

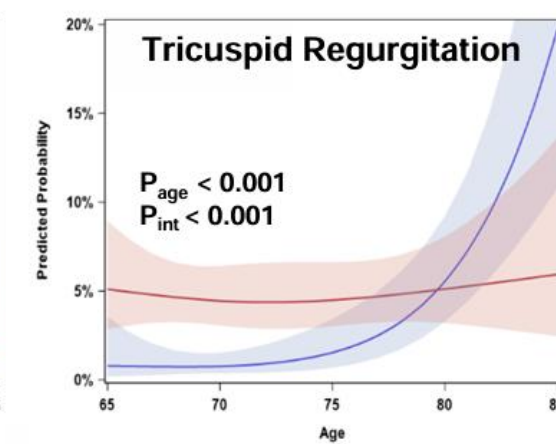
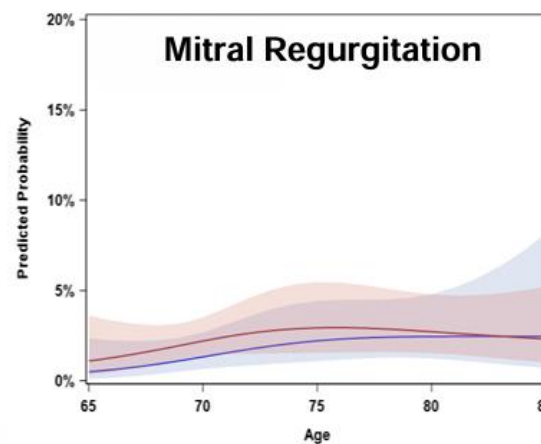
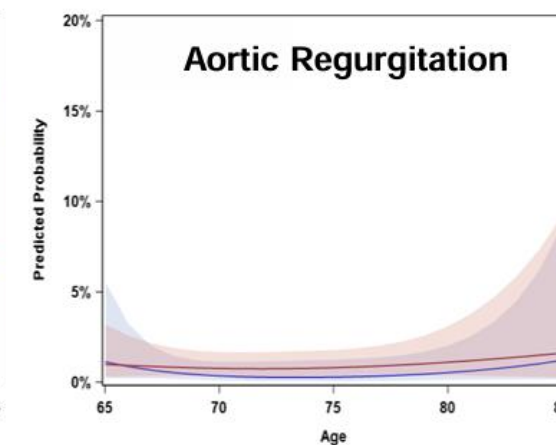
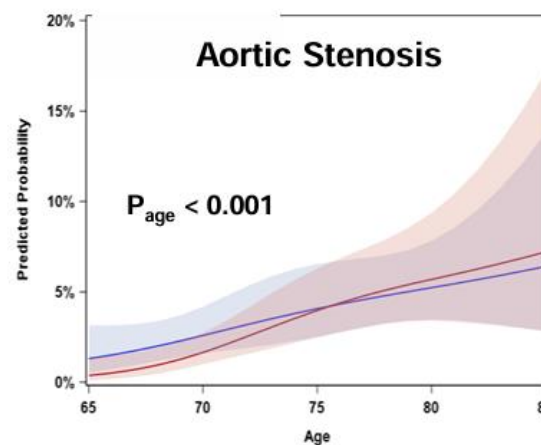
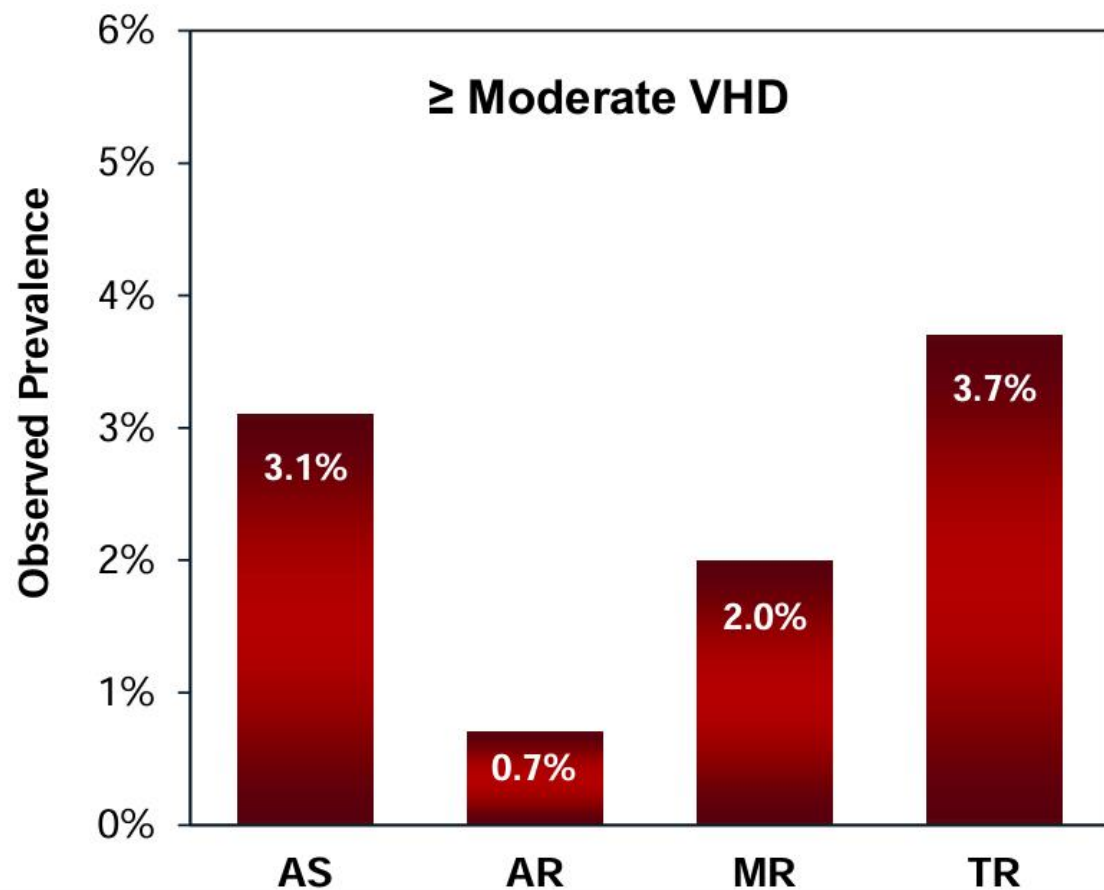


TRICUSPID REGURGITATION

MINIMALLY INVASIVE THERAPIES

JOHN T. SAXON, MD
DECEMBER 5, 2025

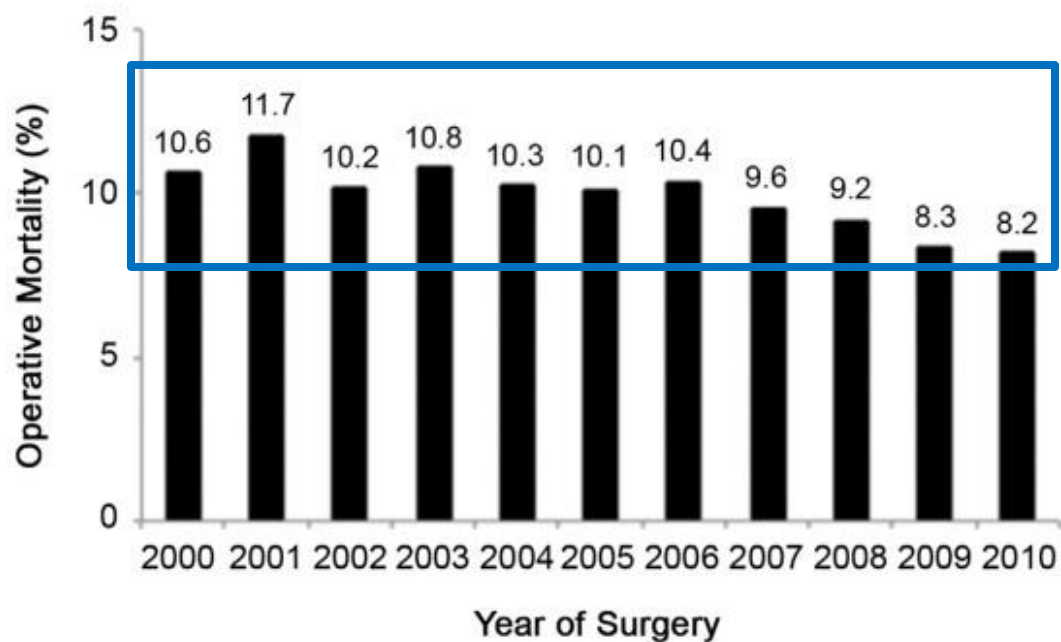
Moderate or Greater VHD by Valve Type



Tricuspid Valve Surgery

High operative mortality

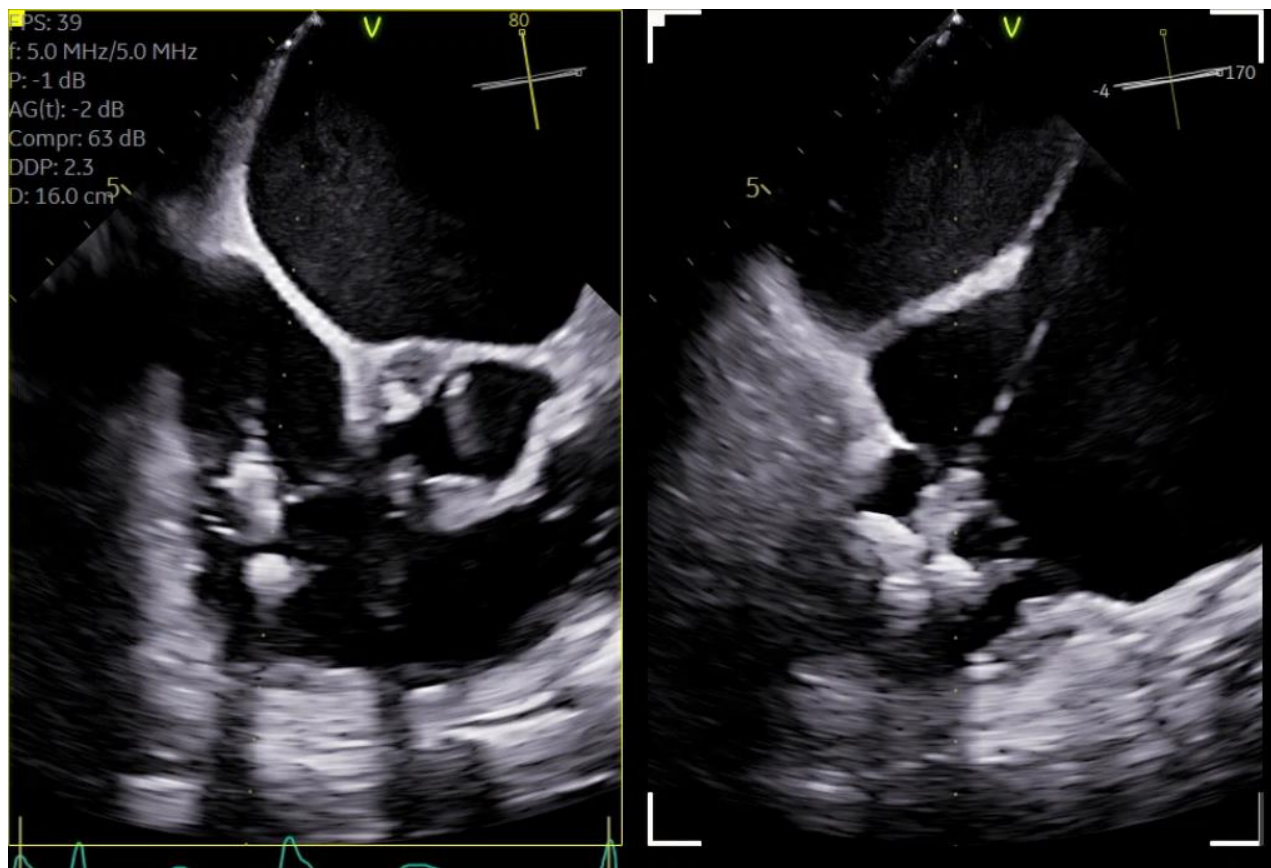
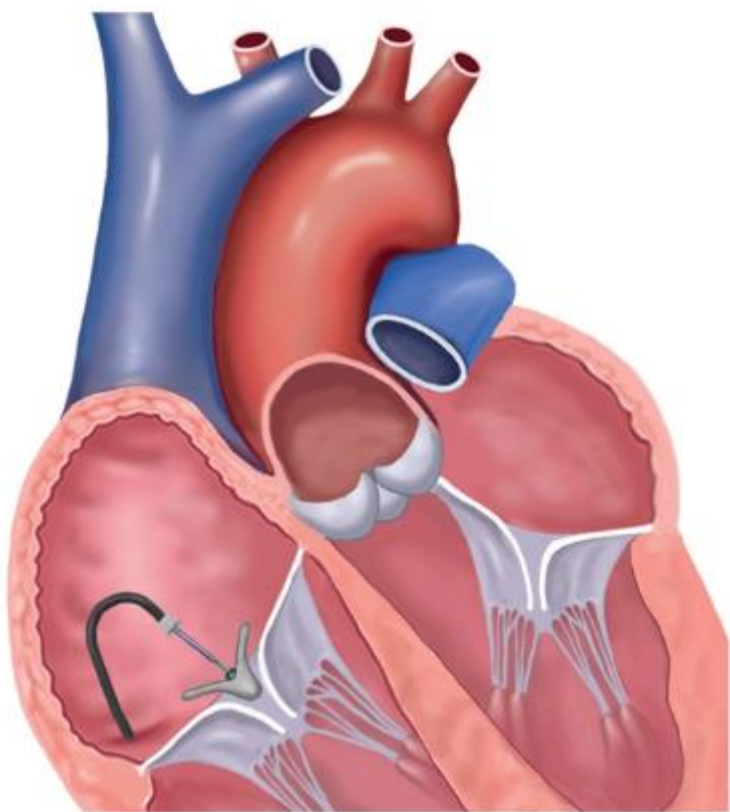
Rarely Isolated



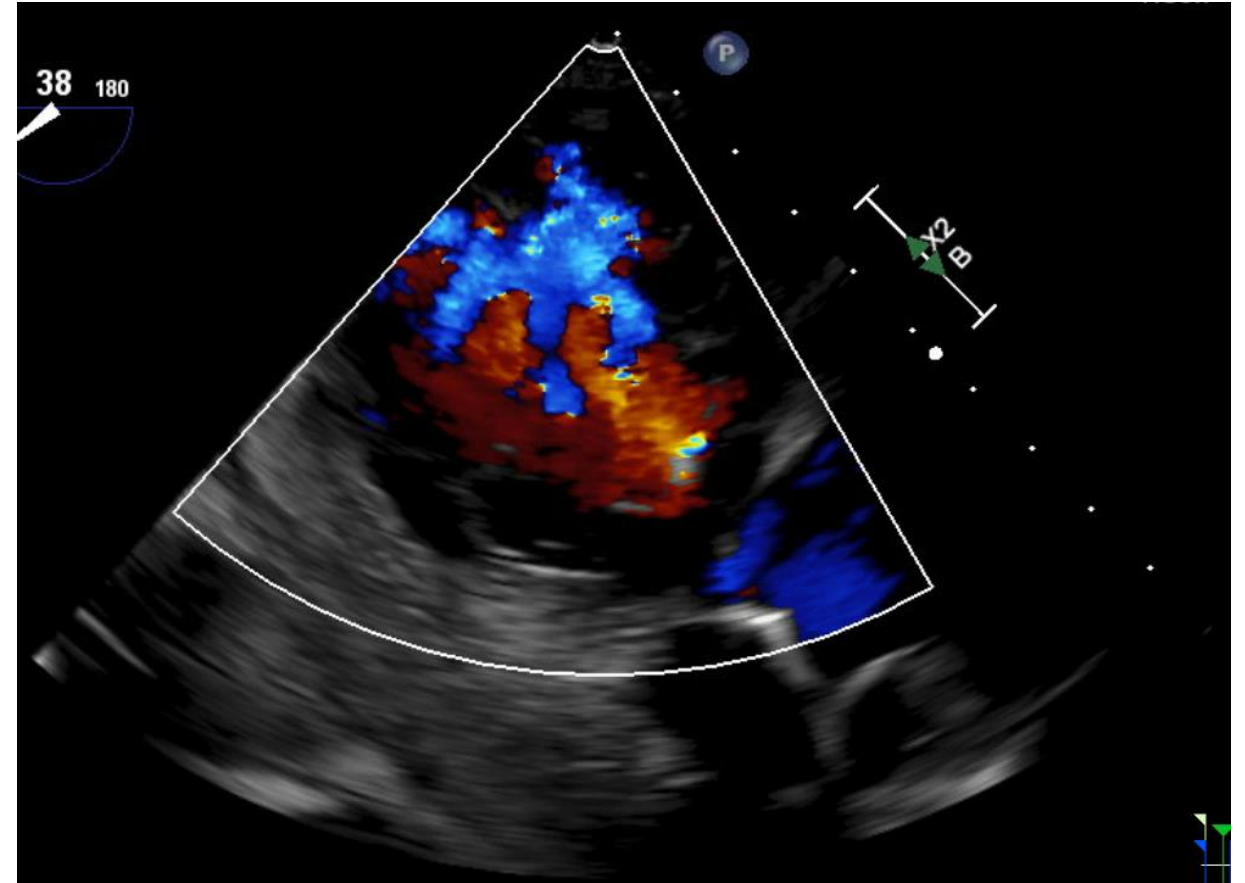
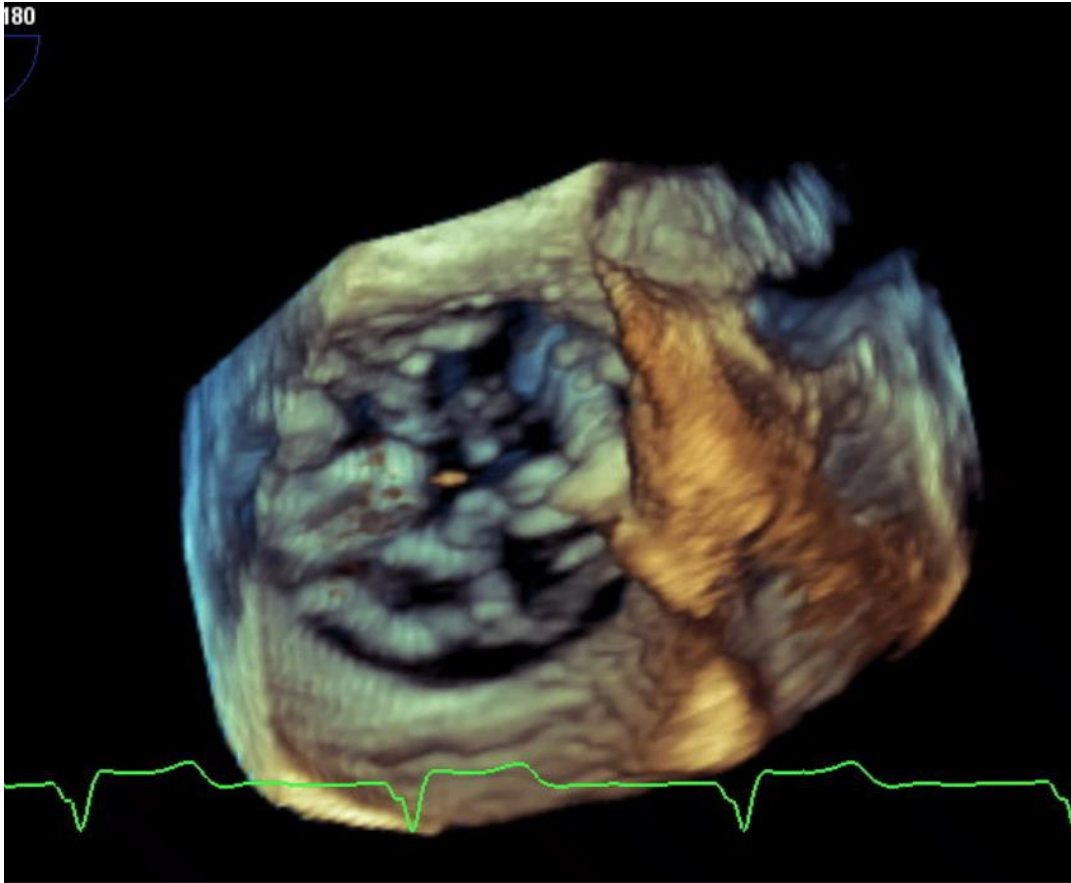
48% mitral
20% mitral + CABG
10% mitral + aortic

