

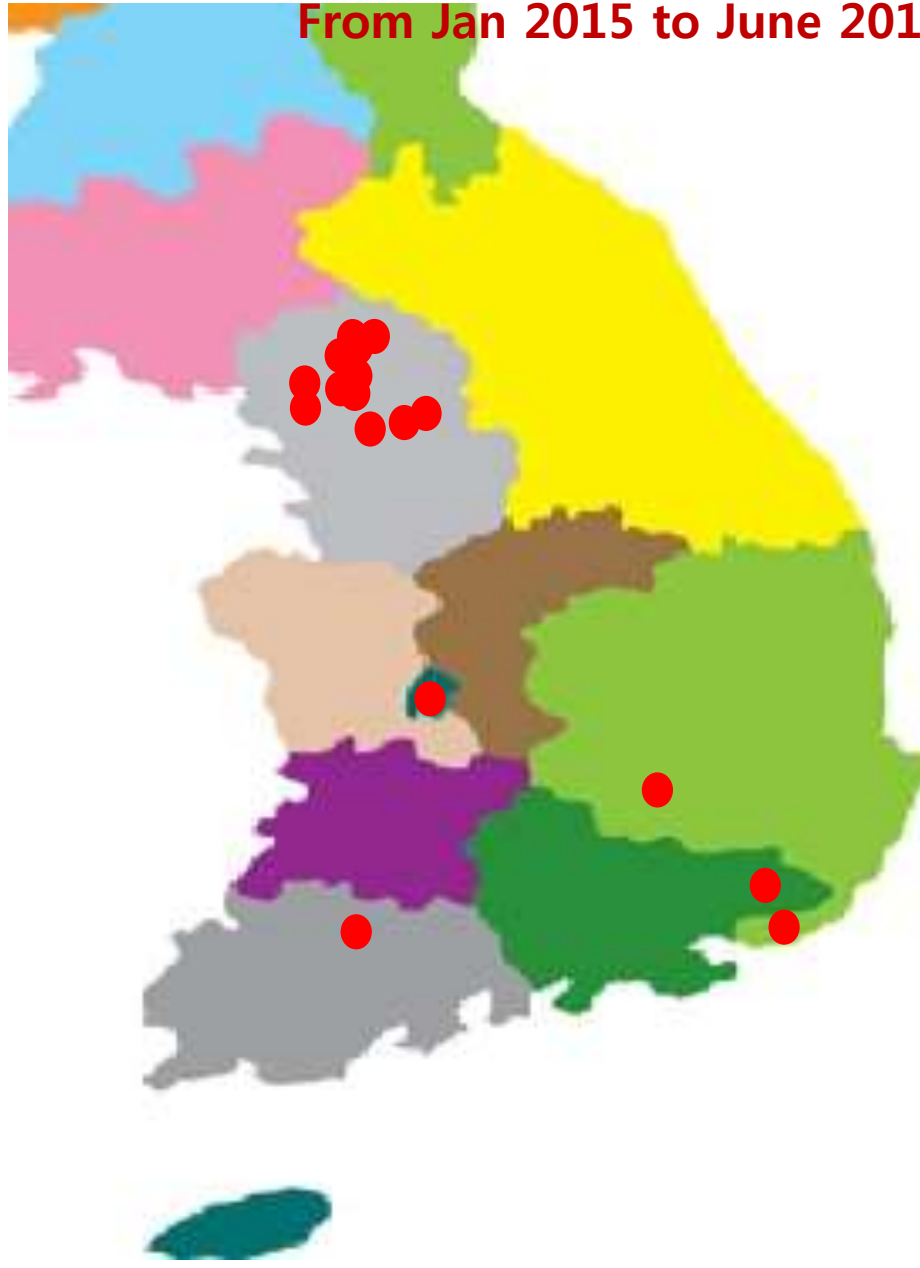
# **TAVR Experience with Edwards SAPIEN 3 in Korea**

**Cheol Woong Yu, MD, PhD**

**Division of Cardiology ,Internal Medicine Department  
Korea University Anam Hospital**

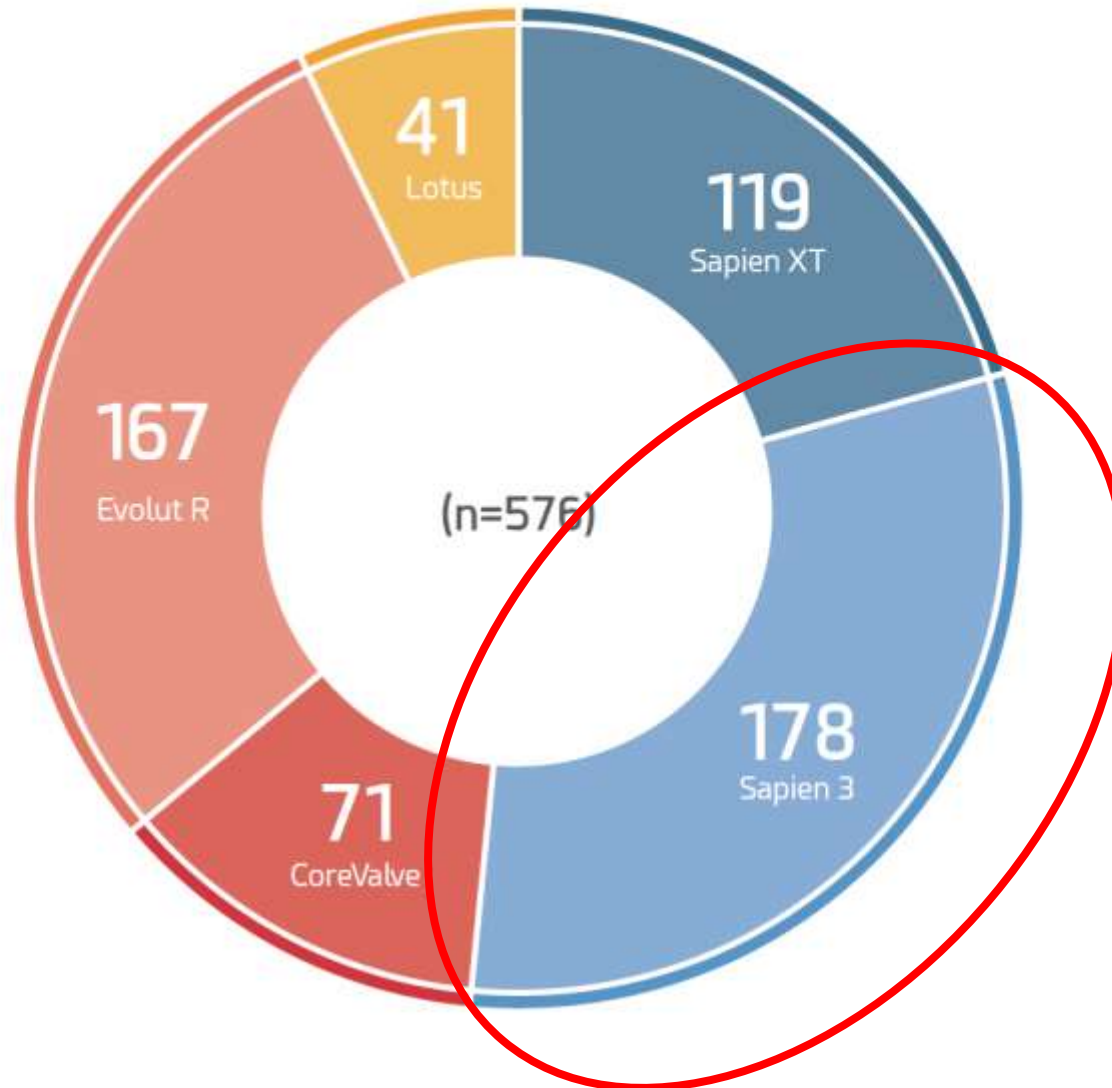
# K-TAVI registry (N=17 sites) n=576

From Jan 2015 to June 2017



Hospital
Gachon University Gil Medical Center
Gangnam Severance Hospital
Korea University Anam Hospital
Pusan National University Hospital
Seoul National University Bundang Hospital
CHA Bundang Medical Center
Samsung Medical Center
Seoul National University Hospital
The Catholic University of Korea
Severance Hospital
Sejong Hospital
ASAN Hospital
AJOU University Medical Center
Pusan National University YANGSAN Hospital
YEUNGNAM University Medical Center
CHONNAM National University Hospital
CHUNGNAM National University Hospital
Korea University Guro Hospital

# Type of valve



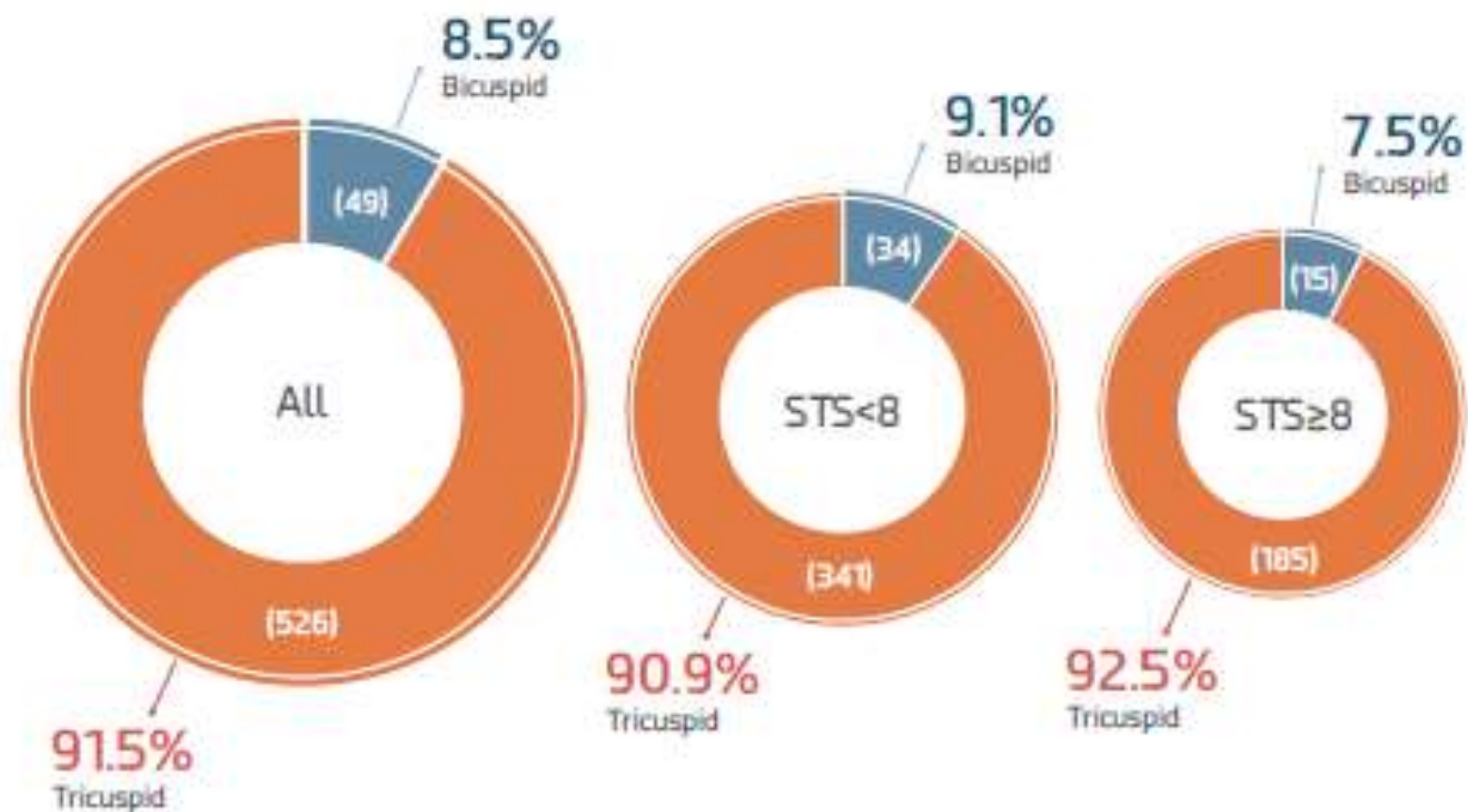
## Distribution of valve morphology



Tricuspid



Bicuspid



# Potential Problems of TAVI in Bicuspid

- **Lack of Standardized Valve Sizing**

- Difficulty of getting annular plane and annulus larger than anticipated
- Smaller supra-annular area than true annular area: supra-annular sizing??
- Inevitable trade off risk of annular rupture and PVL due to frequent severe eccentric calcium

- **Often heavily calcified**

- Incomplete valve expansion
- Paravalvar leak
- Annulus rupture



- **Oval shaped valve area**

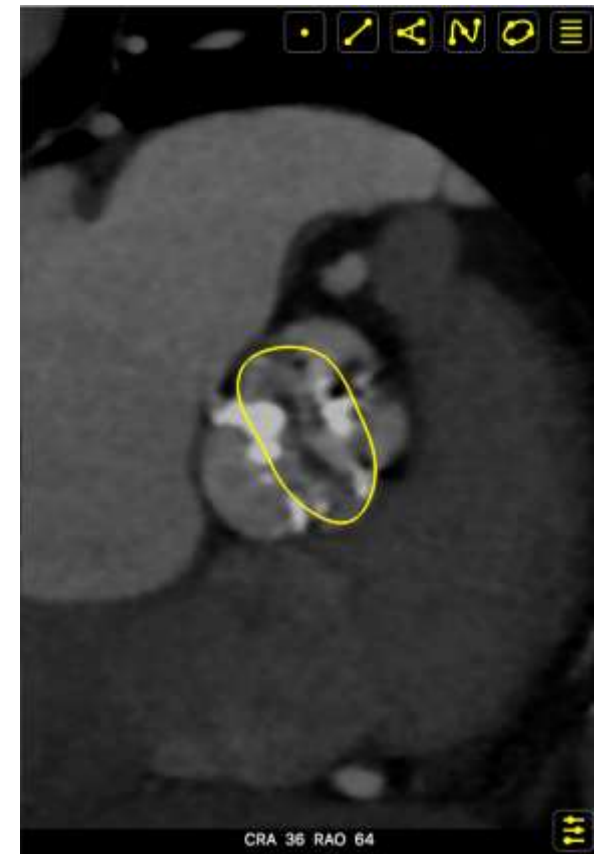
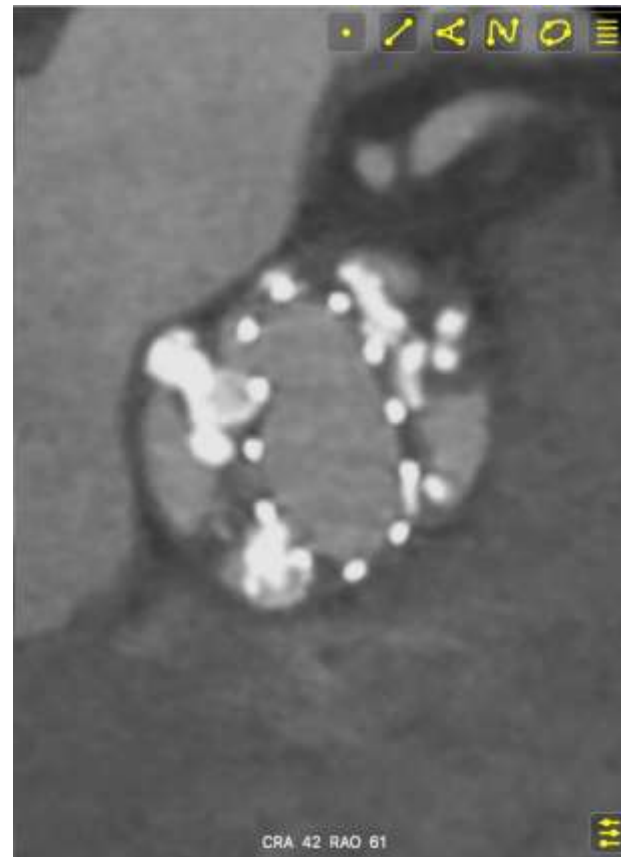
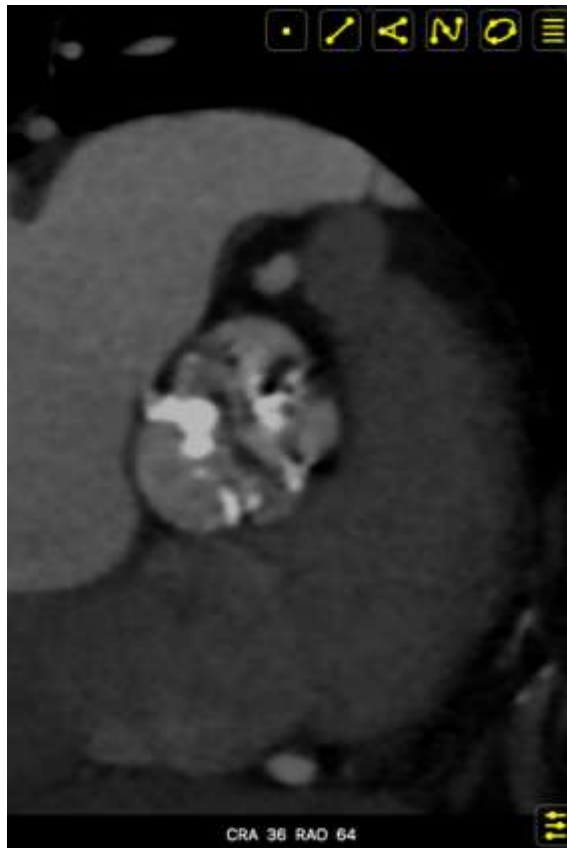
- Risk of paravalvar leak
- Long-term durability of the TAVI valve?

- **Frequently associated with ascending aortic aneurysm**

- Risk of rupture/dissection

**Lower coronary heights, vulnerable to conduction abnormality etc.**

# Concept of supra-annular sizing Pre vs. Post Implant MSCT



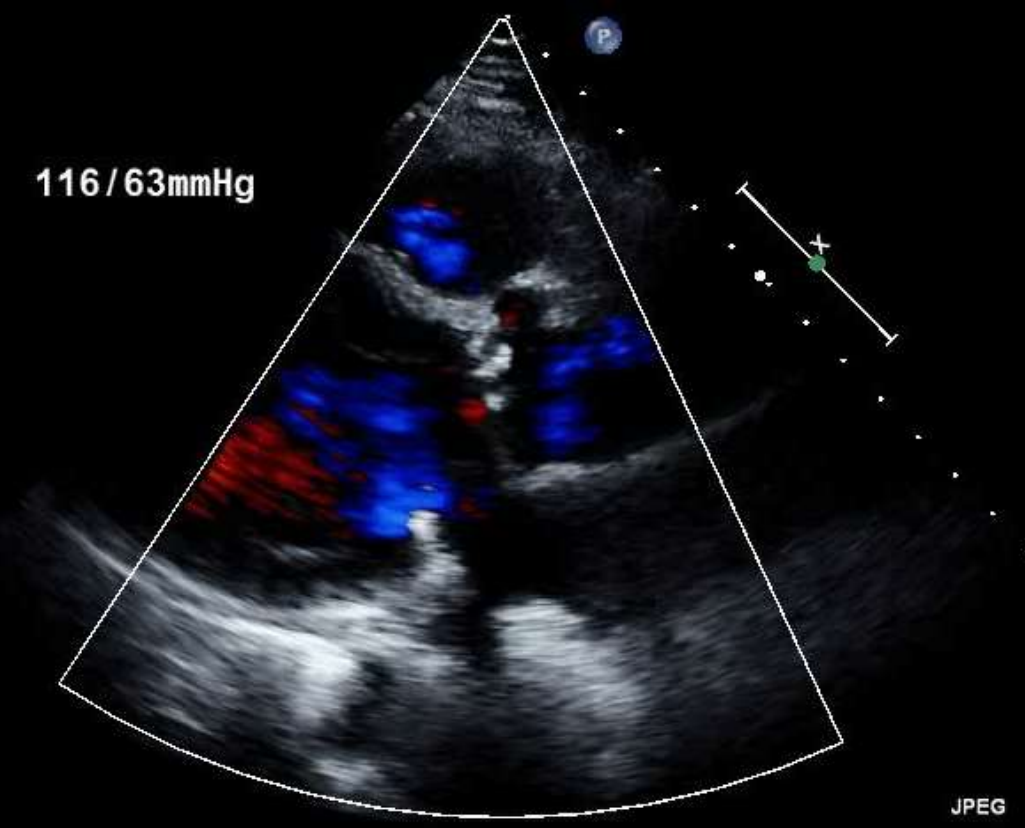
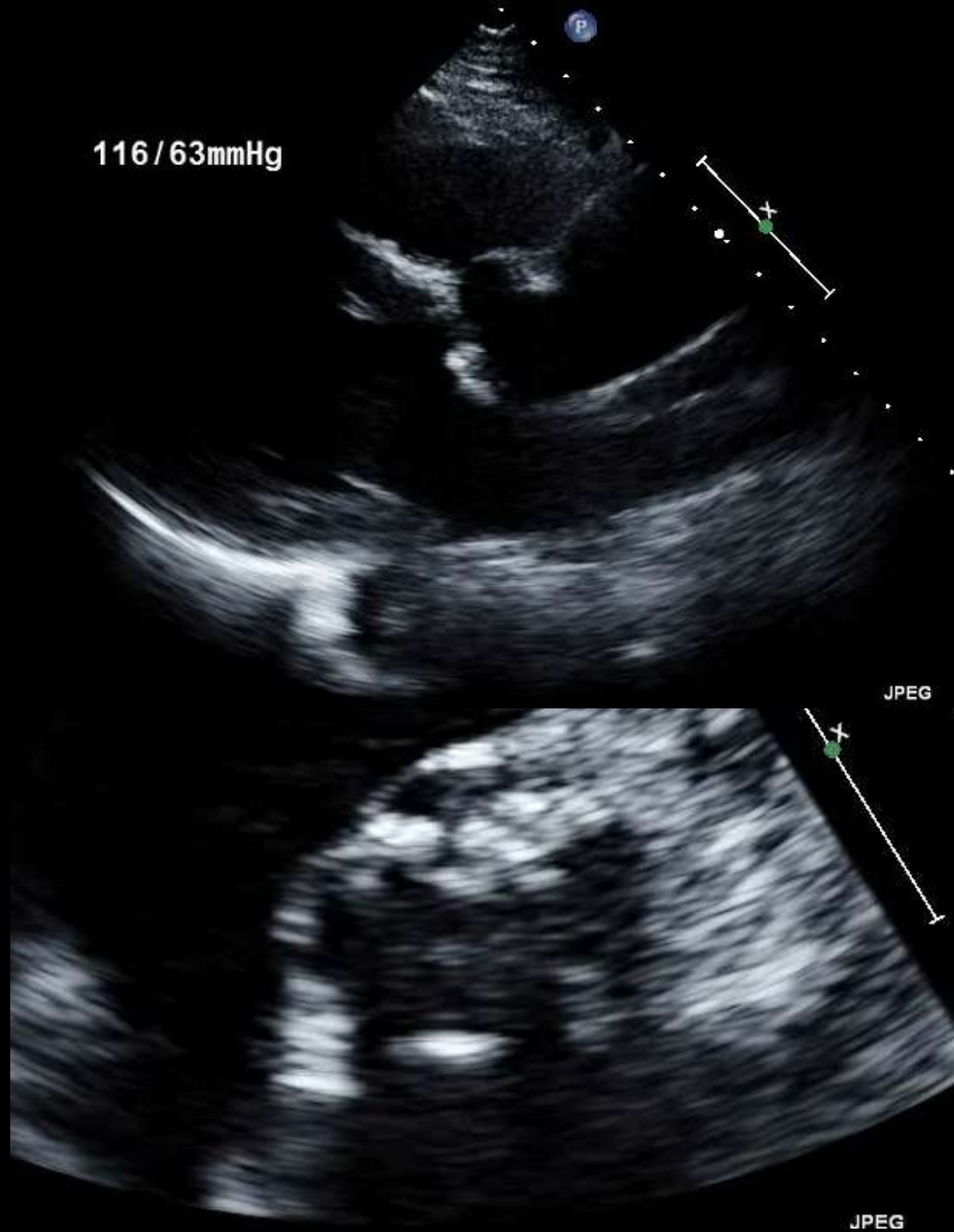
# Lack of Standardized Valve Sizing

