



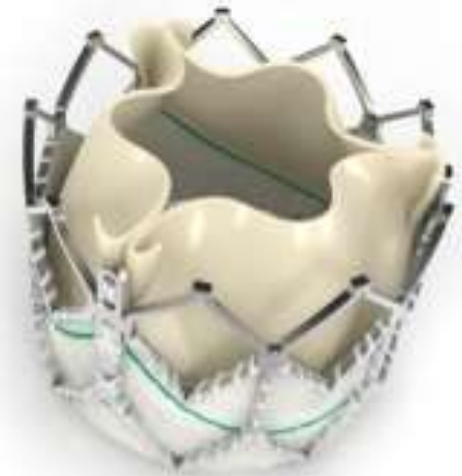
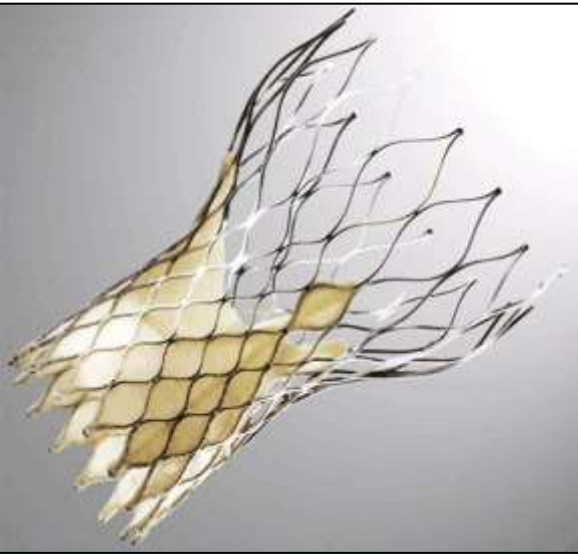
# *Advantage and disadvantage*

## *Sapien 3*

*Kentaro Hayashida MD, PhD, FESC*

*27<sup>th</sup>, April 2017, TCTAP, Seoul*

# Balloon vs. self expandable?

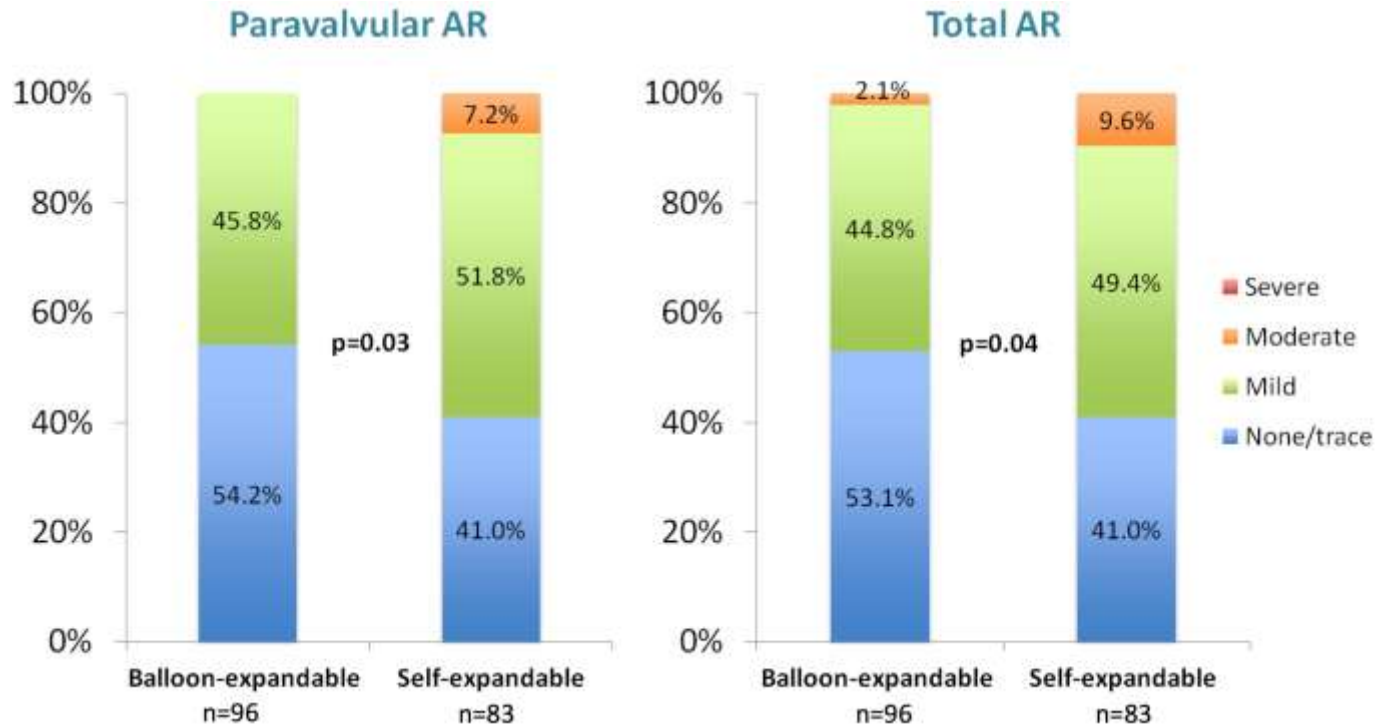


PVL  
Pacemaker  
TS, DA

Annulus rupture  
STJ injury  
Coronary occlusion  
TA, TAO

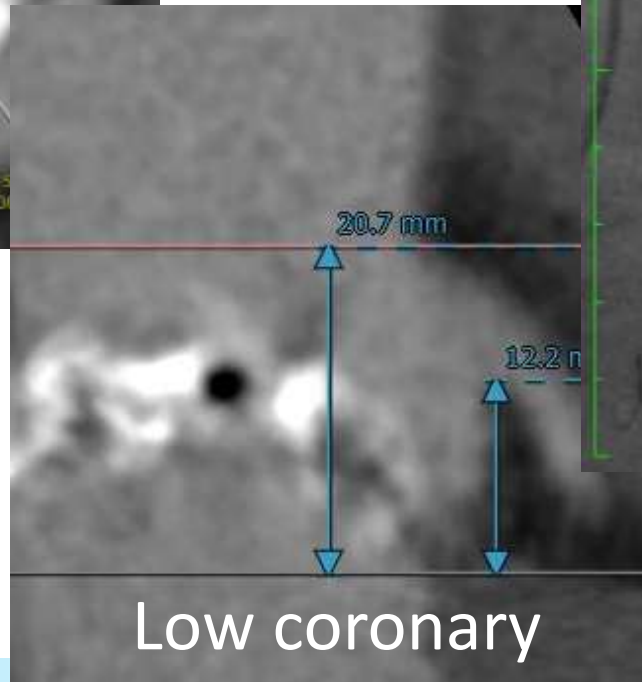
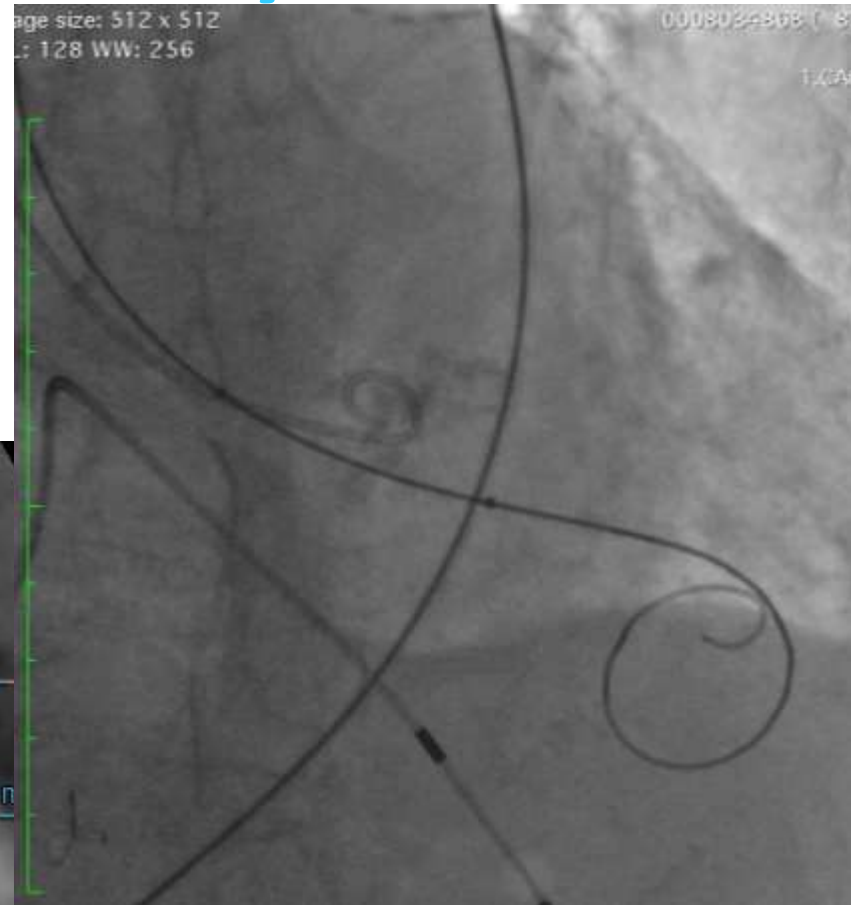
# CHOICE trial

	Balloon-expandable (n=121)	Self-expandable (n=117)	p-value
<b>Death</b>			
From any cause	5/121 (4.1%)	6/117 (5.1%)	0.77
From CV causes	5/121 (4.1%)	5/117 (4.3%)	0.99

