Educational Objectives

At the conclusion of this activity, learners should be able to:

1. To describe the role of percutaneous ventricular assist devices in patients with cardiogenic shock.

2. To describe the role of surgically implanted ventricular assist devices in patients with cardiogenic shock.

3. To understand the importance of a shock team concept in dealing with this complex patient population.
Cardiogenic Shock

Etiology is quite varied

- acute on chronic decompensated heart failure
- acute decompensated heart failure
- acute coronary syndrome
- peripartum cardiomyopathy
- fulminant myocarditis
- cardiac allograft failure
- Other causes
  - refractory v. tach or v. fib unresponsive to conventional therapy
  - hypothermia
  - acute anaphylaxis
  - pulmonary embolism
  - sepsis-related cardiac dysfunction
  - drug overdose.
Cardiogenic Shock

- Patients who remain in cardiogenic shock with:
  - evidence of hypotension that is medically refractory
  - does not respond to inotropes or vasopressors
  - should be evaluated for percutaneous mechanical circulatory support (MCS) candidacy by a heart care team.
    - Intra-aortic balloon pump (IABP)
    - Impella
    - TandemHeart
    - Extracorporeal membrane oxygenation (ECMO)

- MAIN OBJECTIVE: Devices to maintain appropriate perfusion to end organs (Class IIb, Level of Evidence: C).

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**Table 1. Suggested Indications for Percutaneous MCS**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complications of AMI</td>
<td>Ischemic mitral regurgitation is particularly well suited to these devices as the hemodynamic disturbance is usually acute and substantial. Acutely depressed LV function from large AMI during and after primary PCI is an increasing indication for temporary MCS use. Cardiogenic shock from RV infarction can be treated with percutaneous right ventricular support.</td>
</tr>
<tr>
<td>Severe heart failure in the setting of nonischemic cardiomyopathy</td>
<td>Examples include severe exacerbation of chronic systolic heart failure as well as acutely reversible cardiomyopathies such as tumoral hypertrophy, tides cardiomyopathy, or peripartum cardiomyopathy. If patients presenting in INTERMACS profile I or II, MCS can be used as a bridge to destination VAD placement or as a bridge to recovery if the ejection fraction rapidly improves. Primary graft failure (adult or pediatric) may be due to acute cellular or antibody-mediated rejection. Cardiac allograft: time, or inadequate organ preservation. Acute RV failure has several potential causes, including recipient pulmonary hypertension, intrapulmonary shunting, and excess volume blood product resuscitation. MCS support provides time for the donor right ventricle to recover function, often with the assistance of isotropic and pulmonary vasodilator therapy.</td>
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<td>Acute cardiac allograft failure</td>
<td>Primary graft failure (adult or pediatric) may be due to acute cellular or antibody-mediated rejection. Cardiac allograft: time, or inadequate organ preservation. Acute RV failure has several potential causes, including recipient pulmonary hypertension, intrapulmonary shunting, and excess volume blood product resuscitation. MCS support provides time for the donor right ventricle to recover function, often with the assistance of isotropic and pulmonary vasodilator therapy.</td>
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<td>Post-transplant RV failure</td>
<td>Primary graft failure (adult or pediatric) may be due to acute cellular or antibody-mediated rejection. Cardiac allograft: time, or inadequate organ preservation. Acute RV failure has several potential causes, including recipient pulmonary hypertension, intrapulmonary shunting, and excess volume blood product resuscitation. MCS support provides time for the donor right ventricle to recover function, often with the assistance of isotropic and pulmonary vasodilator therapy.</td>
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<td>Patients slow to wean from cardiopulmonary bypass following heart surgery</td>
<td>Although selected patients may be transitioned to a percutaneous system for additional weaning, this is rarely done. Patients can be treated with a percutaneous system that is somewhat independent of the cardiac rhythm. For recurrent, refractory, ventricular arrhythmias, ECMO may be required for biventricular failure. Particularly in patients with severe LV dysfunction (EF &lt;20-30%) and complex coronary artery disease involving a large territory (side-branch vessel, left main or three vessel disease). Similar to IABP, complex VT ablation can be made feasible with percutaneous support. MCS allows the patient to remain in VT longer during antiarrhythmia mapping without much concern about systemic hypoperfusion.</td>
</tr>
<tr>
<td>Refractory arrhythmias</td>
<td>Primary graft failure (adult or pediatric) may be due to acute cellular or antibody-mediated rejection. Cardiac allograft: time, or inadequate organ preservation. Acute RV failure has several potential causes, including recipient pulmonary hypertension, intrapulmonary shunting, and excess volume blood product resuscitation. MCS support provides time for the donor right ventricle to recover function, often with the assistance of isotropic and pulmonary vasodilator therapy.</td>
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<td>Peripulmonary use for high-risk PCI</td>
<td>Primary graft failure (adult or pediatric) may be due to acute cellular or antibody-mediated rejection. Cardiac allograft: time, or inadequate organ preservation. Acute RV failure has several potential causes, including recipient pulmonary hypertension, intrapulmonary shunting, and excess volume blood product resuscitation. MCS support provides time for the donor right ventricle to recover function, often with the assistance of isotropic and pulmonary vasodilator therapy.</td>
</tr>
<tr>
<td>High-risk or complex ablation of ventricular tachycardia</td>
<td>Primary graft failure (adult or pediatric) may be due to acute cellular or antibody-mediated rejection. Cardiac allograft: time, or inadequate organ preservation. Acute RV failure has several potential causes, including recipient pulmonary hypertension, intrapulmonary shunting, and excess volume blood product resuscitation. MCS support provides time for the donor right ventricle to recover function, often with the assistance of isotropic and pulmonary vasodilator therapy.</td>
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<tr>
<td>High-risk percutaneous valve interventions</td>
<td>Primary graft failure (adult or pediatric) may be due to acute cellular or antibody-mediated rejection. Cardiac allograft: time, or inadequate organ preservation. Acute RV failure has several potential causes, including recipient pulmonary hypertension, intrapulmonary shunting, and excess volume blood product resuscitation. MCS support provides time for the donor right ventricle to recover function, often with the assistance of isotropic and pulmonary vasodilator therapy.</td>
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Percutaneous temporary MCS