**Avoid Oversizing in Heavily Calcified Valve  
Safety First!**

- **Annular sizing**
- **Supra annular sizing**
- **Balloon sizing**



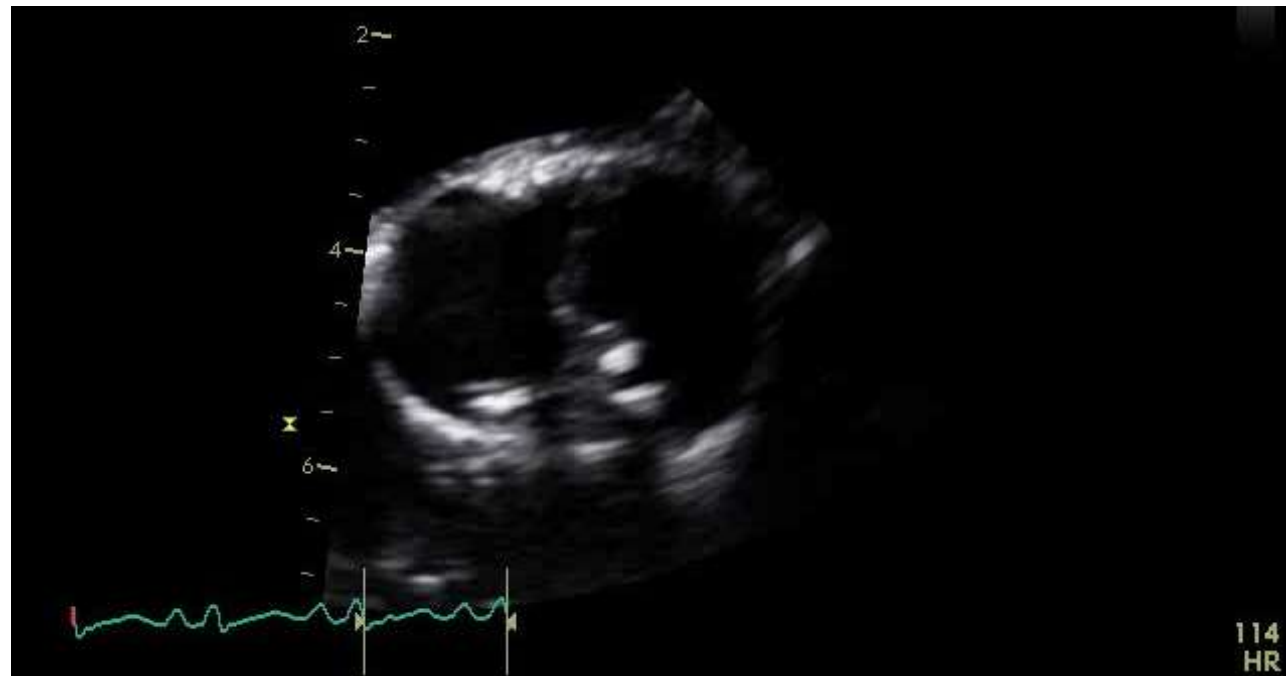
No Rule  
Case by Case

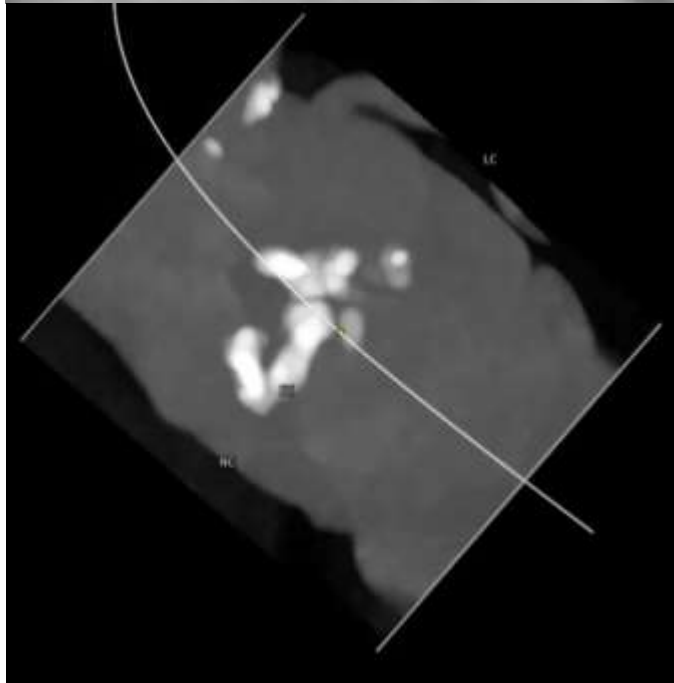
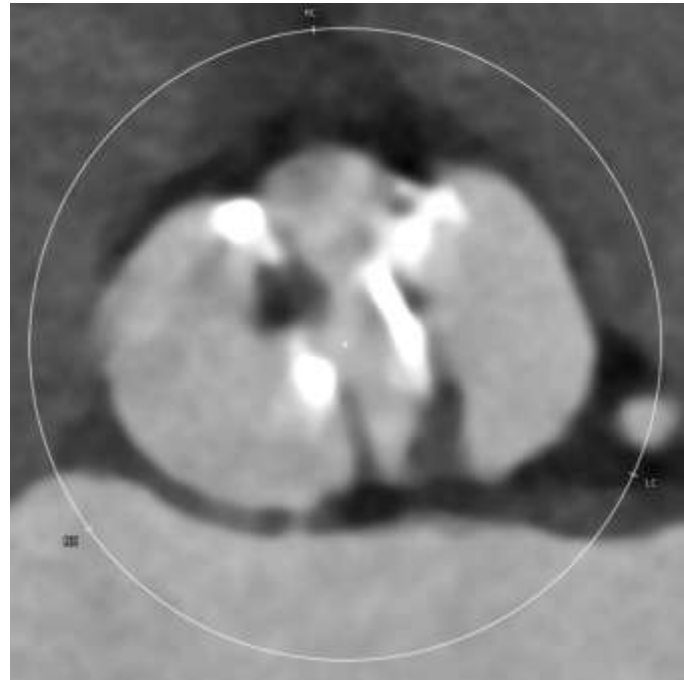
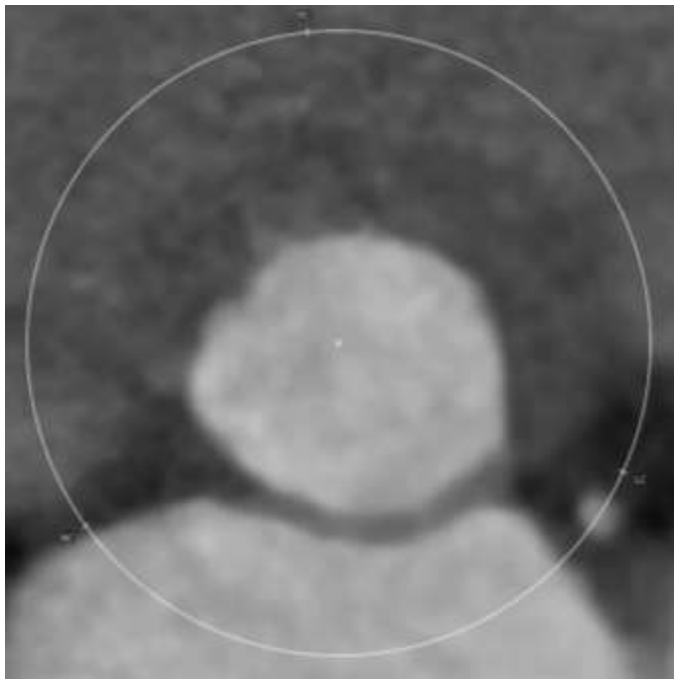
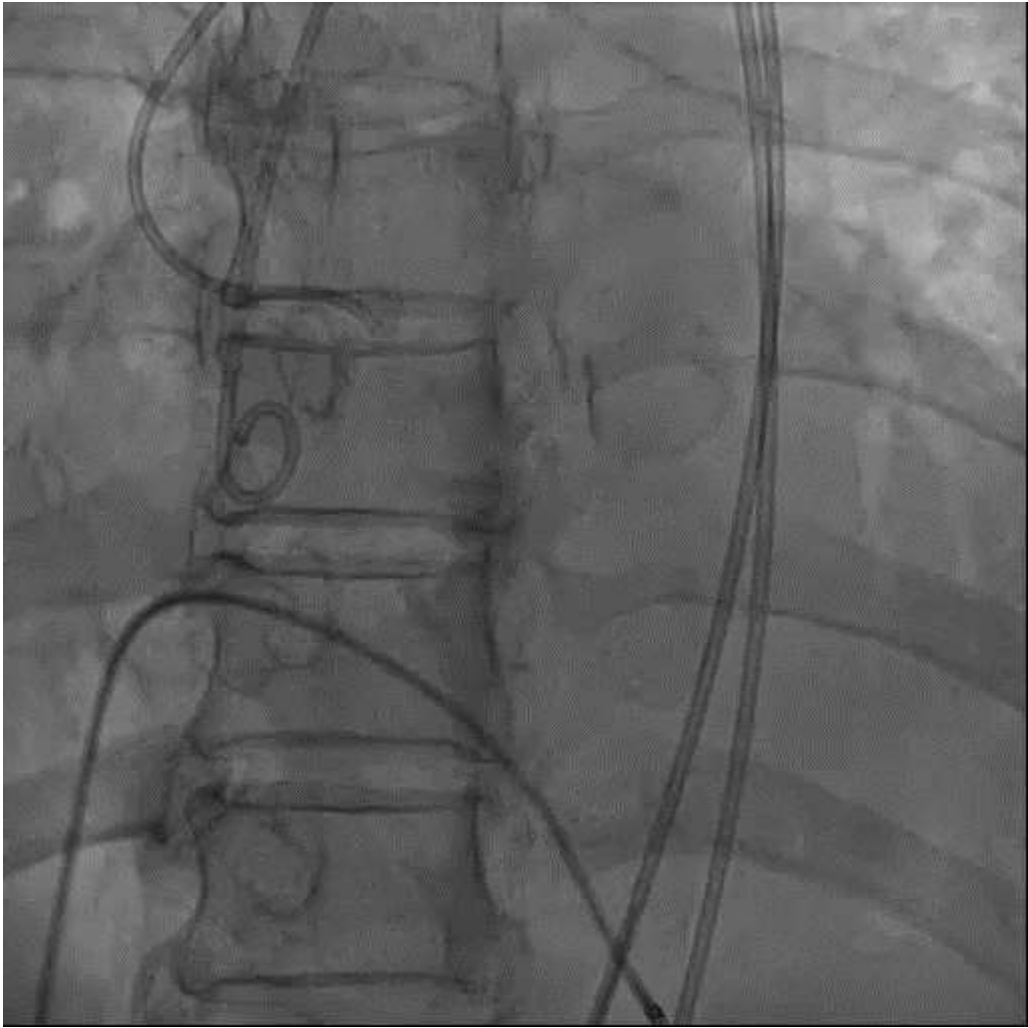


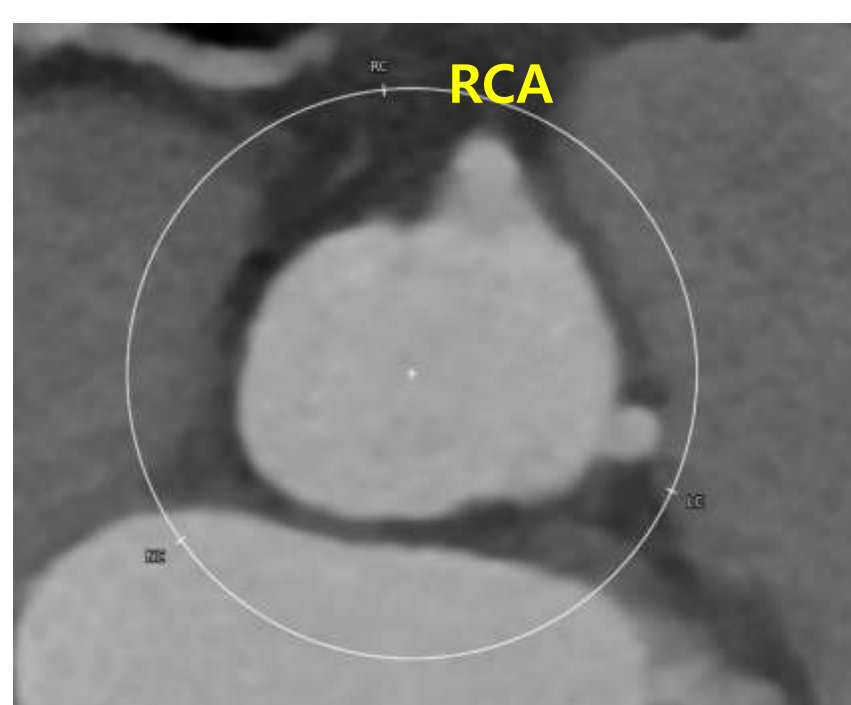
Female / 68 YO  
C.C: Dyspnea (NYHA III) and chest pain (CCS III)

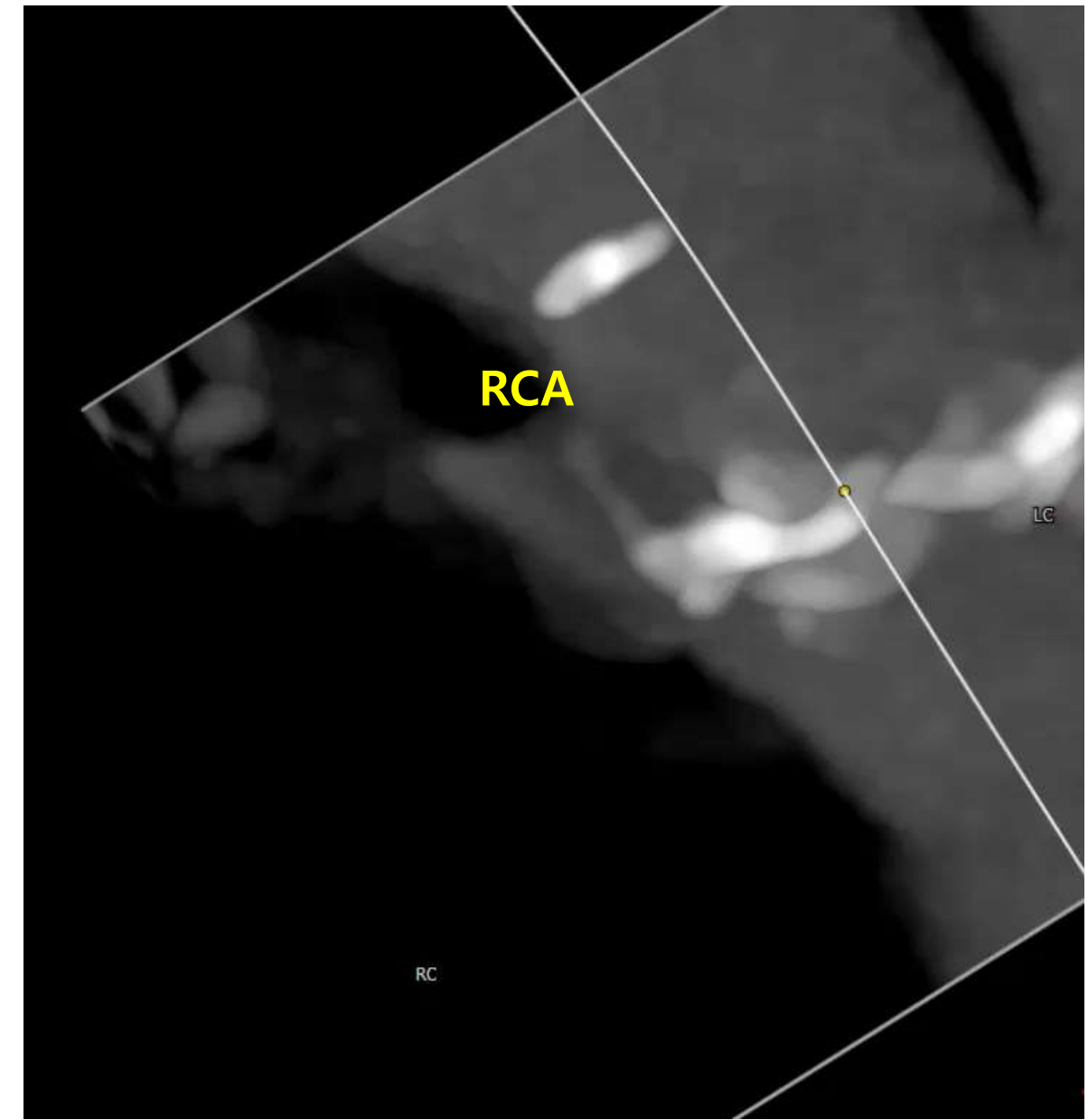
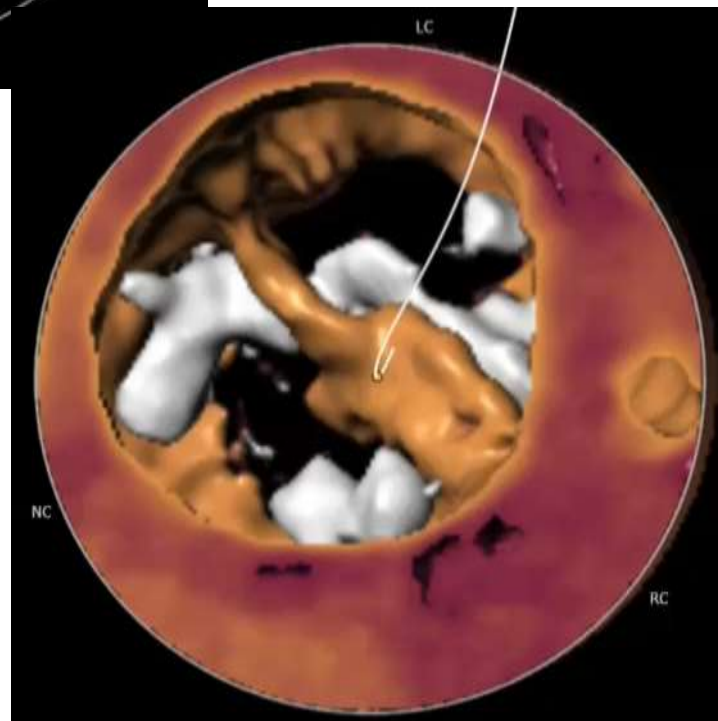
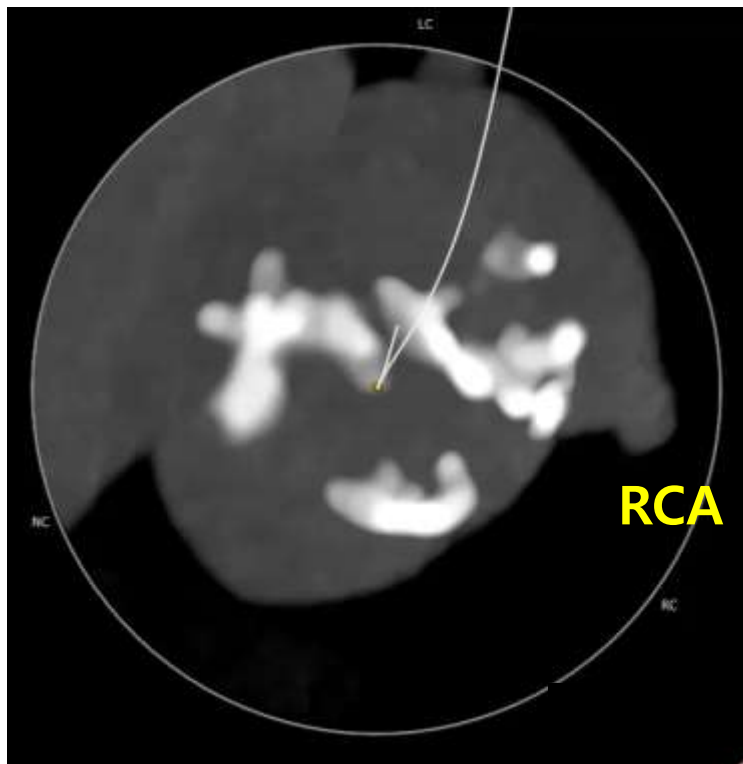
**Bicuspid aortic valve (type 0)**  
**AVA: 0.43cm<sup>2</sup>**  
**Peak/Mean PG 146/93mmHg**  
**Peak Velocity 6m/sec**

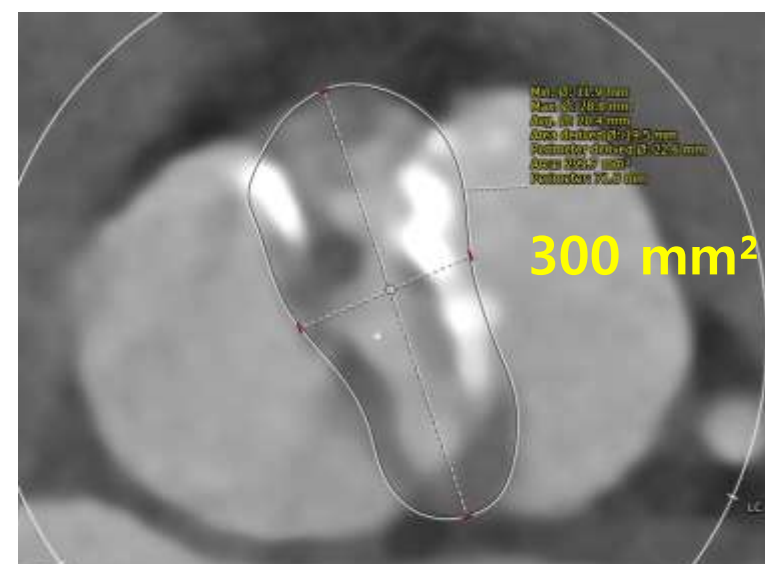
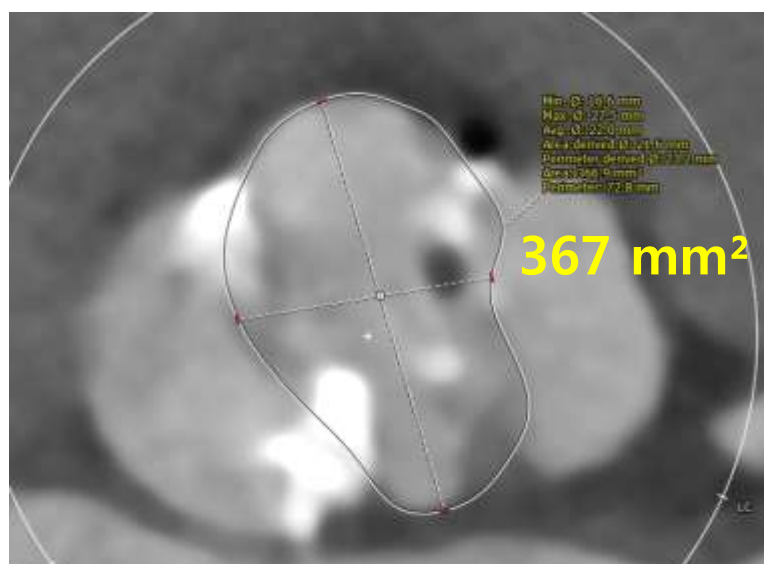
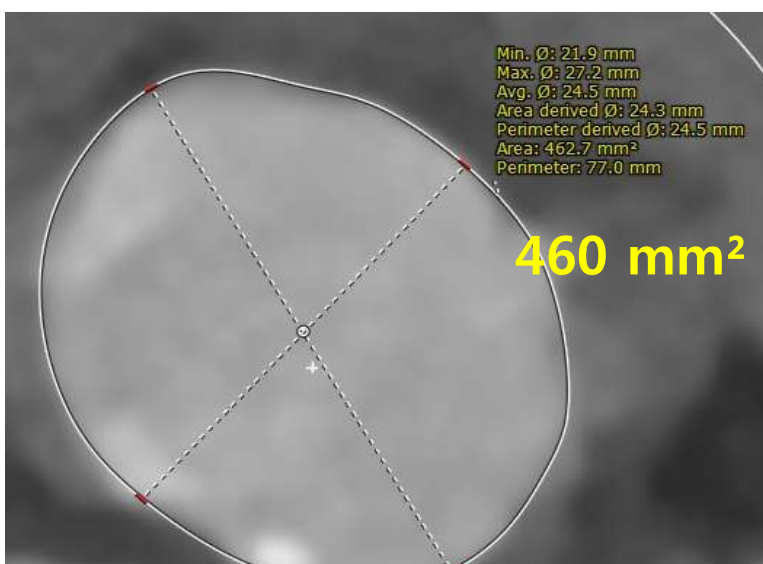




