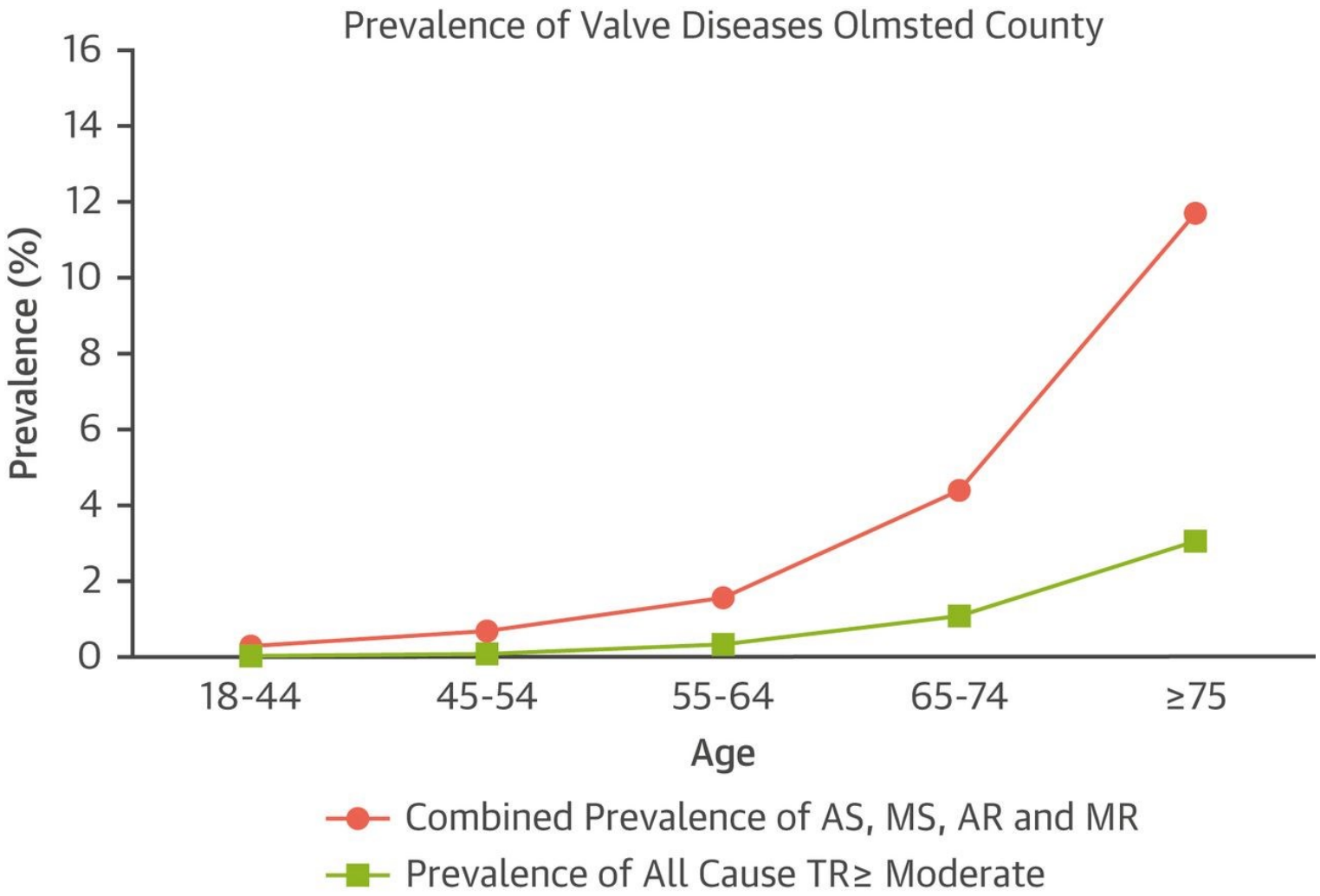
Transcatheter Therapies for Tricuspid Regurgitation

Raj R. Makkar, MD
Smidt Heart Institute, Cedars-Sinai Medical Center, Los Angeles CA

Tricuspid Regurgitation is highly prevalent



- Is more common with age
- Similar in prevalence to aortic stenosis

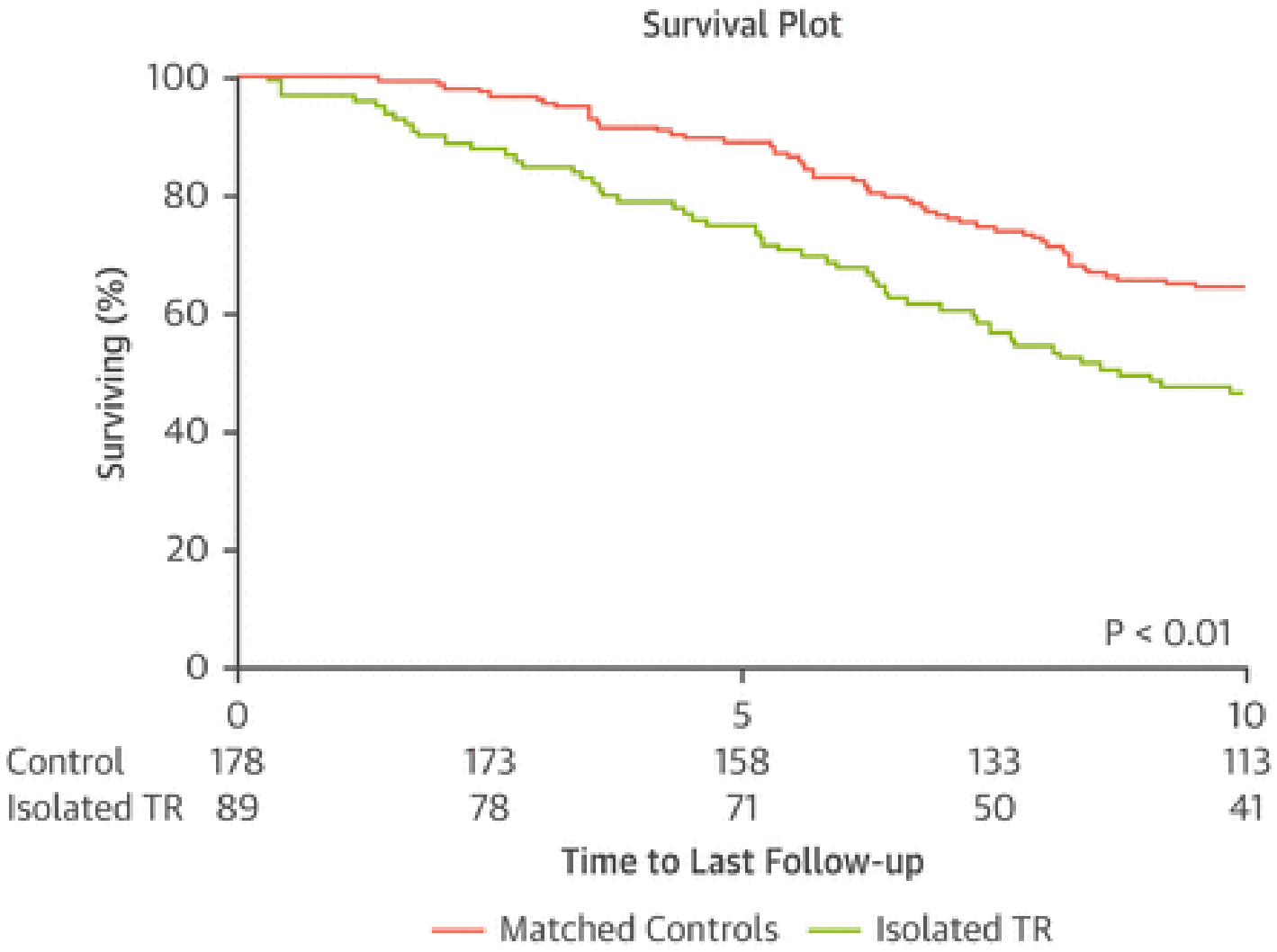
Yan Topilsky, et al. Burden of Tricuspid Regurgitation in Patients Diagnosed in the Community Setting
J Am Coll Cardiol Img. 2019 Mar, 12 (3) 433-442

TR Prevalence amongst different populations

Population	TR severity	TR prevalence (%)	FU	Ref
MitraClip	Moderate to severe	11	1 y	Ohno (2014)
TAVI	Moderate to severe	21	30 d	Barbanti (2015)
TAVI	Moderate to severe	16	1 y	Lindman (2015)
SAVR	Mild to severe	21	4,4 y	Jeong (2014)
Valvuloplasty for rheumatic MS	Moderate to severe	19	12 y	Lee, S.-P (2013)
MV surgery for degenerative MV disease	Severe	6	> 5 y	Rajbanshi (2014)
MV repair in dilated cardiomyopathy	Moderate to severe	20	7,3 y	De Bonis (2015)

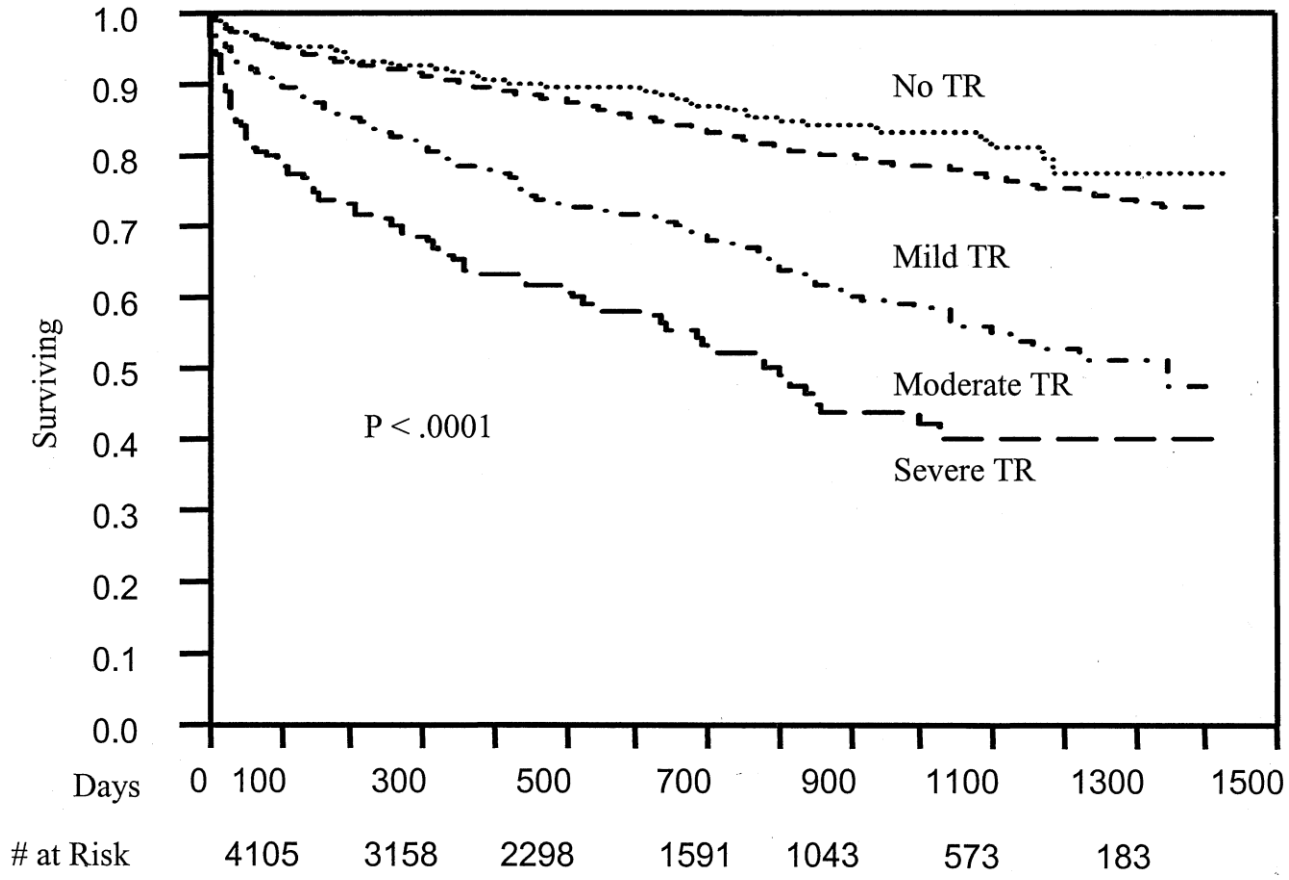
Azeem Latib. TCT 2017

TR is associated with adverse outcomes



Yan Topilsky, et al. Burden of Tricuspid Regurgitation in Patients Diagnosed in the Community Setting
J Am Coll Cardiol Img. 2019 Mar, 12 (3) 433-442

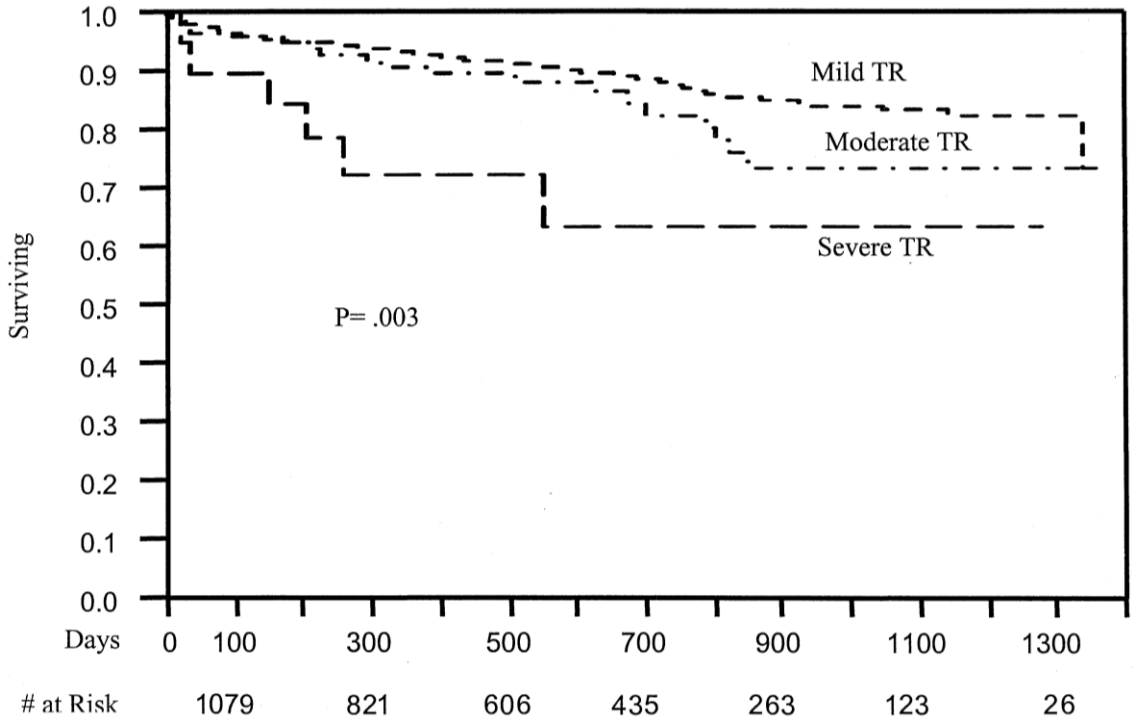
TR Risk of mortality increases with severity



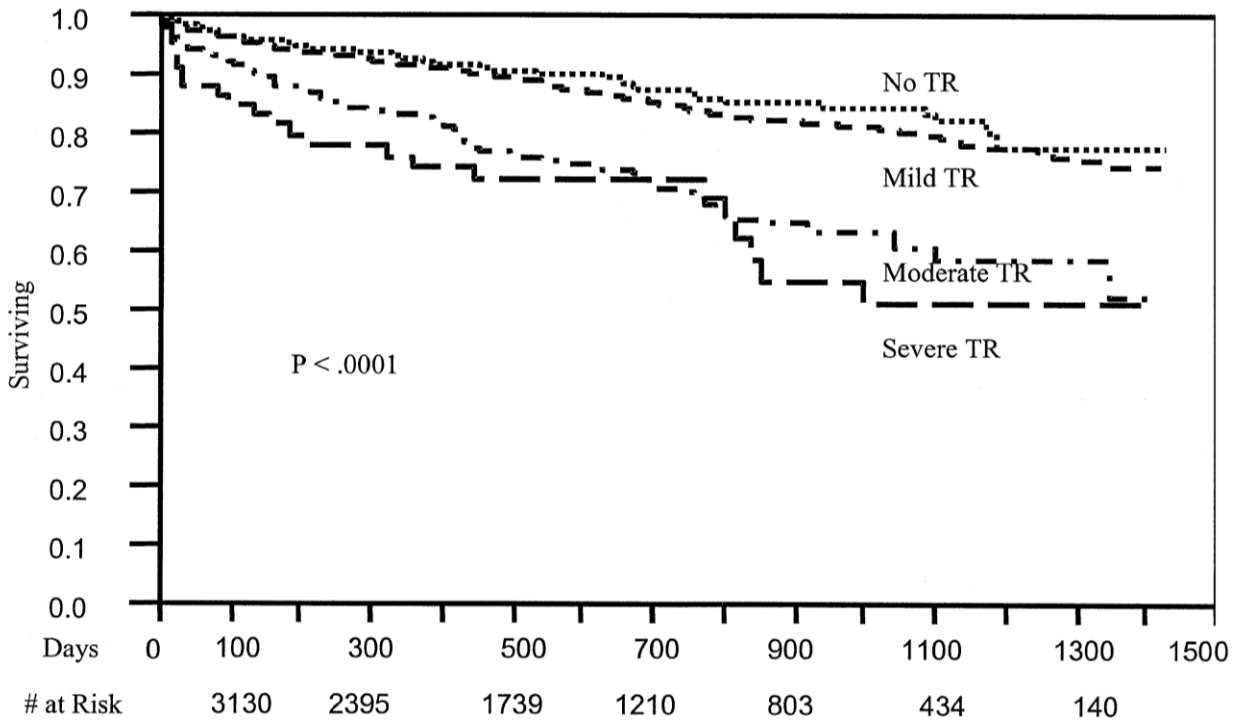
Nath J, Foster E, Heidenreich PA. Impact of tricuspid regurgitation on long-term survival. J Am Coll Cardiol. 2004 Feb 4;43(3):405-9.

TR Risk of mortality increases with severity

In patients with PASP <40mmHg

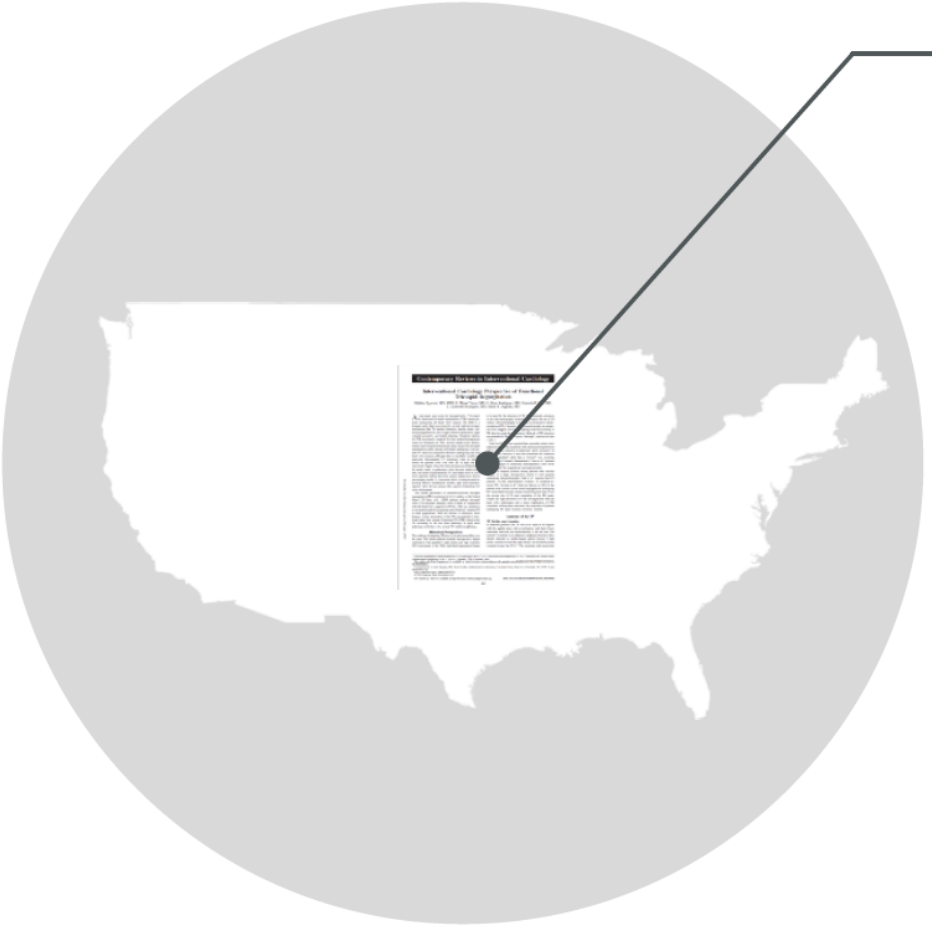


In patients with LVEF > 50%



Nath J, Foster E, Heidenreich PA. Impact of tricuspid regurgitation on long-term survival. J Am Coll Cardiol. 2004 Feb 4;43(3):405-9.

