Device Therapy for Heart Failure

Dr. Shelley Zieroth FRCPC
Assistant Professor, Cardiology, University of Manitoba
Director of Cardiac Transplant and Heart Failure Clinics
St Boniface General Hospital, Winnipeg, MB
Head, Medical Heart Failure Program
WRHA Cardiac Sciences Program
Objectives

- ICD
- CRT (BIV pacers)
- VADs
  (ventricular assist devices) and
- MCS
  (mechanical circulatory support)
General Rx Strategies in HF

<table>
<thead>
<tr>
<th>Asymptomatic</th>
<th>Mild/Mod</th>
<th>Severe</th>
<th>Refractory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angiotensin Converting Enzyme Inhibitors/ARB</td>
<td>β-Blockers – carvedilol, metoprolol, bisoprolol</td>
<td>Diuretics</td>
<td>VAD, Tx</td>
</tr>
<tr>
<td>Beta Blockers</td>
<td>Dig + Spironolactone</td>
<td>Tailored Rx</td>
<td>CRT</td>
</tr>
<tr>
<td>Correct Cause:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arrhythmias</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ischemia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pressure Load</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICD as indicated</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Asymptomatic - Mild/Mod - Severe - Refractory

Correct Cause:
- Arrhythmias
- Ischemia
- Pressure Load
- ICD as indicated

VAD, Tx
Tailored Rx
CRT
Diuretics

β-Blockers – carvedilol, metoprolol, bisoprolol

No Added Salt → 1.5 - 2 gm Na
Activity as Tolerated → Customized Ex Training

Modified from Warner-Stevenson, ACC HF Summit
Cardio-Renal Syndrome

Increased Morbidity and Mortality

Development of Diuretic and Natriuretic Resistance

Impaired Renal Function

Diuretic Therapy

Neurohormonal Activation

Diminished Blood Flow

Decreased Renal Perfusion

Courtesy CHFsolutions website
Ultrafiltration

- Superior wt loss
- Improved and sustained symptom control
- No increase adverse biochemical events

Resources Utilization for HF in 90 Days

<table>
<thead>
<tr>
<th>Resource</th>
<th>UF</th>
<th>SC</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients rehospitalized (%)</td>
<td>18</td>
<td>32</td>
<td>.022</td>
</tr>
<tr>
<td>Rehospitalizations/Patient</td>
<td>0.22</td>
<td>0.46</td>
<td>.037</td>
</tr>
<tr>
<td>Number of rehospitalization days per patient</td>
<td>1.4</td>
<td>3.8</td>
<td>.022</td>
</tr>
<tr>
<td>Days rehospitalized</td>
<td>123</td>
<td>330</td>
<td>.022</td>
</tr>
<tr>
<td>Unscheduled office + ED visits (%)</td>
<td>21</td>
<td>44</td>
<td>.009</td>
</tr>
</tbody>
</table>

Diamonds.....
Devices are A Heart Failure
Doc’s Best Friend

Part 1: ICD’s and CRT
ICDs Reduce Mortality

SCD-HeFT 23% RRR
MADIT-II 31% RRR
MADIT-I 54% RRR
A recent technology assessment document for a Canadian insurance company estimated a cost effectiveness of ICD’s:
- $37,000 / life-year gained
- $51,000 / quality adjusted life-year gained

Current (May 2007) cost estimates per device:
- ICD $26,075
- CRT/ICD $31,665 (a mere $5,590 more than ICD alone)
ICD Statistics: Primary Prevention

For every 100 patients with an ICD for Primary Prevention over 5 years:

- 6-7 deaths prevented
- 30 die regardless
- 15-20 have an inappropriate shock
- 10-15 complications of device (implant or future)
- 30 nothing will happen
CRT
Cardiac Resynchronization Therapy
Hemodynamic Effects of Bi-ventricular Pacing

- Increased LV ejection fraction and fractional shortening
- Increased cardiac output
- Prolonged diastole and LV filling time
- Reduced LV end diastolic and end systolic volumes
- Increased LV synchrony and pulse pressure
- Increased peak oxygen uptake
- Decreased PCWP
- Decreased MR

- Decreased apoptosis and interstitial remodeling
- Decreased TNF-α

Patients with symptomatic (NYHA III-IV) HF despite OMM, and who are in normal sinus rhythm with a QRS duration ≥120 msec and an LVEF ≤35%, (Class I, Level A)


Device Referral Algorithm

1° prevention ICD

LVEF ≤ 35%

Non-ischemic CMO For min 9 mos

NYHA II-III (I??)

