ENGINEERING SOLUTIONS: DEVICES THAT CHANGE THE WAY WE TREAT HF

VALVULAR INNOVATION: THE NEW FRONTIER IN STRUCTURAL HF CARE

Elana Koss, MD
System Director, Structural Heart Echocardiography
Nrothwell Health
Assistant Professor, Zucker School of Medicine at Hofstra/Northwell

April 17, 2026

Northwell℠
Cardiovascular Institute

Nature of Financial Relationship	Ineligible Company
Consultant Fees/Honoraria	Medtronic
Consultant Fees/Honoraria	Abbott
Consultant Fees/Honoraria	Edwards Lifesciences

Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a relevant financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Journal of
Clinical Medicine

MDPI

Review

Structural Interventions in Heart Failure: Mending a Broken Heart

David Katzianer and Chonyang Albert *

Department of Cardiovascular Medicine, Cleveland Clinic Foundation, Cleveland, OH 44195, USA
* Correspondence: albertc2@ccf.org

Northwell℠
Cardiovascular Institute

WHAT'S NEW IN AORTIC VALVE DISEASE:

1. New Frontier in Native Aortic Regurgitation.
   - JenaValve
2. A Paradigm Shift in Timing and Indication for Aortic stenosis
   - EARLY TAVR Study
3. Future
   - Moderate AS Trials (PROGRESS and EXPAND II TAVR)

FDA APPROVED JENAVALVE TAVR SYSTEM- TRILOGY VALVE FOR AORTIC REGURGITATION

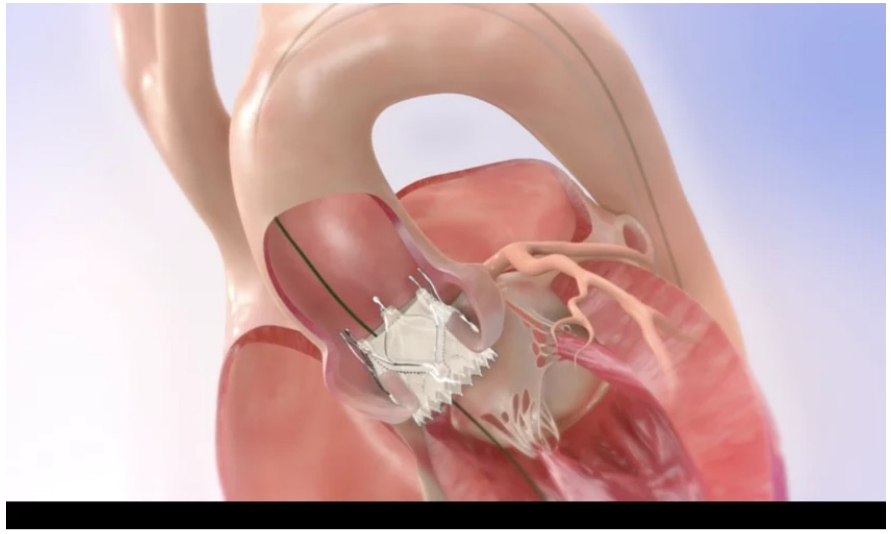
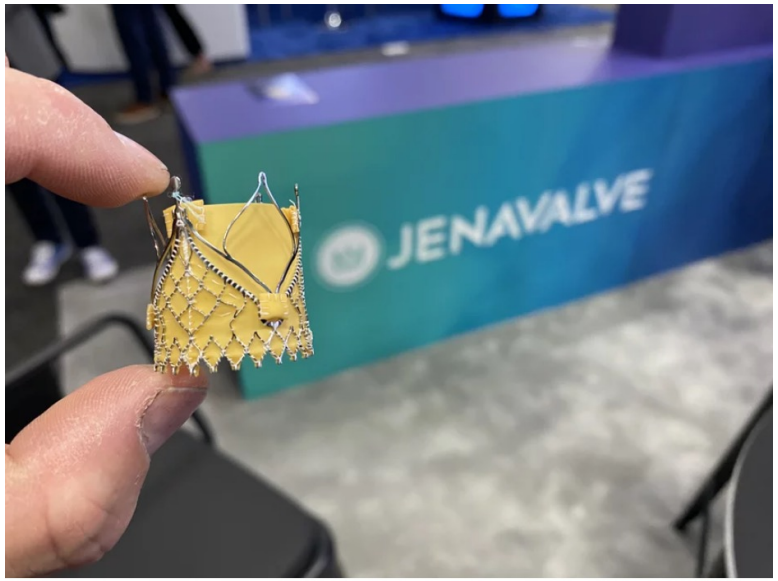


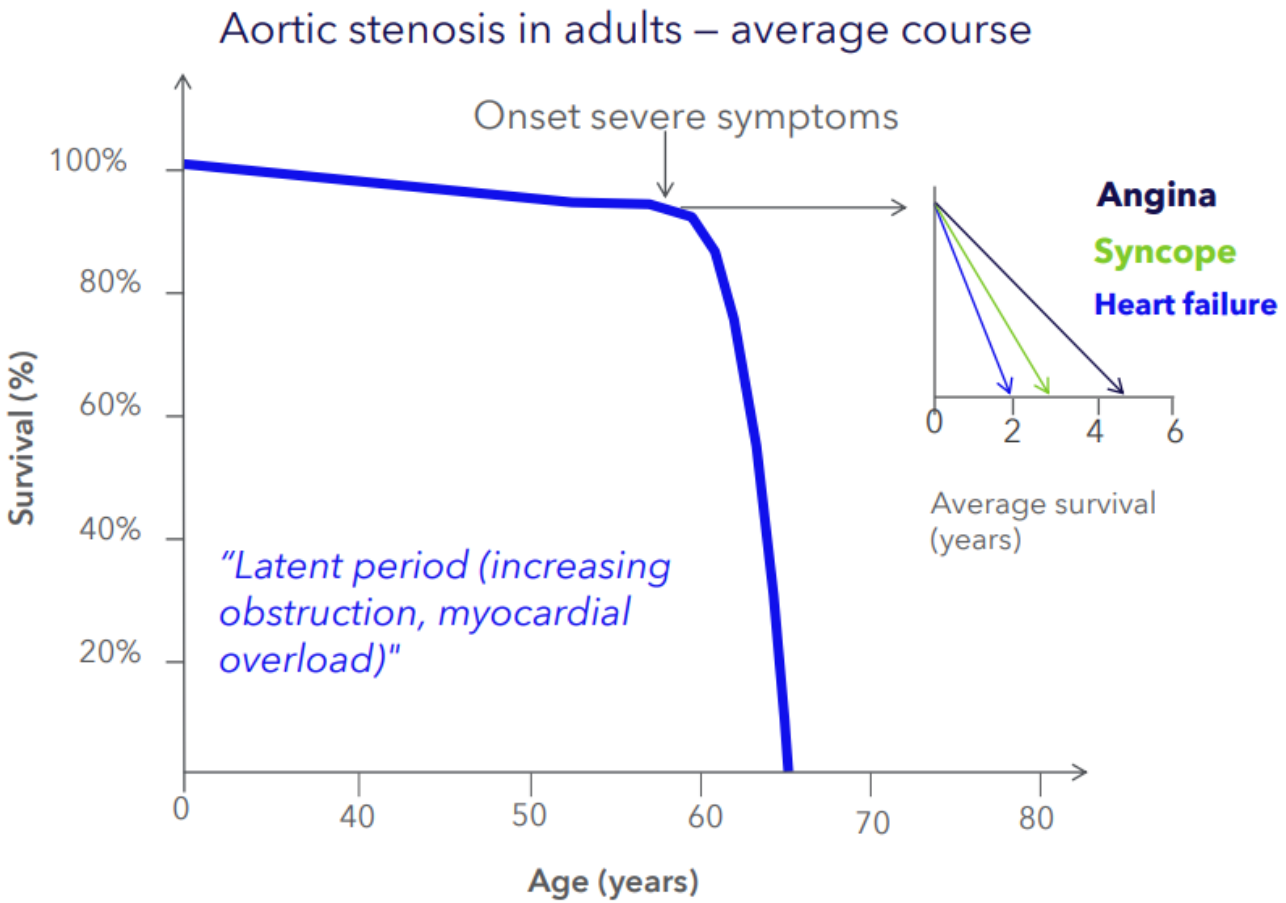
Image courtesy of JenaValve.



The JenaValve Transcatheter Heart System on display at TCT 2023. Photo by Dave Fornell.

- FDA approval for Trilogy Transcatheter Heart Valve System to be used for transcatheter aortic valve replacement (TAVR) procedures in patients with symptomatic, severe aortic regurgitation (AR).
- First TAVR device approved by the FDA for the treatment of symptomatic, severe AR in patients high risk for surgery.
- Unique locators that align the THV with the native cusps of the valve enabling anchoring in pure AR patients. The Trilogy can be used in non-calcified valves.
- The FDA's decision was largely based on positive data from the ALIGN-AR trial, which explored the safety and effectiveness of the Trilogy valve in patients with pure AR

Origin of the Treatment Paradigm for Severe AS



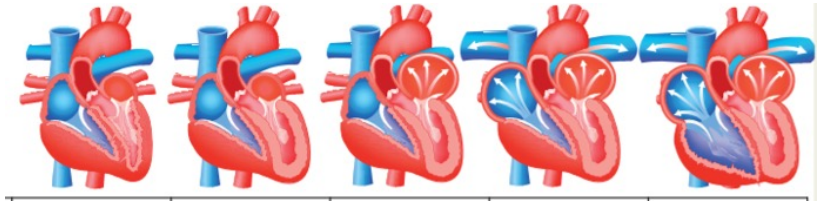
Ross J Jr, et al. Circulation. 1968;38(1 Suppl):61-67.

Assumes there are no important reversible or irreversible structural changes during the "latent period."

Assumes that the onset of symptoms is discrete and easily identifiable and linked to AS severity.

Prognostic Implications of Associated Cardiac Abnormalities Detected on Echocardiography in Patients With Moderate Aortic Stenosis

Stages of Cardiac Damage



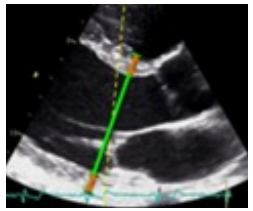
Amanullah M et al. JACC CV Imaging, 2022

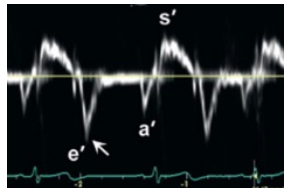
Full Echo protocol designed to allow categorization of patients according to stage of cardiac damage (extra-aortic valve abnormalities)

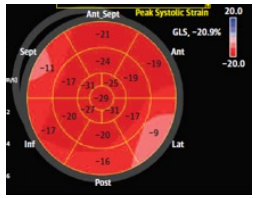
Généreux P. et al, European Heart Journal (2017)

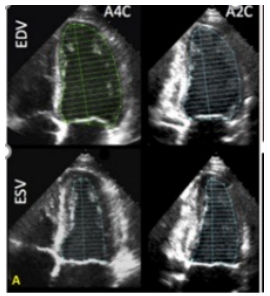
Stage I: LV Damage

- LV hypertrophy (increased LV mass)
- Grade II diastolic dysfunction
- Impaired GLS (≤ 15)
- LVEF< 60%



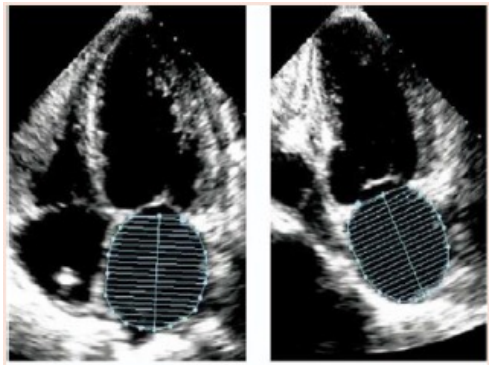






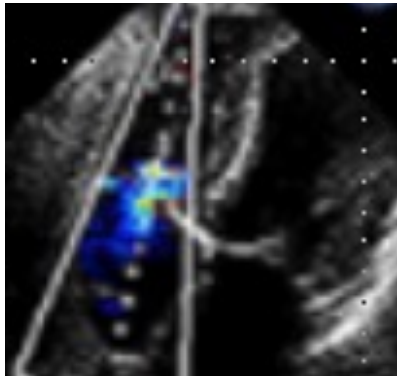
Stage 2: LA or Mitral Damage

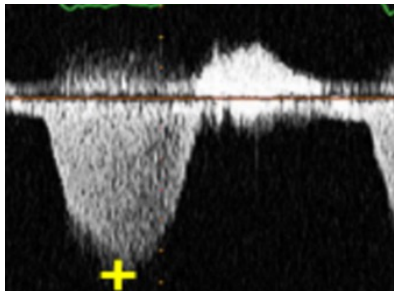
Increased LA volume (>34 ml/m²)



Stage 3: Pulmonary Vascular Damage

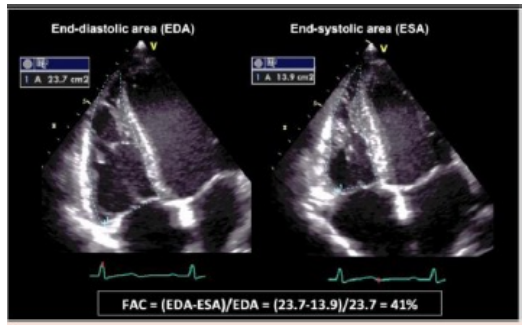
Pulmonary hypertension (PA≥ 60 mm Hg)