- Intra-aortic Balloon Pump
- TandemHeart
- Impella®
- HeartMate PHP™
- iVAC 2L®
- Extracorporeal membrane oxygenation

Intra-aortic balloon pump

- 7.0 - 8.0 French catheter
- Descending thoracic aorta distal to the left subclavian artery.
- Serves 2 functions

Inflation
- At the onset of diastole, the inflation occurs, giving rise to sharp 'P' wave on electrocardiogram.
- Effect: Increased coronary perfusion

Deflation
- Occurs just before end-diastole, resulting in reduction of aortic and diastolic pressures.
- Effect: Decreased diastolic blood pressure

*Please Note: Each individual patient may require more or less support for optimal care.*
Intra-aortic balloon pump

IABP is still the most widely used device for mechanical circulatory support.

In patients with shock,
  There are no hemodynamic effects on the mean blood pressure
  No effects on cardiac output, cardiac power index, serum lactate or
  any effect on the doses of catecholamines.

Recent advances in technology
  Enhanced automation,
  Flexible treatment algorithms,
  Improved insertion speed with smaller catheter shaft diameter
  allowing for sheathless insertion may theoretically permit
  improved support at reduced complication rates.

Intra-aortic balloon pump

Before 2012, American and European guidelines supported IABP use in cardiogenic shock with a class I recommendation.

The IABP-SHOCK II trial:
  Largest randomized multicenter trial in CS complicating AMI
  No significant difference
    primary endpoint 30-day mortality (39.7% versus 41.3%; p=0.69).
    no differences in any of the secondary endpoints
    no subgroups showed a potential advantage of IABP support.
  The 12-month follow-up
    mortality of 52% IABP versus 51% in the control group (p=0.91).

Although IABP support has been in place for nearly 5 decades, the results of IABP-SHOCK II
  influenced recent European revascularisation and also the non-ST-elevation acute coronary syndrome
guidelines: the IABP has been downgraded to a class III A recommendation for routine use in
  cardiogenic shock.

