TAVR for Aortic Insufficiency

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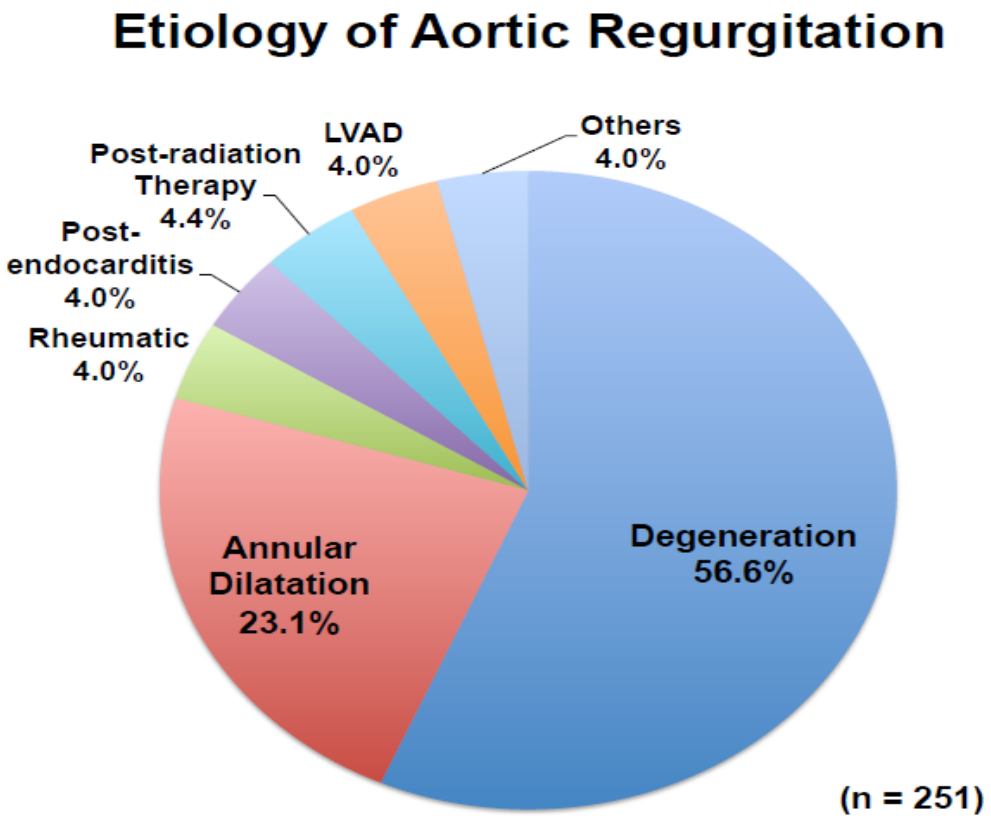
Background

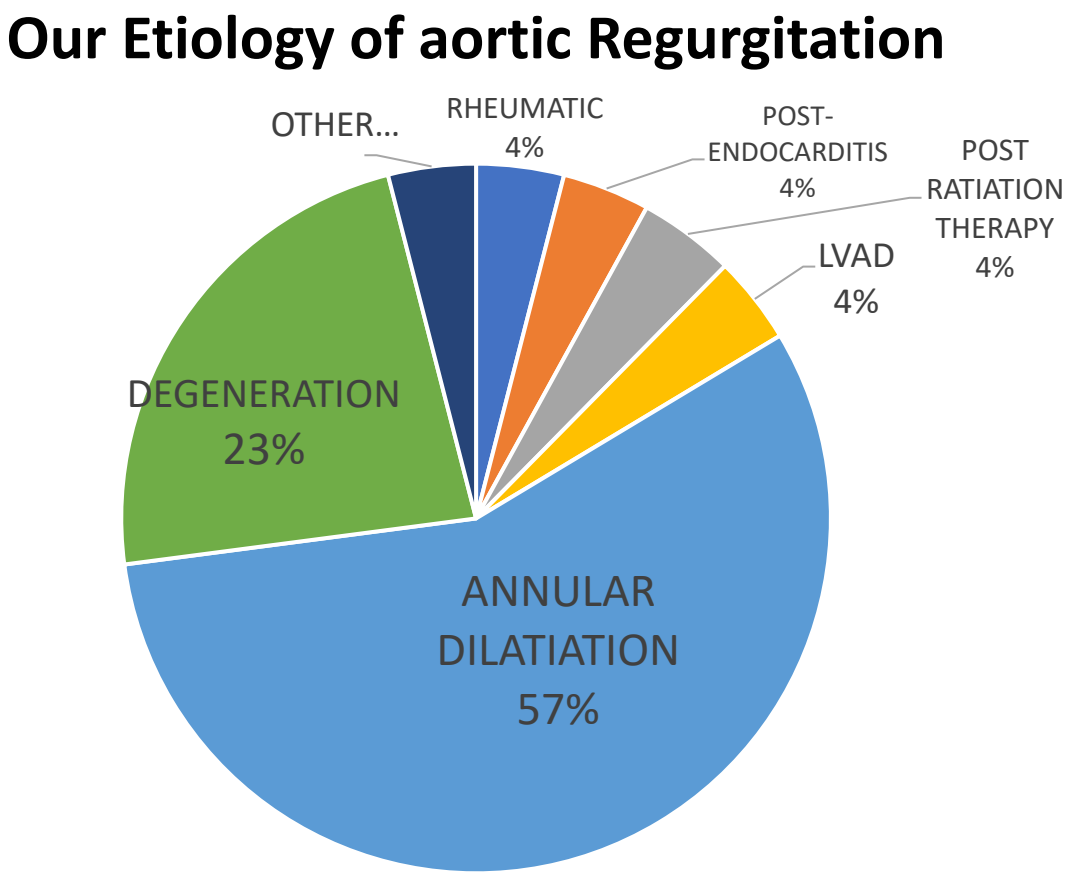
The continued growth of TAVR has been accompanied by an increase in off-label utilization, including the treatment of aortic insufficiency (AI)

Self-expanding TAVR valves appear to be more ideally suited to treat AI given the need to often aggressively oversize the valve; nonthedeless continue valve mobilization (TEVM) its still occurring specially in large annuli.

This conference its dedicated to detect the anatomic and functional restraints of TARV for hight risk AR and the introduction of new Ballon Expandable device, that’s seems to perform well in extreme large annuli.

Etiology of Aortic Regurgitation





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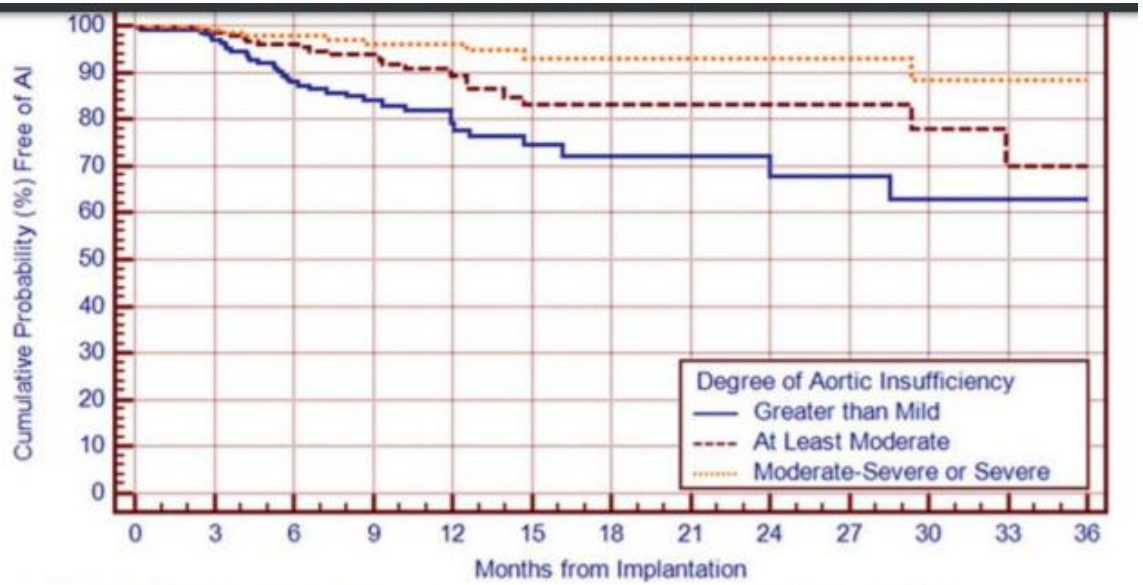
AO-AR CASES: 72

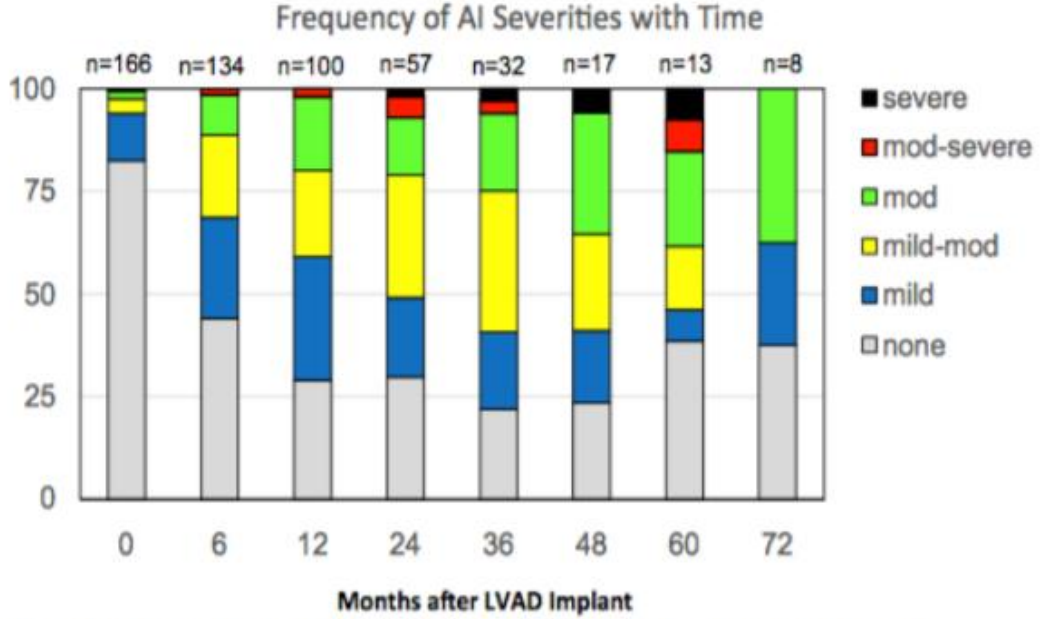
Background

- 1 in 4 patients will develop **de novo** at least mild to moderate AI within 1 year after LVAD

- AI in CF-LVAD patients tends to be progressive

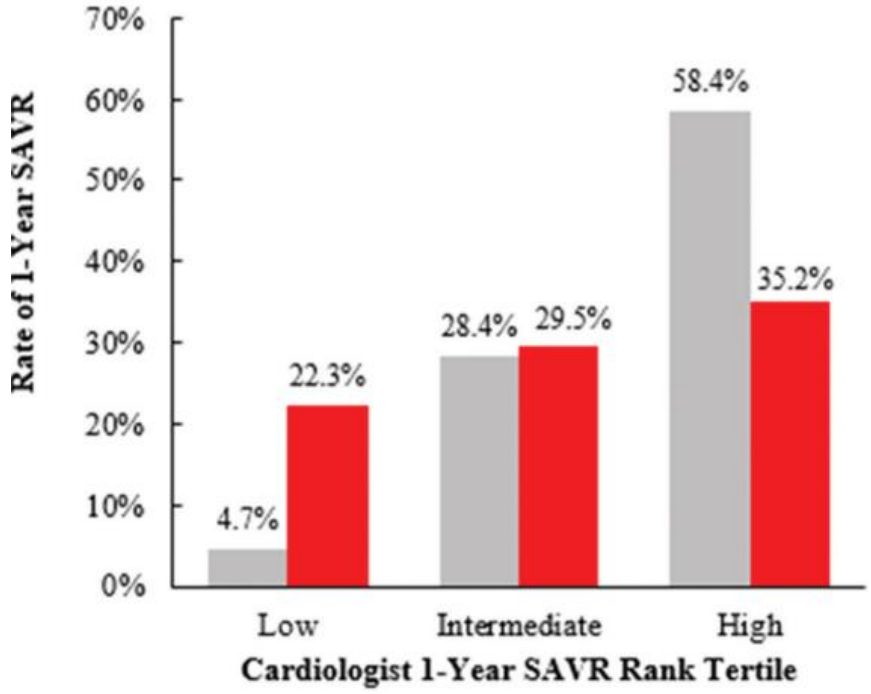


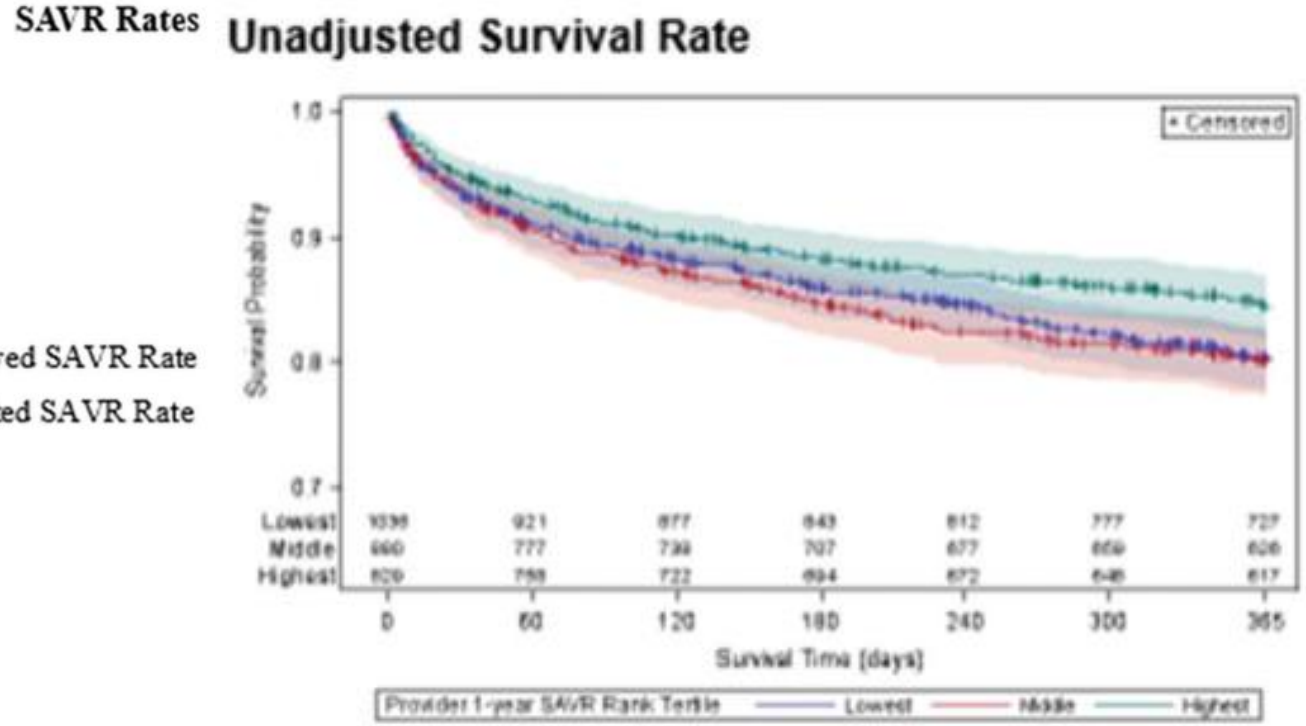
Jorde UP, Uriel N, Nahumi N et al. Circ Heart Fail 2014;7:310-9.



Cowger JA, Aaronson KD, Romano MA et al. JHLT 2014;33:1233-40.

AVR for AR: The Importance of Timely Referrals





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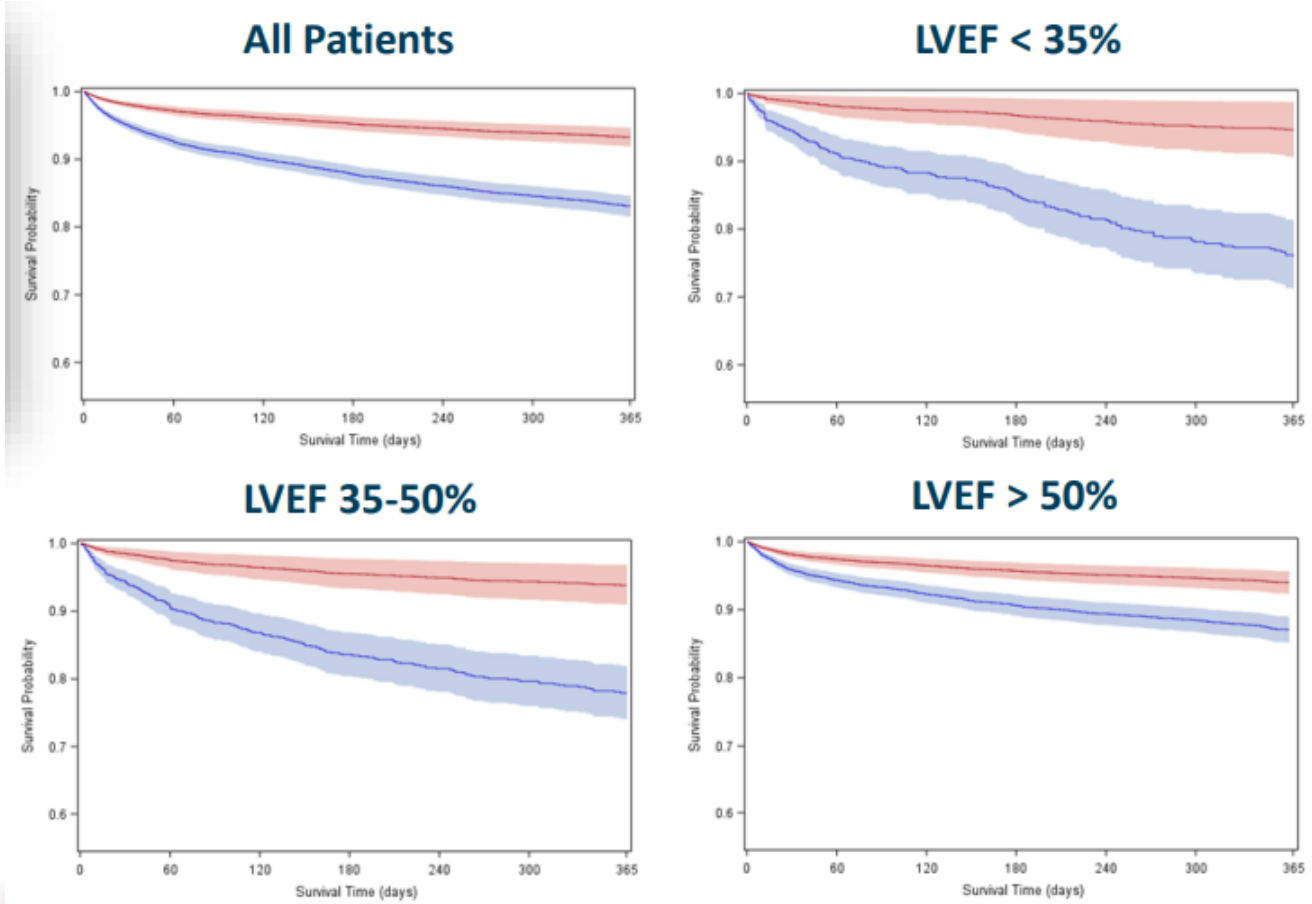
Thourani V, et al. Structural Heart 2021

SAVR EN BENEFITS IN PATIENTS WITH ssAR



US EHR database identified 4,608 patients with severe symptomatic AR between 2008-2016:

- ***9% mortality at 1-year in patients receiving SAVR***
- ***24% mortality at 1-year in patients left untreated***
- ***2.7-fold increased risk of mortality in patients who failed to undergo surgery. (p <0.0001)***

Importantly, only 25.7% of symptomatic,
severe AR patients received SAVR within 1 year of diagnosis

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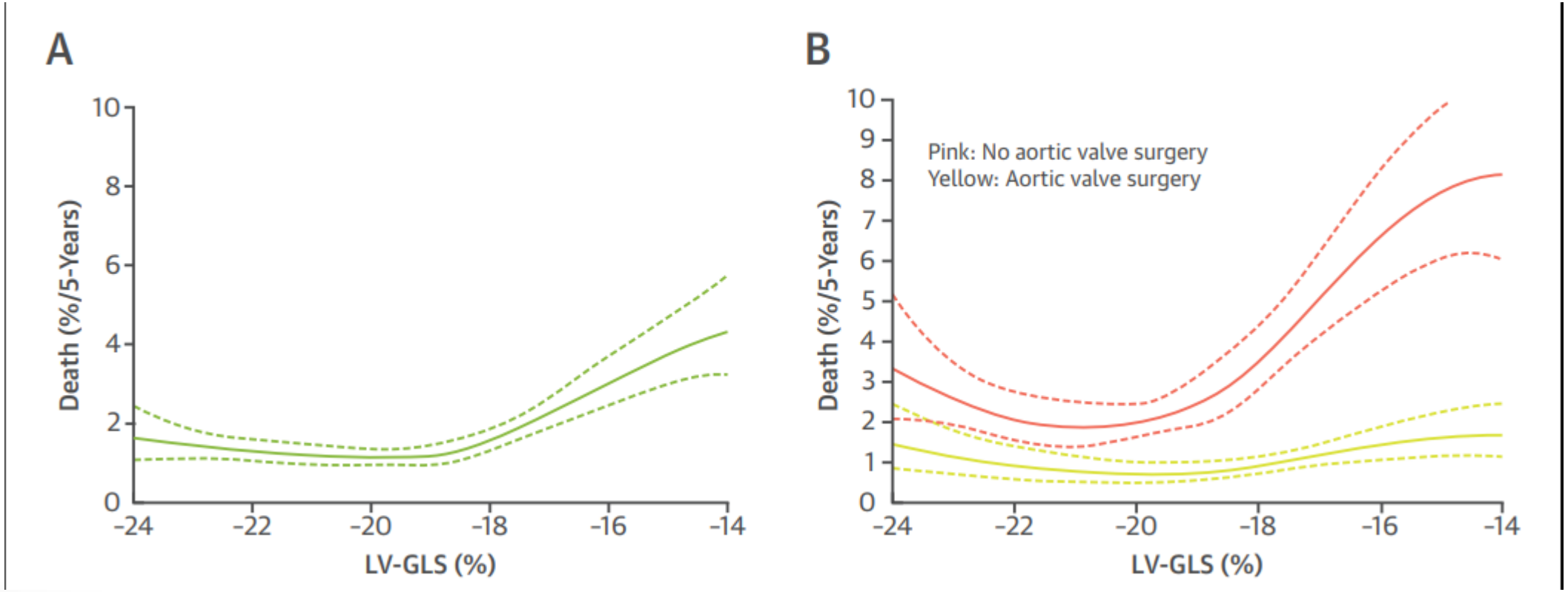
Thourani, V (2022). *Keynote Lecture: TAVR in AR: Anatomical Considerations for Device and Technique Selection* [power point slides]. TCTMD. https://www.tctmd.com/slide/keynote-lecture-tavr-ar-anatomical-considerations-device-and-technique-selection

Risk of Death, Based on LV-GLS in the Study Population as a Whole and in the Study Population Separated on the Basis of Undergoing Aortic Valve Surgery Versus Not



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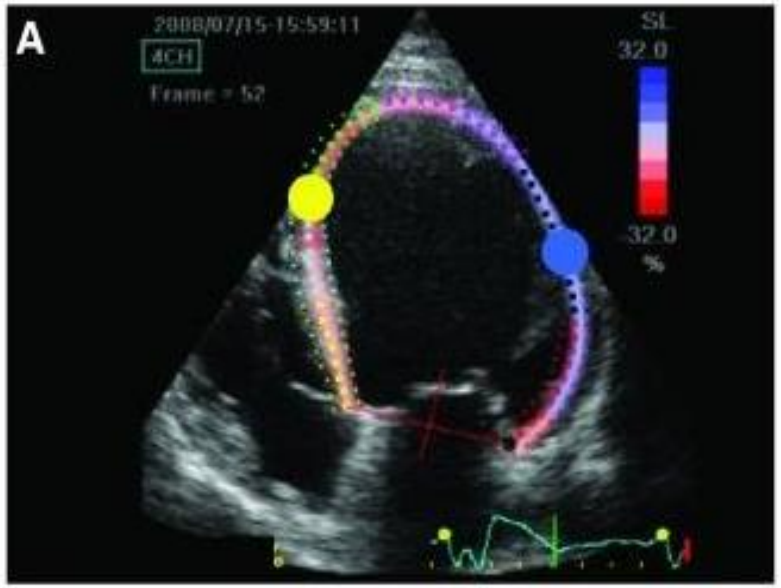
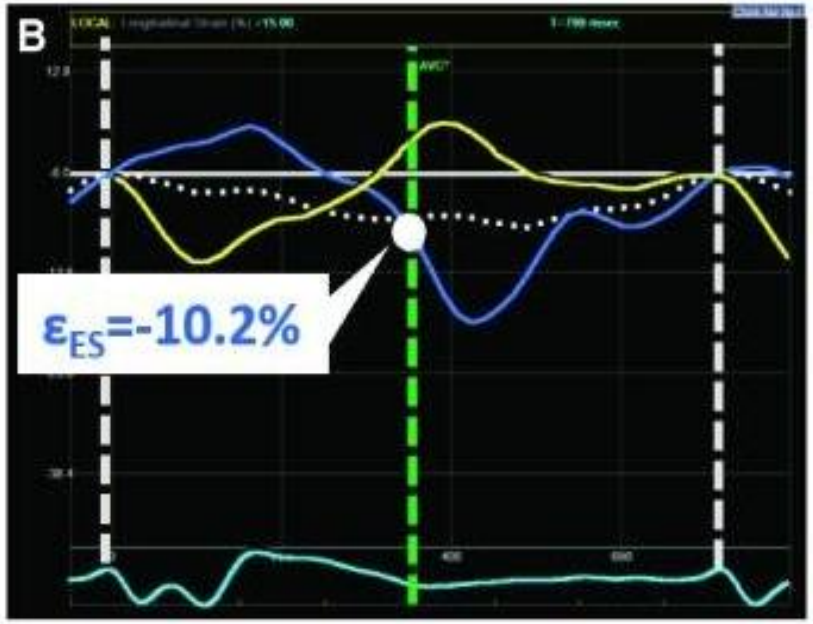
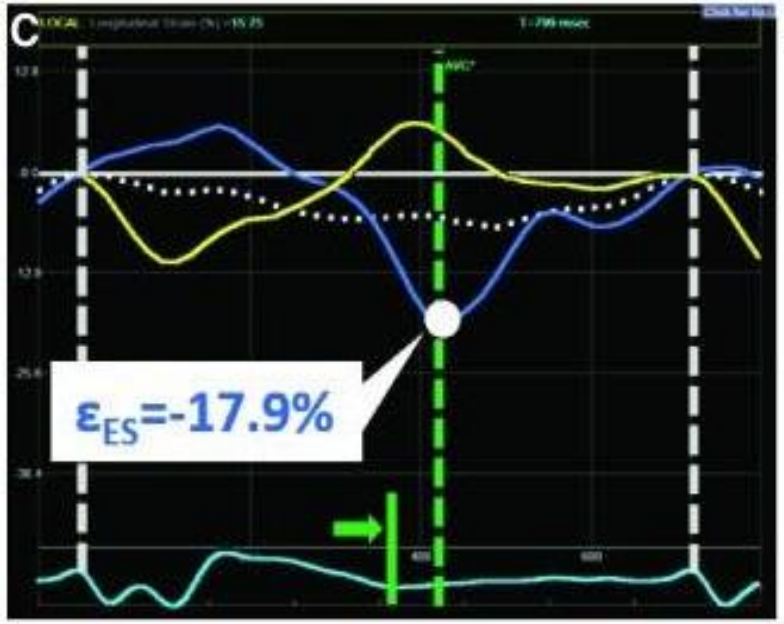
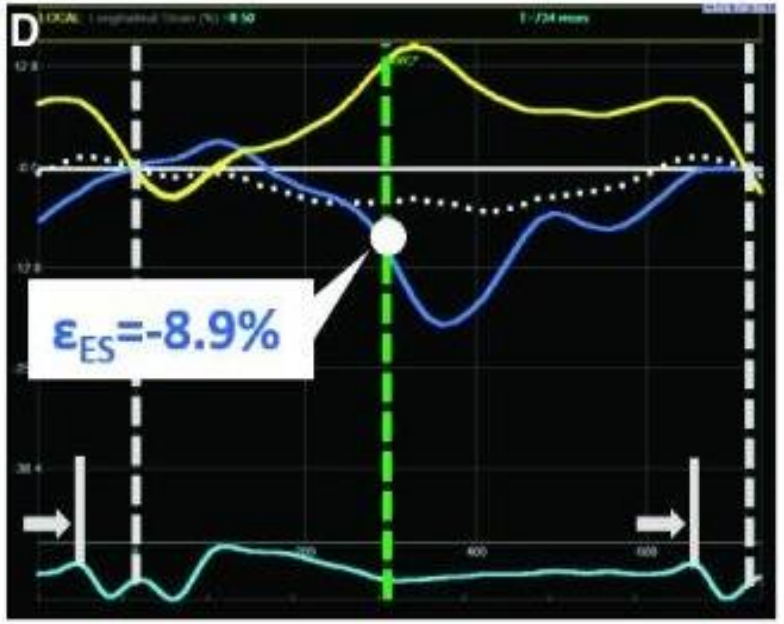
Alashi et al. LV Strain in Chronic Severe AR. JACC: CARDIOVASCULAR IMAGING, VOL. 11, NO. 5, 2018

VENTRICULAR STRAIN

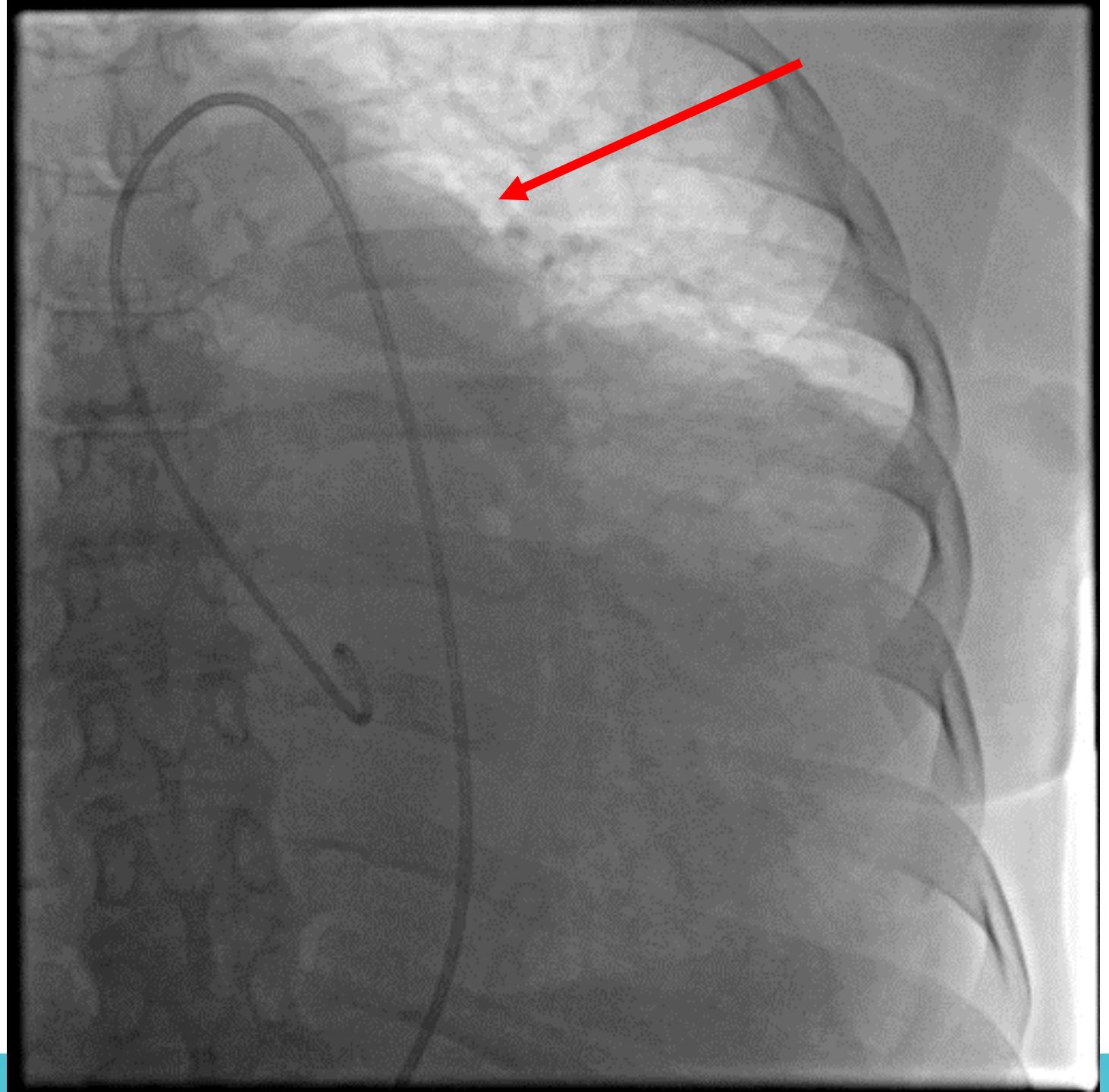








Loss of Aortic Compliance



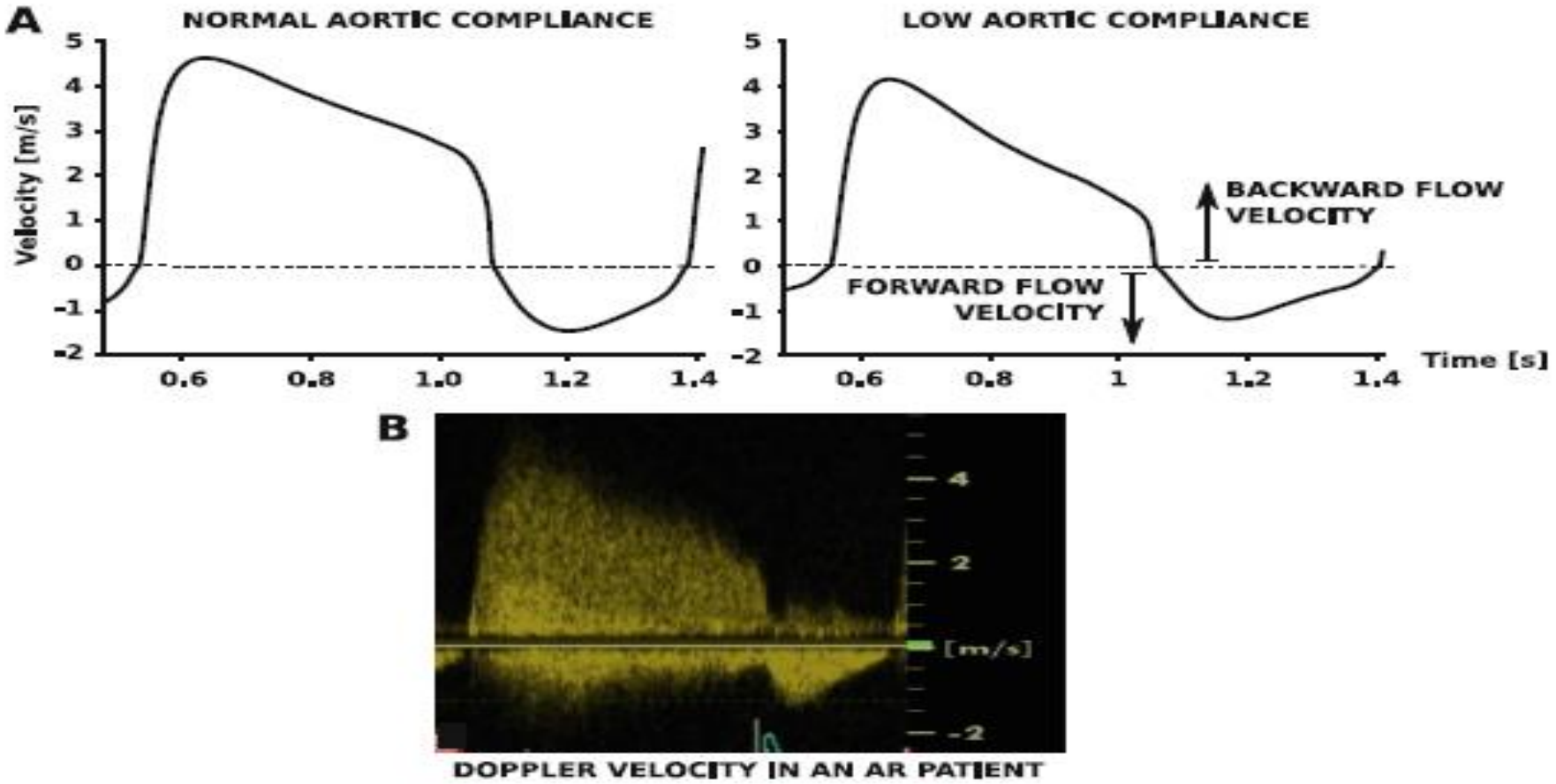


Fig. 6. Simulated and measured blood flow velocities. A: Simulated blood flow velocities at ROA of 0.15 cm2 with normal (left) and low (right) aortic compliance; B: CW Doppler velocity in a 78-year-old patient with AR. Positive axis correspond to backward blood flow velocity.

