Welcome to the 2023 Virtual Pharmacy Residency Conference

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Evaluation of CardioMEMS HF System in Patient's with Heart Failure
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Learning Objectives

At the end of this presentation participants should be able to…

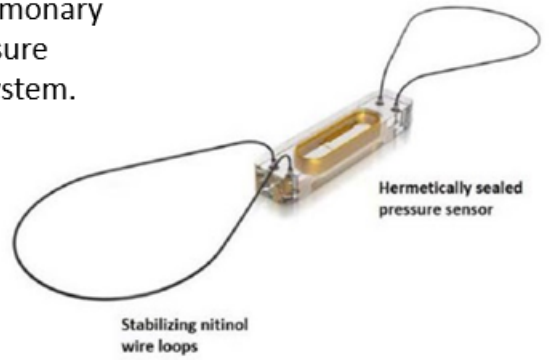
- Describe what CardioMEMS are and how they work
- Recognize who would be a candidate for CardioMEMS
- Identify the AHA/ACC/HFSA guidelines recommendation of implantable pulmonary artery pressure monitoring devices

Heart Failure Background

- According to the Centers for Disease and Prevention (CDC) roughly 6.2 million adults have heart failure in the United States.
- Studies have shown that hemodynamic changes are indicators for heart failure exacerbations and can be observed weeks leading up to acute decompensation.
- While first approved in 2014, the FDA updated the approval for CardioMEMS in February 2022 to include patients with NYHA Class II heart failure and increased natriuretic peptides.
- The goal of these devices is to prevent heart failure hospitalizations by being proactive in medication interventions.

What Are CardioMEMS?

Implantable Pulmonary Artery Pressure Monitoring System.



After placement, patients lay on a patient electronic system or "pillow" daily to record their PA systolic and diastolic pressures, PA pressure mean and heart rate.

The data is transmitted to the healthcare provider and interventions are made based on the readings.

Patient Population

- NYHA Classes II and III
- Elevated natriuretic peptides
- Hospitalization due to heart failure in the last 12 months

How to Adjust Therapy

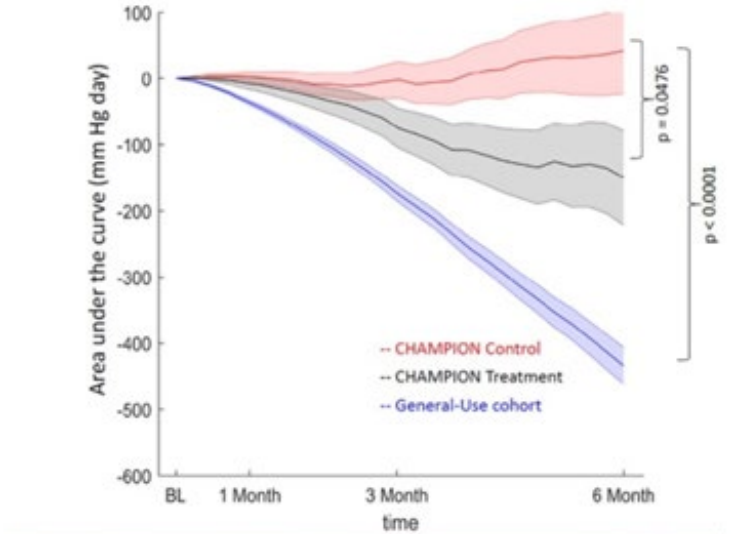
PAD < 10 mmHg	PAD > 25 mmHg
Low PA Pressures (Hypovolemic) PAD *trending* below the normal hemodynamic range	**Elevated PA Pressures (Hypervolemic)** PAD *trending* above the normal hemodynamic range
Poor perfusion in the absence of signs and symptoms of congestion	
Lower or discontinue diuretic • if on thiazide and loop diuretic, lower or discontinue the thiazide diuretic • if only on loop diuretic, lower the dose or discontinue • consider liberalization of oral fluid or salt restriction	**Add or increase diuretic** • increase/add loop diuretic • change loop diuretic • add thiazide diuretic • IV loop diuretic
Lower or hold vasodilators if postural hypotension presents	**Add or increase vasodilators** add or increase nitrate
Re-evaluate PA pressures 2–3 days per week until PA pressures stabilize	**Re-evaluate PA pressures** 2–3 days per week until PA pressures stabilize
Lower or hold ACE/ARB dose if worsening renal function presents with hypotension	**Evaluate other etiologies** if PA pressures remain elevated (e.g., dietary indiscretion, sleep apnea)

ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker

Study Analysis (1)

Impact of Practice-Based Management of Pulmonary Artery Pressures in 2000 Patient Implanted with the CardioMEMS Sensor			
Overview	This study looked at adherence and PA pressure changes in general population patients with implanted PA pressure monitoring systems and compared the results to the CHAMPION Trial results.		
Methods	Pulmonary artery pressure and adherence to transmissions were analyzed for the first 2000 patients who were implanted with the CardioMEMS HF system if they had at least 6 months of follow –up and met the inclusion and exclusion criteria.		
Study Population		CHAMPION Trial (n=550)	General-Use Cohort (n=2000)
	Age (years)	61.58±12.83	69.67±12.26
	Male Sex (%)	399 (72.55)	1169 (59.8)
	Baseline Mean PA Pressure (mmHg)	31.6±10.7	34.9±10.2

Results:

