

# Mitral valve replacement (TMVR) with the AltaValve system. Live in a box case presentation

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# Disclosures

- Consultant/ Proctor/ Investigator 4C Medical



**Stent Cap**

Allows Implant Re-capturability

**24-Fr cells**

Allows Future LA Access

**Fabric Skirt (PET)**

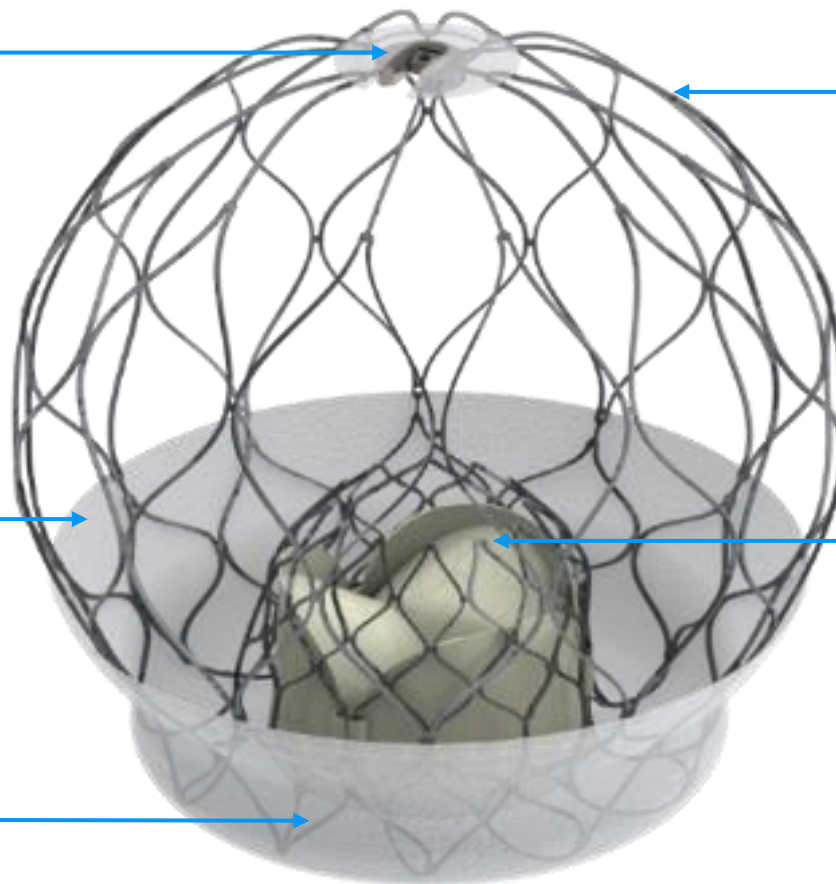
Promotes Sealing

**Tissue Valve**

27mm Bovine Pericardial  
One Size for all Implants

**Annular Ring**

Three Sizes: 40, 46, and 54mm

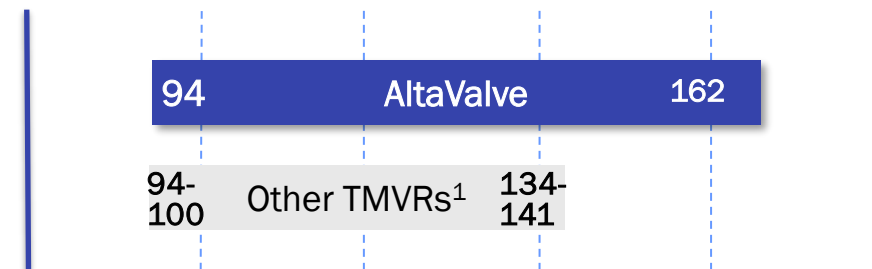


# Designed to Minimize Common Screen Failures

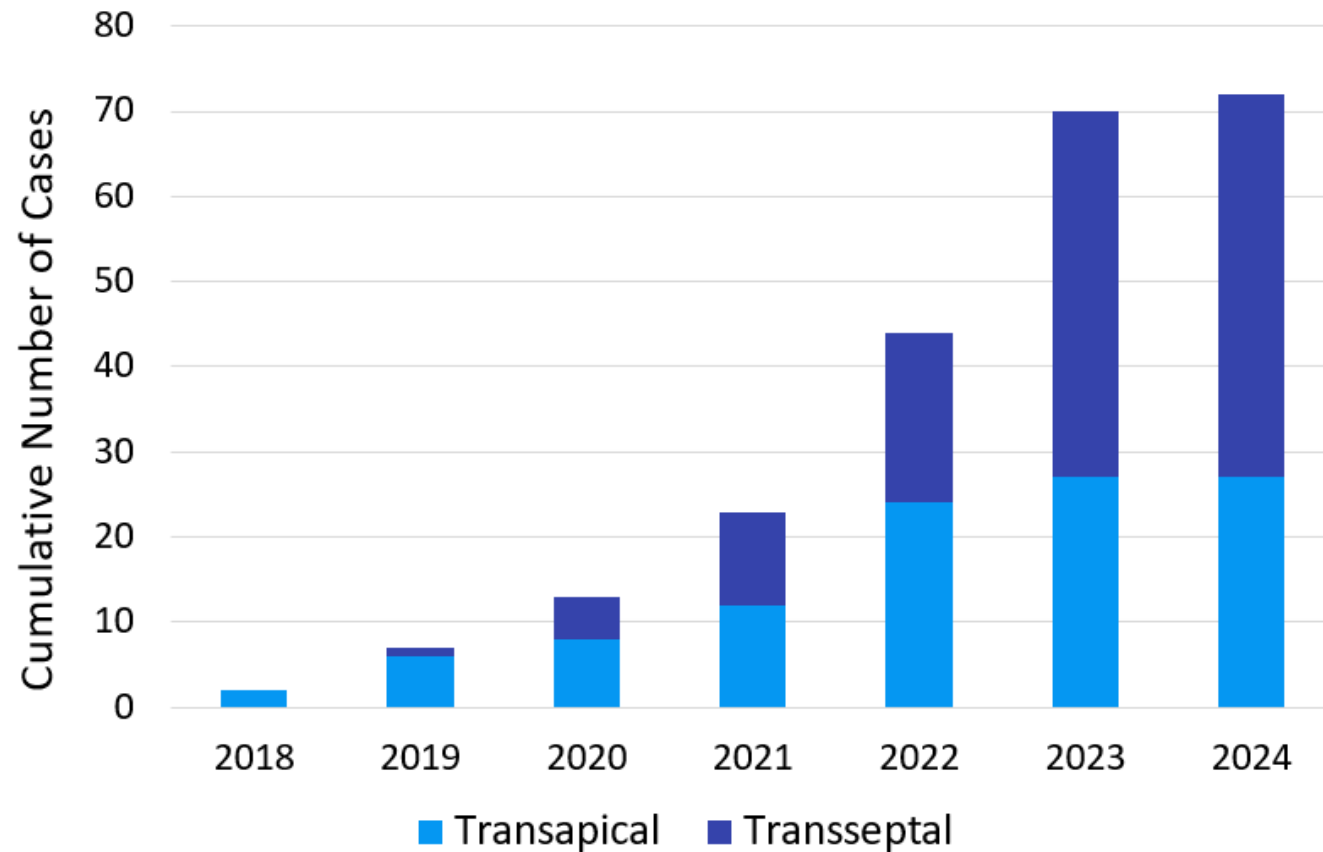


- **Atrial Fixation** by over-expansion in LA
- **Treats wide-range** of MV annular sizes

Range of MV Annulus Perimeter for Treated Patients



# AltaValve Cumulative Clinical Experience



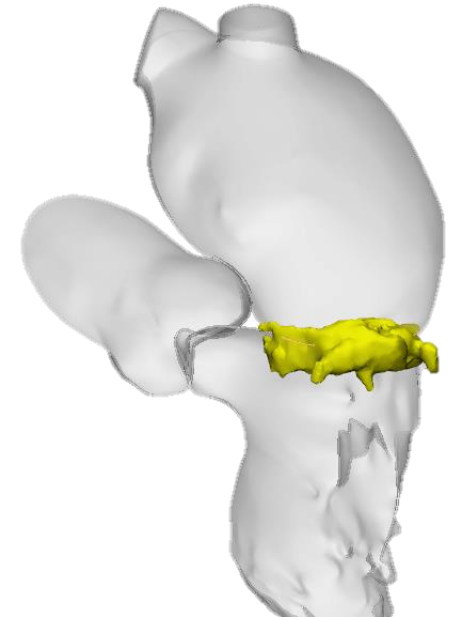
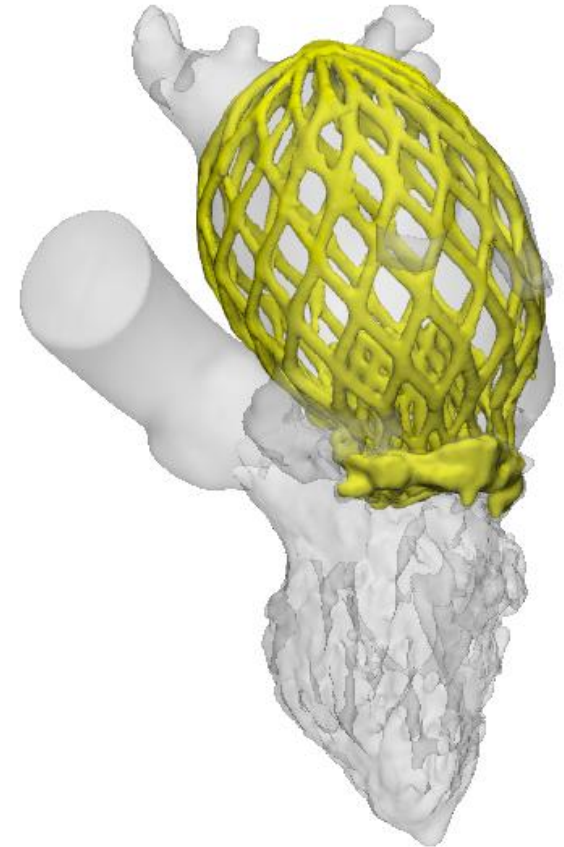
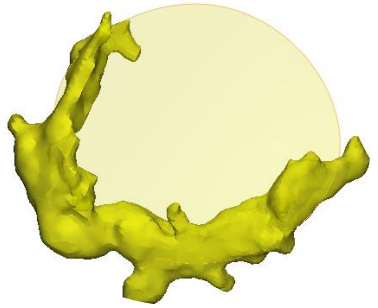
Over 70 patients treated globally using AltaValve!

- 63% Transseptal (TS) Cases
- 56% Early Feasibility Study (EFS)

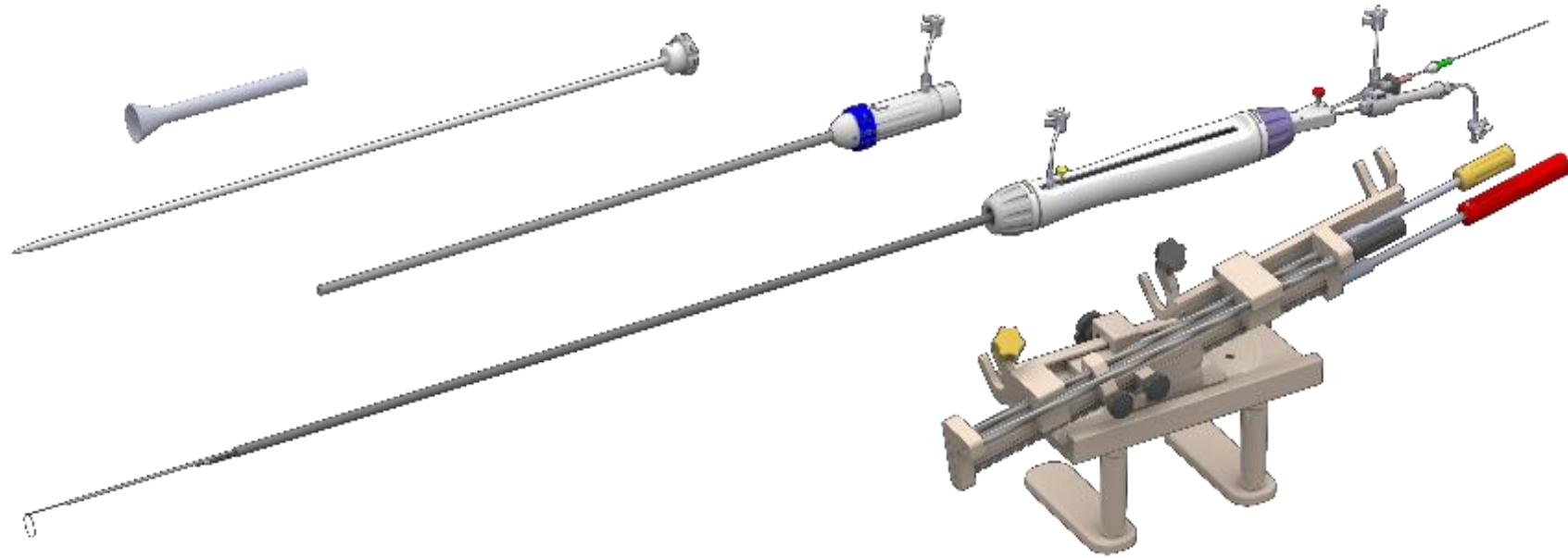
Throughout patient selection and delivery system evolution, **Valve design has remained the same**

# TAVR-Like Deployment in MAC

- AltaValve's cage **conforms to regions with MAC**
  - *Deformations in the outer frame are isolated and do not affect valve function*
- Has minimal interaction with LV, preserving its structure



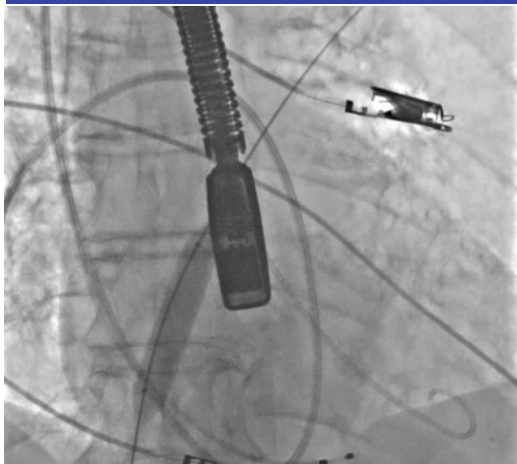
# Low-Profile 29Fr Transseptal (TS) Delivery System



