Pressure Monitoring in Heart Failure

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disclosure

• I have nothing to disclose.
Heart Failure

- Prevalent disease: 2.2%, approximately 5.1 million patients in the US)
- High morbidity and mortality rates
- High economic and psychological burden
Prevalence of heart failure in Korea

- Data from the National Sample Cohort (NSC)
- The prevalence of HF in Korea increased approximately two times (from 0.75% in 2002 to 1.53% in 2013)

![Graph showing prevalence of heart failure over years]

*Fig. 1. Prevalence of heart failure according to sex in 2002-2013.*

Korean Circ J 2016;46(5):658-664
Mortality Trend of HF

- Population-based cohort study using the resources of the Rochester Epidemiology Project conducted in Olmsted County, Minnesota. Patients were 4537 Olmsted County residents.

| Table 3. Mortality Estimates After Onset of Heart Failure Among Men and Women Aged 75 Years* |
|----------------------|----------------------|----------------------|----------------------|----------------------|
| 30 Day               |                      |                      |                      |                      |
| Men                  | 9 (7-10)             | 7 (6-9)              | 7 (6-9)              | 6 (5-7)              |
| Women                | 4 (3-5)              | 4 (3-5)              | 4 (3-5)              | 4 (3-4)              |
| 1 Year               |                      |                      |                      |                      |
| Men                  | 30 (27-33)           | 26 (23-29)           | 25 (22-28)           | 21 (18-24)           |
| Women                | 20 (18-22)           | 19 (17-21)           | 20 (17-22)           | 17 (14-19)           |
| 5 Year               |                      |                      |                      |                      |
| Men                  | 65 (61-69)           | 59 (55-63)           | 58 (53-62)           | 50 (45-54)           |
| Women                | 51 (47-55)           | 50 (46-54)           | 52 (47-56)           | 46 (42-51)           |

Abbreviation: CI, confidence interval.
*The mean age of the cohort was 75 years.
Acute decompensated HF results in more than 1 million hospital admissions per year in the United States.

Rehospitalization for heart failure occurs at a rate close to 50% over 6 months.
14,374 patients who were hospitalized for HF for the first time during January 1, 2000, to December 31, 2004.

HF diagnosis: ICD-9 code

<table>
<thead>
<tr>
<th>Adjustment</th>
<th>2 Hospitalizations*</th>
<th>3 Hospitalizations*</th>
<th>4 Hospitalizations*</th>
<th>&gt; 5 Hospitalizations*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HR 95% CI</td>
<td>HR 95% CI</td>
<td>HR 95% CI</td>
<td>HR 95% CI</td>
</tr>
<tr>
<td>Unadjusted</td>
<td>1.32 (1.25-1.41)</td>
<td>1.51 (1.37-1.67)</td>
<td>1.92 (1.65-2.24)</td>
<td>2.25 (1.87-2.71)</td>
</tr>
<tr>
<td>Age and sex adjusted</td>
<td>1.31 (1.23-1.39)</td>
<td>1.51 (1.37-1.67)</td>
<td>1.93 (1.66-2.24)</td>
<td>2.25 (1.87-2.71)</td>
</tr>
<tr>
<td>Fully adjusted†</td>
<td>1.22 (1.14-1.30)</td>
<td>1.33 (1.20-1.47)</td>
<td>1.64 (1.40-1.91)</td>
<td>1.84 (1.53-2.23)</td>
</tr>
</tbody>
</table>

HR, Hazard ratio.
*Hazard of deaths compared with the risk after 1 hospitalization.
†Model included age; sex; and history of atrial fibrillation, ventricular arrhythmia/cardiac arrest, chronic kidney diseases, dialysis, diabetes, cancer, chronic pulmonary diseases, rheumatoid arthritis, MI, cerebrovascular attack, hypertension, ischemic heart diseases, and dementia.

Am Heart J 2007;154:260-6
Worsening of Heart Failure: increase the risk of death

- PARADIGM-HF

Hospitalization for worsening HF (HR, 6.1; 95% CI, 5.4–6.8)

Figure 1. Mortality (%) after a first event or in patients with no event. CV indicates cardiovascular.

