



# Frontiers in Transcatheter Mitral and Tricuspid Valve Therapies

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# DISCLOSURES

- MNY is a Site Investigator of the CLASPII-TR, ENCIRCLE, HI-PEITHO, PROGRESS clinical trial studies.
- In the past 48 months, MNY has served on an advisory board for Boston Scientific and Medtronic, and speaker for Edwards Lifesciences.

# AGENDA

## I. Primary and Secondary Mitral Valve Regurgitation

- Where we are: Transcatheter Edge-to-Edge Repair (TEER)

## II. Mitral Regurgitation +/- Calcific Mitral Stenosis

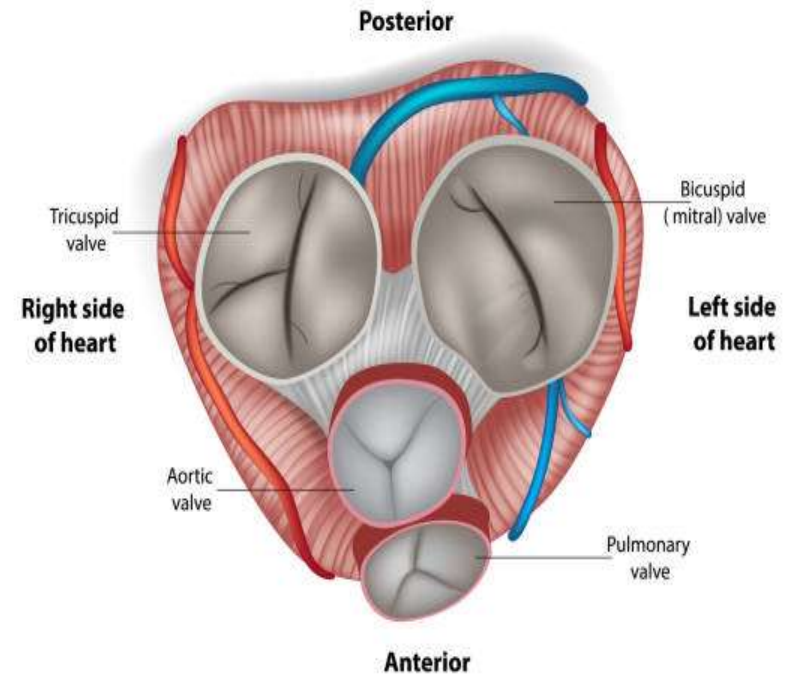
- Where we are going: Transcatheter Mitral Valve Replacement (TMVR)

## III. Tricuspid Valve Regurgitation

- How we get there: Innovation

## IV. Multidisciplinary Heart Team

- Who we are: DHMC



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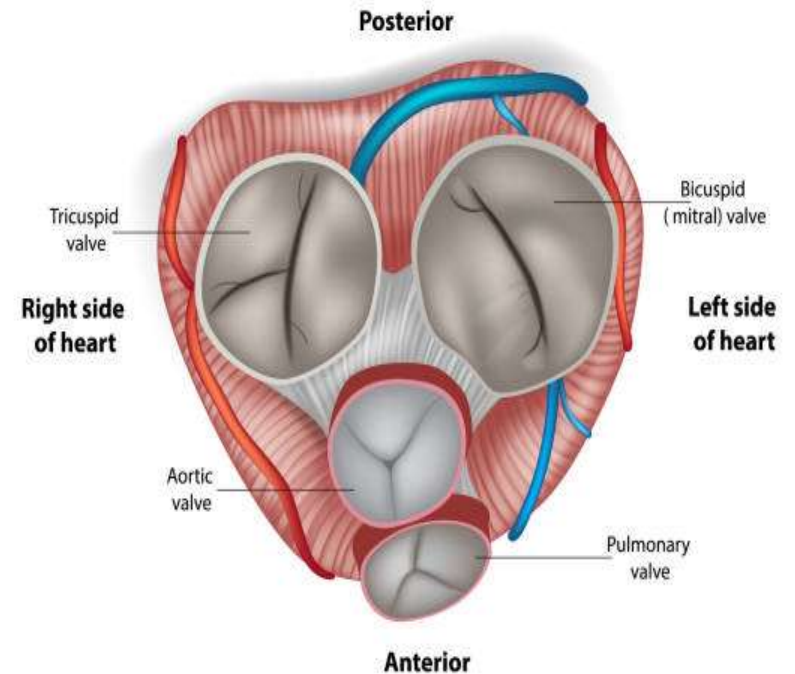
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# The Mitral Valve is Complex

- **MR may be caused by problems with:**

**Mitral valve leaflets**

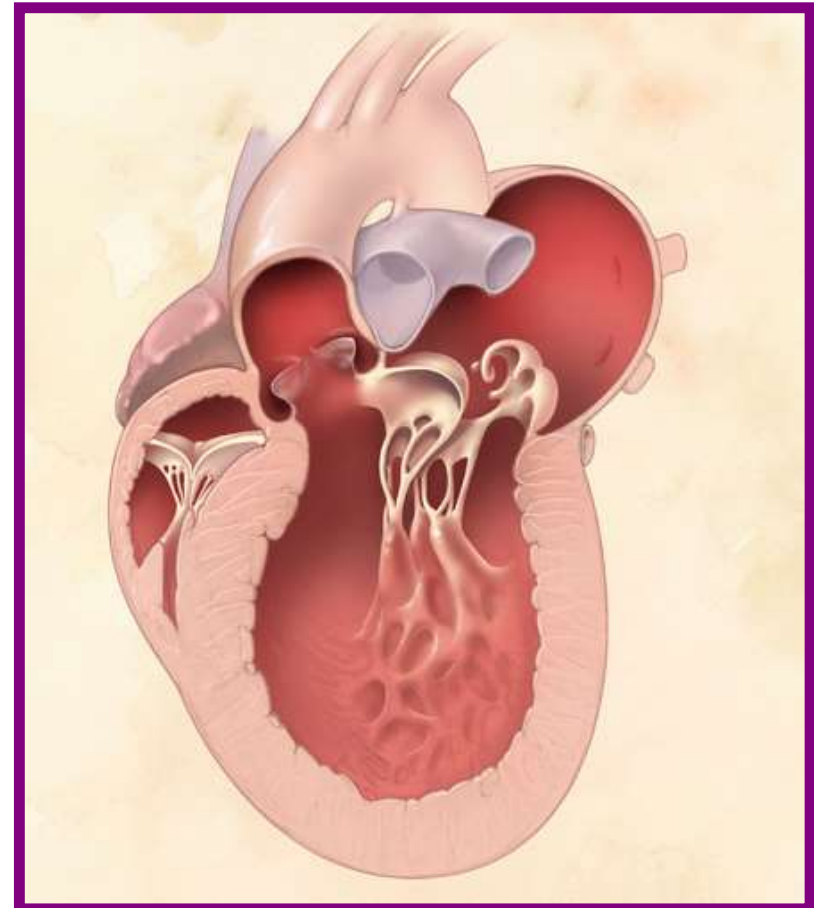
**Chordae tendinae**

**Papillary muscles**

**Annulus**

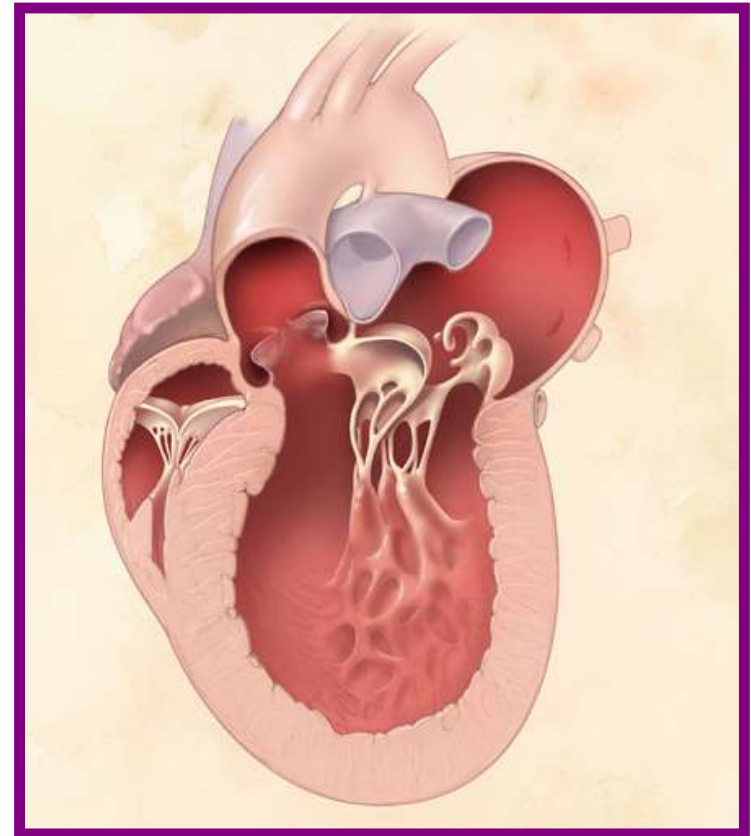
**Left Ventricle**

**Left Atrium**



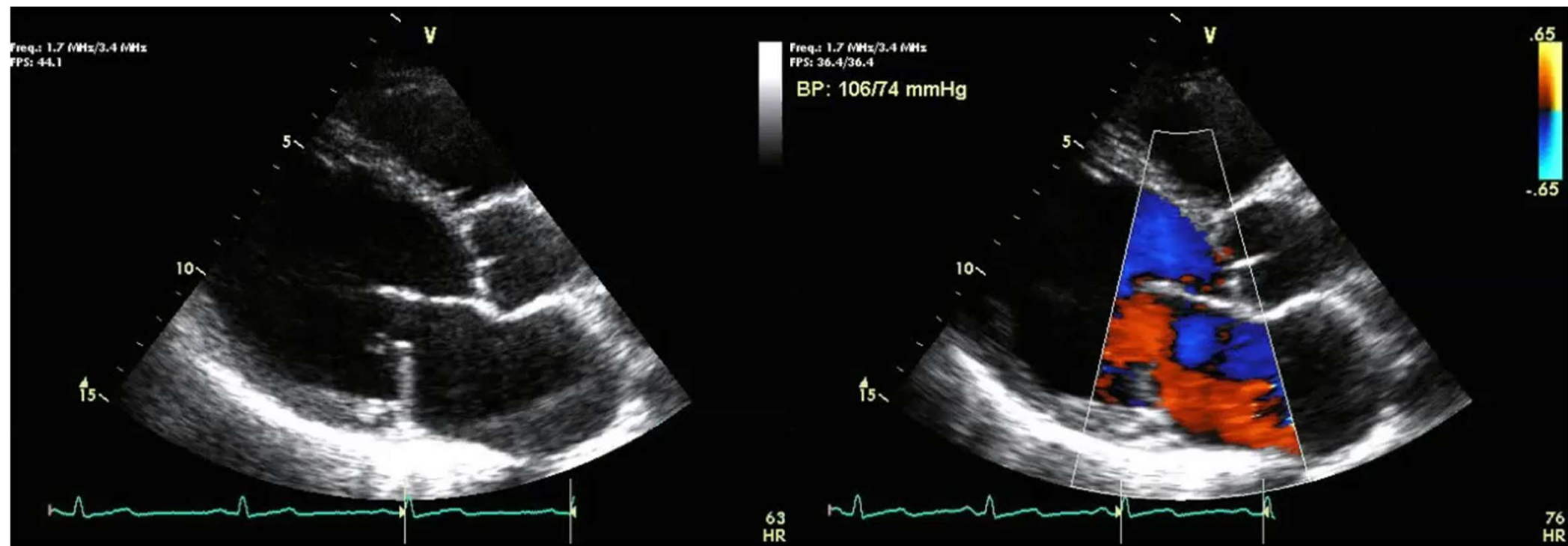
# Mitral Valve Regurgitation

- Mitral regurgitation categorized as “primary” or “secondary” MR
- Problem with the door (leaflets) vs. the frame (ventricle)



# Categories of MR

- \* Primary MR: Valve leaflets are the problem
  - \* Usually caused by prolapse or flail
  - \* Myxomatous degeneration or fibroelastic deficiency

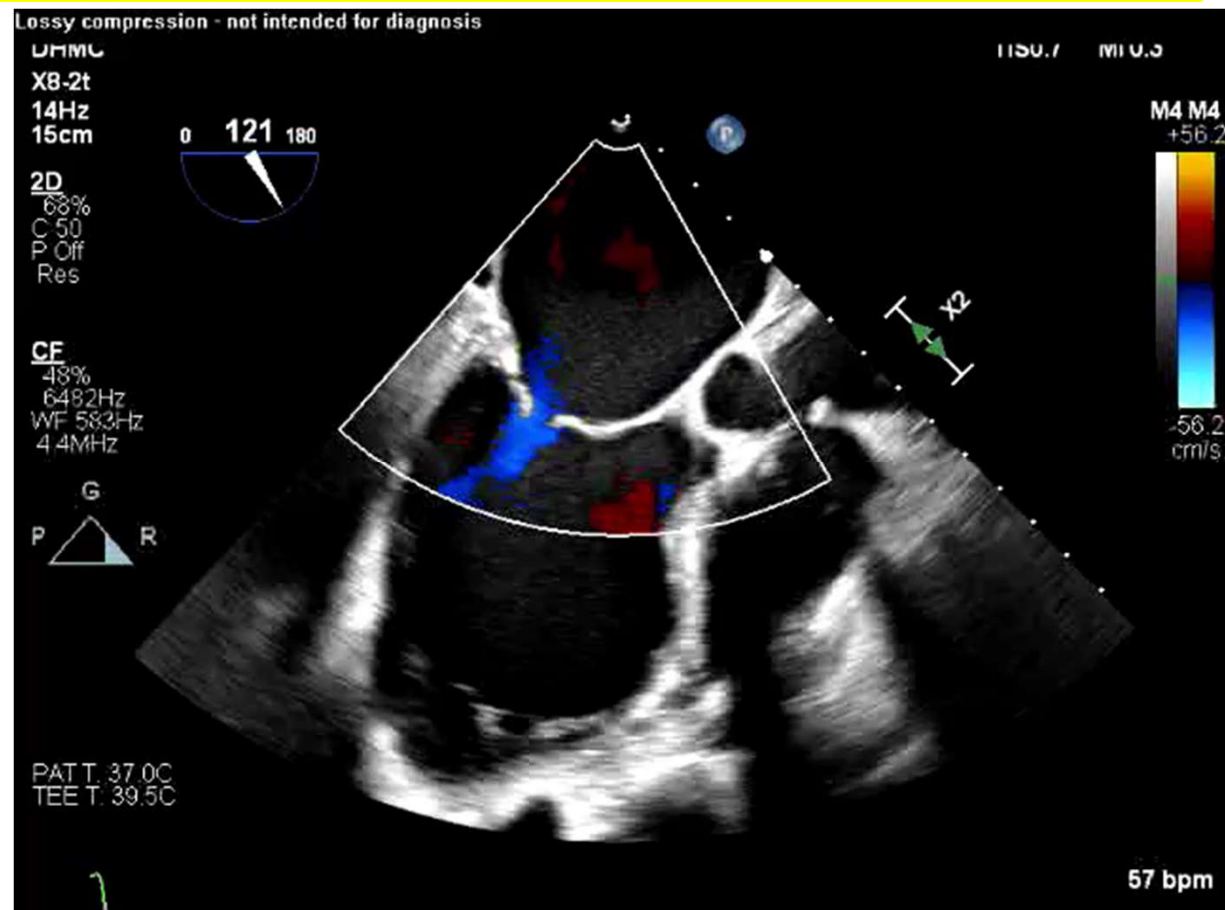


# Categories of MR

**\*Secondary (functional) MR: Ventricle is the problem**

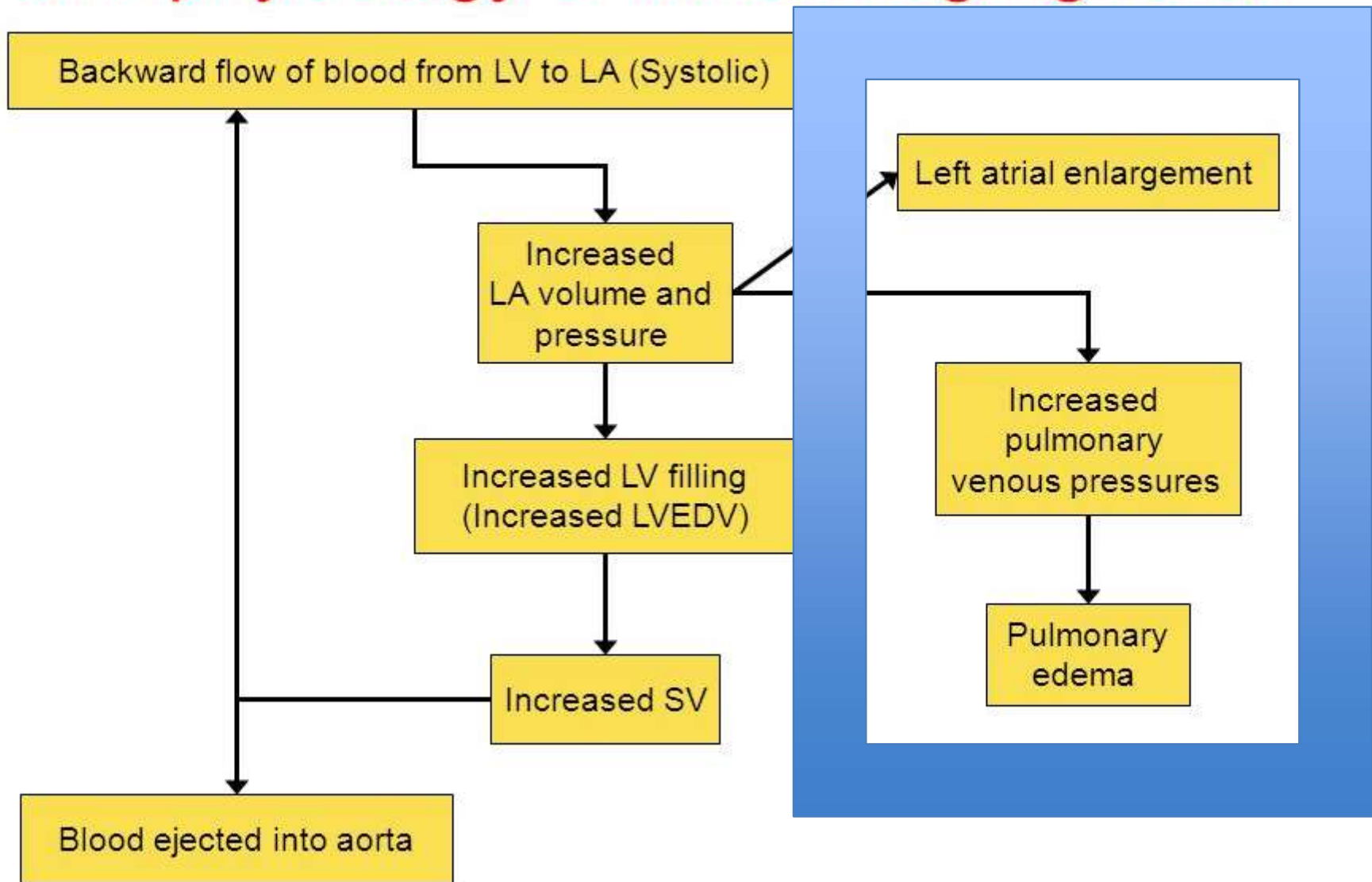
**\*Underlying cardiomyopathy**

**\*Annular dilatation; chordal tethering**





# Pathophysiology of Mitral Regurgitation



# Volume Overload (in chronic MR)

**LV Volume Overload**



**LV Dilates (Eccentric LVH)**

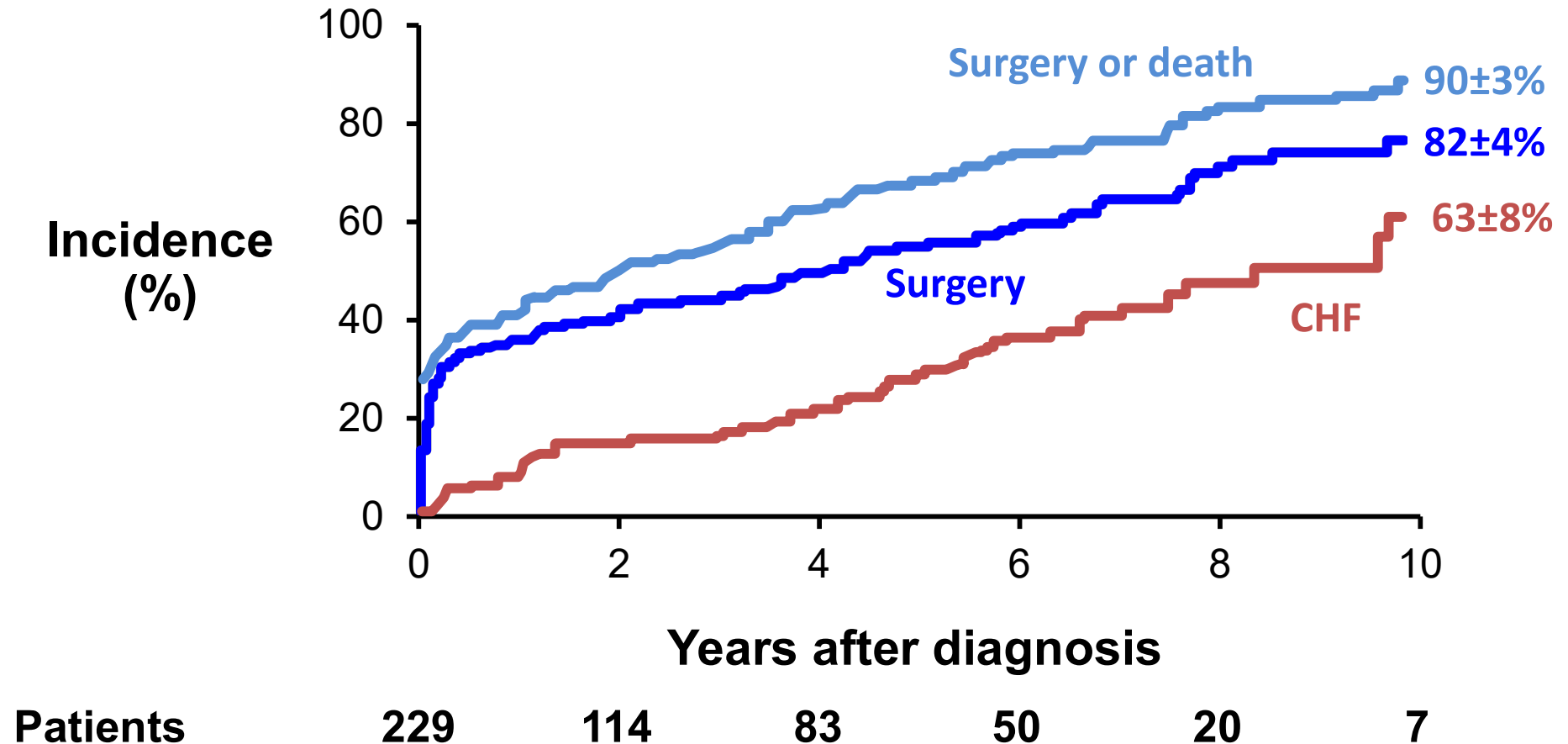


**Progressive remodeling leads to increased wall stress, systolic dysfunction, and heart failure**

**Both primary and secondary MR increase risk of adverse outcomes and mortality**

# Severe MR Due to Flail

## Natural History



# Treatment for Severe Primary MR

- \*Surgical repair can be curative**
- \*Surgical repair can often be very low risk**

# Treatment for Severe Primary MR

## Class 1 Indications:

- Surgical repair indicated when:
  - Symptoms are present
  - or
  - LV is dilated (LVESD  $\geq$  40 mm) or LV EF  $<$  60%

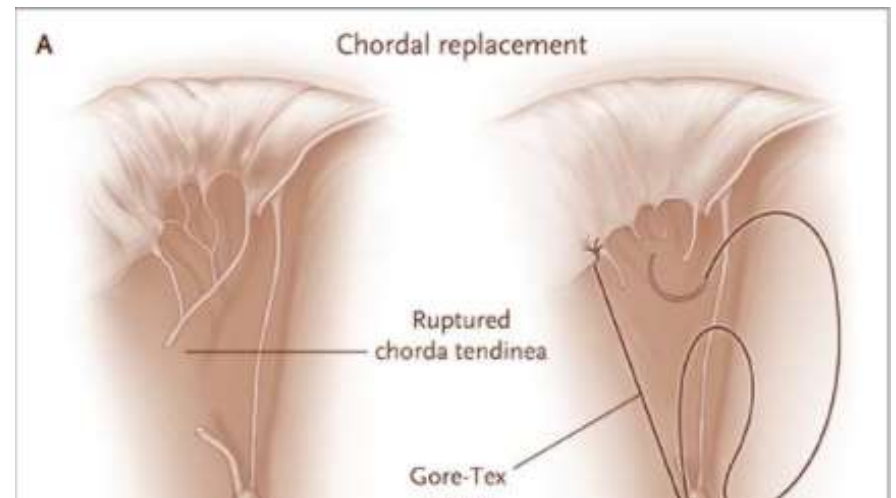
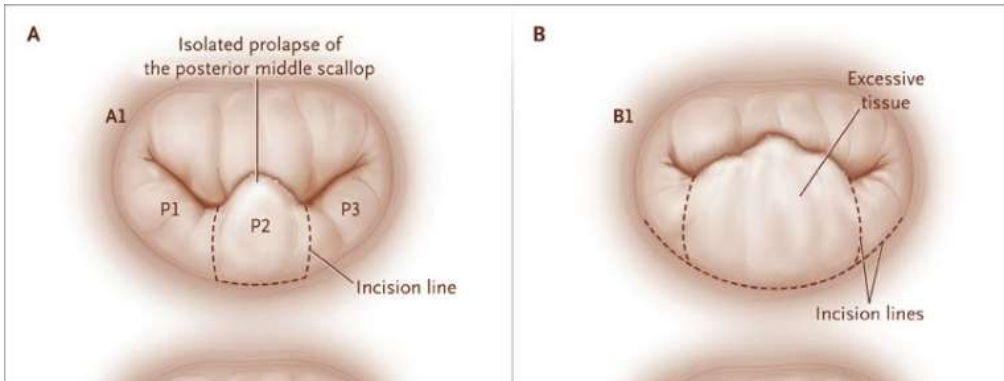
**And is reasonable even before any of the above (2a)**

