

# **TAVR – Conquering Challenging Anatomies**

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# Disclosures

- Research Valve Trial Participation
  - Edwards Lifesciences
  - Abbott
  - Medtronic
- Course Faculty
  - Edwards Lifesciences

# Case 1

- 73 year-old woman
- Recent hospitalization for acute heart failure, found to have reduced LVEF (39%) & severe AS
- CTA revealed Bicuspid Aortic Valve
- STS score 3.1%
- 1/4 elements of frailty
- Deemed Intermediate Risk
- Strongly prefers TAVR

## **Past Medical History**

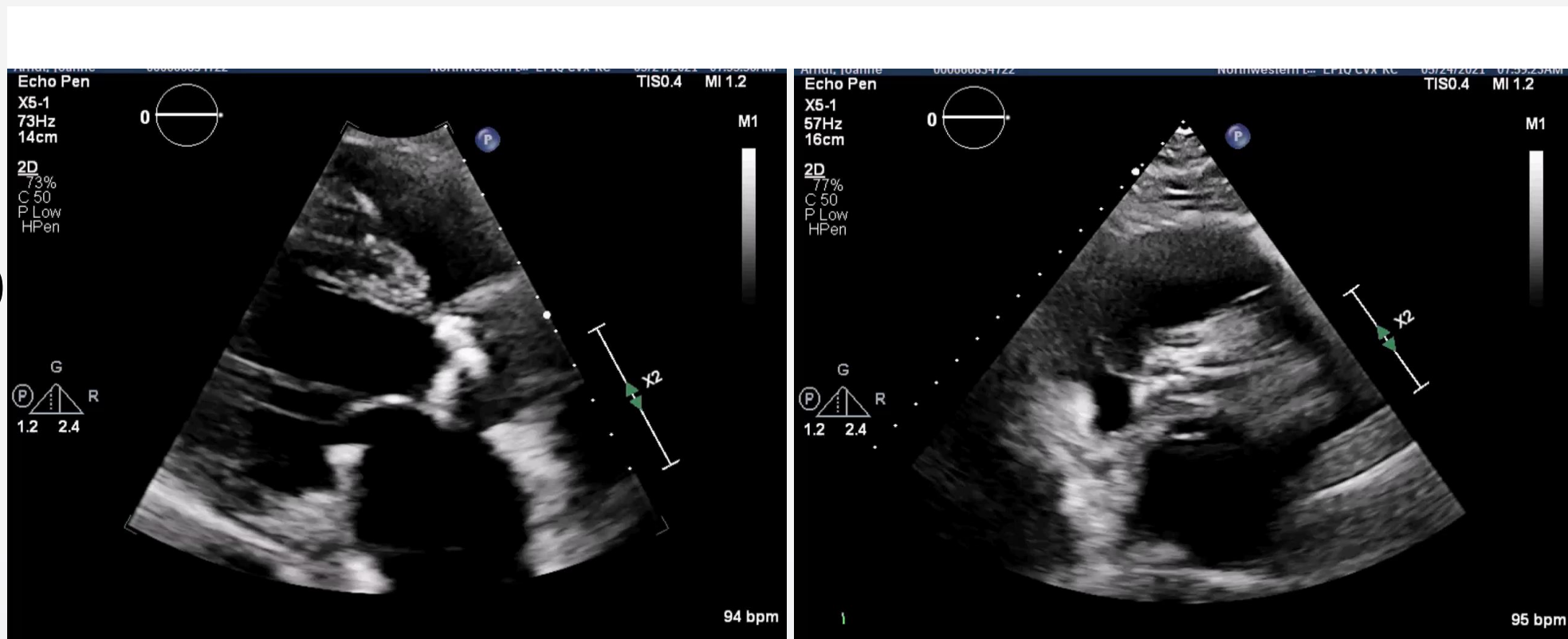
- Systolic Heart Failure
- Non-obstructive CAD
- CVA
- HTN
- DM type II
- Tobacco use with mild COPD

# Echo

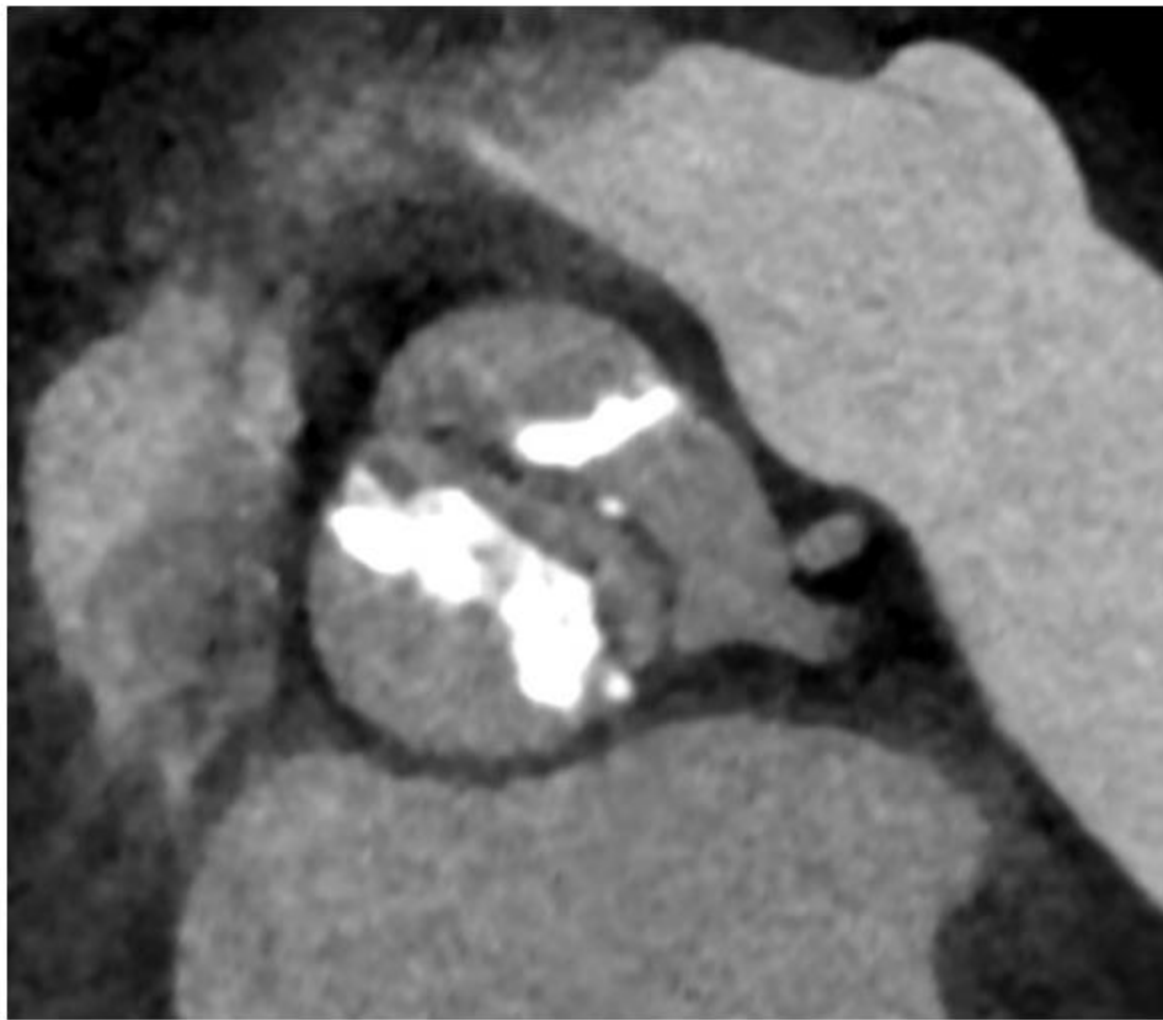
LVEF 39%

Severe AS

- 4.0 m/s
- mean grad 40
- 0.44 cm<sup>2</sup>
- DI 0.12
- No AI



# CT



Sievers Type 1  
Left-Right fusion

- Calcified Raphe
- Calcified Leaflets

Sinuses of Valsalva  
36 x 37 x 37 mm



# Bicuspid Aortic Valve Morphology and Outcomes After Transcatheter Aortic Valve Replacement

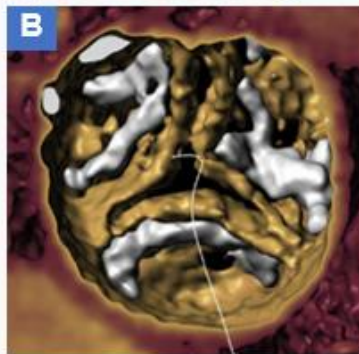
## Tricuspid Aortic Valve

## Bicuspid Aortic Valve

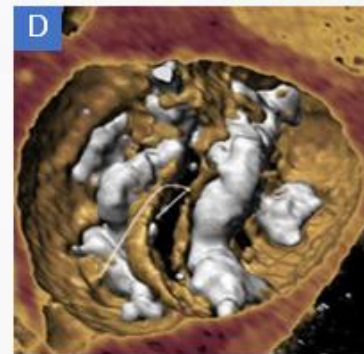
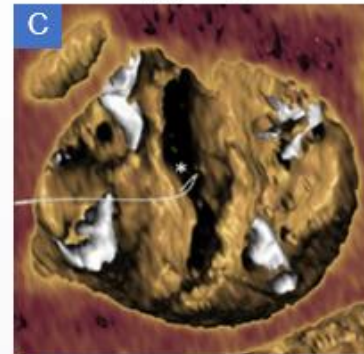
Mild Leaflet  
Calcification



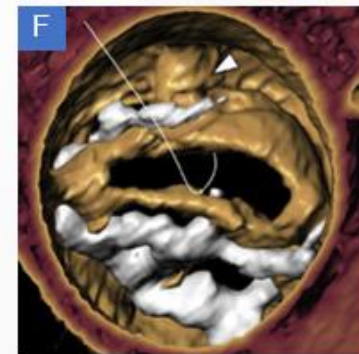
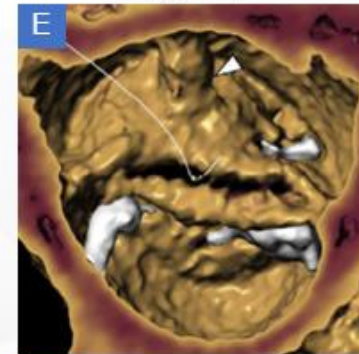
Excess Leaflet  
Calcification



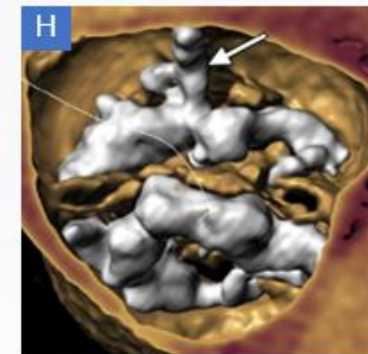
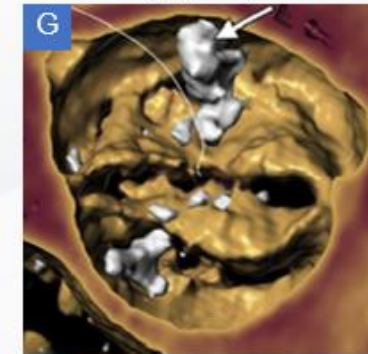
No Raphe  
(type 0)



Noncalcified Raphe  
(type 1)



Calcified Raphe  
(type 1)

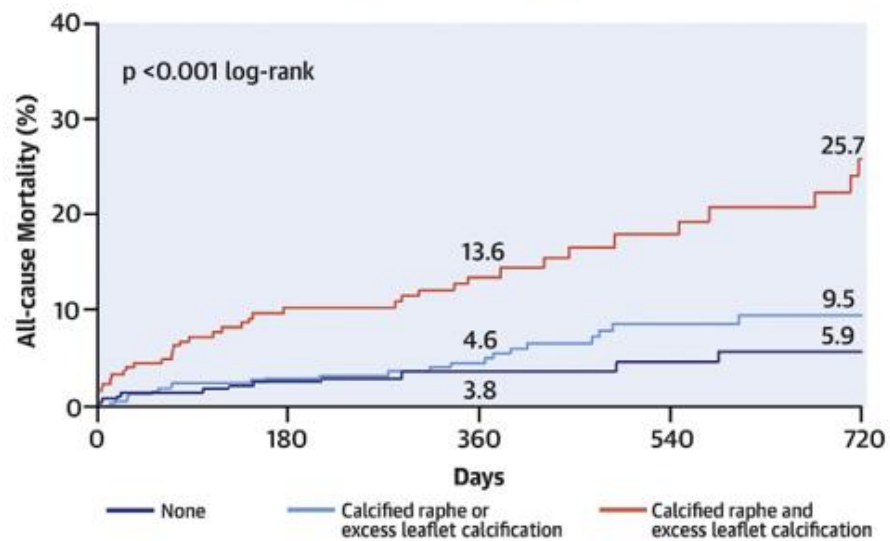
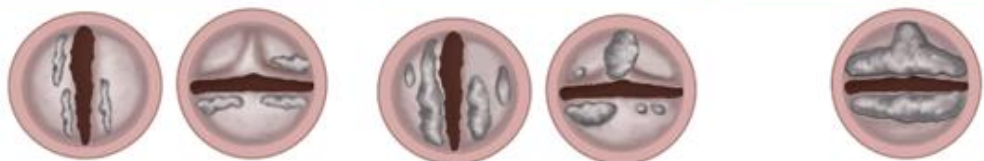