Tricuspid Transcatheter Edge-to-Edge Repair

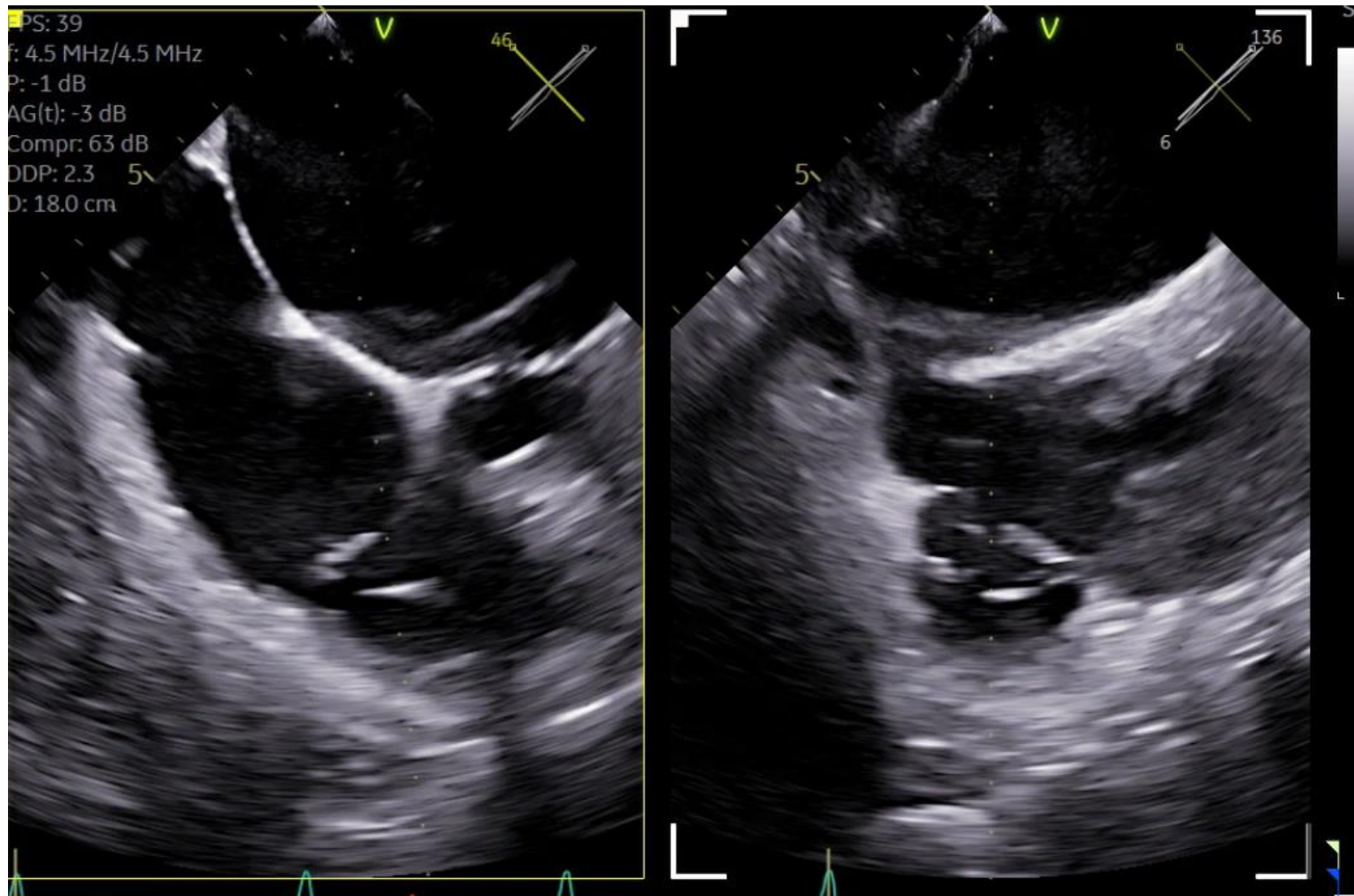
FDA approved Q1 2024

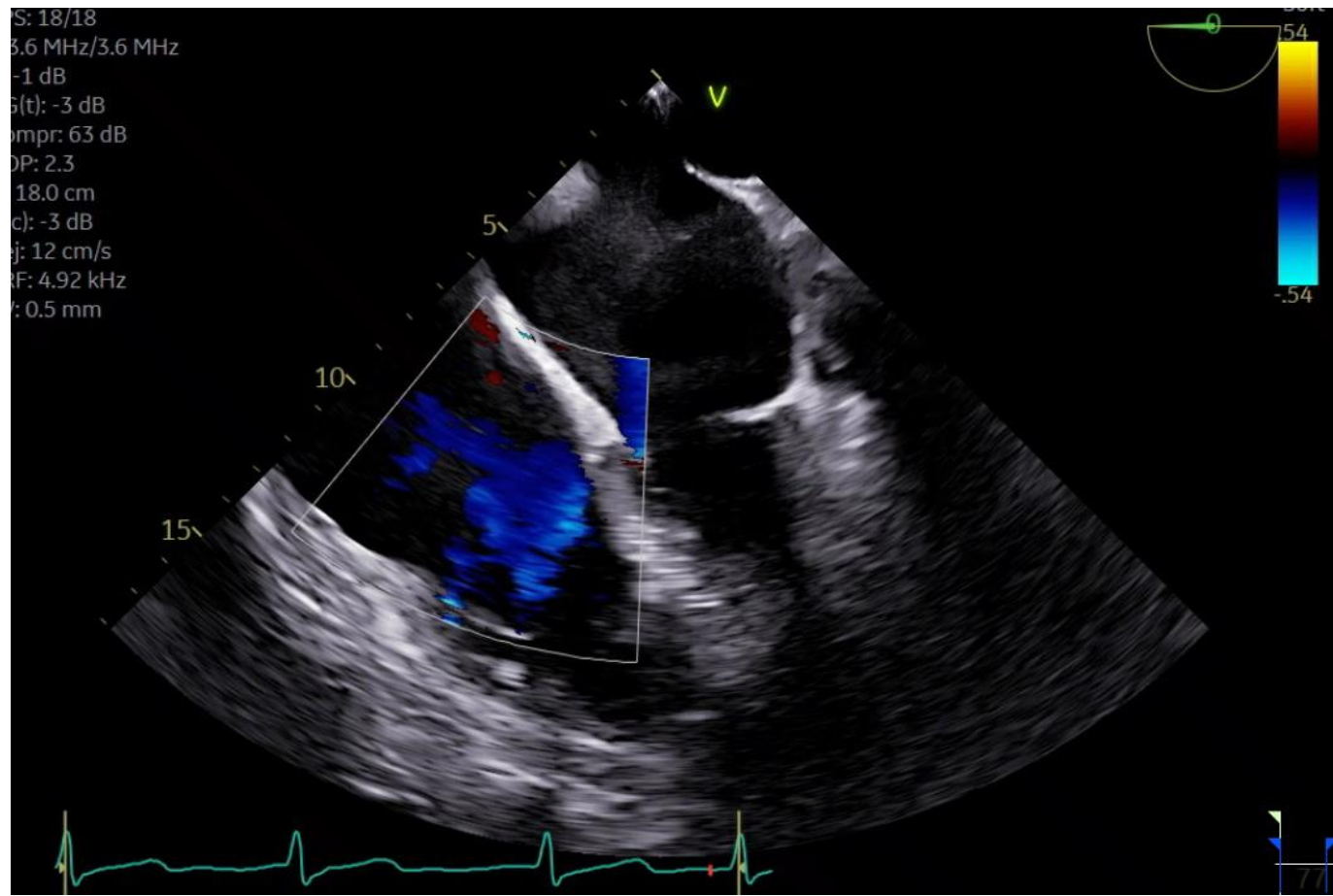


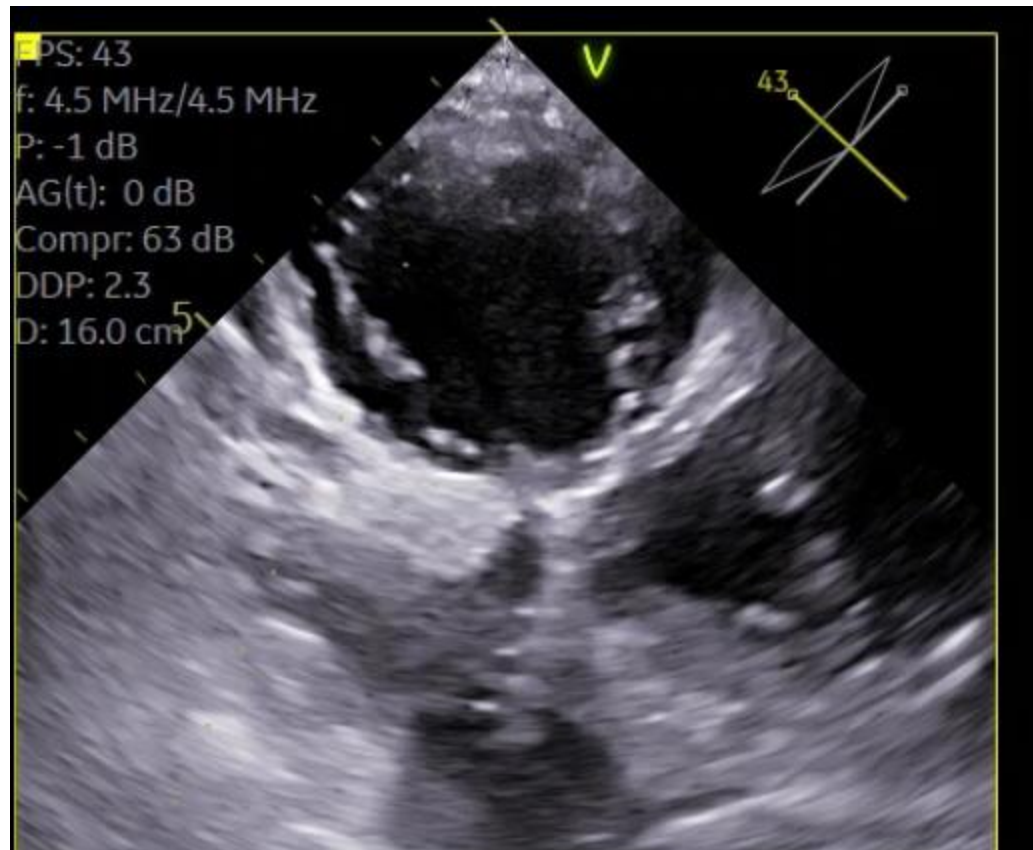
Tricuspid TEER is challenging

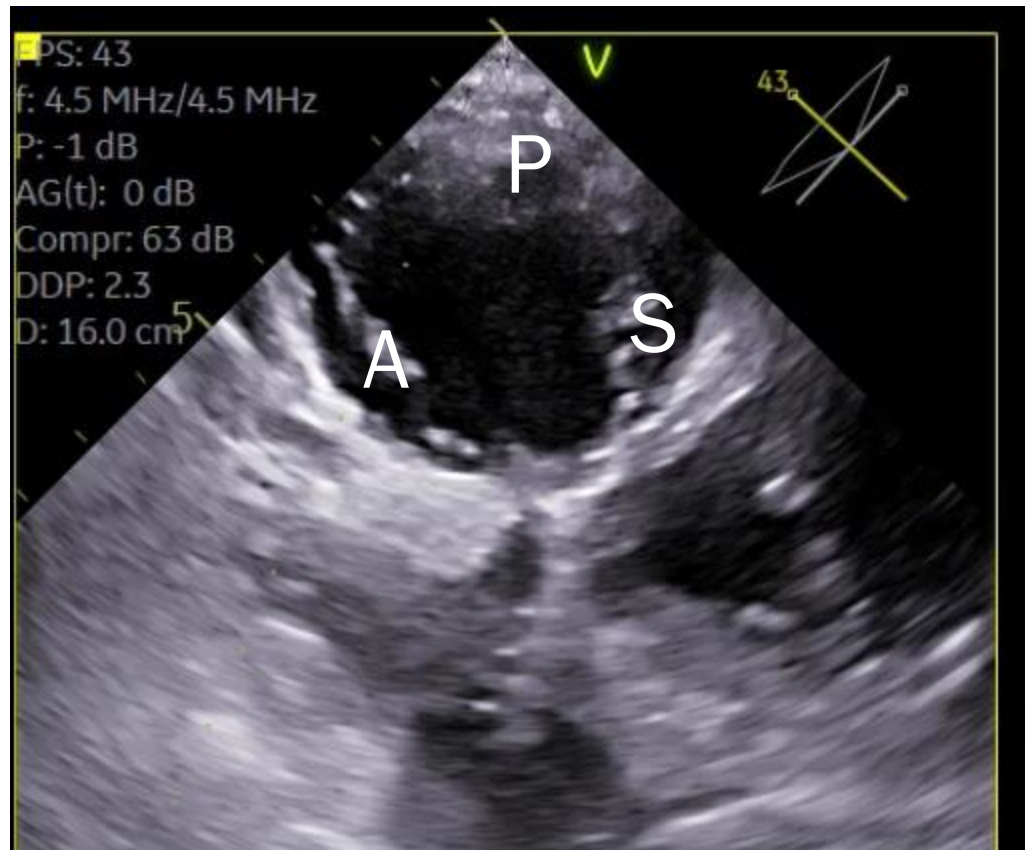


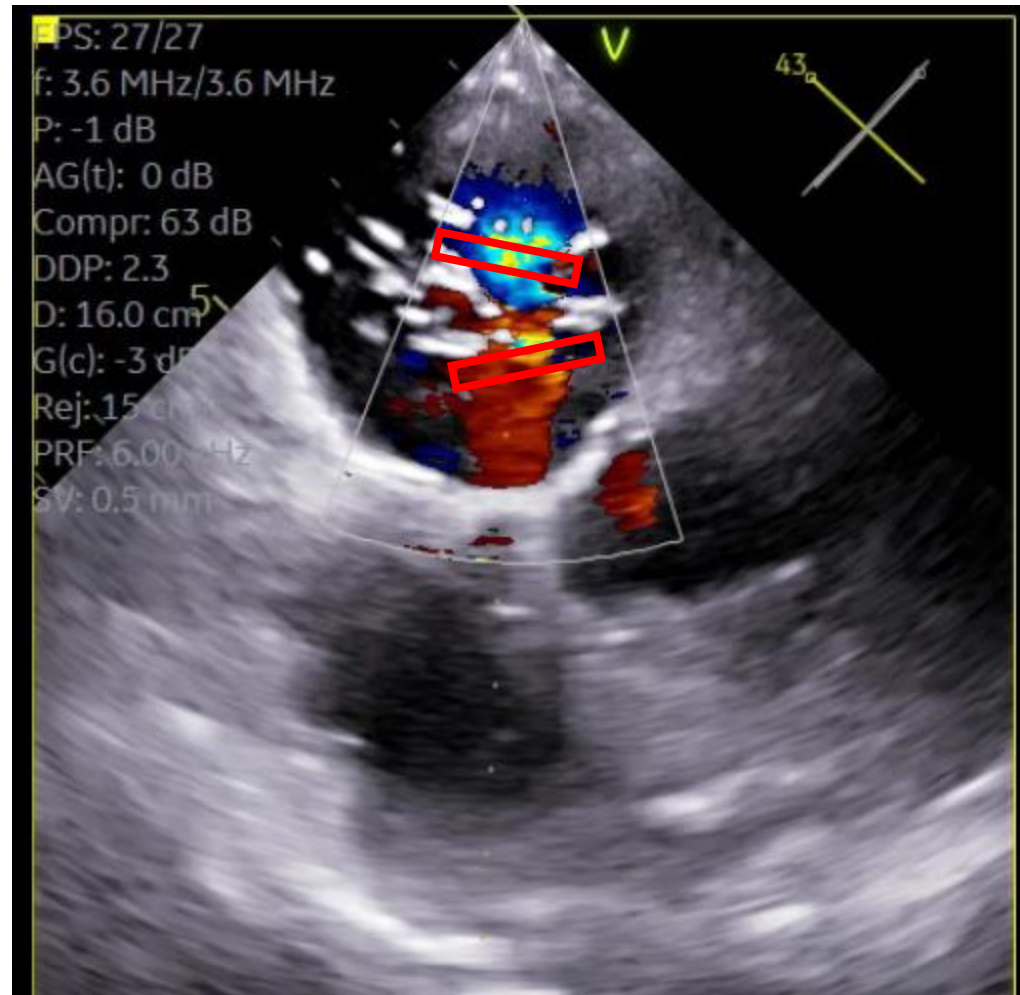
Tricuspid TEER is challenging

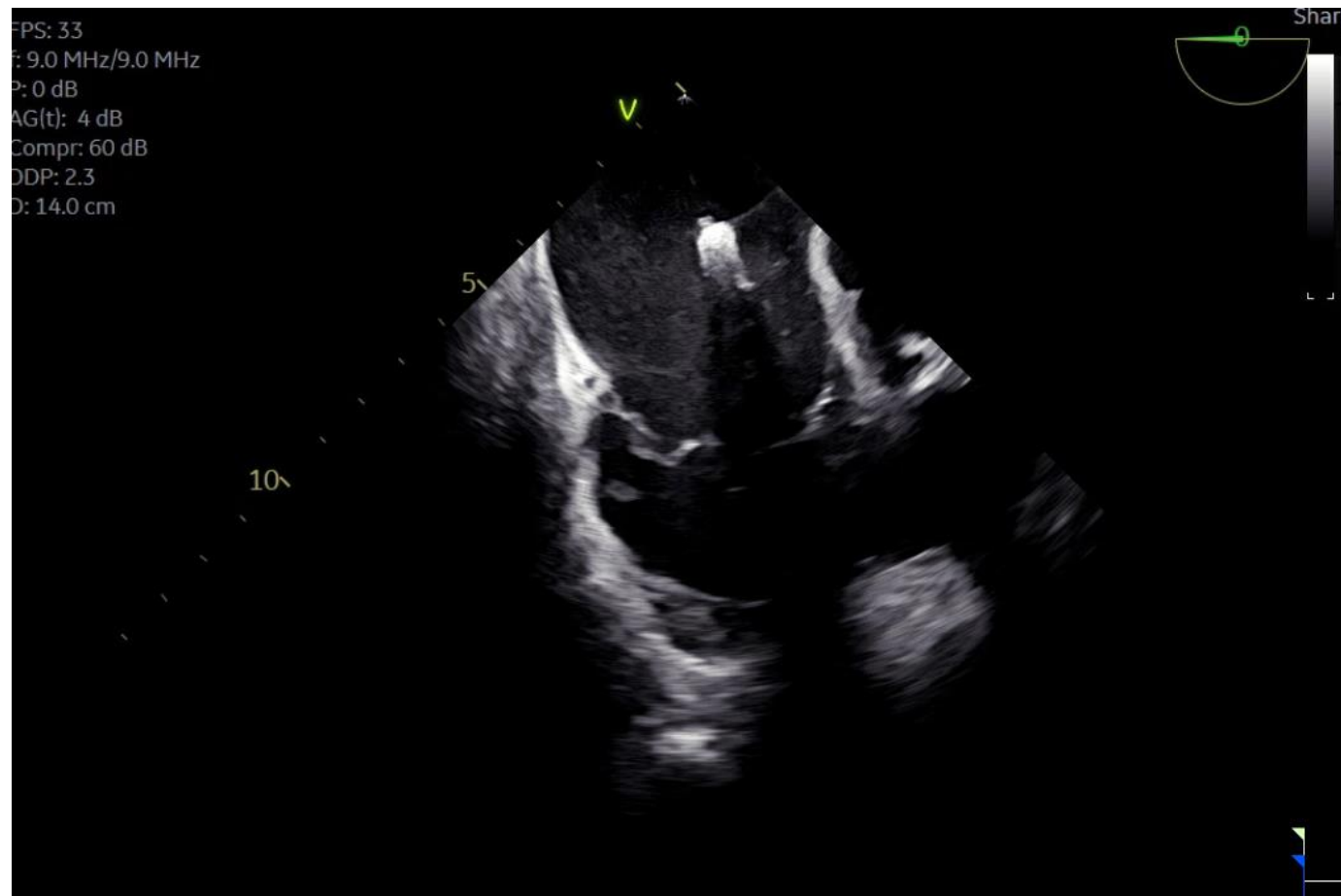


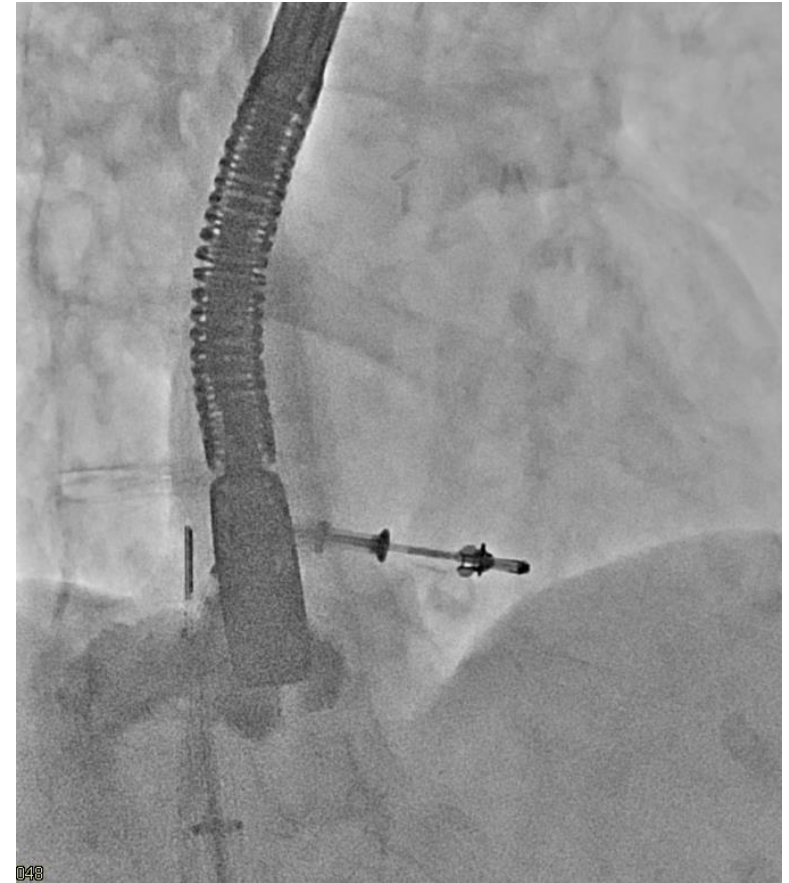
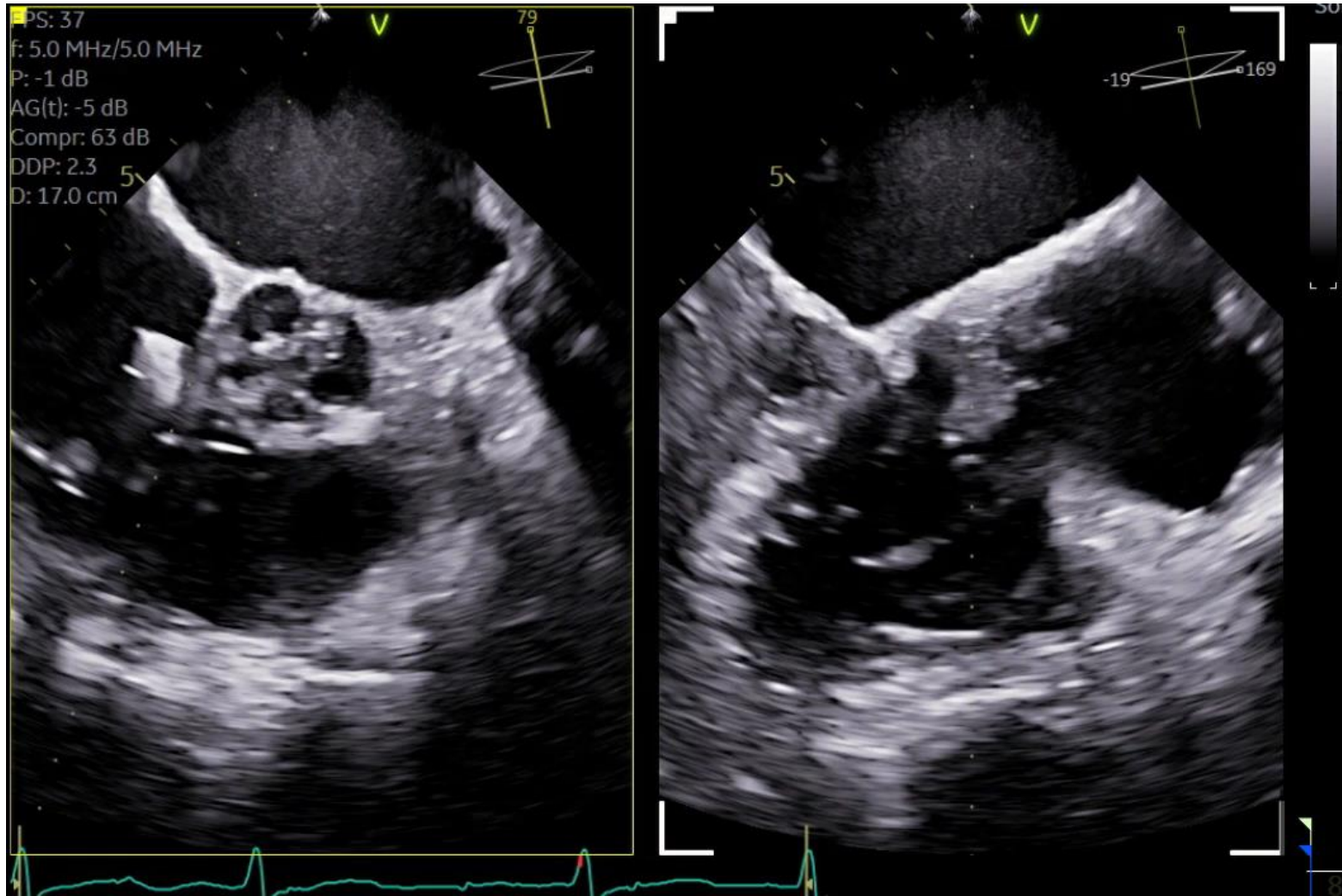