**ACC/AHA CLINICAL PRACTICE GUIDELINE**

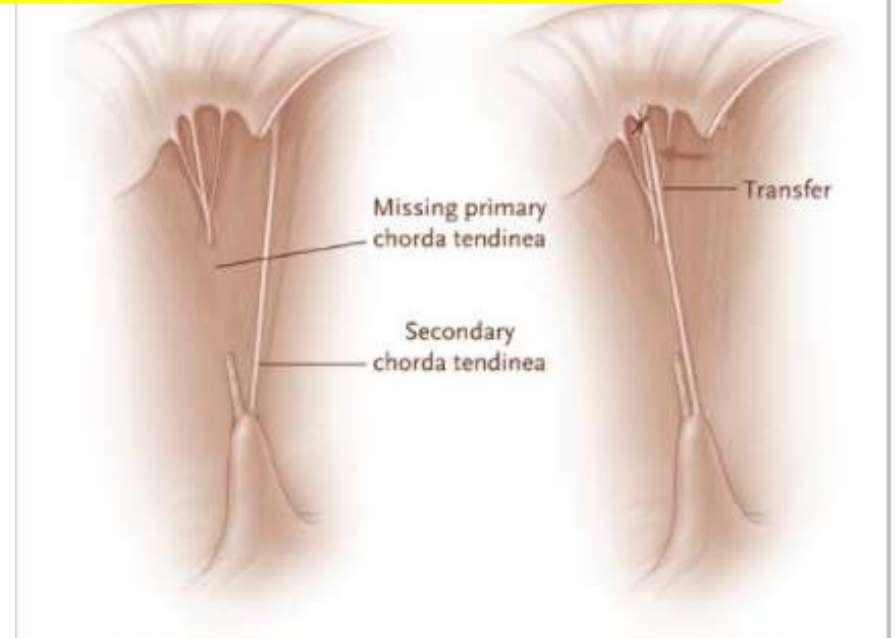
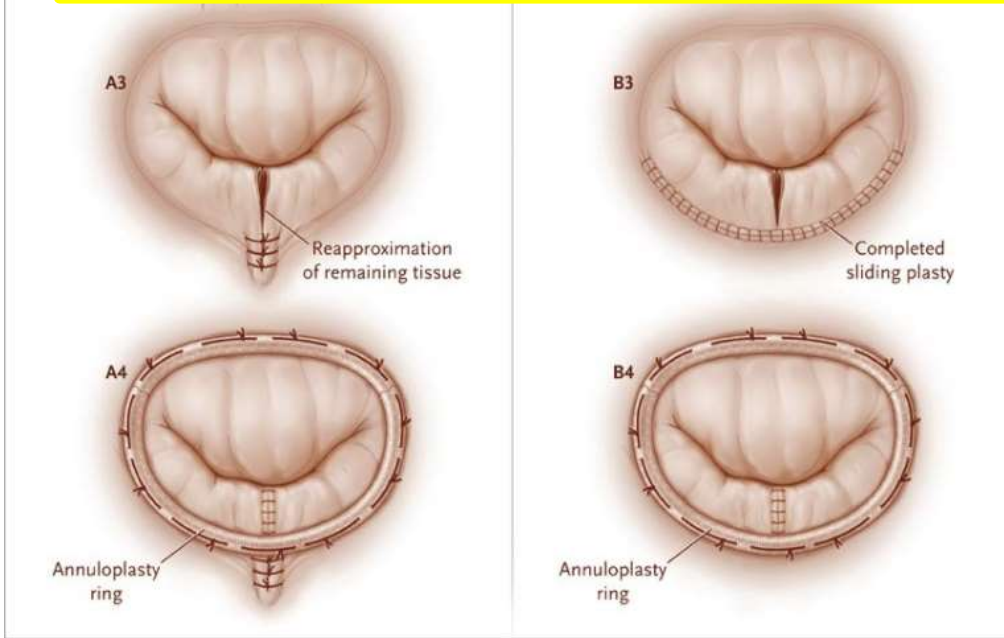
**2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease**

A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

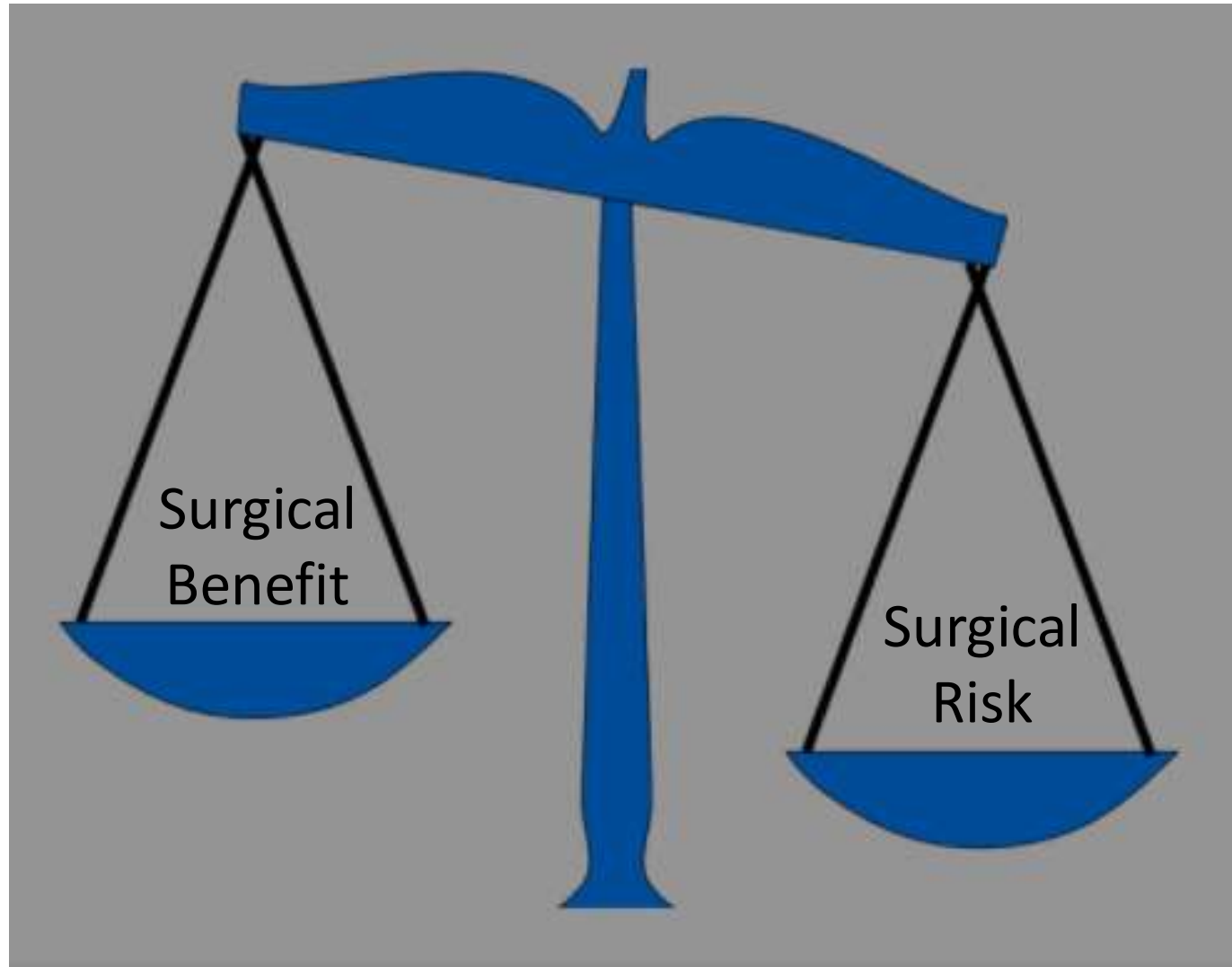
# Surgical MV Repair



These techniques are difficult to replicate with a catheter



# But in Higher-Risk Patients...



# EVEREST II (Landmark Clinical Trial)

- 279 older patients with symptomatic 3-4+ MR
- Randomized 2:1 to TEER vs. conventional mitral valve surgery (repair or replacement)
- Primary composite endpoint = freedom from death, repeat surgery, 3-4+ MR at 12 months
- Primary safety endpoint = composite of MAE within 30 days

Percutaneous Repair or Surgery for Mitral Regurgitation

Ted Feldman, M.D., Elyse Foster, M.D., Donald D. Glower, M.D., Saibal Kar, M.D., Michael J. Rinaldi, M.D., Peter S. Fail, M.D., Richard W. Smalling, M.D., Ph.D., Robert Siegel, M.D., Geoffrey A. Rose, M.D., Eric Engeron, M.D., Catalin Loghin, M.D., Alfredo Trento, M.D., Eric R. Skipper, M.D., Tommy Fudge, M.D., George V. Letsou, M.D., Joseph M. Massaro, Ph.D., and Laura Mauri, M.D., for the EVEREST II Investigators\*



**Table 2. Primary Efficacy End Point at 12 Months and Major Adverse Events at 30 Days in the Intention-to-Treat Population.\***

Event	Percutaneous Repair no. (%)	Surgery	P Value
<b>Primary efficacy end point</b>			
Freedom from death, from surgery for mitral-valve dysfunction, and from grade 3+ or 4+ mitral regurgitation†	100 (55)	65 (73)	0.007
Death	11 (6)	5 (6)	1.00
Surgery for mitral-valve dysfunction‡	37 (20)	2 (2)	<0.001
Grade 3+ or 4+ mitral regurgitation	38 (21)	18 (20)	1.00
<b>Major adverse event at 30 days§</b>			
Any major adverse event	27 (15)	45 (48)	<0.001¶
Any major adverse event excluding transfusion	9 (5)	9 (10)	0.23
Death	2 (1)	2 (2)	0.89
Myocardial infarction	0	0	NA
Reoperation for failed surgical repair or replacement	0	1 (1)	0.74
Urgent or emergency cardiovascular surgery for adverse event	4 (2)	4 (4)	0.57
Major stroke	2 (1)	2 (2)	0.89
Renal failure	1 (<1)	0	1.00
Deep wound infection	0	0	NA
Mechanical ventilation for >48 hr	0	4 (4)	0.02
Gastrointestinal complication requiring surgery	2 (1)	0	0.78
New onset of permanent atrial fibrillation	2 (1)	0	0.78
Septicemia	0	0	NA
Transfusion of ≥2 units of blood	24 (13)	42 (45)	<0.001

➤ **TEER less effective than surgery at reducing MR**

➤ **TEER has superior safety profile**

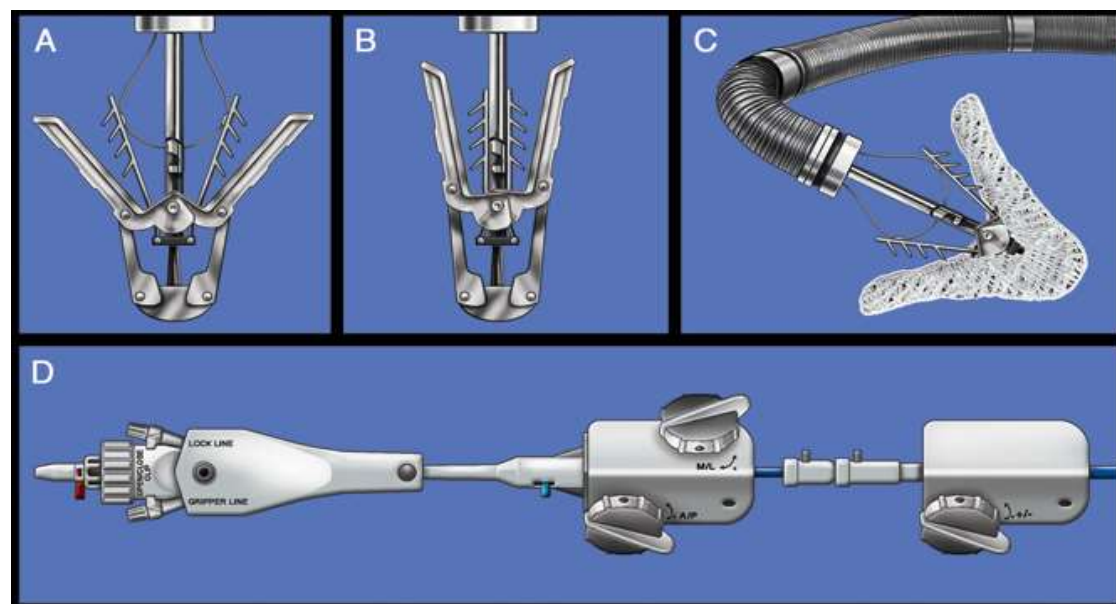
➤ **Comparable overall survival at 4 years**

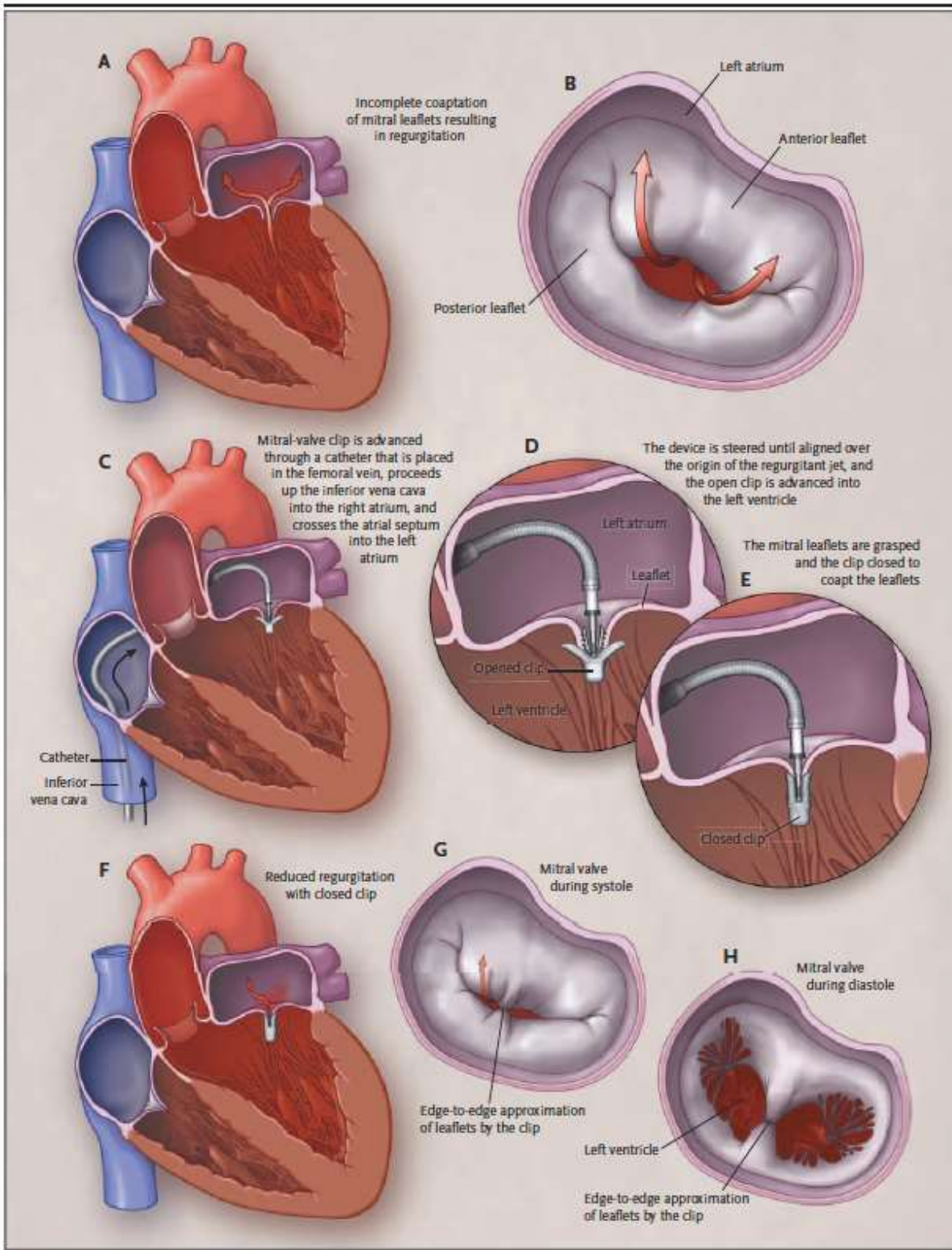
# MitraClip Clip Delivery System

*Approved October 24, 2013*

## Indication for Use:

The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant **symptomatic** mitral regurgitation (MR  $\geq 3+$ ) due to primary abnormality of the mitral apparatus [**degenerative MR**] in patients who have been determined to be at **prohibitive risk for mitral valve surgery by a heart team**, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the **expected benefit** from reduction of the mitral regurgitation.





## Regurgitation

Symptomatic

MDT assessment:

Classical  
R\*

Prohibitive risk

MDT assessment:  
Candidate for  
transcatheter therapy?

Yes

TMVr

No

GDMT†

MDT†  
Classical and  
E/F/U

\*Surgical repair is preferred over replacement for primary MR

†GDMT for heart failure

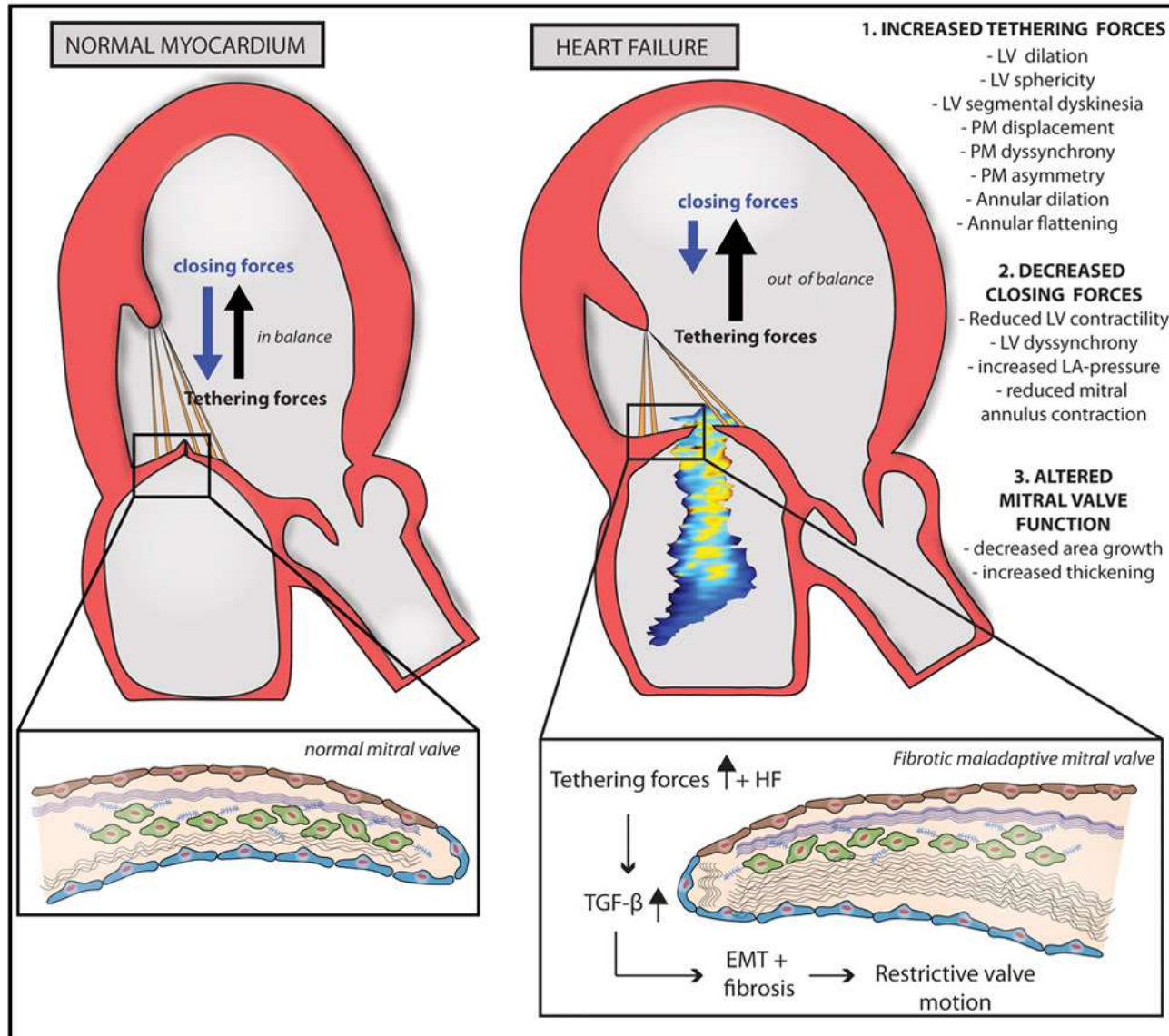
‡GDMT for other cardiac problems such as HTN, HLD, etc.

§SDM and preferential referral to experienced MV surgeon at Heart Valve Center

## Focused Update of the 2017 ACC/AHA Mitral Regurgitation Guideline: Part 2: Medical Management of Mitral Regurgitation

# Secondary “Functional” Mitral Regurgitation

## A Pathophysiologic basis of secondary MR



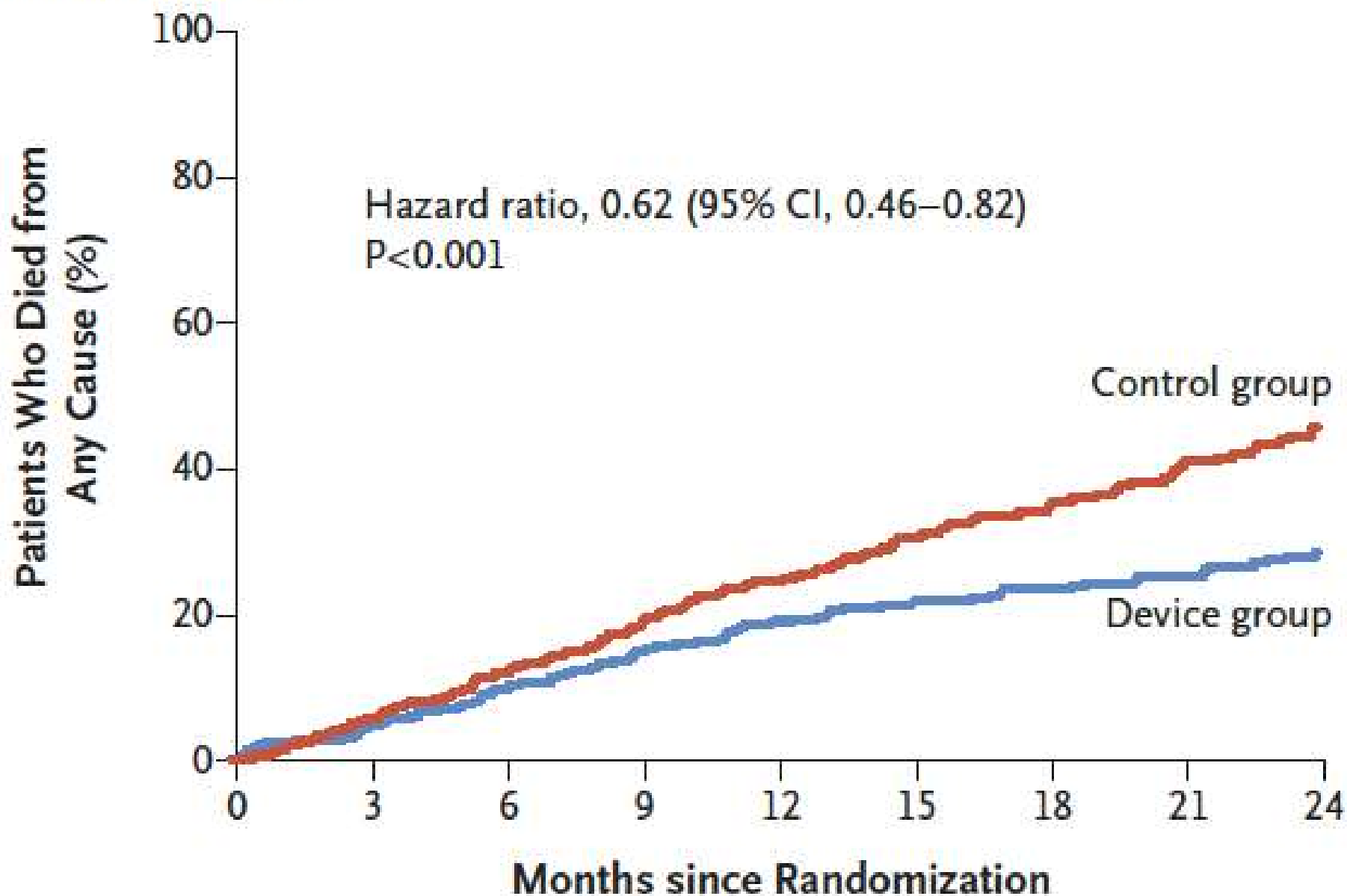
# COAPT (Landmark Clinical Trial)

- 614 patients with symptomatic moderate-to-severe secondary MR; LVEF 20-50%
- Randomized 1:1 to TEER + OMT vs. OMT alone
- Primary effectiveness endpoint = composite of all HF hospitalizations within 24 months
- Primary safety endpoint = freedom from device-related complications at 12 months

## Transcatheter Mitral-Valve Repair in Patients with Heart Failure

G.W. Stone, J.A. Lindenfeld, W.T. Abraham, S. Kar, D.S. Lim, J.M. Mishell, B. Whisenant, P.A. Grayburn, M. Rinaldi, S.R. Kapadia, V. Rajagopal, I.J. Sarembock, A. Brieke, S.O. Marx, D.J. Cohen, N.J. Weissman, and M.J. Mack, for the COAPT Investigators\*

### C Death from Any Cause



#### No. at Risk

Control group	312	294	271	245	219	176	145	121	88
Device group	302	286	269	253	236	191	178	161	124



## Abbott Receives FDA Approval for Expanded Indication for MitraClip™ Device

- The world's first minimally invasive mitral valve repair device now approved to help difficult-to-treat heart failure patients with clinically significant secondary mitral regurgitation
- Approval is based on groundbreaking pivotal data from the COAPT™ Trial
- New indication significantly expands number of people with mitral regurgitation that can be treated with the MitraClip device