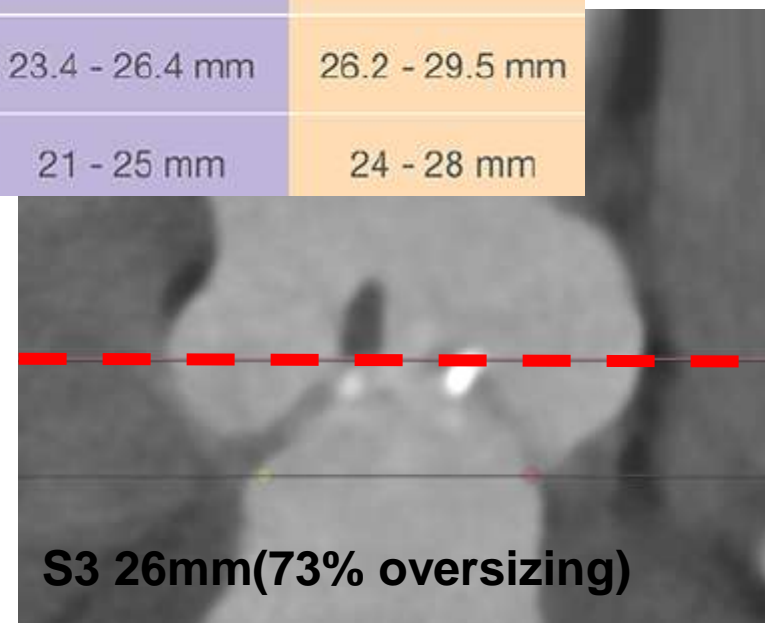
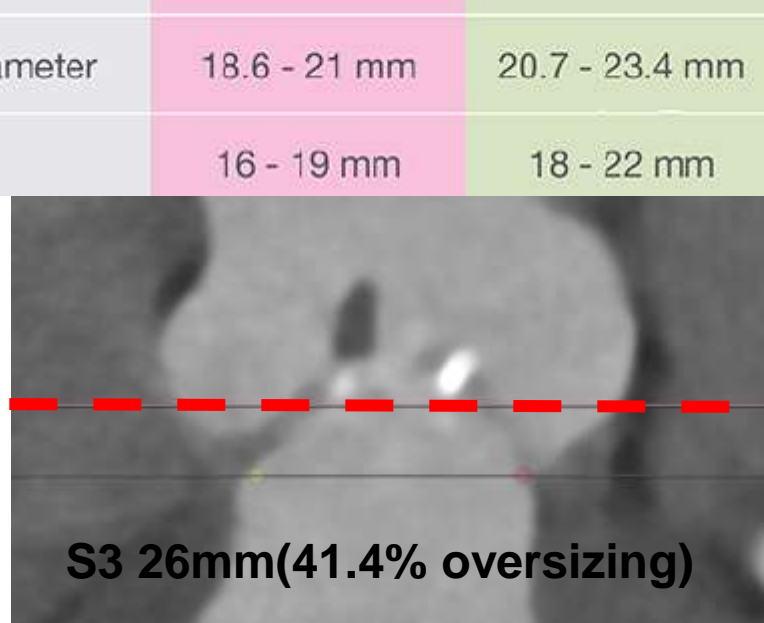
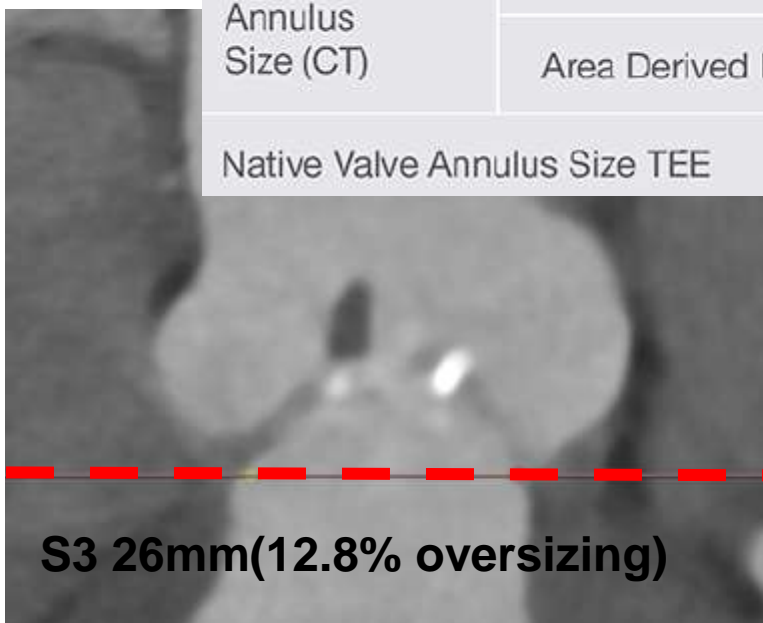








Annulus Sizing		20 mm	23 mm	26 mm	29 mm
Native Valve Annulus Size (CT)	Area	273 - 345 mm <sup>2</sup>	338 - 430 mm <sup>2</sup>	430 - 546 mm <sup>2</sup>	540 - 683 mm <sup>2</sup>
	Area Derived Diameter	18.6 - 21 mm	20.7 - 23.4 mm	23.4 - 26.4 mm	26.2 - 29.5 mm
Native Valve Annulus Size TEE		16 - 19 mm	18 - 22 mm	21 - 25 mm	24 - 28 mm

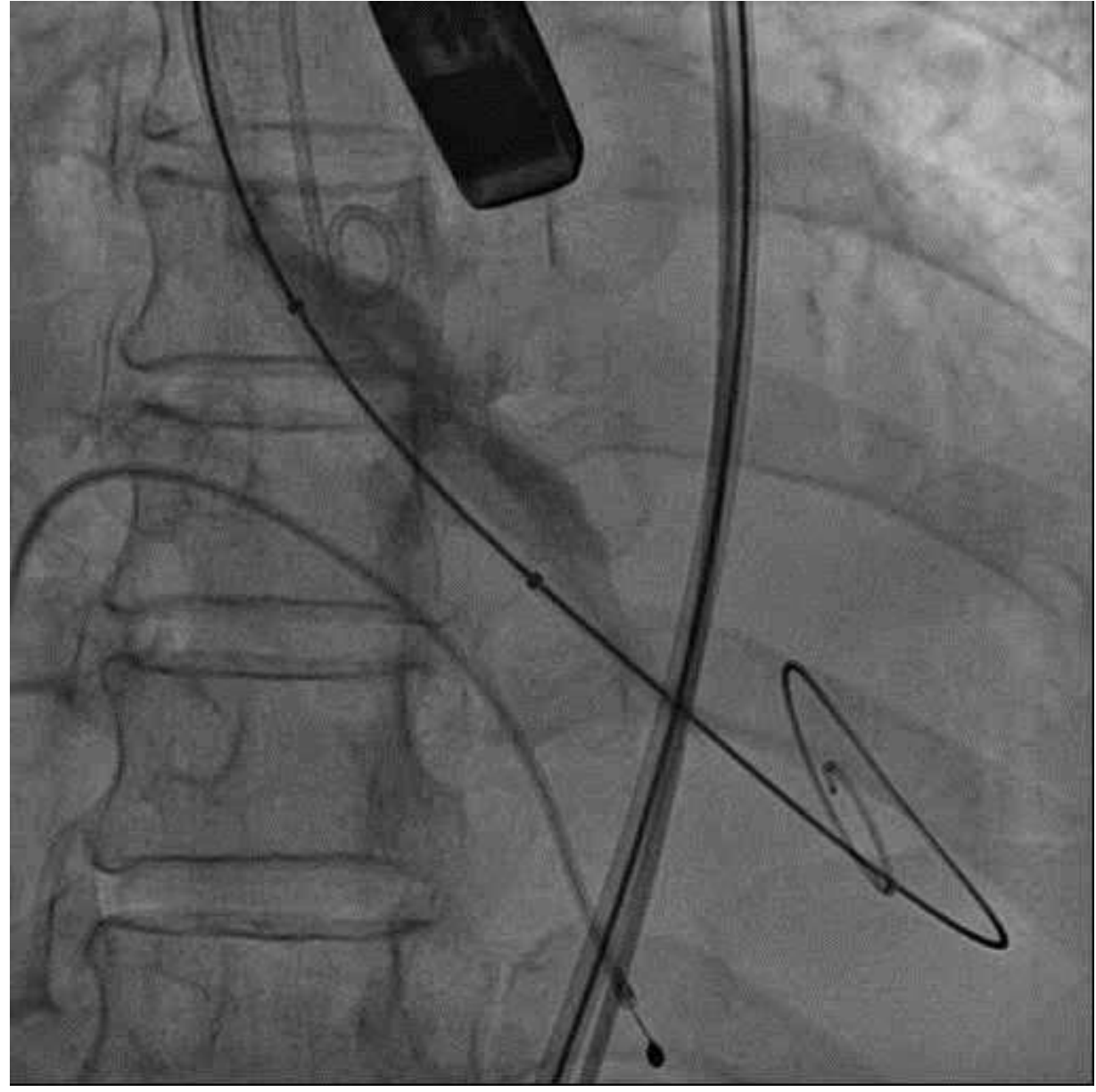
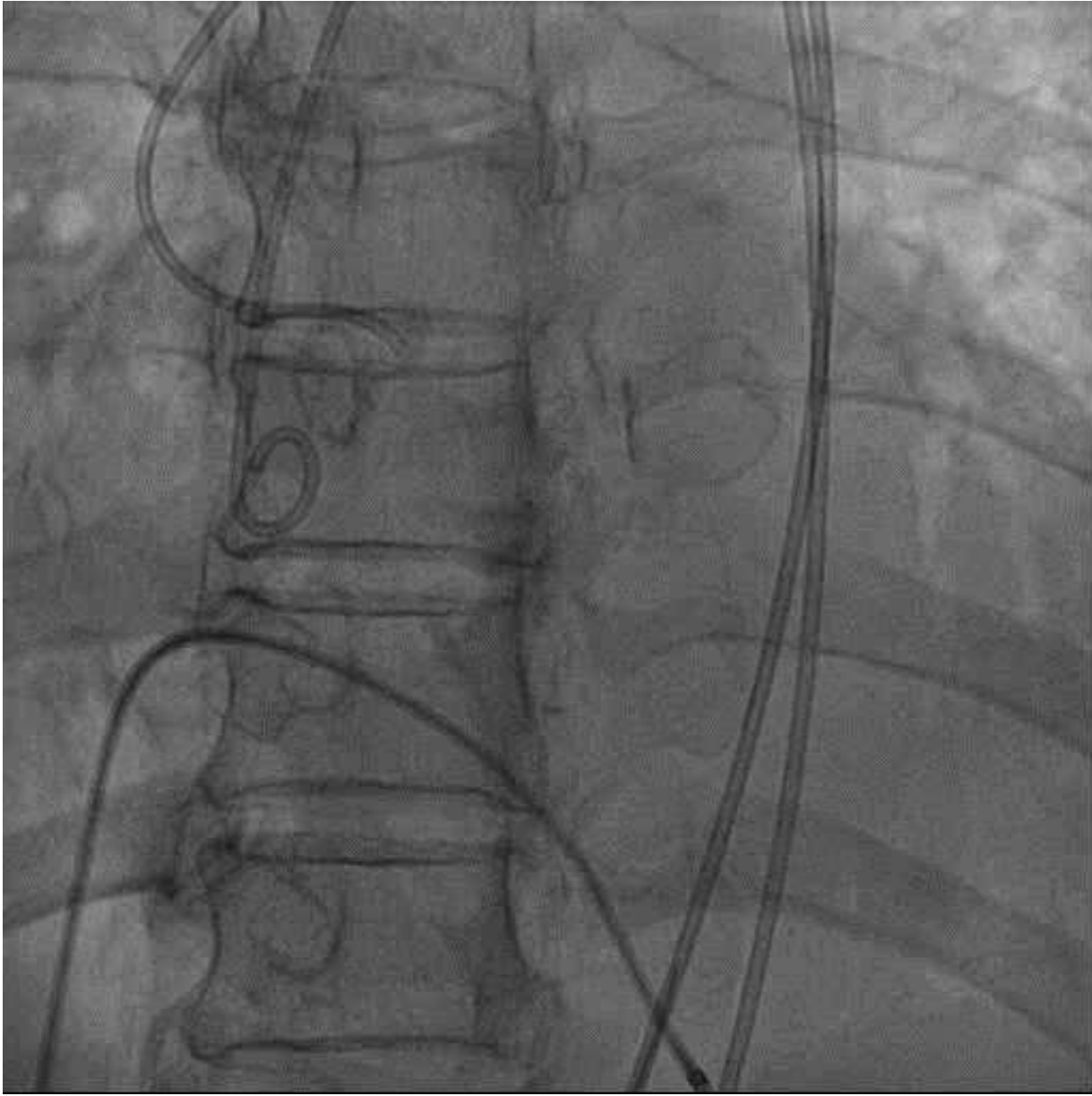


S3 26mm -2cc(3% oversizing)  
S3 23mm (-11.7% undersizing)

S3 26mm -2cc (29.1% oversizing)  
S3 23mm (10.6% oversizing)

S3 26mm -2cc (58% oversizing)  
S3 23mm (35.3% oversizing)

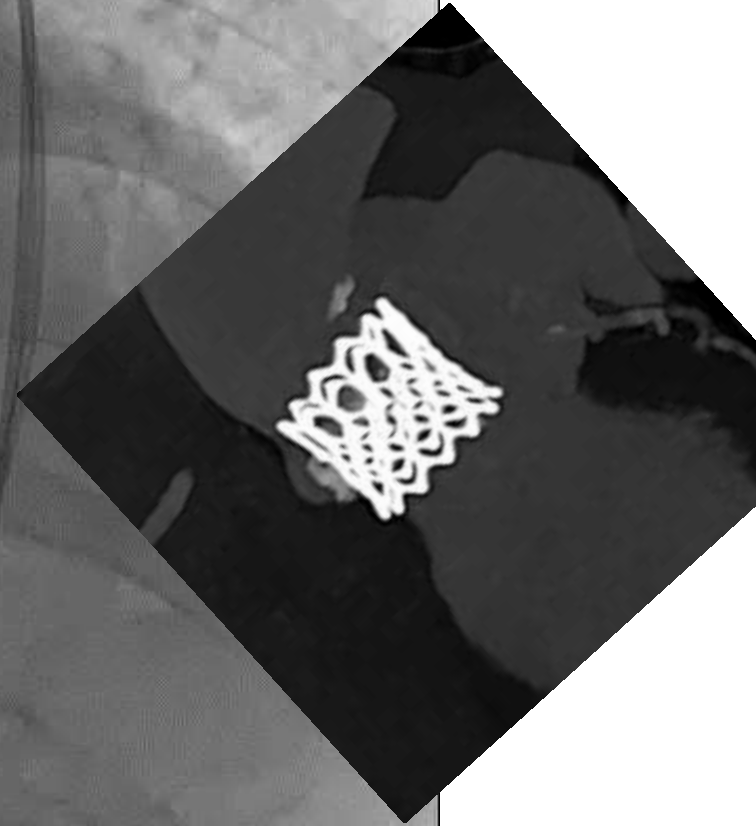
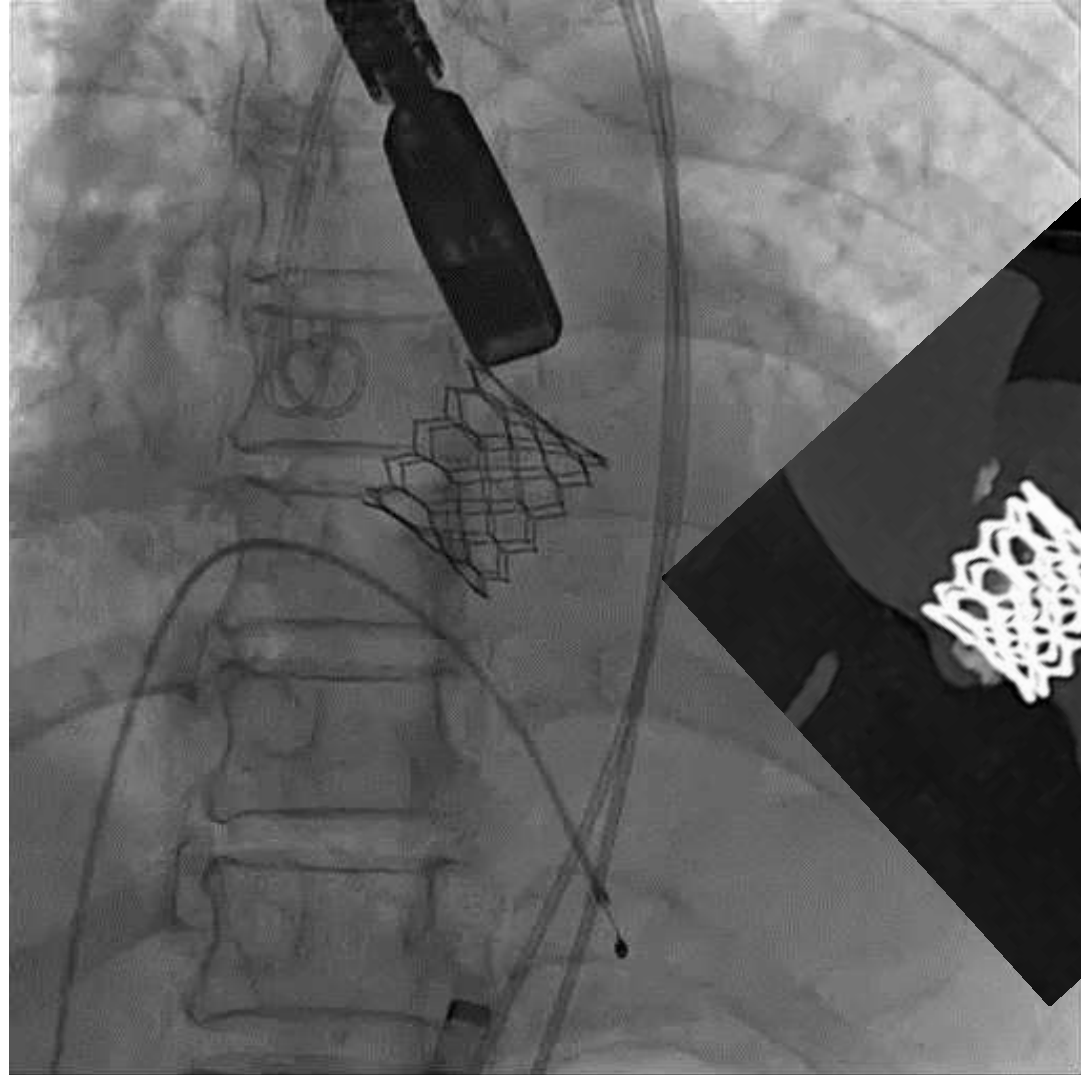
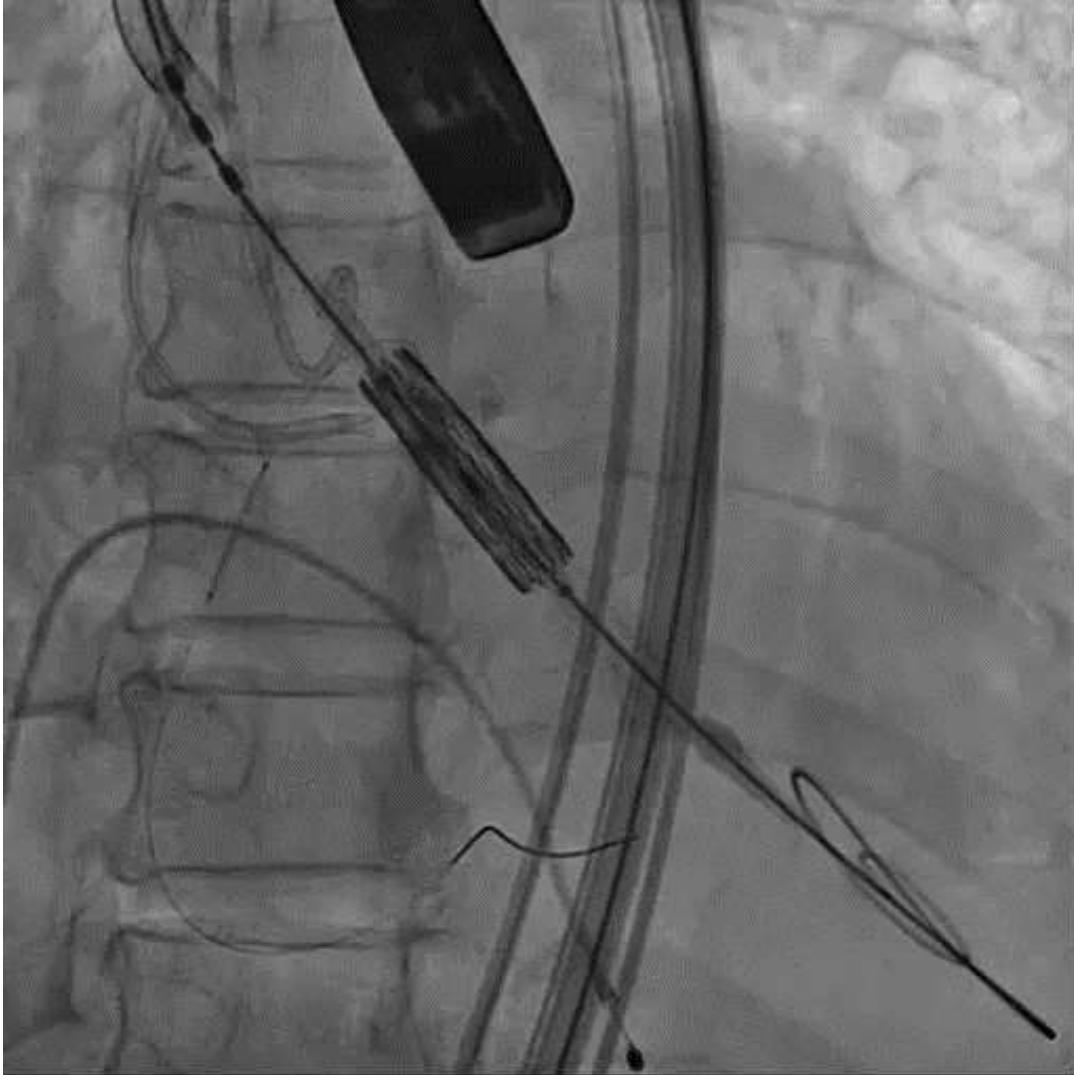
# BAV with 23mm Balloon : Balloon sizing and behavior of heavily calcified leaflet