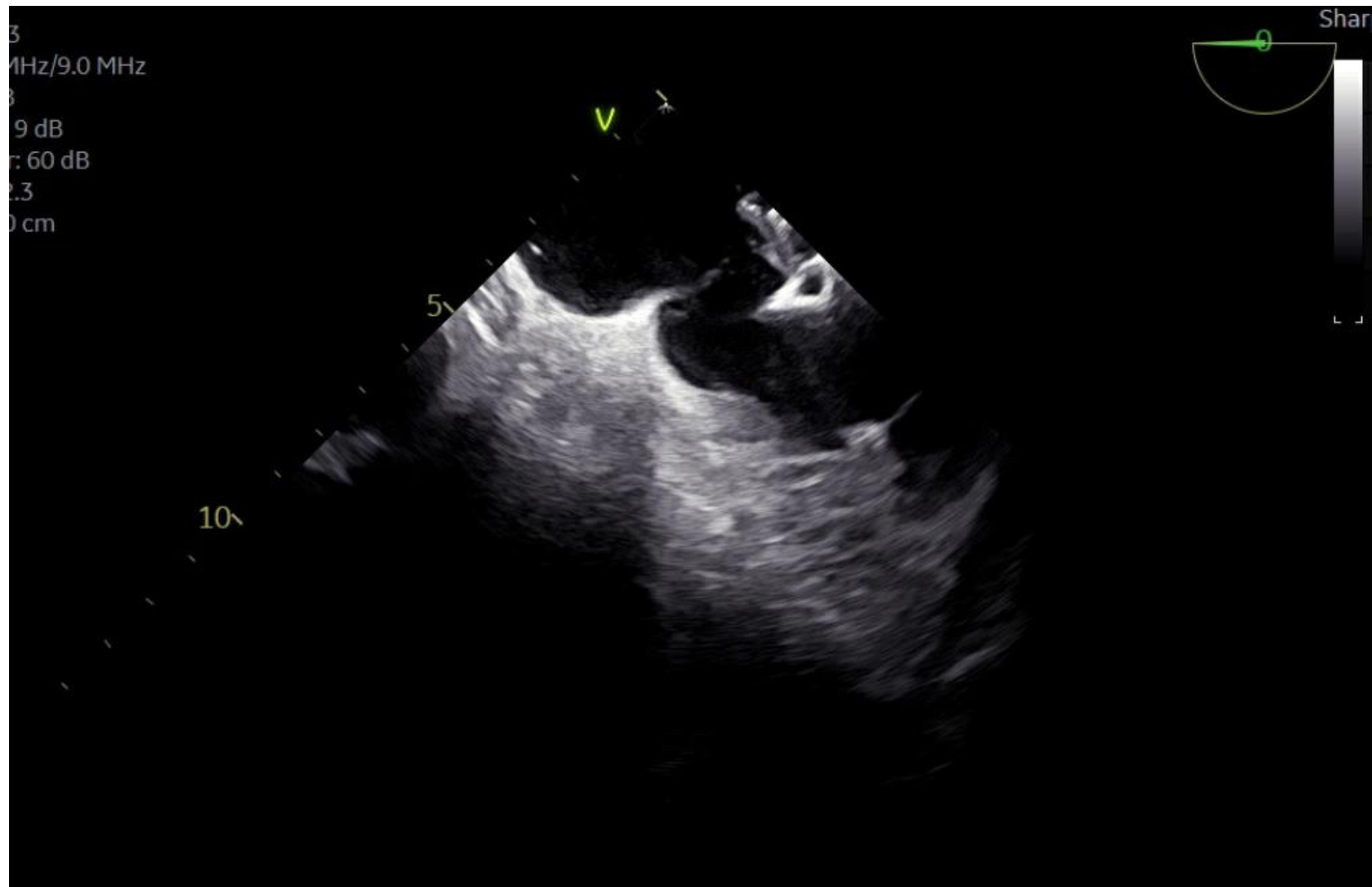


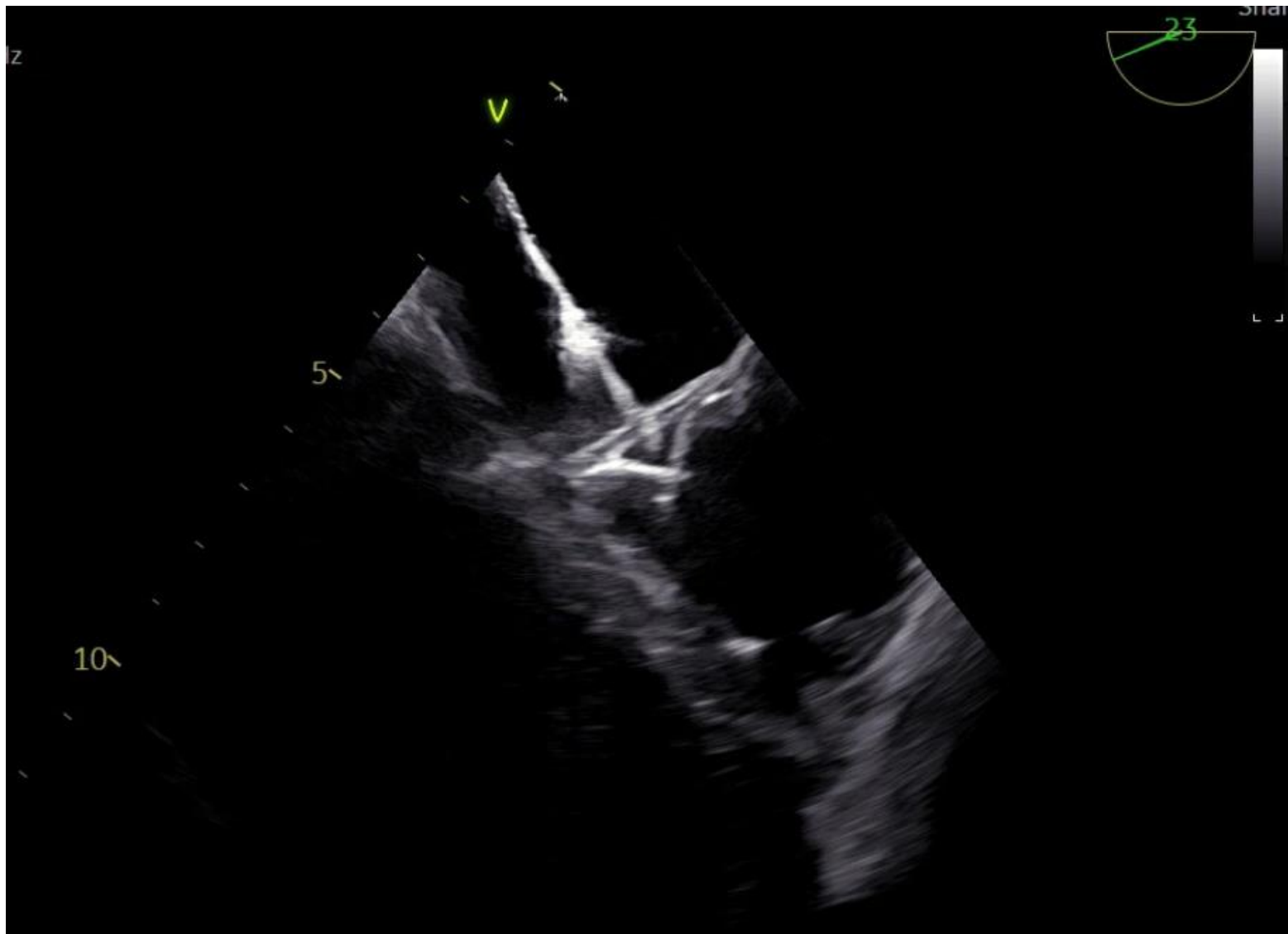


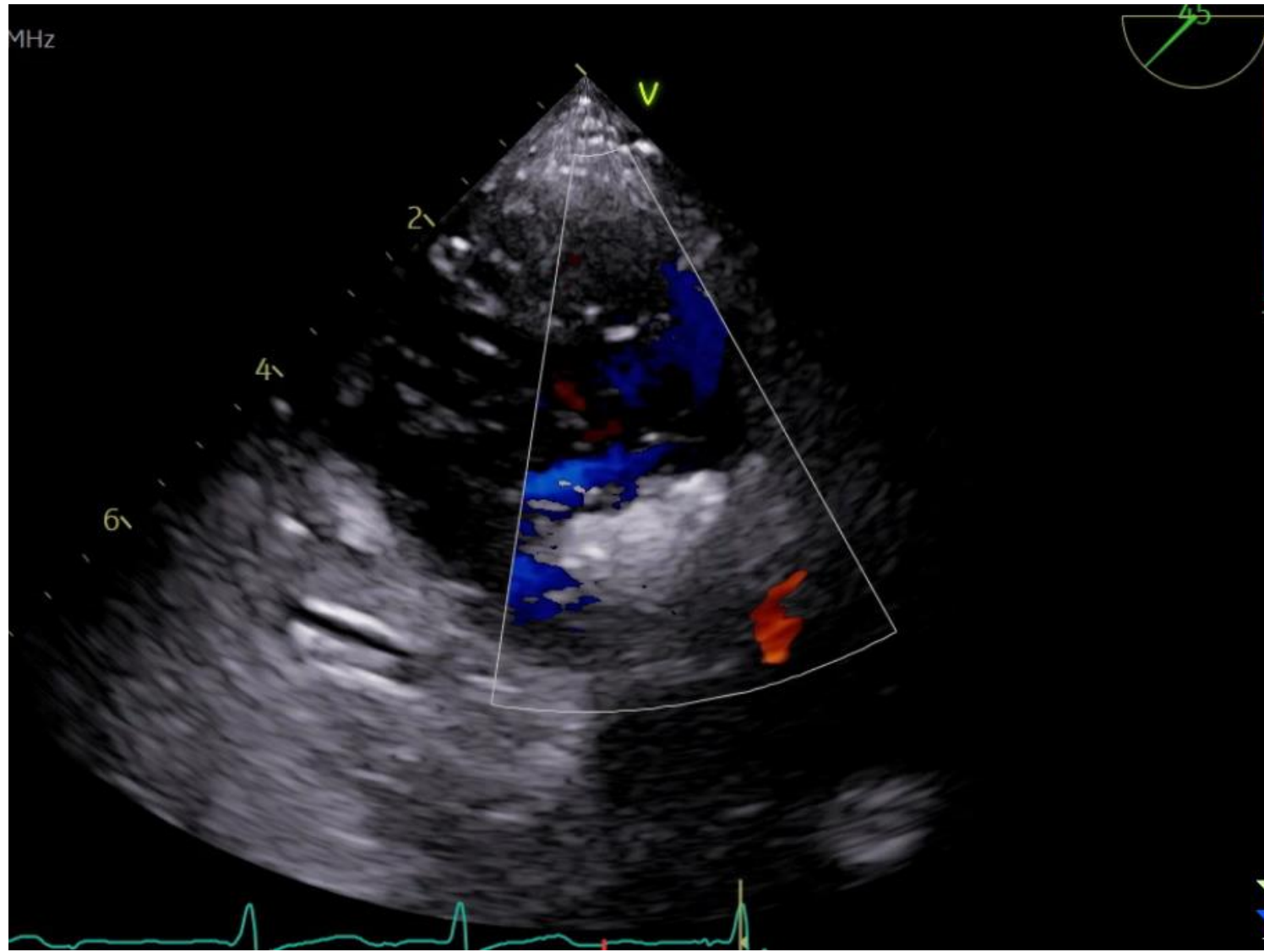


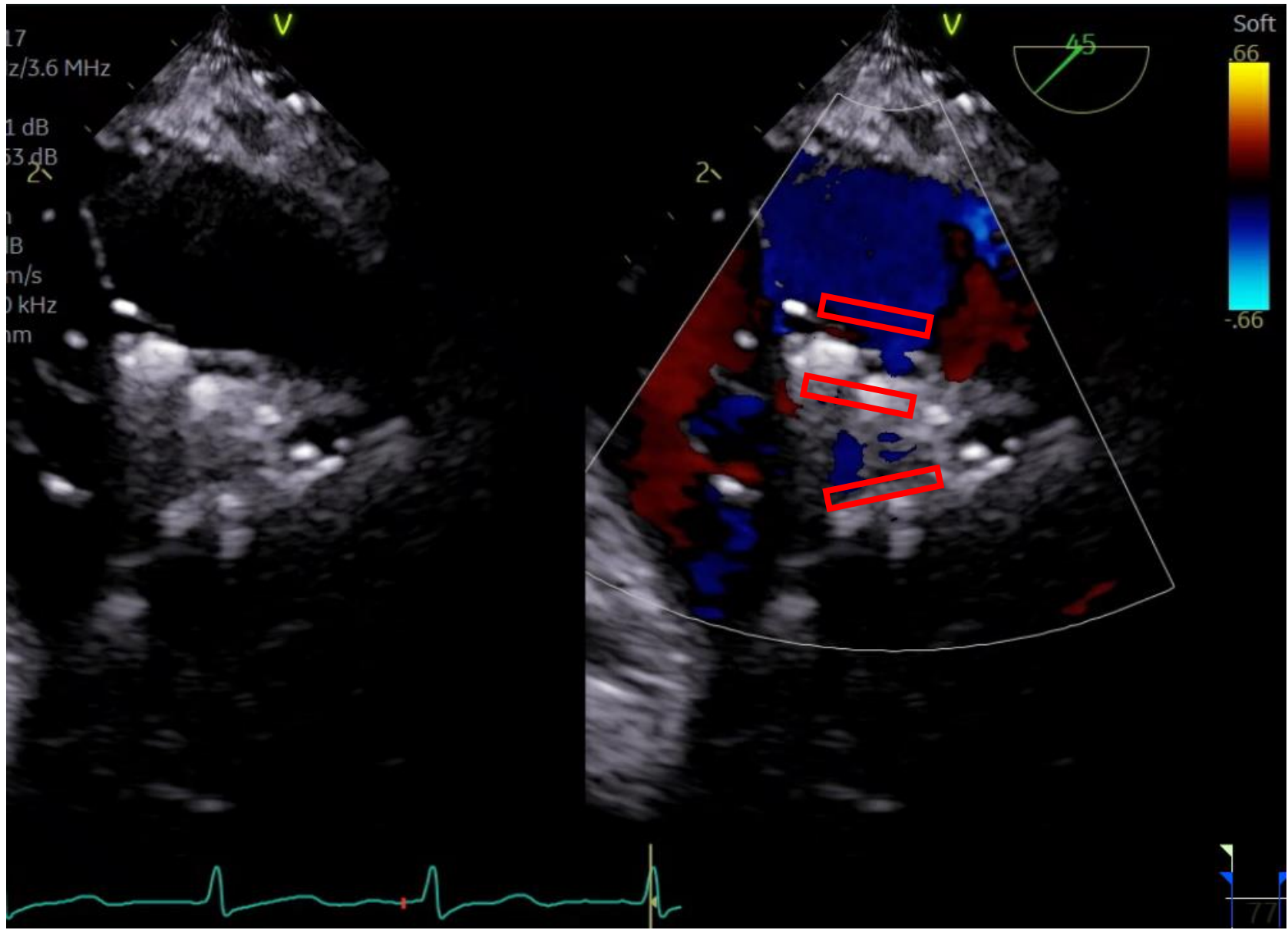


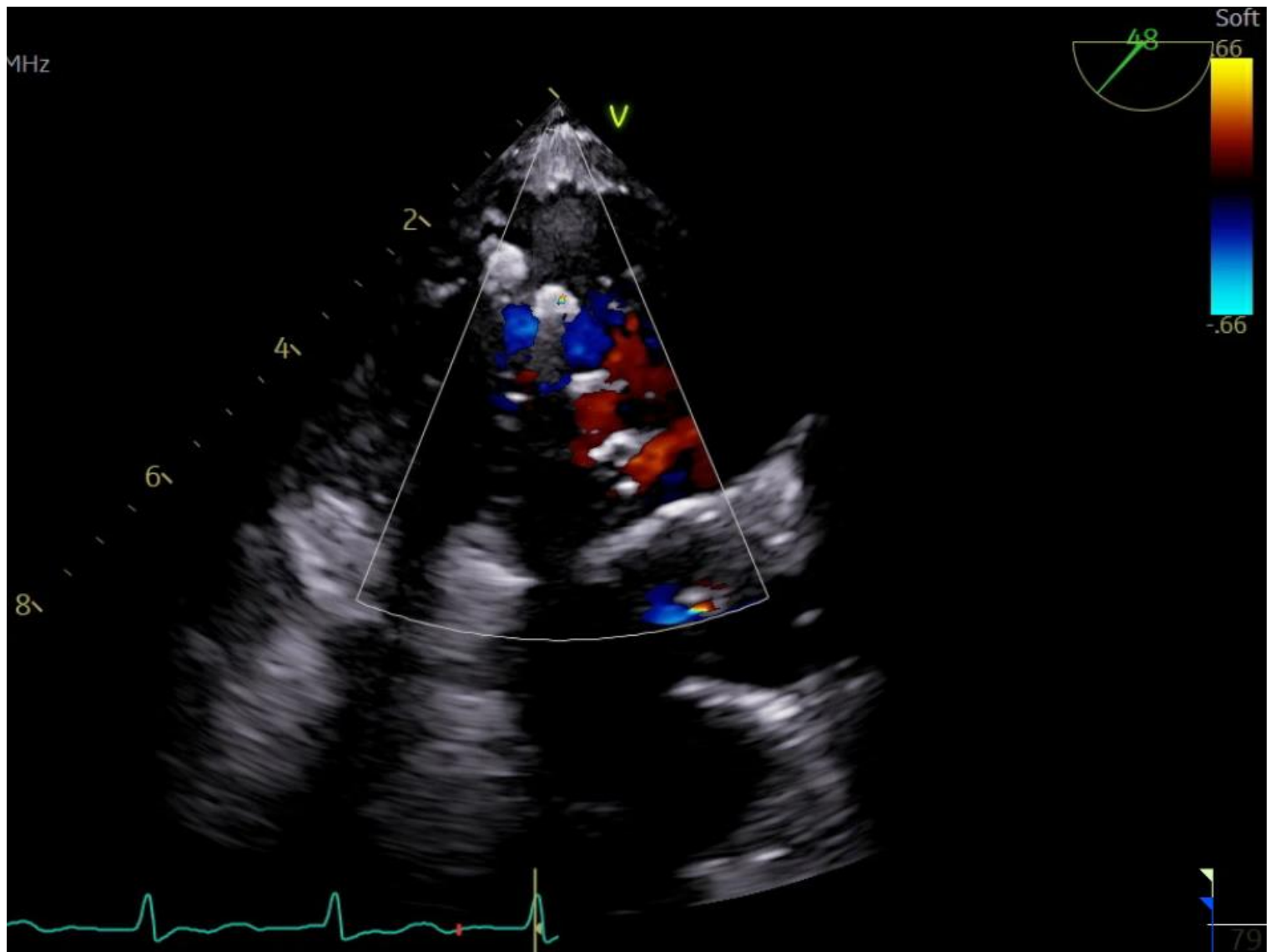




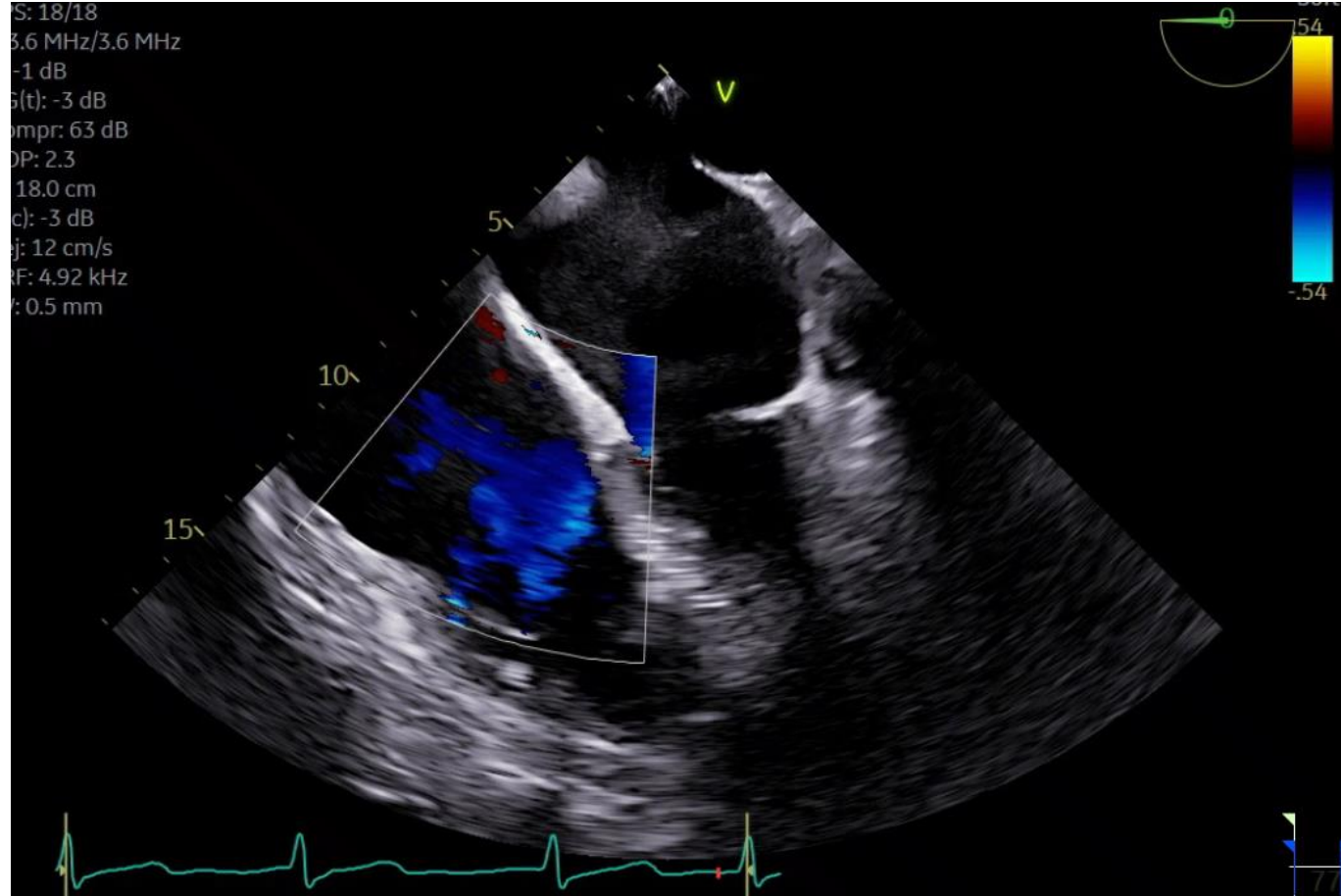




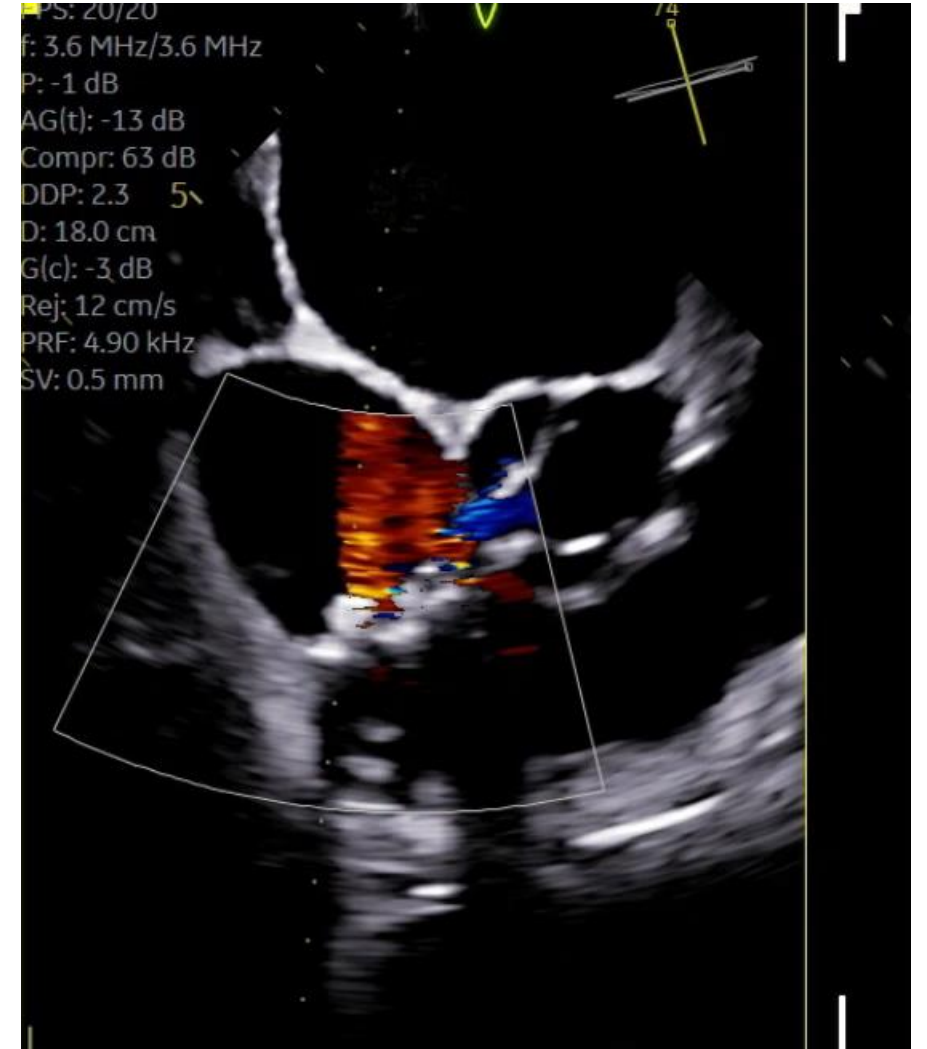




Baseline



Final



TriLuminate Randomized, Controlled Trial

The NEW ENGLAND
JOURNAL *of* MEDICINE

ESTABLISHED IN 1812

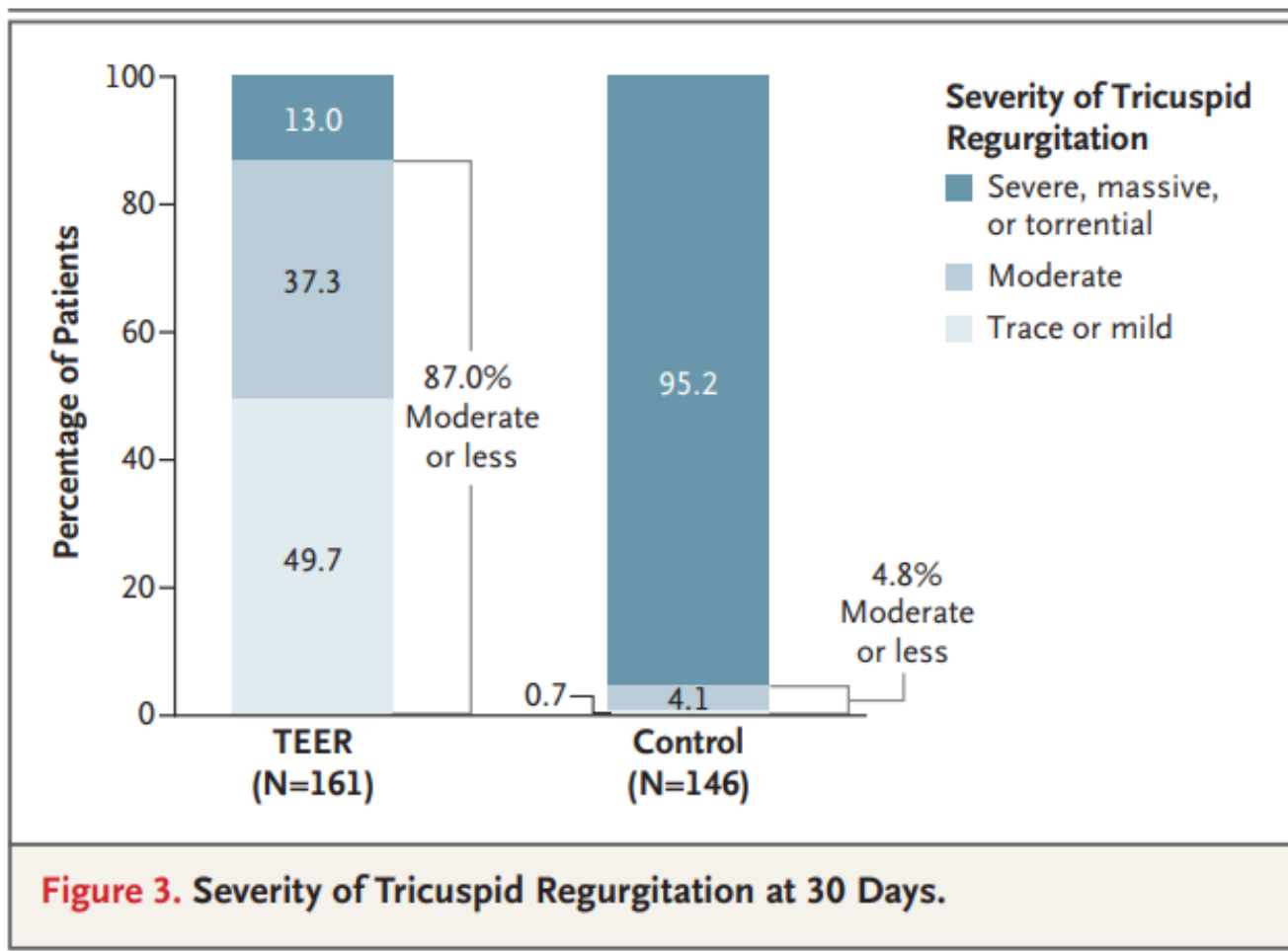
MAY 18, 2023

VOL. 388 NO. 20

Transcatheter Repair for Patients with Tricuspid Regurgitation

Paul Sorajja, M.D., Brian Whisenant, M.D., Nadira Hamid, M.D., Hursh Naik, M.D., Raj Makkar, M.D.,
Peter Tadros, M.D., Matthew J. Price, M.D., Gagan Singh, M.D., Neil Fam, M.D., Saibal Kar, M.D.,
Jonathan G. Schwartz, M.D., Shamir Mehta, M.D., Richard Bae, M.D., Nishant Sekaran, M.D., Travis Warner, M.D.,
Moody Makar, M.D., George Zorn, M.D., Erin M. Spinner, Ph.D., Phillip M. Trusty, Ph.D., Raymond Benza, M.D.,
Ulrich Jorde, M.D., Patrick McCarthy, M.D., Vinod Thourani, M.D., Gilbert H.L. Tang, M.D.,
Rebecca T. Hahn, M.D., and David H. Adams, M.D., for the TRILUMINATE Pivotal Investigators*

TriLuminate: Procedural Results

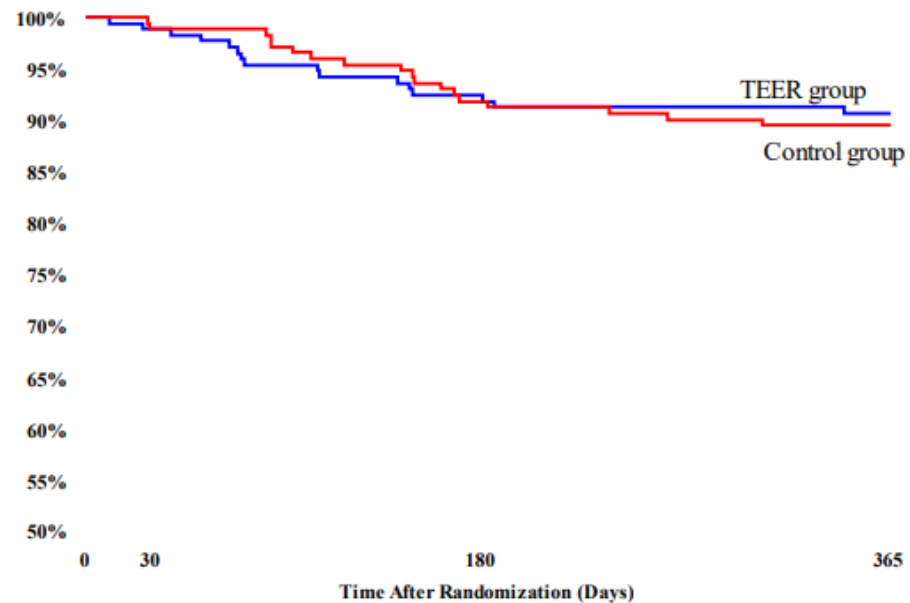


98.8%
technical
success

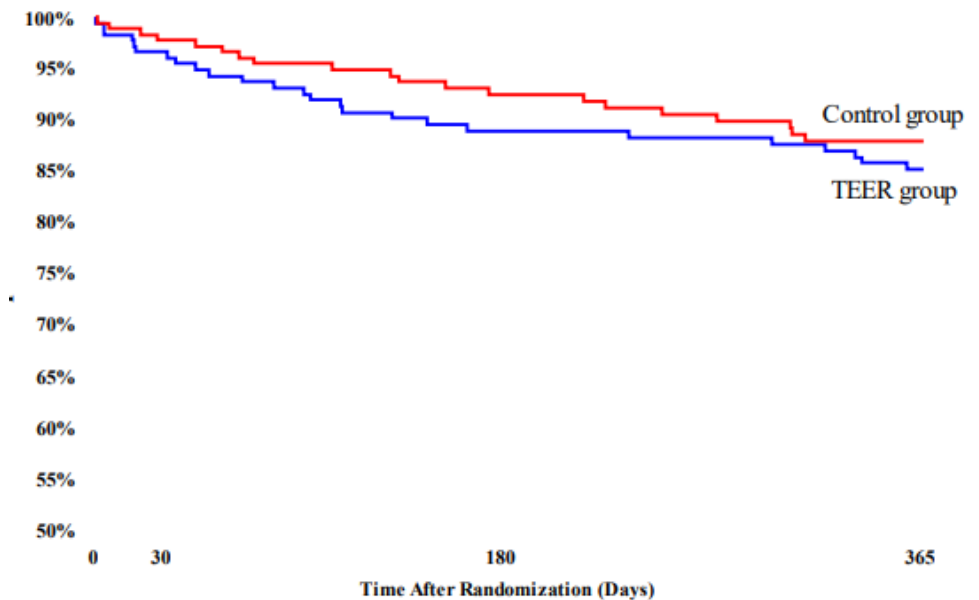
95% moderate or
less TR at 30 days

TriLuminate: Outcomes

Freedom From Mortality or TV Surgery

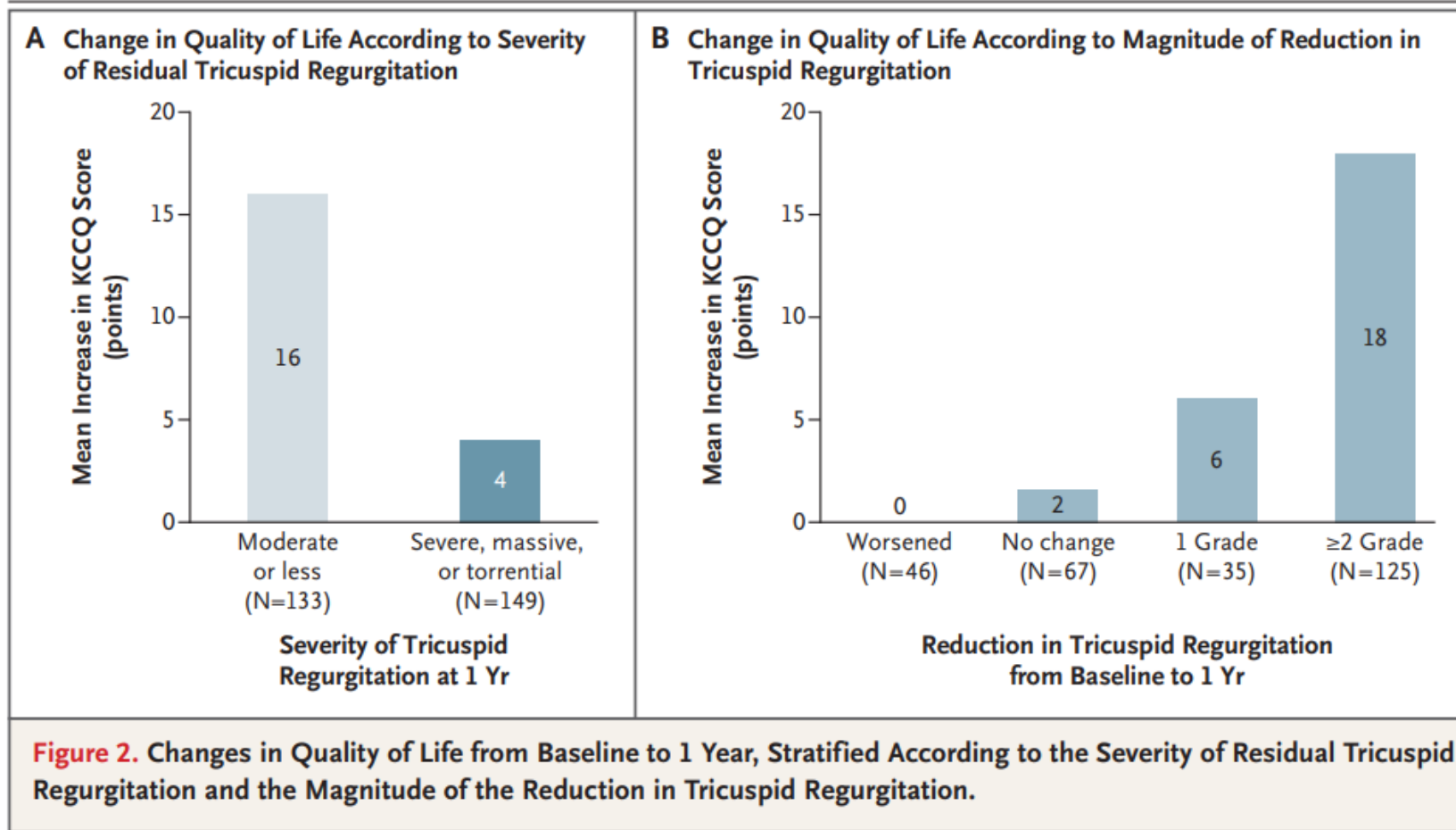


Freedom From HF hospitalization

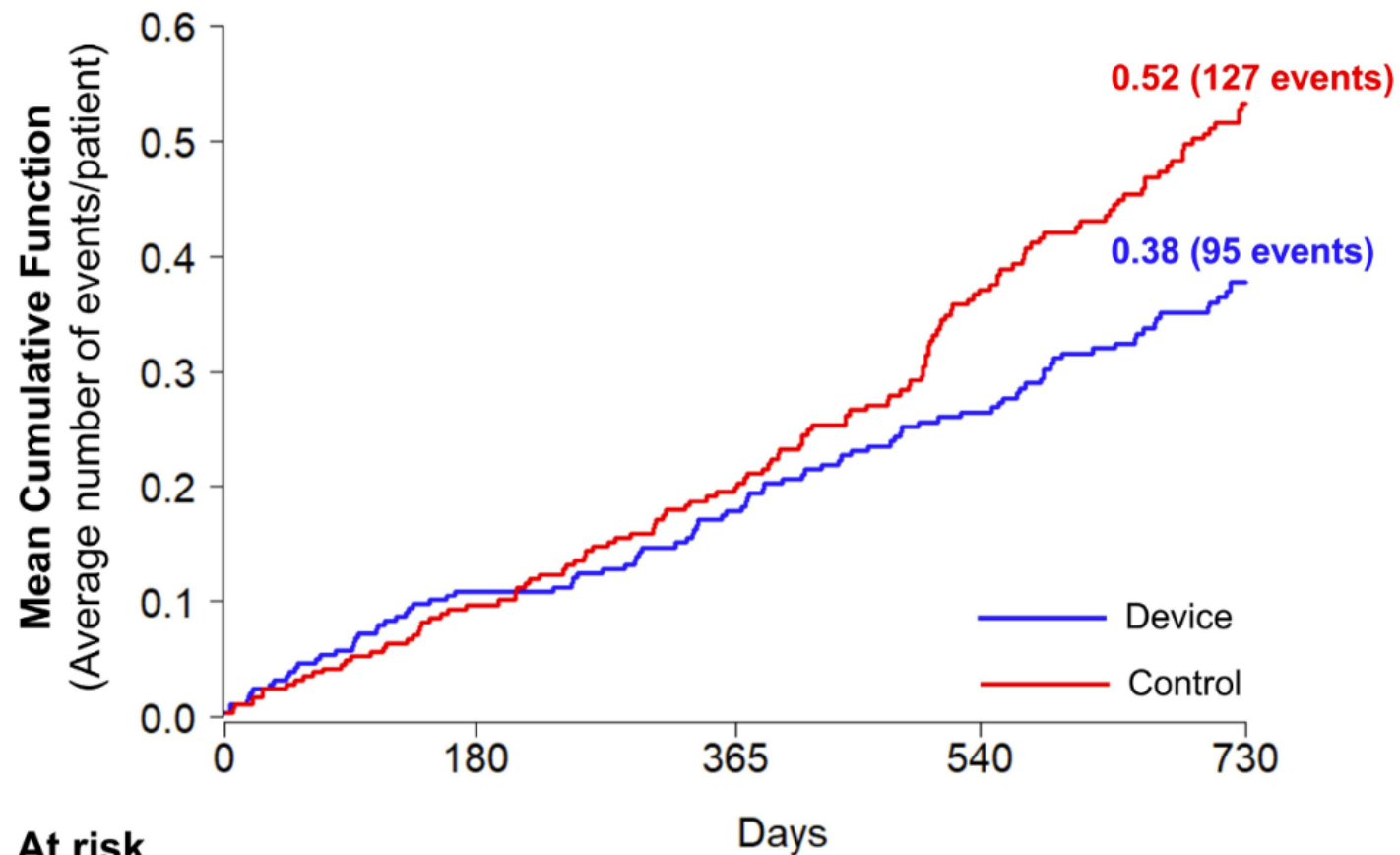
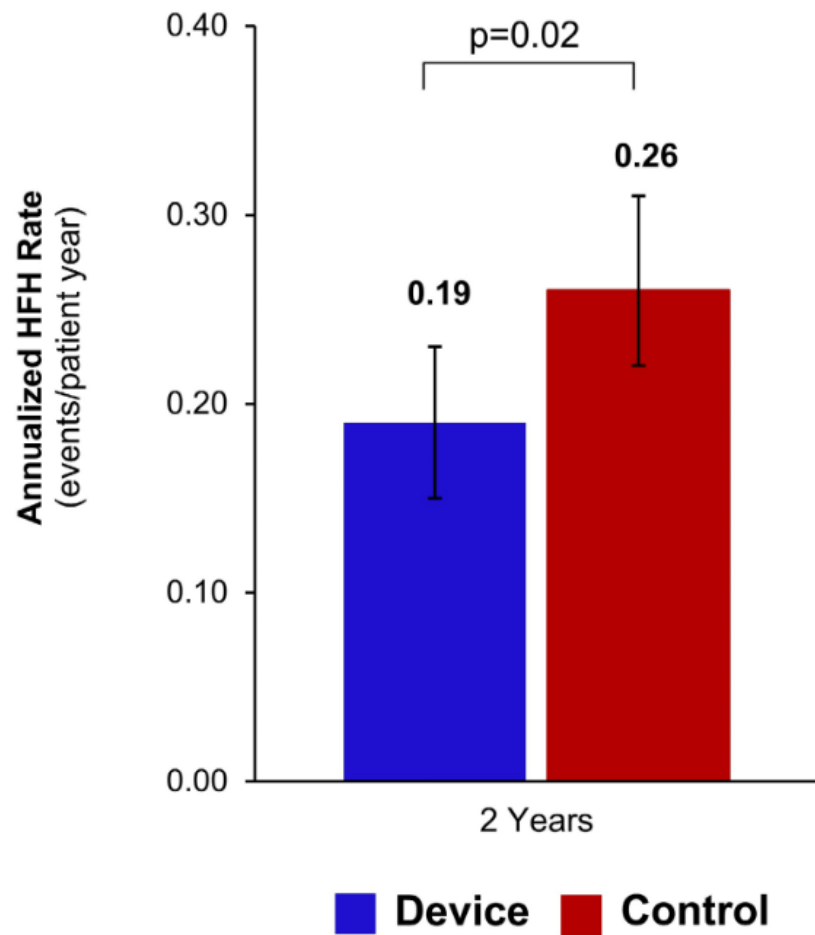


