Interventional Treatment Options for Heart Failure

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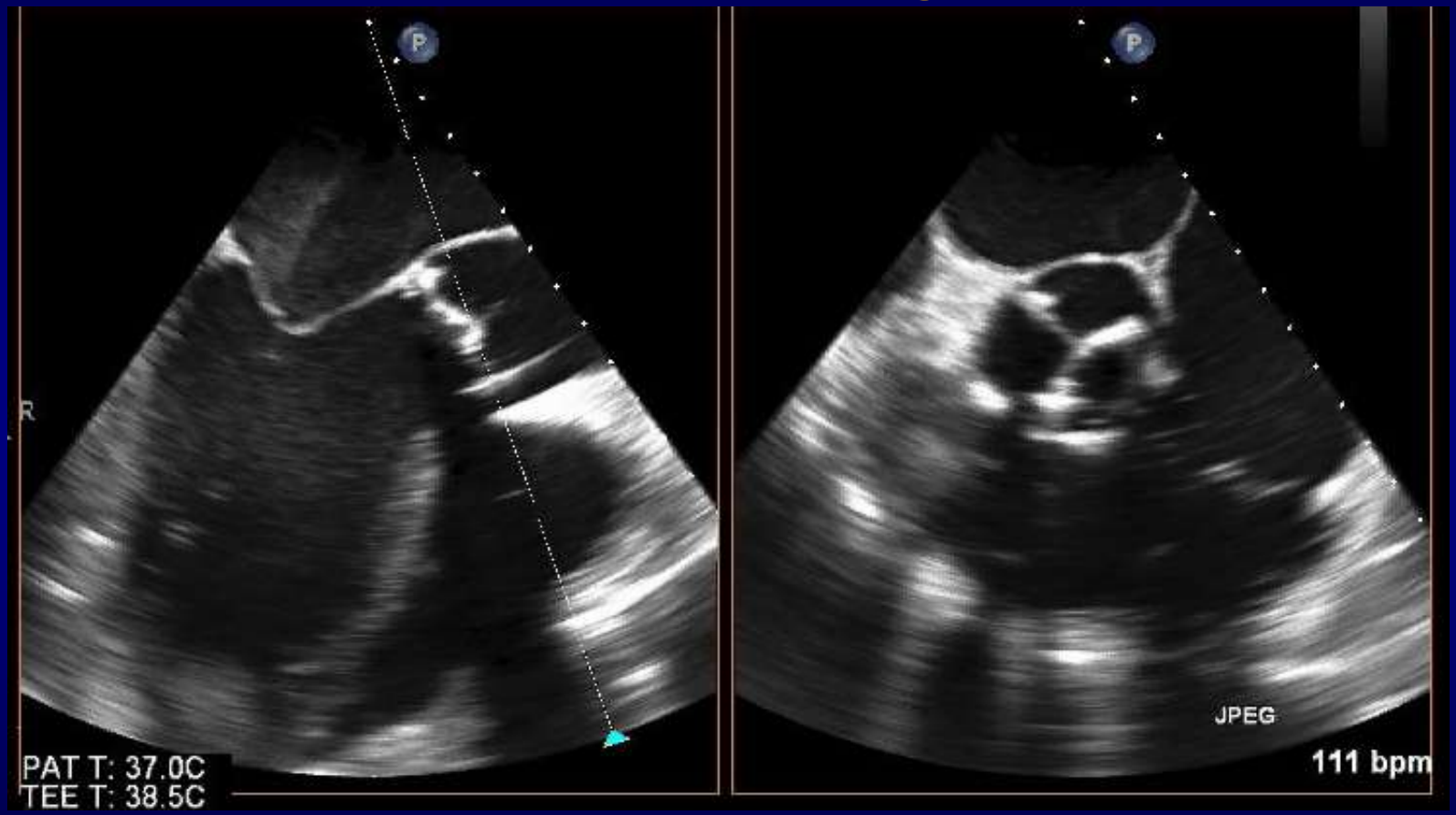
Interventional treatment options for heart failure

- Percutaneous treatment of valvular heart disease
- Stem cell therapy
- Left ventricular restoration therapy: PARACHUTE device
- Implantable pressure sensors
- Intra-atrial shunt devices
- LV assist devices : Temporary and destination

Percutaneous treatment of valvular heart disease

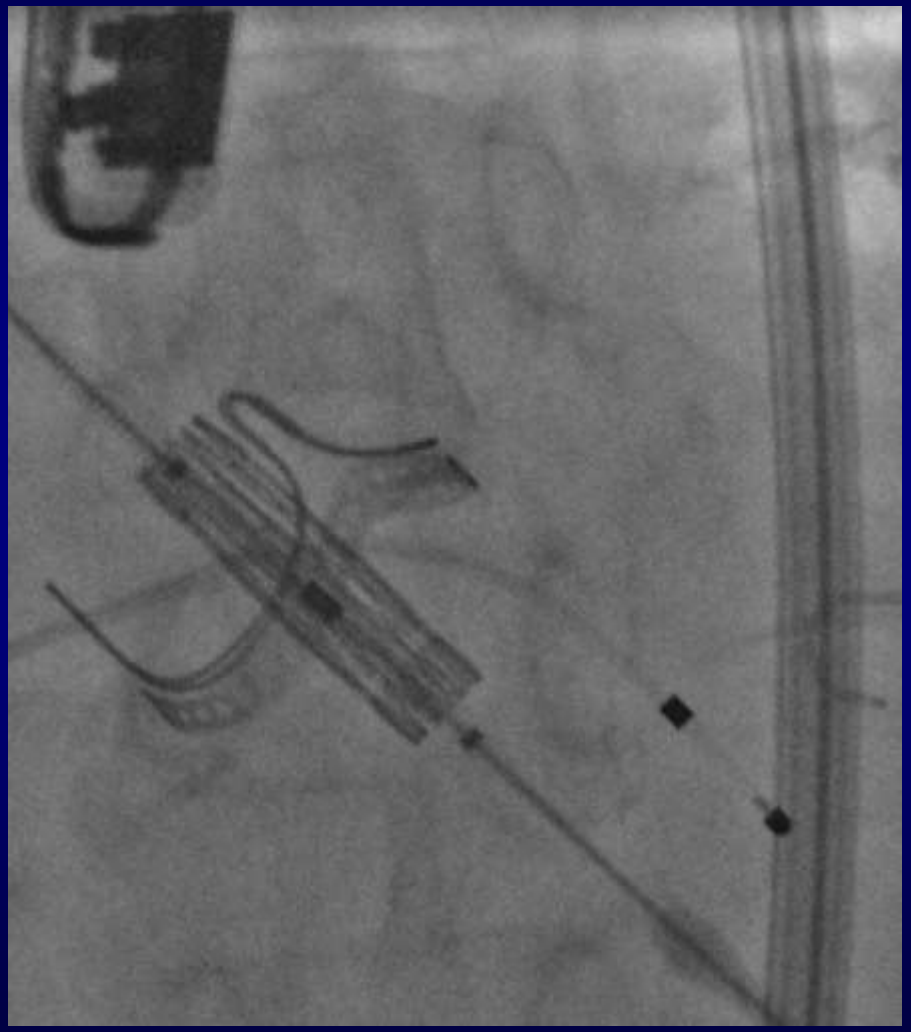
- Mitral valvuloplasty
- Transcatheter valve replacement
- Transcatheter mitral valve repair

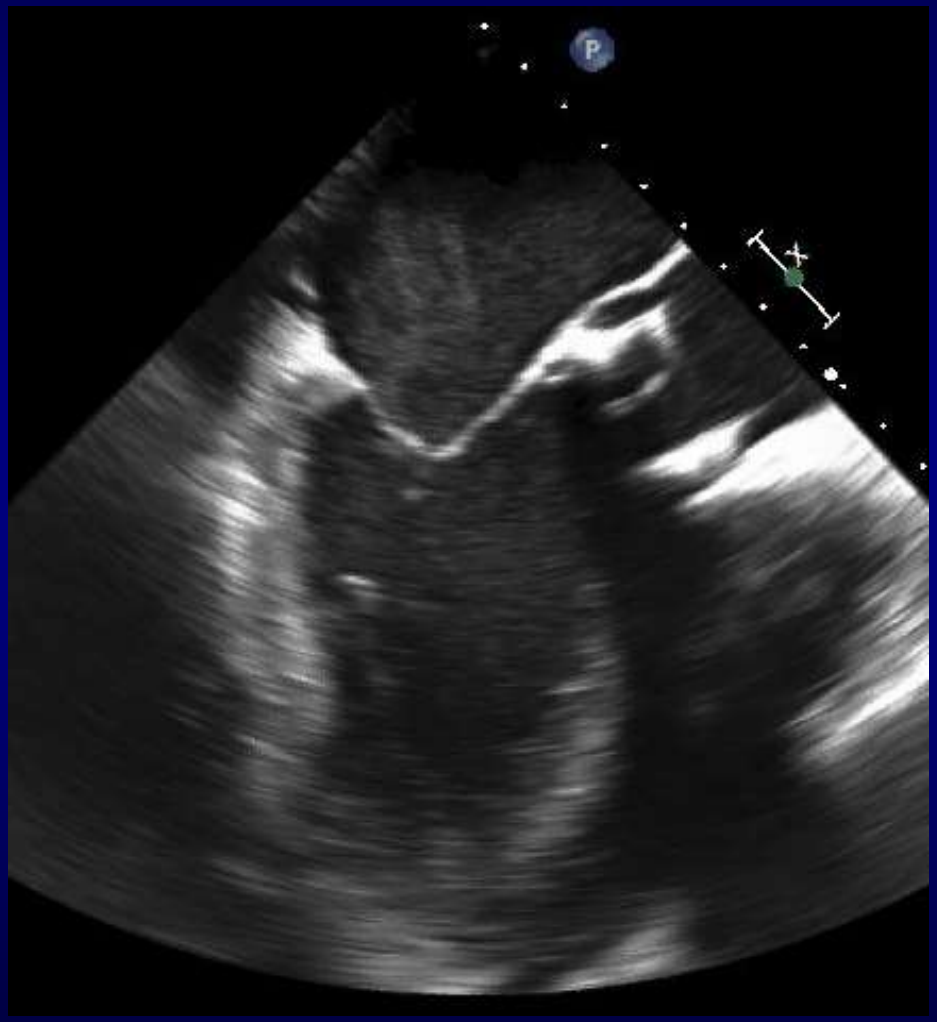
61 y/o male with s/p bioprosthetic AVR
Admission for cardiogenic shock



