Reducing Heart Failure Readmissions with Remote Pulmonary Arterial Pressure Monitoring

Making Sense of the Sensor

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Disclosures

- Van Selby: None
- Amanda Schnell-Heringer: None
Heart failure hospitalizations


Physiologic progression

Remote monitoring: Previous trials

- TELE-HF: Telemonitoring with daily weight change and symptoms
  - No effect on all-cause mortality or readmission
- COMPASS-HF: Remote intracardiac monitoring
  - No significant change in HF-related events
- DOT-HF: Thoracic impedance monitoring
  - No effect on morbidity or mortality
CardioMEMS

- No batteries or leads
- 10 mm nitinol loops keep the device in place
- The sensor contains a capacitor capable of measuring pressure with extremely high fidelity
- Pressure readings transmitted wirelessly using a pillow that is provided to the patient

CardioMEMS: Sensor Implant

- Right heart catheterization
- Selective pulmonary angiography (~10 cc contrast)
- Placement in the lower right or left PA branch, pre-bifurcation
- Vessel lumen: 7-15mm
  - Where a Swan balloon would fit in the wedge position
CHAMPION-HF

- 550 patients with NYHA class III heart failure randomized to remote hemodynamic monitoring vs usual care
  - HF present for at least 3 months
  - At least one hospitalization
  - No EF-related enrollment criteria
- Primary endpoint: Rate of HF hospitalization

CHAMPION-HF: Treatment algorithm

- All patients took daily home pressure readings
- Pressures were reviewed at least once per week, and more frequently if indicated for clinical reasons
- Target pressures:
  - PA systolic pressure 15-35 mmHg
  - PA diastolic pressure 8-20 mmHg
  - PA mean pressure 10-25 mmHg

CHAMPION-HF Results

Risk reduction: 36%

Hemodynamic monitoring leads to more medication changes


CHAMPION: Safety endpoints

- 15 adverse events reported among 575 device implants
  - 7 procedure-related
    - 4 bleeding (groin, epistaxis, hemoptysis)
    - 3 hospitalizations related to anticoagulation
  - No pulmonary infarcts or embolism
  - No events required removal of the sensor
  - No significant differences in adverse events between the two groups.
- No pressure sensor failures in either group
### CHAMPION: NNT to prevent one HF-related hospitalization

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Trial</th>
<th>Mean Duration of Randomized Follow-Up</th>
<th>Annualized Reduction in HF Hospitalization Rates</th>
<th>NNT per year to Prevent 1 HF Hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beta-blocker</td>
<td>COPERNICUS</td>
<td>10 months</td>
<td>33%</td>
<td>7</td>
</tr>
<tr>
<td>Aldosterone antagonist</td>
<td>RALES</td>
<td>24 months</td>
<td>36%</td>
<td>7</td>
</tr>
<tr>
<td>CRT</td>
<td>CARE-HF</td>
<td>29 months</td>
<td>52%</td>
<td>7</td>
</tr>
<tr>
<td>Beta-blocker</td>
<td>MERIT-HF</td>
<td>12 months</td>
<td>29%</td>
<td>15</td>
</tr>
<tr>
<td>ACE inhibitor</td>
<td>SOLVD</td>
<td>41 months</td>
<td>30%</td>
<td>15</td>
</tr>
<tr>
<td>Aldosterone antagonist</td>
<td>EMPHASIS-HF</td>
<td>21 months</td>
<td>38%</td>
<td>16</td>
</tr>
<tr>
<td>Digoxin</td>
<td>DIG</td>
<td>37 months</td>
<td>24%</td>
<td>17</td>
</tr>
<tr>
<td>Angiotensin receptor blocker</td>
<td>Val-HeFT</td>
<td>23 months</td>
<td>23%</td>
<td>18</td>
</tr>
<tr>
<td>Angiotensin receptor blocker</td>
<td>CHARM</td>
<td>40 months</td>
<td>27%</td>
<td>19</td>
</tr>
<tr>
<td>PA pressure monitoring</td>
<td>CHAMPION</td>
<td>17 months</td>
<td>33%</td>
<td>4</td>
</tr>
</tbody>
</table>