No difference in survival / HF hospitalization

TriLuminate: Quality of Life Benefit



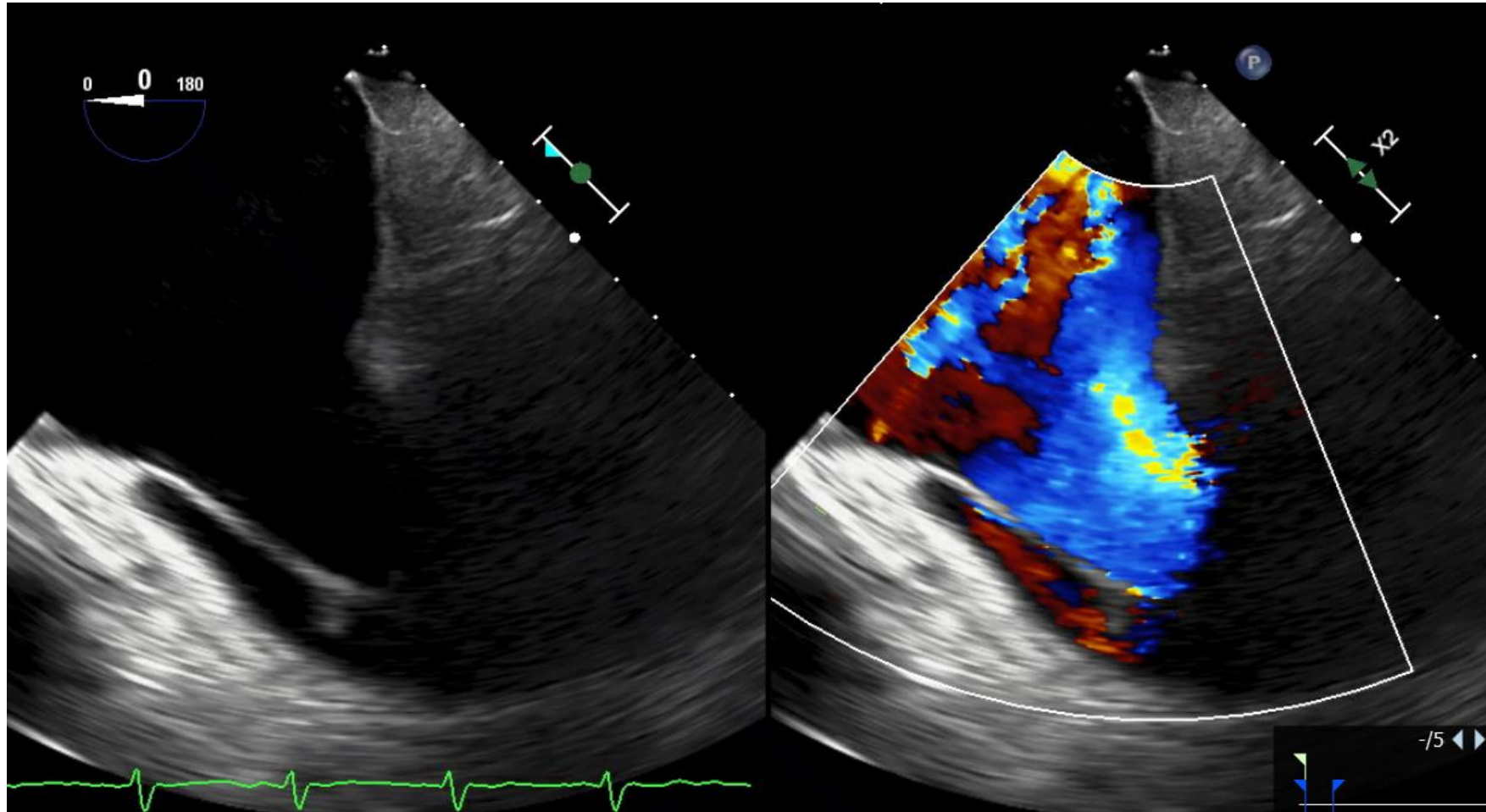
Mean KCCQ
Improvement
12 points



At risk

	0	180	365	540	730
Device	285	265	253	238	205
Control	287	261	247	226	190

Some valves cannot be clipped



Transcatheter Tricuspid Valve Replacement

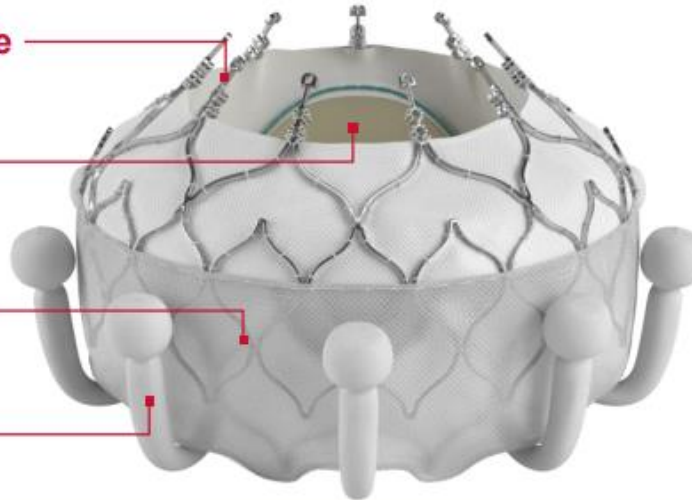
EVOQUE Valve

Nitinol self-expanding frame

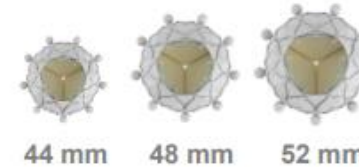
Bovine pericardial tissue

Intra-annular sealing skirt

9 ventricular anchors



Available in three sizes



EVOQUE Delivery System

Transfemoral

28 Fr outer diameter

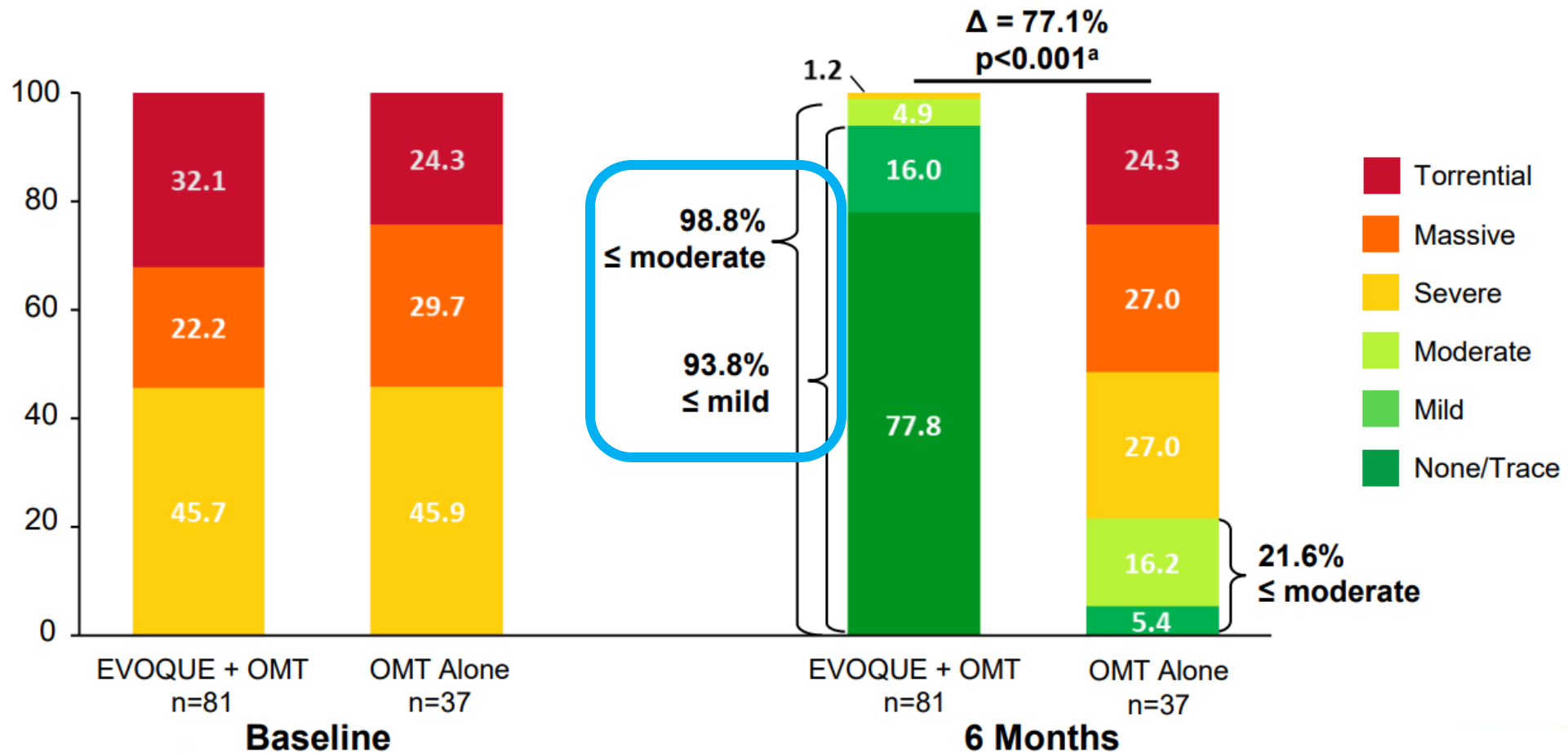
3 planes of movement



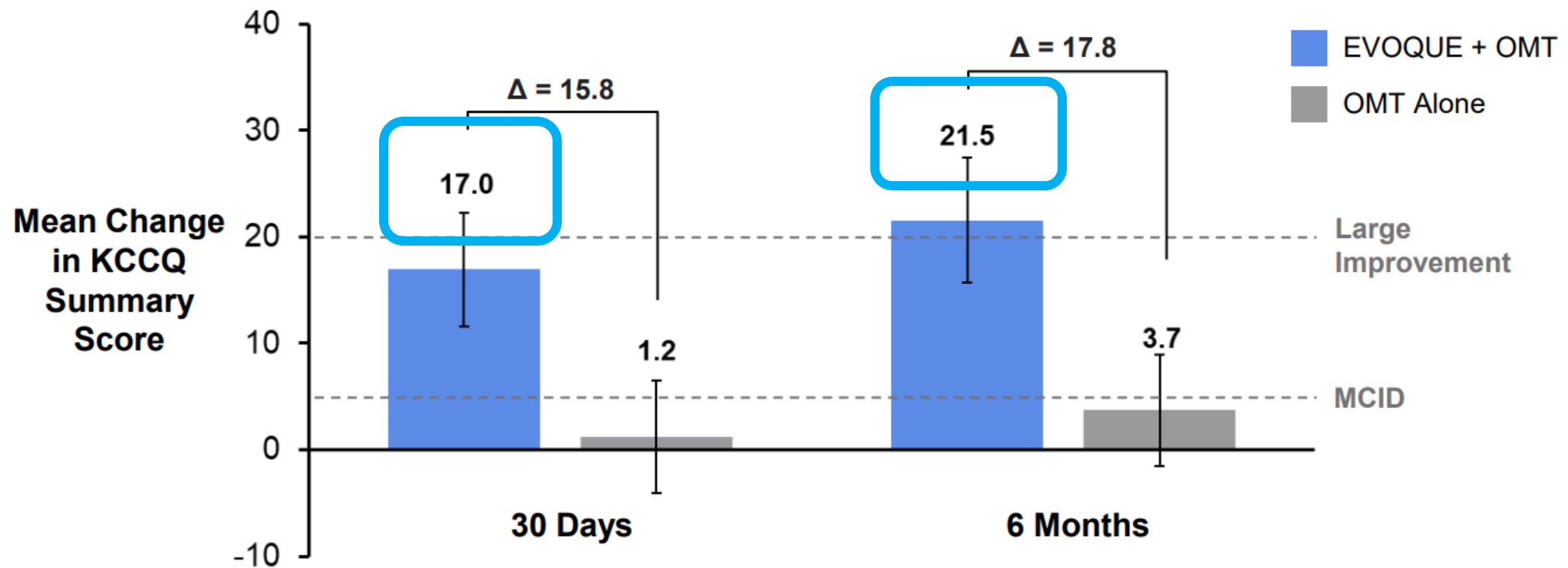
Transcatheter Tricuspid Valve Replacement

CEC-Adjudicated Major Adverse Events	EVOQUE + OMT N=95 % (n)
Cardiovascular mortality	3.2 (3)
Myocardial infarction	1.1 (1)
Stroke	0.0 (0)
New need for renal replacement therapy	1.1 (1)
Severe bleeding ^a	10.5 (10)
Non-elective TV re-intervention	0.0 (0)
Major access site and vascular complication	3.2 (3)
Major cardiac structural complication	2.1 (2)
Device-related pulmonary embolism	1.1 (1)
Arrhythmia and conduction disorder requiring permanent pacing	14.7 (14)
Composite MAE Rate^b	27.4 (26)

Transcatheter Tricuspid Valve Replacement

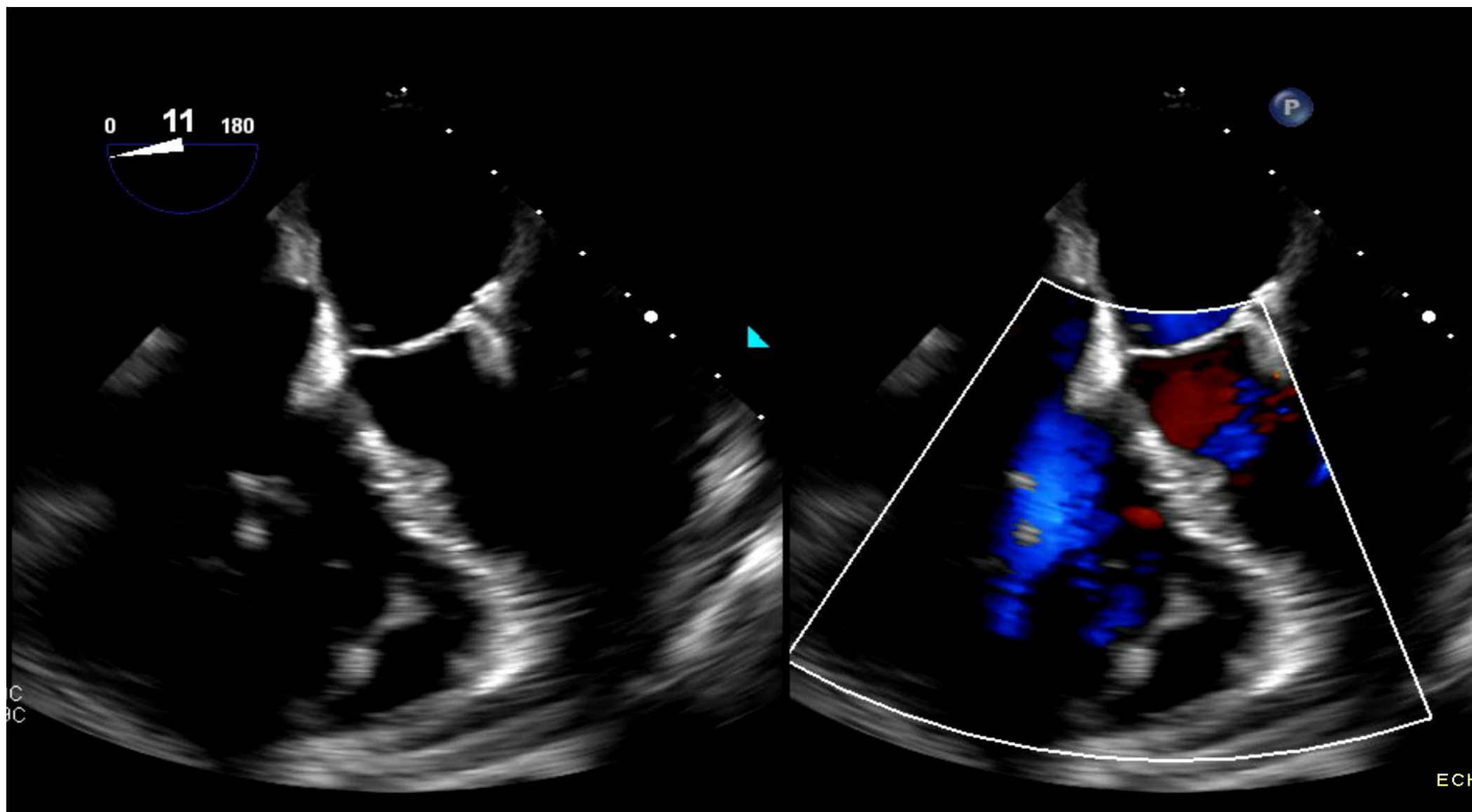


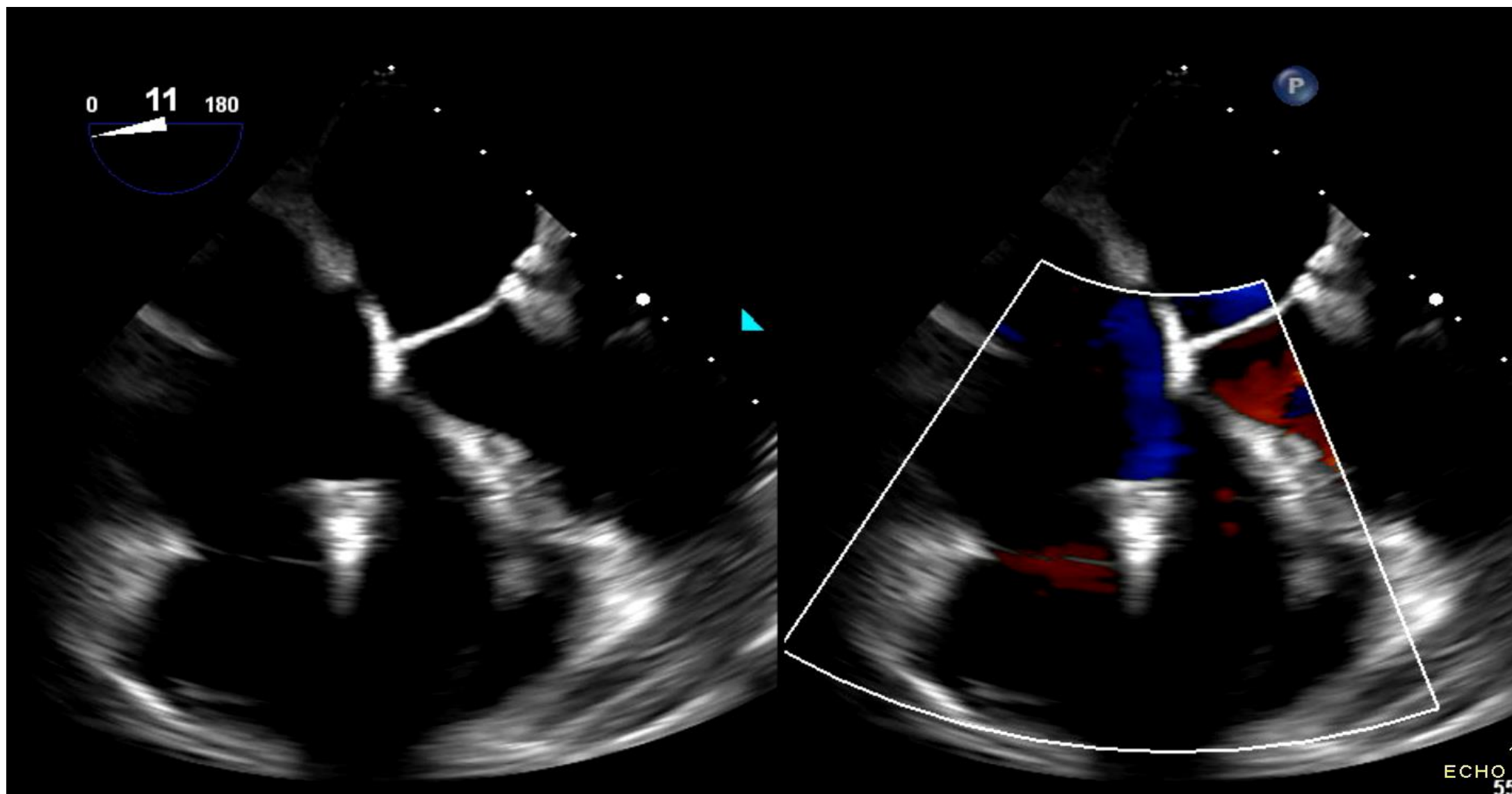
Transcatheter Tricuspid Valve Replacement

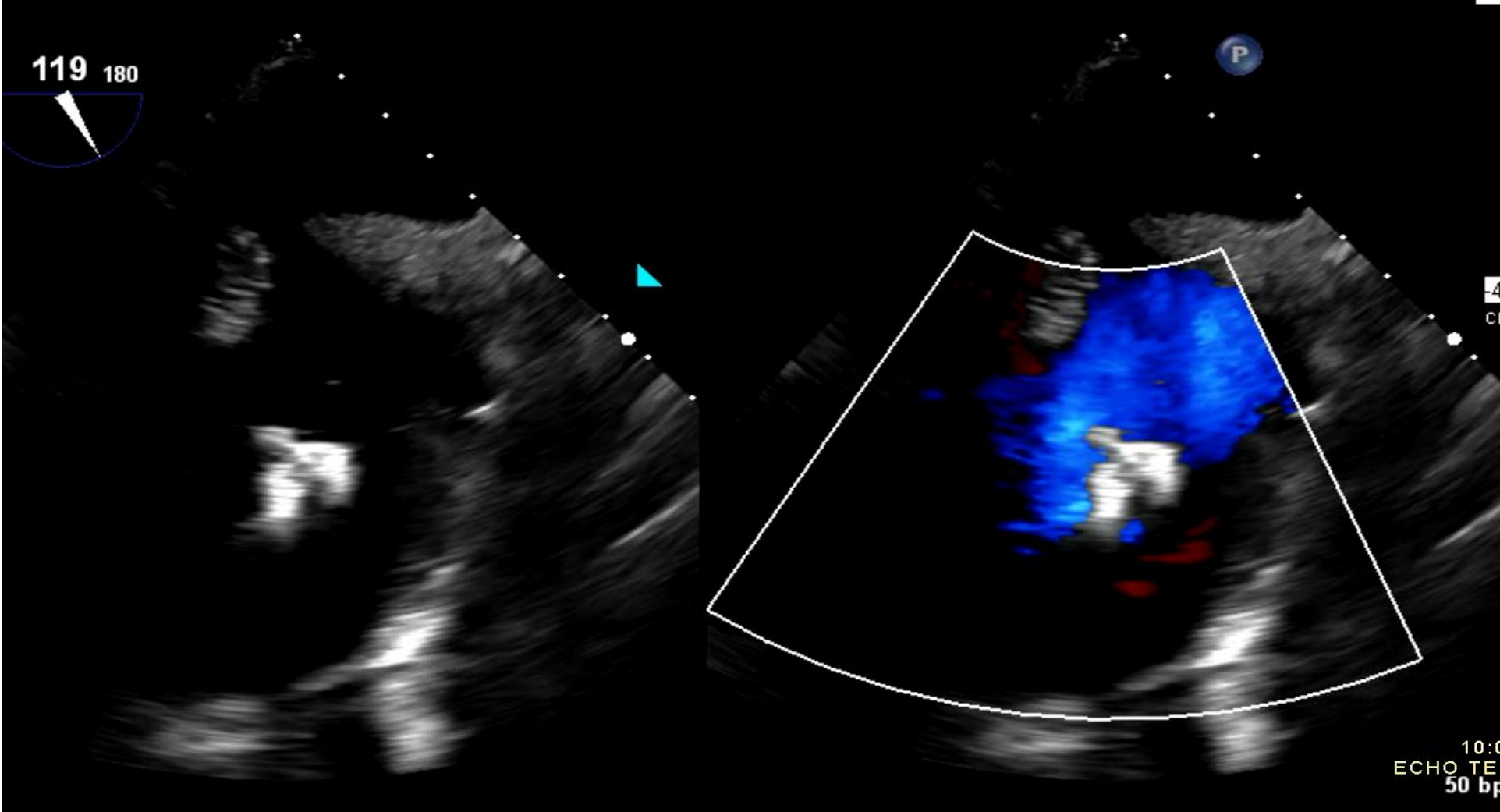


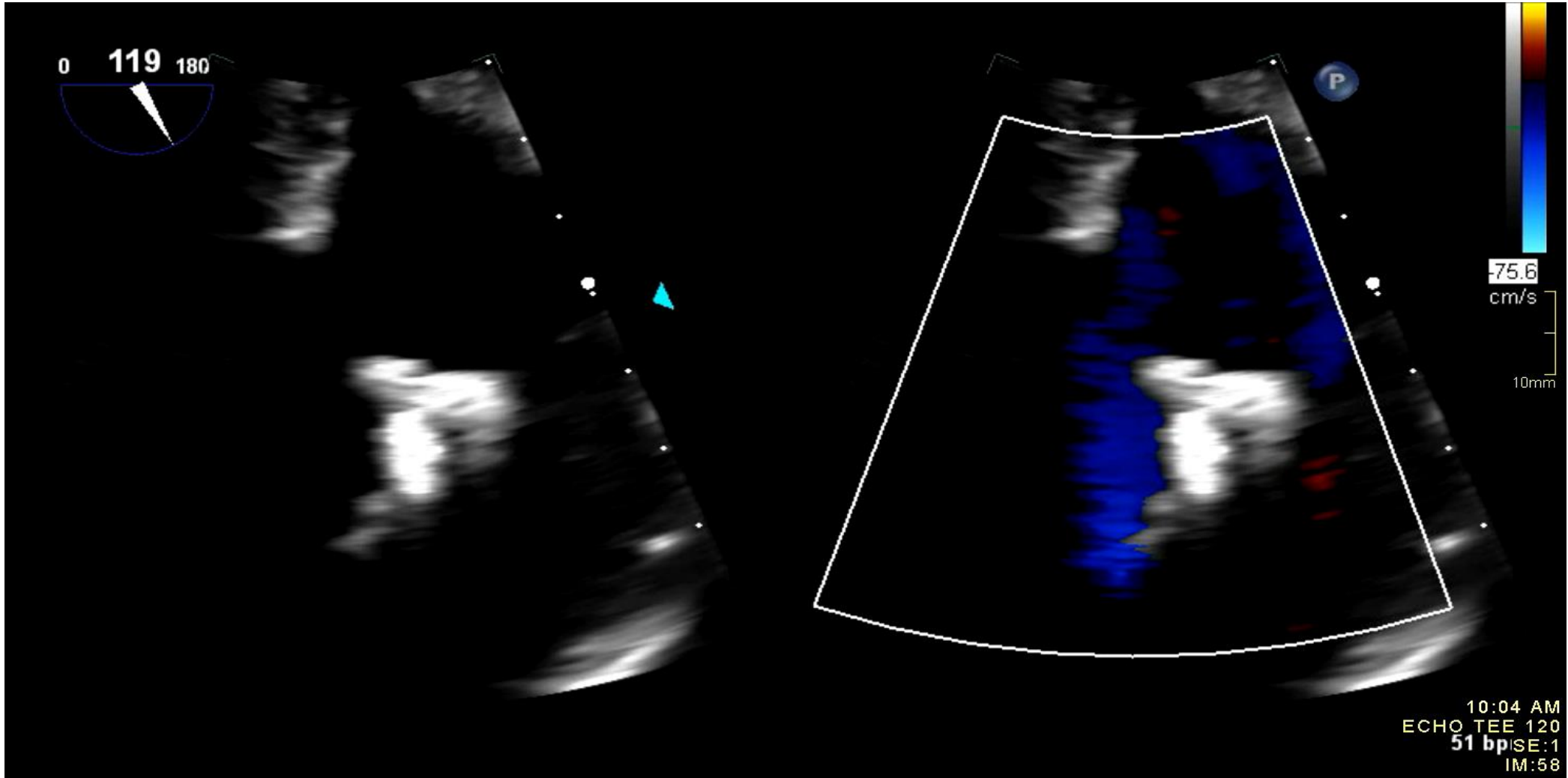
Advantages: Transcatheter Repair vs. Replacement

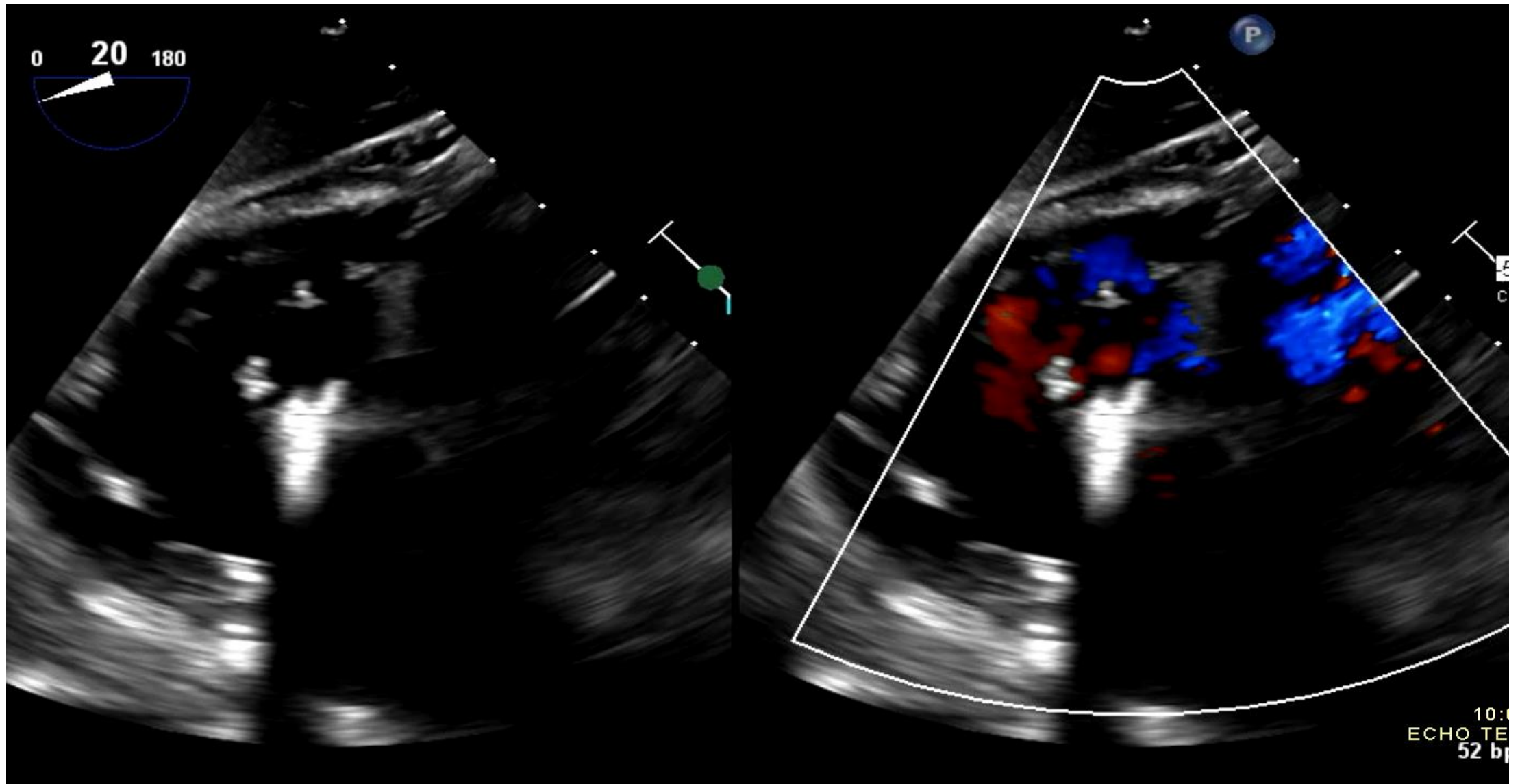
	Complexity	30 day Mortality	Complications	Pacemaker	TR Reduction	Quality of Life Benefit	Anti-Coagulant	Head to Head
Repair		✓	✓	✓			✓	?
Replace	✓				✓	✓		?