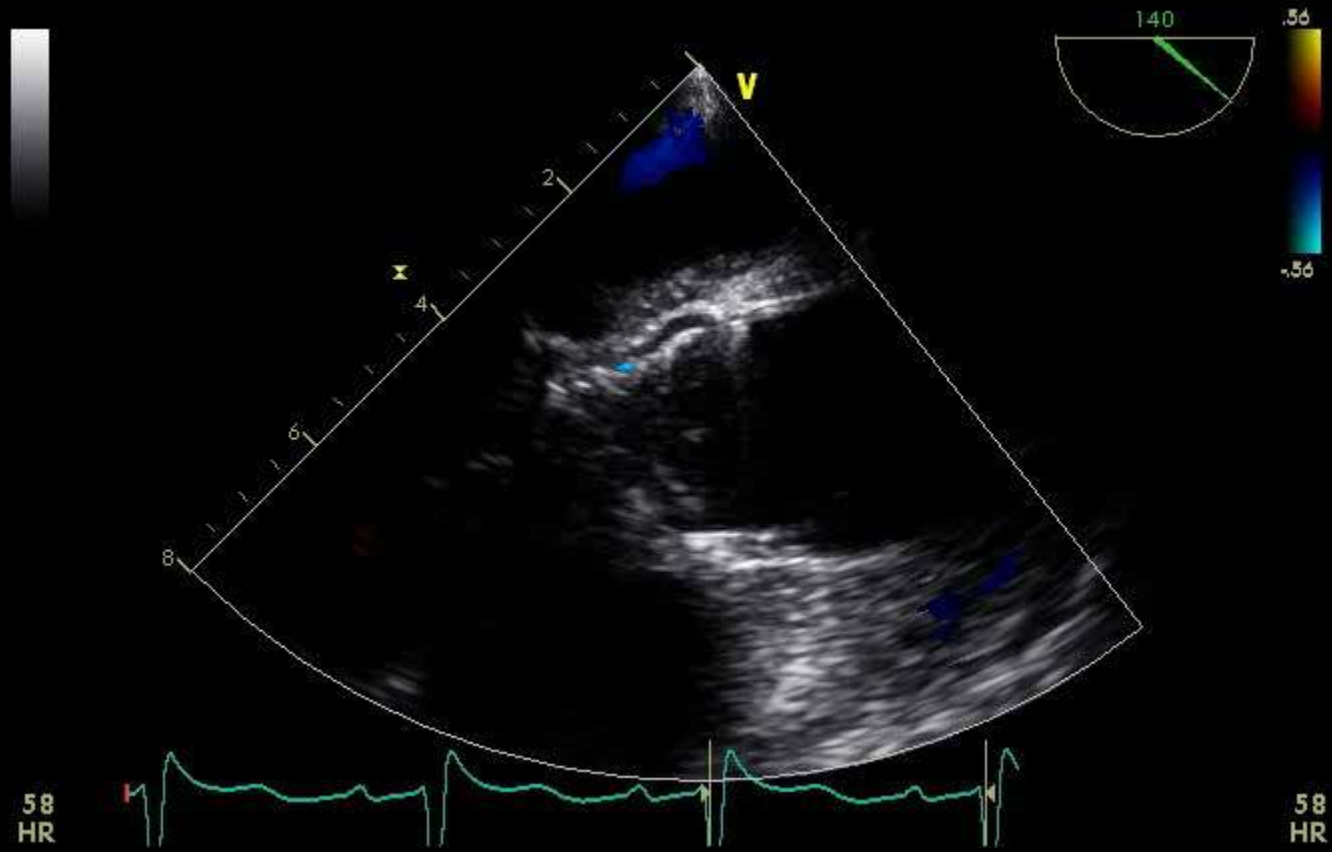
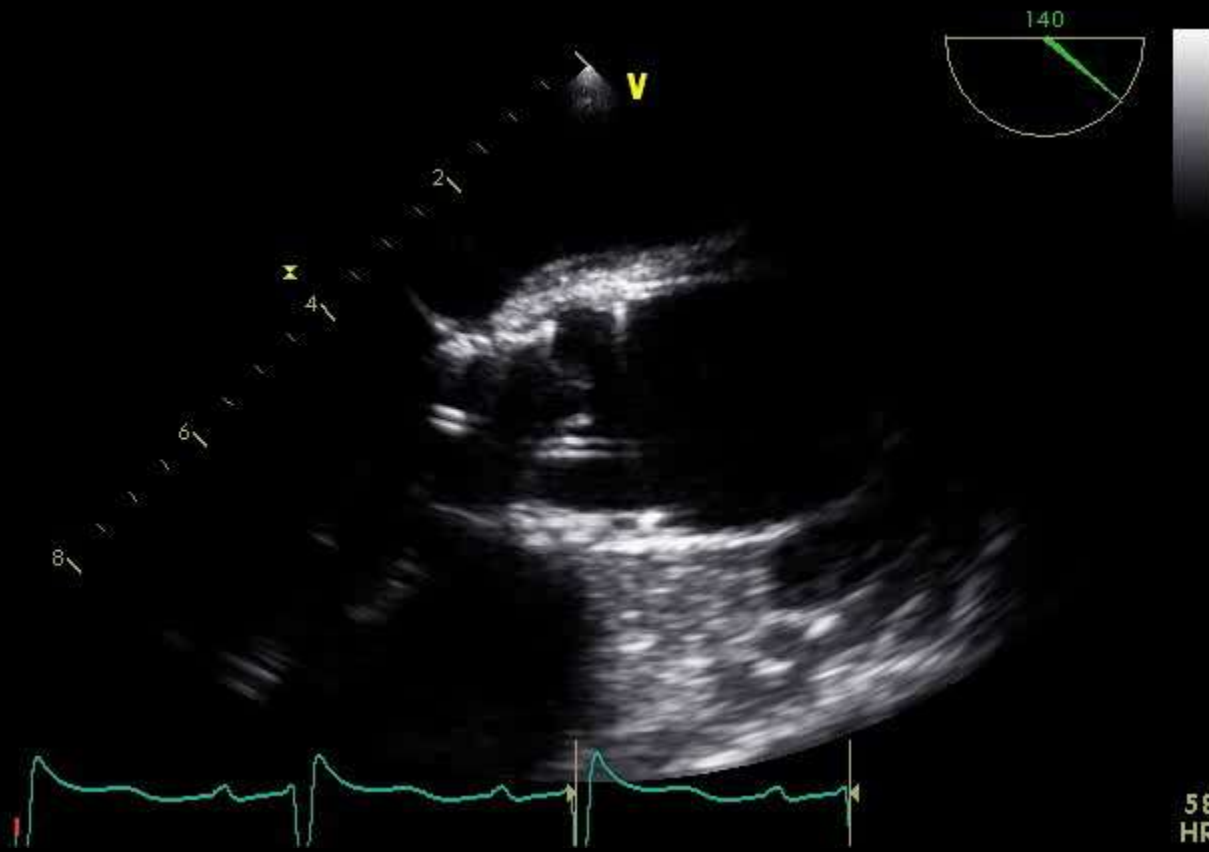
26mm SAPIEN 3 with 2cc underfilling

**supra-annular 58%, mid-valsava 29%, annular 3% oversizing**

For protection of RCA, wire and stent was inserted

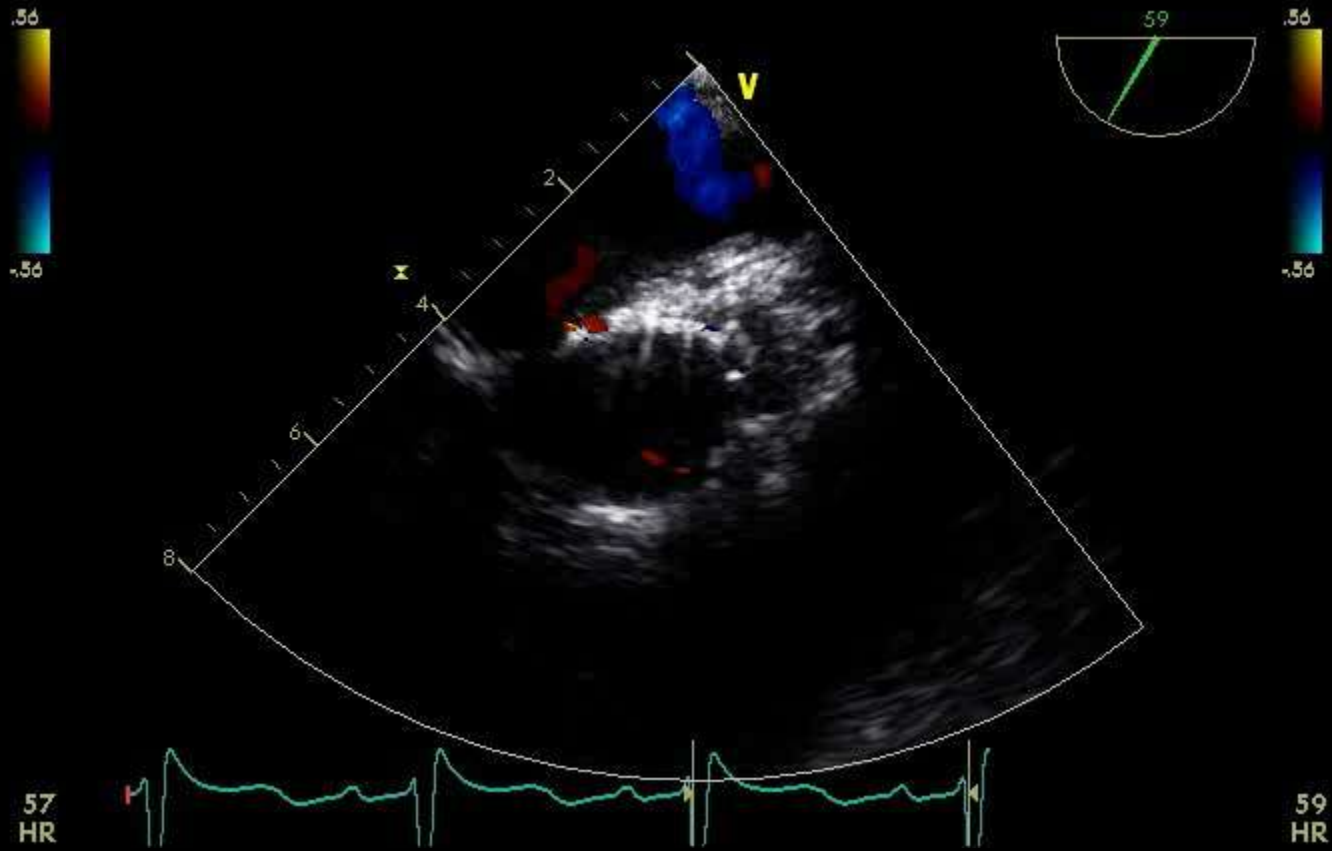
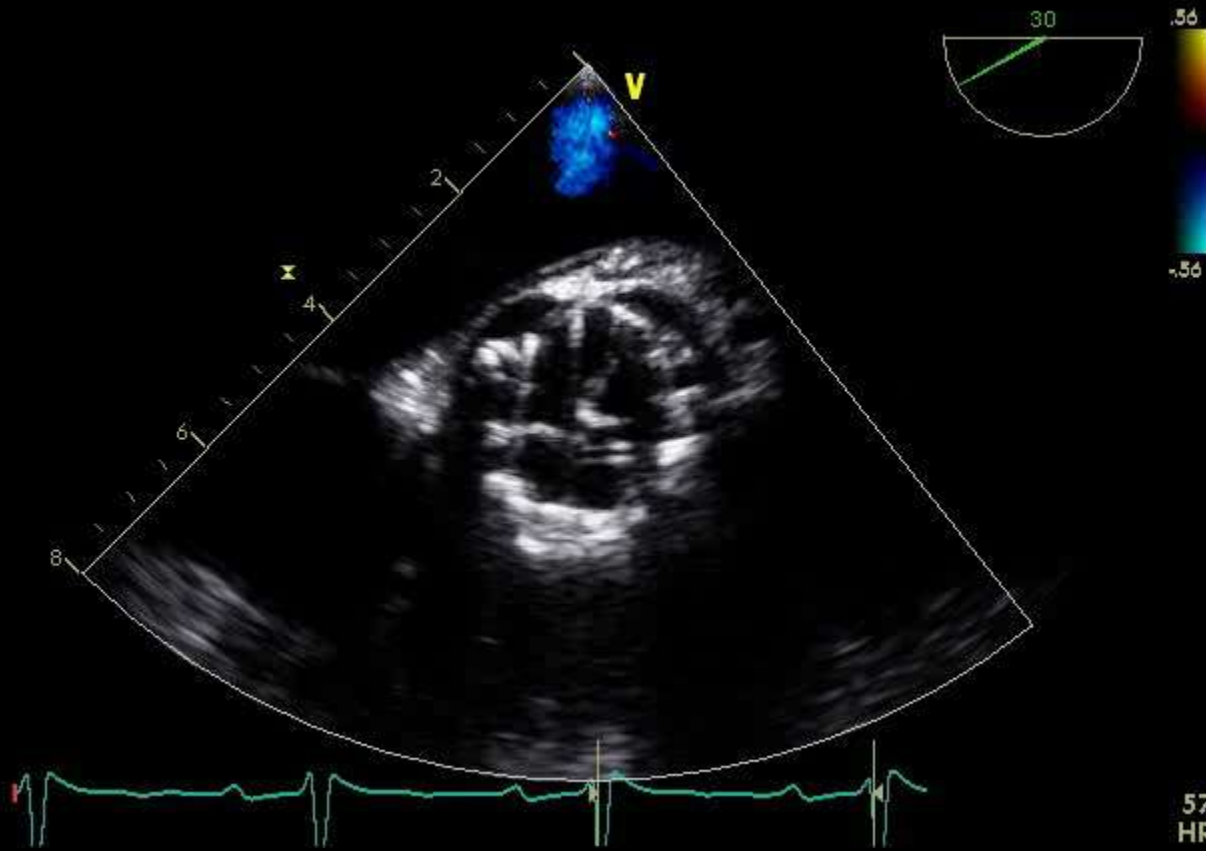


# Transesophageal echocardiography





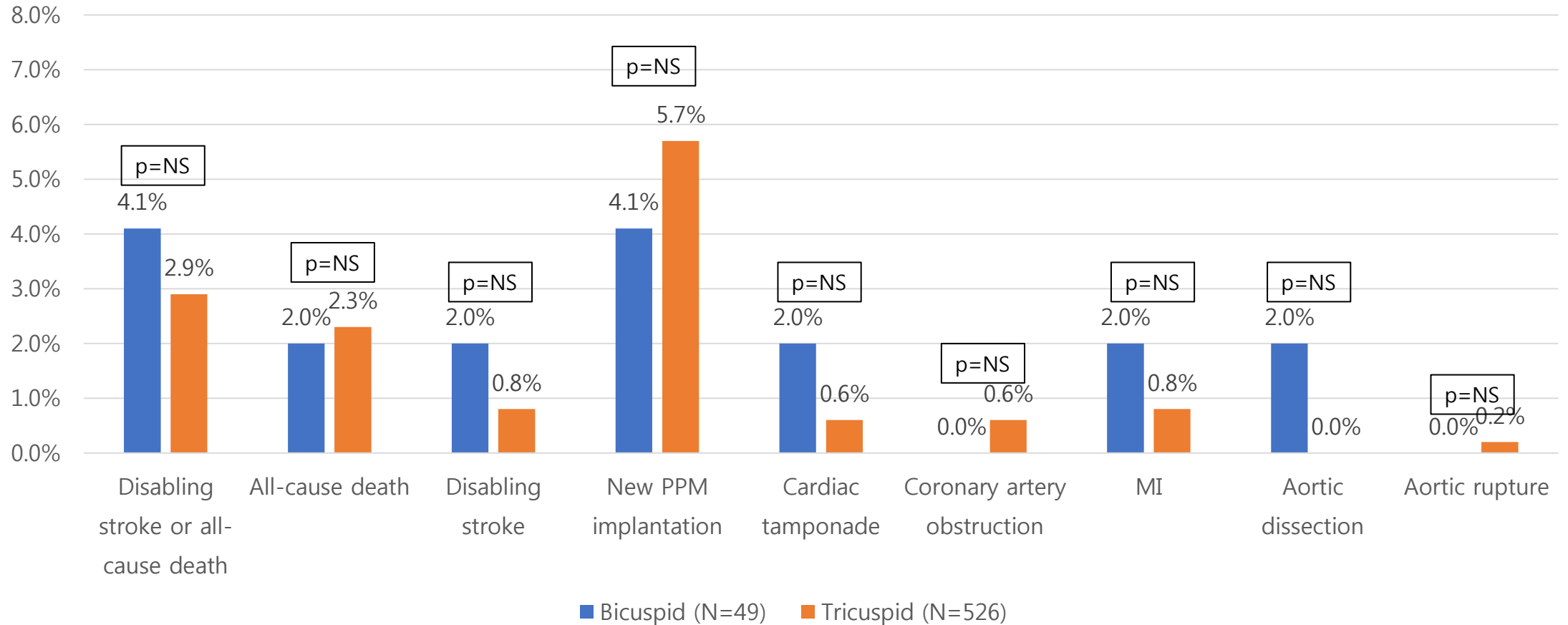
# Transesophageal echocardiography



# Baseline Characteristics

<b>Variable</b>	<b>Bicuspid (N=49)</b>	<b>Tricuspid (N=526)</b>	<b>P-value</b>
<b>Age (Years)</b>	<b>76.6±6.8</b>	<b>79.0±6.1</b>	<b>0.010</b>
<b>Gender – Female</b>	<b>19 (38.8%)</b>	<b>276 (52.5%)</b>	<b>0.067</b>
<b>Height (cm)</b>	<b>155.0±19.4</b>	<b>155.3±13.6</b>	<b>0.860</b>
<b>Weight (kg)</b>	<b>65.0±24.0</b>	<b>59.5±15.5</b>	<b>0.025</b>
<b>DM</b>	<b>16 (32.7%)</b>	<b>188 (35.7%)</b>	<b>0.613</b>
<b>HTN</b>	<b>37 (75.5%)</b>	<b>413 (78.5%)</b>	<b>0.625</b>
<b>Stroke or TIA</b>	<b>10 (20.4%)</b>	<b>77 (14.6%)</b>	<b>0.564</b>
<b>PAOD</b>	<b>5 (10.2%)</b>	<b>75 (14.3%)</b>	<b>0.433</b>
<b>CKD on dialysis</b>	<b>1 (2.0%)</b>	<b>36 (6.8%)</b>	<b>0.354</b>
<b>STS score</b>	<b>5.7±4.6</b>	<b>7.9±9.2</b>	<b>0.105</b>

# In-hospital outcomes



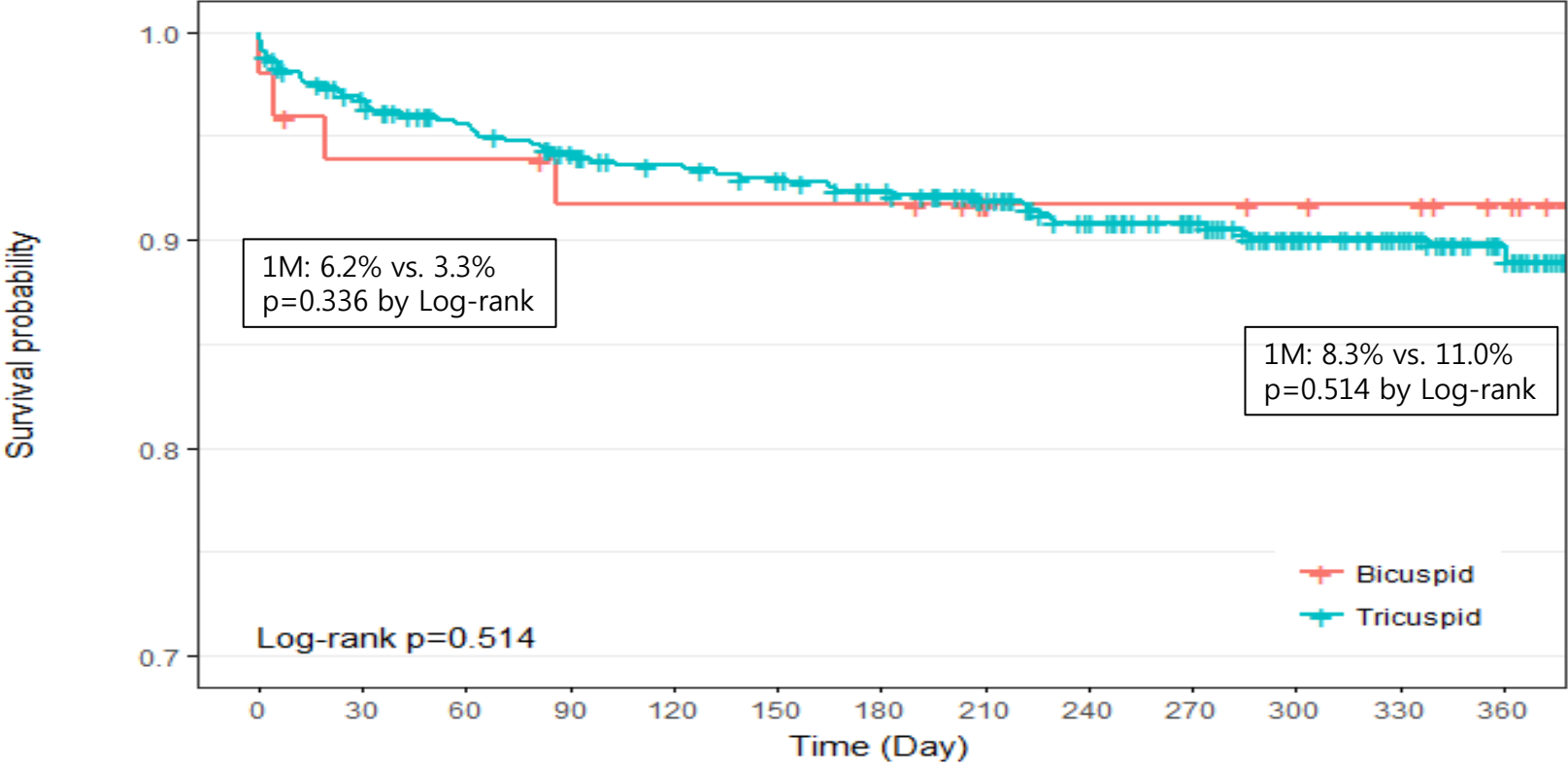
From K-TAVI registry presented at the KSIC 2017

# Paravalvular leakage at discharge

Variable	Bicuspid (N=49)	Tricuspid (N=526)	P-value 0.491
None or Trivial	21 (42.9%)	236 (44.9%)	
Mild	22 (44.9%)	252 (47.9%)	
Moderate	5 (10.2%)	28 (5.3%)	
Severe	0 (0%)	1 (0.2%)	
N/A	1 (2.0%)	9 (1.7%)	

