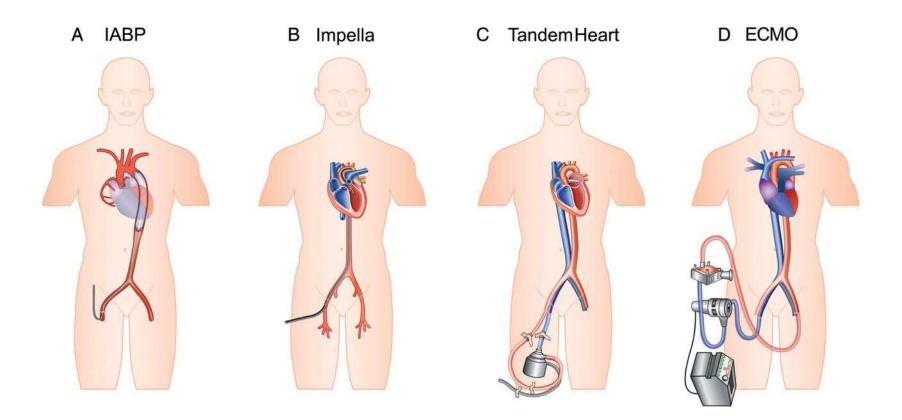
ECMO and Percutaneous LVAD in the ICU 2015

Eduardo de Marchena MD, FACP, FACC, FSCAI Professor of Medicine and Surgery Associate Dean of International Medicine University of Miami Miller School of Medicine

Potential conflict of Interest

- Support for Educational Conferences
 - Most Cardiovascular Corporations
- Current Sponsored Research Support
 - Medtronic
 - CoreValve Trials, Simplicity trials
 - Other Conflicts:
 - 1. Tendyne Medical Inc.
 - Medical Director and stock holder
 - 2. Intergene International LLC -Medical Advisory Board
 - 3. Aegis Medical Medical Advisory Board
 - 4. St. George Medical consultant

Percutaneous assist devices in cardiogenic shock.



Werdan K et al. Eur Heart J 2014;35:156-167

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Mechanical circulatory support in cardiogenic shock

Table 2

Comparison of devices

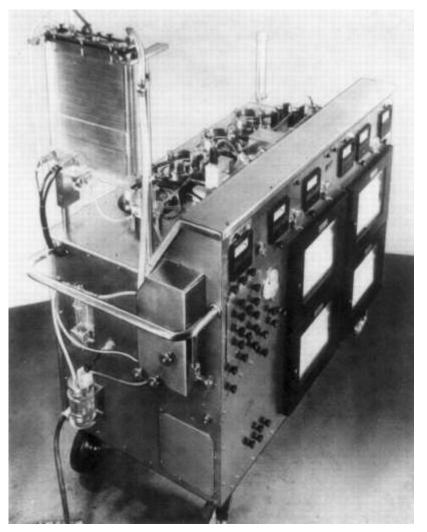
	IABP	ECMO	TandemHeart	Impella 2.5	Impella 5.0
Pump mechanism	Pneumatic	Centrifugal	Centrifugal	Axial flow	Axial flow
Cannula size	7.9 Fr	18-21 Fr inflow;15-22 Fr outflow	21 Fr inflow; 15-17 Fr outflow	13 Fr	22 Fr
Insertion technique	Descending aorta via the femoral artery	Inflow cannula into the right atrium via the femoral vein, outflow cannula into the descending aorta via the femoral artery	21 Fr inflow cannula into left atrium via femoral vein and transseptal puncture and 15–17 Fr outflow cannula into the femoral artery	12 Fr catheter placed retrogradely across the aortic valve via the femoral artery	21 Fr catheter placed retrogradely across the aortic valve via a surgical cutdown of the femoral artery
Haemodynamic support	0.5 – 1.0 L min ⁻¹	>4.5 L min ⁻¹	4 L min ⁻¹	2.5 L min ⁻¹	5.0 L min ⁻¹
Implantation time	+	++	+++	++	++++
Risk of limb ischaemia	+	+++	+++	++	++
Anticoagulation	+	+++	+++	+	+
Haemolysis	+	++	++	++	++
Post-implantation management complexity	+	+++	++++	++	++
Optional active cooling in post- cardiopulmonary resuscitation patients	No	Yes	(Yes)	No	No

ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; +, ++, +++, ++++, relative qualitative grading concerning time ('implantation time'), risk ('risk of limb ischaemia'), intensity ('anticoagulation', 'post-implantation management complexity'), and severity ('haemolysis'). Modified from Ouweneel and Henriques.³²

ECMO History

- 1953- First successful CPB procedure by Dr. Gibbon
- •1956- Clowes & Balser developed first membrane oxygenator
- 1972- First successful adult ECMO.
- 1976- First successful neonatal ECMO.
- 1989- Establishment of ELSO organization.

Gibbon heart-lung machine Model II. Reprinted with permission from reference 5.

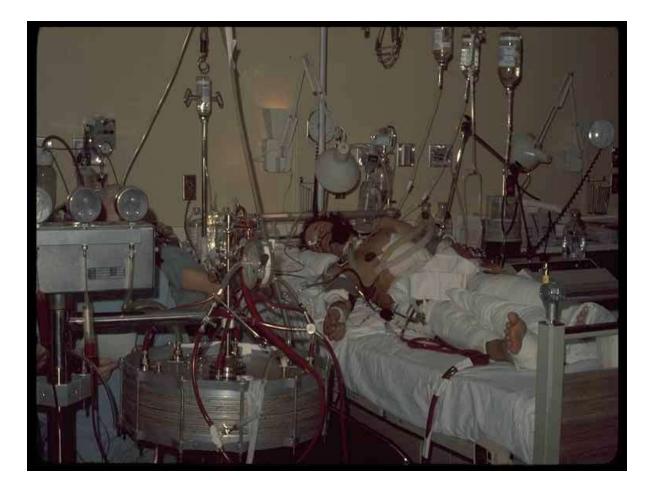


Cohn L H Circulation. 2003;107:2168-2170



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First Successful ECMO Patient



ECMO Concepts

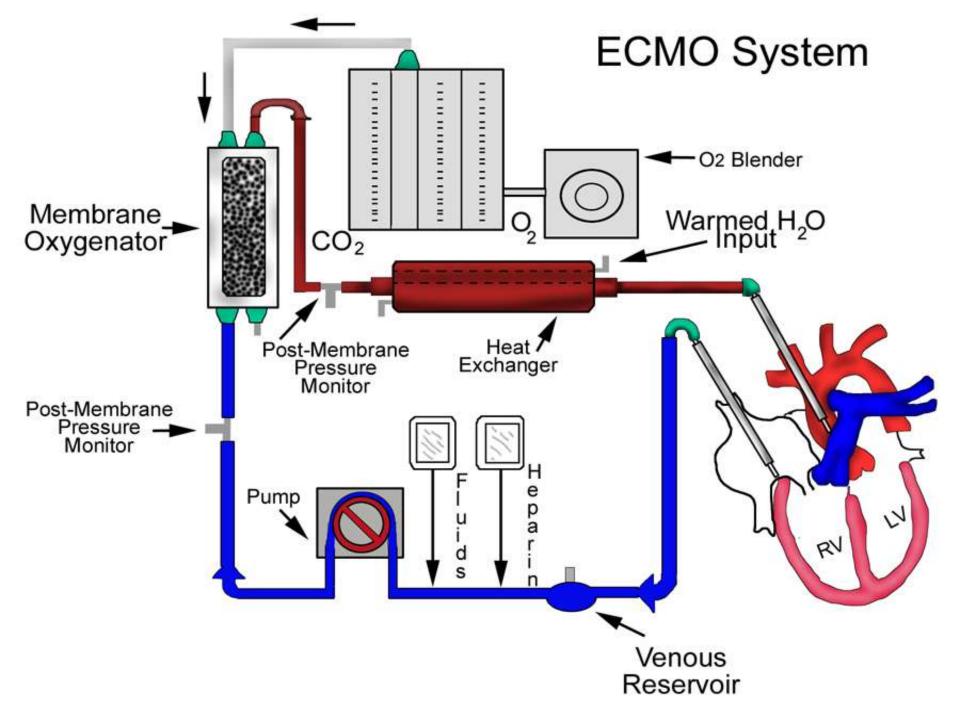
- Blood is circulated outside the body by a mechanical pump
- Outside the body, the blood passes through an oxygenator and heat exchanger.

-----BlEpub 2013 Jan 5. ood oxygenation and decarboxylation determinants during venovenous ECMO for respiratory failure in adults. Schmidt M, et al. ASOIntensive Care Med. 2013 May;39(5):838-46.

ECMO Components

- ECMO pumps: roller (afterload independent) and centrifugal (fewer gaseous microemboli, preload and afterload dependent.)
- Membrane oxygenators mimic the human lung by interspersing a thin membrane of either microporous polypropylene hollow fibre or non-microporous silicone rubber between the gas and blood
- Heat exchanger to minimize bubble emboli.
- Drainage cannula (21F to 28F) and return cannula (15F to 21F)
- Polyvinyl tubing

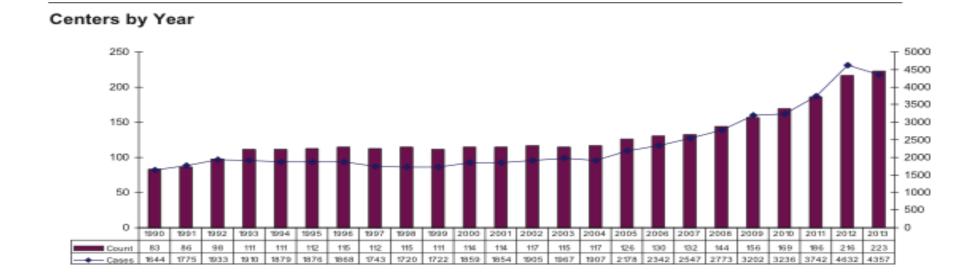
Lafç G et al. Use of extracorporeal membrane oxygenation in adults. Heart Lung Circ. 2014 Jan;23(1):10-23. doi:10.1016/j.hlc 2013.08.009. Epub 2013 Sep 1. PubMed PMID: 24144910



ECMO Improvements

- Devices are more durable
- Longer lasting components
- Improved bio-compatibility
- Less hemolysis
- Decreased pressure drop
- Leave blood activation / coagulation cascade intact
- Smaller design
- Less foreign surface area
- Less hemodilution

ECLS Registry Report January 2014



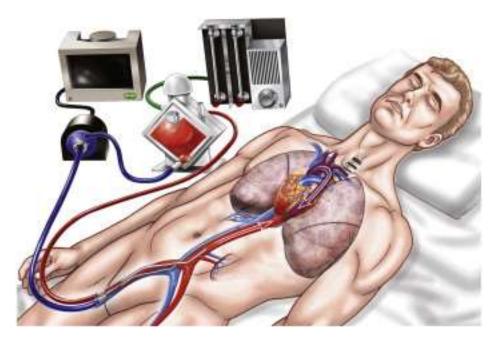


Figure 3 Femoral Venoarterial ECMO When extracorporeal membrane oxygenation (ECMO) is implemented via femoral venous drainage and femoral arterial return in patients with residual native cardiac function and impaired lung function, reinfused oxygenated bl...

