About OMICS Group

OMICS Group is an amalgamation of Open Access publications and worldwide international science conferences and events. Established in the year 2007 with the sole aim of making the information on Sciences and technology 'Open Access', OMICS Group publishes 500 online open access scholarly journals in all aspects of Science, Engineering, Management and Technology journals. OMICS Group has been instrumental in taking the knowledge on Science & technology to the doorsteps of ordinary men and women. Research Scholars, Students, Libraries, Educational Institutions, Research centers and the industry are main stakeholders that benefitted greatly from this knowledge dissemination. OMICS Group also organizes 500 International conferences annually across the globe, where knowledge transfer takes place through debates, round table discussions, poster presentations, workshops, symposia and exhibitions.

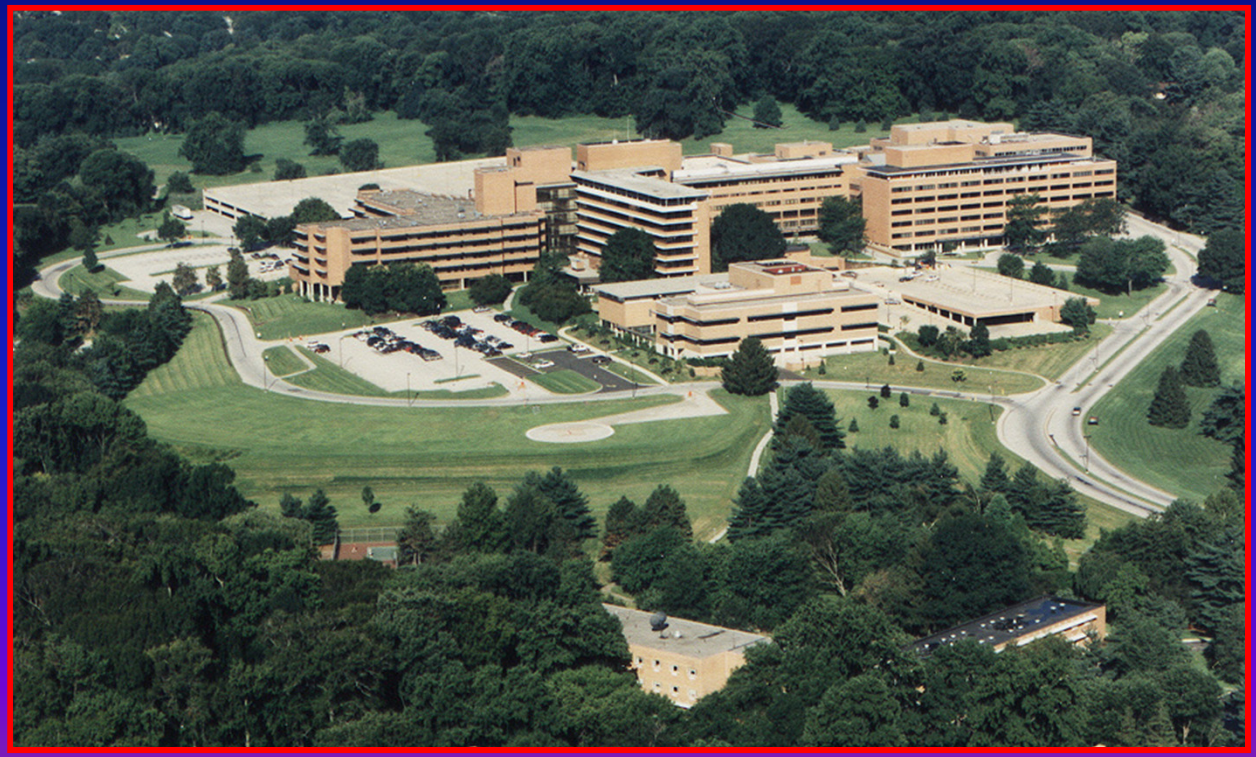
OMICS International Conferences

OMICS International is a pioneer and leading science event organizer, which publishes around 500 open access journals and conducts over 500 Medical, Clinical, Engineering, Life Sciences, Pharma scientific conferences all over the globe annually with the support of more than 1000 scientific associations and 30,000 editorial board members and 3.5 million followers to its credit.

OMICS Group has organized 500 conferences, workshops and national symposiums across the major cities including San Francisco, Las Vegas, San Antonio, Omaha, Orlando, Raleigh, Santa Clara, Chicago, Philadelphia, Baltimore, United Kingdom, Valencia, Dubai, Beijing, Hyderabad, Bengaluru and Mumbai.

