Transcatheter Mitral Options for Mitral Annular Calcification

Abhijeet Dhoble, MD, MPH, FACC, FSCAI
Professor of Medicine
Director, Structural Heart Interventions, UT Health
Co-Director, Heart and Brain Program
UTHealth and Memorial Hermann Hospital – Texas Medical Center

UTHealth Houston
Heart & Vascular

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Disclosures

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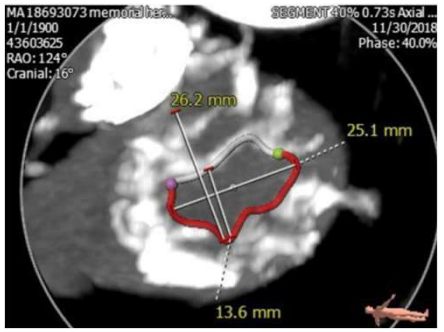
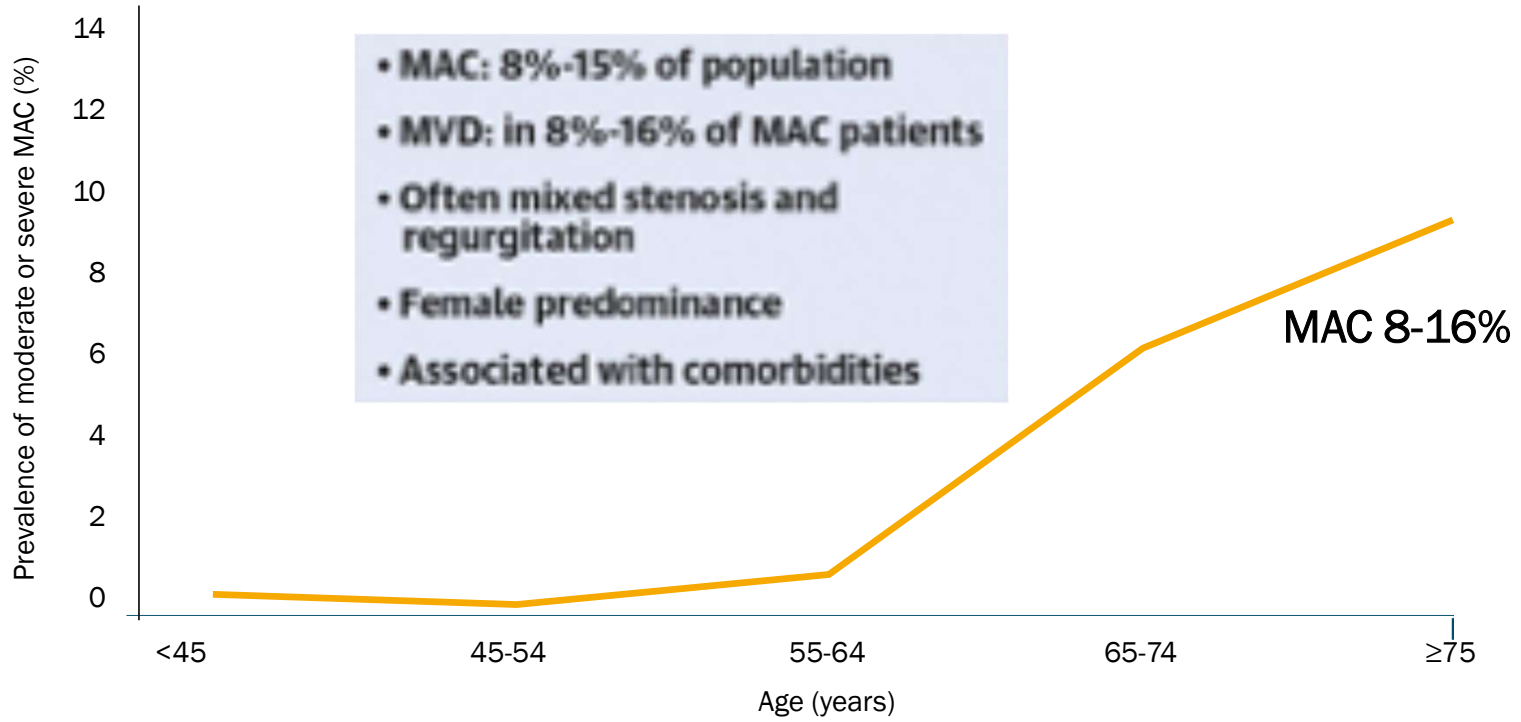
Mitral Annular Calcification

- Mitral annular calcification is an overall poor marker of health (unknown reasons)
  - The Framingham Heart Study showed increased CV mortality
- We still do not have good transcatheter options
- Medical management until severe symptoms develop
- **The heart team** can sometimes formulate a hybrid approach / clinical trial / off-label treatment



Katz R, et al. Framingham Heart Study…Circulation. 1999;99:2685–2690.

Prevalence of Mitral Annular Calcification



Churchill TW et al. JACC. 2023; 80(7):739–751.

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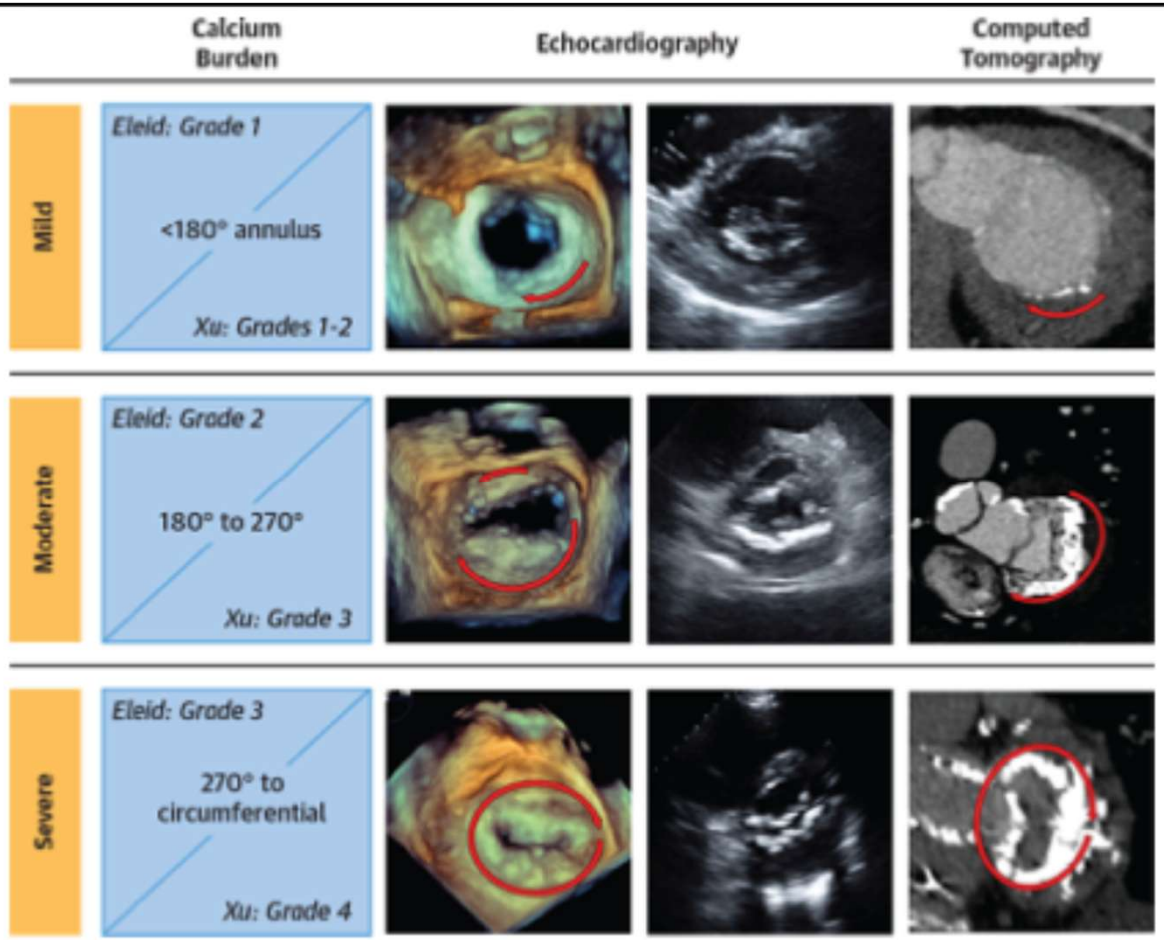
Mitral Stenosis/Regurgitation due to Calcification

- Usually mixed disease (MS + MR)
  - Isolated severe MS or MR is possible, but not common
- Patients typically not suitable for mitral TEER
- Valve replacement usually high risk
  - Surgical
  - Transcatheter

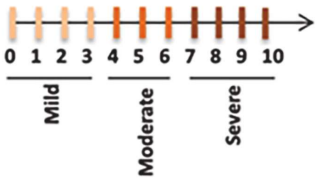
Churchill TW et al. JACC. 2023; 80(7):739–751.

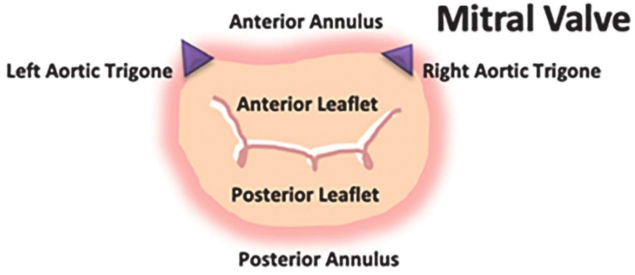
MAC Classification

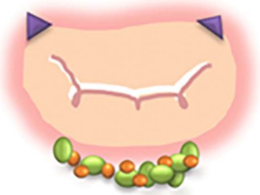
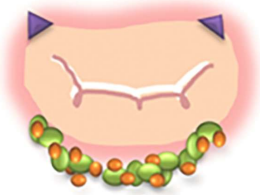
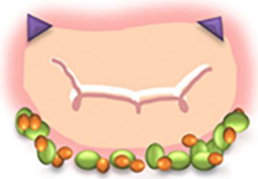
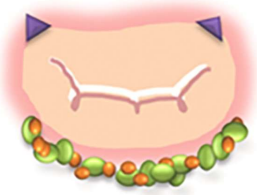
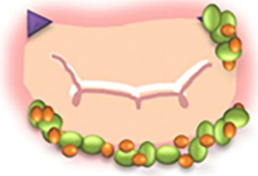
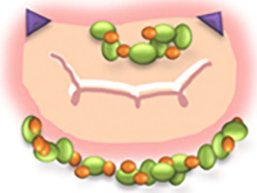
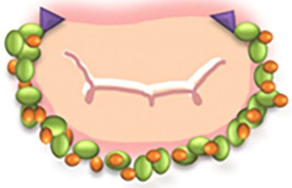
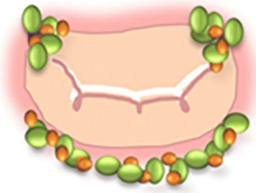
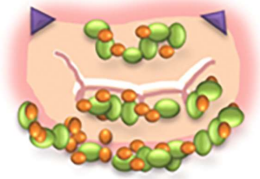


Eleid MF et al. JACC Imaging. 2016

CT-Based MAC Score





I. Calcium Thickness	II. Calcium Distribution	III. Trigone Involvement	IV. Leaflet Involvement
			
<5mm=1	<180°=1	None=0	None=0
			
5-9.99mm=2	180-270°=2	One=1	One Leaflet=1
			
≥ 10mm=3	>270°=3	Both=2	Both Leaflets=2

Guerrera M et al. JACC Img. 2020

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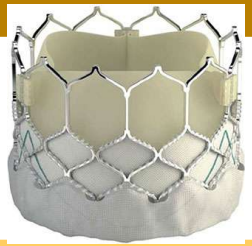
Surgical MVR for MAC

- MAC Attack – Acute surgical complications
- Poor outcomes
- High risk for PVL

Churchill TW et al. JACC. 2023; 80(7):739–751.

