Advanced Heart Failure
and
VAD

Prof Mauro Rinaldi
<table>
<thead>
<tr>
<th>PROFILE-LEVEL</th>
<th>Official Shorthand</th>
<th>General time frame for support</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTERMACS LEVEL 1</td>
<td>“Crash and burn”</td>
<td>Hours</td>
<td>• Short-term VAD</td>
</tr>
<tr>
<td>INTERMACS LEVEL 2</td>
<td>“Sliding fast”</td>
<td>Days to week</td>
<td>• Long-term LVAD</td>
</tr>
<tr>
<td>INTERMACS LEVEL 3</td>
<td>Stable but Dependent</td>
<td>Weeks</td>
<td></td>
</tr>
<tr>
<td>INTERMACS LEVEL 4</td>
<td>“Frequent flyer”</td>
<td>Weeks to few months, if baseline restored</td>
<td>• Medical therapy</td>
</tr>
<tr>
<td>INTERMACS LEVEL 5</td>
<td>“Housebound”</td>
<td>Weeks to months</td>
<td>• Conventional surgery</td>
</tr>
<tr>
<td>INTERMACS LEVEL 6</td>
<td>“Walking wounded”</td>
<td>Months, if nutrition and activity maintained</td>
<td>• HTx waiting list</td>
</tr>
<tr>
<td>INTERMACS LEVEL 7</td>
<td>Advanced Class III</td>
<td></td>
<td>• Mitraclip??</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Cardioband??</td>
</tr>
</tbody>
</table>
**FOCUS on INTERMACS 1**

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The 2013 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support: Executive Summary

<table>
<thead>
<tr>
<th>INTERMACS profile</th>
<th>Description</th>
<th>Time frame for intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Profile 1</td>
<td>Patients with life-threatening hypotension despite rapidly escalating inotropic support, critical organ hypoperfusion, often confirmed by worsening acidosis and/or lactate levels.</td>
<td>Definitive intervention needed within hours.</td>
</tr>
</tbody>
</table>

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**Recommendations for management of patients with decompensated heart failure:**

*Class I:*

1. Short-term mechanical support, including extracorporeal membrane oxygenation, should be used in acutely decompensated patients who are failing maximal medical therapy.

   **Level of evidence: C.**
Primary VAD screening

- Pre-cardiotomy
- Cardiogenic Shock
  - Inotrope + IABP
  - Post-cardiotomy

Secondary VAD screening

- Short-term VAD
  - Recovery
  - Long-term VAD
    - Bridge To Transplant
    - Destination Therapy
      - Elective Transplant

- BRIDGE to BRIDGE
  - Emergency Transplant
  - Destination Therapy
  - Elective Transplant
“Hub and Spoke” model
Acute Cardiogenic Shock

In-hospital mortality 30-60%

MCS Regional Network

Step 1: Cardiology – Cardiac Surgery (Spoke)

Inhospital mortality rate by time-to-reperfusion in patients with shock. The inpatient mortality rate increases progressively with increasing time-to-reperfusion.

Brodie Am Heart J 2003
Cardiogenic Shock: clinical definition

- **Unresponsive Hypotension**
  - Prolonged MAP < 60 mmhg for > 30 min (or decrease in SBP more than 40 mmhg)
  - CI < 1.8 l/min/m² or < 2.2 l/min/m² with inotropic support

- **High filling pressures**
  - CVP > 14 mmhg
  - Wedge pressure > 16 mmhg

- **Inadequate tissue perfusion**
  - SVO2 < 55; Lactate continuously increase (or > 3)
  - Alteration in consciousness
  - Urine output < 30 cc/h
MCS Regional Network

Step 1: Cardiology – Cardiac Surgery (Spoke)

- **Acute Cardiogenic Shock**
  - Inotropic drugs
  - IABP
  - Early revascularization

- **Refractory Cardiogenic Shock**
  - Short-term VAD
  - In hospital mortality > 90%

- LOS despite 2 high dose inotropic drugs and IABP
  - As soon as possible (<12 hours)