Collaboration between CardioVascular Surgery and Cardiology: the use of the minimally invasive and percutaneous Impella® LVAD for management of acute cardiogenic shock, acute decompensated chronic heart failure, and High Risk Cases

Louis Samuels, MD, FACS
Surgical Director, Advanced Heart Failure



The Lankenau Medical Center

"IT MAKES MORE SENSE TO WORK TOGETHER THAN IT DOES TO WORK APART"

HEART FAILURE: TXPLNT & LVADS

STRUCTURAL HEART DISEASE: TAVR & MITRACLIP

ISCHEMIC HEART DISEASE: HYBRIDS (ROBOTIC CABG/PCI)

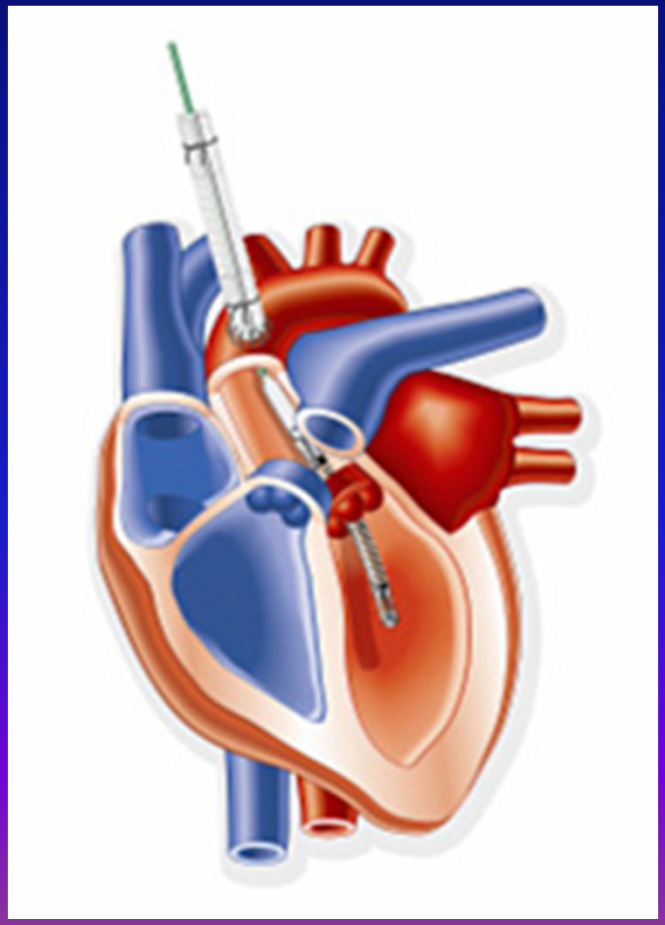
EP: ABLATIONS (ATRIAL/VENTRICULAR) AND LAA LIGATIONS

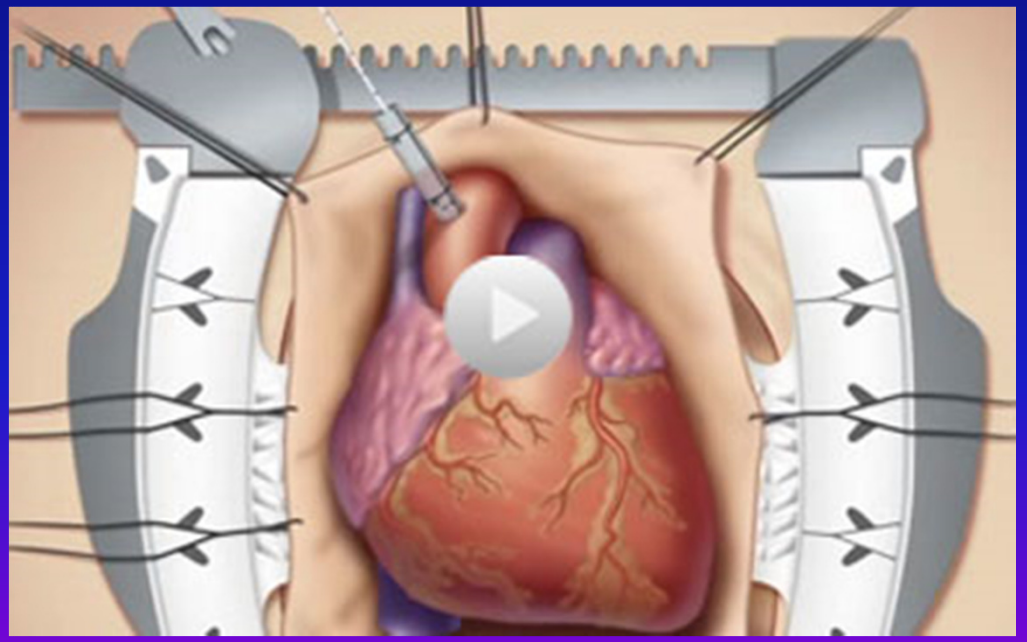
IMPELLA®

AMI-SHOCK
POST-CARDIOTOMY SHOCK
HI-RISK PCI

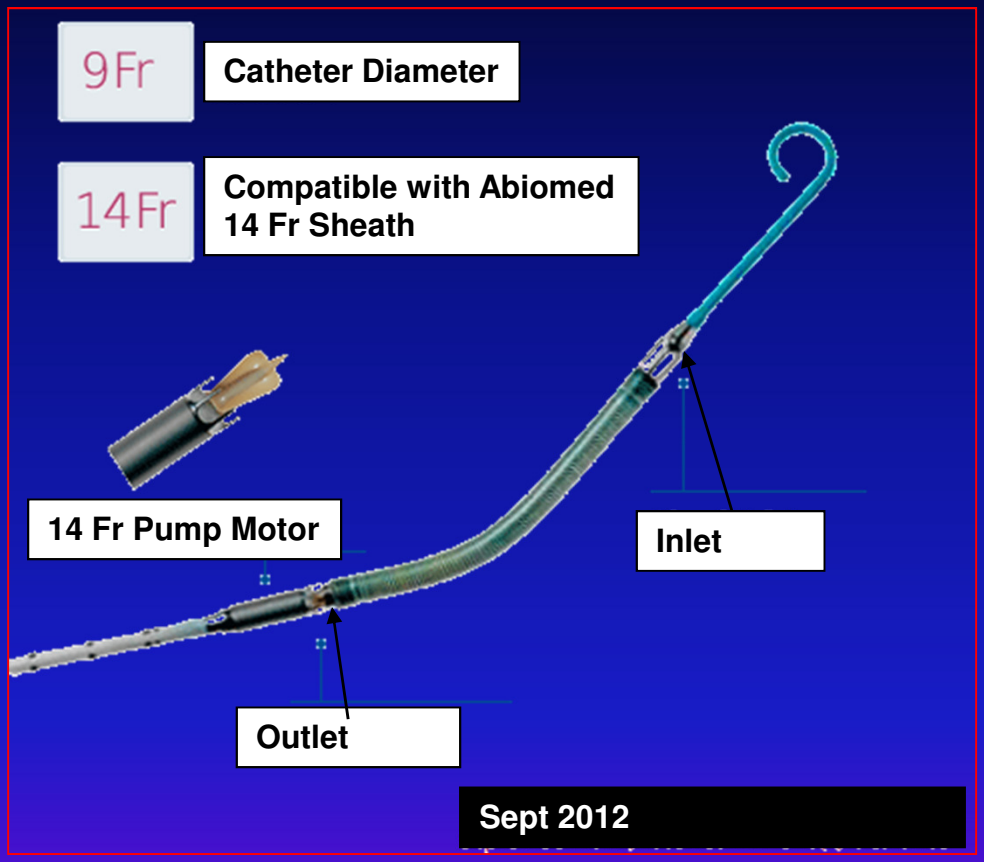


Impella 5.0--Direct Aortic
Full Sternotomy
Mini-Sternotomy





Impella CP



Up to 4 L/min
Percutaneous insertion capability

*FDA Clearance

2009– Europella

Registry of 144 Consecutive pts
undergoing Hi-Risk PCI with Impella 2.5

62% > 70 yrs
54% LVEF <30%
43% turned down for CABG
EuroScore (mean) 8.2

30 Day Outcomes
- Mortality: 5.5%
- MAEs
  - MI: 0%
  - CVA: 0.7%
  - Bleeding: 6.2%
  - Vascular: 4.0%