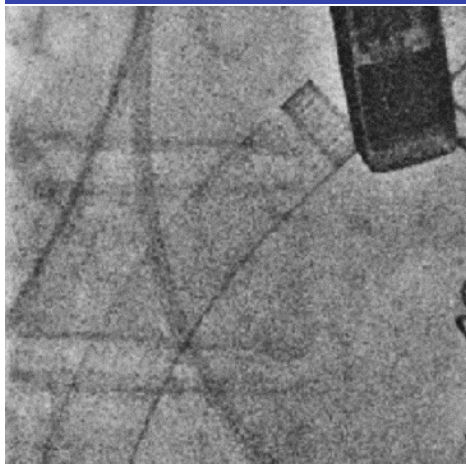
- Designed for **predictable delivery** of AltaValve to the desired location in LA
- Allows for **fully percutaneous approach**
- Stand provides **controlled deployment** and enhanced ease of use
- **Fully recapturable implant** prior to final release\*

# Straight Forward 1-Stage Procedure

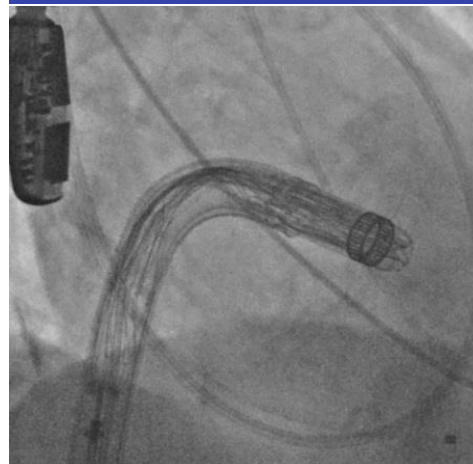
TRANSSEPTAL ACCESS



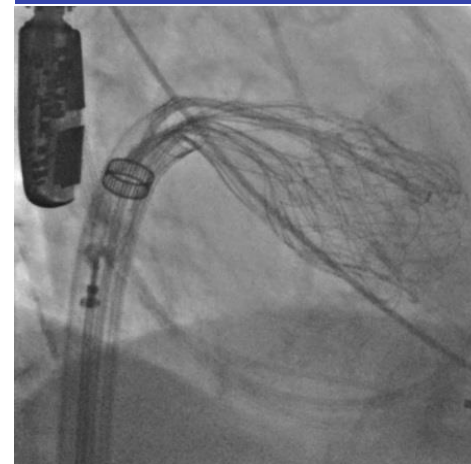
LA ACCESS



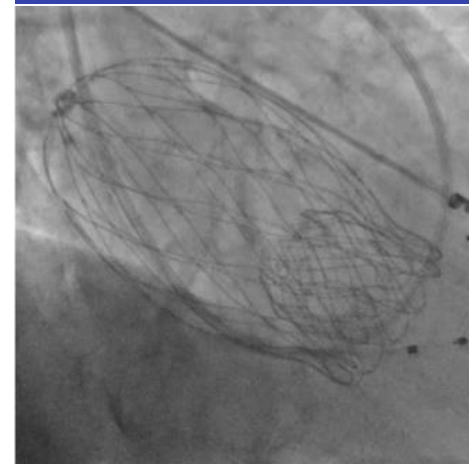
NAVIGATE TO MV PLANE



ALTAVALVE  
DEPLOYMENT



ALTAVALVE RELEASE

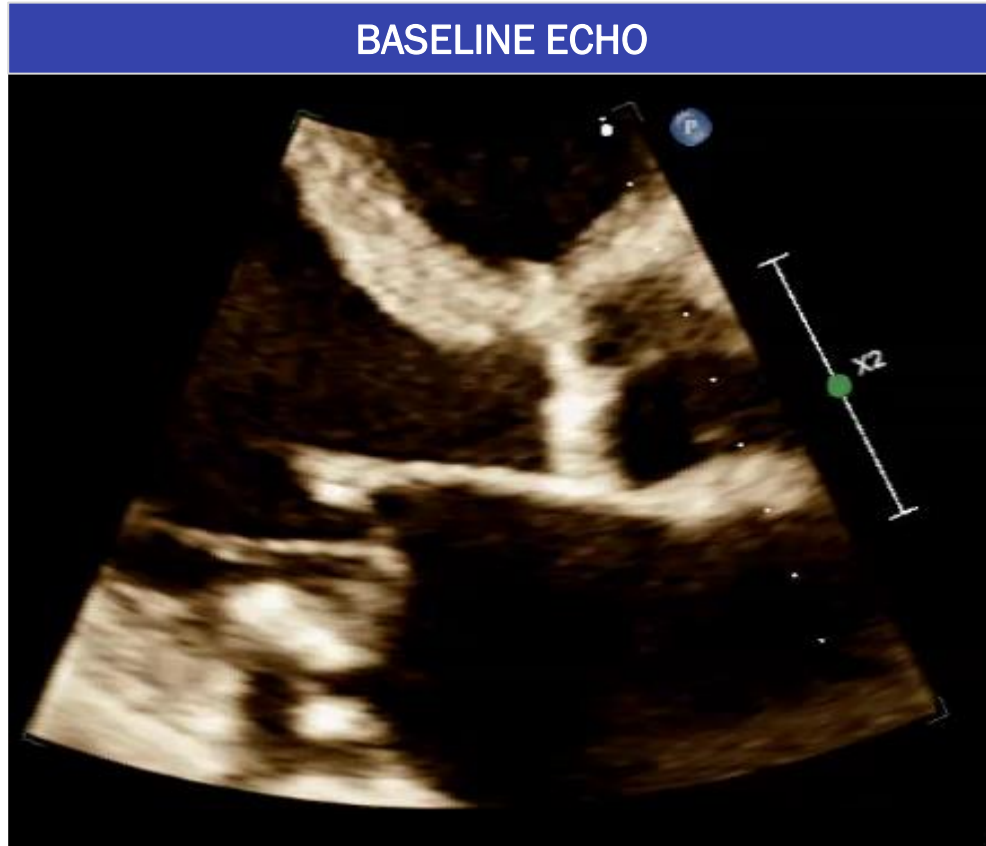


# Evaluable Cohort<sup>1</sup> Patient Demographics

PARAMETER (N = 24)		VALUE
Age	Years	77.0 ± 6.4
Age (>80)	Years	42%
Sex	Male	29%
	<b>Female</b>	<b>71%</b>
BMI		26.4 ± 3.7
NYHA Class	II	21%
	III/IV	79%
STS-PROM, %		5.4 ± 1.9
LVEF, %		53.0 ± 6.4

PARAMETER (N = 24)		VALUE
MR Etiology	FMR	67%
	DMR/Mixed	33%
Mitral Annular Calcification (MAC)	None/Trace	75%
	Mild	8%
	<b>Moderate/Severe</b>	<b>17%</b>
History of Atrial Fibrillation	Chronic AF	38%
	Paroxysmal AF	21%
	None	8%

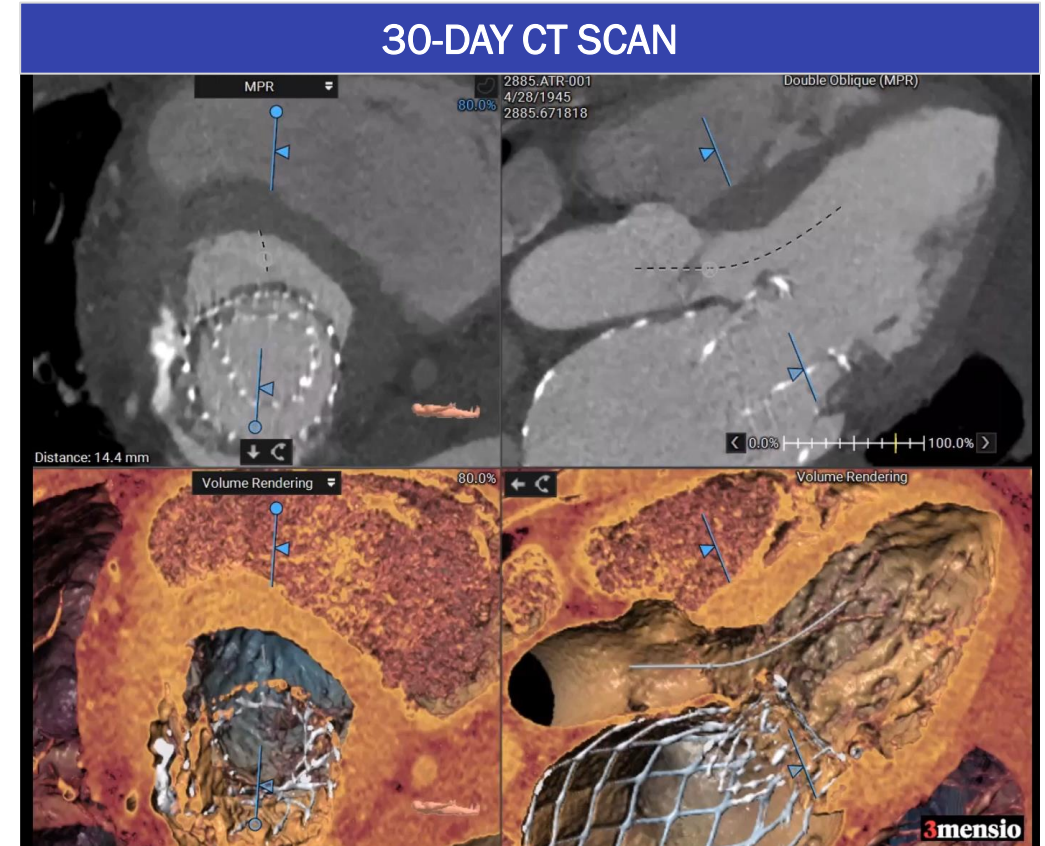
# Most Patients Enrolled in AltaValve EFS Were Excluded from other TMVR Trials



Predicted neo-LVOT for:

Device #1: 1.7cm<sup>2</sup> (Ineligible)

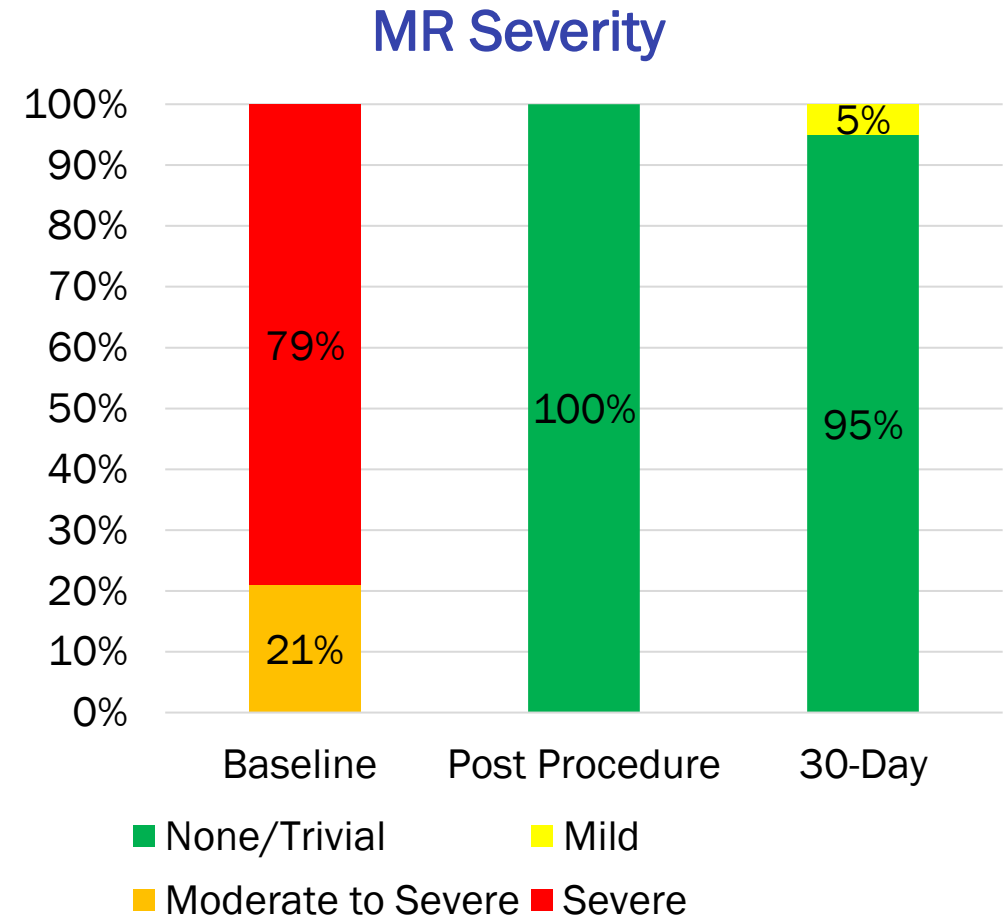
Device #2: 0cm<sup>2</sup> (Ineligible)