From K-TAVI registry presented at the KSIC 2017

# A composite of all cause death or disabling stroke

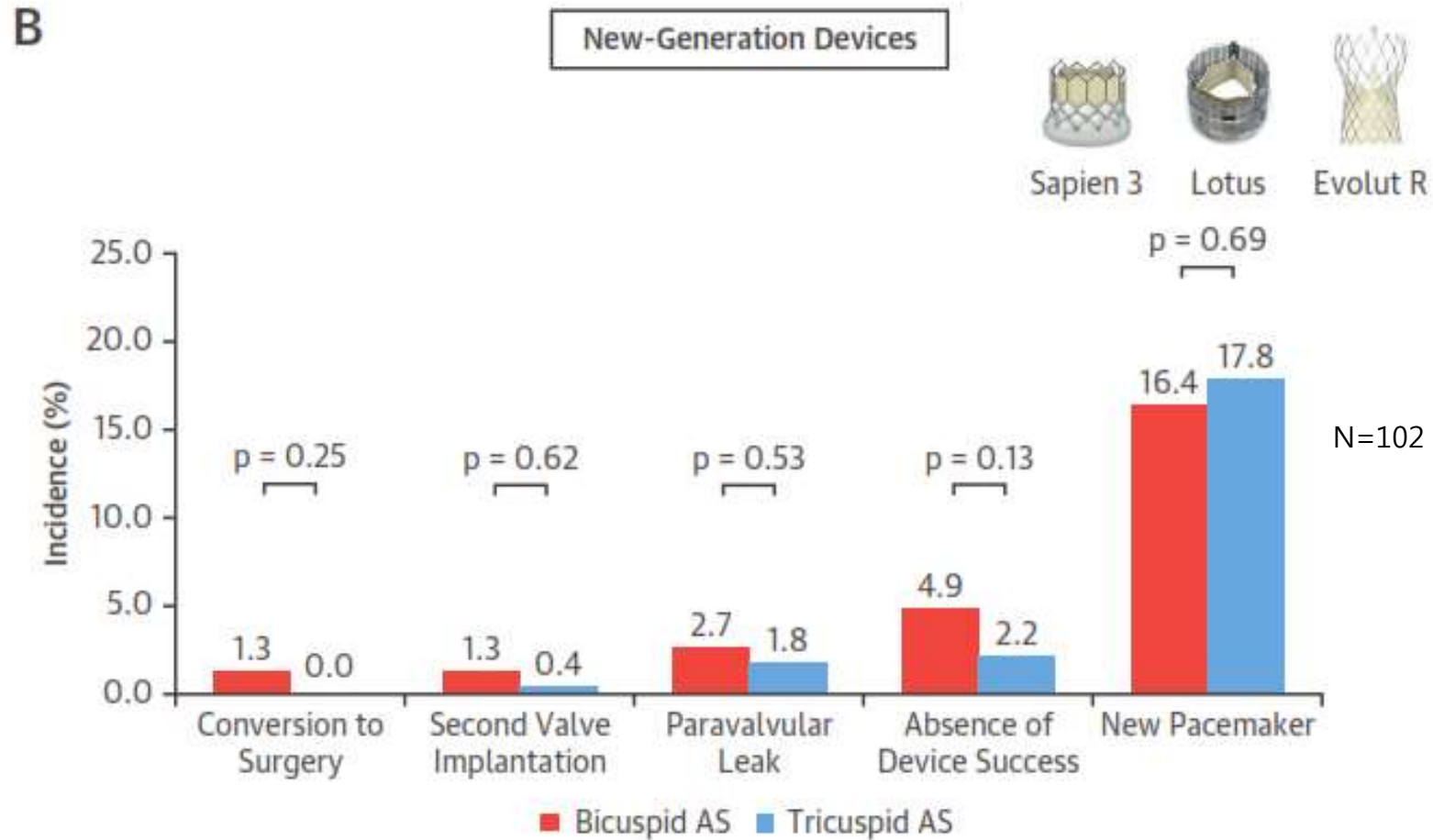


Number at risk

Strata	Bicuspid	49	45	45	43	43	43	43	38	36	36	35	34	31	
Tricuspid	526	500	482	470	459	454	442	426	406	391	360	343	316		
		0	30	60	90	120	150	180	210	240	270	300	330	360	
		Time (Day)													

From K-TAVI registry presented at the KSIC 2017

# 30-Day Outcomes



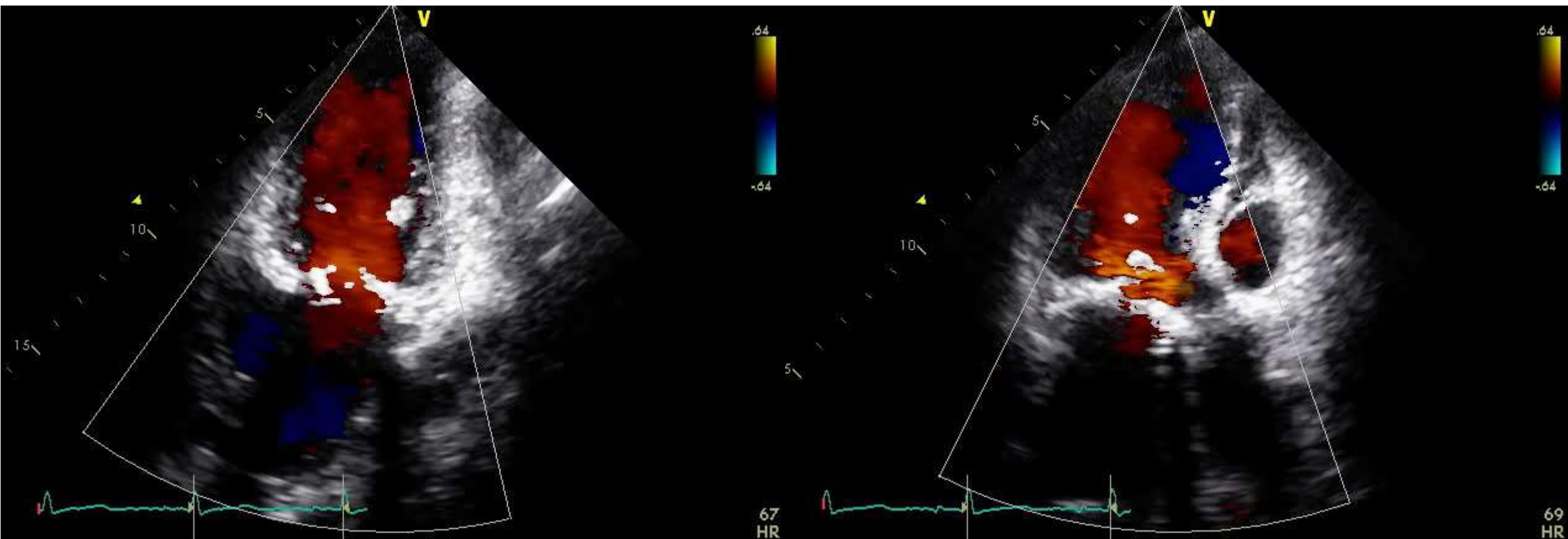
# Mitral V-inV Case Summary

- Female / 82 YO
- C.C: Worsening dyspnea (NYHA IV)
- Past medical history
  - 148 cm 37.2 kg BSA 1.26m<sup>2</sup>
  - s/p AVR(Hancock II 21mm), MVR(Hancock II 27mm) ['01.5.30]
  - HFpEF, severe MR
  - pAF
  - STS PROM 17.843%



# Transthoracic echocardiography

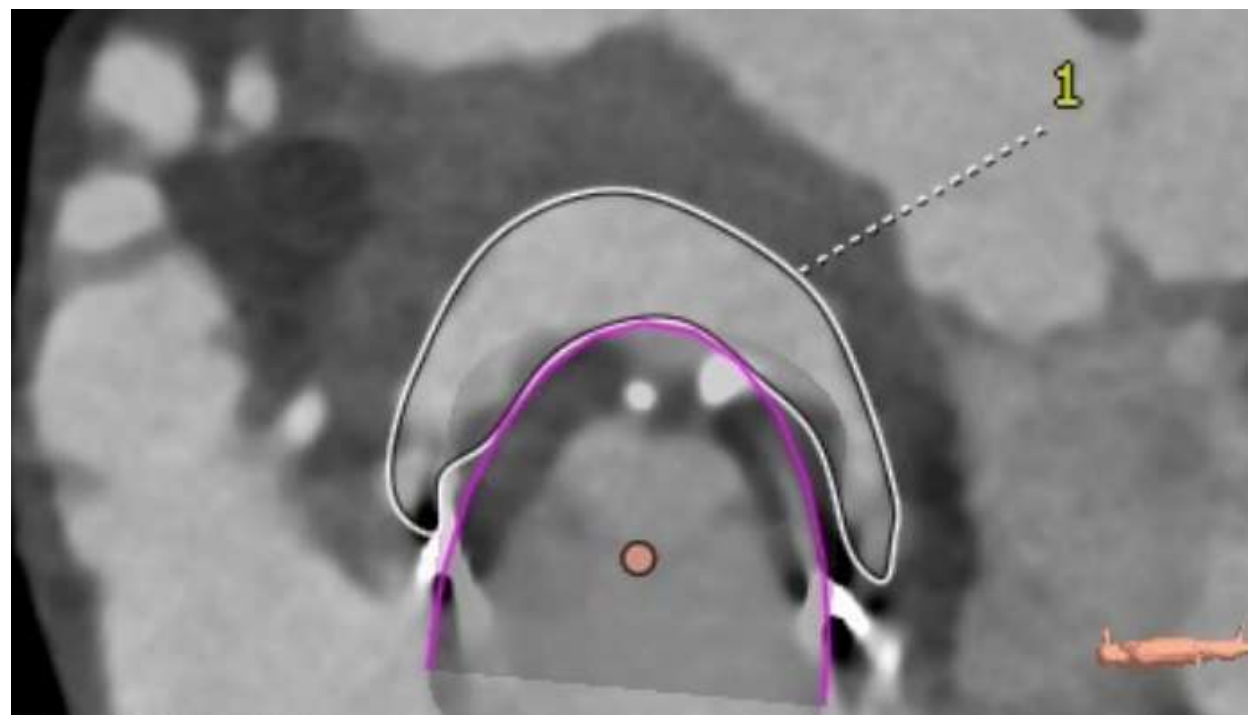
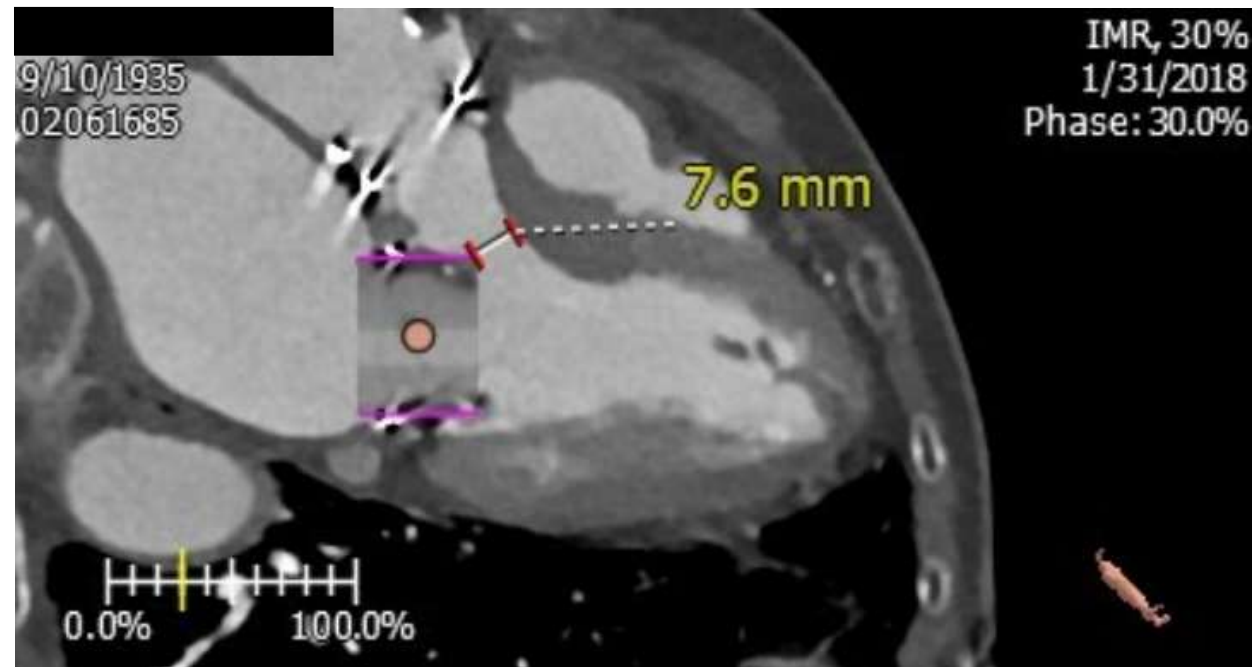
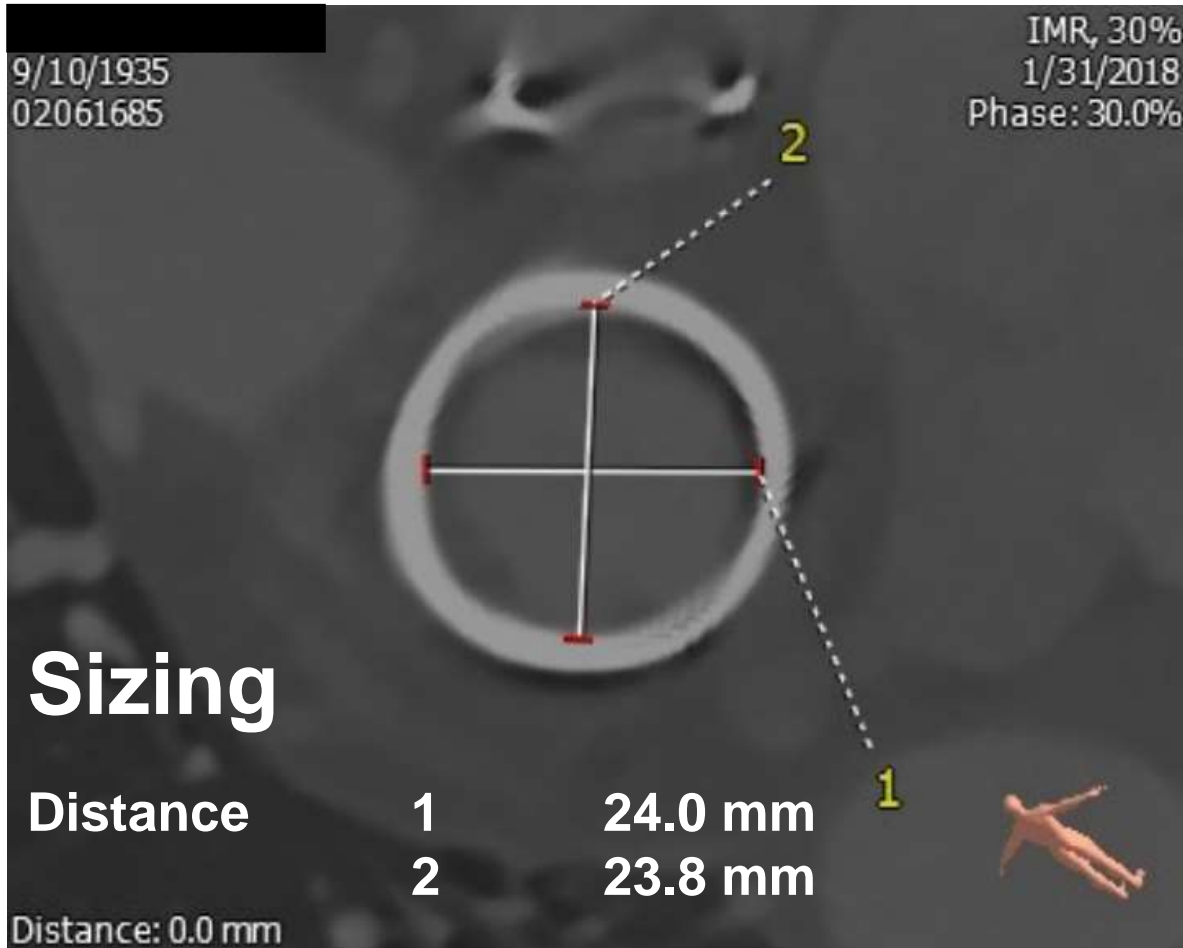
## Mitral valve, post-MVR status



**Severe eccentric MR**  
**PISA = 5.9mm**

**✘ Aortic valve, post-AVR status**  
Peak velocity = 2.21 m/sec  
Peak/mean pressure gradient = 19/8 mmHg

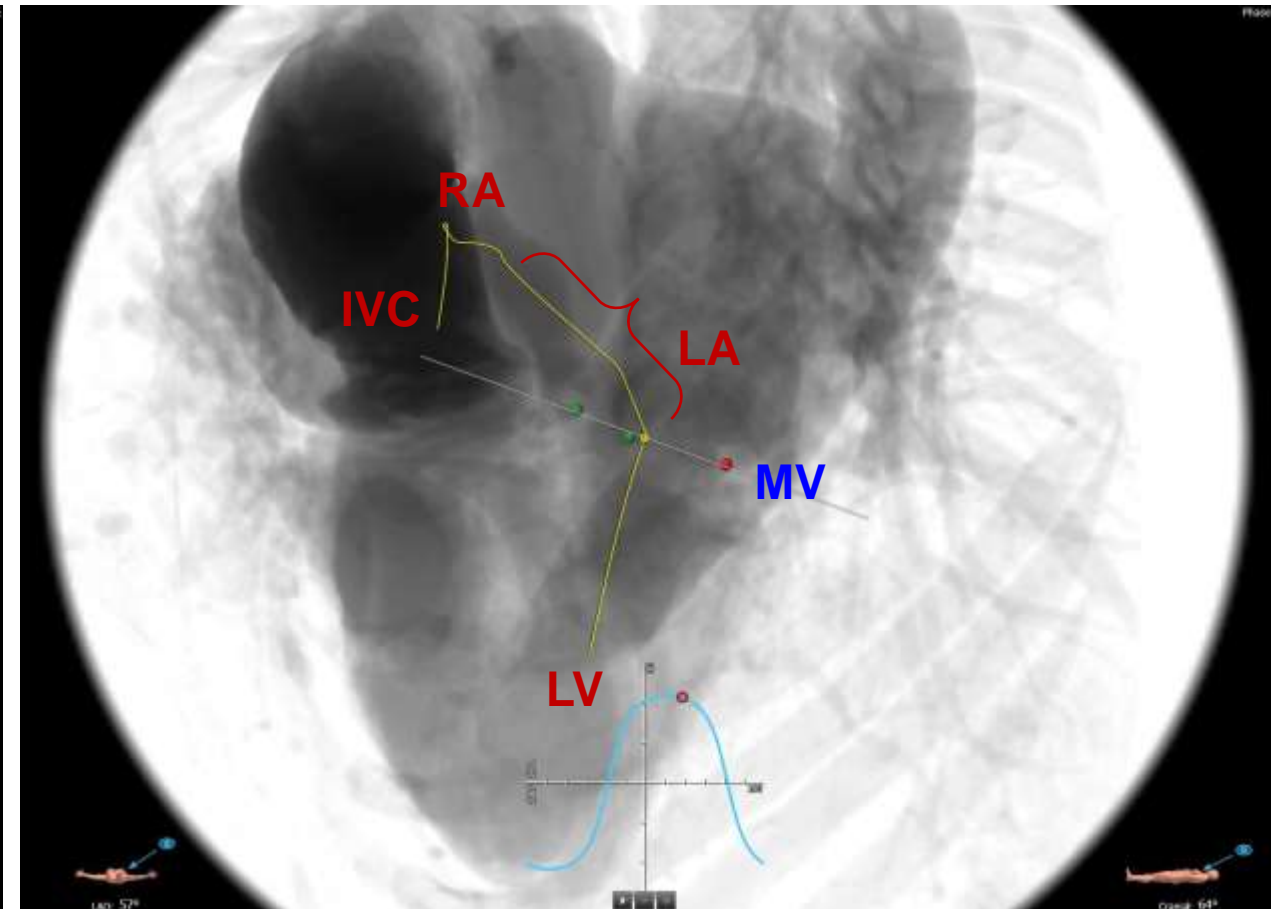
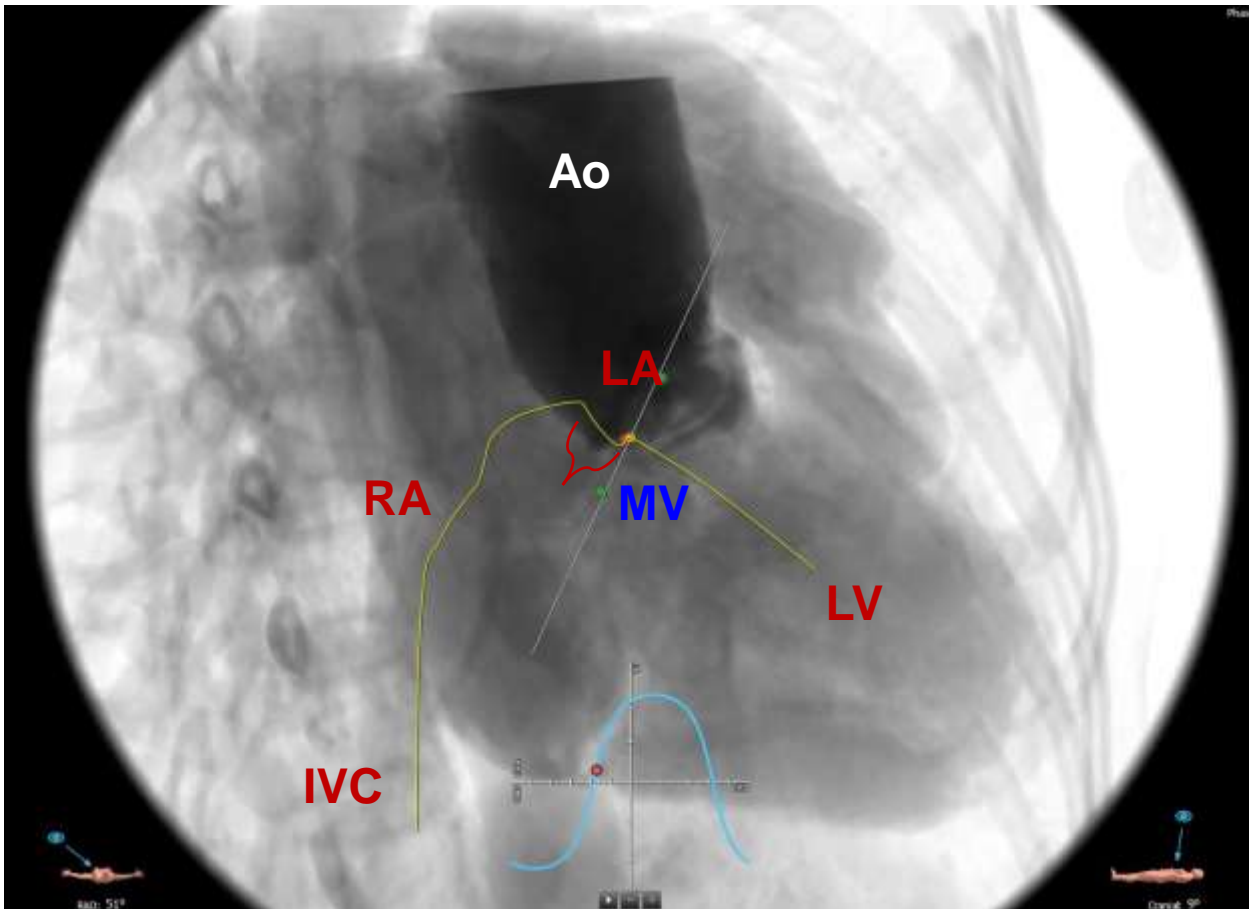




