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# TAVR: Advancing Your Skills Beyond the Basics

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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
- Scientific Advisory Board
- Executive Physician Council

## Company

- Edwards Lifesciences, Abbott
- Medtronic, Abbott
- Boston Scientific Corp



## Balloon-expandable THV Sapien 3

(Cobalt frame, bovine pericardium, outer skirt,  
precise positioning)

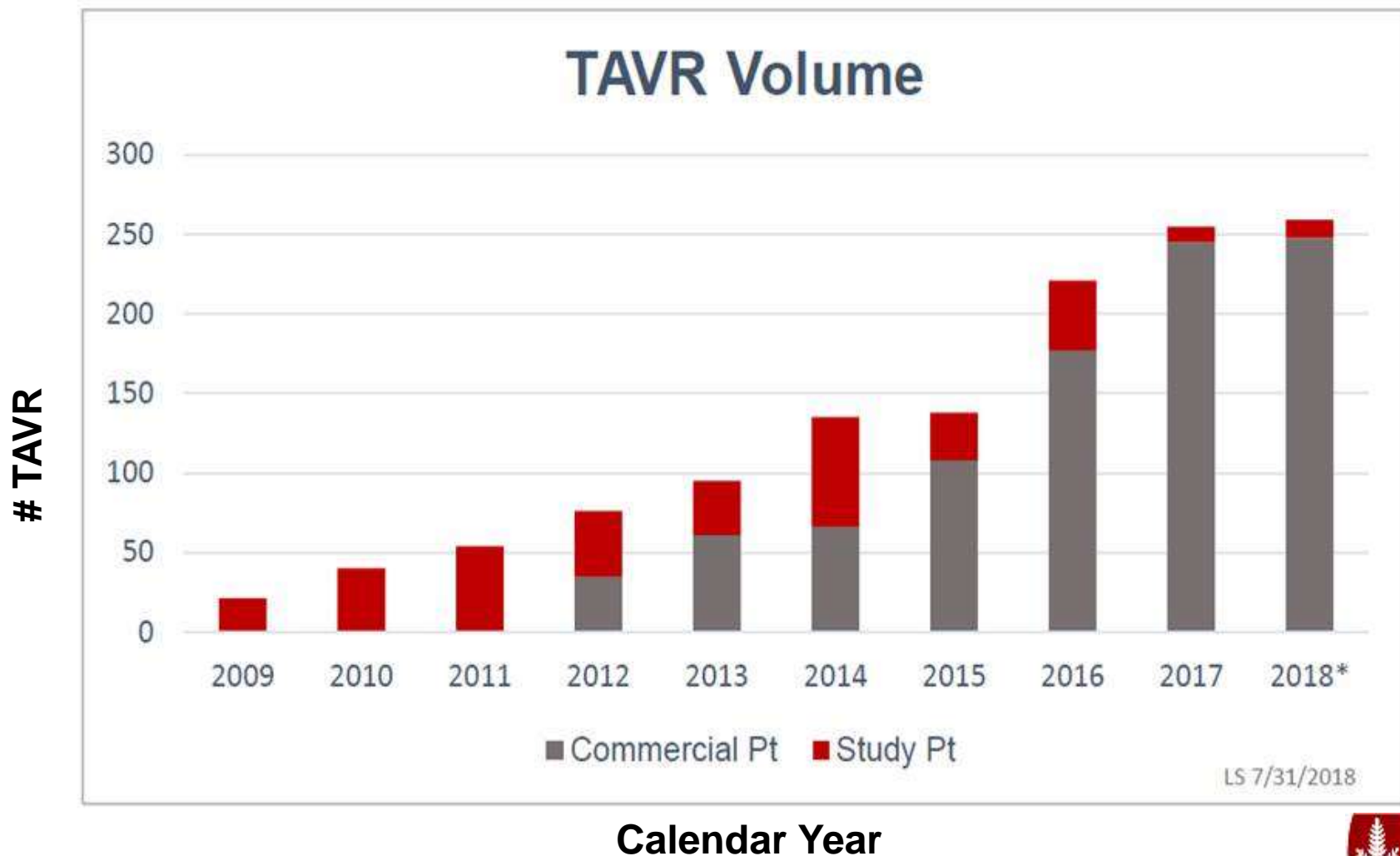


## Self-expandable THV, REPOSITIONABLE Medtronic EvolutR

(Nitinol frame, porcine pericardium, longer skirt)



# Stanford Experience with TAVR



\*Projected



# What are the Advance Skills?

- Vascular Complications
- Coronary Obstruction
- Peri-valvular Leak
- Stroke
- Permanent Pacemaker



# Case

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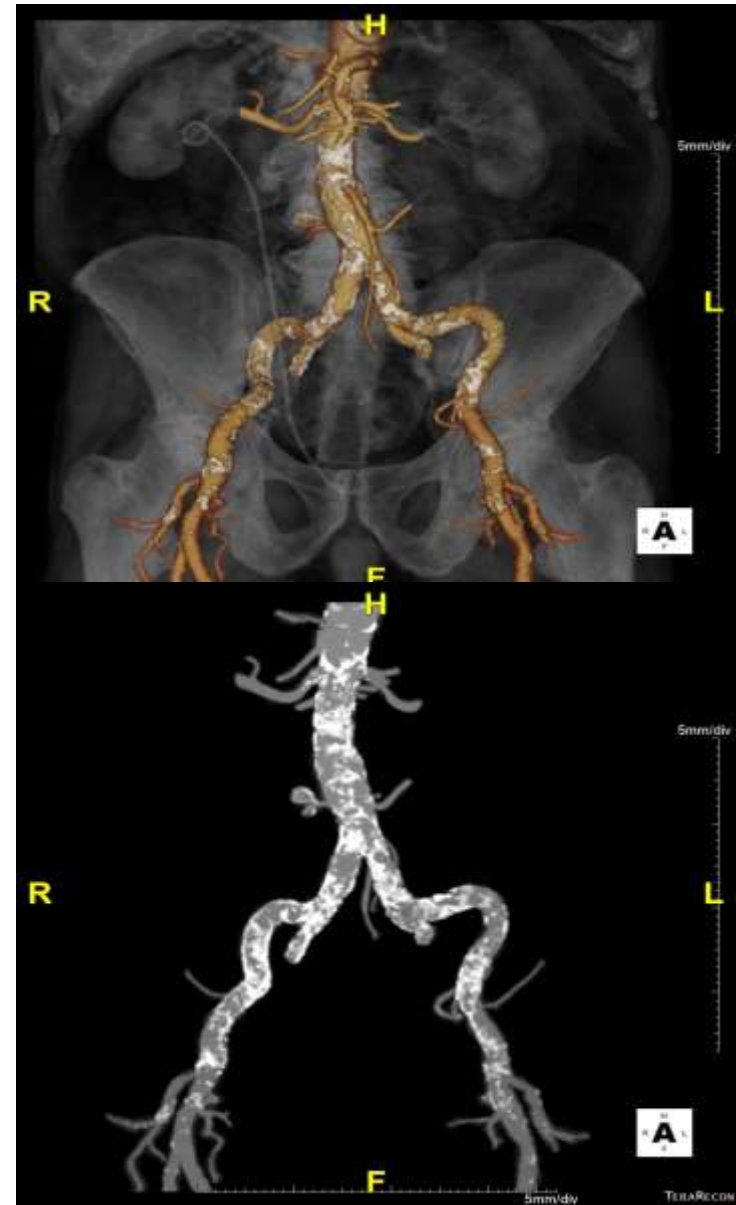
- 92yo male with history of hypertension, hyperlipidemia, paroxysmal AF, CKD (Cr1.2), s/p MI and CABG x 2 in 2014, now with severe aortic stenosis.
- Indication for TAVR:
  - Progressive fatigue, getting more difficult to ride his bike
  - Requires GA for ureteroscopy q4months & Anesthesiologist reluctant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



# CT Analysis:

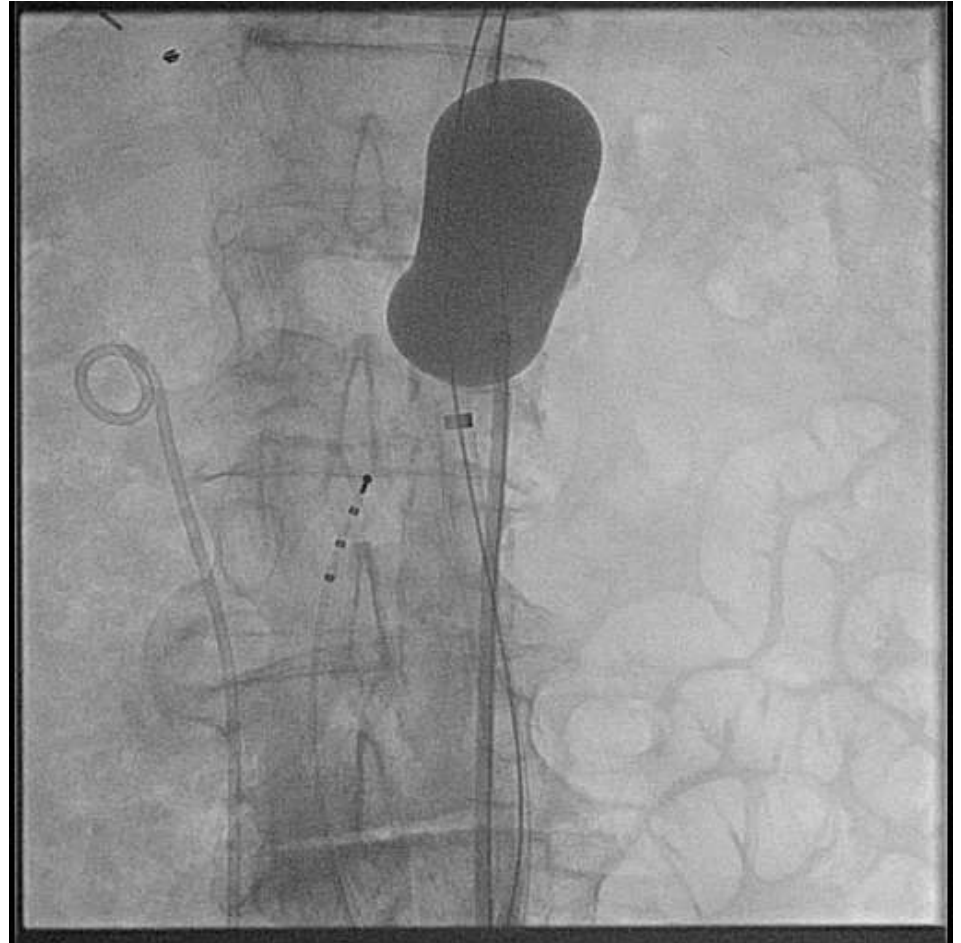
Vessel	Max	Min
RCIA	12.1 mm	12.1 mm
REIA	10.7 mm	9.6 mm
RCFA	9.6 mm	9.1 mm
LCIA	11.9 mm	9.9 mm
LEIA	10.5 mm	8.0 mm
LCFA	11.1 mm	9.3 mm

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 <sup>2</sup>
	Diameter	27.7mm





- Difficulty inserting S3 through Esheath
- Hypotension
- Intubated
- Upsized left sided access to 14Fr
- Inserted Coda balloon
- Withdraw Esheath