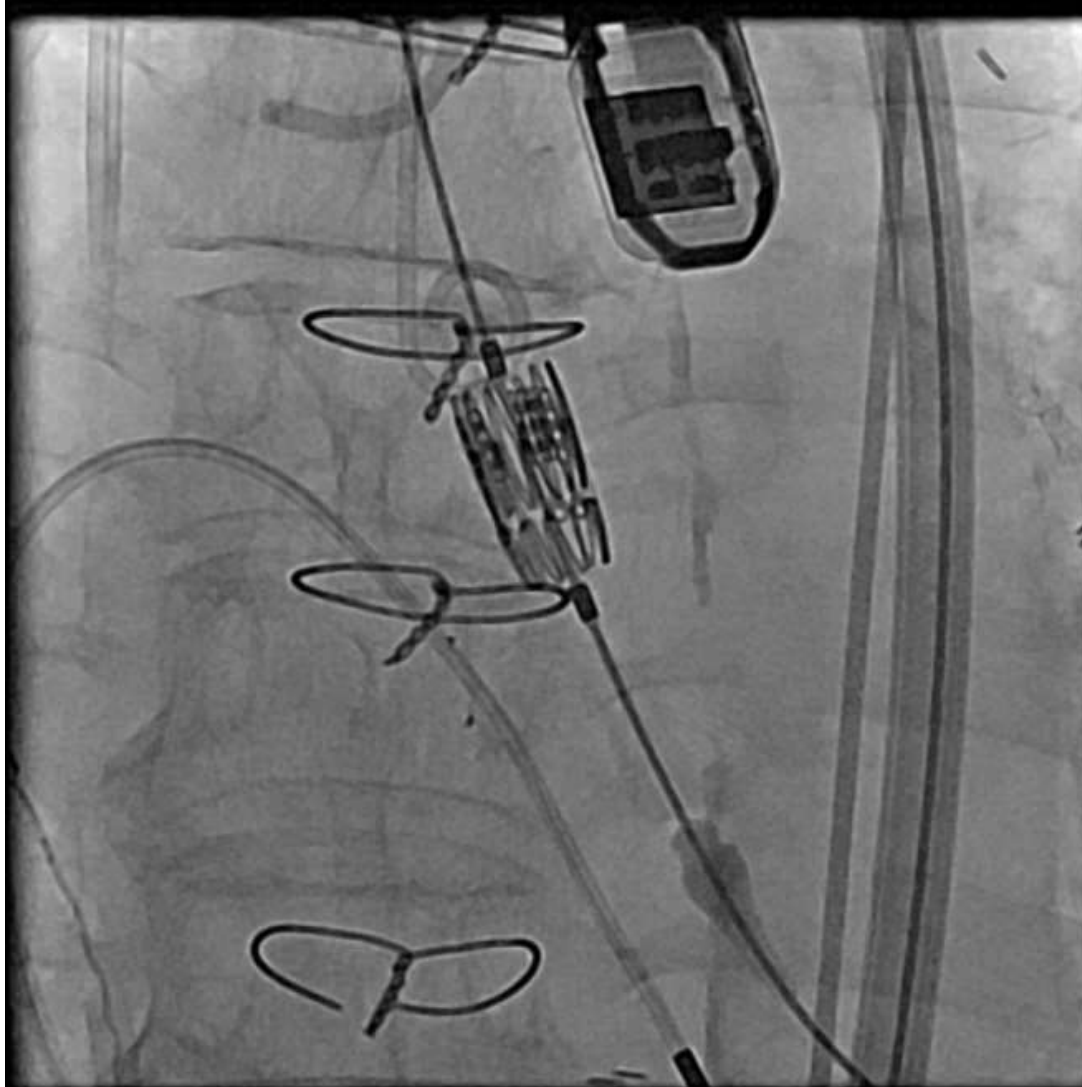


Abdel-Wahab et al. JAMA 2014

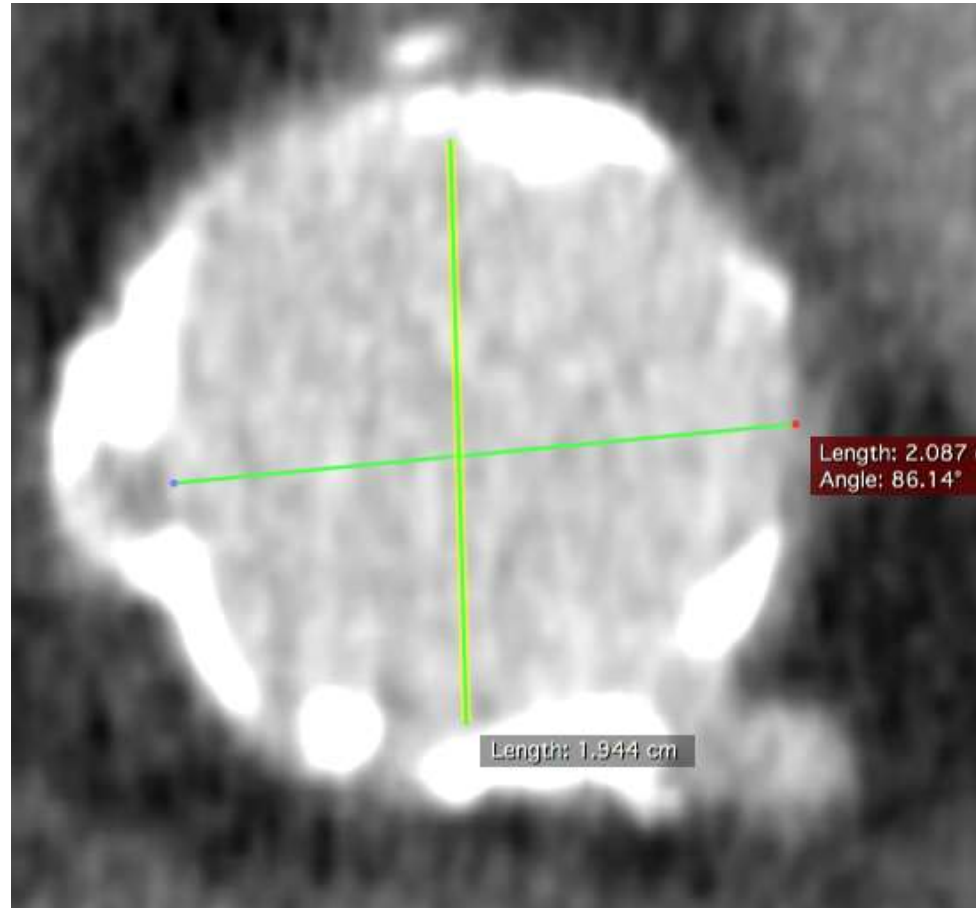
# Case 2: 83 yo female Risk for coronary occlusion