In AHA/ACC guidelines IABP use in cardiogenic shock is still recommended with a Class IIa; LOE B
  recommendation.


Intra-aortic balloon pump

Table 2: Indications and contraindications for the use of IABP therapy

<table>
<thead>
<tr>
<th>Indications</th>
<th>Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute myocardial infarction</td>
<td>Refractory LV failure</td>
</tr>
<tr>
<td>Cardiogenic shock</td>
<td>Refractory ventricular arrhythmias</td>
</tr>
<tr>
<td>Acute MR and VSD</td>
<td>Cardiomyopathies</td>
</tr>
<tr>
<td>Catheterization and angioplasty</td>
<td>Sepsis</td>
</tr>
<tr>
<td>Refractory unstable angina</td>
<td>Infants and children with complex</td>
</tr>
<tr>
<td></td>
<td>cardiac anomalies</td>
</tr>
<tr>
<td>Cardiac surgery</td>
<td></td>
</tr>
<tr>
<td>Weaning from cardiopulmonary bypass</td>
<td></td>
</tr>
</tbody>
</table>

TandemHeart™

- Left atrial – femoral arterial
- Septal puncture
- 17 Fr arterials
- 4 L/min flow at 7500 rpm

TandemHeart™ (Cardiac Assist, Inc, Pittsburgh, PA, USA)
**Impella®**

- Non-pulsatile axial flow
- Suction cannula with turbine in LV to propel blood into ascending aorta
- Impella 2.5, 5.0, CP
- Unload the LV

**iVAC 2L®**

- Percutaneously - femoral artery
- Pulsatile
- 2 L/min using an extracorporeal membrane pump via a 17 French cannula
- In the systolic phase of the heart, blood is aspirated from the LV through the catheter lumen into the membrane pump. During the diastolic phase the pump ejects the blood back through the catheter, subsequently opening the catheter valve and delivering the blood to the ascending aorta through the side outflow port, thereby creating an “extra heart beat”.
- High risk PCI procedures
- Triggered by ECG or arterial pressure
HeartMate PHP™

- Axial flow
- Nitinol cannula 13 Fr into femoral artery
- Once across AV can expand to 24 Fr
- > 4 L/min
- LVEDP and LV volume decreased
- SHIELD-1 – high risk PCI; I (Coronary InterventionS in High-Risk Patients Using a Novel Percutaneous Left Ventricular Support Device)

HeartMate percutaneous Heart Pump™ (HeartMate PHP™, St. Jude Medical, Pleasanton, CA, USA)

Percutaneous temporary MCS- Cardiogenic shock

Data are scarce in use of pVAD for CS
- Meta-analysis published in 2009 - three randomized trials comparing percutaneous MCS (two trials with the TandemHeart™; one with the Impella® 2.5) to IABP, no additional randomized trials have been conducted.
  - Patients treated with active MCS demonstrated higher cardiac index, higher mean arterial pressure, and lower pulmonary capillary wedge pressure.
  - On the other hand, bleeding complications and inflammation were more frequent with MCS therapy, and there was no difference with respect to 30-day mortality.
- Observational studies: Impella® device suggested some benefit with this device in cardiogenic shock.
- In the USpella registry - patients with cardiogenic shock directly treated with Impella® prior to PCI had an overall better survival at hospital discharge compared with those treated after PCI, even when adjusting for potential confounding variables.
- For the iVAC® and for the HeartMate PHP – no randomized clinical trials
  - Registry of only 46 patients in SHIELD-I

Dudek D. Temporary cardiac support during high-risk PCI: HeartMate PHP and the SHIELD I Study. Presented at TCT 2015.
Data: Percutaneous temporary MCS