Darryl Abrams, Alain Combes, Daniel Brodie

Extracorporeal Membrane Oxygenation in Cardiopulmonary Disease in Adults

Journal of the American College of Cardiology, Volume 63, Issue 25, Part A, 2014, 2769 - 2778

http://dx.doi.org/10.1016/j.jacc.2014.03.046

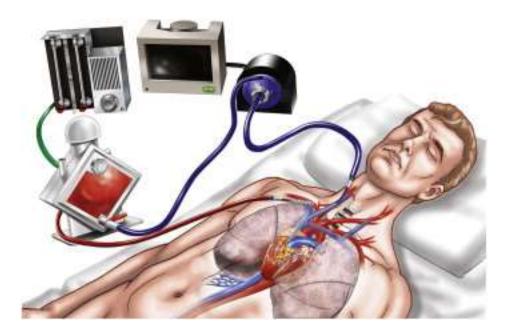


Figure 4 Venoarterial ECMO With Internal Jugular Venous Drainage and Subclavian Arterial Reinfusion An alternative approach to femoral venoarterial extracorporeal membrane oxygenation (ECMO) is drainage from the internal jugular vein and reinfusion into t...

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http://dx.doi.org/10.1016/j.jacc.2014.03.046

VA ECMO

- Femoral access is preferred because of ease but with increased risk of ipsilateral ischemia
- Risk of ipsilateral ischemia can be decreased by inserting an additional arterial cannula distal to the femoral artery cannula
- Right common carotid artery or Axillary/Subclavian artery can be used if femoral access is contraindicated (PVD)
- Increased risk of watershed cerebral infarction
- Use of the subclavian artery offers the advantage of allowing patients on ECMO to ambulate

-Extracorporeal membrane oxygenation with right axillary artery perfusion.Navia JL et al. Ann Thorac Surg. 2005;79(6):2163.

VA ECMO (Respiratory and . <u>Central:</u> Hemodynamic)

- Drained (venous) Right Atrium
- Returned (arterial) Left Atrium or Proximal Aorta
- <u>Peripheral:</u>
- Drained (venous) Femoral or Jugular Vein
- Returned (arterial) Femoral, Carotid or Axillary, Subclavian

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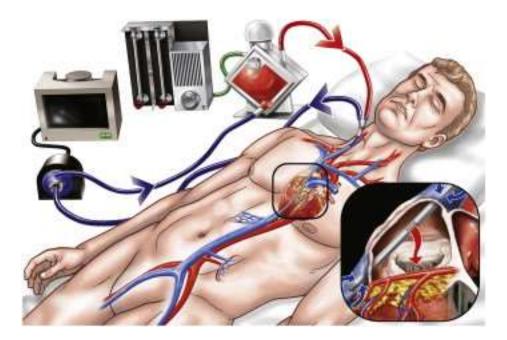


Figure 2 Single-Site Venovenous Extracorporeal Membrane Oxygenation A dual-lumen cannula in the internal jugular vein permits both venous drainage and reinfusion without the need for femoral cannulation. (Inset) Deoxygenated blood is withdrawn through p...

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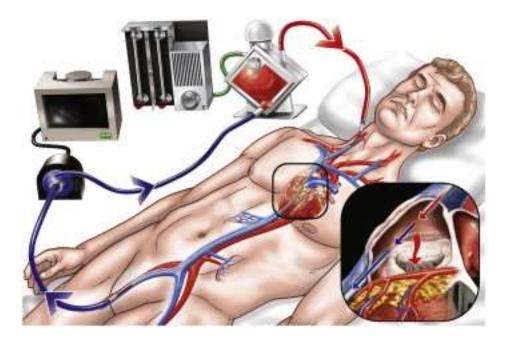


Figure 1 Two-Site Venovenous Extracorporeal Membrane Oxygenation Venous blood is withdrawn from a central vein, pumped through an oxygenator, and reinfused into a central vein. (Inset) Drainage and reinfusion ports in close proximity may lead to oxygena...

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VV ECMO (Respiratory Support)

- Cannulae are usually placed in the right common femoral vein (for drainage) and right internal jugular vein (for infusion).
- Provides respiratory support

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Indications and Highest Level of Evidence for ECMO in Cardiopulmonary Disease

Respiratory		
	ARDS	Randomized controlled trials
	Hypercapnic respiratory failure	Prospective feasibility studies
	Bridge to lung transplantation	Cohort studies
	Primary graft dysfunction after lung transplantation	Cohort studies
Cardiac		
	Myocardial infarction– associated cardiogenic shock	Cohort studies
	Fulminant myocarditis	Cohort studies
	Sepsis-associated cardiomyopathy	Case series
	Pulmonary hypertension	Case series
	Extracorporeal cardiopulmonary resuscitation	Cohort studies with propensity analyses
	Post-cardiotomy cardiogenic shock	Cohort studies
	Primary graft failure after heart transplantation	Cohort studies
	Bridge to VAD implantation or heart transplantation	Cohort studies
	Prevention of acute right ventricular failure after LVAD implantation	Cohort studies

Potential ECMO Benefits in Cardiogenic Shock & Cardiac Arrest

- Easy to implement
- Fast cannulation / initiation of support
- Can be performed at beside, cath lab or O.R.
- Biventricular support at high blood flow rates
- Potential to support patients with lung injury as well
- Hemofiltration can be added
- Avoid more expensive implantable device insertions in non-qualified candidates

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ECMO Cardiac Indications & Outcomes

Table 1 Indications for ECMO in cardiac failure

Indication for ECMO	Highest quality studies available	
Indication for ECMO Myocardial infarction-associated cardiogenic shock Fulminant myocarditis Sepsis-associated cardiomyopathy Decompensated pulmonary hypertension with right ventricular failure Bridge to VAD or heart transplantation Right ventricular support during LVAD implantation in biventricular failure Pulmonary embolism with refractory shock Post-cardiotomy cardiogenic shock Primary graft failure post-heart transplantation	Cohort studies Cohort studies Case series Case series Cohort studies Cohort studies Cohort studies Case series Cohort studies Cohort studies Cohort studies Cohort studies	
Cardiac arrest (ECPR)	Cohort studies with propensity analyses	

VAD ventricular assist device, LVAD left ventricular assist device, ECPR extracorporeal cardiopulmonary resuscitation

Abrams D et al. What's new in extracorporeal membrane oxygenation for cardiac failure and cardiac arrest in adults? Intensive Care Med. 2014 Apr;40(4):609-12.

Fulminant Myocarditis

- 2001 to 2006, 11 pts w/fulminant myocarditis
- 5 BiVAD/6 ECMO
- 21 +/- 5 days on BiVAD vs 13 +/- 4 days in ECMO.
- 1 patient died in each group
- No transplantation
- Quicker recovery of renal and hepatic function on ECMO

O.N. Pages, S. Aubert, A. Combes, et al. Paracorporeal pulsatile biventricular assist device versus extracorporal membrane oxygenation-extracorporal life support in adult fulminant myocarditis J Thorac Cardiovasc Surg, 137 (2009), pp. 194–197

Sepsis-associated Cardiomyopathy

- 1/08 9/11
- 14 patients, (28-66 yrs)
- No hx of CMP
- ECMO for septic shock refractory to conventional treatment w/severe myocardial dysfunction & multi-organ failure
- LVEF 16% (10% to 30%),Cl 1.3 L/min/m (0.7-2.2)
- SVRI was 3162 (2047-7685)
- 10 patients (71%) were discharged to home and alive after 13 months (3-43).
- All 10 survivors w/normal LVEF
 Schmidt, et al. Venoarterial extracorporeal membrane oxygenation support for refractory cardiovascular dysfunction during severe bacterial septic shock Crit Care Med, 41 (2013), pp. 1616–1626

Massive Pulmonary Embolism

- 1/92 12/05
- 43 patients were referred for ECLS for presumed massive PE
- 7 felt clinically stable and all survived to discharge
- 15 excluded all died : prolonged CPR (5), irreversible injury (4), age > 70 yrs (3), wt > air transportation limit (3) & prolonged intubation (3).
- 21 pts placed on ECLS (2 V-V, 19 V-A), 8 w/cardiac arrest
- 13 of 21 pts (62% survived and were doing well 1 year from hospital discharge.

------Maggio P, Hemmila M, Haft J, Bartlett R.Extracorporeal life support formassivepulmonaryembolism. J Trauma 2007Mar 62(3):570-6.

ECLS Registry Report

International Summary January, 2014



Extracorporeal Life Support Organization 2800 Plymouth Road Building 300, Room 303 Ann Arbor, MI 48109

Overall Outcomes

	Total Patients	Survived ECLS		Survived to DC or Transfer	
Neonatal					
Respiratory	27,007	22,782	84%	20,093	74%
Cardiac	5,425	3,339	62%	2,206	41%
ECPR	980	626	64%	388	40%
Pediatric					
Respiratory	6,149	4,034	66%	3,496	57%
Cardiac	6,784	4,443	65%	3,388	50%
ECPR	2,071	1,123	54%	840	41%
Adult					
Respiratory	5,146	3,317	64%	2,905	56%
Cardiac	4,042	2,255	56%	1,636	40%
ECPR	1,238	476	38%	355	29%
Total	58,842	42,395	72%	35,307	60%

Centers by Year



ECMO Titration VenoVenous

- Oxygenation is determined by flow rate
- Elimination of CO2 can be controlled by adjusting the rate of countercurrent gas flow through the oxygenator

Blood oxygenation and decarboxylation determinants during venovenous ECMO for respiratory failure in adults. Schmidt M, et al. ASOIntensive Care Med. 2013 May;39(5):838-46. Epub 2013 Jan 5.

Respiratory Management

Ventilator settings are reduced during ECMO in order to avoid barotrauma, volutrauma and oxygen toxicity.

Plateau airway pressures should be maintained less than 20 cm H2O and FiO2 less than 0.5.

Reduction of ventilator support is usually accompanied by increased venous return and cardiac output

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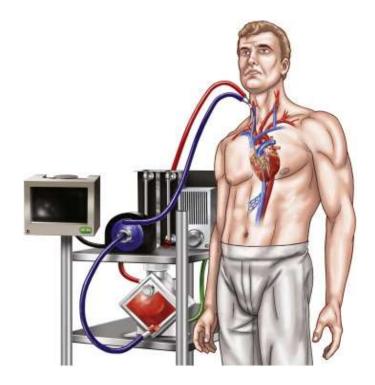


Figure 5 ECMO in the Ambulatory Patient Upper-body configurations and compact circuits facilitate mobilization in patients with respiratory failure requiring extracorporeal membrane oxygenation (ECMO).