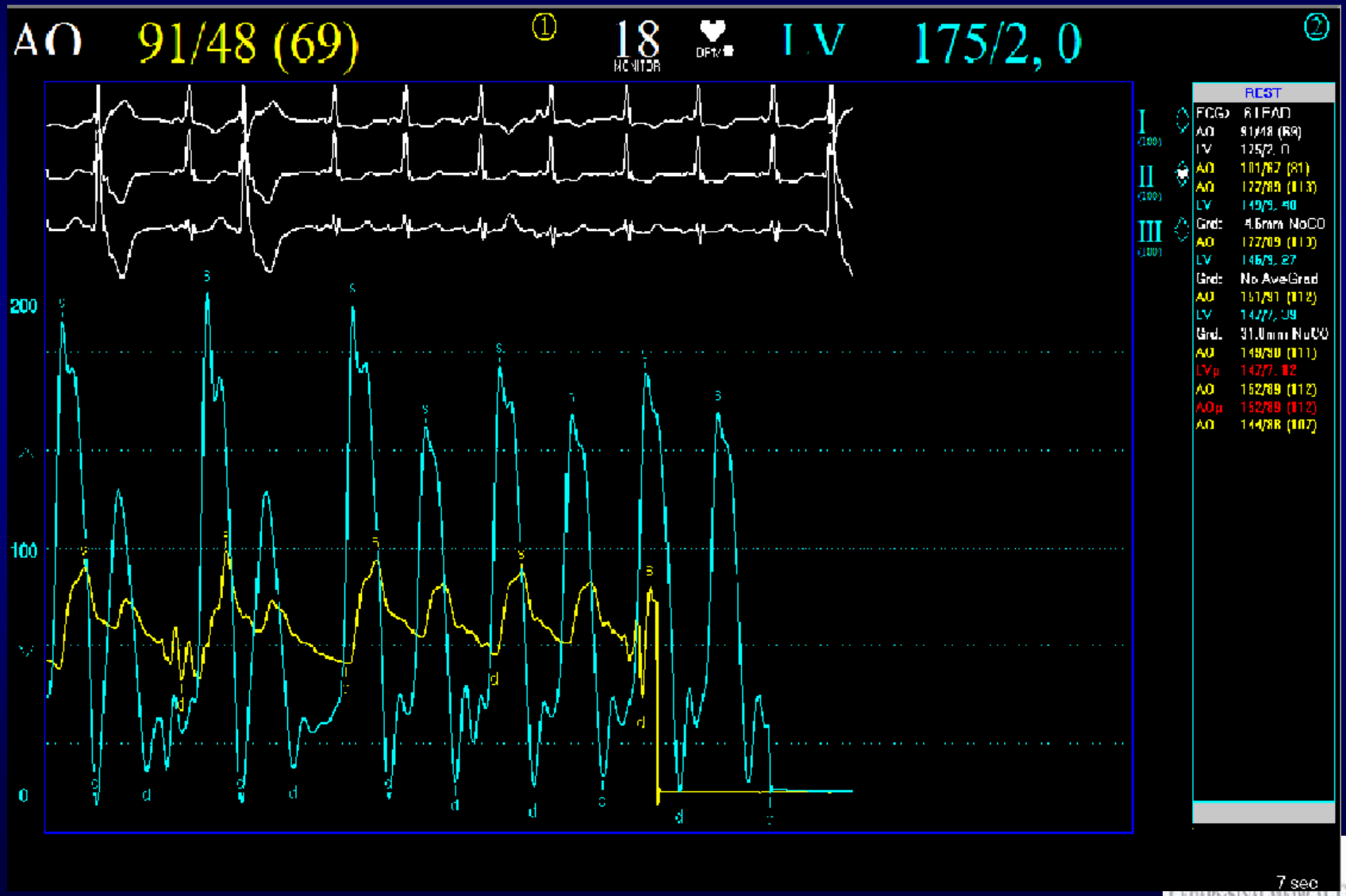
Severe LV dysfunction (LVEF <10%) with LV thrombus
AV vmax 3.37 m/s, Peak PG = 45 mmHg, Mean PG = 23 mmHg, AVA = 0.36cm2