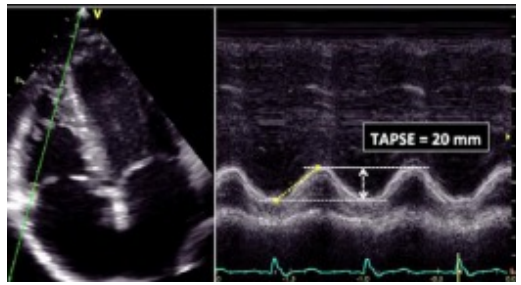




Stage 4: RV Damage

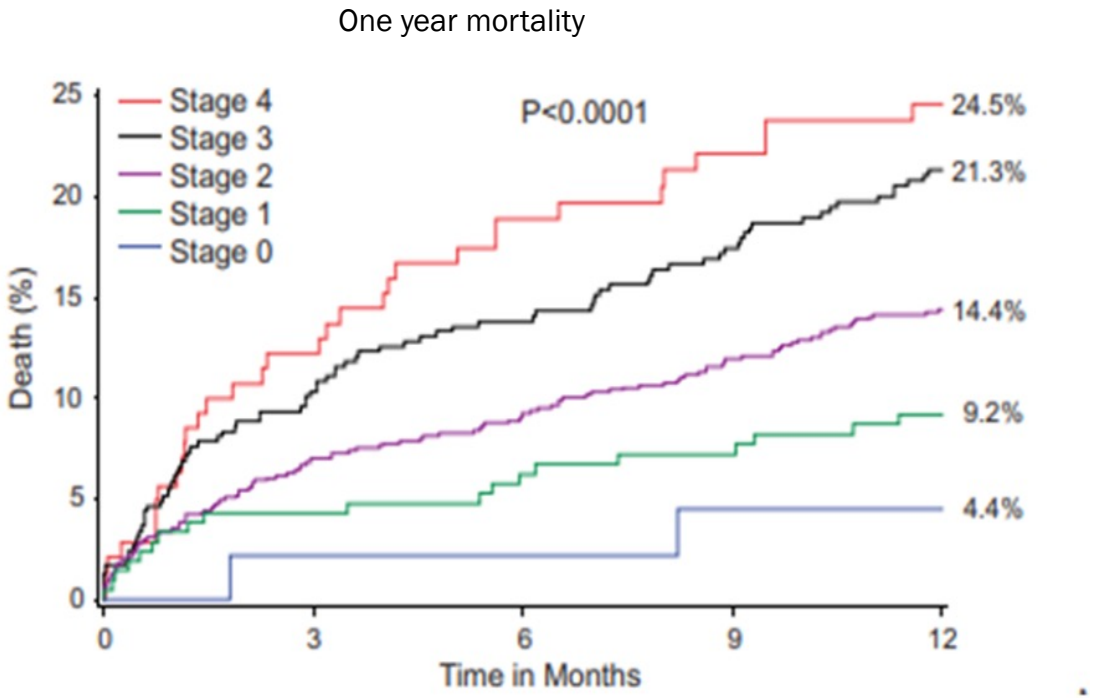
Moderate or severe RV dysfunction





CARDIAC DAMAGE IS SILENT & IMPAIRS SURVIVAL

Staging Classification of Aortic Stenosis Based on the Extent of Cardiac Damage



Généreux P. et al, European Heart Journal (2017)

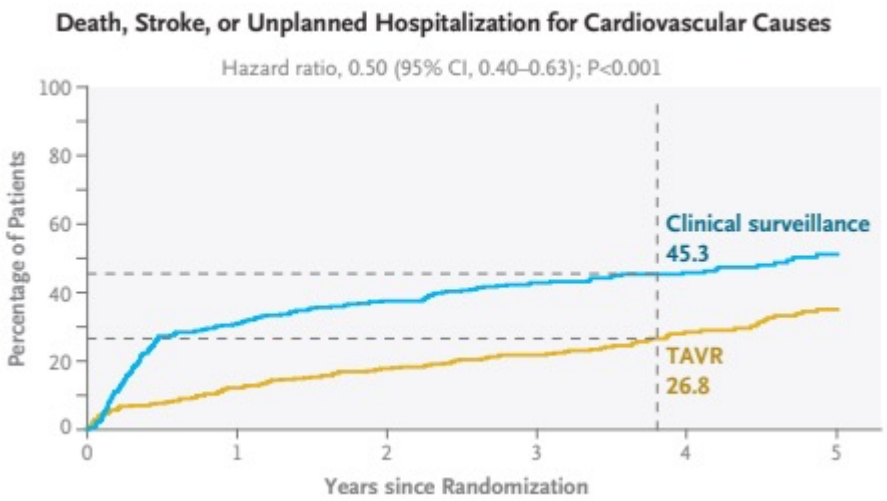
- 1,161 patients with symptomatic severe AS who underwent AVR in PARTNER 2A and 2B trials (surgical AVR or TAVR)
  - Stage 0 (no cardiac damage) 2.8%
  - Stage 1 (LV damage) 12.8%
  - Stage 2 (LA or MV damage) 50.8%
  - Stage 3 (Pulmonary vascular damage) 24.9%
  - Stage 4 (RV damage) 8.7%
- 85% of these patients at the time of diagnosis and treatment already had substantial cardiac damage
- One year mortality 24.5% in patients with Stage 4 (RV damage), compared to patients with Stage 0 (no cardiac damage)
- "Extent of cardiac damage independently associated with increased mortality after AVR (HR 1.46 per each increment in stage."
  - 1 year mortality after AVR/TAVR shows a graded increase relative to the degree of cardiac damage

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JANUARY 16, 2025 VOL. 392 NO. 3

Transcatheter Aortic-Valve Replacement for Asymptomatic Severe Aortic Stenosis

P. Généreux, A. Schwartz, J.B. Oldemeyer, P. Pibarot, D.J. Cohen, P. Blanke, B.R. Lindman, V. Babaliaros, W.F. Fearon, D.V. Daniels, A.K. Chhatriwalla, C. Kavinsky, H. Gada, P. Shah, M. Szerlip, T. Dahle, K. Goel, W. O'Neill, T. Sheth, C.J. Davidson, R.R. Makkar, H. Prince, Y. Zhao, R.T. Hahn, J. Leipsic, B. Redfors, S.I. Pocock, M. Mack, and M.B. Leon, for the EARLY TAVR Trial Investigators*



EARLY TAVR Findings:

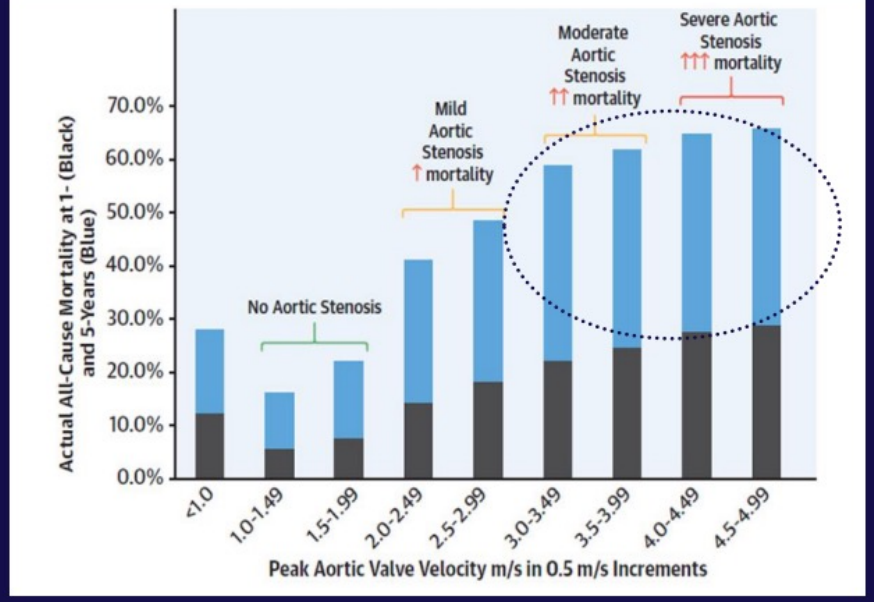
- Among patients with asymptomatic severe aortic stenosis, a strategy of early TAVR was superior to clinical surveillance in reducing the incidence of death, stroke, or unplanned hospitalization for cardiovascular causes.
- 50% reduction in the primary endpoint (death, stroke, unplanned CV hospitalization) at 3.8 years
- Clinical surveillance arm more than 70% converted to symptoms by 2 years and underwent AVR.

"Early TAVR means early evaluation, organized care, and treating promptly. We can't sit back and wait for things to progress slowly because 40% of patients in a carefully done trial still presented with acute valve syndrome that increased their risk for death, stroke and heart failure" (P Genereux)

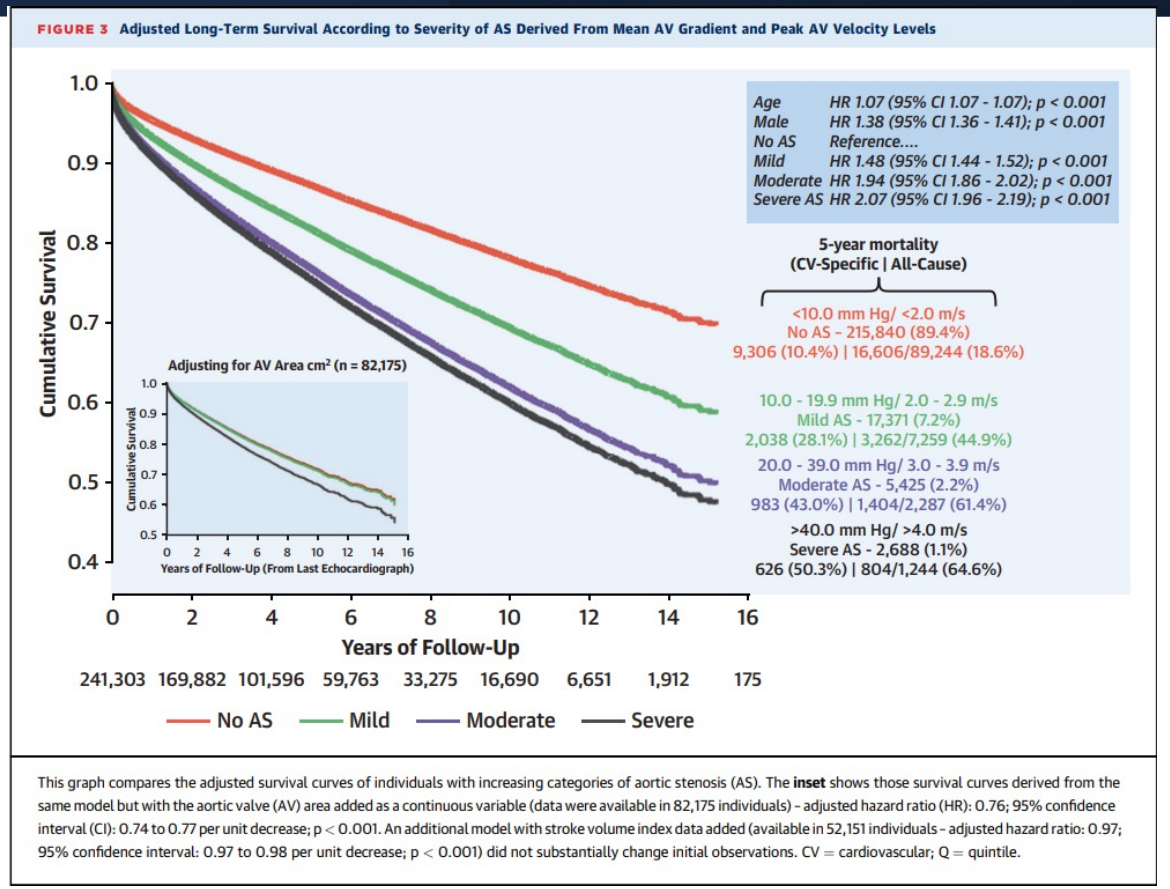
Why Moderate AS is bad

Poor Long-Term Survival in Patients with Moderate AS

CENTRAL ILLUSTRATION Moderate Native Valvular Aortic Stenosis and Long-Term Survival: 1- and 5-Year Mortality per Increment in Peak Aortic Valve Velocity



- National Echo Database of Australia
- **Mortality similar between moderate and severe AS**



This graph compares the adjusted survival curves of individuals with increasing categories of aortic stenosis (AS). The **inset** shows those survival curves derived from the same model but with the aortic valve (AV) area added as a continuous variable (data were available in 82,175 individuals - adjusted hazard ratio (HR): 0.76; 95% confidence interval (CI): 0.74 to 0.77 per unit decrease; $p < 0.001$. An additional model with stroke volume index data added (available in 52,151 individuals - adjusted hazard ratio: 0.97; 95% confidence interval: 0.97 to 0.98 per unit decrease; $p < 0.001$) did not substantially change initial observations. CV = cardiovascular; Q = quintile.

Strange et. al; Poor Long-Term Survival in Patients With Moderate Aortic Stenosis. JACC VOL. 74, NO. 15, 2019:1851 – 6 3

Rationale for Trial in Symptomatic Moderate AS:

Are we intervening too late?

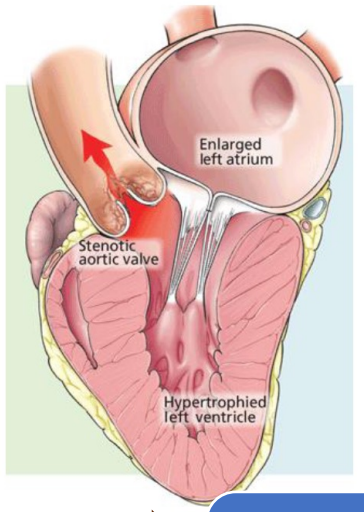
AS is a continuous disease process punctuated by:

- Clinical events (AF, cardiac symptoms)
- Sub-clinical myocardial damage and Structural changes (LVH,PAH, RH failure)

Progression can be rapid and undetected

Patients may present late

Cardiac Consequences of AS



2 RCT Moderate AS with features of myocardial damage TAVR+GDMT vs. GDMT

- PROGRESS (SAPIEN+ GDMT vs. GDMT)
- EXPAND II TAVR (CORE Valve + GDMT vs. GDMT)

Does earlier diagnosis and treatment improve clinical outcomes?