Get in touch with the hub centre activating the Regional Network

Inhospital mortality 40-60%
## Currently available percutaneous MCS

<table>
<thead>
<tr>
<th></th>
<th>iVAC 2L&lt;sup&gt;®&lt;/sup&gt;</th>
<th>TandemHeart™</th>
<th>Impella&lt;sup&gt;®&lt;/sup&gt; 5.0</th>
<th>Impella&lt;sup&gt;®&lt;/sup&gt; 2.5</th>
<th>Impella&lt;sup&gt;®&lt;/sup&gt; CP</th>
<th>ECLS (multiple systems)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Catheter size (F)</strong></td>
<td>11 (expandable)</td>
<td>–</td>
<td>9</td>
<td>9</td>
<td>9</td>
<td>17–21 venous</td>
</tr>
<tr>
<td><strong>Cannula size (F)</strong></td>
<td>17</td>
<td>21 venous</td>
<td>21</td>
<td>12</td>
<td>12</td>
<td>16–19 arterial</td>
</tr>
<tr>
<td><strong>Flow (L/min)</strong></td>
<td>Max. 2.8</td>
<td>Max. 4.0</td>
<td>Max. 5.0</td>
<td>Max. 2.5</td>
<td>Max. 3.7–4.0</td>
<td>Max. 7.0</td>
</tr>
<tr>
<td><strong>Pump speed (rpm)</strong></td>
<td>Pulsatile, 40 mL/beat</td>
<td>Max. 7500</td>
<td>Max. 33 000</td>
<td>Max. 51 000</td>
<td>Max. 51 000</td>
<td>Max. 5000</td>
</tr>
<tr>
<td><strong>Insertion/placement</strong></td>
<td>Percutaneous (femoral artery)</td>
<td>Percutaneous (femoral artery + vein for left atrium)</td>
<td>Peripheral surgical (femoral artery)</td>
<td>Percutaneous (femoral artery)</td>
<td>Percutaneous (femoral artery)</td>
<td>Percutaneous (femoral artery + vein)</td>
</tr>
<tr>
<td><strong>LV unloading</strong></td>
<td>+</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>–</td>
</tr>
<tr>
<td><strong>Anticoagulation</strong></td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td><strong>Recommended duration of use</strong></td>
<td>–21 days</td>
<td>–14 days</td>
<td>10 days</td>
<td>10 days</td>
<td>10 days</td>
<td>–7 days</td>
</tr>
<tr>
<td><strong>CE-certification</strong></td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td><strong>FDA</strong></td>
<td>–</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td><strong>Relative costs</strong></td>
<td>++</td>
<td>+++++++</td>
<td>++++</td>
<td>++++</td>
<td>++++</td>
<td>+(+)+</td>
</tr>
</tbody>
</table>

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Peripheral precutaneous ECMO

**Distal perfusion**
8-10 fr
200 cc/min
Femoral artery

**Arterial cannula**
18-22 fr Edwards
High flow, multiperforated flexible

**Venous cannula**
22-24 fr Edwards multiperforated
2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care (Endorsed by the American Heart Association, the Cardiological Society of India, and Sociedad Latino Americana de Cardiologia Intervencion; Affirmation of Value by the Canadian Association of Interventional Cardiology—Association Canadienne de Cardiologie d’intervention)
Left ventricular overload on ECMO

2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care (Endorsed by the American Heart Association, the Cardiological Society of India, and Sociedad Latino Americana de Cardiologia Intervencion; Affirmation of Value by the Canadian Association of Interventional Cardiology—Association Canadienne de Cardiologie d’intervention)
Left ventricular unloading

- Subendocardial ischemia
- LV end-diastolic increasing
- LV overloading
- LV impairment
Anterolateral Mini left thoracotomy
Right Ventricular and Pulmonary Function Evaluation
switch from V-A ECMO to A-A Centrifugal Pump