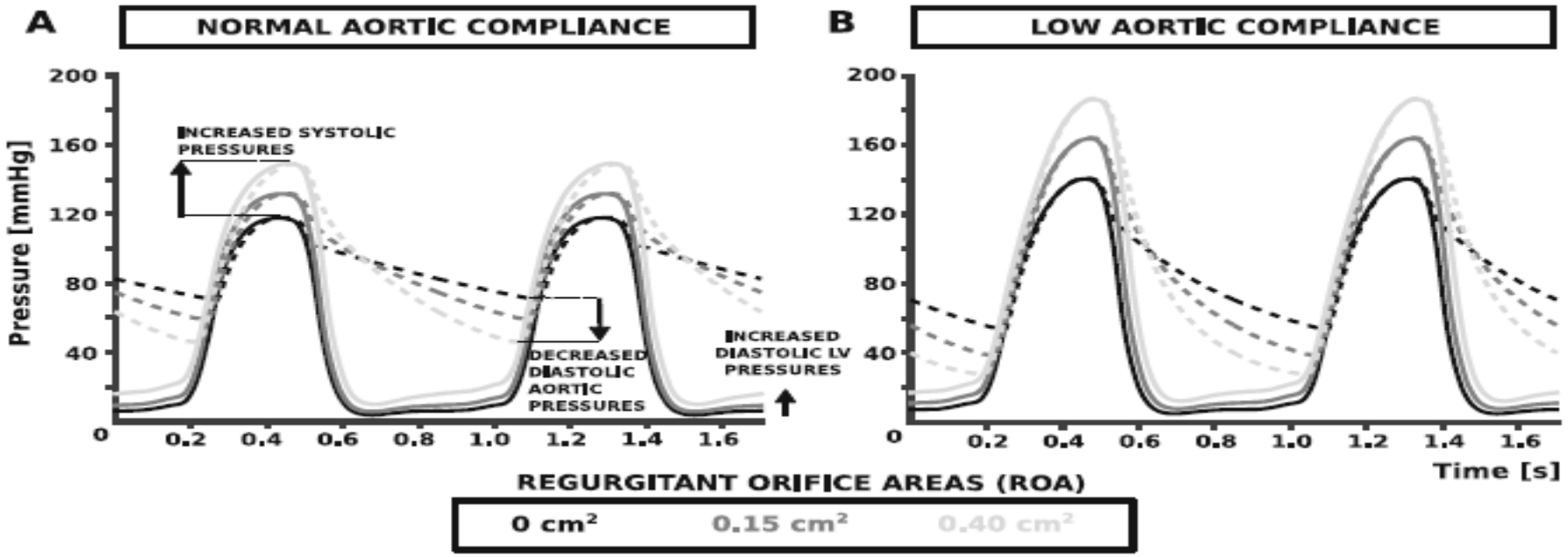


Fig. 4. Effect of AR and aortic compliance on pressure. Aortic pressures (dashed line) and left ventricular pressures (solid line) for normal (A) and low (B) aortic compliance displayed for each AR degree: ROA of 0 cm2 (black), 0.15 cm2 (gray) and 0.40 cm2 (light gray) (Color figure online).

A

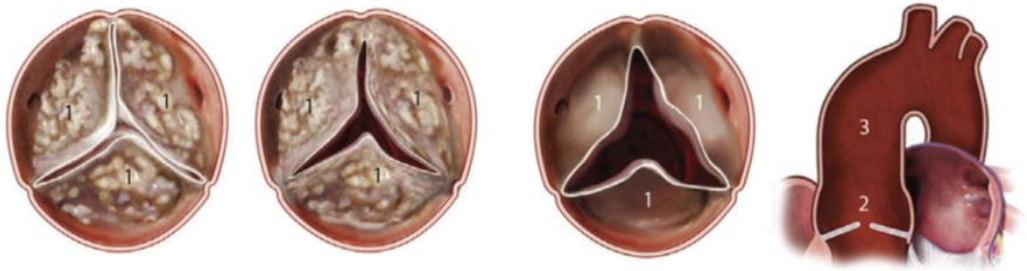
Morphological Features of Aortic Valve Stenosis or Regurgitation

Calcific Aortic Valve Stenosis

1- Nodular calcific deposits on aortic side

Aortic Valve Regurgitation

1- Minimal or absent cusp calcification
2- Dilated aortic root
3- Frequent coexistence of dilated ascending aorta



Technical Challenges of TAVR in Aortic Valve Regurgitation

- Suboptimal Fluoroscopic Visualization of the Native Valve
- Insufficient Anchoring and Sealing of the Transcatheter Device
  - Risk of Misplacement and Migration of the Device
  - Risk of Residual Valvular Regurgitation

B

Device	Design; Delivery Access	Features
ACURATE (Symetis)	Self-expandable nitinol stent; Transapical Transfemoral	Self-positioning at supra-annular level; fixed in a waistlike manner, thereby covering the aortic annulus (hourglass design); tactile feedback reducing the risk of malpositioning; possibility of partial resheating
JenaValve* (JenaValve Technology)	Self-expandable nitinol stent; Transapical	Feeler-guiding positioning and clip fixation mechanism of the native aortic valve leaflet; retrievable and repositionable
CoreValve Revalving System (Medtronic)	Self-expandable nitinol frame; Transfemoral	The lower portion of the prosthesis has high radial force to expand and exclude the native leaflets and to avoid recoil; the middle portion is constrained to avoid the coronary arteries and the upper portion is flared to center and fix the stent frame firmly in the ascending aorta and to provide longitudinal stability and coaxial positioning
Direct Flow (Direct Flow Medical)	Non-metallic framework and two inflatable rings; Transfemoral	Peculiar anchoring mechanisms (inflatable rings) not requiring calcium for sealing; repositionability and retrievability; functional during positioning (ensures hemodynamic stability); fully retrievable
Engager** (Medtronic)	Self-expandable nitinol stent; Transapical	Trapping of valve leaflets in order to stabilize the sytem and to avoid coronary ostia occlusion
Helio dock** (Edwards Lifesciences)	Self-expandable nitinol stent; Transfemoral	The dock is fixed inside the aortic root and assists in annular fixation of a standard balloon-expandable SAPIEN XT transcatheter heart valve by incorporating and entrapping the native cusps
CoreValve Evolute R** (Medtronic)	Self-expandable; Transfemoral	Recapturability and repositionability; supra-annular position
J-Valve (JieCheng Medical Technology)	Self-expandable nitinol stent; Transapical	Featured by three U-shape anatomically oriented devices-graspers-which facilitate 'self-positioning' during implantation and provide extra-radial fixation by embracing the native valve leaflets (clip mechanism). The two stages releasing design facilitates accurate position
Lotus** (Boston Scientific)	Nitinol frame with an Adaptive SealTM Technology; Transfemoral	Mechanically deployed with possibility to retrieve and reposition; early functional during deployment

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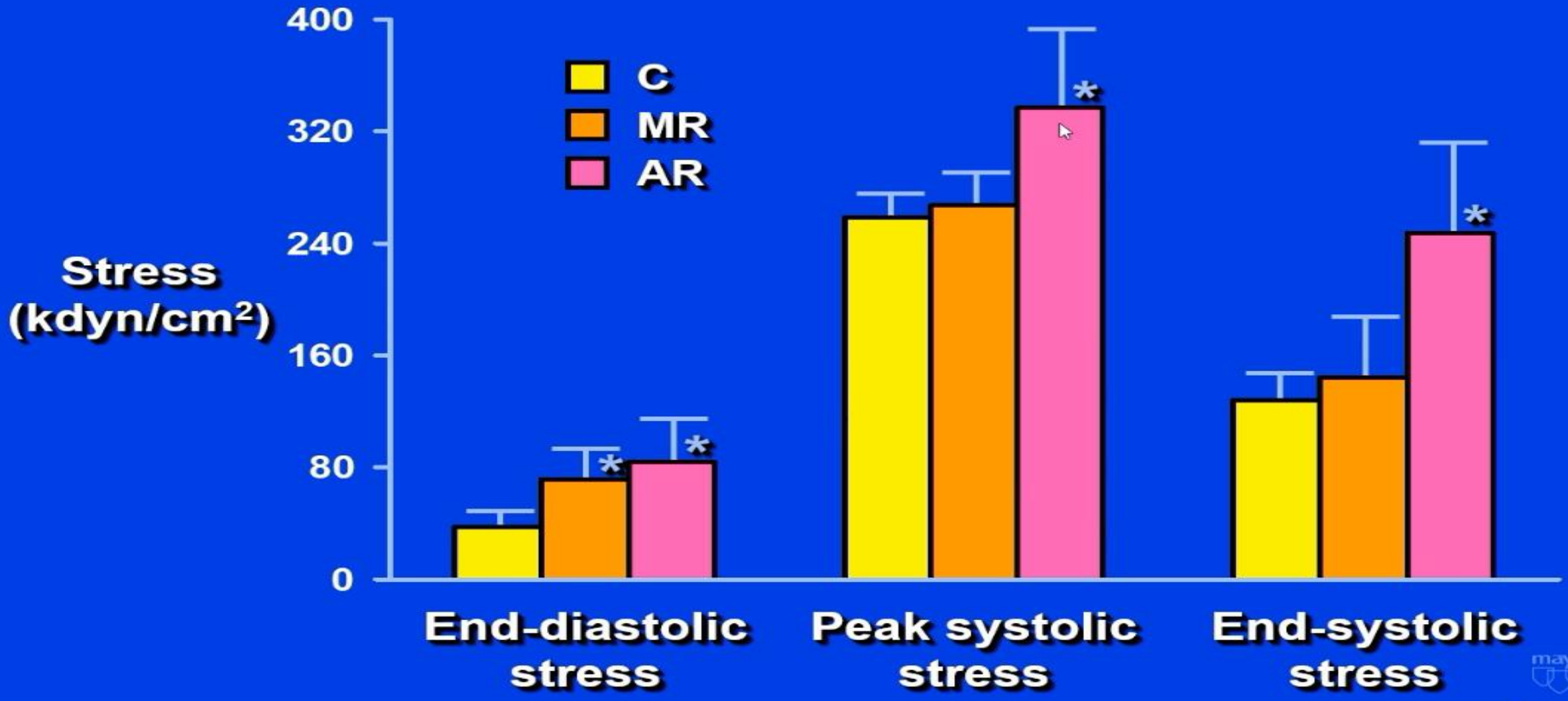
Edwards Sapiens 3:
- Balloon Expandable
- External Adaptative Seal

Valve Regurgitations
Differences in Loading Conditions



mayo

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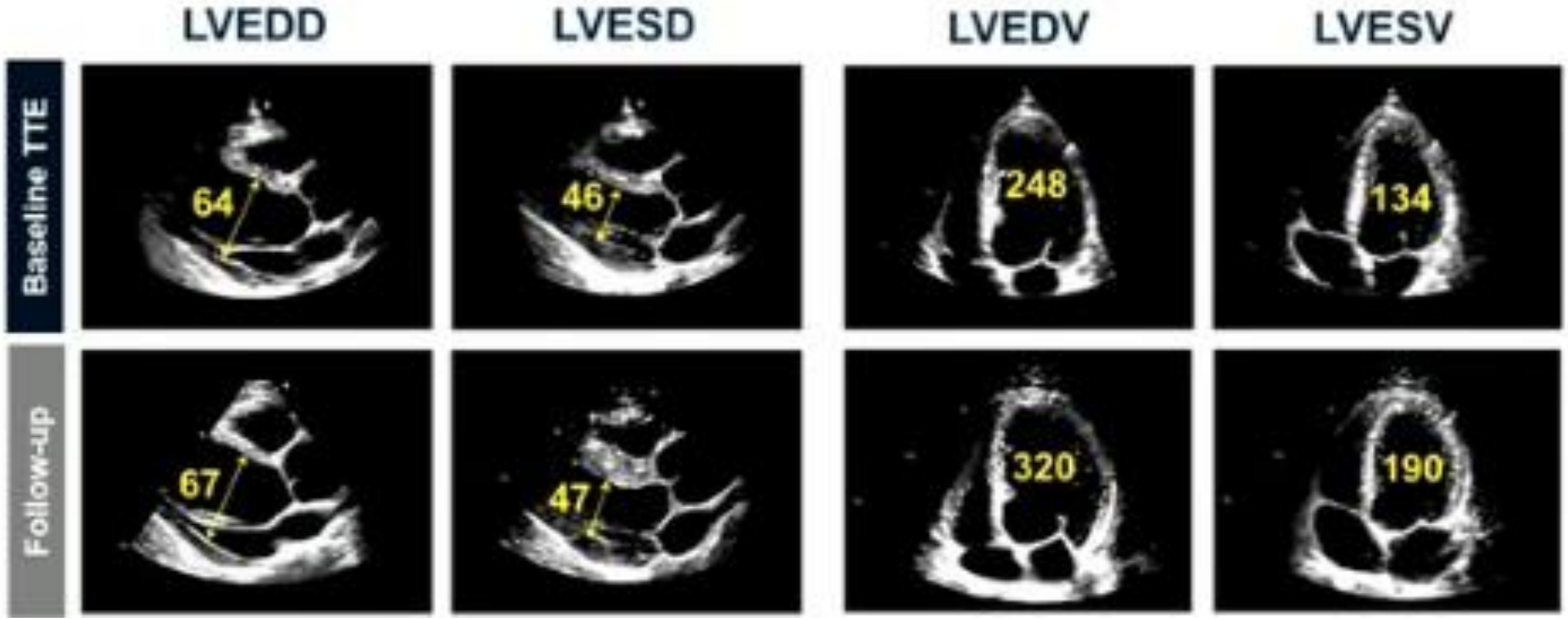
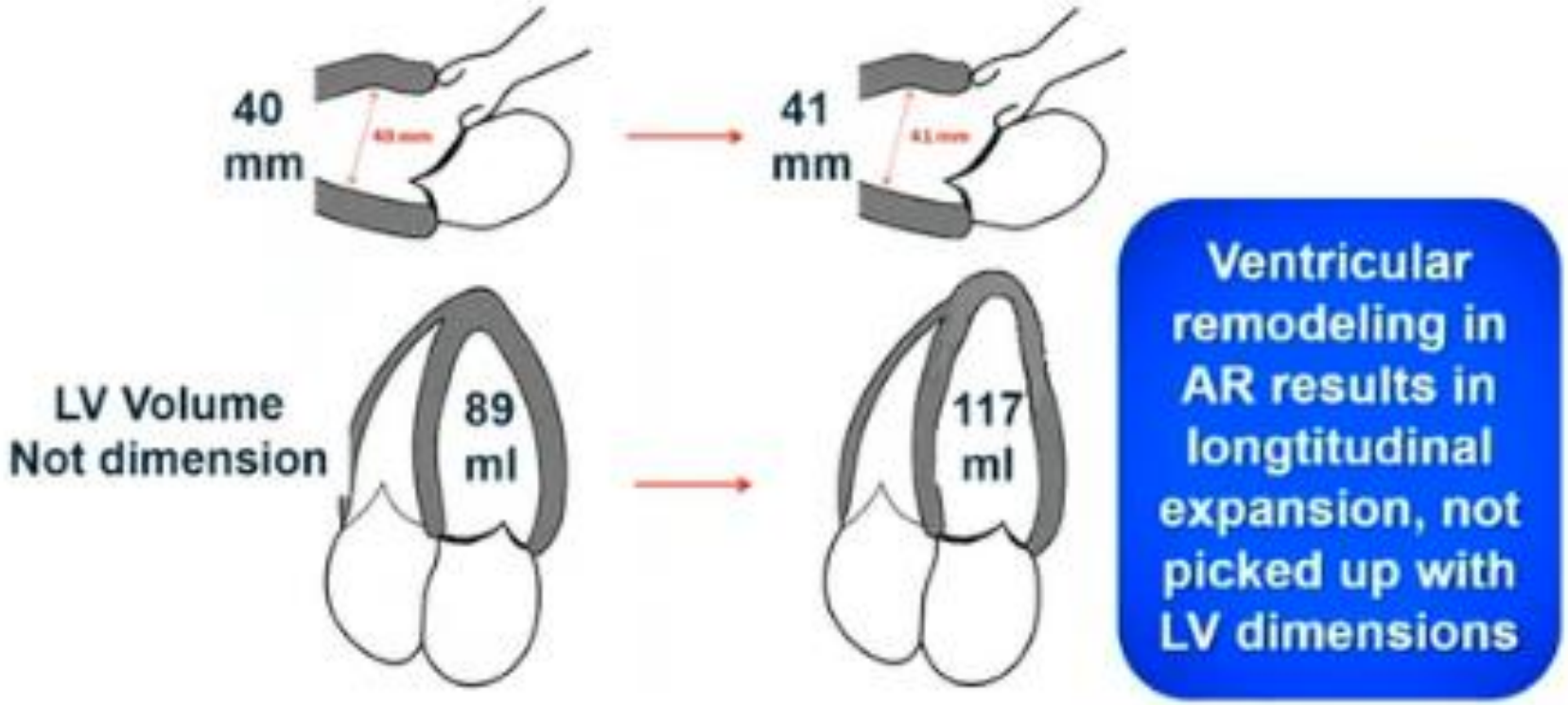
Linear vs Volumetric Assessment of LV size

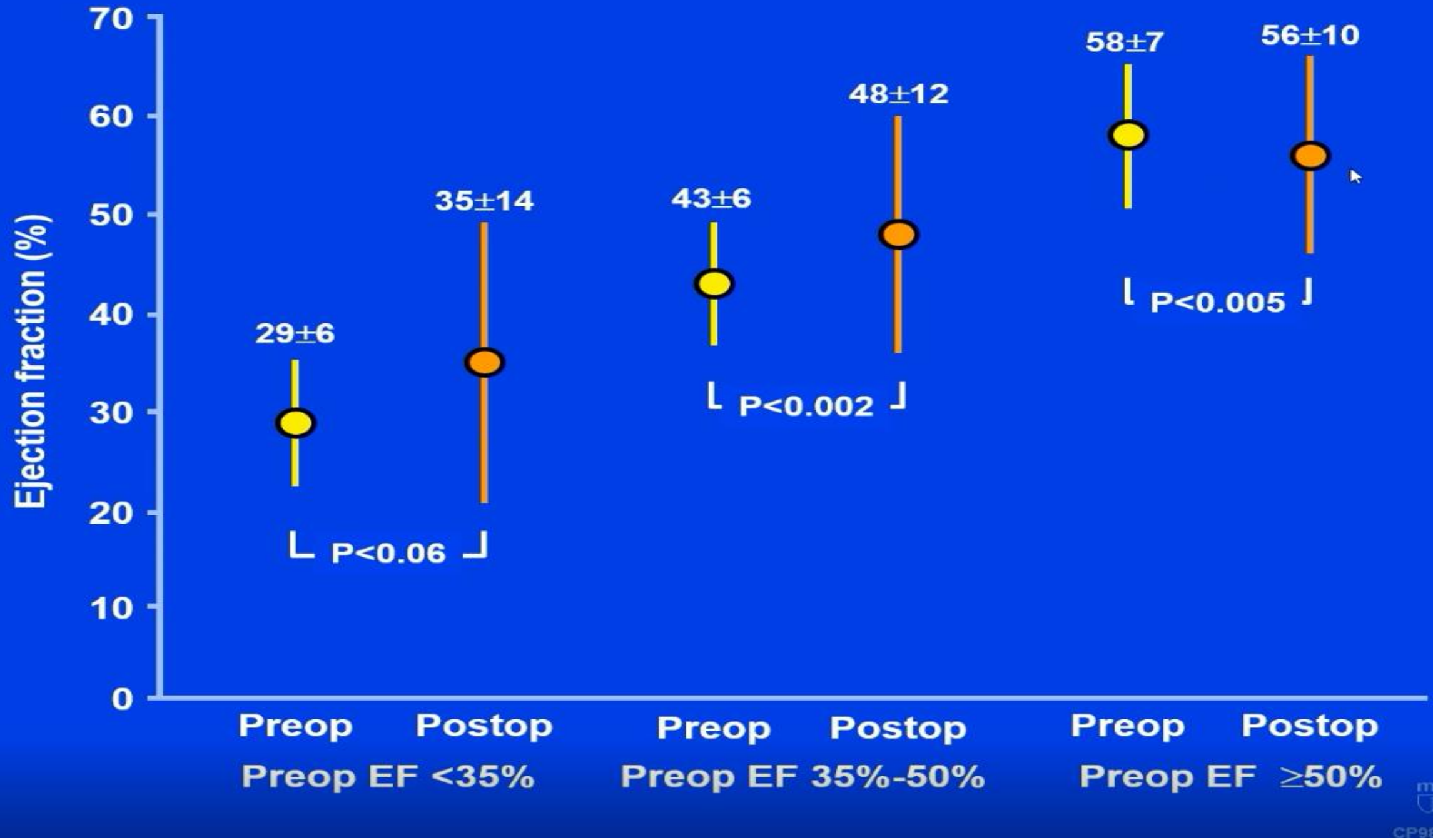


Anand V et al. J Am Soc Echo. 2021.Apr;34(4):352-359.

Pattern of Ventricular Remodeling in Aortic Regurgitation

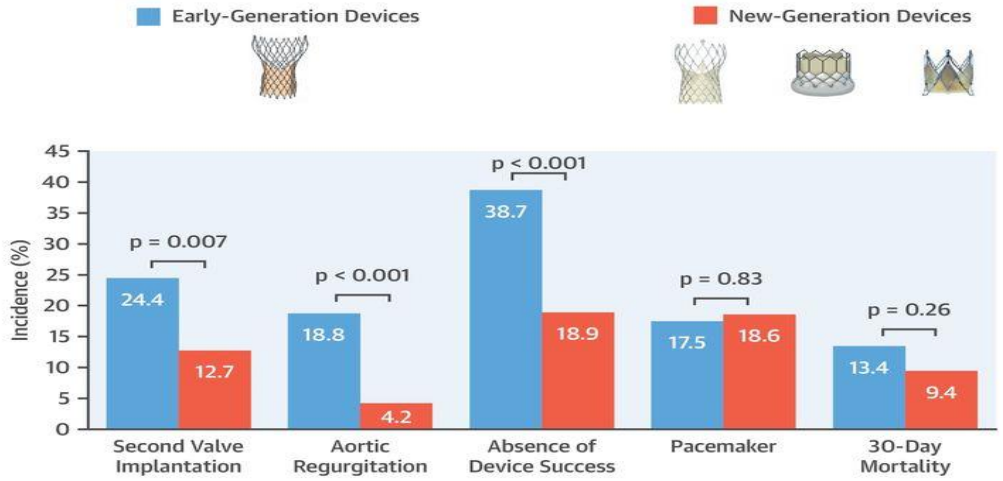


Ilustration from Nushimura RA

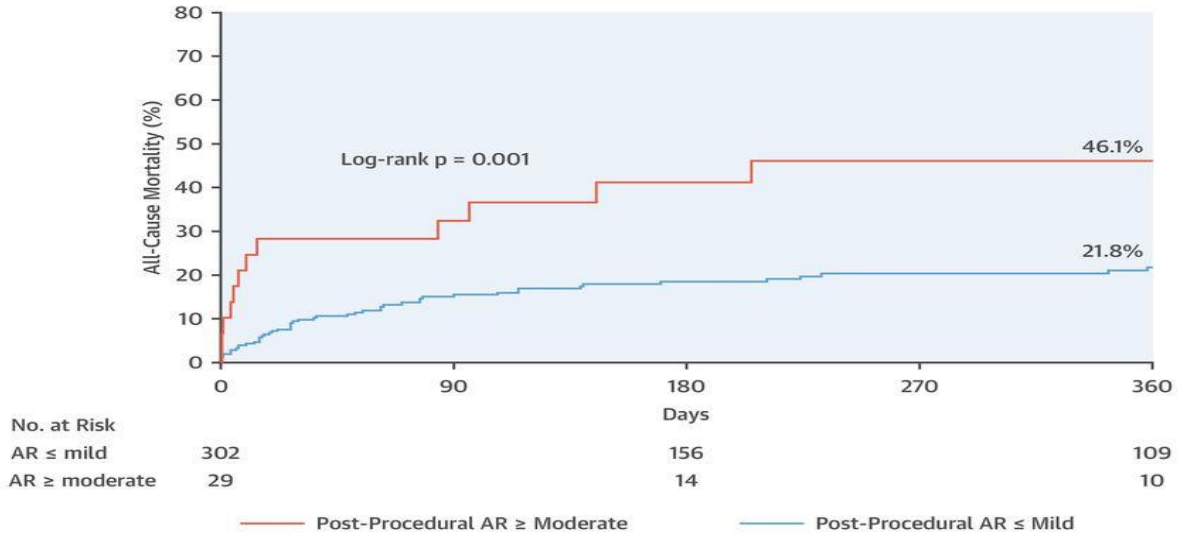


CENTRAL ILLUSTRATION: TAVR for Pure Native Aortic Valve Regurgitation

Outcomes According to Devices



Mortality and Post-Procedural Aortic Regurgitation



Yoon, S.-H. et al. J Am Coll Cardiol. 2017;70(22):2752–63.

Outcomes According to Devices

Mortality and Post-Procedural Aortic Regurgitation

All cause mortality predictors

TABLE 4 Predictors of All-Cause Mortality

	Univariable Model		Multivariable Model	
	HR (95% CI)	p Value	HR (95% CI)	p Value
Age, yrs	1.00 (0.98–1.02)	0.98		
Female	1.05 (0.65–1.72)	0.84		
NYHA functional class IV at baseline	1.33 (0.79–2.26)	0.29		
STS score	1.03 (1.01–1.06)	0.019	1.03 (1.00–1.06)	0.037
Creatinine, mg/dl	1.00 (0.80–1.25)	0.99		
Peripheral vascular disease	1.42 (0.81–2.50)	0.23		
Chronic pulmonary disease	1.34 (0.80–2.25)	0.26		
Prior cerebrovascular accident	0.78 (0.31–1.94)	0.59		
Prior coronary artery bypass graft surgery	1.41 (0.84–2.37)	0.19		
LVEF ≤45%	1.89 (1.15–3.10)	0.012	1.78 (1.07–2.94)	0.026
Mitral regurgitation ≥ moderate at baseline	1.99 (1.22–3.25)	0.006	2.11 (1.29–3.45)	0.003
Pulmonary hypertension	1.41 (0.83–2.40)	0.20		
Transfemoral access	0.81 (0.48–1.34)	0.41		
New-generation devices	0.69 (0.42–1.12)	0.13		
Need for second valve implantation	1.69 (0.93–2.96)	0.087		
Post-procedural aortic regurgitation ≥ moderate	2.72 (1.45–5.10)	0.002	2.85 (1.52–5.35)	0.001
Late experience	0.83 (0.50–1.36)	0.46		

CI = confidence interval; HR = hazard ratio; other abbreviations as in Table 1.

