Heart Failure
Pathophysiology and management.
Update 2009.

Understanding clinical and functional measures of CHF

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Background: Heart Failure Hospitalizations (HFH)

**HF in US (2002 data):**
HFH per year: 1 million
AHA, 2002 Heart and Stroke Statistical Update.
[www.nhlbi.nih.gov](http://www.nhlbi.nih.gov)

**HF in Europe (ESC Guidelines 2005):**
HF costs: 1% ÷ 2% overall Health Care consumption in Europe
(HFH = 75% of all costs)

“...advanced HF and related acute decompensation have become the single most costly medical syndrome in cardiology.”

ESC guidelines for diagnosis and treatment of chronic HF (update 2005).
(Task Force of ESC); EHJ; doi:10.1093/eurheartj/ehj205
How to prevent HF?
Not an easy task!

Several clinical and functional measures are usually applied to evaluate the clinical status and the functional class of HF patients, but all of them have important limitations in predicting new events, since

- They are subjective parameters or conditioned by psychological factors (NYHA class, dyspnoea, QoL)
- They are useful to identify the current clinical status (echocardiography, 6’ WT, exercise test)
- They are capable of predicting heart failure deterioration only few days in advance (body weight, oedema)
Clinical signs to detect and predict HF

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rest heart rate &gt; 100 bpm</td>
<td>7</td>
<td>99</td>
<td>6</td>
</tr>
<tr>
<td>Pulmonary rales</td>
<td>13</td>
<td>91</td>
<td>27</td>
</tr>
<tr>
<td>Leg Oedema</td>
<td>10</td>
<td>93</td>
<td>3</td>
</tr>
<tr>
<td>Ill heart sound</td>
<td>31</td>
<td>95</td>
<td>61</td>
</tr>
</tbody>
</table>

*Mc Murray J. The signs and symptoms of HF.*

*In: Ball SG, Campbell RWF, Frances GS. International Handbook of Heart Failure. Euromed Communication Ltd, 1994, pp 5-12.*
Real time transmission of a fast VT in the VF window
ATP delivery during charge interrupted VT (patient asymptomatic)
HRV, Night Heart Rate and Physical Activity (early markers of acute events)

Intrathoracic impedance Concept

Heart Failure Exacerbation

Pulmonary Congestion

Decrease in Intrathoracic Impedance
OptiVol System

OptiVol Fluid Trends (June 2003 to June 2004)

OptiVol Fluid index is an accumulation of the difference between the daily and reference impedance.

- \( P \) = Program
- \( I \) = Interrogate

OptiVol fluid index

- OptiVol Threshold

Thoracic impedance (ohms)

- Daily
- Reference

Observation and Alert Threshold

Accumulation of the difference between the daily and reference impedance

Reference impedance slowly adapts to daily impedance

Daily impedance is the average of each day’s measurements
Intrathoracic Impedance and CHFH prediction

Less Fluid

More

Relative Baseline

CHF Admission

Days Before Hospitalization

Impedance (Ω)

-21

-14

-7

0
OptiVol clinical results

- 33 pz, III / IV NYHA, follow-up 20 ± 8.4 months
- HFH prediction: 15.3 ± 10.6 days
- Sensitivity = 76.9%

Yu CM & al; Circulation 2005; 112: 841-8
Medtronic CareLink System

The patient puts the Carelink Monitor antenna on the device to interrogate.

The Monitor sends the data through a standard telephone line to a secure web site.

The physician may check the data on the Carelink Clinician website.
HF monitoring
CareLink website CRT-D

VT/VF episodes

AF burden

OptiVol fluid index is an accumulation of the difference between the daily and reference impedance.
28 OptiVol events occurred in 23/67 patients:

- In 20 episodes data were evaluated using a CareLink transmission
  - 6 episodes: in-hospital visits were required
  - 10 episodes: therapy adaptation after phone assessment
  - 4 episodes: no action needed

- In 8 episodes an in-hospital visit was performed without using CareLink:

**OptiVol algorithm:**
- 91% sensitivity (20 alerts in 22 HF episodes)
- 71% PPV (20 HF episodes for 28 alerts)

It’s a monitoring system based on cross check of two sensors usually implemented in dual sensor devices:

- **MINUTE VENTILATION (MV)** ⇒
  - MVR = MV @ Rest
  - MVA = MV @ Exercise

- **PATIENT ACTIVITY (G)** ⇒
  - W = Workload

Functional status is defined by daily analysis of MVR & MVA compared with W.

