71; p = 0.0023).
LIMITATIONS OF RIGHT HEART CATHETERIZATION IN THE DIAGNOSIS AND RISK STRATIFICATION OF PATIENTS WITH PULMONARY HYPERTENSION RELATED TO LEFT HEART DISEASE: INSIGHTS FROM A WIRELESS PULMONARY ARTERY PRESSURE MONITORING SYSTEM

Raina, et al. JHLT. 2015.21

• This CHAMPION sub-study compared the use of the CardioMEMS™ HF System with RHC to diagnose and stratify risk in patients with PH.

• RHC identified 320 patients with PH (defined as mean PA pressure > 25 mmHg) and among these patients mean PA pressure obtained from RHC was similar to the CardioMEMS HF System’s first-week PA pressure.

• RHC also identified 217 patients without PH (defined as mean PA pressure readings ≤ 25 mmHg) and 51% of them met this definition according to data obtained from the CardioMEMS HF System (18.5 for the RHC vs. 18.4 for the CardioMEMS HF System, p = 0.9208).

• The other 49% of patients identified by RHC as not having PH had first-week mean PA pressure readings > 25 mmHg with the CardioMEMS HF System, indicating PH.

• Among the 217 patients using the CardioMEMS HF System diagnosed by RHC as non-PH, the 49% with first-week mean PA pressure readings > 25 mmHg had significantly higher heart failure hospitalization rates than the 51% of patients with readings ≤ 25 mmHg (0/49 vs. 0.25/year, p = < 0.0001).

KEY TAKEAWAYS:

• This analysis suggests that using RHC alone may result in PH underdiagnoses in patients with heart failure.

• In this study, the more frequent PA pressure monitoring with the CardioMEMS HF System provided better diagnostic and risk stratification compared with single RHC.

THERAPY GUIDED BY PA PRESSURE ALONE VS. SIGNS AND SYMPTOMS

PRESSURE FOR ACTION: IMPLANTABLE PULMONARY ARTERY PRESSURE SENSOR MEASUREMENTS ALONE BEAT CLINICAL SIGNS TO GUIDE PREVENTION OF HEART FAILURE HOSPITALIZATIONS

Goldberg LR, et al. HRS 2015 Abstract AB36-02.22

• Data analysis from the CHAMPION clinical trial during the six-month primary endpoint period:
  – 550 patients: 270 in the treatment group and 280 in the control group.
  – All interventions for patients in the PA pressure-managed group were characterized prospectively by investigators as triggered primarily by clinical findings OR by changes in PA pressure.

• Heart failure hospitalization rates were lowest in patients for whom all diuretic interventions were triggered by PA pressure (0.39 events/patient-year), despite this cohort having the highest baseline PA pressure (Figure 8).

• There was a statistically significant 67% RRR of heart failure hospitalizations if a patient’s diuretic interventions were managed with PA pressure alone vs. clinical signs only (HR 0.33; 95% CI 0.16 to 0.59; p = 0.0007).

• Medication changes based on PA pressure information were more effective in reducing heart failure hospitalizations than using signs and symptoms alone.

KEY TAKEAWAYS:

• Heart failure hospitalization rates (events/patient-year) were significantly reduced if a patient’s diuretic management therapies were managed by:
  – PA pressure only compared to clinical signs (67% reduction).
  – PA pressure and clinical signs compared to clinical signs (46% reduction).

• Heart failure hospitalization rates were most effectively reduced by a management strategy based on PA pressures without reliance on clinical changes.

• This supports the strategy of early intervention prior to clinical signs to avert clinical decompensation and heart failure readmissions.1,2

CONCLUSION:

Managing medical therapy based on PA pressures, along with follow-up lab and patient assessments, led to significantly better outcomes than managing based on clinical signs and symptoms.
Medication changes based on PA pressure information were more effective in reducing heart failure hospitalizations than using signs and symptoms alone.

