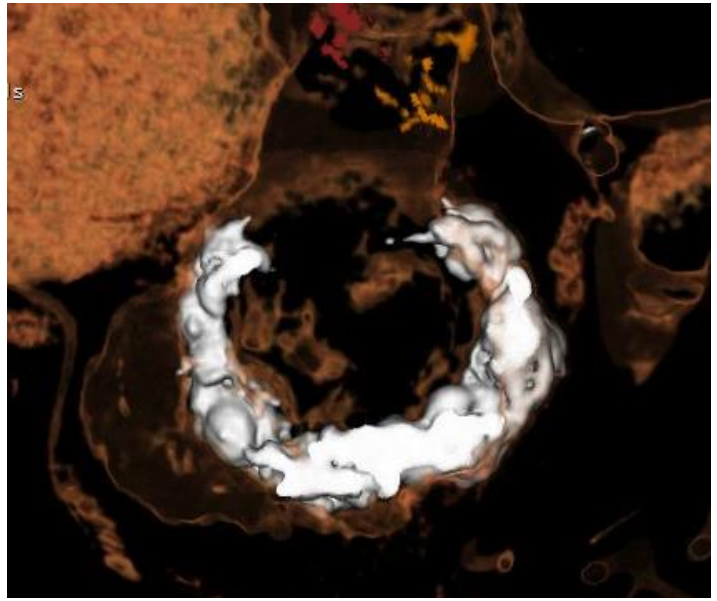
Mitral valve calcification: transcatheter options



Dr. Alison Duncan

MB BS BSc PhD FRCP FESC

The Royal Brompton Hospital

Part of Guys and St Thomas' NHS Foundation Trust

alison.duncan14@nhs.net

Conflict of Interests

I have received honoraria and consultancy fees from

- Abbott Laboratories
- Edwards LifeSciences
- Medtronic

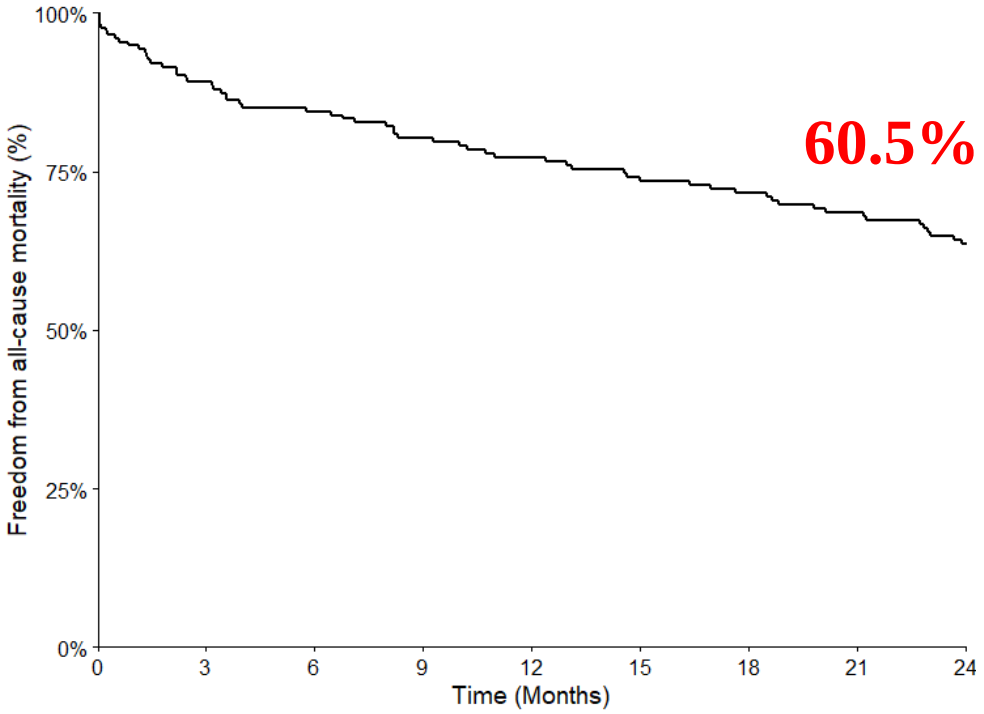
Mitral Calcification

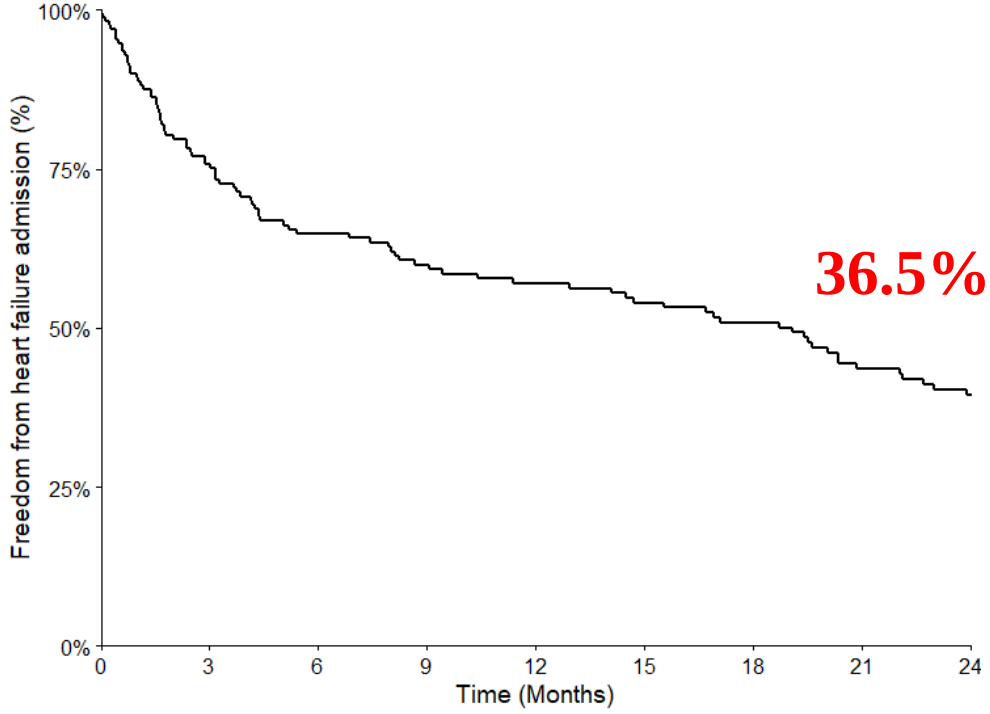
- Calcific degenerative process

- 10% of the population, 40% in septuagenarians

Mitral Calcification

- **Poor 2-year prognosis in MAC / significant MR when left untreated**



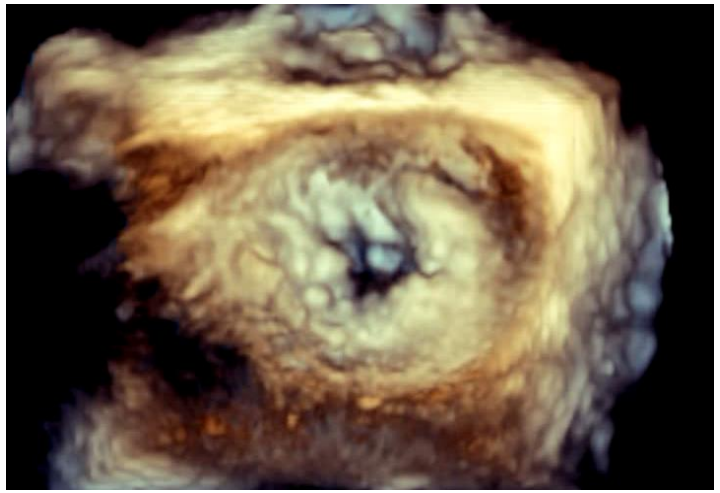


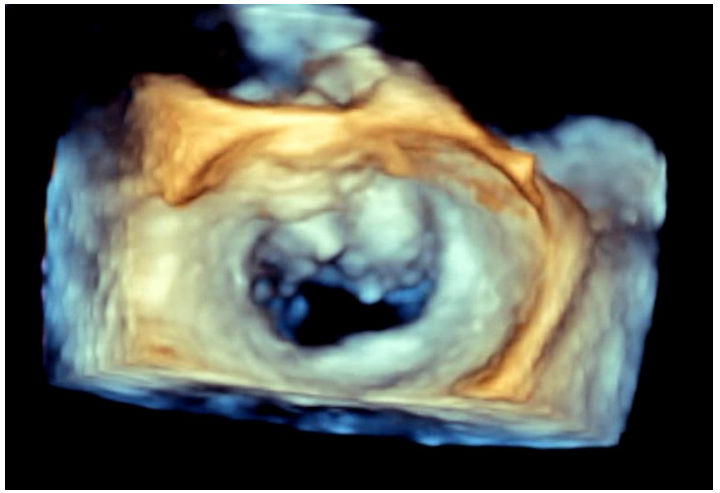
Ahmed A et al. AATS Mitral Conclave

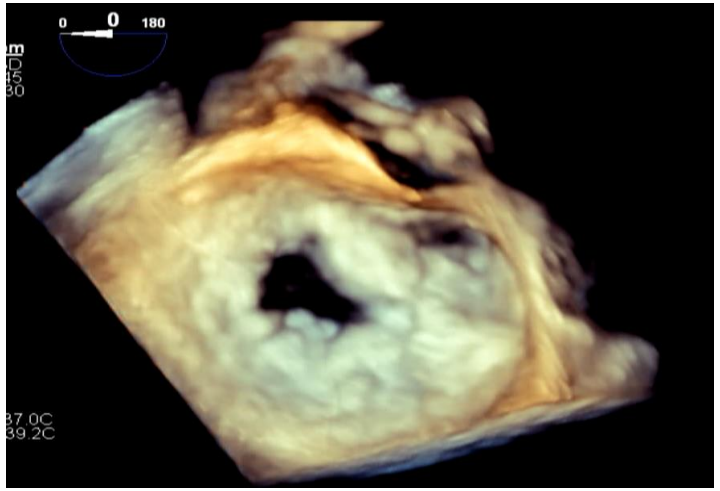
Framingham 16-year follow-up:

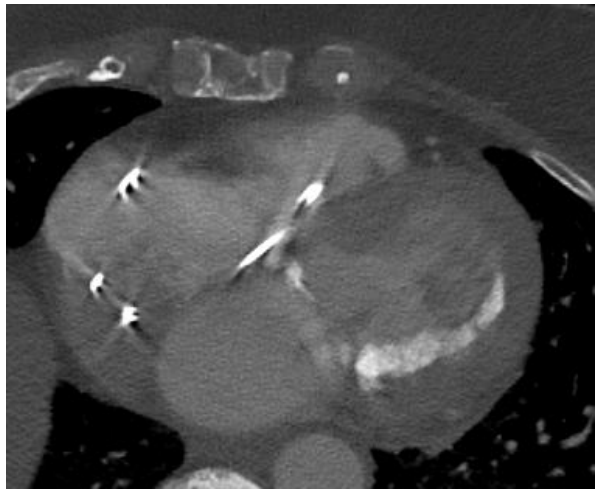
every 1mm ↑ increase in MAC = 10% ↑risk for CV disease (HT, CAD, PVD, CV mortality, and all-cause mortality)