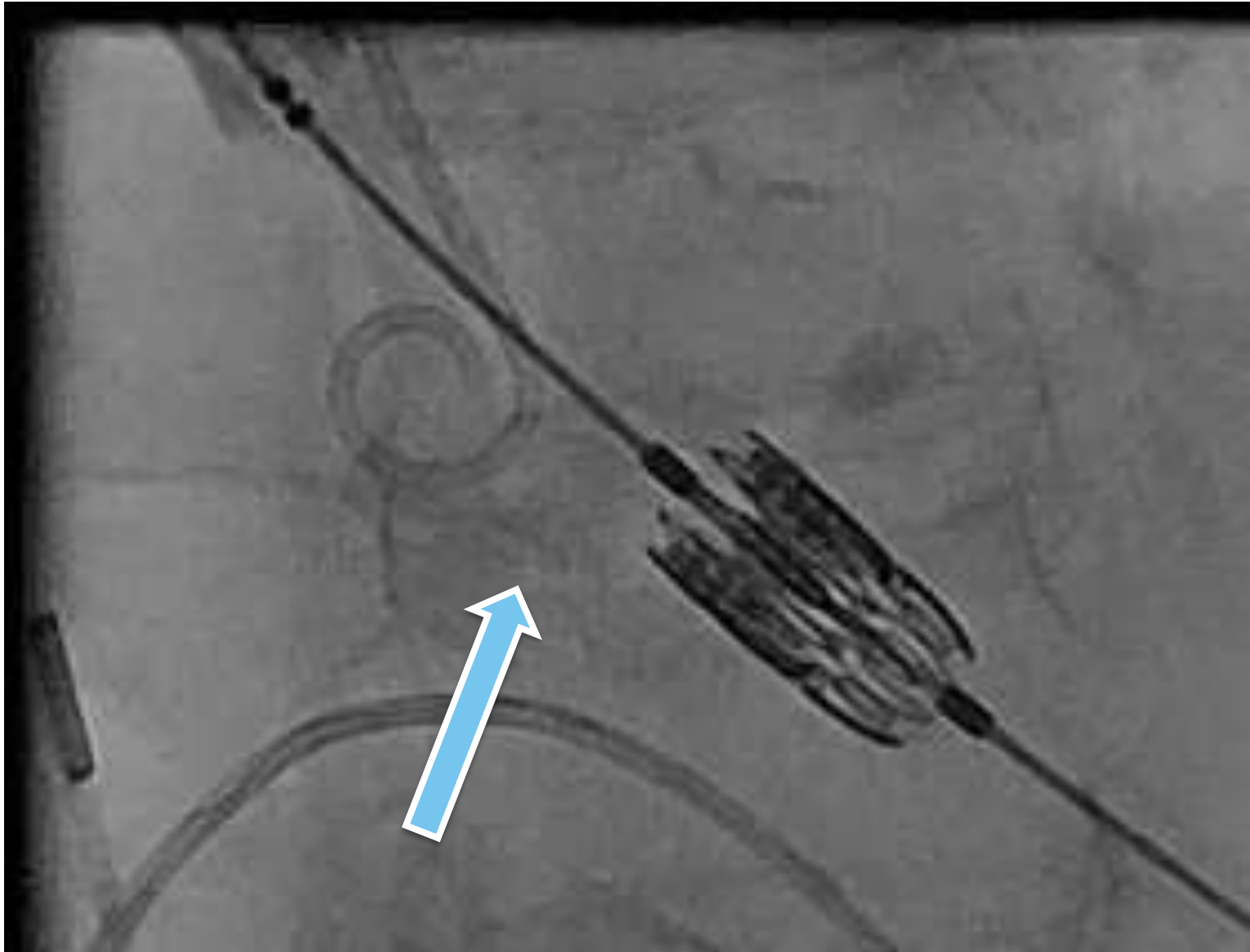


# Pacemaker is important

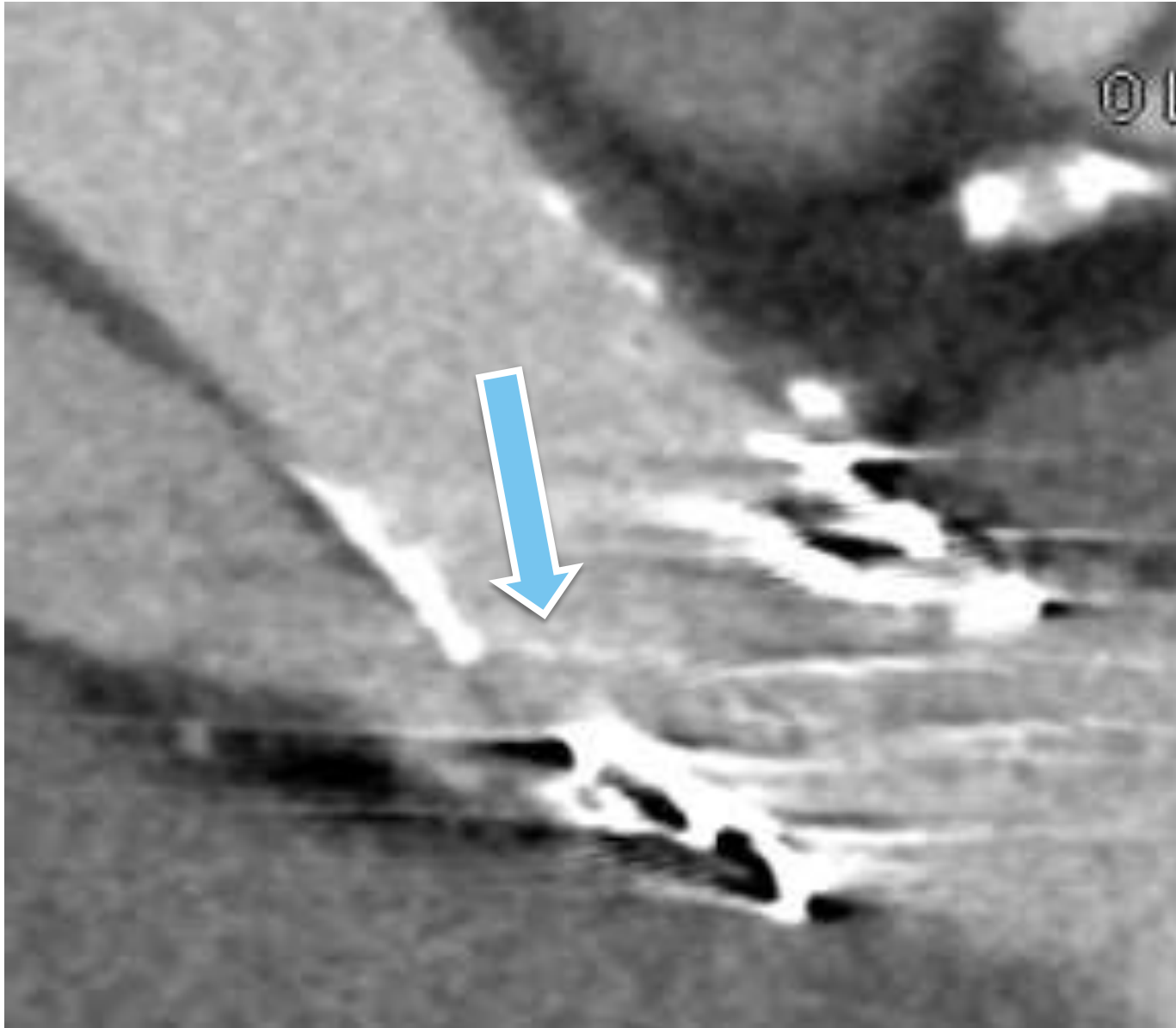


# Narrow ST-junction



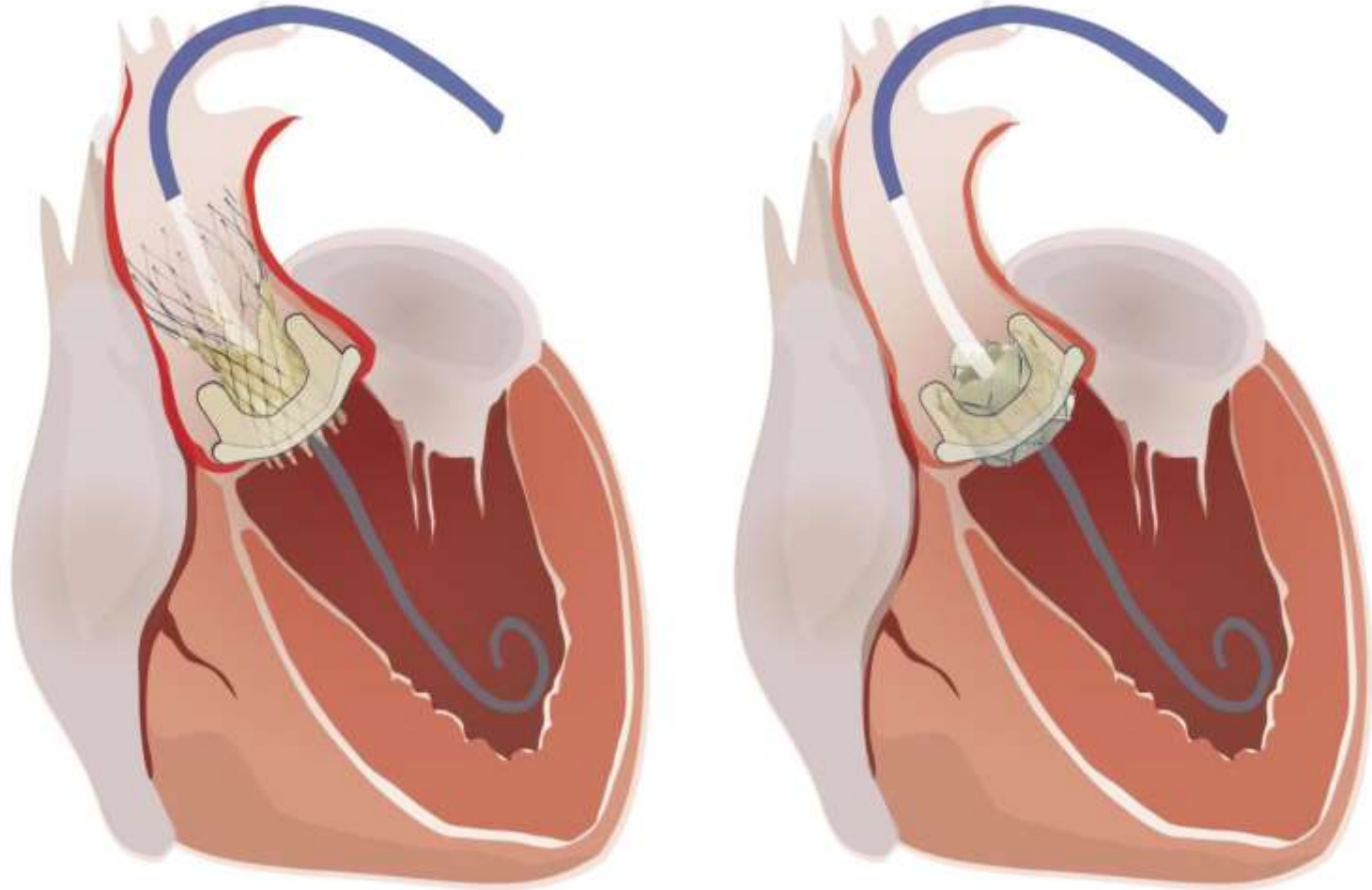




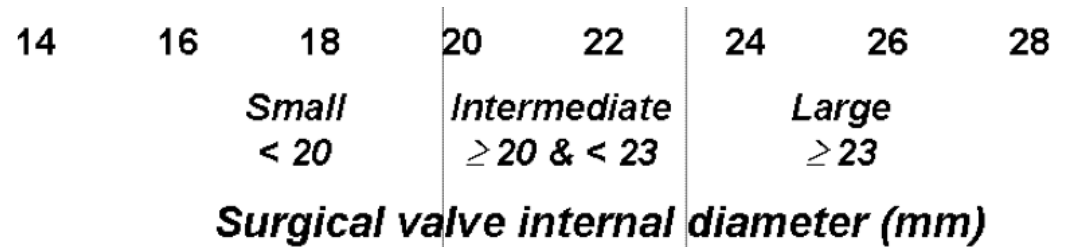




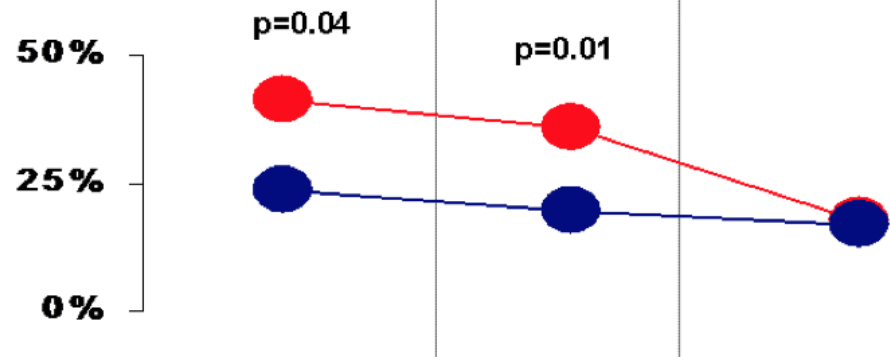
# Valve in valve procedure



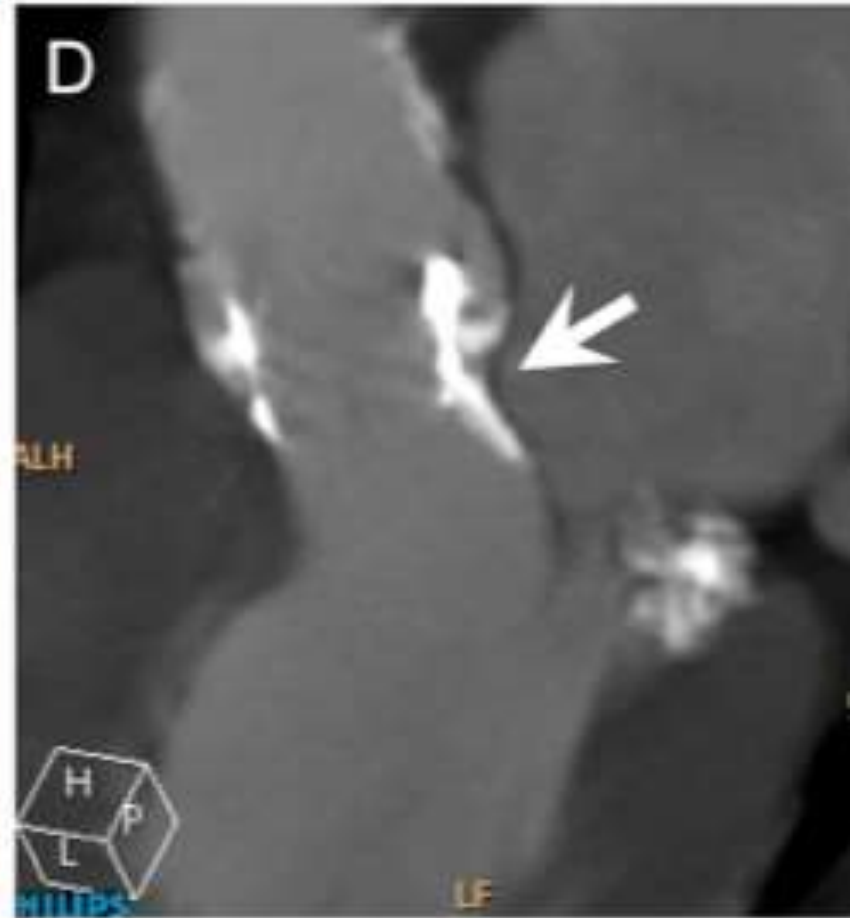
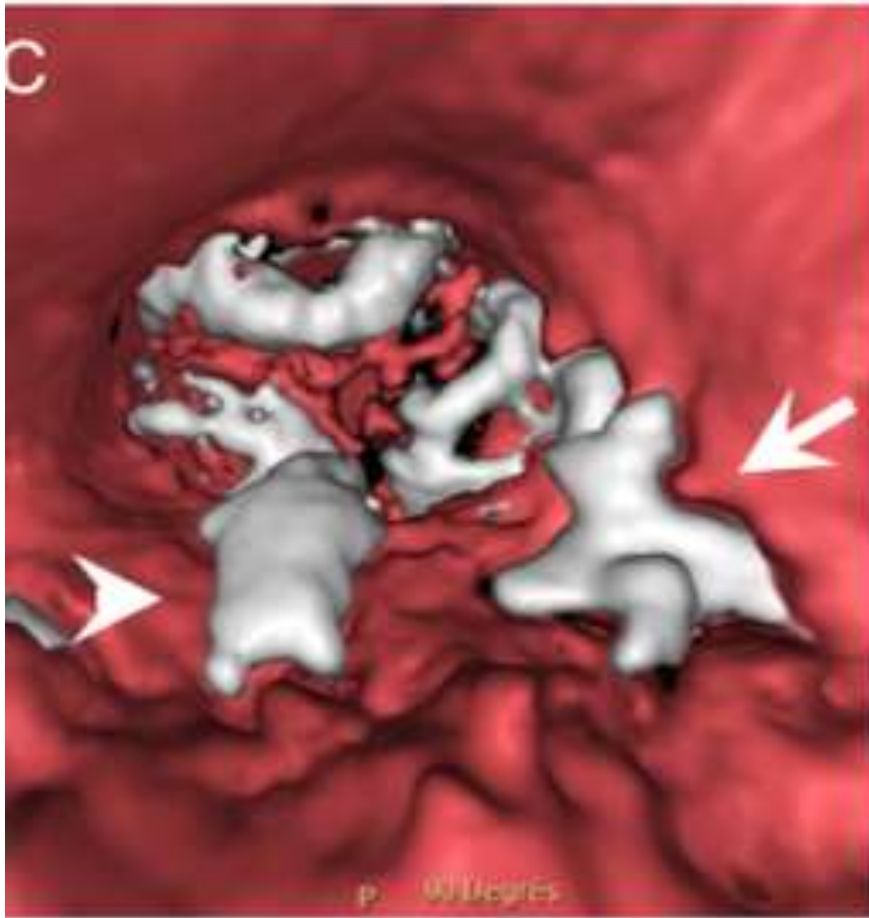
# PG after VIV procedure