Transcatheter Mitral Valve Replacement With Sapien Valve (TMVR)



Mitral Valve-in-MAC

(NOT Approved)

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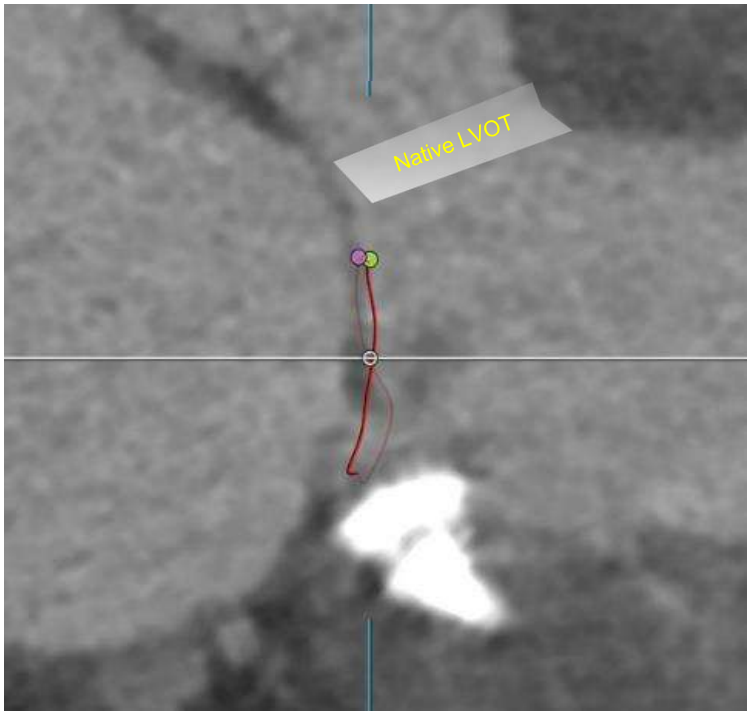
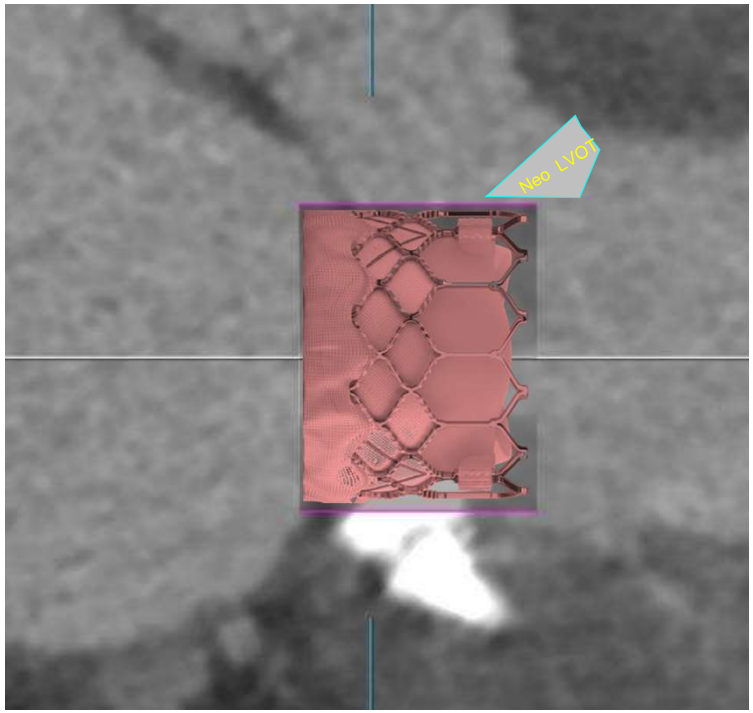
LVOT Obstruction – Major determinant





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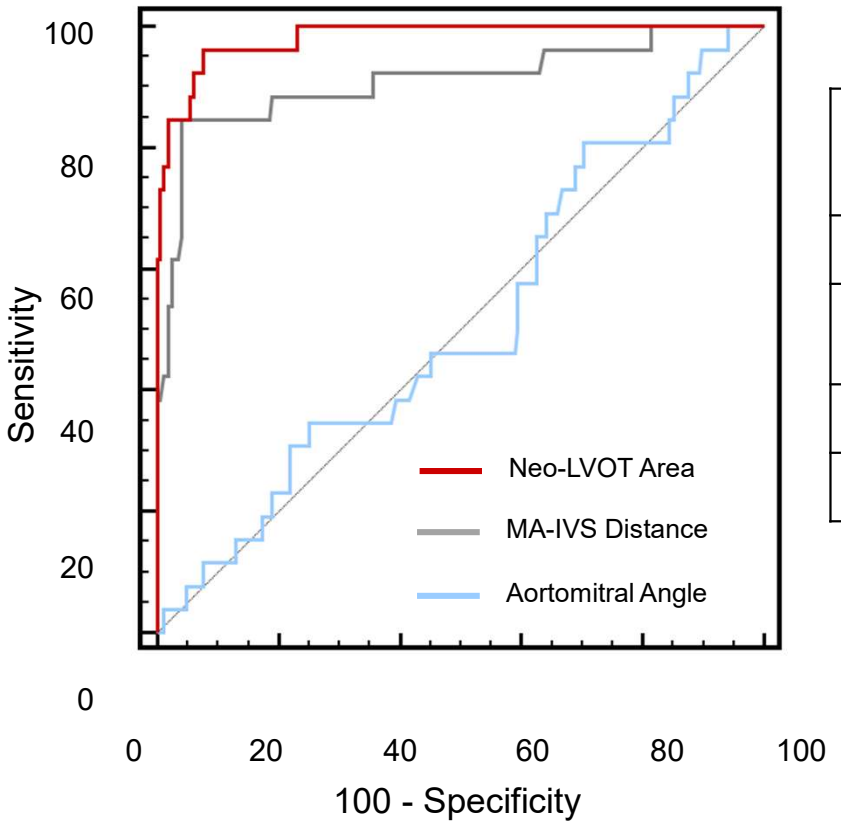
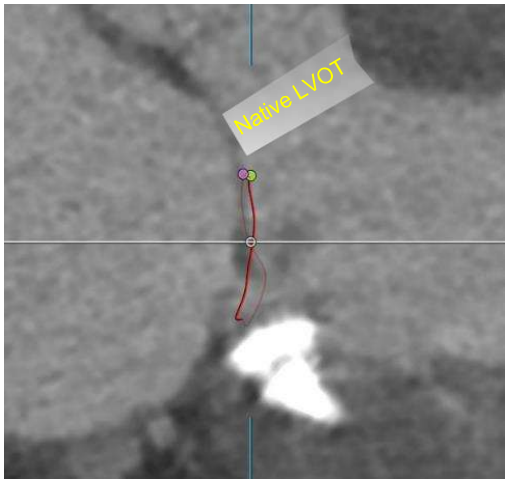
LVOT Obstruction and Prediction

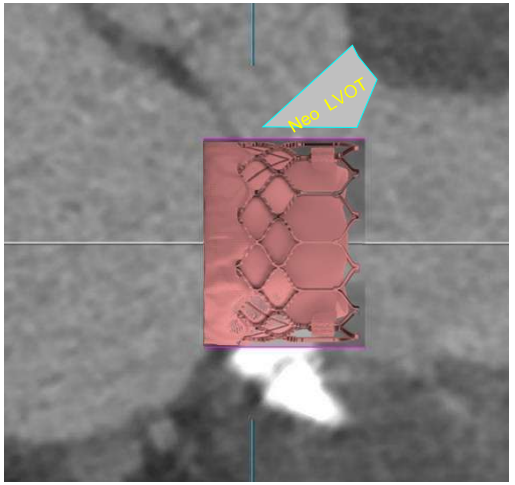


	Neo-LVOT Area	MA-IVS Distance	Aortomitral Angle
• AUC	• **0.98**	• **0.91**	• **0.53**
• Cut-off	• **170 mm²**	• **17.8 mm**	• **–**
Sensitivity	• **96%**	• **85%**	**–**
Specificity	• **92%**	• **96%**	**–**

$p < 0.001$

$p = 0.047$

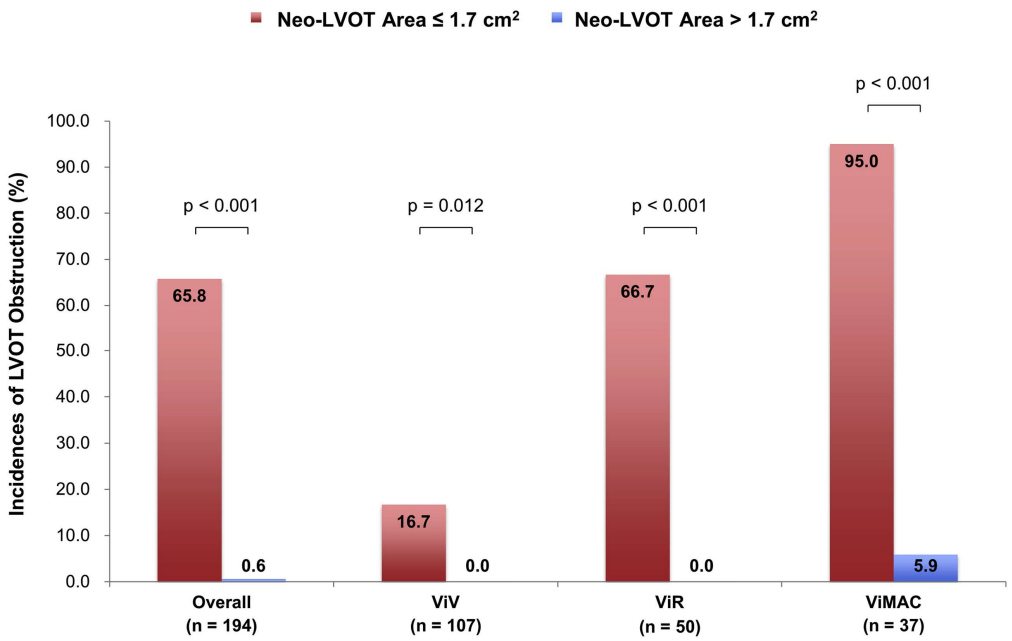




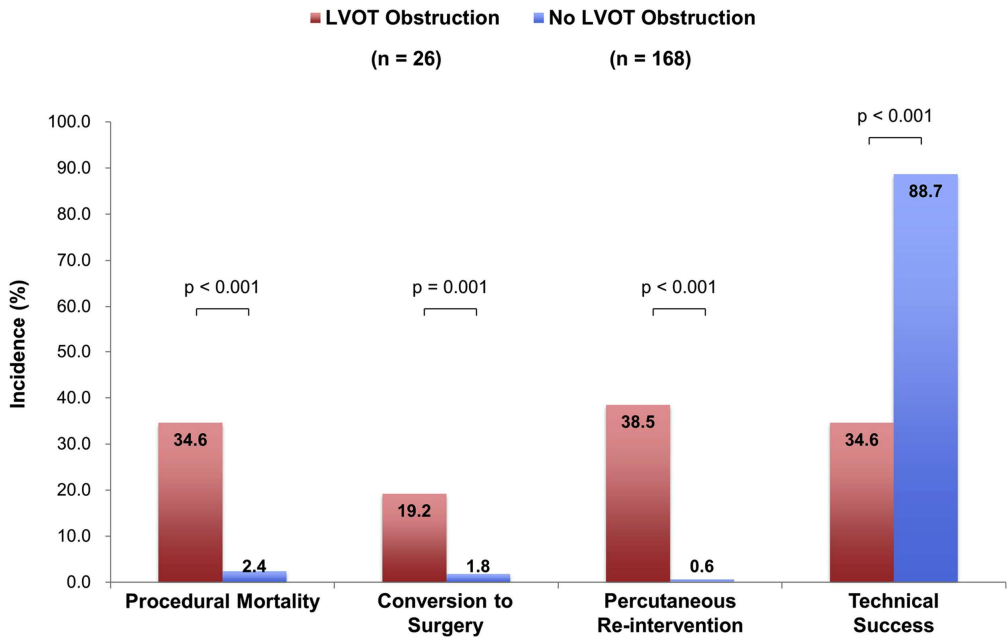
Yoon SH, .. Dhoble A et al. JACC Card Intv. 2019 Jan 28;12(2):182-193

How LVOT Obstruction Affect TMVR Procedures

Frequencies of LVOT Obstruction



Outcomes of LVOT Obstruction



Yoon SH, Whisenant BK, Bleiziffer S, Delgado V, …. Dhoble A et al. JACC Card Intv. 2019 Jan 28;12(2):182-193

