Percutaneous Support in Advanced Heart Failure

Shelley Hall, MD FACC

Chief of Transplant Cardiology, Mechanical Circulatory Support and Heart Failure

Baylor University Medical Center

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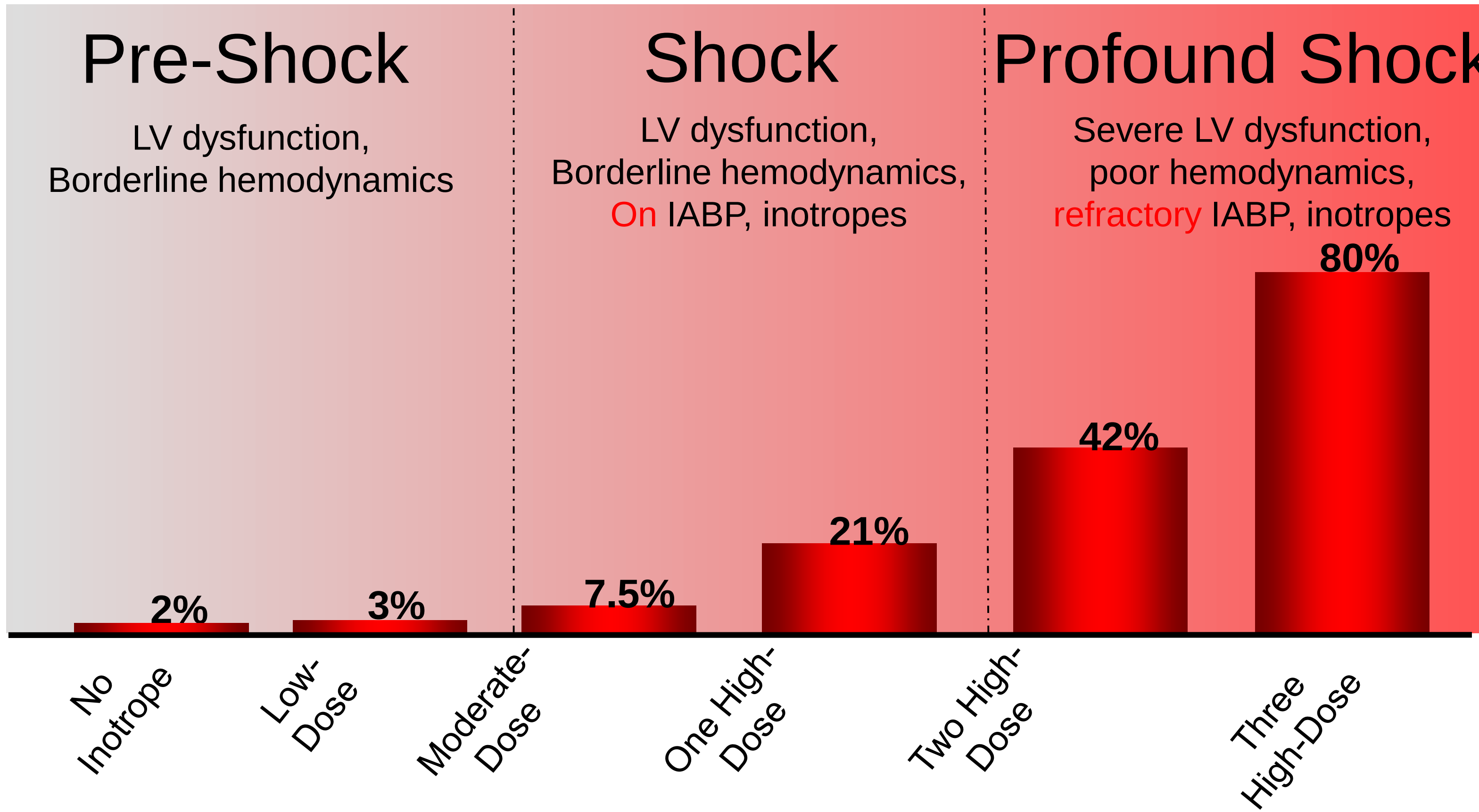
Negative Impact of Inotropes in Cardiogenic Shock



Mortality Risk with Inotrope Dosing

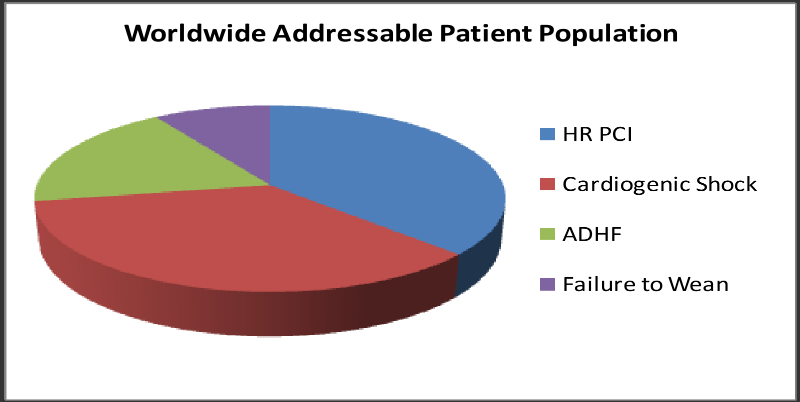
Adapted from Samuels LE et al , J Card Surg. 1999 Jul-Aug;14(4):288-93

Acute vs Chronic Heart Failure: Syndrome Characteristics Are Different

Acute Heart Failure	Chronic Heart Failure
❑ Sudden Onset of Organ Failure (hours)	❑ Gradual Onset of Organ Failure (years)
❑ Cardiogenic shock (> 50% mortality)	❑ Graded in Severity
❑ Emergency Circulatory Support	❑ Scheduled Circulatory Support
❑ > 50% Bi-ventricular	❑ < 50% Biventricular
❑ Younger	❑ Older
❑ Better end organ status	❑ End organs chronically deteriorated
❑ Early support favors good outcome	❑ Dependent on OMM pre MCCS
More Likely Recoverable	***Less Likely Recoverable***

Acute Percutaneous Market Opportunity

Large addressable patient population for acute percutaneous MCS exceeding 200k patients annually in the U.S. and major European markets



- ***Patients currently treated by medical management or devices***
- ***IABP is currently the most widely used device and standard of care***

- *Recent studies including SHOCK II have questioned the effectiveness of IABP*
- *Clinicians are searching for new options to rapidly stabilize hemodynamically compromised acute heart failure patients*

For Investigational use only. Not available for commercial use.

6th INTERMACS Annual Report

Device strategy at time of implant	Implant date era						Total	
	2006–2007		2008–2010		2011–2013			
	n	%	*n*	%	*n*	%	*n*	%
BTT listed	185	42.4%	1,335	39.2%	1,453	21.7%	2,973	28.2%
BTT likely	85	19.5%	884	26.0%	1,474	22.0%	2,443	23.2%
BTT moderate	49	11.2%	337	9.9%	677	10.1%	1,063	10.1%
BTT unlikely	28	6.4%	104	3.1%	222	3.3%	354	3.4%
DT	64	14.7%	666	19.6%	2,786	41.6%	3,516	33.4%
BTR	17	3.9%	38	1.1%	3	1.0%	93	0.9%
Rescue therapy	8	1.8%	24	1.0%	28	0.4%	60	0.6%
Other	0	0.0%	14	0.4%	26	0.4%	40	0.4%
Total	436	100.0%	3,402	100.0%	6,704	100.0%	10,542	100.0%