## Death From Any Cause, According to Morphological Features

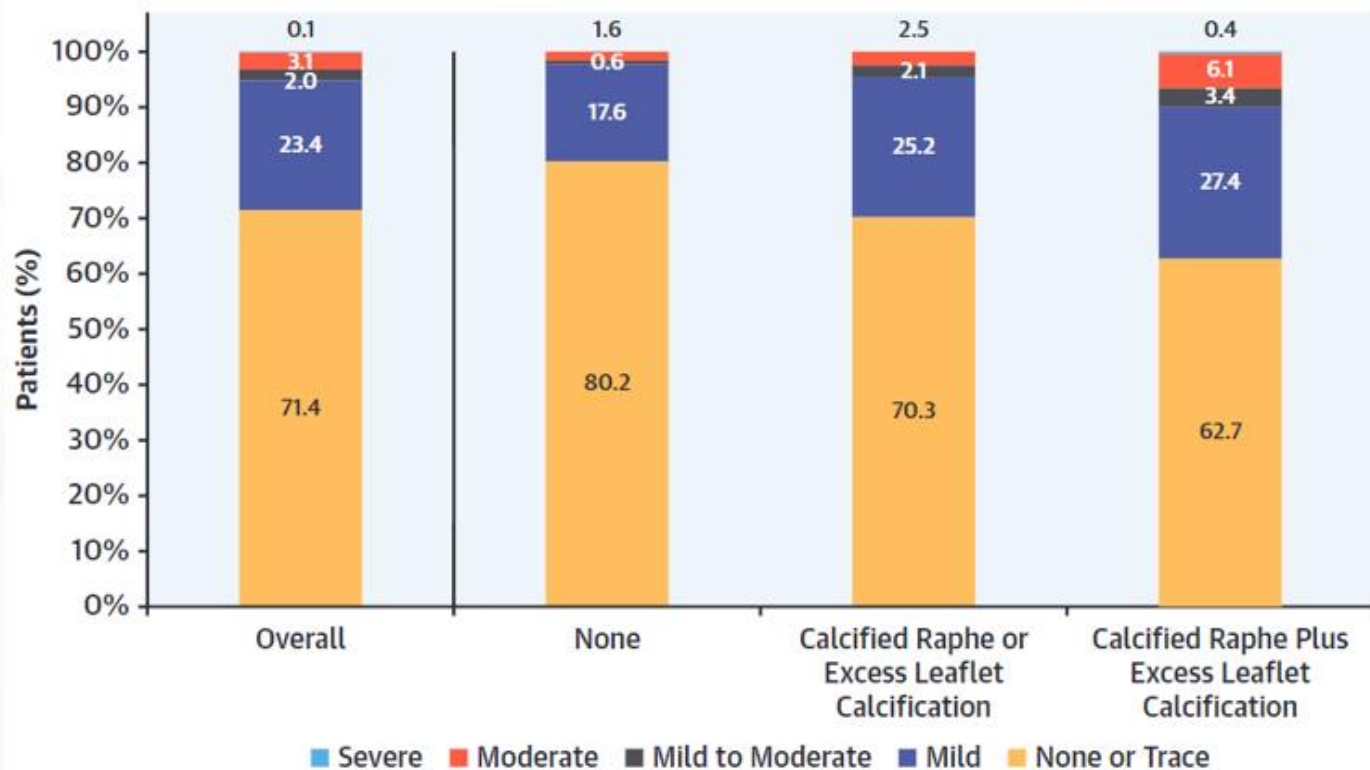
No Calcified Raphe or Excess Leaflet Calcification (31.3%)

Calcified Raphe or Excess Leaflet Calcification (42.6%)

Calcified Raphe Plus Excess Leaflet Calcification (26.0%)

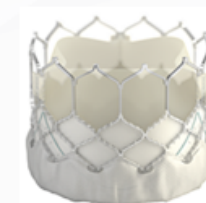


## Paravalvular Aortic Regurgitation Stratified by Morphological Features





# Association Between Transcatheter Aortic Valve Replacement for Bicuspid vs Tricuspid Aortic Stenosis and Mortality or Stroke Among Patients at Low Surgical Risk



181 382 Consecutive patients underwent transcatheter aortic valve replacement with third- and fourth- generation balloon-expandable transcatheter heart valves (Sapien 3 and Sapien 3 Ultra<sup>3</sup>) and were included in the registry

21 721 Excluded  
 14 274 Nonbicuspid or tricuspid  
 6 470 Prior surgical aortic bioprosthetic valve  
 599 Pure aortic valve insufficiency and no aortic stenosis  
 377 Unknown  
 1 Patient with follow-up, <30 d

159 661 Patients included in the analysis

37 660 Patients at low surgical risk (surgical risk of mortality <3%)<sup>b,c</sup>

3 243 Bicuspid aortic stenosis

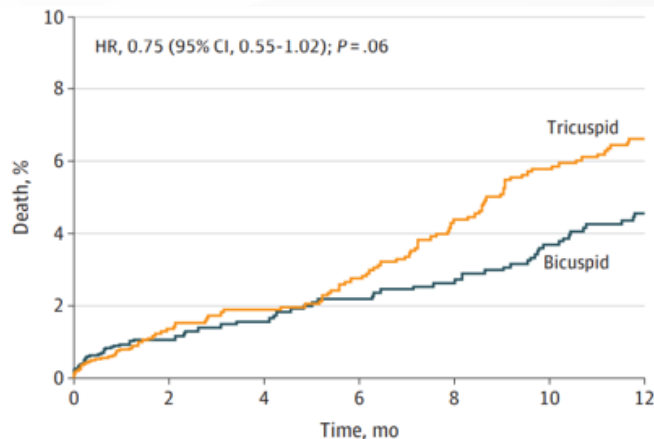
3 447 Tricuspid aortic stenosis

Propensity score matching

3 168 Bicuspid aortic stenosis

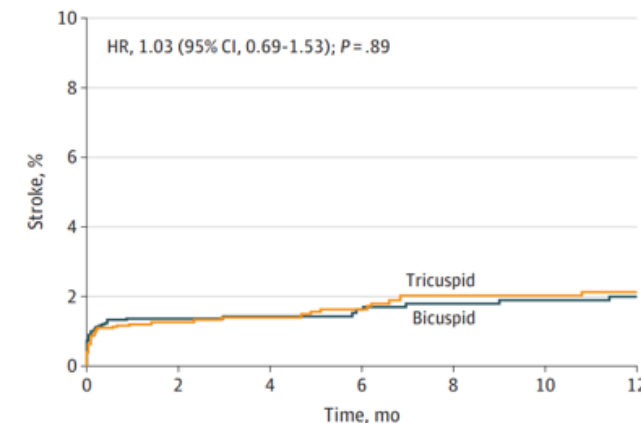
3 168 Tricuspid aortic stenosis

## All-cause mortality



No. at risk	0	2	4	6	8	10	12
Bicuspid	3168	1300	1130	1111	1102	1081	779
Tricuspid	3168	1430	1273	1253	1230	1204	888

## Stroke



No. at risk	0	2	4	6	8	10	12
Bicuspid	3168	1285	1117	1097	1087	1065	770
Tricuspid	3168	1409	1253	1232	1205	1182	874



## JACC: Cardiovascular Interventions

# The PARTNER 3 Bicuspid Registry for Transcatheter Aortic Valve Replacement in Low-Surgical-Risk Patients



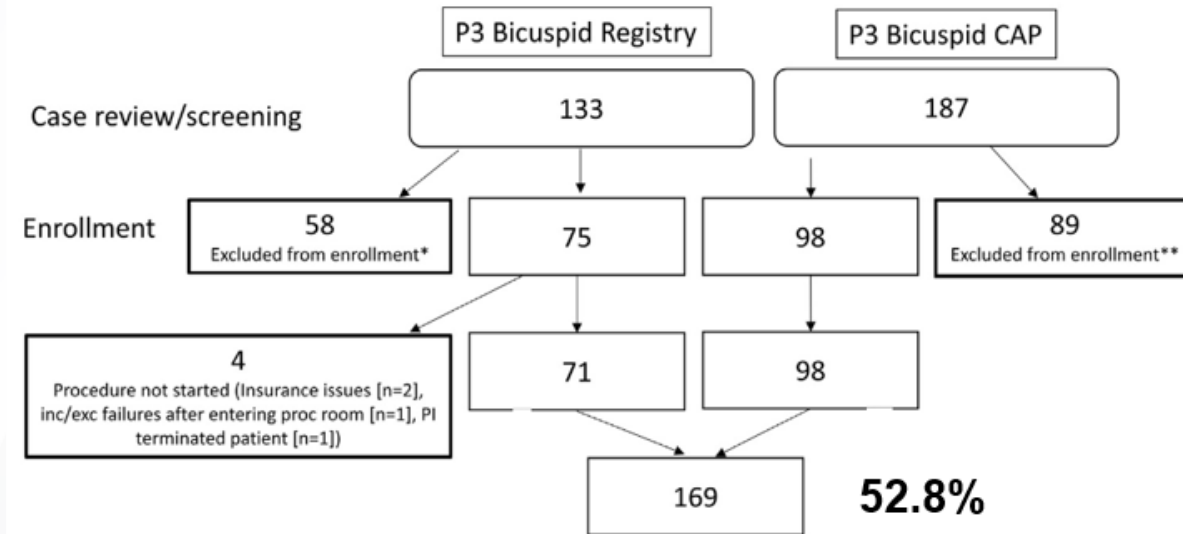
169 patients enrolled (out of 320)