MITRAL AND TRICUSPID VALVE DISEASE IN 2026

Expanding Options and Tools in the Toolbox

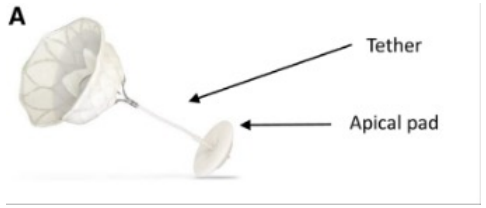
MITRAL TRANSCATHETER THERAPIES: CURRENT AND EMERGING DEVICES

Current M-TEER Devices

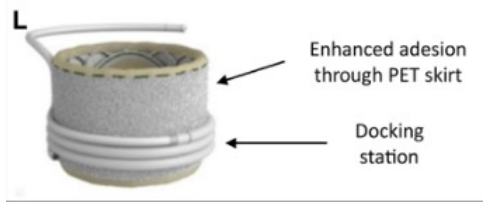
MitraClip

PASCAL

Commercial TMVR Devices

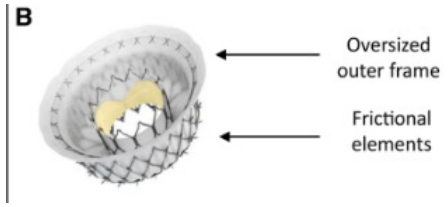


Tendyne

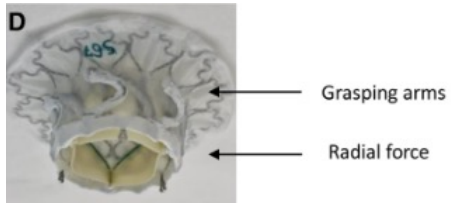


SAPIEN M3

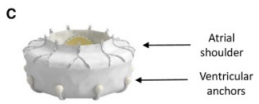
Investigational Devices



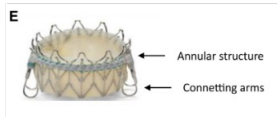
Intrepid



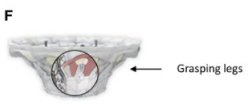
Innovalve



EVOQUE Eos

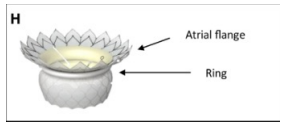


Saturn

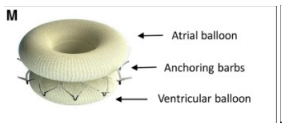


Cardiovalve

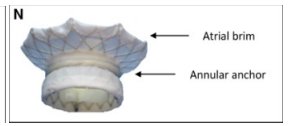
Cephea



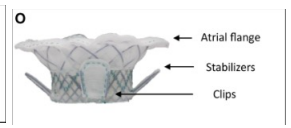
HighLife



ValvSync



Tioga



Palmetto Valve

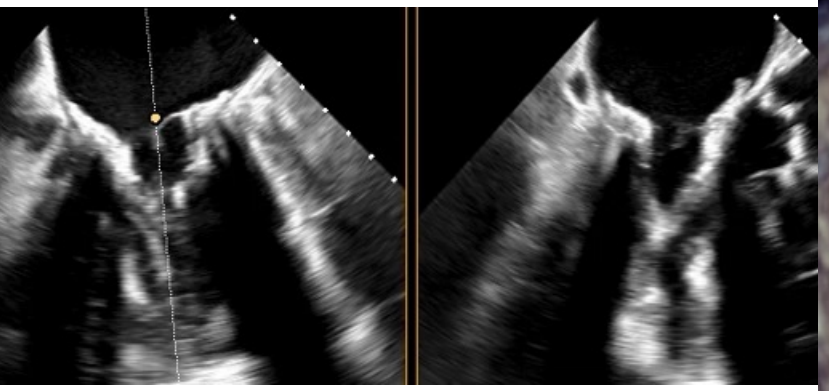
Circulation: Cardiovascular Interventions
Volume 18, Issue 10, October 2025; Page e015298
https://doi.org/10.1161/CIRCINTERVENTIONS.125.015298

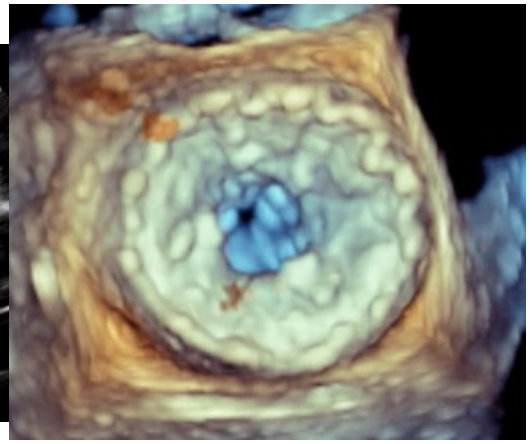
CURRENT FDA APPROVED TMVR DEVICES

- **Tendyne Transapical TMVR (SUMMIT Trial)**
  - FDA approved May 2025
  - Transapical Approach

Indications:

- Symptomatic severe mitral valve dysfunction
  - moderate-to-severe or severe MR, or
  - severe mitral stenosis, or
  - moderate MR with moderate-or-greater mitral stenosis
- associated ***with severe MAC*** in patients who are unsuitable for mitral valve surgery or M-TEER by MDHT.





Courtesy: Ythan Goldberg

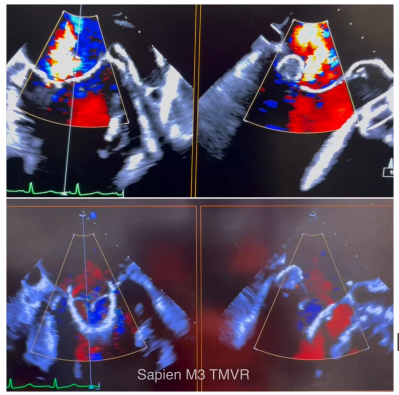
- **SAPIEN M3 Trans-septal TMVR (ENCIRCLE Trial)**
  - FDA approved December 2025
  - First approval of a fully percutaneous TMVR device for patients with limited options based on 1 year data for ENCRIRCLE trial

Indications:

- Symptomatic moderate-severe or severe MR in patients who are unsuitable for surgery or M-TEER by MDHT

Additional Indication:

- Symptomatic mitral valve dysfunction (moderate-to-severe or severe MR, severe MS or moderate MR with moderate MS) associated with MAC in patients unsuitable for surgery or M-TEER.

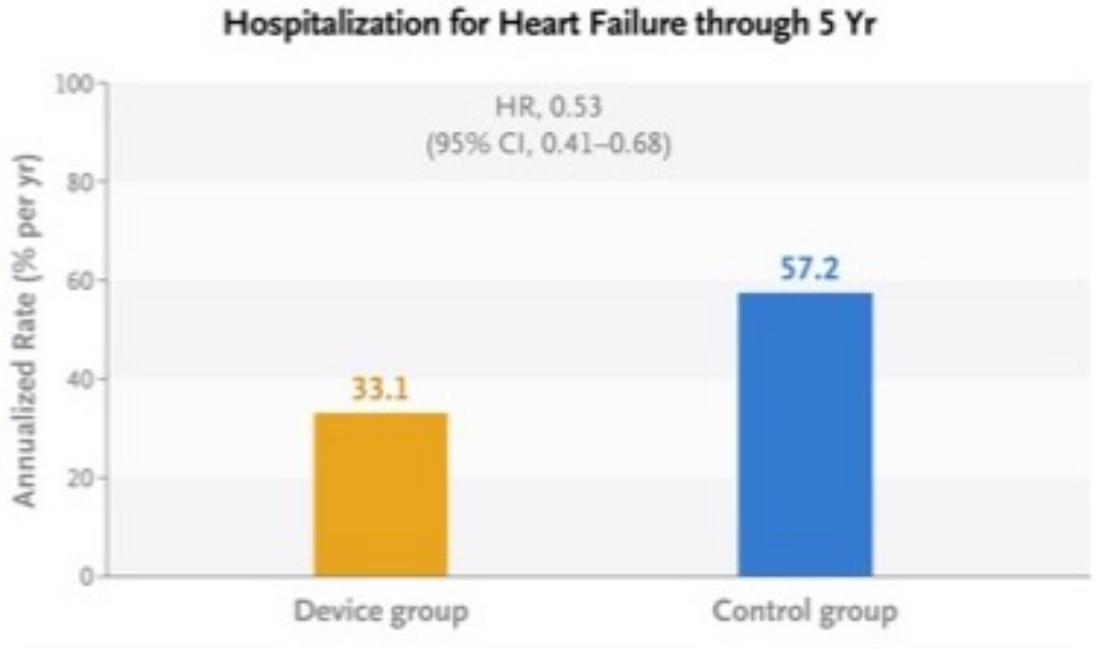


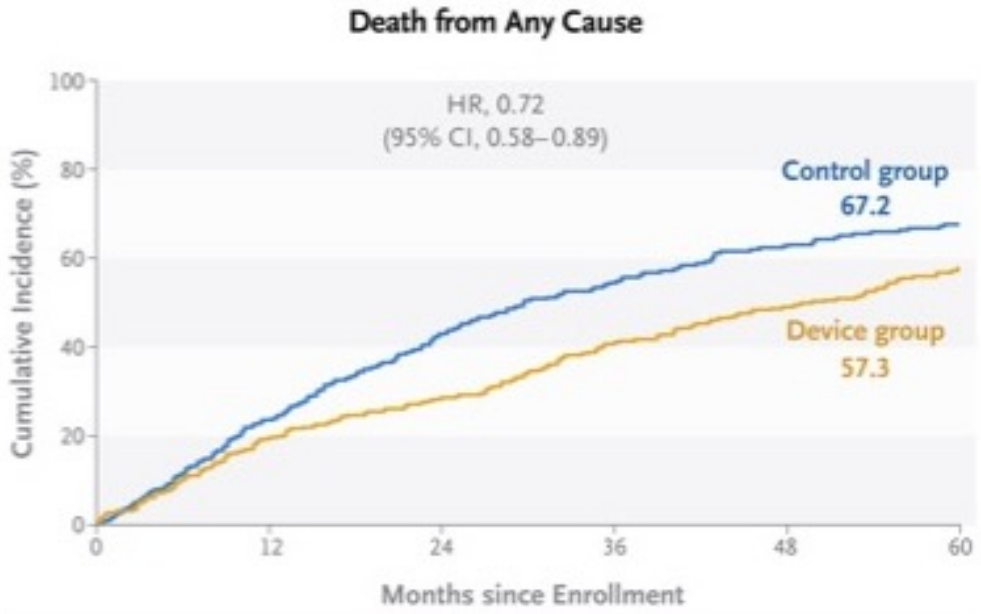
ORIGINAL ARTICLE

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

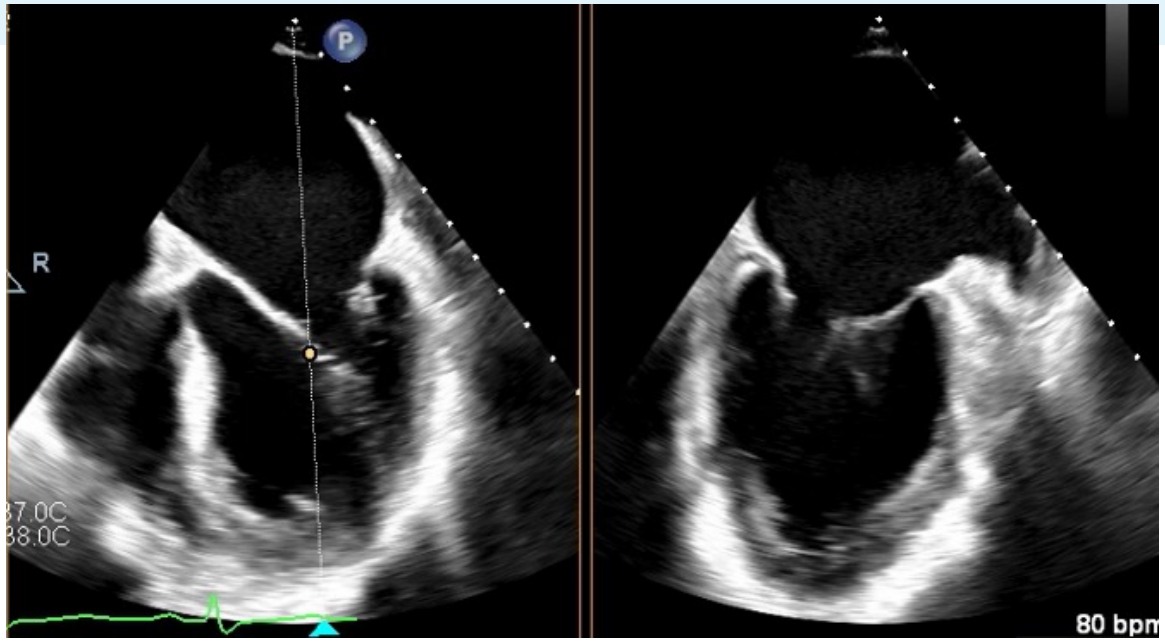


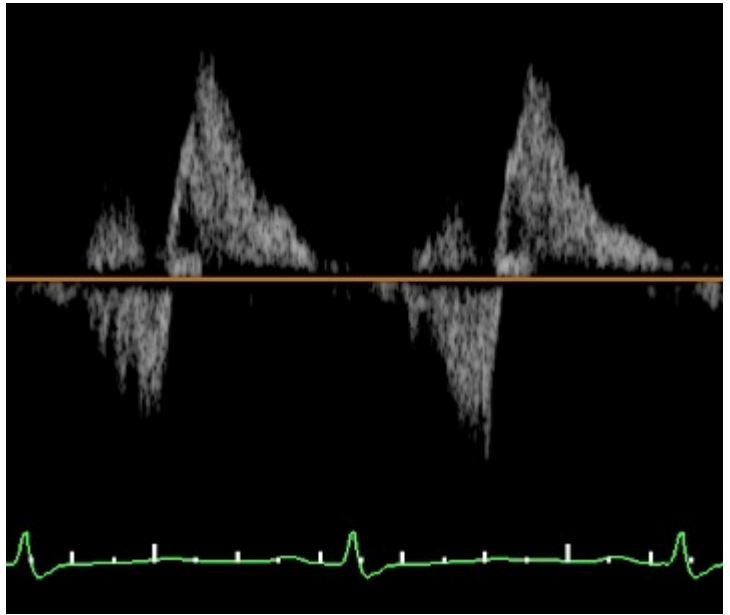


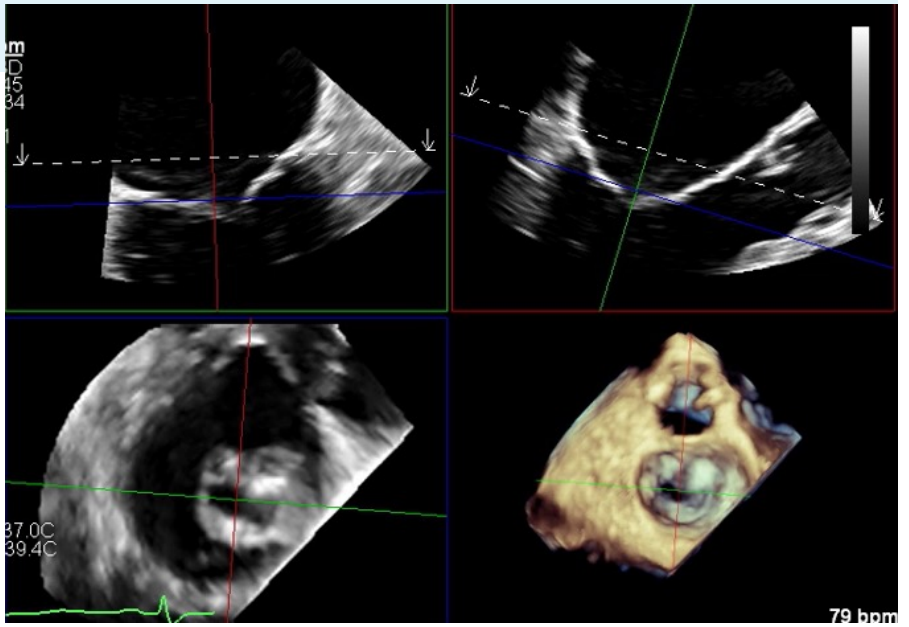
CONCLUSIONS

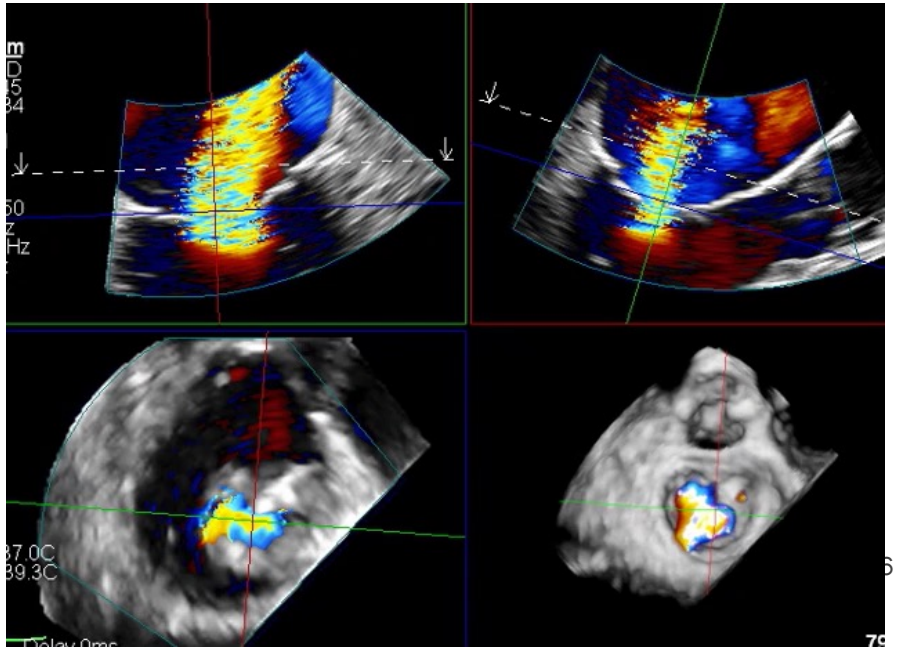
Among patients with heart failure and moderate-to-severe or severe secondary mitral regurgitation, transcatheter edge-to-edge repair led to a lower rate of hospitalization for heart failure and lower mortality at 5 years.