## Neo-LVOT

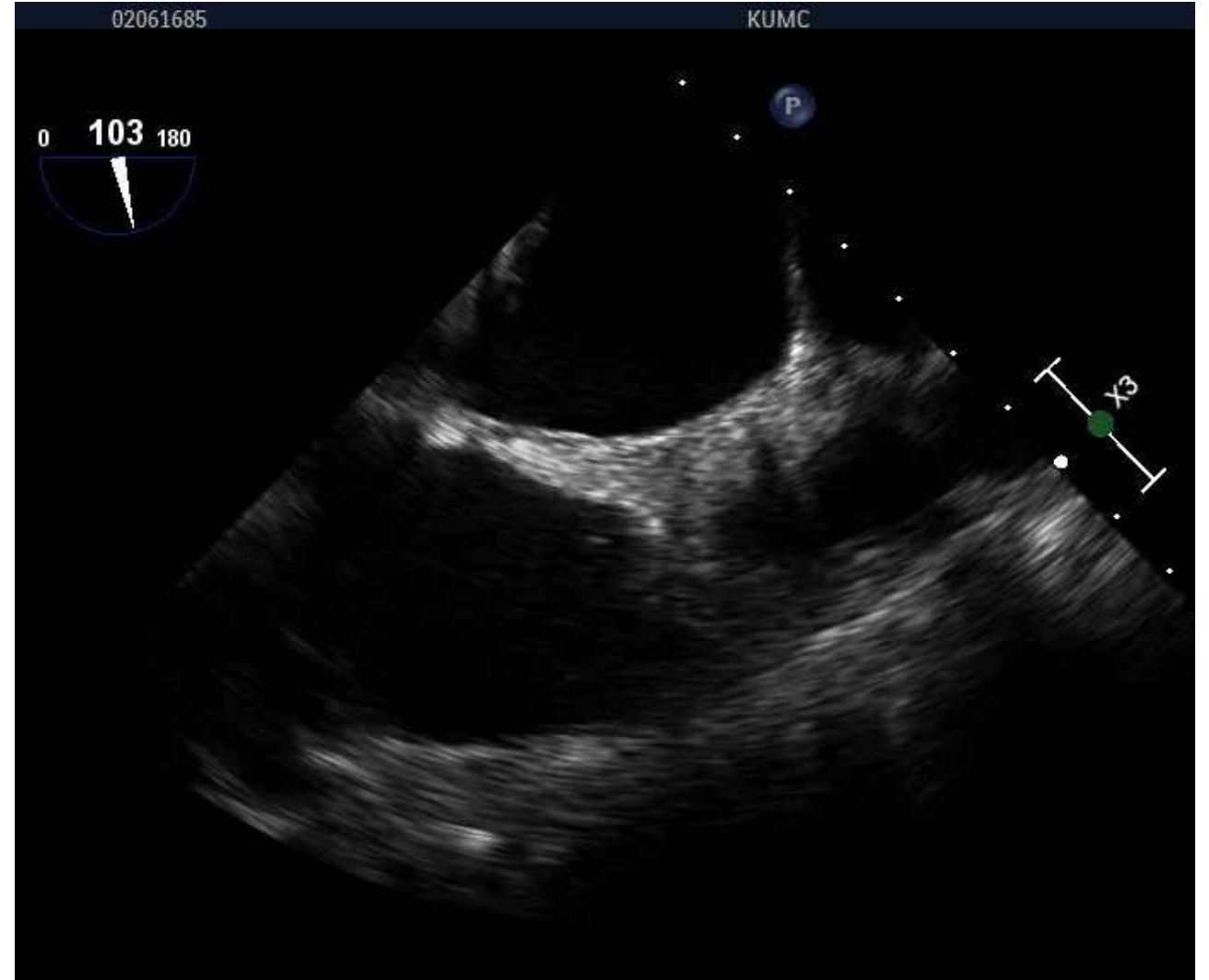
Polygon shape	Area	323.9 mm <sup>2</sup>
	Perimeter	112.2 mm
	Aortic-Mitral Angle	41.5 °

# Prediction of wire and device path



# Septal puncture

SL1 sheath and dilator with Brockenbrough needle

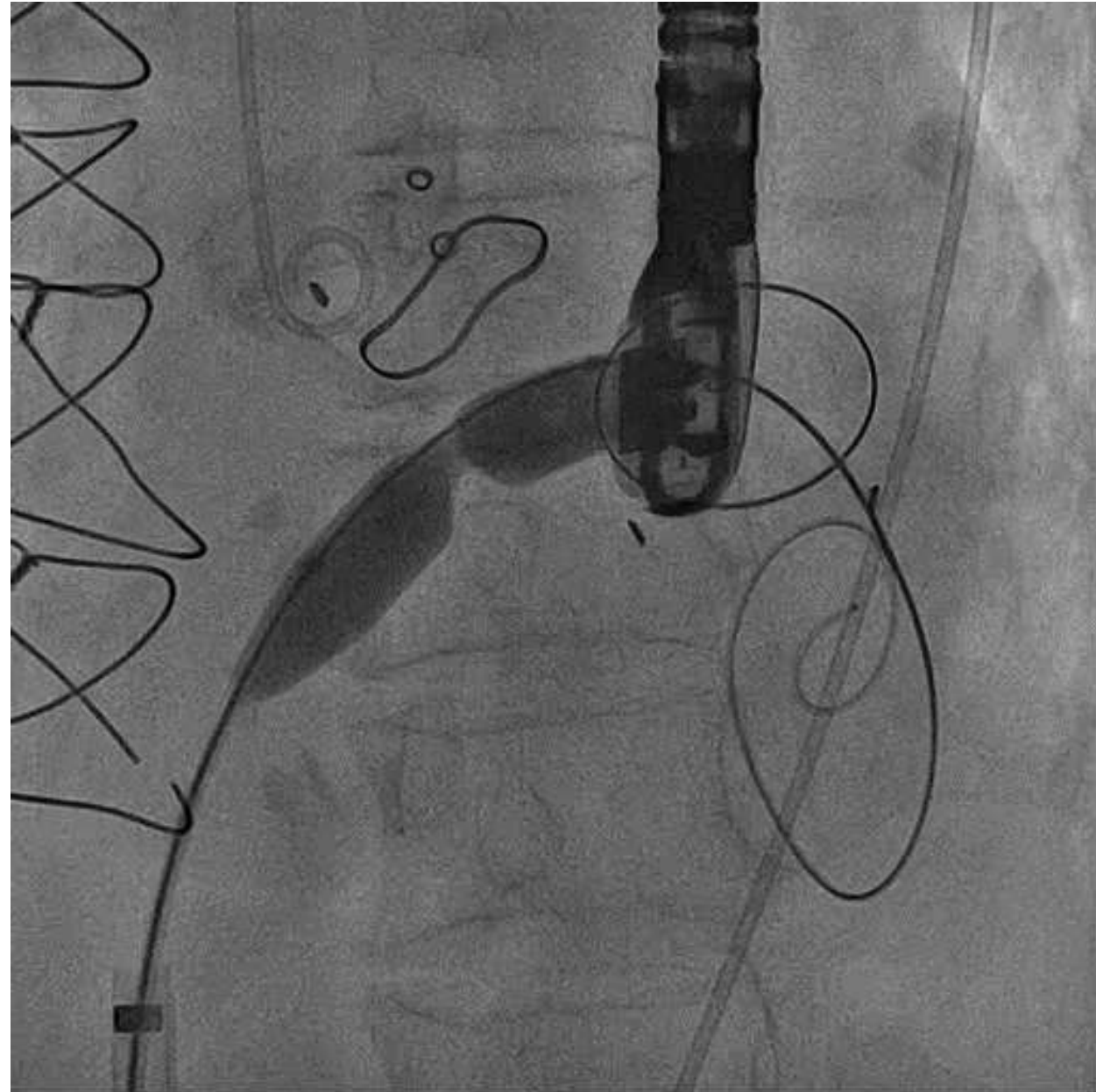
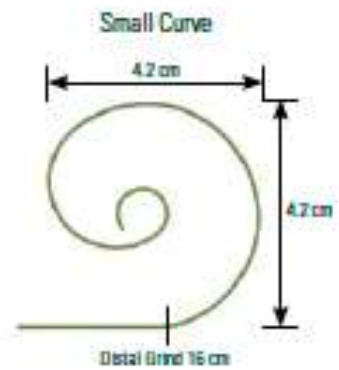


# Interatrial balloon dilatation

Balloon: Mustang 12.0mm X 40mm

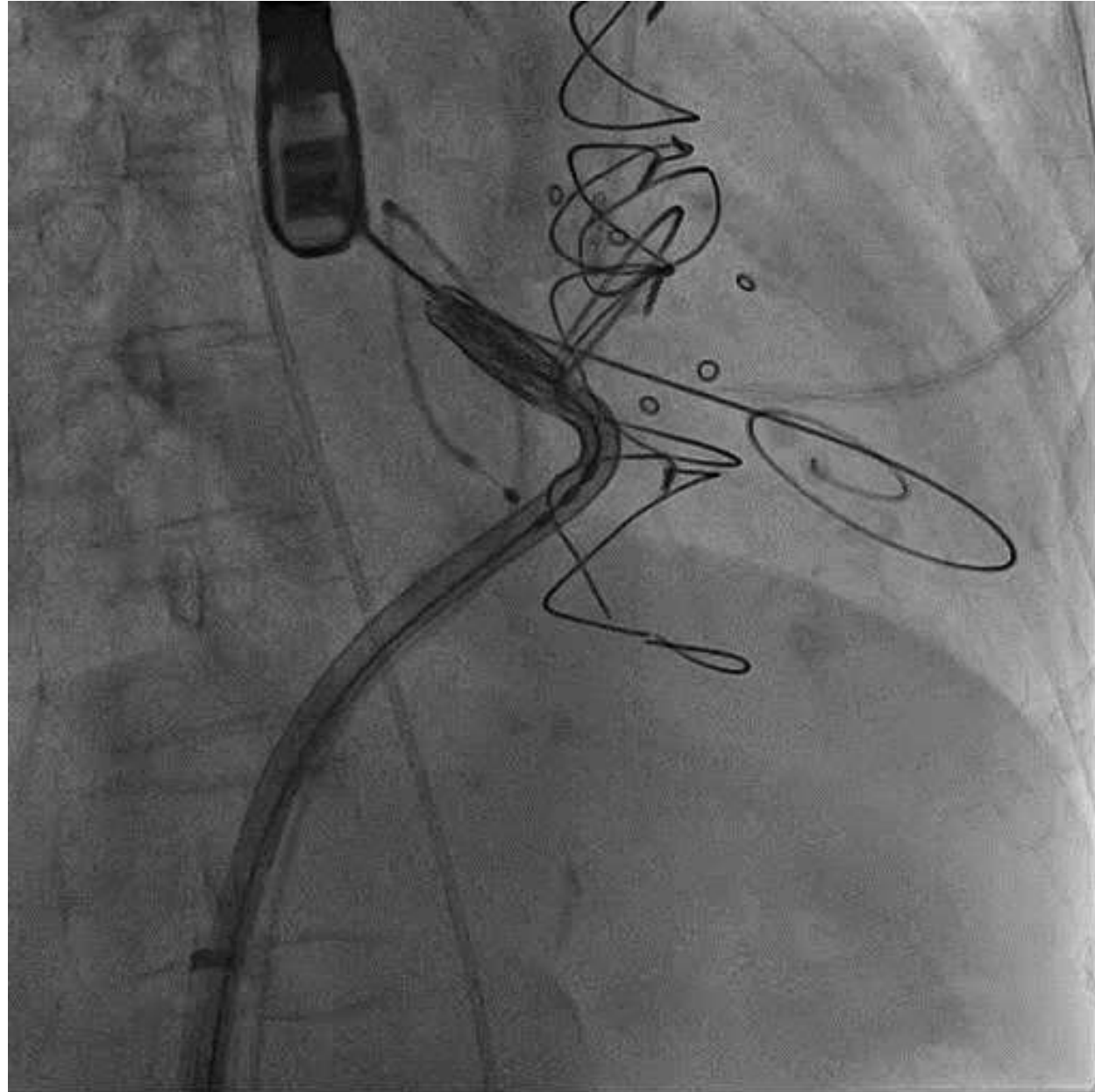
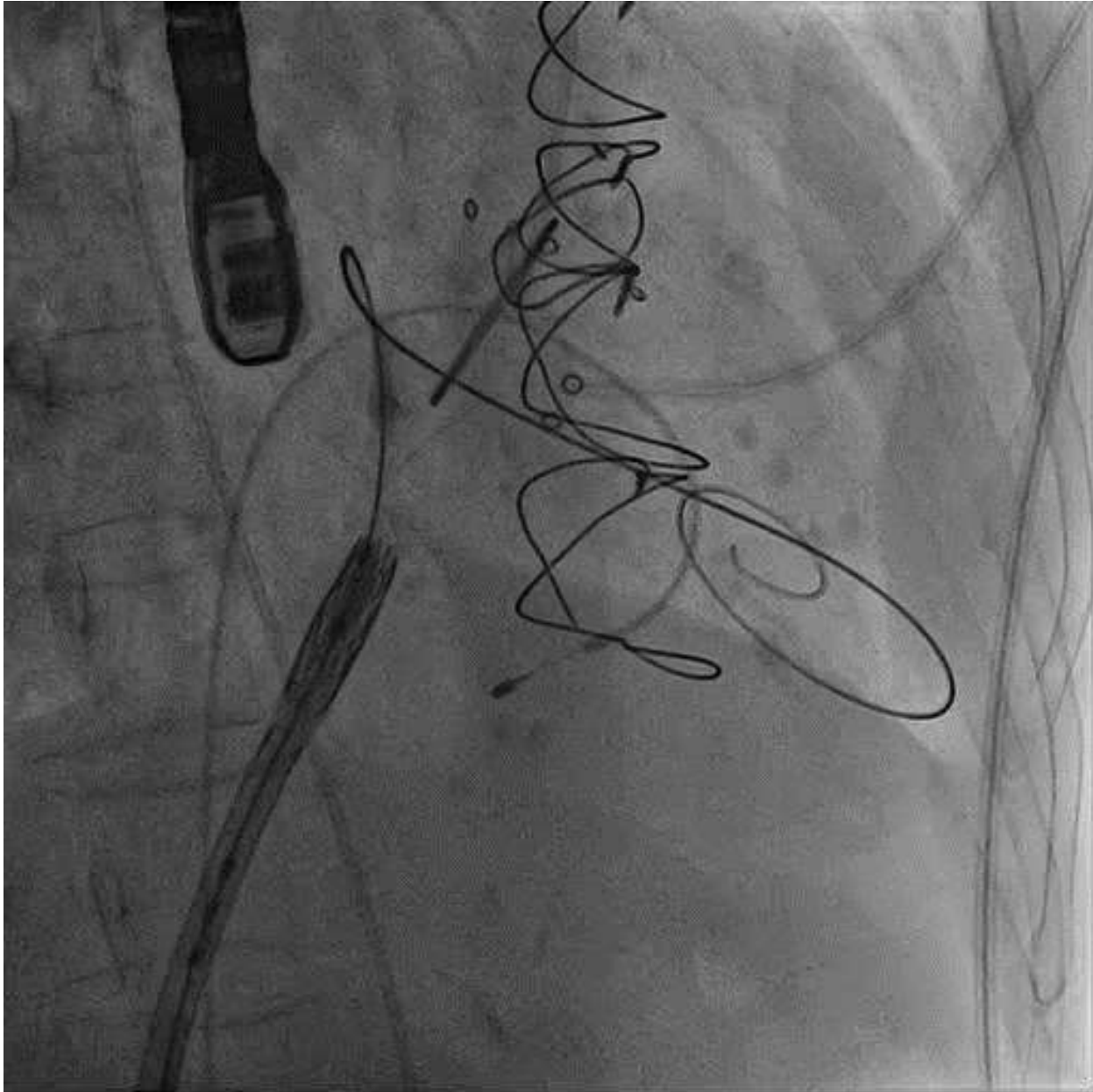


**Safari wire**



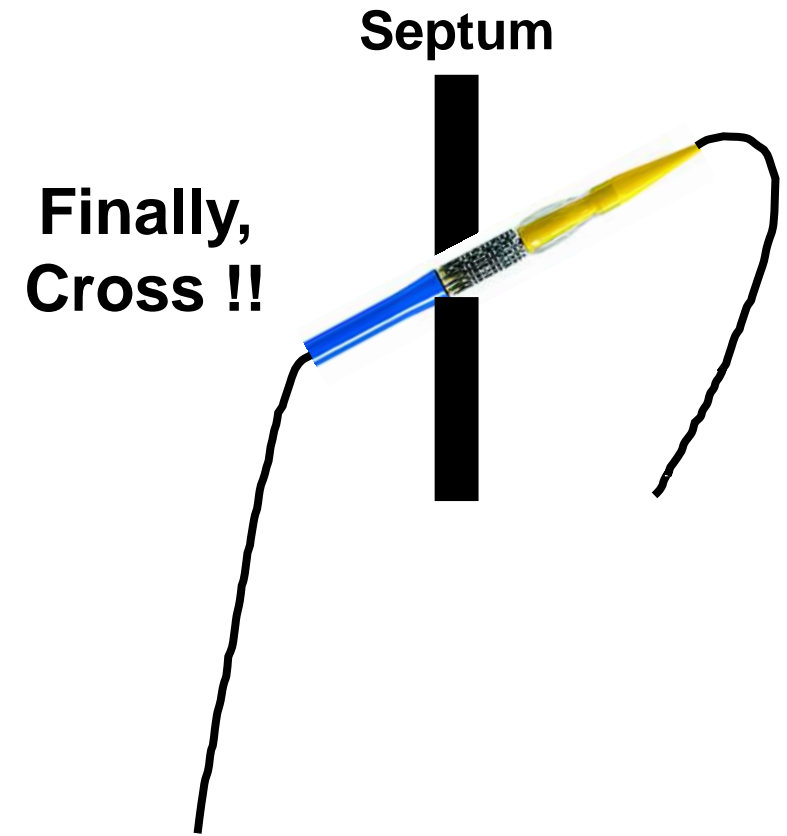
# Crossing inter-atrial septum

26mm Sapien-3 valve (21ml, nominal pr.)

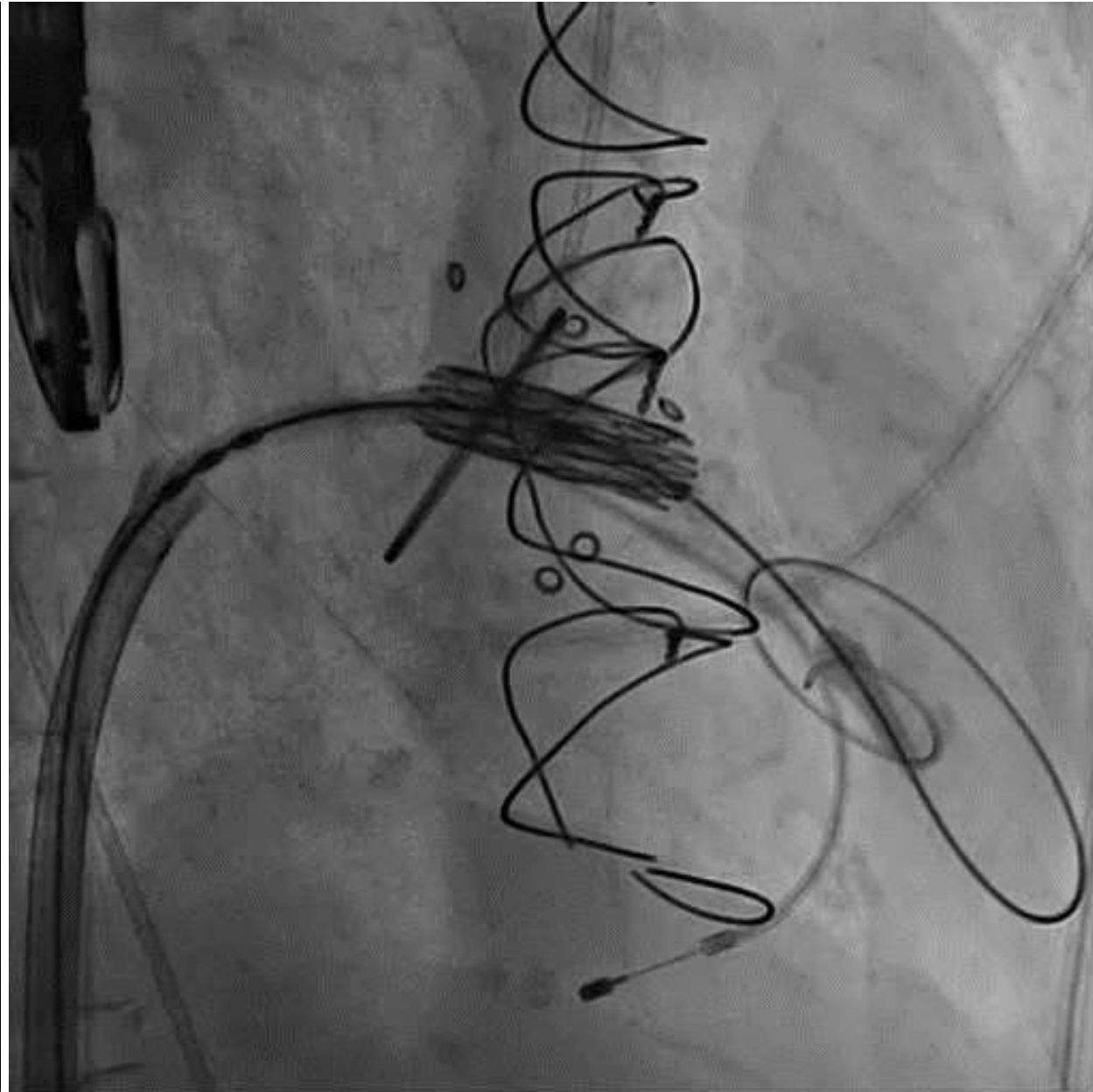
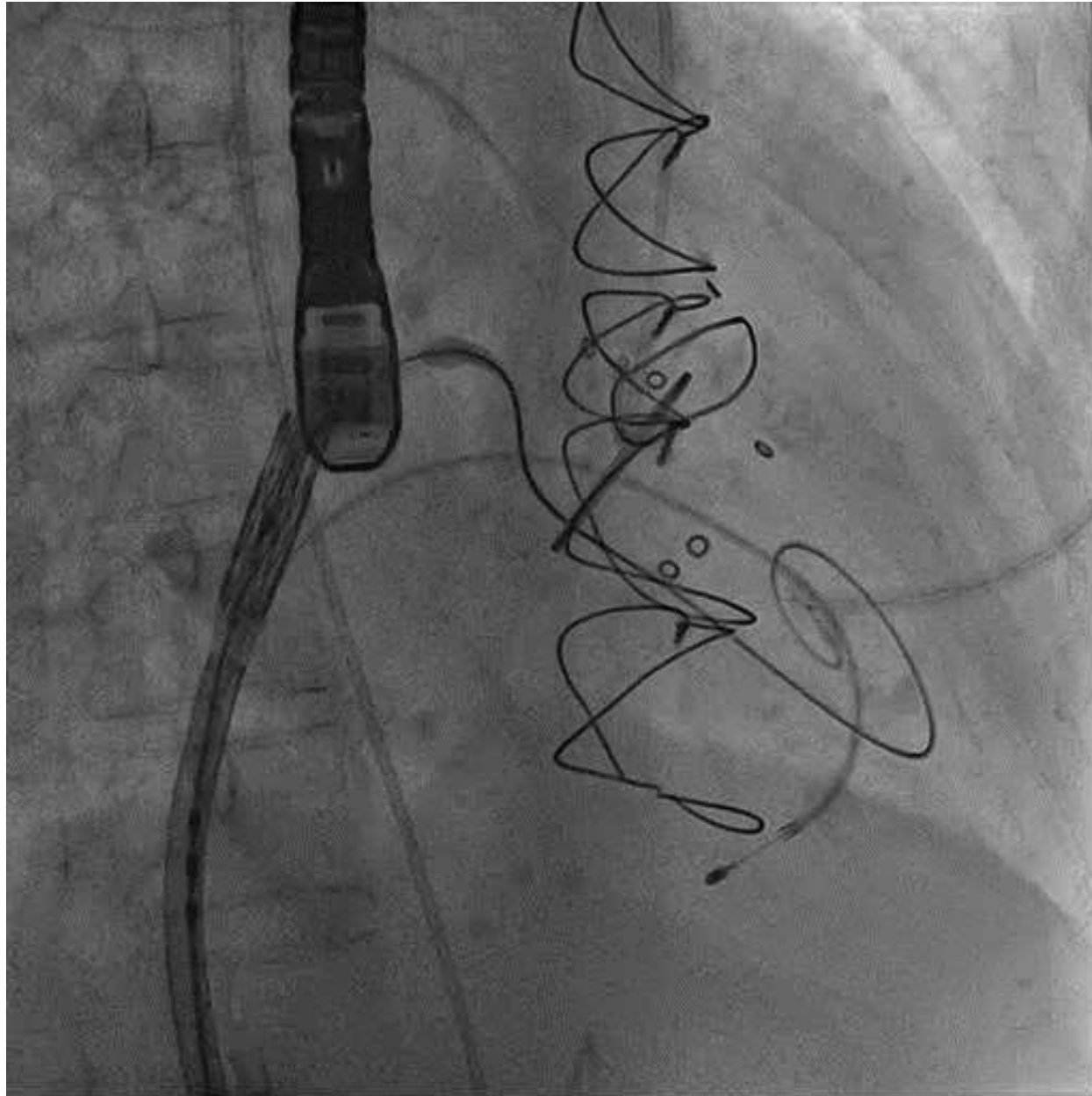


# Crossing inter-atrial septum

26mm Sapien-3 valve (21ml, nominal pr.)