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Extracorporeal Membrane Oxygenation in Cardiopulmonary Disease in Adults

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ECMO Titration; VA ECMO

- Arterial oxyhemoglobin saturation of >90 percent for VA ECMO
- Venous oxyhemoglobin saturation of 70 to 80 percent for VA ECMO, measured on the venous line
- Adequate tissue perfusion, as determined by the arterial blood pressure, venous oxygen saturation, and blood lactate level

VA ECMO Hemodynamic Management

- Flow rate must be high enough to provide adequate perfusion pressure and VO2 but low enough to provide sufficient preload to maintain left ventricular output.
- Aggressive diuresis is usually warranted once the patient is stable on ECMO
- Left ventricular output must be monitored by frequent echo and pulsatility
- Minimize inotropes to rest heart
- Low dose inotrope to ensure some contractility and adequate emptying of the left ventricle

VA ECMO Hemodynamic Management

- LV output may worsen in the setting of insufficient unloading of the distended left ventricle
- Can lead to increased cavity pressure, pHTN, pulmonary vascular injury & ARDS
- IABP can be added to central ECMO to increase pulsatility, improve coronary perfusion, and decrease the ventricular afterload. (Doll et al showed higher survival)
- Percutaneous atrial septostomy but does not improve stasis and req repair
- Impella can be used with peripheral ECMO to facilitate LV unloading and prevent stasis

N. Doll et al. Five-year results of 219 consecutive patients treated with extracorporeal membrane oxygenation for refractory postoperative cardiogenic shock Ann Thorac Surg, 77 (January (1)) (2004), pp. 151–157 Lafç G et al. Use of extracorporeal membrane oxygenation in adults. Heart Lung Circ. 2014 Jan;23(1):10-23.

Cheng A, Swartz MF, Massey HT. Impella to unload the left ventricle duringperipheral extracorporeal membrane oxygenation. ASAIO J. 2013Sep-Oct;59(5):533-6.

Weaning

- Enhanced aortic pulsatility correlates with improved left ventricular function
- VA ECMO trials are generally short because of the higher risk of thrombus formation.

Weaning

- Increased heparin given potential stasis/ thrombosis at low ECMO flows
- Echo to asses cardiac recovery
- Modest inotropic support initiated several hours prior to weaning.
- Flows are slowly reduced to 1–2 L/min with decannulation if stable after 1–2 h

in adults. Heart Lung Circ. 2014 Jan;23(1):10-23.

ECMO Complications

- Bleeding
- Hemorrhage into body cavities
- Systemic thromboembolism due to thrombus formation within the ECMO circuit
- Hemolysis
- Cannulation-related issues
- Distal ischemia
- HIT
- Renal Injury

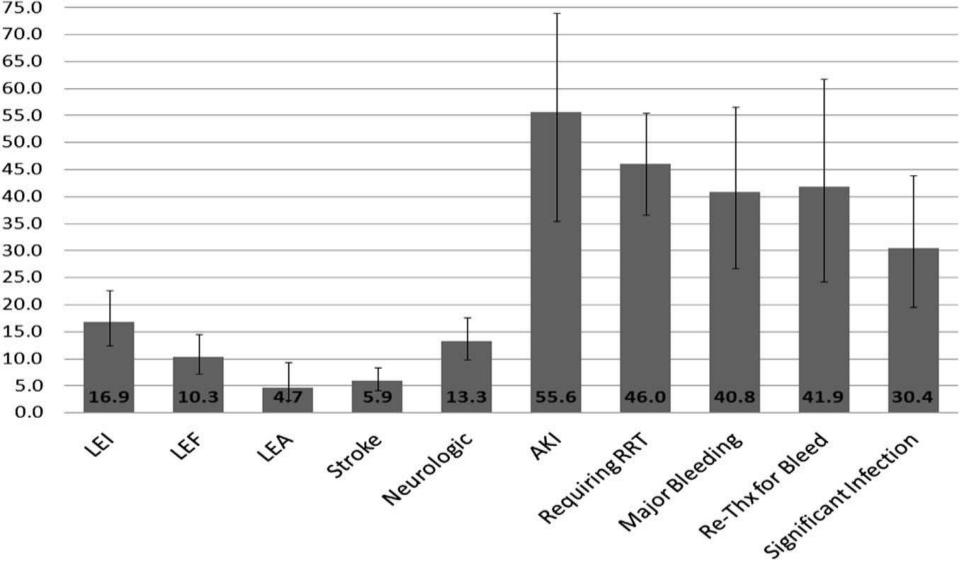
VA ECMO Complications

- Pulmonary hemorrhage
- Cardiac thrombosis
- retrograde blood flow in the ascending aorta and stasis can occur if LV output is not maintained
- Coronary or cerebral hypoxia –
- I. Blood infused into the femoral artery from the ECMO circuit will preferentially perfuse the lower extremities and the abdominal viscera
- II. Blood from the heart will selectively perfuse the heart, brain, and upper extremities.
- III. The O2 saturation of the blood perfusing the lower extremities and abdominal viscera may be substantially higher than that perfusing the heart, brain, and upper extremities.
- IV. Can be unrecognized unless O2 sat is monitored in upper extremity

Meta-Anaylsis of ECMO Complications

- 27 studies & 1866 pts
- Studies w/> 10pts and > yr 2000
- Cumulative survival 534/1529 pts
- Significant associated morbidity
- Difficult to separate complications from underlying disease and ECMO (Renal failure)

Cheng R, et al. Complications of extracorporeal membrane oxygenation for treatment of cardiogenicshock and cardiac arrest: a meta-analysis of 1,866 adultpatients. Ann Thorac Surg. 2014 Feb;97(2):610-6.



 Cheng R, et al. Complications of extracorporeal membrane oxygenation for treatment of cardiogenic shock and cardiac arrest: a meta-analysis of 1,866 adultpatients. Ann Thorac Surg. 2014 Feb;97(2):610-6.

ELSO Indications

- Acute severe heart or lung failure with high mortality risk despite optimal conventional therapy
- ECLS is considered at 50% mortality risk, ECLS is indicated in most circumstances at 80% mortality risk.

Ethical Considerations

- "Bridge to Nowhere" Unable to be bridged to recovery, transplant or destination device
- Introducing the "Bridge to Nowhere" upfront
- Is their DNR on ECMO (capping ECMO)
- Prolonging Death with ECPR
- Use of resource intensive technology in the absence of data that establishes a clear benefit

dilemmasencountered with the use of extracorporeal membrane oxygenation in adults. Chest.2014 Apr;145(4):876-82.

ELSO Contraindications

- Absolute: Unrecoverable heart and not a candidate for a transplant or VAD
- Relative: Anticoagulation contraindicated, Advanced age, obesity

Conclusion

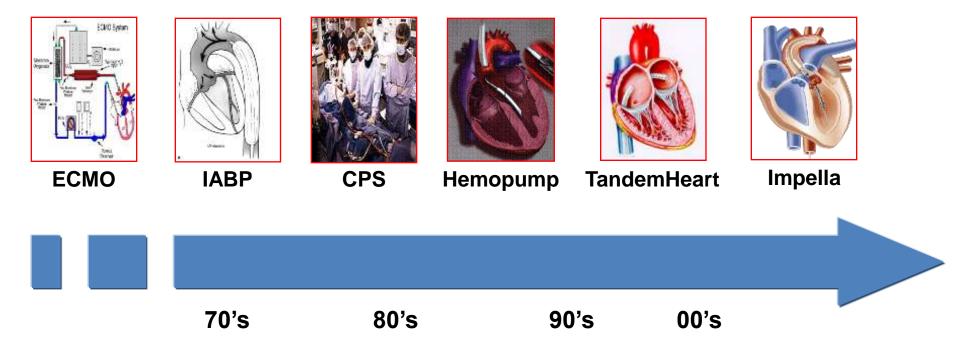
- ECMO has an evolving role in acute cardiac failure and cardiac arrest with significant life saving potential
- Questions remain about optimal patient populations and clinical scenarios
- Larger randomized controlled trials are needed to best understand the appropriate role of ECMO for its various potential indications

Percutaneous LVAD for High Risk Angioplasty Why use support?





Historical Perspectives Percutaneous LV support





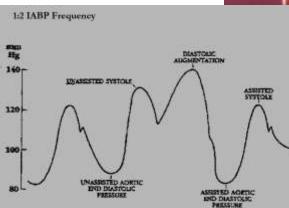
Comparison of Support Devices

	IABP	CPS	TandemHeart	Impella
Catheter Size	7.5-9.0	21/18	21/17/15	9
Cannula Size	8.5-10	21/18	21/17/15	12
# Insertion Sites	1	≥2	≥2	1
Anticoagulation	+	+++	+++	+
Transeptal	No	No	Yes	No
Limb ischemia	+	+++	+++	+
Priming volume	No	Yes	Yes	No
Unloads LV	No	No	Yes	Yes
Requires stable rhythm	Yes	No	No	No
Improves hemodynamics	+	+++	+++	++

IABP Support

PROs:

- Mature technology
- Increases modestly Cardiac Output
- Increases Coronary Perfusion
- Ease of Use
- Low Complication rate?



V diastole

LV systole

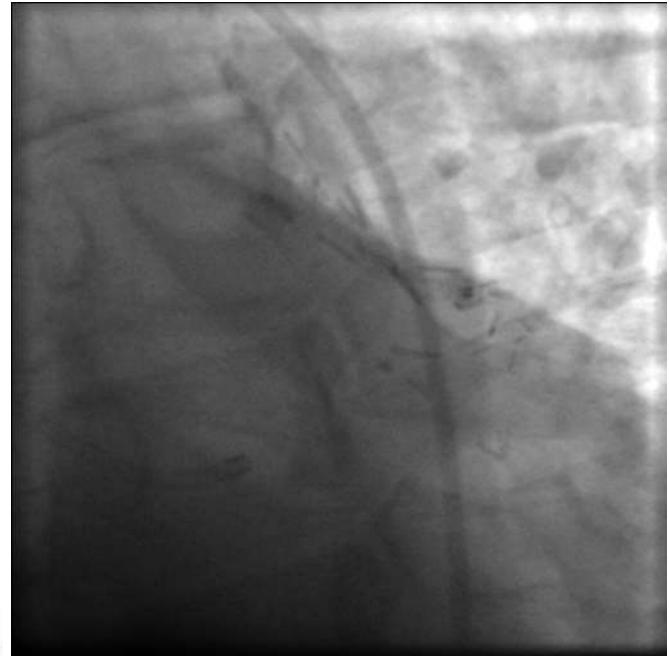
CONs:

- Does not unload the heart
- Require some cardiac power
- Require a stable rhythm
- No proven benefit on mortality

