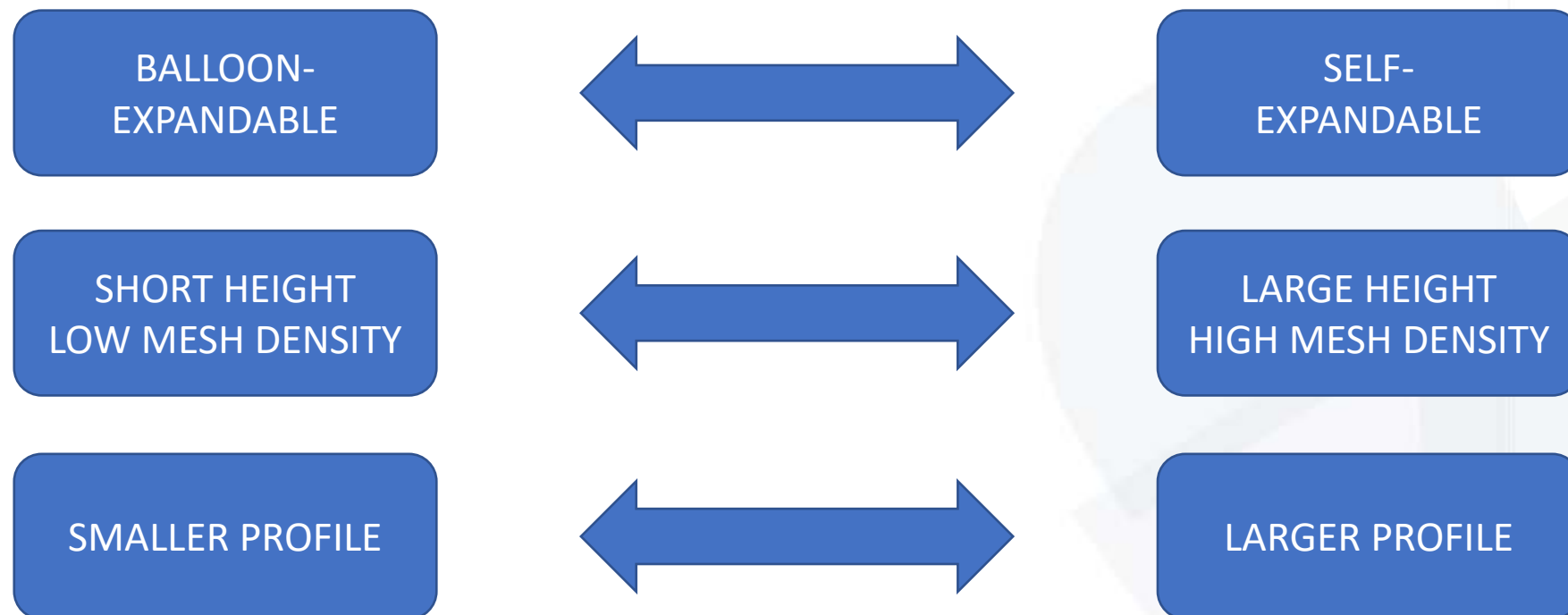


# Choosing the first TAVR

Ignacio J. Amat-Santos, MD, PhD  
Director, Interventional Cardiology  
HCU – VALLADOLID, Spain

# Different mechanisms



# STRENGTHS / WEAKNESSES

MY OWN POINT OF VIEW



Experience

Coro.re-access



Evolut Pro+



C.Alignment

Aggressive pre-dilation



Acurate neo2



Hemodynamics

PPM rate



Navitor



Re-access

Slow recapture



Hydra



Pure AR

Small annuli



Jena V



Prize?

Experience



Venus APlus

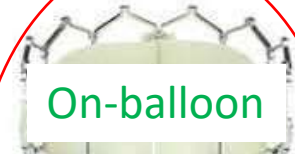


Experience

Not on-balloon



Sapien-3U



On-balloon

Crossability



Myval



Crimped

Trackability

Vienna



Hemodynamics

Not-resheathable

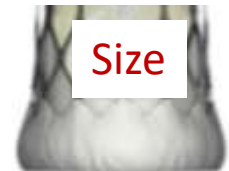


Allegra



Motorized

Size



Vitaflow

## AVOID RISKS

- LIFE THREATENING
- CONDUCTION DISTURBANCES
- DIFFICULT CORON.RE-ACCESS

## GOOD HEMODYNAMICS:

- NO LEAK
- NO RESIDUAL GRADIENTS

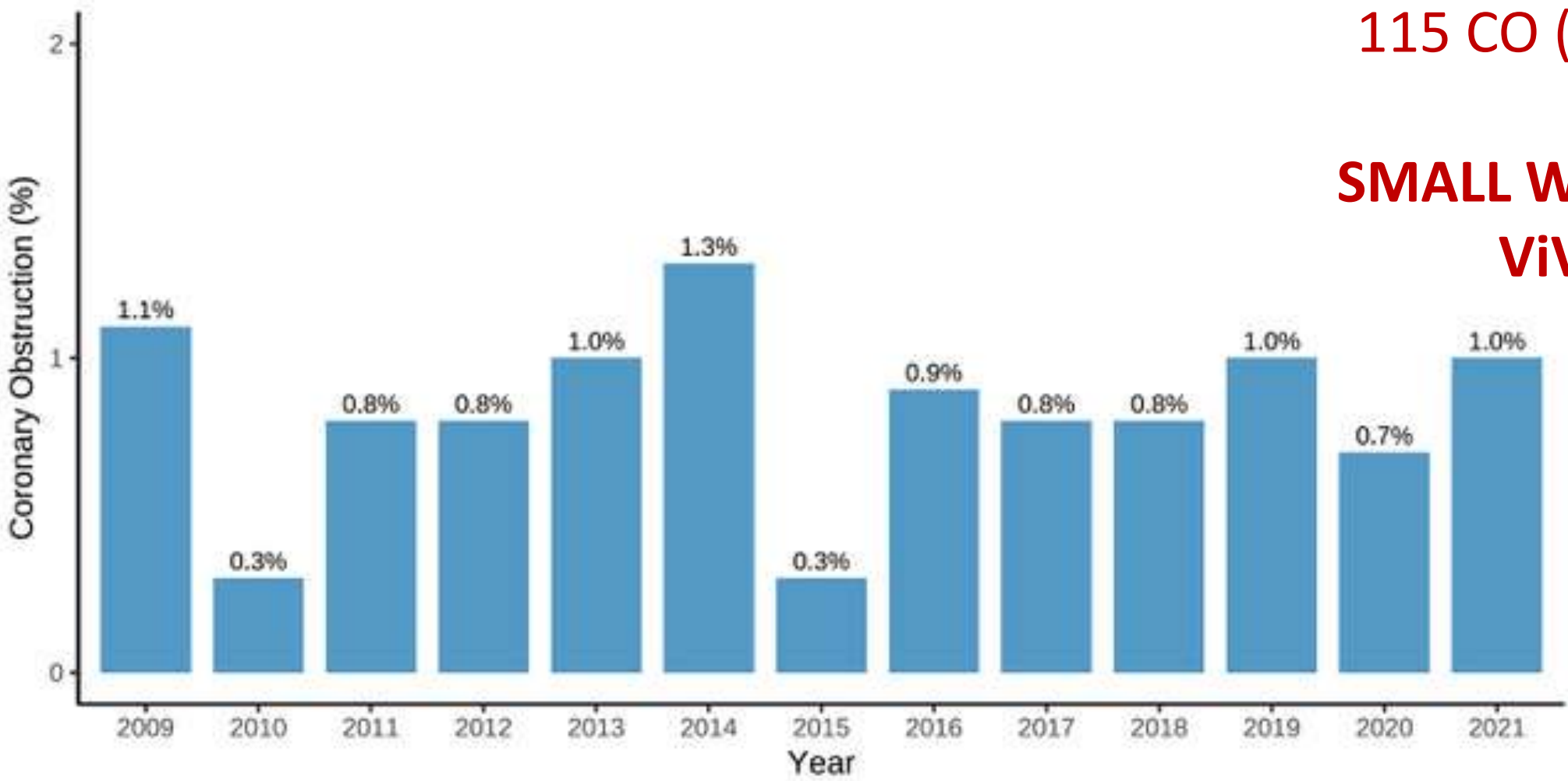
# AVOID RISKS

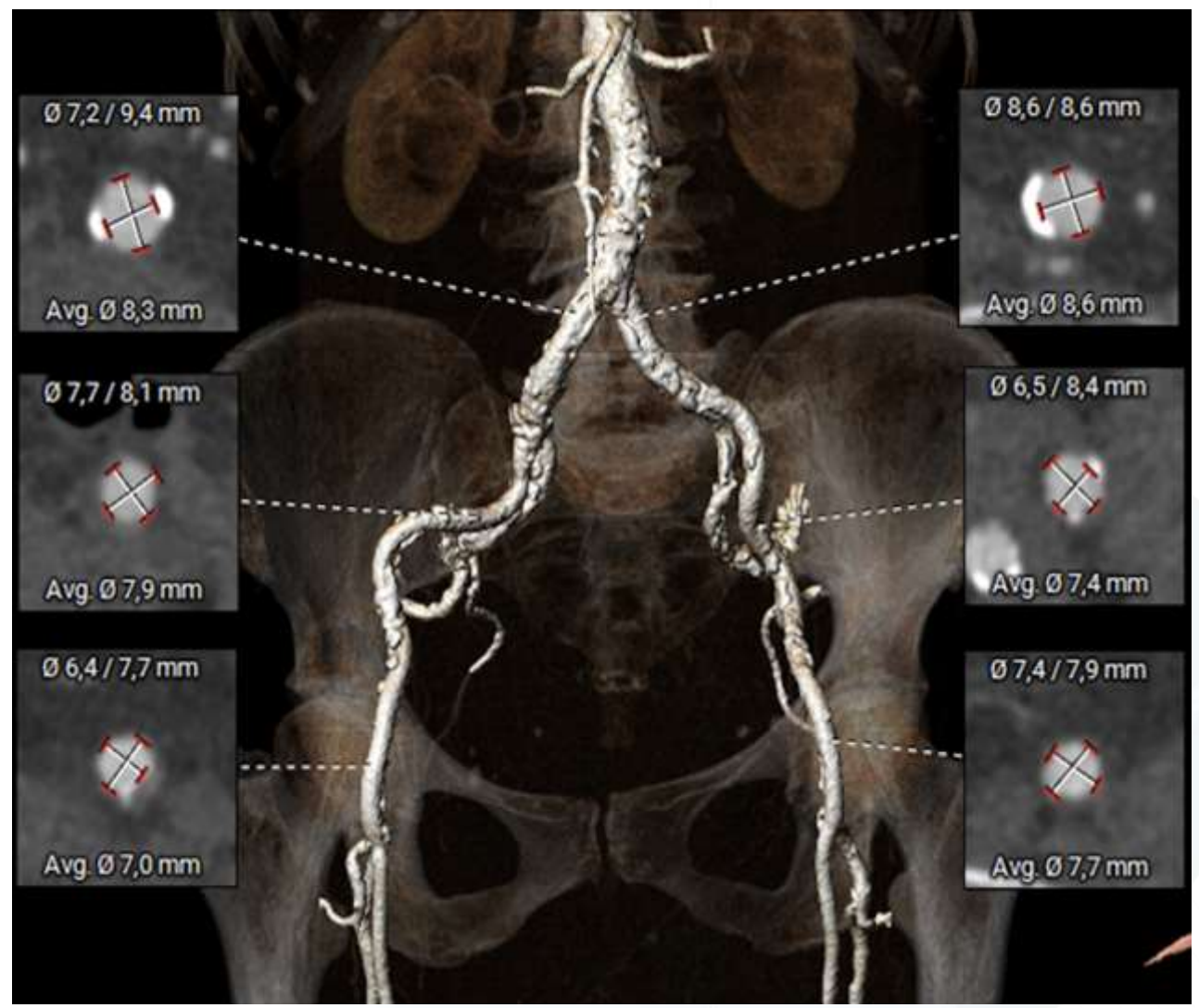
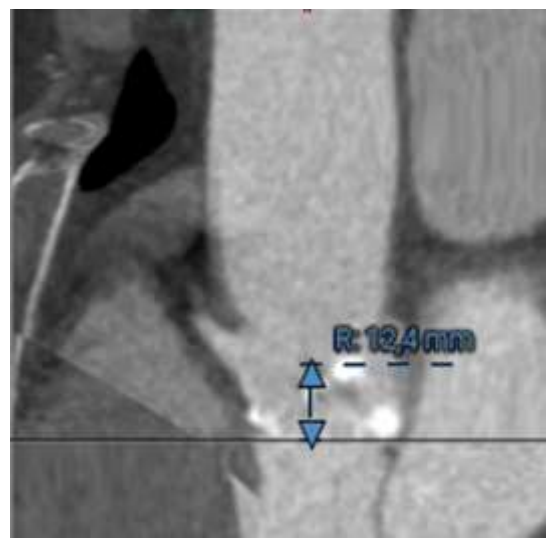
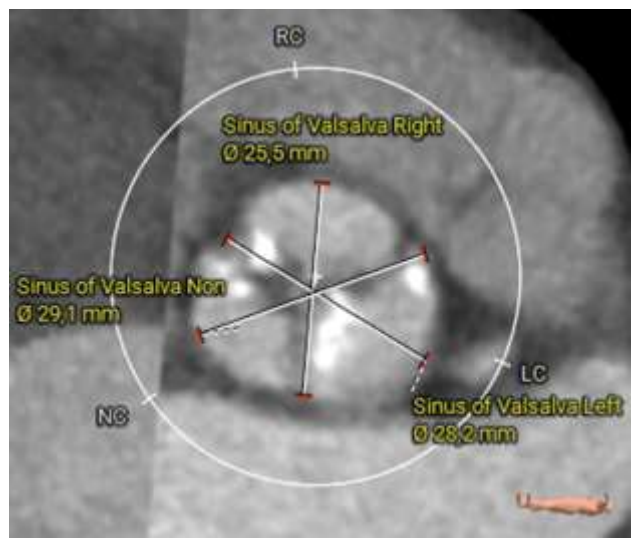
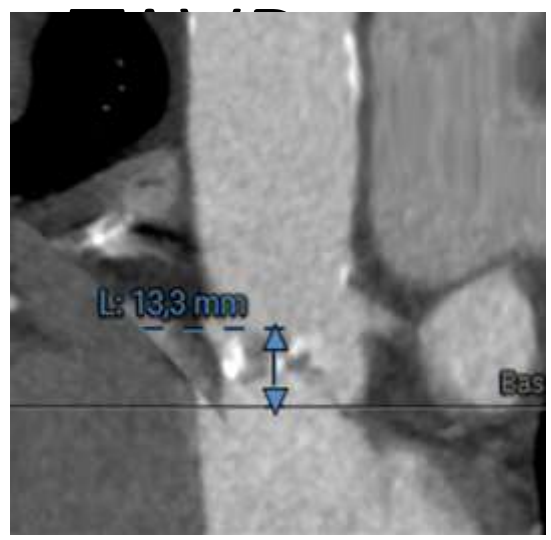
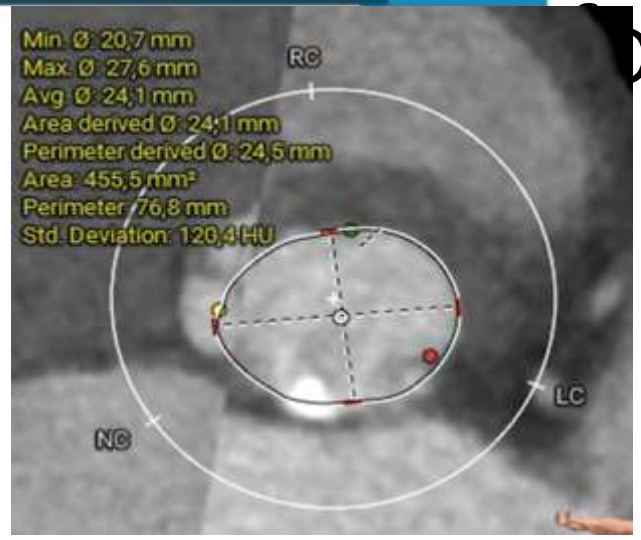
- LIFE THREATENING
- CONDUCTION DISTURBANCES
- DIFFICULT CORON.RE-ACCESS

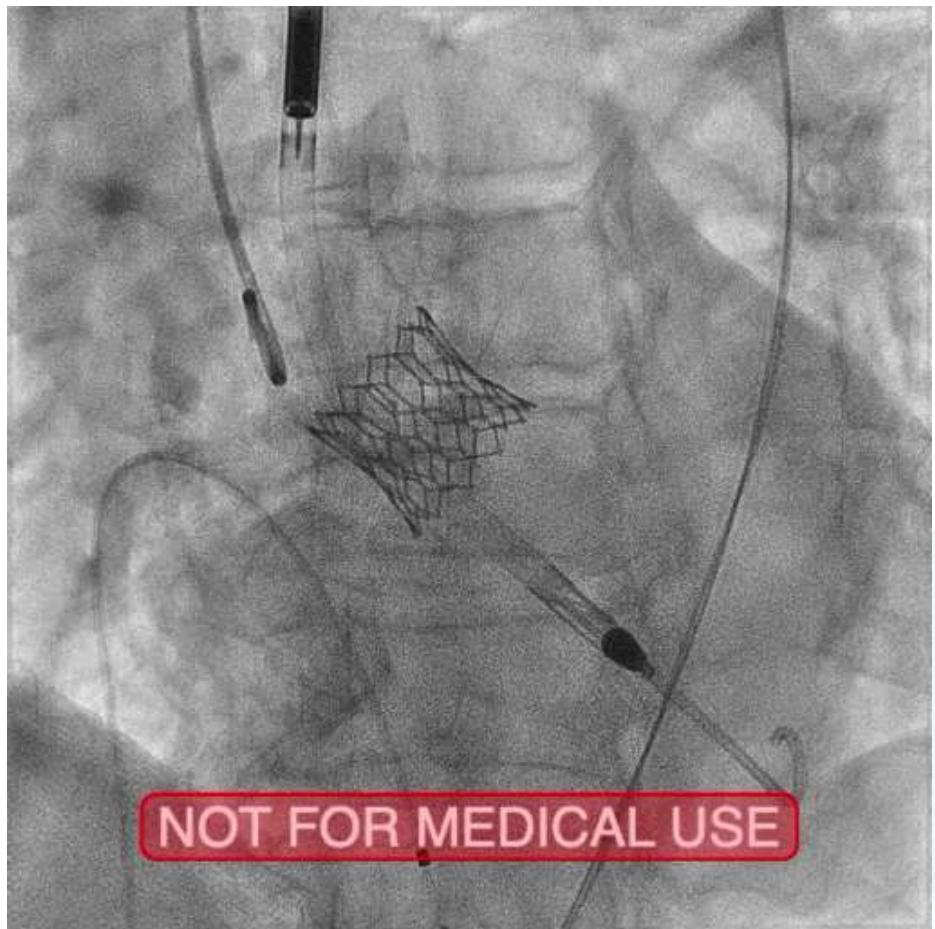
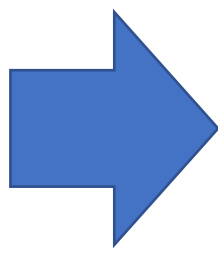
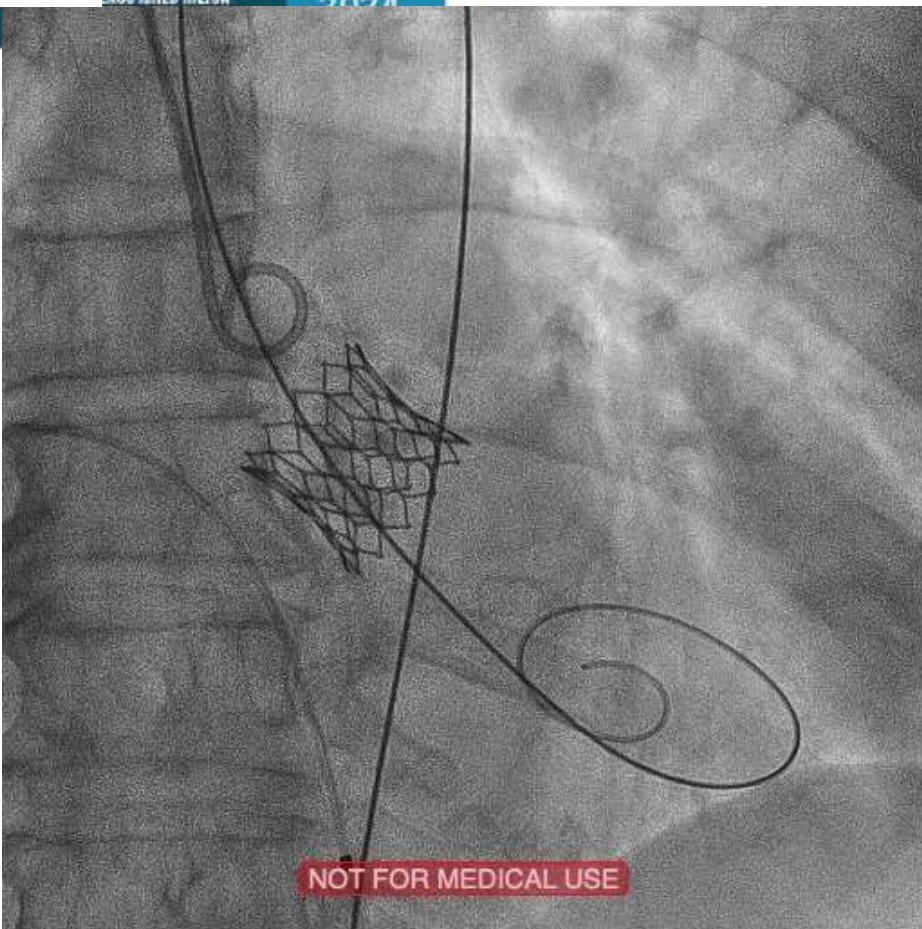
# Risk of coronary obstruction

13.675 TAVI,  
115 CO (0.8%)

**SMALL WOMEN  
ViV**



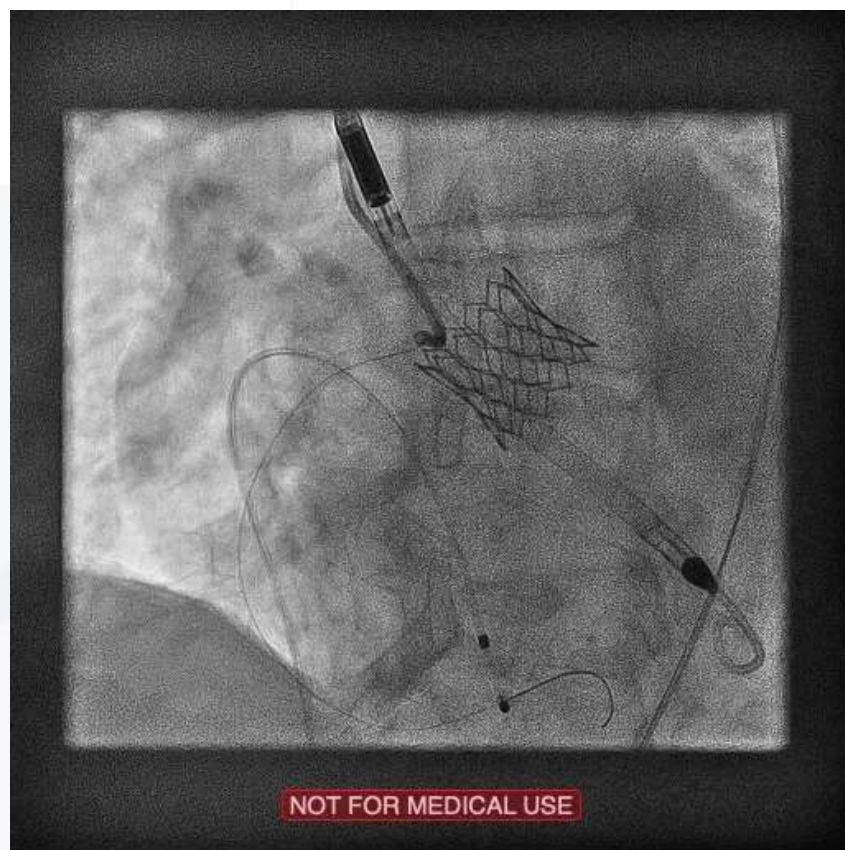
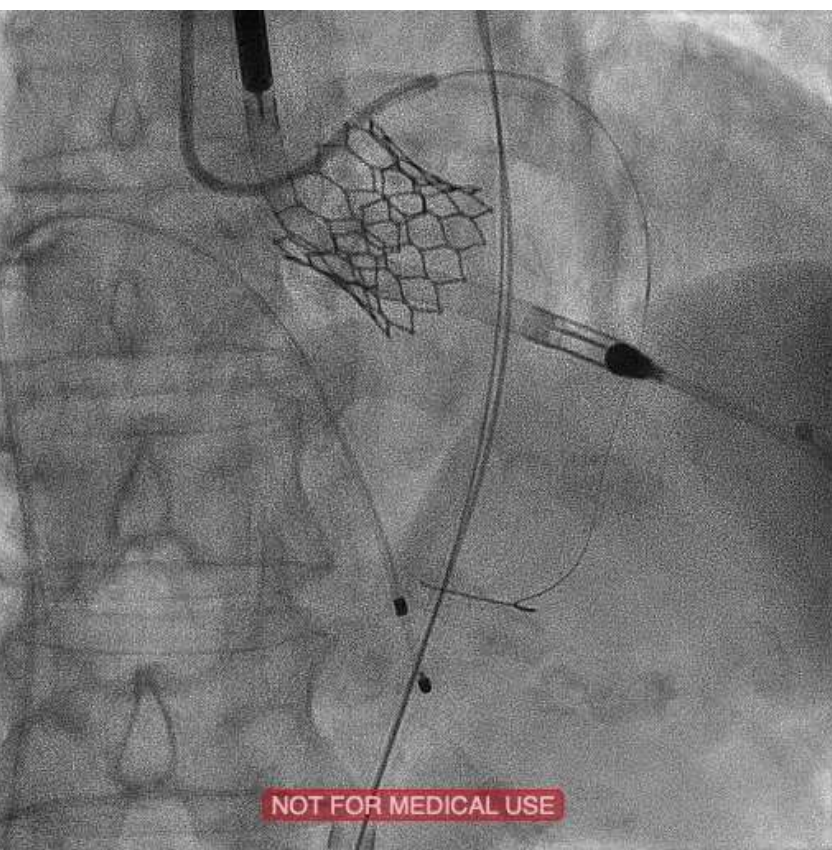