Mean age 71.0 years

45% Female

85.8% Sievers type I

STS score 1.4%



### 30 Day Outcomes

Death 0.0%

Stroke 1.2%

Pacemaker 6.5%

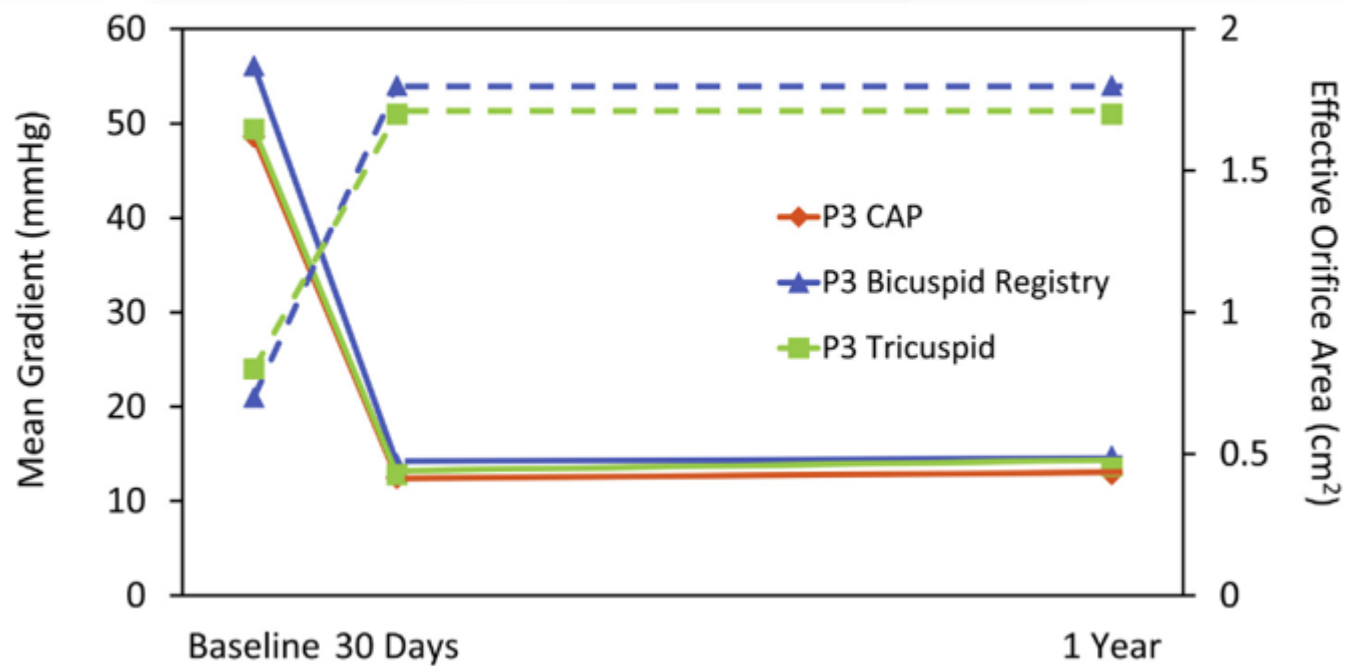
Conversion 0.0%

AI None/Trace 71.8%

Mild 26.3%

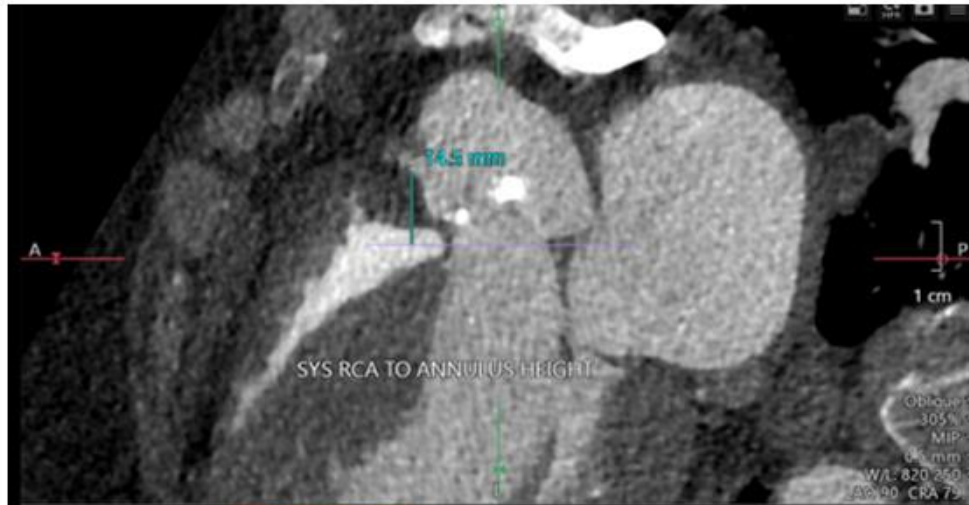
>Mild 1.9%

### Through 1 year

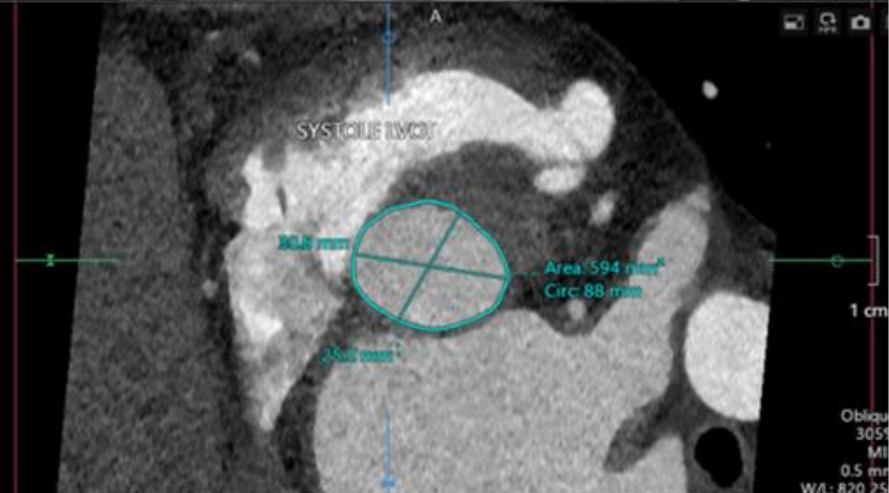
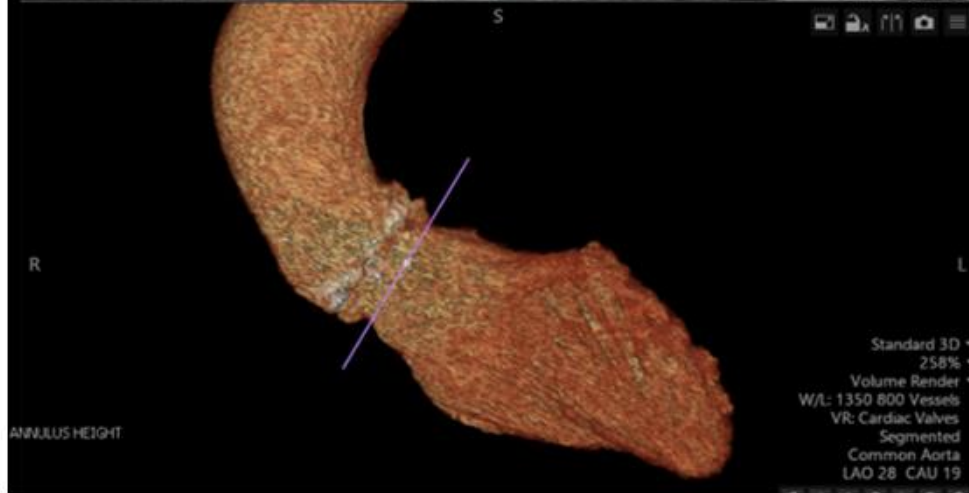
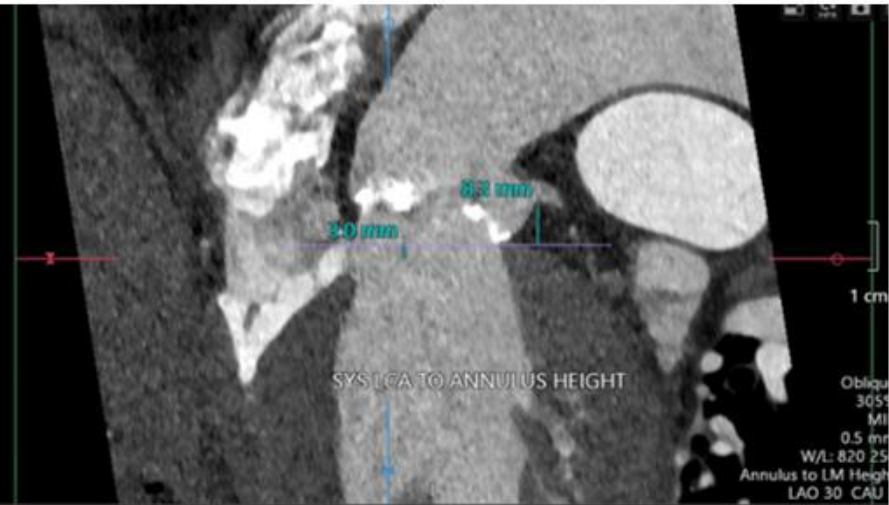


# CT

RCA  
14.8 mm

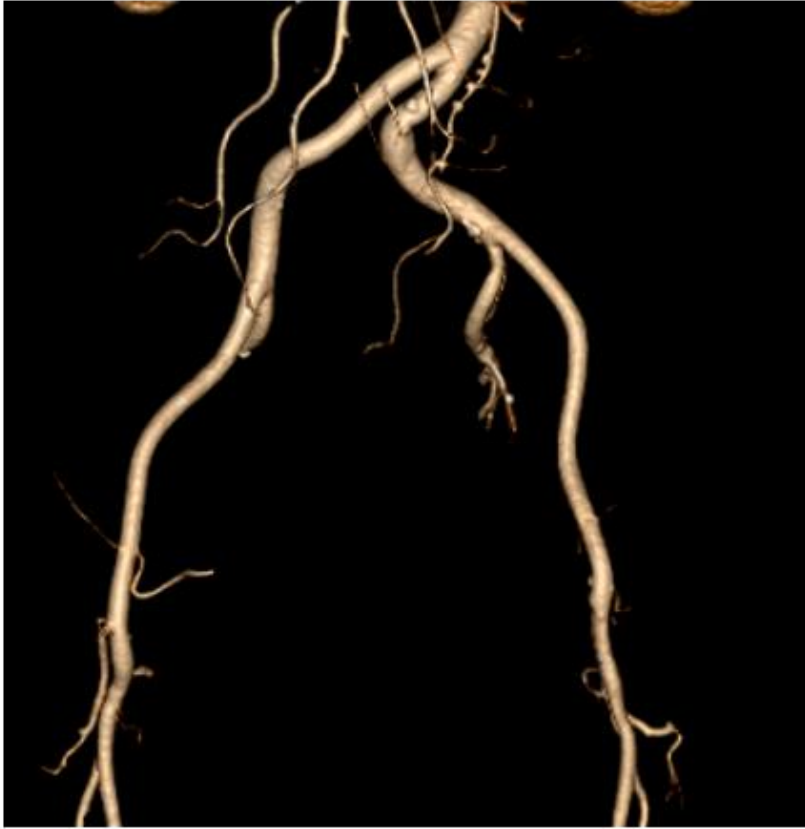


LM  
?8.3 mm

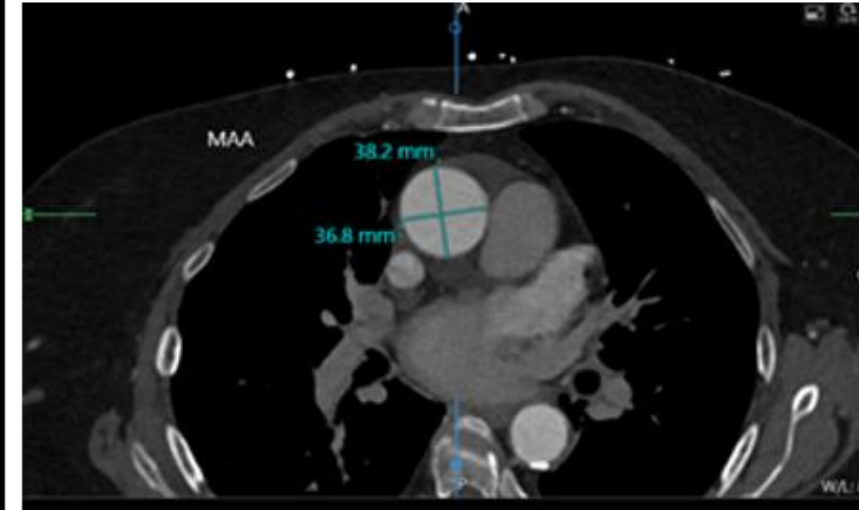


Annulus 22 x 30 mm (551 mm<sup>2</sup>)

# CT



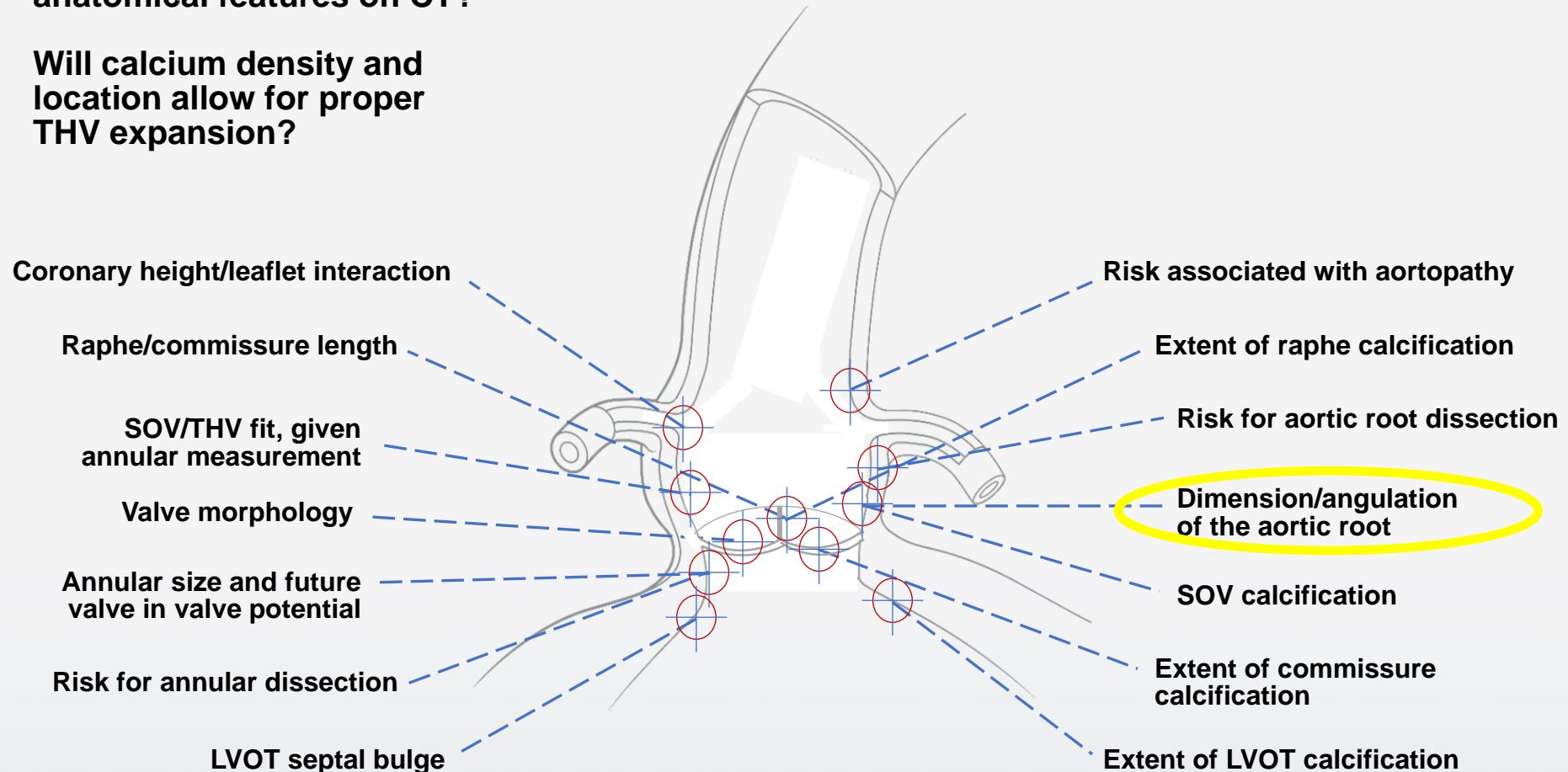
SOV 37 x 38 mm



# BAV and TAVR – Anatomical Considerations

Are there unfavorable anatomical features on CT?

