Implantierbarer hämodynamischer Monitor bei Herzinsuffizienzpatienten

Ein sinnvolles neues Monitoring-Tool?

Dr. Mattias Roser, MD
Head of Electrophysiology
Dept. of Internal Medicine/Cardiology
Charité Campus Benjamin Franklin
Berlin, Germany
„The very essence of cardiovascular medicine is the recognition of early heart failure“

Sir Thomas Lewis (1881-1945)

... and the early recognition of worsening heart failure!
Myocardial Damage
- CAD
- Cardiomyopathy
- HTN
- Diabetes
- ...

Compensatory mechanisms
- Adrenergic nervous system
- RAAS
- Cytokine systems
- ...

Myocardial Remodeling → Pump Failure
Electrical Remodeling → SCD/Arrhythmic Death

Adapted from: Braunwals’s Heart Disease, 9th Edition
Worsening Heart Failure Leading to HF Hospitalizations Contributes to Disease Progression

With each subsequent HF-related admission, the patient leaves the hospital with a further decrease in cardiac function.

Graph adapted from: Gheorghiade MD, et al. Am J. Cardiol. 2005
HF Hospitalizations are a Strong Predictor of Mortality

Data from the EFFECT study, 
n = 9,138 patients\textsuperscript{1}

Data from the Setoguchi et al., 
n = 14,374 patients\textsuperscript{2}

Each admission decreases a patient’s chance of survival!
Early Recognition of Heart Failure

Electrophysiological Criteria
- Heart rate variability (HRV)
- Mean ventricular rate at rest
- PVCs/hr.
- AF Burden
- % CRT

Signs & Symptoms
- Dyspnea
- Orthopnea
- Jugular Venous Pressure
- Pulmonary Edema
- Peripheral Edema
- Fatigue
- Activity
- Weight

Imaging
- Chest X-ray
- Echokardiography
- U/S IVC

Device-based criteria
- Intrathoracic impedance
- Intracardiac Impedance

How good are we?

Laboratory
- B type natriuretic peptide
- NT-pro BNP
- MRproANP
<table>
<thead>
<tr>
<th></th>
<th>Sensitivity, %</th>
<th>Specificity, %</th>
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</thead>
<tbody>
<tr>
<td><strong>History</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart failure</td>
<td>60</td>
<td>90</td>
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<tr>
<td>Myocardial infarction</td>
<td>40</td>
<td>87</td>
</tr>
<tr>
<td>Coronary disease</td>
<td>52</td>
<td>70</td>
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<tr>
<td><strong>Symptoms</strong></td>
<td></td>
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<tr>
<td>Dyspnea on exertion</td>
<td>66–84</td>
<td>34–52</td>
</tr>
<tr>
<td>Orthopnea</td>
<td>50–66</td>
<td>47–77</td>
</tr>
<tr>
<td>Edema</td>
<td>46–51</td>
<td>73–76</td>
</tr>
<tr>
<td>Fatigue &amp; weight gain</td>
<td>31</td>
<td>70</td>
</tr>
<tr>
<td><strong>Physical exam</strong></td>
<td></td>
<td></td>
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<tr>
<td>Rales</td>
<td>24–66</td>
<td>84–100</td>
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<tr>
<td>Elevated JVP</td>
<td>57–70</td>
<td>79–93</td>
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<tr>
<td>S3 gallop</td>
<td>68–73</td>
<td>42–73</td>
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<td>Valsalva maneuver</td>
<td>73</td>
<td>65</td>
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<tr>
<td><strong>Chest radiography</strong></td>
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<td></td>
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<tr>
<td>Pulmonary vascular redistribution</td>
<td>60–65</td>
<td>68–80</td>
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<tr>
<td>Interstitial edema</td>
<td>27–60</td>
<td>73–87</td>
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</table>

TIM-HF Trial: Telemonitoring of Weight and Blood Pressure Do Not Reduce Readmission or Mortality

- Randomized study of 710 patients
- Primary Endpoint: Total Mortality
- Control Group: Standard-of-care (no telemonitoring)
- Treatment Group: Telemonitoring of weight and BP information
- **Results:** No difference in all-cause death or HF hospitalizations

<table>
<thead>
<tr>
<th>End Point</th>
<th>Telemonitoring n = 354 (%)</th>
<th>Usual care n = 356 (%)</th>
<th>HR (95% CI)</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td>All-cause mortality</td>
<td>15.3</td>
<td>15.4</td>
<td>0.97 (0.67-1.41)</td>
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<tr>
<td>Cardiovascular-related mortality</td>
<td>11.3</td>
<td>12.9</td>
<td>0.86 (0.56-1.31)</td>
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<tr>
<td>All-cause readmission</td>
<td>54.2</td>
<td>50.3</td>
<td>1.12 (0.91-1.37)</td>
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</table>
TELE-HF Trial: Telemonitoring of Weight and Symptoms Do Not Reduce Readmission or Death

- Randomized study of 1653 patients
- Primary endpoint: Readmission for any reason or death from any cause within 180 days after enrollment
- Control group = Standard-of-care (no telemonitoring)
- Treatment group = telemonitoring of symptoms and weight
- **Results**: No difference in number of deaths, readmissions or days in hospital

![Graph showing re-hospitalization and death rates comparing telemonitoring and standard-of-care groups.](image)
DOT-HF Trial: Monitoring Impedance With Audible Alert Increased HF Hospitalizations

Monitoring intrathoracic impedance (Optivol™ algorithm, Medtronic) with an audible alert did not improve mortality and increased HF hospitalizations.
Time Course of Decompensation

Physiologic Markers of Acute Decompensation

- Hemodynamically Stable
- Presymptomatic Congestion
- Decompensation

* Graph adapted from Adamson PB, et al. Curr Heart Fail Reports, 2009.*
CardioMEMS™ HF System

Pulmonary Artery Pressure Sensor

Patient Electronics System

CardioMEMS™ HF Website
Case A.D., 51 y/o
Case A.D., 51 y/o

- NICM, first decompensation 05/2015
- Rapid progression of Heart Failure
- Monthly Hospitalizations due to HF

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<tr>
<th>Patientenbezogen</th>
<th>Charité Standard</th>
<th>Datum</th>
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... what to do?

Frequent Flyer Program?

- Personal nursing staff
- Pick-Up service
- 5* meals
- Free alcoholic beverages
- Single bed room
- Second breakfast
- Free Pay-TV
- Report ready on day of discharge
- Room with garden view
- Free headphones
- Express Check-In
CardioMEMS™ Implantation June 2016
Clinical Course

Implantation and OMT-Adjustment

Medical Intervention (phone-call)
Clinical Course

- Bicycle accident
- Surgical Osteosynthesis
- Med. Adjustment

Medical Intervention (phone-call)

Implantation and OMT-Adjustment
Patients managed with PA pressure data had **significantly fewer HF hospitalizations** as compared to the control group.
CHAMPION Clinical Trial: PA Pressure-guided Therapy Reduces Mortality

HFrEF Patients on ACE/ARB and Beta Blocker Prior to Implant

57% Reduction
[HR 0.43, 95% CI 0.24-0.76, p=0.0026]

Abraham W., Abstract 902-04, presented @ ACC 2015 in San Diego, USA.
CardioMEMS™ – The Real World Experience

- Easy to implant – „straight forward“ procedure
- Reliable PAP-measurements
- Reduction of HF-hospitalizations
- Reduction of Mortality (?)

BUT...

- Patient compliance necessary
- Need for (already) established telemonitoring clinic
- Reimbursement not clear (yet)
CardioMEMSTM HF System

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mattias.roser@charite.de