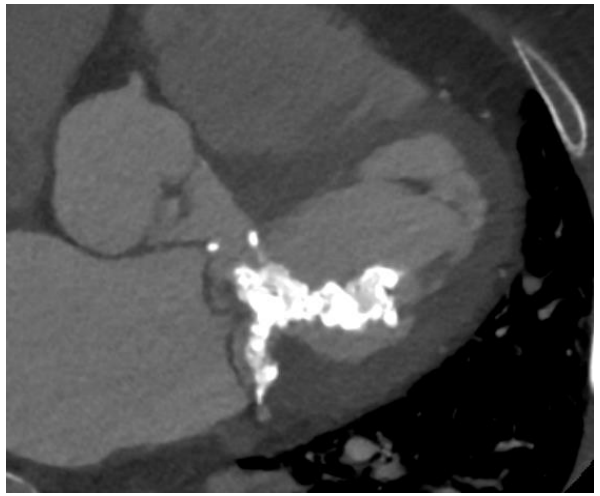
Mitral Calcification

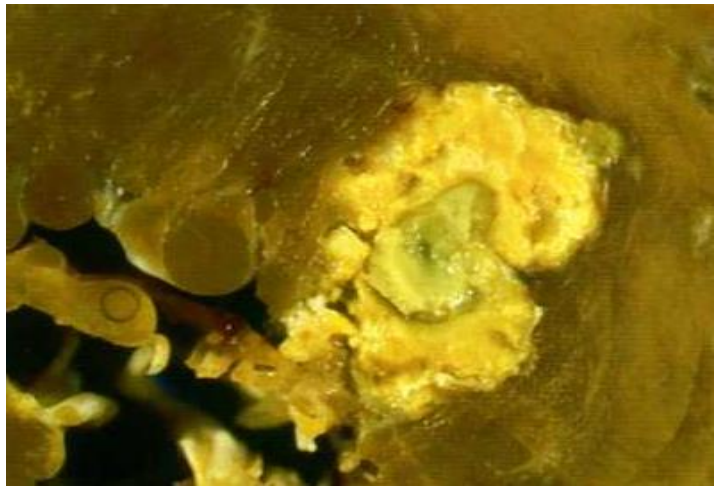












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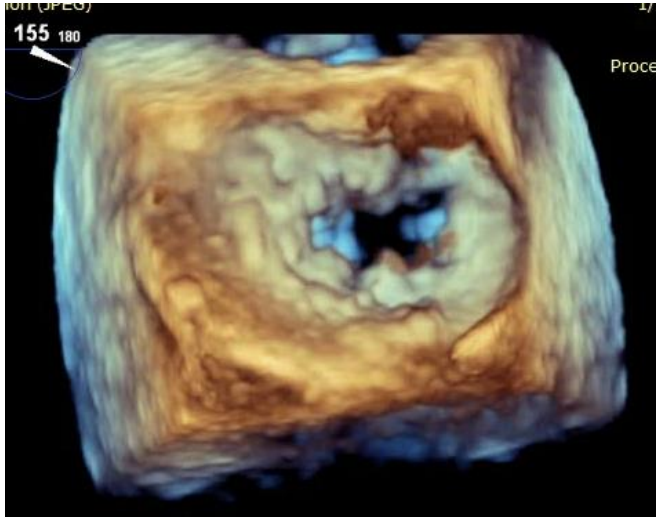
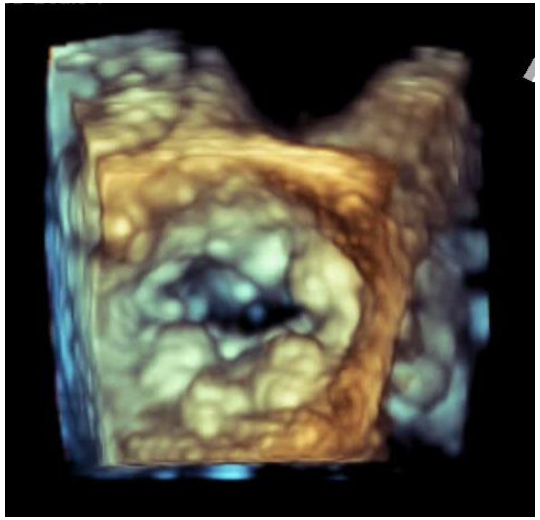
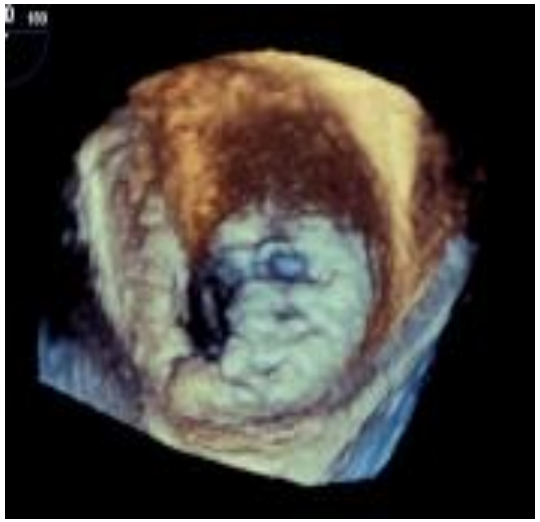
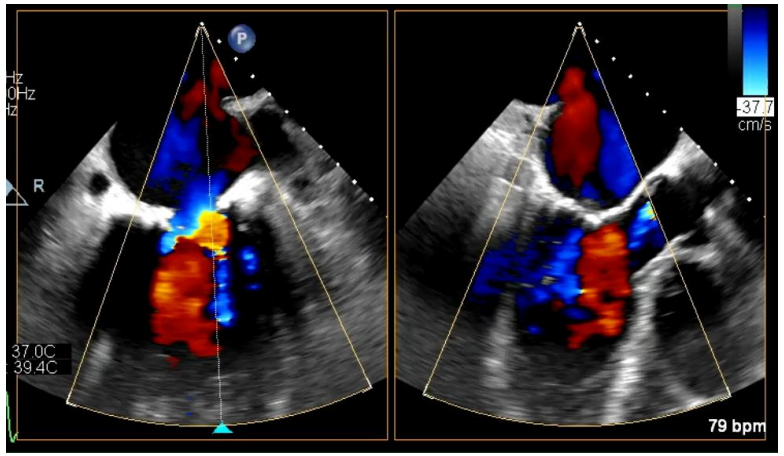






Mitral Calcification

- Associated with mitral stenosis and mitral regurgitation



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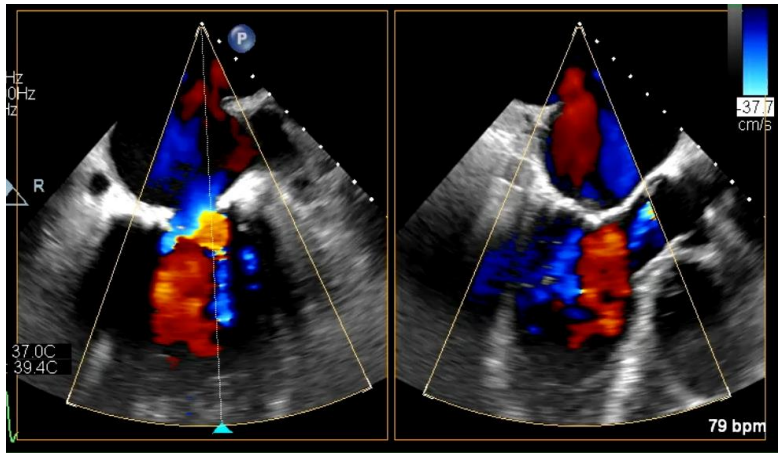
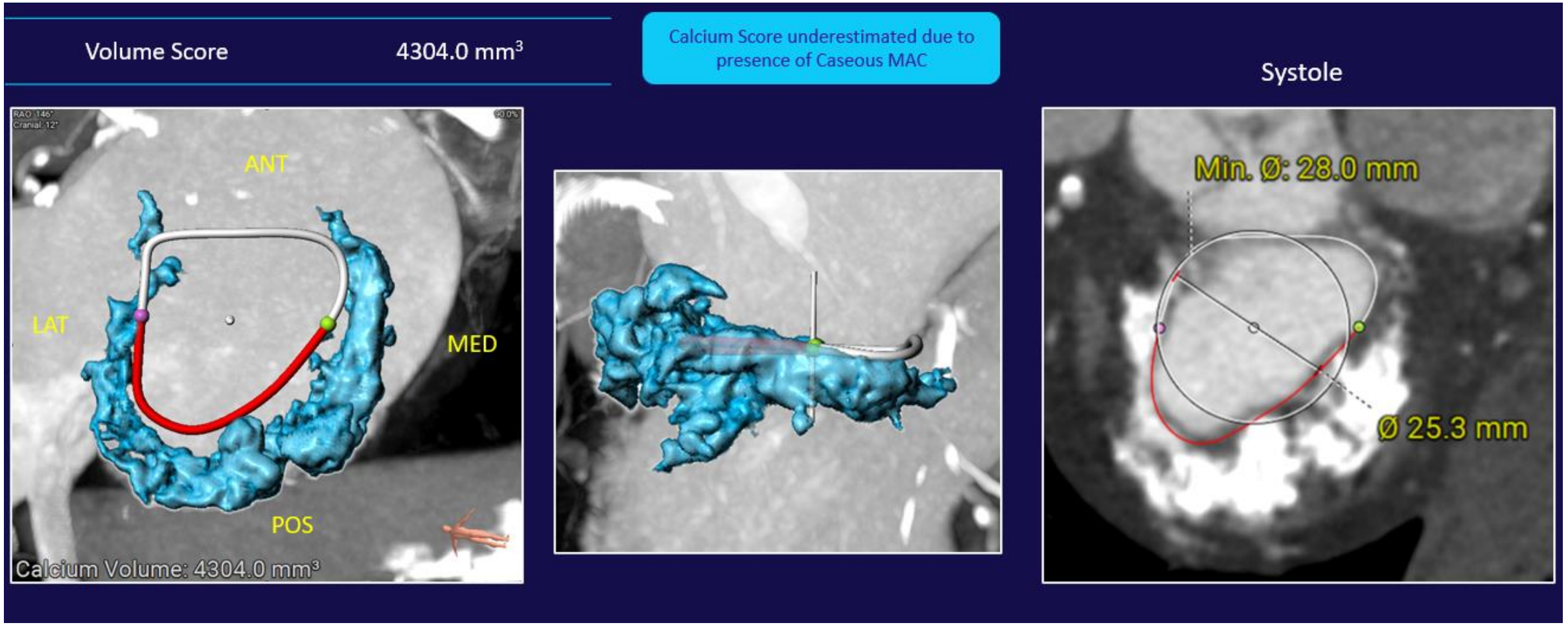


- Surgery can be prohibitive (clinical and technical reasons)
- Co-morbidities (chronic kidney disease, peripheral arterial disease) common
- Transcatheter options available but high screen-fail rate

CT screening: Annulus too small



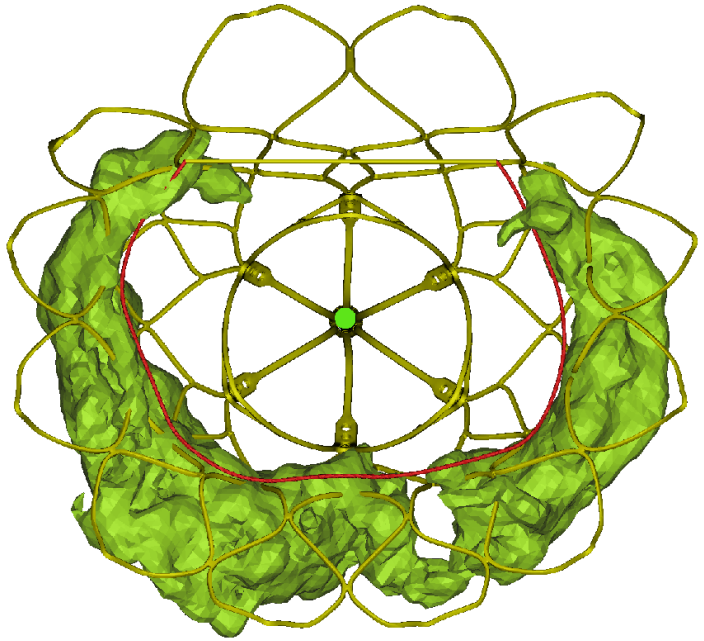
Smallest Tendyne: 25mm AP, 35mm intercommissural, 100 perimeter

Device over-sizing required for mitral calcification

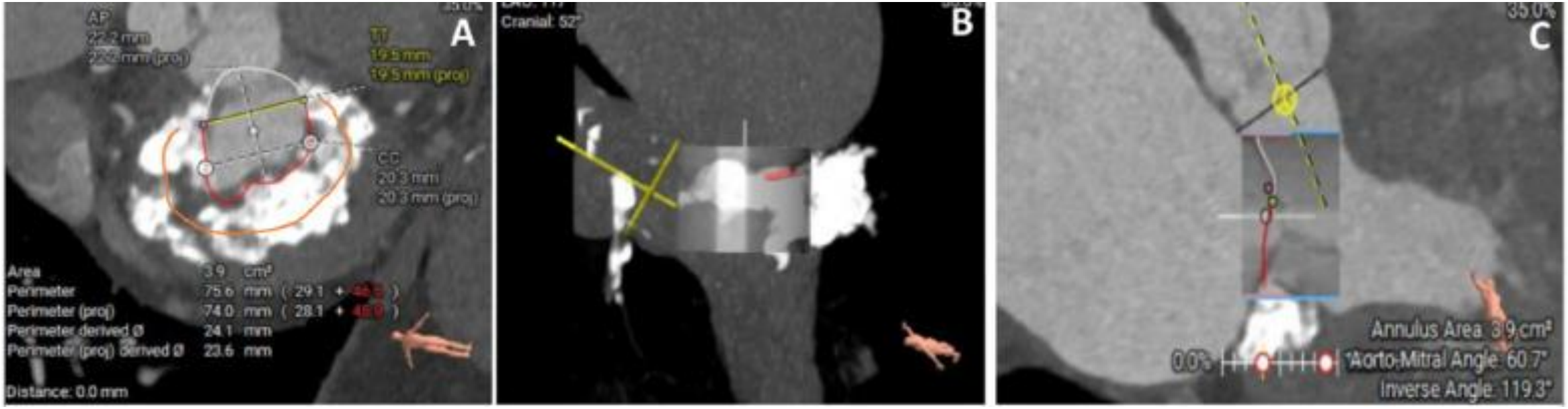
Heavier oversizing acceptable for severe MAC

- to accommodate changes in annular dimensions after balloon valvuloplasty
- to accommodate irregular MAC and provide enough sealing to prevent PVL

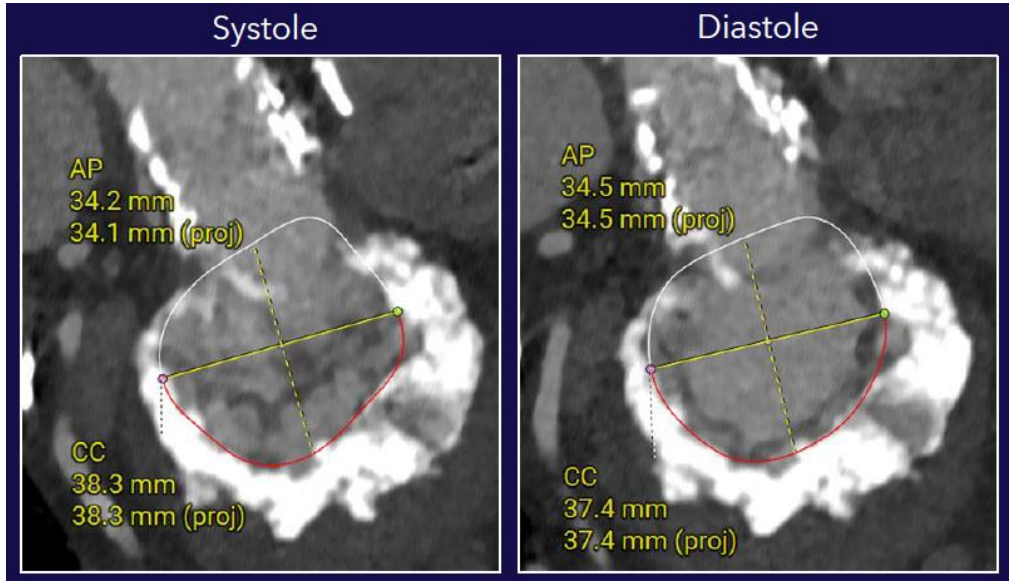
- **SL Oversizing:** sometimes as high as 35%
- **Perimeter Oversizing:** sometimes as high as 35%
- **IC Oversizing:** sometimes as high as 50%