Hemodynamic condition of patient at time

Anticipated risk

Need for HD support after PCI

<table>
<thead>
<tr>
<th>Patient With Left Main, Last Remaining Conduit, or severe Multivessel Disease</th>
<th>Anticipated Noncomplex PCI</th>
<th>Anticipated Technically Challenging or Prolonged PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal or mildly reduced left ventricular function</td>
<td>None</td>
<td>IABP/Impella as back up</td>
</tr>
<tr>
<td>Severe left ventricular dysfunction (EF &lt; 35%) or recent decompenated heart failure</td>
<td>IABP/Impella as back up</td>
<td>Impella or TandemHeart, choice dependent upon vascular anatomy, local expertise, and availability. ECMO for uncorrectable hypoxemia or RV failure.</td>
</tr>
</tbody>
</table>

A suggested schema for use of support devices for high-risk PCI based upon clinical and anatomic circumstances. The greater the likelihood of hemodynamic compensation or collapse the greater the potential benefit of MCS.

AMI and CS: Physiology

![AMI and CS: Physiology Diagram](image)
What about the right heart?

Impella RP®

- Non-pulsatile axial flow
- Suction cannula with turbine in inferior vena cava to propel blood into pulmonary artery
- Unload the RV

Impella RP® systems (Abiomed Europe, Aachen, Germany)
PROTEK DUO

- Dual lumen catheter with inflow from RA to PA
- Unload the RV
- Can combine with oxygenator
- Enhanced mobility

TandemHeart™ (Cardiac Assist, Inc, Pittsburgh, PA, USA)

Profound Cardiogenic Shock

- Decreased organ perfusion
  - Persistent lactic acidosis >3.2
  - Decreasing urine output
  - Cool and diaphoretic extremities
  - Altered mental status
  - Rise of creatinine of >1 mg/dL in 24 hours
  - Elevation in transaminases or development of pulmonary edema or hypoxia
  - High dose of one or more inotropes
  - Persistent cardiac index < 1.8 L/min/kg with concomitant hypotension despite fluid resuscitation.
  - Impaired oxygenation and/or ventilation + continuing cardiogenic shock with inappropriate end organ perfusion ............ ECMO consideration.
Indications / Types for ECMO

- **Cardiac failure** with inadequate tissue perfusion manifested as hypotension and low cardiac output despite adequate intravascular volume. Shock persists despite volume administration, inotropes and vasoconstrictors, and intraaortic balloon counterpulsation if appropriate.

- **Respiratory failure** with worsening hypoxia/hypercarbia refractory to maximal medical and ventilator therapy due to reversible etiology.

- **Extracorporeal cardiopulmonary resuscitation (E-CPR)** using extracorporeal membrane oxygenation (ECMO) support during inhospital cardiac arrest.

ECMO

- Modified cardiopulmonary bypass circuit for temporary life support for patients with potentially reversible cardiac and/or respiratory failure.

- ECMO provides gas exchange as well as cardiac support thereby allowing for recovery from existing lung and/or cardiac disease.
Various Configuration of ECMO

Patient Selection for ECMO

<table>
<thead>
<tr>
<th>Indication</th>
<th>Contraindication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percutaneous support</td>
<td>Age greater than 75 years</td>
</tr>
<tr>
<td>Acute fulminant myocarditis</td>
<td>Active malignancy with expected survival less than 1 year</td>
</tr>
<tr>
<td>Acute myocardial infarctions</td>
<td>Severe peripheral vascular disease</td>
</tr>
<tr>
<td>Failed graft implant for early graft failure</td>
<td>End-stage renal disease on dialysis</td>
</tr>
<tr>
<td>Extravascular subendarteral or ventricular fibrillation</td>
<td>Advanced Fontinal disease</td>
</tr>
<tr>
<td>Hypovolemia</td>
<td>Current uncontrolled hemorrhage or other contraindication to systemic anticoagulation</td>
</tr>
<tr>
<td>Acute cerebrovascular injury</td>
<td>Uncontrolled cerebrovascular injury with ongoing neuroendovascular recanalization</td>
</tr>
<tr>
<td>Patentry embolus</td>
<td>Witnessed cardiopulmonary arrest with cardiopulmonary resuscitation of greater than 30 minutes with signs of spontaneous circulation</td>
</tr>
<tr>
<td>Postpartum cardiomyopathy</td>
<td></td>
</tr>
</tbody>
</table>

