CardioMEMS Heart Failure Management System

ANMED CARDIOVASCULAR SYMPOSIUM 2016
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Disclosures

None
Heart Failure – A Growing Global Concern

Prevalence and Incidence

- Overall 2.1% prevalence: 5.1M heart failure patients in 2010
- 825,000 people ≥ 45 years of age are newly diagnosed each year 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.

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

2. The European Society of Cardiology, ESC HF Guideline, 2008
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 diagnosis.\(^1\)

- Hospitalization rate did not change significantly from 2000.\(^1\)

Average length of hospital stay
- Approximately 5 days (US).\(^2\)
- 11 days (Europe).\(^3\)

HF is also associated with high readmission rates:
- ~25% all-cause readmission within 30 days and ~50% within 6 months.\(^4,5\)

Data from Organization for Economic Cooperation and Development, 2009.

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1. CDC NCHS National Hospital Discharge Survey, 2000-2010
HF Hospitalizations are a Strong Predictor of Mortality

Data from the EFFECT study, n = 9138 patients\(^1\)

![Graph showing the percentage of survivors over time for patients with different numbers of hospitalizations.]

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.\(^1\)

Data from Setoguchi et al., n = 14,374 patients\(^2\)

![Graph showing the cumulative mortality curve for all-cause mortality after each subsequent hospitalization for HF.]

KP cumulative mortality curve for all-cause mortality after each subsequent hospitalization for HF.\(^2\)

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

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*Study projections assumes HF prevalence remains constant and continuation of current hospitalization practices
Medicare’s Hospital Readmissions Reduction program penalizes hospitals that have above average all-cause readmissions within 30 days following HF discharge.

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>

3. CMS Hospitals Readmissions Reductions Program of the Patient Protection and Affordable Care Act (PPACA), 2010.
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

Capomolla, 2005. N = 366

<table>
<thead>
<tr>
<th>Variable</th>
<th>Estimate of</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
<th>NPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>JVP Edema</td>
<td>RAP</td>
<td>48</td>
<td>78</td>
<td>60</td>
<td>69</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10</td>
<td>94</td>
<td>55</td>
<td>60</td>
</tr>
<tr>
<td>Pulse Press</td>
<td>Cardiac Index</td>
<td>27</td>
<td>69</td>
<td>52</td>
<td>44</td>
</tr>
<tr>
<td>S3 Dyspnea</td>
<td>PCWP</td>
<td>36</td>
<td>81</td>
<td>69</td>
<td>54</td>
</tr>
<tr>
<td></td>
<td></td>
<td>50</td>
<td>73</td>
<td>67</td>
<td>57</td>
</tr>
<tr>
<td></td>
<td></td>
<td>13</td>
<td>90</td>
<td>60</td>
<td>48</td>
</tr>
</tbody>
</table>

Table adapted from Capomolla S, et al. Eur J Heart Failure, 2005.
### Reliability of Weight in Assessing Decompensation

Weight changes have low sensitivity for decompensation

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


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Lewin, 2005. N = 77\(^1\)  
Abraham, 2011. N = 156\(^2\)
Randomized study of 1653 patients

Primary endpoint: Readmission for any reason or death from any cause within 180 days after enrollment

Control group = Standard-of-care (no telemonitoring)

Treatment group = telemonitoring of symptoms and weight

Results: No difference in number of deaths, readmissions or days in hospital

Monitoring intrathoracic impedance (OptiVol™ algorithm, Medtronic) with an audible alert did not improve mortality and increased HF hospitalizations.
Intra-thoracic impedance has been shown to be more sensitive than weight changes. Impedance still has a high false-positive rate when used to predict acute events.

### Sensitivity of Impedance

<table>
<thead>
<tr>
<th>Study</th>
<th>FP/pt/yr</th>
<th>PPV %</th>
<th>Sensitivity %</th>
</tr>
</thead>
<tbody>
<tr>
<td>SENSE-HF²</td>
<td>1</td>
<td>4.7</td>
<td>20.7-42.1</td>
</tr>
<tr>
<td>DEFEAT-PE⁴</td>
<td>0.96</td>
<td>16.07</td>
<td>26.6%</td>
</tr>
</tbody>
</table>

**Note:**

Results from FAST¹ and MID-HeFT³ are not included in the table above as these studies used a broader definition of True Positive and therefore cannot be compared to the results from SENSE-HF. Definition for True Positive was comparable but not the same in the calculations for Sensitivity, FP/pt/yr, and PPV% between SENSE-HF and DEFEAT-PE; therefore, these numbers should not be directly compared.