Circulation. 2016;133:2254-2262
Conventional Therapy:
: to prevent heart failure hospitalization

Table 2. Clinical End Points, According to Treatment Group. *

<table>
<thead>
<tr>
<th>End Point</th>
<th>Telemonitoring (N = 826)</th>
<th>Usual Care (N = 827)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary end point: death or readmission no. (%)</td>
<td>432 (52.3)</td>
<td>426 (51.5)</td>
<td>0.75</td>
</tr>
<tr>
<td>Secondary end points</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death — no. (%)</td>
<td>92 (11.1)</td>
<td>94 (11.4)</td>
<td>0.88</td>
</tr>
<tr>
<td>Readmission — no. (%)</td>
<td>407 (49.3)</td>
<td>392 (47.4)</td>
<td>0.45</td>
</tr>
<tr>
<td>Readmission for heart failure — no. (%)</td>
<td>227 (27.5)</td>
<td>223 (27.0)</td>
<td>0.81</td>
</tr>
<tr>
<td>No. of days in hospital</td>
<td>7.2±14.6</td>
<td>7.0±14.9</td>
<td>0.27</td>
</tr>
<tr>
<td>No. of readmissions — no. (%)</td>
<td></td>
<td></td>
<td>0.20</td>
</tr>
</tbody>
</table>

* Plus–minus values are means ±SD.

Telemonitoring in patients with heart failure.

Circulation, 2008;118:1433-1441
Transition From Chronic Compensated to Acute Decompensated Heart Failure

ePAD in patients with no event

Circulation, 2008;118:1433-1441
Transition From Chronic Compensated to Acute Decompensated Heart Failure

Panel A

Panel B

Panel C

Circulation, 2008;118:1433-1441
Pathophysiology of Congestion and Decompensation

PROACTIVE AND ACTIONABLE
Real-time monitoring of PAP with the CardioMEMS HF™ system provides a direct and early indicator of worsening heart failure.⁷

REACTIVE AND INEXACT
Traditional physiologic markers, such as patient weight, symptoms, and blood pressure, occur late in the decompensation process and leave little time to react before hospitalization.⁷

-30  -20  -10  0
Time Preceding Hospitalization (Days)

HEMODYNAMICALLY STABLE  PRESYMPTOMATIC CONGESTION  DECOMPENSATION

Filling Pressure Increase
Intrathoracic Impedance Changes
Autonomic Adaptation

Weight Change
Symptoms
Hospitalization
COMPASS-HF Study

- Prospective, multicenter, randomized, single-blind, parallel-controlled trial of 274 New York Heart Association functional class III or IV HF patients
- Chronicle (Medtronic Inc., Minneapolis, Minnesota) (n = 134) or control (n = 140) group.
- Complication-free rate of 91.5%

Figure 4 Kaplan-Meier Curves of Survival Free From an HF-Related Hospitalization

Figure 3 Distribution of All Heart Failure–Related Events

Event rates were compared with a negative binomial regression model.
COMPASS-HF Study

- Prospective, multicenter, randomized, single-blind, parallel-controlled trial of 274 NYHA class III or IV HF patients
- Chronicle (Medtronic Inc., Minneapolis, Minnesota) (n = 134) or control (n = 140) group.
- Complication-free rate of 91.5%

Failed to get FDA approval
The CardioMEMS HF system

- FDA approved (May 2014)
- As an approach to reducing HFH in patients with chronic HF, NYHA functional class III

(A) CardioMEMS sensor or transmitter.
(B) Transcatheter is implanted into a distal branch of the descending pulmonary artery.
(C) Patient is instructed to take daily pressure readings from home using the home electronics.
(D) Information transmitted from the monitoring system to the database is immediately available to the investigators for review.