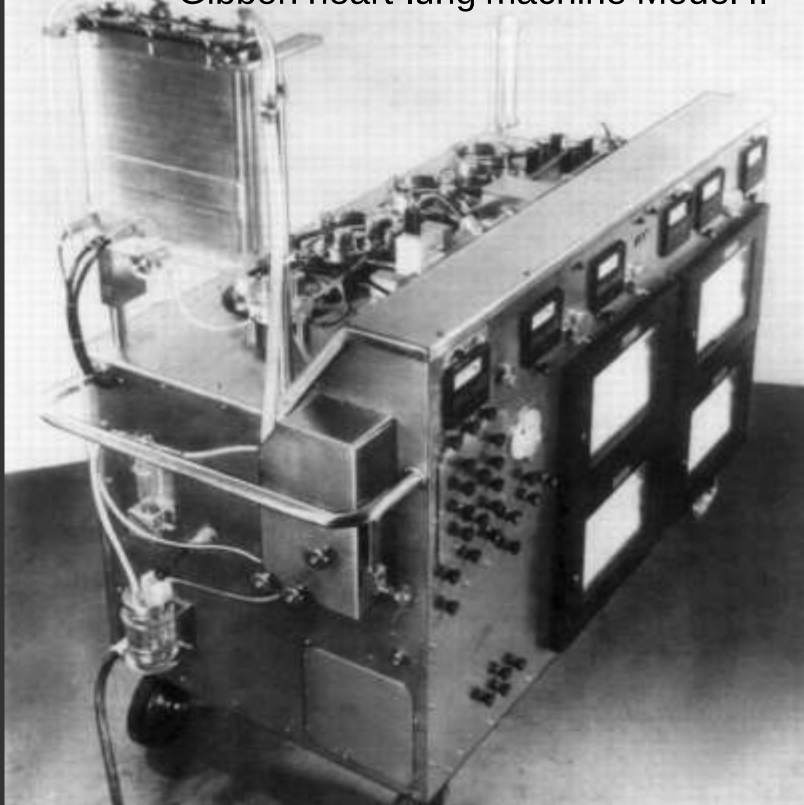
Kirklin et al, J Heart Lung Transplant. 2014 Jun;33(6):555-64.

Indications for Temporary Mechanical Circulatory Support

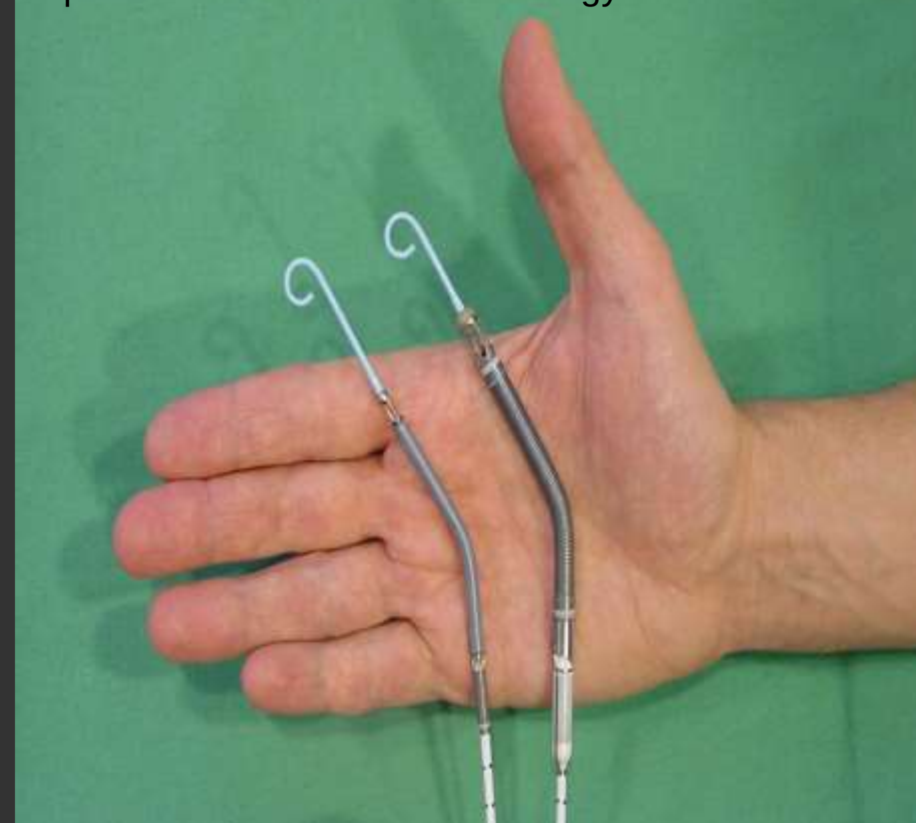
- Cardiogenic shock
  - Post AMI
  - Post Cardiotomy
  - Decompensated cardiomyopathy
    - Ischemic
    - Non-Ischemic

- As bridge to :
  - Transplantation
  - Device
  - Recovery

Then and now..


Gibbon heart-lung machine Model II

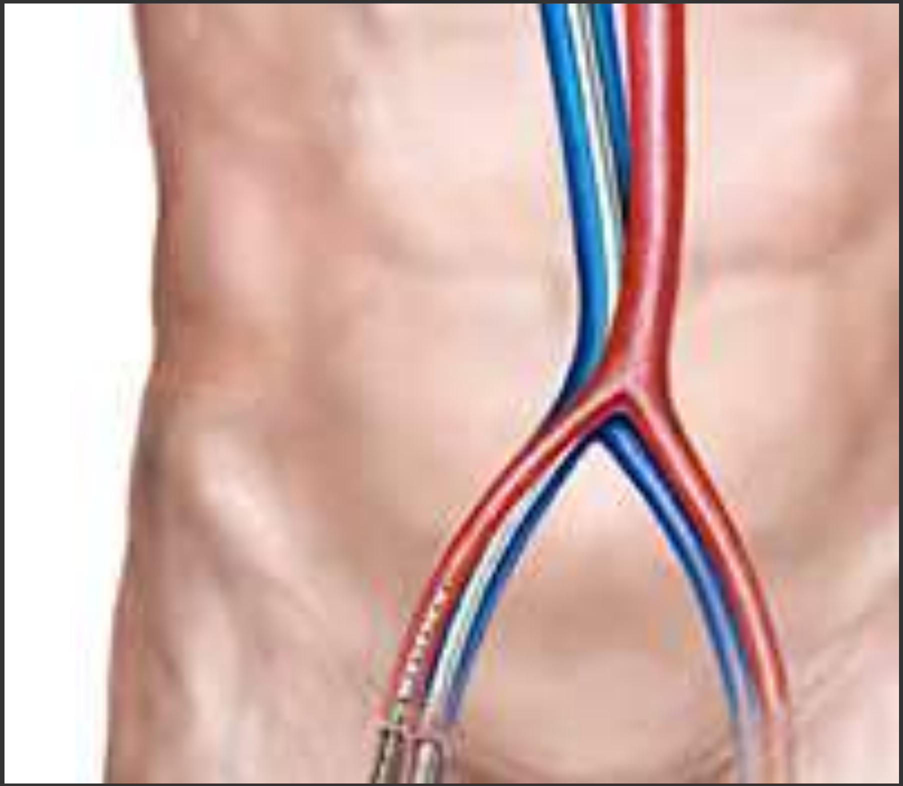
Copyright ©2003 American Heart Association


Impella® LP 2.5 and 5.0 Technology

Acute/Intermediate Support

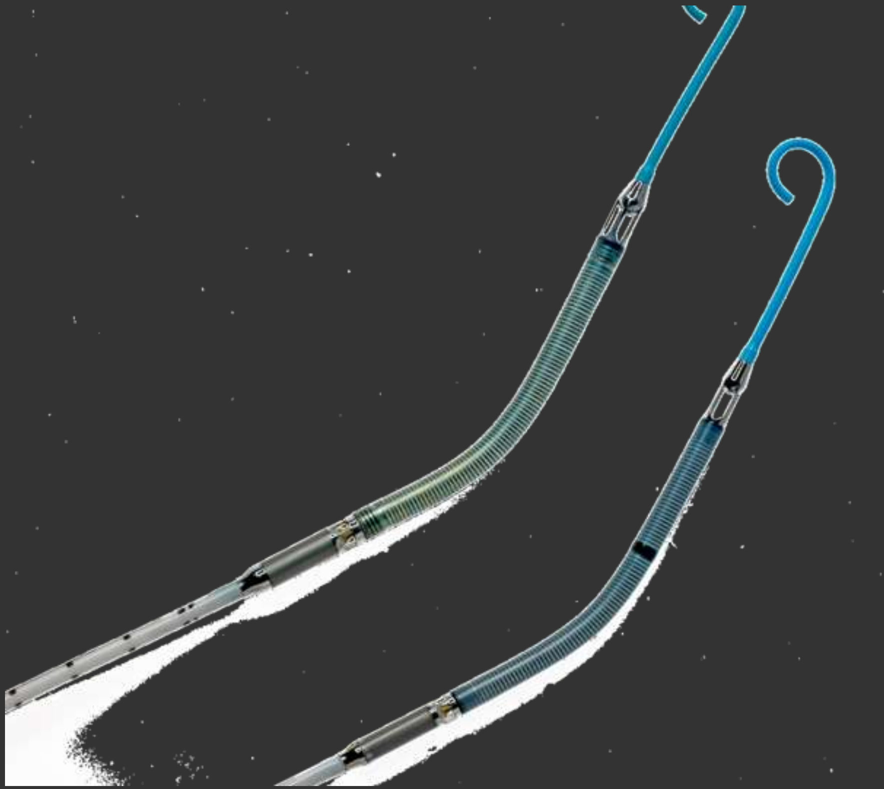
- Percutaneous
  - IABP
  - Tandem
  - Impella
  - ECMO
- Surgical
  - ECMO
  - Centrimag
  - PVAD
  - Syncardia TAH