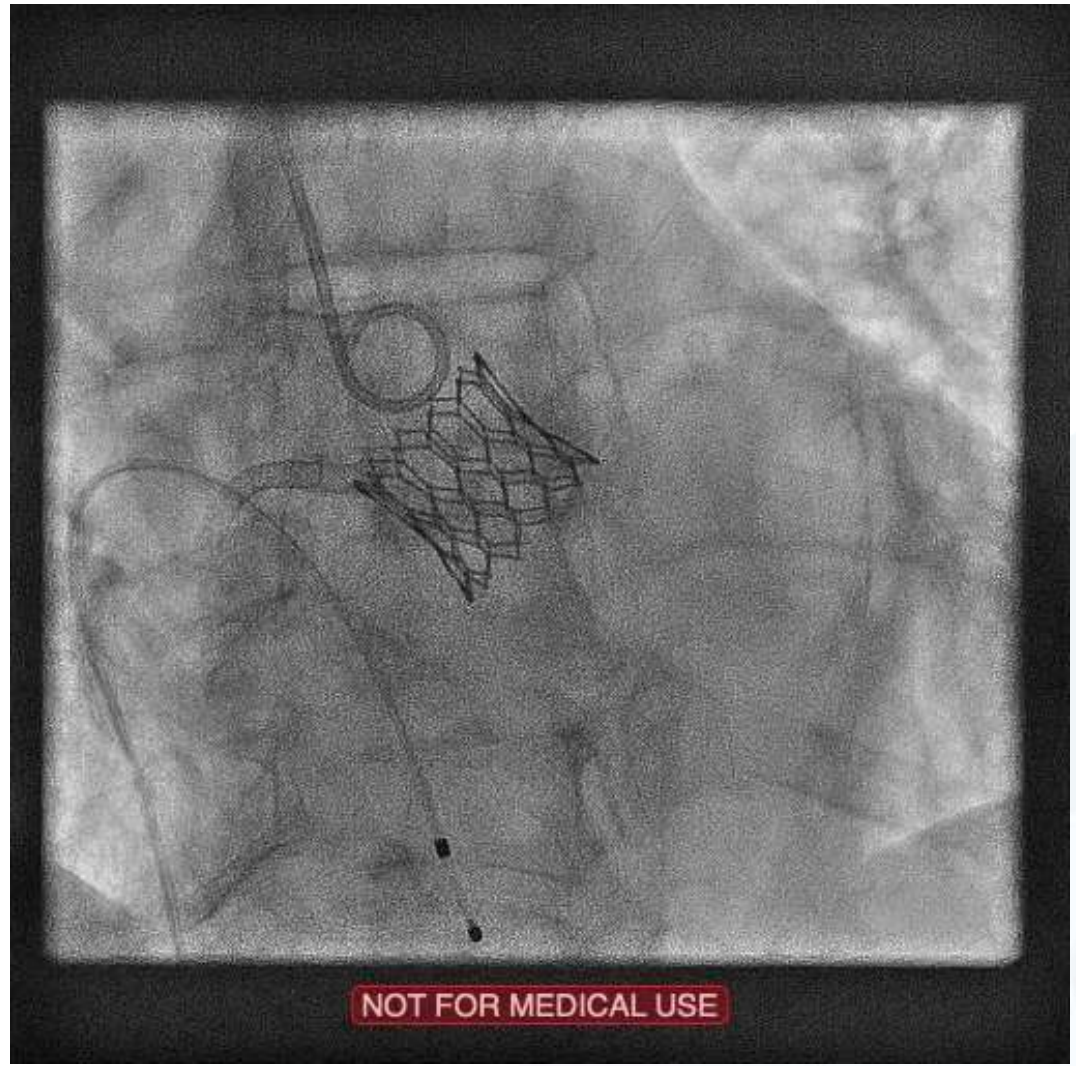
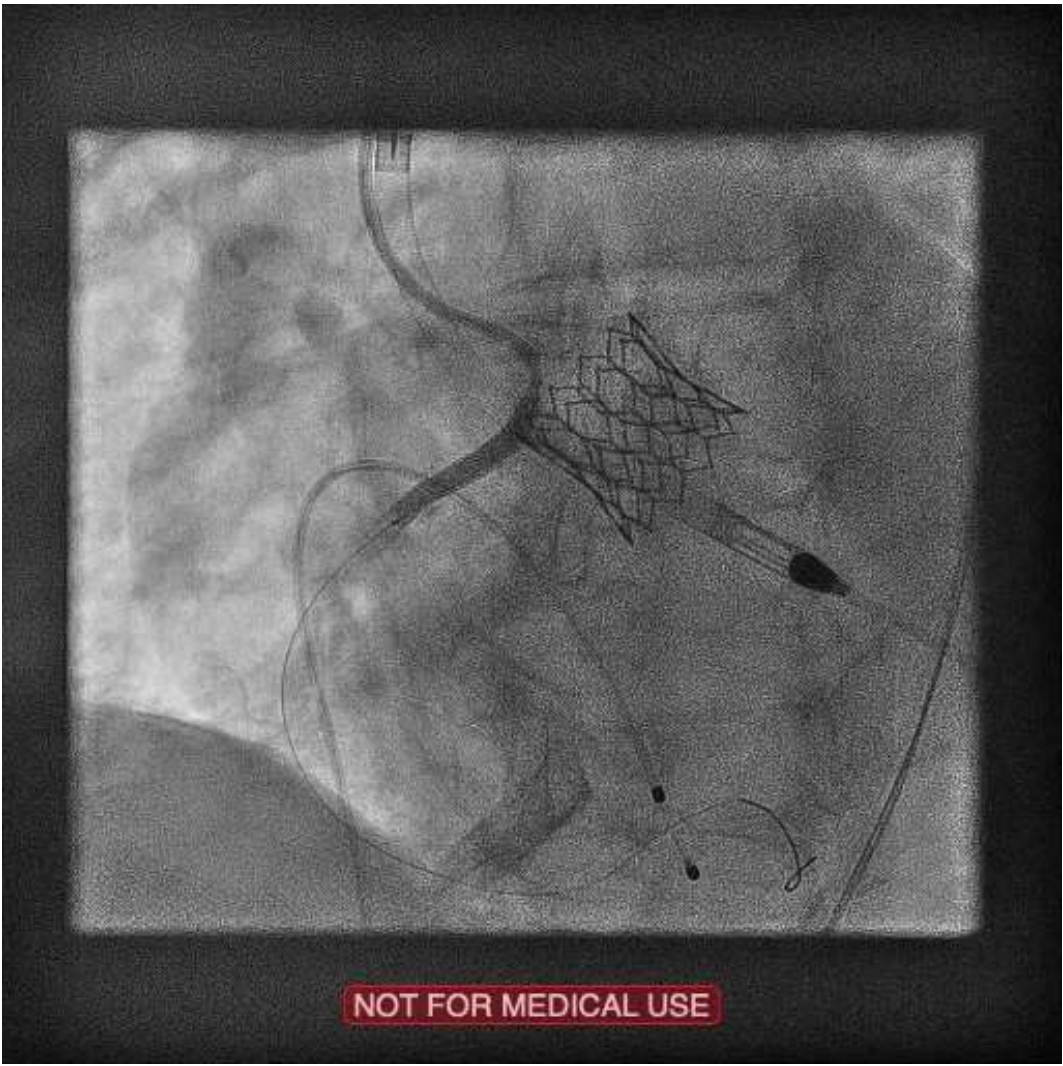


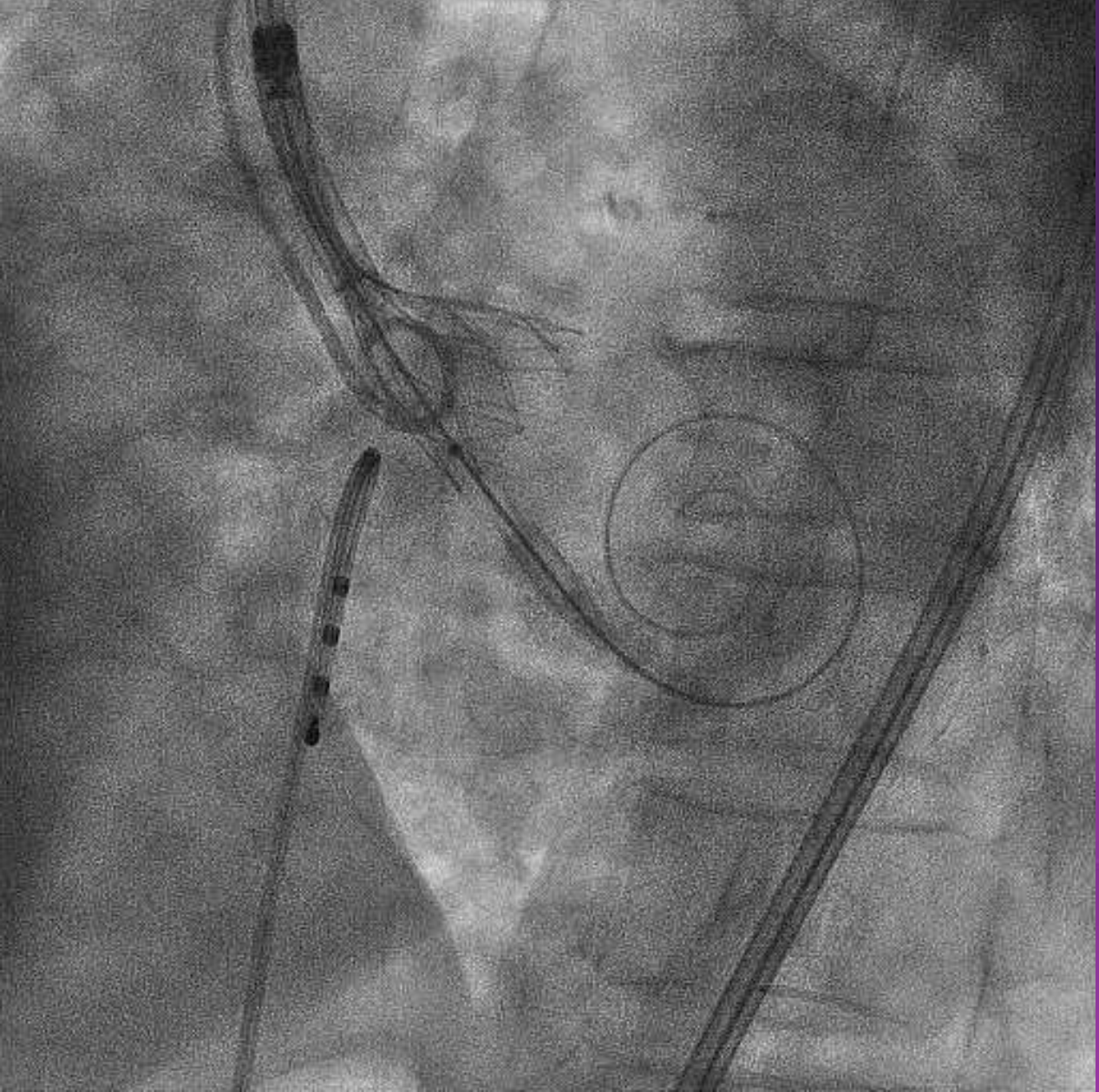
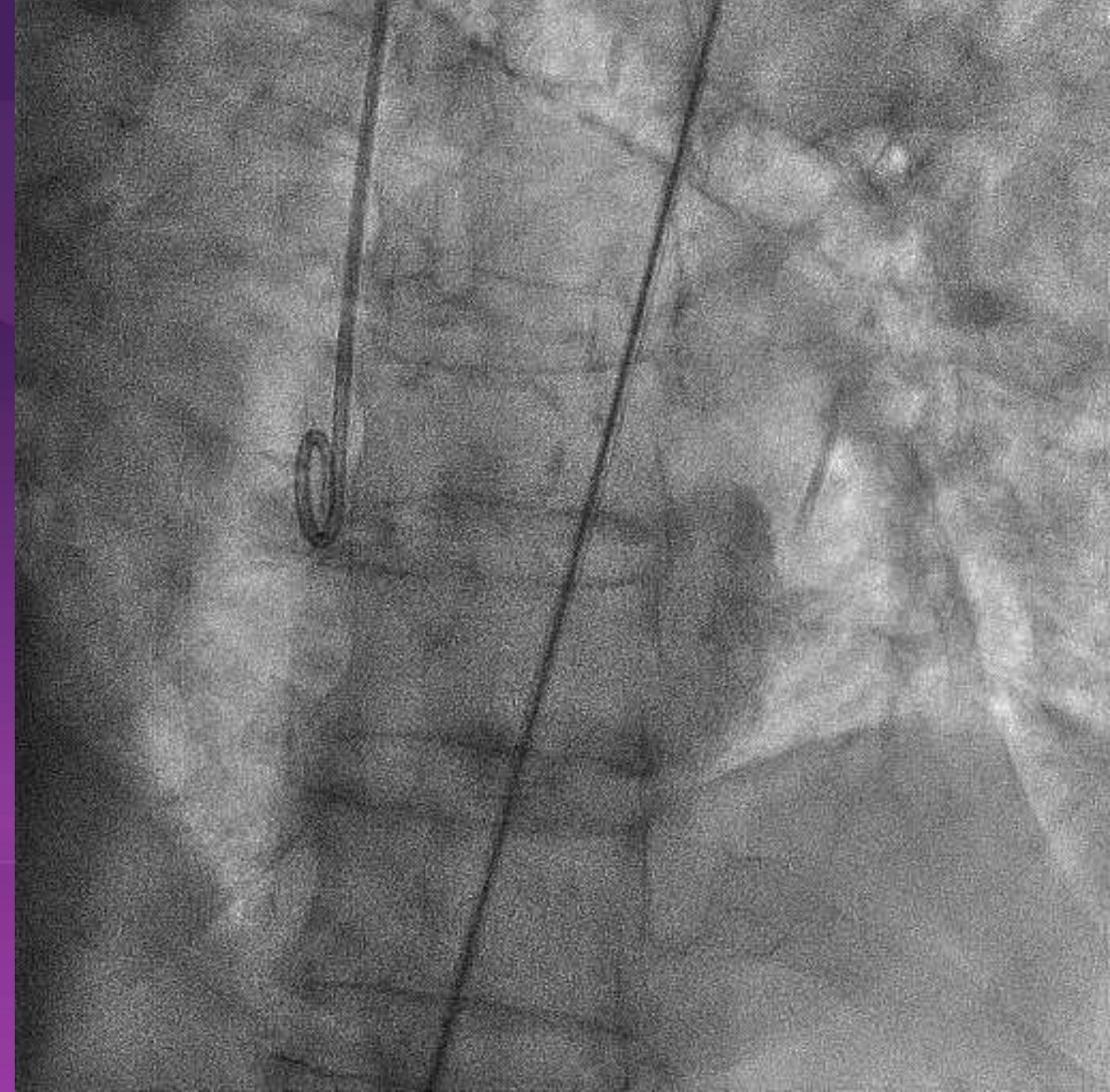
Immediately after, the patient developed anginal chest pain and hemodynamic instability. The aortography demonstrated the absence of filling of the RCA.

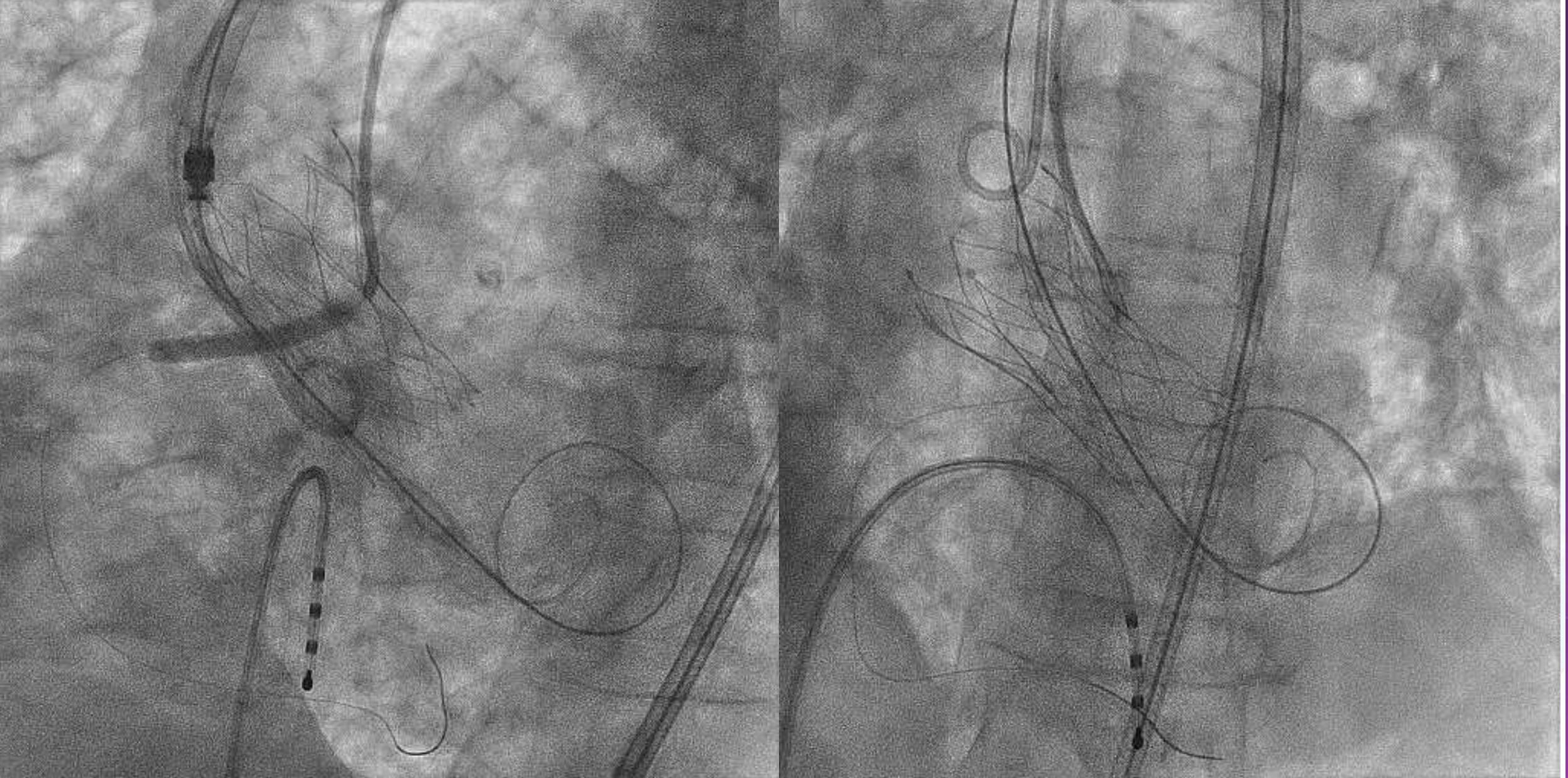
Therefore, the patient was emergently intubated and hemodynamic support was started with vasopressors and percutaneous insertion of an Impella CP.







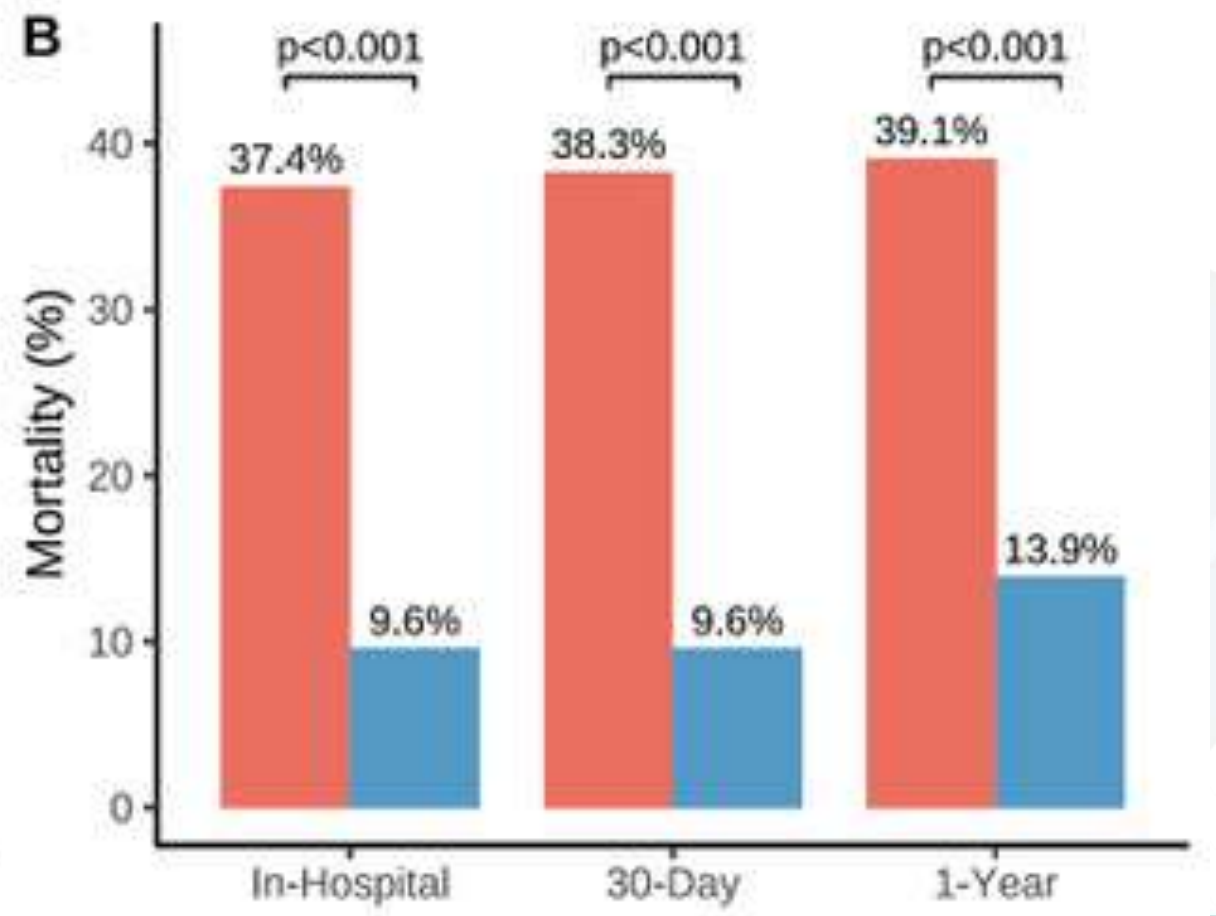
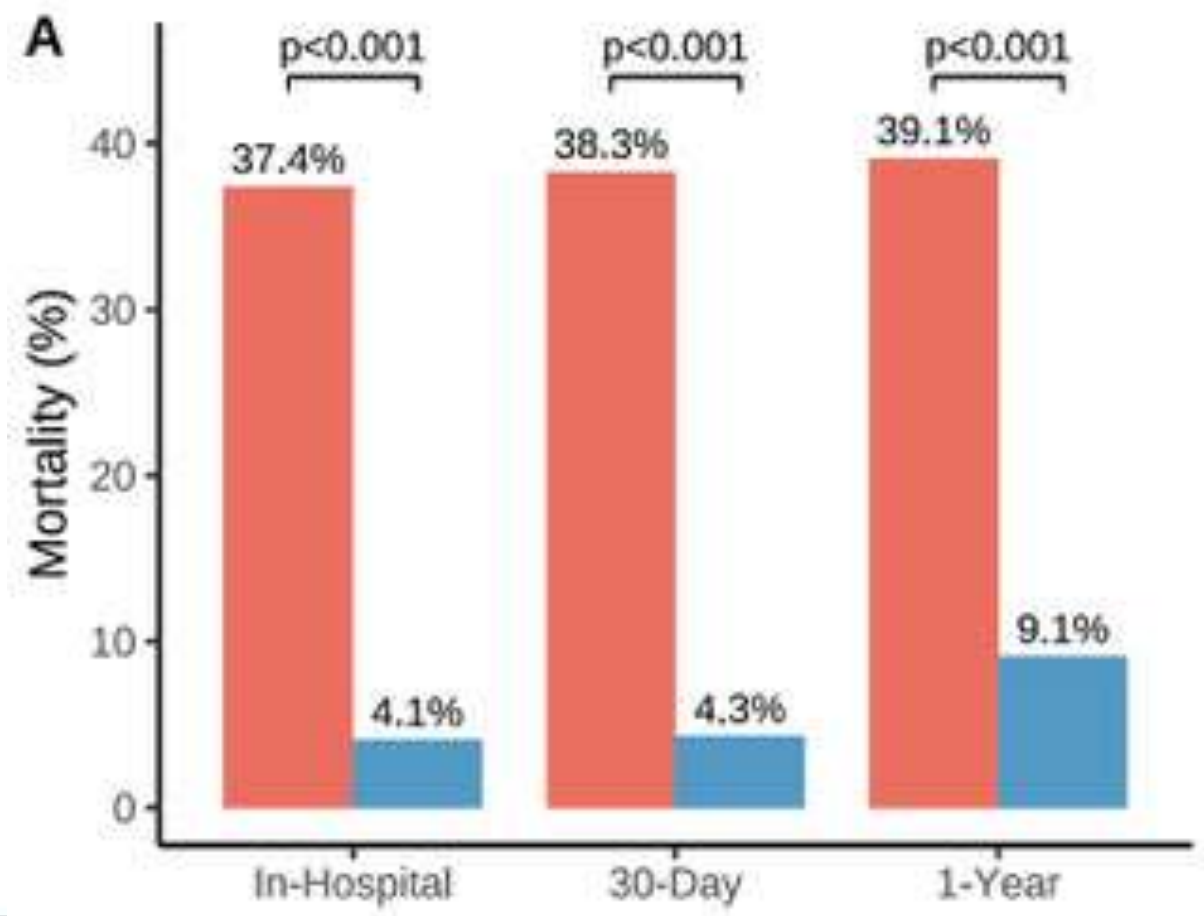




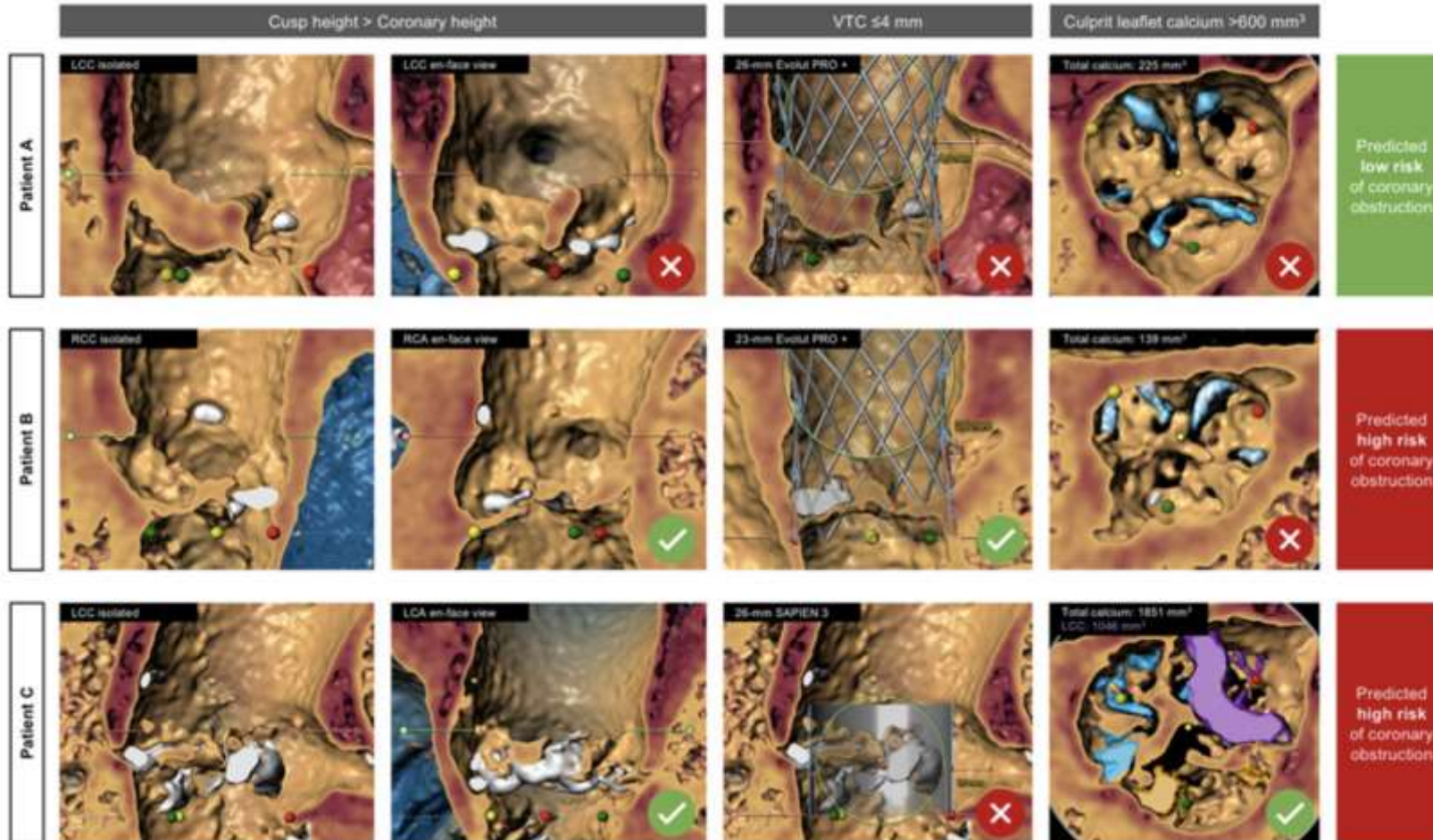
# Features of CO

- **Valve-in-valve** (21.7% vs 3.1%;  $p= 0.001$ ).
- **Coronary protection was performed in 21 (18.2%)** patients, only with a coronary guidewire in 15 (71.4%) of them and with an undeployed stent in the remaining 6 (28.6%) patients.
- **CO prediction was not precise**, especially in native valves
- In fact, almost the **half of the patients** NO factor of CO in CT