- ✓ Successful AltaValve implant
- ✓ 30-Day LVOT area of 5.6cm<sup>2</sup>

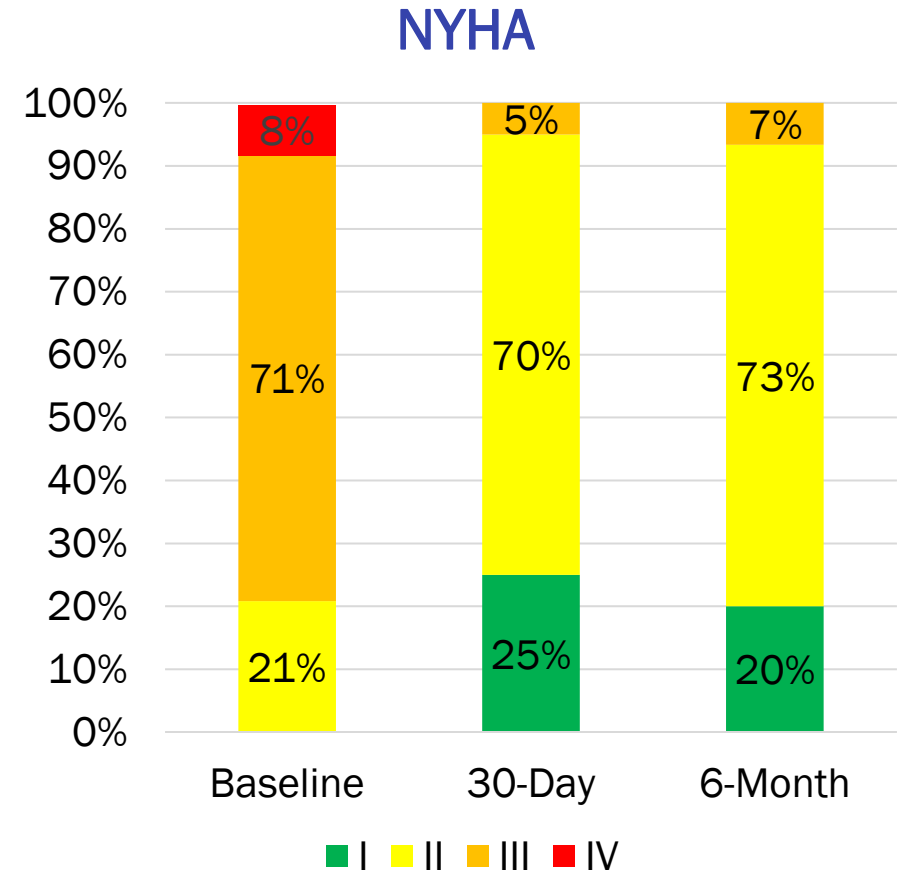
# Procedural Characteristics

CHARACTERISTICS (N = 24)	VALUE
Annular ring size used	
40mm	29% (7/24)
46mm	46% (11/24)
<b>54mm</b>	<b>25% (6/24)</b>
Delivery system used	
Transseptal (TS)	46% (11/24)
Transapical (TA)	54% (13/24)
Technical success	96% (23/24) <sup>1</sup>
Conversion to surgery <sup>1</sup>	4% (1/24)
<b>Procedural mortality</b>	<b>0% (0/24)</b>
<b>Major femoral bleeding</b>	<b>0% (0/24)</b>

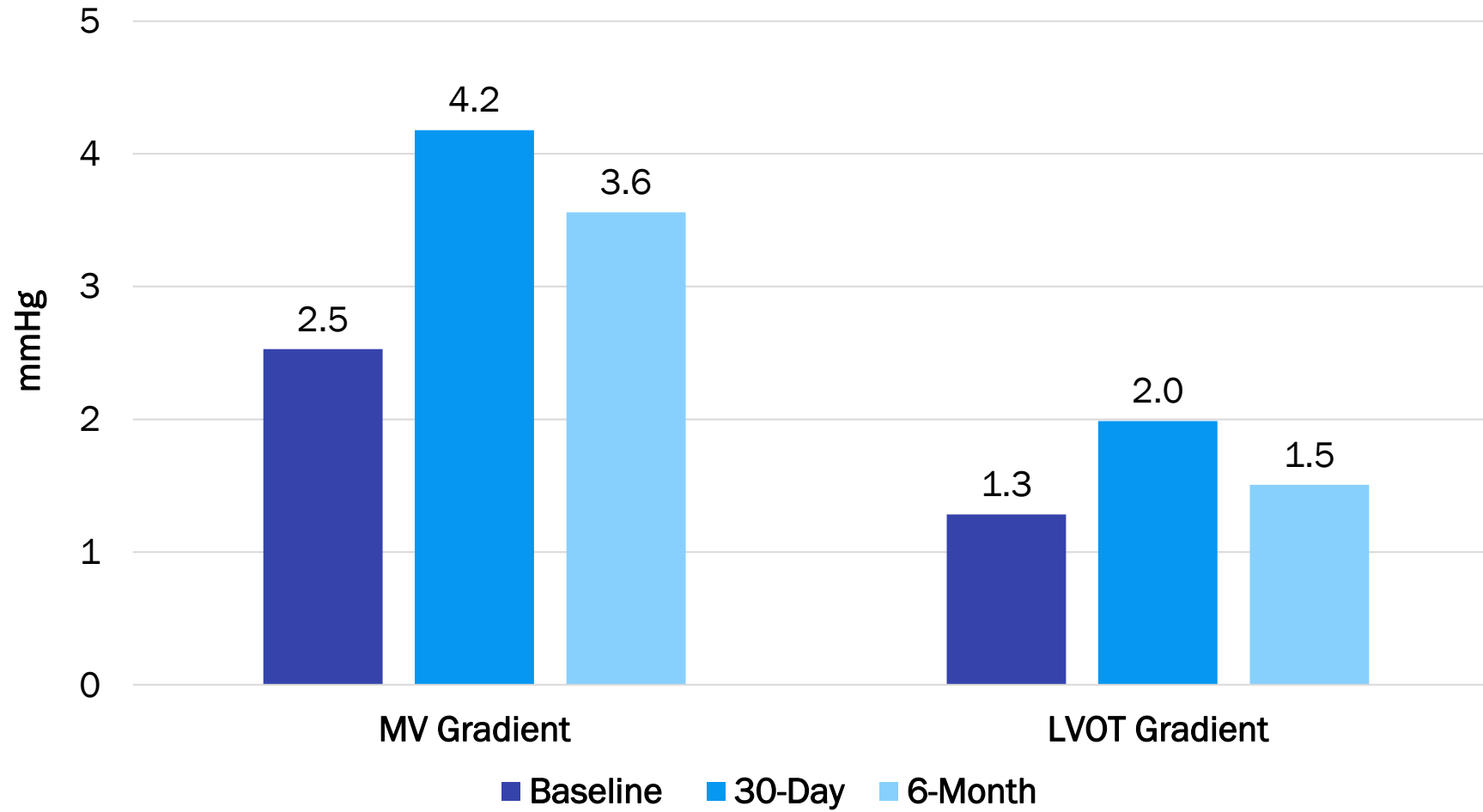


# 30-Day and 6-Month Clinical Outcomes

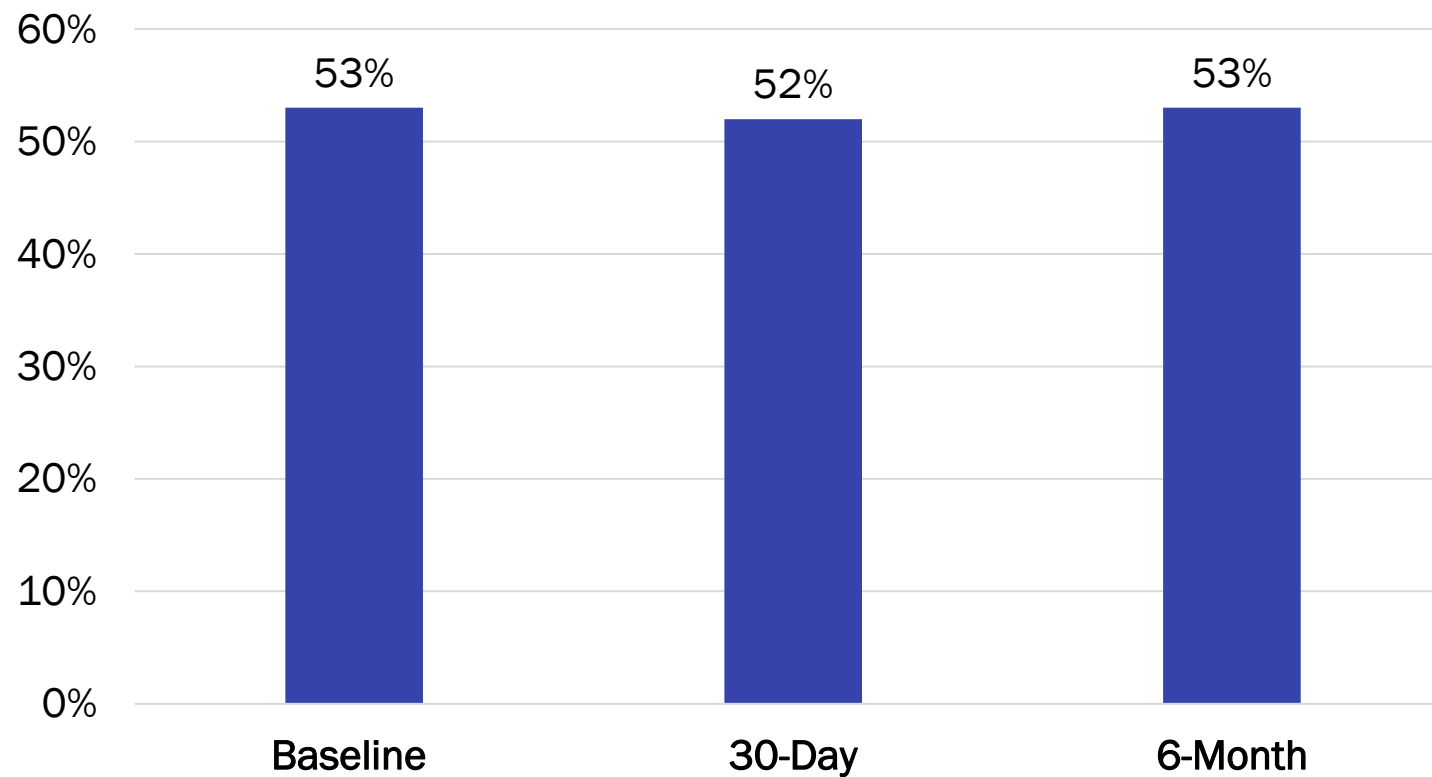
OUTCOME	30-DAY	6-MONTH
Mortality		
All-Cause	13% (3/24)	17% (4/24)
Cardiac	8% (2/24)	8% (2/24)
TS Cardiac	0% (0/11)	0% (0/11)
Stroke	0% (0/24)	0% (0/24)
Thrombosis	0% (0/24)	0% (0/24)
New Pacemaker Implantation	0% (0/24)	0% (0/24)
MV Reintervention	0% (0/24)	0% (0/24)
New Afib	0% (0/24)	0% (0/24)