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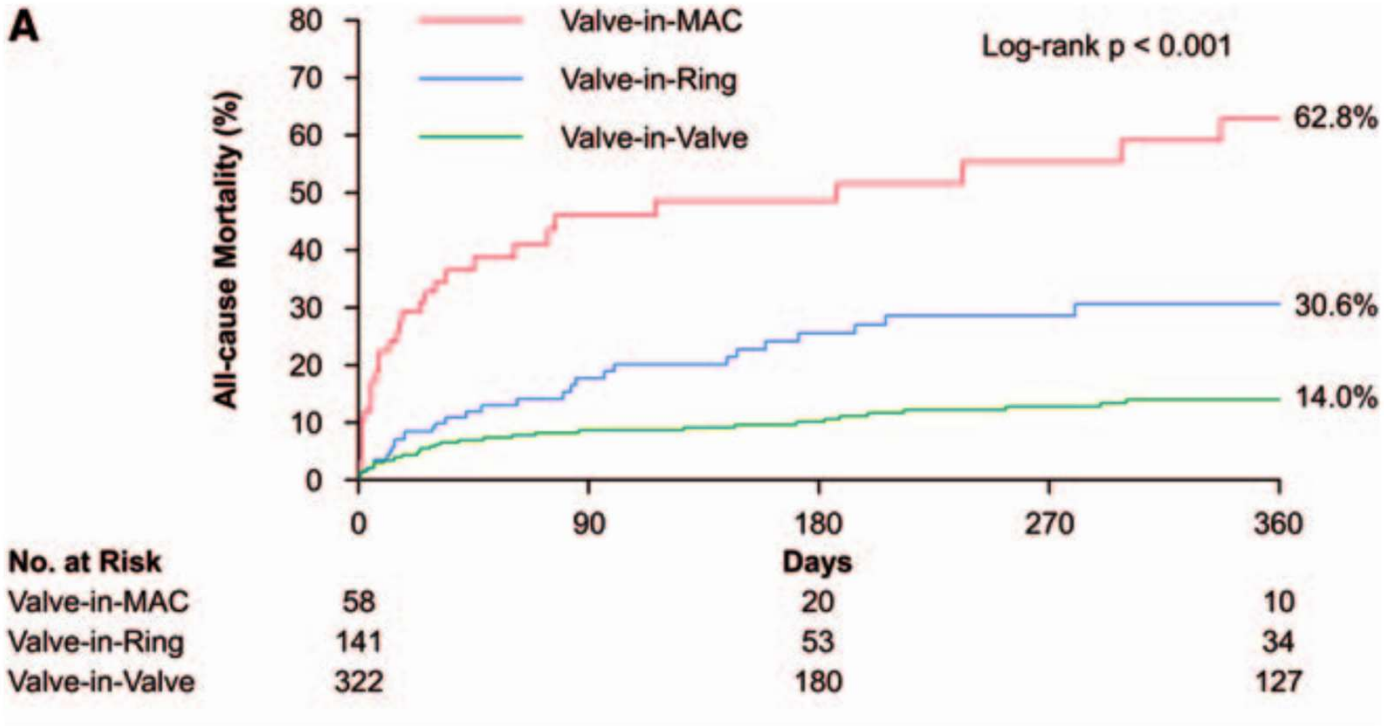
Outcomes of TMVR with Sapien valve



Independent predictors of mortality: STS score, COPD, prior ring or MAC

Yoon SH, ..Dhoble A et al. Eur Heart J. 2019 Feb 1;40(5):441-451.

Adjuvant Therapies to facilitate TMVR

Leaflet Modification

- Lampoon
- Batman

Septal Reduction

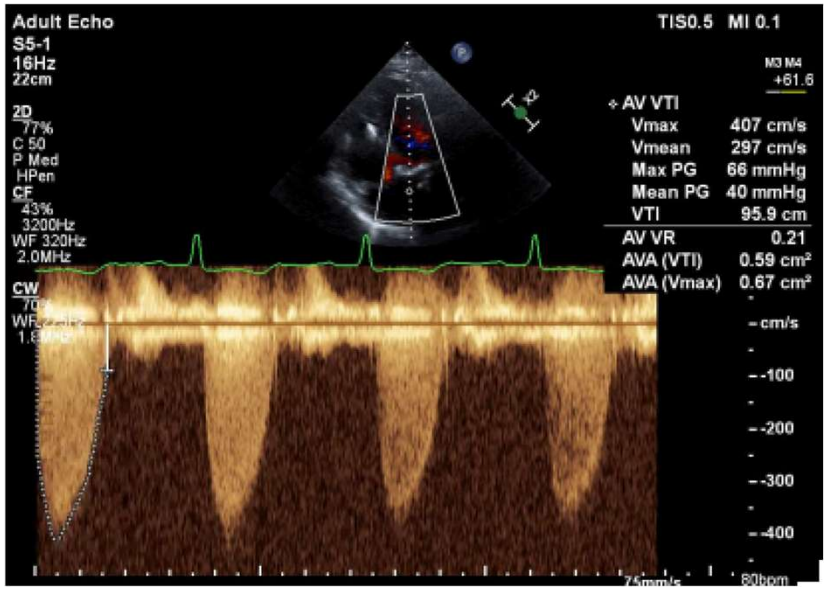
- Alcohol septal ablation
- Seasame

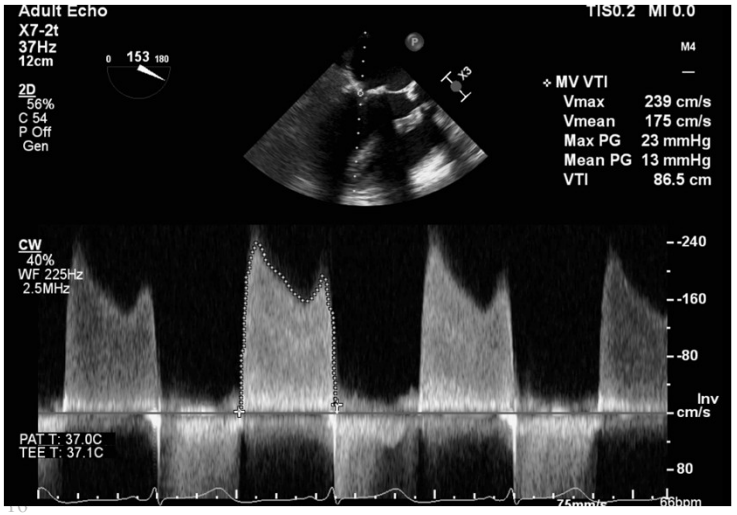
Calcium modification

- PMBV
- Lithotripsy

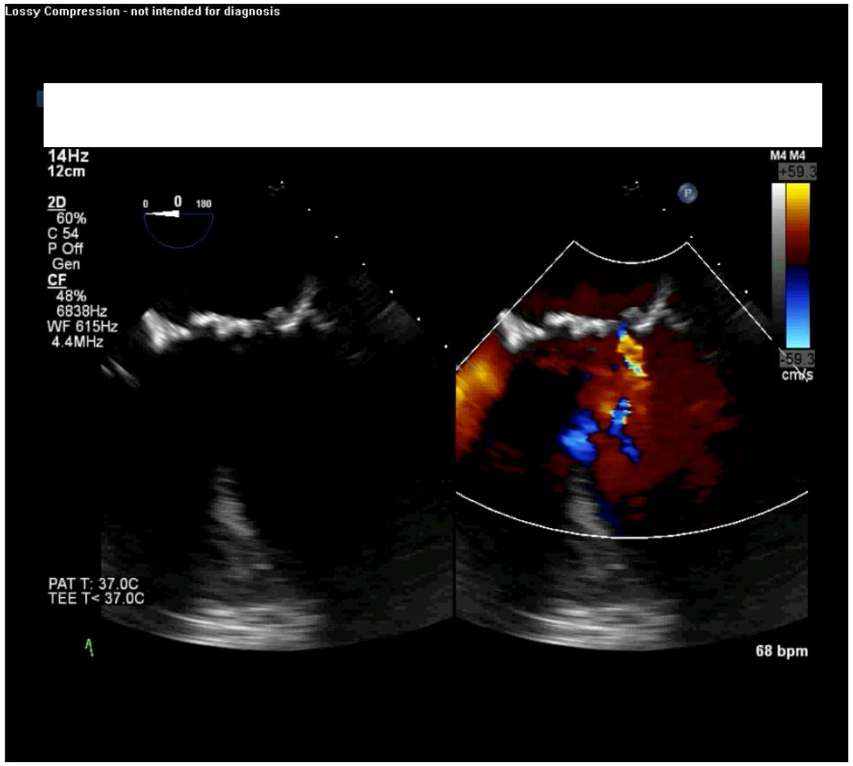
SEVERE AS + MS

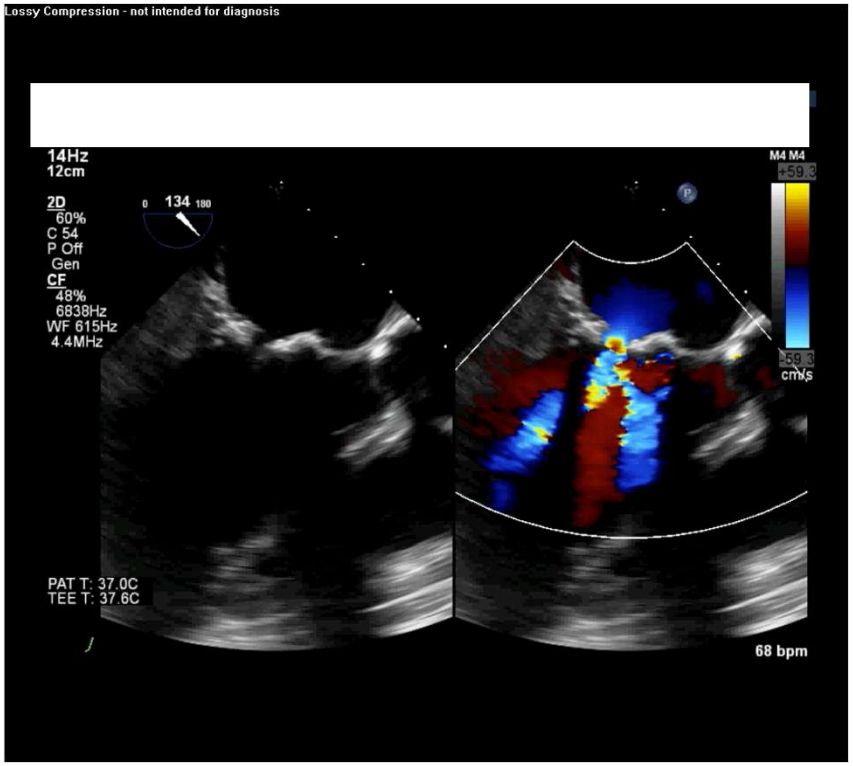
- 73 years old woman with CAD, PVD, HTN, HLP, DM-2, OSA, and morbid obesity (BMI 49). Severe calcific AS + MS
- <u>STS:</u> AVR + MVR:10.8%
- <u>Symptoms:</u> DOE and chest pain (NYHA IV, CCS I)
- GFR 47
- LVEF 65%



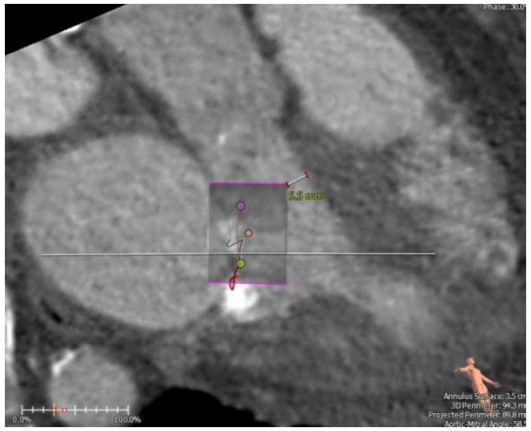


TEE

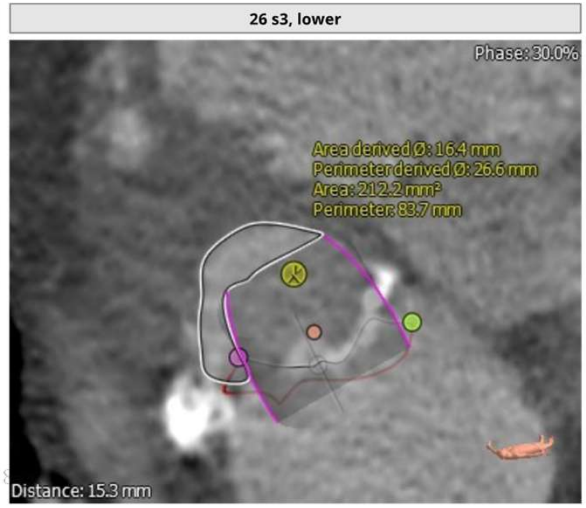

Lossy Compression - not intended for diagnosis
14Hz
12cm
2D
60%
C 54
P Off
Gen
CF
48%
6838Hz
WF 615Hz
4.4MHz
M4 M4
+59.3
-59.3
cm/s
PAT T: 37.0C
TEE T< 37.0C
68 bpm


Lossy Compression - not intended for diagnosis
14Hz
12cm
2D
60%
C 54
P Off
Gen
CF
48%
6838Hz
WF 615Hz
4.4MHz
M4 M4
+59.3
-59.3
cm/s
PAT T: 37.0C
TEE T: 37.6C
68 bpm