### CardioMEMSTM System

- FDA approved May 28, 2014
- No batteries or leads
- Indication
  - For wirelessly measuring and monitoring PA pressure and HR
  - In patients with NYHA class III HF who have been hospitalized for HF within the previous year
  - Hemodynamic data are used by physicians with the goal of better HF management and to reduce HF hospitalization
- Certification: requires 3 proctored implants
UCSF criteria/considerations for CardioMEMS

- At least one HF-related hospitalization in the past year
- No contraindication for DAPT
- Necessary adherence, as demonstrated by:
  - Regular lab monitoring
  - Able to take meds as instructed
  - Attend MD appts regularly
- Able to lie flat
- No major psychosocial barriers to appropriate transmissions and follow-up
- Major exclusions:
  - PE/DVT
  - GFR<25, unresponsive to diuretics, HD
  - Major cardiovascular event within 2 months
  - Coagulopathy
  - Hypersensitivity to ASA/Plavix

Patient Cases
Case 1: Ms C

- 70 year old woman with HFrEF: EF 40%
- ACC/AHA stage C, NYHA functional class III
- Past Medical History: Gout, dyslipidemia, OSA, peripheral neuropathy, obesity, and emphysema
- One HF hospitalization in the previous year
- Six office and ED visits for HF
- Did not tolerate up titration of oral therapies due to side effects

Post-implant medication changes
Adherence Affects PAD

Case 1, continued

- Current medications:
  - Losartan 150 mg daily
  - Bumetanide 4 mg BID, chlorothiazide 250 mg BID
  - Carvedilol 50 mg BID
  - Isosorbide mononitrate 180 mg BID

<table>
<thead>
<tr>
<th></th>
<th>ED visits for HF</th>
<th>Hospitalizations for HF</th>
<th>Telephone calls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-implant</td>
<td>2</td>
<td>1</td>
<td>14</td>
</tr>
<tr>
<td>Post-implant</td>
<td>0</td>
<td>0</td>
<td>65</td>
</tr>
</tbody>
</table>

- Due to body habitus, difficulty with pressure transmissions
Case 2: Mr F

- 60 y.o. male with NIDCM due to prior alcohol and cocaine use. Pt reports no recent use of cocaine and minimal weekly ETOH use.
- HFrEF: EF 20%
  - ACC/AHA Stage C, NYHA Class III
  - CRT-D, cirrhosis, paroxysmal atrial fibrillation, sleep apnea, COPD.
  - Worsening HF symptoms despite maximal treatment.
  - Two HF admissions in the previous year
Increase in PAD and HR

Case 3: Ms K

- 66 year old woman with HFpEF due to restrictive cardiomyopathy associated with prior radiation
  - NYHA class III
  - DM, CKD stage III, obesity
- One HF hospitalization in the previous year
- Difficult physical exam
- Ongoing difficulty with fluid retention, fluctuating renal function
- CardioMEMS implanted 1/21/2015
August 2015: worsening creatinine

Creatinine (mg/dL)

8/3: Septra for UTI

Resource utilization

<table>
<thead>
<tr>
<th></th>
<th>Hospitalizations/ED visits</th>
<th>Office visits</th>
<th>Telephone calls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-implant</td>
<td>3</td>
<td>7</td>
<td>28</td>
</tr>
<tr>
<td>Post-implant</td>
<td>0</td>
<td>4</td>
<td>105</td>
</tr>
</tbody>
</table>
Hemodynamic monitoring in HFpEF