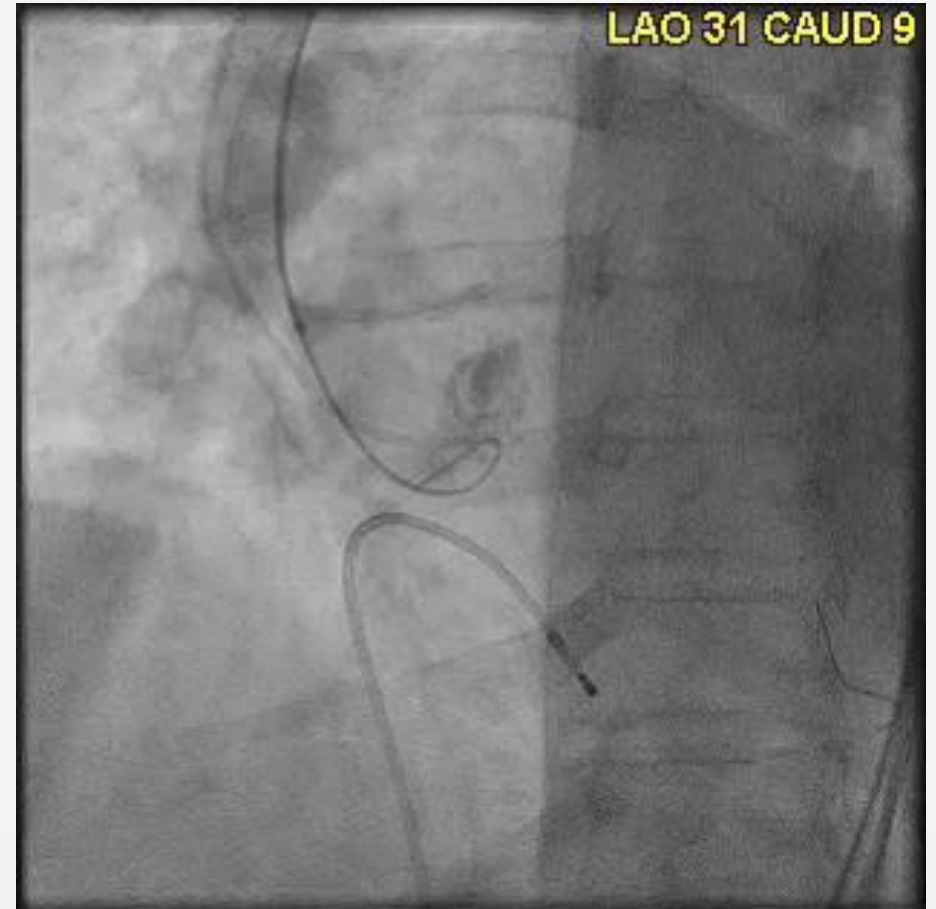
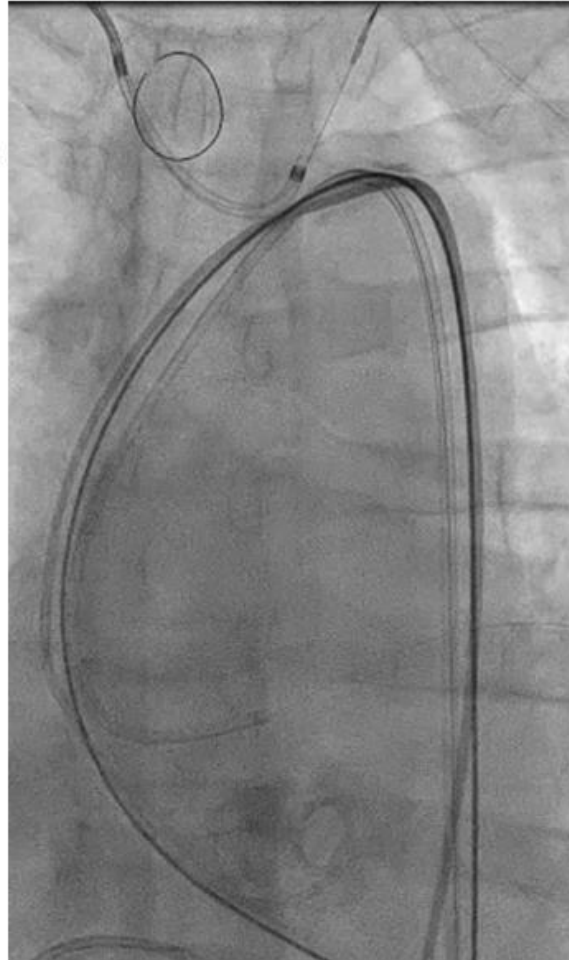
Will calcium density and location allow for proper THV expansion?



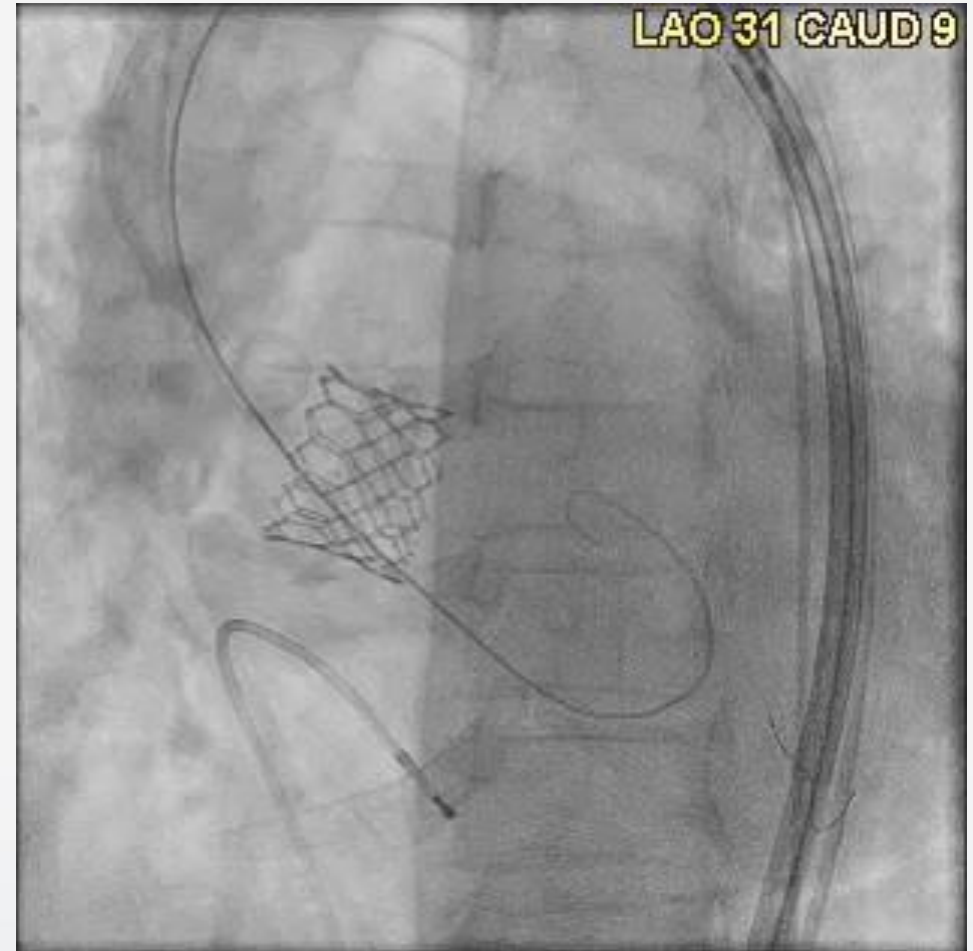


# The Plan

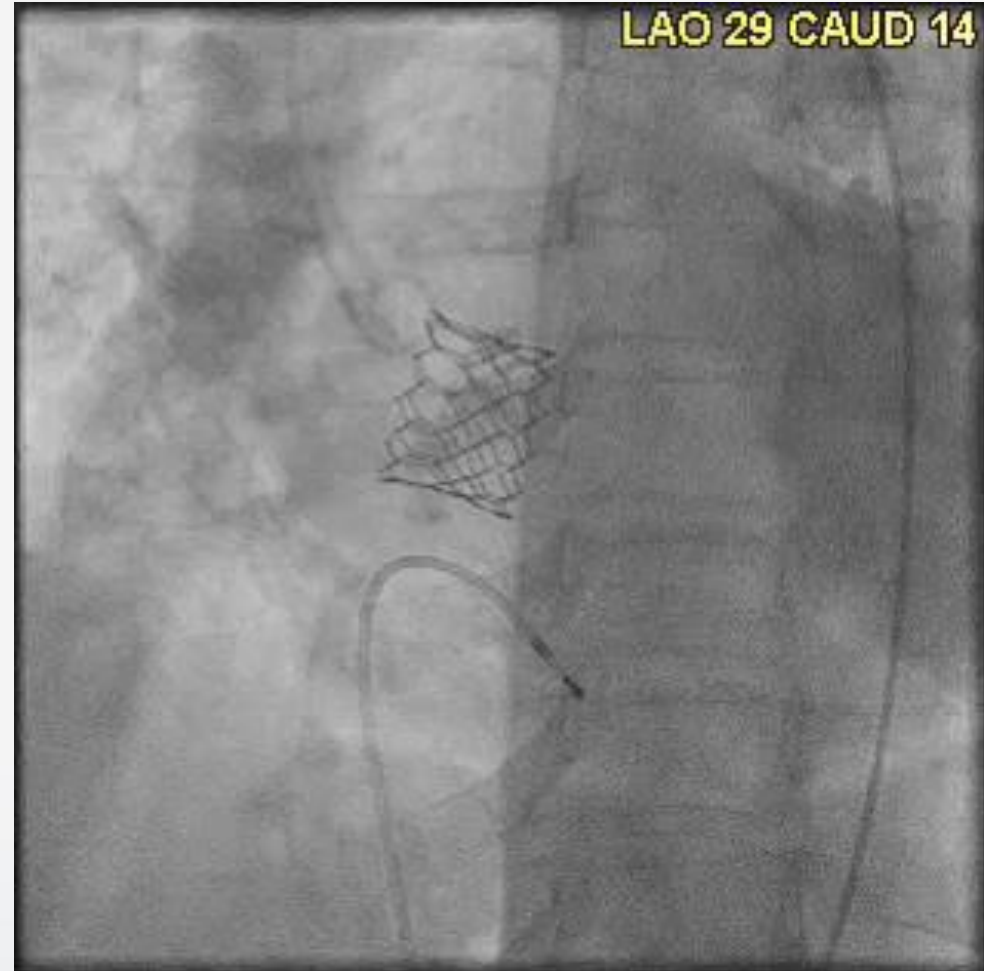
26 mm SAPIEN 3 Ultra  
Right transfemoral approach  
Cerebral Protection Device  
Pre-wire Left Coronary



# Valve Deployment



# Treatment Outcome



# Treatment Outcome

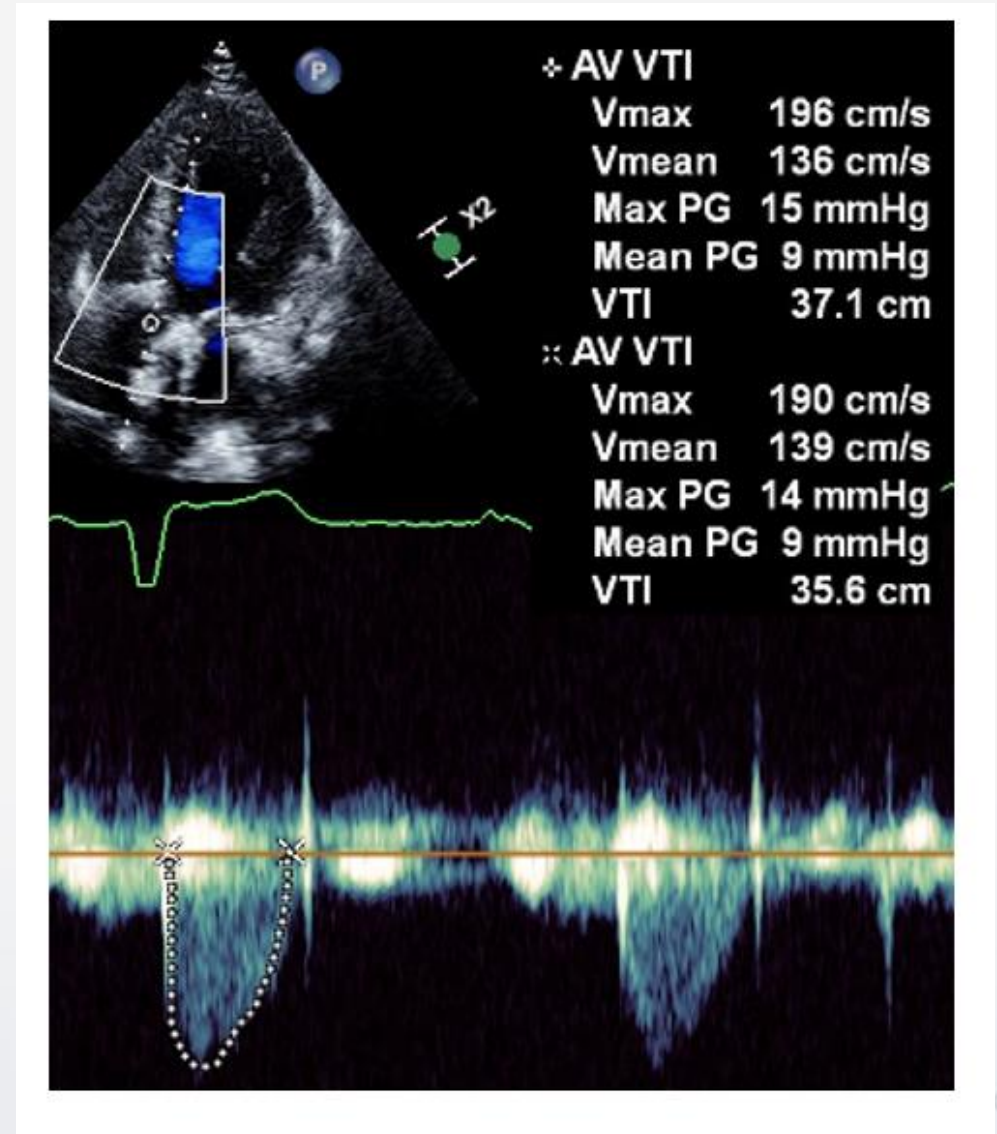
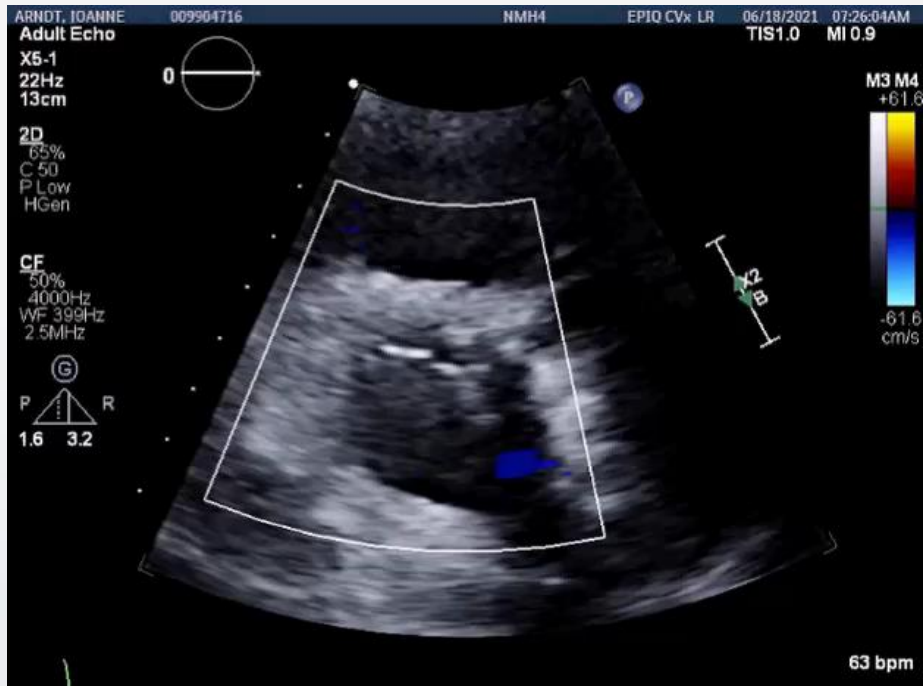
LVEF 54%

