

The 21st Century Approach to Structural Heart Disease

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Disclosures

- Travel reimbursement from Abbott Vascular

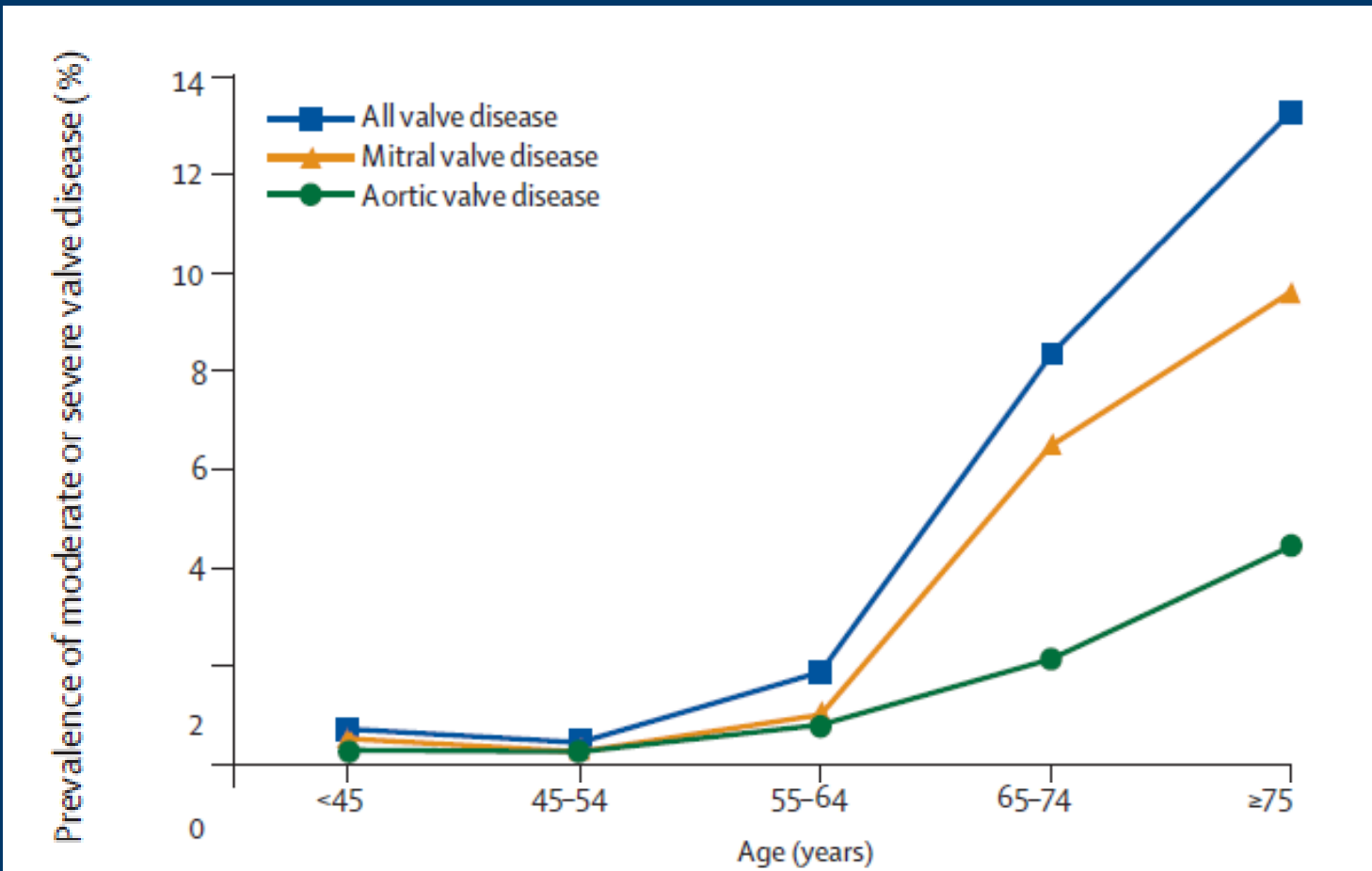
Mitraclip:

Transcatheter Mitral Valve Repair

Case Report

- 89 y/o female, known severe mitral regurgitation
- *Chief Complaint:* increasing fatigue, dyspnea on exertion, weakness
- *Hx:* HLD, HTN, CKD, GERD, Hx Breast Cancer 2003 s/p lumpectomy, squamous cell 2007, right nephrectomy 1970, severe MR, osteoporosis
- *STS score MV Repair* – 5%
- *STS score MV Replacement* – 8.3%
- Surgical evaluation: Patient at high risk for mitral valve surgery

Prevalence of Mitral Valve Disease



Mechanism of Mitral Regurgitation

- **Degenerative:** valve components are abnormal
 - Prolapse
 - Ruptured chordae/flail leaflet
 - Rheumatic disease
 - Congenital abnormality
 - Endocarditis
- **Functional:** valve components are normal
 - LV dilation and remodeling leads to ...
 - Annular enlargement
 - Papillary muscle displacement

Indications for Mitral Valve Surgery

- **Class I**

- **Symptomatic** (NYHA II-IV) with LVEF > 30%
- Asymptomatic with **LVEF 30-60% and/or ESDd \geq 40mm**

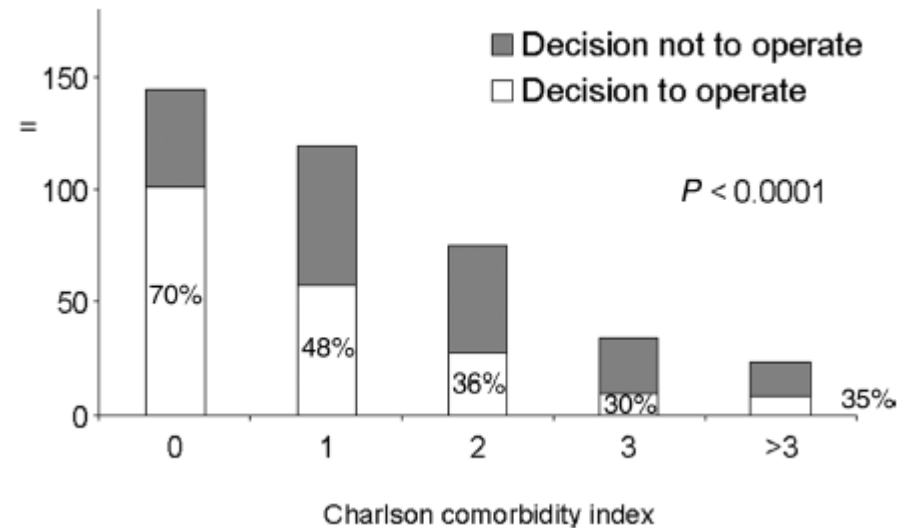
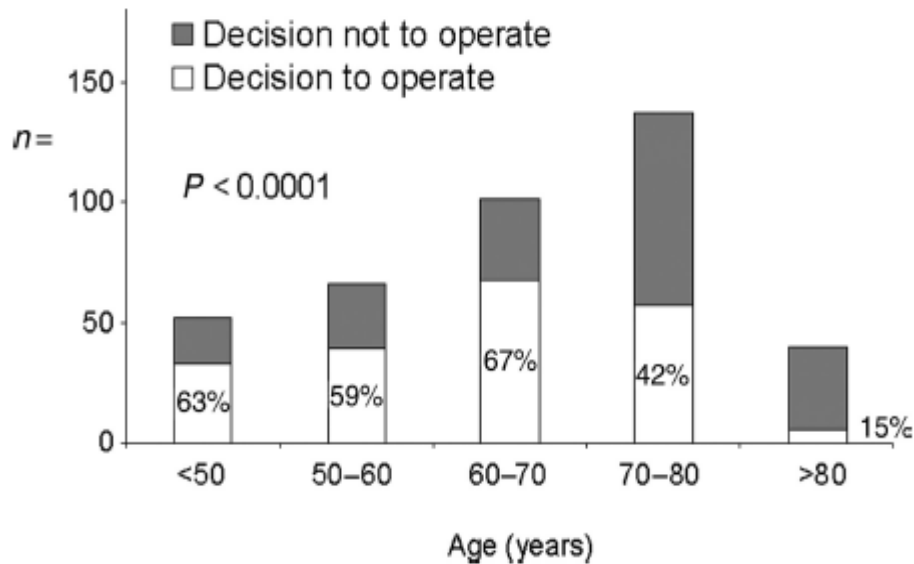
- **Class IIa**

- Asymptomatic with preserved LV function (e.g. LVEF > 60% and ESDd \leq 40mm) +/- the presence of **new onset AF or pulmonary hypertension or if expected surgical mortality <1%**
- Patients with severe **functional MR** undergoing CABG or AVR

- **Class IIb**

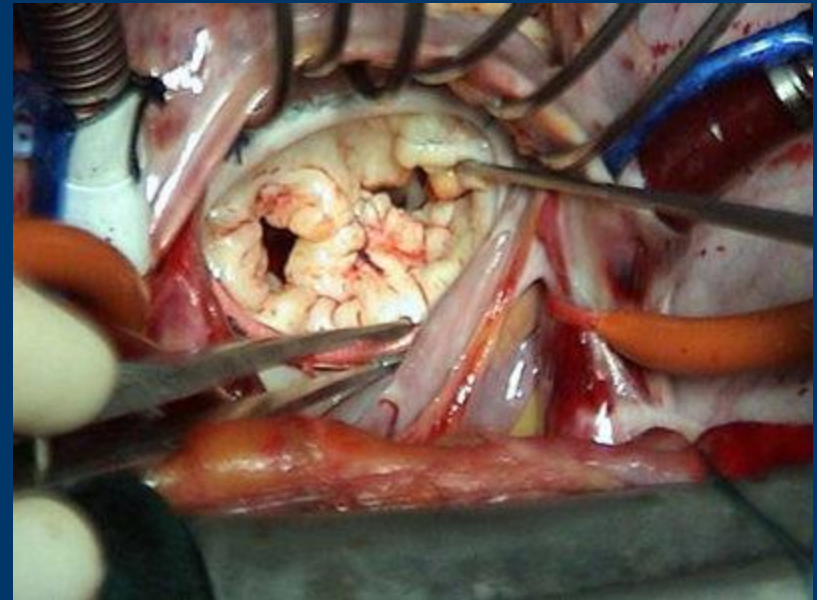
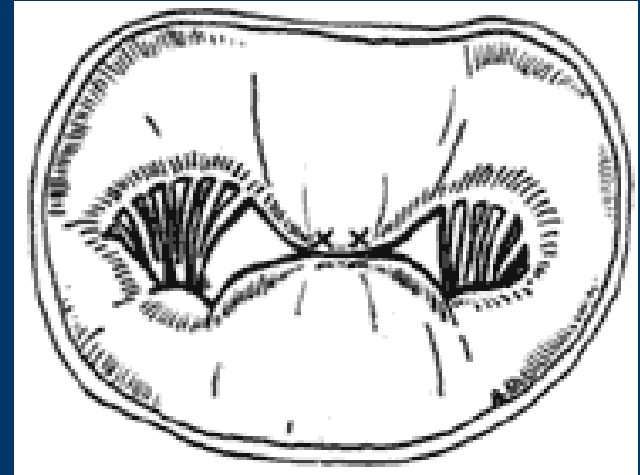
- Symptomatic (NYHA III-IV) with **LVEF \leq 30%** in setting of degenerative MR
- Severely symptomatic (NYHA III-IV) in the setting of **functional MR**

Underuse of Mitral Valve Surgery in Symptomatic Patients

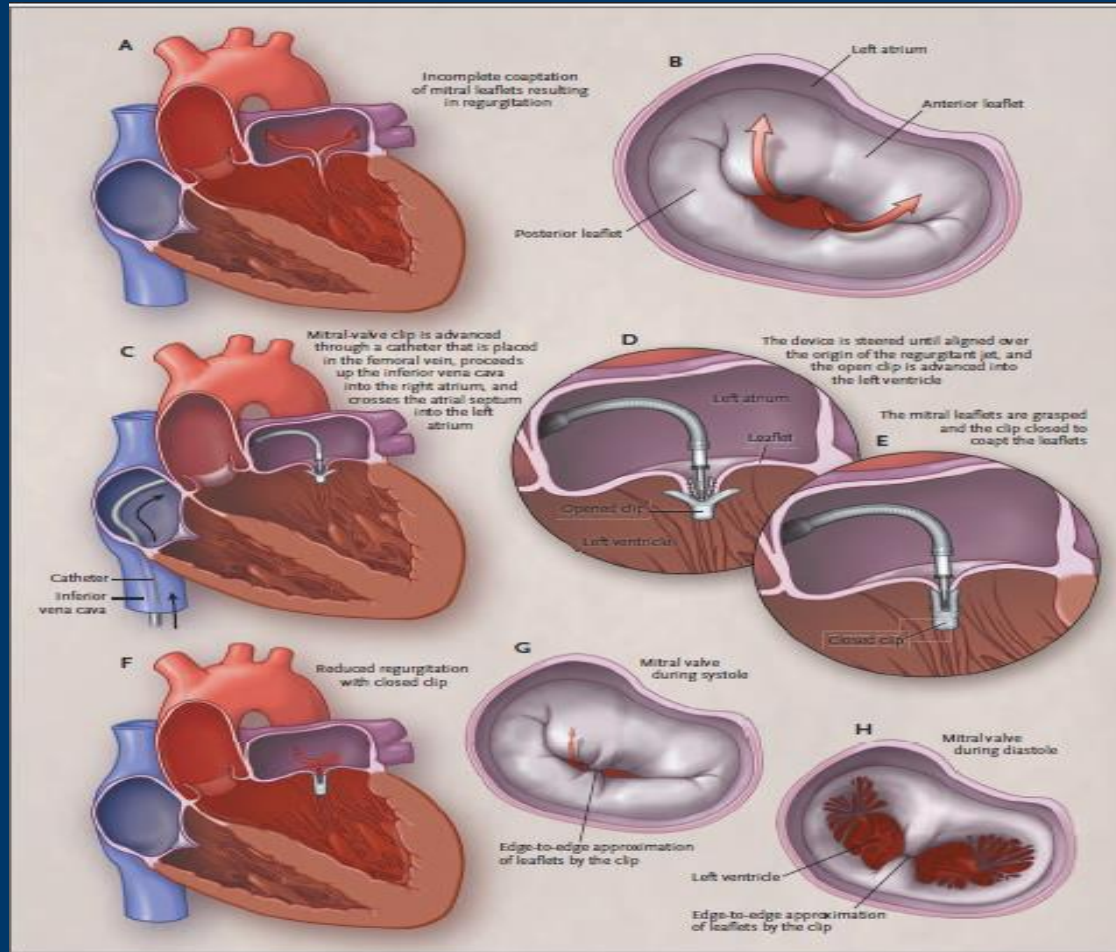


Edge-to-Edge Repair: Surgical Technique

- Described by Alfieri in 1992
 - Suture part of anterior and posterior leaflet edges together
 - Usually applied to A2-P2 central segment
 - Facilitates proper leaflet coaptation
 - Creates tissue bridge
 - Restrains LV wall