STS Score

LVEF < 45%
Mitral Regurgitation > Moderate at baseline

POST-PROCEDURAL AORTIC REGURGITATION > MODERATE

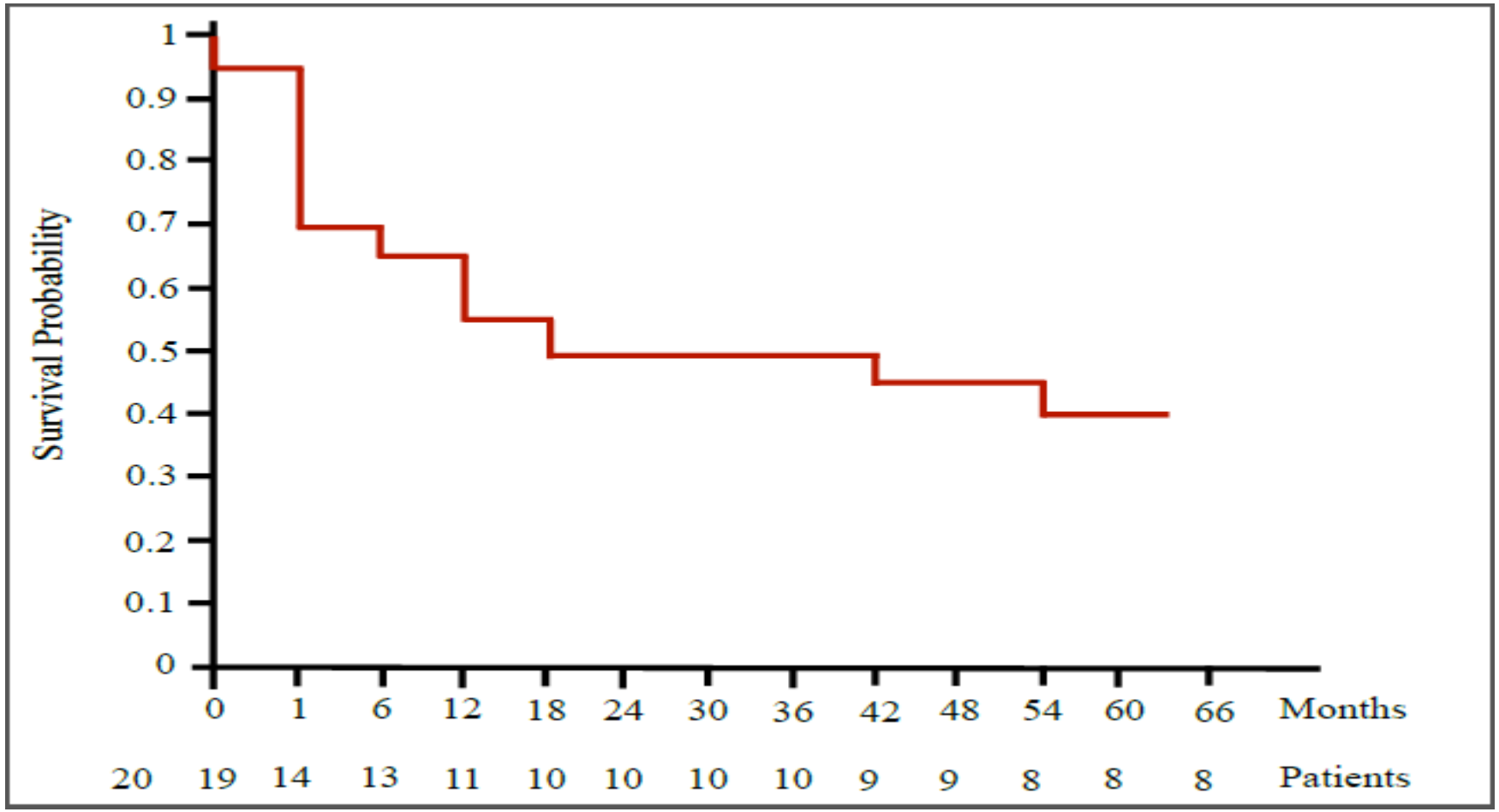
Transcatheter Aortic Valve Replacement Using The CoreValve Prosthesis for the Treatment of Severe Aortic Regurgitation: A Single Center Learning Curve

Over 10 years

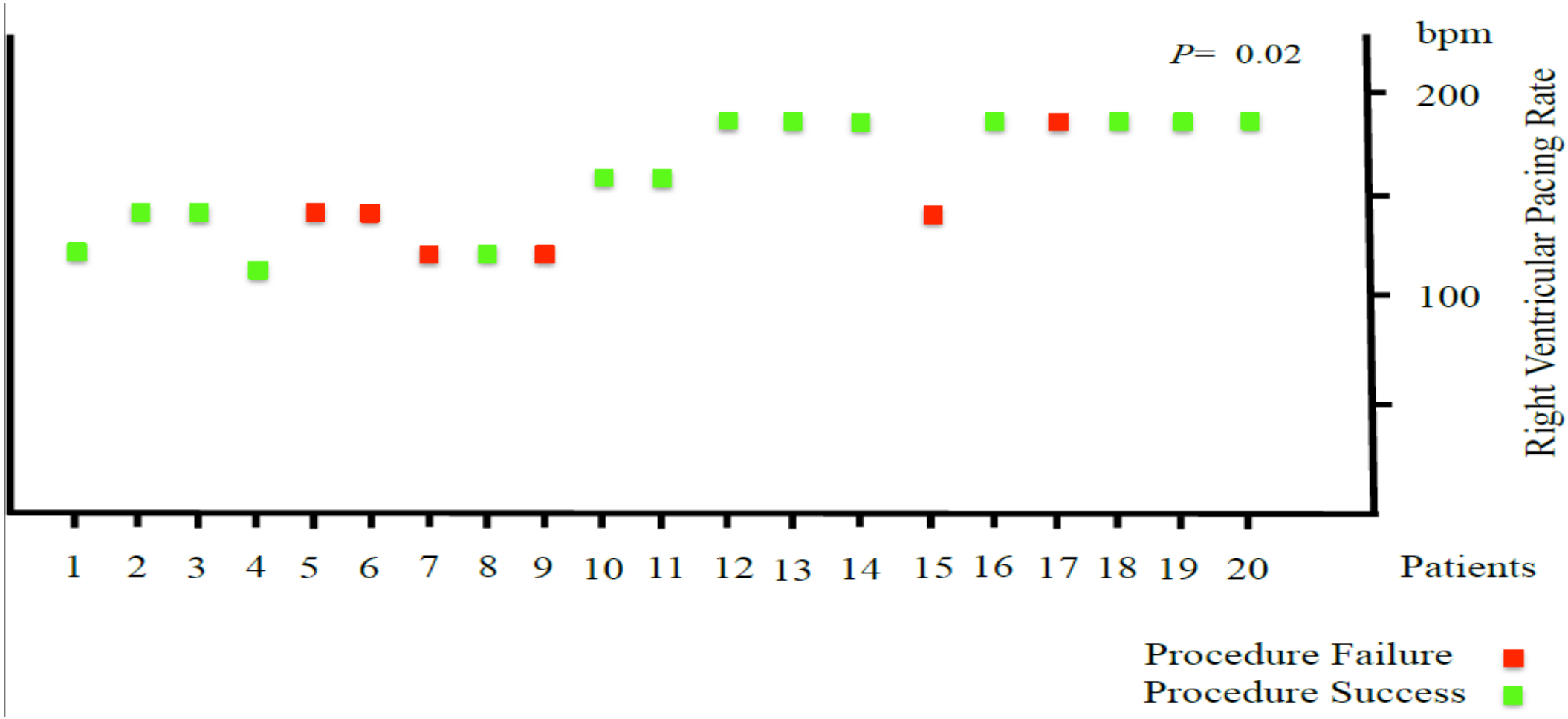
Short Tittle: TAVR for NAVR

Author block:

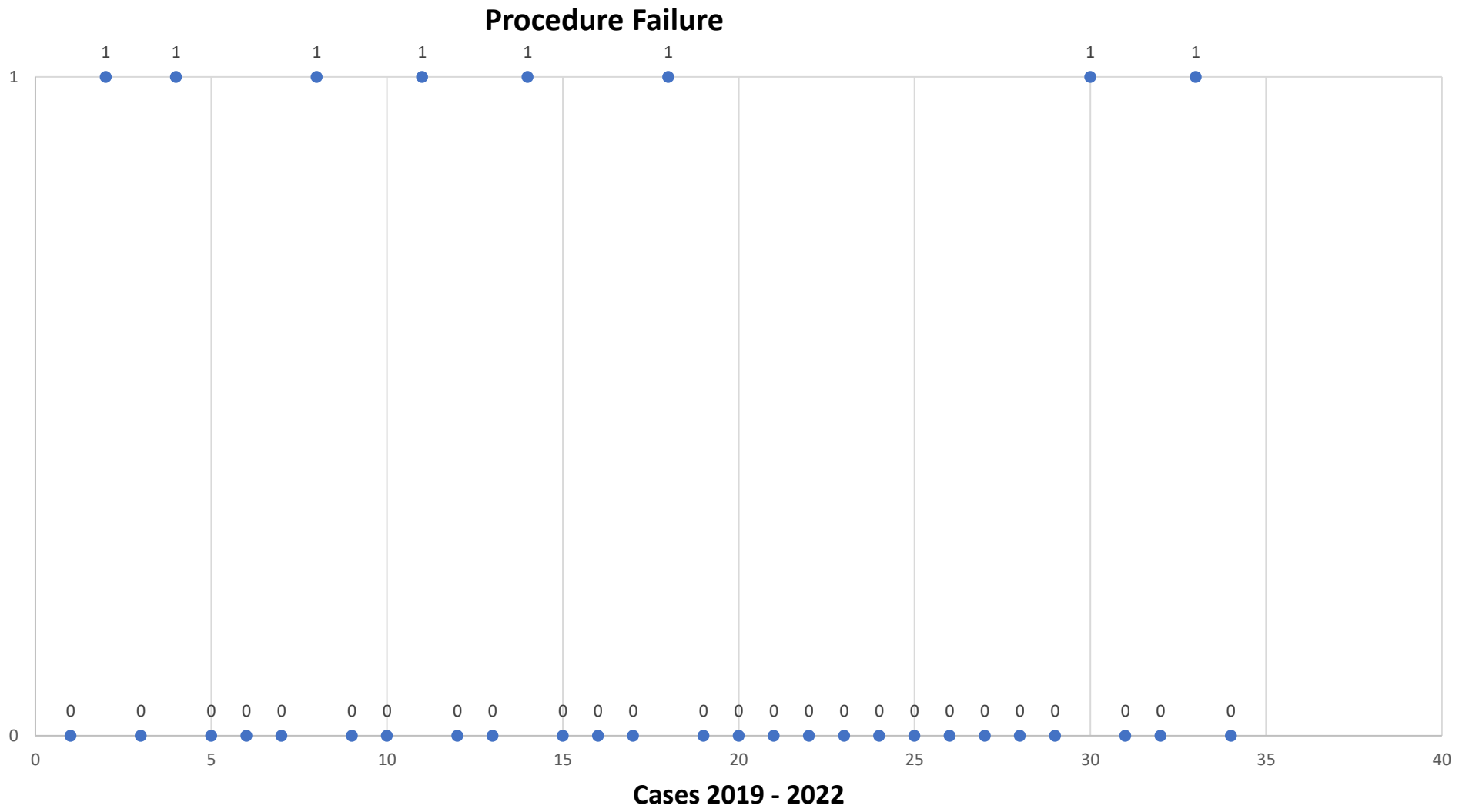
Giselle A. Baquero MD, Angela Cucalon MD, David Hernandez MD, Camilo Arana MD, Jaime Fonseca MD, Bernardo Caicedo, MD, William W. O'Neill MD, Eduardo de Marchena MD, Antonio Dager MD


Survival Probability
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0 1 6 12 18 24 30 36 42 48 54 60 66 Months
20 19 14 13 11 10 10 10 10 9 9 8 8 8 Patients

2019


P= 0.02
bpm
200
100
Right Ventricular Pacing Rate
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20
Patients
Procedure Failure
Procedure Success

2019



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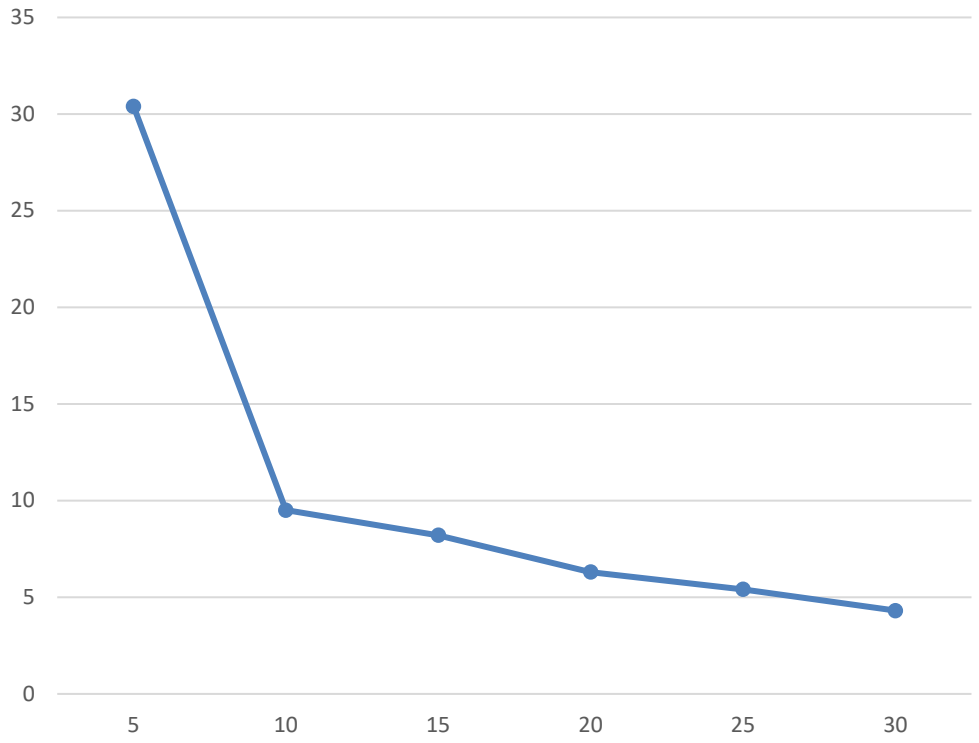
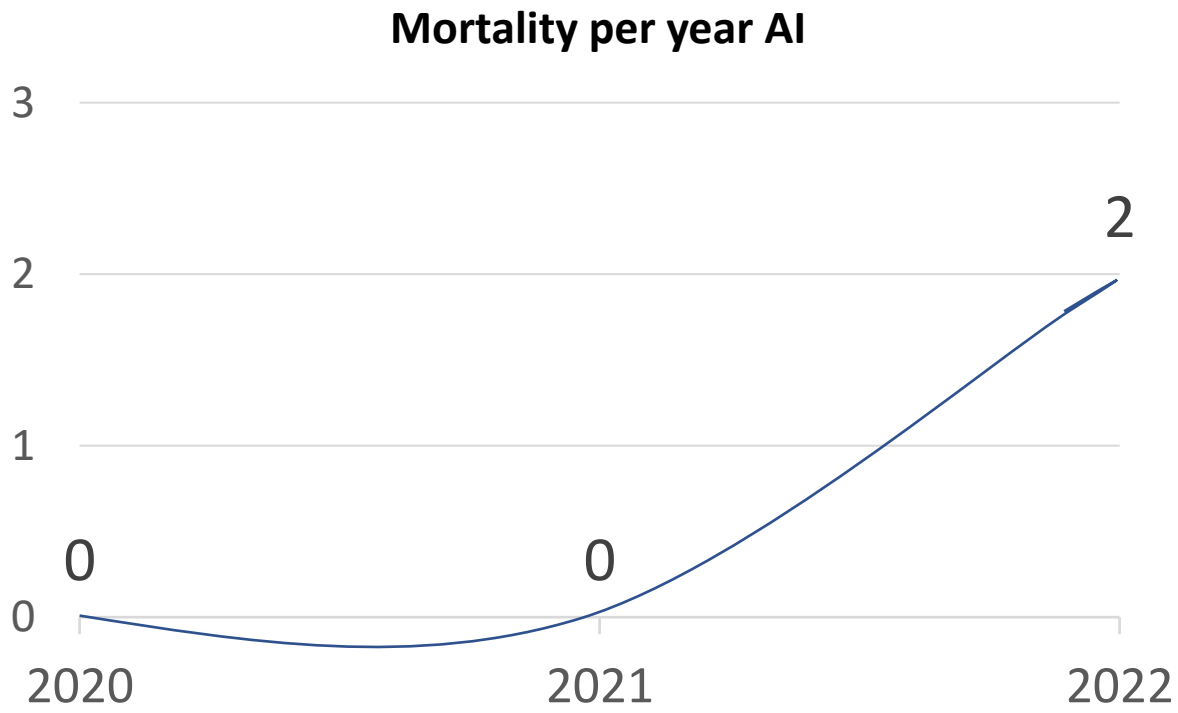
Procedure Failure

2019



2020 - 2022



YEAR	CASES AI
2019	10
2020	5
2021	14
2022	15

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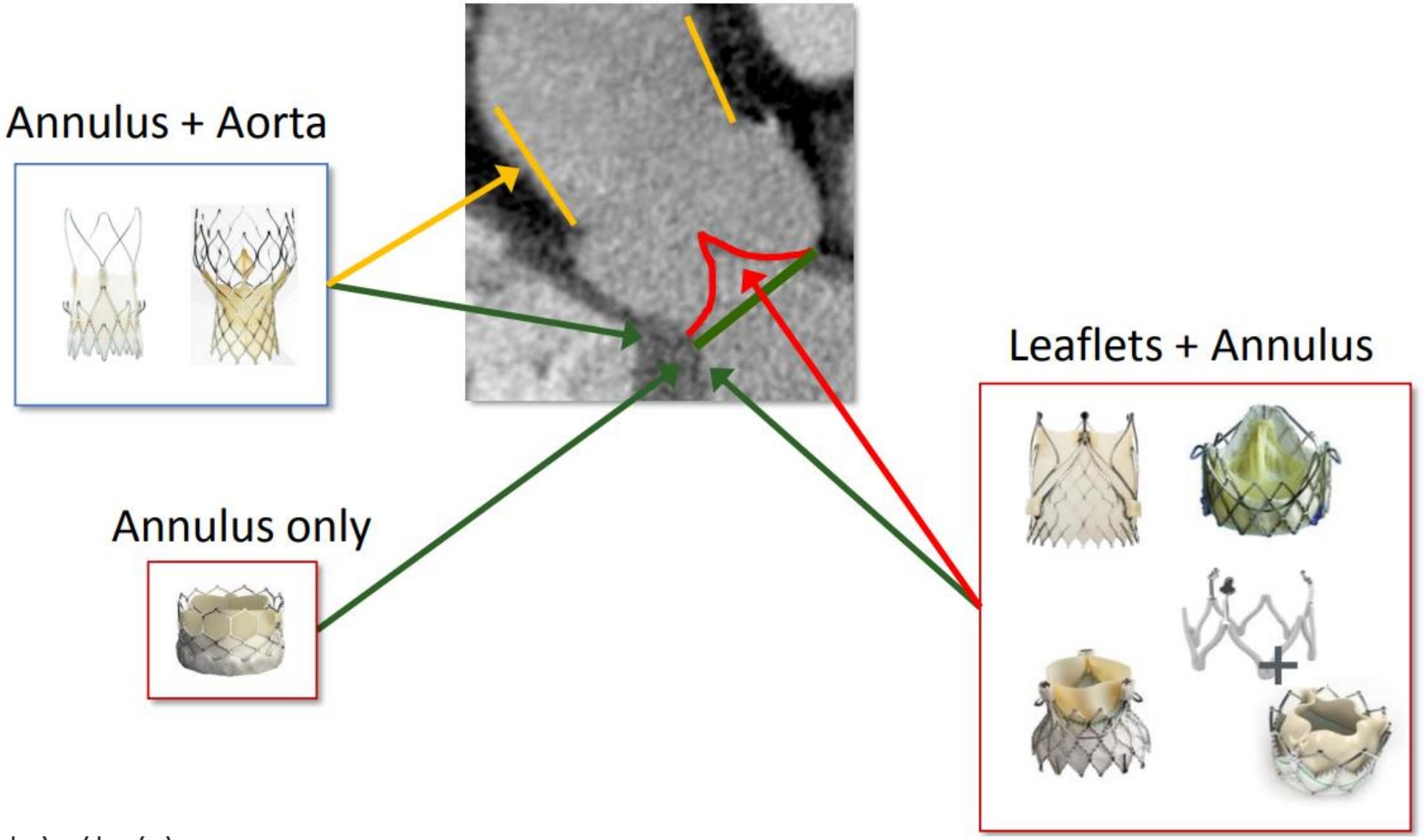


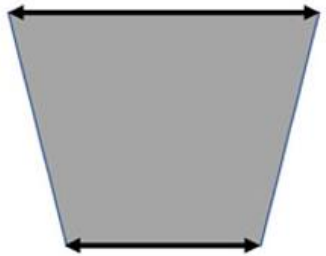
Makkar, R (2022). Off-label use of TAVR devices to treat Aortic Regurgitation [power point slides]. TCTMD. https://www.tctmd.com/slide/tips-and-tricks-workhorse-tavr-devices

Anatomic reference: LVOT

Tube

Sizing based on

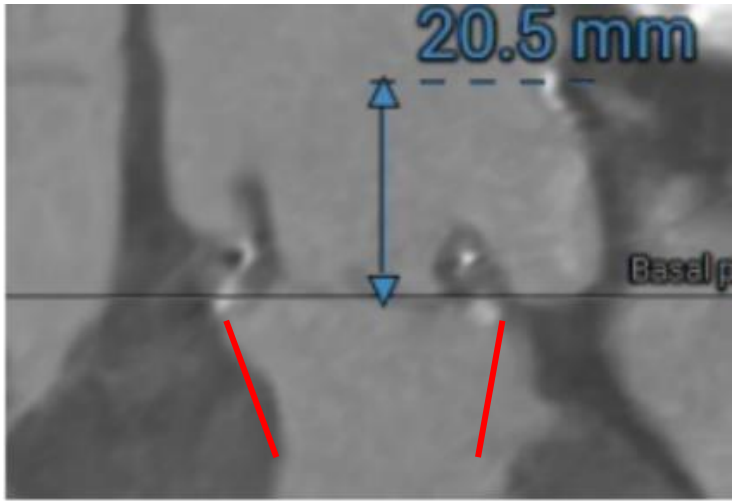
the annulus

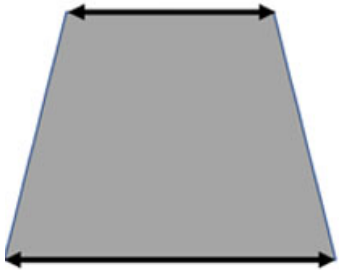


Flare

Sizing based on

the annulus

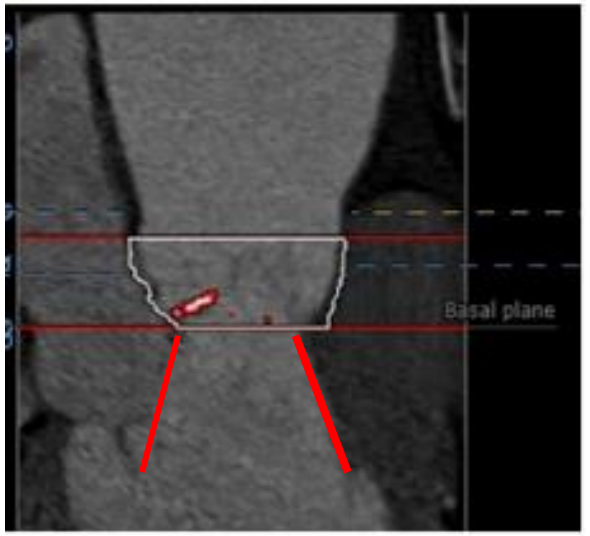




Taper

Sizing based on

the ICD



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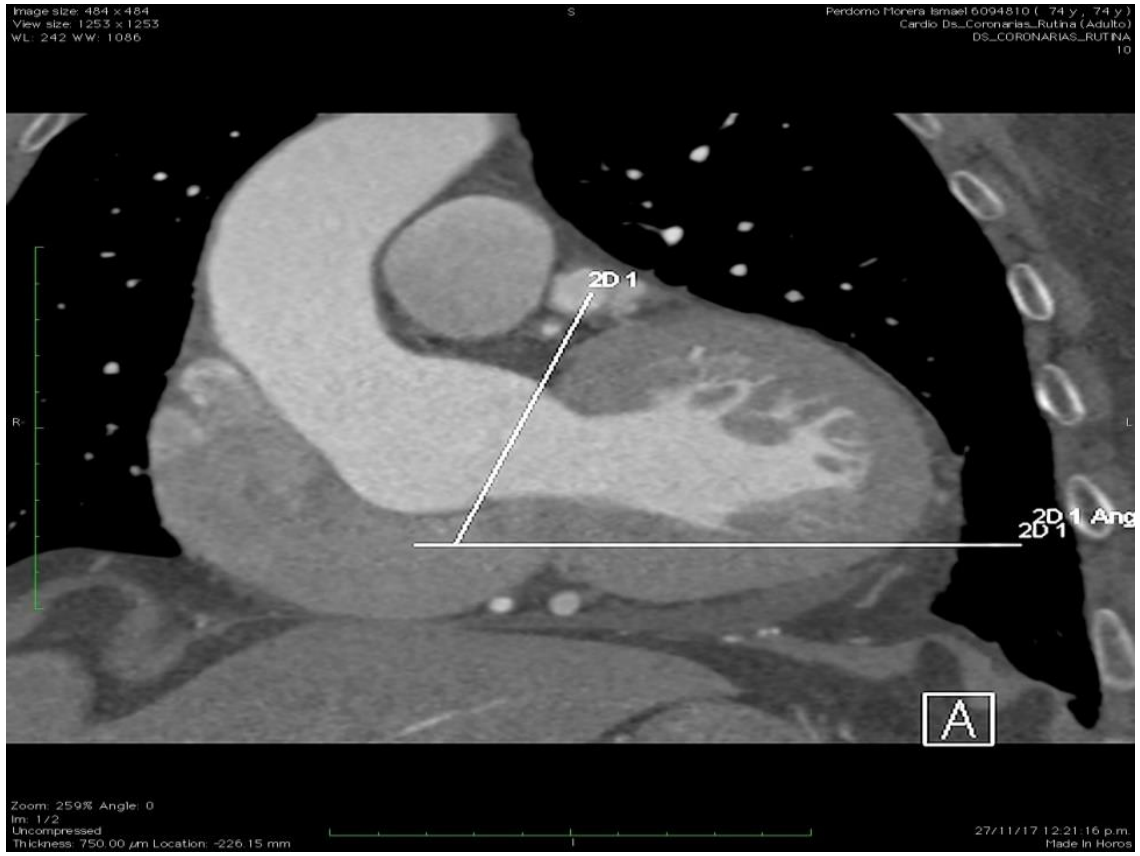
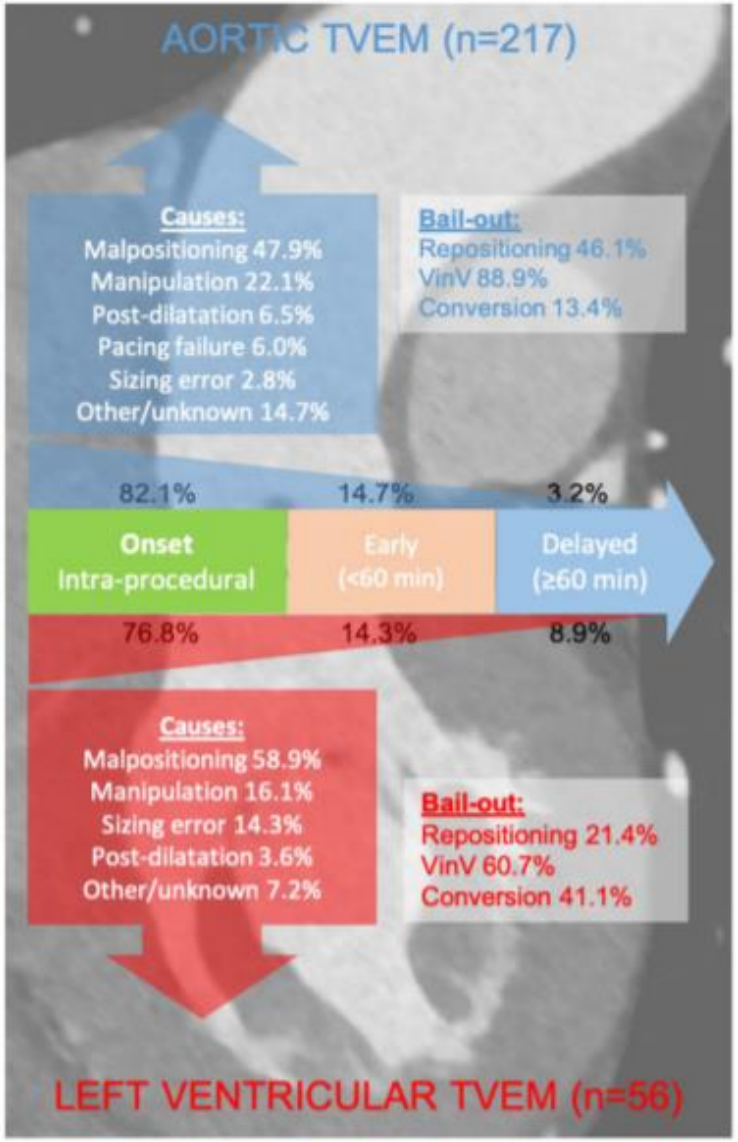
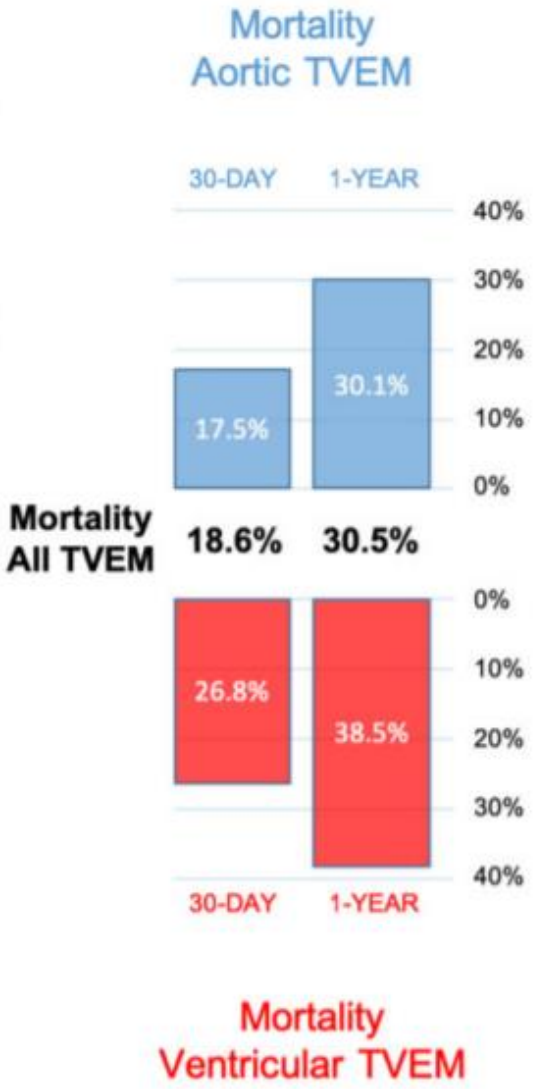
Anatomic reference: Aortic position



Angle: 86°



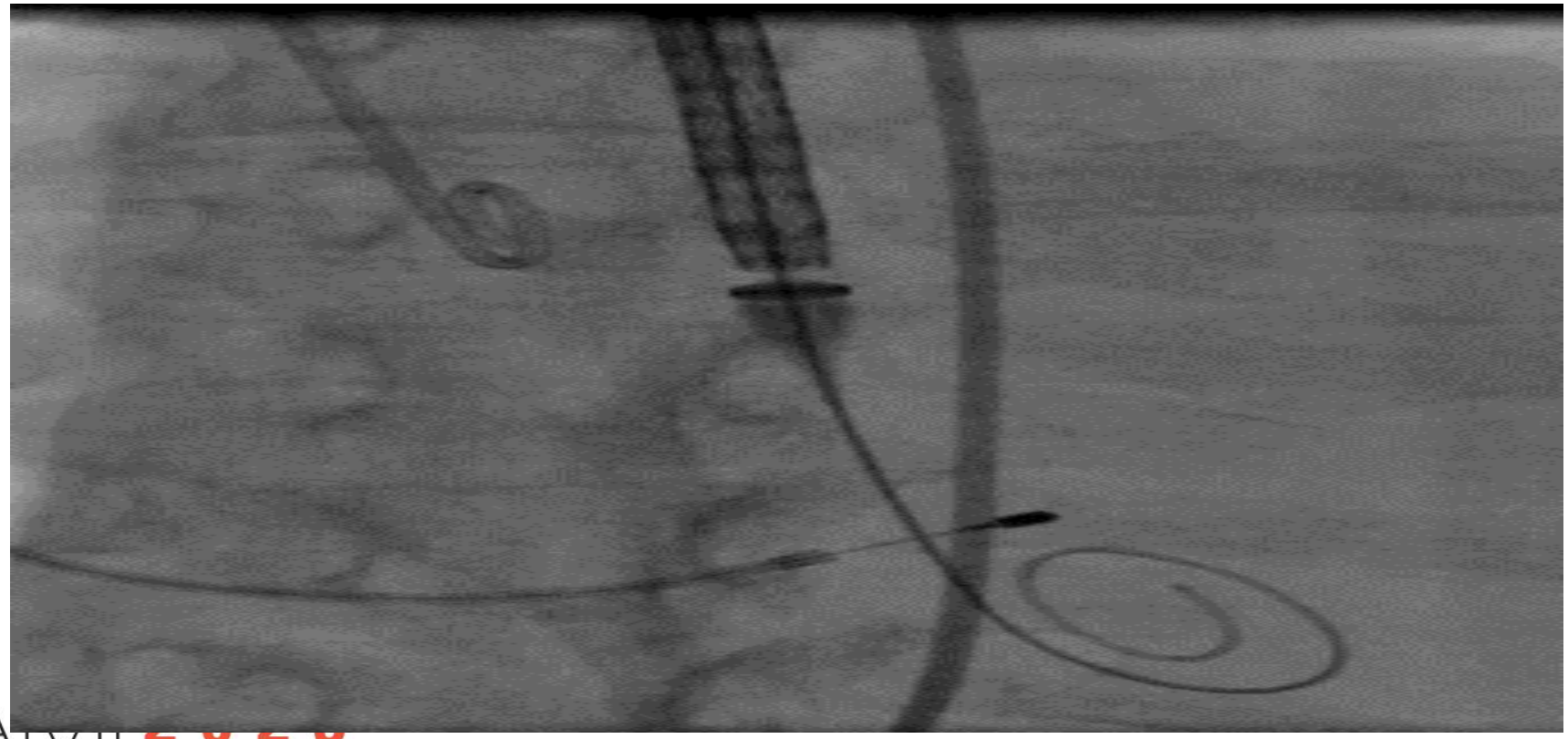


Take home figure Overview of the main causes, onset, bail-out strategies, and outcome of transcatheter valve embolization and migration stratified according to aortic and ventricular embolization. TVEM, transcatheter valve embolization and migration; VinV, valve-in-valve.

Incidence and outcome of peri-procedural transcatheter heart valve embolization and migration: the TRAVEL registry (TranscatheteR HeArt Valve EmboLization and Migration). European Heart Journal (2019) 0, 1–10. doi:10.1093/eurheartj/ehz429

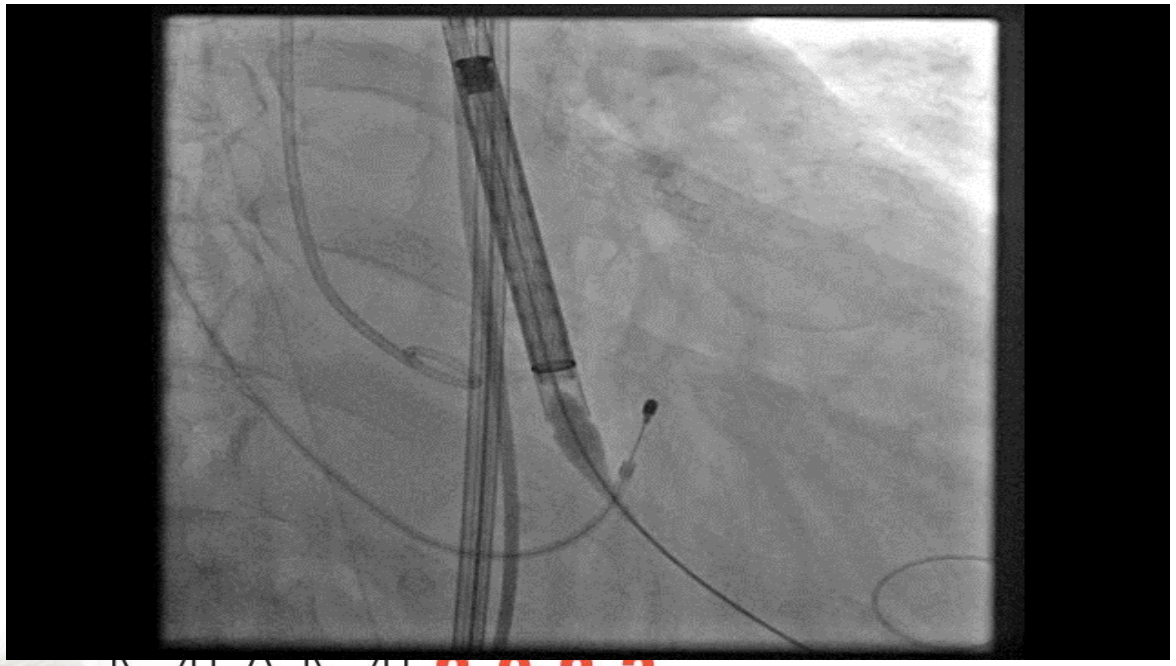
PHASES FOR DEVICE RELEASE

First Phase: Absence of Displacement, Peacemaker not needed (stable system).



