Five Pearls of Cardiac Devices

1. Consider Chronotropy (CO = SV x HR)
2. Define Trajectory (and keep defining it)
3. Respect the Vitals (and don’t walk away)
4. Define Risk (including risk of doing nil)
5. Device (Know how they work and pitfalls)
76 yo AA F
Presents with Chest Pain
Presenting ECG (11:49 PM)
Post-VF arrest ECG (12:01 AM)
Proximal LAD Thrombus
Post-PCI Angiography
Right Heart Catheterization
Cardiac Index = 2.81 L/min/m²

- Aortic
  - PaO₂ 81%
- Pulmonary
  - PaO₂ 54%
Pearl #1: Chronotropy

• CO = HR x Stroke Volume

-Thus, if you DOUBLE the heart rate you will DOUBLE the cardiac output
-Increasing the HR is much easier than increasing the stroke volume--but requires a high energy price
Post-Arrest CXR
Post-Cath Lab
Data Summary

• Post – VF arrest, complete heart block
• Abciximab and RV temp wire started
• Prox LAD thrombus, PCI → sinus tach
• 3.5 x 15 mm Xience DES
• Diagonal angioplasty Trek 2.5 x 8 mm
• TIMI 3 flow
• IABP with improved hemodynamics
• Evolving respiratory failure / shock
Pearl # 2: Trajectory

“Nothing stays the same in the ICU”

• Acute, severe respiratory failure
• Rising pressor / inotrope requirement
• Post-PCI shock
• End-organ hypoperfusion
Pearl #3: Assess “Vitals”

• **Obvious**: Temp, HR, BP, O2 Sat
• **Less Obvious**: mental status, UOP, breathing pattern, pulse pressure
• **Vital monitoring**: 12L EKG, telemetry
• **Vital labs**: pH (VBG often faster than ABG) lactate, BUN, LFTs, INR, trop, CK
  
  – CORRELATE TIMING OF LABS WITH SITUATION
Options

A. Continue IABP, Mech. Vent, vasopressors
B. Return to cath lab for Impella 2.5
C. Go to the OR for HeartMate II
D. Go to the OR for axillary Impella 5.0
E. Initiate extracorporeal membrane oxygenation (ECMO)
F. Consult palliative care
“To do nothing for the gomers was to do something, and the more conscientiously I did nothing the better they got.”

-Samuel Shem

The House of God
The Mechanical Revolution

• First year of medical school (2003)
  – PA catheter + IABP (Pre-ESCAPE, SHOCK II)

• Internship (2007)
  – Occasional Tandem Heart, Impella
  – Durable LVAD uncommon

• Advanced HF Fellowship (2012-2014)
  – Axial and centrifugal CF-LVADs exploding
  – One-year survival approaching 90%
  – Impella 2.5, Impella 5.0, VA-ECMO common
Left Ventricular Assist Devices
Low-Profile Long-Term Support

A (Patients can be fully mobile)

Left ventricular assist device (LVAD) connected to heart

Battery

A cable connects the external control unit and internal LVAD through a small hole in the abdomen

Control unit

B

LVAD pumps blood into the aorta (to the body)

Blood from the left ventricle enters the LVAD

LVAD

Cable connecting to control unit

Heart is shown in cross-section
Bridge or Destination Therapy
Can you spot the LVAD?
Heart Ware HVAD
Heart Ware HVAD
MCS vs Medical Therapy

![Survival Curve Graph]

- Red line: VELVAS (n=68)
- Blue line: OMM (n=61)

Percent Survival

Months Post Enrollment

Evolution of Devices
Today’s LVAD Patient
Rise in Mechanical Devices

Implants: June 2006 – December 2013
INTERMACS Hospital Activation and Patient Enrollment
Primary Prospective Implants: June 23, 2006 to December 31, 2013

J Heart Lung Transplant 2014;33:555-64
HeartMate II Post-Approval Study

- The post-approval study examined outcomes of patients treated with HMII (n=169) vs an INTERMACS control group comprised of:
  - HM XVE (n=135) and
  - Thoratec IVAD (n=34)
- and consisted of concurrent controls (n=55) and historical controls (n=114)
- Enrolled April-August 2008 at 77 US centers

J Am Coll Cardiol 2011;57:1890-8
Quality of Life (at 6 months)

6 Minute Walk Distance

Minneapolis Living with Heart Failure

NYHA Functional Class

Kansas City Cardiomyopathy Score

* p<0.05 vs. baseline

J Am Coll Cardiol 2010; 55: 1826-34
LVAD Candidates?

