Evolving Sensor Strategies & Remote Monitoring to Reduce Heart Failure Hospitalization

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Overview

- Background
- Sensors
  - Simple & Sophisticated
  - Need for Device-integrated approach
- Clinical impact of Remote Monitoring on HF
  - Outcomes
  - Monitoring HF progression
The Goal: Stabilize Disease Progression

- Cumulative effect of recurrent acute heart failure events leads to progressive decline in cardiac function

- Sensor strategies and timely intervention may help

Gheorghiade M, et al, AJC 2005
Device Based Heart Failure Management

- **Simple Sensors**
  - Heart rate and derivatives
  - Accelerometers
  - Impedance-based
  - S3
  - Respiratory

- **Sophisticated Sensors**
  - Pressure: left atrial pressure, pulmonary artery pressure, RV dP/dt, etc.
  - Heart Sound: PEA
  - C Output: Doppler
  - Chemicals: PO$_2$, PCO$_2$, pH, electrolytes and glucose
  - Biomarkers: TNF, BNP, etc.

Merchant F, Dec GW and Singh JP. Circulation EP, 2010:3: 357
Putting it all together: Sensing & Intervening

**Chronic HF**
- Neurohormonal status
- Compliance
- Myocardial risk

**Triggers**
- Ischemia
- Electrolytes
- Endothelial function
- Arrhythmias

**Co-Morbid**
- Diabetes
- HT
- COPD
- AF

**Sophisticated Sensors**
- Hemodynamic Instability
  - LAP
  - PADP
  - RV dp/dt
  - PEA
  - Impedance-based measures
- Neurohormones
- Inflammatory markers
  - CRP
  - IL-6
  - BNP, etc
- Acute vascular changes
  - MR
  - Venous drainage

**Device-derived Measures**
- Physical Activity
- Heart Rate
- HRV
- Impedance-based measures
- S3
- RR variability
- Arrhythmias

Heart Failure Hospitalization
Left Atrial Pressure Sensor Device

Futility leads to termination of trial

• Homeostasis Study: Safety & Efficacy
• LAPTOP-HF Study (Early termination)- Results at HFSA 2016
• Beat-to-beat hemodynamic assessment
• Engaging the patient: 3 phases
  • Observation, Titration & Dynamic Rx.

Merchant F, Dec GW and Singh JP. Circulation EP, 2010:3: 357
Pulmonary Artery Pressure Monitoring
Stand Alone Sensor

- Catheter-based delivery system
- Implanted PA branch diameter 7-15 mm
- Target range (mmHg):
  - PA systolic: 15-35
  - PA diastolic: 8-20
  - PA mean: 10-25

Survival or Freedom from First HF Hospitalization

29% relative risk reduction

Champion Study, Lancet 2010
Device-integrated Sensors: Prognosticating Failure Hospitalizations

- PARTNERS-HF
- 694 CRT patients followed up for 1 year
- 141 HF hospitalizations
- Device diagnostic criteria when positive, were associated with a 5.5 fold increased risk for HF hospitalization

Whellan DJ et al, JACC 2010: 55: 1803
We still need to learn to use the data……

DOT-HF Study: Proactive intervention with Audible Impedance Alerts

- 335 patients randomized to OptiVol information with audible alerts
- Heart Failure hospitalizations near 2-fold higher in the Access arm versus control arm
- 3-fold increase in outpatient visits
- Role of Impedance measures questionable?

Tiered Risk Stratification
Using Device-based Simple Sensors

- **Clinical risk score**
  - **Contak-Renewal Study & HF-HRV Study**
  - Variables extracted from device were dichotomized with score of 1 for:
    - SDANN < 43
    - mean HR > 74
    - Footprint < 29
    - Physical activity % < 5.
  - Total score = sum of dichotomized variables
    - Low (1)
    - Moderate: 2-3
    - High: 4

Singh JP et al Europace 2010
**Further Refinement in Sensor Strategies**

**MultiSENSE Study (HeartLogic™)**

**Heart Sounds**
Signs of elevated filling pressure (S3)

**Thoracic Impedance**
Fluid accumulation and pulmonary edema

**Respiration**
Rapid breathing and reduced tidal volume – shortness of breath

**Posture**
Increased night elevation angle as indicator of Orthopnea or PND

**Activity Response**
Physiologic changes as a result of activity – such as signs of dyspnea on exertion

**Heart Rate and Arrhythmias**
Heart rates as indicator of cardiac status; atrial arrhythmias related to HF status

**GOAL:** Create a high performing composite indicator of worsening heart failure status
The Multiple Sensor Approach
Appropriate Identification of the HF patient

Multi-sensor changes before a HF Admission
Impedance change only with NO event

Patient A: (True Positive)
Patient B: (False Positive)

Relative Tidal Volume
Thoracic Impedance (RV-Can)

Goal for Multisensor data to be combined into a single alert
Rapid Shallow Breathing = Respiratory Rate/Tidal Volume
Is There a Need for Remote Monitoring?

- Implantation of cardiac electronic devices has substantially increased
- Subsequent monitoring is an integral part of device & patient care
  - Device & patient variables, disease data
- Significant clinical workload
  - Further enhanced around advisories, recalls, ERI etc.
CONNECT Trial
Reducing Time to Clinical Decisions & Health Care Utilization

- RCT
- 1997 patients with ICD / CRT
- In-office vs. remote follow up with automatic alerts
- 15 month follow up

Noteworthy Results
- Clinical time from event to clinical decision was 22 vs. 4.6 days
- Reduction in mean length of stay per CV hospitalization (4 vs. 3.3 days)
- Savings of $1800 / hospitalization

Crossley GH et al J Am Coll Cardiol 2011:57:1181
ALTITUDE Study
Does Remote Follow up Influence Hard Endpoints?

- Significantly increased survival in remotely monitored group by nearly 50%
- Reasons:
  - Earlier notification and intervention
  - Engaged and motivated patients

- 194,000 patients on Boston Scientific Latitude system
- 69,556 on network versus 124,450 with conventional clinic follow up, non-randomized
- Remote transmissions
  - 3-4 times / month
  - Additional clinic visits 2/year

Saxon et al, Circulation 2010;122:2359
Extent of Remote Monitoring & Survival
Graded Impact on Outcome (n= 269,471)

Changing Paradigm within Remote Monitoring

Adapted from AS Desai and LW Stevenson, NEJM 2010; 363: 2364-2367
Summary

• **Where are we now?**
  – Paradigm shift in management of Implantable devices
  – Continuous monitoring permits enhanced care
  – But still no concrete uniform strategy

• **Widespread adoption is inevitable**
  • Evolution in device-derived sensor strategies will enable patient-centric care
  • Clinical outcomes studies underway

• **Where do we need to be?**
  – Uniformity in practice
  – Sensors coupled with remote monitoring integrated into clinical practice, will facilitate personalized medicine
  – Additional creation of self-management strategies for patients
Thank you!
New Device Derived Sensor Measures

Some Data

Variability in Respiratory Rate

Audible + Sub audible S3

Cox regression model of event-free time
p<0.001, HR=4.9 (95% CI: 2.2 - 11)

Cumulative proportion with HF events
Time from end of baseline to first HF event (days)

10%-90% range <= 4
10%-90% range > 4

Siejko K, et al. PACE; Mar 2013