
How to Manage Complication TAVR Case

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

- Grant/Research Support
- Grant/Scientific Advisory Board
- Executive Physician Council

Company

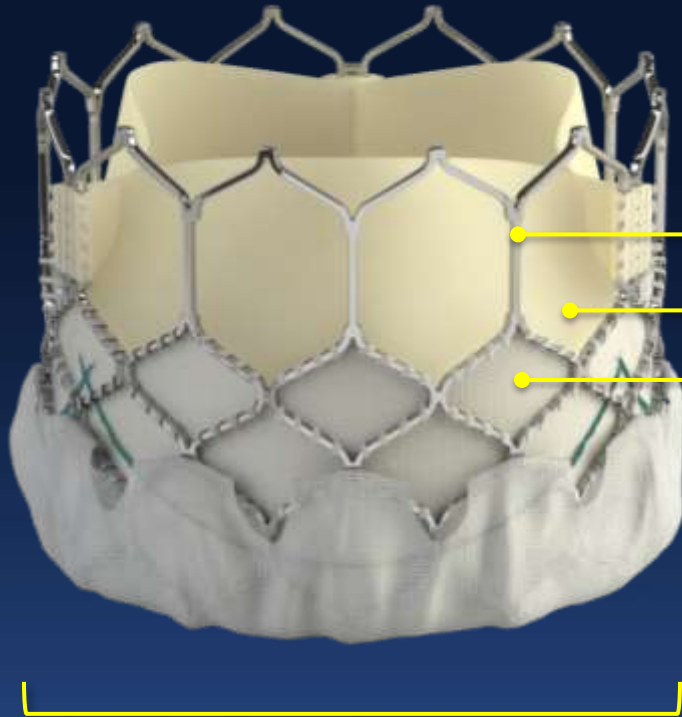
- Edwards Lifesciences
- Medtronic
- Boston Scientific Corp



SAPIEN 3 THV

Low frame height

- Respects the cardiac anatomy



Frame design

- Enhanced frame geometry for low delivery profile
- High radial strength for circularity

Bovine pericardial tissue

- Scalloped leaflet shape
- CE ThermoFix* process is intended to minimize the risk of calcification

Inner Skirt

- Polyethylene terephthalate (PET)

Outer skirt

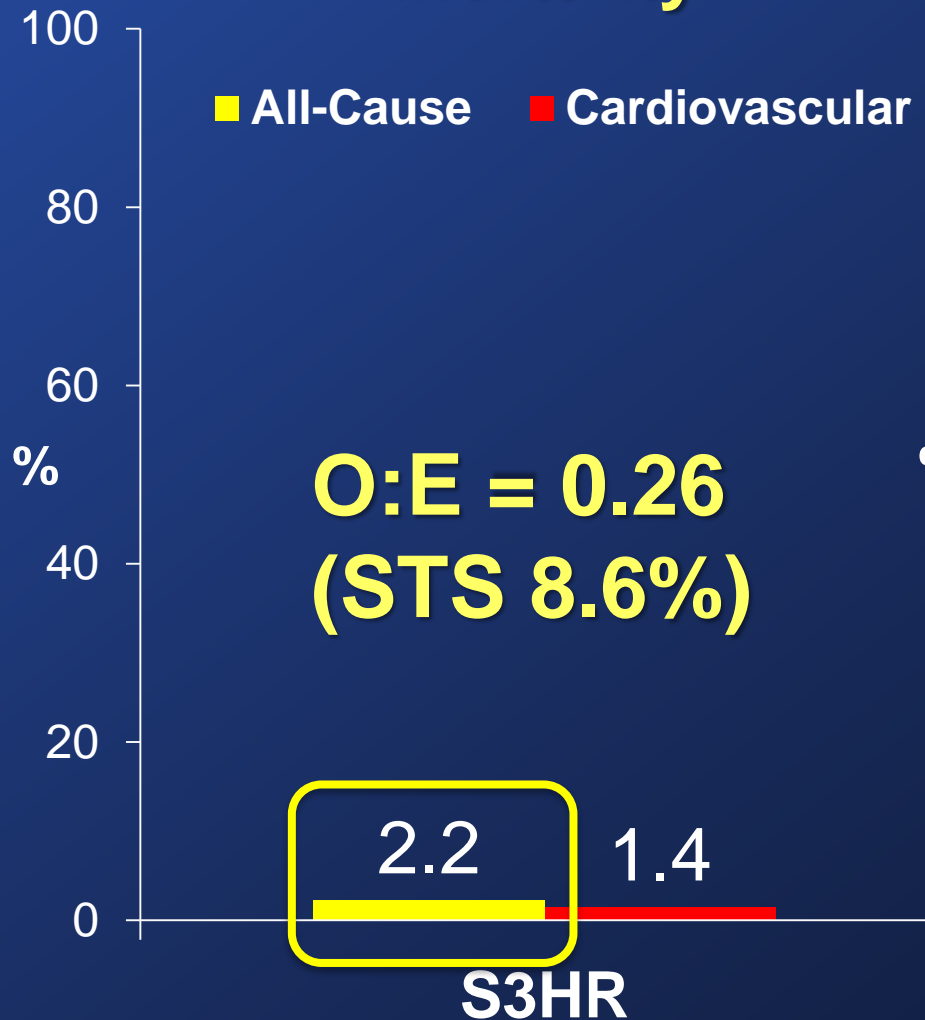
- PET outer skirt designed to reduce paravalvular leak

Mortality and Stroke: S3HR

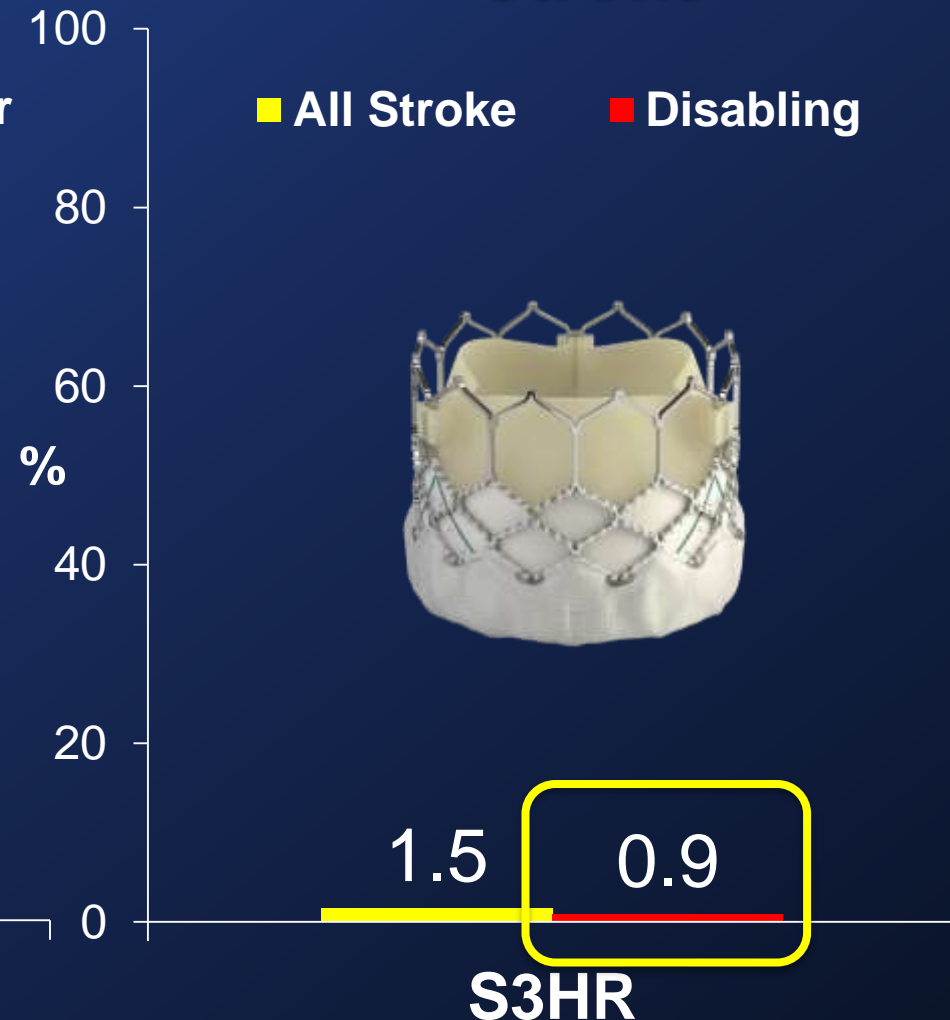
At 30 Days (As Treated Patients)



Mortality



Stroke

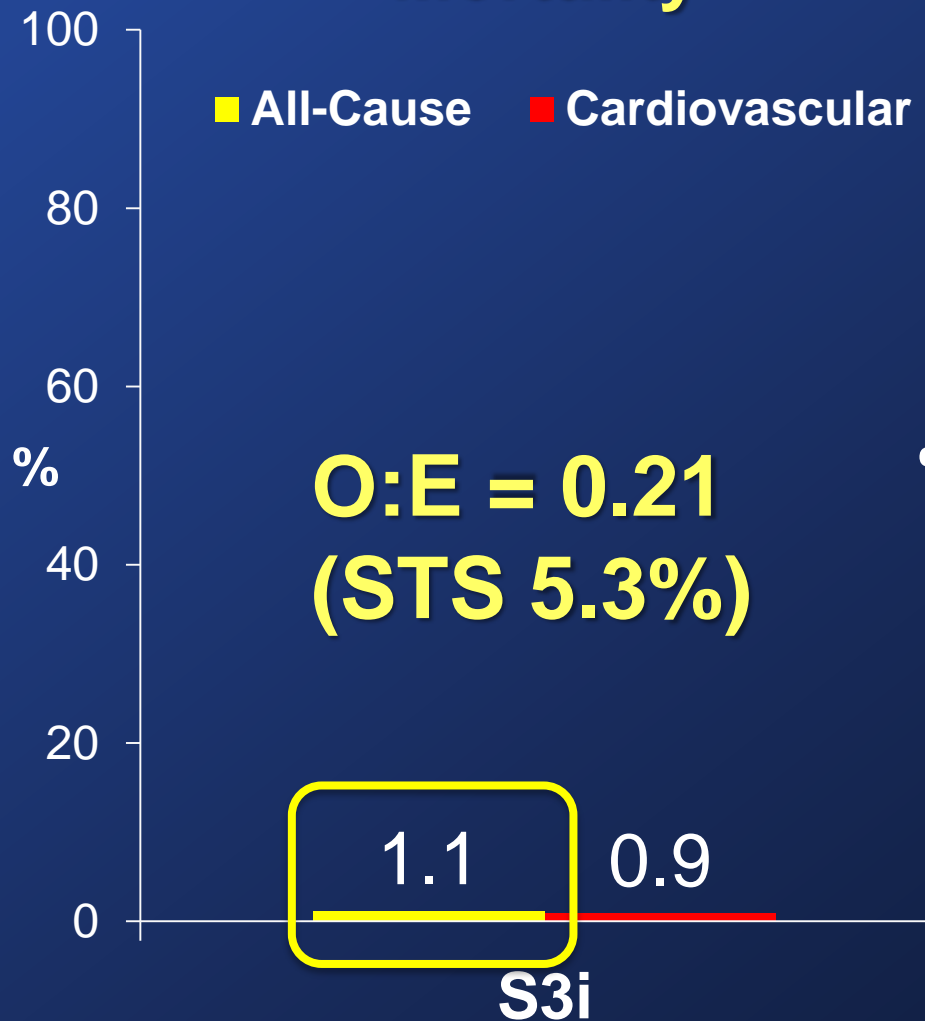


Mortality and Stroke: S3i

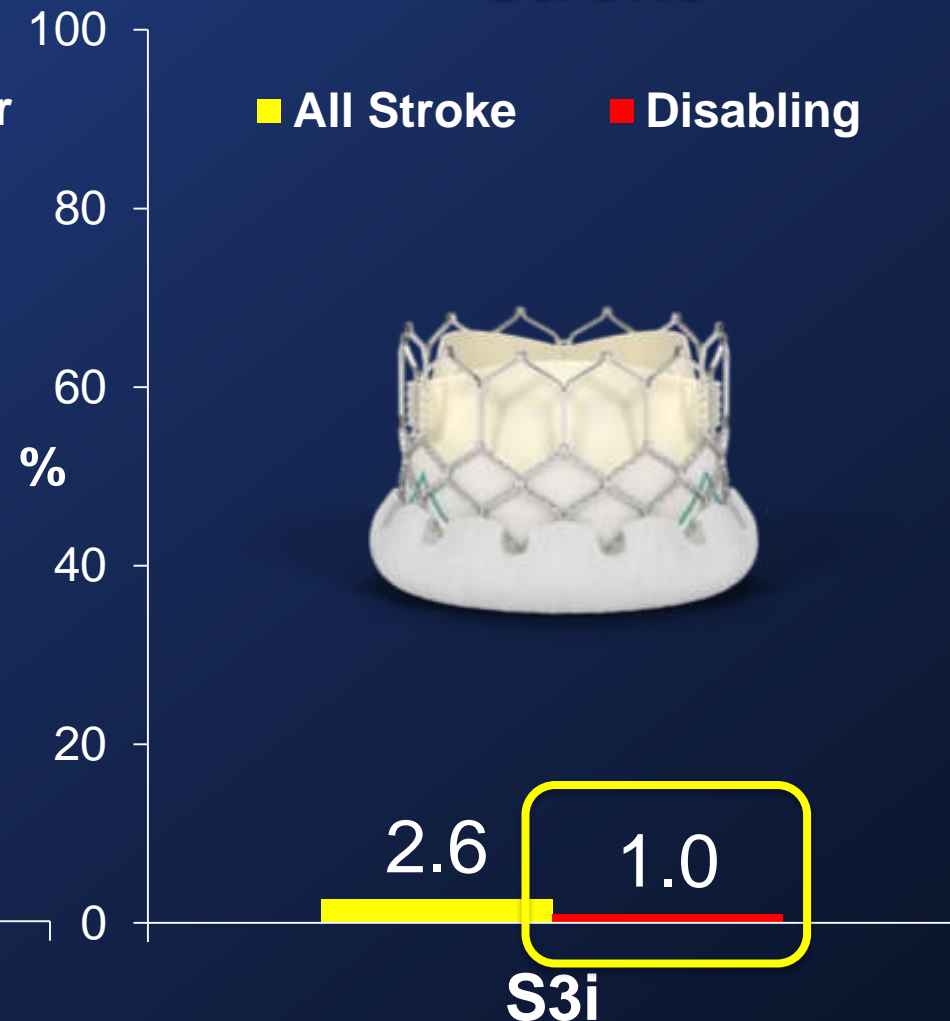
At 30 Days (As Treated Patients)



Mortality



Stroke



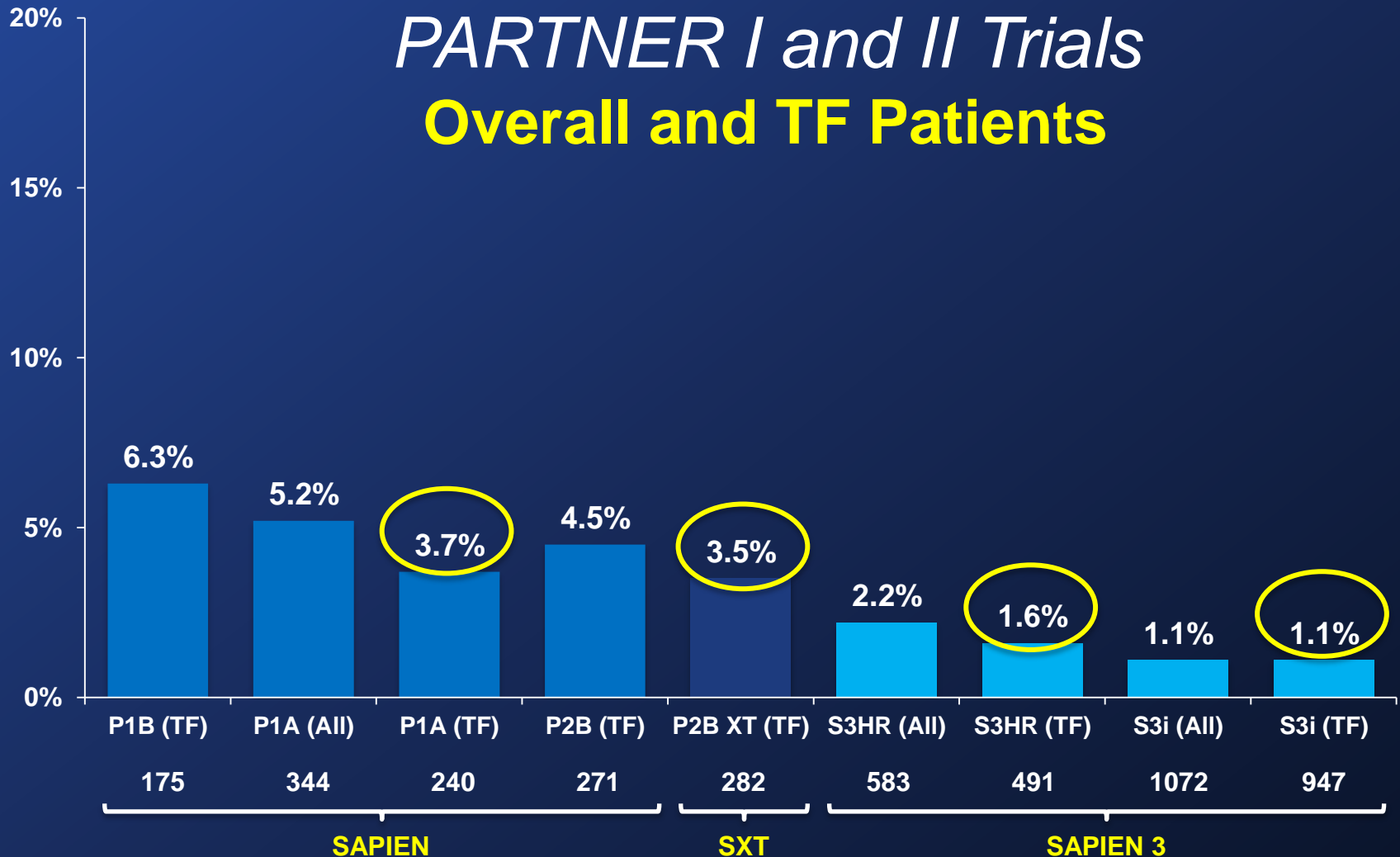
All-Cause Mortality at 30 Days

Edwards SAPIEN Valves



PARTNER I and II Trials

Overall and TF Patients



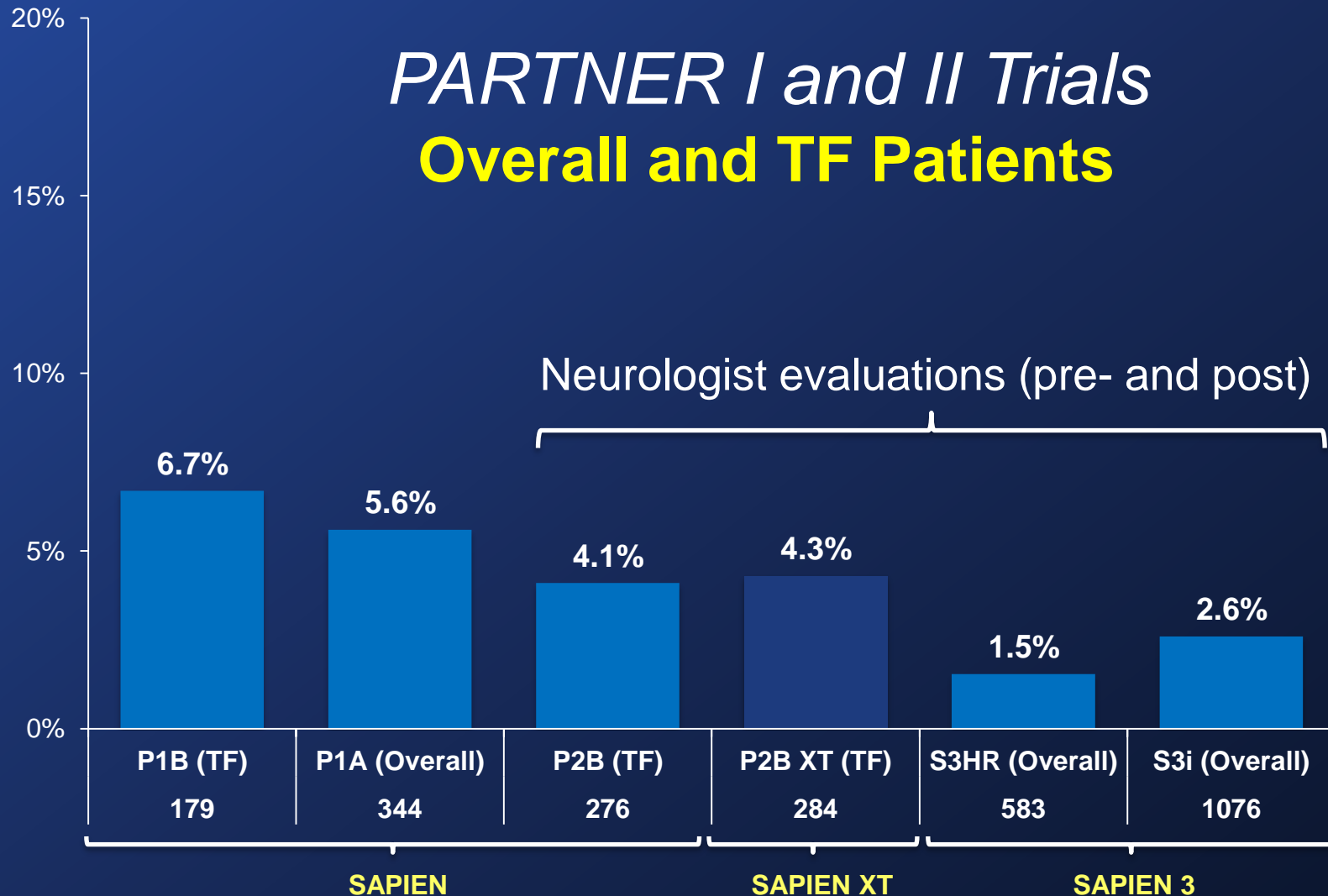
All Strokes at 30 Days

Edwards SAPIEN Valves



PARTNER I and II Trials

Overall and TF Patients



Stanford Experience with TAVR

Yearly Volume

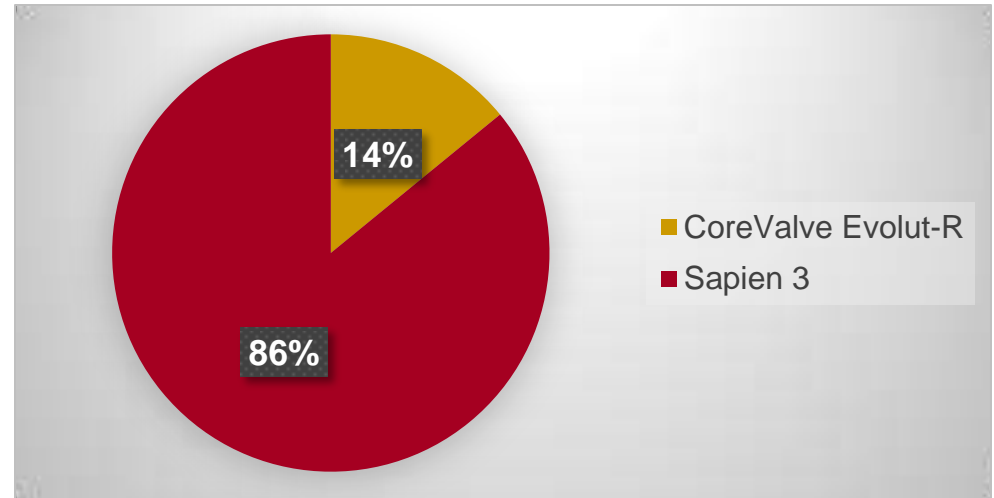


Fiscal Year



In 2017....

