

How to minimize and deal with Post TAVR complications?

Raj R. Makkar, MD

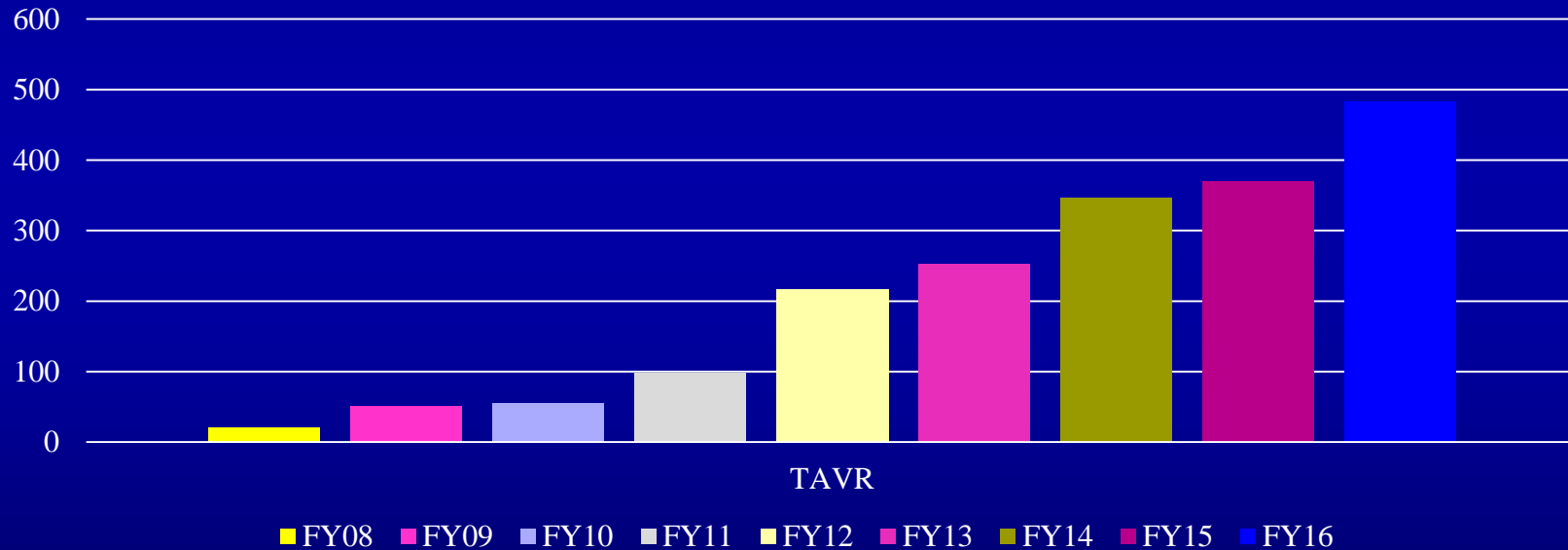
Cedars-Sinai Heart Institute, Los Angeles....

Cedars Sinai TAVR Program

533 TAVRs in Calender Year 2016

309 TAVRs in 2017 (thru July 11)

Volume by Fiscal Year



Key TAVR complications

- Paravalvular AI
- Aortic Root Injury
- Left Main Occlusion
- Pericardial Tamponade
- Vascular Injury
- Stroke
- Myocardial Stunning and Hemodynamic Collapse
- Conduction System disorder and heart block
- Valve Thrombosis
- Endocarditis

Incidence, Predictors, and Outcomes of Aortic Regurgitation After Transcatheter Aortic Valve Replacement

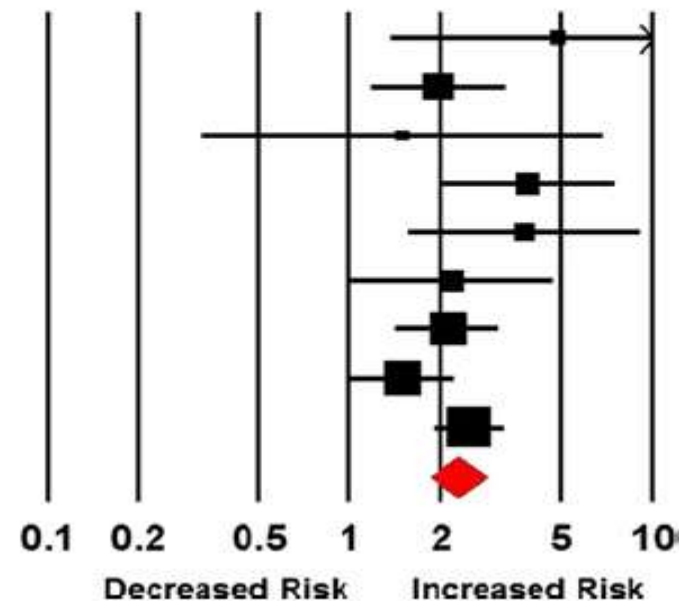
Meta-Analysis and Systematic Review of Literature

Meta-analysis of 45 studies, 12,926 patients

Moderate/severe AR post TAVR is associated with increased 1-year mortality

Study name	Statistics for each study				
	Hazard ratio	Lower limit	Upper limit	Z-Value	p-Value
Lemos*	4.900	1.367	17.570	2.439	0.015
Hayashida	1.970	1.187	3.271	2.621	0.009
Amabile	1.500	0.329	6.829	0.524	0.600
Sinning	3.890	2.020	7.491	4.063	0.000
Tamburino	3.785	1.572	9.112	2.969	0.003
Fraccaro	2.190	1.023	4.686	2.020	0.043
Kodali	2.110	1.433	3.107	3.783	0.000
Moat	1.490	1.002	2.215	1.971	0.049
Gilard	2.490	1.909	3.248	6.728	0.000

Hazard ratio and 95% CI



HR 2.27 (95% CI 1.84-2.80)

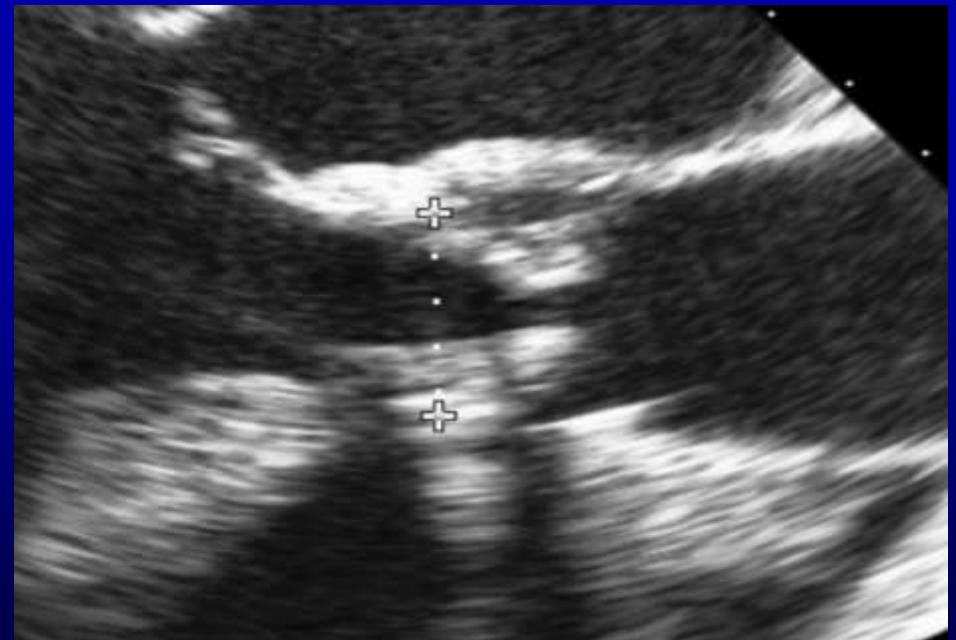
TAVI annulus sizing in 2011

Intraprocedural TEE



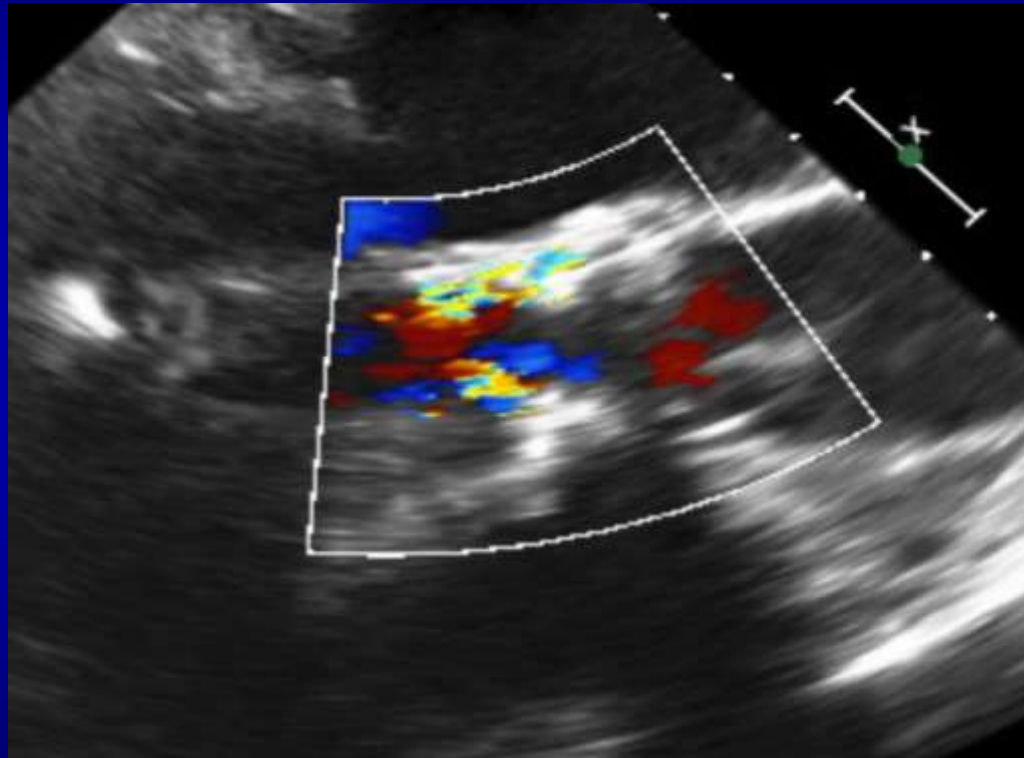
Hinge-point-hinge-point
18.5 mm

20.7 mm



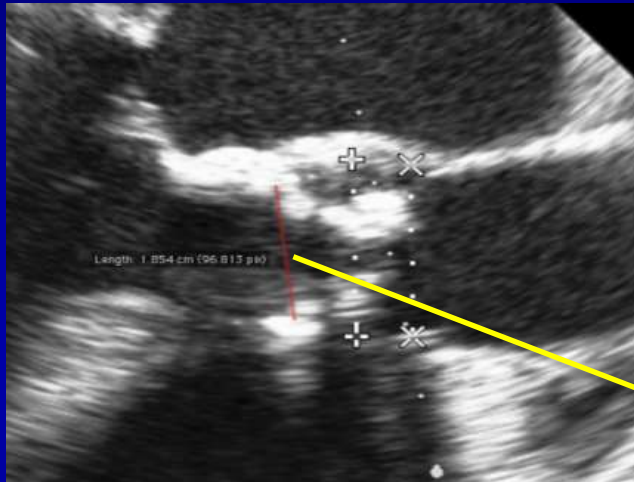
23 mm Sapien

Moderate PV AI

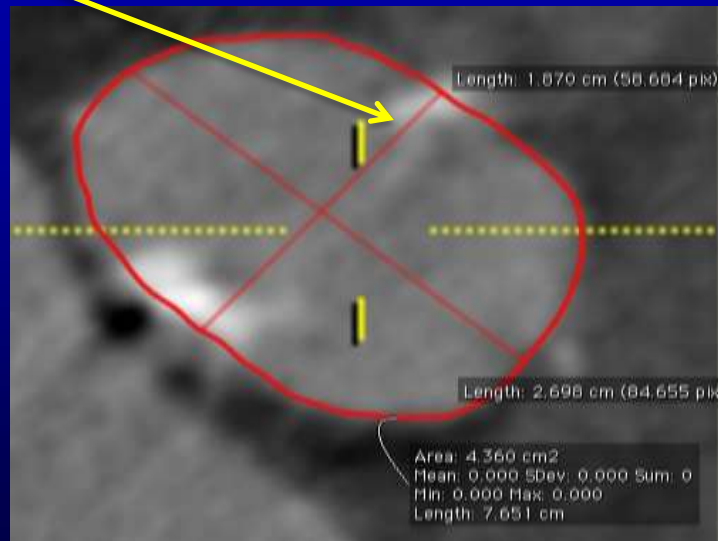


TAVI annulus sizing in 2011

Retrospective analysis of baseline CT



Hinge-point-hinge-point
18.5 mm



D_{\max} =27.0 mm

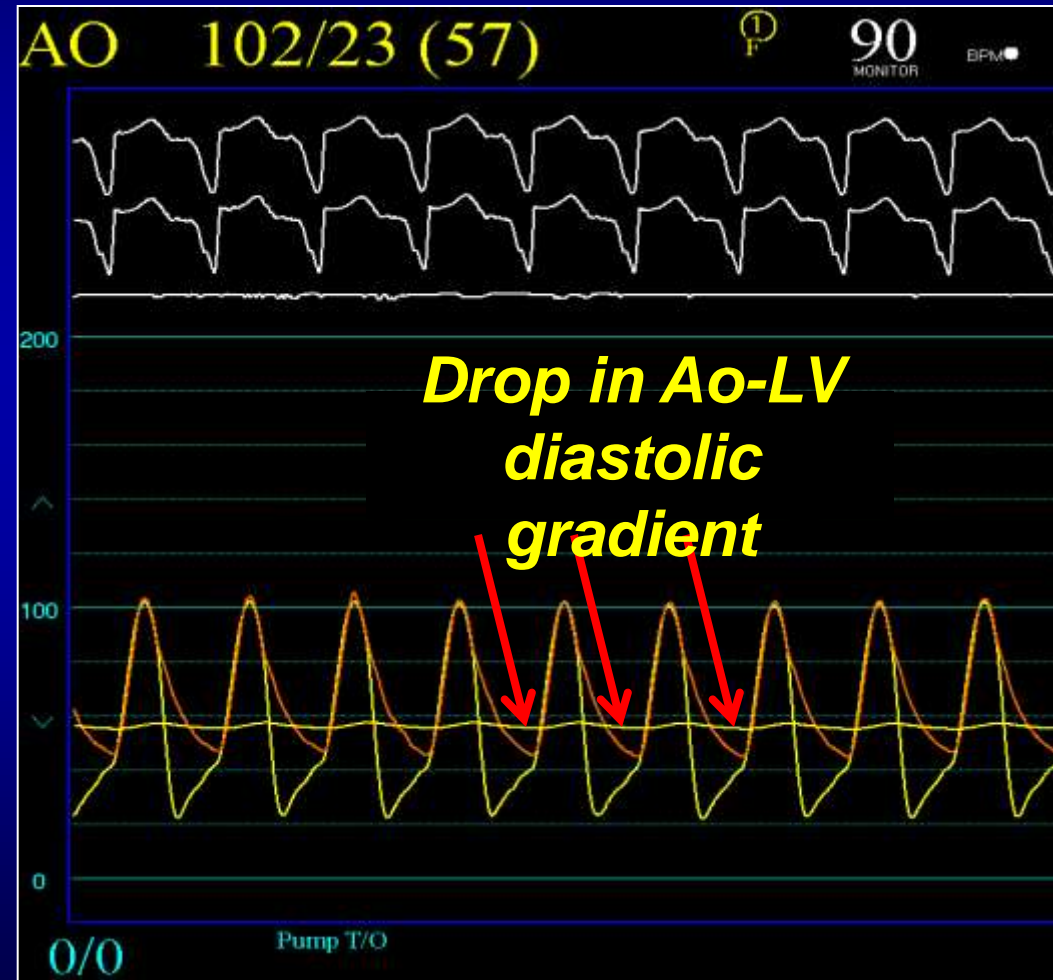
D_{\min} =18.7 mm

D_{mean} =22.9 mm

D_{circ} =24.3 mm

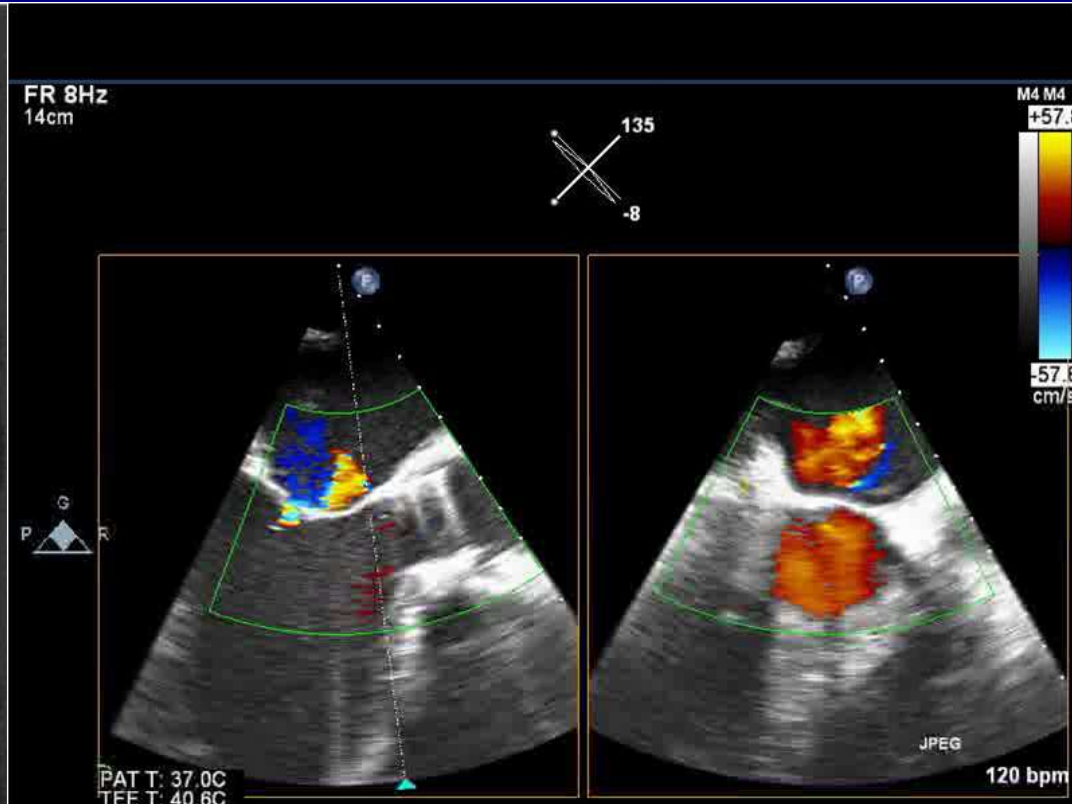
D_{CSA} =23.6 mm

Significant paravalvular AI post valve deployment



Final Result after post-dilatation

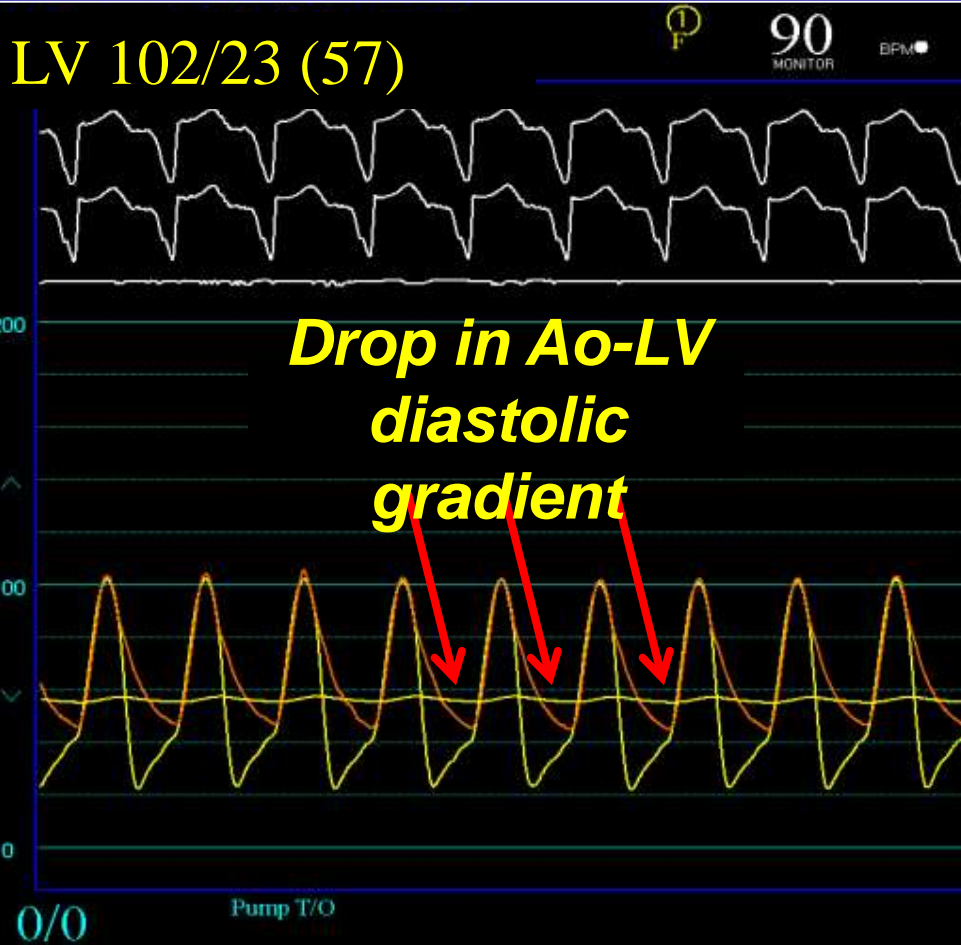
Mild paravalvular AI



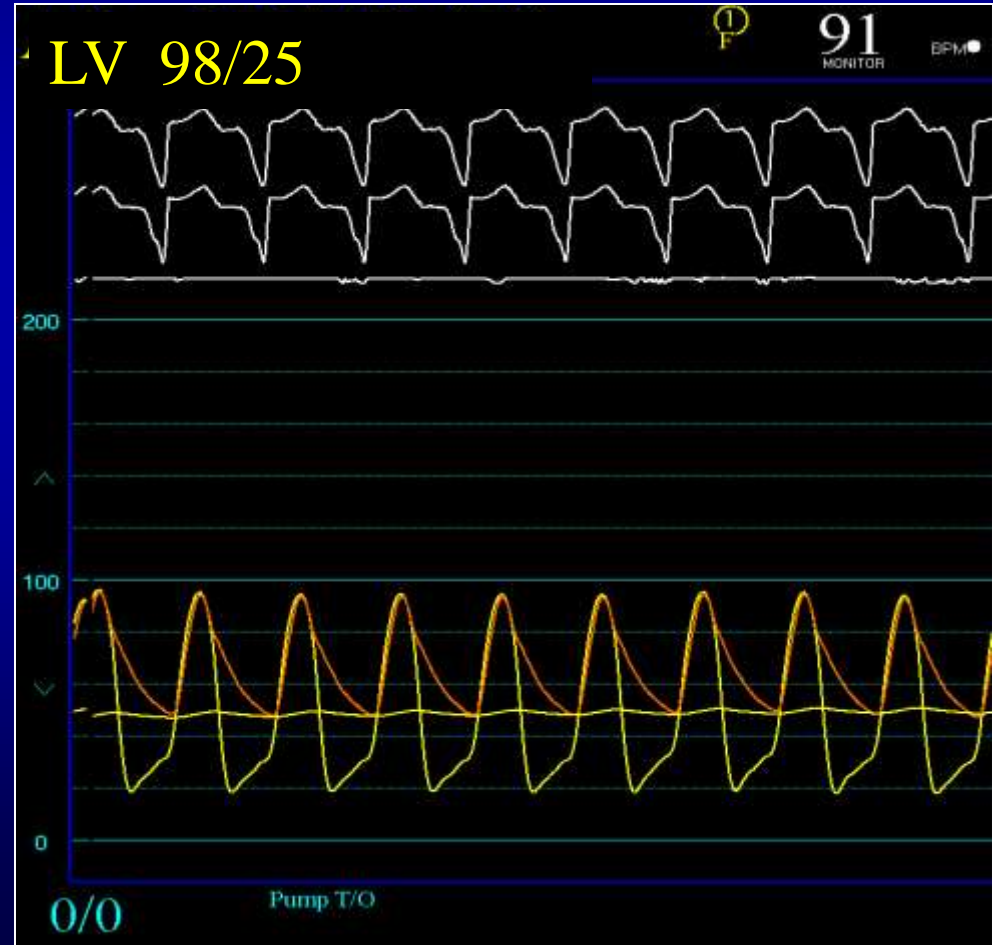
Final Hemodynamics after post-dilatation

Restoration of Ao-LV diastolic gradient and improvement in LV diastolic pressure

Severe AI after Valve deployment



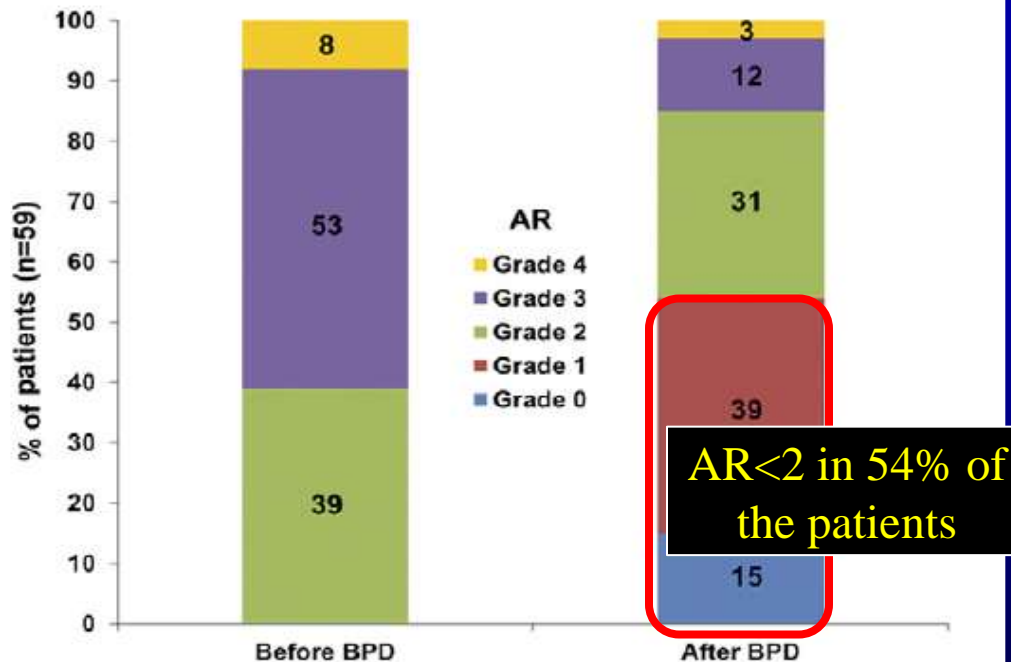
Resolution of AI after post-dilatation



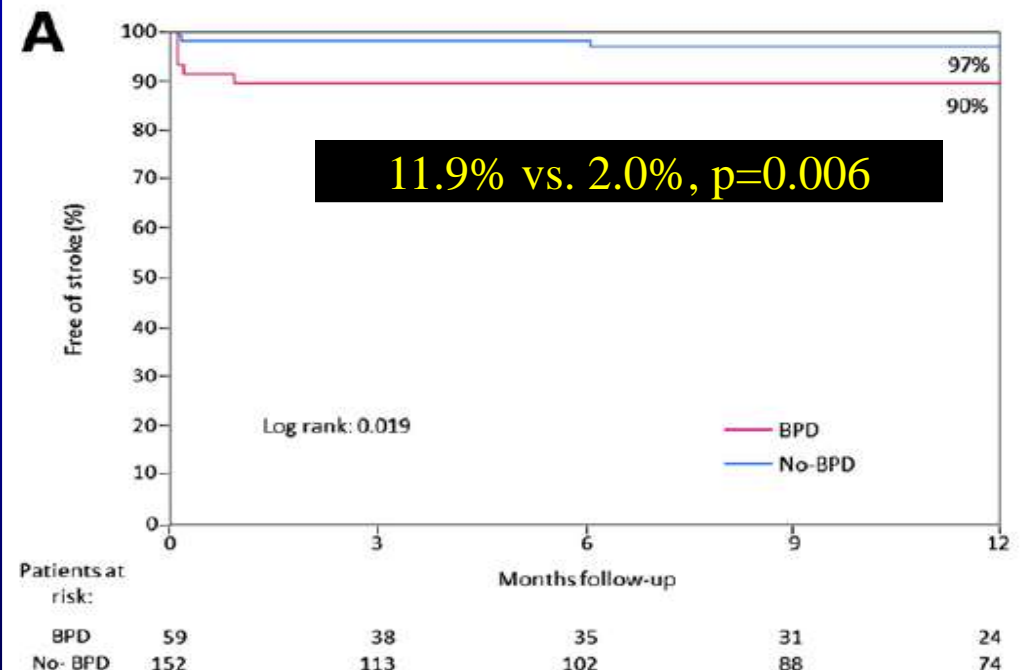
Efficacy and Safety of Balloon post-dilatation after TAVR with Balloon-expandable Valves

211 patients undergoing Edwards valve implantation, f/u 12 months
 Post-dilatation performed in patients with $AR \geq 2$: n=59 (28%)

Reduction of at least 1 degree of AR in 71% of the patients



Increased stroke rates after balloon post-dilatation



87 y/o male referred for TAVR

NYHA 3 heart failure, diastolic

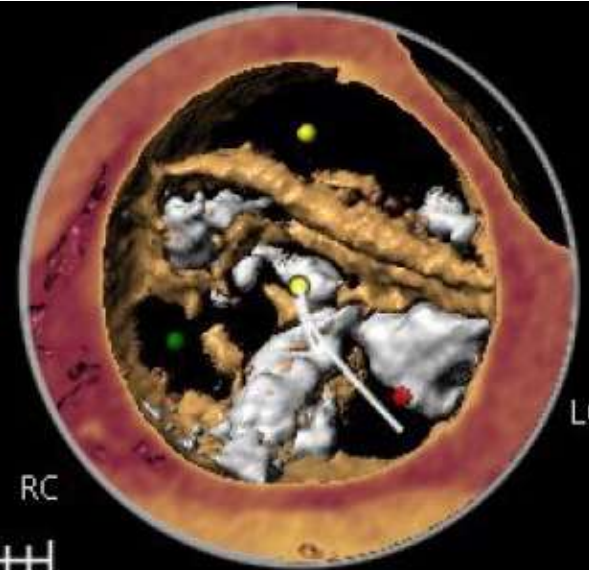
Severely calcified aortic valve

Mean gradient 34mmHg
AVA 0.5cm²

Mean PG 34 mmHg
VTI 71.0 cm

Severe MR

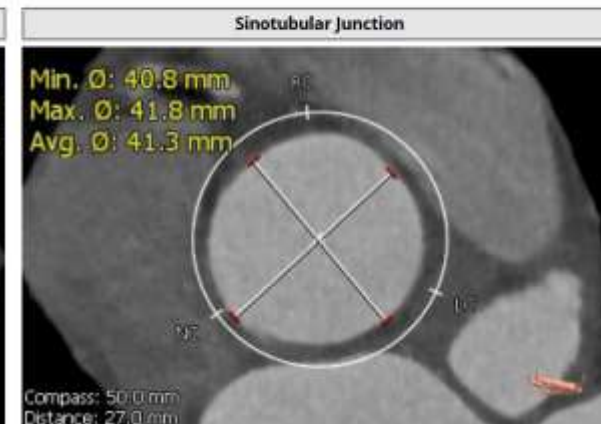
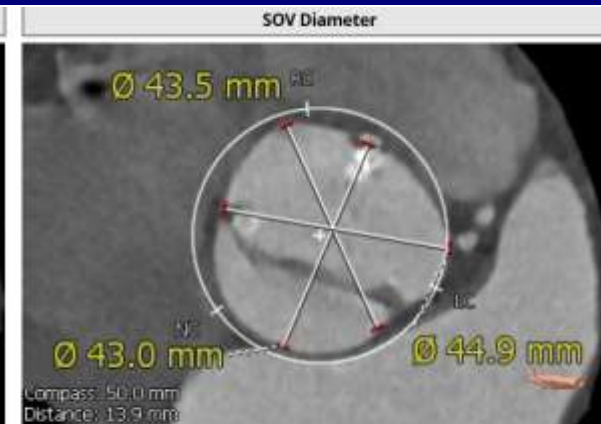
Bicuspid valve with heavily calcified raphe



Pre-TAVR CT Plan for 29mm Sapien3

Annular dimensions (28.9x32.8, mean 30.9mm), Area 722mm²

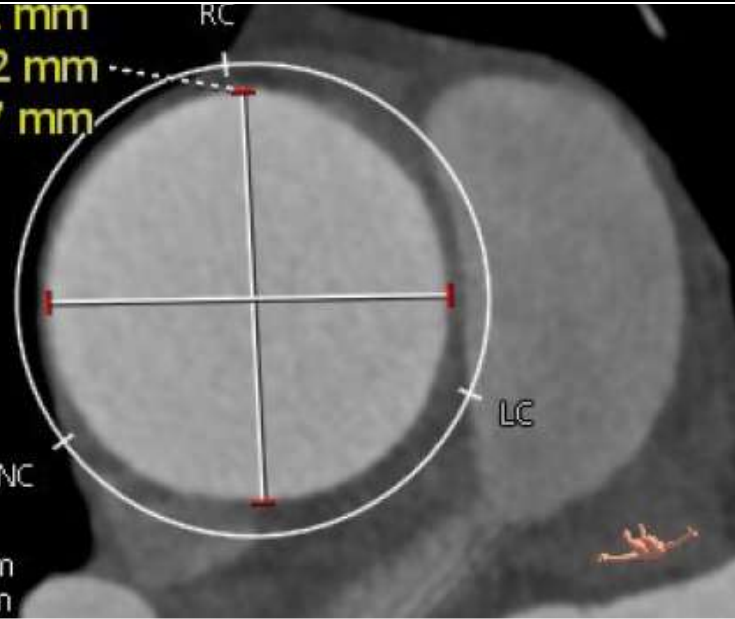
Area derived Ø: 30.3 mm Min. Ø: 28.9 mm
 Perimeter derived Ø: 31.0 mm Max. Ø: 32.8 mm
 Area: 722.4 mm² Avg. Ø: 30.9 mm
 Perimeter: 97.5 mm



High-risk features on pre-TAVR

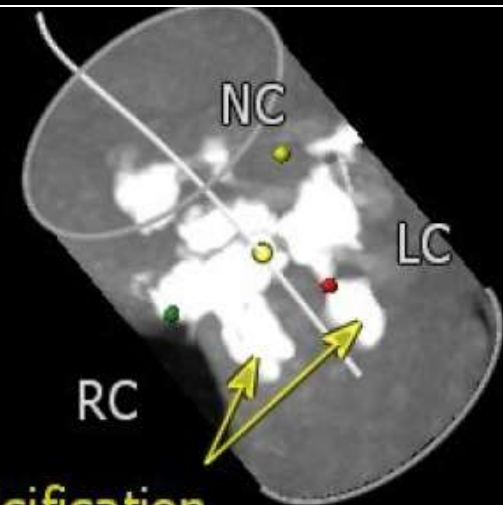
Dilated ascending aorta
47.2x48.2mm, mean 47.7mm