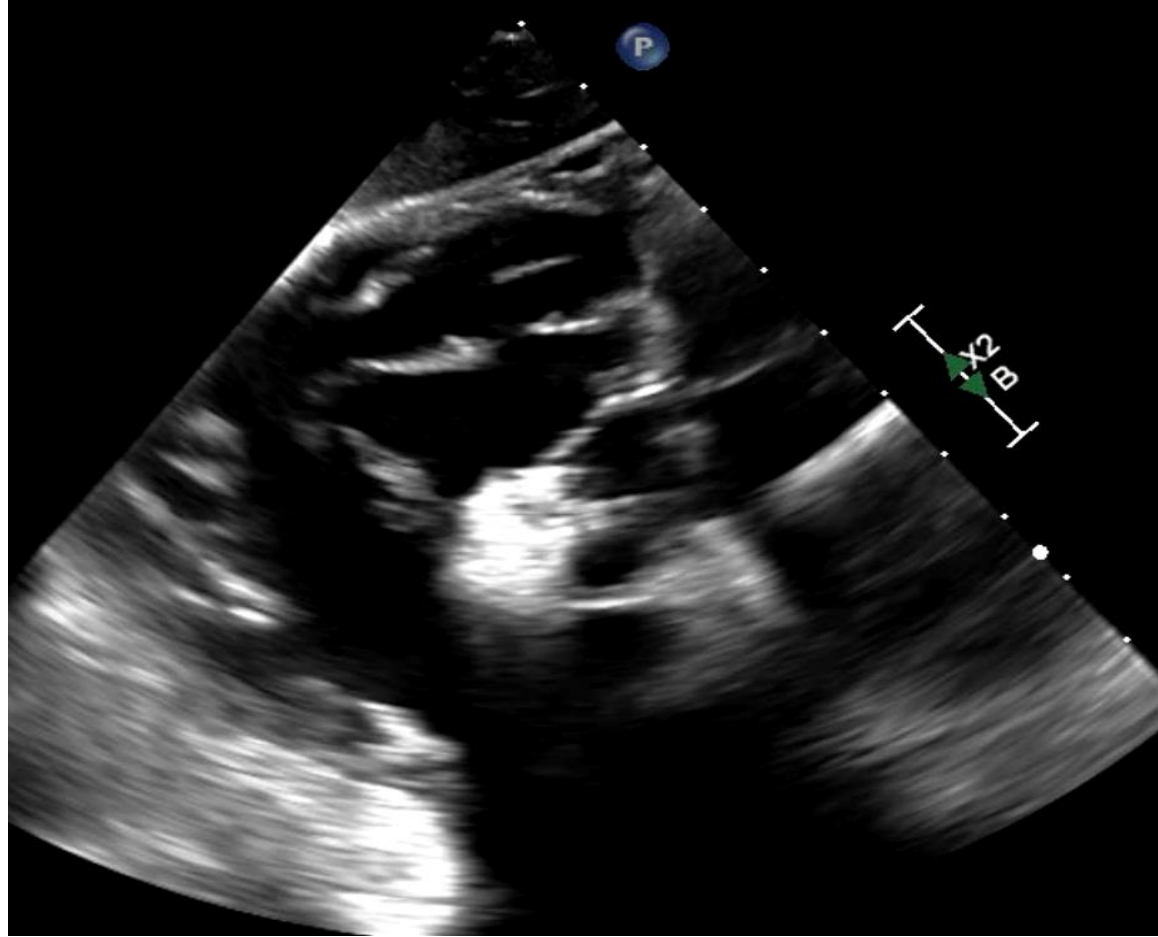












All prior TEER devices are SLDA



Proceed with EVOQUE TTVR

All intact TEER (secure bileaflet attachment) measure **7 mm or less** from closest commissure

“Neo-Annulus” perimeter measurements to finalize EVOQUE sizing



Proceed with EVOQUE TTVR

Intact TEER (secure bileaflet attachment) measure **more than 7 mm** from closest commissure

Clip Liberalization to Facilitate TTVR “CLEFT”

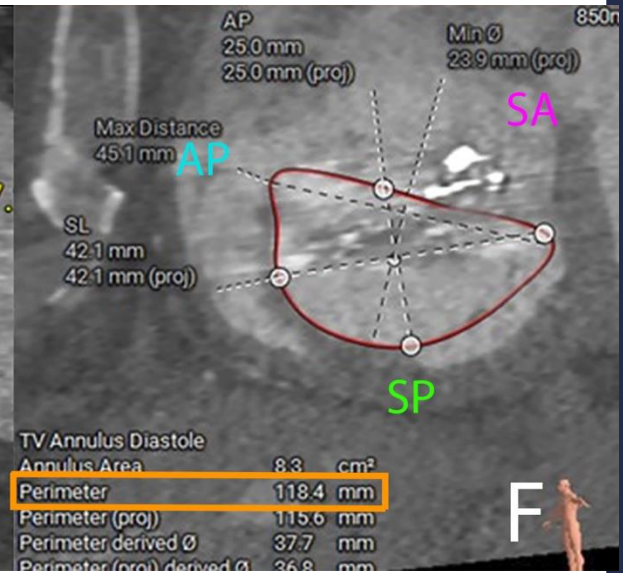
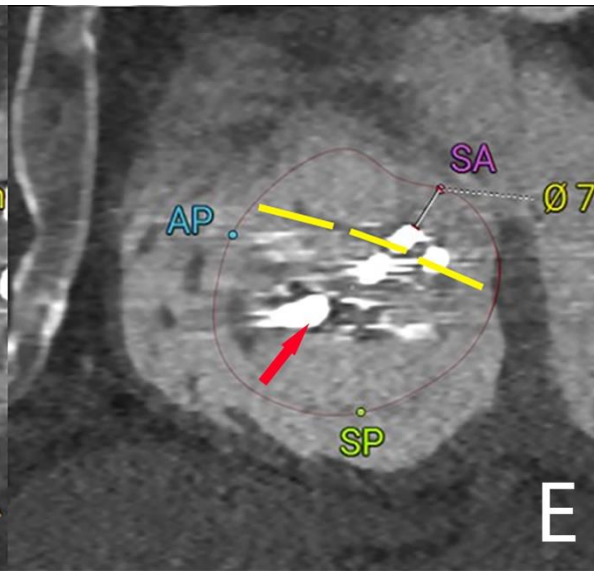
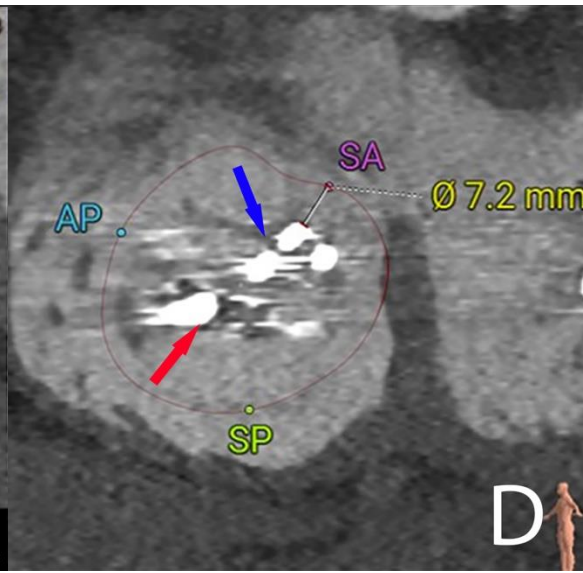
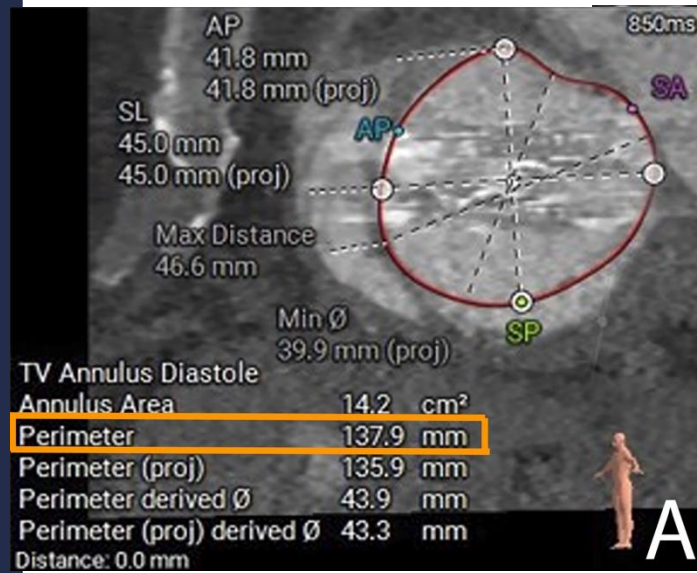


Proceed with EVOQUE TTVR

Annulus Perimeter 137

Measure the “Neo-annulus”: Incorporate Tissue Bridge

Neo-Annulus Perimeter 118



All prior TEER devices are SLDA



Proceed with EVOQUE TTVR

All intact TEER (secure bileaflet attachment) measure **7 mm or less** from closest commissure

“Neo-Annulus” perimeter measurements to finalize EVOQUE sizing



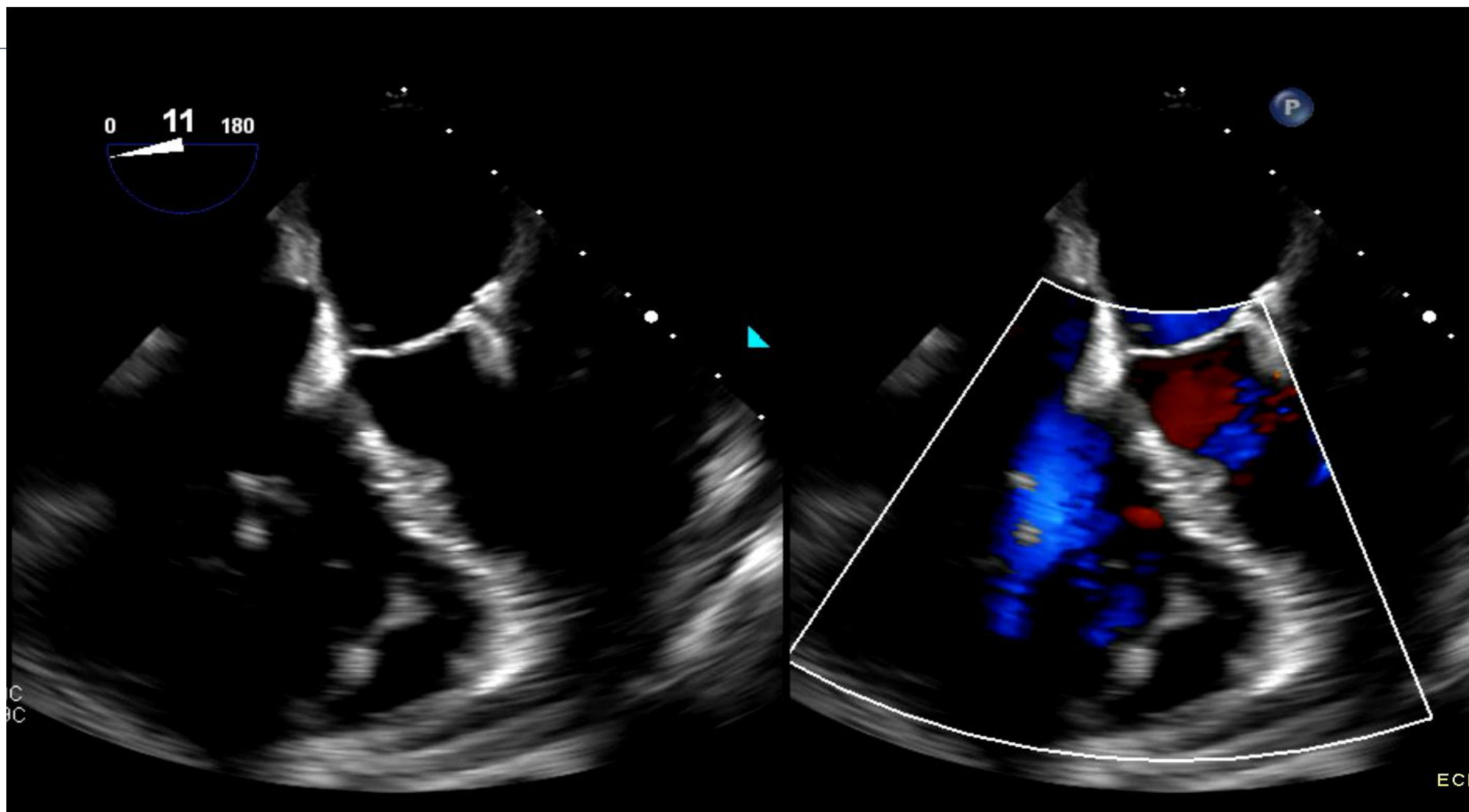
Proceed with EVOQUE TTVR

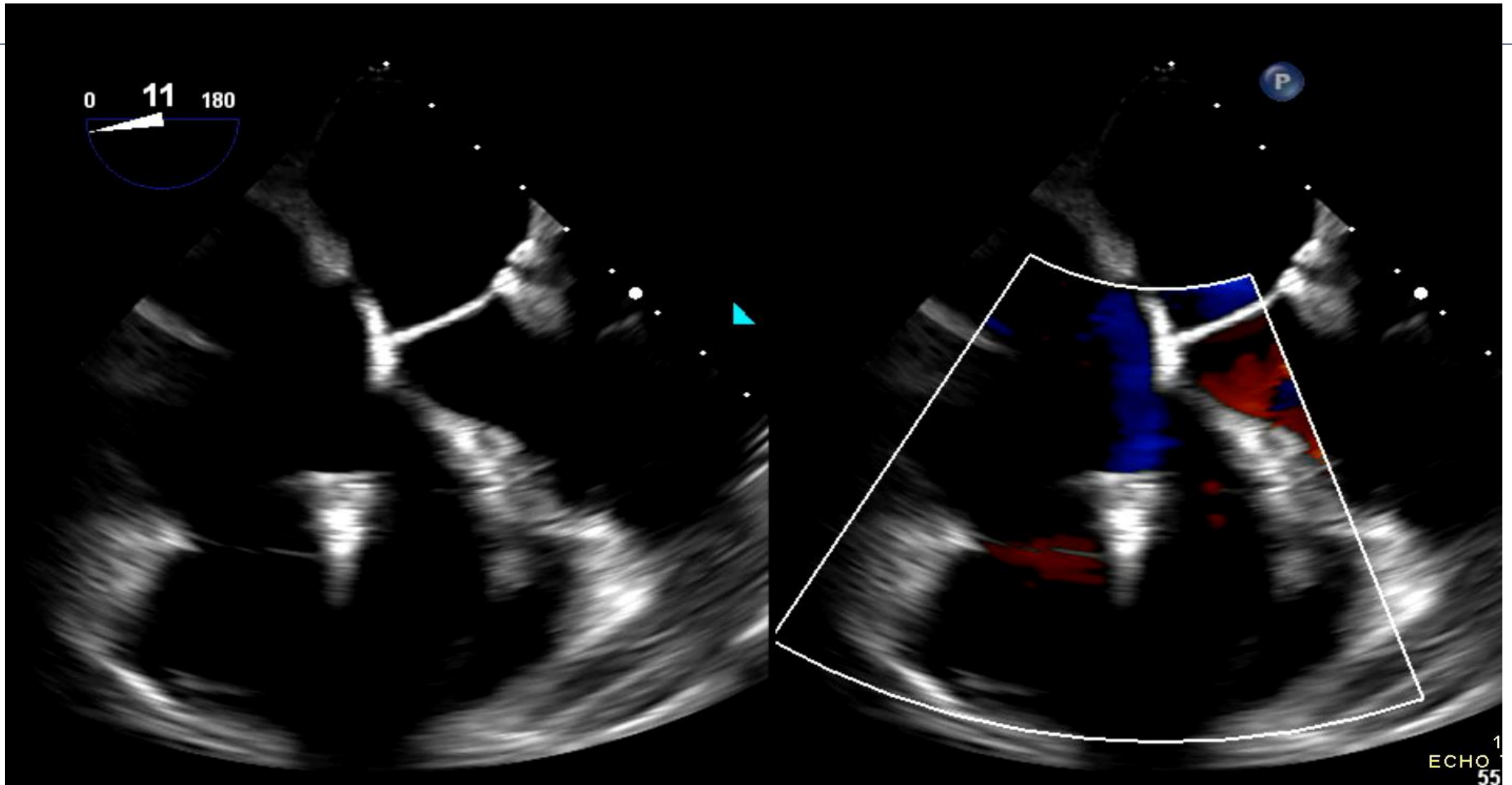
Intact TEER (secure bileaflet attachment) measure **more than 7 mm** from closest commissure

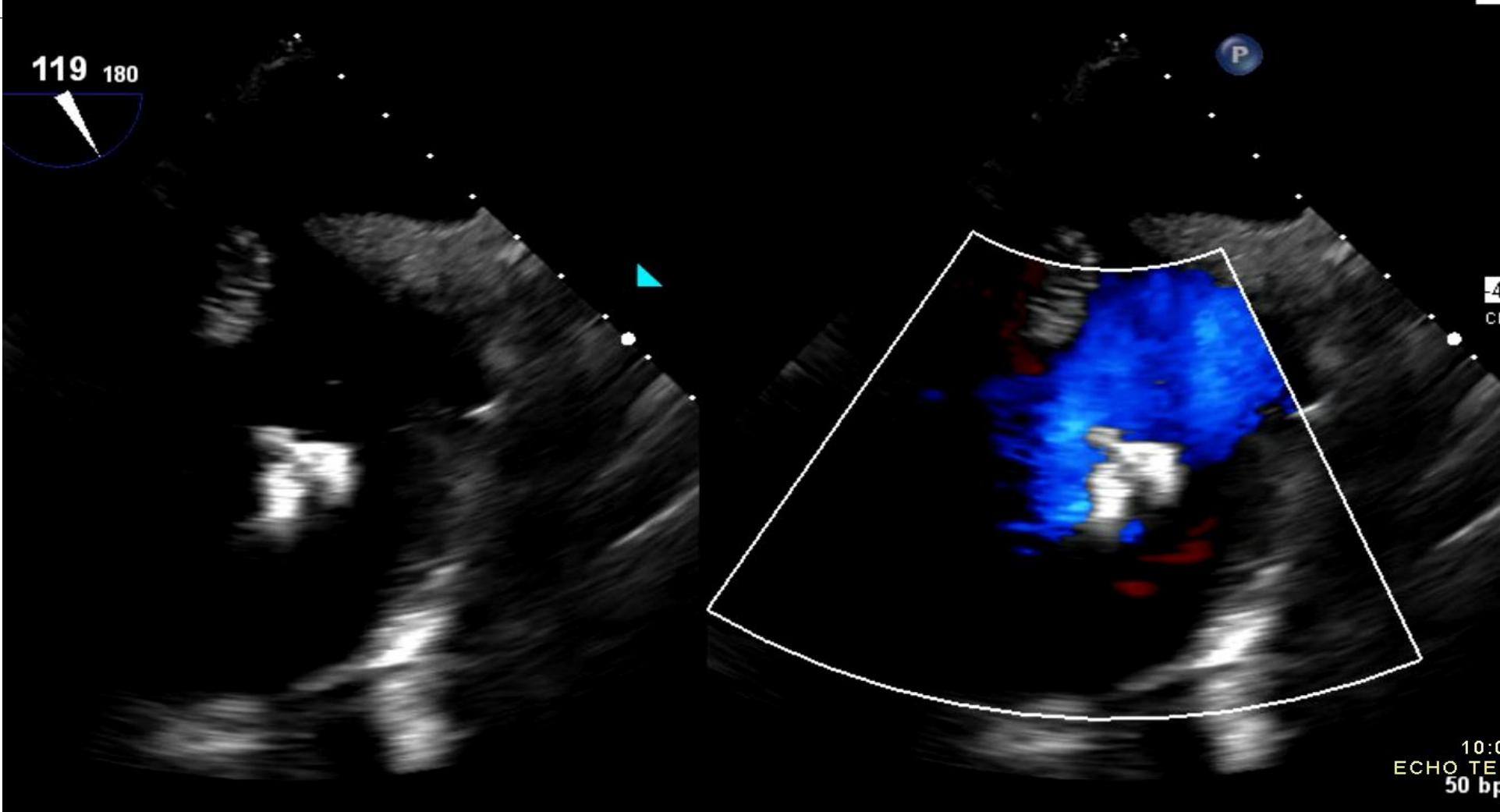
Clip Liberalization to Facilitate TTVR “CLEFT”

