CARDIOMEMS
Wave of the Future!

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I have no financial disclosures of any kind, unfortunately.

HEART FAILURE – A GROWING GLOBAL CONCERN

Prevalence and Incidence
- Overall 2.1% prevalence: 5.1M heart failure patients in 2010¹
- 825,000 people ≥ 45 years of age are newly diagnosed each year with HF¹
- 15M heart failure patients in the ESC 51-member countries²
  - Overall 2-3% prevalence²

Mortality
- For AHA/ACC stage C/D patients diagnosed with HF:
  - 30% will die in the first year²,³
  - 60% will die within 5 years.⁴

HF prevalence in the US is projected to increase 46% from 2012 to 2030, resulting in > 8M people ≥ 18 years of age with HF²

¹. AHA 2014 Statistics at a Glance, 2014
². The European Society of Cardiology, ESC HF Guideline, 2008
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 $70B by 2030 → a 2-fold increase from 2013.¹
- 50% of the costs are attributed to hospitalization.²


Study projections assume HF prevalence remains constant and continuation of current hospitalization practices.

ECONOMIC RISKS OF HF READMISSIONS IN THE US

Medicare’s Hospital Readmissions Reduction program penalizes hospitals that have above average all-cause readmissions within 30 days following HF discharge.

22.7%

Percent withholding of all inpatient Medicare payments will increase to up to 3% by 2015 and beyond.³

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>2013</th>
<th>2014</th>
<th>2015+</th>
</tr>
</thead>
<tbody>
<tr>
<td>% payment withholding</td>
<td>up to 1%</td>
<td>up to 2%</td>
<td>up to 3%</td>
</tr>
</tbody>
</table>

HEART FAILURE IS ASSOCIATED WITH HIGH HOSPITALIZATION AND READMISSION RATES

- In 2010, there were 1 million hospitalizations in the US with HF as the principal diagnosis¹.
- Hospitalization rate did not change significantly from 2000¹.
- Average length of hospital stay:
  - Approximately 5 days (US)²
  - 11 days (Europe)²
- HF is also associated with high readmission rates:
  - ~25% all-cause readmission within 30 days and ~50% within 6 months³.


Data from Organization for Economic Cooperation and Development, 2009.

¹ CDC NCHS National Hospital Discharge Survey, 2000-2010
² Yancy et al. JACC, 2006.
WORSENING HEART FAILURE LEADING TO HF HOSPITALIZATIONS CONTRIBUTES TO DISEASE PROGRESSION

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

Graph adapted from: Gheorghiade MD, et al. Am J. Cardiol. 2005

Data from the EFFECT study, n = 9138 patients

Among 1 year survivors after index EFFECT-HF discharge, the number of heart failure hospitalizations in the preceding year stratified the risk of death in crude analysis.


HF HOSPITALIZATIONS ARE A STRONG PREDICTOR OF MORTALITY


Studies show each admission decreases a patient’s chance of survival.

TIME COURSE OF DECOMPENSATION

Physiologic Markers of Acute Decompensation
INCREASES IN PRESSURE START THE CYCLE OF WORSENING HEART FAILURE

PHYSIOLOGIC MARKERS OF ACUTE DECOMPENSATION

CLINICAL EXAMINATION HAS LIMITED RELIABILITY IN ASSESSING FILLING PRESSURES

Data from clinical evaluations has poor sensitivity and predictive value in determining hemodynamic profile

Table adapted from Capomolla S, et al. Eur J Heart Failure, 2005.
The pulmonary artery pressure sensor is implanted via a right heart catheterization procedure via femoral vein approach.
Patients with moderate NYHA class III HF for at least 3 months, irrespective of LVEF and a HF hospitalization within the past 12 months were included in the study.

**Primary Endpoint:** Rate of HF Hospitalization

- **Treatment:** 270 Pts
- **Control:** 280 Pts

- 26 (9.6%) Exited < 6 Months
- 11 (4.0%) Other

- 20 (7.1%) Death
- 6 (2.2%) Other

**Secondary Endpoints:**
- Change in PA Pressure at 6 months
- Days alive outside of hospital
- QOL


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

**CHAMPION CLINICAL TRIAL: REASONS FOR MEDICATION CHANGES**

- Based on signs & symptoms
- Based on knowledge of PA pressures

CHAMPION CLINICAL TRIAL: HF Meds can be more effectively titrated with Pulmonary Artery (PA) pressure information.

Compared to the control group, patients managed with PA pressures had significantly more total medication changes, resulting in <1 incremental medication change/month.


CHAMPION CLINICAL TRIAL: By targeting pressure ranges and titrating medications, overall PA pressures can be reduced.

Monitoring of PA pressure with the CardioMEMS™ HF System allows managing the pressure spikes that lead directly to exacerbation, as well as the long-term trends.

Compared to the control group, patients managed with PA pressure had persistently lower mean PA pressures over the treatment period.