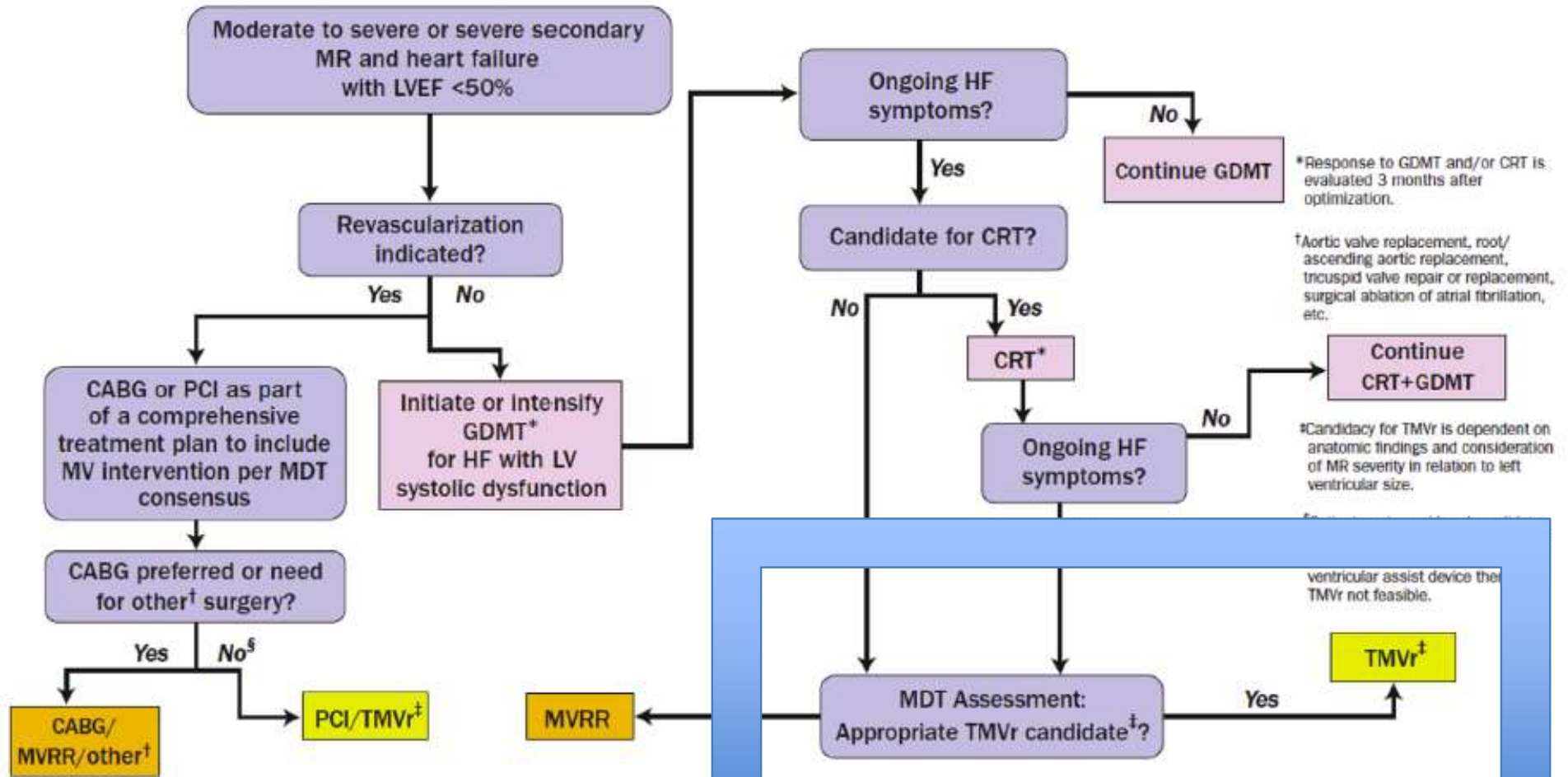
The world's first minimally invasive mitral valve repair device now approved to help difficult-to-treat heart failure patients with clinically significant secondary mitral regurgitation



**FIGURE 9B** Intervention for Symptomatic Secondary MR

**B**

**Intervention for Symptomatic Secondary MR**



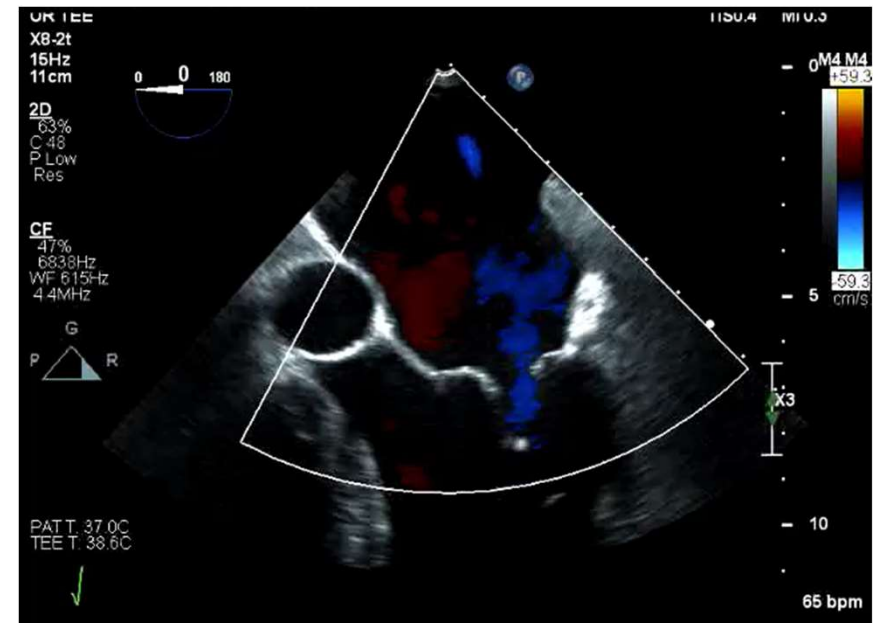
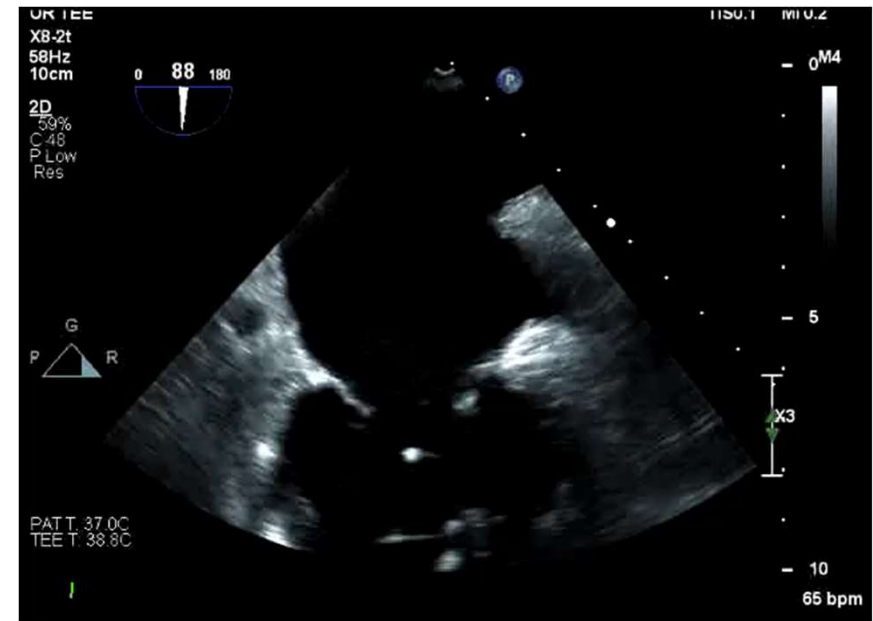
AAD = antiarrhythmic drug; AF, atrial fibrillation; CABG = coronary artery bypass graft; CRT = cardiac resynchronization therapy; GDMT = guideline-directed medical therapy; HF = heart failure; LVEF = left ventricular ejection fraction; MVRR = mitral valve repair or replacement; PCI = percutaneous coronary intervention; TMVr = transcatheter mitral valve repair.



# Case: 75 year old male with dyspnea on exertion

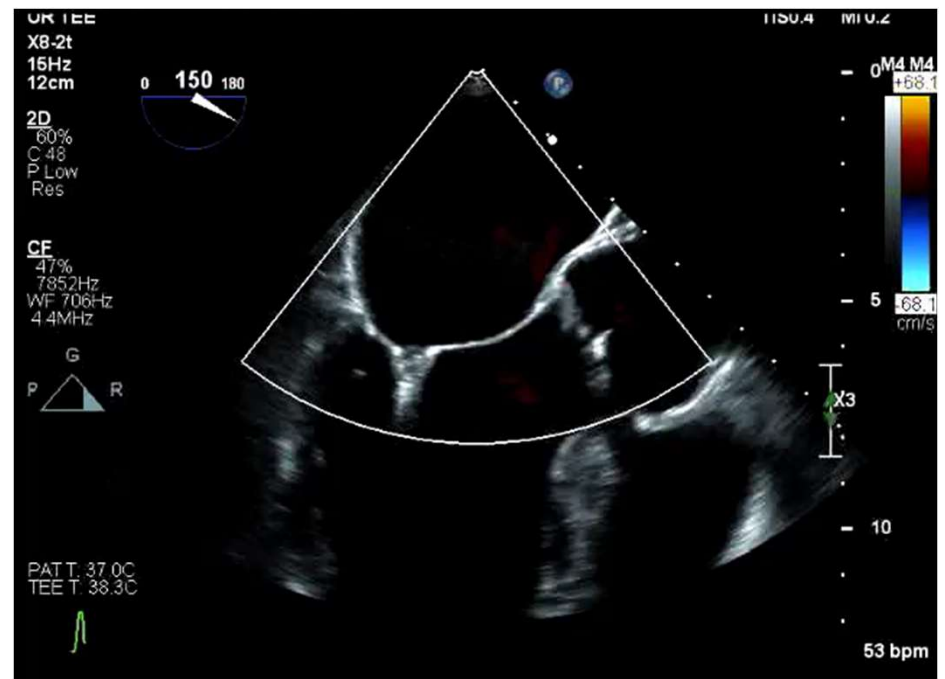
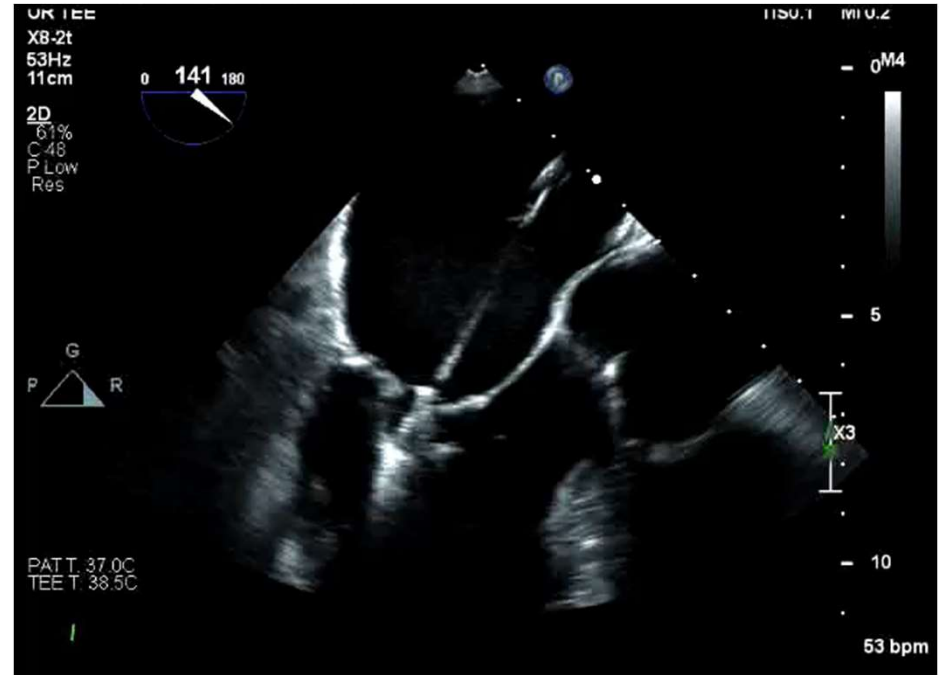
## Past Medical History:

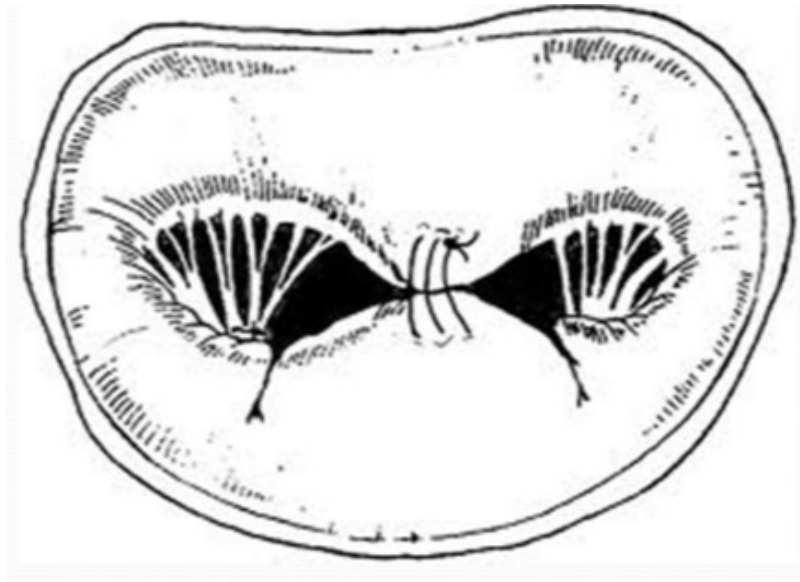
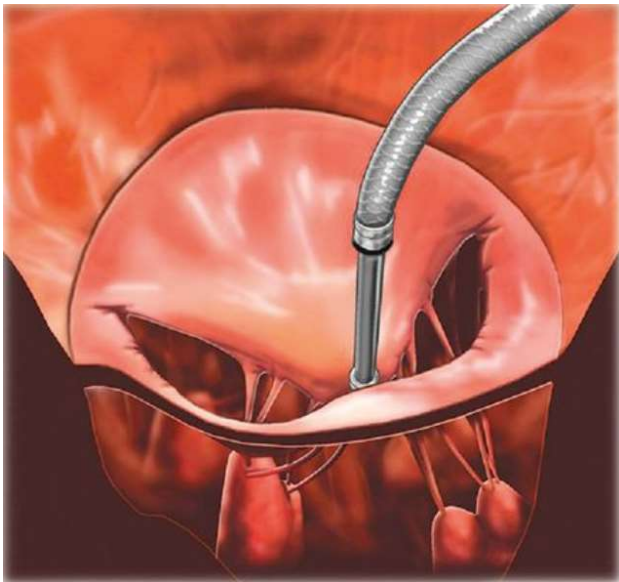
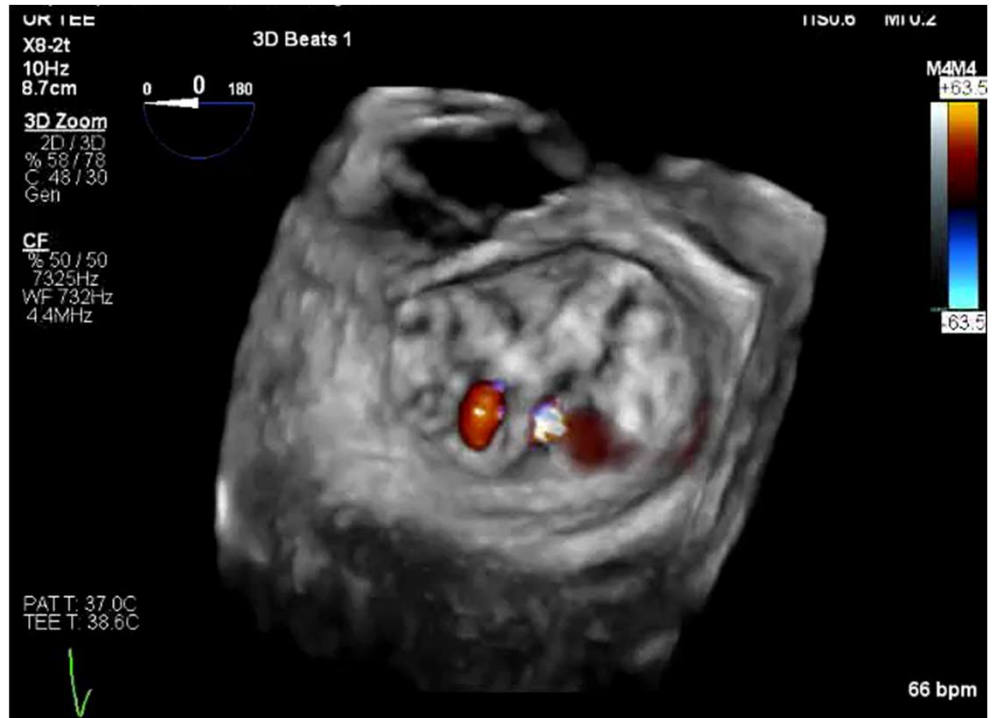
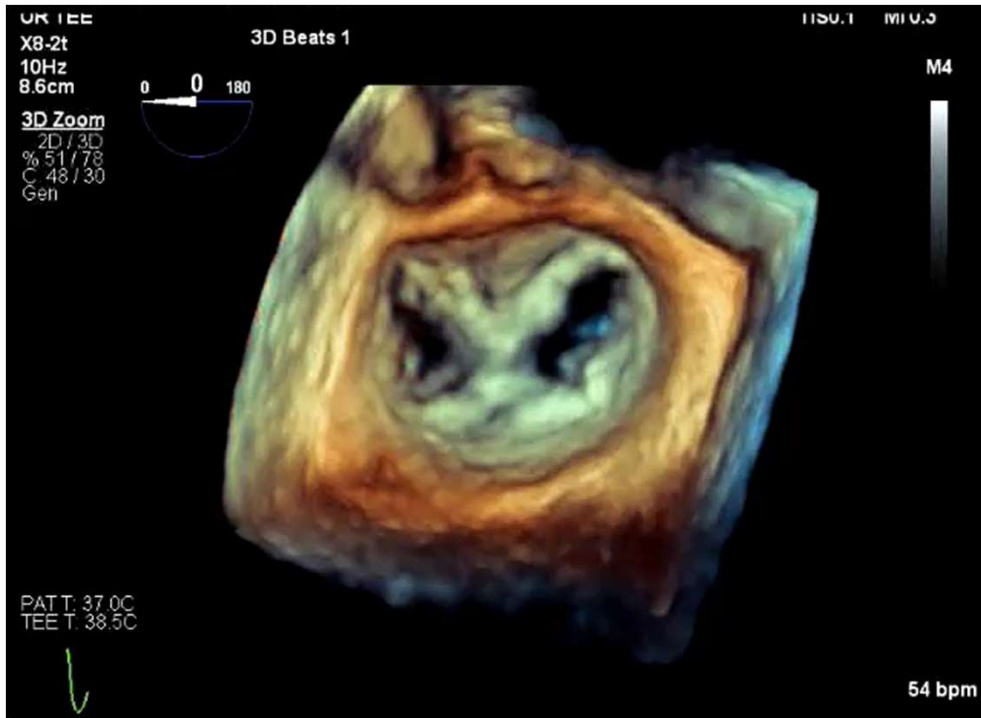
- CAD s/p PCI LAD
- Severe mitral valve regurgitation
- Pulmonary hypertension
- Atrial fibrillation/flutter on A/C
- Type II DM with Stage III CKD
- OSA
- Diverticulitis s/p colectomy and colostomy





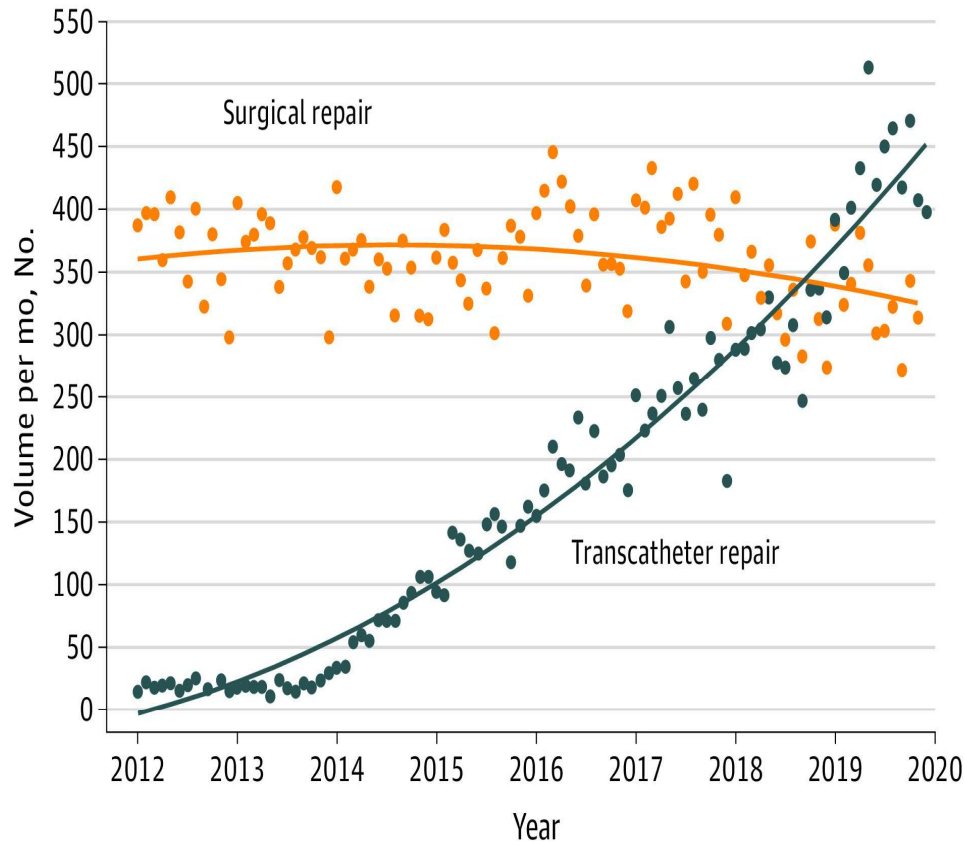
# Transcatheter Edge-to-Edge Repair



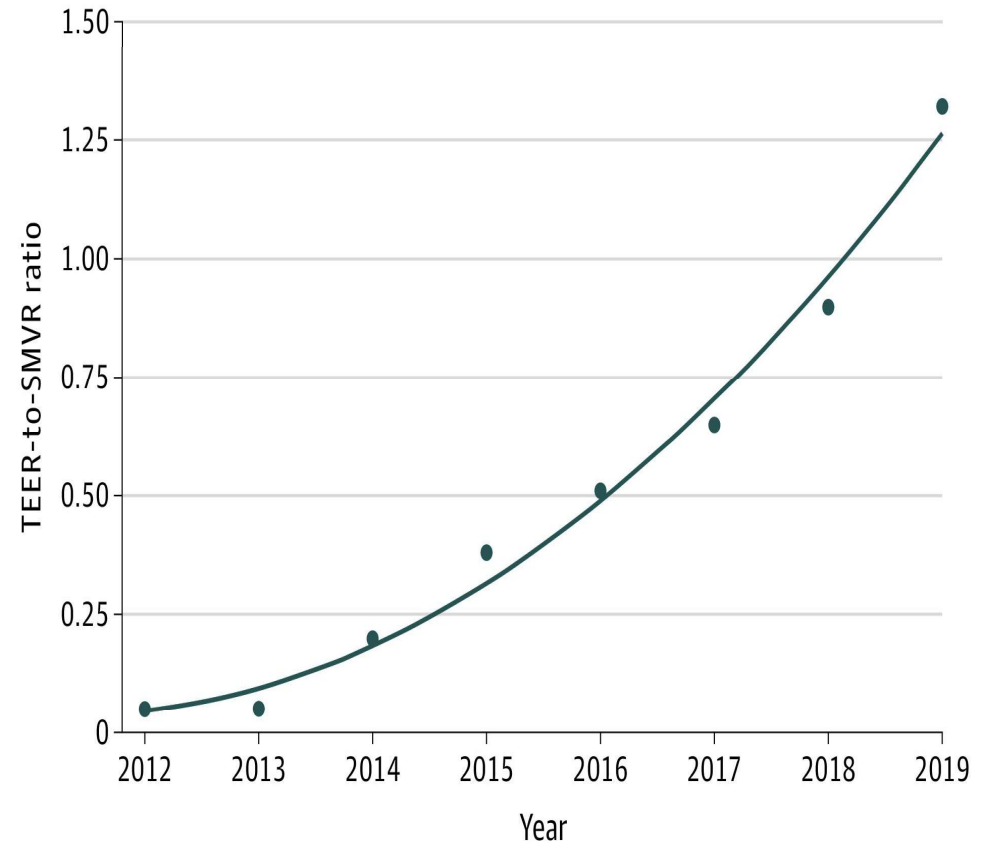


# Transcatheter Mitral Valve Therapy in the US

**A** Monthly volumes of SMVR and TEER



**B** Annualized ratio of TEER to SMVR



May 4, 2022

## Trends in Transcatheter vs Surgical Mitral Valve Repair Among Medicare Beneficiaries, 2012 to 2019

Michael N. Young, MD<sup>1</sup>; Stephen Kearing, MS<sup>2</sup>; Mazen A. Albaghdadi, MD, MSc<sup>3</sup>; et al

[Author Affiliations](#) | [Article Information](#)

*JAMA Cardiol.* 2022;7(7):770-772. doi:10.1001/jamacardio.2022.0775

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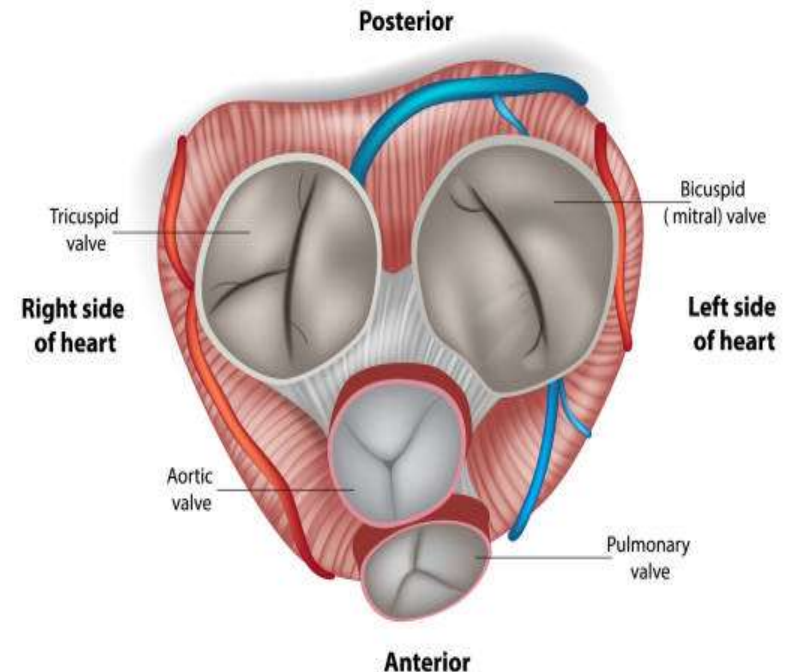
- Where we are going: Transcatheter Mitral Valve Replacement (TMVR)

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- How we get there: Innovation