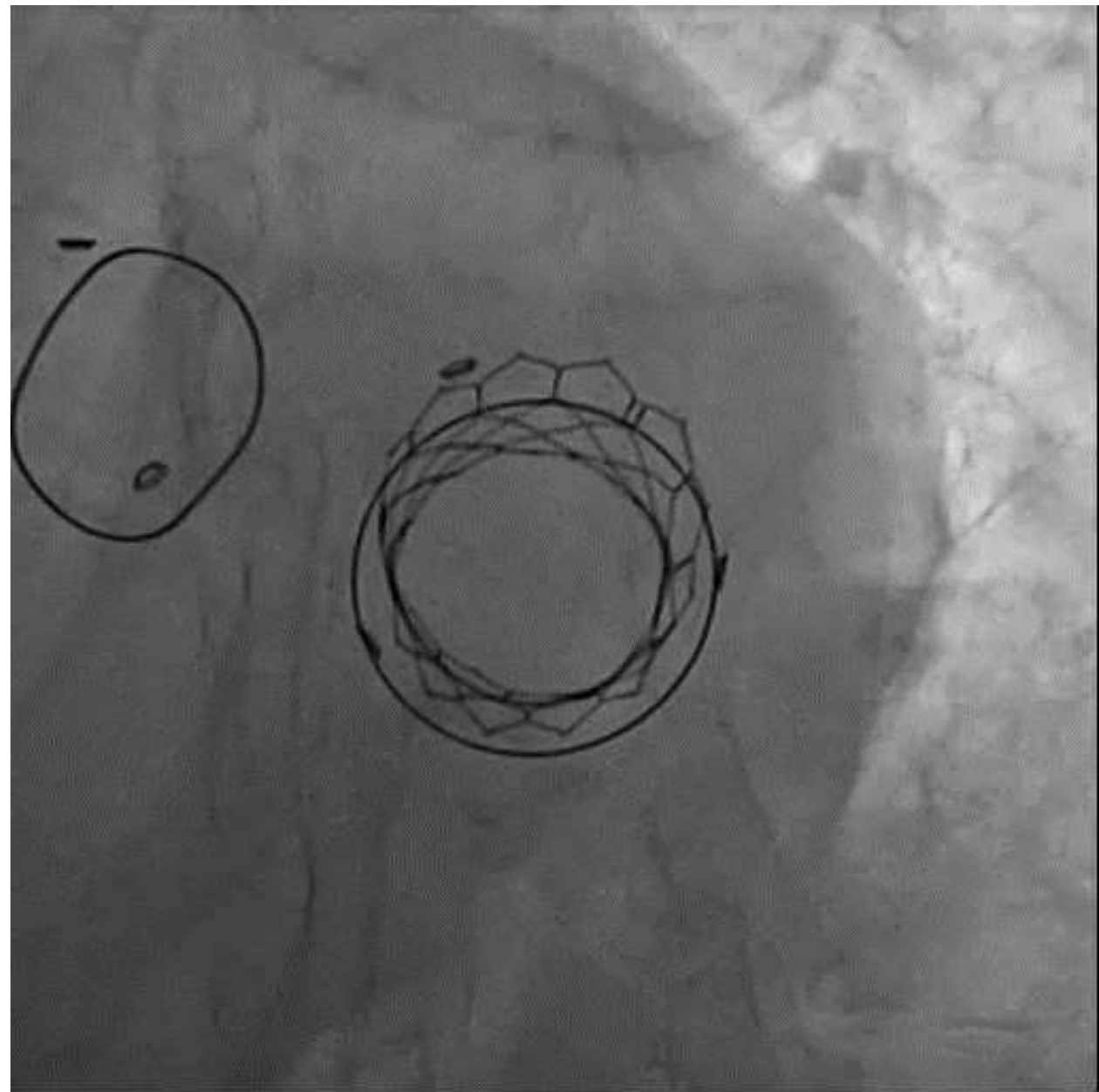
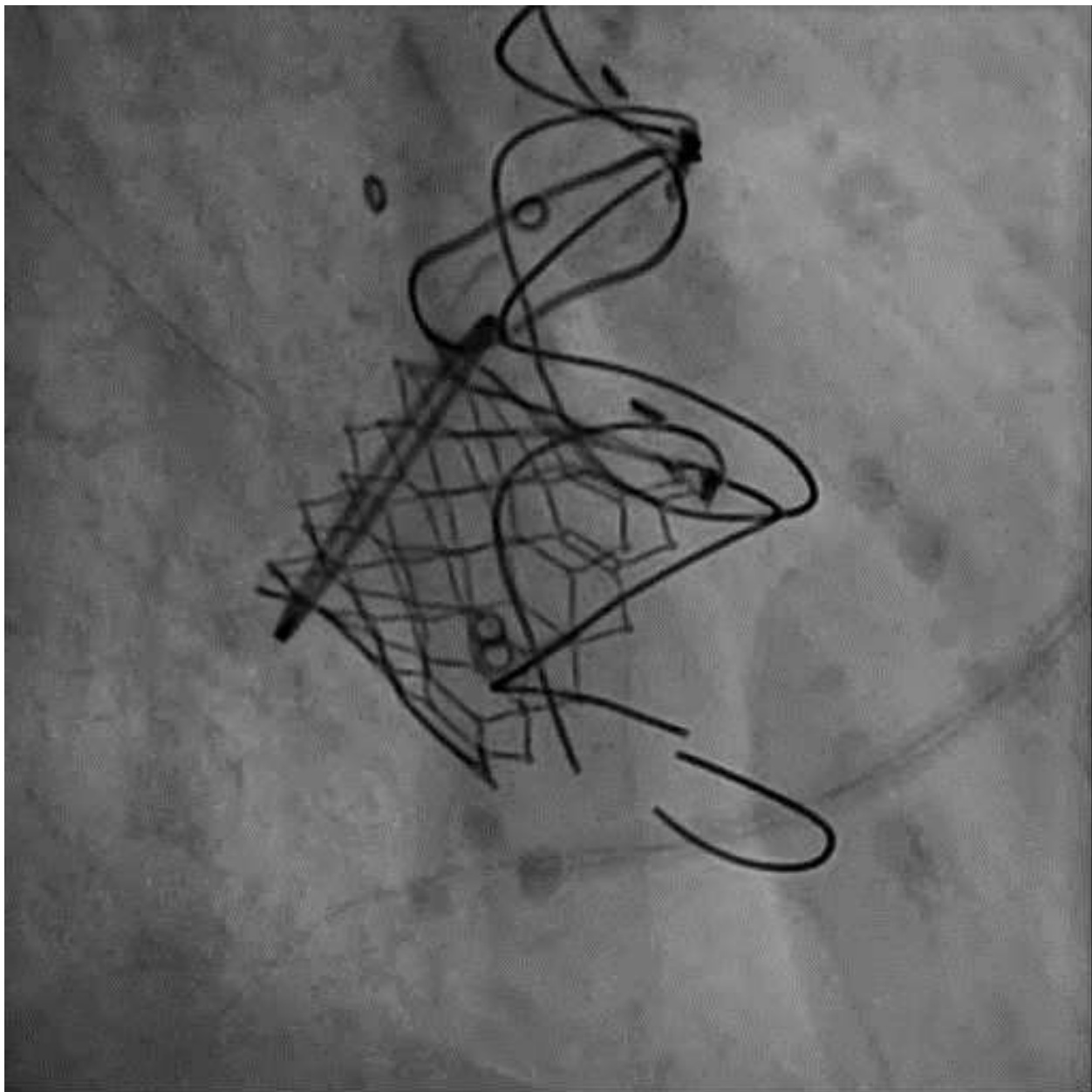


# Crossing inter-atrial septum and valve implantation



# Final images

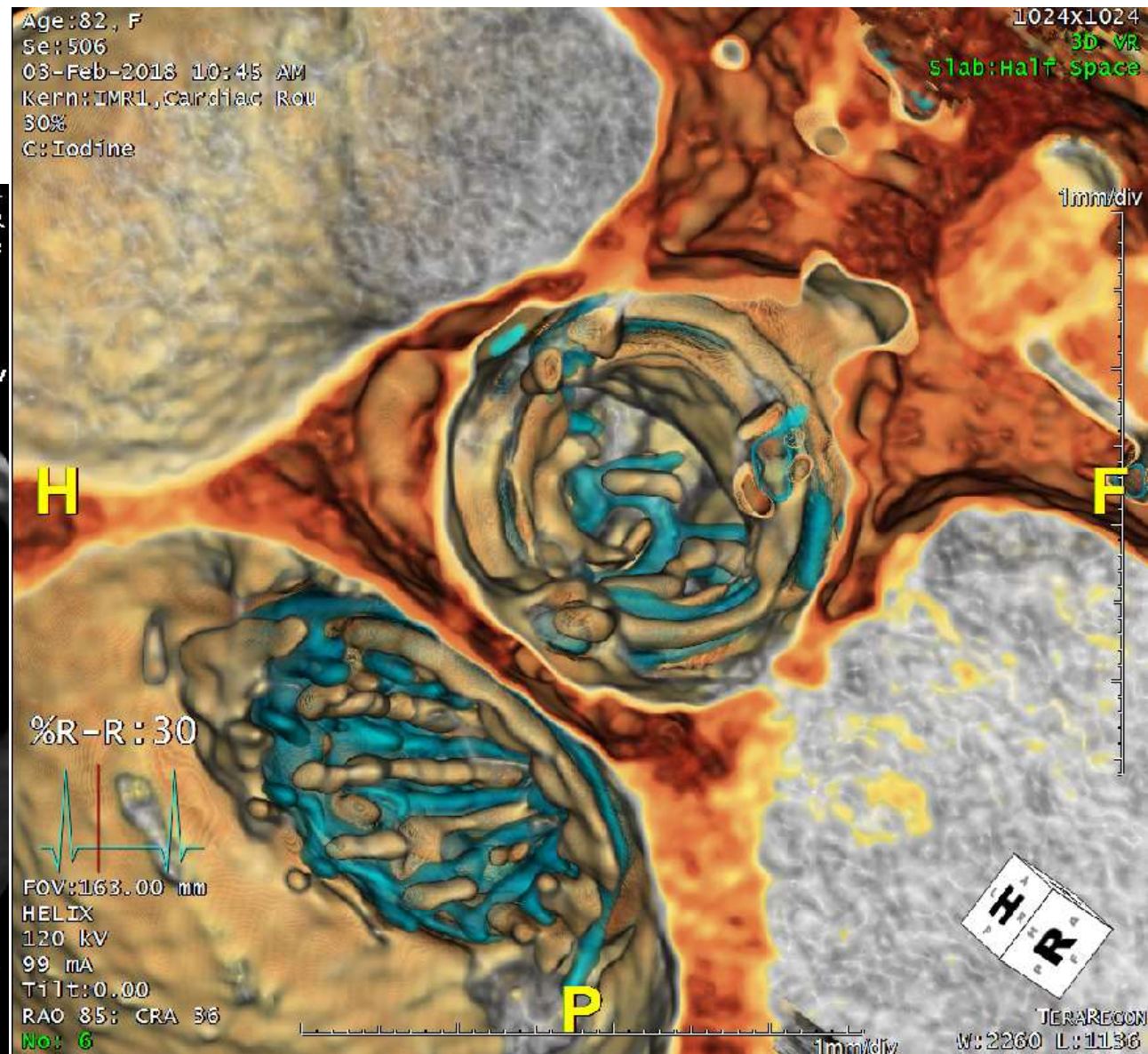
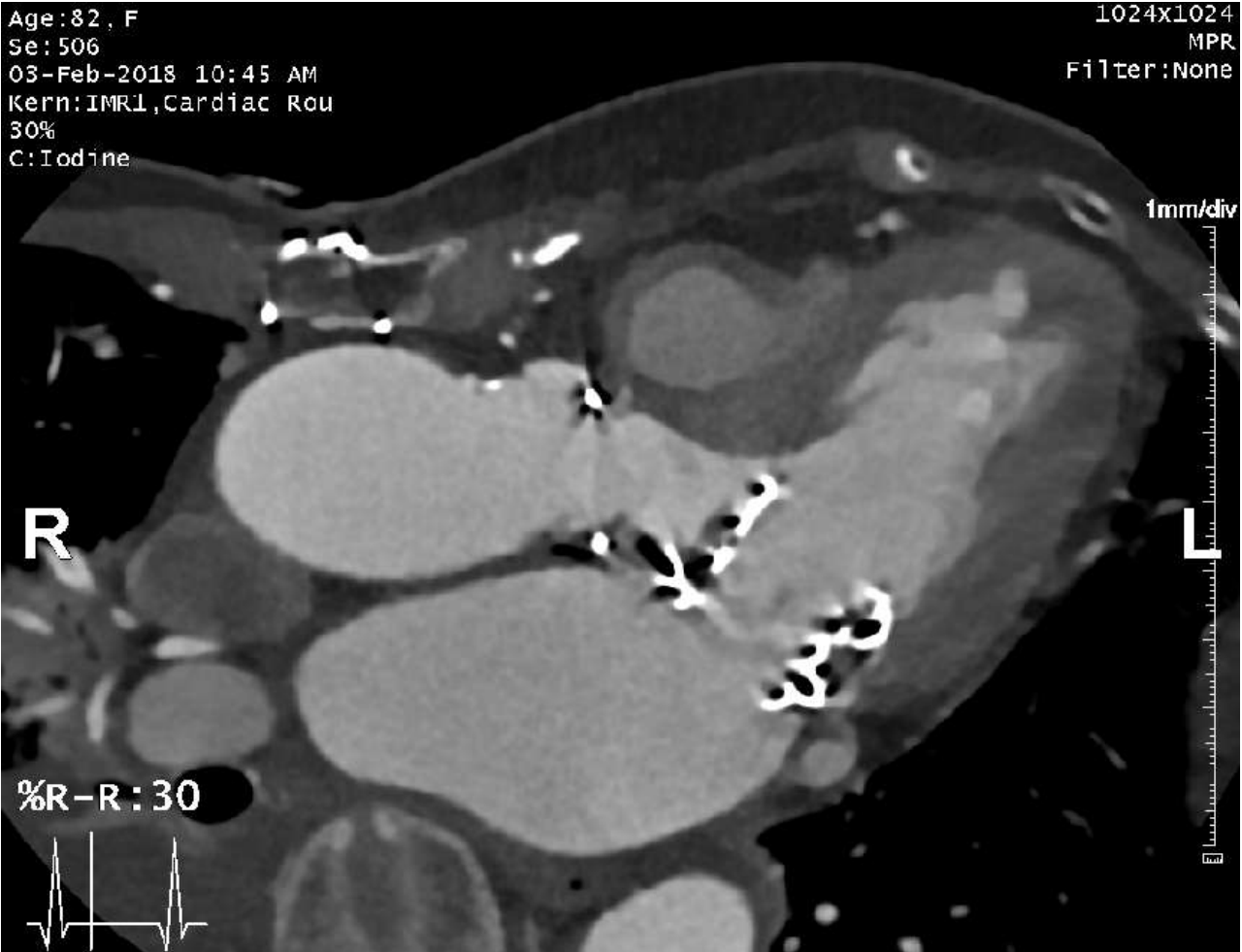
26mm Sapien-3 valve



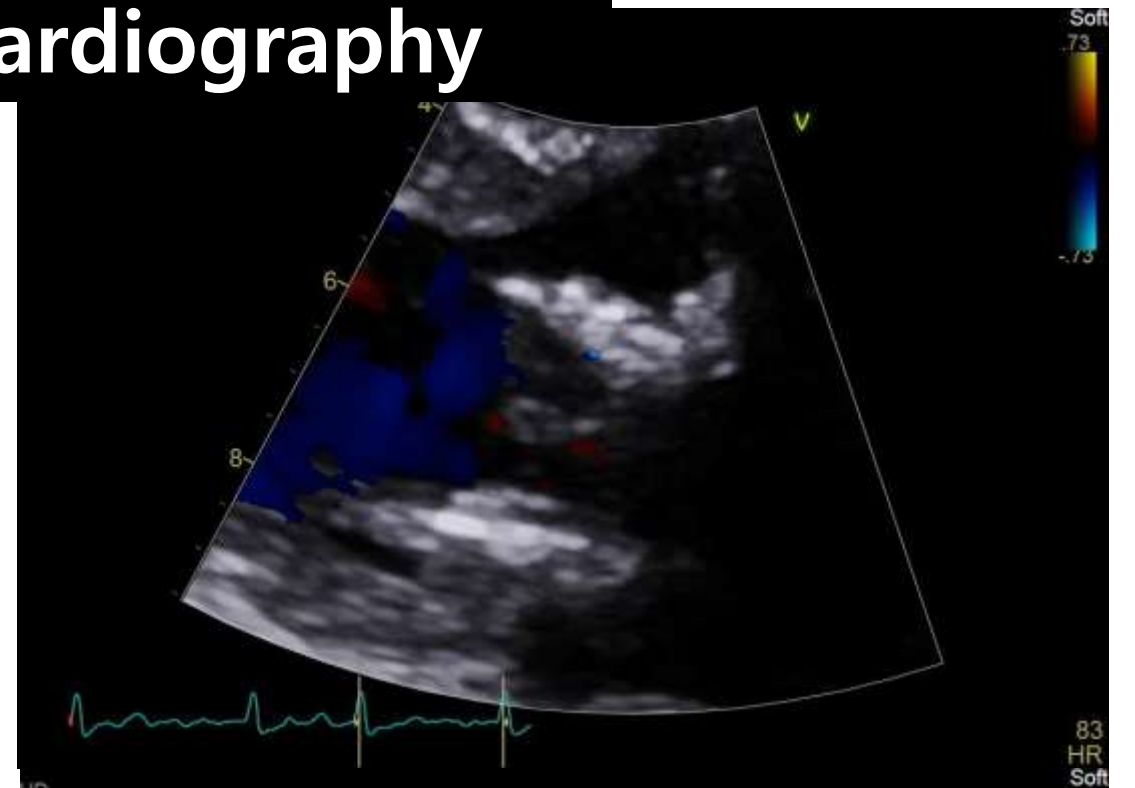
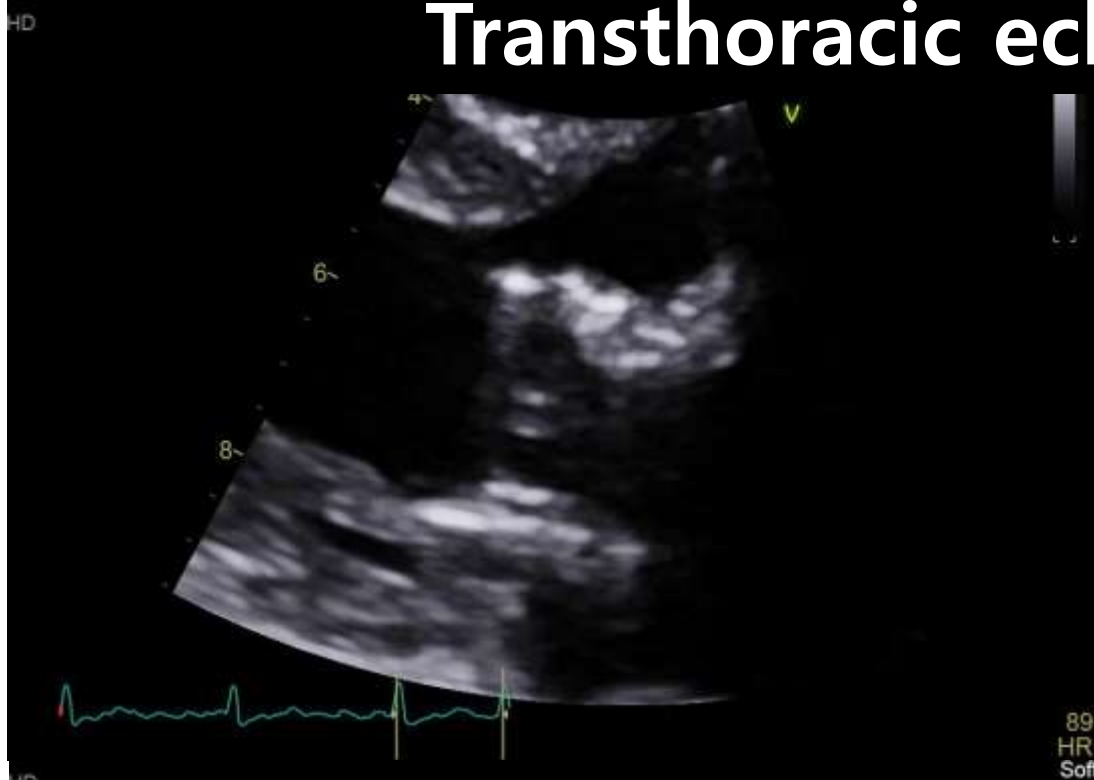


# Post-procedure CT

## Neo-LVOT



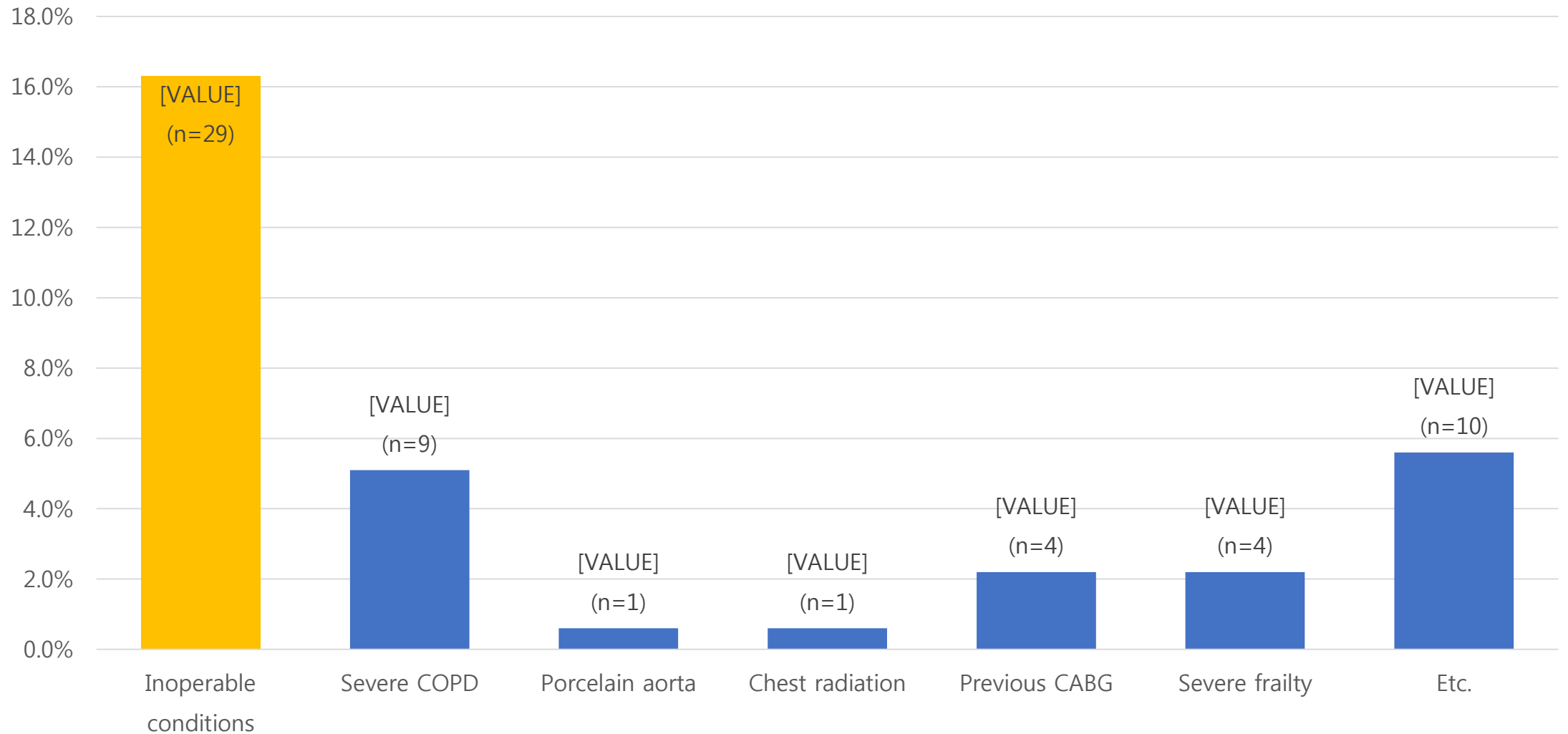
# Transthoracic echocardiography



# Baseline Characteristics (Sapien 3, n=98)

<b>Variable</b>	<b>Statistics</b>
<b>Age (Years)</b>	<b>78.6±5.8</b>
<b>Gender – Female</b>	<b>90 (50.6%)</b>
<b>DM</b>	<b>54 (30.3%)</b>
<b>HTN</b>	<b>139 (78.1%)</b>
<b>Atrial fibrillation or flutter</b>	<b>19 (10.7%)</b>
<b>Stroke or TIA</b>	<b>21 (11.8%)</b>
<b>CAD</b>	<b>73 (41.0%)</b>
<b>PAOD</b>	<b>22 (12.4%)</b>
<b>Creatinine (mg/dL)</b>	<b>1.37±1.60</b>
<b>CKD on dialysis</b>	<b>10 (5.6%)</b>
<b>STS score</b>	<b>6.21±5.79</b>