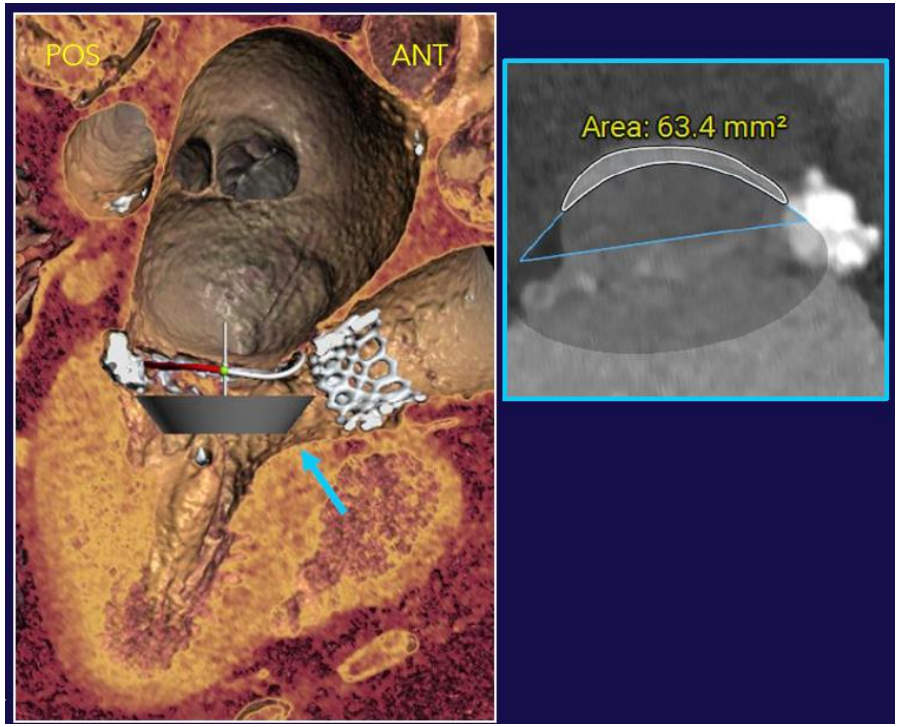


CT screening: LVOTO



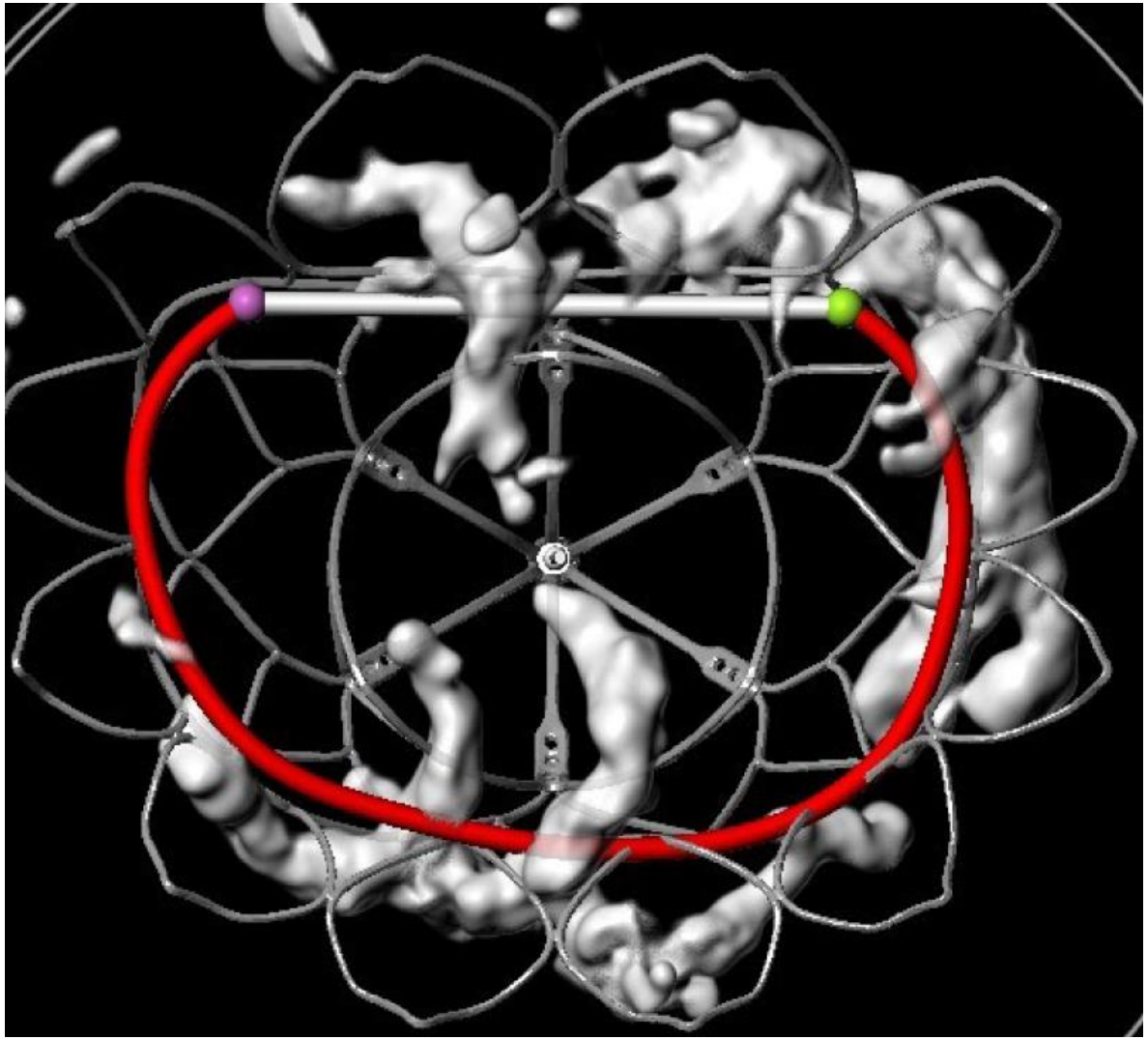
CT screening: LVOT too small





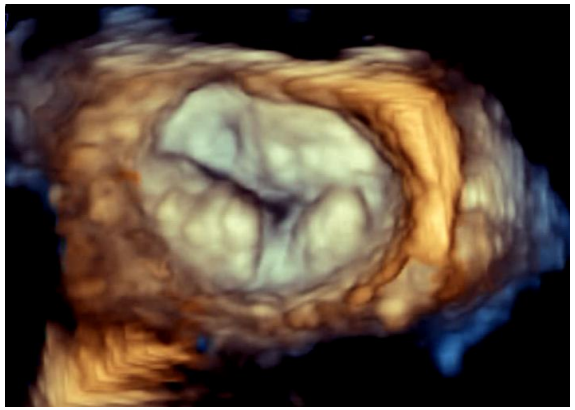
Minimum Neo-LVOT Area:	
End Systole	0.63 cm^2

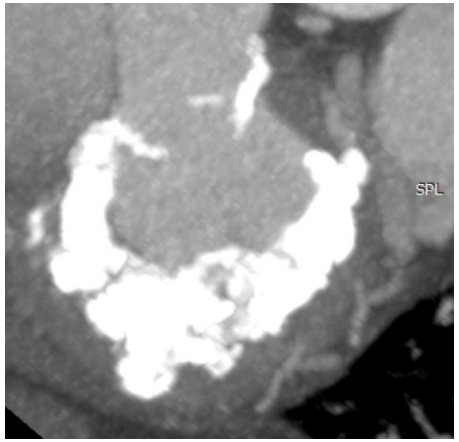
CT screening: protruding spicules

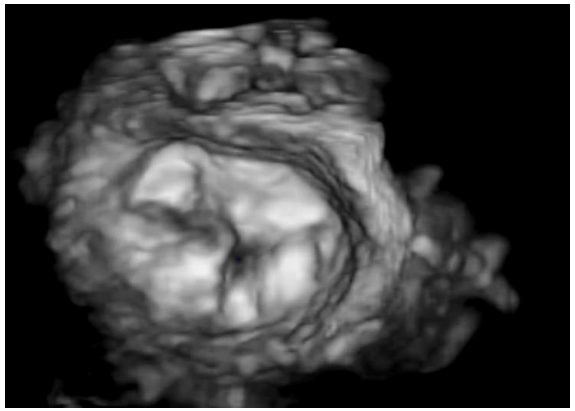


Potential Transcatheter Options

- Valve-in-MAC using TAVI device
- Valve-in-MAC using TA-Tendyne
- Valve-in-MAC using TF-Intrepid
- Valve-in-MAC using TF-Sapien M3







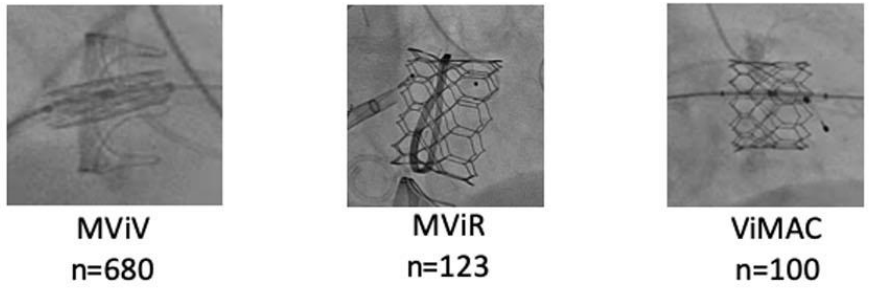
Valve-in-MAC

Thirty-Day Outcomes of Transcatheter Mitral Valve Replacement for Degenerated Mitral Bioprostheses (Valve-in-Valve), Failed Surgical Rings (Valve-in-Ring), and Native Valve With Severe Mitral Annular Calcification (Valve-in-Mitral Annular Calcification) in the United States: Data From the Society of Thoracic Surgeons/American College of Cardiology/Transcatheter Valve Therapy Registry

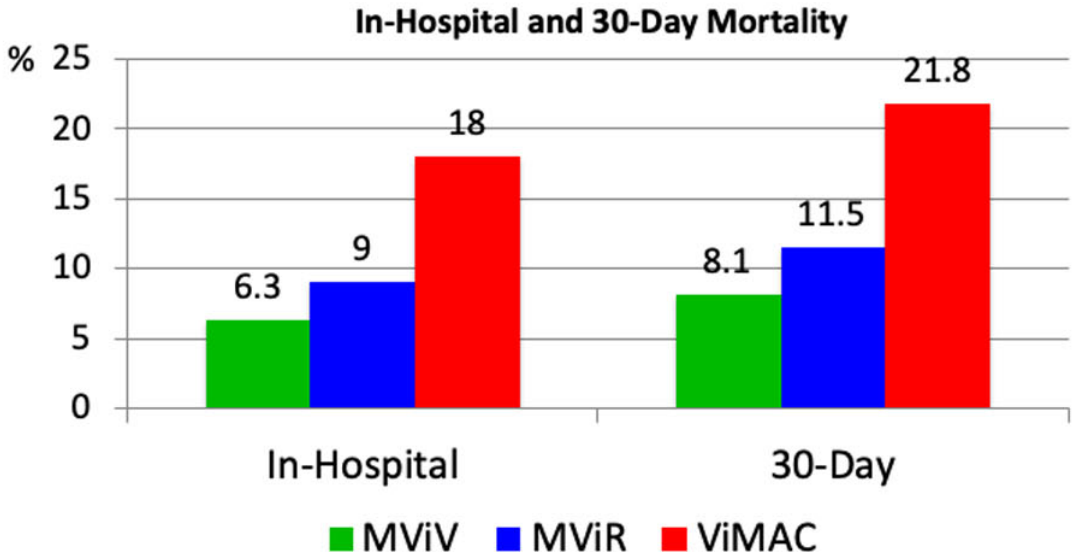
Mayra Guerrero, MD, Sreekanth Vemulapalli, MD, Qun Xiang, MS, Dee Dee Wang, MD, Mackram Eleid, MD, Allison K. Cabalka, MD, Gurpreet Sandhu, MD, ... SHOW ALL ..., and Ted Feldman, MD | AUTHOR INFO & AFFILIATIONS

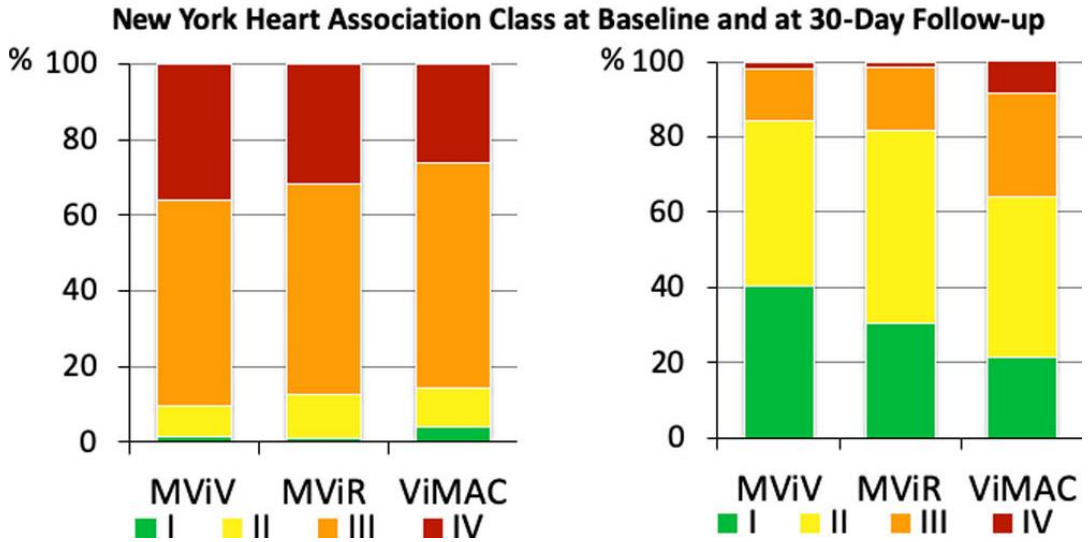
Circulation: Cardiovascular Interventions • Volume 13, Number 3 • https://doi.org/10.1161/CIRCINTERVENTIONS.119.008425

Early experience with MViV, MViR and ViMAC in the United States (TVT Registry 2013 to 2017)