## IV. Multidisciplinary Heart Team

- Who we are: DHMC



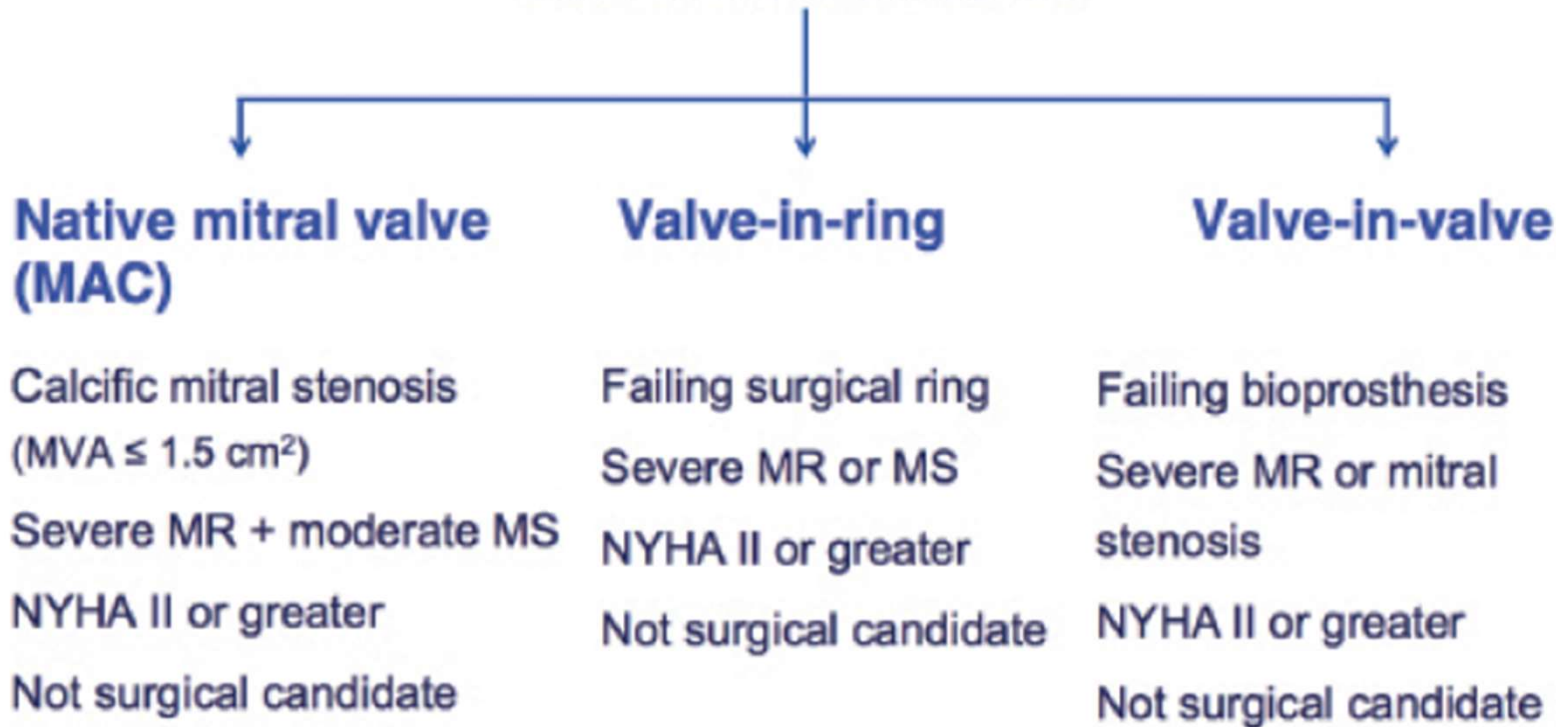
# Mitral Disease not amenable to TEER

- Mitral annular calcification
- Mixed mitral valve disease (MR + MS)
- Failed surgical bioprosthetic mitral valve ring
- Failed surgical bioprosthetic mitral valve

# The MITRAL Trial

## Mitral Implantation of TRAnscatheter vaLves

### Inclusion criteria



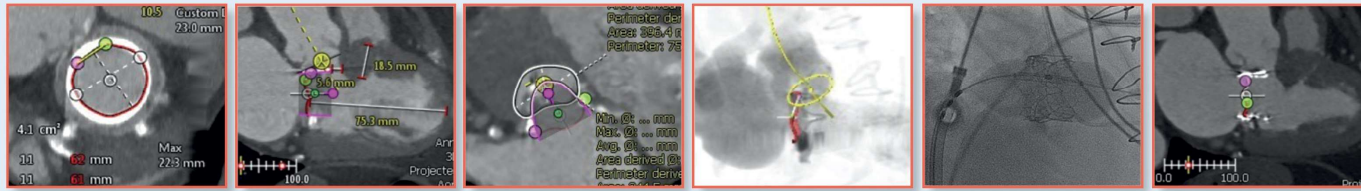
- 91 patients in non-randomized open label study 2015-2018
- Safety and feasibility of TAVR in the Mitral Position



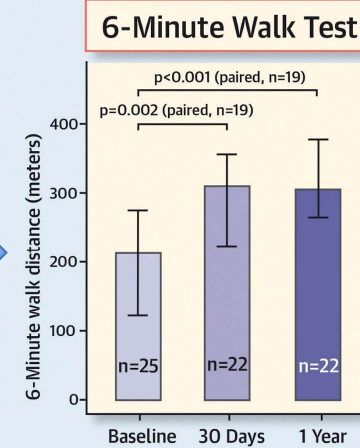
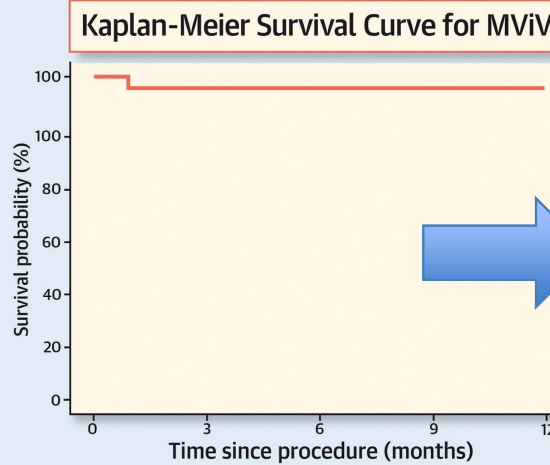
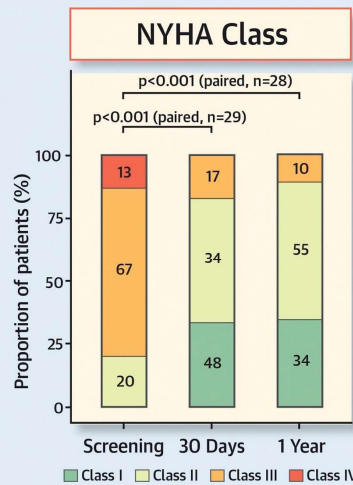


# Transcatheter Mitral Valve-In-Valve

## CENTRAL ILLUSTRATION: 30-Day and 1-Year Outcomes of Mitral Valve-in-Valve in the Mitral Implantation of Transcatheter Valves Trial



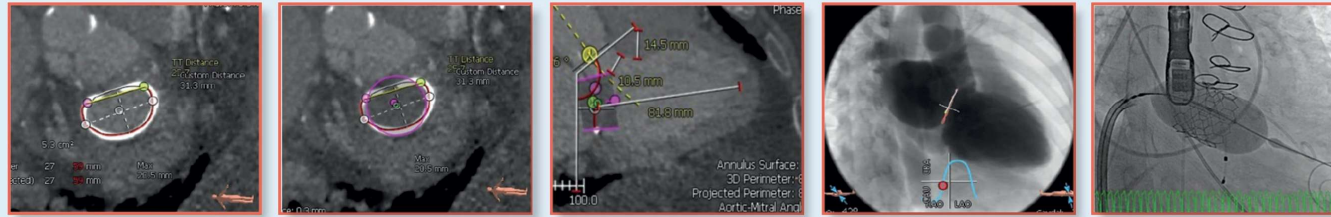
Median STS score 9.4%  
30-day mortality 3.3%  
1-year mortality 3.3%



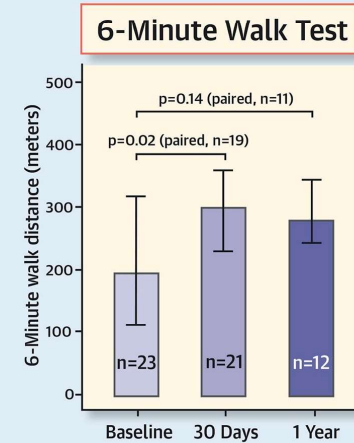
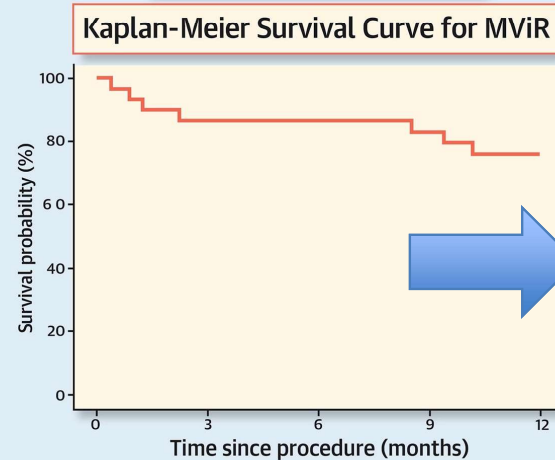
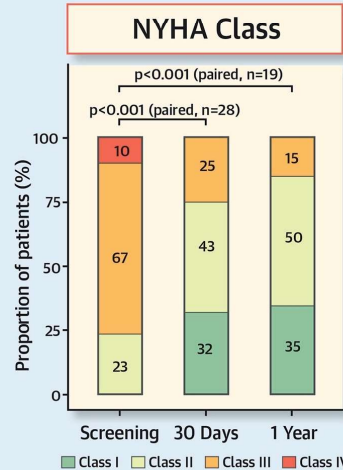
Guerrero, M. et al. J Am Coll Cardiol Interv. 2021;14(8):859-72.

# Transcatheter Mitral Valve-in-Ring

## CENTRAL ILLUSTRATION: 30-Day and 1-Year Outcomes of Valve-in-Ring in the Mitral Implantation of Transcatheter Valves Trial



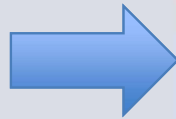
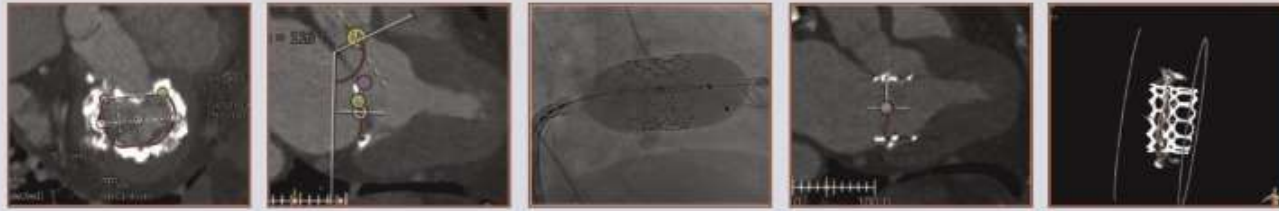
Median STS score 7.6%  
30-day mortality 6.7%  
1-year mortality 23.3%



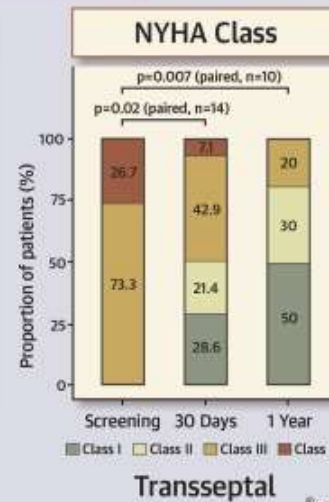
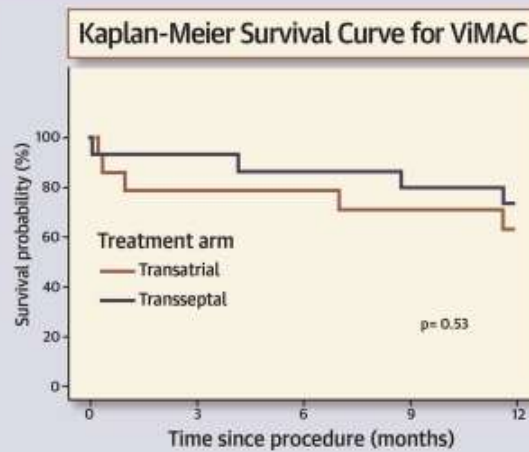
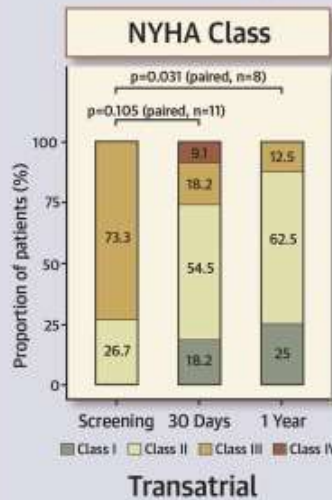
Guerrero, M. et al. J Am Coll Cardiol Interv. 2021;14(8):846-58.

# Transcatheter Mitral Valve-in-MAC

## CENTRAL ILLUSTRATION: 30-Day and 1-Year Outcomes of Valve-in-Mitral Annular Calcification in the Mitral Implantation of Transcatheter Valves Trial



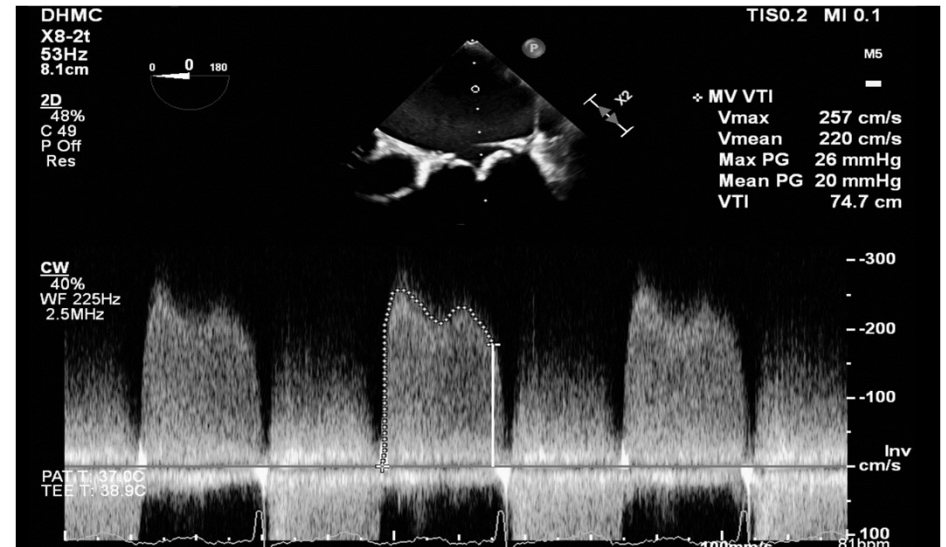
Transseptal ViMAC 30-day mortality=6.7%  
 Transatrial ViMAC 30-day mortality=21.4%  
 Similar all-cause mortality at 1 year  
 Sustained improvement of symptoms at 1 year in both groups

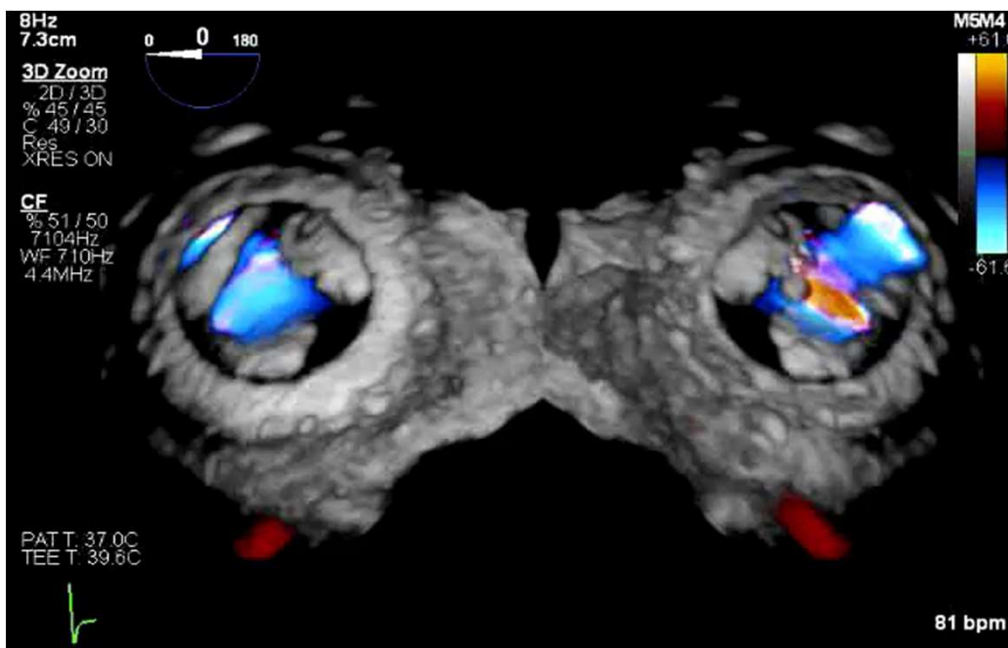
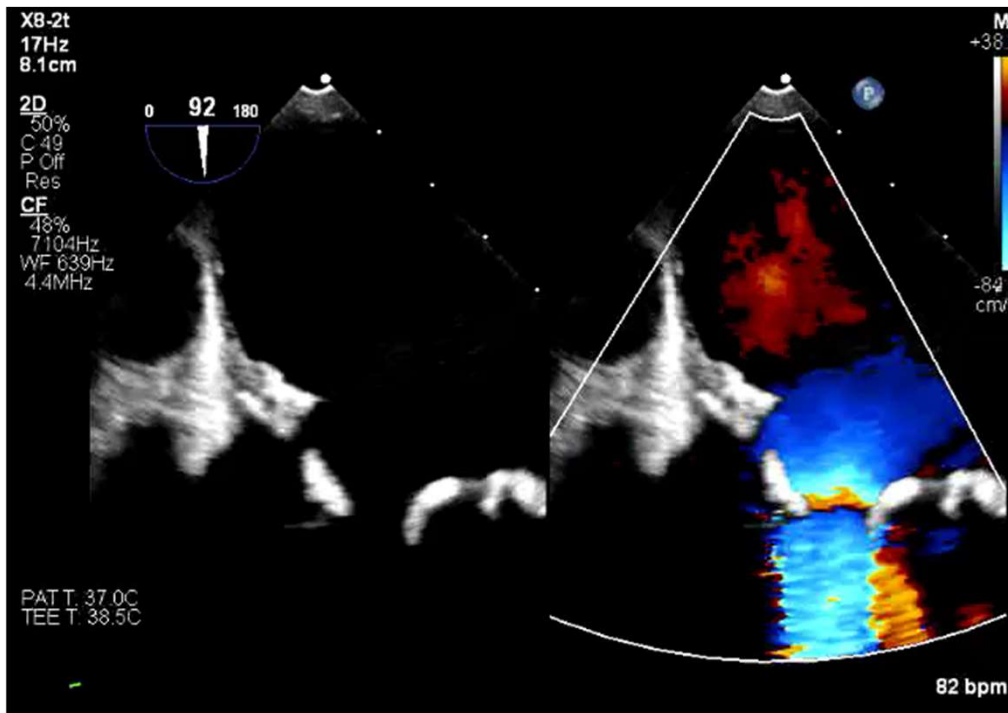


Guerrero, M. et al. J Am Coll Cardiol Interv. 2021;14(8):830-45.

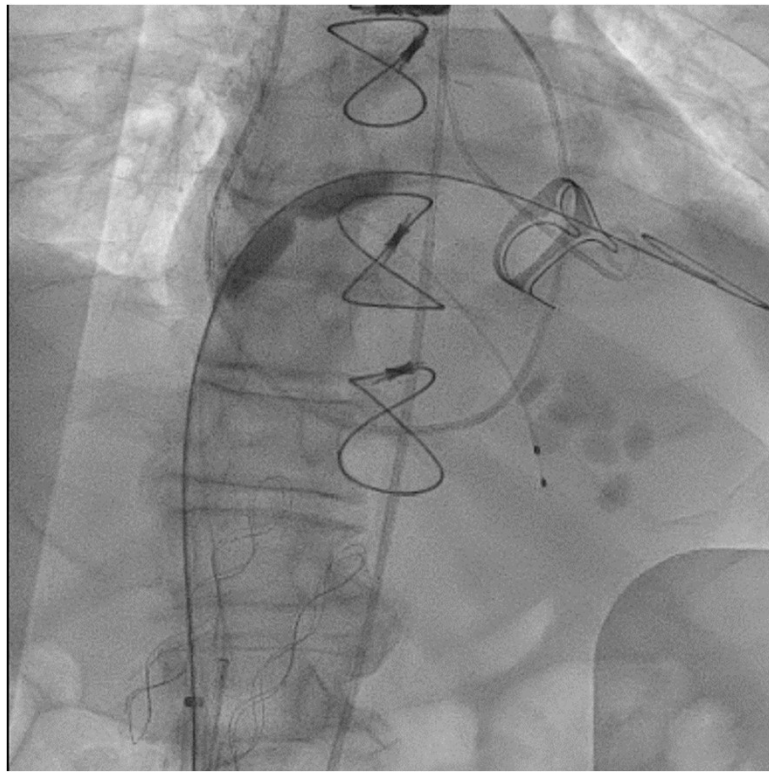
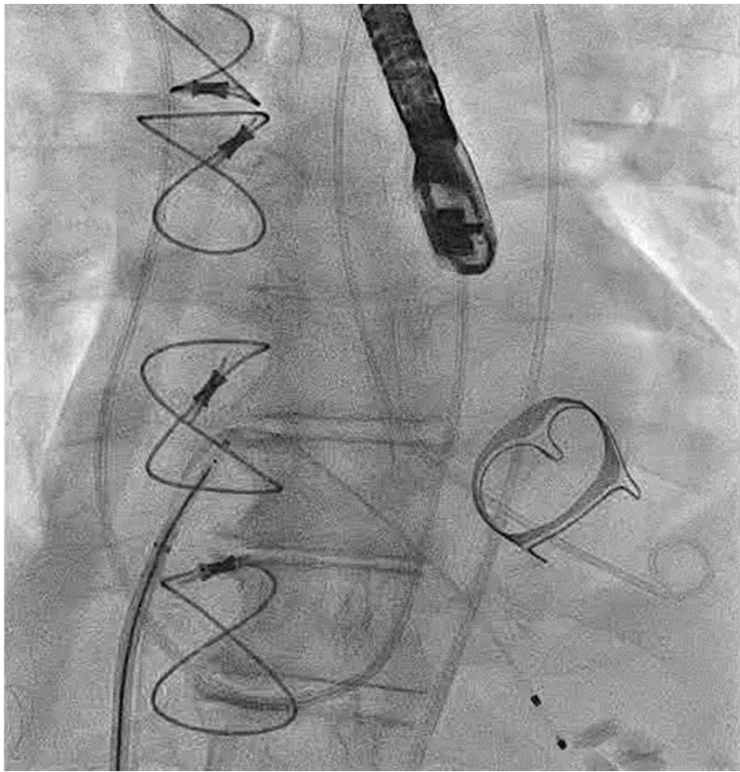
# Case: 90 year old male with h/o MVR (31 Carpentier Edwards) 2005, HTN, PTSD

- Primary symptoms of shortness of breath, orthopnea, and PND
- TTE: LVEF 60%, mean MV gradient 17 mmHg at 64 bpm. 3-4+ MR

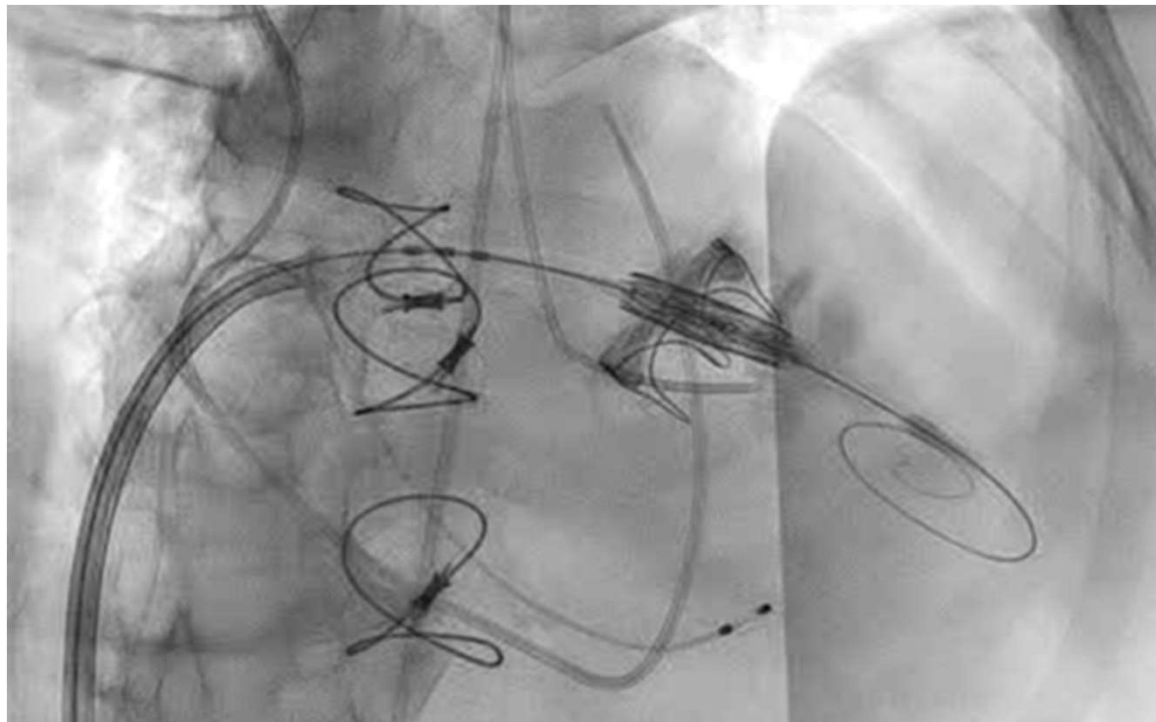
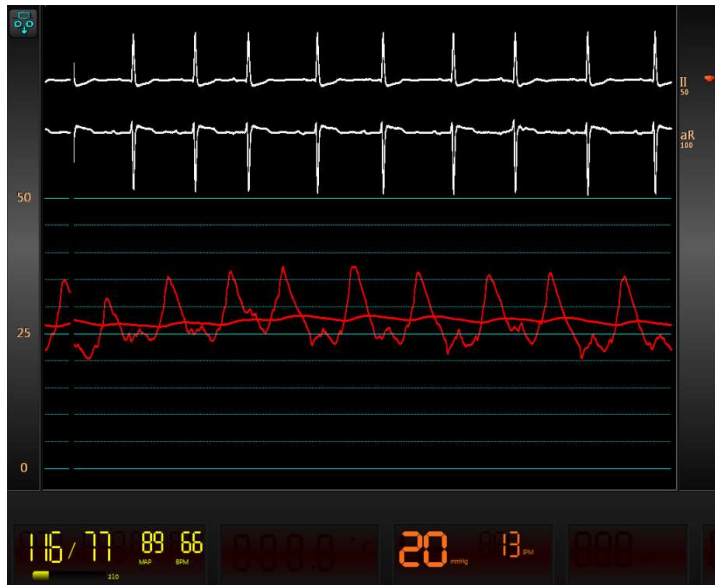