Patients are largely undertreated with surgery



1,600,000
Number of
moderate to severe TR cases

250,000
Number of
new TR cases annually

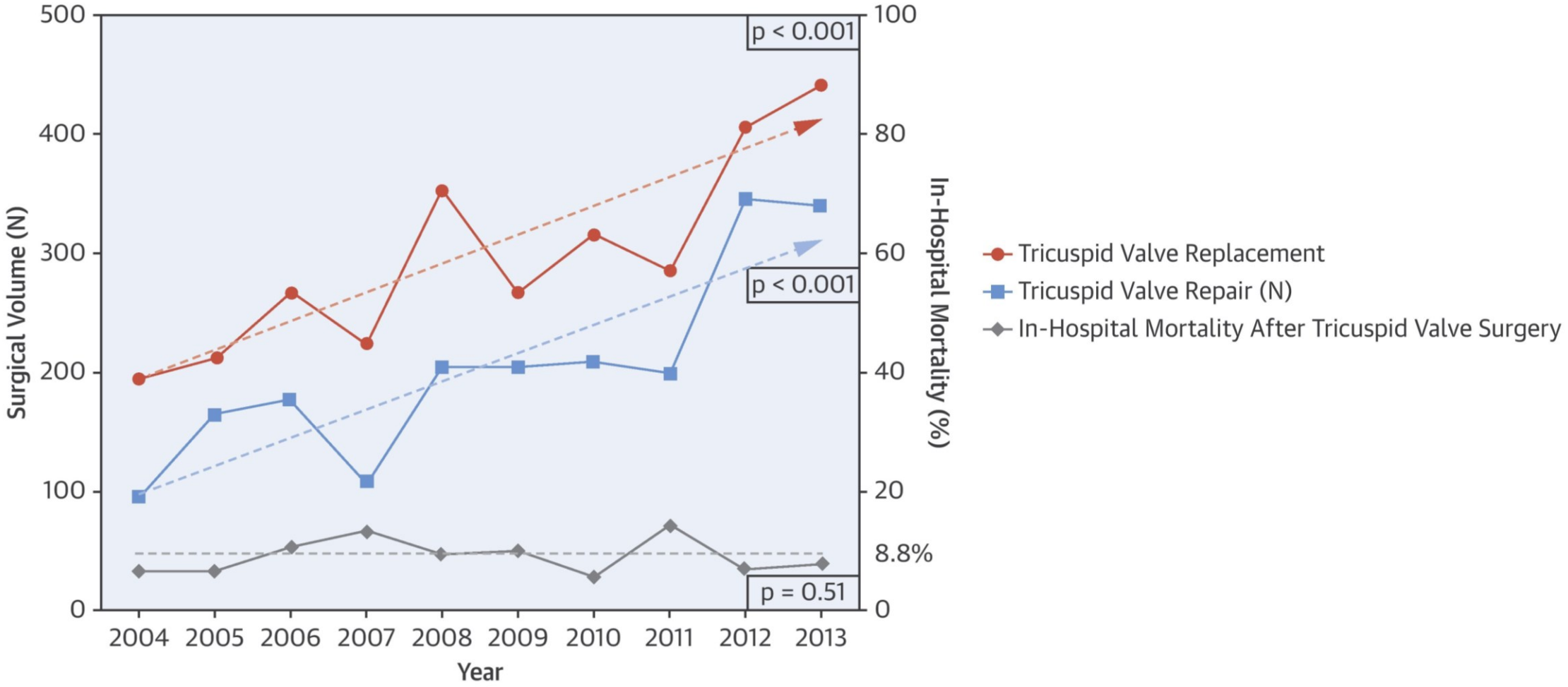
<8,000
Number of
TR surgeries

<0.5%
of TR cases treated surgically

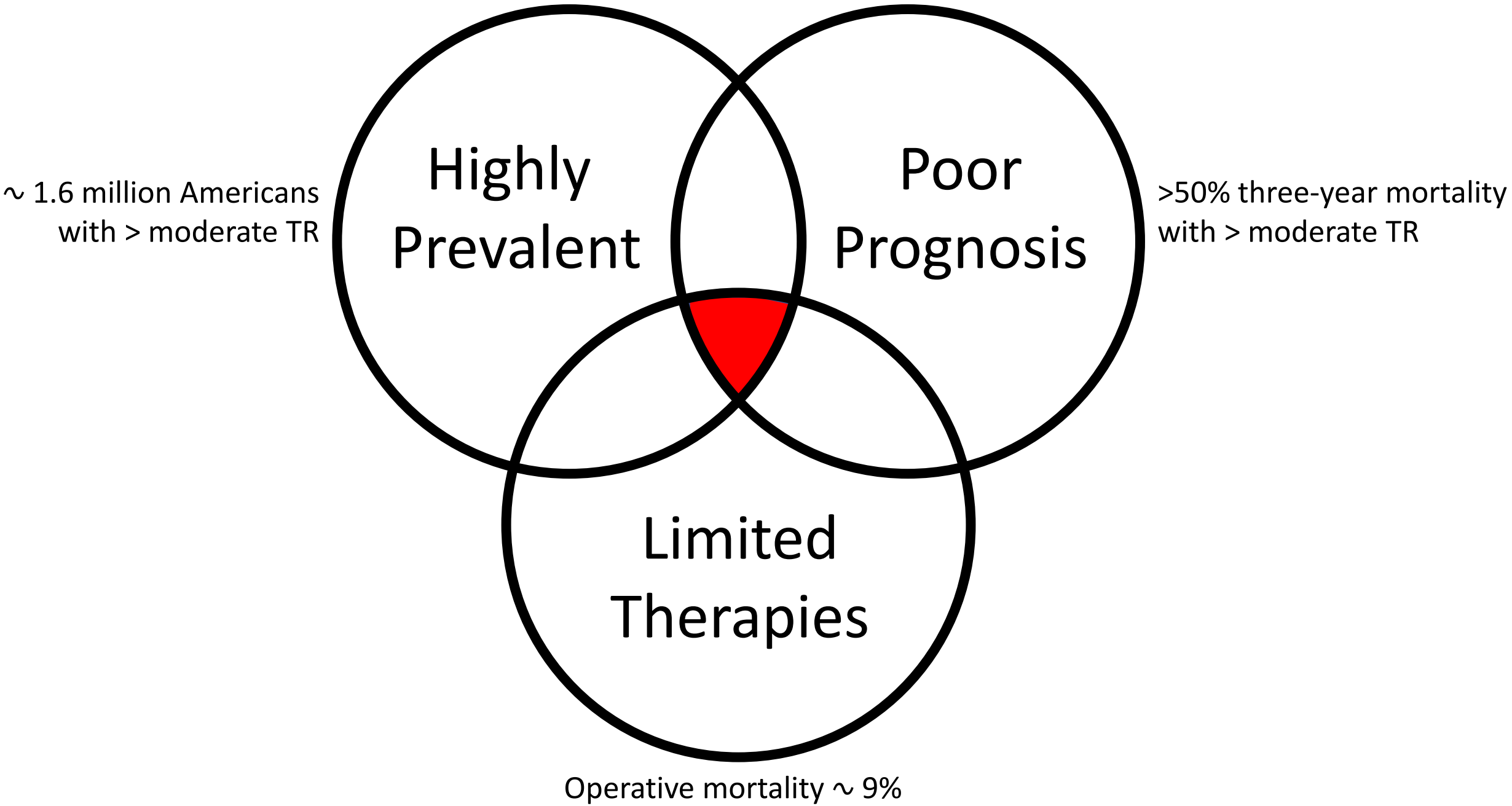
90%
are repair

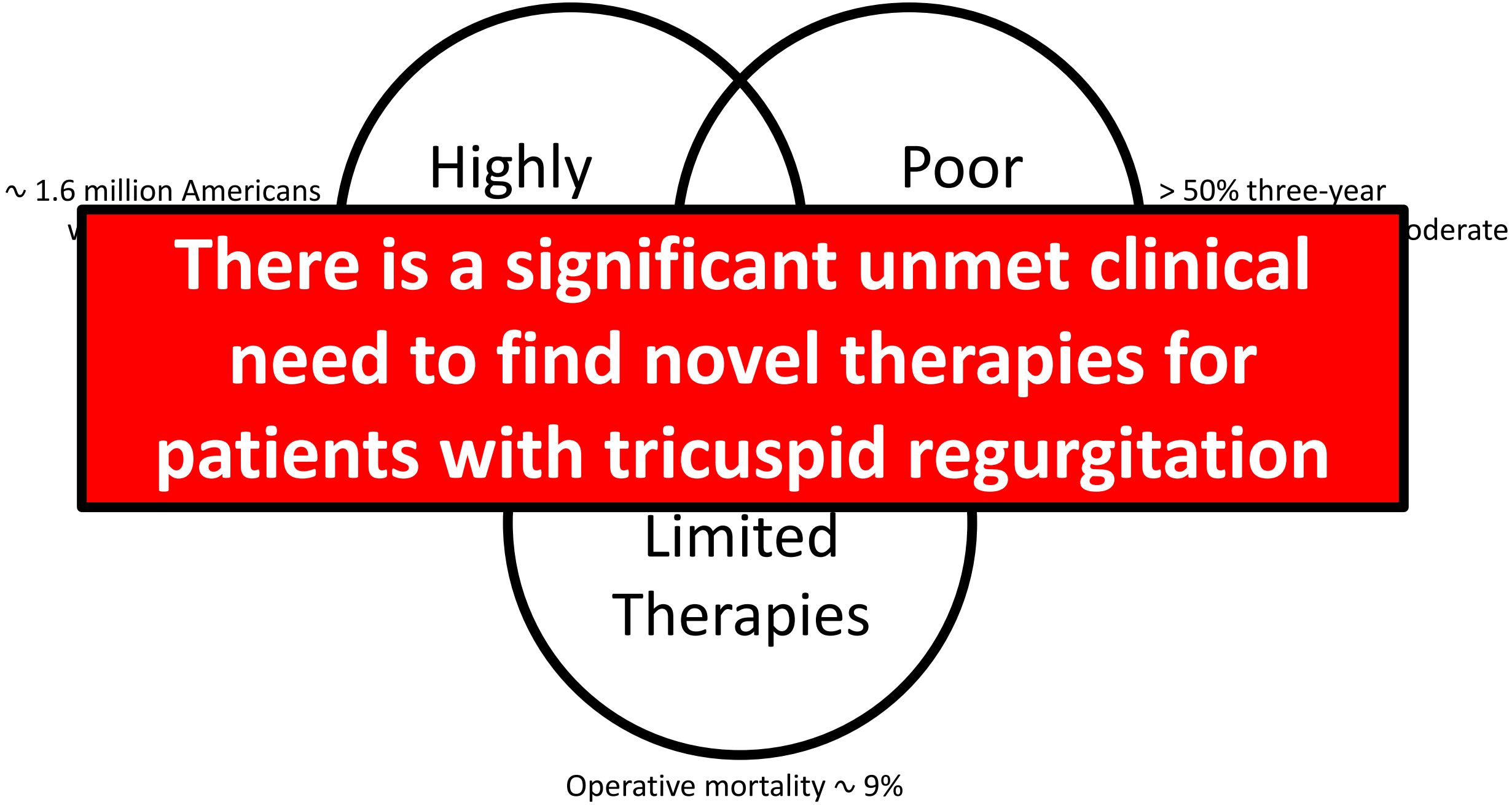
Agarwal et al. Interventional Cardiology Perspective on fTR
Circ Cardiovascular Intervention 2009; 565-573

Operative Mortality for TR remains high



C.J. Zack, E.A. Fender, P. Chandrashekar, et al. National trends and outcomes in isolated tricuspid valve surgery
J Am Coll Cardiol, 70 (2017), pp. 2953-2960


~ 1.6 million Americans
with > moderate TR
Highly
Prevalent
Poor
Prognosis
>50% three-year mortality
with > moderate TR
Limited
Therapies
Operative mortality ~ 9%



There is a significant unmet clinical need to find novel therapies for patients with tricuspid regurgitation

Tricuspid Valve – No longer the forgotten valve

Images in Cardiovascular Medicine

The Forgotten Valve

Isolated Severe Tricuspid Valve Stenosis

Mohammed Al-Hijji, MD; Jae Yoon Park, MD; Abdallah El Sabbagh, MD; Muhammad Amin, MD, PhD; Joseph J. Maleszewski, MD; Daniel D. Borgeson, MD

Review

Tricuspid valve and percutaneous approach: No longer the forgotten valve!

Valve tricuspide et traitements percutanés : décidément plus la valve oubliée !

Claire Bouleti[a, b, c], Jean-Michel Juliard[a, c, d], Dominique Himbert[a, c, d], Bernard Iung[a, b, c, d], Eric Brochet[a, c], Marina Urena[a, c], Marie-Pierre Dilly[e], Phalla Ou[b, d, f], Patrick Nataf[b, d, g], Alec Vahanian[a, b, c, d]

Show more

EDITORIAL COMMENTARY

"Forgotten" valve or "enigmatic" valve? Further insights into the tricuspid valve in patients undergoing mitral valve surgery

Elizabeth H. Stephens, MD, PhD, and Michael A. Borger, MD, PhD

Education in Heart

OPEN ACCESS

Secondary tricuspid valve regurgitation: a forgotten entity

Pilar Tornos Mas,[1] José F Rodríguez-Palomares,[2] Manuel J Antunes[3]

ORIGINAL ARTICLE

HSR Proceedings in Intensive Care and Cardiovascular Anesthesia 2012; 4(4): 261-267

Tricuspid valve surgery

C.A. Mestres[1], G. Fita[2], V.M. Parra[3], J.L. Pomar[1], J.M. Bernal[4]

[1]Department of Cardiovascular Surgery, Hospital Clínico. University of Barcelona. Barcelona, Spain; [2]Department of Anesthesiology, Hospital Clínico, University of Barcelona, Barcelona, Spain; [3]National Chest Institute and School of Medicine, University of Chile, Santiago Chile; [4]Department of Cardiovascular Surgery, Hospital Universitario Valdecilla, University of Cantabria, Santander, Spain

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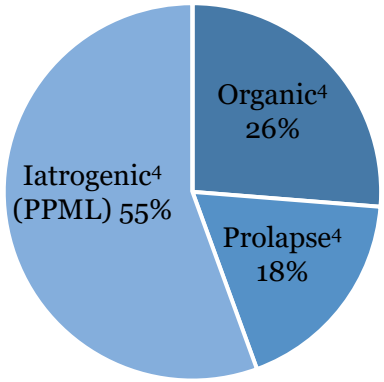
European Heart Journal (2010) **31**, 2841–2843
doi:10.1093/eurheartj/ehq303

EDITORIAL

The forgotten valve: lessons to be learned in tricuspid regurgitation

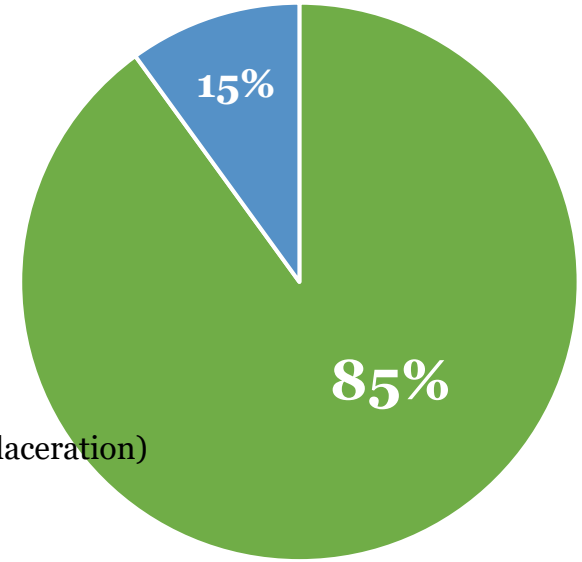
Julia Mascherbauer and Gerald Maurer*

ETIOLOGIES OF TRICUSPID REGURGITATION[1,2,3]



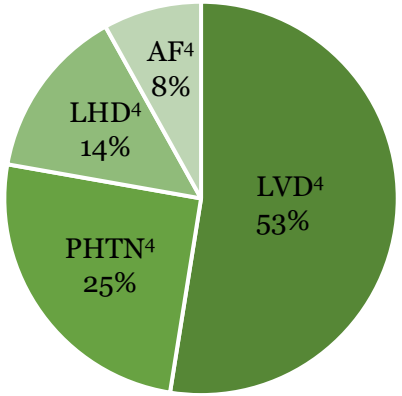
PRIMARY 15%

- Organic
  - Rheumatic
  - Myxomatous
  - Ebstein anomaly
  - Endomyocardial fibrosis
  - Endocarditis
  - Carcinoid disease
  - Traumatic (blunt chest injury, laceration)
- Prolapse
- Iatrogenic (pacemaker/ defibrillator)



SECONDARY 85%

- Left Valve Disease
  - Aortic
  - Mitral
- Pulmonary Hypertension
  - WHO group 2
- Left heart disease
  - Systolic (HFrEF)
  - Diastolic (HFpEF)
- Idiopathic
  - AF



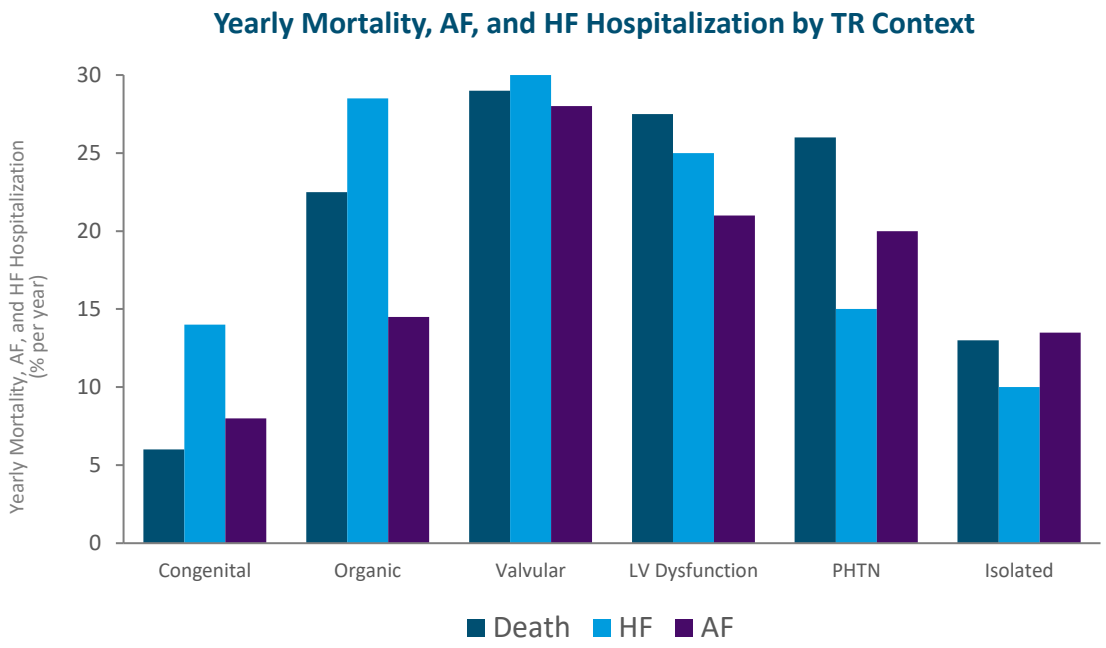
Current pathway leads to medical management for the majority of patients

*The TriClip Implant is not indicated for patients with severe mitral regurgitation.

1. Asmarats et al JACC Vol 71, No 25, 2018. 2.Topilsky, JACC CV Imaging 2018. 3.Data on file at Abbott

TR has Poor Long Term Survival[1]

Linearized Yearly Mortality by TR Clinical Context[1]



36% of Patients with Severe TR die within 1 year of diagnosis[2]
10 Year Survival = 14%[1]

- The poorest survival was seen with **functional TR** associated with **left valvular disease**, or associated with **LV systolic dysfunction**[1]
- Followed by **functional TR** associated with **PHTN** and **organic TR**[1]
- Was ominous even in **isolated TR**, with no other systemic or cardiac comorbidity[1]

*The TriClip Implant is not indicated for patients with severe mitral regurgitation.

1. Topilsky et al Burden of TR in Patients Diagnosed in the Community Setting JACC CV Imaging 2018.

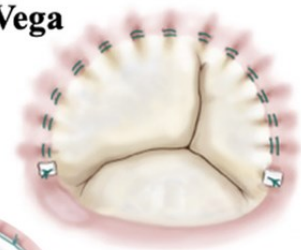
2. Nath et al Impact of TR on long term survival. J Am Coll Cardio. 2004;43;405-409.

Surgical tricuspid landscape

Suture annuloplasty

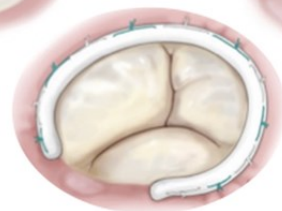
Kay

De Vega



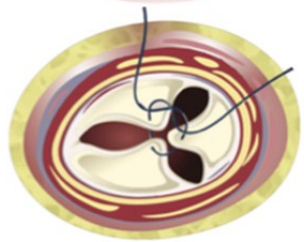
Ring annuloplasty

Ring

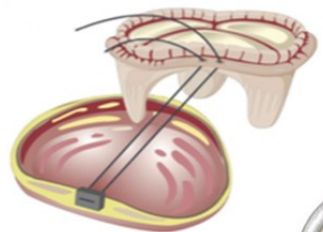


Coaptation enhancement

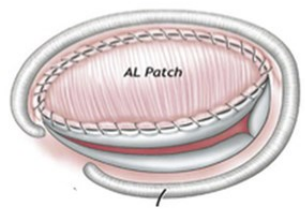
Clover



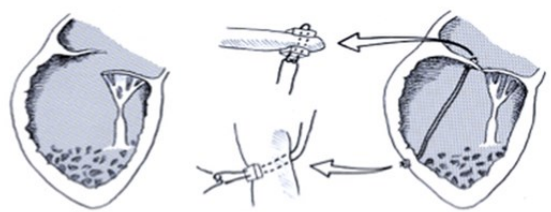
Replacement



Leaflet augmentation



Neochordae repair



Transcatheter tricuspid landscape

Trialign

TriCinch

MIA

PASTA

Cardioband

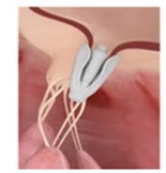
Millipede

DaVingi

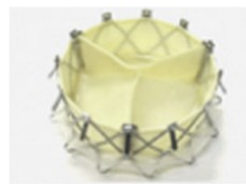
MitraClip

FORMA

PASCAL

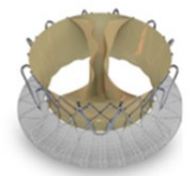


NaviGate



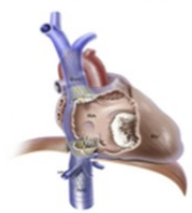
Lux

TriSol



TRiCares

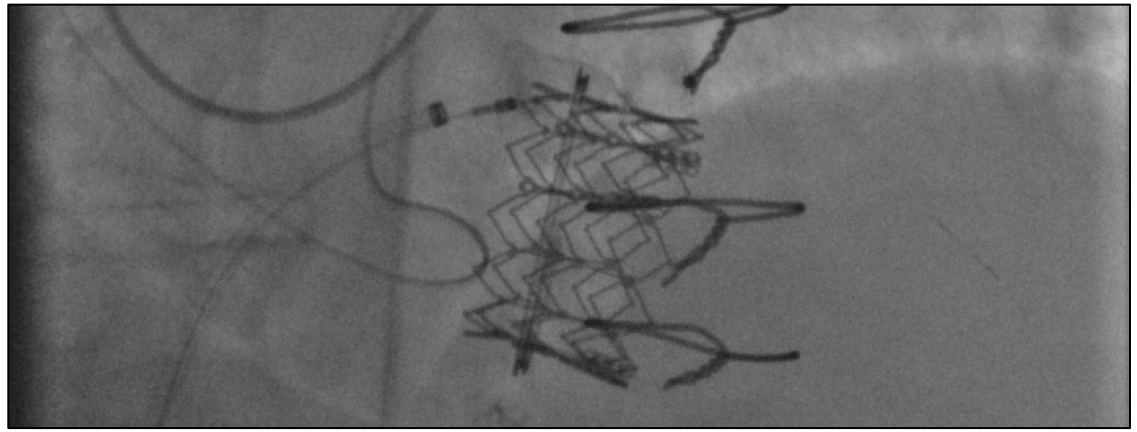
TricValve



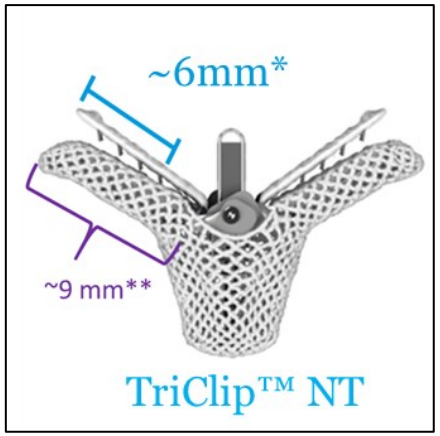
Tricento

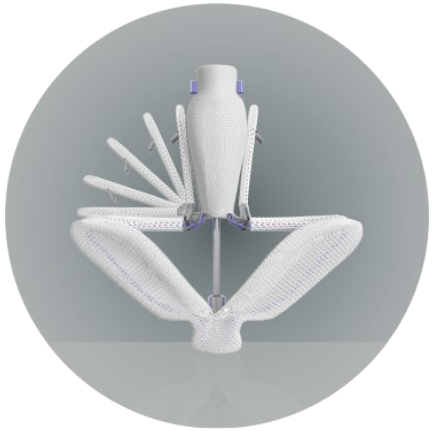
Current options to treat tricuspid regurgitation

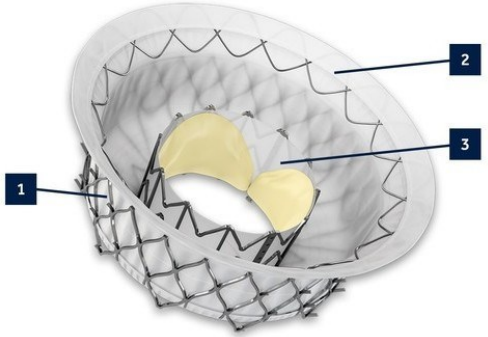
Off-label use of commercially available devices