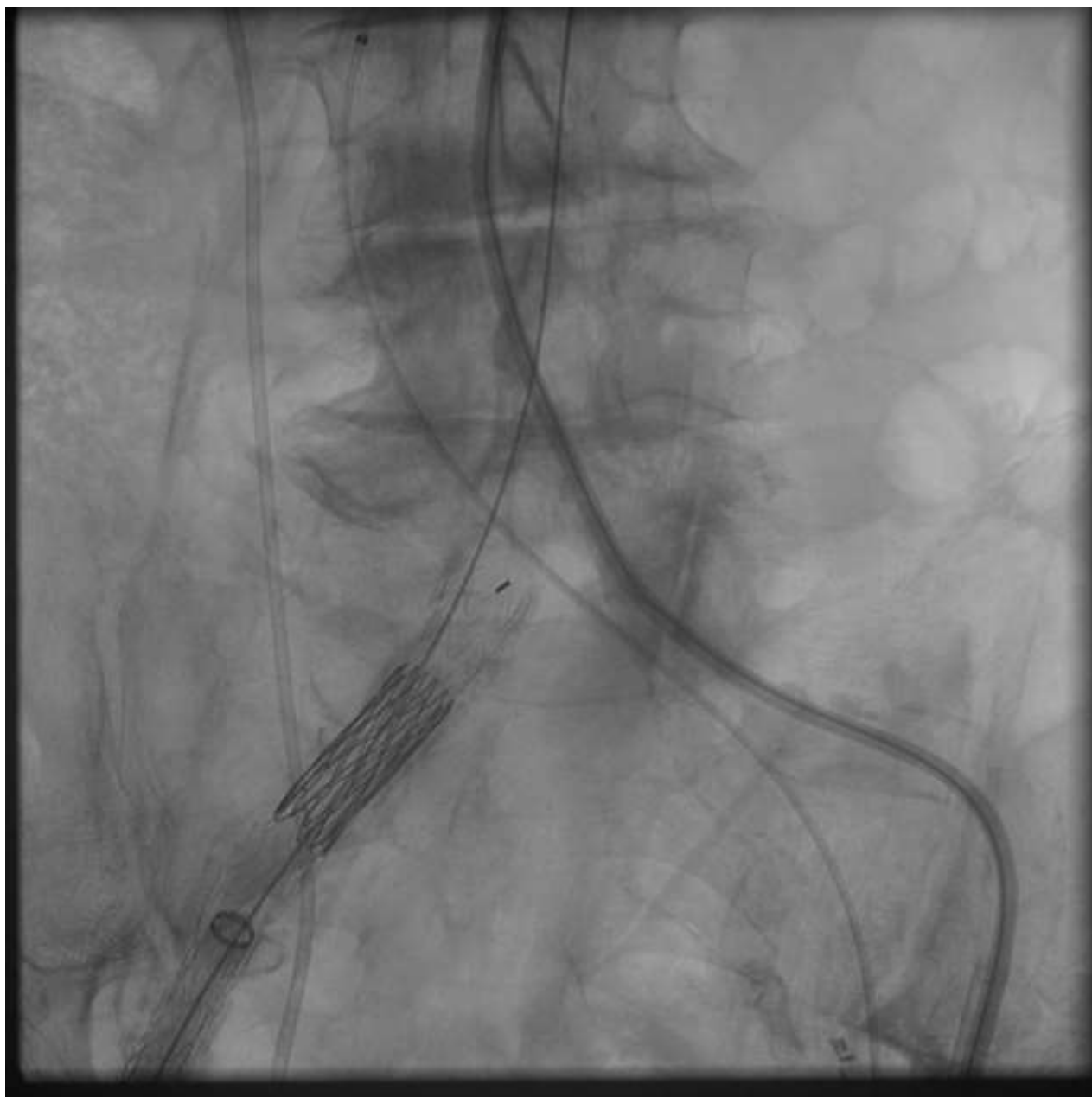


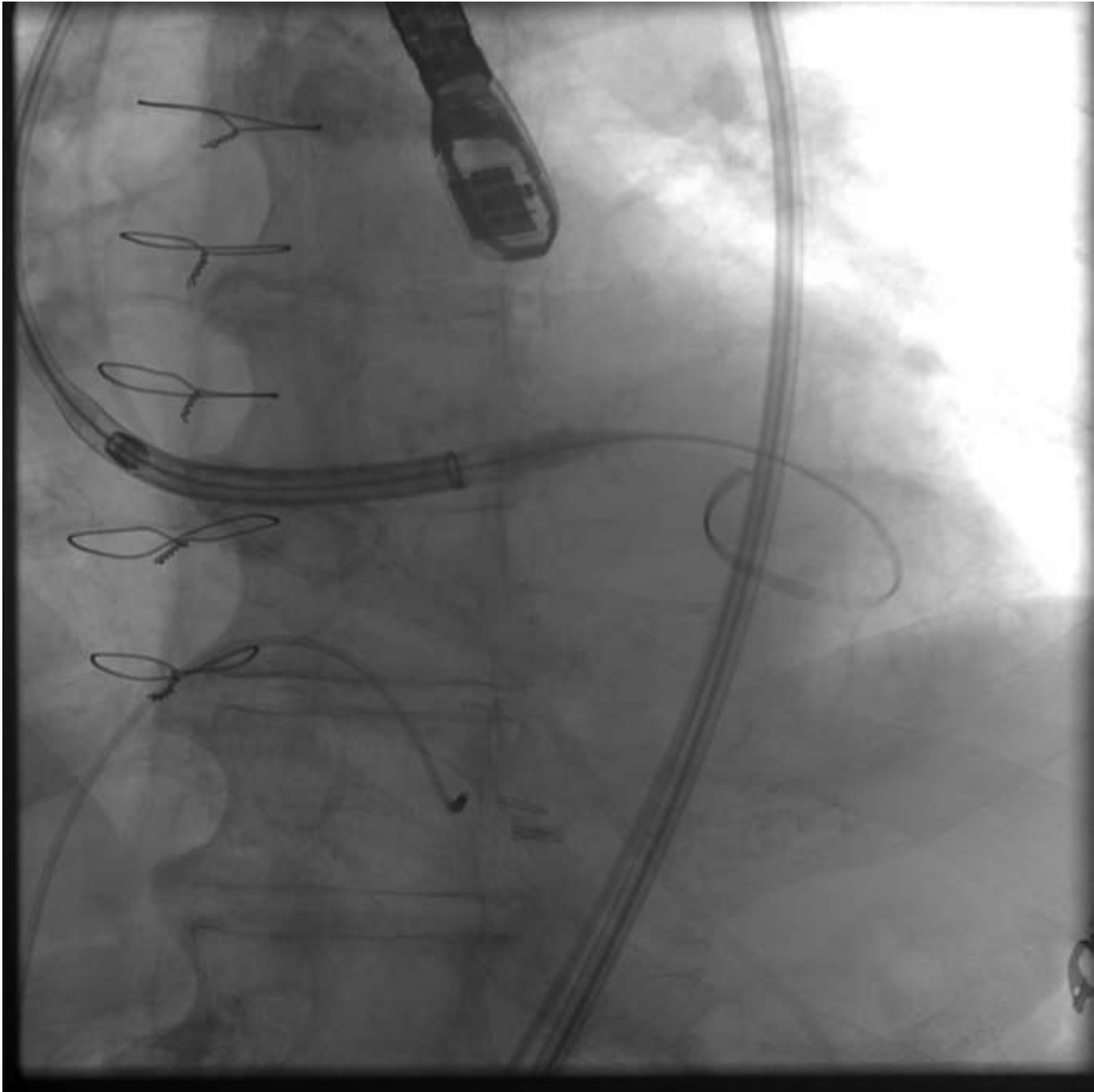




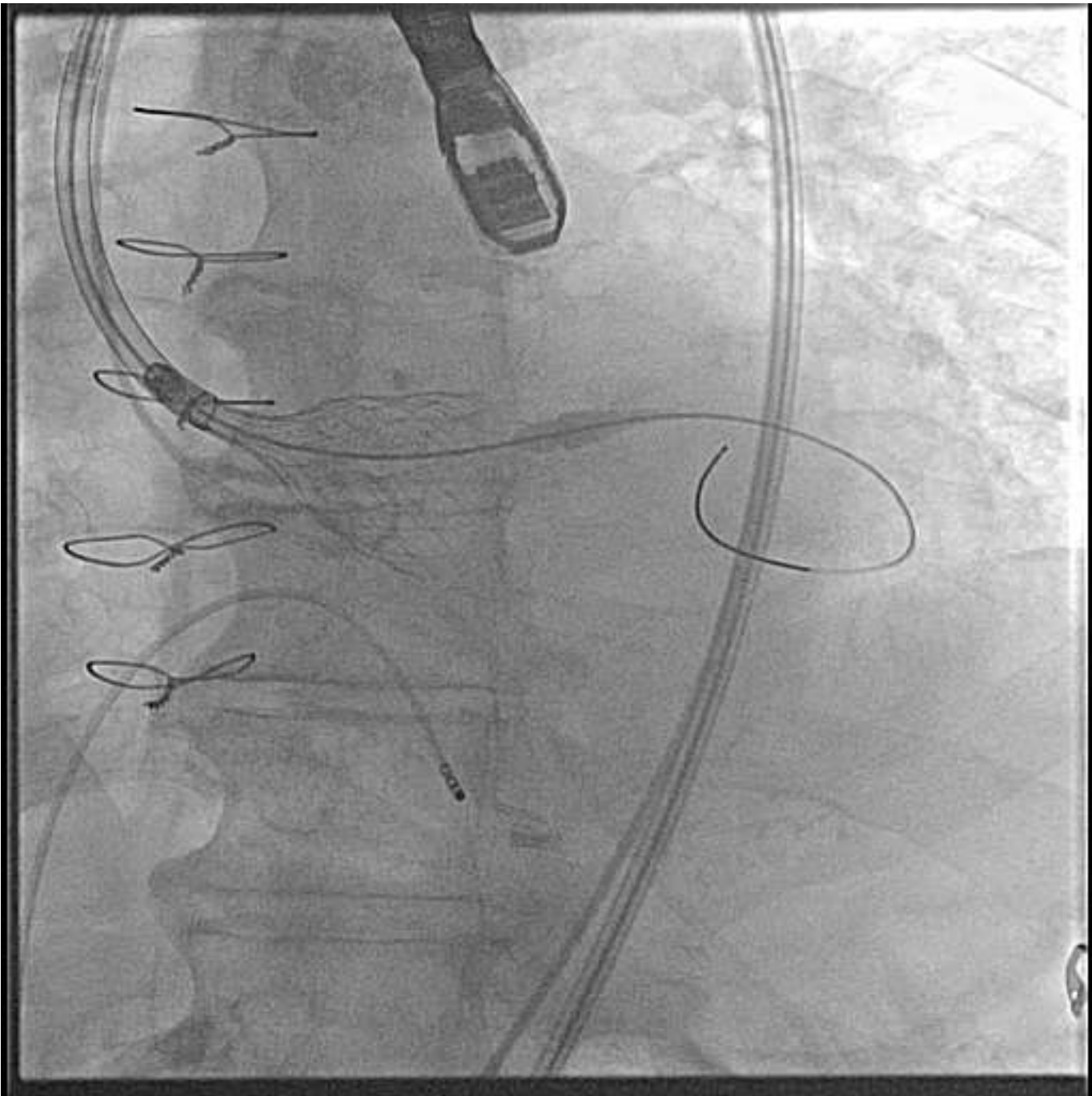
# What to do?

- 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











# Take Home Message

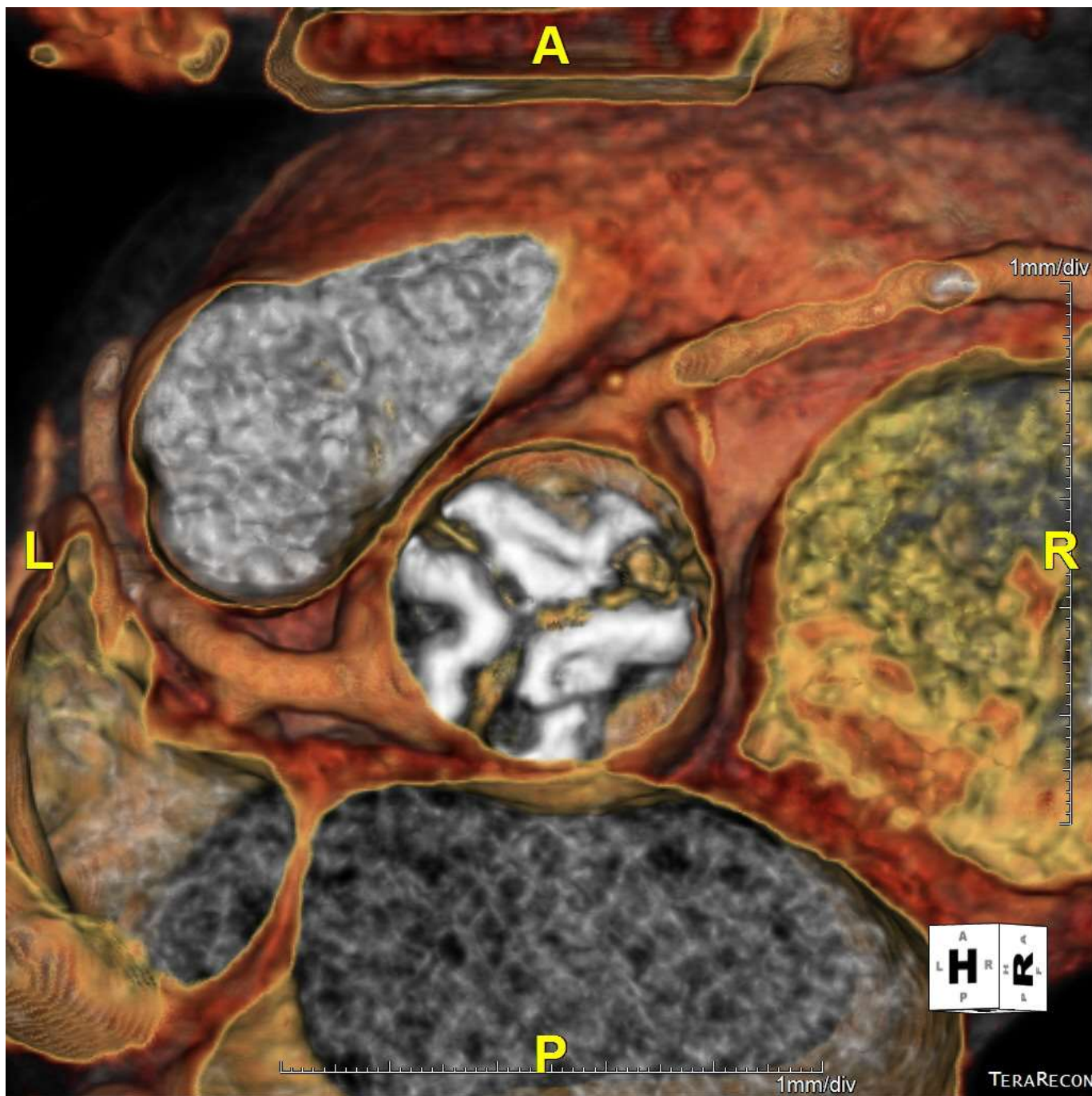
- Be prepared for major vascular complications
  - Be familiar with bailout equipment e.g. aortic occlusion balloons +/- peripheral covered stents
  - Be aware of help available at hospital—vascular surgery / CTS

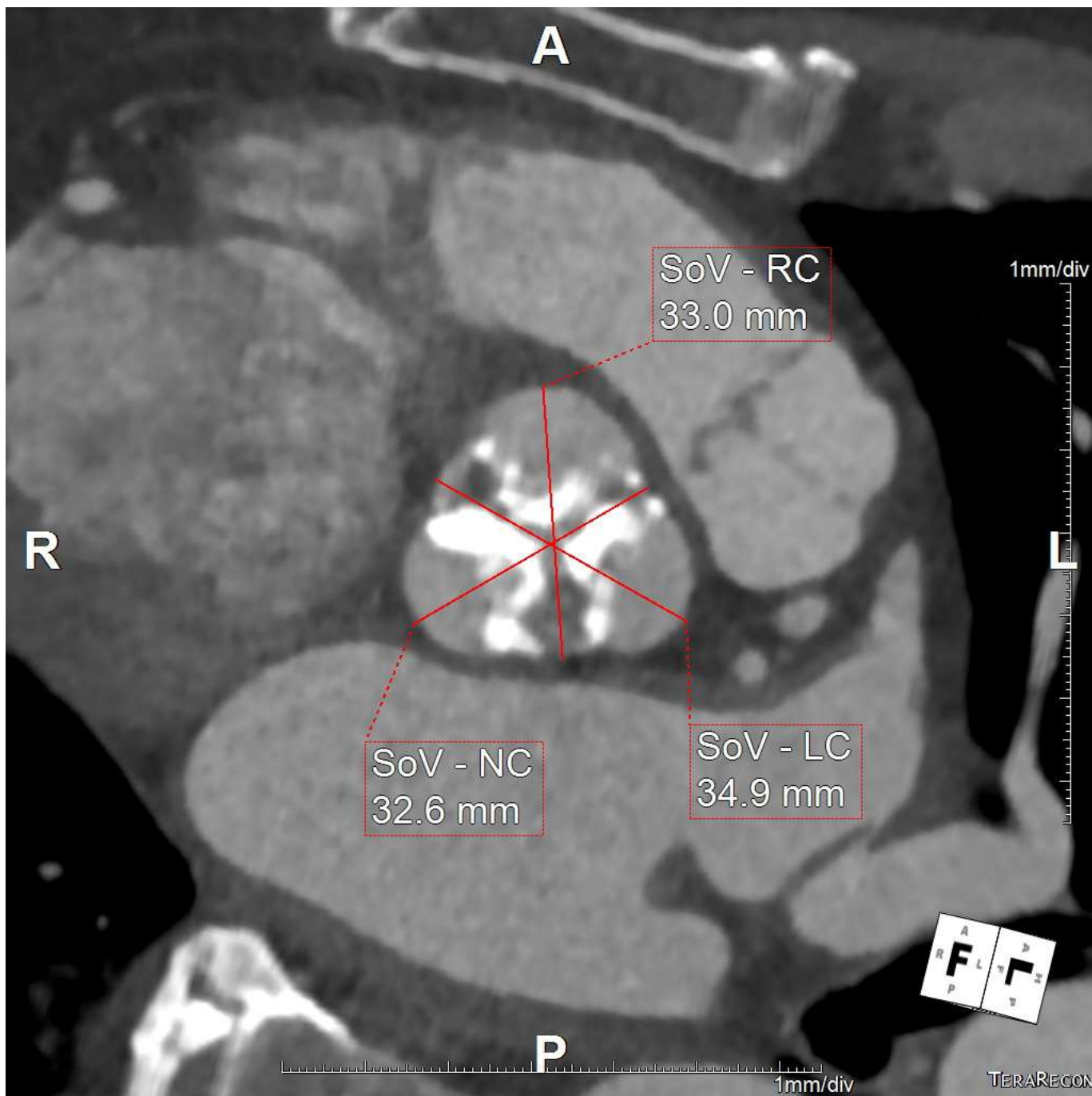
# Case Presentation : F.C.

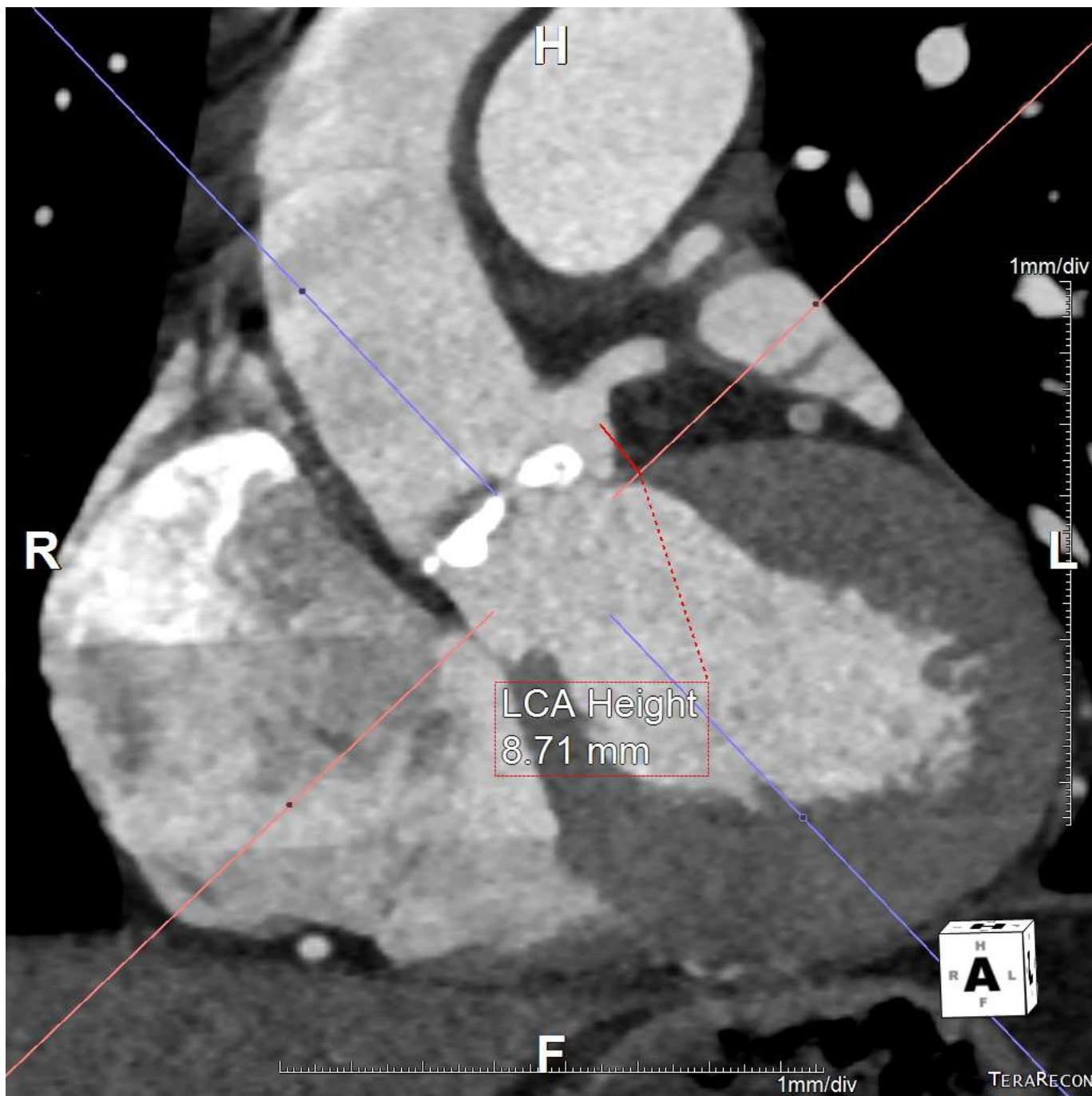
- 81 year old man with HTN, HL, Prostate CA and symptomatic AS with DOE and fatigue.
- Normal PFTs, Frail 0/4, creatinine 0.97.
- Echo: mean gradient 60, EF 49%.
- Coronary: 40-50% LAD, FFR 0.83.
- Vascular Access: greater than 8mm bilaterally
- STS: 1.9%, low risk
- Self-pay, off label use.
- 29mm S3