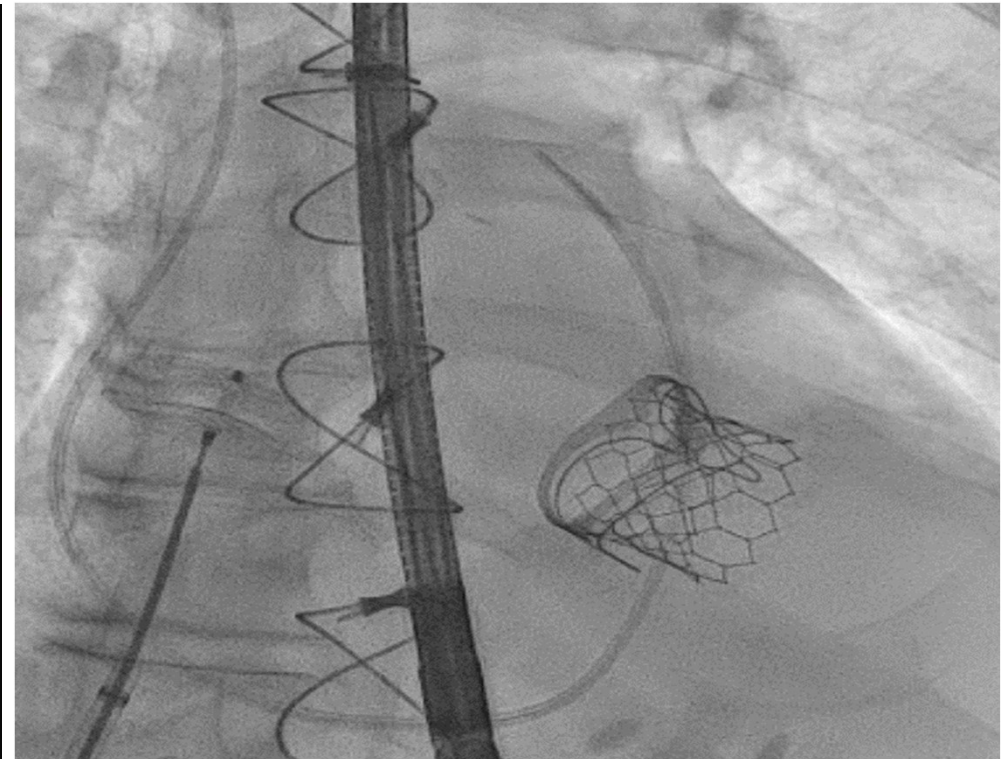
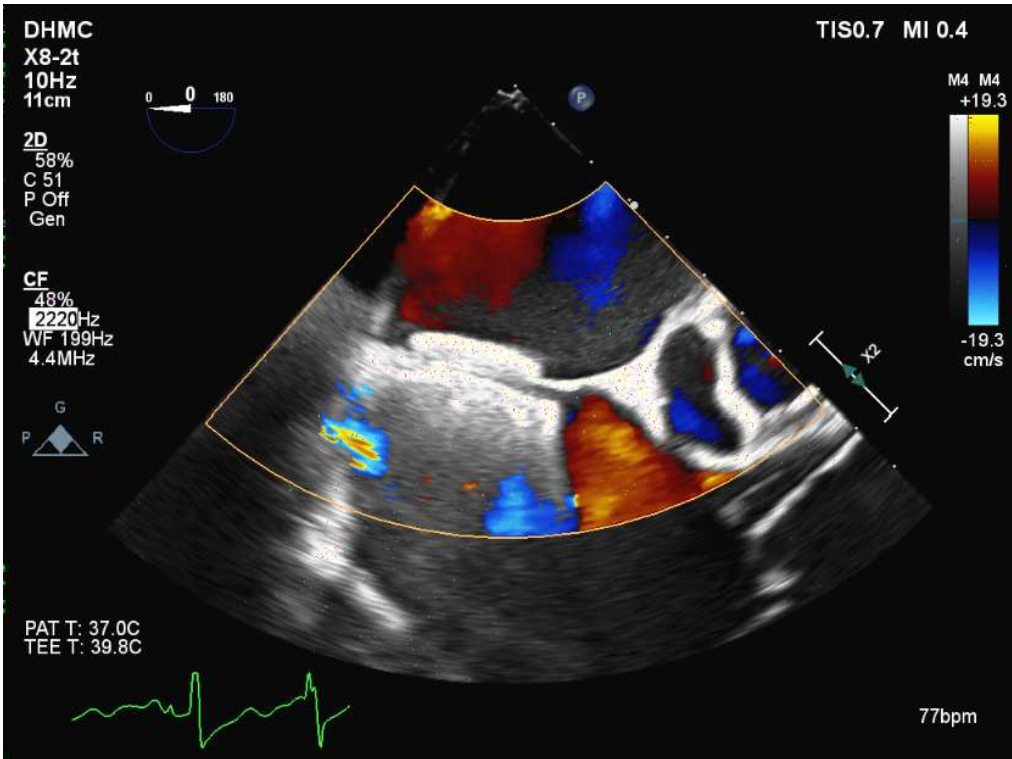
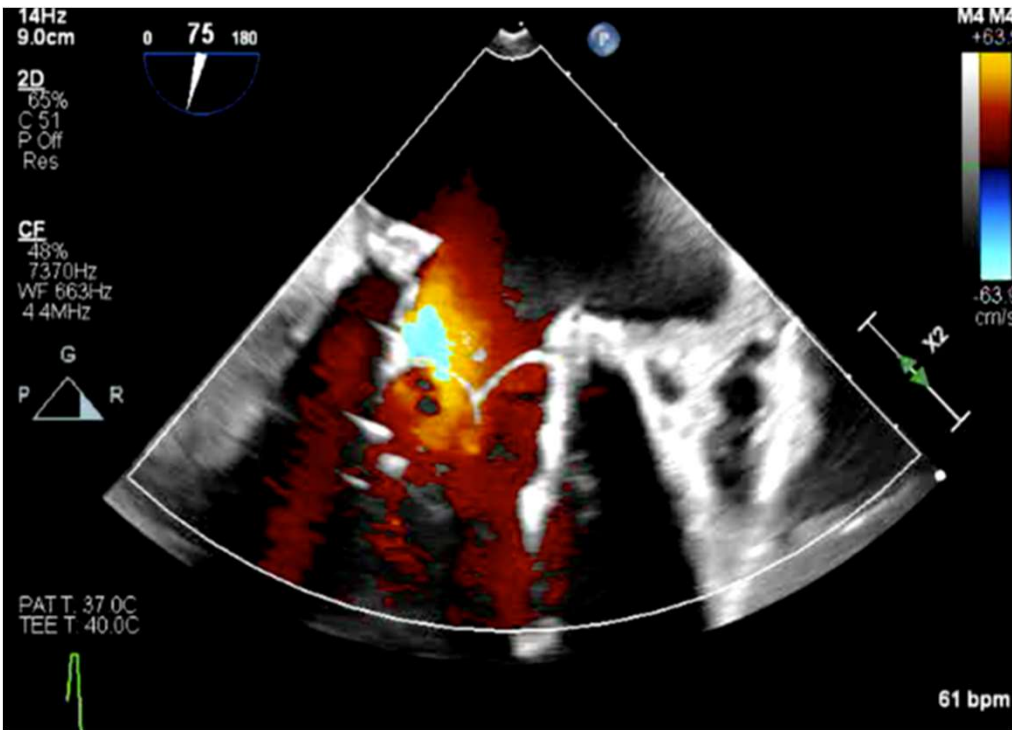


**TEE: Two leaflets  
non-mobile, MVA  
0.94, mean gradient  
19 mmHg at 81 bpm,  
3+ anterior MR**

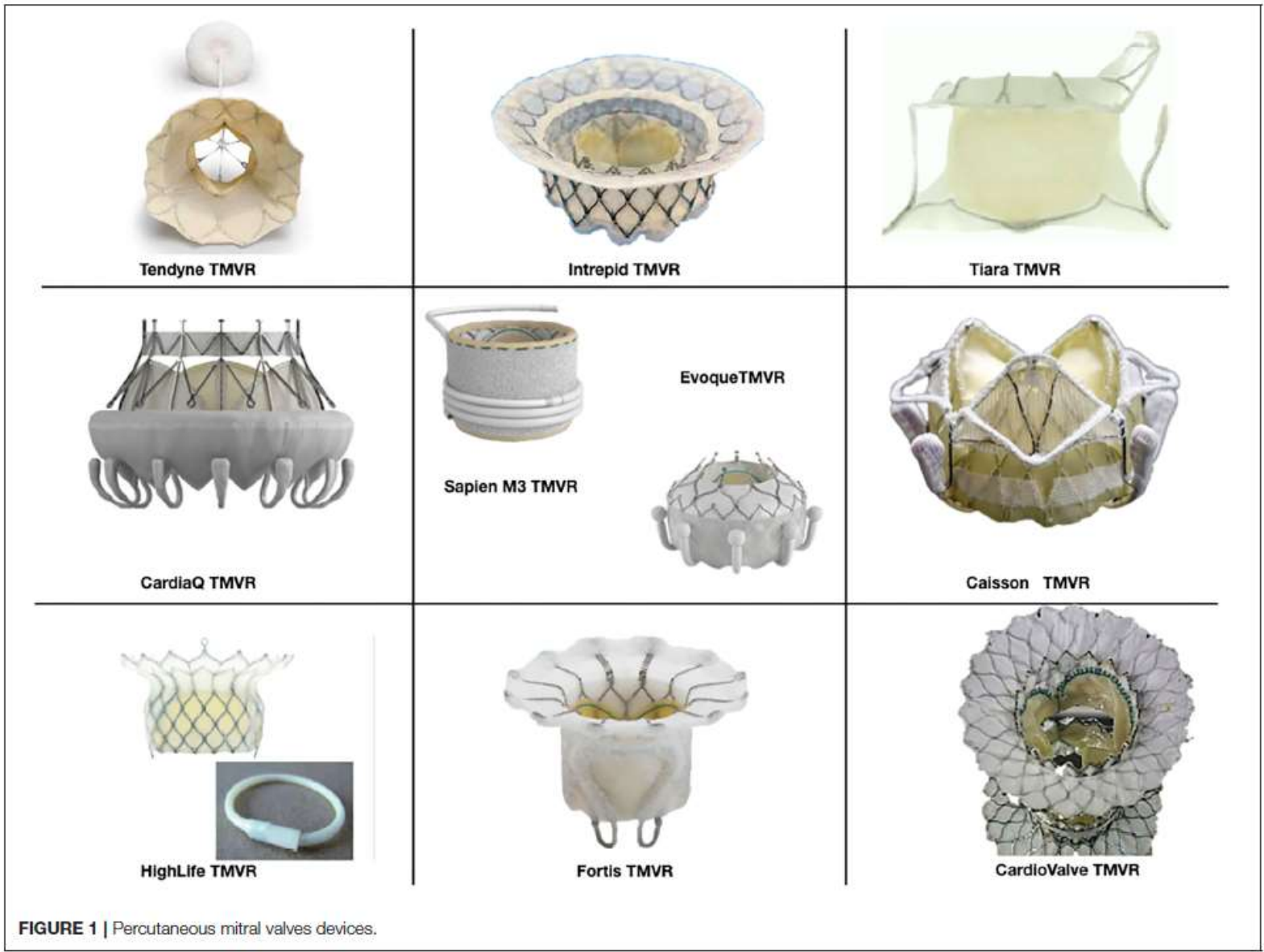


1. Transseptal puncture
2. Atrial septostomy
3. TMVR





# Investigational TMVR Devices





**TABLE 2** | Transcatheter mitral valve devices.

Device	Manufacture	Access size sheath	Anchoring mechanism	Valve size	Effective orifice area	Valve position	Recapture	Shape	Frame	Leaflets
Tendyne	Abbott	TA 34 Fr.	Apical tether	Outer (sealing) frame ranges 30–43 mm in the SL dimension and 34–50 in the IC dimension	3.2 cm <sup>2</sup>	Intra-annular	Fully recapturable system after complete deployment	D-shaped (outer stent) Circular (inner frame)	Nitinol, double frame; Self-expandable	Porcine pericardium, trileaflet
Intrepid	Medtronic	TA 33Fr.	Radial force and sub-annular cleats	Inner stent—27 mm (Outer stent—43, 46, and 50 mm)	2.4 cm <sup>2</sup>	Intra-annular	No	Circular	Double stent, self-expanding, nitinol	Bovine pericardium, trileaflet
TIARA	Neovasc	TA 32, 36 Fr.	3 ventricular anchoring tabs (onto the fibrous trigone and posterior shelf of the annulus)	35 and 40 mm	6.5–12 cm <sup>2</sup>	Intra-annular	No	D-shaped	Self-expanding, nitinol	Bovine pericardium, trileaflet
CardiaQ	Edwards Lifesciences	TA/TF 33 Fr.	Mitral annulus capture with native leaflet engagement	30 mm	NA	Supra-annular	No	Circular	Self-expanding, nitinol	Bovine pericardium, trileaflet
Sapiens M3	Edwards Lifesciences	TF/TA 20 Fr.	Nitinol dock system	29	NA	Intra-annular	No	Circular	Balloon-expandable, cobalt-chromium frame	Bovine pericardium, trileaflet
Caisson	LivaNova	TF 31 Fr.	4 sub-annular anchoring feet 3 atrial holding features	36A 42A 42B	NA	Supra-annular	Recapturable/retrievable	D-shaped	2 components (anchor and valve); Nitinol, self-expandable.	Porcine Pericardium, trileaflet
HighLife	HighLife SAS	TA39 Fr. (TF artery for loop placement)	External anchor; valve in sub-annular mitral ring	31 mm	NA	Intra-annular	No	Circular	2 components (ring and valve); Nitinol, self-expandable	Bovine pericardium, trileaflet
Fortis	Edwards Lifesciences	TA 42 Fr.	2 opposing paddles	29 mm	NA	Intra-annular	No	Circular	Cloth-covered, self-expanding, nitinol	Bovine pericardium, trileaflet
CardioValve	CardioValve	TF 28-Fr.	24 focal "sandwiching" points	3 sizes (range 40–40 mm)	NA	Intra-annular	No	Circular	Dual nitinol frame	Bovine pericardium, trileaflet
Evoque	Edwards Lifesciences	TF 28-Fr.	External anchor	2 sizes (44 and 48 mm)	NA	Intra-annular	No	Circular	Self-expanding, nitinol with fabric skirt to minimize paravalvular leak	Bovine pericardium, trileaflet

Fr, French; TA, transapical; TF, transfemoral.

# ENCIRCLE TRIAL



The ENCIRCLE Trial is studying the safety and effectiveness of the Edwards SAPIEN M3 System in patients with severe mitral regurgitation

## Commercially Unsuitable Cohort\*

Subjects must be symptomatic, have at least 3+ mitral regurgitation (MR), and be deemed unsuitable for commercially available surgical or transcatheter treatment options

## Anatomical Criteria

### Computed Tomography (CT)

- Commissural diameter  $\leq$  45mm
- LV diameter (1 cm below annulus)  $\geq$  35mm
- No significant risk of LVOT obstruction as assessed by CT Core Lab
- No calcification that would interfere with SAPIEN M3 system

### Echocardiography (Echo)

- FMR, DMR or Mixed
- MR  $\geq$  3+
- LVEF  $\geq$  30%
- LVEDD  $<$  70mm
- No commissural jet, flail, or prolapse that would increase risk of PVL
- No severe RV dysfunction
- No severe pHTN

# Trial Design

The ENCIRCLE trial has a main study and two registries, enrolling subjects deemed unsuitable for commercially available surgical or transcatheter treatment options.<sup>†</sup>

Subjects deemed unsuitable for commercial treatment options  
as assessed by Heart Team

Main Study  
(n = Up to 300)

MAC Registry  
(n = 100)

Failed TEER Registry  
(n = 100)

PRIMARY ENDPOINT:  
Death & Heart Failure Rehospitalization at 1 year

Follow-up: 30 days, 6 mos, 1 year and annually through 5 years

# ENCIRCLE

SAPIEN M3 System Transcatheter Mitral Valve Replacement via Transseptal Access

PI: Michael Young, MD

**Objective:** To establish the safety and effectiveness of the SAPIEN M3 system in subjects with symptomatic, at least 3+ mitral regurgitation (MR) for whom commercially available surgical or transcatheter treatment options are deemed unsuitable due to clinical, anatomic or technical considerations.

**Rationale:** There is an unmet clinical need to provide treatment options to patients with at least 3+MR, despite optimized medical therapy, who are not amenable to currently available surgical or transcatheter methods. This study will evaluate whether the SAPIEN M3 system is safe and effective in treating this patient population.

## **Eligible Patients:**

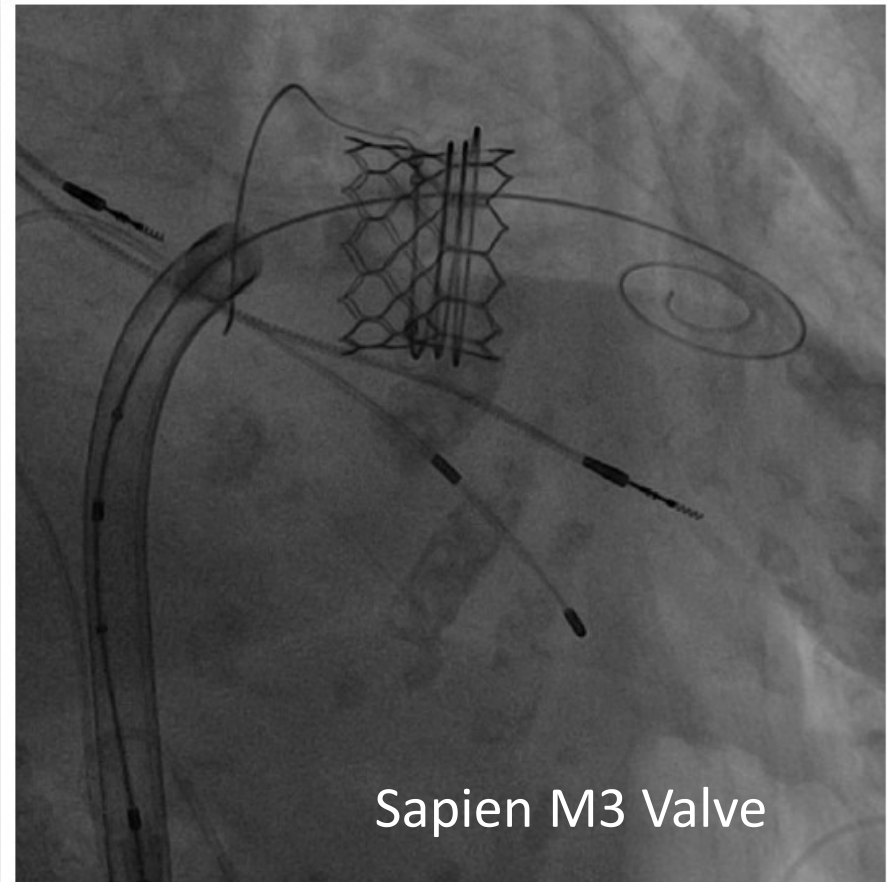
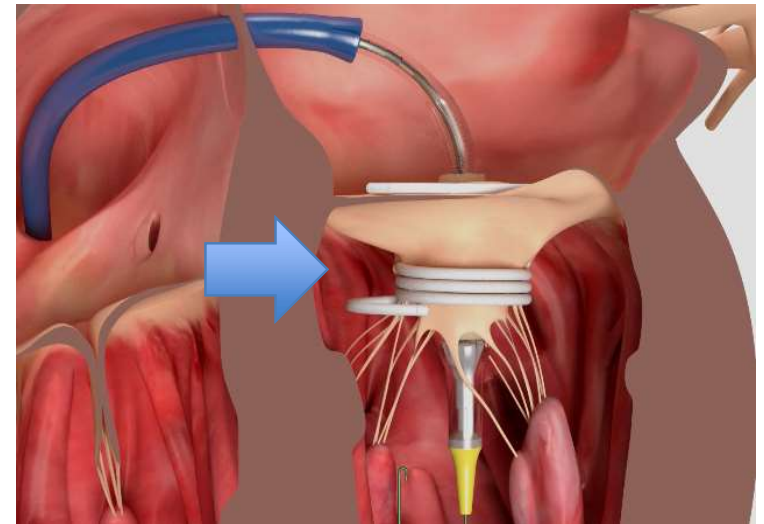
### Inclusion

- 18 years of age or older
- MR  $\geq$  3+
- NYHA functional class  $\geq$  II
- Unsuitable for commercially available surgical or transcatheter treatment options



Research Nurse:  
Erin Downey, RN  
Phone: 5-6134  
Pager: 7261

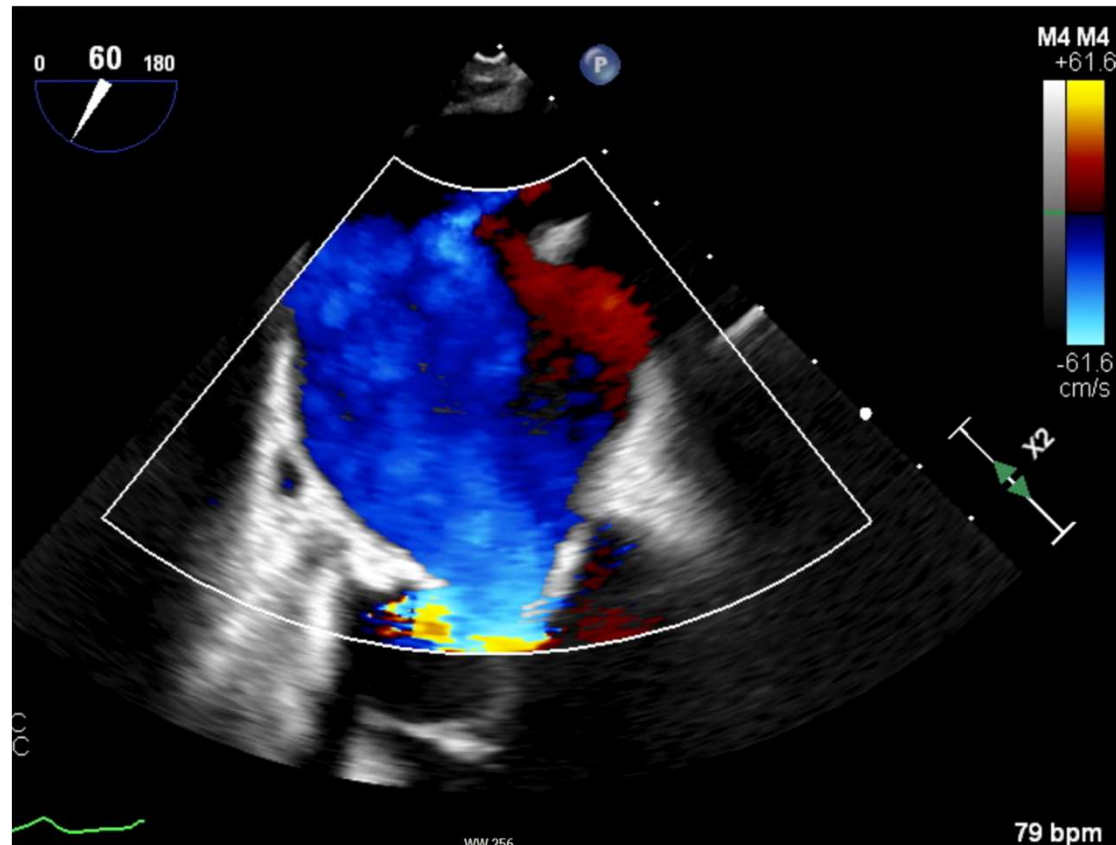
Learn more at  
[clinicaltrials.gov](http://clinicaltrials.gov)  
by scanning the  
QR code!