- **Inclusion criteria:**
  - LVEF ≤ 25%
  - Peak VO2 <14 ml/kg/min (or 50% age- and sex-predicted)
  - And either
    - NYHA class IIIb-IV symptoms for at least 45 of the prior 60 days on maximally tolerated oral heart failure medications, or
    - Dependence on IV inotropes for at least 14 days, or
    - Dependence on an IABP for at least 7 days
  - Not a candidate for transplantation

- **Exclusion criteria:**
  - Irreversible renal, pulmonary or hepatic dysfunction or active infection
**LVADs Of The Future**

Pipeline: getting bigger by getting smaller

<table>
<thead>
<tr>
<th></th>
<th>HVAD™</th>
<th>MVAD™</th>
<th>IV-VAD™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure</td>
<td>Surgical</td>
<td>Minimally Invasive</td>
<td>Catheter Delivery System</td>
</tr>
<tr>
<td>Flow</td>
<td>10 L/min</td>
<td>10 L/min</td>
<td>3 L/min</td>
</tr>
<tr>
<td>Patient Class</td>
<td>Late Class IV</td>
<td>Class IV</td>
<td>Class III / Early Class IV</td>
</tr>
<tr>
<td>Treatable Pop.</td>
<td>100,000</td>
<td>350,000</td>
<td>1,000,000</td>
</tr>
</tbody>
</table>
Common Complications of LVADs

• Driveline infections / sepsis
• Ventricular arrhythmias (suck-down, RV fail)
• GI bleeding (any common cause + AVMs)
• Nose bleeds
• Neurologic events (hemorrhagic / ischemic)
• LVAD failure (electrical, mechanical, thrombus)
• Right heart failure
• Aortic Insufficiency (de novo)
• Hemolysis (baseline vs in setting of thrombus)
Pearl #4: Assess Risk

• Considerations for Mechanical Support
  – Nobody dies from LV dysfunction alone
  – Assess end-organs !!! -cause, acuity, severity
  – Trajectory, trajectory, trajectory... (UOP)
  – Evaluate the RV, relationship with LV, lungs
  – Oxygenation, Ventilation, Acid-Base
  – Arterial, Venous Access (potential pitfalls)
  – Define the Goals of Care
    • Bridge to recovery, durable support, transplant
Why Not Just Throw in LVAD?

- INTERMACS profile 1 avoided

<table>
<thead>
<tr>
<th>Patient Profile at Time of Implant</th>
<th>Pre 2001</th>
<th>2001</th>
<th>2012 (Jan-Jun)</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>Unspecified</td>
<td>1</td>
<td>.</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>1 Critical Cardiogenic Shock</td>
<td>860</td>
<td>298</td>
<td>148</td>
<td>1307</td>
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<tr>
<td>2 Progressive Decline</td>
<td>1627</td>
<td>708</td>
<td>329</td>
<td>2664</td>
</tr>
<tr>
<td>3 Stable but Inotrope dependent</td>
<td>750</td>
<td>519</td>
<td>246</td>
<td>1515</td>
</tr>
<tr>
<td>4 Resting Symptoms</td>
<td>441</td>
<td>233</td>
<td>117</td>
<td>791</td>
</tr>
<tr>
<td>5 Exertion intolerant</td>
<td>91</td>
<td>66</td>
<td>27</td>
<td>184</td>
</tr>
<tr>
<td>6 Exertion limited</td>
<td>59</td>
<td>31</td>
<td>14</td>
<td>104</td>
</tr>
<tr>
<td>7 Advanced NYHA Class 3</td>
<td>47</td>
<td>6</td>
<td>8</td>
<td>61</td>
</tr>
<tr>
<td>Total</td>
<td>3876</td>
<td>1861</td>
<td>896</td>
<td>6633</td>
</tr>
</tbody>
</table>
Targeting INTERMACS Level 3

Predicted 1-year mortality according to patient age. The 3 lines illustrate the effect of INTERMACS Level and the prevalence of risk factors in the specified level.
## Maybe Organ Function is Key?

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Estimate</th>
<th>SE</th>
<th>OR (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (per 10 yrs)</td>
<td>0.274</td>
<td>0.12</td>
<td>1.32 (1.05-1.65)</td>
<td>0.018</td>
</tr>
<tr>
<td>Albumin (per g/dl)</td>
<td>-0.723</td>
<td>0.23</td>
<td>0.49 (0.31-0.76)</td>
<td>0.002</td>
</tr>
<tr>
<td>Creatinine (per mg/dl)</td>
<td>0.740</td>
<td>0.22</td>
<td>2.10 (1.37-3.21)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>INR (per unit)</td>
<td>1.136</td>
<td>0.32</td>
<td>3.11 (1.66-5.84)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Center volume &lt;15</td>
<td>0.807</td>
<td>0.34</td>
<td>2.24 (1.15-4.37)</td>
<td>0.018</td>
</tr>
</tbody>
</table>