TAVR valve with mean gradient 3 mmHg

Trivial paravalvular AI

New LBBB – resolved that day

Next day echo mean grad 9, no AI





# Other Considerations: TAVR in BAV (especially younger patients)

- Risk of Heart Block / need for Pacemaker
- Coronary Artery (Re)Access
- Continued Aortic Surveillance
- Lifetime Management – What is the next valve plan?
  - SAVR after TAVR
  - TAV-in-TAV
  - Valve-in-Valve TAVR



# Key Takeaways

- BAV was excluded from pivotal TAVR trials
- The early experience of TAVR in BAVR was associated with increased
  - Paravalvular AI
  - Annular Injury
  - Pacemaker need
  - Stroke
- Significant raphe and/or leaflet calcification in BAV can increase procedure risk
- TAVR in BAV with current generation SAPIEN valves is safe and effective

## Case 2

- 73 year-old man
- Recent DOE, fatigue
- Echo showed severe AS
- CTA revealed Trileaflet Aortic Valve
- STS score 3.5%
- 1/4 elements of frailty
- Deemed Intermediate Risk
- Strongly prefers TAVR

### **Past Medical History**

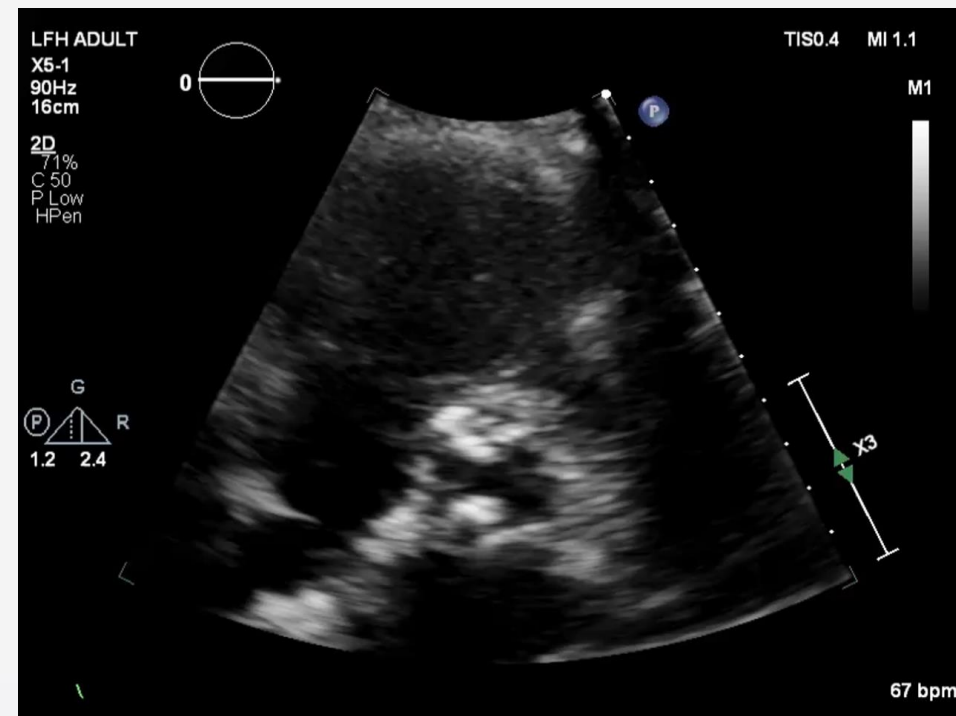
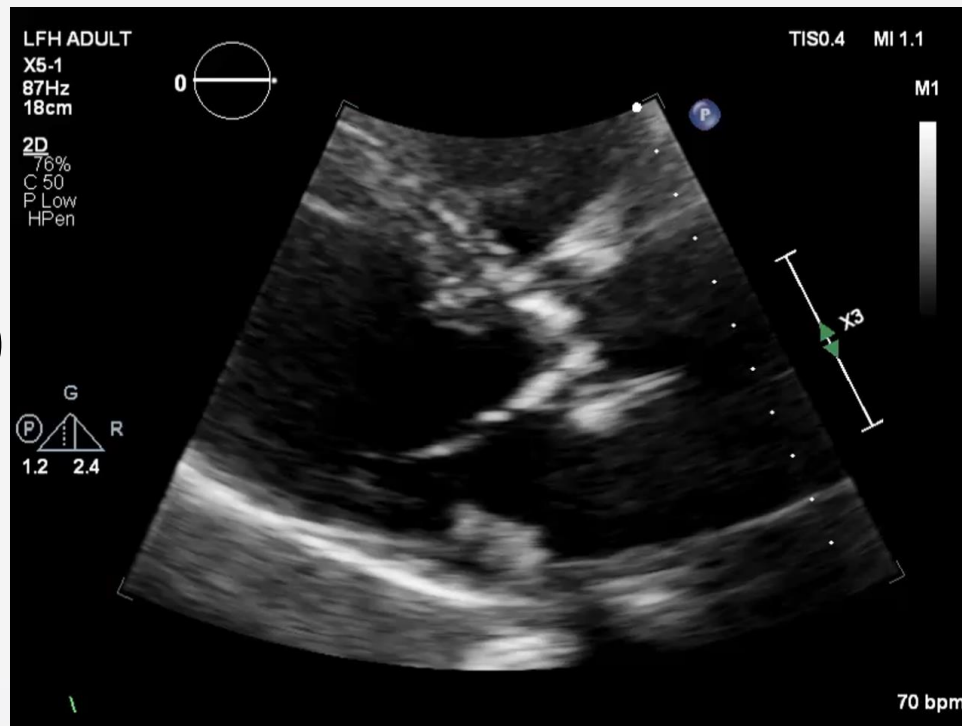
- HFpEF
- AS
- Mild CAD by coronary CTA
- HTN
- Hyperlipidemia
- Obesity
- Peripheral neuropathy
- Sleep Apnea
- Rheumatic fever as a child