Deployment of SAPIEN 3 THV
No ECMO

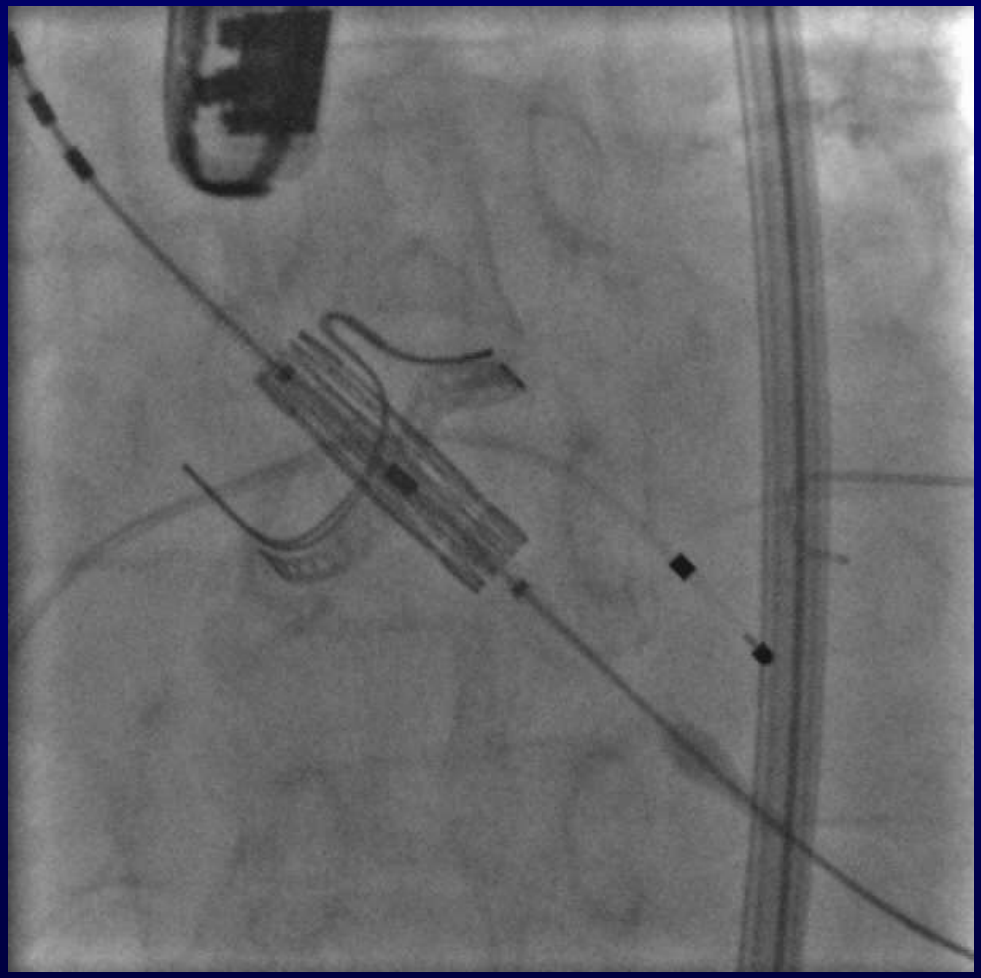


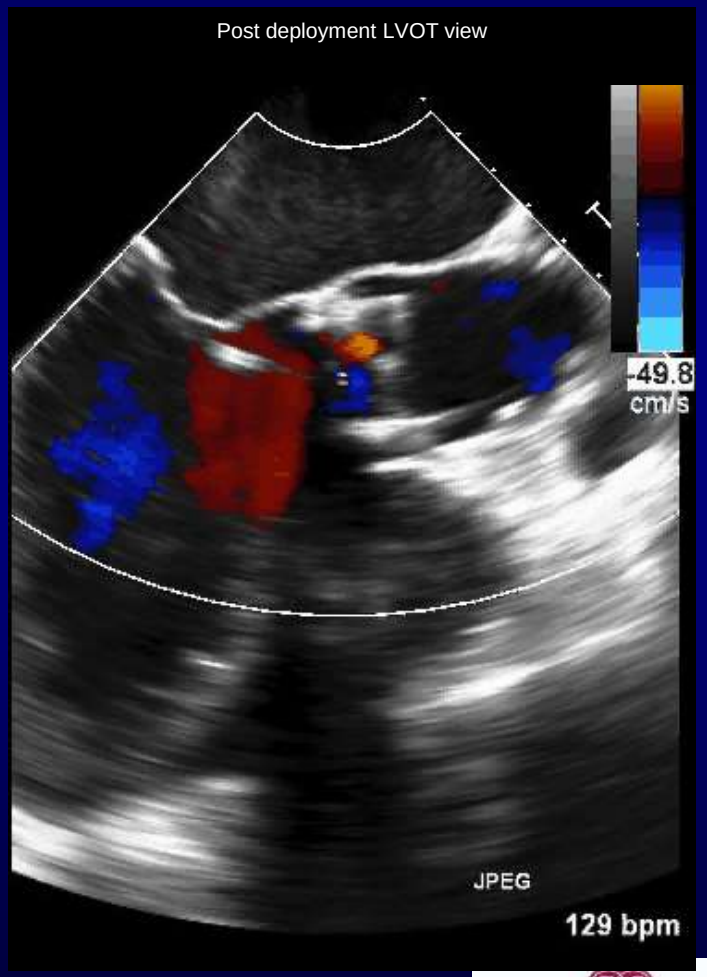


Pre VIV Ao-LV gradient

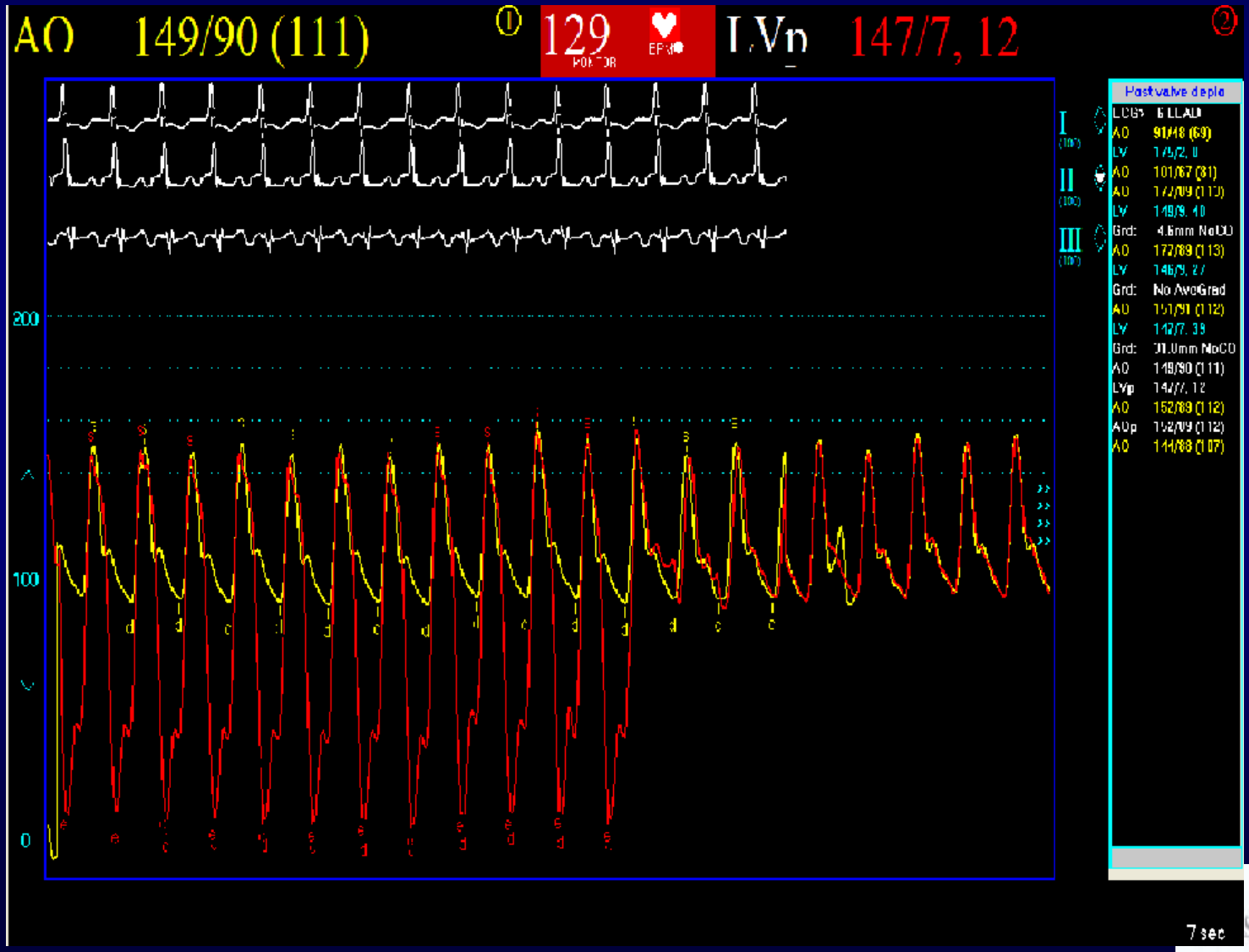


Emergency aortic valve in valve with a 26 mm SAPIEN 3



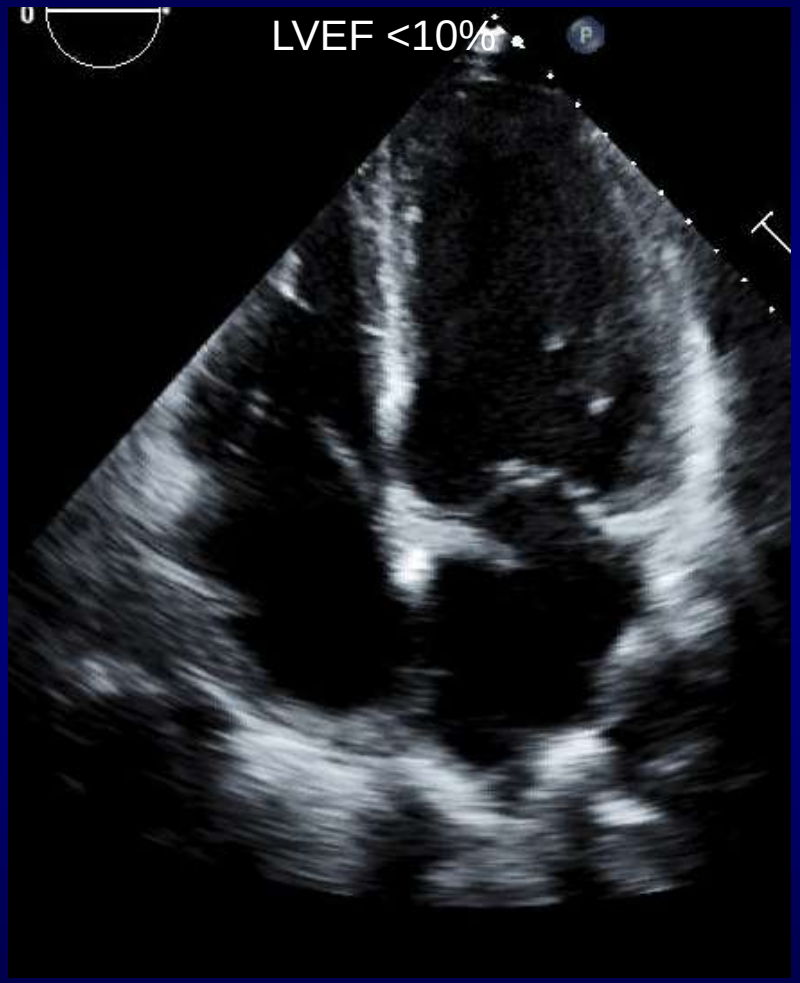


Post Valve in Valve

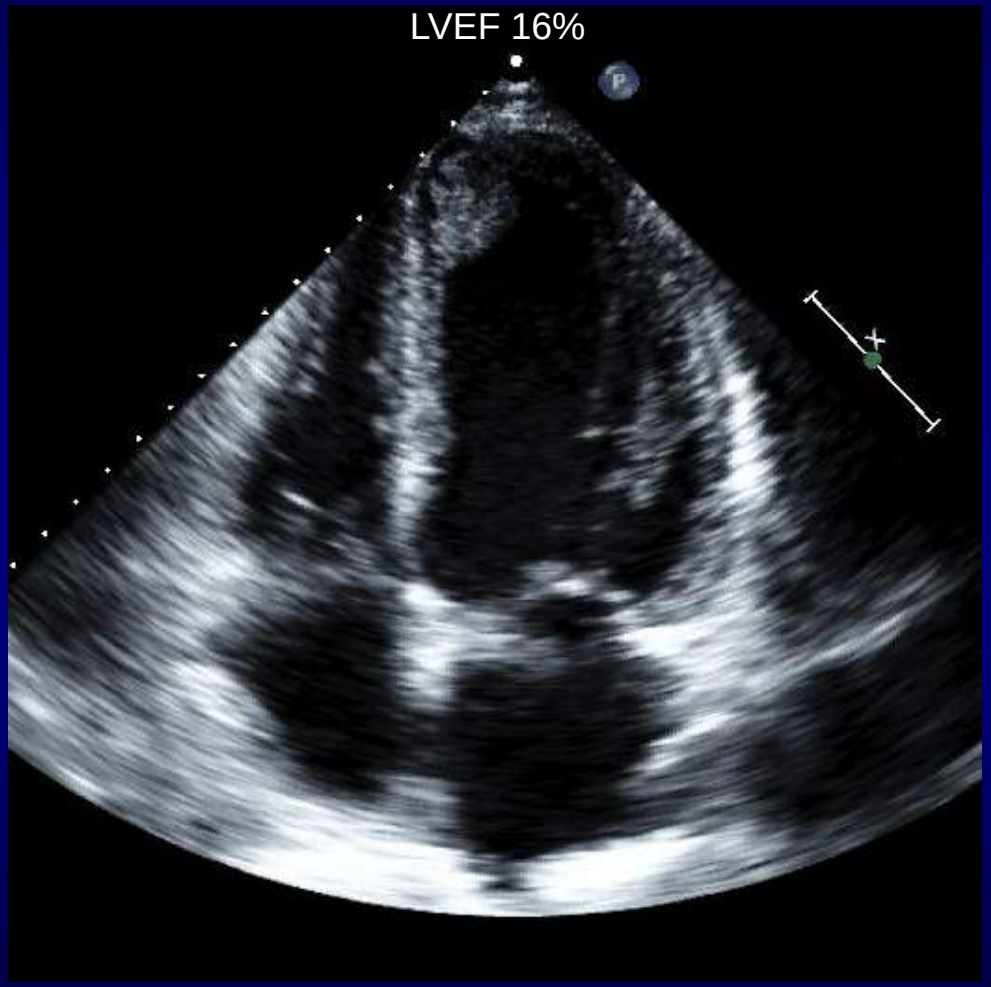


1 POD TTE

Pre 4 chamber view
LVEF <10%

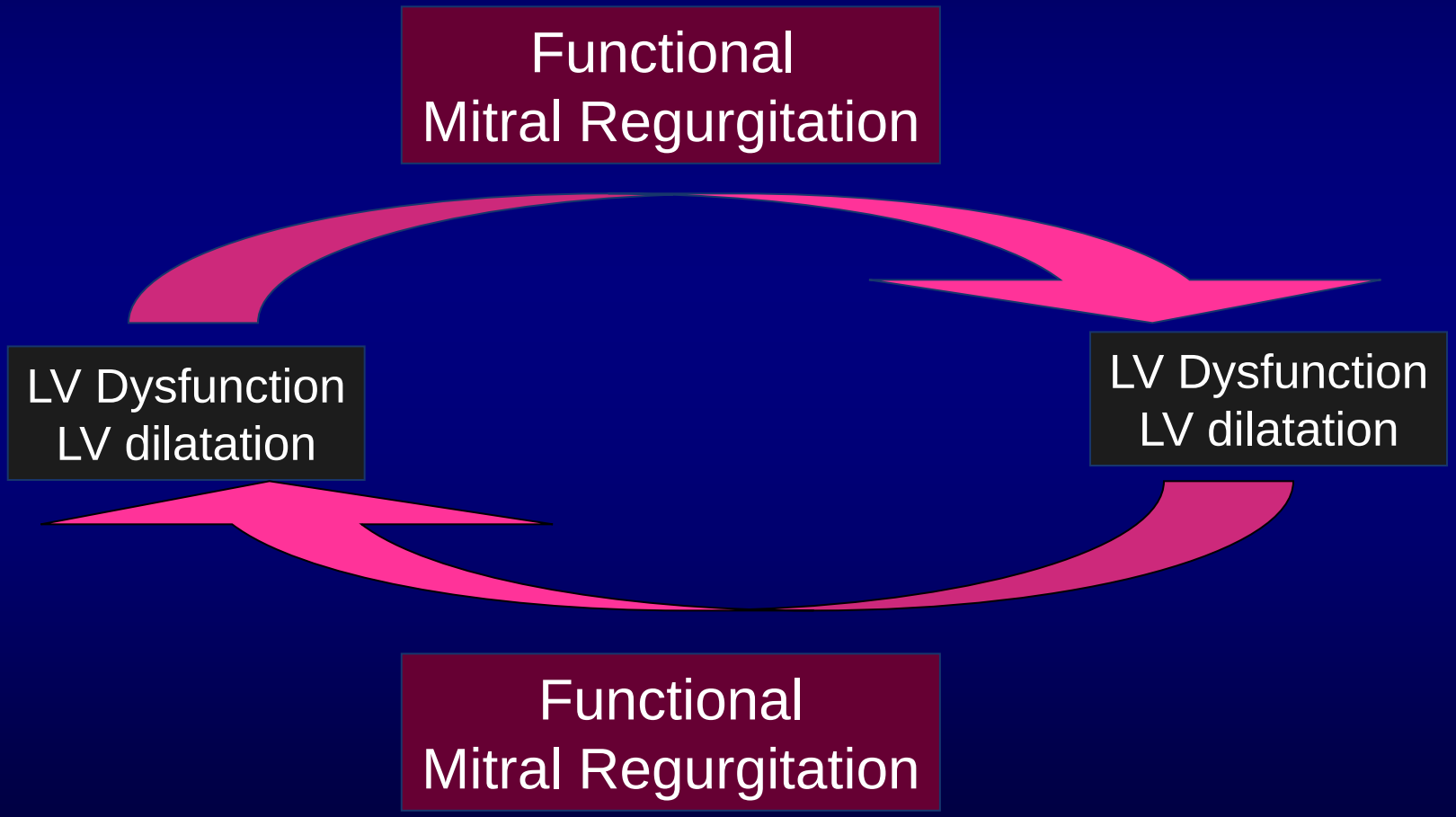


1 POD 4 chamber view
LVEF 16%



LV dysfunction improved
Trace AR, Peak PG = 16 mmHg, Mean PG = 10 mmHg

Functional MR and LV dysfunction



Treatment of FMR

- Medical treatment is the mainstay
- The role of surgery is controversial