- **77yo F admitted to outside hospital with acute coronary syndrome and 3VD. Pt had PCI to LM and pLAD with LCx infarct. IABP complicated by leg ischemia. Cardiogenic shock with new severe MR and inotrope dependent.**

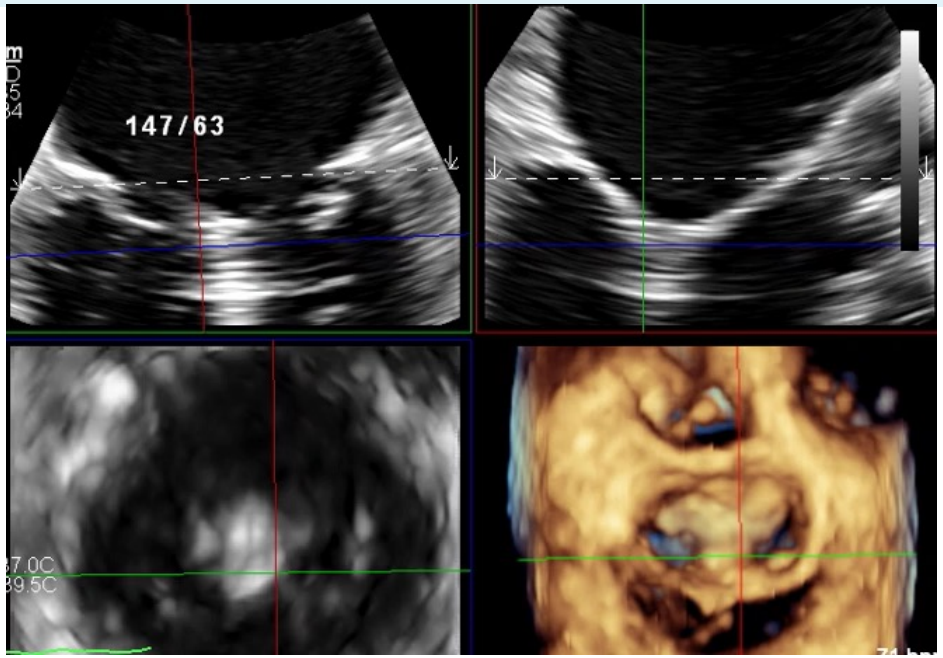


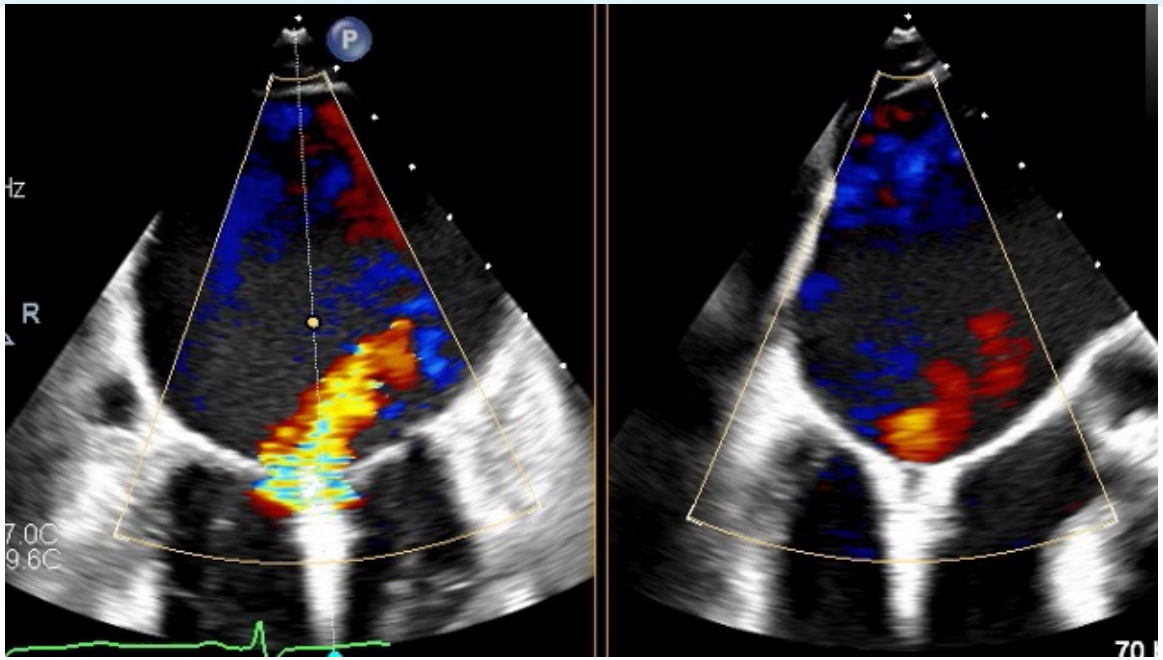


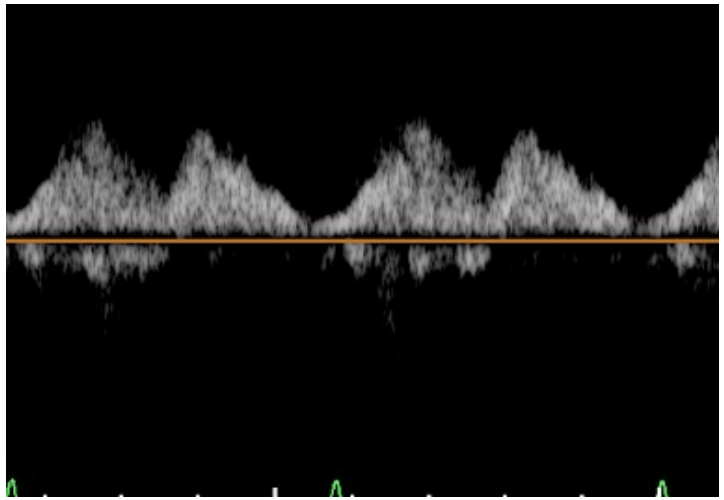




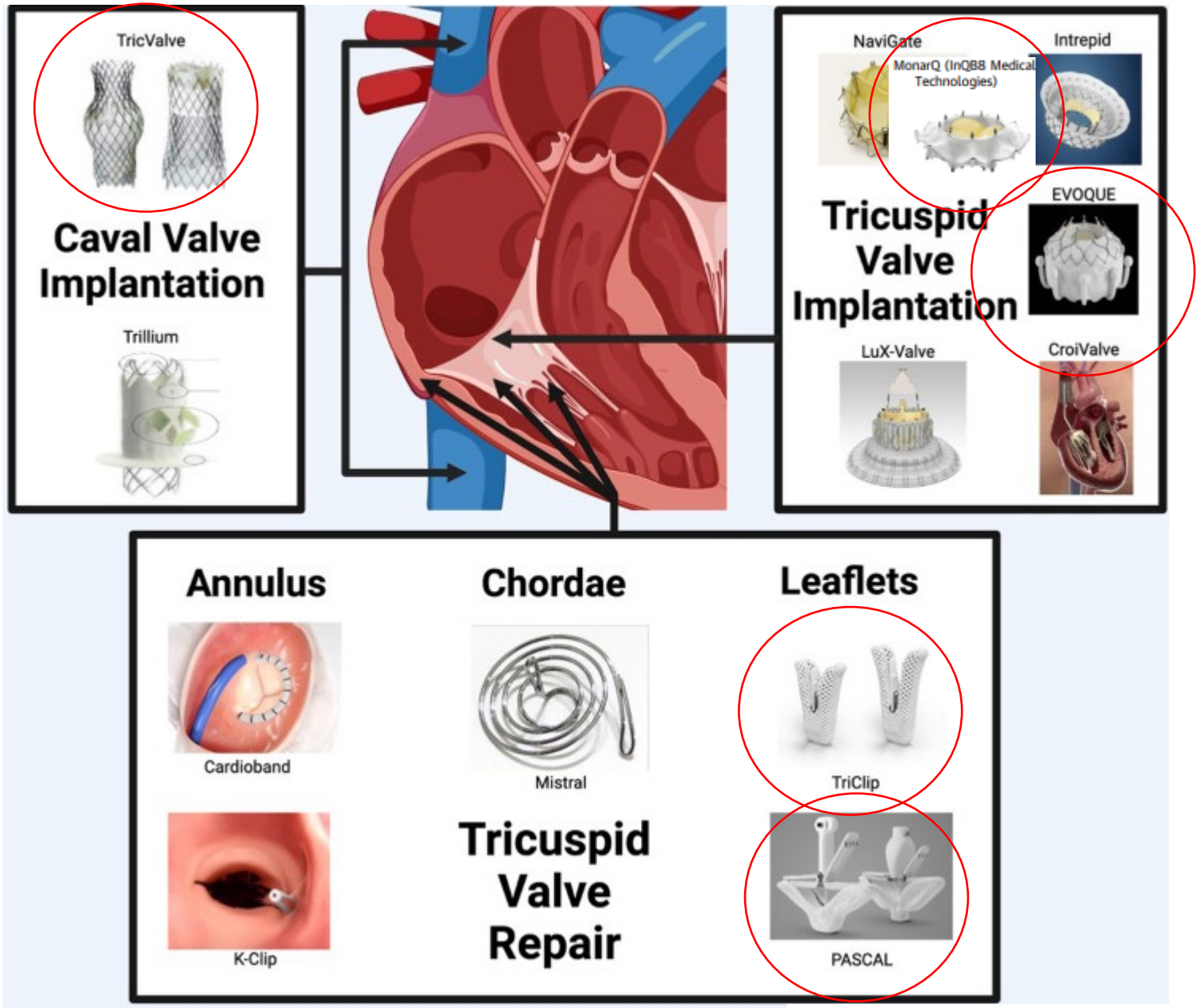
MitraClip G5 XTW on A2/P2. Inotrope weaned off within 24 hours and discharged post-op day 3.





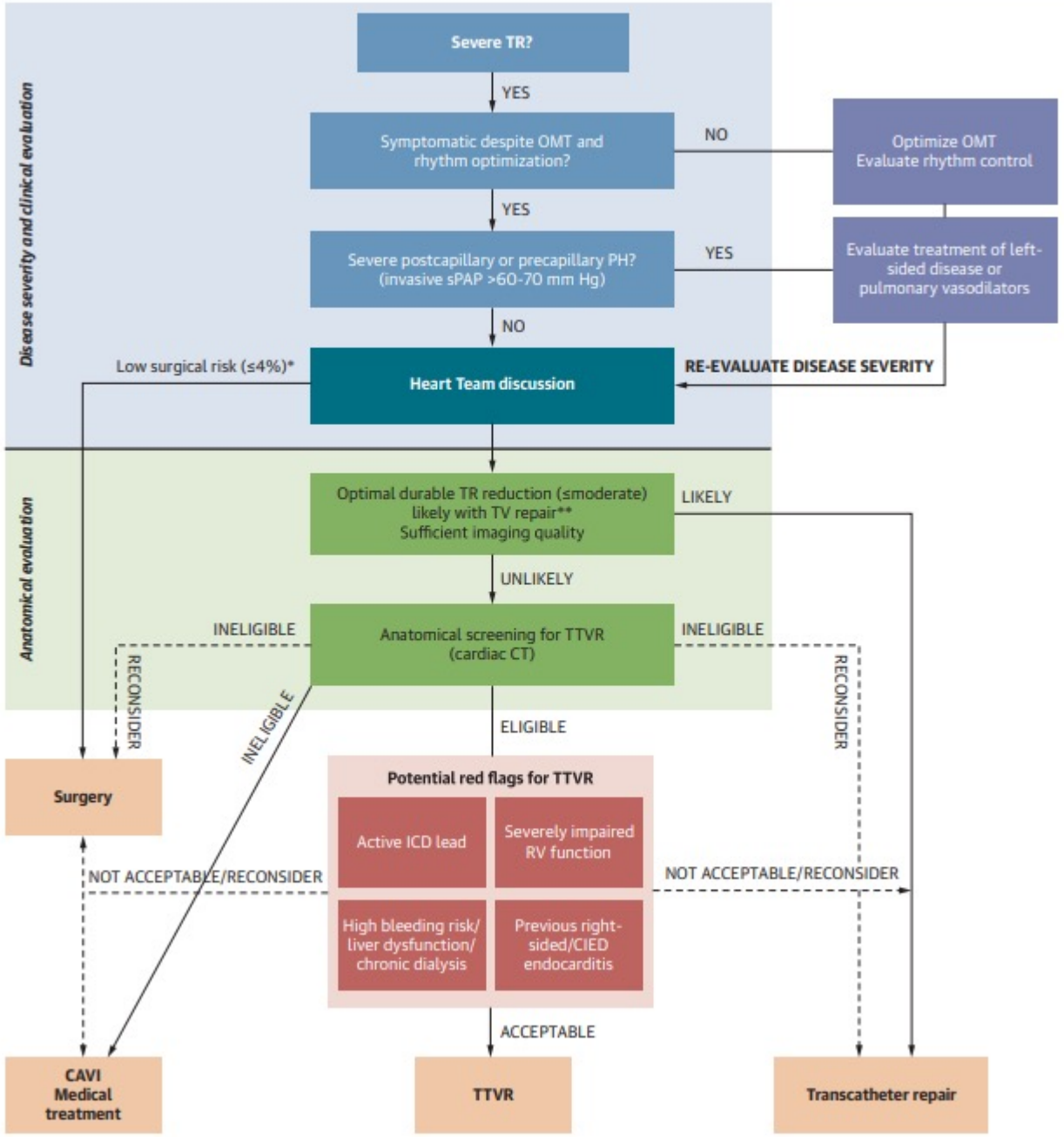


DEVICES FOR CURRENT TREATMENT OF SEVERE TR



H. Seligman et al. / Journal of the Society for Cardiovascular Angiography & Interventions 2 (2023) 101201 (modified)

TREATMENT ALGORITHM FOR SEVERE TR



Clinical Factors:

Symptom burden?	Bleeding risk?
Mechanism of TR?	Need for future intervention?
Annulus characteristics?	Surrounding structures at risk?
Leaflet characteristics?	Importance of durable solution?
Coaptation gap size?	Overall co-morbidity?
RV reserve?	Futility?
Current/future pacing needs?	Safety vs efficacy?