Valve	# of Cases
Sapien 3	209
CoreValve Evolut R	33



Complications	
PPM/ ICD	5.7%
Death	1.6%
Major Vasc	0.8%
Stroke	0.8%

Conversion to open 2.1%



Technical Lessons:

- Vascular measurements, tortuosity and calcifications
- Annulus measurement and confirmation
- *No predilatation*
- Optimization of valve function after deployment
- Know your valve-in-valve dimensions



Technical Lessons:

- Vascular access:
 - ❑ Choice of TAVR systems
 - ❑ Lindequist wire for tortuosity
 - ❑ Edward dilator sets for femoral iliac/aortic dilatation
 - ❑ Dry Seal sheath vs Cordis sheath
 - ❑ Ultrasound guidance for vascular access (avoid anterior calcium as well as side puncture)



Technical Lessons:

- Annular measurements:
 - ❑ There should be quality control of area measurements
 - ❑ If in between size, larger valve with volume subtraction or smaller valve with additional volume. Depends on calcification of outflow, valve, age....
 - ❑ If not clear, verify with TEE



Technical Lessons:

- TAVR procedures are getting pretty routine
- Technical challenges in routine cases are low
- However, “devils are in the details”
- Vascular “safety”
- Annular “efficacy”
- Care “uniformity”



TAVR Complications

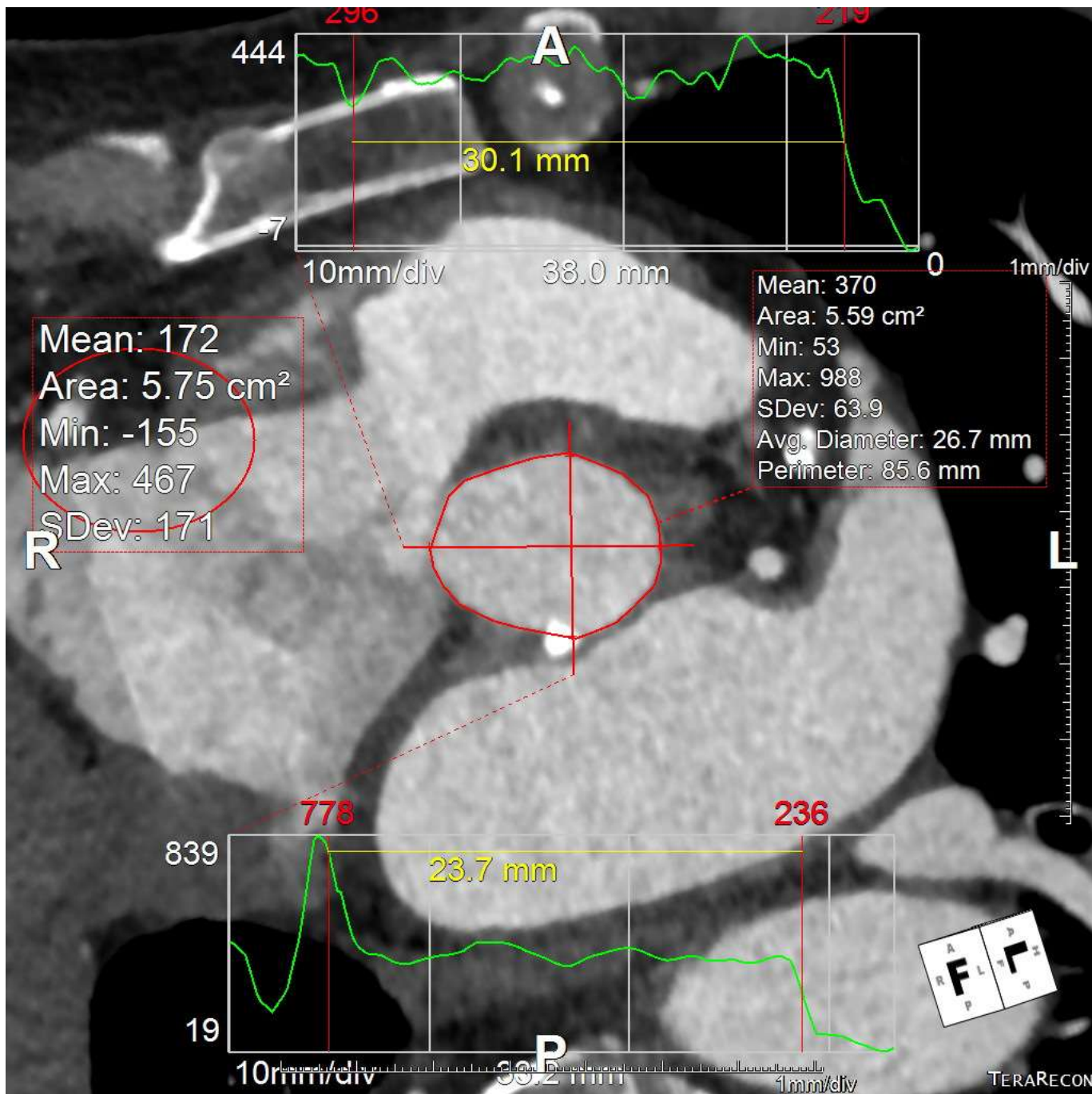
- Stroke
 - Coronary obstruction
 - Bleeding and Vascular Complications
 - Annular Rupture
-
- Aortic Regurgitation
 - Permanent Pacer Implantation

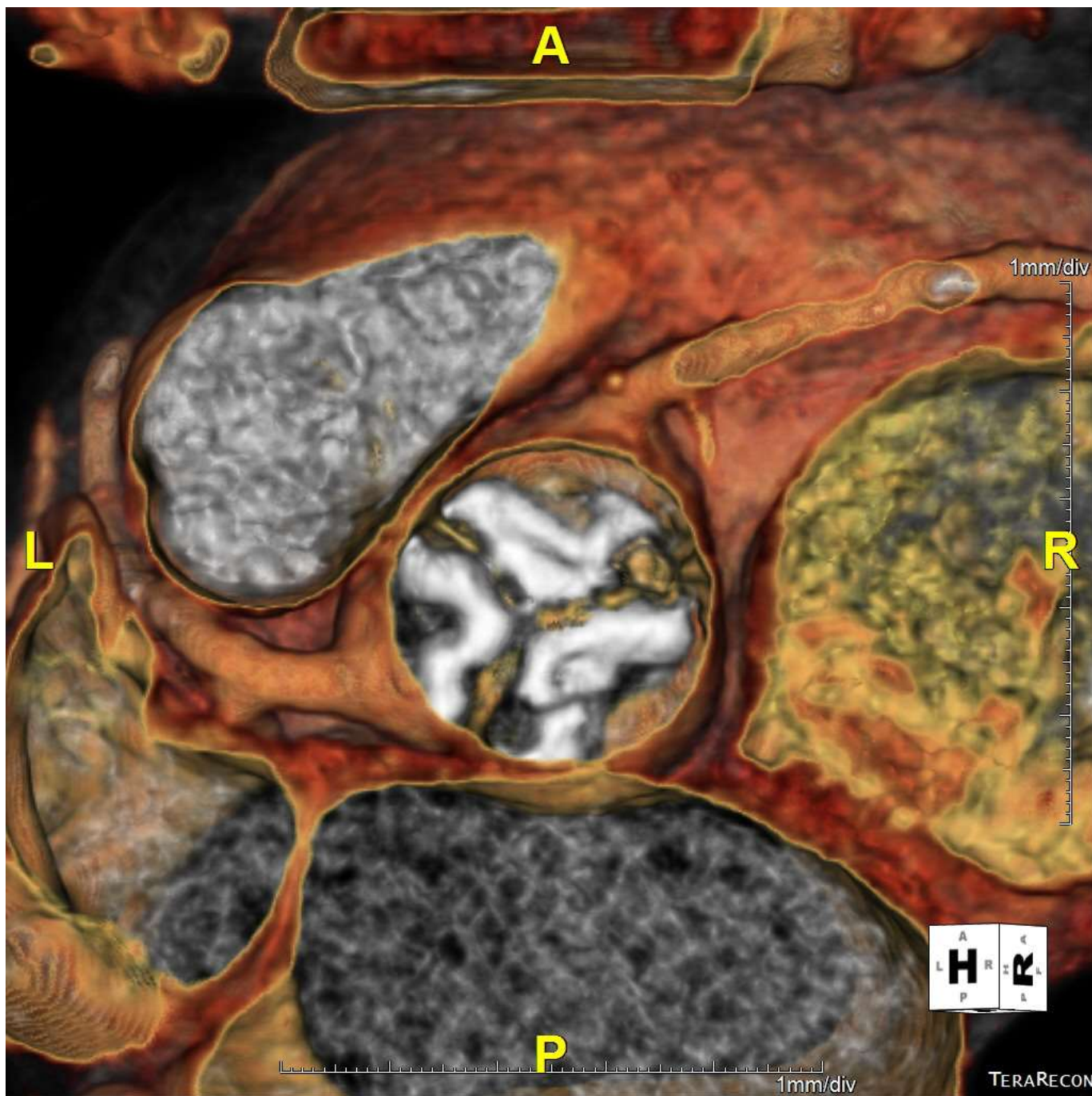


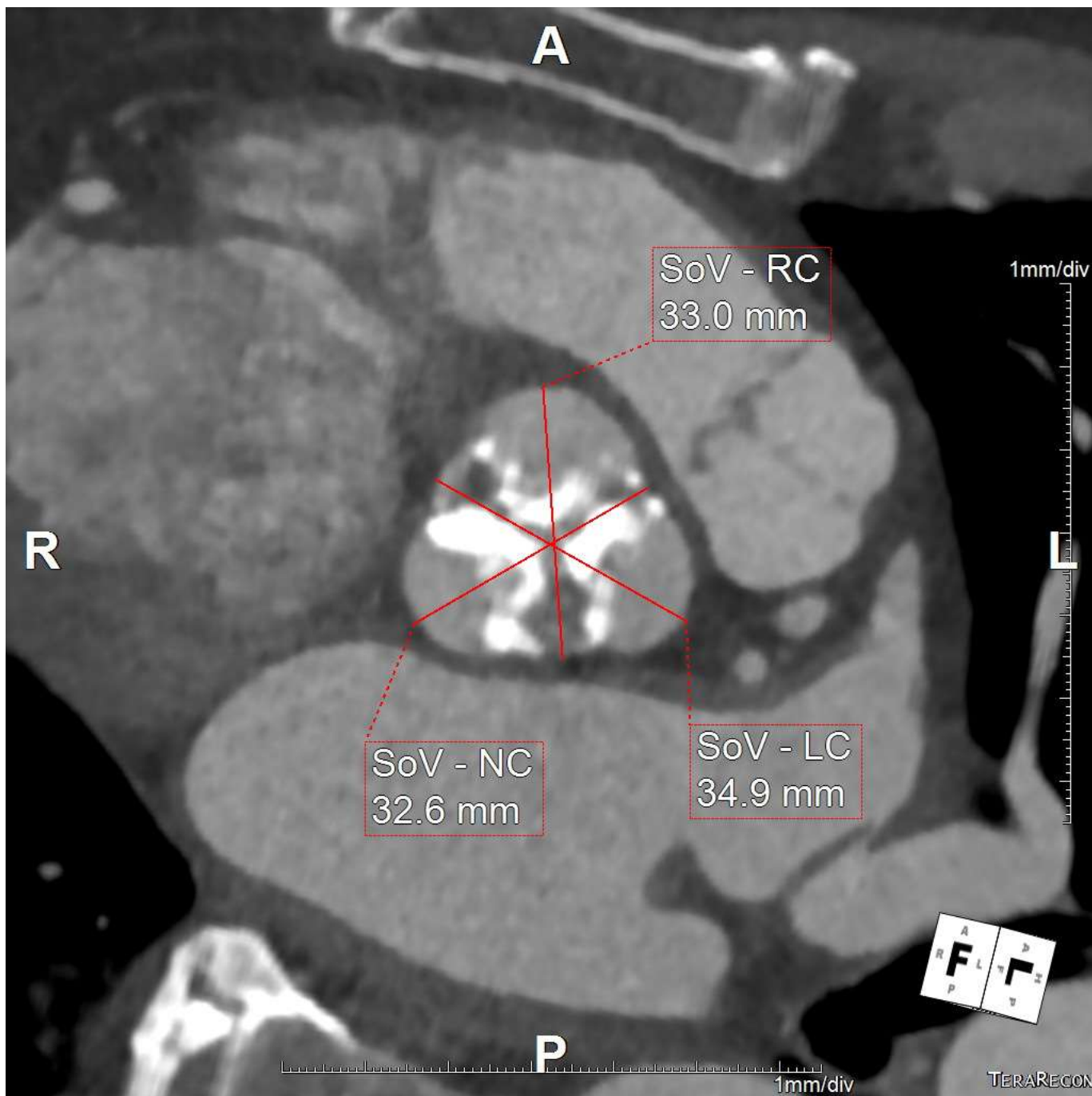
Case Presentation : F.C.

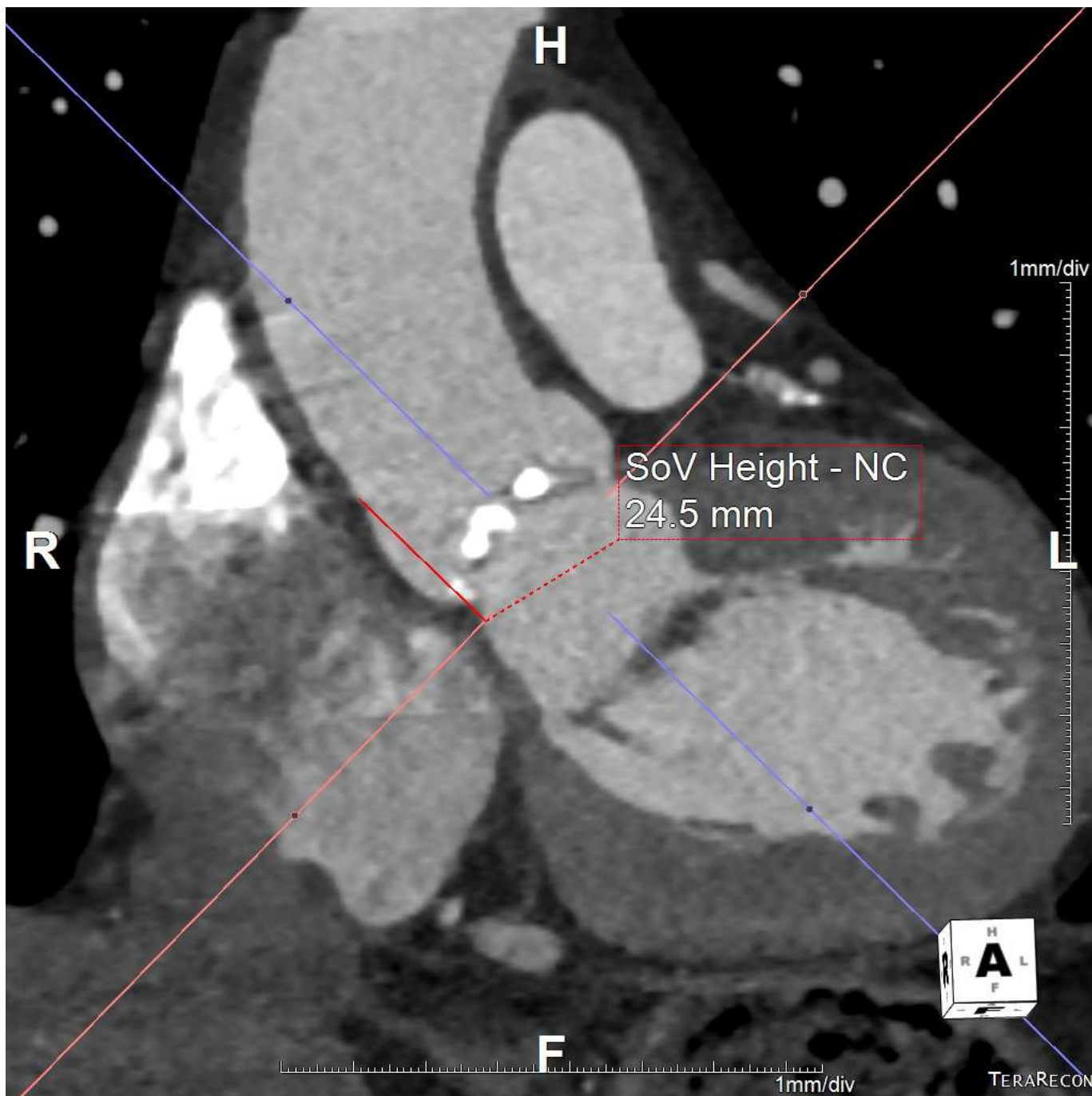
- 81 year old man with HTN, HL, Prostate CA and symptomatic AS with DOE and fatigue.
- Normal PFTs, Frail 0/4, creatinine 0.97.
- Echo: mean gradient 60, EF 49%.
- Coronary: 40-50% LAD, FFR 0.83.
- Vascular Access: greater than 8mm bilaterally
- STS: 1.9%, low risk
- Self-pay, off label use.
- 29mm S3

