Transcatheter treatment in lifetime management of MR

Success rate and durability

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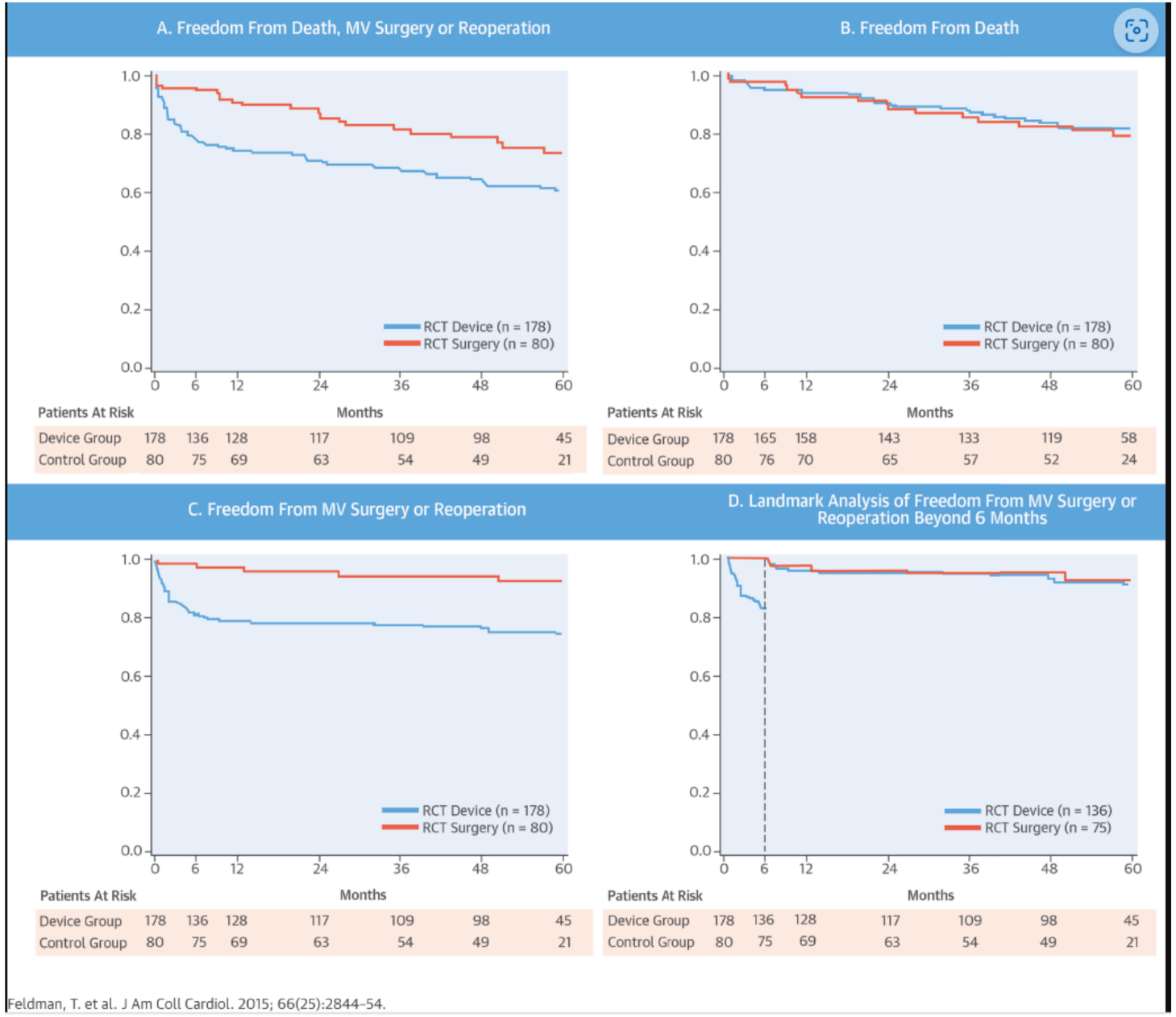
Conflicts of Interest

Speaker's name: Alison Duncan

I am a consultant for, and have received honoraria from

- **Abbott Laboratories**
- **Edwards Lifesciences**
- **Medtronic**

Evidence base for success of MV-TEER



Feldman, T. et al. J Am Coll Cardiol. 2015; 66(25):2844-54.

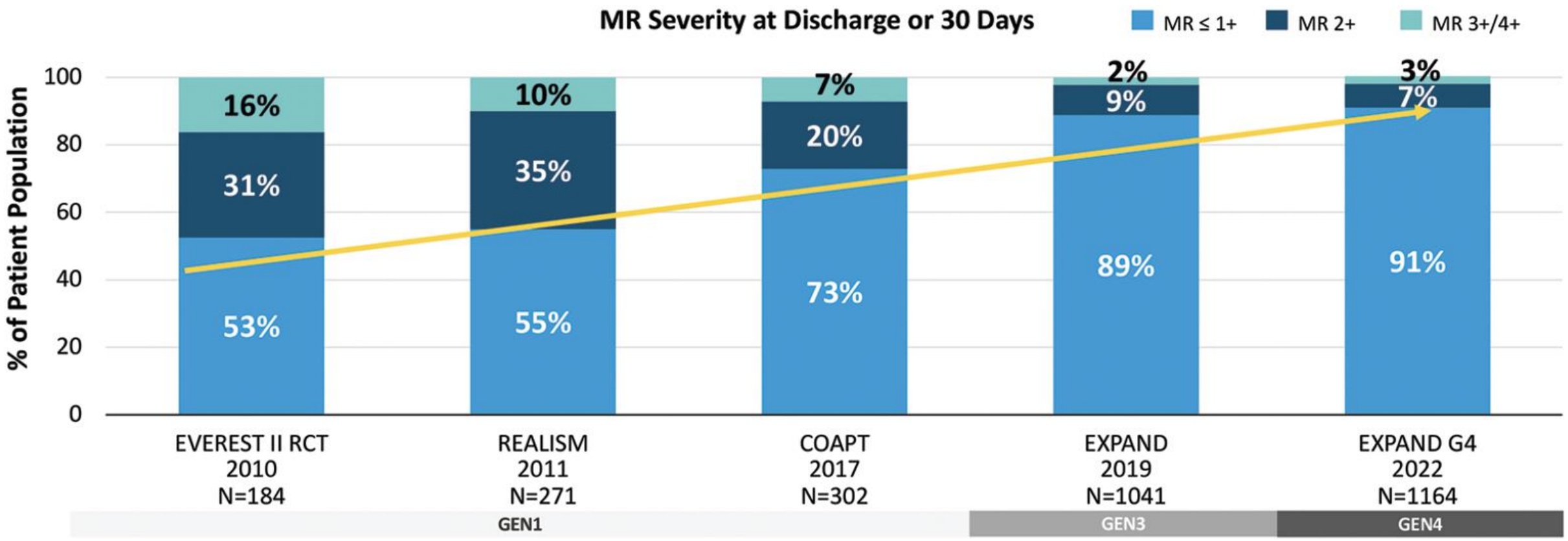
Journal of the American College of Cardiology
Volume 66, Issue 25, 29 December 2015, Pages 2844-2854

Original Investigation

Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation: 5-Year Results of EVEREST II

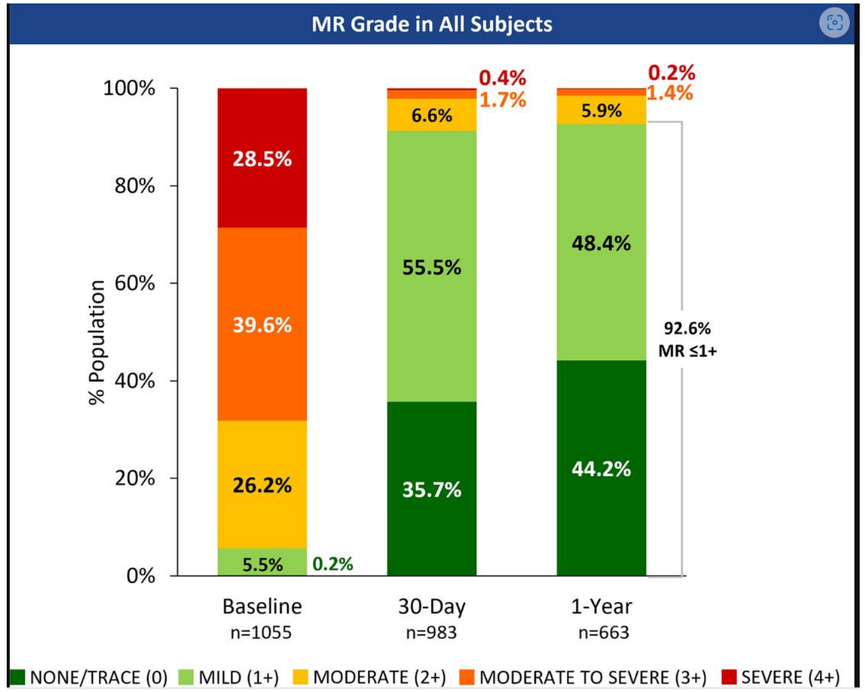
Ted Feldman MD *, Saibal Kar MD †, Sammy Elmariah MD, MPH ‡ §, Steven C. Smart MD *, Alfredo Trento MD ‖, Robert J. Siegel MD †, Patricia Apruzzese MS §, Peter Fail MD ¶, Michael J. Rinaldi MD #, Richard W. Smalling MD, PhD **, James B. Hermiller MD ††, David Heimansohn MD ‡‡, William A. Gray MD §§, Paul A. Grayburn MD ‖‖, Michael J. Mack MD ¶¶, D. Scott Lim MD ##, Gorav Ailawadi MD ***, Howard C. Herrmann MD †††, Michael A. Acker MD ‡‡‡, Frank E. Silvestry MD †††...Laura Mauri MD § ###

MR reduction improves with every device generation



Contemporary Success of MV-TEER: Reduction MR?

EXPAND G4, n=1164



STRUCTURAL

1-Year Outcomes With Fourth-Generation Mitral Valve Transcatheter Edge-to-Edge Repair From the EXPAND G4 Study

Ralph Stephan von Bardeleben, MD,[a] Paul Mahoney, MD,[b] M. Andrew Morse, MD,[c] Matthew J. Price, MD,[d] Paolo Denti, MD,[e] Francesco Maisano, MD,[e] Jason H. Rogers, MD,[f] Michael Rinaldi, MD,[g] Federico De Marco, MD,[h] William Rollefson, MD,[i] Bassem Chehab, MD,[j] Mathew Williams, MD,[k] Guillaume Leurent, MD,[l] Federico M. Asch, MD,[m] Evelio Rodriguez, MD[c]

Contemporary Success of MV-TEER: Reduction MR?

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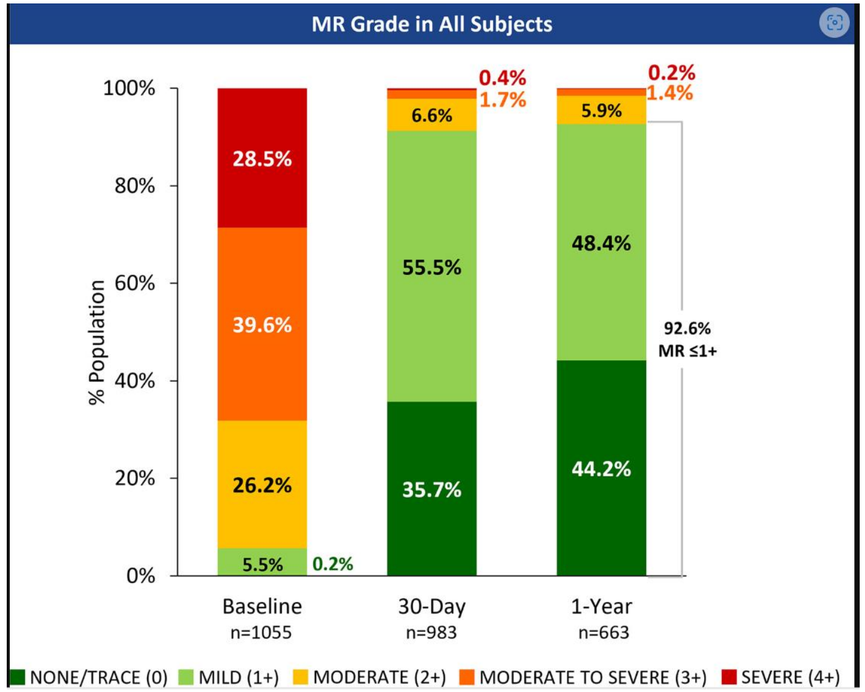

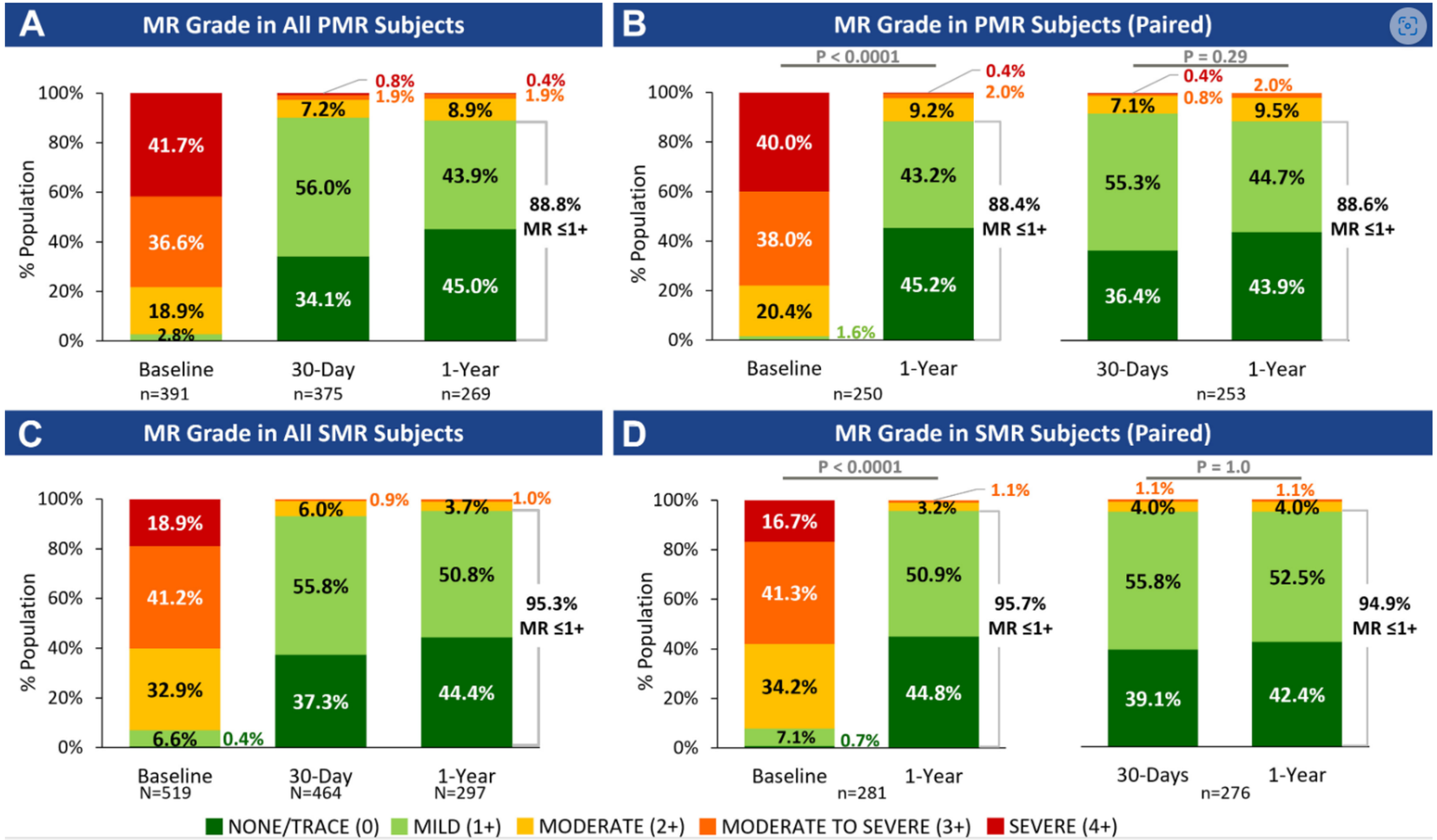

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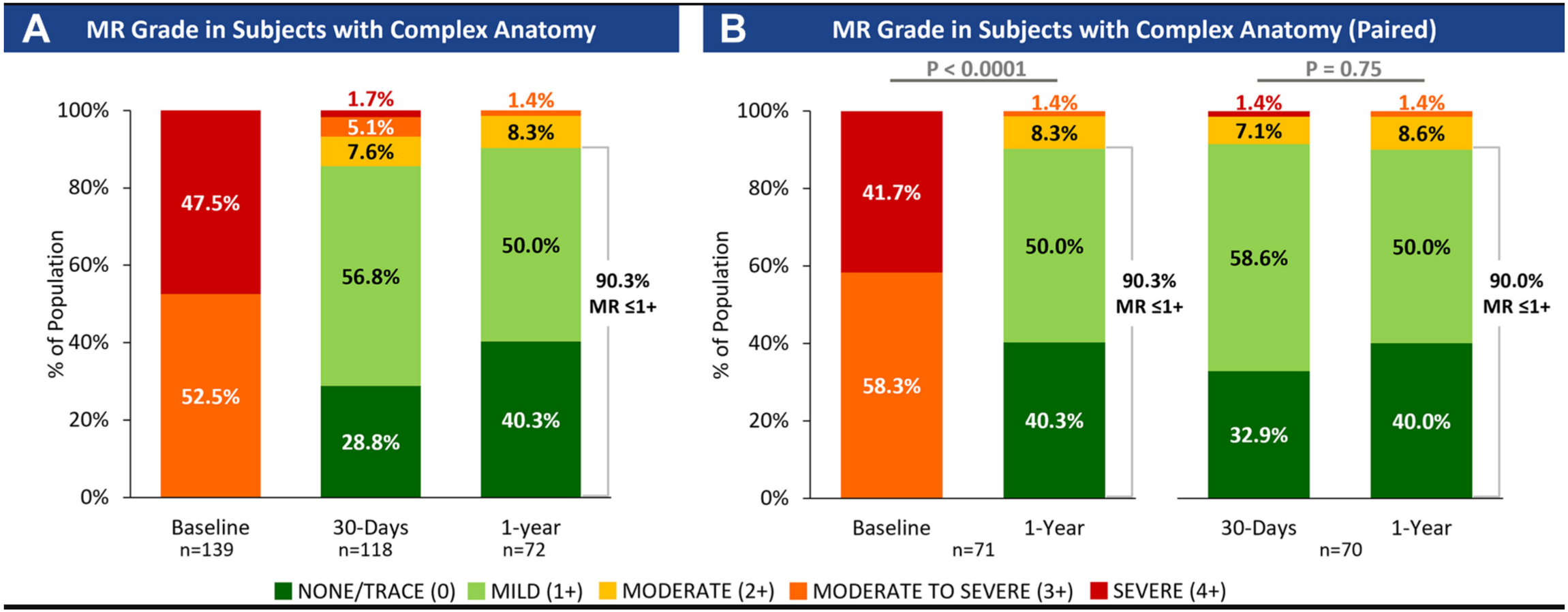
Contemporary Success of MV-TEER: Reduction MR complex anatomy?



STRUCTURAL

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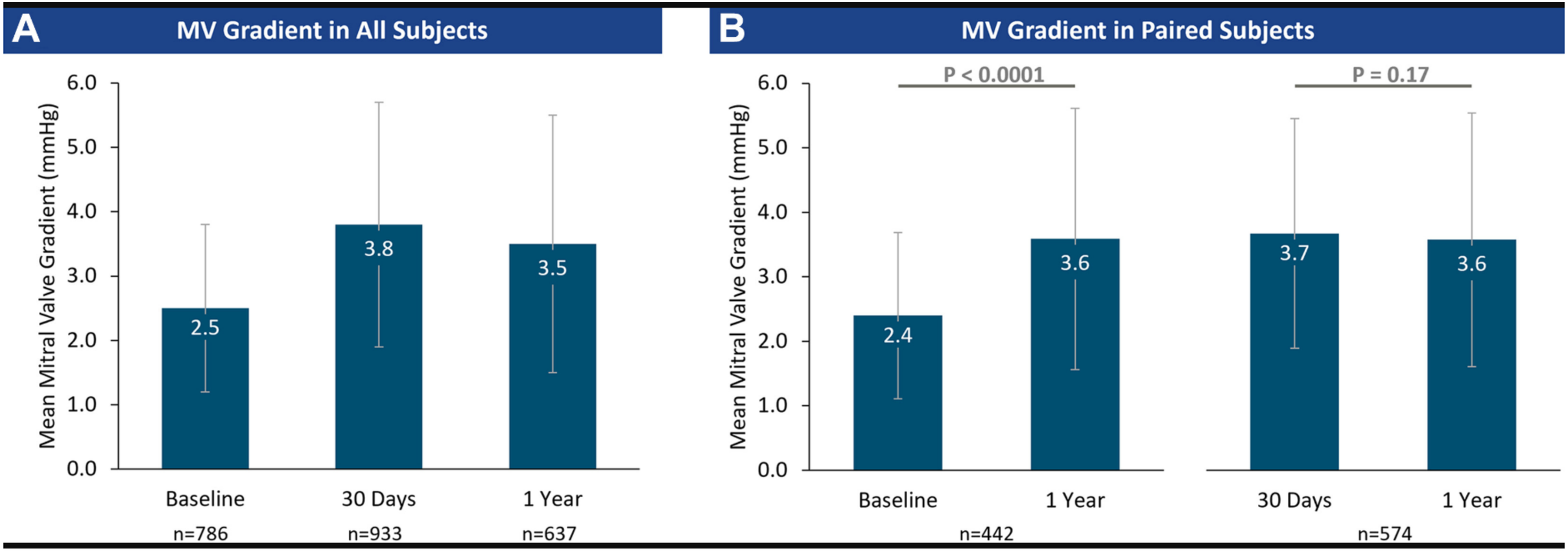
Contemporary Success of MV-TEER: Reduction MR at expense of MS?