Cardiac CT

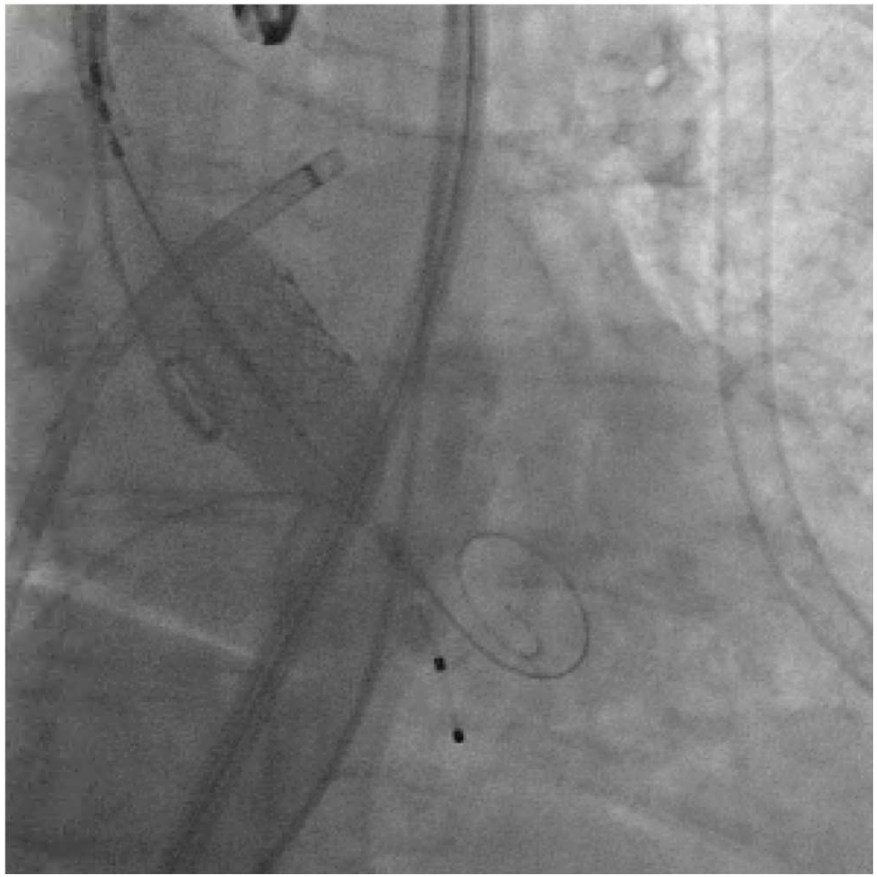



26 s3
Phase: 30.0%
Area derived Ø: 15.3 mm
Perimeter derived Ø: 28.9 mm
Area: 184.6 mm²
Perimeter: 90.8 mm
Distance: 12.3 mm

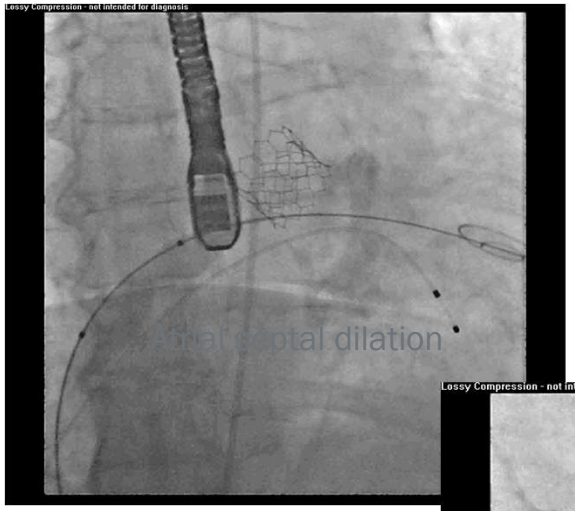

26 s3, lower
Phase: 30.0%
Area derived Ø: 16.4 mm
Perimeter derived Ø: 26.6 mm
Area: 212.2 mm²
Perimeter: 83.7 mm
Distance: 15.3 mm

Proposed Plan

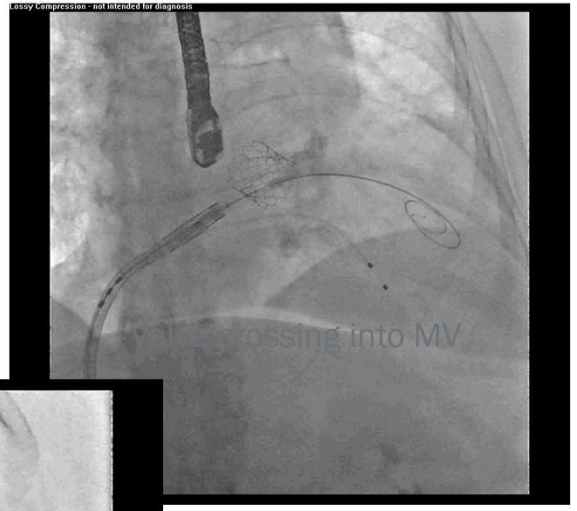
- TAVR with 23 mm S3
- TMVR with 26 mm S3 (higher placement)
- Septal ablation – as needed



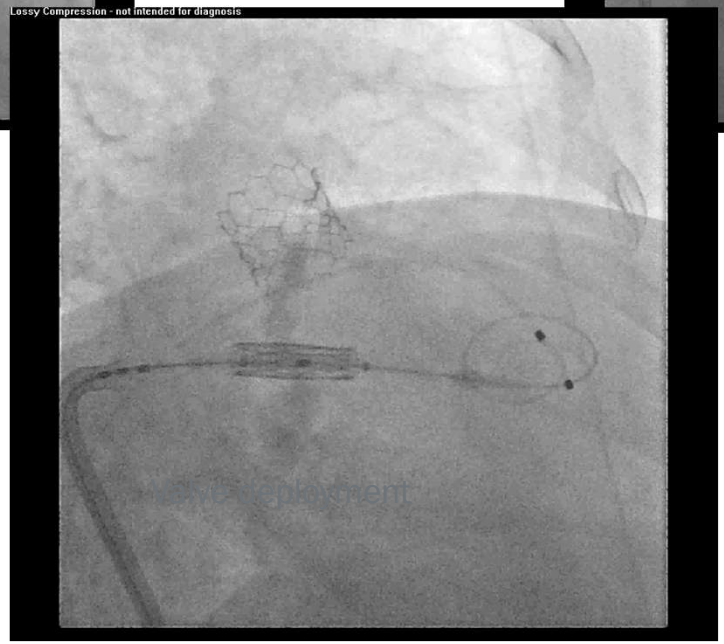
TMVR



Atrial septal dilation

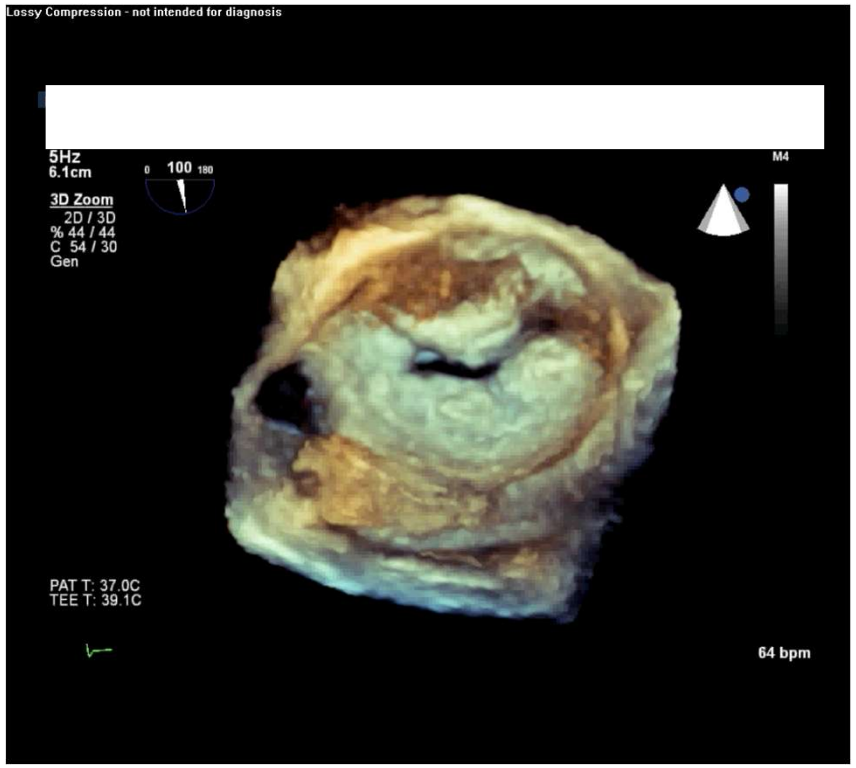


Valve crossing into MV



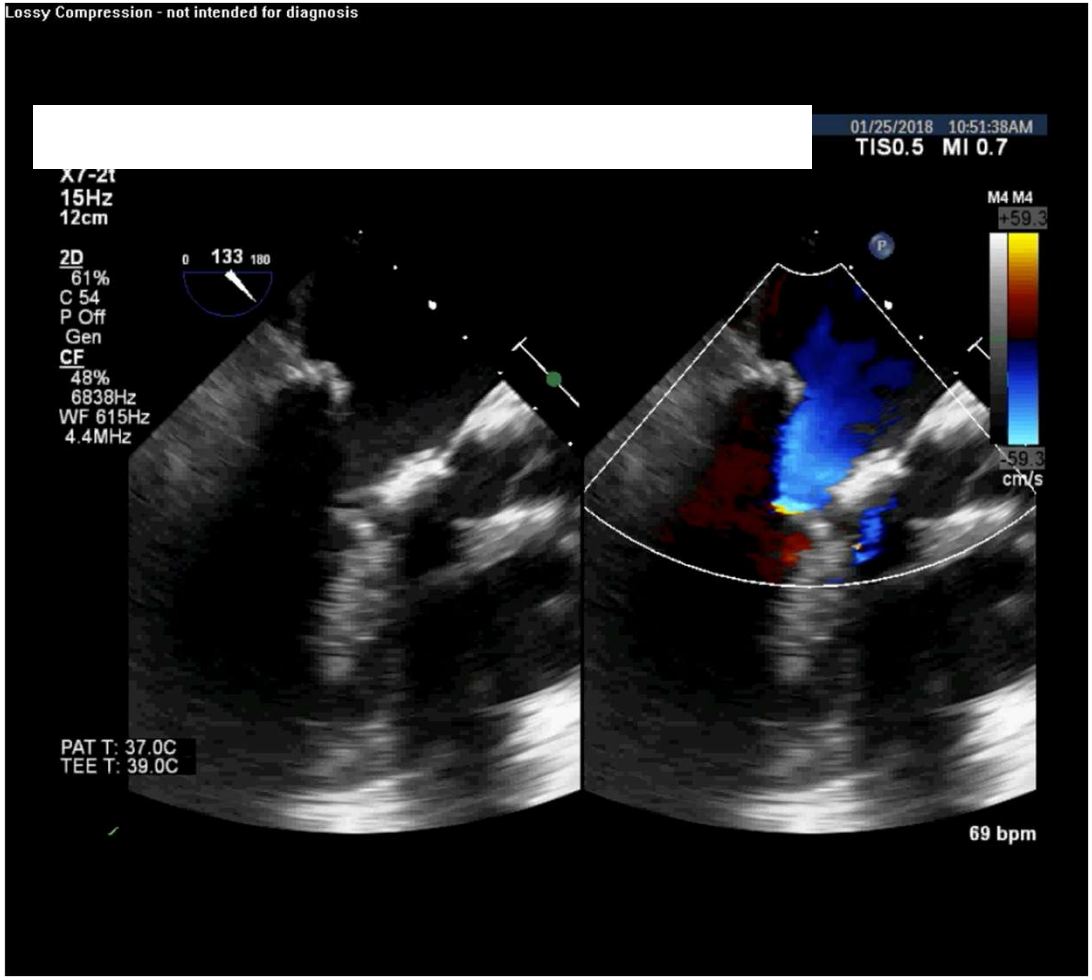
Valve deployment

3D TEE


Lossy Compression - not intended for diagnosis
5Hz
6.1cm
0 100 180
M4
3D Zoom
2D / 3D
% 44 / 44
C 54 / 30
Gen
PAT T: 37.0C
TEE T: 39.1C
64 bpm


Lossy Compression - not intended for diagnosis
6Hz
7.8cm
0 85 180
M4
3D Zoom
2D / 3D
% 52 / 44
C 54 / 30
Gen
PAT T: 37.0C
TEE T: 39.0C
77 bpm