  - Often high risk since patients have low EF
  - Symptomatic improvement
  - High recurrence
  - No mortality benefit
  - No census whether repair is better than replacement

Percutaneous Mitral Valve Repair

MitraClip® System

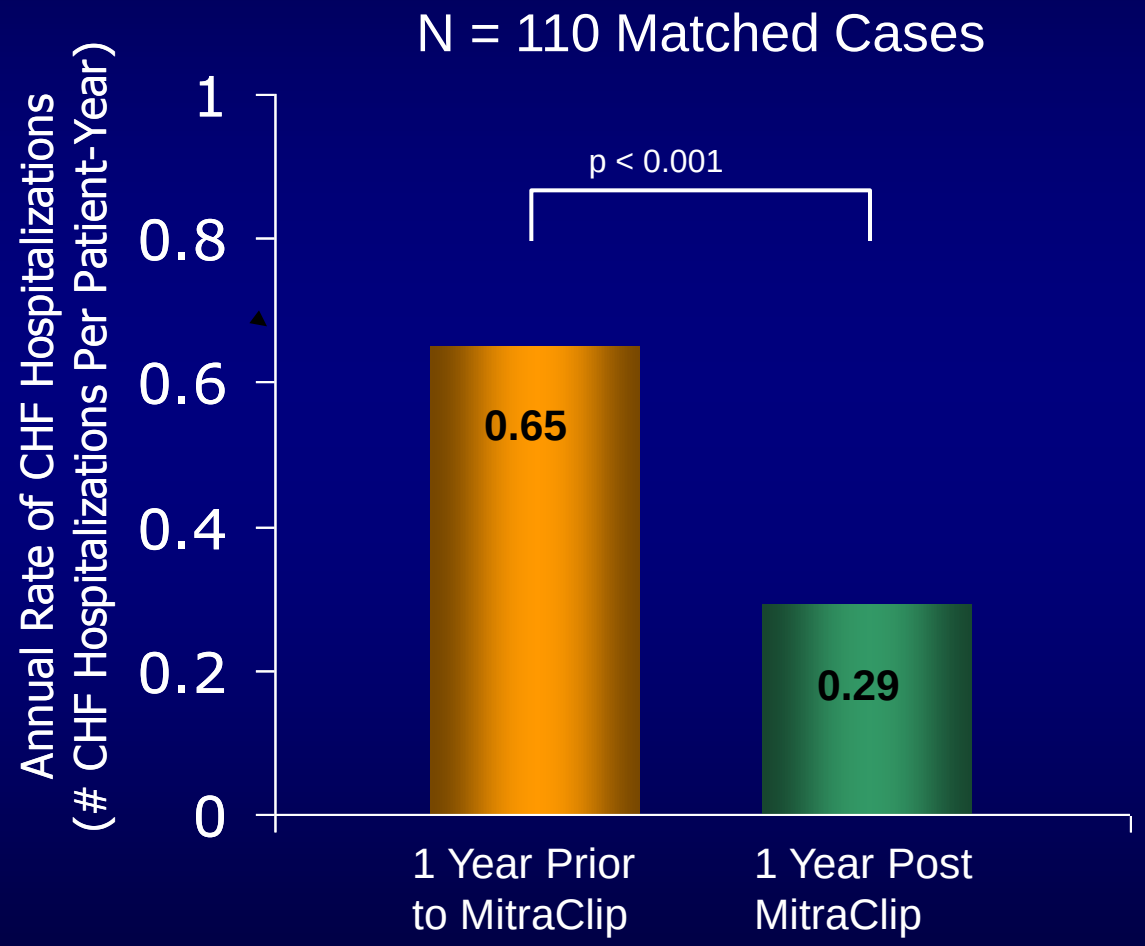
Cedars-Sinai Medical Center

MitraClip for Functional MR

- EVEREST trial, and non randomized data from Registries in Europe
- Safe
- MR reduction
- Clinical Improvement
- Favorable LV remodeling
- No randomized studies in this subgroup to demonstrate survival benefit

Hospitalizations for CHF

"EVEREST II High Surgical Risk FMR Patients"



Trial design

420 patients enrolled at up to 75 US sites

Significant FMR (≥3+ by core lab)

