Ambulatory Monitoring of Pulmonary Artery Pressure: Why and How

18th Annual San Diego Heart Failure Symposium
Primary Care and Internal Medicine Physicians
January 19-20, 2018

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Presenter Disclosure Information

I will discuss off-label use of medications and/or devices during this discussion.

I do not have financial relationships with industry related to this presentation.
Overview of the Talk

- Discussion of the Burden of Heart Failure and Readmissions
- Prior Attempts of Remote Monitoring
- Ambulatory Pulmonary Artery Pressure Monitoring (CardioMEMS™): Champion Trial
- The application of CardioMEMS™ in practice
- The future of remote HF monitoring
Heart Failure prevalence in the US is projected to increase 46% by 2030. Patients with HF will rise to 8M in 2030, one in every 33 people.

Circ Heart Fail. 2013;6:606-619

Heidenreich et al
Forecasting the Impact of Heart Failure
Economic Burden of Heart Failure 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

80% of costs related to hospitalization

*Circ Heart Fail. 2013;6:606-619* | Heidenreich et al
Forecasting the Impact of Heart Failure
HF-related Hospitalizations are strong Predictors of Mortality

Each admission decreases a patient’s chance of survival
Current HF Management
How well do current tools keep patients stable and out of the hospital?

90%
of HF hospitalizations due to symptoms of pulmonary congestion\(^1,2\)

\[\text{AT DISCHARGE}\]

Post-hoc analysis of 463 acute decompensated HF patients from DOSE-HF and CARRESS-HF

40%
moderate to severe congestion\(^3\)

60%
absent or mild congestion\(^3\)

\[\text{AT 60-DAY FOLLOW-UP}\]

41%
of previously decongested patients had severe or partial re-congestion\(^3\)

TODAY’S TOOLS ARE INADEQUATE
at relieving congestion (inpatient) and preventing re-congestion and readmission (outpatient) – even at well-established HF management programs and with the best HF-trained specialists.

How problematic are readmissions?
Vicious Cycle of Congestion in HF

Desai et al. Am J Cardiol 2015; vol. 116 open-access Web publication
The Iceberg Analogy

Photo by National Geographic
## Current HF Management

How do current parameters impact HF hospitalization?

<table>
<thead>
<tr>
<th>Trial</th>
<th>N</th>
<th>Parameter Monitored/ Clinician Interaction</th>
<th>Impact on HF Hospitalization</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEN-HMS</td>
<td>426</td>
<td>Signs/symptoms, daily weights, BP, nurse telephone support</td>
<td>None</td>
<td>Cleland JG et al. JACC, 2005</td>
</tr>
<tr>
<td>BEAT-HF</td>
<td>1,437</td>
<td>Signs/symptoms, daily weights, nurse communications</td>
<td>None</td>
<td>Ong MK et al. AHA 2015 LBCT</td>
</tr>
<tr>
<td>INH</td>
<td>715</td>
<td>Signs/symptoms, telemonitoring, nurse coordinated DM</td>
<td>None</td>
<td>Angermann DE et al. Circ Heart Fail, 2012</td>
</tr>
</tbody>
</table>

Multiple trials studying >8500 patients have demonstrated that current markers have NO IMPROVEMENT ON HF HOSPITALIZATION.
Current HF Management:
Why aren’t current parameters working?

Current HF Management:
How can we get ahead of symptoms associated with acute decompensation?

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.

Intracardiac Pressures:
CardioMEMSTM: PA Sensor Technology

**Sensor** = hermetically sealed capsule containing a **inductor coil** and **pressure-sensitive capacitor**

**Anchor** = Nitinol wire loops extend to stabilize the sensor in the implant location

Change in blood pressure affects resonant frequency

Tracked by external measurement system → pulmonary artery pressure
Comparison of a Radiofrequency-Based Wireless Pressure Sensor to Swan-Ganz Catheter and Echocardiography for Ambulatory Assessment of Pulmonary Artery Pressure in Heart Failure

Hugo E. Verdejo, MD,* Pablo F. Castro, MD,* Roberto Concepción, MD,† Marcela A. Ferrada, RN,* Mario A. Alfaro, MD,† Milton E. Alcaino, MD,† Carlos C. Deck, MD, FASCI,† Robert C. Bourge, MD‡

Santiago, Chile; and Birmingham, Alabama

12 HF patients NYHA III/IV
Wireless PAP measurements

Oral warfarin continued throughout study

Echocardiographic evaluation of TR flow velocity (VTR) to obtain the systolic pulmonary artery pressure

Swan Gantz (SG) catheter measurements used as reference for calibration

Echo-Doppler PAP measurements at 2, 14, 30, 60, and 90 days
SG measurements were repeated at day 60
Correlation was observed for the $P_a_{sys}$ measurement between HFS and SG ($r^2 = 0.90$ at the initial implant and $r^2 = 0.94$ at follow up, $p < 0.01$)
Prospective, multicenter
Randomized single-blinded trial