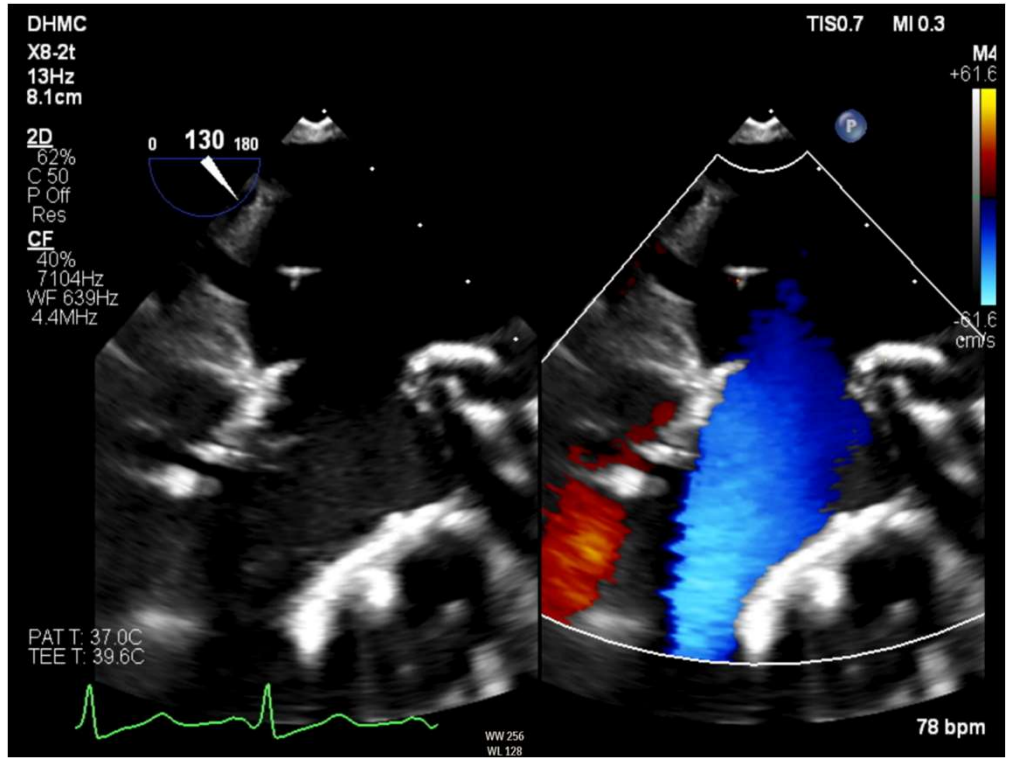
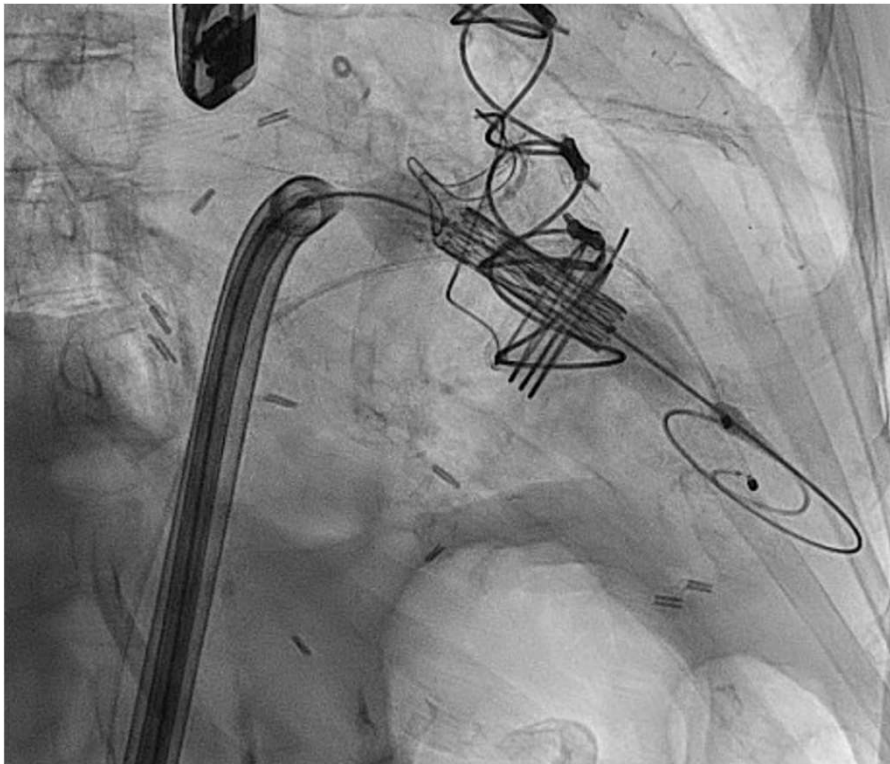
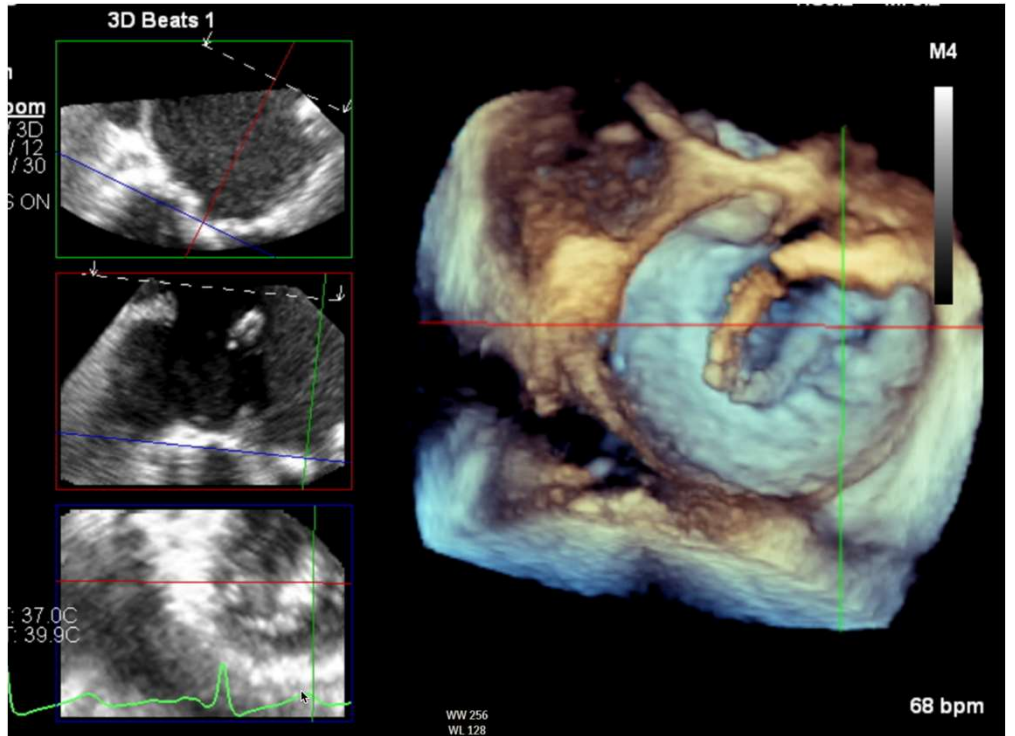
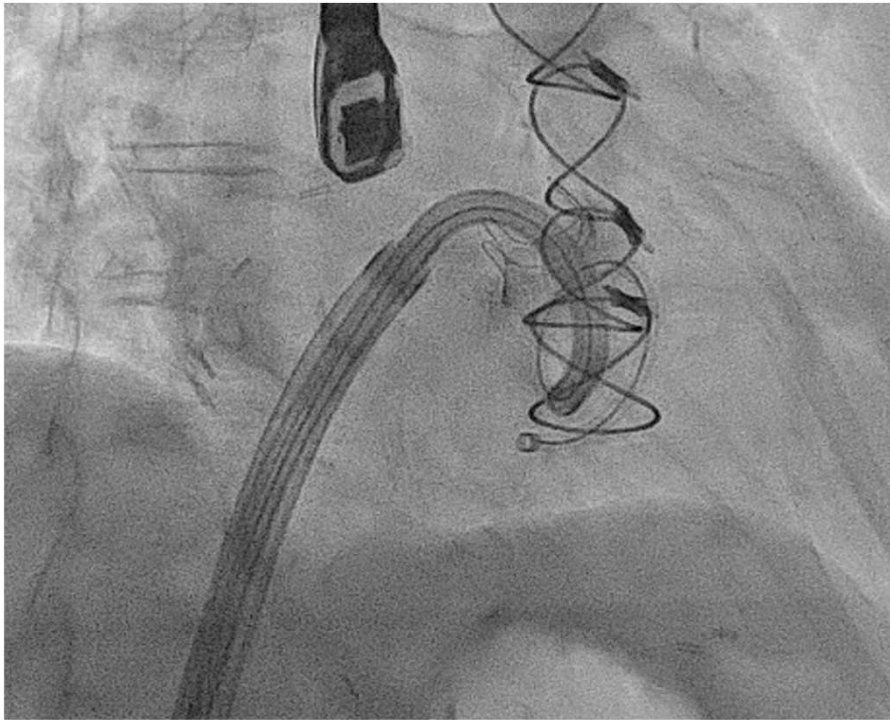


Sapien M3 Valve

# Case: Elderly female with prior sternotomy, ischemic CM, and severe functional MR

- NYHA Class IV symptomatology with DOE, orthopnea, and BLE





# AGENDA

## I. Primary and Secondary Mitral Valve Regurgitation

- Where we are: Transcatheter Edge-to-Edge Repair (TEER)

## II. Mitral Regurgitation +/- Calcific Mitral Stenosis

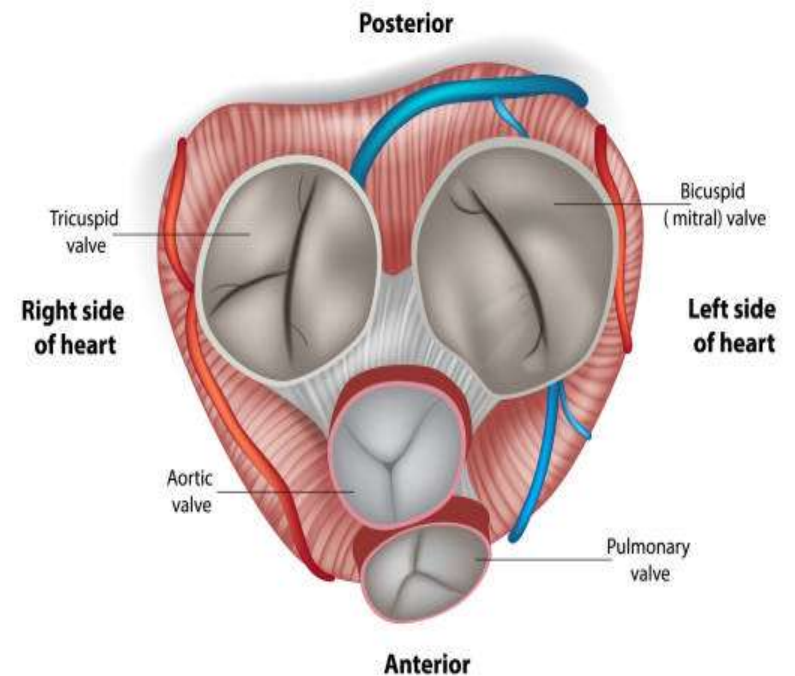
- Where we are going: Transcatheter Mitral Valve Replacement (TMVR)

## III. Tricuspid Valve Regurgitation

- How we get there: Innovation

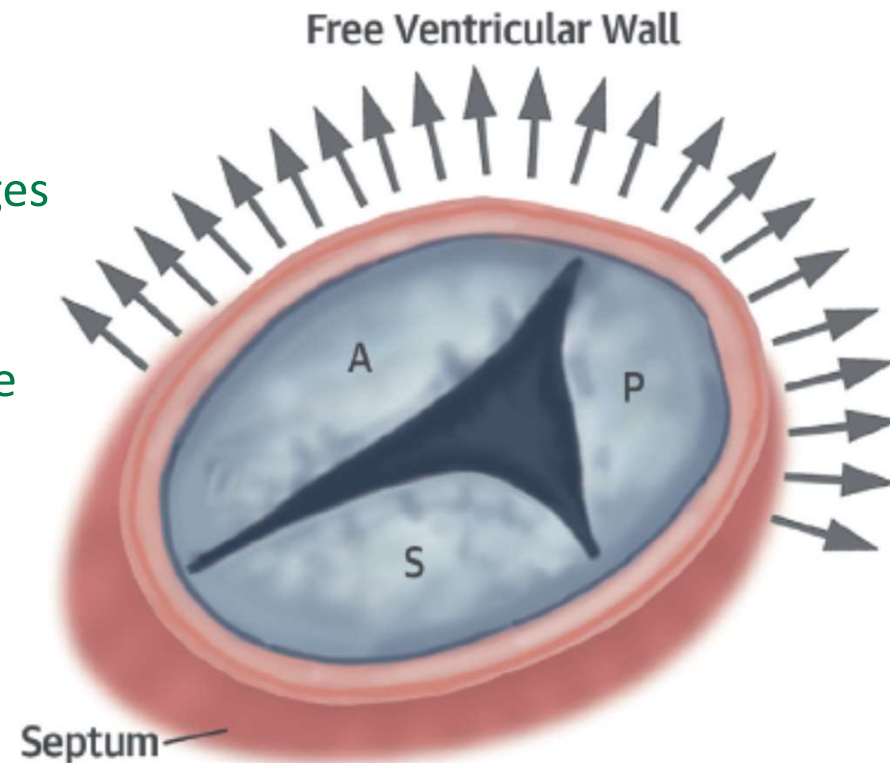
## IV. Multidisciplinary Heart Team

- Who we are: DHMC



# Tricuspid Valve Regurgitation

- Primary or secondary pathology
  - Often secondary to left heart pathologies that can lead to RV pressure/volume changes over time
- Annular dilatation is asymmetric and progressive
- Tricuspid valve disease is not always treated concomitantly with left heart surgery
- Operation for severe functional tricuspid regurgitation carries higher conferred risk





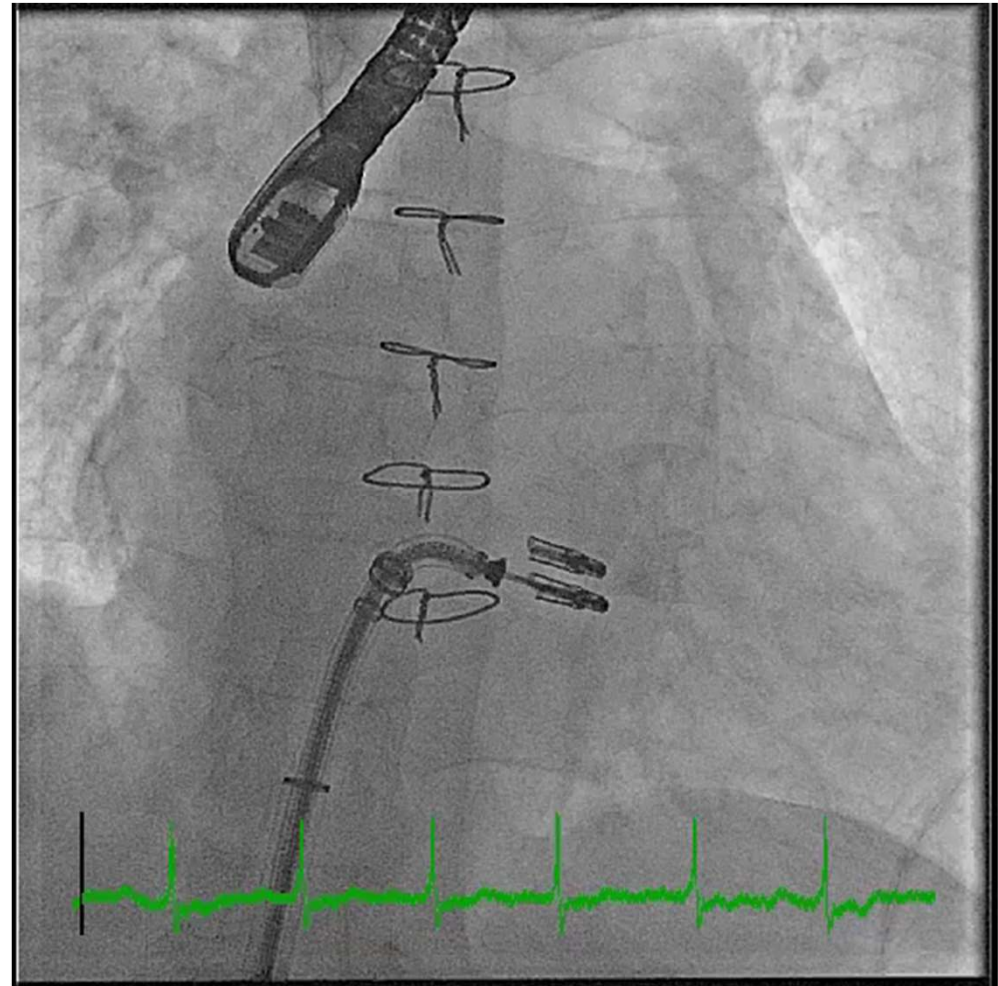
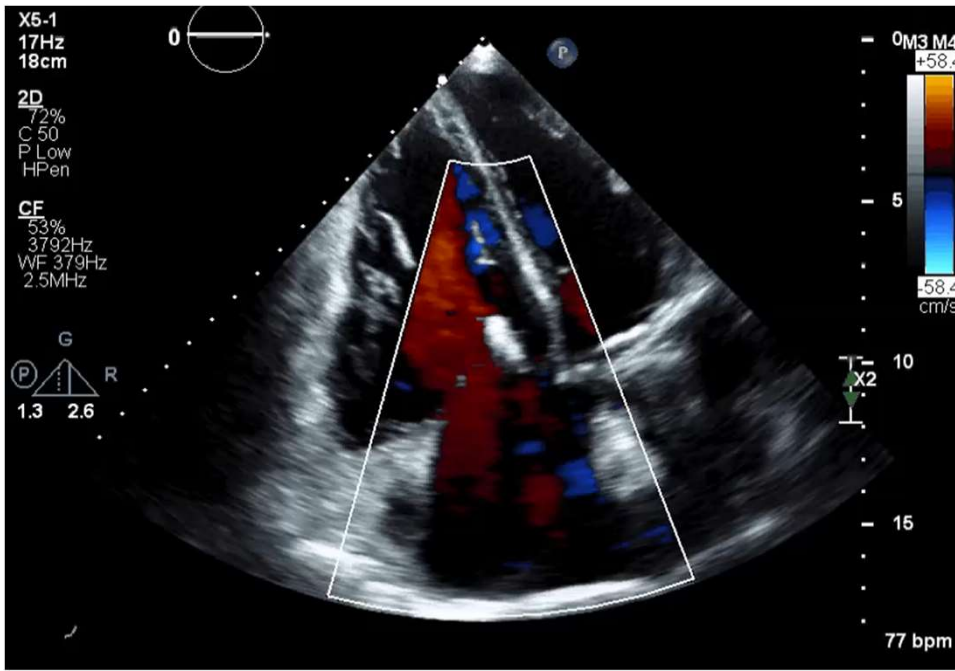
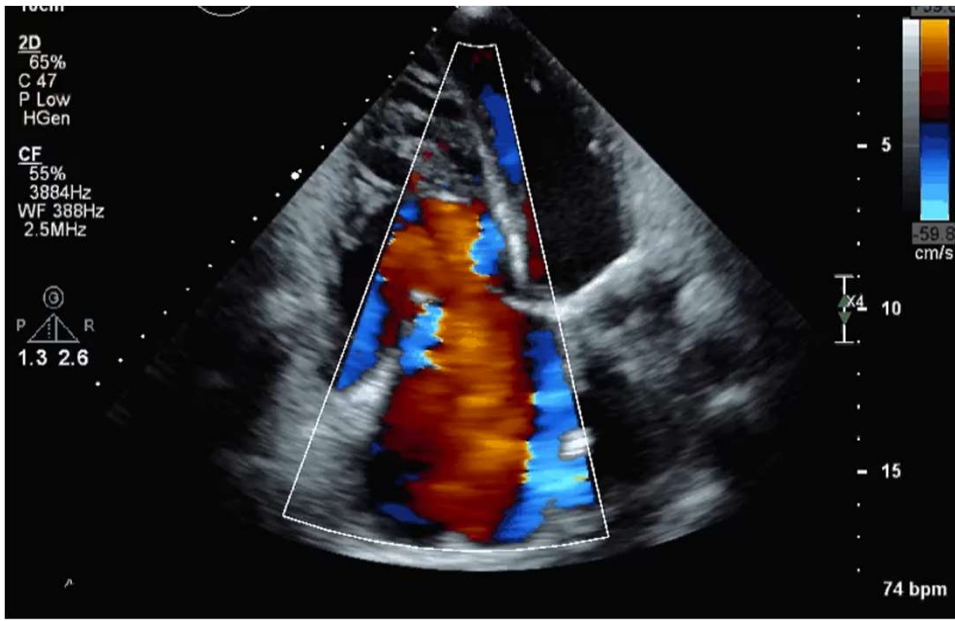
# Tricuspid valve edge-to-edge repair

- “Bicuspidalization” of the tricuspid valve (Kay procedure) studied as a potential transcatheter option for FTR

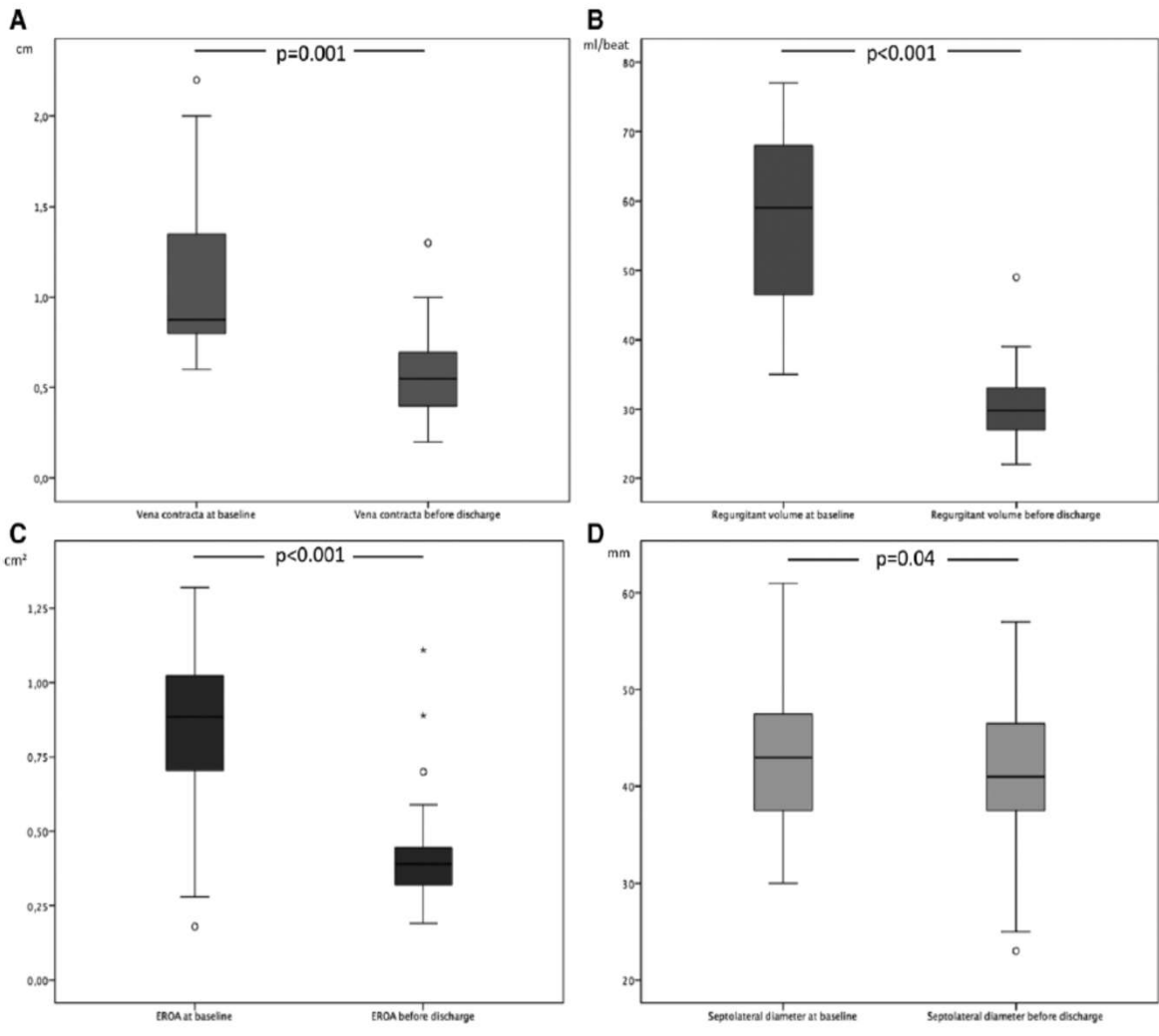


**Figure 3.** “Zipping technique” to achieve bicuspidalisation of the tricuspid valve. A) Schematic view of the tricuspid valve treated with three MitraClips. B) Corresponding fluoroscopic view following implantation of three MitraClips.

*Vismara et al. JACC Interventions 2016.  
Braun et al. EuroIntervention 2017.*



# Early observational data (Mitralclip in TV)



Mean age 76.6 +/- 10 years; 93% NYHA III-IV; prevalent cardiovascular comorbidities

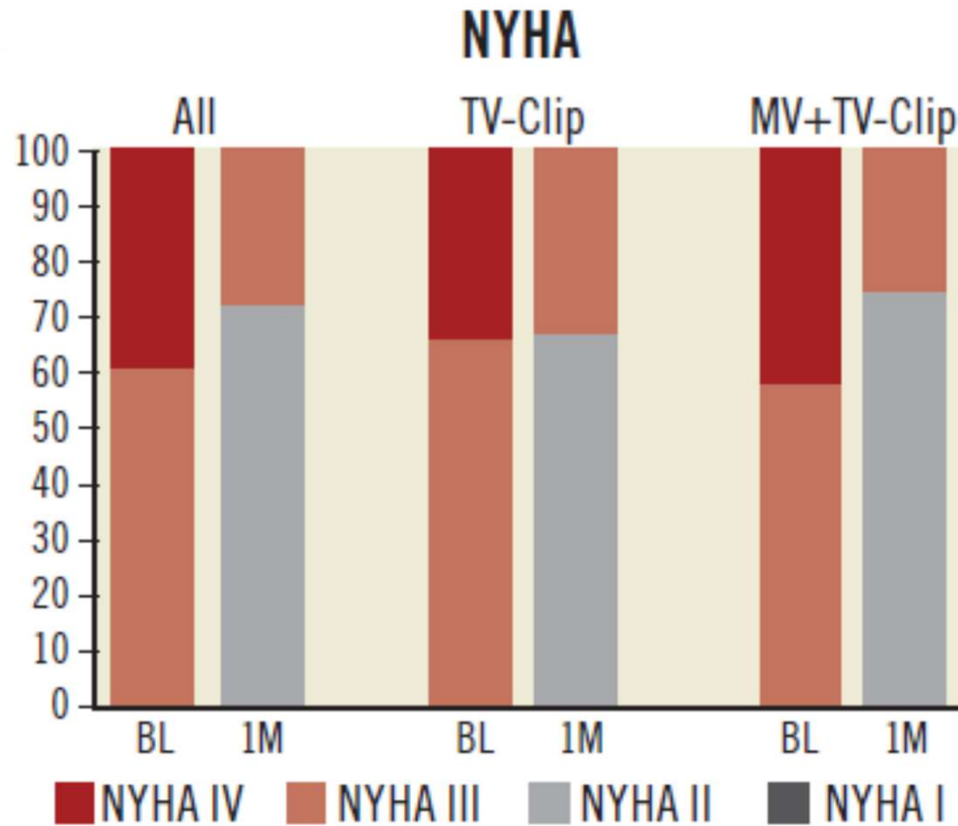
97% procedural success

TR not completely eliminated and often reduced by one grade →

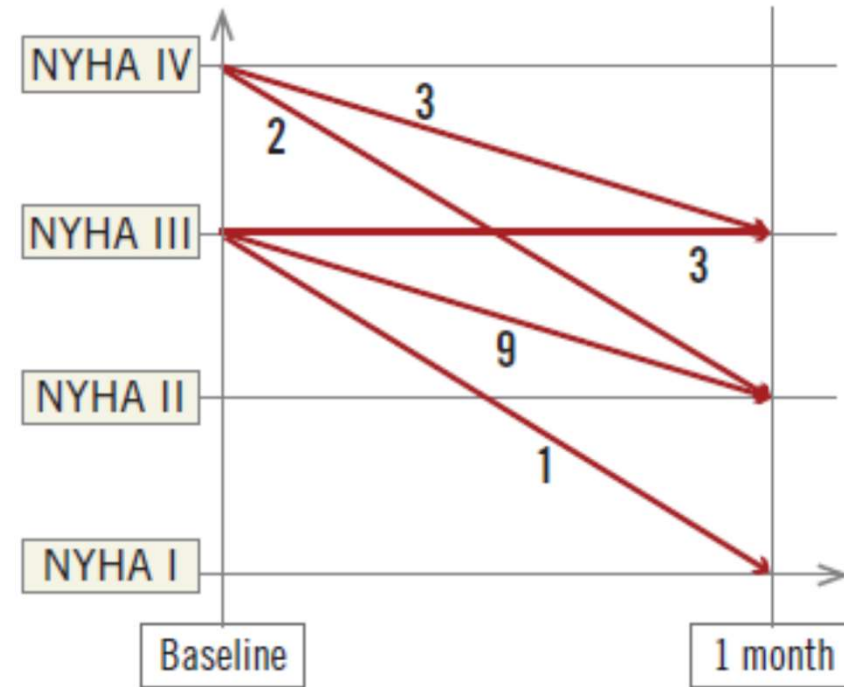
- Improvement in NYHA class
- Discharge 6 MWT improved compared to baseline

# Early observational data (Mitralclip in TV)

**A**



**B**



- Mean TR grade decreased from 3.4+/-0.6 to 1.8+/-1.0 (p<0.001).
- Improvements in NYHA Class, 6MWT, and QOL (measured by MLHFQ score).