Extremely high risk for mitral valve surgery

Specific valve anatomic criteria

Randomize 1:1

398 patients have been enrolled in the trial

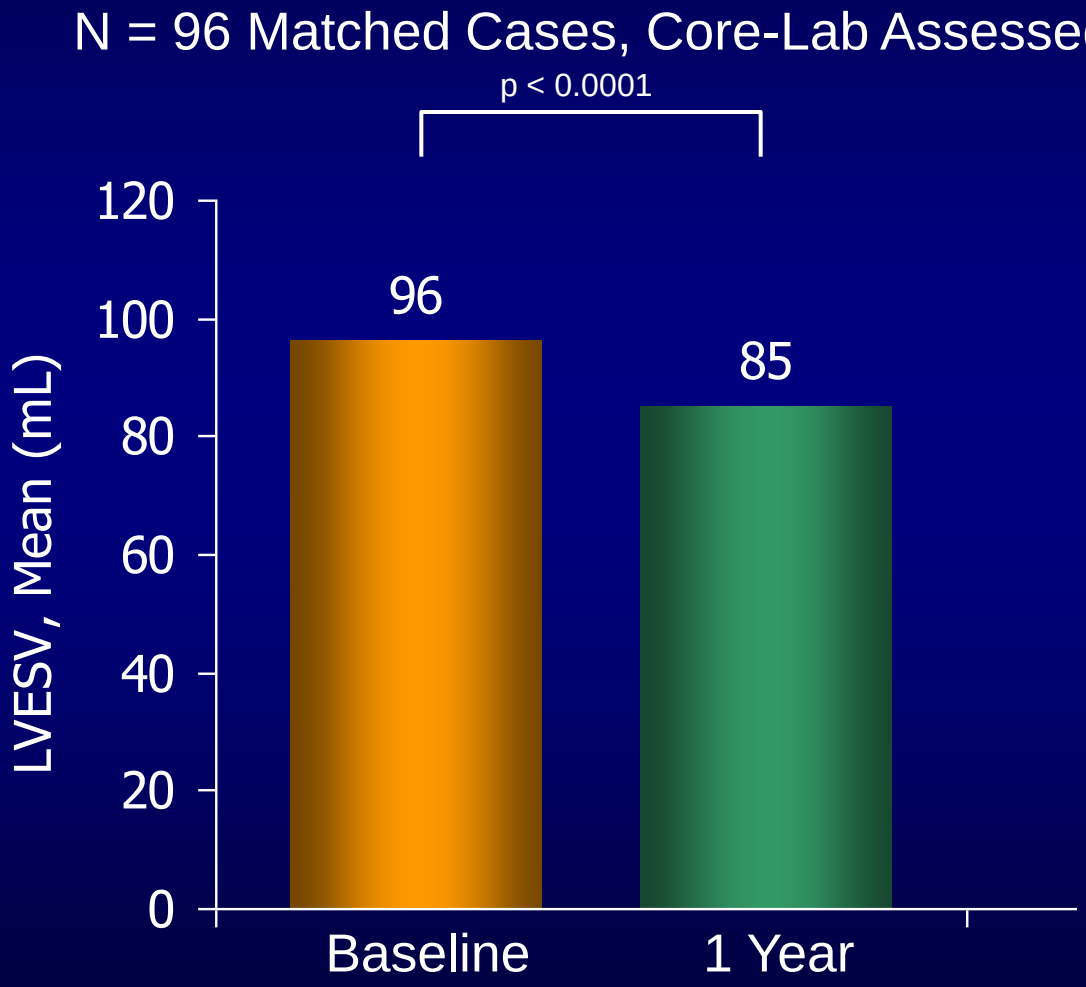
N=210

N=210

Clinical and TTE follow-up:

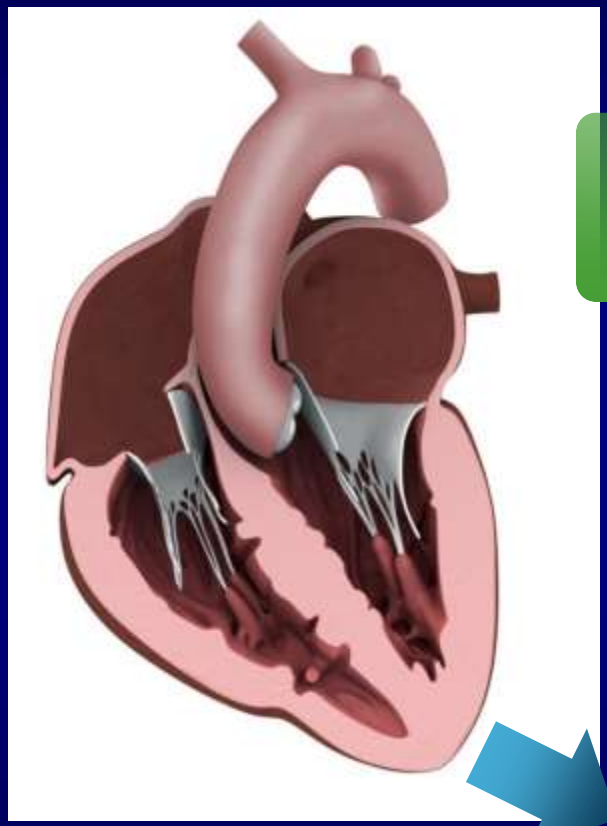
1, 6, 12, 18, 24, 36, 48, 60 months

Left Ventricular End Systolic Volume
"EVEREST II High Surgical Risk FMR Patients"



PARACHUTE Device

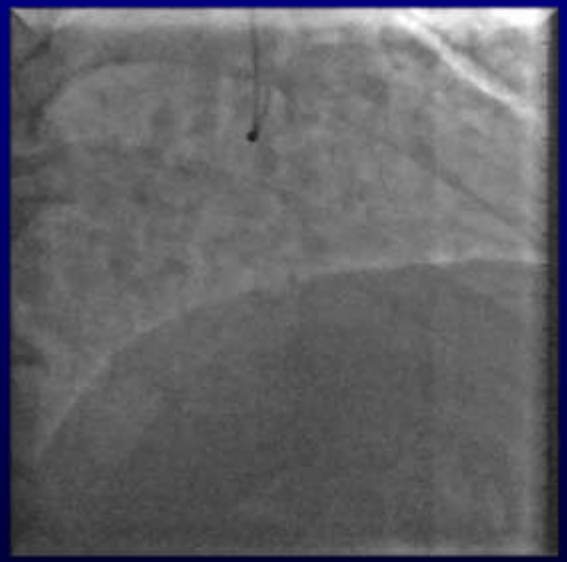
Ischemic Cardiomyopathy is the Most Common Cause of CHF

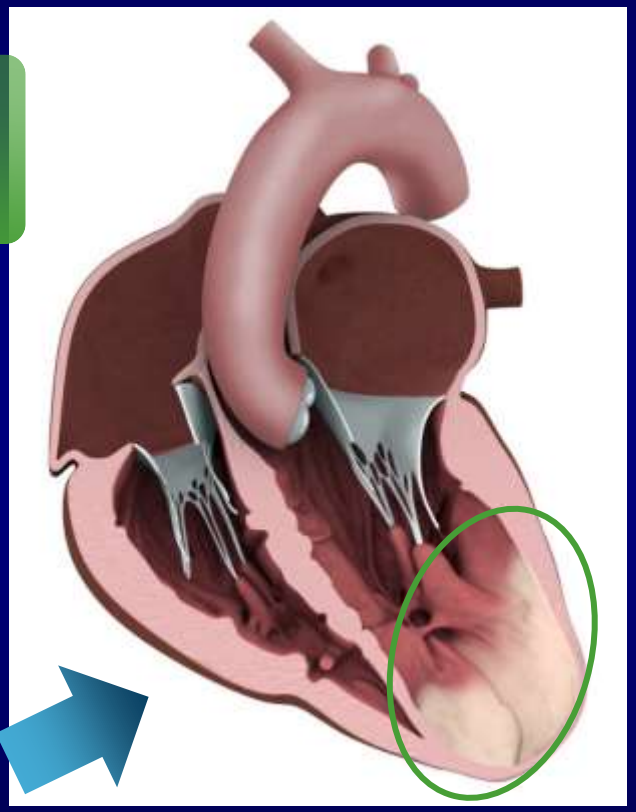


24% of MI Patients Progress into HF

Eccentric WMA leads to inefficient pump function

LV remodeling/dilation





Percutaneous Ventricular Restoration with PRACHUTE device

PARACHUTE IMPLANT

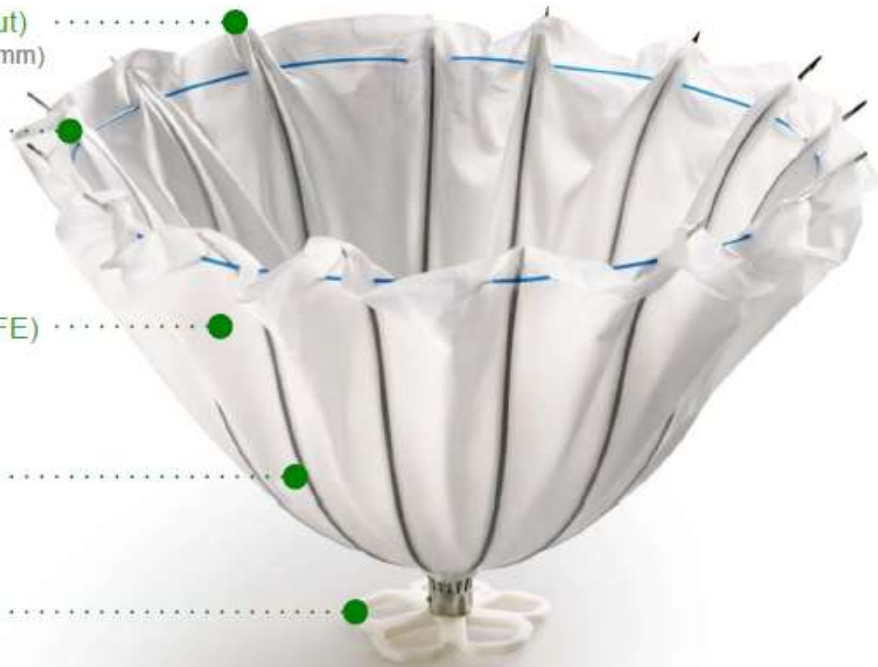
Anchor (Laser Cut)
Engages LV Wall (2mm)

Suture (Polypropylene)
Collapses Device. Supports ePTFE at the Edge

Membrane (ePTFE)
Dual layer occlusive membrane. Allows tissue growth.