Min. Ø: 47.2 mm
Max. Ø: 48.2 mm
Avg. Ø: 47.7 mm



Severe LVOT calcification

LAO: 24°
Cranial: 74°



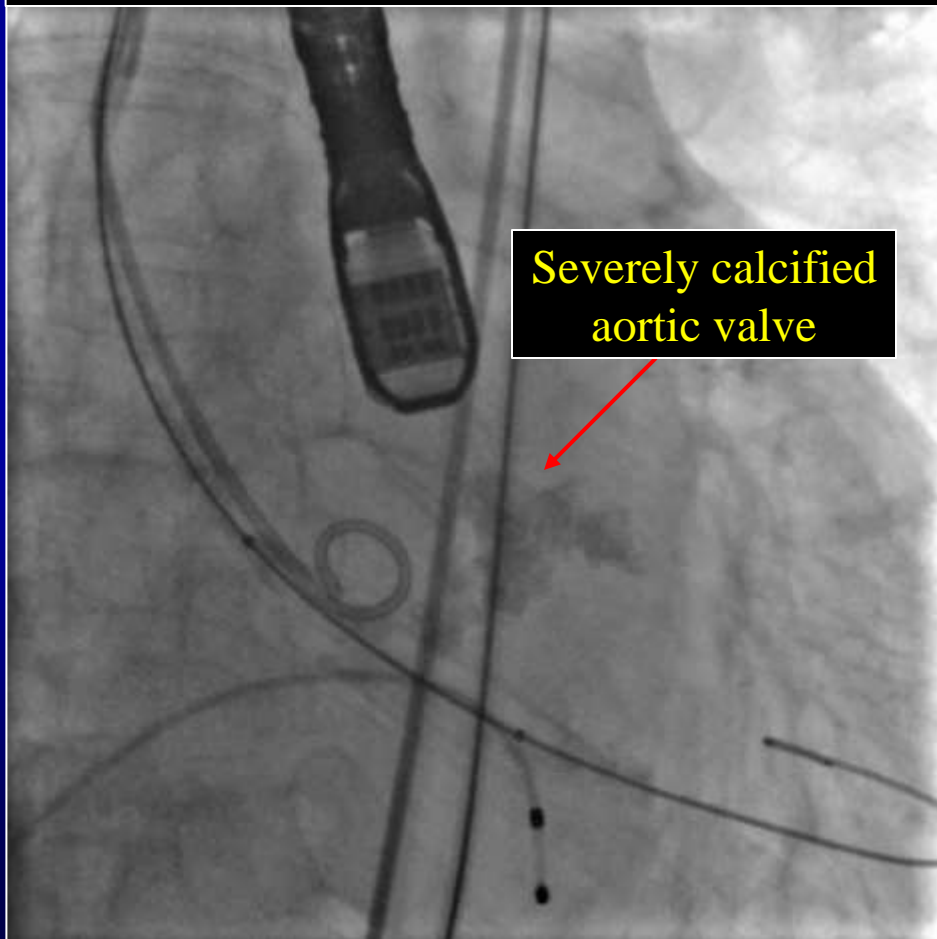
LVOT calcification



29mm Sapien 3 deployment

Predilation with 23mm x 4cm Z-Med II Balloon

Careful predilation, heavily calcified valve



29mm Sapien 3



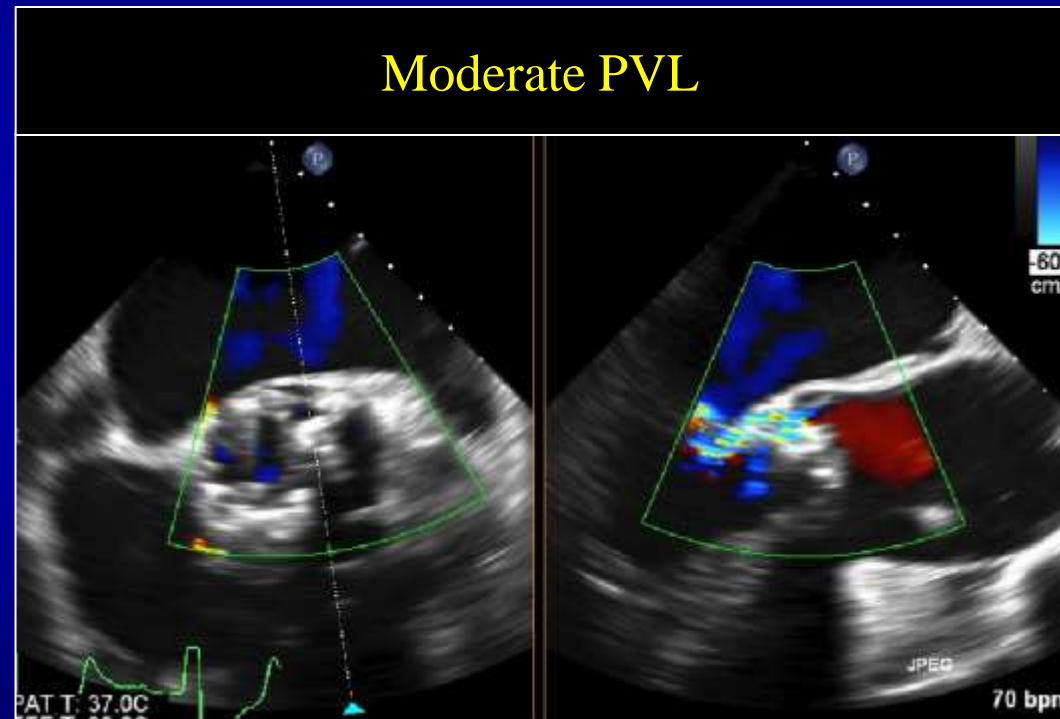
Eccentric deployment of Sapien3

Well expanded valve, but eccentrically located

Eccentric deployment of Sapien3

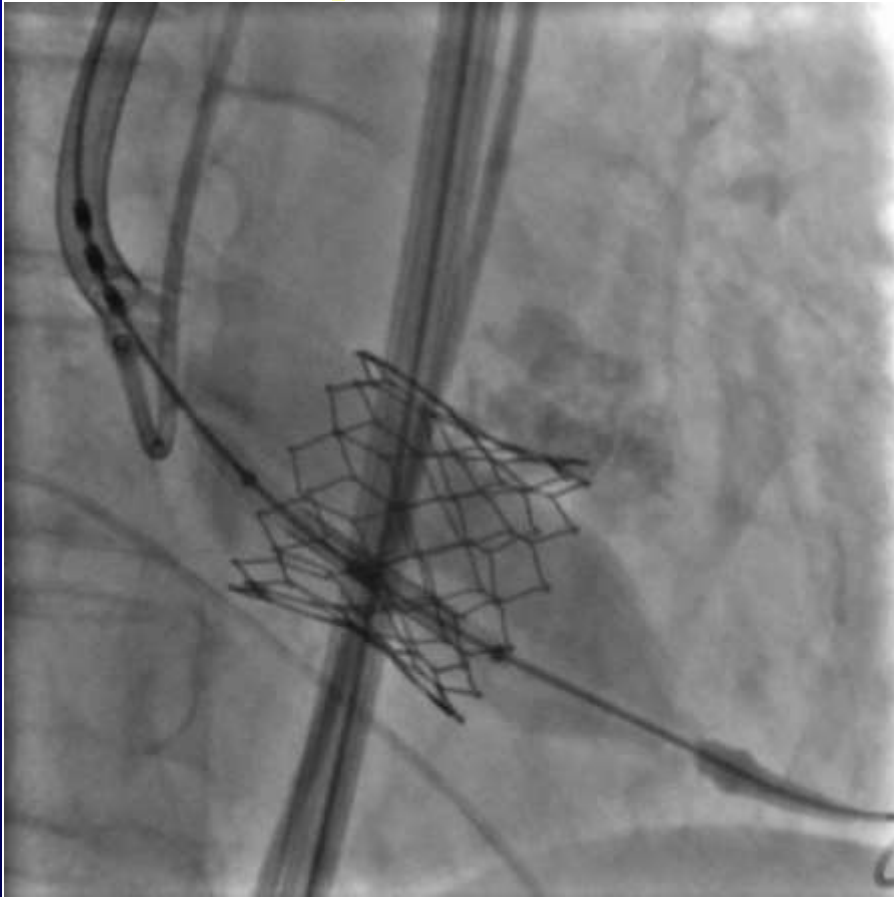


Moderate PVL

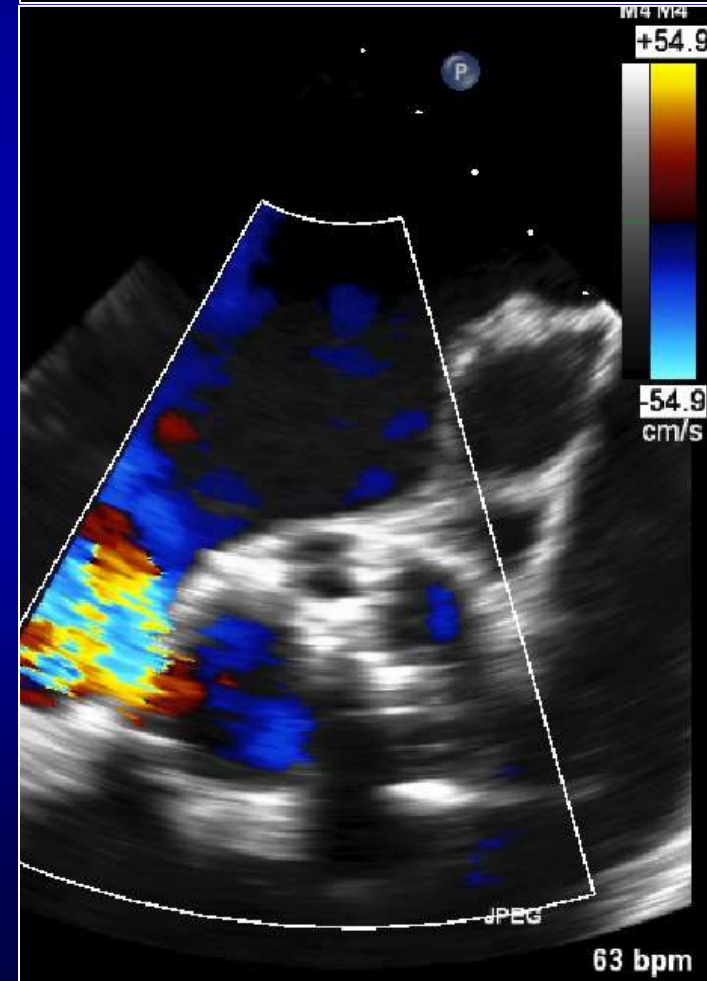


Persistent PVL despite post-dilation

Post-dilation performed with the Sapien3 balloon

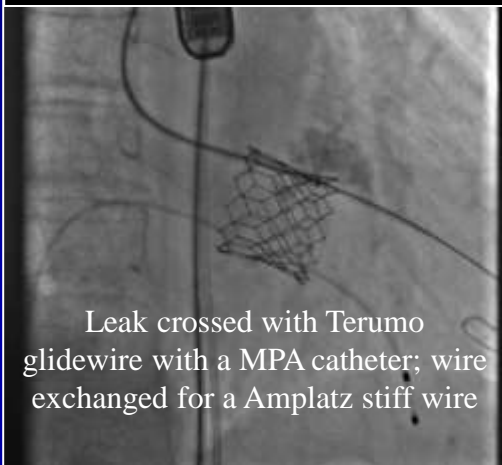


Persistent PVL despite post-dilation



PVL closure performed immediately after post-dilation due to persistent moderate PVL

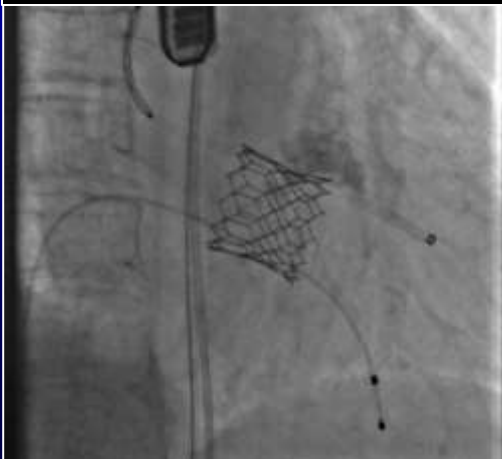
Step 1: Shuttle sheath across the leak



Step 2: Amplatz wire removed from the LV



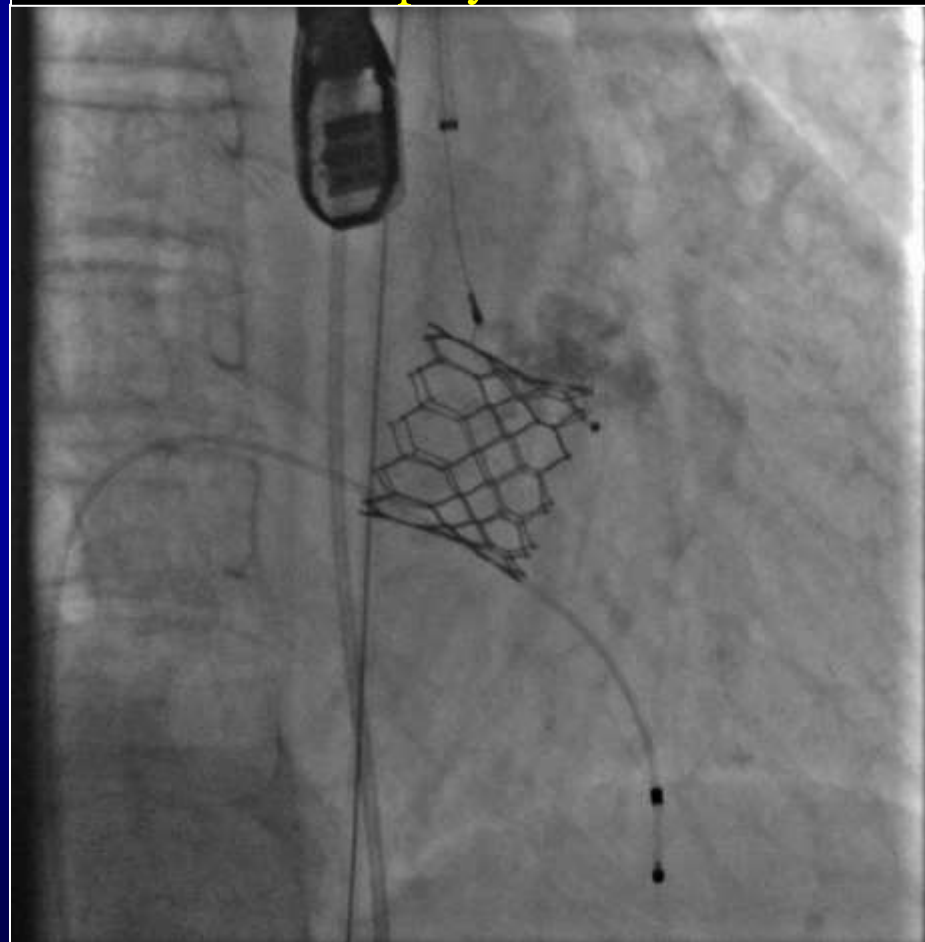
Step 3: 10mm AVP 2 plug advanced



Step 4: 10mm AVP 2 plug deployed

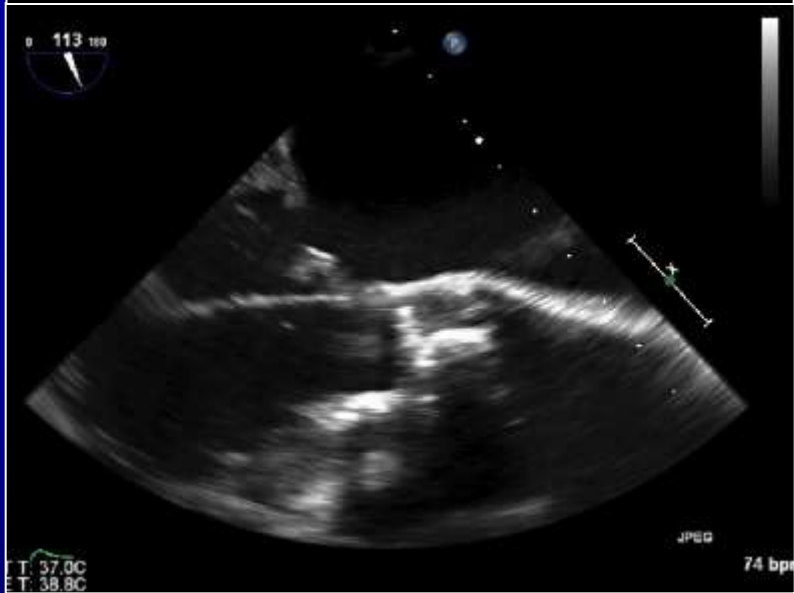


Final result s/p 10mm AVP 2 plug deployment

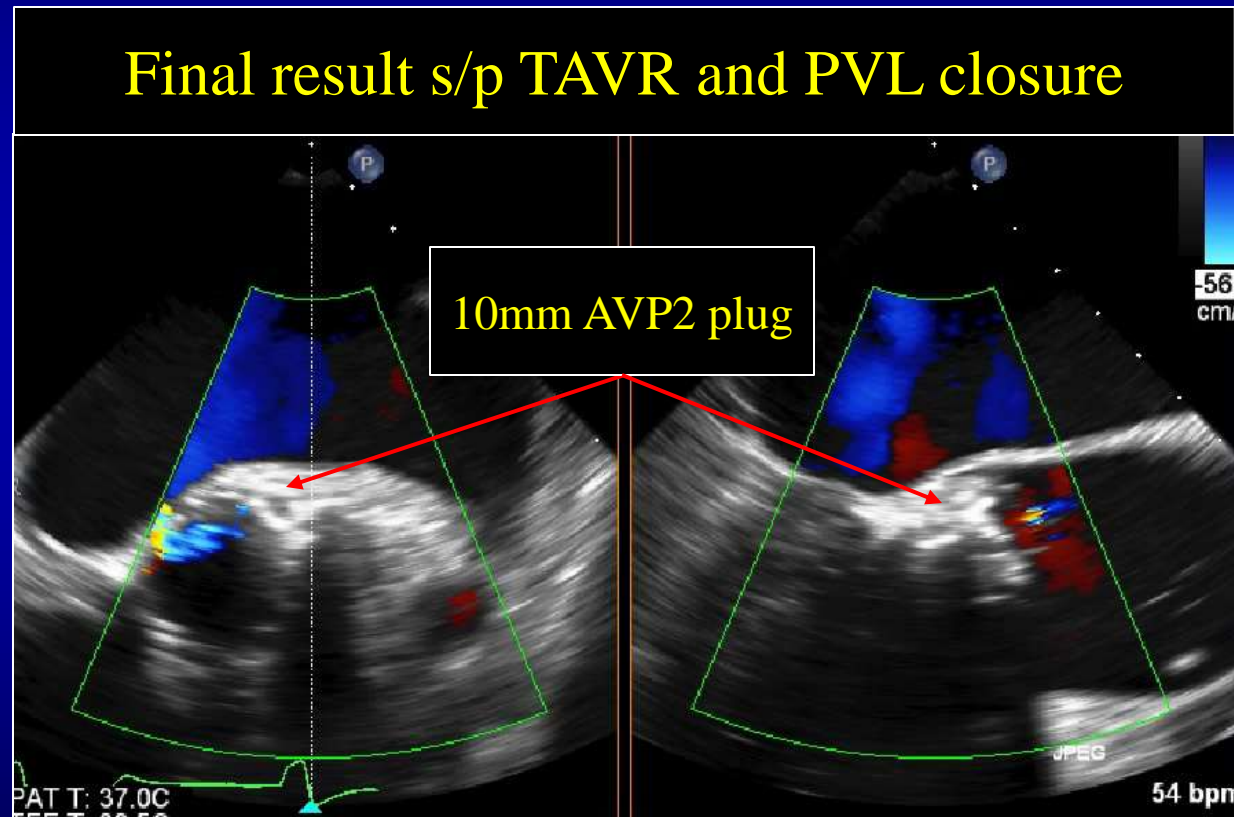


TEE guidance during the procedure

Position of wire through the PVL confirmed with TEE

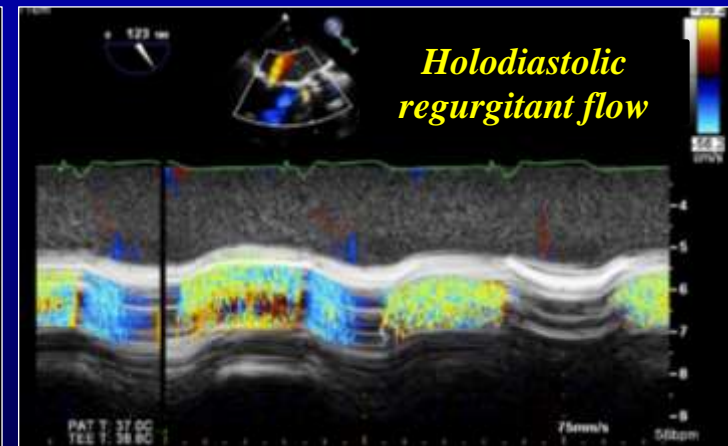
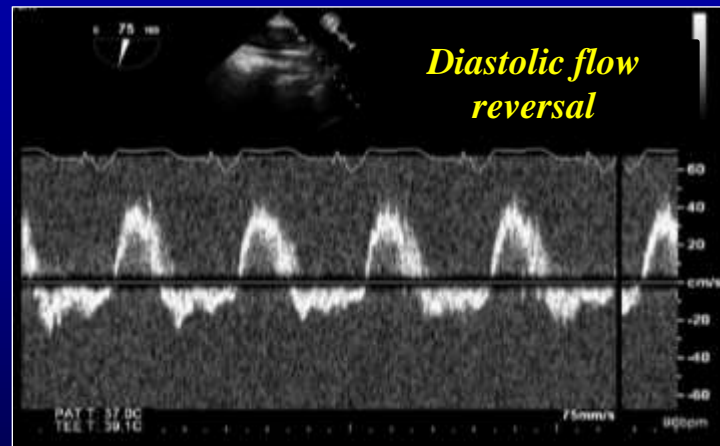
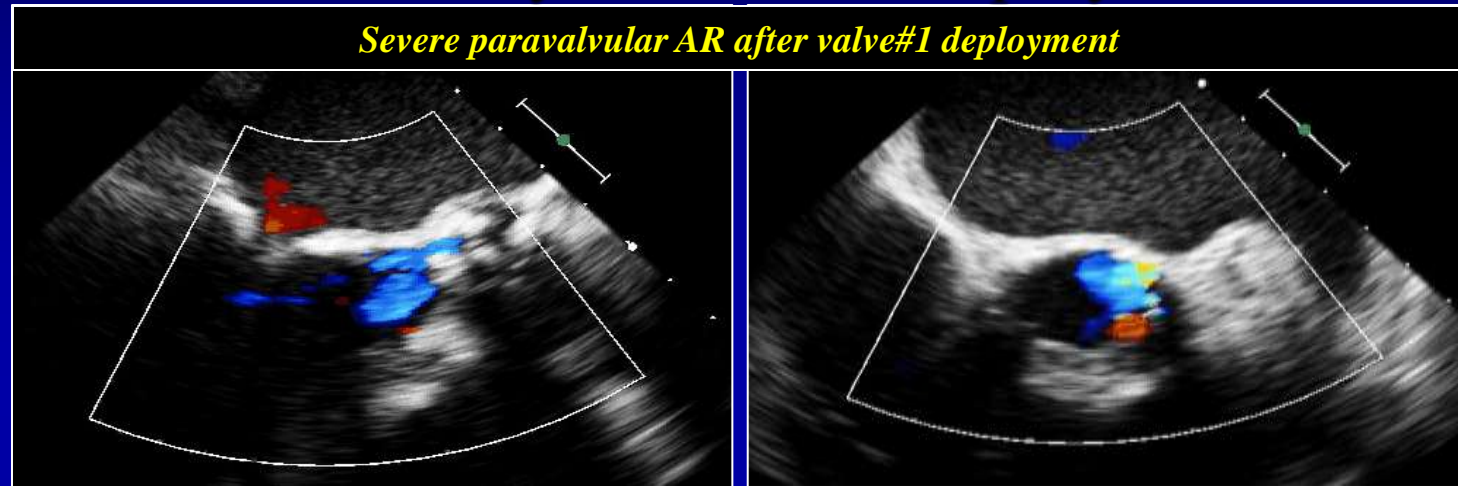
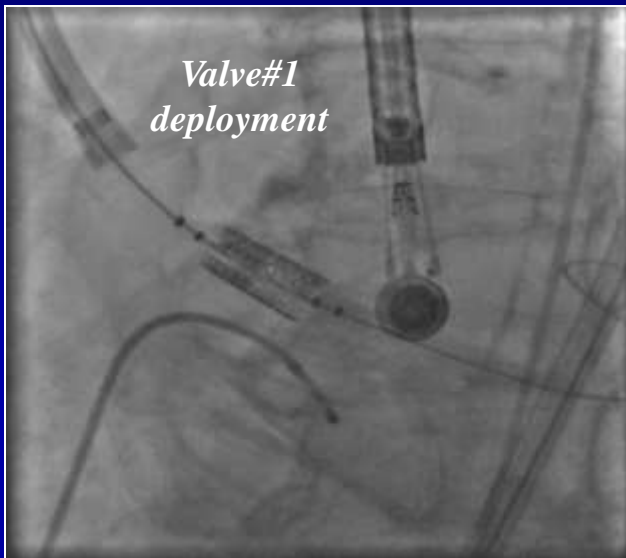


Final result s/p TAVR and PVL closure

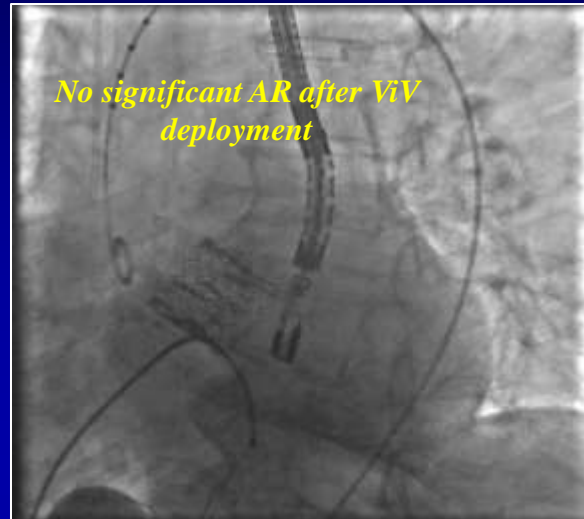
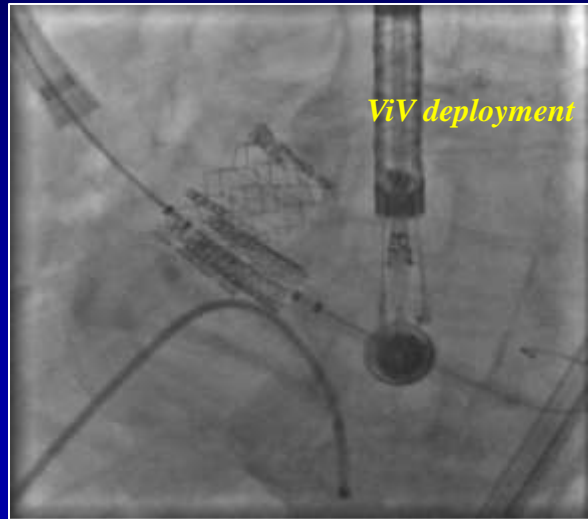


84 y/o male undergoing TAVR with 26mm Edwards-SAPIEN valve

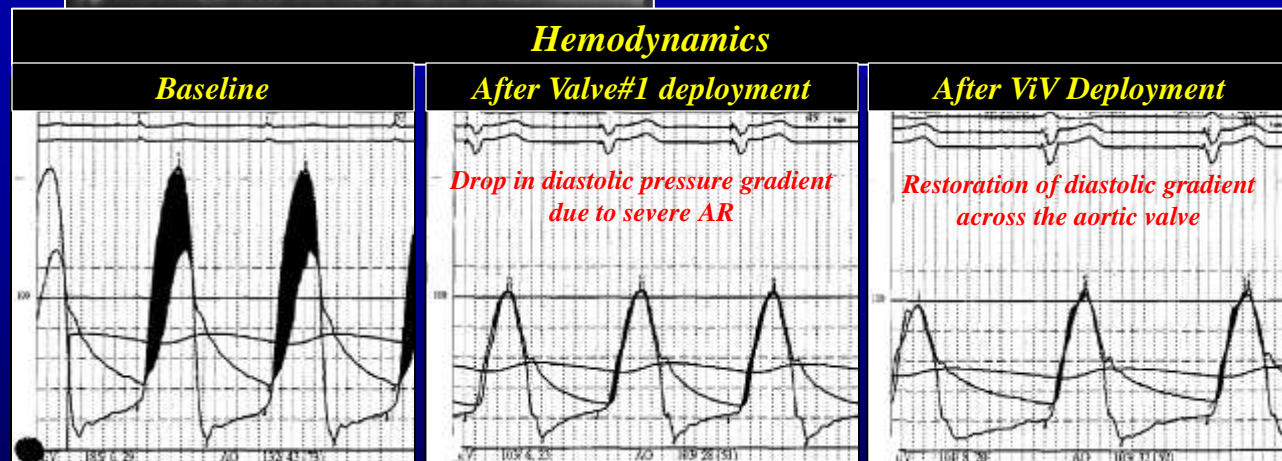
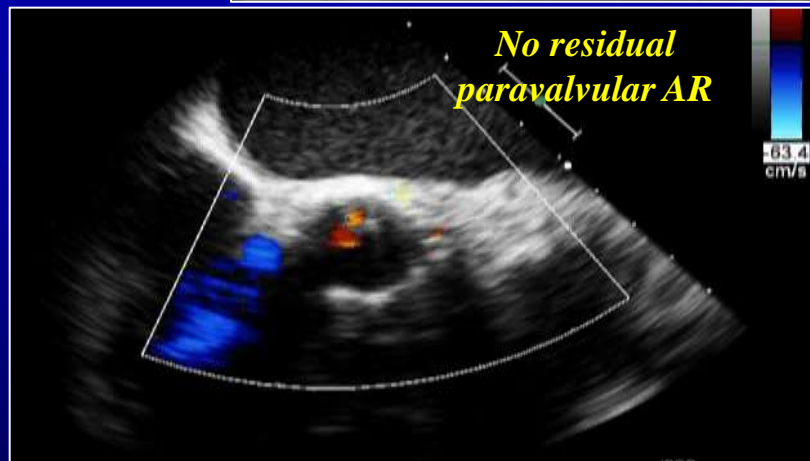
Severe PV AR noted immediately after valve deployment



Paravalvular AR managed with ViV deployment of 26mm Edwards-SAPIEN valve



- Discharged home on Day#3 post-procedure
- NYHA Class 2 on 1 month follow-up

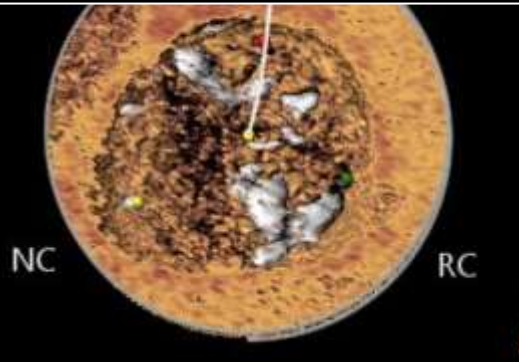


65 y/o male with bicuspid AS presenting for TAVR

Plus 5 ccs: Annular area 841.4mm²



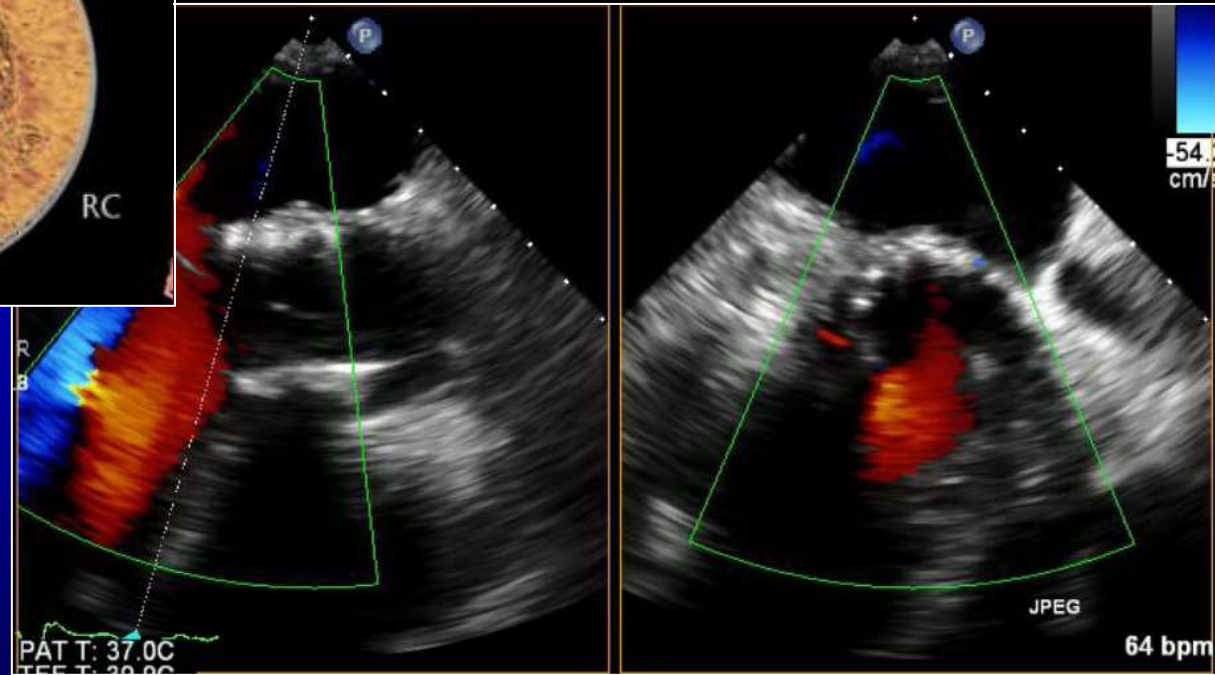
Bicuspid AS



29mm Sapien 3



Final result Mild residual PVL

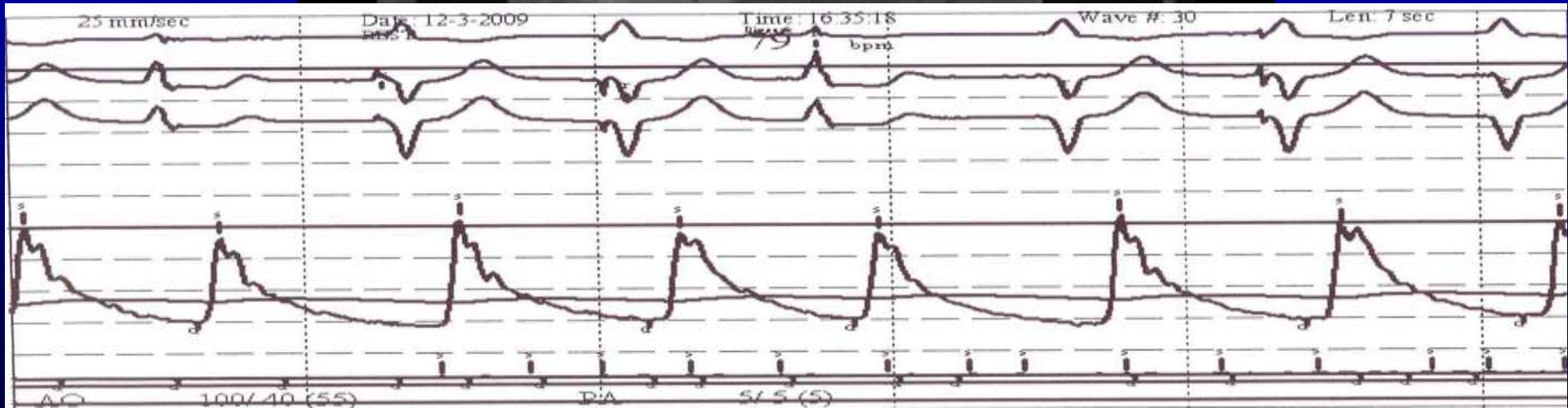


Key Points for Paravalvular AI

- Cross sectional sizing using CT or 3D echocardiography
- Post dilatation with extra volume in the balloon
- Too high or low-deploy second valve
- If post dilatation carries risk of root injury consider plugging the leak

TAVI in 80 y female with radiation chest deformity *2009*





cm

**Mitral
Annulus
Calcium**

R

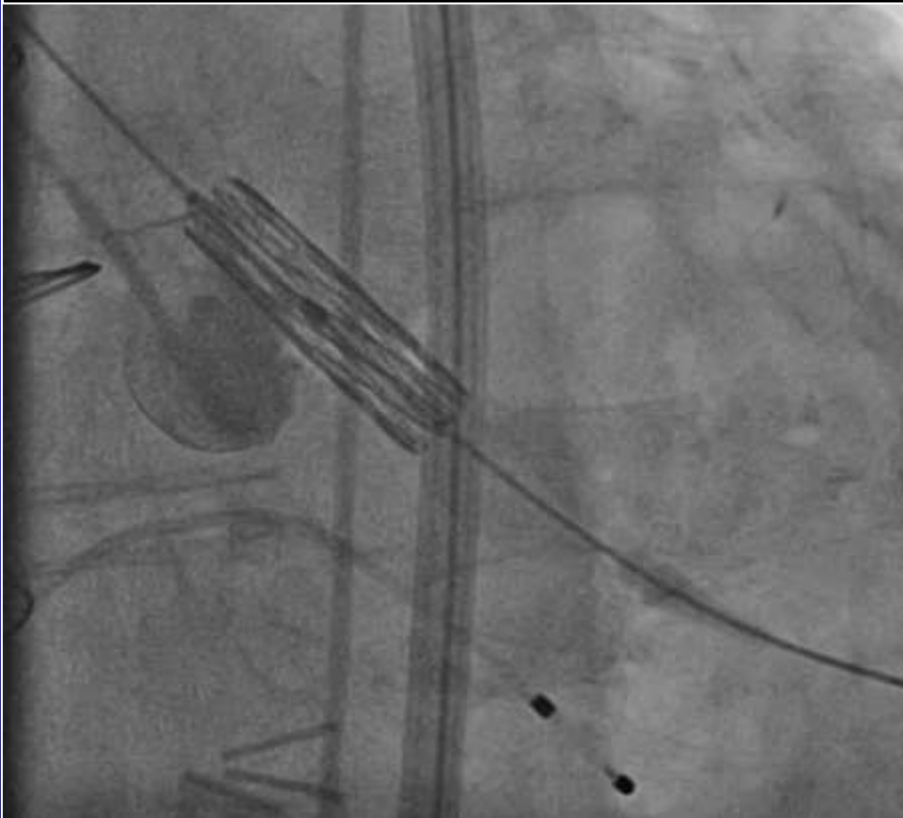
A



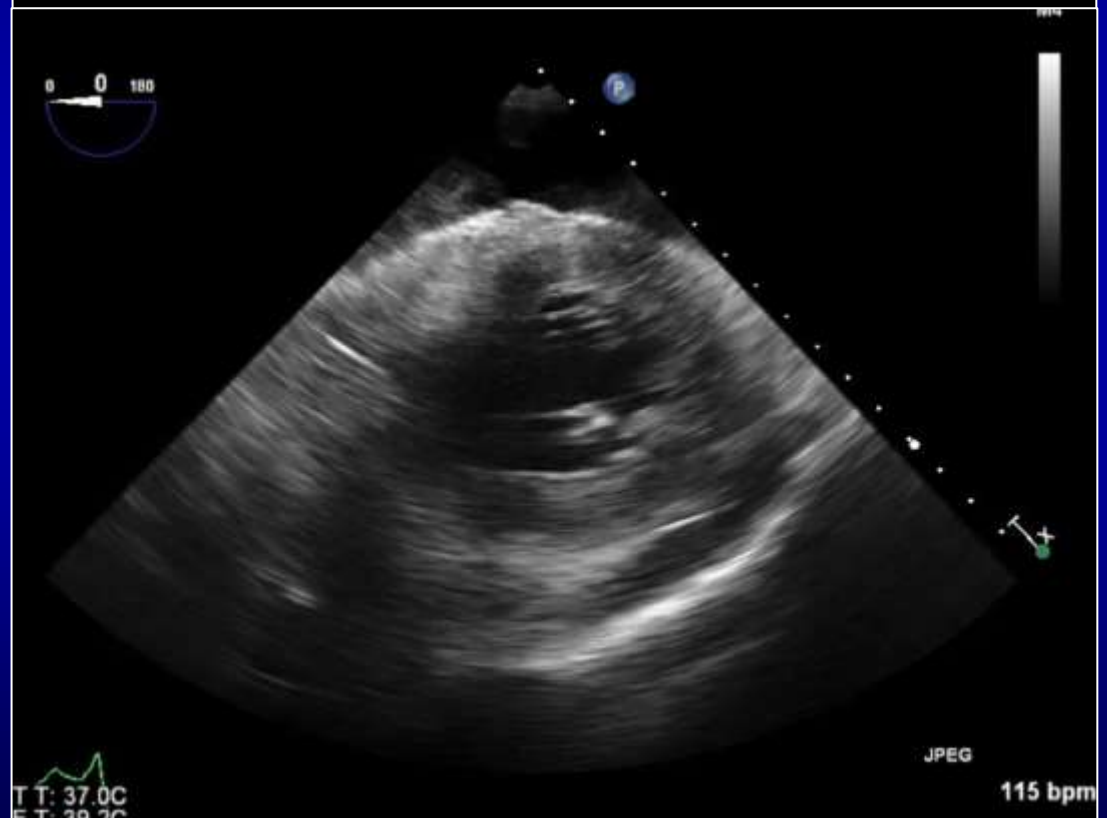
**Outflow
Tract
Calcium
Continues
to Left
Valve**