Valve Implantation

Prior surgical TV replacement
Unfavorable annulus
Unfavorable leaflets
Unfavorable chordae
Pacing leads
No concern for RV reserve

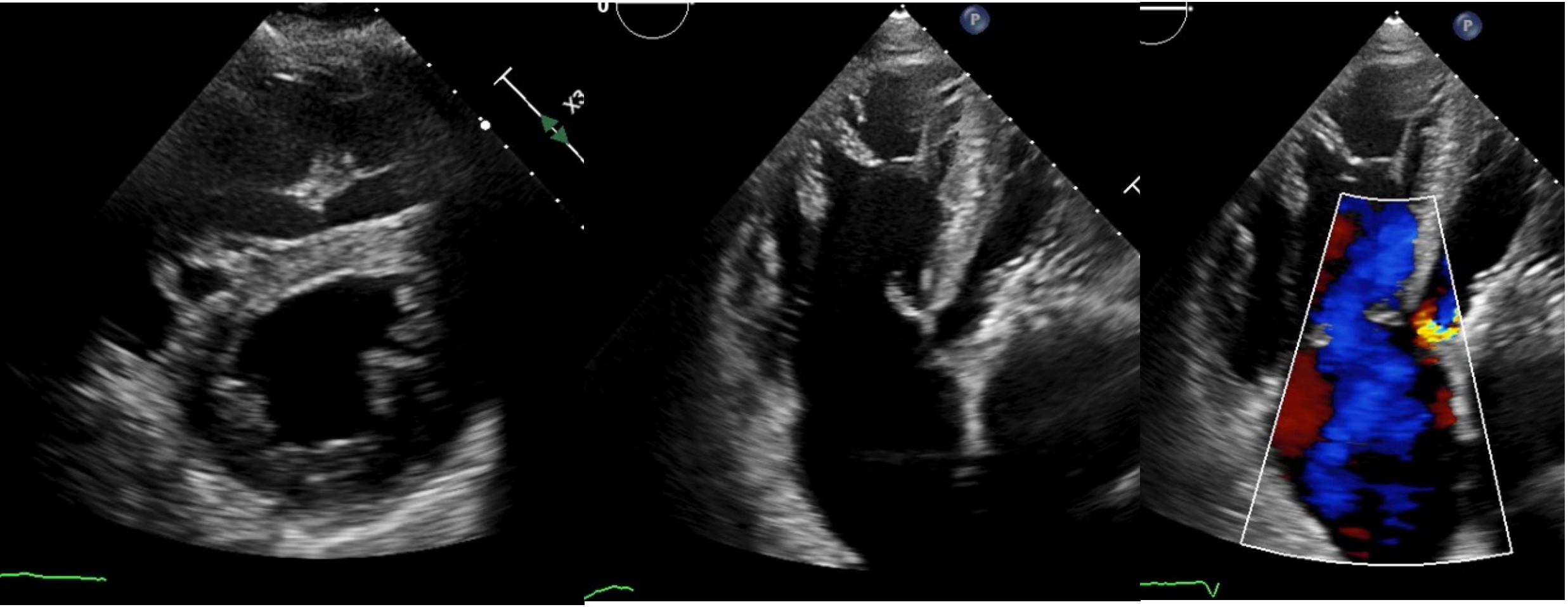
Valve Repair

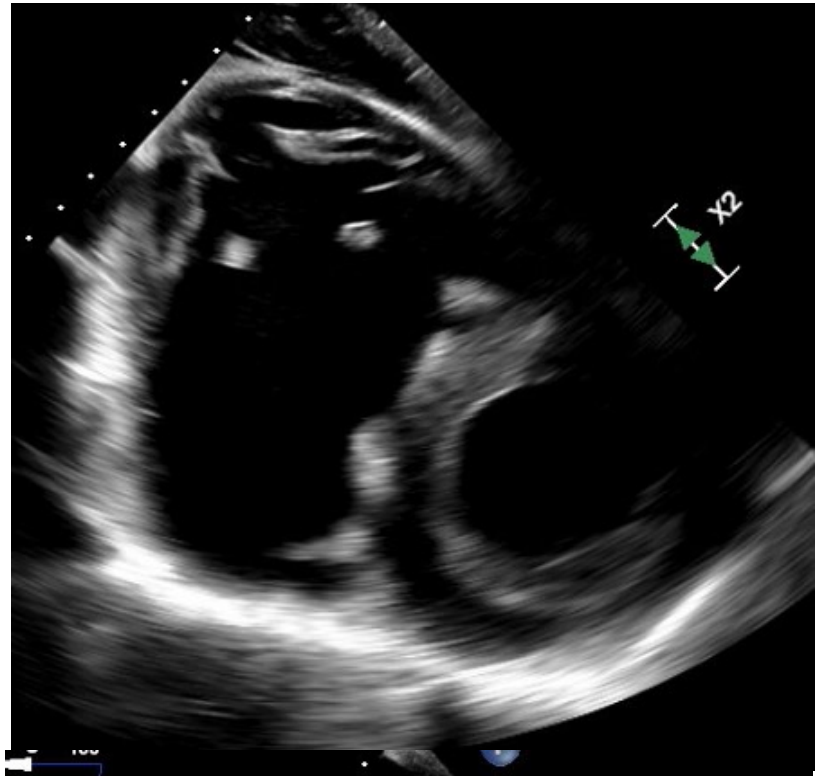
Favorable annulus
Favorable leaflets
Favorable chords
No pacing leads

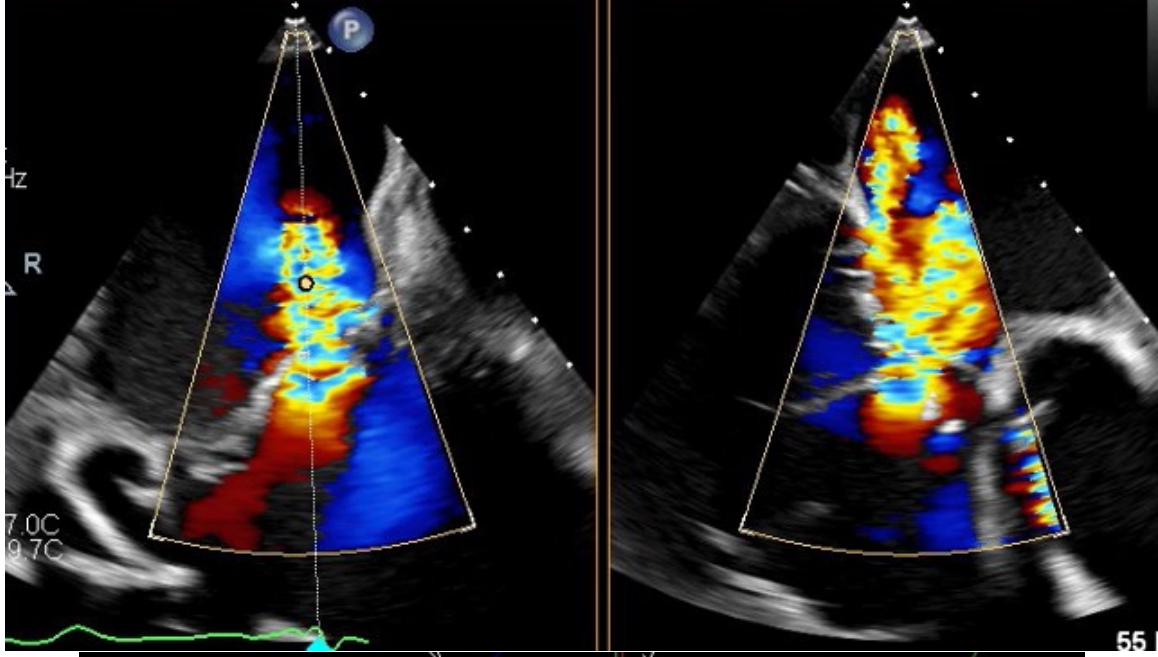
JACC VOL. 85, NO. 3, 2025
JANUARY 28, 2025:265–291

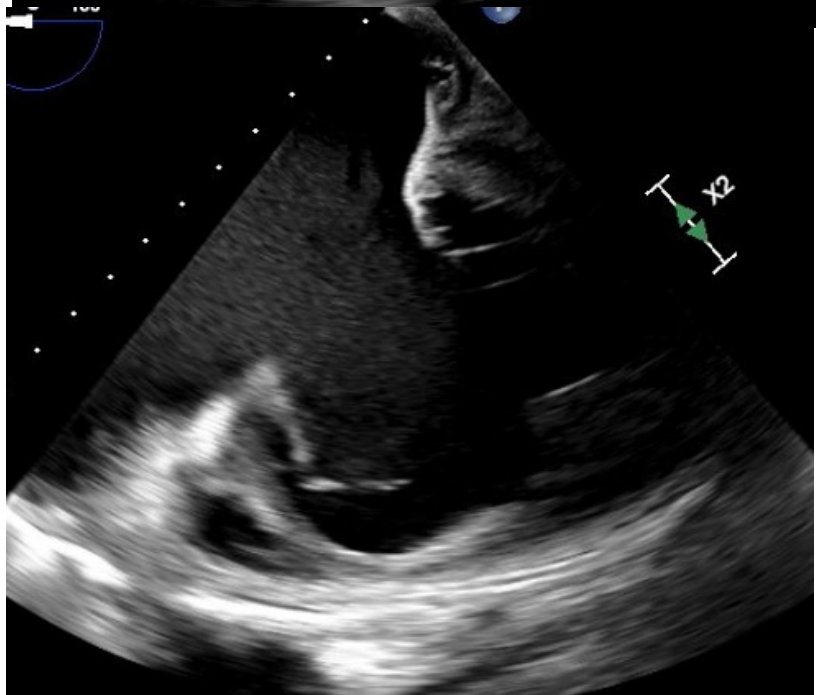
72 yo M referred to SH clinic for progressive fatigue/DOE NYHAII and severe TR on GDMT

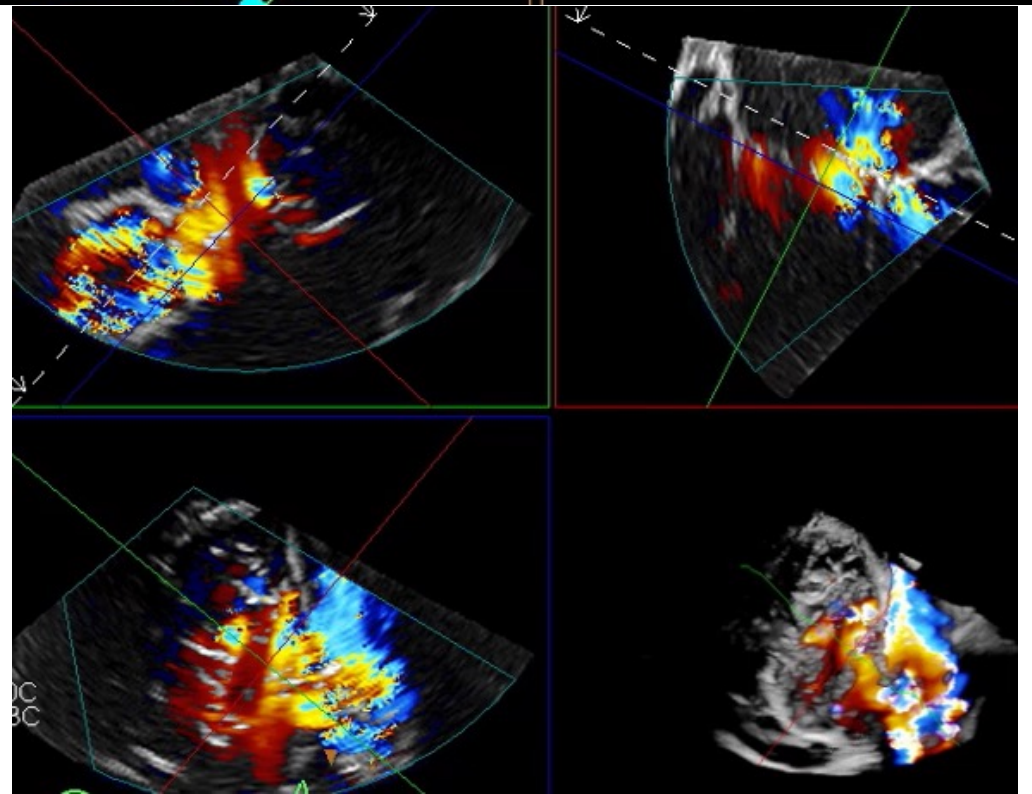
- **PMH: bio MVR and LAA exclusion in 2013 for degenerative MR, Mitral VIV (29 SAPIEN-in-33mm Edwards bovine), OSA, PAF, HTN.**
- **TTE showed: Severe RV enlargement with moderately reduced RV function, severe bi-atrial enlargement and severe TR. Normally functioning mitral VIV.**