Lancet 2011; 377: 658–66
(E) Transmitted information consists of pressure trend information and individual pulmonary artery pressure waveforms

Lancet 2011; 377: 658–66
• Patients with minimal HF congestive symptoms and minimal evidence of poor perfusion had hemodynamic monitoring pressure target values of:
  • Pulmonary artery systolic pressure 15-35 mm Hg.
  • Pulmonary artery diastolic pressure 8-20 mm Hg.
  • Pulmonary artery mean pressure 10-25 mm Hg
PAP-guided Treatment

Managing Trends of Ambulatory Pulmonary Artery (PA) Pressures

**Low PA pressures (Hypo-volemic)**
Trending below normal

- Lower or discontinue diuretic:
  - If on thiazide and loop diuretic, lower or discontinue thiazide diuretic
  - If only on loop diuretic, lower doses or hold doses
  - If not on diuretics, consider liberalization of oral fluid and
- Re-evaluate PA pressure trends in response to diuretic change for 1-2 days
- If on vasodilators, lower dose or discontinue if postural hypotension present
- Re-evaluate PA pressure trends 2-3 days per week

**Normal PA pressures (Opti-volemic)**
Trending within normal

- No medication changes required based on normal PA pressures:
  - Continue current diuretic and/or vasodilator treatment regimen
  - Consider up titration of current ACC/AHA guideline-directed medical therapies under
- Evaluate PA pressure trends weekly to maintain stabilization
- If suspicion of poor perfusion, consider other interventions:
  - Admission for monitoring and adjustment of medical management
  - IV therapeutic agents or IV fluid repletion
  - Invasive hemodynamic monitoring to

**Elevated PA pressures (Hyper-volemic)**
Trending above normal

- Increase or add diuretic:
  - Add loop diuretic or increase loop diuretic dose
  - Add thiazide diuretic or increase thiazide diuretic dose
  - Consider short course of IV loop
- Re-evaluate PA pressure trends in response to diuretic change for 1-2 days
- If no PA pressure response or continued trend elevations observed, consider vasodilator change:
  - Add nitrates or increase dose
- Re-evaluate PA pressure trends 2-3 days per week until stabilization achieved

FIGURE 1 Pulmonary Artery Pressure Treatment Guidelines
CHAMPION Trial

- CHAMPION was a prospective, multicentre (n=64), single-blind, clinical trial undertaken in the USA.
- NYHA functional class III heart failure for at least 3 months, irrespective of left ventricular ejection fraction or cause, and a hospitalisation for heart failure within the past 12 months.
- Primary endpoint: heart failure-related hospitalisations during the 6 months.

Lancet 2011; 377: 658–66
# CHAMPION Trial

<table>
<thead>
<tr>
<th>Treatment group (n=270)</th>
<th>Controlled group (n=280)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td>51 (13)</td>
</tr>
<tr>
<td><strong>Male sex</strong></td>
<td>194 (72%)</td>
</tr>
<tr>
<td><strong>White</strong></td>
<td>196 (73%)</td>
</tr>
<tr>
<td><strong>Body mass index (kg/m²)</strong></td>
<td>31 (7)</td>
</tr>
<tr>
<td><strong>Left ventricular ejection fraction (≥40%)</strong></td>
<td>62 (23%)</td>
</tr>
<tr>
<td><strong>Ischaemic cardiomyopathy</strong></td>
<td>158 (56%)</td>
</tr>
<tr>
<td><strong>CRT or CRT-D device</strong></td>
<td>91 (34%)</td>
</tr>
<tr>
<td><strong>ICD device</strong></td>
<td>88 (33%)</td>
</tr>
<tr>
<td><strong>Time from CRT, CRT-D, or ICD to CM implant (days)</strong></td>
<td>868 (33)</td>
</tr>
</tbody>
</table>

**Comorbidities**

- **Hypertension**: 207 (78%) vs. 220 (76%)
- **Coronary artery disease**: 182 (67%) vs. 202 (72%)
- **Diabetes mellitus**: 120 (43%) vs. 139 (50%)
- **Atrial fibrillation/flutter or tachycardia**: 120 (44%) vs. 136 (48%)
- **Chronic obstructive pulmonary disease**: 76 (28%) vs. 83 (30%)
- **Chronic kidney disease**: 54 (20%) vs. 54 (19%)

