Heart Failure Management: Integration of Device Sensor Data into Clinical Practice

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Background

- Despite current therapies and disease management approaches, the rate of heart failure hospitalization remains unacceptably high
  - > 1.1 million heart failure hospitalizations annually
  - > 25% readmission rate at 1 month; 50% at 6 months
  - > $18 billion in annual direct costs
- Current methods for monitoring heart failure patients have not adequately addressed this issue
Limitations of Available Monitoring Systems

• Weight and Symptoms – Recent large, landmark clinical studies (Tele-HF, TIM-HF) investigating the effectiveness of telemonitoring demonstrated no benefit in reducing HF hospitalizations

• BNP - PRIMA Study guided identification of patients at risk for HF events, but showed no significant reduction in HF-related admissions

• Device-Based Diagnostics - May be useful for identifying patients that may be at higher risk for a HF hospitalization(PARTNERS-HF Study), but have not yet demonstrated a reduction in HF-related hospitalizations

Tele-HF: Yale Heart Failure Telemonitoring Study; NEJM, 2010
TIM-HF: Telemonitoring Intervention in Heart Failure, Eur J. Heart Failure, 2010
PRIMA: Can Pro-BNP guided heart failure therapy improve morbidity and mortality? J Am Coll Card, 2010
PARTNERS-HF: Combined Heart Failure Device Diagnostics Identify Patients at Higher Risk of Subsequent Heart Failure Hospitalizations. J Am Coll Card, 2010
Background

• Workflow issues add to the burden of follow-up care and impair adequate disease management
• 50% of patients admitted to the hospital have no contact with a physician within 30 days following discharge
• Typical in-office visits are an impractical way to assure prompt and ongoing patient follow-up
• Thus, there is a critical need for enhanced means to monitor patients and to streamline workload
Device-Based Home Monitoring Systems
Implantable CRT and ICD Devices May Offer Unique Means to Monitor Heart Failure Patients

- Objectively track physiological measures of relevance longitudinally over time
- Report values and trends to the clinician remotely via web-based information systems
- Provide thresholds or algorithms for “early warning”
- Evaluate the efficacy of acute and chronic treatments
- Empower clinicians and patients to better manage their heart failure
Atrial Depolarization
Heart rate
AFIB/ATACH
APACE

Ventricular Rate Response
Heart rate
VT/VF
VPACE

Patient Activity
Heart Rate Variability
Impedance (fluid status, respiration)
Physiological Premise of Implantable HF Device Diagnostics (1)

-21  -14  -7  0  Days

Proactive

Reactive

Heart Failure Event

Symptoms
Physiological Premise of Implantable HF Device Diagnostics (2)

-21  -14  -7  0  Days

- Proactive

Physiologic Changes

Medical Intervention

Averted Heart Failure Event
Heart Rate Variability and Patient Activity as Measures of Heart Failure Clinical Status
Autonomic Mechanisms in Heart Failure

• Sympathetic activation and parasympathetic withdrawal occur in the setting of heart failure

• Heart rate variability (HRV) provides an integrated measure of autonomic function or the balance between these two systems

• Low HRV – indicative of high sympathetic and low parasympathetic activity – is associated with poor outcomes in heart failure patients
Continuous HRV Before Hospitalization

Heart Rate Variability (ms)

Night Heart Rate (BPM)

Patient Activity (minutes/day)

Days Relative to Hospital Admission

Adamson PB et al *Circulation* 2004;110:2389-2394
Intrathoracic Impedance as a Measure of Heart Failure Clinical Status
Impedance Decreases with Increasing Lung Wetness

“Wetter” Lungs
Superior Performance of an Intrathoracic Impedance-Derived Fluid Index Versus Daily Weight Monitoring in Heart Failure Patients: Results of the Fluid Accumulation Status Trial (FAST)

William T. Abraham, Steven Compton, Blair Foreman, Garrie Haas, Robert C. Canby, Robert Fishel, Scott McRae, Gloria B. Toledo, and Shantanu Sarkar
On behalf of the FAST Study Group

Presented at the Annual Meeting of the Heart Failure Society of America, September 2009
**FAST Results:**
**Accuracy of Fluid Index vs. Weight at Nominal Thresholds**

<table>
<thead>
<tr>
<th></th>
<th>Fluid Index*</th>
<th>Weight†</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sensitivity (%)</strong></td>
<td>76.4 (60.8, 87.1)</td>
<td>22.5 (12.5, 37.1)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Unexplained Detection Rate (/pt/yr)</strong></td>
<td>1.9 (1.7, 2.1)</td>
<td>4.3 (3.2, 5.8)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Data are Generalized Estimator Equation (GEE) adjusted estimates (95% Confidence Interval)

Fluid Index Threshold = 60 Ω•days
Weight Threshold = 3lbs in one day or 5 lbs in 3 days
FAST: Results

Unexplained Detections (subject-1yr-1)

Sensitivity (%)

Fluid Index

Weight

nominal

Unexplained Detections (subject⁻¹yr⁻¹)
ICD/CRT: Prediction of HF Events

Monitoring of Fluid Status in Heart Failure Patients by Intrathoracic Impedance Measurement (Home CARE II)

Objective:

Development of an intrathoracic impedance based detection algorithm as a predictor for clinically relevant HF events

Enrollment planned:

300 pts. with ICD/CRT-D indication, NYHA II-IV, EF ≤35% increased risk for HF related hospitalizations