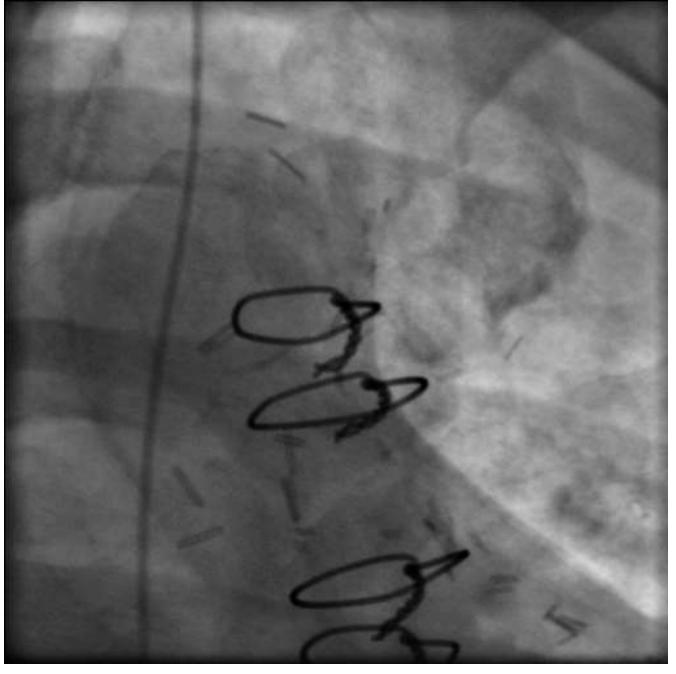


Unstable angina 6 months after Coronary artery bypass

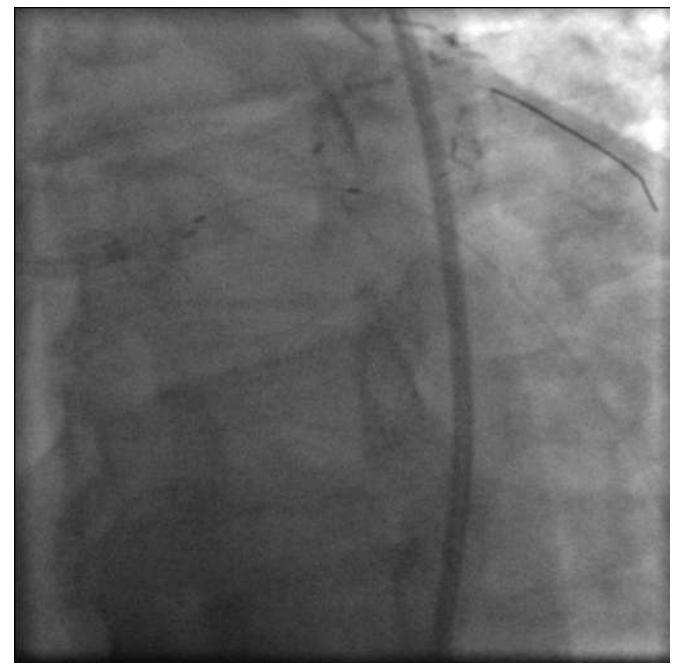
- 52 Y/O woman, nurse
- Had familial hypercholesterolemia
- Had 2 vessel CABG for LM stenosis
- Admitted with sudden onset of Unstable angina 6 months after sugery



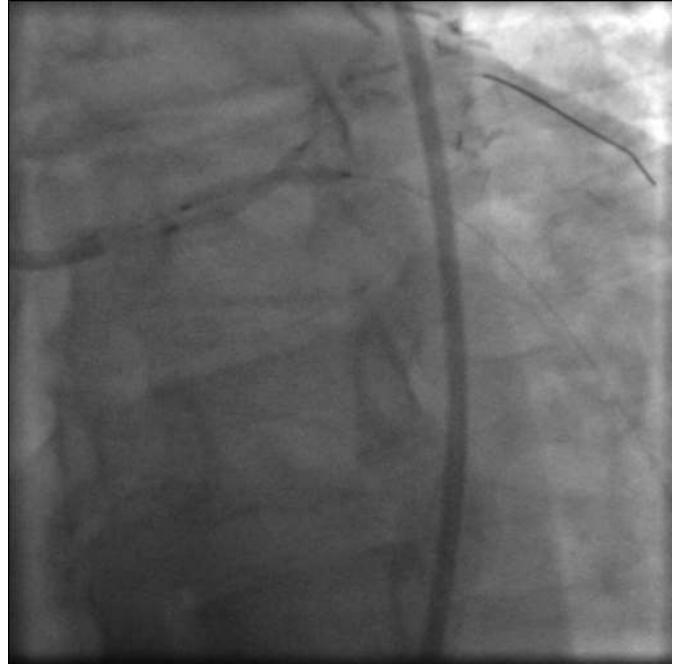




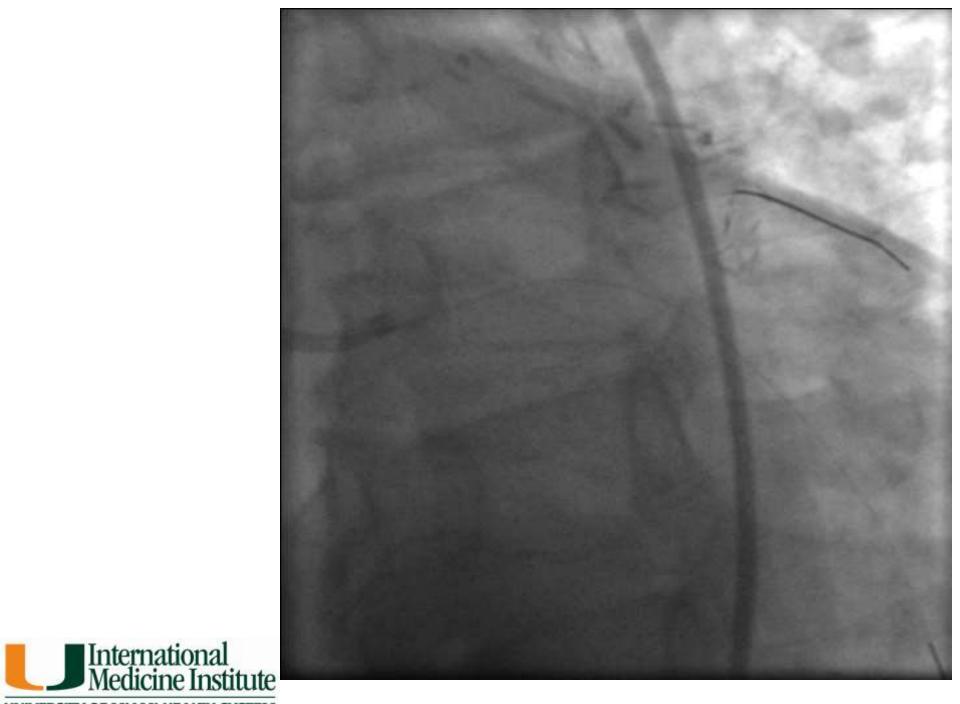




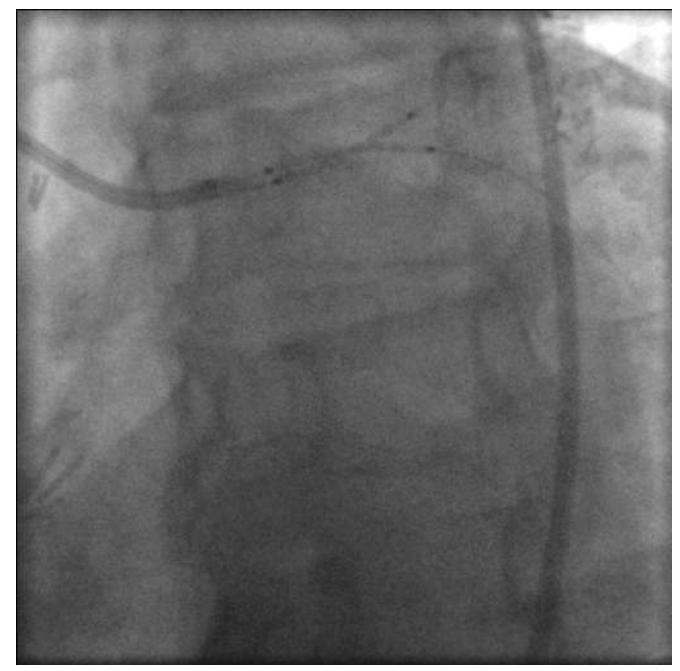




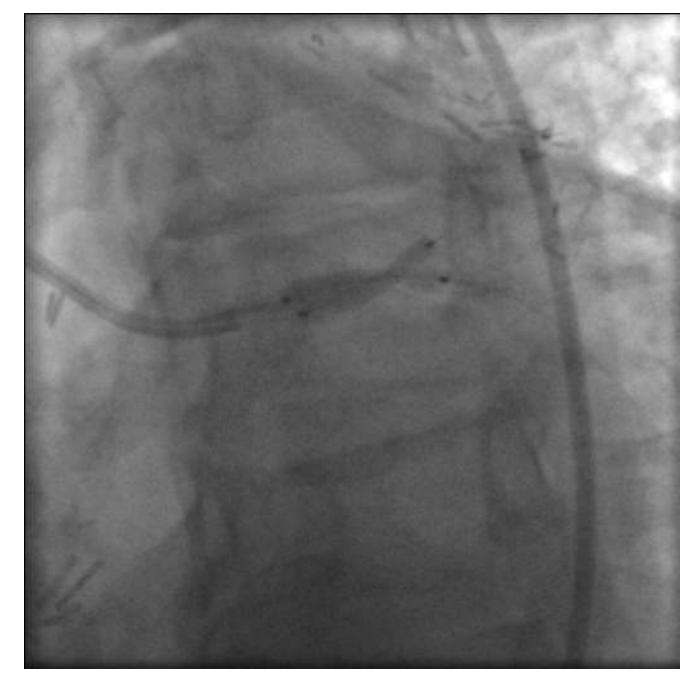




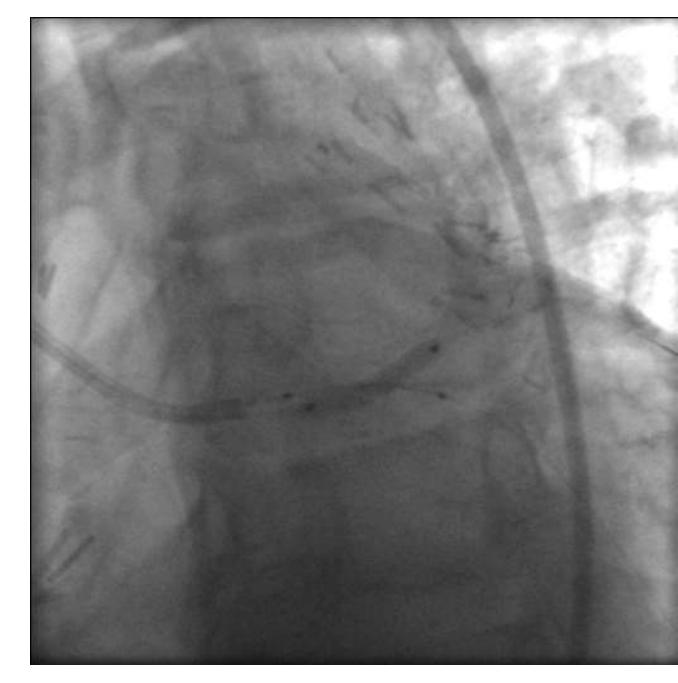
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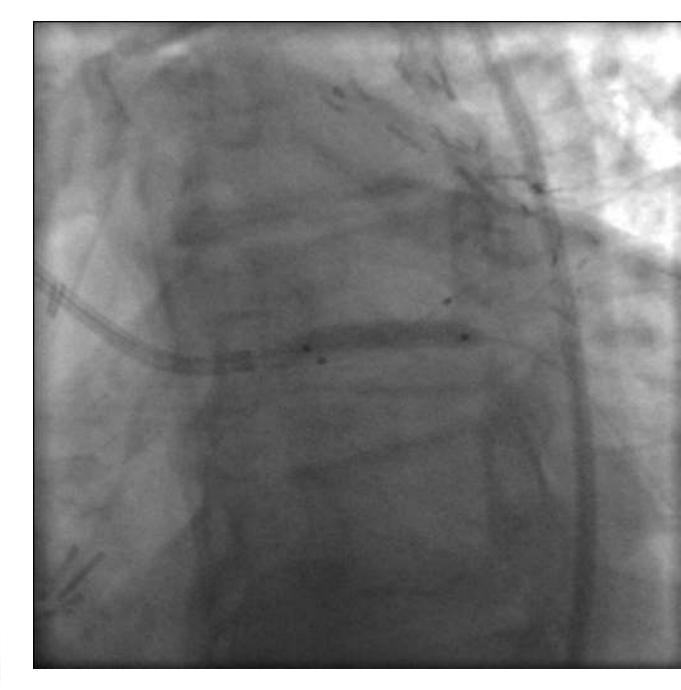