74 y/o male undergoing TAVR with 29mm Sapien 3

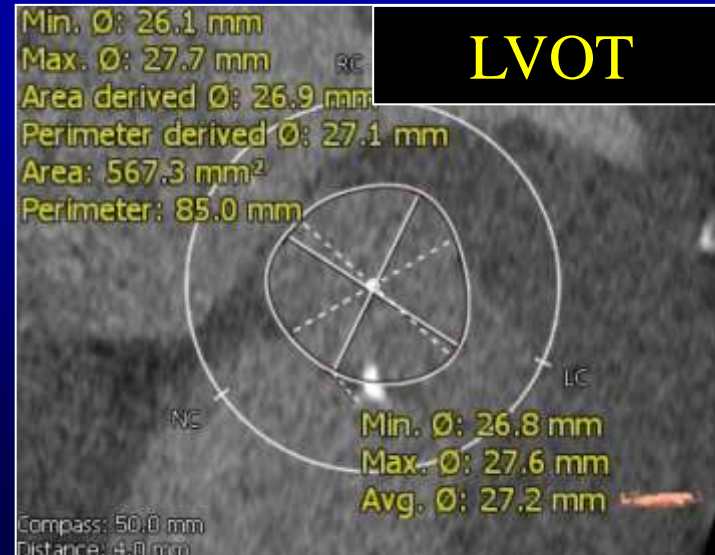
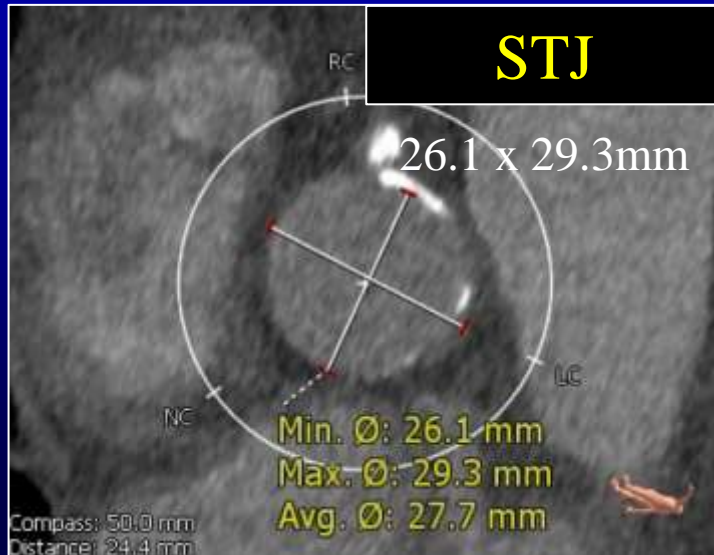
29mm Sapien 3 deployed



Large pericardial effusion noted post-valve deployment, with drop in BP



Pre-TAVR CT analysis

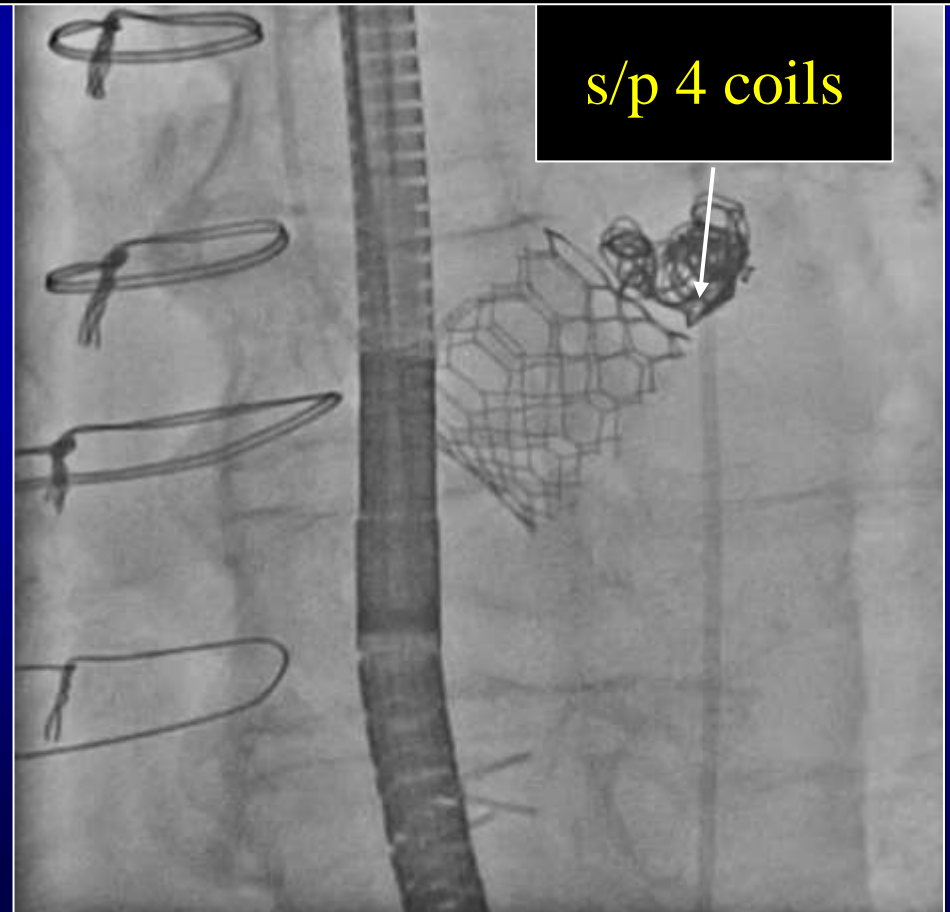
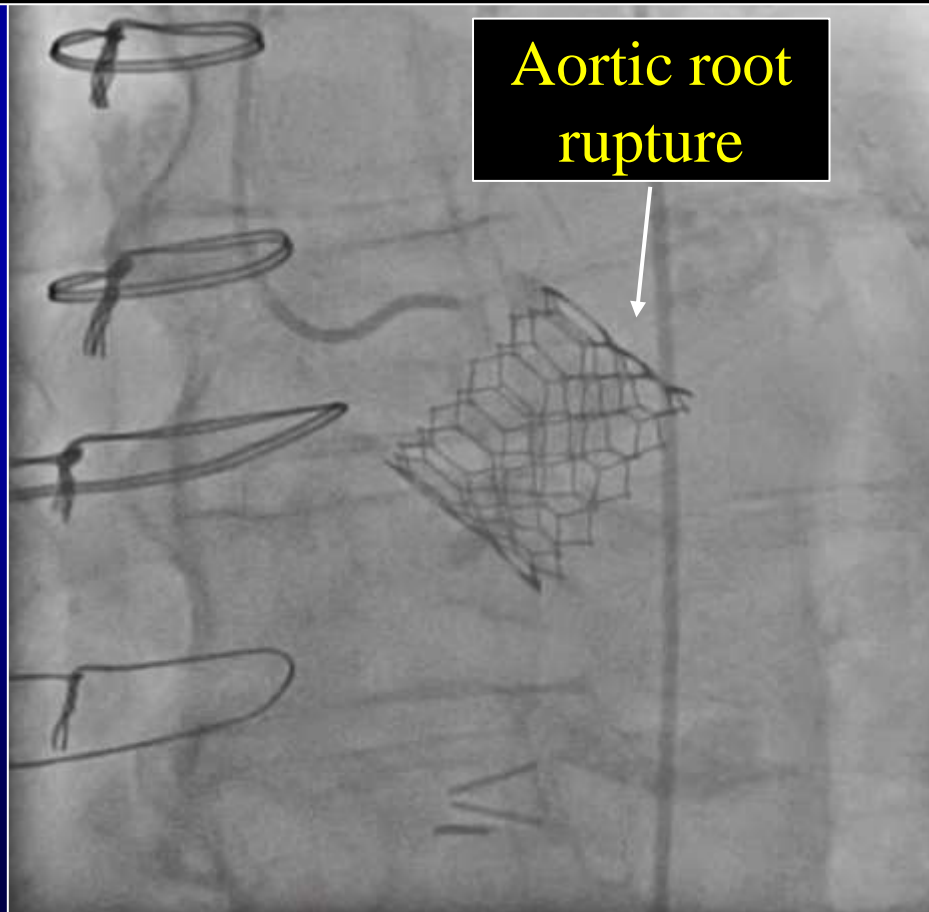


Aortic root angiogram revealed the site of aortic root rupture

root rupture

Root rupture site successfully closed with 4 coils

Patient transferred to the ICU, extubated on Day 1, transferred out of the ICU on Day 4, doing well



88 y/o female with severe AS undergoing TAVR

Pre-TAVR LM angiography



Pre-TAVR CT

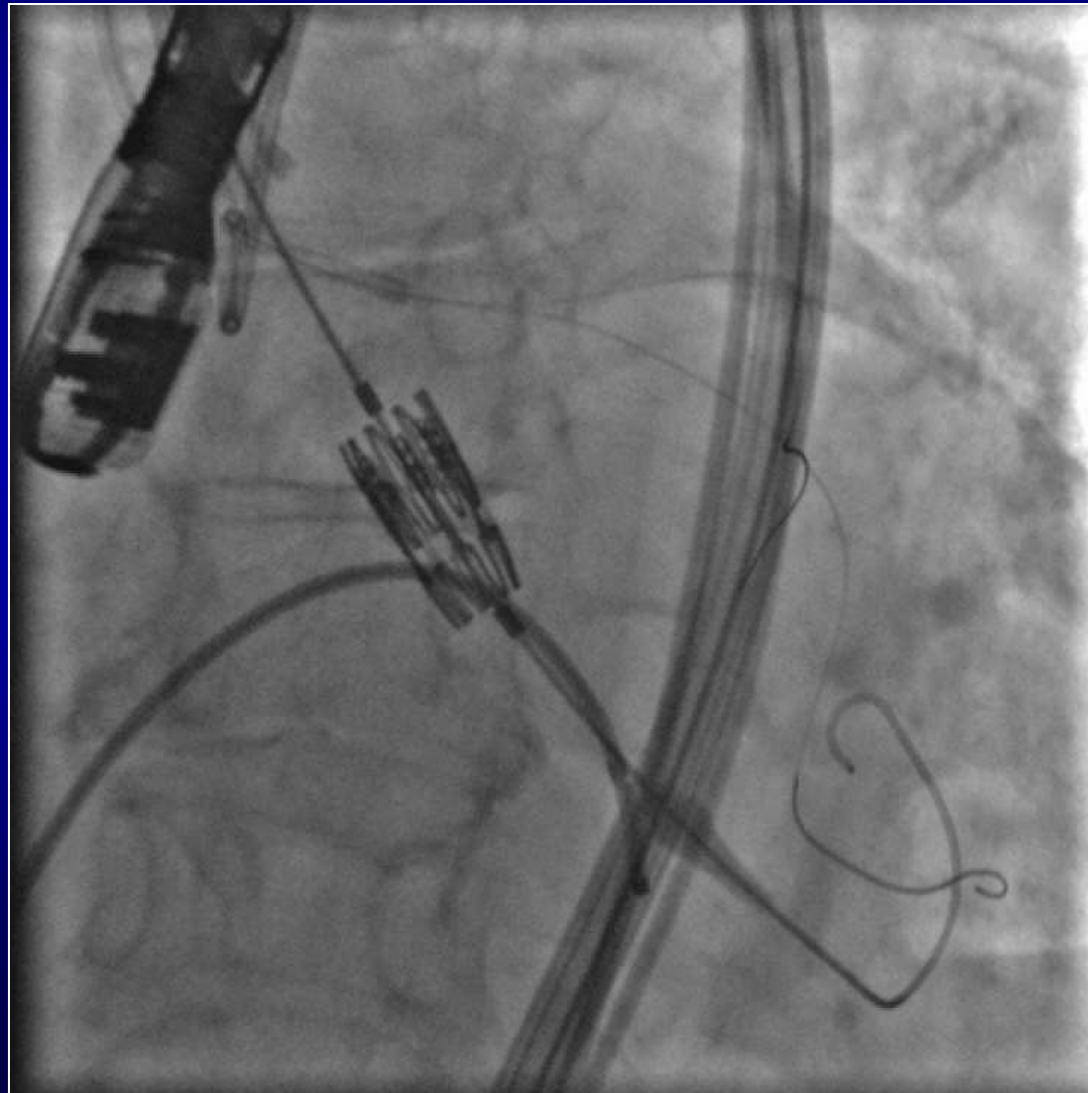


Annulus

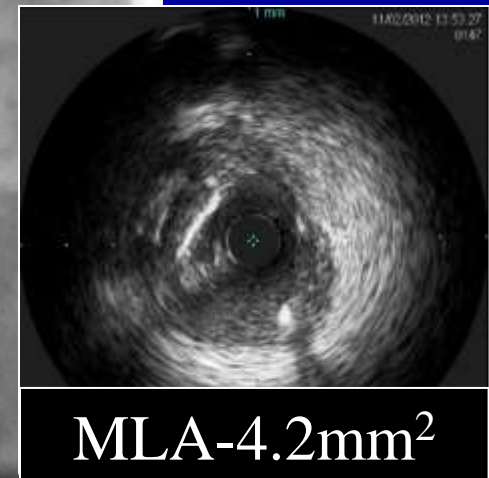
Shallow
SOV

Plan for 26-mm Edwards-Sapien XT valve

LM protected with 2 balance wires in the LAD and CX

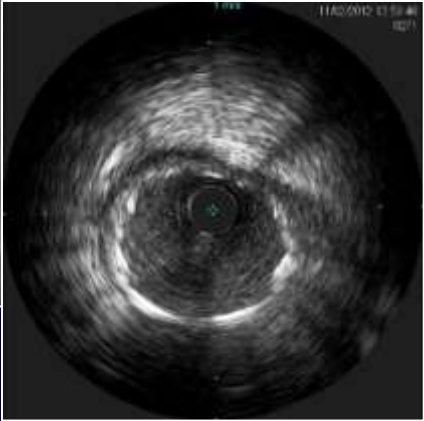
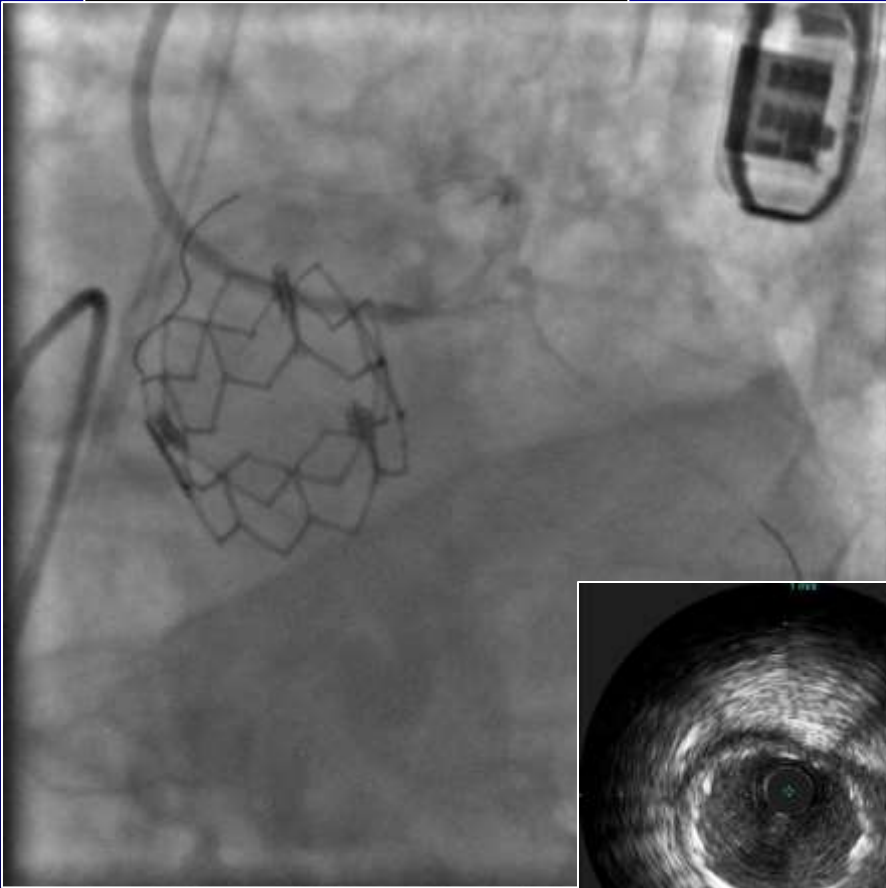
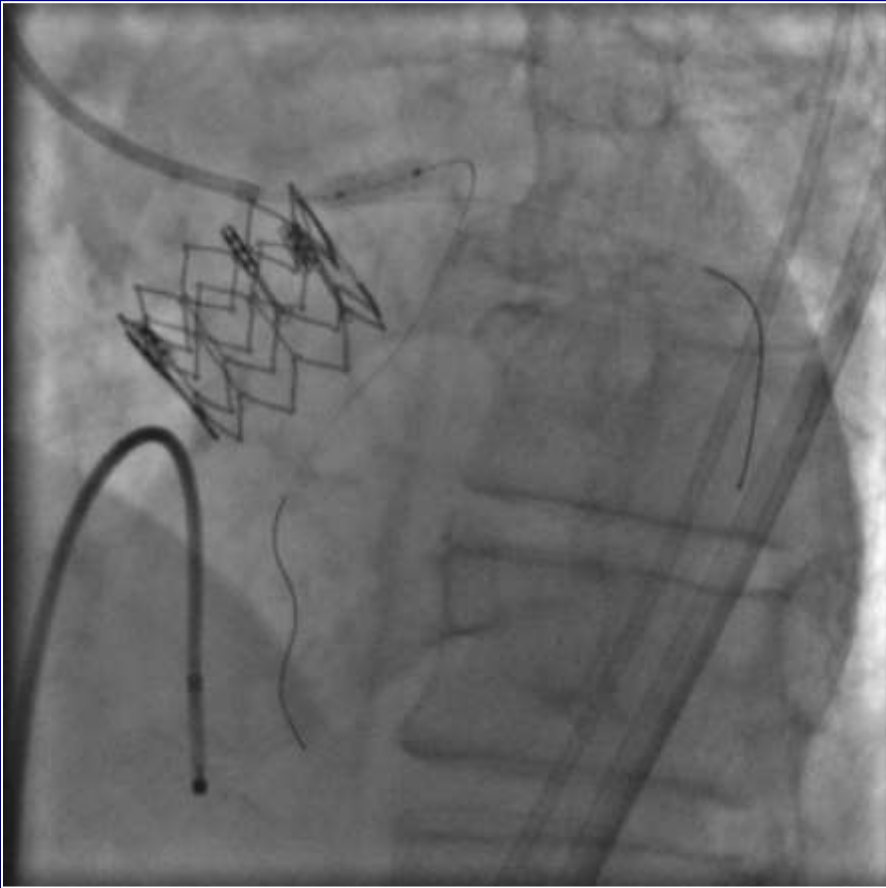


**Routine selective injection post valve deployment,
showing a new ostial LM 80% stenosis**
No clinical signs



Deployment of a 3.5mmX12mm Xience stent in the LM

Final result



Case: LM occlusion noted 1 month post TAVR

Due to risk of LM obstruction, TAVR with a 26mm Sapien3 performed with coronary protection

Low LM height (6.8mm)



26mm Sapien3 deployed with coronary protection



LM angiogram prior to removing the stent undeployed

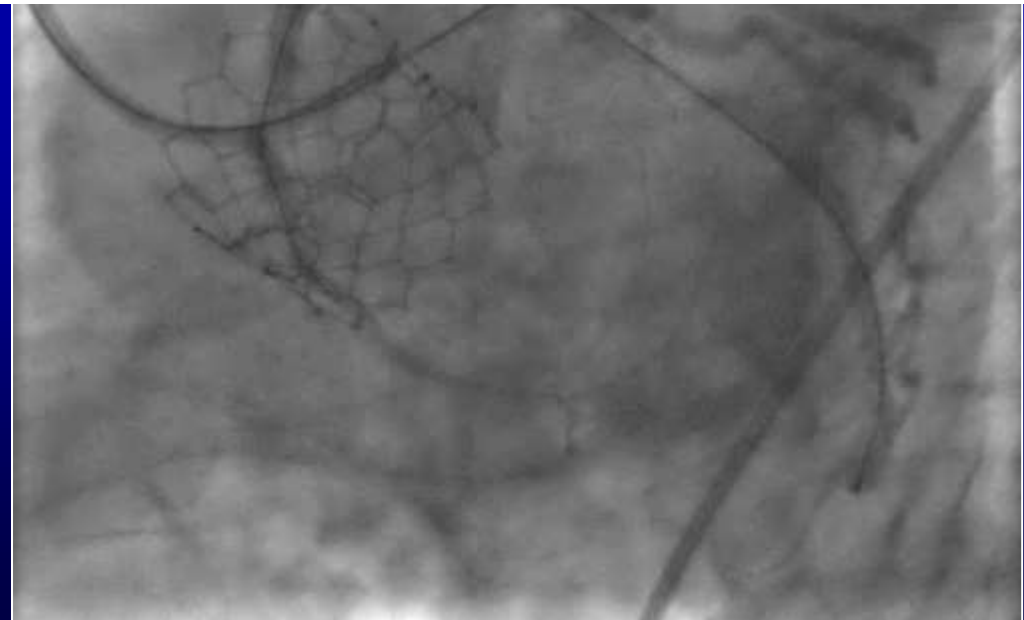
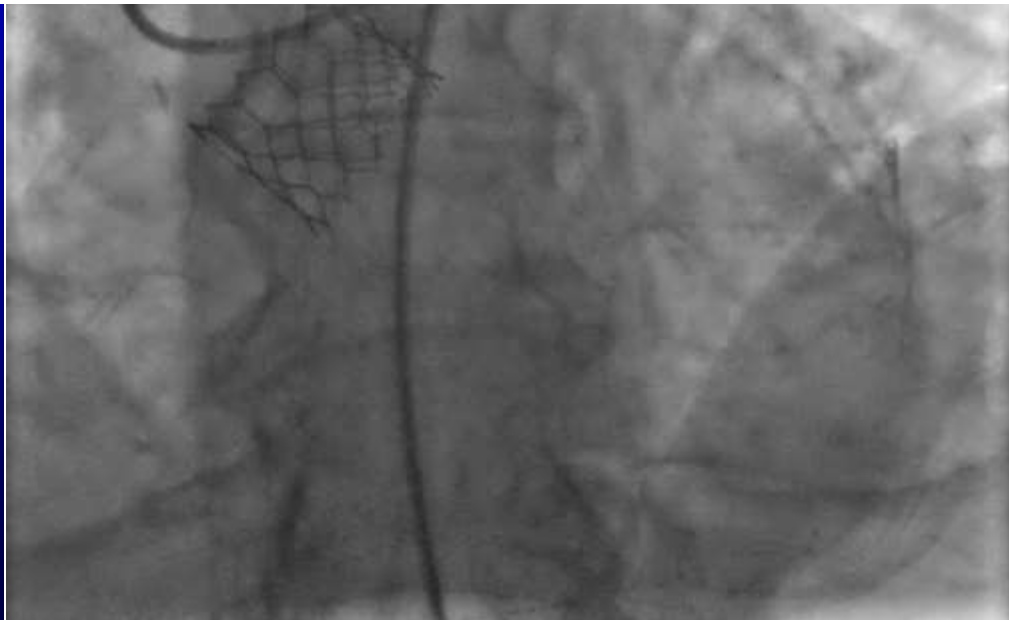


95% ostial LM impingement by the calcified aortic valve leaflet noted 1 month post-TAVR

Successful stenting with DESx2



Adequate visualization of the LM after TAVR is important in cases where the risk of LM occlusion is high, even in the absence of hemodynamic compromise



79 y/o female undergoing transcatheter ViV implantation

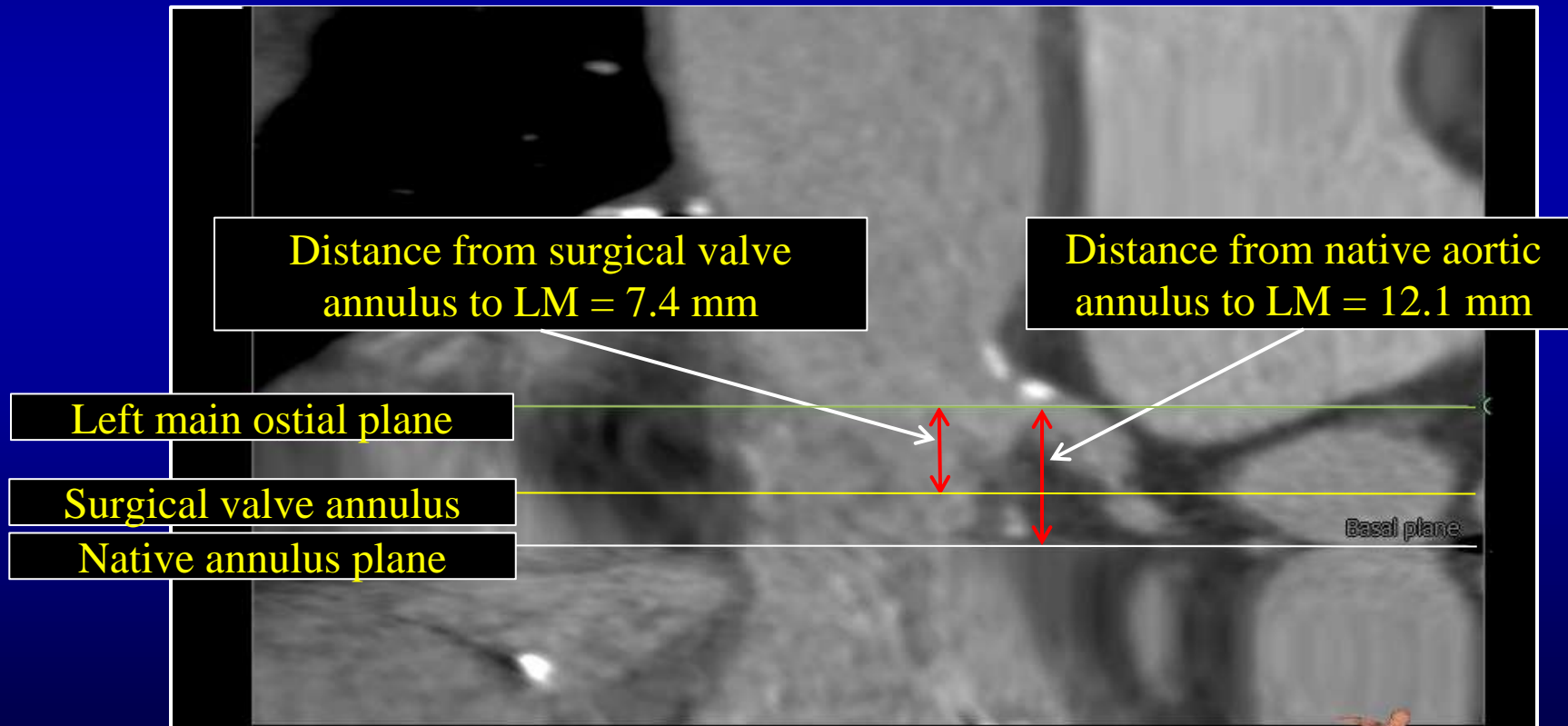
Degenerative 23-mm St. Jude Toronto SPV bioprosthetic aortic valve with significant AR



**Toronto SPV St. Jude
Stentless Prosthetic Valve**

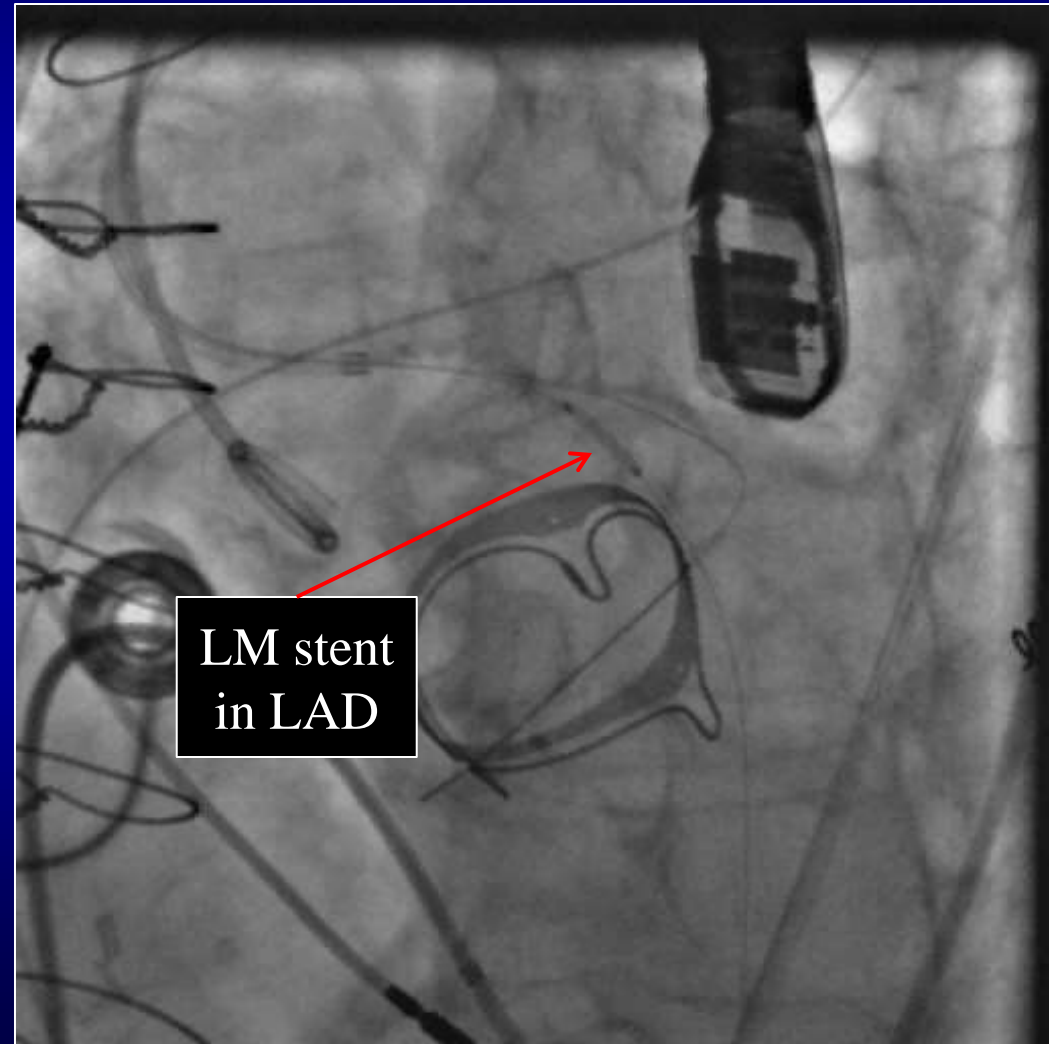
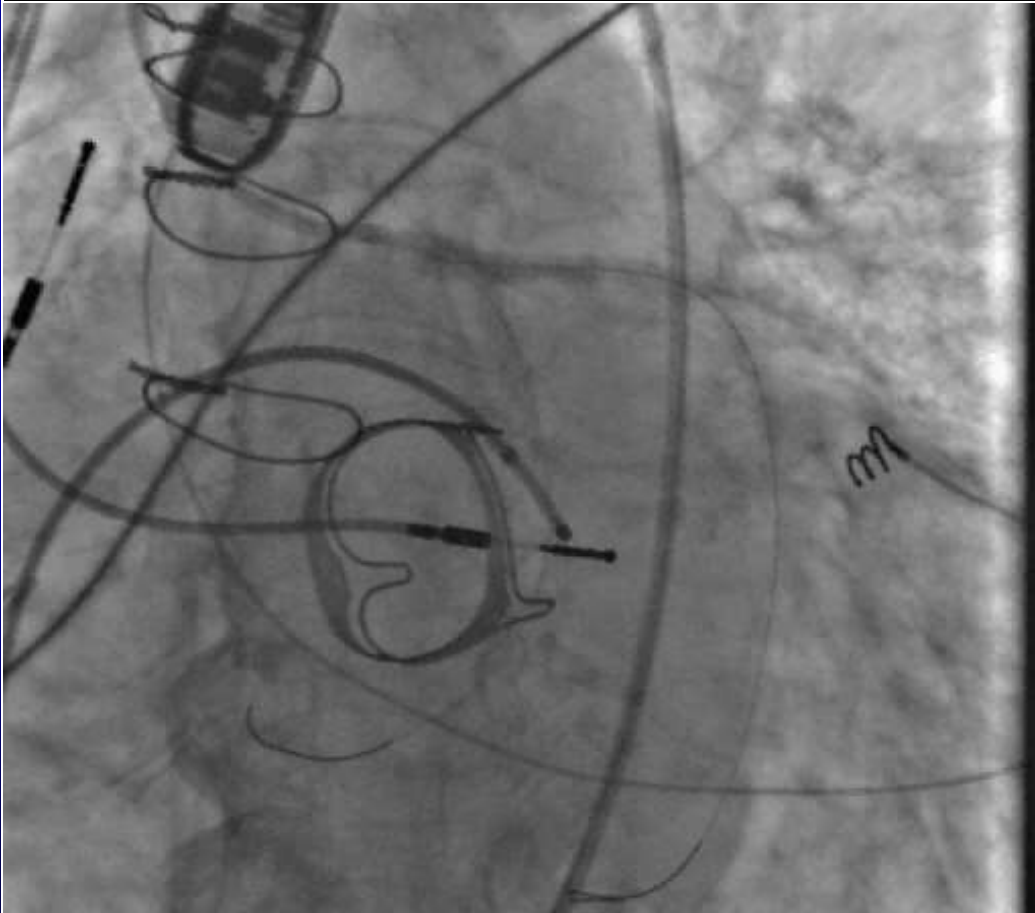
Low left main

