Remote monitoring of heart failure

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The need for remote monitoring

- Heart failure has emerged as a major public health problem affecting several million patients.

- Despite advances in diagnosis & management of HF, rehospitalization rates are 27% at one month and 50% at 6 months – highest for any medical condition.

- How to monitor patients in remote areas or those living alone without support?

- Remote monitoring may be the answer to be “proactive” rather than “episodic & reactive.”
What parameters to monitor?

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Potential Measurements for HF Monitoring</th>
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</thead>
<tbody>
<tr>
<td><strong>Patient-reported data</strong></td>
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<tr>
<td>Signs and symptoms of congestion</td>
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<tr>
<td>Signs: Jugular venous distension, peripheral edema, pulmonary congestion/rales, pleural effusions, S3 gallop</td>
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<tr>
<td>Symptoms: Dyspnea on exertion, orthopnea, paroxysmal nocturnal dyspnea, fatigue, abdominal fullness, anorexia, nausea, vomiting</td>
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<tr>
<td>Daily weight</td>
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<td>Sodium intake</td>
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<td>Medication adherence/persistence</td>
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<tr>
<td><strong>Laboratory data</strong></td>
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<tr>
<td>INR</td>
<td></td>
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<tr>
<td>Natriuretic peptides (BNP and NT-proBNP)</td>
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<tr>
<td>Other biomarkers</td>
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<tr>
<td><strong>Directly recorded data</strong></td>
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<tr>
<td>Heart rate</td>
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<tr>
<td>Blood pressure</td>
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<tr>
<td>Atrial/ventricular arrhythmias</td>
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<tr>
<td>Percentage pacing</td>
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<tr>
<td>Pressure sensor data</td>
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<tr>
<td>RV outflow</td>
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<tr>
<td>Left atrial</td>
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<tr>
<td>Pulmonary artery</td>
<td></td>
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<tr>
<td>Device parameters</td>
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<tr>
<td>Battery</td>
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<tr>
<td>Alerts</td>
<td></td>
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<tr>
<td>Leads</td>
<td></td>
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<tr>
<td>Calculated/derived data</td>
<td></td>
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<tr>
<td>Heart rate variability</td>
<td></td>
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<tr>
<td>Activity level</td>
<td></td>
</tr>
<tr>
<td>Intrathoracic impedance</td>
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</tbody>
</table>

**Notations:**
- BNP = B-type natriuretic peptide
- INR = international normalized ratio
- NT-proBNP = N-terminal pro-B-type natriuretic peptide
- RV = right ventricular
Physiological basis for remote monitoring

Prehospitalization pressure changes start 3 weeks before symptoms develop with subsequent decompensation.
Can pre-hospitalization treatment make a difference?

Timely detection of changes in filling pressures may provide an opportunity to intervene and prevent decompensation.
Classification of sensors for remote monitoring of Heart Failure

• **Electrophysiologic Sensors**
  - Available in ICD’s, CRT’s, PM’s
  - Sensing atrial and ventricular arrhythmias
  - Cardiac autonomic tone HRV, night-day heart rate

• **Hemodynamic Sensors**
  - RV pressures and estimated PA pressure (ePAD) (Chronicle Medtronic)
  - Left atrial pressure (HeartPOD St Jude)
  - Direct pulmonary pressure measurement (Champion, CardioMEMS, Atlanta Remon, BSC)

• **Impedance Monitoring**
  - Optivol Fluid Status Monitoring System (Medtronic)

• **Other**
  - Derived from accelerometer activity: less than 1 hour/day averaged over 1 week
  - CO monitoring sVO2 measurements via sensor located in RV
  - Peak endocardial activation (PEA)
Electrophysiological Sensors

- Available in ICD’s, CRT’s and pacemakers
- Senses atrial and ventricular arrhythmias
- Cardiac autonomic tone, heart rate variability, day-night heart rate are assessed

Table 1  Comparison of heart failure monitoring capabilities of devices

<table>
<thead>
<tr>
<th></th>
<th>Biotronik Home Monitoring™</th>
<th>Boston Scientific Latitude™</th>
<th>Medtronic CareLink™</th>
<th>St Jude Merlin.net™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data transmission</td>
<td>GSM network</td>
<td>Analogue phoneline</td>
<td>Analogue phoneline</td>
<td>Analogue phoneline</td>
</tr>
<tr>
<td>CRT therapy delivery</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Arrhythmia documentation</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Activity levels</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Heart rate levels</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Heat rate variability</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Thoracic impedance</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

GSM, global system for mobile communications.