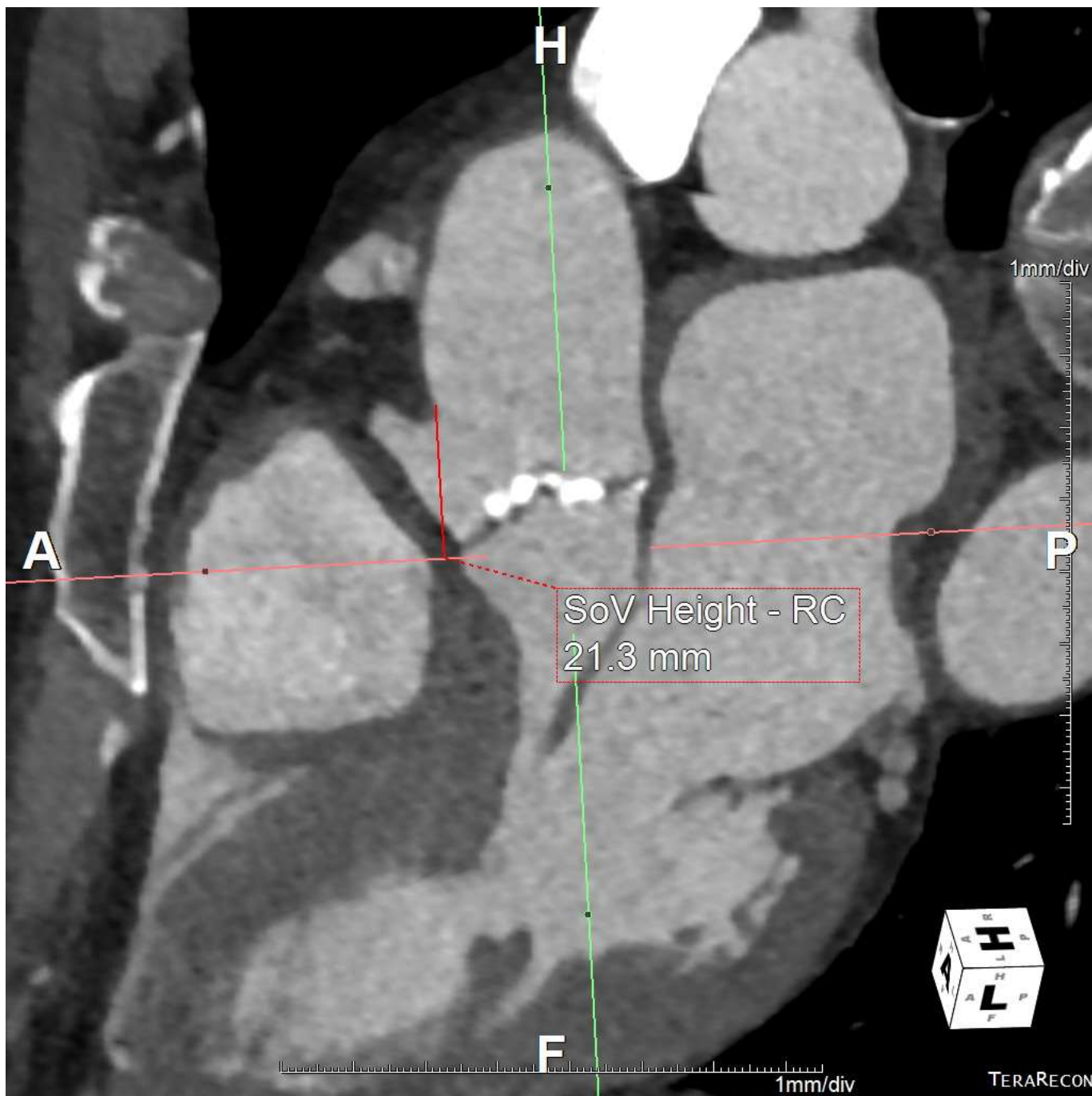


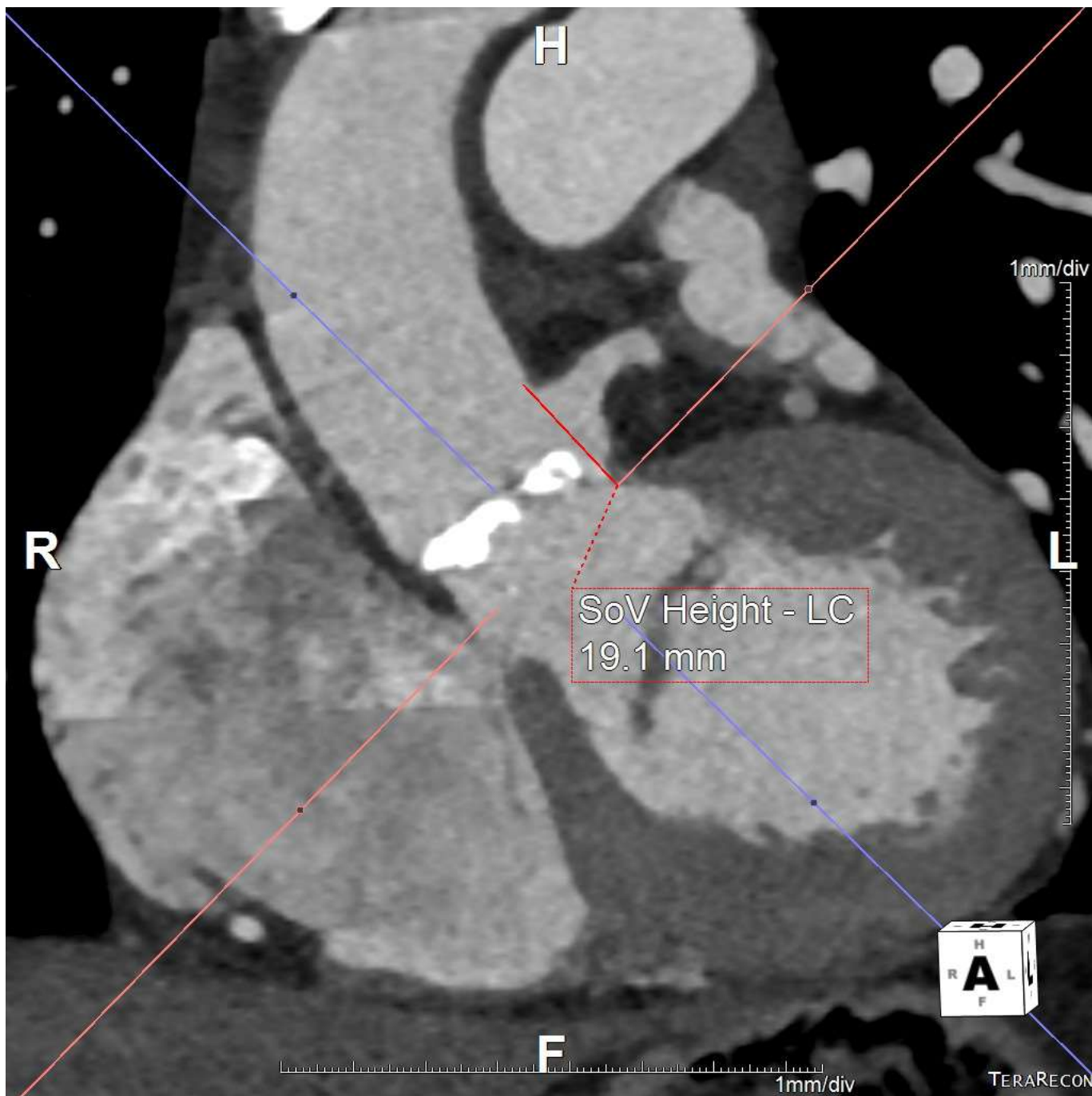


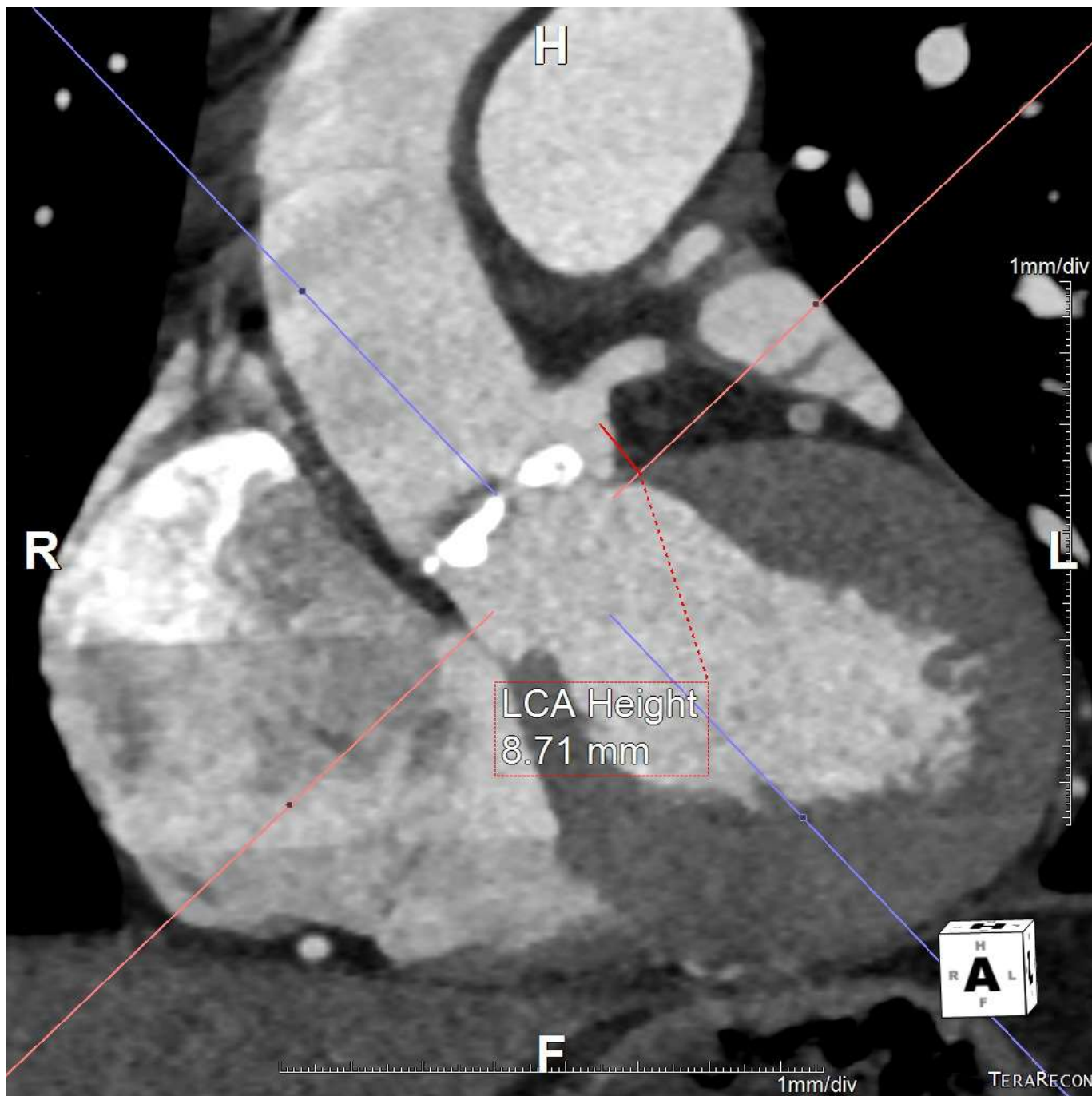


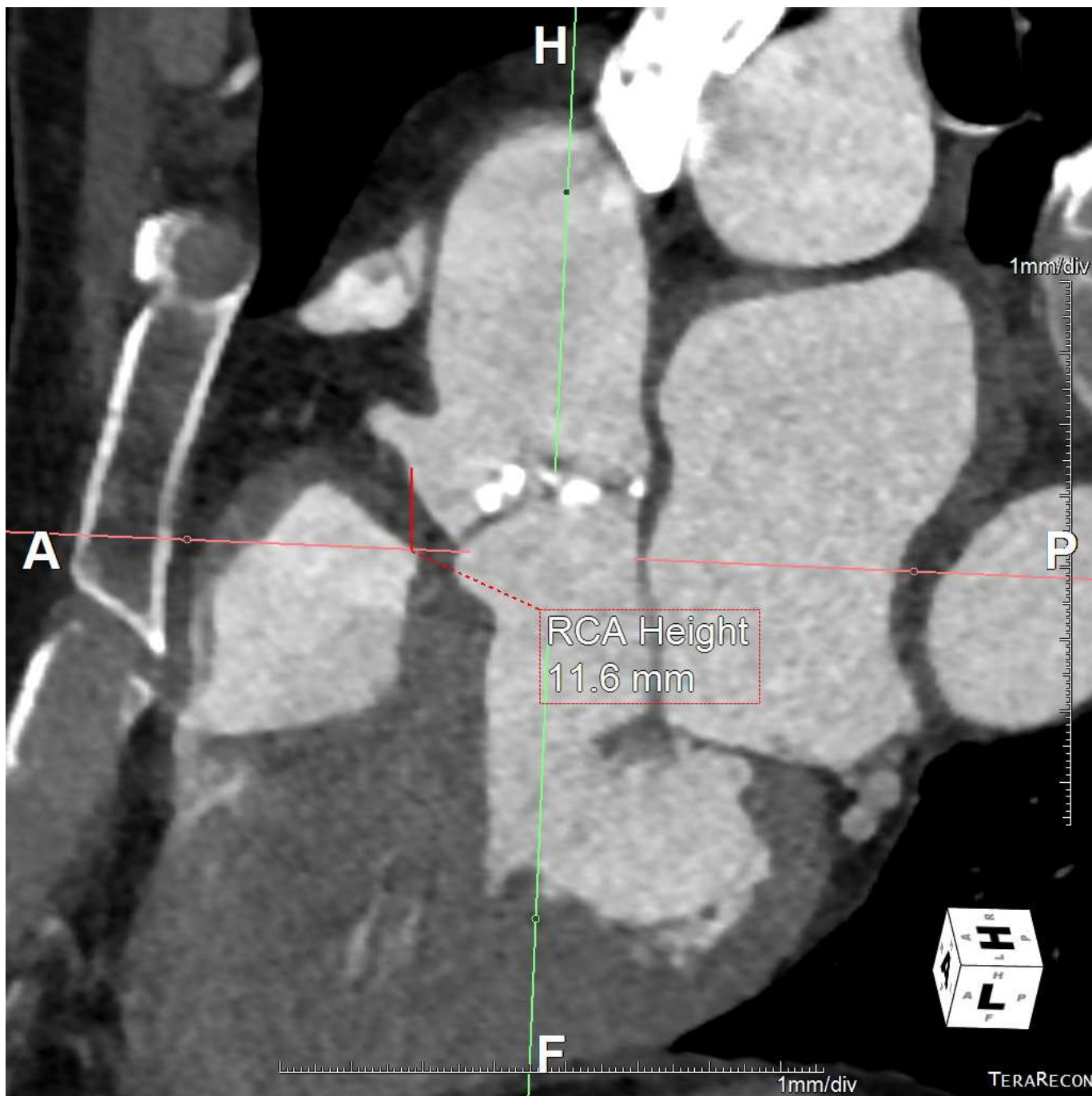












Derived



Hypotension
VF
CPR

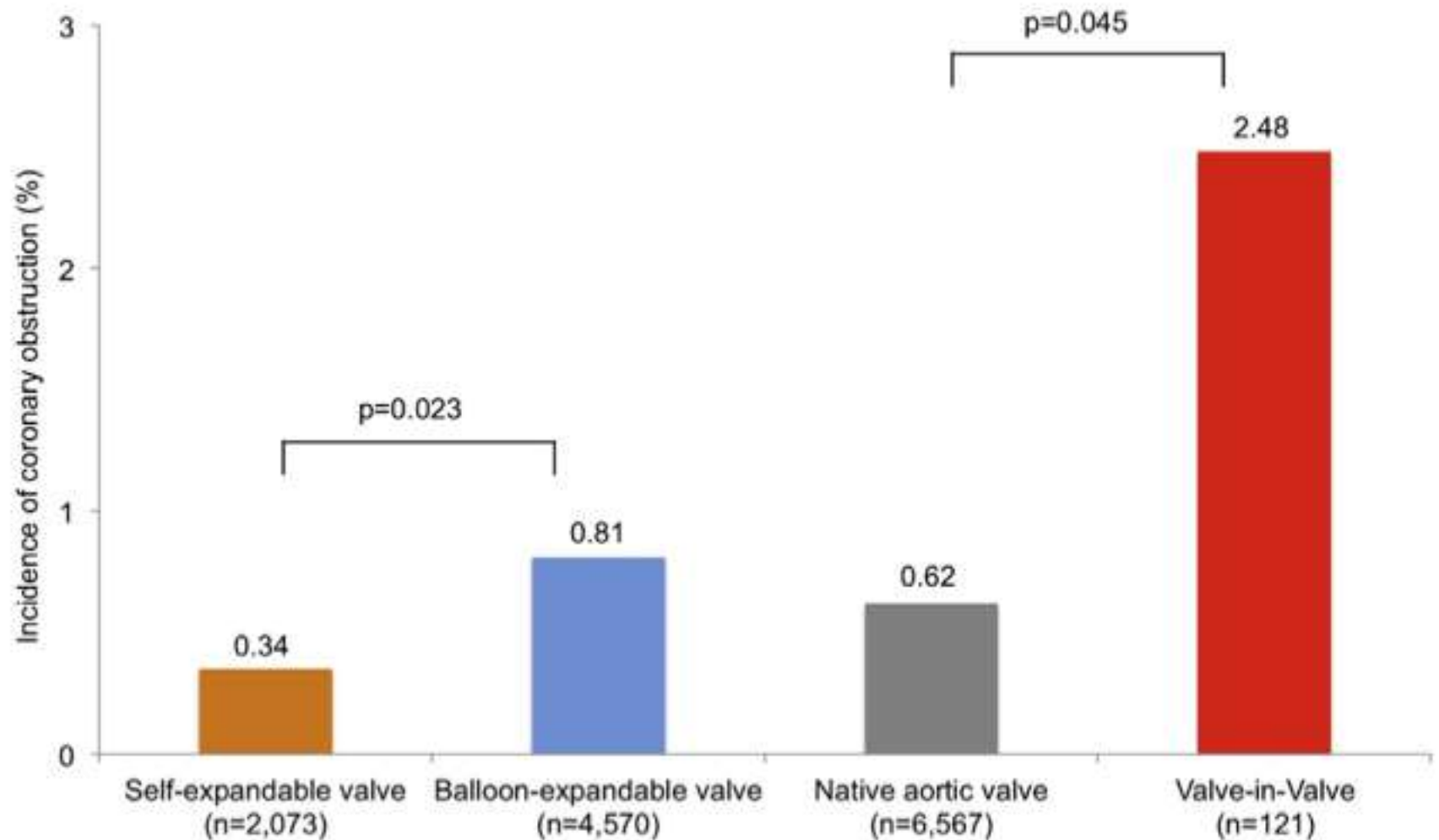


Case Presentation (2): F.C.

- Complete coronary obstruction
- Fem-fem bypass with 18F A and 25F V
- Sternotomy with removal of the S3
- 23mm Magna Ease valve
- Extubate POD 1
- Post-op AF
- D/C POD 8
- Normal LV (EF 58%) 1 month later and normal activities



Incidence of Coronary Obstruction According to Valve Type and Valve-in-Valve Procedure



Clinical Presentation and Management

Table 3	Clinical Presentation and Management of Coronary Obstruction Following TAVI (n = 44)	
Procedural complications		
Need for cardiopulmonary resuscitation		18 (40.9)
Need for hemodynamic support		16 (36.4)
CPB		7 (43.8)
IABP		4 (25.0)
Fem-Fem CPB		3 (18.8)
ECMO		1 (6.3)
Impella		1 (6.3)
Inotropes		30 (68.2)
Valve embolization		2 (4.5)
Need for a second valve		3 (6.8)
Cardiac tamponade		3 (6.8)

Clinical Presentation and Management

Table 3

**Clinical Presentation and Management of
Coronary Obstruction Following TAVI (n = 44)**

30-day outcomes

Myocardial infarction	21 (47.7)
Peak CK-MB, $\mu\text{g/l}$	82.4 (24.3–240.6)
New Q waves*	5 (35.7)
New left bundle branch block	4 (9.1)
New pacemaker	1 (2.3)
Major vascular complications	5 (11.4)
Major or life-threatening bleeding	7 (15.9)
Acute renal failure	9 (20.4)
Dialysis	2 (4.5)
Stroke	4 (9.1)
Death	18 (40.9)
Hospitalization length, days	6 (3–17)

CT Data

- Pre-TAVR CT data were available in 28 of 44 pts with coronary obstruction (63.6%)
- Pts with coronary obstruction exhibited a smaller
 - Aortic annulus area
 - SOV diameter
 - STJ diameter
 - LCA height

Table 4

Computed Tomography Data, According to the Occurrence of Coronary Obstruction Following TAVI

	Coronary Obstruction (n = 28)	Control Subjects (n = 345)	p Value
Annulus diameter, mm	22.9 ± 3.1	24.4 ± 2.9	0.010
Annulus area, mm ²	387 (375–424)	476 (405–560)	0.002
Aortic SOV diameter, mm	28.1 ± 3.8	31.9 ± 4.1	<0.001
Sinotubular junction, mm	25.2 ± 3.1	28.0 ± 3.9	0.003
Relation prosthesis size/annulus	1.09 ± 0.11	1.05 ± 0.09	0.084
Relation SOV/annulus	1.25 ± 0.17	1.31 ± 0.14	0.054
Left coronary height, mm	10.6 ± 2.1	13.4 ± 2.1	<0.001
Right coronary height, mm	12.4 ± 3.2	14.1 ± 2.4	0.003
Left coronary height, mm*	10.4 ± 2.0	13.5 ± 2.0	<0.001
Right coronary height, mm†	11.3 ± 2.1	14.0 ± 2.4	0.048
Calcium score, Agatston units	2,354 ± 1,187	2,872 ± 1,726	0.290

CT Data: Case-Matched Analysis

- In the case-matched analysis
 - The SOV diameter remained smaller (HR 1.37)
 - The LCA height remained lower (HR 2.17)

Table 5

CT Data From the Case-Matched Analysis, According to the Occurrence of Coronary Obstruction Following TAVI

	Coronary Obstruction (n = 27)	Control Subjects (n = 27)	OR (95% CI)	p Value
Annulus diameter, mm	23.0 ± 0.6	23.6 ± 0.4	1.15 (0.92–1.45)	0.510
Annulus area, mm ²	410 ± 18	458 ± 17	1.01 (0.99–1.02)	0.126
Aortic SOV diameter, mm	28.3 ± 0.8	31.3 ± 0.6	1.37 (1.13–1.66)	0.011
Relation prosthesis size/annulus	1.08 ± 0.02	1.05 ± 0.02	0.02 (0.01–3.99)	0.315
Relation SOV/annulus	1.26 ± 0.04	1.34 ± 0.03	20.0 (1.28–333)	0.003
Left coronary height, mm	10.7 ± 0.4	13.3 ± 0.3	2.17 (1.62–2.90)	<0.001
Right coronary height, mm	12.7 ± 0.8	14.2 ± 0.4	1.36 (1.10–1.68)	0.047
Calcium score, Agatston units	2,284 ± 318	2,733 ± 313	1.00 (0.99–1.10)	0.333

Anatomical Leaflet, Coronary, Sinus Modeling

Left Coronary Artery

Ostium diameter	5.1 mm
Vessel height	12.3 mm
Leaflet length	14.2 mm
Nodule thickness	4.0 mm
Sinus width	1.8 mm

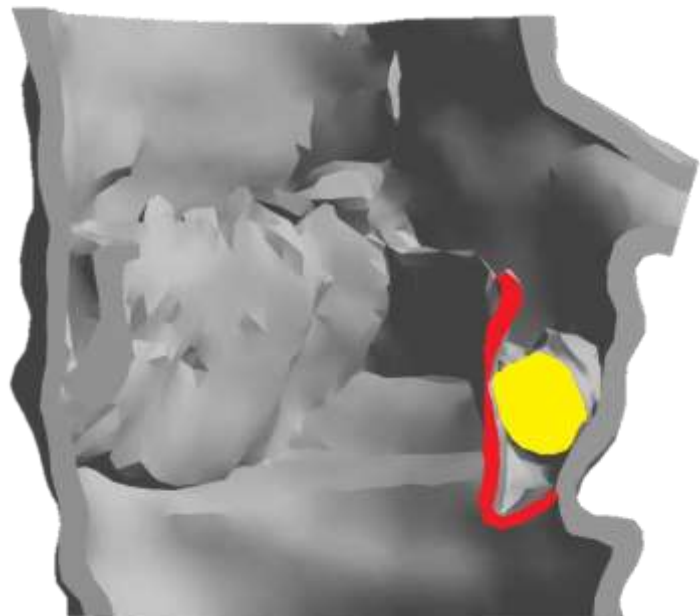
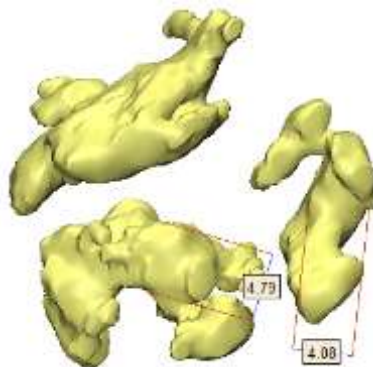
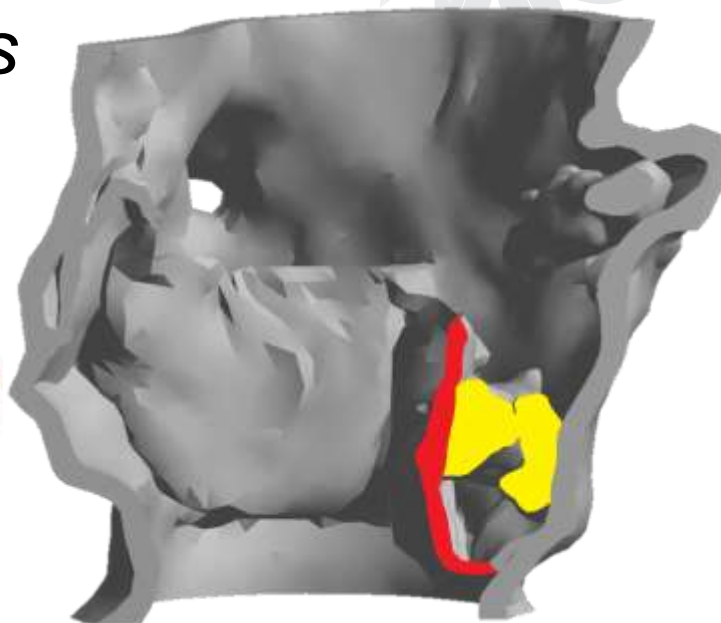
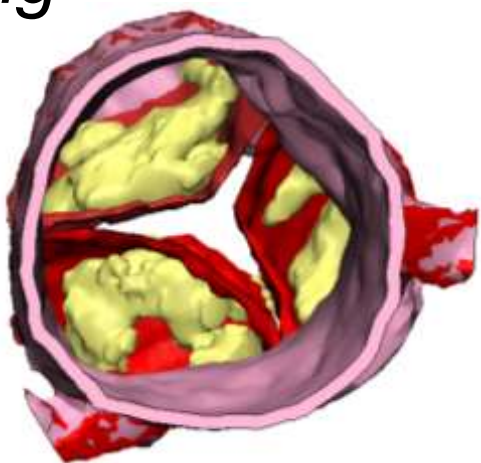
Reconstructions