*Sjauw KD, et al. Supported High-Risk Percutaneous Coronary Intervention with Impella 2.5 Device. J Am Coll Cardiol. 2009;54:2430-2434.

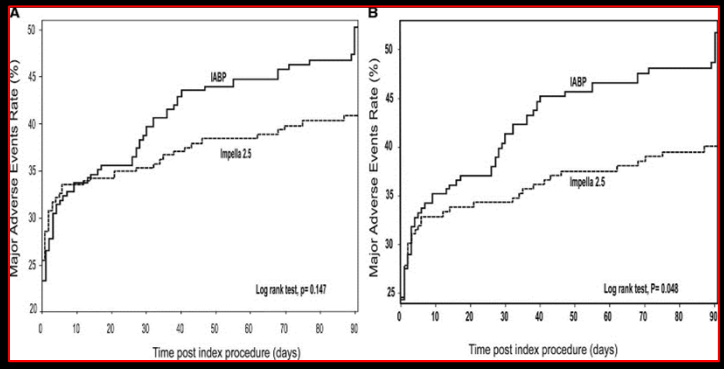
2012– PROTECT II Trial

TRIAL DESIGN:
- Prospective, randomized clinical trial of hemodynamic support with **Impella 2.5 versus IABP**
- Symptomatic patients with severe, complex multivessel, or left main disease,
- some patients present with clinical features that make CABG clinically unattractive.

METHODS:
-452 symptomatic patients with complex 3-vessel disease or unprotected left main coronary artery disease and severely depressed left ventricular function randomized to IABP (n=226) or Impella 2.5 (n=226) support during non-emergent high-risk PCI.

RESULTS:
Primary end point was the 30-day incidence of MAEs (i.e. Death, MI, CVA, ARF, CV Compl. Req. surg, VT, CPR, AI, failure of PCI)

	Impella	**IABP**
Death	6.9%	6.2%
Survival	**93.1%**	**93.8%**
MAE:	35.1%	40.1%
90-day follow-up		
MAE:	40.6%	51.0%

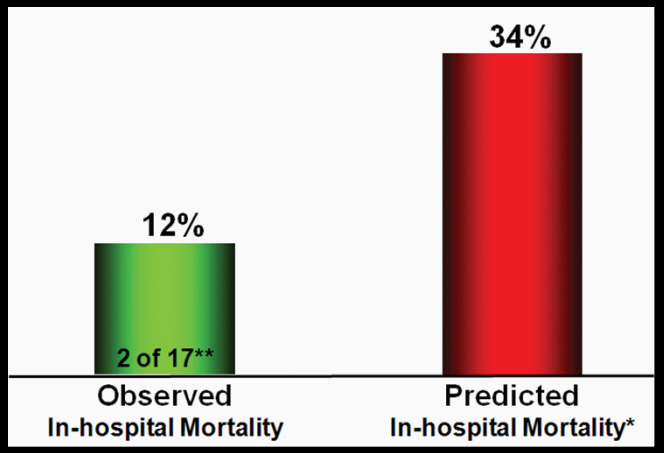


CONCLUSIONS:
The 30-day incidence of MAEs was not different for patients with IABP or Impella 2.5 hemodynamic support. Trends for improved outcomes were observed for Impella 2.5-supported patients at 90 days.

