Mechanical Circulatory Support (MCS): What Every Pharmacist Needs to Know!

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Disclosures

Research Funding
Bristol-Myers Squibb (Eliquis)
Texas Department of Public Health (Opioids)

Advisory Board
La Jolla Pharmaceuticals (Giaprezza)
Objectives

At the completion of this activity, the **pharmacist** participant will be able to:
• Discuss the function of various MCS devices
• Evaluate the appropriateness of different MCS devices in a given patient population
• Compare and contrast different pharmacotherapy required based on the type of MCS device and patient-specific characteristics.

At the completion of this activity, the **technician** participant will be able to:
• Identify different types of MCS
• Describe how MCS devices improve blood flow
• Discuss anti-coagulation requirements for a given MCS device
What is MCS?

• Assistance (mechanical) in helping the heart to provide an adequate cardiac output

• Recent increase in implants, device technology and long term management

• Pharmacy personnel may see patients with MCS in the ambulatory care, community or inpatient settings
Outline

• Intra-aortic Balloon Pump (IABP)

• Ventricular Assist Device (VAD)
  – Spend most of our time here

• Extra-corporeal Membrane Oxygenation (ECMO)
MCS Treatment Strategies

Mechanical afterload reduction
- Make it easier for heart to pump, but not actually pump for heart

Heart Pump
- Take over majority of heart pumping function from native ventricle
Intra-aortic Balloon Pump (IABP)

- Indications: Myocardial infarction +/- cardiogenic shock, heart failure

- Mechanism of action
  - Mechanical afterload reduction
  - Increased coronary artery perfusion
  - Does NOT provide pumping function

- Improves hemodynamic parameters
  - No effect on mortality or outcomes

Cochrane Database Syst Rev. 2015 Mar 27;(3).
# IABP-SHOCK-II Trial

## Table 3. Clinical Outcomes.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>IABP (N=300)</th>
<th>Control (N=298)</th>
<th>P Value</th>
<th>Relative Risk with IABP (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary end point: all-cause mortality at 30 days</td>
<td>119 (39.7%)</td>
<td>123 (41.3%)</td>
<td>0.69</td>
<td>0.96 (0.79–1.17)</td>
</tr>
<tr>
<td>Reinfarction in hospital</td>
<td>9 (3.0%)</td>
<td>4 (1.3%)</td>
<td>0.16</td>
<td>2.24 (0.70–7.18)</td>
</tr>
<tr>
<td>Stent thrombosis in hospital</td>
<td>4 (1.3%)</td>
<td>3 (1.0%)</td>
<td>0.71</td>
<td>1.32 (0.30–5.87)</td>
</tr>
<tr>
<td>Stroke in hospital</td>
<td>2 (0.7%)</td>
<td>5 (1.7%)</td>
<td>0.28</td>
<td>0.40 (0.08–2.03)</td>
</tr>
<tr>
<td>Ischemic</td>
<td>2 (0.7%)</td>
<td>4 (1.3%)</td>
<td>0.45</td>
<td>0.49 (0.09–2.71)</td>
</tr>
<tr>
<td>Hemorrhagic</td>
<td>0</td>
<td>1 (0.3%)</td>
<td>0.50</td>
<td>—</td>
</tr>
<tr>
<td>Peripheral ischemic complications requiring intervention in hospital</td>
<td>13 (4.3%)</td>
<td>10 (3.4%)</td>
<td>0.53</td>
<td>1.29 (0.58–2.90)</td>
</tr>
<tr>
<td>Bleeding in hospital*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Life-threatening or severe</td>
<td>10 (3.3%)</td>
<td>13 (4.4%)</td>
<td>0.51</td>
<td>0.76 (0.34–1.72)</td>
</tr>
<tr>
<td>Moderate</td>
<td>52 (17.3%)</td>
<td>49 (16.4%)</td>
<td>0.77</td>
<td>1.05 (0.74–1.50)</td>
</tr>
<tr>
<td>Sepsis in hospital</td>
<td>47 (15.7%)</td>
<td>61 (20.5%)</td>
<td>0.15</td>
<td>0.77 (0.54–1.08)</td>
</tr>
</tbody>
</table>

Pharmacy Implications

• Requires anticoagulation
• Limb ischemia
• Bleeding/thrombocytopenia
  – Difficult to distinguish HIT
• Infections

• Longer duration = higher risk of side effects
Ventricular Assist Devices

• Mechanical device that pumps blood for the heart to vital organs

• Two categories of VADs
  – Percutaneous → (short term)
  – Surgical → (longer term)

• Effective at increasing cardiac output but have severe adverse effects associated with use
Percutaneous VADs

Impella (Abiomed)

Tandem Heart (Cardiac Assist Technologies)