Multivariable predictors (p < 0.05) of 90-day mortality in the derivation cohort and the formula for calculating the HeartMate II Risk Score (HMRS). Calculation of HMRS: HMRS = (0.0274 × [age in years]) − (0.723 × [albumin g/dl]) + (0.74 × [creatinine mg/dl]) + (1.136 × [INR]) + (0.807 × [center LVAD volume <15*]). *Enter value of 1 if total center LVAD volume is <15 and 0 if ≥15. Other variables entered into multivariable analysis (all p > 0.05 in final model): sex, LVAD indication, pre-operative inotrope, vasopressor and/or vasodilator use, pre-operative ventilator support and/or IABP support, RVSWi, hematocrit, platelets, aspartate aminotransferase, total bilirubin, and implant era. Model fit was inferior when blood urea nitrogen was entered in place of creatinine into the aforementioned model. Likewise, entering right atrial pressure and/or mean pulmonary artery pressure in place of RVSWi did not improve modeling.
Contemporary 90-Day Risk

BTT & DT Patients (N=1101)

Low Risk (HMRS < 1.58)

Medium Risk (HMRS: 1.58-2.48)

High Risk (HMRS > 2.48)

P (Log-Rank) < 0.001

At Risk:
455 322 223 162 121
422 275 205 136 97
224 129 91 61 48

Percent Survival

Months
0 6 12 18 24

Validation Cohort

P < 0.001
AUC: 0.64

P < 0.001
P = 0.002

P = 0.247

Low Risk 228
Medium Risk 194
High Risk 111

Mortality

0% 5% 10% 15% 20% 25% 30% 35%
Pearl #5: Know Thy Device
Pressure-Volume Relationship
End-Systolic Pressure-Volume

![Graph showing relationships between pressure and volume with annotations for Positive Inotropic Effect, Baseline ESPVR, and Negative Inotropic Effect.](image)
Effective Arterial Elastance (Ea)
Acute Heart Failure

NORMAL

FAILURE
Acute Heart Failure

- Loss of contractility
- Rightward shift in end-diastolic relation
- Loss in LV compliance, “overload” state
- Increased LV diastolic pressures
  - Reduced Ao to coronary pressure gradient
  - Reduced coronary flow, increased injury
- Decrease in stroke volume
- Increase in mitral regurgitation
Beyond the IABP...

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock

Holger Thiele, M.D., Uwe Zeymer, M.D., Franz-Josef Neumann, M.D., Miroslaw Ferenc, M.D., Hans-Georg Olbrich, M.D., Jörg Hausleiter, M.D., Gert Richardt, M.D., Marcus Hennersdorf, M.D., Klaus Empen, M.D., Georg Fuernau, M.D., Steffen Desch, M.D., Ingo Eitel, M.D., Rainer Hambrecht, M.D., Jörg Fuhrmann, M.D., Michael Böhm, M.D., Henning Ebelt, M.D., Steffen Schneider, Ph.D., Gerhard Schuler, M.D., and Karl Werdan, M.D., for the IABP-SHOCK II Trial Investigators*
PCI + IABP – SHOCK II

P = 0.92 by log-rank test

Control

IABP

Mortality (%) vs. Days since Randomization

0 5 10 15 20 25 30
0 10 20 30 40 50
IABP: Completely Obsolete?

• May still have a practical niche:
  – Mild slowly progressing low-output heart failure (defined by invasive hemos)
  – Anticipate short need while going to OR for definitive therapy, closely monitored
  – Post-operative low-output “boost”
  – UNOS Status 1A categorization
  – Vascular access “issues” warranting lower profile indwelling device
Impella Axial Flow Pump
Impella Axial Flow Pump

- 9 French catheter
- 21 French micro-axial pump
- Impella LD (direct)
- Blood Outlet
- Blood Inlet
- 21 Fr Pump Motor
- Impella 5.0 (peripheral)
Impella Axial Flow Pump
Axillary Access: Advantage?
Inlet Cage 3.5-4.0 cm from AV
Impella (5.0)
Impella (5.0)

• Intrinsic contractility unchanged
• Increased mean arterial pressure
• Increased afterload
• Decreased preload
• Increased Ao-coronary gradient
  – Improved myocardial oxygen delivery
• Reduced stroke work (LV)
  – Possibly reduced infarct size
RECOVERY I Trial: Impella 5.0

Average cardiac index (l/min/m²)

$\text{Pre support} \quad \text{On support}$

$p < 0.0001$

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Patient’s individual cardiac index
Impella 5.0

• The Ideal Patient: “Resting the LV”
  – Isolated LV failure due to CAD
  – Post-infarct / ischemic VT / VF
  – Post-cardiotomy / post-CABG
  – Expect reasonably quick recovery
  – Normal RV function
  – Normal pulmonary function
  – Available axillary access: allows HOB elevate
Impella 5.0