LM 7.4mm, RCA 12.1mm



LM protected with 2 Balance wires and Xience 4.0 x 12 mm stent in the LAD

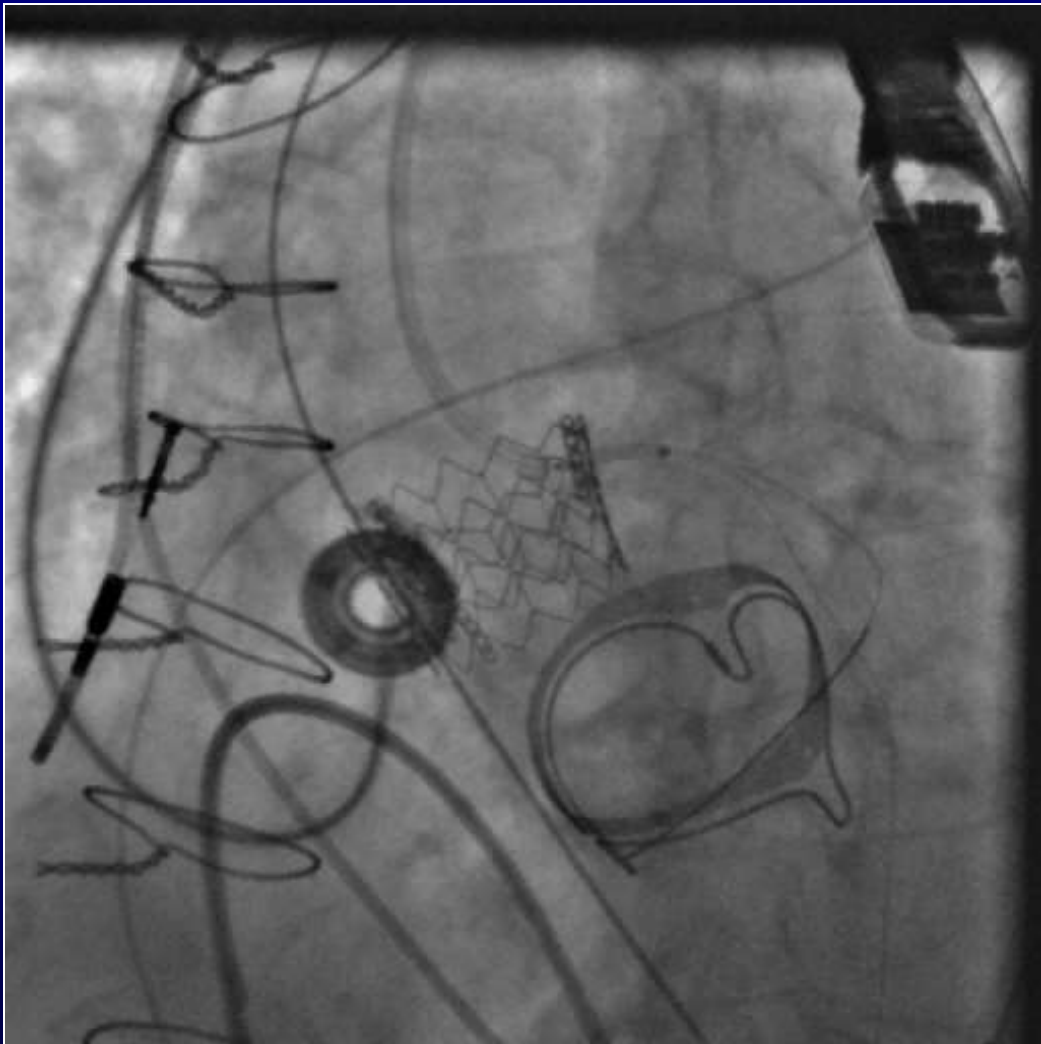
No significant LM stenosis at baseline



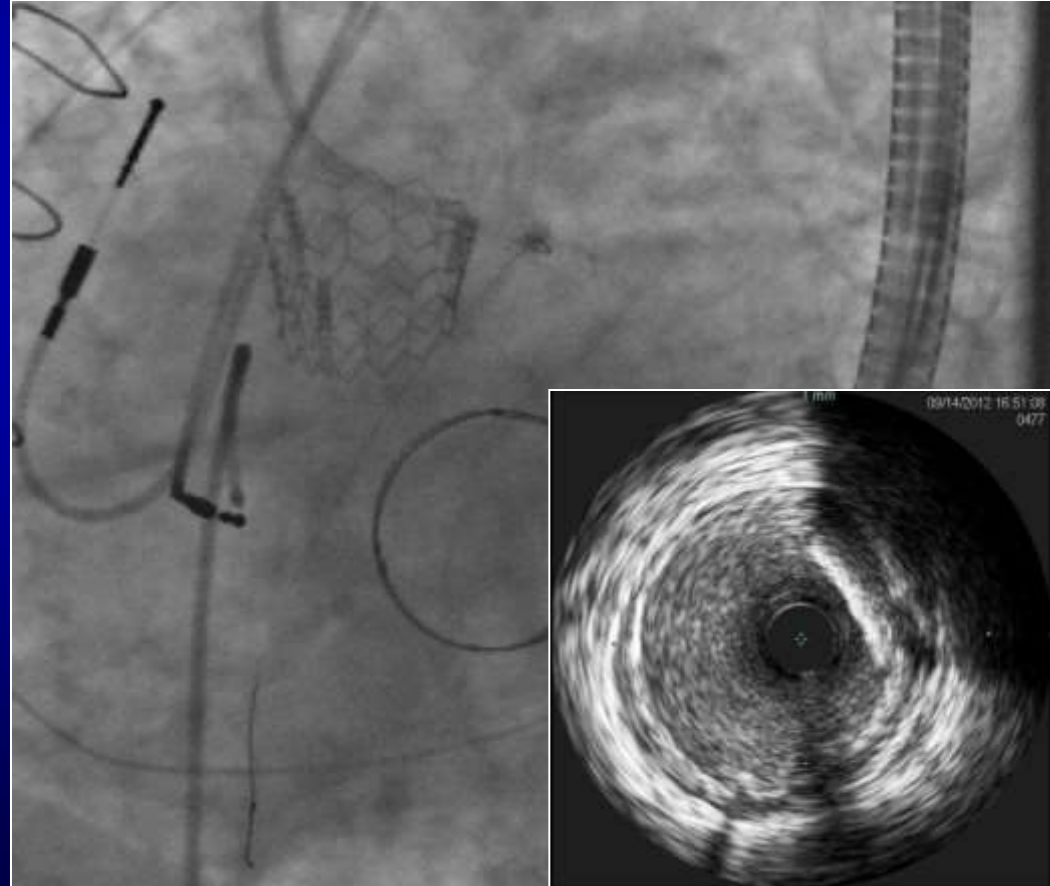
Significant LM compromise due to the prosthetic valve



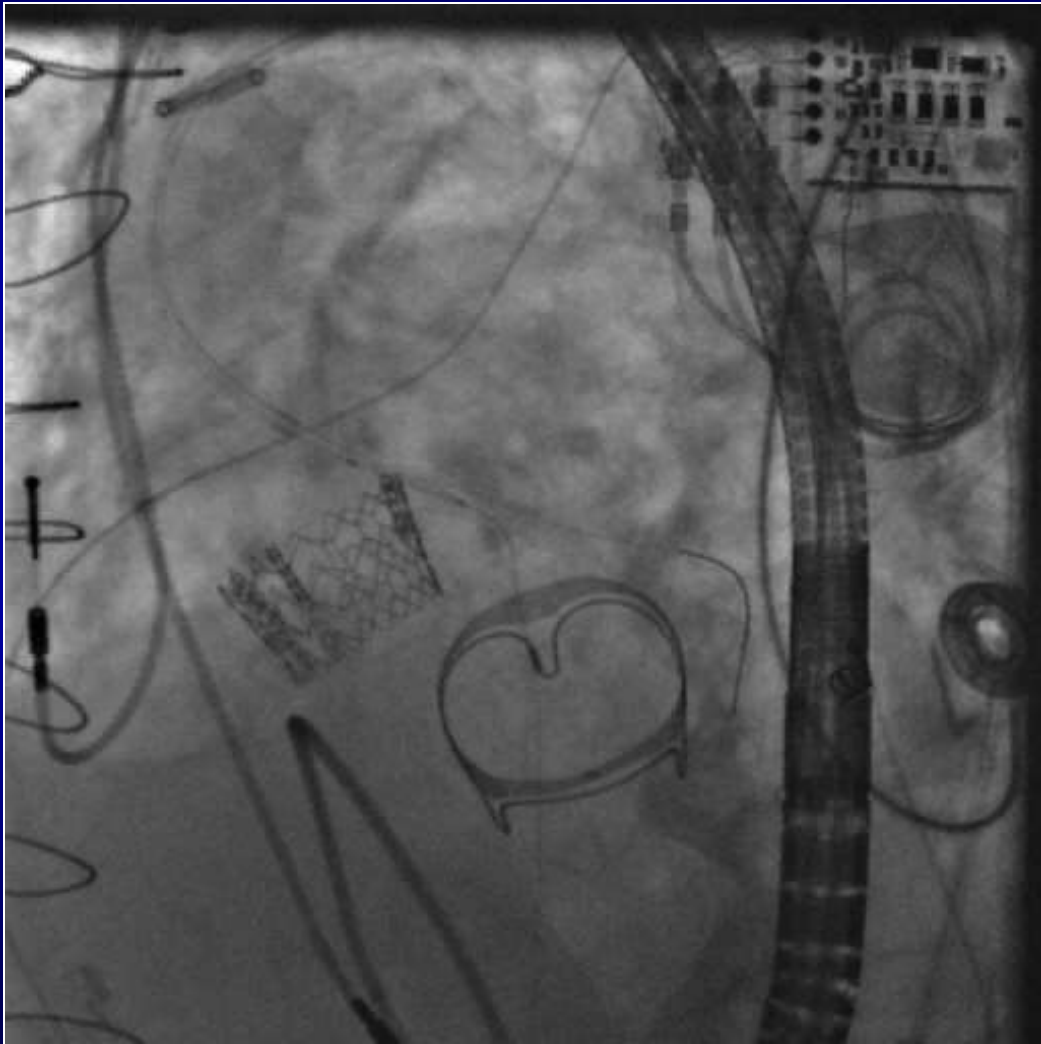
Xience 4.0 x 12 mm stenting to ostial LM, with residual ostial LM stenosis



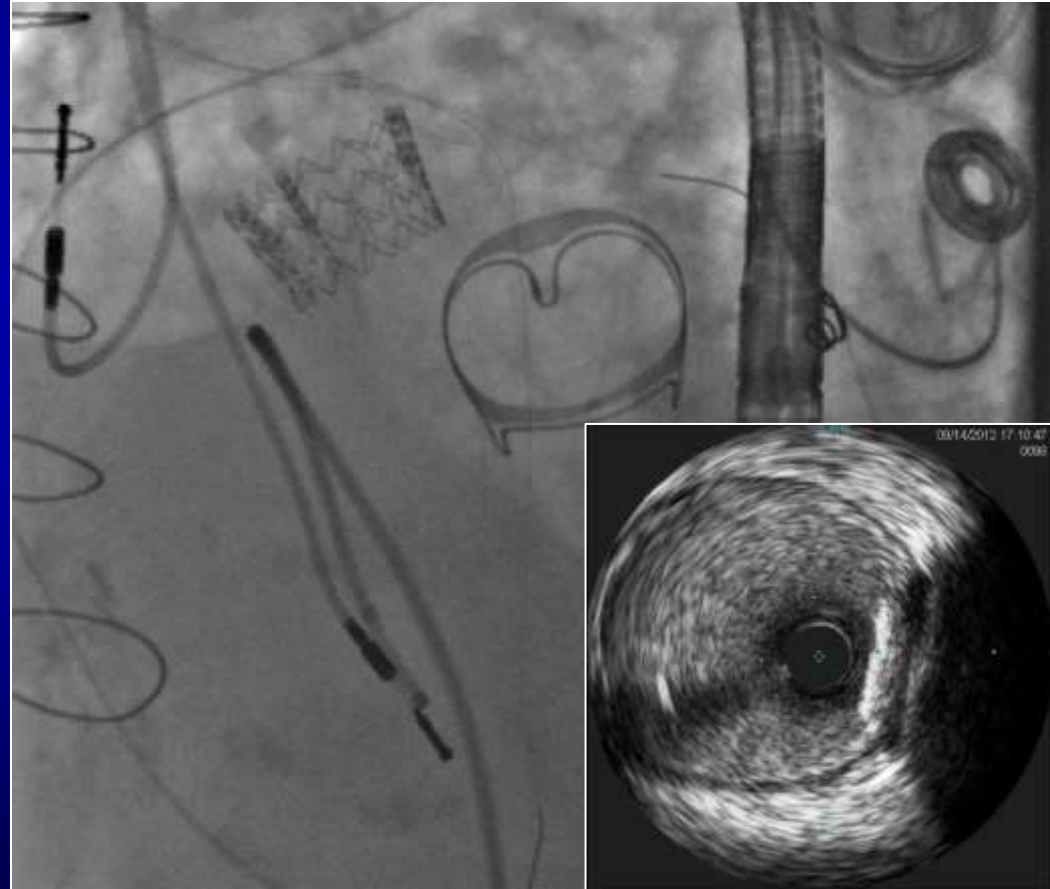
Residual ostial LM stenosis after stent deployment



4.0 x 12 mm VeriFlex BMS to the ostial LM



Final result s/p Xience 4.0x12 and Veriflex 4.0x12

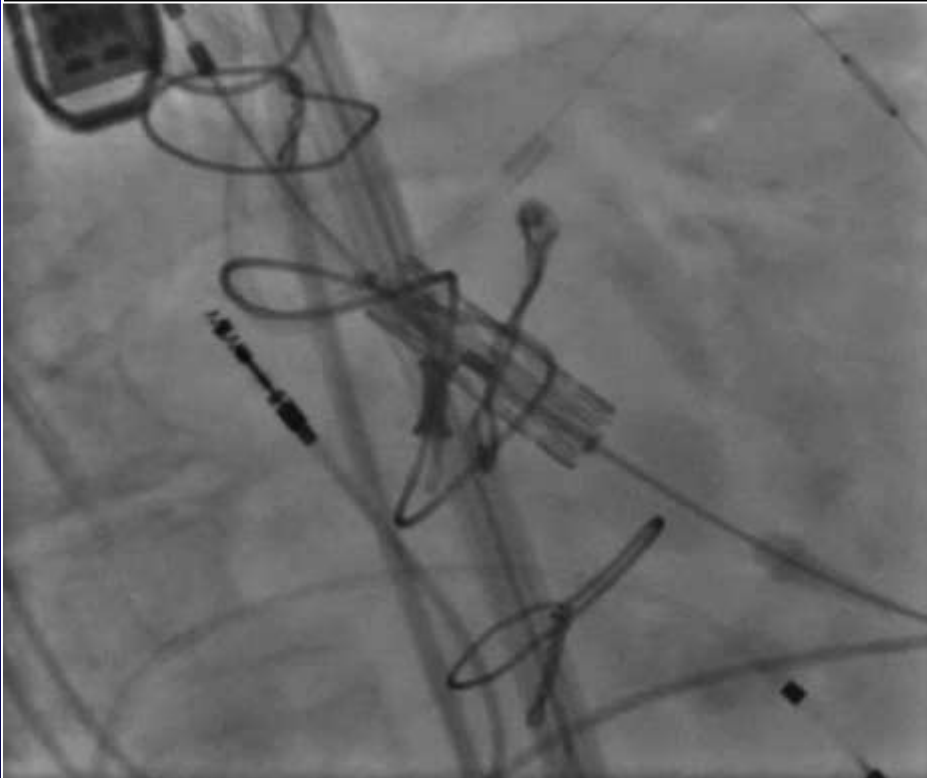


74 y/o female undergoing ViV with 23mm Sapien 3

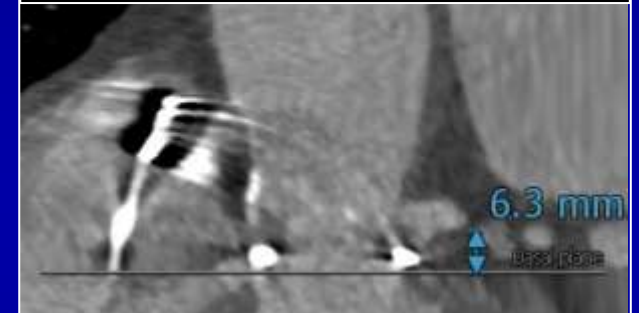
Degenerative 21mm Mitroflow valve

23mm Sapien 3 deployed

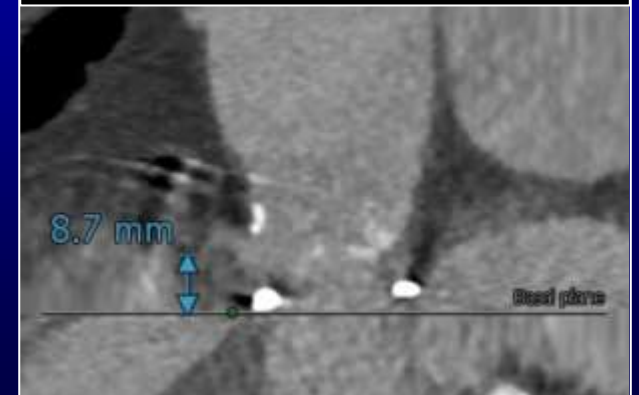
Left and right coronaries protected
due to low coronary height



Low LM height
6.3mm

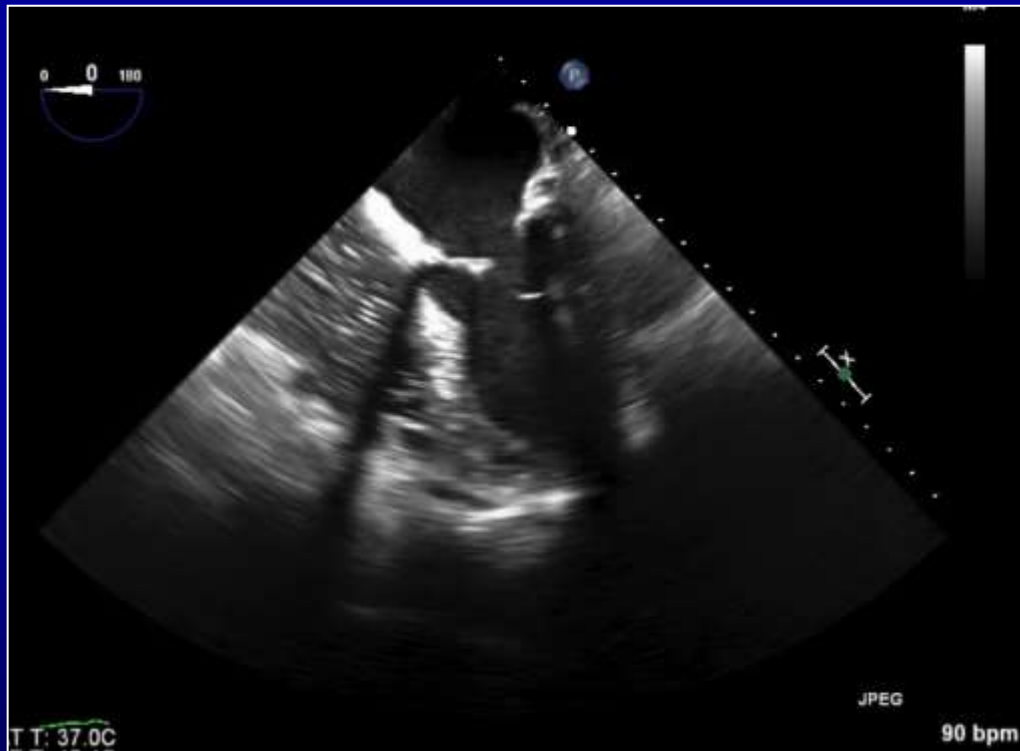


Low RCA height
8.7mm

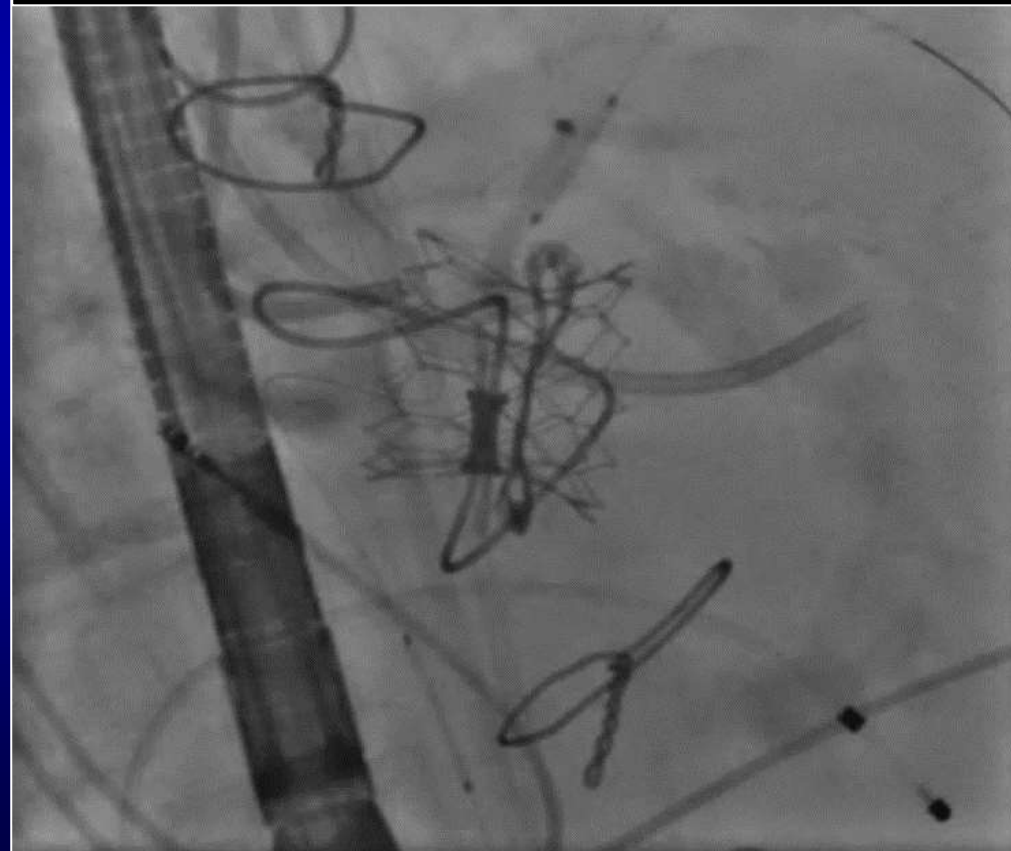


Cardiac arrest immediately following valve deployment

LM noted to be occluded



Occluded LM with no flow
Pre-positioned stent pulled from the LAD into the LM and deployed



Persistent cardiac arrest and ventricular fibrillation despite ostial LM stenting

Immediately placed on cardiopulmonary bypass



**LM wired by drilling through the
Mitroflow leaflet**

A 0.018 inch Astada 30 peripheral
guidewire through a Corsair

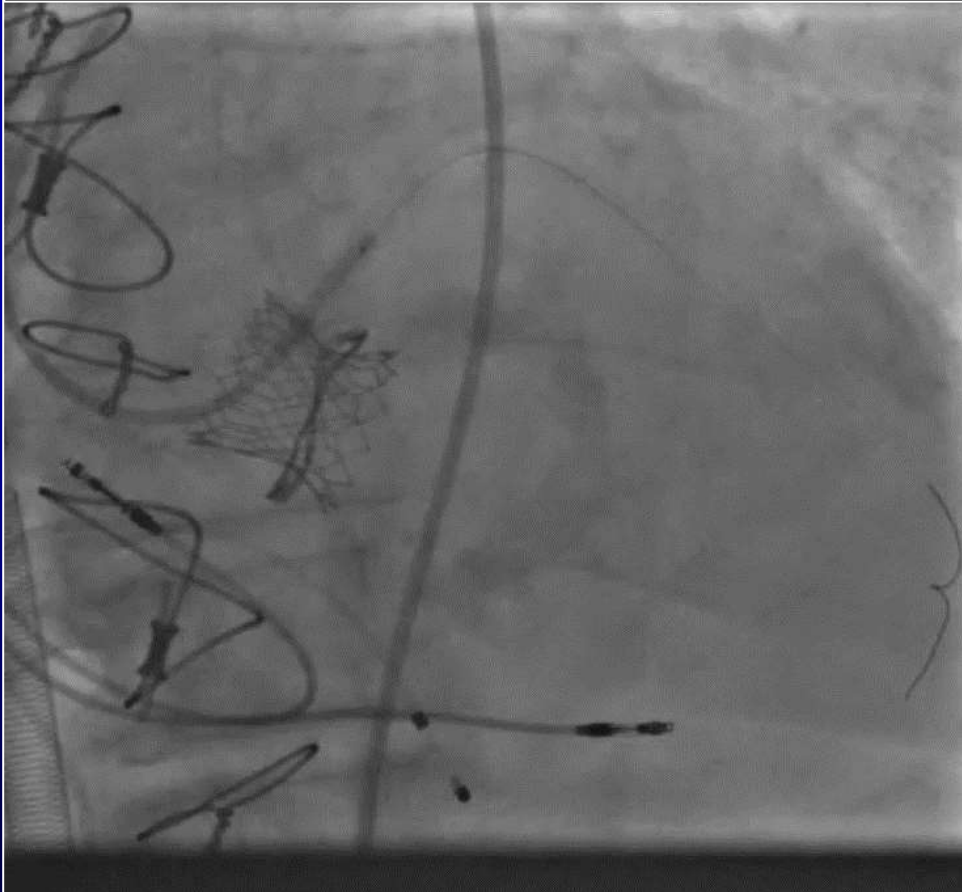
Unable to cross with Miracle Bro,
Ultimate Bro, Gaia 2nd, Confianza Pro

2nd LM stent deployed into the ostial LM

Restoration of TIMI 3 flow

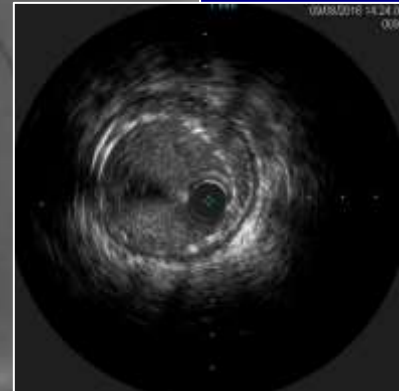
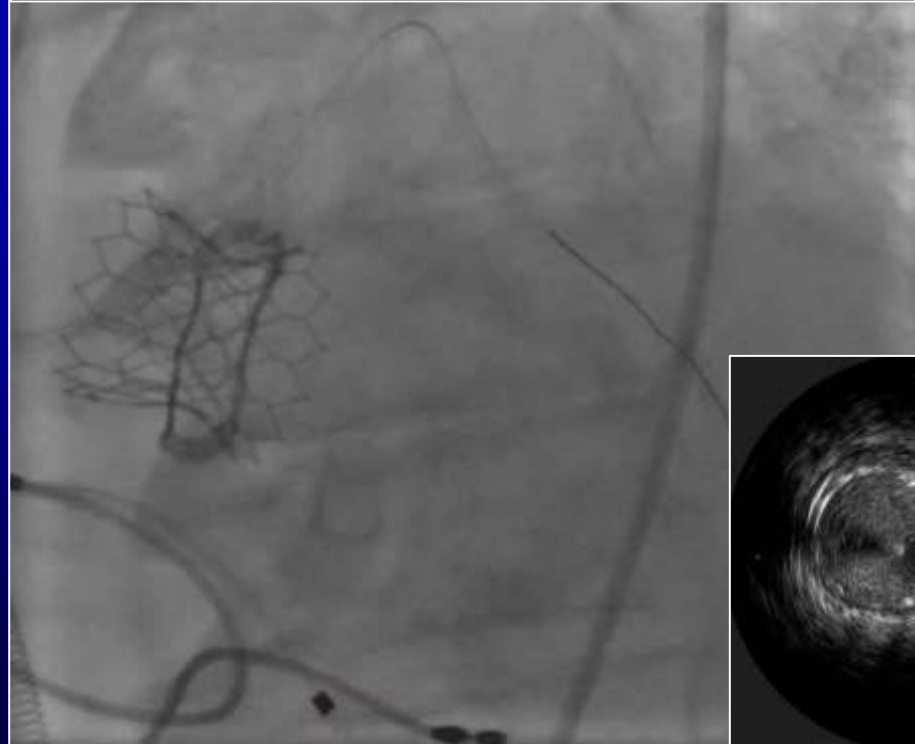
Cardiopulmonary bypass discontinued at the end of the procedure
Patient transferred to the ICU, discharged home 4 days later

Ostial LM stented



**Final result
TIMI 3 flow**

Stent extending from the LM ostium
into the TAVR valve frame

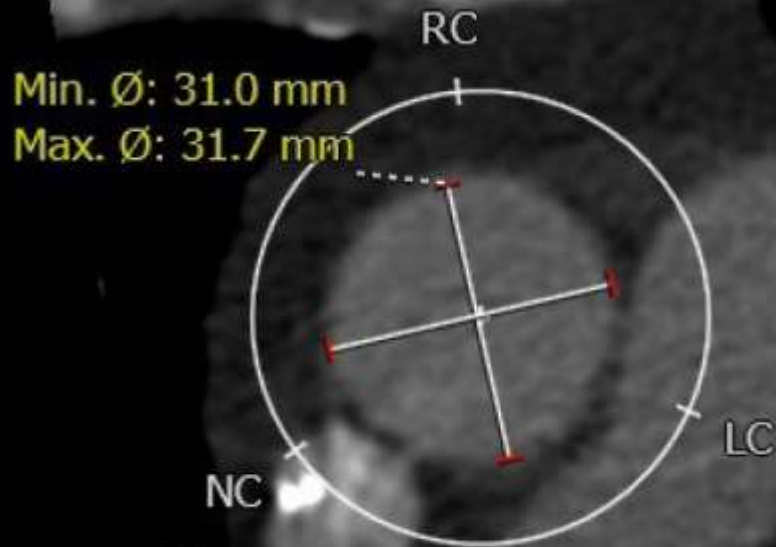


68 y/o female referred for TAVR

Cross-sectional CT for pre-TAVR work-up

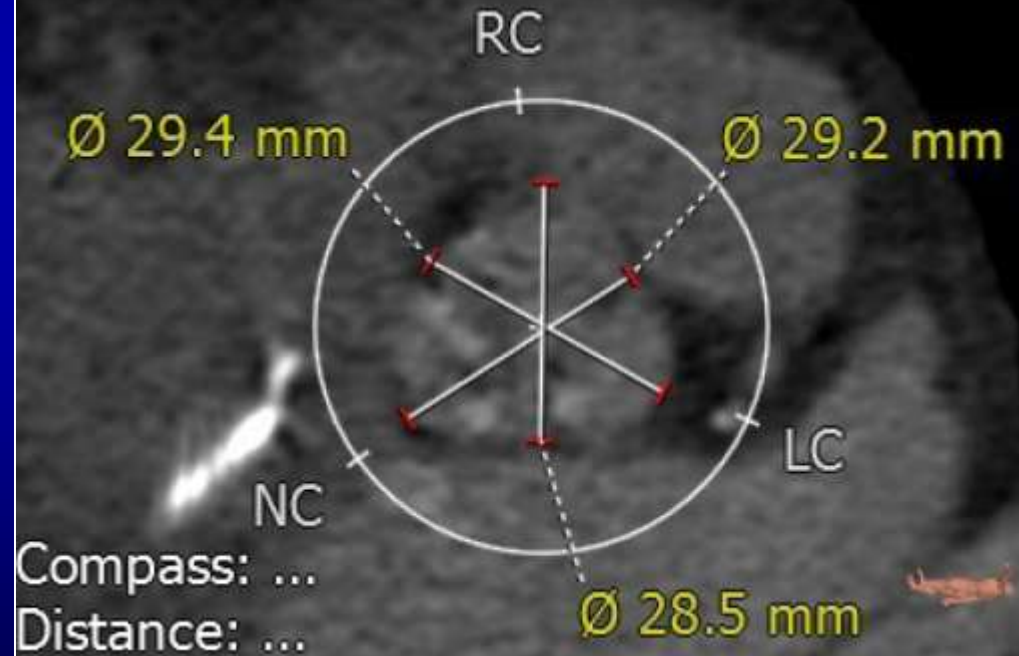
Plan for 26mm CoreValve

Aortic annulus



Compass: 50....
Distance: 55....

Sinus of valsalva



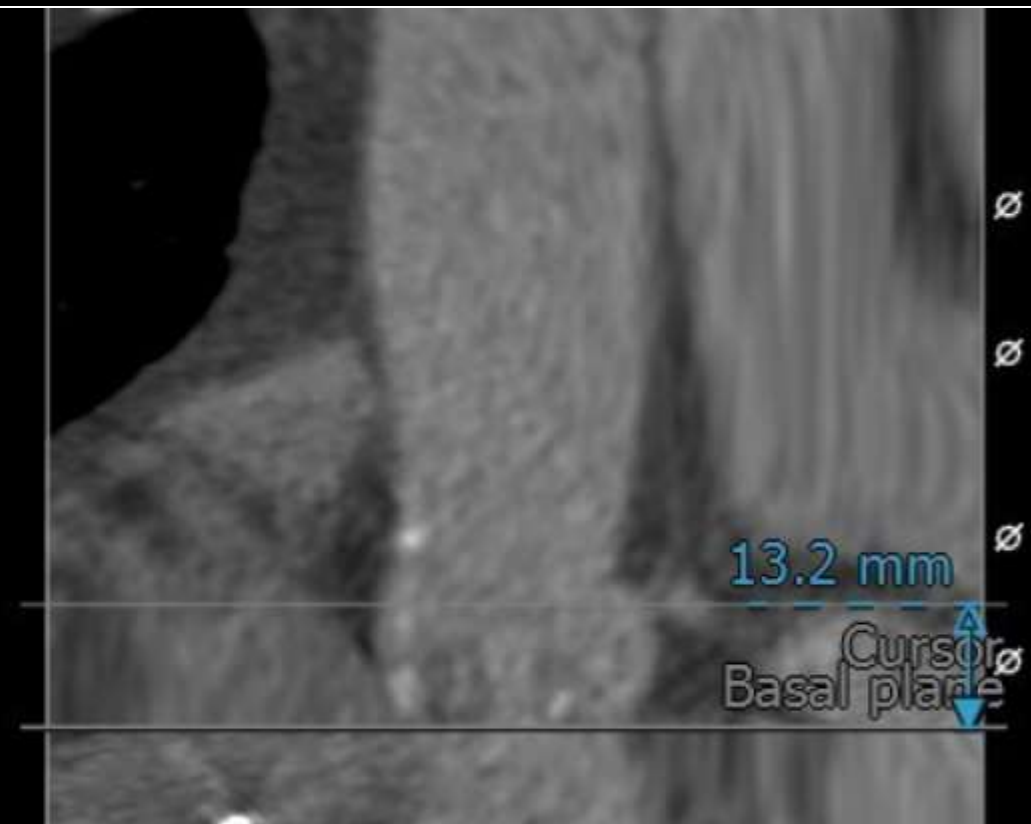
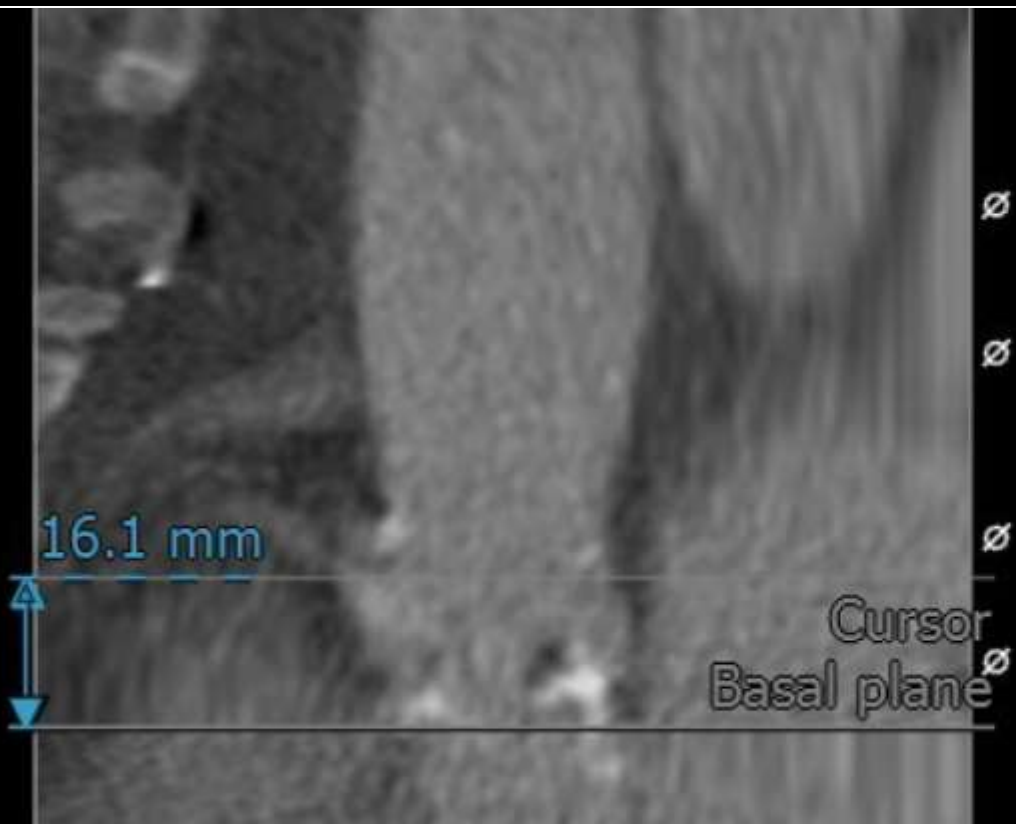
Compass: ...
Distance: ...