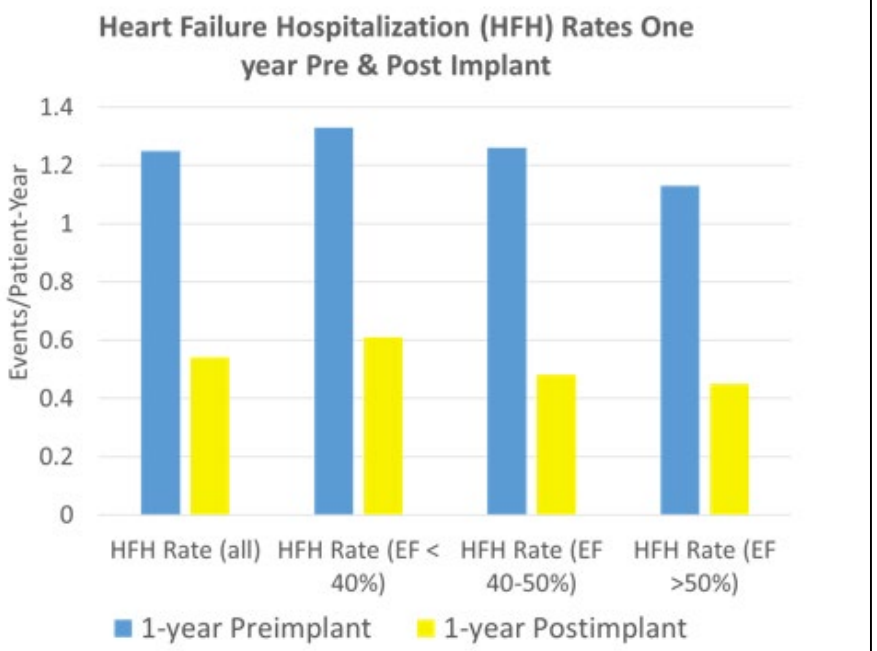


CHAMPION Control	(275pts)	3.1 ± 6.7 (270pts)	-5.5 ± 24.7 (251pts)	42.0 ± 65.0 (228pts)
CHAMPION Treatment	(270pts)	-7.0 ± 7.7 (266pts)	-59.3 ± 27.6 (257pts)	-150.1 ± 71.0 (236pts)
General-Use cohort	(2000pts)	-32.8 ± 2.9 (1920pts)	-156.2 ± 10.6 (1816pts)	-434.0 ± 27.5 (1655pts)

Study Analysis (2)

Lower Rates of Heart Failure and All-Cause Hospitalizations During Pulmonary Artery Pressure-Guided Therapy for Ambulatory Heart Failure	
Overview	The study looked at the safety and efficacy of CardioMEMS in patients that were underrepresented in the CHAMPION Trial one year after implantation
Methods	Multi-center, prospective, open-label, single-arm trial
Study Population	Cohort: n=1214 Sensor Implantation: n=1200 Completed 12 Month Follow-Up: n=875
Primary Endpoint	Heart failure hospitalization rate for the year after the implantation of the PA pressure monitoring system versus the heart failure hospitalization rate one year

Results:



Place in Guidelines

Recommendation for Wearables and Remote Monitoring (Including Telemonitoring and Device Monitoring) Referenced studies that support the recommendation are summarized in the Online Data Supplements.		
COR	**LOE**	**Recommendation**
2b	**B-R**	1. In selected adult patients with NYHA class III HF and history of a HF hospitalization in the past year or elevated natriuretic peptide levels, on maximally tolerated stable doses of GDMT with optimal device therapy, the usefulness of wireless monitoring of PA pressure by an implanted hemodynamic monitor to reduce the risk of subsequent HF hospitalizations is uncertain.[1–4]
Value Statement: Uncertain Value (B-NR)		2. In patients with NYHA class III HF with a HF hospitalization within the previous year, wireless monitoring of the PA pressure by an implanted hemodynamic monitor provides uncertain value.[4–7]

Conclusion

- The use of PA pressure monitoring devices in patients with congestive heart failure is a viable option for preventing heart failure exacerbations and hospitalizations.
- Medication interventions made in response to PA pressure changes in both clinical trials and the general population lead to improved patient care.
- These devices should be utilized for patients who meet criteria for use to improve outcomes, as well as decrease cost on the healthcare system.

Knowledge Questions

- How are CardioMEMs implanted?
  A. Open heart surgery
  B. Catheter through femoral vein
  C. Small incision in the abdomen
  D. They aren't implanted they stick to the chest
- CardioMEMs is approved for heart failure in patients with New York Heart Association (NYHA) class(es):
  A. Classes I & II
  B. Classes II & III
  C. Class IV
  D. Classes I, II, III, & IV

Resources

Heart Failure. cdc.gov. Centers for Disease Control and Prevention. https://www.cdc.gov/heartdisease/heart_failure.htm. Updated October 14, 2022. Accessed November 13, 2022.

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CardioMEMS HF System – P100045/S056. Food and Drug Administration. Updated May 11, 2022. Accessed November 15, 2022. https://www.fda.gov/medical-devices/recently-approved-devices/cardiomems-hf-system-p100045s056

Zile MR, Adamson PB, Cho YK, et al. Hemodynamic factors associated with acute decompensated heart failure: part 1–insights into pathophysiology. J Card Fail. 2011; 17:282–291. doi: 10.1016/j.cardfail.2011.01.010

Heywood JT, Jermyn R, Shavelle D, et al. Impact of practice-based management of pulmonary artery pressures in 2000 patients implanted with the cardioMEMS sensor.

Patient management clinical quick guide. Abbott. 2019. Accessed January 20, 2022.

Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart Failure: a report of the American college of cardiology/American heart association joint committee on clinical practice guidelines. Circ Heart Fail. 2022;145:e895–e1032. DOI: 10.1161/CIR.0000000000001063

Questions & Discussion