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1-Year Outcomes With Fourth-Generation Mitral Valve Transcatheter Edge-to-Edge Repair From the EXPAND G4 Study

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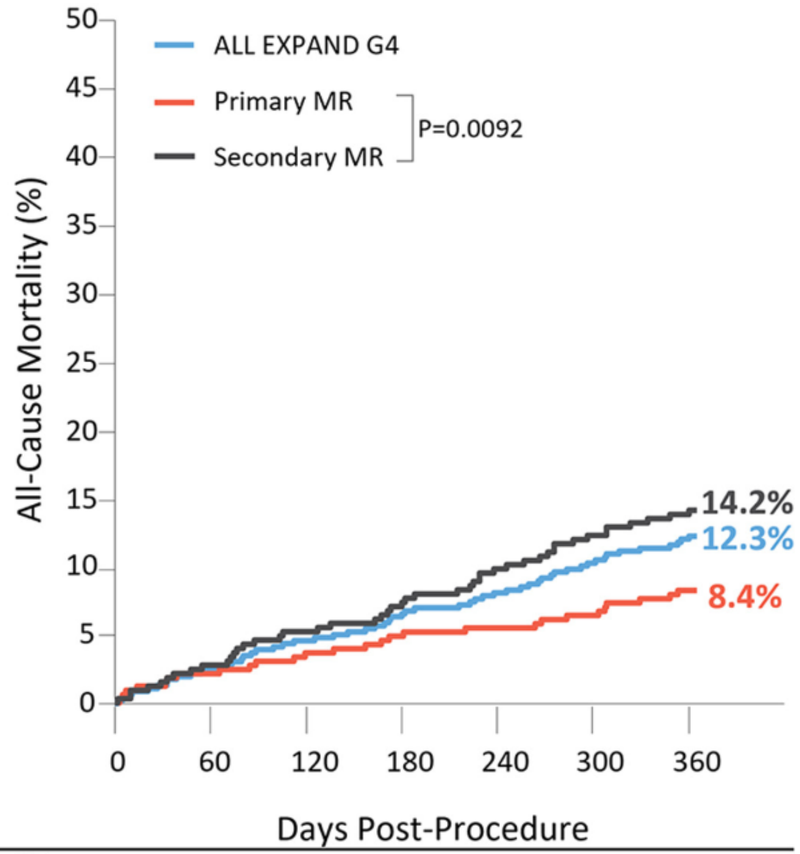
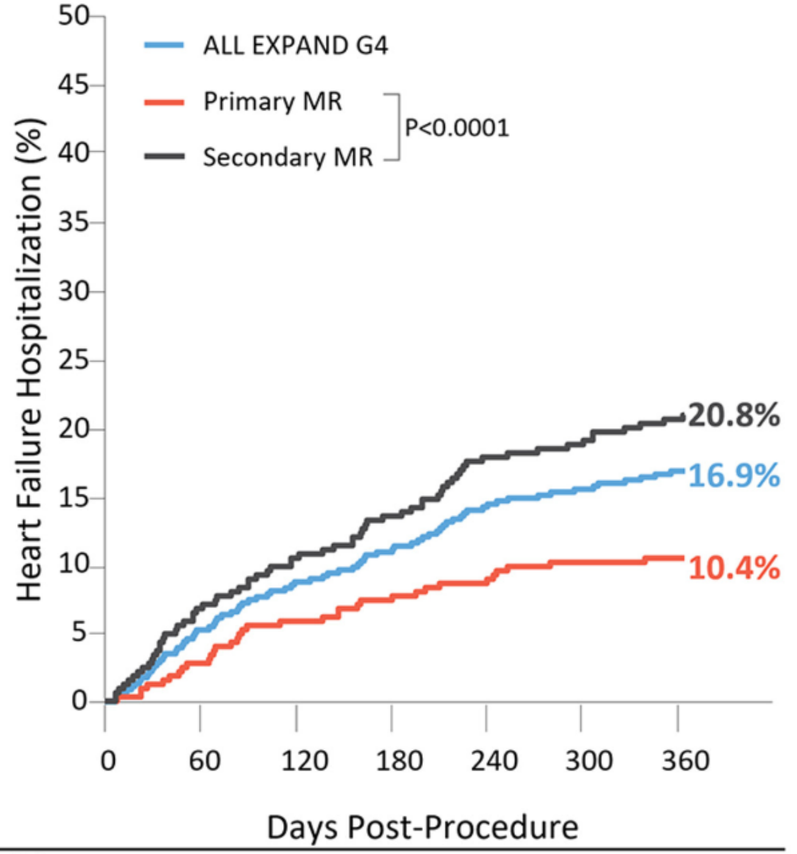
Contemporary Success of MV-TEER: Clinical outcome?

A All-Cause Mortality



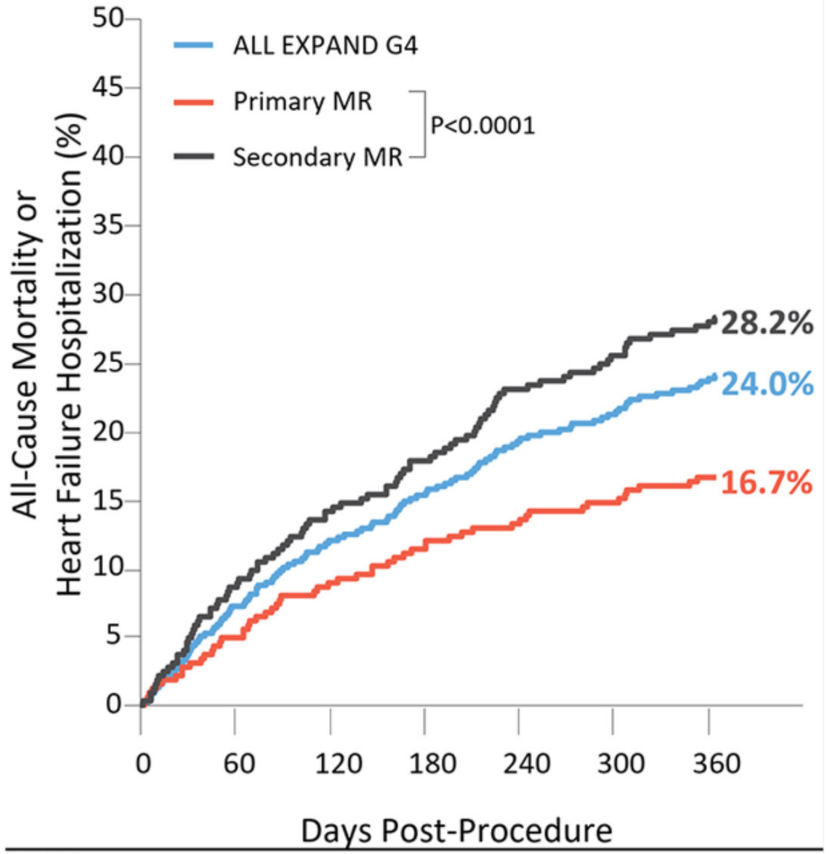
# at Risk					
EXPAND G4	1164	1125	956	778	
PMR	432	420	364	309	
SMR	554	529	452	370	

B Heart Failure (HF) Hospitalization



# at Risk					
EXPAND G4	1164	1102	868	672	
PMR	432	415	340	281	
SMR	554	516	401	308	

C All-Cause Mortality or HF Hospitalization



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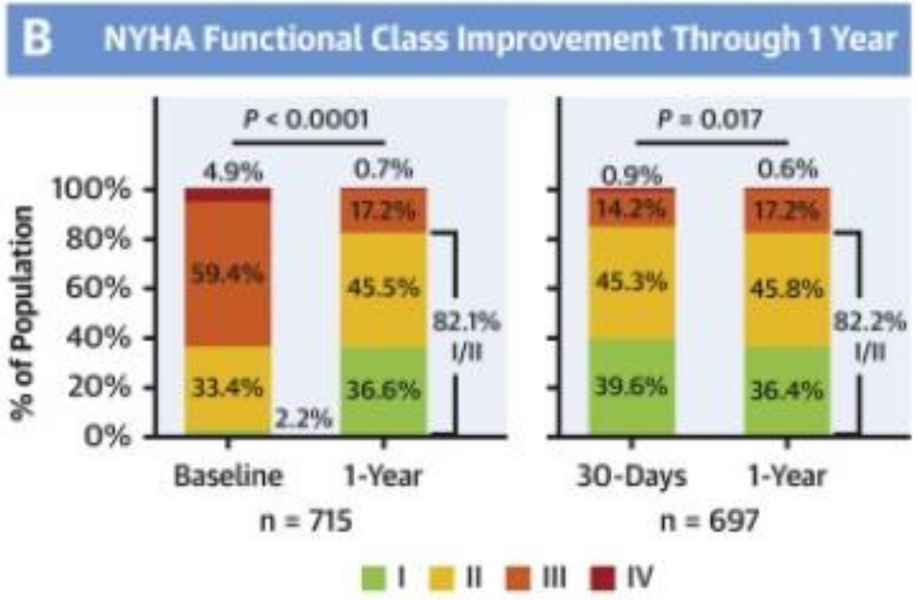
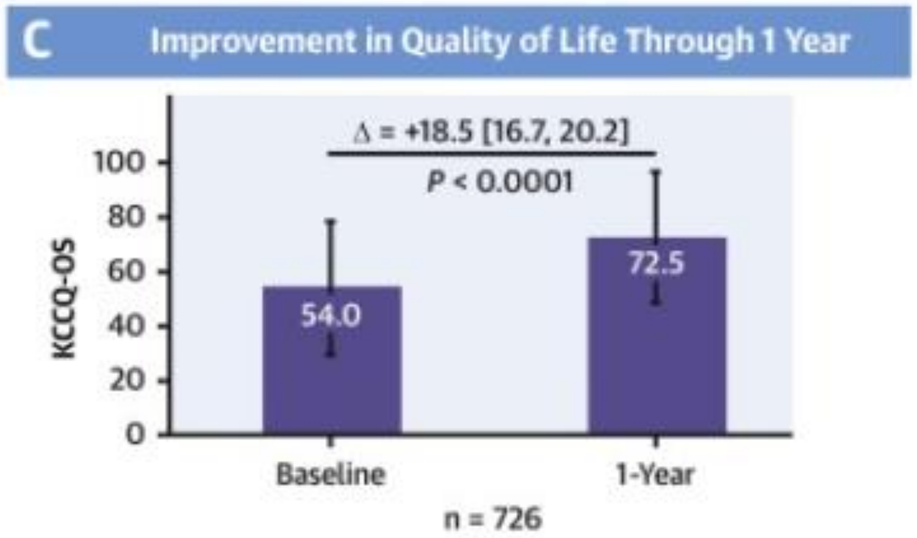
Contemporary Success of MV-TEER: Clinical Outcome?





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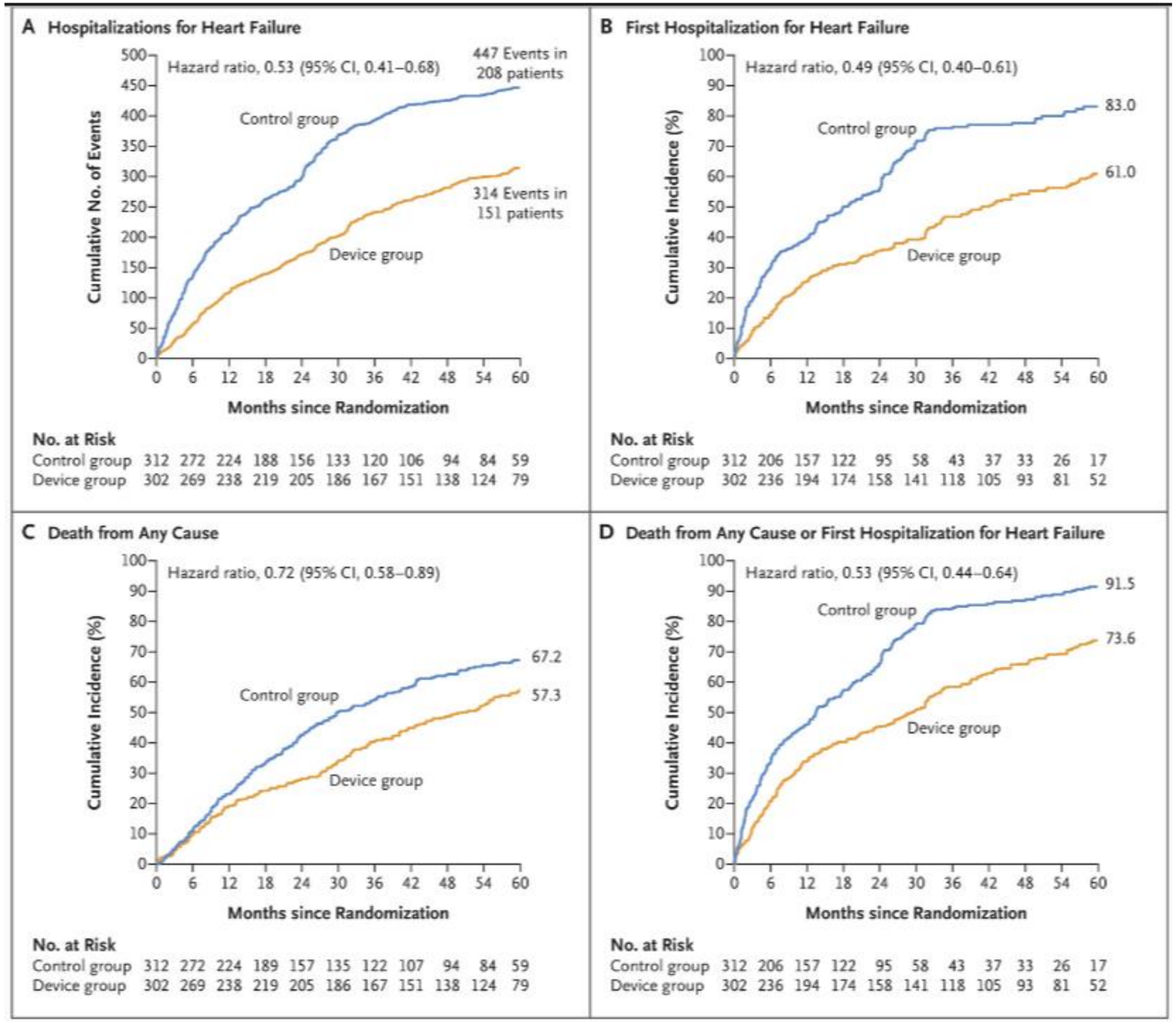
Success rate and durability of MV-TEER: 5-year outcomes COAPT



ORIGINAL ARTICLE

Five-Year Follow-up after Transcatheter Repair of Secondary Mitral Regurgitation

Authors: Gregg W. Stone, M.D., William T. Abraham, M.D., JoAnn Lindenfeld, M.D., Saibal Kar, M.D., Paul A. Grayburn, M.D., D. Scott Lim, M.D., Jacob M. Mishell, M.D., +10, for the COAPT Investigators Author Info & Affiliations

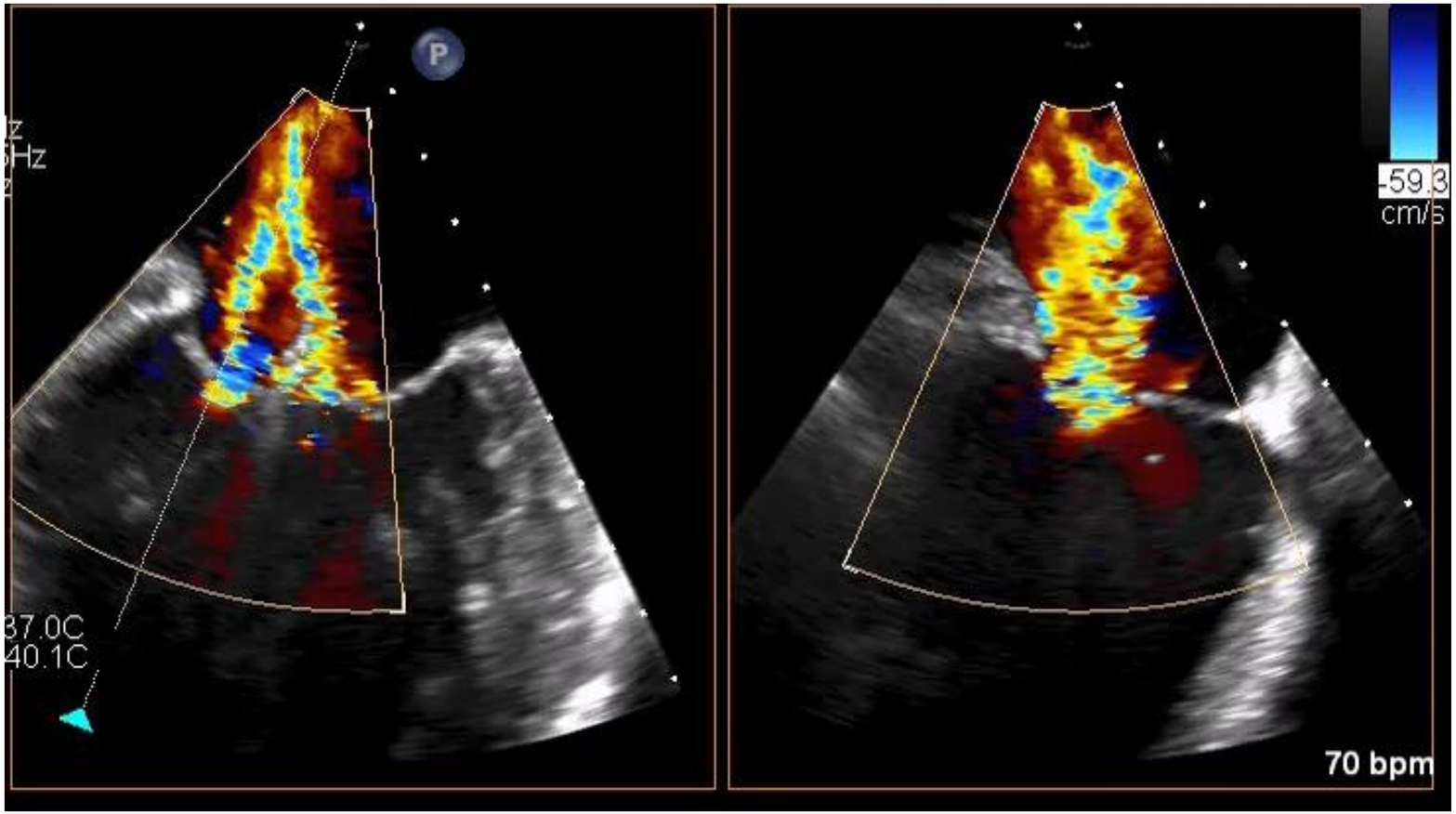
Published March 5, 2023 | N Engl J Med 2023;388:2037-2048 | DOI: 10.1056/NEJMoa2300213 | VOL. 388 NO. 22

Success rate and durability of MV-TEER:

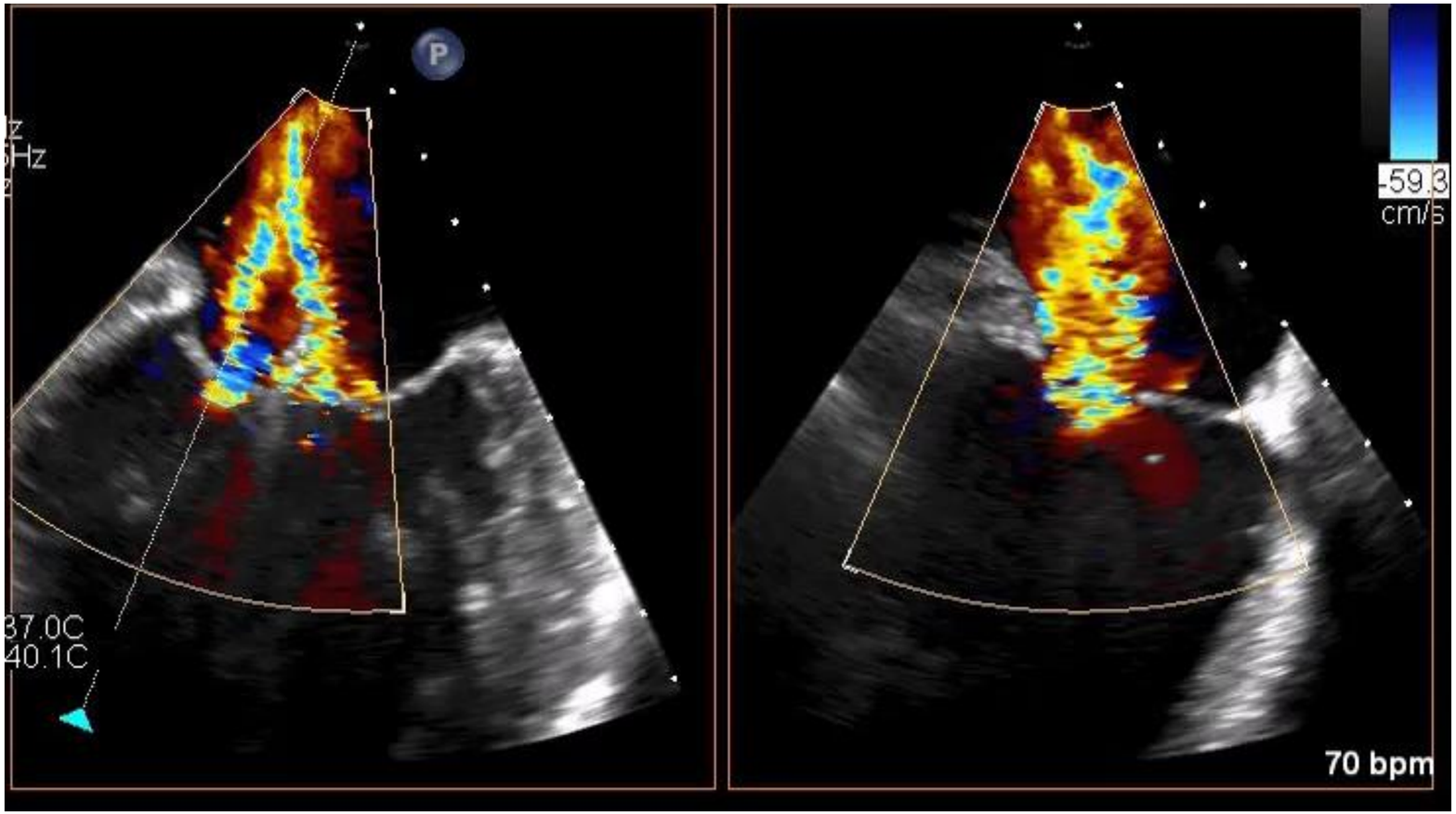
- Firm grasp of leaflets achieved during MV-TEER predicts a highly durable result
- Failure rates after 30-days: nothing happens over the next 5 years

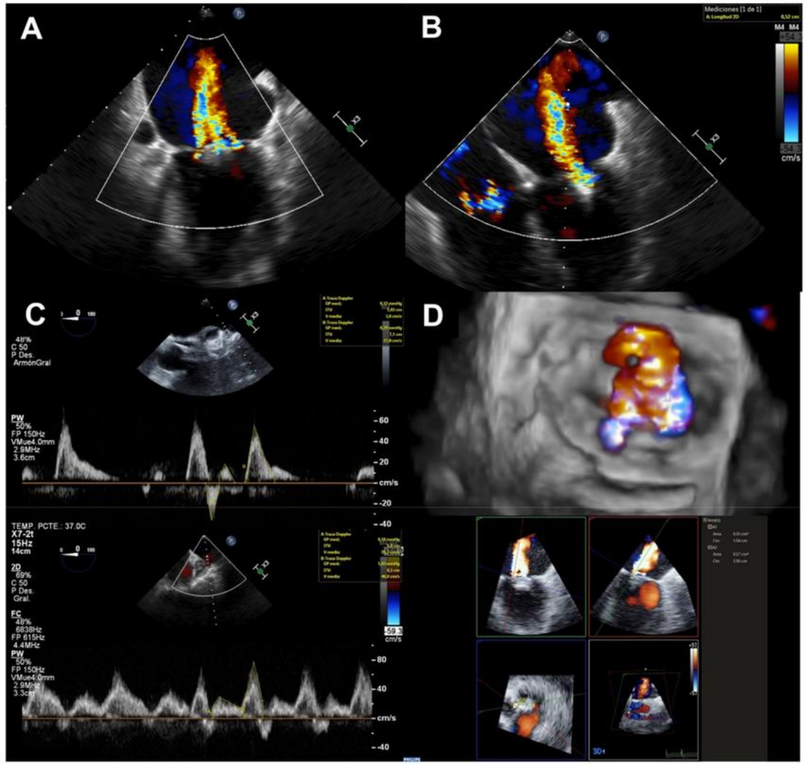
- But of course in SMR there is progression of disease, especially ischaemic disease, and this is not progression of MV disease treated before with MV-TEER

How to manage residual / recurrent MR?



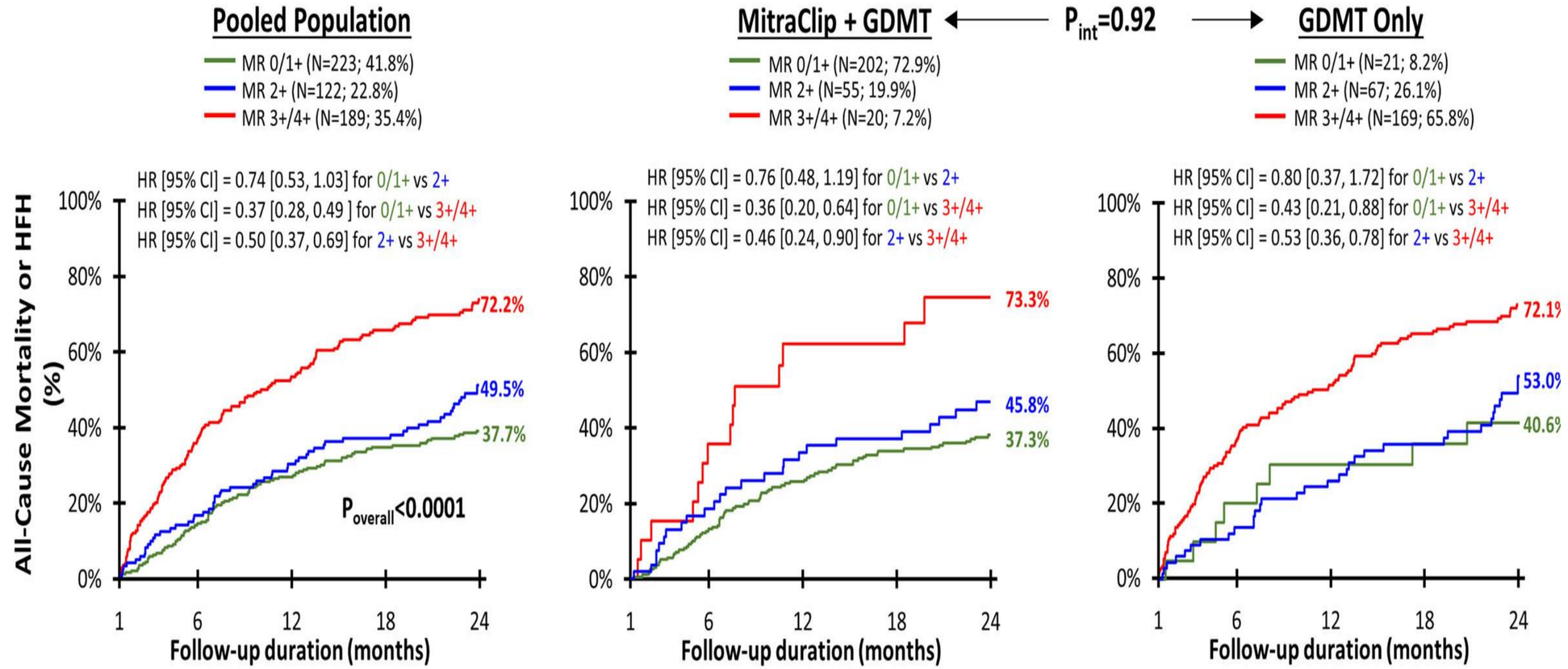
How to manage residual / recurrent MR?





How to manage residual / recurrent MR?

In SMR: optimal MR reduction still debated…..



Number at risk					
MR 0/1+	223	192	163	146	115
MR 2+	122	102	84	73	45
MR 3+/4+	189	120	86	63	45

Number at risk					
MR 0/1+	202	176	150	134	105
MR 2+	55	45	37	34	25
MR 3+/4+	20	13	7	7	4

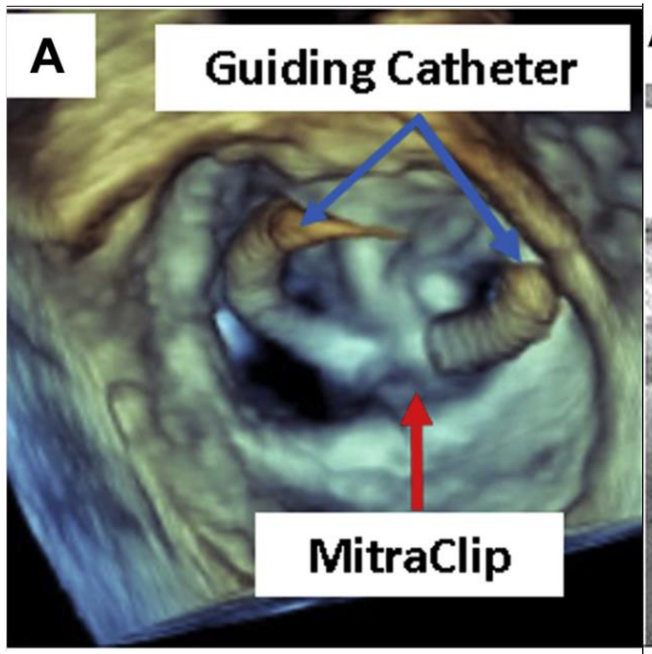
Number at risk					
MR 0/1+	21	16	13	12	10
MR 2+	67	57	47	39	20
MR 3+/4+	169	107	79	56	41

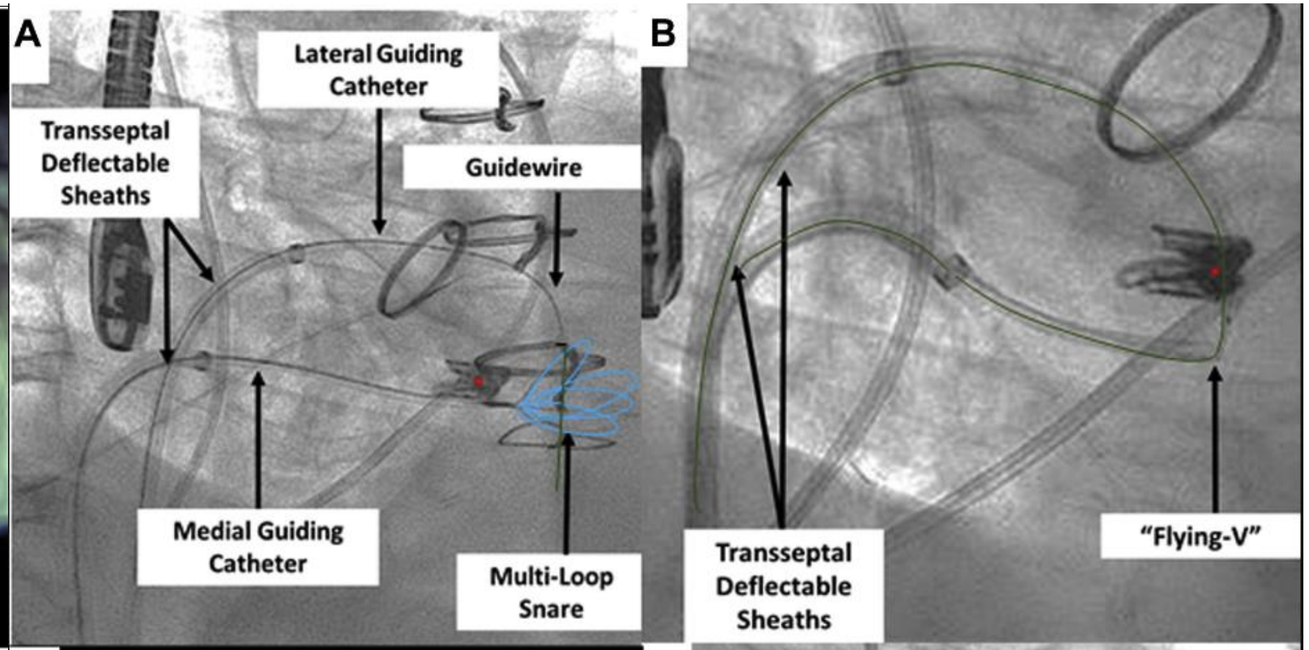
Kar et al. Circulation 2021;144:426-437

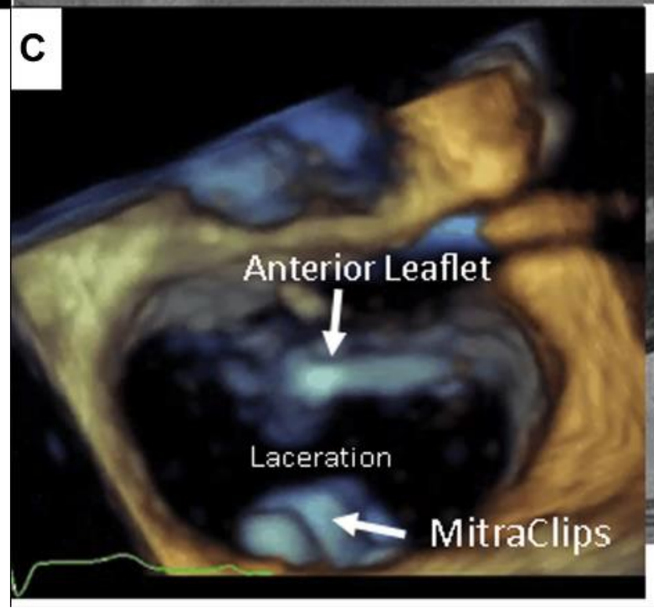
How to manage residual / recurrent MR?

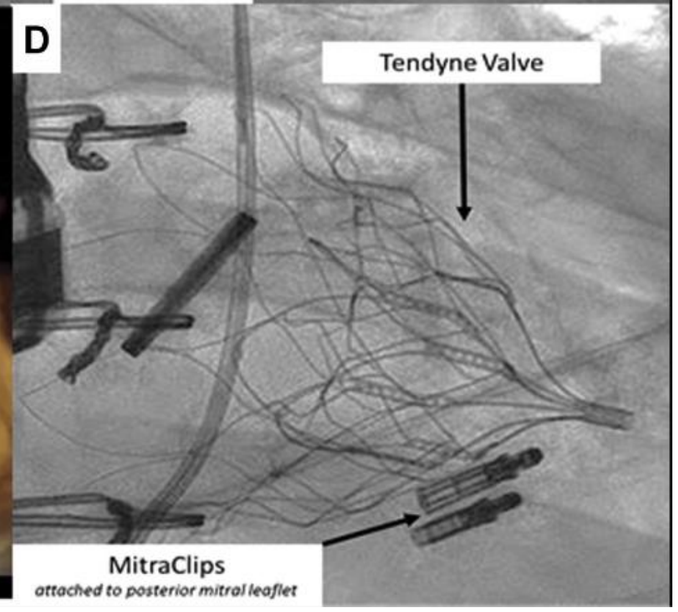
- Repeat MV-TEER if transvalvular mean gradient and valve area permit
- Commissural MR can be treated with plugs
- Intra-device MR with Amplatzer Vascular Plug or Amplatzer Duct Occluder
- Transcatheter annular reduction therapy
- Cardiac surgery
- TMVR (ELASTA-Clip)

How to manage unsuccessful MV:TEER? “Clip it, Cut it, Replace it”









ELSEVIER

JACC: Cardiovascular Interventions
Volume 13, Issue 20, 26 October 2020, Pages 2361-2370

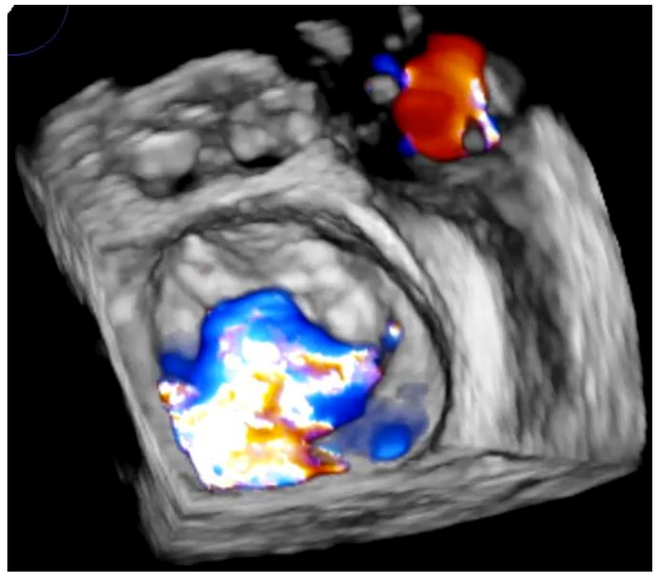
Focus on Mitral Valve Interventions

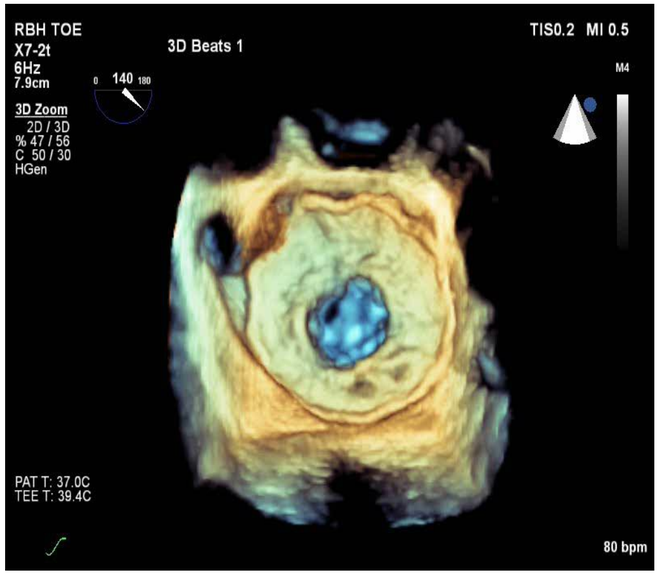
Electrosurgical Detachment of MitraClips From the Anterior Mitral Leaflet Prior to Transcatheter Mitral Valve Implantation

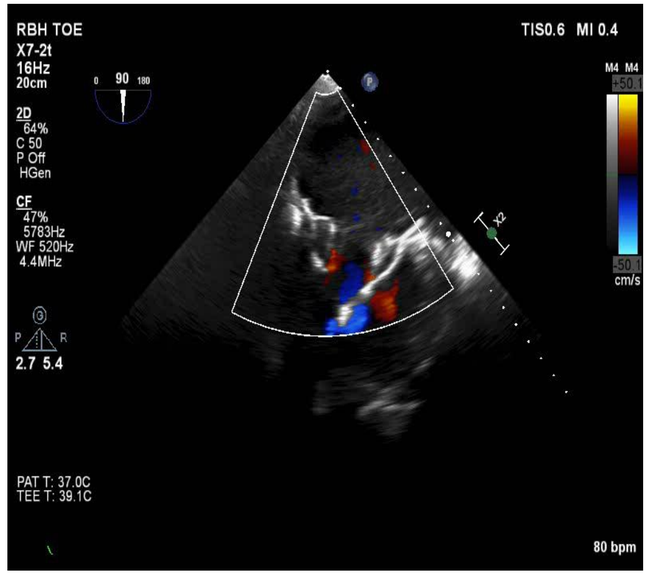
John C. Lisko MD, MPH [a] *, Adam B. Greenbaum MD [a] *, Robert A. Guyton MD [a], Norihiko Kamioka MD [a], Kendra J. Grubb MD, MHA [a], Patrick T. Gleason MD [a], Isida Byku MD [a], Jose F. Condado MD [a], Andres Jadue MD [a], Gaetano Paone MD [a], Peter C. Block MD [a], Lucia Alvarez MD [a], Joe Xie MD [a], Jaffar M. Khan MD [b], Toby Rogers MD, PhD [b], Robert J. Lederman MD [b] †, Vasilis C. Babaliaros MD [a] †

Show more

Consider TMVR to “guarantee” a durable result?