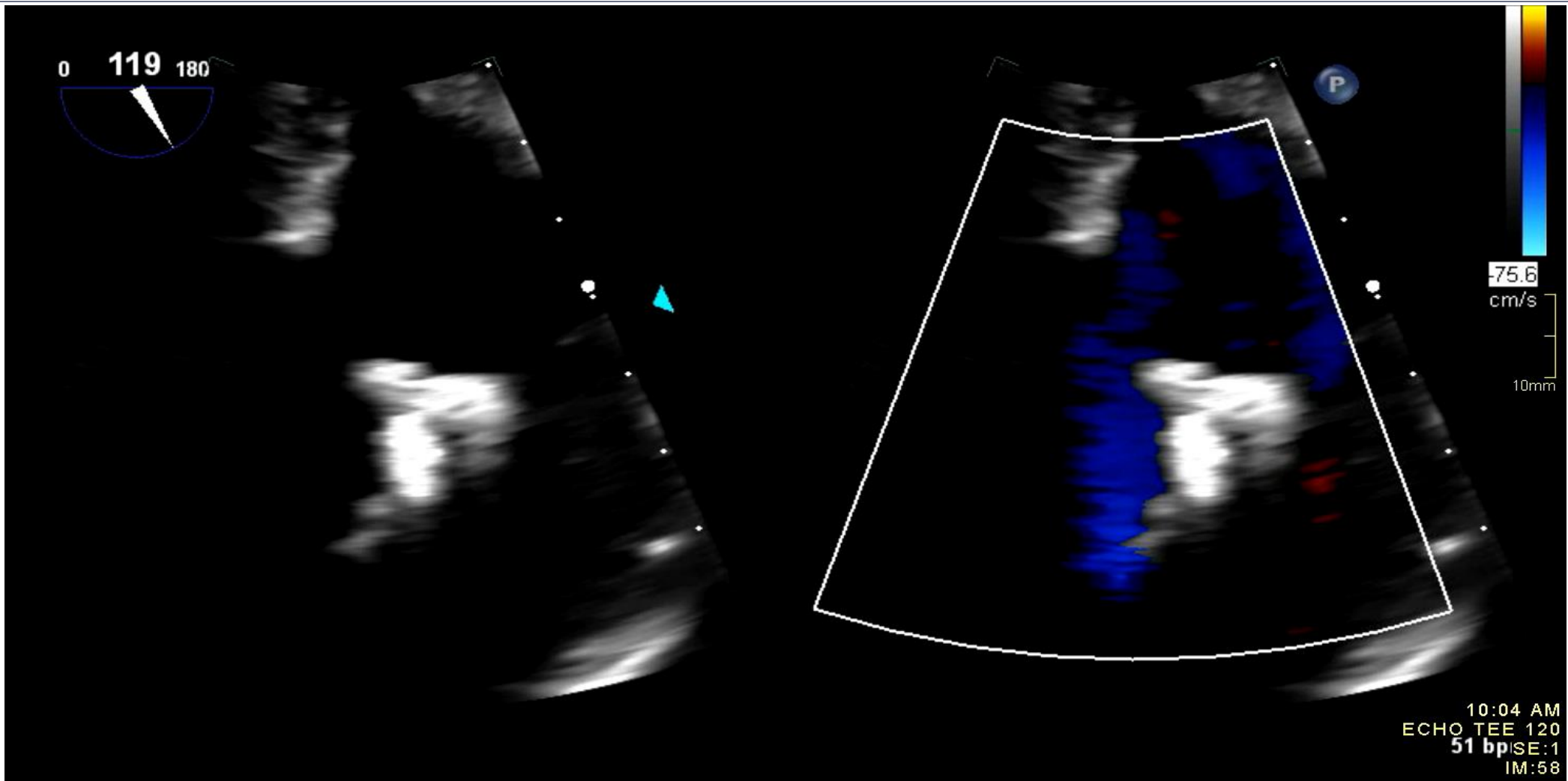


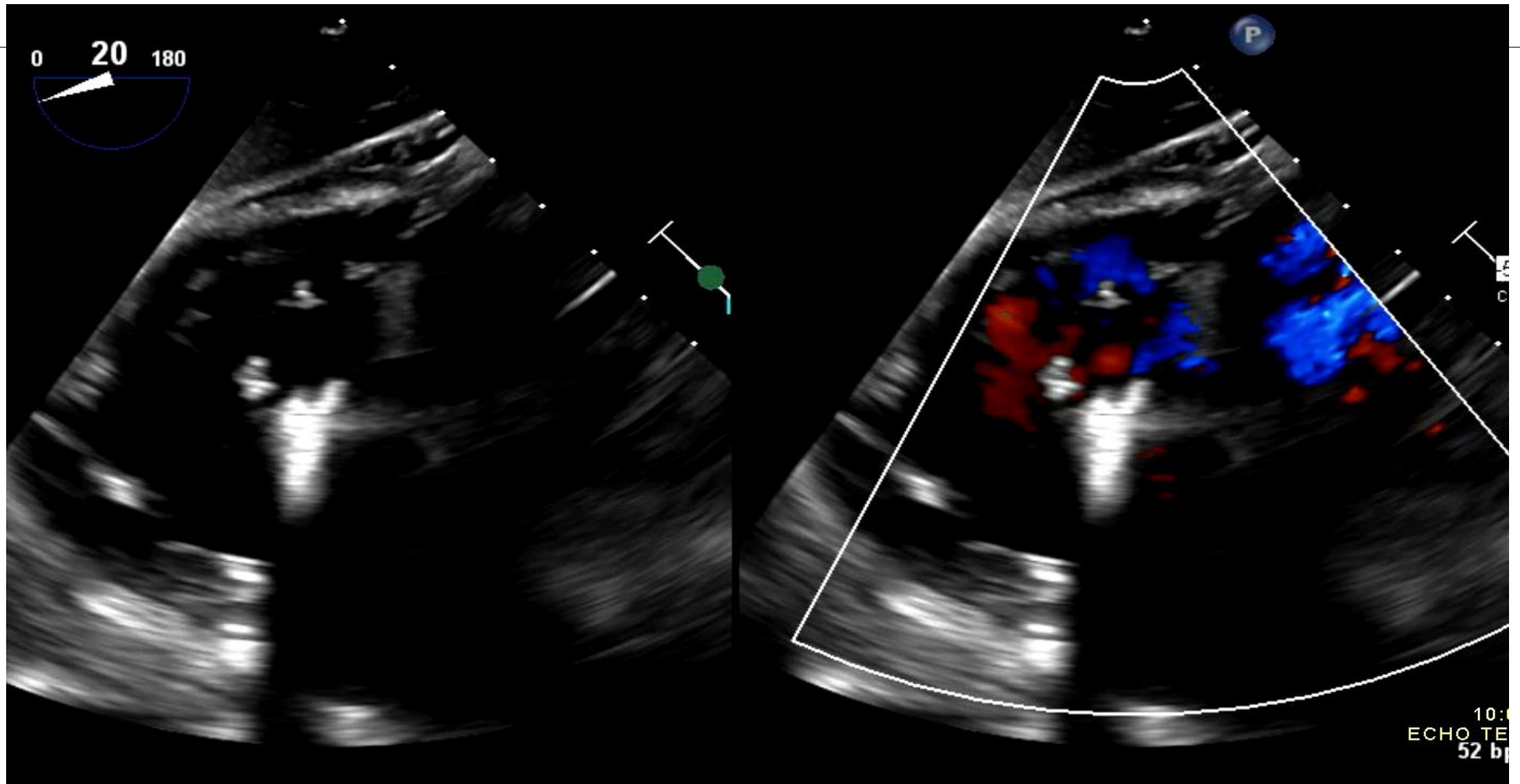
Proceed with EVOQUE TTVR

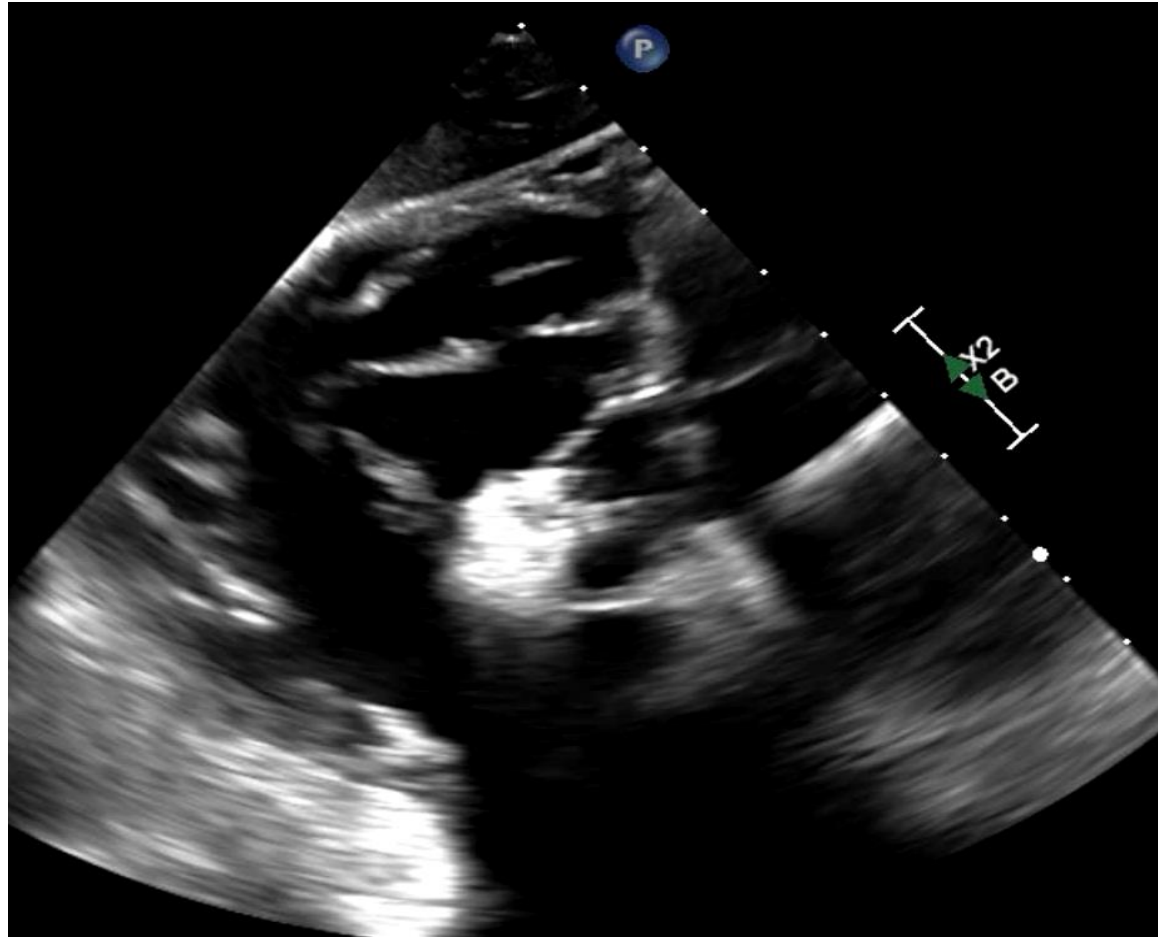


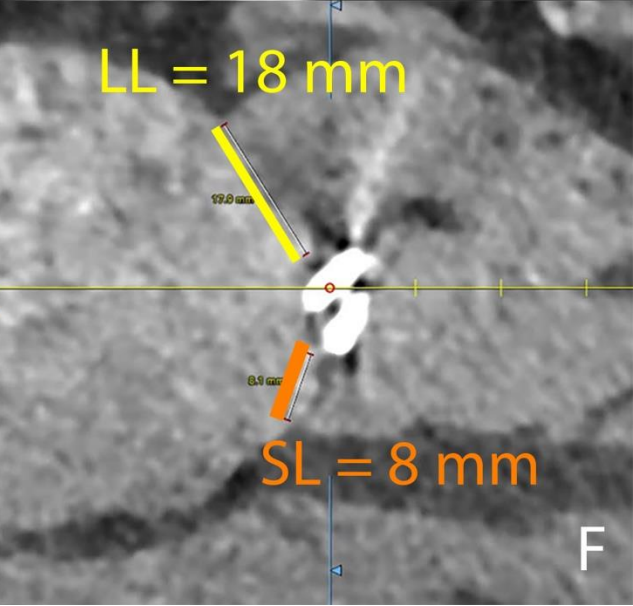
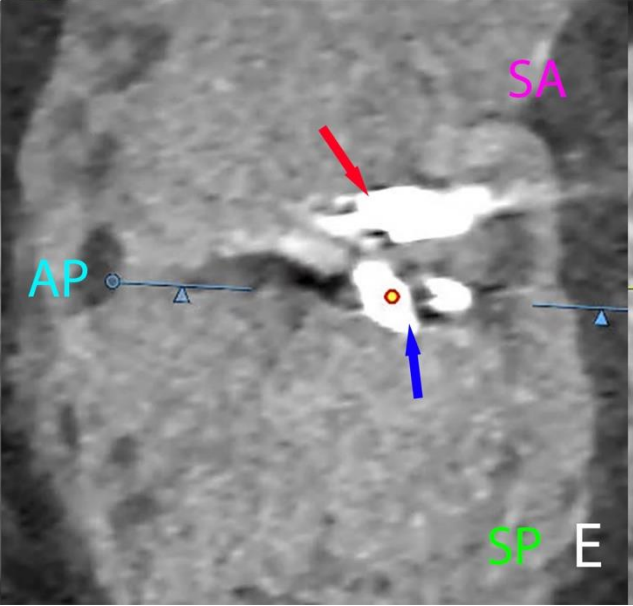
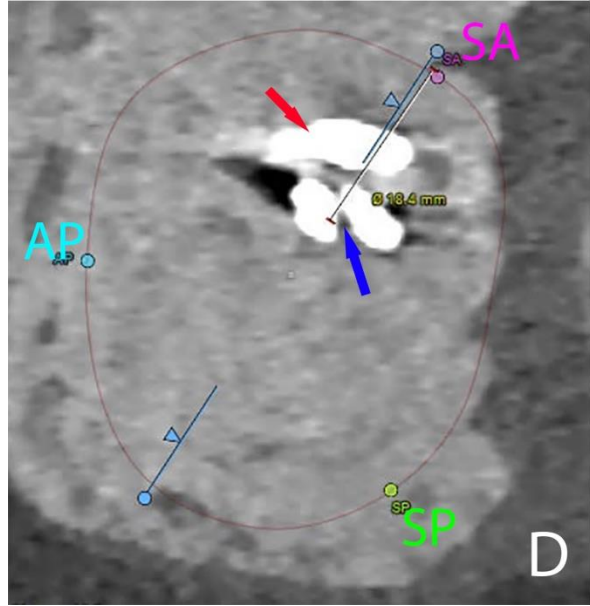
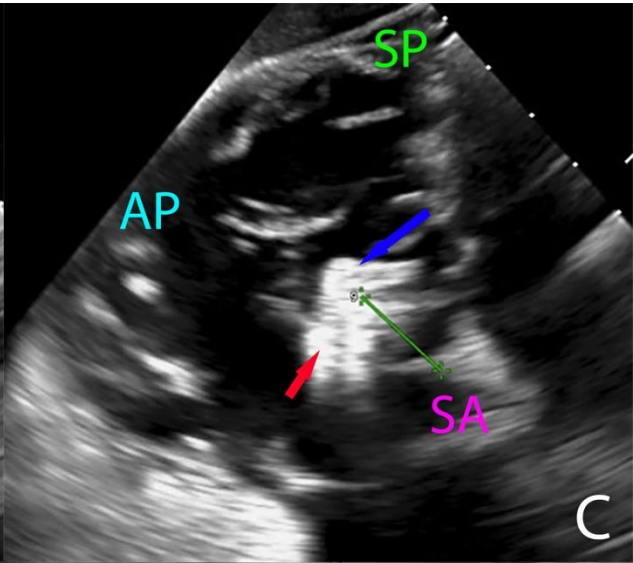
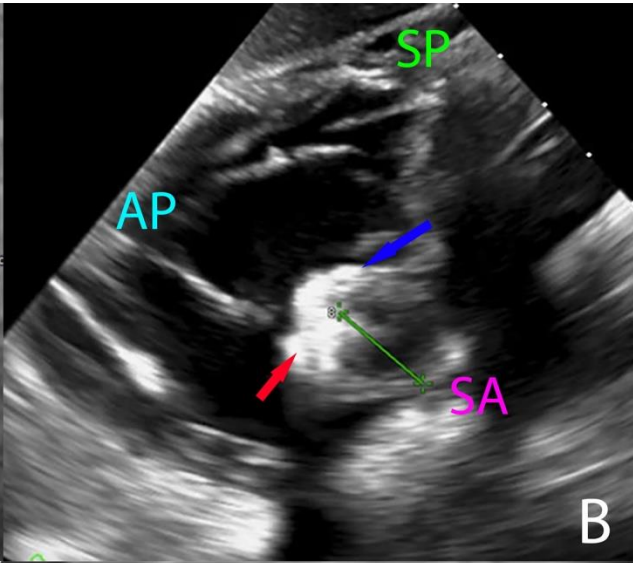
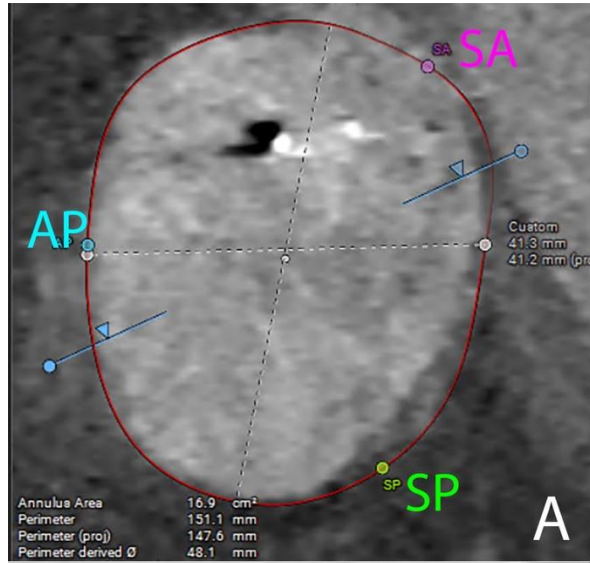


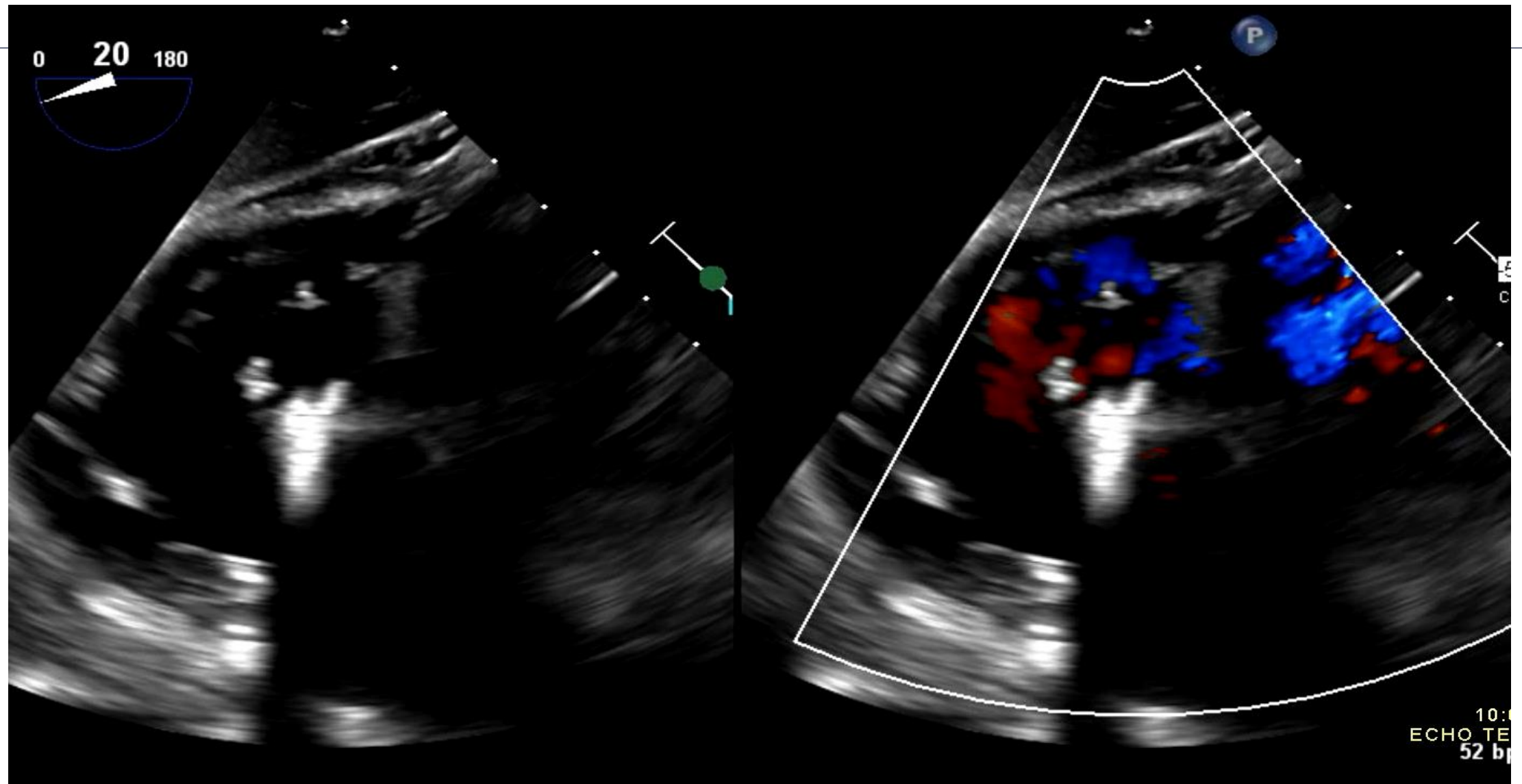




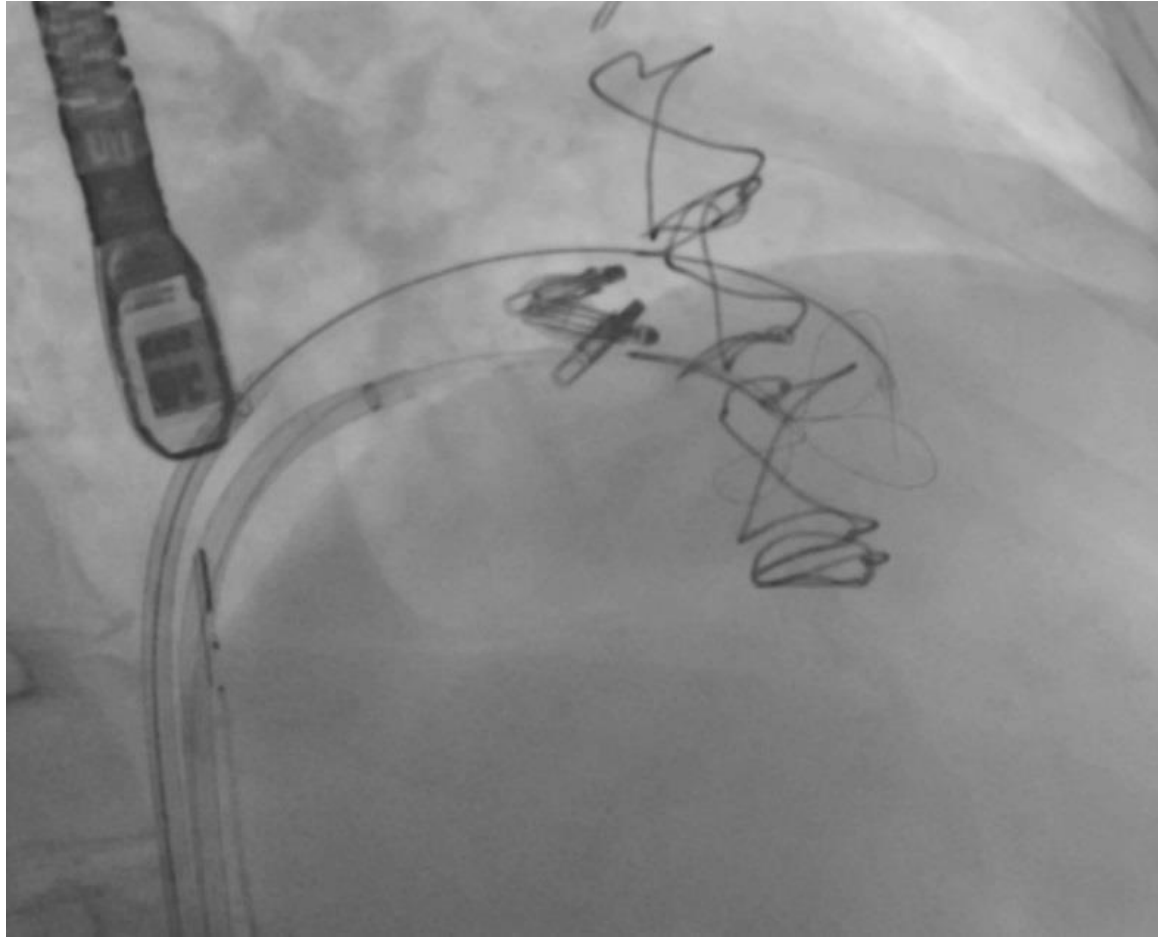


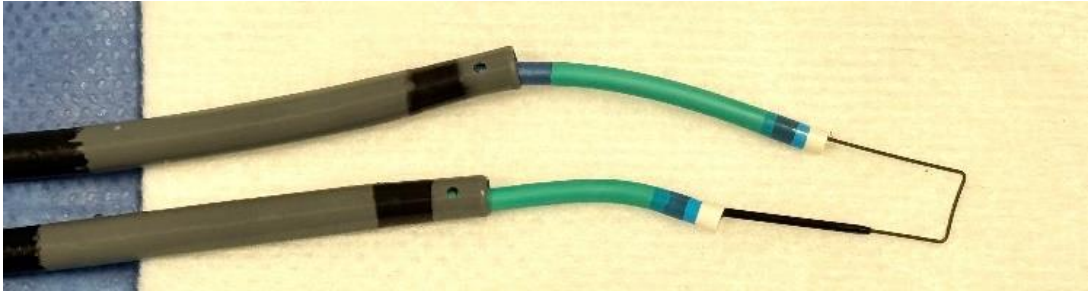


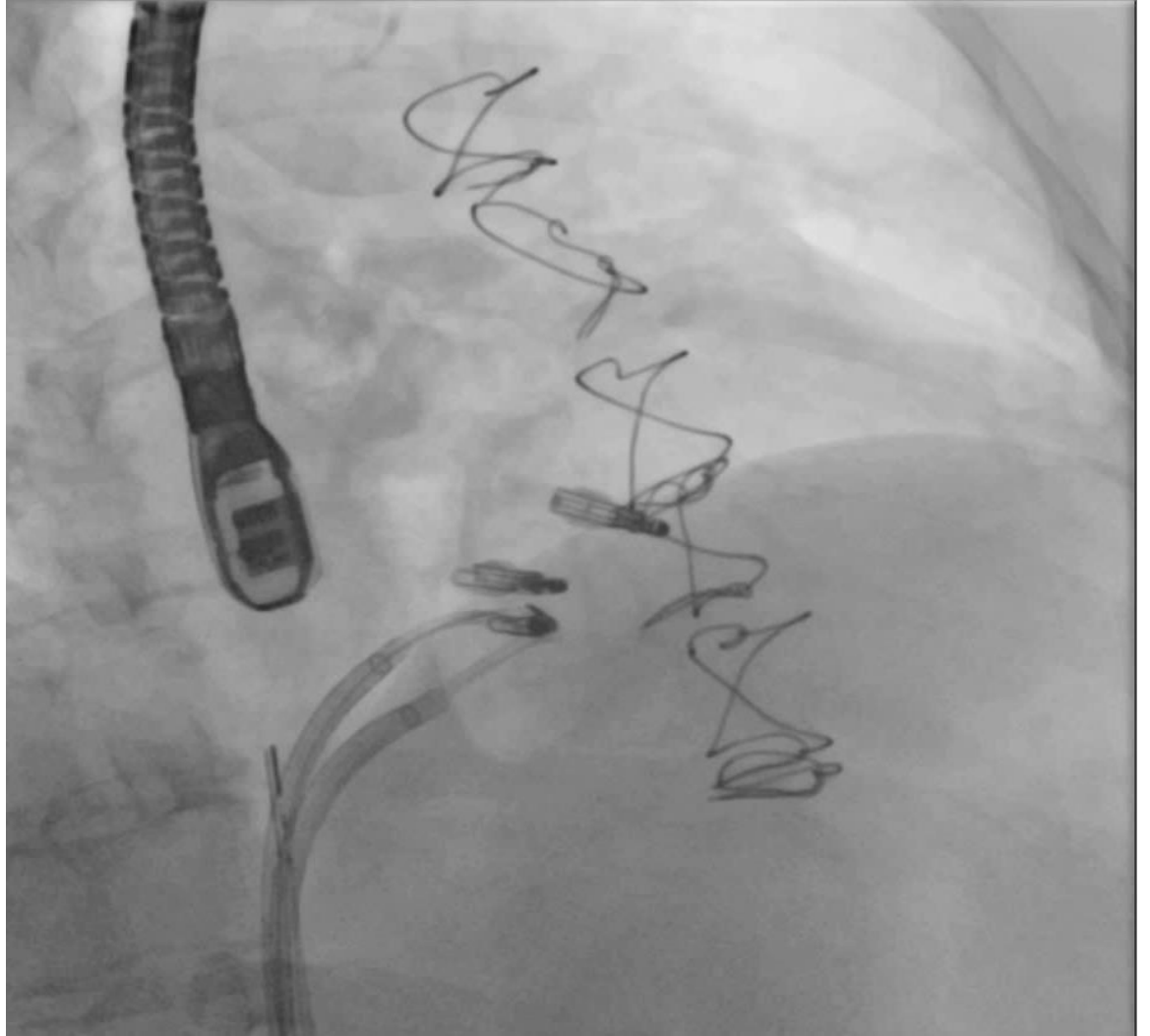






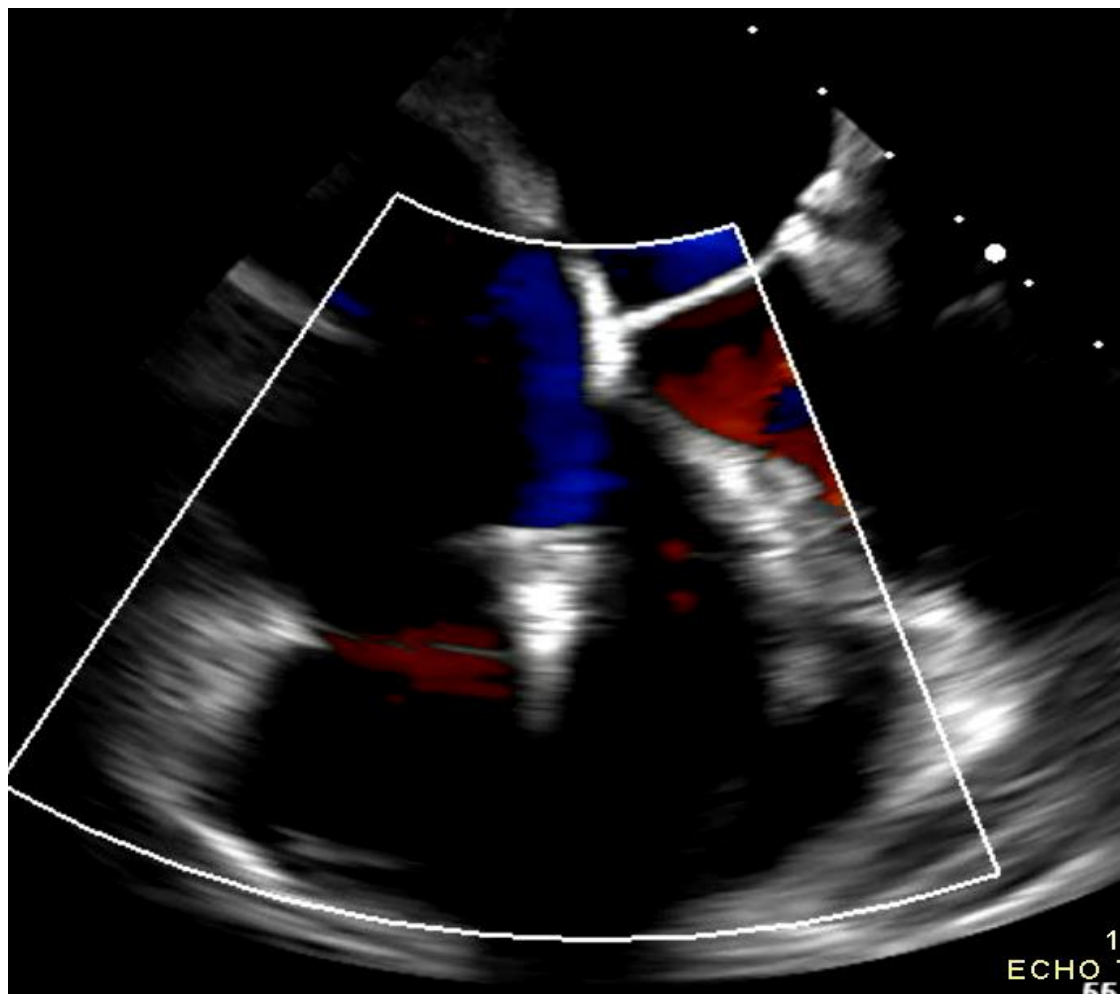




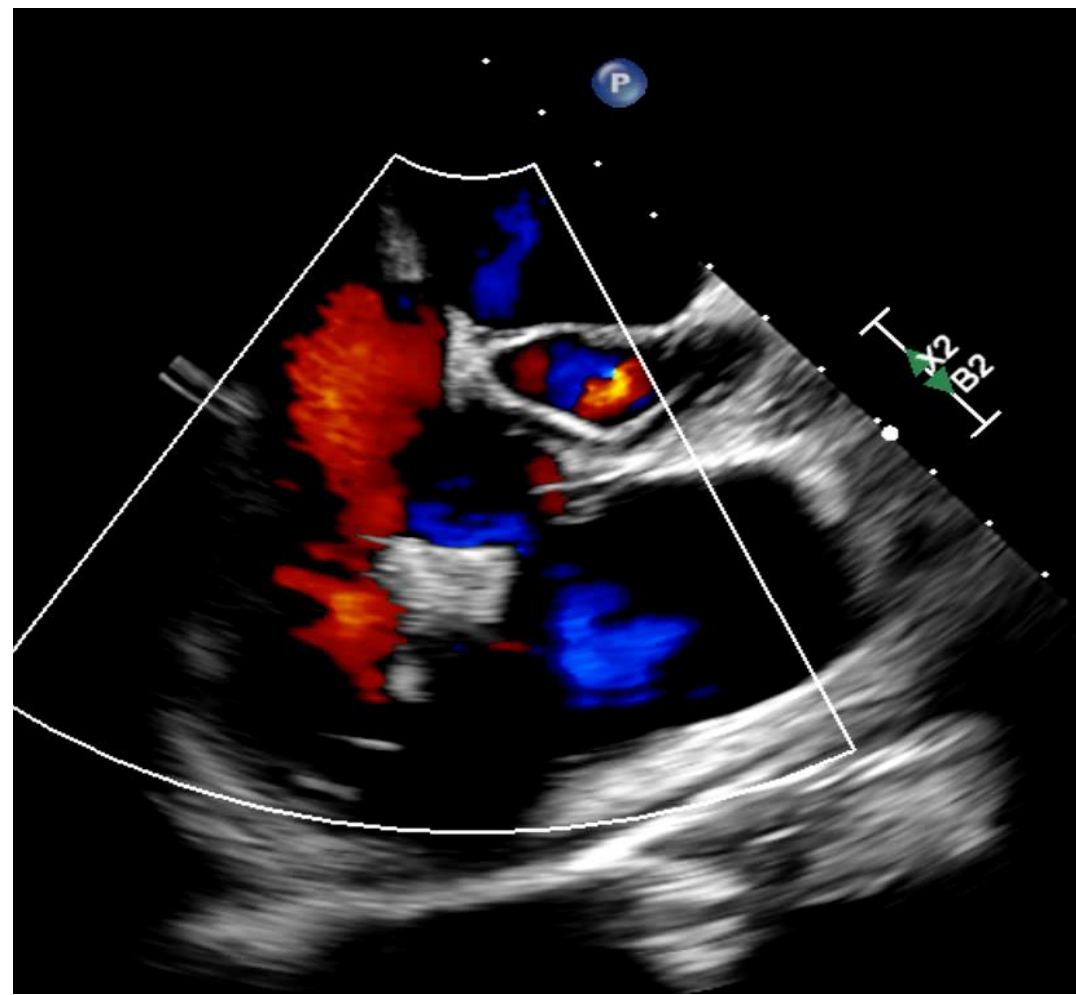


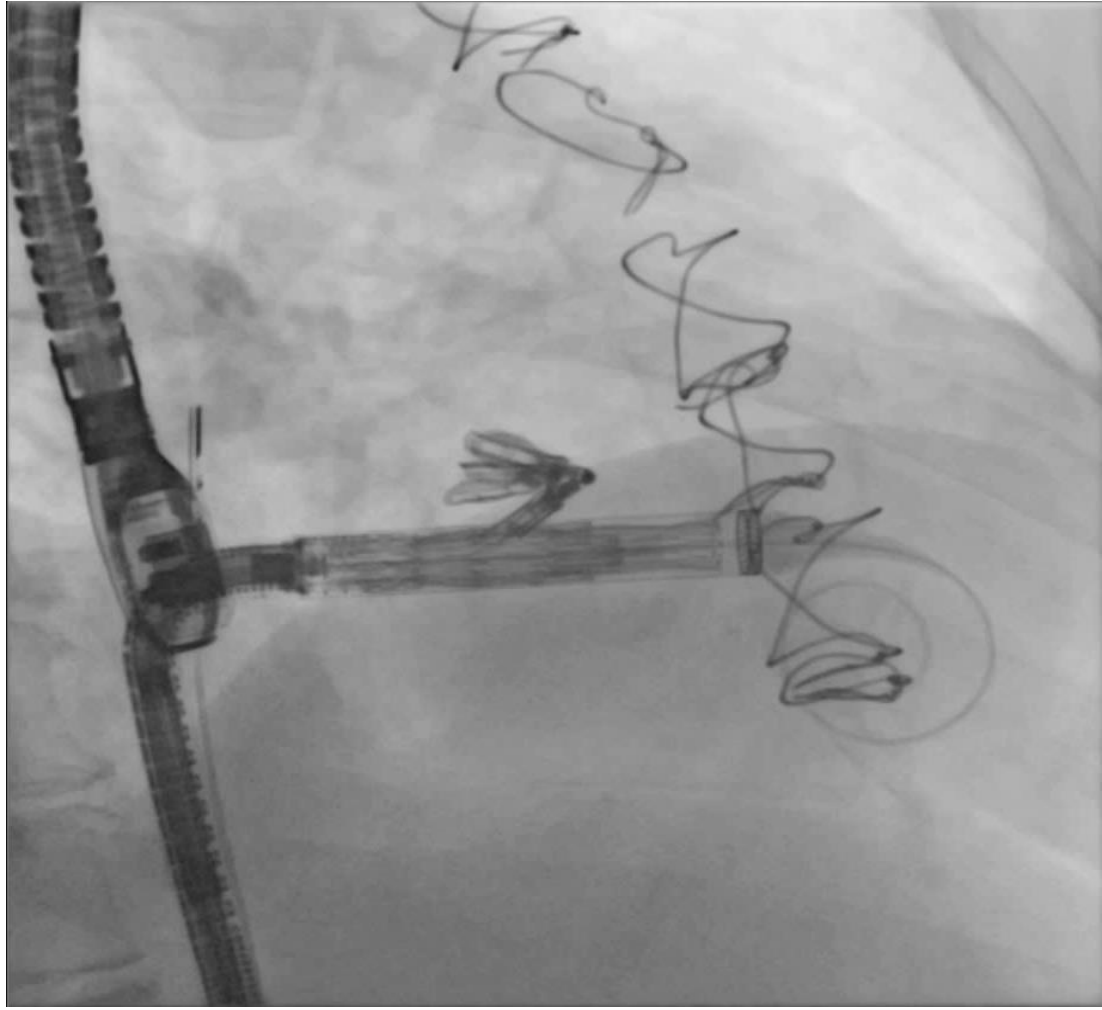


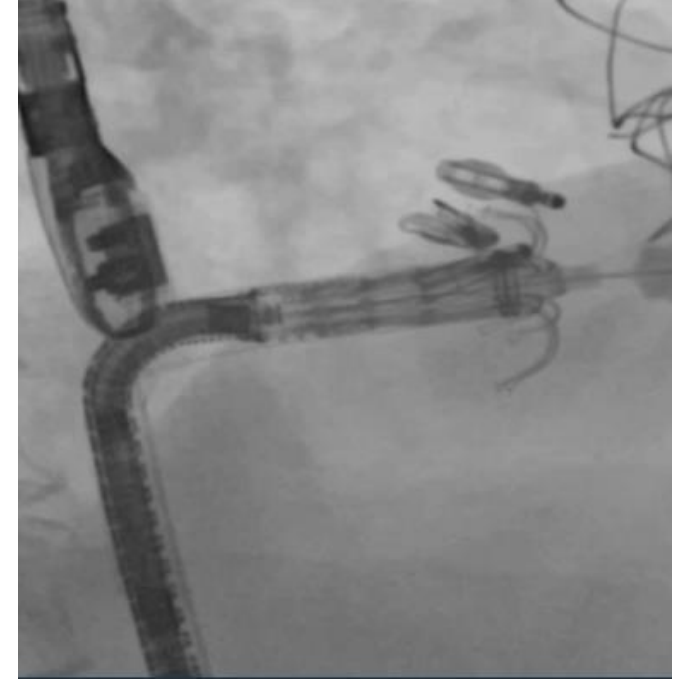
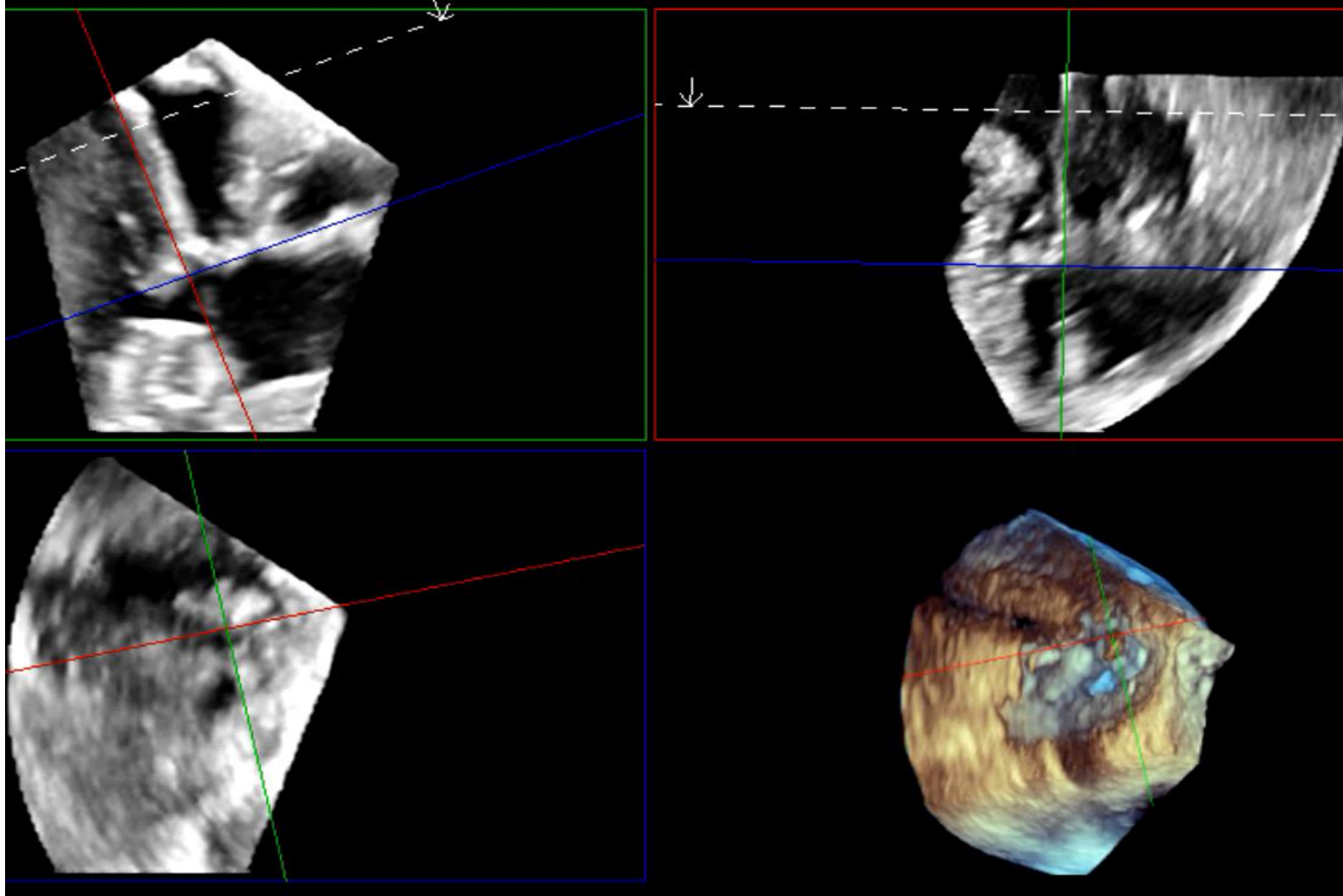
Baseline