Emerging dedicated devices in research protocols

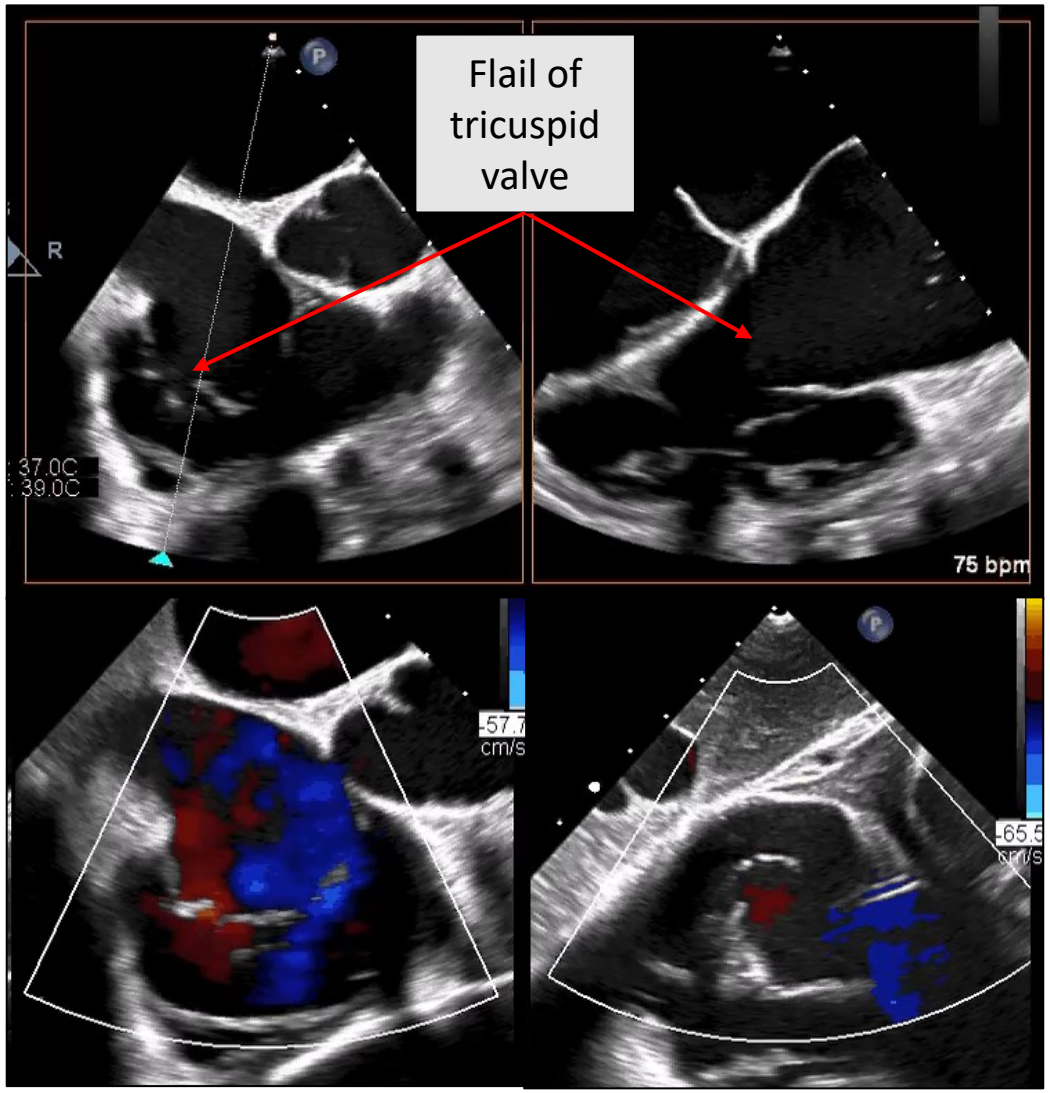






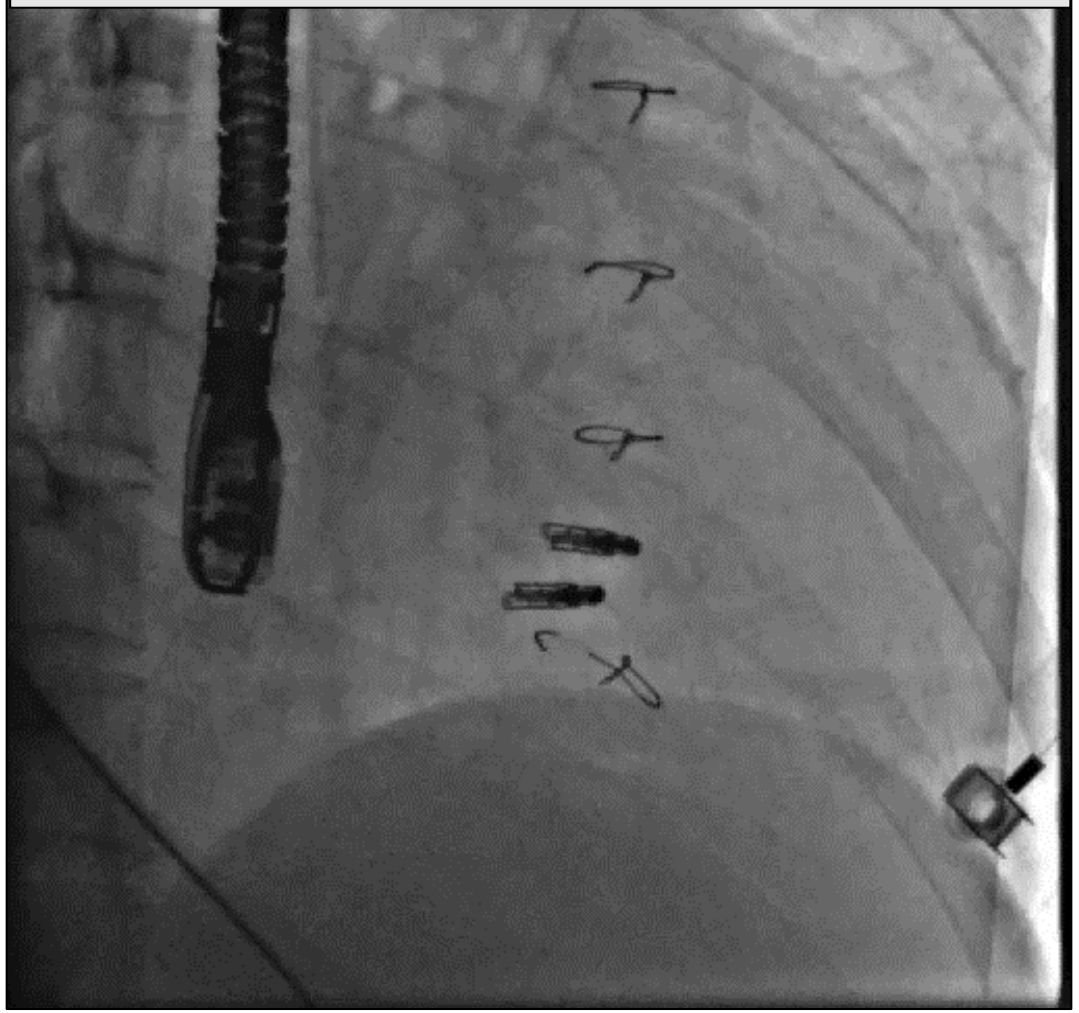
Off-label MitraClip in Tricuspid Valve

- 22-year-old female transferred from OSH on pressors
- History of HOCM treated with OHT in 2003
  - Complicated by rejection in 2013
- Severe TR of the transplanted heart due to flail of the tricuspid valve secondary to RV biopsy
- Transferred for consideration of transcatheter therapies



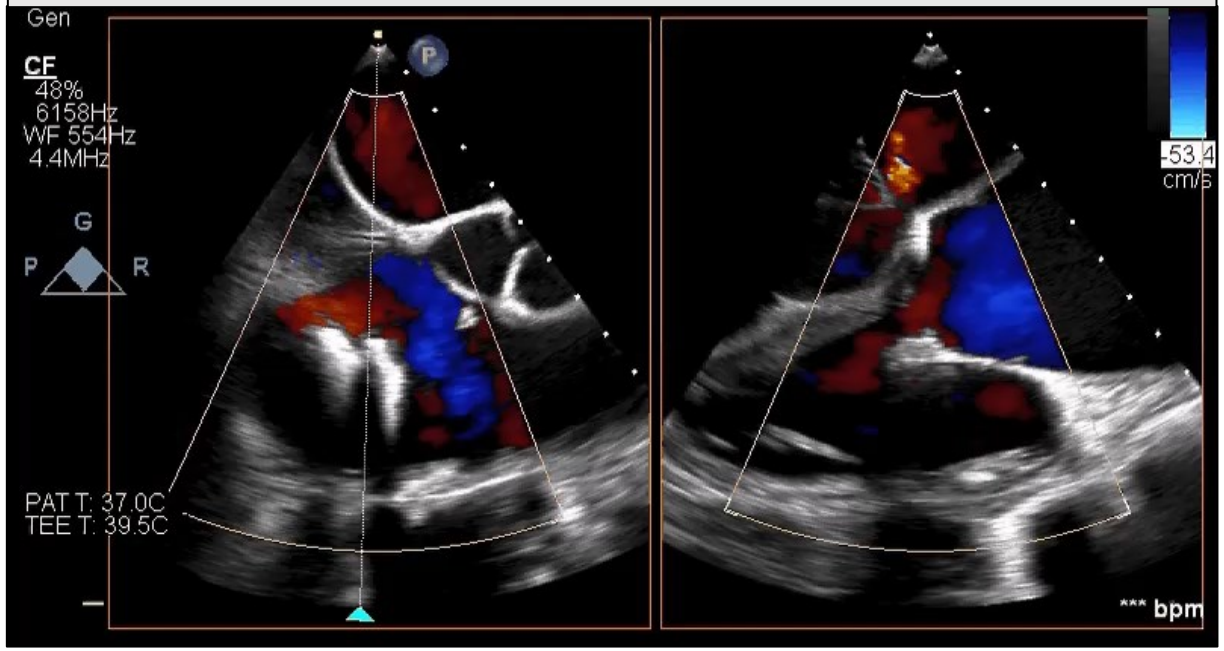
Off-label MitraClip in Tricuspid Valve

MitraClip x 2 to the tricuspid valve



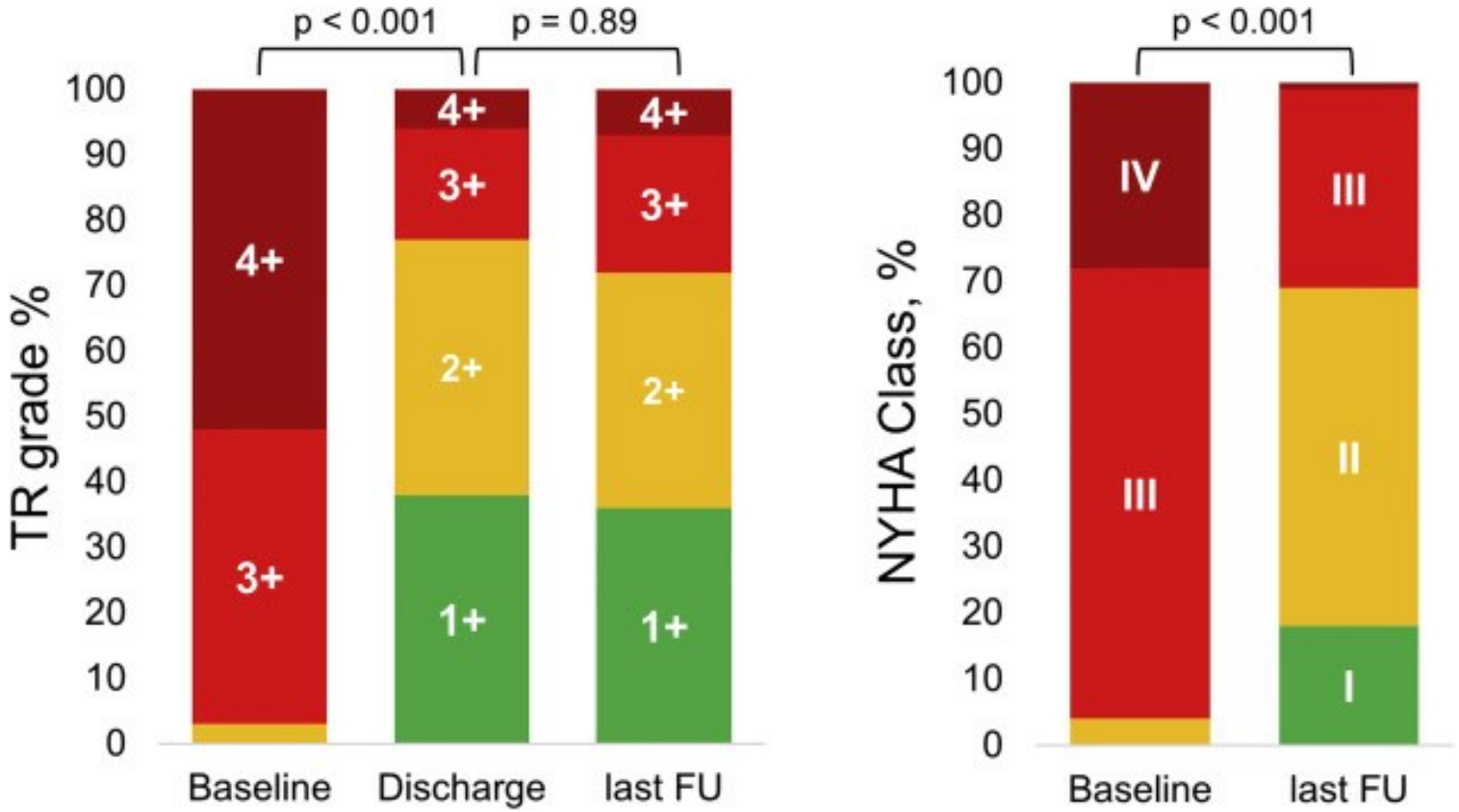
Patient successfully weaned from dobutamine and discharged home in 4 days

Final result: Mild-moderate TR



Off-label MitraClip in Tricuspid Valve

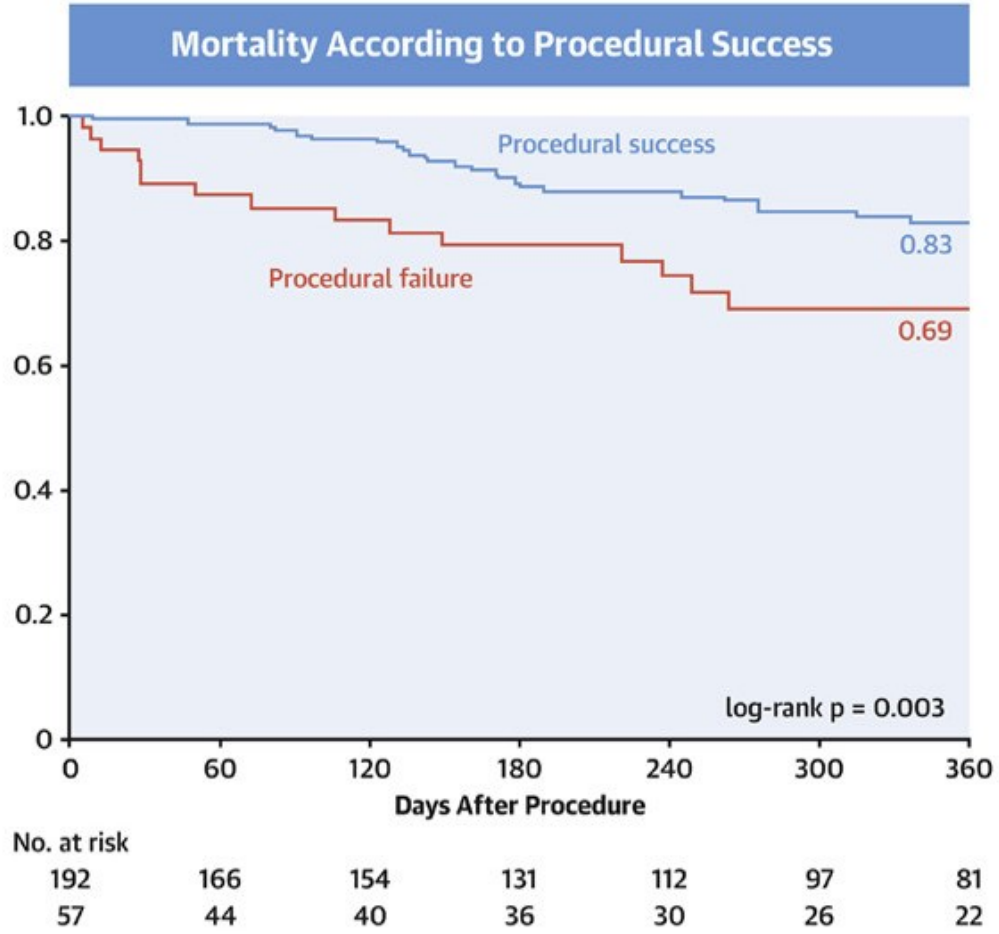
- Insights from the TriValve Registry
  - 249 patients treated with off-label or compassionate MitraClip



Mehr M, et al. One year outcomes after edge-to-edge valve repair for symptomatic tricuspid regurgitation JACC Cardiovasc Interven. (2019) 12:1451–61.

Off-label MitraClip in Tricuspid Valve

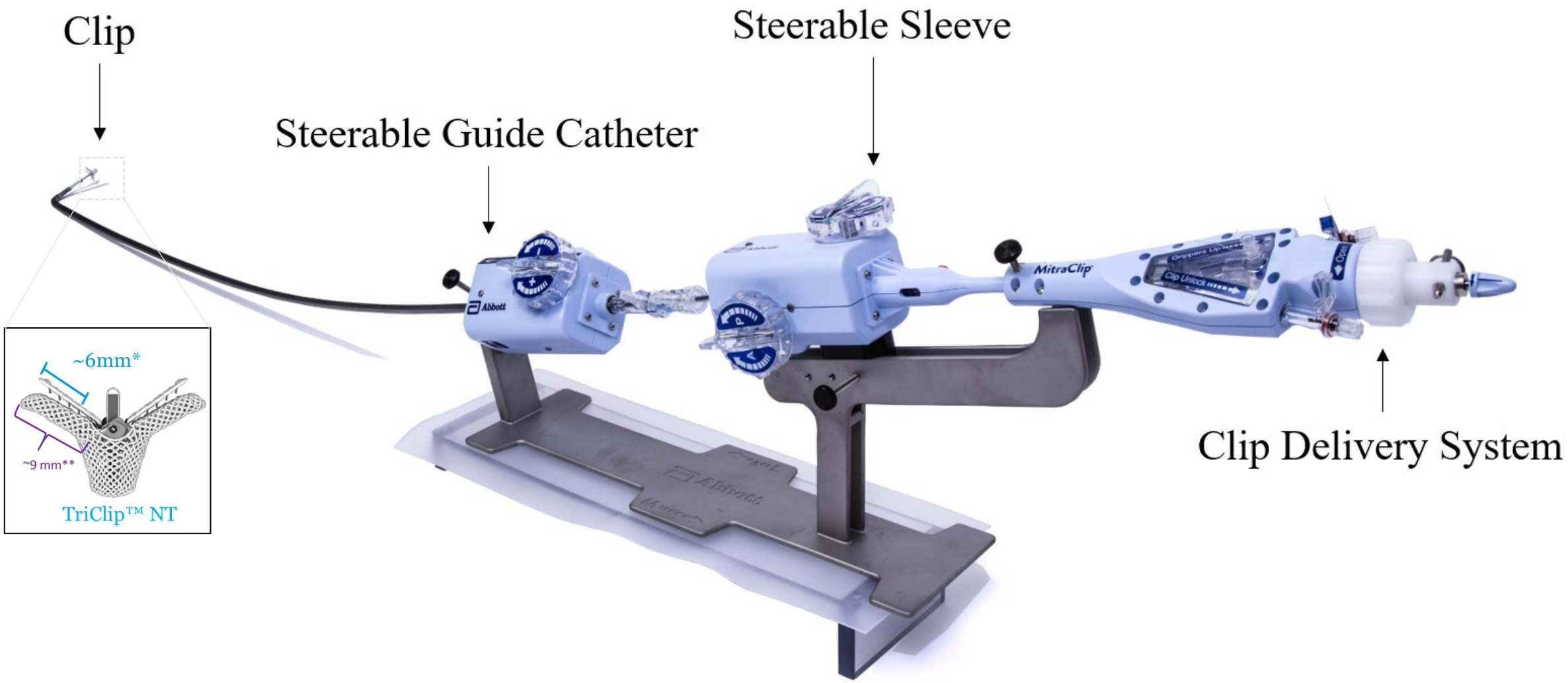
CENTRAL ILLUSTRATION: Kaplan-Meier Estimates of 1-Year Mortality According to Procedural Failure After Edge-to-Edge Tricuspid Valve Repair



Mehr, M. et al. J Am Coll Cardiol Intv. 2019;12(15):1451-61.

- Transcatheter tricuspid edge-to-edge repair can achieve TR reduction at 1 year, resulting in significant clinical improvement.
- Predictors of procedural failure and 1-year mortality identified here may help select patients who will benefit most from this therapy.

Dedicated Device: TriClip



TRILUMINATE | Baseline Characteristics

Variable	All Patients (n=85)
Age, mean (years)	77.8 ± 7.9
Male / Female (%)	34% / 66%
Hypertension	86%
Prior MI	17.6%
A-fib	92%
Prior Aortic Intervention	11%
Prior Mitral Intervention	33%
Replacement – Surgery	25%
Replacement – Percutaneous	7.1%
Repair – Surgery	28.6%
Repair – Percutaneous	32.1%
Other	14.3%
CRT/ICD/PPM	14%
Renal Disease	46%
Diabetes	22%

Variable	All Patients (n)
RV End Diastolic Dimension (cm)	5.27 ±0.67 (81)
NYHA FC III/IV	75%
EuroSCORE II	8.6 ± 10.9%
LVEF	59.39 ± 8.09% (73)
TAPSE	1.44 ± 0.31 (79)
PA Pressure, systolic (mmHg)	38.9 ± 16.0
6MWT (m)	277.47 ± 137.20 (76)
BNP	534.13 ± 353.84
NT-proBNP	3626.78 ± 13579.21
Tricuspid Regurgitation Grade	
Moderate	6% (5)
Severe	29% (24)
Massive	29% (24)
Torrential	37% (31)

Nickenig G, Lancet online 7Nov 2019, and Supplement

TRILUMINATE Study
Essential Results:

Mean Age = 77.8 + 7.9 year

65.9% Female

100%

Implant success rate

90.5%

Acute Procedural Success rate

87%

TR reduction of at least 1 grade at 1 Year

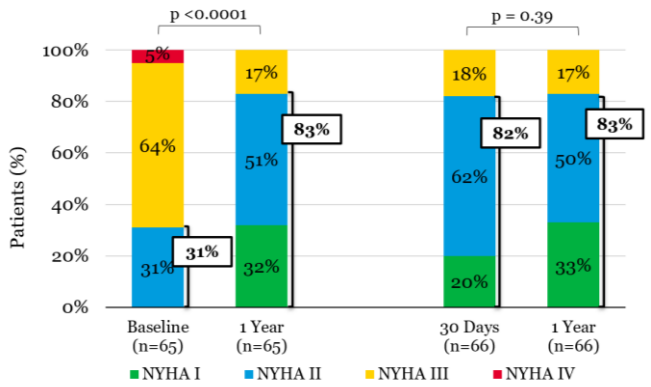
Mean Improvement in KCCQ-OS score of 20 points from baseline to 1 Year

2.2

On average number of clips used

152 min

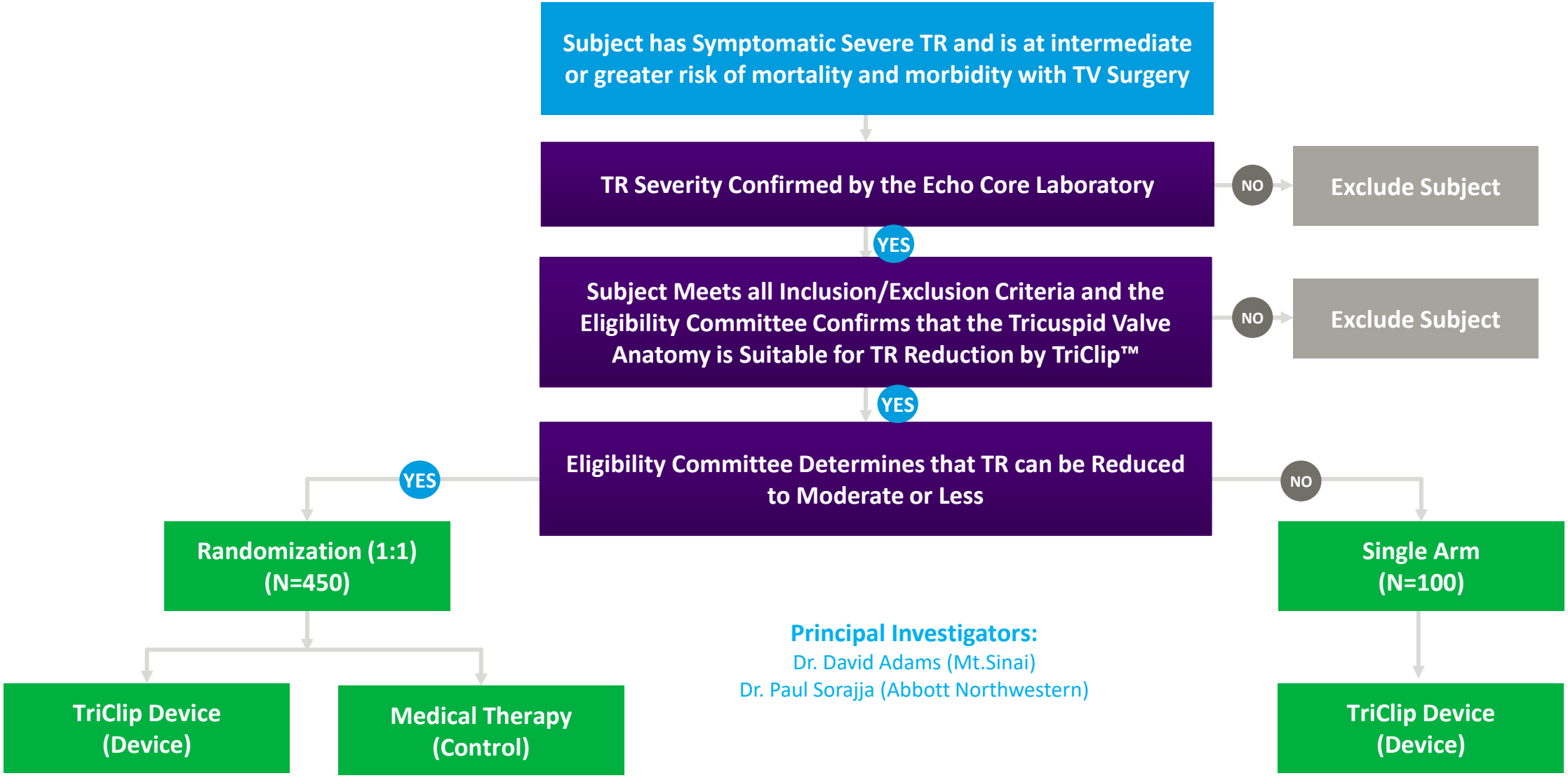
Average procedure time



At 1 Year, a significantly greater proportion (83%) of subjects were categorized as NYHA class I or II compared to 31% of subjects at baseline.