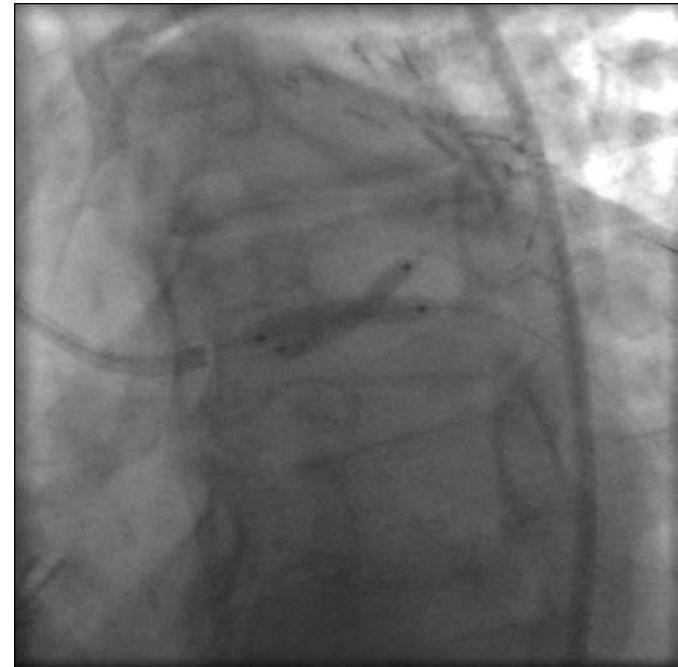




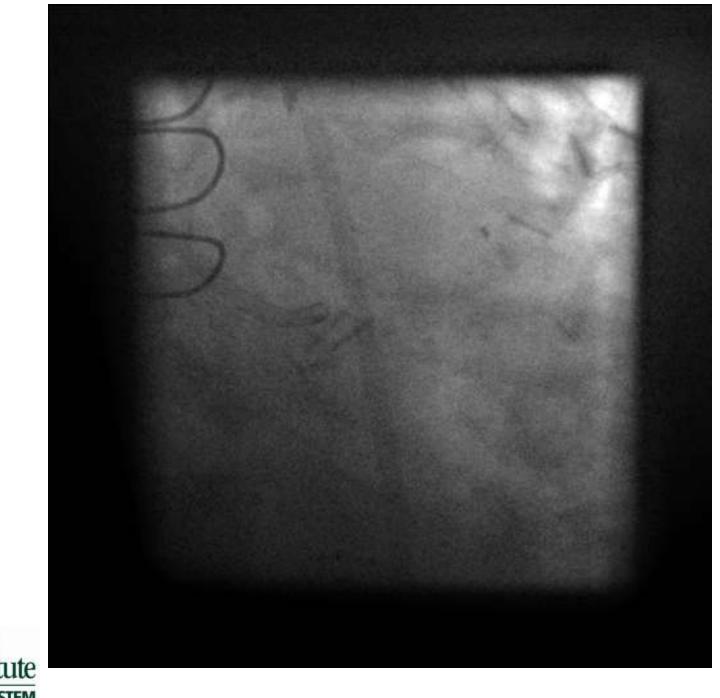




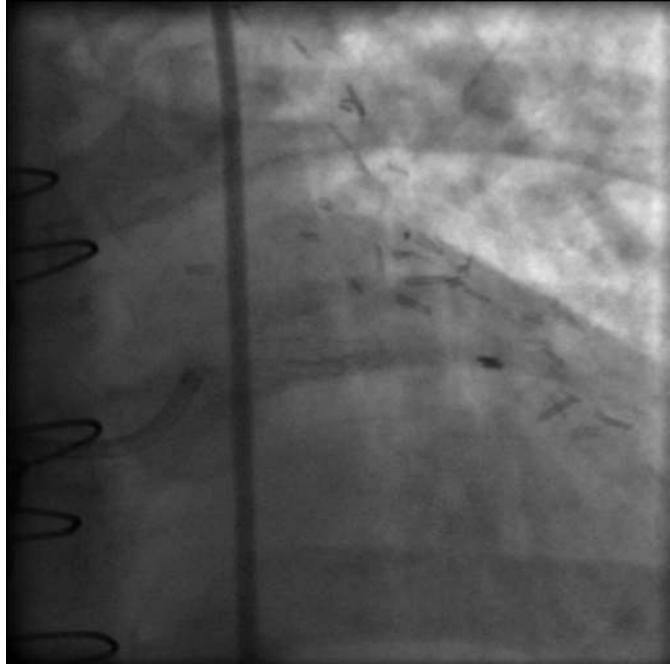






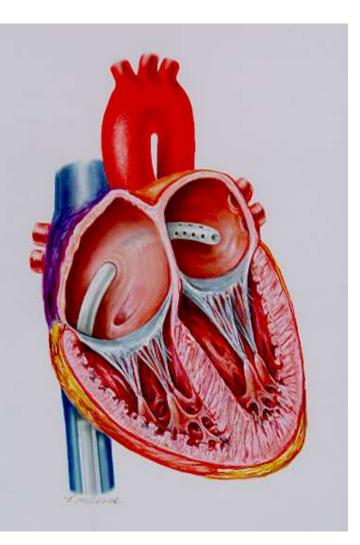








Cardiac Assist TandemHeart



- Access to LA via standard transseptal technique
- Left atrial to Femoral Artery assist at 4-5 I/min

Cardiac Assist TandemHeart Controller

Pump







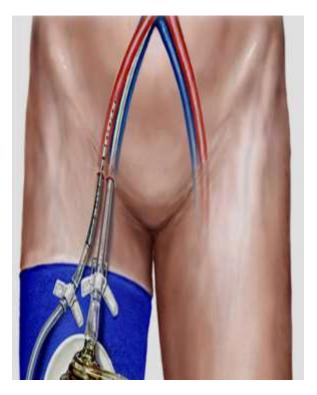
Cannula



TandemHeart PTVA® System Arterial Cannula

- Approved indiction:
 Extracorporeal
 circulatory support
 for up to 6 hrs.
- Medtronic Bio-Medicus arterial cannula, percutaneous access (15-17F)
- Flow 4-5 I/min

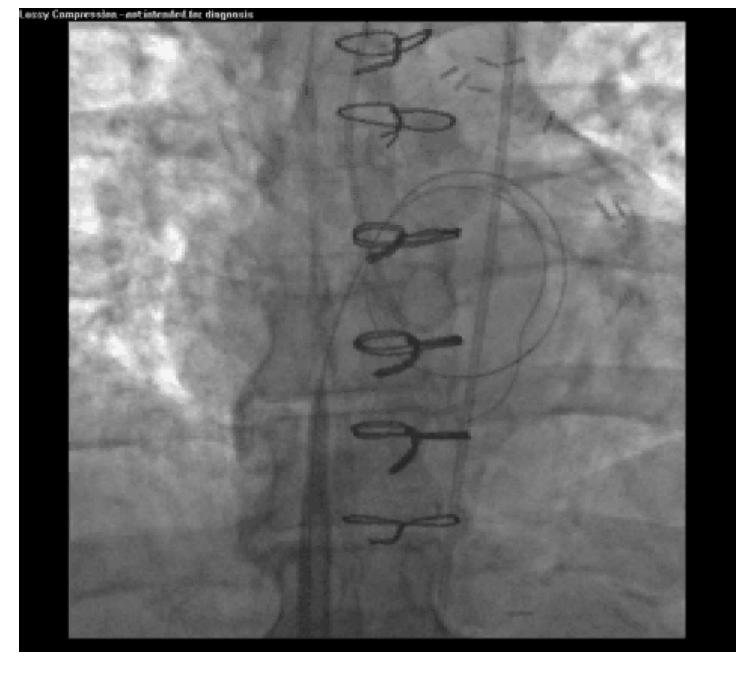




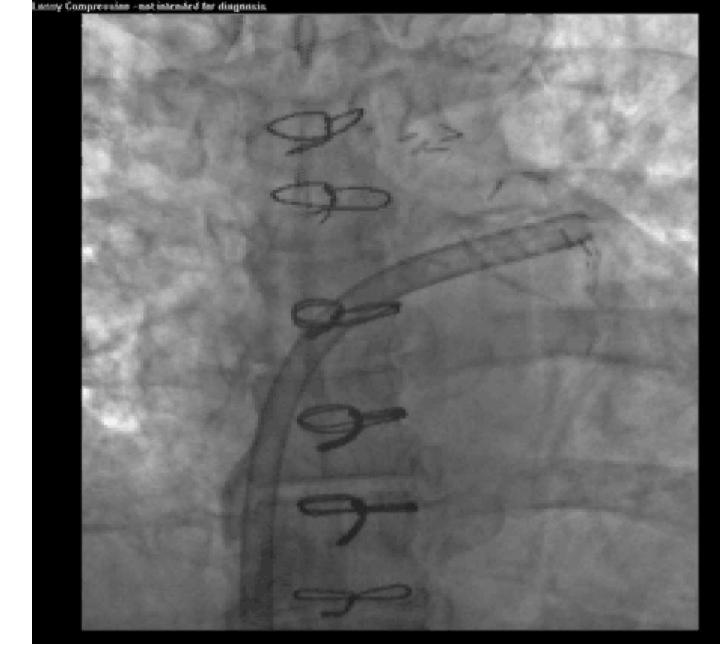
Tandem Heart LVAD Support for Unprotected Complex Left Main Intervention

- 57 year old man with low HDL, hypertension
- Inferior MI 13 years ago; RCA occluded since then
- Abnormal stress test led to cath 3 years ago: 100% RCA, 70% distal LM.
- CABG 3 years ago (LIMA-LAD; veins to RI and CM).
- Now has a strongly positive stress test, global ischemia.
- Cath: Vein grafts occluded. LIMA non-functioning. 100% native RCA; 70-80% distal LM.
- <u>Heavy</u> Ca⁺⁺
- Left main intervention with percutaneous LVAD support.