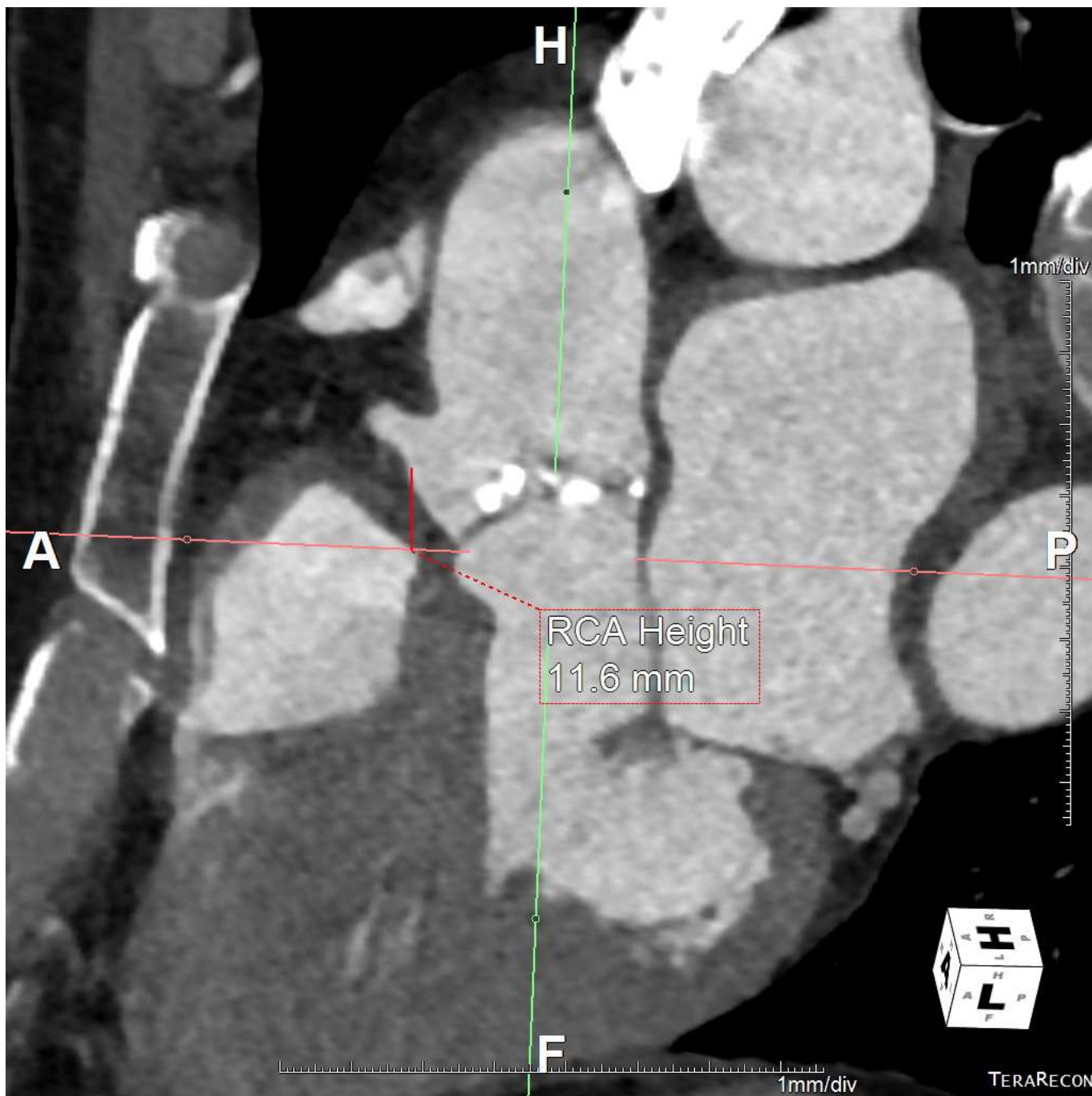












Derived



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



# 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

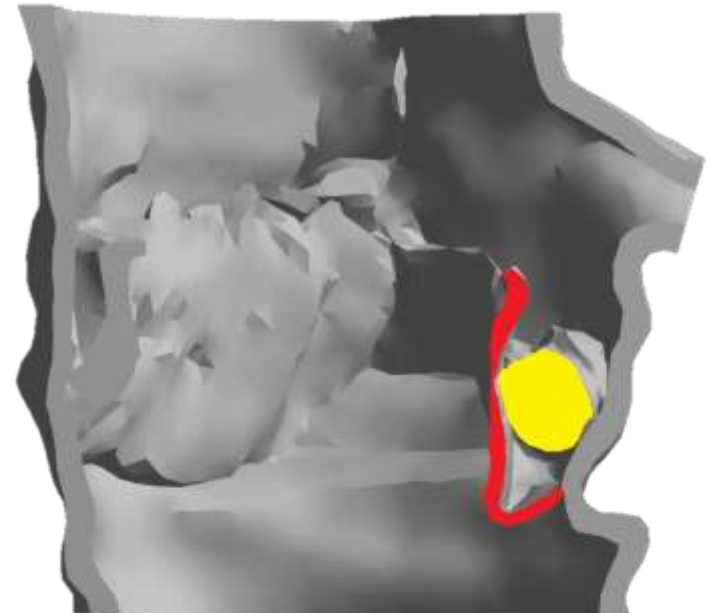
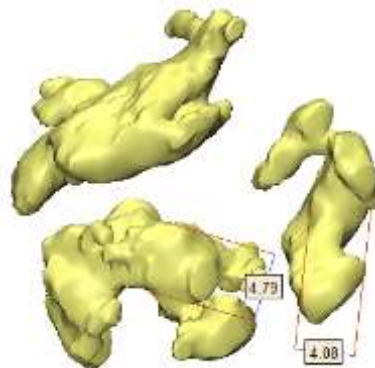
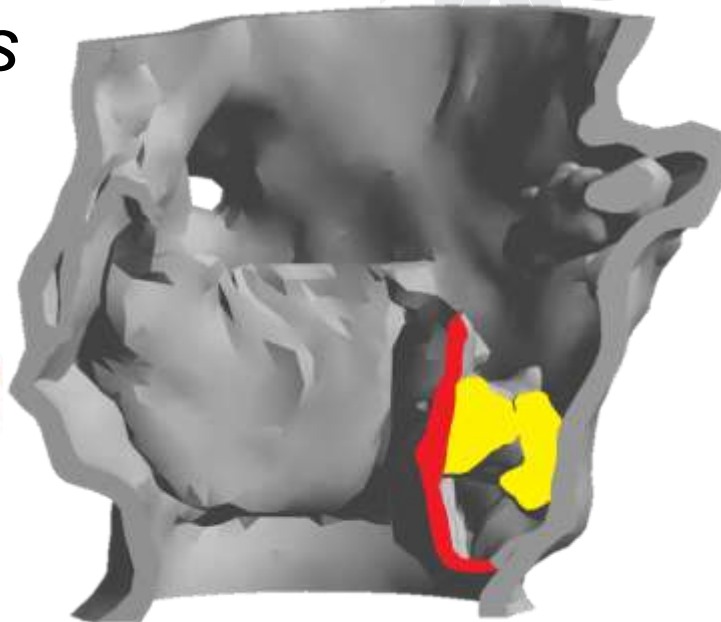
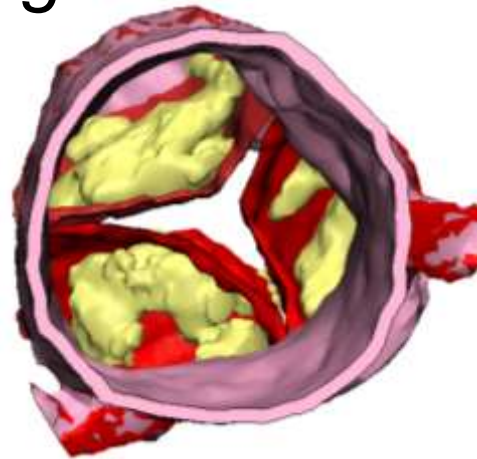
## Reconstructions

### -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



# 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?

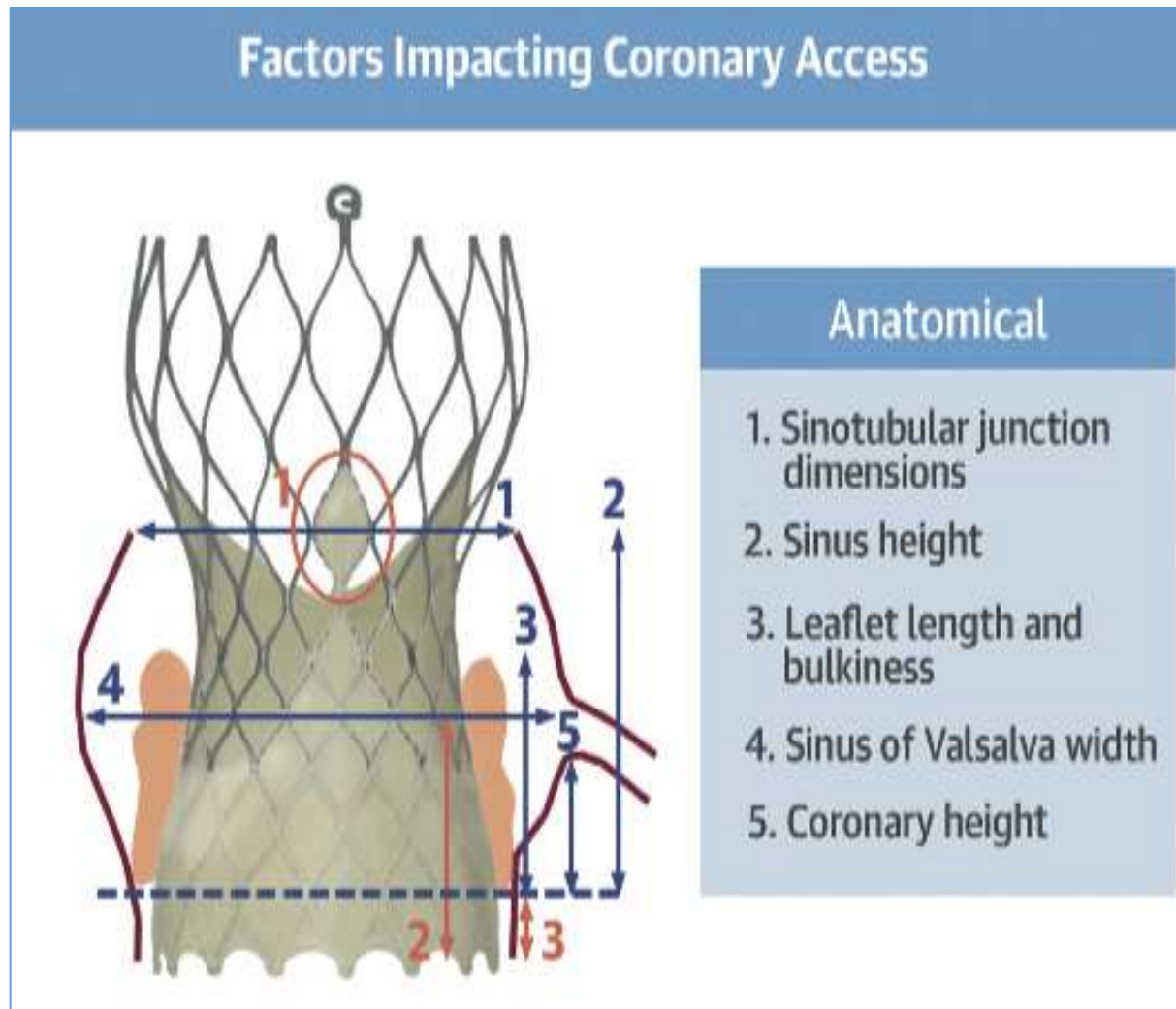


# Treatment of CAD: Before, During or After TAVR?

- Before: For complex lesions (e.g. rotoblator)
  - More time, contrast devoted to the procedure
  - Another procedure, interacts with LV demand
- During: Convenient for the patients
  - Simpler for patients, address supply and demand, support if necessary
  - More contrast, time, DAPT loaded
- After: New lesions
  - Access through valve frame may be unpredictable

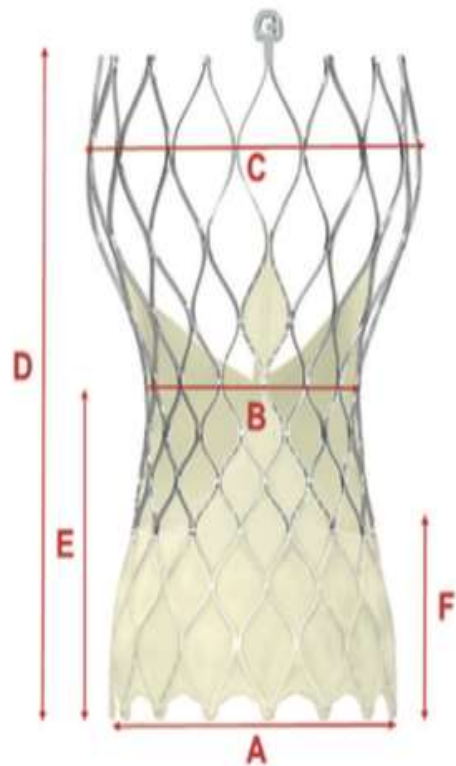


# Reaccess to Coronaries: Anatomic Considerations



# Understand the Device

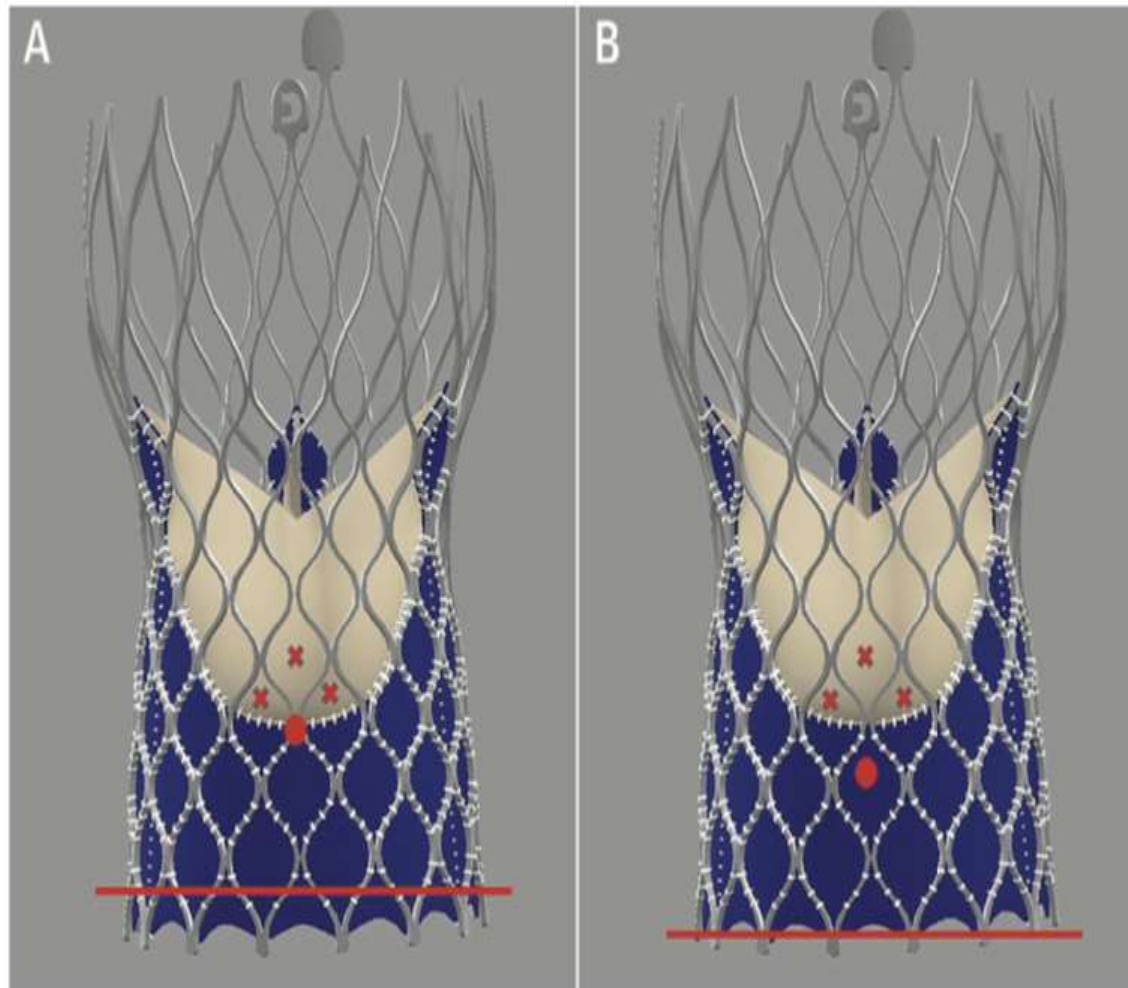
**FIGURE 1** Repositionable Self-Expanding Valves With and Without an External Pericardial Wrap: Features and Dimensions