The MitraClip System



EVEREST II Study Design

Design: RCT comparing mitralclip vs. surgery in a 2:1 randomization fashion

Inclusion Criteria

- 3+ or 4+ chronic MR AND
 - Symptomatic with EF > 25% and LVSDd < 55mm
 - OR
 - Asymptomatic with . . .
 - EF 25%-60% *or*
 - LVSDd > 40 mm *AND*
 - Atrial Fibrillation *or*
 - PASP > 50 at rest or > 60 with exercise

Exclusion Criteria

- Anatomical criteria making percutaneous closure untenable
- Recent MI
- Prior mitral valve surgery or valvuloplasty
- Not candidate for surgery

EVEREST II: Efficacy Results

Event	MitraClip	Surgery	p-value
<i>Composite Efficacy Endpoint</i>	<i>100 (55%)</i>	<i>65 (73%)</i>	<i>0.007</i>
Death	11 (6%)	5 (6%)	1.00
<i>Surgery for MV dysfunction</i>	<i>37 (20%)</i>	<i>2 (2%)</i>	<i>< 0.001</i>
Grade 3+ or 4+ MR	38 (21%)	18 (20%)	1.00

EVEREST II: Safety Results

Event	MitraClip	Surgery	p-value
<i>Any Major Adverse Event</i>	27 (15%)	45 (48%)	< 0.001
- <i>Excluding transfusion</i>	9 (5%)	9 (10%)	0.23
Transfusion \geq 2U PRBC	24 (13%)	42 (45%)	< 0.001
Urgent CT surgery	4 (2%)	4 (4%)	0.57
Renal failure	1 (< 1%)	0	1.00
Stroke	2 (1%)	2 (2%)	0.89
Mechanical ventilation \geq 48 hrs	0 (0%)	4 (4%)	0.02

EVEREST II Trial: Summary

- Surgery was found to be superior to MitraClip in terms of primary efficacy endpoint
 - Driven by need for MV surgery in MitraClip group
- MitraClip was found to be superior to Surgery in terms of primary safety endpoint
 - Driven entirely by need for transfusions with surgery
- MitraClip patients did experience durable improvements
 - Quality of Life measurements
 - LV ejection fraction
 - LVEDV and dimensions
 - Severity of MR

EVEREST II High Risk Registry: Summary

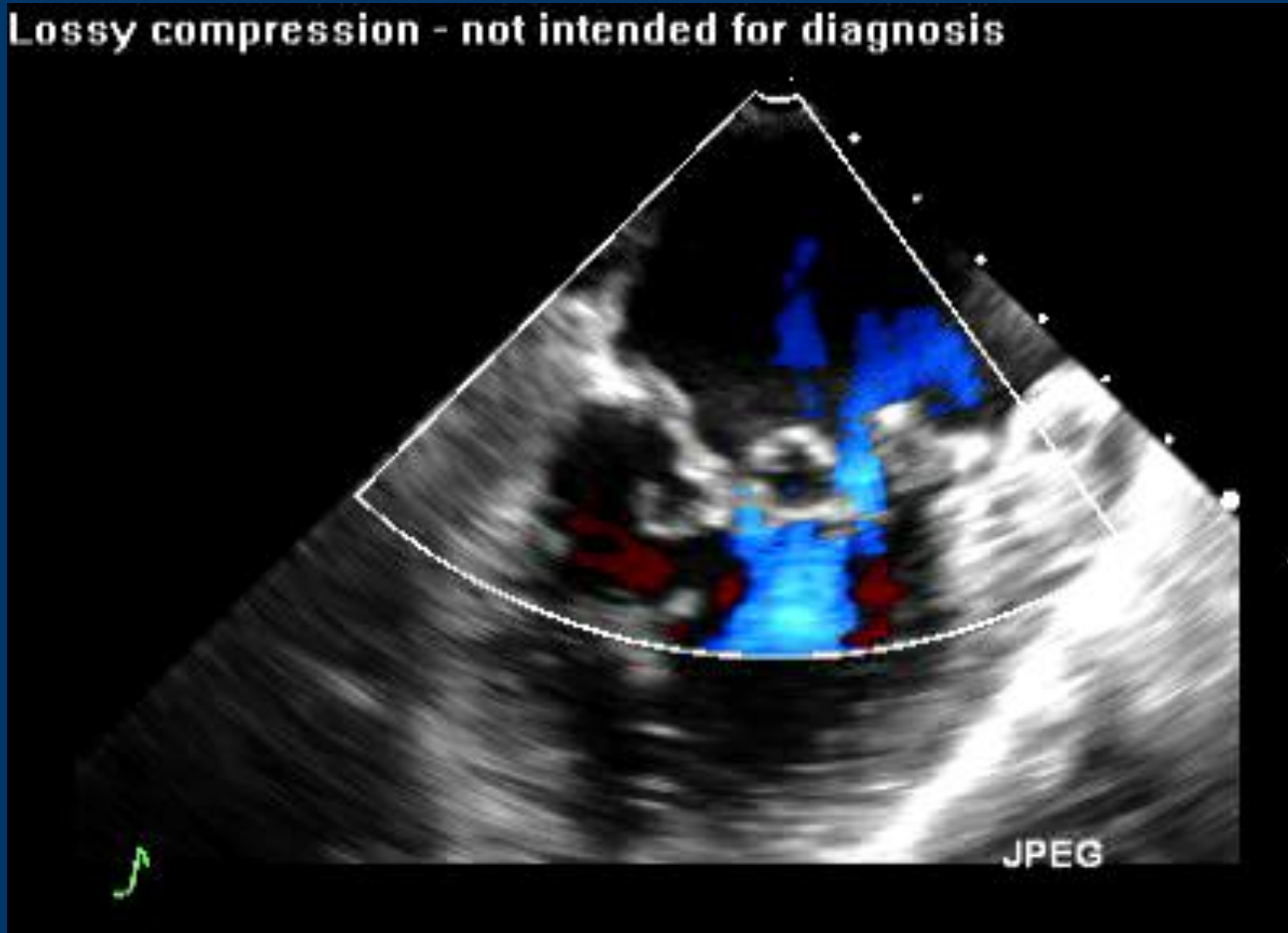
- **Patients with severe MR at high surgical risk could be successfully treated with MitraClip**
 - Procedural mortality rate at 30 days less than predicted for surgery and similar to comparator control group
 - Durable improvements in NYHA functional class, decrease in severity in MR and improvement in LV volumes
- **Limitations**
 - Comparator group recruited retrospectively
 - Limited number of patients
 - Heterogeneous group with regards to determination of “high risk”

Current Status of MitraClip

- October 24, 2013: FDA approved the MitraClip for the following commercial indication:
 - “*The MitraClip is intended to treat patients with significant symptomatic **degenerative mitral regurgitation** with MR \geq 3+ who have too high a risk for surgery*”
- COAPT trial to evaluate the role of MitraClip in treating functional MR is ongoing

Pre-Procedure

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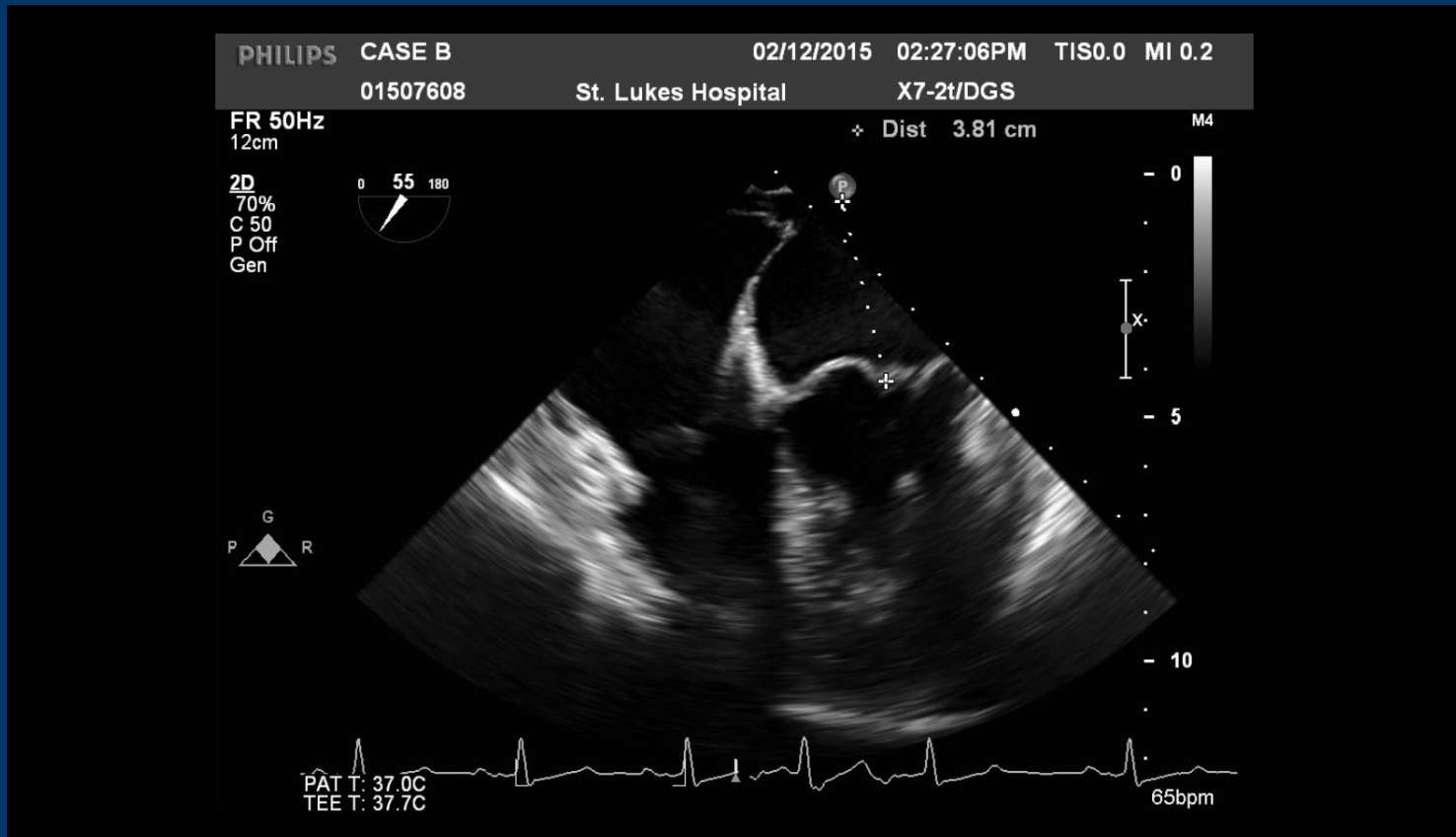


Pre-procedure

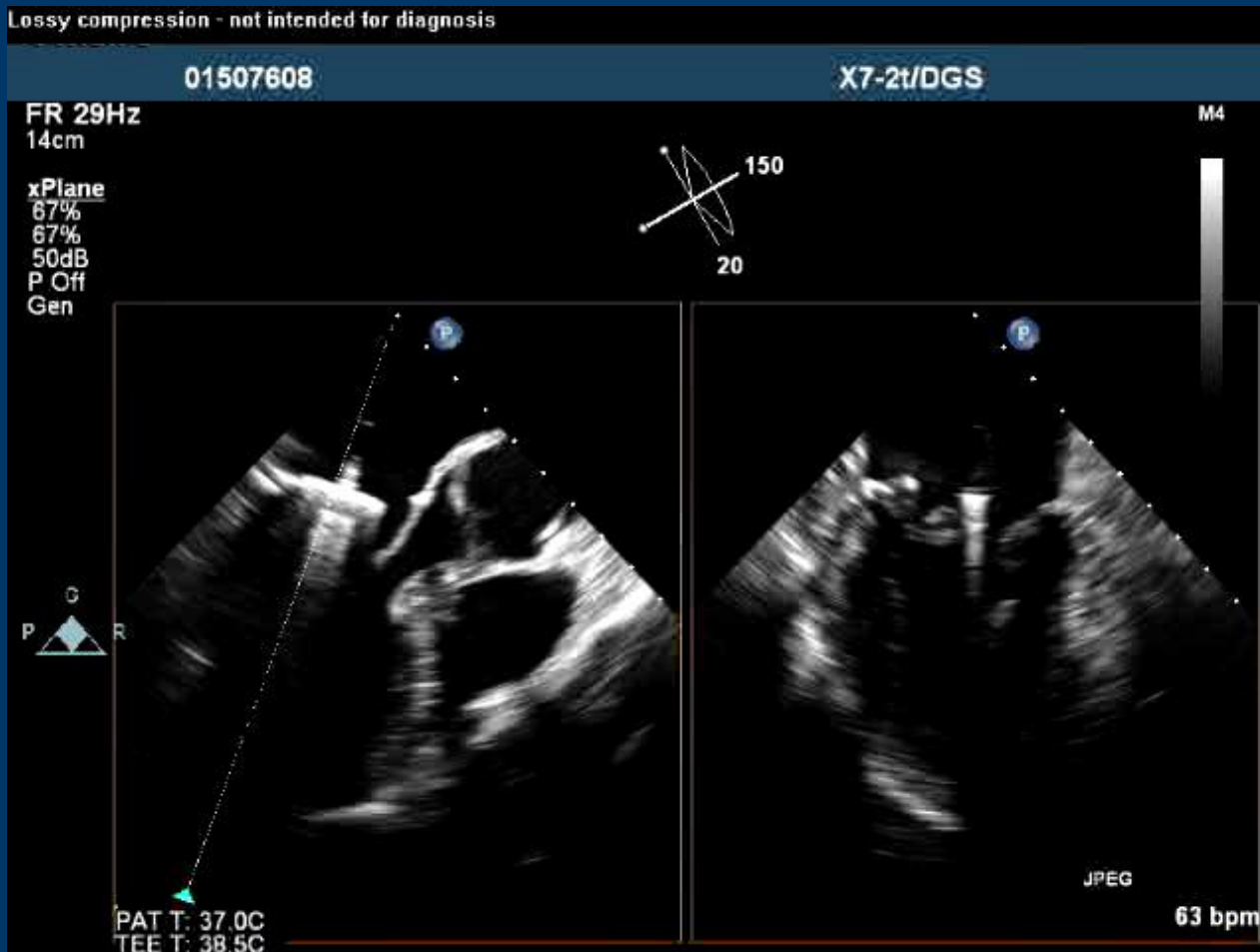
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Crossing the Septum