1. Lurz, Philip MD, PhD as presented at PCR eCourse 2020

TRILUMINATE Pivotal Study - Trial Overview



Principal Investigators:
Dr. David Adams (Mt.Sinai)
Dr. Paul Sorajja (Abbott Northwestern)

2021 PCR london valves

Real-world Outcomes for Tricuspid Edge-to-Edge Repair: Initial 30-Day Results from the TriClip™ bRIGHT Study

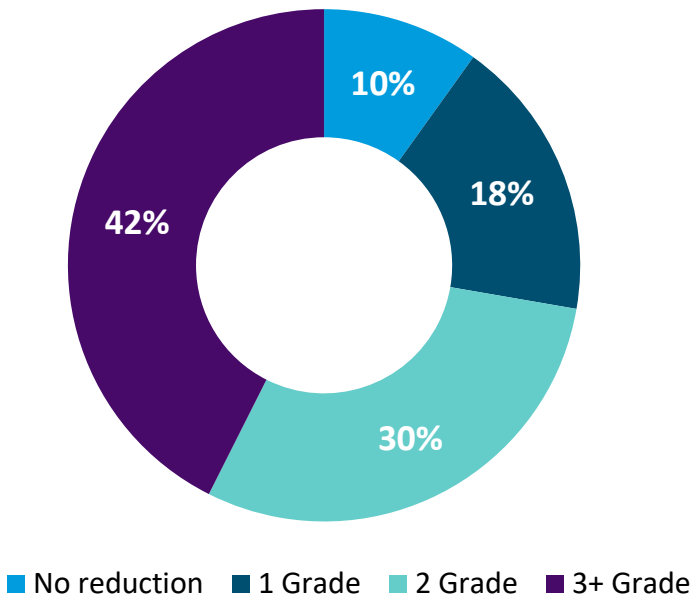
Philipp Lurz, Robert Schueler, Bjoern Goebel, Helge Moellmann, Georg Nickenig, Raffi Bekeredjian, Rodrigo Estevez, Iskandar Atmowihardjo, Alexander Schmeisser, Erwan Donal

TriClip™ bRIGHT Study is sponsored by Abbott

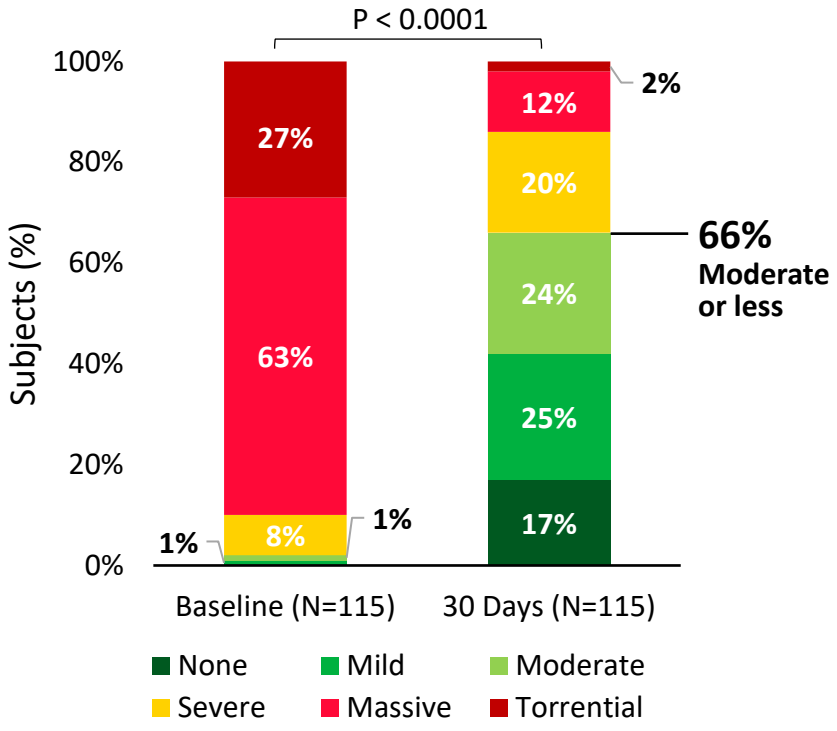
Significant TR Reduction

90% of subjects had TR reduced by at least 1 grade at 30 days with the majority (66%) reduced to moderate or less.

TR GRADE REDUCTION AT 30 DAYS (paired, N=115)

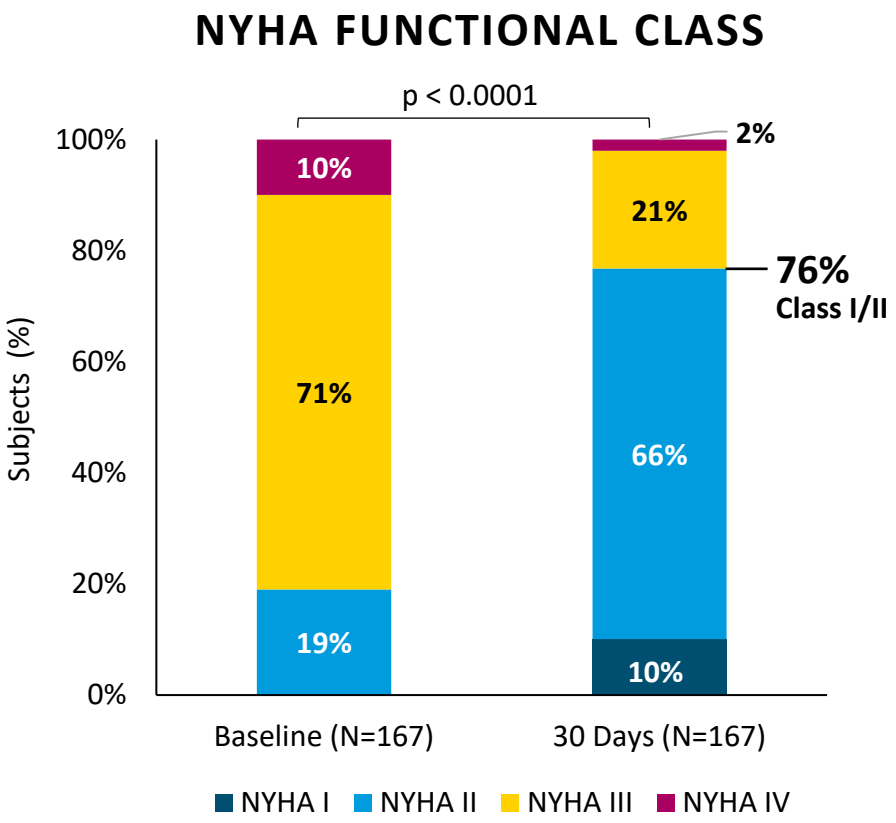


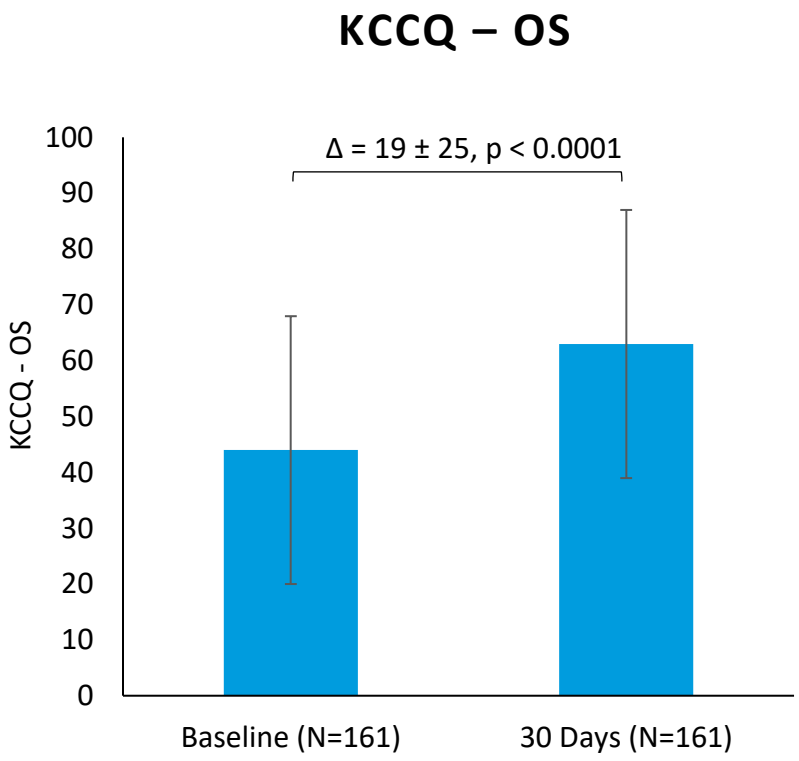
TR GRADE (CORE LAB)



Significant Clinical Improvements

Majority of subjects experienced significant improvements in NYHA functional class and KCCQ-OS score.





PASCAL Platform for Tricuspid Regurgitation

Central Spacer

Bridge the coaptation gap

Elongation

Navigate in dense chordae

Nitinol Design

Passive closure, acute implant flexing

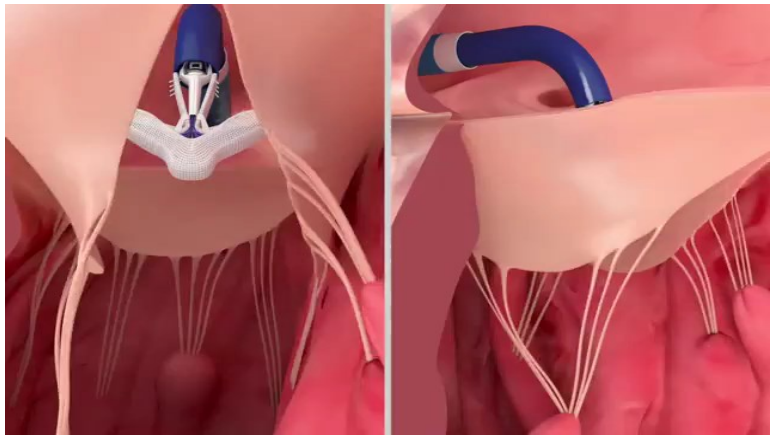
Independent Clasps

Staged leaflet capture and adjustment

The PASCAL Platform

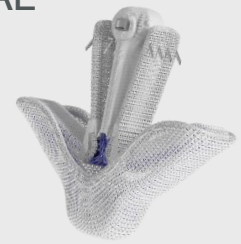
PASCAL

PASCAL Ace



PASCAL Ace

A narrow profile and **central spacer** designed to complement PASCAL and provide additional options for patients



CAUTION: Investigational device. Limited by Federal (or United States) law to investigational use.

CLASP TR EFS

The Edwards PASCAL TrAnScatheter Valve RePair System in Tricuspid Regurgitation (CLASP TR) Early Feasibility Study

Prospective, multicenter, single-arm study

Purpose:
Evaluate the safety and performance of the Edwards PASCAL Transcatheter Valve Repair System in tricuspid regurgitation

Principal Investigator:
Susheel K. Kodali, MD

Patients with Symptomatic Severe Tricuspid Regurgitation

Heart Team Assessment

- Severe functional or degenerative TR
- Symptomatic despite optimal medical therapy
- Patient appropriate for the device

PASCAL Repair System

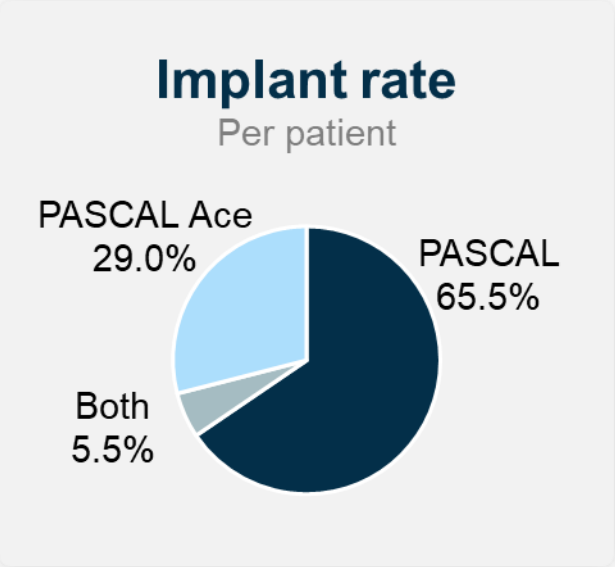
Follow-up: 30 days, 6 months, 1 year and annually through 5 years

Primary Endpoints:
- Freedom from device or procedure-related adverse events at 30 days

NCT03745313

PASCAL Transcatheter Valve Repair System in Tricuspid Regurgitation

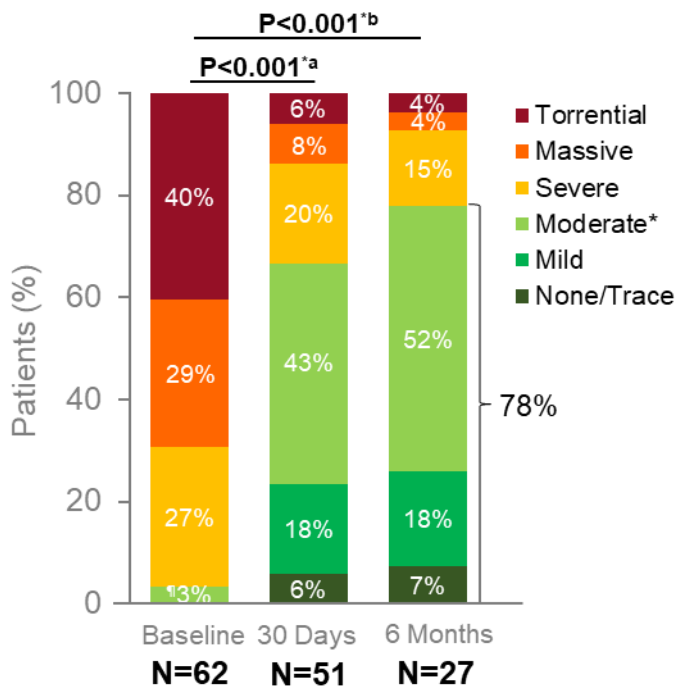
	N = 63 % (n/N) or Mean ± SD
Successful implant rate[1,2] (ITT)	91% (57/63)
Successful implant rate[1] (AT)	100% (57/57)
Procedural success[3]	98% (44/45)
Clinical success[4]	87% (40/46)
Mean number of devices implanted per patient	1.5 ± 0.57 (57)
Device time (implant insertion to release), mins	159 ± 129 (56)



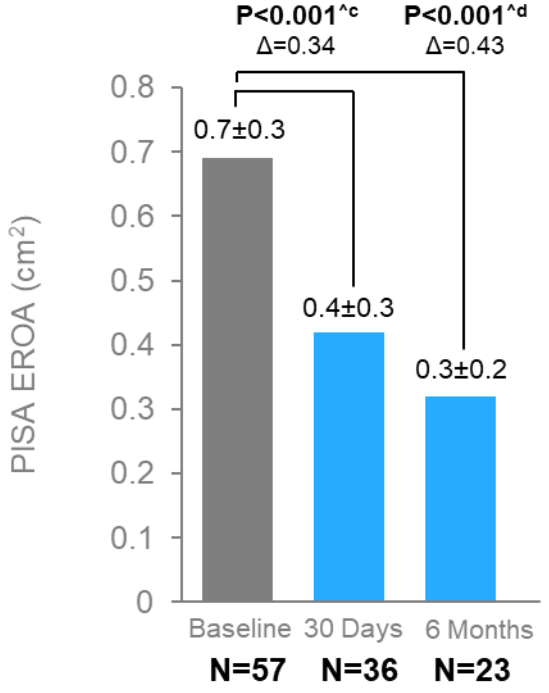
[1]Implant deployed as intended and delivery system retrieved as intended at the time of the patient's exit from the cardiac catheterisation laboratory.
[2]Implants were successfully retrieved in six patients whose leaflets were unable to be captured due to complex anatomy with no adverse sequelae.
[3]Implant success with at least one grade reduction in TR at the end of the procedure without surgical or percutaneous intervention prior to hospital discharge.
[4]Procedural success without MAEs at 30 days. *MAEs,* major adverse events; *ITT,* intention to treat; *AT,* as treated

Significant Improvements in Echocardiographic Outcomes at 6 Months by Core Lab[1]

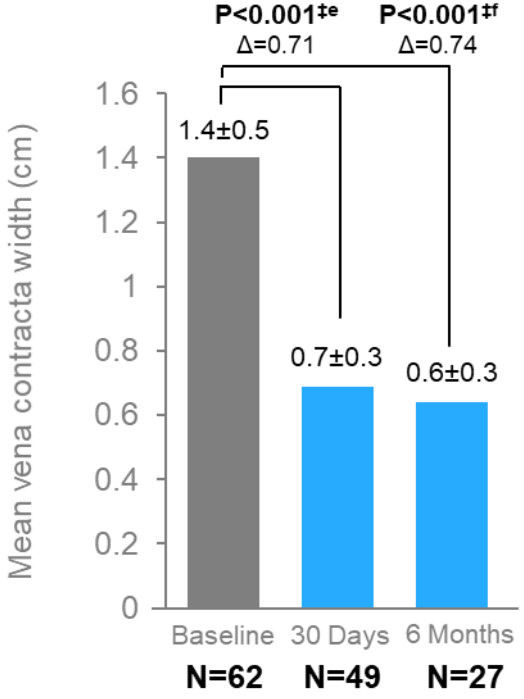
TR Severity



PISA EROA



Vena Contracta Width

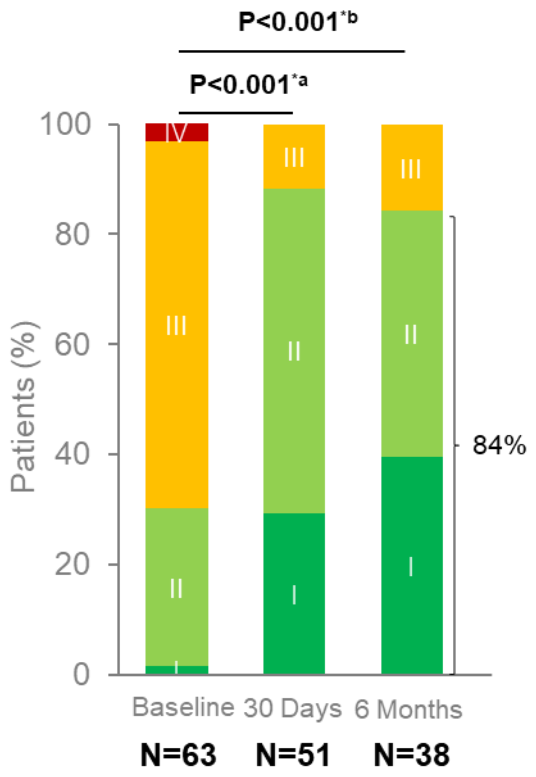


89% achieved ≥1 grade reduction and 70% achieved ≥2 grade reductions at 6 months

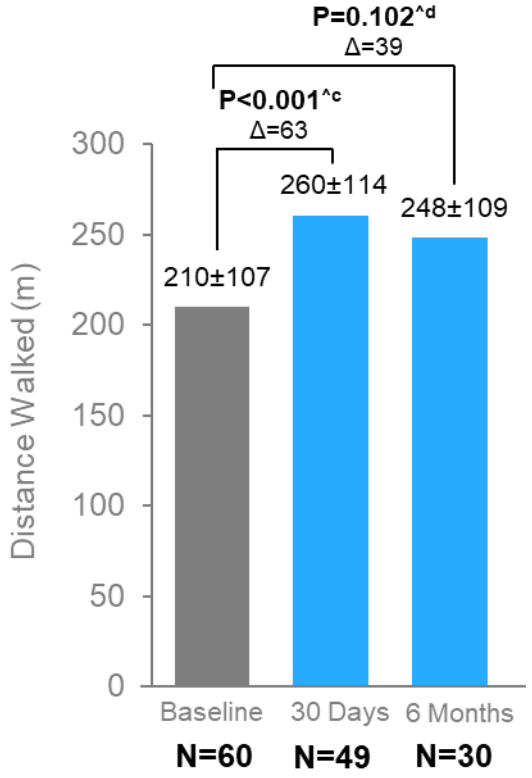
[1]Cardiovascular Research Foundation. Two patients initially considered to have severe TR at baseline by transoesophageal echocardiography (TEE) were reclassified as moderate TR by transthoracic echocardiography (TTE). Graphs show unpaired data. *Wilcoxon signed-rank test for moderate TR or less. [a]n=51; baseline=4%; 30 days=67%. [b]n=27; baseline=7%; 6 months=78%. ^Paired t-test for mean±SD PISA EROA. [c]n=34; baseline=0.75±0.28 cm^2; 30 days=0.41±0.26 cm^2. [d]n=20; baseline=0.75±0.32 cm^2; 6 months=0.32±0.19 cm^2. ‡Paired t-test for mean±SD vena contracta width. [e]n=49; baseline=1.4±0.45 cm; 30 days = 0.69±0.33 cm. [f]n=27; baseline=1.4±0.49 cm; 6 months=0.64 ± 0.32 cm. *PISA EROA,* proximal isovelocity surface area effective regurgitant orifice area; *TR,* tricuspid regurgitation.

Improved Clinical, Functional, and Quality of Life Outcomes Sustained at 6 Months

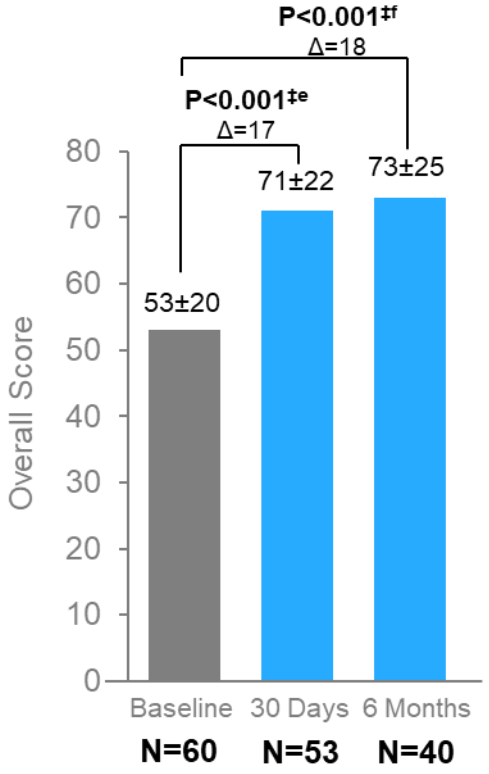
NYHA Class



6MWT



KCCQ Score



Graphs show unpaired data. *Wilcoxon signed-rank test for NYHA. [a]n=51; baseline=30%; 30 days=88%. [b]n=38; baseline=32%; 6 months=84%. ^Paired t-test for mean±SD for 6MWD. [c]n=47; baseline=202±104 m; 30 days=265±112. [d]n=30; baseline=210±109 m; 6 month=248±109. ‡Paired t-test for mean±SD for KCCQ. [e]n=51; baseline=54±21; 30 days=71±23. [f]n=39; baseline=54±22; 6 months=73±26. *NYHA Class,* New York Heart Association; *6MWD*, 6-minute walk distance; *KCCQ,* Kansas City Cardiomyopathy Questionnaire.

THE 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 Transcatheter Tricuspid Valve Repair System and optimal medical therapy (OMT) compared to OMT alone in patients with Tricuspid Regurgitation.