Ayesha Hasan et al EHJ (2011) 32, 1457-1
Merlin.net® PCN Version 6
Enhanced Remote Care Solutions

- Optimized Merlin.net® Patient Care Network Reports
- LeadAssurance™ Alert
- New VT/VF Alerts
- CorVue® Thoracic Impedance Monitoring for Unify™/Unify Quadra™/Fortify™ ICDs
- Broadband Connectivity for Merlin@home® transmitter
CorVue® Thoracic Impedance Monitoring

- CorVue® Thoracic Impedance Monitoring monitors transthoracic impedance over time across multiple vectors
- An increase of fluid in the lungs may cause changes in impedance
- Lower impedance measurements over a period of time may indicate a higher probability of a heart failure event
Advantages of CorVue® Algorithm

Vectors:
- RV Coil to Can
- RV Ring to Can
CorVue® Thoracic Impedance Monitoring

- CorVue® Impedance Monitoring is available in the following device families:
  - Fortify®
  - Unify®
  - Unify Quadra®

- The feature can be enabled in previously implanted models of these device families
Remote Monitoring of CorVue® Thoracic Impedance Monitoring

- Automatic data uploads occur every seven days

- RF remote monitoring does not require patient interaction

- The impedance monitoring report is available on Merlin.net® PCN

- There is currently no alert for CorVue® Thoracic Impedance Monitoring in the US
Remote Options for Viewing CorVue®
Thoracic Impedance Monitoring Trended Data

Arrhythmia and Device Management Application

Heart Failure Management Application
Merlin@home® Transmitter Broadband Connectivity

Merlin@home transmitter

Merlin.net® Patient Care Network

Wireless Adapter

Encrypted Broadband

Ethernet cable

Router, switch, hub, gateway or modem

Broadband Connection
Hemodynamic Sensors

- Several studies have linked the prognosis in HF to PCWP, RA pressure and PASP.

- Echo helps to measure inflow patterns and MR and TR reflect the filling pressures and predict outcome.

- Serial invasive monitoring of intra cardiac and PA pr. is useful to optimize medical & device based therapy.

- The possibility & opportunity to continuously monitor intra cardiac pressures using implantable sensors is promising.
Which Hemodynamic Sensors?

**Chronicle Phase I:**
*Chronicle IHM* accurate in continuous monitoring of hemodynamic condition

**COMPASS-HF:**
*Chronicle IHM-guided care* reduced rate of all HF-related events by 21% (*p=NS*) and time to first HF-related hospitalization by 36% (*p=0.03*).

**CHAMPION:**
*CardioMEMS’ pulmonary artery pressure system* significantly reduces HF hospitalizations at 6 months.

**REDUCEHF:**
Pivotal evaluation of the safety & effectiveness of Chronicle+ICD guided care

*Enrollment stopped early due to pressure sensor performance (35% powered)*

**ALPS Program:**
- Continuous automatic pressure
- Low power communication
- Patient self-management
- MD intervention as needed

**Other competitive notables:**
- **LAPTOP-HF** (STJ): pivotal evaluation of LAP management system
- **PAPIRUS** (BSX): pilot program to evaluate RemonCHF ultrasonic pressure sensor
Cardiomems
Hemodynamic sensors and pressure monitoring

decompensation--

systolic and diastolic HF

Pressure elevates early and causes decompensation

HF hospitalization

+ 12 %
Hemodynamic sensors and pressure monitoring

Vanderheyden et al. Circ Heart Failure 2010;55:1803-1810
Multimodality Sensor Strategy

Combining ePAD and Impedance (n=16 pts, NYHA III, EF < 30%)

Vanderheyden et al. Circ Heart Failure 2010;55:1803-1810
Rationale for multimodality sensor strategy

Multi parameter sensing improves accuracy

PARTNERS – HF Trial (JACC 2010; Vol 55, Issue 17: 1803-1810)

- Patient activity level
- Atrial fibrillation duration
- Ventricular rate during af
- Intrathoracic impedance
- Night heart rate
- HRV
- % pacing in CRT
- Appropriate ICD shocks
Interpretation and stages of evolution

Heart failure hospitalization follows a slow increase in cardiac filling pressures that can be detected and treated.

