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Creating Devices for Personalized Health Monitoring: Cardiovascular Monitoring Case Studies

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Creating Devices for Personalized Health Monitoring: Cardiovascular Monitoring Case Studies

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DISCLOSURES

• I have received research funding from:
  – US Department of Defense
  – National Heart Lung and Blood Institute
  – Worcester Polytechnic Institute (New Technology Development Grant)
  – St. Jude Medical
  – Philips Healthcare
  – Sanofi Aventis
  – Biotronik
  – Otsuka Pharmaceuticals
  – Astra Zeneca
PRESENTATION AGENDA

- Present new results using a transthoracic bioimpedance monitoring system to detect heart failure decompensation
- Discuss a smartphone-based arrhythmia detection system
WHAT IS HEART FAILURE?

– A set of symptoms resulting from failure of the heart to pump blood to meet the metabolic demands of the body.

– Diagnosis is defined by signs and symptoms.

No clear, straightforward diagnostic test for HF

- Respiratory problems
- Labored breathing
- Difficulty breathing when lying flat
- Paroxysmal nocturnal dyspnea
- Pulmonary edema
- Fatigue
- Exercise intolerance
- Edema

- Weight gain
- Distended neck veins
- Nausea
- Diminished appetite
- Excessive urination during night
- Fluid retention
- Angina
- Cardiac rhythm disorders
Each year there are 1.1 million HF admissions in the US. The mean cost of each HF hospitalization is $18,000.

- 27% of HF patients re-hospitalized within 30 days; 50% within 6 months.
- Hospitals are penalized for early readmissions after HF hospitalization.
- Pulmonary congestion is difficult to recognize in its early stages due to the late appearance of symptoms.
- Fluid accumulation is often detected too late to avert hospitalization.
- Weight monitoring has low patient compliance.

**Monitoring Options for Heart Failure Patients**

- **Traditional monitoring** - Patient keeps a diary to self-monitor weight, blood pressure, and symptoms

- **Tele Monitoring** – automated system to simplify the monitoring of weight, blood pressure, and symptoms
  
  Large studies have shown that telemonitoring of symptoms, weight, and symptoms to clinics does not reduce HF-related hospitalizations.

- **Implantable device remote monitoring** – Implantable cardiac devices collect information which provide insights into HF progression
  
  e.g., ICD device with the capability to measure AF burden, heart rate variability, intra-thoracic impedance, or filling pressure changes
Intrathoracic bioimpedance predicts HF decompensation

The challenge
- 1 in 3 of HF patients re-hospitalized within 30 days
- Clinical predictors show poor predictive capabilities

Clinical observation*
- PARTNERS-HF study - Patients with >=1 abnormal HF statistic trend have 5-fold higher risk for hospitalization within 30 days
- Mid-HeFT study – Thoracic impedance monitoring is more reliable and detects fluid changes earlier than symptom onset
HF MONITORING RE-EXAMINED

- Currently, HF monitoring is restricted to patients with implantable devices
- A minority of HF patients are eligible for such devices
- New technologies are needed to monitor for acute decompensated HF (ADHF)
- Might transthoracic bioimpedance work?
FLUID ACCUMULATION VEST SYSTEM

Measurement Vest
- Textile electrodes
- Sized to participants

Measurement Electronics
- Connects to vest
- Bluetooth to Smartphone

Secure Cloud Service

Smartphone
- App detects measurements
- Stores and sends data to secure cloud service
SENTINEL–HF: INTERIM ANALYSIS

• We have recruited 107 participants admitted with ADHF to UMMC.

• Participants are trained on the use of a FAV–smartphone dyad to obtain and transmit a 5-minute bioimpedance measurement once daily for 45-days after discharge.

• Readmission and diuretic dosing adjustments are identified using participant report and causes adjudicated using medical records.

• Daily bioimpedance is analyzed.
**SENTINEL-HF STUDY: A REPRESENTATIVE HF COHORT**

### Demographics
- **Age, y**: 67 ± 12
- **Men**: 57%

### Race
- Caucasian: 88%
- Other: 12%

### Medical history
- Hypertension: 76%
- Atrial fibrillation: 46%
- Diabetes mellitus: 51%
- Chronic lung disease: 24%
- Coronary heart disease: 22%

### Psychosocial characteristics
- Cognitively impaired: 11%
- Depressed: 17%

### Clinical characteristics
- Length of index hospital stay, days: 5 ± 3
- Body mass Index, kg/m²: 33 ± 10
- Ejection fraction, %: 48%

### Discharge medications
- Aspirin: 69%
- Loop diuretic: 83%
- ACE inhibitor/ARB: 41%

### 45-day outcomes
- HF-related rehospitalization: 10%
- Diuretic up-titration: 10%

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**Age distribution**
- 65 y: 28
- 66-75 y: 11
- 76-85 y: 15
- 85 y+: 6

**Dropouts per age category**
- -50 y: 5
- 51-60 y: 1
- 61-70 y: 3
- 71-80 y: 4
- 81 y+: 3
INTERIM ANALYSIS RESULTS – SUCCESS RATE

- Despite their advanced age and high burden of comorbid diseases, study participants with ADHF were able to make daily bioimpedance measurements using a FAV and transmit them using a smartphone.
- This proves the feasibility and acceptability of using HF monitors in the community.

Relative number of successful measurements

- >= 75%: 17 patients
- < 75%: 7 patients
TRANSTHORACIC BIOIMPEDANCE PREDICTS EARLY READMISSION FOR HF

- Early readmission was common and predicted up to 7 days in advance by an algorithm analyzing transthoracic bioimpedance.