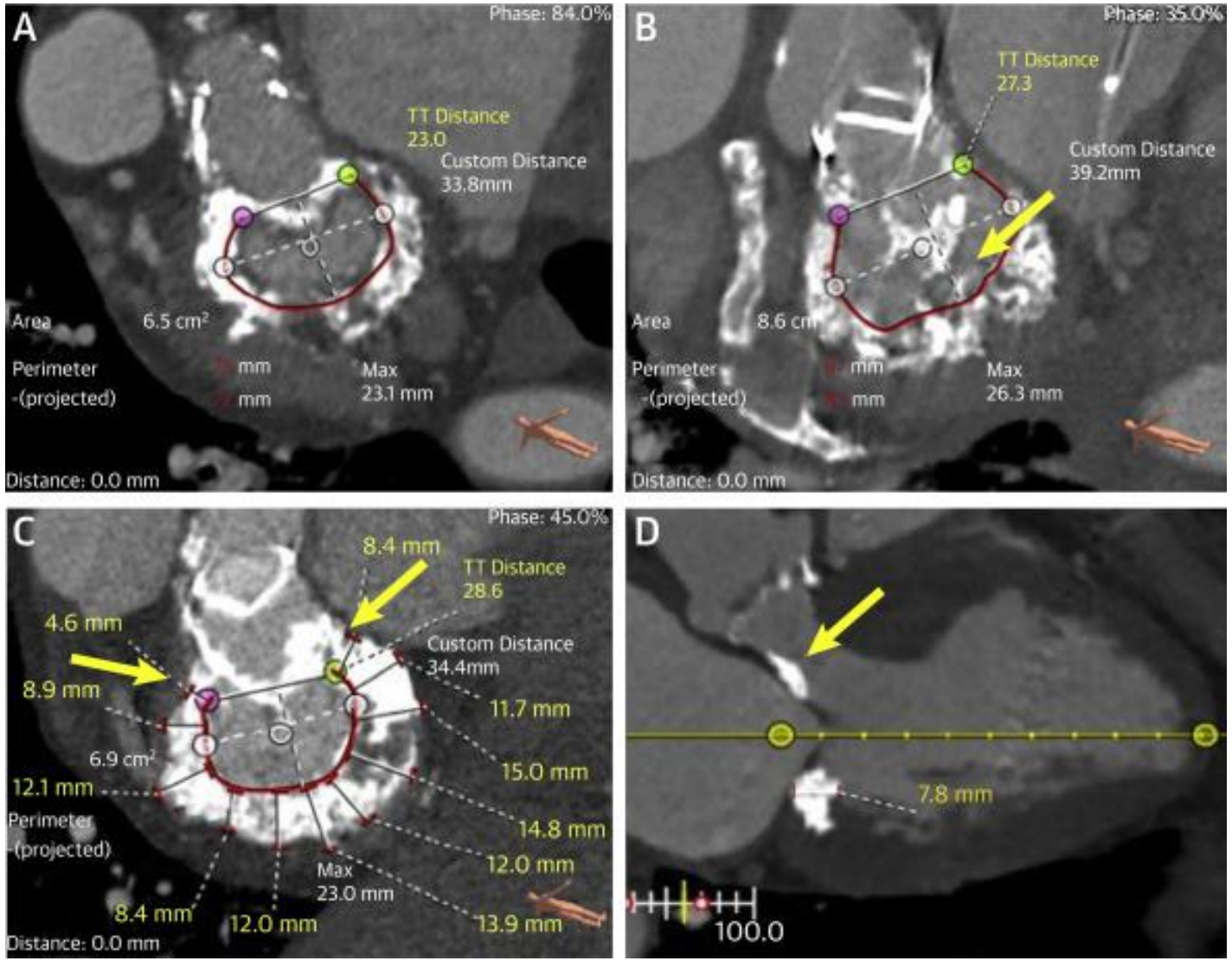


MViV n=680 | MViR n=123 | ViMAC n=100

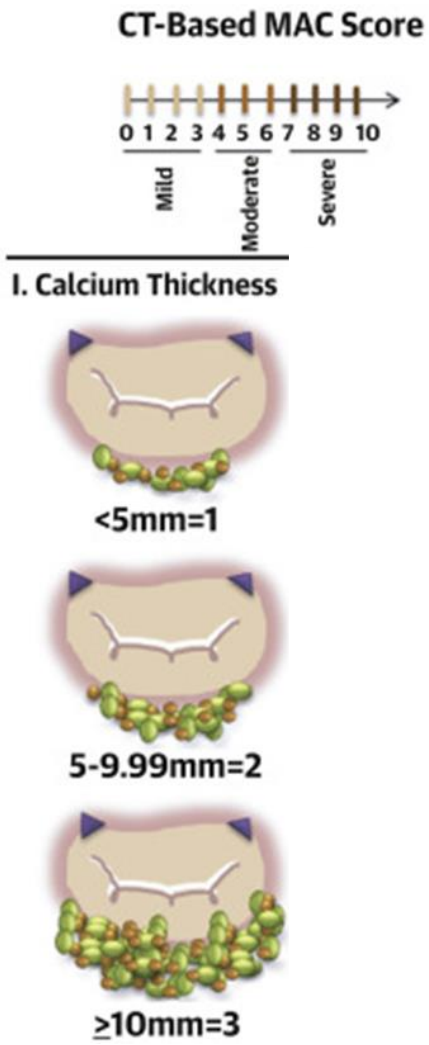


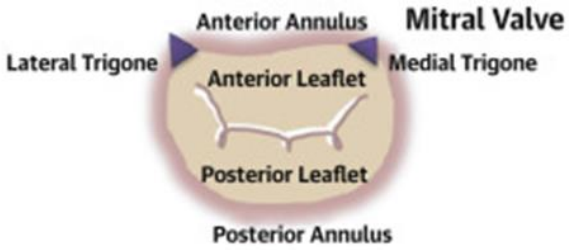


Standardised Classification of MAC



MAC Assessment





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VOL. 13, NO. 9, 2020

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ORIGINAL RESEARCH

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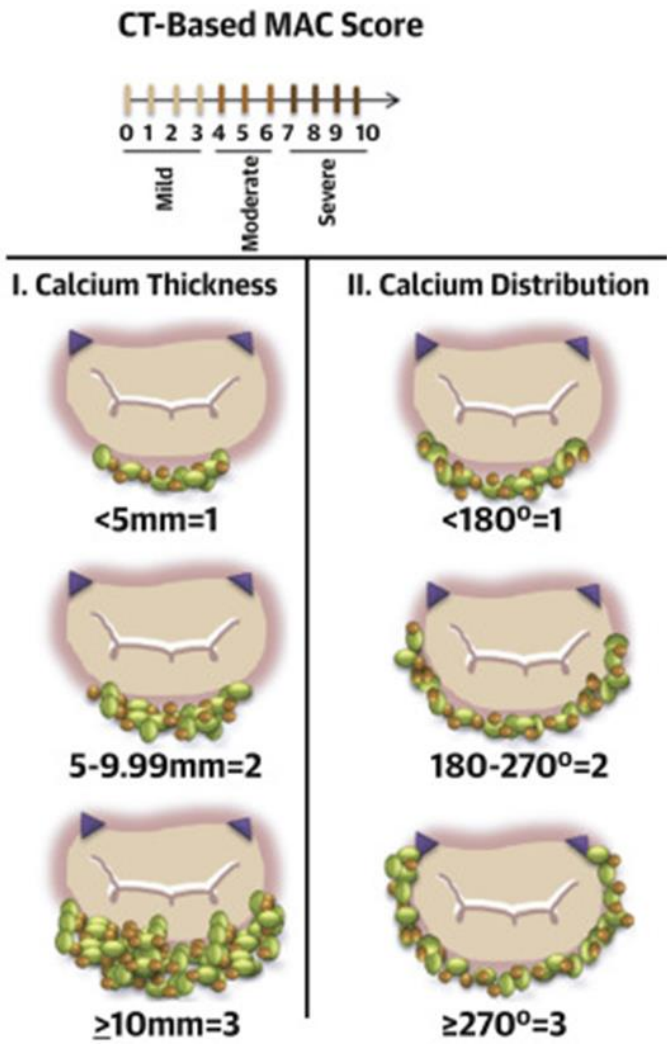

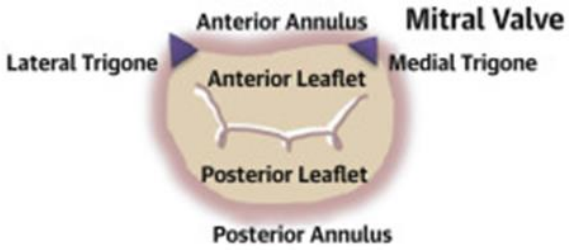

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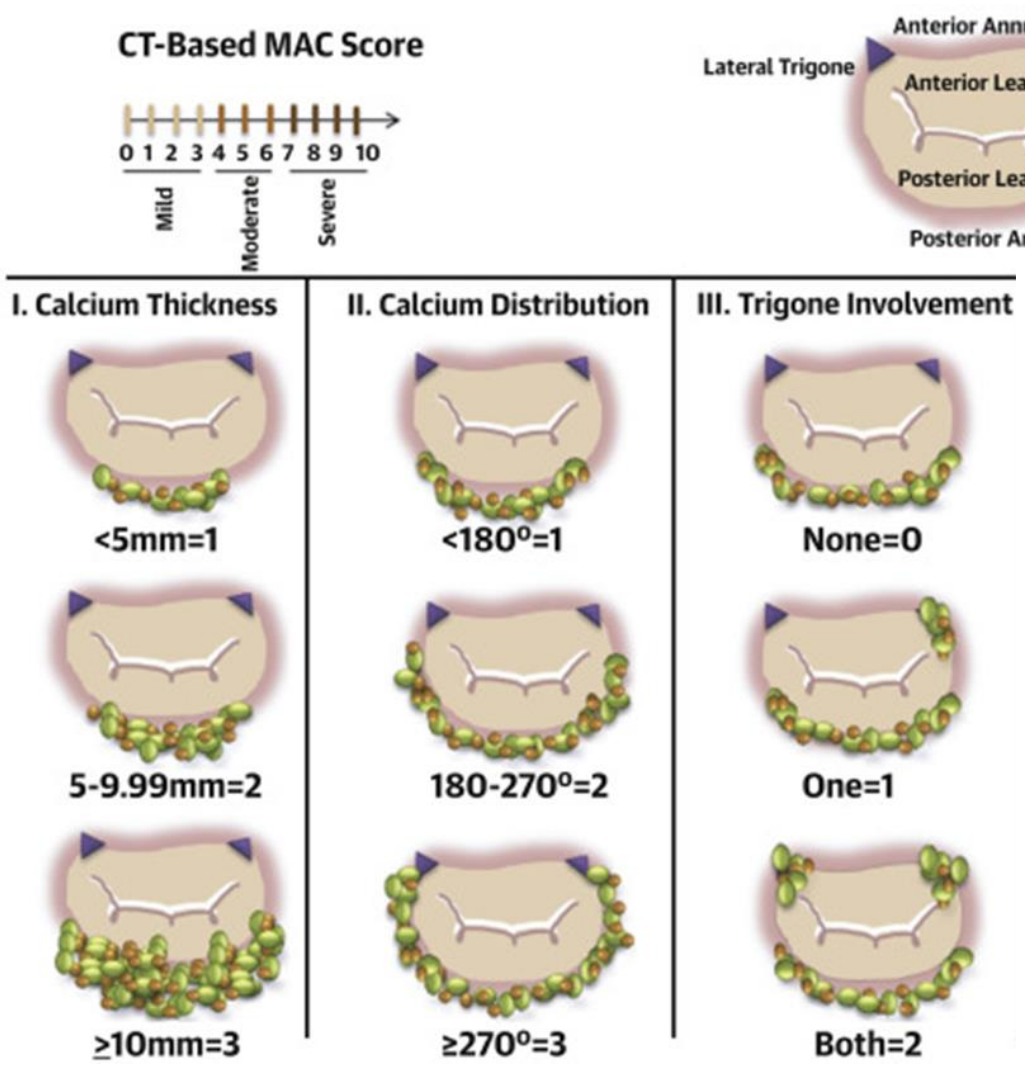

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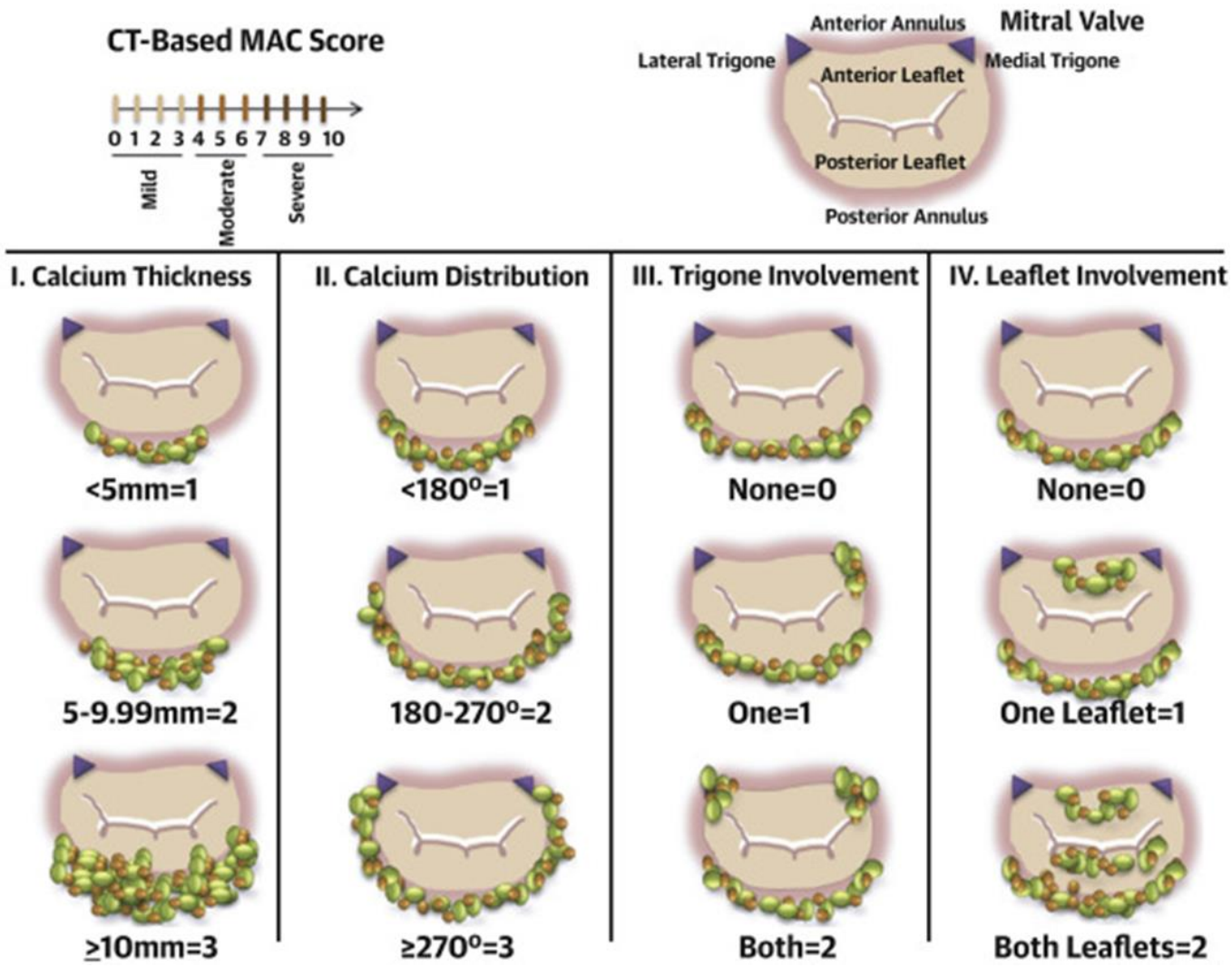