Group ■ CO ■ Control



# Score predicting CO



Cusp >  
Coronary height

Prosthesis to CO  
> 4mm

Calcium of  
the leaflet

# Mitigationg risk CO

- Coronary obstruction **more common after BE-TAVI** than a SE-TAVI (VIVID registry)
- **Inability to reposition or retrieve BE-TAVI**
- The **Acurate neo device** has an upper crown that caps the native leaflets below the coronary ostia, probably the lowest rate of CO



Evolut Pro+



Vienna



Navitor



Acurate neo2



Allegra



Vitaflow



# Preservation of coronary access

- High prevalence of CAD in TAVI patients
- Possible need for re-access

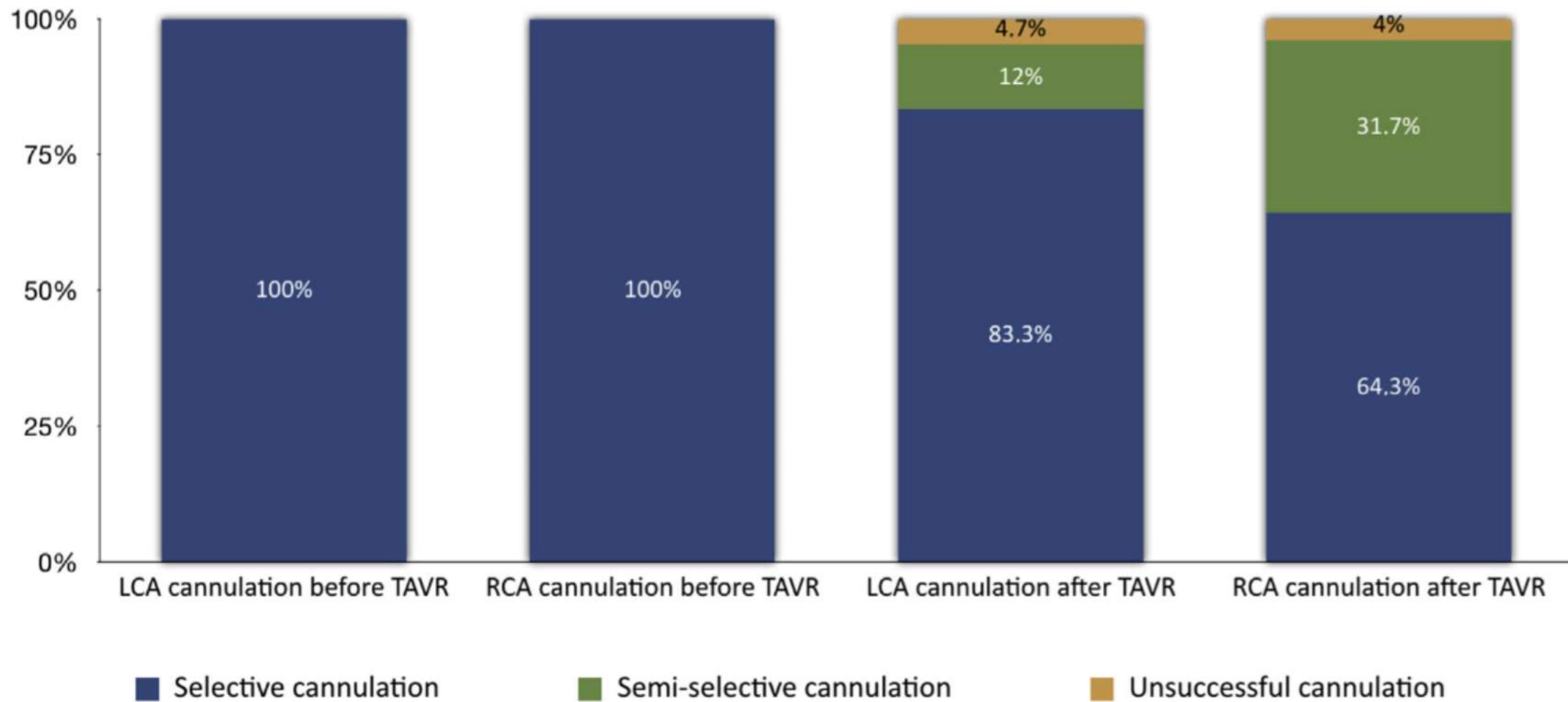
- **Key:** TAVI valve that allows easy coronary access

- **Principal factors determining ease of coronary Access:**

- Frame height
- Frame mesh density.

- **BE-TAVI** usually extend above the coronary ostia, but they have a low-density mesh and large cells

- **Acurate neo** valve has a short stent that usually sits below the ostia



# Theoretical basis of “patient-tailored” alignment


The Accurate Commissure Alignment  
project

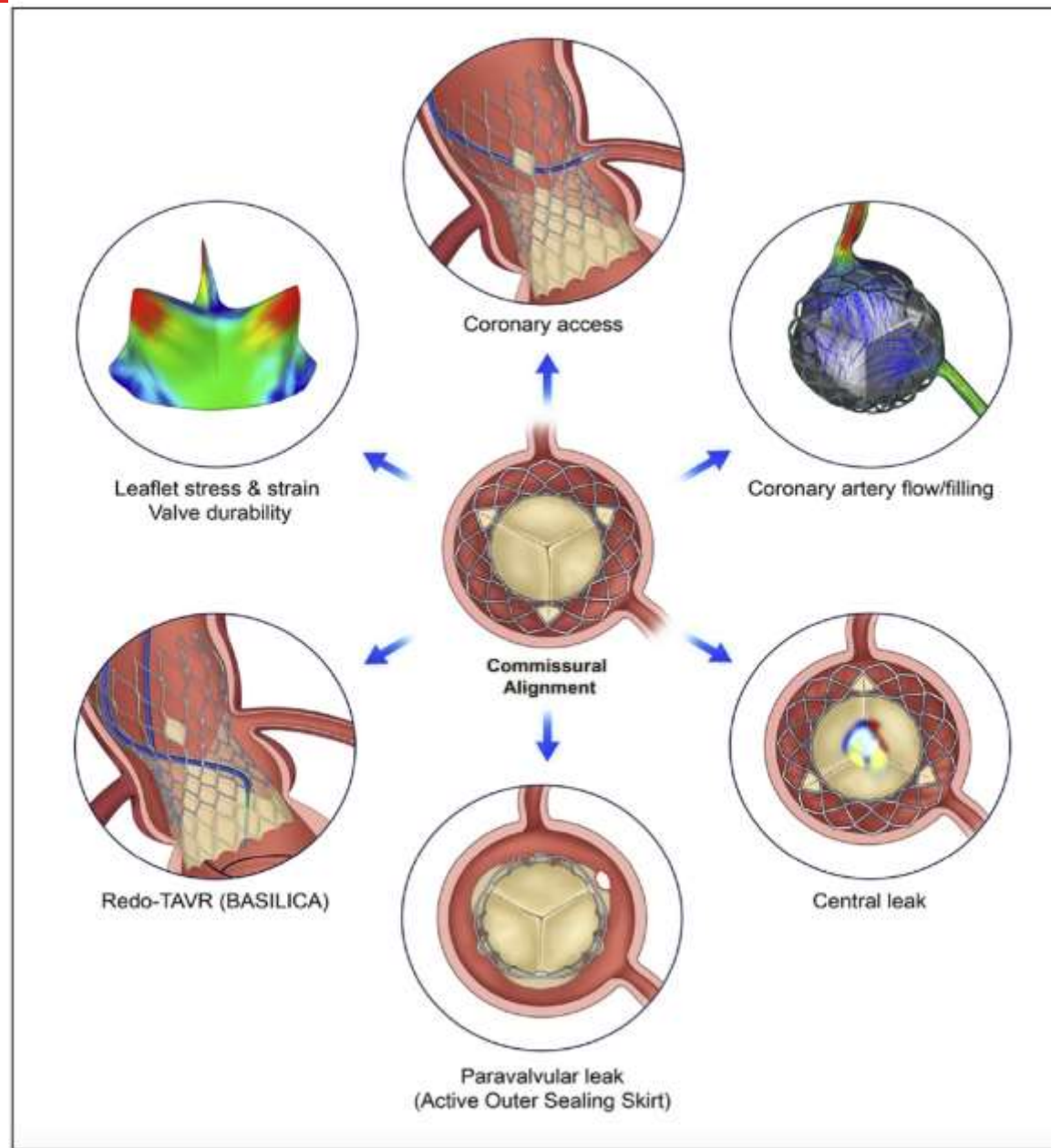
# First publication on “patient-tailored” alignment

- Spanish Journal of Cardiology

## Accurate commissural alignment during ACURATE neo TAVI procedure. Proof of concept





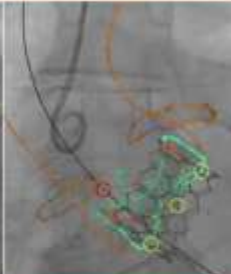

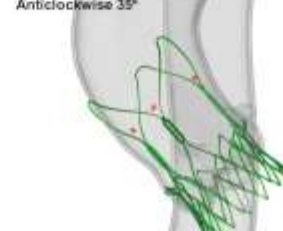




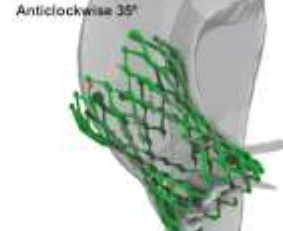



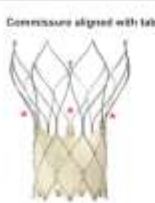
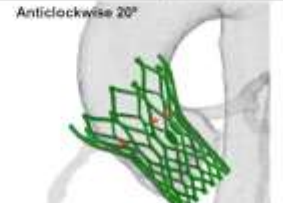


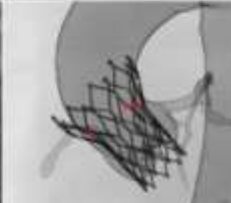
Alineamiento comisural preciso durante el TAVI con ACURATE neo. Prueba de concepto

Alfredo Redondo<sup>a,b,◇</sup>, Félix Valencia-Serrano<sup>c,◇</sup>, Sandra Santos-Martínez<sup>a,b</sup>, José Raúl Delgado-Arana<sup>a,b</sup>, Alejandro Barrero<sup>a,b</sup>, Ana Serrador<sup>a,b</sup>, Hipólito Gutiérrez<sup>a,b</sup>, Israel Sánchez-Lite<sup>d</sup>, Teresa Sevilla<sup>a,b</sup>, Ana Revilla<sup>a,b</sup>, Carlos Baladrón<sup>a,b</sup>, Won-Keun Kim<sup>e</sup>, Manuel Carrasco-Moraleja<sup>a,b</sup>, J. Alberto San Román<sup>a,b</sup>, Ignacio J. Amat-Santos<sup>a</sup>, 



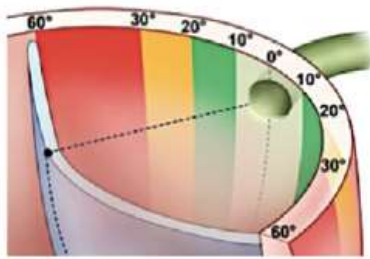
# Feasible of “patient-tailored” commissural alignment with all devices

- “ACA device”

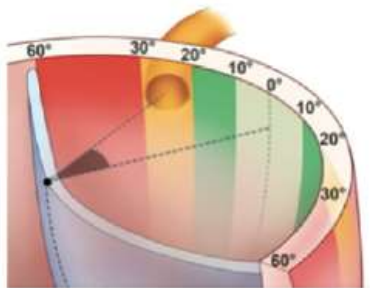
A. Devices	B. Neo-commissures (*)	C. Predicted ACA orientation	D. ACA maneuvers	E. Actual ACA Implant	F. Confirmation of ACA
Myval Sapien 3	Double line wire commissures are attached 	Commissures at 60° when crimping 			
Acurate	Commissure aligned with tabs 	Anticlockwise 35° 			
Evolut	One commissure aligned with C-tab 	Anticlockwise 35° 			
Portico	Commissure aligned with tabs 	Anticlockwise 20° 			

# First doubts on the “perfect efficacy” of this strategy

## Coronary Ostial Eccentricity

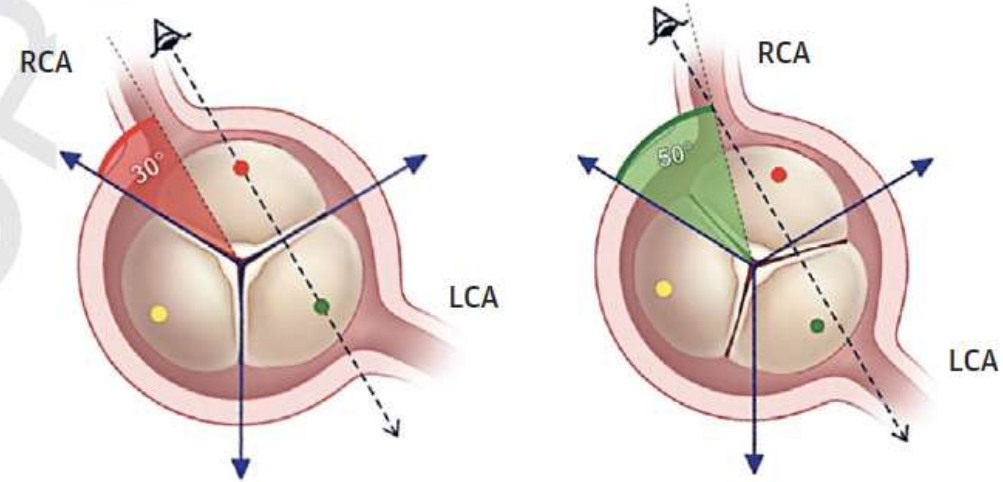


Centered



Moderate eccentricity

## Possible Optimization in Case of Coronary Ostial Eccentricity



→ Projected THV commissures

→ Projected THV commissures

R/L Cusp Overlap View

Coronary Ostia Overlap View



First publication on commissural alignment

# Commissural Versus Coronary Optimized Alignment During Transcatheter Aortic Valve Replacement



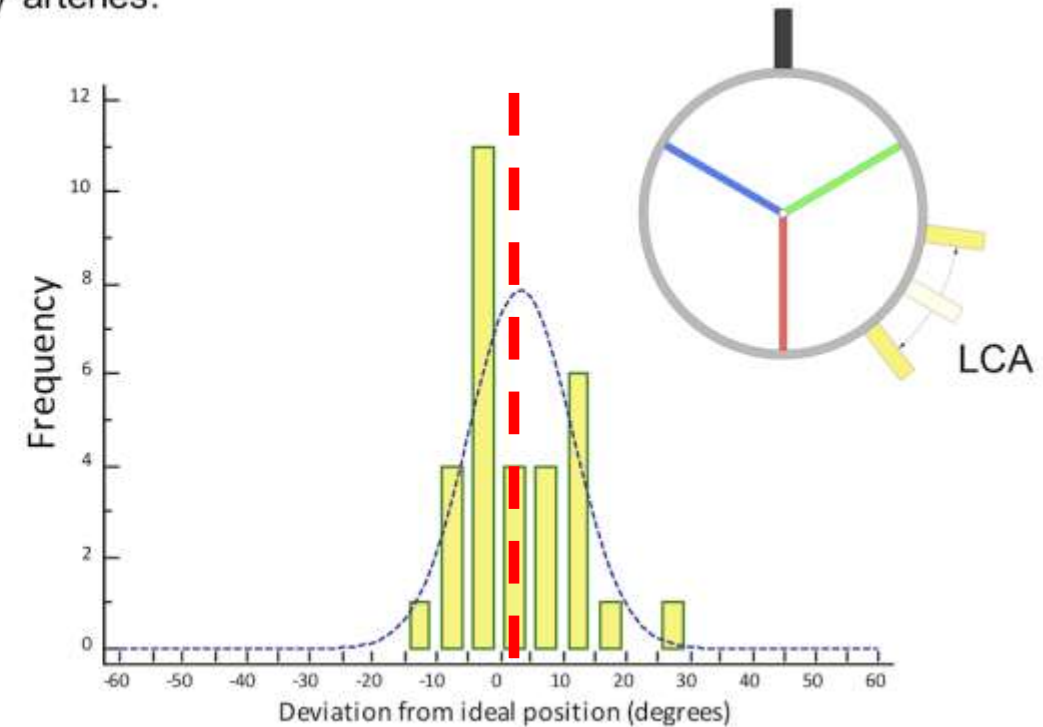
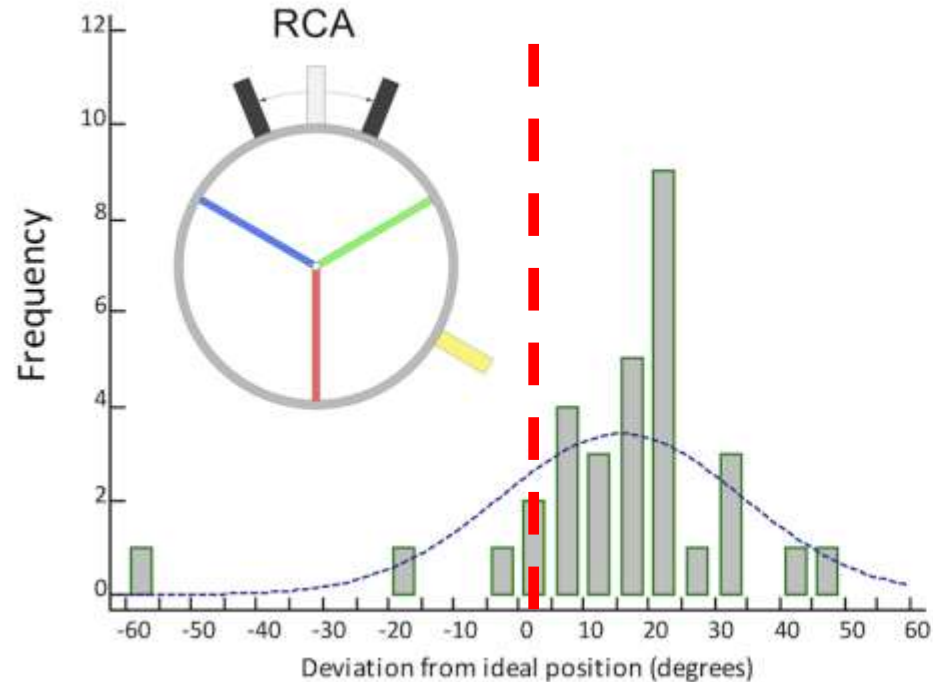
Alfredo Redondo, MD,<sup>a</sup> Carlos Baladrón Zorita, ENG, PhD,<sup>a</sup> Didier Tchétché, MD,<sup>b</sup> Sandra Santos-Martinez, MD,<sup>a</sup> Jose Raúl Delgado-Arana, MD,<sup>a</sup> Alejandro Barrero, MD,<sup>a</sup> Hipólito Gutiérrez, MD,<sup>a</sup> Ana Serrador Frutos, MD,<sup>a</sup> Cristina Ybarra Falcón, MD,<sup>a</sup> Mario García Gómez, MD, PhD,<sup>a</sup> Manuel Carrasco Moraleja, MSc,<sup>a</sup> Teresa Sevilla, MD, PhD,<sup>a</sup> Israel Sanchez Lite, MD,<sup>c</sup> Esther Sanz, RN,<sup>a</sup> J. Alberto San Román, MD, PhD,<sup>a</sup> Ignacio J. Amat-Santos, MD, PhD<sup>a</sup>



# How often are coronary ostial “eccentric”

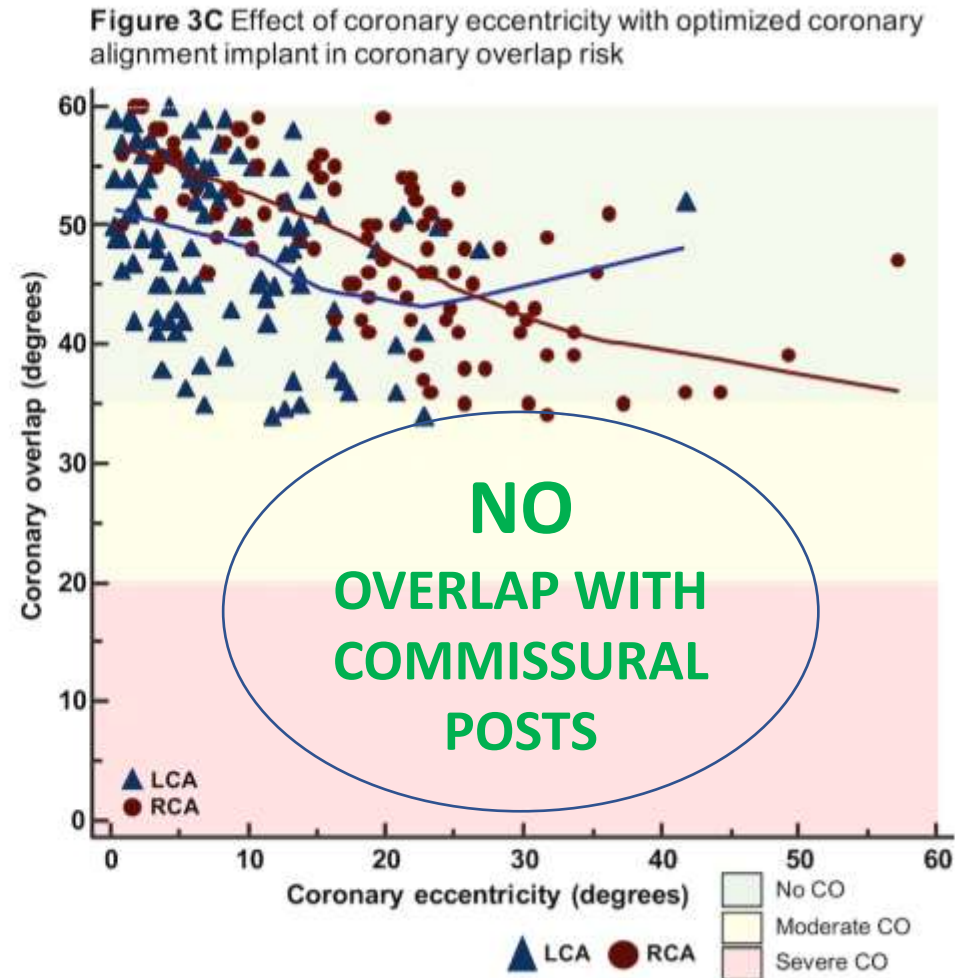
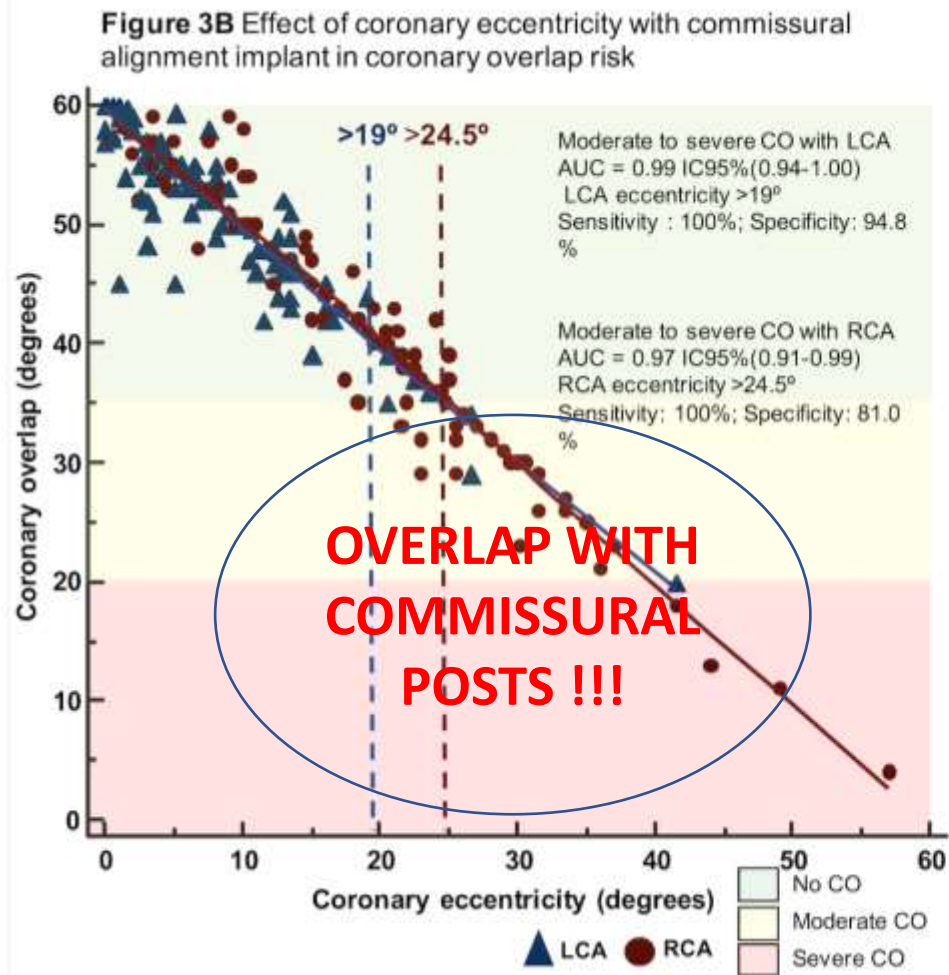
- Variability of coronary ostia

Figure 3A Coronary eccentricity histogram for right (RCA) and left (LCA) coronary arteries.