Post TEE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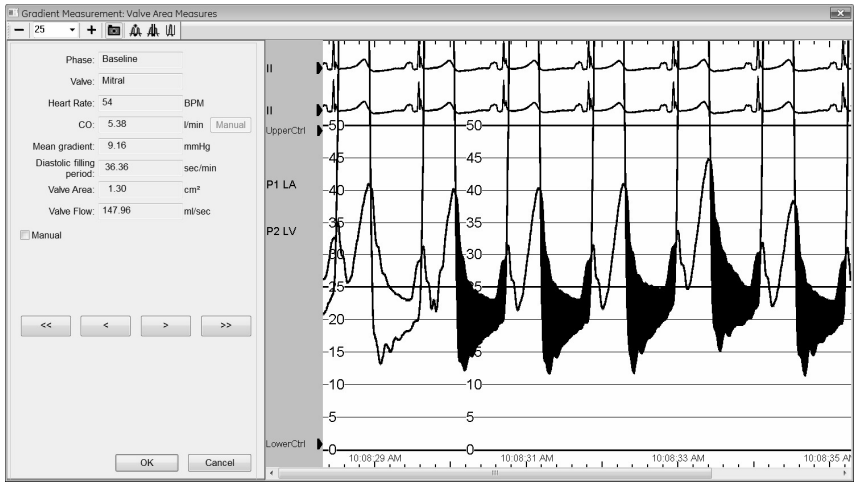
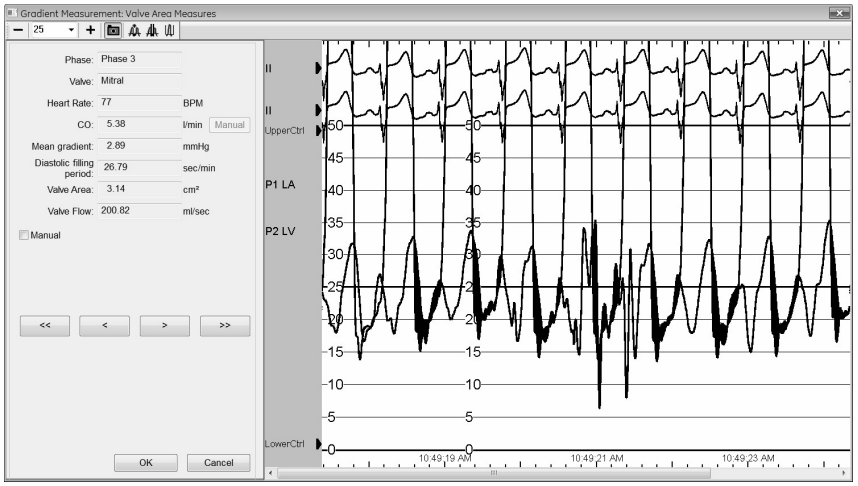
01/25/2018 10:51:38AM
TIS0.5 MI 0.7
15Hz
12cm
2D
61%
C 54
P Off
Gen
CF
48%
6838Hz
WF 615Hz
4.4MHz
0 133 180
M4 M4
+59.3
-59.3
cm/s
PAT T: 37.0C
TEE T: 39.0C
69 bpm