<table>
<thead>
<tr>
<th>Ejection Fraction</th>
<th>Randomization Group</th>
<th>No. of Heart Failure Hospitalizations</th>
<th>Annualized Rate of Hospitalization for Heart Failure</th>
<th>Incidence Rate Ratio (95% CI; P Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥40%</td>
<td>Treatment group (n=62)</td>
<td>29</td>
<td>0.43</td>
<td>0.50 (0.35–0.70; &lt;0.0001)</td>
</tr>
<tr>
<td></td>
<td>Control group (n=57)</td>
<td>59</td>
<td>0.86</td>
<td></td>
</tr>
<tr>
<td>≥50%</td>
<td>Treatment group (n=35)</td>
<td>13</td>
<td>0.41</td>
<td>0.30 (0.18–0.48; &lt;0.0001)</td>
</tr>
<tr>
<td></td>
<td>Control group (n=31)</td>
<td>31</td>
<td>1.39</td>
<td></td>
</tr>
<tr>
<td>&lt;40%</td>
<td>Treatment group (n=208)</td>
<td>153</td>
<td>0.67</td>
<td>0.74 (0.63–0.89; 0.0010)</td>
</tr>
<tr>
<td></td>
<td>Control group (n=222)</td>
<td>220</td>
<td>0.90</td>
<td></td>
</tr>
</tbody>
</table>

CI indicates confidence interval.

Case 4: Ms W

- 72 yo woman s/p bilateral lung transplant
- Referred to UCSF HF clinic for treatment of HFpEF
  - NYHA class III symptoms
  - Severe diastolic dysfunction
  - Hypertension
  - A-fib
- One hospitalization for HF in the year prior
- Ongoing volume overload, dyspnea, hypoxemia, pulmonary edema, and worsening renal function
- Implanted with CardioMEMS 2/11/2015
Throughout the month of May, the patient called the office multiple times per week:

- Weight gain
- Worsening lower extremity edema
- Increasing dyspnea and fatigue

Increased edema, SOB. Rx Diuril

Progressive edema
Diuril increased

No improvement. Diuril continued

Edema to thighs and abdomen. Diuril continued

Hospitalized for ARF
Ms W, conclusion

- Creatinine peaked at 4.7
- Hospitalized for acute renal failure
- Discharged, but continued to have problems with edema and dyspnea

Hemodynamic vs clinical management strategies

<table>
<thead>
<tr>
<th></th>
<th>HF Hospitalization Rate (events/year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control Group</td>
<td>1.17</td>
</tr>
<tr>
<td>PAP Managed Clinical</td>
<td>1.22</td>
</tr>
<tr>
<td>Trigged Rx Only</td>
<td></td>
</tr>
<tr>
<td>Baseline PA Mean</td>
<td>50.0 mmHg</td>
</tr>
<tr>
<td>PAP Managed</td>
<td>0.63</td>
</tr>
<tr>
<td>Clinical Patients</td>
<td></td>
</tr>
<tr>
<td>PAP Managed Rx Only</td>
<td></td>
</tr>
<tr>
<td>Baseline PA Mean</td>
<td>20.0 mmHg</td>
</tr>
<tr>
<td>PAP Managed Patients</td>
<td></td>
</tr>
<tr>
<td>Clinical and PAP</td>
<td></td>
</tr>
<tr>
<td>Trigged Rx</td>
<td></td>
</tr>
<tr>
<td>Baseline PA Mean</td>
<td>32.0 mmHg</td>
</tr>
</tbody>
</table>

*P < 0.05 vs. Control Patients (unmonitored)

Goldberg LR et al, HRS 2015
Conclusions

- Most HF hospitalizations are due to congestion
- Monitoring PAP/PAWP can identify impending events prior to weight gain or worsening symptoms
- CardioMEMS can effectively reduce hospitalizations for heart failure when:
  - Patients are well-selected
  - The office is equipped to handle the increased volume
  - A clear treatment algorithm based on hemodynamic data is used
    - Don’t just go by clinical signs/symptoms, use the complete picture
- Ongoing post-approval CardioMEMS registry will provide valuable insights to real world benefits and limitations of hemodynamic monitoring