**Figure 9.** Frequency of medication changes by drug class

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>PA Pressure Guided Heart Failure Management</th>
<th>SOC Heart Failure Management Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Medication Changes</td>
<td>2468</td>
<td>1547</td>
</tr>
<tr>
<td>Diuretic (Loop or Thiazide)</td>
<td>1061</td>
<td>585</td>
</tr>
<tr>
<td>Vasodilator (Nitrate and Hydralazine)</td>
<td>293</td>
<td>104</td>
</tr>
<tr>
<td>ACEI/ARB</td>
<td>293</td>
<td>144</td>
</tr>
<tr>
<td>BB</td>
<td>239</td>
<td>160</td>
</tr>
<tr>
<td>Aldosterone Antagonist</td>
<td>96</td>
<td>68</td>
</tr>
</tbody>
</table>

**Figure 10.**

**MEDICATION INCREASES AND DECREASES IN RESPONSE TO PA PRESSURE:**

- Medication changes based on PA pressure information were more effective in reducing heart failure hospitalizations than using signs and symptoms alone.

- Knowledge of ambulatory PA pressures leads to more interventions that reduce heart failure events compared with standard clinical assessment.

- The current study is focused on the degree and nature of the interventions made.

- Most medication interventions in CHAMPION were adjustments in diuretics.

- It is not known when vasodilators would be more effective than diuretics to maintain lower filling pressures. Neither is it known how titration of ACEIs/ARBs and BBs should be modulated by knowledge of ambulatory filling pressures that are too high or too low.

- The current analysis validates the target pressure ranges and the algorithm for intervention that can be used as a starting point to reduce heart failure hospitalizations and improve patient outcomes in previously hospitalized NYHA Functional Class III patients.
**MEDICARE-ELIGIBLE POPULATIONS**

**PULMONARY ARTERY PRESSURE-GUIDED HEART FAILURE MANAGEMENT REDUCES 30-DAY READMISSIONS**


- This data analysis from the CHAMPION clinical trial evaluated 30-day readmissions and heart failure hospitalizations between patients monitored with the CardioMEMS™ HF System and those not monitored over a period of 18 months.
- 245 patients were included in the analysis: 120 in the PA pressure treatment group and 125 in the SOC control group.
- In this analysis, patients managed with PA pressure compared to those managed according to SOC experienced:
  - 58% reduction in all-cause 30-day readmissions (0.07 vs. 0.18; HR 0.42; p = 0.0062).
  - 78% reduction in heart failure 30-day readmissions (0.02 EPPY vs. 0.10 EPPY; HR 0.22; p = 0.0027).
  - 49% reduction in heart failure hospitalizations (0.34 EPPY vs. 0.67 EPPY; HR 0.51; p < 0.0001).

*Event rates are based on events/patient-year.

**KEY TAKEAWAYS:**
- This retrospective analysis of the CHAMPION clinical trial demonstrated that PA pressure-guided management of Medicare-eligible heart failure patients significantly reduced 30-day readmissions, which may help to alleviate the economic burden associated with heart failure readmissions.
- This analysis supports results from the CHAMPION clinical trial demonstrating a 37% reduction in heart failure hospitalizations and improved quality of life with PA pressure-guided heart failure management in NYHA Class III heart failure patients irrespective of Medicare eligibility.

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**Figure 11.** Subgroup analysis: Medicare-eligible population shows significant reduction in 30-day readmissions

*Statistically significant reductions in 30-day readmission and heart failure hospitalization in Medicare-eligible patients 65 years or older (n = 245), when PA pressures are monitored using the CardioMEMS™ HF System.*

Patients with common heart failure comorbidities have consistent reduction in heart failure hospitalizations with PA pressure-guided therapy. Table 2 summarizes the rate of heart failure hospitalizations across the different studies.

### The CHAMPION Trial Subgroup Analyses: Reduction of Heart Failure Hospitalization in Patient Groups with Common Comorbidities