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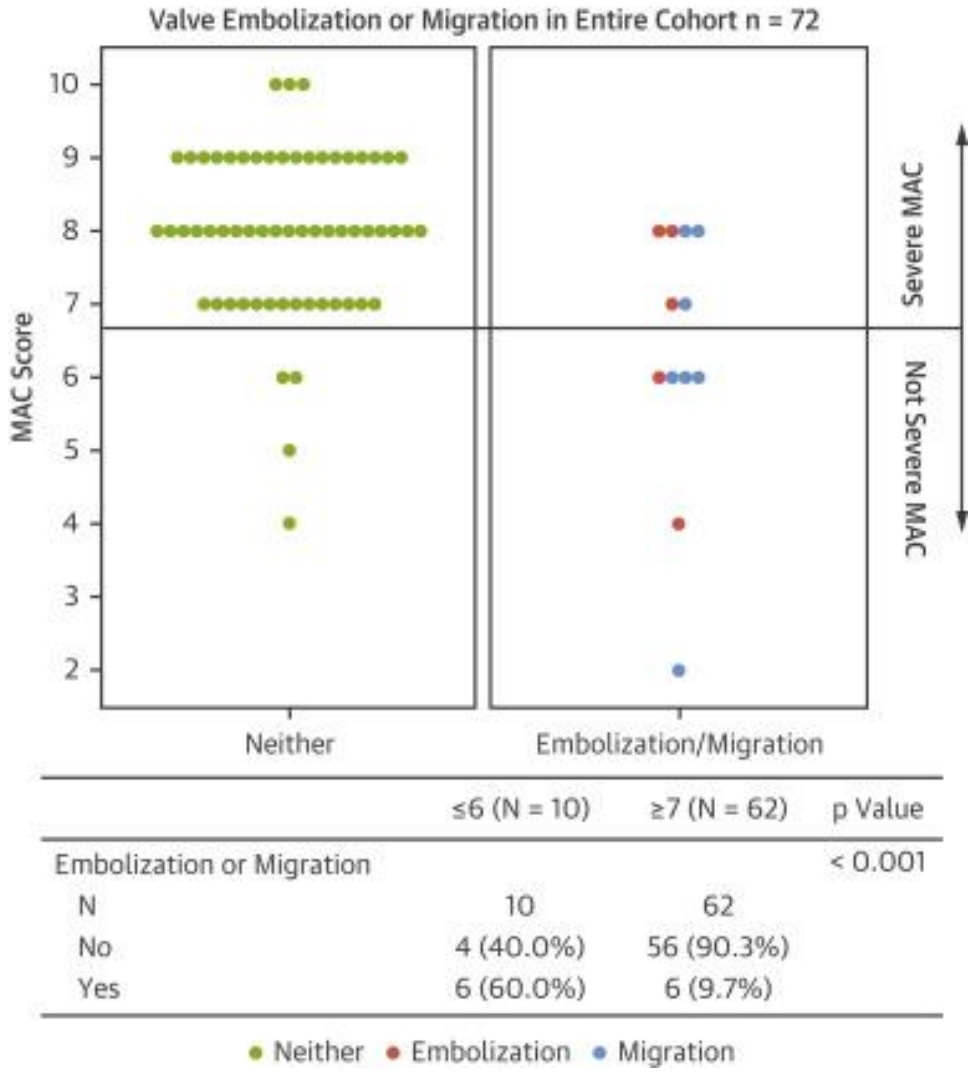
Issues with Valve-in-MAC

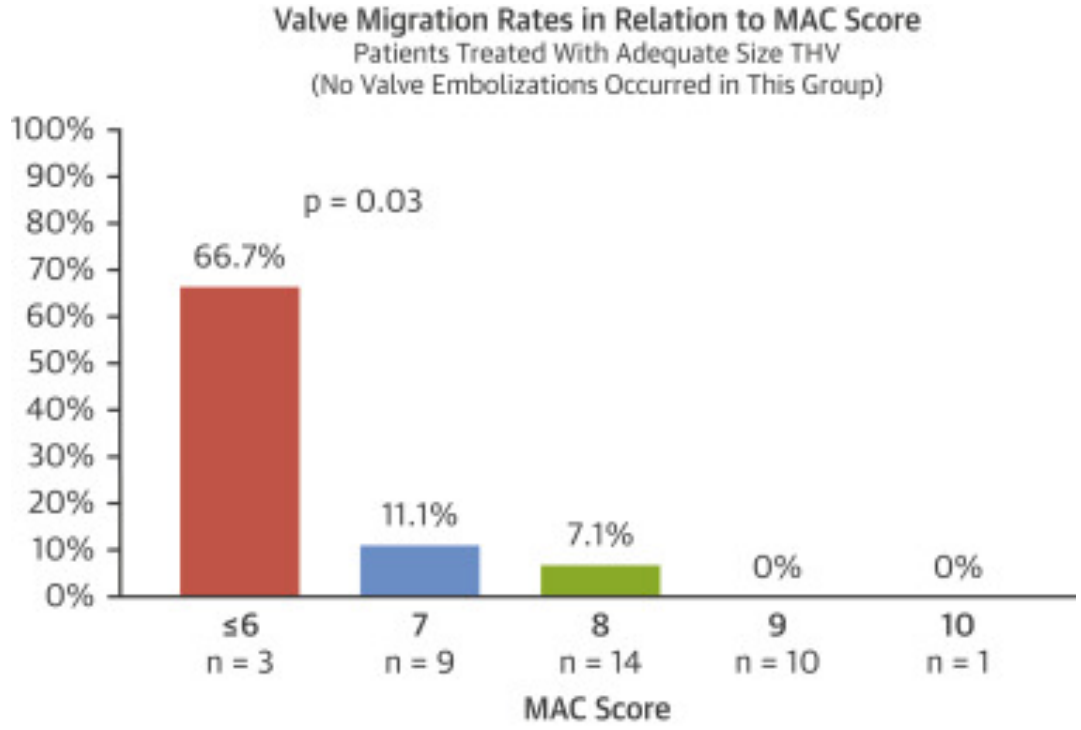


	≤6 (N = 10)	≥7 (N = 62)	p Value
Embolization or Migration			< 0.001
N	10	62	
No	4 (40.0%)	56 (90.3%)	
Yes	6 (60.0%)	6 (9.7%)	

● Neither ● Embolization ● Migration

MAC score 7 - embolization/migration 12.5%
MAC score ≥8 - 8.7%
MAC score of ≥9 - zero (p = 0.023)

MAC ≤6: OR 5.86 [1.00-34.26]; p = 0.049



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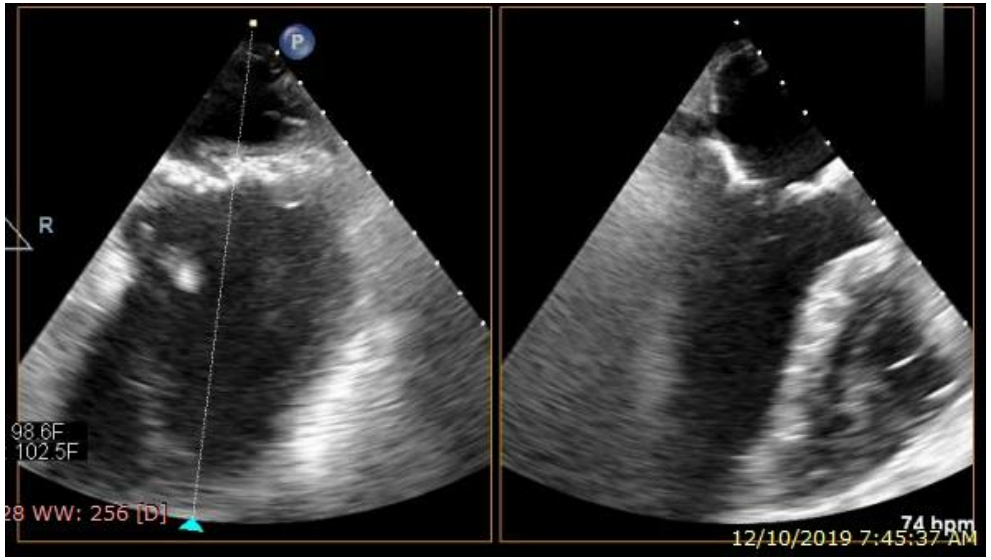
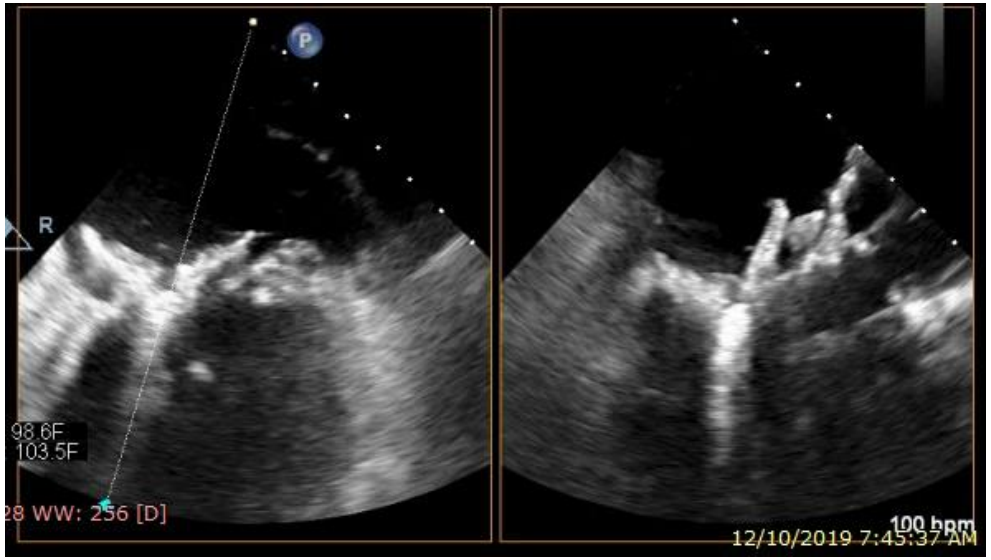
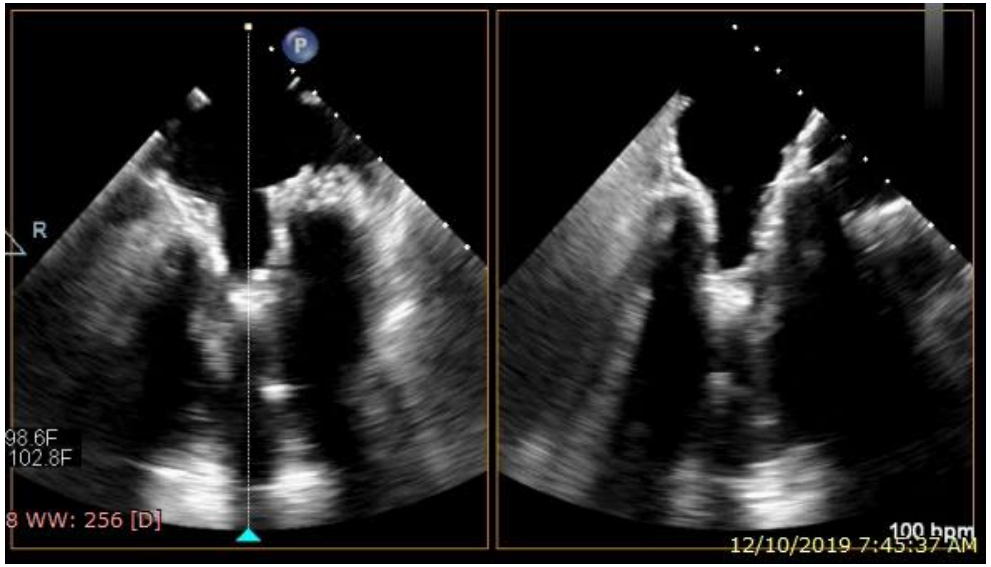
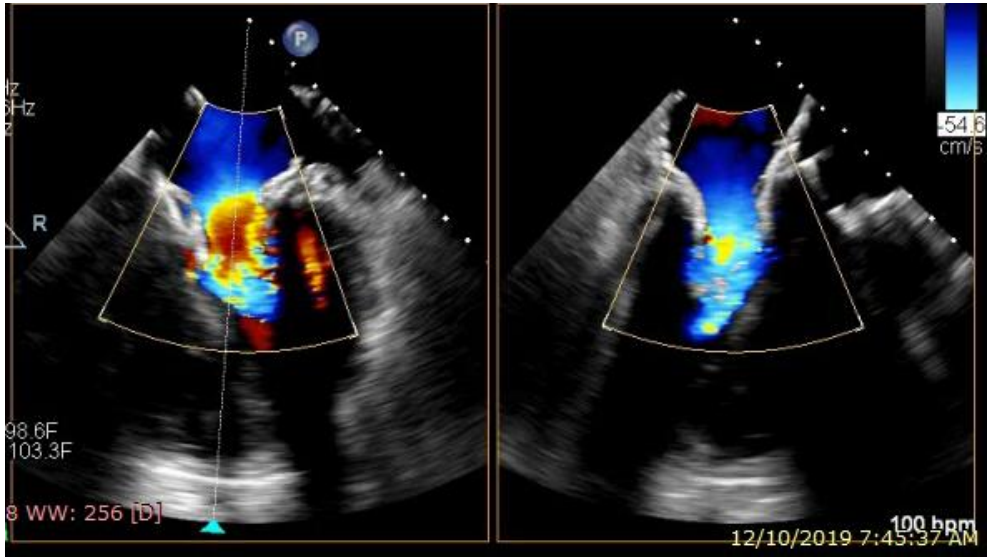
Tendyne-in-MAC