Cross-sectional CT for pre-TAVR work-up

Assessment of LM and RCA height from the annulus

RCA height
16.1 mm

LM height
13.2 mm

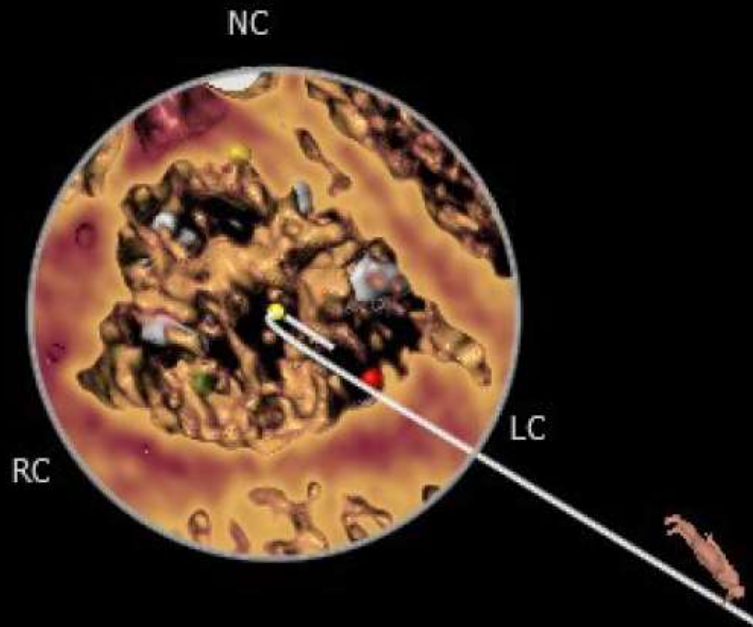


Cross-sectional CT for pre-TAVR work-up

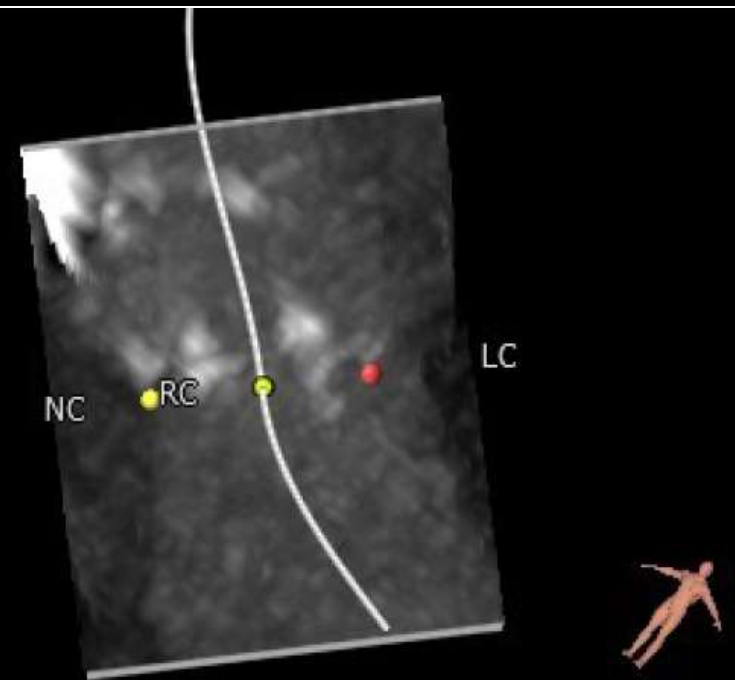
Assessment of annular and leaflet calcification

Minimal annular and leaflet calcification

RAO: 71°
Cranial: 37°



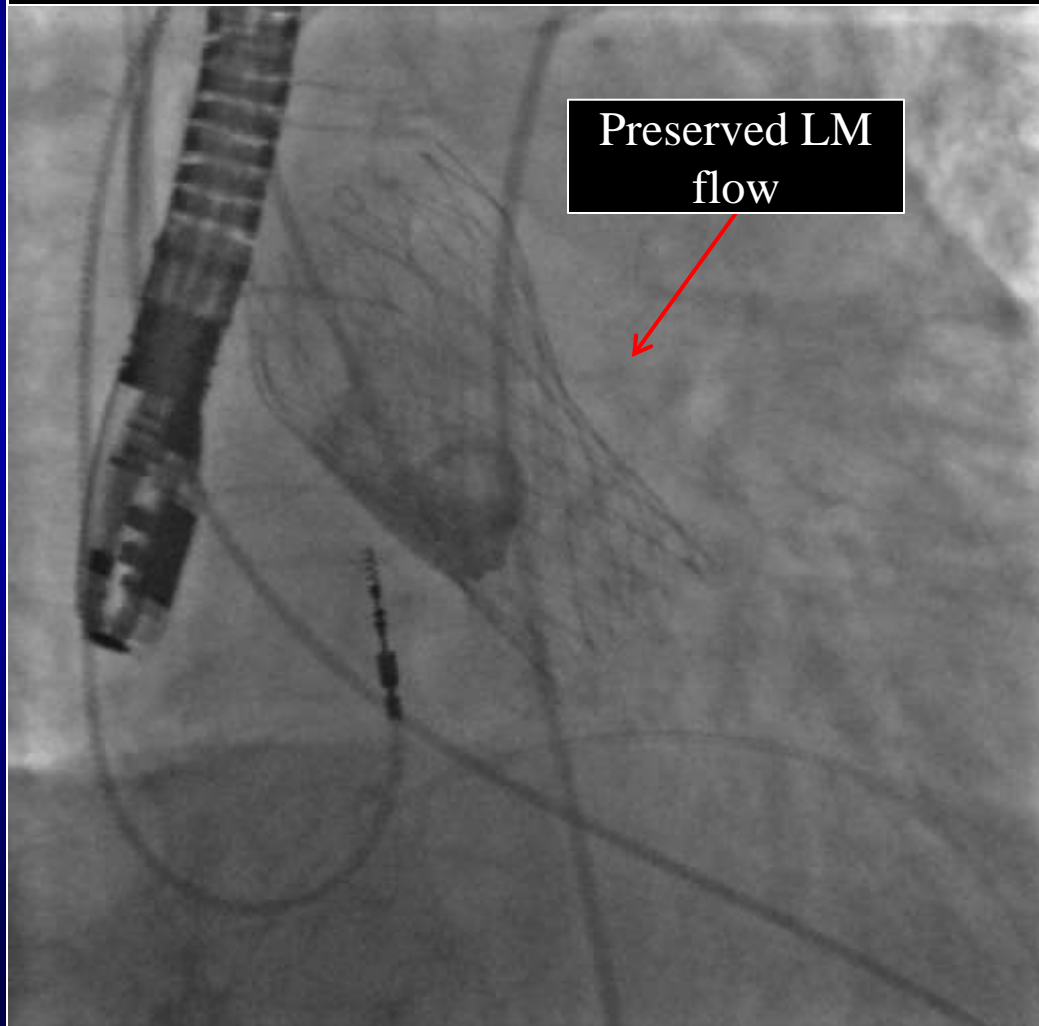
LAO: 20°
Cranial: 3°



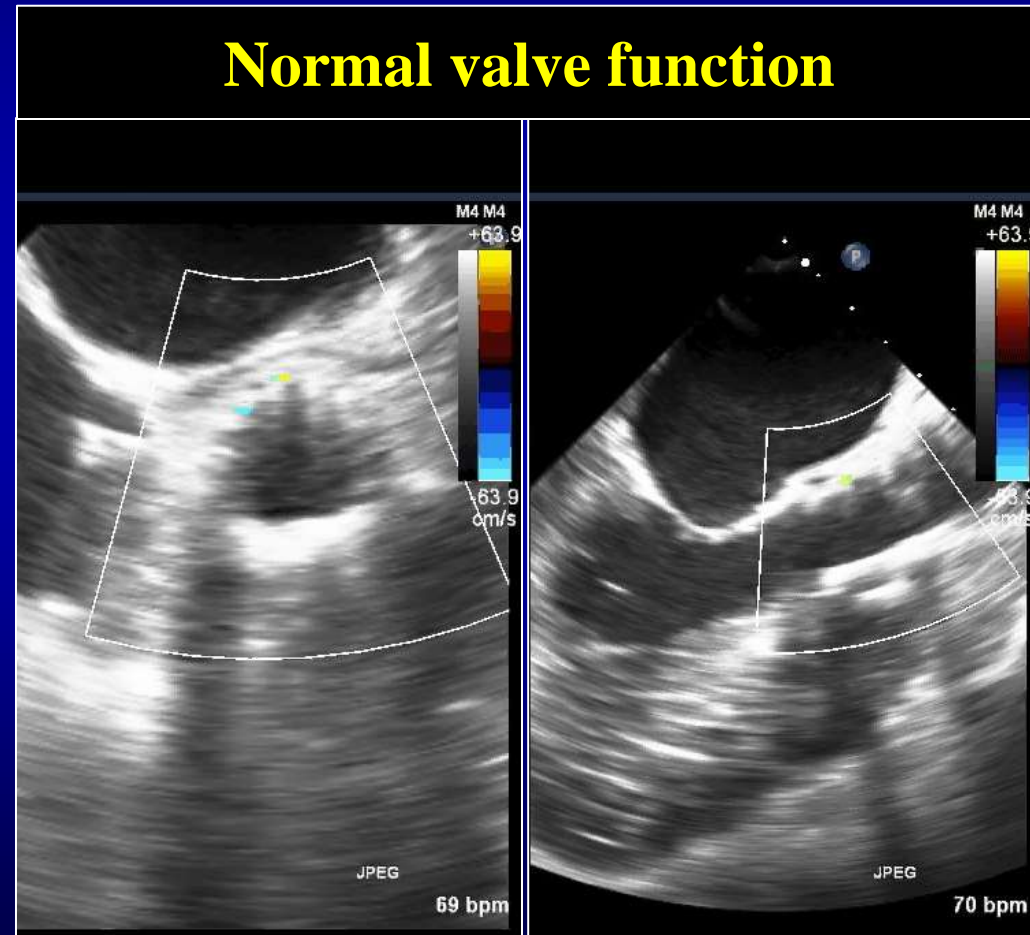
26mm CoreValve deployed

Normal valve function immediately post-deployment

26mm CoreValve deployed

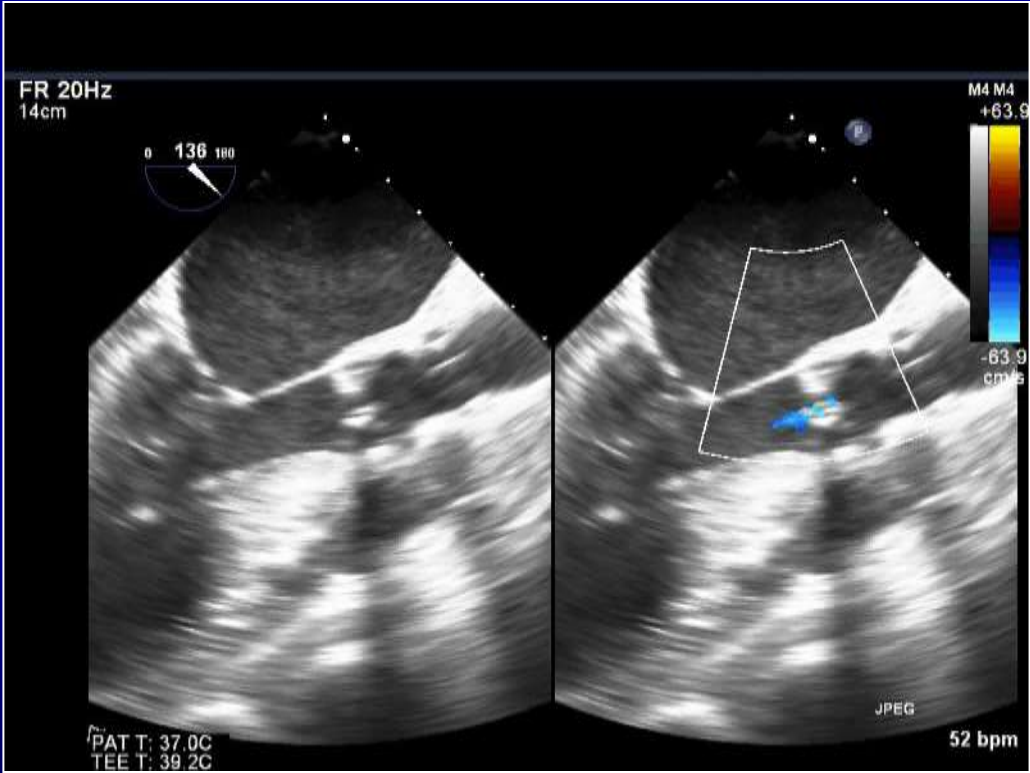
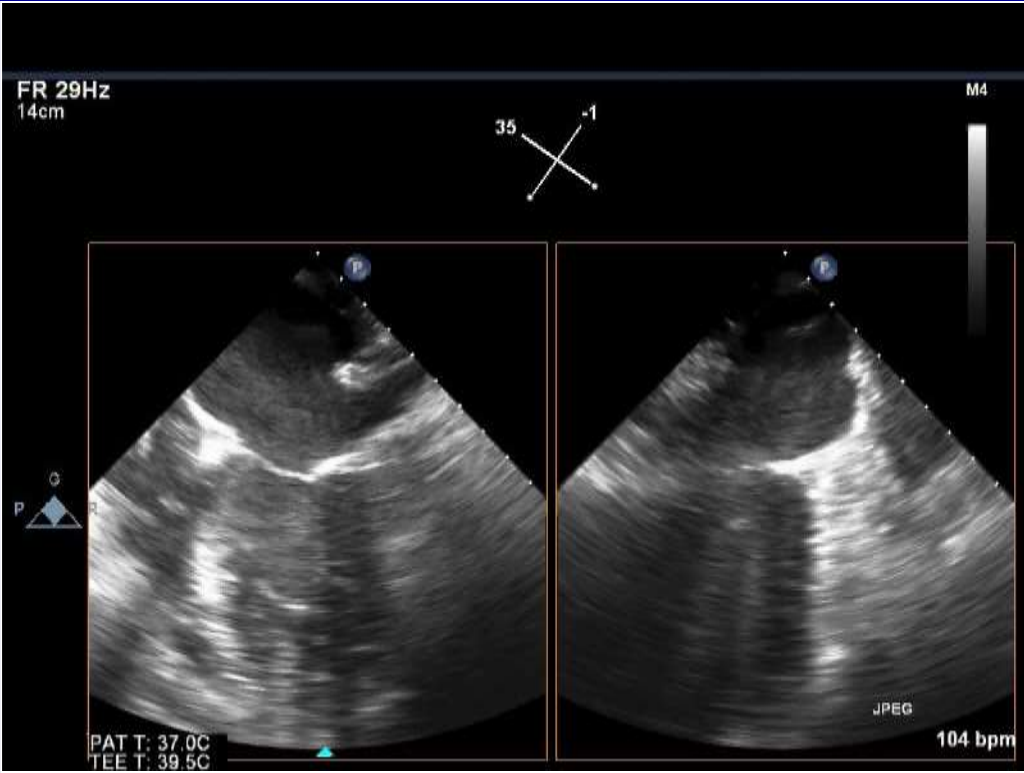


Normal valve function

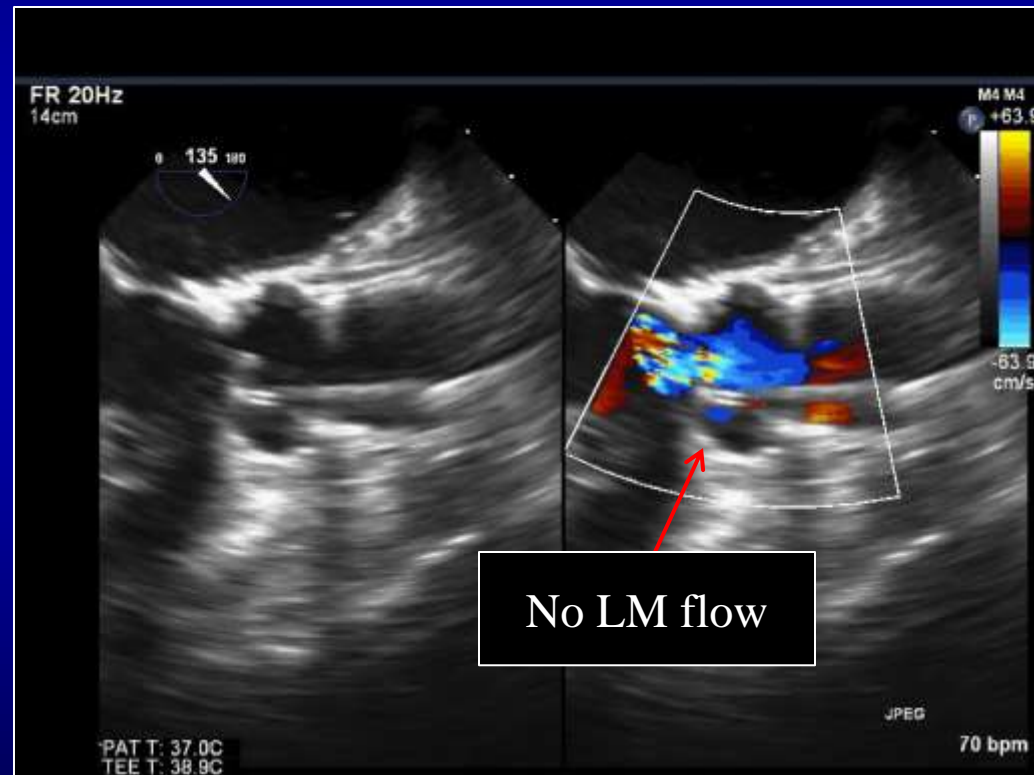
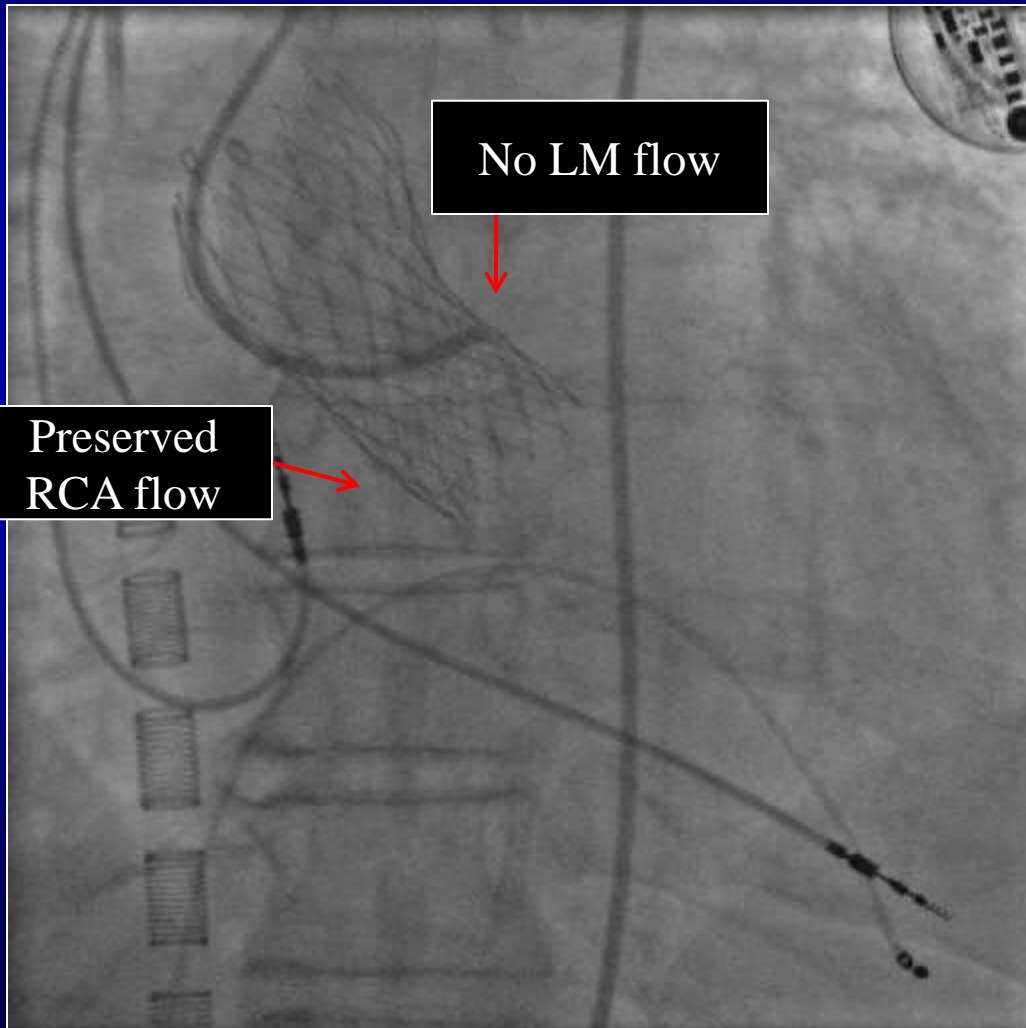


Progressive hemodynamic compromise in the next few minutes

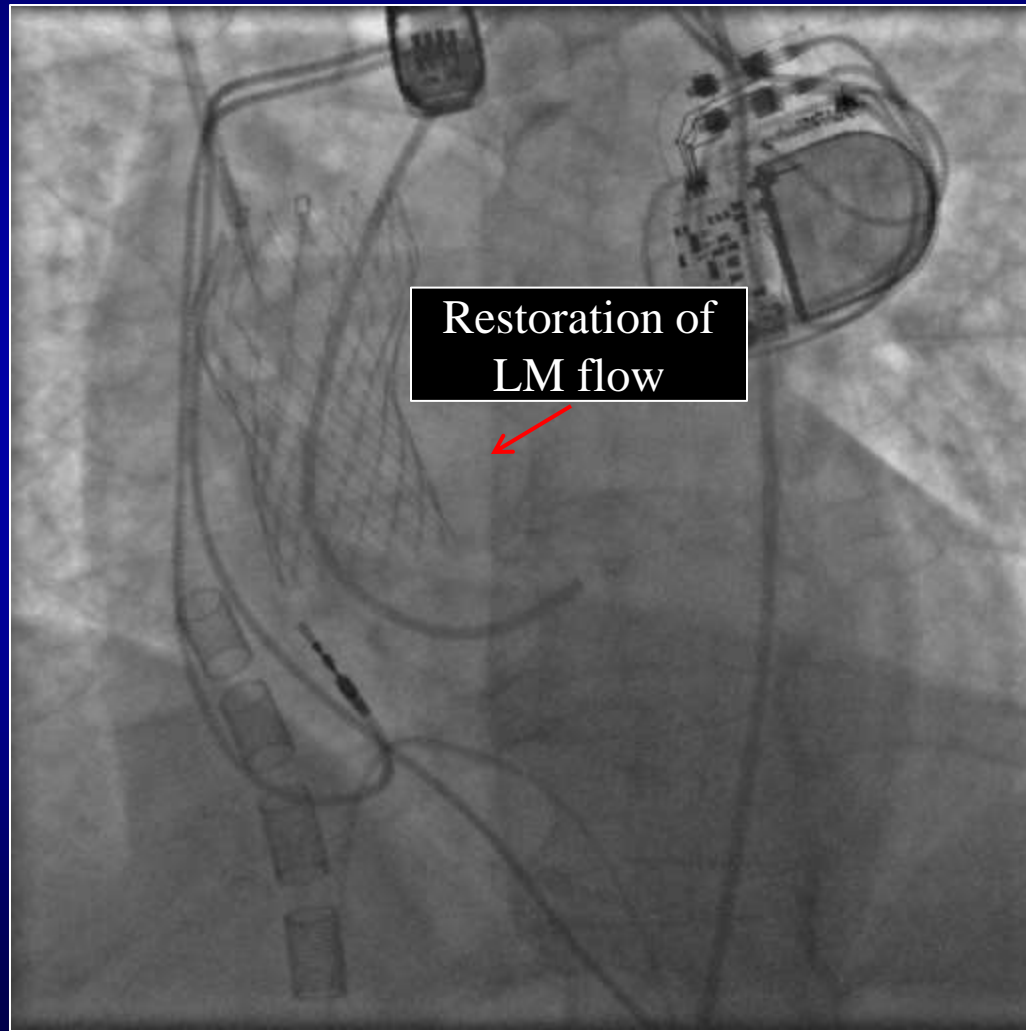
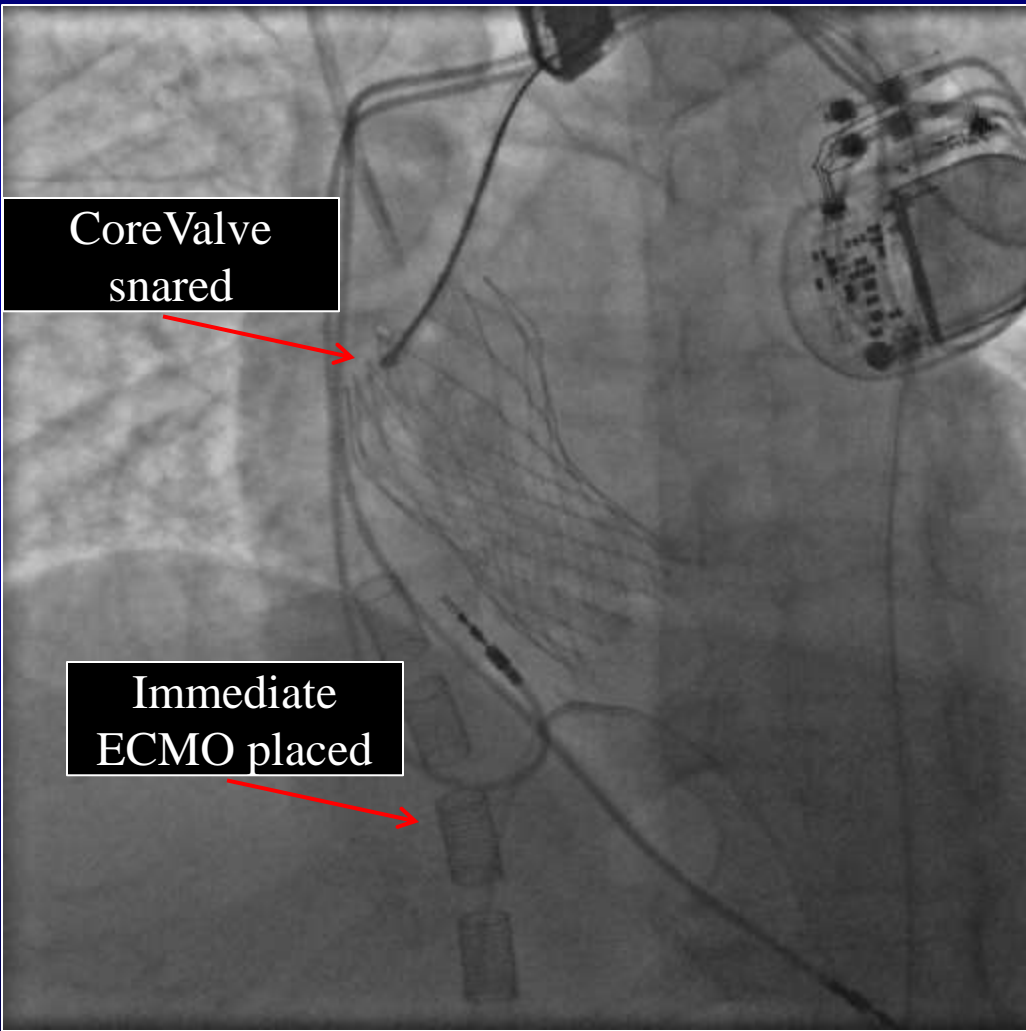
Ventricular fibrillation with multiple cycles of CPR



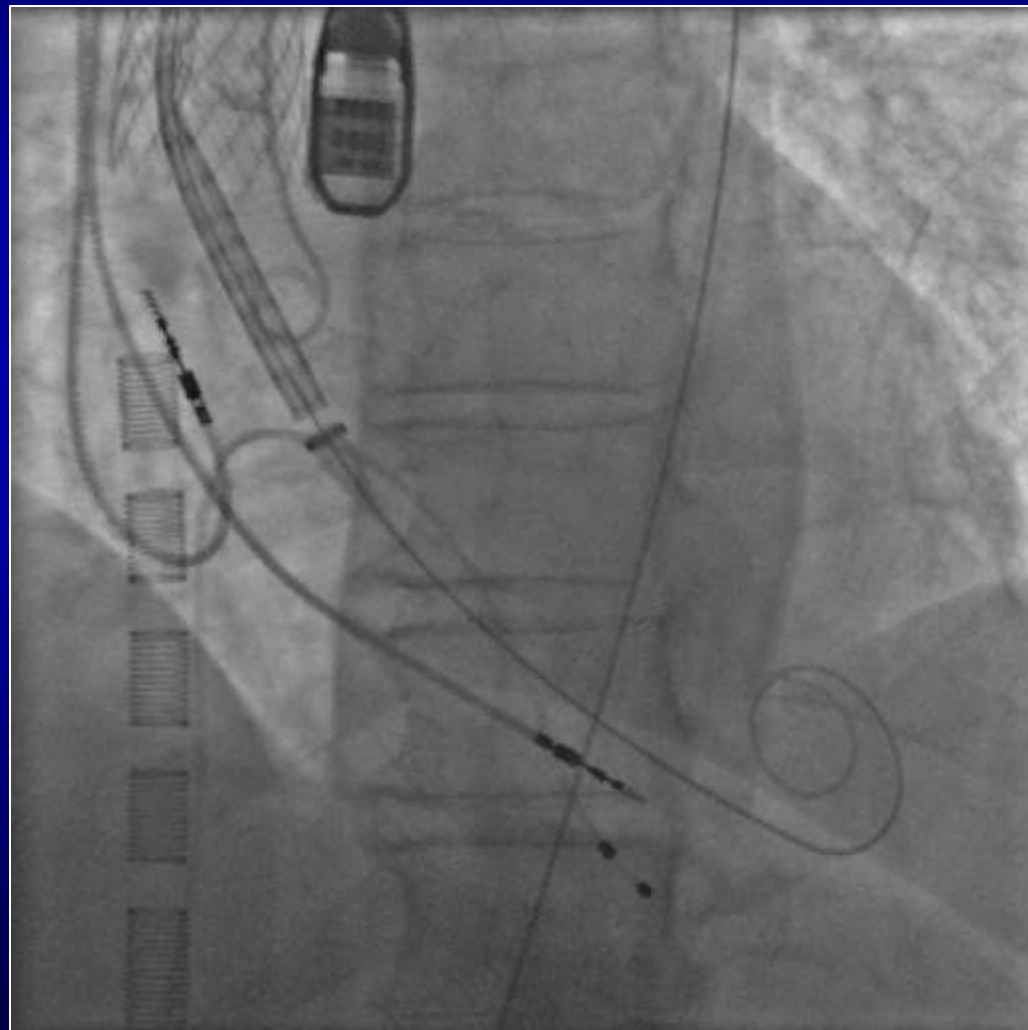
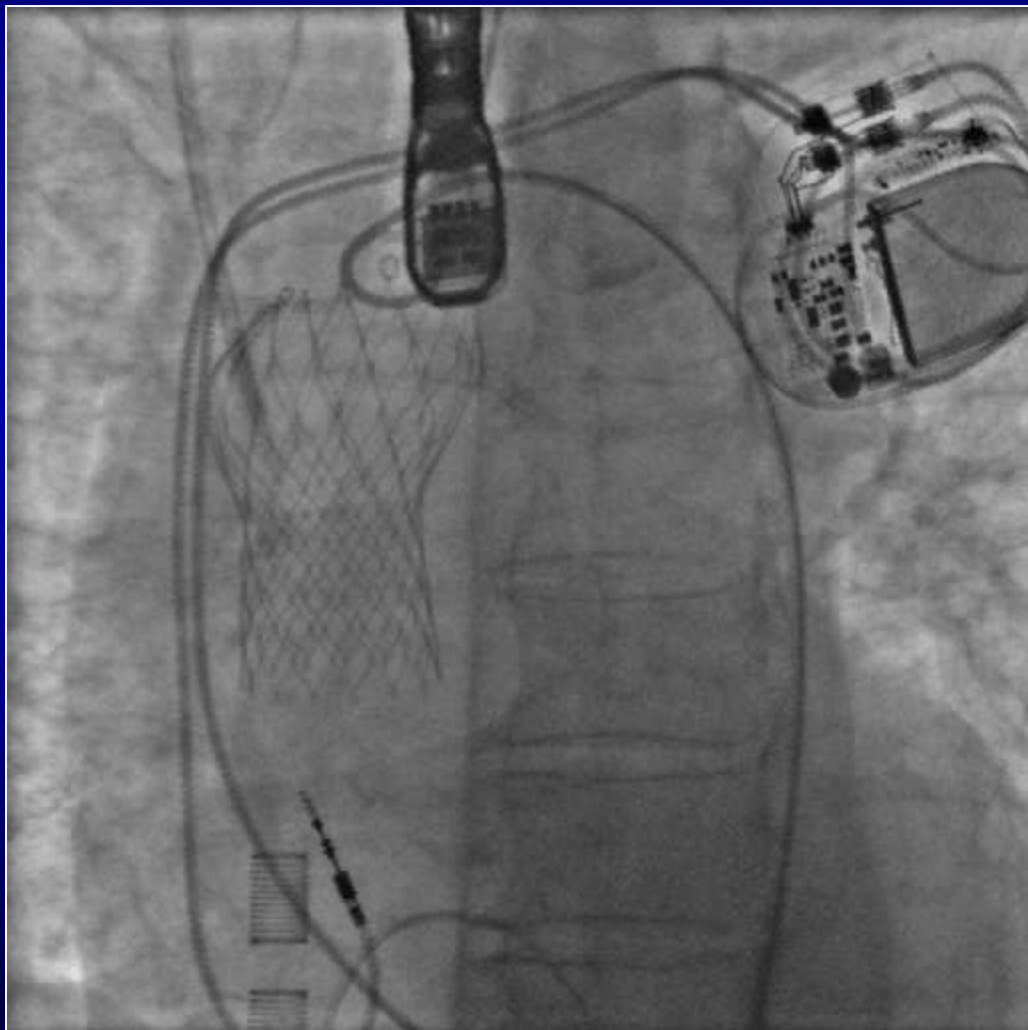
LM occlusion noted



CoreValve snared into ascending aorta with restoration of LM flow



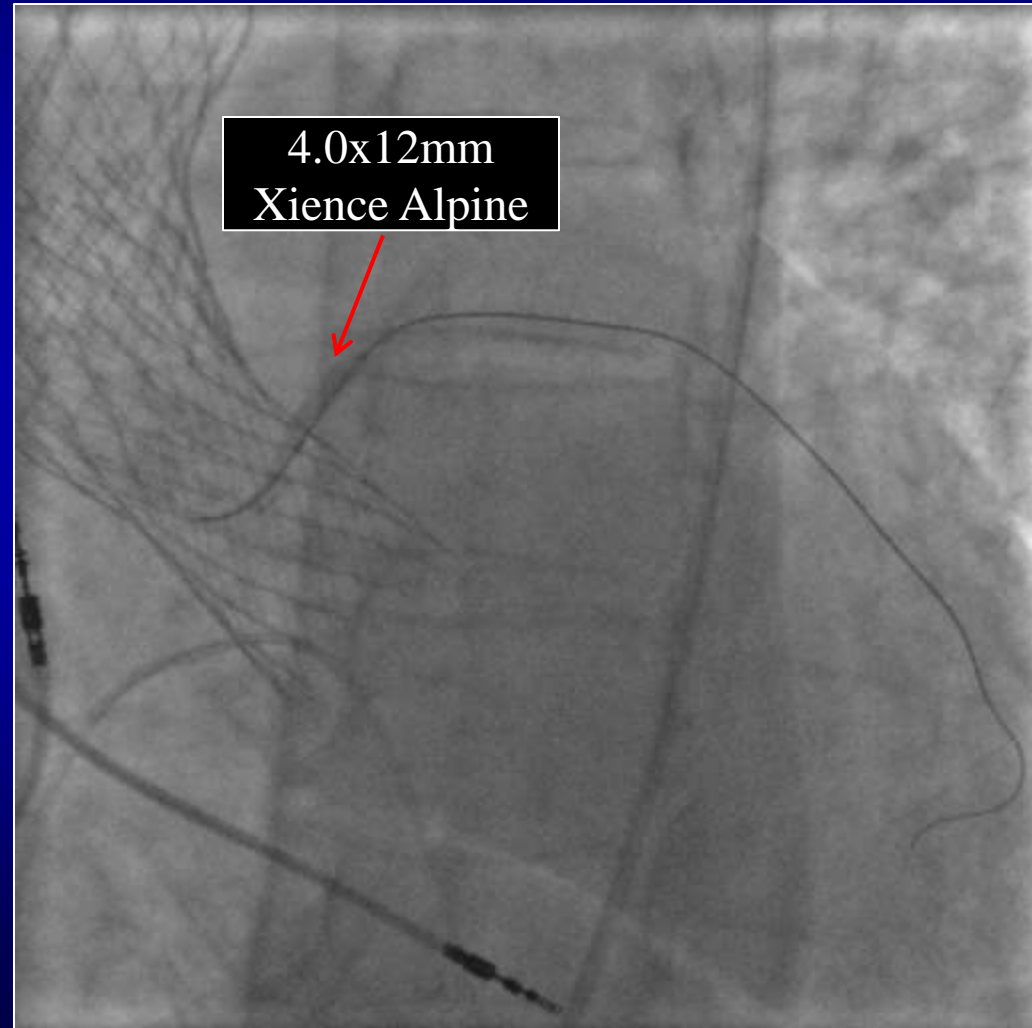
23mm CoreValve deployed across the native aortic valve