• Contraindications
  – Mechanical aortic valve
  – Ventricular septal defect
  – Hypertrophic cardiomyopathy
  – LV thrombus
  – Severe aortic insufficiency
VA-ECMO Circuit

- ICV-RA-Femoral vein
  - Cannula 23F-25F
- Centrifugal flow pump
- Oxygenator
- Femoral-iliac
  - Cannula 17F-21F
- Antegrade perfusion
VA-ECMO Circuit
Oxygenator Technology

• 1\textsuperscript{st} gen. involved “bubbling” O2 into blood
  – Allowed direct gas-blood interface
  – Blood trauma, hemolysis, microemboli

• 2\textsuperscript{nd} gen. membrane oxygenators
  – Silicone membrane (non-micropores)
    • More durable but less efficient, lung injury
  – Polypropylene hollow-fiber (micropores)
    • Common in the OR, efficient but less durable

• 3\textsuperscript{rd} gen. polymethylpentene (PMP)
<table>
<thead>
<tr>
<th>Complication</th>
<th>Incidence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood clots (oxygenator, pump, tubing, hemofilter)</td>
<td>3.2-22</td>
</tr>
<tr>
<td>Bleeding (surgical site, cannulation site, gastrointestinal tract, intracranial, tracheostomy)</td>
<td>5.3-79</td>
</tr>
<tr>
<td>Pump failure</td>
<td>4.7-20</td>
</tr>
<tr>
<td>Oxygenator failure</td>
<td>21</td>
</tr>
<tr>
<td>Neurologic complications (intracranial bleed, stroke, seizure, encephalopathy)</td>
<td>13-33</td>
</tr>
<tr>
<td>Limb ischemia</td>
<td>13-25</td>
</tr>
<tr>
<td>Problems during cannulation</td>
<td>0.8-8</td>
</tr>
<tr>
<td>Nosocomial infection</td>
<td>17-49</td>
</tr>
<tr>
<td>Renal failure</td>
<td>30-58</td>
</tr>
</tbody>
</table>
VA-ECMO: Pressure-Volume
VA-ECMO

- Hemodynamic Effects
  - Increased preload (LVEDP and PW will rise)
  - Increased MAP (improved BP support)
  - Increased LV afterload (LV can dilate)
  - Decreased intrinsic LV stroke volume
  - Decreased RA pressure
  - Decreased RV afterload and stroke work
Adult Cardiac Use VA-ECMO
### VA-ECMO: Outcomes

**Registry International Summary, July 2012**

<table>
<thead>
<tr>
<th></th>
<th>Total Cases</th>
<th>Survive to Discharge or Transfer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>%</td>
</tr>
<tr>
<td><strong>Neonatal</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Respiratory          | 25,746      | 19,232                           | 75%
| Cardiac              | 4,797       | 1,912                            | 40%
| ECPR                 | 784         | 304                              | 39%
| **Pediatric**        |             |                                  |
| Respiratory          | 5,457       | 3,061                            | 56%
| Cardiac              | 5,976       | 2,913                            | 49%
| ECPR                 | 1,562       | 630                              | 40%
| **Adult**            |             |                                  |
| Respiratory          | 3,280       | 1,808                            | 55%
| Cardiac              | 2,312       | 891                              | 39%
| ECPR                 | 753         | 207                              | 27%
| **Total**            | 50,667      | 30,958                           | 61%
VA-ECMO

• The “ECMO” Patient
  – Severe heart failure
  – Severe end-organ injury
  – Biventricular failure
  – Cardiopulmonary failure
  – Isolated RV failure
  – Pulmonary embolism
VA-ECMO

• Contraindications
  – Irreversible lung disease
  – Irreversible cardiac disease and contraindication to durable VAD or transplant
  – Inability to tolerate anticoagulation
  – Refractory septic shock (relative)
  – Severe coagulopathy, thrombocytopenia
Return to the Case

- Emergent broncoscopy showed DAH
- Rising inotrope / pressor requirement
- VA ECMO performed at bedside
- After 3 days of ECMO & IABP
  - A-line and echo: improved LV function
  - Oxygenation, acidosis resolved
  - End-organ function restored
  - Left leg vascular complications
Five Pearls

1. Consider Chronotropy
2. Define Trajectory
3. Respect the Vitals
4. Define Risk (including risk of doing nil)
5. Device (Know how they work and pitfalls)
ICU Management of VADs?
VAD Management Strategies

The LVAD patient is not that unique
Use invasive monitoring (PA and arterial lines)
Set the LVAD speed and “walk away”
Watch for RV failure, tamponade, volume shifts
Watch for arrhythmias
Watch for infections
Continue to follow the “five pearls”
Pearl # 6: CALL OUR TEAM

• Consult the Heart Failure Service
• Discussions ongoing for:
  – Cardiogenic shock response team