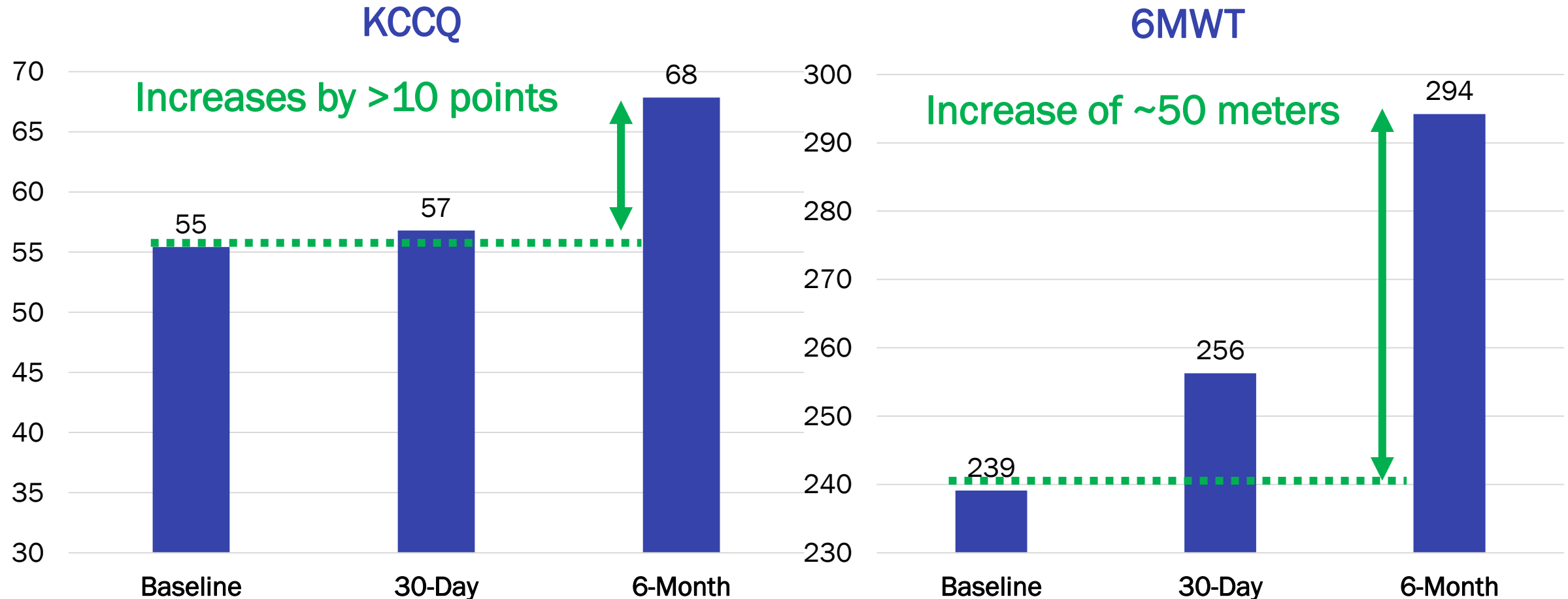
# No MV or LVOT Gradient Post-Procedure



# No Reduction in LVEF

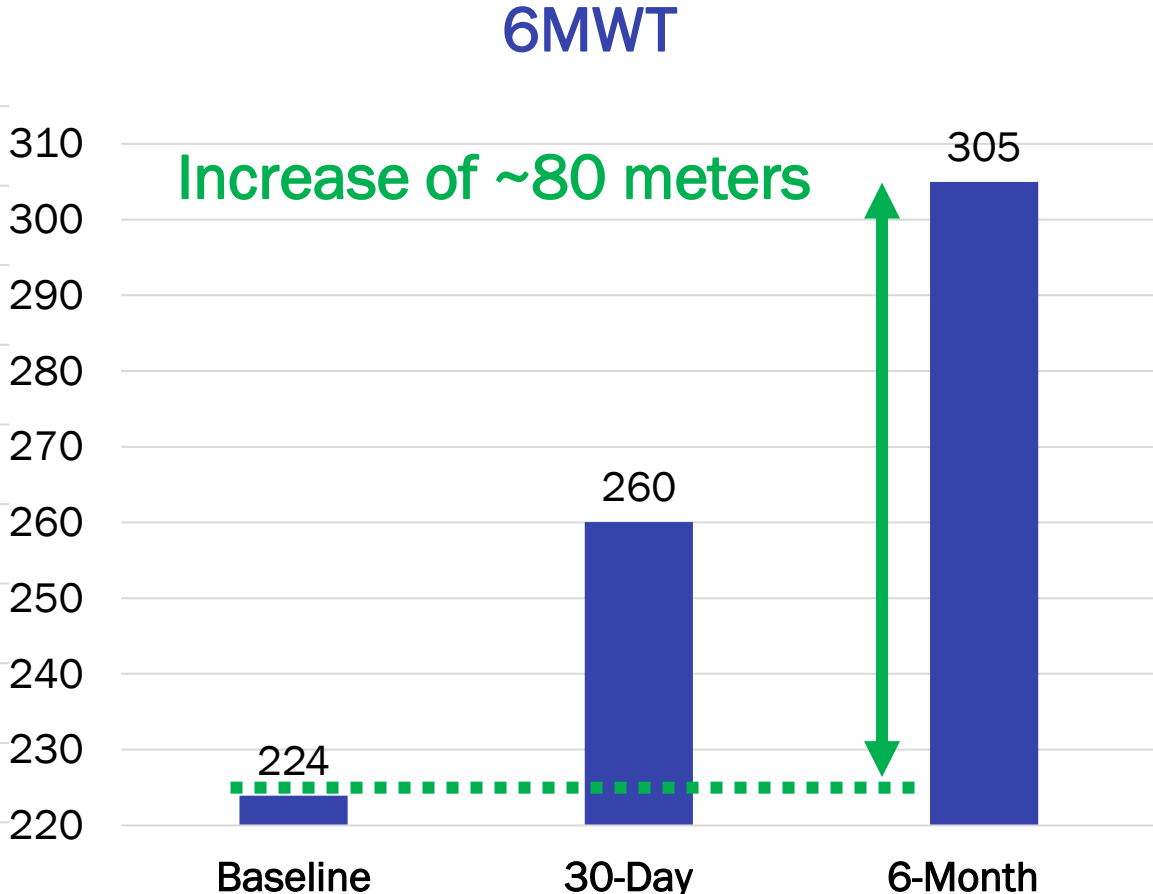
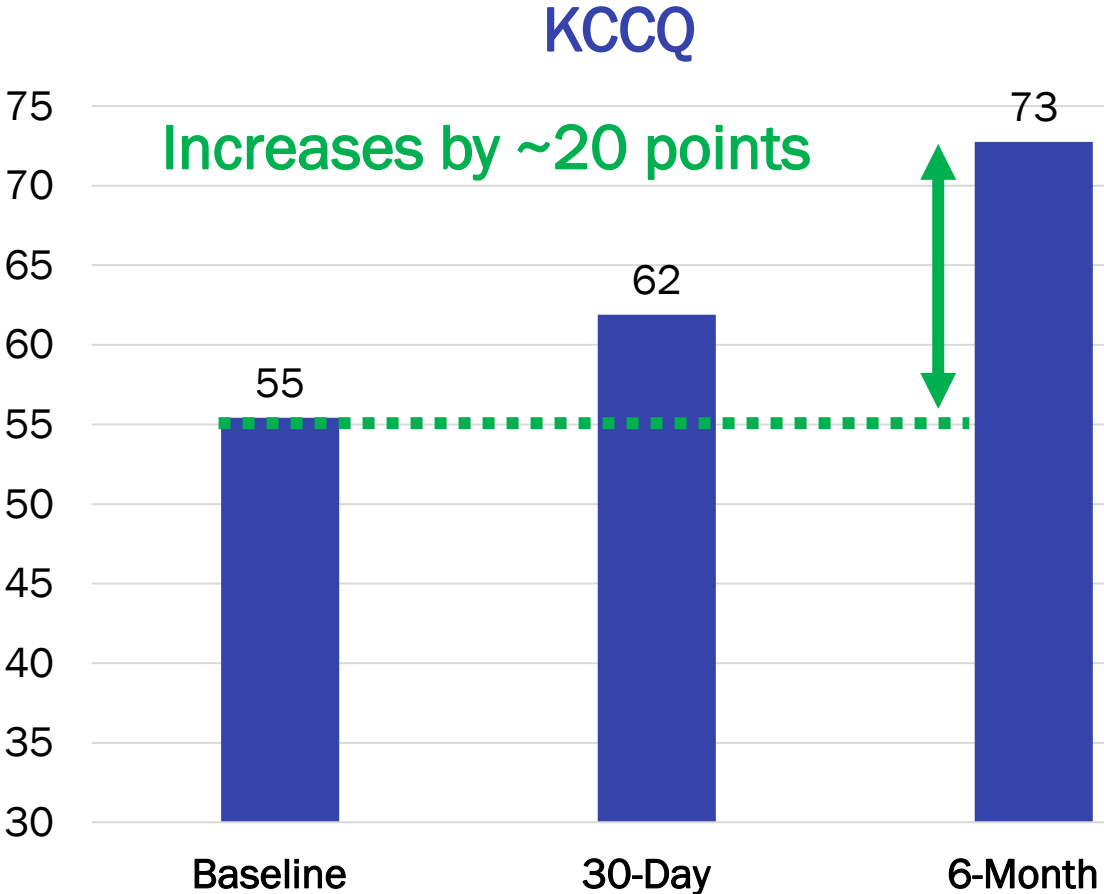


# Improvement in Quality of Life & Functional Outcomes



*Since ~50% were treated via TA approach, it takes >30-day to see actual improvement post treatment*

# Improvement in Quality of Life & Functional Outcomes TS Patients

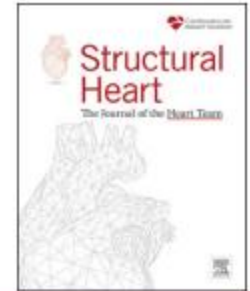




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# Structural Heart

journal homepage: [www.structuralheartjournal.org](http://www.structuralheartjournal.org)



Original Research

## AltaValve Atrial Fixation System for the Treatment of Severe Mitral Regurgitation and Mitral Annular Calcification

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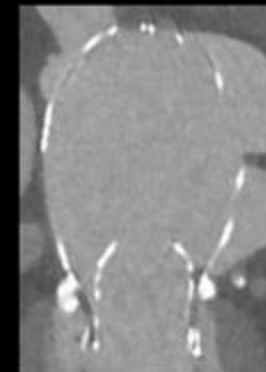
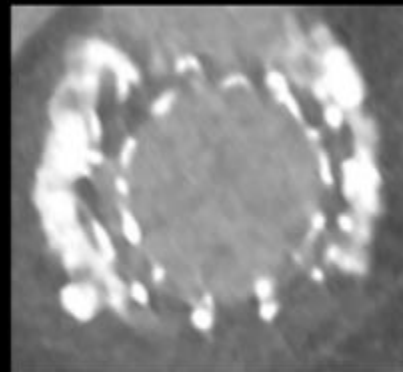
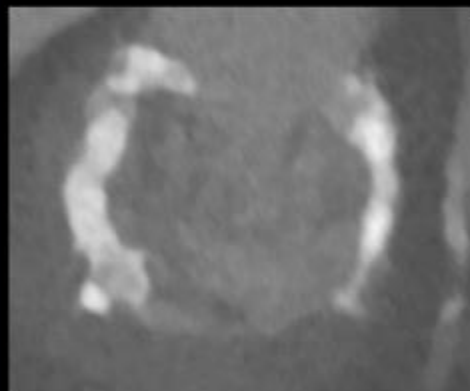
<sup>g</sup> Interbalkan Medical Center, Thessaloniki, Greece

**a** Pre-procedural CT

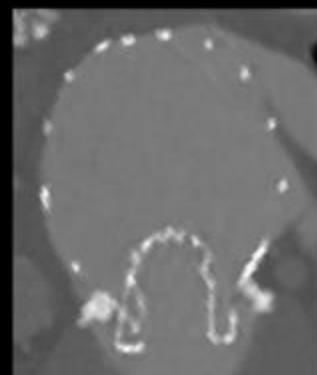
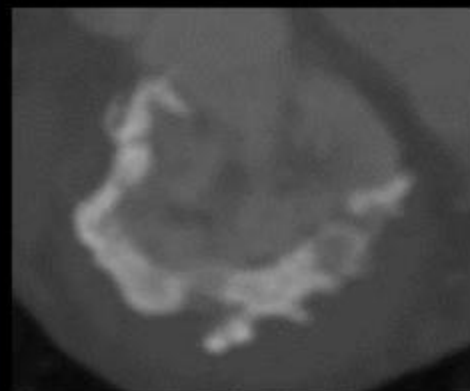
**b** Post-procedural fluoro

**c** Follow-up CT

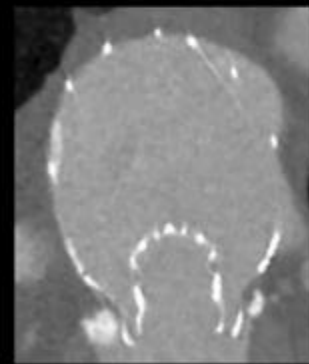
Subject 2

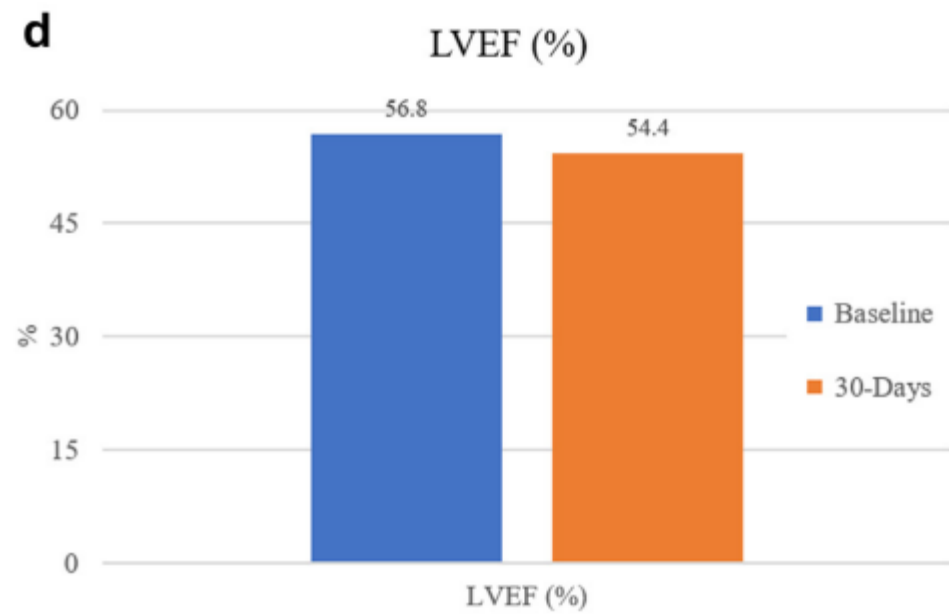
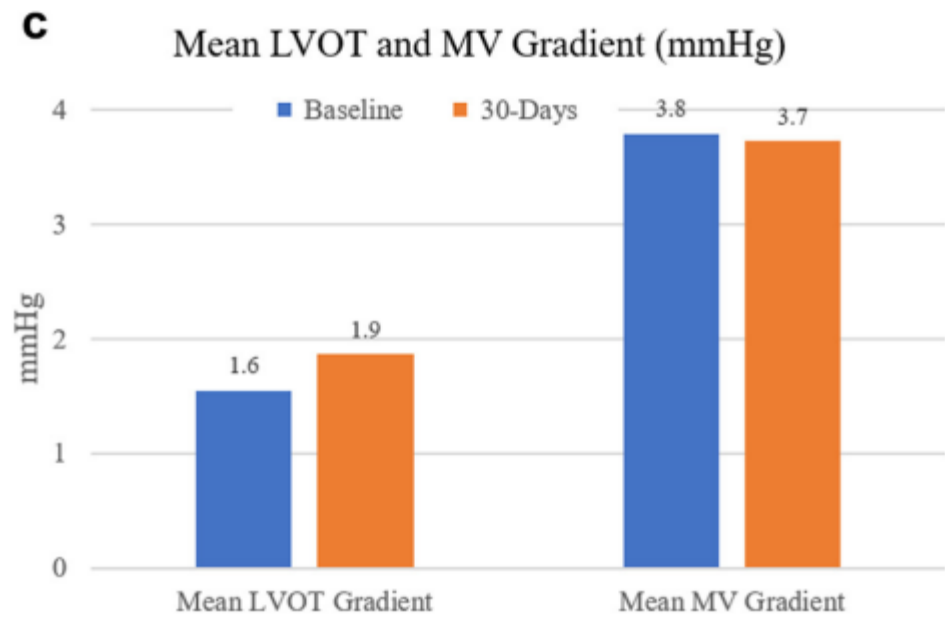
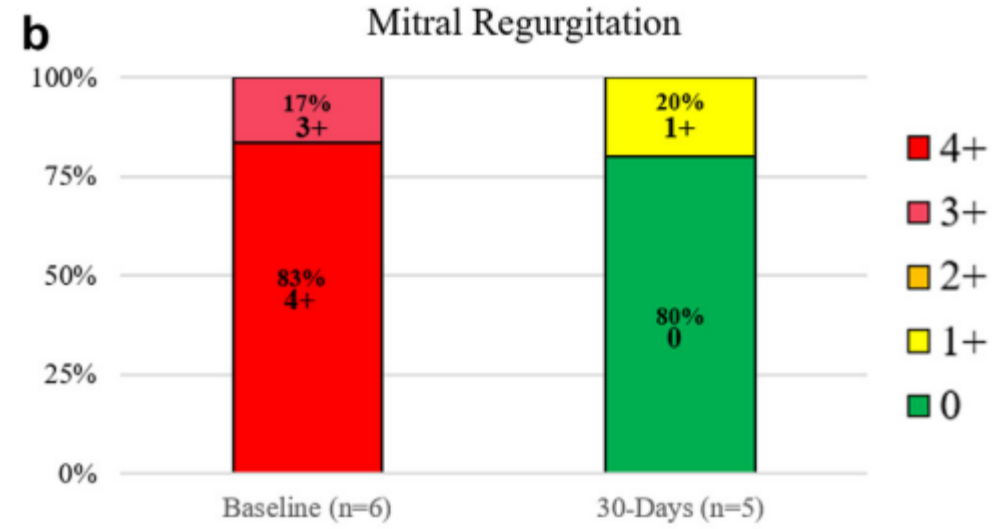
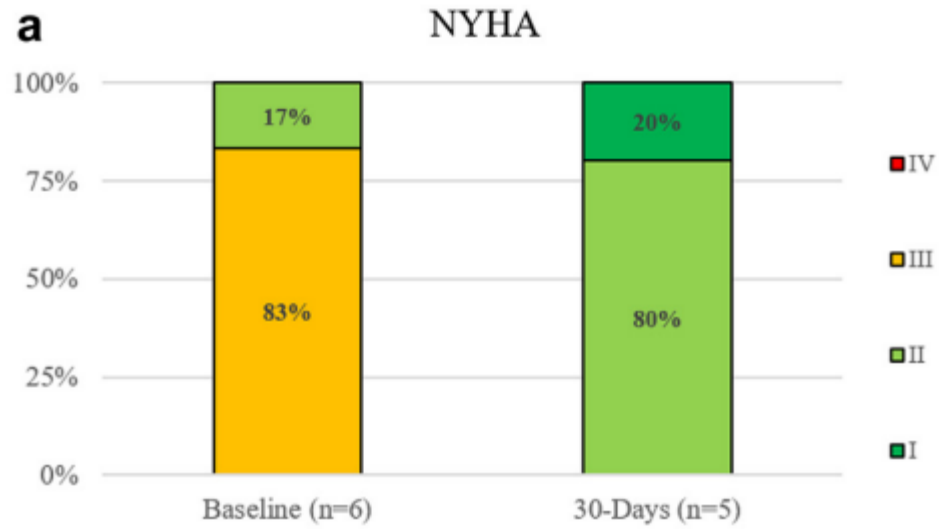