Clip Alignment



Clip in LV

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Clip in LV

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Failed Grasp

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Successful Grasp

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Successful Grasp

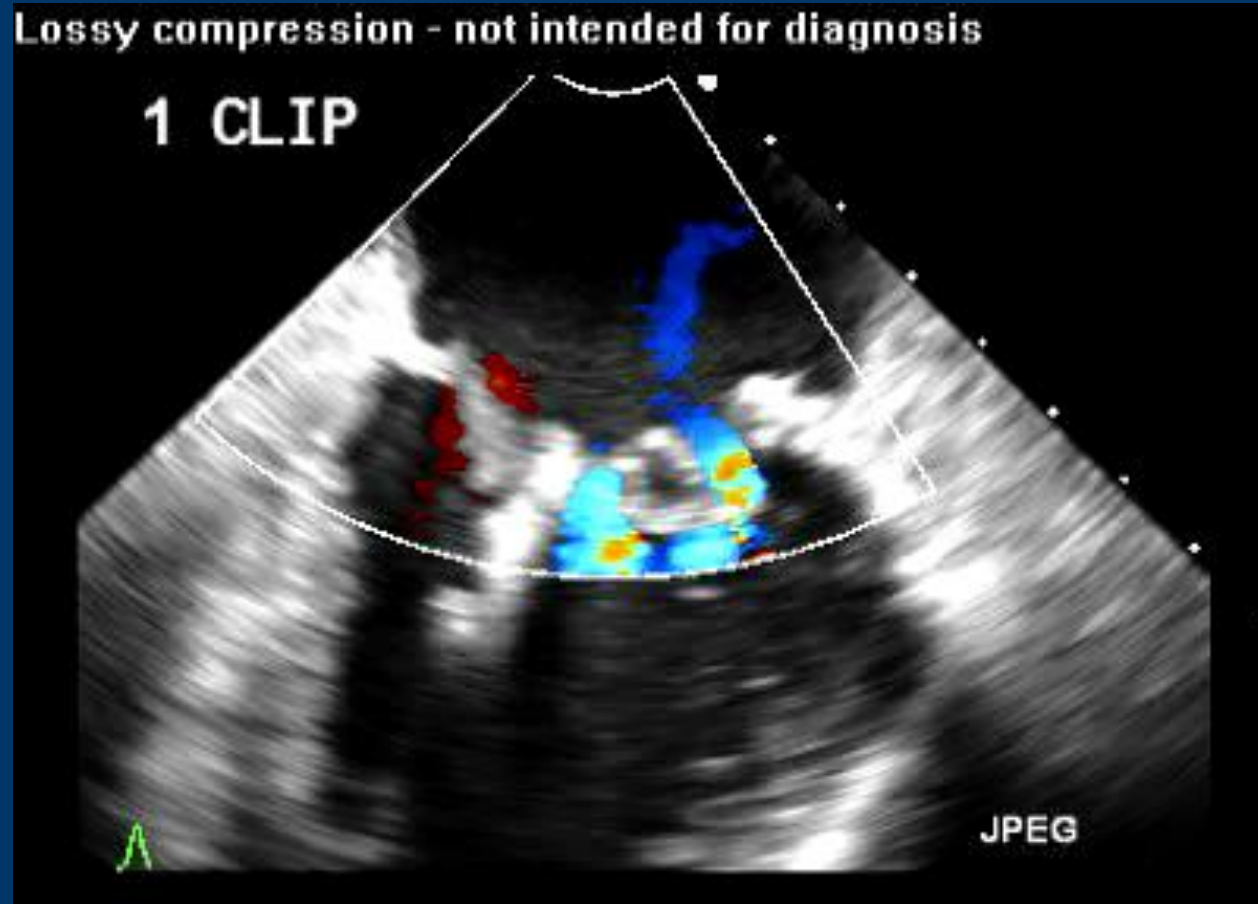
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3D Imaging



Residual MR



Advancing 2nd Clip

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2nd Grasp

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CLIP 2

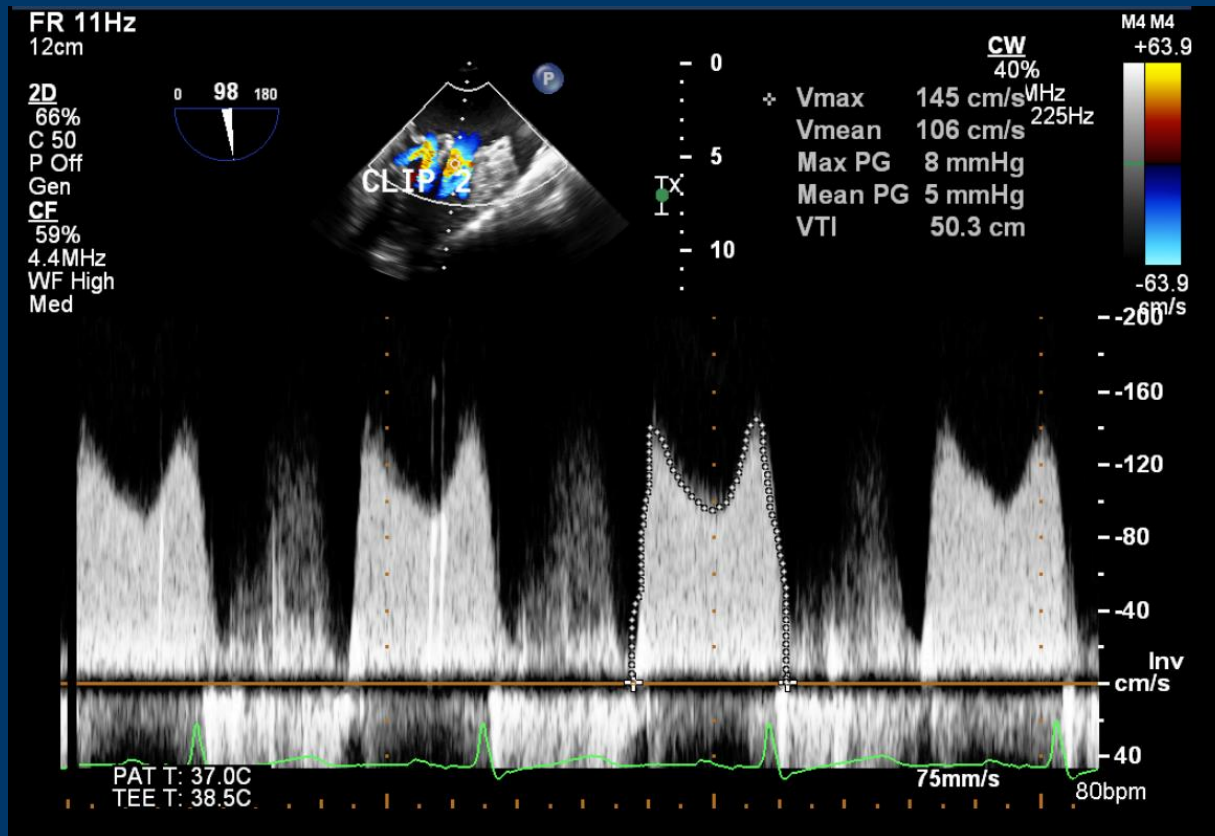


2nd Grasp

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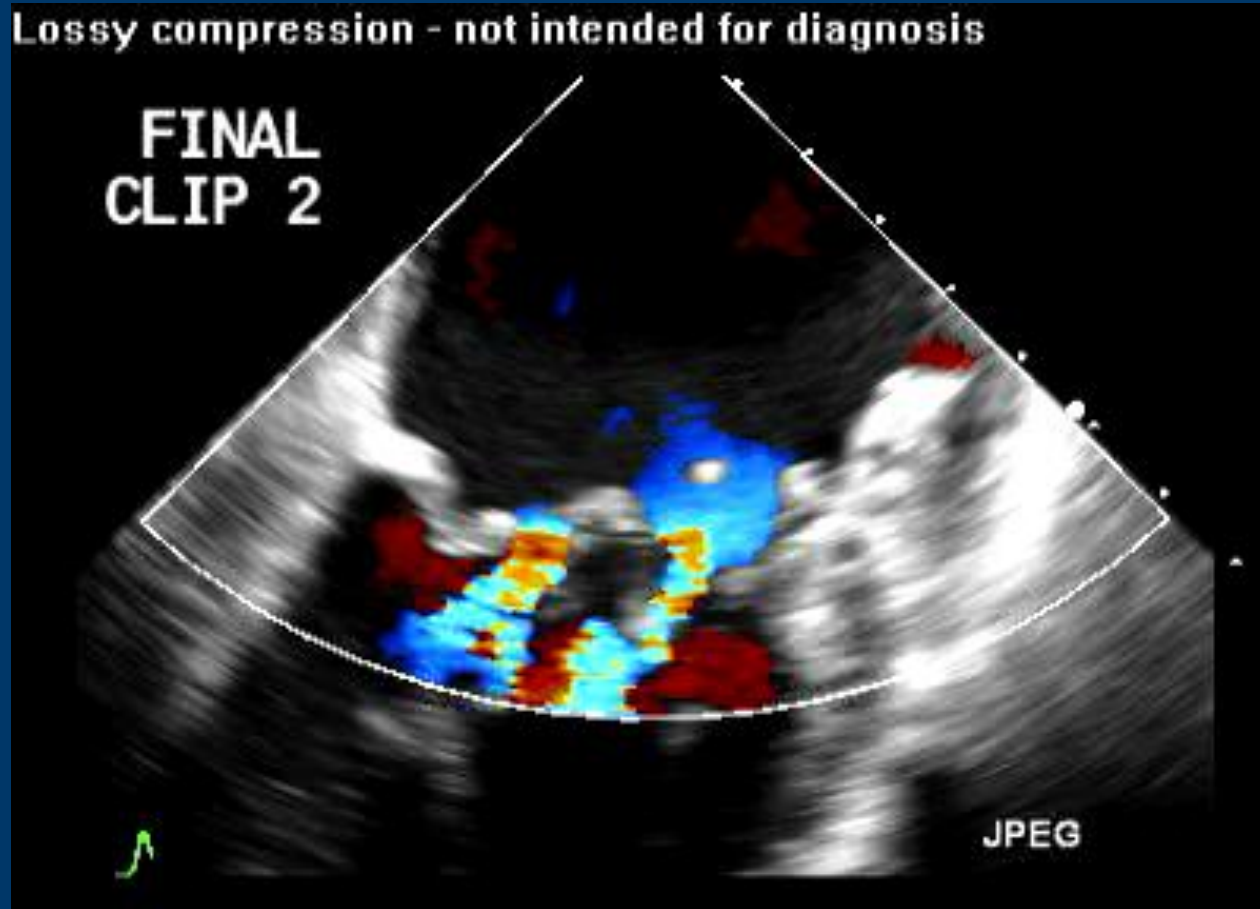
Mitral Valve Gradient



3D imaging – 2 clips



Final Result



Home the next day!



Left Atrial Appendage Closure:
*Prevention of Thromboembolism
in Atrial Fibrillation*

Case Report: Pills or Procedure?

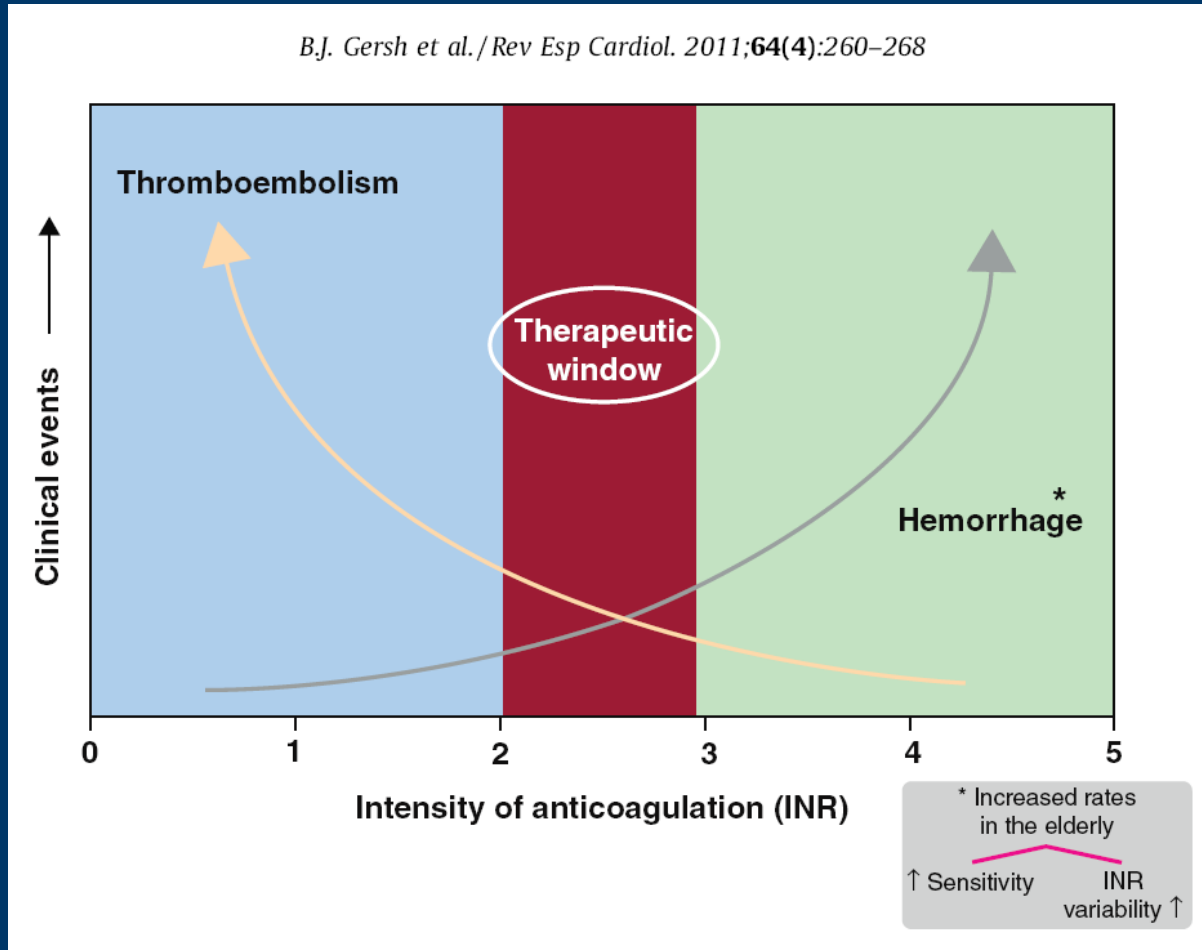
- 80 year old gentleman
- History of CAD, prior MI
- Permanent atrial fibrillation
- High risk for stroke (CHADS 2 score = 3)
- Recurrent bleeding on warfarin
- What are the remaining options?