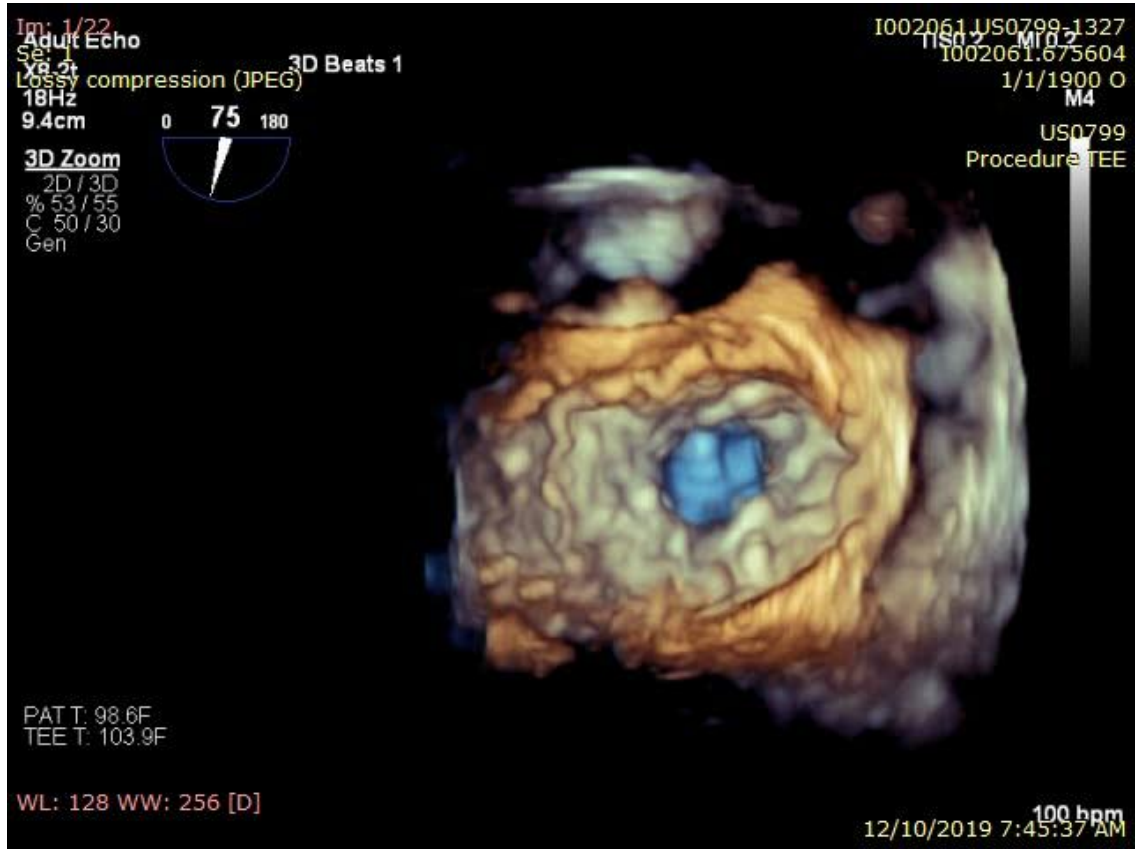




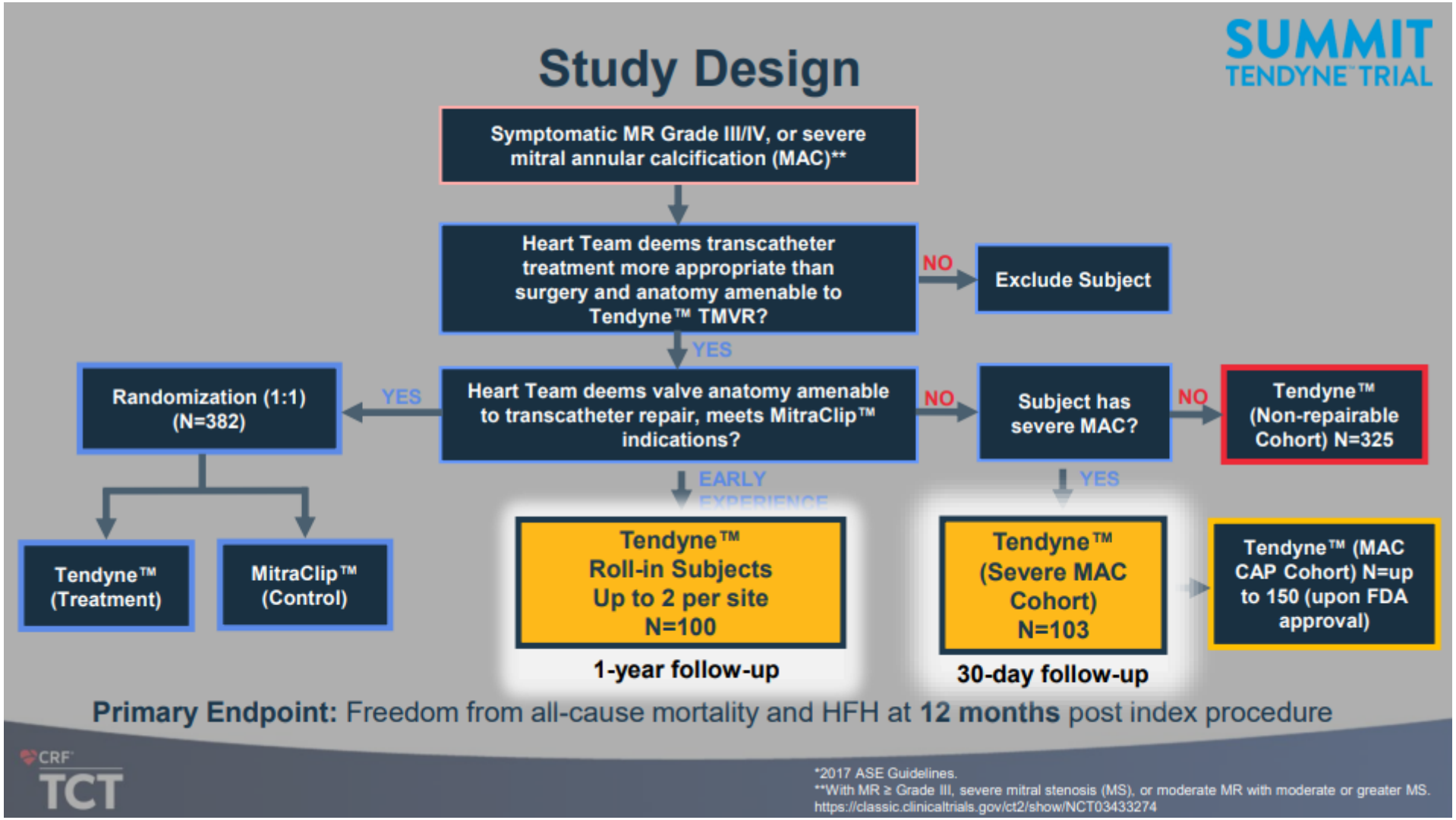




Tendyne-in-MAC



Tendyne-in-MAC: Clinical Results



Subject Screening and Enrollment

SUMMIT TENDYNE™ TRIAL

474 patients Screened in US and Canada
MR 3+ or greater, Severe MS, or Moderate MR+MS

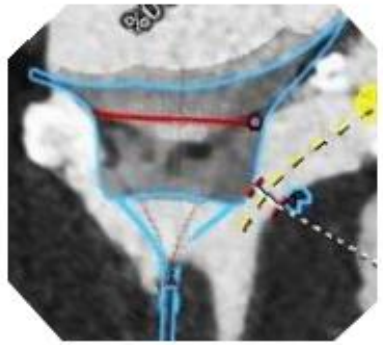
120 patients approved by Subject Eligibility Committee

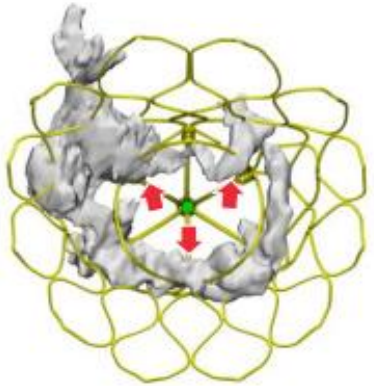
17 patients exited prior to treatment

103 patients treated with Tendyne™ TMVR system

Primary Reasons for Screening Failure (75%):

- Insufficient neoLVOT
- Annular dimensions outside of treatable range
- Interaction with inner valve frame



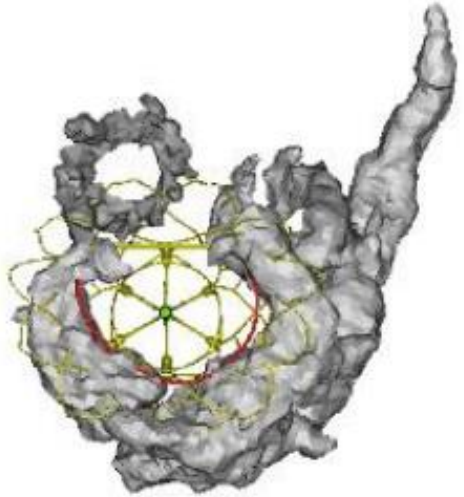


Tendyne-in-MAC: Clinical Results

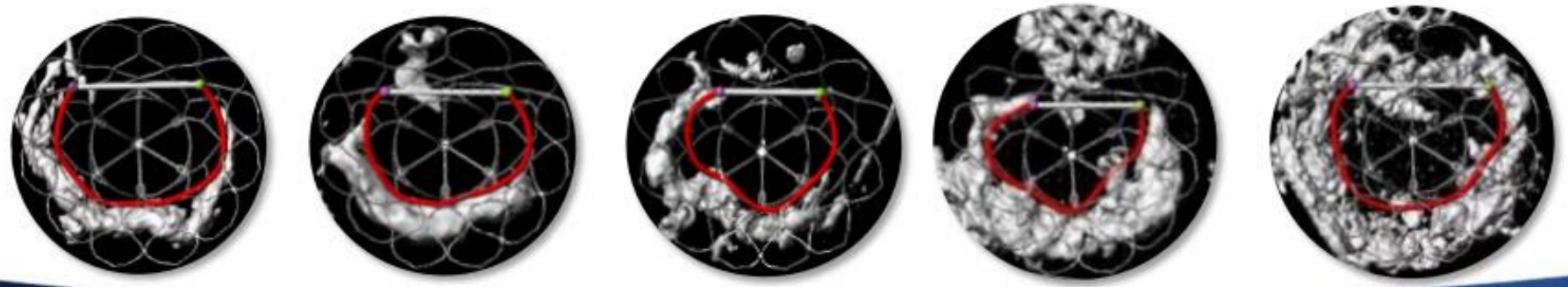
MAC Severity Treated

SUMMIT TENDYNE™ TRIAL

Median MAC Volume in Severe MAC Cohort: ~4000 mm³



Maximum
~38,000 mm³



CRF TCT

SUMMIT Severe MAC

Tendyne-in-MAC: Clinical Results

Baseline Characteristics

SUMMIT TENDYNE™ TRIAL

Subject Characteristics (N=103)	n (%) or mean ± SD
Age (yrs)	78.0 ± 6.5
Men	46 (44.7)
BMI	30.1 ± 6.4
NYHA functional class ≥ III	76 (73.8)
Frailty Score ≥2	57 (55.3)
Hypertension	92 (89.3)
Coronary artery disease	63 (61.2)
Prior myocardial infarction	16 (15.5)
Prior CABG	28 (27.5)
COPD	30 (29.1)
Diabetes mellitus	54 (52.4)

	n (%) or mean ± SD
Heart Failure Hosp within 12 mo	30 (29.1)
GFR< 60 mL/min/1.73 m²	57 (55.3)
LV ejection fraction (%)	56.1 ± 9.5
Grade III or IV MR severity	89 (89.0)
Etiology of MR	
Primary	93 (90.3)
Secondary	7 (6.8)
Mixed	3 (2.9)
Severe MS	11 (10.7)
Severe MS & MR ≥ Grade II	7 (6.8)
STS-PROM (%)	7.1 ± 3.9

Tendyne-in-MAC: Clinical Results

Clinical Outcomes

SUMMIT TENDYNE™ TRIAL

Procedural Events	n (%)
Procedural survival	101 (98.1)
Technical success*	97 (94.2)
Valve implanted†	103 (100)
Emergency surgery/intervention	6 (5.8)
CPB	3 (2.9)
Procedural stroke	0 (0)

*MVARC definition
†One valve retrieved with secondary valve implanted

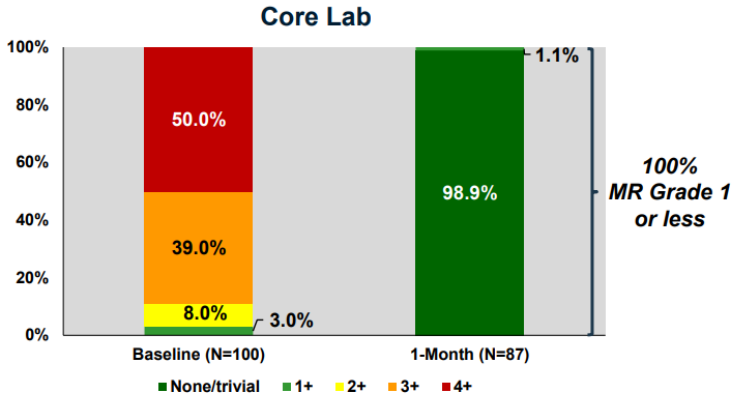
30-Day Events*	n (%)
All-cause mortality	7 (6.8)
Cardiovascular mortality	7 (6.8)
Disabling stroke	1 (1.0)
Myocardial infarction	1 (1.0)
Post-op mitral reintervention	2 (2.0)
Device thrombosis	0 (0)
Major bleeding	22 (21.4)