Subject 3



Subject 4





Recorded live case

# Demographics

## STS Score

Procedure Type: **Isolated MVR**

- Sex: Male
- Age: 68
- Height: 170 cm
- Weight: 66 kg
- BMI: 23 kg/m<sup>2</sup>
- NYHA Class: III
- Ejection Fraction: 40%
- Type of MR: FMR
- Grade of MR: Severe

PERIOPERATIVE OUTCOME	ESTIMATE %
Operative Mortality	2.62%
Morbidity & Mortality	12.6%
Stroke	1.14%
Renal Failure	1.63%
Reoperation	6.01%
Prolonged Ventilation	6.9%
Deep Sternal Wound Infection	0.057%
Long Hospital Stay (>14 days)	5.34%
Short Hospital Stay (<6 days)*	30%

# Clinical Assessment – Frailty/Medical History

6-minute Walk Test 14Feb2024: 288 meters

Parameter	SpO2, %	BP	HR	Respiration Dyspnea/Fatigue
Pre-Test	96	110/70	64	7/7
End of Test	99		81	12/13

Lab	Value 14Feb2024	Normal Value
WBC	5.73	4.0-11.0 K/ $\mu$ L
Hemoglobin	13.3	11.5-16.5 g/dL
Hematocrit	40.1	37-47%
Platelets	235	150-400 K/ $\mu$ L
Creatinine	1.1	0.5-0.9 mg/dL
eGFR	68	>60 ml/min
NT-proBNP	<b>1418</b>	<738 pg/mL
BUN	-	8-23 mg/dL
Albumin	3.7	3.5-5.2 g/dL

## Medical History and Medications

- 2000: Inferior wall infarction
- 2000-2020: Multivessel CAD
- **Medications:**
  - ACE/ARB/CCB: Perindopril
  - Beta Blocker: Carvedilol
  - Diuretic: Furosemide
  - Other: Nitroglycerin, Pantoprazole, Trimetazidine, Atorvastatin

# Risk Factors – Cardiac History

Risk Factors	
Aortic Stenosis	No
Aortic Regurgitation	Trivial
Tricuspid Regurgitation	Moderate
Mitral Stenosis	No
Heart Failure	Chronic HFrEF
Hypertension	Yes
Hyperlipidemia	Yes
Atrial Fibrillation	None
Atrial Flutter	None
Vtach/Vfib	No
Alcohol Use	Unk
Smoking Status	Former
Pneumonia	No
COPD	Mild (14Feb24: FVC 85%/FEV1 81%)
Diabetes	No

Risk Factors	
Coronary Artery Bypass	No
Previous Valve Procedure	No
LAA Occlusion	No
Pacemaker/ICD	No
CAD	08Nov00: PCI x 1 LAD 12Oct06: PCI x 3, LAD, OM1, RCA 04Jun13: PCI x 1 LAD 25Nov20: PCI x IM, LCx, RCS 14Feb24: no obstructive CAD
PAD	Yes
Cerebrovascular Disease	No
Syncope	No
Hx of Endocarditis	No
Hx of Cancer	No
Immunocompromised	Unk
Autoimmune Disease	Unk
GI Bleed	No

# Right Heart Catheterization

DATE: 14Feb2024

**PAP= 50/12** Mean 29 mmHg

**PWP: v=43 mmHg** Mean 21 mmHg

**TGP= 8 mmHg**

**RA= v= 11** Mean 5mmHg

**PVR= 2.2 w.u.**

**RV= 50/7mmHg**

**SvO2= 62.3 %**

**SaO2- 98%**

**C.O.=3.6 L/min**

**C.I.= 2.1 mL/beat**

**SV= 51.43 mL/beat**

**Hb= 12.9 g/dL**

# Echo Assessment

LVOT & Aortic Echo Assessments	
TTE (2/14/2024)	
Aortic Valve Peak Velocity	130 cm/s
AV Pressure Gradient	4 / 7 mmHg
AVA	3.4 cm <sup>2</sup>
Velocity Ratio	0.75
LVOT Diameter	2.4 cm
LVOT Pressure Gradient	2 / 5 mmHg

Mitral Valve Echo Assessments	
TTE (2/14/2024)	
MV Peak Velocity	83 cm/s
MV Pressure Gradient	1 / 3 mmHg
MVA	3.5 cm <sup>2</sup>
Mitral stenosis	none
MAC	mild

# Incremental Risk Factors

## Left Ventricular Diastology

TTE (2/14/2024)

LA Volume (unindexed) 145 ml

E/e' Average 16.0

E/A Ratio 1.5

TR Peak Velocity 249 cm/s

## Right Ventricle Function

TTE (2/14/2024)

RV dimensions (if possible) Base 4.5 cm  
Mid 2.5 cm  
Long 8.8 cm

RV s' 12 cm/s

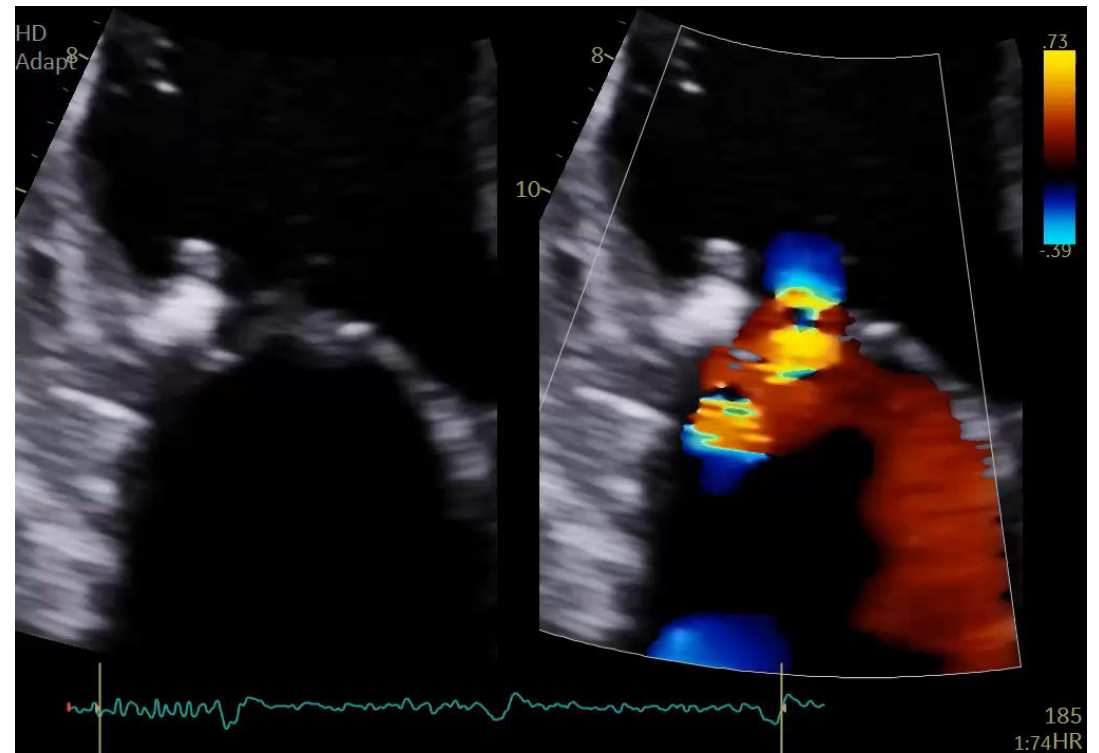
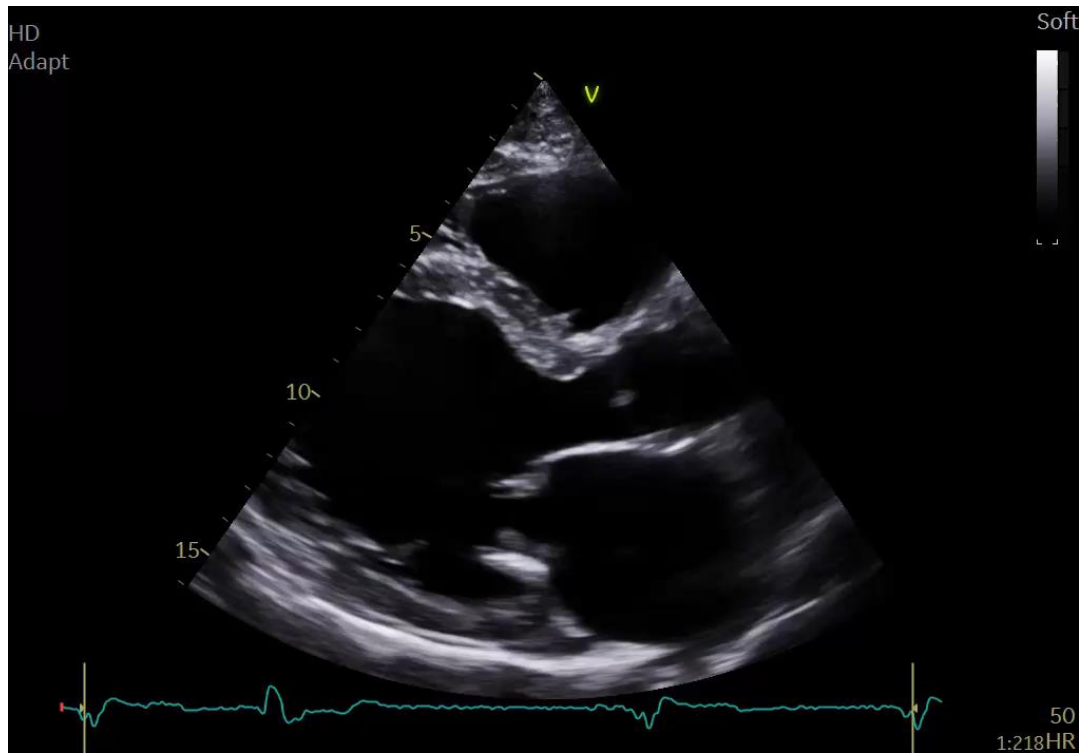
TAPSE 2.3 cm