Atrial Fibrillation and Stroke

- Atrial Fibrillation is one of the MOST common cardiac arrhythmias seen in clinical practice
- Untreated , it is associated with a nearly FIVEFOLD increase in stroke
 - Strokes are often more severe in patients with AF
 - PAF and persistent AF are associated with the same incremental risk of cerebrovascular events

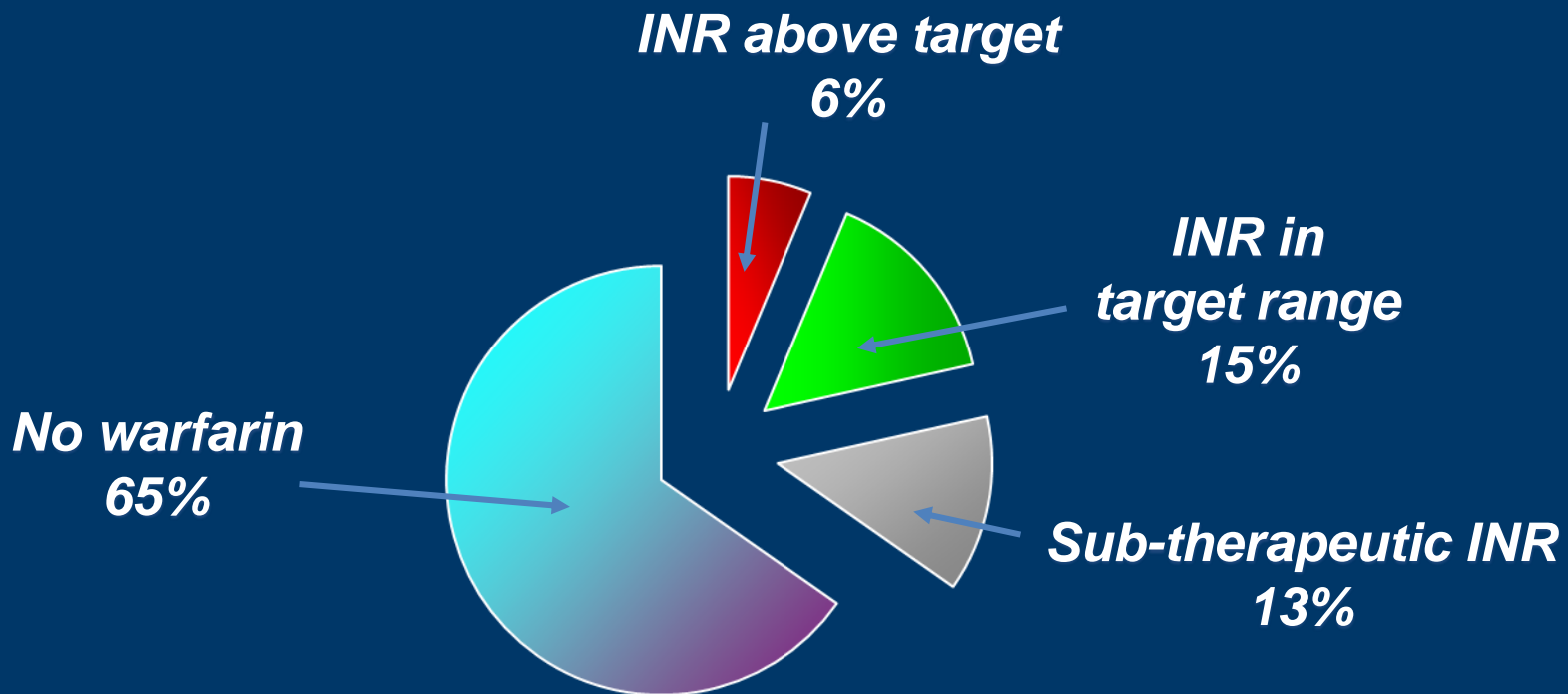
Thromboembolism vs Hemorrhage

B.J. Gersh et al. / Rev Esp Cardiol. 2011;64(4):260-268

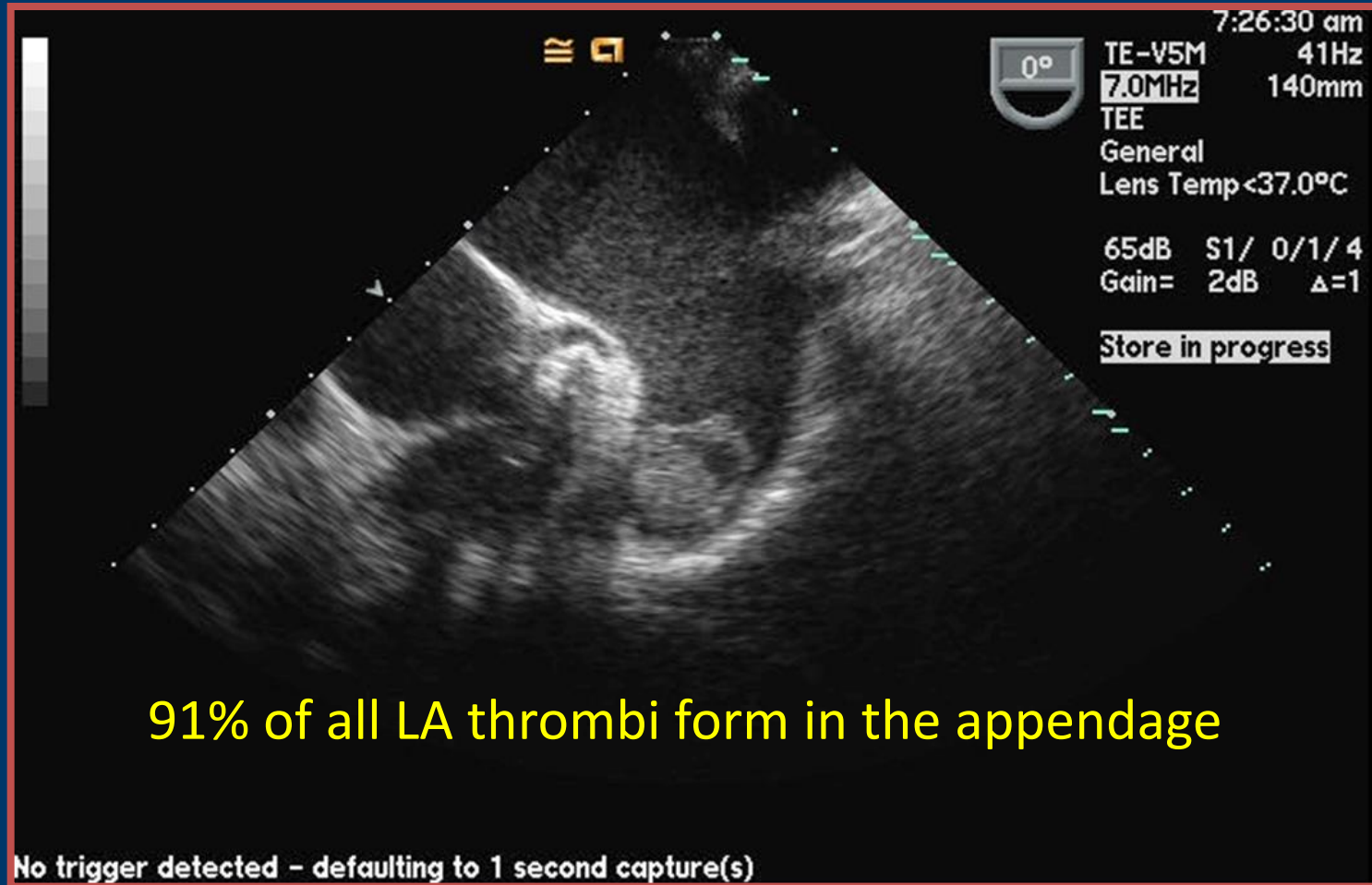


Inadequate VKA Treatment for AF

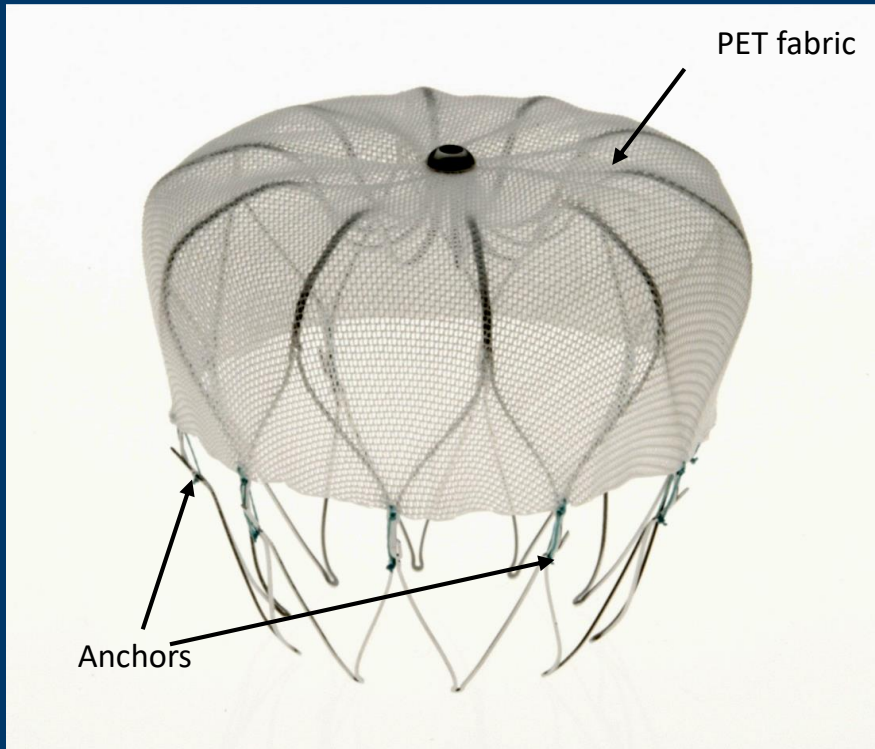
Adequacy of Anticoagulation in Patients with AF in Primary Care Practice



Thrombus in LAA



WATCHMAN® LAA Closure System Implanted Device



Frame: Nitinol structure

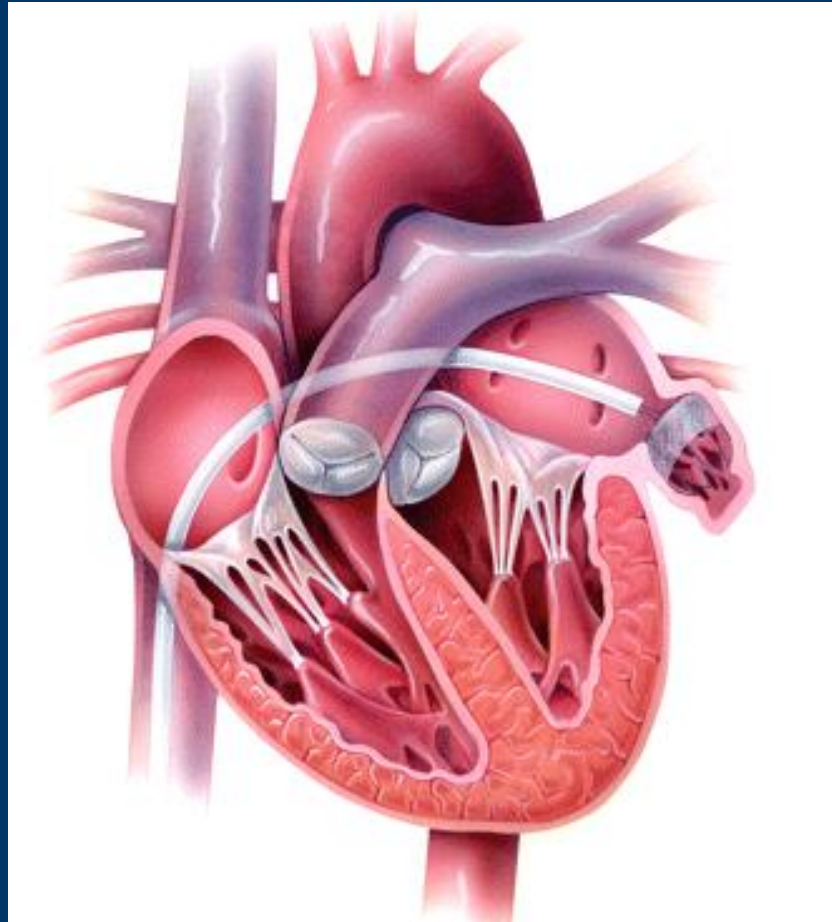
- Available sizes:
 - 21, 24, 27, 30, 33 mm (diameter)
 - 10 Fixation anchors around device perimeter engage LAA tissue
 - Contour shape accommodates most LAA anatomy

Fabric Cap: (PET) Fabric Polyethyl terephthalate

- Designed to prevent harmful emboli from exiting during the healing process
- 160 micron filter