*O' Neill WW, et al. A Prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus IABP in pts undergoing high-risk PCI: the PROTECT II study. Circulation 2012;126:1717-27.

2013– RECOVER I Trial

- *Post-cardiotomy Shock*:* (USA)
  - 16 Pts with post-cardiotomy shock
  - Impella 5.0
  - Survival**:
    - **In-hospital: 88%**
    - 3-month: 81%
    - 1-yr: 75%



**STS Risk Calculator for Mortality: 34%

*Griffith BP, Anderson MB, Samuels LE, Pae WE Jr, Naka Y, Frazier OH. The RECOVER I: a multicenter prospective study of Impella 5.0/LD for postcardiotomy circulatory support. J Thorac Cardiovasc Surg. 2013 Feb;145(2):548-54.

RECOVER 1 TRIAL– Case Study

65 year old man
Ischemic CM– EF 15%
PMH: HTN, DM, Chol
Cath: 3 VD
Viability Scan: (+)

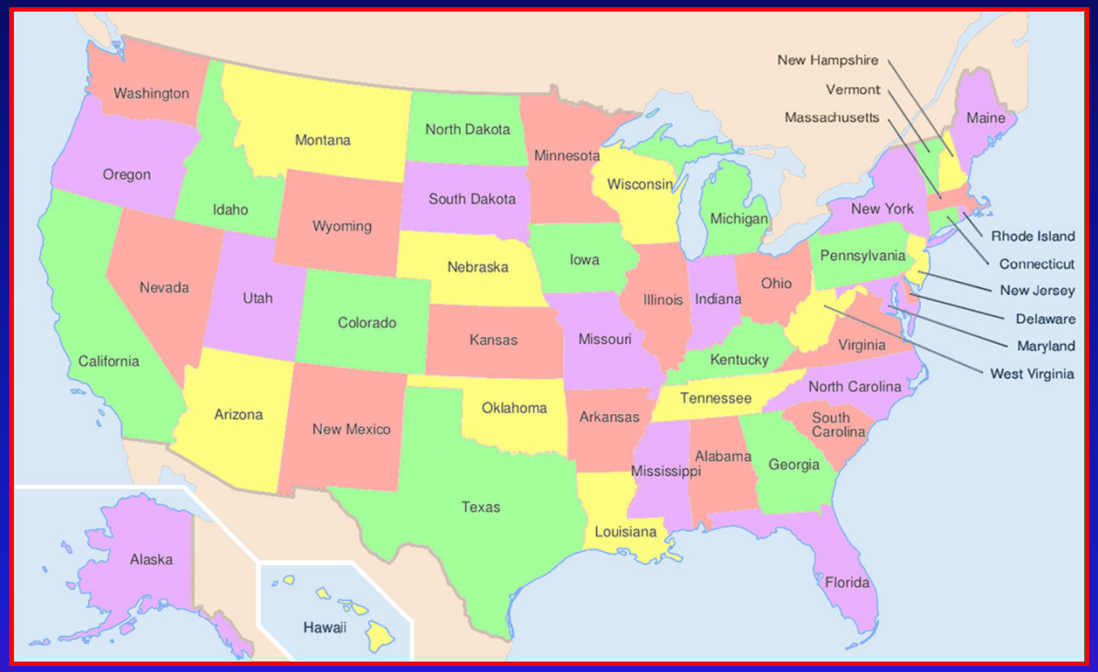
CABG X 3
2 days of Impella Support
LOS: 7 days





USpella

Impella 2.5®, Impella 5.0®, Impella LD®, And Impella CP™ Data Registry



Retrospective multi- institutional observational registry of patients to develop best practice guidelines for clinical support.

***In addition to USPella Registry previously published for Impella 2.5®**
Maini B, et al. Real-world use of the Impella 2.5 circulatory support System in complex high-risk coronary intervention. The USPella Registry. Catheter Cardiovasc Interv. 2012;80:717-25.

2013-2014-- Lankenau Heart Institute



Mission: To Combine CardioVascular And Cardiology Resources to Provide Optimal Cardiac Care



Facilities Upgrade
- inpt and outpt

Personnel Recruitment
- specialists

Equipment Acquisition
- interventional, operative, imaging

Research & Education Funding Support
- symposia, publications, trials

EMPHASIS ON MINIMALLY-INVASIVE PROCEDURES





HYBRID ROOMS

"CARDIOVASCULAR BOARD"
(Weekly Meetings– Complex Cases)