Patients with symptomatic severe TR despite medical therapy

Multidisciplinary Heart Team Assessment

- ≥ severe TR as assessed by echo core lab
- NYHA Class II-IVa
- ≥ intermediate mortality risk with tricuspid valve surgery

PASCAL Repair System + OMT

OMT alone

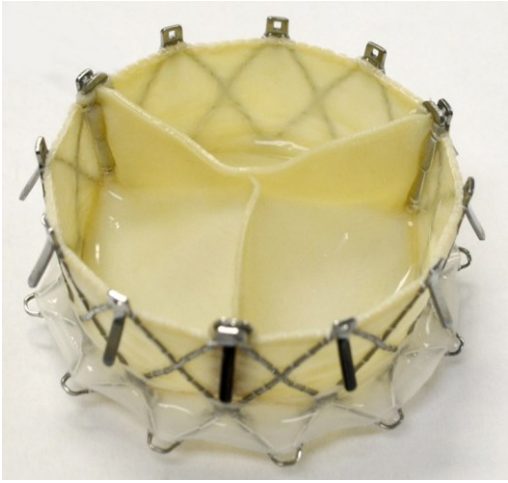
Primary Endpoint at 24 months

- Composite endpoint including all-cause mortality, RVAD implantation or heart transplant, tricuspid valve intervention, heart failure hospitalizations, and Quality of Life improvement (measured by KCCQ score)

NCT04097145

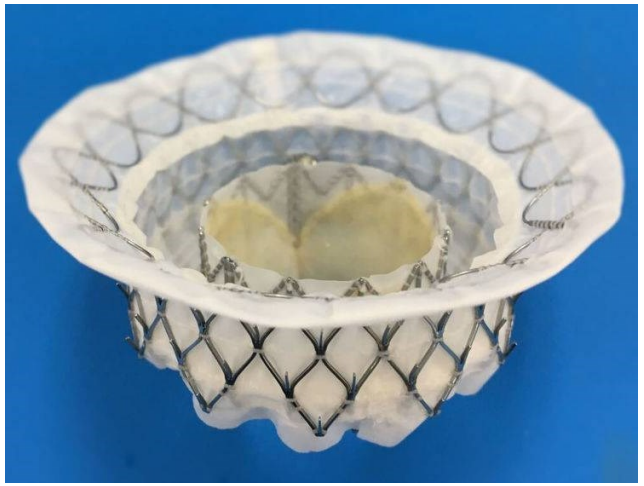
Transcatheter Tricuspid Valve Replacement

Devices with FIM experience



Navigate

Lux



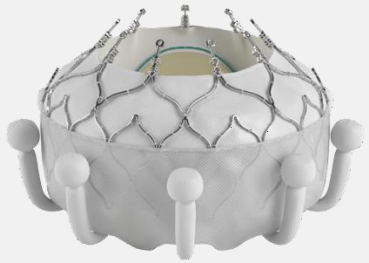
Intrepid

Evoque

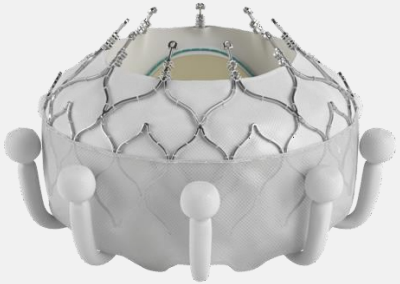
EVOQUE Tricuspid Valve Replacement System

Transfemoral replacement may address current tricuspid challenges

EVOQUE Valve



44 mm



48 mm

EVOQUE Delivery System

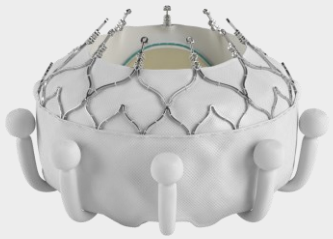
EVOQUE Stabilizer, Base, and Plate

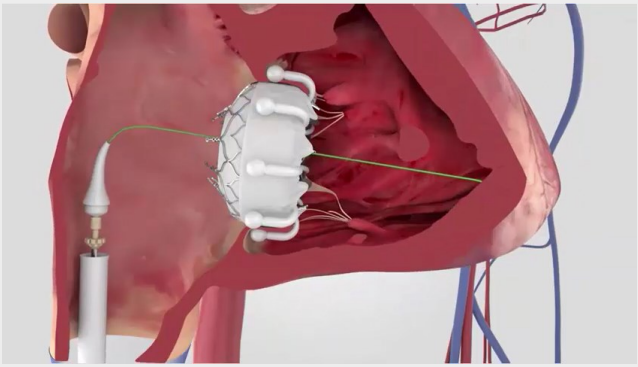
What did we study?

THE TRISCEND STUDY

EVOQUE Tricuspid Valve Replacement System

Unique valve design engages leaflets, chords, and annulus to achieve secure placement





Atraumatic anchors compatible with pre-existing leads and respect the native anatomy

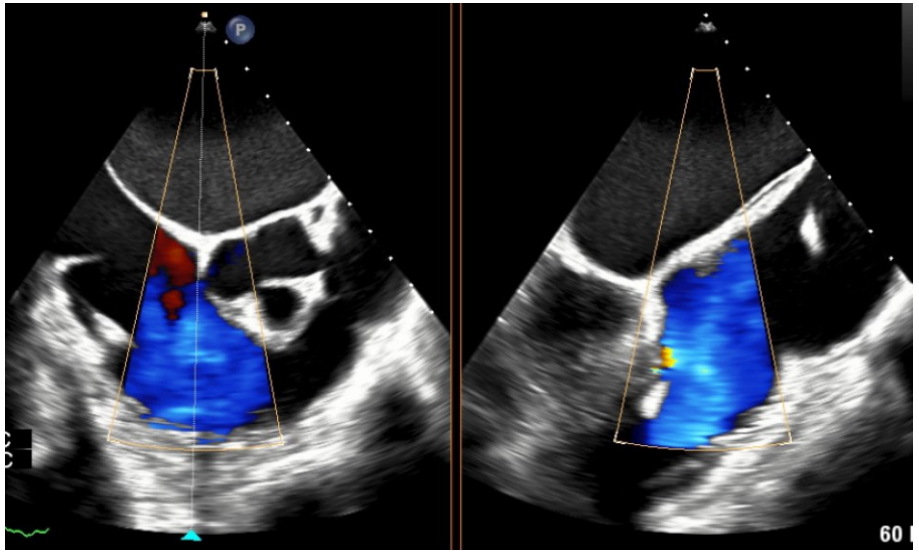
Conforming frame designed to achieve optimal retention force

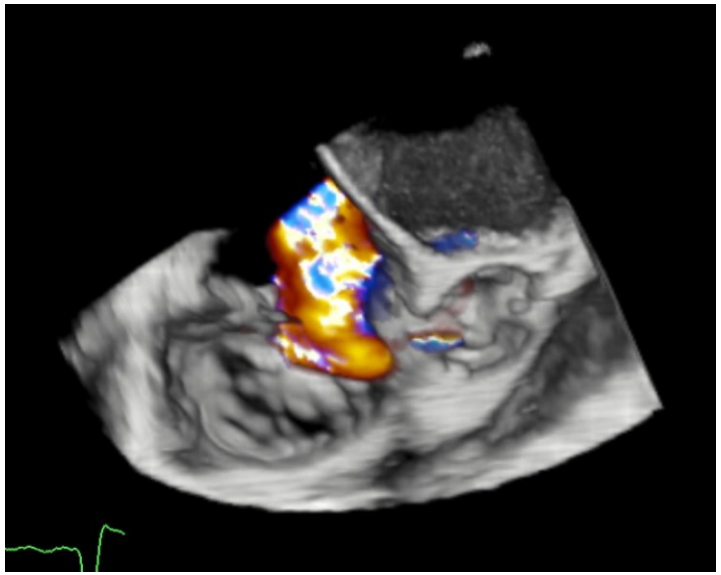
Multiple sizes offer treatment for a broad range of tricuspid pathologies and anatomies **(44, 48, 52 mm)**

28F transfemoral delivery system **compatible with all valve sizes**

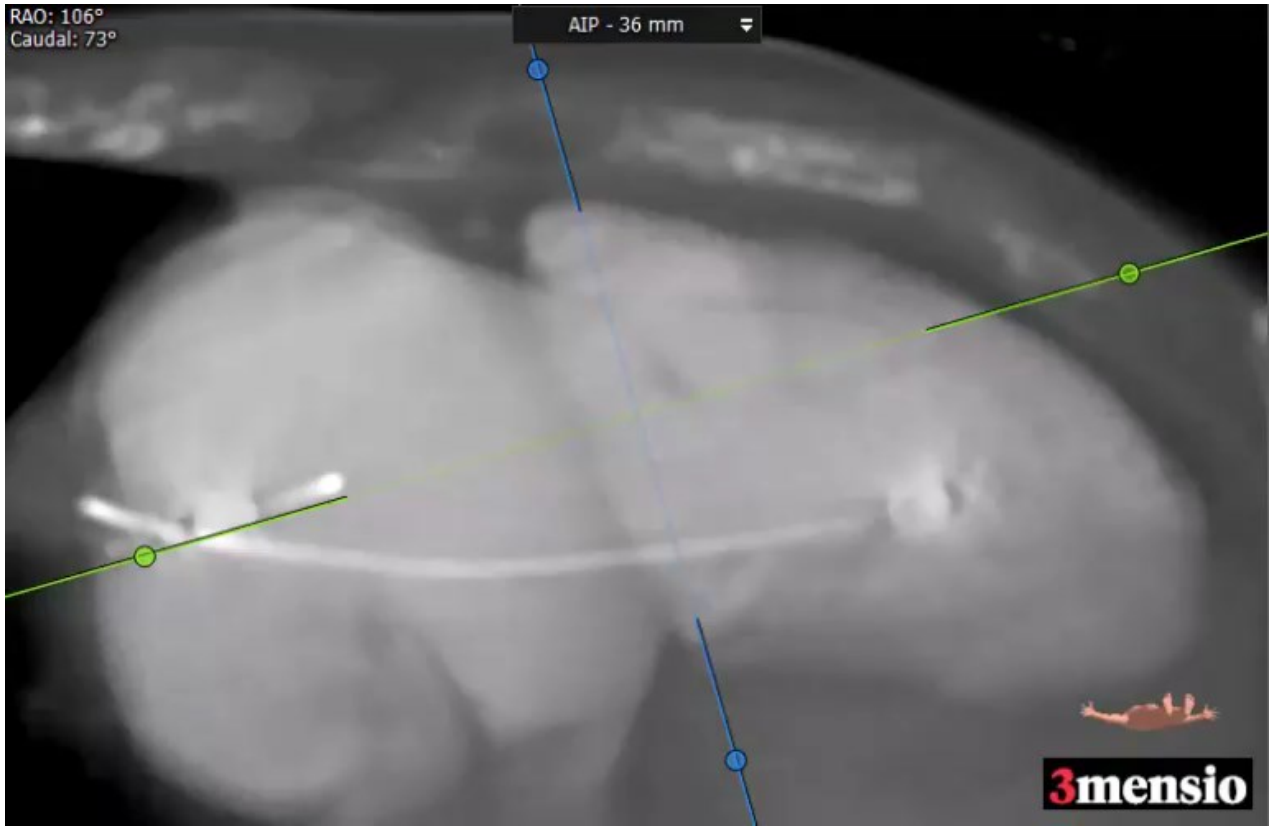
Transcatheter Tricuspid Valve Replacement

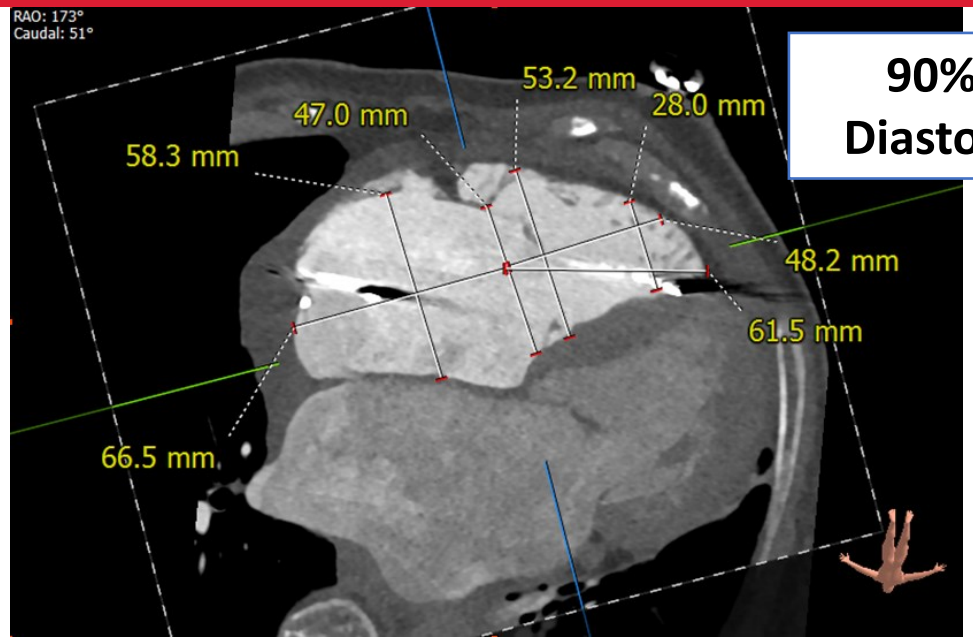
- 74-year-old female with worsening peripheral oedema and shortness of breath.
- History of atrial fibrillation, permanent pacemaker insertion, and previous TIA.
- Two hospital admissions with right sided heart failure
  - Echo demonstrated severe TR
  - Referred for consideration of transcatheter therapy



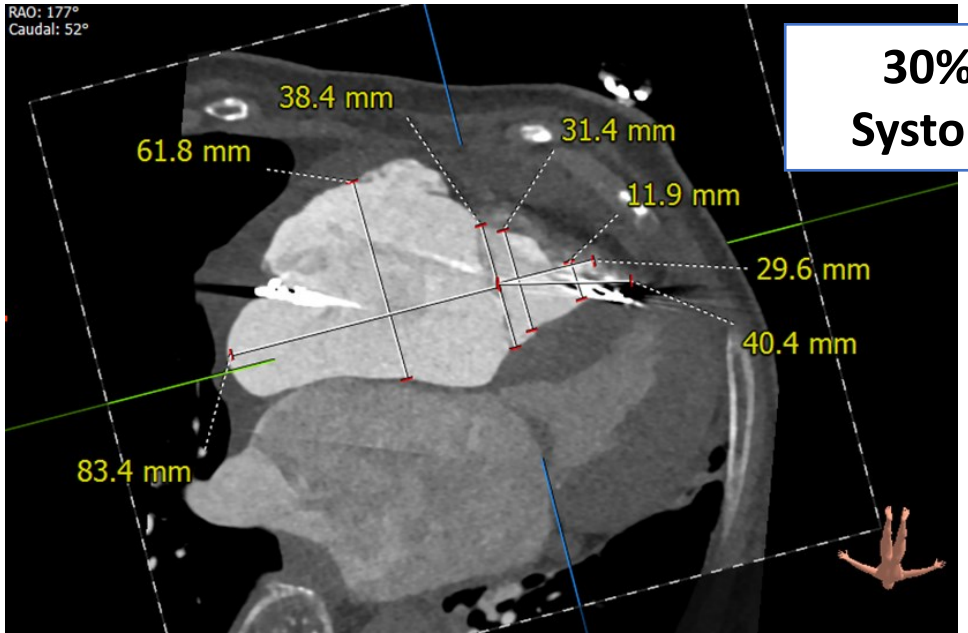


CT Screening to assess RV & TV anatomy



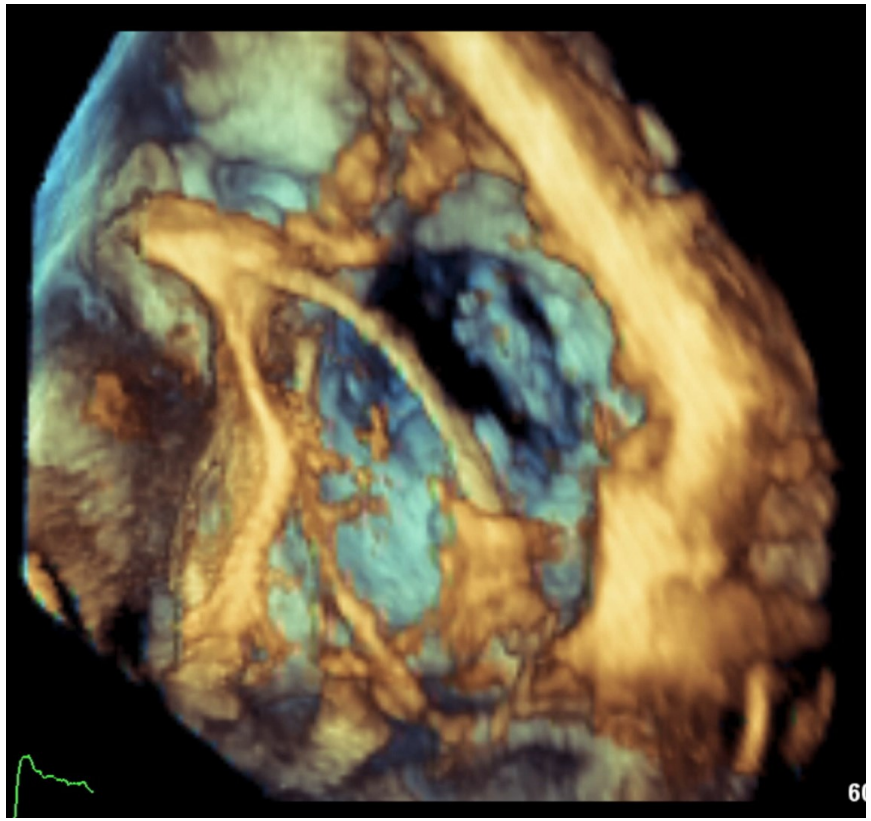


90% Diastole

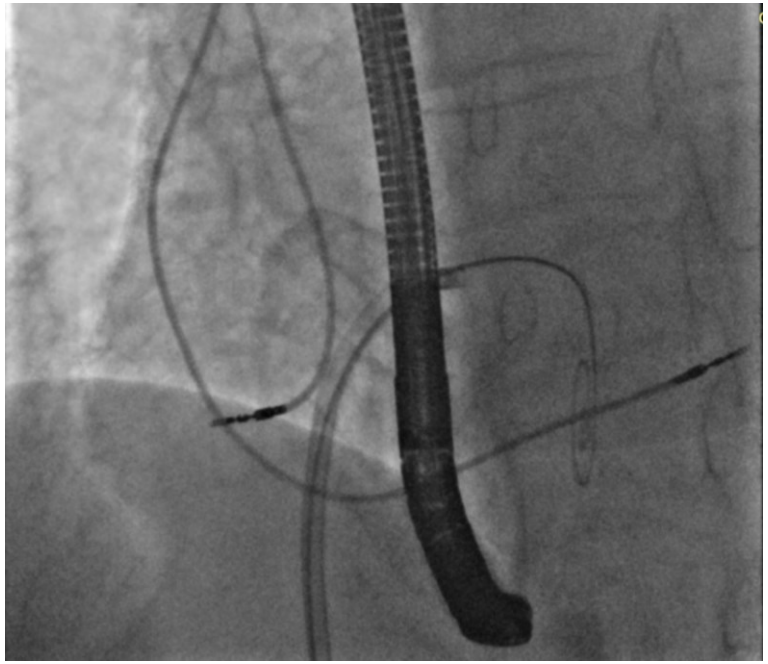


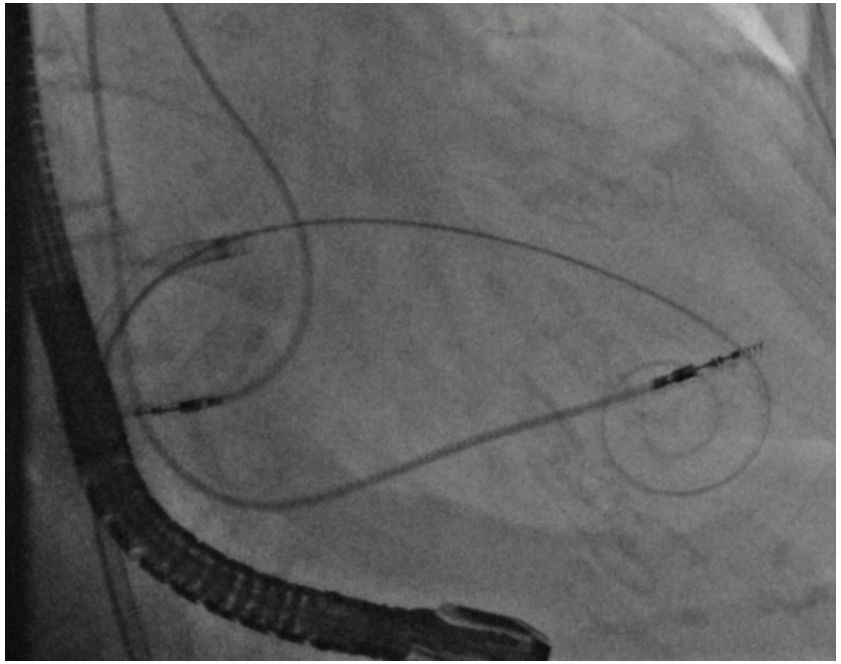
30% Systole

Procedure: Safari Wire Placement



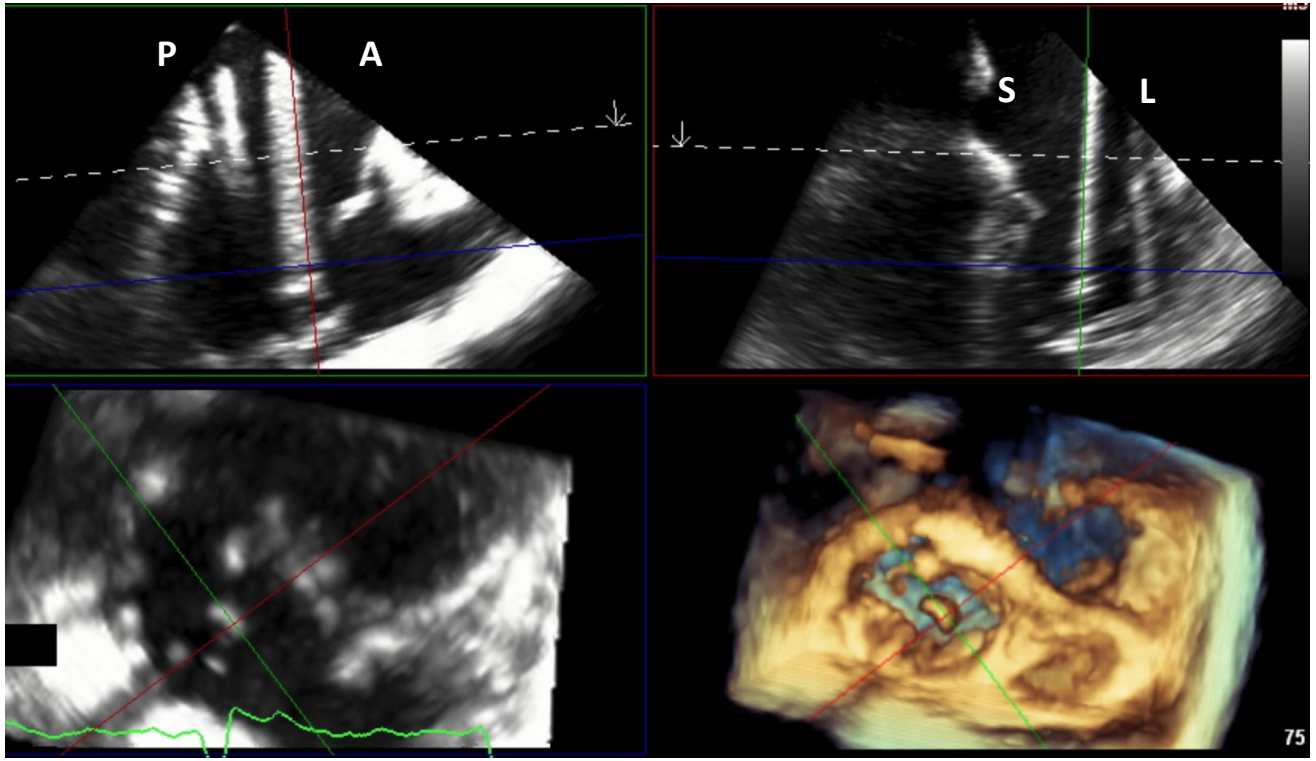
Safari wire advanced on septal side of both RA and RV leads