Mechanisms of Worsening Heart Failure

Increased pressure is the proximate cause of congestion

- Precipitating cause
  - Sympathetic activation
  - Venous redistribution (fast)

- Increased L Heart Filling
  - LAP/PAP
  - Pulmonary capillary transudation
  - Decompensation / hospitalization

- Renal and dietary
  - Fluid retention (slow)

Pressures rise early and have few confounders
COMPASS Trial: Monitoring of Hemodynamic Data

Prospective, multicenter randomized, single-blind trial of 274 class III/IV HF patients

Increases in PA Pressures – Not Body Weight – Precede HF Hospitalization

# Managing Pressures in the Heart Failure Patient

<table>
<thead>
<tr>
<th>Pressures</th>
<th>Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>When patients are stable</td>
<td>- Their pressures remain very stable over time.</td>
</tr>
<tr>
<td>When patients decompensate</td>
<td>- Pressures increase, leading to exacerbation.</td>
</tr>
<tr>
<td>The pressures return to baseline when the exacerbation is treated and</td>
<td>- Pressures reflect the underlying volume state in HF patients.</td>
</tr>
<tr>
<td>volume returns to normal</td>
<td>- Strongly supports the hypothesis that measuring those pressures</td>
</tr>
<tr>
<td></td>
<td>frequent or continuously using implantable devices and managing those</td>
</tr>
<tr>
<td></td>
<td>pressures may be a superior management strategy.</td>
</tr>
<tr>
<td>Managing to targeted pressure ranges</td>
<td>- Can reduce overall pressures and ultimately lead to a reduction in HF events.</td>
</tr>
</tbody>
</table>
CardioMEMS™ HF System

Pulmonary Artery Pressure Sensor → Patient Electronics System → CardioMEMS™ HF System Website
The pulmonary artery pressure sensor is implanted via a right heart catheterization procedure via femoral vein approach.
1. **Access PA with PA Catheter:**
   - Insert PA Catheter through a 12Fr sheath placed in the femoral vein.
   - With balloon inflated, advance PA Catheter to a wedge position within the lower lobe of the left or right PA.
   - Measure PAP, PCWP, and CO.
2. Identify and Access Target Implant Site

- Perform angiogram (5cc) through the PA catheter.
  - Target implant vessel is within the lower lobe of either lung and the vessel is directed towards the feet and back.
  - Vessel diameter is > 7 mm and has < 30 degree angulation where body of Sensor will be placed.
  - Vessel diameter is < 8 mm where the distal loop of Sensor will be placed.
- Place delivery guidewire across the target implant site.
- Retract and remove the PA catheter while maintaining guidewire position.
Implant Procedure

3. Introduce and Deploy Sensor:

- Remove the sensor from the package and flush the guidewire lumen with saline.
- Introduce the sensor delivery catheter over the guidewire through the sheath and into position at the target implant site.
- Release the sensor: Unscrew the cap on the delivery catheter hub, then retract and remove the wires from the catheter.
- Retract and remove the delivery catheter while maintaining guidewire and sensor position.
4. Prepare for Baseline Calibration

- Insert the PA catheter over the guidewire into the main PA.
- Remove the guidewire.
- Position the PA catheter tip approximately 5-10 cm proximal to the sensor or within the opposite lung and measure PA pressure.
- Acquire the sensor signal using the Hospital Electronics System antenna placed under the patient’s back centered under the sensor position.
Implant Procedure

5. Baseline Calibration

- Set Mean PA Pressure Baseline
- Set Cardiac Output Baseline
- Press the “Take Reading” button to capture baseline reading(s)
- Remove antenna from under patient’s back
- Remove pulmonary artery catheter and introducer sheath
- Close venous access site per standard of care
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.

550 Pts with CardioMEMS™ HF System Implants
All Pts Take Daily readings

Treatment
270 Pts
Management Based on PA Pressure + Traditional Info

Control
280 Pts
Management Based on Traditional Info

Primary Endpoint: Rate of HF Hospitalization

26 (9.6%) Exited < 6 Months
15 (5.6%) Death
11 (4.0%) Other

26 (9.6%) Exited < 6 Months
20 (7.1%) Death
6 (2.2%) Other

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

CHAMPION Trial

Inclusion Criteria:

- Age > 18
- NYHA Class III heart failure for at least 3 months
- Irrespective of EF
- Hospitalized for CHF within last 12 months
- Guideline directed drug and device therapy

Exclusion Criteria:

- Recurrent DVT or PE
- CRT device implanted < 3 months
- Stage IV or V CKD
- Inability to take dual antiplatelet therapy for 1 month
CHAMPION Clinical Trial: Managing to Target PA Pressures