WATCHMAN[®] LAA Closure System

WATCHMAN Access System



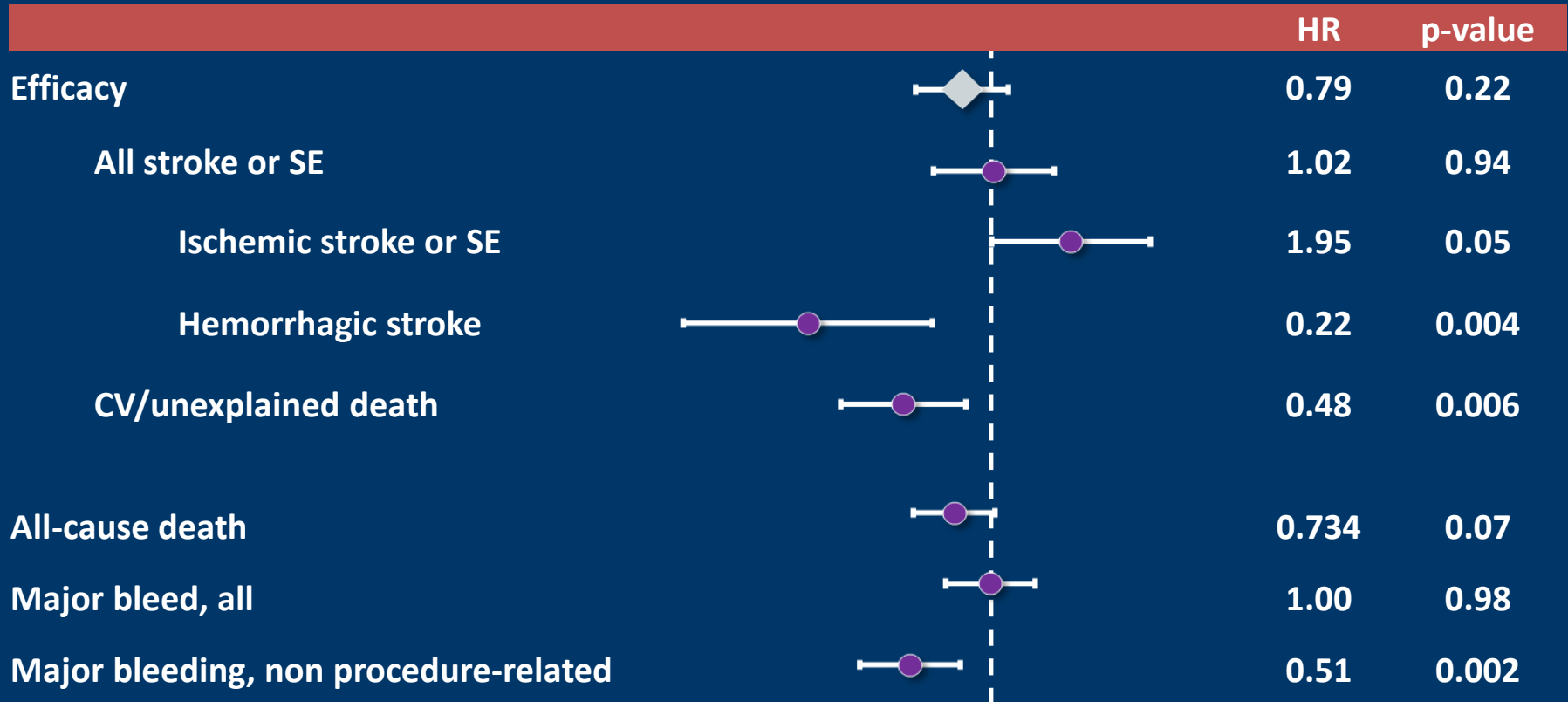
Saint Luke's

MID AMERICA HEART INSTITUTE

PROTECT AF Clinical Trial

- Prospective, randomized study of WATCHMAN[®] LAA Device vs. Long-term warfarin Therapy
- 2:1 allocation ratio device to control
- 800 patients enrolled from February 2005 to June 2008
 - 93 roll-in; 707 randomized
- 59 enrolling centers (U.S. & Europe)
- WATCHMAN non-inferior to warfarin for stroke protection and mortality

PROTECT/PREVAIL Meta-analysis



Procedural Outcomes

TABLE 7 Comparison of Outcomes in Device Patients in PROTECT AF, CAP, and PREVAIL

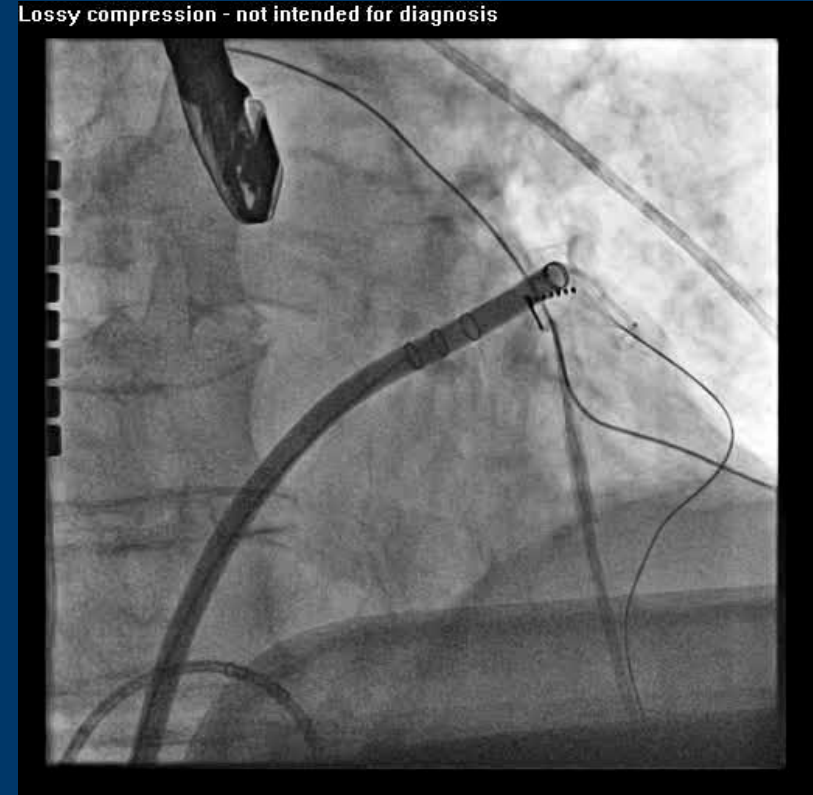
	PROTECT AF	CAP	PREVAIL	p Value
Implant success	90.9	94.3	95.1	0.04
All 7-day procedural complications	8.7	4.2	4.5	0.004
Pericardial effusion requiring surgery	1.6	0.2	0.4	0.03
Pericardial effusion with pericardiocentesis	2.4	1.2	1.5	0.318
Procedure-related strokes	1.1	0.0	0.7	0.02
Device embolization	0.4	0.2	0.7	0.368

Abbreviations as in [Tables 3](#) and [6](#).

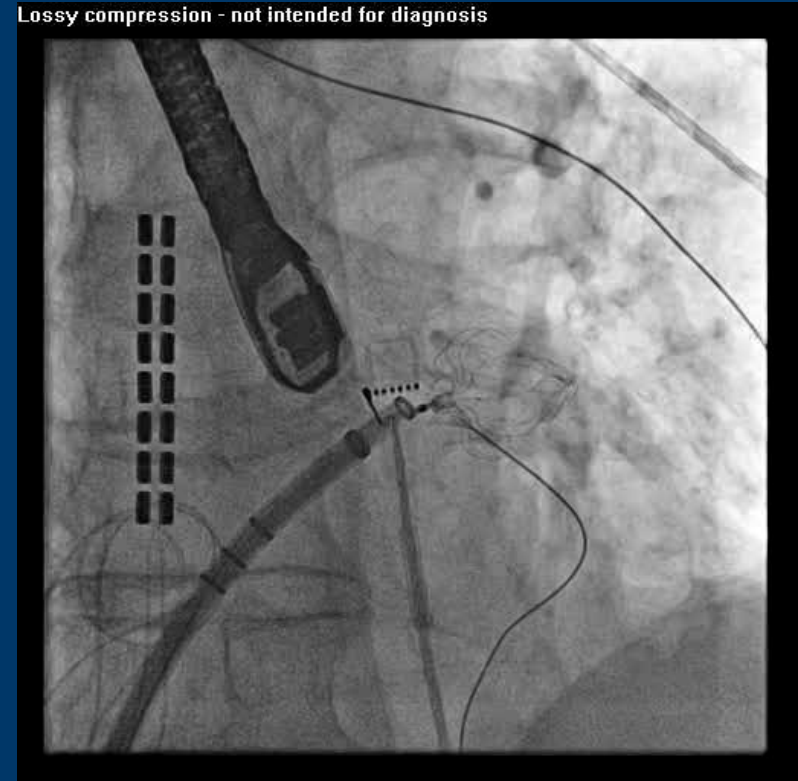
WATCHMAN Approval

- FDA approval received in March 2015
- Indicated for patients:
 - With non-valvular AF
 - Who are at increased stroke risk
 - Who are recommended for anticoagulation
 - Who are suitable for warfarin
 - Who have an appropriate reason to seek a non-drug alternative to anticoagulation

Left Atrial Appendage



WATCHMAN Deployment



LAA Closure: Summary

- The WATCHMAN[®] Device is an alternative to oral anticoagulation in patients with atrial fibrillation
- WATCHMAN appears to be equivalent to warfarin, with a trend toward improved outcomes
- Saint-Luke's MAHI was the highest enrolling site for PROTECT-AF study, and is a teaching site
- New LAA closure devices are under investigation

Paravalvular Leak Closure:

Avoiding repeat open-heart surgery

Case Presentation

- 70 y/o male with prior mechanical MVR, severe paravalvular MR, acute CHF, on inotropic support
- PMH: CAD, CABG, ICM, melanoma, cirrhosis, COPD
- Not a surgical or LVAD candidate
- Recurrent heart failure admissions

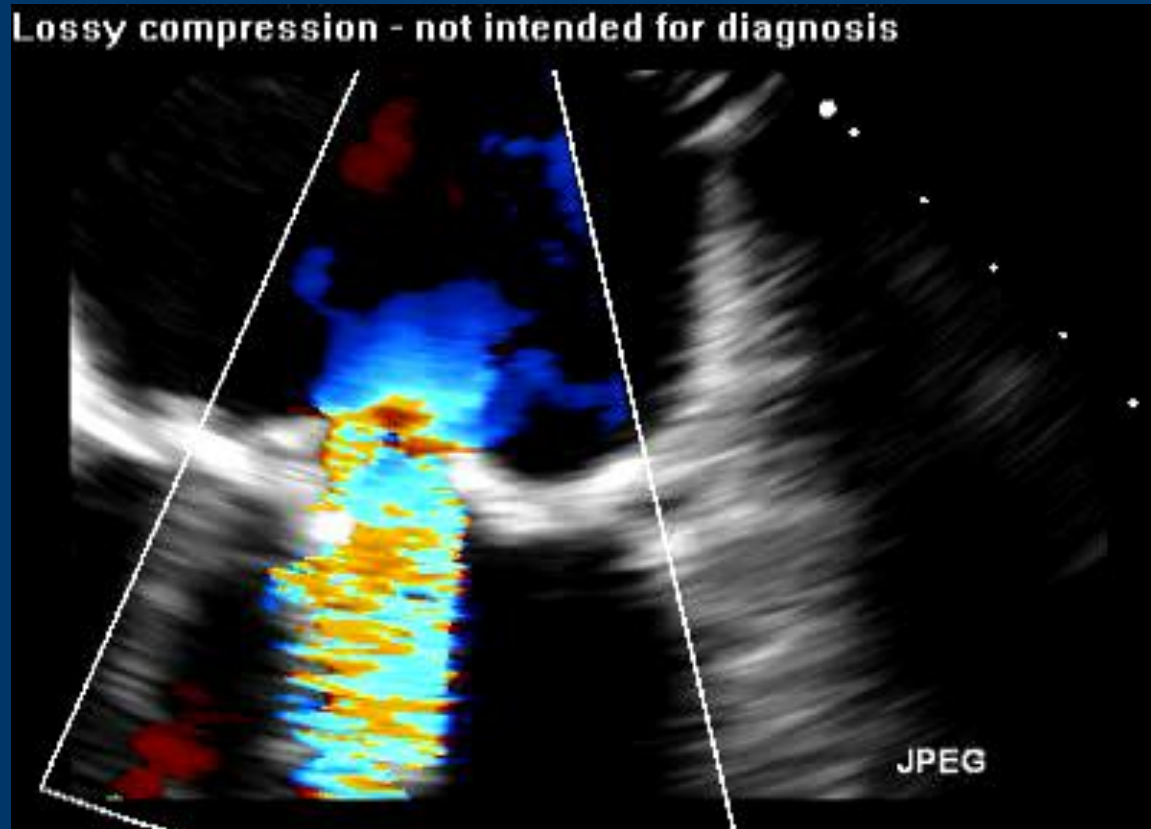
Paravalvular Leak

- Affects up to 27% of surgical prosthetic valves
 - 90% are mild leaks
 - More common with MVR
- 30-50% following 1st generation TAVR valves
 - Up to ½ of these are moderate or severe
 - Much lower rates with current devices
- Can be symptomatic or asymptomatic
 - CHF
 - hemolysis

Surgery for PVL

- Surgery can be high-risk
 - Operative mortality 6.6% on average
 - >50% risk for major complications
 - Residual or recurrent PVL in 20% of patients
- Transcatheter PVL closure first reported in 1992