# Inoperable Conditions



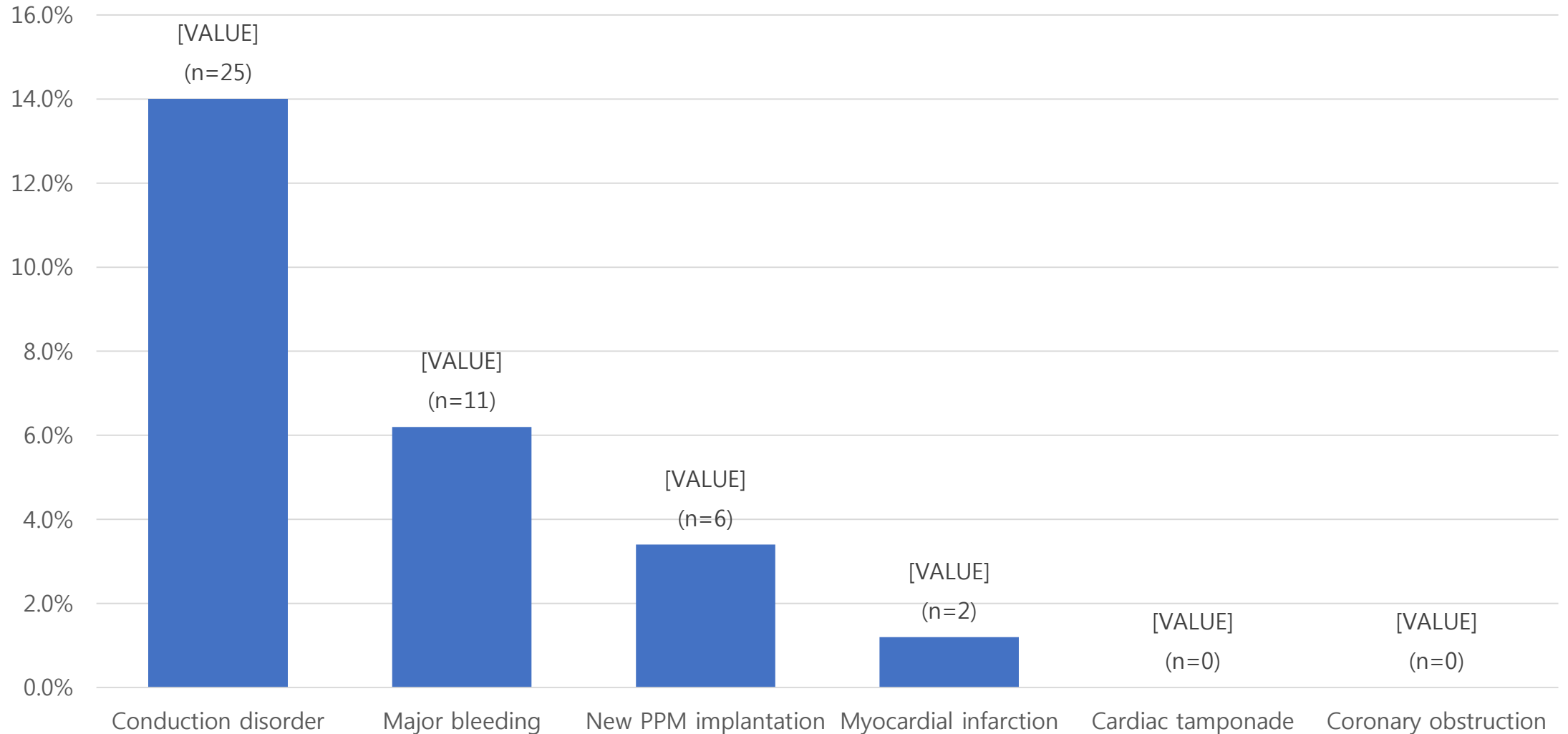
# Procedural Characteristics (N=98)

<b>Variable</b>	<b>Statistics</b>
<b>Approach</b>	
Femoral	99.4%
Apical	0.6%
<b>Operation room</b>	
Hybrid room	67.4%
Cath room	32.6%
<b>Anesthesia duration (mins)</b>	<b>114.7±32.7</b>
General anesthesia	64.6%
Conscious sedation	35.4%
<b>Puncture to close time (mins)</b>	<b>69.1±26.5</b>

# Procedural Characteristics (N=98)

Variable	Statistics
Device success	96.6%
Valve size	
23 mm	43.8%
26 mm	46.6%
29 mm	9.6%
Post ballooning	5.1%
TAV-in-TAV deployment	1.1%

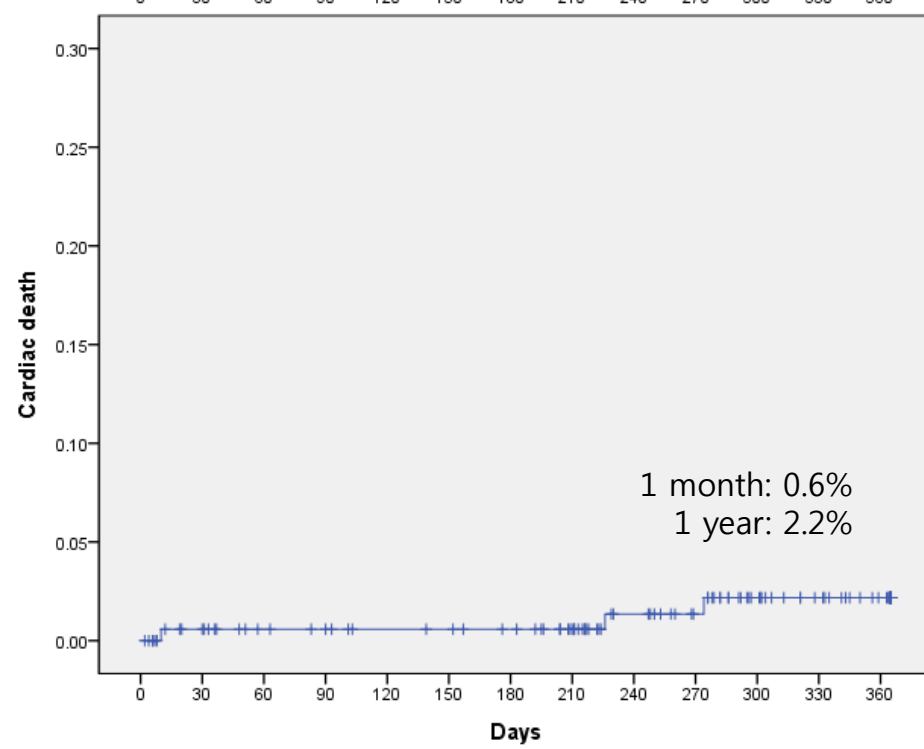
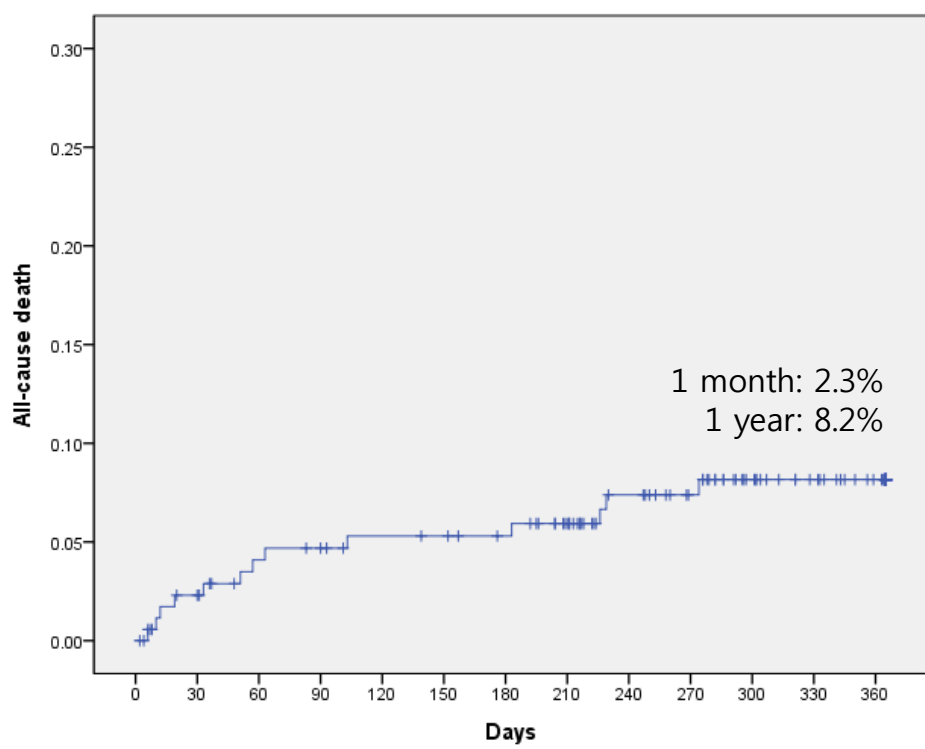
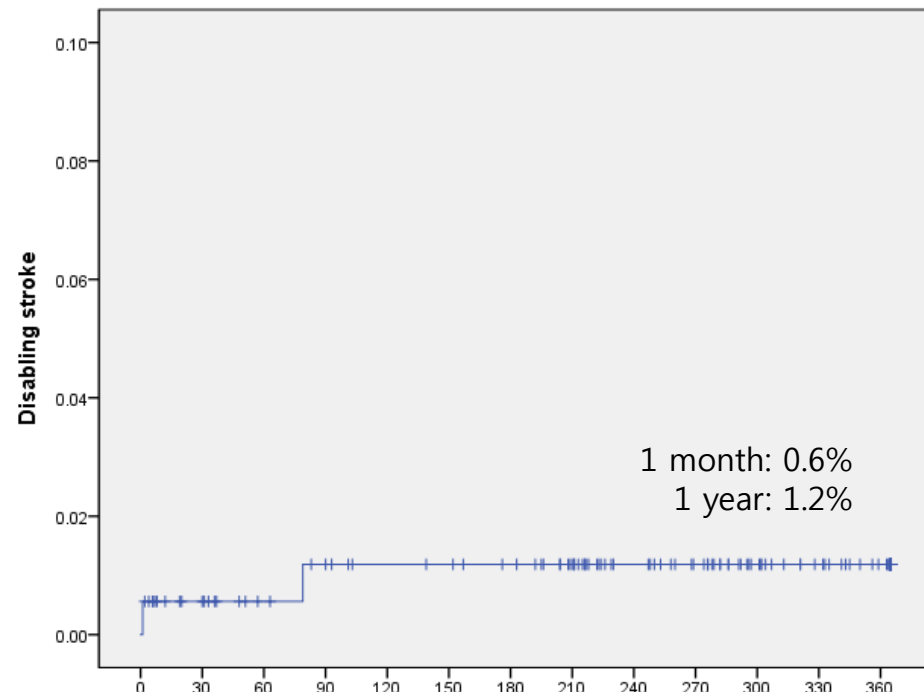
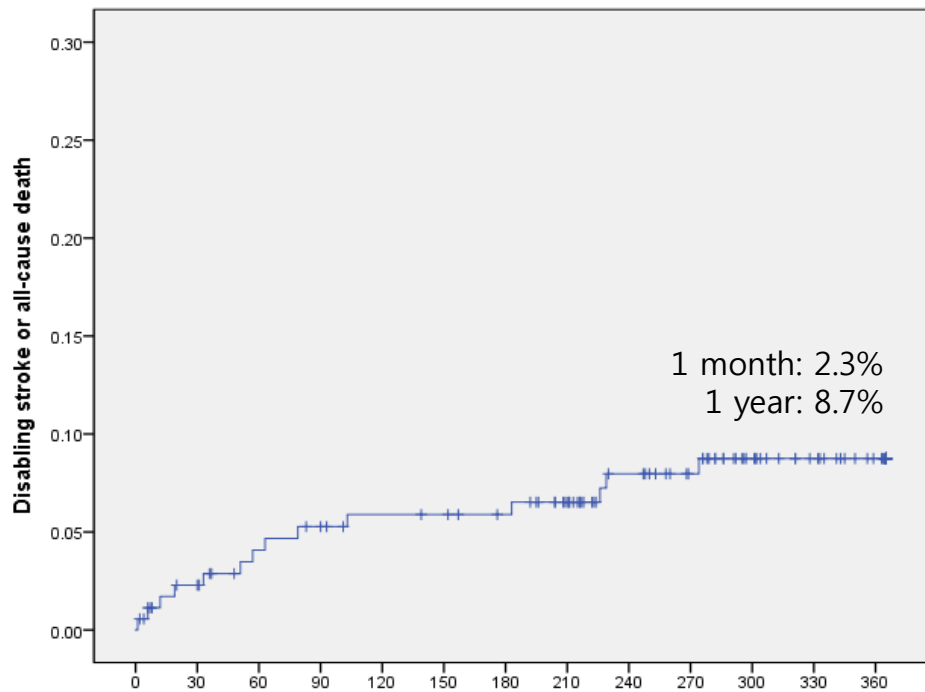
# In-hospital complications

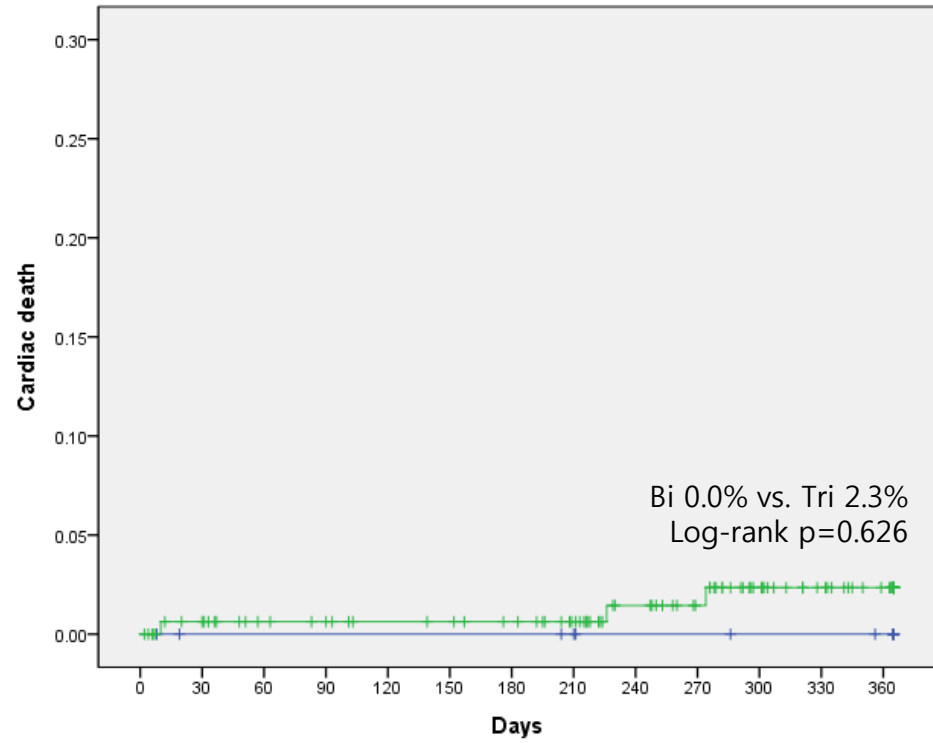
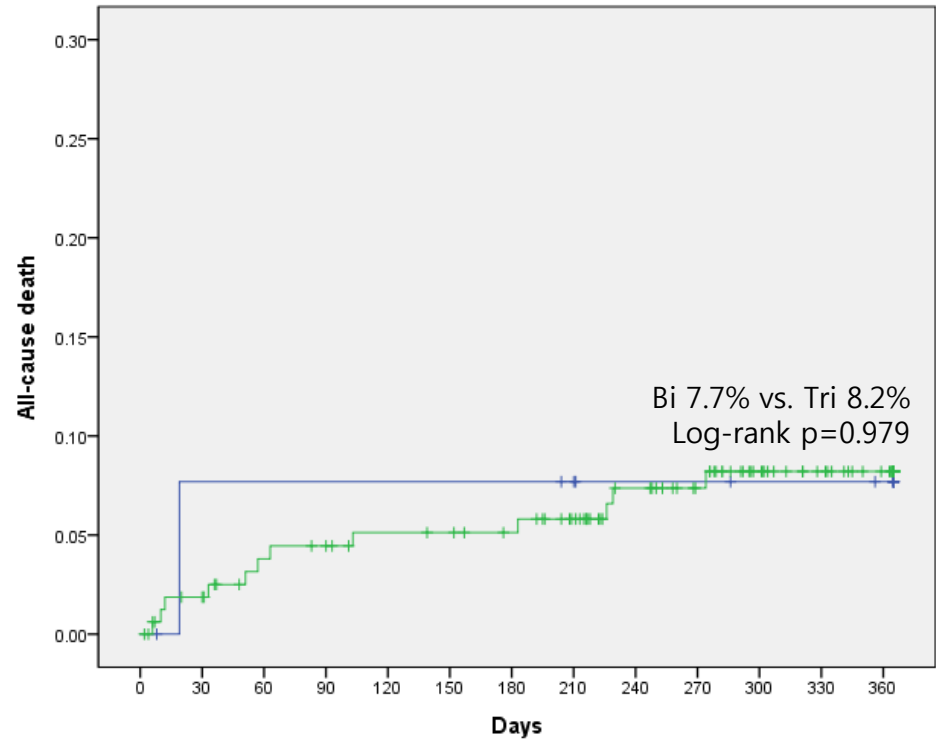
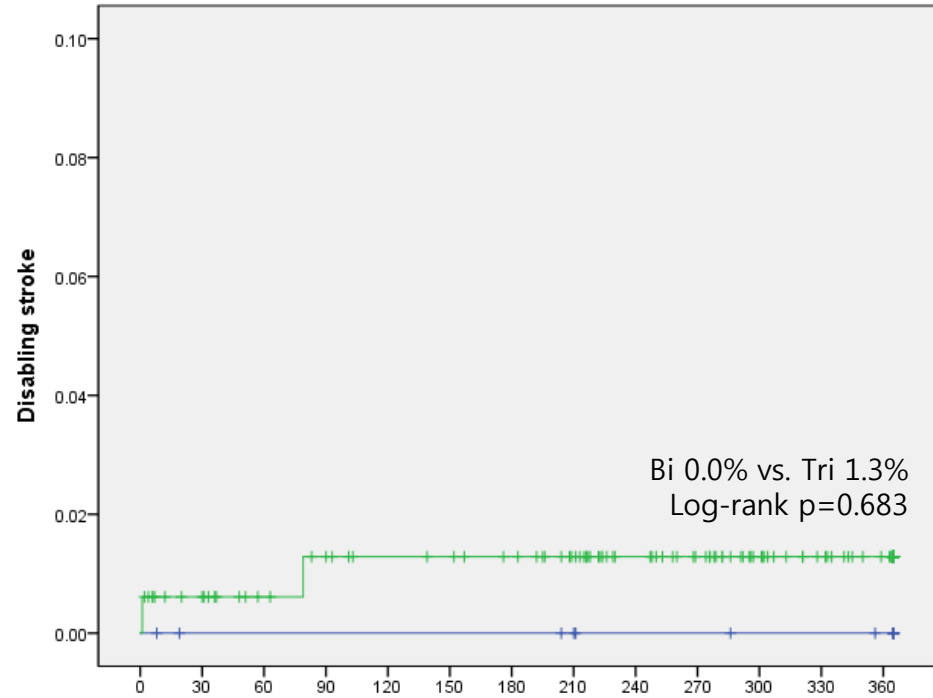
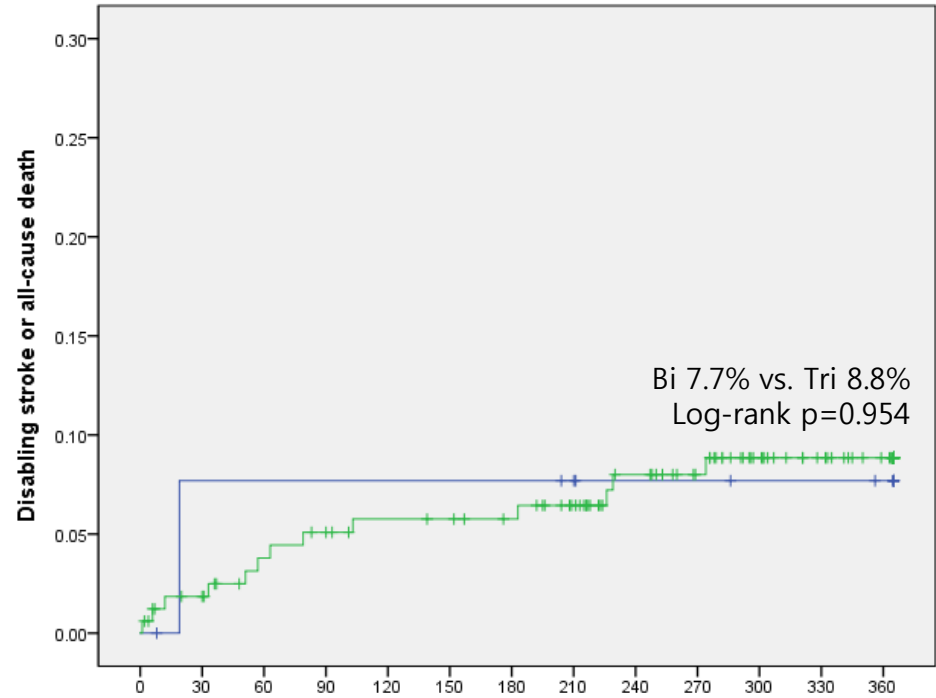


# In-hospital outcomes

<b>Variable</b>	<b>Statistics</b>
<b>Hospitalization period (Days)</b>	<b>11.1±7.1</b>
<b>TAVI to discharge (Days)</b>	<b>6.4±5.5</b>
<b>Disabling stroke or all-cause death</b>	<b>3 (1.7%)</b>
<b>All-cause death</b>	<b>3 (1.7%)</b>
<b>Cardiac death</b>	<b>1 (0.6%)</b>
<b>Disabling stroke</b>	<b>1 (0.6%)</b>







- Bicuspid  
- Tricuspid

# In summary

- After introducing new generation devices, TAVI experiences is increasing for complex patients subset such as bicuspid AS in Korea.
- Even though there are several issues to be solved about TAVI using new generation devices for bicuspid AS, which have showed similar clinical outcomes compared with TAVI for tricuspid AS in Korea.
- Transcatheter mitral ViV using Sapien 3 valve is feasible for patient with failed bioprosthetics. We expect that mitral ViV using Sapien 3 valve would increase and help patients with mitral bioprosthetic failure in Korea.

**Thank you for your attention**