CardioVascular Surgery



Interventional Cardiology



HF Cardiology



Electrophysiology



NP Clinician

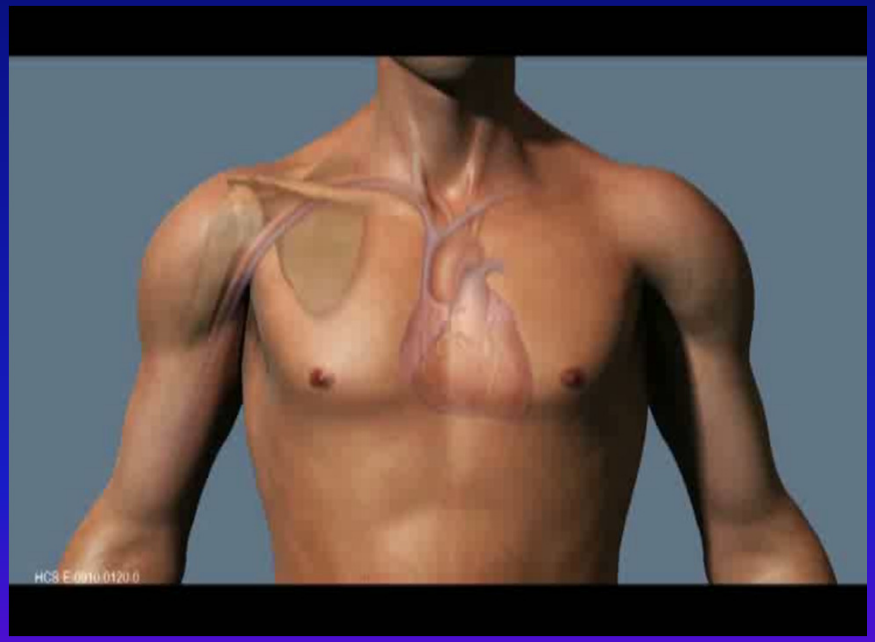


VP Cardiac Service Line



ECMO
Impella®
Heartmate®
High Risk Cases

Trans-Axillary Implantation Technique





MLHS Pilot Study/Registry: Use of the Impella LVAD in Med-Surg Patients with Acute Cardiogenic Shock, Acute Decompensated Chronic HF, and Other High Risk Procedures

Initiation Date: December 12, 2012

PI: Louis Samuels, MD

Participants:, CardioVascular Surgeons,
Interventional Cardiologists
HF Cardiologists
Electrophysiologists

Project Coordinator: Elena Casanova-Ghosh, CRNP

Methods

Patient candidates:

1. Acute Cardiogenic Shock (ACS)
2. Acute Decompensated Chronic Heart Failure (AD-CHF)
3. High Risk PCI
4. High Risk VT Ablation
5. Pre & Post-Cardiotomy Cardiogenic Shock

Determinants of candidacy:

1. Suboptimal hemodynamics on inotropic and/or vasopressor therapy
2. STS Risk Calculator Combined M/m > 50%
3. Multi-disciplinary decision (i.e. Cardiology/CV Surgery) based on complexity (i.e. risk/benefit/alternative) of case– model similar to TAVR

Device Selection:

CP: for PCI, VT Ablation, immediate deployment when surgery not feasible

5.0: Need for maximal support

Registry/Database– Abbreviated

Date	Age	Sex	Indication	Diagnosis	EF (%)	Device/Access	Intent	Dur (days)	Outcome	Other	Site
2012											
12/12/12	47	F	AD-CHF	Alcoholic CM	35	5.0 TAx	BTR	8	S		
2013											
4/13/13	29	M	PCS– AVR	Post-Card	15	5.0 TFem	BTR	1	E-- MOSF	ECMO	L
10/9/13	76	M	AD-CHF	Isch CM	30	5.0 TAx	BTDT	14	S	Jarvik	L
2014– Expanded to 2 Sites											
1/13/14	79	M	AD-CHF	Isch CM	15	5.0 TAx	BTR	13	E– Isch Bowel	PCI	L
2/13/14	75	F	ACS	Myocarditis	5	5.0 TAx	BTR	12	E– MOSF		L
4/13/14	82	F	AMI-S	AMI	40	CP TFem	BTR	3	S	PCI	L
4/14/14	54	F	AMI-S	AMI	30	5.0 TAx	BTR	4	S	PCI	L
5/19/14	80	M	AD-CHF	Valv/Isch CM	10	CP TFem	BT-TAVR	1	E– Card-Pulm	PCI, BAV	B
6/13/14	62	M	AD-CHF	Isch CM	20	CP TFem	BTR	3	E--MOSF	PCI	B
6/17/14	83	M	AD-CHF	Isch CM	25	CP TFem	BTR	1	S	PCI	B
7/11/14	76	M	AD-CHF	Isch CM	25	CP TFem	BTR	1	S	PCI	B
7/17/14	79	M	VT	VT	50	CP TFem	BTR	1	S	VTA	B
9/13/14	72	M	AMI-S	AMI-VSD/MR	55	CP TAx	BTR	38	E—MOSF	CABG/VSD/MR	L
9/16/14	73	M	AD-CHF	Isch CM	15	CP TFem	BTR	1	S	PCI	B
9/24/11	67	F	AD-CHF	Tako Tsu CM	10	CP TFem	BTR	3	S		L
10/14/14	41	M	AD-CHF	Isch CM	15	5.0 TAx	BTT	8	E—MOSF	ECMO	L
10/14/14	76	M	VT	Dil CM	20	CP TFem	BTR	2	E– Cardiac		L
10/26/14	59	M	AMI-S	AMI	10	CP TFem	BTR	1	S	PCI/ECMO	B
11/14/14	57	F	AMI-S	AMI	25	CP TFem	BTR	2	E-- MOSF	PCI	L
11/18/14	83	M	AMI-S	AMI	15	CP TFem	BTR	3	S	PCI	B
11/19/14	84	M	AD-CHF	Isch CM	35	CP TFem	BTR	1	S	PCI	B
12/9/14	83	M	AD-CHF	Isch CM	25	CP TFem	BTR	1	S	PCI	B
12/11/14	78	M	AD-CHF	Isch CM	30	CP TFem	BTR	1	S	PCI	B
12/26/14	27	M	PC–CABG	Post-Card	15	5.0 TAx	BTT	Ongoing	S	CABG/ECMO	L
2015											
1/12/15	80	M	PC– AoDi	Post-Card	25	CP TFem	BTR	Expired	E-MOSF	Ao Diss Repair	L
3/20/15	48	M	AD-CHF	IDCM	15	5.0 TAx	BTD	Ongoing	TBD		L
4/17/15	37	M	AD-CHF	IDCM	5	5.0 Tax	BTT	Ongoing	TBD		L