	23mm Evolut R / PRO	26 mm Evolut R / PRO	29mm Evolut R / PRO	34mm Evolut R
A. Inflow Diameter	23 mm	26 mm	29 mm	34 mm
B. Waist Diameter	20 mm	22 mm	23 mm	24 mm
C. Outflow Diameter	34 mm	32 mm	34 mm	38 mm
D. Frame height	45 mm	45 mm	45 mm	46 mm
E. Commissure Height	26 mm	26 mm	26 mm	26 mm
F. Skirt Height	13 mm	13 mm	13 mm	14 mm

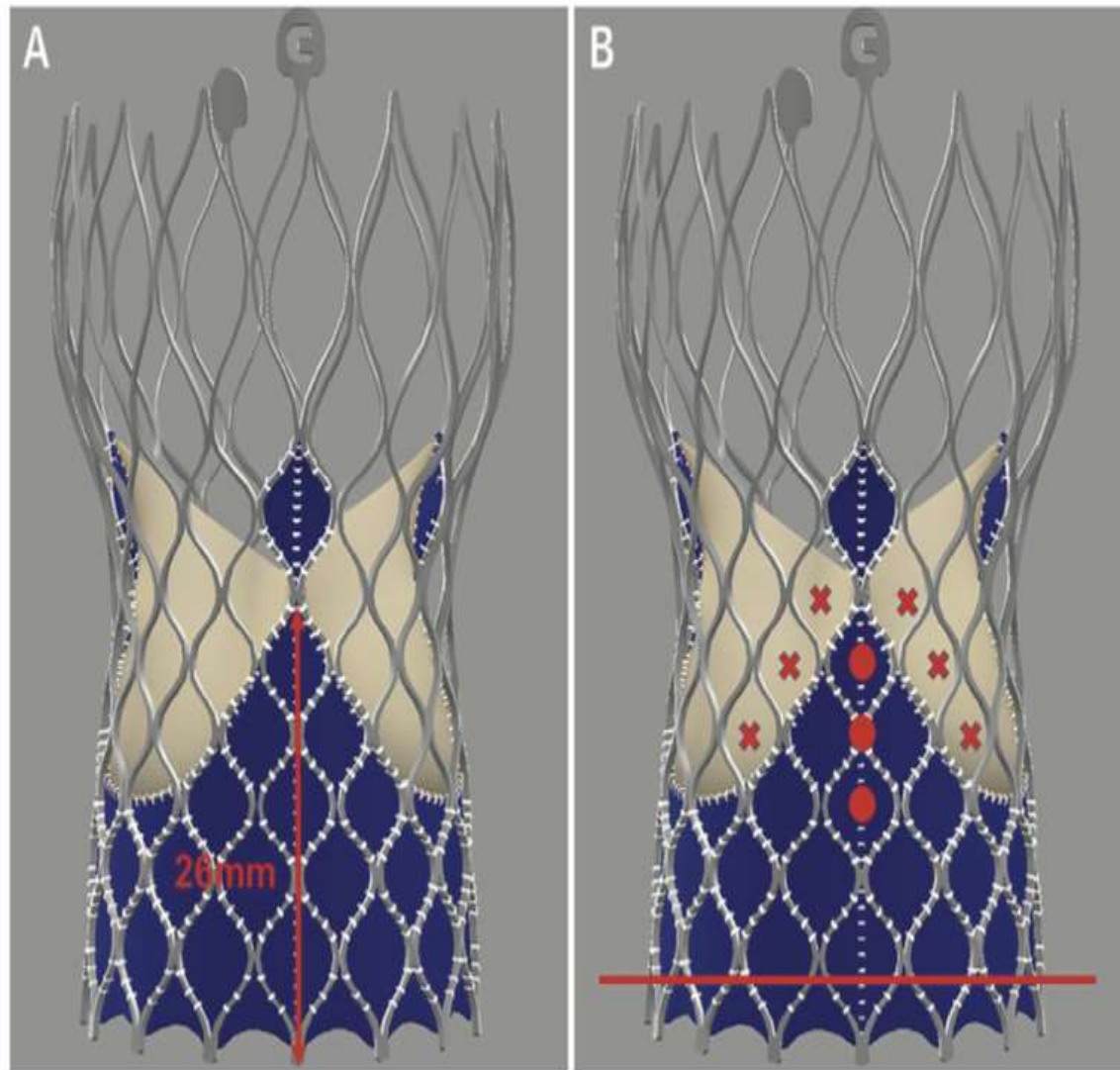
Various dimensions of the Evolut-R and Evolut-PRO CoreValve (Medtronic, Galway, Ireland) are listed for comparison.

# Self-Expanding Valve and Coronary Depending on Implantation Depth



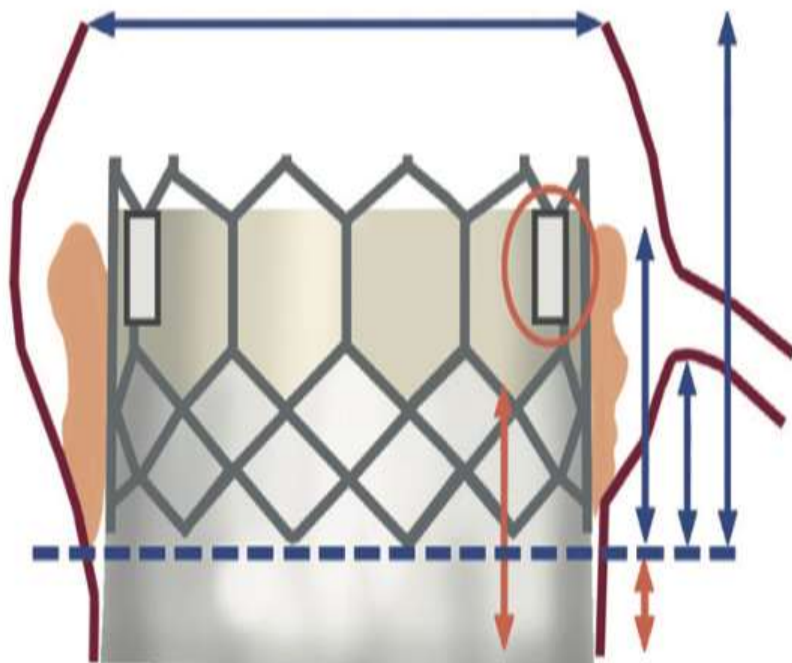


# Self-Expanding Valve and Coronary Access if Ostia Lines up with



# Reaccess to Coronaries: Considerations S3

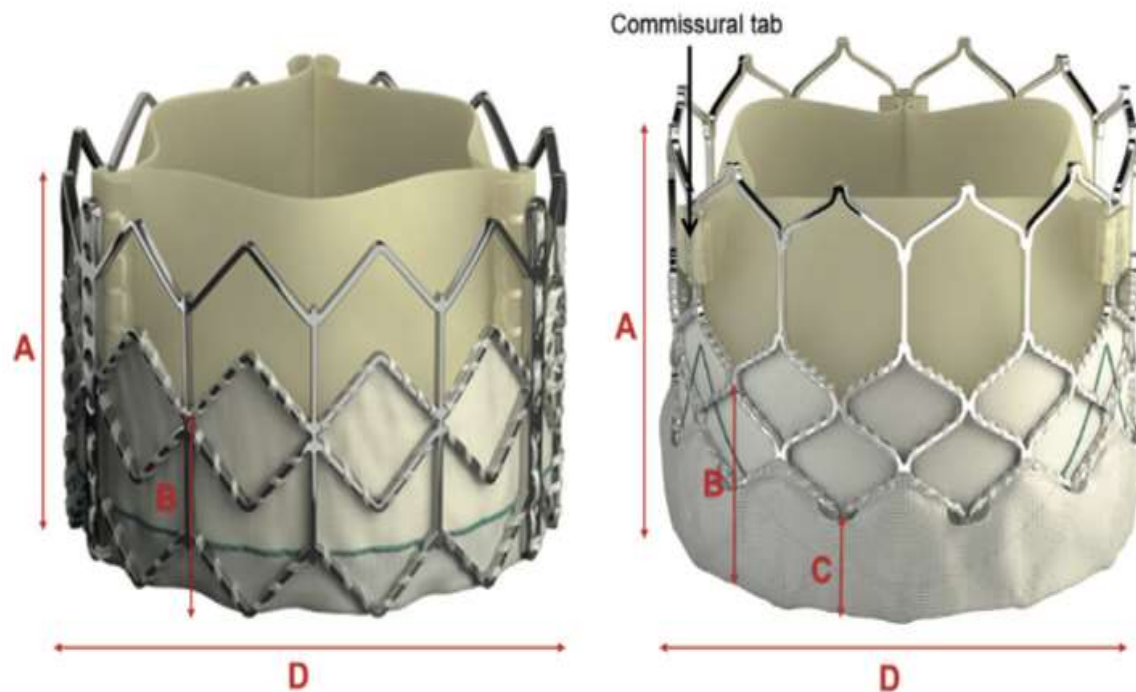
<sup>1</sup>Yudi, et al., *J Am Coll Cardiol* 2018; 71(12):1360–78



## Device and Procedural

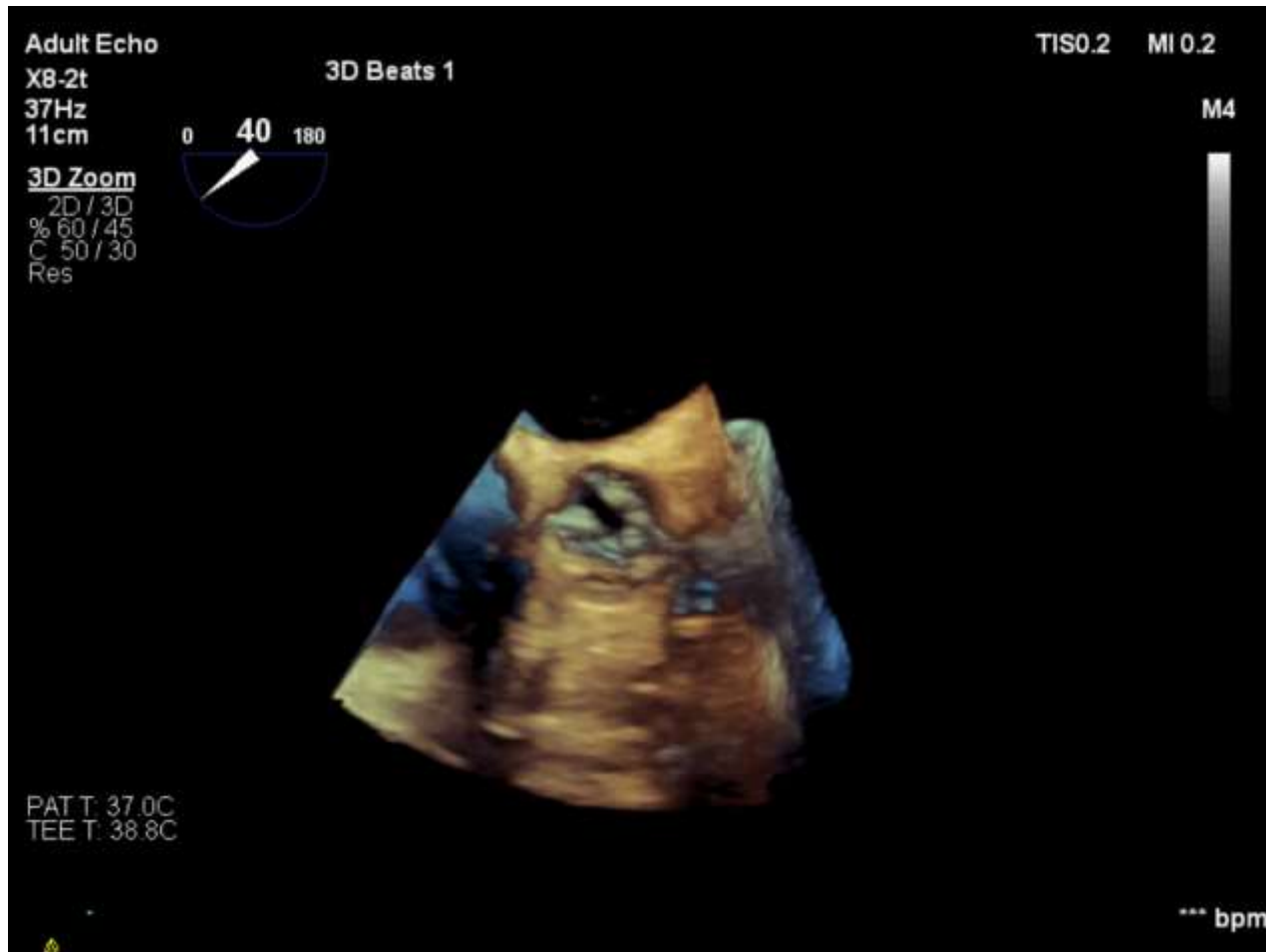
1. Commissural tab orientation
2. Sealing skirt height
3. Valve implant depth



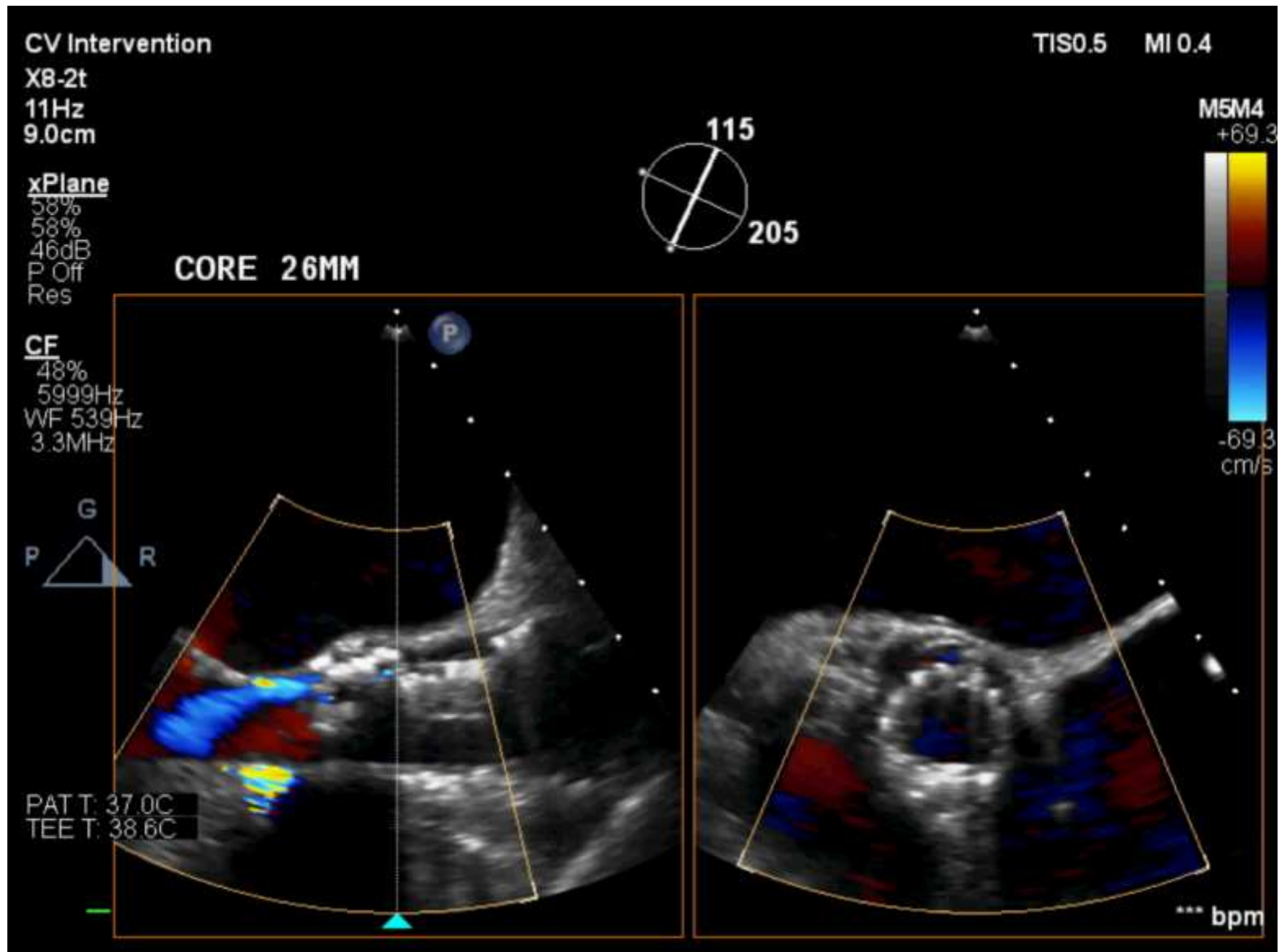


	23 mm Sapien XT	26 mm Sapien XT	29 mm Sapien XT	20 mm Sapien 3	23 mm Sapien 3	26 mm Sapien 3	29 mm Sapien 3
A. Frame Height	14 mm	17 mm	19 mm	15.5 mm	18 mm	20 mm	22.5 mm
B. Inner Skirt Height	6.7 mm	8.7mm	11.6 mm	7.9 mm	9.3 mm	10.2 mm	11.6 mm
C. Outer Skirt Height	N/A	N/A	N/A	5.2 mm	6.6 mm	7.0 mm	8.1 mm
D. Valve Diameter	23 mm	26 mm	29 mm	20 mm	23 mm	26 mm	29 mm