Frame (Nitinol)
16 Arms Laser Cut from a Single Tube

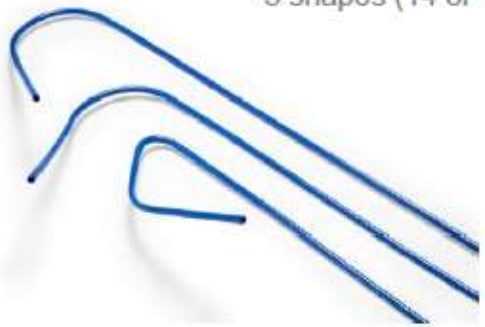
Foot (Urethane)
Radiopaque. Shock Absorber



	65mm	75mm	85mm	95mm
Standard (+3mm)	X	X	X	X
Short	X	X	X	X

GUIDE CATHETER

3 shapes (14 or 16Fr)



DELIVERY SYSTEM

20cc balloon is inflated to anchor device

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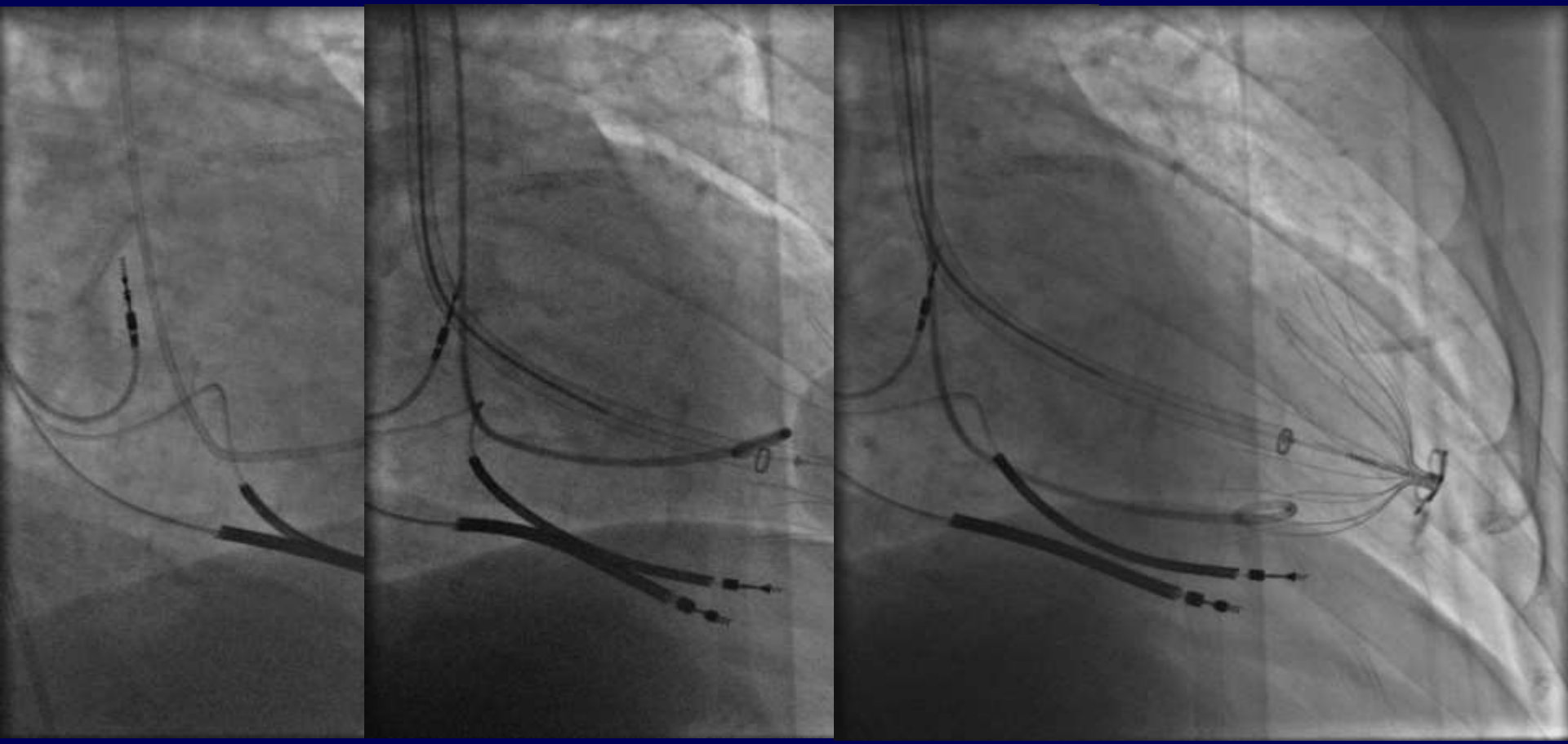
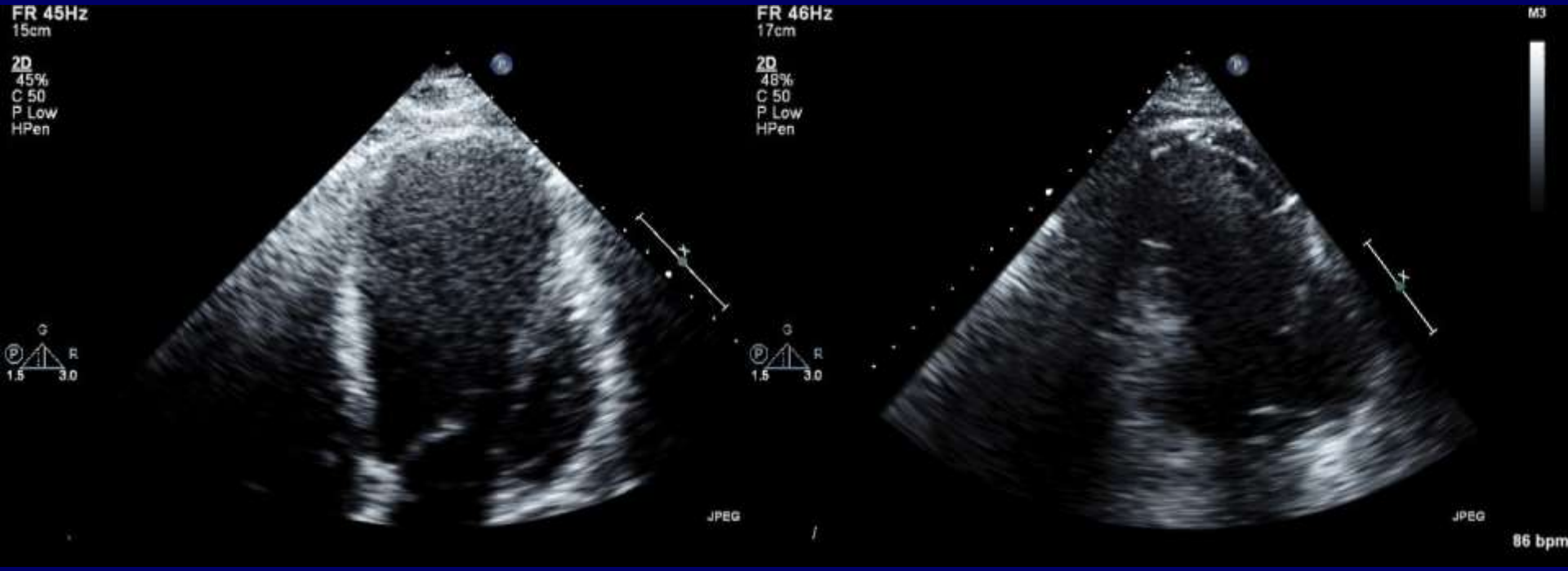
PARACHUTE Implantation



PARACHUTE Implantation

Preprocedure ***Postprocedure***



NYHA class I at 1 year follow-up

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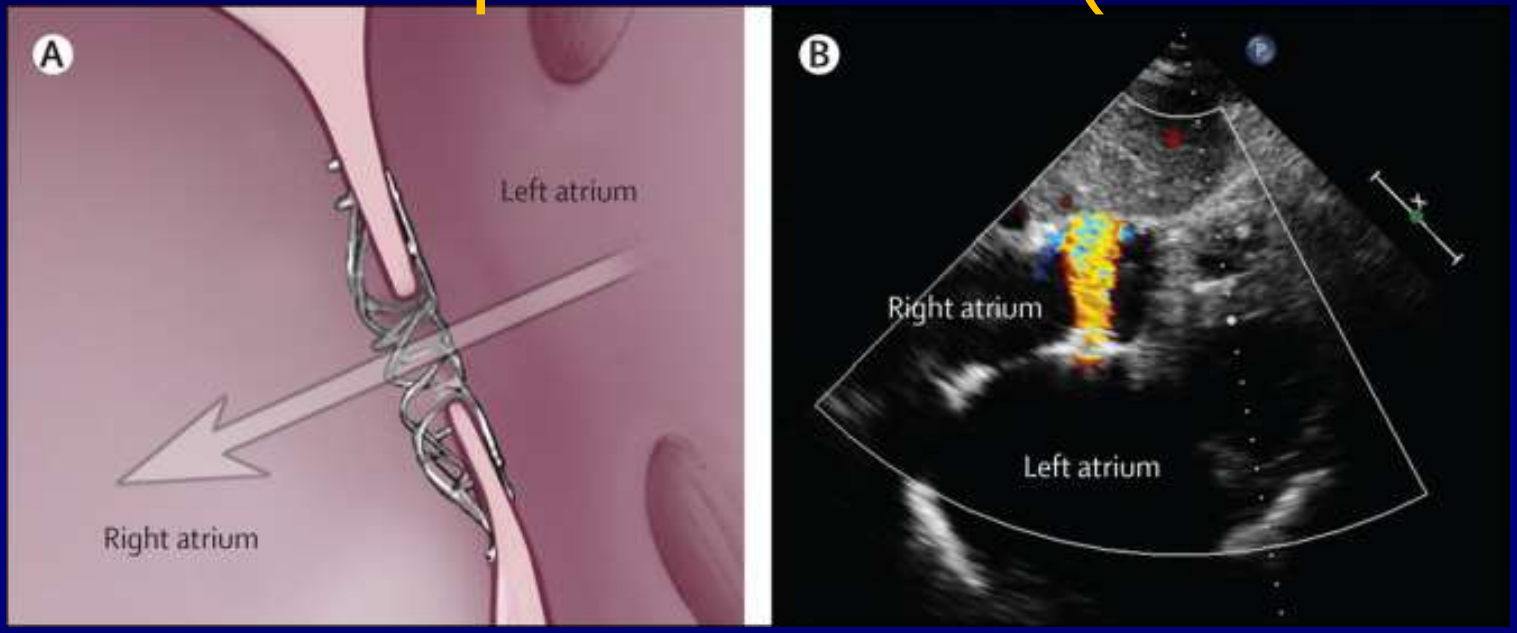
PARACHUTE Summary

- The Percutaneous Ventricular Partitioning Device (Parachute® device) has been in development and in Clinical Programs.
- There is no randomized, controlled data to date.
  - However, early safety, feasibility and clinical data is encouraging
- The pivotal US trial (Parachute IV) is ongoing where, and if, this device fits in the treatment of Congestive Heart Failure.