<table>
<thead>
<tr>
<th>Subgroup or Comorbidity</th>
<th>n (control)</th>
<th>n (treatment)</th>
<th>Follow-up Period (months)</th>
<th>Reduction of Heart Failure Hospitalization Rate in Treatment Group vs. Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare population</td>
<td>125</td>
<td>120</td>
<td>18</td>
<td>49%, p &lt; 0.0001</td>
</tr>
<tr>
<td>HFpEF</td>
<td>56</td>
<td>59</td>
<td>18</td>
<td>50%, p &lt; 0.0001</td>
</tr>
<tr>
<td>HFpEF following GDMT</td>
<td>174</td>
<td>163</td>
<td>17</td>
<td>43%, p &lt; 0.0001</td>
</tr>
<tr>
<td>CRT-D or ICD following GDMT</td>
<td>146</td>
<td>129</td>
<td>18</td>
<td>43%, p &lt; 0.0001</td>
</tr>
<tr>
<td>History of MI</td>
<td>137</td>
<td>134</td>
<td>15</td>
<td>46%, p &lt; 0.001</td>
</tr>
<tr>
<td>COPD</td>
<td>96</td>
<td>91</td>
<td>15</td>
<td>41%, p = 0.0009</td>
</tr>
<tr>
<td>Pulmonary hypertension</td>
<td>163</td>
<td>151</td>
<td>15</td>
<td>36%, p = 0.0002</td>
</tr>
<tr>
<td>AF</td>
<td>135</td>
<td>120</td>
<td>15</td>
<td>41%, p &lt; 0.0001</td>
</tr>
<tr>
<td>CKD</td>
<td>150</td>
<td>147</td>
<td>15</td>
<td>42%, p = 0.0001</td>
</tr>
</tbody>
</table>

KEY TAKEAWAY:
- LVAD patients who received PA pressure-guided therapy (15 out of 27 patients) had significantly shorter times to VAD intervention (p = 0.001), more changes to medical therapy based on hemodynamic information (p = 0.0005) and shorter times between VAD intervention and heart transplantation (p = 0.001).
The CardioMEMS™ HF System Commercial Experience: Results from Real-world Studies

HEMODYNAMIC-GUIDED HEART-FAILURE MANAGEMENT USING A WIRELESS IMPLANTABLE SENSOR: INFRASTRUCTURE, METHODS, AND RESULTS IN A COMMUNITY HEART FAILURE DISEASE-MANAGEMENT PROGRAM


KEY TAKEAWAY:

• Hemodynamic-guided heart failure management leads to significant improvements in NYHA Class and heart failure hospitalization rate in a small single-center study in a real-world setting, compared with usual care delivered in a comprehensive disease-management program:
  – Three-fold greater improvement in KCCQ scores.
  – Increase in 6MWD: Average increase of 96 meters at 90 days vs. no increase in the SOC group.

Post-approval Observational Study of the CardioMEMS™ HF System Large (N = 2000) Observational Study from the First 2000 Commercially Implanted Patients


Observational Study from the First 2000 Commercially Implanted Patients from the Merlin.net™ Patient Care Network Database

Impact of Practice-Based Management of PA Pressures in 2000 Patients Implanted with the CardioMEMS Sensor


Patients consistently upload pressures:
Median 1.2 days between transmissions


Providers consistently treat pressures:
Larger treatment effect in the real-world than CHAMPION
PATIENTS’ PRESSURE REDUCTION STRATIFIED BY EF AND BY GENDER

Pressures Are Reduced Equally Well in HFrEF and HFpEF, as Well as Male and Female

**Figure 13.** AUC mean PA pressure stratified by EF

**Figure 14.** AUC mean PA pressure stratified by gender


Pressure Changes Stratified by Baseline PA Pressure

**Figure 15.** CHAMPION control cohort

**Figure 16.** CHAMPION treatment cohort

**Figure 17.** General-use cohort

Greatest reduction in mean PA pressure observed for CardioMEMS™ HF System patients with higher baseline PA pressure. Patients in the treatment group with baseline PA pressure at goal, remained at goal over time.


**KEY TAKEAWAYS:**

- High transmission compliance.
- Data drove appropriate patient care.
- Same results in HFpEF and HFrEF.
- “Long-term patient acceptance and adherence is clearly demonstrated.”
- “The magnitude of pressure lowering ... was significantly larger than was seen in the pivotal clinical trial.”
Ambulatory Hemodynamic Monitoring Reduces Heart Failure Hospitalizations in “Real-World” Clinical Practice


Real-world Use of the CardioMEMS™ HF System: Reduced Heart Failure Hospitalization and Associated Costs in a Large Retrospective Cohort (n = 1114) from a Medicare Claims Database — 6 and 12 Months of Follow-up

Figure 18. Cumulative heart failure hospitalization during period before and after CardioMEMS™ PA Sensor implant

- 45% reduction at 6 months
  - $13,190 per patient — year.
  - $10,510 per patient — six months.