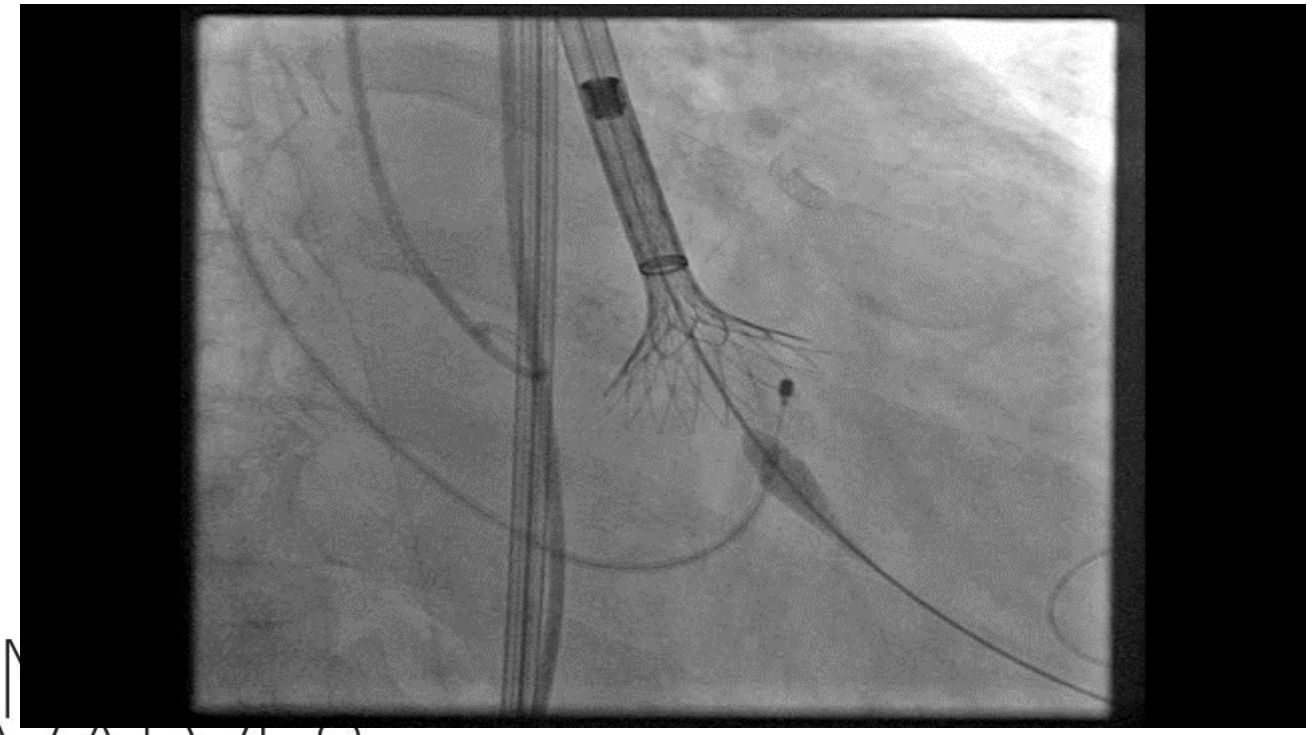
First Phase: Should start peacemaker at 130 to 150 bpm.

No PPM



PPM 130

Second phase: Even with PPM 150 BPM the system hasn't achieved annular contact with the annular system, you can tell by the movement. Displacement should be avoided and Increase pacing at 170-180 BPM.



BPM 150

Critical moment to release the device

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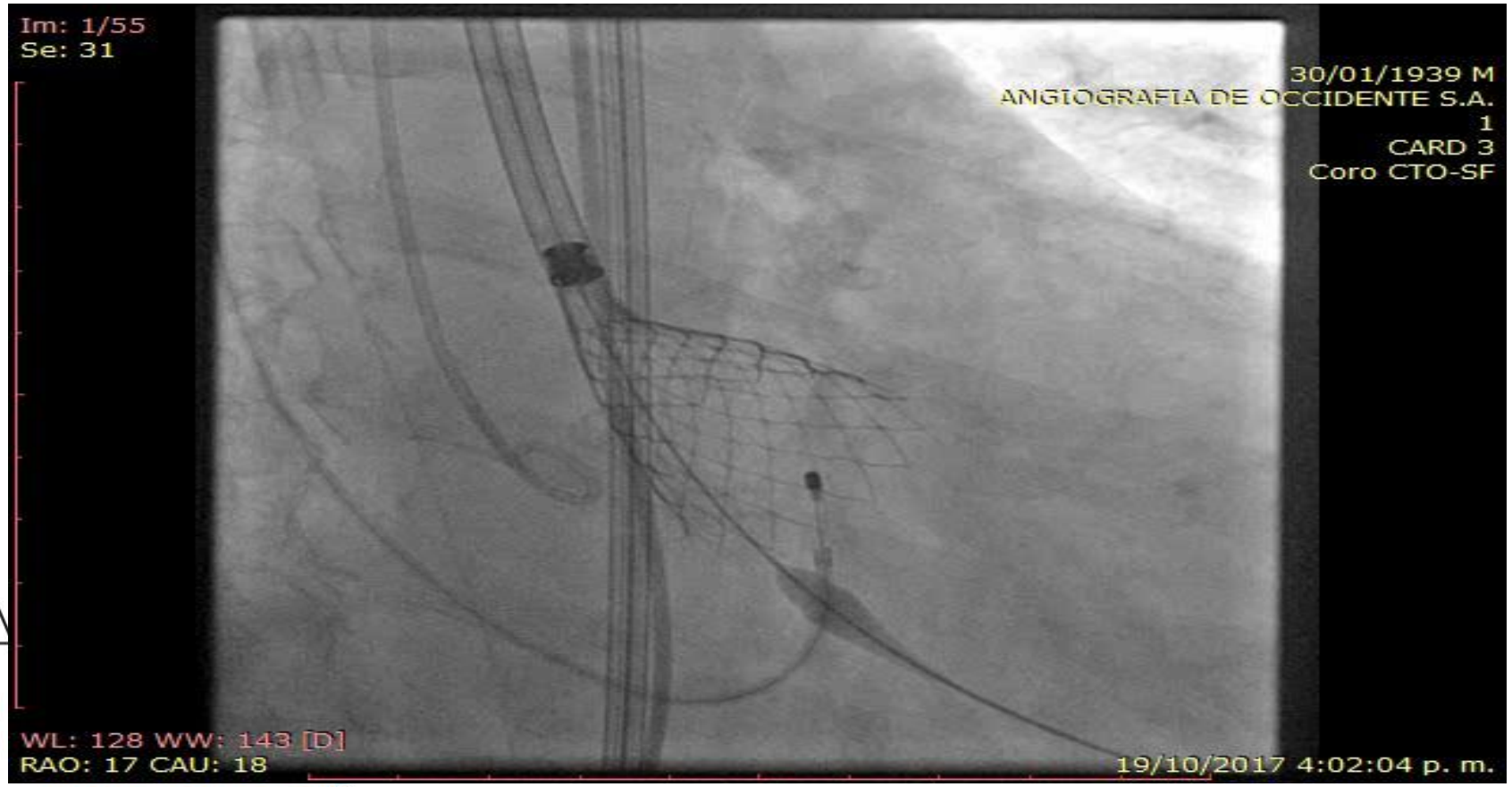
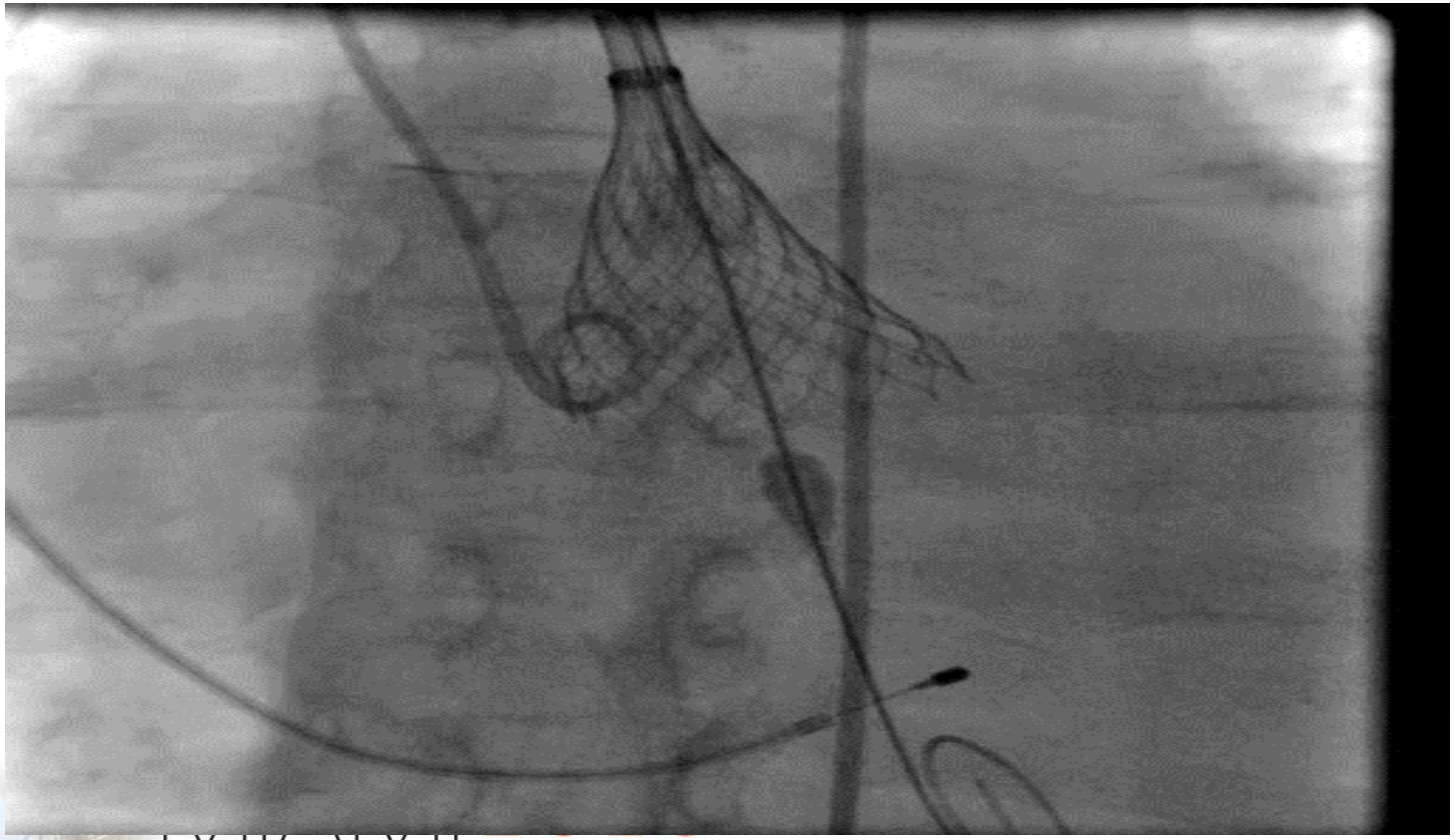
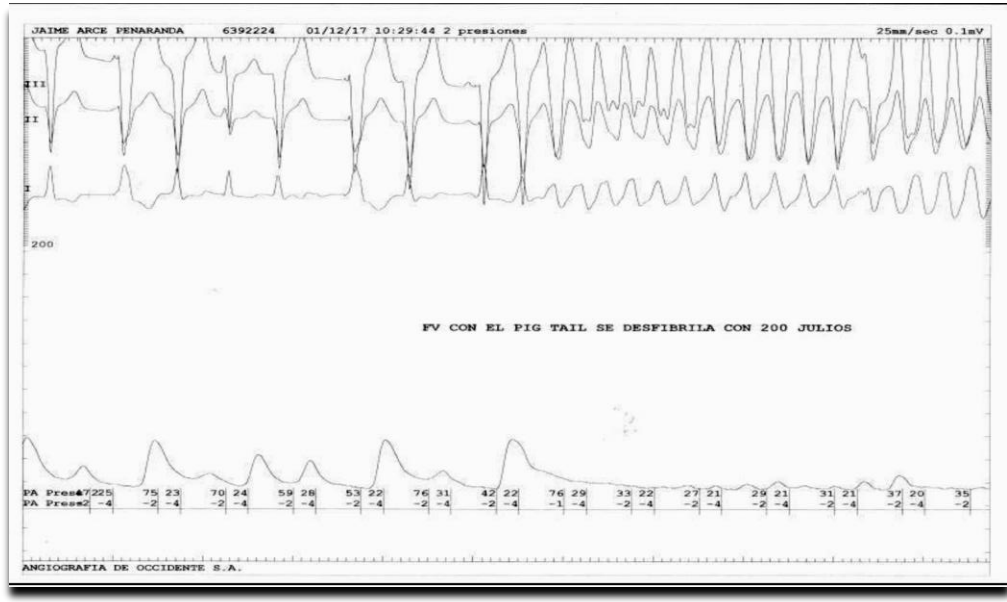
Third Phase: SPIN OFF Movement.

At no-Recapture point the valve is still out of adequate contact, and is still bound to migrate unless we increase the pulse rate. (BPM 160-180)



Fourth phase: No movement, achieved at rates between 180 - 200 BPM.





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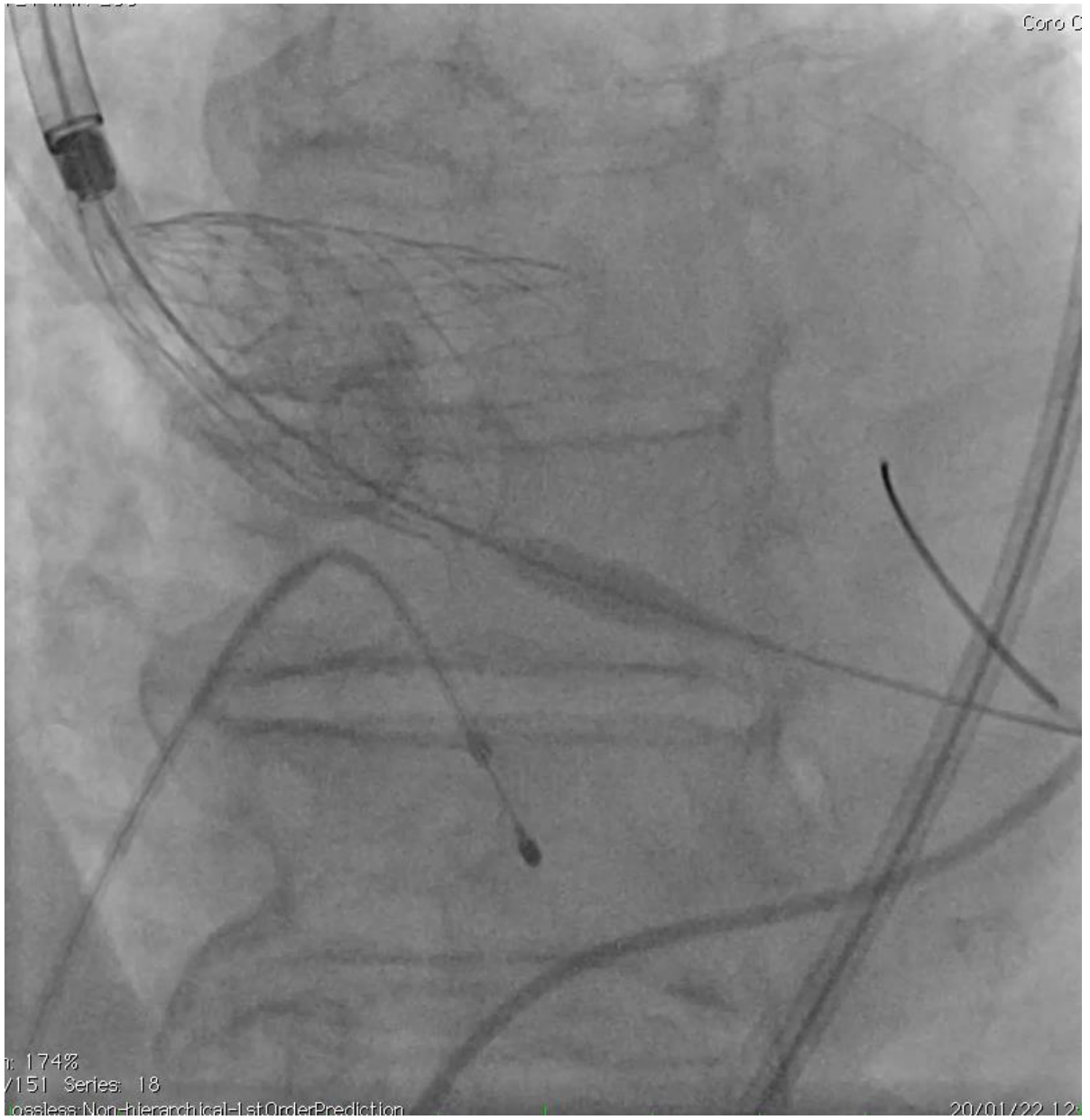
FIFTH PHASE



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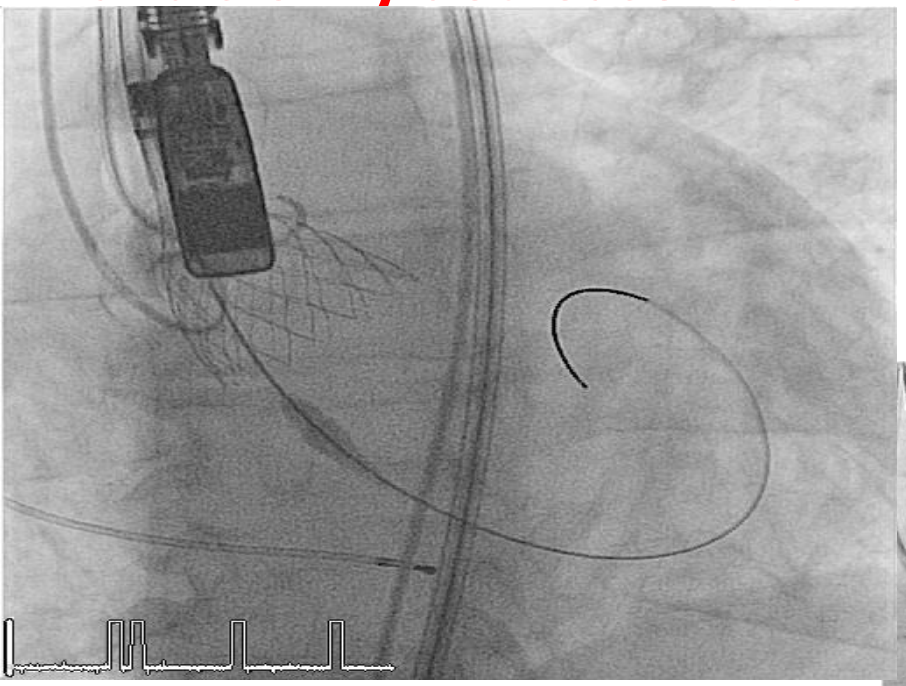
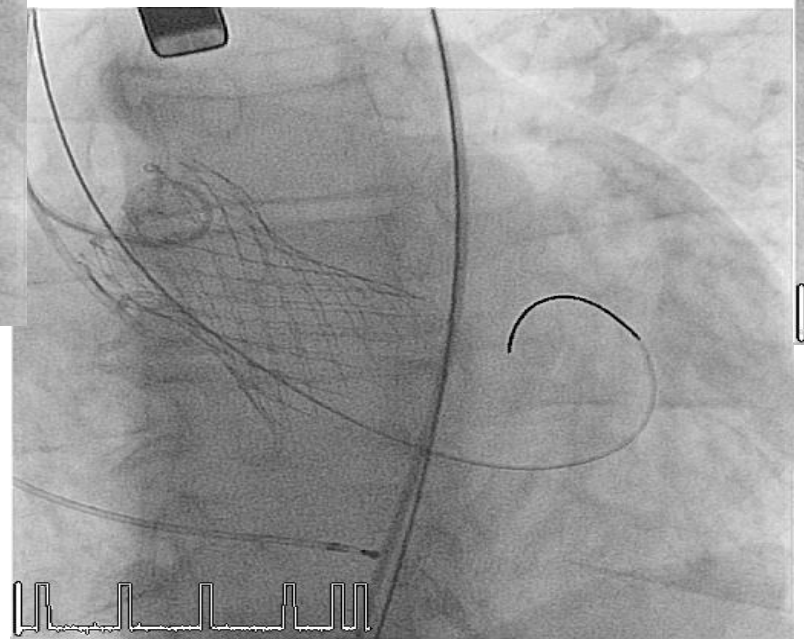
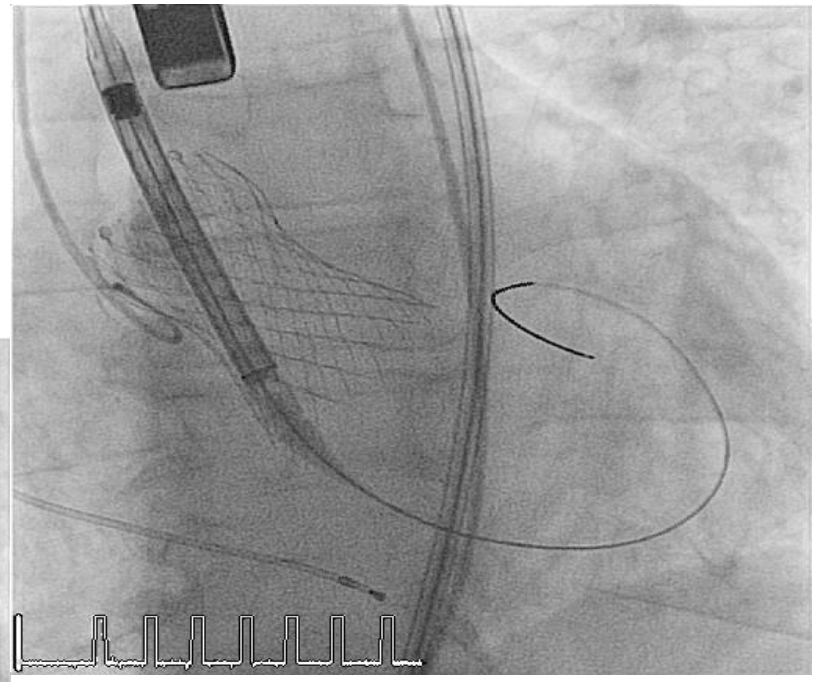
Ventricular Migration of Prosthesis

This phase should always be done under pacing and fluoroscopy visualization, and slowly decrease rate without stopping abruptly to avoid this:







Case of Migration

Male N I

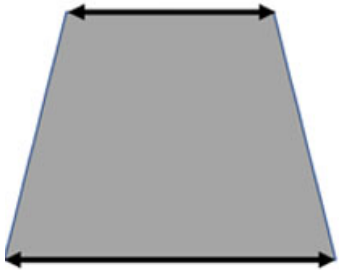
88 YO

HTA

DM

Aortic Regurgitation

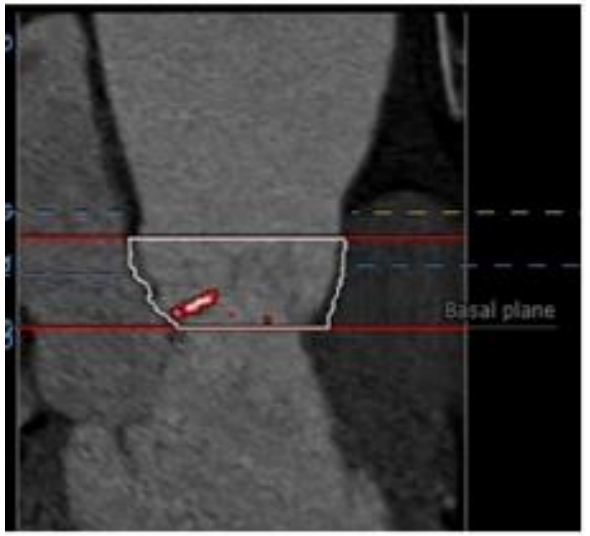
Perimeter 108

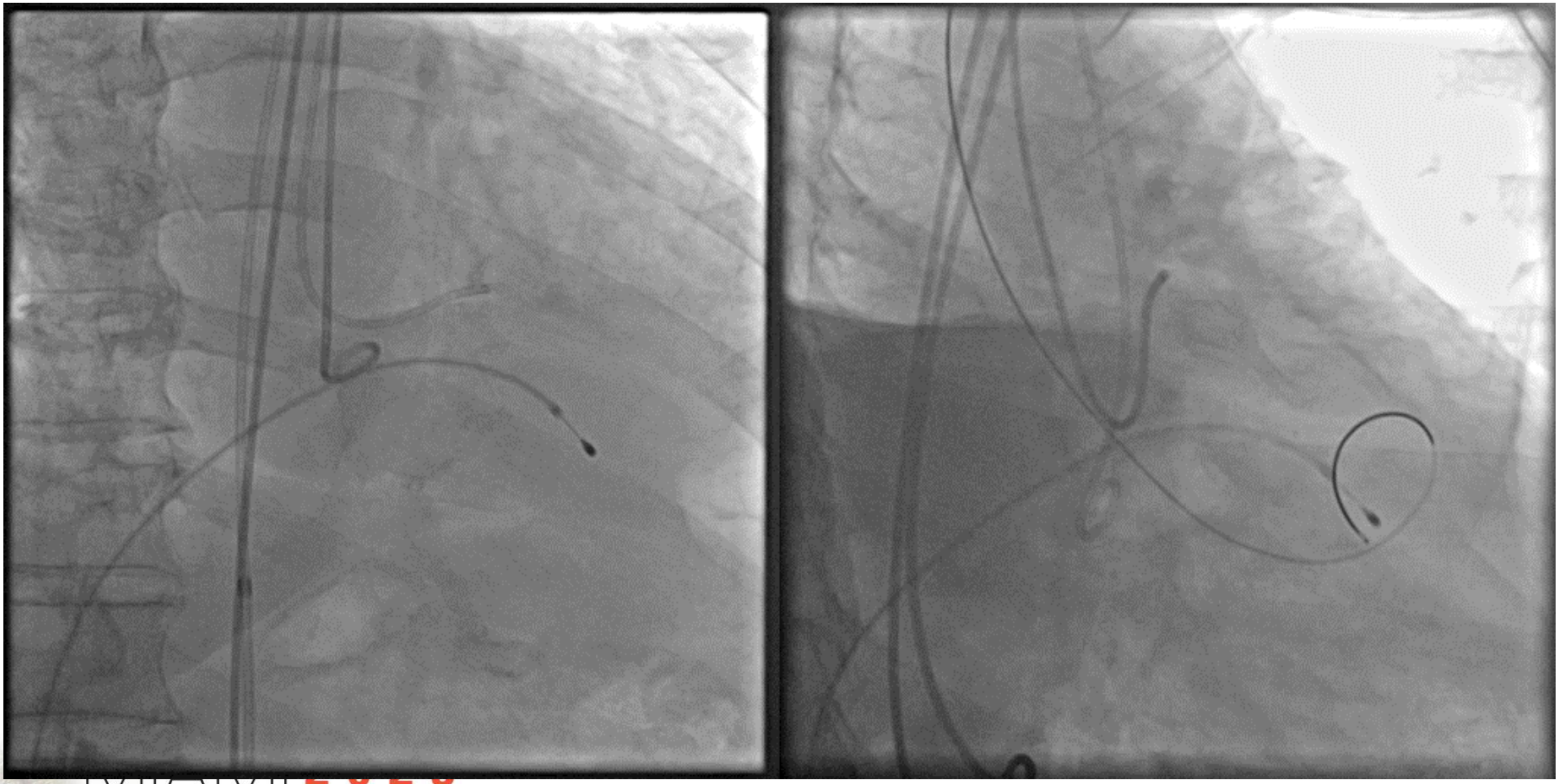


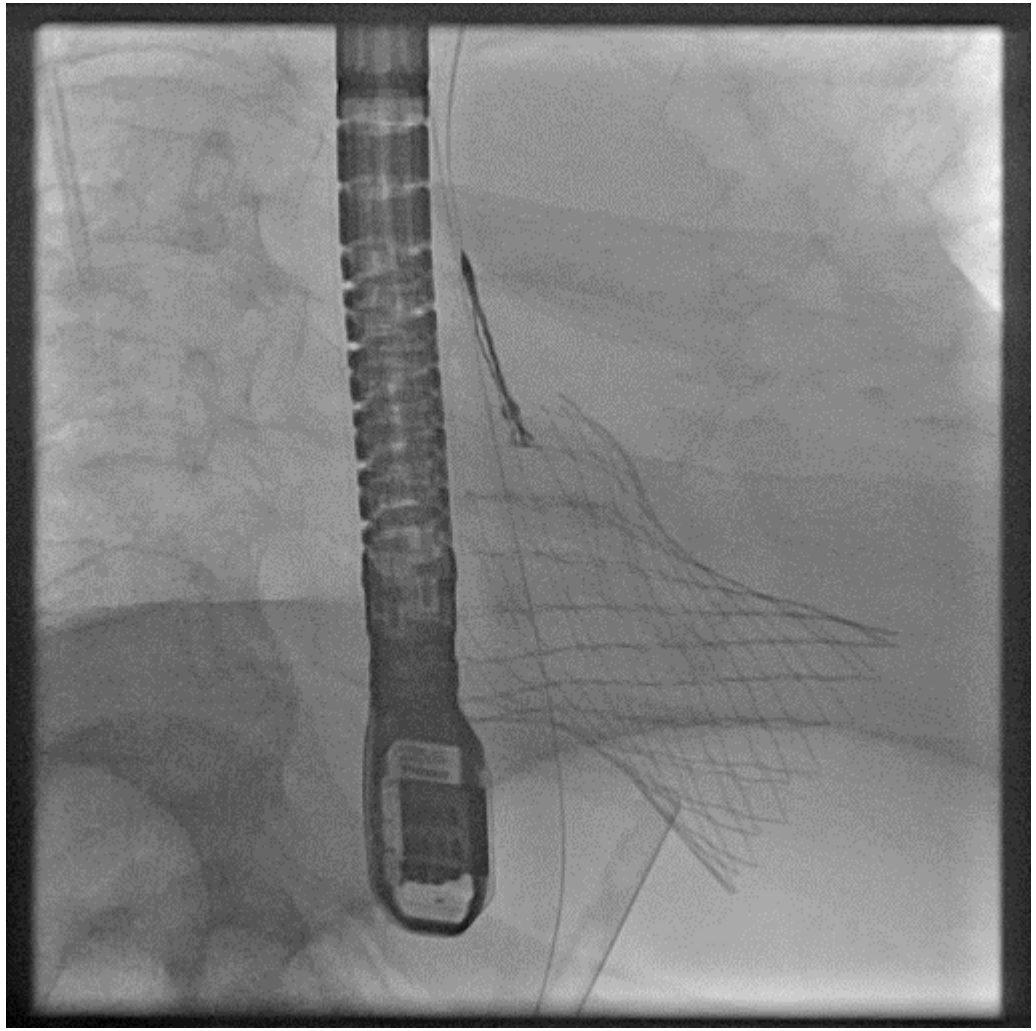
Taper

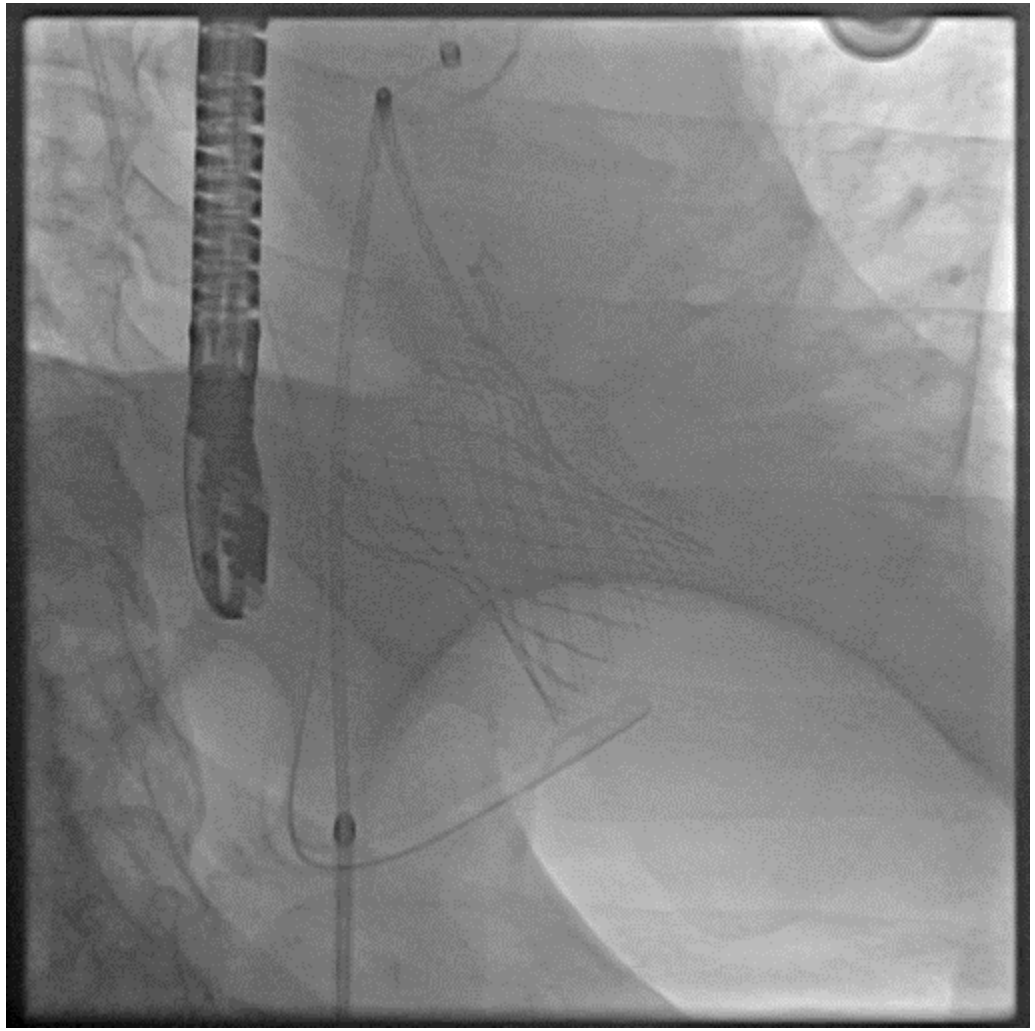
Sizing based on

the ICD

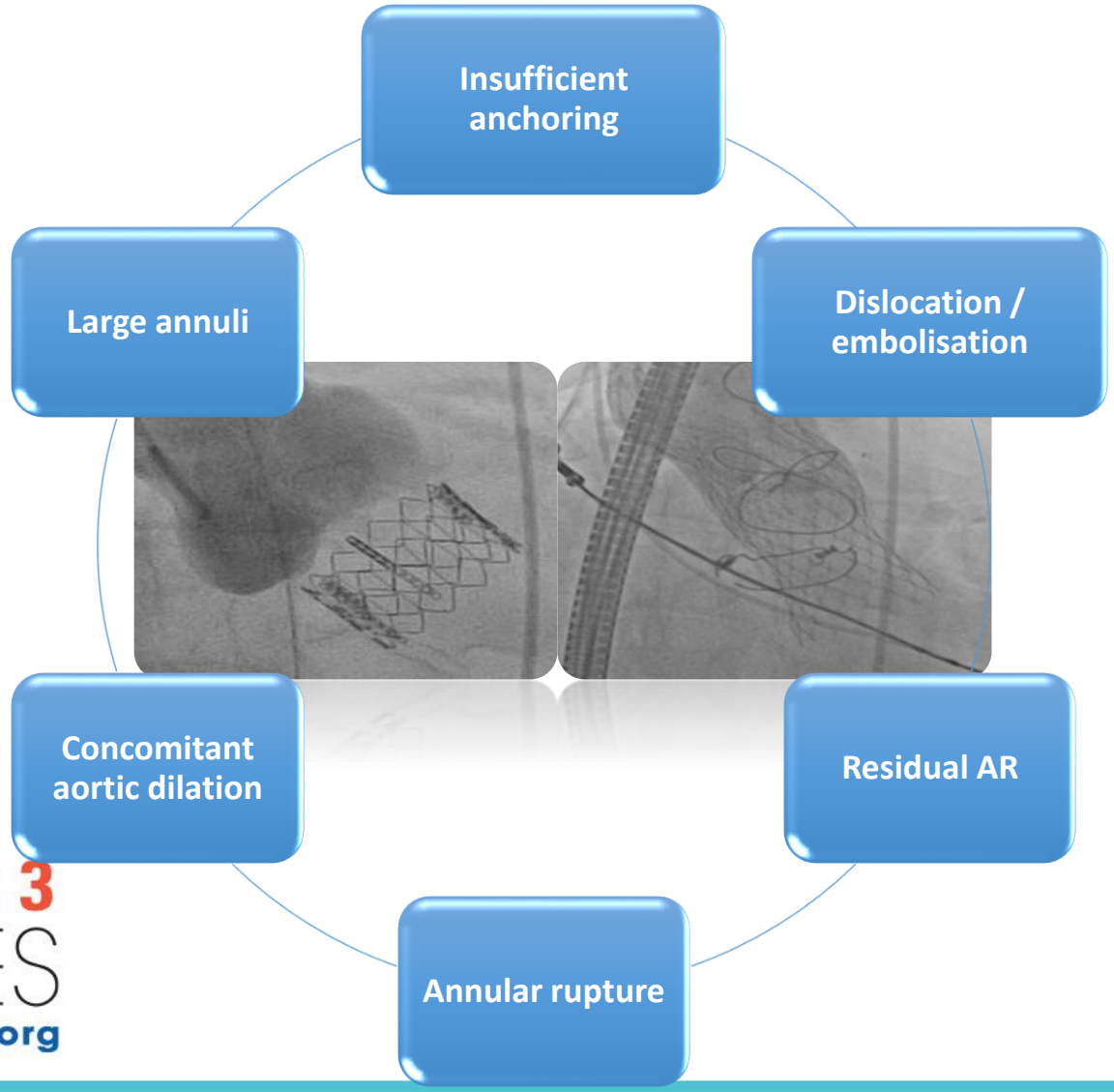




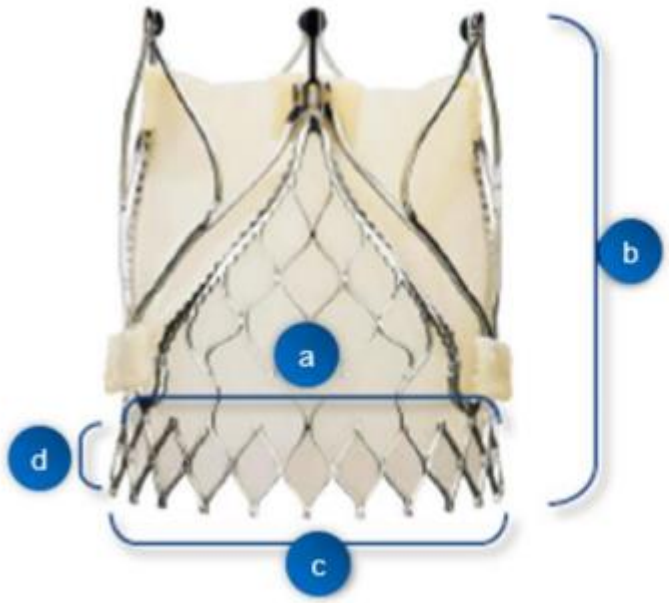




Challenges in treatment of non-calcified



JenaValve Trilogy Key Dimensions



		Size 23	Size 25	Size 27
a	Annulus Diameter (OD)	26 mm	28 mm	30 mm
b	Height (THV restricted to OD)	31.3 mm	33.7 mm	35.7 mm
c	OD (THV unrestricted)	28 mm	30 mm	32.4 mm
d	Sealing Ring Height (@ max. annulus dia.)	7 mm	7 mm	8 mm
	Corresponding Annulus Diameter	21-23.6 mm	22.6-25.2 mm	24.2-27 mm
	Corresponding Annulus Perimeter*	66-74 mm	71-79 mm	76-85 mm

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Thourani, V (2022). *Keynote Lecture: TAVR in AR: Anatomical Considerations for Device and Technique Selection* [power point slides]. TCTMD. https://www.tctmd.com/slide/keynote-lecture-tavr-ar-anatomical-considerations-device-and-technique-selection

Clinical Outcomes - Presented At ACC /21

30-Day Clinical Endpoints	
All-cause mortality	2.9% (2)
Cardiovascular mortality	1.4% (1)
Stroke	2.9% (2)
Disabling stroke	0.0%
Nondisabling stroke	2.9% (2)
Vascular access site complications	
Major	5.7% (4)
Minor	2.9% (2)
Bleeding complications	
Life threatening	4.3% (3)
Major	2.9% (2)
Minor	5.7% (4)
Acute kidney injury (stage 3)	0.0%
Permanent pacemaker implantation	22.9% (16)

Thourani, V (2022). *Keynote Lecture: TAVR in AR: Anatomical Considerations for Device and Technique Selection* [power point slides]. TCTMD. https://www.tctmd.com/slide/keynote-lecture-tavr-ar-anatomical-considerations-device-and-technique-selection