**Laboratory and haemodynamic analyses**

- **Creatinine (μmol/L)**: 122 (44.2) vs. 122 (44.2)
- **GFR (ml/min per 1.73m²)**: 60 (22) vs. 62 (23)
- **Systolic blood pressure (mm Hg)**: 121 (23) vs. 123 (23)
- **Diastolic blood pressure (mm Hg)**: 72 (13) vs. 72 (13)
- **Heart rate (beats per min)**: 72 (13) vs. 73 (12)
- **Pulmonary artery mean pressure (mm Hg)**: 29 (10) vs. 30 (10)

**Drugs**

- Angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers: 205 (76%) vs. 222 (79%)
- β blocker: 243 (90%) vs. 256 (91%)
- Aldosterone antagonist: 117 (43%) vs. 114 (41%)
- Loop diuretic: 248 (92%) vs. 258 (92%)
- Hydrochlorothiazide: 36 (13%) vs. 33 (13%)
- Nifedipine: 64 (24%) vs. 56 (20%)

Data are number (%) or mean (SD). Percentages are based on the number of patients who were randomly assigned. CRT= cardiac resynchronisation therapy. CRT-D = cardiac resynchronisation therapy with defibrillator. ICD= implantable cardioverter defibrillator. CM=CMRS =Medtronic sensor.

## Table 1: Baseline demographic characteristics of patients

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Treatment group (n=270)</th>
<th>Controlled group (n=280)</th>
<th>All patients (n=550)</th>
<th>Risk (95% CI)</th>
<th>p value (vs. control)</th>
<th>NNT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary efficacy endpoints</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart failure-related hospitalisations up to 6 months (number; events per patient per 6 months)</td>
<td>NA</td>
<td>84 (0.32)</td>
<td>120 (0.44)</td>
<td>NA</td>
<td>0.77 (0.60-0.95)</td>
<td>8.00</td>
</tr>
<tr>
<td><strong>Primary safety endpoints</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device-related or system-related complications</td>
<td>2 (8%)</td>
<td>3 (1%)</td>
<td>3 (1%)</td>
<td>8 (1%)</td>
<td>5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pressure sensor failures</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Prespecified supplementary efficacy endpoints</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart failure-related hospitalisations during entire randomised follow-up</td>
<td>NA</td>
<td>158</td>
<td>254</td>
<td>NA</td>
<td>0.63 (0.52-0.77)</td>
<td>4</td>
</tr>
</tbody>
</table>

## Table 2: Effect of wireless implantable haemodynamic monitoring on safety and efficacy endpoints

**Figure 3: Cumulative heart failure-related hospitalisations during entire period of randomised single-blind follow-up (A), and freedom from first heart failure-related hospitalisation or mortality during the entire period of randomised follow-up (B)**

Lancet 2011; 377: 658–66
Sustained efficacy of haemodynamic-guided management of heart failure to reduce admissions to hospital, both during a randomised clinical trial setting, as well as in a follow-up setting.

Reduction of hospitalization by 48% after use hemodynamic guided management in control group.

Lancet, 2016;387:453-461
CHAMPION Trial

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J Am Coll Cardiol HF 2016;4:333–44
CHAMPION Trial

**Table 4: Renal Function**

<table>
<thead>
<tr>
<th></th>
<th>All Patients</th>
<th>Blind Therapy Group</th>
<th>p Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Active Monitoring Group</strong> (N = 270)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline creatinine</td>
<td>1.40 ± 0.47 (270)</td>
<td>1.35 ± 0.42 (280)</td>
<td>0.56</td>
</tr>
<tr>
<td>Creatinine change from baseline to 6 months</td>
<td>0.10 ± 0.45 (230)</td>
<td>0.07 ± 0.38 (235)</td>
<td>0.28</td>
</tr>
<tr>
<td>Baseline GFR</td>
<td>60.4 ± 22.5 (270)</td>
<td>61.8 ± 23.2 (280)</td>
<td>0.56</td>
</tr>
<tr>
<td>GFR change from baseline to 6 months</td>
<td>-3.1 ± 17.0 (230)</td>
<td>-1.0 ± 16.4 (235)</td>
<td>0.20</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Patients With Chronic Kidney Disease at Baseline (eGFR &lt; 60)</strong></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Active Monitoring Group</strong> (N = 150)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline creatinine</td>
<td>1.7 ± 0.41 (150)</td>
<td>1.6 ± 0.34 (147)</td>
<td>0.40</td>
</tr>
<tr>
<td>Creatinine change from baseline to 6 months</td>
<td>0.1 ± 0.54 (128)</td>
<td>0.1 ± 0.44 (123)</td>
<td>0.99</td>
</tr>
<tr>
<td>Baseline GFR</td>
<td>43.5 ± 9.09 (150)</td>
<td>44.4 ± 9.12 (147)</td>
<td>0.46</td>
</tr>
<tr>
<td>GFR change from baseline to 6 months</td>
<td>1.0 ± 14.48 (128)</td>
<td>0.6 ± 12.60 (123)</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Values are mean ± SD (n). *p value testing treatment versus control obtained from exact Wilcoxon rank sum test. Abbreviation as in Table 1.
Intracardiac Pressures: Relationship to Mortality