# Echo

LVEF 60%

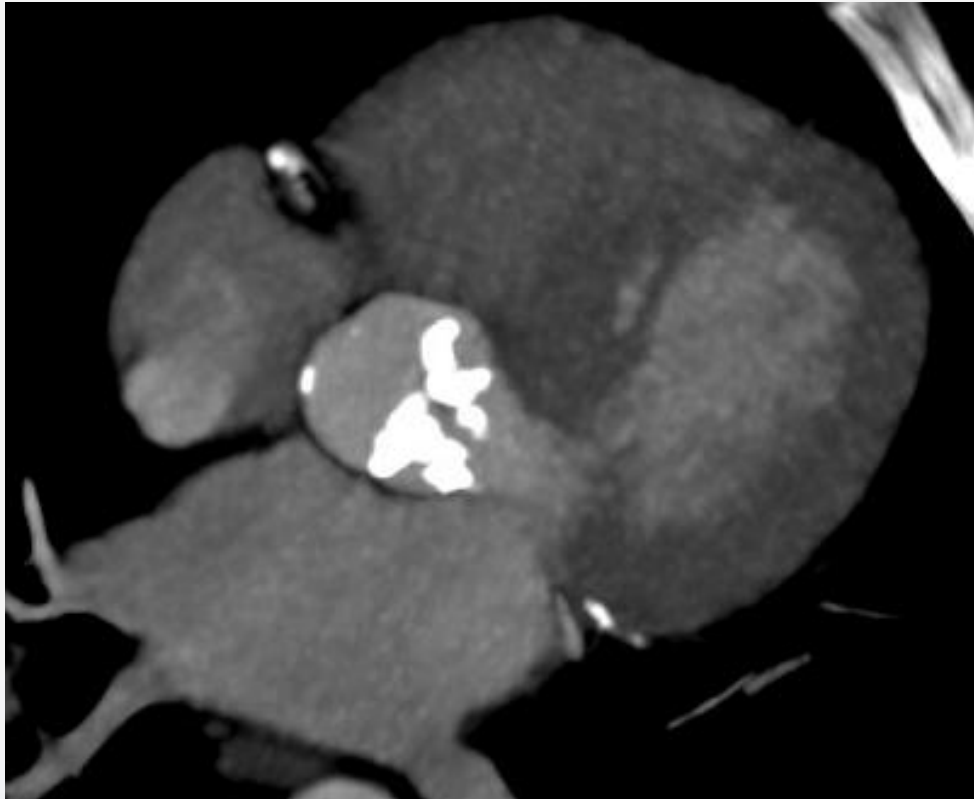
Severe AS

- 4.4 m/s
- mean grad 40
- 0.90 cm<sup>2</sup>
- DI 0.31
- trivial AI

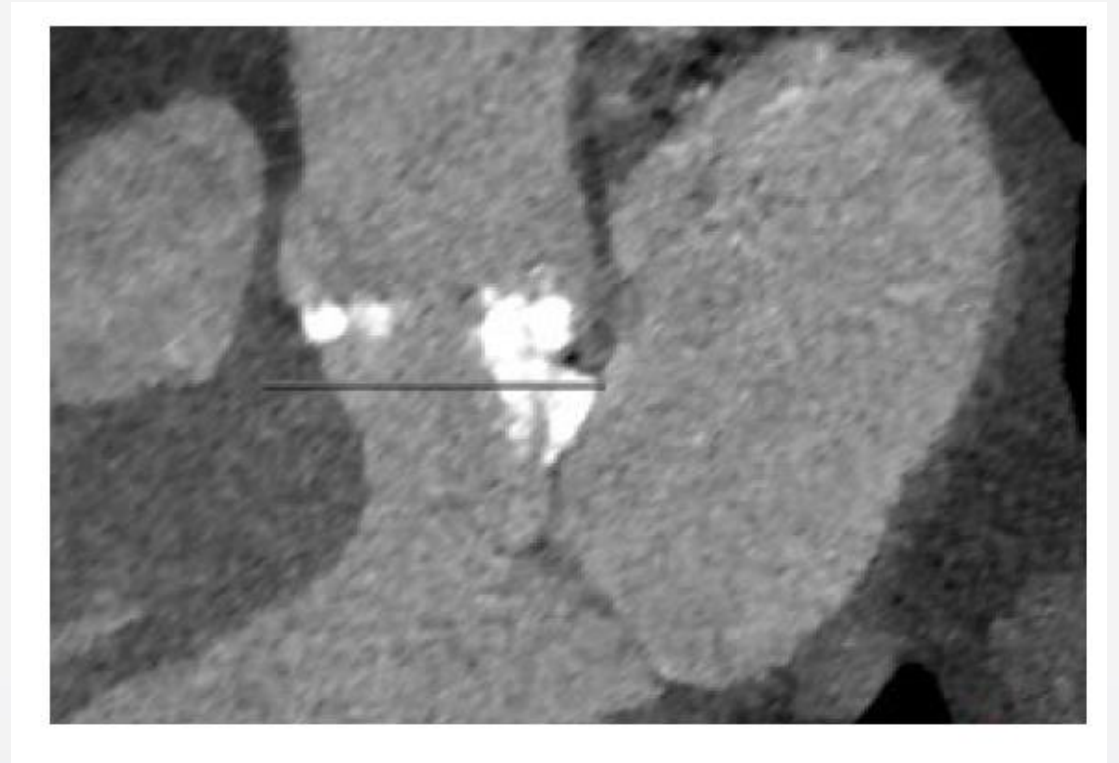


Trileaflet Valve

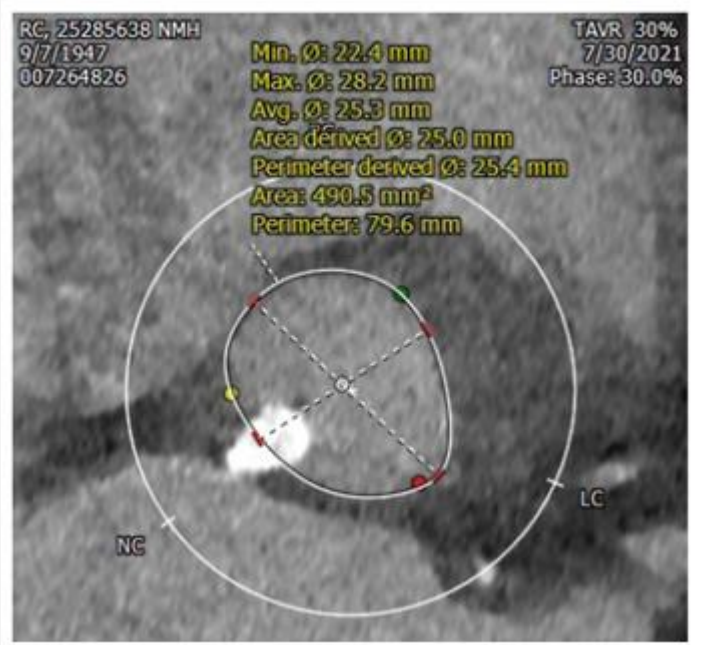
Calcium score 3700



CT



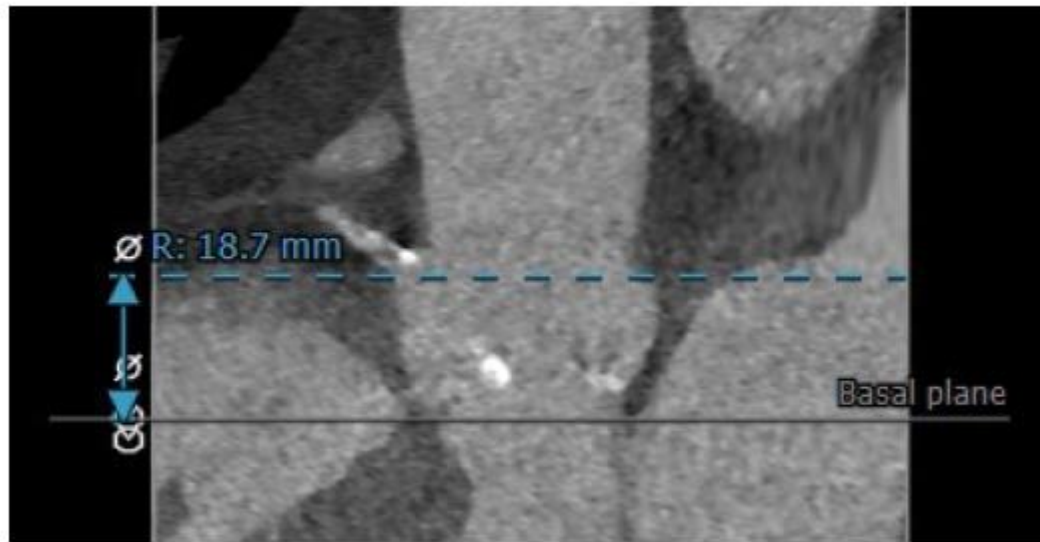
Annulus 22.4 x 28.2 mm (491mm<sup>2</sup>)



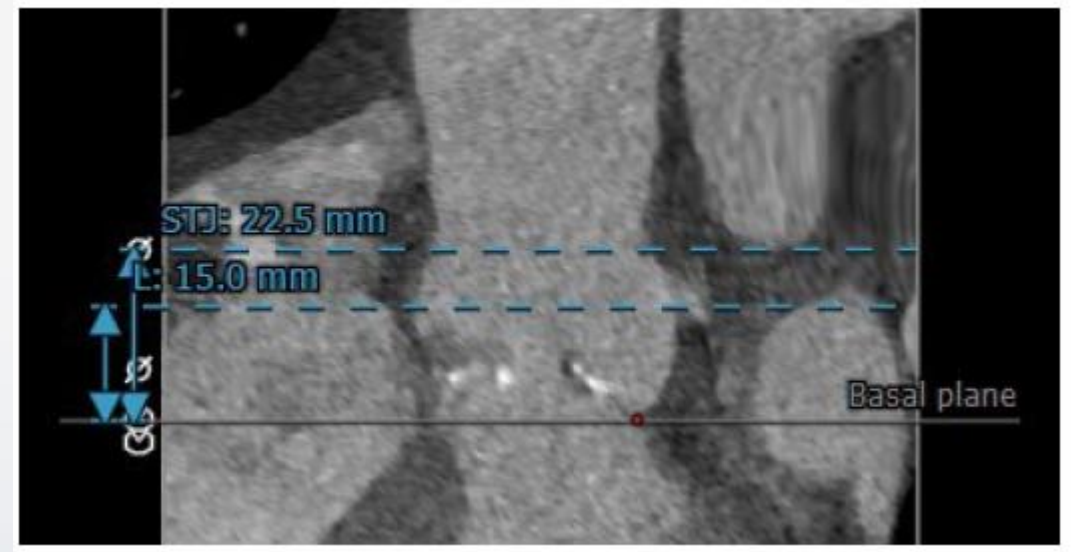
Sinuses of Valsalva >31 mm



RCA 18.7 mm



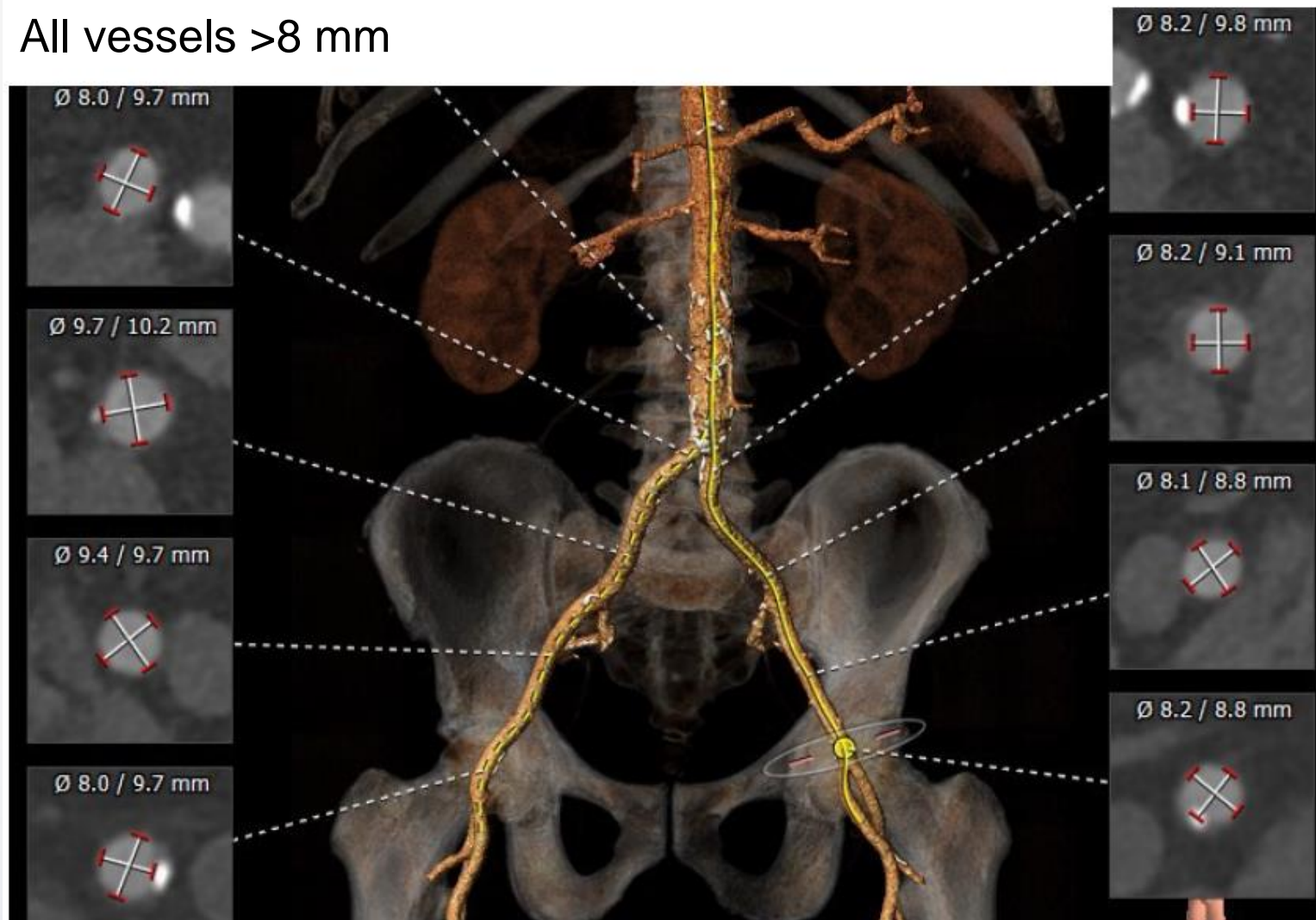
LMCA 15.0 mm





# CT

All vessels >8 mm

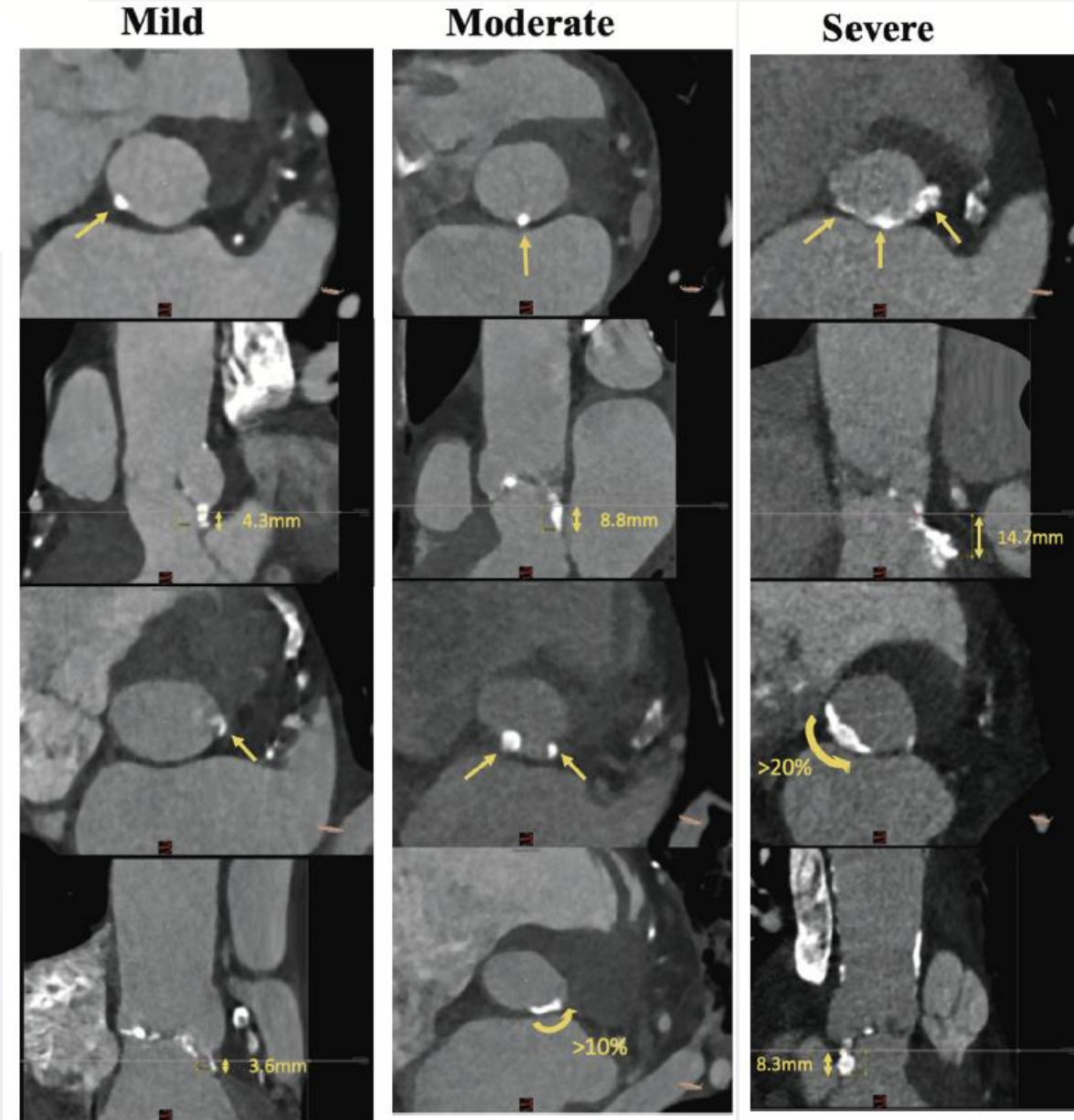


# The Problem with LVOT Calcium

- Fear of annular rupture
- Underexpansion of TAVR valve
- Traditionally associated with increased paravalvular AI, sometimes requiring a second valve
- Not well studied – severe LVOT calcium often cited as an exclusion criteria in pivotal TAVR trials