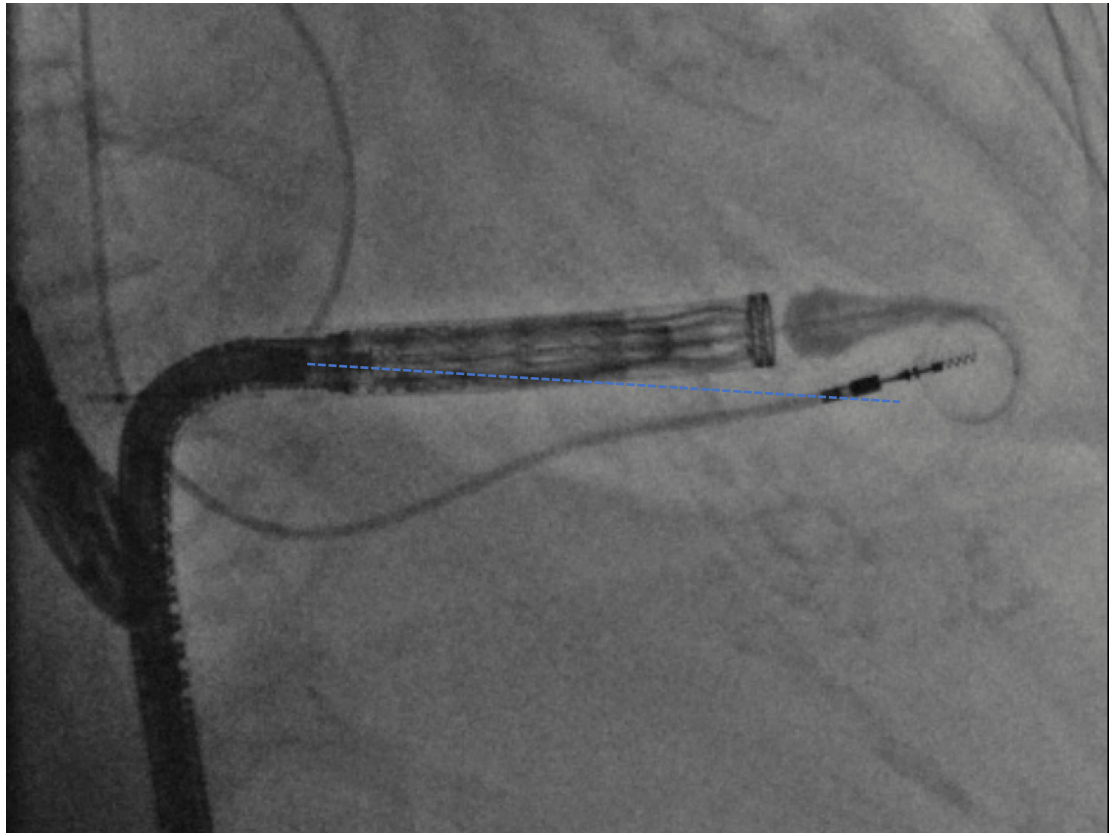




A combination of LAO and RAO fluoro projections were used to confirm wire positioning in relation to pacing leads

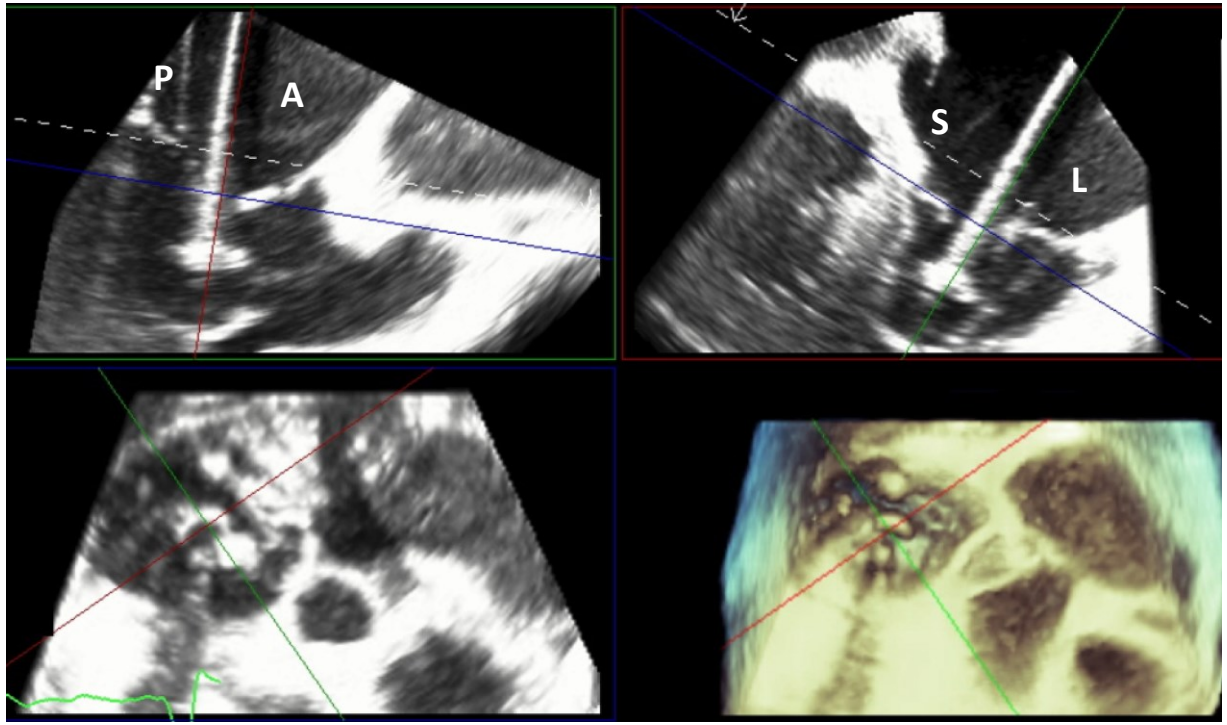
Procedure: Establish depth, position & trajectory

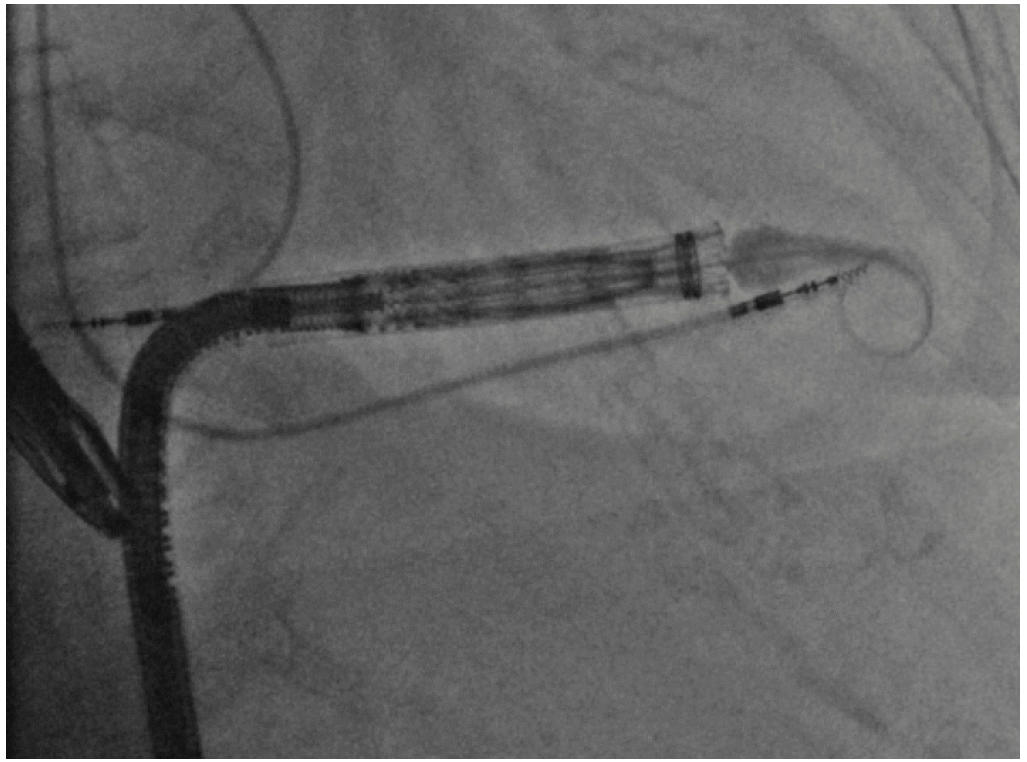




Interaction of the tapered tip with the RV was preventing the capsule from getting coaxial to the TV in A-P.

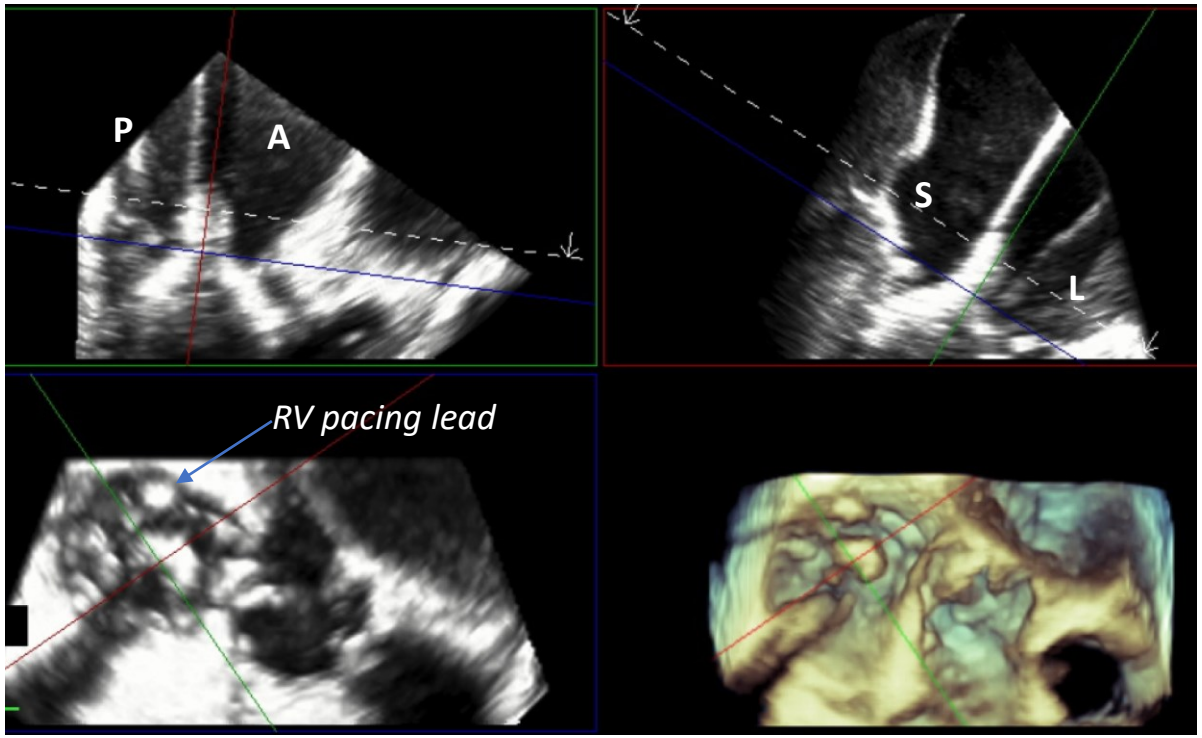
Procedure: Establish depth, position & trajectory

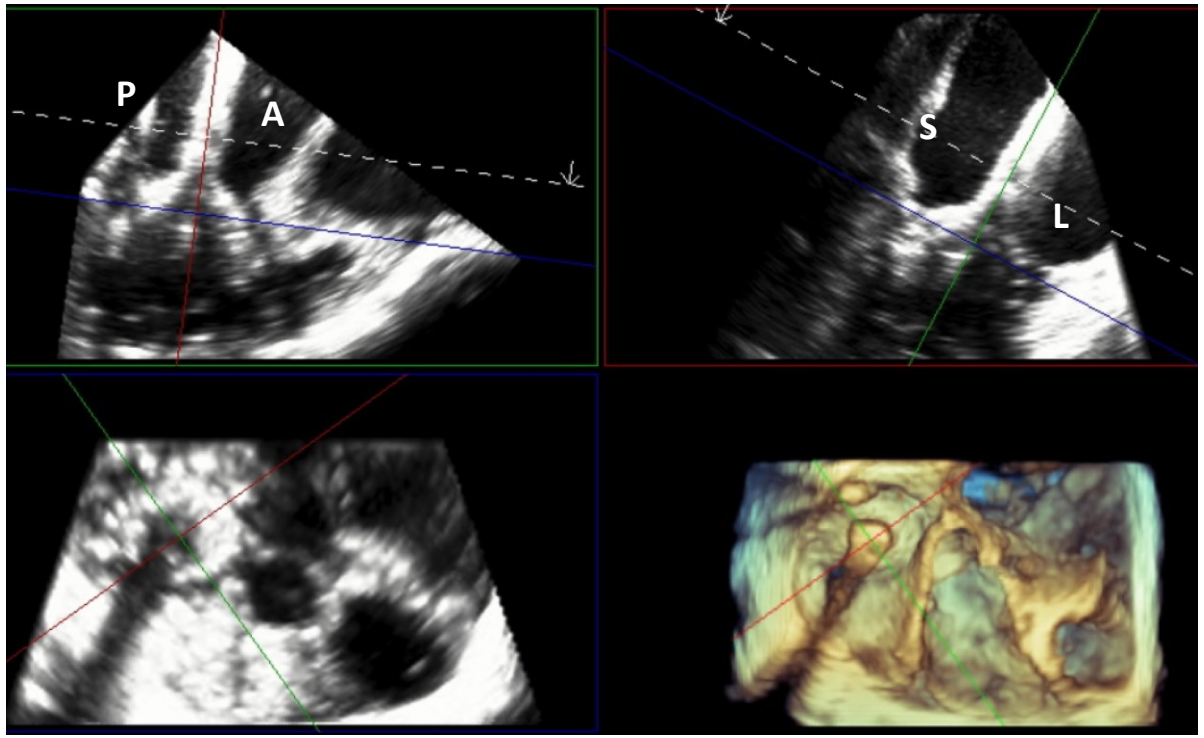




We were able to regain coaxiality and continue to expose the anchors, in a controlled way with the EVOQUE delivery system.

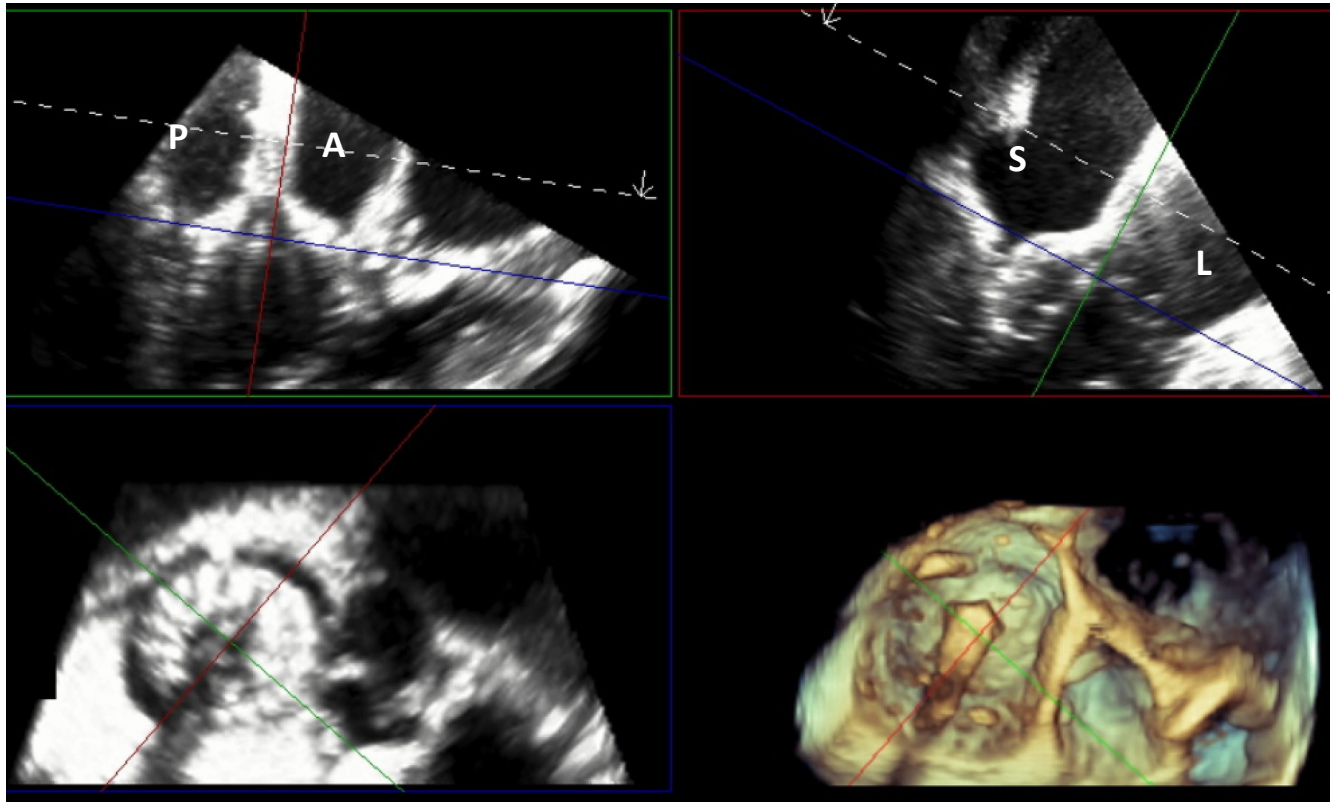
Procedure: Valve Expansion

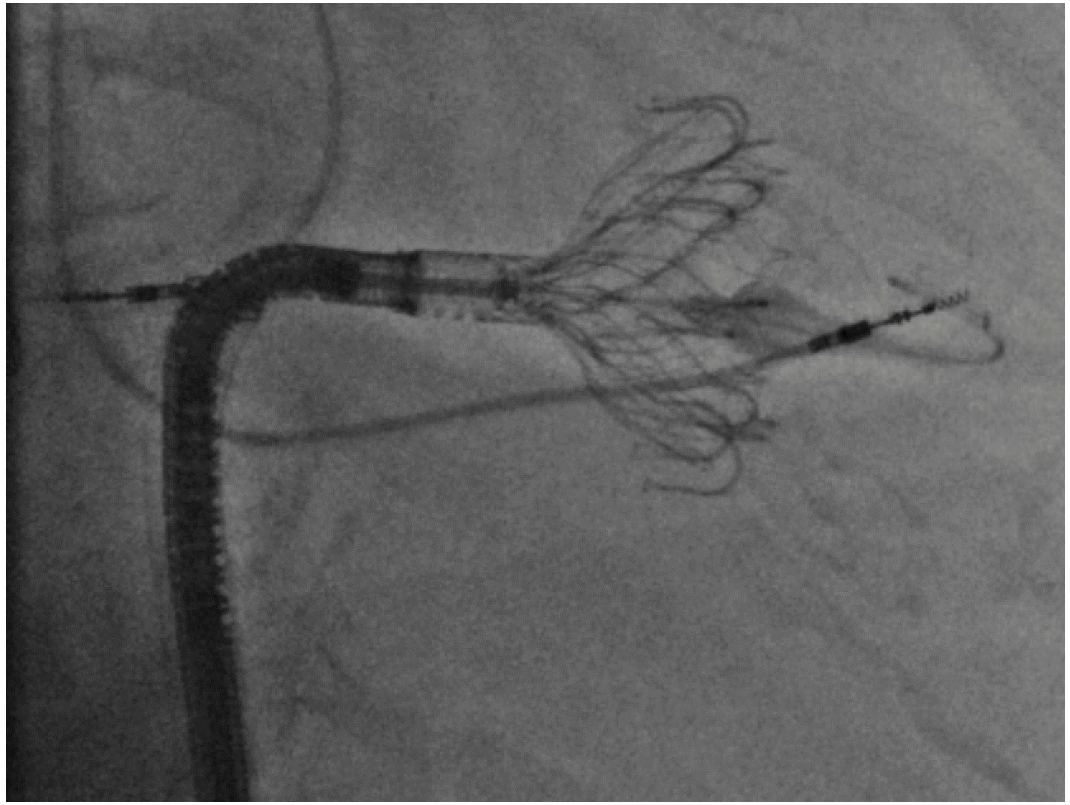




Complete capture of all leaflets/ scallops.
Confirmed RV pacing lead position in posteroseptal commissure, as planned.

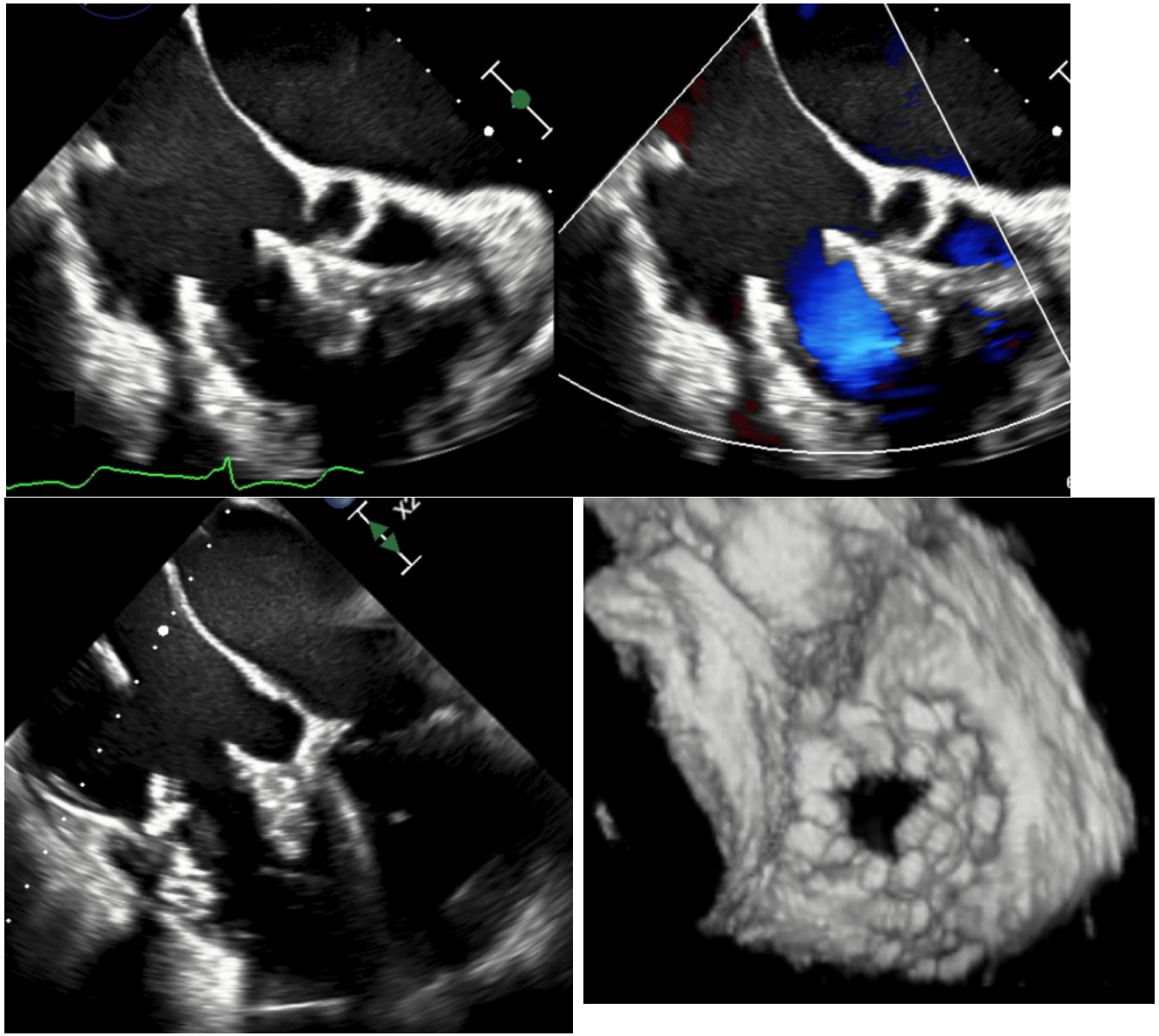
Procedure: Valve Release

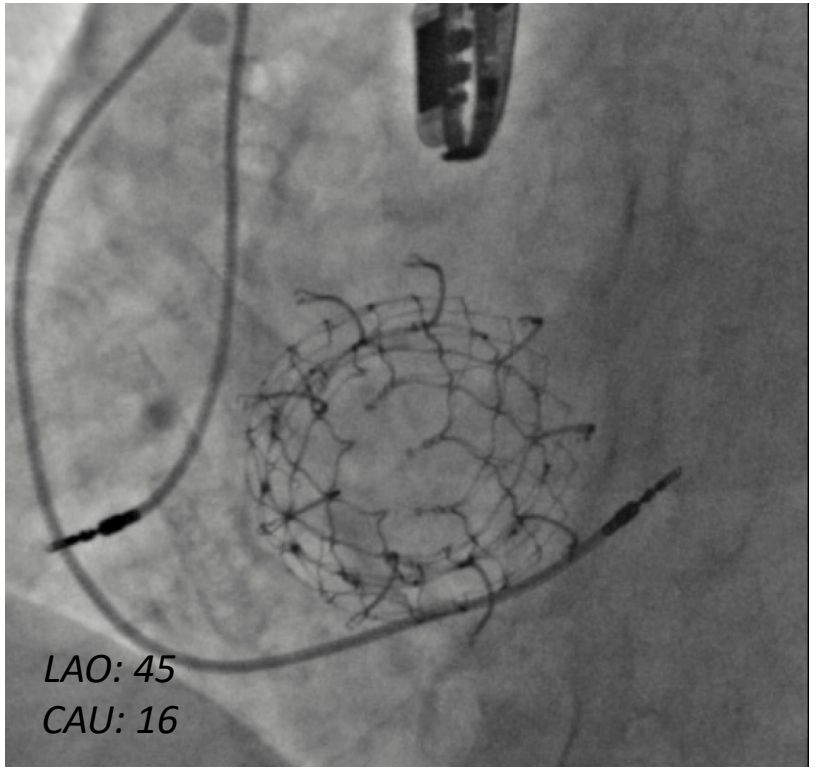




Stable release with no change in final valve position.