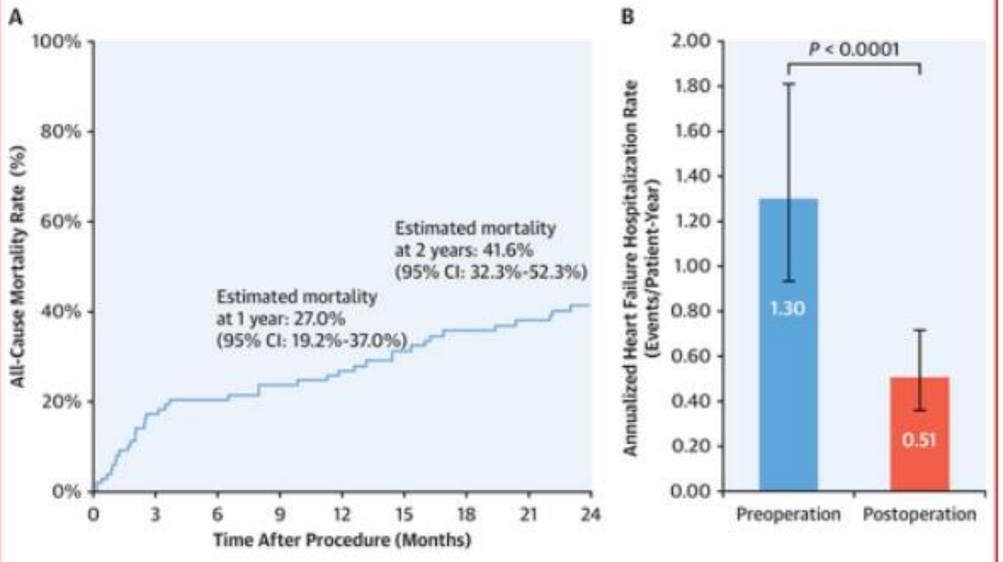






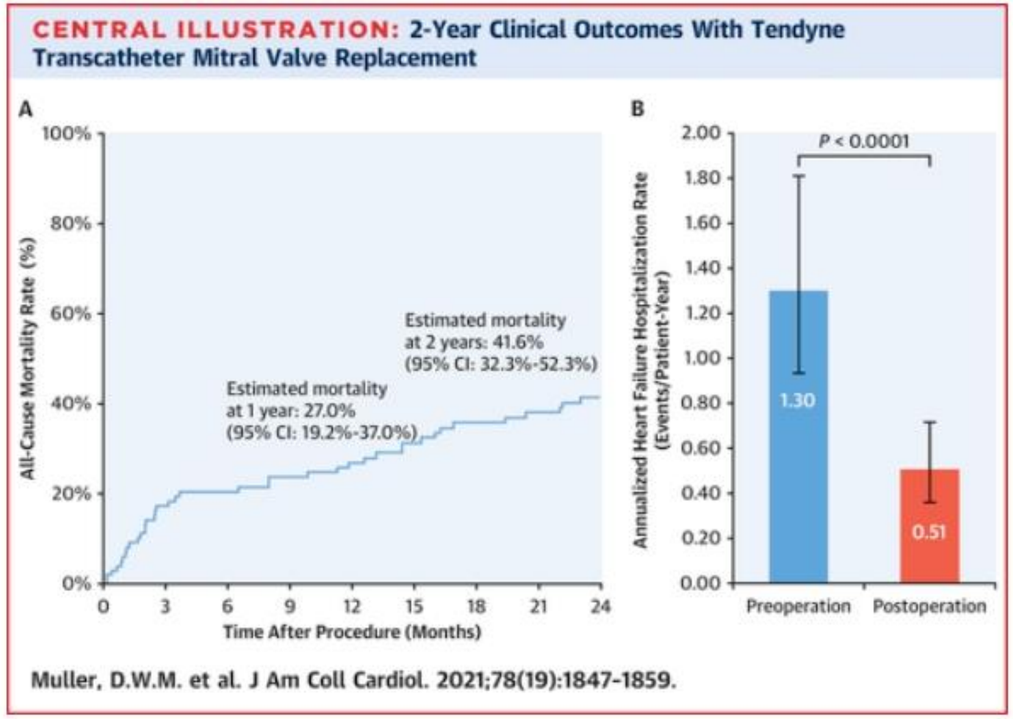
Success of TMVR: Clinical Outcomes? Reduction MR?

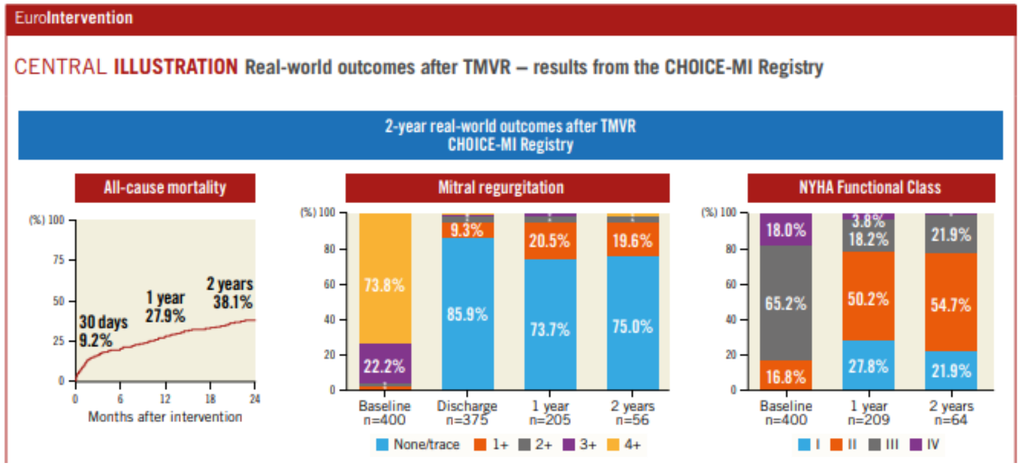
CENTRAL ILLUSTRATION: 2-Year Clinical Outcomes With Tendyne Transcatheter Mitral Valve Replacement



Muller, D.W.M. et al. J Am Coll Cardiol. 2021;78(19):1847-1859.

Success of TMVR: Clinical Outcomes? Reduction MR?





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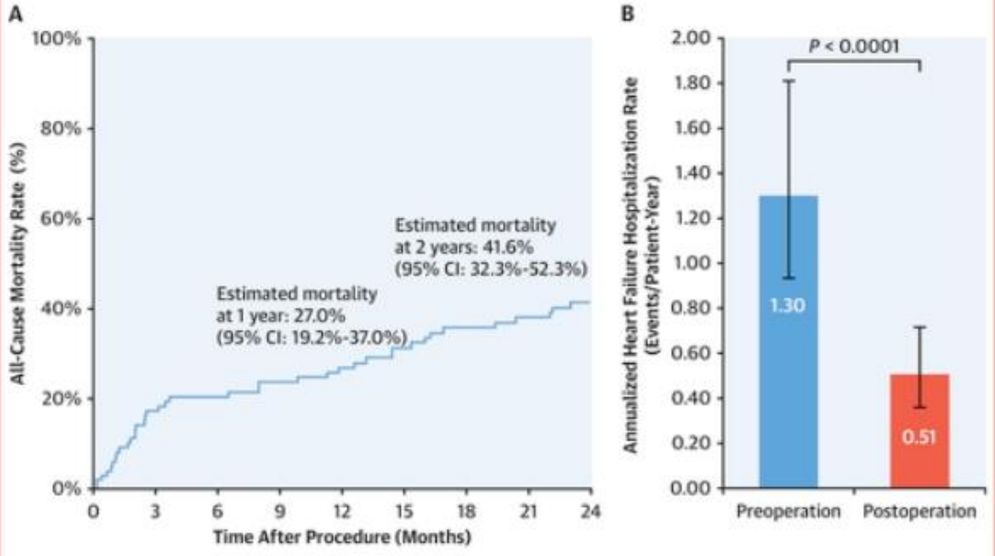
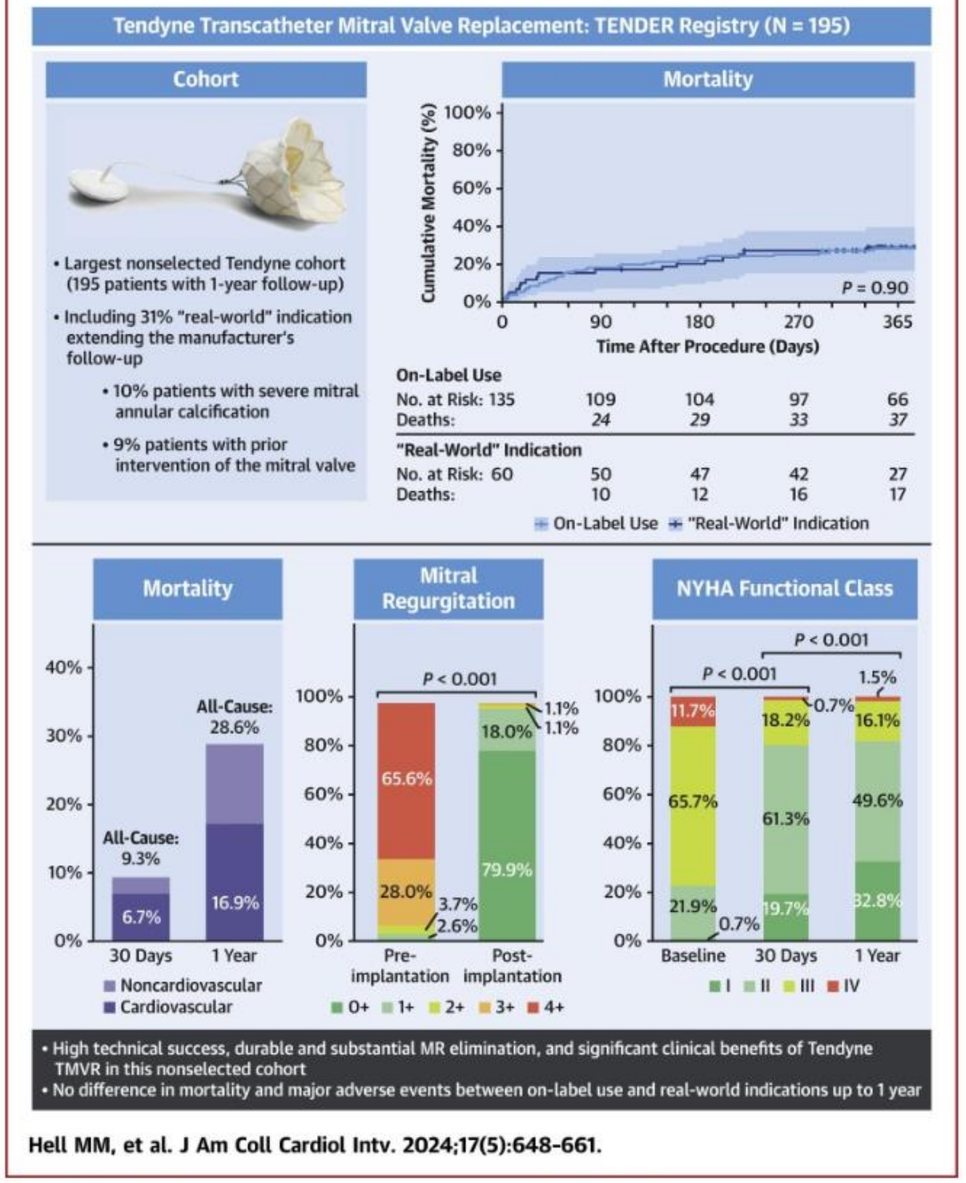


Muller, D.W.M. et al. J Am Coll Cardiol. 2021;78(19):1847-1859.

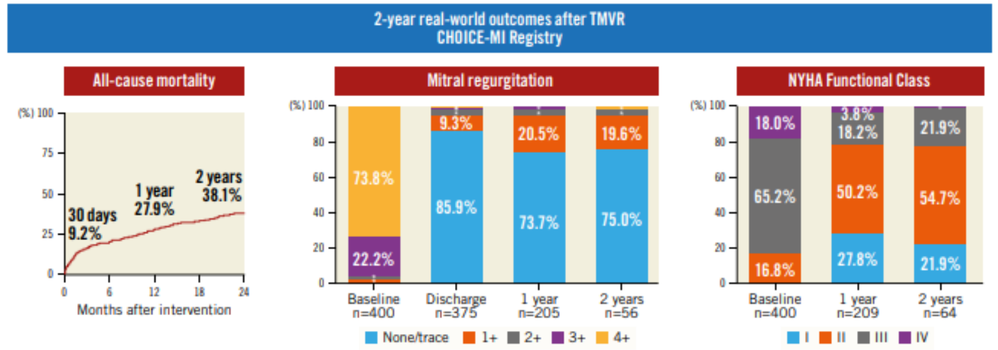
CENTRAL ILLUSTRATION: TENDER Registry Outcomes



Hell MM, et al. J Am Coll Cardiol Intv. 2024;17(5):648-661.

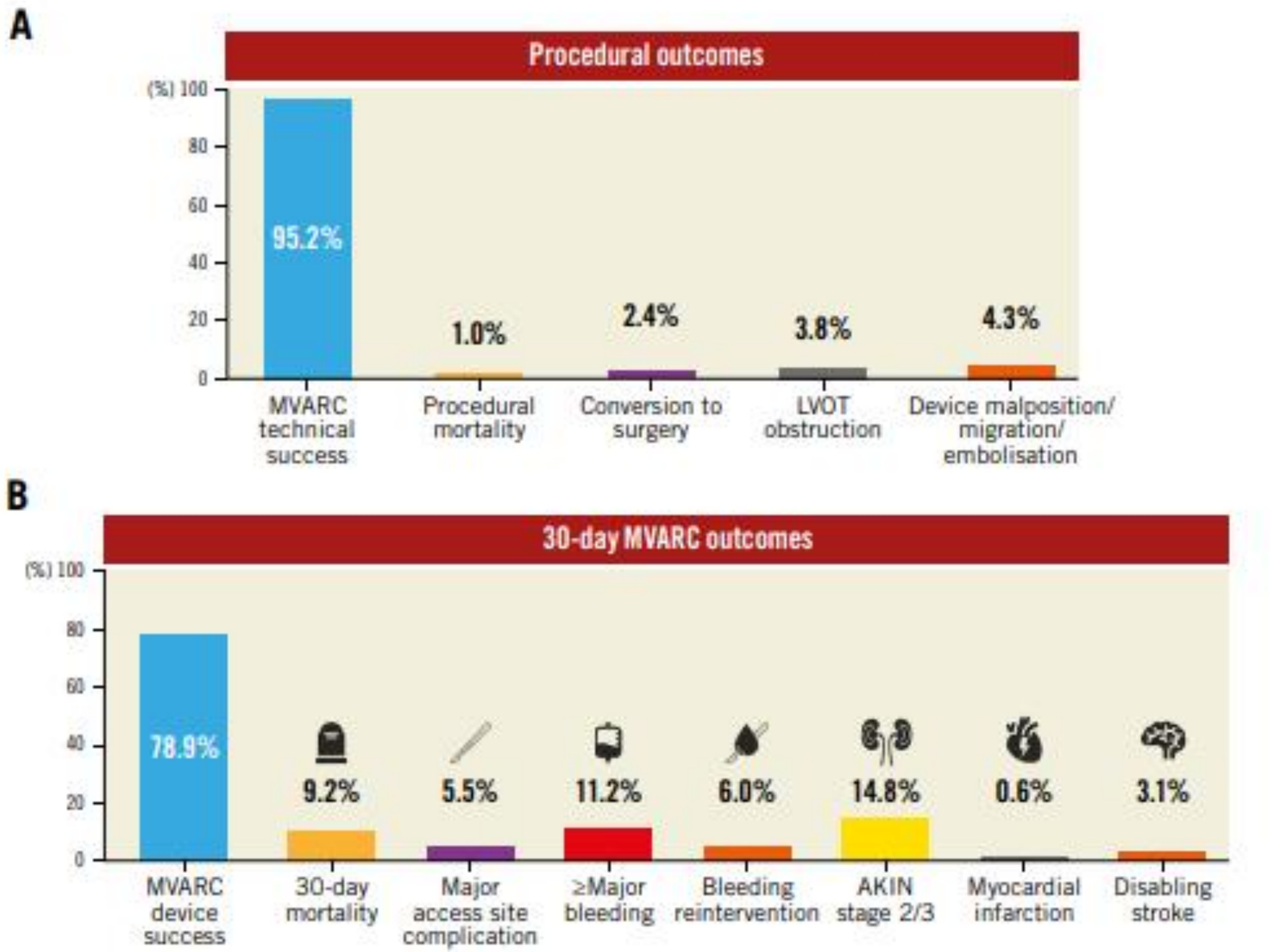
EuroIntervention

CENTRAL ILLUSTRATION Real-world outcomes after TMVR – results from the CHOICE-MI Registry



Success of TMVR: Clinical Outcomes? Reduction MR?

CHOICE-MI



Ludwig et al. EuroIntervention 2023

Success of TMVR: Clinical Outcomes? Reduction MR?

TENDER-Registry

TABLE 3 1-Year Follow-Up: Mortality and Major Adverse Events

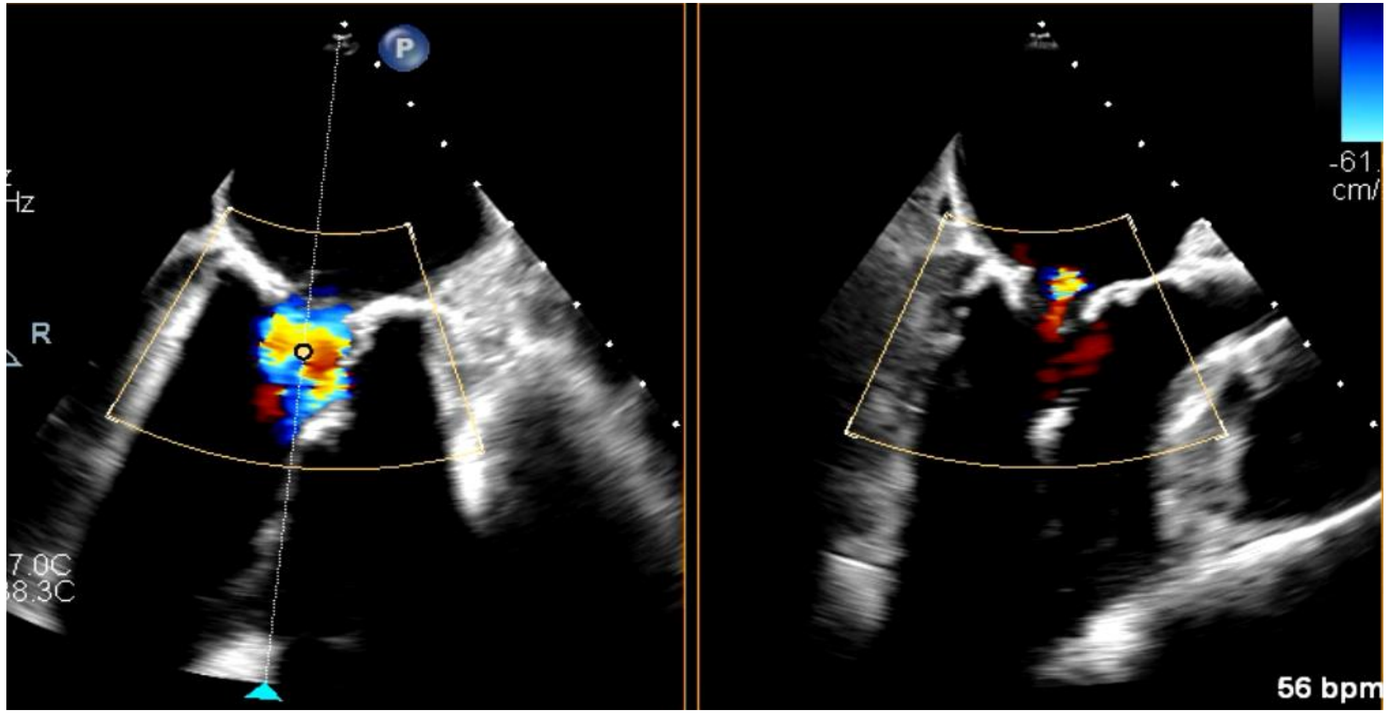
	Total Cohort	On-Label Use	"Real-World" Indications	*P* Value
Mortality				
1-y mortality	(n = 189)	(n = 131)	(n = 58)	
Cardiovascular mortality	32 (16.9)	21 (16.0)	11 (19.0)	0.620
All-cause mortality	54 (28.6)	37 (28.2)	17 (29.3)	0.881
Further adverse events				
HF hospitalization	43/169 (25.4)	32/117 (27.4)	11/52 (21.2)	0.393
MV reintervention or surgery (only postdischarge)	7/172 (4.1)	5/120 (4.2)	2/52 (3.8)	1.000
MV reintervention or surgery (in-hospital and postdischarge)	8/173 (4.6)	5.0 (6/121)	2/52 (3.8)	1.000
Disabling stroke (only postdischarge)	4/168 (2.4)	1/117 (0.9)	3/51 (5.9)	0.084
Disabling stroke (in-hospital and postdischarge)	7/169 (4.1)	4/118 (3.4)	3/51 (5.9)	0.432
Myocardial infarction	2/160 (1.3)	1/113 (0.9)	1/47 (2.1)	0.503
Myocardial infarction (in-hospital and postdischarge)	5/162 (3.1)	4/115 (3.5)	1/47 (2.1)	1.000
New-onset atrial fibrillation (only postdischarge)	9/168 (5.4)	7/117 (6.0)	2/51 (3.9)	0.724
New-onset atrial fibrillation (in-hospital and postdischarge)	23/168 (13.7)	17/116 (14.7)	6/52 (11.5)	0.809
New conduction disturbances (only postdischarge)	2/169 (1.2)	0/117 (0)	2/52 (3.8)	0.093
New conduction disturbances (in-hospital and postdischarge)	6/172 (3.5)	3/118 (2.5)	3/54 (5.6)	0.380
Specific device adverse events				
Valve thrombosis	5/167 (3.0)	4/118 (3.4)	1/49 (2.0)	1.000
Valve migration	1/167 (0.6)	0/119 (0)	1/48 (2.1)	0.287
Paravalvular leak more than mild	9/172 (5.2)	8/117 (6.8)	1/55 (1.8)	0.275

Values are n (%) or n/N (%).