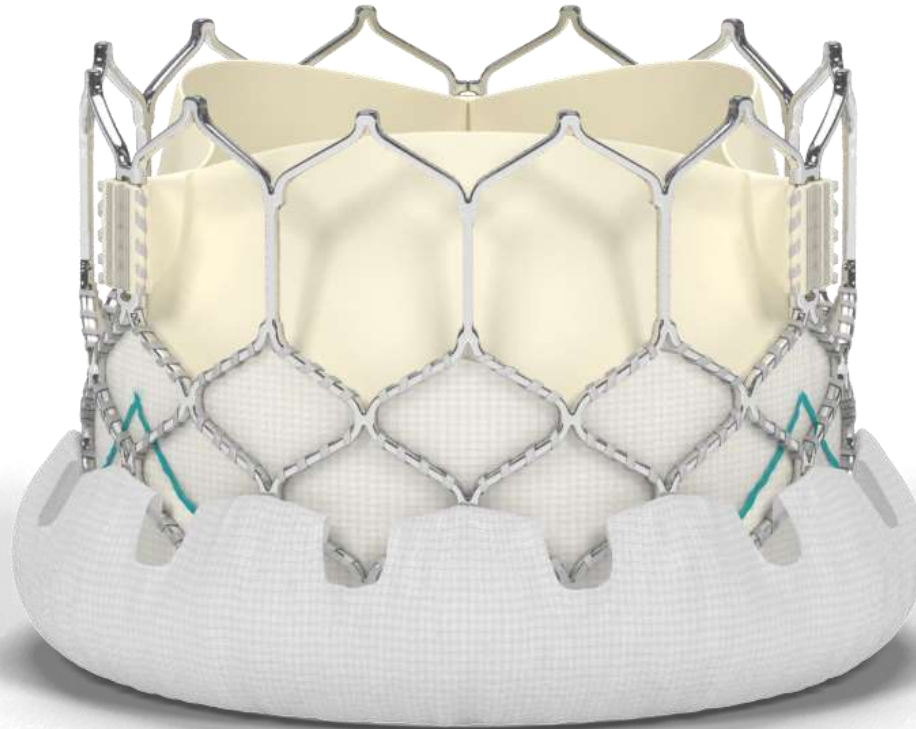
**C**  
**Rate of Post-procedural mean gradients  $\geq 20$ mmHg (%)**



# Calcium column leads to mitral valve



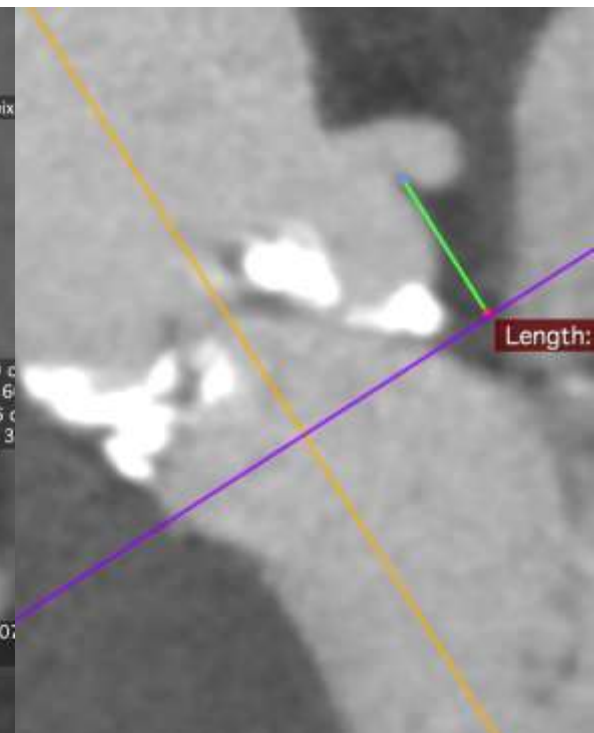
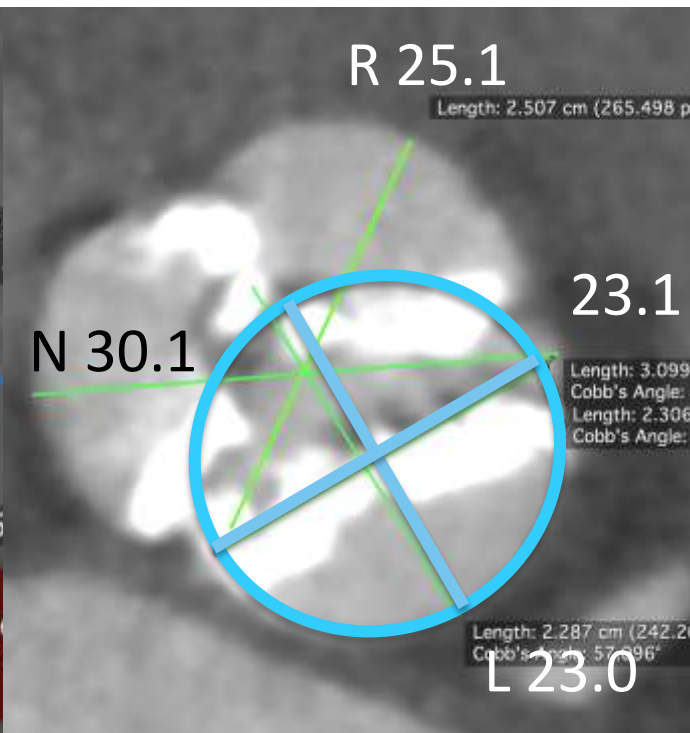
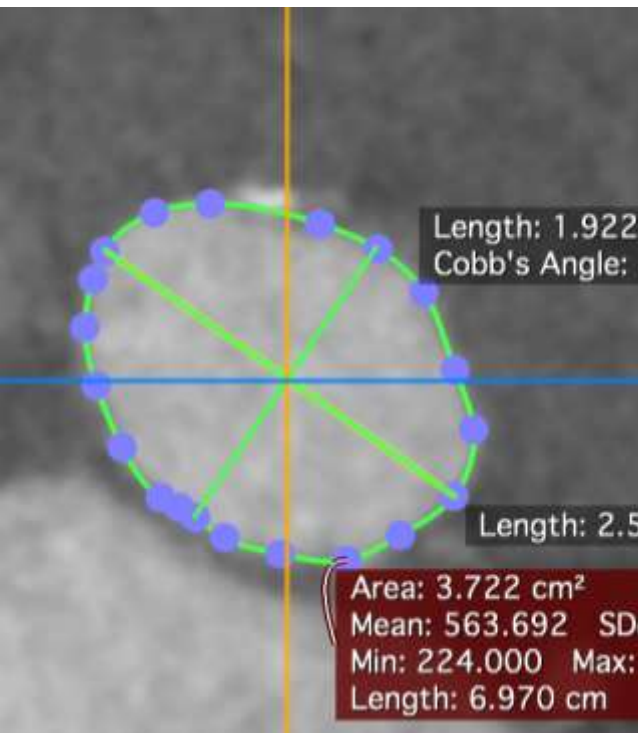
# Edwards Sapien 3