X2


P
R

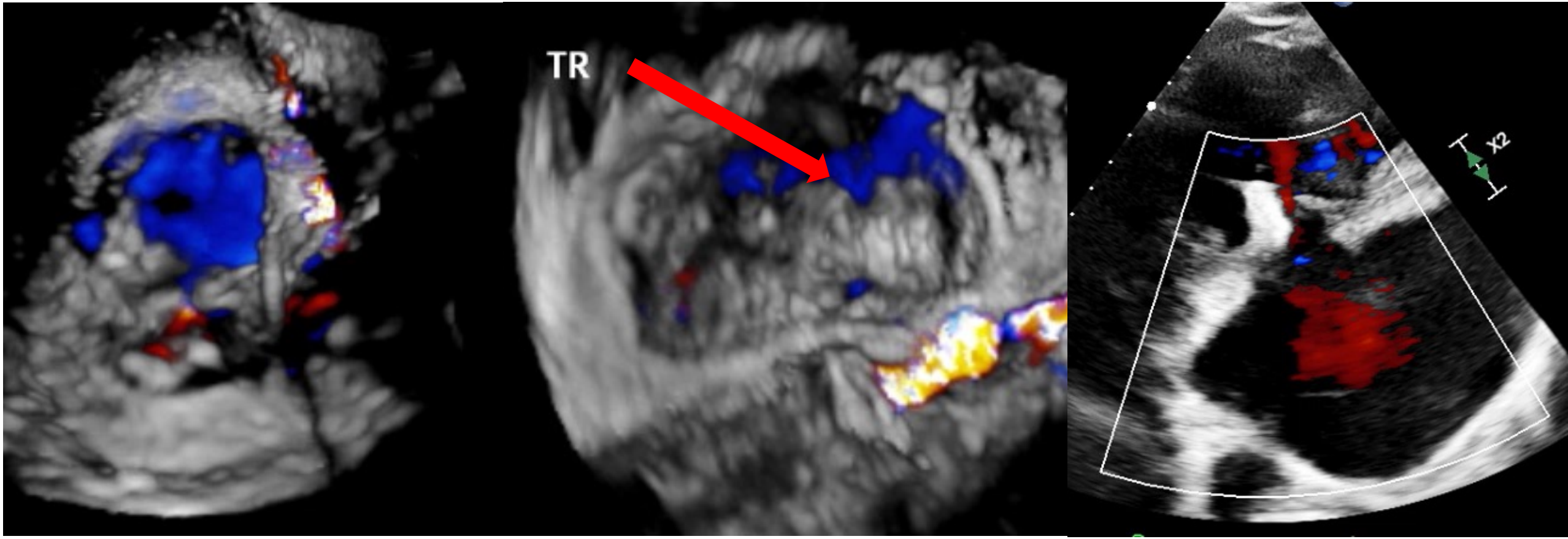

X2



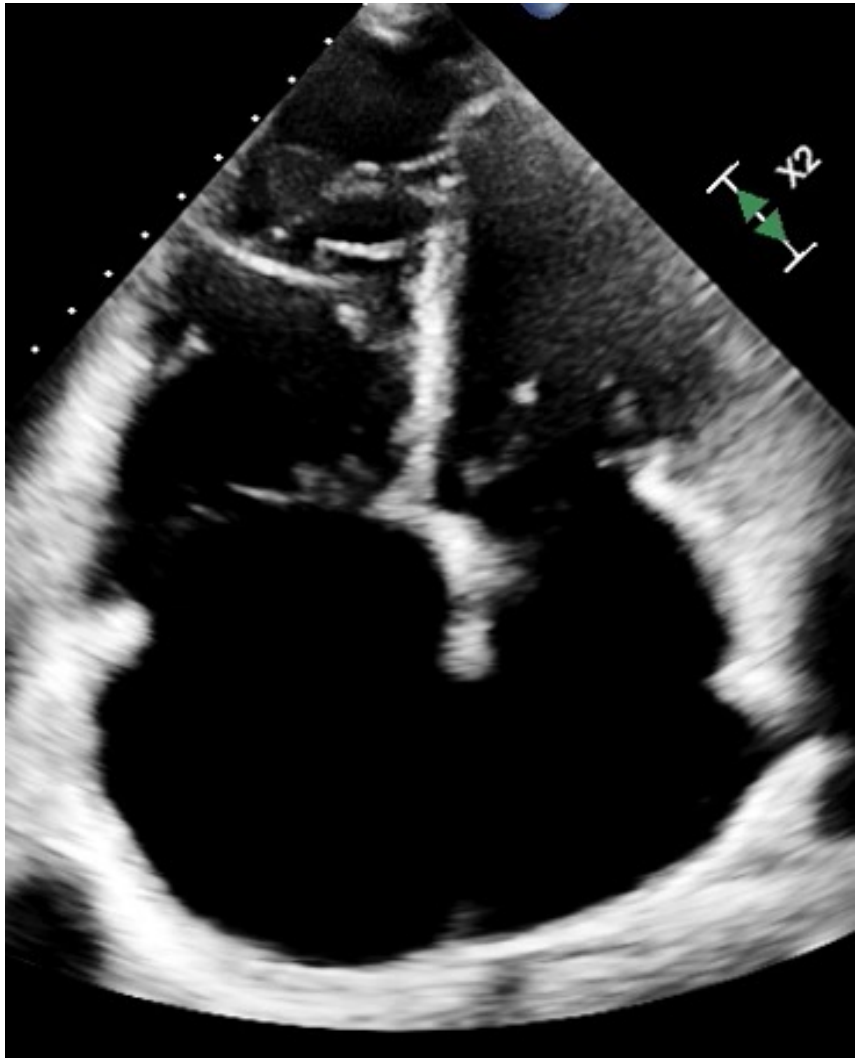
Pre

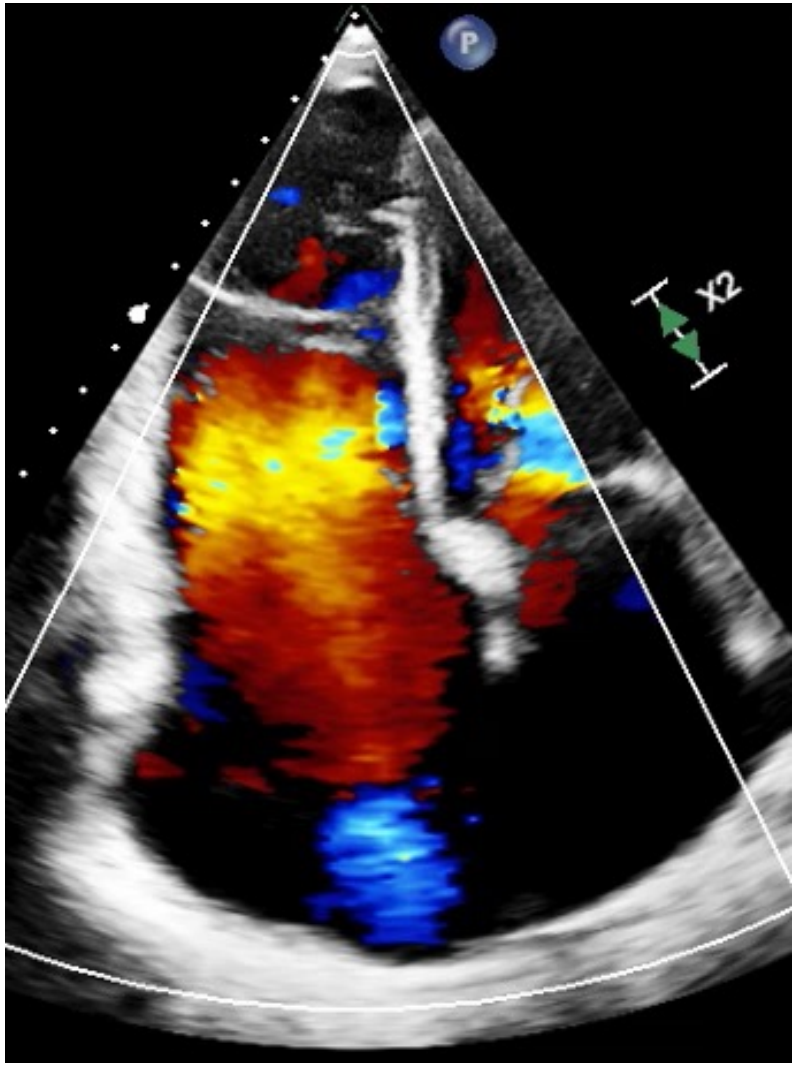
Post TriClip XTW

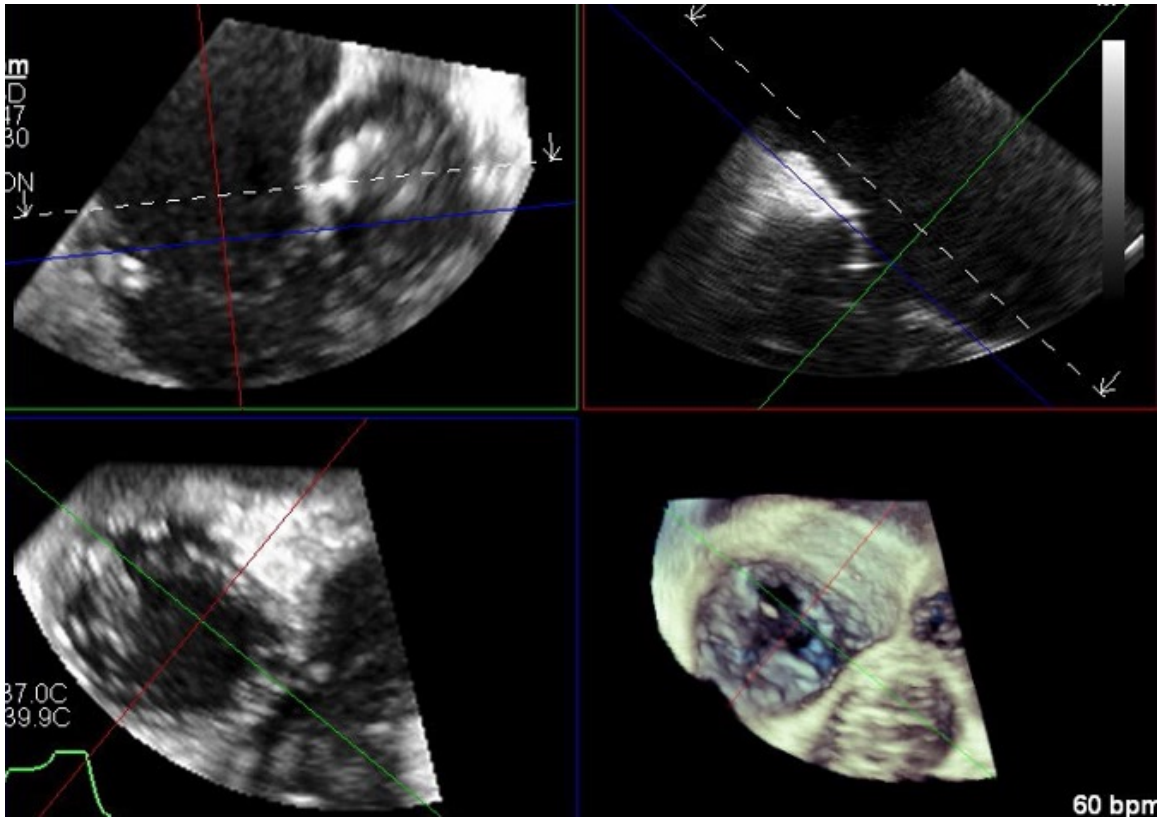
Discharge TTE

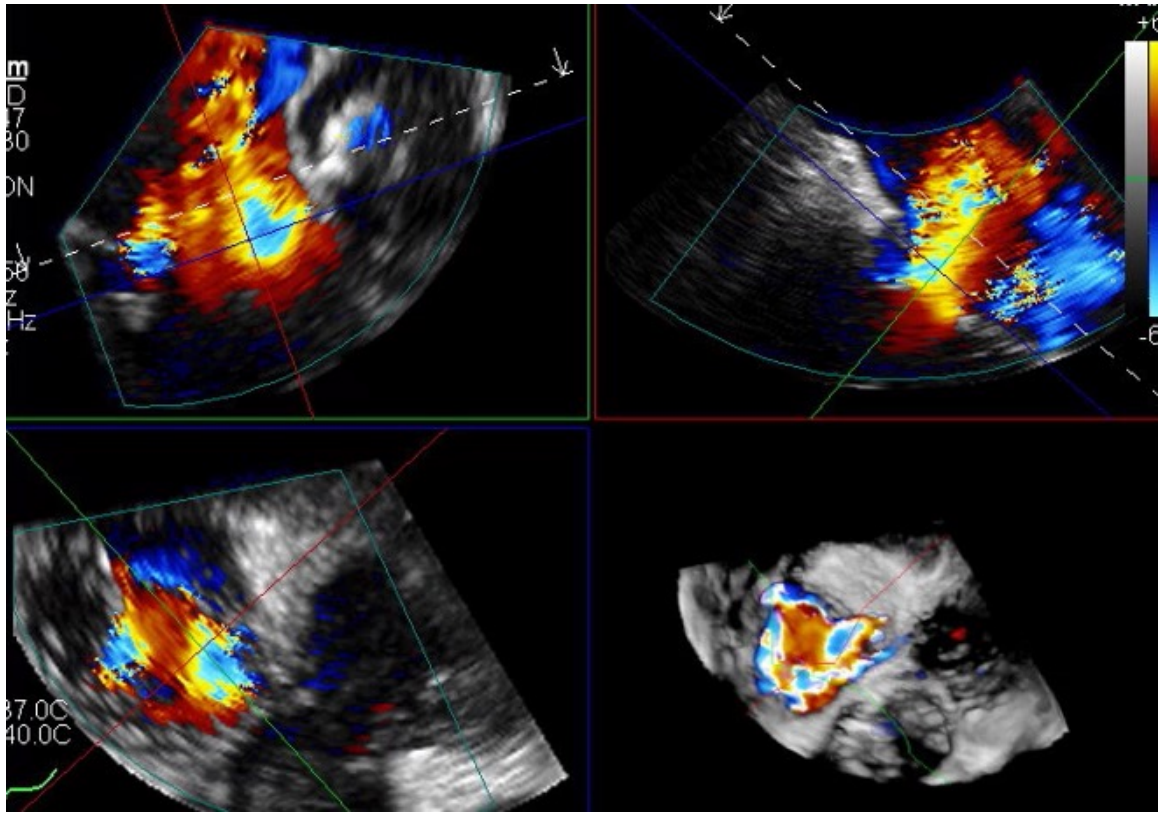


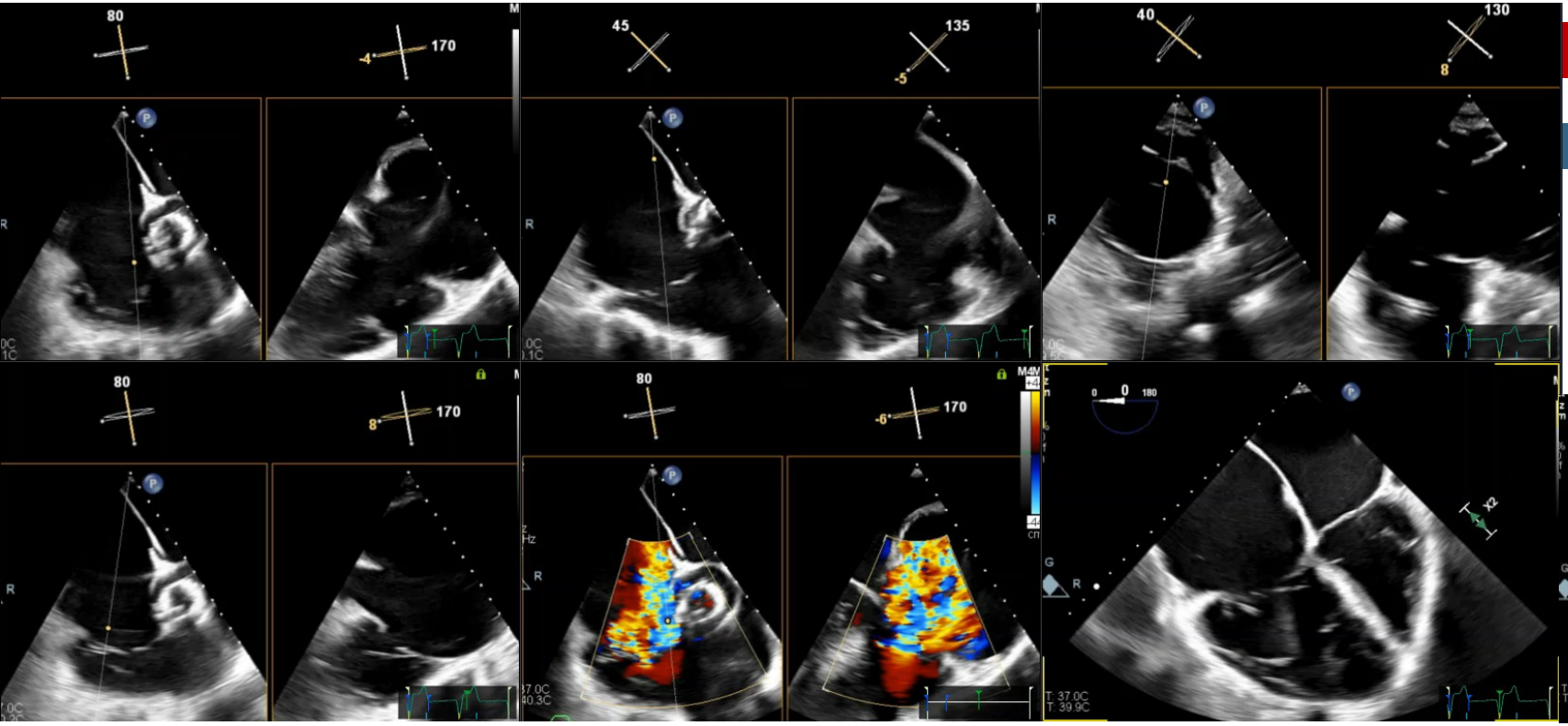
89 yo F referred to structural heart clinic for worsening TR
PMH: thoracic aortic aneurysm s/p bio Bentall in 2003 s/p TAV-SAV (CORE valve) in 2015, HTN, A-fib, SSS s/p PPM explanted for infection and replaced with a Micra (2022)

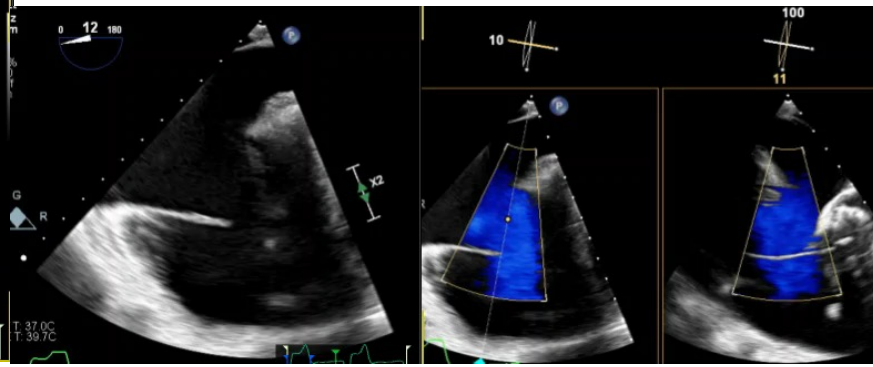





37.0C
39.9C
60 bpm


37.0C
40.0C



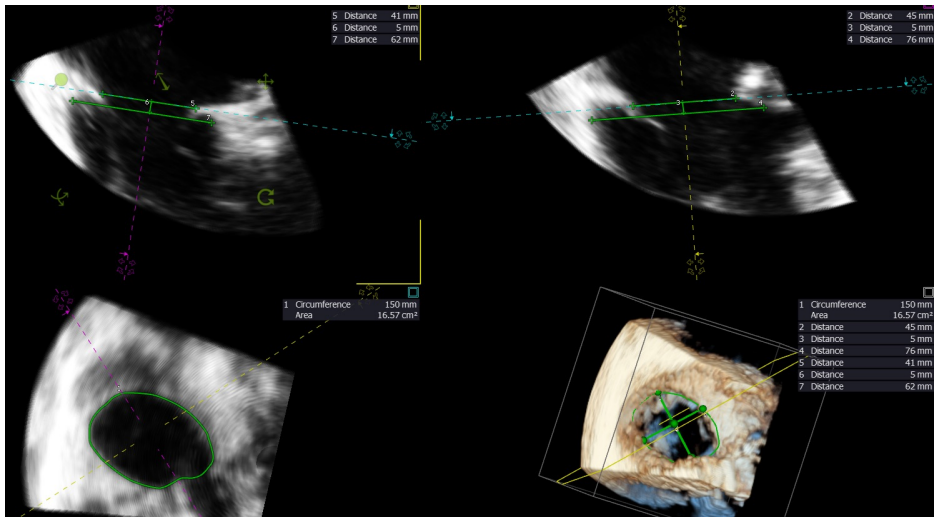


Echo Notes:

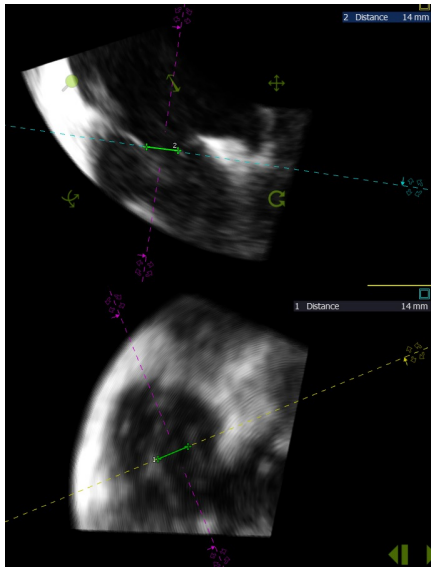
ME: All leaflets visualized by 2D/3D

DE: All leaflets visualized by 2D/3D

TG: All leaflets visualized by 2D/3D



TVA Circumference (mm)	150
TEE PDD Diastole (mm)	47.7
TEE Basal RV SL Dim (mm)	62
Largest SL Gap (mm)	14



Edwards Lifesciences — EVOQUE Tricuspid Valve Replacement