- Transthoracic bioimpedance monitoring may offer possibilities for reducing HF readmissions by enabling identification and treatment of outpatients with early HF decompensation.
Atrial Fibrillation: A Complex Disease with Far-Reaching Impact

Miyasaka Circulation 2006;11:119; Go JAMA 2001;285:2370
American Heart Association
Atrial Fibrillation: A Disease Diagnosed Using Technology Developed in 1903
Automated AF Detection Algorithm Development

- Electrocardiographic data was obtained from consenting UMMHC patients with AF who wore Holter monitors (IRB-Pro00000008).
- Data from patients in MIT-BIH AF Database were also used.
- Time Varying Coherence Function, Root Mean Squared and Shannon Entropy examined.

TVCF of subject 8455 of the MIT-BIH AF database according to each beat and normalized frequency.
DEVELOPMENT OF A COMPREHENSIVE AUTOMATED ALGORITHM FOR DETECTION OF THE 3 MAJOR ATRIAL ARRHYTHMIAS
AF Monitoring: A Change is Needed

• AF is associated with high risk for stroke and hospitalization

• AF can come and go (paroxysmal), leading to delays in diagnosis

• New monitoring technologies are needed
A mobile phone application for data recording using a camera
(The application uses the camera lens and light to acquire
information about heart rate and rhythm)

(a) Green band PPG signal, (b) HR_{ECG} (thin black line) and HR_{GREEN} (thick blue line) during spontaneous breathing, (c) HRV power spectral density plots from ECG (thin black line) and GREEN (thick blue line).
AN IPHONE PROTOTYPE OF THE AF DETECTION APPLICATION

McManus, Lee, Chon. *HeartRhythm*. 2013
We recruited a cohort of 76 patients undergoing cardioversion.

Table 1: Baseline characteristics of the study sample

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>Total (N = 76)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y) mean (SD)</td>
<td>65.3 (11.6)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>59 (77)</td>
</tr>
<tr>
<td>White, n (%)</td>
<td>73 (96)</td>
</tr>
<tr>
<td>Body mass index (kg/m²), mean (SD)</td>
<td>31.0 (8.3)</td>
</tr>
<tr>
<td>Medical characteristics, n (%)</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>54 (71)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>47 (62)</td>
</tr>
<tr>
<td>Current smoking</td>
<td>6 (8)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>21 (28)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>22 (29)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>16 (21)</td>
</tr>
<tr>
<td>Sleep apnea</td>
<td>12 (16)</td>
</tr>
<tr>
<td>Coronary artery bypass</td>
<td>8 (11)</td>
</tr>
<tr>
<td>Prior cardioversion</td>
<td>20 (27)</td>
</tr>
<tr>
<td>Stroke</td>
<td>9 (12)</td>
</tr>
<tr>
<td>Treatment characteristics, n (%)</td>
<td></td>
</tr>
<tr>
<td>Beta-blocker</td>
<td>47 (62)</td>
</tr>
<tr>
<td>Calcium channel blocker</td>
<td>15 (20)</td>
</tr>
<tr>
<td>Statin</td>
<td>42 (56)</td>
</tr>
<tr>
<td>Antiarrhythmic drug</td>
<td>19 (31)</td>
</tr>
<tr>
<td>Class I</td>
<td>5 (7)</td>
</tr>
<tr>
<td>Class III</td>
<td>18 (24)</td>
</tr>
<tr>
<td>Digoxin</td>
<td>4 (5)</td>
</tr>
<tr>
<td>Procedural characteristics, mean (SD)</td>
<td></td>
</tr>
<tr>
<td>Number of shock</td>
<td>1.1 (0.4)</td>
</tr>
<tr>
<td>Joules delivered, mean (SD)</td>
<td>226 (86)</td>
</tr>
</tbody>
</table>
A Novel Application Running An AF Detection Algorithm Detects AF

McManus, Lee, Chon. *HeartRhythm*. 2013

**Algorithm**

<table>
<thead>
<tr>
<th>Algorithm</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>RMSSD/mean</td>
<td>0.9818</td>
<td>0.9150</td>
<td>0.9533</td>
</tr>
<tr>
<td>Shannon entropy</td>
<td>0.9750</td>
<td>0.8218</td>
<td>0.9097</td>
</tr>
<tr>
<td>RMSSD/mean + Shannon entropy</td>
<td>0.9619</td>
<td>0.9752</td>
<td>0.9676</td>
</tr>
</tbody>
</table>

**Diagram:**

1. Obtain Pulsatile signal from iPhone 4S camera
2. Pulse peak detection
3. Obtain RR Intervals
4. Calculate RMSSD/mean & Shannon Entropy
5. Both higher than threshold values?
   - No: Go back to step 4
   - Yes:
     - Declare Irregular
     - Declare Regular
A SMARTPHONE APP CAN IDENTIFY AF

• In a prospectively recruited cohort, we found that a novel algorithm analyzing signals from an iPhone 4S accurately distinguished pulse recordings during AF from sinus rhythm.

• NHLBI-funded study is underway to explore the acceptability and usability of the smartphone-based application in the community.

McManus, Lee, Chon. HeartRhythm. 2013
THANK YOU FOR ATTENDING!

“Now this is not the end. It is not even the beginning of the end. But it is, perhaps, the end of the beginning.”

Winston Churchill
ACKNOWLEDGEMENTS

• Special thanks to the following collaborators:
  – Umass: Dr. Chad Darling, Dr. Jane Saczynski
  – WPI: Dr. Ki Chon