# How often are coronary ostial “eccentric”

- Variability of coronary ostia

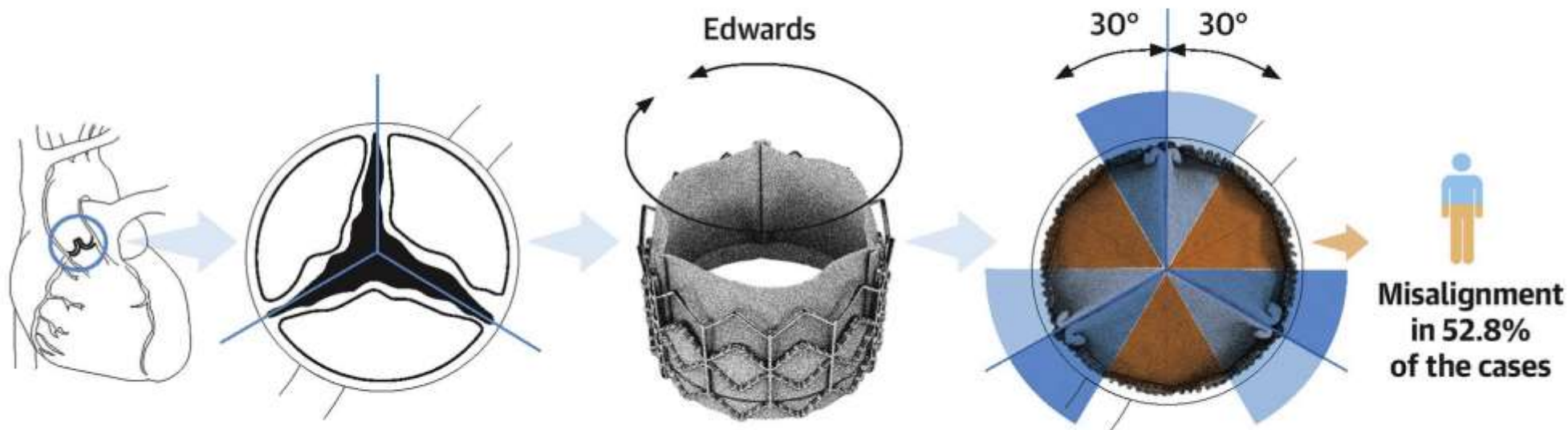




## GOOD HEMODYNAMICS:

- NO LEAK
- NO RESIDUAL GRADIENTS

## CENTRAL ILLUSTRATION: Main Outcomes of Aligned Versus Misaligned Balloon-Expandable Transcatheter Aortic Valve Replacement (N = 324)

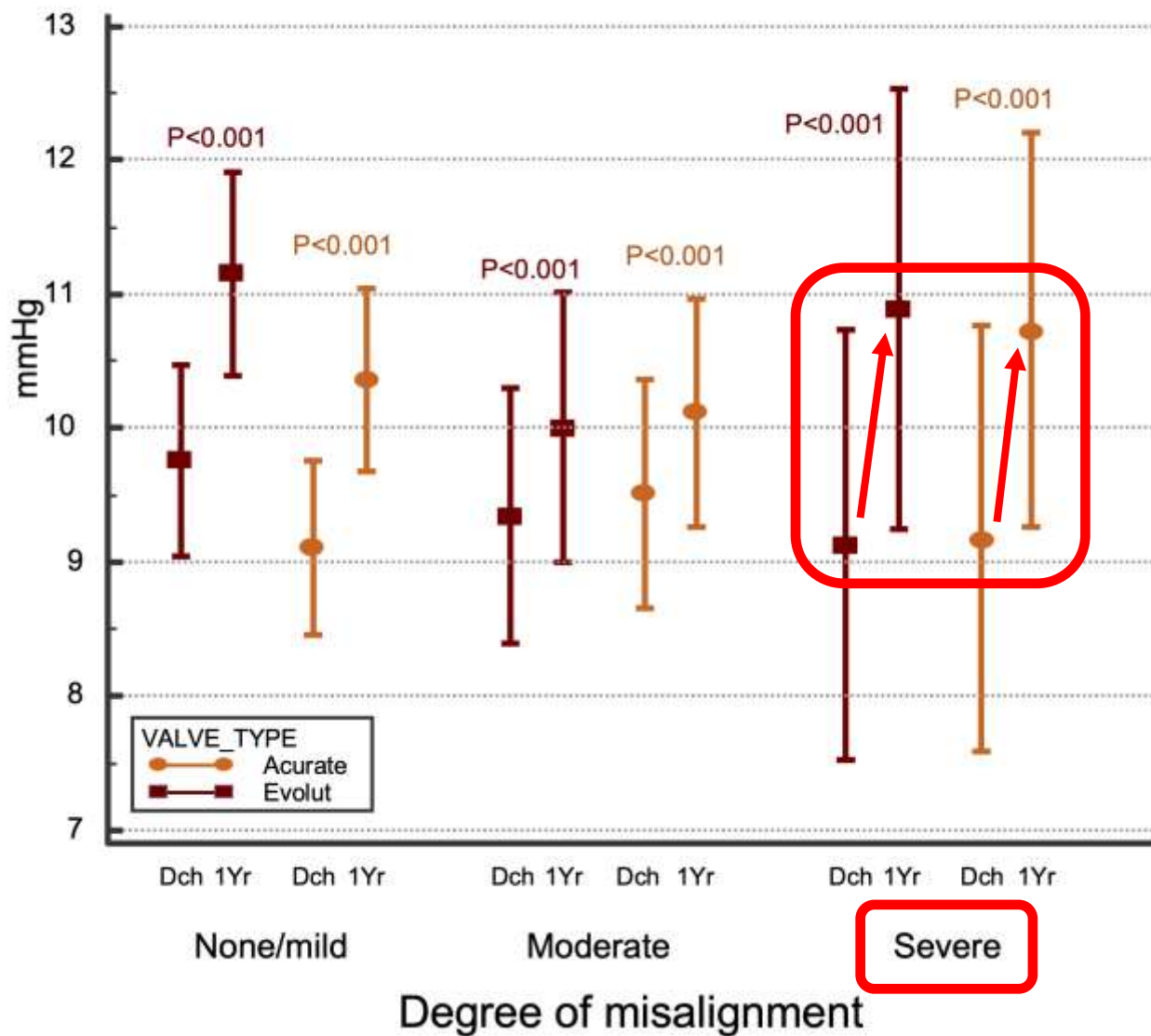


Outcome	Aligned (n = 153)	Misaligned (n = 171)	Odds Ratio [95% CI]
VARC-2 Early Safety	98.5%	94.3%	0.27 [0.04-1.10]
Aortic regurgitation > mild	3.6%	5.7%	1.55 [0.44-6.36]
Residual gradient (>20 mm Hg)	7.2%	7.4%	1.02 [0.37-2.86]
Relative AV gradient increase	8.3%	17.6%	2.35 [1.05-5.69]

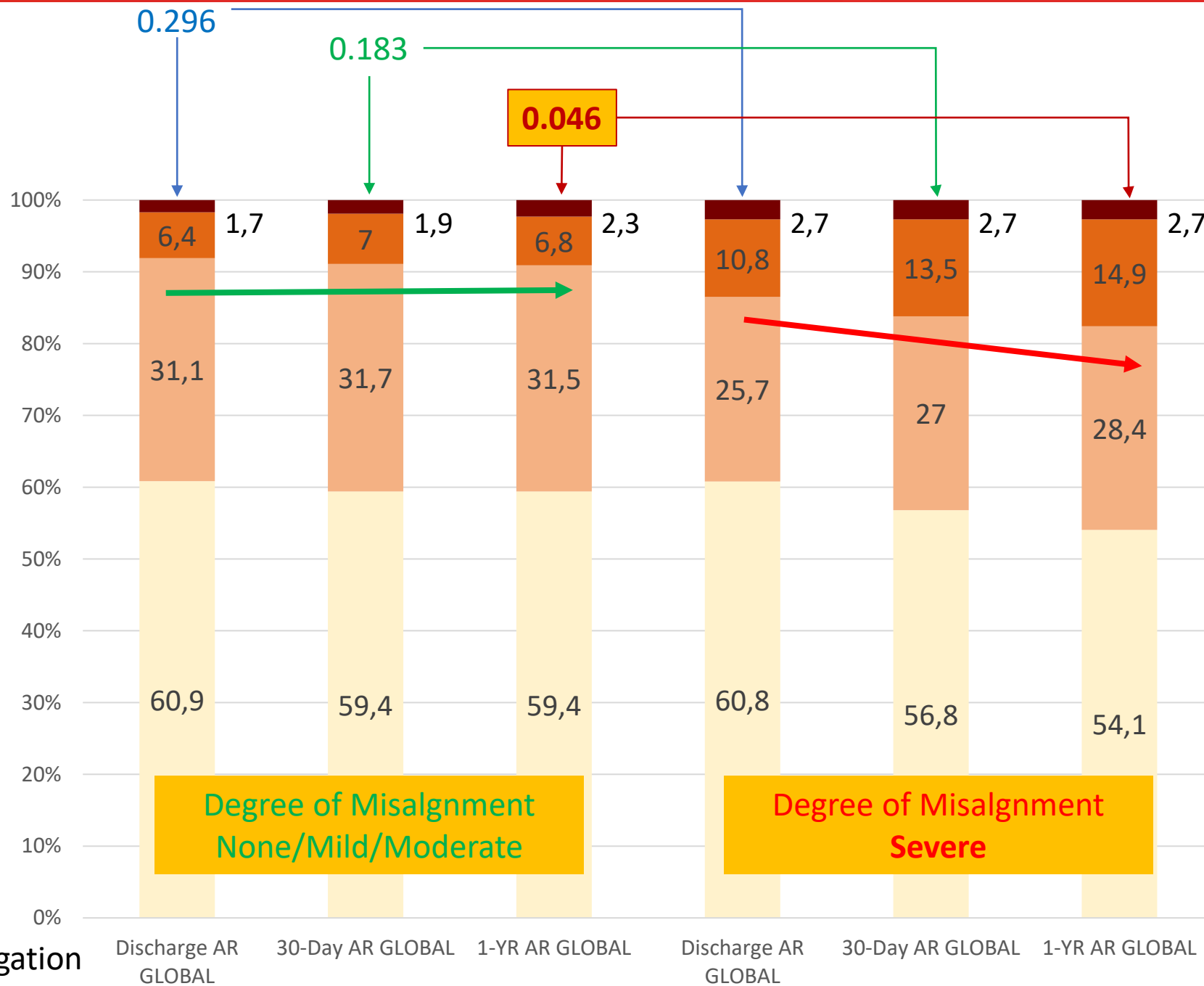
Raschpichler M, et al. J Am Coll Cardiol Interv. 2022;15(11):1126-1136.

## Global population

### A. Changes in mean aortic gradient from discharge to 1 year follow up



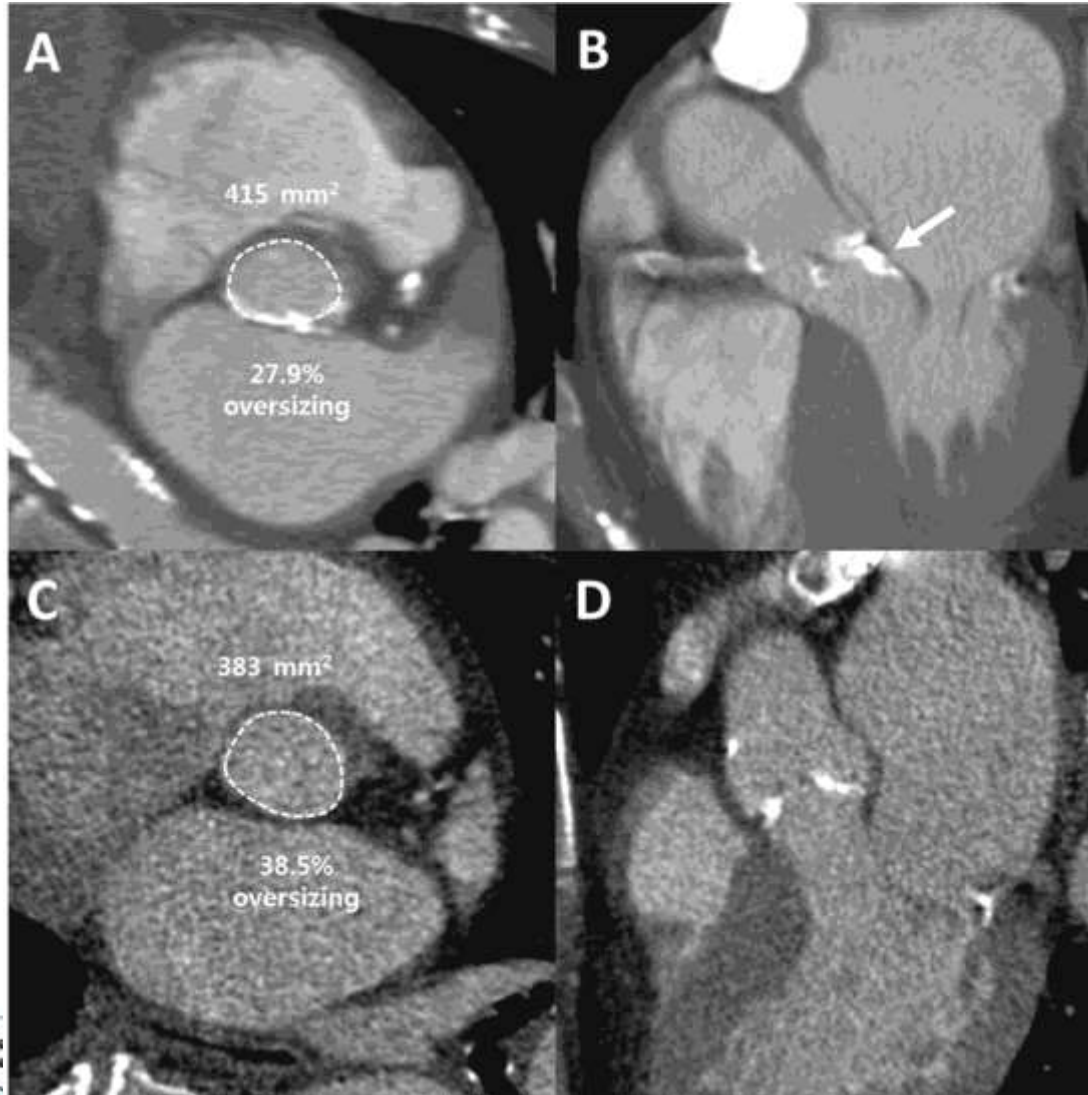
# AORTIC GRADIENTS



- None
- Mild
- Moderate
- Severe

Under investigation

# Risk of annular rupture

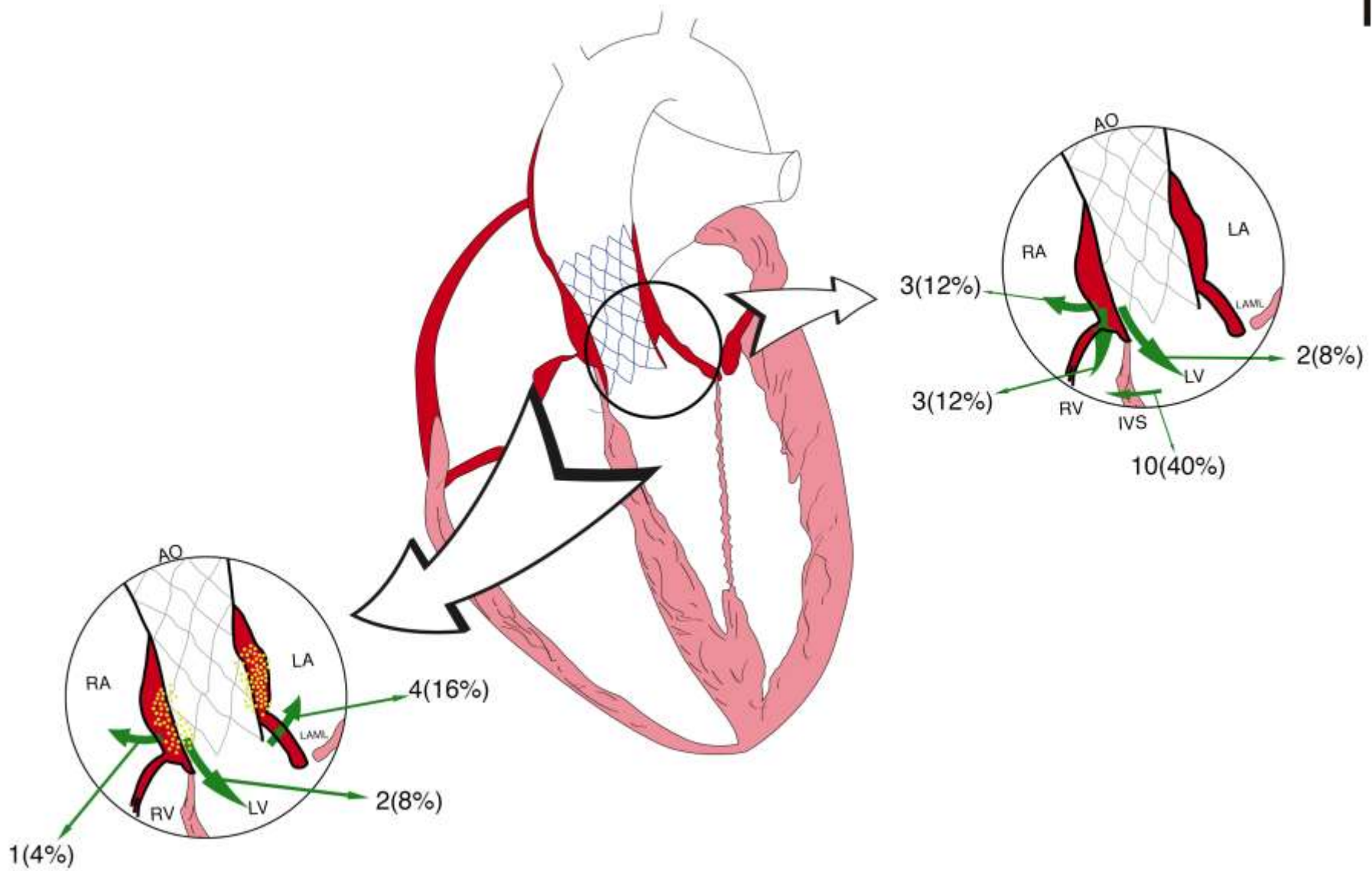


CALCIFICATION

OVER-SIZING

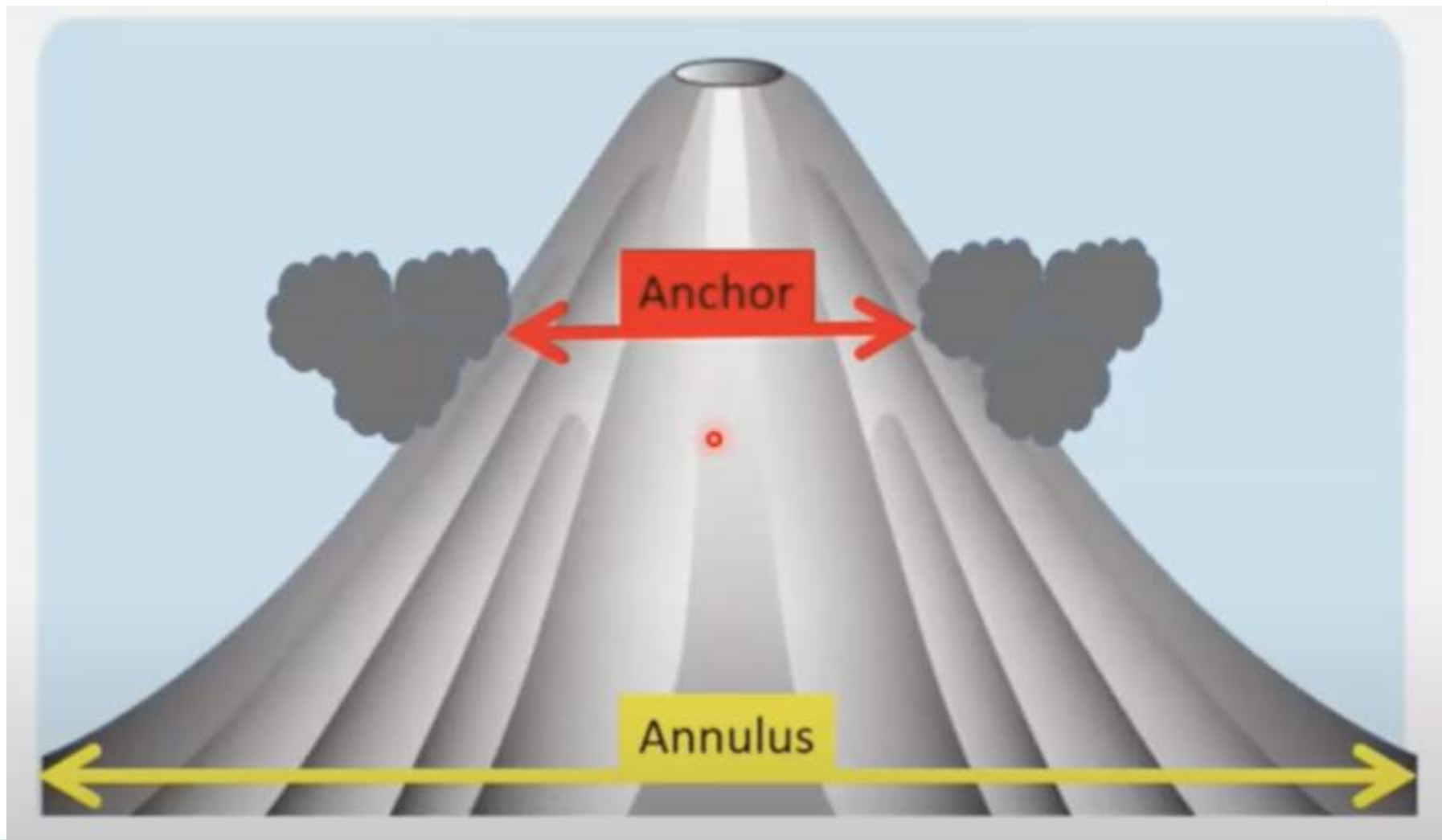
POST-DILATION

BE-TAVI  
UNDER-SIZED





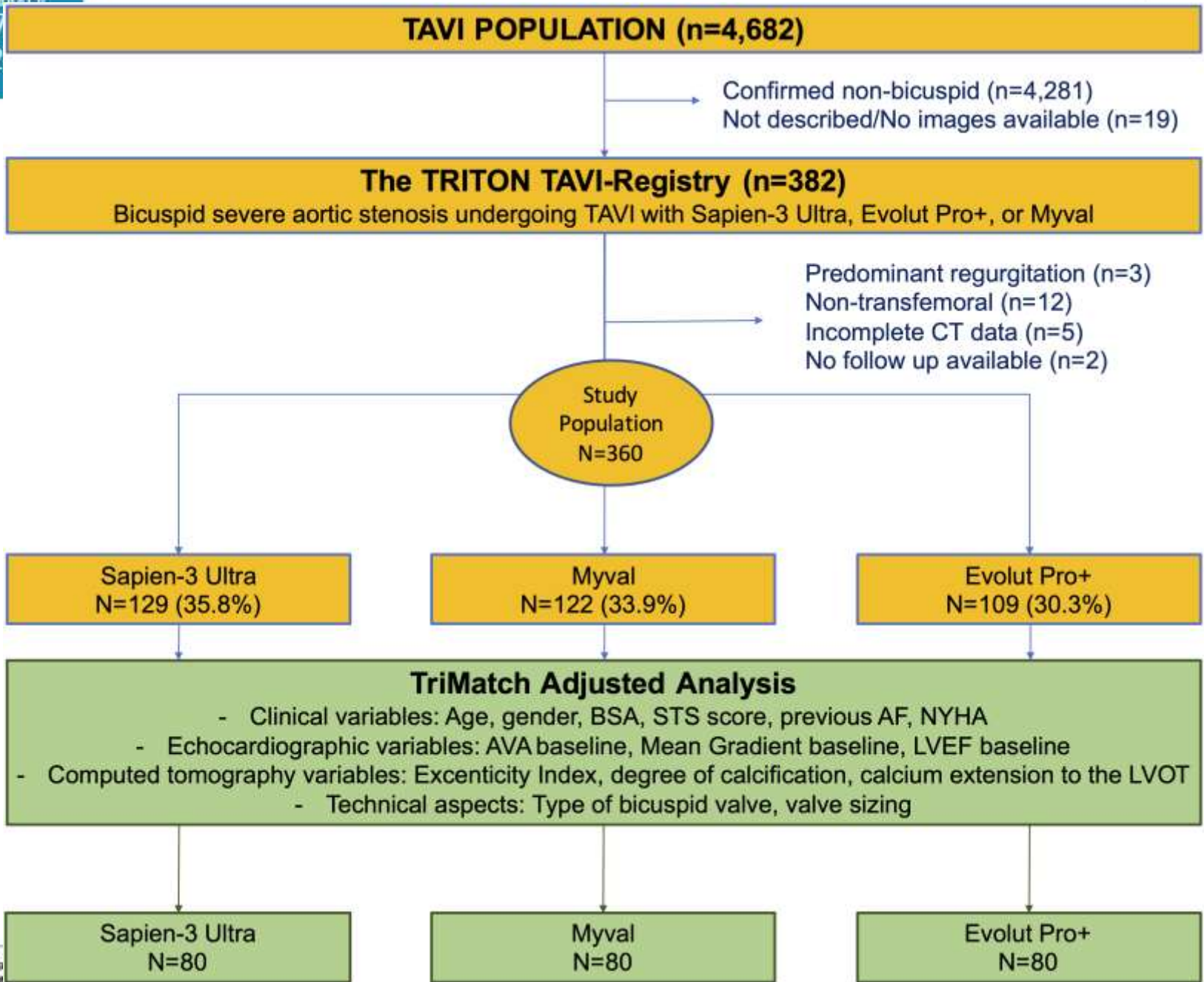
# Risk of underexpansion / leak / Bicuspid