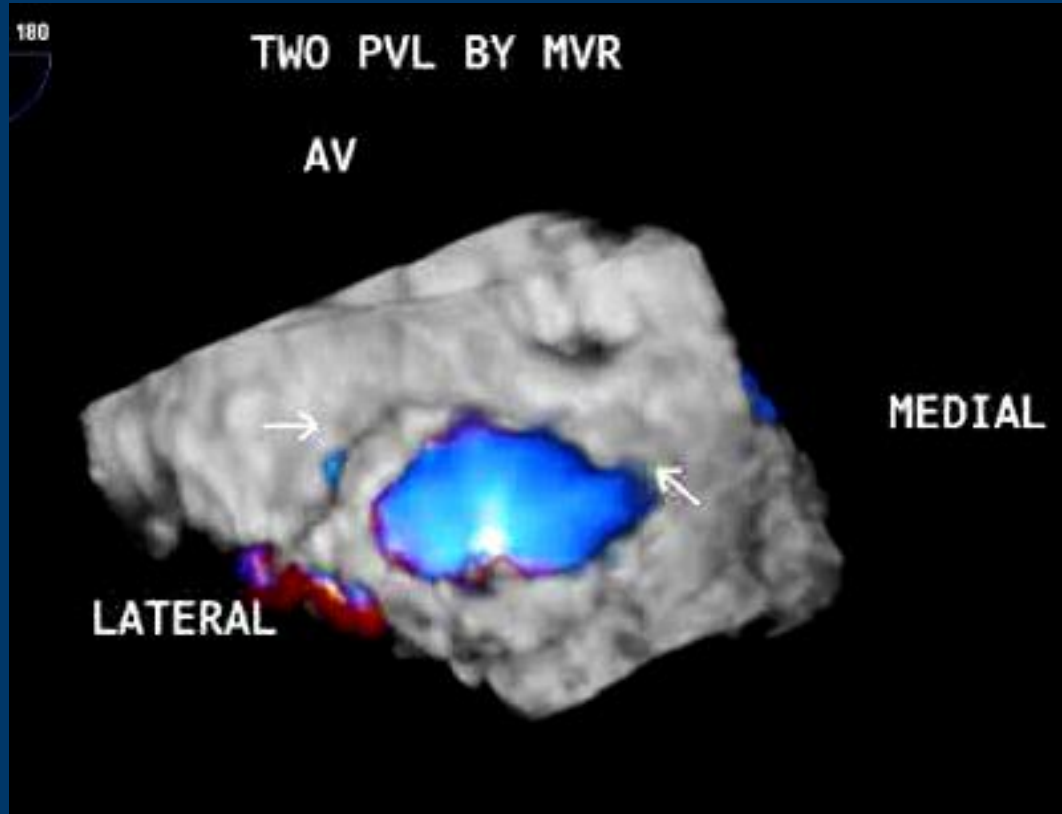
Severe MR – 2 jets



3D TEE



3D TEE



Crossing PVL



Transeptal Puncture

Agilis Sheath

Telescoping multipurpose guides

Stiff Angled Glide Wire

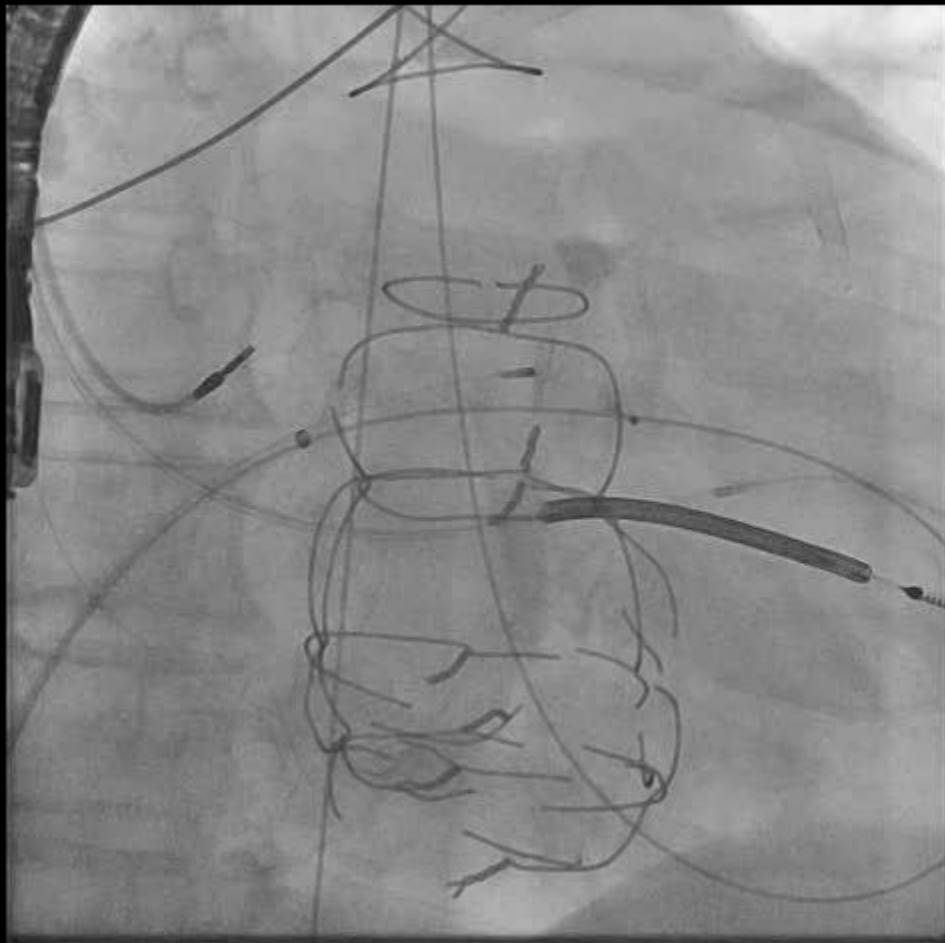
Wire across PVL



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Amplatzer Plugs



AVP 2

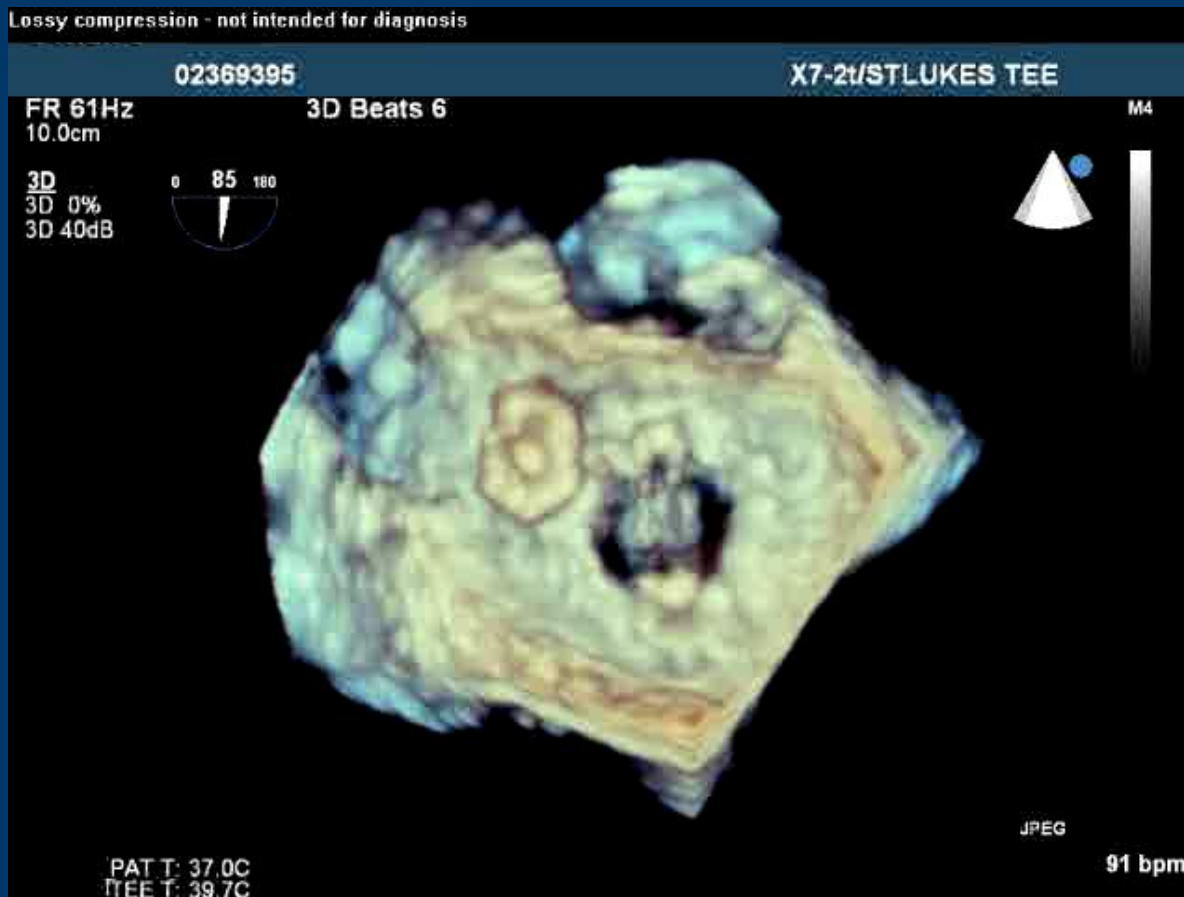


AVP 3

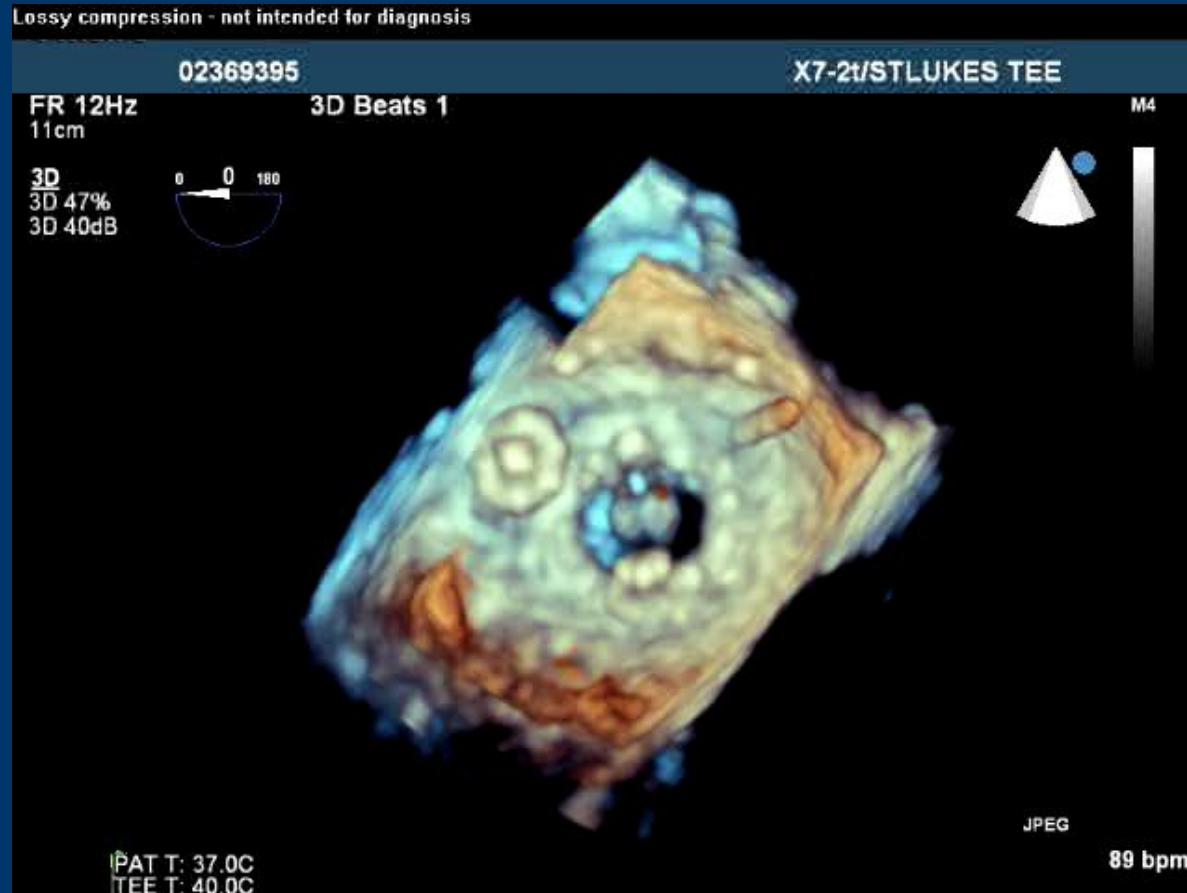


AVP 4

1st Plug Deployed



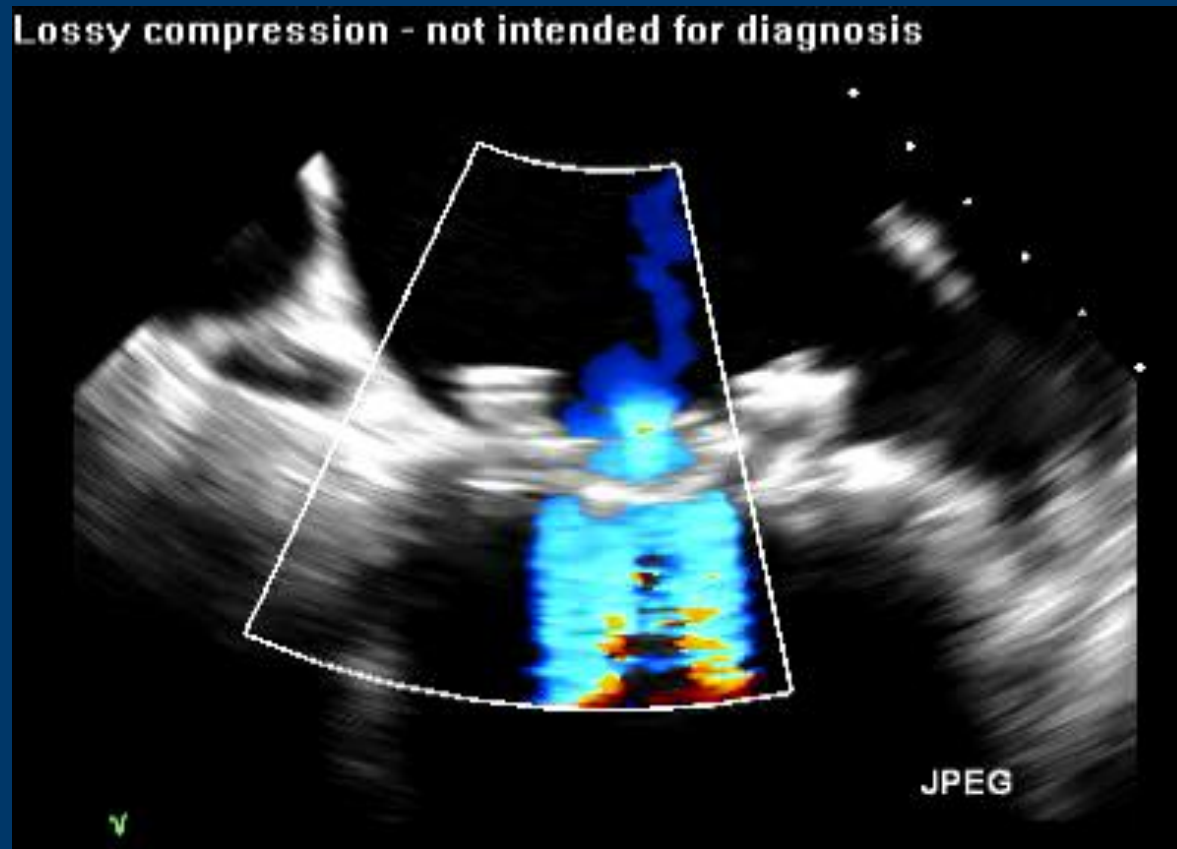
2nd Leak Wired



Final Result

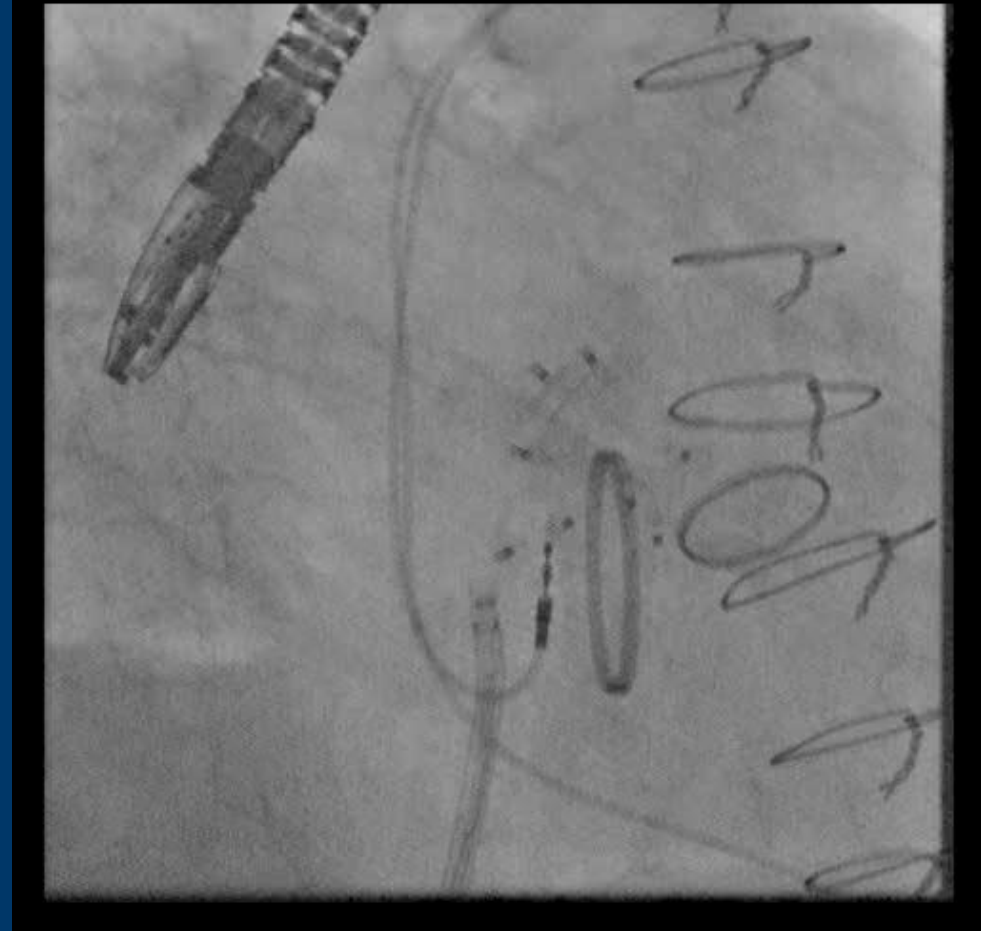


Final Result



Uh oh

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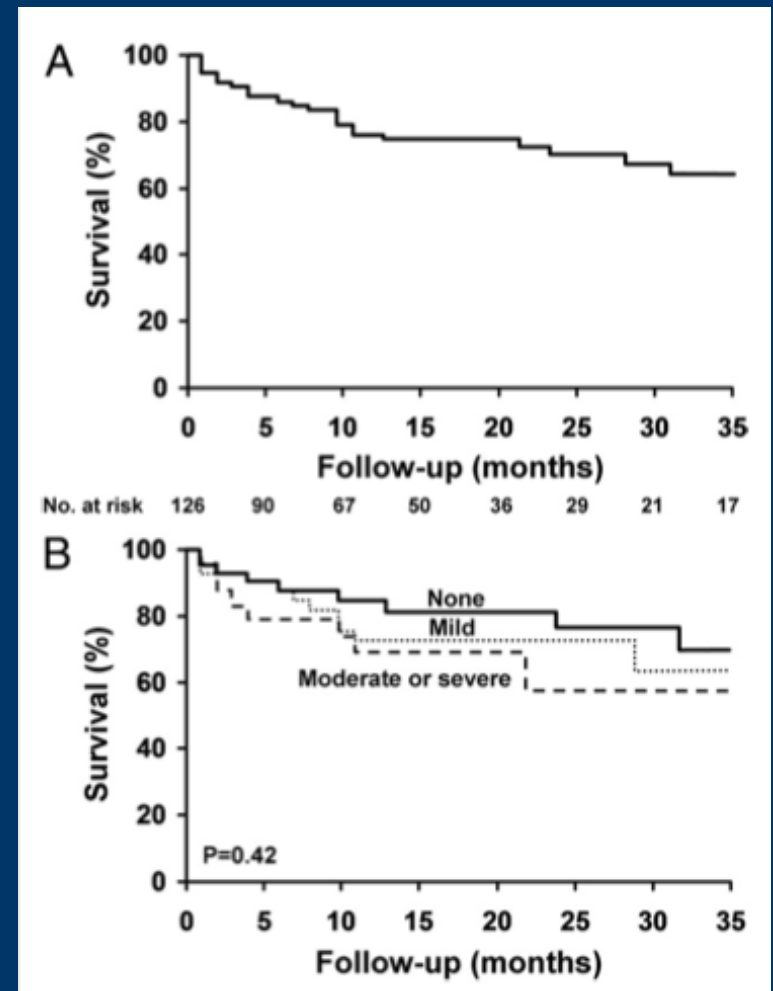


PVL Closure: Complications

- Valve Obstruction
- Device embolization
- Stroke
- Other procedural complications
 - Bleeding
 - Infection
 - Pericardial effusion

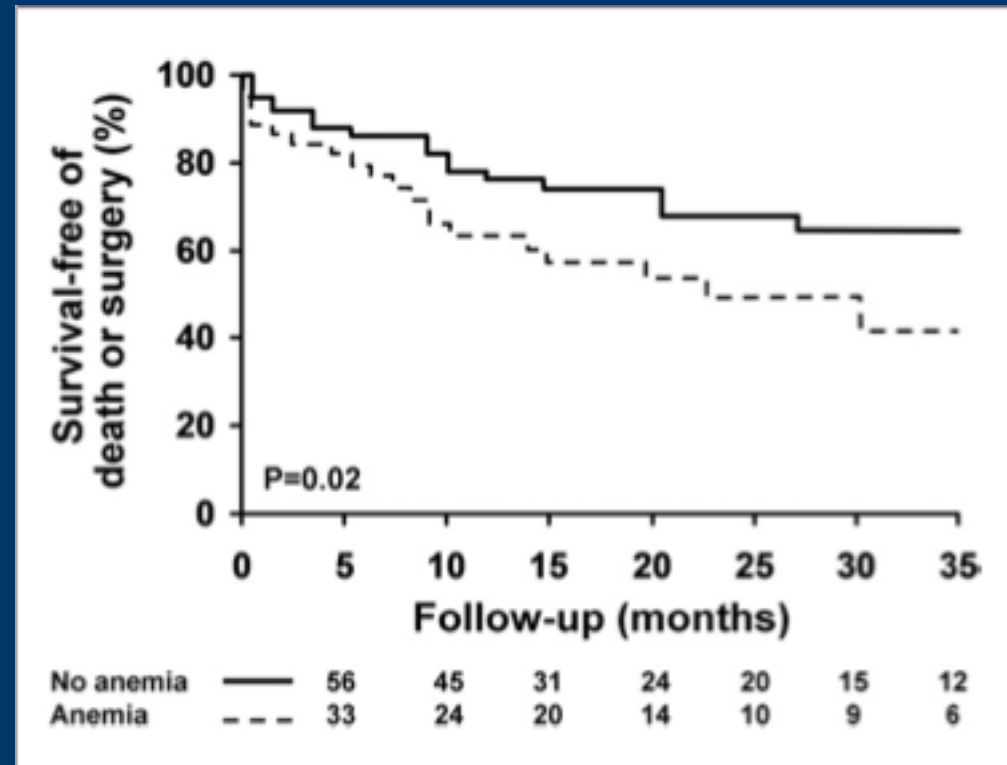