# Echo – Mechanism of MR

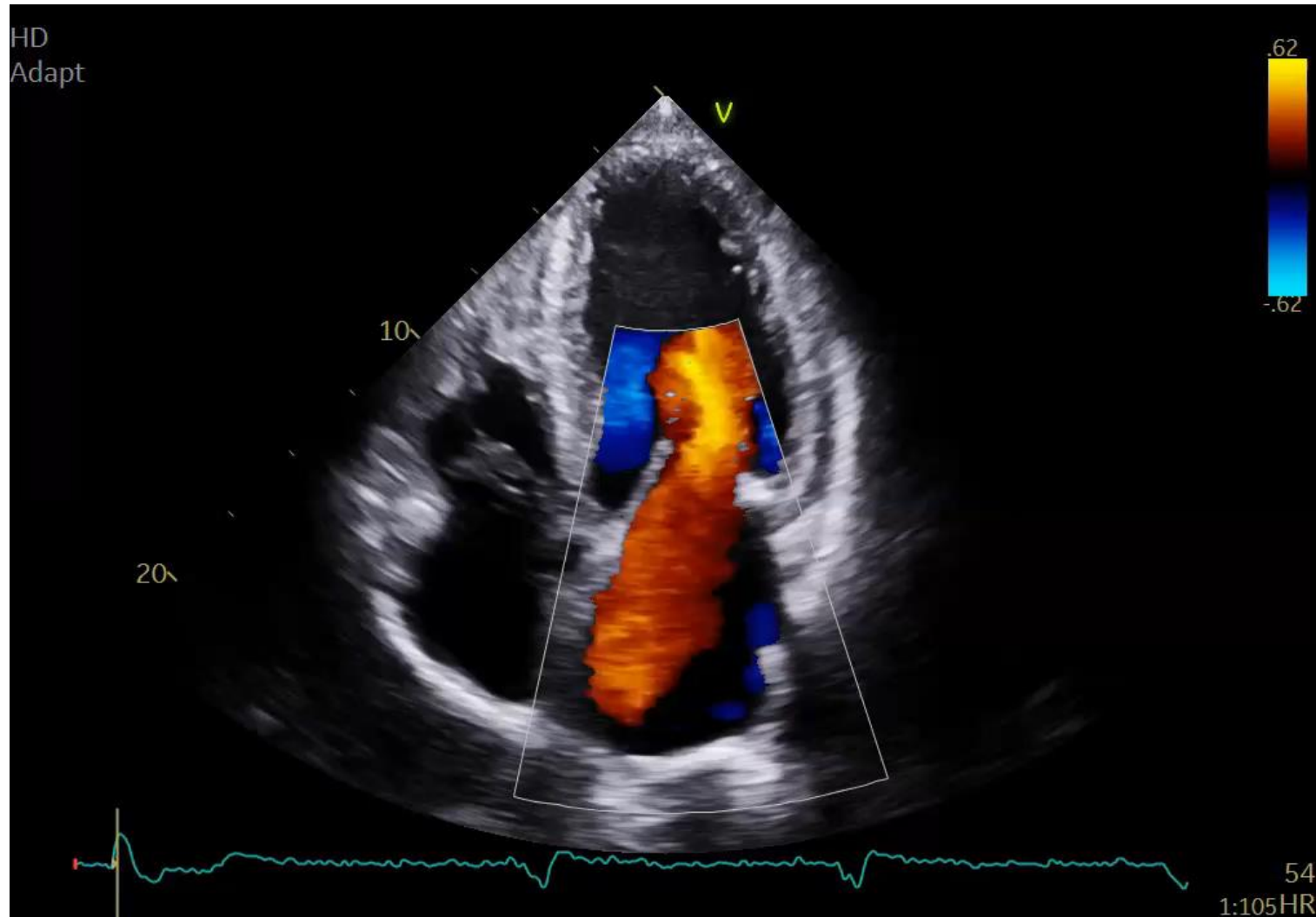
DMR

TTE (2/14/2024)

Likely Carpentier Class II due to anterior MV leaflet prolapse  
Likely due to elongation of the posterior papillary muscle



# Echo – MR Grade



**MR Grade**

TTE (2/14/2024)

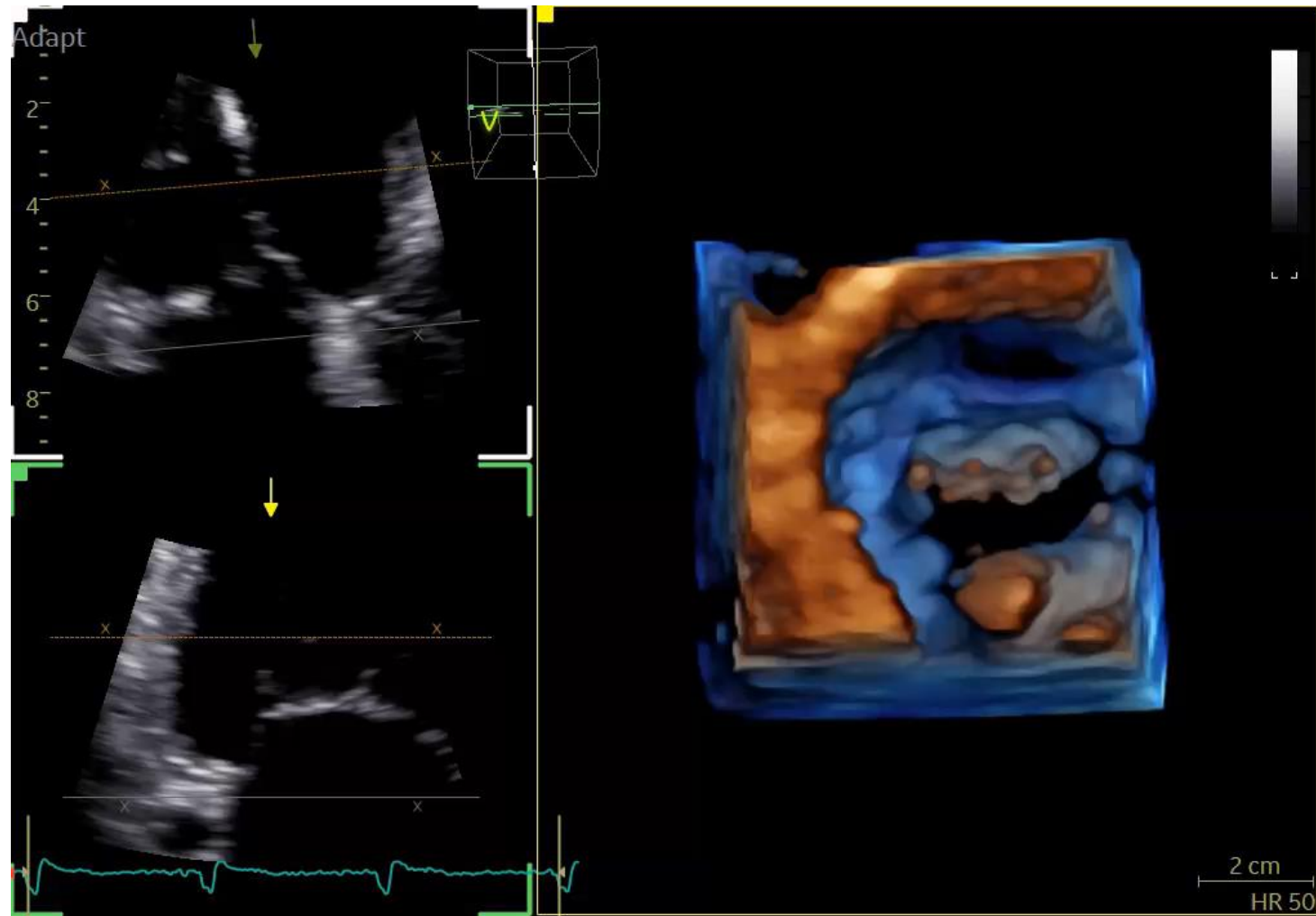
Grade 4+

Regurg Vol = 82 mL

Regurg Frac = 46%

EROA = 0.37 cm<sup>2</sup>

# Echo – 3D TTE



# Echo – LV & RV



## Measurements

TTE (2/14/2024)

EDD = 6.8 cm

ESD = 5.3 cm

IVS=1.0 cm

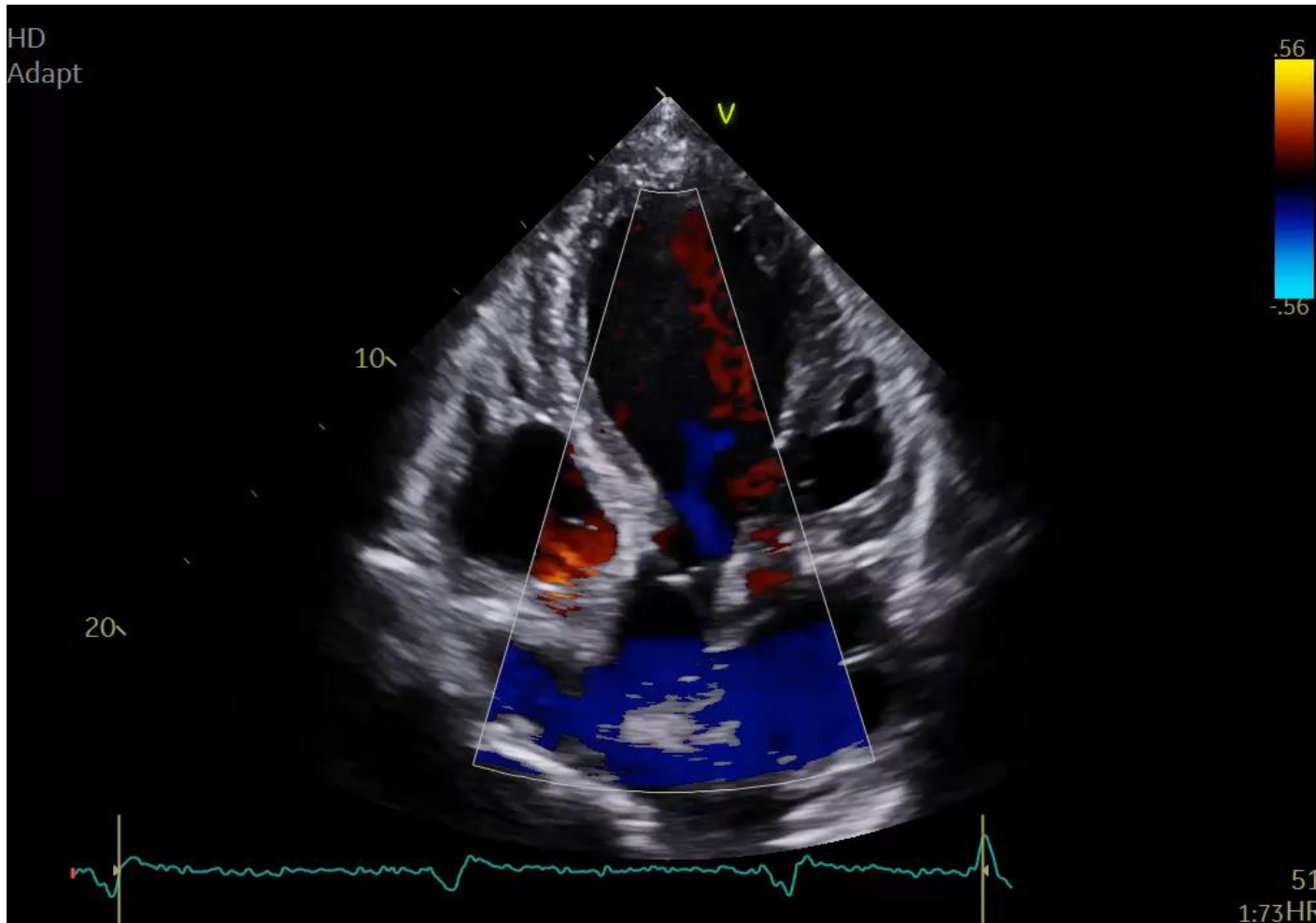
LVPW=0.9 cm

LVEDV = 317 mL

LVEF = 40%

RV Size and Function:  
Mildly dilated, normal function

# Echo – Aortic Valve



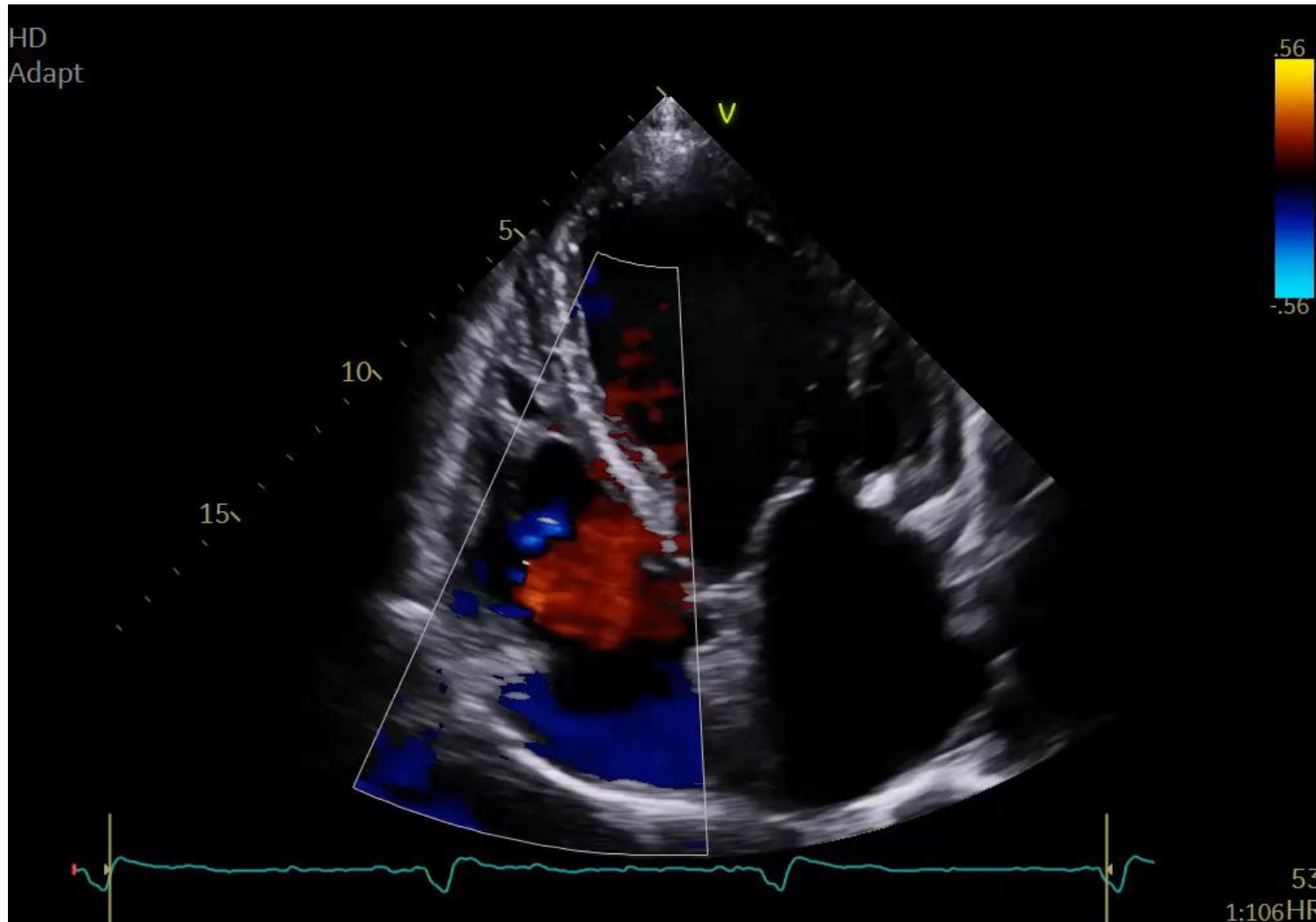
## Measurements

TTE (2/14/2024)