Abbreviations as in Tables 1 and 2.

Hell et al. JACC Cardiovasc Int 2024

Success of TMVR in MAC: Clinical Outcomes? Reduction MR?

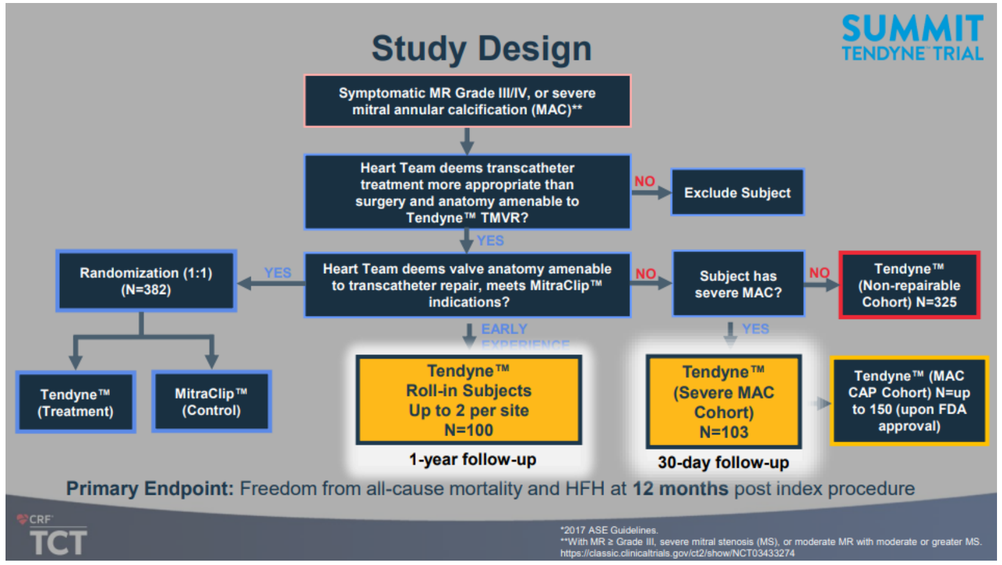


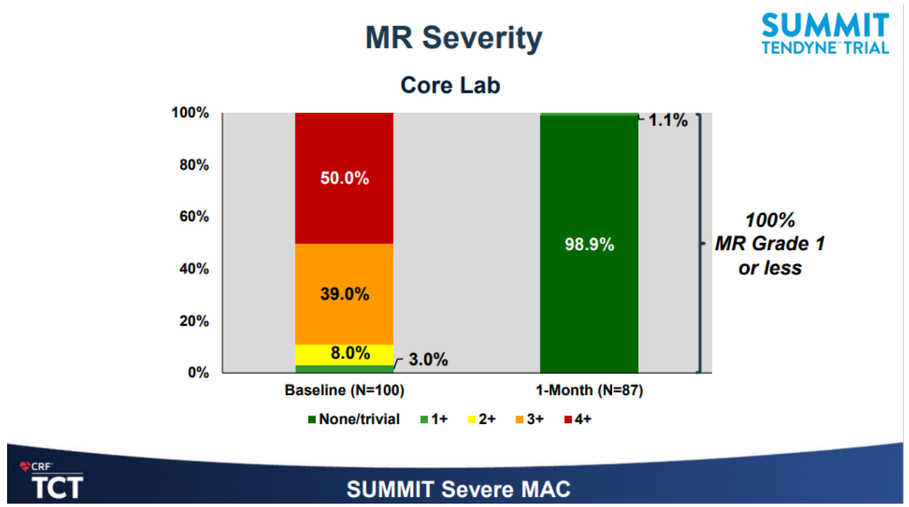
PROCEDURAL OUTCOMES	N=11
Technical Success*	100.0% (11/11)
Procedural Mortality	0.0% (0/11)
LVOT Obstruction	0.0% (0/11)
Valve Embolization or Malposition	0.0% (0/11)
Conversion to Open Heart Surgery	0.0% (0/11)
MV Re-intervention	0.0% (0/11)
Pre-dilation Balloon Valvuloplasty	54.5% (6/11)

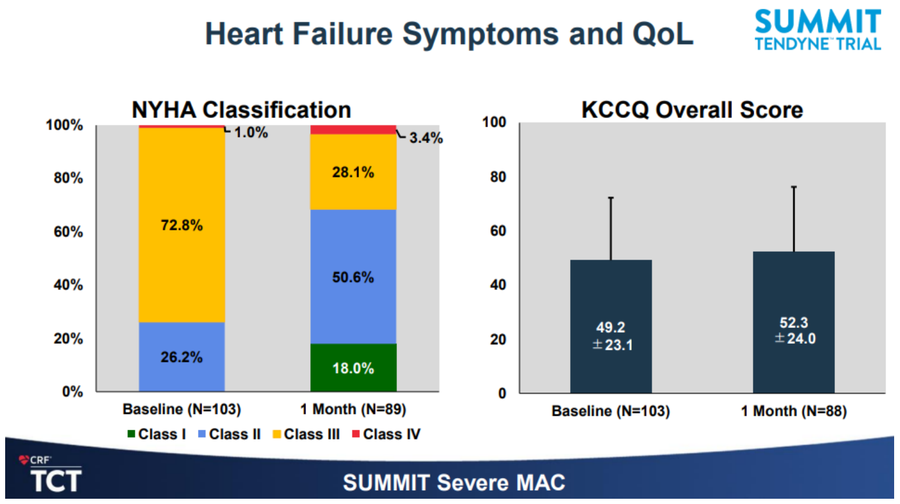
6-MONTH OUTCOMES	N=11
All-cause Mortality	9.1% (1/11)
Cardiovascular Mortality	9.1% (1/11)
Stroke or TIA	9.1% (1/11)
Myocardial Infarction	0.0% (0/11)
Cardiac Arrest	0.0% (0/11)
New Cardiac Arrhythmia	18.2% (2/11)
MV Re-intervention**	9.1% (1/11)
Bioprosthetic Valve Dysfunction	0.0% (0/11)
Endocarditis	0.0% (0/11)
Echo at 6-month Visit	
MR Grade ≥ 1+	0.0% (0/9)
PVL ≥ 1+	0.0% (0/9)

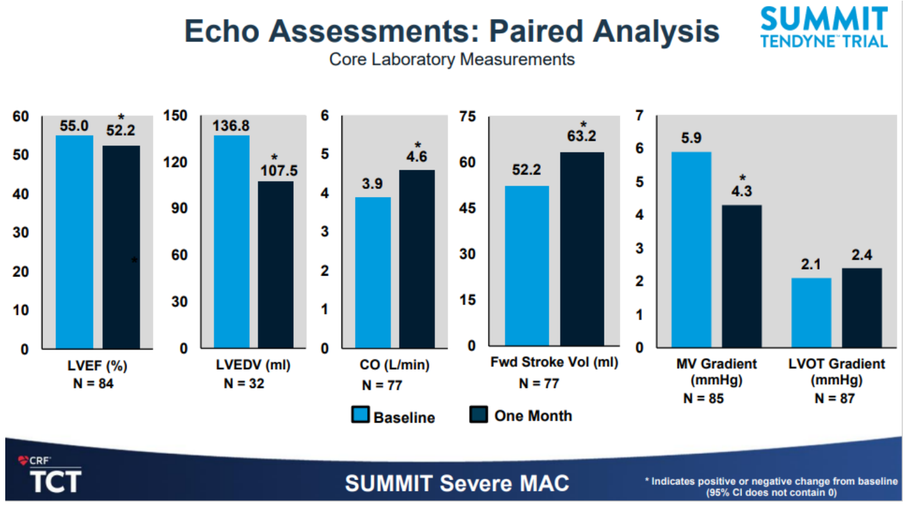
Sorajja et al. JACC 2019

Success of TMVR in MAC: Clinical Outcomes? Reduction MR?

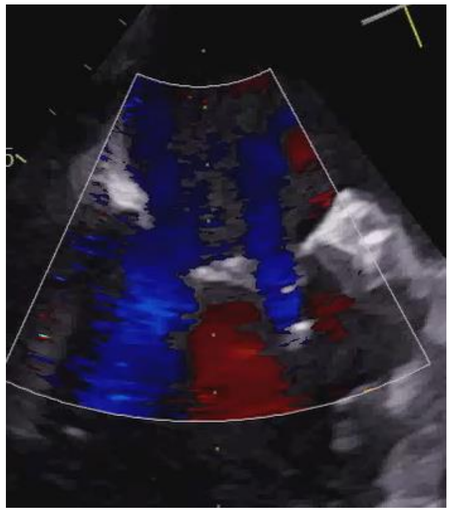


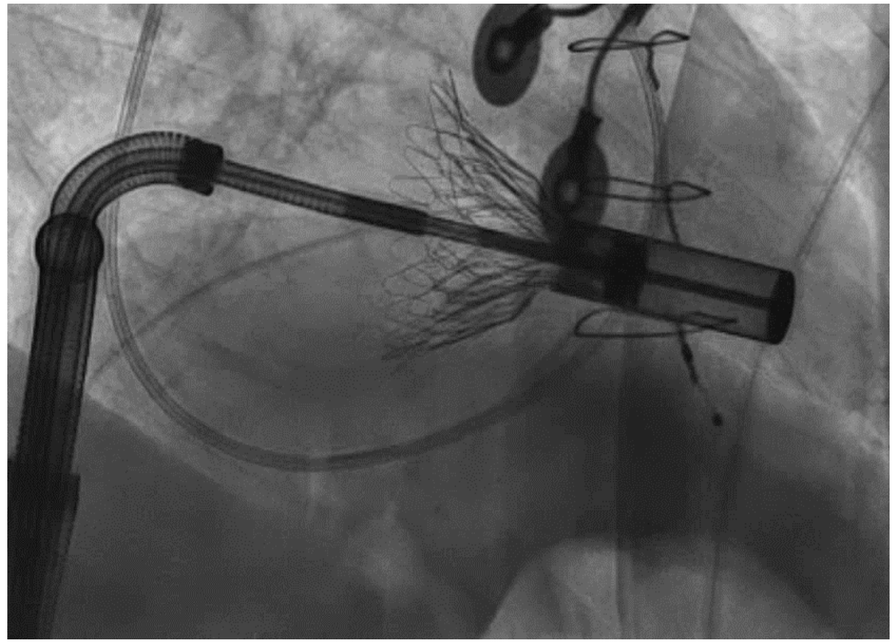


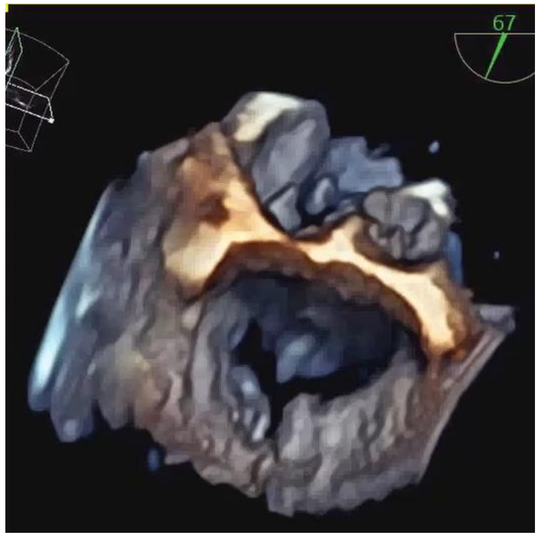




Success of TMVR: Clinical Outcomes better with TF-TS systems?







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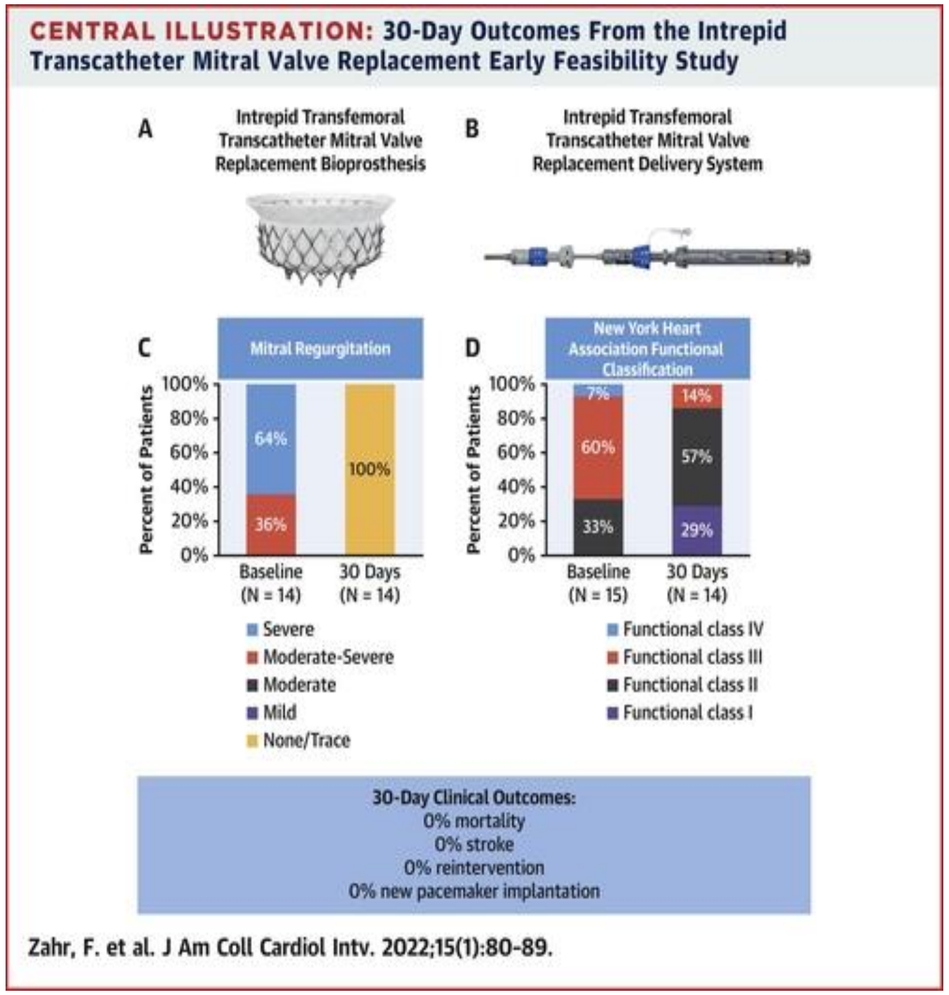

	N=33	
KM rate (# of subjects with event)	0-30 days *# pts expected for visit = 33*	0-365 days *# pts expected for visit = 27*
All-cause mortality	0.0% (0)	6.7% (2)
Cardiovascular mortality	0.0% (0)	3.3% (1)
All Stroke	0.0% (0)	0.0% (0)
Myocardial infarction	3.0% (1)	6.4% (2)
MVARC major vascular complications (procedural)	24.2% (8)	24.2% (8)
≥ MVARC major bleeding event	27.3% (9)	30.9% (10)
≥ Stage 2 acute kidney injury	0.0% (0)	0.0% (0)
Reoperation (or reintervention)	3.0% (1)	3.0% (1)
New-onset atrial fibrillation/atrial flutter[1]	11.8% (2)	29.9% (5)
Clinically significant thrombosis[2]	0.0% (0)	3.4% (1)
Cardiovascular hospitalization	6.1% (2)	22.3% (7)
Heart failure	0.0% (0)	6.7% (2)
MV endocarditis (definite)	0.0% (0)	3.4% (1)

Data published in Zahr et al. *JACC Intv.* 2023 Oct 10:S1936-8798(23)01357-2.

Success of TMVR: Clinical Outcomes better with TF-TS systems?

The Intrepid‡ TMVR-TF EFS 1-year results have been reported in 33 patients[1].

Procedural and acute safety outcomes favorable

- 1 year all-cause mortality 6.7%, mean MV gradient 4.6mmHg
- 6 major and 3 extensive MVARC bleeding events
- 8/9 bleeding events were access site related
- 1/9 extensive gastrointestinal bleed

1-Year Outcomes Following Transfemoral Transseptal Transcatheter Mitral Valve Replacement

Intrepid TMVR Early Feasibility Study Results

Firas Zahr, MD,[a] Howard K. Song, MD, PhD,[a] Scott Chadderdon, MD,[a] Hemal Gada, MD,[b] Mubashir Mumtaz, MD,[b] Timothy Byrne, MD,[c] Merick Kirshner, MD,[c] Samin Sharma, MD,[d] Susheel Kodali, MD,[e] Isaac George, MD,[e] William Merhi, DO,[f] Leora Yarboro, MD,[g] Paul Sorajja, MD,[h] Vinayak Bapat, MD,[h] Tanvir Bajwa, MD,[i] Eric Weiss, MD,[i] Jeremy J. Thaden, MD,[j] Elizabeth Gearhart, MS,[k] Scott Lim, MS, MD,[g] Michael Reardon, MD,[l] David Adams, MD,[d] Michael Mack, MD,[m] Martin B. Leon, MD[e]

ABSTRACT

BACKGROUND High surgical risk may preclude mitral valve replacement in many patients. Transcatheter mitral valve replacement (TMVR) using transfemoral transseptal access is a novel technology for the treatment of mitral regurgitation (MR) in high-risk surgical patients.

OBJECTIVES This analysis evaluates 30-day and 1-year outcomes of the Intrepid TMVR Early Feasibility Study in patients with ≥moderate-severe MR.

METHODS The Intrepid TMVR Early Feasibility Study is a multicenter, prospective, single-arm study. Clinical events were adjudicated by a clinical events committee; endpoints were defined according to Mitral Valve Academic Research Consortium criteria.

RESULTS A total of 33 patients, enrolled at 9 U.S. sites between February 2020 and August 2022, were included. The median age was 80 years, 63.6% of patients were men, and mean Society of Thoracic Surgeons Predicted Risk of Mortality for mitral valve replacement was 5.3%. Thirty-one (93.9%) patients were successfully implanted. Median postprocedural hospitalization length of stay was 5 days, and 87.9% of patients were discharged to home. At 30 days, there were no deaths or strokes, 8 (24.2%) patients had major vascular complications and none required surgical intervention, there were 4 cases of venous thromboembolism all successfully treated without sequelae, and 1 patient had mitral valve reintervention for severe left ventricular outflow tract obstruction. At 1 year, the Kaplan-Meier all-cause mortality rate was 6.7%, echocardiography showed ≤mild valvular MR, there was no/trace paravalvular leak in all patients, median mitral valve mean gradient was 4.6 mm Hg (Q1-Q3: 3.9-5.3 mm Hg), and 91.7% of survivors were in NYHA functional class I/II with a median 11.4-point improvement in Kansas City Cardiomyopathy Questionnaire overall summary scores.

CONCLUSIONS The early benefits of the Intrepid transfemoral transseptal TMVR system were maintained up to 1 year with low mortality, low reintervention, and near complete elimination of MR, demonstrating a favorable safety profile and durable valve function. (J Am Coll Cardiol Intv 2023;16:2868-2879)

[1]Zahr et al. *JACC Intv.* 2023 Dec 11;16(23):2868-2879.