-2-dimensional

- CT-derived measurements

-3-dimensional

- To predict apposition of leaflets

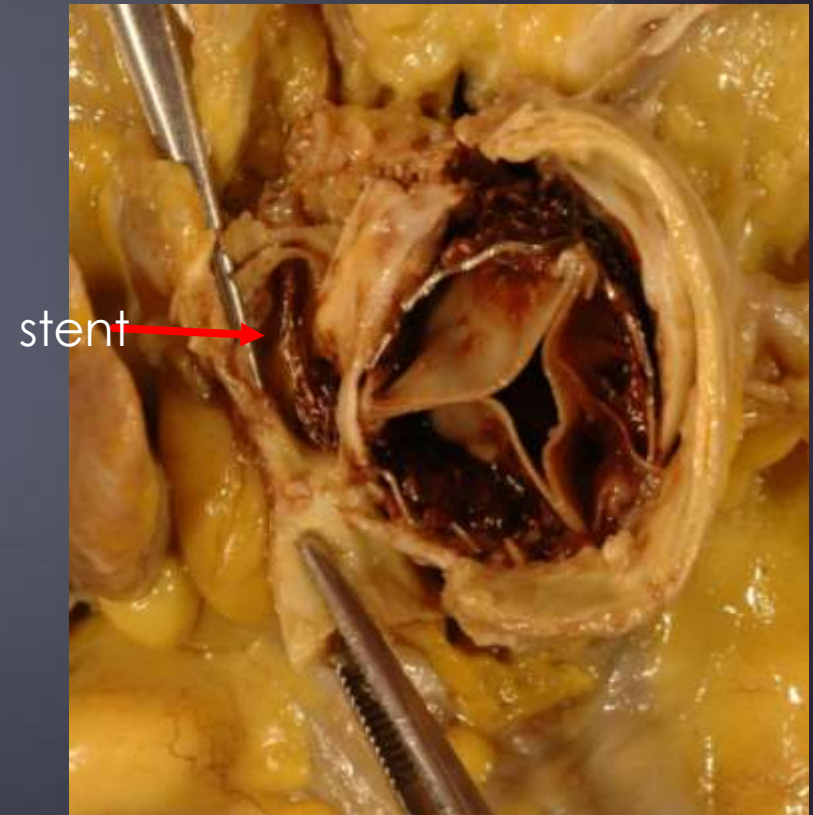
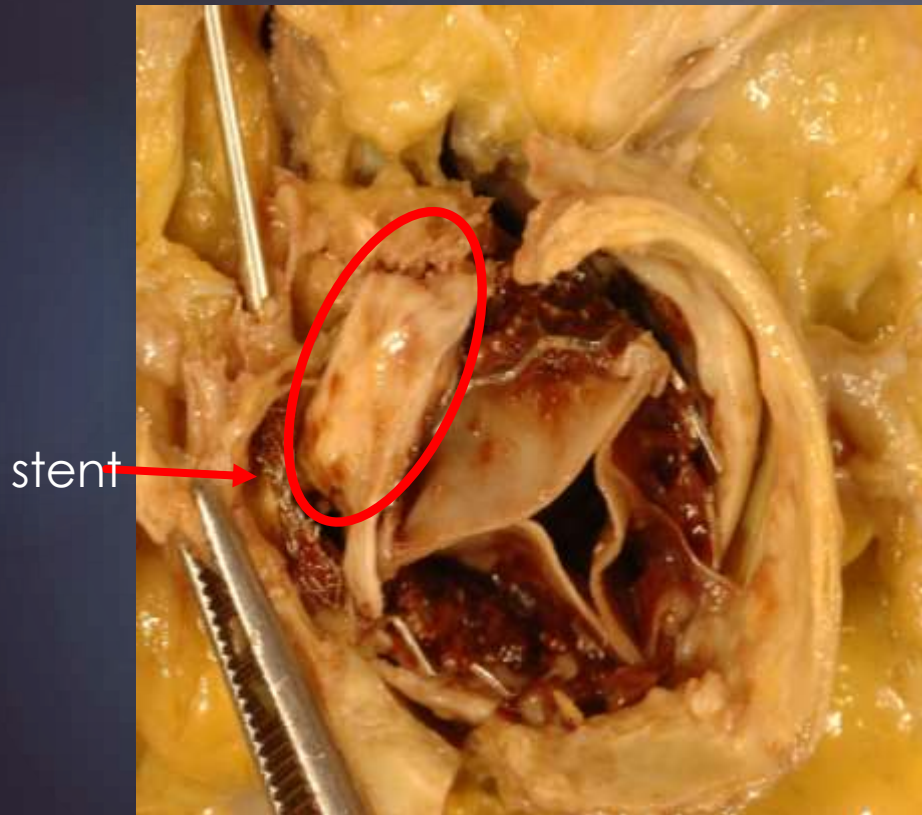


Retrospective Relook

- SoV Diameters: 33/34.9.....Low risk
- LCA height: 8.7.....high risk
- RCA height: 11.6.....high risk
- Large Valve: 29mm S3
- Bulky nodule in L and R: 4 to 5mm
- LCA: $35 - (29 + 5) = 1$
- RCA: $33 - (29 + 4) = 0$
- VIP: PARTNER3 vs Medicare self pay vs overseas



Crushed stent between sinus and thickened valve leaflet



Conclusions

- Coronary obstructions occur in about 1% of TAVR
- LCA protection with un-deployed stent is standard protection technique but snorkeling may still lead to crushed stent. Not really a good option for low risk patients.
- Pre-op better evaluation of leaflet calcium bulk and 3D modeling may be helpful
- Predilating with sizing balloon in high STS risk patients may help to evaluate leaflet movements and protect LCA
- But in low risks, self expanding valve? Abort if obstructed? SAVR?





Case

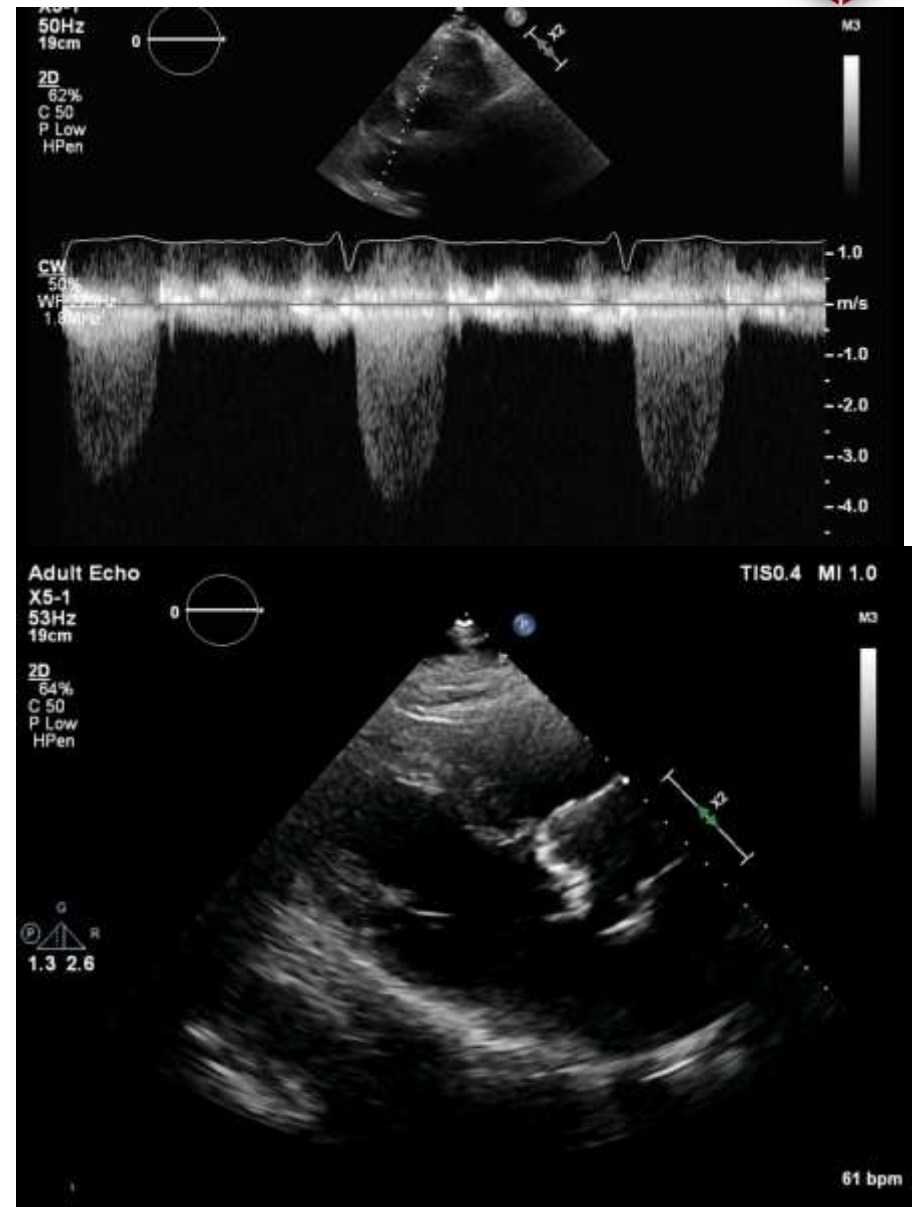
- 92yo male with history of hypertension, hyperlipidemia, paroxysmal AF, CKD (Cr1.2), ureteral TCC, s/p MI and CABG x 2 in 2014, now with severe aortic stenosis.
- Indication for TAVR:
 - Progressive fatigue, getting more difficult to ride his bike
 - Requires GA for ureteroscopy q4months & Anesthesiologist reluctant to administer GA
 - Cardiac Surgical review: Clinically high risk for redo sternotomy & AVR, STS 6.7%



Echo & Frailty Analysis

Echo Variable (TTE)	Measure
Jet Velocity	4.0 m/sec
Mean Gradient	40 mmHg
Calculated AVA	0.88 cm ²
Calculated AVA index	0.45 cm ² /m ²
Ejection Fraction	55 %
Severity of AR	Mild
Severity of MR	Mild -mod
Severity of TR	Mild
RV Pressure	39mmHg

Frailty	
BMI	27.57
Serum Albumin	4.0g/dL
ADL	6/6
Grip Strength	40kg
15Ft Walk Test	6.1sec
Score	0/4

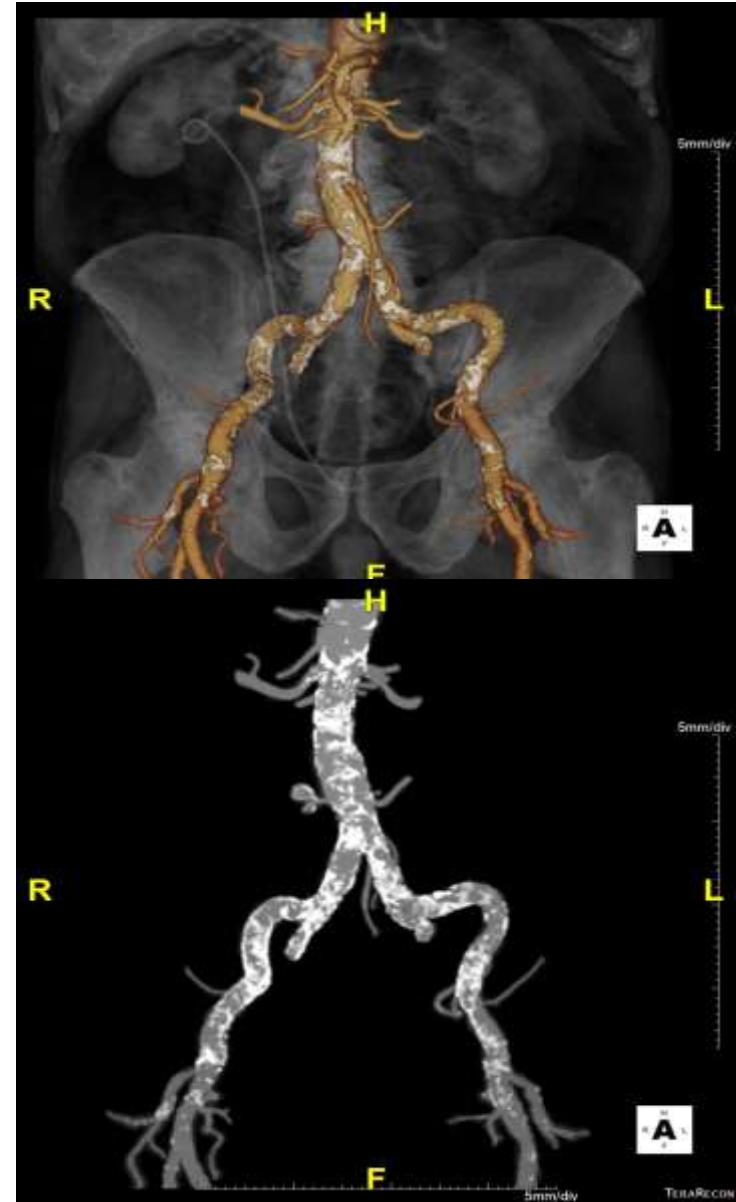




CT Analysis:

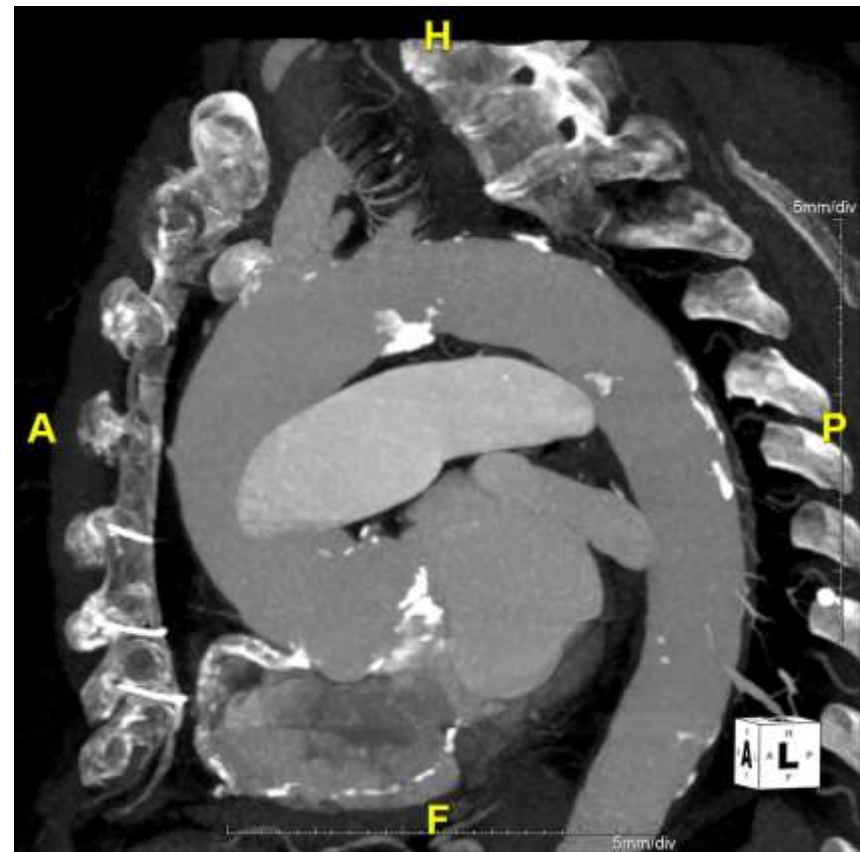
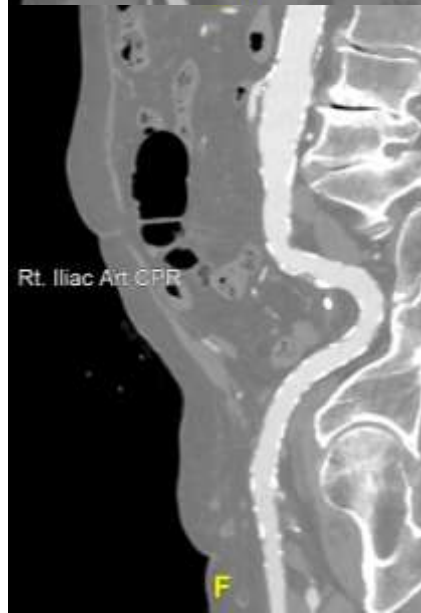
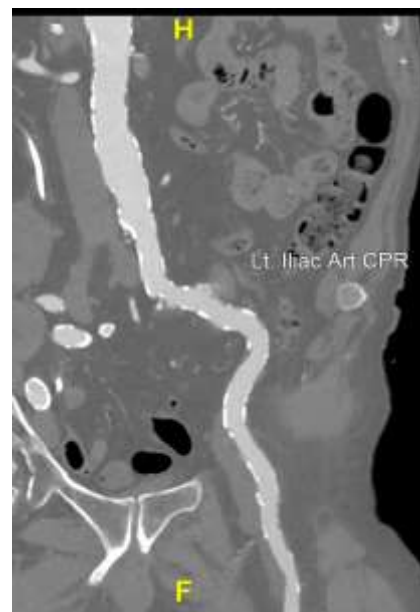
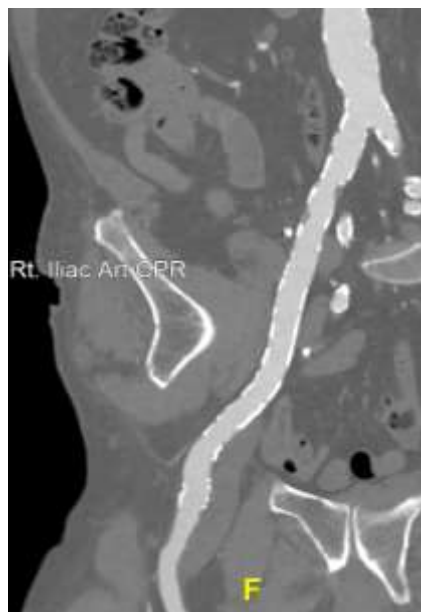
Vessel	Max	Min
RCIA	12.1 mm	12.1 mm
REIA	10.7 mm	9.6 mm
RCFA	9.6 mm	9.1 mm
LCIA	11.9 mm	9.9 mm
LEIA	10.5 mm	8.0 mm
LCFA	11.1 mm	9.3 mm

Aortic measurements		
SOV Diameters	RCC	40.7 mm
	LCC	41.9 mm
	NCC	40.0 mm
Coronary Heights	LCA	21.1 mm
	RCA	21.1mm
Annulus	Perimeter	88.6mm
	Area	601 mm ²
	Diameter	27.7mm



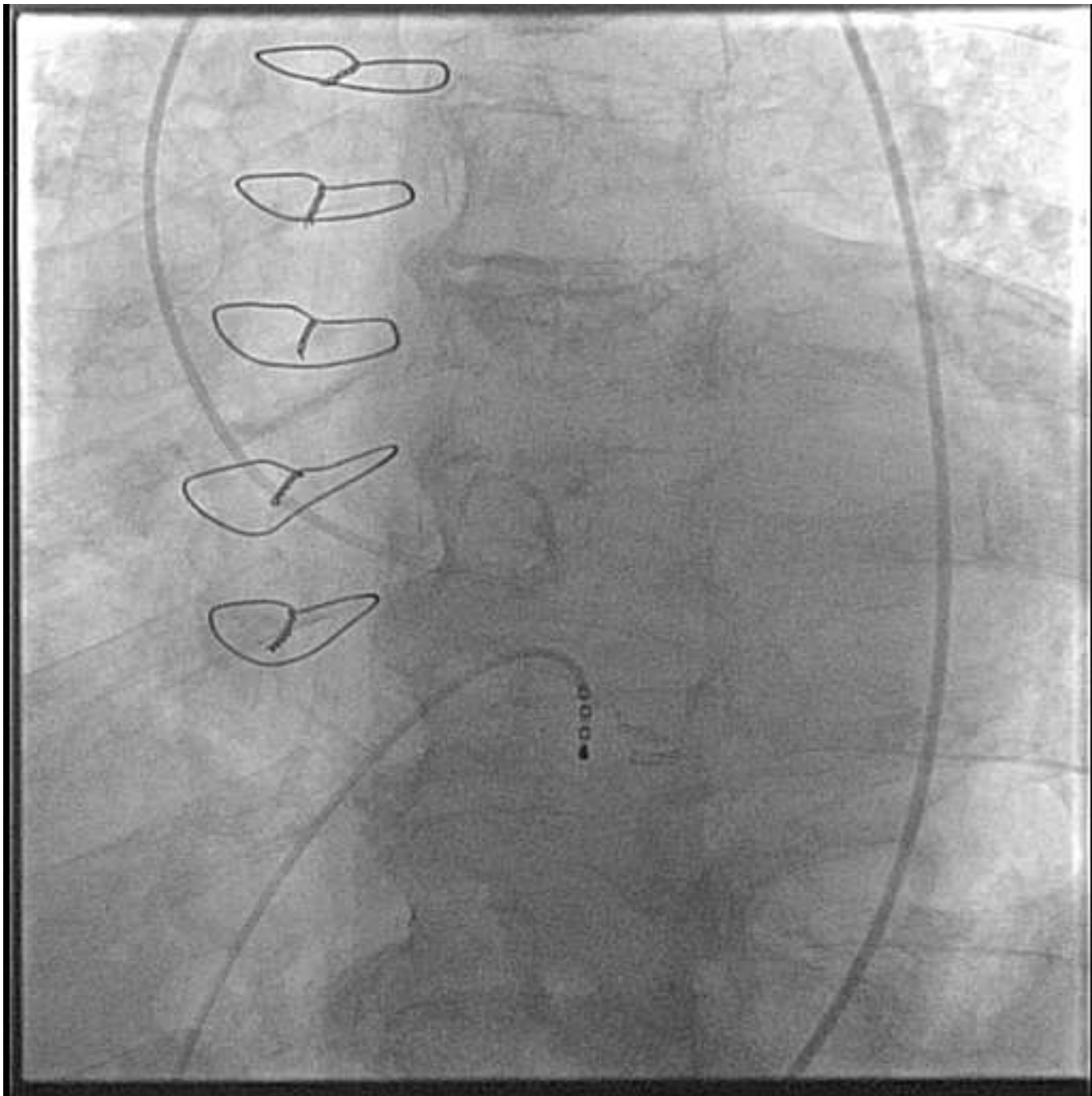


CT Analysis:



Cath Lab

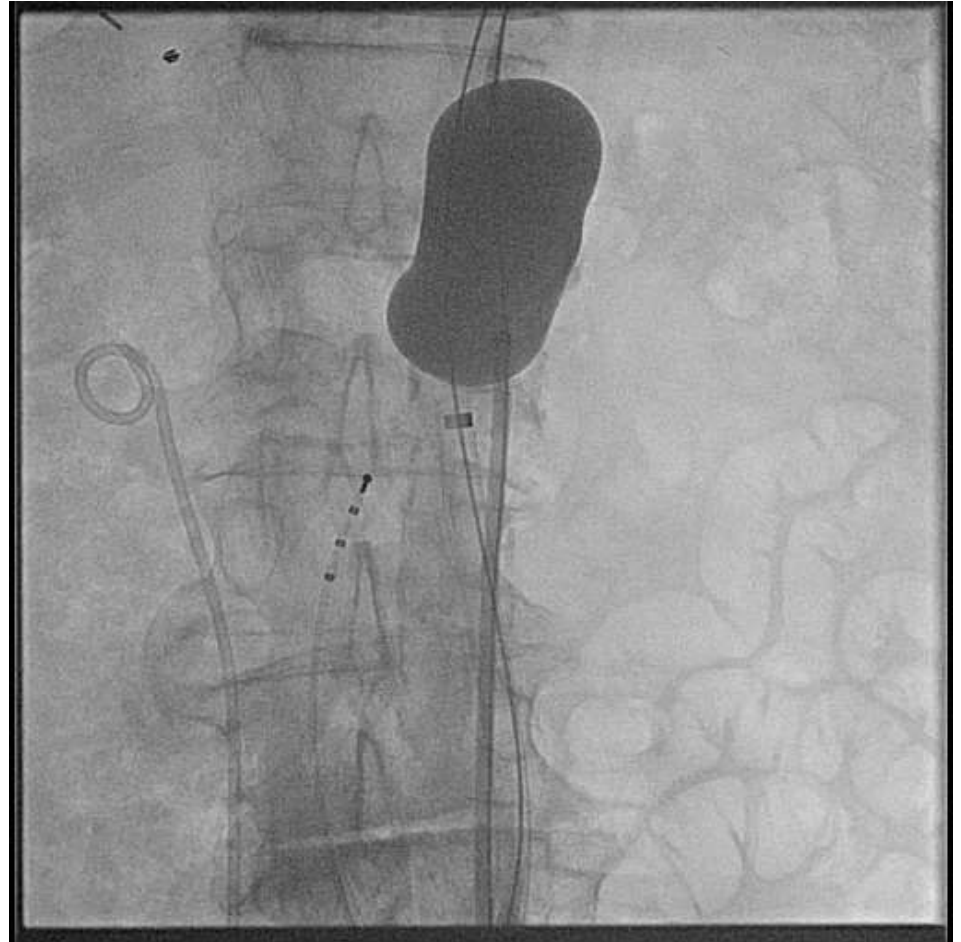








- Intubated
- Upsized left sided access to 14Fr
- Inserted Coda balloon



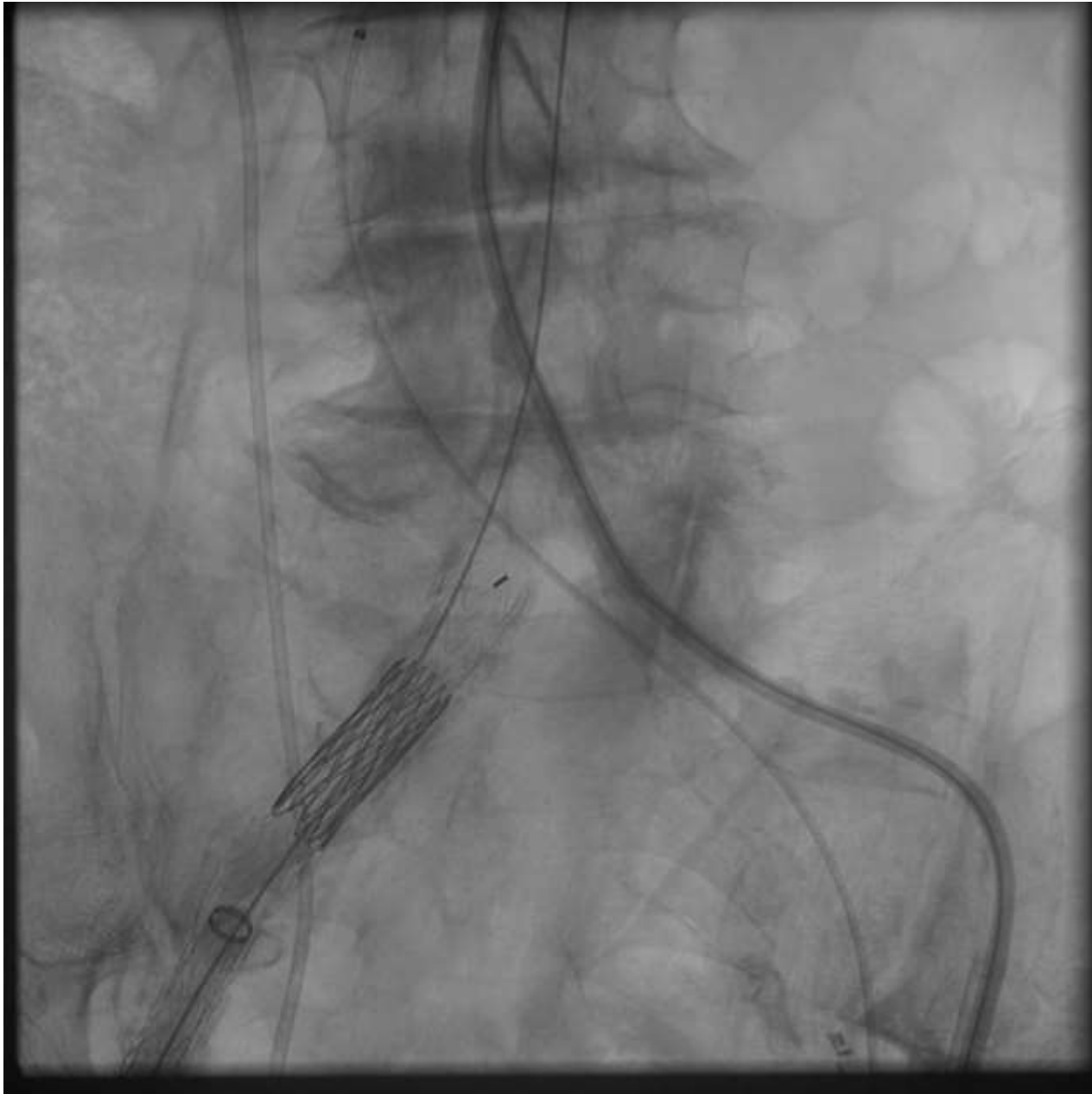






What to do?

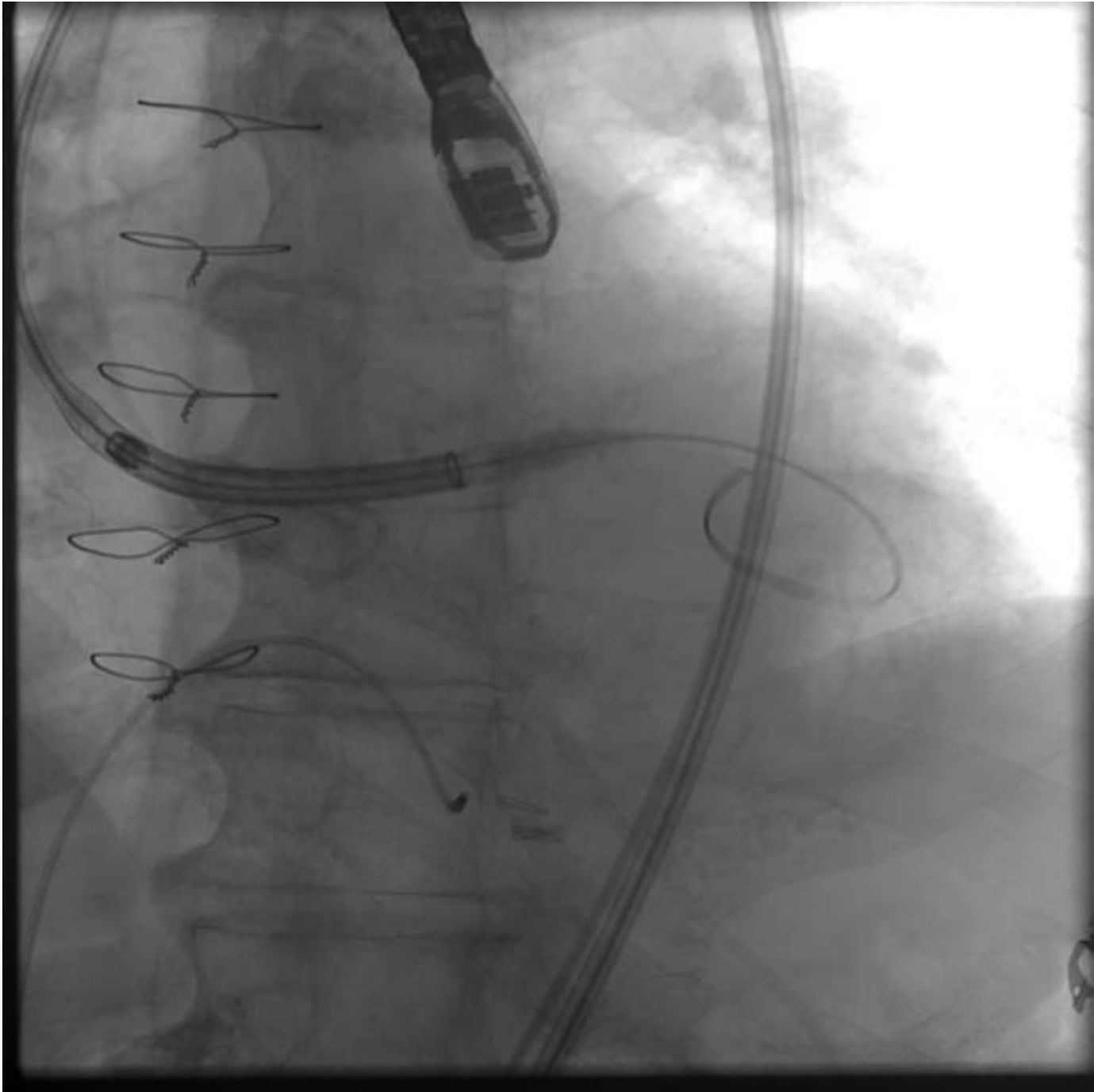
- Withdrew sheath
- Removed sheath and exchanged for 18Fr Gore Dry Seal Sheath
- 8mm balloon to expand TAVR
- Stented through TAVR with Gore Limb 16 x12 mm covered stent
- Post dilated valve and stent with 12 x 80mm balloon

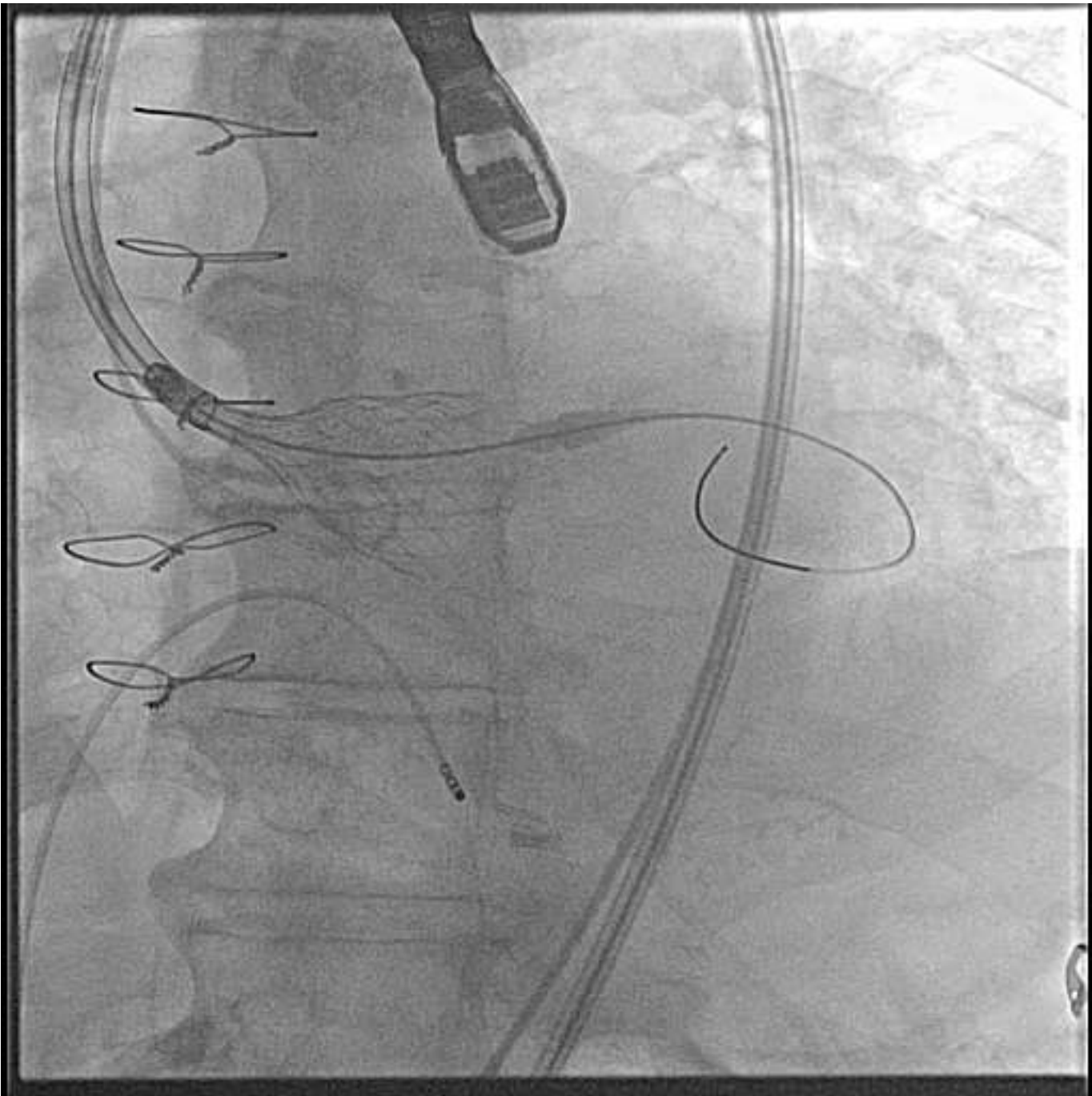


What now?



- Stop or re-attempt TAVR?







Adult Echo

X8-2t

11Hz

12cm

xPlane

63%

63%

50dB

P Off

Res

CF

48%

6208Hz

WF 558Hz

4.4MHz



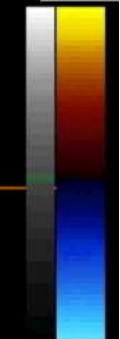
PAT T: 37.0C
TEE T: 38.5C

TIS0.6

MI 0.4

M4M4

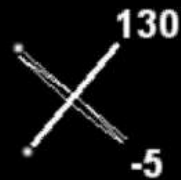
+53.8



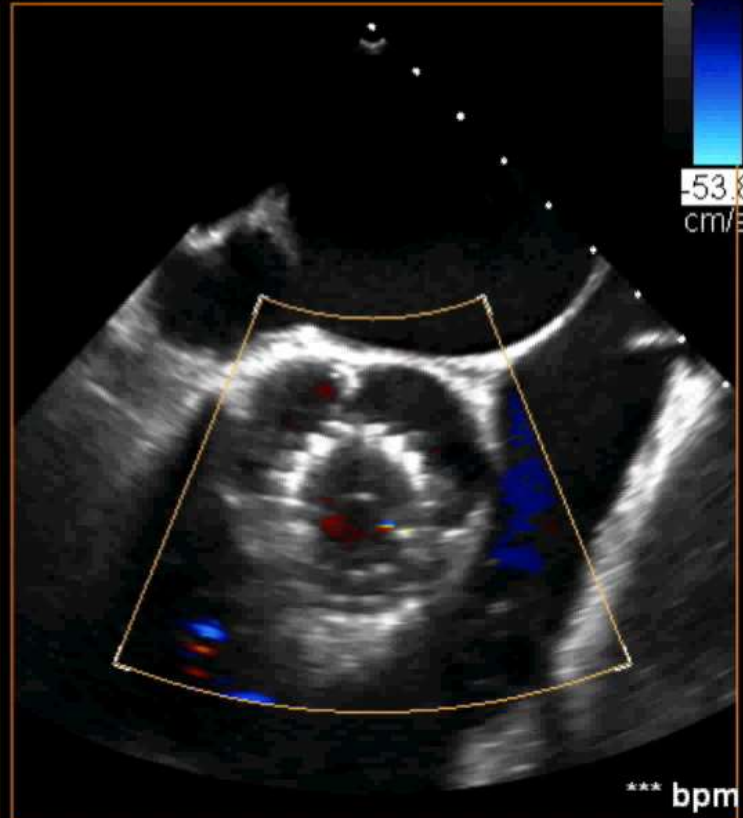
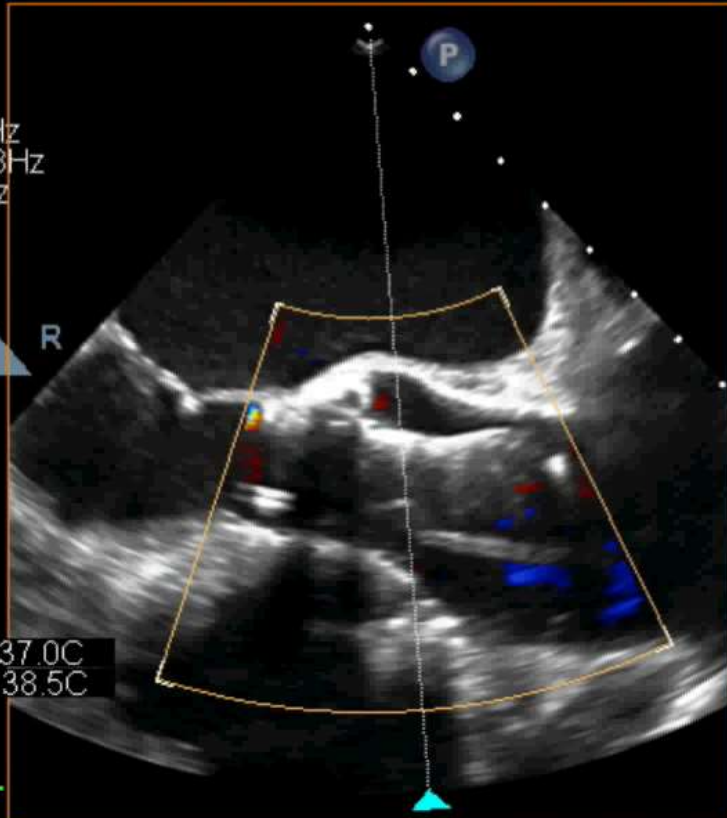
-53.8

cm/s

*** bpm



29MM CV EVOLUT R



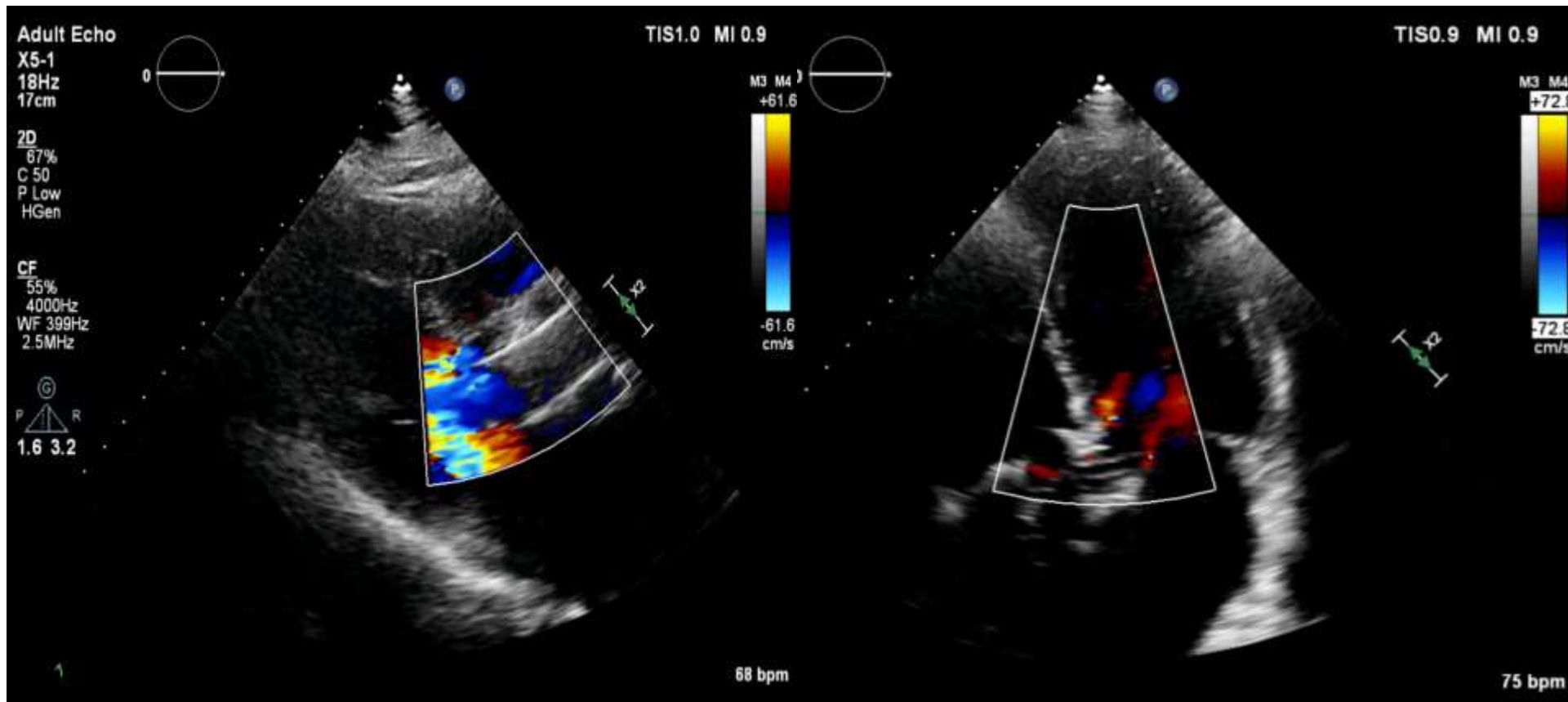


Progress in hospital

- Discharged from ICU Day 2
- Discharged home Day 5



Echo: 1 month review





-
- Echo post TAVR
 - Mean Gradient 9mmhg
 - Mild peri-valvular AR
 - LVEF 56%
 - On review appointment- well, returned to riding his bike