Temporary Devices: Tandem Heart pVAD



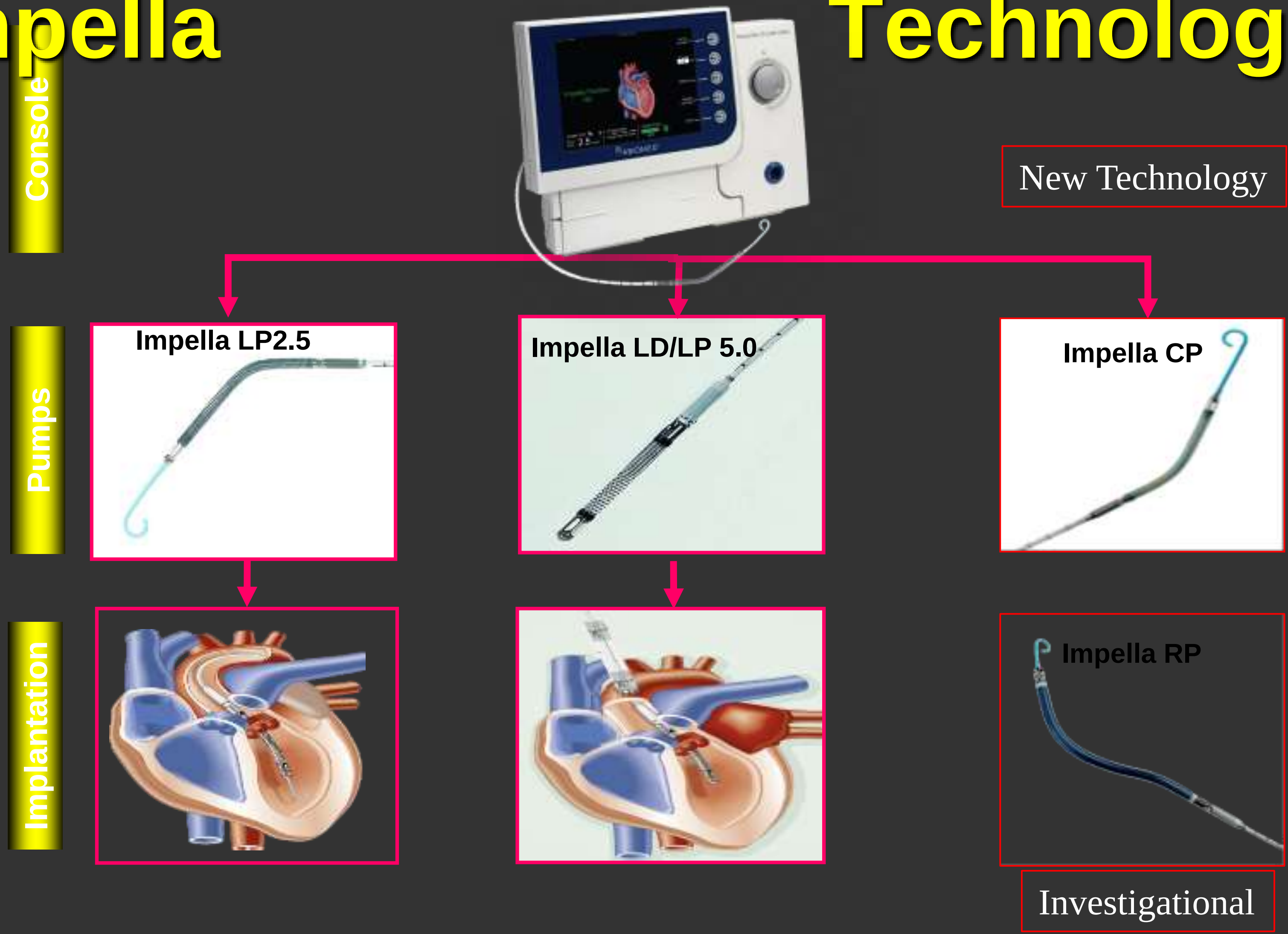
- Continuous-flow centrifugal assist device placed extracorporeally
- Cannula in femoral vein through intraatrial septum into LA
- Pump withdraws oxygenated blood from the left atrium, propels it by a magnetically driven impeller through the outflow port
- Blood returns into femoral artery via arterial cannula

Impella®



- Miniaturized VAD that uses a micro-axial blood pump to support the patient's circulatory system
- Two main designs:
  - Impella® 2.5
  - Impella® 5.0

Impella Technology



Principles of Impella Design

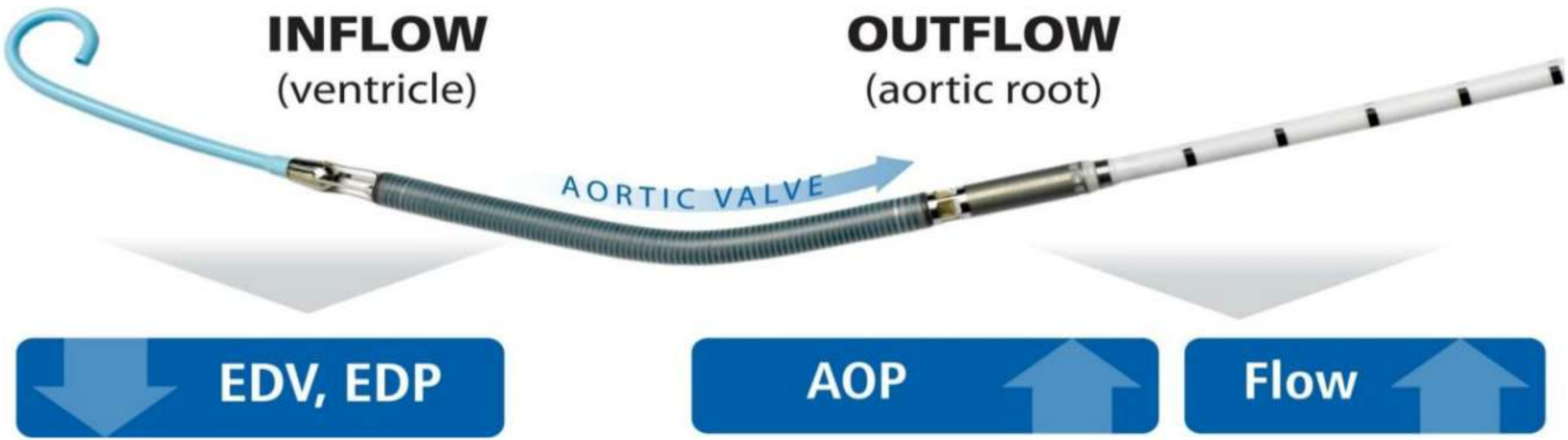
Ideal Cardiac Assist | **Impella Support**

Designed for simple Use ⟷
- World's Smallest Heart Pump
- Independence of Timing Signals

Systemic Hemodynamic Support ⟷
- Augments Net Cardiac Output

ABIOMED

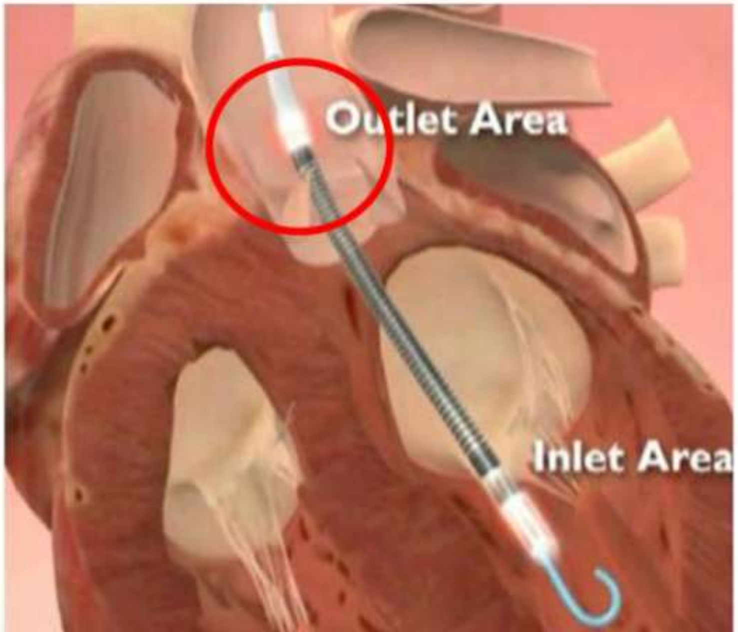
Physiological Results of Impella® Support