14Fr compatible

# Measurement of BAV

## Type 1 R-N

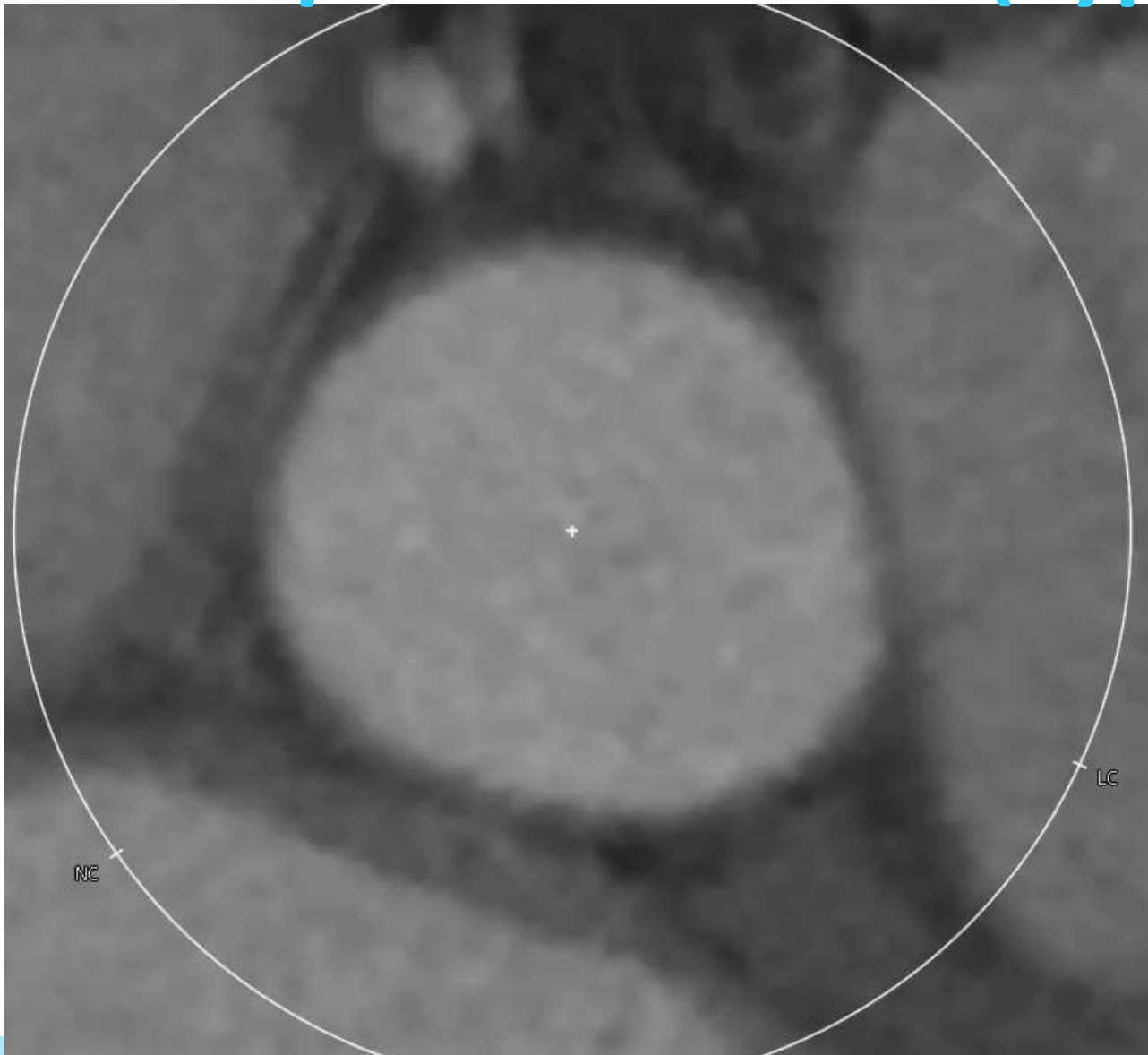


19.2 x 25.5 mm  
372 mm<sup>2</sup>

23.0 x 23.1 mm

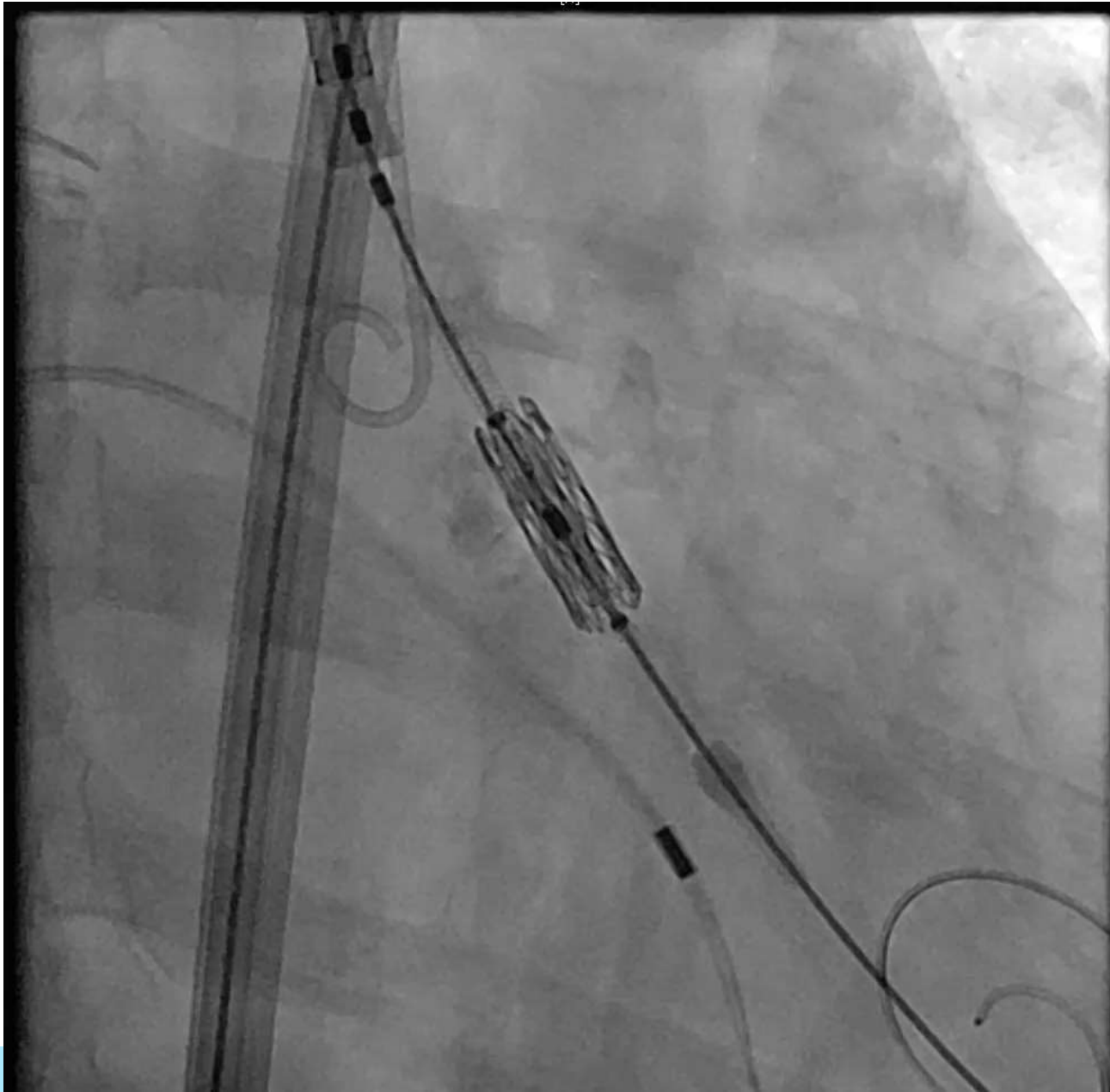
11.5 mm

# Bicuspid aortic valve (Type 0)



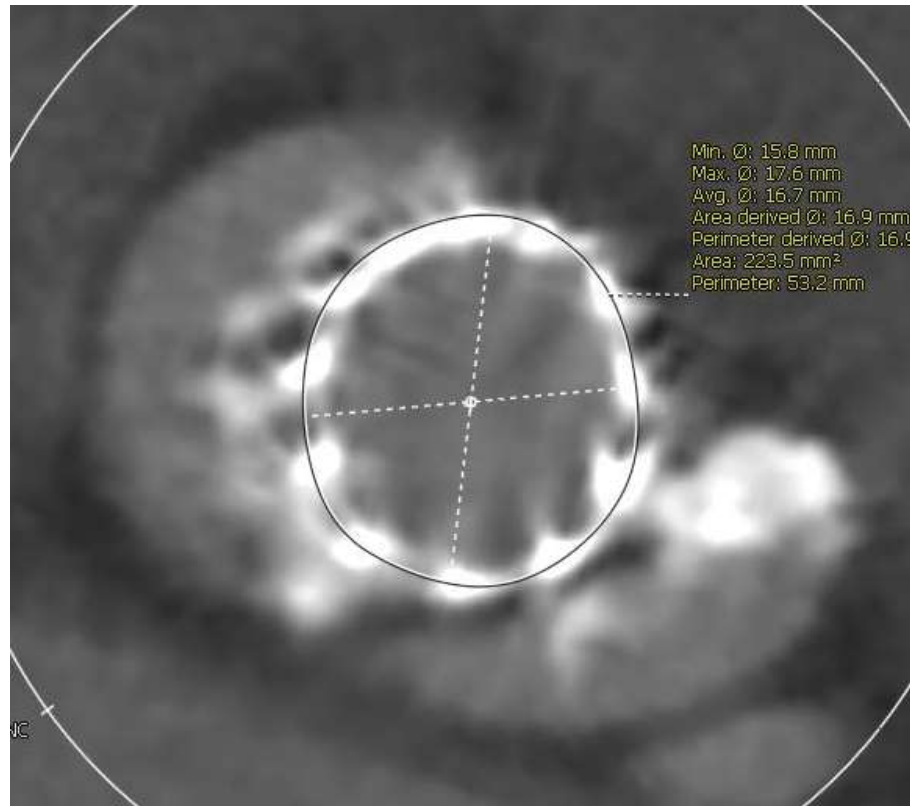


# TAVI with SAPIEN3 20mm (nominal volume)

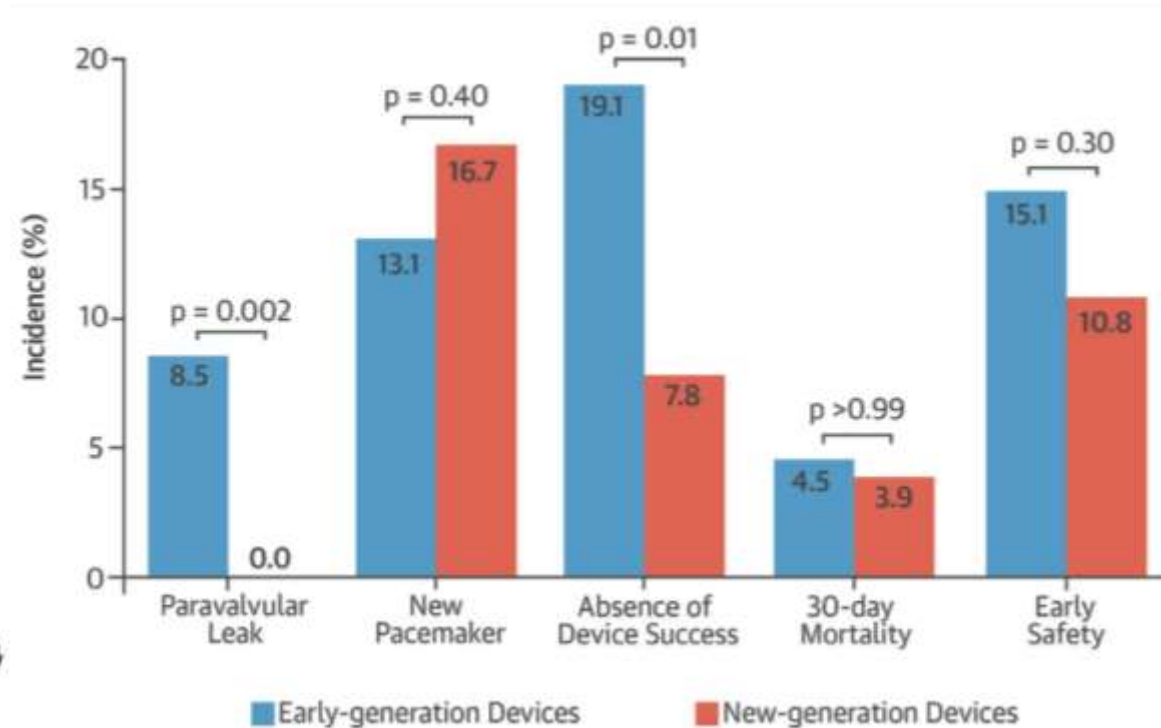
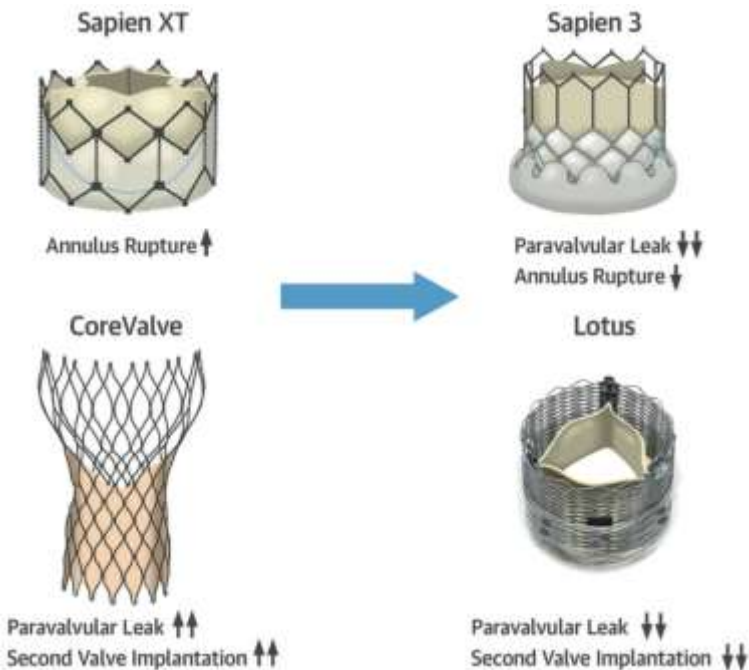