Key Takeaways:

- Real-world reduction in heart failure hospitalization after CardioMEMS™ PA Sensor implant:
  - 45% reduction at six months.
- Significant cost reductions for hospitalization:
  - $10,510 per patient — six months.
  - $13,190 per patient — year.

These benefits support the real-world effectiveness of this approach to heart failure management.

Association of Ambulatory Hemodynamic Monitoring with Clinical Outcomes in a Concurrent Matched Cohort Analysis


Study Objective:

This study examined the impact of ambulatory hemodynamic monitoring on clinical outcomes in patients with heart failure, asking the following questions:

- Is ambulatory hemodynamic monitoring associated with differences in rates of survival or heart failure hospitalization in a non-trial setting?
- Are results sustained at 12 months?

Figure 19. Time series of heart failure hospitalizations in the 12 months before PA pressure sensor implant

- 24% reduction in heart failure hospitalization rate in the treatment (CardioMEMS PA Sensor) arm, p < 0.001.

Figure 20. Cumulative events after PA pressure sensor implant

- 24% reduction in heart failure hospitalization rate in the treatment (CardioMEMS PA Sensor) arm, p < 0.001.
CONCLUSION:
In this large, retrospective, Medicare administrative claims analysis, the authors observed:

• Significantly lower rates of all-cause mortality (30%) and heart failure hospitalization (24%) among heart failure patients implanted with a CardioMEMS™ PA Sensor versus a contemporary cohort of matched controls (p < 0.001 for each).

• Reduced rates of heart failure hospitalization and mortality for CardioMEMS™ HF System patients are similar to outcomes from the CHAMPION trial, even though patients in this study are significantly older.

• Meaningful reductions in the number of days lost to death or hospitalization (17.5–18.5 days), a metric that is meaningful to patients, physicians and payers.


Kaplan-Meier survival analysis during the 12-month follow-up period shows a 30% reduction in mortality in the treatment (CardioMEMS™ PA Sensor) arm, p < 0.001.

Kaplan-Meier survival analysis in the matched population

B. Kaplan-Meier survival analysis in the matched population

C. Combined outcome of heart failure hospitalization or death

No. at Risk
Control Cohort 1087 1037 991 944 908 862 862
Treatment Cohort 1087 1037 991 944 908 862 862

HR 0.70 (95% CI 0.59–0.83) p < 0.001

Kaplan-Meier survival analysis in the matched population

No. at Risk
Control Cohort 1087 1000 931 891 850 805 764
Treatment Cohort 1087 1037 991 944 908 862 862

HR 0.73 (95% CI 0.64–0.84) p < 0.001

Combined outcomes during the 12-month follow-up period show a 27% reduction in heart failure hospitalizations or death in the treatment (CardioMEMS PA Sensor) arm, p < 0.001.

Combined outcome of heart failure hospitalization or death

No. at Risk
Control Cohort 1087 1000 931 891 850 805 764
Treatment Cohort 1087 1037 991 944 908 862 830

HR 0.70 (95% CI 0.59–0.83) p < 0.001

Reduction in Mortality

Reduction in Mortality

Reduction in Heart Failure Hospitalization or Death

Reduction in Heart Failure Hospitalization or Death

Reduction in Mortality

Reduction in Mortality
MONITORING PULMONARY ARTERIAL HYPERTENSION USING AN IMPLANTABLE HEMODYNAMIC SENSOR


STUDY OBJECTIVE:

Pilot study (N = 26) designed to evaluate the feasibility and early safety of monitoring patients with PAH and right-sided heart failure using the CardioMEMS™ HF System. **Note:** The objective of this pilot study was to test the feasibility of monitoring therapy, not necessarily to use the CardioMEMS HF System to guide the therapy.

**Figure 21.** Hemodynamic response measured by the CardioMEMS™ HF System for patients at Allegheny General Hospital. Plots show mean ± SE. Asterisks show statistically significant differences (p < 0.05) from 0-month baseline. Number of patients at each time point is shown below the x-axes.