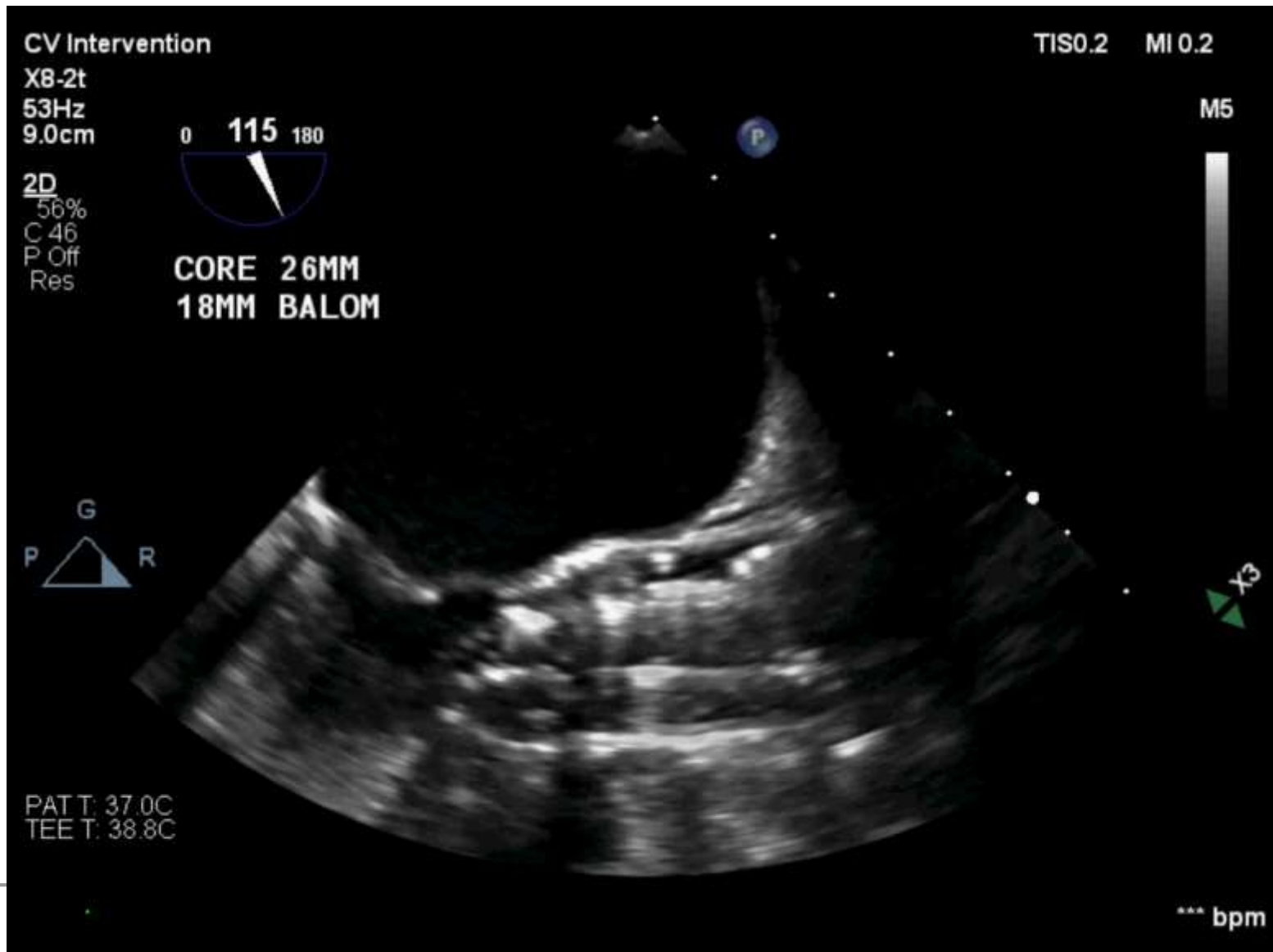
# PVL Immediate Post Implant



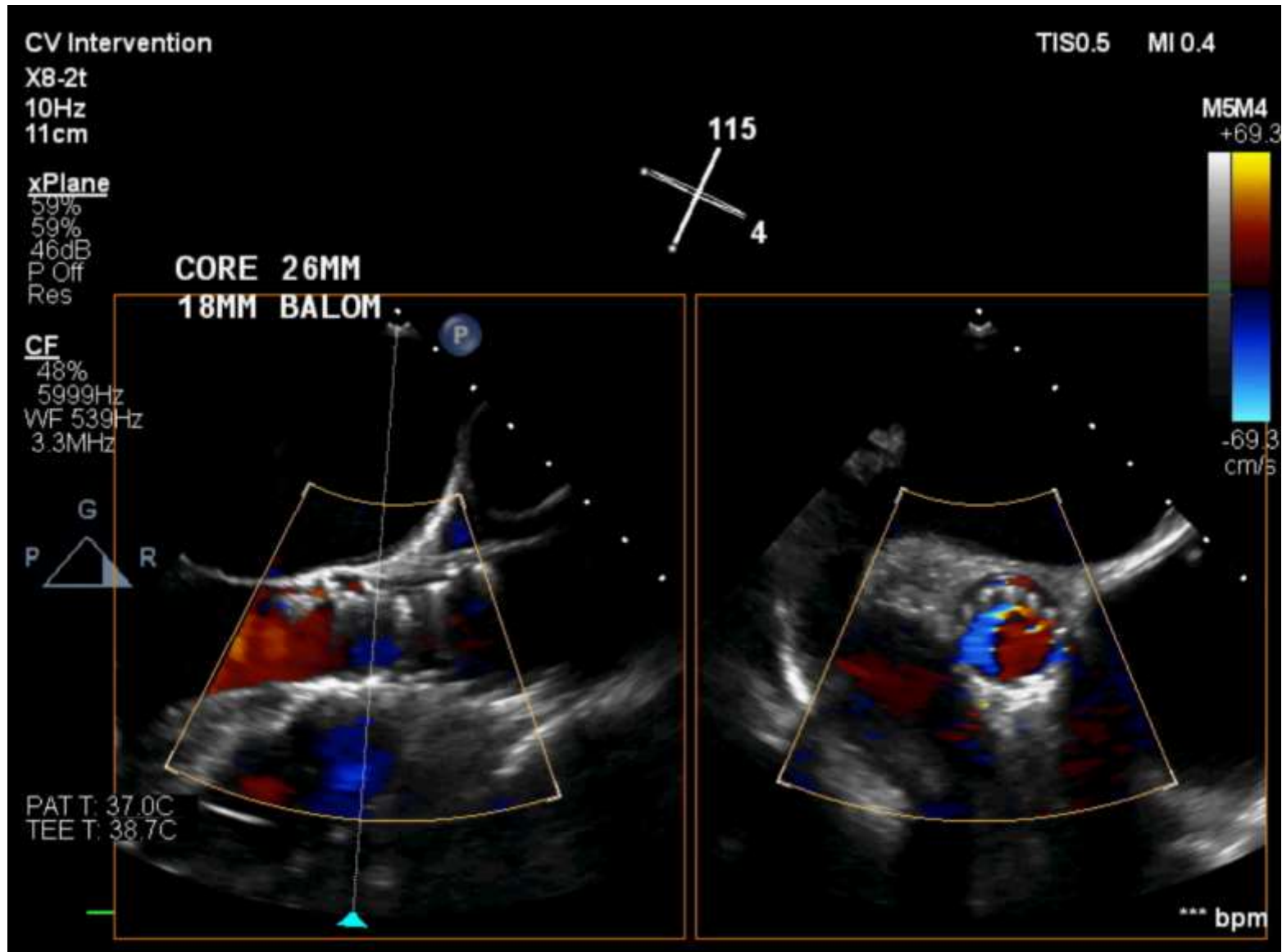
# Post 26mm Evolut R



# Balloon Dilatation

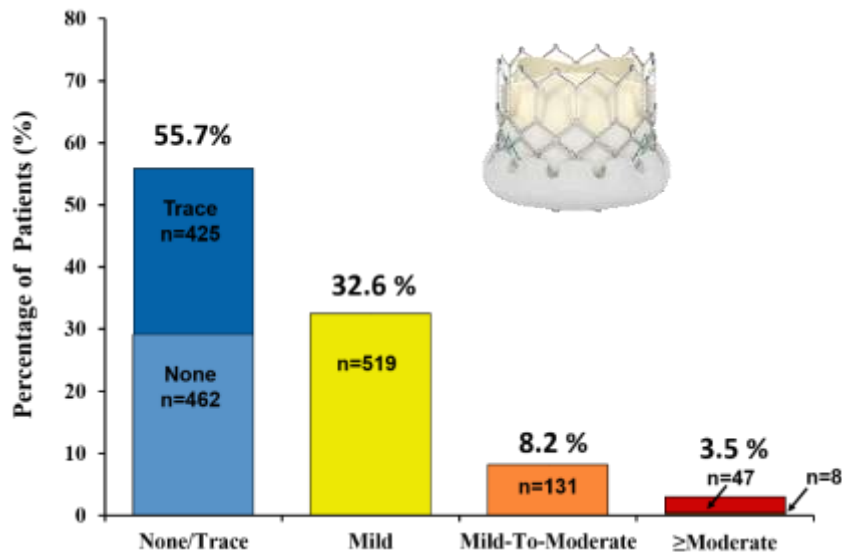


# Post Dilatation



# Prevalence of Paravalvular Regurgitation with New Generations of THVs

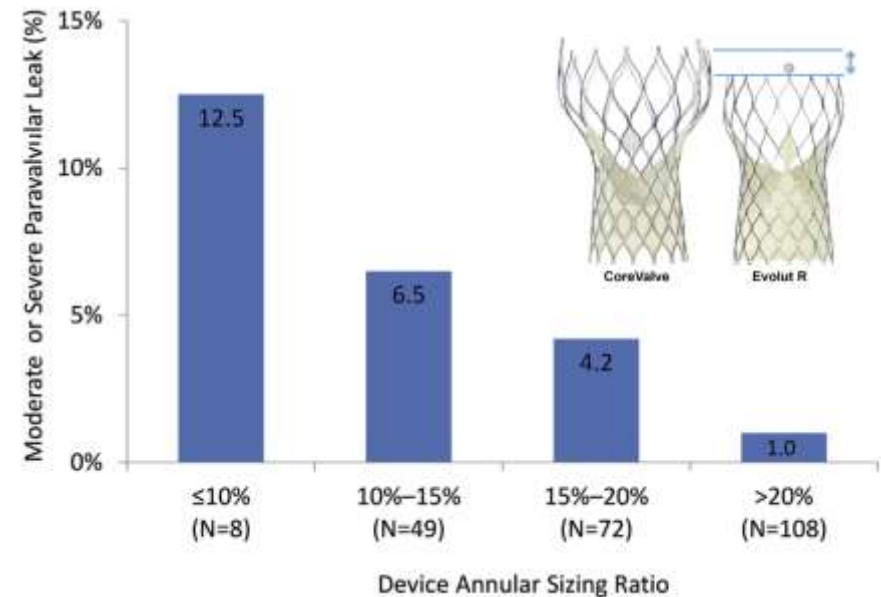
## PARTNER 2 – SAPIEN 3 Registry



**3.5 %  $\geq$  Moderate PVR**  
**40.8% Mild PVR**

*Pibarot et al. TCT 2016*

## EVOLUT R US Study



**5.7 %  $\geq$  Moderate PVR**  
**32.6 % Mild PVR**

*Popma, JACC Int 2017; 10: 268-275*



JAMA Cardiology | Original Investigation

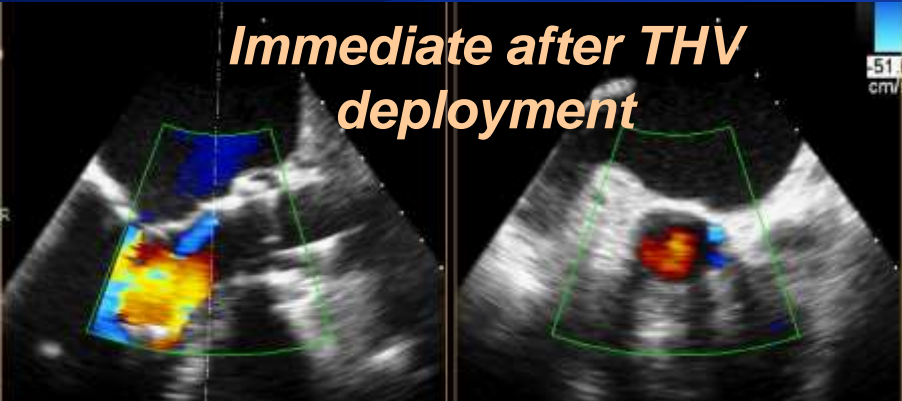
## Association of Paravalvular Regurgitation With 1-Year Outcomes After Transcatheter Aortic Valve Replacement With the SAPIEN 3 Valve

Philippe Pibarot, DVM, PhD; Rebecca T. Hahn, MD; Neil J. Weissman, MD; Marie Arsenault, MD; Jonathan Beaudoin, MD; Mathieu Bernier, MD; Abdellaziz Dahou, MD, MS; Omar K. Khaliq, MD; Federico M. Asch, MD; Oumhani Toubal, MD; Jonathon Leipsic, MD; Philipp Blanke, MD; Feifan Zhang, PhD; Rupa Parvataneni, MS; Maria Alu; Howard Herrmann, MD; Raj Makkar, MD; Michael Mack, MD; Richard Smalling, MD; Martin Leon, MD; Vinod H. Thourani, MD; Susheel Kodali, MD

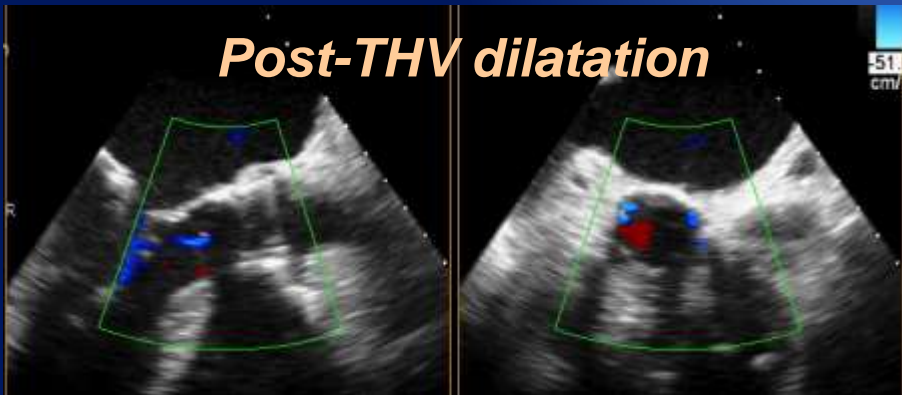
- ◆ None/Trace PVR (n = 887, 55.7%)
- ◆ Mild PVR (n = 519, 32.6%)
- ◆ Mild to Moderate PVR (n = 131, 8.2%)
- ◆ At Least Moderate PVR (n = 55, 3.5%)