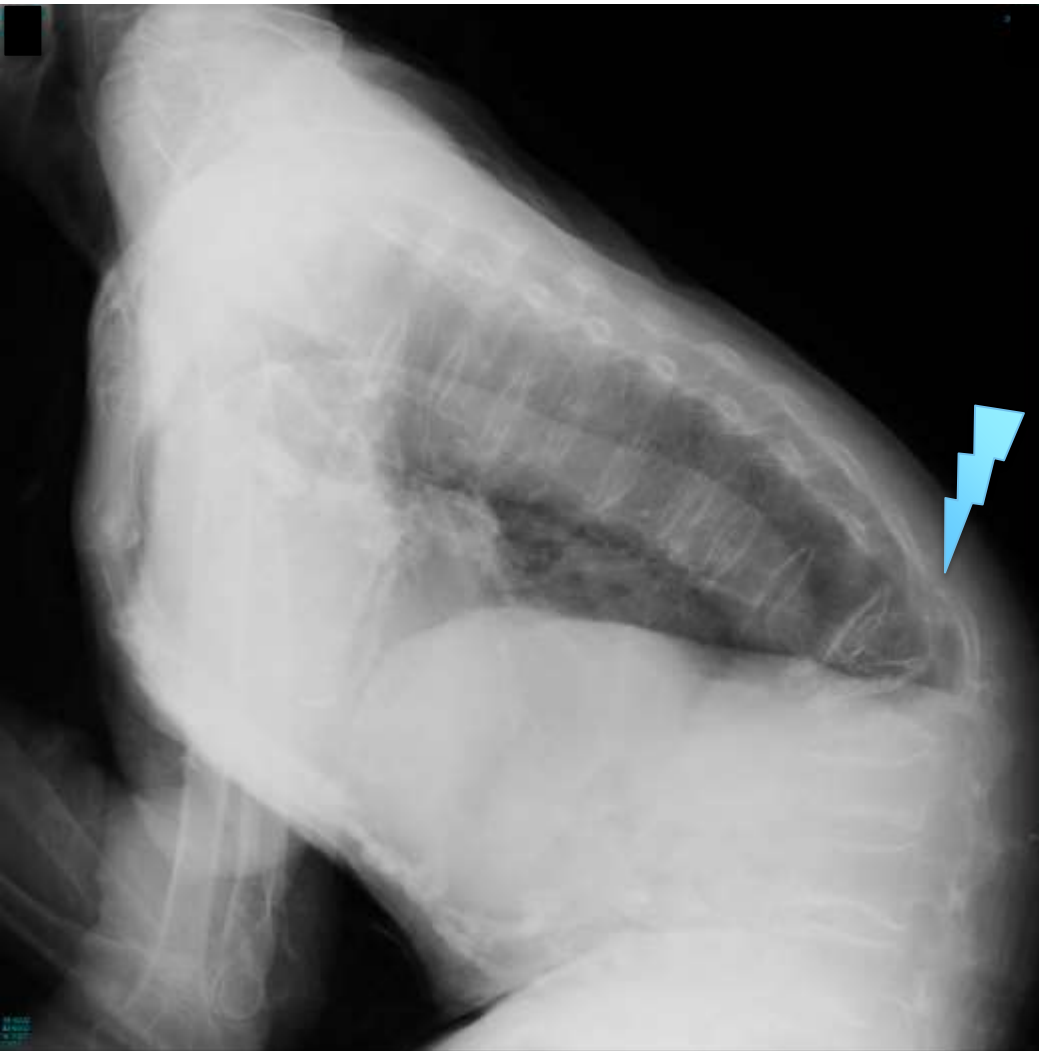
# Post-procedural MDCT



# New generation devices improves clinical outcomes of TAVI for bicuspid valve



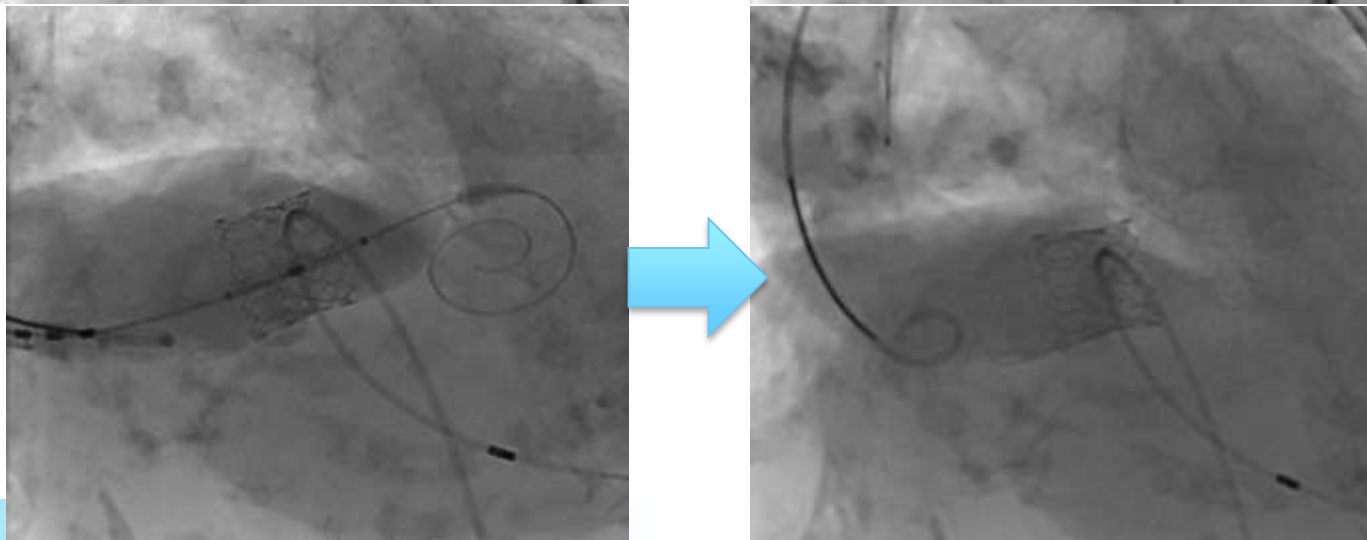
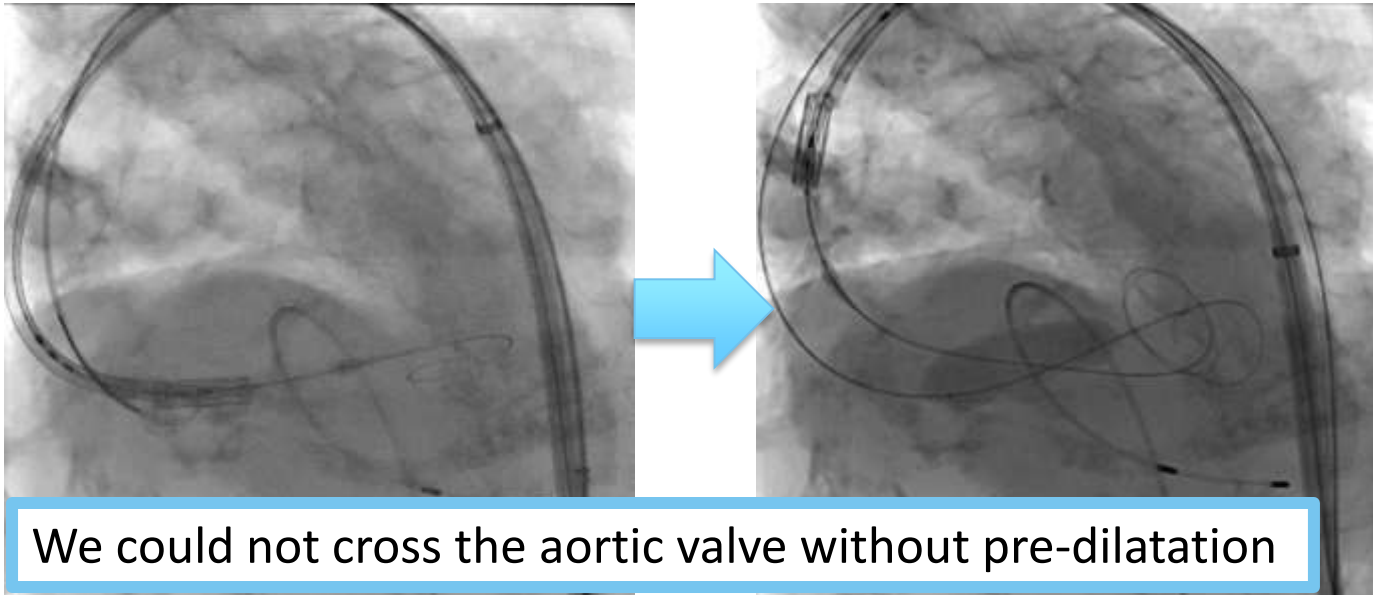
# Severe kyphosis