Mitral Hemodynamics

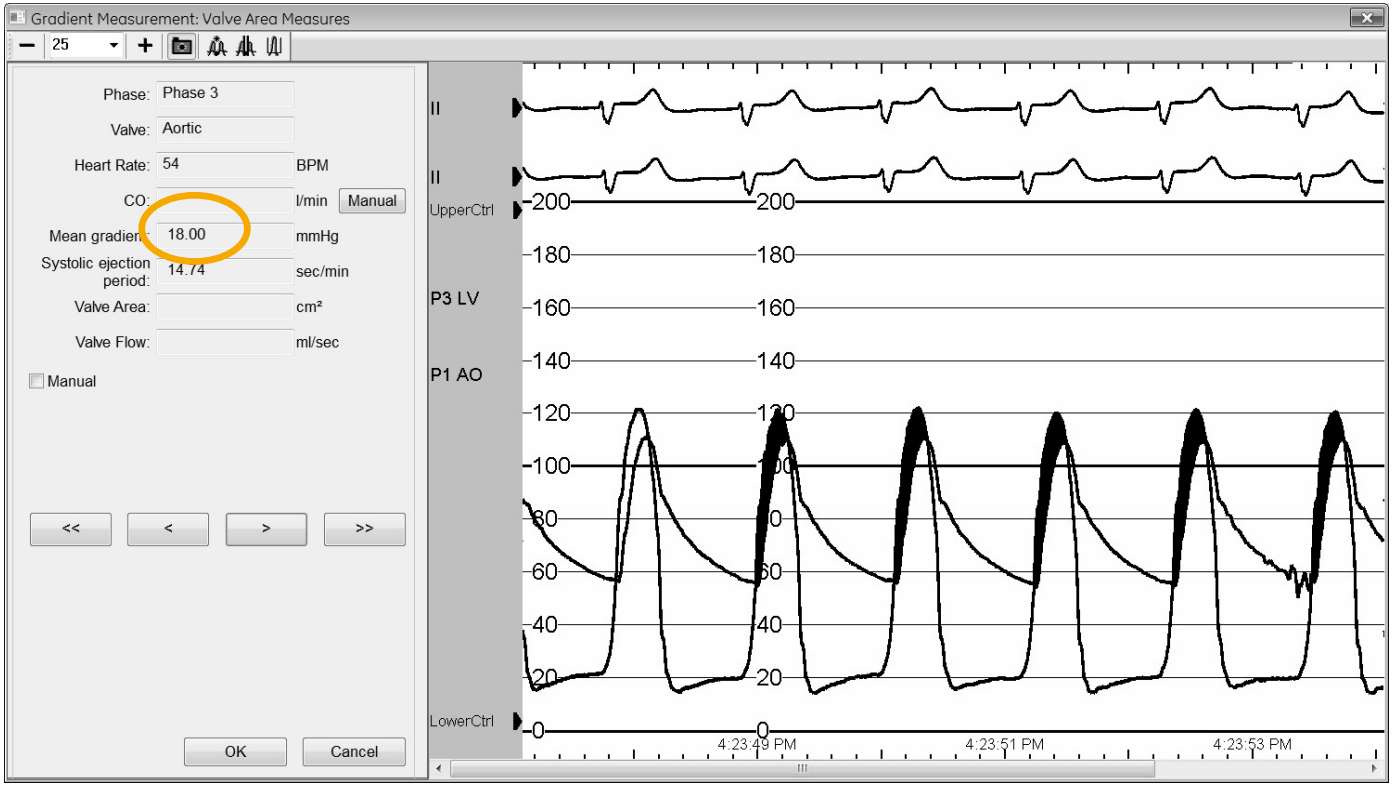
Pre



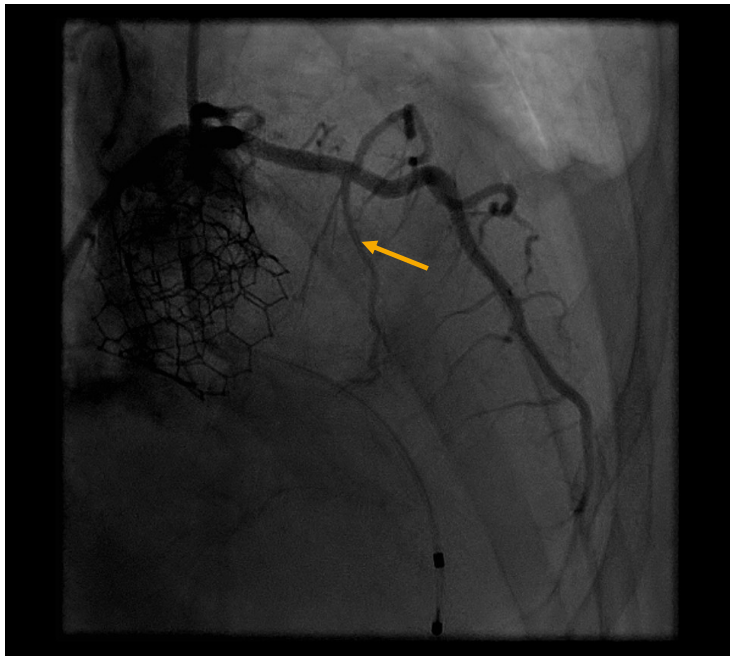
Post

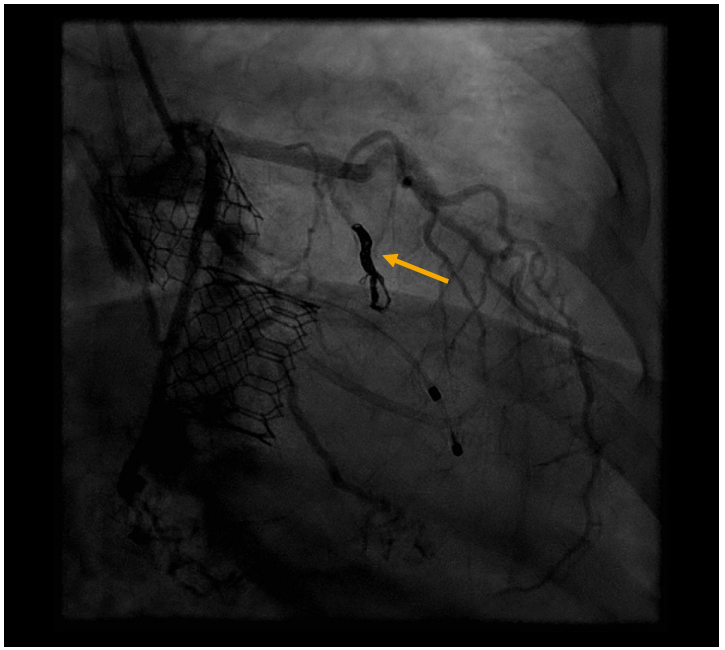


Aortic Hemodynamics



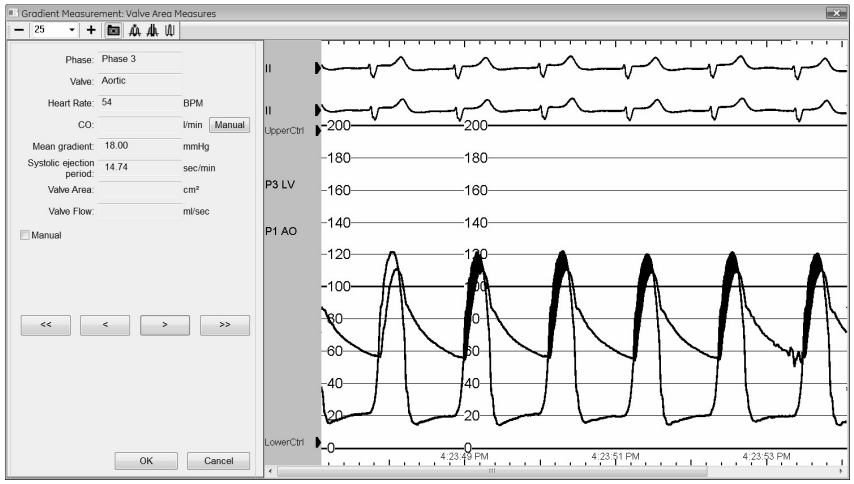
Septal Coiling



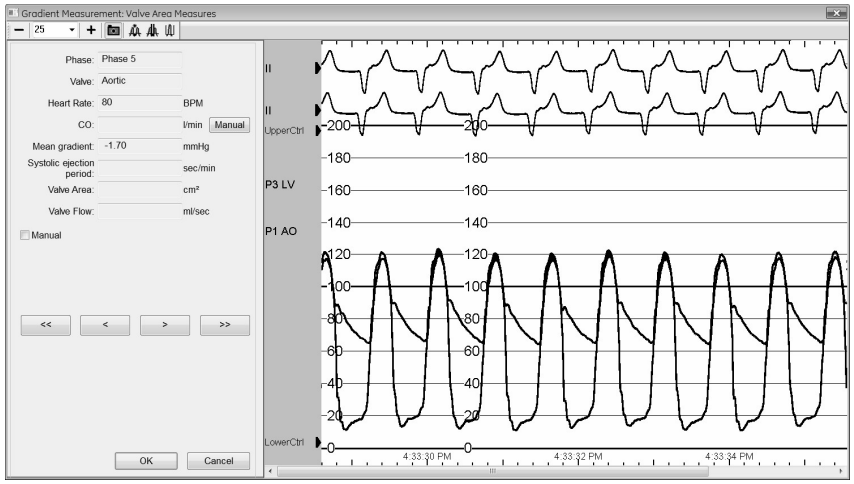


LVOT Hemodynamics

Pre



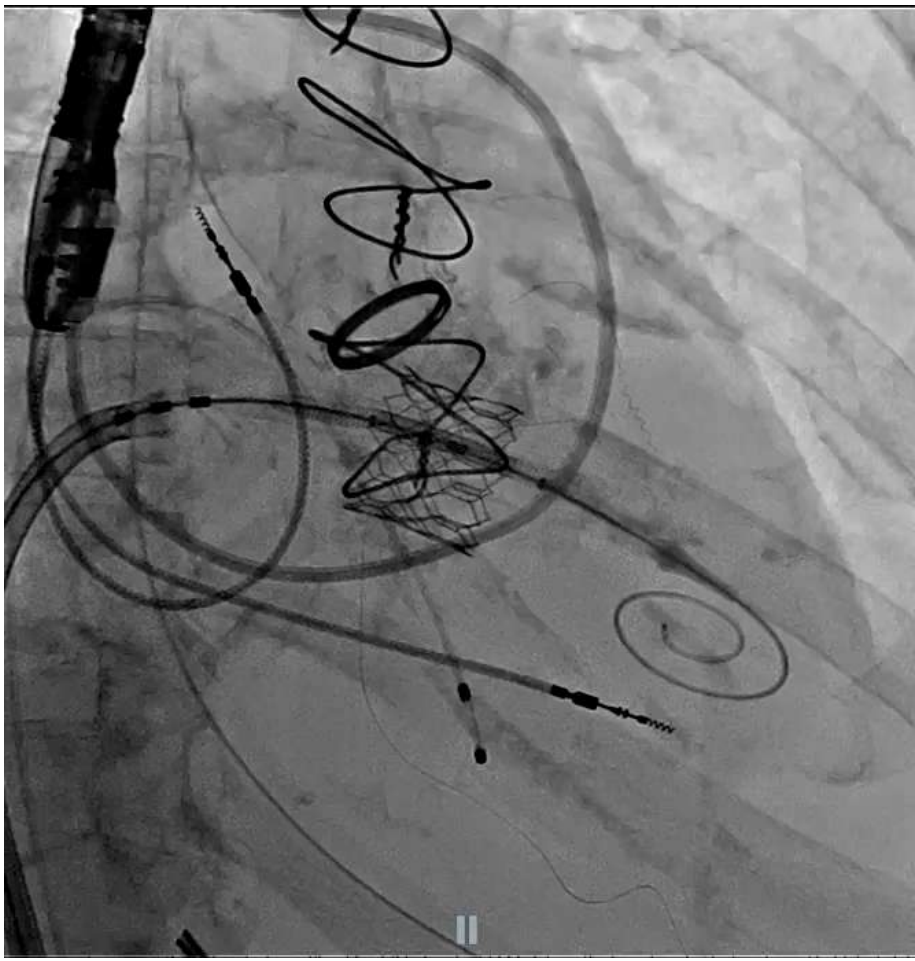
Post

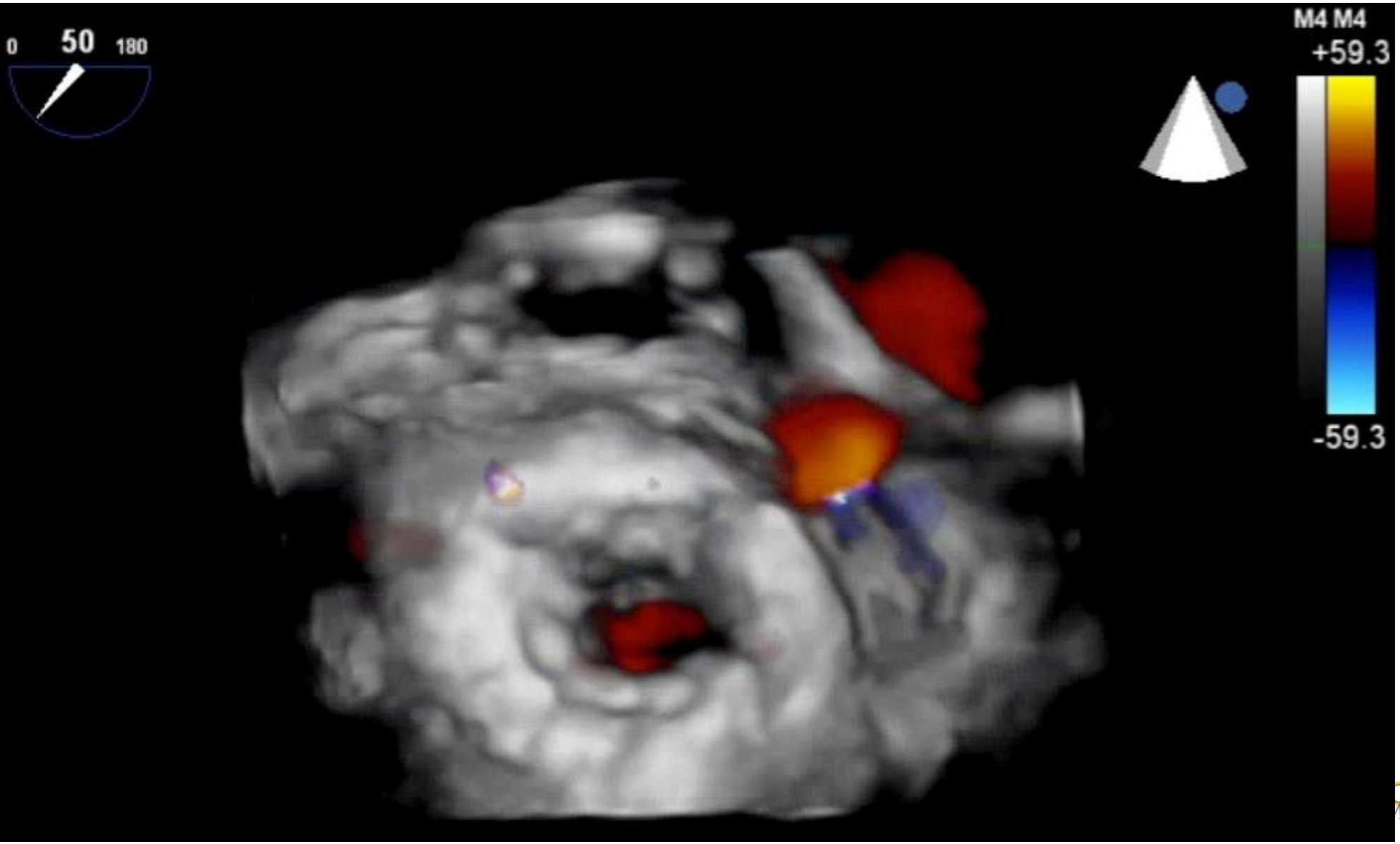


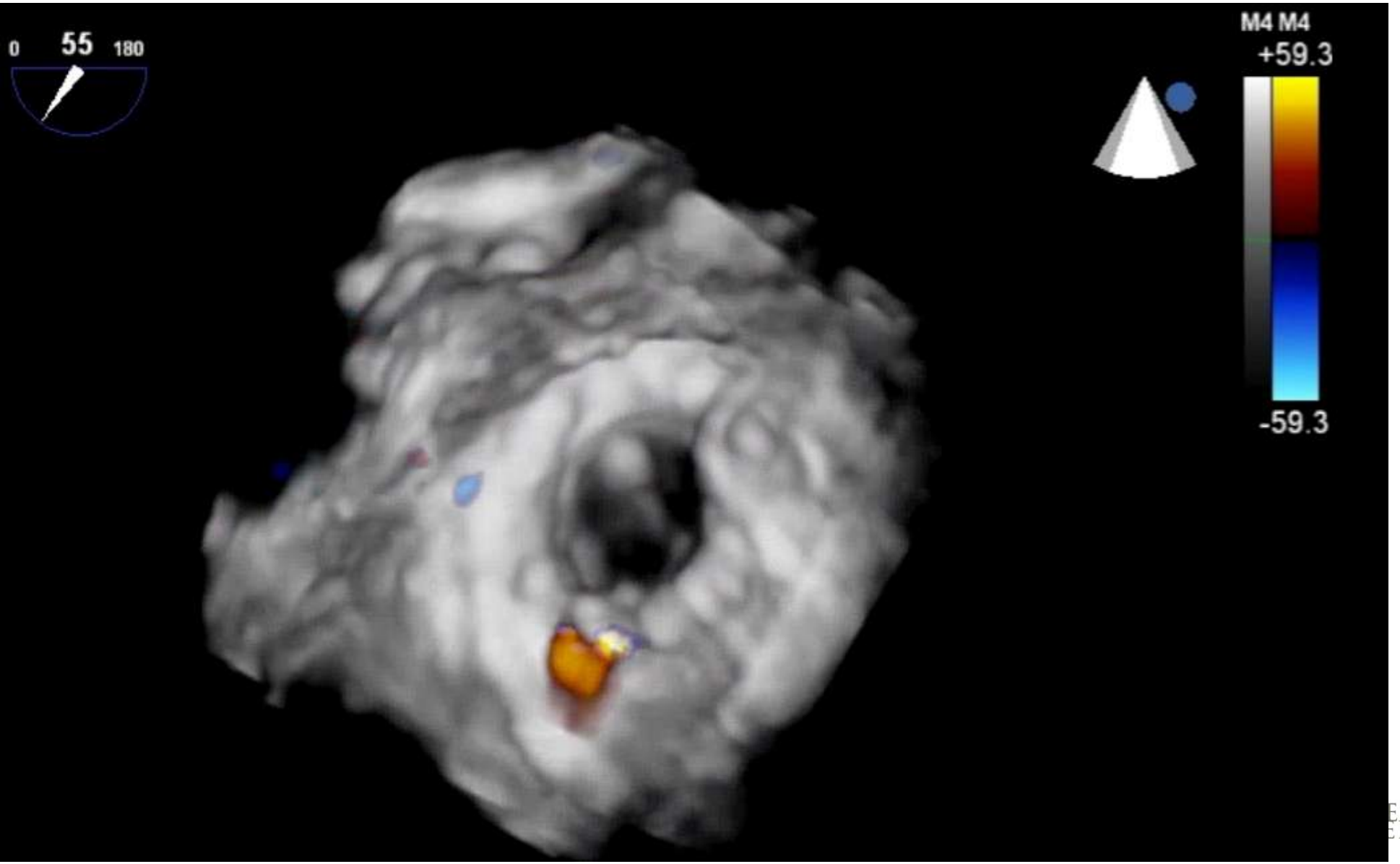
Later needed a PPM and iASD closure...