Clinical Case N°1

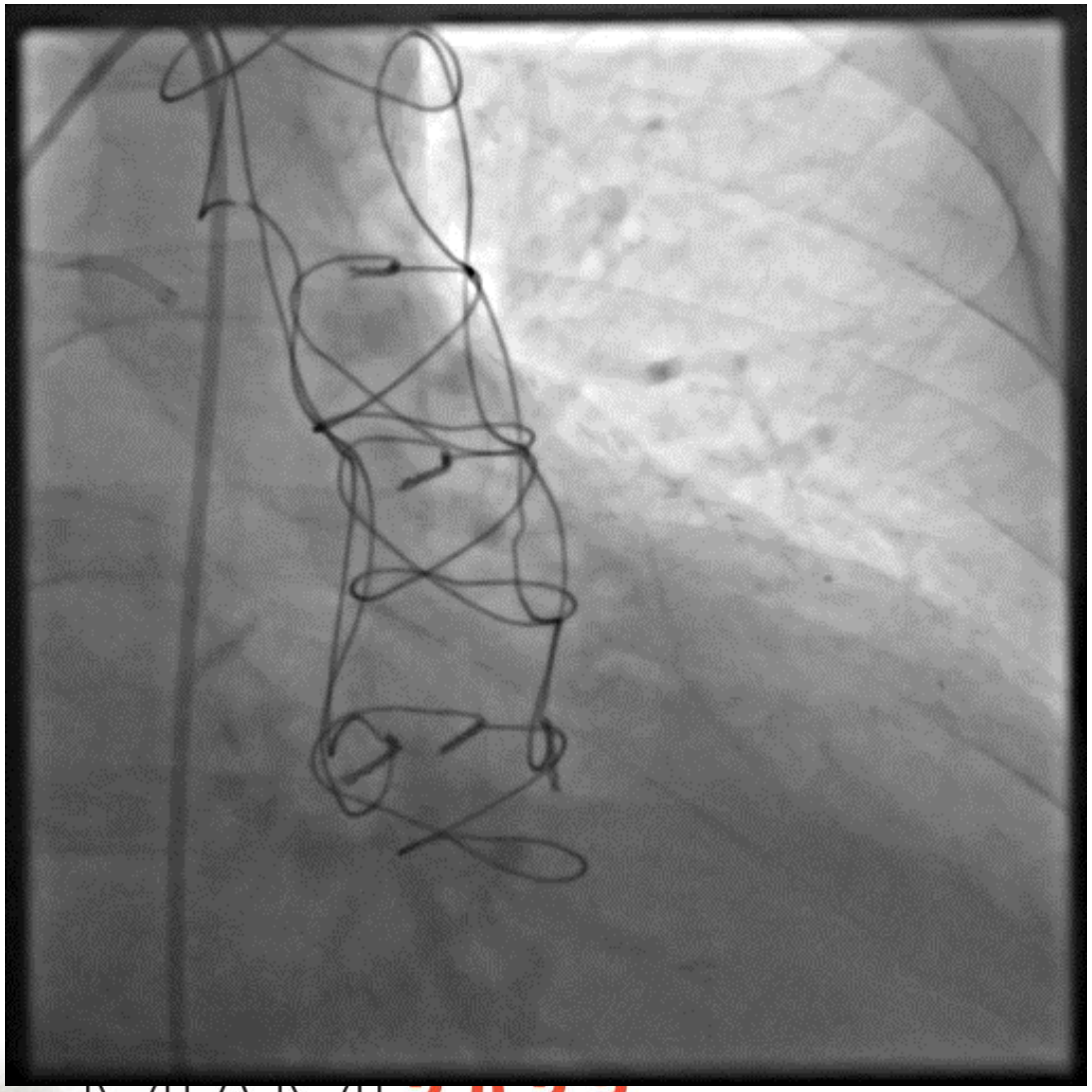
J C

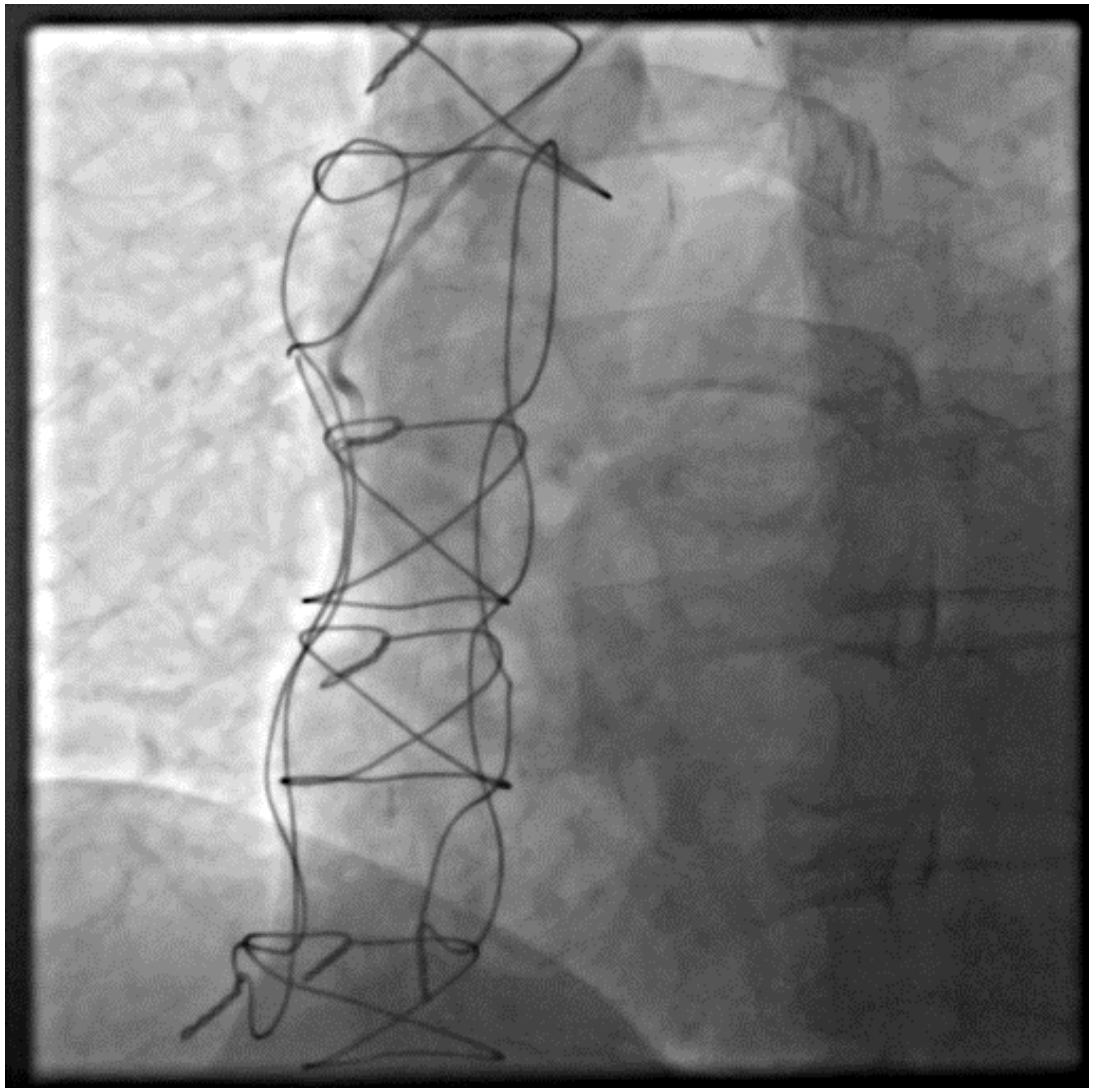
STS 4.8

78 YO

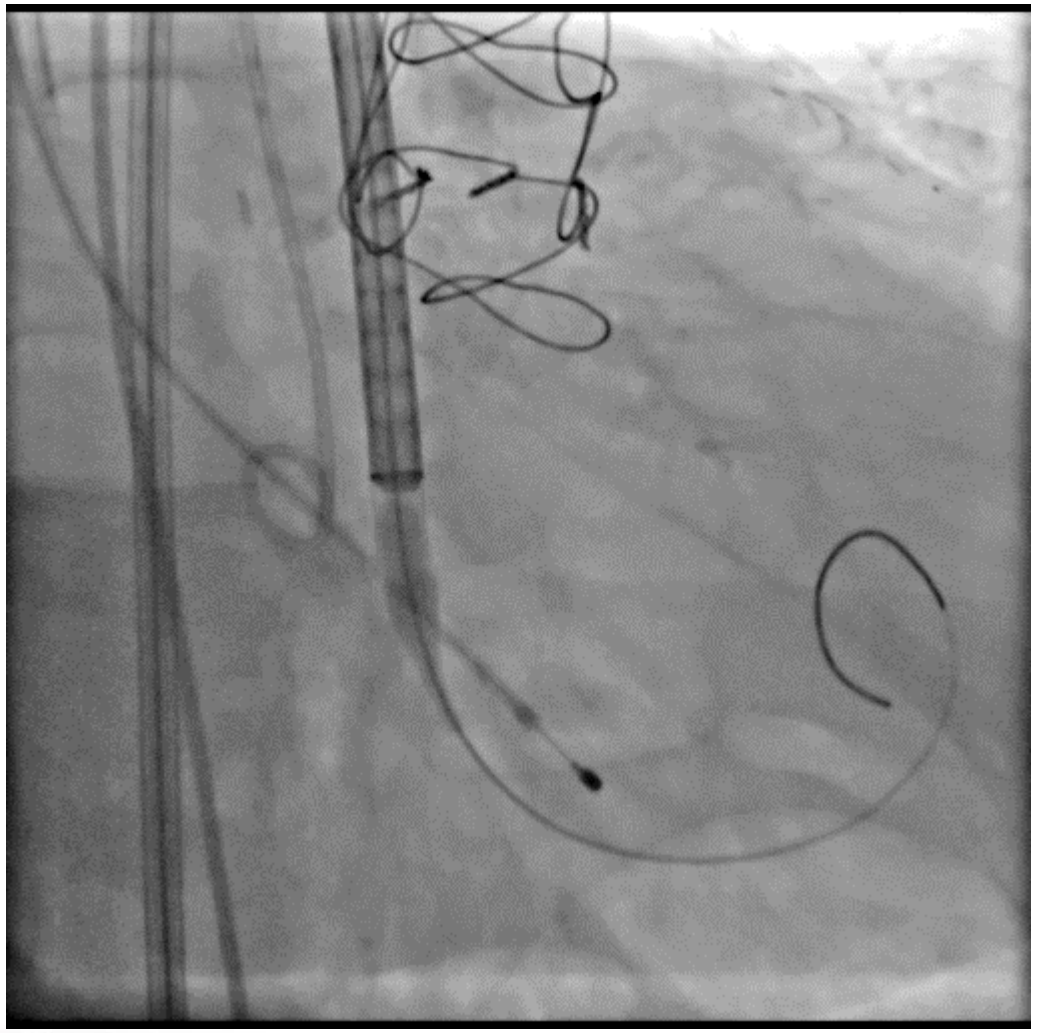
HTN

FE 35%

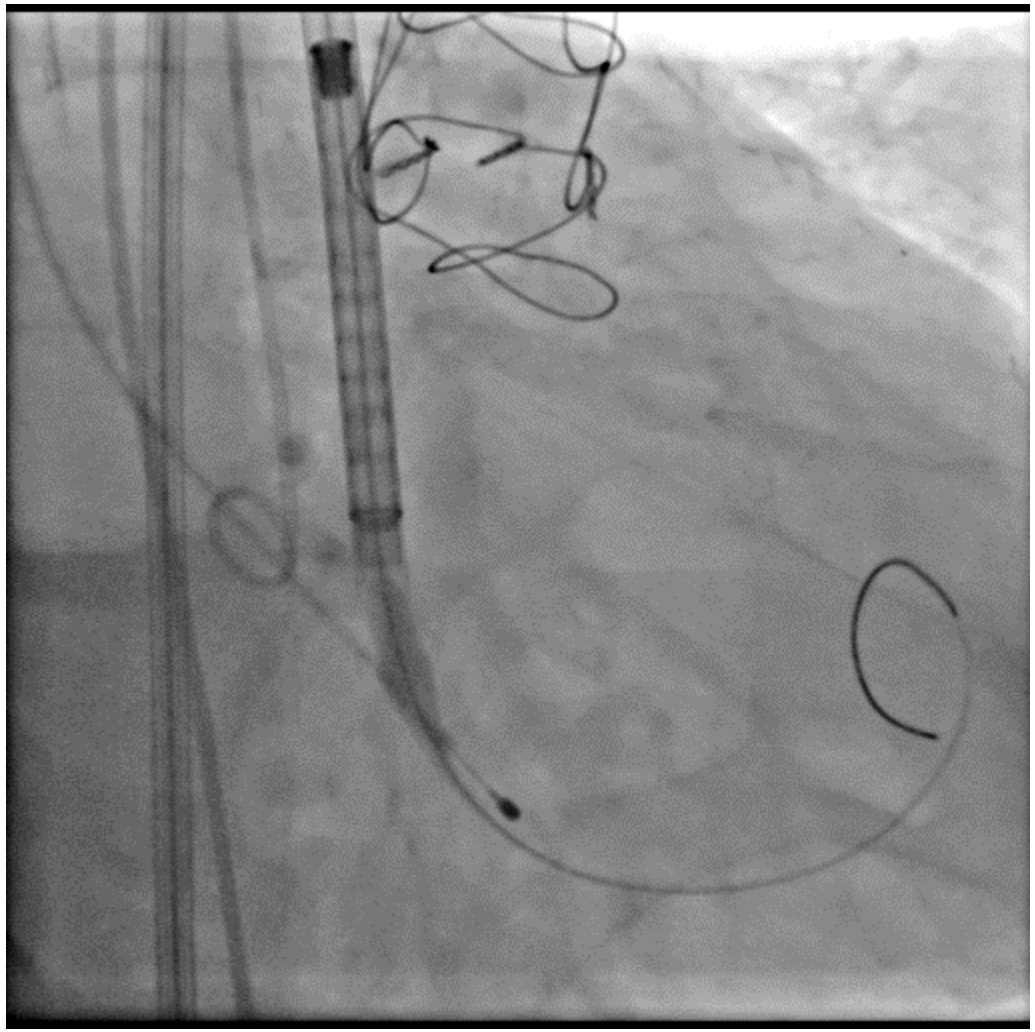




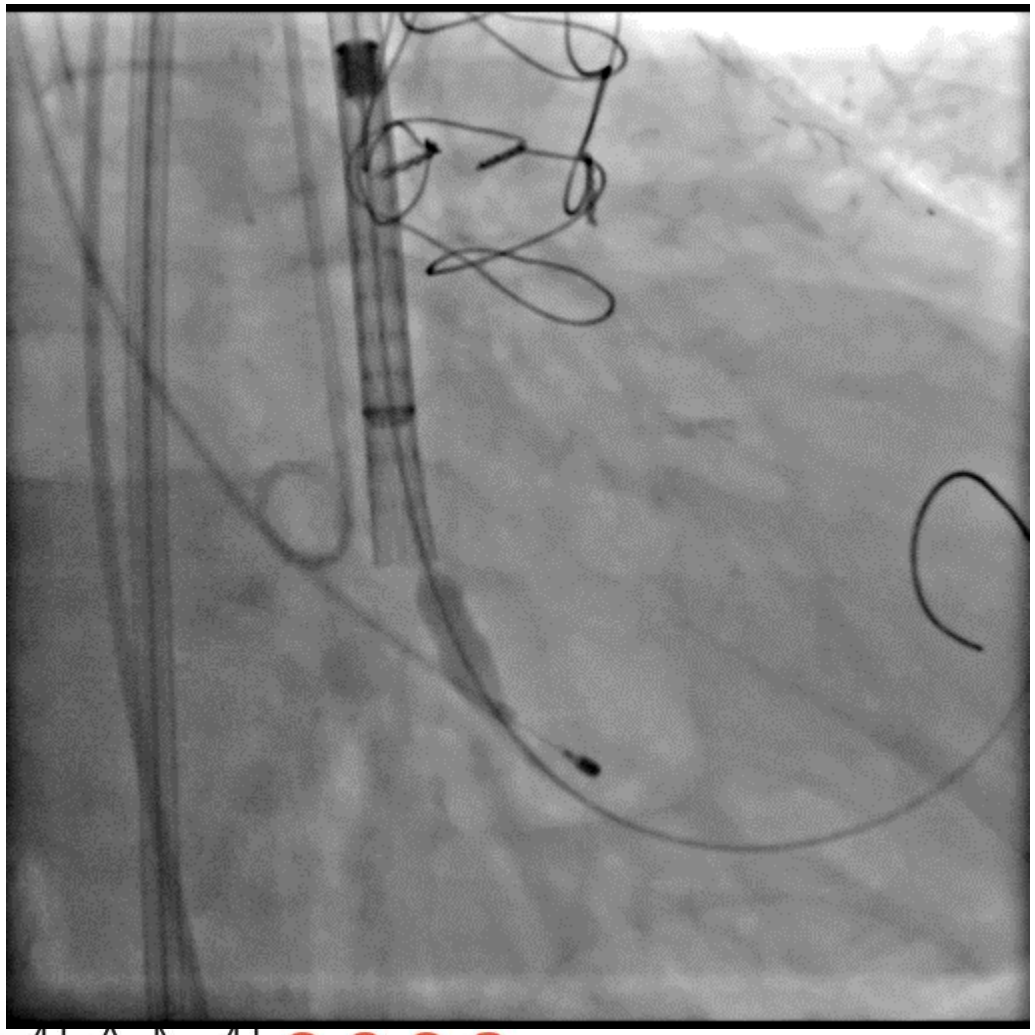
PHASE 1 NPPM



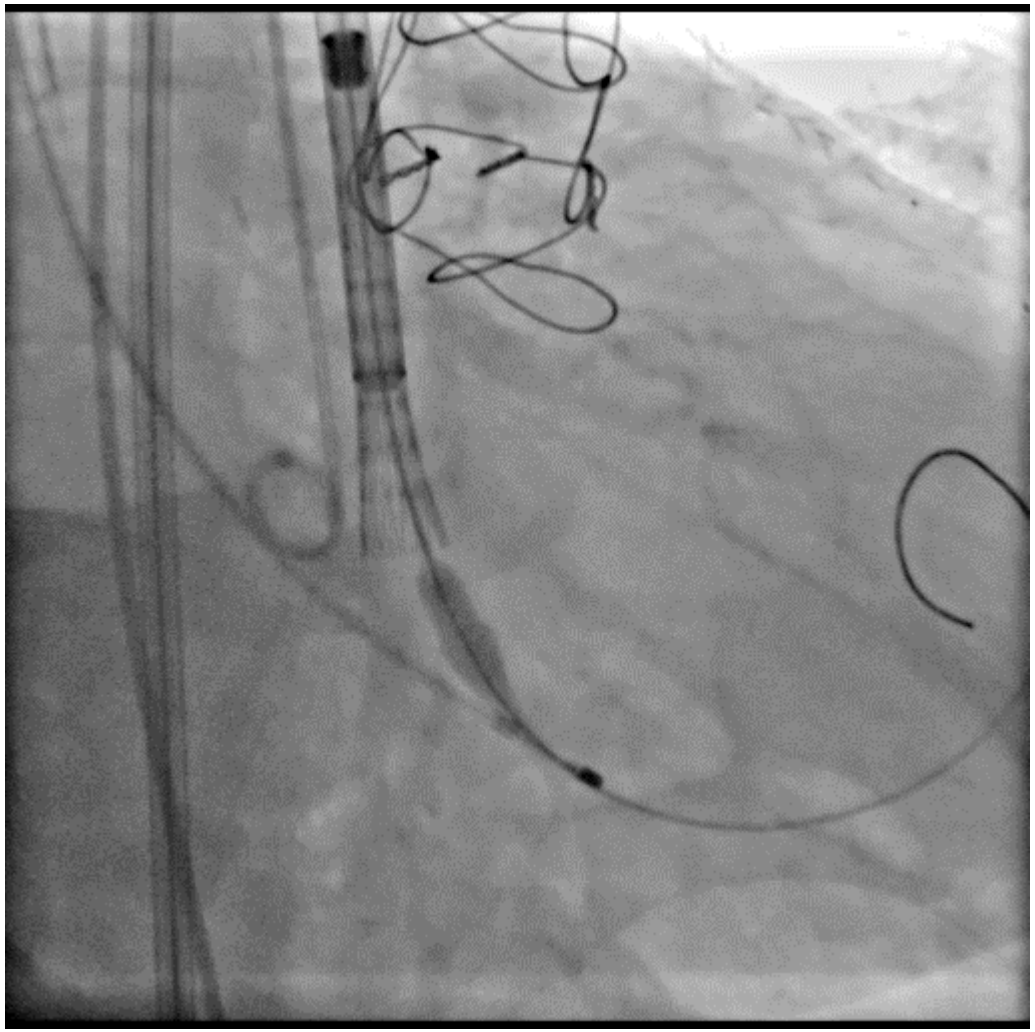
PHASE 1 PPM 140



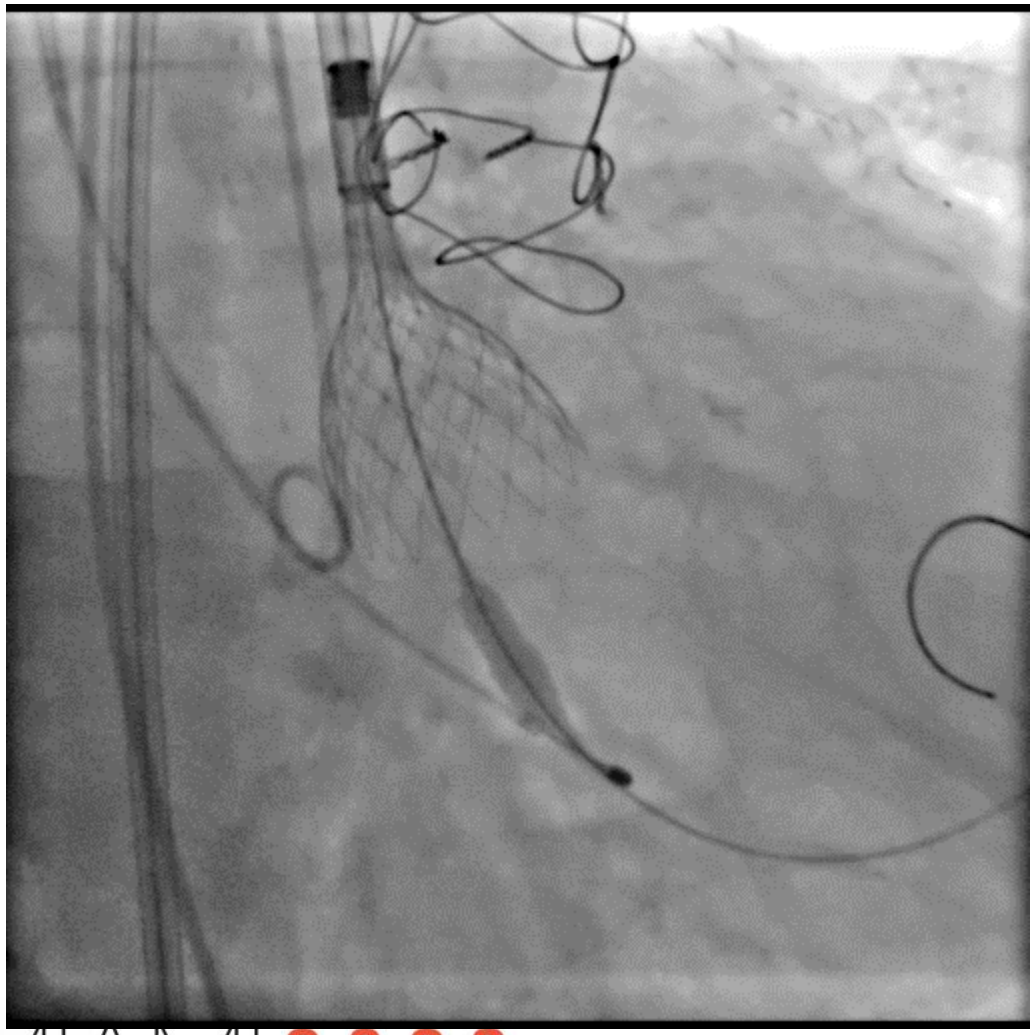
PHASE 2 NPPM 160



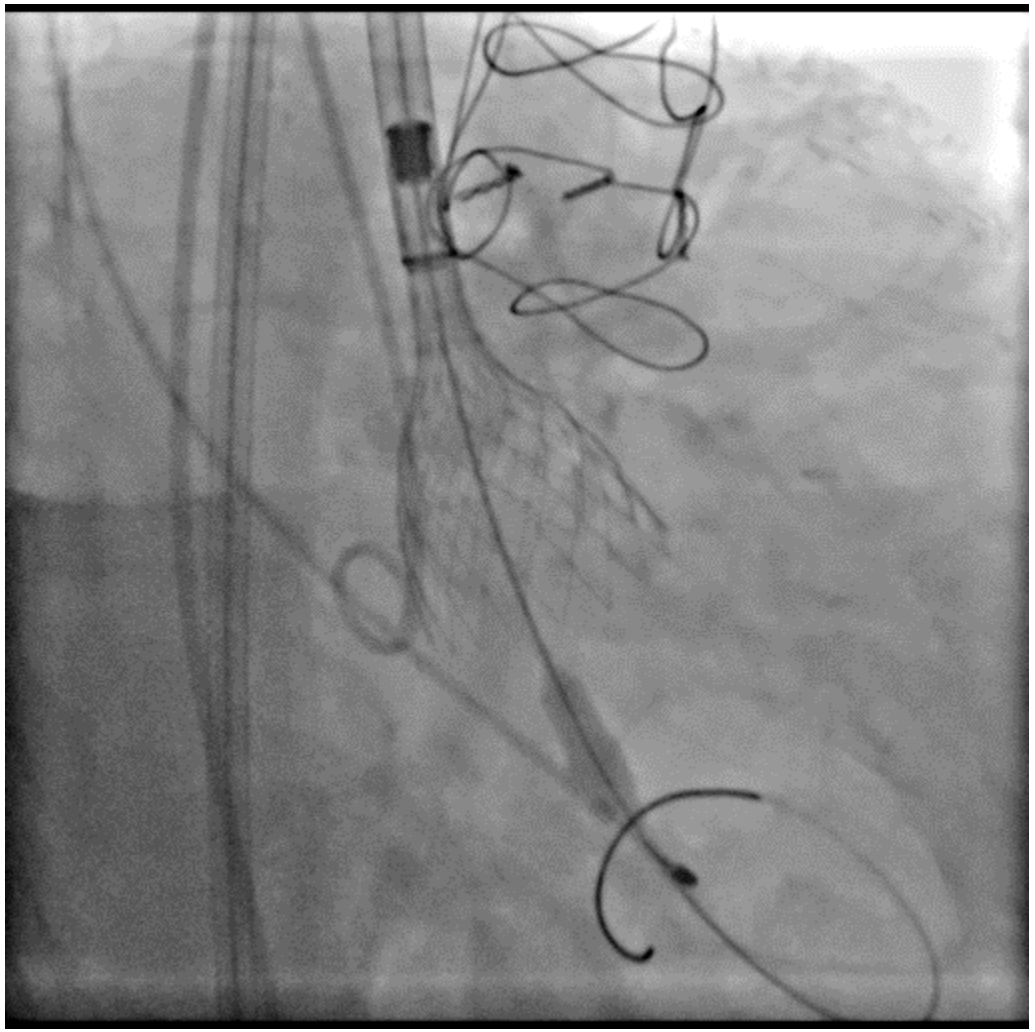
PHASE 3 NPPM 170



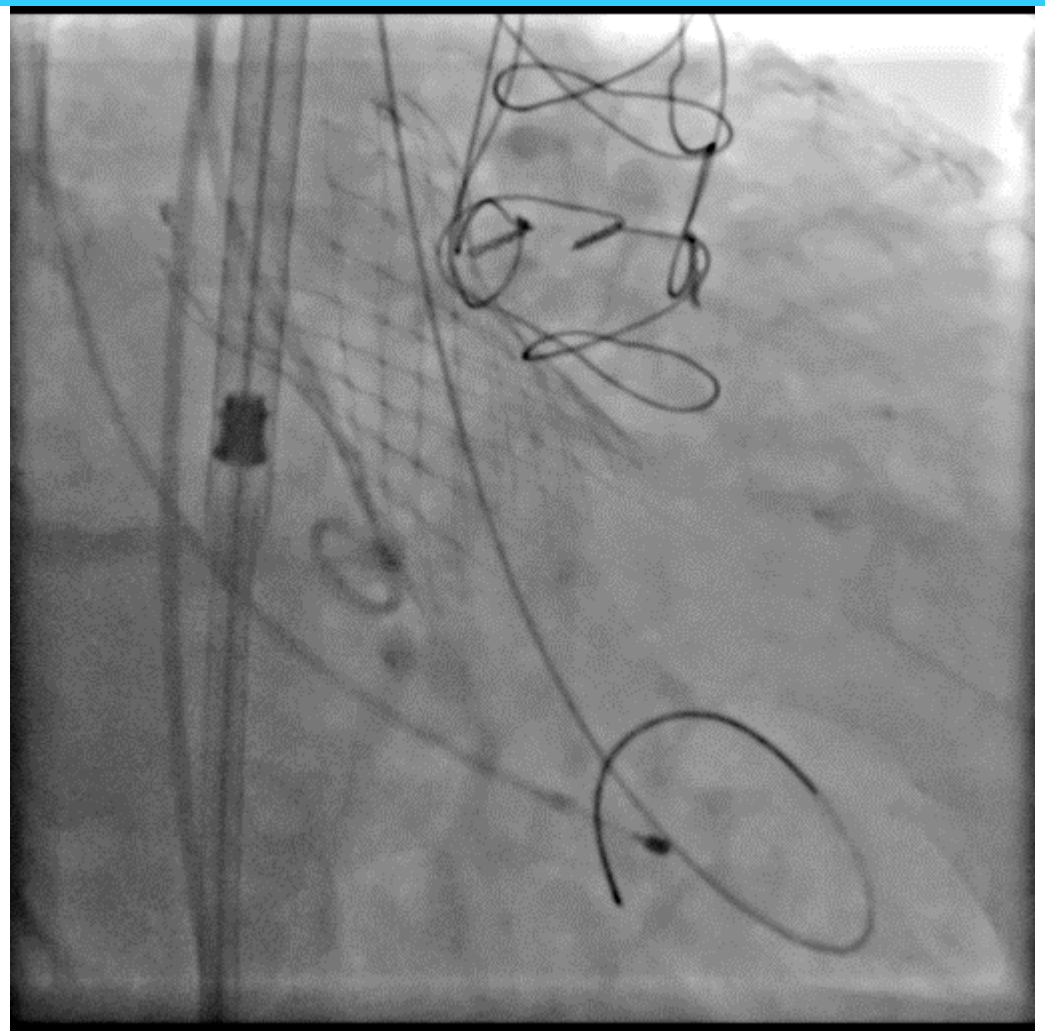
PHASE 4 NPPM 140

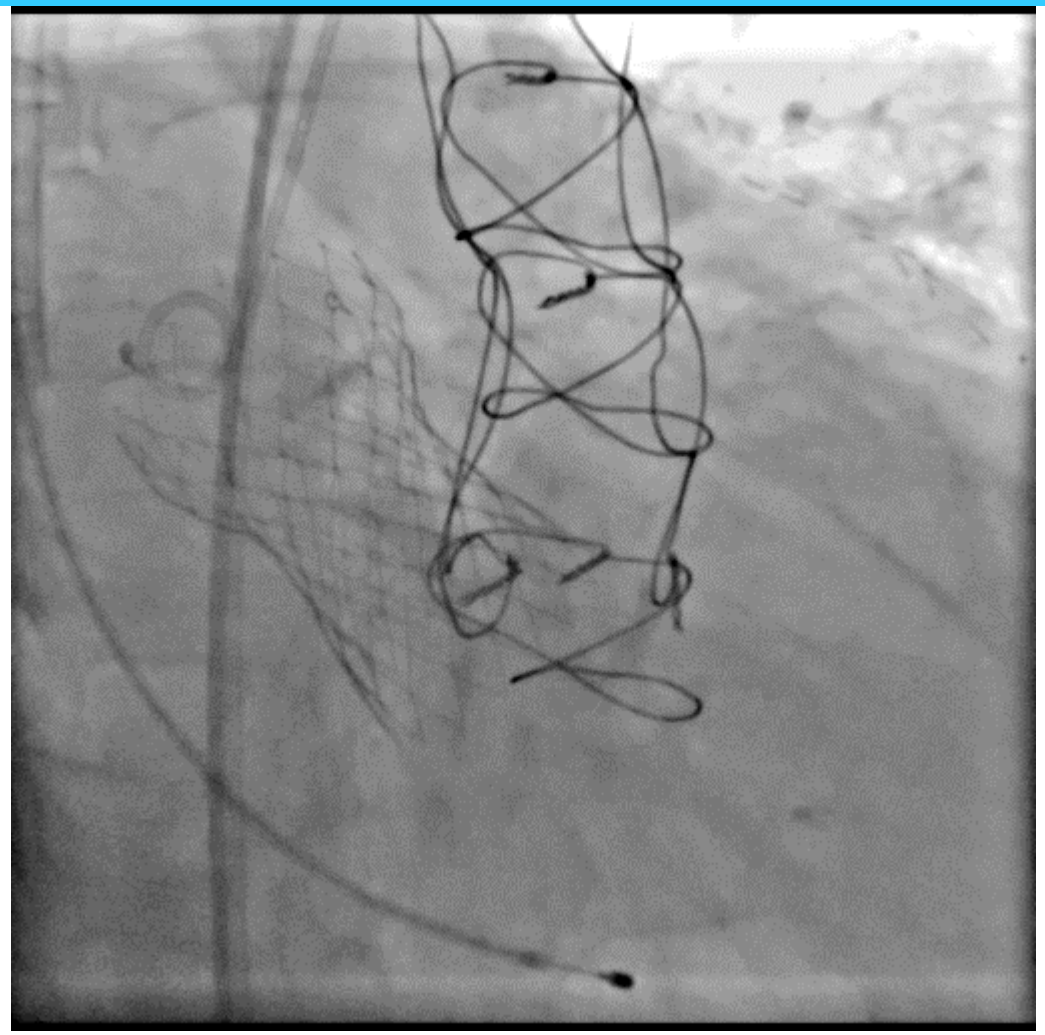


PHASE 5 NPPM 160



Final Result





Case N. 2

O H

STS 4.8

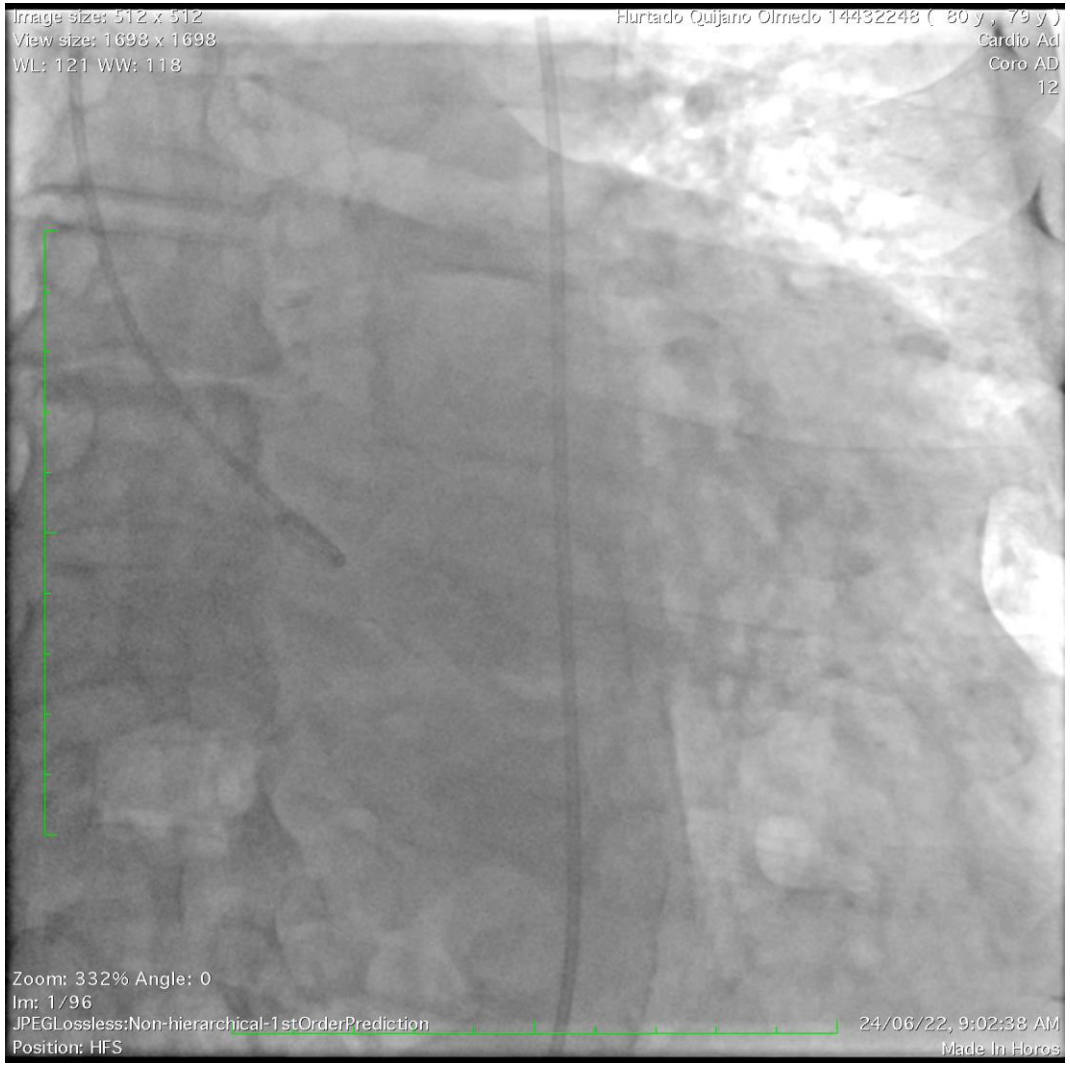
79 YO

HTN

Atrial fibrilation

FE 45%

Diagnosis



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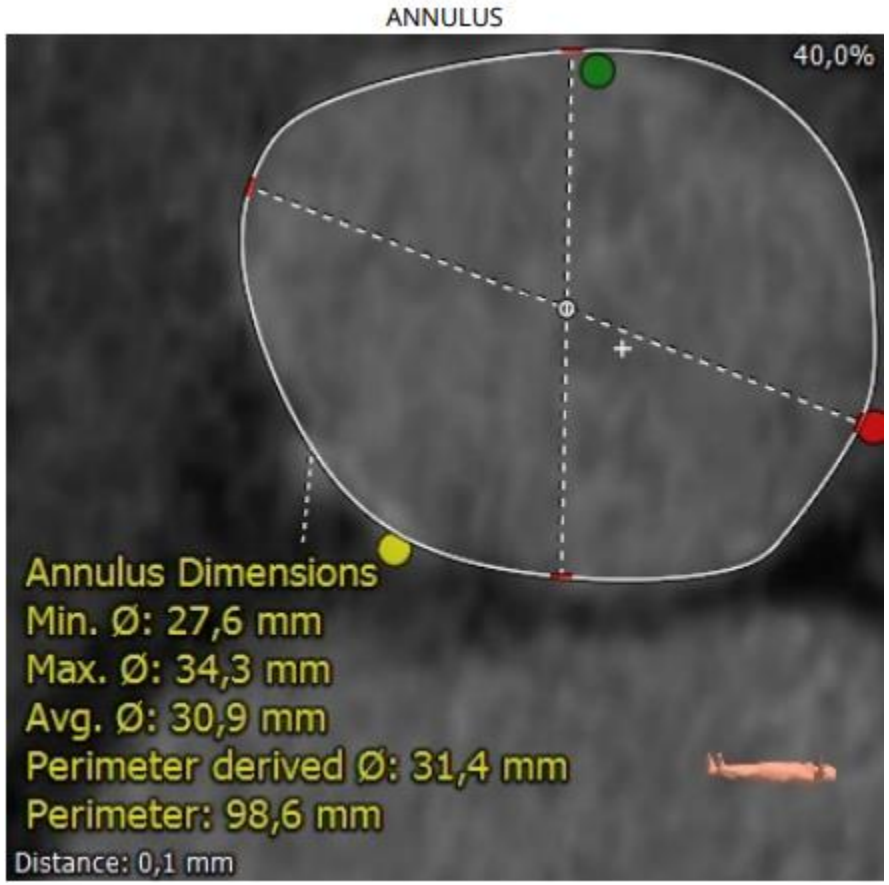
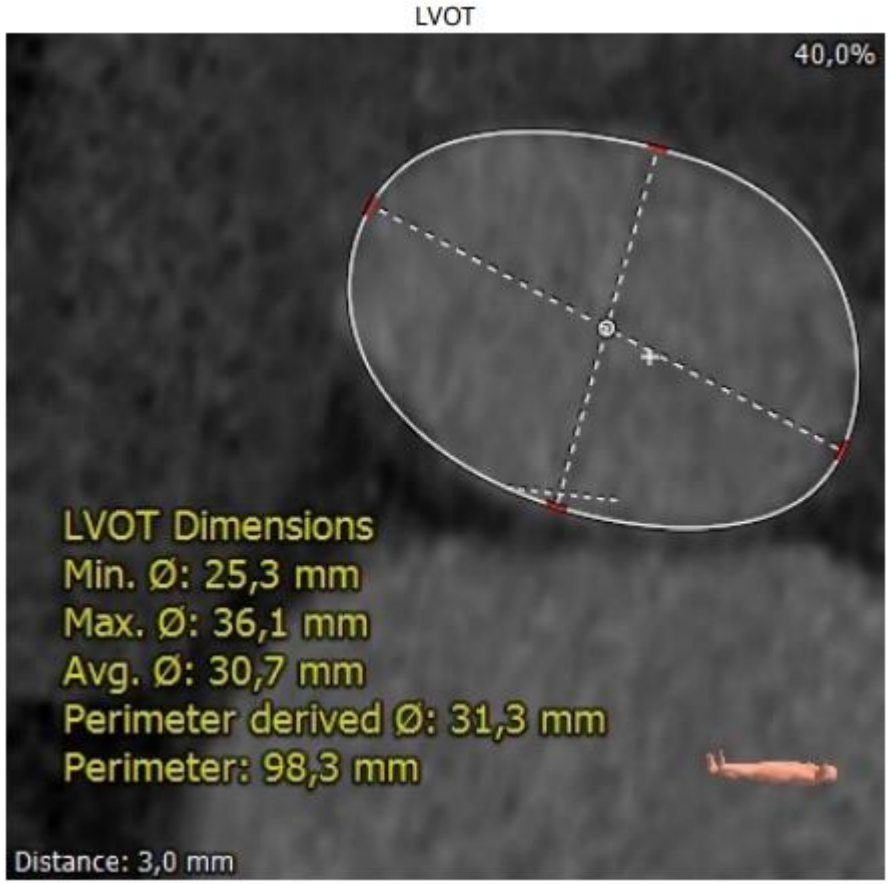
ANNULAR PERIMETER: 101



LVOT PERIMETER: 99mm



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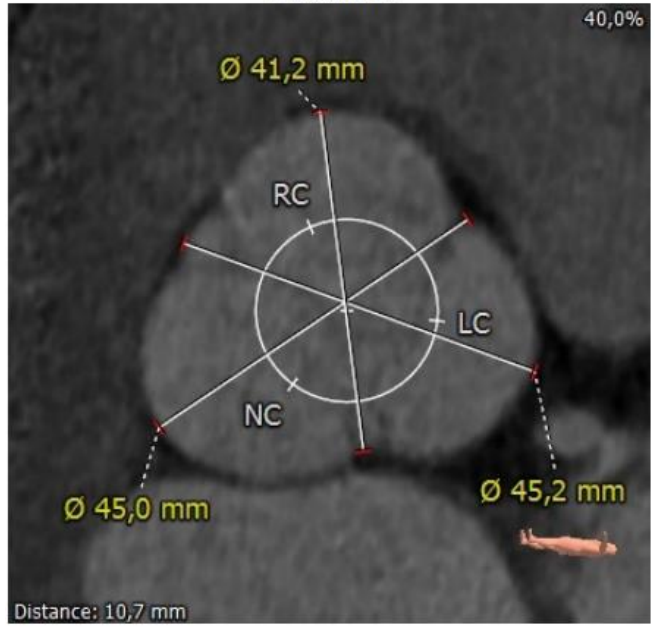
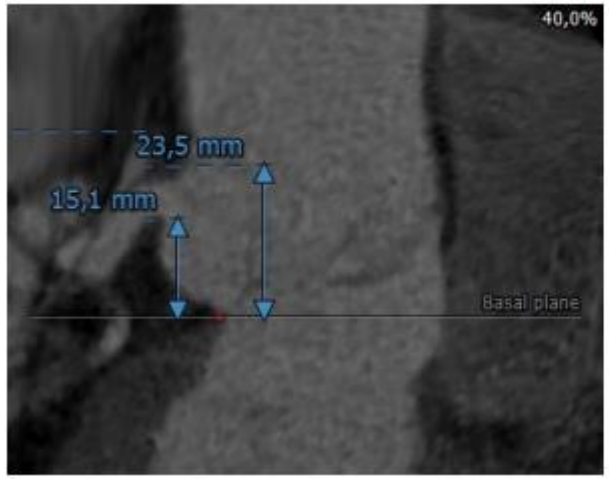
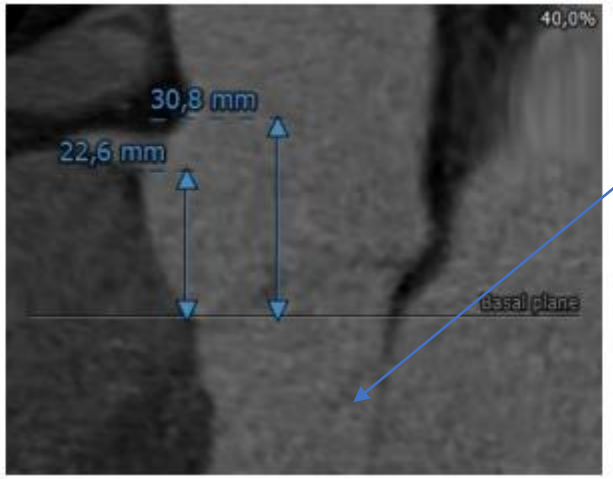
SOV DIAMETER



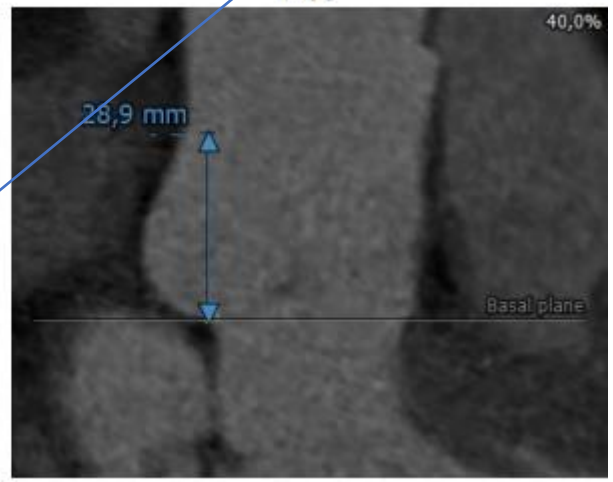
TUBULAR SHAPE LVOT

LCC





NCC



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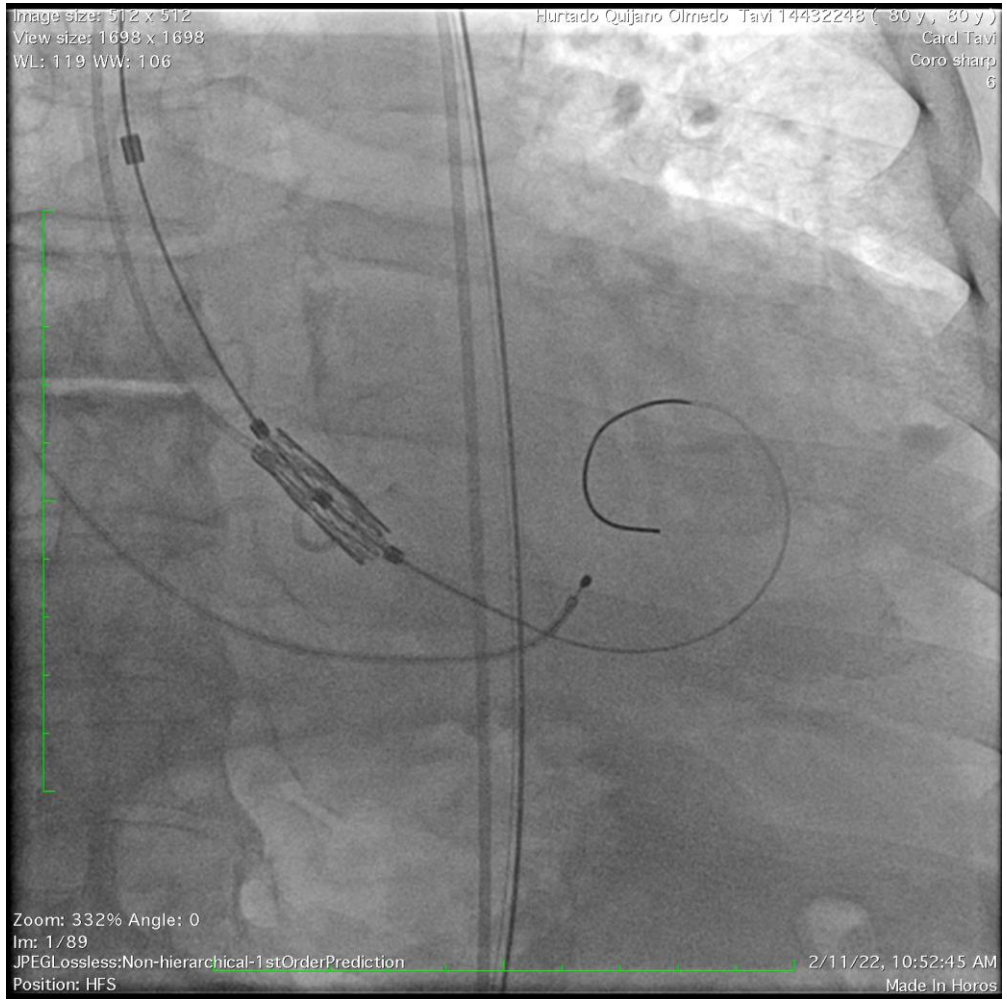
Aortic position Angle


Image size: 512 x 512
View size: 1698 x 1698
WL: 119 WW: 106
Hurtado Quijano Olmedo Tavi 14432248 (80 y , 80 y)
Card Tavi
Coro sharp
3
Zoom: 332% Angle: 0
Im: 1/66
JPEGLossless:Non-hierarchical-1stOrderPrediction
Position: HFS
2/11/22, 10:34:47 AM
Made In Horos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View size: 1698 x 1698
WL: 119 WW: 106
Hurtado Quijano Olmedo Tavi 14432248 (80 y , 80 y)
Card Tavi
Coro sharp
6
Zoom: 332% Angle: 0
Im: 1/89
JPEGLossless:Non-hierarchical-1stOrderPrediction
Position: HFS
2/11/22, 10:52:45 AM
Made In Horos

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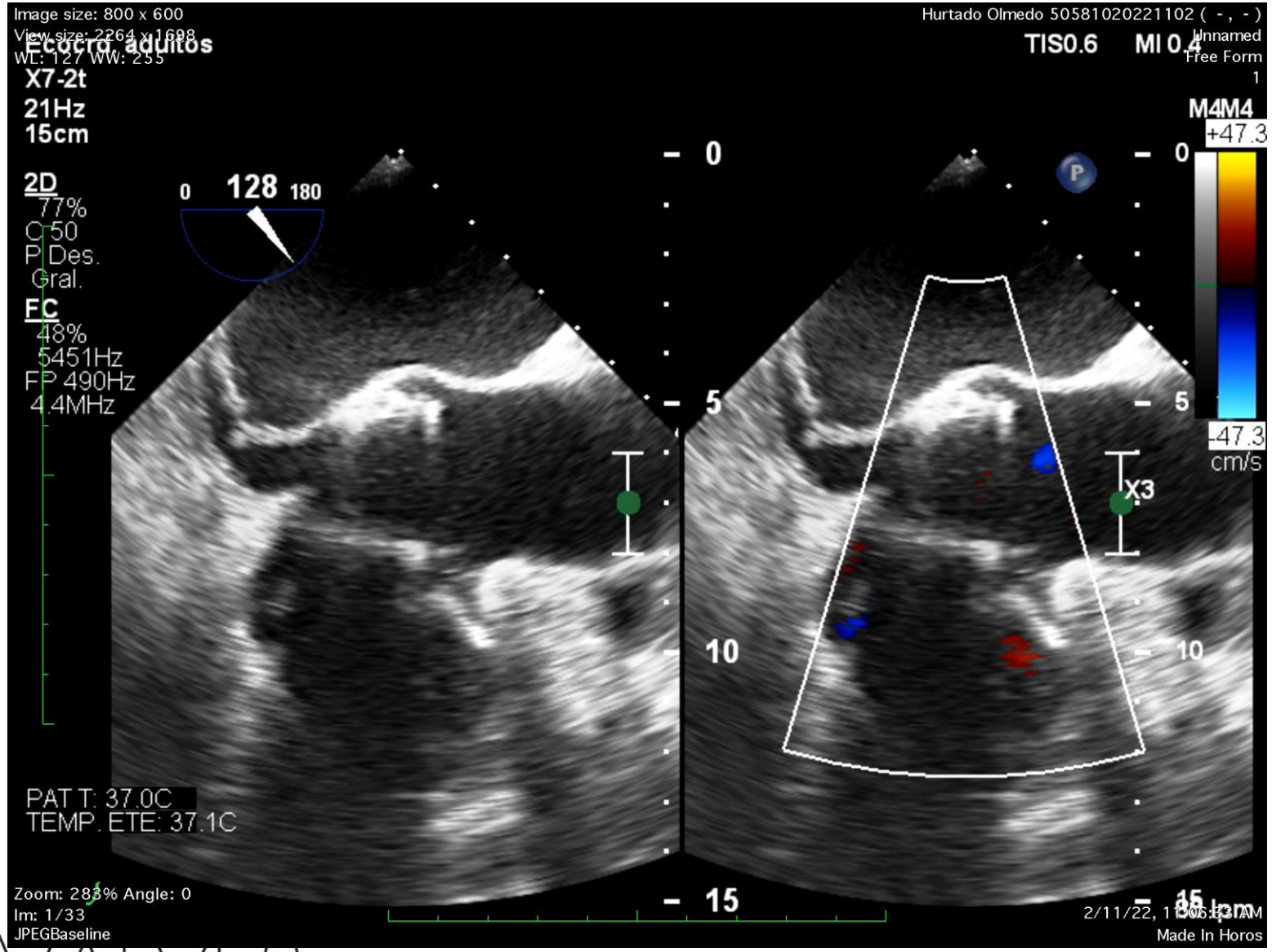

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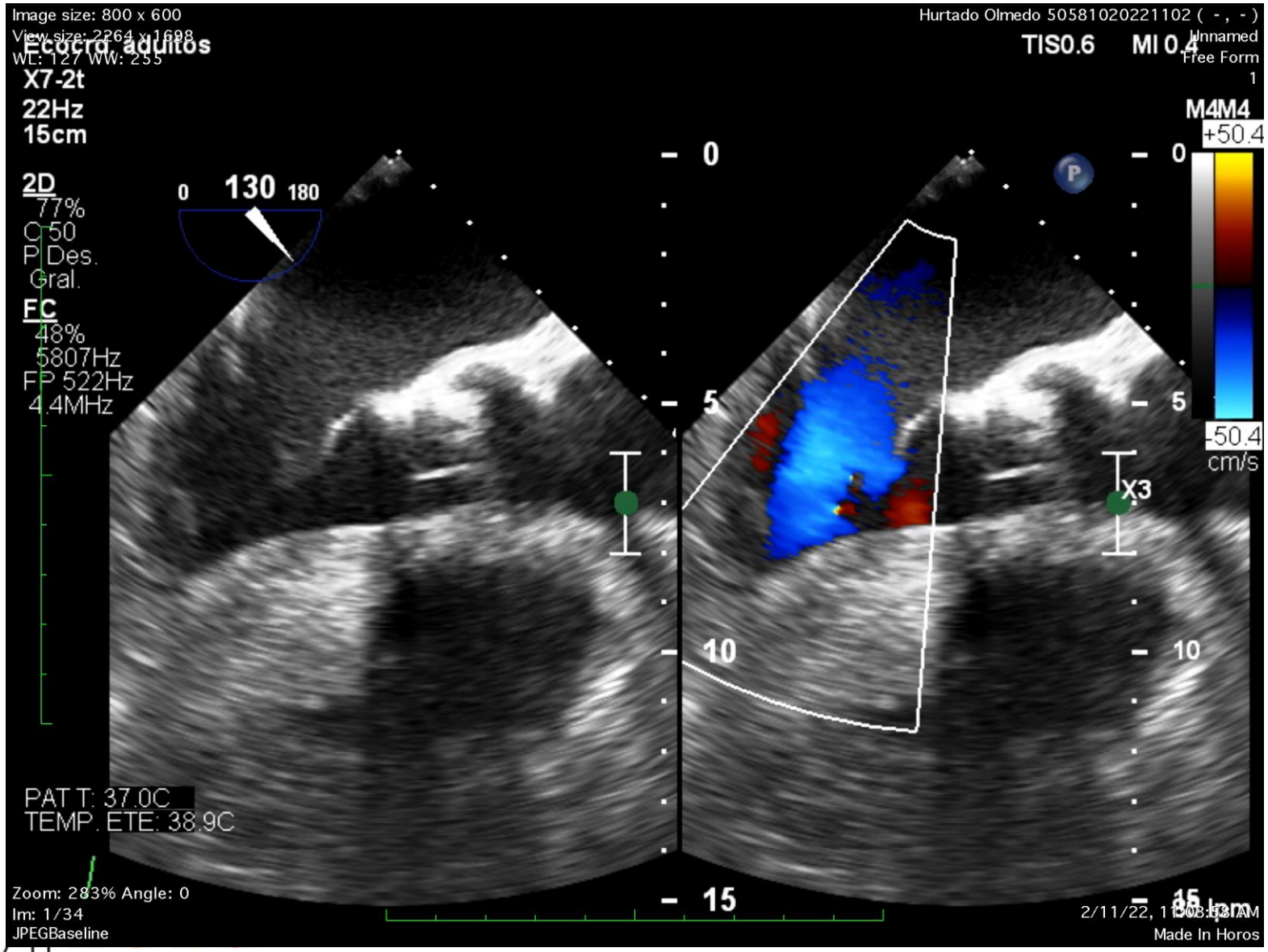
MiamiValves.org



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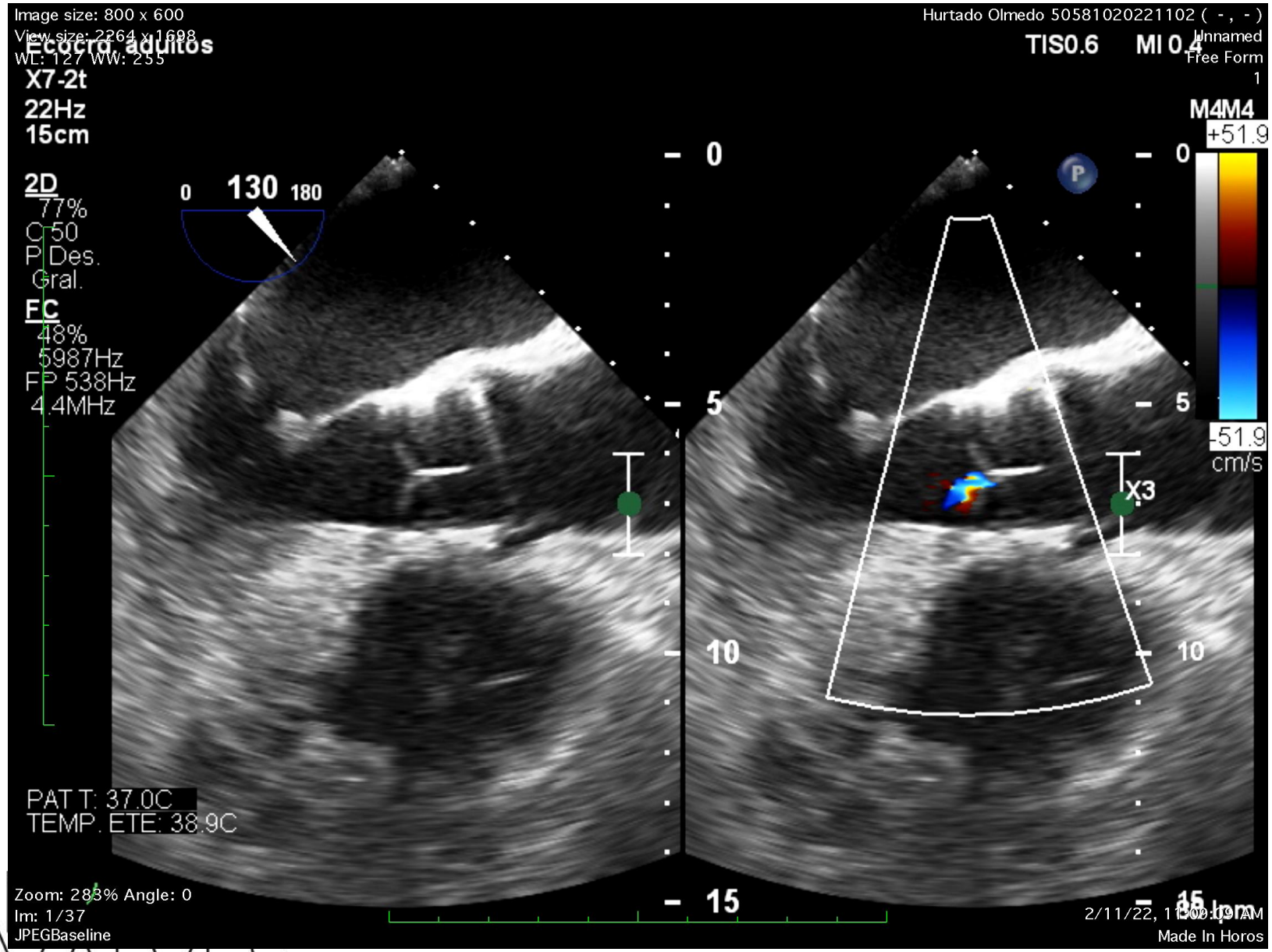