550 patients
64 sites in the US

October 2009 until March 2010

NYHA functional Class
III HF
(h/o HF ≥ 3 mos)

Standard-of-care HF management
CardioMEMs

Follow up: month 1, 3, 6, then every 6 months thereafter, up to 36 months
Transmitted information

Pressure trend information

Target hemodynamic monitoring pressure values

$P_{A_{sys}}$ pressure 15-35 mmHg
$P_{A_{dia}}$ pressure 8-20 mmHg
$P_{A_{mean}}$ pressure 10-25 mmHg
Cumulative Heart Failure-related Hospitalization

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

Lancet 2011; 377: 658-66
Freedom from first Heart Failure-related hospitalization or mortality

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

Lancet 2011; 377: 658–66
Vol 377  February 19, 2011  William T Abraham
St. Jude Medical, Inc. Merlin.net™ Patient Care Network
PA Sensor Patients of Interest Report for San Diego VA Medical Center (weekly values based on data collected as of January 17, 2016, 11:59:59 PM)

Weekly Average PA Diastolic (Weekly PAD) Pressure outside threshold range
None

Weekly change ≥ 5 mmHg with Weekly PAD within threshold range
None

Non-Compliant: No readings in last 5 days
None

Log into Merlin.net for more information.

* PA Sensor Patients of Interest Report subscription preferences can be changed in the user profile.
* This email address is NOT monitored. Please do not reply.
Interventions Linked to Decreased Heart Failure Hospitalizations During Ambulatory Pulmonary Artery Pressure Monitoring

**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

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

  - Evaluate PA pressure trends weekly to maintain stabilization

**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

  - 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

  - Re-evaluate PA pressure trends in response to diuretic change for 1-2 days
Interventions Linked to Decreased Heart Failure Hospitalizations During Ambulatory Pulmonary Artery Pressure Monitoring
Interventions Linked to Decreased Heart Failure Hospitalizations During Ambulatory Pulmonary Artery Pressure Monitoring

### All Patients

<table>
<thead>
<tr>
<th></th>
<th>Active Monitoring Group (N = 270)</th>
<th>Blind Therapy Group (N = 280)</th>
<th>p Value*</th>
</tr>
</thead>
<tbody>
<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>

### Patients With Chronic Kidney Disease at Baseline (eGFR <60)

<table>
<thead>
<tr>
<th></th>
<th>Active Monitoring Group (N = 150)</th>
<th>Blind Therapy Group (N = 147)</th>
<th>p Value*</th>
</tr>
</thead>
<tbody>
<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>
Novel devices

Telemonitoring in chronic heart failure

Ayesha Hasan\(^1\) and Vince Paul\(^2\)

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A. Hasan and V. Paul

Telemonitoring in chronic heart failure
### CHAMPION Trial results:
Number Needed to Treat to Prevent One HF-related hospitalization

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Trial</th>
<th>Mean Duration of Randomized Follow-Up</th>
<th>NNT/Year to Prevent 1 HF Hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beta-blocker(^1)</td>
<td>COPERNICUS</td>
<td>10 months</td>
<td>7</td>
</tr>
<tr>
<td>Aldosterone antagonist(^2)</td>
<td>RALES</td>
<td>24 months</td>
<td>7</td>
</tr>
<tr>
<td>CRT(^3)</td>
<td>CARE-HF</td>
<td>29 months</td>
<td>7</td>
</tr>
<tr>
<td>Beta-blocker(^4)</td>
<td>MERIT-HF</td>
<td>12 months</td>
<td>15</td>
</tr>
<tr>
<td>ACE inhibitor(^5)</td>
<td>SOLVD</td>
<td>41 months</td>
<td>15</td>
</tr>
<tr>
<td>Aldosterone antagonist(^6)</td>
<td>EMPHASIS-HF</td>
<td>21 months</td>
<td>16</td>
</tr>
<tr>
<td>Digoxin(^7)</td>
<td>DIG</td>
<td>37 months</td>
<td>17</td>
</tr>
<tr>
<td>Angiotensin receptor blocker(^8)</td>
<td>Val-HeFT</td>
<td>23 months</td>
<td>18</td>
</tr>
<tr>
<td>Angiotensin receptor blocker(^9)</td>
<td>CHARM</td>
<td>40 months</td>
<td>19</td>
</tr>
<tr>
<td>PA pressure monitoring(^10)</td>
<td>CHAMPION</td>
<td>18 months</td>
<td>&lt; 4</td>
</tr>
</tbody>
</table>


PA PRESSURE MONITORING LED TO LOWER NNT to prevent one HF-related hospitalization vs. other therapies.
Current HFpEF Management

What are the current recommendations?

