Implantable Hemodynamic Monitoring: Putting It Into Practice

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Disclosures

- Previously employed by Abbott in past 12 months

Objectives

1. Describe strategies to identify appropriate patients for hemodynamic monitoring

2. Discuss the infrastructure requirements needed for remote hemodynamic monitoring
**Current HF Management:**

Can we reliably use weight change as an indicator of rising pressure?

<table>
<thead>
<tr>
<th>Weight Gain</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 kg weight gain over 48-72 hrs</td>
<td>9%</td>
<td>97%</td>
</tr>
<tr>
<td>2% weight gain over 48-72 hrs</td>
<td>17%</td>
<td>94%</td>
</tr>
<tr>
<td>3 lbs in 1 day or 5 lbs in 3 days</td>
<td>22.5%</td>
<td>-</td>
</tr>
</tbody>
</table>

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*Rationale for NO CORRELATION*

Daily weights do not correlate with filling pressures.

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Need for Earlier Markers of Decompensation
Pressure Changes are the Gold Standard for Actionable Intervention

Studies in Hemodynamic Monitoring Preceding CHAMPION

Hypothesis of the CHAMPION Trial

In addition to basing treatment on signs and symptoms

PA pressure data obtained by the CardioMEMS HF System

Heart failure hospitalizations
Delivers insight into the early onset of worsening HF to more proactively manage HF patients and improve outcomes.

CardioMEMS™ HF System:
Provides clarity in the management of heart failure

CHAMPION Study Design

Treatment Group (n=270)

Control Group (n=280)

Primary endpoints analyzed when last enrolled patient reached 6 months

Primary endpoints
PA pressures uploaded without physician access
PA pressures uploaded with physician access

Primary endpoint analyzed:
33% Relative Risk Reduction in HF Hospitalizations in Treatment Group vs. Control Group

Patients managed with PA pressure data had significant relative risk reduction as compared to the control group.

CHAMPION Trial results:
Primary Safety Endpoints and Secondary Endpoints

<table>
<thead>
<tr>
<th></th>
<th>Treatment (n = 270)</th>
<th>Control (n = 280)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Safety Endpoints</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device-related or system-related complications (%)</td>
<td>3 (1%)</td>
<td>3 (1%)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Pressure-sensor failures (%)</td>
<td>0</td>
<td>0</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Secondary Endpoints</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change from baseline in PA mean pressure (mean AUC [mm Hg x days])</td>
<td>-156</td>
<td>33</td>
<td>0.008</td>
</tr>
<tr>
<td>Number and proportion of patients hospitalized for HF (%)</td>
<td>55 (20%)</td>
<td>40 (29%)</td>
<td>0.03</td>
</tr>
<tr>
<td>Days alive and out of hospital for HF (mean ± SD)</td>
<td>174.4 ± 31.1</td>
<td>172.1 ± 37.6</td>
<td>0.02</td>
</tr>
<tr>
<td>Quality of life (Minnesota Living with Heart Failure Questionnaire, mean ± SD)</td>
<td>45 ± 26</td>
<td>51 ± 25</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Both primary safety endpoints and all secondary endpoints were met at 6 months.

Pre-specified Subgroup Analysis
Rate of HF Hospitalizations by Baseline Ejection Fraction

<table>
<thead>
<tr>
<th>Group</th>
<th>Rate of HF Hospitalizations</th>
<th>Treatment</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduced (EF&lt;40%)</td>
<td>0.36</td>
<td>N=208</td>
<td>N=222</td>
</tr>
<tr>
<td>Preserved (EF≥40%)</td>
<td>0.33</td>
<td>N=42</td>
<td>N=57</td>
</tr>
</tbody>
</table>

Pre-commercial experience demonstrated:
SAFETY, REDUCTION IN HF HOSPITALIZATIONS/ADMISSIONS, IMPROVEMENT IN QOL, AND...

COMMERCIAL EXPERIENCE:
ANALYSIS OF FIRST COMMERCIAL PATIENTS AND SINGLE-CENTER STUDIES

<table>
<thead>
<tr>
<th>Site Name</th>
<th># patients</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lancaster General</td>
<td>26</td>
<td>83% relative risk reduction in HF admissions (p &lt; 0.001)</td>
</tr>
<tr>
<td>Ohio State University</td>
<td>23</td>
<td>54% relative risk reduction in 6-month HF hospitalization</td>
</tr>
<tr>
<td>Baylor University</td>
<td>8</td>
<td>Mean PA pressure improvement, 5 patients improved from NYHA FCIII to NYHA FCII</td>
</tr>
<tr>
<td>USC</td>
<td>32</td>
<td>Zero procedure or system-related complications</td>
</tr>
</tbody>
</table>

Initial commercial experience demonstrated:
SAFETY, REDUCTION IN HF HOSPITALIZATIONS/ADMISSIONS, IMPROVEMENT IN QOL, AND...
COMMERCIAL EXPERIENCE:
ANALYSIS OF FIRST 2,000 CONSECUTIVE PATIENTS POST FDA APPROVAL

Commercial utilization of the CardioMEMS™ HF System to guide HF therapy leads to SIGNIFICANT LOWERING OF CARDIAC FILLING PRESSURES.