# Post-Dilatation: Reduces PVL and Increases Valve Area

*Immediate after THV deployment*



*Post-THV dilatation*



## Balloon Expandable

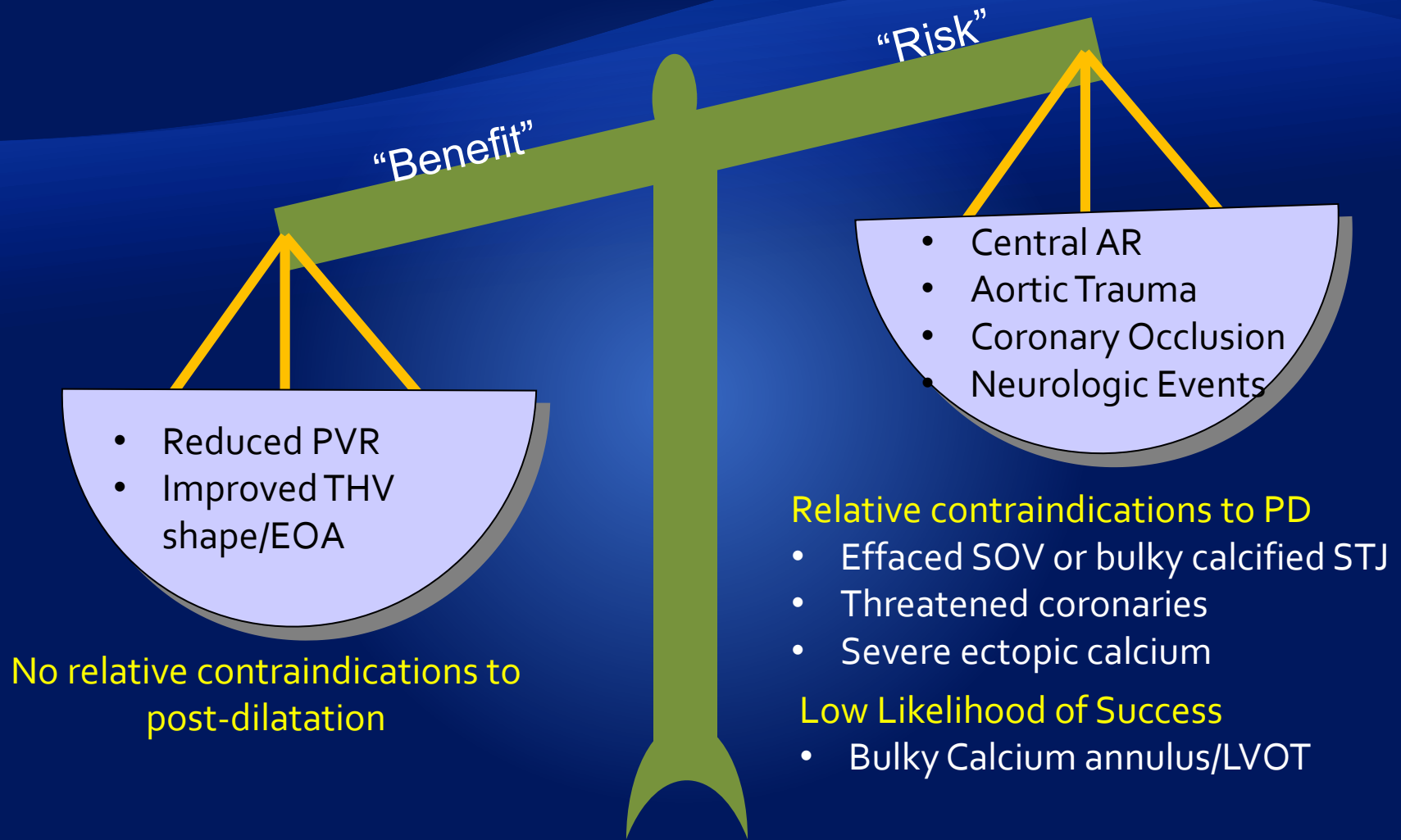
- ◆ Use valve delivery balloon
- ◆ Never add more than 1-2 cc to balloon
- ◆ Perform under rapid pacing

## Self Expanding Valve

- ◆ Size balloon based on annulus size (Consider non-compliant balloon)
- ◆ Use balloon sized to minimum dimension of annulus
- ◆ Consider upsizing balloon if necessary
- ◆ Perform under rapid pacing



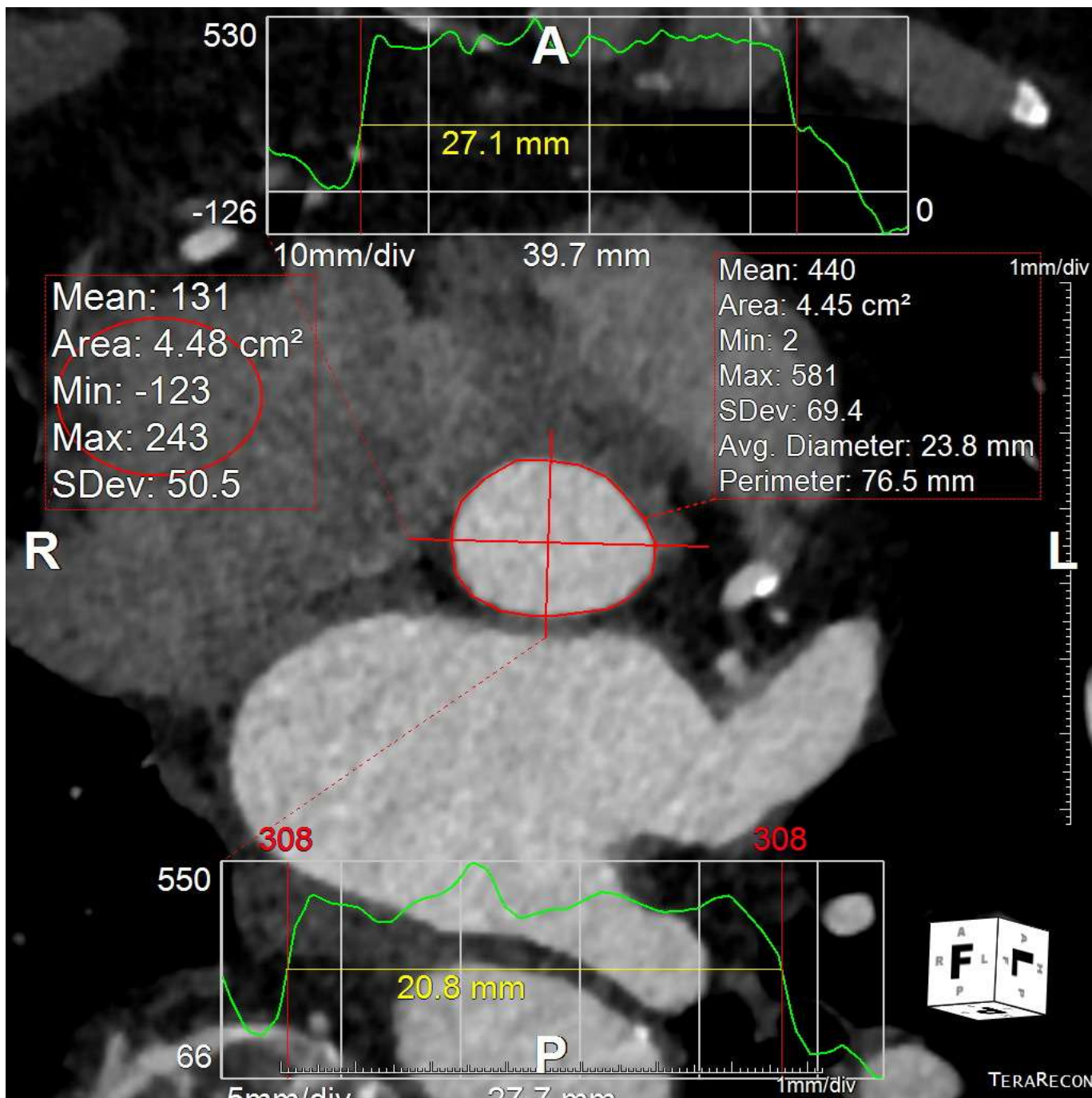
# Post-dilatation Risk-Benefit Analysis

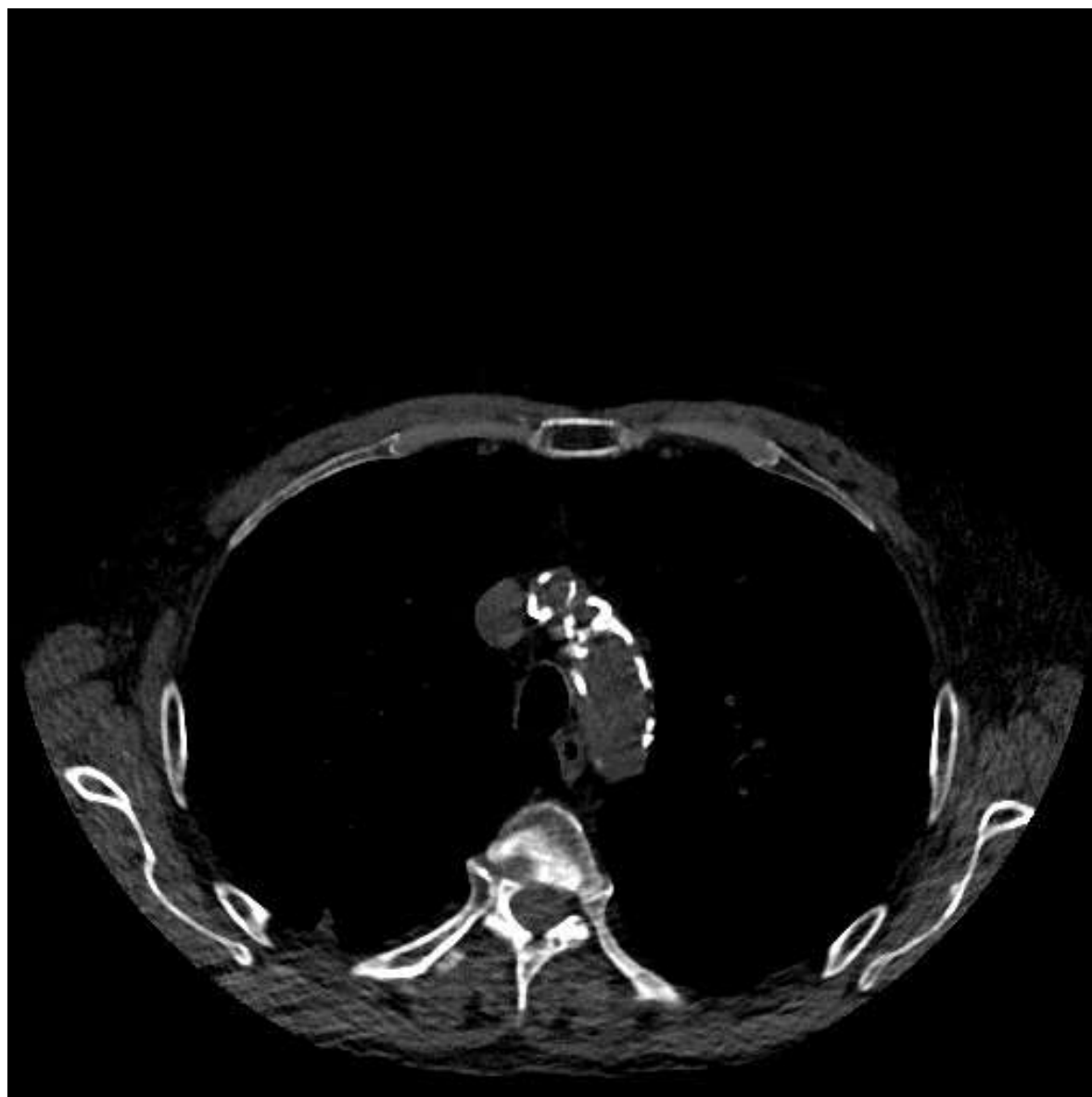


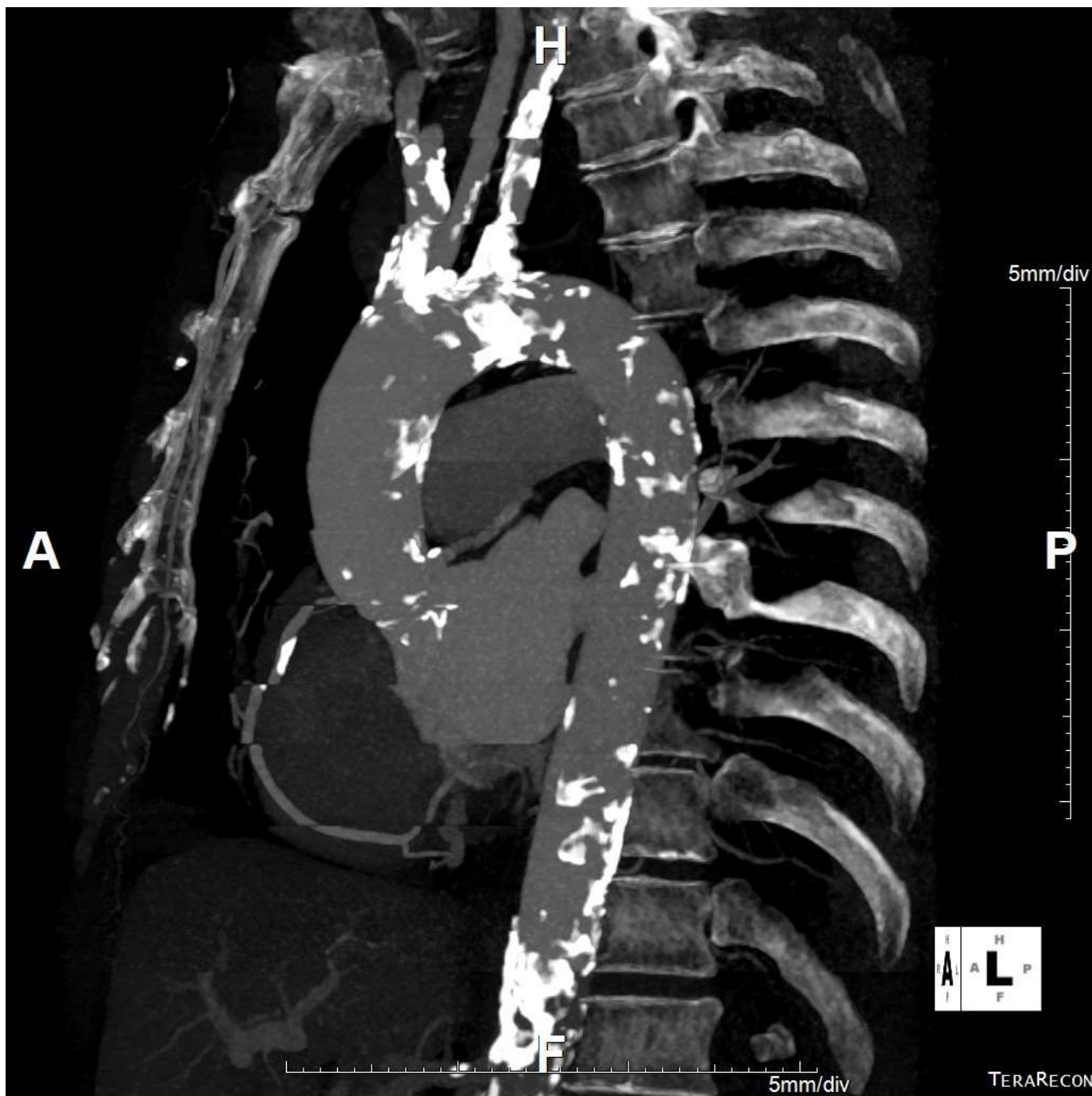
# Case Presentation : B.I.