*All events adjudicated by independent CEC per MVARC definitions

Tendyne-in-MAC: Clinical Results

MR Severity

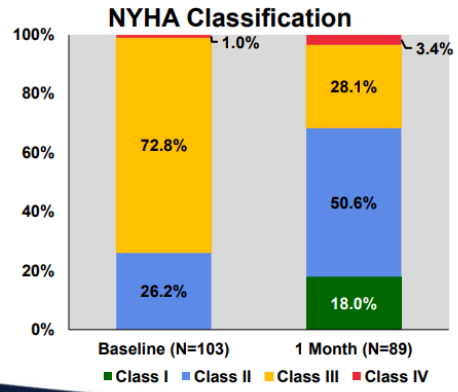
SUMMIT TENDYNE™ TRIAL

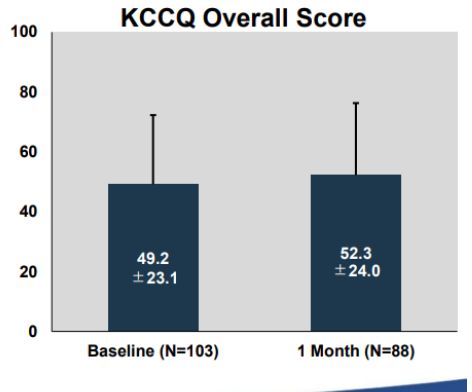


CRF TCT SUMMIT Severe MAC

Heart Failure Symptoms and QoL

SUMMIT TENDYNE™ TRIAL



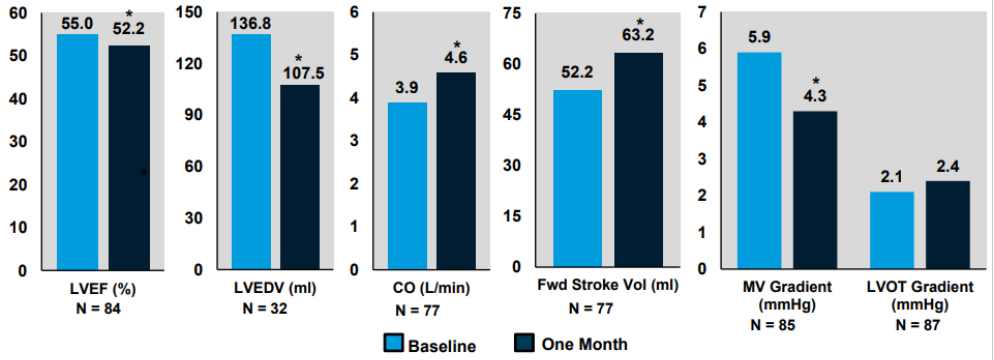


CRF TCT SUMMIT Severe MAC

Echo Assessments: Paired Analysis

Core Laboratory Measurements

SUMMIT TENDYNE™ TRIAL



CRF TCT SUMMIT Severe MAC

* Indicates positive or negative change from baseline (95% CI does not contain 0)

Tendyne-in-MAC: Clinical Results

Tendyne in Severe MAC

INTERVENTIONS FOR VALVULAR DISEASE AND HEART FAILURE

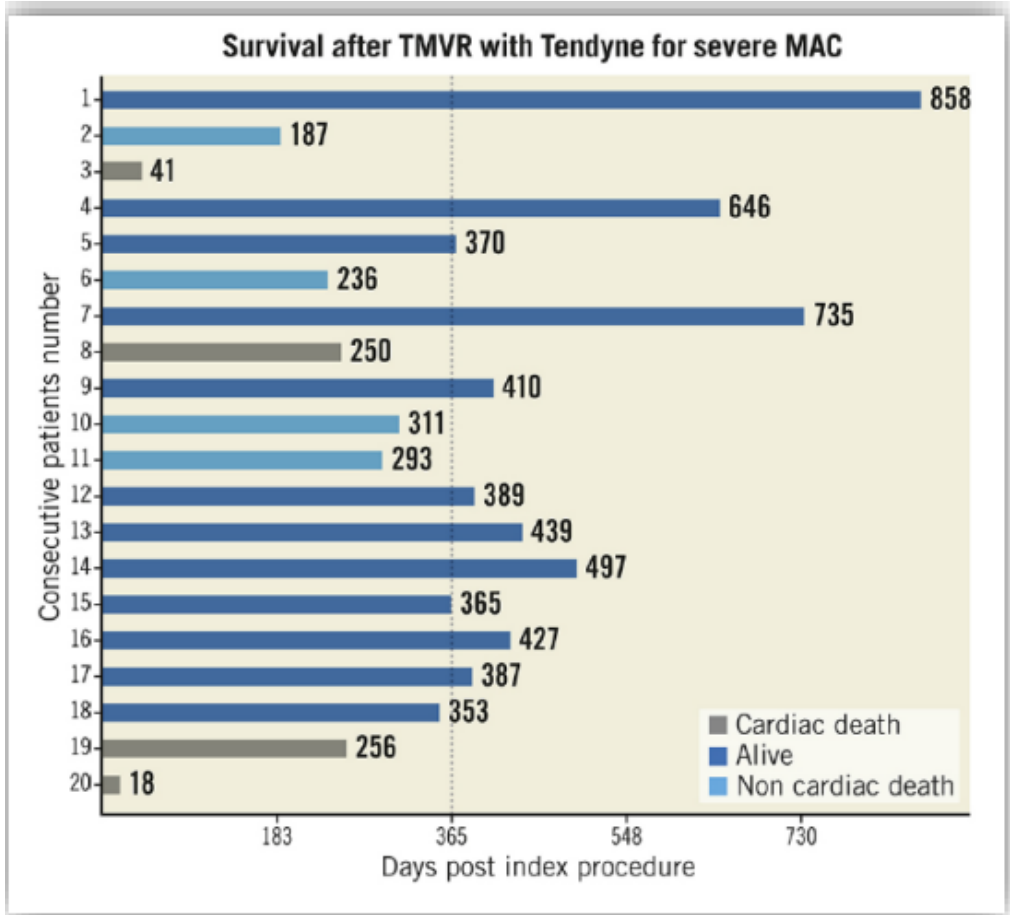
Early outcomes of transcatheter mitral valve replacement with the Tendyne system in severe mitral annular calcification

EuroIntervention 2022;17:1523-1531. DOI: 10.4244/EIJ-D-21-00745

Mario Gössl[1], MD; Vinod Thourani[2], MD; Vasilis Babaliaros[3], MD; Lenard Conradi[4], MD; Bassem Chehab[5], MD; Nicolas Dumonteil[6], MD; Vinay Badhwar[7], MD; David Rizik[8], MD; Benjamin Sun[1], MD; Richard Bae[1], MD; Robert Guyton[3], MD; Michael Chuang[9], MD; Philipp Blanke[10], MD; Paul Sorajja[1], MD

1. Valve Science Center, Minneapolis Heart Institute Foundation, Minneapolis, MN, USA; 2. Department of Cardiovascular Surgery, Marcus Valve Center, Piedmont Heart Institute, Atlanta, GA, USA; 3. Emory Structural Heart and Valve Center, Atlanta, GA, USA; 4. University Heart & Vascular Center Hamburg, Hamburg, Germany; 5. Ascension Via Christi Hospital, Wichita, KS, USA; 6. Groupe CardioVasculaire Interventionnel, Clinique Pasteur, Toulouse, France; 7. West Virginia University Heart and Vascular Institute, Morgantown, WV, USA; 8. HonorHealth, Scottsdale, AZ, USA; 9. Beth Israel Deaconess Medical Center, Boston, MA, USA; 10. Department of Radiology, St. Paul's Hospital and University of British Columbia Vancouver, BC, Canada

CRF TCT



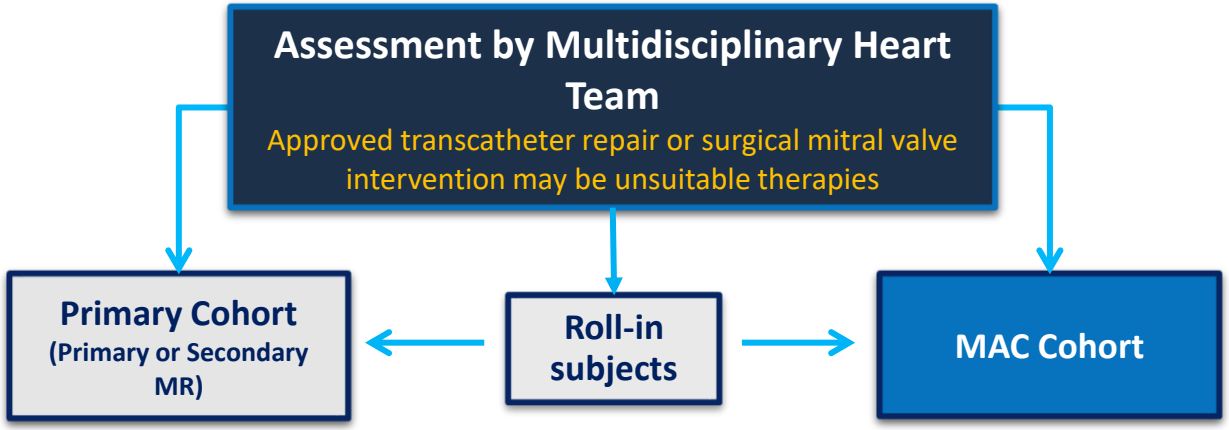
30-day mortality: 5%

1-year CV mortality: 20%

MAC Cohort Inclusion Criteria

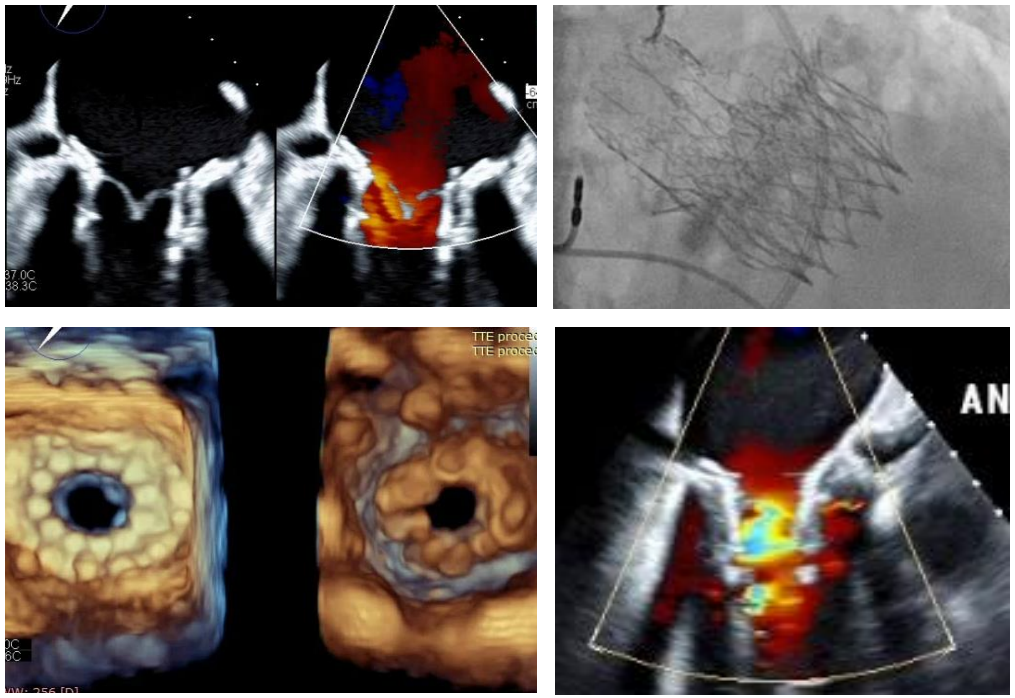
INCLUSION CRITERIA

- Patients with Moderate-to-Severe or Severe MR with presence of MAC, ***OR***
- Patients with Moderate MR, Mitral Stenosis with presence of MAC



Primary Endpoint:
All-Cause Mortality at 1 year[1]

[1] Performance goal based on comparative literature



Baseline Characteristics

The Intrepid‡ TMVR-TF System has been used to treat patients with MAC who have mitral valve anatomies deemed unsuitable for TEER by the Multidisciplinary Heart Team as part of the APOLLO Trial MAC Cohort.

Subject Demographics			
	Patient 1	**Patient 2**	**Patient 3**
Age and Sex	77-year-old male	66-year-old male	85-year-old female
Disease Etiology / Morphology	Primary / Type IIA	Primary / Type II; Concurrent IIIA	Primary / Type IIIA
NYHA	Class II	Class III	Class III
STS Score – PROM	8.0%	2.3%	27.7%
Cardiac History			
Atrial Fibrillation/Flutter	Yes	Yes	Prior atrial fibrillation
Prior SAV or TAV	SAV	SAV	None
Prior PPI, ICD, CRT-D	CRT-D	PPI	None
RV function	Normal	Moderate Dysfunction	Normal
Case Planning			
Device Size	48 mm	48 mm	42 mm

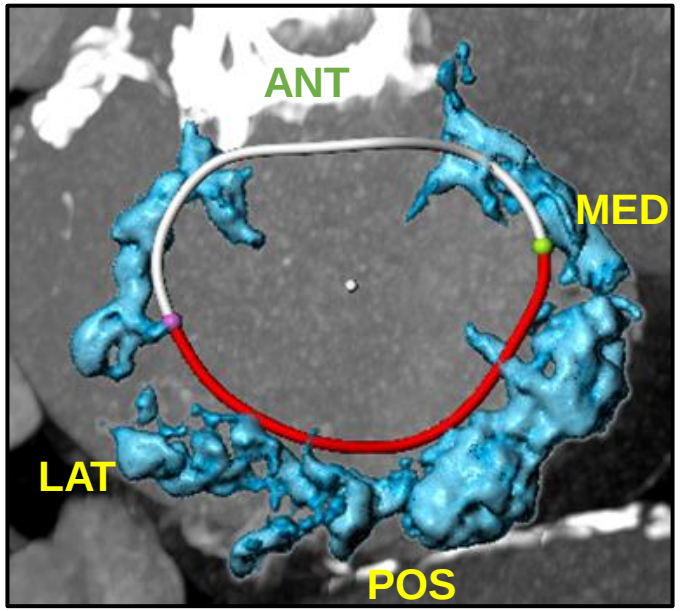
Baseline Characteristics

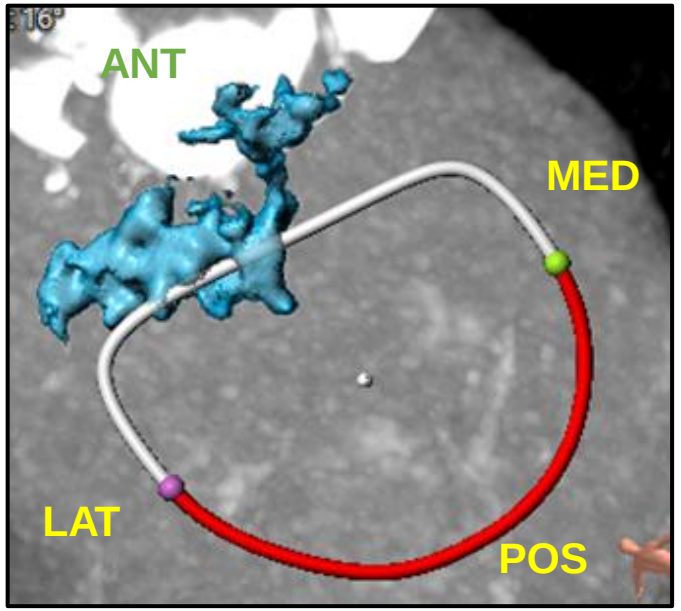
Echo Core Lab Data			
	Patient 1	**Patient 2**	**Patient 3**
MR Grade	Severe	Moderate-Severe	Moderate-Severe
MAC Grade	Severe	Mild	Severe
LVEF	56%	39%	65%
TR Grade	Moderate	Mild	Trivial
LVEDV	154 mL	215 mL	170 mL
LVESV	67 mL	131 mL	58 mL
PASP	41 mmHg	39 mmHg	36 mmHg
MV Mean Gradient	5.0 mmHg	6.6 mmHg	4.0 mmHg