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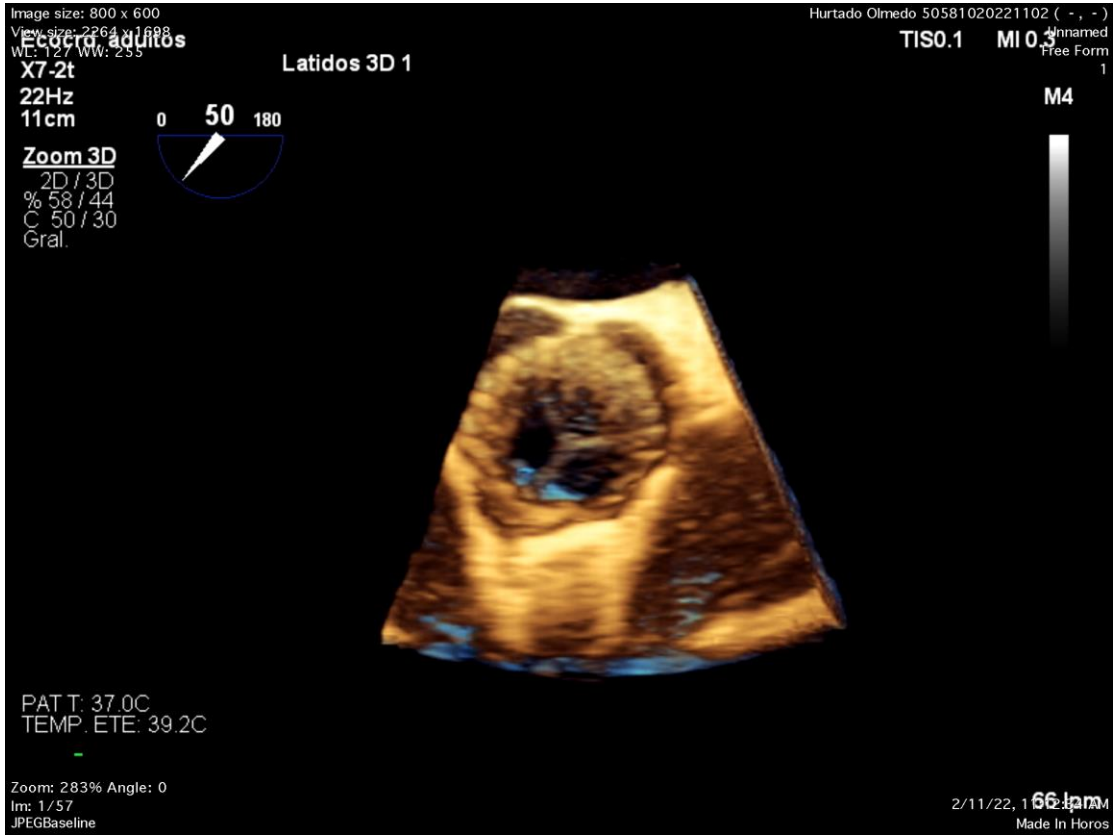
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Hurtado Olmedo 50581020221102 (- , -)
Ecocrd. adultos
TIS0.1 MI 0.3
Unnamed
Free Form
1
X7-2t
22Hz
11cm
Latidos 3D 1
M4
0 50 180
Zoom 3D
2D / 3D
% 58 / 44
C 50 / 30
Gral.
PAT T: 37.0C
TEMP. ETE: 39.2C
Zoom: 283% Angle: 0
Im: 1/57
JPEGBaseline
66 lpm
Made In Horos


Image size: 800 x 600
Hurtado Olmedo 50581020221102 (- , -)
Ecocrd. adultos
TIS0.1 MI 0.3
Unnamed
Free Form
1
X7-2t
22Hz
11cm
Latidos 3D 1
M4
0 50 180
Zoom 3D
2D / 3D
% 58 / 44
C 50 / 30
Gral.
PAT T: 37.0C
TEMP. ETE: 39.1C
Zoom: 283% Angle: 0
Im: 1/37
JPEGBaseline
74 lpm
Made In Horos

Clinical Case

E A

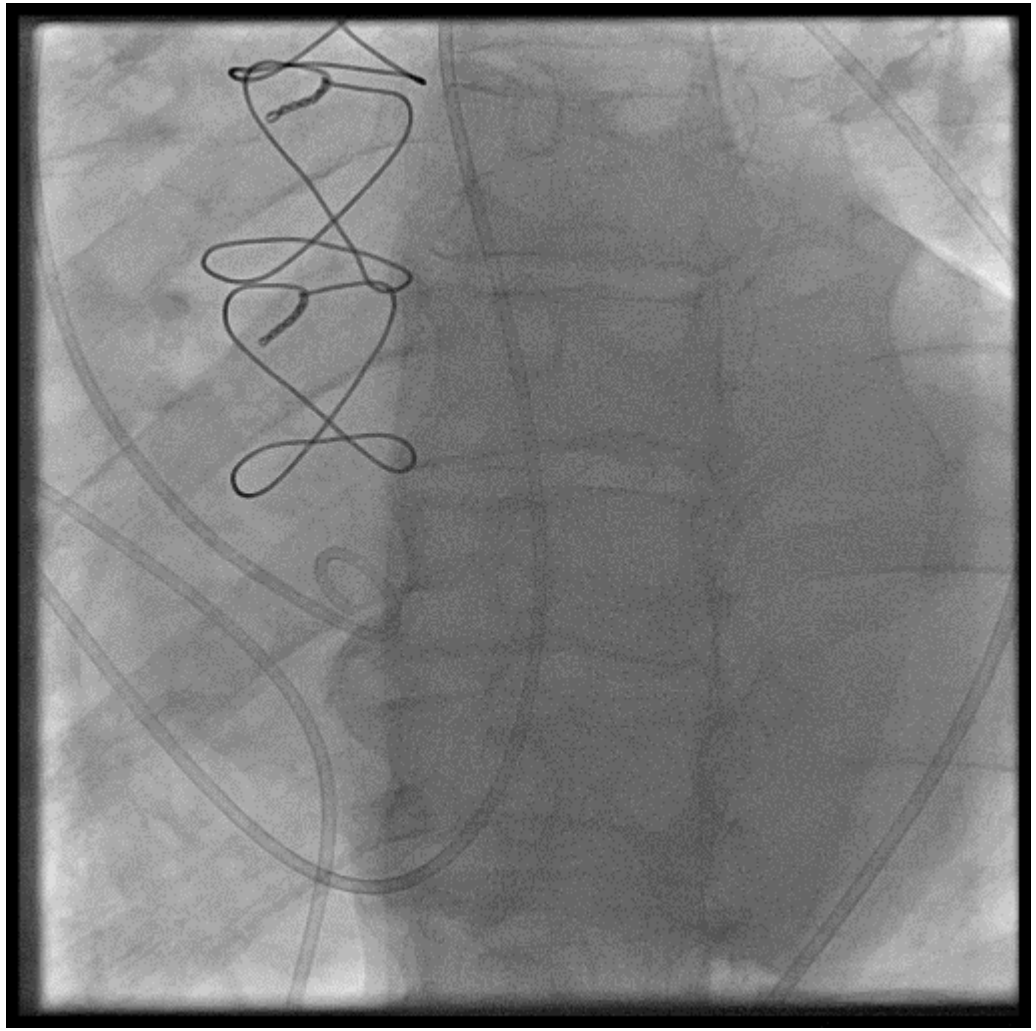
74 YO

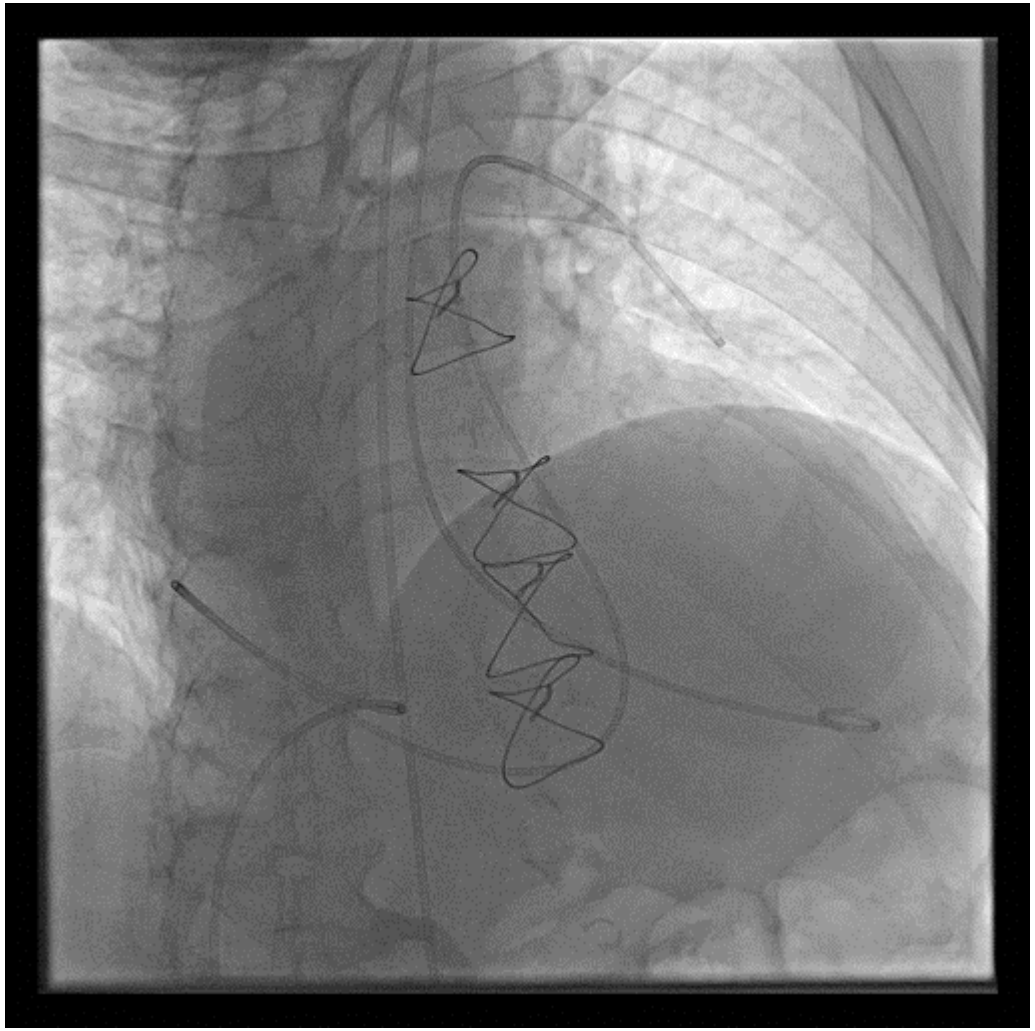
HTN

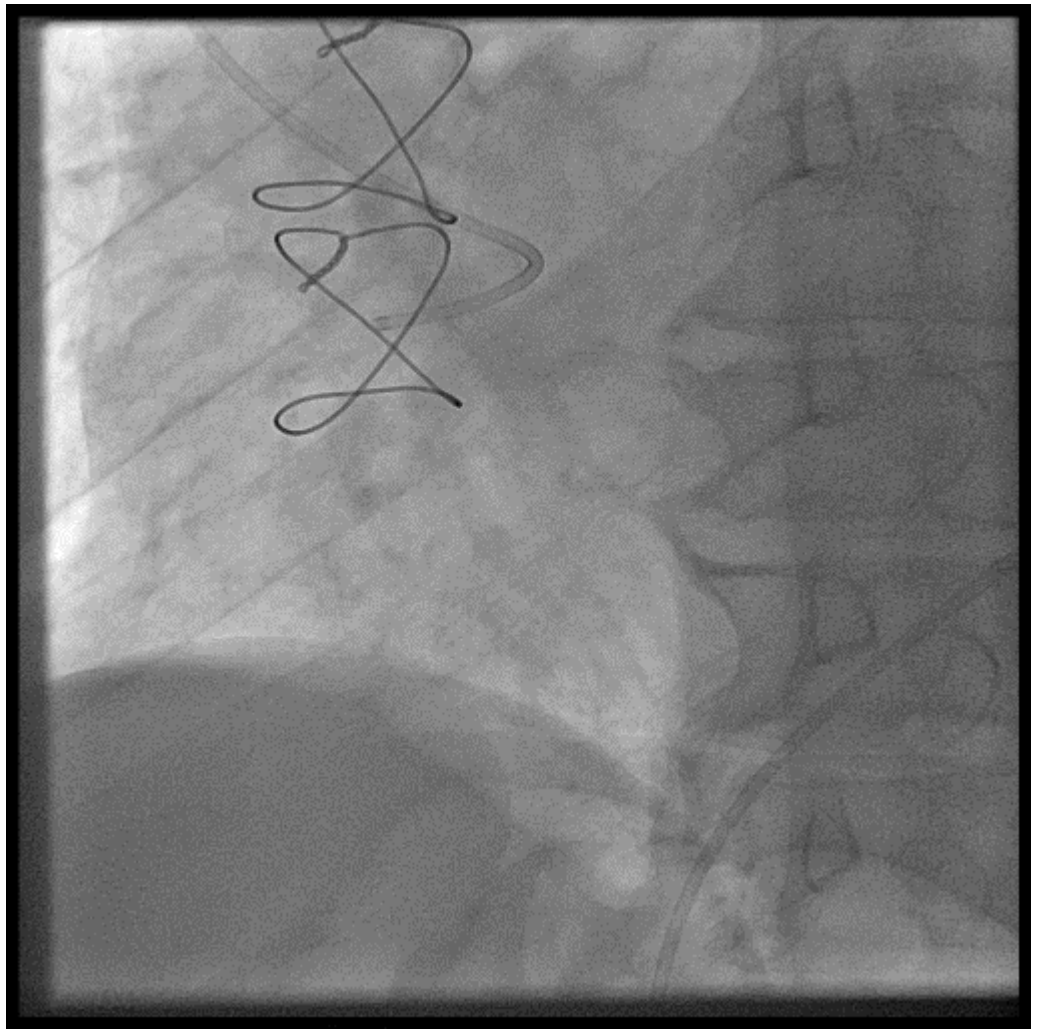
ATRIAL FIBRILATION

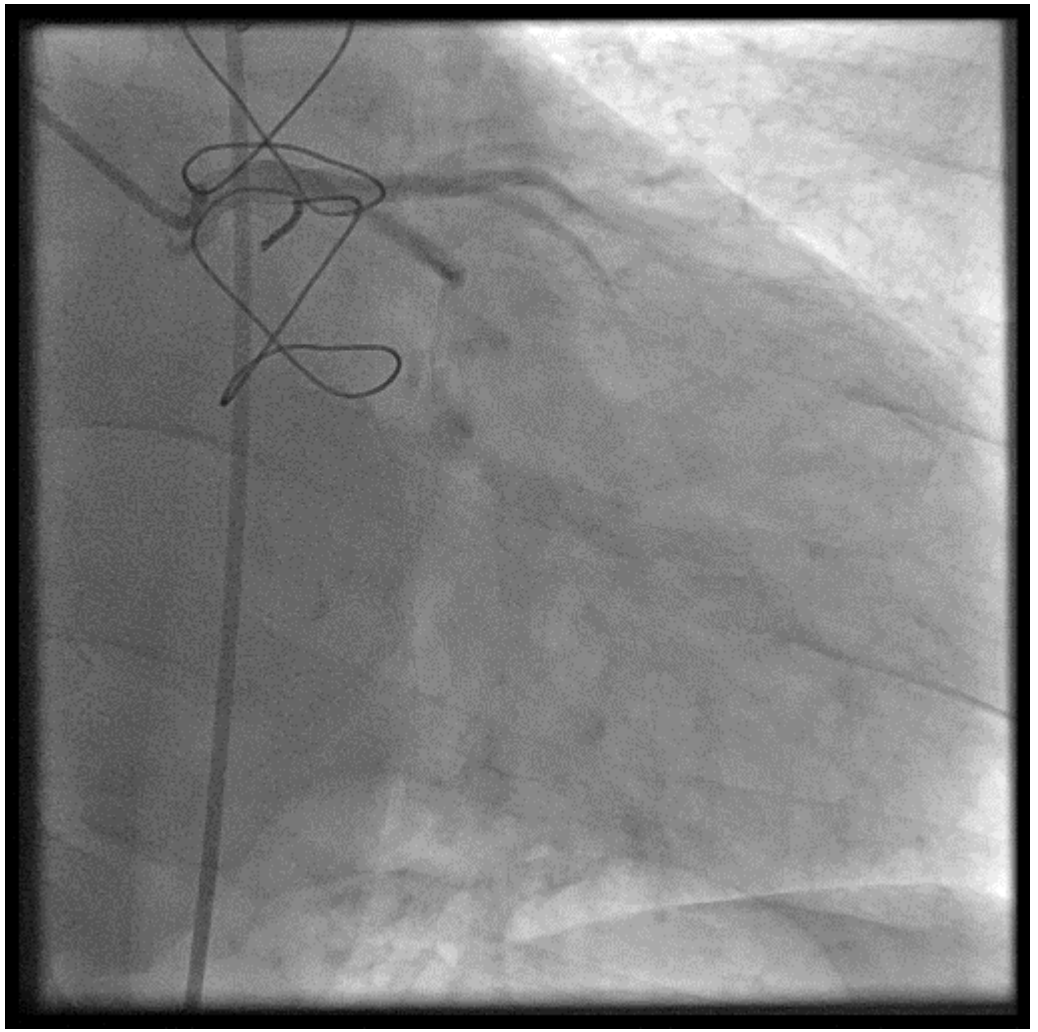
MITRAL VALVE REPLACEMENT

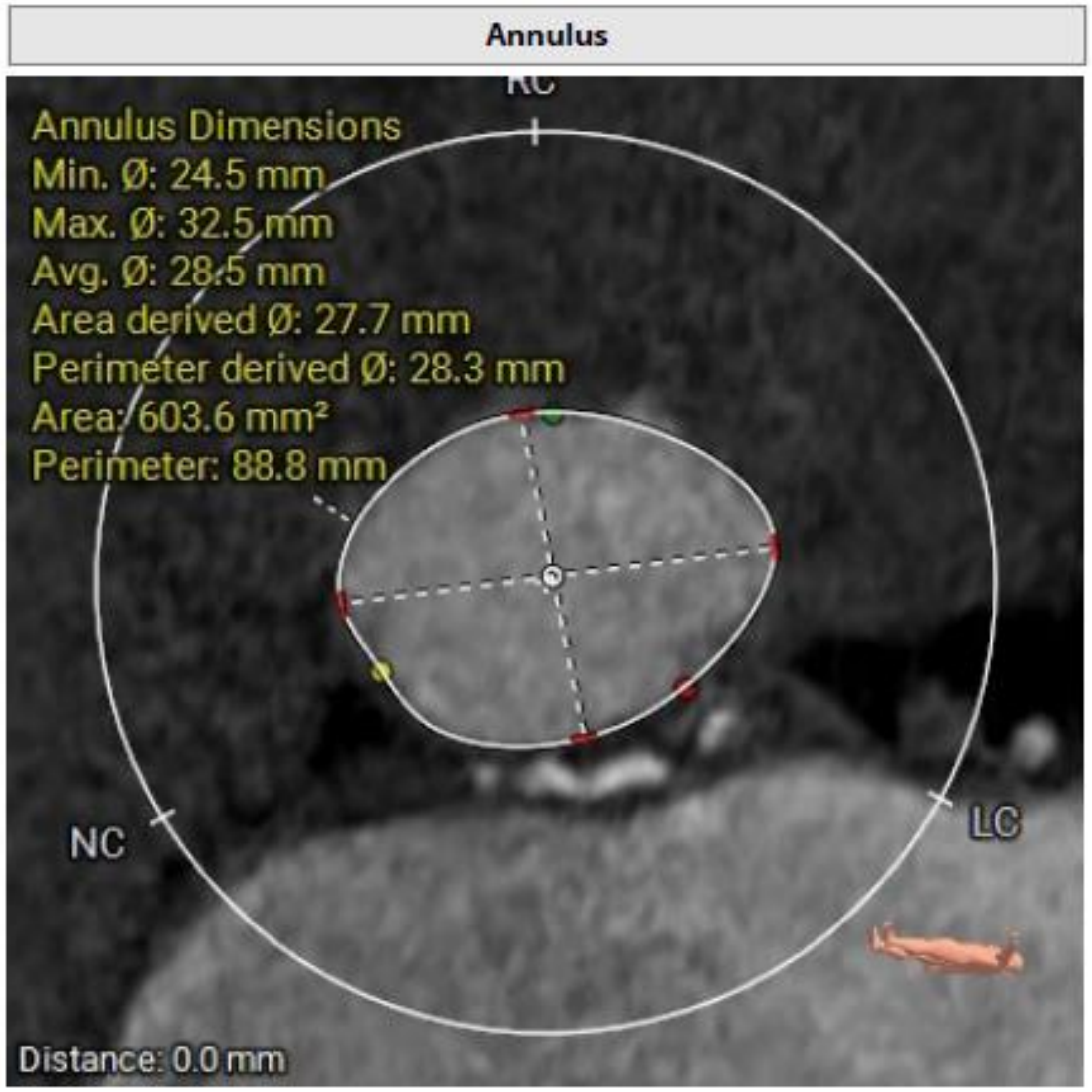
FE 31%

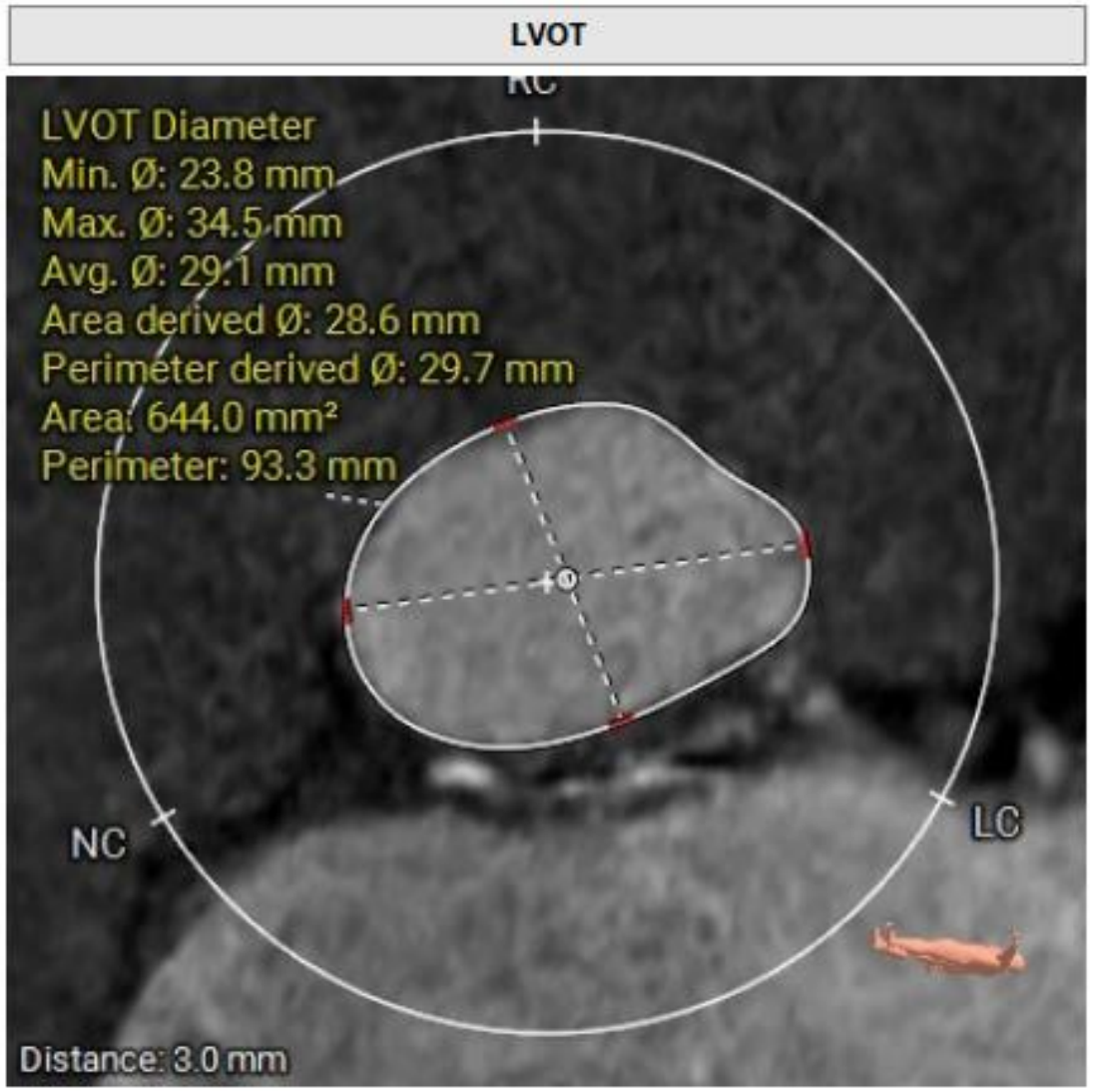




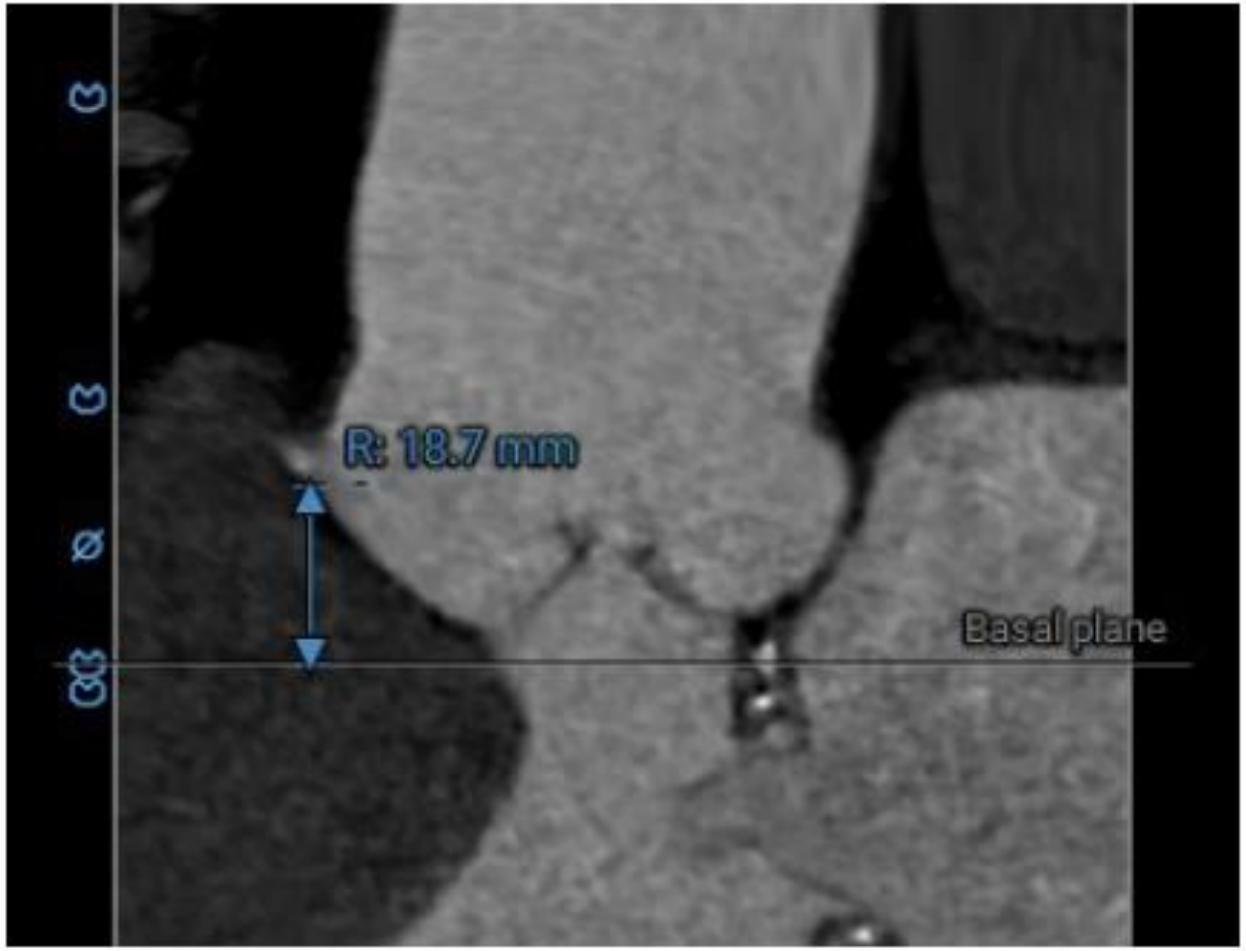




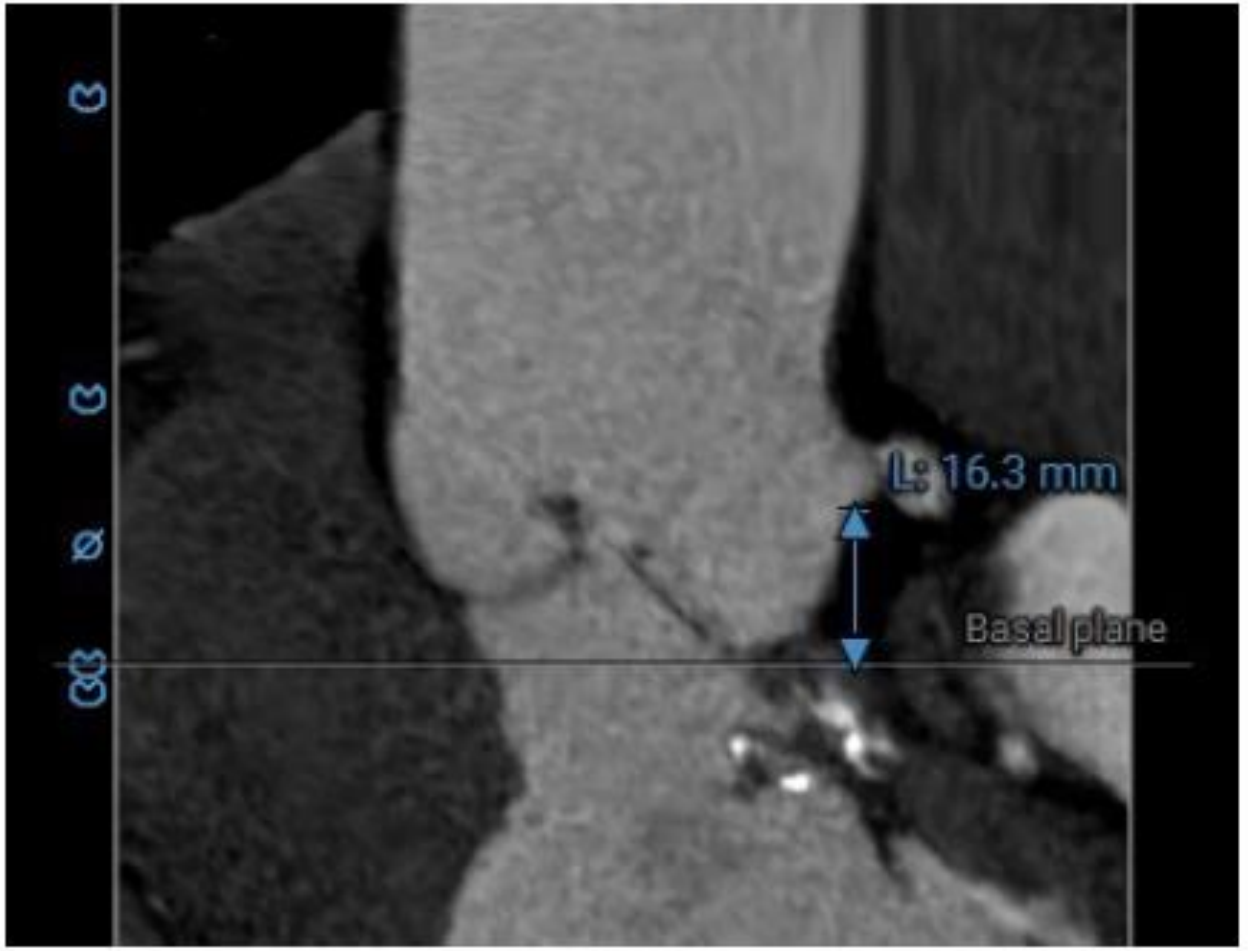

Annulus
Annulus Dimensions
Min. Ø: 24.5 mm
Max. Ø: 32.5 mm
Avg. Ø: 28.5 mm
Area derived Ø: 27.7 mm
Perimeter derived Ø: 28.3 mm
Area: 603.6 mm²
Perimeter: 88.8 mm
RC
NC
LC
Distance: 0.0 mm