SUMMARY: CHAMPION CLINICAL TRIAL

- Pulmonary Artery Pressure
- Medication Changes based on Pulmonary Artery Pressure (p < 0.0001)
- Pulmonary Artery Pressure Reduction (p = 0.008)
- Reduction in Heart Failure Hospitalizations (p = 0.0001)
- Quality of Life Improvement (p = 0.024)

Managing pressures to target goal ranges:
- PA Pressure systolic 15–35 mmHg
- PA Pressure diastolic 8–20 mmHg
- PA Pressure mean 10–25 mmHg

REDUCTION in Heart Failure Hospitalizations:

- 28% in Non-responding Patients
- 37% in Responding Patients
CHAMPION CLINICAL TRIAL: PA PRESSURE-GUIDED THERAPY IMPROVES OUTCOMES IN PATIENTS WITH PRESERVED EJECTION FRACTION

- Preserved Ejection Fraction Heart Failure (HFpEF) or diastolic HF patients represent ~50% of all HF patients.
- Pulmonary artery pressure-guided therapy significantly reduced HF hospitalizations in HFpEF patients in the treatment group by 46% at 6 months (p < 0.0001) and by 50% at 18 months (p < 0.0001).
- The effect in HFpEF patients demonstrates an estimated NNT = 2.

CHAMPION CLINICAL TRIAL: SUB-ANALYSIS SHOWS REDUCED HF HOSPITALIZATIONS IN CHRONIC KIDNEY DISEASE PATIENTS

- Study Compared Class III HF patients with Chronic Kidney Disease (CKD) managed with PA pressure (n = 150) to those managed with Standard of Care (SOC) (n = 147).
- For HF patients with CKD PA pressure monitoring reduced heart failure hospitalizations by 42% compared to SOC.
  - (0.48 vs. 0.83, HR 0.58, p < 0.001)
- Changes in CKD indicators (creatinine and GFR) were not adversely affected in the PA pressure monitored group.
- Intensified HF medical therapy due to PA pressure monitoring was safe and did not adversely affect renal function.

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; 0.0001 vs. control)</td>
</tr>
<tr>
<td>COPD</td>
<td>96</td>
<td>91</td>
<td>31% (p = 0.0008 vs. control)</td>
</tr>
<tr>
<td>Pulmonary hypertension</td>
<td>163</td>
<td>151</td>
<td>38% (p = 0.0002 vs. control)</td>
</tr>
<tr>
<td>AF</td>
<td>135</td>
<td>120</td>
<td>41% (p = 0.0001 vs. control)</td>
</tr>
<tr>
<td>Chronic Kidney Disease</td>
<td>150</td>
<td>147</td>
<td>42% (p &lt; 0.0001 vs. control)</td>
</tr>
</tbody>
</table>

6. Abraham et al., HFSA 2014
CHAMPION CLINICAL TRIAL: SUBSTANTIAL REDUCTION IN HOSPITALIZATIONS AND MORTALITY IN PATIENTS ON GDMT

Abraham, et al. ACC 2015

Reduction in HF Hospitalizations
43%

SUMMARY: MANAGING PRESSURES TO MAINTAIN HEALTH AND MANAGE ACUTE EVENTS

Enables proactive and personalized HF management

9. Anker SD, et al. AHA 2010

PULMONARY ARTERY PRESSURE DATABASE

Trend Data

Discrete data

<table>
<thead>
<tr>
<th>Reading</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
<td>Systolic</td>
<td>24</td>
</tr>
<tr>
<td>Mean</td>
<td>15</td>
</tr>
<tr>
<td>Diastolic</td>
<td>16</td>
</tr>
<tr>
<td>Heart Rate</td>
<td>81</td>
</tr>
</tbody>
</table>
ELEVATED PA MEAN PRESSURE TREATMENT STRATEGIES

Elevated PA Pressure (Hyper-volemic)
PA Pressure trending above the normal hemodynamic range

Add or increase diuretic
- increase/add loop diuretic
- change loop diuretic
- add thiazide diuretic
- IV loop diuretic

Add or increase vasodilators
- add or increase nitrates

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

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

CASE STUDY – SUBJECT 13-011

86-year-old male
ICM EF 30%
CM Implant 8/11/2009

MEDICAL HISTORY
- Coronary artery disease
- s/p CRT
- s/p ICD
- Conduction Disease
- Left BBB, SSS, VT
- Myocardial Infarction
- Mitral and tricuspid regurgitation
- Hypertension
- Pulmonary hypertension
- COPD
- Diabetes
- Hypothyroidism
- Hypertension
- Chronic renal insufficiency
- Peripheral artery disease
- Abdominal aortic aneurysm

BASELINE HF MEDICATIONS
ACE intolerance secondary to renal dysfunction
Carvedilol 3.125 mg BID
Isosorbide 30 mg BID
Amiodarone 200 mg QD

HEMODYNAMICS AT IMPLANT
PA 34/10(23)
PCWP 16
CO 3.3
PVR 2.12

BASELINE VITALS
BP 136/77
HR 70
Weight 61.8 kg.
BMI 21.9

BASELINE LABS
SCr 1.7
GFR 41

SWITCHING LOOP DIURETIC
Stop Furosemide
Start Torsemide 5 mg QD
↓ Torsemide 20 mg QD
↑ Torsemide 25 mg BID
↑ Furosemide 40 mg BID

BP 120/70 HR 64 WGT 135 lbs.