Commercial utilization of the CardioMEMS™ HF System to guide HF therapy leads to SIGNIFICANT LOWERING OF CARDIAC FILLING PRESSURES.

Mean AUC Values

Hemodynamic Candidates

WHERE? WHAT? HOW? WHY? WHEN?
CardioMEMS™ HF System
Indications for Use

The CardioMEMS HF System is indicated for wirelessly measuring and monitoring pulmonary artery (PA) pressure and heart rate in New York Heart Association (NYHA) Class III heart failure patients who have been hospitalized for heart failure in the previous year. The hemodynamic data are used by physicians for heart failure management and with the goal of reducing heart failure hospitalizations.

CardioMEMS™ HF System
Contraindications

The CardioMEMS HF System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

CardioMEMS™ HF System
Clinical Considerations

The following patients may not be appropriate for implantation of the CardioMEMS HF System:

- Patients with an active infection.
- Patients with a history of recurrent (> 1) pulmonary embolism or deep vein thrombosis.
- Patients unable to tolerate a right heart catheterization.
- Patients with a Glomerular Filtration Rate (GFR) <25 ml/min who are non-responsive to diuretic therapy or who are on chronic renal dialysis.
- Patients with congenital heart disease or mechanical right heart valve(s).
- Patients with known coagulation disorders.
- Patients with a hypersensitivity or allergy to aspirin, and/or clopidogrel.
- Patients who have undergone implantation of a Cardiac Resynchronization Device (CRT) within the past 3 months.
- If the patient’s BMI is greater than 35, measure the patient’s chest circumference at the axillary level. If the chest circumference is > 165cm, sensor implantation should not occur.
Who would you select?

Let’s look at a few Case Studies to determine who would be an appropriate candidate for CardioMEMS™ HF System implant and monitoring.

Case Study #1

Demographics: 65 yo Caucasian Male
CM: Ischemic, EF 29%, NYHA Class III
Last Hospitalization: 7 months

Baseline Vitals
- HR: 86
- BP: 118/74
- Wt: 212
- BMI: 28.6

Baseline Labs
- Cr: 1.1
- GFR: 78

Medical History
- PAH
- CAD
- Scheduled for ICD soon; not a CRT, CRT-D candidate
- Hypertension

Medications
- Warfarin
- Carvedilol 25 mg BID
- Lisinopril 40 mg daily
- Furosemide 40 mg BID
- Potassium 20 mEq KCL BID

WHAT DO YOU THINK?
Case Study #1

This would be an appropriate patient to implant.

- This patient is displaying functional class III symptomology and it was clearly documented in his last office visit note.
- He was also hospitalized within the last 12 months for exacerbation of heart failure.

- Items to consider:
  - Patient is on warfarin, ASA/clopidogrel combo would not be necessary.
  - Also, it would be necessary to check INR prior to implant to ensure a safe procedure.

Case Study #2

Demographics: 82 yo Caucasian Female

CM: Nonischemic, EF 75%, NYHA Class III

Last Hospitalization: 18 months

<table>
<thead>
<tr>
<th>Baseline Vitals</th>
<th>Baseline Labs</th>
<th>Medical History</th>
<th>Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>HR: 107</td>
<td>Cr: 0.8</td>
<td>A fib</td>
<td>Apixaban 5 mg</td>
</tr>
<tr>
<td>BP: 132/90</td>
<td>GFR: 87</td>
<td>Pulmonary Hypertension</td>
<td>Metoprolol Succinate 25 mg BID</td>
</tr>
<tr>
<td>Wt: 200</td>
<td></td>
<td>DMII</td>
<td>Lisinopril 10 mg daily</td>
</tr>
<tr>
<td>BMI: 31.3</td>
<td></td>
<td>Hypertension</td>
<td>Furosemide 80 mg twice a day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute Renal dysfunction in the past</td>
<td>KCL 40 mEq twice a day</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Metolazone 2.5 mg as needed</td>
</tr>
</tbody>
</table>

IS THIS A GOOD CANDIDATE?
Case Study #2

This would not be an appropriate patient to implant.

