Remote Monitoring for Heart Failure:
The Weight is Over!

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Heart Failure Epidemic


U.S. Census Bureau Projections

- The population age 65 and older is expected to more than double between 2012 and 2060, from 43.1 million to 92.0 million
- The older population would represent just over one in five U.S. residents by the end of the period, up from one in seven today
- The increase in the number of the “oldest old” would be even more dramatic — those 85 and older are projected to more than triple from 5.9 million to 18.2 million, reaching 4.3 percent of the total population.

Burden on Society

- Heart failure is the #1 reason for hospital admission in patients age 65 and older
- 5.1 million people in the U.S. with heart failure
- 670,000 new cases each year
- 6.5 million hospital days
- Heart failure costs the United States $39.2 billion annually ($0.37 / $1)
- 30 day readmission rates nationally ~ 25%
- 6 month readmission rate nationally ~ 50%

Economic Burden of HF Will Continue to Rise Through 2030*

- The AHA estimates that the total medical costs for HF are projected to increase to $708 by 2030 → a 2-fold increase from 2013.1
- 50% of the costs are attributed to hospitalization.2

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* Study projections assumes HF prevalence remains constant and continuation of current hospitalization practices
Heart Failure Pathophysiology

Time Course of Decompensation

HF management has relied on patient-reported symptoms, as well as impedance, blood pressure and weight gain changes that often manifest only after decompensation has begun.

Physiologic Markers of Acute Decompensation


Pulmonary artery pressure sensor - CardioMEMs

CardioMEMS™ HF System

The CardioMEMS™ HF System provides ambulatory pulmonary artery (PA) pressure monitoring. The PA Sensor is permanently implanted in the distal pulmonary artery via a right-heart catheterization procedure. Patient-initiated sensor readings are wirelessly transmitted to an external electronics unit. Directly monitoring PA pressure not only enables early detection of worsening heart failure, but also allows the titration of medications for proactive and personalized patient management. Data stored in a secure website for clinicians to access and review.

CHAMPION Clinical Trial: Managing to Target PA Pressures

Primary Endpoint: rate of HF Hospitalization

550 Pts w/CMEMS Implants

All Pts Take Daily readings

Treatment

270 Pts

Management Based on PA Pressure + Traditional Info

Control

280 Pts

Management Based on Traditional Info

26 (9.6%) Exited < 6 Months

Primary Endpoint: rate of HF Hospitalization

< 6 Months

15 (5.6%) Death

11 (4.0%) Other

Secondary Endpoints included:

- Change in PA Pressure at 6 months
- No. of patients admitted to hospital for HF
- Days alive outside of hospital
- QOL

PA pressures were managed to target goal pressures by physicians with appropriate titration of HF medications.

Target Goal PA Pressures:

- PA Pressure Systolic 15 – 35 mmHg
- PA Pressure diastolic 8 – 20 mmHg
- PA Pressure mean 10 – 25 mmHg
CHAMPION Clinical Trial: PA Pressure-guided Therapy Reduces HF Hospitalizations

Patients managed with PA pressure data had significantly fewer HF hospitalizations as compared to the control group.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Control</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device-related or system-related complications</td>
<td>0.017</td>
<td>0.017</td>
</tr>
<tr>
<td>Pressure-sensor failures</td>
<td>0.0001</td>
<td>0.0001</td>
</tr>
<tr>
<td>Change from baseline in PA mean pressure (mm Hg) [mean ± SD]</td>
<td>0.058</td>
<td>0.058</td>
</tr>
<tr>
<td>Number and proportion of patients hospitalized for HF (%)</td>
<td>0.029</td>
<td>0.029</td>
</tr>
<tr>
<td>Days alive and out of hospital for HF (mean ± SD)</td>
<td>0.018</td>
<td>0.018</td>
</tr>
<tr>
<td>Quality of life (Minnesota Living with Heart Failure Questionnaire, mean ± SD)</td>
<td>0.142</td>
<td>0.142</td>
</tr>
</tbody>
</table>

* Total of 8 DSRCs including 2 events in Consented but not implanted patients (n = 25)


CHAMPION Clinical Trial: Both Primary Safety Endpoints and All Secondary Endpoints Were Met at 6 months