Demographics/Indications

No: 25 pts

Age: 66.4 yrs (27 – 84 yrs)

Sex: 19 M 6 F

Conditions:

Ischemic CM	10
AMI	6
Post-Card	3
Dil CM	1
VT	1
Alcoholic CM	1
Myocarditis	1
Tako Tsub CM	1
Valv/Isch CM	1

EF: 23.8% (5 – 55%)

Indications:

PCI	**15**
Elective	1
Urgent	8
Emergent	7
Post-Card	**2**
CABG	1
AVR	1
Ao Dissection	
Pre/Post Surg	**1**
VSD/MR	1
AD-CHF w/out PCI	**4**
Alcoholic CM	1
Isch CM	1
Tako Tsubo	1
Myocarditis	1
VT Ablation	**2**

Device/Duration

Device:

5.0	(8)
CP	(17)

Intent:

BTR	(21)
BTT	(2)
BT-DT	(1)
BT-TAVR	(1)

Approach:

Trans-Ax	(8)
Trans-Fem	(17)

Duration*: 8.4 days (1 – 38 days)

Duration (days):

1	10
2	2
3	4
4	1
5	---
6	---
7	---
>7	6
Ongoing	1

*Excluding Ongoing Patients

Results

Hospital Survival*: 61% (14 of 23)

Case	Age	Indication	Cause of Death	Discussion
J.J.	29	Post-AVR Shock	Cardio-Pulmonary	Intraop Catastrophe, etiology ?
F.L.	79	Ischemic CM	Ischemic Bowel	Low Output State, Pt Selection?
A.S.	75	Myocarditis	MOSF	Management (Transition to DT versus D/C)
J.L.	80	Ischemic/Valvular CM	Cardio-Pulmonary	Pt Selection? (ECMO or Nothing)
W.T.	62	AMI-Shock	Cardiac	Pt Selection? (ECMO or Nothing)
R.N.	72	AMI-Shock/VSD/MR	Sepsis	Management
D.G.	41	AMI-Shock	Sepsis	Management
W.K.	76	Ischemic CM/VT	Cardiac	Pt Selection? (ECMO or Nothing)
M.P.	57	AMI-Shock (cocaine)	Cardiac	Management (Transition to DT versus D/C)

Case Presentations

AMI-Shock: Impella Assisted RCA PCI

Idiopathic CM: Impella Assisted VT Ablation

Tako Tsubo CM: Impella Assisted Support

AMI-Shock: Impella Assisted RCA PCI (S.C.)

10/26/14: 59 yo Indian Man presents with Cardiac Arrest
EMS– VFib– Defibrillated, Intubated
Txf to Cath Lab

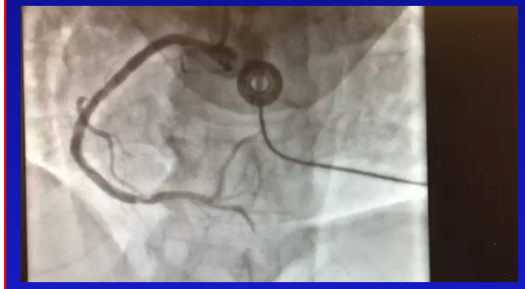
Cath: 100% RCA
PCI: IABP-Assisted RCA PCI
Cardiogenic Shock: Impella CP
Hypoxemia: ECMO

10/29/14: ECMO Removed

11/7/14: Percutaneous Tracheostomy (Pneumonia/VDRF)

11/26/14: Discharged to Rehab Center







Idiopathic CM: Impella Assisted VT Ablation (R.R.)