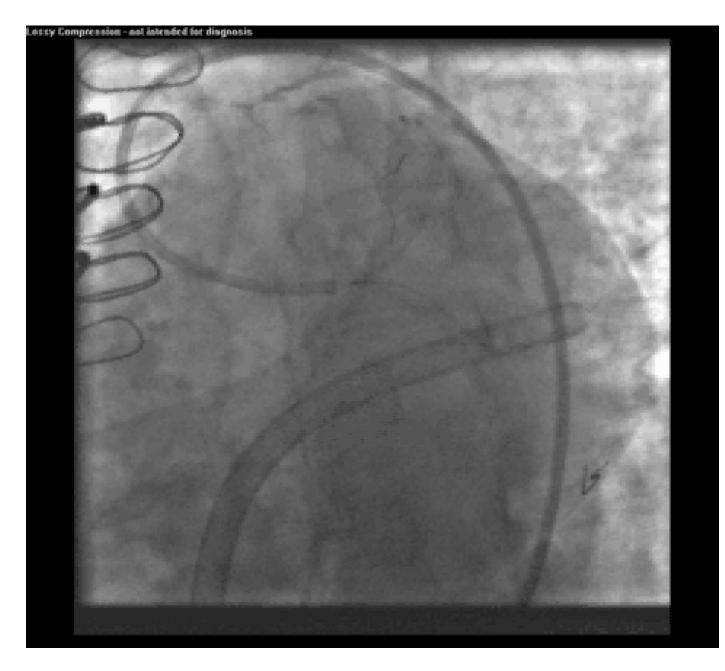






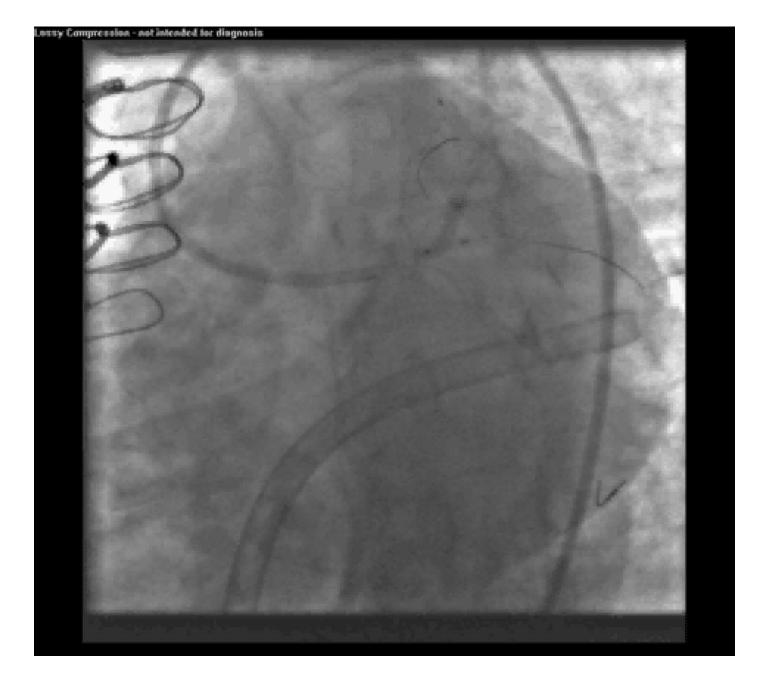




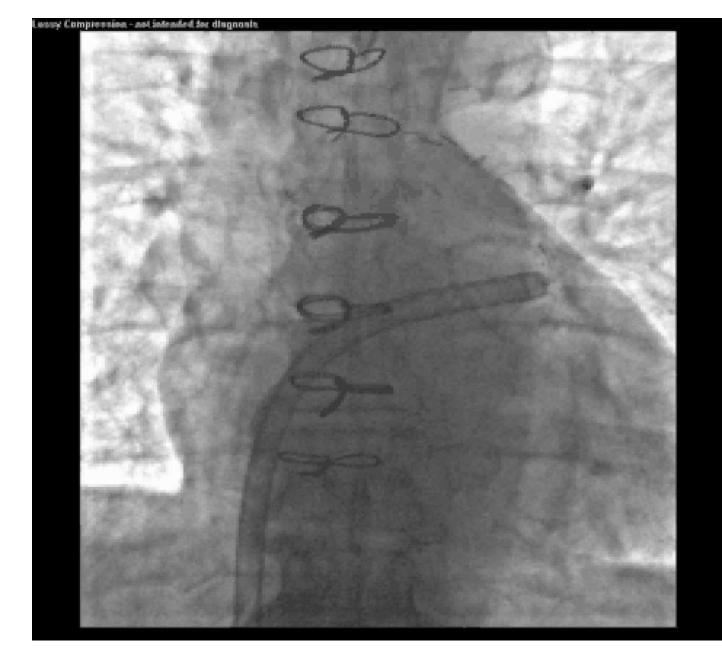




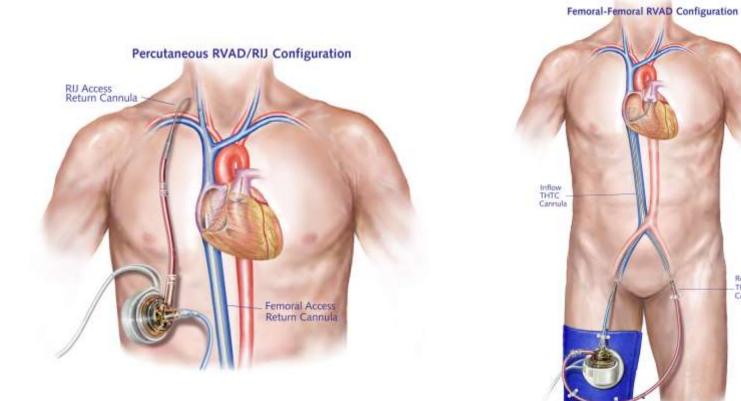




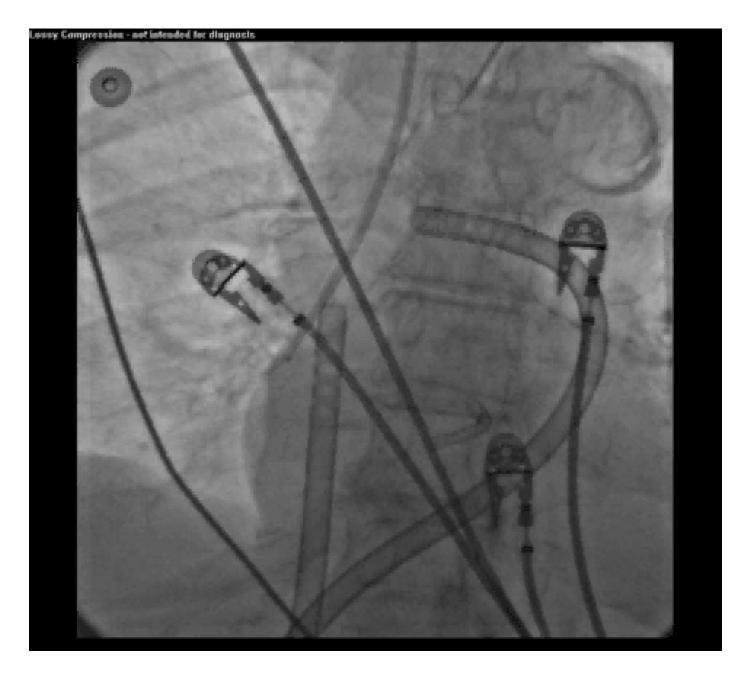




TandemHeart RVAD Applications

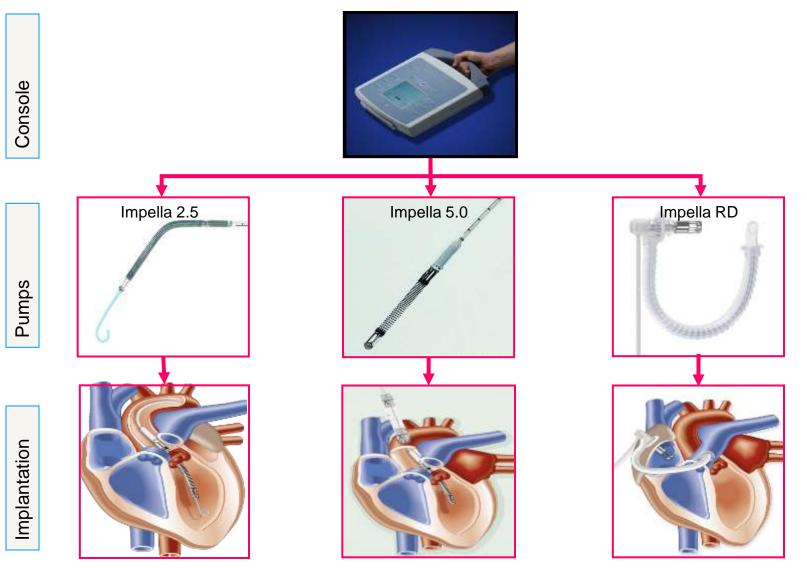


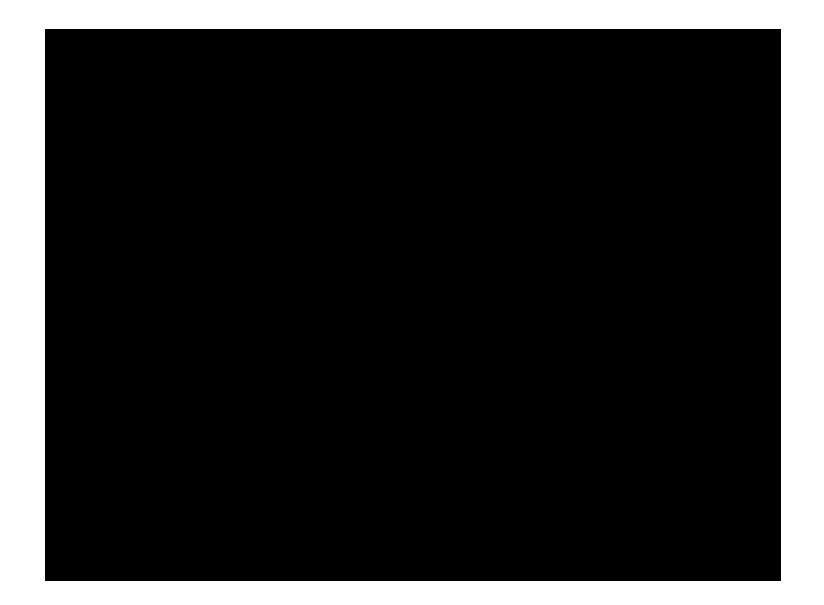
Return THTC Cannula