- Chronicle Phase II, COMPASS-HF, REDUCE-HF

Circ Heart Fail. 2017;10:e003594.
Hemodynamic-guided Heart Failure Care: Greater Reduction In PA Pressure

### Table. Baseline Characteristics of the Generalized Patient Population Compared With the CHAMPION Cohort

<table>
<thead>
<tr>
<th></th>
<th>CHAMPION Clinical Trial Cohort (n=550)</th>
<th>General-Use Cohort (n=2000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>61.59±12.83</td>
<td>69.67±12.26</td>
</tr>
<tr>
<td>Male sex, n (%)</td>
<td>399 (72.55)</td>
<td>1169 (59.80)</td>
</tr>
<tr>
<td>Ejection fraction ≥40%, %</td>
<td>21.72*</td>
<td>33.79*</td>
</tr>
<tr>
<td>Baseline PA pressure, mm Hg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic PA pressure</td>
<td>46.4±14.5</td>
<td>49.7±14.1</td>
</tr>
<tr>
<td>Diastolic PA pressure</td>
<td>24.5±9.1</td>
<td>25.4±8.3</td>
</tr>
<tr>
<td>Mean PA pressure</td>
<td>31.6±10.7</td>
<td>34.9±10.2</td>
</tr>
</tbody>
</table>

# Pulmonary Artery Pressure-Guided Management of Patients With HFrEF

| TABLE 4 Unadjusted Mortality and Mortality Adjusted for Absolute Changes in HF Medication Dose Over 6 Months |
|---------------------------------|---------------------------------|
| Group 1 EF ≤40% and at Least 1 ACEI/ARB or BB (n = 445) | Group 2 EF ≤40% and Both ACEI/ARB and BB (n = 337) |
| Unadjusted mortality              | 0.63 (0.41-0.96)               | 0.43 (0.24-0.76)               |
| Mortality adjusted for changes in neurohormonal antagonist doses* | 0.65 (0.43-0.99)               | 0.45 (0.25-0.80)               |
| Mortality adjusted for changes in vasodilator agent doses† | 0.64 (0.42-0.98)               | 0.44 (0.25-0.78)               |

Values are hazard ratio (95% confidence interval) from Cox proportional hazards model for mortality. *Model includes covariates for 6-month changes in daily dosages (mg) of ACEI/ARB and beta-blockers. †Model includes covariates for 6-month changes in daily dosages (mg) of nitrates and hydralazine.

EF = ejection fraction; other abbreviations as in Tables 1 and 3.
“Real-World” Data: HFrEF

A

B

HR 0.55, 95% CI (0.49-0.61)
p<0.001

HR 0.66, 95% CI (0.57-0.76)
p<0.001

Pre-implant: 0 -1mo 2mo 3mo 4mo 5mo 6mo
Post-implant: 1114 1114 1114 1114 1114 1114 1114

Number at risk

Pre-implant: 480 480 480 480 480 480 480
Post-implant: 480 450 435 409 394 373 357