550 Pts with CardioMEMS™ HF System Implants
All Pts Take Daily readings

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>270 Pts</td>
<td>280 Pts</td>
</tr>
<tr>
<td>Management Based on PA Pressure +Traditional Info</td>
<td>Management Based on Traditional Info</td>
</tr>
</tbody>
</table>

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

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

CHAMPION Trial

A

Control group (254 hospital admissions for heart failure)
Treatment group (158 hospital admissions for heart failure)

Hazard ratio 0.63
(95% CI 0.52-0.77);
p=0.0001

Number at risk
Control group 280 267 252 215 179 137 105 67 25 10 0
Treatment group 270 262 244 210 169 131 108 82 29 5 1

B

Control group (138 patients with event)
Treatment group (107 patients with event)

Hazard ratio 0.73
(95% CI 0.57-0.94);
p=0.0146

Freedom from hospital admission or mortality (%)
CHAMPION CLINICAL Trial: Both Primary Safety Endpoints and All Secondary Endpoints Were Met at 6 months

<table>
<thead>
<tr>
<th></th>
<th>Treatment (n = 270)</th>
<th>Control (n = 280)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Safety Endpoints</strong></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><strong>Total</strong></td>
<td>8 (1%)*</td>
<td>&lt; 0.0001</td>
<td></td>
</tr>
<tr>
<td><strong>Secondary Endpoints</strong></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>80 (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 ± 37.8</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>
CHAMPION Clinical Trial: Reasons for Medication Changes

Number of medication changes during Primary Endpoint Period

- Total: 2517
- Based on signs & symptoms: 1113 & 1061
- Based on knowledge of PA pressures: 1404

- Treatment
- Control

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

Heart failure hospitalization rates are most effectively reduced by a management strategy based on PA pressures alone without reliance upon Clinical Changes.

Data analysis from the CHAMPION clinical trial to determine if therapeutic changes of diuretics based on PA pressure in the absence of clinical signs has an impact on HF hospitalization rates.

In CHAMPION all interventions for patients in the PA pressure managed group were characterized prospectively by investigators as triggered primarily by clinical findings OR by changes in PA pressure.

Supports the strategy of early intervention prior to clinical signs to avert decompensation and heart failure readmissions.

Goldberg et al. HRS 2015
CHAMPION Clinical Trial: By Targeting Pressure Ranges and Titrating Medications, Overall PA Pressures Can Be Reduced

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

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.

## CHAMPION Clinical Trial: The Number Needed to Treat (NNT) to Prevent One HF-related Hospitalization is Lower vs. Other Therapies

<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>
Economic Analysis shows that PA pressure Monitoring is Cost Effective

Cost reduction is attributable to:

- Reduction in hospitalization
- Reduction in mortality
- Improvement in quality of life

$30,167 ICER
BELOW THE US ACCEPTED ICER THRESHOLD OF $50,000 PER QALY
Well under the World Health Organization threshold of approximately $160,000 for the US

1. Adamson et al HRS 2015
2. Weinstein MC Med Care 2008
3. Neumann et al NEJM 2014
Summary: CHAMPION Clinical Trial

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

Summary: Managing Pressures to Maintain Health and Manage Acute Events

Enables proactive and personalized HF management 1-3

May be used in risk stratification, but not actionable 4-7

Unreliable, late, and indirect markers 8,9


9. Anker SD, et al. AHA 2010
CASE STUDIES FROM THE
CHAMPION CLINICAL TRIAL
Pulmonary Artery Pressure Database

Trend Data

Discrete data

<table>
<thead>
<tr>
<th>Reading</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic:</td>
<td>24</td>
</tr>
<tr>
<td>Mean:</td>
<td>19</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 nitrate