Right Atrium -> LV apex

Femoral artery

Centrifugal pump

Oxigenator
Right Ventricular and Pulmonary Function Evaluation

switch from V-A ECMO to A-A Centrifugal Pump

Right Atrium → LV apex → Femoral artery

Centrifugal pump → Oxigenator
Right Ventricular and Pulmonary Function Evaluation
switch from V-A ECMO to A-A Centrifugal Pump

Right Atrium
LV apex
Femoral artery

Right Ventricular Function Evaluation
Centrifugal pump

Oximeter
Pulmonary Function Evaluation
Right Ventricular and Pulmonary Function Evaluation

switch from V-A ECMO to A-A Centrifugal Pump

LV apex

Femoral artery

Centrifugal pump
Piemonte Regional Network
2008 – 2017
192 pazienti
25 centri afferenti: 7 fuori regione

Ospedale di Alessandria
Ospedale di Novara
Ospedale di Cuneo
Ospedale di Rivoli

Ospedale di Moncalieri
Ospedale di Aosta
Ospedale di Perugia
Ospedale di Asti

Ospedale di Alba
Ospedale di Potenza
Ospedale di Biella
Ospedale San Luigi

Ospedale di Pinerolo
Ospedale di Cosenza
Ospedale di Cirìè
Ospedale di Chieri

Ospedale di Genova
Fondazione Maugeri di Veruno/Torino
Centro Cardiologico Monzino
Policlinico di Bari

Torino - Ospedale Maria Vittoria
Torino - Ospedale Sant'Anna
Torino - Ospedale San Giovanni Bosco
Torino - Ospedale Mauriziano

Torino - Molinette
Piemonte Regional Network

Etiologia

- Post-ischemica: 47%
- CMPD a coronarie sane: 21%
- Valvolare: 3%
- Post-miocardite: 5%
- Altro: 3%
- Postcardiotomica: 21%
**VA ECMO in Cadiogenic shock**

**MCS Piemonte Regional Network**

n= 146 patients INTERMACS level 1 2008-2017

<table>
<thead>
<tr>
<th>Results</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>52 /146</td>
<td>36%</td>
</tr>
<tr>
<td>Recovery</td>
<td>50 /146</td>
<td>34%</td>
</tr>
<tr>
<td>Bridge to emergency transplant</td>
<td>32 /146</td>
<td>22%</td>
</tr>
<tr>
<td>Bridge to long term LVAD</td>
<td>12 /146</td>
<td>8%</td>
</tr>
<tr>
<td><strong>Survival to discharge</strong></td>
<td>84 /146</td>
<td>57%</td>
</tr>
</tbody>
</table>
VA ECMO in Cadiogenic shock
MCS Piemonte Regional Network

n= 146 patients INTERMACS level 1

Results

Sepsis
Positive blood cultures and Clinical signs of infection

Major bleedings
Surgical revision or evidence of bleeding > 4 blood units transfusion
# VAD/ECMO Risk factors for death

## Multivariate analysis

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postcardiotomic</td>
<td>0.003</td>
</tr>
<tr>
<td><strong>No left ventricular venting</strong></td>
<td>0.01</td>
</tr>
<tr>
<td>Central approach</td>
<td>0.01</td>
</tr>
<tr>
<td>External ECMO</td>
<td>0.22</td>
</tr>
<tr>
<td><strong>Instable ECMO</strong></td>
<td>0.02</td>
</tr>
<tr>
<td>Previous cardiac arrest (CPR)</td>
<td>0.15</td>
</tr>
<tr>
<td>Miocardial infarction</td>
<td>0.32</td>
</tr>
<tr>
<td>Previous MOF</td>
<td>0.04</td>
</tr>
</tbody>
</table>
VADs/ECMO changing outcomes
Turin Experience 2005-2017

- Regional Network
- Increasing Experience
- Systematic LV venting
Piemonte Regional Network Experience

Durable LVAD (81 pts) - Implants per year

until September
Piemonte Regional Network Experience
Long term LVAD

**Gender**

- Femmina: 56
- Maschio: 8

**Etiology**

- CMPD post-ischemica: 26
- CMPD idiopatica: 1
- CMPD valvolare: 1
- CMP ostruttiva: 36