★ Significant bend of the aorta

# Totally horizontal aortic root

Balloon dilatation via the contralateral access

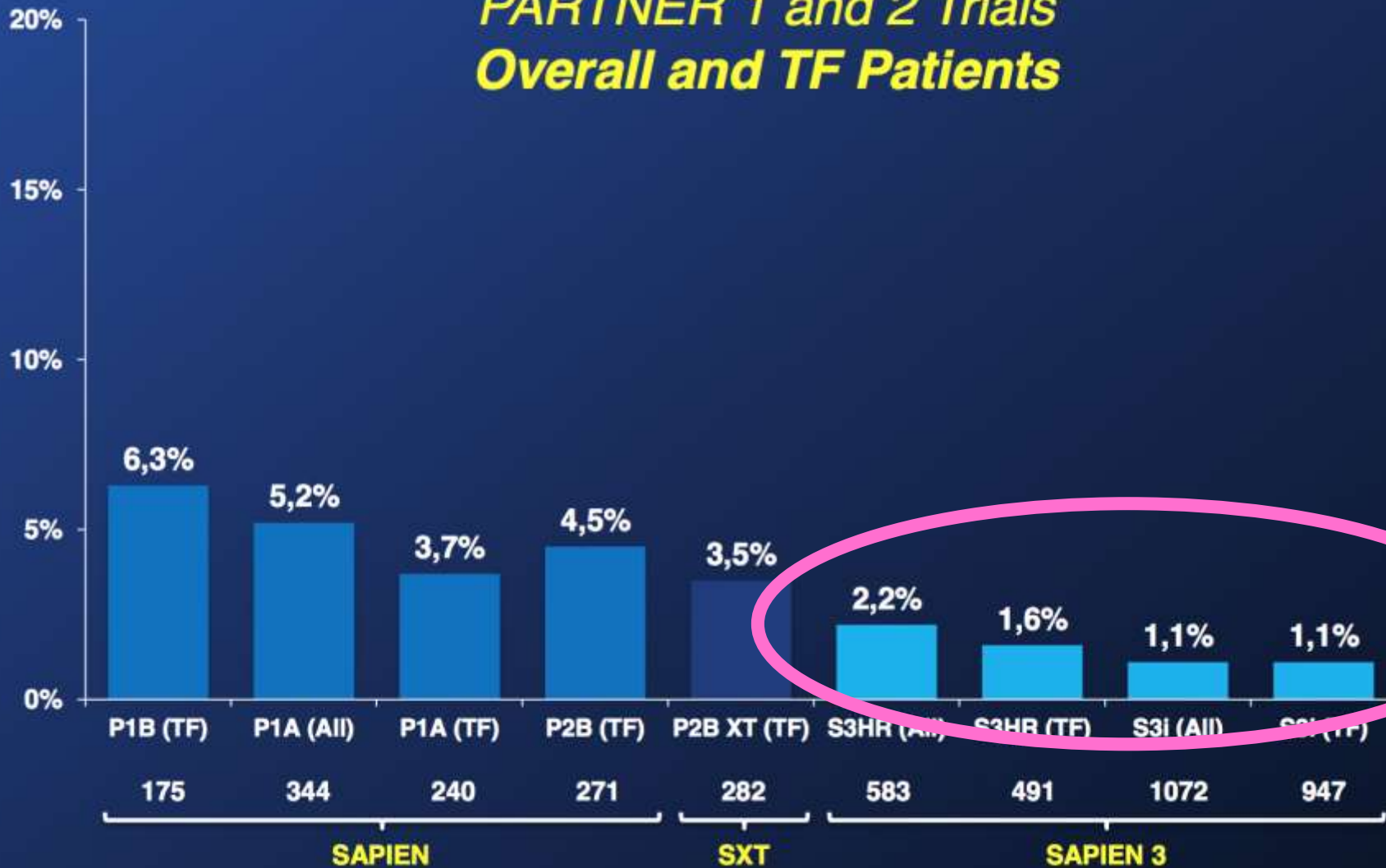


# All-Cause Mortality at 30 Days

## Edwards SAPIEN Valves (As Treated Patients)



*PARTNER 1 and 2 Trials  
Overall and TF Patients*





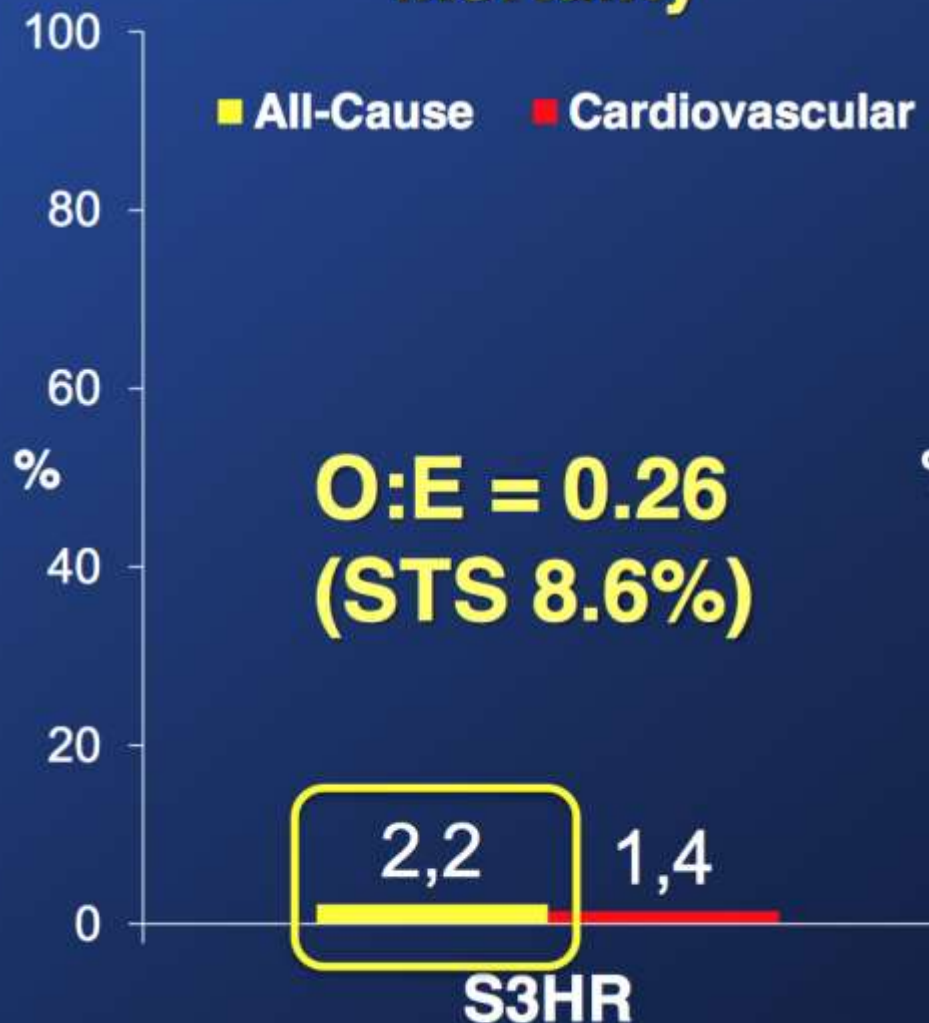
# Mortality and Stroke: S3HR

At 30 Days (As Treated Patients)