- 81 year old man with HTN, HL, COPD, PAD with severe symptomatic AS with SOB.
- AS: Mean gradient 31mmHg, EF 34%. V1/V2 0.22
  - Dobutamine stress: 4mcg/kg/min stopped due to VT
- CAD: No significant disease
- COPD: FEV1 17%, DLCO 31%
- PAD: aorto-bifemoral with Dacron grafts, aorto-renal and IMA bypass, carotid bruits, renal artery stenosis
- STS: 12.1%, stroke risk 2.5%









# Case Presentation (2): B.I.

- High Risk TAVR 26mm Sapien 3
- Cut down to Dacron aortabifemoral graft
- Calcified arch and great vessels



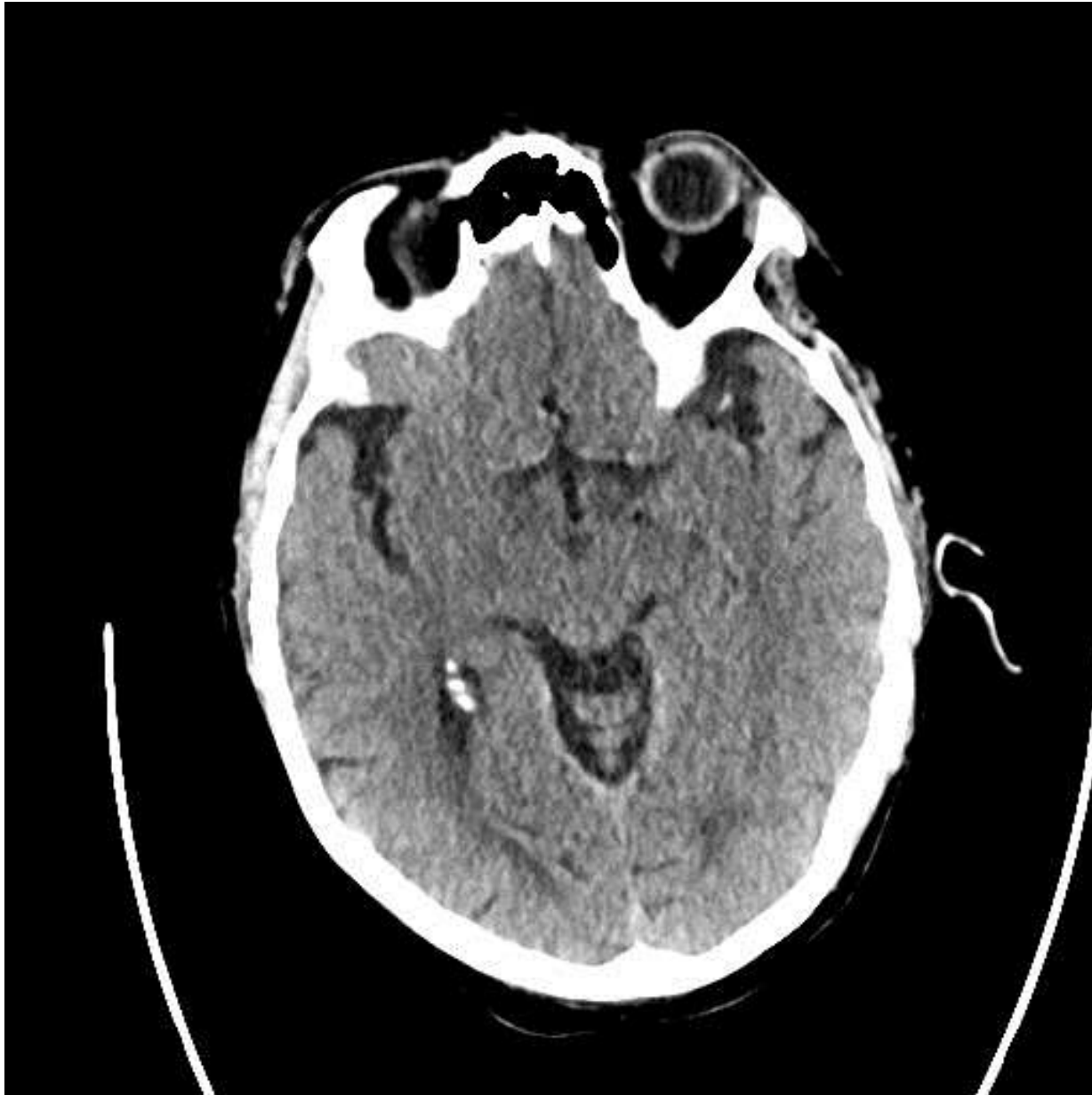
# Case Presentation (3): B.I.

- Successful TAVR deployment with trace perivascular leak
- Repair of Dacron aorto-bifemoral graft
- Extubated, awake, responsive and moves all extremities. Transferred from recovery to cardiac floor
- In usual state at 5AM, at 6:20AM, found to have fluctuating dysarthria, aphasia, R facial droop and R-hemiplegia. Improve with higher BP of greater than 150. Stroke Code was called.

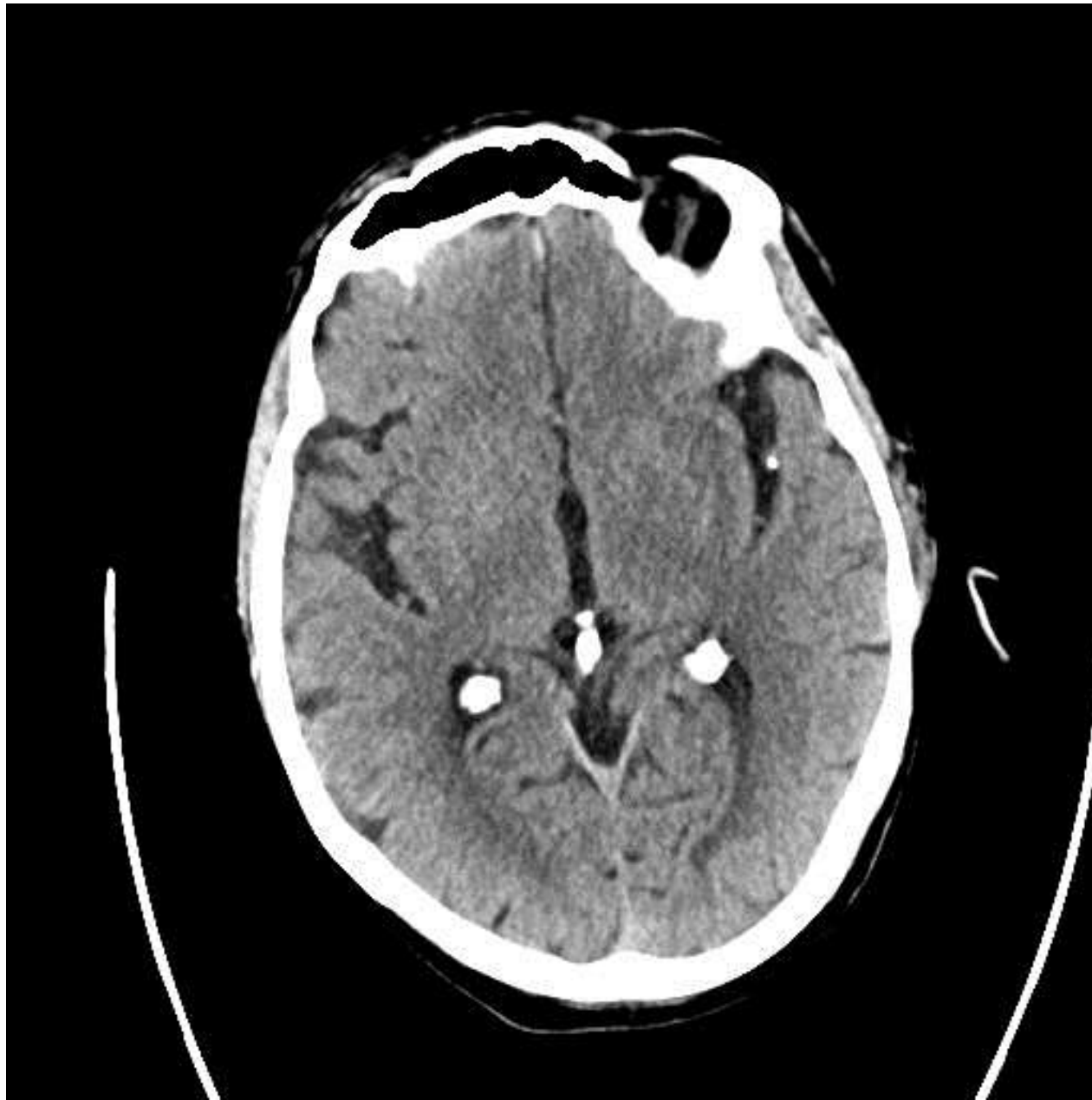


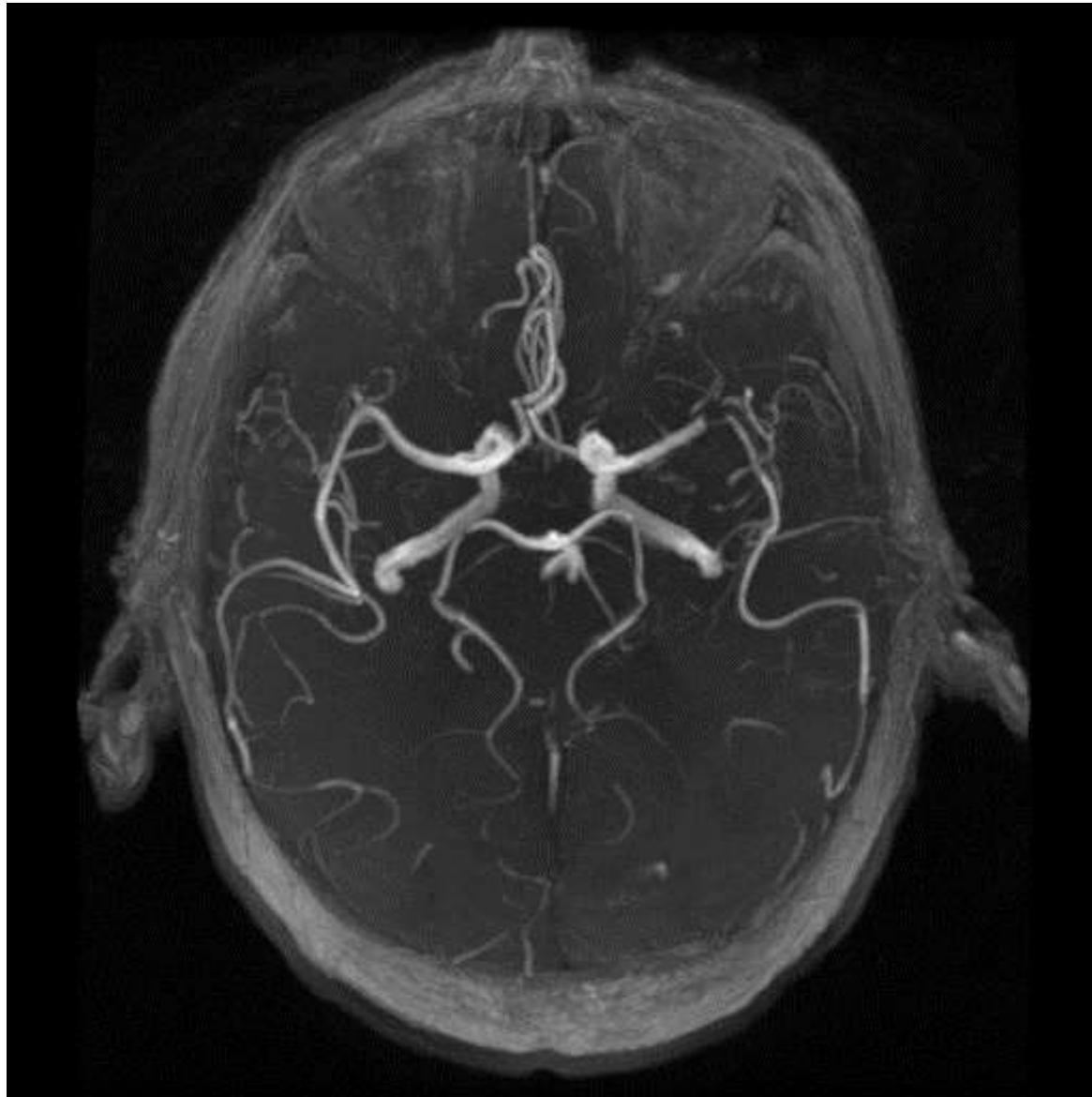


6:45AM

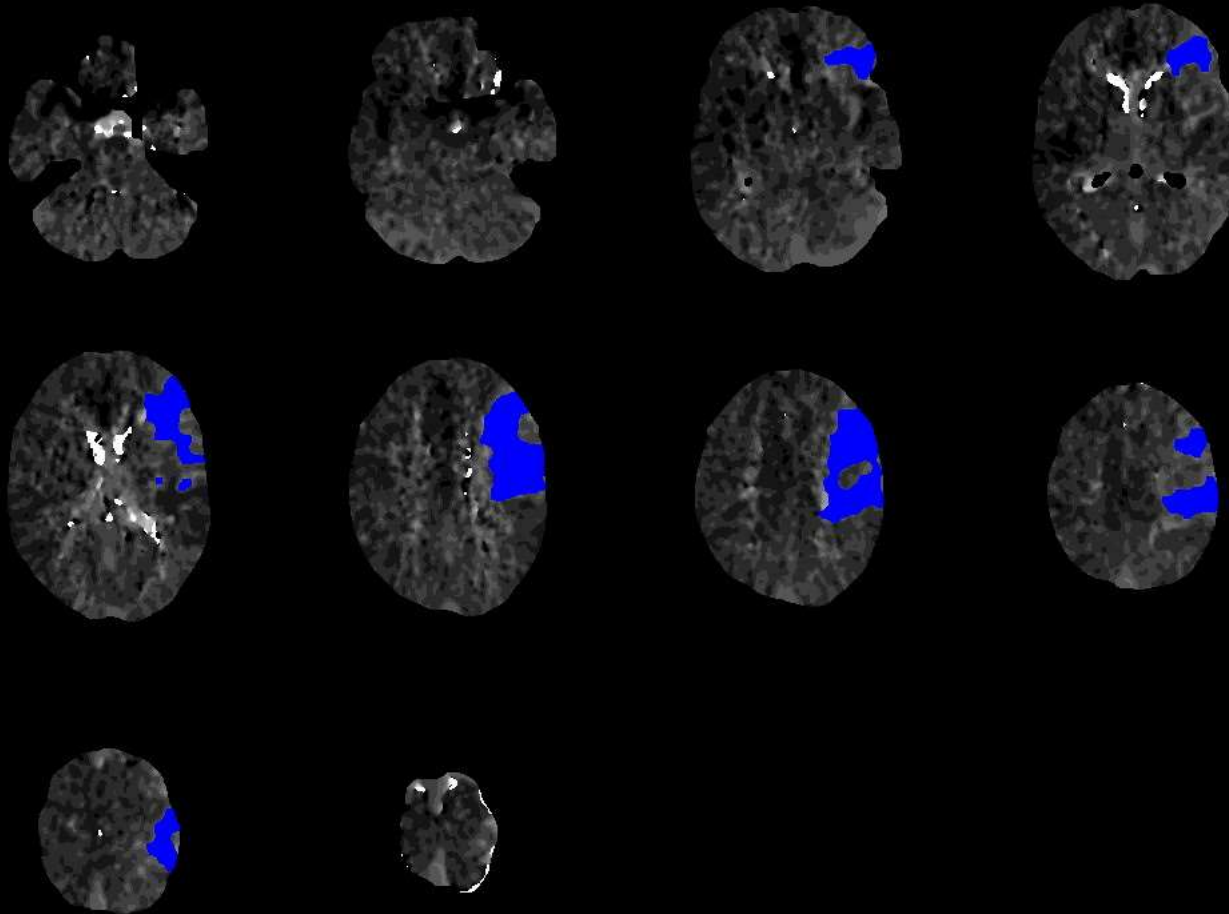








9:06 AM



Tmax>10.0s volume: 0 ml  
Tmax>8.0s volume: 0 ml  
Tmax>6.0s volume: 0 ml  
Tmax>4.0s volume: 65 ml