**A.**

**B.**

**C.**

**D.**

**KEY RESULTS:**

Significant reductions in PA pressures ($PAP_m$, 42 ± 13 to 34 ± 14 mmHg) and elevations in CO (5.8 ± 1.5 to 6.8 ± 1.8 L/min) were observed over one year of CardioMEMS HF System-monitored therapy. There were also observed elevations in SV, vascular compliance, SVi and Eff, as well as reductions in SW and TPR.
In the AUC analyses shown below, SV, TPR and compliance all exhibited significant changes at 12 months relative to baseline (p < 0.05). In patients that were highly managed (nine or more medication changes) within the first 4 months (most with serial changes in parenteral prostacyclins, based on knowledge of hemodynamics), early hemodynamic changes were well-visualized and captured using the CardioMEMSTM HF System. Therefore, home monitoring and capturing significant changes in hemodynamic responses to changes in drug therapy over time are feasible.

Figure 22. Cumulative hemodynamic response illustrated by AUC analyses across 365 days for patients at Allegheny General Hospital

\( PAP, TPR, SV \) and compliance are shown as mean (solid line) ± SE of the cumulative change over time. All p < 0.05 at 12 months, relative to baseline.

Changes in NYHA Class from baseline (p < 0.001), natriuretic peptides (p < 0.01) and Minnesota Living with Heart Failure Questionnaire quality of life score (p < 0.001) for the implanted cohort with at least one-month follow-up post-implant (n = 24) were all encouraging. These improvements mirrored the hemodynamic changes illustrated in the figures above. In addition, 6MWD correlated with CardioMEMS HF System-determined hemodynamics.

These changes were analyzed to demonstrate potential alternative efficacy endpoints that could be used in future trials of the device in PAH and to visualize the parallel between patterned hemodynamic changes obtained through monitoring with the CardioMEMS HF System and other outcomes assessed in clinic.
The case example below shows early clinical worsening for a patient weeks prior to a heart failure hospitalization and subsequent hemodynamic recovery.

**Figure 23.** Example of acute right ventricular failure because of medication noncompliance. Patient medication noncompliance (blue shading) resulted in rise in deteriorating hemodynamics and heart failure hospitalization (orange shading). IV diuresis and reinstitution of medications (red shading) resulted in an improvement in all parameters.

**KEY TAKEAWAYS:**
- PAH is a progressive chronic disease that ultimately progresses to right heart failure and death.
- This feasibility study of 26 patients with PAH indicates that the CardioMEMS™ HF System can be used to monitor and effect favorable changes in hemodynamics, and may help guide medical therapy in these patients, resulting in improved outcomes.
- Improvements in patients’ hemodynamics correlated with improvements in NYHA functional class, natriuretic peptide levels, quality of life and 6MWD.
- Use of the CardioMEMS HF System in this pilot study was associated with short- and long-term safety.

**CONCLUSION:**
The CardioMEMS HF System provided useful information to monitor PAH therapy, and demonstrated short- and long-term safety. Larger clinical trials are needed before its widespread use to guide therapy in patients with severe PAH with right-sided heart failure.
HEMODYNAMIC-GUIDED MANAGEMENT OF HEART FAILURE (GUIDE-HF)


- Largest trial ever (N = 3600) to study hemodynamic-guided heart failure management.
- Includes patients currently indicated for the CardioMEMS™ HF System, as well as heart failure patients with NYHA Class II and IV, and heart failure patients with elevated natriuretic peptides without recent heart failure hospitalization.
- Randomized arm (N = 1000) to evaluate the effects of the CardioMEMS HF System on heart failure hospitalization and death, as well as quality of life and functional capacity in NYHA Class II–IV patients with a heart failure hospitalization in the past 12 months or elevated natriuretic peptide levels in the previous 30 days, regardless of left ventricular ejection fraction.
- Single arm (N = 2600) to determine whether PA pressure-guided care is as effective in NYHA Class III patients enrolled based on elevated natriuretic peptide levels as it is in those with a prior heart failure hospitalization.
- Secondary endpoints: Cumulative heart failure event rates 12 months post-implant versus heart failure event rates 12 months pre-implant.
- Positive results will help lead to entry into ACC and AHA heart failure guidelines and obtain CMS National Coverage Determination.