Procedure: Final Result

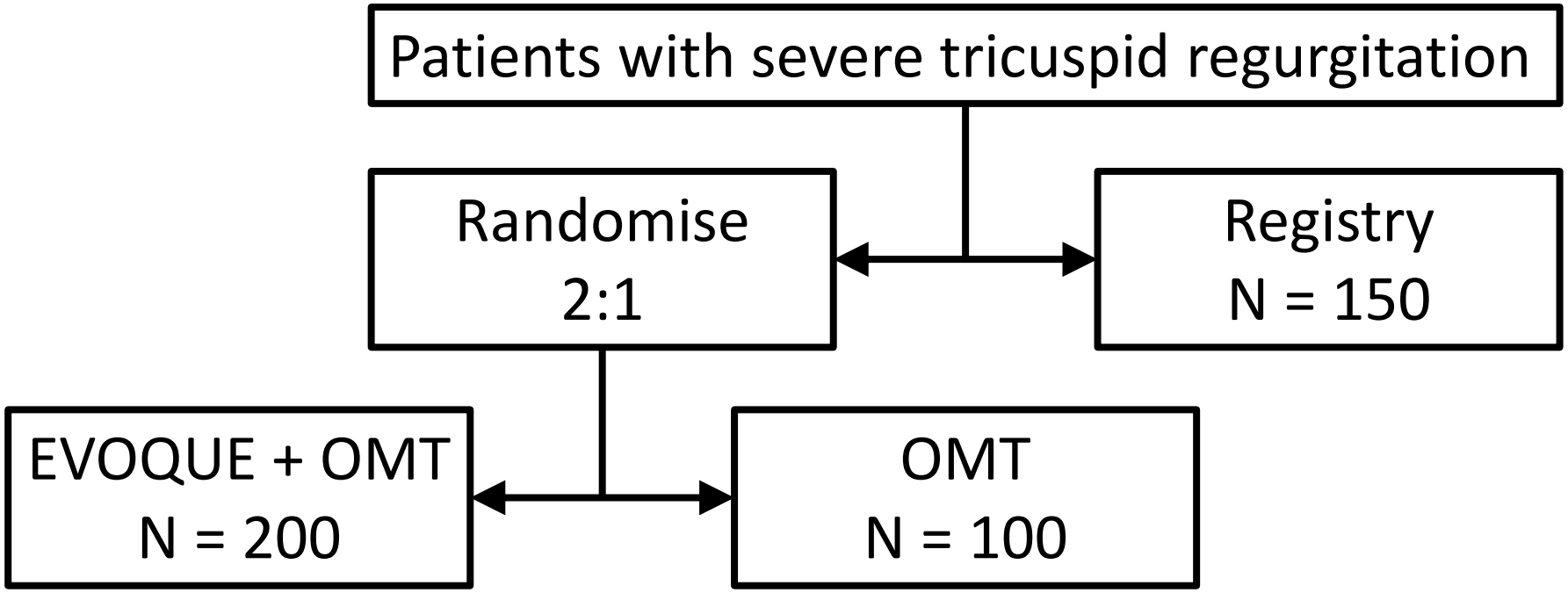




***TR reduction**: Severe to None*

Mean PG 1mmHg

EVOQUE TRISCEND II Pivotal Study



EVOQUE TRISCEND II Pivotal Study

STUDY OUTCOMES:

Thirty Days:

- Major adverse events

Six Months:

- TR reduction
- QoL Indices
- Functional Indices

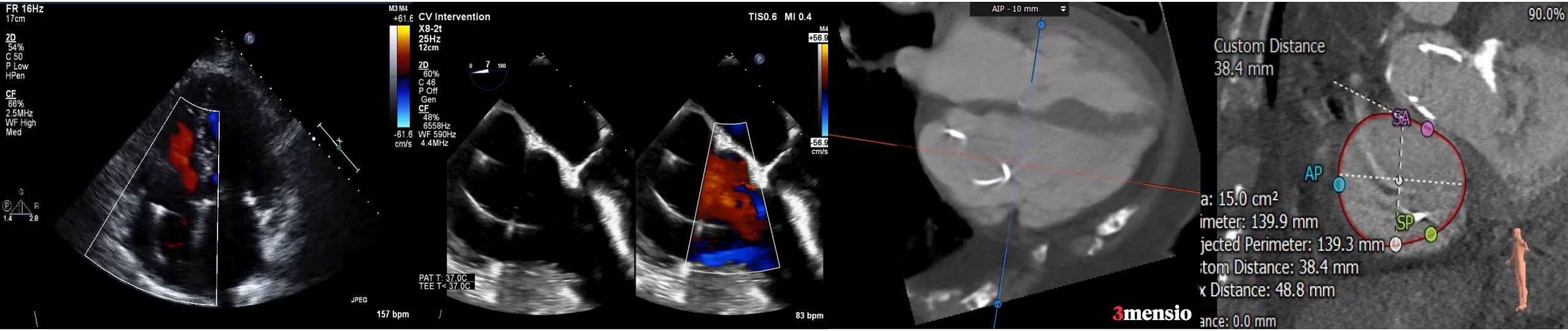
Twelve Months: pre-specified hierarchical composite outcomes

1. All-cause mortality
2. RVAD implantation or heart transplant
3. Tricuspid valve surgery or percutaneous tricuspid intervention
4. HF hospitalizations
5. QOL improvement
6. NYHA functional class improvement
7. 6MWD improvement

EVOQUE Example 2

91-year-old female with severe functional tricuspid regurgitation

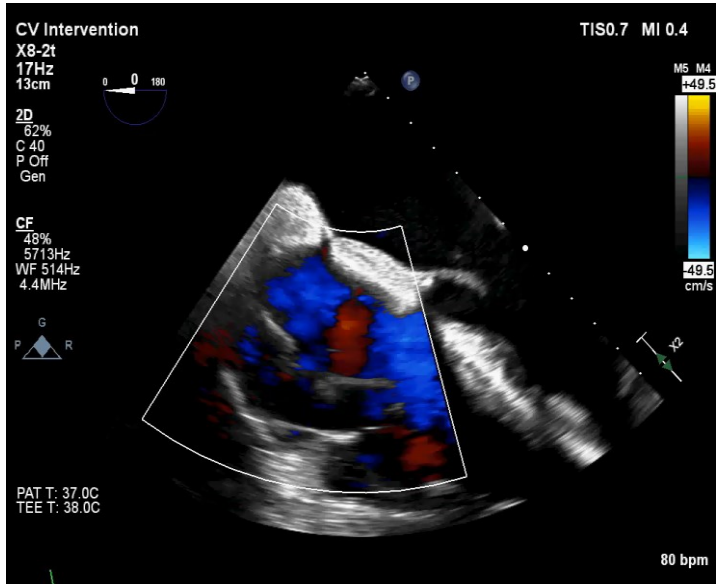
NYHA III Heart Failure Symptoms,
Hx SAVR,
Dual chamber pacemaker,
Hx of DVT s/p IVC filter,
Hypertension



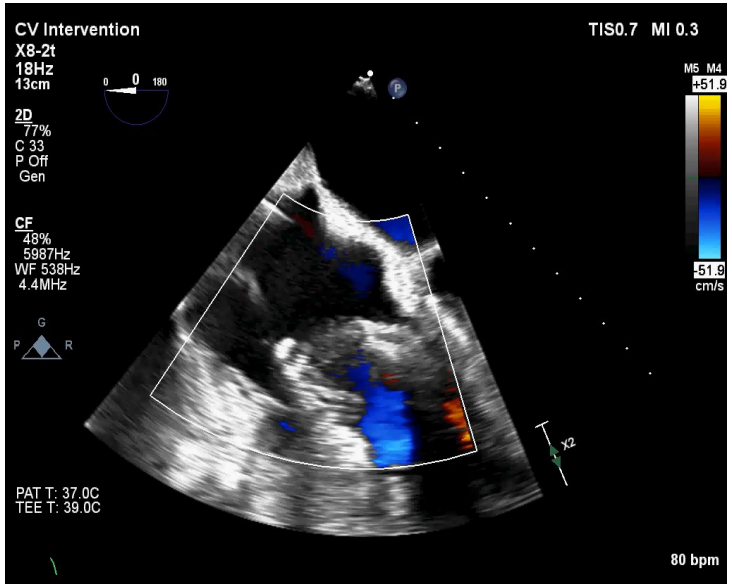
EVOQUE Example 2

91 year old female with severe functional tricuspid regurgitation
- treated with 44mm EVOQUE TTVR

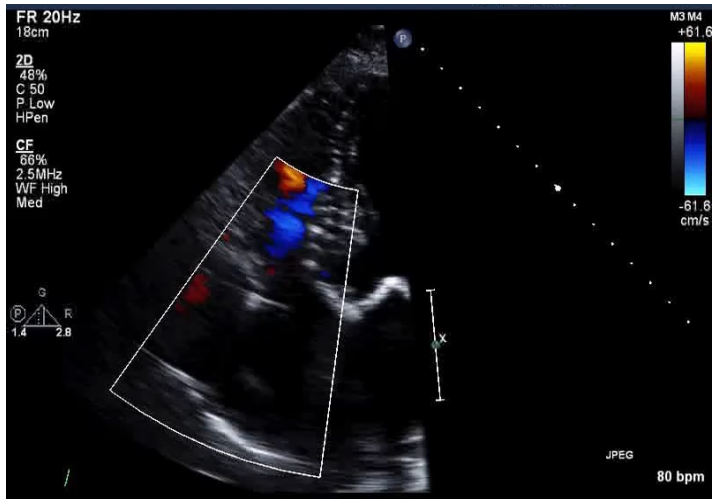
TEE Pre-Procedure

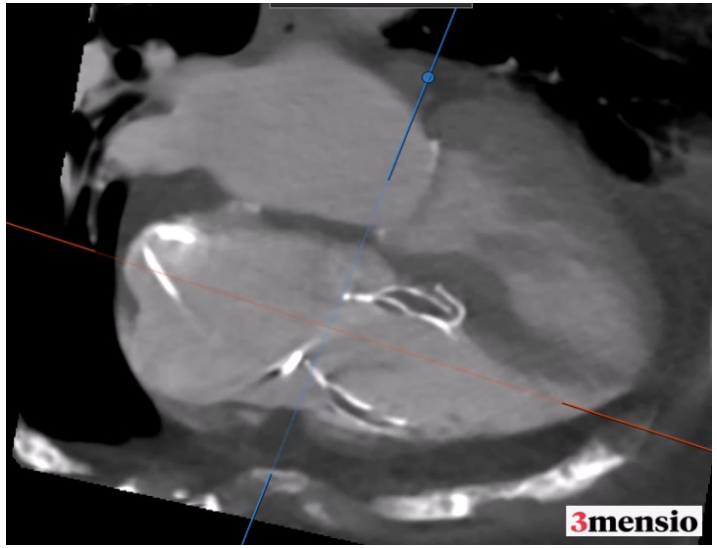


TEE Post-Procedure

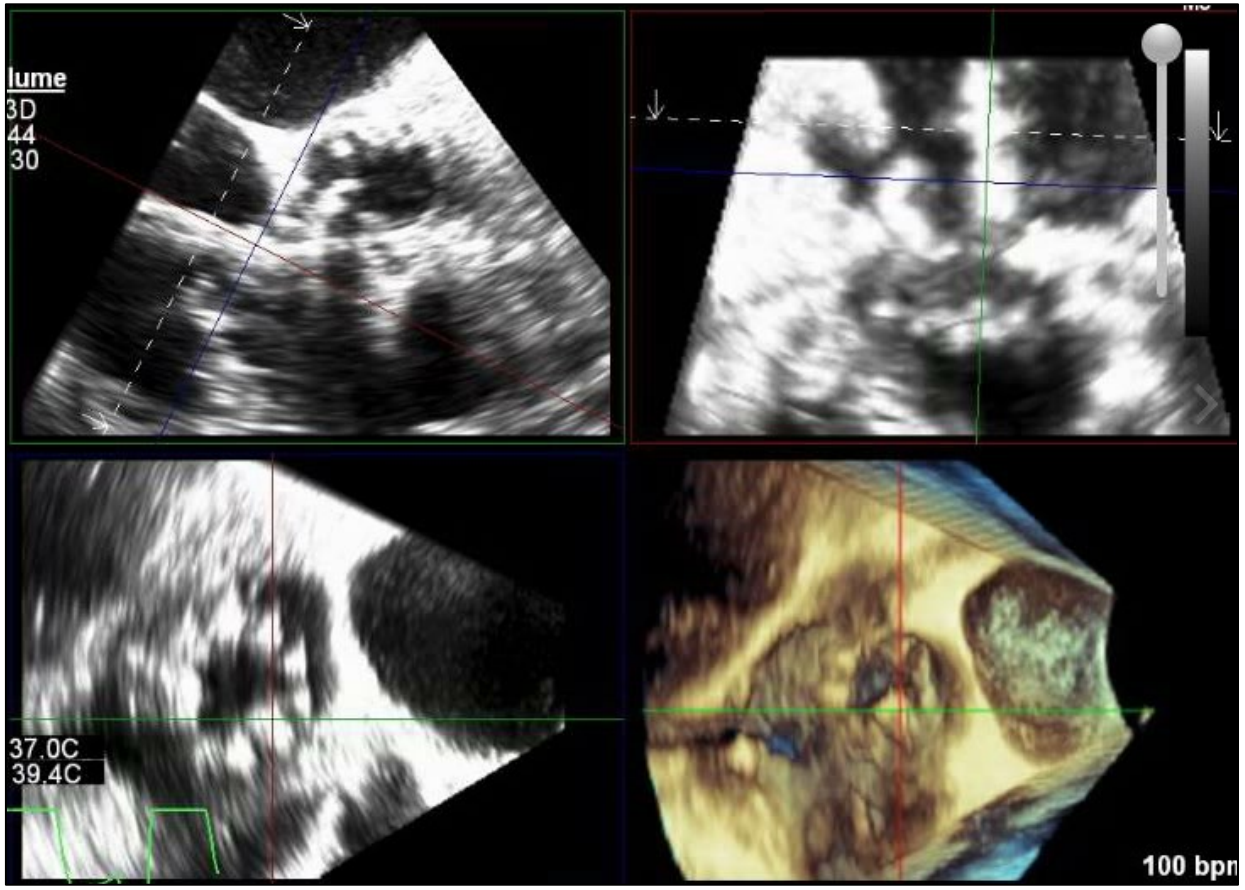


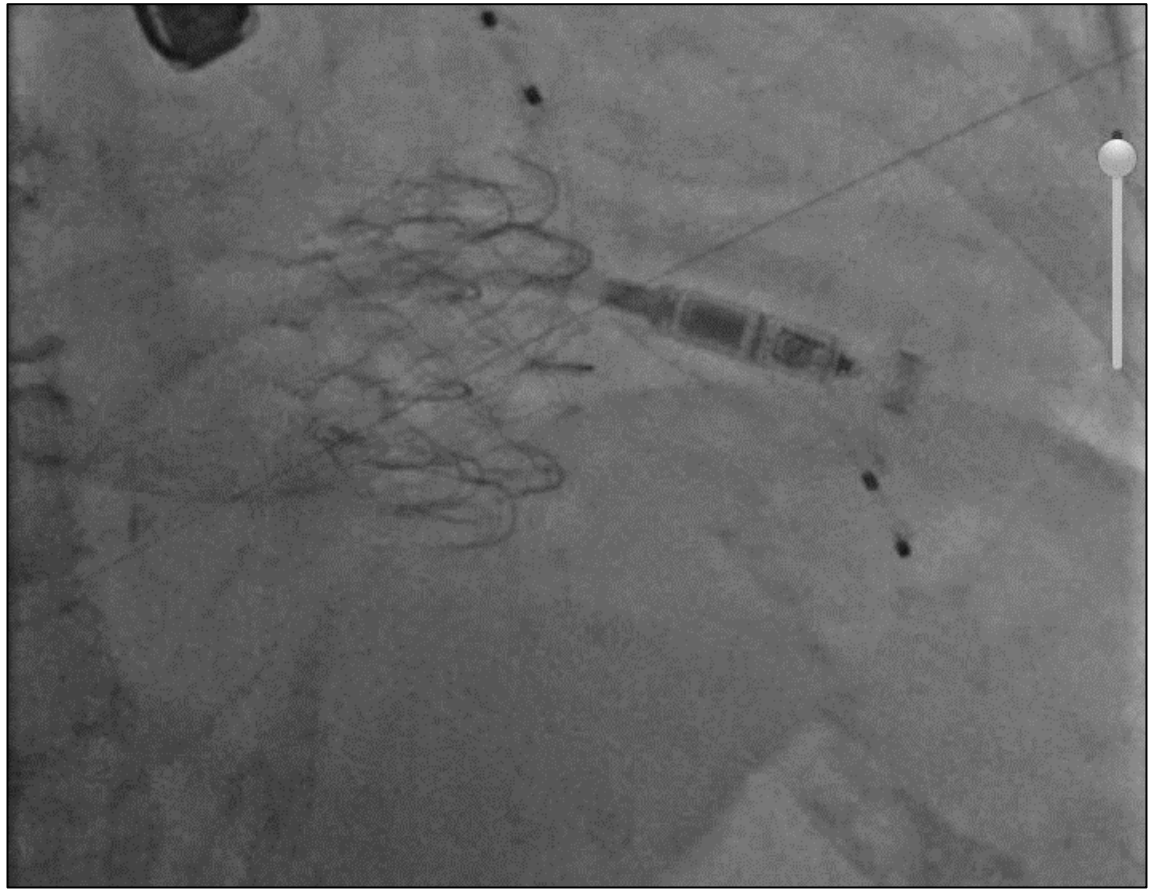
Day 30 Follow-up





EVOQUE Example 4: MICRA positioning

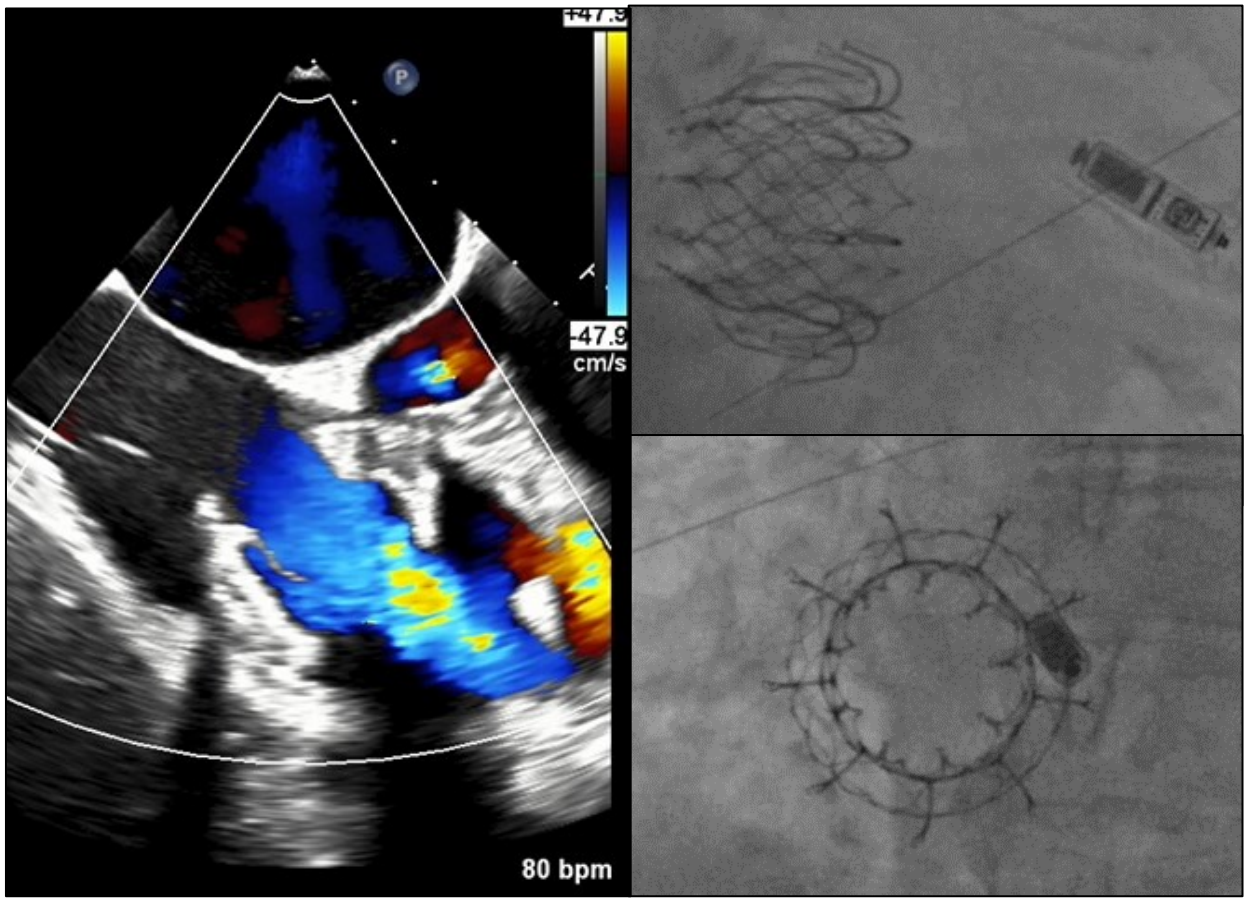




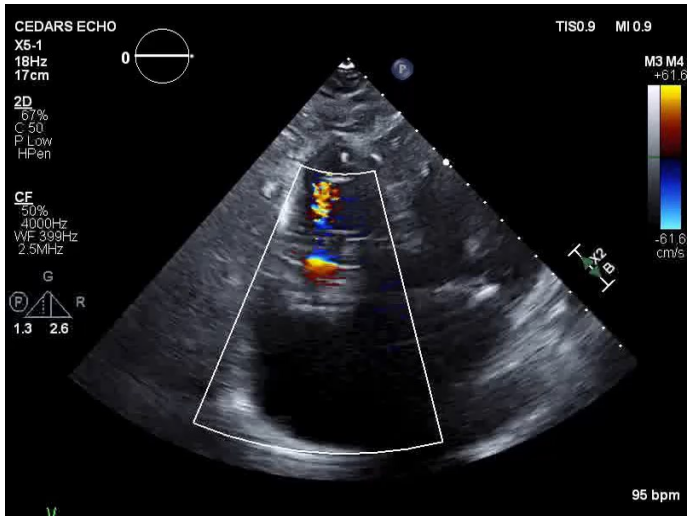
EVOQUE Example 4: Result

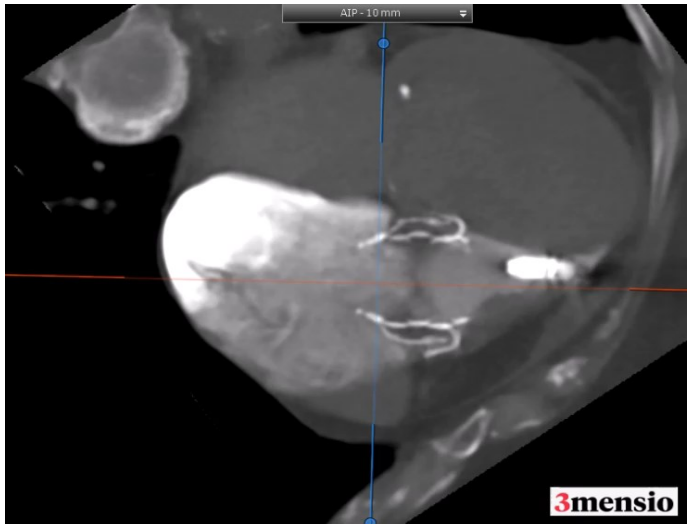
84-year-old female with severe functional TR

- **Treated with 44mm EVOQUE TTVR**
- **CHB treated with MICRA Implantation**



Day 30 Follow-up



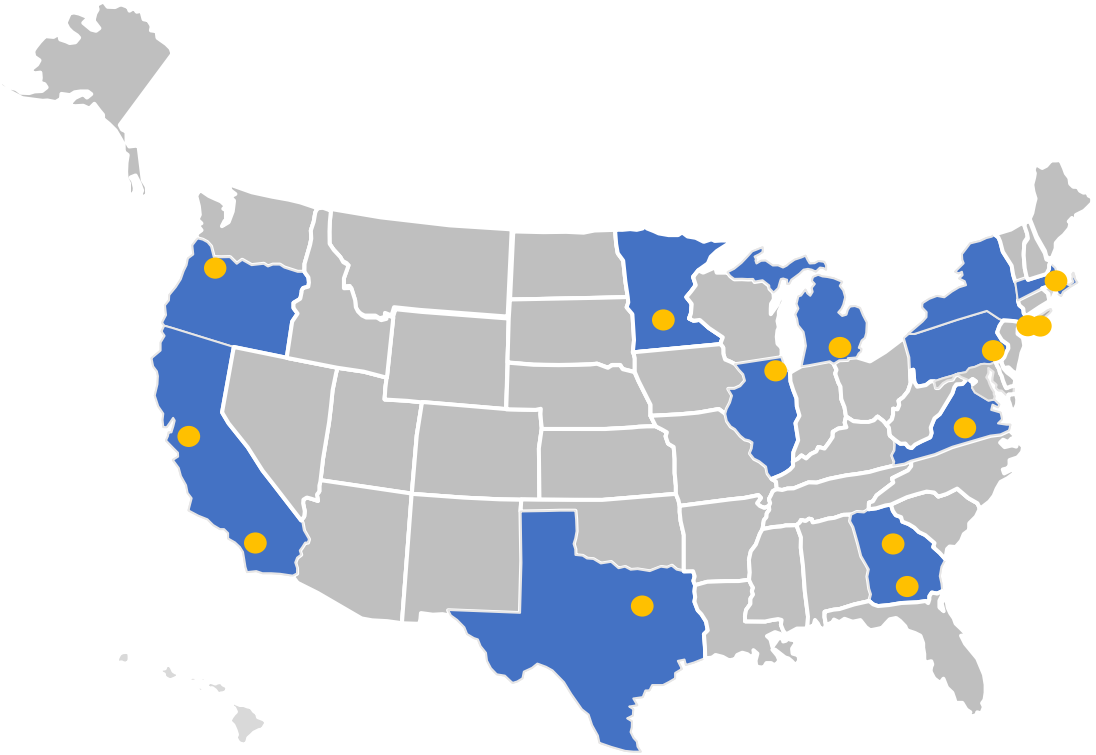


Transfemoral tricuspid valve replacement in patients with TR: the TRISCEND study 6-month outcomes

How was the study executed?