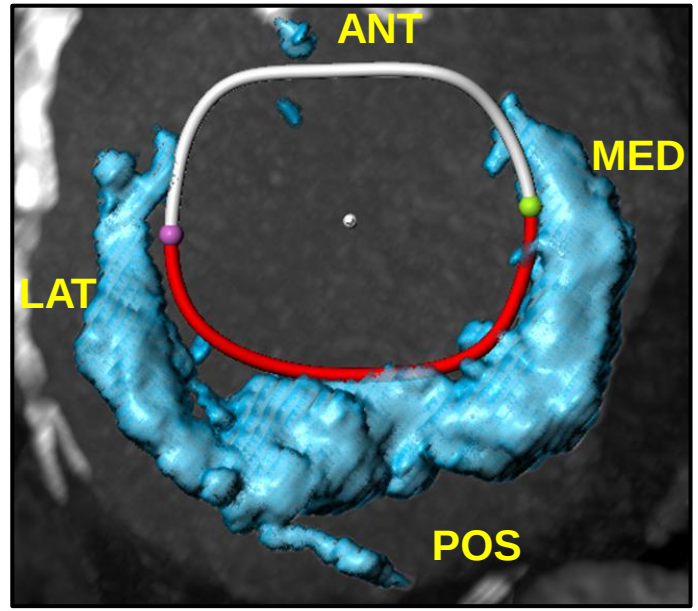
Intrepid clinical results: Apollo Trial

CT Mitral Annular Calcification

Patient 1	Patient 2	Patient 3
MAC: Severe	MAC: Mild	MAC: Severe







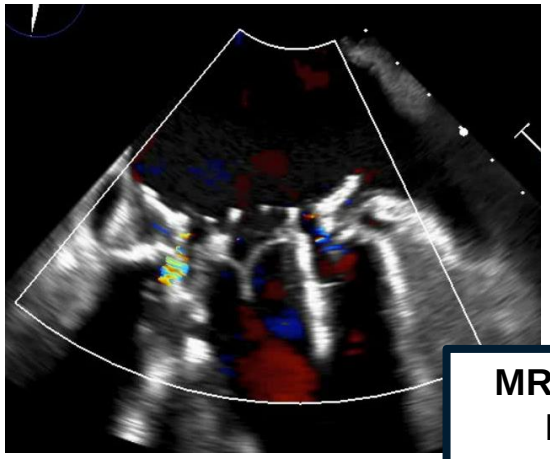
MAC Volume Score*	MAC Volume Score	MAC Volume Score
5156 mm^3	1136 mm^3	8519 mm^3

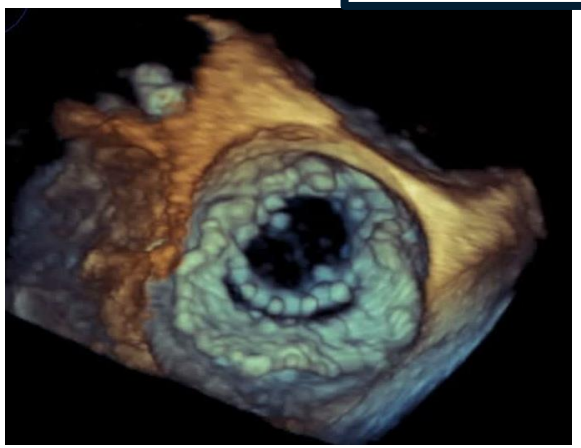
*Score may be underestimated in patient 1 due to regions of possible caseous MAC

Intrepid clinical results: Apollo Trial

Post-Deployment Results

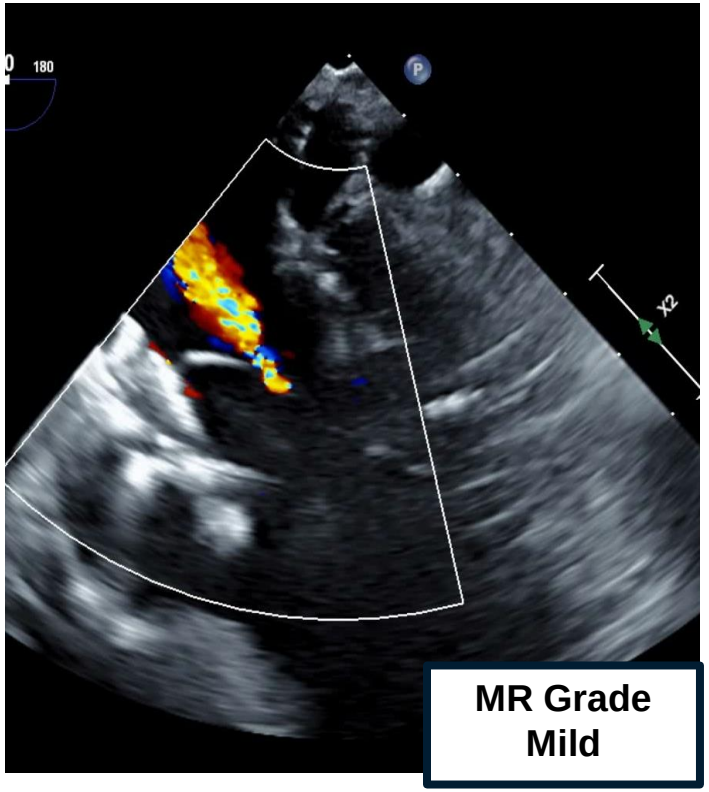
Patient 1





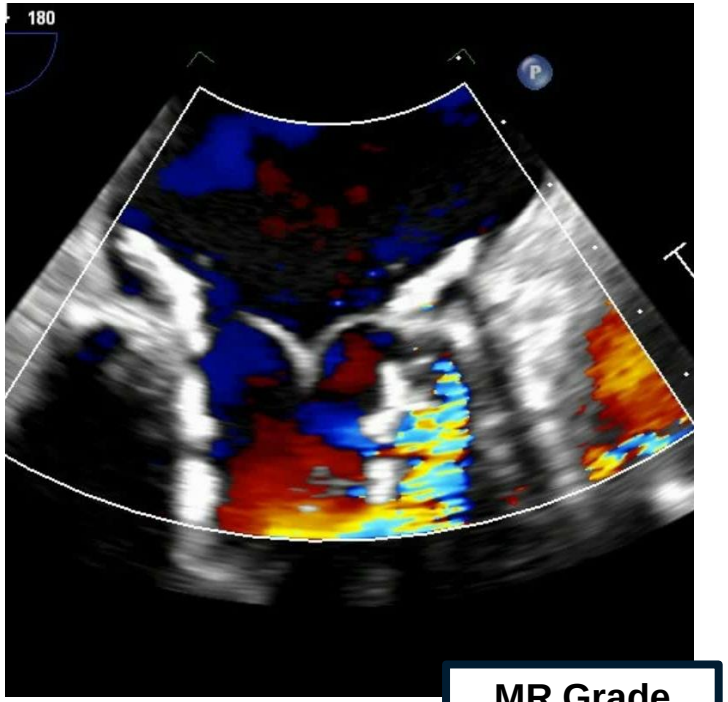
MR Grade Mild

Patient 2



MR Grade Mild

Patient 3



MR Grade Trace

Device-in-MAC: “Real-World” Clinical Results

Device-in-MAC: "Real-World" Clinical Results

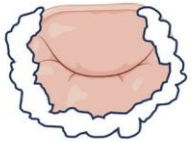
CENTRAL ILLUSTRATION: Outcomes Following Transcatheter Mitral Valve Replacement for Patients With Mitral Annular Calcification

CHOICE-MI Registry

Median Age
76 years

N = 279

Median EuroSCORE II
6.2%

$MAC_{none/mild}$		$MAC_{mod/sev}$
n = 222 (79.6%)		n = 57 (20.4%)
		
85.9%	MR Elimination	80.8%
+++	Symptom Improvement	+++
24.9%	2-Year CV Mortality	21.3%
8.8%	Major Bleeding	21.6%
8.2%	Acute Kidney Injury	26.8%

- Rates of MR elimination, symptom improvement, and survival were similar for patients with none/mild MAC and those with moderate/severe MAC
- TMVR in patients with moderate/severe MAC is associated with higher rates of postprocedural complications (major bleeding: 21.6% vs 8.8%; *P* = 0.02; acute kidney injury: 26.8% vs 8.2%; *P* < 0.001) than in patients with none/mild MAC

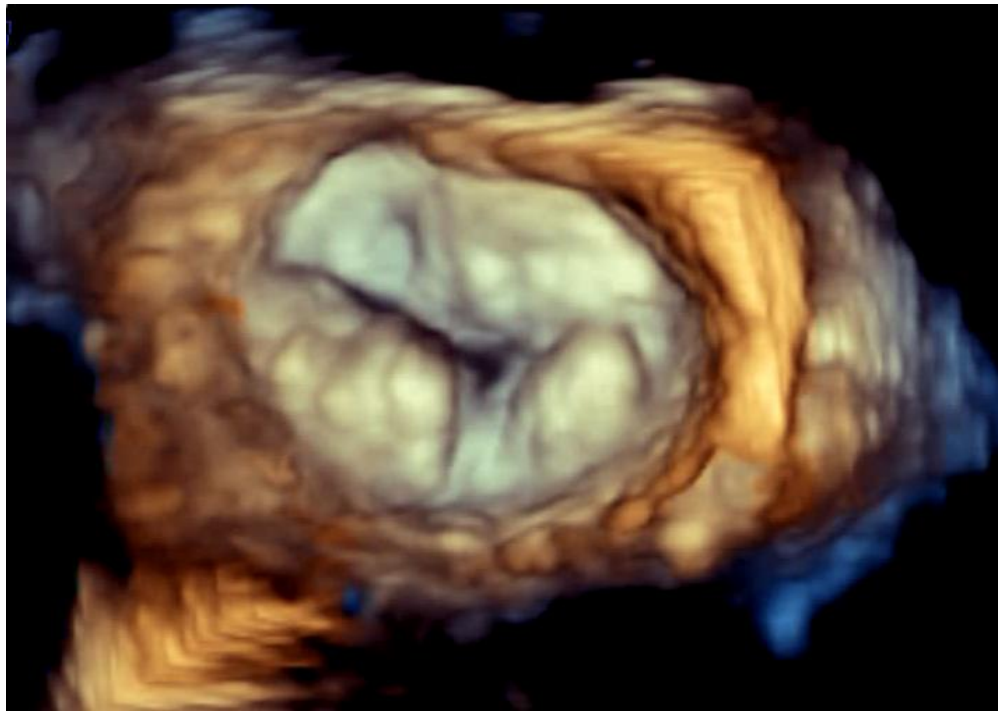
Coisne A, et al. JACC Cardiovasc Interv. 2024;17(18):2141-2153.

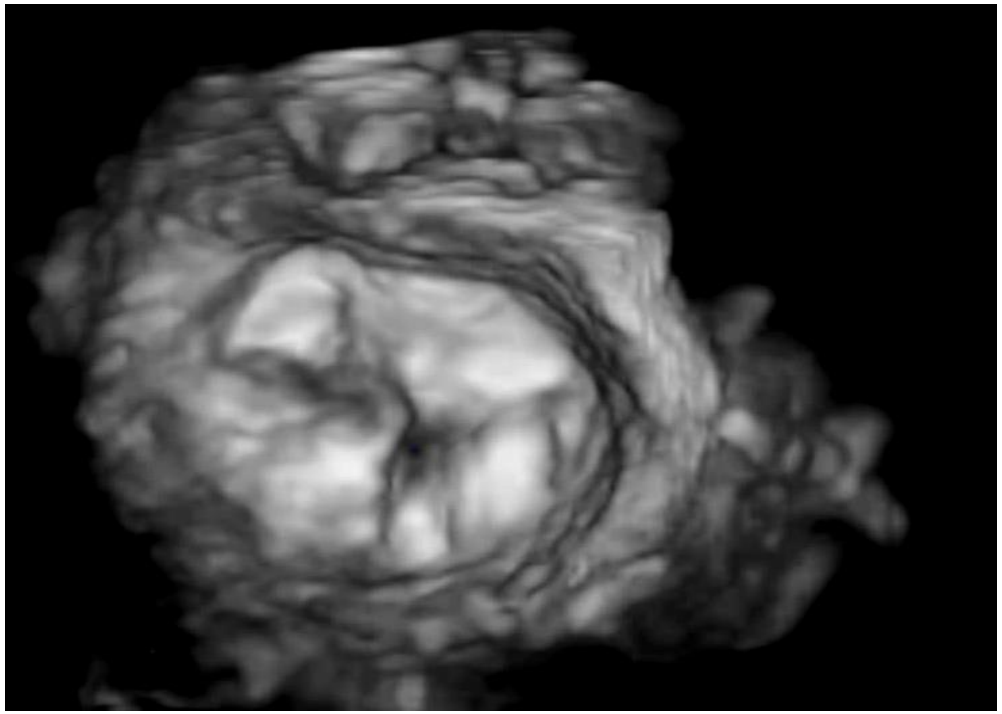
Device-in-MAC: “Real-World” Clinical Results

TMVI may be considered in symptomatic patients with extensive MAC and severe MV dysfunction at experienced Heart Valve Centres with expertise in complex MV surgery and transcatheter interventions.[542,680,681]	IIb	C

2025 ESC/EACTS Guidelines for the management of valvular heart disease. EHJ 2025 00, 1-102

= Mitral Valve “Conundrum”





Mitral valve calcification: transcatheter options

Thank you very much for your kind attention