Take Home Message

- Be prepared for major vascular complications
 - Be familiar with bailout equipment e.g. aortic occlusion balloons +/- peripheral covered stents
 - Be aware of help available at hospital—vascular surgery / CTS

Annular Rupture

Bernhard Reimers, MD
Humanitas University, Rozzano –
Milan, Italy

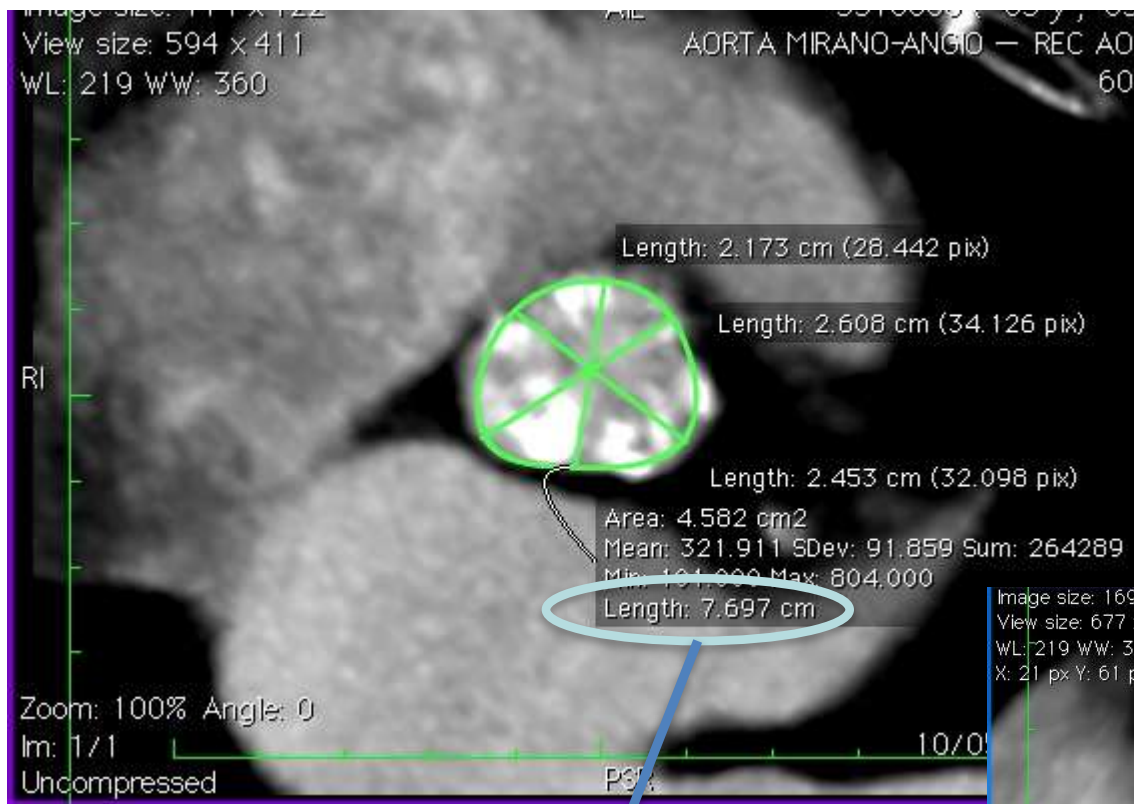
17 May 2013

The patient

- 85 years-old lady
- severe aortic stenosis (aortic valve area 0.6 mm²), LVEF 40%) symptomatic for heart failure for 2 years
- COPD
- Chronic renal failure
- Euroscore 20%
- refused by surgeon in 2012, she refused TAVI
- after multiple hospitalization for acute heart failure, she accepted TAVI

TAVI

Measurement of aortic annulus and distance between left main and annulus by angioCT:

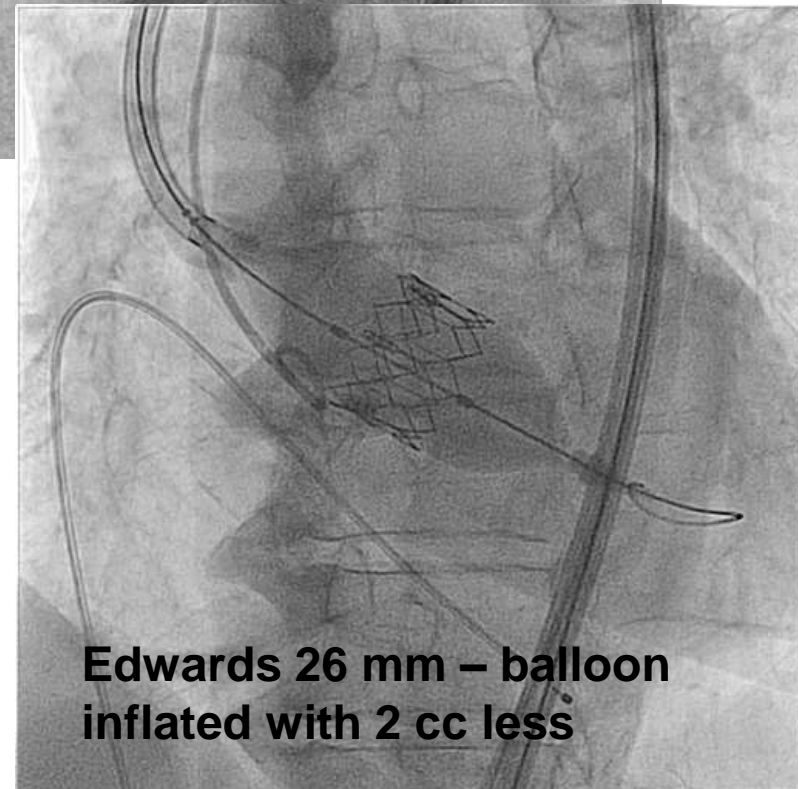
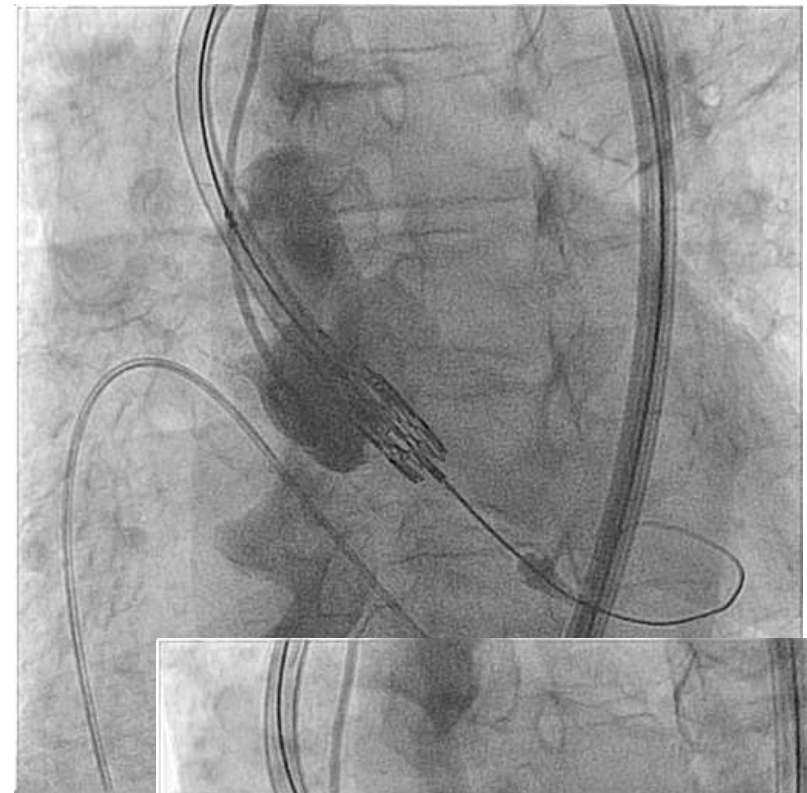
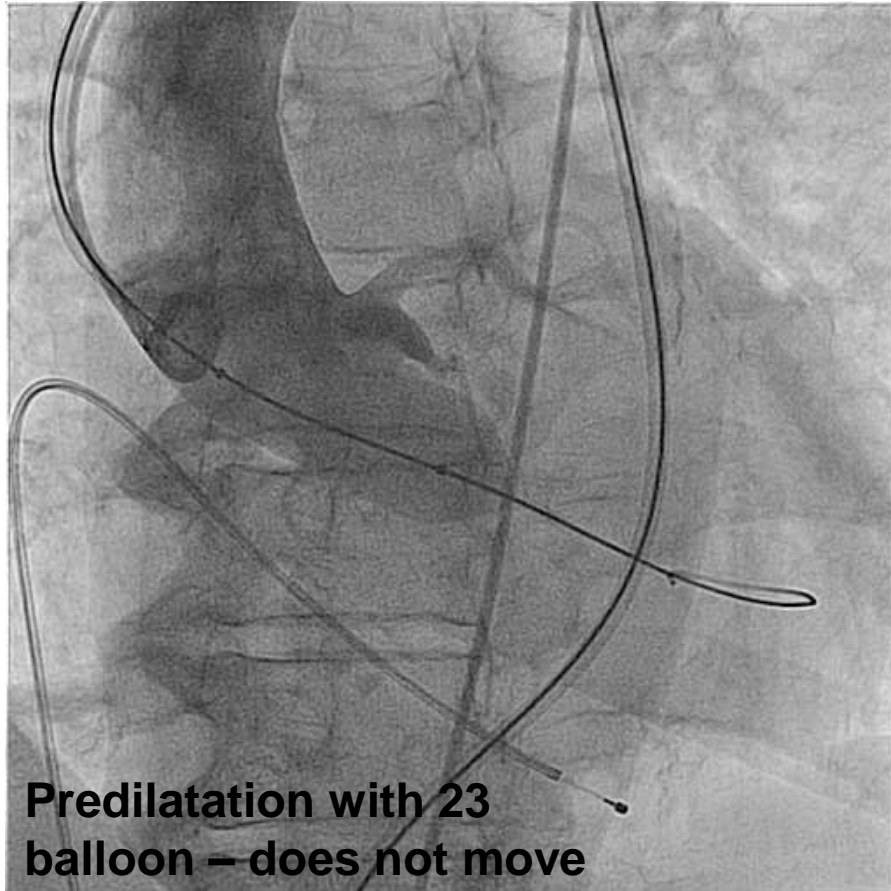


- High subvalvular calcification; higher risk of perivalvular regurgitation with Corevalve