# Early Challenges of Tricuspid TEER

- Complex anatomy of the tricuspid valve with three leaflets that precludes the “double orifice” strategy utilized for MR
- TEE visualization of the tricuspid valve leaflet insertion is challenging compared to TEER
- Outcome data limited to small studies/case series
- Clinical trials ongoing

Edwards PASCAL TrAnScatheter Valve RePair System Pivotal Clinical Trial (CLASP II TR): A prospective, multicenter, randomized, controlled pivotal trial to evaluate the safety and effectiveness of transcatheter tricuspid valve repair with the Edwards PASCAL Transcatheter Valve Repair System and optimal medical therapy (OMT) compared to OMT alone in patients with tricuspid regurgitation



Edwards

Short Title: CLASP II TR Pivotal Clinical Trial

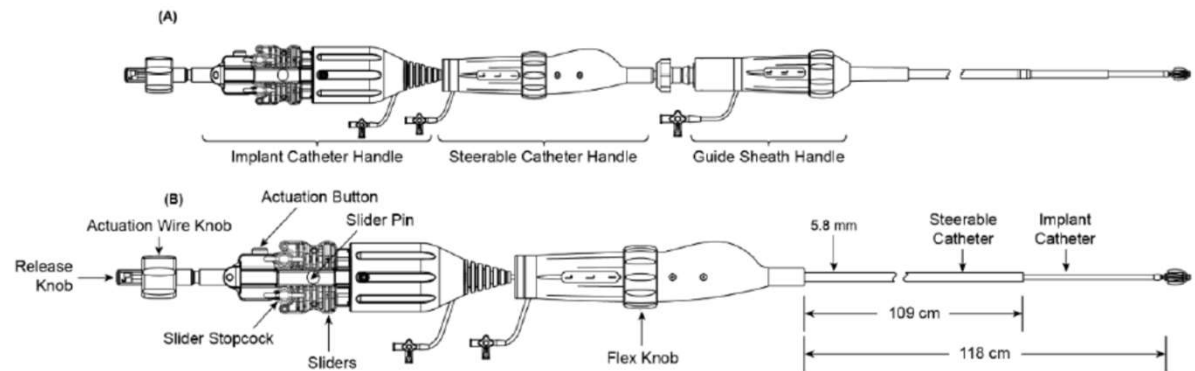
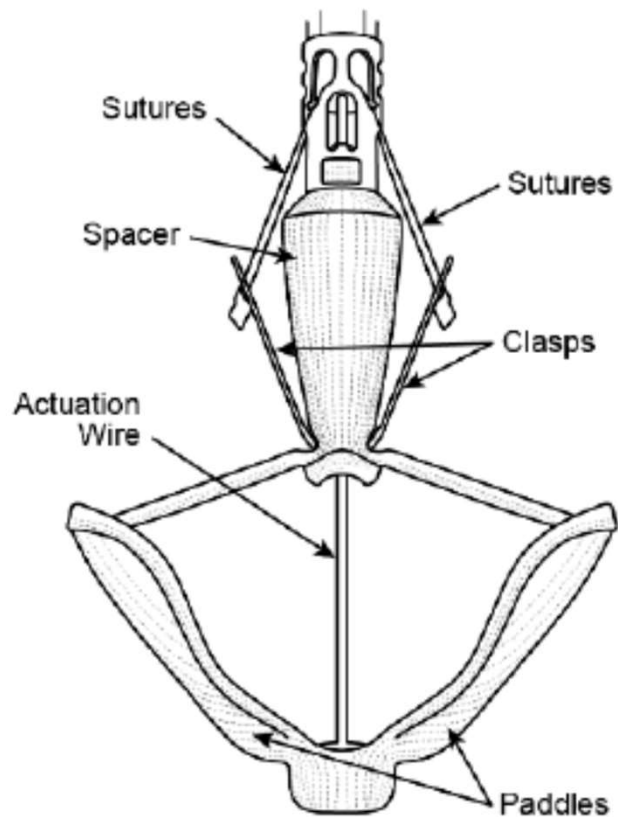
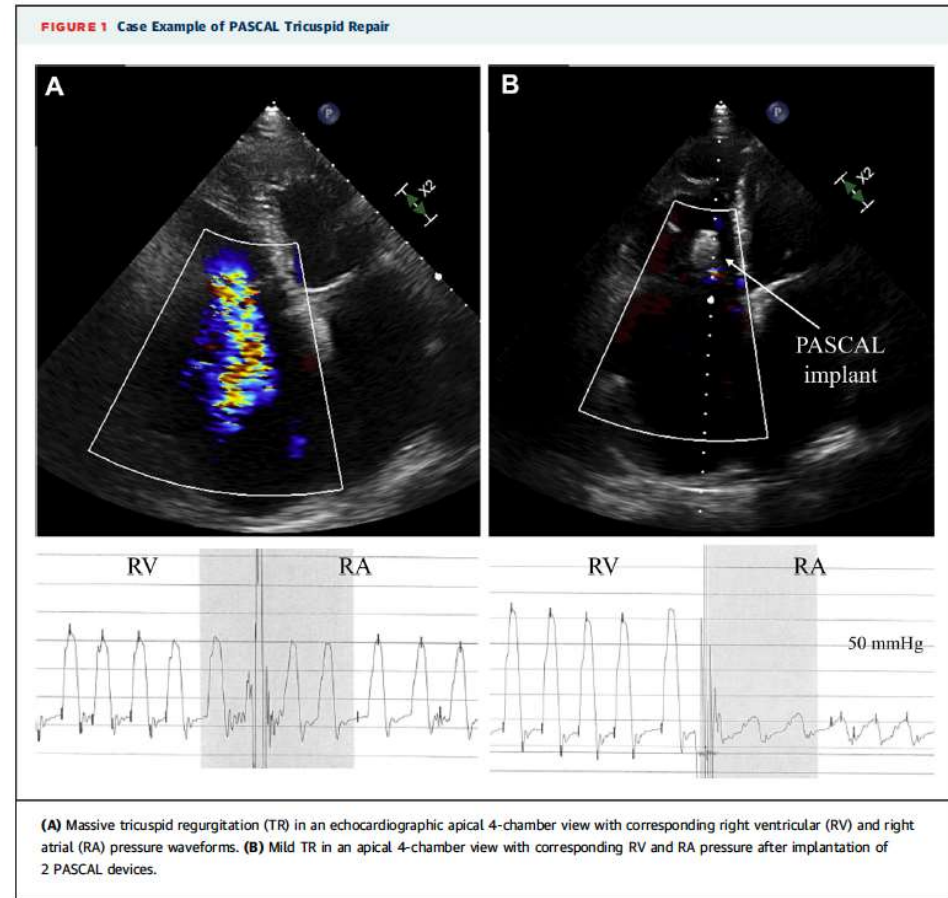
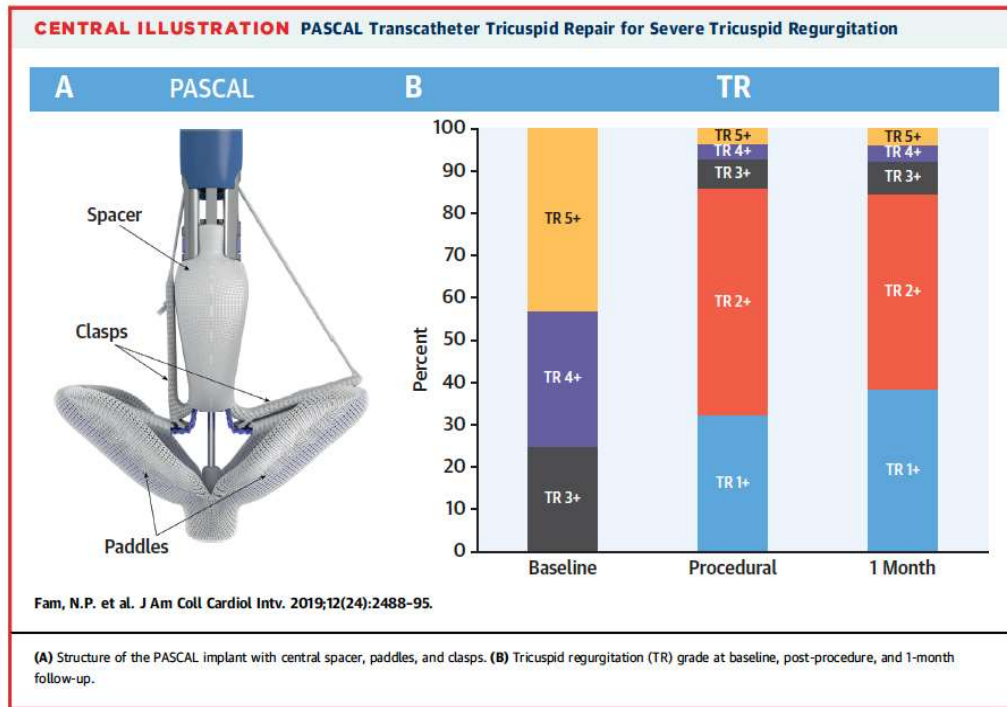


Figure 6. PASCAL Implant

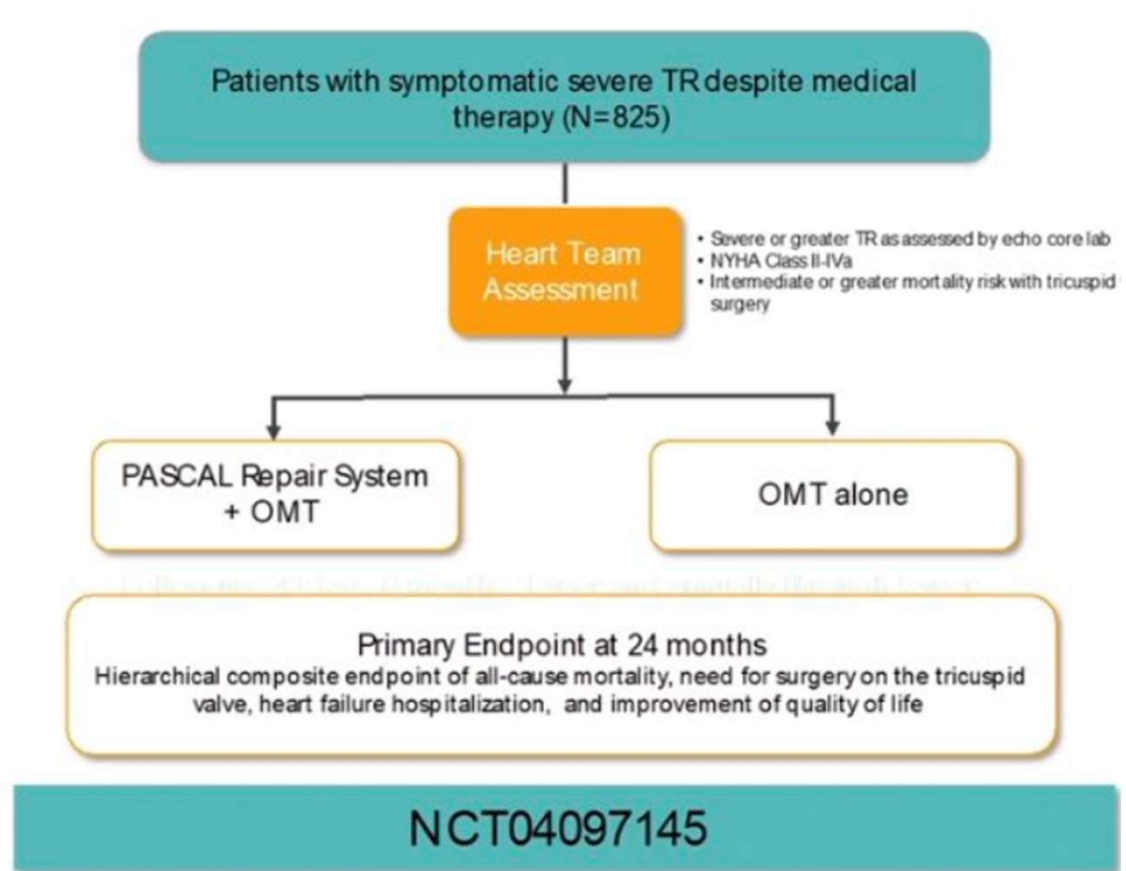
# First-in-human trials



# CLASP II TR Trial

## The Edwards PASCAL TrAnScatheter Valve RePair System Pivotal Clinical Trial (CLASP II TR)

- Prospective, multicenter, randomized, controlled pivotal trial
- Purpose | Evaluate the safety and effectiveness of the PASCAL Repair System and optimal medical therapy (OMT) compared to OMT alone in patients with symptomatic severe TR





# CLASP II TR

PASCAL Transcatheter Valve Repair System  
Pivotal Clinical Trial

PI: Michael Young, MD, RPVI

**Question:** For patients with severe tricuspid regurgitation, is it safe and effective to use the Edwards PASCAL transcatheter valve repair system in addition to optimal medical therapy versus optimal medical therapy alone?

**Rationale:** Compassionate use of the PASCAL system in patients with severe or greater TR showed a decrease in severity of TR to  $\leq 2+$ , a decrease in NYHA to 1 or 2, and a significant improvement in 6 minute walk distances.



**Eligible Patients:**

1. Severe (4+) or greater functional/degenerative TR
2. NYHA II-IV
3. LVEF >25%
4. PASP  $\leq$  70 mmHg

**Research Nurse:**  
Hannah Ellis, RN  
Phone: 5-6228  
Pager: 7561

Learn more at  
[clinicaltrials.gov](http://clinicaltrials.gov)  
by scanning the  
QR code!



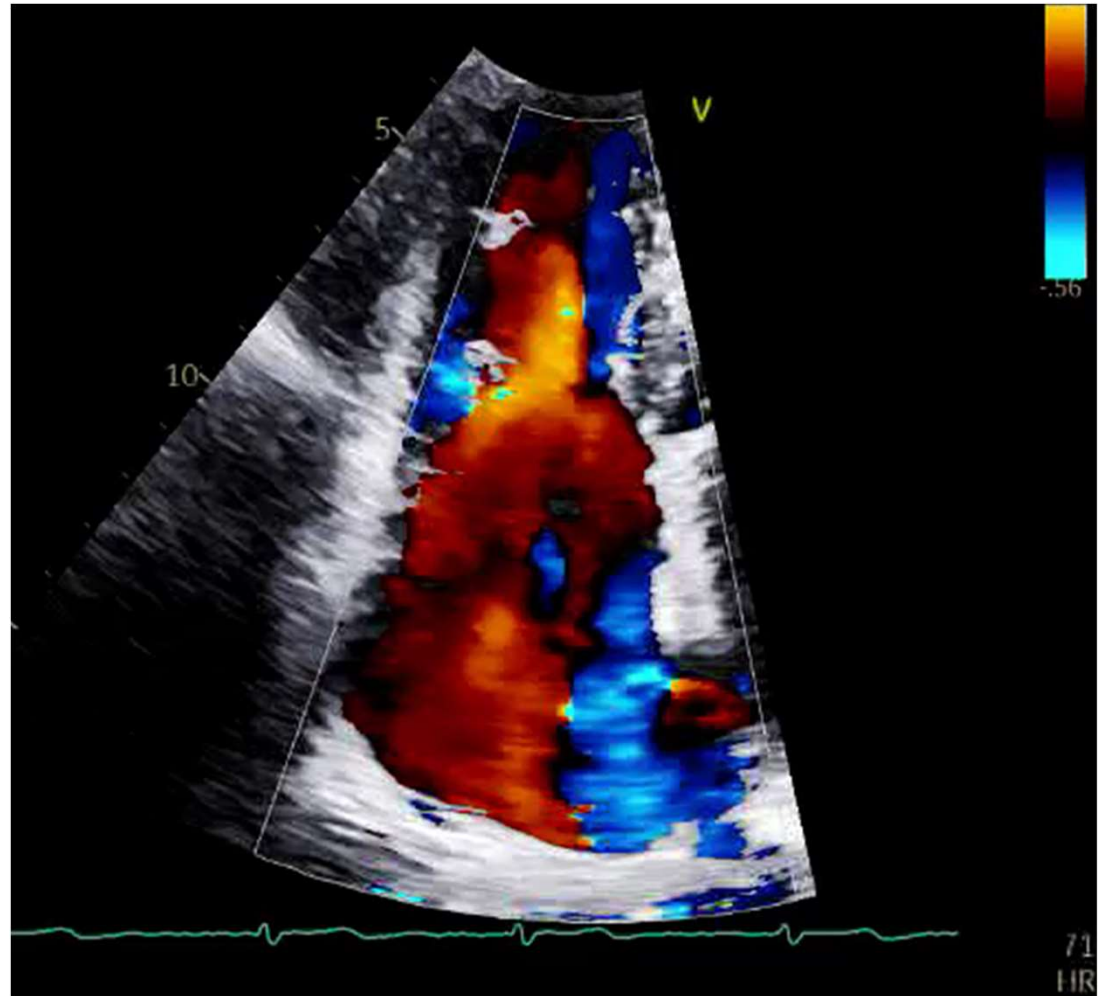
*“My energy has returned. I am quilting! My daughter was shocked when she walked in and saw me mopping and readying to wax my kitchen floor. I hadn’t done that in years!”*



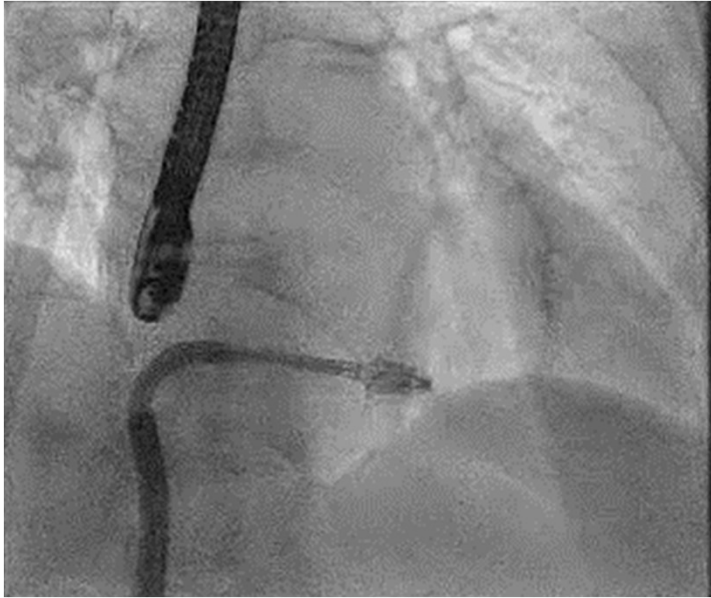
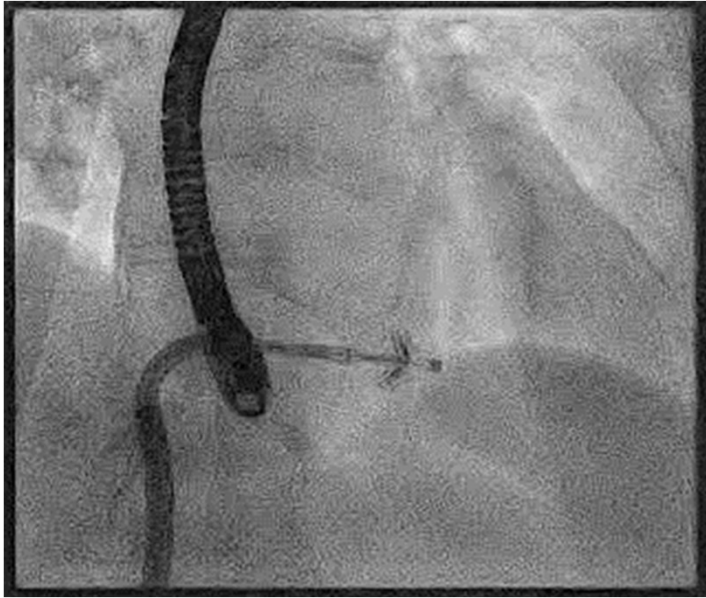
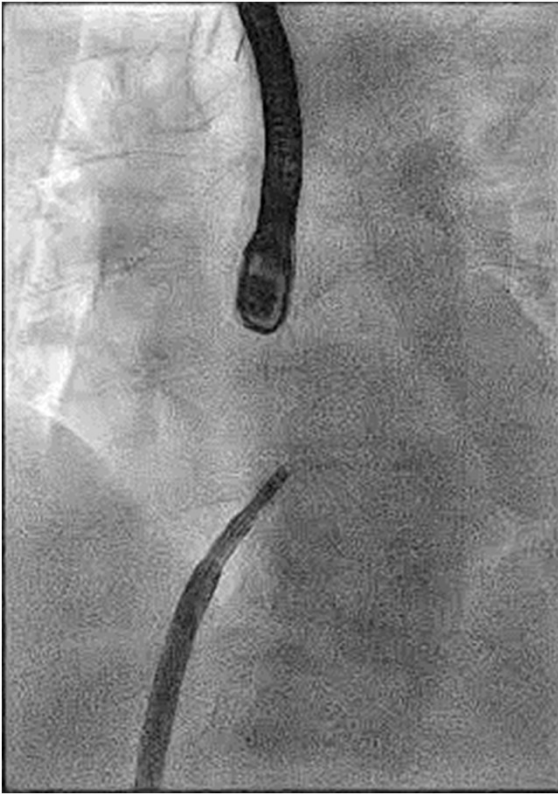
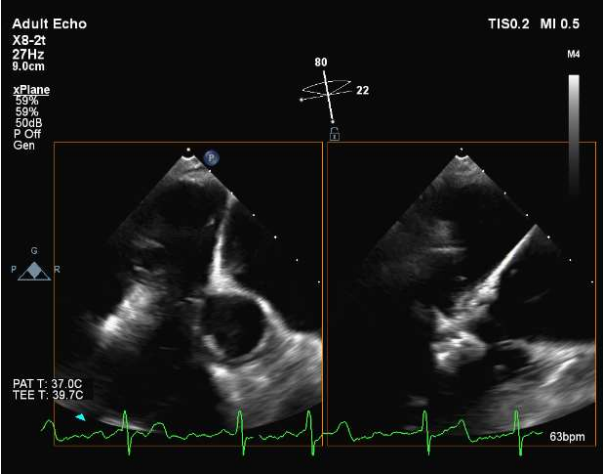
# Case: 81 year old female with severe TR, atrial fibrillation, type II DM, HTN, h/o colon cancer

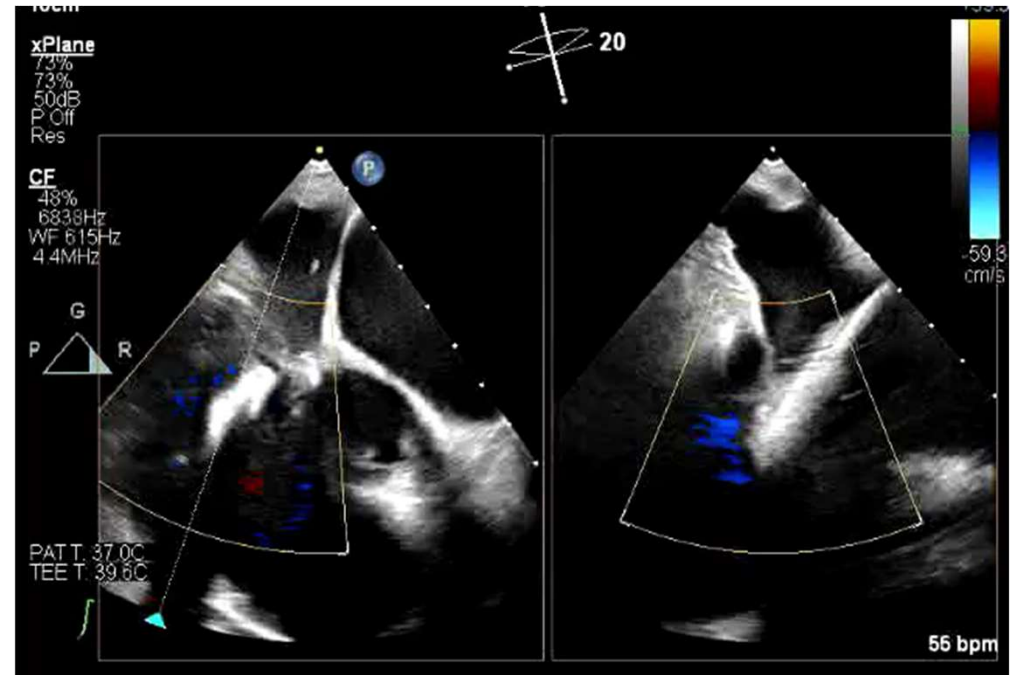
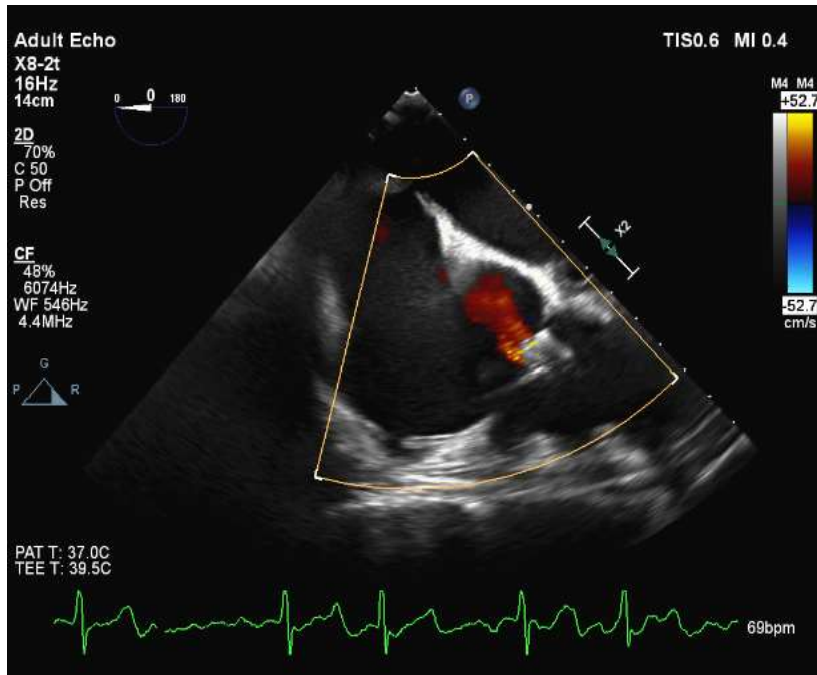
- Primary symptoms of shortness of breath and fatigue
- TTE: LVEF 55%, RV mildly dilated with normal systolic function, RVSP ~41 mmHg, severe (4+/4+) TR.
- TEE: Severe (4+/4+) functional TR due to malcoaptation due to tricuspid annular dilatation.