Intratrial shunt device for pts with Heart failu with preserved EF (HFPEF

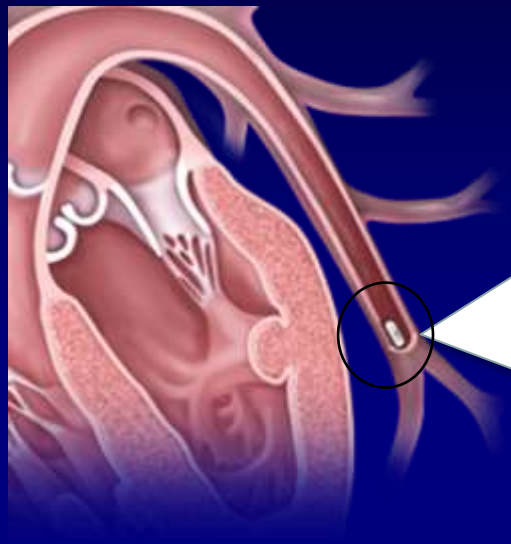


- Early open label non randomized study
- Moderate improvement of PWP and exercise capacity at 6 months
- Patency of shunt at 6 months

Hasenfuß G et al. Lancet 2016;387:1298

Pulmonary Artery Pressure Monitoring With CardioMEMS

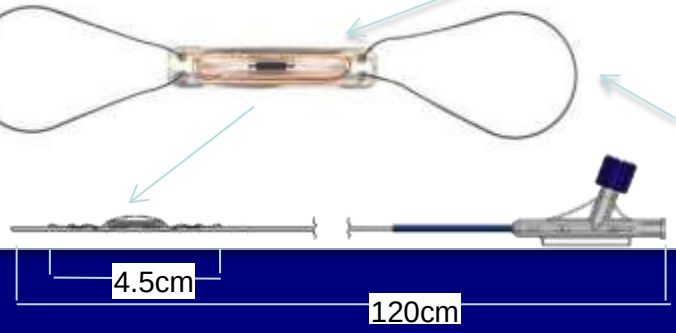
CardioMEMS HF Monitoring System



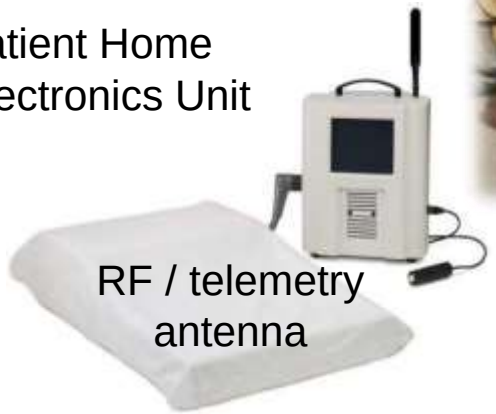
Pressure Sensor on Delivery Catheter released into LPA

Sensor
- Powered by RF
- LC oscillator
- 3.5 x 2 x 15mm

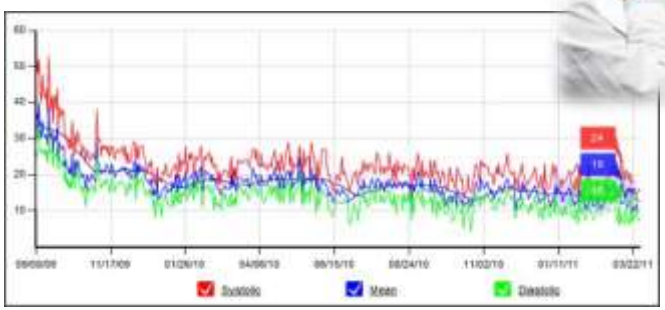
Nitinol retention loops
- 10 mm diameter



Patient Home Electronics Unit



PA Pressure Database



Physician Access Via Secure Website

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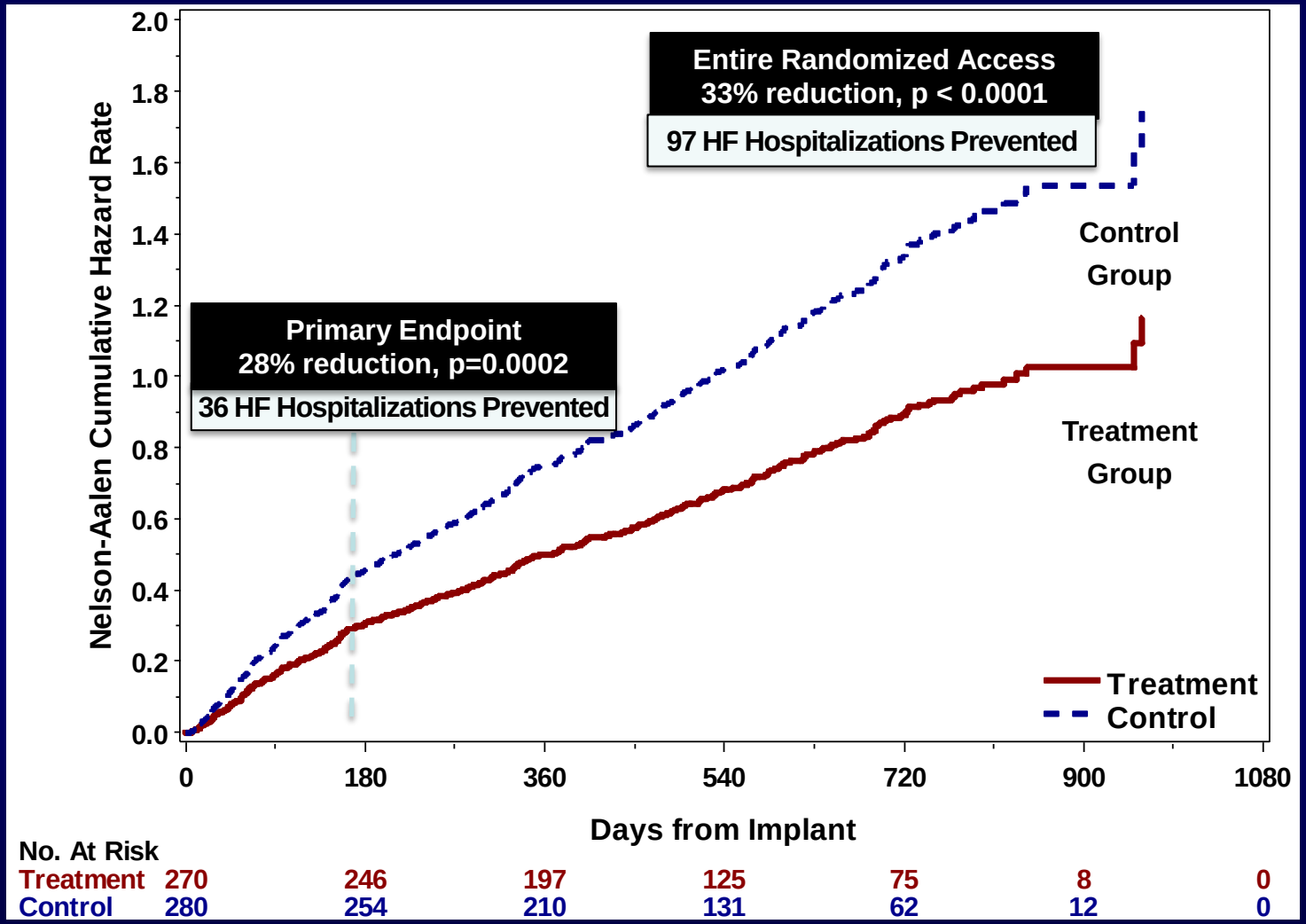
Durable Reduction of HF Hospitalizations



Abraham et al. *The Lancet* 2011;377:658-666

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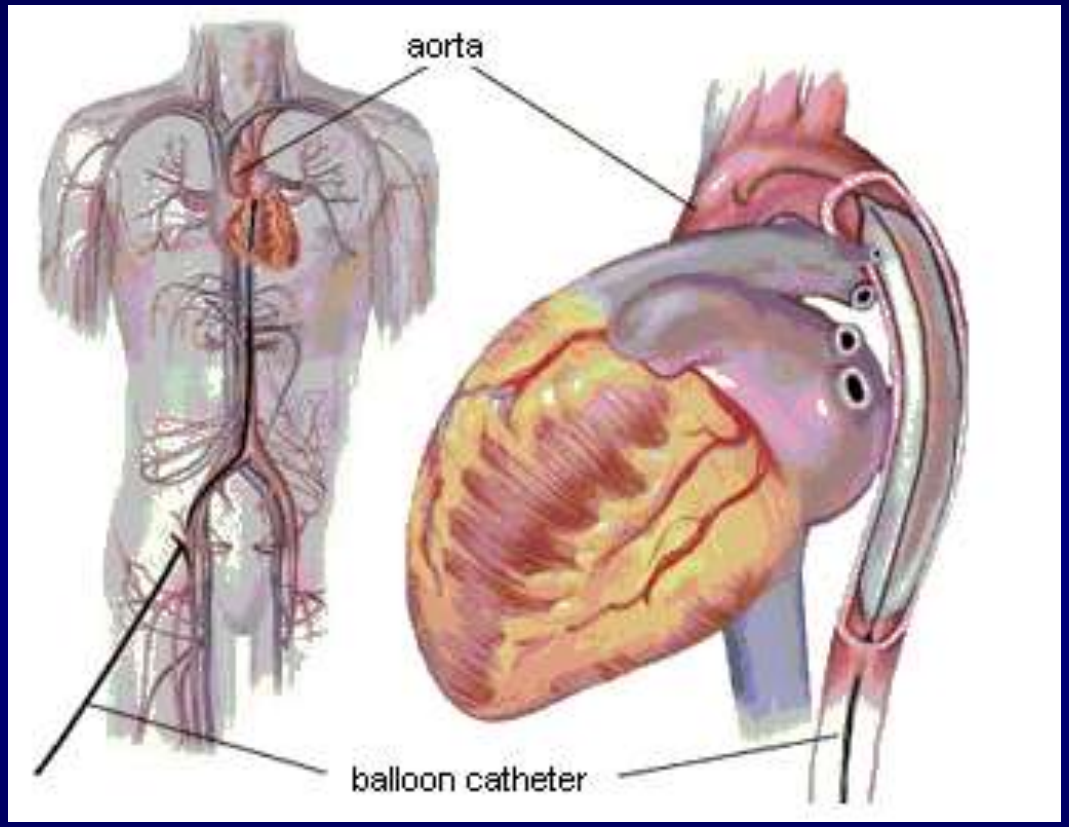
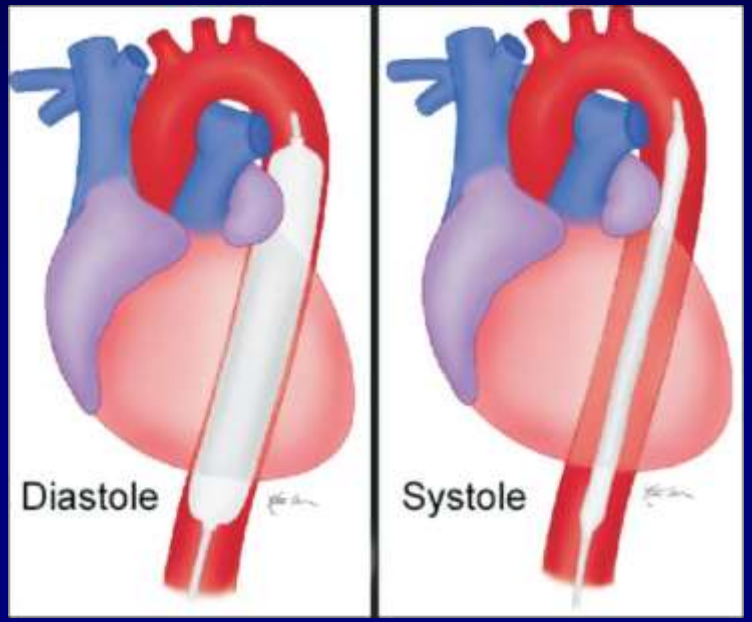
Left Ventricular Assisted Device (LVAD)