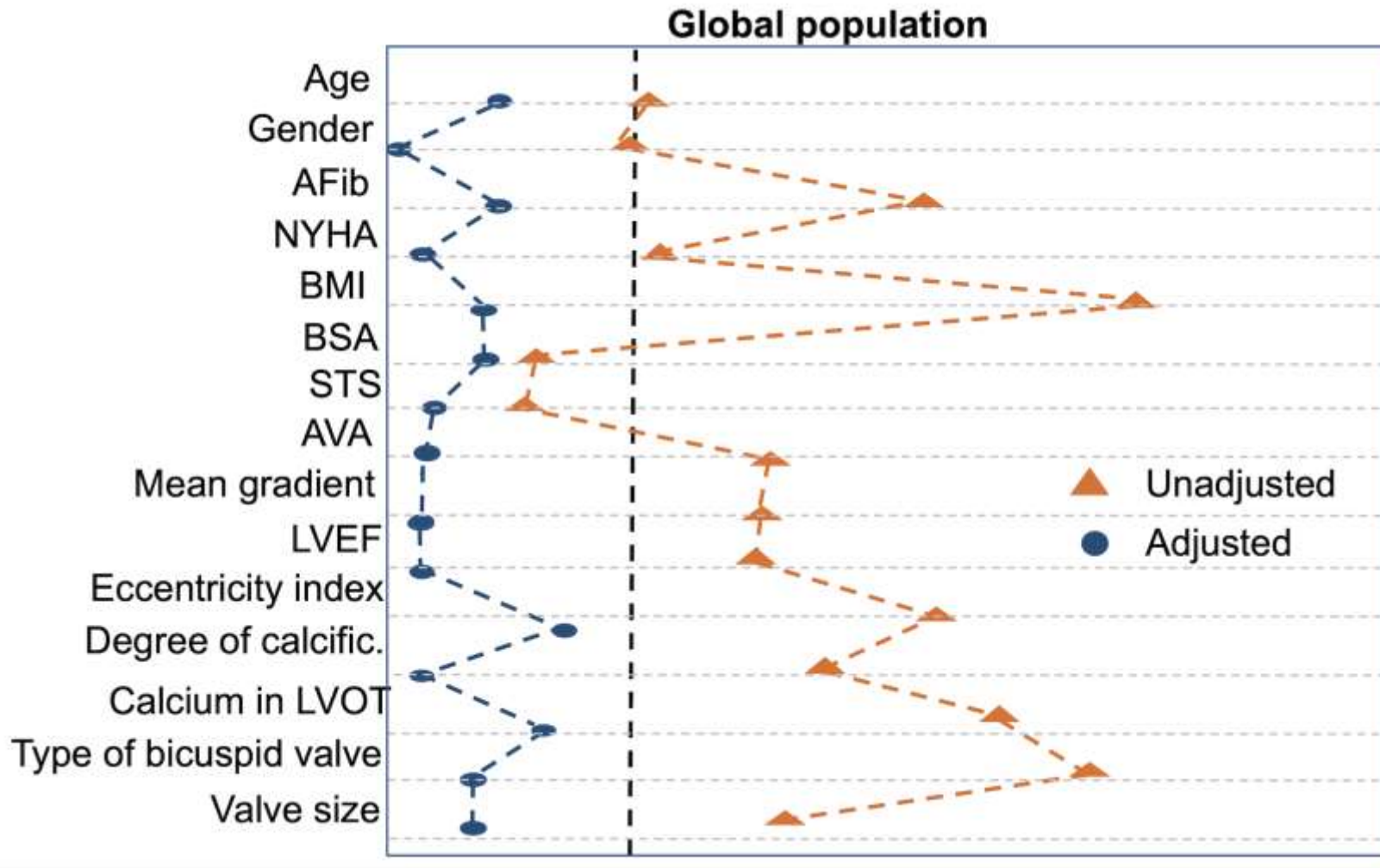




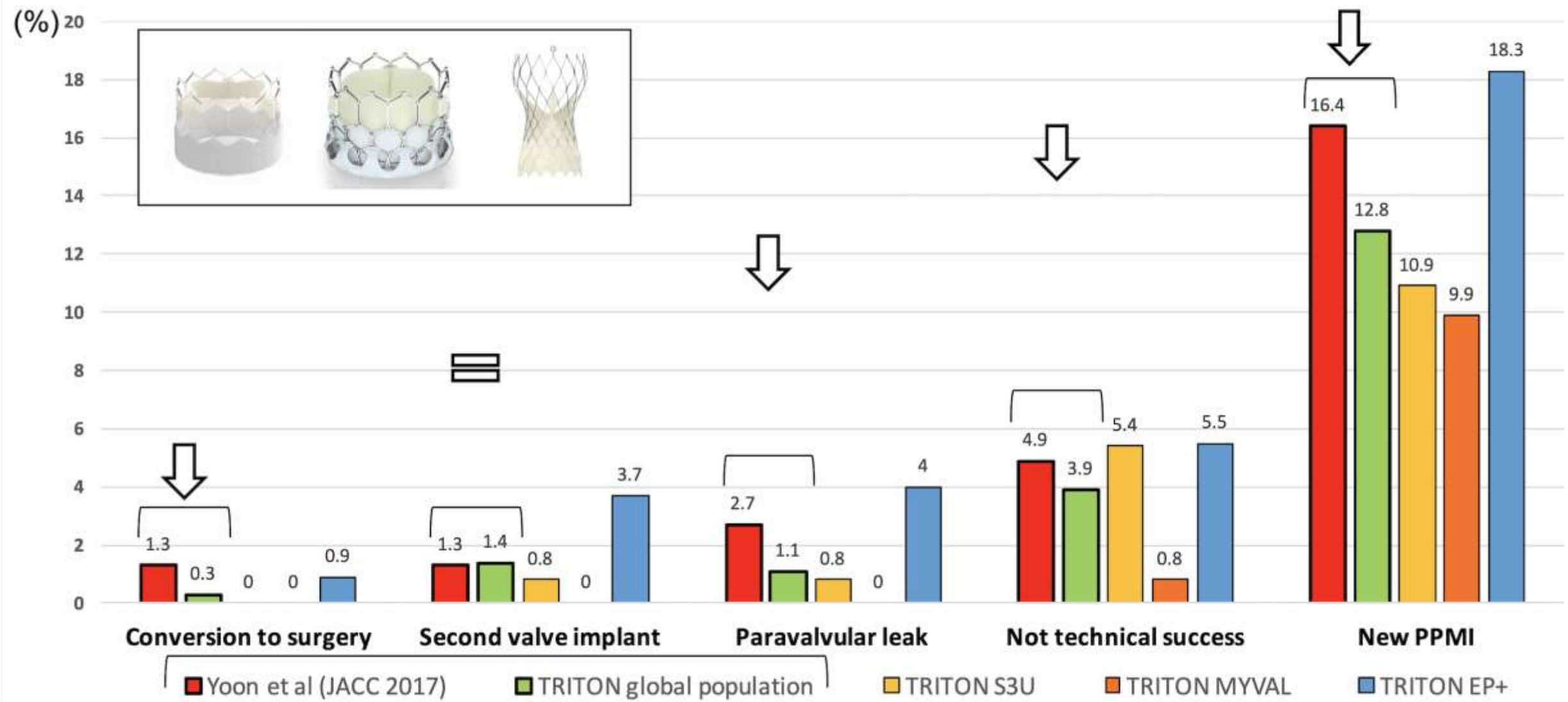
# Risk of underexpansion / leak / Bicuspid

- **Complications arising more frequently** after TAVI in this cohort: PVL, nonuniform/noncircular valve deployment, device migration, and annular rupture
- Some authors suggest that **self-expanding valve may be preferable** to a balloon-expandable device, both to conform to an asymmetric valve orifice and to reduce risk of annular rupture

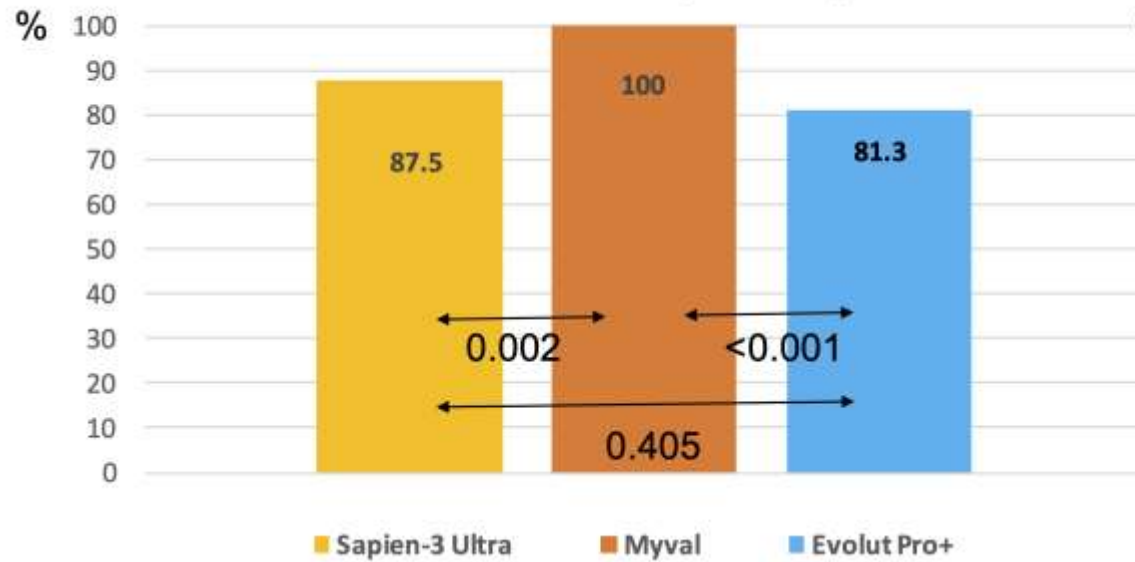




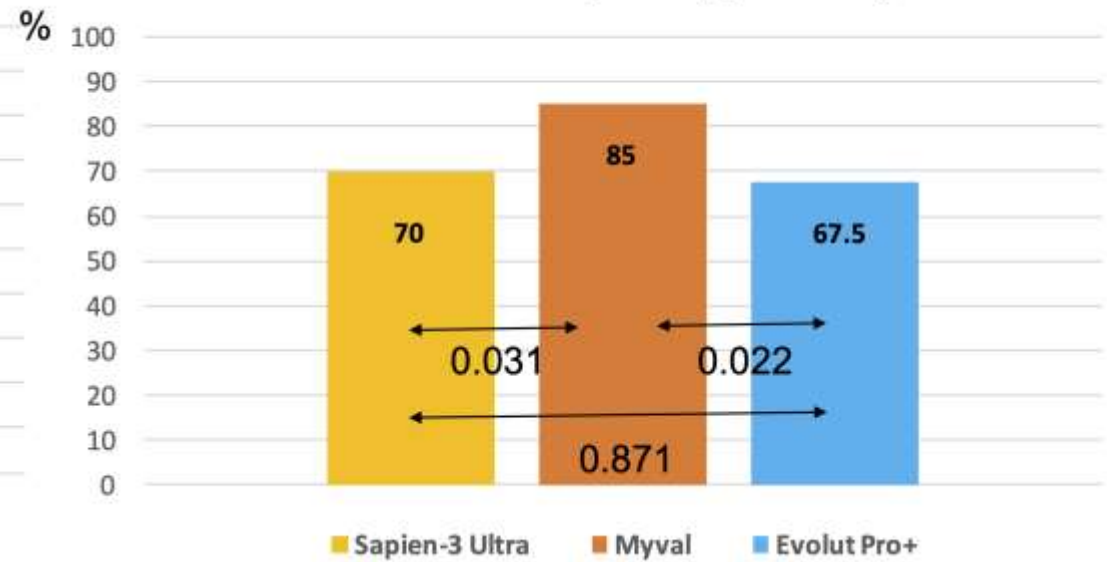
**MAIN OUTCOMES ACCORDING TO DEVICE AND COMPARED TO PRIOR PUBLICATION**

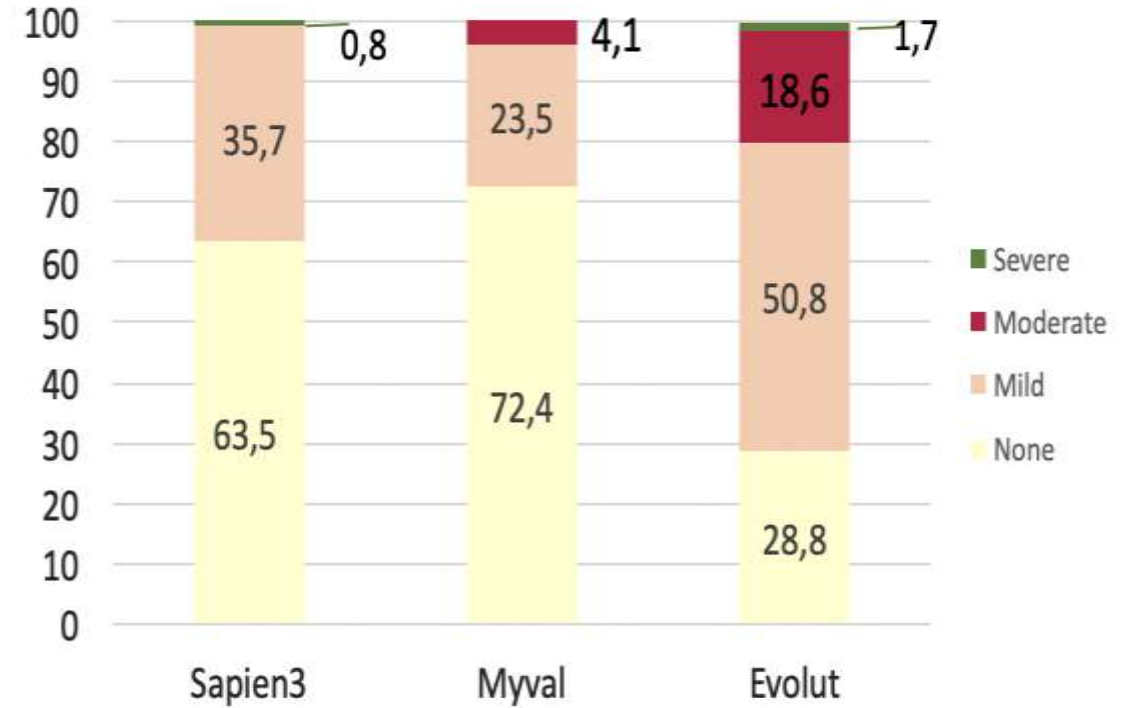
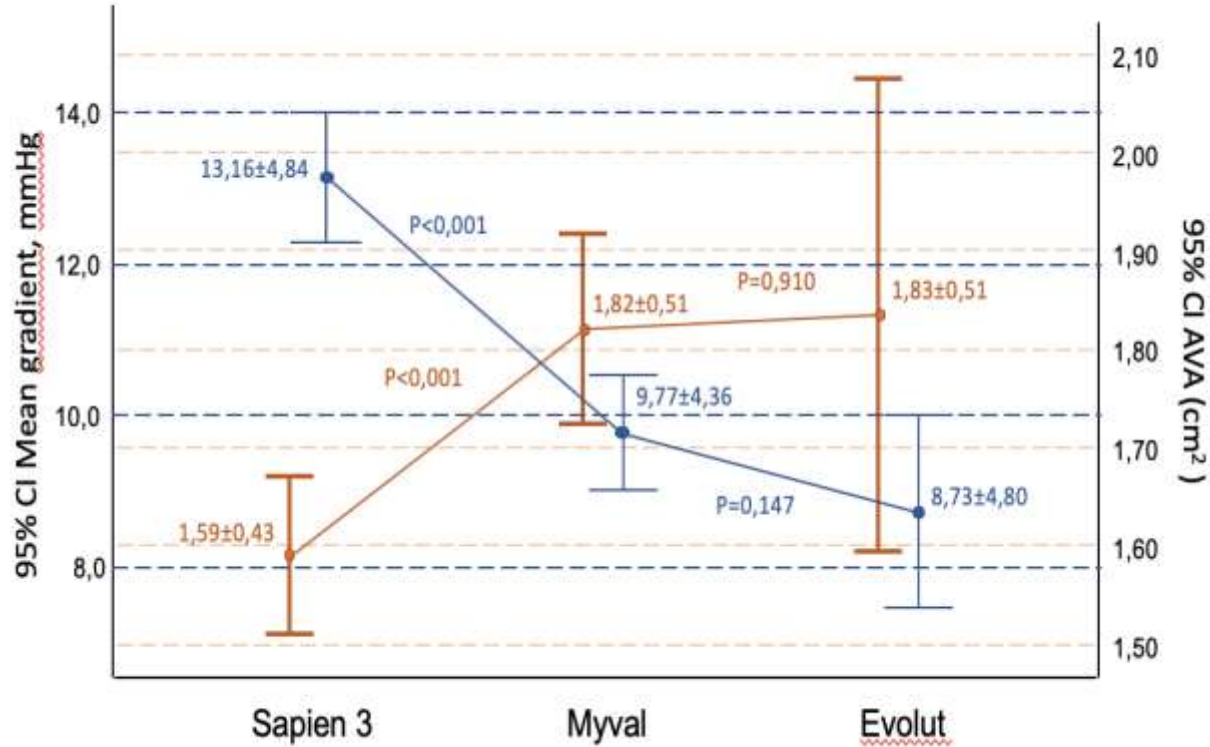


**A. Device success (Matched)**



**B. Early safety (Matched)**







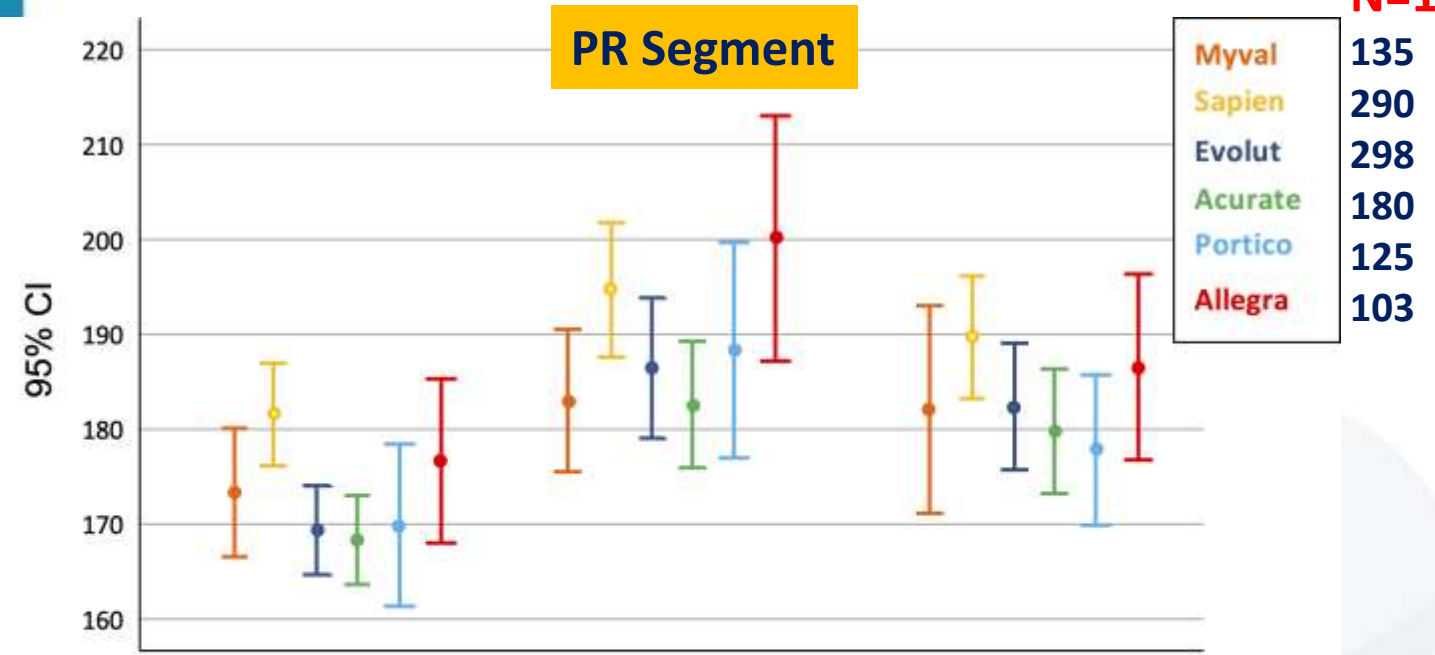
## AVOID RISKS

- LIFE THREATENING
- CONDUCTION DISTURBANCES
- DIFFICULT CORON.RE-ACCESS

## GOOD HEMODYNAMICS:

- NO LEAK
- NO RESIDUAL GRADIENTS

**N=1131**

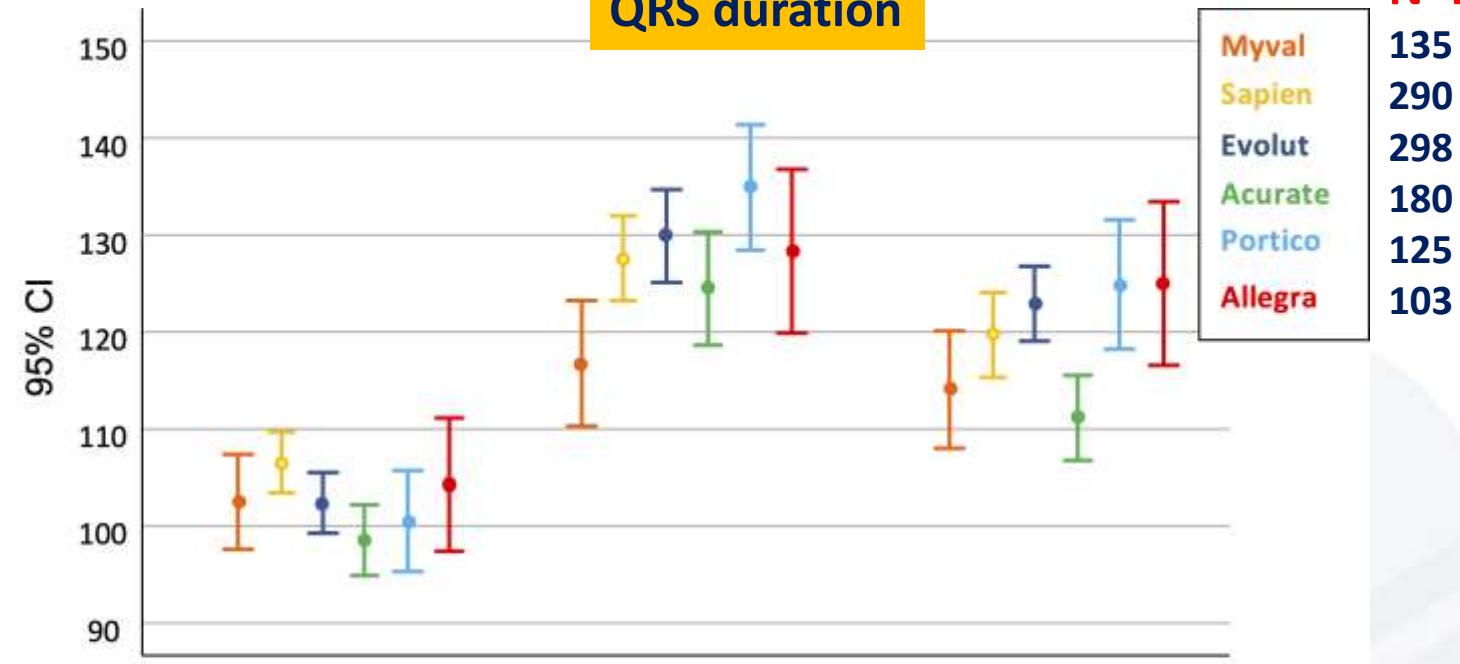


	PR PRE	PR POST	PR DISCHARGE
Myval - Sapien	0.097	0.051	0.226
Myval - Evolut	0.342	0.504	0.967
Myval - Acurate	0.227	0.929	0.715
Myval - Portico	0.525	0.414	0.525
Myval - Allegra	0.554	<b>0.024</b>	0.556

Table shows the p-values of the PR comparison between valve types in each time period.

**QRS duration**

**N=1131**



	QRS PRE	QRS POST	QRS DISCHARGE
Myval - Sapien	0.200	0.006	0.153
Myval - Evolut	0.929	0.001	0.015
Myval - Acurate	0.177	0.075	0.435
Myval - Portico	0.569	<0.001	0.019
Myval - Allegra	0.695	0.030	0.040

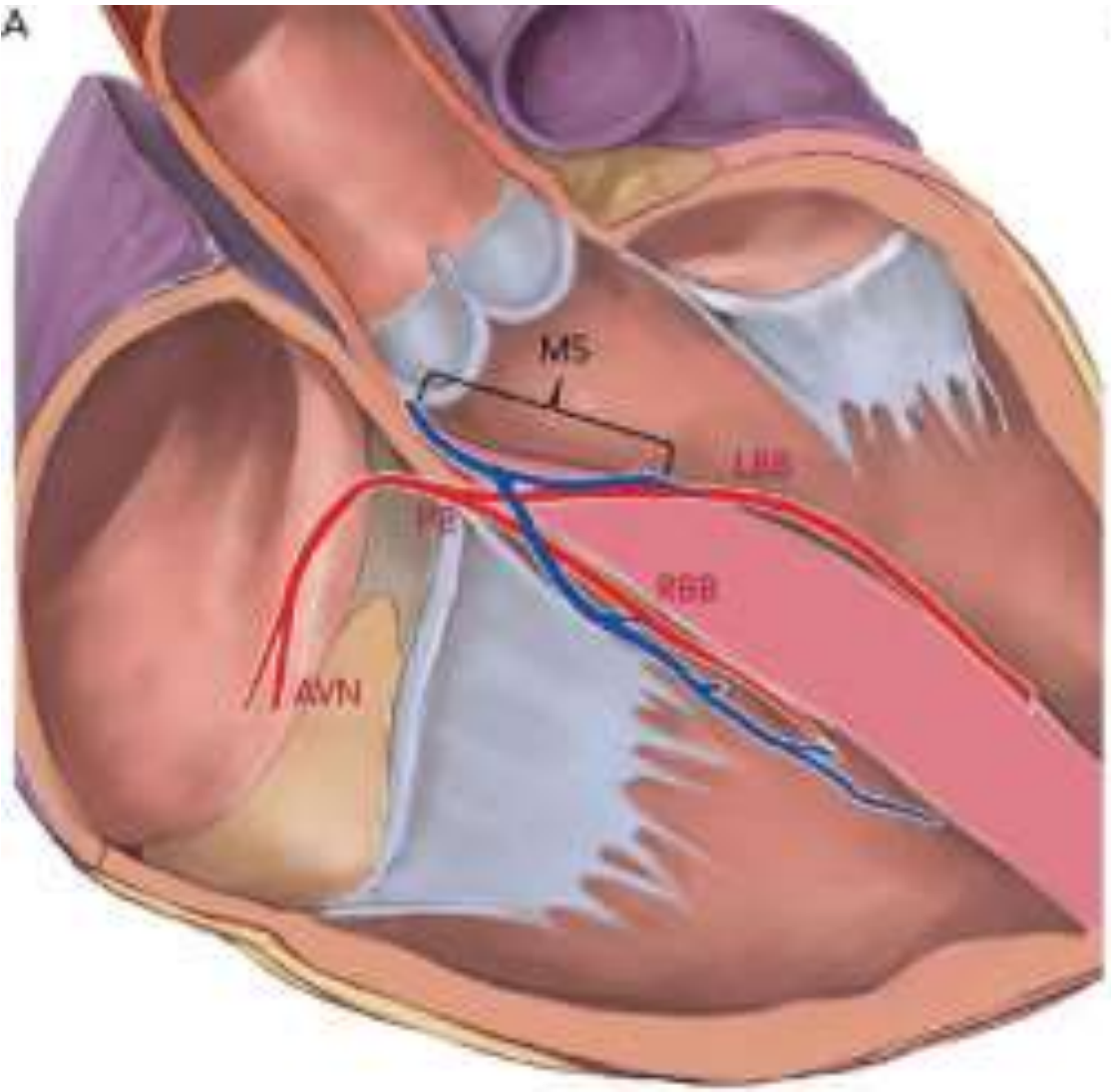
Table shows the p-values of the QRS comparison between valve types in each time period.