Preliminary study:
- Sensitivity 88%; Specificity 95%; PPV 71%; NPV 98%
- **Prediction of HFH 13 ± 8 days in advance** (min 3 gg; max 30 gg)

Landolina M, HRS 2006
MV Sensor: discrimination between rest and activity

* Calculated every 24 h

Bonnet JL & al; “Circadian variations in MV can be reproduced by a PM sensor”. PACE, 1998; Vol. 21(4) part I: 701-704
MVA, MVR and W behaviour before HFH
RV hemodynamic monitoring in HF

Adamson P. & al; JACC 2003; 41: 565-71
Implantable Hemodynamic monitors

*The “Chronicle” system*

- **Chronicle® IHM**
- **Home Monitor**
- **Secure Network**
- **Clinician access**

- RV Systolic Pressure
- RV Diastolic Pressure
- Estimated Pulmonary Artery Diastolic Pressure plus...
- Other patient specific data as available.
Implantable Hemodynamic monitors

*Compass-HF Trial (follow-up 6 months)*

### Efficacy Objective

<table>
<thead>
<tr>
<th></th>
<th>Chronicle (n =134)</th>
<th>Control (n = 140)</th>
</tr>
</thead>
<tbody>
<tr>
<td># of Pts with Events</td>
<td>41</td>
<td>56</td>
</tr>
<tr>
<td>Total HF Related</td>
<td>74</td>
<td>102</td>
</tr>
<tr>
<td>Events</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitalizations</td>
<td>63</td>
<td>89</td>
</tr>
<tr>
<td>Emergency Department</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>Visits</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Event Rate / 6months*</td>
<td>0.70</td>
<td>0.89</td>
</tr>
<tr>
<td>% Reduction in Event</td>
<td>22% (p=0.27)</td>
<td></td>
</tr>
<tr>
<td>Rate was 1.2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Hypothesized event rate was 1.2

In spite of being measured by a sensor put on the tip of a right ventricular lead, the PEA signal reflects the whole myocardium contractility and it depends mainly on LV contractility, such as LV dp/dt.

(Contractility and Peak Endocardial Acceleration PEA during experimental coronary occlusion – L. Padeletti et al. – 1997)
RESULTS

Best fitting was obtained with a Boltzmann sigmoid curve

OAVD was taken as the inflection point of the sigmoid curve
AV e VV optimal programming in CRT
(area method)

AV Delay (ms)

PEA (g)
CRT Device Optimization with Echo Potential Targets

- Stroke Volume (Aortic VTI)
- Trans-mitral Flow
- Intra-Ventricular Synchrony
VV Optimizing by measuring intrinsic depolarization wave front (D)

QuickOpt™ Algorithm (SJM)
Intracardiac impedance to predict heart failure

Study on 9 pigs in which heart failure was induced by high rate cardiac stimulation

End diastolic and end systolic impedance decreased by 30% after HF induction.
No significant reduction for transthoracic impedance.

Good relationship between intracardiac impedance and end diastolic left ventricular pressure.

Patient has CRT device with wireless transmitter.

Data from device and sensors is automatically and wirelessly transmitted to in-home communicator.

Following Physicians are alerted to device abnormalities, according to customizable rules.

In-home communicator:
- Transmission of all data that physician normally collects during in-office follow-up, e.g., device settings, diagnostics, ECG, battery life, etc.
- Data is uploaded to a server facility, reviewed and archived.
- Call center also provides customer & patient support.

Call center:
- Physicians can access patient & device data from any Internet-enabled PC.
- Patients also have limited access.

External sensors (e.g., weight scale, BP cuff):
- HF patients take daily weight and blood pressure readings.

HF physicians are alerted to significant variations in weight or blood pressure.
Some technical alerts were detected by AIDA, you should consult the PM screen to learn more.