Long-Term Follow-Up of Percutaneous Repair of Paravalvular Prosthetic Regurgitation

- Severity of residual leak did not predict survival
- Freedom from death/surgery
 - No leak - 63.3%,
 - Mild leak - 58.3%
 - Moderate/severe leak - 30.3%



Long-Term Follow-Up of Percutaneous Repair of Paravalvular Prosthetic Regurgitation

- The presence of hemolytic anemia was related to poorer survival and increased need for cardiac surgery before and after multivariate adjustment.

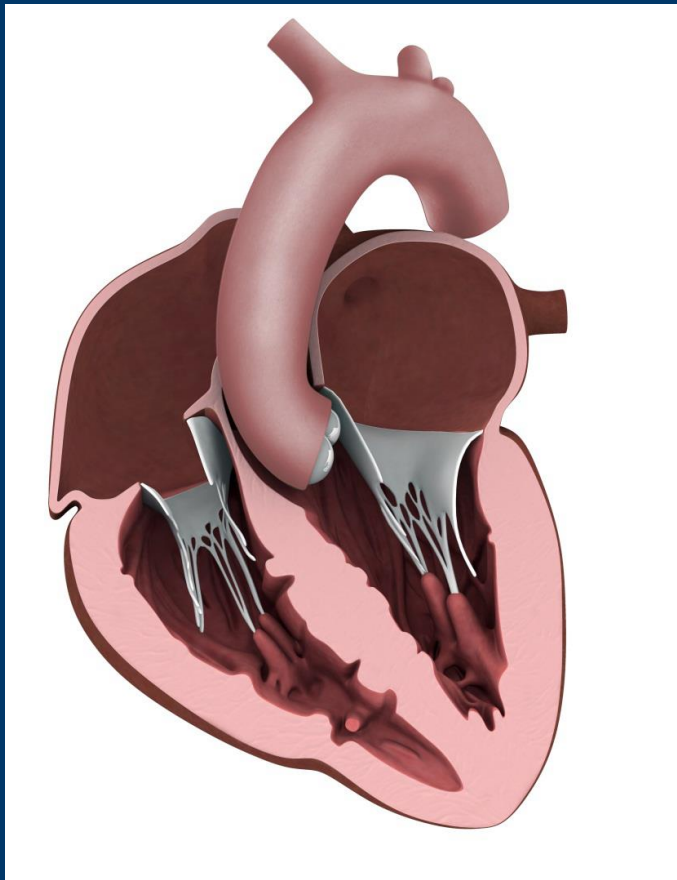


Parachute Implant: *Ventricular Reshaping in Heart Failure*

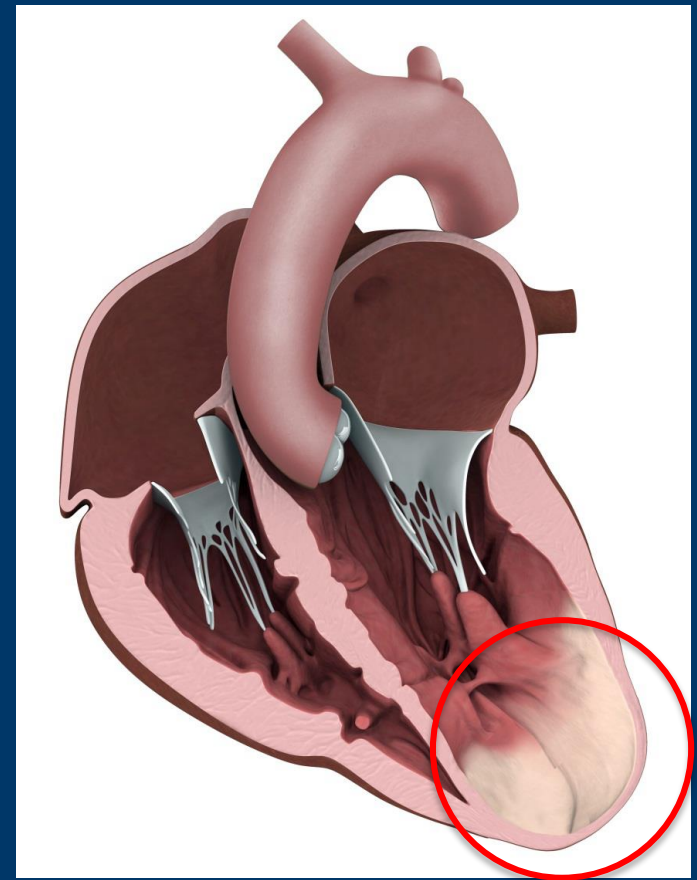
Case Report

- 68 y/o male with myocardial infarction in 1975
- Congestive heart failure
 - LVEF 25%
 - Anterior and apical akinesis
 - short of breath with mild exertion (NYHA III)

Anterior Myocardial Infarction



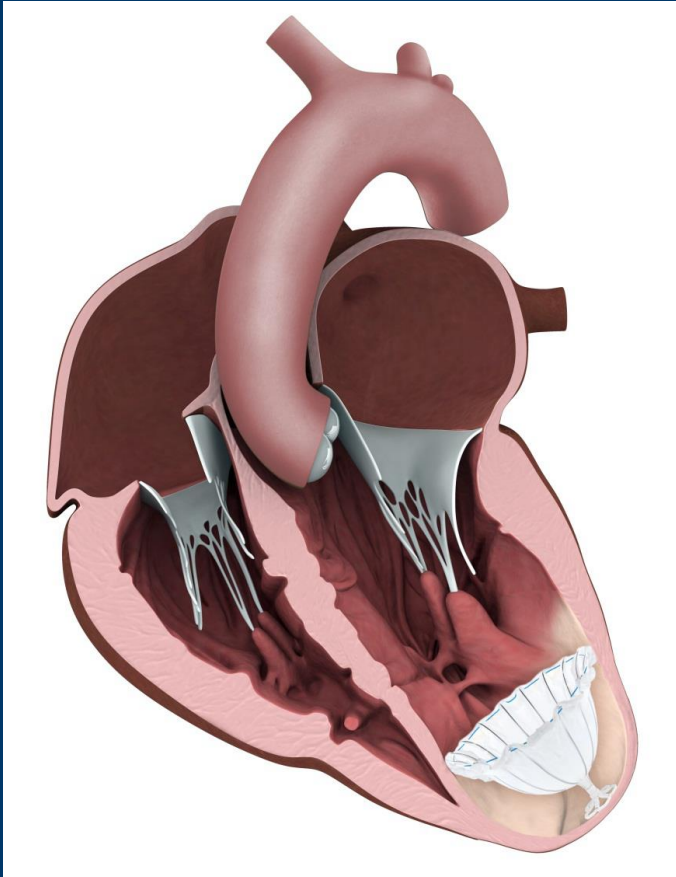
- Scarring
- Ventricular Remodeling
- Wall motion abnormality