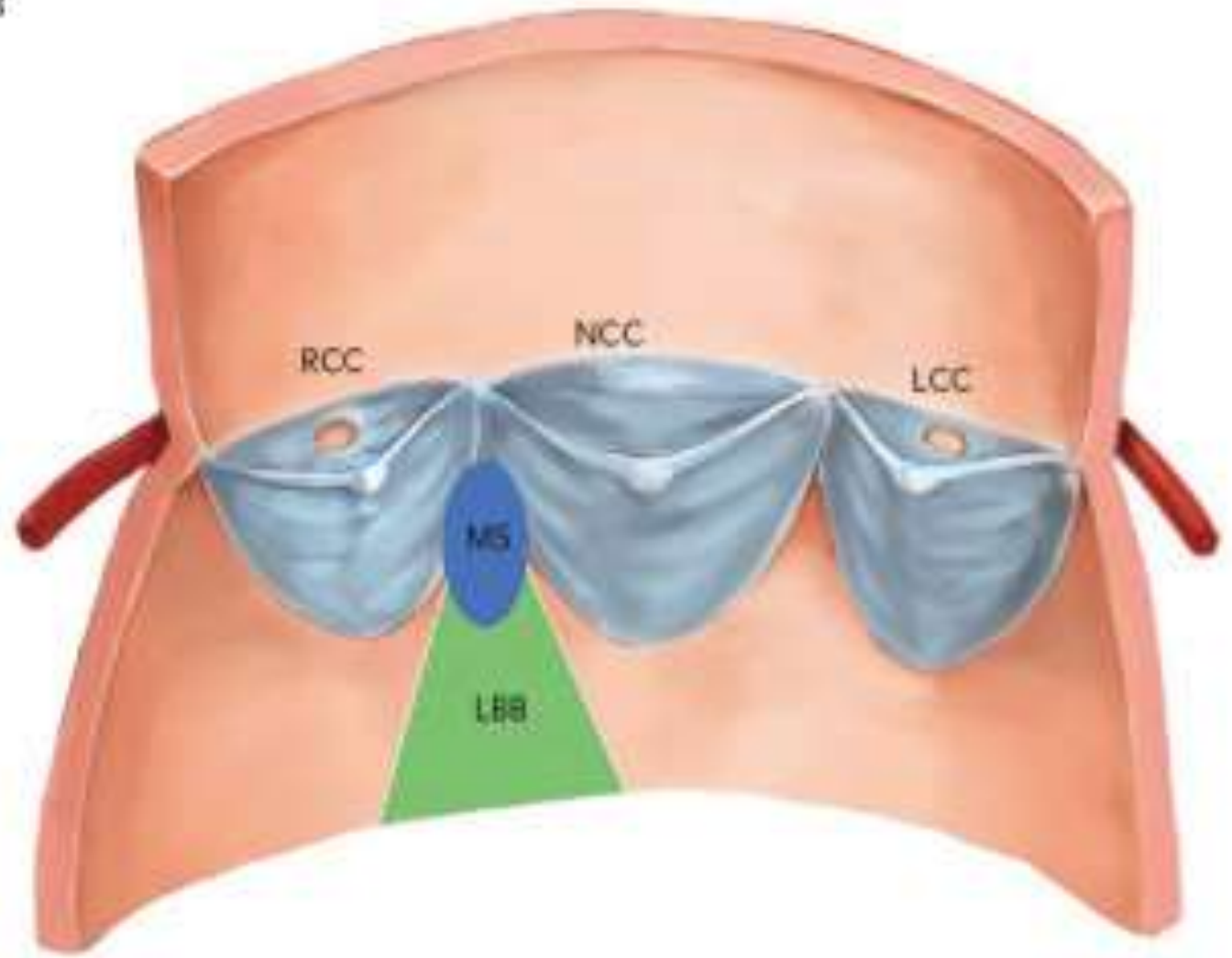
# PACEMAKER RATE

	Global population n=1131	Myval n=135	Sapien 3 n=290	p	Evolut n=298	p	Acurate n=180	p	Portico n=125	p	Allegra n=103	p
PPI	176 (15.9)	10 (7.4)	39 (13.4)	0.069	53 (18.5)	0.003	16 (9.1)	0.585	36 (29.5)	<0.001	22 (22)	0.001

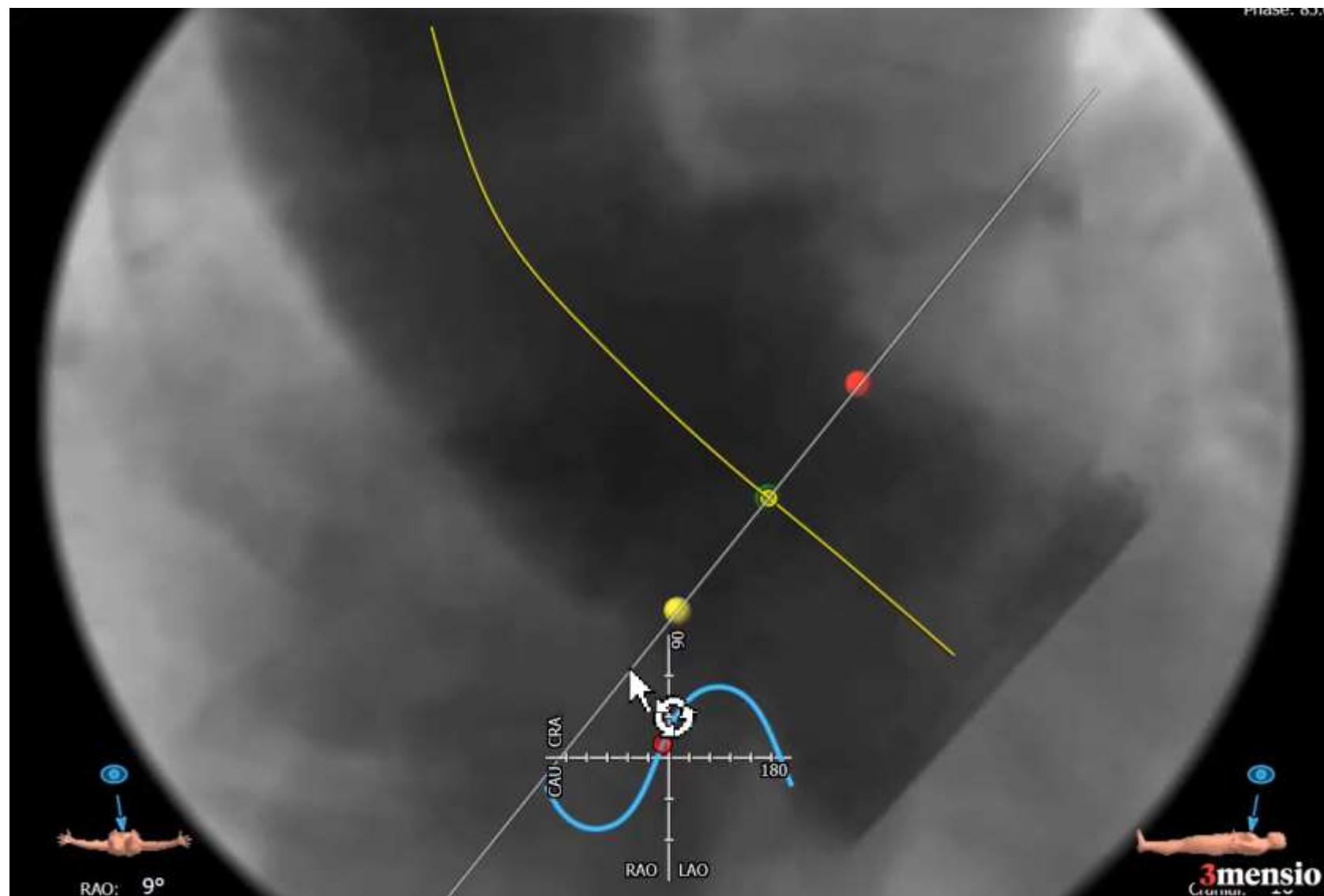
A



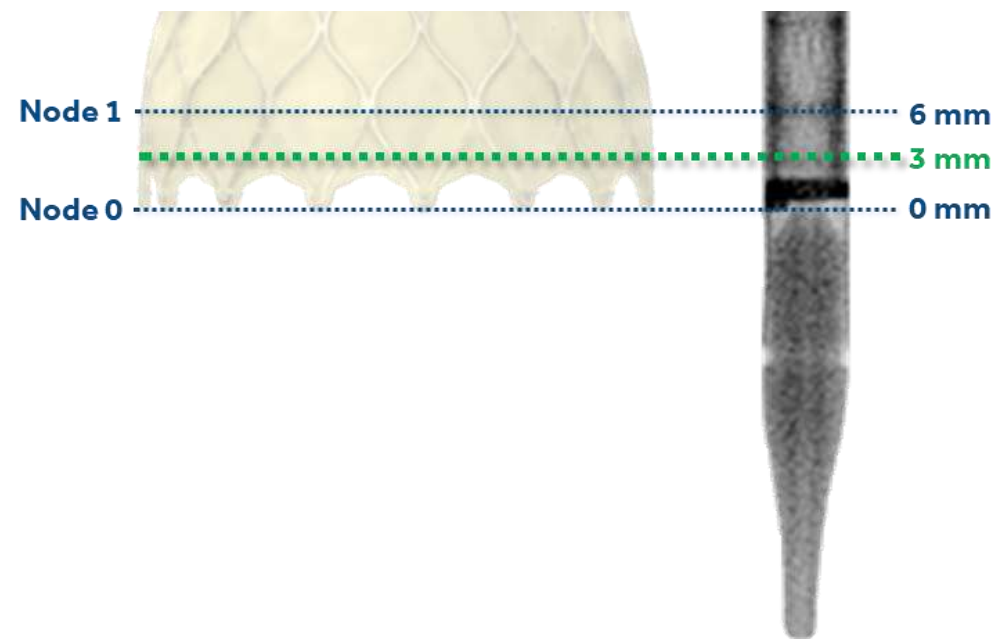
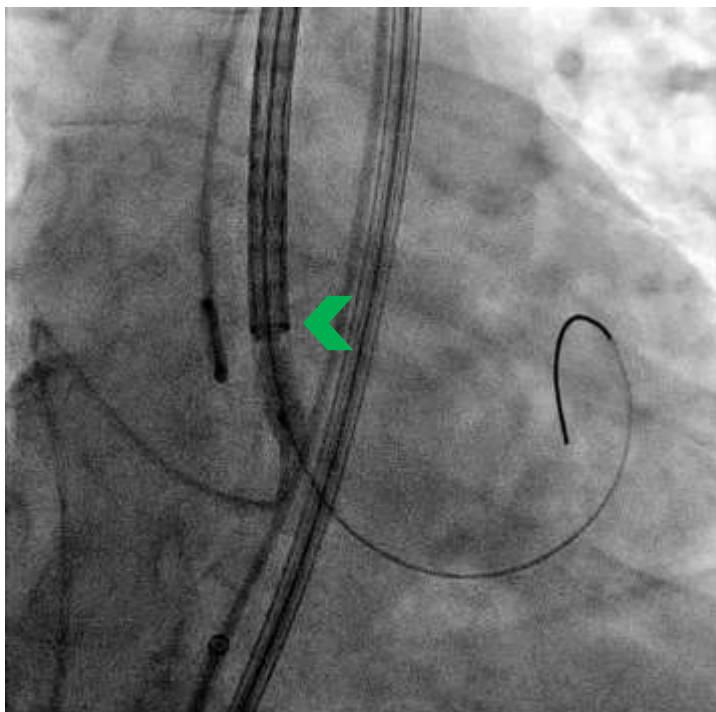
B



# 1- CUSP OVERLAP VIEW

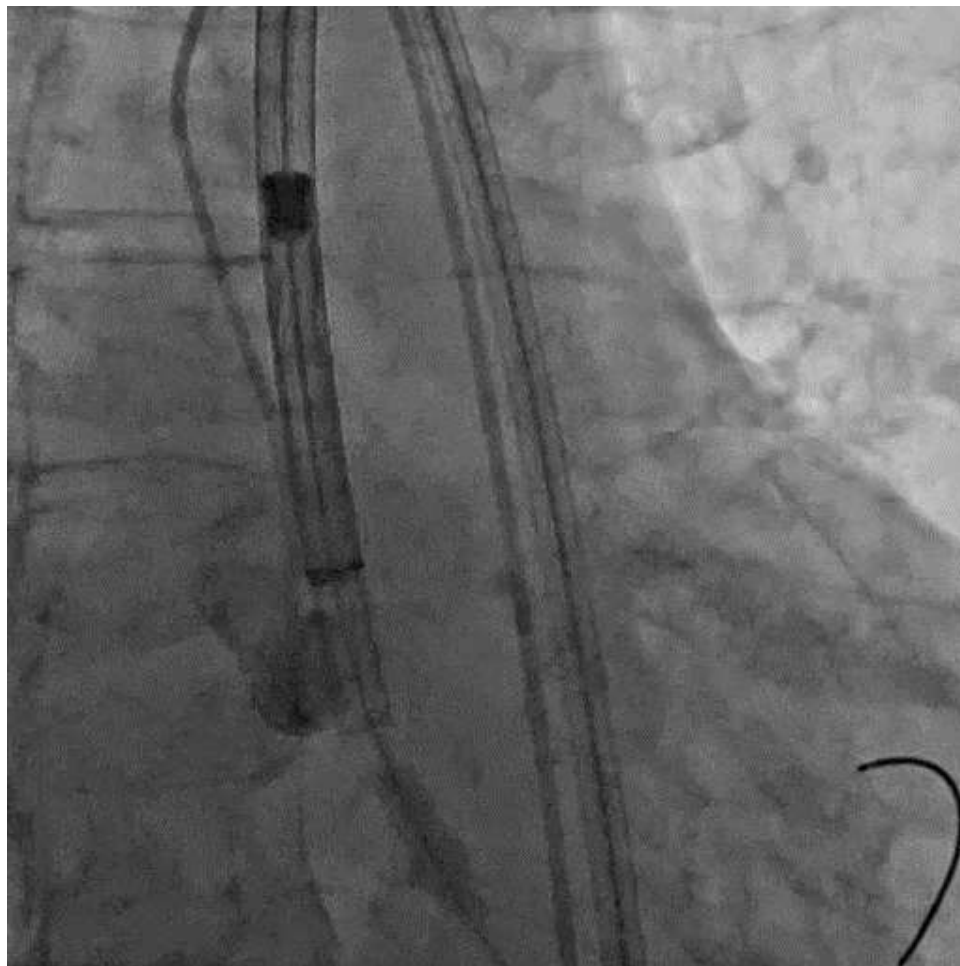


- 2-RADIOPAQUE MARKER BAND AT MID PIGTAIL
- 3- AIM IMPLANT DEPTH 3mm



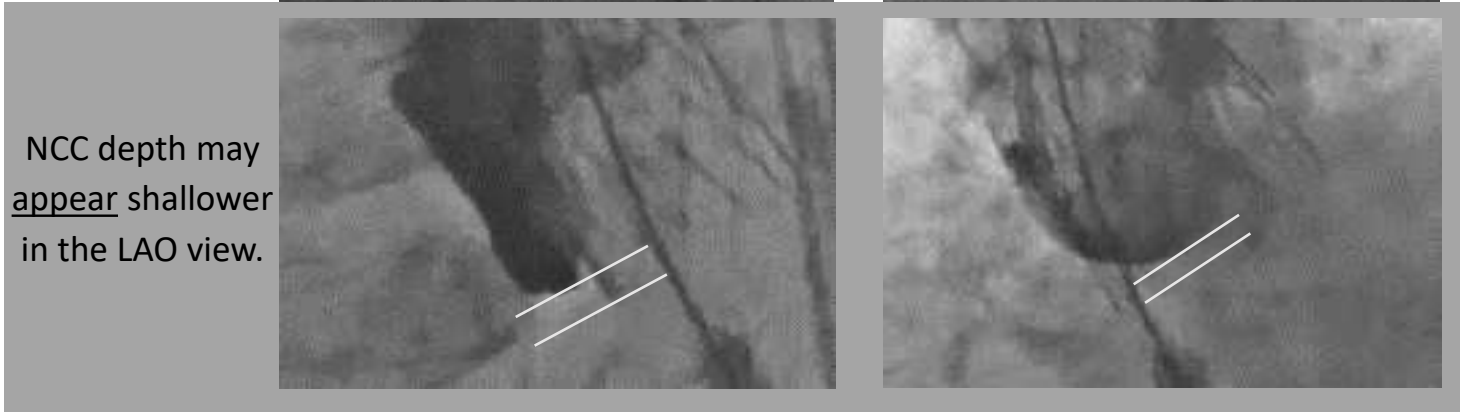
3 mm Target Implant Depth

#### 4- SLOW DEPLOYMENT (CONSIDER PACING)

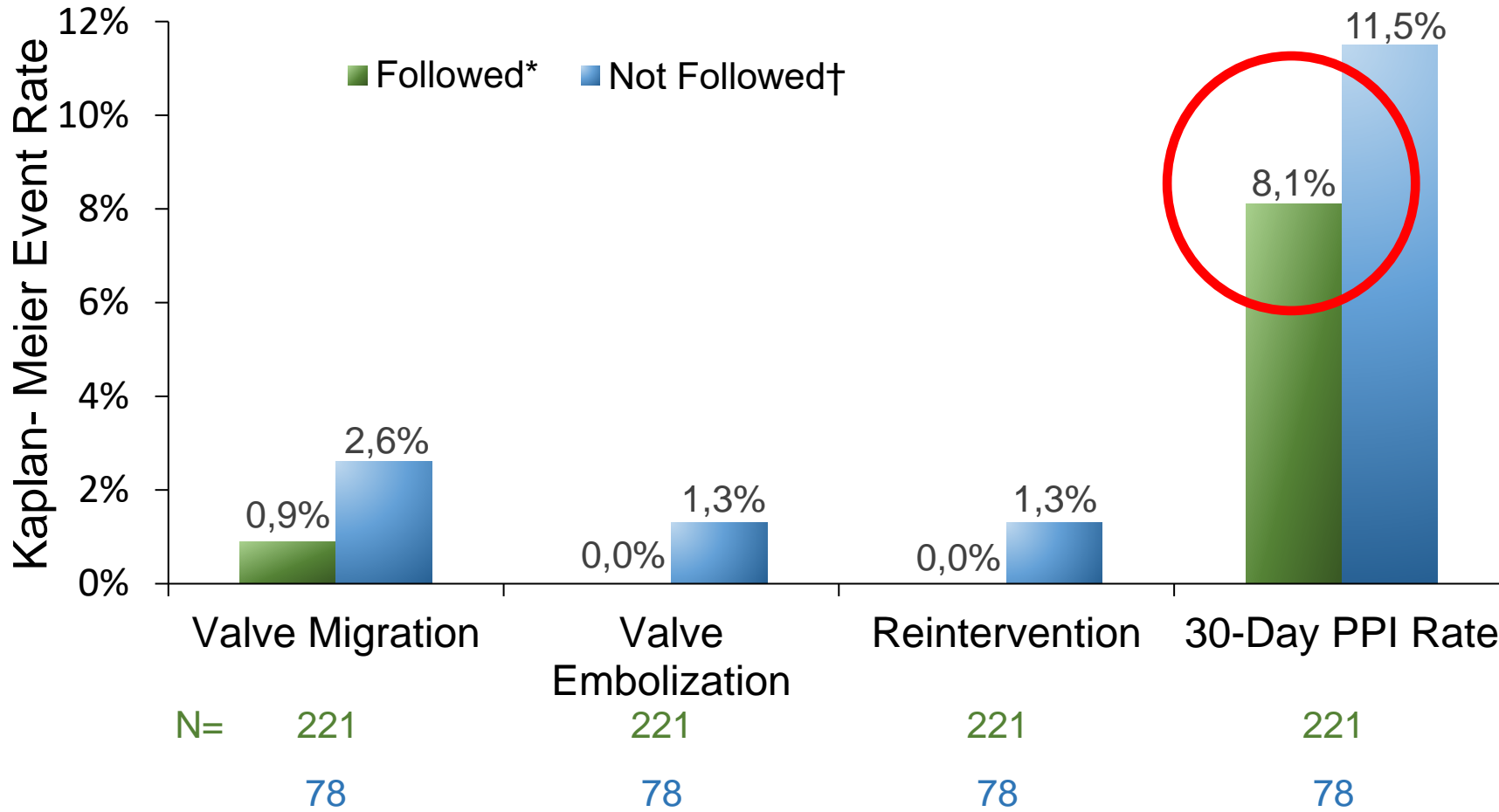




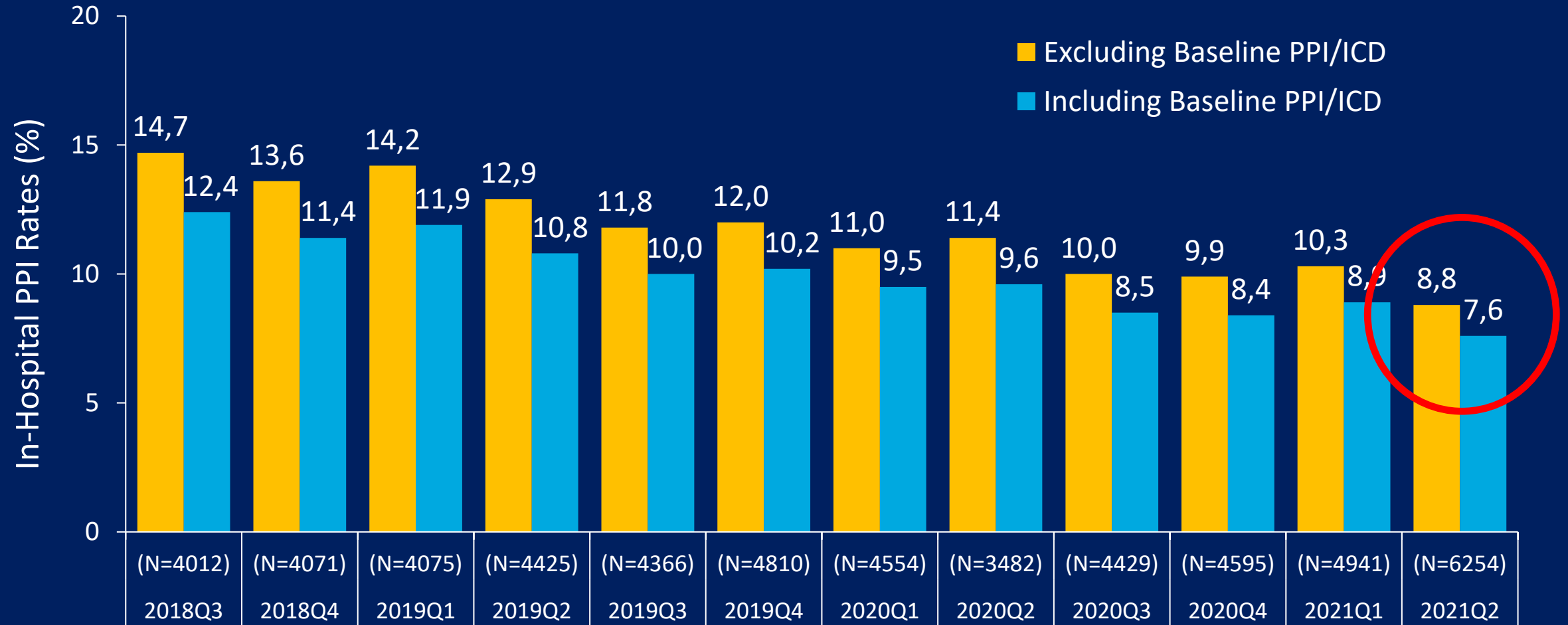
5- MOVE TO 3 CUSP COPLANAR VIEW AND ROLL TO LAO TO MINIMIZE PARALLAX

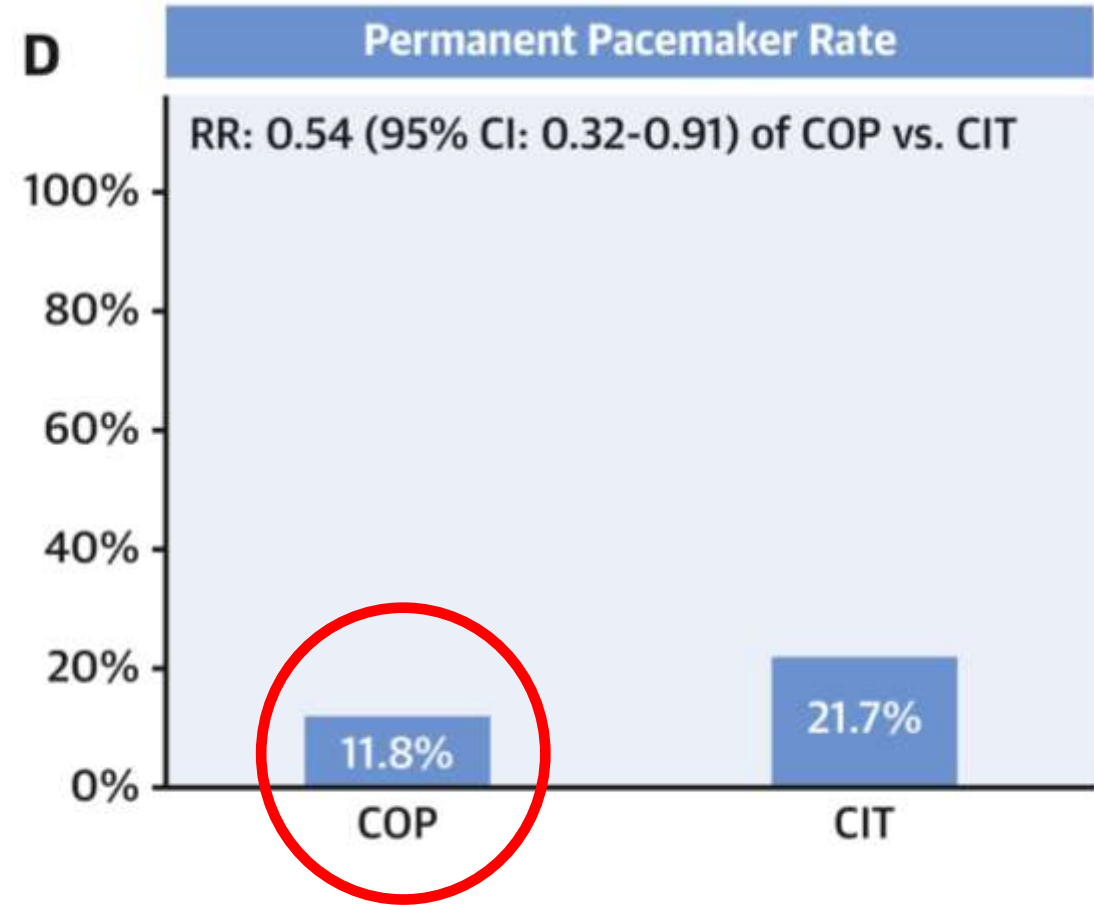
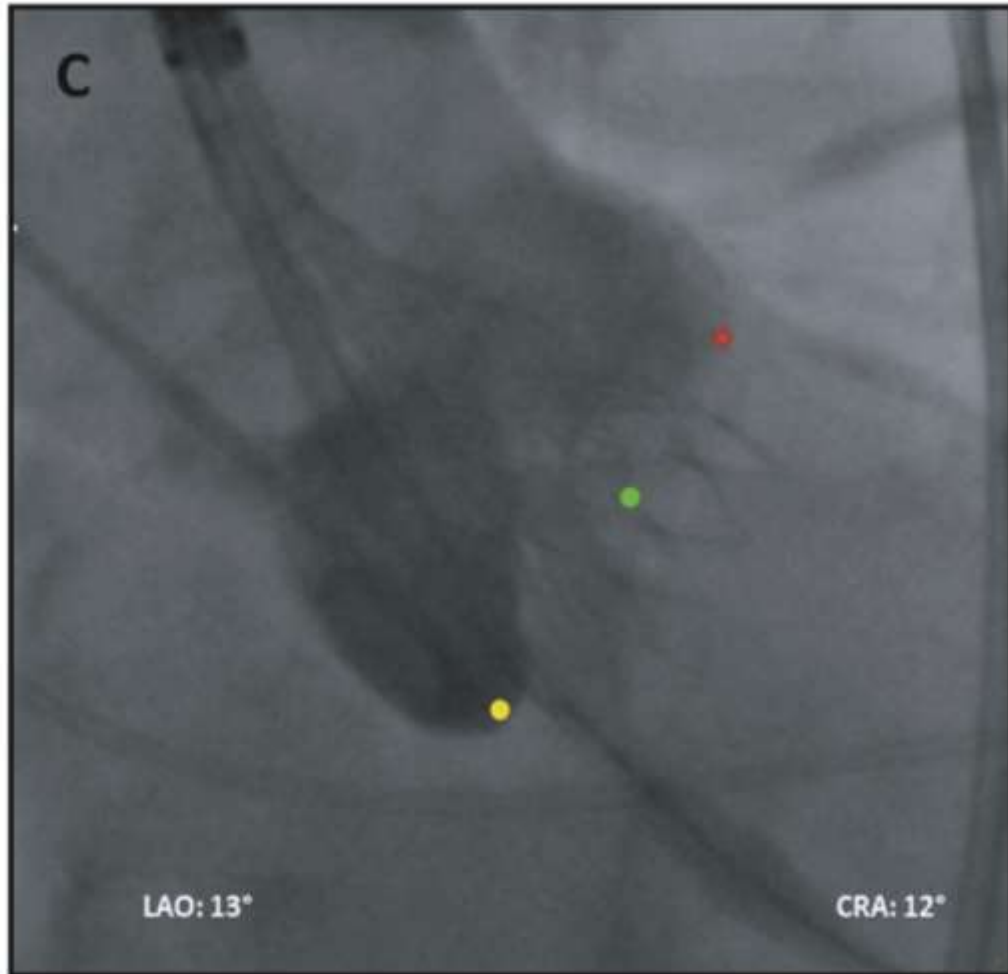