Durability of TMVR: Assessing device: 3-year outcome Tendyne

- Expanded Clinical Study Tendyne TMVR
- 191 patients
- 70 completed 3-year follow-up

Duncan A et al. JACC Interventions 2024;17:1625-1627

Durability of TMVR: Assessing device: 3-year outcome Tendyne

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- 191 patients
- 70 completed 3-year follow-up

- MV reintervention required in 6 of 191 patients (3.1%)
- 4 adjustments of tether tension for paravalvular leak [PVL] mitigation
- 1 explant for device thrombus
- 1 transcatheter PVL closure
- PVL (any severity) 17 of 191 patients (8.9%)
- Endocarditis 12 of 191 patients (6.3%)
- Asymptomatic thrombus in 11 of 191 patients (5.8%)

Duncan A et al. JACC Interventions 2024;17:1625-1627

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- Asymptomatic thrombus in 11 of 191 patients (5.8%)

- 60 patients underwent TTE at 3 years
- There was no evidence of structural valve deterioration, embolization, or fracture
- 59 (98.3%) patients had no MR, 1 had mild (1+) MR
- Mean MV gradient 3.8±1.5 mmHg (baseline 2.9±1.2 mmHg, P=0.003)

Duncan A et al. JACC Interventions 2024;17:1625-1627

Case Presentation TMVR Durability

78 year old lady

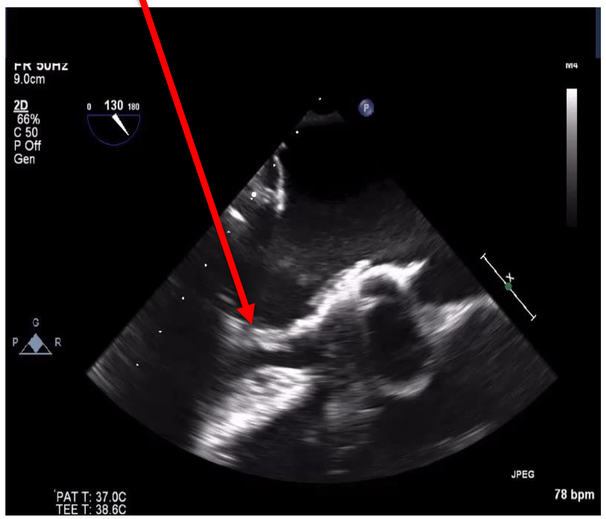
Surgical mitral valve repair (38mm Carpentier Edwards Physio 2 ring), AF ablation, LAA excision, November 2012

Recurrent MR 2014

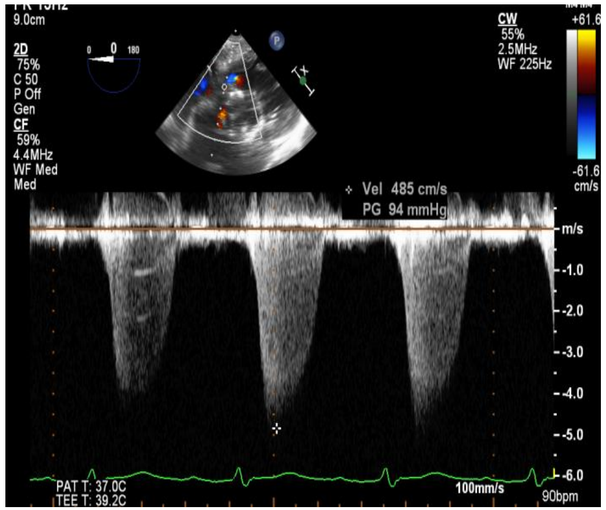
- Compassionate Use Transapical Tendyne – January 2015
- Developed peri-procedural dynamic LVOT obstruction
- Supported with IABP then VA-ECMO post-op
- LVOTO treated with 22mm CP stent in LVOT 5 days after Tendyne

Tendyne TMVI Procedure, LVOTO, and Post-Op LVOT Stent

LVOT obliteration after Tendyne deployment



Severe dynamic LVOTO after Tendyne



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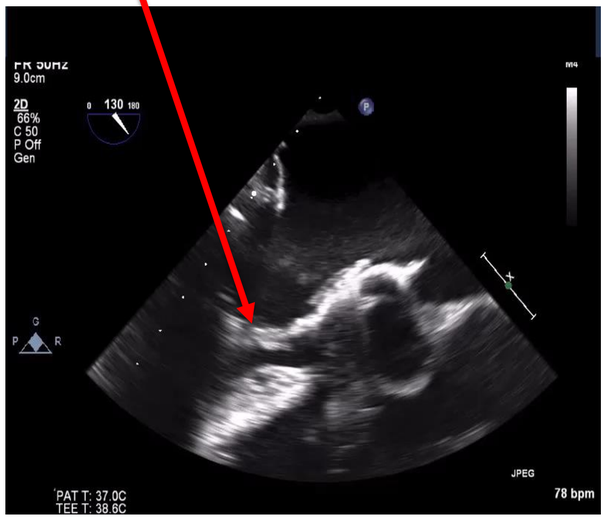
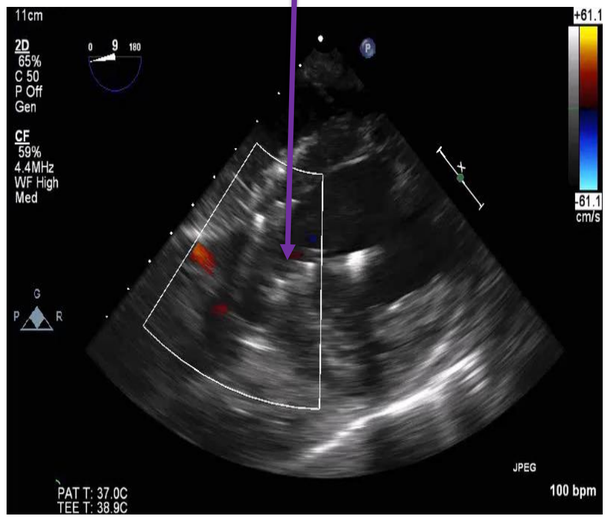
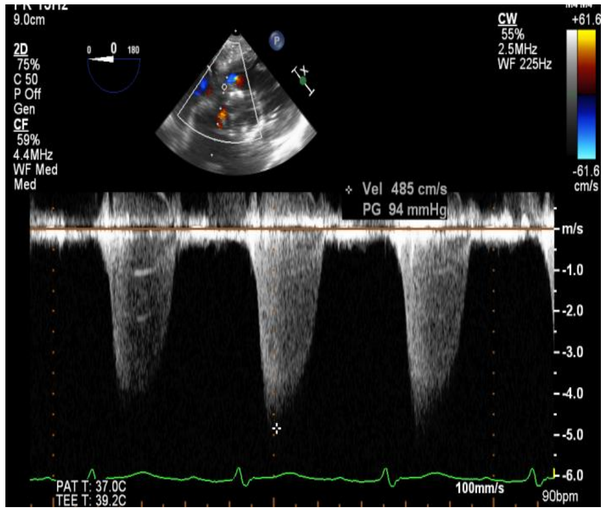


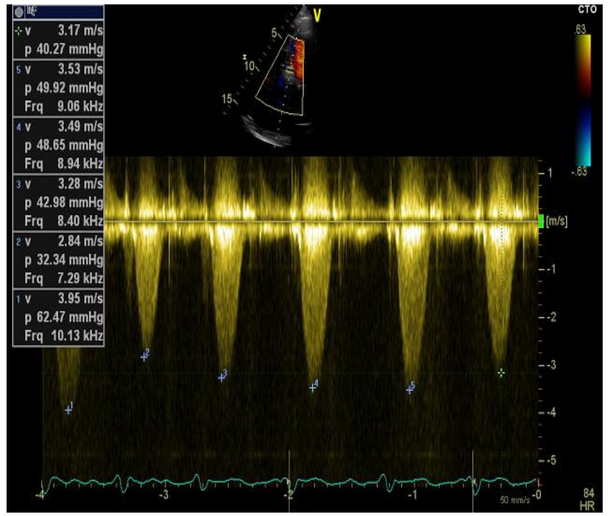
Opening LVOT with CP stent after Tendyne



Severe dynamic LVOTO after Tendyne



Reduction in LVOT gradient straight after LVOT stent



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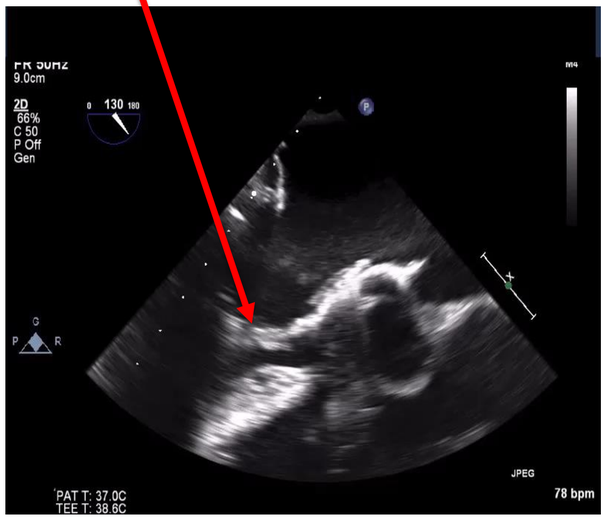

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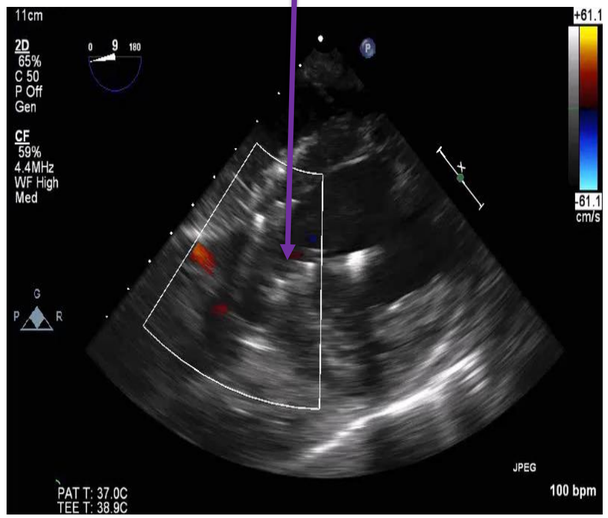
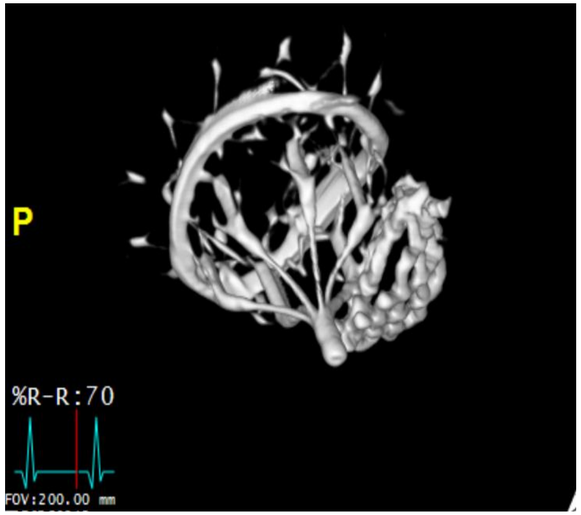


MSCT after Tendyne with CP stent in LVOT



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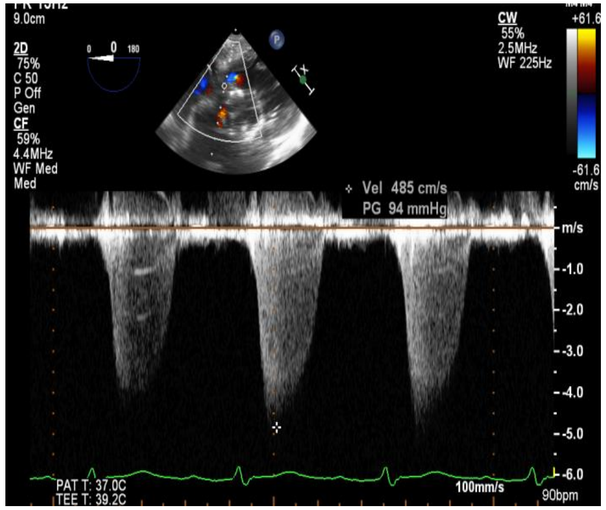
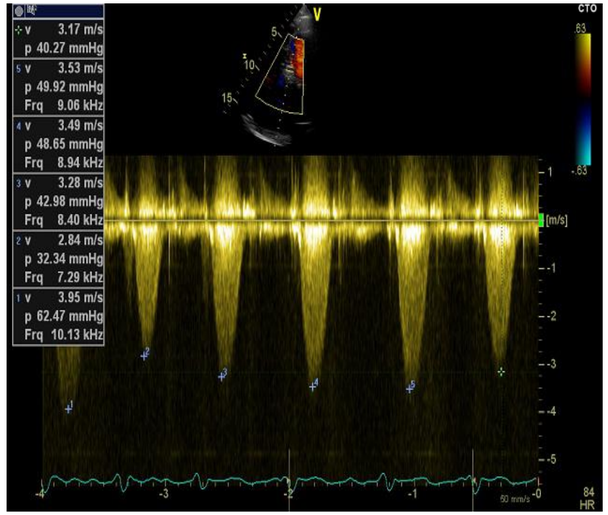
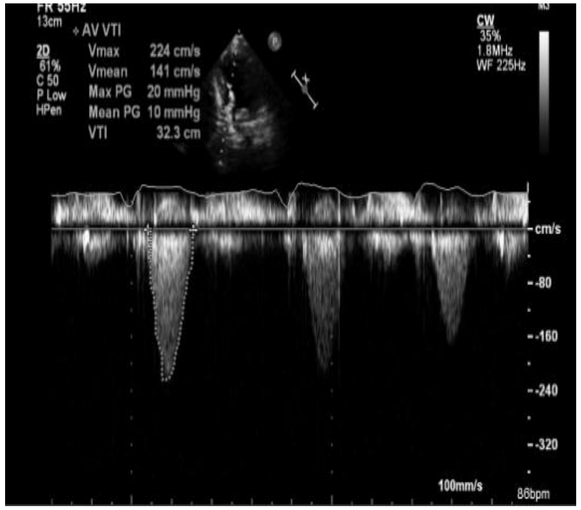


Reduction in LVOT gradient straight after LVOT stent



Peak LVOT gradient on discharge echo



8-years after Tendyne TMVI

Post Tendyne follow-up

- Length of hospital stay 65 days, weaning from VA-ECMO and frailty
- Annual follow-up thereafter – normal Tendyne function, no mitral regurgitation, NYHA Class I, BNP 216ng/dL

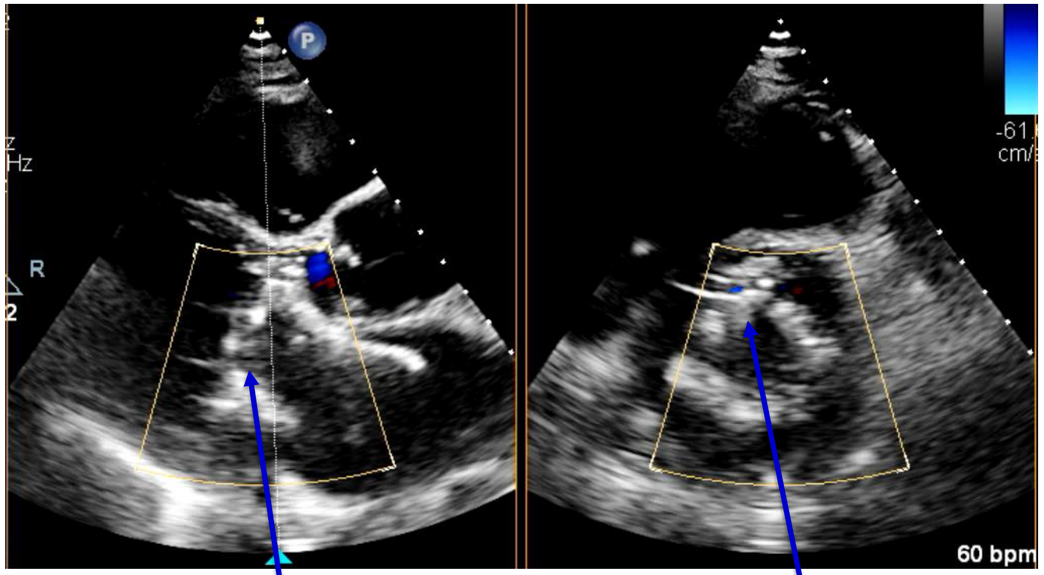
Co-morbidities

- Atrial flutter/fibrillation – on life-long warfarin
- CRT-P 31/5/2016
- Thrombocytopenia, possible underlying myelofibrosis

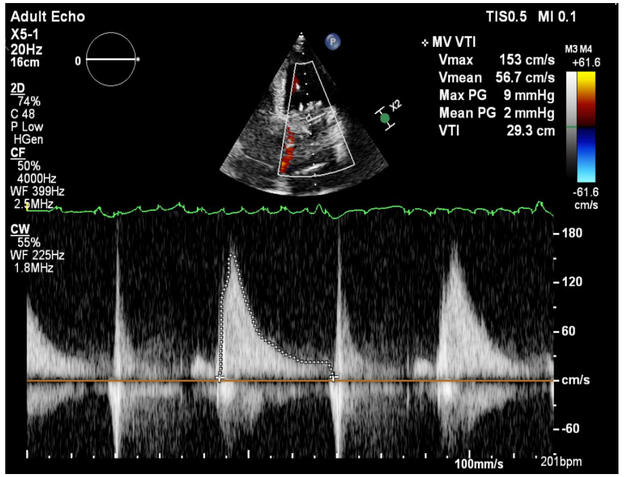
8-years after Tendyne TMVI

Patient clinically well, remained active, manages two flights of stairs, NYHA Class I, no lower limb oedema

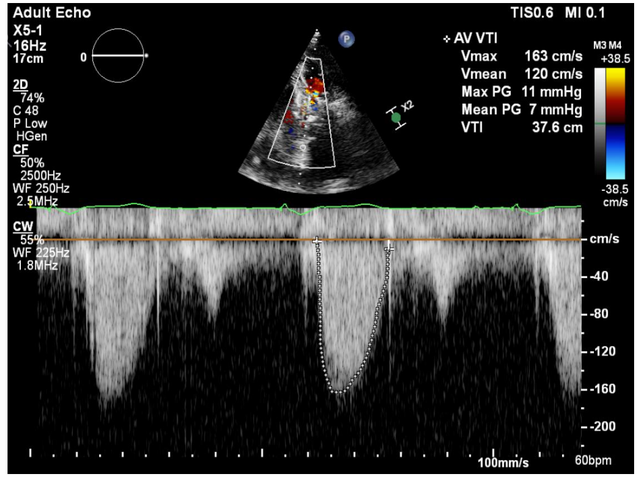
TTE: well-functioning Tendyne, no transvalvular MR, mean MV gradient 2mmHg, peak LVOT 11mmHg, RVSP 28mmHg