**Figure 24.**

GUIDE-HF Trial Schematic
Healthcare Economics

HEALTH ECONOMIC IMPACT OF A PULMONARY ARTERY PRESSURE SENSOR FOR HEART FAILURE TELEMONITORING: A DYNAMIC SIMULATION


SUMMARY:
This simulation estimated the reductions of heart failure hospitalizations with PA guided care, the improvement on quality of life and the economic savings as a result of implementation in the German healthcare system. This simulation also showed the rise of heart failure prevalence numbers in the context of an aging population, and given the considerable burden of heart failure, the potential of a PA pressure monitoring system to improve the management of heart failure patients and enable cost savings at the same time is substantial.

PULMONARY ARTERY PRESSURE-GUIDED HEART FAILURE MANAGEMENT: US COST-EFFECTIVENESS ANALYSES USING THE RESULTS OF THE CHAMPION CLINICAL TRIAL


KEY RESULTS:
The primary effectiveness endpoint was the ICER comparing the costs and QALYs of heart failure hospitalization outcomes in the CHAMPION treatment and control groups. The model was used to extrapolate this endpoint to five years.

Over the five-year projections, patients in the treatment group had average QALYs of 2.56 with a total cost of $140,966; patients in the control group had QALYs of 2.16 with a total cost of $133,681. The ICER was $18,515 per QALY (Table 3).

CONCLUSION:
This study, based on the results of the CHAMPION clinical trial, used standard economic modelling to show that PA pressure-guided management of heart failure using the CardioMEMS™ HF System is cost-effective from the perspective of U.S. payers. The ICERs, when considered for heart failure management or comprehensive management, were well below the conventional U.S. acceptability threshold of $50,000.

Table 3. Cost-effectiveness analysis base case and survival over a five-year time horizon

<table>
<thead>
<tr>
<th></th>
<th>Primary CEA Endpoint: Heart Failure Hospitalization Outcomes</th>
<th>All-cause Hospitalization Outcomes</th>
<th>Comprehensive Patient Management Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Treatment Group</td>
<td>Control Group</td>
<td>Treatment Group</td>
</tr>
<tr>
<td>Cumulative average cost</td>
<td>U.S. $56,974</td>
<td>U.S. $52,149</td>
<td>U.S. $140,966</td>
</tr>
<tr>
<td>Cumulative QALYs</td>
<td>2.56</td>
<td>2.16</td>
<td>2.56</td>
</tr>
<tr>
<td>Cumulative average years of survival</td>
<td>3.70</td>
<td>3.47</td>
<td>3.70</td>
</tr>
<tr>
<td>ICER (U.S. $/QALY)</td>
<td>U.S. $12,262</td>
<td>U.S. $18,515</td>
<td>U.S. $29,592</td>
</tr>
<tr>
<td>Cost reduction for each patient under treatment post implant (U.S. $/year)(^a)</td>
<td>U.S. $4,443</td>
<td>U.S. $5,261</td>
<td>U.S. $5,296</td>
</tr>
</tbody>
</table>

\(^a\) Costs saving per life year for the treatment group.

COST-EFFECTIVENESS OF REMOTE CARDIAC MONITORING WITH THE CARDIOMEMS HEART FAILURE SYSTEM


KEY RESULTS:
Mortality trends are lower for the CardioMEMS™ HF System vs. SOC:
• Based on the model’s base case, half (50.4%) of the original CardioMEMS HF System patients were dead at 60 months vs. 50% mortality at 40 months for patients on SOC.
• At the end of the 60 months, 49.6% of CardioMEMS HF System patients remained alive vs. 23.8% of SOC patients.

Cost/QALY was in the high-value space:
• Device cost/QALY was well below $50,000, remaining in the high-value space (based on ACC and AHA guidelines).