Table 21. Recommendations for Treatment of HFpEF

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic and diastolic blood pressure should be controlled according to published clinical practice guidelines</td>
<td>I</td>
<td>B^{27,91}</td>
</tr>
<tr>
<td>Diuretics should be used for relief of symptoms due to volume overload.</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>Coronary revascularization for patients with CAD in whom angina or demonstrable myocardial ischemia is present despite GDMT</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>Management of AF according to published clinical practice guidelines for HFpEF to improve symptomatic HF</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>Use of beta-blocking agents, ACE inhibitors, and ARBs for hypertension in HFpEF</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>ARBs might be considered to decrease hospitalizations in HFpEF</td>
<td>IIb</td>
<td>B^{589}</td>
</tr>
<tr>
<td>Nutritional supplementation is not recommended in HFpEF</td>
<td>III: No Benefit</td>
<td>C</td>
</tr>
</tbody>
</table>

Circulation 2013 ACCF/AHA Heart Failure Guideline
October 15, 2013  Yancy et al
Table 5. Heart Failure Hospitalization Rates by Baseline Ejection Fraction Subgroup: 6-Month Primary End Point Period

<table>
<thead>
<tr>
<th>Ejection Fraction</th>
<th>Randomization Group</th>
<th>No. of Heart Failure Hospitalizations</th>
<th>6 mo Rates of Hospitalization for Heart Failure</th>
<th>Incidence Rate Ratio (95% CI; P Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥50%</td>
<td>Treatment group (n=35)</td>
<td>9</td>
<td>0.18</td>
<td>0.50 (0.29–0.86; 0.0129)</td>
</tr>
<tr>
<td></td>
<td>Control group (n=31)</td>
<td>10</td>
<td>0.35</td>
<td></td>
</tr>
<tr>
<td>&lt;40%</td>
<td>Treatment group (n=208)</td>
<td>73</td>
<td>0.36</td>
<td>0.76 (0.61–0.91; 0.0085)</td>
</tr>
<tr>
<td></td>
<td>Control group (n=222)</td>
<td>101</td>
<td>0.47</td>
<td></td>
</tr>
</tbody>
</table>

Cl indicates confidence interval.
IDENTIFYING patients most likely to benefit from CardioMEMS HF System is critical. Some patients are too sick (NYHA IV); some patients are too well (NYHA I-II).

Patient compliance and HF team workflow revision are important to ensure appropriate interpretation and management of individual patients.

Scaling the service requires process and workflow considerations.
Heart Failure treatment is frequently reactive, and many patients are hospitalized because the warning signs are not recognized in time.

Typical tests and in-office questions that providers may ask the patient:

- Listen to the heart for signs of elevated S3 heart sounds
- Listen to the heart for signs of depressed cardiac contractility
- Listen to lung sounds for signs of pulmonary edema
- Measure blood pressure
- Measure if resting heart rate is elevated
- Ask “How many pillows do you sleep on at night?”
- Ask “Are you out of breath? Have difficulty breathing?”
- Ask “Have you been feeling tired?”
- Ask “Have you gained weight?”
Introducing HeartLogic™ Heart Failure Diagnostic

HeartLogic™ shifts heart failure patient management from reactive treatment to proactive care, and was validated in the MultiSENSE Study to have:

- **High sensitivity** of 70% for detecting heart failure events
- **Weeks of advance notice** of a potential heart failure event
- **Low burden** of less than 2 alerts per patient per year

HeartLogic™ incorporates multiple sensors with a single composite alert:

- Heart Sounds: S1 & S3
- Impedance: Thoracic
- Respiration: Rate & Volume
- Activity: Time Spent Active
- Heart Rate: Night

Multiple sensor measurements combined into a single, simple index with alert.

Available on **LATITUDE™ NXT** for patients with **Resonate™** family of ICDs & CRT-Ds.

Boehmer, J et al., JACC-HF, 2017;5(3),2 1 6 – 2 5

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A comprehensive report via LATITUDE NXT details HeartLogic and a diverse set of heart failure sensors.

(a) HeartLogic™ Alert Notification

(b) HeartLogic™ Composite Index

(c) HeartLogic™ Configurable Threshold

(d) HeartLogic™ Contributing Trends

(e) HeartLogic™ Detailed Trend Data
Our Solution

Patient Compliance is the REAL problem to solve

50% Heart failure patients in emergency present with peripheral edema

Peripheral edema 10 to 14 days before emergency hospital admission

50% Heart failure patients readmitted within 6 months

76% of these are avoidable

HeartFelt Technologies
Conclusions:

1. The clinical and economic burden of HF in America continues to be on the rise.
2. The CardioMEMS™ device MAY be a resource to guide therapy (to reduced readmissions for congestion).
3. Patient selection is crucial for remote hemodynamic monitoring.
The Iceberg Analogy

Photo by National Geographic
Just don’t leave your patients hanging

Photo by Carla Lombardo Ehrlich (World Wildlife Foundation)
Any other options?

DOC VADER

ON "READMISSIONS"

ZDoggMD