Percutaneous VADs

- Indications (short term)
  - Myocardial Infarction with cardiogenic shock
  - Intra-operative support (high risk patients)

- Complications
  - Bleeding
  - Bloodstream infections
  - Valve damage
  - Risk of stroke
  - Hemolysis
  - Renal failure
Impella® Purge Solution

• Requires purge solution through system
  – Flows in opposite direction of blood being drawn into the catheter
  – Creates a pressure barrier that prevents blood from entering the device motor

• Standard Purge Solution
  – 5% Dextrose with 50 units/ml heparin
    • Can increase to D20% to increase viscosity and decrease purge flow
    • Do NOT use normal saline as purge solution
Surgical VADs

• Indications
  – End-stage heart failure (refractory)
  – Rescue or salvage therapy

• Bridge to Transplant
  – Get transplant or listed for transplant

• Destination Therapy
  – Patients who are not transplant candidates
    • Improve quality of life, symptoms
Types of LVADs

HeartWare® device and Controller

HeartMate 3™
Pharmacy Implications

• Require anticoagulation to prevent thrombosis
  – Heparin for short term VADS
  – Warfarin for surgical VADs
    • INR goal 2-3, some use lower 2-2.5

• Infections
  – Driveline infection, may require replacement

• Hemolysis
  – Monitor LDH

• CPR?
LVAD Education: Blood Pressure Maintenance
2,562 views

Sentara Advanced Heart Failure Center provides ongoing patient education for our VAD patients.

https://www.youtube.com/watch?v=c-Vj-0veNso
Extracorporeal Membrane Oxygenation

• Highest level of life support
  – Not available everywhere
  – Last line, high mortality

• Provides gas exchange of blood (oxygenation/ventilation)
  – +/- cardiac output (Veno-arterial ECMO)

• Indications:
  – Respiratory failure (hypoxic or hypercapnic)
  – Cardiogenic shock
  – Pulmonary hypertension/embolism with right heart failure
  – Bridge to decision for VAD/transplant

Figure 1. Central ECMO cannulation.

Figure 2. Peripheral ECMO cannulation.
Pharmacy Implications

• Hematologic complications
  – Coagulopathy
    • Hemolysis, thrombocytopenia, DIC; thrombosis
    • Bleeding risk from cannula and anticoagulation
    • Heparin commonly used, aPTT 60-80 secs

• Infection
• Limb ischemia
• Drug dosing
Drug Dosing in ECMO

Drug
Effect

Organ dysfunction
Disease state

Dilution/Vd
ECMO circuit
Increased cardiac output
Disease state

Dzierba AL, et al. Crit Care 2017;21
Drug Dosing in ECMO

• Lack of studies with clinical endpoints
  – Most measure drug levels, not outcomes

• Recommendations:
  – Utilize therapeutic drug monitoring when available
    • Many drug require higher doses
  – Avoid lipophilic drugs
  – Rely of PK data

Dzierba AL, et al. Crit Care 2017;21
Knowledge Assessment

Which of the following mechanical circulatory support devices doesn’t act as a pump for the heart, but makes it easier for the heart to pump?

a. Intra-aortic balloon pump
b. Ventricular assist device
c. Extra-corporeal membrane oxygenation
Knowledge Assessment

Medication dosing is effected the greatest when using which of the following MCS modalities?

a. Intra-aortic balloon pump
b. Ventricular assist device
c. Extra-corporeal membrane oxygenation
Additional Resources

• 2013 International Society for Heart and Lung Transplantation Guidelines for mechanical circulatory support.

• Extracorporeal Life Support Organization
  – www.elso.org

• Interagency Registry for Mechanically Assisted Circulatory Support
  – https://www.uab.edu/medicine/intermacs/

Questions?