CONCLUSION:
• The CardioMEMS HF System was found to be cost-effective, with an ICER of $44,832 per QALY.
• This places the CardioMEMS HF System in the high-value category compared to LVADs ($128K–$209K/QALY) and CRT-D ($62K/QALY).
• “For heart failure patients meeting current indications, the CardioMEMS HF System may represent an important clinical advance, while at the same time being a cost-effective treatment for heart failure.”
Table 4. Model results: base case

<table>
<thead>
<tr>
<th>Five-year costs and outcomes</th>
<th>CardioMEMSTM</th>
<th>SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total costs</td>
<td>$188,880</td>
<td>$162,772</td>
</tr>
<tr>
<td>Implant: device, procedure, complications</td>
<td>$19,111</td>
<td>$0</td>
</tr>
<tr>
<td>Inpatient costs</td>
<td>$108,124</td>
<td>$113,199</td>
</tr>
<tr>
<td>Outpatient costs (including monitoring)</td>
<td>$61,645</td>
<td>$49,573</td>
</tr>
<tr>
<td>Total accumulated QALYs</td>
<td>2.509</td>
<td>1.926</td>
</tr>
<tr>
<td>ICER (cost per QALY gained)</td>
<td>$44,832</td>
<td></td>
</tr>
</tbody>
</table>

Table 5. Base case input parameters: costs

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Cost (USD)a</th>
<th>Source(s)</th>
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<tbody>
<tr>
<td>CardioMEMSTM device (per device)</td>
<td>$17,750</td>
<td>Average sales price</td>
</tr>
<tr>
<td>Implantation procedure</td>
<td>$1,280</td>
<td>Medicare: $1,138; CPT 93451, 93568, 33210, 2016 MFS; Commercial: $1,707 (MFS x 1.5)</td>
</tr>
<tr>
<td>Complications, each</td>
<td>$5,770</td>
<td>Martinson et al inflated to 2016</td>
</tr>
<tr>
<td>Hospitalizations</td>
<td></td>
<td>Takes into account % Medicare vs. commercial</td>
</tr>
<tr>
<td>Heart failure hospitalization</td>
<td>$21,007</td>
<td>Martinson et al inflated to 2016</td>
</tr>
<tr>
<td>Non-heart failure hospitalization</td>
<td>$24,367</td>
<td>Martinson et al inflated to 2016</td>
</tr>
<tr>
<td>Monthly monitoring</td>
<td>$47</td>
<td>Martinson et al inflated to 2016</td>
</tr>
<tr>
<td>Outpatient costs, routine care (per year)</td>
<td>$19,576</td>
<td>Martinson et al inflated to 2016</td>
</tr>
</tbody>
</table>

a. Costs are presented in 2016 dollars and were inflated or discounted as described in the methods. All costs are weighted based on the assumption that 75% of patients are covered by Medicare and 25% have commercial coverage.

THE COST-EFFECTIVENESS OF REAL-TIME PULMONARY ARTERY PRESSURE MONITORING IN HEART FAILURE PATIENTS: A EUROPEAN PERSPECTIVE


STUDY OBJECTIVE:
Heart failure treatment guided by physicians using the CardioMEMS HF System has been shown to reduce heart failure hospitalizations, but uncertainty remains regarding the value of the CardioMEMS HF System in European health systems where healthcare costs are significantly lower than in the United States.

METHODS:
A Markov model was developed to estimate the cost-effectiveness of PAP-guided treatment of heart failure using the CardioMEMS HF System compared with usual care. Cost-effectiveness was measured as the incremental cost per QALY gained.

KEY RESULTS:
- In the base case analysis over a time horizon of 10 years, PAP-guided heart failure therapy increased cost compared with usual care by £10,916 (£14,030) (i.e., from £6,189 in usual care to £17,104 in PAP-guided heart failure therapy).
- QALYs per patient for usual care and PAP-guided patients were 2.57 and 3.14, respectively, an increase of 0.57 QALY with PAP-guided treatment.
- The resultant ICER is £19,274 (£24,772) per QALY gained.
- The base case analysis did not include staff time due to a lack of data.
- Running the model with estimated staff time included resulted in an increased ICER of between £22,342 and £25,464 per QALY gained (£28,709–£32,721).

CONCLUSION:
The analysis indicates that the CardioMEMS HF System could provide a cost-effective means for heart failure physicians to manage and treat patients outside of face-to-face clinic appointments, shifting care from the hospital/clinic to the home, reducing resource-intensive hospitalizations and improving the quality of life of patients suffering from heart failure.