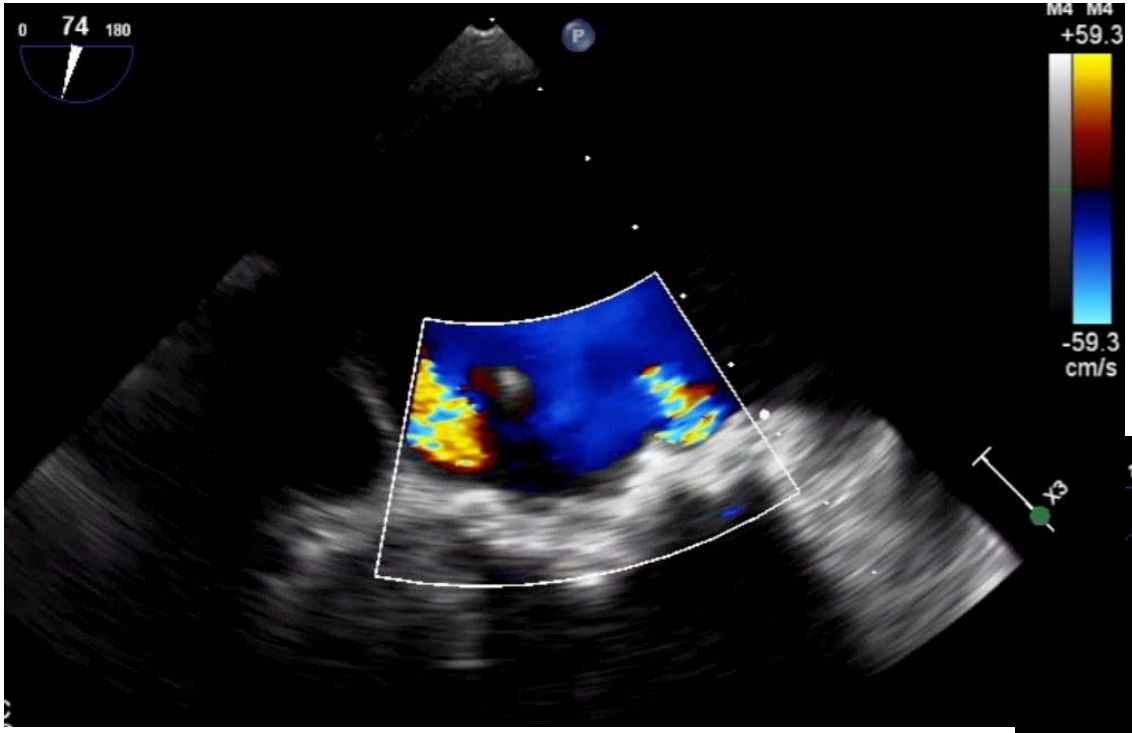
SEVERE MAC WITH MS

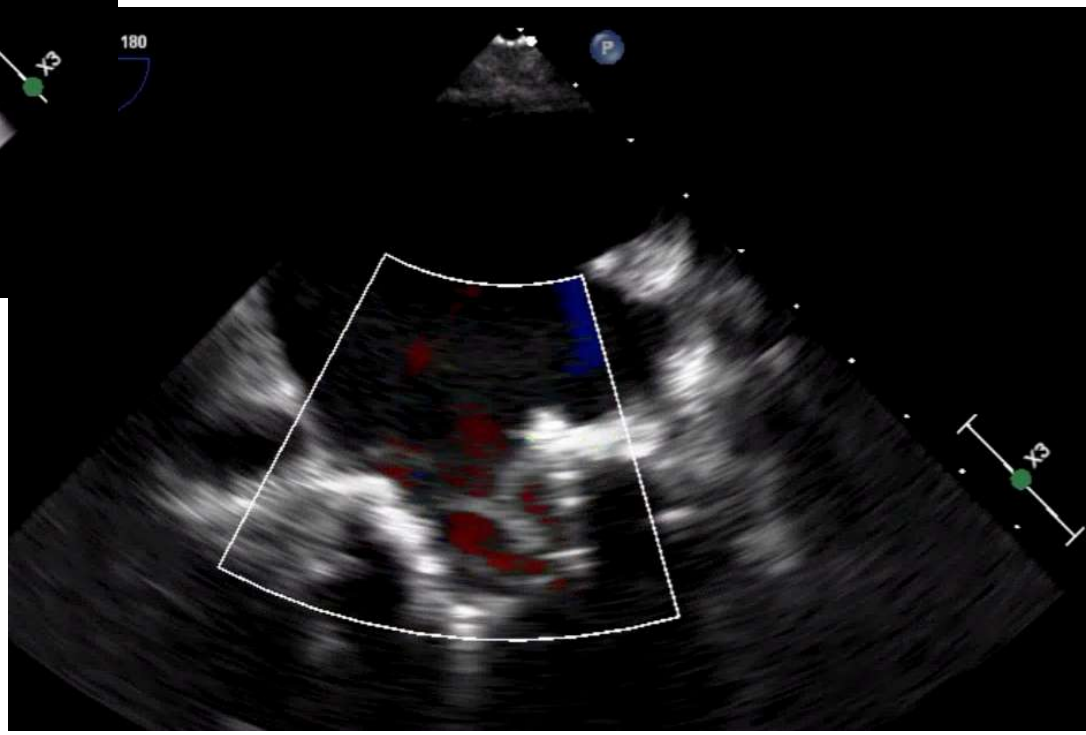
- 63 years old woman with PVD, HTN, Pulm HTN
- <u>STS:</u> MVR:10.8%
- GFR 40
- LVEF 65%



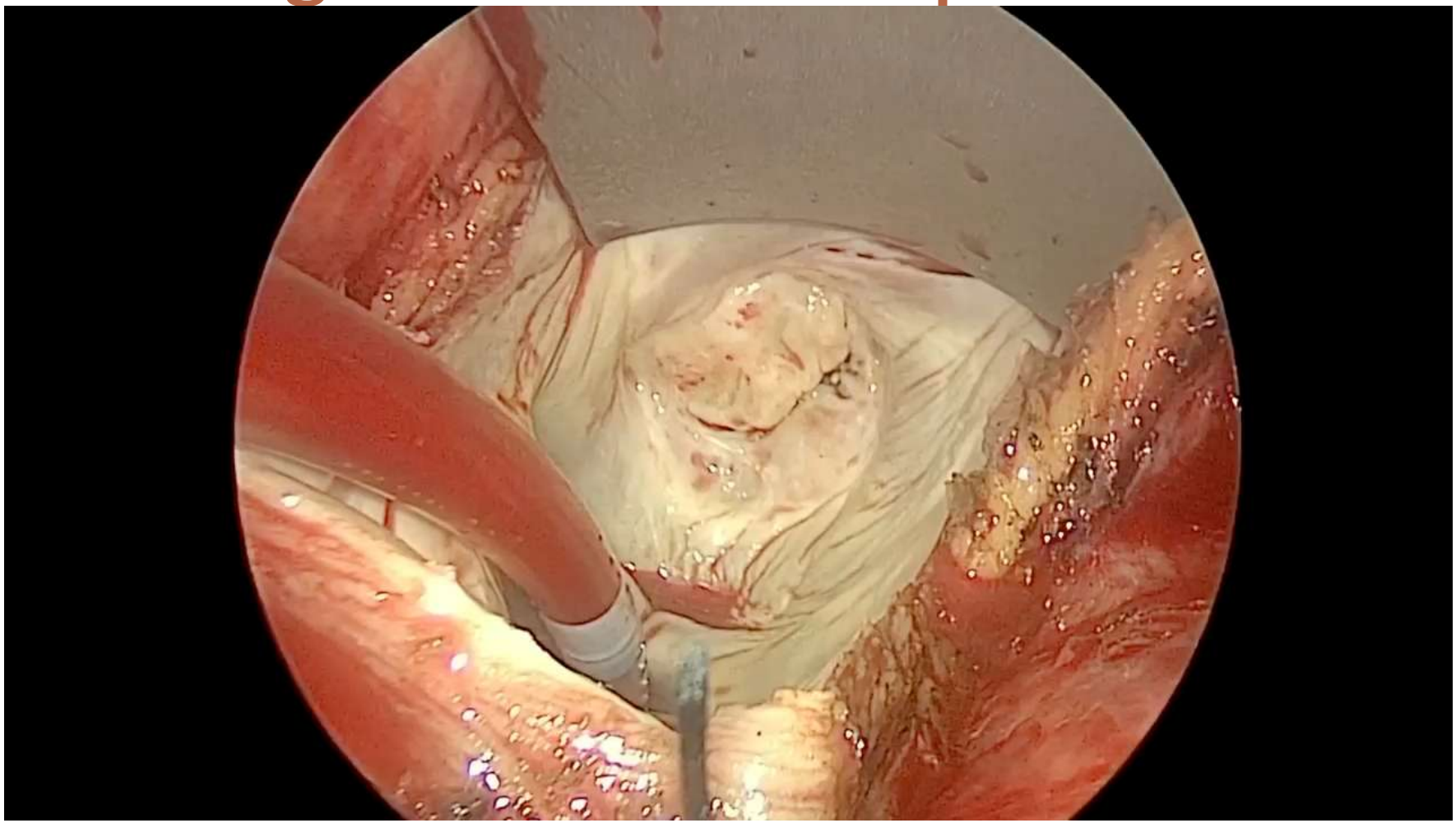

0
50
180
M4 M4
+59.3
-59.3


0
55
180
M4 M4
+59.3
-59.3


0
74
180
M4 M4
+59.3
-59.3
cm/s
X3


180
X3

Surgical TMVR with Sapien Valve



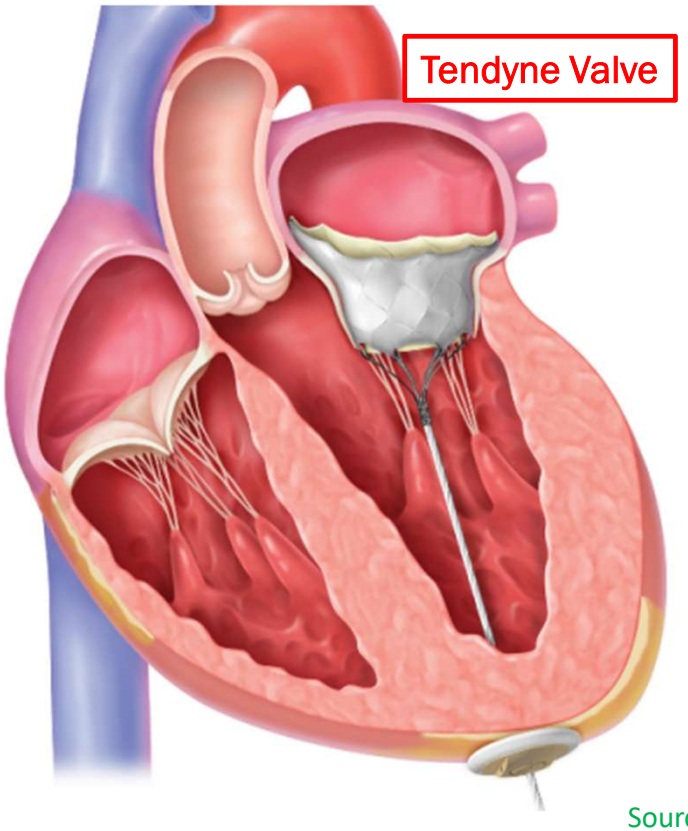
Millar J and Ailawadi G. JTCVS 2023

Dedicated TMVR Systems

Transcatheter Mitral Valve Replacement (TMVR)

FDA Approved in May 2025

- For mitral valve disease with severe MAC
- Transapical only
- For inoperable patients



Source: Abbott

FDA.gov

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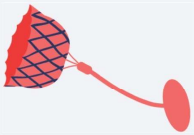
Overview of the SUMMIT-MAC Study



The first prospective pivotal trial evaluating a dedicated TMVR device (Tendyne) for patients with severe MAC, a population traditionally considered untreatable, or requiring high-risk surgery.

TRIAL DESIGN & POPULATION

Multicenter

103 patients with severe MAC & mitral regurgitation (MR) or stenosis

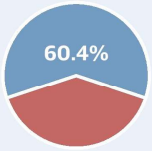
Single-arm

1-year follow-up

RESULTS

Primary Endpoint
Freedom from:

- All-cause mortality
- Heart failure hospitalization



% OF PATIENTS WHO ACHIEVED PRIMARY ENDPOINT

SECONDARY ENDPOINT RESULTS

MR reduction

NYHA functional class I/II

+18.7 points

KCCQ-OS score

The Tendyne TMVR system may address a treatment gap for mitral valve disease in high surgical risk patients with severe MAC.

Sorajja P, et al. JACC. 2026;10.1016/j.jacc.2025.10.025

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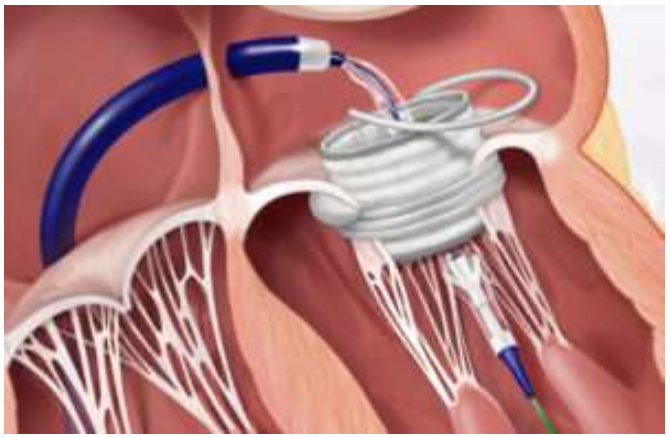
Transcatheter Mitral Valve Replacement (TMVR)

FDA Approved in Dec 2025
- For MR/MS/MAC
- Trans-septal approach
- For inoperable patients

Sapien M3 Valve



Source: Edwards

FDA.gov

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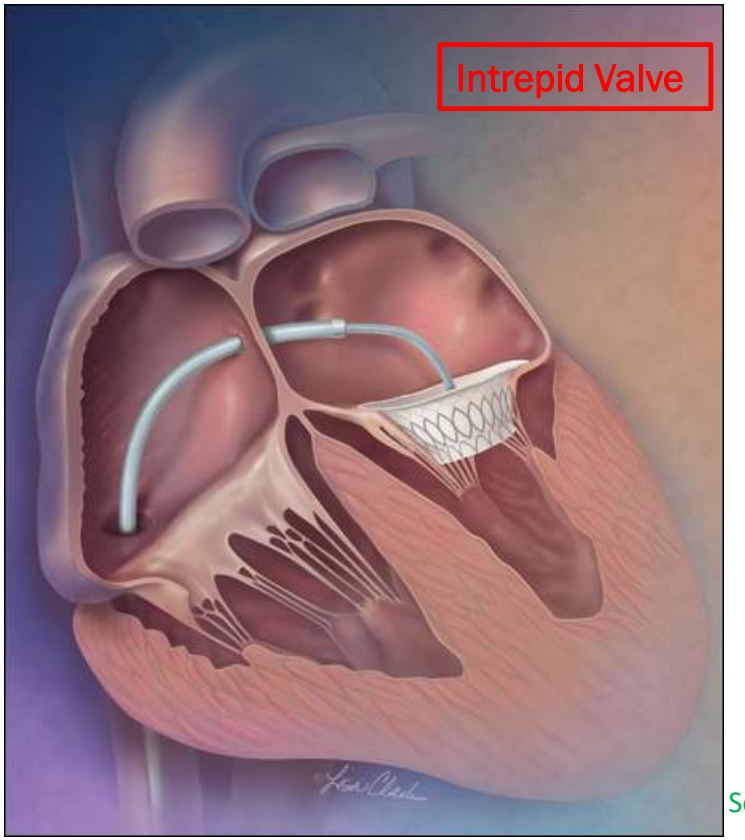
Transcatheter Mitral Valve Replacement (TMVR)

Only available as a part of Clinical Study (APPOLO)

- For patients not suitable for TEER or surgery
- MAC with Mitral Regurgitation (≥2+)