IABP, pLVAD and ECMO: Physiology

Surgically placed temporary MCS

- *Extracorporeal membrane oxygenation*
- *CentriMag*
- *AbioMed*
Surgically placed temporary MCS: CentriMag

Magnetically levitated
Flow ~ 10 liters/min

Uni or biventricular
LVAD – inflow LA or LV; outflow to aorta
RVAD – inflow RA with outflow to PA

Can couple RVAD with oxygenator for V-V ECMO

Short term (30d in Europe, 6 hrs FDA)

Regular use beyond – “bridge to bridge”

Moving on to recovery, permanent MCS or patients being bridged to heart transplantation.


Surgically placed temporary MCS: CentriMag

There are no randomized trials with this device.
Single institution - 66 patients ; ~60% survival
12 of 40 patients having myocardial recovery,
12 undergoing successful heart transplantation
16 LVAD

All devices were implanted via sternotomy with central cannulation and peripheral cannulas to successfully tunnel the cannulas subcutaneous outside of the body.

Multi-institutional success
near 50% survival at 30 days


Surgically placed temporary MCS: CentriMag

A

B

Surgically placed temporary MCS: CentriMag

a

b
Surgically placed temporary MCS: Abiomed

Uni- or Biventricular
Pulsatile
6 liters / minute
Controller
  Vacuum
  Heart Rate
LVAD - LA or LV inflow with outflow to aorta (sewn)
RVAD - RA inflow to pulmonary artery (sewn)
Disadvantage – bleeding; Advantage – mobility
Similar to the CentriMag device
  There are no randomized trials in this patient population.
  30 day multi-center registry data ~ 40% survival
  67% in-hospital survival
  - single institutional after MI when LV apex
  - aggressive heart transplantation strategy


Cardiogenic Shock: BiVAD vs LVAD vs ECMO

- ECMO
  - Neuro status unknown
  - Profound pulmonary failure
  - Recent use of thrombolytics
  - Post cardiotomy—often easiest if lungs/RV questionable
  - Profound Shock
- BiVAD
  - Profound shock with MSOF
  - Intractable VT/VF
  - RV infarct
  - Severe RV dysfunction—(high CVP with low PAP)
- LVAD alone if no evidence of MSOF/severe RVF
Short Term VADs

- Impella
- Tandem Heart
  - Percutaneous LVAD
  - Percutaneous RVAD
- ECMO
- CentriMag
- Abiomed

Primary Indications:
- Post - Cardiotomy Shock
- Post HTx Complications
- Post AMI Cardiogenic Shock
- Fulminant Acute Myocarditis

Primary Goal: Bridge to Recovery
Bridge to Decision
Bridge to Bridge

Durable, long term left ventricular assist devices (LVADs) should be reserved for patients in acute cardiogenic shock who:
- a) are not likely to recover without long-term MCS,
- b) too ill to maintain normal hemodynamics of temporary MCS or who cannot be weaned from temporary MCS / inotropes,
- c) have capacity for meaningful recovery and
- d) are without irreversible end-organ damage (Class IIa, level of evidence: C)

The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) created in 2006 shows a steady decline in patients implanted with a profile of 1 or critical cardiogenic shock with a current rate of 14.3%

The most commonly used LVADs currently are the HeartMate II and HeartWare devices.

In addition, there is an increasing use of the HeartMate III, HeartAssist5 and Jarvik in Europe with the trials underway in the United States.

Full hemodynamic support with flow between 5-10 liters per minute.


Surgically placed durable MCS: LVAD

ECMO use prior to LVAD is not well understood, weaning protocols make it difficult to ascertain uni-ventricular function and make it nearly impossible to predict right ventricular function after LVAD implantation.

LVAD support - single institution has been reported with a survival of 37, 32 and 30 % at 1, 2 and 4 years post-implantation, respectively.

This stresses the importance of not only salvage, but long term, meaningful utility and need for better predictors of RV function after uni-ventricular permanent support.

Long term LVAD implantation following temporary MCS - “bridge to bridge” strategy

This strategy can be used with both pVADs, surgically implanted MCS or ECMO. An important factor in patients surviving cardiogenic shock could be stabilization of hemodynamics.