# Impact of Left Ventricular Outflow Tract Calcification on Procedural Outcomes After Transcatheter Aortic Valve Replacement

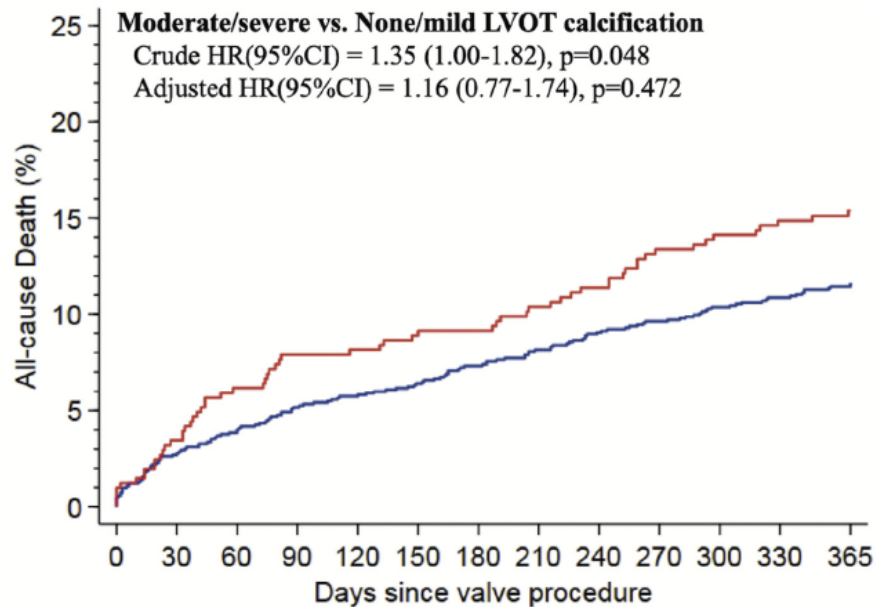
- Single-center 1635 TAVR patients 2007-18
- 407 (24.9%) with moderate or severe LVOT calcification



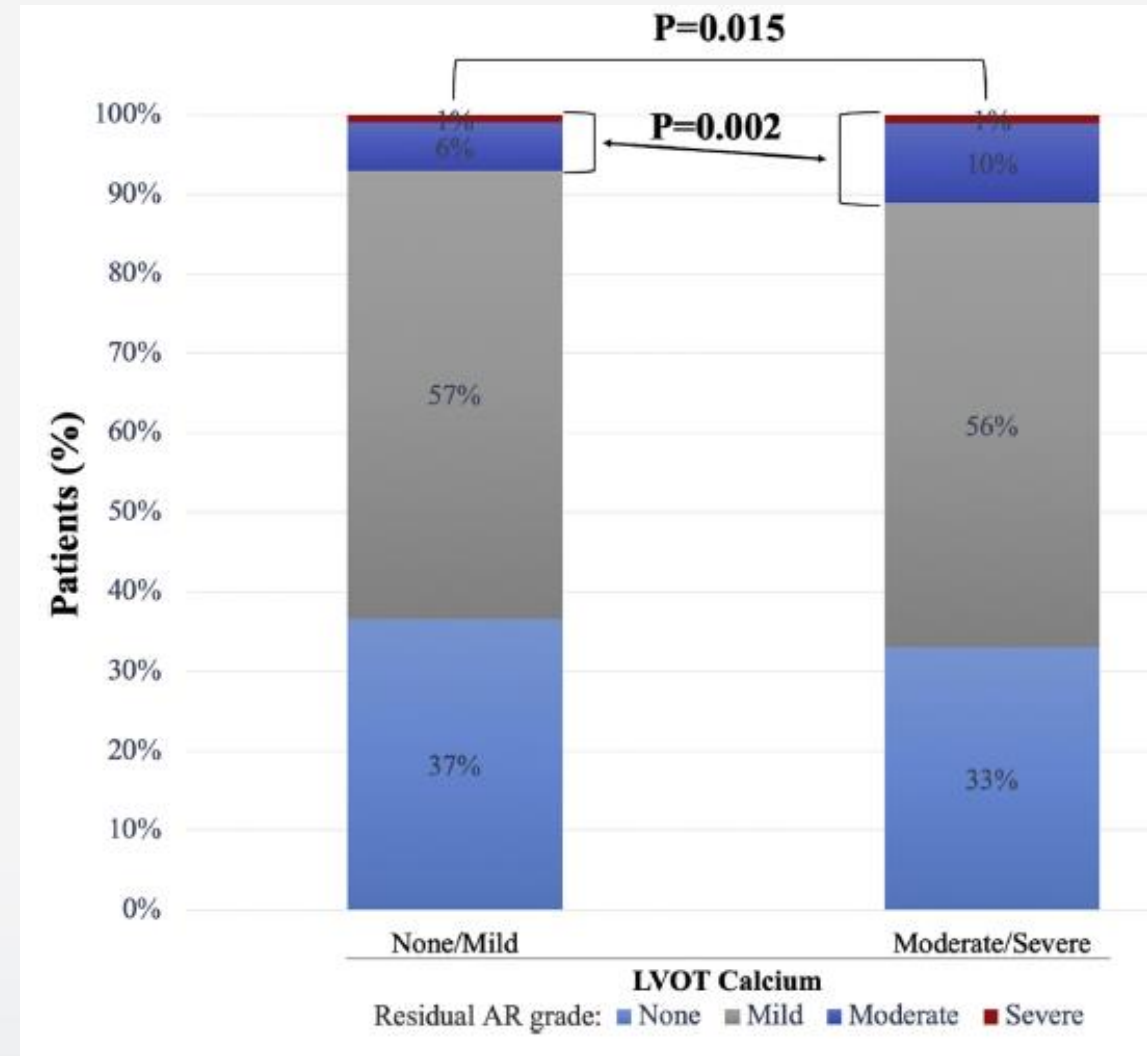
# LVOT Calcification in TAVR

## Moderate or Severe LVOT Calcium

- More annular rupture 2.3% vs. 0.2% (p<0.001)
- More need for >1 valve 2.9% vs. 0.8% (p=0.004)
- More residual AI 11.1% vs. 6.3% (p=0.002)



Number at risk		0	30	60	90	120	150	180	210	240	270	300	330	365
none/mild	1228	1186	1167	1150	1142	1134	1123	1113	1102	1095	1086	1079	1079	931
moderate/severe	407	392	379	372	371	367	366	360	356	348	345	342	342	309



# LVOT Calcification in TAVR

## Procedural Outcomes According to Left Ventricular Outflow Tract Calcium Stratified by Transcatheter Heart Valve Design

	LVOT Calcium		RR (95% CI)	Crude Rate Ratio		Interaction p value
	None or Mild [A] (n = 1,228)	Moderate or Severe [B] (n = 407)		[B] vs [A] RR (95% CI)	p value	
<b>Bail-out valve-in-valve</b>						
balloon-expandable	2/566 (0.4%)	3/176 (1.7%)		4.82 (0.81-28.67)	0.084	}*
self-expanding	8/587 (1.4%)	9/184 (4.9%)		3.59 (1.40-9.17)	0.008	
mechanically-expandable	0/75 (0%)	0/47 (0%)				
<b>Annular rupture</b>						
balloon-expandable	2/566 (0.4%)	7/176 (4.0%)		11.47 (2.40-54.72)	0.002	
self-expanding	0/587 (0%)	1/184 (0.5%)				
mechanically-expandable	0/75 (0%)	0/47 (0%)				
<b>Relevant residual aortic regurgitation</b>						
balloon-expandable	21/566 (3.7%)	13/176 (7.4%)		1.97 (1.01-3.85)	0.047	}*
self-expanding	43/587 (7.3%)	23/184 (12.5%)		1.65 (1.03-2.66)	0.038	
mechanically-expandable	2/75 (2.7%)	1/47 (2.1%)		0.78 (0.07-8.48)	0.841	

\*p for interactions [balloon-expandable x self-expanding] were 0.774 and 0.491, respectively.



# LVOT Calcification in TAVR

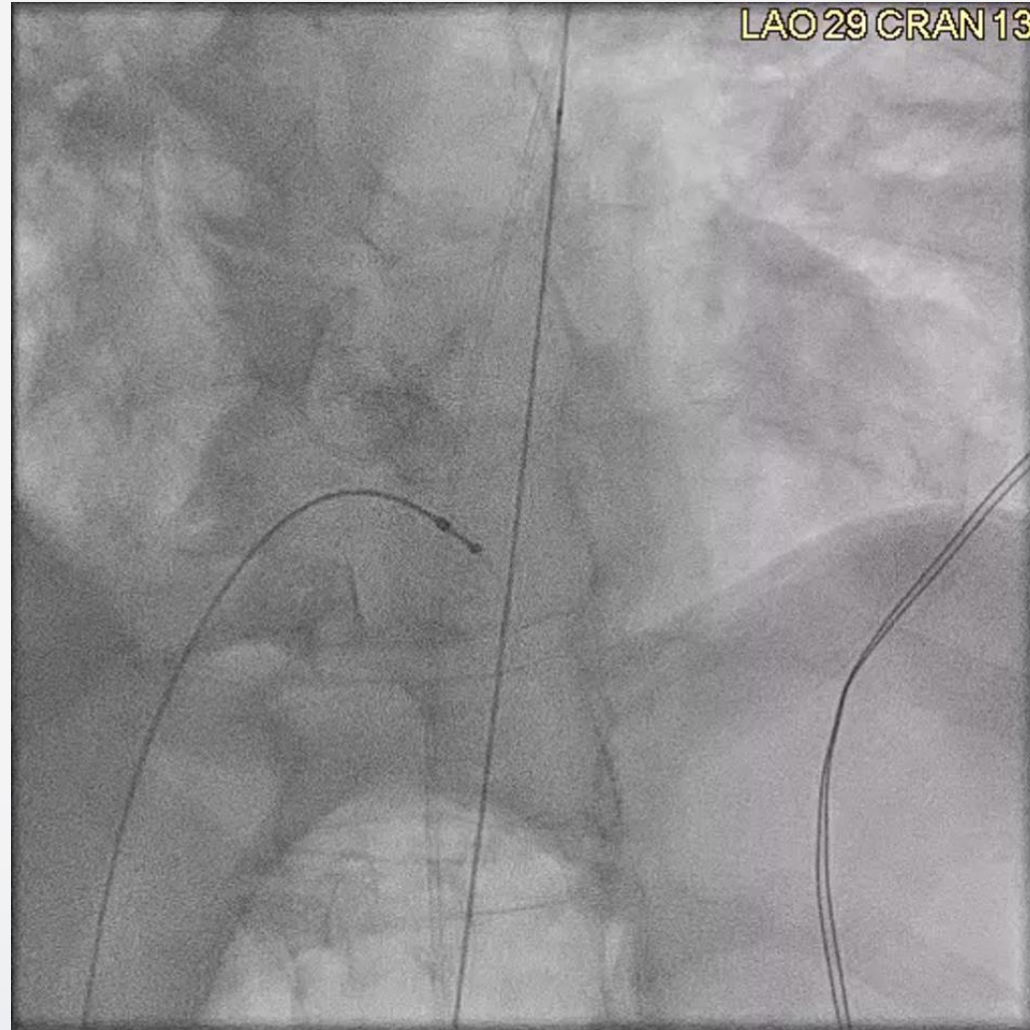
## Procedural Outcomes According to Left Ventricular Outflow Tract Calcium Stratified by Transcatheter Heart Valve Generation

	LVOT Calcium		RR (95% CI)	Crude Rate Ratio [B] vs [A]		Interaction p value
	None or Mild [A] (n = 1,228)	Moderate or Severe [B] (n = 407)		RR (95% CI)	p value	
<b>Bail-out valve-in-valve</b>						
Sapien THV/XT or Corevalve	4/432 (0.9%)	7/183 (3.8%)		4.13 (1.22-13.95)	0.022	0.693
Sapien 3 or Evolut R/PRO	5/552 (0.9%)	4/153 (2.6%)		2.89 (0.78-10.63)	0.111	
<b>Annular rupture</b>						
Sapien THV/XT or Corevalve	0/432 (0%)	6/183 (3.3%)		1.62 (1.05-2.49)	0.039	†
Sapien 3 or Evolut R/PRO	2/552 (0.4%)	2/153 (1.3%)		3.61 (0.51-25.44)	0.198	
<b>Relevant residual aortic regurgitation</b>						
Sapien THV/XT or Corevalve	41/432 (9.5%)	30/183 (16.4%)		1.61 (1.04-2.49)	0.032	0.836
Sapien 3 or Evolut R/PRO	12/552 (2.2%)	6/153 (3.9%)		1.80 (0.69-4.72)	0.231	