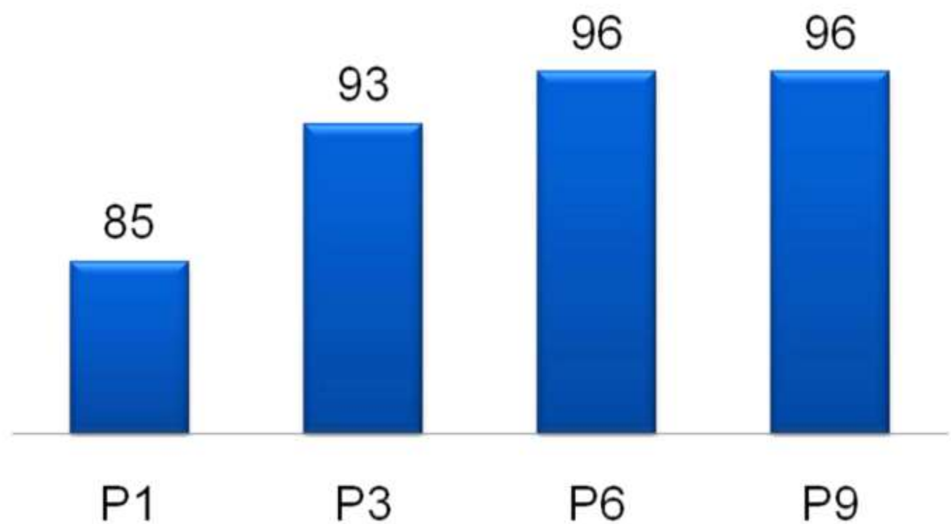
Impella Increases AOP

AOP Increase…Remmelink, et al., Cath Cardiov Interv (2007)

Impella Outlet in Aortic Root



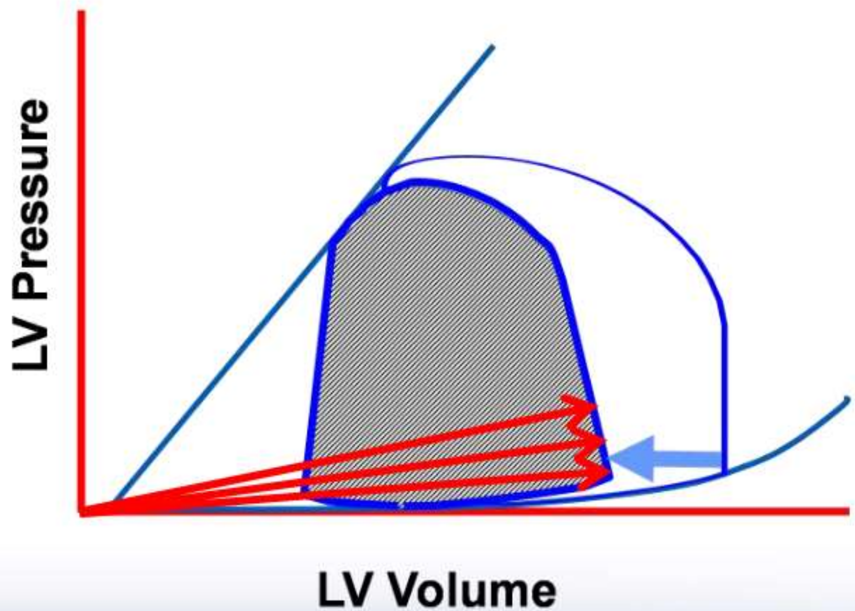
Mean AOP (p=0.001)



Impella 2.5 Support Level

Higher O_2 Supply

Reduced Wall Tension Reduces Microvascular Resistance



Ventricular Unloading Reduces:

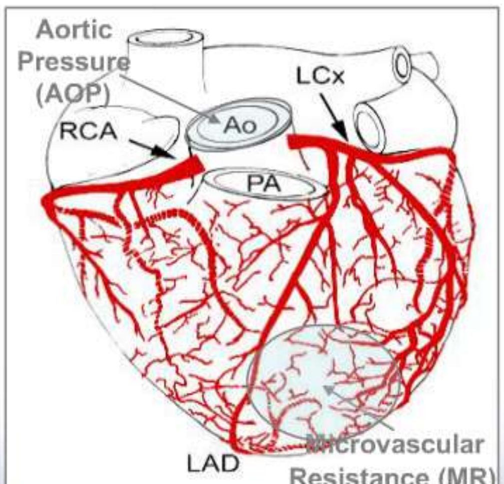
- **End Diastolic Pressure, Volume (EDP, EDV)**
  - **Wall Tension**
    - **Microvascular Resistance**

Remmelink et al., Cath Cardiov Interv. 2007

Higher O_2 Supply Example

Increased Myocardial Blood Flow, Aqel et al. (2008)

Blood Flow (Coronary Arteries & Microvasculature) α $\frac{\text{AOP}}{\text{MR}}$



Example of Improvement in Myocardial Perfusion with Impella Support (Tc-99 MIBI Imaging)

Impella OFF

Under-perfused area

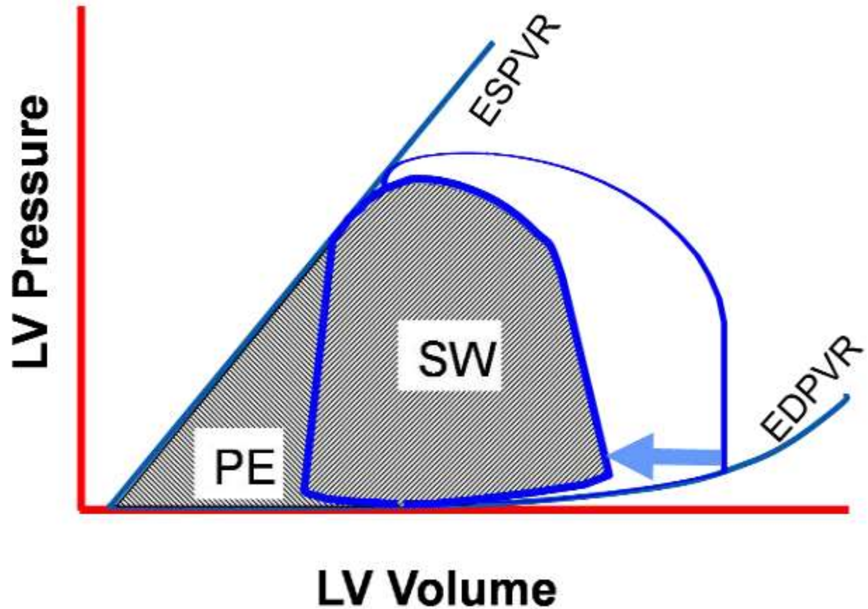
Impella ON

Impella increases perfusion

ABIOMED

O_2 Demand Lower

Ventricular Unloading Reduces Myocardial O_2 Demand



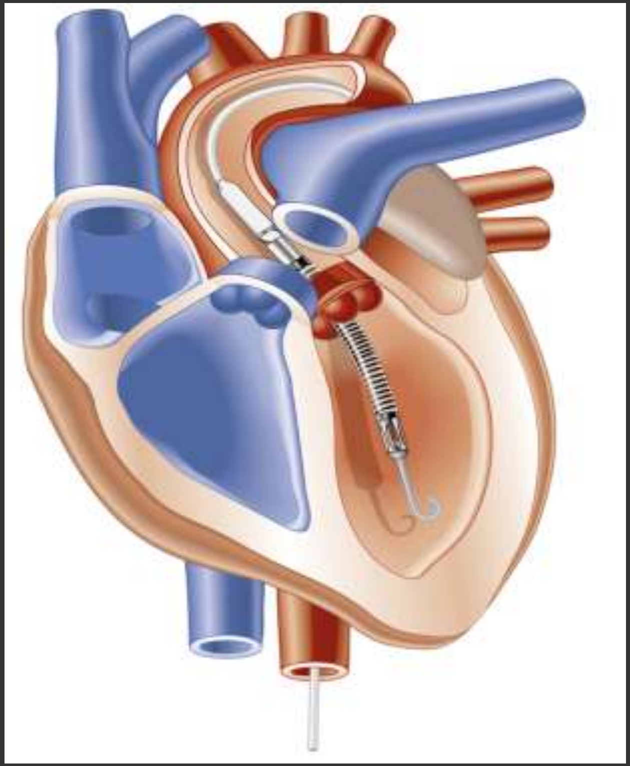
Ventricular Unloading Reduces:

- **End Diastolic Pressure, Volume (EDP, EDV)**
  - **Pressure-Volume Area (PVA)**
    - **Kinetic + Potential Energy**
      - **Myocardial O_2 Demand[1,2]**

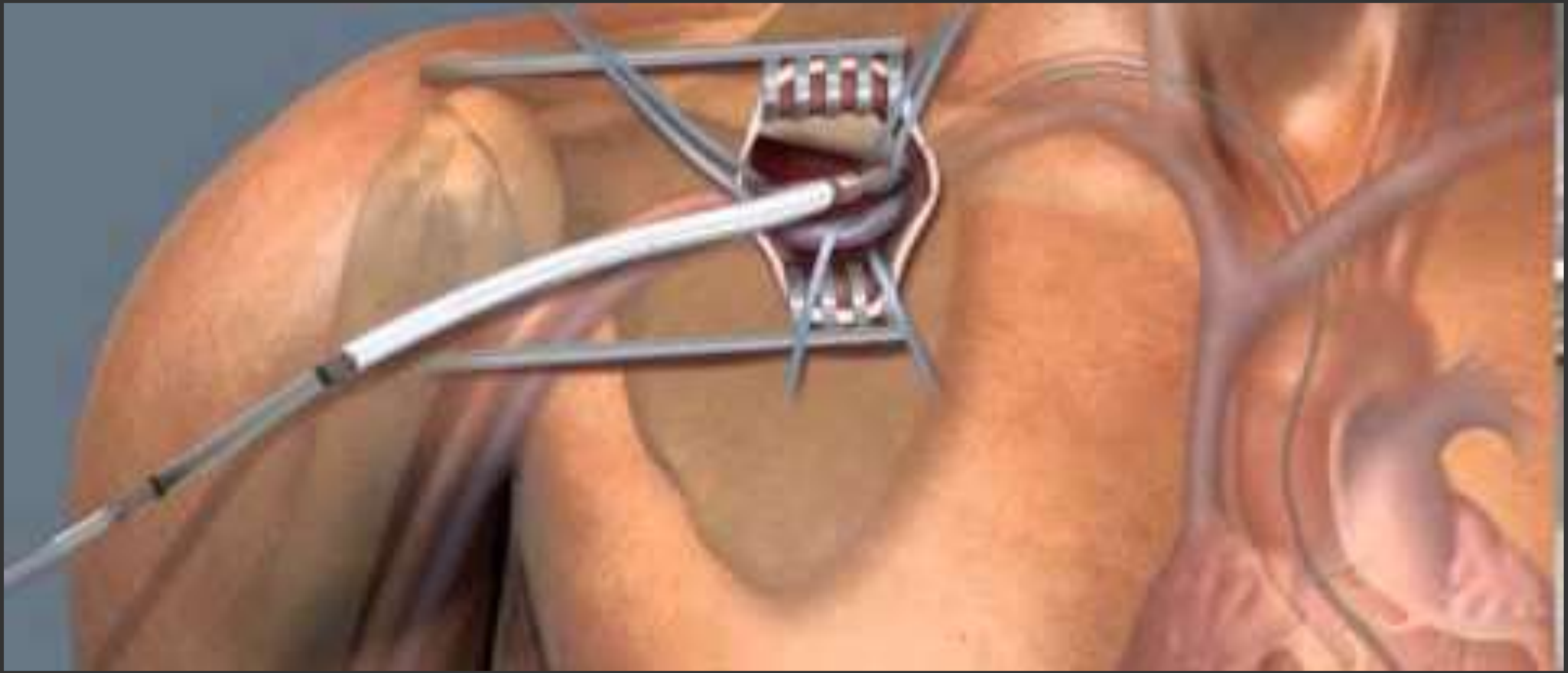
1. *Sarnoff S, Braunwald, G, et al., Hemodynamic determinants of oxygen consumption of the heart with special reference to the tension-time index., XXth International Physiological Congress, Brussels, August, 1956*
2. *Braunwald G, Myocardial oxygen consumption: the quest for its determinants and some clinical fallout. J. Am. Coll. Cardiology, 1999; 34;1365-1368*

Insertion

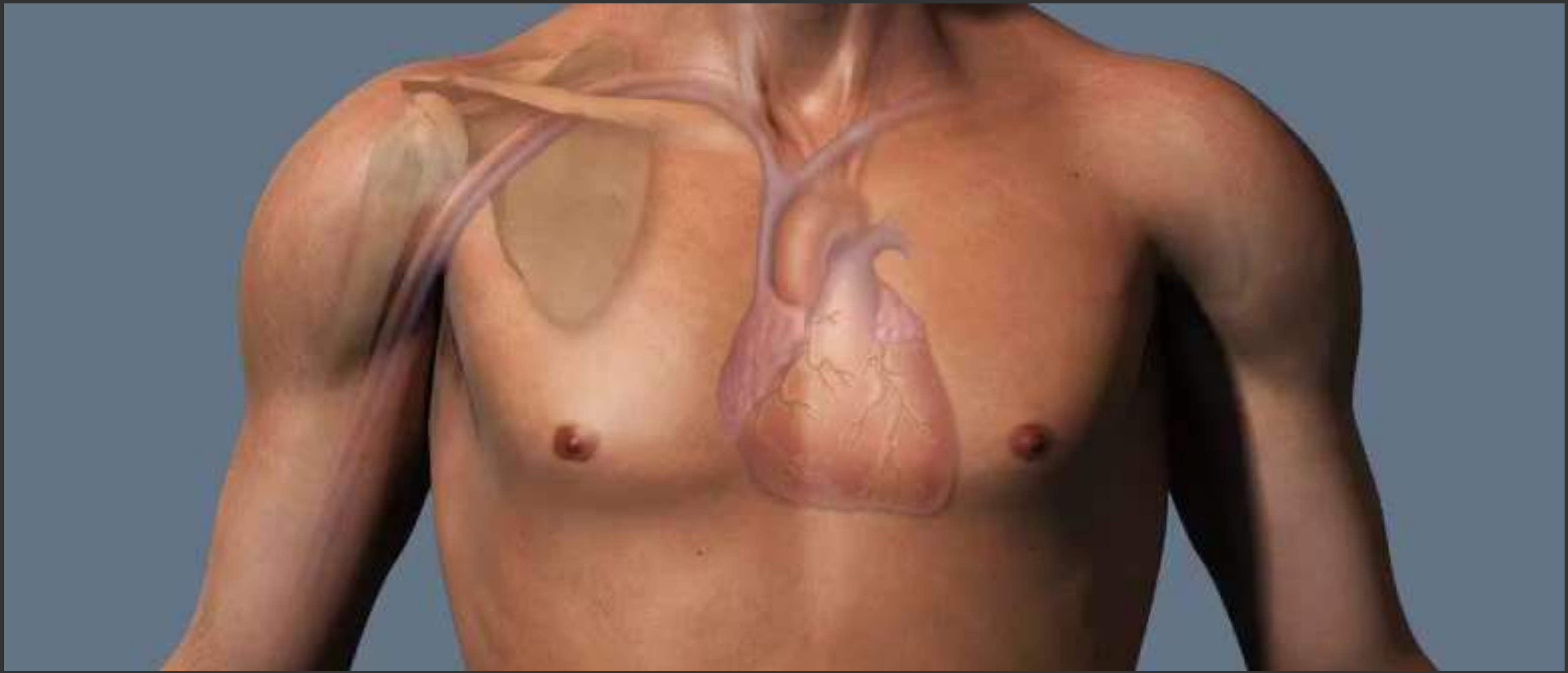
- Percutaneous placement
  - Femoral artery
  - Axillary artery
  - Impella 5.0 requires vascular cutdown
- Catheter needs to sit across the aortic valve