There are increasing reports of success of early temporary mechanical support at a community hospital followed by immediate transfer to a tertiary care center for evaluation for more permanent LVAD or transplantation [36,37].

No randomized studies exist on the topic of bridge to bridge.

Surgically placed durable MCS: LVAD

INTERMACS registry: 502 patients underwent VAD implantation following a myocardial infarction of which 443 were LVADs. Baseline characteristics of this patient population were that:

- 67 % were in INTERMACS profile 1 (critical cardiogenic shock)
- 58 % having IABP, 37 % on mechanical ventilation and 18 % on ECMO.
- Despite the relative sickness of this group, there was a 77.7 % survival at one year post-implantation similar to the control group where only 13% of patients were in profile 1.

In a multi-institutional center, 68 patients were identified as having undergone temporary MCS prior to durable LVAD implantation with one year survival of 70 %.

In comparison, patients without prior MCS had survivals of 77% for profile 1 and 82% for profiles 2 and 3 (p<0.001), suggesting that although hemodynamics can be improved with reversal of cardiogenic shock, a continued operative morbidity and mortality exists in these subgroup of patients.


Surgically placed durable MCS: BiVAD

- A decision for durable mechanical support:
  - Total artificial heart (TAH)
  - Permanent LVAD with planned temporary right sided VAD (RVAD).
    - Wean of temporary RVAD
    - If not able to wean, long term RVAD vs conversion to TAH.
    - The strategy of moving forward with permanent LVAD with planned temporary RVAD has shown equivalent outcomes to TAH with ~45% one year survival.


Surgically placed durable MCS: BiVAD

- Off-label
  - HeartWare devices for support as bridge to transplantation with moderate success of nearly 50% survival.
  - The INTERMACS survival of patients with biventricular VADs continues to be 50% as well similar to survival of patients suffering from acute cardiogenic shock.

Cardiogenic Shock: Bridge to Bridge

- Early MCS key—prior to development of MSOF
- Post MI; Fulminant myocarditis
  - Is the LV/RV recoverable?
    - Acute MI; Fulminant myocarditis
    - How long is support anticipated?
    - Are adjuvant procedures needed?
      - CABG; repair of valve etc
  - A potential transplant candidate?
  - Intracorporeal vs Extracorporeal?
    - Can we get the patient home?
- Bridge to Bridge: Tandem; Impella
- Acute—pVAD
- Semi elective—Intracorporeal

VADS for Cardiogenic Shock Acute MI

- Change in the treatment paradigm of CS-AMI unresponsive to standard treatment
  - Early LVAD implantation
  - BIVADs/ECMO for profound shock; VT
    - severe RV dysfunction
  - Bridge to Decision
    - Transplant
    - Recovery
    - Destination
- Apical cannulation in CS-AMI is safe and effective
- Percutaneous LVADs RVADs ECMO
  - Tandem Heart; Impella
How Far Can We Go to Improve Outcomes?

```
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17
Survival (%)
```

**Years Post-Transplantation**

- **HTx**
- **LVAD**
- **OMM**
- **LDSH**

**Half-life = 9.1 years**  
**Conditional Half-life = 11.6 years**  

**Improvemnts with:**
- Devices
- Management
- Patient Selection

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**Conclusions for Cardiogenic Shock and Advanced Support Therapies**

- Must match etiology with device
- Wide Array of Devices
  - Short Term – Percutaneous
    - Intra-aortic Balloon Pump
    - TandemHeart
    - Impella®
    - HeartMate II
    - Impella 2.5
    - Extracorporeal membrane oxygenation
  - Short Term – Non-Percutaneous
    - CentriMag
    - Abiomed
    - ECMO
  - Long Term
    - Left Ventricular Assist Devices
    - Total Artificial Heart
    - Heart Transplantation
    - Hospice
Conclusions for Cardiogenic Shock and Advanced Support Therapies

• Bridge to decision
  – Recovery
  – LVAD
  – Transplant

• Heart Shock Team approach

Thank You