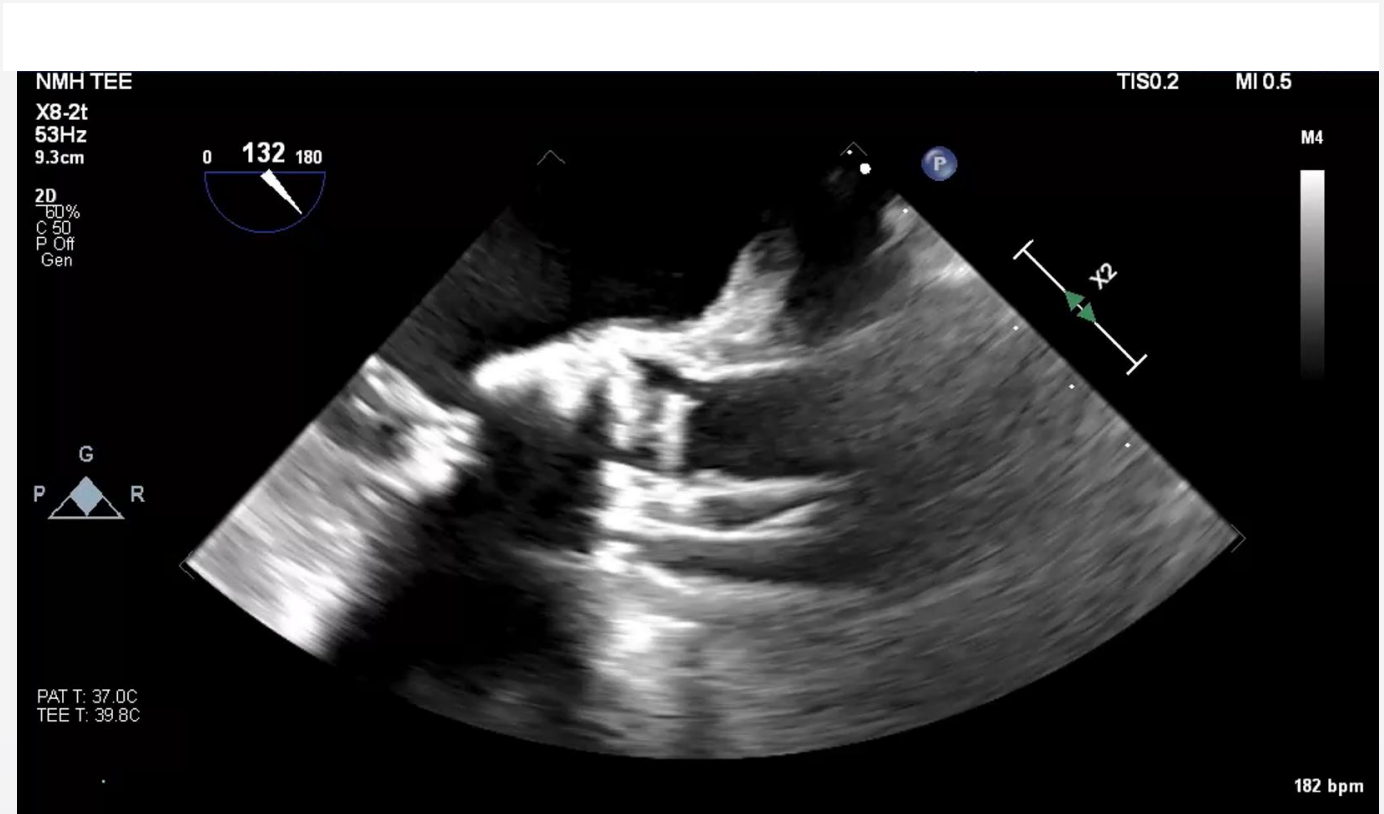
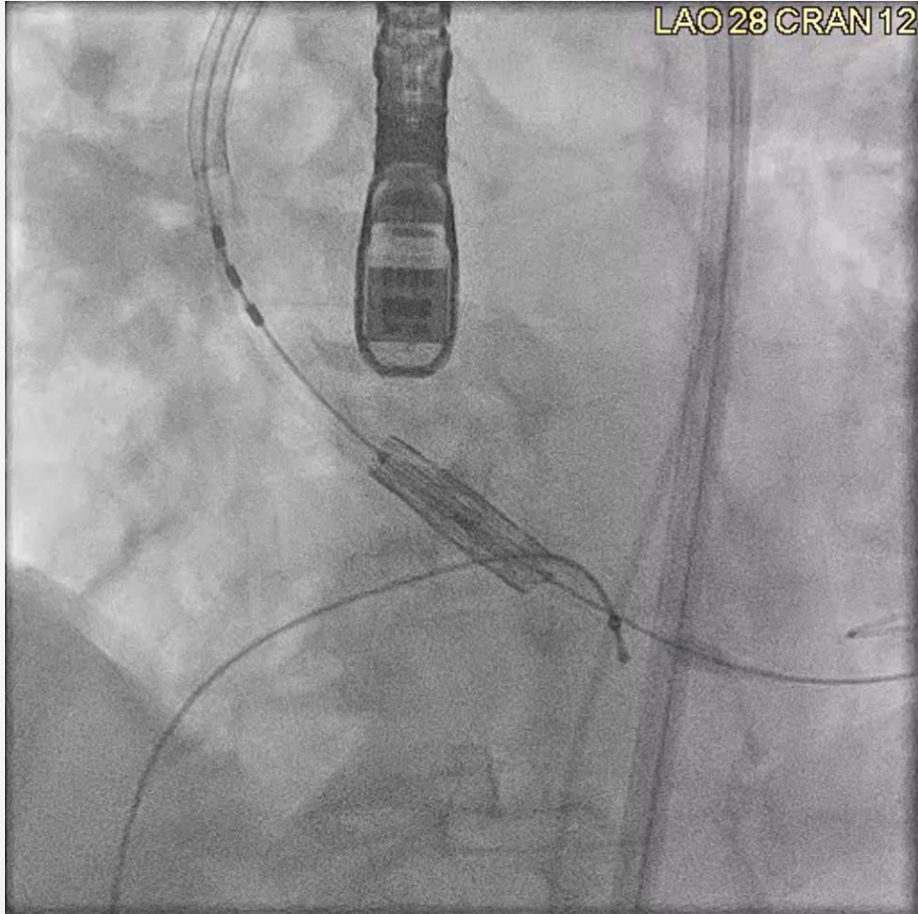
†Continuity correction with p value of Fisher exact test.

# The Plan

- Right transfemoral
- 26 mm SAPIEN 3
- TEE guidance



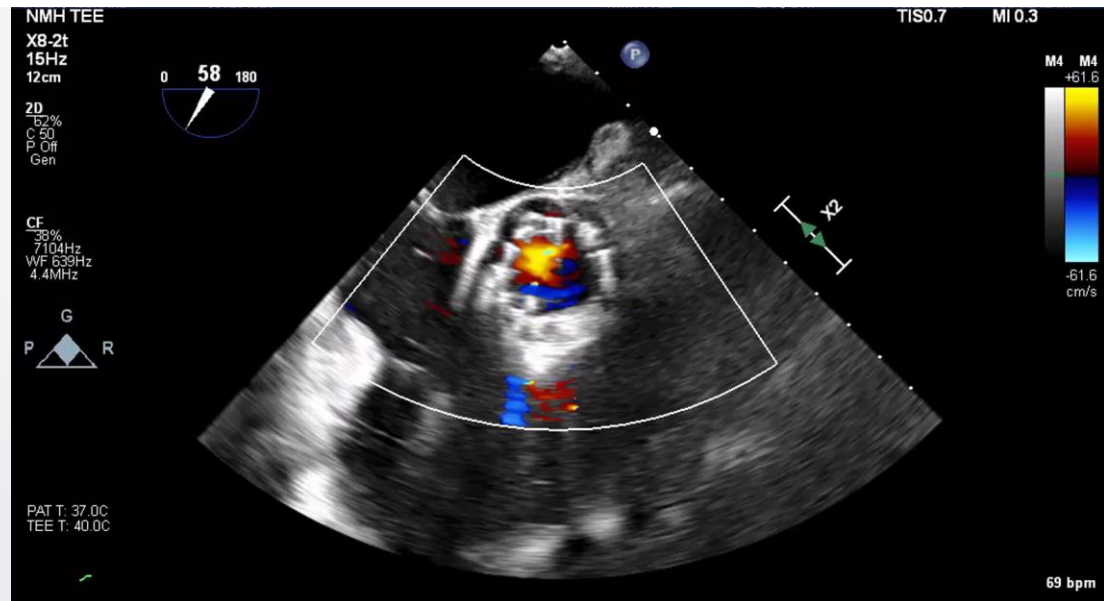
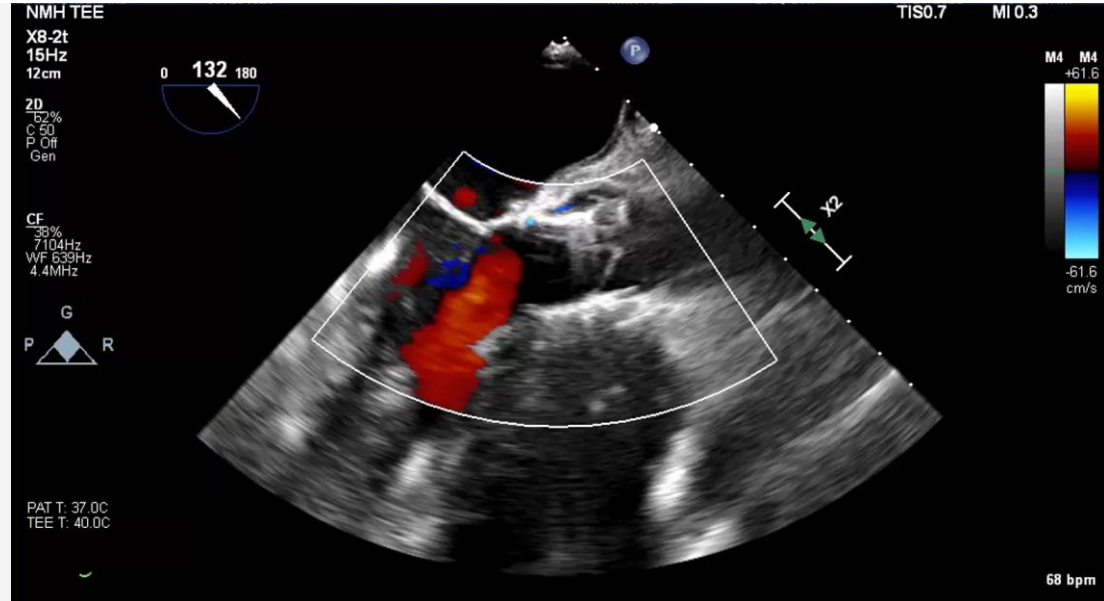
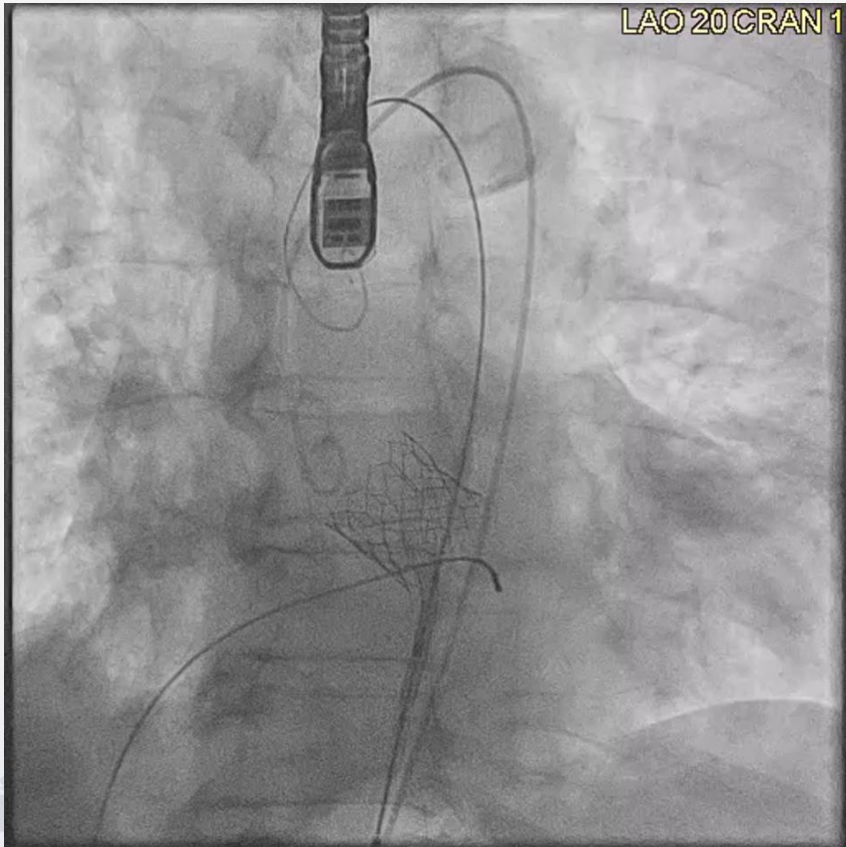
# Valve Deployment





# Treatment Outcome

- LVEF 65%
- TAVR valve with mean gradient 9 mmHg
- Trivial paravalvular AI



# Key Takeaways

- LVOT calcium is a high risk anatomical feature for TAVR
- In the presence of significant LVOT calcification, care must be taken with TAVR valve sizing and deployment
- Latest generation valves, including SAPIEN 3 (and Ultra), have an improved safety and efficacy profile for LVOT calcium