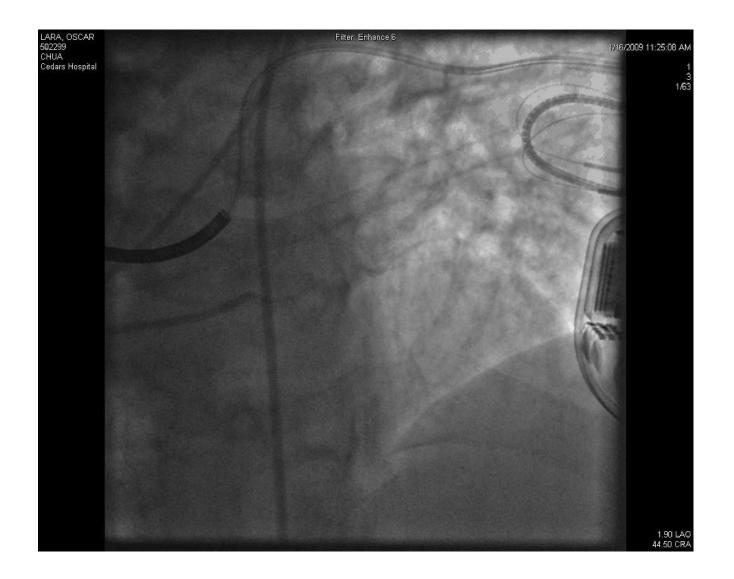


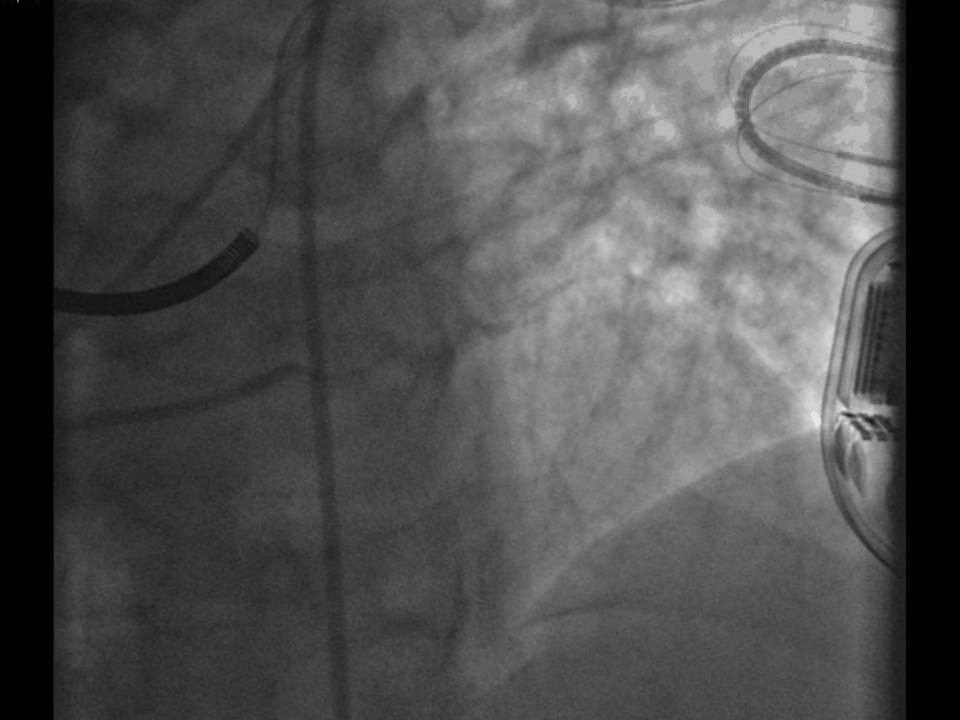


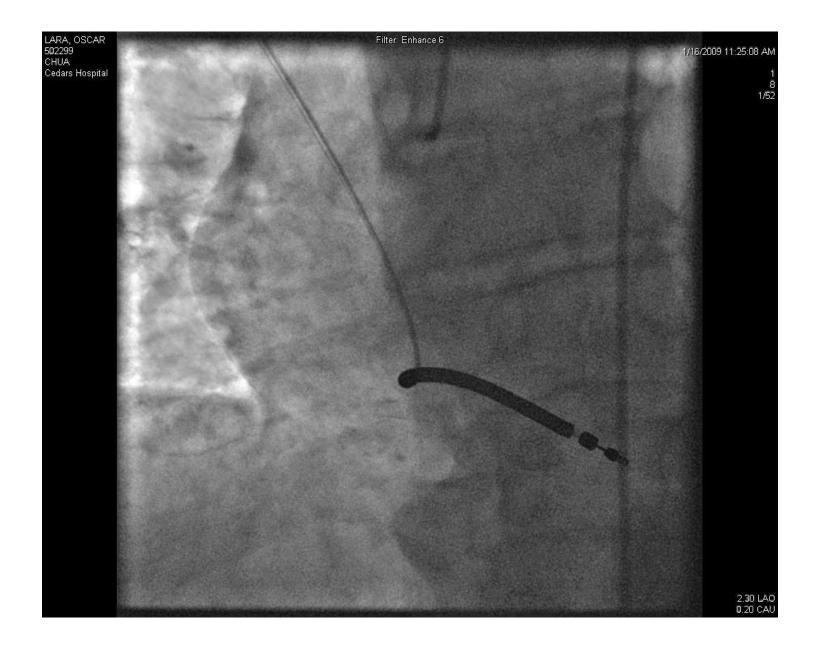
IMPELLA Platform



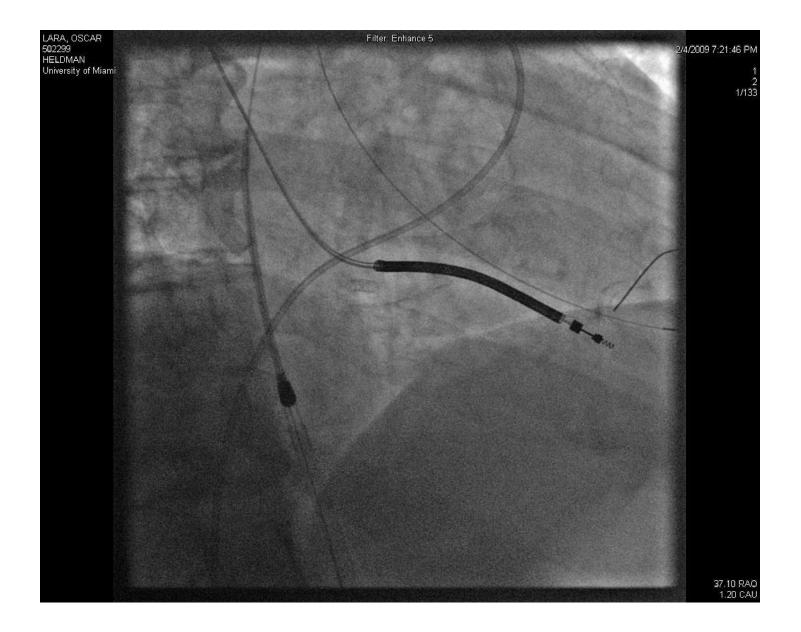


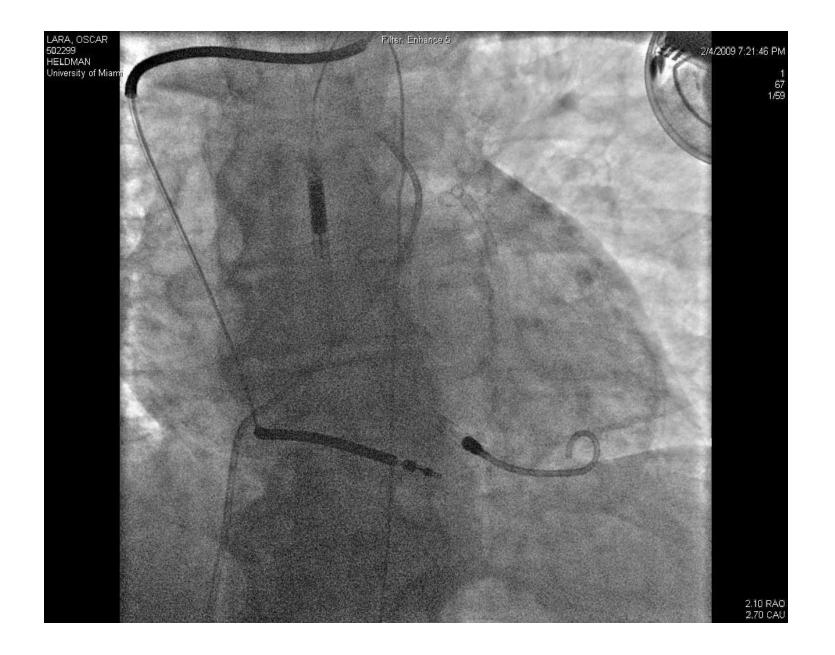




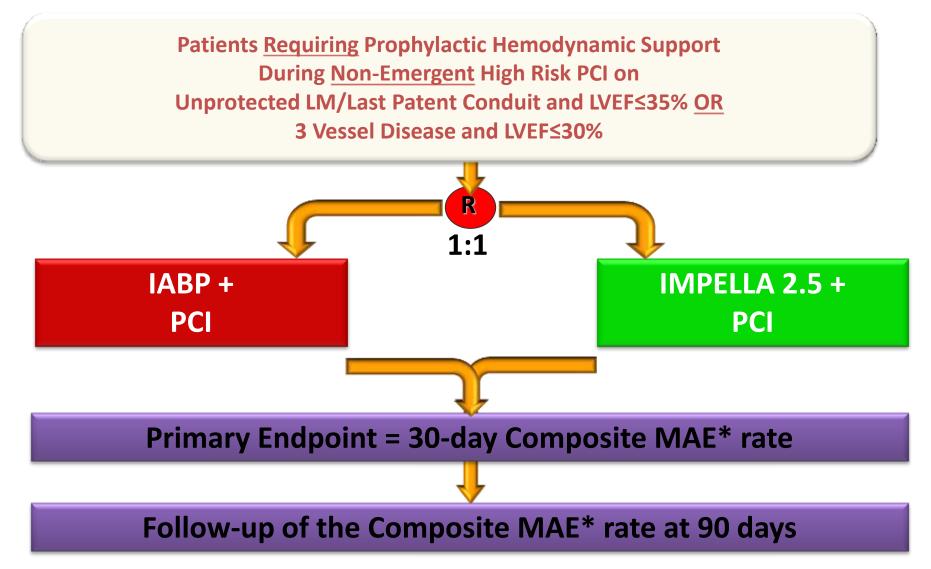








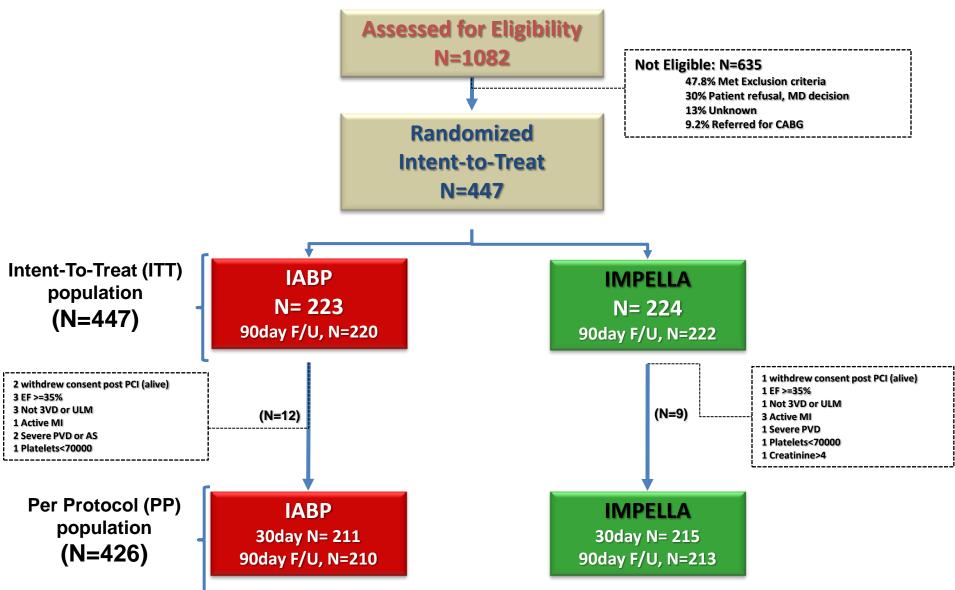
PROTECT II Trial Design



*Major Adverse Events (MAE) :