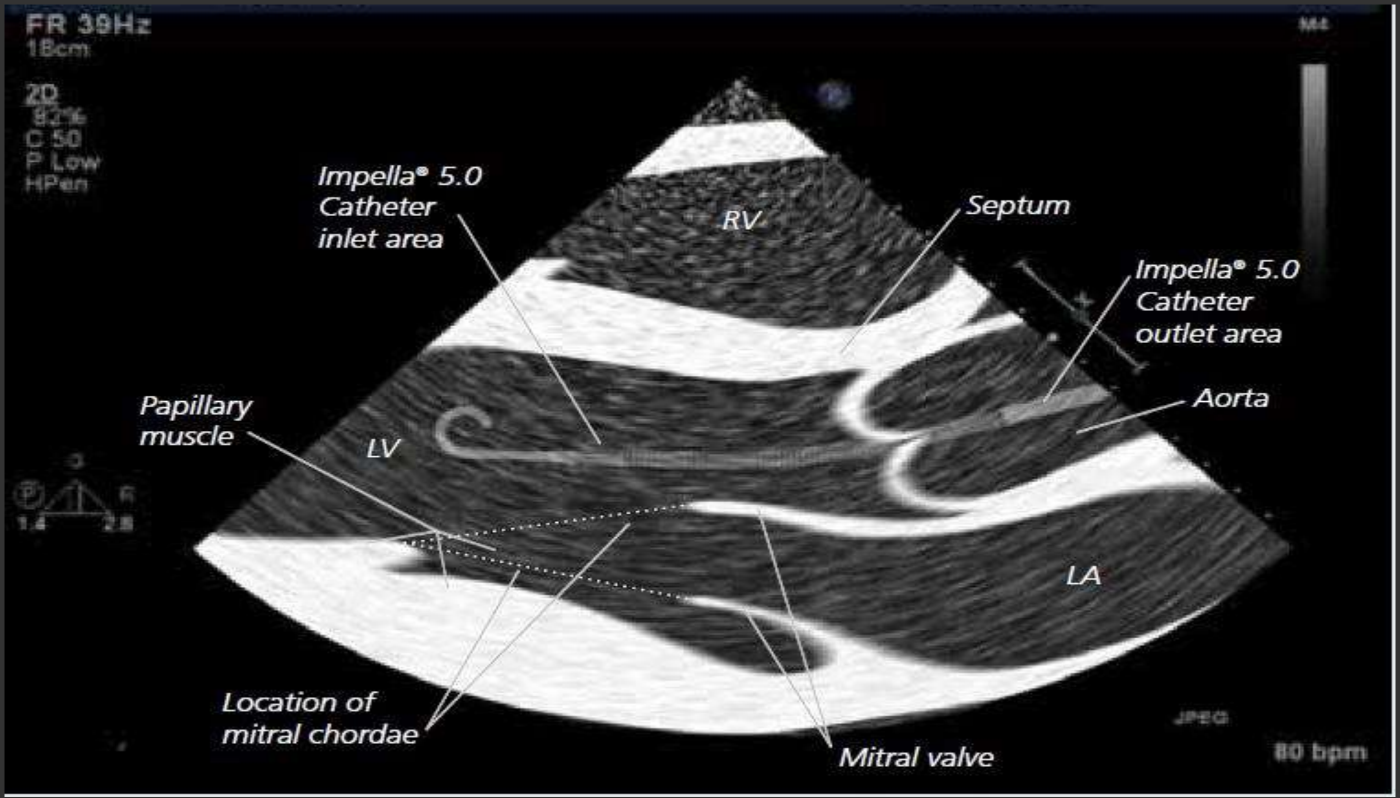
Axillary Artery Insertion



Axillary Implantation

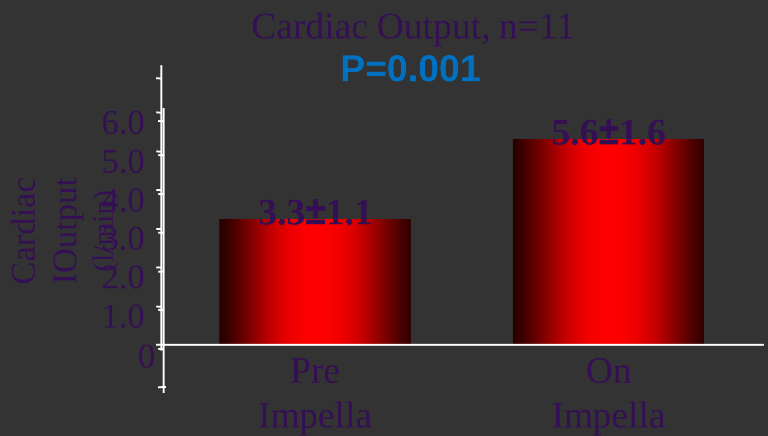


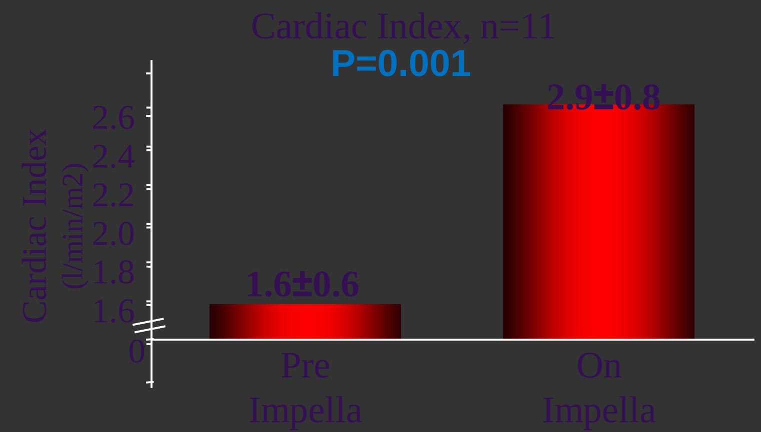
TTE Confirmation

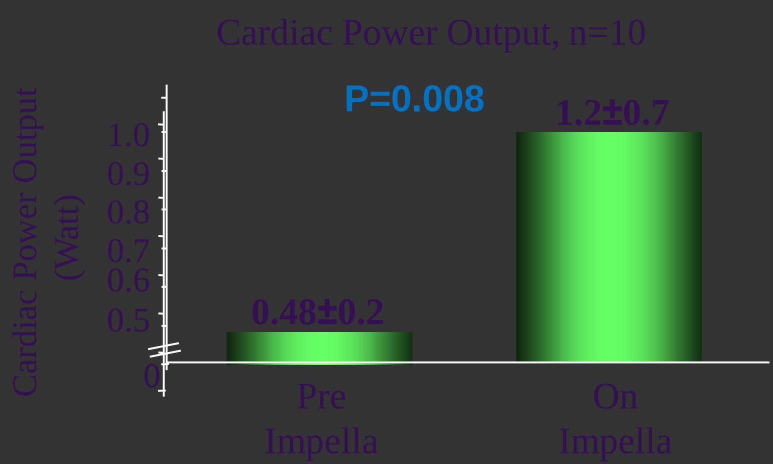


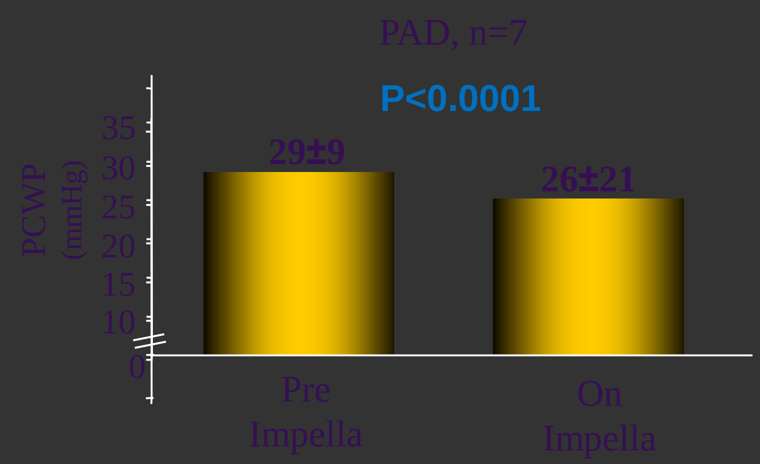
Ambulatory Impella

Hemodynamics

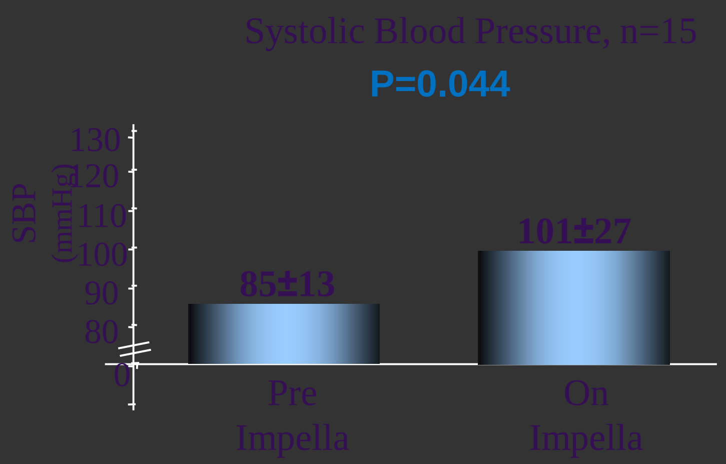


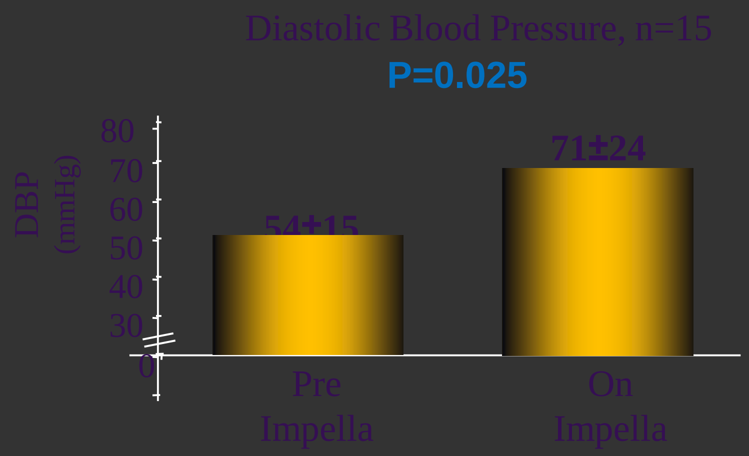


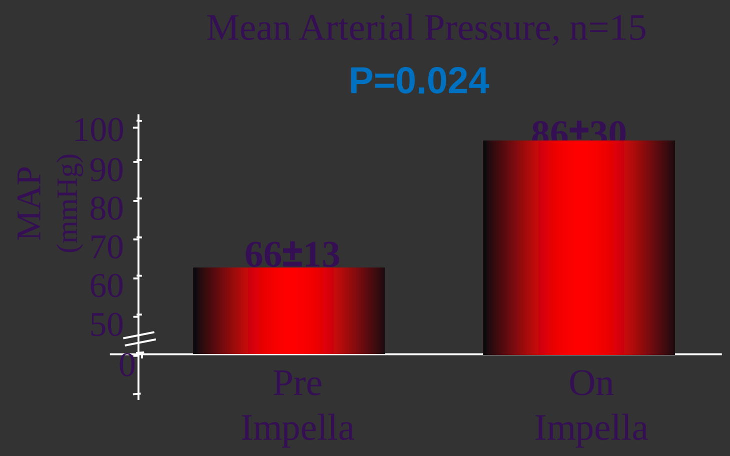




Hemodynamics, cont.







Impella® - Benefits

- Actively unloads left ventricle
- Increases cardiac output up to 5 L/min
- Axillary approach allows for greater patient mobility
- Percutaneous placement
- "The Impella Test" as a predictor of success for long term LVAD support

Clinical Guidelines for Impella

- 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention. *JACC 2011*
  - High risk patients: Class IIb
  - PCI and Cardiogenic Shock: Class I

- 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction. *Circulation 2012*
  - STEMI and Cardiogenic Shock: Class IIb
  - STEMI and urgent CABG: Class IIa

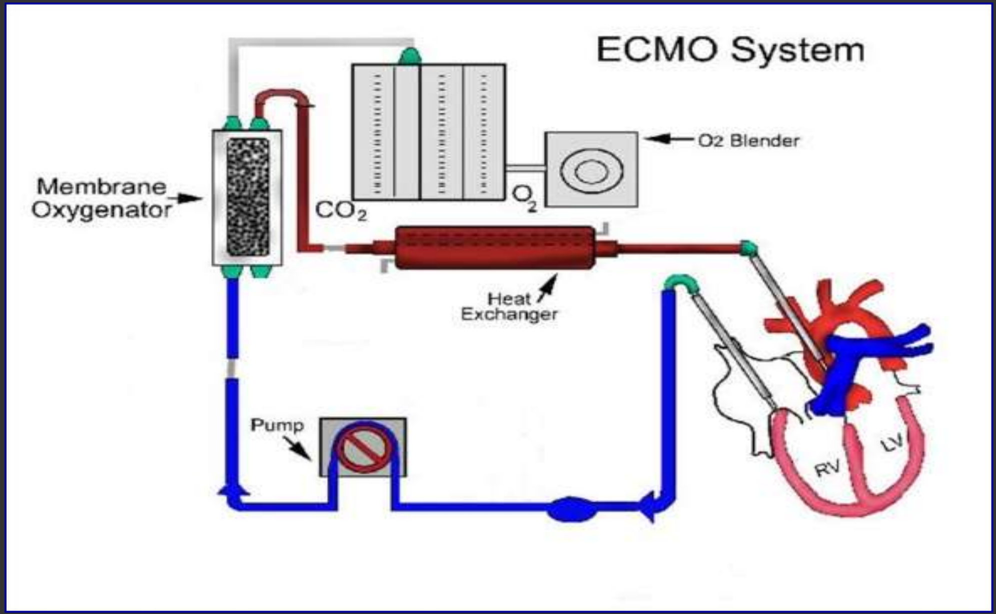