Patient ID:	31296994	Hospital:	North Shore Univ. Hosp	Report Date:	2024/11/02	Created By:	CK / DC

CT Screening Results: **Anatomically Suitable**

Optimal Valve Size:	**52mm**
Additional sizing considerations:	Significant tethering
Fluoro Angle:	**RAO: 29°**
RA Height - Systole:	**94.2 mm**
TEE PDD Diastole:	47.8 mm

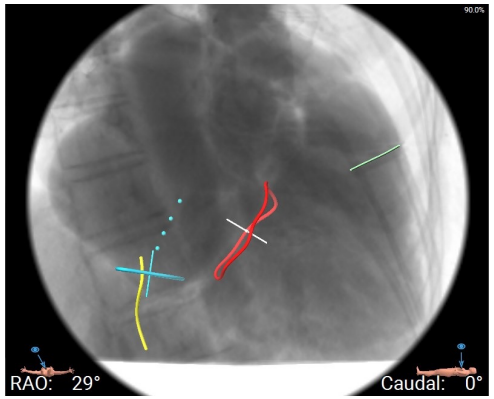
Comments:

Patient Initials: (J, J): Female

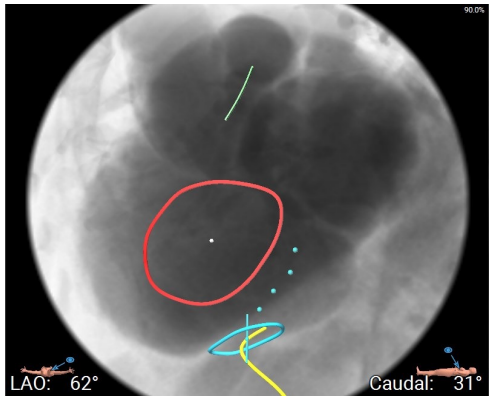
1. Isolated S-Post leaflet/chordal/pap continuity that may make leaflet capture challenging around SP comm.
2. Narrow IVC ostium with tortuosity in proximal IVC. Note proximity of ICV ostia to TVA.
3. Micra Present

CT Study Date:	2024/09/11	Pt Wt (kg):	47.6
TEE study date:	2024/08/12	Pt Wt (kg):	47.7

Implant:

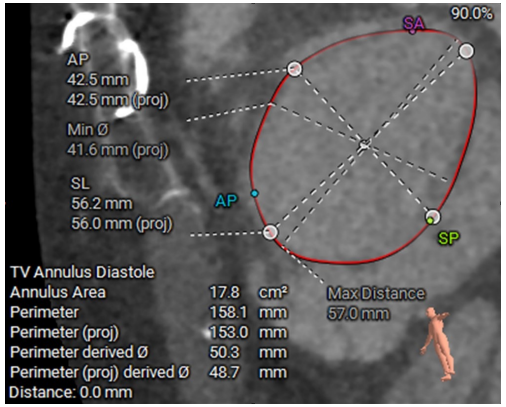


En Face:

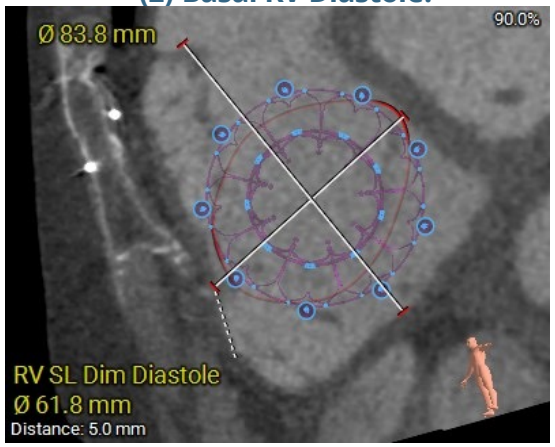


CT Anatomical Sizing	Diastole	Systole
(1) TV Annulus Oversizing	6.8	11.8%
(2) Basal RV Oversizing	-6.1%	10.9%

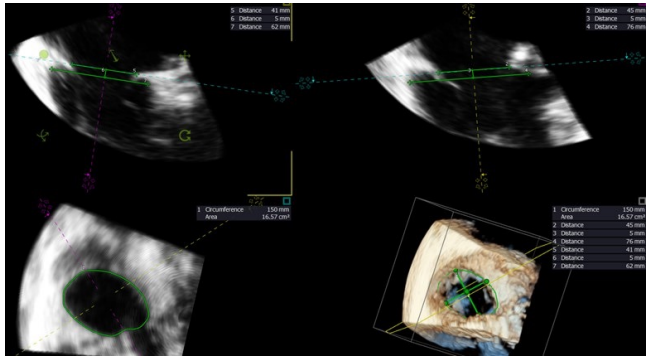
(1) TVA Diastole:

