Heart Failure Challenges and Unmet needs

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Heart Failure is one of the most

- common
- disabling
- deadly
- costly

medical conditions encountered by a wide range of physicians in both primary and secondary care
Prevalence and Incidence of Heart Failure

<table>
<thead>
<tr>
<th>Region</th>
<th>Prevalence (Million)</th>
<th>Incidence (/100,000 population)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Western Europe</td>
<td>5.3</td>
<td>1,400</td>
</tr>
<tr>
<td>Eastern Europe</td>
<td>1.3</td>
<td>1,300</td>
</tr>
<tr>
<td>Former USSR</td>
<td>5.6</td>
<td>1,900</td>
</tr>
<tr>
<td>USA</td>
<td>4.9</td>
<td>1,800</td>
</tr>
<tr>
<td>Japan</td>
<td>2.4</td>
<td>1,900</td>
</tr>
<tr>
<td>Other</td>
<td>2.8</td>
<td>1,100</td>
</tr>
<tr>
<td>Worldwide</td>
<td>23</td>
<td></td>
</tr>
</tbody>
</table>

2-3% of the general population

10-20% of people in 70-80 years old

The lifetime risk for developing Heart Failure is 1 in 5 for both men & women

HF incidence in Italy (2004): First admission to Hospital

ANMCO Database
Impact of Heart Failure on Quality of Life

Stewart et al., JAMA 1989
PF=Physical Functioning; RP=Role limitations due to Physical problems; RM=Role limitations due to Mental problems; SF=Social functioning; MH=Mental Health; E=Energy & vitality; P=Pain; HP=general Perceived Health

Hobbs et al. Eur Heart J 2002

Stewart et al., JAMA 1989

CARDIOCENTRICINO
More Malignant Than Cancer?
5-Year survival following a first admission for HF in 1991

Stewart et al., Eur J Heart Fail 3:315;2001
The changing face of heart failure

Owan et al. NEJM 2006
The changing face of heart failure

Most common etiologies of heart failure with Preserved Ejection Fraction
- Aging
- Obesity
- Metabolic syndrome
- Hypertension

Owan et al. NEJM 2006
Healthcare resource utilization is massive

Heart Diseases:
- CHD (40%)
- HF (30%)
- Arrhythmias (20%)
- Miscellaneous (10%)

Bueno et al JAMA 2010; AHA Statistics 2011
Therapeutic goals in heart failure

Asymptomatic phase
- Prevent or slow-down ventricular remodeling (disease progression)

Symptomatic phase
- Improve quality of life
- Reduce hospitalization frequency and duration stay
- Reduce mortality
How to therapeutically approach the disease?

Established Therapies

**Drugs:**
- ACE-inhibitors
- Sartans
- Beta-blockers
- Antialdosterone antagonists
- If-channel blocker (ivabradine)

**Valve repair / Replacement**
- Aortic valve
- Mitral valve

**Cardiac Electronic Implantable Devices**
- Pacemaker
- Implantable Cardioverter-Defibrillator
- Cardiac Resynchronization Therapy

Emerging Therapies

**Renal Denervation**

**Sympathetic / Parasympathetic modulation**
The opportunity: In the era of CRT, heart failure has become a curable disease!

History

72 yrs old lady
Paroxysmal atrial fibrillation
Moderate hypertension
Sleep apnea
Moderate renal failure

- 1st diagnosis HF in 1995
  - No coronary artery disease
  - Optimal drug therapy

- Recurrent episodes of HF decompensation
  - Progressive intolerance to heart failure medication

- CRT-D implantation in 2001

2012: NYHA Class I
Follow-up by home doctor and remotely
No episode of atrial fibrillation since 2001
The opportunity: In the era of CRT, heart failure has become a curable disease!

**History**
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**Phenotype**
- Female
- No CAD
- LBBB on surface ECG
- QRS duration 175 ms

2012: NYHA Class I
Follow-up by home doctor and remotely
No episode of atrial fibrillation since 2001
The challenge: in the era of CRT, heart failure is still an evolving disease!

History

56 yrs old gentleman
Paroxysmal atrial fibrillation
Sleep apnea
Moderate renal failure

- 1st diagnosis HF in 2001
  - PTCA LAD
  - Optimal drug therapy
  - Reduced ejection fraction (LVEF 25%)
  - ICD implantation for primary prevention of SCD in 2002

- Recurrent episodes of HF decompensation
  - Upgrade of ICD to CRT-D in 2005
  - Ablation of paroxysmal atrial fibrillation in 2007

- Frequent hospitalization due to HF decompensation
  - Implantation of MitraClip in 2010

- Persistent symptoms of HF (NYHA class III)
  - Implantation of WiCS system in 2011

NYHA Class II, HF out-patient clinic
## The unmet needs

### Tailoring device therapy

- Enhance response in responders to CRT
- Reduce proportion of non-responders to CRT
  - e.g. electrical and mechanical adjunctive therapies
- Early adoption of more physiological electrical therapies
  - e.g. CRT instead of IPG (therapy conversion)
- More accurate selection of therapy sequence
  - e.g. CRT, MitraClip instead of MitraClip, CRT
- Defining the therapy escalation strategy
- Identification of pheno-/geno-type more susceptible to a given device therapy

### Orphan disease treatment

“No treatment has yet been shown, convincingly, to reduce morbidity and mortality in heart failure patients with preserved ejection fraction…”

“….. Diuretics are used to control sodium and water retention and relieve breathlessness and oedema. Adequate treatment of hypertension and myocardial ischaemia is also considered to be important, as is control of the ventricular rate in patients with AF…”

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### Co-morbidities therapy

- Atrial Fibrillation
- Hypertension
- Sleep apnea
- Renal dysfunction

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Device may play a role

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ESC CPG on HF 2012
Conclusion: Hybrid Therapies in Heart Failure

- CRT-P
- CRT-D
- ICD

Endocardial Wireless Pacing

Neurostimulation

MitraClip

Percutaneous LV plication

Micro implantable RV/LV pump