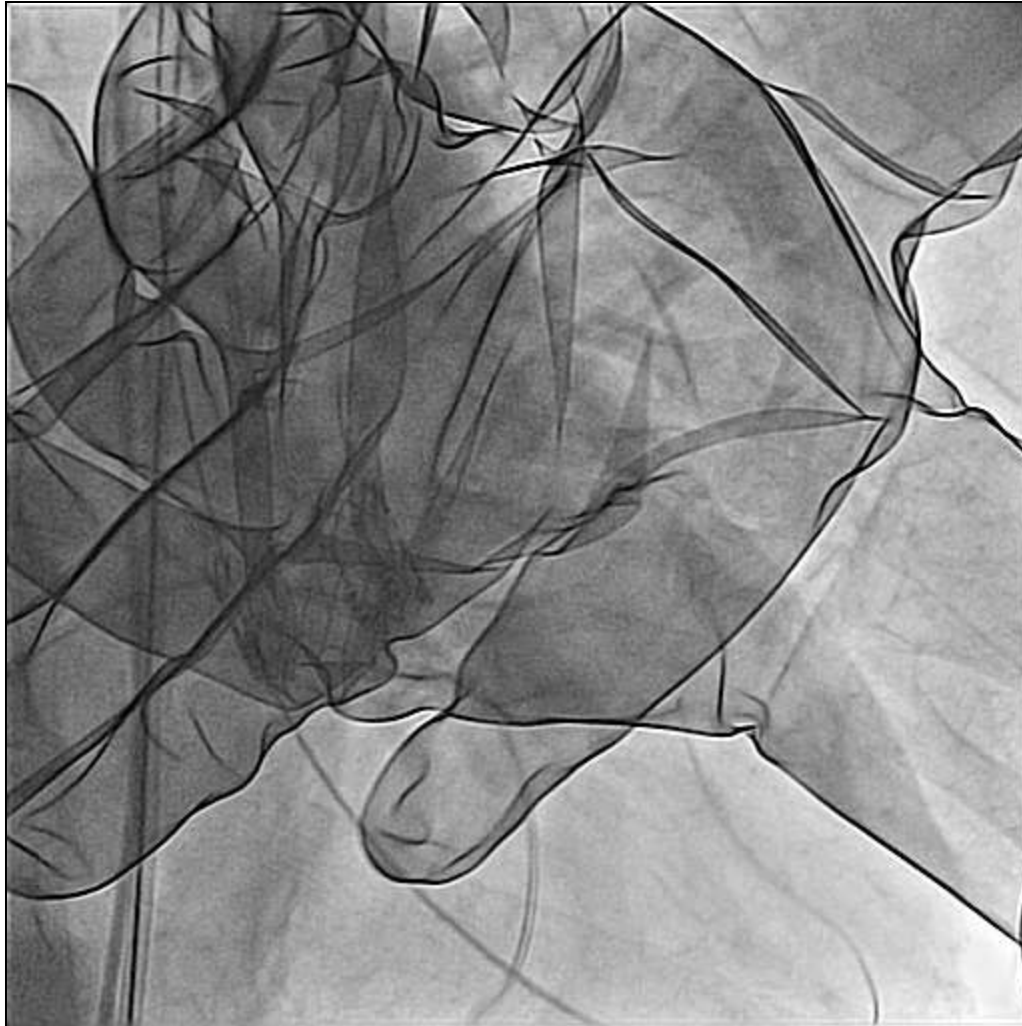
- Edwards 26 mm



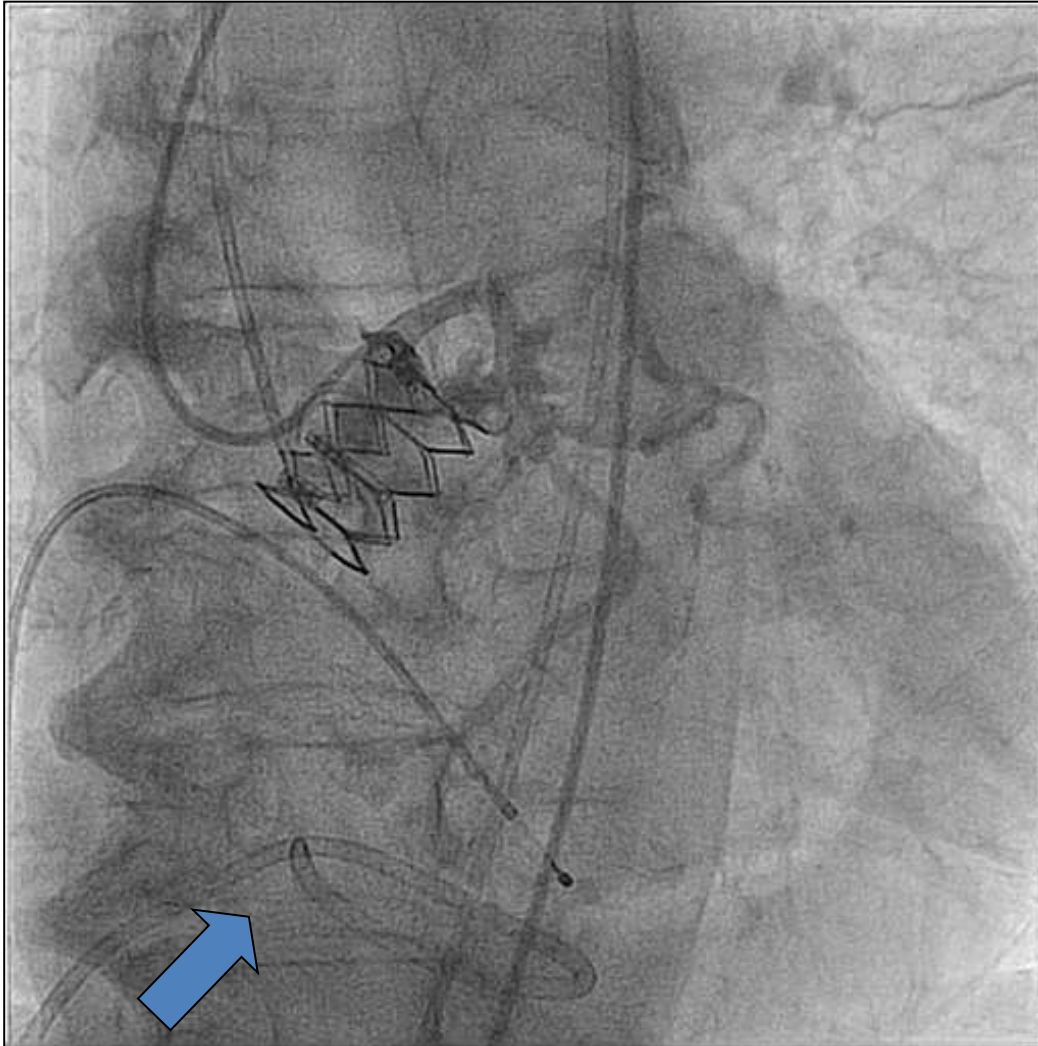
TAVI



**Apparently good result but patient in shock.
Massage using led gloves**

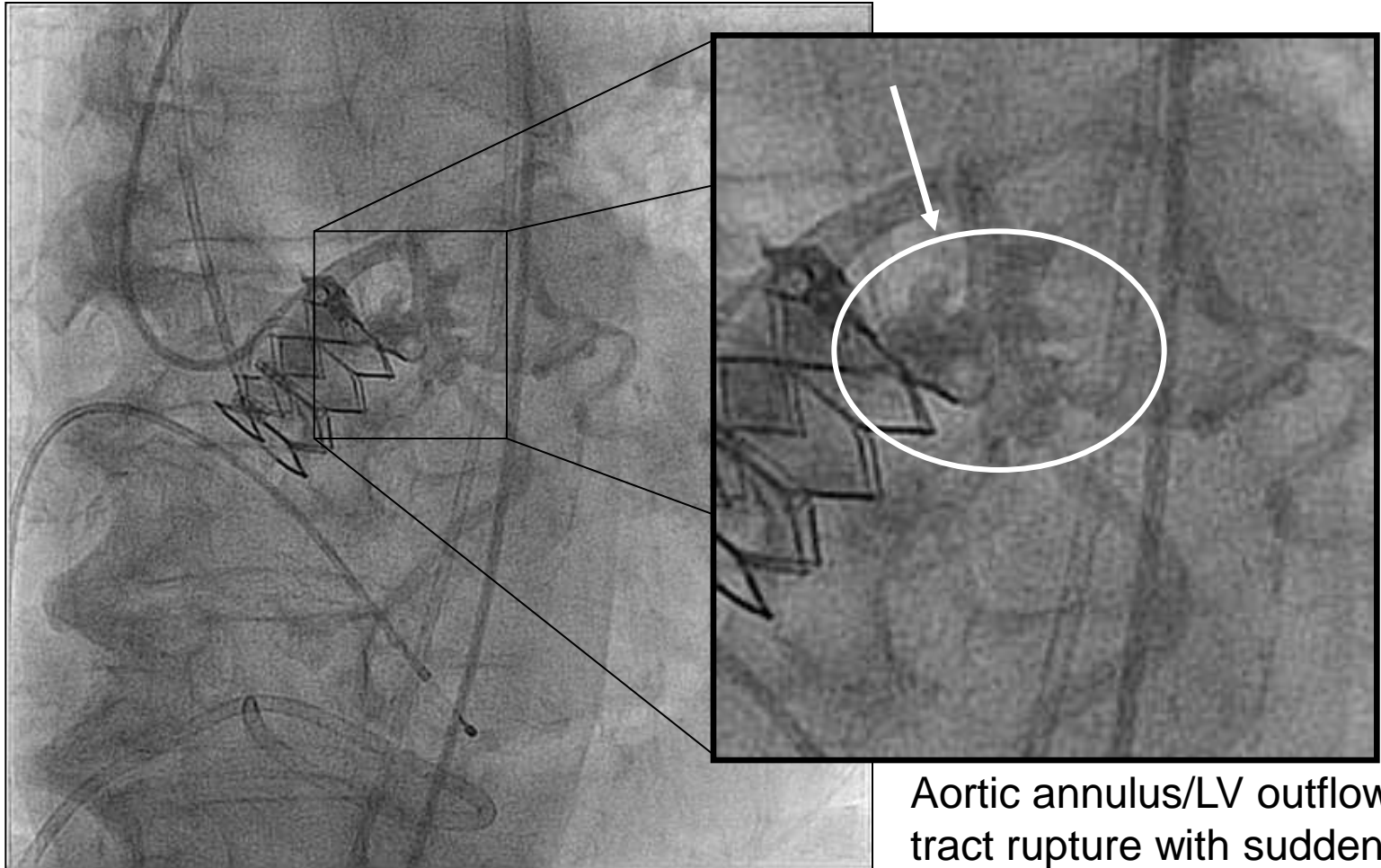


Patient little improved : Coronary control and
search for leakage



Pericardiocentesis

Rupture of LV outflow-tract



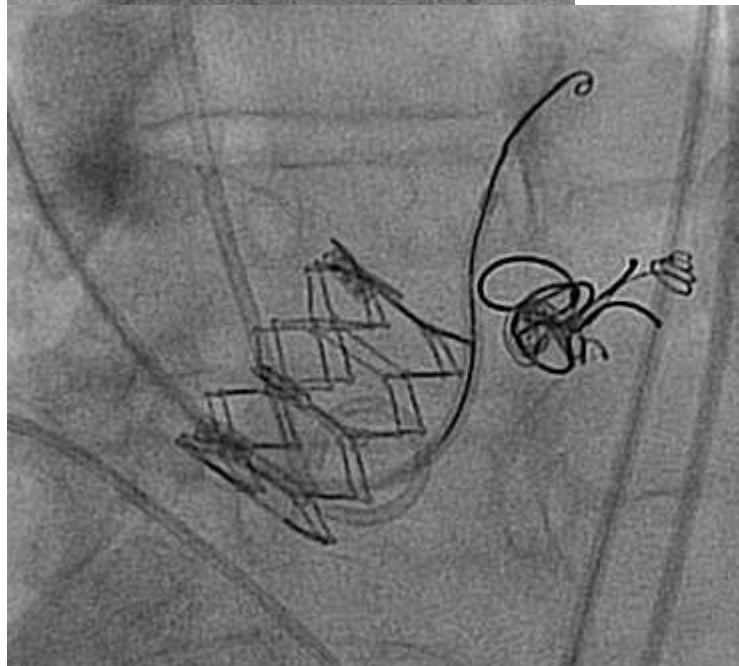
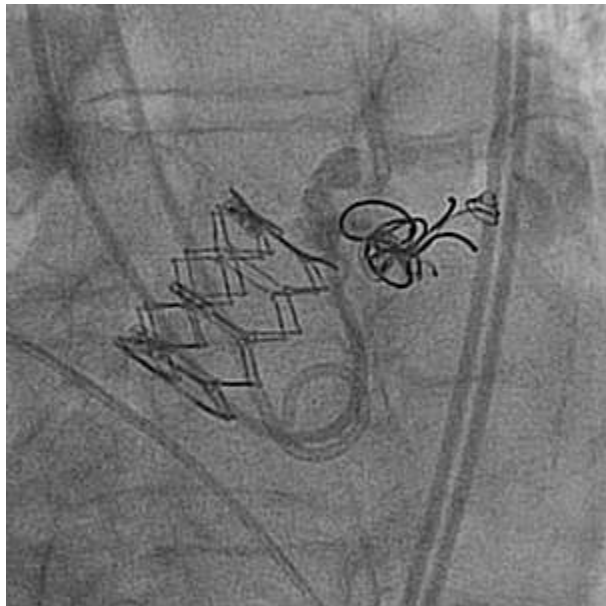
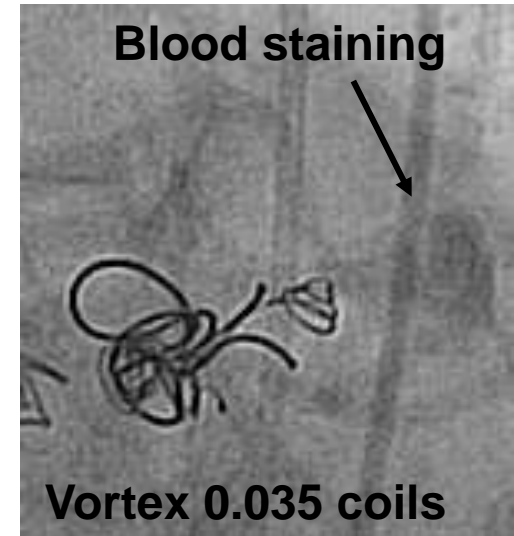
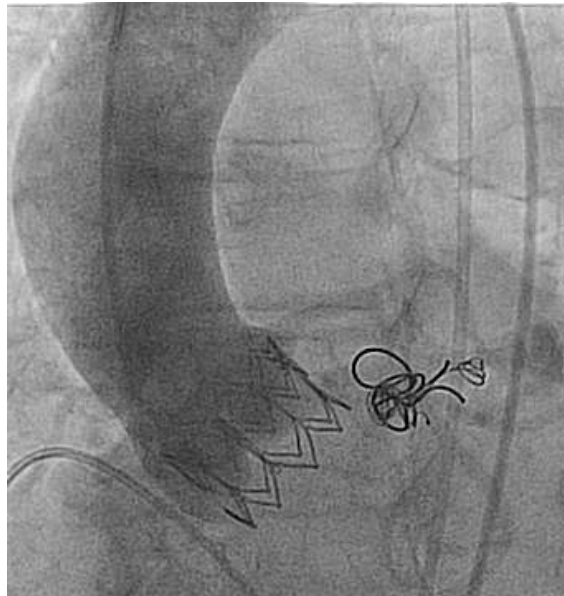
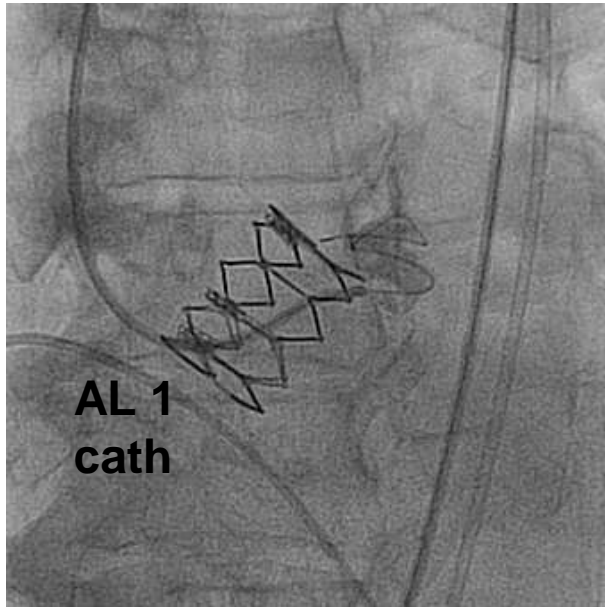
Aortic annulus/LV outflow tract rupture with sudden hemodynamic collapse

What to do?

patient unstable;

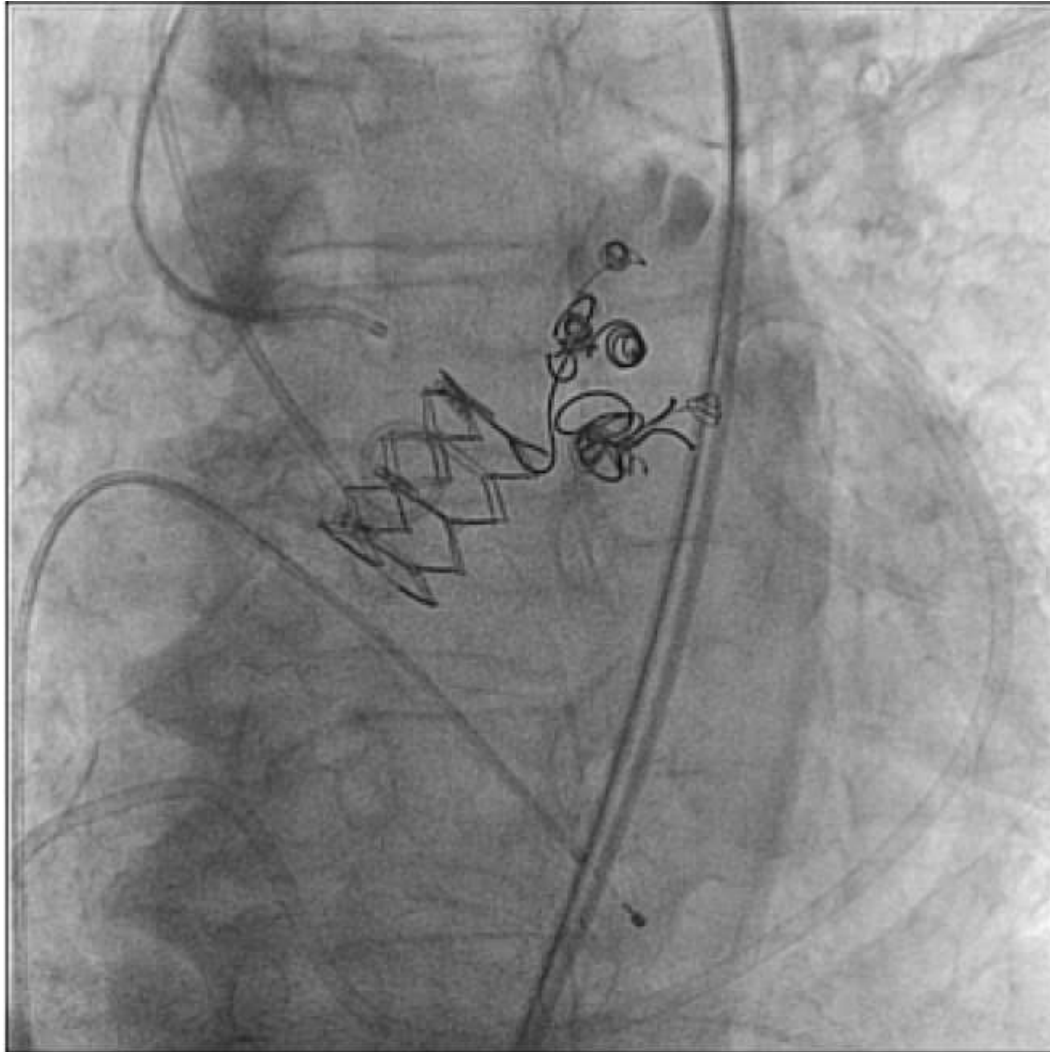
really no candidate for surgery.

Small hole, lets try to fix it (desperate attempt).



multiple 0.035"
Vortex (BSC) coils
deployed in
pericardium with
cessation of
bleeding. Drained
and partially re-
infused 1000cc

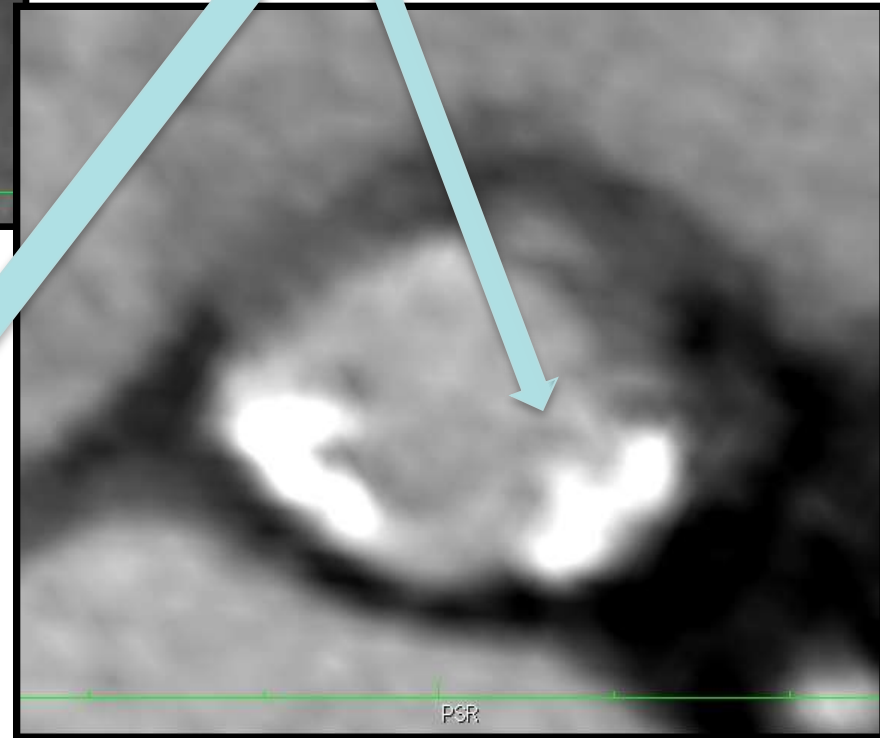
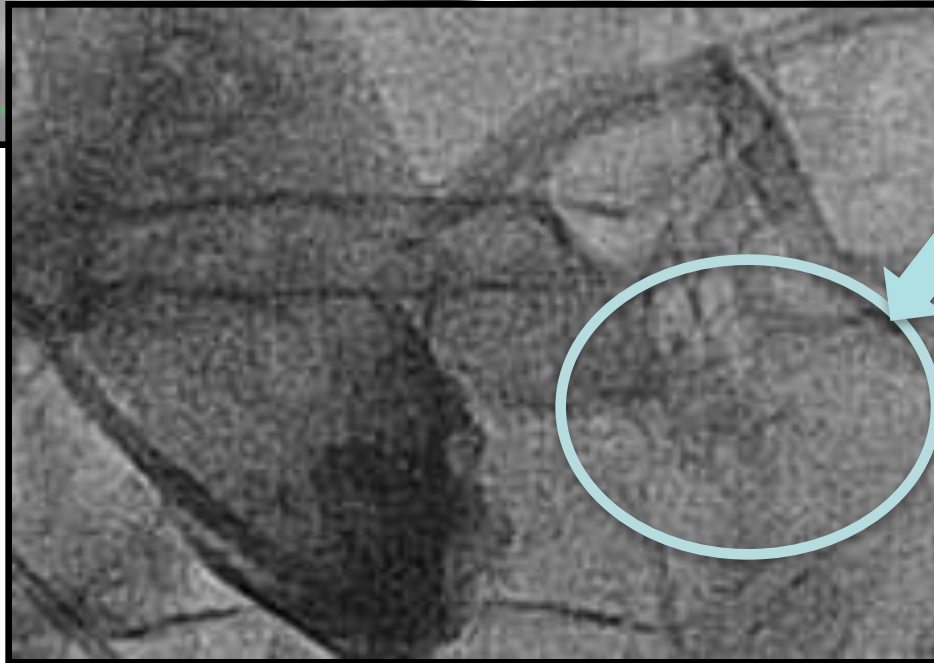
Final



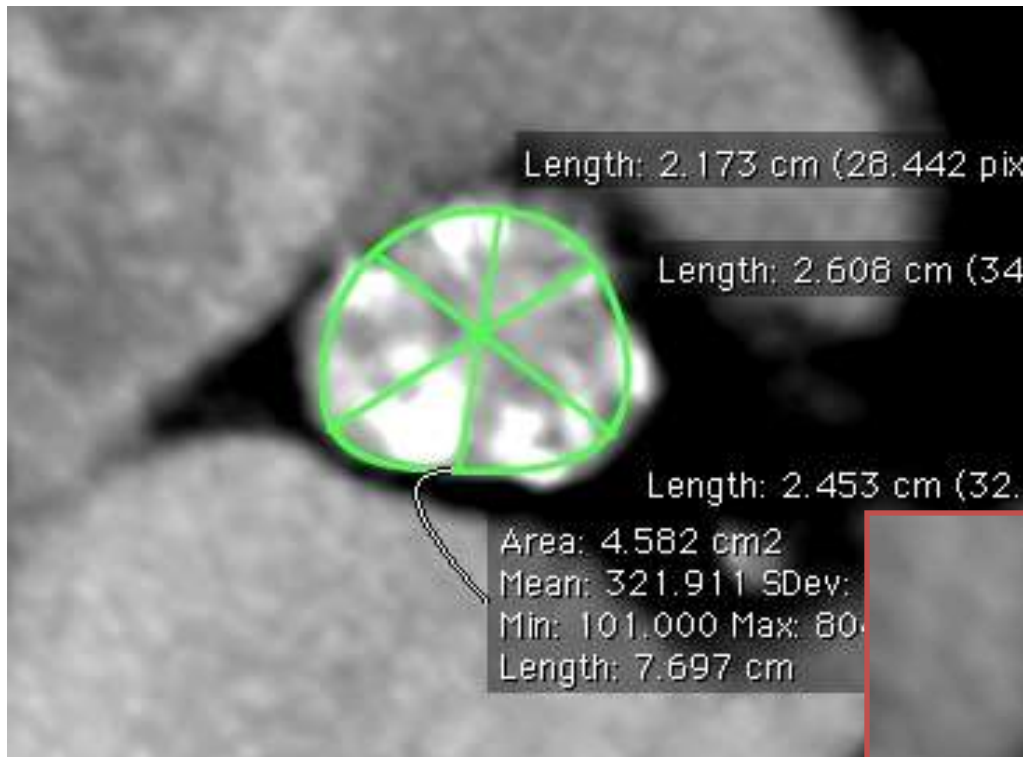
Pericardium
catheter in
better position

Aftermath

- Reason of rupture: Big trunk of sub-valvular calcium cracked by too big valve
- Big amount of subvalvular calcium - Predictable? CoreValve better?



Let's have a close look on measurements again:



Wrong measurements of annulus?

**Diameters 19 x 22 mm;
area 322mm²; area
perimeter 6.61**

**Diameters 21 x 26 mm;
area 458mm²; area
perimeter 7.69**

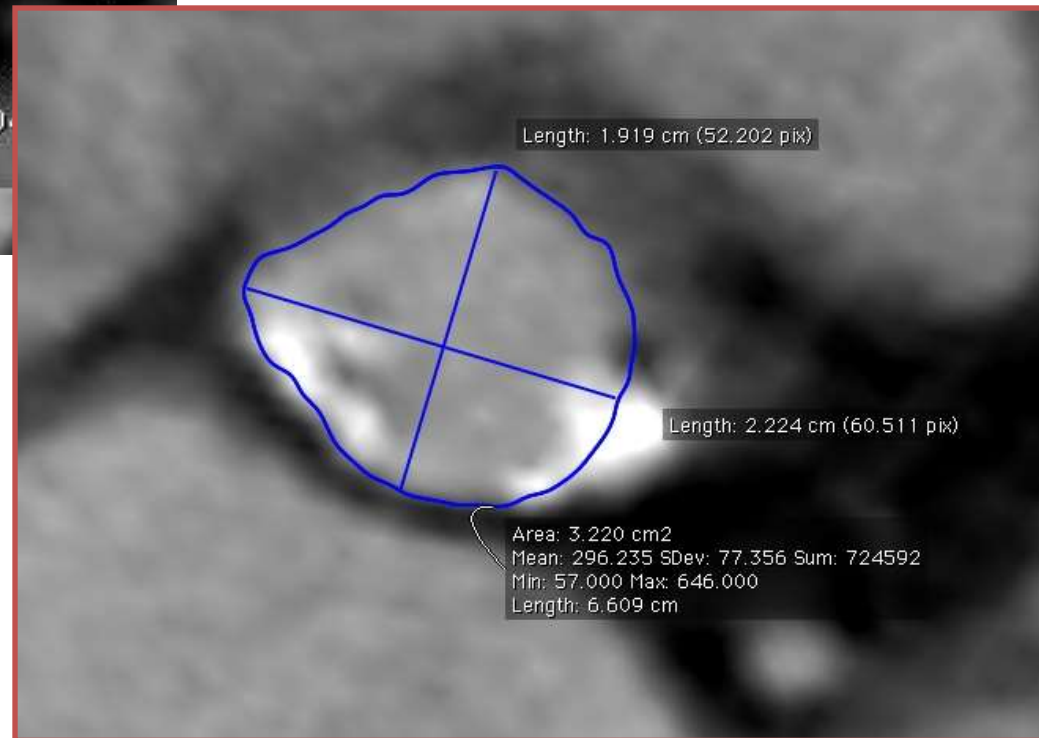


Table 6 Manufacturer-suggested aortic annulus and aortic root dimensions for TAVI/TAVR

	Aortic annulus diameter, mm	Distance aortic annulus to left main ostium, mm	Ascending aorta diameter, mm	Sinus of Valsalva width, mm	Sinus of Valsalva height, mm
Edwards Sapien XT 23 mm	18–22	≥ 10			
Edwards Sapien XT 26 mm	21–25	≥ 10			
Edwards Sapien XT 29 mm	24–27	≥ 10			
Medtronic CoreValve 26 mm	20–23		≤ 40	≥ 27	≥ 15
Medtronic CoreValve 29 mm	23–27		≤ 43	≥ 29	≥ 15
Medtronic CoreValve 31 mm	26–29		≤ 43	≥ 29	≥ 15

TAVI, transcatheter aortic valve implantation; TAVR, transcatheter aortic valve replacement.

Table 7 Manufacturer recommendations for CT-based sizing of the self-expanding Medtronic CoreValve

	Mean diameter, mm	Perimeter/circumference, mm	Area, mm ²
Medtronic CoreValve 23 mm	18–20	56.5–62.8	254.5–314.2
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Medtronic CoreValve 29 mm	23–27	72.3–84.8	415.5–572.6
Medtronic CoreValve 31 mm	26–29	81.7–91.1	530.9–660.5

**Diameters 21 x 26 mm;
area of perimeter 76.9mm
area 458mm²;**

Edwards 26mm (-2cc)

**Diameters 19 x 22 mm;;
area of perimeter 66.1 mm
area 322mm²**

Edwards 23mm

- At day 27 patient died the night following bronchoscopy (performed for intrapulmonary bleeding by experienced operator)

-Patient conscious until then, able to communicate with family

R.I.P.

Anatomical and Procedural Features Associated with Aortic Root Rupture During Balloon-Expandable Transcatheter Aortic Valve Replacement

Marco Barbanti, Tae-Hyun Yang, Josep Rodés-Cabau, Corrado Tamburino, David A. Wood, Hasan Jilaihawi, Philipp Blanke, Raj R. Makkar, Azeem Latib, Antonio Colombo, Giuseppe Tarantini, Rekha Raju, Ronald K. Binder, Giang Nguyen, Melanie Freeman, Henrique B. Ribeiro, Samir Kapadia, James Min, Gudrun Feuchtner, Ronen Gurtvich, Faisal Alqoofi, Marc Pelletier, Gian Paolo Ussia, Massimo Napodano, Fabio Sandoli de Brito, Jr., Susheel Kodali, Bjarne L. Norgaard, Nicolaj C. Hansson, Gregor Pache, Sergio J. Canovas, Hongbin Zhang, Martin B. Leon, John G. Webb and Jonathon Leipsic

Circulation. published online June 7, 2013;

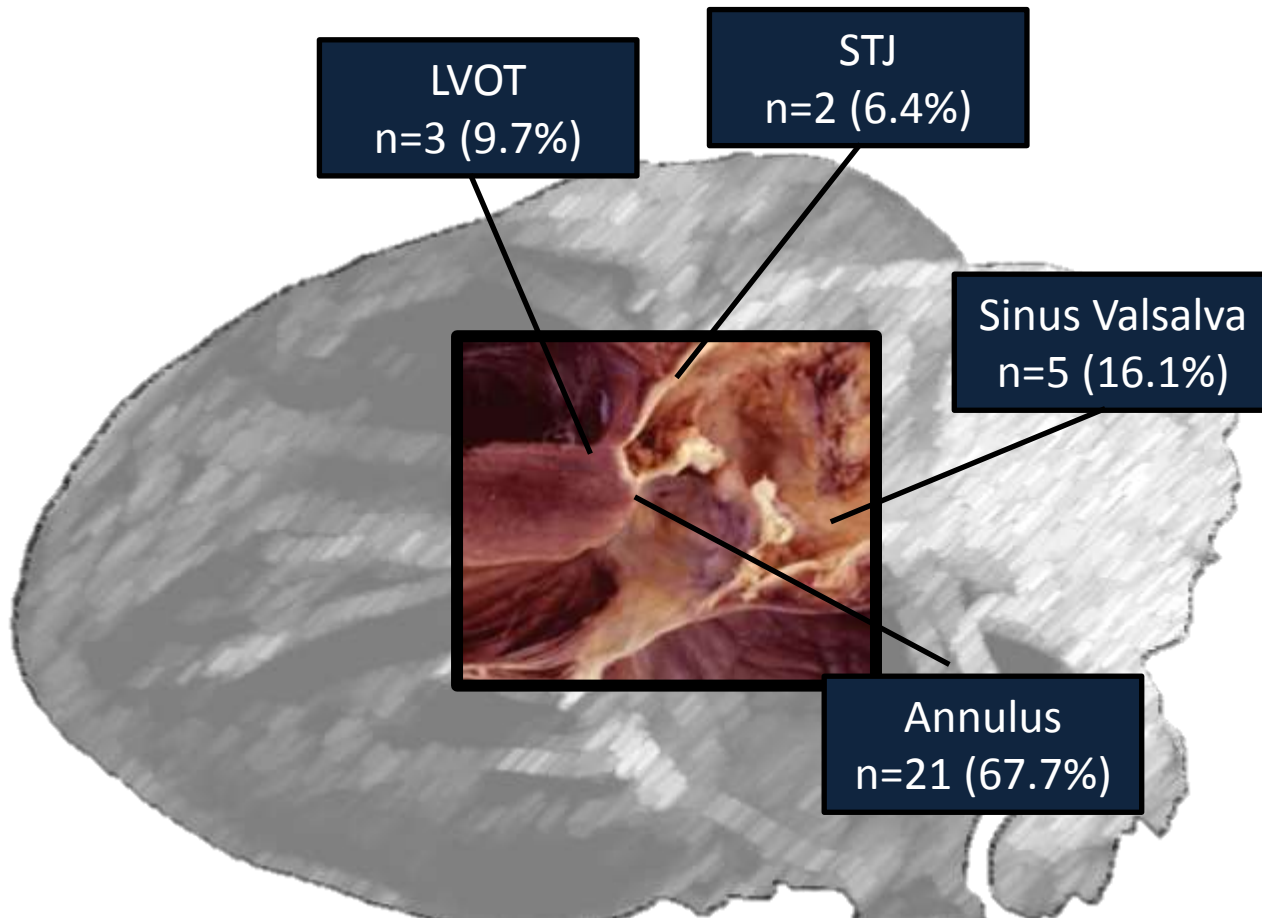
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Rupture Type & Location

Root injury was represented by an uncontained rupture in 20 cases (64.5%) and by a contained peri-aortic rupture/hematoma in 11 cases (35.5%).