Parachute Device

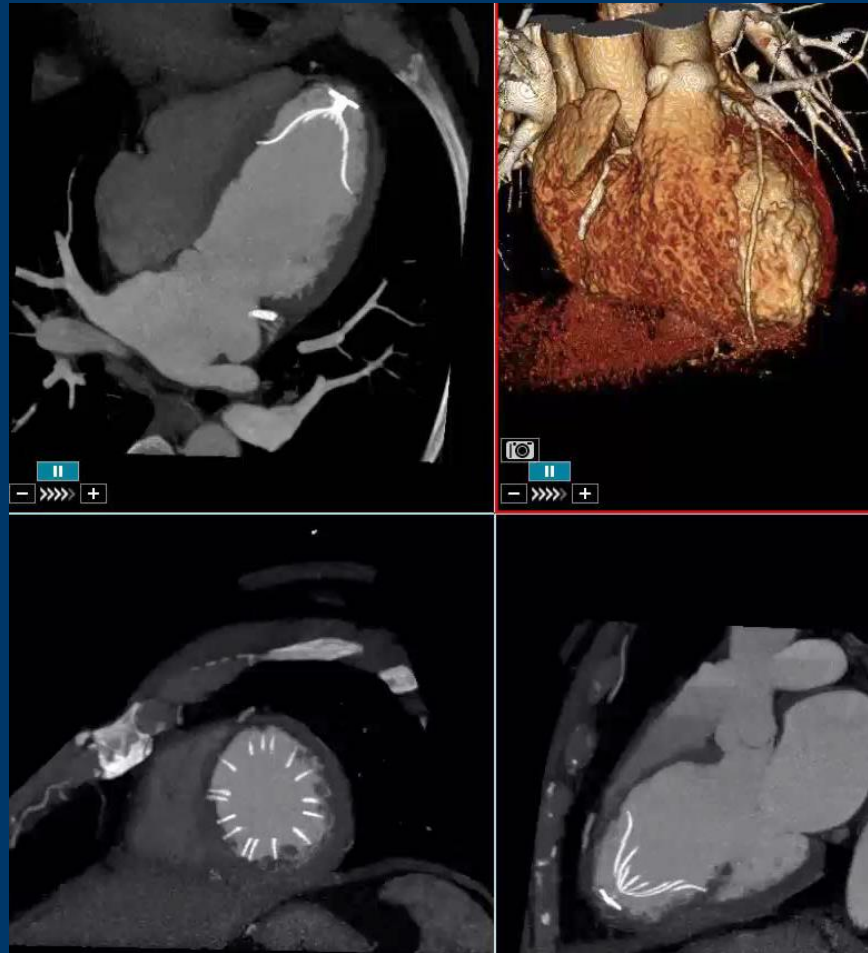


Mechanism of Action

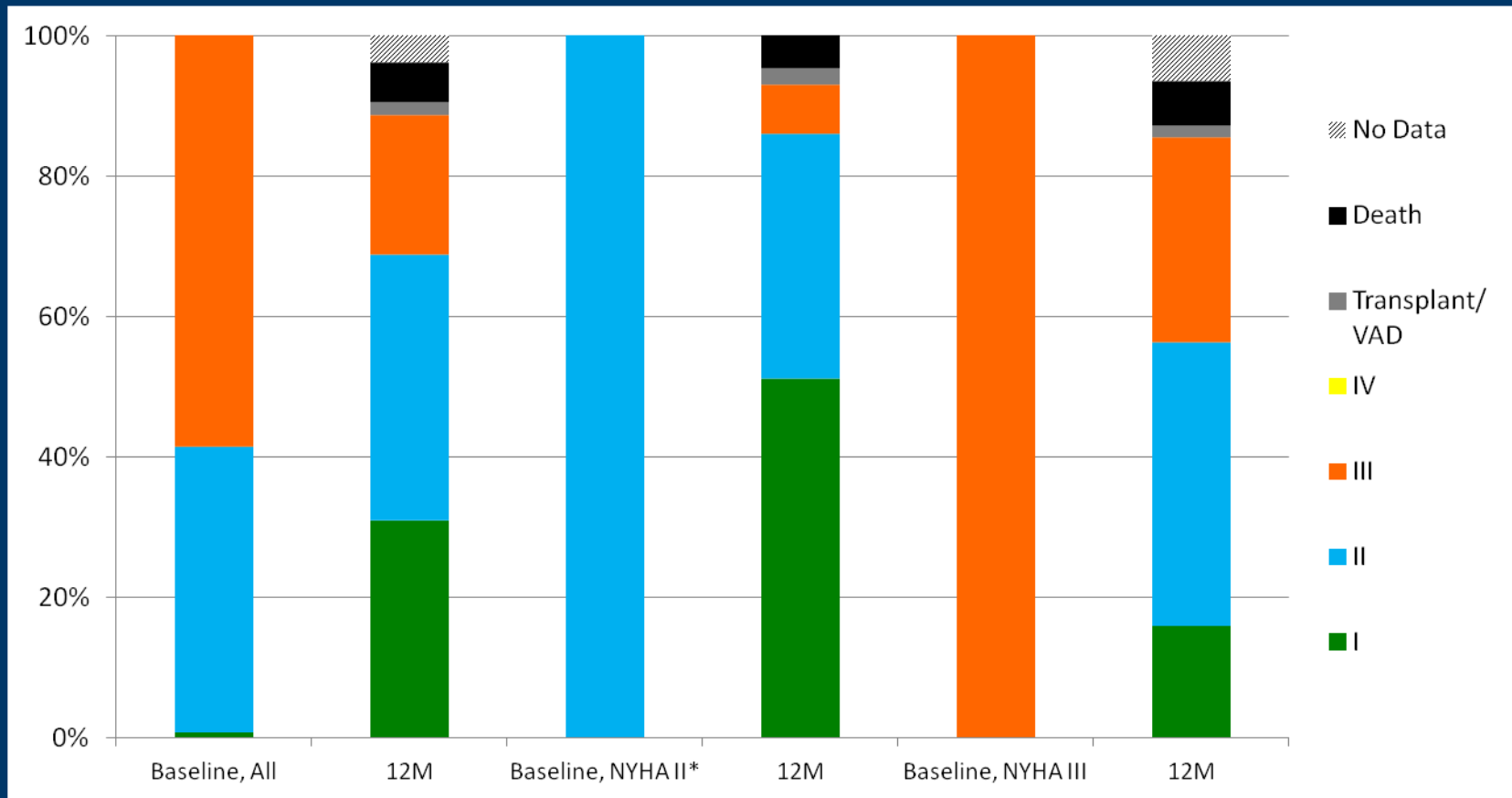


- Reduced LV volume
- Reduced wall stress
- Preserved LV geometry
- Improved LV compliance
- Better LV apical ejection

Parachute Implant



NYHA Classification

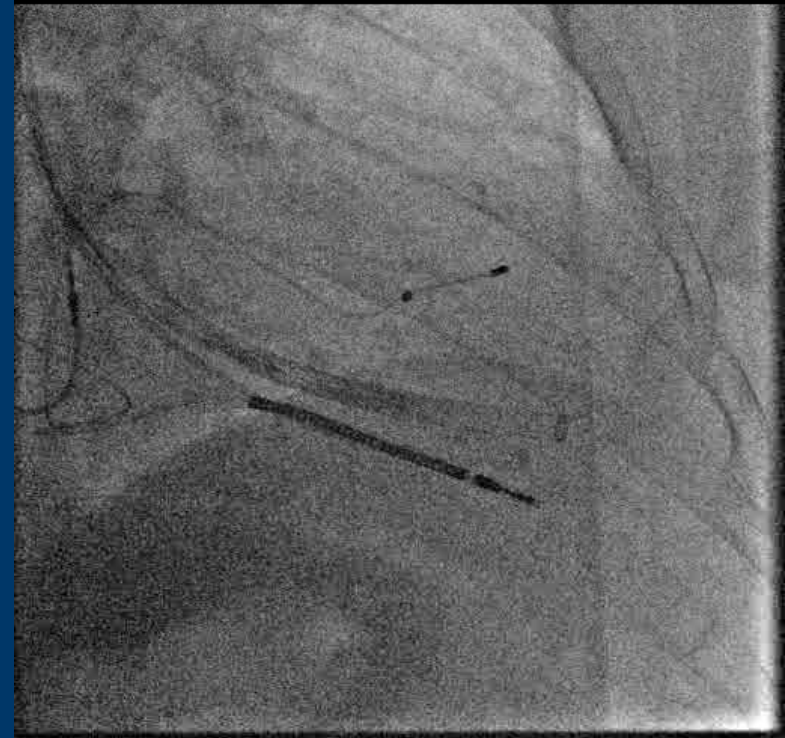


Parachute Implant

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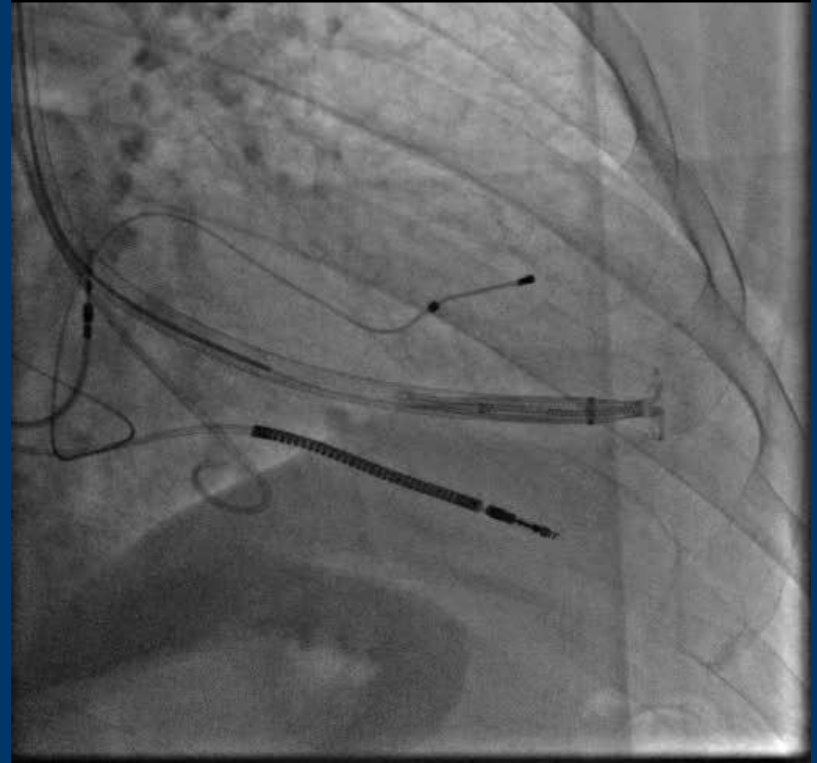


Parachute Implant

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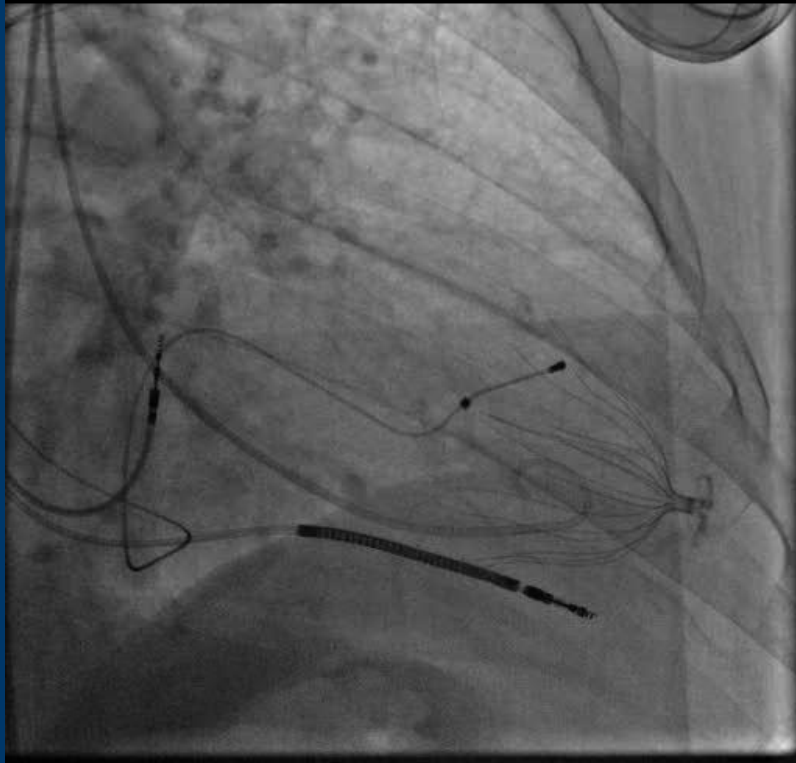


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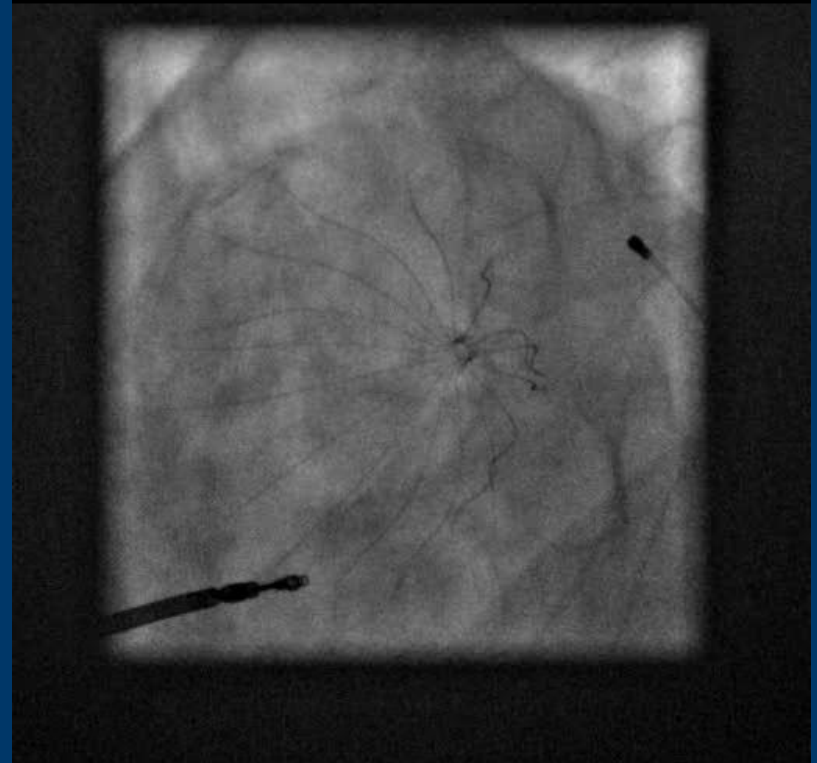


Parachute Implant

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Lossy compression - not intended for diagnosis



Parachute: Conclusions

- 96% procedural success rate
- Improvements in mortality and repeat hospitalization compared to historical data
- Functional improvements seen in non-randomized studies
- First randomized trial is ongoing

Thank You