- Use of Mechanical Circulatory Support: American Heart Association. *Circulation 2012*
  - Acutely decompensated heart failure patients: Class IIa

- 2013 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support. *The Journal of Heart and Lung Transplantation, 2013*
  - Temporary mechanical support for patients with multi-organ failure: Class I

- 2013 ACCF/AHA Guideline for the Management of Heart Failure, *Journal of American College of Cardiology 2013*
  - "Bridge to Recovery" or "Bridge to Decision" for patients with acute, profound hemodynamic compromise: Class IIa

Reimbursement and coding information:
Inpatient Hospital = ICD.9 Code 37.68, commonly MS-DRG 216/217
Physician = CPT codes 33990 (insertion), 33992 (removal), 33993 (repositioning)

Categories referencing Impella include Percutaneous LVAD, PVAD, Non-durable MCS, TCS and percutaneous MCSD

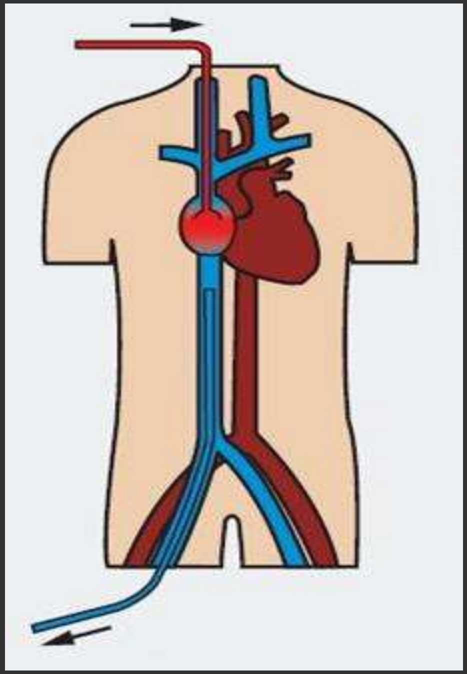


Short Term Support Devices
ECMO

ECMO

- Miniaturized heart-lung machine
  - Functions as artificial lung
  - Functions as artificial heart
- Two main types:
  - VV ECMO
  - VA ECMO