8/24/2014: 79 yo Man presents with
Near syncope.
Hx of HTN, Chol, VT,
AFib,Hypothyroid,
Adrenal Insuff.,Prostate CA, Colon CA

8/28/2014: EP Procedure

Impella CP (TFem)
Endocardial Mapping
3D Epicardial Mapping (CARTO)
RF Ablation of VT– arising from
Right Coronary Cusp of Aort
DC CVN of AFib

8/30/2014: Discharged to Home





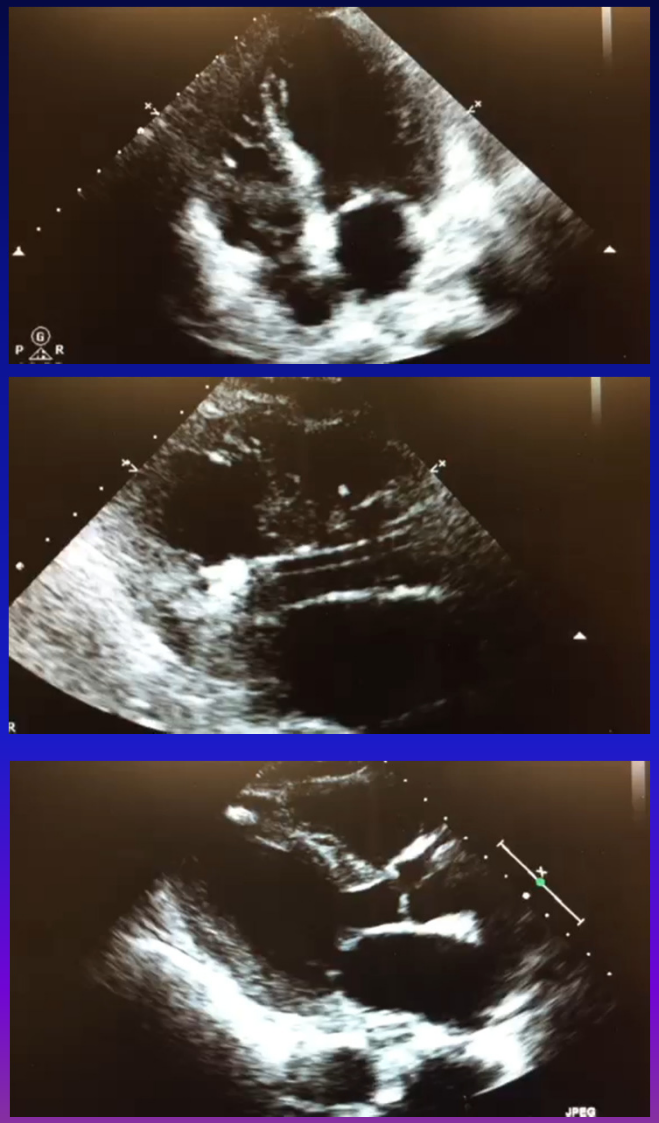


Tako Tsubo CM: Impella Assisted Support (G.S.)

9/24/2014: 67 year old woman presents
to ER with SOB, CP, diaphoresis.
Intubated
HR 160s
EKG: diffuse ST Segment elevation
PMH: Tako Tsubo CM, Multiple Myeloma,
CKD (Creat 2.8 – 3.8)
Echo: Severe LV dysfunction, apical ballooning
Cath Lab: **Ao 145/134**
RA 16
PAP 42/29
W 22
CI 2.2
Impella CP– Transfemoral

9/26/14: Impella Removed

10/10/14: Discharged to home



Recent Case

3/19/15: 49 yo man with IDCM, SOB

PMH: JAK 2 Mutation

Echo: Severe Bi-V dysfunction, LVEF 5-10%

Cath Lab:

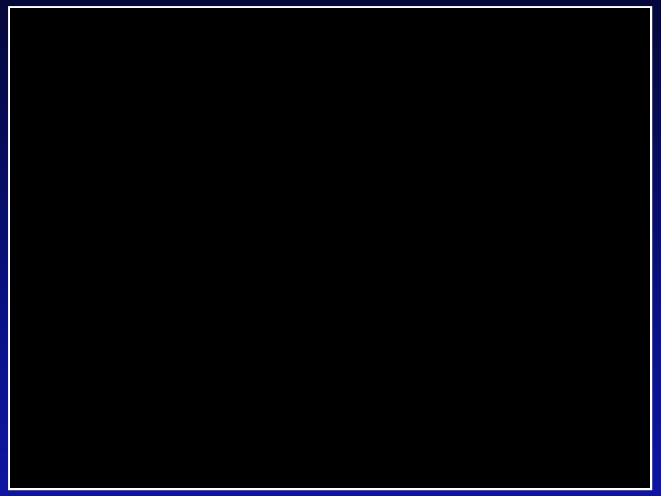
3/20/15: Impella 5.0– TransAx

Plan: Txf'd to TxpInt Center

Syncardia TAH Implanted









Most Recent Case

4/16/15: 37 yo man with known non-ischemic CM presents with SOB. Found to be in rapid AF.

PMH: Morbid obesity, OSA, Diabetes

Echo: LV dysfunction, LVEF 10-15%

4/17/15: Decompensated during sedation for TEE directed CVN. Intubated, inotropes, pressors

Impella 5.0– TransAx Implanted

4/19/15: Developed hypoxemia and hypercapnea. CXR suggestive of pneumonia.

