Intracardiac Hemodynamic Monitoring – CardioMEMS

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Disclosures

• None
Objectives

• Understand the pathophysiology of congestion

• Learn how to use IHM – CardioMEMs

• Understand clinic benefits of IHM - CardioMEMs
Heart Failure – A Growing Global Concern

Prevalence and Incidence

• Overall 2.4% prevalence: 5.1 million patients >20 years of age with heart failure in 2010

• 825,000 people ≥ 45 years of age are newly diagnosed each year with HF

• HF prevalence in the US is projected to increase 25% from 2013 to 2030, resulting in >8M people ≥ 18 years of age with HF.

Mortality

• For AHA/ACC stage C/D patients diagnosed with HF:
  – 30% will die in the first year.
  – 60% will die within 5 years

• In 2009, 56000 death were attributable to HF.

Circulation 2012; 125: e2–e220
Health care burden of Heart failure

• In 2010, there were 1 million HF hospitalizations in the US

• The mean length of stay is \(~6\) days

• In-hospital mortality is \(\sim 2\) to \(4\%\)

• In 2010, there were 1.80 million HF office visits

Projections show that by 2030, the total cost of HF will increase almost 120\% to $70 billion
• HF is associated with high readmission rates: ~25% all-cause readmission within 30 days and ~50% within 6 months

• The mortality rate is increased after HF hospitalizations.

• With each subsequent HF-related admission, the patient leaves the hospital with a further decrease in cardiac function.

What is the cause of HF hospitalization?

**Acute decompensated Heart failure (ADHF)**

New onset or gradual or rapidly worsening HF signs and symptoms requiring urgent therapy for pulmonary and systemic congestion due to elevated ventricular filling pressures
What do we know about these patients?

<table>
<thead>
<tr>
<th></th>
<th>ADHERE</th>
<th>OPTIMIZE HF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior HF (%)</td>
<td>75</td>
<td>87</td>
</tr>
<tr>
<td>New onset HF (%)</td>
<td>25</td>
<td>13</td>
</tr>
<tr>
<td>Cardiogenic shock (%)</td>
<td>2</td>
<td>&lt;1</td>
</tr>
<tr>
<td>LVEF &lt;40% (%)</td>
<td>59</td>
<td>52</td>
</tr>
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</table>

The majority of patients admitted with ADHF are known to the medical system and to medical providers.
Are there an **upstream strategies** that may be capable of **detecting early HF destabilization** and **implementing therapies** to restabilize the patient and **avert hospitalization**?
Benefit of Intensive weight and symptom monitoring

Daily measurement of body weight, for example, has a sensitivity of only 9% but a 97% specificity for the development of a HF exacerbation.

Monitoring of weight and symptoms do not reduce readmission or death.

Time course of Decompensation

Adamson PB, et al. Curr Heart Fail Reports, 2009
The Concept of Pressure-Guided Heart Failure Therapy

Heart Failure Hospitalization

Pre-Symptomatic Hemodynamic Changes ("Hemodynamic Congestion")

Symptoms ("Clinical Congestion")

Days

Heart Failure Hospitalization

Averted Heart Failure Hospitalization

Medical Intervention

Pre-Symptomatic

Days

Proactive

Reactive
COMPASS-HF

NYHA III patients

36% reduction in heart failure

J Am Coll Cardiol. 2008;51(11):1073-1079
Managing pressures to target goal ranges:

- PA Pressure systolic 15–35 mmHg
- PA Pressure diastolic 8–20 mmHg
- PA Pressure mean 10–25 mmHg

A Pressure-guided Therapy Reduces HF Hospitalizations

- Freedom from device- or system-related complications was 98.6%
- Overall freedom from pressure-sensor failures was 100%

Complete follow-up results from the CHAMPION randomised trial

New access to pulmonary artery pressure during open access resulted in 48% reduction in admissions to hospital for heart failure

Interventions during the study

Managing Trends of Ambulatory Pulmonary Artery (PA) Pressures

**Low PA pressures (Hypovolemic)**
- Trending below normal

- Lower or discontinue diuretic:
  - If on thiazide and loop diuretic, lower or discontinue thiazide diuretic
  - If only on loop diuretic, lower doses or hold doses
  - If not on diuretics, consider liberalization of oral fluid and