Residual LM stenosis after 2nd CoreValve deployment

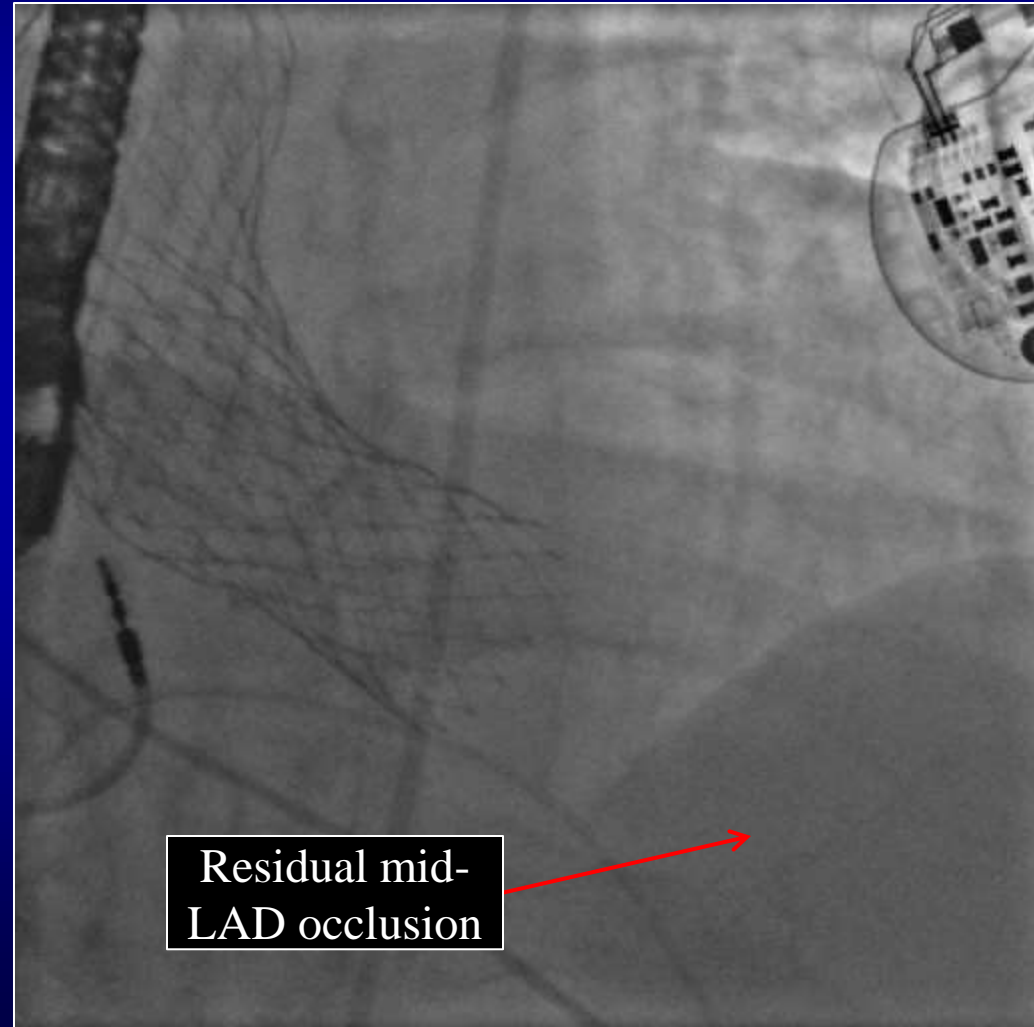
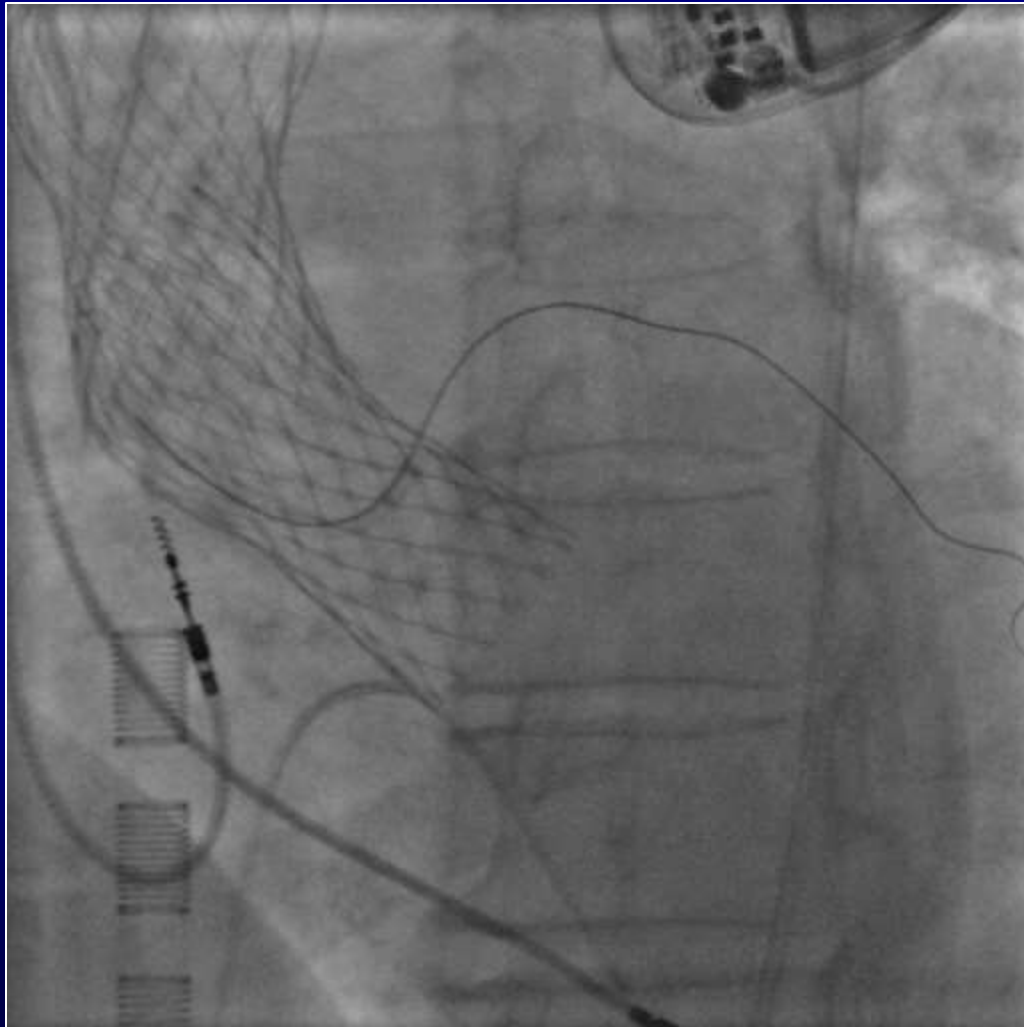
4.0 x 12mm Xience Alpine stent deployed

Residual ostial LM stenosis



Final angiographic result

ECMO removed after LM stent deployment



Residual mid-LAD occlusion

Clinical impact of coronary protection during transcatheter aortic valve implantation: first reported series of patients

Yigal Abramowitz, MD; Tarun Chakravarty, MD; Hasan Jilaihawi, MD; Mohammad Kashif, MD; Yoshio Kazuno, MD; Nobuyuki Takahashi, MD; Yoshio Maeno, MD, PhD; Mamoo Nakamura, MD; Wen Cheng, MD; Raj R. Makkar*, MD

Cedars-Sinai Heart Institute, Los Angeles, CA, USA

Cedars-Sinai approach for coronary protection

LM significant disease or LM ostial stent

Anatomical factors

- Low LM
- Narrow SOV
- Severe AV calcification

Valve-in-valve

- Mitroflow
- Trifecta
- Stentless
- Homografts

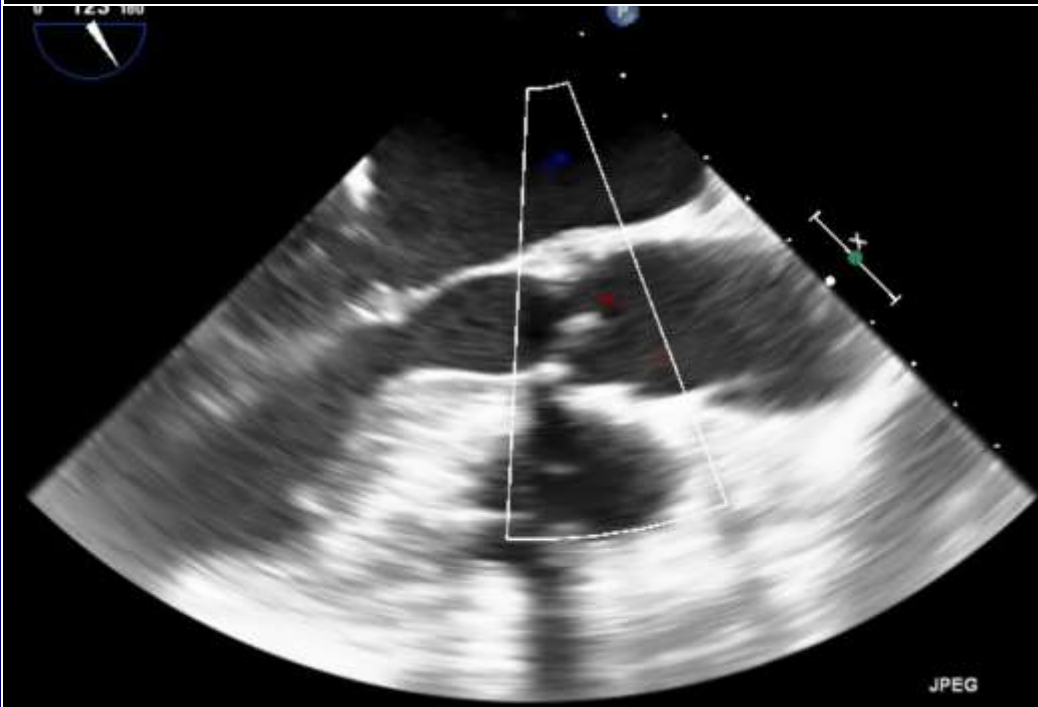
Coronary protection

TAVR in Mitroflow with cracking of the Mitroflow valve ring

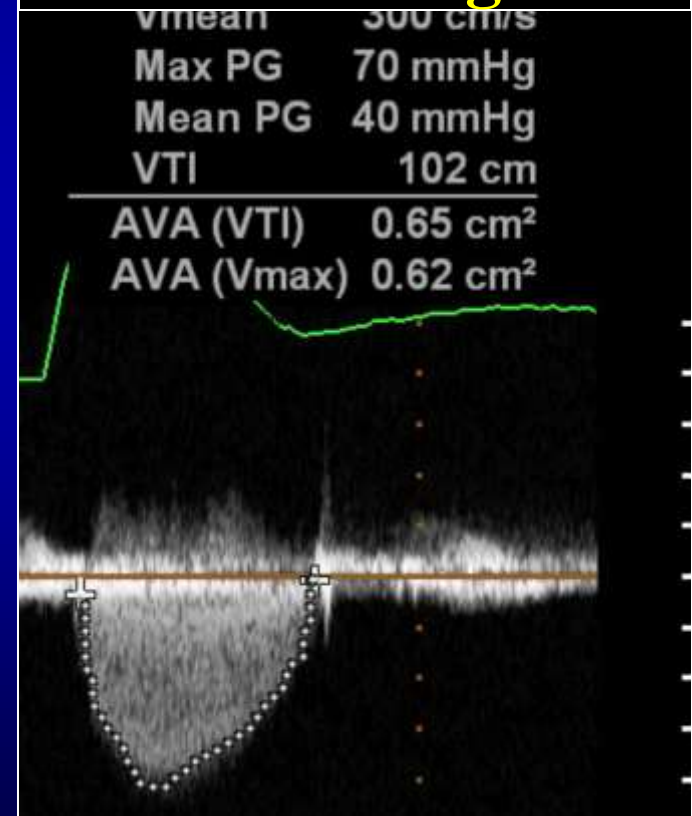
90 y/o female referred for transcatheter ViV

Deemed high-risk due to advanced age and comorbidities

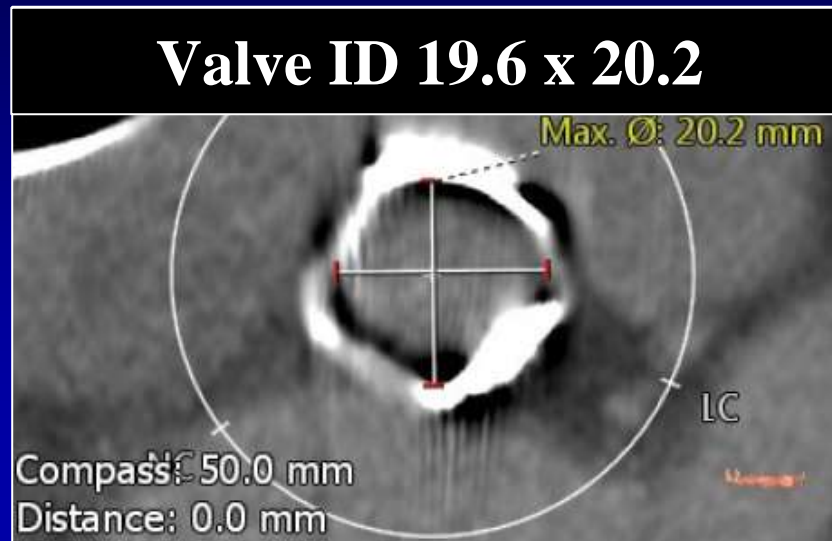
Severe aortic stenosis of #21 Mitroflow



Mean gradient 40mmHg



CT evaluation for TAVR



Low RCA height (5.5mm)



Low LM height (7.4mm)

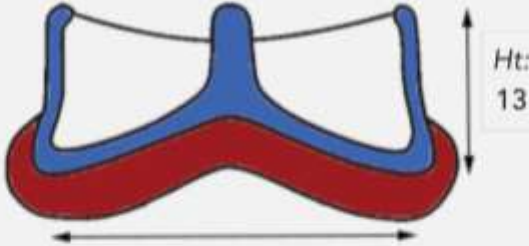


Plan for 20mm Sapien3 valve

Left and right coronary protection due to low coronary height

< Mitroflow Valve Size

Mitroflow, 21



Ht: 13

Stent ID: 17.3

! True ID 17

THV Selector

< Valve Size TAVI Choices

TAVI Valve Choices For:
Mitroflow, 21

Sapien 20	Core Valve Not Recommended
Portico Not Recommended	Jena Not Recommended
Lotus Not Recommended	S3 Not Recommended
Accurate TA Not Recommended	Accurate NEO Not Recommended

Home Stented Stentless Sutureless TAVI

Transcatheter ViV with a 20mm Sapien3

Coronary protection with 2 stents in LAD and LCx



Hemodynamics

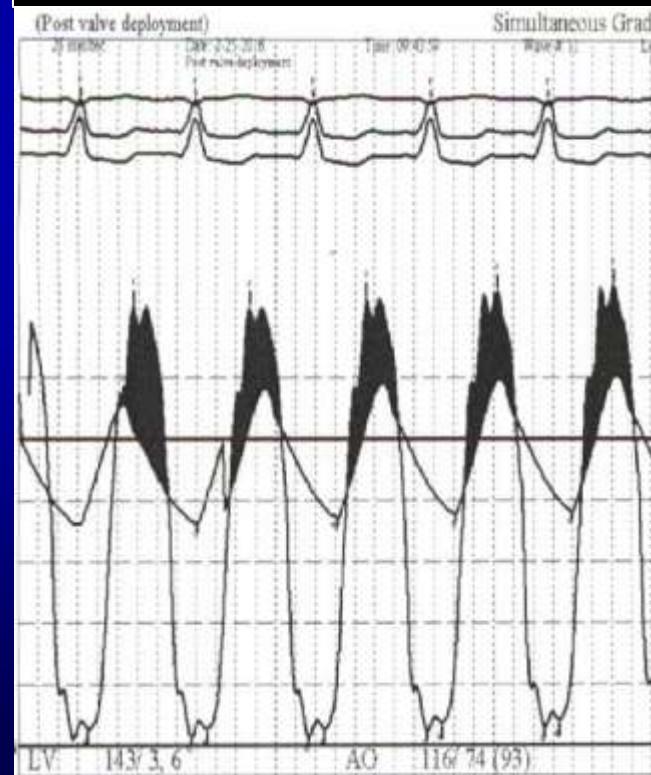
Baseline

Mean gradient 34.5mmHg



Post-valve deployment

Mean gradient 23.3mmHg



Post-dilation performed with a 22x4.5cm True Balloon



Reduction in gradients with post-dilation, but still high residual gradients

Post-valve deployment
Mean gradient 23.3mmHg

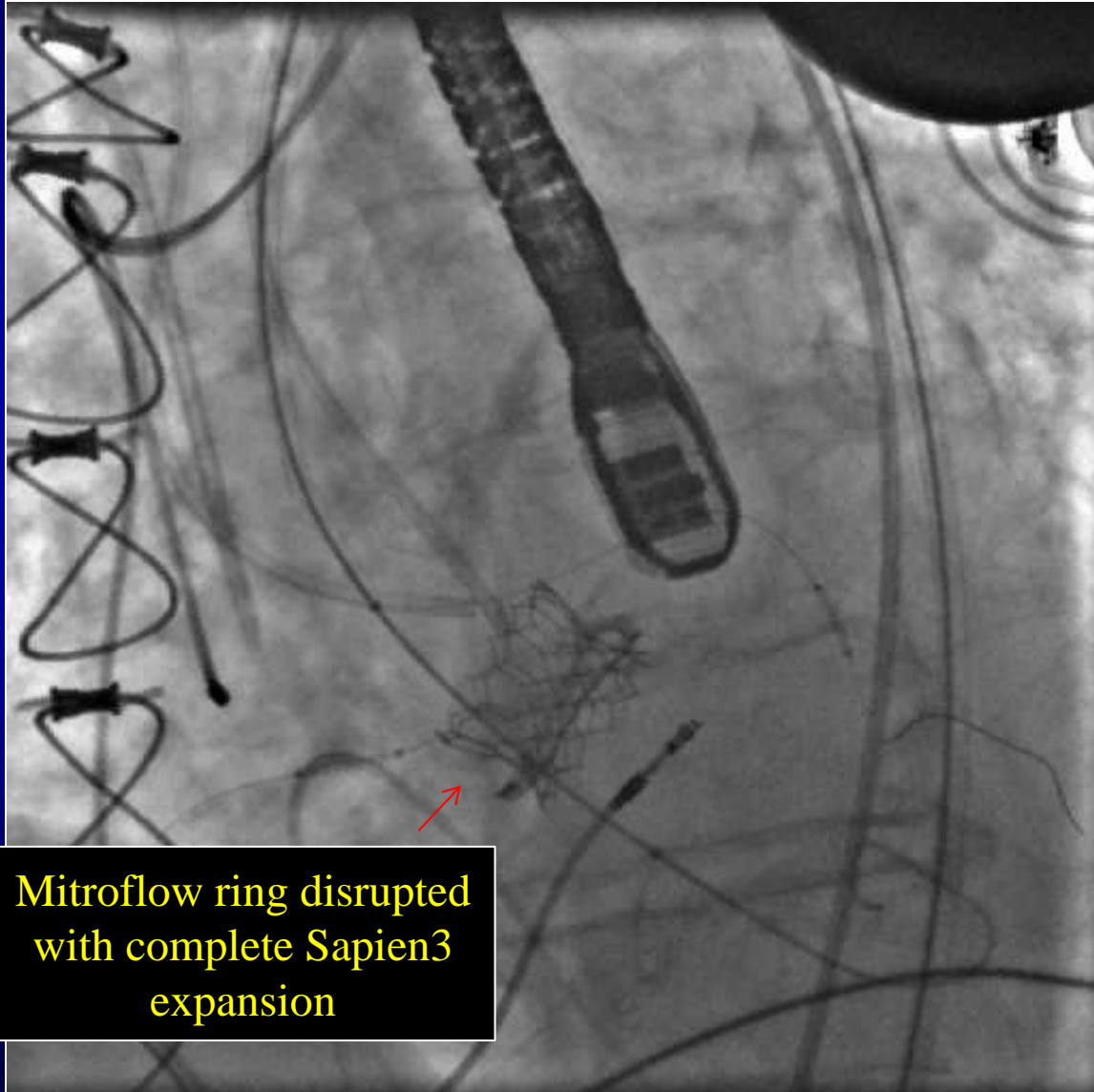


After 1st post-dilation
Mean gradient 12.5mmHg



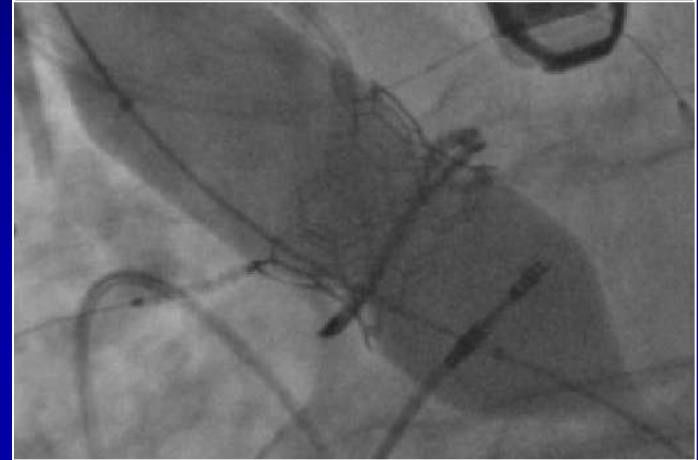
Post-dilation performed with a 22x4.5cm True Balloon

MitroFlow valve ring fractured

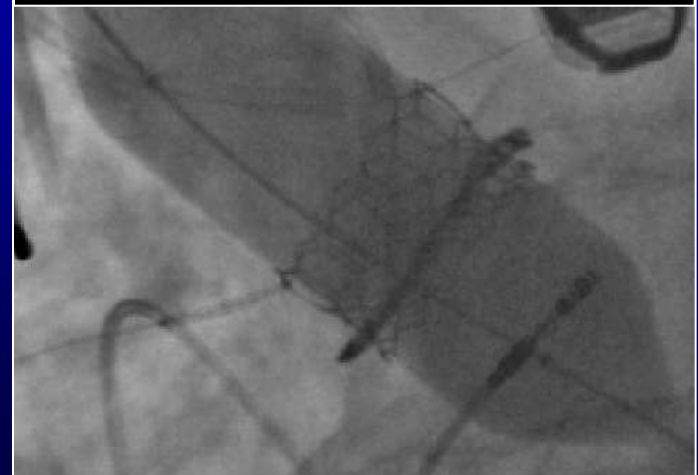


Mitroflow ring disrupted
with complete Sapien3
expansion

Before post-dilation



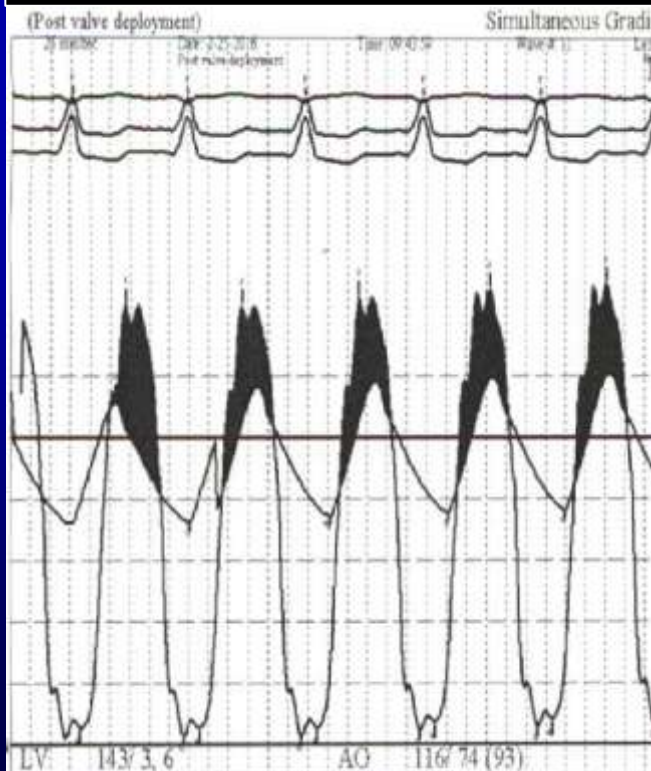
After post-dilation



Hemodynamics

Successful reduction in gradients with fracturing the Mitroflow ring

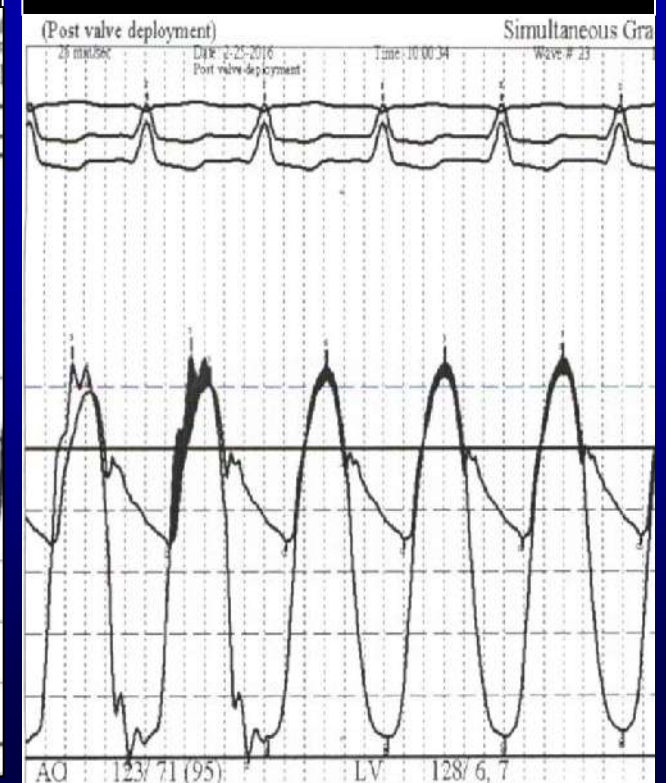
Post-valve deployment
Mean gradient 23.3mmHg



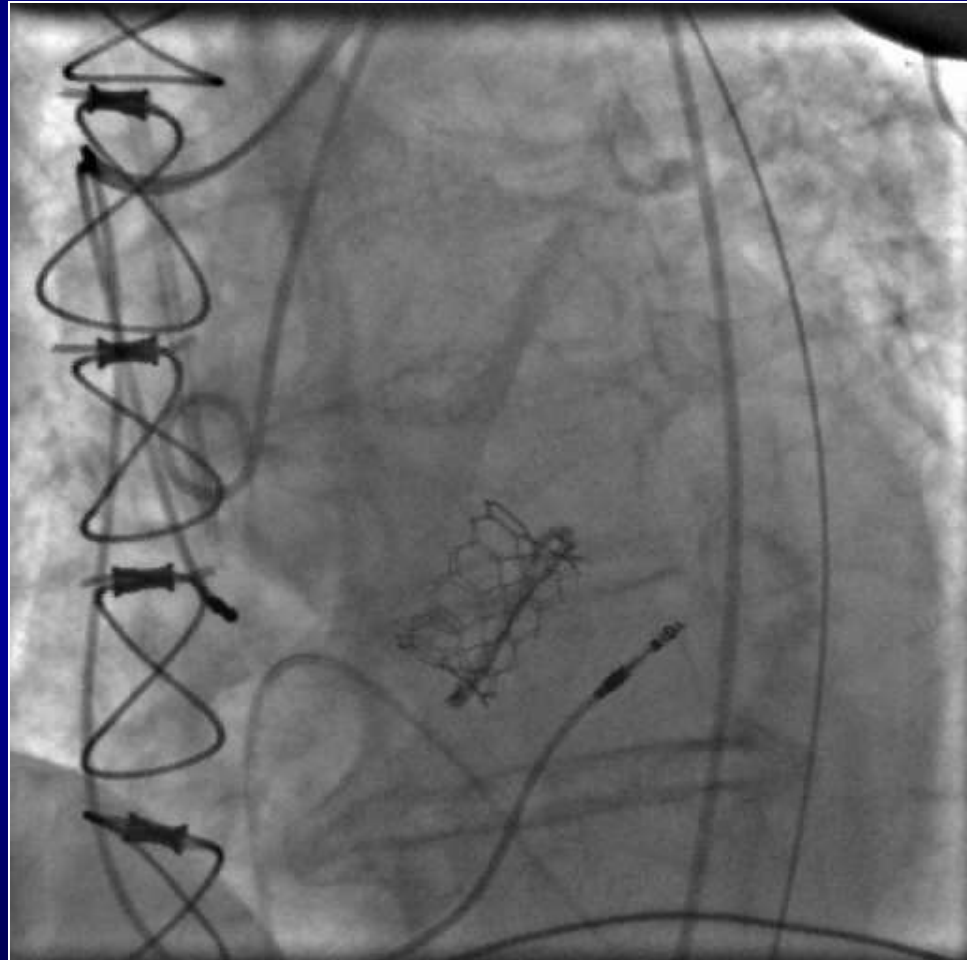
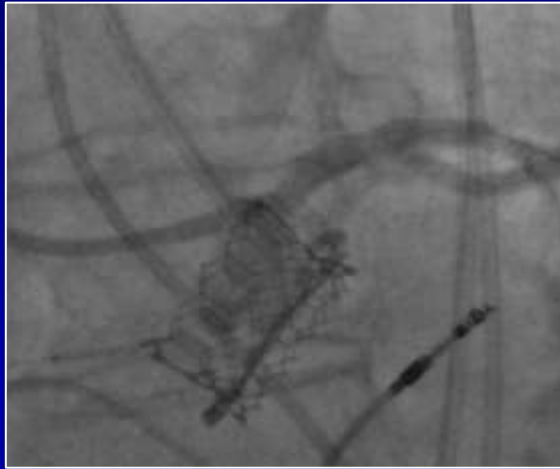
After 1st post-dilation
Mean gradient 12.5mmHg



After 2nd post-dilation with fracturing of the Mitroflow ring
Mean gradient 5.8mmHg



Ostial RCA and ostial LM stents deployed for coronary protection



Background

- 78 yr old female patient w/ PMHx severe symptomatic AS, HTN, HL, atrial fibrillation, and congestive heart failure.
- Symptoms: worsening fatigue and shortness of breath over the past year with multiple admission for heart failure

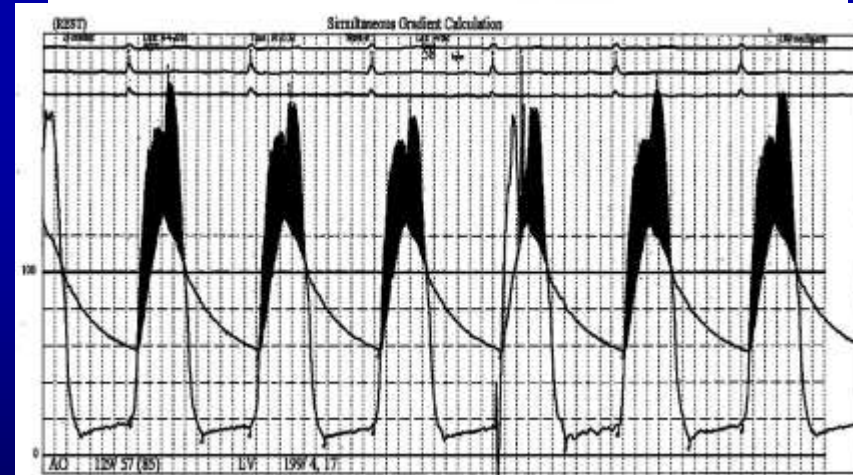
Procedure

Intra-procedure TEE pre-TAVR



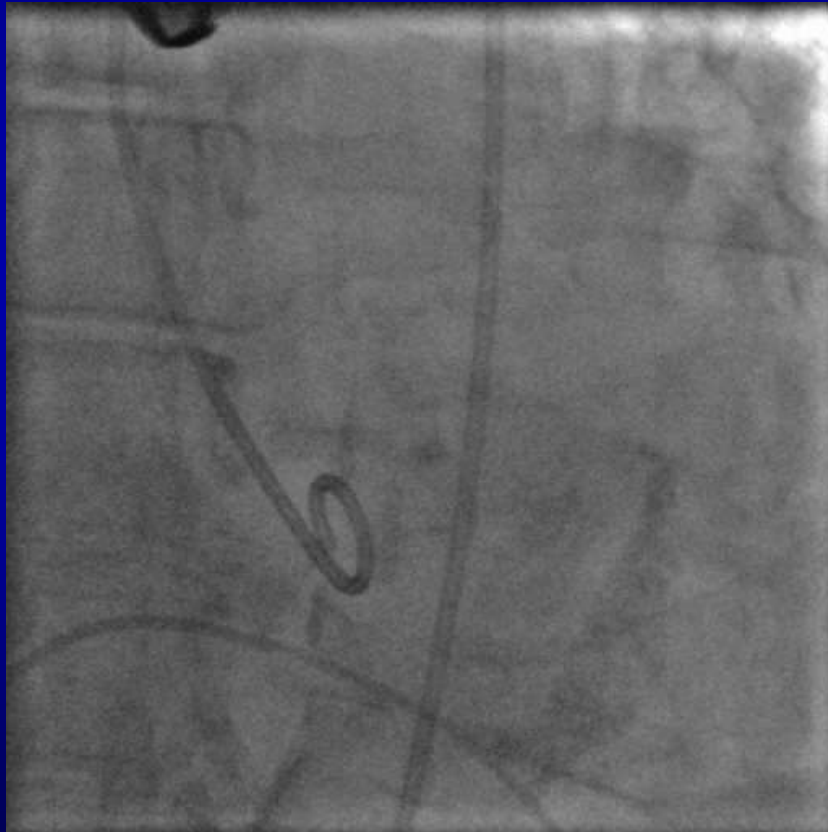
Baseline Hemodynamics

AD	183 / 82	(122) SA	70	18:34:42
LV	5 / 4,	4	70	18:34:42
AO	129 / 57	(85)	58	18:35:32
LV	199 / 4,	17	58	18:35:32
Aortic Grd	51.9 mm/ 361 ms/ 70.0 p-p		58	18:35:32

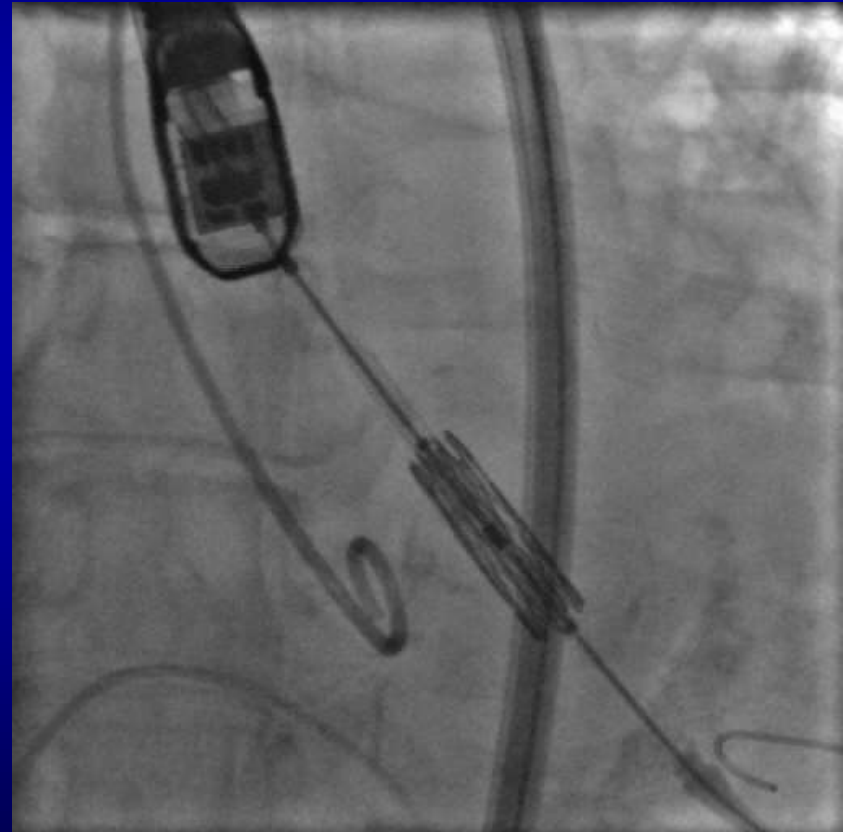


Procedure

Baseline Aortic Root Angiography



23S3 Valve Deployment

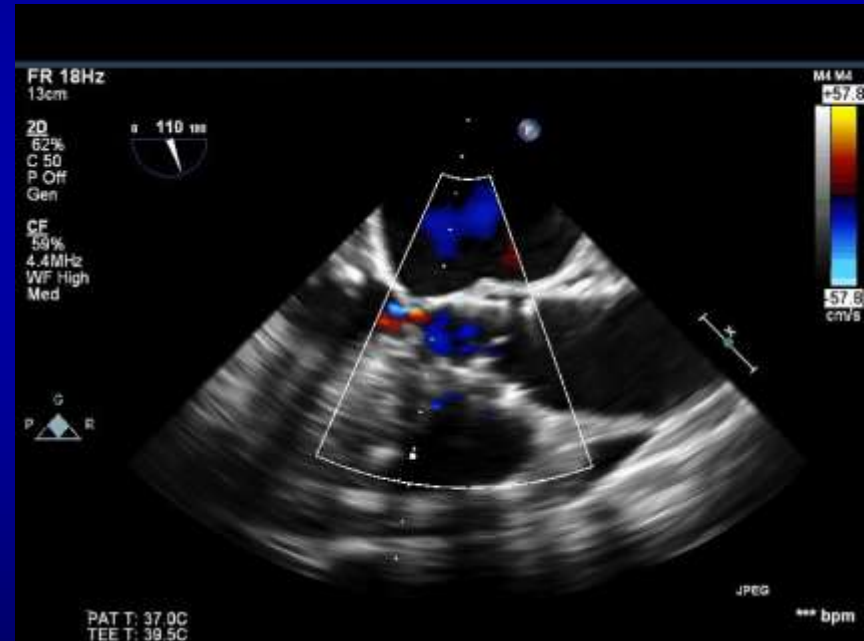


Procedure

TEE post-TAVR deployment



TEE post-TAVR deployment

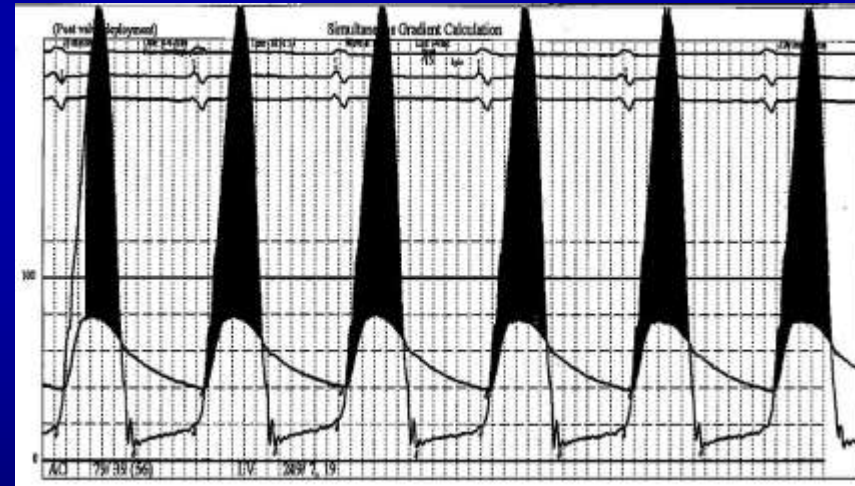


Procedure

Post-TAVR Hemodynamics

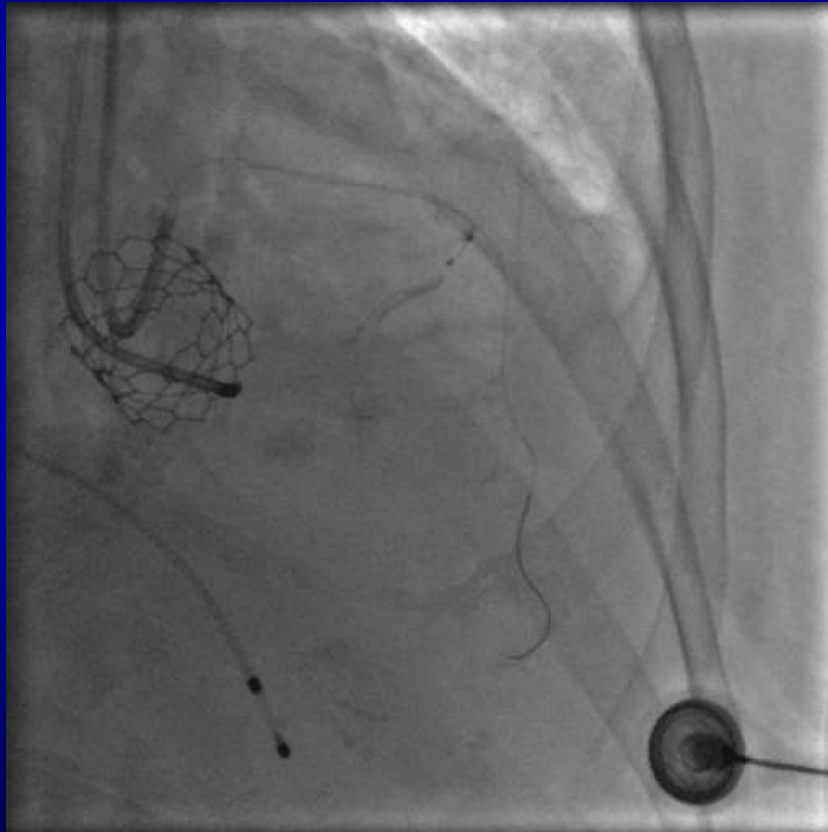
AO	211 / 73	(117) SA	44	18:45:24
LV	253 / 15,	30	44	18:45:24
Aortic Grd	29.2 mn/ 385 ms/ 42.0 p-p		44	18:45:24
AO	91 / 45	(65)	50	18:49:24
LV	259 / 10,	21	50	18:49:24
AO	90 / 44	(64)	51	18:49:45
LV	120 / 8,	22	51	18:49:45
Aortic Grd	18.5 mn/ 232 ms/ 30.0 p-p		51	18:49:45
Aortic Grd	96.5 mn/ 505 ms/ 168.0 p-p		50	18:49:24
AO	84 / 41	(60)	49	18:50:30
LV	98 / 9,	20	49	18:50:30
Aortic Grd	13.3 mn/ 184 ms/ 14.0 p-p		49	18:50:30
AO	79 / 39	(56)	49	18:51:13
LV	249 / 7,	19	49	18:51:13
Aortic Grd	96.3 mn/ 483 ms/ 170.0 p-p		49	18:51:13
AO	171 / 80	(113)	43	18:52:16
LV	249 / 11,	18	43	18:52:16
Aortic Grd	47.1 mn/ 359 ms/ 78.0 p-p		43	18:52:16
AO	113 / 53	(77)	47	18:54:33
LV	132 / 11,	20	47	18:54:33
Aortic Grd	20.3 mn/ 197 ms/ 19.0 p-p		47	18:54:33
AO	105 / 50	(73)	55	19:50:06
LV	157 / 11,	22	55	19:50:06
Aortic Grd	41.8 mn/ 356 ms/ 52.0 p-p		55	19:50:06