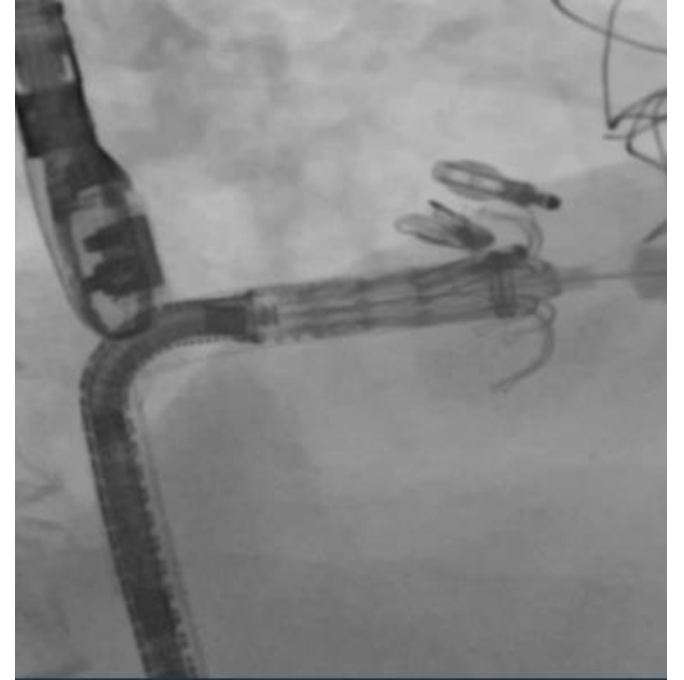
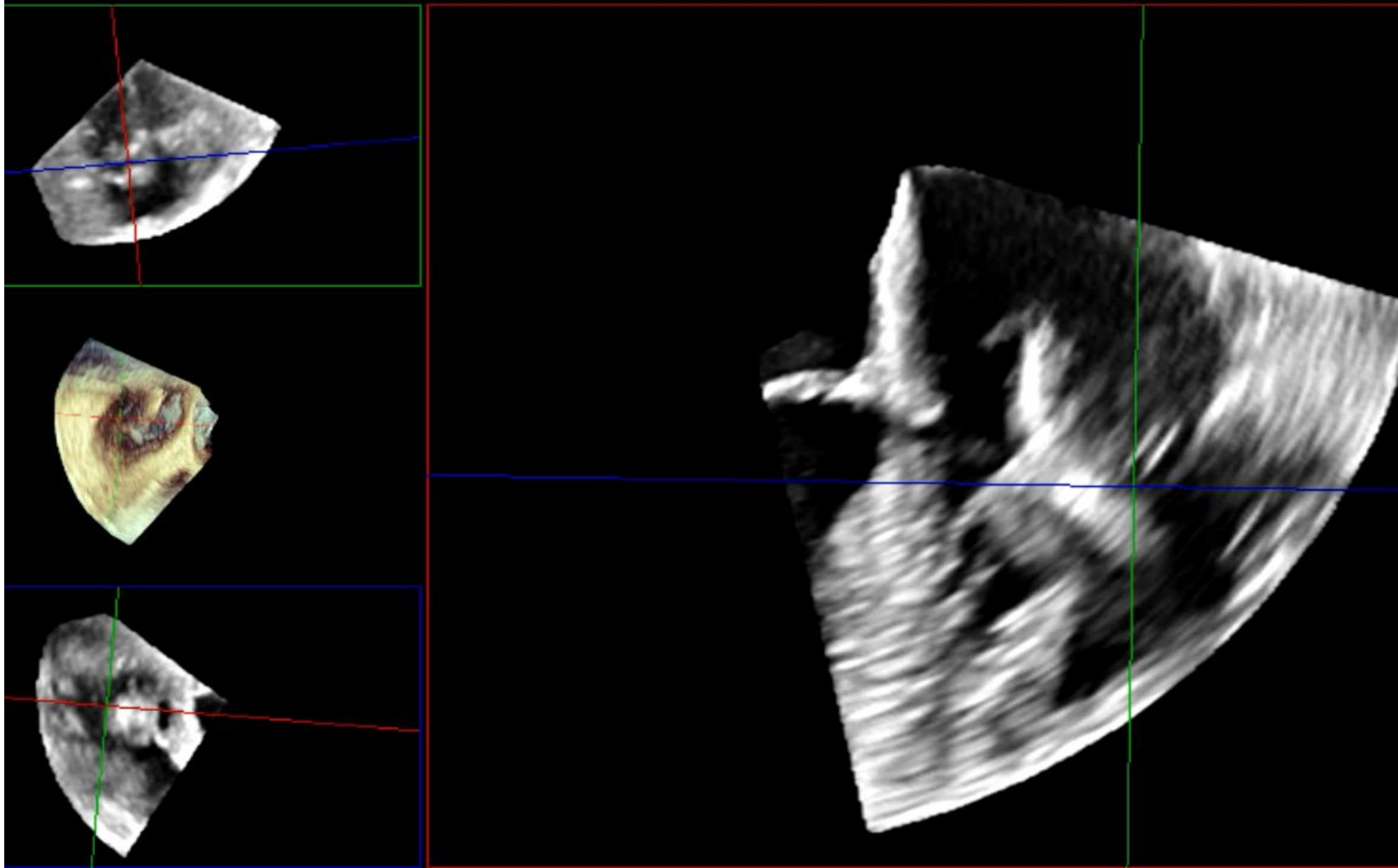


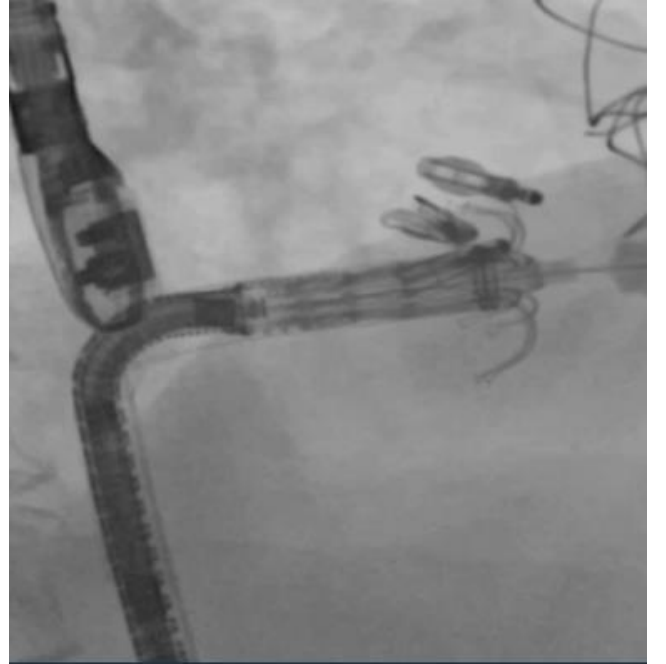
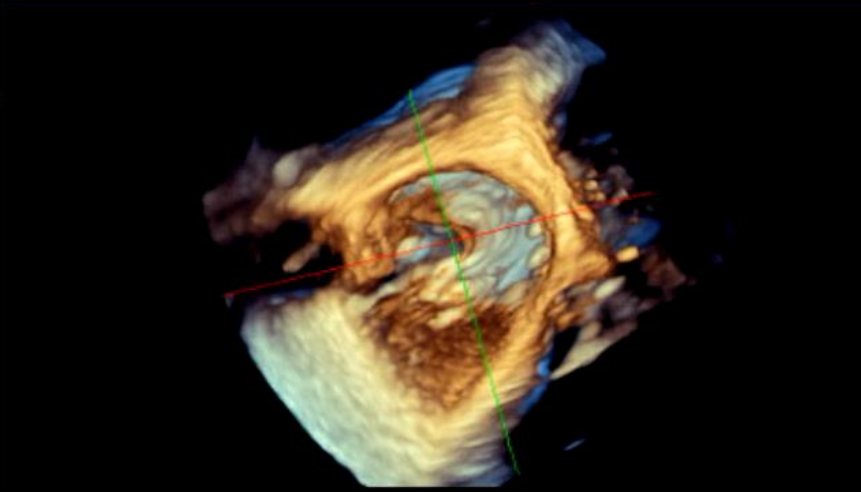
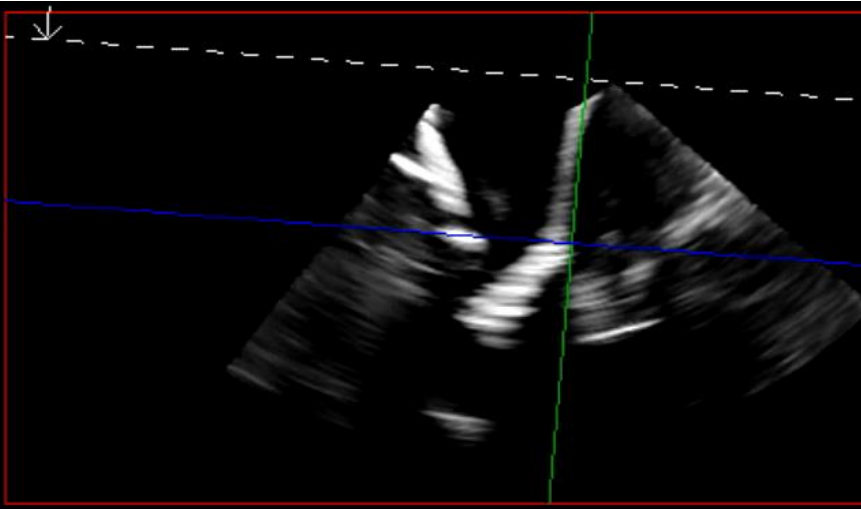
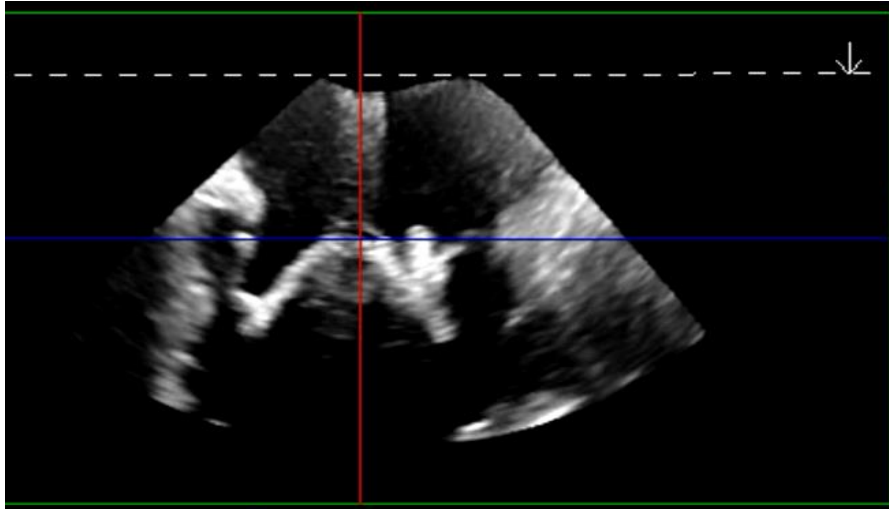
After laceration

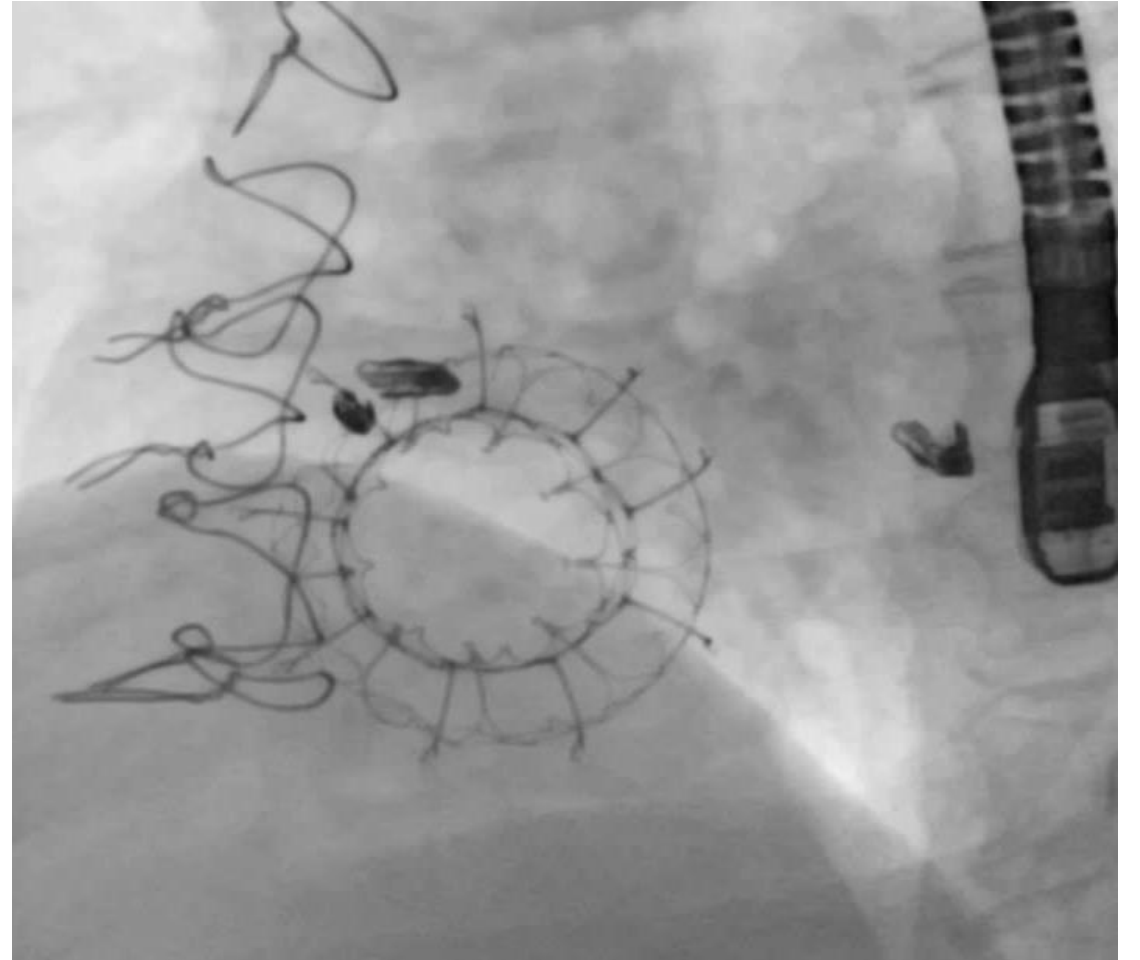
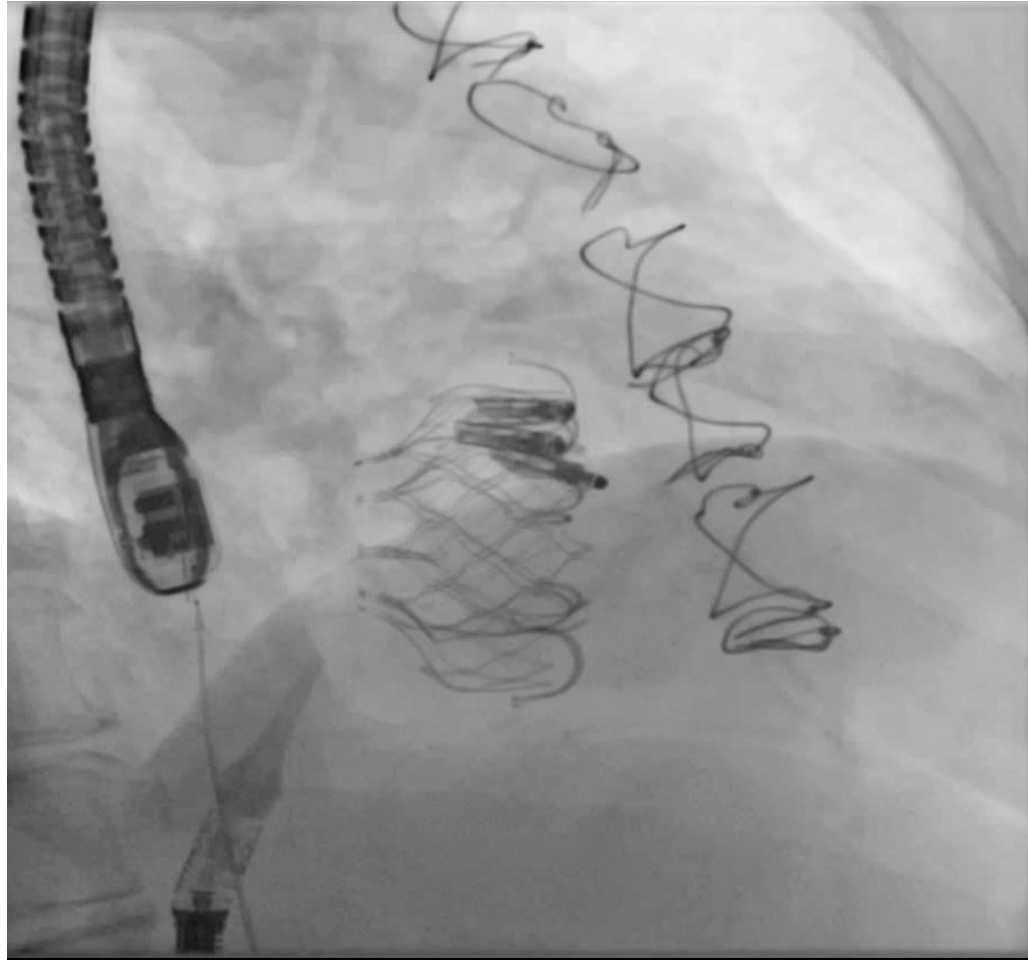


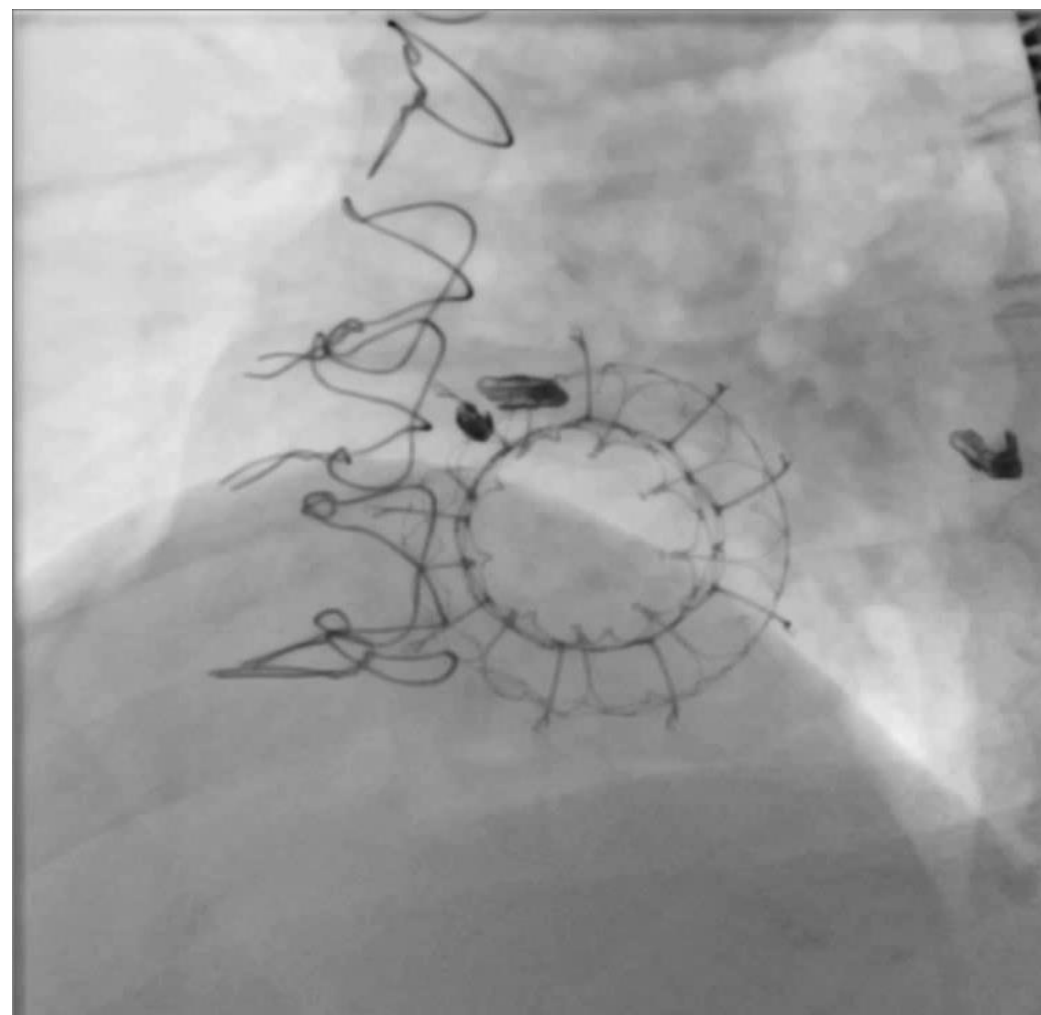








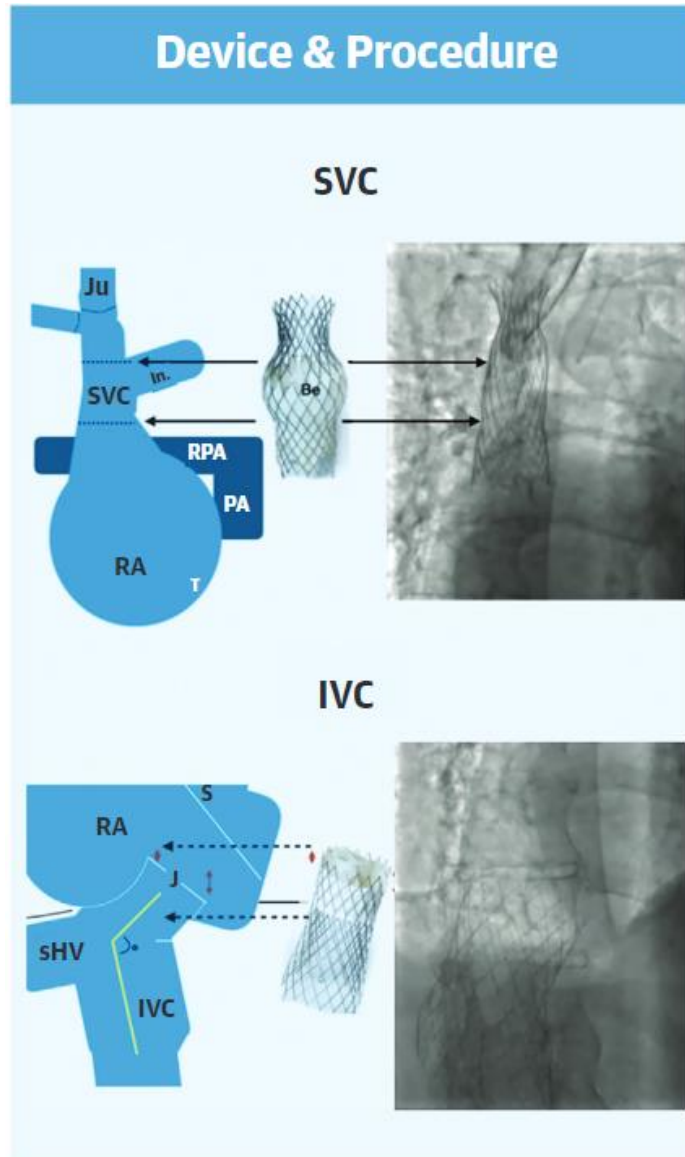




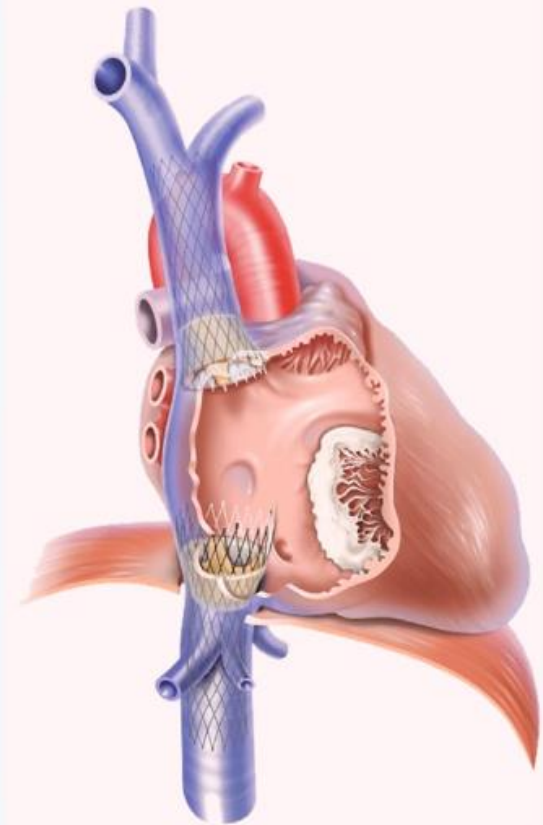
Conclusions

- Tricuspid Regurgitation is common and associated with significant HF symptoms and reduced survival.
- Tricuspid Valve Surgery has high operative mortality and does not improve survival over medical therapy alone.
- Tricuspid Transcatheter Edge-to-Edge Repair (T-TEER) is safe and effective, but does not on average appear to impact mortality or HF hospitalization.
- Transcatheter Tricuspid Valve Replacement is effective at reducing TR and is associated with large quality of life benefits, at the cost of more complications and a requirement for anticoagulation.
- Trials of novel devices are ongoing.