- **Stage one:** Treat filling pressures that go-up
  - Lower the peaks
- **Stage two:** Lower the plateaus
- **Stage three:** increase and decrease diuretics as needed

Once we know how to respond

**Empower the patient**
OptiVol® Fluid Status Monitoring helps physicians track the daily fluid status of their heart failure patients.
A new CRT-P device from Sorin – The New Living™ CHF is equipped with an implantable PEA sensor to monitor HF. This lead detects cardiac muscle vibrations that correlate with LV dP/dTmax.
SEEQ from Medtronic
Device Gallery

HeartPOD

Piix Corventis

Nuvant

Carelink

Zoe Fluid Status monitor

Remon Technologies Wireless Telemetry

Biotronic Cardio Messenger

ALPS
Does remote monitoring help?
Yes it does!

A Meta-Analysis of Remote Monitoring of Heart Failure Patients

Catherine Klersy, MD, MSc,* Annalisa De Silvestri, MSc,* Gabriella Gabutti, MA,† François Regoli, MD,*‡ Angelo Auricchio, MD‡
Pavia, Italy, and Lugano, Switzerland

Home Monitoring for Heart Failure Management

Anh L. Bui, MD, Gregg C. Fonarow, MD
Los Angeles, California

(JACC 2009)

(JACC 2012)
Does remote monitoring help?
Yes it does!

(Circulation. 2010;121:1086-1095)

Heart Failure

Physician-Directed Patient Self-Management of Left Atrial Pressure in Advanced Chronic Heart Failure

Jay Ritzema, MRCP; Richard Troughton, FRACP, PhD; Iain Melton, FRACP; Ian Crozier, FRACP, MD; Robert Doughty, FRACP, MD; Henry Krum, FRACP, PhD; Anthony Walton, FRACP; Philip Adamson, MD; Saibal Kar, MD; Frediman K. Shah, MD; Mark Richards, FRACP, DSc; Neal L. Eigler, MD; James S. Whiting, PhD; Garrie J. Haas, MD; J. Thomas Heywood, MD; Christopher M. Frampton, PhD; William T. Abraham, MD; on Behalf of the Hemodynamically Guided Home Self-Therapy in Severe Heart Failure Patients (HOMEOSTASIS) Study Group

(Circulation. 2012;125:2985-2992)

Heart Failure

Remote Monitoring Reduces Healthcare Use and Improves Quality of Care in Heart Failure Patients With Implantable Defibrillators

The Evolution of Management Strategies of Heart Failure Patients With Implantable Defibrillators (EVOLVO) Study

Maurizio Landolina, MD*; Giovanni B. Perego, MD*; Maurizio Lunati, MD; Antonio Curnis, MD; Giuseppe Guenzati, MD; Alessandro Vicentini, MD; Gianfranco Parati, MD; Gabriella Borghi, MS; Paolo Zanaboni, PhD; Sergio Valsecchi, PhD; Maurizio Marzegalli, MD

- CHAMPION Trial 46,550 patients – Abraham et al Lancet 2011
- HOMEOSTASIS Study  Adamson et al JACC 2003
Does remote monitoring help?
No it doesn’t!

- COMPASS-HF study (274 pts. 6m follow up) – Bourge et al JACC 2008
- TELE-HF – Chaudhry et al, NEJM 2010
- TIM-HF – Koehler F et al, Circulation 2011
- SPAN-CHF – Konstam et al, J.Card Fail 2011
Conclusions

- The expanding role of implantable sensors is leading to a paradigm shift in HF management.
- Implantable sensors will become part of routine monitoring – we are on the learning curve to utilize this data.
- Sensor-based interpretation allows for personalization and customization of dosage – one size does not fit all!
- Evolving sensor strategies will facilitate risk stratification and predicting ADHF and help to avoid hospitalization.
- Multimodality sensors will help better management when strategically used.
Point to ponder:
Remote monitoring data had been transmitted to the medical professional
Legally liable or not?

Thank you