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MAWanat@uh.edu
Additional Slides
<table>
<thead>
<tr>
<th>Baseline Variable</th>
<th>No. of Patients</th>
<th>IABP 30-day mortality (%)</th>
<th>Control 30-day mortality (%)</th>
<th>Relative Risk (95% CI)</th>
<th>P Value for Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>187</td>
<td>44.4</td>
<td>43.2</td>
<td>1.03 (0.74–1.43)</td>
<td>0.61</td>
</tr>
<tr>
<td>Male</td>
<td>411</td>
<td>37.3</td>
<td>40.5</td>
<td>0.92 (0.72–1.18)</td>
<td></td>
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<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;50 yr</td>
<td>70</td>
<td>19.4</td>
<td>44.1</td>
<td>0.44 (0.21–0.95)</td>
<td>0.09</td>
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<tr>
<td>50–75 yr</td>
<td>334</td>
<td>34.6</td>
<td>36.5</td>
<td>0.95 (0.71–1.27)</td>
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<tr>
<td>&gt;75 yr</td>
<td>184</td>
<td>53.7</td>
<td>50.0</td>
<td>1.07 (0.81–1.41)</td>
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<tr>
<td>Diabetes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>195</td>
<td>42.9</td>
<td>46.7</td>
<td>0.92 (0.67–1.26)</td>
<td>0.82</td>
</tr>
<tr>
<td>No</td>
<td>399</td>
<td>37.2</td>
<td>38.9</td>
<td>0.96 (0.74–1.23)</td>
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<tr>
<td>Hypertension</td>
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<tr>
<td>Yes</td>
<td>410</td>
<td>42.9</td>
<td>40.4</td>
<td>1.06 (0.84–1.34)</td>
<td>0.05</td>
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<tr>
<td>No</td>
<td>183</td>
<td>28.9</td>
<td>43.0</td>
<td>0.67 (0.45–1.01)</td>
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<td>Type of MI</td>
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<tr>
<td>STEMI/LBBB</td>
<td>412</td>
<td>41.0</td>
<td>42.9</td>
<td>0.96 (0.77–1.21)</td>
<td>0.76</td>
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<tr>
<td>Non-STEMI</td>
<td>177</td>
<td>37.5</td>
<td>38.3</td>
<td>0.98 (0.67–1.43)</td>
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<tr>
<td>STEMI type</td>
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<tr>
<td>Anterior</td>
<td>216</td>
<td>35.4</td>
<td>43.7</td>
<td>0.81 (0.58–1.13)</td>
<td>0.14</td>
</tr>
<tr>
<td>Nonanterior</td>
<td>196</td>
<td>48.3</td>
<td>42.2</td>
<td>1.16 (0.85–1.57)</td>
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<tr>
<td>Previous infarction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Yes</td>
<td>131</td>
<td>47.9</td>
<td>33.3</td>
<td>1.44 (0.93–2.11)</td>
<td>0.04</td>
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<tr>
<td>No</td>
<td>466</td>
<td>37.3</td>
<td>43.3</td>
<td>0.86 (0.69–1.07)</td>
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<tr>
<td>Hypothermia</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Yes</td>
<td>226</td>
<td>48.1</td>
<td>44.2</td>
<td>1.09 (0.82–1.44)</td>
<td>0.31</td>
</tr>
<tr>
<td>No</td>
<td>372</td>
<td>35.1</td>
<td>39.3</td>
<td>0.89 (0.68–1.16)</td>
<td></td>
</tr>
<tr>
<td>Blood pressure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;80 mm Hg</td>
<td>161</td>
<td>50.7</td>
<td>46.4</td>
<td>1.08 (0.79–1.50)</td>
<td>0.76</td>
</tr>
<tr>
<td>≥80 mm Hg</td>
<td>432</td>
<td>35.9</td>
<td>39.2</td>
<td>0.92 (0.72–1.17)</td>
<td></td>
</tr>
</tbody>
</table>
Intermacs - Implants per Year by Device Type
Primary Prospective Implants: June 23, 2006 to September 30, 2017

Device Type: LVAD, RVAD, BiVAD, TAH

Number of Implants per Year

Year


78 238 1171 3 68 22 1 83 30 100 24 2 84 29 1 104 25 3 77 39 2 109 1 129 55 4 123 53 1 91 48 1 62 13

3000
2500
2000
1500
1000
500
0
Exhibit 6: Patient Profile at Time of Implant by Implant Period

Patient profile status provides a general clinical description of the patients at the time of implantation.

<table>
<thead>
<tr>
<th>PATIENT PROFILE AT TIME OF IMPLANT</th>
<th>IMPLANT DATE PERIOD</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 2010</td>
<td>2010 - 2013</td>
</tr>
<tr>
<td>Critical Cardiogenic Shock</td>
<td>632</td>
<td>1253</td>
</tr>
<tr>
<td>Progressive Decline</td>
<td>914</td>
<td>3192</td>
</tr>
<tr>
<td>Stable but Inotrope Dependent</td>
<td>330</td>
<td>2415</td>
</tr>
<tr>
<td>Resting Symptoms</td>
<td>196</td>
<td>1214</td>
</tr>
<tr>
<td>Exertion Intolerant</td>
<td>42</td>
<td>244</td>
</tr>
<tr>
<td>Exertion Limited</td>
<td>23</td>
<td>109</td>
</tr>
<tr>
<td>Advanced NYHA Class 3</td>
<td>19</td>
<td>55</td>
</tr>
<tr>
<td>Unspecified</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>TOTAL</td>
<td>2156</td>
<td>8486</td>
</tr>
</tbody>
</table>

INTERMACS September 2017 Report