## RESULTS OF OPTIMIZE PRO STUDY: FOLLOWING OFFICIAL RECOMMENDATIONS



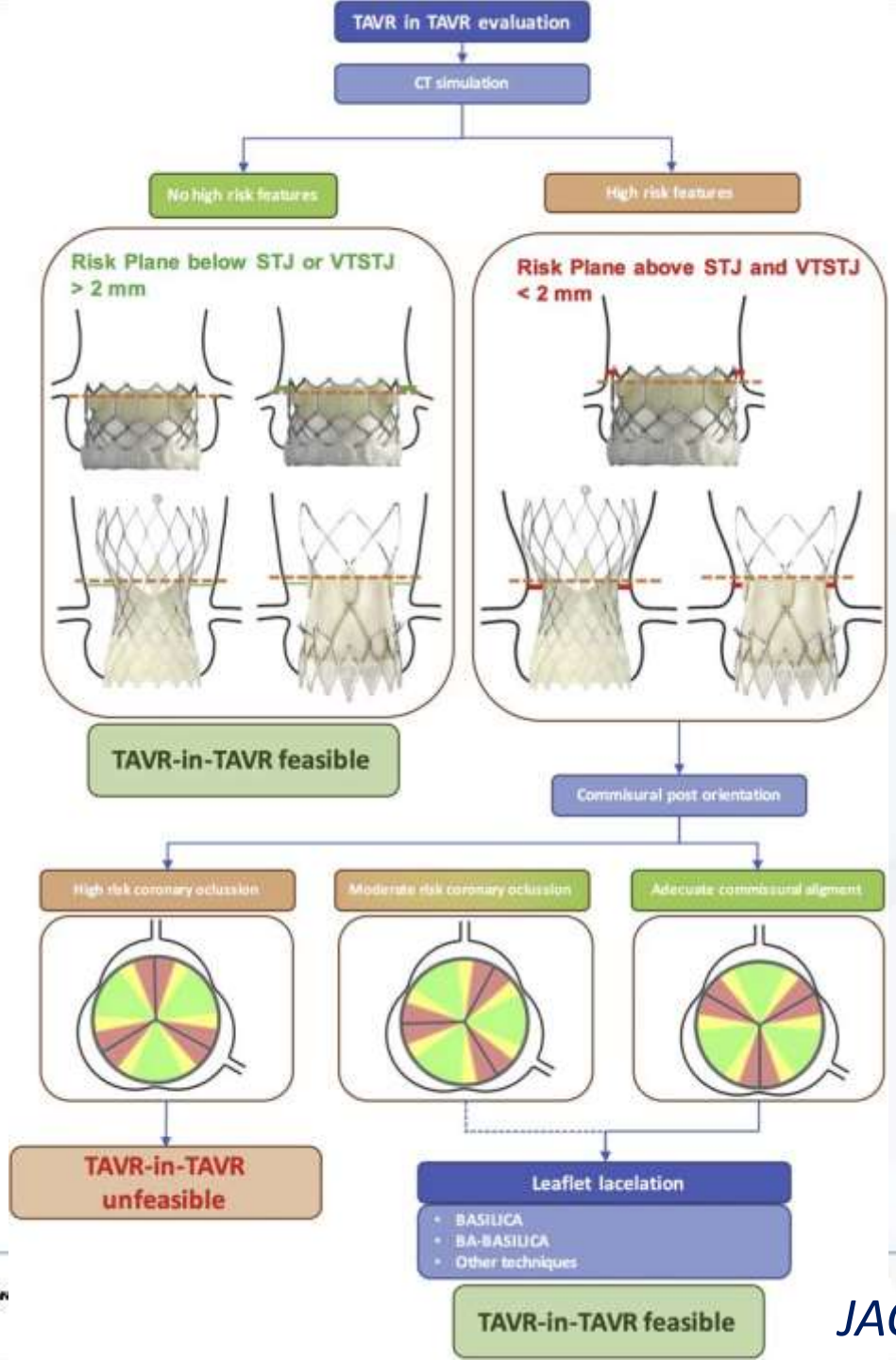
# IN-HOSPITAL PACEMAKER RATES BY QUARTER





# Valve-in-valve procedures

- Increased risk of coronary obstruction
- Elevated postprocedural pressure gradients
- **NO** difference between the CoreValve and Sapien valves in the incidence of coronary obstruction
- **HIGHER** postprocedural gradient with Sapien valves



# Severe LV dysfunction

- **If not-severe calcification**

- Navitor provides more stable hemodynamics during deployment
- Accurate neo with no paciente also stable

- **If severe calcification**

- BE-TAVI to avoid severe PVL and post-dilation

# Pure (non-cacified) Ao Reg



# PRIOR EVIDENCE

## Transcatheter Aortic Valve Replacement in Pure Native Aortic Valve Regurgitation

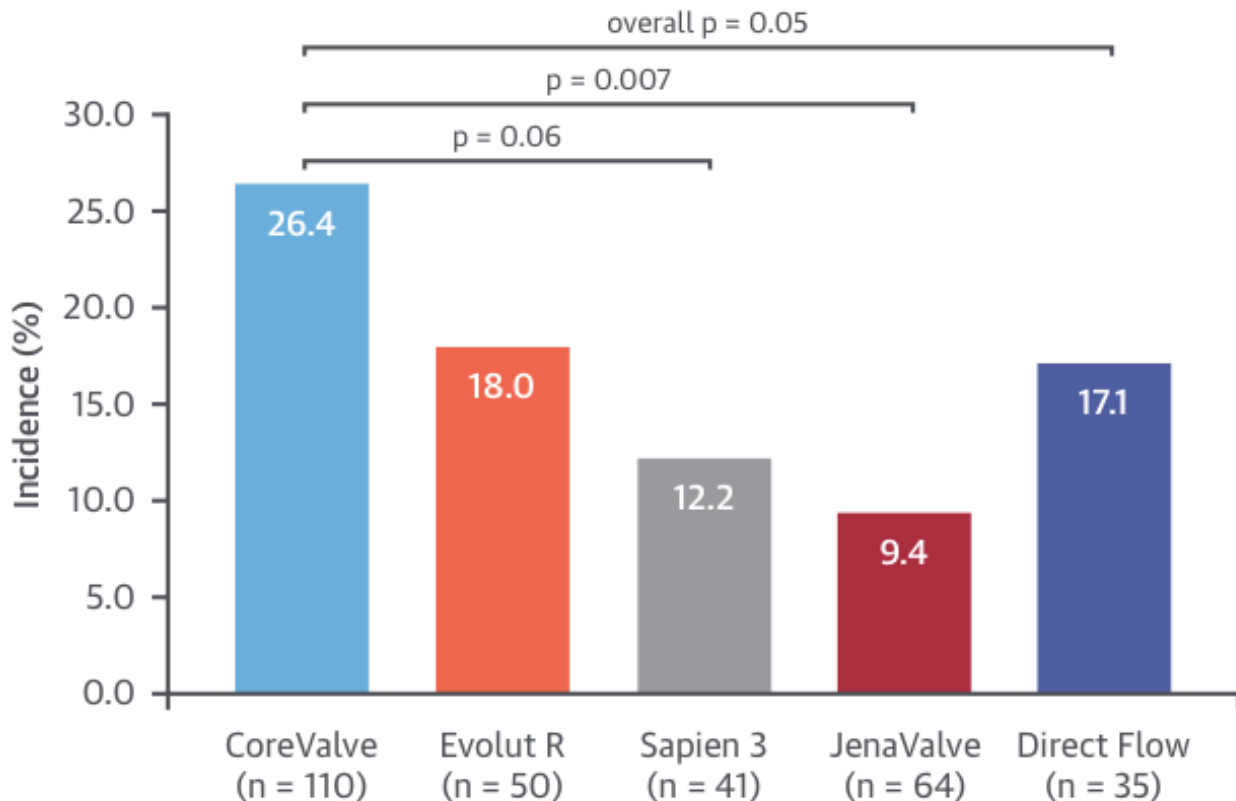
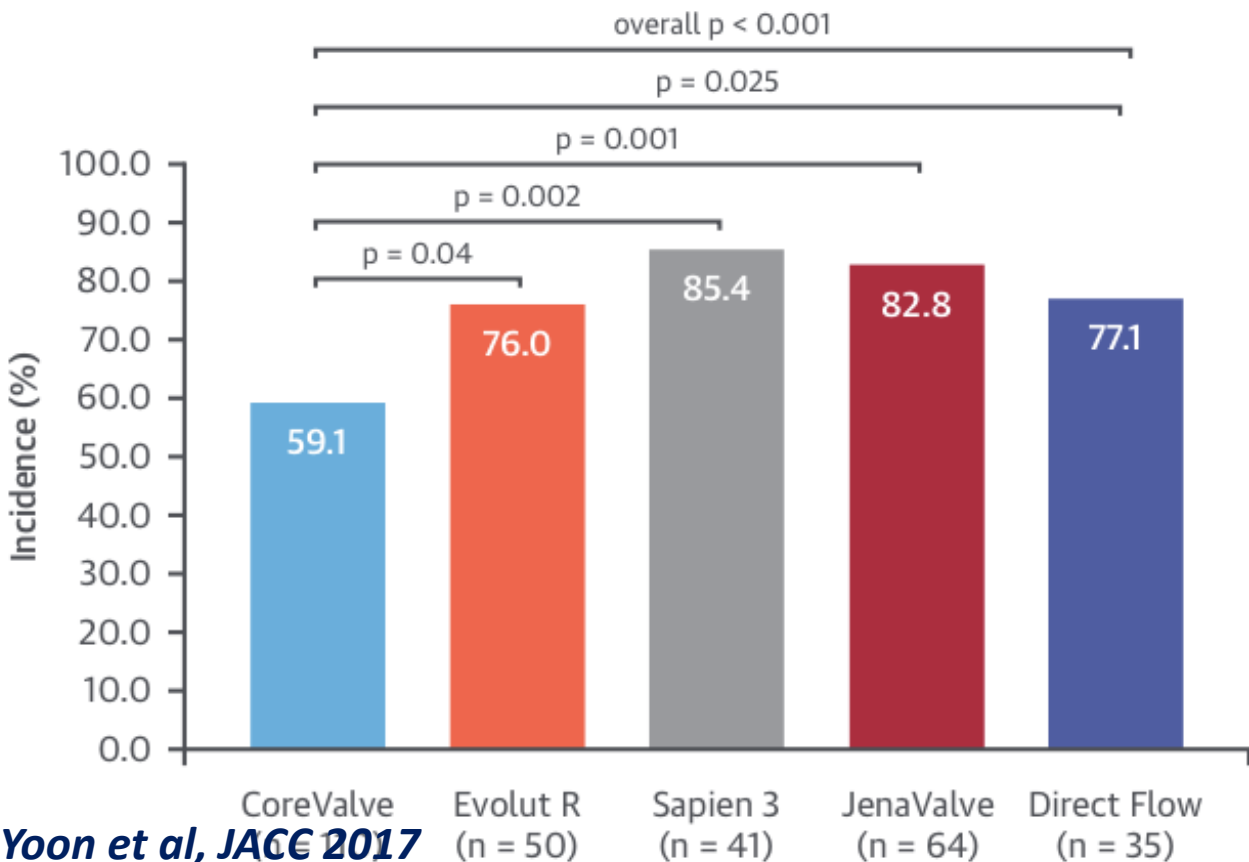


Sung-Han Yoon, MD,<sup>1</sup> Tobias Schmidt, MD,<sup>2</sup> Sabine Bleiziffer, MD,<sup>3</sup> Niklas Schofer, MD,<sup>4</sup> Claudia Fiorina, MD,<sup>5</sup> Antonio J. Muñoz-García, MD,<sup>6</sup> Ermela Yzeiraj, MD,<sup>7</sup> Ignacio J. Amat-Santos, MD,<sup>8</sup> Didier Tchetché, MD,<sup>9</sup> Christian Jung, MD,<sup>10</sup> Buntaro Fujita, MD,<sup>11</sup> Antonio Mangieri, MD,<sup>12</sup> Marcus-Andre Deutsch, MD,<sup>13</sup> Timm Ubben, MD,<sup>14</sup> Florian Deuschl, MD,<sup>15</sup> Shingo Kuwata, MD,<sup>16</sup> Chiara De Biase, MD,<sup>17</sup> Timothy Williams, MD,<sup>18</sup> Abhijeet Dhole, MD,<sup>19</sup> Won-Keun Kim, MD,<sup>20</sup> Enrico Ferrari, MD,<sup>21</sup> Marco Barbanti, MD,<sup>22</sup> E. Mara Vollema, MD,<sup>23</sup> Antonio Miceli, MD,<sup>24</sup> Cristina Giannini, MD,<sup>25</sup> Guilherme F. Attizzani, MD,<sup>26</sup> William K.F. Kong, MD,<sup>27</sup> Enrique Gutierrez-Ibanez, MD,<sup>28</sup> Victor Alfonso Jimenez Diaz, MD,<sup>29</sup> Harindra C. Wijeyesundara, MD,<sup>30</sup> Hidehiro Kaneko, MD,<sup>31</sup> Tarun Chakravarty, MD,<sup>32</sup> Moody Makar, MD,<sup>33</sup> Horst Slevvert, MD,<sup>34</sup> Christian Hengstenberg, MD,<sup>35</sup> Bernard D. Prendergast, MD,<sup>36</sup> Flavien Vincent, MD,<sup>37</sup> Mohamed Abdel-Wahab, MD,<sup>38</sup>

Second Valve Implantation

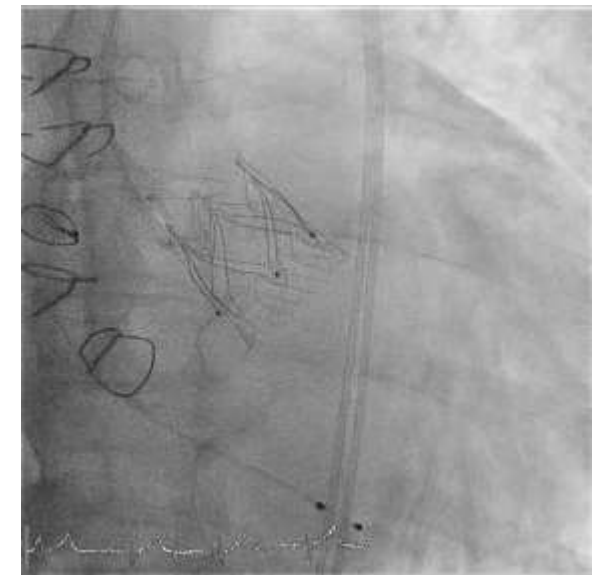
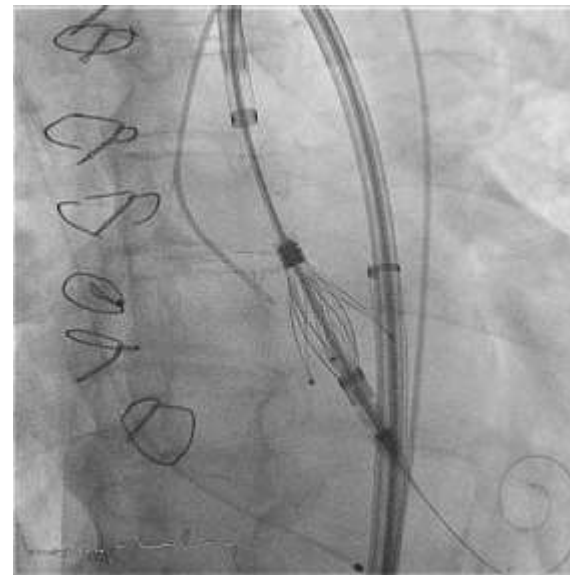
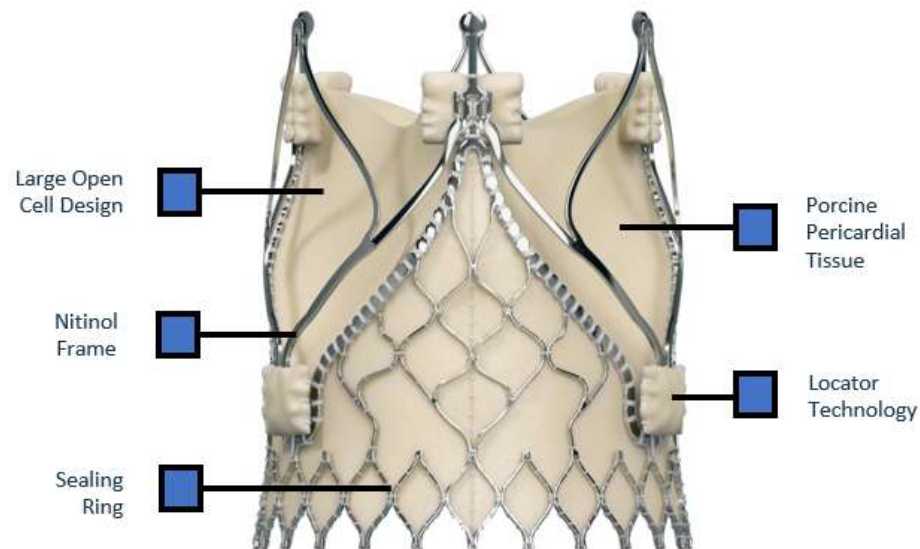


### Device Success



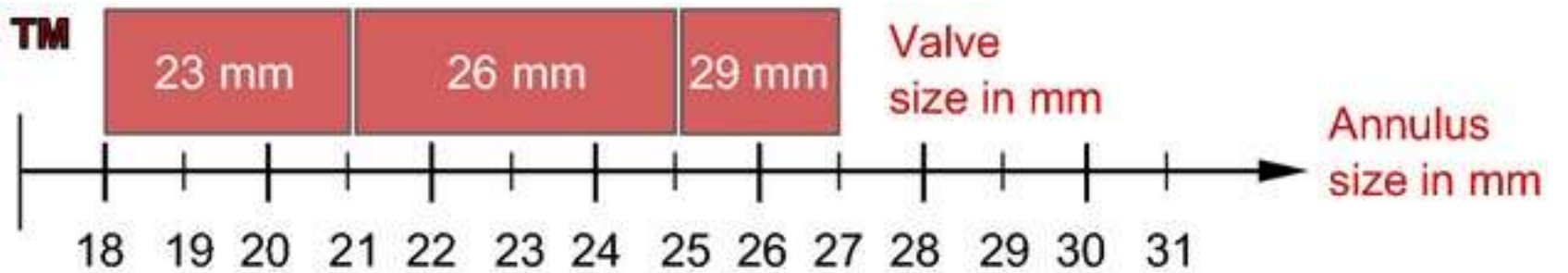
# Jenavalve Trilogy TAVR System

- The Trilogy TAVI System features unique locators that align the THV with the native cusps of the valve and ensures anatomically correct alignment
- The locators “clip” onto the native leaflets, enabling anchoring in pure AR patients with non-calcified valves.

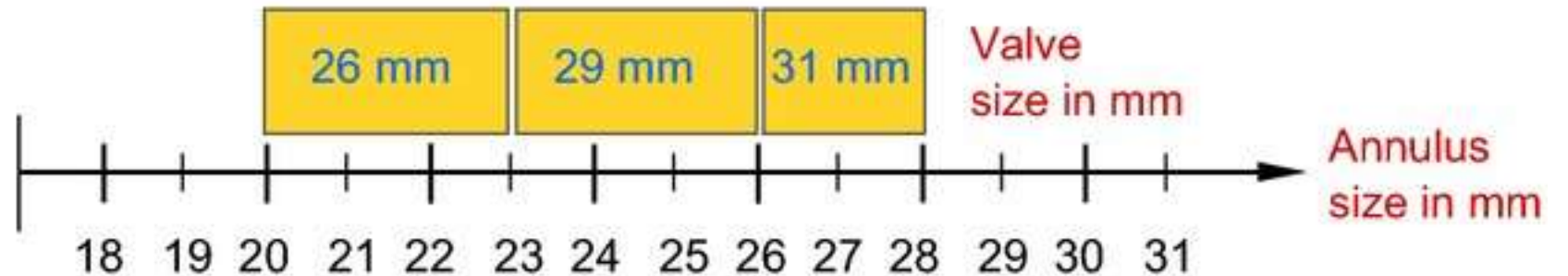


**Left:** Jenavalve Trilogy valve, **Center:** prosthesis with locators spread during implantation, seating the locators in the sinuses  
**Right:** Valve after implantation with perfect position and no paravalvular regurgitation.