AR: trace

AS: none

# Echo – Tricuspid Valve



## Measurements

TTE (2/14/2024)

TR Grade: 1+

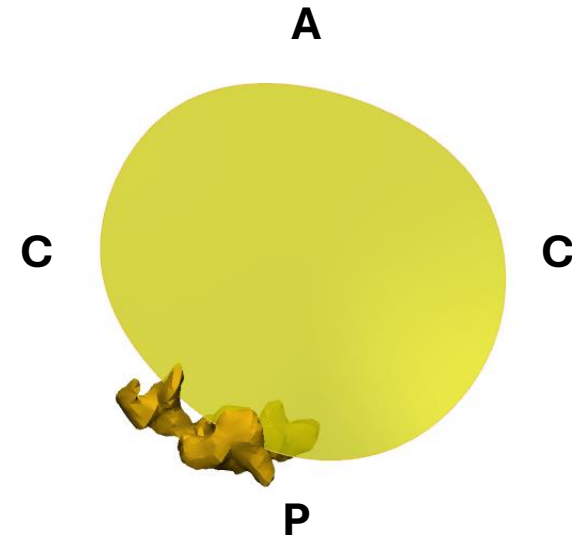
Stenosis: none

PASP= 33 mmHg

Tricuspid Annulus  
diameter=5.0 cm

# Mitral Annulus Sizing

Parameter	Diastole	Systole
AP Diameter (mm)	43.1	39.4
CC Diameter (mm)	44.7	42.5
Avg. Diameter (mm)	43.9	41.0
Ellipse Ratio	0.96	0.93
Perimeter (mm)	142.1	132.2
Area (mm <sup>2</sup> )	1529	1329

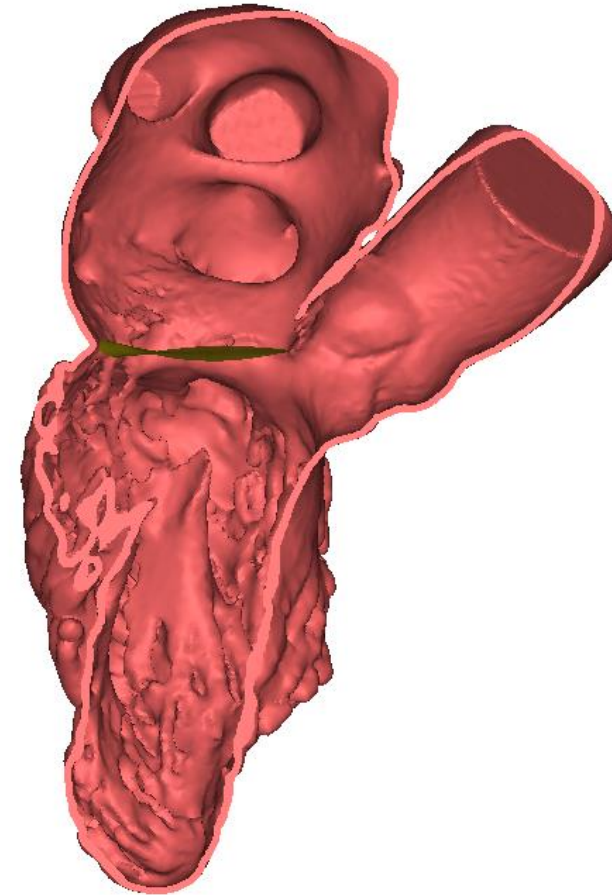


Parameter	OS
AP Diameter	37%
CC Diameter	27%
Perimeter	28%
Area	72%

OS calculations based on 54mm annular ring in systole

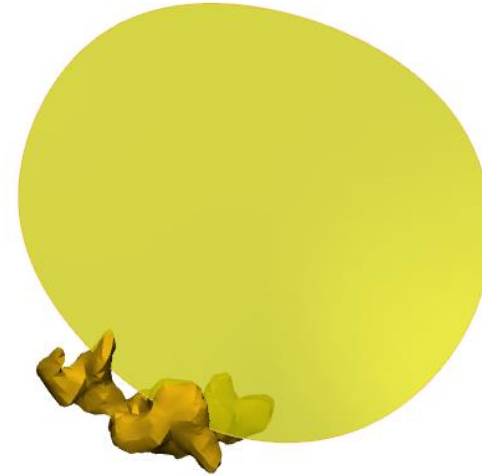
# Left Ventricle Analysis

Parameter	Measurement
LVED Volume (cc)	340
LVES Volume (cc)	226
LVEF (%): CT	34%
LVEDD (mm)	65
LA Tilt Angle	23°
Aorta-Mitral Angle	133°

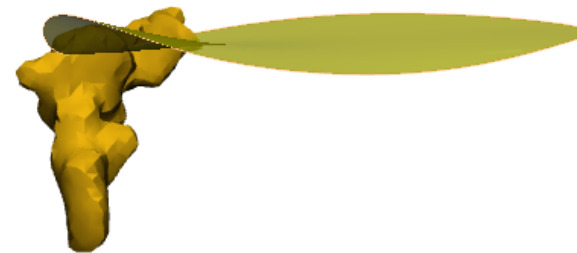


# Mitral Annulus Calcium (MAC)

Parameter	Measurement
MAC Severity	Mild
MAC Coverage (deg)	60
MAC Volume (cc)	0.5
MAC Depth (mm)	16
MAC Protrusion (mm)	N/A



**MAC (Surgeon View)**



**MAC (AP View)**

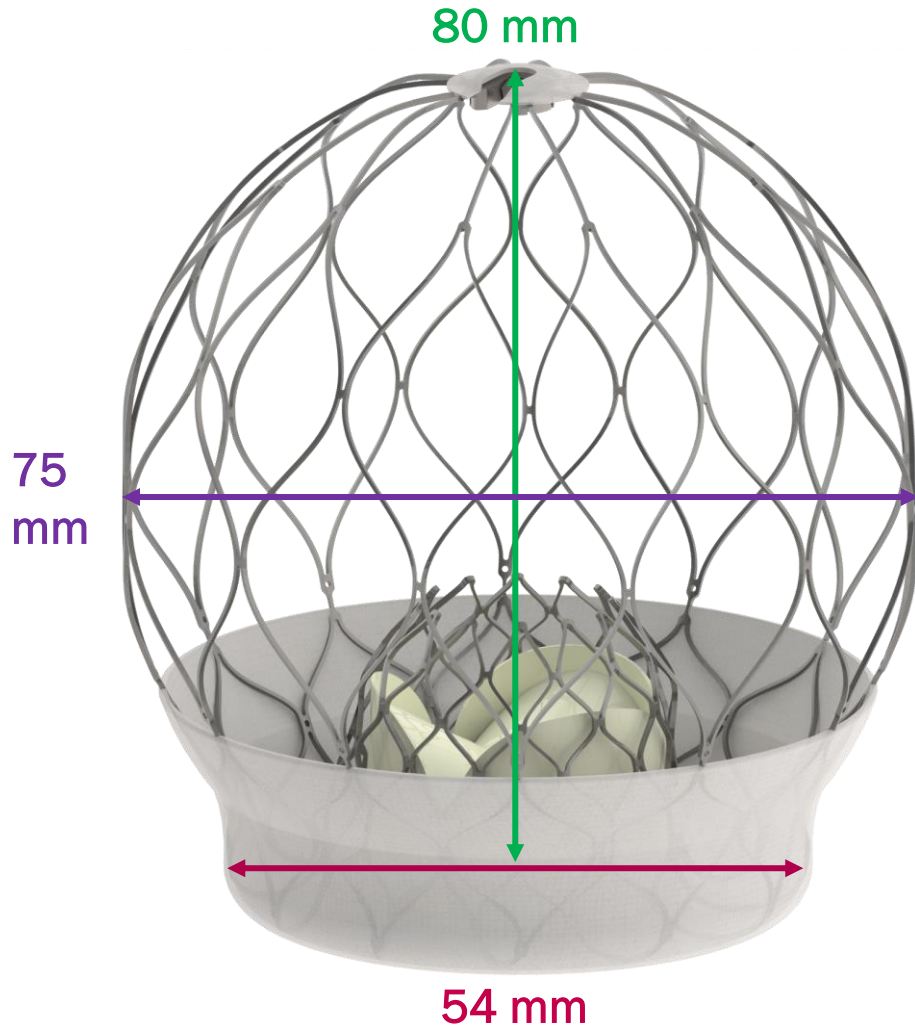
# Left Atrium Dynamics

Parameter	Diastole	Systole
LA Height (mm)	68.7	74.2
LA Width: AP (mm)	59.2	61.4
LA Width: SL (mm)	64.8	65.4
LA Width (Average)	62.0	63.4
LA Ellipse Ratio	0.92	0.94
LA Volume (mL)	171.2	187.1
LA Volume Change (%)	9.2%	
Mitral Valve Motion (mm)	6.3	



*Red: Systole*  
*Blue: Diastole*

# AltaValve Sizing



## OVERSIZING ANALYSIS

**Implant Size (80 x 75 x 54)**  
**(80 mm Tall, 75 mm Wide, 54 mm Ann. Ring)**

LA Height 8% - 16%

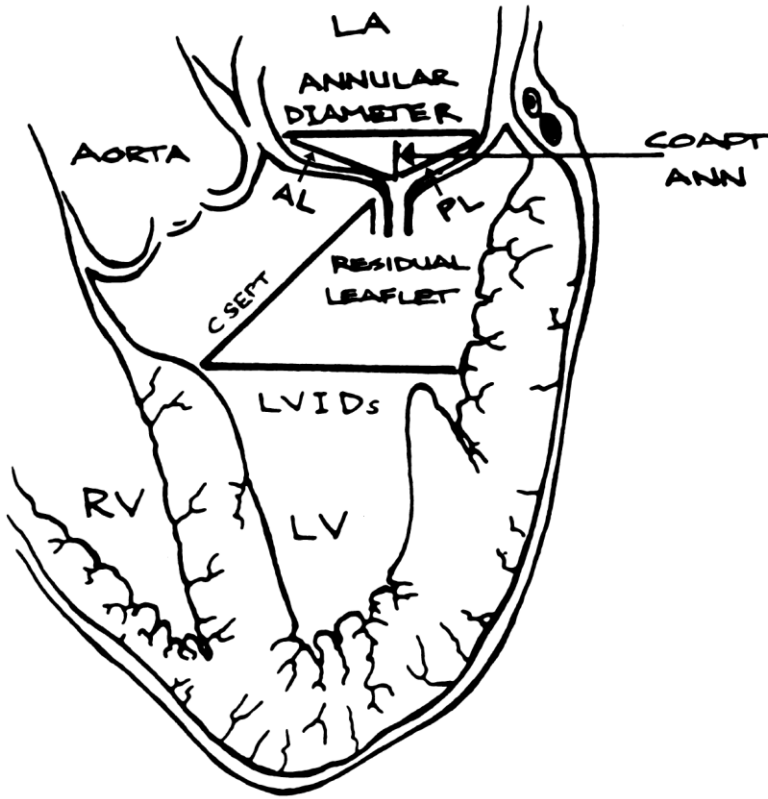
LA Width 18% - 21%

MV Perimeter: Systole 28%

MV Area: Systole 72%

# Risk Factors for SAM

Maslow et al. (1999)

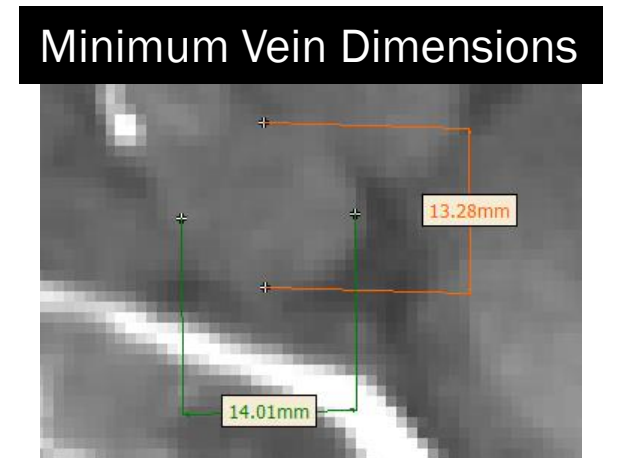
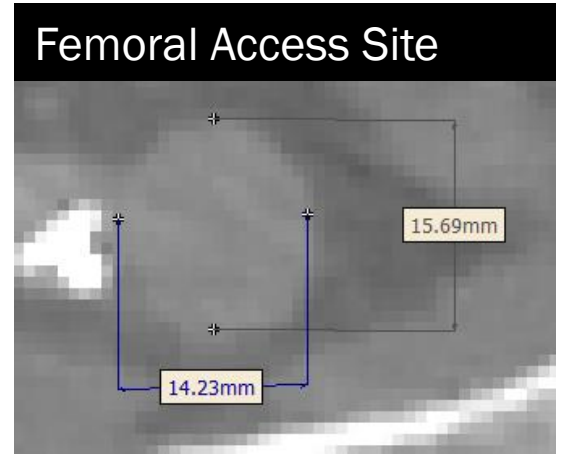
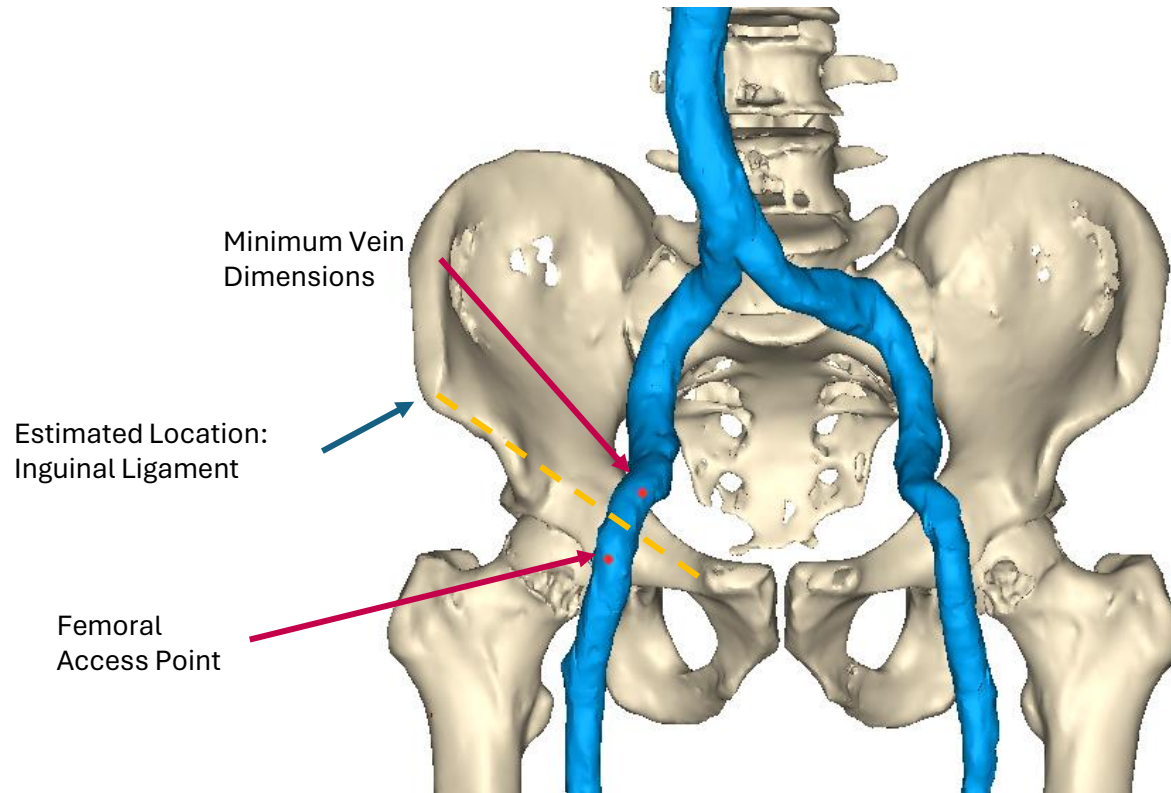