iSchemaViewRAPID



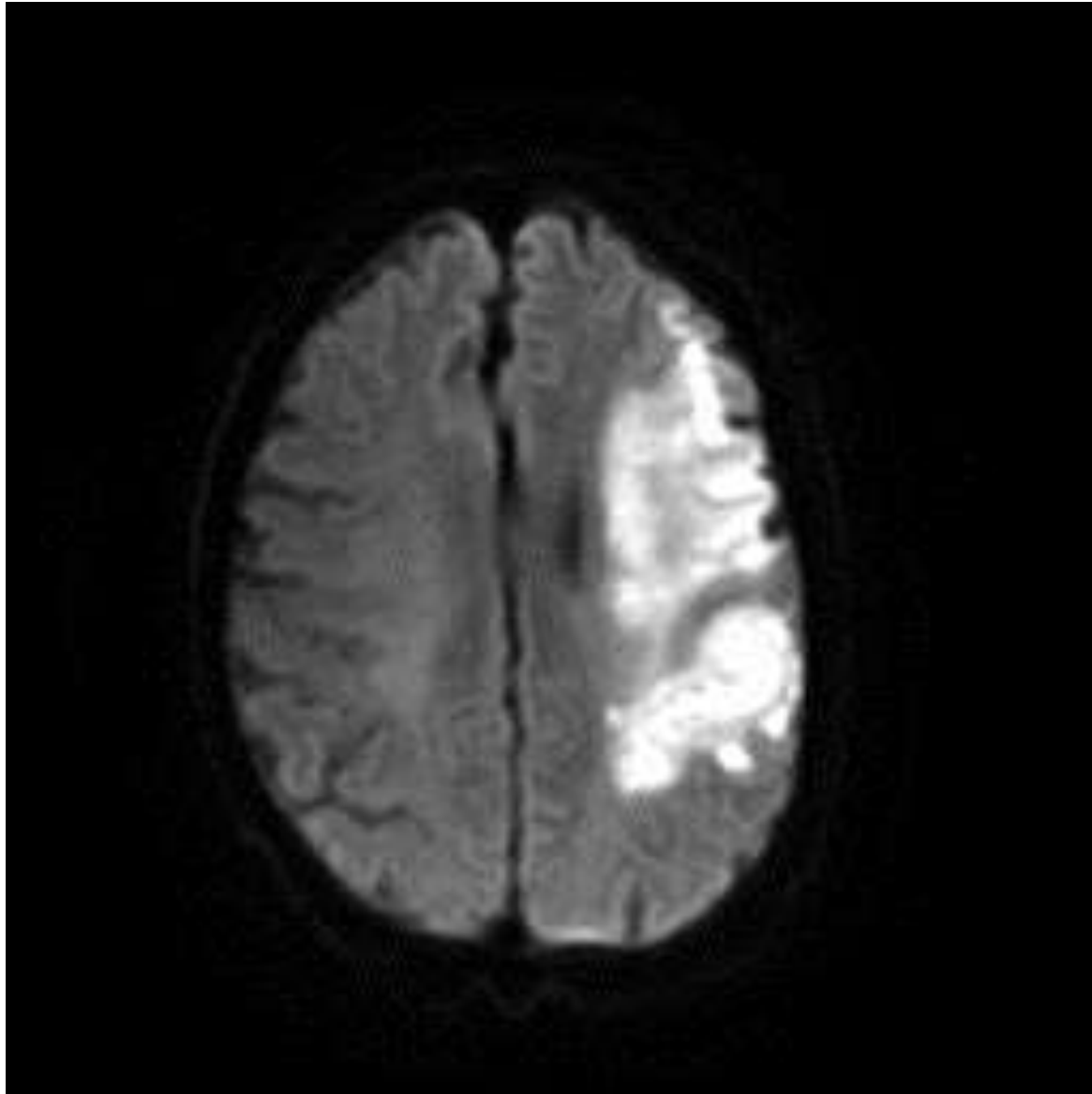
tPA given  
at  
9:30AM

Repeat  
CT at  
12:45 PM





Next Day  
MRI



# Case Presentation (4): B.I.

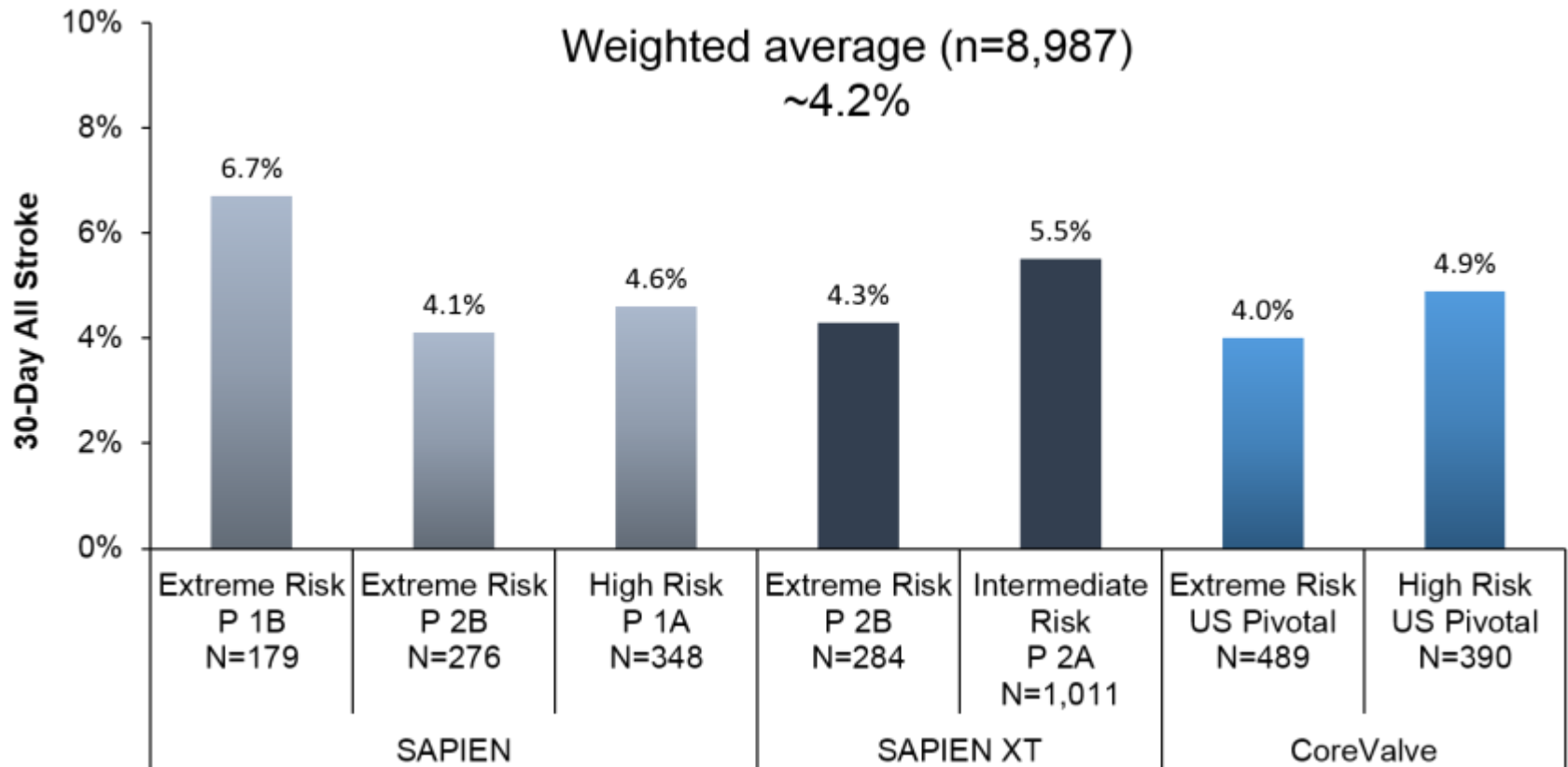
- CTA: Embolus vs calcified stenosis in left MCA bifurcation and M2. No complete occlusion on CTA, slight decrease perfusion by CBF.
- Moderate occlusion of left common carotid; severe occlusion of left vertebral; moderate to severe narrowing of right common carotid.
- MRI confirms acute stroke. tPA given within 3 hours.
- Large groin hematoma.
- No hemorrhagic transformation but no improvement
- 3 days post-TAVR, family withdrawn support.



Would Cerebral Protection Prevented  
the CVA?



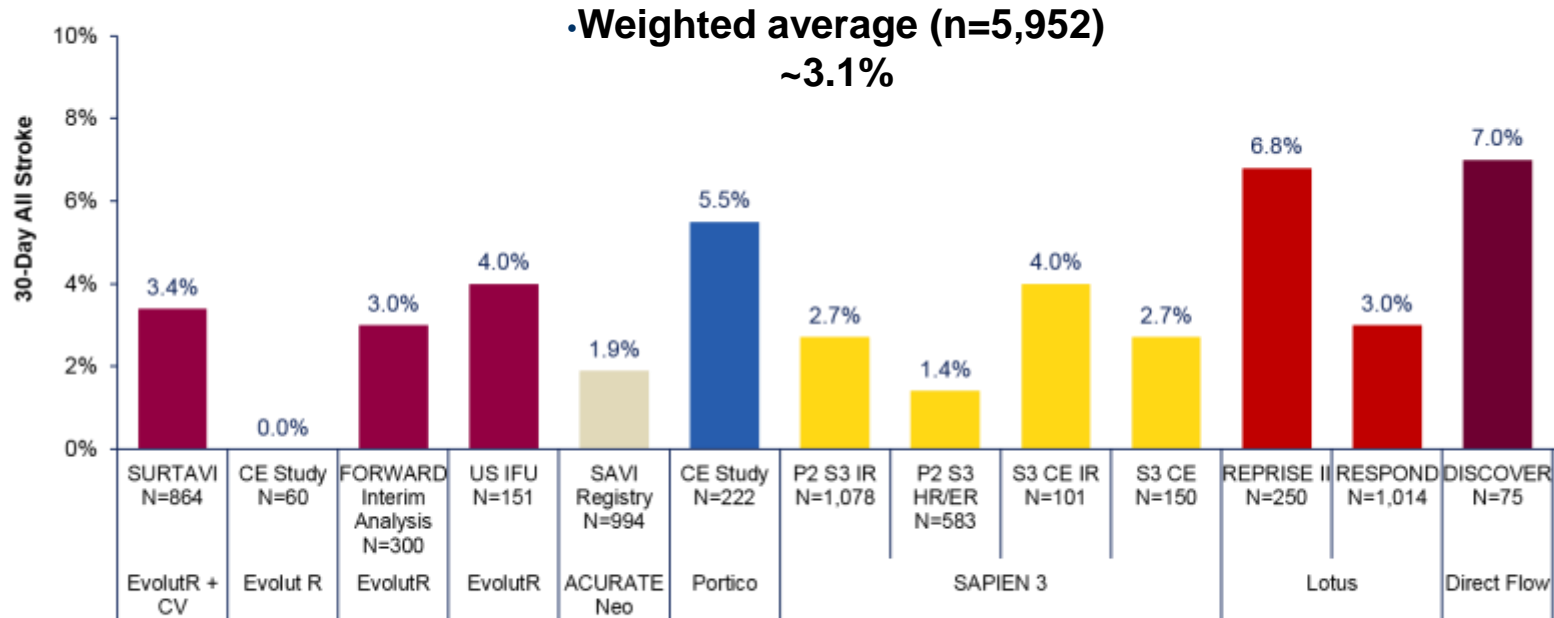
# Stroke Rates in Randomized Trials



<sup>1</sup>Leon, et al., *N Engl J Med* 2010;363:1597-1607; <sup>2</sup>Webb, et al., *J Am Coll Cardiol Interv* 2015;8:1797-806; <sup>3</sup>Smith, et al., *N Engl J Med* 2011;364:2187-98;

<sup>4</sup>Leon, et al., *N Engl J Med* 2016;374:1609-20; <sup>5</sup>Popma, et al., *J Am Coll Cardiol* 2014;63:1972-81; <sup>6</sup>Adams, et al., *N Engl J Med* 2014;370:1790-8;;

# Stroke Rates with Contemporary Devices



<sup>1</sup>Manoharan, et al., *J Am Coll Cardiol Interv* 2015; 8: 1359-67; <sup>2</sup>Moellman, et al., presented at PCR London Valves 2015; <sup>3</sup>Linke, et al., presented at PCR London Valves 2015; <sup>4</sup>Kodali, et al., *Eur Heart J* 2016; doi:10.1093/eurheartj/ehw112; <sup>5</sup>Vahanian, et al., presented at EuroPCR 2015; <sup>6</sup>Webb, et al. *J Am Coll Cardiol Interv* 2015; 8: 1797-806; <sup>7</sup>DeMarco, et al, presented at TCT 2015; <sup>8</sup>Meredith, et al., presented at PCR London Valves 2015; <sup>9</sup>Falk, et al., presented at EuroPCR 2016; <sup>10</sup>Kodali, presented at TCT 2016; Reardon, M Published in NEJM March 2017

# What are, or are not, predictors of stroke and cerebral damage in TAVR?

Factor	Is or is not a predictor of/ associated with	Outcome	Patient Segment	Trial Type	Size	Reference
<b>Logistic EuroSCORE</b>	<b>is not a predictor of</b>	<b>Stroke</b>	TAVR (Log EuroSCORE average 16-33)	Meta-analysis of EU Registries	9,786	Zeinah et al EU TAVR Registry Review and Meta Analysis. ACTA 2015
Post-dilatation and valve dislodgement	is a predictor of	Stroke and TIA	Severe AS TAVR (STS 4-10)	Case series	1,061	Nombela-Franco, et al. Circulation 2012
Transarterial vs Transapical access	is a predictor of	Stroke and TIA	Severe AS TAVR (log EuroSCORE 25 +/-5)	Meta-analysis	10,037	Eggebrecht, et al. Eurointervention 2012
Smaller indexed valve area, Cerebrovascular disease, TAVR vs SAVR	is a predictor of	Stroke or TIA	Severe AS high-risk (STS 10-15)	RCT (PARTNER)	657	Miller, et al. JTCVS 2012
Age, hyperlipidemia, post-dil	is a predictor of	DW-MRI lesion number post TAVR	Severe AS TAVR	Case series	42	Samim, et al. Clin Res Cardiol 2015
Age, severity of atheroma (arch and descending), catheterization time	is a predictor of	DW-MRI lesion number post TAVR	Severe AS TAVR, CoreValve	Case series	31	Fairbairn, et al. Heart 2012
Peak transaortic gradient	is a predictor of	DW-MRI total lesion volume post TAVR	Severe AS TAVR	Case series	42	Samim, et al. Clin Res Cardiol 2015



# Conclusion

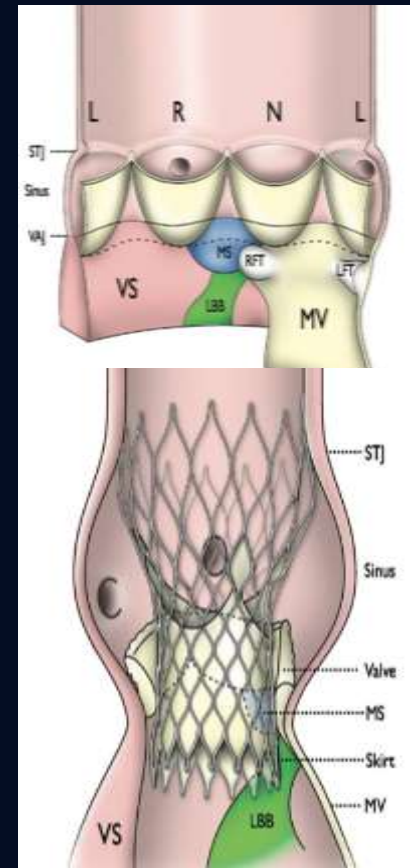
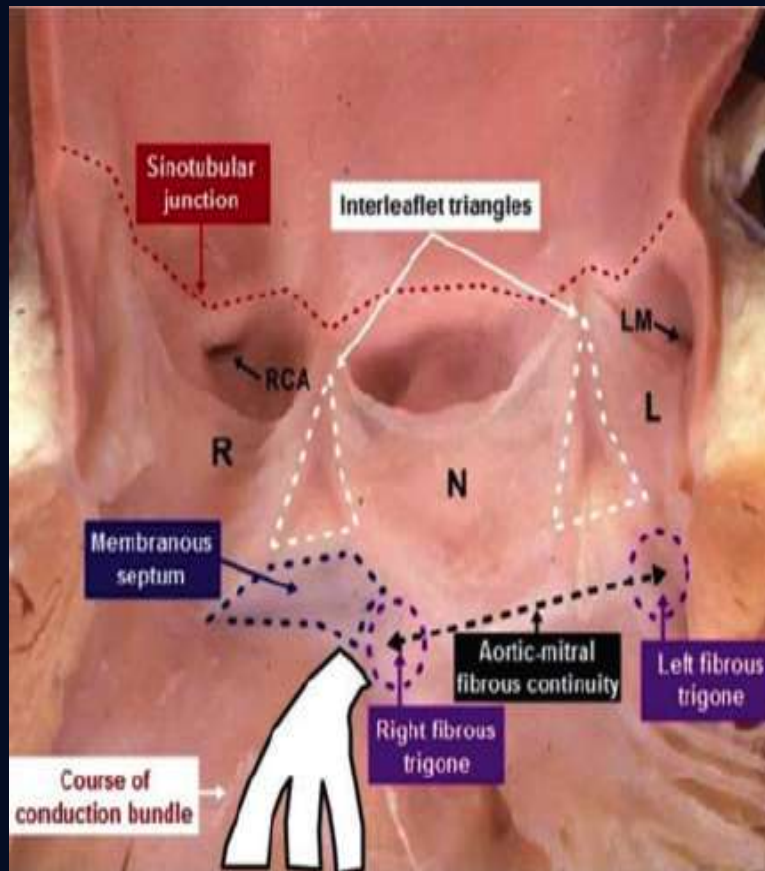
- In the current era of TAVR, stroke is still a devastation outcome and occurs in about 3%
- Predictability is poor, atheroma load/CVA may be the best additional predictor. Also, valve-in-valve cracking?
- CEP will help to decrease some peri-procedural stroke but not all
- The highest risk patient (e.g. our patient) will need complete vascular protection.



# Predictors of Conduction Disturbances

Clinical	Anatomic	Procedure and Operator-Related
Male Gender	Variations in location of left bundle exit point	Radial force of the prosthesis
Age>75 years	Septum thickness	Implant depth
Right bundle branch block (RBBB)	Thickness of the non-coronary cusp	Balloon aortic valvuloplasty
Other pre-existing conduction disturbance	Elevated left coronary cusp calcium	Learning curve

# TAVR and Cardiac Conduction



# How Do We Gauge Implant Depth?

- Transesophageal echocardiography
  - Maybe not be the most “minimalist” way of doing the procedure
  - In inexperienced centers, the lack of 3-dimensional imaging and general lack of visualization may impair assessment
- Aortography
  - 2-dimensional, only partial reference-based imaging
  - Relies on the ability of contrast to fill the base of the native coronary cusps
  - Contrast aortography of a coaxial projection of the valve prosthesis may not show the representative depth relative to the native annulus
    - To this end, what is the true optimal depth of implantation as assessed in clinical trials? Is this reliable and/or valid?

# Advance Skills Set

- TAVR is a relative straight forward procedure with low complication rate and excellent short to medium term outcome if:
  - ❑ Proper screening with emphasize of access vessel size, calcification and tortuosity
  - ❑ Attention to calcium distribution and volume in the leaflets and annulus
  - ❑ No predilatation, use CPD in “high” risk cases
  - ❑ Attention to implant depth with proper viewing angles
  - ❑ Careful determination of perivalvular leak with sparing use of post-dilatation