Predictors of aortic root rupture



Univariate		
	Odds Ratio (95%CI)	P value
LVOT calcifications moderate/severe	10.92 (3.23-36.91)	<0.001
Prosthesis oversizing ≥ 20%	8.38 (2.67-26.33)	<0.001

How to prevent annular rupture?

The Impact of Integration of a Multidetector Computed Tomography Annulus Area Sizing Algorithm on Outcomes of Transcatheter Aortic Valve Replacement

A Prospective, Multicenter, Controlled Trial

Patient specific THV selection through integration of MDCT data to allow the most appropriate valve choice with more modest oversizing (or even undersizing) of those patients with features that would predispose them to potential annular rupture.

How to prevent aortic rupture

Balloon-expandable THV intentional underexpansion

Underexpansion and Ad Hoc Post-Dilation in Selected Patients Undergoing Balloon-Expandable Transcatheter Aortic Valve Replacement

Marco Barbanti, MD,* Jonathon Leipsic, MD,* Ronald Binder, MD,* Danny Dvir, MD,*
John Tan, MD,* Melanie Freeman, MBBS,* Bjarne Norgaard, MD,† Nicolaj Hansson, MD,†
Anson Cheung, MD,* Jian Ye, MD,* Tae-Hyun Yang, MD,* Kasia Maryniak, MD,* Rekha Raju, MD,*
Angus Thompson, MBBS, PhD,* Philipp Blanke, MD,* Sandra Lauck, PhD, RN,* David Wood, MD,*
John Webb, MD*

Vancouver, British Columbia, Canada; and Aarhus, Denmark

- ❑ 47 patients undergoing TAVR with underfilled THV (study group)
- ❑ 87 patients undergoing TAVR with nominally filled THV
- ❑ All patients had pre- and post CT (THV stent geometry, expansion, eccentricity assessment)
- ❑ The study cohort then was divided in three subgroups (Groups A, B, and C) according to the percentage of volume reduction from the THV balloon

Intraprocedural TEE and BAV during angiography

Usefulness of contrast injection during balloon aortic valvuloplasty before transcatheter aortic valve replacement: a pilot study

Marco Barbanti^{1,2*}, MD; Carmelo Sgroi¹, MD, FSCAI; Sebastiano Immè¹, MD; Patrizia Aruta¹, MD; Wanda Deste¹, MD; Simona Gulino¹, MD; Stefano Cannata¹, MD; Alessandra Giarratana¹, MD; Vera Bottari¹, MD; Daniela Giannazzo¹, MD; Valeria Garretto³, MD; Martina Patanè¹, MD; Emanuele Benvenuto¹, MD; Davide Capodanno¹, MD; Corrado Tamburino^{1,2}, MD, PhD, FESC, FSCAI

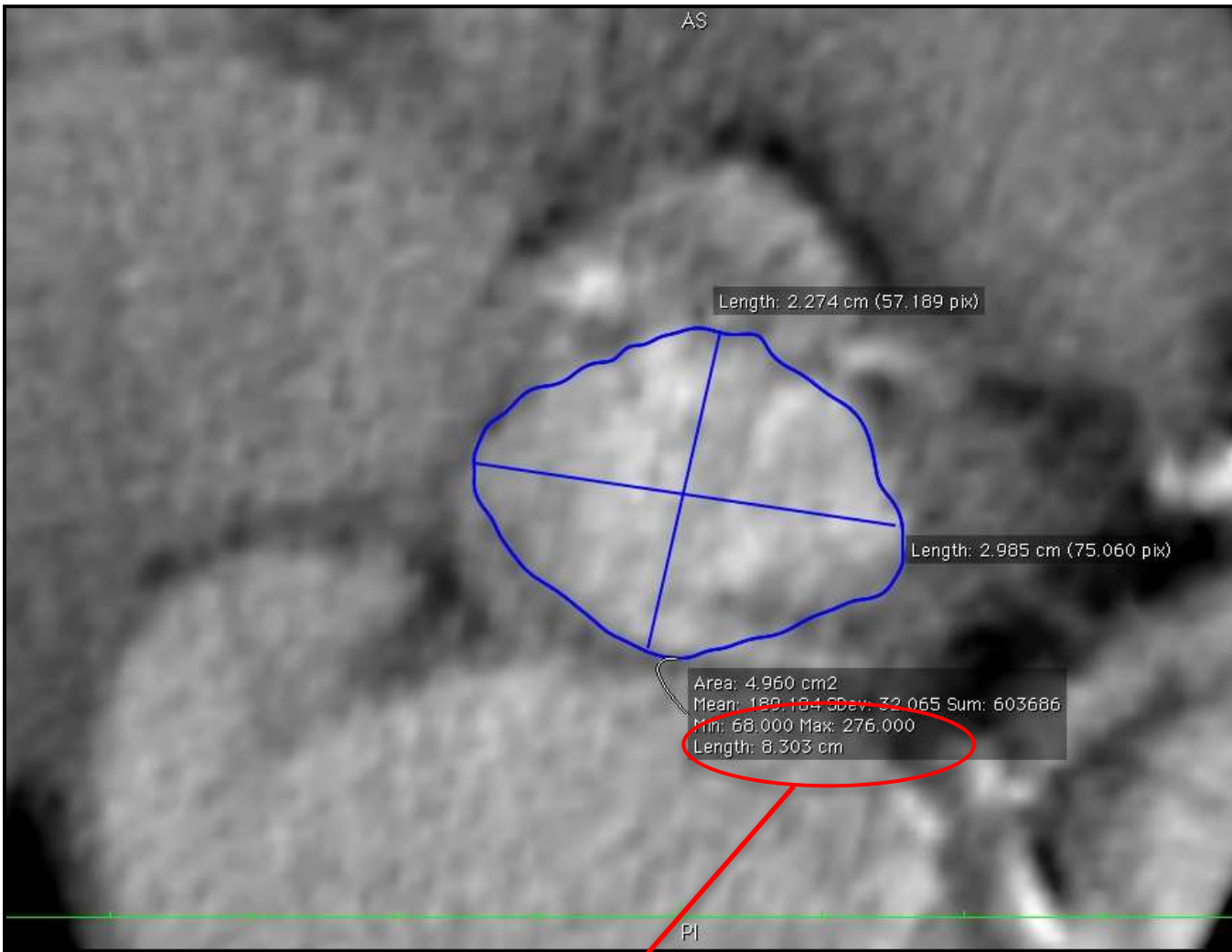
- ☐ In 12 (10.8%) patients the THV size implanted was different from the recommendations provided by the noninvasive imaging exams (CT, TEE)
- ☐ In 9 cases (75.0%) a larger THV
- ☐ In 3 cases (25.0%) a smaller THV
- ☐ Device success (VARC) in this particular subset of patients was 100%

3 weeks earlier

Ventricular embolization of Edwards Valve

Bernhard Reimers, MD
Humanitas University, Rozzano – Milan, Italy

26 April 2013



Edwards 26 mm

- BP, 75 years-old
- Severe aortic stenosis symptomatic for recurrent angina
- Refused by surgeon because of severe myelodysplastic anemia
- Difficult measurement of aortic annulus @ CT scan (low quality, high calcium)


SCCT expert consensus document on computed tomography imaging before transcatheter aortic valve implantation (TAVI)/transcatheter aortic valve replacement (TAVR)

Journal of
Cardiovascular
Computed Tomography

Stephan Achenbach, MD, FSCCT^{a,*}, Victoria Delgado, MD^b, Jörg Hausleiter, MD^c, Paul Schoenhagen, MD^d, James K. Min, FSCCT^e, Jonathon A. Leipsic, MD, FSCCT^f




Journal of Cardiovascular Computed Tomography (2012) 6, 366–380

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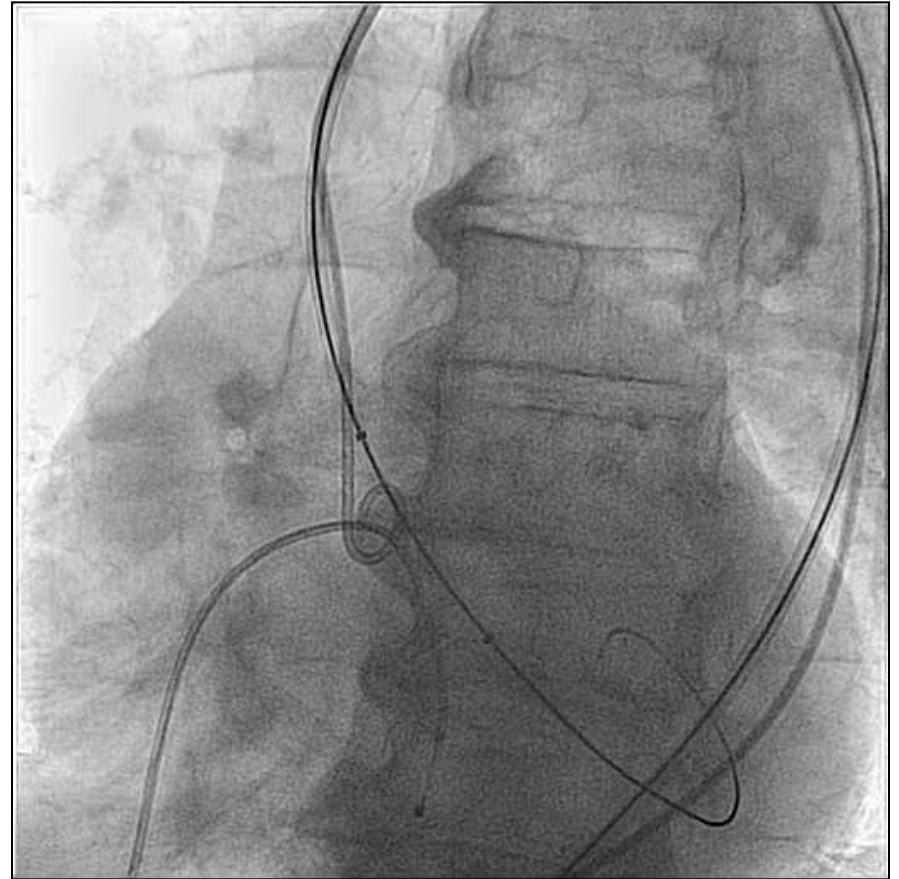
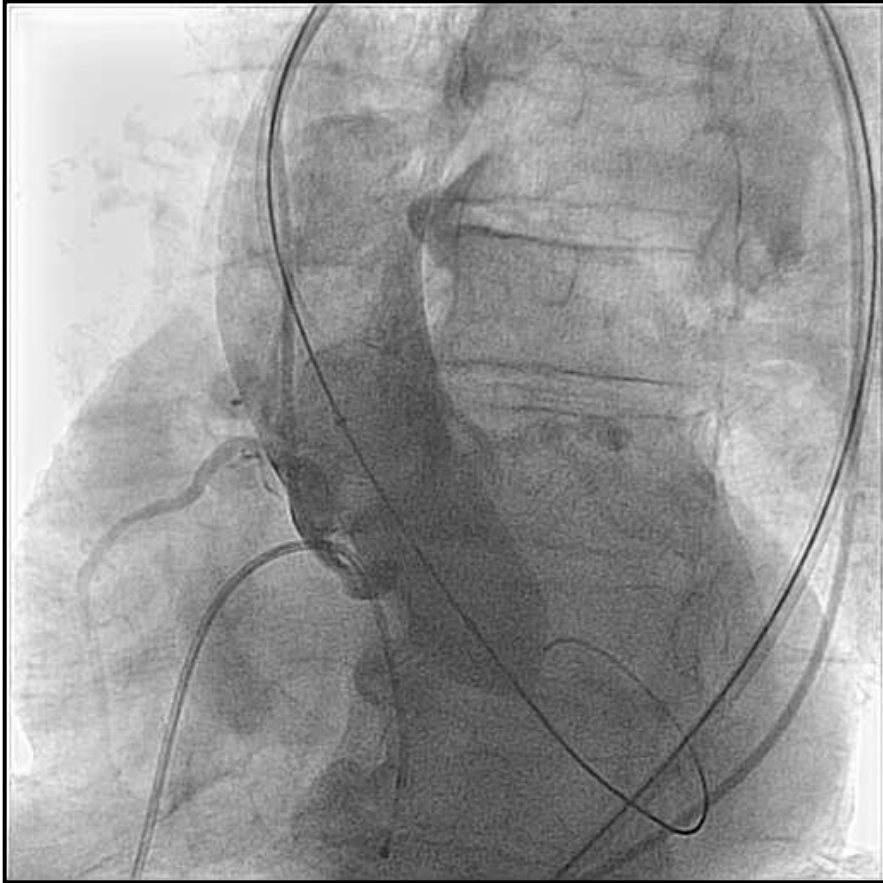
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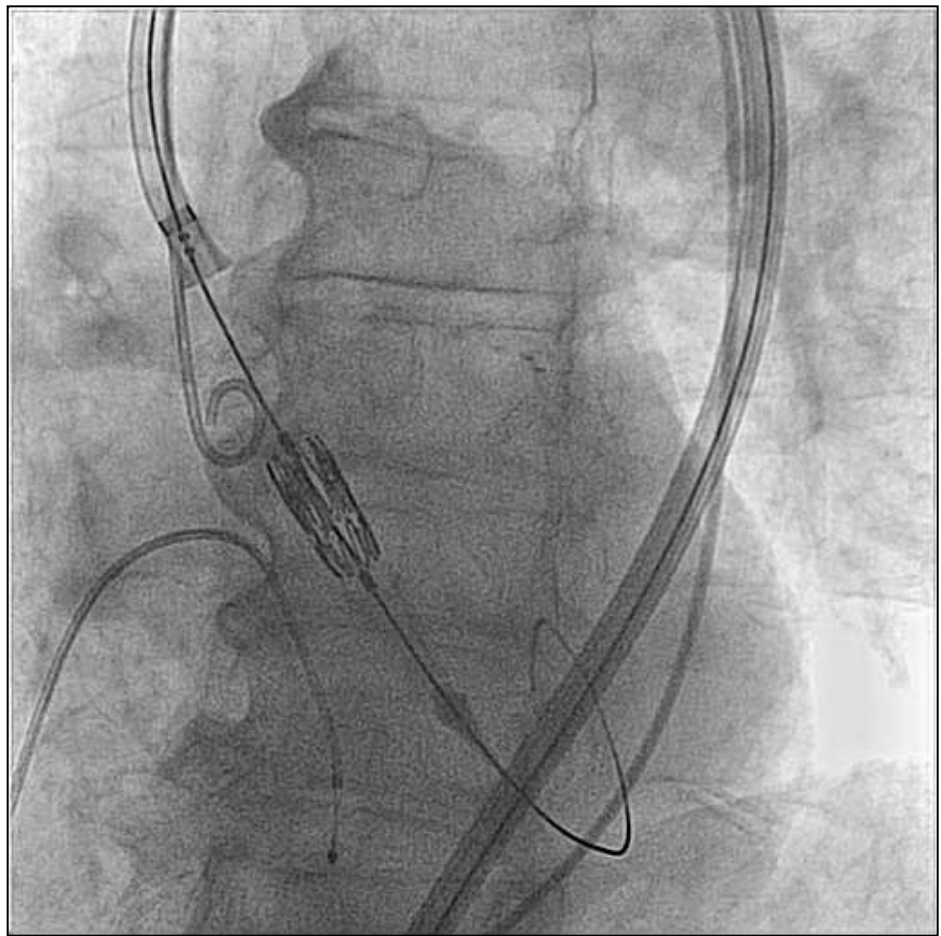
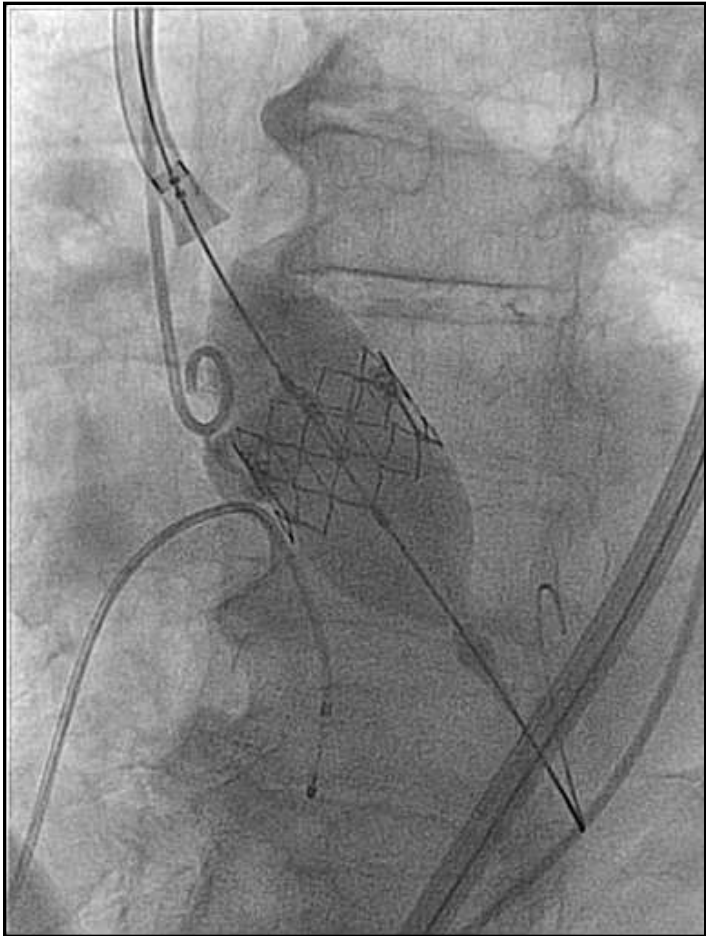
Diameters 22 x 29 mm; perimeter of area 83.1mm; area 490mm²

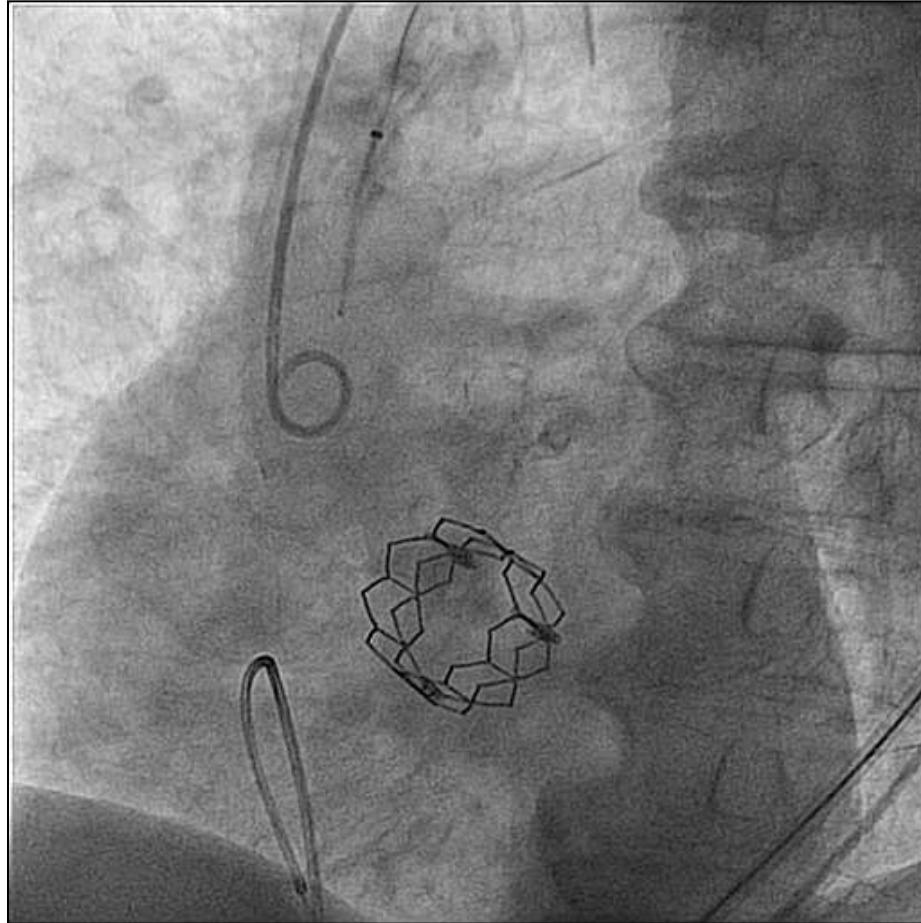
Just to make sure measurements were ok !



**23 mm balloon
does not move**

EDWARDS 26 mm





Stable patient went directly into OR, successful removal of Edwards/Sapien valve and surgical implantation of bioprosthesis. Uneventful recover and discharged 12 days later.