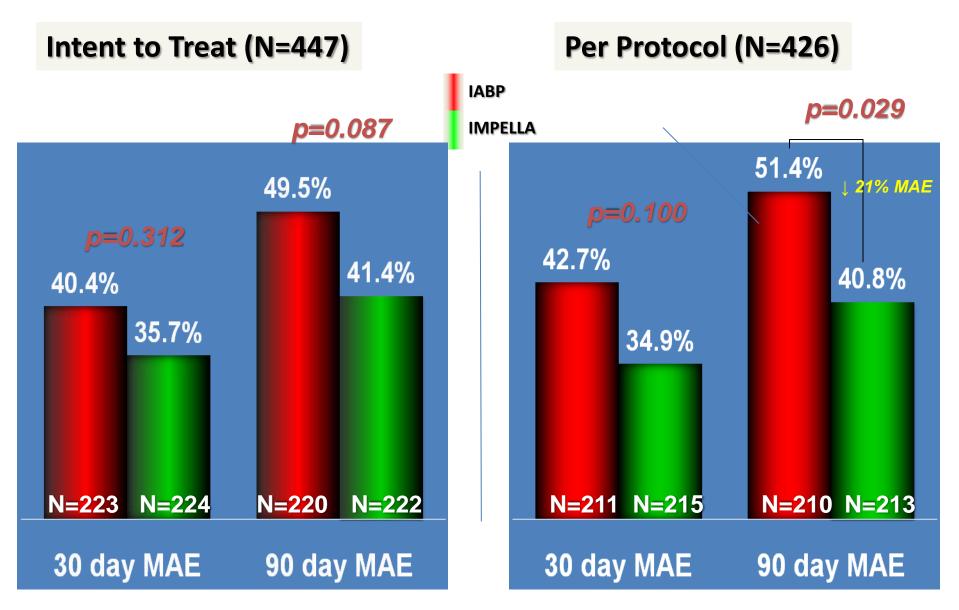
Death, Stroke/TIA, MI (>3xULN CK-MB or Troponin), Repeat Revasc, Cardiac or Vascular Operation of Vasc. Operation for limb ischemia, Acute Renal Dysfunction, Increase in Aortic insufficiency, Severe Hypotension, CPR/VT, Angio Failure

PROTECT II Study Flow



Per Protocol population= Patients that met all inclusion and exclusion criteria. Per Protocol population was pre-specified and patients were identified prospectively prior to the statistical analysis.

PROTECT II MAE Outcome



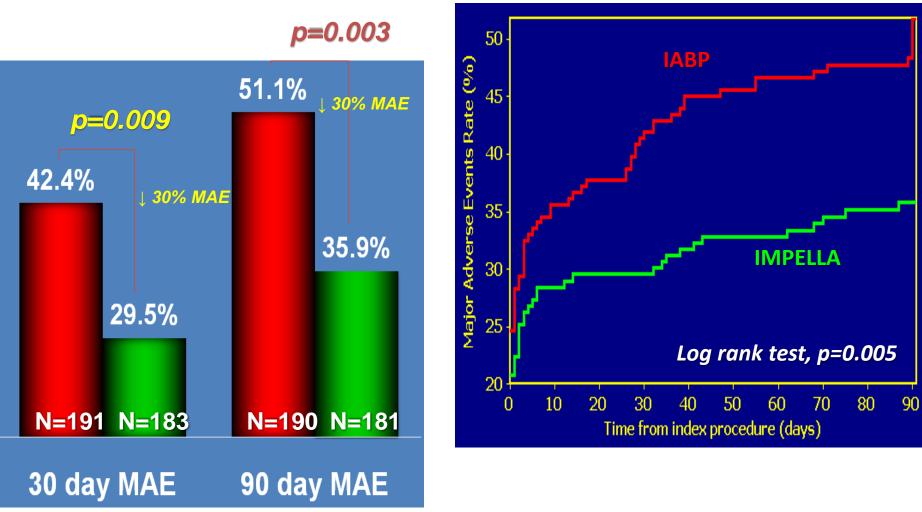
MAE= Major Adverse Event Rate

Per Protocol= Patients that met all incl./ excl. criteria.

PROTECT II MAE Outcome Pre-specified High Risk PCI Without Atherectomy Group

Per Protocol (N=374)

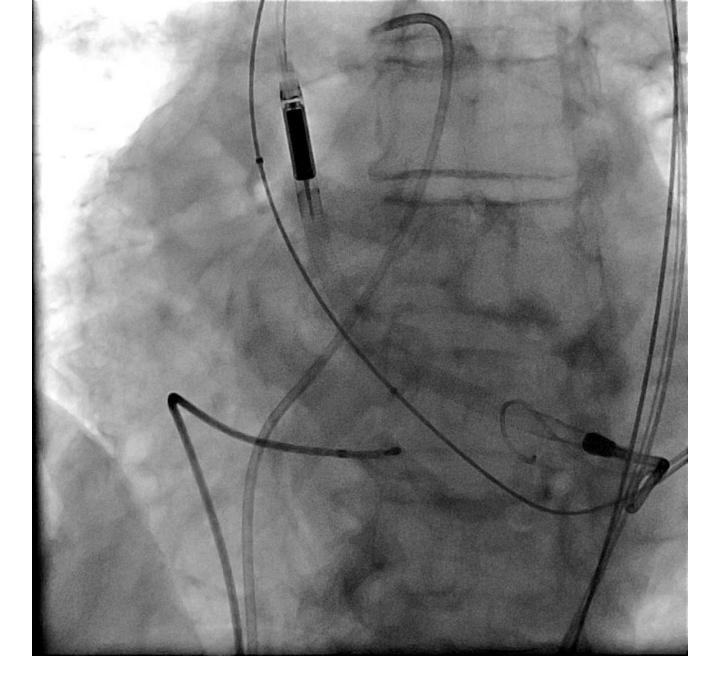
Per Protocol (N=374)

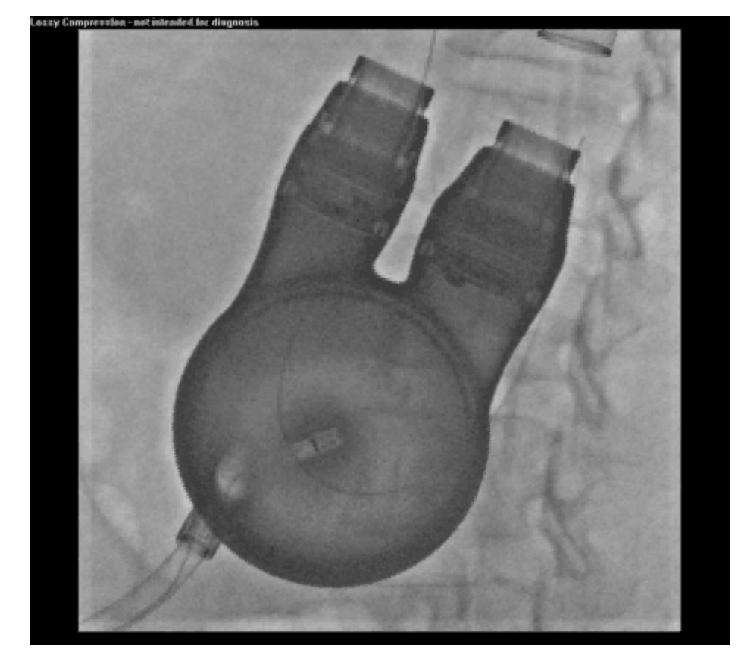


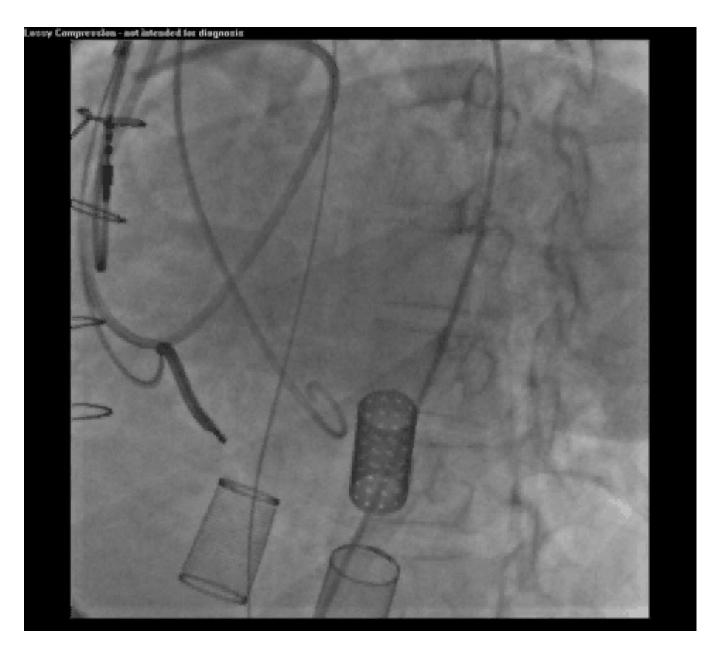
Per Protocol= Patients that met all incl./excl. criteria.

Comparison of Support Devices

	IABP	CPS	TandemHeart	Impella
Catheter Size	7.5-9.0	21/18	21/17/15	9
Cannula Size	8.5-10	21/18	21/17/15	12
# Insertion Sites	1	≥2	≥2	1
Anticoagulation	+	+++	+++	+
Transeptal	No	No	Yes	No
Limb ischemia	+	+++	+++	+
Priming volume	No	Yes	Yes	No
Unloads LV	No	No	Yes	Yes
Requires stable rhythm	Yes	No	No	No
Improves hemodynamics	+	+++	+++	++







CasesCourtesy of Alan Heldman FACC, University of Miami Miller School of Medicine

Thank you

5.2 million