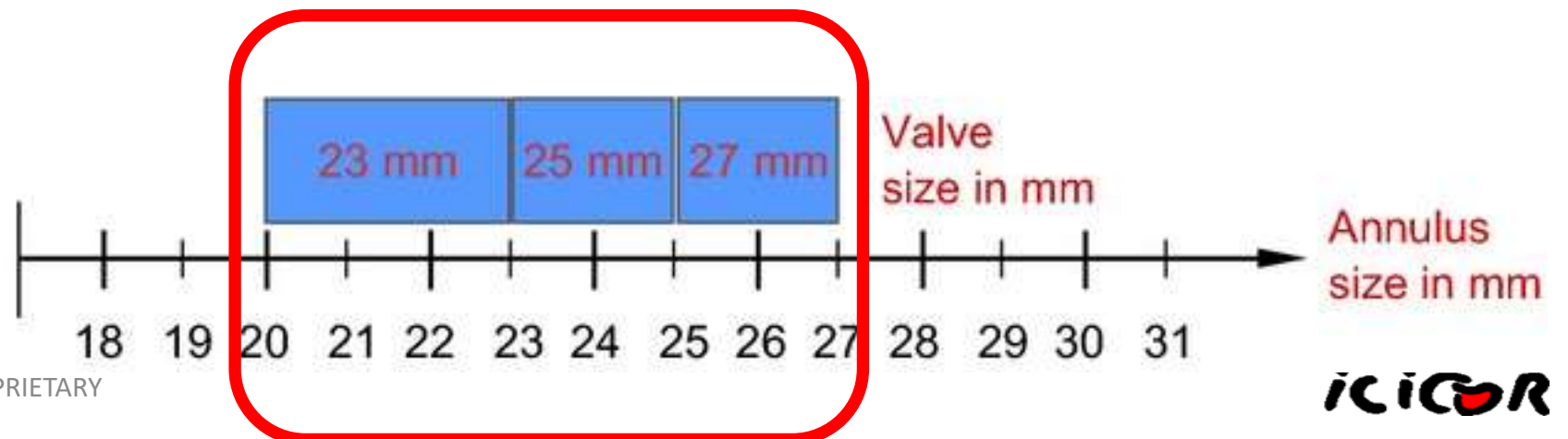
# Edwards-Sapien™ XT Valve



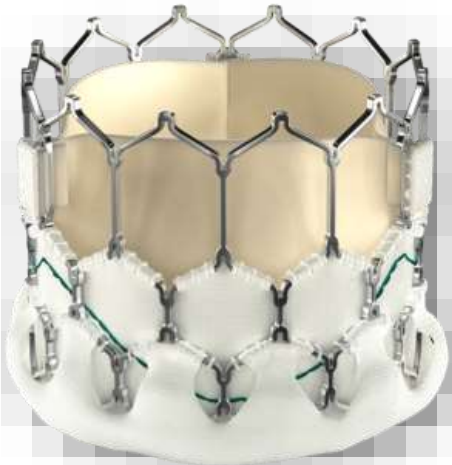
# Core Valve™



# Jena Valve™



# PURE<sup>AR</sup> STUDY

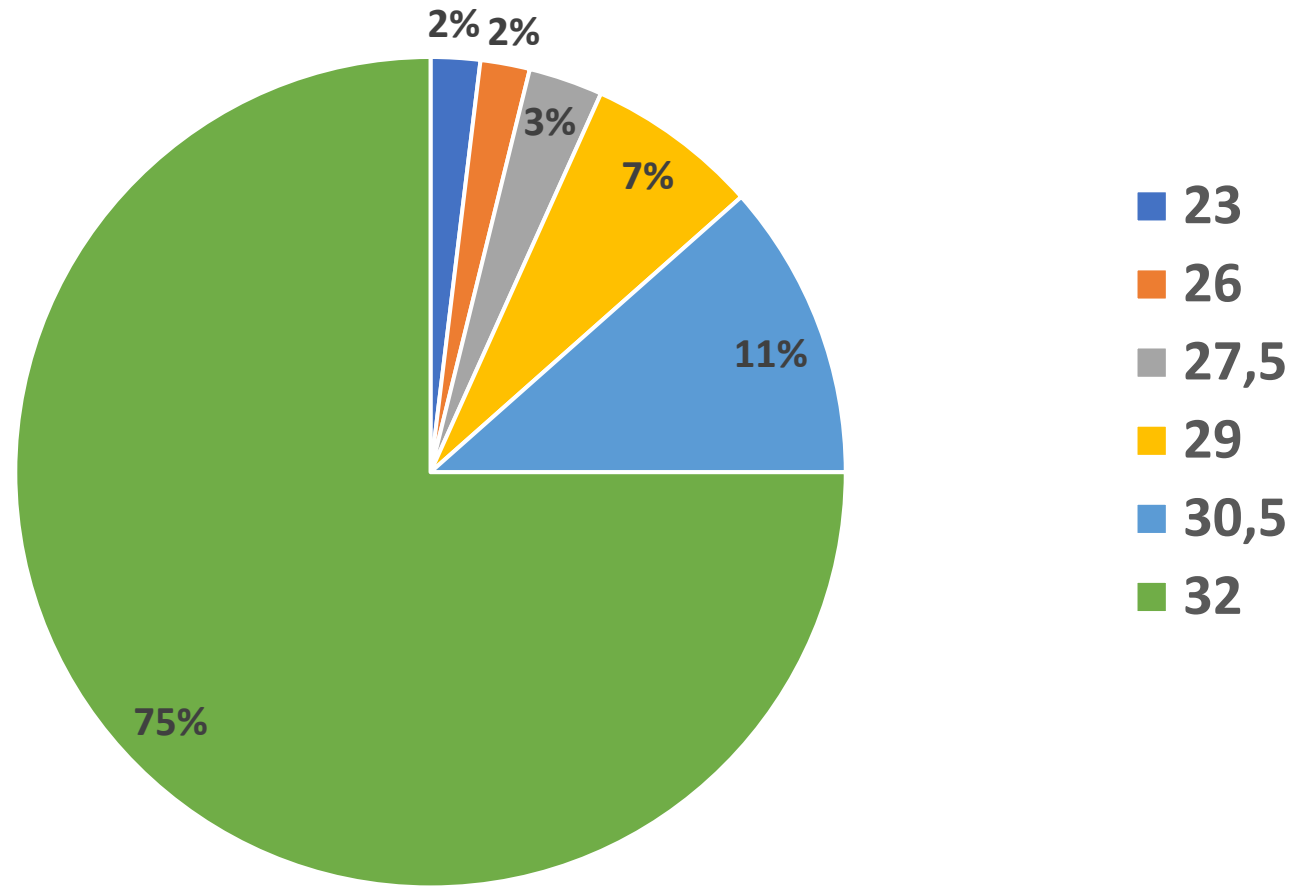


*Just accepted in Eurointervention*

N=113 PTS	
AGE	78.4 ± 7.46
GENDER (Male)	73 (64.6%)
URGENT	14 (12.4%)
EUROSCORE II	3.48 ± 2.7
STS SCORE	2.71 ± 1.7

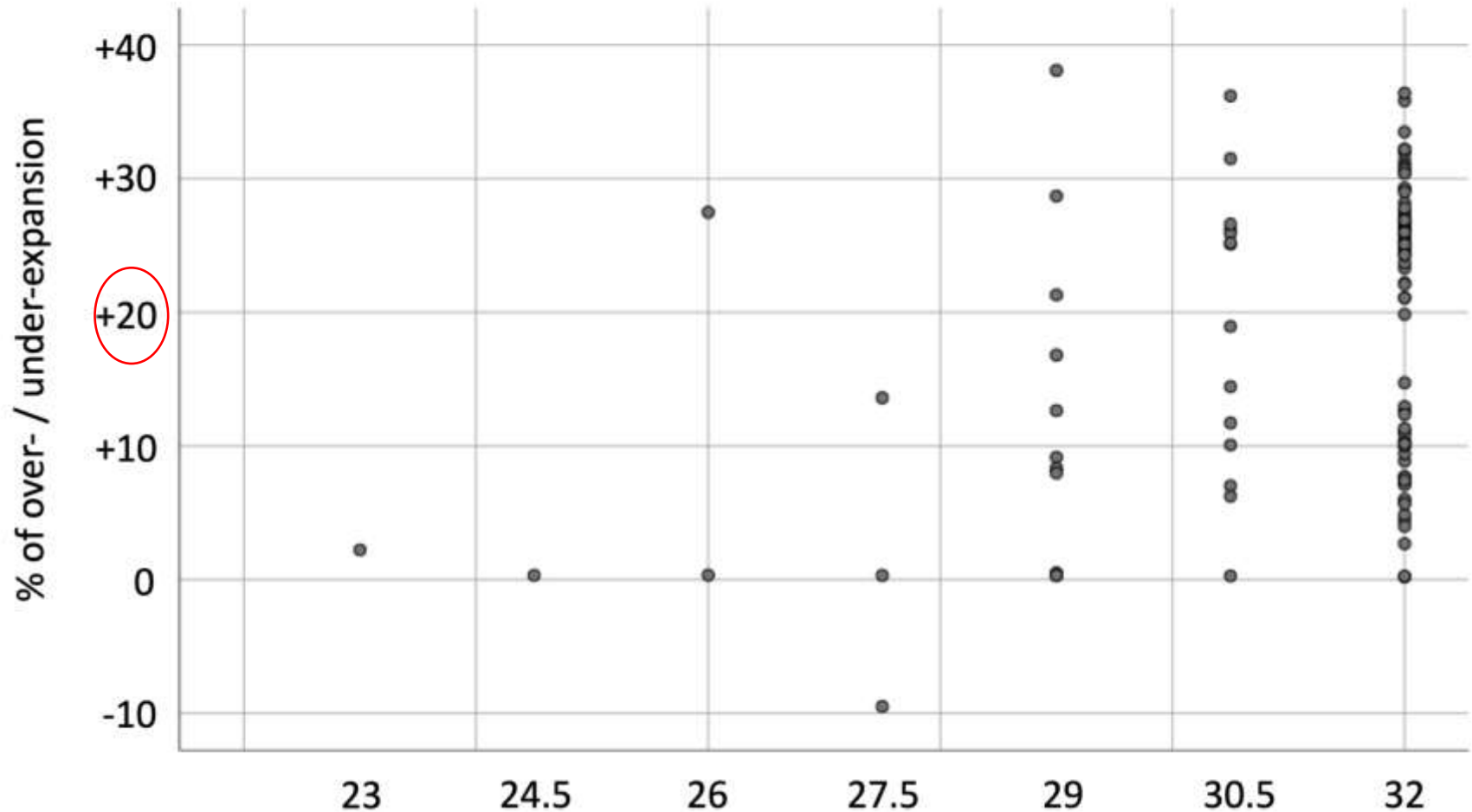
ANNULAR MEASUREMENTS	
AA AREA	<b>638.5 ± 106.1 mm<sup>2</sup></b>
AA PERIMETER	88.5 ± 8.0 mm
LM HEIGHT	14.8 ± 3.6 mm
RC HEIGHT	17.4 ± 3.8 mm
CALCIUM (AA, LVOT)	<b>17 (15%)</b>
STJ DIAMETER	37.0 ± 5.6 mm
SoV DIAMETER	39.15 ± 6.0 mm

### VALVE SIZES



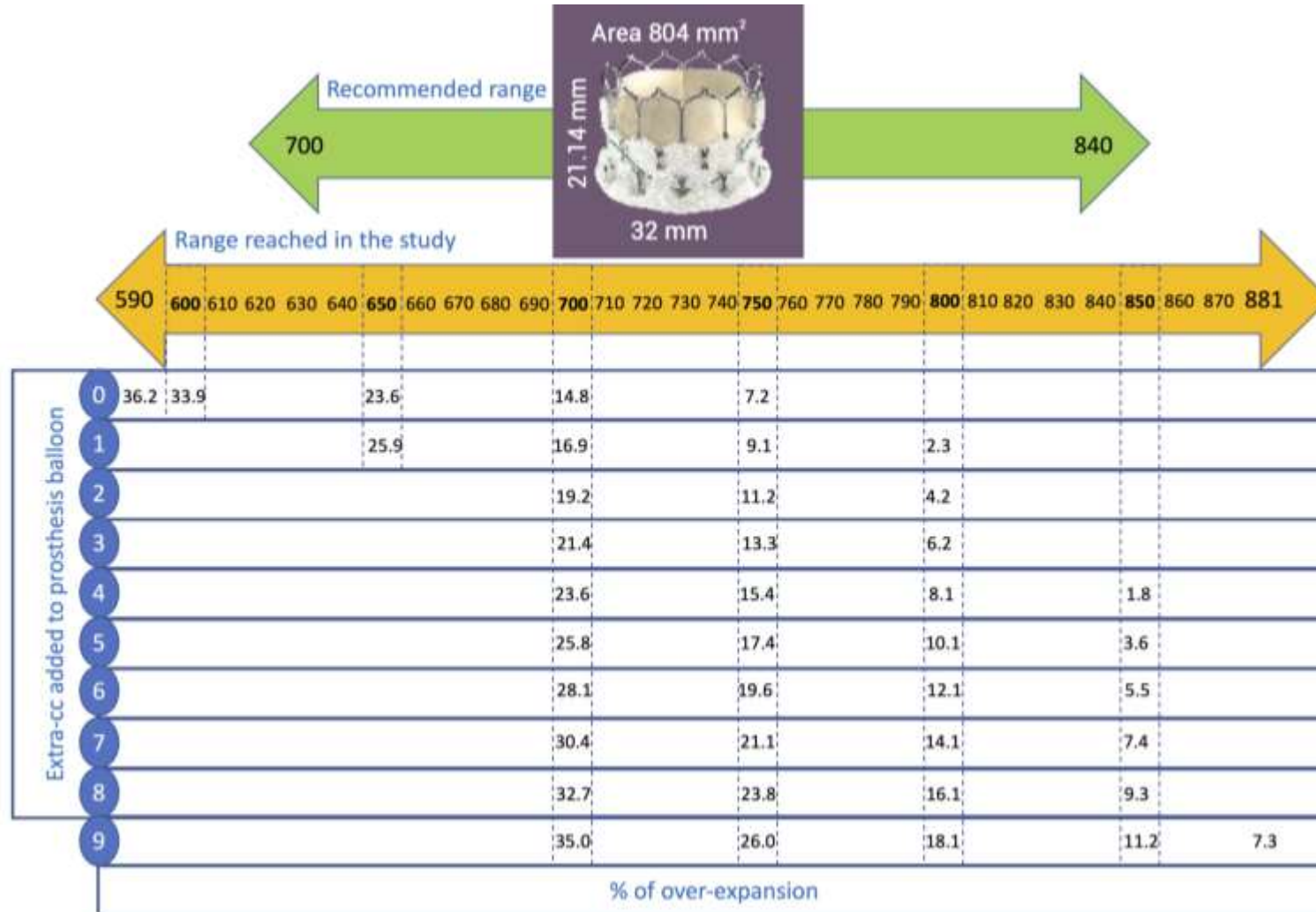
# RANGE OF EXTRA-CC: 0 – 10 cc

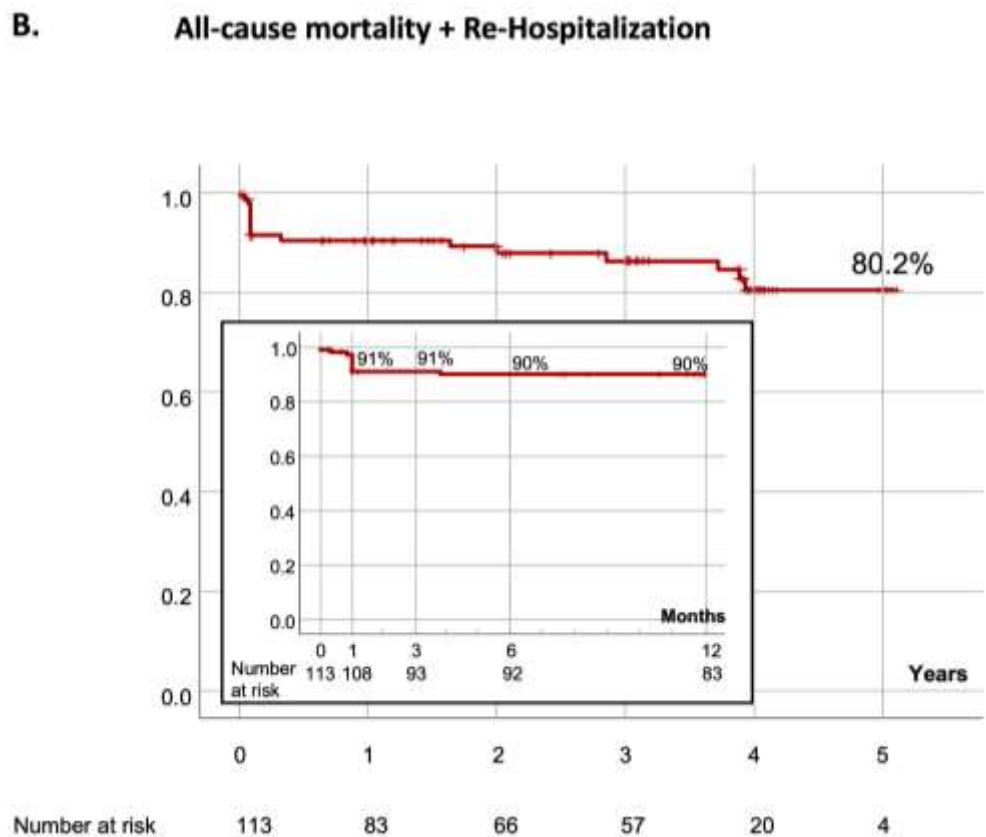
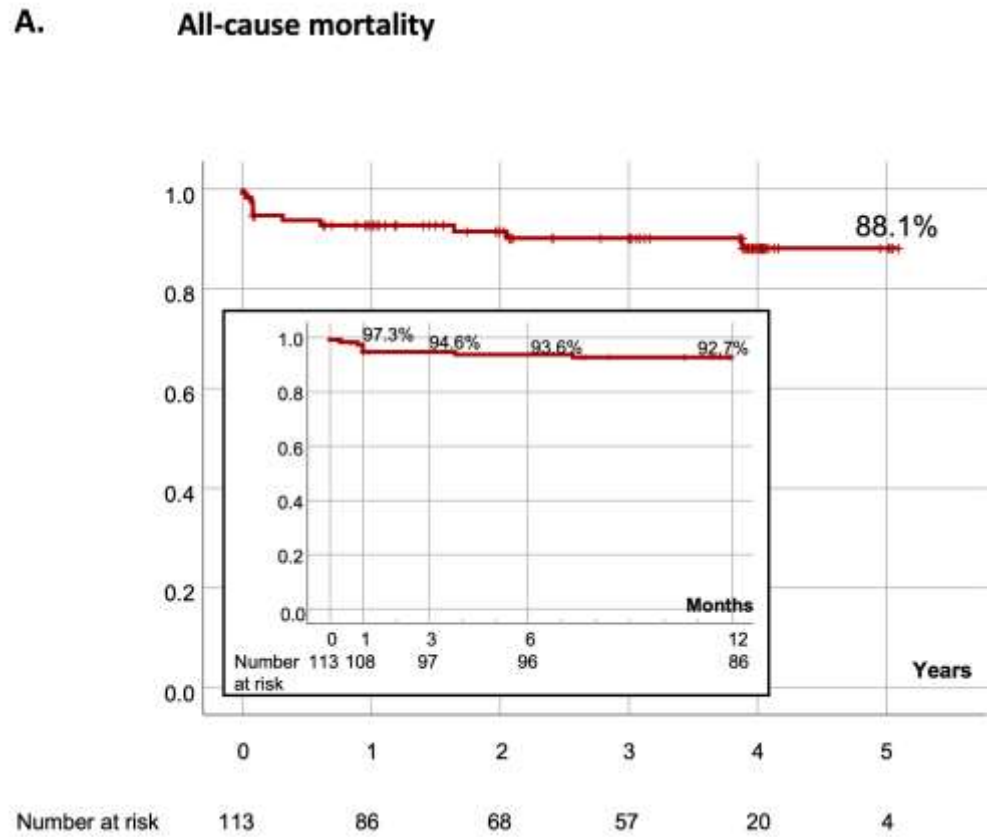
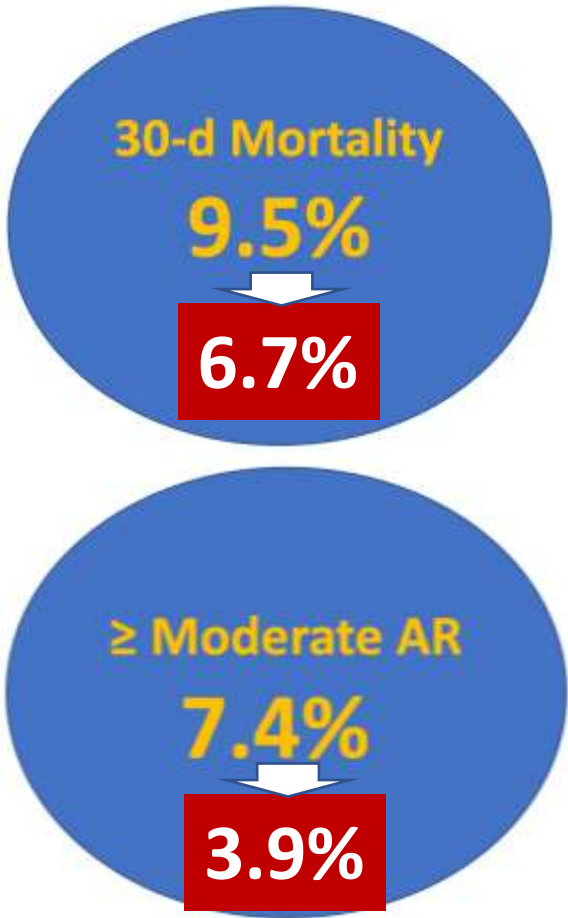
## A. DEGREE OF OVERSIZING ACCORDING TO DEVICE SIZE





# 32 mm Valve



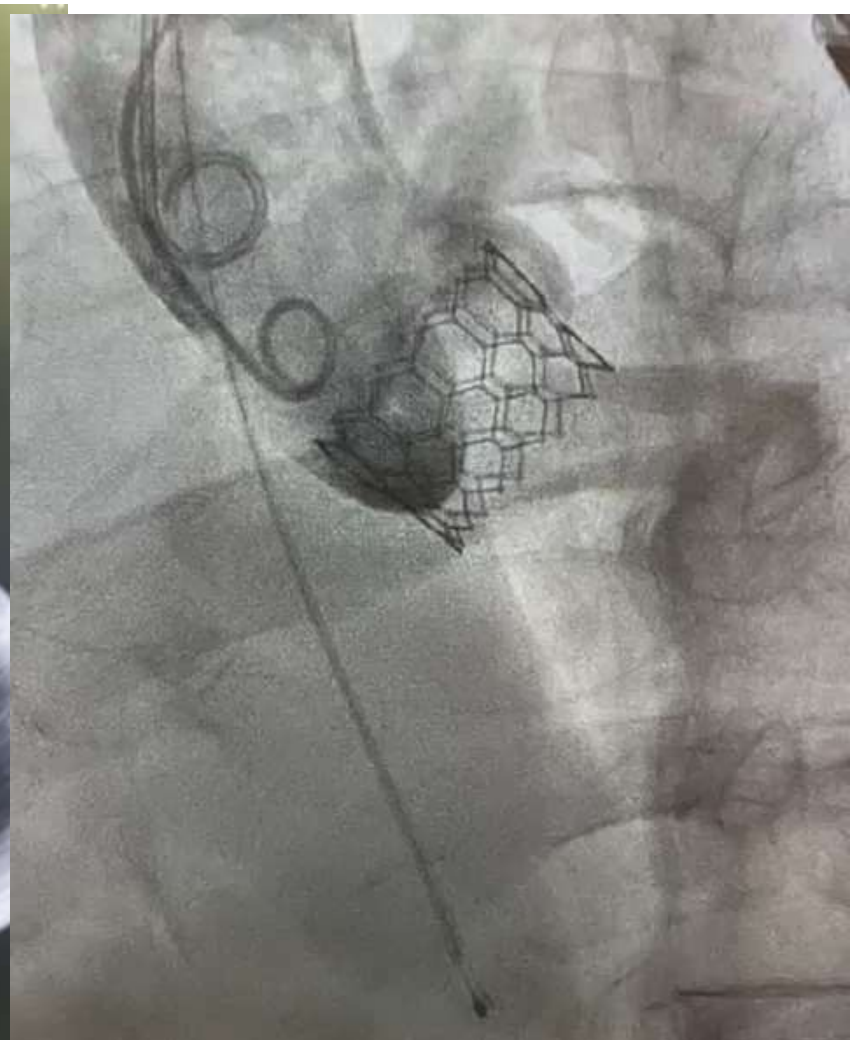
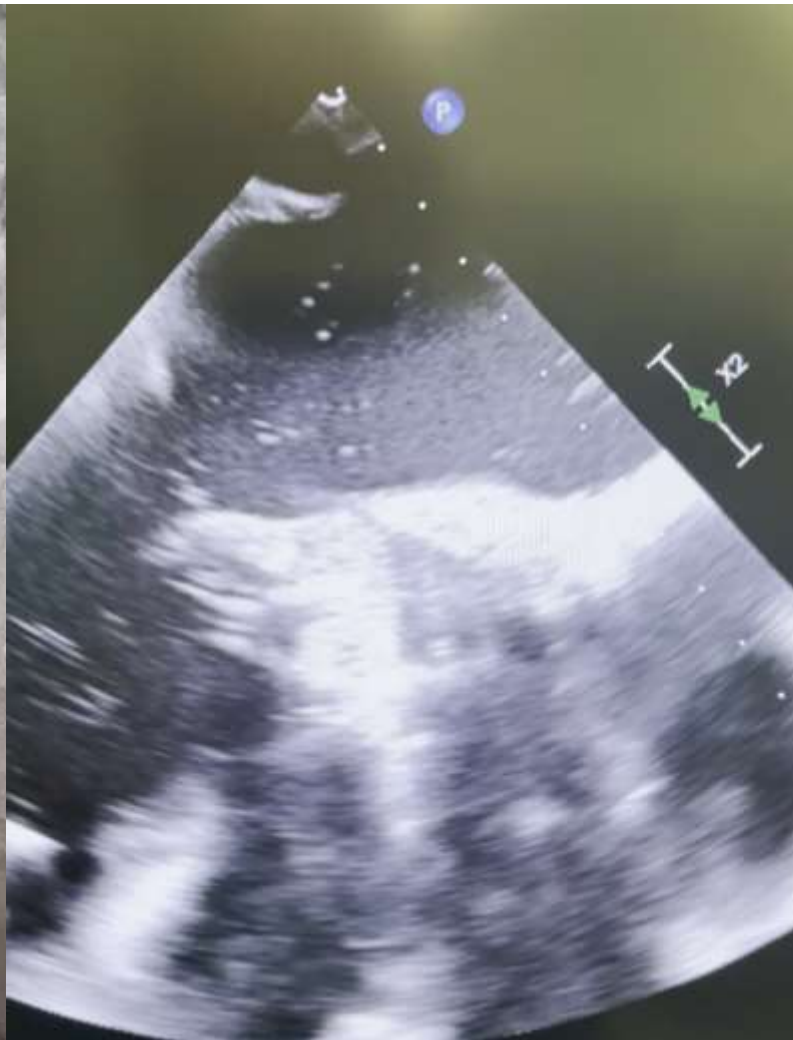
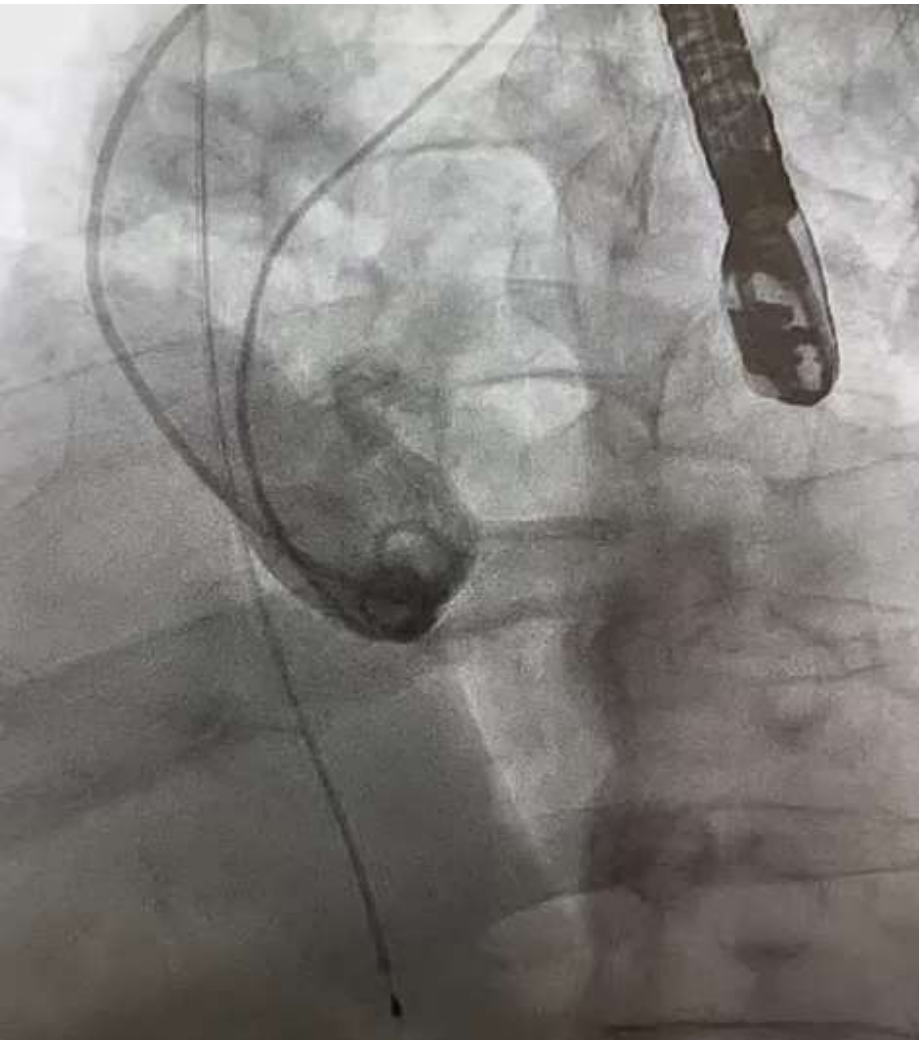


MYVAL 32+ 3cc.

PREVENT DISLODGE

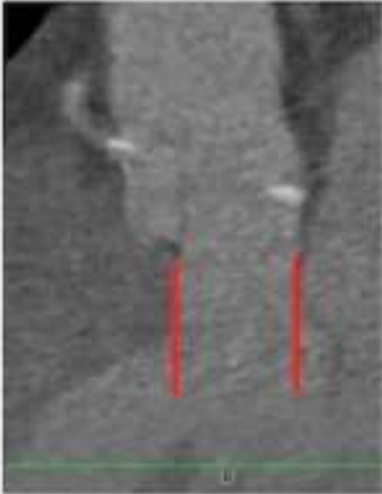


PUT ALL VOLUME IN !!



### TUBULAR (12.4%)

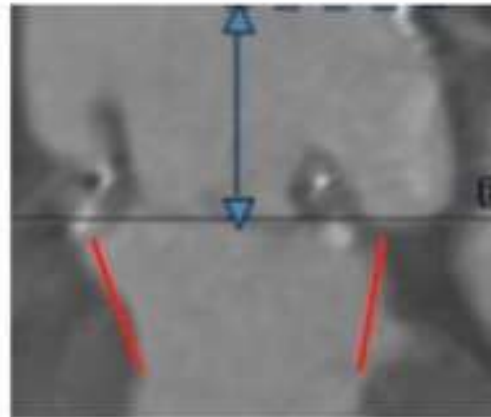
Codominant (annulus – LVOT)  
(Sizing based on the annulus)



EMBOLIZATION RATE: 0%

### FLARED (58.4%)

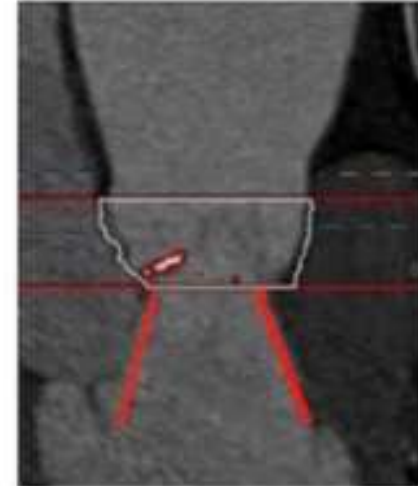
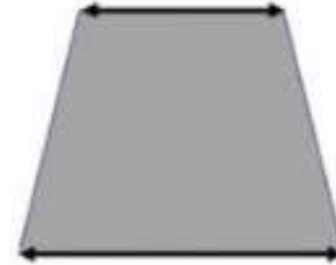
Annular dominant  
(Sizing based on the annulus)



EMBOLIZATION RATE: 0%

### TAPERED (28.3%)

LVOT dominant  
(Sizing based on the LVOT)



EMBOLIZATION RATE: 12.5%

# Other anatomical subgroups

- **Extreme iliac or aortic tortuosity**, in which a flexible delivery system such as Navitor or Acurate neo may be advantageous
- **Small iliofemoral vessels**, in which a low-profile 14-F Evolut R/Navitor/Myval may be favorable
- **Mechanical mitral valve** replacement and **marked septal bulge**, in which a self-expanding prosthesis may be preferred

# FINAL REFLECTIONS

- Most patients can be successfully treated with any valve type
- Each operator balance between valve types and personal experience
- The technical challenges associated with different anatomic scenarios, along with the strengths and weaknesses of the various transcatheter aortic valves, will allow an optimal valve to be selected for each and every patient, minimizing complications and maximizing success