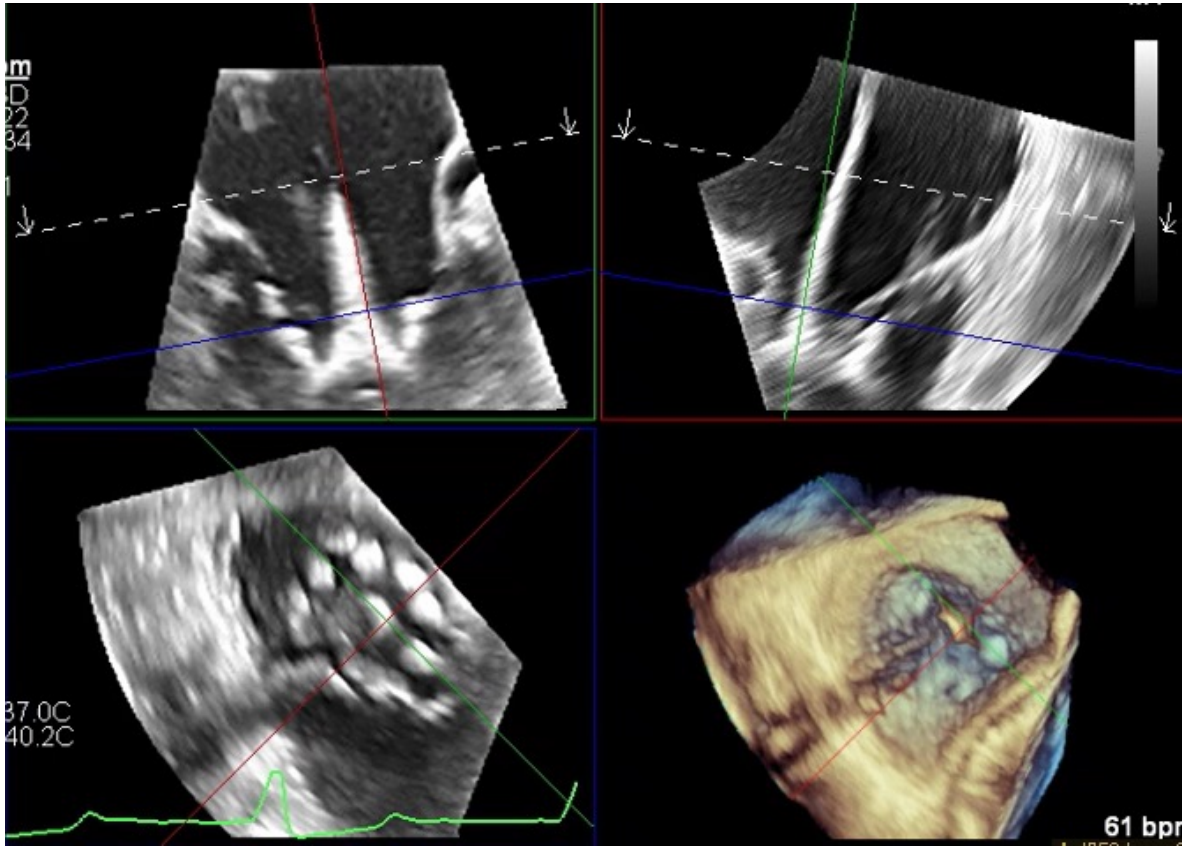


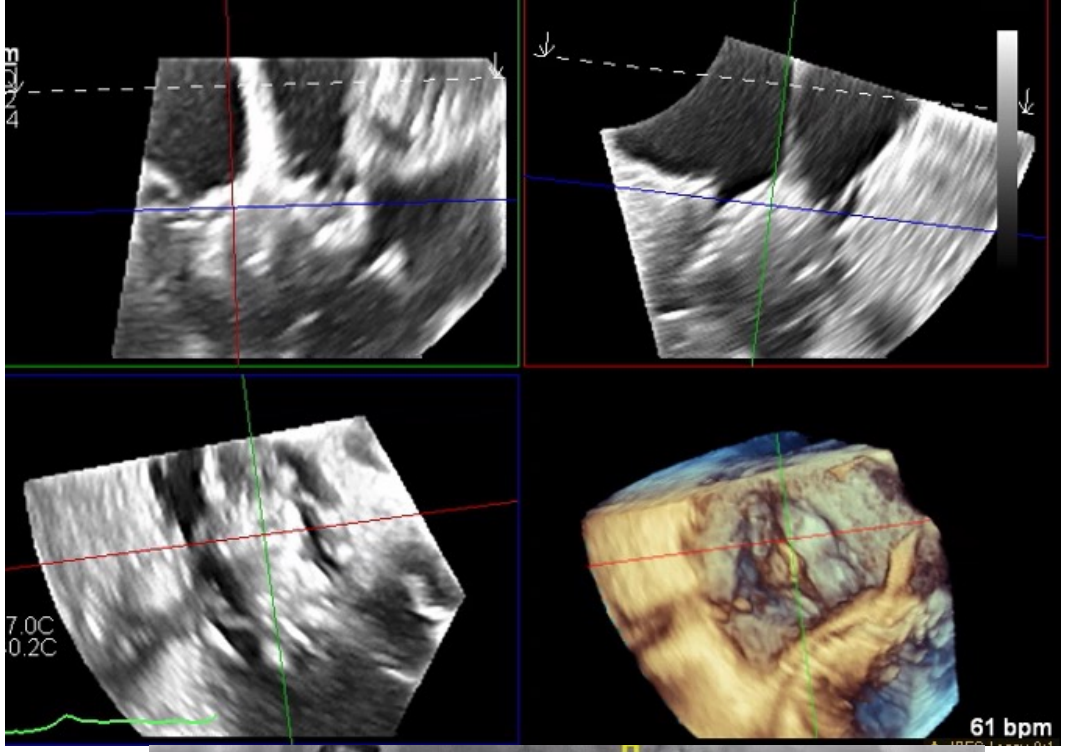
(2) Basal RV Diastole:

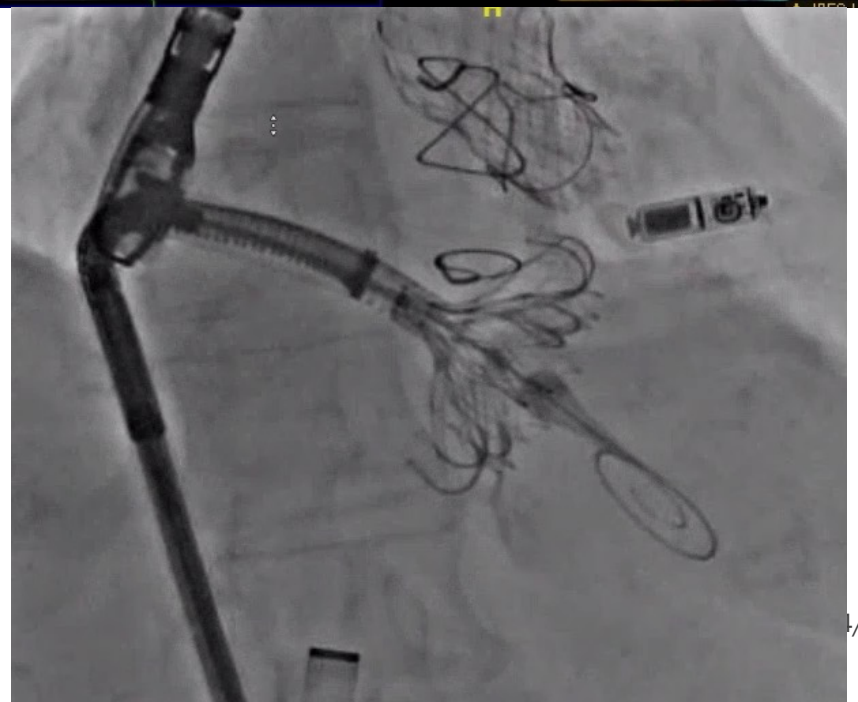


TEE PDD Diastole Measurements:

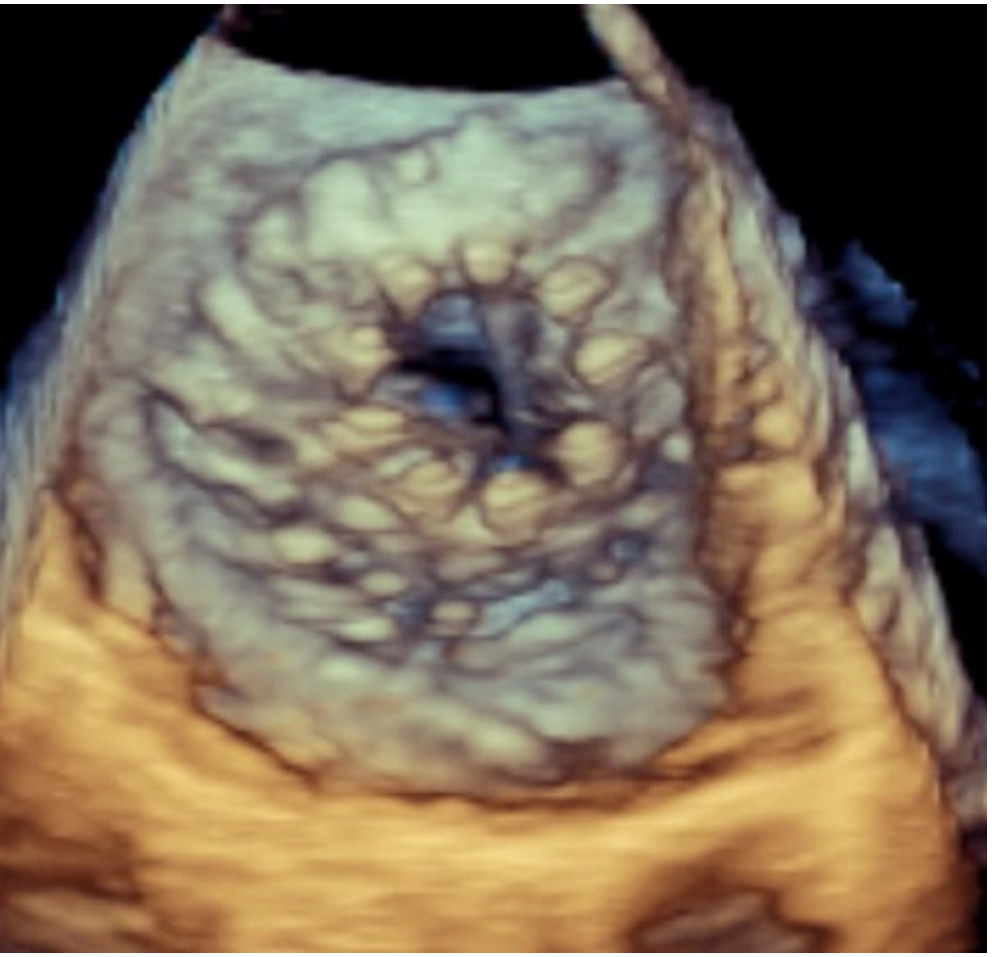


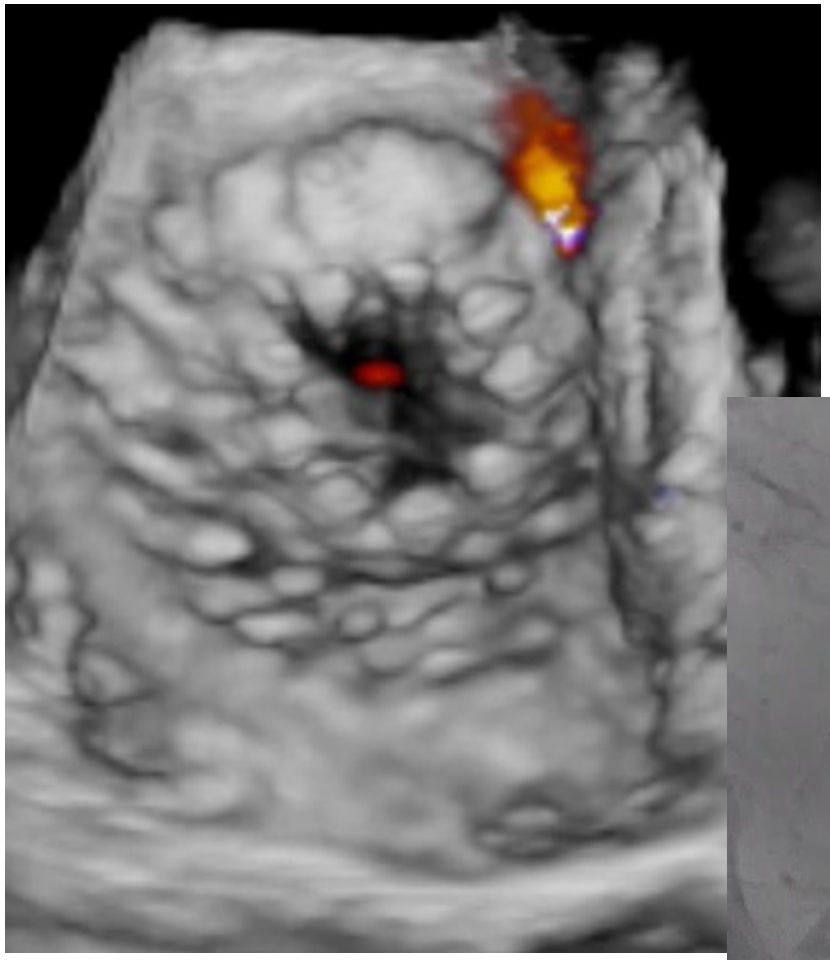

37.0C
40.2C
61 bpm

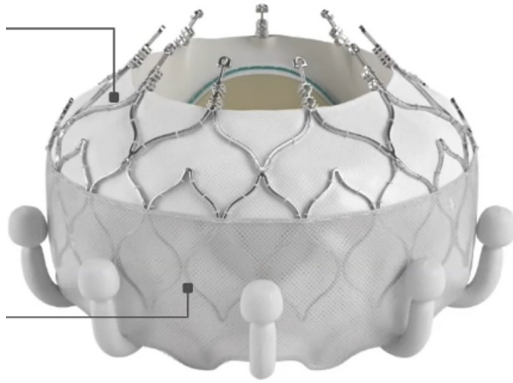

61 bpm

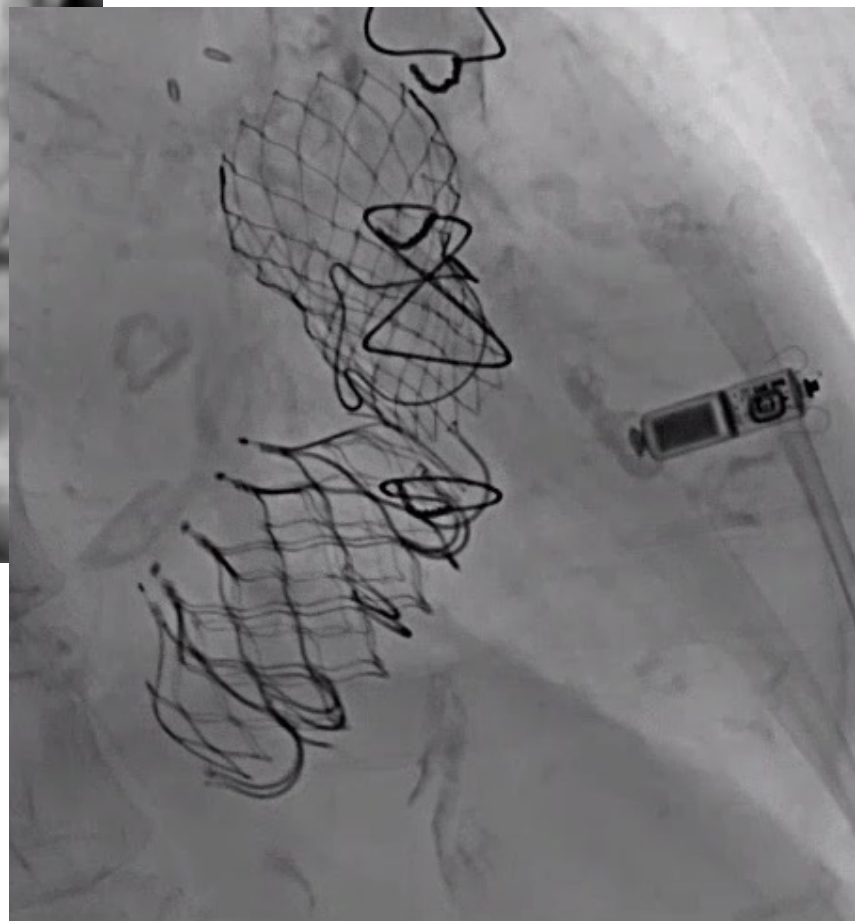


52MM EVOQUE TTVR









NEXT FRONTIER IN TRICUSPID INTERVENTION

- More accurate and reliable assessments of RV function (3D RVEF, MRI)
- Improved TR quantitation
- Earlier diagnosis and intervention (medical therapy and device)
- Trials redesign for outcomes detection.
- Device selection (T-TEER vs. TTVR)- which device for which patient?
- Who not to treat? How much RV dysfunction is too much?
- New an improved TTVR devices
  - Expanded sizing
  - Less conduction disturbances
  - Bleeding/anticoagulation

WHERE VALVE THERAPY FITS IN HEART FAILURE CARE

- Early identification and intervention to prevent cardiac damage and poor patient outcomes
- New mitral/tricuspid transcatheter therapies have expanded the treatment landscape
  - -M-TEER first line for many patients
  - -TMVR and TTVR now address populations previously untreatable.
  - -Evolution in patient selection, device selection and timing of treatment
- Optimal outcomes require early evaluation, organized care and multi-disciplinary heart team approach.

THANK YOU

Northwell[SM]
Cardiovascular Institute