<table>
<thead>
<tr>
<th>End Point</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>Therapy-related or system-related complications</td>
<td>0.017</td>
<td>0.017</td>
</tr>
<tr>
<td></td>
<td>Pressure-sensor failures</td>
<td>0.0001</td>
<td>0.0001</td>
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<tr>
<td>Secondary Endpoints</td>
<td>Days alive and out of the hospital for HF (mean ± SD)</td>
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CHAMPION Clinical Trial: PA Pressure-Guided Therapy Benefits Patients with Common HF Comorbidities

<table>
<thead>
<tr>
<th>Comorbidity</th>
<th>N size (control)</th>
<th>N size (treatment)</th>
<th>HF Hospitalization rate reduction at 15 months in treatment group</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of myocardial infarction</td>
<td>137</td>
<td>134</td>
<td>46% (p &lt; 0.001 vs. control)</td>
</tr>
<tr>
<td>COPD1,2</td>
<td>96</td>
<td>91</td>
<td>47% (p = 0.0026 vs. control)</td>
</tr>
<tr>
<td>Pulmonary hypertension3</td>
<td>143</td>
<td>151</td>
<td>32% (p = 0.0006 vs. control)</td>
</tr>
<tr>
<td>AF4</td>
<td>135</td>
<td>123</td>
<td>47% (p = 0.0001 vs. control)</td>
</tr>
<tr>
<td>Chronic Kidney Disease5</td>
<td>180</td>
<td>187</td>
<td>47% (p = 0.0001 vs. control)</td>
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CHAMPION Clinical Trial: TIM-HF Trial: Telemonitoring of Weight and Blood Pressure Do Not Reduce Readmission or Mortality

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<tr>
<th>End Point</th>
<th>Telemonitoring (n = 344)</th>
<th>Trial arm (n = 396)</th>
<th>P-value</th>
</tr>
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<tbody>
<tr>
<td>All-cause mortality</td>
<td>16.3</td>
<td>13.6</td>
<td>0.017 (log-rank)</td>
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<tr>
<td>Cardiovascular mortality</td>
<td>113</td>
<td>12.0</td>
<td>0.05 (log-rank)</td>
</tr>
<tr>
<td>All-cause readmission</td>
<td>54.2</td>
<td>50.0</td>
<td>0.07 (log-rank)</td>
</tr>
</tbody>
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CHAMPION Clinical Trial: DOT-HF Trial: Monitoring Impedance with Audible Alert Increased HF Hospitalizations

Monitoring hemodynamic impedance (Calypso® algorithm, Medtronic) with an audible alert did not improve mortality and increased HF hospitalizations.

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CHAMPION CLINICAL TRIAL: THE NUMBER NEEDED TO TREAT (NTN) TO PREVENT ONE HF-RELATED HOSPITALIZATION IS LOWER VS. OTHER THERAPIES

<table>
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<tr>
<th>Intervention</th>
<th>NTN</th>
<th>Mean Duration of Randomized Therapy (months)</th>
<th>Annualized Reduction in HF Hospitalization Rate</th>
<th>NTN per year to Prevent HF Hospitalizations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bevoroxaban</td>
<td>5</td>
<td>12 months</td>
<td>30%</td>
<td>7</td>
</tr>
<tr>
<td>Amlodipine</td>
<td>16</td>
<td>9 months</td>
<td>30%</td>
<td>2</td>
</tr>
<tr>
<td>Candesartan</td>
<td>16</td>
<td>9 months</td>
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<tr>
<td>All pressures</td>
<td>17</td>
<td>9 months</td>
<td>30%</td>
<td>2</td>
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Pulmonary Artery Pressure Database

**Trend Data**

- Systolic: 24
- Mean: 19
- Diastolic: 16
- Heart Rate: 81

**Discrete data**

- Systolic: 24
- Mean: 19
- Diastolic: 16
- Heart Rate: 81

Case Studies
CardioMEMS Experience

- 25 implants
- The first patient was implanted and several days later aspirated and developed respiratory failure, was not intubated because of DNR order. Eventually was made comfort care and died in the hospital
- One patient admitted multiple times for anemia
- Same patient admitted for lethargy and acute kidney injury after having his diuretics were increased despite normal pressures
- Patient admitted for acute SOB. PA pressures were normal, dx with COPD exacerbation
- 61% reduction in HF hospital days

CardioMEMS Experience

- What have I learned so far?
  - Patients don’t change their behavior because they have a PA sensor implanted
  - We probably, in general, undertreat with diuretics and vasodilators
  - There is more hemodynamic variation than I thought there would be
  - Fluid intake makes a difference!
  - Make sure other disease processes are not life-limiting

Thank you!

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