Post-TAVR Pressure Waveforms



Septal Ablation Procedure

Septal Ablation

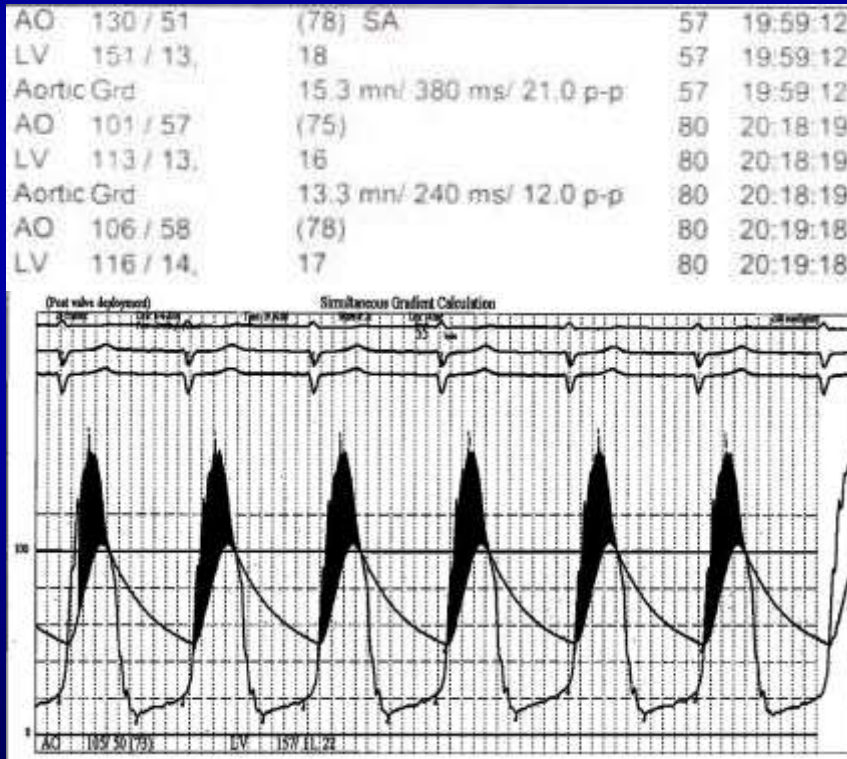


Septal Ablation



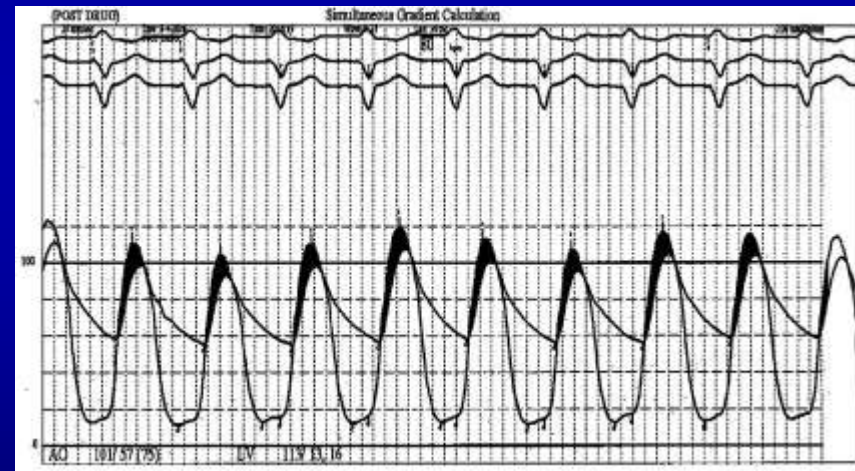
Septal Ablation Procedure

Hemodynamics Post-Ablation



Gradient after 1st septal ablation

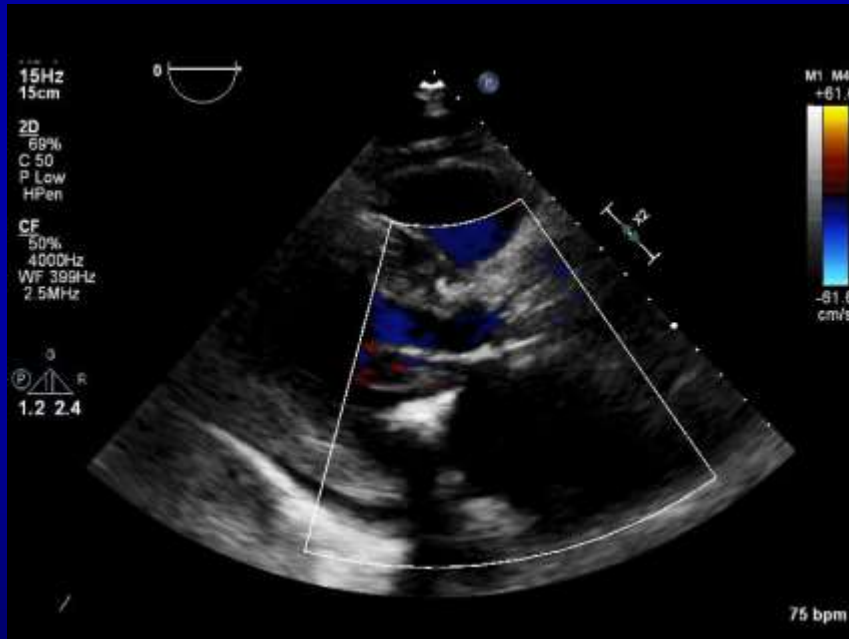
Final Pressure waveforms



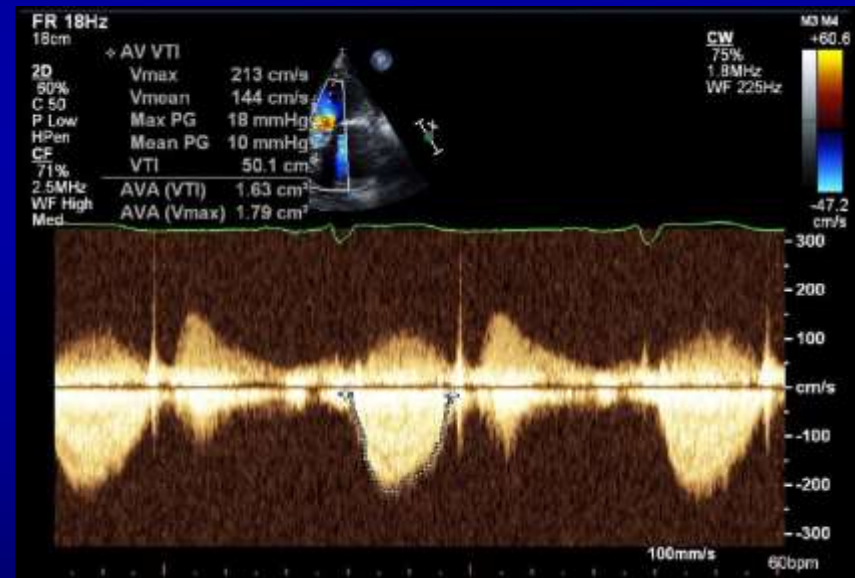
Gradient after 2nd septal ablation

Post-procedure TTE

Parasternal Long Axis



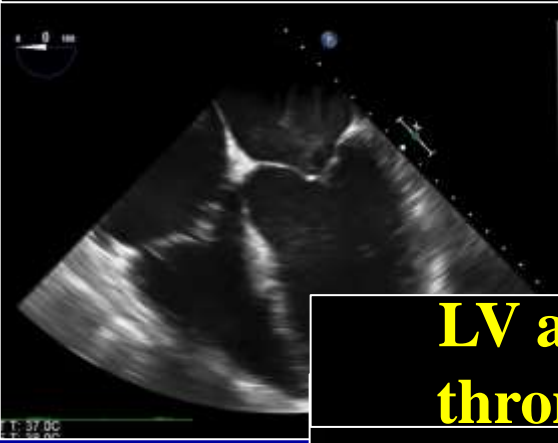
CW Doppler



61 y/o male with EF 10% presenting in cardiogenic shock, on 2 inotropes, with persistent hypotension

Patient transferred from OSH for heart transplant evaluation

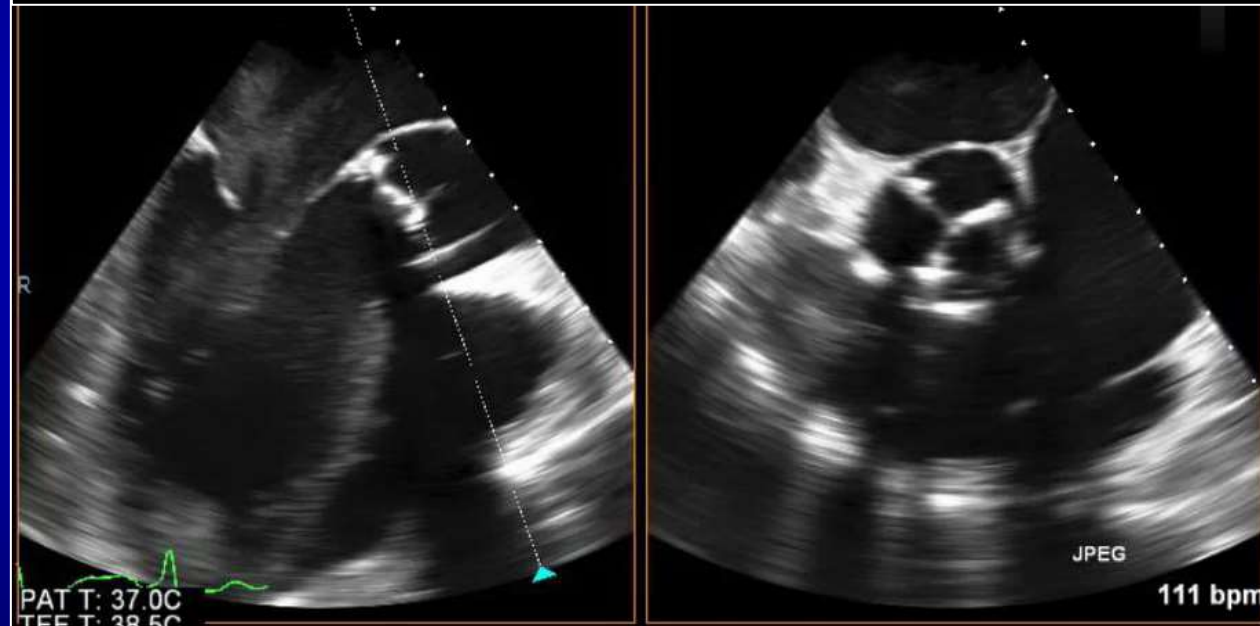
Baseline EF 10%



LV apical thrombus



Severely stenotic bioprosthetic aortic valve #27 Edwards valve



Patient emergently brought to the cath lab for transcatheter aortic ViV

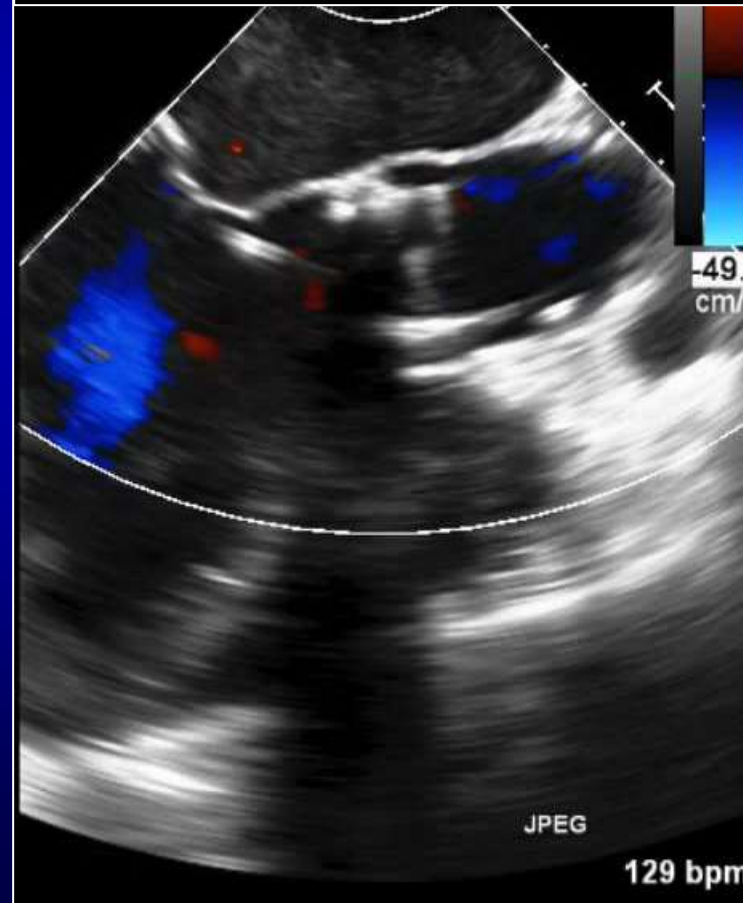
26mm Sapien 3 valve deployed

26mm Sapien 3 valve deployed

26mm Sapien 3



**Final result
Mild PVL**

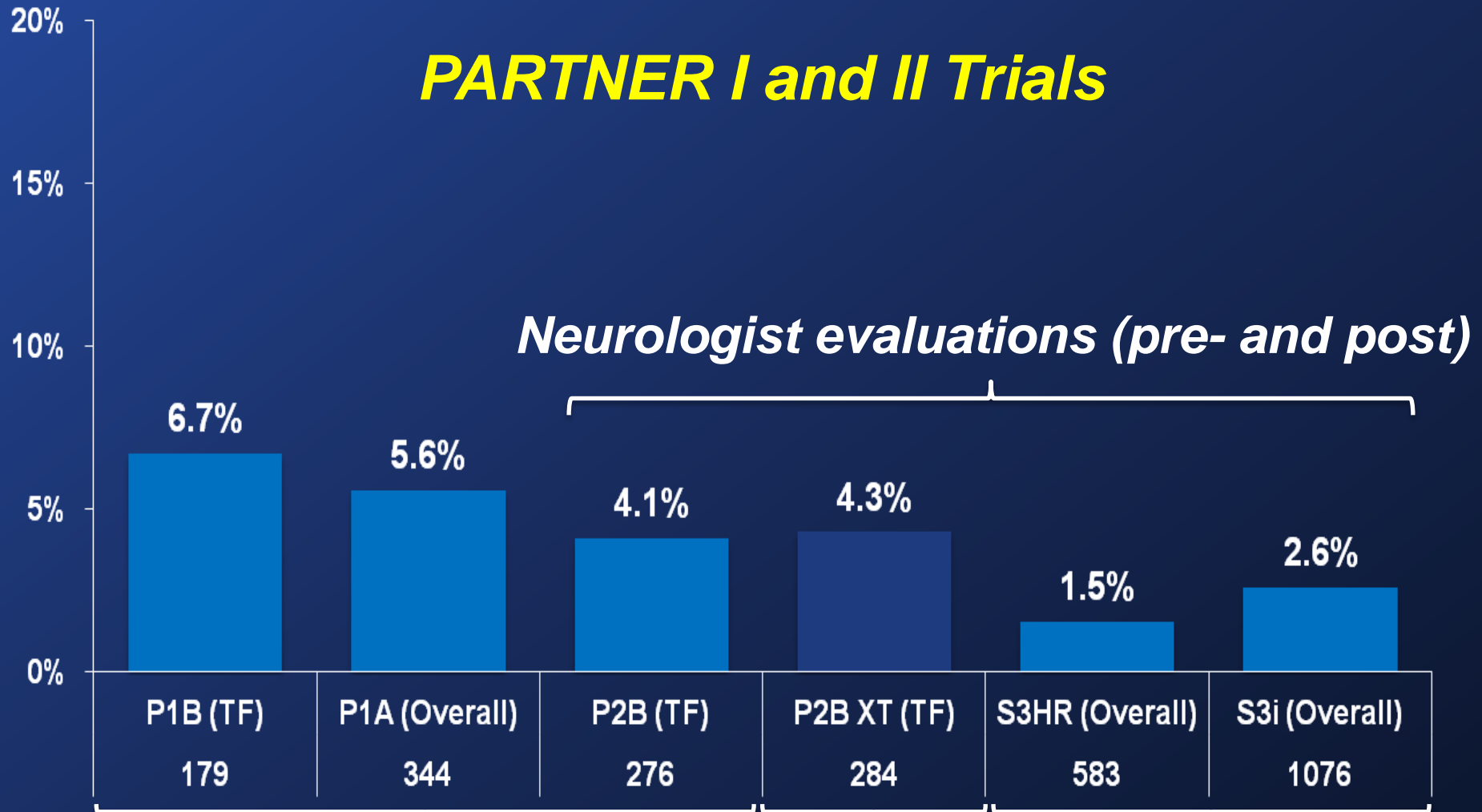


- **Patient transferred to the ICU**
- **No complications**
- **Discharged home in 10 days**

All Strokes at 30 Days

Edwards SAPIEN Valves

PARTNER I and II Trials



SAPIEN

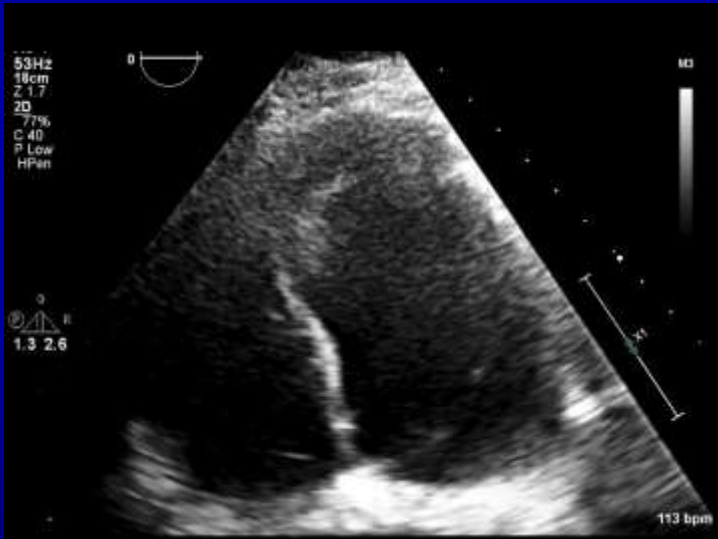
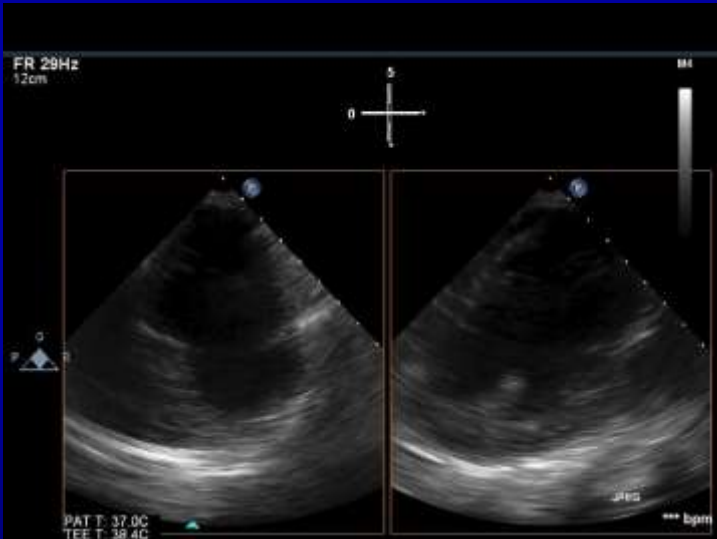
SAPIEN XT

SAPIEN 3

72 year old Male with LVEF 15-20% and Critical AS

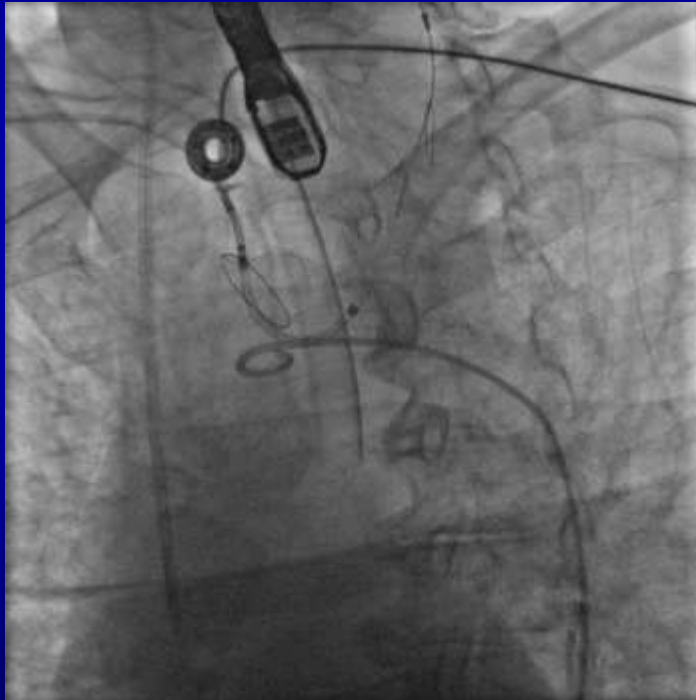
TEE

TTE



Compassionate Use of Sentinel in 2016: Successful TAVR, No Stroke

Claret Sentinel Device

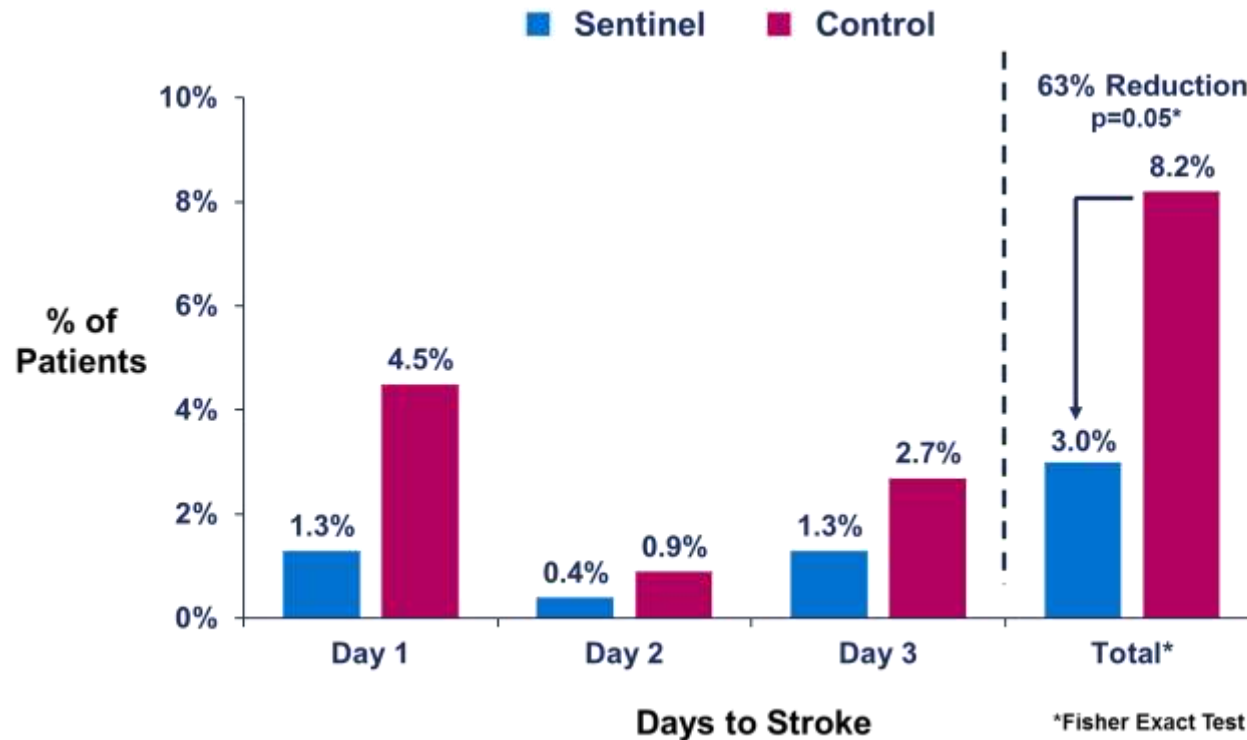


23mm S3 Transfemoral TAVR

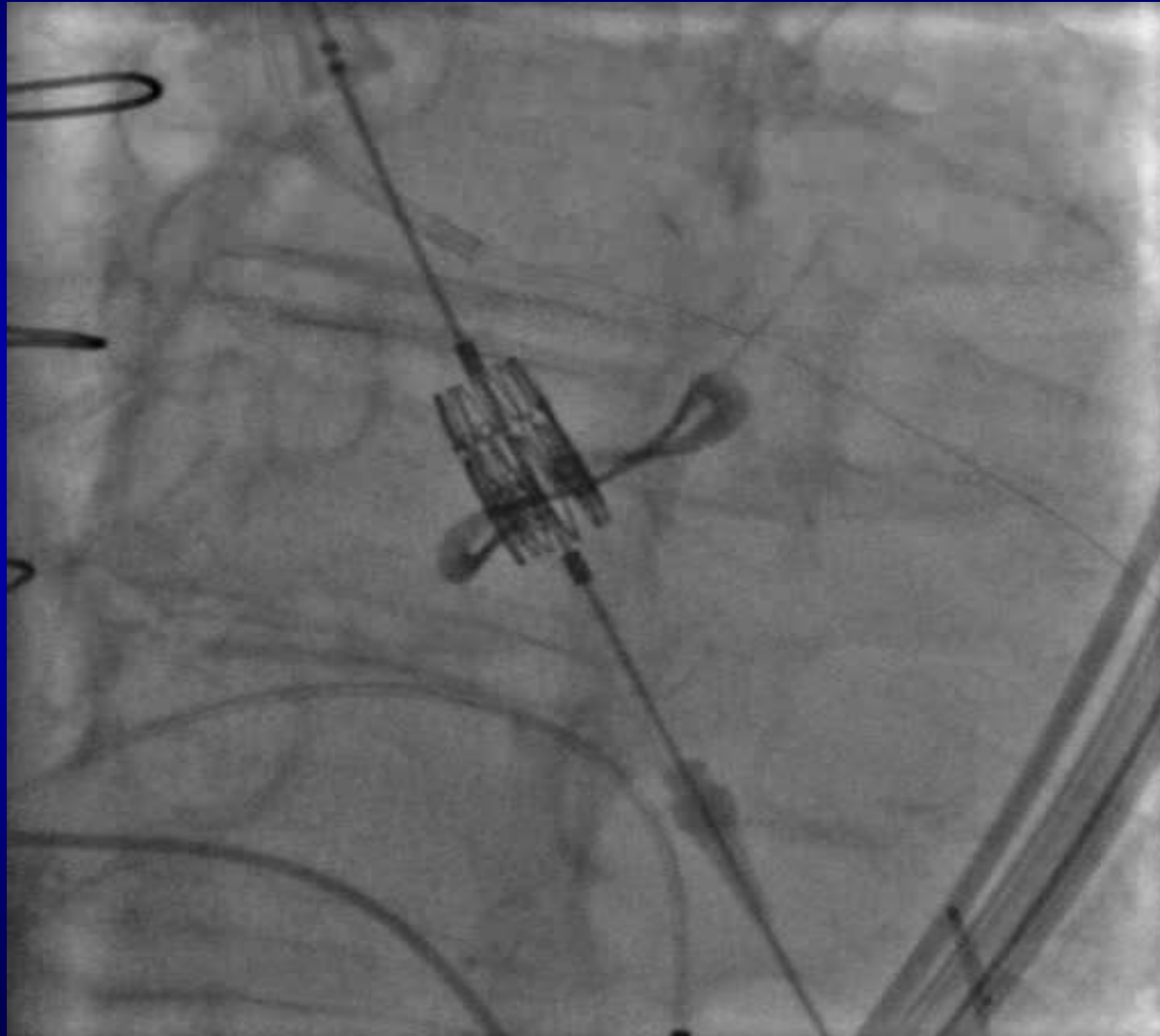


SENTINEL study shows significant procedural stroke reduction

Results from SENTINEL multi-national randomized trial of n=363 TAVI patients with vs. without protection using Sentinel™ cerebral embolic protection system shows a significant reduction in procedural stroke (63%)

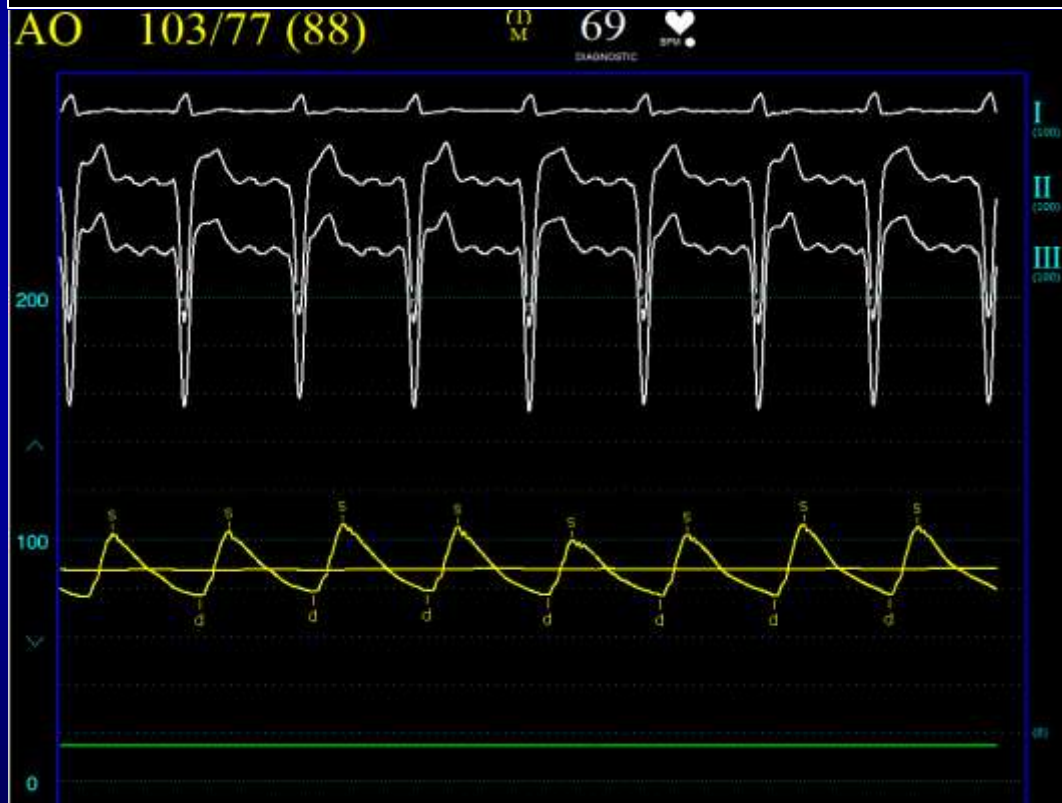


80y male with 23 mm Mitraflow and AS+AR

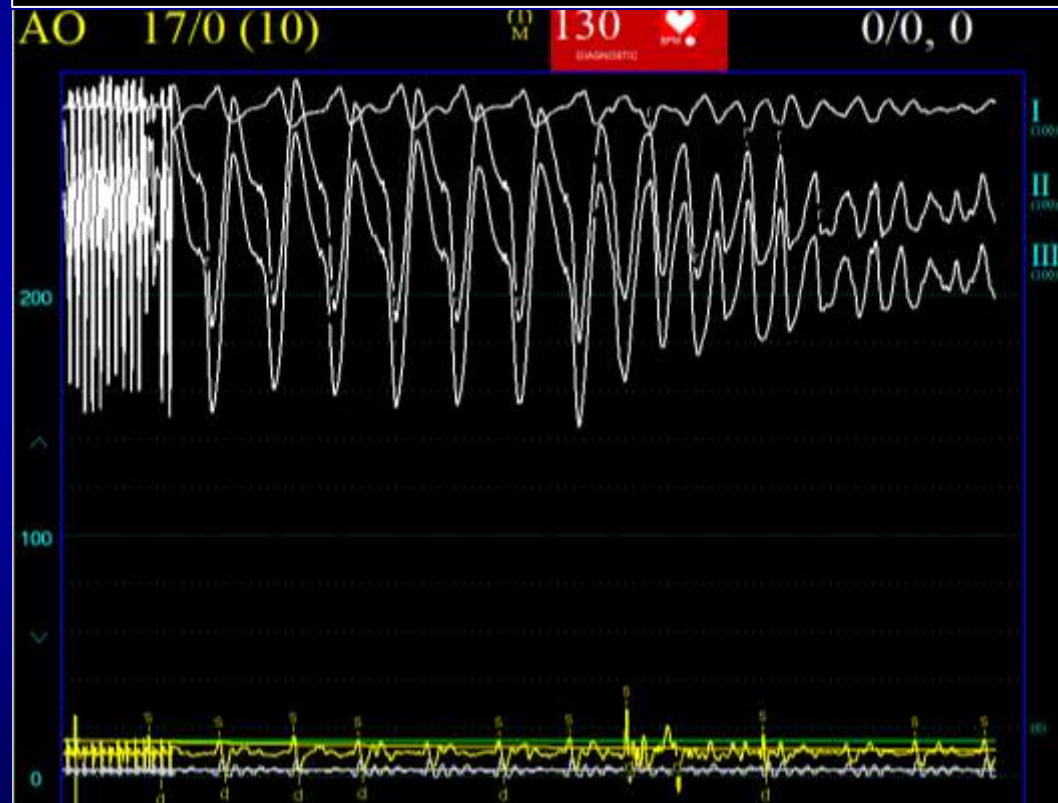


Hemodynamics

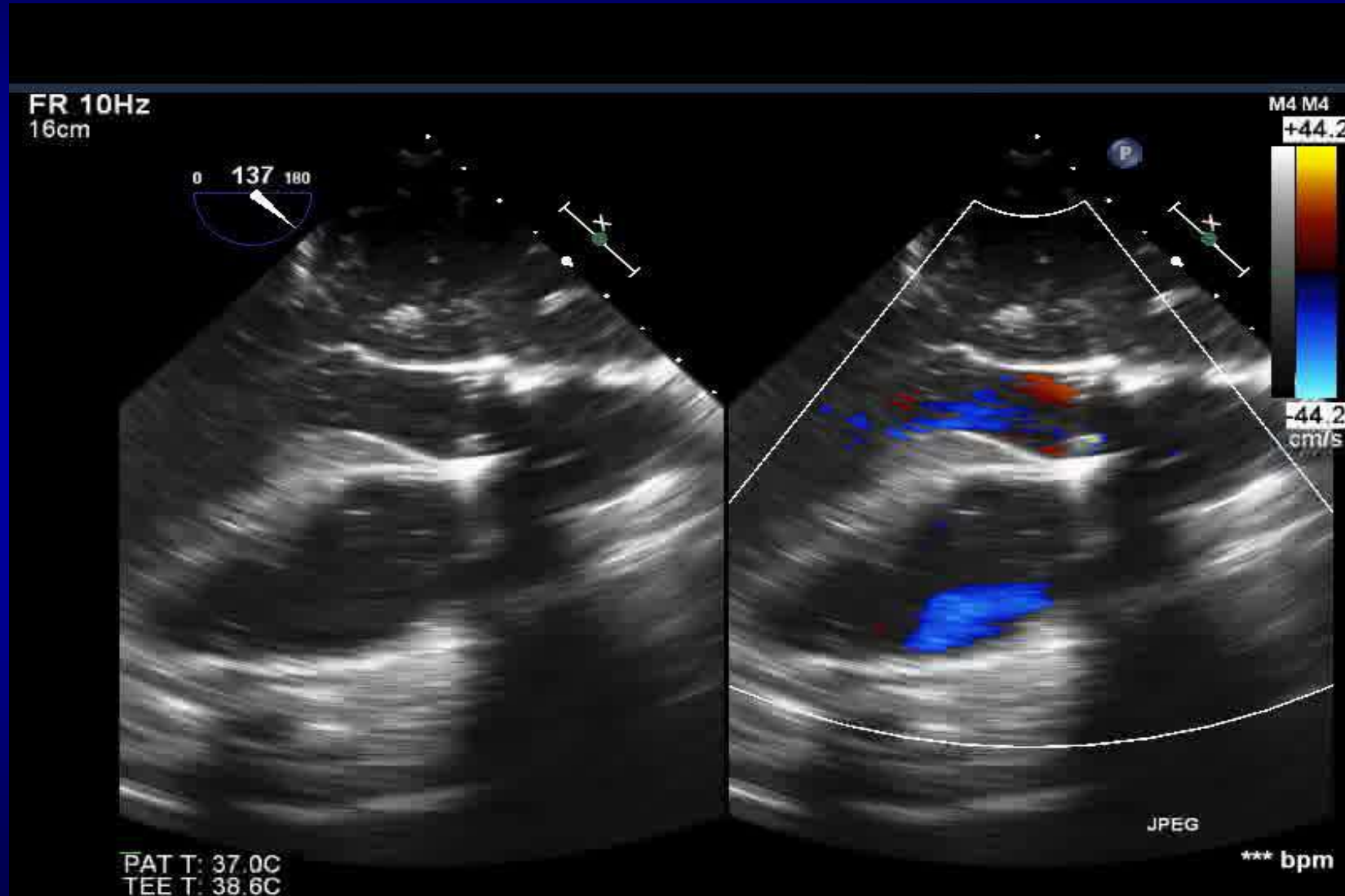
Pre-deployment



Post-deployment



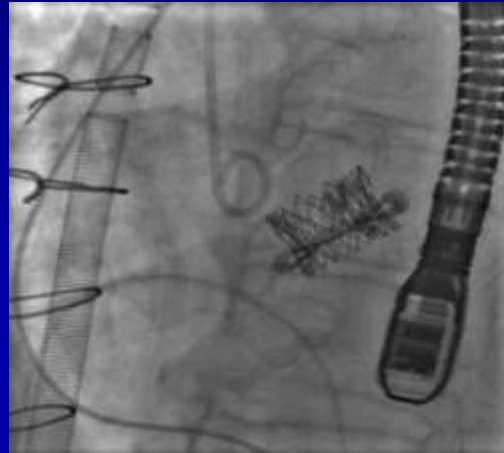
Post deployment TEE



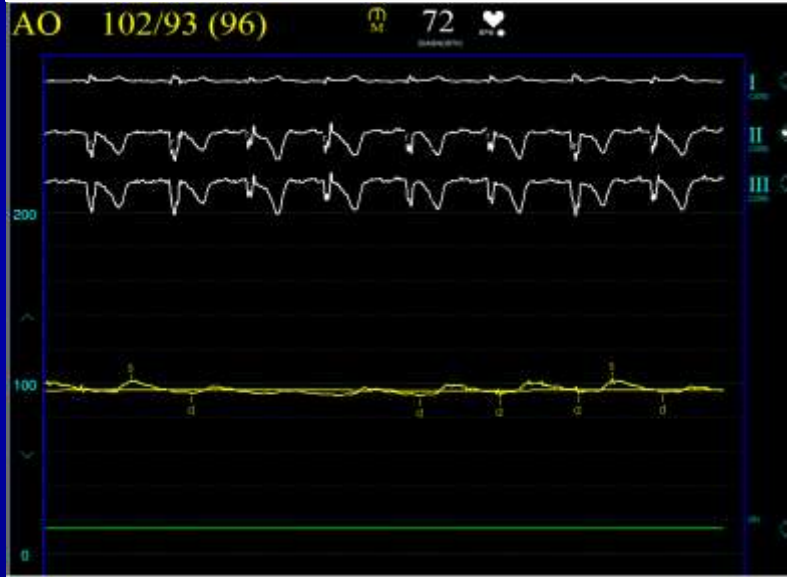
What is the problem here?
Is the valve mounted correctly?