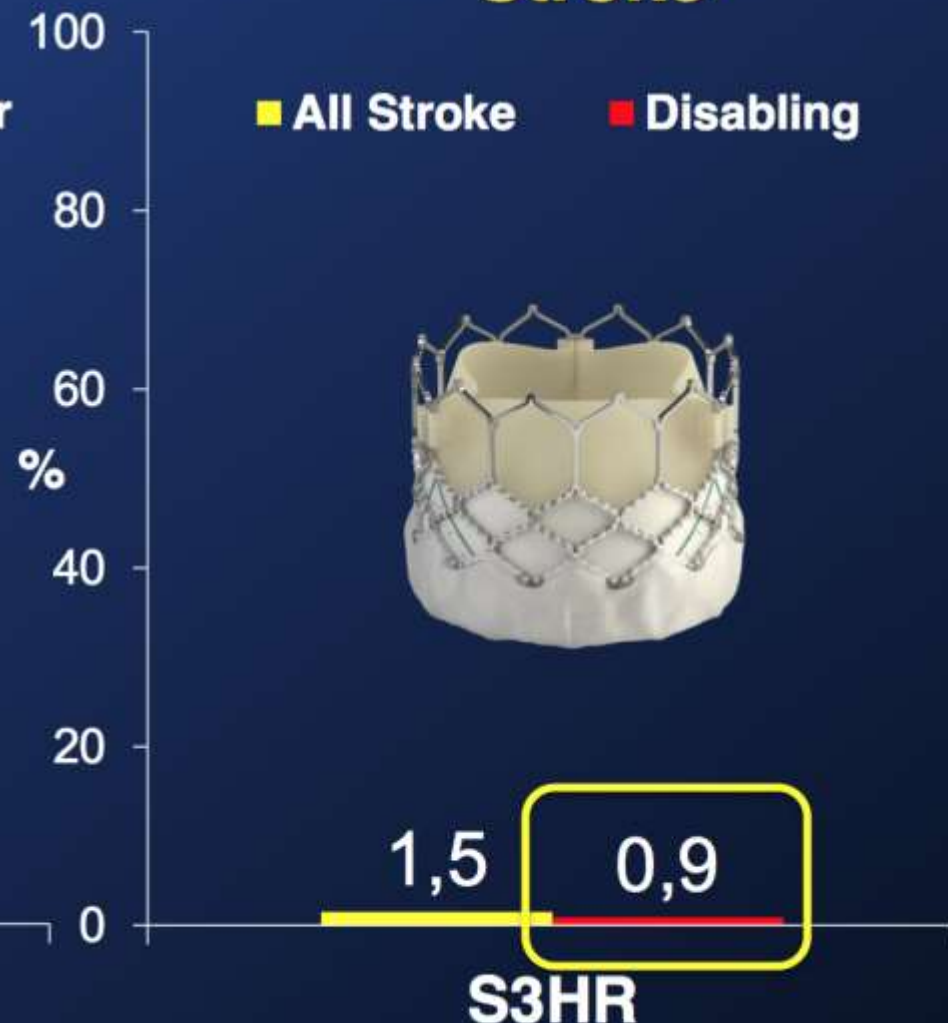
## Mortality

■ All-Cause ■ Cardiovascular



## Stroke

■ All Stroke ■ Disabling

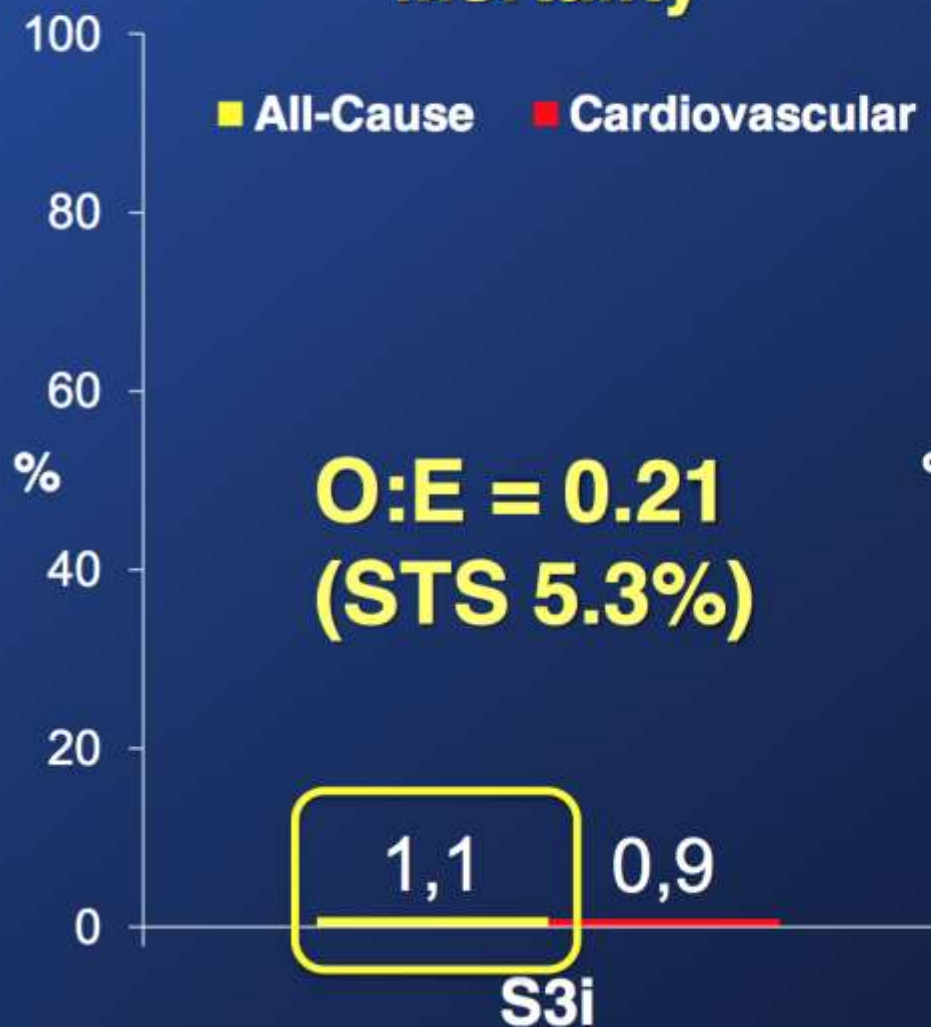


# Mortality and Stroke: S3i

## At 30 Days (As Treated Patients)



### Mortality



### Stroke





# Superiority Analysis

## Components of Primary Endpoint (VI)

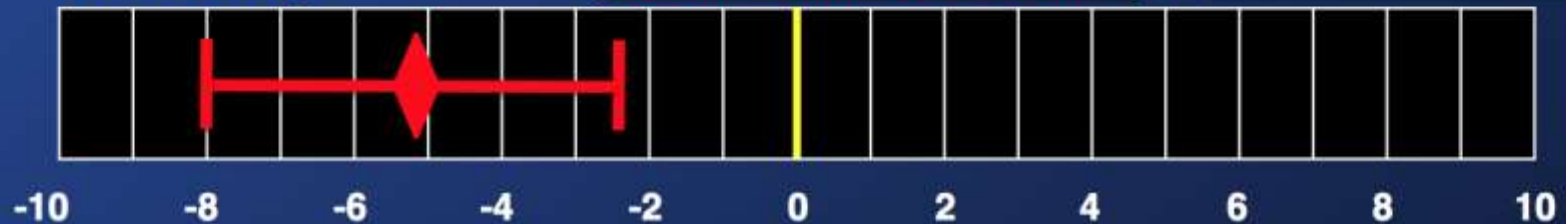


← Favors TAVR      Favors Surgery →

### Mortality

Weighted Difference -5.2%  
Upper 2-sided 95% CI -2.4%

Superiority Testing  
p-value < 0.001



### Stroke

Weighted Difference -3.5%  
Upper 2-sided 95% CI -1.1%

Superiority Testing  
p-value = 0.004



### AR ≥ Moderate

Weighted Difference +1.2%  
Lower 2-sided 95% CI +0.2%

Superiority Testing  
p-value = 0.0149





# OCEAN-TAVI registry

*14/100 cen*  
*>1600 case*  
*30-40% sho*

- Keio Univ
- Toyohashi
- Teikyo Univ
- New Tokyo
- Kokura
- Yokohama
- Sendai
- Kamakura
- Ogaki
- Kishiwada
- Osaka City Univ
- Tokyo Bay
- Toyama



# OCEAN-TAVI registry

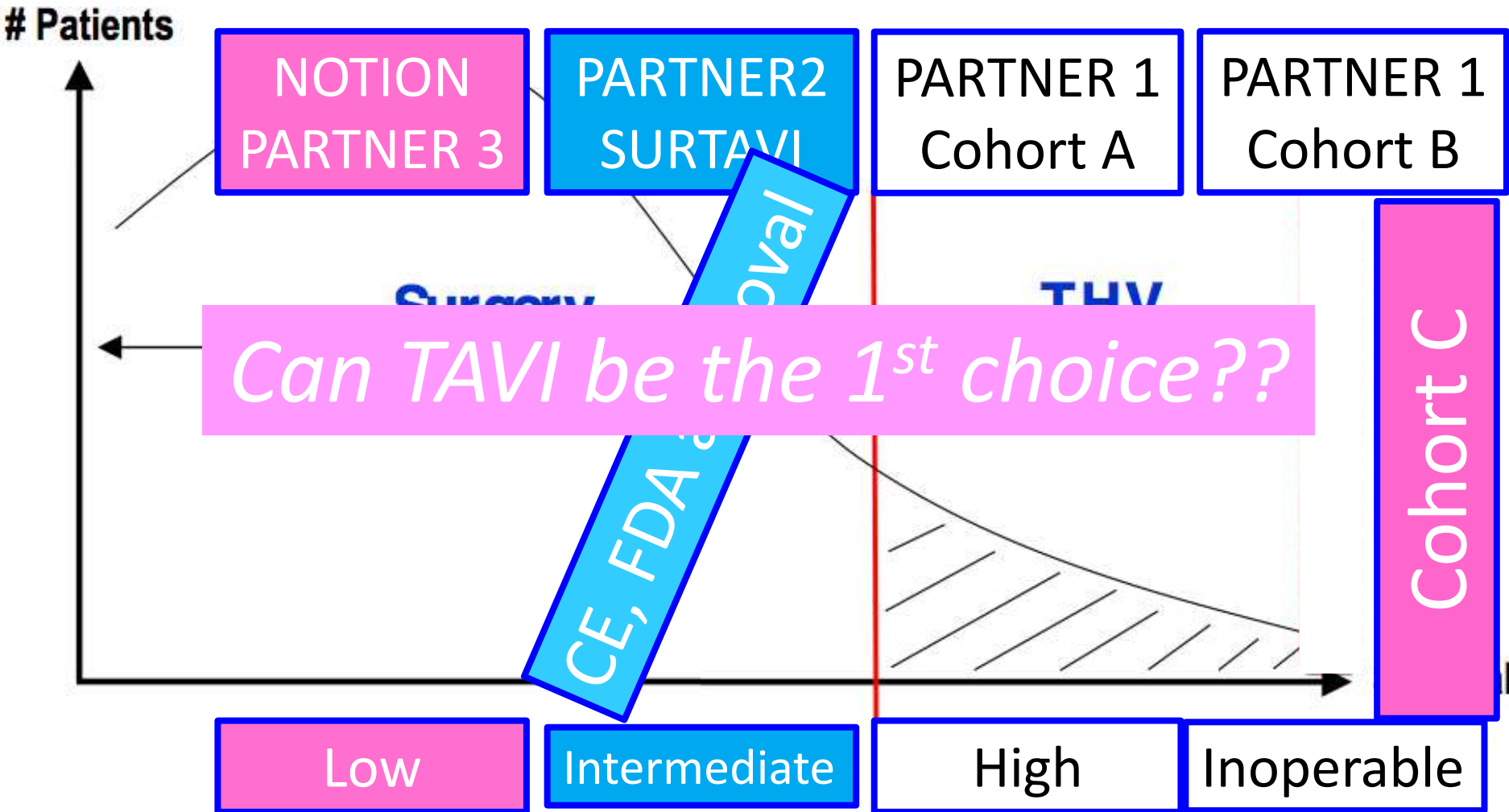
## (Oct 2013 – July 2016)

Patient	N=1613
Age, years	84.4 ± 5.1
<b>STS PROM, %</b>	<b>8.3 ± 7.0</b>
<b>Edwards Sapien XT</b>	<b>1328 (82.3%)</b>
<b>Edwards Sapien 3</b>	<b>141 (8.7%)</b>
Medtronic CoreValve	144 (8.9%)
<b>30-day mortality</b>	<b>1.7%</b>
<b>O:E ratio</b>	<b>0.20</b>

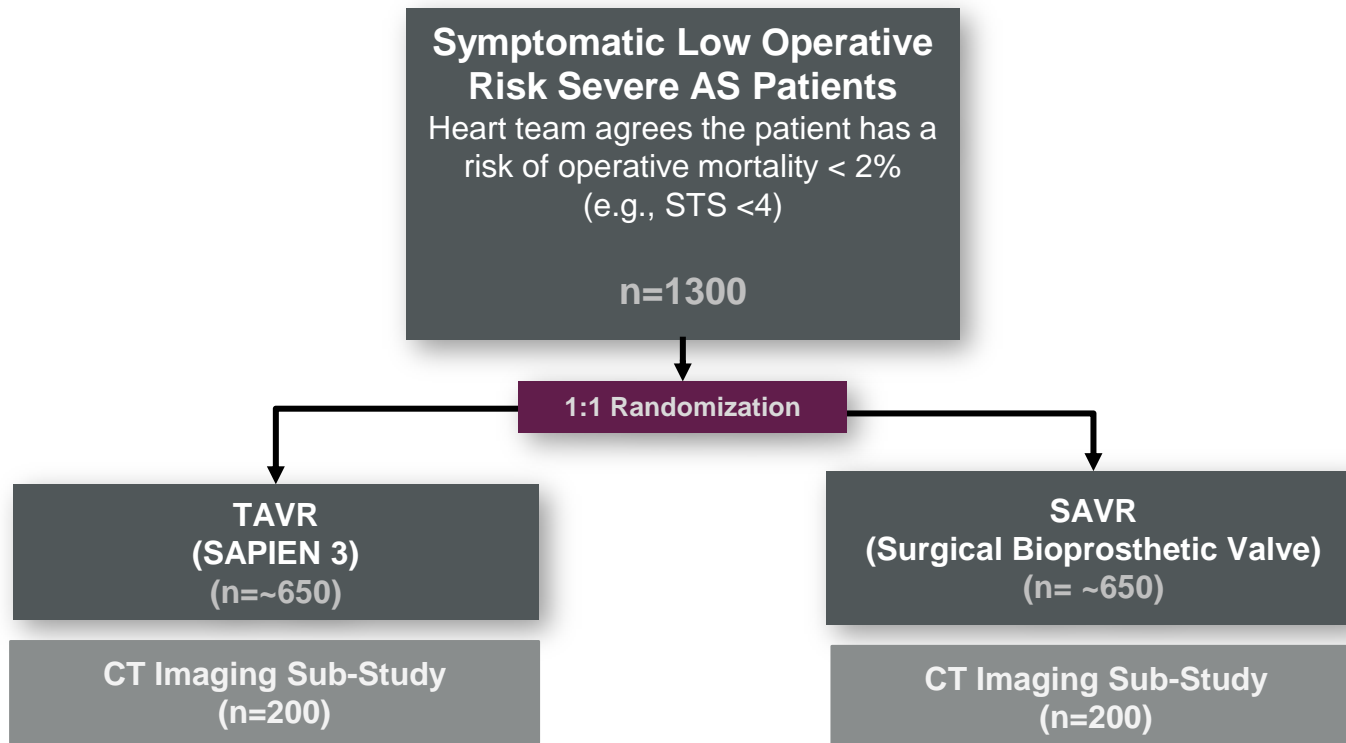
# Keio experience: SAPIEN 3 (May 2016-)

N = 147	Value
<b>In-hospital mortality</b>	<b>0</b>
Cerebral infarction, n (%)	1 (0.7%)
<b>Major vascular complications</b>	<b>1 (0.7%)</b>
New PM implantation, n (%)	10 (7.1%)
Coronary obstruction, n (%)	2 (1.4%)
≥moderate PVL	1 (0.7%)

# Indication for TAVI



# PARTNER III Trial Design



**Primary Endpoint: Composite of all-cause mortality, all stroke, and re-hospitalization at 1 year post procedure (non-inferiority)**

**Follow-up: 30 day, 6 month, and annually through 10 years**

# Conclusion

- Sapien 3 provides less paravalvular leak, less vascular complication, low PM implantation rate and better coaxiality.
- These improvements lead to simplifying the procedure, lower mortality and better outcomes
- Care should be taken for special anatomy.





#PCRtokyo