# Severe Tricuspid Valve Regurgitation – NYHA Class IV



# Transcatheter TV Repair

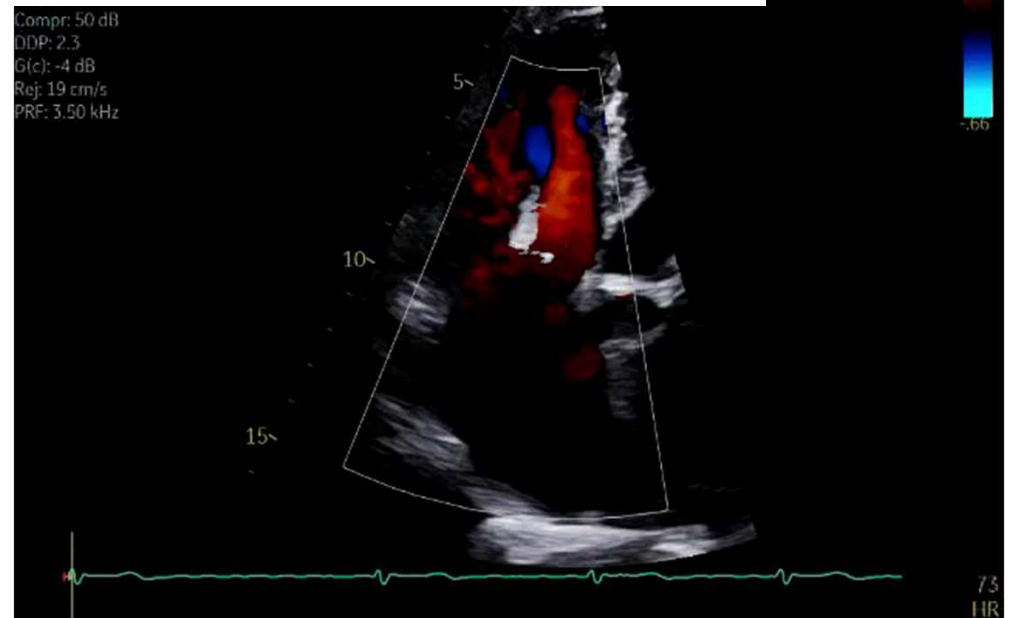





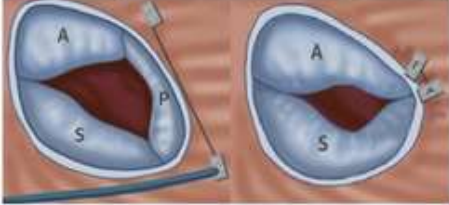



8. Compared to the prior study 12/18/2020 the right ventricle has decreased in size and normalized in function. The residual tricuspid regurgitation appears mild.

## Discharged POD#1

**1 month follow-up:  
NYHA Class I  
TTE with mild residual TR**



# Investigational Tricuspid Valve Devices

<p><b>Leaflet Coaptation Devices</b></p>	
<p><b>Direct Suture Annuloplasty</b></p>	 <p><b>Trialign</b></p>
<p><b>Ring Annuloplasty</b></p>	 <p><b>Cardioband</b>      <b>TriCinch</b>      <b>Millipede IRIS</b></p>
<p><b>Valve Replacement</b></p>	 <p><b>NaviGate</b>      <b>Evoque</b></p>
<p><b>Stented Valves in SVC/IVC</b></p>	 <p><b>Sapien XT</b>      <b>Sapien S3</b>      <b>TricValve</b></p>





# AGENDA

## I. Primary and Secondary Mitral Valve Regurgitation

- Where we are: Transcatheter Edge-to-Edge Repair (TEER)

## II. Mitral Regurgitation +/- Calcific Mitral Stenosis

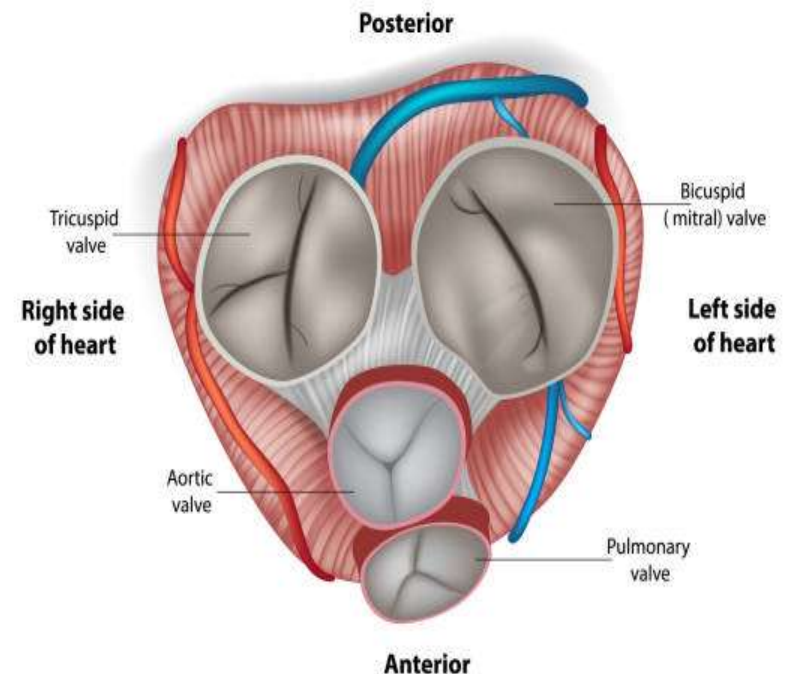
- Where we are going: Transcatheter Mitral Valve Replacement (TMVR)

## III. Tricuspid Valve Regurgitation

- How we get there: Innovation

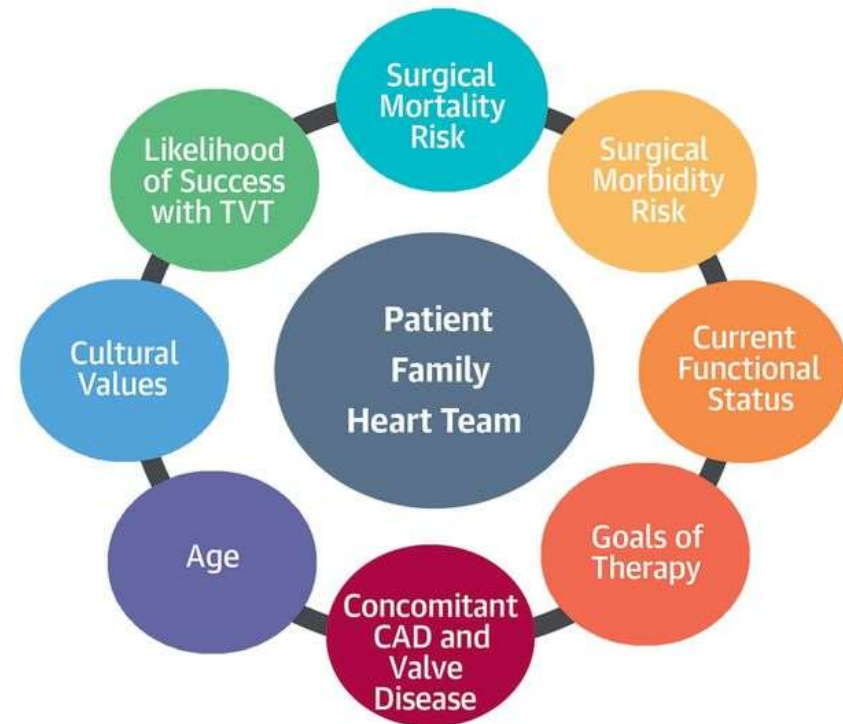
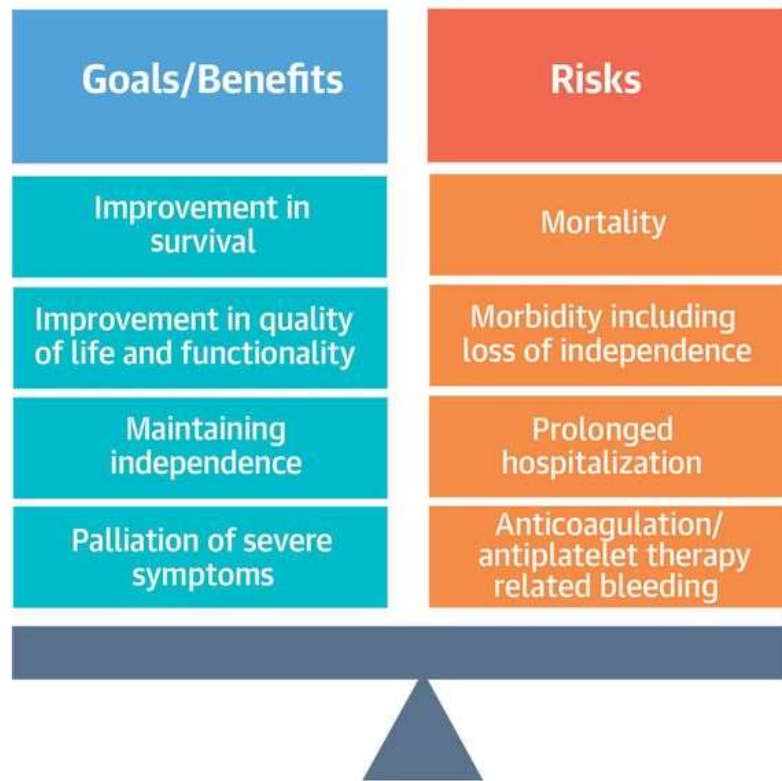
## IV. Multidisciplinary Heart Team

- Who we are: DHMC

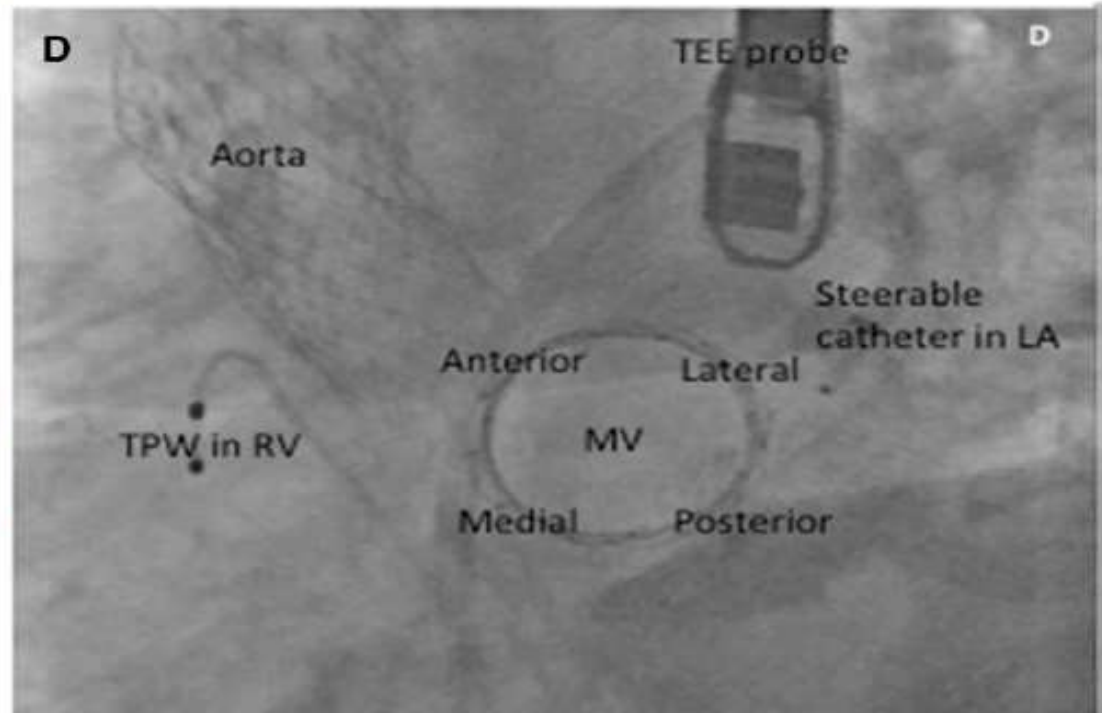
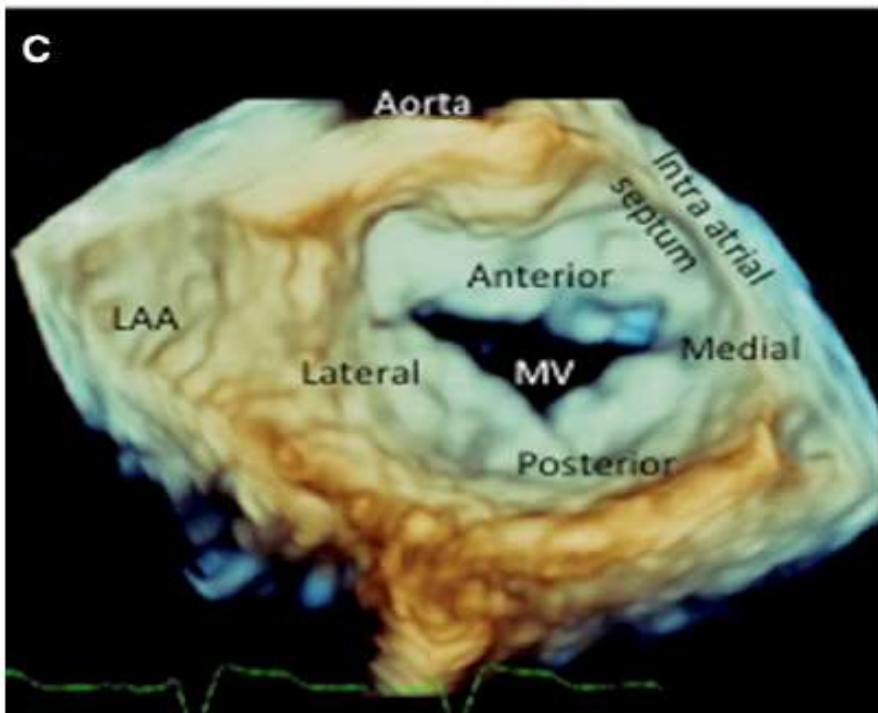
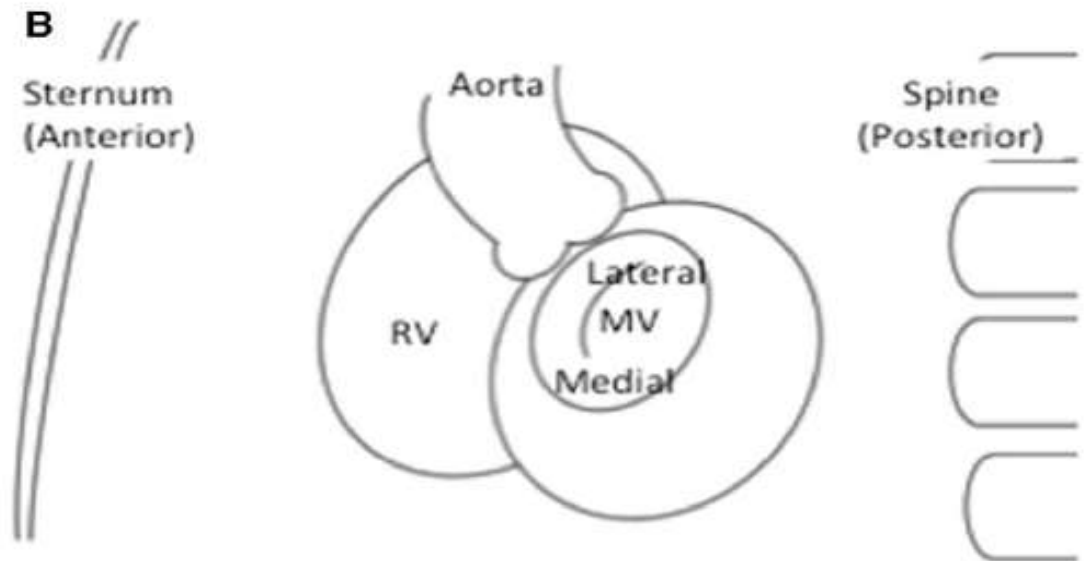
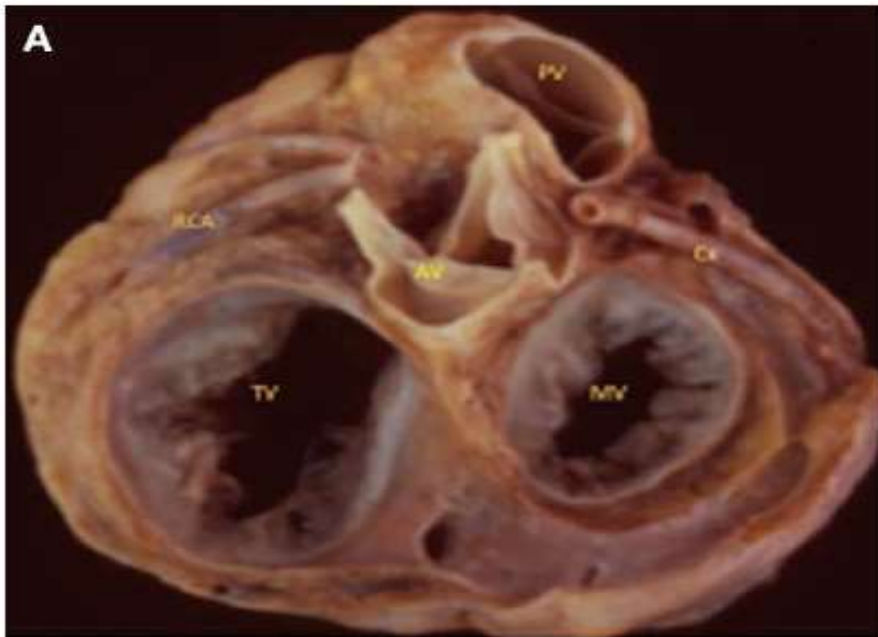


# Multidisciplinary Heart Team

## CENTRAL ILLUSTRATION: Successful Management of Valvular Heart Disease in the Elderly



Kodali, S.K. et al. *J Am Coll Cardiol.* 2018;71(18):2058-72.

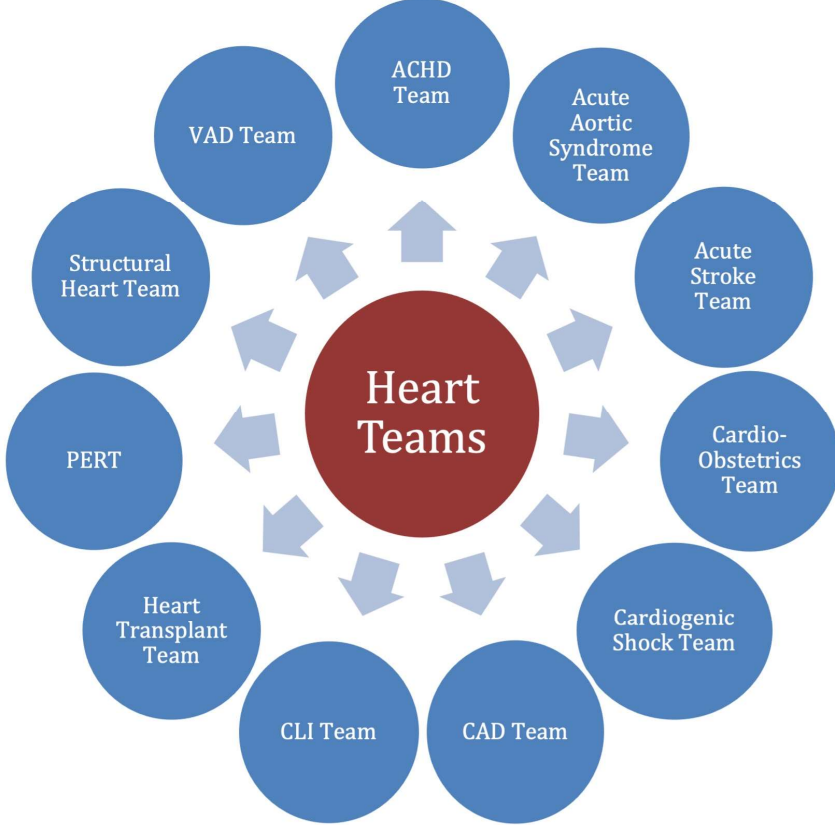


# Multidisciplinary Heart Team

**CENTRAL ILLUSTRATION: Successful Management of Valvular Heart Disease in the Elderly**

Goals/Benefits	Risks
Improvement in survival	Mortality
Improvement in quality of life and functionality	Morbidity including loss of independence
Maintaining independence	Prolonged hospitalization
Palliation of severe symptoms	Anticoagulation/antiplatelet therapy related bleeding

Kodali, S.K. et al. J Am Coll Cardiol. 2018;71(18):2058-72.



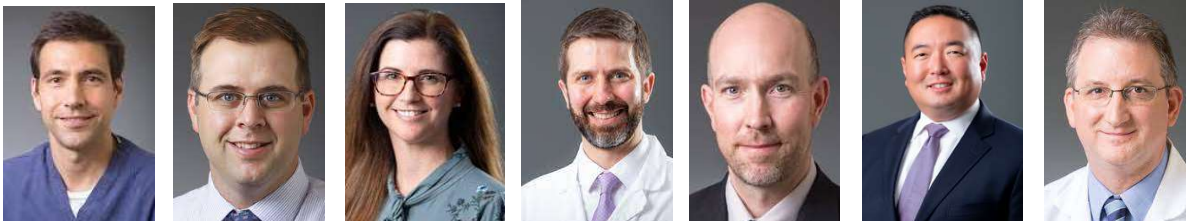
# Structural Heart Team at Dartmouth



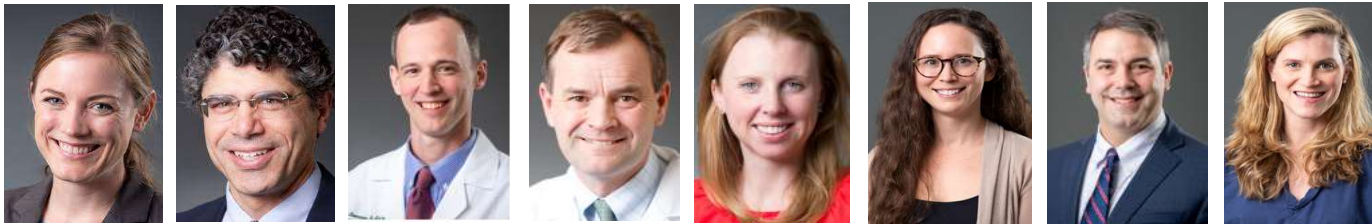
Interventional Cardiology  
Cardiac Surgery



Randy McDonald, RN



Cardiac Imaging



Cardiac Anesthesia



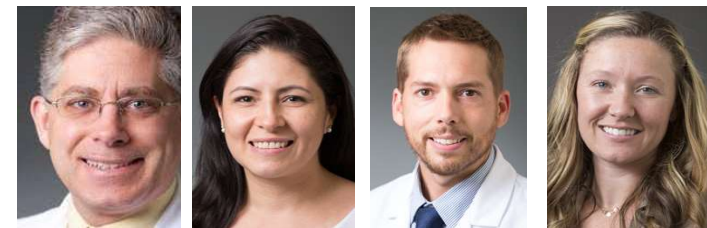
Advanced  
Heart Failure



Electrophysiology



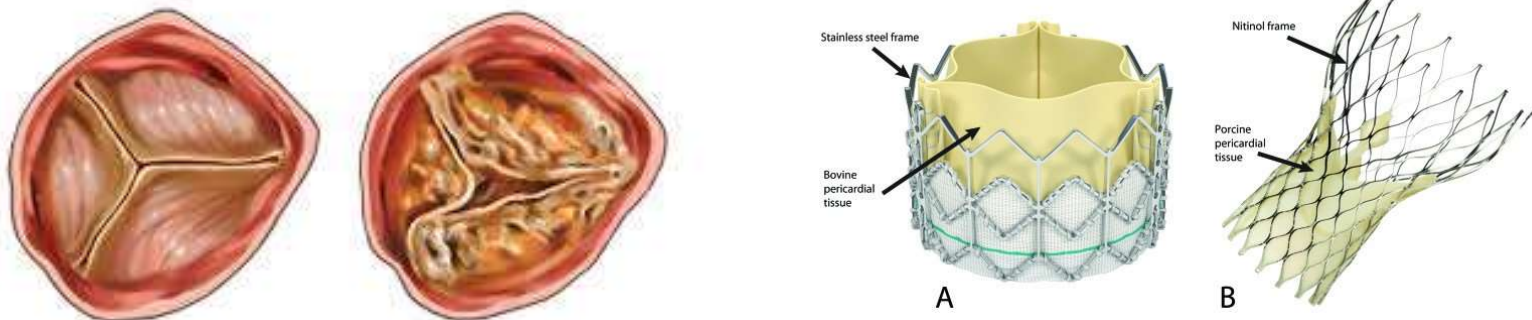
SHD APP Service



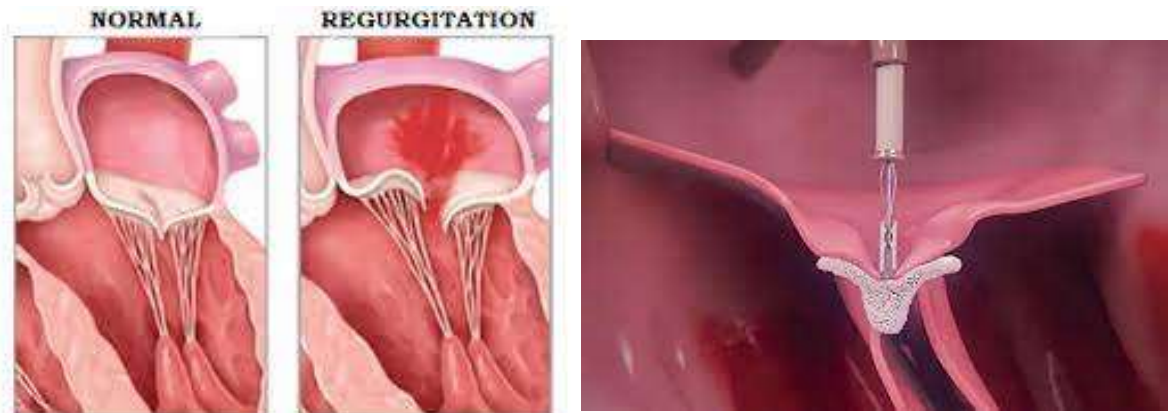
Stroke Neurology

# Interdisciplinary Care Teams

- TAVR Team Meeting (every Thursday 7:00 AM)



- Mitral-Tricuspid (MTV) Meeting (Thursdays 7:30AM)



# TAKE HOME POINTS

- **Percutaneous Therapies for Mitral/Tricuspid Disease**
  - Growing evidence base supporting the safety and efficacy of TEER
- There are numerous emerging mitral and tricuspid valve devices (e.g. annuloplasty, valve replacement) under development and investigation.
- The **Multidisciplinary Heart Team** is the centerpiece in delivering high-value, patient-centered care for SHD.