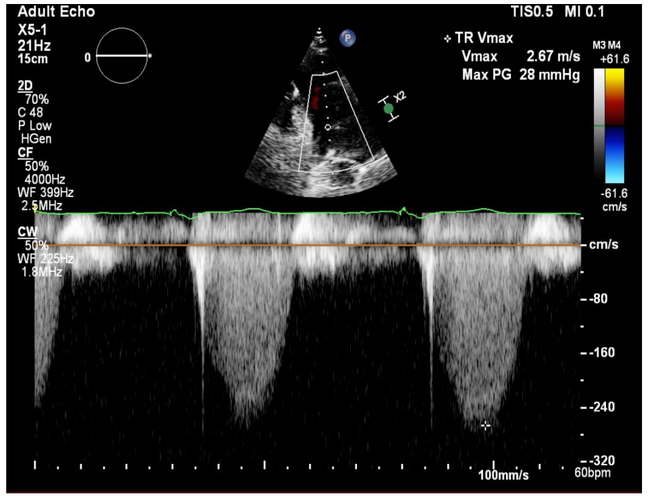


No transvalvular MR



High velocity colour Doppler in LVOT

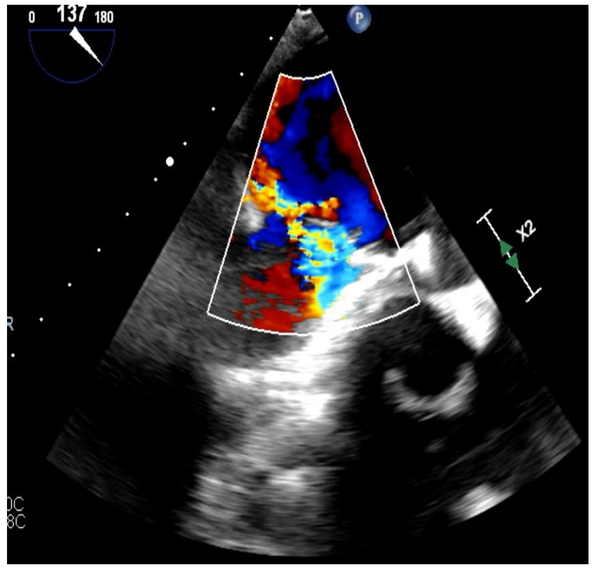


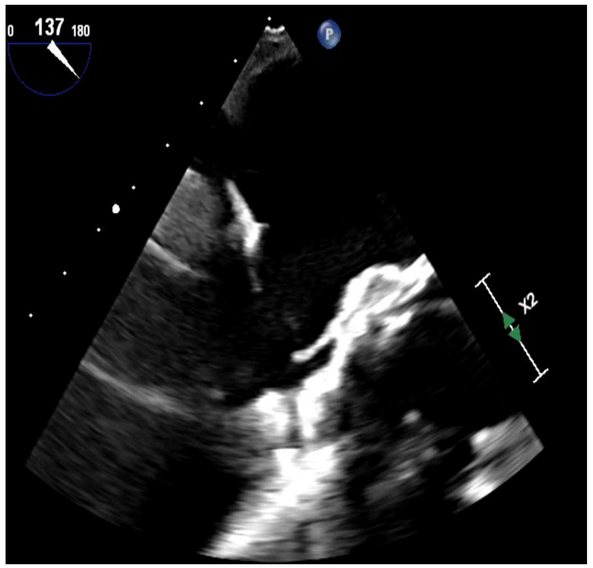


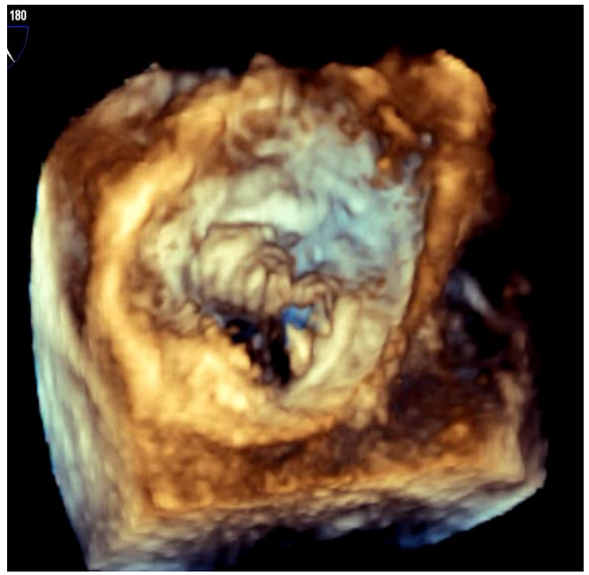
Almost 9-years after Tendyne TMVI

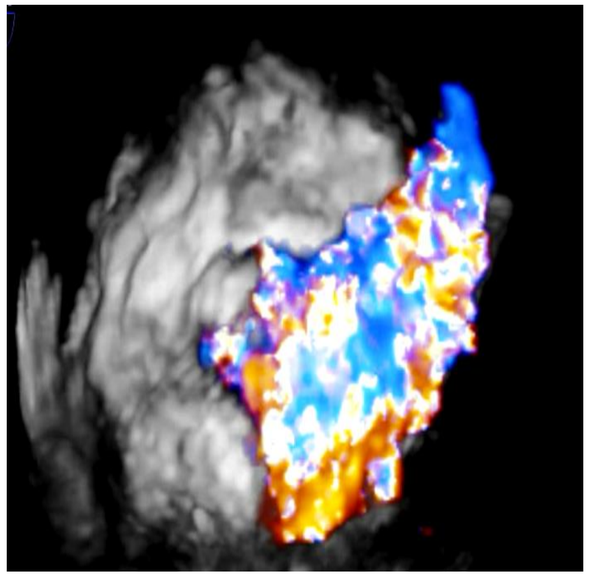
- Admitted Oct 2023 sudden acute severe decompensated congestive cardiac failure (3x negative blood cultures)

TOE: degenerated Tendyne leaflet with severe transvalvular MR. No PVL





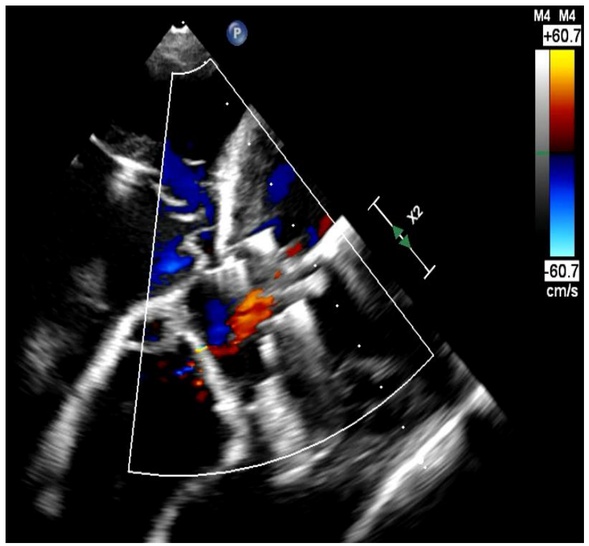


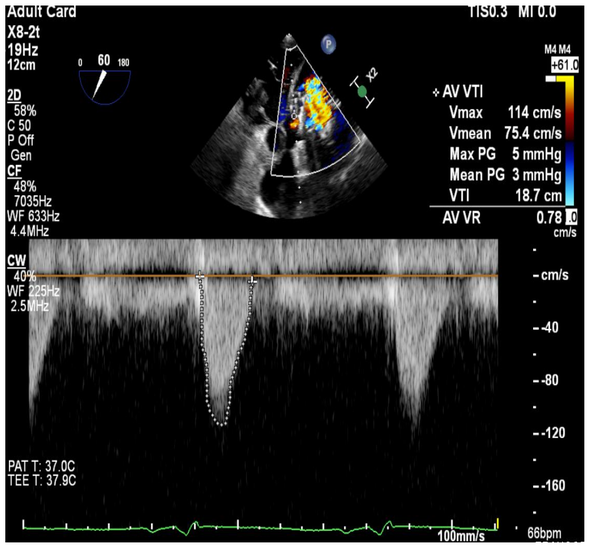


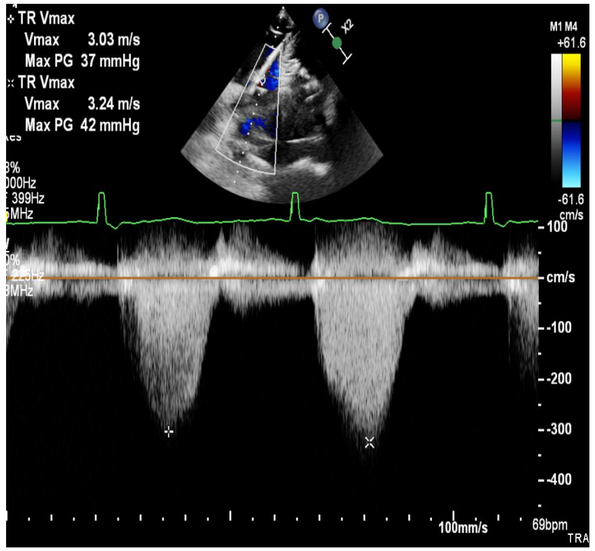
Almost 9-years after Tendyne TMVI

- Admitted Oct 2023 sudden acute severe decompensated congestive cardiac failure (3x negative blood cultures)

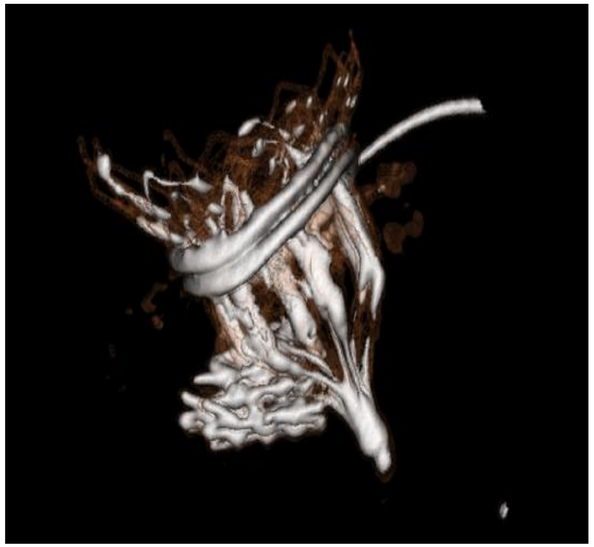
TOE: stable position of LVOT stent with no gradient







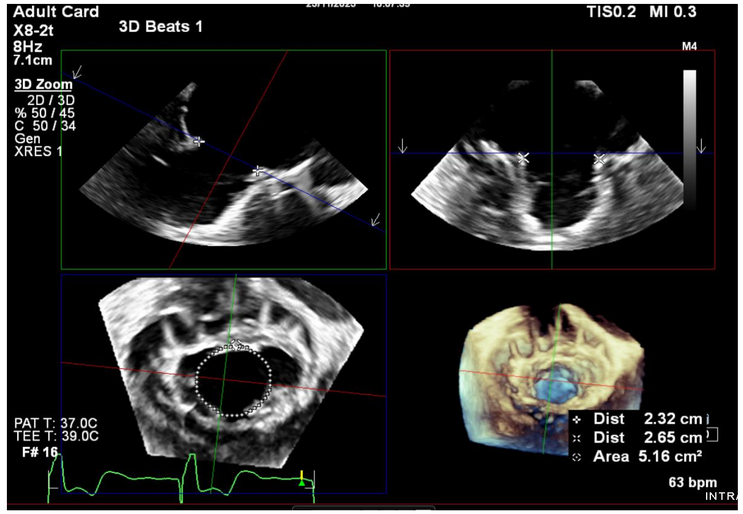
RVSP 42mmHg



LVOT stent on CT

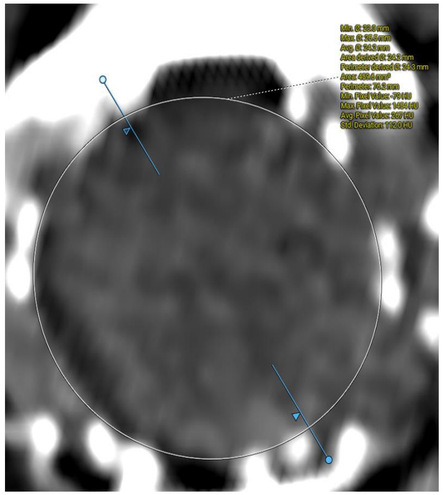
Tendyne TMVI Procedure, LVOTO, and Post-Op LVOT Stent

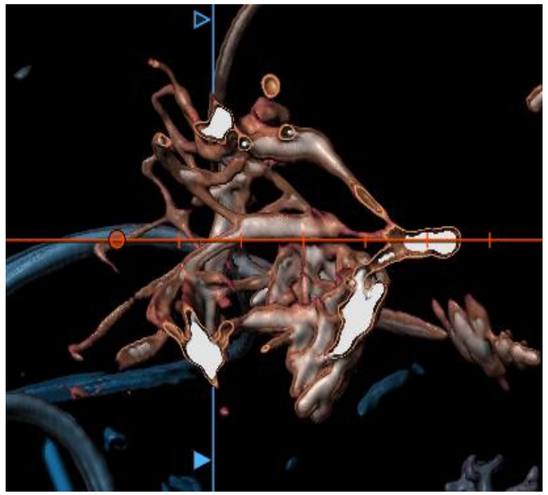
- Not for redo surgery due to patient frailty and thrombocytopenia (admission platelet count 19mg*10^9/L)
- Consider ViV procedure

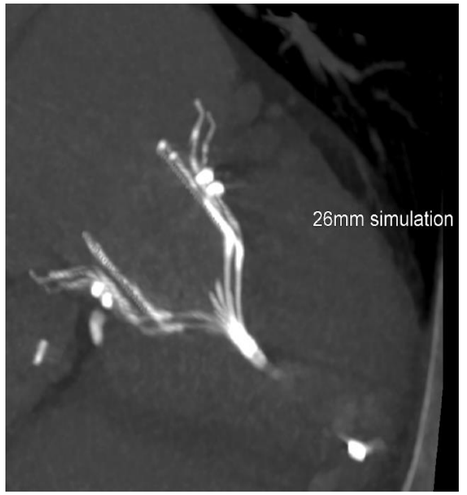


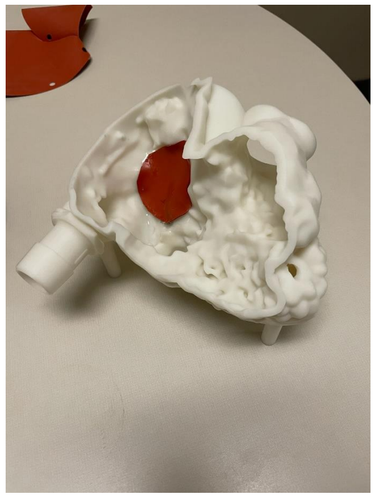
Pre-procedural planning:
TOE suggested inner Tendyne dimension 2.3cm*2.6cm, area 5.16cm2

Pre-procedural planning: MSCT confirmed Tendyne inner ring 23mm*25.5mm, 3D print confirmed use 26mm Sapien



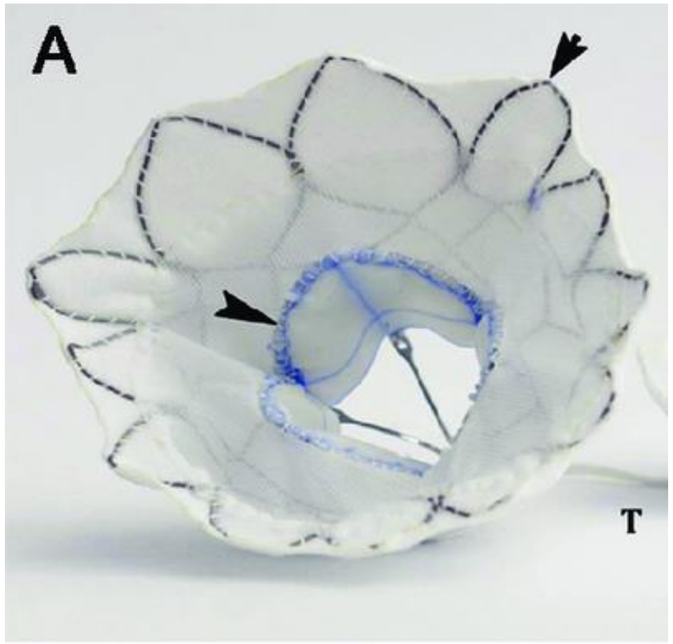






Tableside SAPIEN skirt modification

- SAPIEN has large open cells on outflow portion
- During balloon expansion of SAPIEN in Tendyne, the SAPIEN could migrate atrially, losing the sealing element
- Blood could flow LV→LA due to inner Tendyne “valley”



Tableside SAPIEN skirt modification

- SAPIEN skirt modification necessary to cover outflow cells
- Dacron felt skirt sutured onto a 26mm SAPIEN prosthesis
- SAPIEN then prepped and loaded in standardised fashion



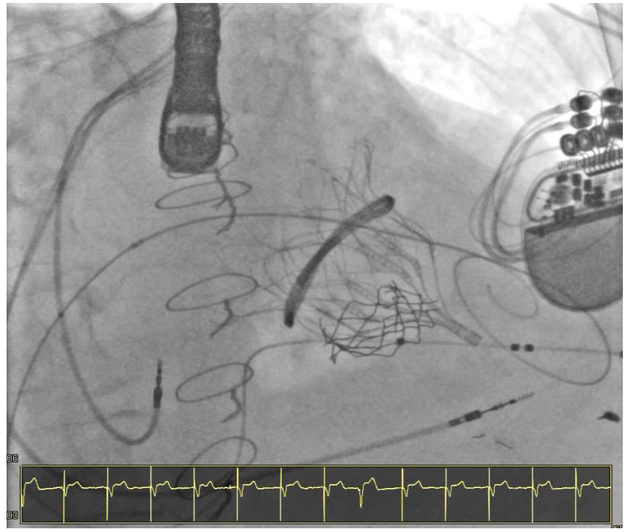

Transcatheter ViV Sapien-in-Tendyne

Degenerated Tendyne-in-ring

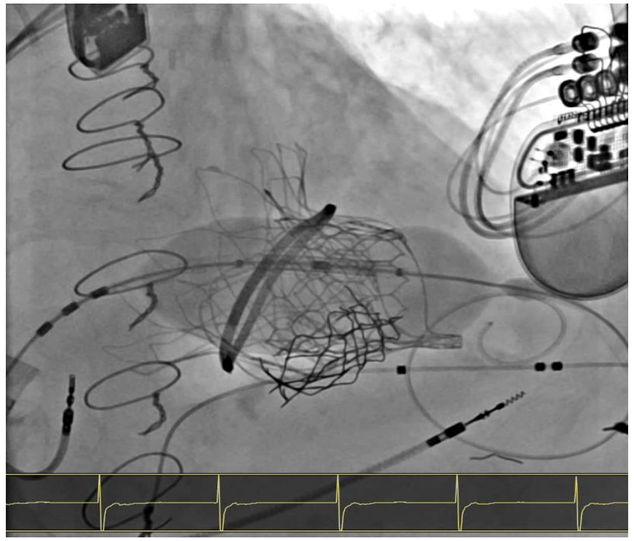
Severe MR

LA V 70mmHg
mean 31mmHg
LVEDP 18mmHg

Atrial septostomy 14*40mm Atlas Gold balloon



Safari wire at LV apex, 26mm Sapien deployed at nominal volume under rapid ventricular pacing at 140bpm on LV wire

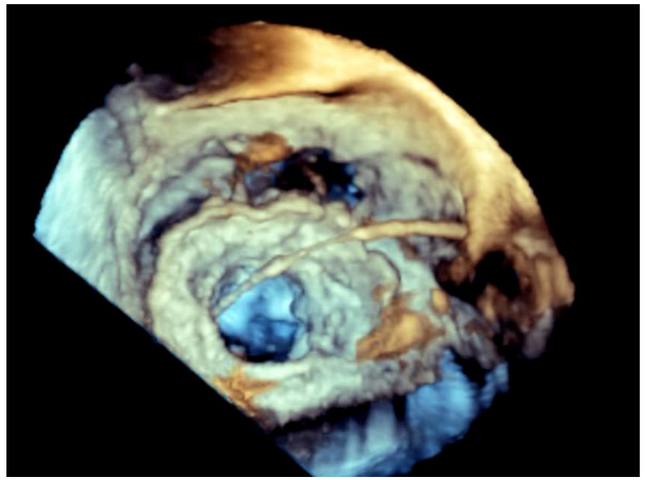


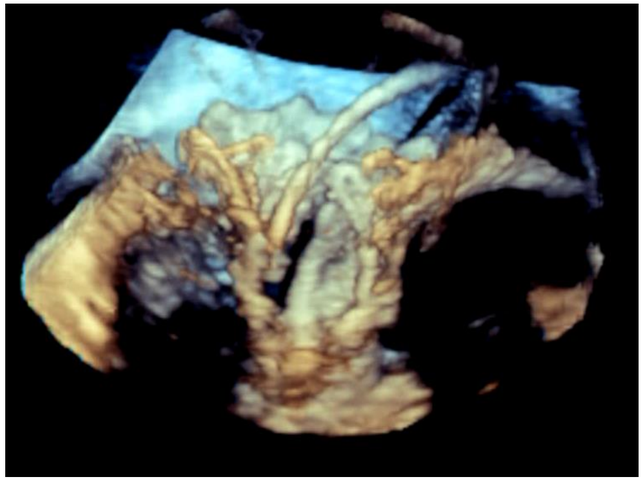
LA V 30mmHg
mean 22mmHg
LVEDP 19mmHg

ASD closed with 24mm Amplatzer ASD occluder

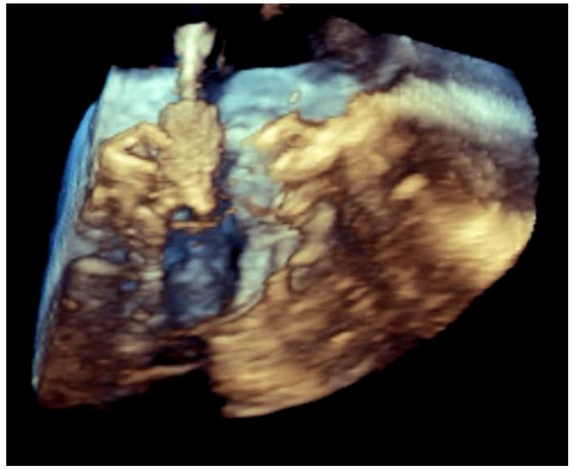
Transcatheter ViV Sapien-in-Tendyne

3D TOE ensuring Safari wire directed through centre of Tendyne inner ring and not one of the outer ring cells