ECMO



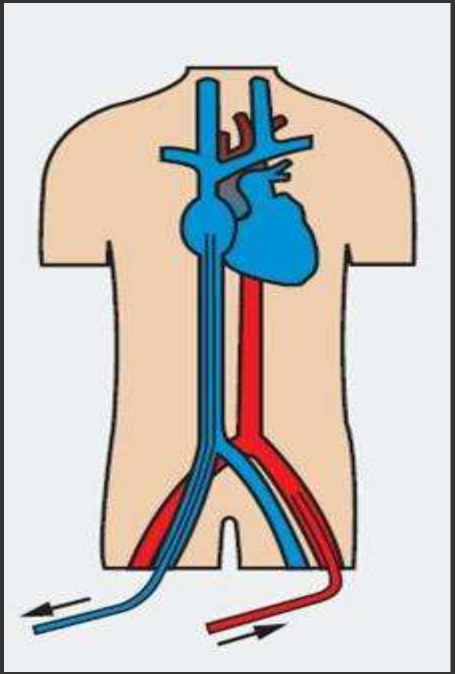
Veno-Venous (VV)

- Blood circulated from venous system and returned to venous system after oxygenation
- Lung support only

ECMO

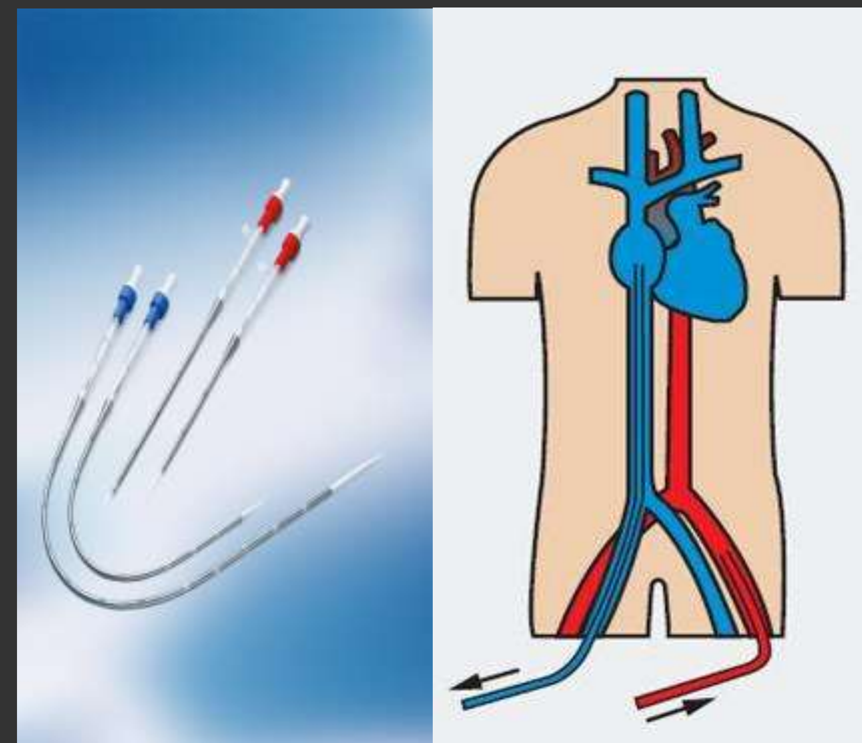
Veno-Arterial (VA)

- Blood circulated from the venous system and returned to arterial system after oxygenation
- Provides heart and lung support



VA ECMO – Insertion

- Percutaneous placement
  - Venous Cannula (drains deoxygenated blood)
  - Arterial Cannula (returns oxygenated blood)
- Seldinger technique
- Large cannulas
  - May need a reperfusion line to distal extremity
  - Vascular Cutdown
- No radiologic assistance required



VV ECMO – Insertion

- Single lumen catheter
  - Similar to VA ECMO
  - R. Internal jugular vein
- Dual lumen catheter
  - Percutaneously placed (single access point)
  - Allows for patient mobilization
  - Requires fluoroscopy assistance

Walking ECMO

http://www.youtube.com/watch?v=oEeNCuIdaG8

Baylor's ECMO Transport

- Transport by ground or air with CareFite®
- Safe and efficient
- Admitted 12 ECMOs from outside hospitals
  - 4 from different health care systems
  - 8 from within BHCS

Baylor's RED Team

- **R**apid **E**CMO **D**eployment Team
  - Composed of CT Surgeon, ECMO specialist and perfusionist
  - Implemented an ECMO primed circuit and an ECMO insertion cart that is ready at all times
  - Can go anywhere in the hospital and implement ECMO therapy

History

- 62 yo AA woman
- 2000 Dilated Cardiomyopathy, normal cors, EF 25%
- Med mgmt with usual GDMT
- 2009 BiV ICD
- 2013 steady deterioration, 3 hospitalizations
  - Progressive renal insufficiency
  - Dbx and DA
  - Transferred to our center for eval for cardiac replacement therapy

PMHx

- Low grade Breast CA 2010, - neg nodes, pt elected for bilateral mastectomy
- AODM for 15 yrs – oral meds until mid 2013 when lantus started
- 40 ppy smoker – quit 2007
- Normal renal function until 2013
- Supportive family

Evaluation

- Day 1
  - Arrived on Dbx 5, DA 5
  - Hemos: RA 30, RV 65/30, PA 74/43 mean 51, PW 42, CI 1.0, SVO2 27%
  - Labs: BNP 3341, Na 125, Cr 2, Hct 30,Cr Cl 49
- Day 2-5
  - Completed tx eval
  - Added Primacor, bumex drip
  - Blood type B, 100 kg, 0% PRAs
- Day 6
  - Meds: Prim .75, Dbx 5, DA 5, Bumex 1
  - Hemos: RA 26, PA 61/35 mean 45, CI 1.8, SVO2 37%, PCW 20, Ao 85/55 mean 65
  - Approved and listed Status 1A
  - Labs: Na 119, K 3, Cr 1.4, Hct 25

Impella

- Day 7
  - Intubated for surgical implant of Impella 5.0, complicated by extensive bleeding requiring transfusion 3U pRBCs
- Day 8
  - Hemos: RA 14, PA 44/28, mean 34, PCW 16, CO 4.8, CI 2.4, SVO2 59%, Ao 92/75 mean 88
  - Labs: Na 124, K 3.4, Cr 1.5, Hct 19, plasma Hg 23
  - Extubated
- Day 9-16
  - Meds: Weaned off DA, decreased Dbx to 3, Prim to .5
  - Labs: best Na 130, best Cr 1.3, best Hct 27
  - Swan removed Day 12 due to fever. Final hemos: RA 12, PA 54/26 mean 35, PCW 18, SVO2 62%, CI 2.3 on Prim .5, Dbx 5.
  - Patient monitored by daily SVO2, bp and clinical signs
  - Clinical Course: perisistent oozing requiring 3 more units pRBCs as well as possible hemolysis +- DIC; febrile syndrome with WBC26K. Only positive culture was urine for >100K yeast. Minimal ambulation but in and out of bed to chair tolerated.

Success

- Day 17
  - Suitable donor found.
  - SVO2 45%
  - Labs: Na 130, K 4.2, Cr 1.4, Hct 24
- Day 18-26
  - Extubated POD#2, acute renal insuff, extensive periop bleeding, post op afib (spontaneously resolved POD8)
  - Transferred to tele POD#3, all CT out POD#3
- Day 27 (POD#10)
  - Discharged to rehab facility
  - Labs: Na 136, K 3.9, Cr 1, Hct 31

Our Process

- Primarily Axillary so that we can rehab patient
- Transplant Candidate
  - Is renal function marginal?
  - Are pulmonary pressures unresponsive?
  - Implant Impella 5.0 and attempt to wean off inotropes and reassess renal function
- VAD Candidate
  - Is renal function marginal?
  - Is RV function marginal?
  - Implant Impella 5.0 and attempt to wean off inotropes and reassess.
  - If RV still needs inotropes, high likelihood of needing RV support post VAD

Conclusions

- Impella is a useful tool for short term mechanical circulatory support as bridge to transplant (our longest support over 30 days)
  - Improves renal function (thus proving cardiorenal vs intrinisic renal disease)
  - Improves pulmonary hypertension
  - Helps determine if RV function can improve enough to tolerate long term VAD if needed
- Current techniques are still laborious and periprocedural bleeding requiring transfusion is too common
- The need for easier insertion and minimizing bleeding is imperative