Varghese et al. (2014)

PARAMETER	RISK DEFINITION	THE-019
LVEDD	< 45mm	65
LVEDS	< 25mm	52
Septal Bulge Thickness	> 15mm	15
Coap. to Septal Wall Dist.	< 25mm	36
Anterior Leaflet Length	-	24
Posterior Leaflet Length	> 15mm	12
Aorta Mitral Angle	< 120°	133°

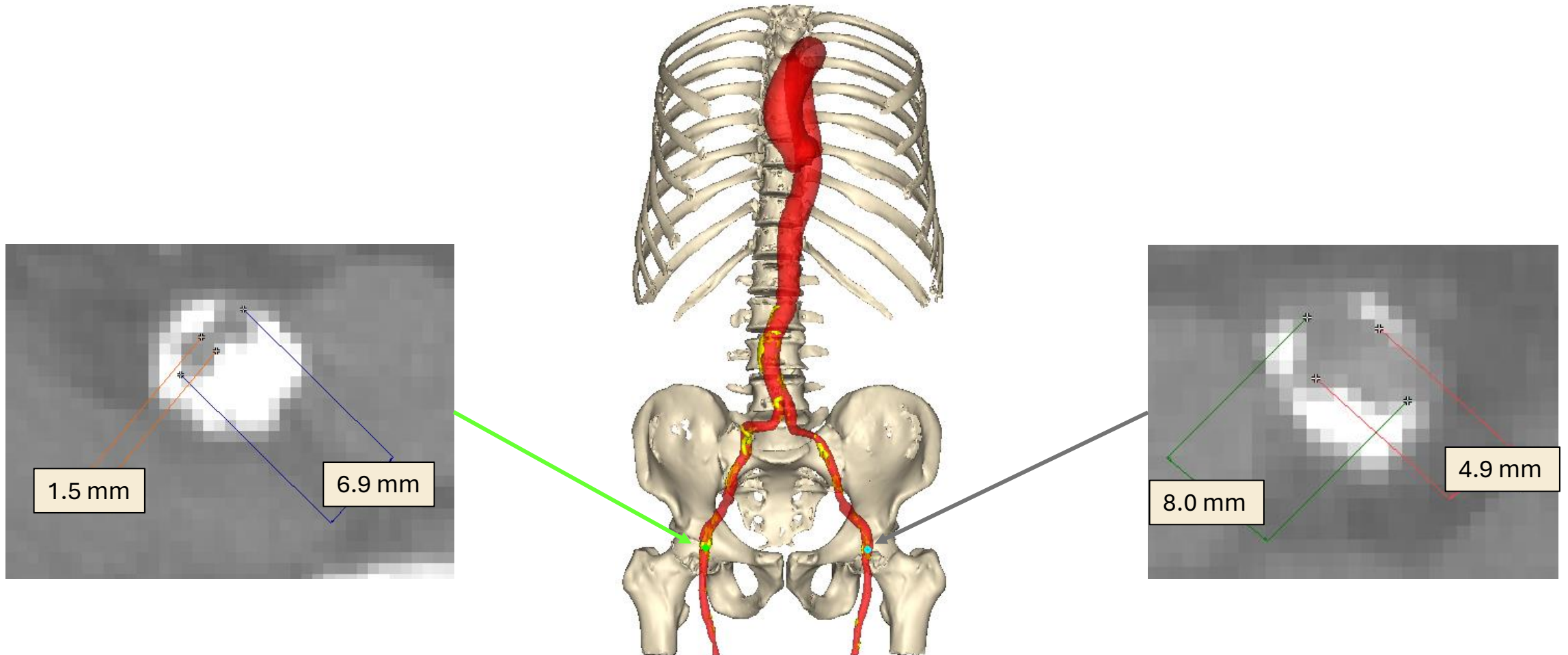
# Femoral Vasculature

*Pathway not tortuous; dimensions acceptable*



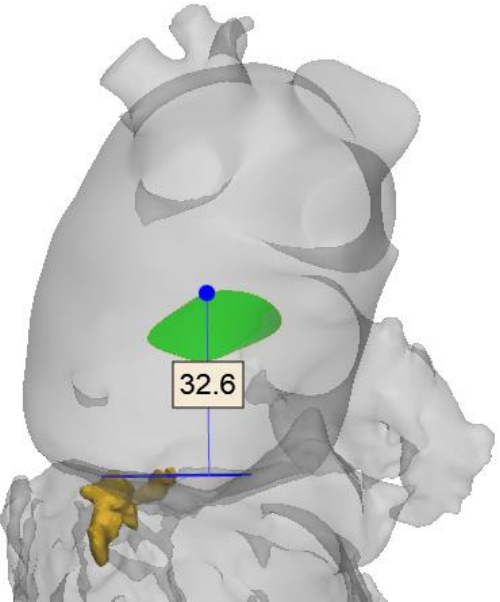
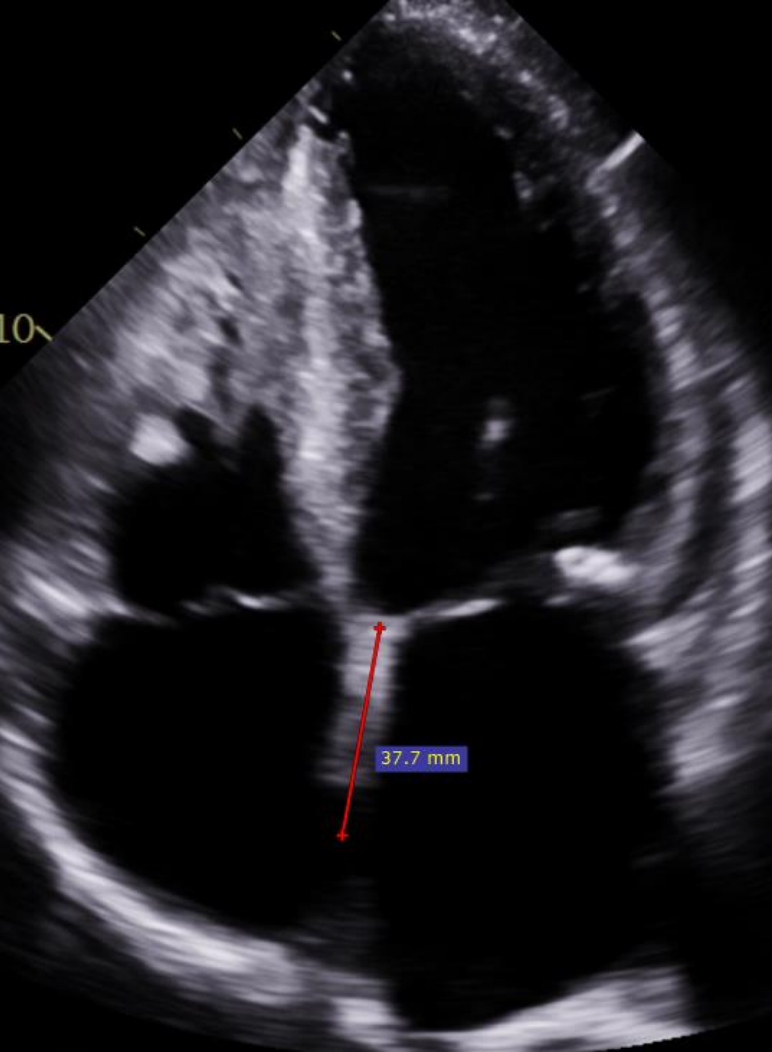
# Arterial Access

*Right femoral artery has major calcific constriction*



# Septal Access

IMAGING MODALITY	SEPTAL HEIGHT (cm)
TTE	3.7
CT	3.2



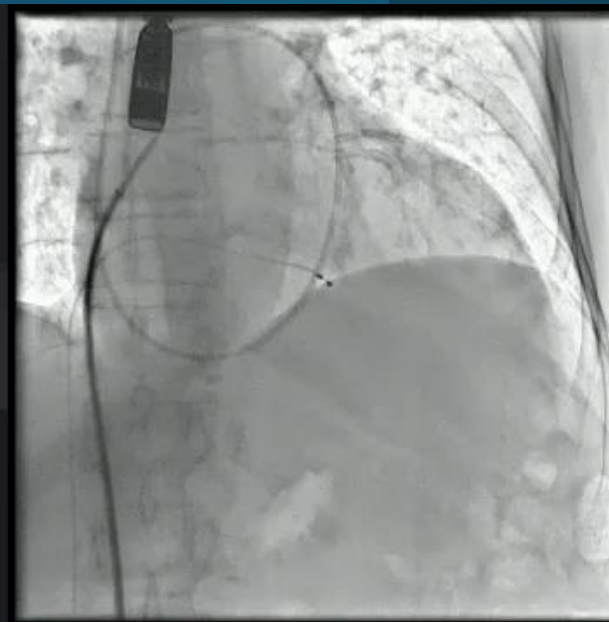
*Goal*

- Posterior Puncture
- Puncture range: 3-4 cm

# Recorded live case set up

- Primary axis right femoral vein
- left femoral artery for arterial pressure and potential IABP access
- Left femoral vein for temporary pacemaker
- Right radial artery for LV pressure monitoring (pig tail)
- RIJ for central venous access and PA pressure monitoring
- 4D TEE monitoring

FULLY PERCUTANEOUS APPROACH



OneView

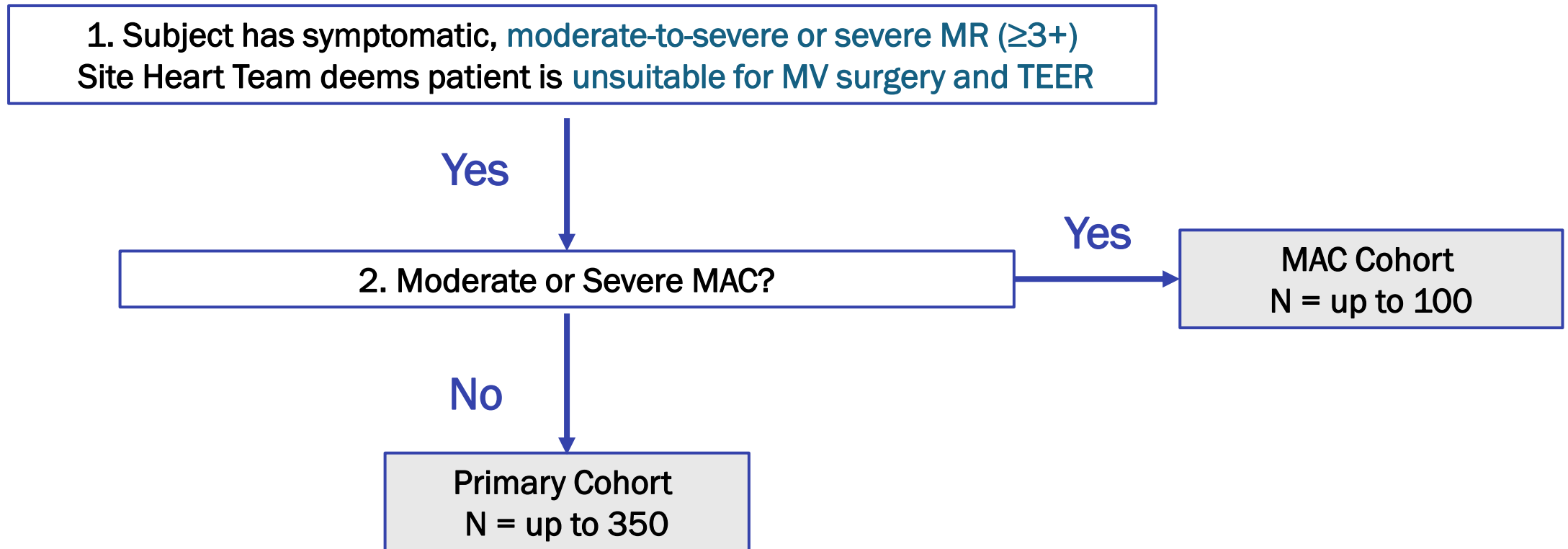


# Immediate ECHO outcome



# AltaValve Pivotal Trial Overview

- Targeted to initiate enrollment in mid 2024 in Europe and US
- Only TS system is planned to be utilized in the trial



# THANK YOU!



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