2nd valve deployed

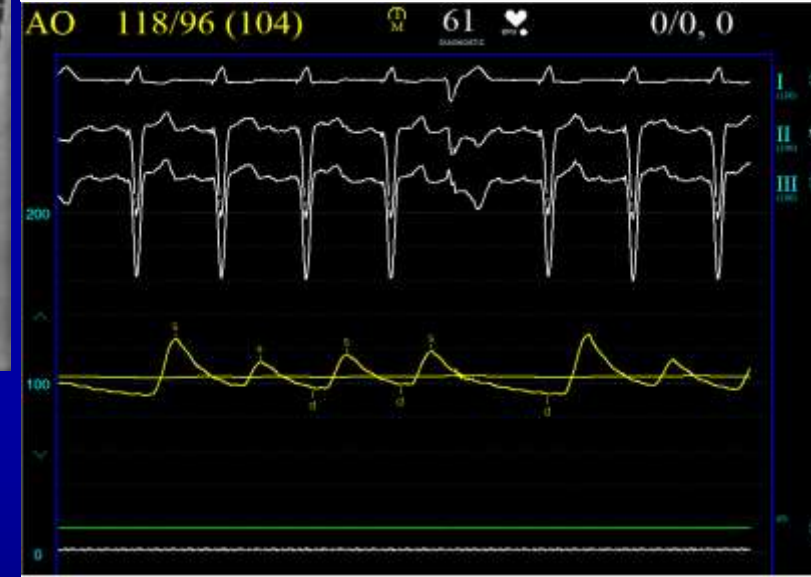
ViV Post deployment



On pump hemodynamics

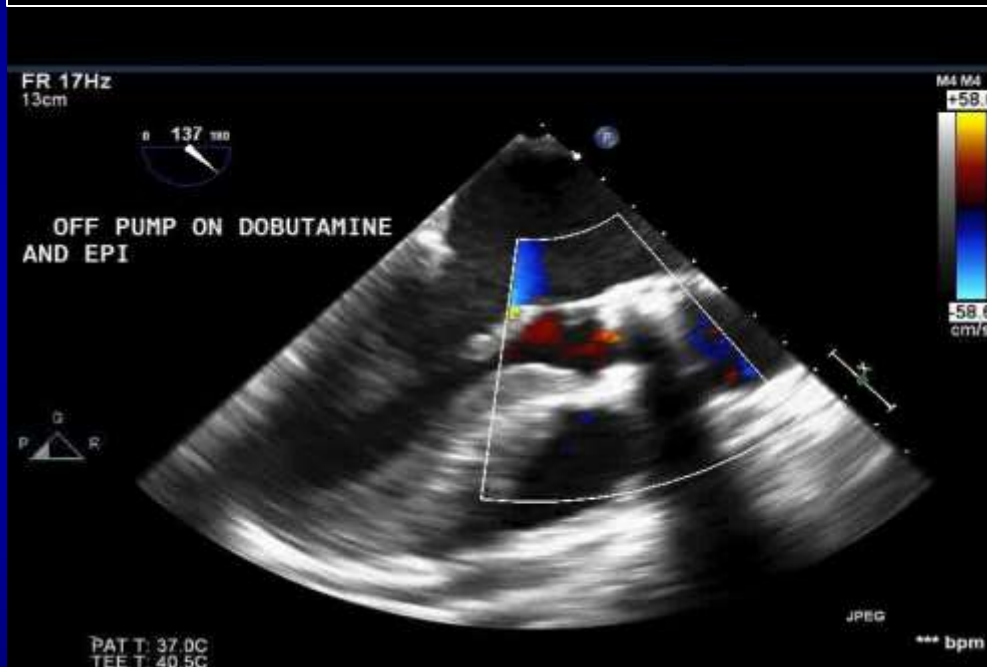


Post 2nd valve hemodynamics



LV systolic function post TAVR

Post 2nd valve TEE

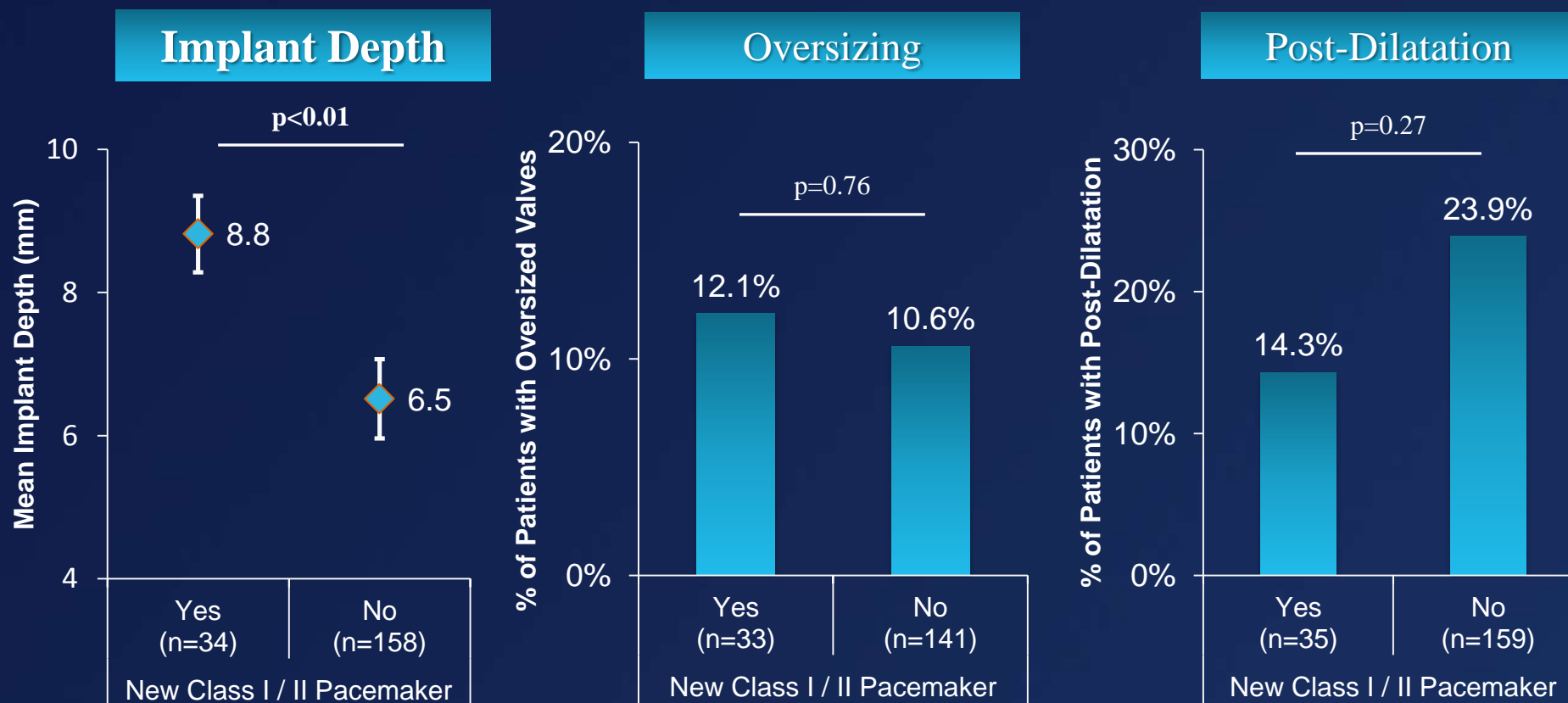


Pre discharge TTE



Procedural Considerations

ADVANCE II confirmed that implant depth is the strongest procedural predictor of new PPM¹



Error bars are standard error

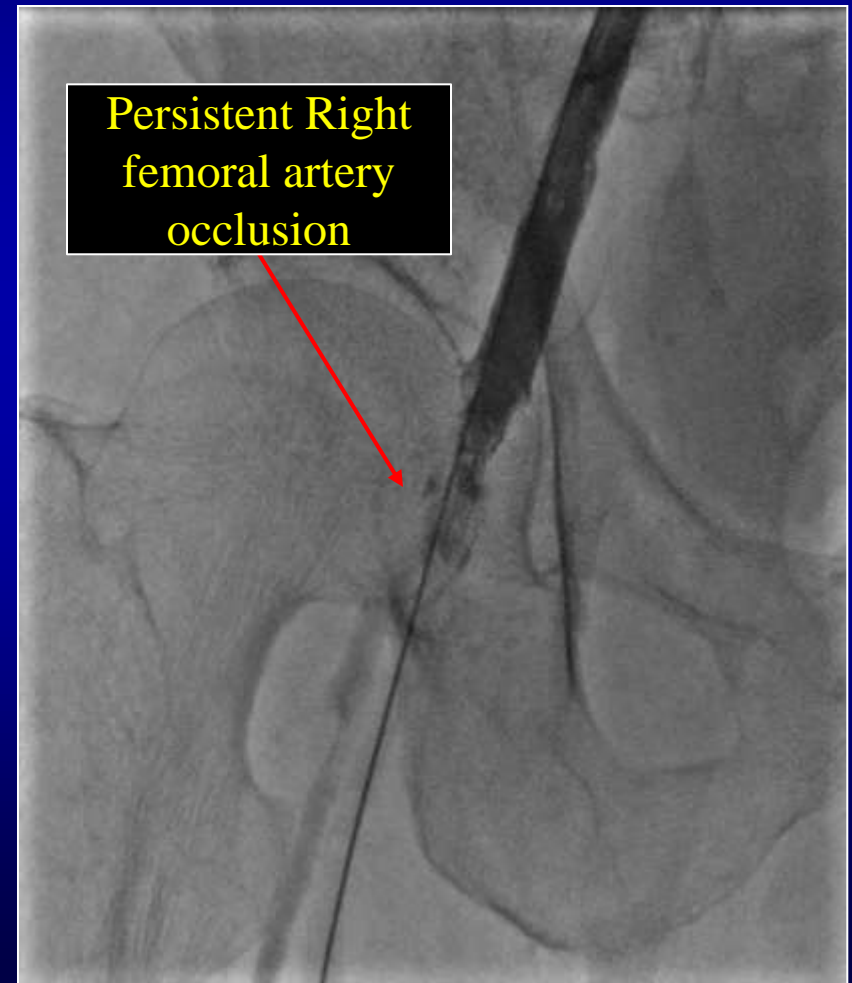
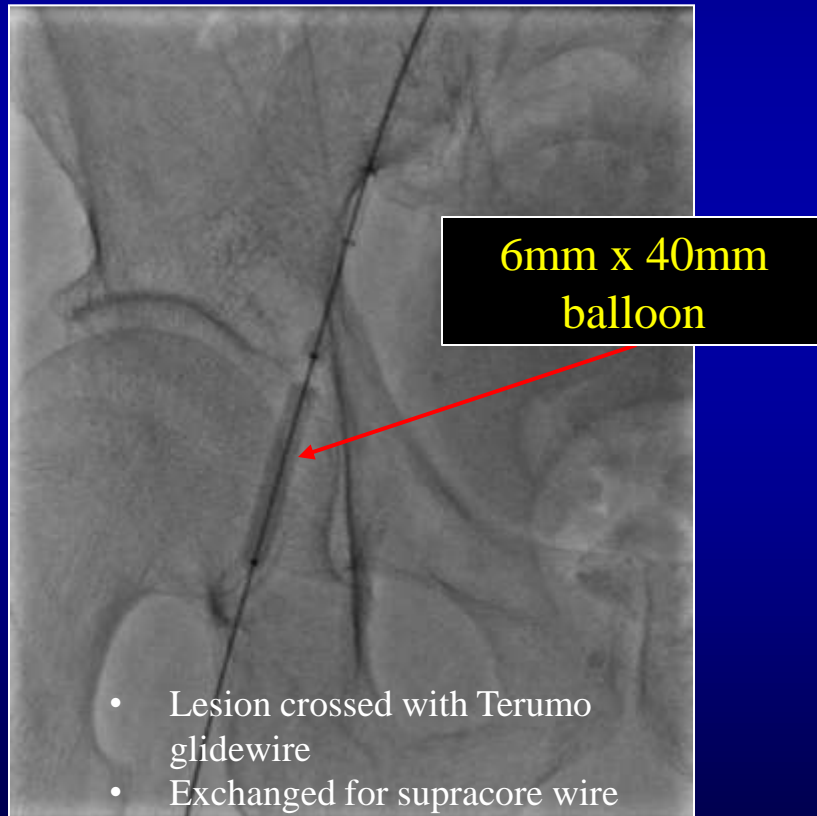
Implant depth defined as the distance from the lower edge of the non-coronary leaflet to the ventricular edge of the frame

*Oversizing occurs when a valve is implanted in an annulus that is smaller than the range defined by the CoreValve sizing guide

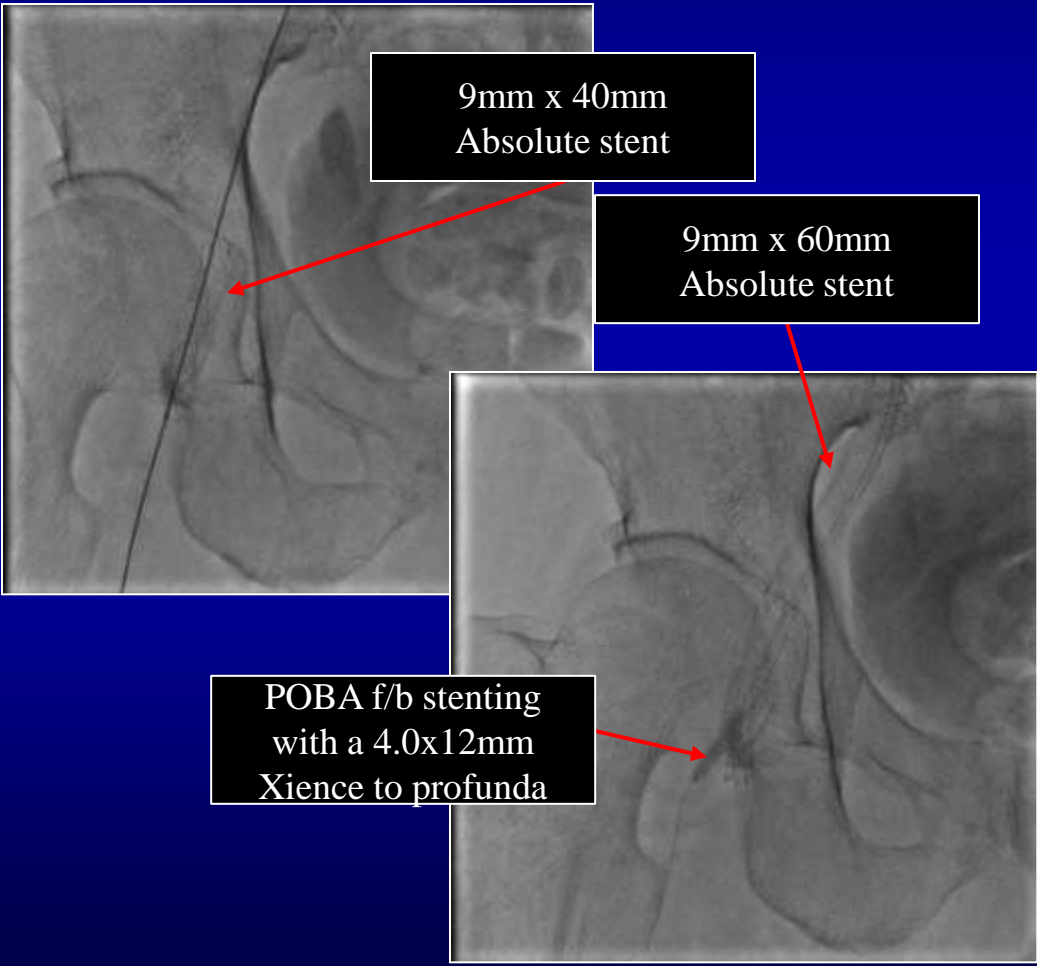
% Oversizing = $100 \times \frac{[\text{Perimeter of CoreValve} - \text{CT Derived Perimeter of the Annulus}]}{\text{CT Derived Perimeter of the Annulus}}$

POBA performed with a 6mm x 40mm balloon

Persistent occlusion of the right femoral artery



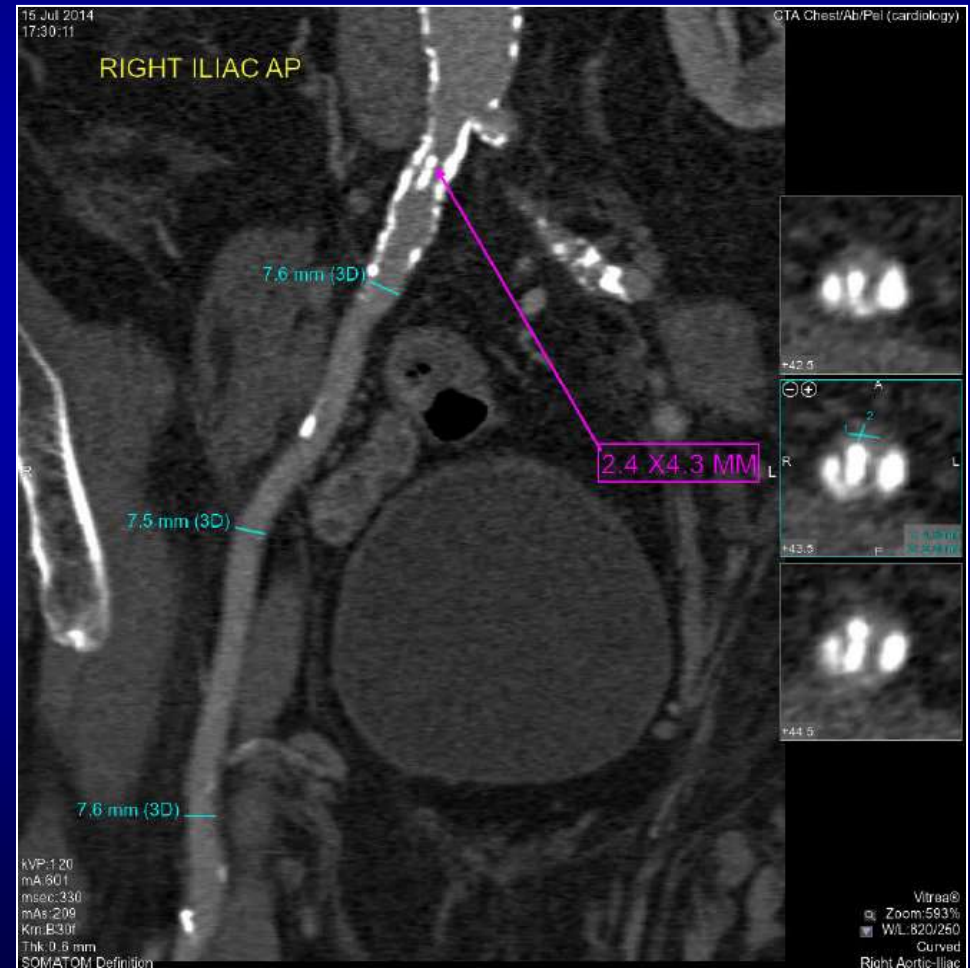
Final result s/p stenting to right iliofemoral and profunda



88 y/o female with severe AS referred for TAVR

Extreme risk for surgical AVR due to multiple comorbidities

Not a candidate for transfemoral approach



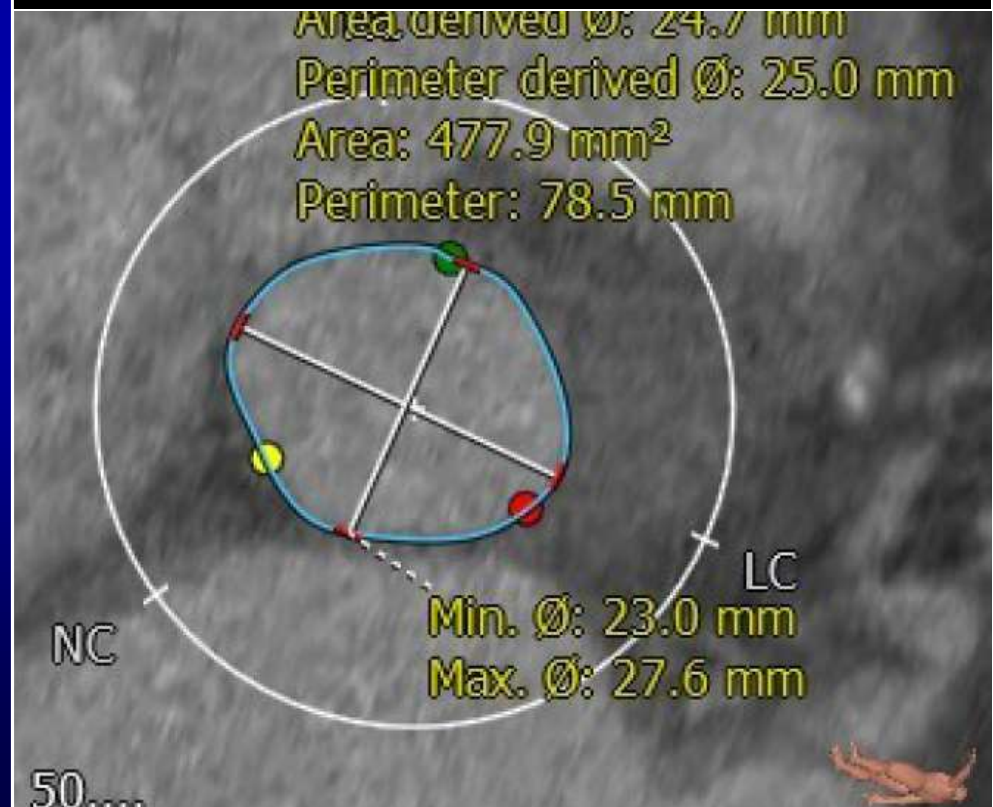
Plan for 26-mm Sapien-XT

Left subclavian approach

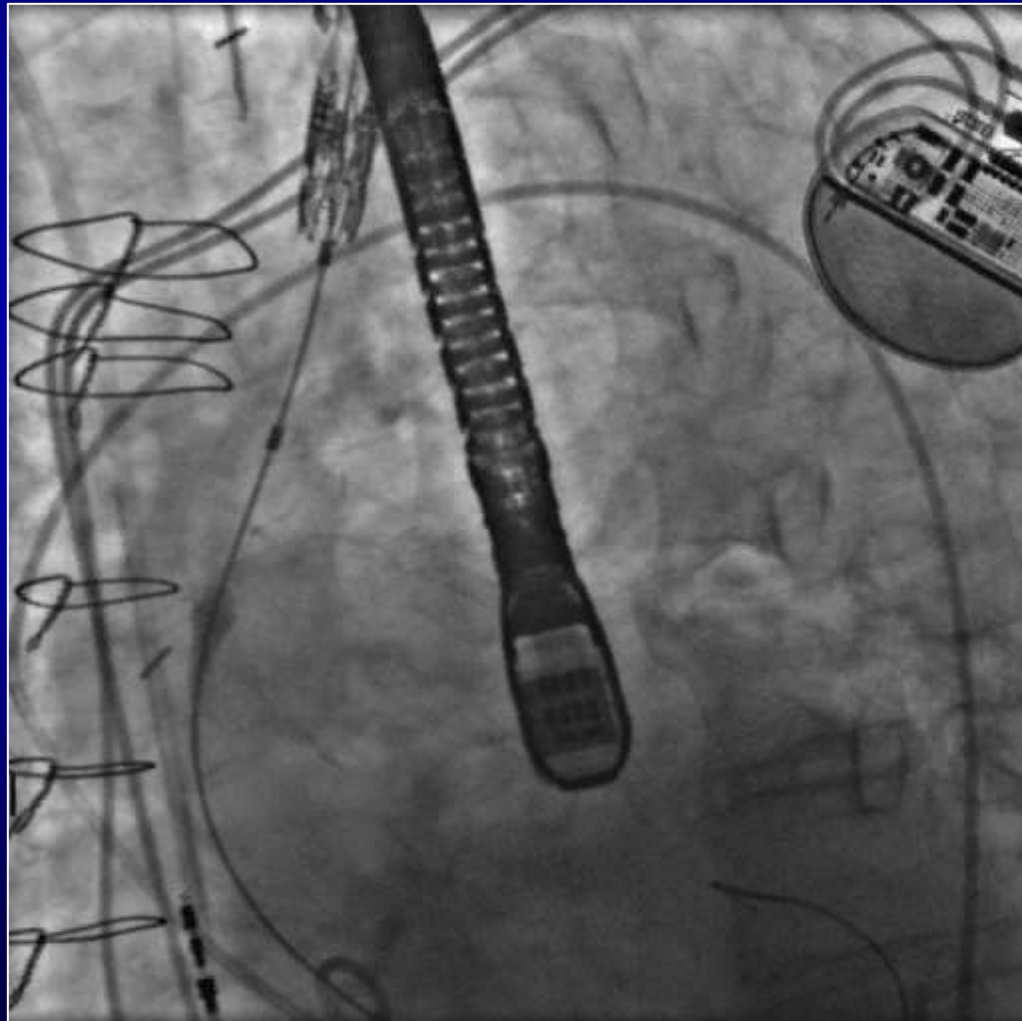
Deemed high-risk for transapical and transaortic approach



Area 477.9mm²; Perimeter 78.5mm;
Dmin 23mm; Dmax 27.6mm



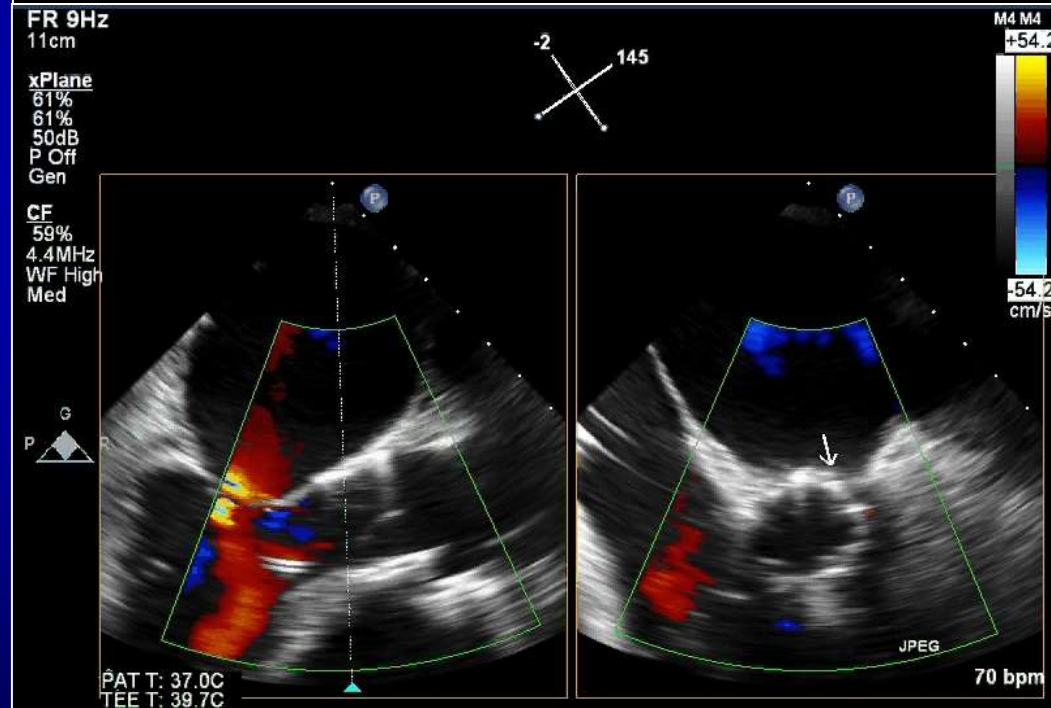
Valve positioning being performed by the left subclavian approach



s/p 26-mm Sapien-XT by subclavian approach

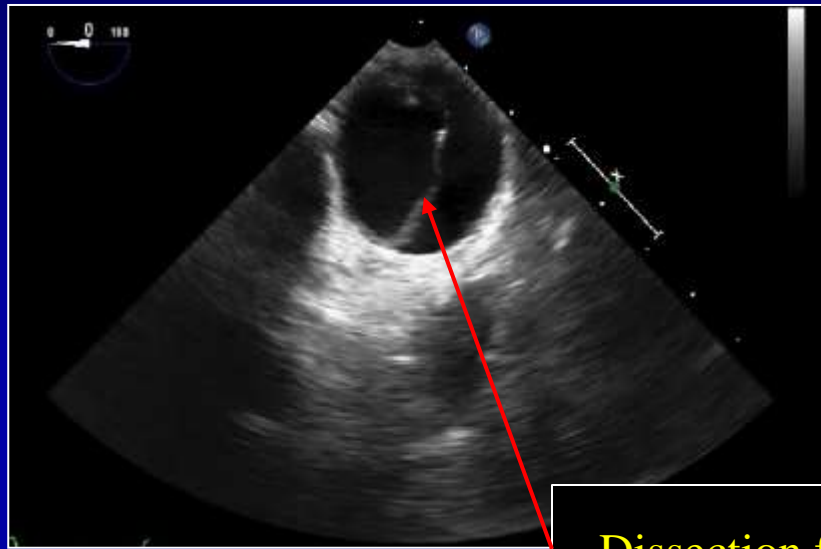


Trivial PV aortic regurgitation

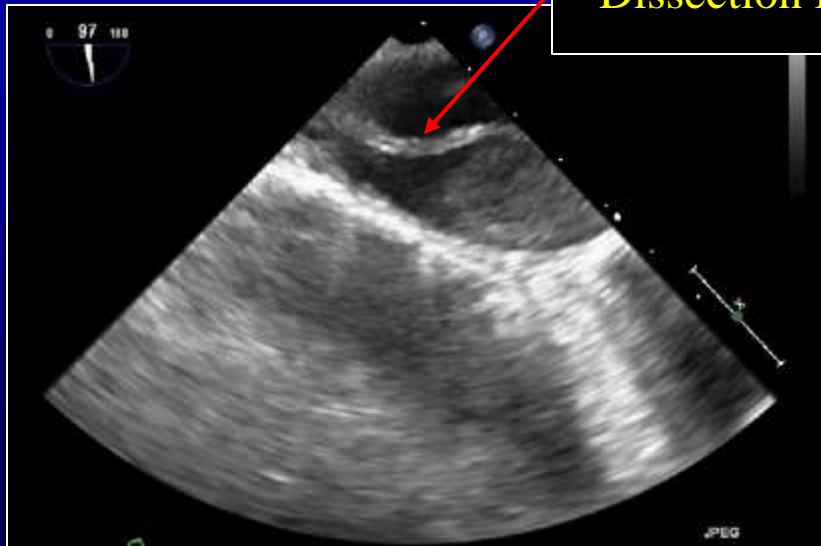


Type B aortic dissection

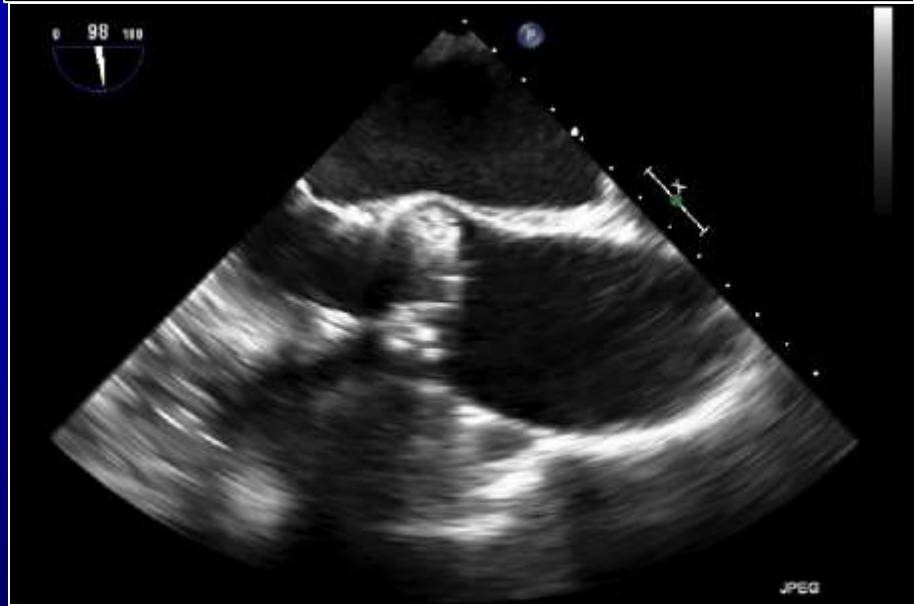
Managed medically, no intervention performed



Dissection flap



No dissection in the ascending aorta



Key Aspects of Preventing & Dealing with Complications

- Multidisciplinary procedure planning with incorporation of imaging, especially CT
- Must have a bailout strategy and drills for different scenarios such as left main occlusion, root injury, pericardial tamponade, access to neurointerventionalist if there is stroke
- Easy access to heart lung machine and anesthesiologist is critical in hemodynamic compromise
- A good working knowledge of peripheral interventions to deal with vascular complications