Chair: Maier, Würzburg, Germany
ClinicalTrials.gov, NCT00711360
Atrial Tachyarrhythmias

Clinical Effect of HF Management via HM with a Focus on AF (effecT)

300 pts. with CRT-ICD, documented episode of paroxysmal AF

Home Monitoring activated
Control HM deactivated

Follow-up: 12 months

Composite endpoint: CV mortality or hospitalization, inappropriate ICD therapy

Chair: Schalij, Leiden, The Netherlands
ClinicalTrials.gov, NCT00811382
## Some Ongoing Home Monitoring Trials

<table>
<thead>
<tr>
<th>Acronym</th>
<th>n</th>
<th>Device</th>
<th>Pts.</th>
<th>Endpoint</th>
</tr>
</thead>
<tbody>
<tr>
<td>VIRTUE</td>
<td>120</td>
<td>PM</td>
<td>DDD, no AF</td>
<td>workload</td>
</tr>
<tr>
<td>QUANTUM</td>
<td>150</td>
<td>ICD</td>
<td>prim./second.</td>
<td>anxiety</td>
</tr>
<tr>
<td>Euro-Eco</td>
<td>312</td>
<td>ICD</td>
<td>prim./second.</td>
<td>FU costs</td>
</tr>
<tr>
<td>SPIRIT-ICD</td>
<td>500</td>
<td>ICD</td>
<td>MADIT II</td>
<td>mortality</td>
</tr>
<tr>
<td>IMPACT</td>
<td>2718</td>
<td>ICD/CRT</td>
<td>CHADS(_2) ≥1</td>
<td>embolic events</td>
</tr>
<tr>
<td>HOME-CARE II</td>
<td>300</td>
<td>ICD/CRT</td>
<td>any ICD</td>
<td>HF hospital</td>
</tr>
<tr>
<td>IN-TIME</td>
<td>620</td>
<td>ICD/CRT</td>
<td>chronic HF</td>
<td>HF events</td>
</tr>
<tr>
<td>effecT</td>
<td>300</td>
<td>CRT-D</td>
<td>parox. AF</td>
<td>CV hospital</td>
</tr>
<tr>
<td>Castle-AF</td>
<td>420</td>
<td>Ablation/ICD</td>
<td>AF+NYHA≥II</td>
<td>HF hospital</td>
</tr>
<tr>
<td>Total</td>
<td>5,440</td>
<td></td>
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</tbody>
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Implantable Hemodynamic Monitors

- PA Pressure Sensors
- RV Pressure Sensors
- LV Pressure Sensor
- LA Pressure Sensor
The Pulmonary Artery Pressure Measurement System*

Catheter-based delivery system

MEMS-based pressure sensor

Home electronics

PA Measurement database

*CardioMEMS Inc., Atlanta, Georgia, USA
Primary Results of the CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients (CHAMPION) Trial

Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial

William T Abraham, Philip B Adamson, Robert C Bourge, Mark F Aaron, Maria Rosa Costanzo, Lynn Warner Stevenson, Warren Strickland, Suresh Neelaguru, Nirav Raval, Steven Krueger, Stanislav Weiner, David Shavelle, Bradley Jeffries, Jay SYadav, for the CHAMPION Trial Study Group*

Summary
Background Results of previous studies support the hypothesis that implantable haemodynamic monitoring systems might reduce rates of hospital admission in patients with heart failure. We undertook a single-blind trial to assess this approach.

Methods Patients with New York Heart Association (NYHA) class III heart failure, irrespective of the ejection fraction, and a previous hospital admission for heart failure were enrolled in 64 centres in the USA. They were randomly assigned by use of a centralised electronic system and assigned to management with a wireless implantable...
Cumulative HF Hospitalizations Over Entire Randomized Follow-Up Period

- Treatment
- Control

Cumulative Number of HF Hospitalizations

<table>
<thead>
<tr>
<th>Days from Implant</th>
<th>Treatment</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>270</td>
<td>280</td>
</tr>
<tr>
<td>90</td>
<td>262</td>
<td>267</td>
</tr>
<tr>
<td>180</td>
<td>244</td>
<td>252</td>
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<tr>
<td>270</td>
<td>209</td>
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<tr>
<td>360</td>
<td>168</td>
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<tr>
<td>450</td>
<td>130</td>
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<tr>
<td>540</td>
<td>107</td>
<td>105</td>
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<tr>
<td>630</td>
<td>81</td>
<td>67</td>
</tr>
<tr>
<td>720</td>
<td>28</td>
<td>25</td>
</tr>
<tr>
<td>810</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>900</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

p < 0.001, based on Negative Binomial Regression
Physician-Directed Patient Self-Management of Left Atrial Pressure in Advanced Chronic Heart Failure
Circulation published online Feb 22, 2010;
**HF Event Rates**  
(ADHF and All-Cause Death)  
Comparison of Periods with and without LAP-Guidance

<table>
<thead>
<tr>
<th>Period</th>
<th>Annualized Event Rate</th>
<th>P-values</th>
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<tbody>
<tr>
<td>12-mo period before enrollment</td>
<td>1.4 (1.1-1.9)</td>
<td>0.054</td>
</tr>
<tr>
<td>First 3 mo Observation Period</td>
<td>0.68 (0.33-1.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>After mo 3 Titration/Stability Periods</td>
<td>0.28 (0.18-0.45)</td>
<td>0.041</td>
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