21
**Post-approval Study**

**REDUCTION OF HF HOSPITALIZATION IN THE CARDIOMEMS™ HF SYSTEM POST-APPROVAL STUDY**


---

**Figure 25.**

---

**MEDICATION CHANGES SIGNIFICANTLY REDUCED IN FIRST 90 DAYS VS. SECOND 90 DAYS IN THE PAS**

**Figure 26.** Medication changes — first 90 days vs. second 90 days

---

65% of the overall heart failure medication changes were made in the first 90 days, with trends of stabilization and significantly fewer medication changes during the second 90 days.

---

**Figure 27.** The CardioMEMS™ HF System PAS short-term results: REDUCED heart failure hospitalization and MEAN PA pressure

---

Significantly greater reductions in mean PA pressure for the PAS cohort relative to the CHAMPION control group after six months, and qualitatively greater reductions compared to the CHAMPION treatment group.
Clinical Research Papers by Topic

**IMPROVED QUALITY OF LIFE AND FUNCTIONAL CAPACITY**

**DECREASED HEART FAILURE HOSPITAL ADMISSIONS AND READMISSIONS**

**OPTIMIZED MANAGEMENT IN HfPEF**

**DECREASED PA PRESSURES**

**THE CARDIOMEMS™ HF SYSTEM IS PROACTIVE AND ACTIONABLE; GDRT IS REACTIVE AND INEXACT**

**REHOSPITALIZATION = INCREASED MORTALITY**

**REDUCED MORTALITY**

**PATIENT SELECTION AND WORKFLOW**
- Adamson White Paper (on Map).

**REIMBURSEMENT/HEALTHCARE ECONOMICS/REDUCED HOSPITALIZATION COSTS**

**ACRONYM DEFINITIONS**

<table>
<thead>
<tr>
<th>ACRONYM</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>6MHW</td>
<td>six-minute hall walk</td>
</tr>
<tr>
<td>6MWD</td>
<td>six-minute walk distance</td>
</tr>
<tr>
<td>ACC</td>
<td>American College of Cardiology</td>
</tr>
<tr>
<td>ACEI</td>
<td>angiotensin-converting enzyme inhibitor</td>
</tr>
<tr>
<td>AF</td>
<td>atrial fibrillation</td>
</tr>
<tr>
<td>ARB</td>
<td>angiotensin receptor blocker</td>
</tr>
<tr>
<td>ACC</td>
<td>area under curve</td>
</tr>
<tr>
<td>BB</td>
<td>beta blocker</td>
</tr>
<tr>
<td>BL</td>
<td>baseline</td>
</tr>
<tr>
<td>bpm</td>
<td>beats per minute</td>
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<td>CEA</td>
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<td>CI</td>
<td>confidence interval</td>
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<tr>
<td>CKD</td>
<td>chronic kidney disease</td>
</tr>
<tr>
<td>CMS</td>
<td>Centers for Medicare &amp; Medicaid Services</td>
</tr>
<tr>
<td>CO</td>
<td>cardiac output</td>
</tr>
<tr>
<td>comp</td>
<td>compliance</td>
</tr>
<tr>
<td>COPD</td>
<td>chronic obstructive pulmonary disease</td>
</tr>
<tr>
<td>CPT</td>
<td>Current Procedural Terminology</td>
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<td>chronic obstructive pulmonary disease</td>
</tr>
<tr>
<td>CPT</td>
<td>Current Procedural Terminology</td>
</tr>
</tbody>
</table>
The hemodynamic data are used by physicians for heart failure management and with the goal of Class III heart failure (HF) patients who have been hospitalized for heart failure in the previous year.


Contraindications: The CardiMEMS HF System is contraindicated for patients with an inability to take dual anticoagulants or anticoagulants for one-month post implant.

Potential Adverse Events: Potential adverse events associated with the implantation procedure include, but are not limited to, the following: Infection, Arhythmias, Bleeding, Hematoma, Thrombus, Myocardial infarction, Transient ischemic attack, Stroke, Death, and Device embolization.

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