Hemodynamic Support in Cath Lab Potential Emergency Applications

- Cardiogenic shock – MI, valvular disease, CM
- Bridge to transplant
- Bridge to bridge (implantable LVAD)
- Post operative CGS with isolated RV dysfunction
- Cardiovascular collapse in cath lab

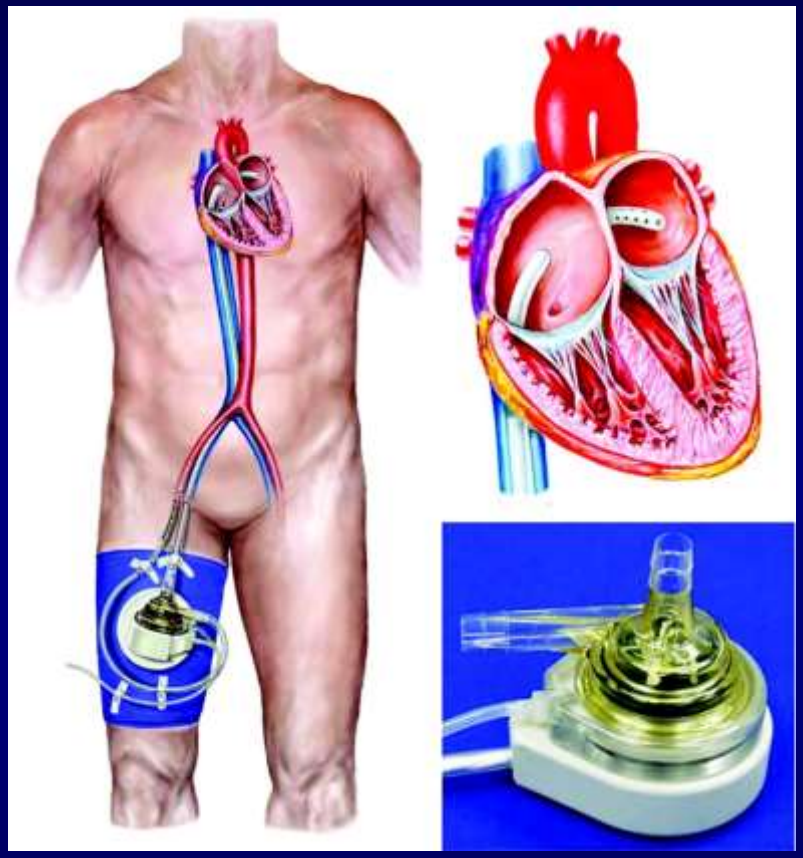
Current Percutaneous Options….Limited

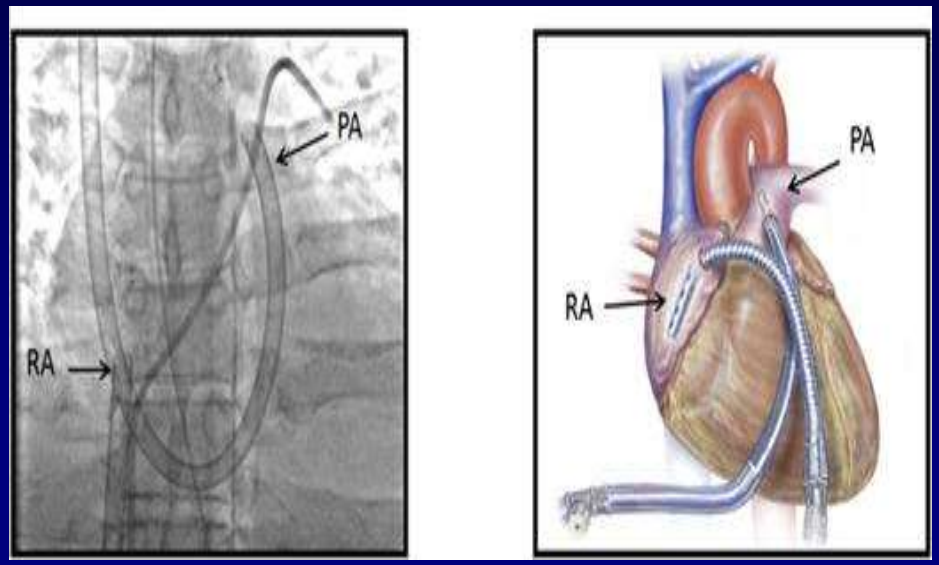


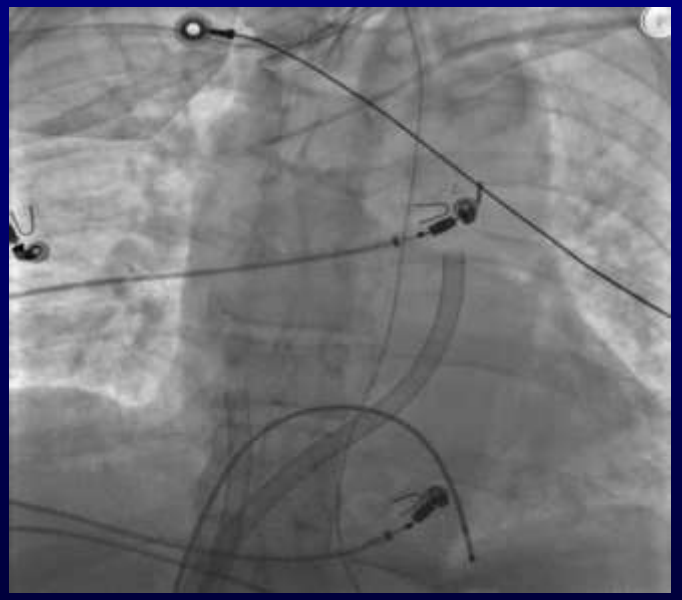


IABP
(Intra-aortic balloon pump)

TandemHeart PVAD



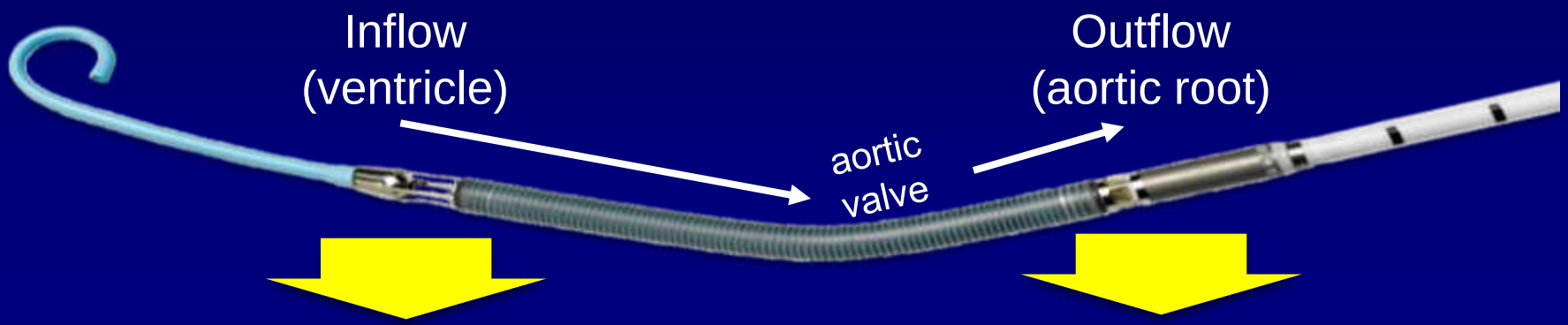




TandemHeart Circuit (Transseptal access)

Principles of Impella Design

Mimic Heart's Natural Function



EDV, EDP

AOP

Flow

O_2 Demand

O_2 Supply

Cardiac Power Output

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Conclusion

- Incidence of heart failure continues to rise
- There is a need for less invasive interventional options for patients with endstage heart disease
- Important interventional tools include:
  - Transcatheter valve repair/replacement
  - Implantable pressure monitors
  - LV partitioning techniques
  - Implantable assist devices
- The treatment options continue to rise