- This patient is displaying functional class III symptomology and it was clearly documented in her last office visit note.
- She has not been hospitalized for exacerbation of heart failure within the last 12 months.
- Items to note:
  - No ASA/clopidogrel combo will be necessary for this patient post implant due to current apixaban for A fib.
  - Also, careful consideration should be made with diuretic dosing due to her previous Acute Kidney Injury in the past.
- Should she be hospitalized for HF, she would be a candidate.

Case Study #3

Demographics: 67 yo Hispanic Female

CM: Nonischemic, EF 60%

Last Hospitalization: 5 months

Baseline Vitals
- HR: 67
- BP: 126/83
- Wt: 265
- BMI: 43

Baseline Labs
- Cr: 0.5
- GFR: 94

Medical History
- A fib
- Pulmonary Hypertension
- Obesity
- DMII
- Gout
- Hx DVT-remote

Medications
- Warfarin
- Isosorbide dinitrate 20 mg TID
- Metoprolol succinate 12.5 mg Daily
- Spironolactone 25 mg daily
- Furosemide 60 mg twice a day

Would you implant this patient?
Case Study #3

This would be an appropriate patient to implant.

- This patient is displaying functional class III symptomology and it was clearly documented in the last office visit note.
- This patient has also had at least one hospitalization for heart failure in the last 12 months.
- Items to note –
  - Patient is on Coumadin, so ASA/Plavix will not be necessary post implant.
  - INR should be drawn prior to implant to ensure safety during and after the implant procedure.
  - Additionally, BMI is over 35, so a chest circumference will need to be determined, to ensure it is less than 165cm.

Case Study #4

**Demographics:** 56 yo Caucasian Male

**CM:** Ischemic, EF 15%

**Last Hospitalization:** 7 months

<table>
<thead>
<tr>
<th>Baseline Vitals</th>
<th>Baseline Labs</th>
<th>Medical History</th>
<th>Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>HR: 72</td>
<td>Cr: 1.1</td>
<td>CAD</td>
<td>Recently decreased doses due to symptomatic hypotension.</td>
</tr>
<tr>
<td>BP: 94/48</td>
<td>GFR: 80</td>
<td>Hyperlipidemia</td>
<td>Carvedilol 3.125 mg BID</td>
</tr>
<tr>
<td>Wt: 398</td>
<td></td>
<td>Acute renal failure</td>
<td>Lisinopril 2.5 mg daily</td>
</tr>
<tr>
<td>BMI: 51</td>
<td></td>
<td>Dyspnea at rest</td>
<td>Furosemide 100 mg BID</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Venous insufficiency</td>
<td>Spironolactone 6.25 mg daily</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OSA</td>
<td>ASA 325 mg daily</td>
</tr>
</tbody>
</table>

**Baseline Labs**

- Cr: 1.1
- GFR: 80

**Medical History**

- CAD
- Hyperlipidemia
- Acute renal failure
- Dyspnea at rest
- Venous insufficiency
- OSA
- Recently decreased doses due to symptomatic hypotension.
- Carvedilol 3.125 mg BID
- Lisinopril 2.5 mg daily
- Furosemide 100 mg BID
- Spironolactone 6.25 mg daily
- ASA 325 mg daily

**WHAT ELSE SHOULD YOU CONSIDER?**
Case Study #4

This would not be an appropriate patient to implant.

- This patient is displaying functional class III symptomology clearly documented in the last office visit note.
- This patient has also had at least one hospitalization for heart failure in the last 12 months.
- Items to note –
  - this patient’s BMI is above 35, so a chest circumference will need to be obtained prior to implant.
  - His blood pressure is also fairly low, this may be very difficult to titrate meds accordingly. He is on low doses of therapy, due to intolerance,
  - this along with his dyspnea at rest indicates that he has progressed past functional class III to functional class IV.

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Where Do I Find Them?

- Query list of all patients discharged last 12 months with HF
- Screen at 7 day post hospitalization OVs
- At HF hospitalization discharge
- EP clinic list of change-out

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Where Do I Find Them?

- Outreach to primary care, referring community, patient community, hospital departments

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Have the Data, Now What?