V-V ECMO Implanted

Outcome: TBD



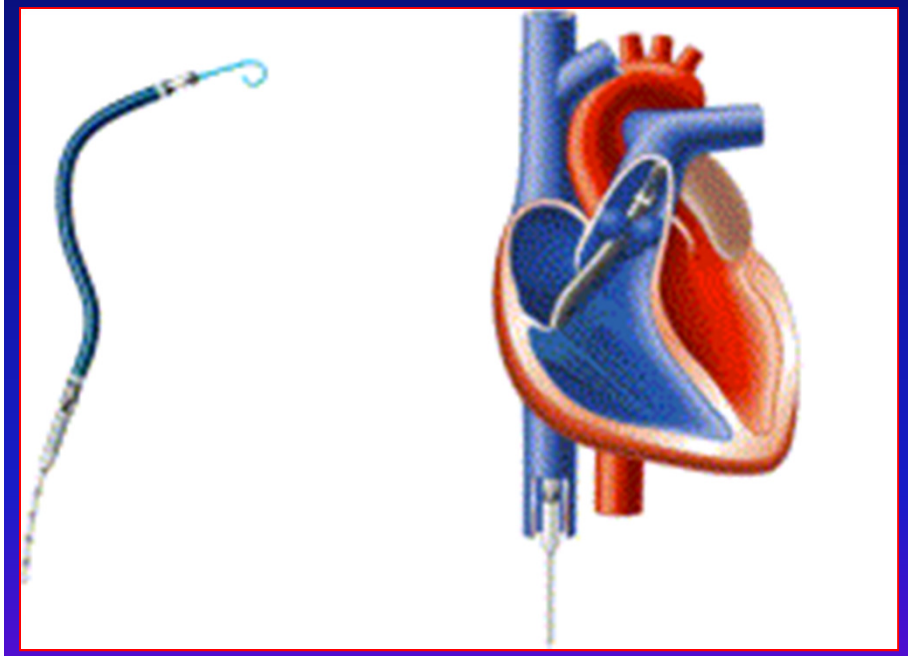


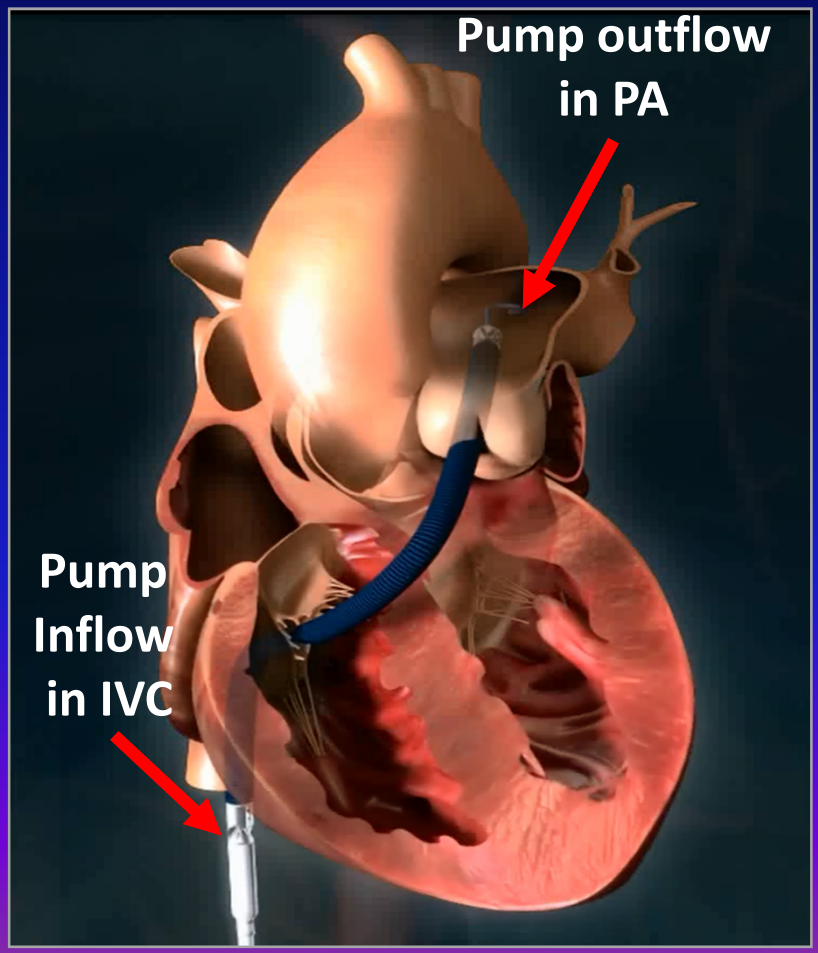
Conclusions

1. **A collaborative team of subspecialists optimize outcomes in the most advanced and complex cases of cardiac disease.**
2. **The Impella LVAD platform is useful in a variety of medical and surgical conditions of acute cardiogenic shock, acute decompensated chronic heart failure, and high risk interventions.**
3. **Adverse outcomes consist of a variety of causes, most notably refractory cardiopulmonary failure and multiple organ system failure.**
4. **Patient selection, implantation technique, timing of explantation, and peri-procedural management are being examined.**

Future Initiative

Introduce Impella RVAD





THANK YOU





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SamuelsL@mlhs.org
SamuelsLE@aol.com

Thanks' for your kind attention!!!!!!



Let Us Meet Again

We welcome you all to our future conferences of OMICS International

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