Refer for ICD consideration. Unless contraindicated

Ischemic**

CRT/BIV

LVEF ≤ 35%

CMO with QRS ≥120ms and NSR (or rate controlled afib)

NYHA III-IV

Refer for CRT +/-ICD consideration, Unless contraindicated

** LVEF 30 d post MI or 90 days post revascularization
Echo Dyssynchrony

Pre-CRT

Post-CRT
Diamonds.....
Devices are A Heart Failure
Doc's Best Friend

Part 2: VADS
Mechanical Circulatory Support

Left Ventricular Assist Device/System

- Short Term Support
  - LV Recovery
  - Device Removal

- Long-Term Support and “Destination Therapy”

Intermediate Support
- Bridge to Transplant
- and Transplant Candidacy
ECMO: Extracorporeal Membranous Oxygenation

- V-V (primary lung)
- V-A (primary heart)
- Peripheral or central cannulation
ECMO: Post-Cardiotomy Shock

74% alive at 5 years
24% survive to discharge

Fig 1. Kaplan-Meier survival curve of all patients who received extracorporeal membrane oxygenation (ECMO).

Recovery Devices (Short Term)

- Levitronix Centrimag Pump
- Impella LP
- Impella LD +RD
- BVS 5000 Pump
- AB5000 Ventricle
Longterm Devices

- Novacor LVAD
- Levacor
- HeartMate II
REMATCH RESULTS

LVAD vs OMM

1 yr p=0.002
2 yr p=0.09
## VAD Survival and Complications

**INTERMACS: Jun 23, 2006 – May 31, 2007**

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Episodes</th>
<th>Patients</th>
<th>% of 204</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Malfunction</td>
<td>24</td>
<td>18</td>
<td>9.8%</td>
</tr>
<tr>
<td>Bleeding</td>
<td>148</td>
<td>76</td>
<td>37.2%</td>
</tr>
<tr>
<td>Cardiac/Vascular</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right Heart Failure</td>
<td>13</td>
<td>13</td>
<td>6.4%</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>0</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Cardiac Arrhythmia</td>
<td>60</td>
<td>40</td>
<td>19.6%</td>
</tr>
<tr>
<td>Pericardial Drainage</td>
<td>17</td>
<td>14</td>
<td>6.8%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>34</td>
<td>31</td>
<td>15.2%</td>
</tr>
<tr>
<td>Arterial Non-CNS Thromb</td>
<td>3</td>
<td>3</td>
<td>1.5%</td>
</tr>
<tr>
<td>Venous Thromb Event</td>
<td>11</td>
<td>10</td>
<td>4.9%</td>
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<tr>
<td>Hemolysis</td>
<td>8</td>
<td>6</td>
<td>2.9%</td>
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<tr>
<td>Infection</td>
<td>136</td>
<td>77</td>
<td>37.7%</td>
</tr>
<tr>
<td>Neurologic Dysfunction</td>
<td>49</td>
<td>39</td>
<td>19.1%</td>
</tr>
<tr>
<td>Renal Dysfunction</td>
<td>39</td>
<td>34</td>
<td>16.7%</td>
</tr>
<tr>
<td>Hepatic Dysfunction</td>
<td>20</td>
<td>16</td>
<td>12.8%</td>
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<tr>
<td>Respiratory Failure</td>
<td>56</td>
<td>42</td>
<td>20.6%</td>
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<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wound Dehiscence</td>
<td>4</td>
<td>3</td>
<td>1.5%</td>
</tr>
<tr>
<td>Psychiatric Episode</td>
<td>13</td>
<td>12</td>
<td>5.9%</td>
</tr>
<tr>
<td>Other AEs</td>
<td>75</td>
<td>50</td>
<td>24.5%</td>
</tr>
</tbody>
</table>

**Total AEs (prospective)** 710
REMATCH RESULTS

- LVAD
- OMM
- OHTx
- RM Late
- Post RM
- Lung Tx
CCTN: Mechanical Circulatory Support (VAD/Impella+ECMO) Algorithm

Potential MCS Candidate
- Bridge to recovery, candidacy, transplant

- marginal hemodynamics
  CI < 2.0 L/min/m²
  PCWP > 20 mmHg
  MvO₂ < 60%
  U/O < 30cc/hr x 2hrs

- maximal medical therapy, eg
  Dobutamine > 5 ug/kg/min
  Milrinone > 0.5 ug/kg/min
Conclusion

Device therapy has revolutionized advanced heart failure treatment.

Mechanical circulatory support or ventricular assist devices can be useful as:
- Bridge to Transplant
- Bridge to Recovery
- Potential for Destination Therapy