**Age**

- 20-29: 1
- 30-39: 3
- 40-49: 12
- 50-59: 13
- 60-69: 30
- 70-75: 5

**INTERMACS profile**

- n° 1: 10
- n° 2: 16
- n° 3: 26
- n° 4: 8
- n° 5: 0
- n° 6: 4
- n° 7: 0

- Femmina: 56
- Maschio: 8

- CMPD post-ischemica: 26
- CMPD idiopatica: 1
- CMPD valvolare: 1
- CMP ostruttiva: 36

- 20-29: 1
- 30-39: 3
- 40-49: 12
- 50-59: 13
- 60-69: 30
- 70-75: 5

- n° 1: 10
- n° 2: 16
- n° 3: 26
- n° 4: 8
- n° 5: 0
- n° 6: 4
- n° 7: 0
Piemonte Regional Network Experience
Durable LVAD (81 pts)

New generation devices
### Piemonte Regional Network Experience
**Long term LVAD**

<table>
<thead>
<tr>
<th>In hospital mortality</th>
<th>Others LVAD</th>
<th>3/28</th>
<th>11%</th>
</tr>
</thead>
<tbody>
<tr>
<td>HVAD + HM III</td>
<td></td>
<td>2/53</td>
<td>3%</td>
</tr>
<tr>
<td>Total Mortality</td>
<td></td>
<td>5/81</td>
<td>6.0%</td>
</tr>
</tbody>
</table>
Piemonte Regional Network Experience HeartWare – HVAD and Heartmate III

Surgical approaches

53 LVAD implantations

- Thoracotomy 100% redo
- DoubleMini-Thorac 75% redo

Surgical approaches:
- Sternotomy
- Minist/MiniThorac
- MiniThorac/MiniThorac
- Thoracotomy

Thoracotomy 100% redo
DoubleMini-Thorac 75% redo
Minimally invasive LVAD implantation

Bridge to transplant
Complex redo surgery

Double minithoracotomy and subcostal approach
Minimally invasive LVAD implantation
Piemonte Regional Network Experience
HeartWare – HVAD (44 patients)

KM - HVAD Censored (HTx/Recovery)

Censored

0  2  4  6  8  10  12  14  16  18  20  22  24  26  28  30  32  34  36

Months

77%

67%

53%

42%

21%

SHFM
Piemonte Regional Network Experience
HeartWare - HVAD

ITT HVAD (44 pts)

KM - HVAD ITT Censored

BTT  DT  BTC
# Piemonte Regional Network Experience
## HeartWare - HVAD

HVAD Implants n = 44, deaths = 13

<table>
<thead>
<tr>
<th>Primary cause/mode of death</th>
<th>n</th>
<th>%</th>
<th>Mean time (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurologic event</td>
<td>5</td>
<td>11.4</td>
<td>14.4</td>
</tr>
<tr>
<td>Right Heart Failure</td>
<td>2</td>
<td>4.5</td>
<td>39</td>
</tr>
<tr>
<td>Major infection</td>
<td>1</td>
<td>2.3</td>
<td>2</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>1</td>
<td>2.3</td>
<td>12</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>1</td>
<td>2.3</td>
<td>8</td>
</tr>
<tr>
<td>Multisystem Organ Failure</td>
<td>1</td>
<td>2.3</td>
<td>47</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>4.5</td>
<td>15.5</td>
</tr>
</tbody>
</table>
Long term LVAD Follow-up
81 implants

Mean Follow-up 22.68 ±14.48 months
Mean Follow-up 681 days
Mean Hospital Stay 40.3 days

Hospital/home days

94% Home
6% Hospital
IDEAL VAD

- Biocompatible
- Reduced dimension
- Reliable (10 million beats/years or 4 billion cycles/years)
- Low energy requirements
- Easy to implant and.....to explant
- Allowing the discharge of the patient
- Cheap.....