- Re-evaluate PA pressure trends in response to diuretic change for 1-2 days

- If on vasodilators, lower dose or discontinue if postural hypotension present

- Re-evaluate PA pressure trends 2-3 days per week

**Normal PA pressures (Opti-volemic)**
- Trending within normal

  - No medication changes required based on normal PA pressures:
    - Continue current diuretic and/or vasodilator treatment regimen
    - Consider uptitration of current ACC/AHA guideline-directed medical therapies under

  - Evaluate PA pressure trends weekly to maintain stabilization

**Elevated PA pressures (Hyper-volemic)**
- Trending above normal

- Increase or add diuretic:
  - Add loop diuretic or increase loop diuretic dose
  - Add thiazide diuretic or increase thiazide diuretic dose
  - Consider short course of IV loop

- Re-evaluate PA pressure trends in response to diuretic change for 1-2 days

- If no PA pressure response or continued trend elevations observed, consider vasodilator change:
  - Add nitrate or increase dose

- Re-evaluate PA pressure trends 2-3 days per week until stabilization achieved

**Graph:**
- All Medication Changes
- Diuretic (Loop and Thiazide)
- Vascularator (nitrates and hydralazine)
- ACE/ARB
- Beta Blocker
- Aldosterone Antagonist

*P<0.05 PA Pressure Guided HF Management vs. Standard of Care HF Management

**Bar Graph:**
- PA Pressure Guided HF Management (Treatment Group)
- Standard of Care HF Management Only (Control Group)
Days between transmissions ranged from 1.07 days in the first 30 days after implantation to 1.27 days after 6 months. Use of the system was observed at a median of 98.6%

Average time from the most recent HFH to device implantation was 63.2 ± 47.5 days

The median number of HFHs per patient was 0.92 at 6 months before and 0.37 at 6 months after device implantation.
HFrEF vs. HFpEF

Circulation. 2008;118:1433-1441
HFrEF vs. HFpEF

Circ Heart Fail 2014; 7: pp. 935-944
Cost effectiveness

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Cost (USD)</th>
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<tbody>
<tr>
<td>CardioMEMs device (per device)</td>
<td>$17,750</td>
</tr>
<tr>
<td>Implantation procedure</td>
<td>$1,280</td>
</tr>
<tr>
<td>Complications, each</td>
<td>$5,770</td>
</tr>
<tr>
<td>Hospitalizations</td>
<td></td>
</tr>
<tr>
<td>HF hospitalization</td>
<td>$21,007</td>
</tr>
<tr>
<td>Non-HF hospitalization</td>
<td>$24,367</td>
</tr>
<tr>
<td>Monthly monitoring</td>
<td>$47</td>
</tr>
<tr>
<td>Outpatient costs, routine care (per year)</td>
<td>$19,576</td>
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</tbody>
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<table>
<thead>
<tr>
<th></th>
<th>CardioMEMS</th>
<th>Standard of Care</th>
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<tbody>
<tr>
<td>Five-year costs and outcomes</td>
<td></td>
<td></td>
</tr>
<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>Incremental cost-effectiveness ratio (cost per QALY gained)</td>
<td>$44,832</td>
<td></td>
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*Clinical Cardiology. 2017;40:430–436*
Contraindications

• Patients with an active infection
• History of recurrent deep vein thrombosis or pulmonary embolism
• Unable to tolerate a right heart catheterization
• Patients with an estimated glomerular filtration rate < 25 ml/min who are unresponsive to diuretic therapy or on chronic renal dialysis
• Congenital heart disease or mechanical right heart valve
• Known coagulation disorders
• Hypersensitivity to aspirin or clopidogrel
• Patients who have undergone implantation of CRT-D within the past 3 months
• Body mass index (BMI) > 35 kg/m² and chest circumference > 165 cm
Benefits of PA guided management

• Behavioral remodeling
• Return of volume homeostasis
• Reduction in ventricular and atrial size
• Improved activity and confidence to plan
• Patient empowerment
In Summary

• HF and HF hospitalizations are highly prevalent, associated with high morbidity and mortality rates, and has a high financial clinical burden

• Weight monitoring, telemedicine and other implantable electrical devices are not effective in reducing HF hospitalization.

• When used appropriately, implantable hemodynamic monitoring with CardioMEMS can be very effective reducing the risk of rehospitalization.

• IHM is effective in patient with HFrEF and HFpEF

• Use of IMH is cost effective
Thank You