## Recommendations for exercise, multidisciplinary management and monitoring of patients with heart failure

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
<th>Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>It is recommended that regular aerobic exercise is encouraged in patients with HF to improve functional capacity and symptoms.</td>
<td>I</td>
<td>A</td>
<td>321, 618–621</td>
</tr>
<tr>
<td>It is recommended that regular aerobic exercise is encouraged in stable patients with HFrEF to reduce the risk of HF hospitalization.</td>
<td>I</td>
<td>A</td>
<td>618, 619</td>
</tr>
<tr>
<td>It is recommended that patients with HF are enrolled in a multidisciplinary care management programme to reduce the risk of HF hospitalization and mortality.</td>
<td>I</td>
<td>A</td>
<td>622–625</td>
</tr>
<tr>
<td>Referral to primary care for long-term follow-up may be considered for stable HF patients who are on optimal therapy to monitor for effectiveness of treatment, disease progression and patient adherence.</td>
<td>IIb</td>
<td>B</td>
<td>626, 627</td>
</tr>
<tr>
<td>Monitoring of pulmonary artery pressures using a wireless implantable haemodynamic monitoring system (CardioMEMS) may be considered in symptomatic patients with HF with previous HF hospitalization in order to reduce the risk of recurrent HF hospitalization.</td>
<td>IIb</td>
<td>B</td>
<td>628, 629</td>
</tr>
<tr>
<td>Multiparameter monitoring based on ICD (IN-TIME approach) may be considered in symptomatic patients with HFrEF (LVEF ≤35%) in order to improve clinical outcomes.</td>
<td>IIb</td>
<td>B</td>
<td>630</td>
</tr>
</tbody>
</table>

European Heart Journal (2016) 37, 2129–2200
The CardioMEMS HF system

• Ongoing RCT
• Hemodynamic-GUIDEd management of heart failure (GUIDE-HF),
Conclusions

• Self-management by patients had largely been unsuccessful because of the advanced age of HF patients and the complexity of treatment.

• Ambulatory monitoring of intracardiac pressures was clinically useful when translated into systematic pharmacological interventions.

• Future study will confirm efficacy of pressure monitoring device, such as mortality.
Thank you for your attention.
CHAMPION Trial Rationale and Design

Table 1. Inclusion Criteria
- Written informed consent and authorization to use and disclose health information.
- 18 years of age or older.
- Diagnosis of HF for \( \geq \) 3 months, with preserved or reduced LVEF.
- Diagnosis of NYHA functional class III HF at screening visit.
- If subject has a reduced LVEF, they must be receiving a beta-blocker for 3 months and an ACE-I or ARB for 1 month unless, in the investigator’s opinion, the subject is intolerant to beta-blockers, ACE-I, or ARB. Beta-blocker and ACE-I (or ARB) doses should be stable for 1 month before study entry.
- At least 1 HF-related hospitalization within 12 months of screening visit.
- BMI \( \leq \) 35 kg/m\(^2\). **Subjects with BMI > 35 kg/m\(^2\) require** additional screening. If the BMI is > 35 kg/m\(^2\) and the chest circumference is \( >52 \) in and \( <65 \) in, the distance from the skin on the subject’s back to the pulmonary artery must be \( <10 \) cm and confirmed by angiogram of the lateral view during the catheterization before placement of the pressure sensor. If the distance is \( >10 \) cm, the subject will not receive a sensor and will not be eligible for the study.
- Pulmonary artery branch diameter between 7 and 15 mm.
- Female subjects of childbearing age with a negative urine or serum pregnancy test at the screening visit and agreeing to use a reliable mechanical or hormonal form of contraception during the study.
Exclusion Criteria

- Active infection.
- History of recurrent (>1) pulmonary embolism or deep vein thrombosis.
- Unable to tolerate an RHC, in the investigator’s opinion.
- Implantation of CRT<3 months before enrollment.
- Experienced a major cardiac event (eg, myocardial infarction, stroke) within 2 months of screening visit.
- **GFR<25 mL/min or chronic renal dialysis.**
- Likely to undergo heart transplantation within 6 months of screening visit.
- Congenital heart disease or mechanical right heart valve(s).
- Diagnosed coagulation disorders.
- Hypersensitivity or allergy to aspirin and/or clopidogrel.
- Enrolled in concurrent studies that may confound the results of this study.
- Clinical condition that would not allow them to complete the study, in the investigator’s opinion.