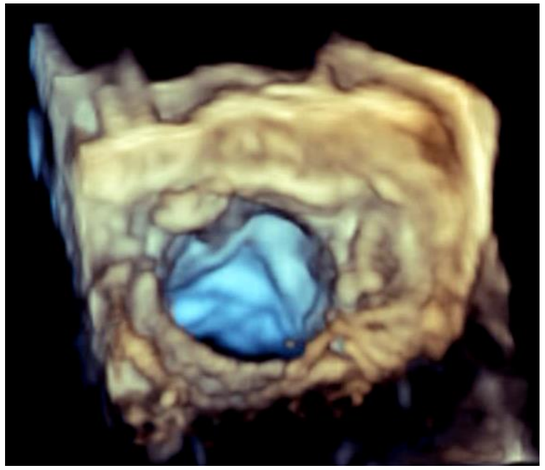


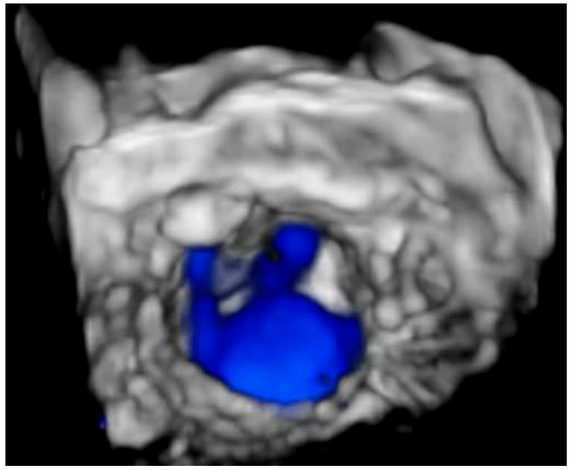


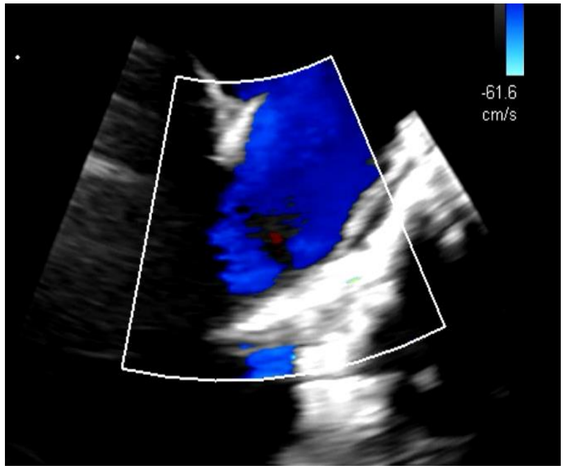
3D TOE guiding SAPIEN trajectory



SAPIEN in Tendyne with reduction of MR



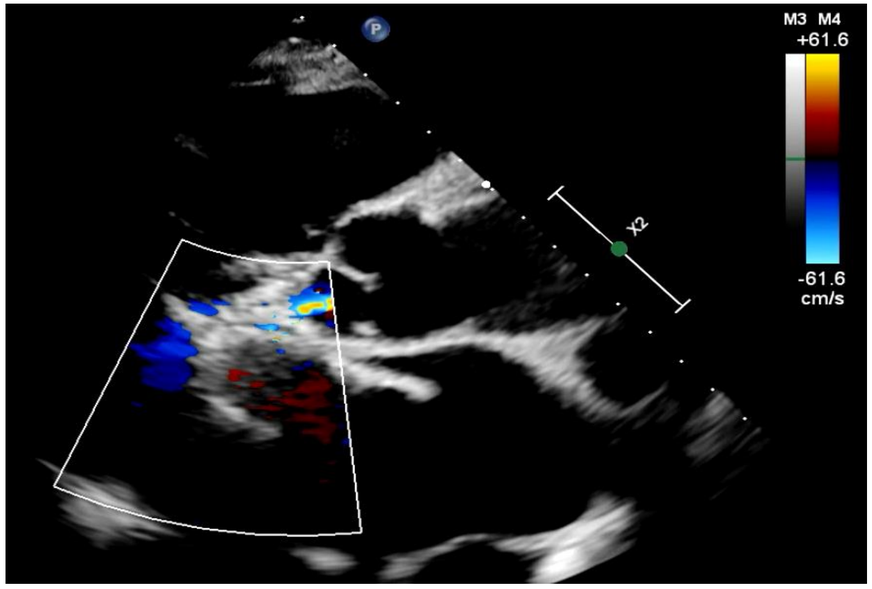


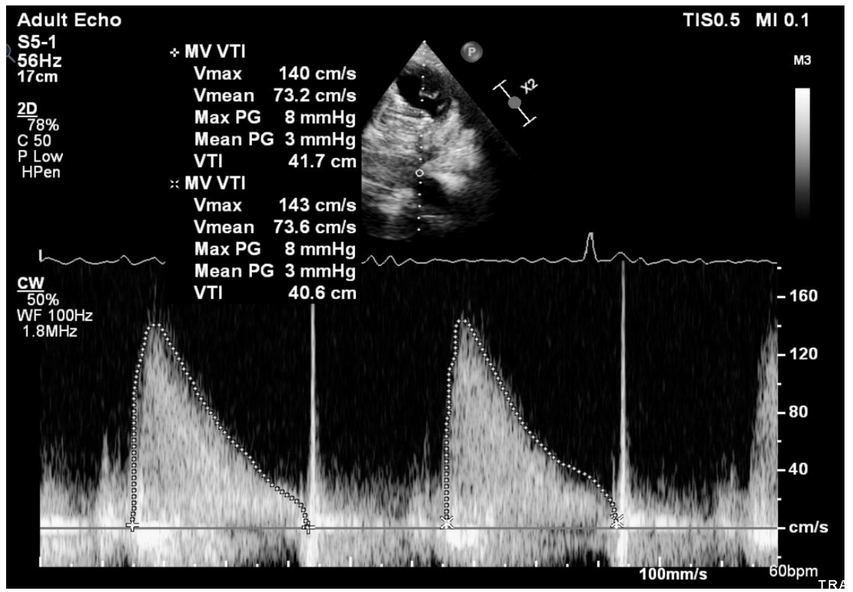


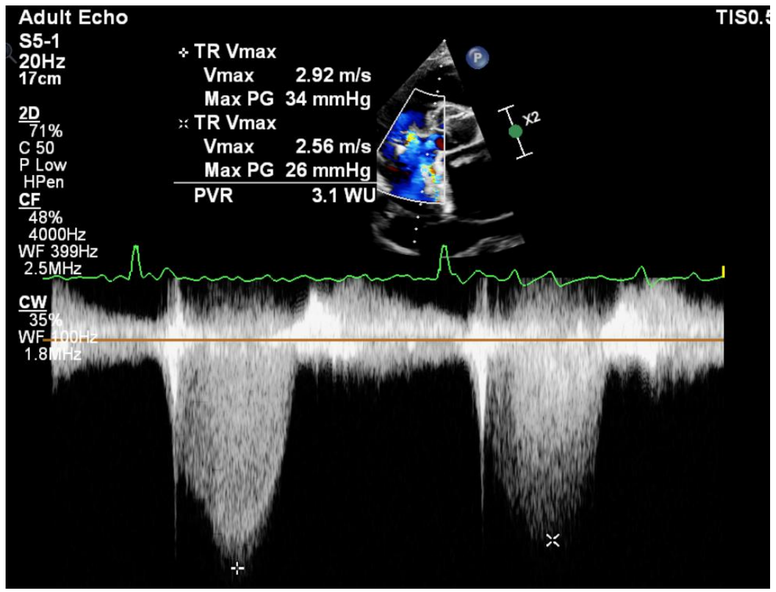
Outcome

- No immediate post-procedural complications
- Length of hospital stay 6 weeks; IV diuretics for off-loading and improvement of thrombocytopenia (to 100mg*10^9/L)
- Discharged back home, independent activities of daily living
- Bendroflumethiazide, bisoprolol , candesartan, dapagliflozin, furosemide, spironolactone, warfarin (target INR 2.0)
- 3-month follow-up: NYHA Class II

10-month follow-up echo: LVEF 39%, mild transvalvular MR, mean MV gradient 3mmHg, LVOT 9mmHg, RVSP 34mmHg



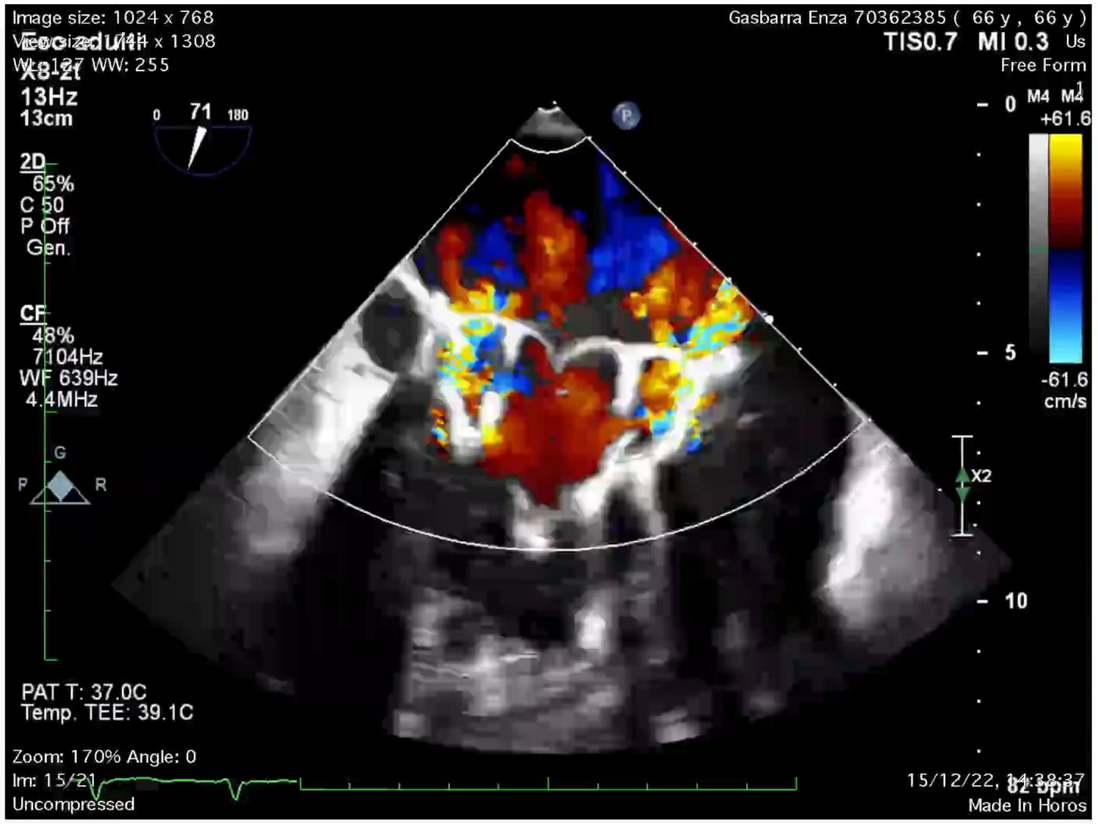




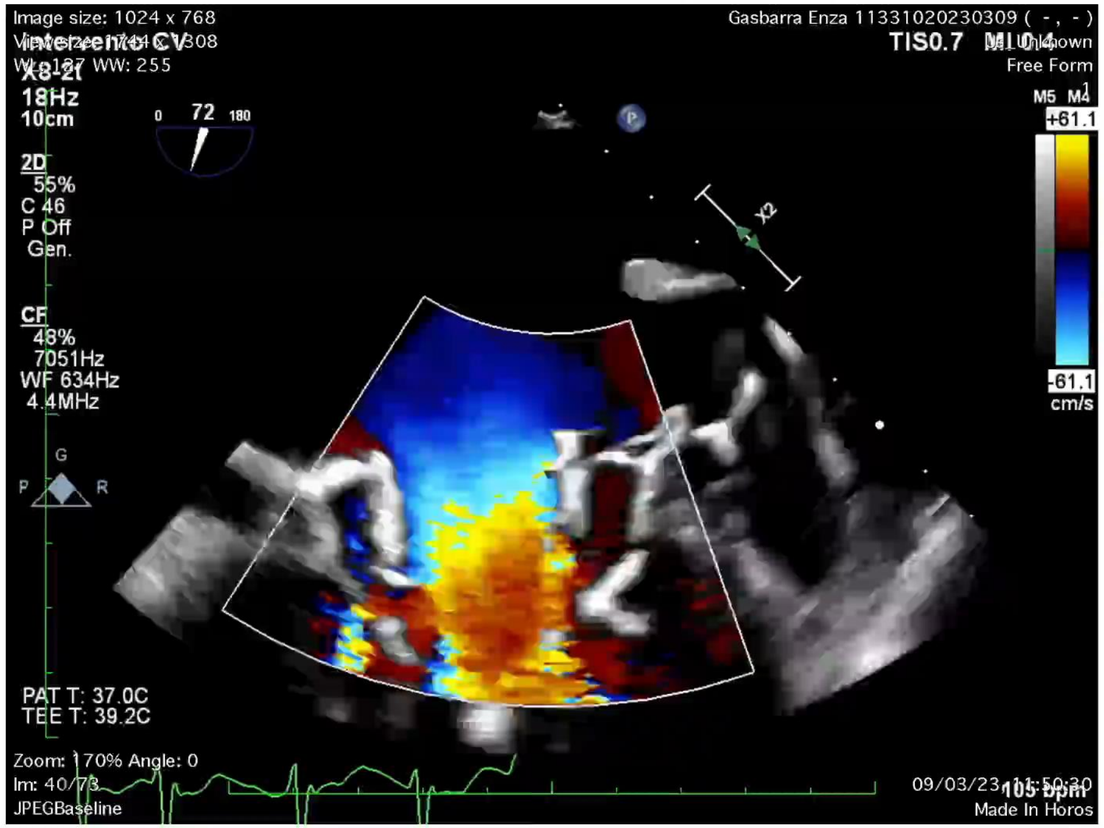
Another SAPIEN-inTendyne

Comparison

Pre

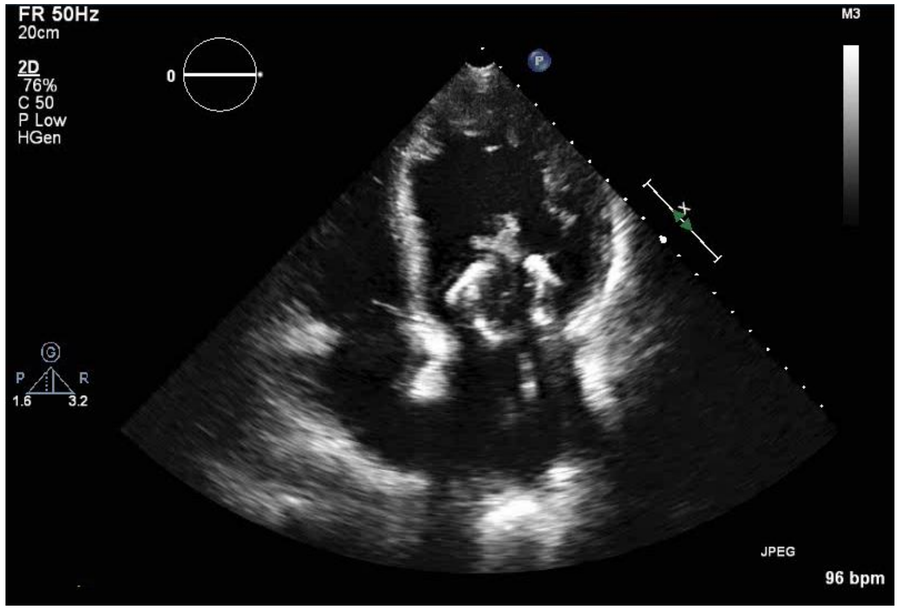


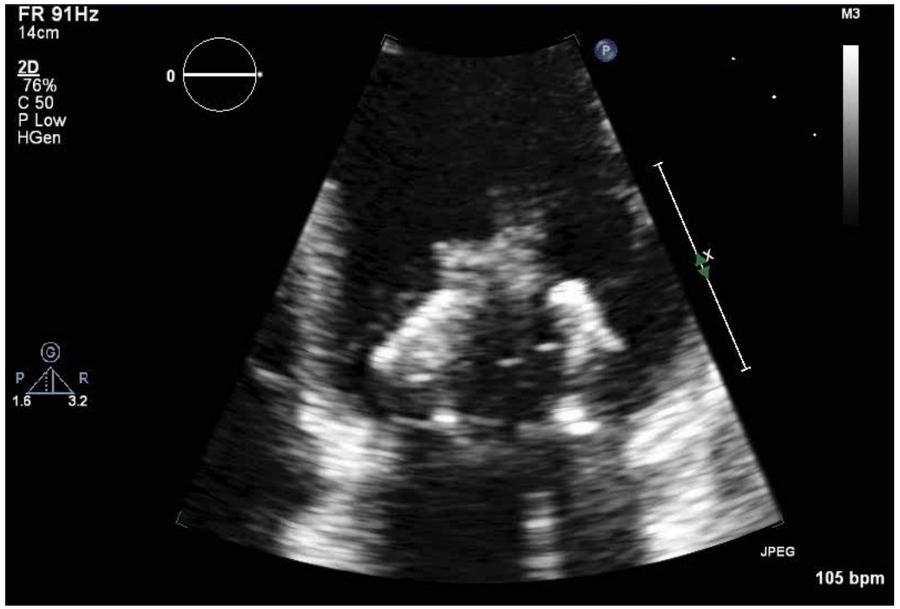
Post

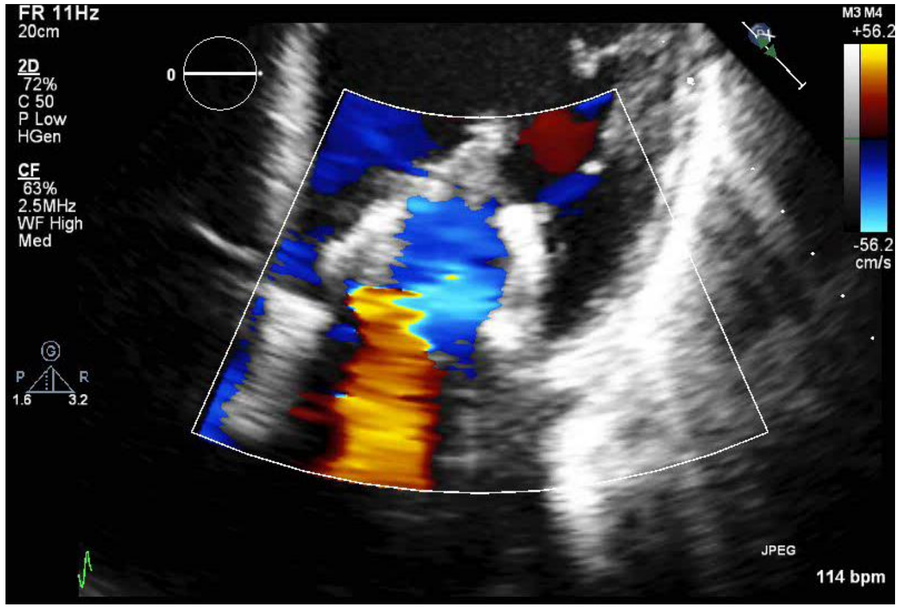


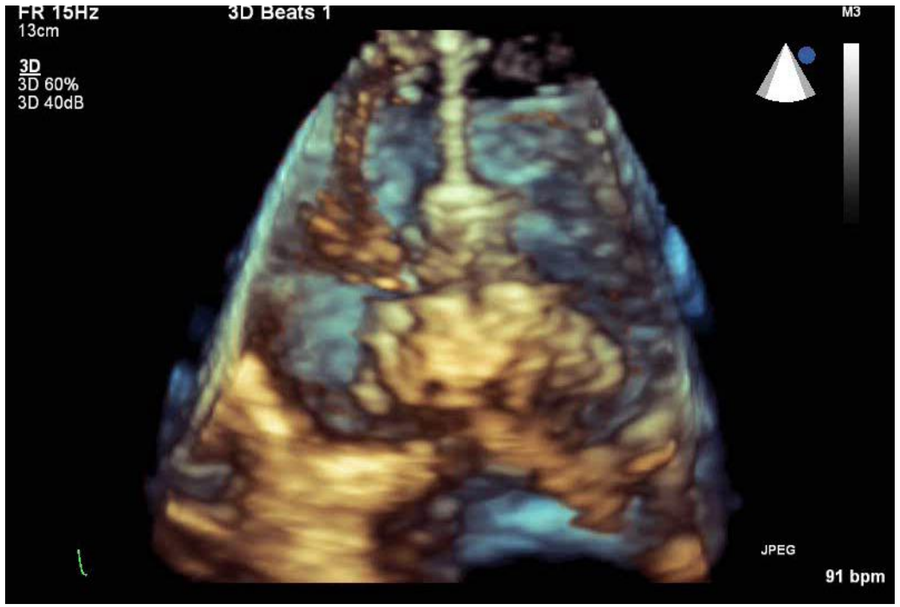
Denti P et al. EuroIntervention 2024;20

Durability: requirement for anticoagulation









Success rate and durability: MV-TEER vs TMVR

- 3-year Tendyne results not comparable with MV-TEER outcome data
- TMVR patients chose not to treat with a TEER device and their mortality is high
- Issue might not be durability – issue more how can we get more effectiveness
- Will TMVR and its elimination of MR lead to more effectiveness in TEER eligible patients?
- Longer-term outcomes for TMVR needed
- No prospective head-to-head TMVR vs eligible or in-eligible TEER patients

Thank you very much for your kind attention