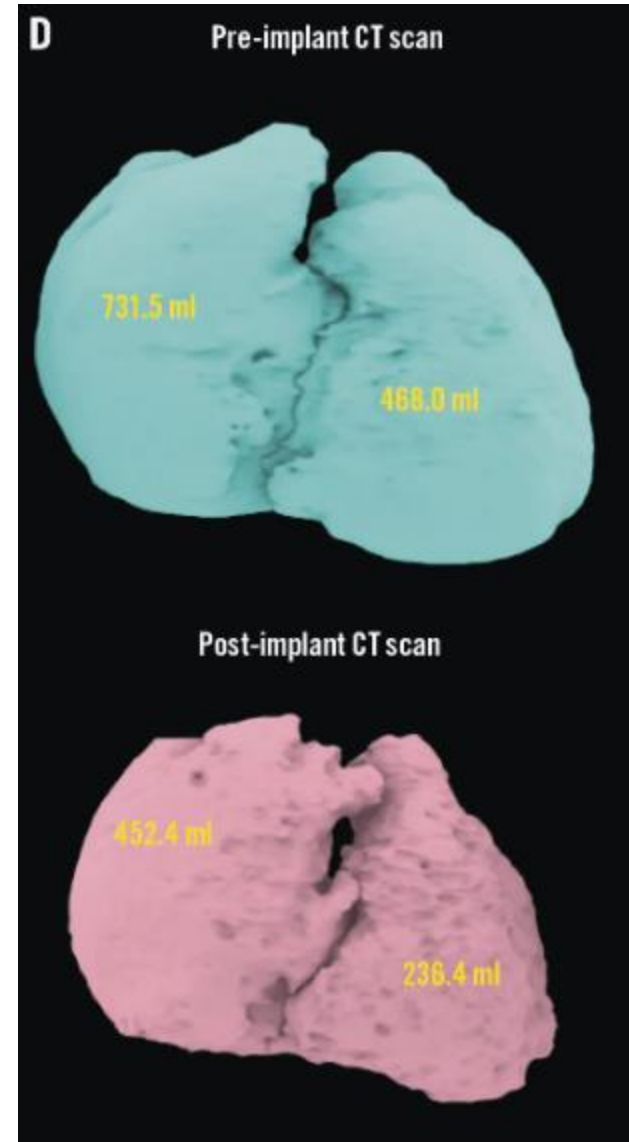
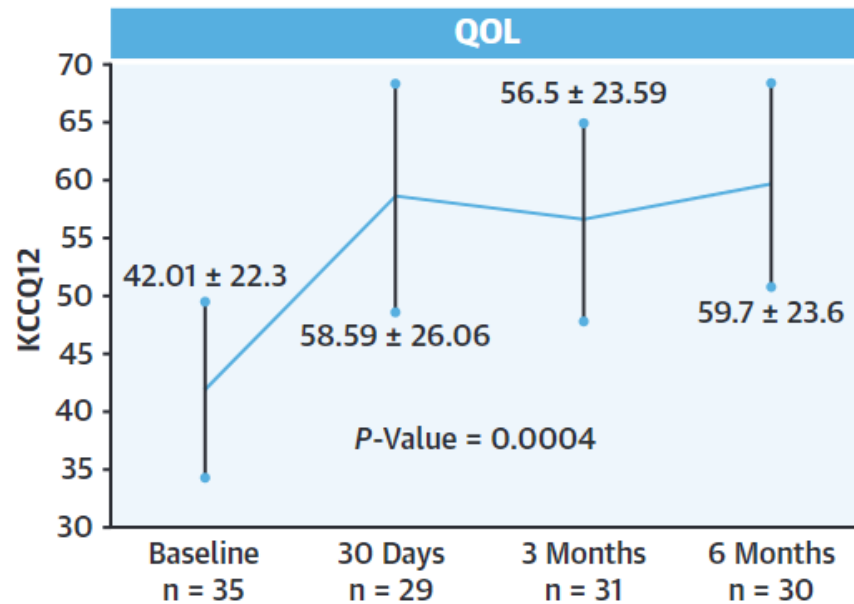
Tric Valve: Heterotopic valve implantation

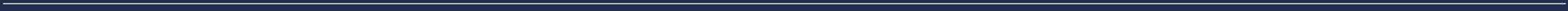
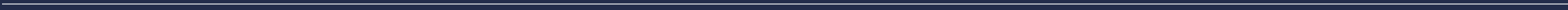


- 97% Technical success
- 0% 6-month cardiac death
- Persistent functional improvement

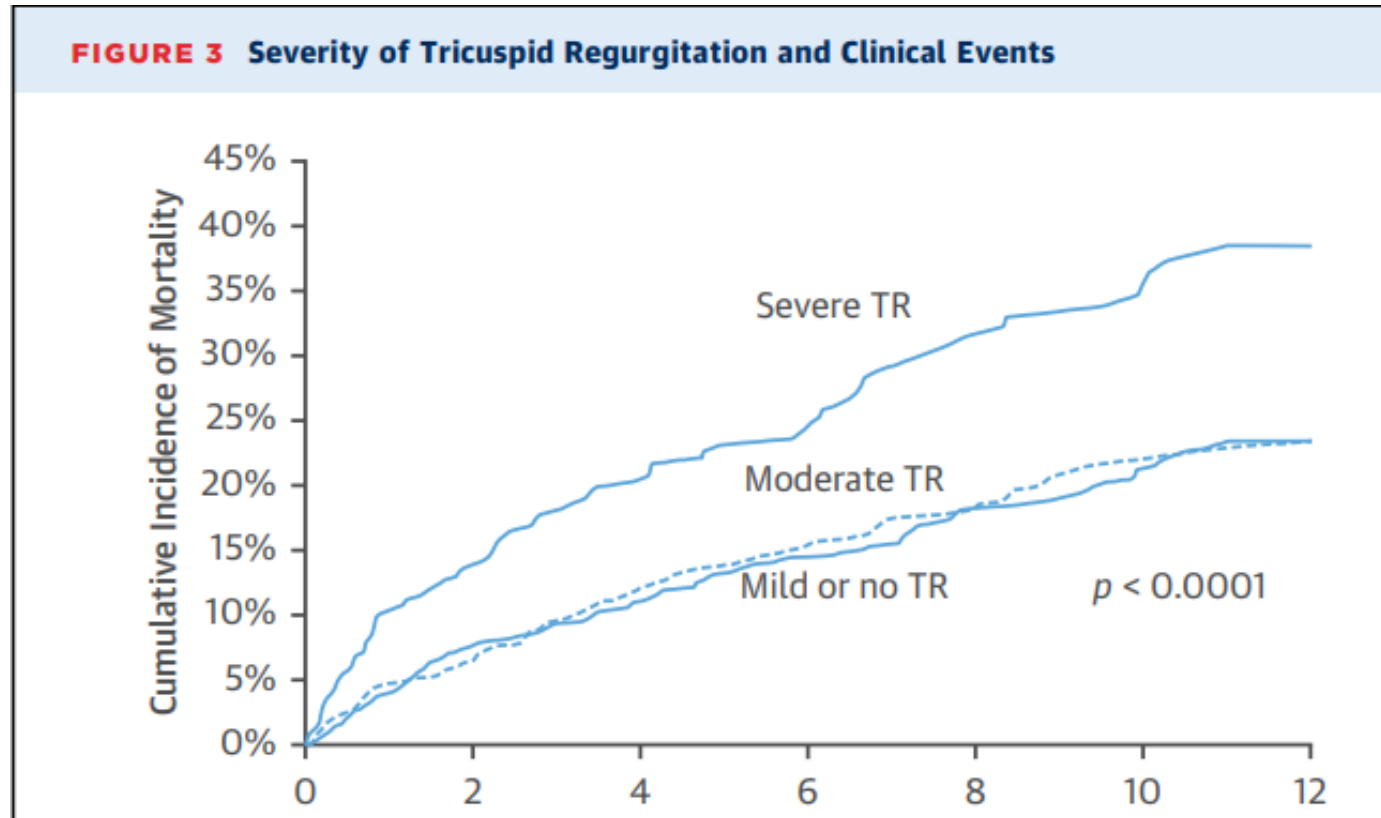


Tric Valve: Heterotopic valve implantation

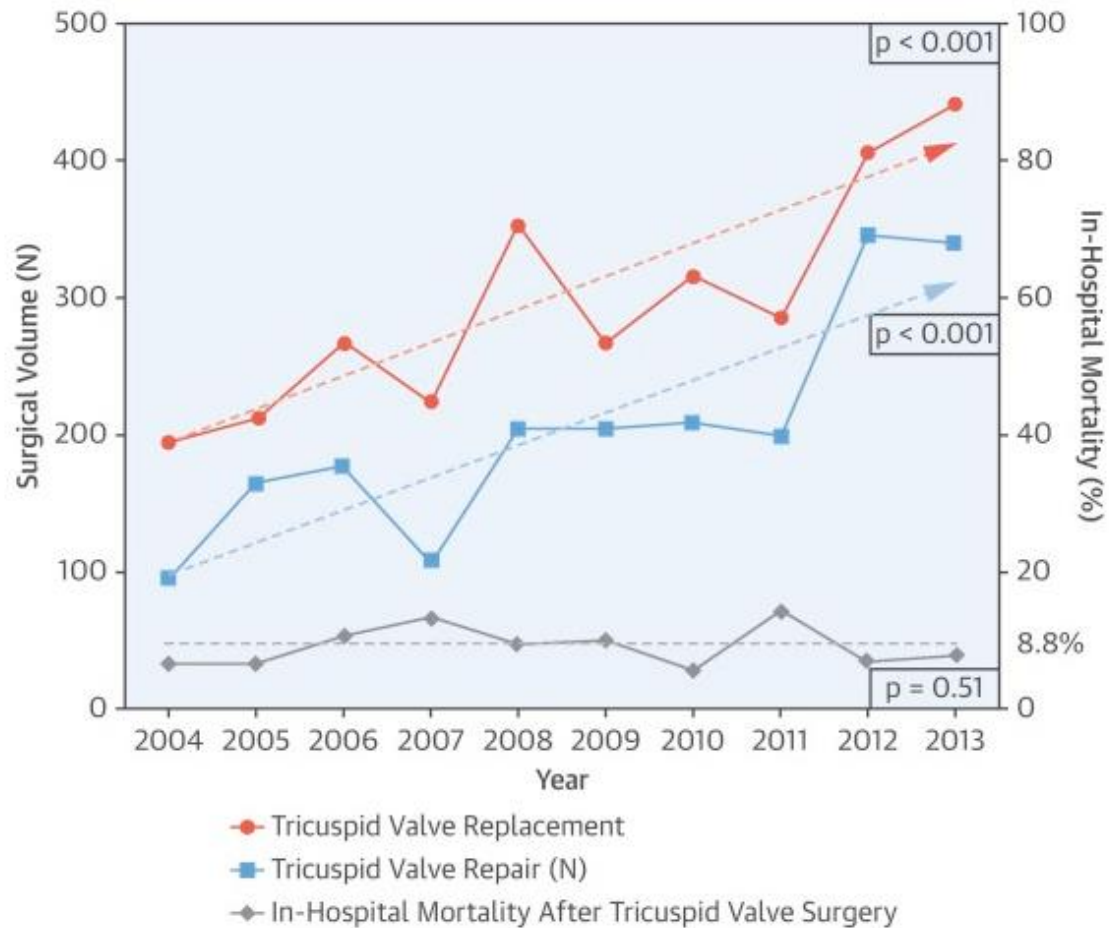




Severe TR is common in M-TEER patients

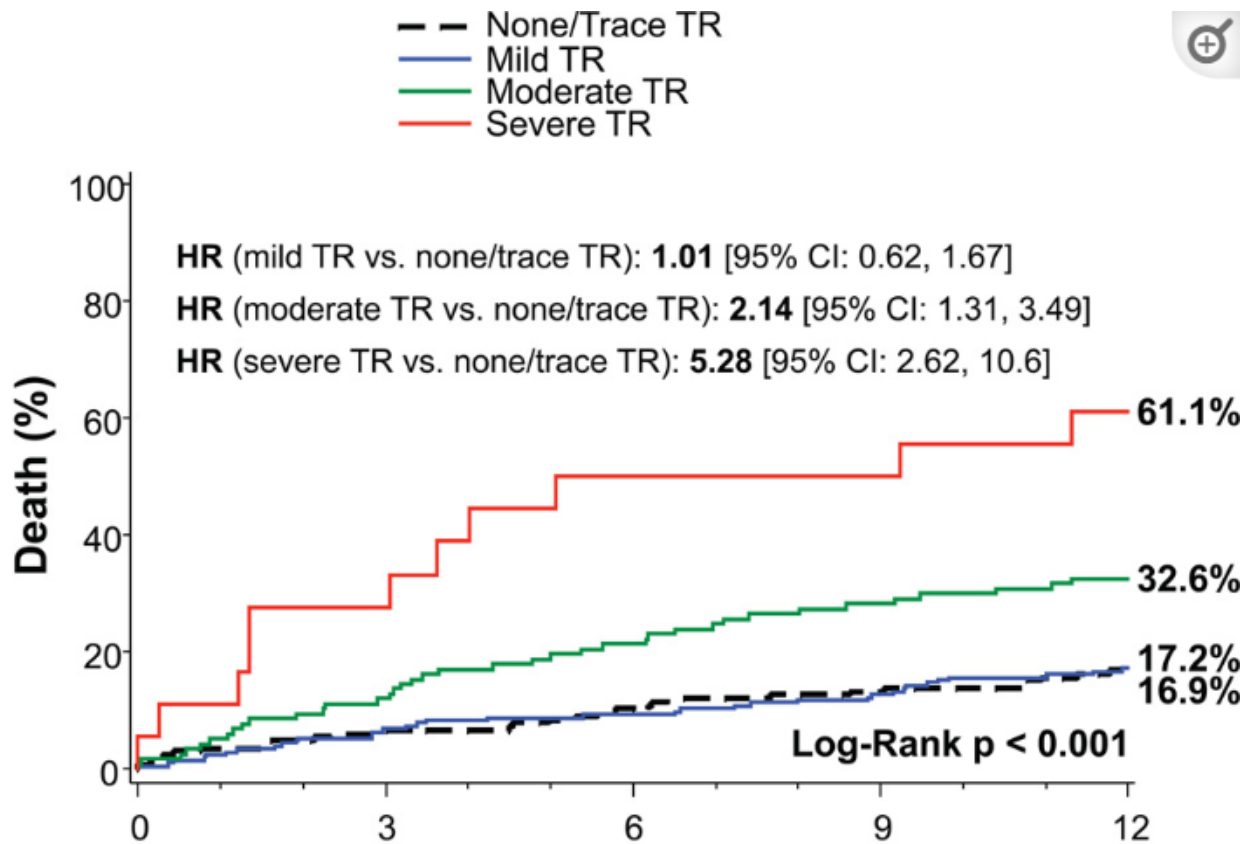


Isolated TR surgery



In-hospital
mortality
~10%

Impact of TR



Severity of tricuspid regurgitation is an independent predictor of survival

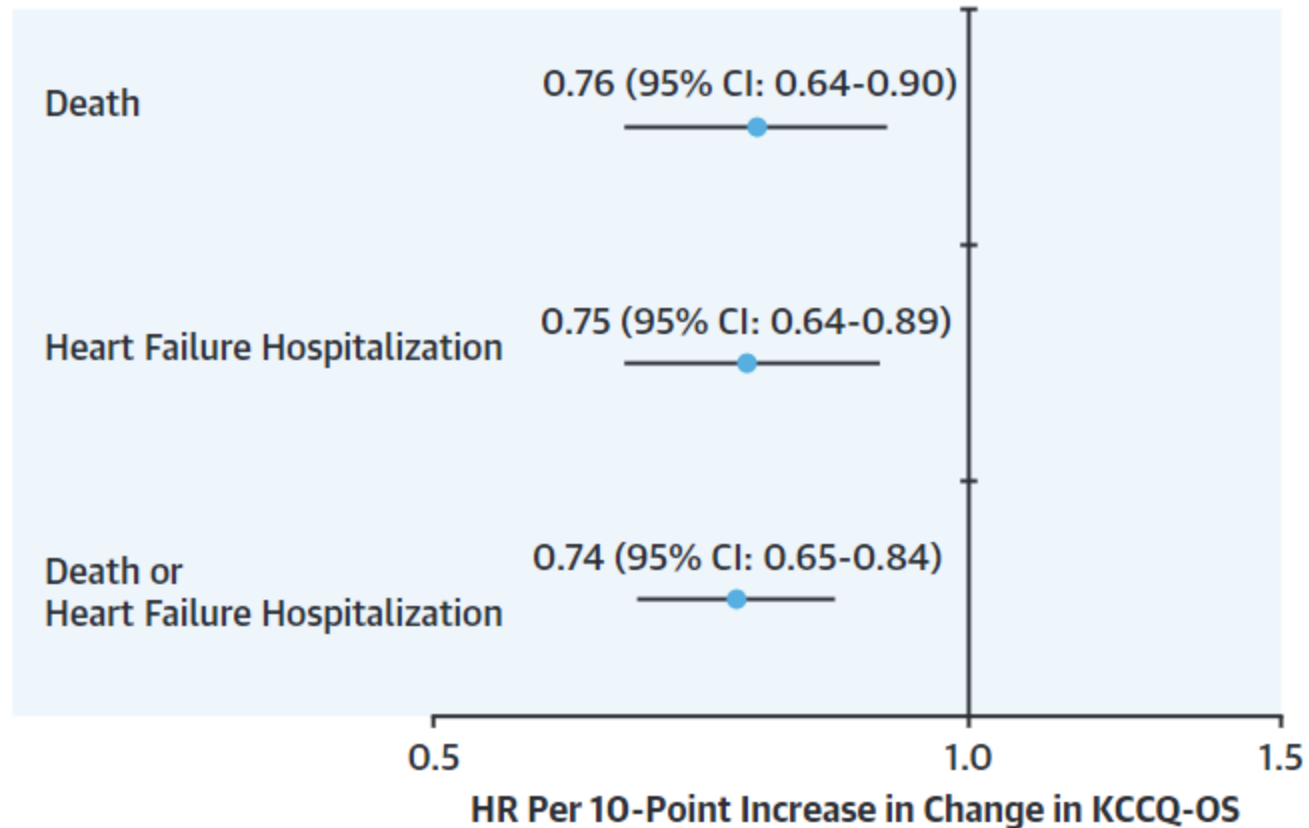
TriLuminate: Results

Table 2. Primary and Secondary End Points.*

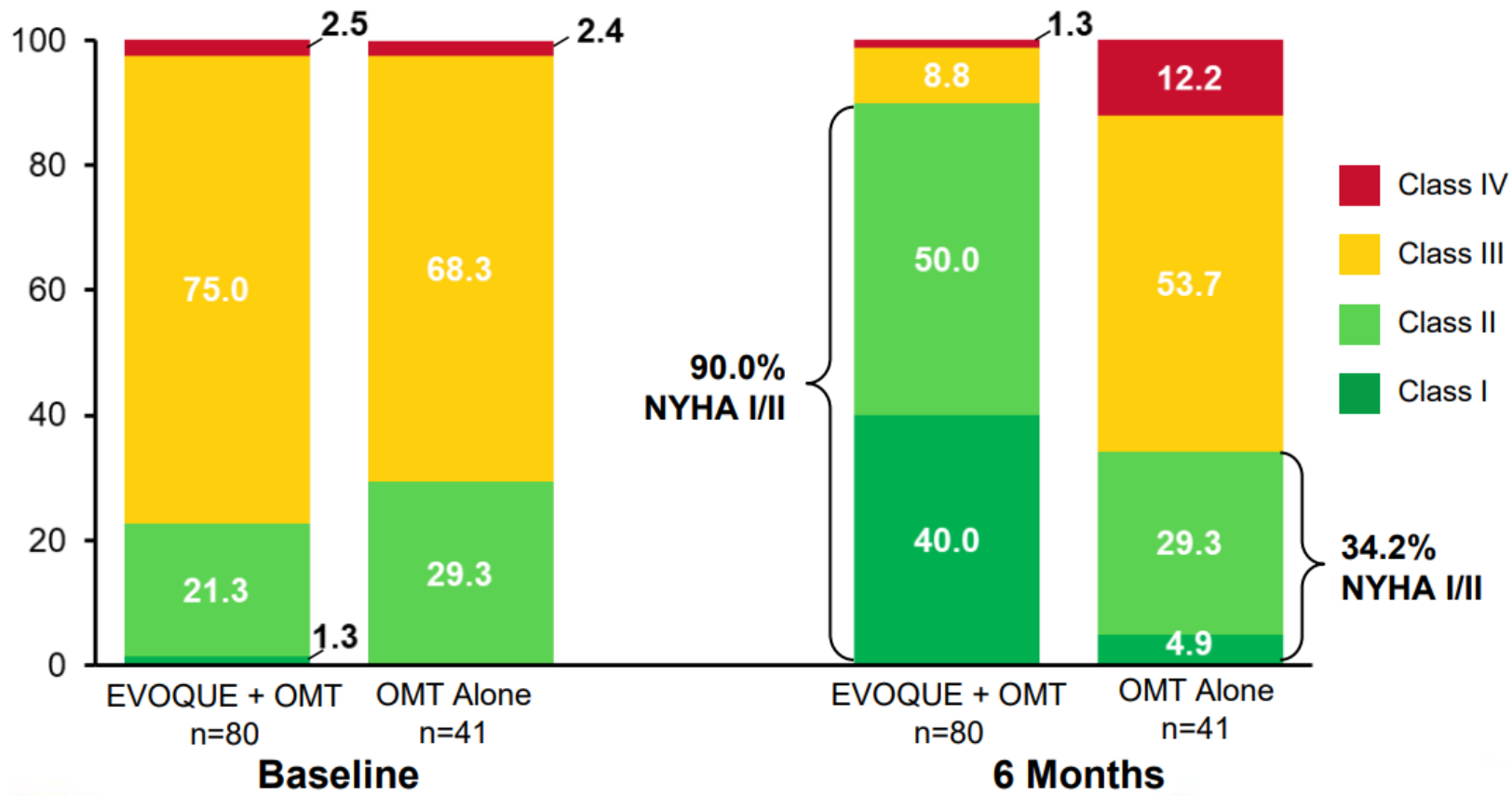
End Point	TEER Group (N=175)	Control Group (N=175)	Difference (95% CI)	P Value
Primary				
Hierarchical composite of death from any cause or tricuspid-valve surgery; hospitalization for heart failure; and improvement of ≥ 15 points in KCCQ score at 1 yr — no. of wins†	11,348	7643	1.48 (1.06 to 2.13)	0.02
Secondary, listed in hierarchical order				
Kaplan–Meier estimate of percentage of patients with freedom from major adverse events through 30 days after the procedure (lower 95% confidence limit)‡	98.3 (96.3)	—	—	<0.001
Change in KCCQ score from baseline to 1 yr — points§	12.3 \pm 1.8	0.6 \pm 1.8	11.7 (6.8 to 16.6)	<0.001
Tricuspid regurgitation of no greater than moderate severity at 30-day follow-up — no. of patients/total no. (%)¶	140/161 (87.0)	7/146 (4.8)	—	<0.001
Change in 6-min walk distance from baseline to 1 yr — m	-8.1 \pm 10.5	-25.2 \pm 10.3	17.1 (-12.0 to 46.1)	0.25

TriLuminate: Quality of Life






FIGURE 4 Change in KCCQ-OS at 1 Month After Tricuspid-Edge-to-Edge Transcatheter Valve Repair and Subsequent Outcomes



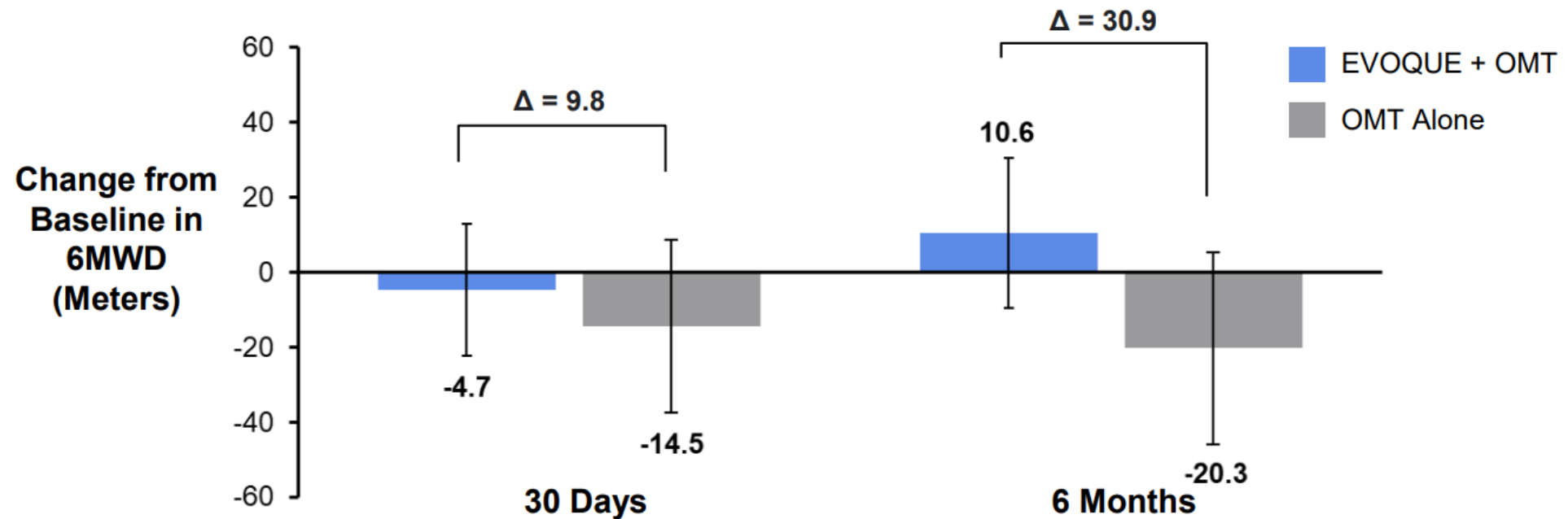
Transcatheter Tricuspid Valve Replacement



Transcatheter Tricuspid Valve Replacement

Primary Endpoints	First 150	Total Cohort
Safety (30 Days) <ul style="list-style-type: none">• Composite MAE rate		
Effectiveness (6 Months) <ul style="list-style-type: none">• TR grade reduction• Hierarchical composite of KCCQ, NYHA and 6MWD		
Hierarchical Composite (1 Year) <ol style="list-style-type: none">1. All-cause mortality2. RVAD implant or heart transplant3. TV surgery or intervention4. Annualized heart failure hospitalization5. KCCQ, NYHA, 6MWD		

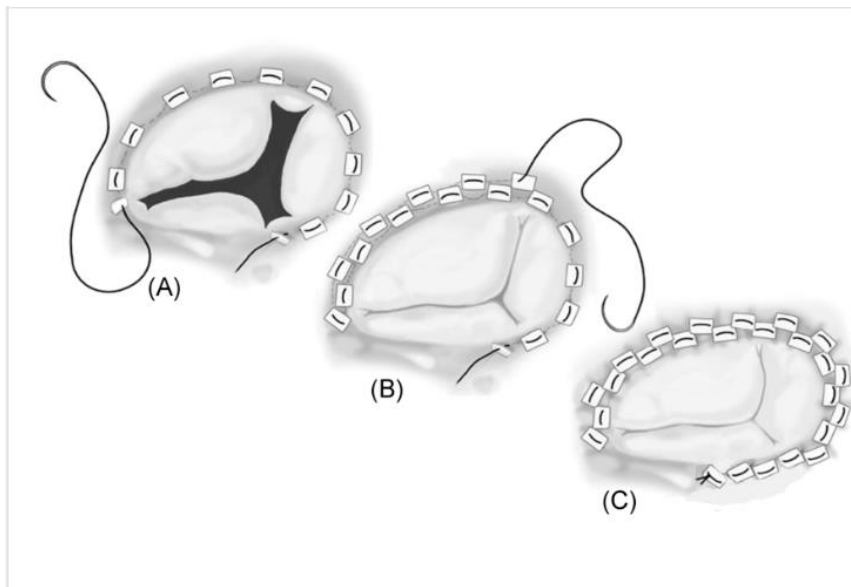
Transcatheter Tricuspid Valve Replacement



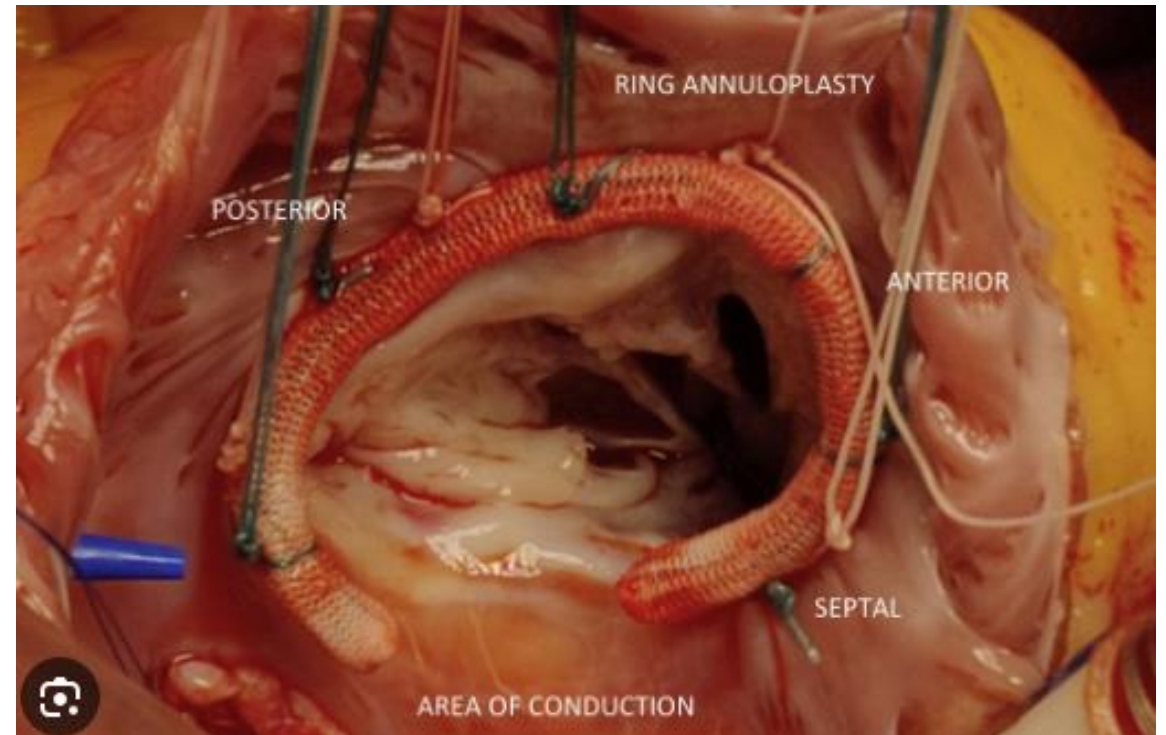
Baseline mean 6MWD (meters)	243.0	253.5	247.0	265.4
	n=81	n=39	n=73	n=34

Surgical Tricuspid Valve Repair

Suture Annuloplasty

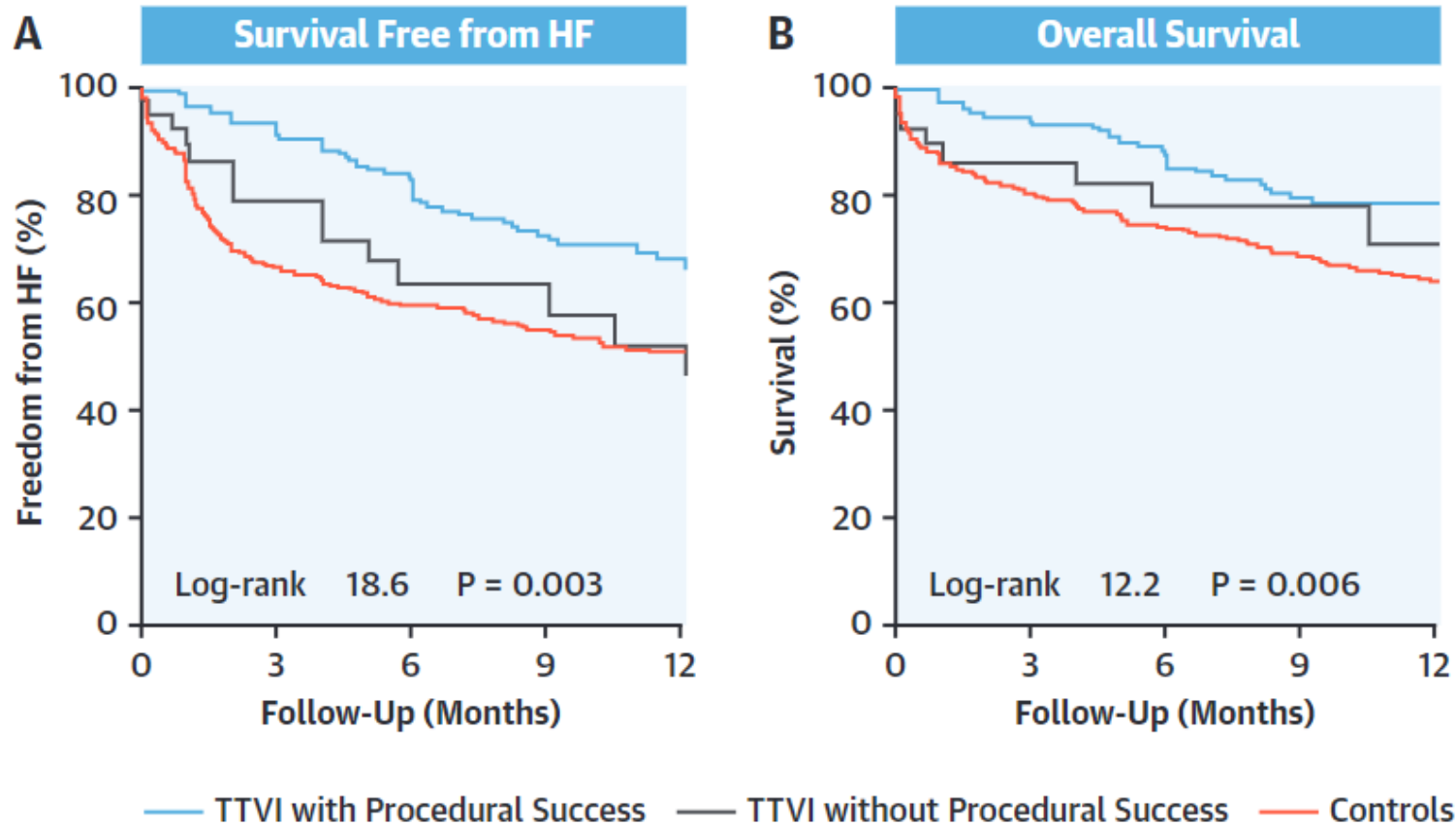


Incomplete rings



TriValve Registry - Results

FIGURE 1 Impact of Procedural Success



Procedural
success
86%