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 12-013

<table>
<thead>
<tr>
<th>75-year-old female</th>
<th>ICM EF 30-35%</th>
<th>CM Implant 8/29/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDICAL HISTORY</td>
<td>BASELINE HF MEDICATIONS</td>
<td>HEMODYNAMICS AT IMPLANT</td>
</tr>
<tr>
<td>▪ Hypertension</td>
<td>Lisinopril 5 mg QD</td>
<td>PA 34/10 (20)</td>
</tr>
<tr>
<td>▪ Valvular Heart Disease</td>
<td>Carvedilol 12.5 mg BID</td>
<td>PCWP 10</td>
</tr>
<tr>
<td>▪ Moderate MR, Mild TR, Mild AR</td>
<td>Furosemide 40 mg QD</td>
<td>CO 3.5</td>
</tr>
<tr>
<td>▪ Atrial Fibrillation</td>
<td>Digoxin 0.125mg QD</td>
<td></td>
</tr>
<tr>
<td>▪ Diabetes</td>
<td></td>
<td>BASELINE VITALS</td>
</tr>
<tr>
<td>▪ Chronic Renal Insufficiency</td>
<td></td>
<td>BP 144/69</td>
</tr>
<tr>
<td>▪ Iron Deficiency Anemia</td>
<td></td>
<td>HR 64</td>
</tr>
<tr>
<td>▪ Sick Sinus Syndrome</td>
<td></td>
<td>Weight 130 lbs.</td>
</tr>
<tr>
<td>▪ s/p pacemaker</td>
<td></td>
<td>BMI 23.8</td>
</tr>
<tr>
<td>▪ Pulmonary Hypertension</td>
<td></td>
<td>BASELINE LABS</td>
</tr>
<tr>
<td>▪ Echo 9/2007 RSVP 50-60 mmHg</td>
<td></td>
<td>SCr 1.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>GFR 47</td>
</tr>
</tbody>
</table>
Titration and Switching Loop Diuretic and Addition of Thiazide Diuretic
### Case Study – Subject 13-011

<table>
<thead>
<tr>
<th>86-year-old male</th>
<th>ICM EF 30%</th>
<th>CM Implant 8/11/2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDICAL HISTORY</td>
<td>BASELINE HF MEDICATIONS</td>
<td>HEMODYNAMICS AT IMPLANT</td>
</tr>
<tr>
<td>▪ Coronary artery disease</td>
<td>ACE intolerance secondary to renal dysfunction</td>
<td>PA 34/10(23)</td>
</tr>
<tr>
<td>▪ s/p CRT</td>
<td>Carvedilol 3.125 mg BID</td>
<td>PCWP 16</td>
</tr>
<tr>
<td>▪ s/p ICD</td>
<td>Isosorbide 30 mg BID</td>
<td>CO 3.3</td>
</tr>
<tr>
<td>▪ Conduction Disease</td>
<td>Amiodarone 200 mg QD</td>
<td>PVR 2.12</td>
</tr>
<tr>
<td>▪ Left BBB, SSS, VT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Myocardial Infarction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Mitral and tricuspid regurgitation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Hypertension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Pulmonary hypertension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ COPD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Diabetes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Hyperlipidemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Hypothyroidism</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Chronic renal insufficiency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Peripheral artery disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Abdominal aortic aneurysm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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

- Extra dose of Torsemide

- Stop Torsemide 20 mg QD
- Start Torsemide 20 mg QD

- Start Torsemide 25 mg BID
- Stop Furosemide
- Start Furosemide 40 mg BID

BP 120/70 HR 64 WGT 135lbs.
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 nitrate

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 06-010

<table>
<thead>
<tr>
<th>69-year-old male</th>
<th>ICM EF 35%</th>
<th>CM Implant 1/11/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MEDICAL HISTORY</strong></td>
<td><strong>BASELINE HF MEDICATIONS</strong></td>
<td><strong>HEMODYNAMICS AT IMPLANT</strong></td>
</tr>
<tr>
<td>▪ Coronary artery disease</td>
<td>▪ Lisinopril 20 mg QD</td>
<td>▪ PA 40/25(29)</td>
</tr>
<tr>
<td>▪ s/p ICD</td>
<td>▪ Carvedilol 6.25 mg BID</td>
<td>▪ PCWP 17</td>
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<tr>
<td>▪ Mitral valve disease</td>
<td>▪ Furosemide 40 mg QD</td>
<td>▪ CO 4.0</td>
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<tr>
<td>▪ Ventricular fibrillation</td>
<td>▪ Amiodarone 200 mg QD</td>
<td><strong>BASELINE VITALS</strong></td>
</tr>
<tr>
<td>▪ CABGx2</td>
<td></td>
<td>▪ BP 124/88</td>
</tr>
<tr>
<td>▪ Arterial stent of the kidney</td>
<td></td>
<td>▪ HR 72</td>
</tr>
<tr>
<td>▪ Mitral valve repair</td>
<td></td>
<td>▪ Weight 180 lbs.</td>
</tr>
<tr>
<td>▪ Thyroid disease</td>
<td></td>
<td>▪ BMI 26.6</td>
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<tr>
<td>▪ Gout</td>
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<td><strong>BASELINE LABS</strong></td>
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<tr>
<td>▪ Acute renal failure</td>
<td></td>
<td>▪ SCr 1.3</td>
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<tr>
<td>▪ Chronic anemia</td>
<td></td>
<td>▪ GFR 58</td>
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<tr>
<td>▪ AAA repair</td>
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Initiation of Long-acting Nitrates