Source: Medtronic

Clinicaltrials.gov

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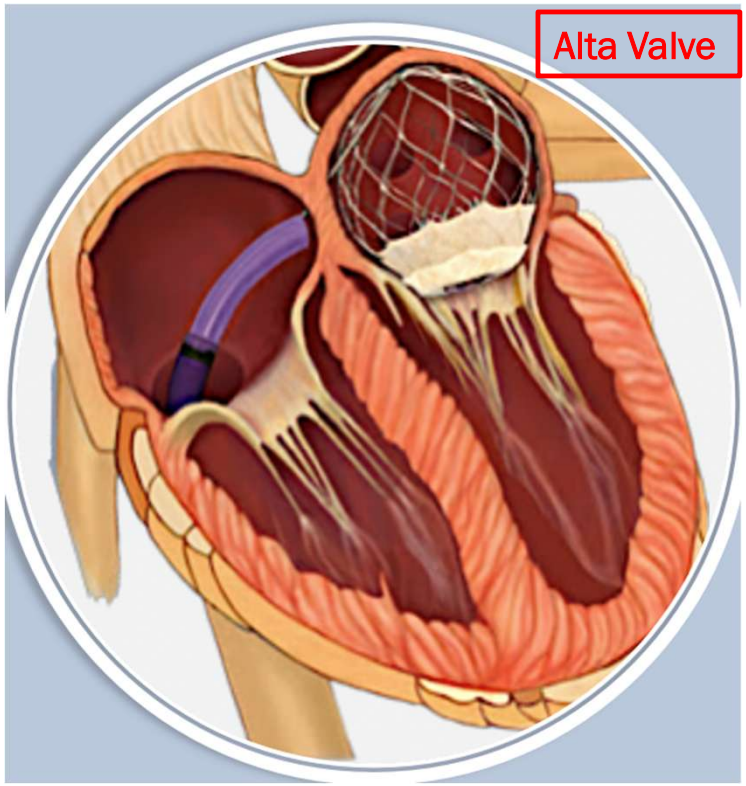
Transcatheter Mitral Valve Replacement (TMVR)

Only available as a part of Clinical Study (ATLAS)

- For patients not suitable for TEER or surgery
- MAC with Mitral Regurgitation
- Supra-annular design – does not affect LVOT



Source: 4C Medical

Clinicaltrials.gov

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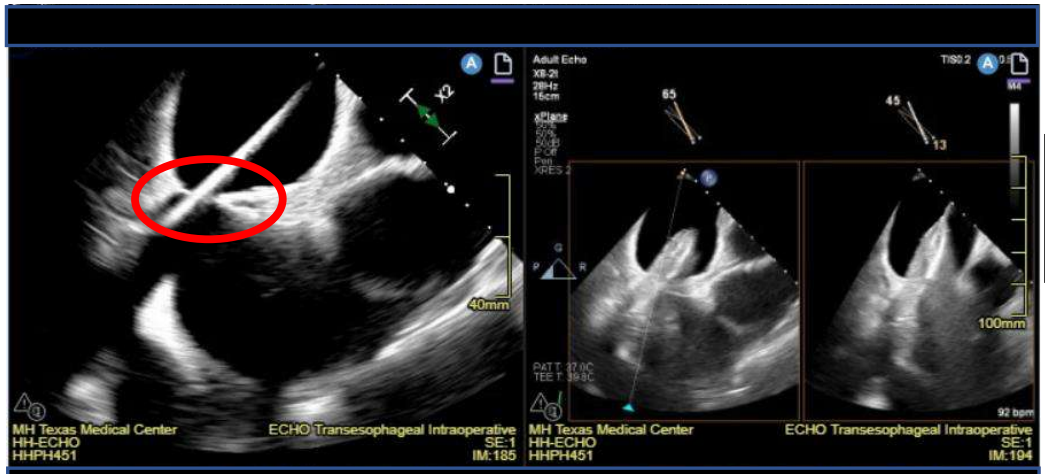
Pt with MR, unsuitable for mTEER

- 80 years old man with Severe mitral regurgitation, prior PFO closure, HTN
- eGFR 45
- LVEF 35-40%
- <u>STS PROM:</u>
  - Replacement 15%

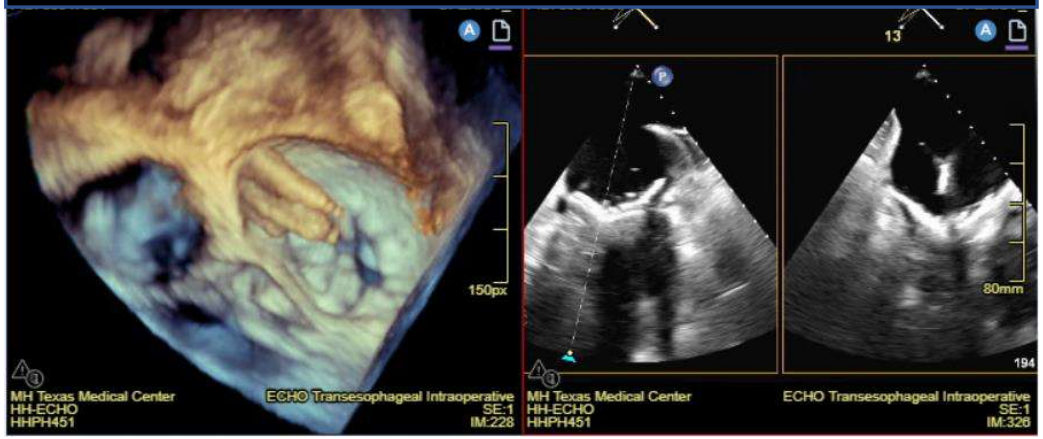
→ Heart team discussion → Decision to proceed with APOLLO Enrollment

Transseptal puncture midway between posterior wall of LA and inferior margin of the occluder



Balloon dilation of IAS with 14x40 non-compliant balloon

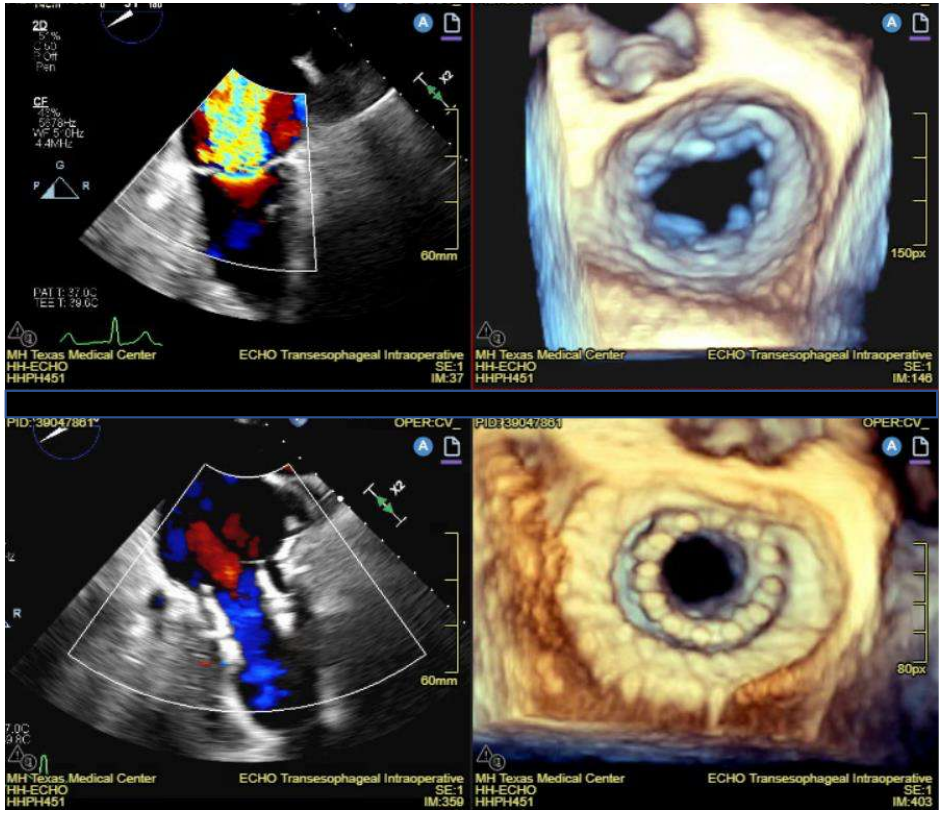
Intrepid delivery sheath 2 cm into left atrium prior to valve delivery



Final deployment of Intrepid Valve

Severity of MR prior Intrepid delivery

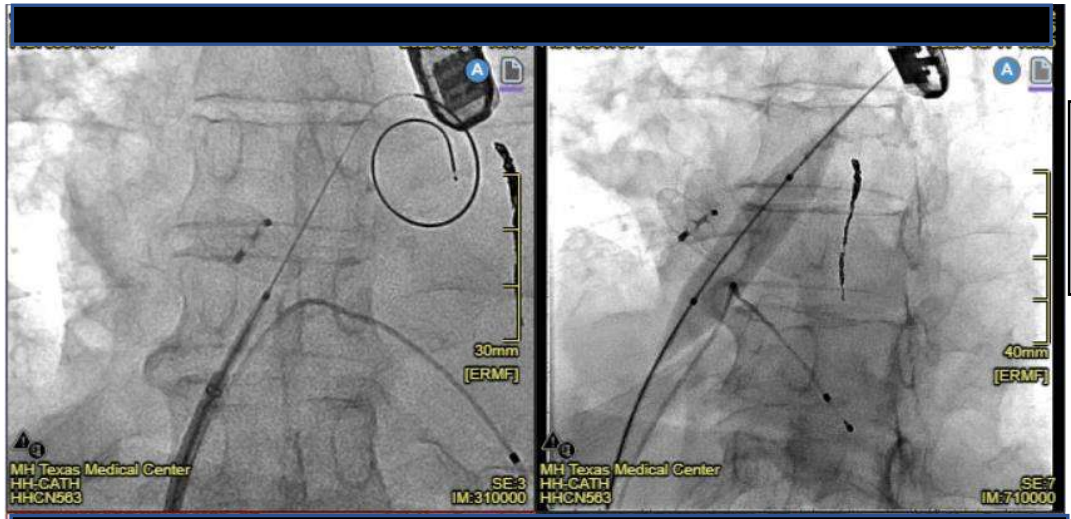
3-D view of native Valve with significant mitral annular calcification



No MR post Intrepid delivery

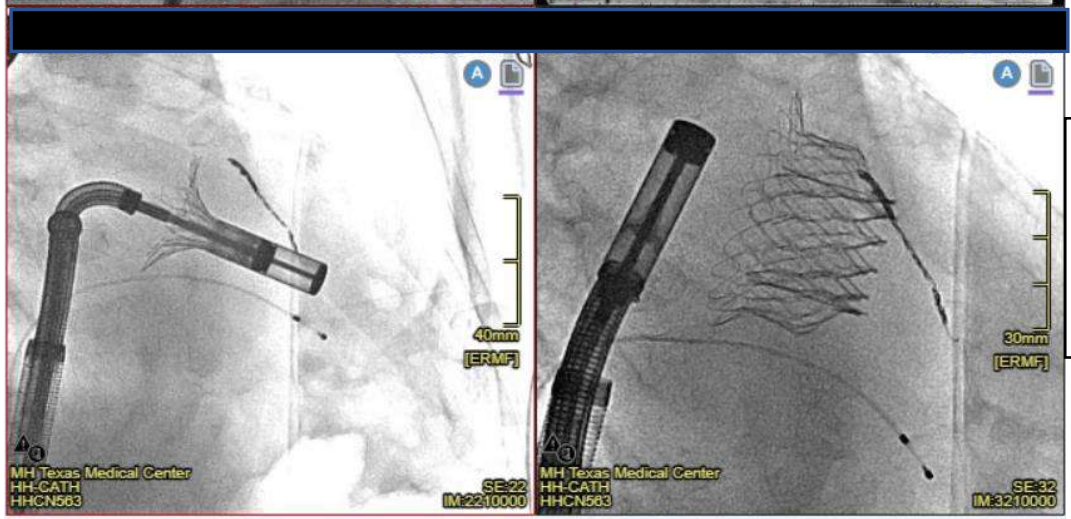
Valve position optimal post Intrepid delivery

Trans-septal puncture inferior and posterior to the inferior margin of the septal occluder



Balloon dilation of the septum primum with a 14x40 mm non-compliant balloon

Deploy valve to 50% of capsule position before final deployment under rapid pacing



Valve fully deployed with normal function and stable hemodynamics without paravalvular leak

Conclusion

- Calcified MS remains a challenge with very limited therapies, even today
- The risk of LVOT obstruction is an important deterrent
- With acceptable anatomy, 1-month mortality of <5%
- Many exciting clinical trials for MAC and new devices in the pipeline

Abhijeet Dhoble
517-944-1246
abhijeet.dhoble@uth.tmc.edu
@dhoble7