Workflow Considerations

Outpatient Considerations

- Who Reviews Data
  - Site champion
  - Nurse/PA/NP/CNS
  - Medical assistant
  - Physician
  - EP clinic (if already reviewing TI)

- Who makes intervention decision?
  - Advanced Practice Provider
  - Nurse with Protocol
  - Physician of record?
  - Physician of the week?
Outpatient Considerations

- When
  - At least weekly
  - Utilize threshold settings
  - Utilize Patient of Interest Reports

- What type of CardioMEMs data would prompt:
  - Earlier/more frequent review of data
  - A phone call to the patient
  - Office visit & who will see the pt and in what time frame
  - Physician notification
  - Hospital admission

Outpatient Considerations

- If billing monthly physiologic code:
  - Who submits q 31 days?
    - Consider person who is reviewing, making changes, signing and billing is employed by and where that revenue will go
    - Have a discussion prospectively with EP clinic that may be billing physiologic code already for TI
    - Utilize billing counter in Merlin to keep track of when appropriate to bill
    - Must have at least 10 days of non-consecutive data points to bill for the physiologic code (93297, 93299)

Clinical Care of Patient with Hemodynamic Monitor

- Review of data
  - Follow site program guidelines for when to
    - Review data more frequently
    - Call patient
    - Notify specified clinician (NP/PA/CNS/Nurse/Physician)
    - Schedule office visit
    - Arrange hospital admission

- Follow treatment guidelines for optivolemic, elevated, or reduced PA pressures
Managing Trends of Ambulatory PA Pressures

<table>
<thead>
<tr>
<th>Low PA Pressure (Hypovolemic)</th>
<th>Elevated PA Pressure (Hyper-volemic)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PA Mean Pressure trending below the normal hemodynamic range</td>
<td>PA Mean Pressure trending above the normal hemodynamic range</td>
</tr>
</tbody>
</table>

- Poor perfusion in the absence of signs & symptoms of congestion
- Lower or discontinue diuretic
  - if on thiazide and loop diuretic, lower or D/C the thiazide diuretic
  - if only on loop diuretic, lower the dose or discontinue
  - consider liberalization of oral fluid or salt restriction

- Lower or hold vasodilators
  - if postural hypotension present

Low PA Pressure (Hypo-volemic)

PA Mean Pressure trending below the normal hemodynamic range

- Lower or hold ACE/ARB dose
  - if worsening renal function present with hypotension

Re-evaluate PA pressures
2-3 days per week until PA pressures stabilize

Elevated PA Pressure (Hyper-volemic)

PA Mean Pressure trending above the normal hemodynamic range

- Evaluate other etiologies
  - if PA pressures remain elevated i.e. dietary indiscretion, sleep apnea, etc.

Add or increase vasodilators
- add or increase nitrate

Re-evaluate PA pressures
2-3 days per week until PA pressures stabilize

PA PRESSURE RANGES:
- PA Systolic: 15 - 35 mmHg
- PA Diastolic: 8 - 20 mmHg
- PA Mean: 10 - 25 mmHg

Clinical Care of Patient with Hemodynamic Monitor

- Follow pressure trends frequently/daily after treatment to assure trending back to PA goals:
  - Pulmonary artery systolic pressure 15 – 35 mmHg
  - Pulmonary artery diastolic pressure 8 – 20 mmHg
  - Pulmonary artery mean pressure 10 – 25 mmHg
- Develop a plan for pressures that do not trend back to goal target ranges
- Adjust individual patient notification thresholds as clinically appropriate
- Document in Merlin system therapies, medication changes, progress notes etc.
- Document same in patient’s medical records

RS 56 yo male NICM EF 15%

Carvedilol increased to 6.25 BID, furosemide made prn PAD=6 Told to stop inappropriate prn furosemide usage

Carvedilol increased to 12.5 BID
KT 59 yo female ICM

What if you called patient and:
- no weight change
- abdominal bloating
- no PND,
- change in DOE
- PAM is 29?

2/11: 58/38 PAM 29; extra bumex 2 mg
2/12: 48/31 PAM 23; extra bumex 2 mg
2/13: 48/32 PAM 23; cont bumex extra 2mg x 2 more days
2/19: increase aldactone at OV
2/26: increase aldactone to 2 tabs daily
3/5: 32/20 PAM 14, stable no med changes

DT 63 YO male with ICM EF 25%

Each note indicated a dose of torsemide 20 mg x 1 or for 3 days.
Hospitalized at outside hospital for CP; w/u negative

Ambulatory Implantable Hemodynamic Monitoring:
Final Thoughts

- Clear reduction in HF hospitalizations
- Significantly Improves QOL
- Allows personalized, prospective care based on accurate, actionable, surrogate, signal
- Planning before implementing is key; consider how you manage your remote information now
- Patient will benefit:
  - Right intervention at right time
  - Improvement in functional status
  - Reduce chance of hospitalization
THANK YOU-
Celebrate the success!!