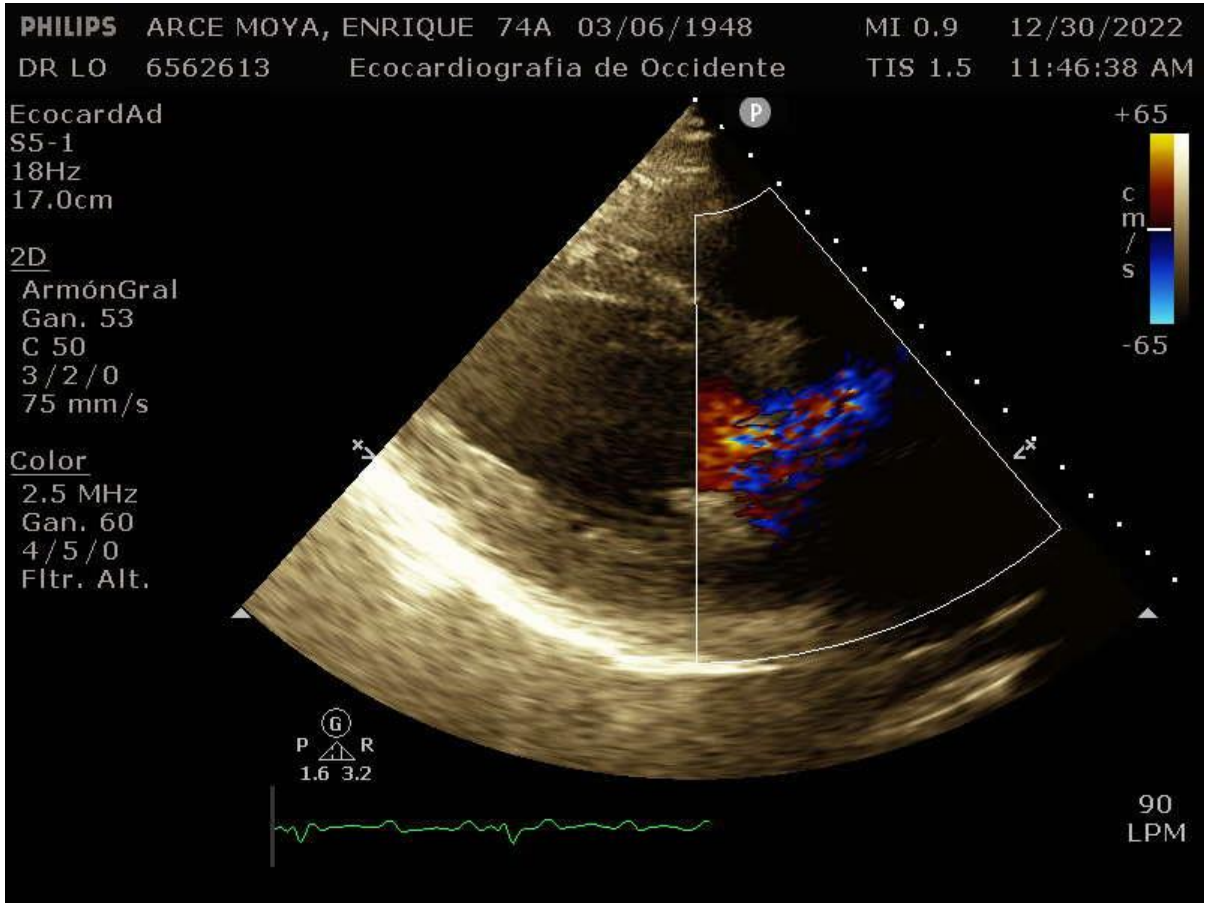

LVOT
LVOT Diameter
Min. Ø: 23.8 mm
Max. Ø: 34.5 mm
Avg. Ø: 29.1 mm
Area derived Ø: 28.6 mm
Perimeter derived Ø: 29.7 mm
Area: 644.0 mm²
Perimeter: 93.3 mm
RC
NC
LC
Distance: 3.0 mm

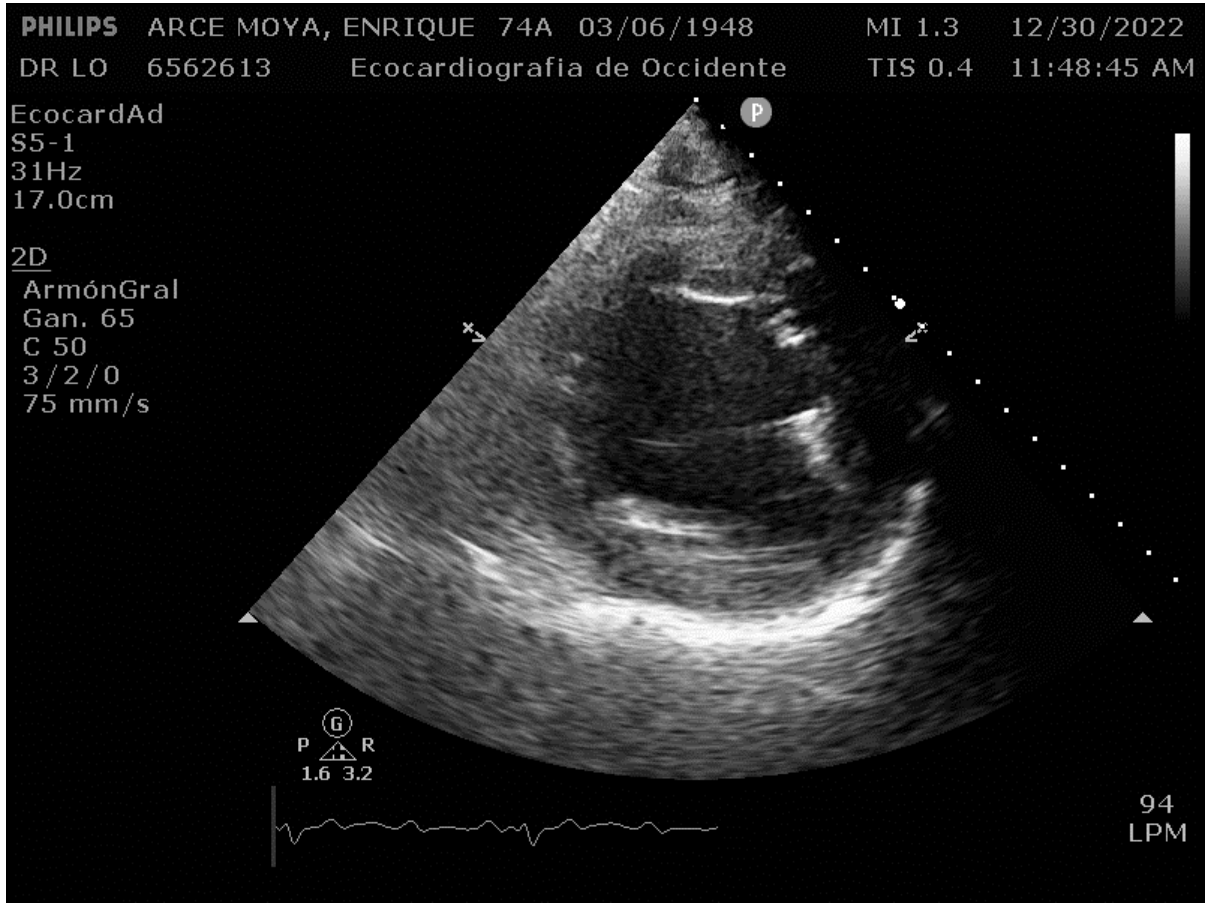
RCA Height



LCA Height







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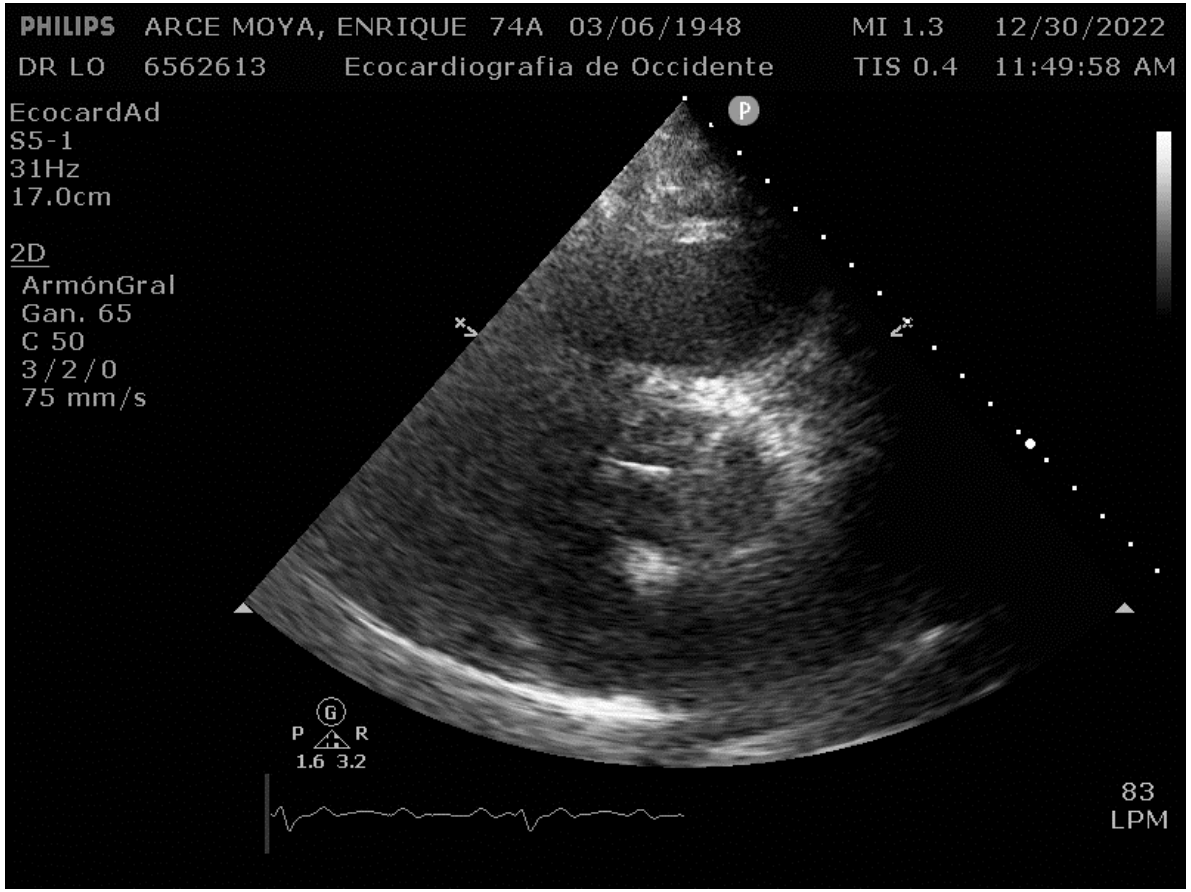
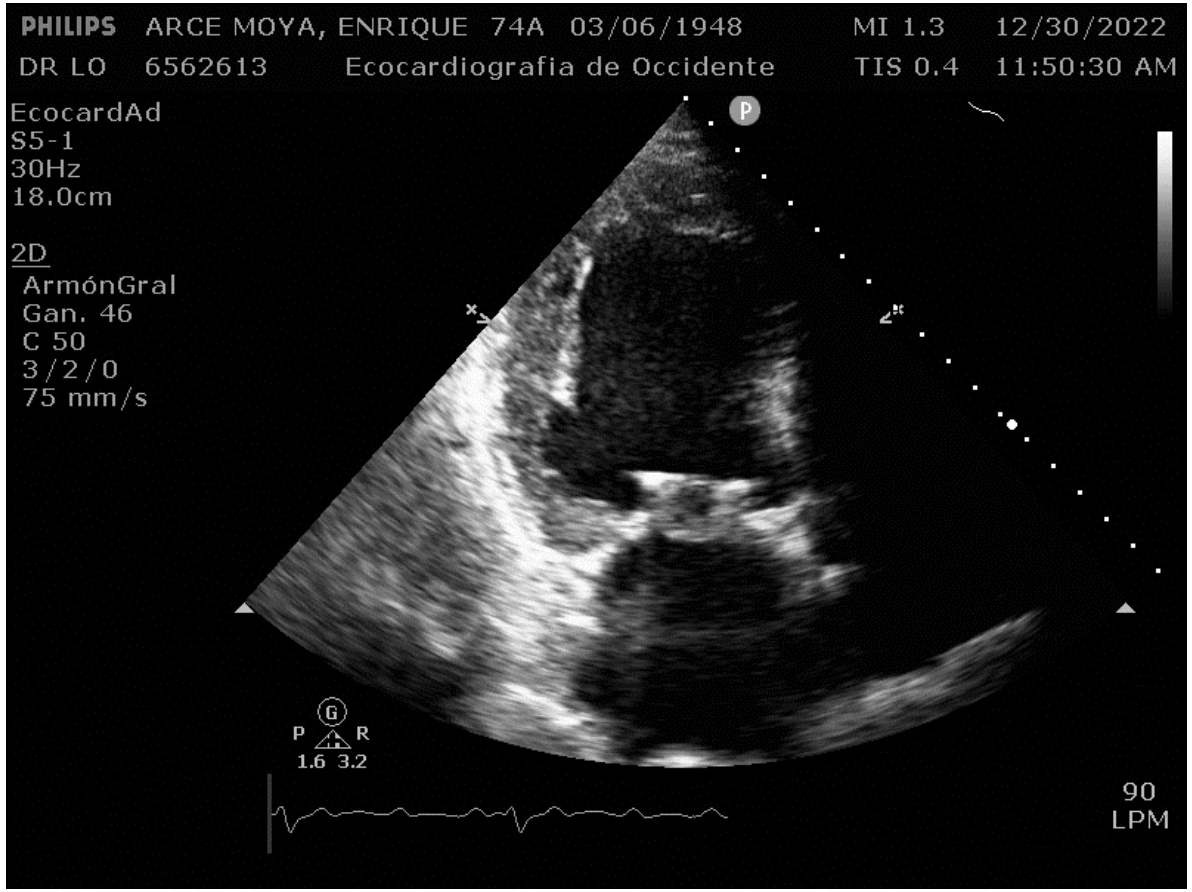
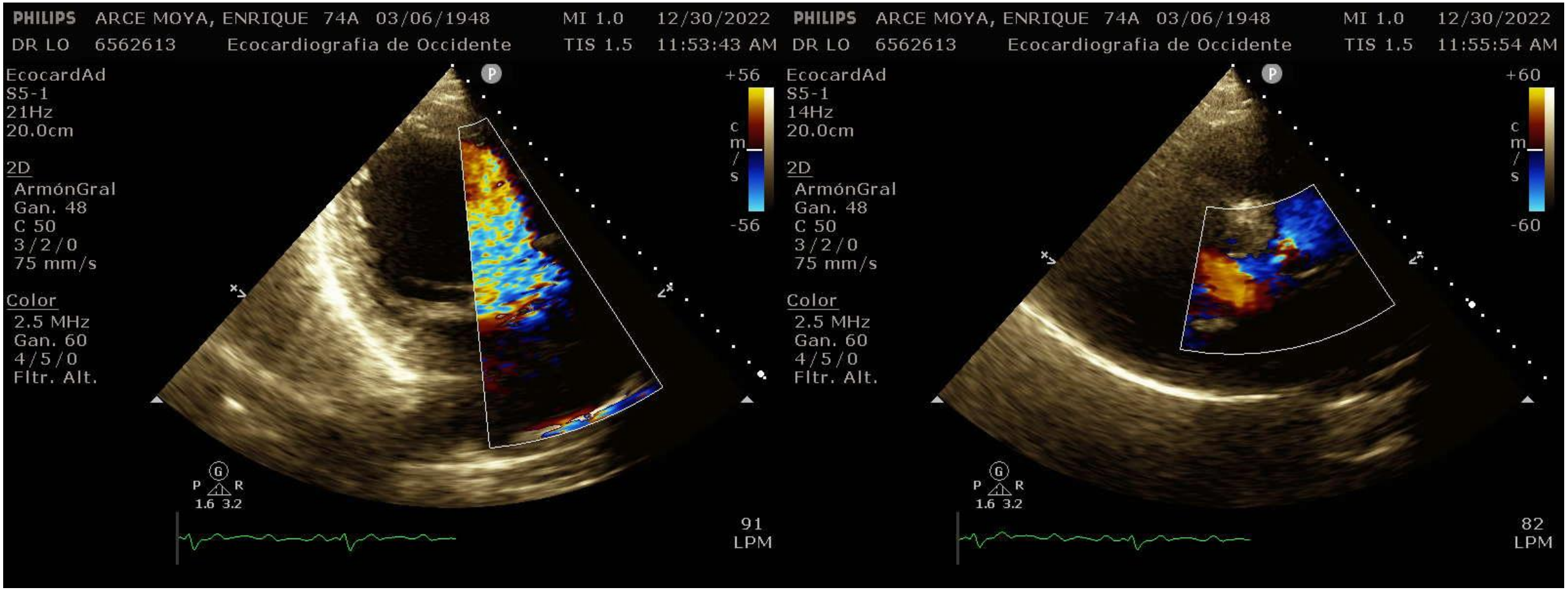

PHILIPS ARCE MOYA, ENRIQUE 74A 03/06/1948 MI 1.3 12/30/2022
DR LO 6562613 Ecocardiografia de Occidente TIS 0.4 11:49:58 AM
EcocardAd
S5-1
31Hz
17.0cm
2D
ArmónGral
Gan. 65
C 50
3/2/0
75 mm/s
P
G
P R
1.6 3.2
83
LPM


PHILIPS ARCE MOYA, ENRIQUE 74A 03/06/1948 MI 1.3 12/30/2022
DR LO 6562613 Ecocardiografia de Occidente TIS 0.4 11:50:30 AM
EcocardAd
S5-1
30Hz
18.0cm
2D
ArmónGral
Gan. 46
C 50
3/2/0
75 mm/s
P
G
P R
1.6 3.2
90
LPM



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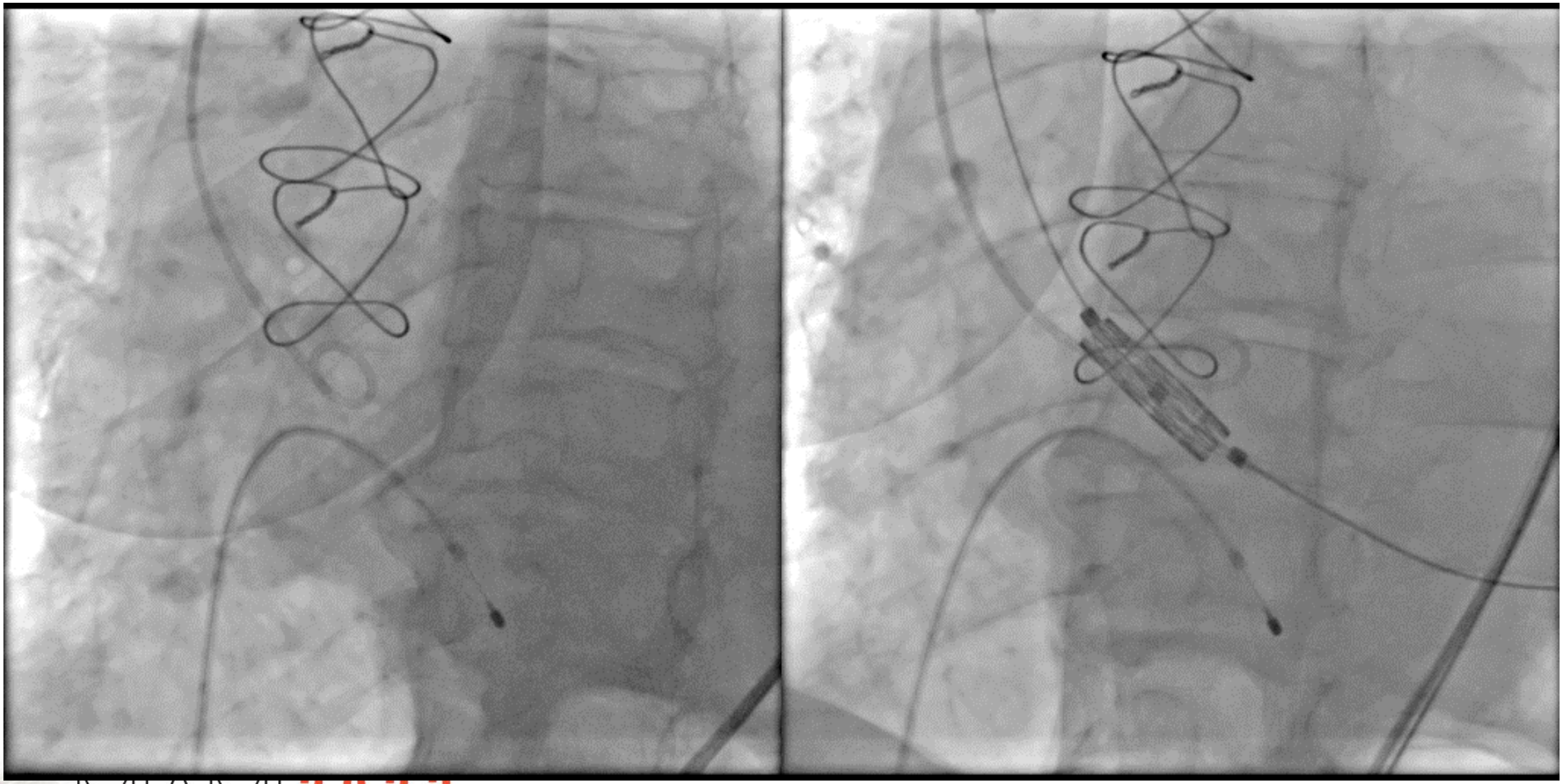

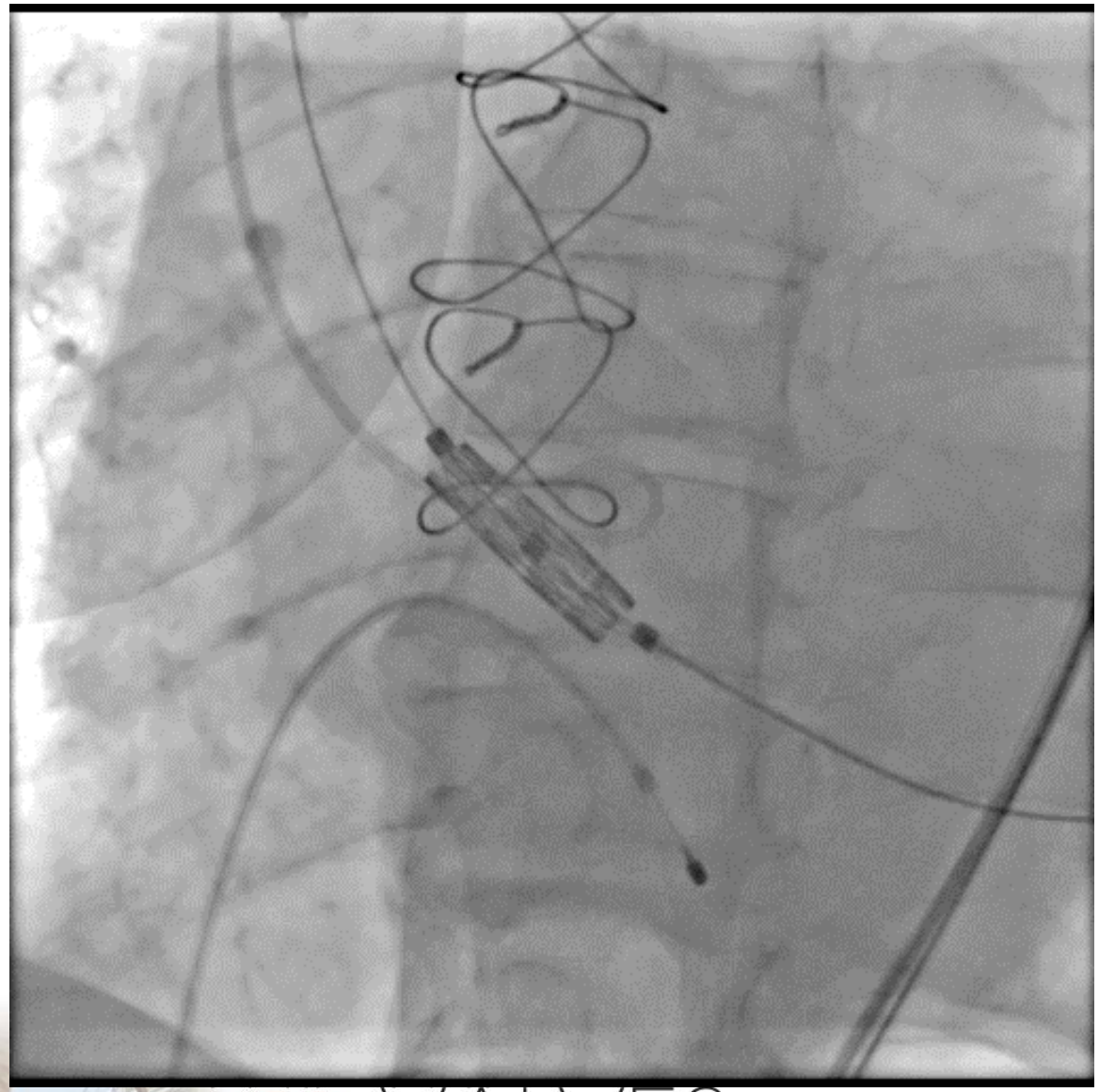

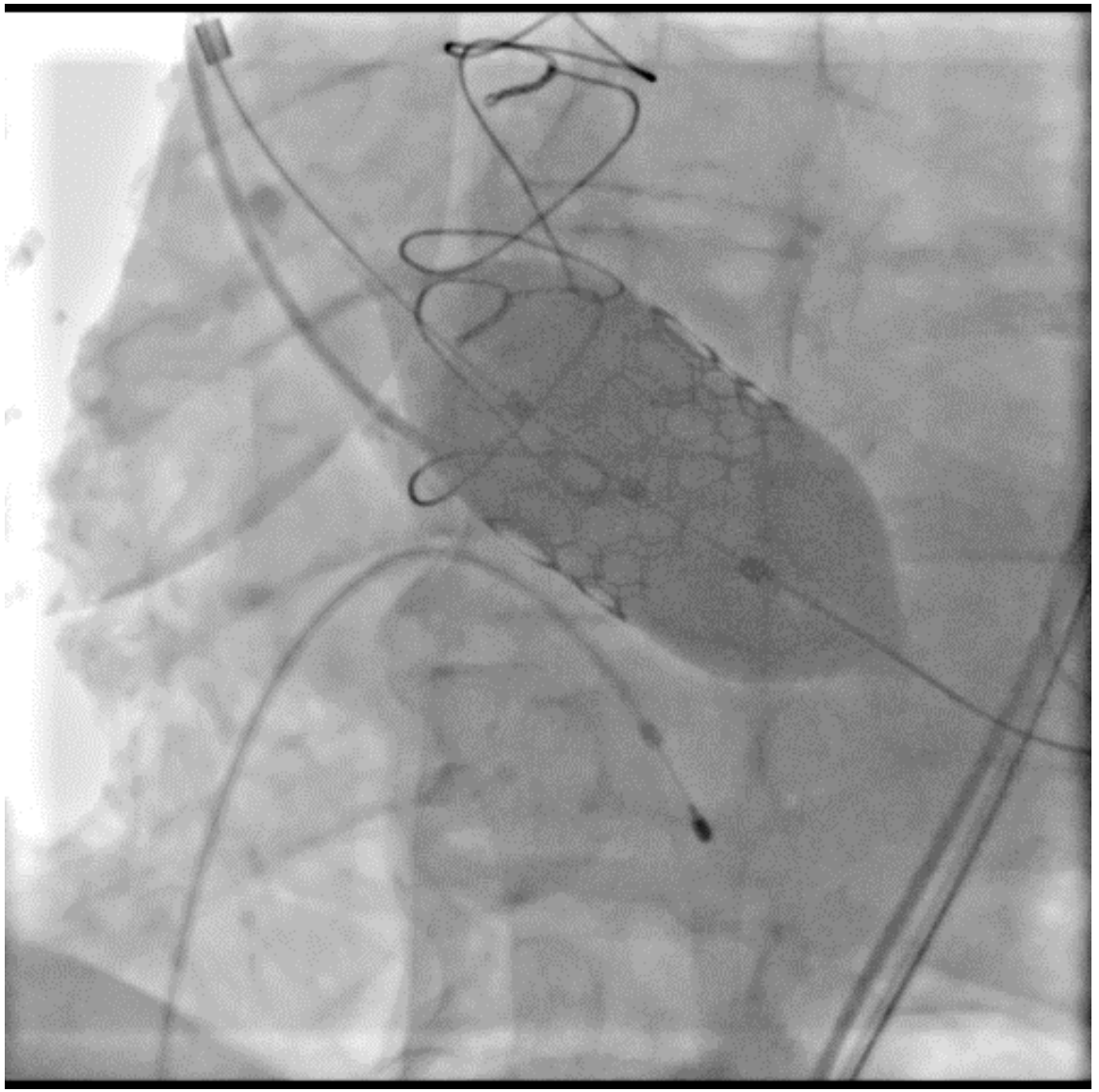

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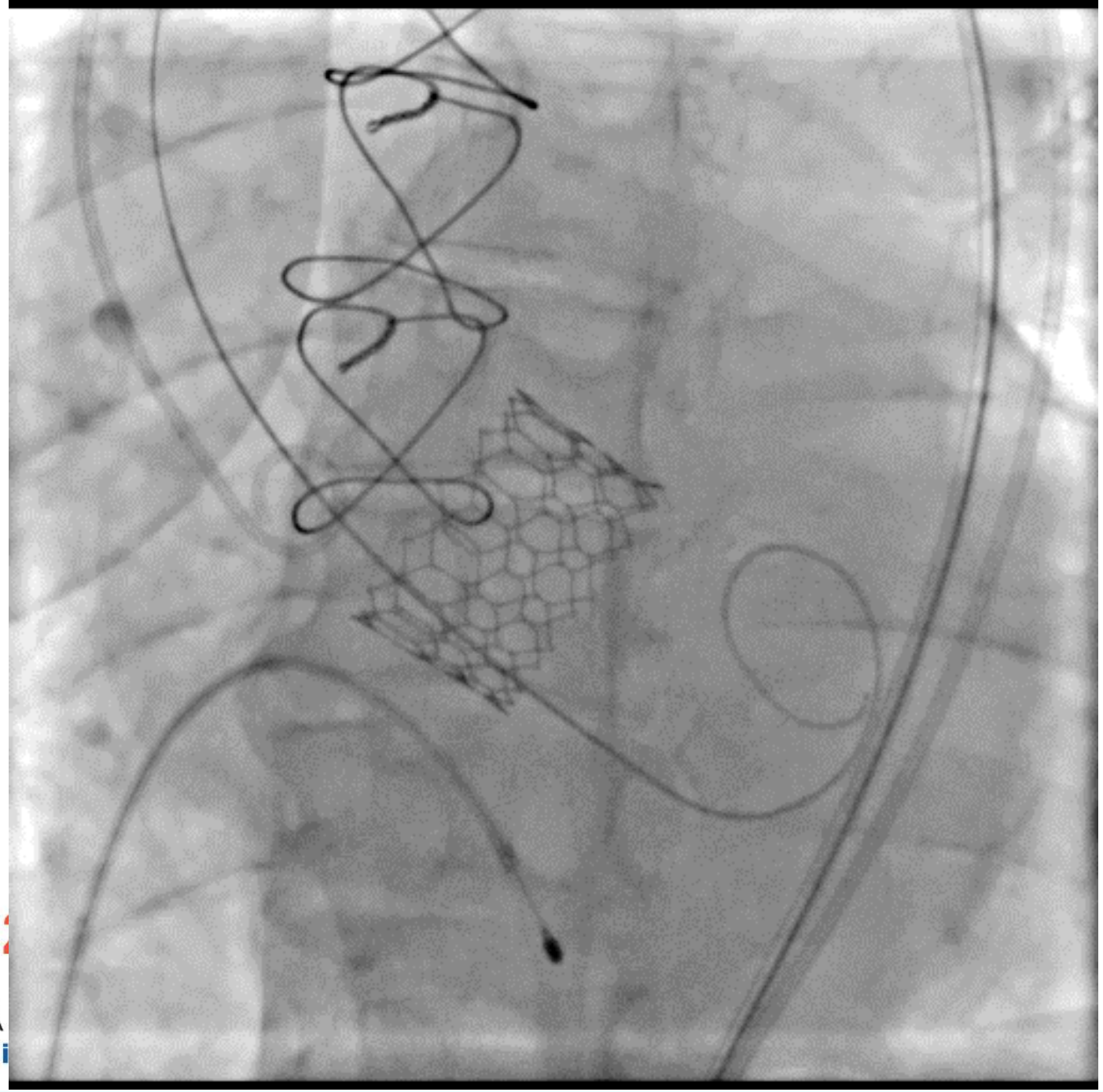

KEY POINTS

- Once at the No-Recapture point (pre-release) and recovery of PA continue drive with pacemaker. (DO NOT SUSPEND ABRUPTLY THE DRIVE WITH PACEMAKERS IN THE FINAL PHASE OF LIBERATION).
- Gradual decrease of heart rate under fluoroscopy visualization.
- Rapid reduction or suspension of the drive with pacemaker implies risk of dislocation of the device due to increased preload.

CONCLUSIONS:

In the general cohort, the TAVR for NAVR is associated with high rates of complications during the procedure.

However, new generation devices (NGD) were associated with better procedure results:

- **Lower rate of second valve implant**
- **Aortic insufficiency less to moderate post-procedure**

CONCLUSIONS:

- **Post-procedure aortic insufficiency greater than moderate was associated with increased mortality from all causes, late mortality and re-hospitalizations.**

- **The accumulated experience and the technology of the device have allowed to increase the OFF LABEL use of the TAVR for the aortic valve disease.**

PURE study (**P**ercutaneous **U**pdated management of pure aortic **RE**gurgitation with Myval device)

Why this study?

Transcatheter aortic valve implantation (TAVI) to treat patients with severe symptomatic aortic stenosis (AS) is a well-established procedure. However, the anatomic and structural alterations of the valve in pure aortic regurgitation (P-AR) are distinct to those in degenerative AS. The feasibility of TAVI in a non-calcified P-AR using non-dedicated devices approved only for AS is considered an off-label procedure but has shown promising results in published case series. Novel balloon-expandable valves (BEV) offer the attractive option of extra-large sizes that might be of particular interest in this setting. According to the current European and American guidelines, surgical intervention is indicated when significant AR is accompanied by symptoms, decreased left ventricular (LV) systolic function, or severe LV dilatation, with TAVI being considered as a bail-out option for high-risk or inoperable patients. Since TAVI is a challenging intervention in these cases due to the anatomic complexity (aortic annulus dimensions, aortic root dilation, and the lack of sufficient annular calcification) it is indicated only for carefully selected patients as an off-label indication due to its multiple challenges with unpredictable immediate and long-term results. The aim of this study is to evaluate the safety and feasibility of TAVI in P-AR with a novel BEV device with available extra-large sizes.

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