THE TRISCEND STUDY

Participating Sites

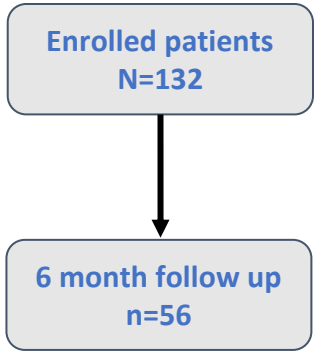


CA	Cedars Sinai Medical Center
IL	Northwestern Medical Center
OR	Oregon Health & Science University
NY	Columbia University Medical Center/NYPH
MI	Henry Ford Hospital
GA	Piedmont Heart Institute
TX	Baylor Heart Hospital Plano
GA	Emory University Hospital
CA	Stanford University
PA	Hospital of the University of Pennsylvania
MA	Massachusetts General Hospital
VA	University of Virginia Health System
NY	Montefiore Medical Center
MA	Brigham and Women's Hospital

Reflects patient enrollment in the current data set

THE TRISCEND STUDY

Study Enrollment



Follow up not due n=29
Pending visit n=27
Missed visit n=10
All-cause mortality n=5
Exited for other reasons n=5

Baseline characteristics	N=132 N (%) or Mean ± SD
Age, years	79.2 ± 7.39
Female	97 (74%)
EuroSCORE II (%)	5.3 ± 4.3
STS score (MV repair)[1]	7.4 ± 5.39
NYHA functional class III or IV	76%
TR grade ≥severe[2]	113 (88%)
Atrial fibrillation	119 (90%)
Pulmonary hypertension (sPAP ≥30 mmHg)	104 (79%)
Diabetes	25 (19%)
Chronic kidney disease	73 (55%)
History of ascites	26 (20%)
Prior stroke	16 (12%)
CABG surgery	26 (20%)
Prior valve surgery/intervention	50 (38%)
Pacemaker or ICD	46 (35%)
TR etiology	
Functional	93 (70.5%)
Degenerative	9 (6.8%)
Mixed/other	30 (22.7%)

[1]n=130 [2]Core lab: Baylor, Scott and White Research Institute; TR regurgitation at baseline available in 129 patients.
CABG, coronary artery bypass graft; ICD, implantable cardioverter defibrillator; NYHA, New York Heart Association; sPAP, systolic pulmonary artery pressure; STS, Society of Thoracic Surgeons; TR, tricuspid regurgitation

Procedural Characteristics and Hospital Disposition

Procedural Characteristics	n/N (%) or Mean ± SD (N)
Percutaneous	132/132 (100%)
• **Right femoral vein access**	125/132 (94.7%)
• **Left femoral vein access**	7/132 (5.3%)
Device success (per device)*	128/133 (96.2%)
Device time (implant insertion to release), mins	72.8 ± 28.15 (130)

Hospital Disposition	n/N (%) or Median (Min,Max)
Length of Stay (days)	3 (0,35)
Discharge Location	
Home	114/129 (88.4%)
Home with Services	6/129 (4.7%)
Skilled Nursing Facility	6/129 (4.7%)
Other	3/129 (2.4%)

*Device deployed and delivery system retrieved at exit from the cardiac catheterization laboratory. One patient had two device attempts.

Major Adverse Events (MAEs) at 30 Days

CEC Adjudicated Events	N=124[a] N (%)
Cardiovascular mortality	3 (2.4%)
Myocardial infarction	0 (0%)
Stroke	0 (0%)
Renal complications requiring unplanned dialysis or renal replacement therapy	1 (0.8%)
Severe bleeding[b]	22 (17.7%)
Major access site and vascular complications	2 (1.6%)
Non-elective tricuspid valve re-intervention, percutaneous or surgical	2 (1.6%)
Major cardiac structural complications	1 (0.8%)
Device-related pulmonary embolism	0 (0%)
Composite MAE Rate	**23 (18.5%)**
Other Events	**N=132[c]** N (%)
All cause mortality	4 (3.%)
Site-Reported Events	**N=76[d]** N (%)
New permanent pacemaker	8 (10.5%)

81.5% of patients had no MAEs at 30 days

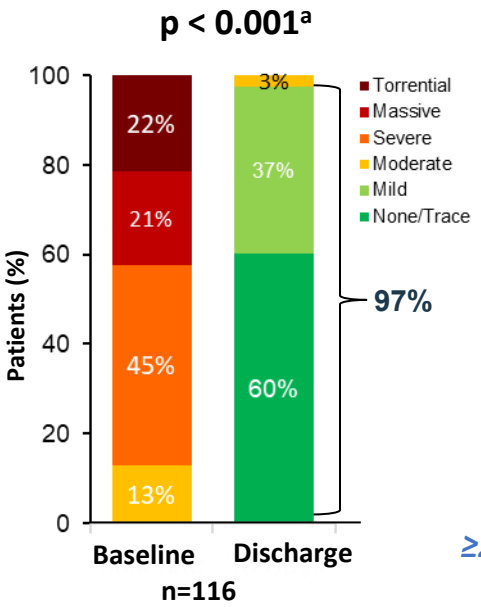
[a]Denominator for % calculation includes all patients who reached 30-day follow-up as well as any patients who experienced an MAE prior to follow-up. [b]Severe bleeding is defined as major, extensive, life-threatening or fatal bleeding per Mitral Valve Academic Research Consortium (MVARC). [c]Of 132 enrolled patients, 4 patients died of all causes. [d]76 patients did not have a pre-existing pacemaker and reached 30-day follow-up.

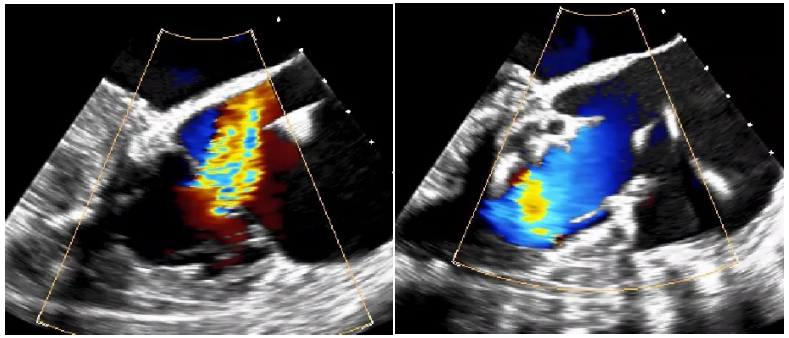
What are the essential results?

THE TRISCEND STUDY

Significant Reduction in TR Severity by Core Lab[1] at 6 Months

TR Severity at Discharge



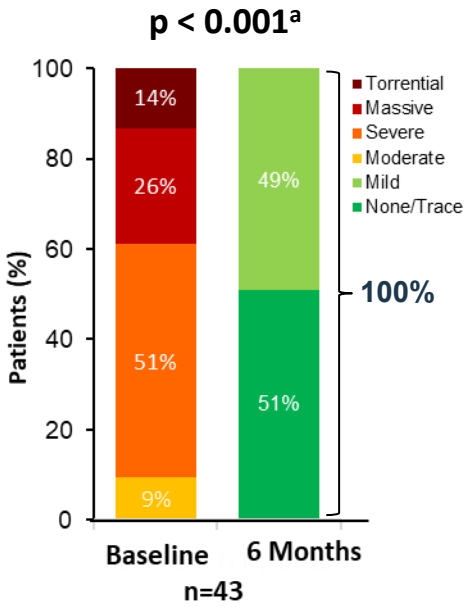


No residual TR post implant with EVOQUE valve

≥1 grade reduction in 100% at discharge and 6 months

≥2 grade reduction in 95% at discharge and 98% at 6 months

TR Severity at 6 Months

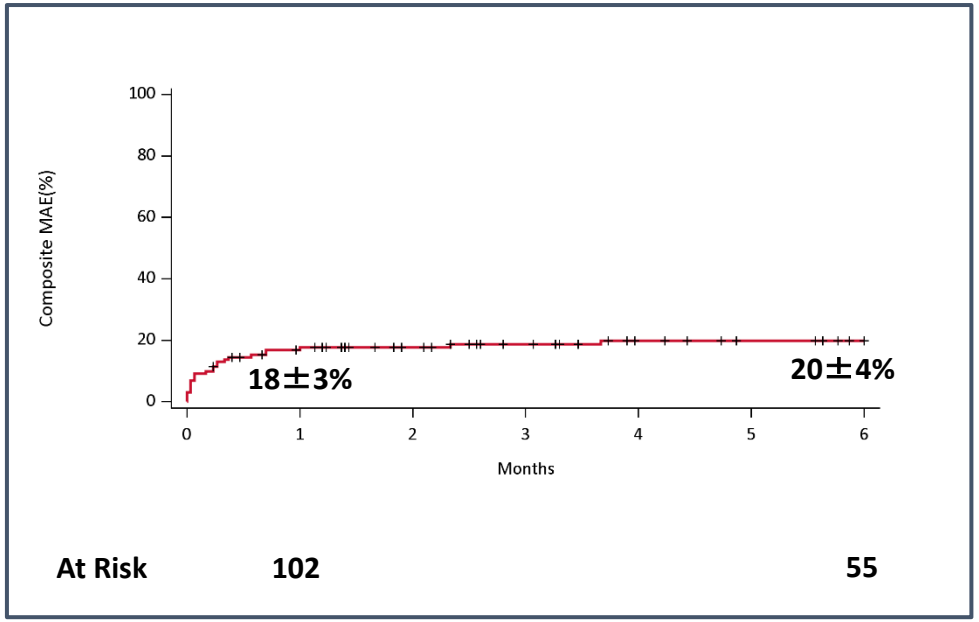


[1]Core lab: Baylor, Scott and White Research Institute; [a]Wilcoxon signed-rank test
TR, tricuspid regurgitation

THE TRISCEND STUDY

Composite Major Adverse Events (%) to 6 Months

Kaplan-Meier Analysis

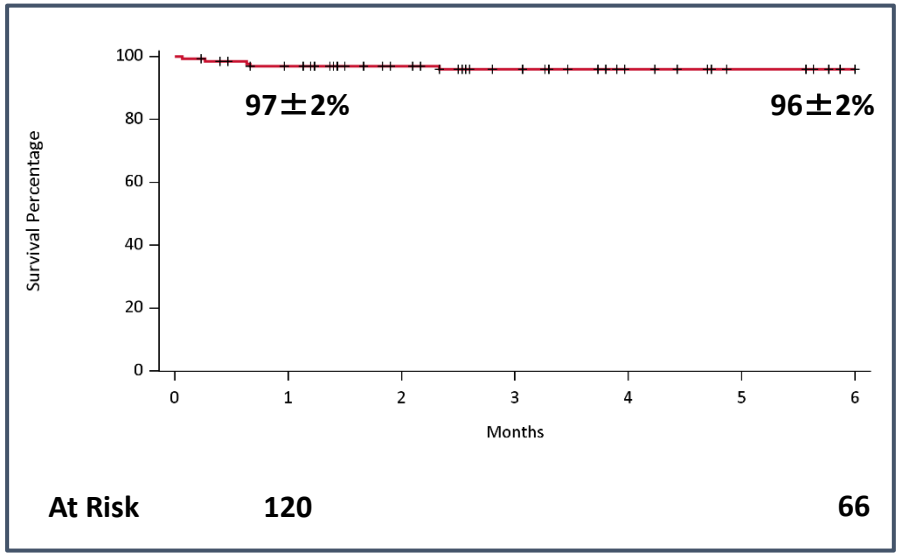


CEC adjudicated MAEs between 30 days and 6 months included: 2 non-elective tricuspid valve re-interventions (PODs 49 and 110), 2 severe bleeds (traumatic hematoma at POD 32 and GI bleed at POD 127), 1 cardiovascular death (cardiac arrest POD 70)

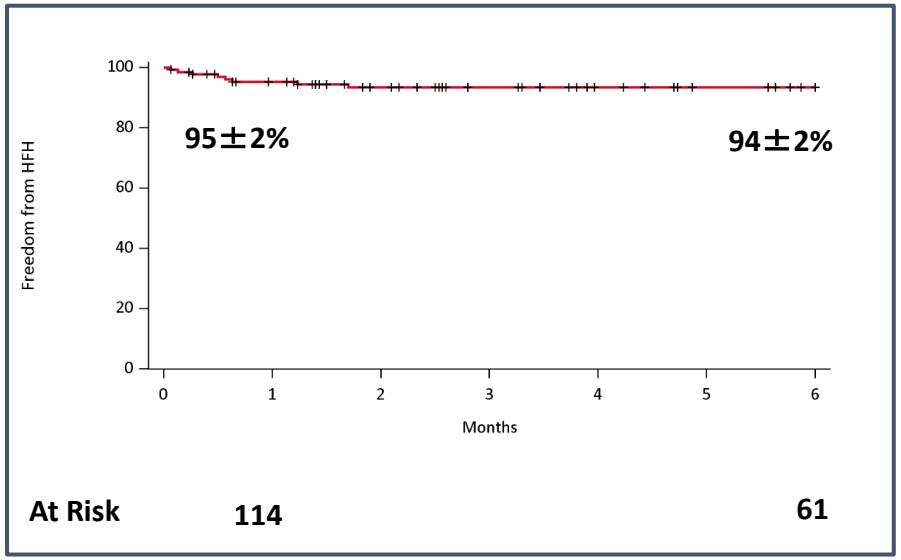
THE TRISCEND STUDY

High Survival Rate and Freedom from Heart Failure Hospitalization to 6 Months

Survival



Freedom from Heart Failure Hospitalization

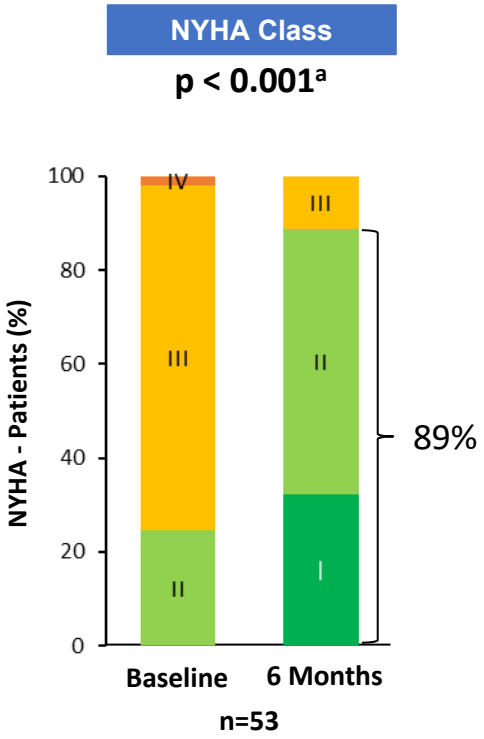


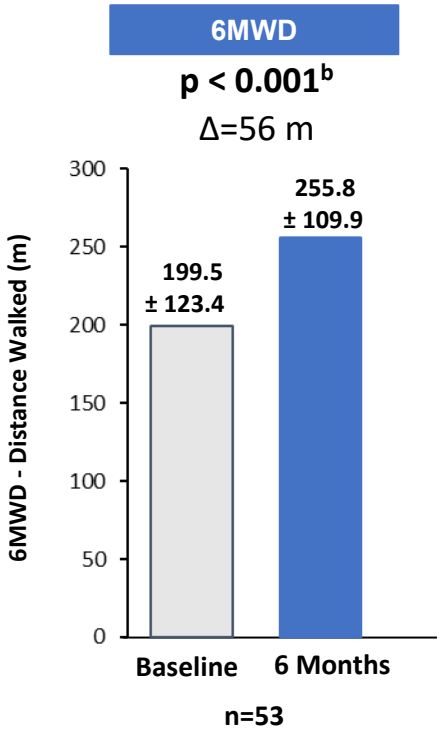
Kaplan-Meier analysis

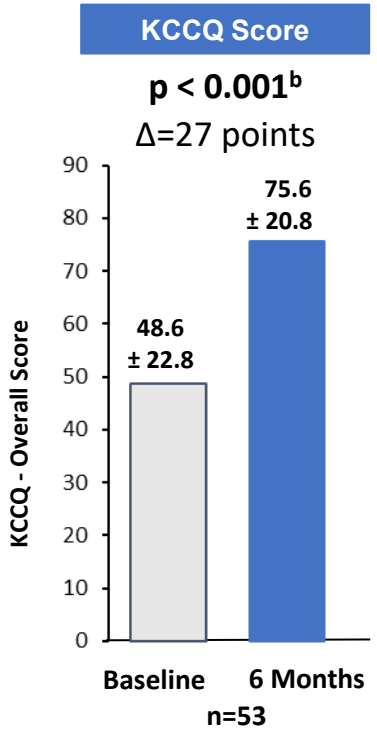
Why is this important?

THE TRISCEND STUDY

Significantly Improved Functional and Quality of Life Outcomes at 6 Months







Data are presented as Mean ± SD, 95% CI by normal approximation. [a]Wilcoxon signed-rank test; [b]Paired t-test.
NYHA Class, New York Heart Association functional classification; 6MWD, 6-minute walk distance;
KCCQ, Kansas City Cardiomyopathy Questionnaire

The essentials to remember

What?	• The transfemoral EVOQUE Tricuspid Valve Replacement System may be an important therapy for an undertreated TR patient population
How?	• We report the 6-month outcomes from the prospective, single-arm, multicentre TRISCEND study in patients with ≥moderate TR
What are the results?	• Significant TR reduction by core laboratory assessment, with 100% of patients having mild or less TR at 6 months in patients with predominantly ≥severe TR at baseline • 96% survival rate and 94% freedom from heart failure hospitalization • Significant improvements in NYHA class, KCCQ score, and 6MWD
Why is this important?	• Transfemoral tricuspid valve replacement with the EVOQUE system demonstrated favorable 30-day outcomes sustained at 6 months • Randomized pivotal trial (TRISCEND II, NCT04482062) is underway

Transcatheter Therapies for Tricuspid Regurgitation

- There is renewed interest and focus on the tricuspid valve in the era of transcatheter valve technologies
- There are a number of concepts that have been shown to be feasible with early acceptable safety and efficacy results
- Increasing experience with off-label use of existing technologies:
  - Increasing experience with edge-to-edge repair using the MitraClip/Triclip system with good early results, but questions on long-term durability
  - Tricuspid valve-in-valve and valve-in-ring using TAVR devices is straightforward procedure with excellent risk benefit profile
- On-going protocols with dedicated devices to treat TR with valve replacement look promising in EFS. Pivotal trials are ongoing.

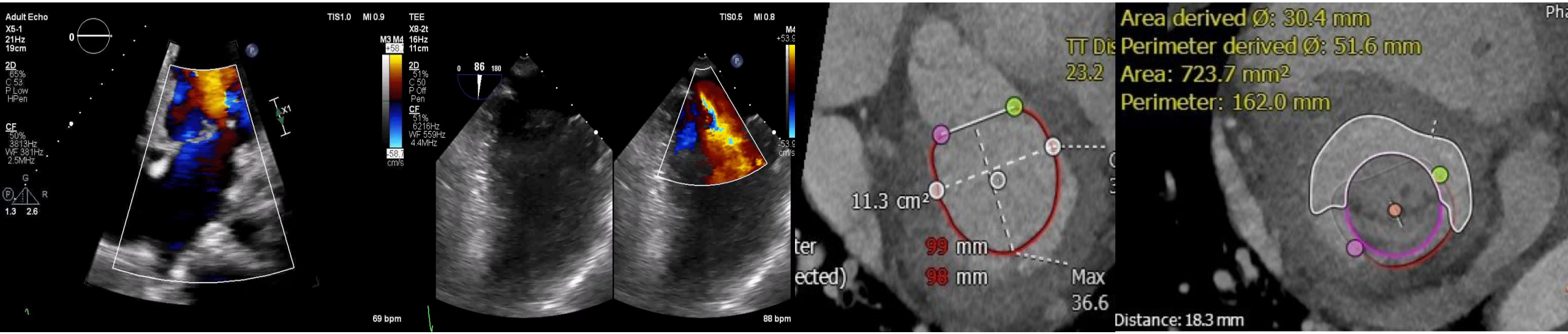
Key question: TR is associated with adverse outcomes but does treating functional TR result in improved clinical outcomes

Double Valve Replacement: M3 & EVOQUE Example

60-year-old female with severe mitral regurgitation

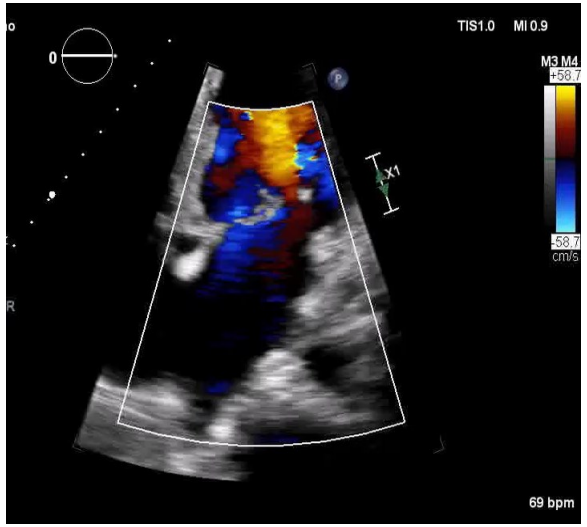
- **Deemed not a surgical candidate**
- **Considered for TMVR**

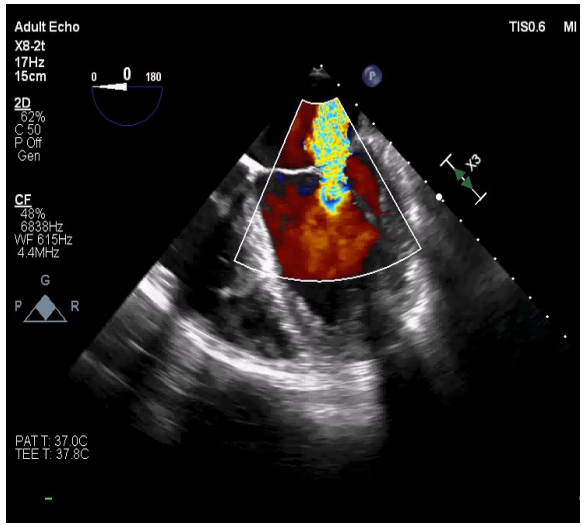
NYHA Class III,
Congestive Heart Failure
Atrial Fibrillation
Obesity (previously 400lbs)
Severe PAH



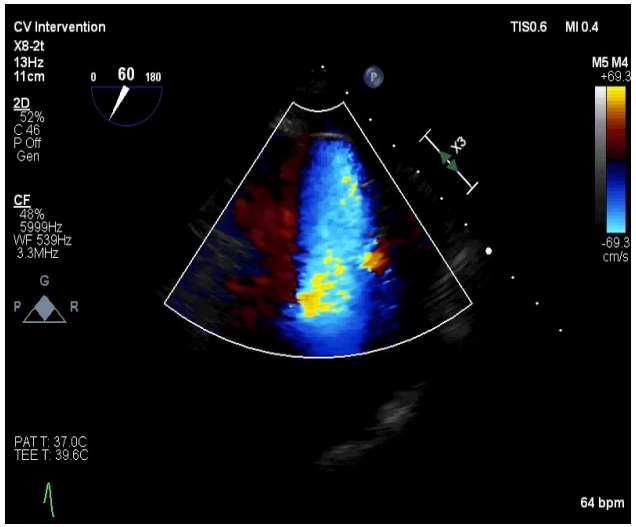
M3 & EVOQUE Example

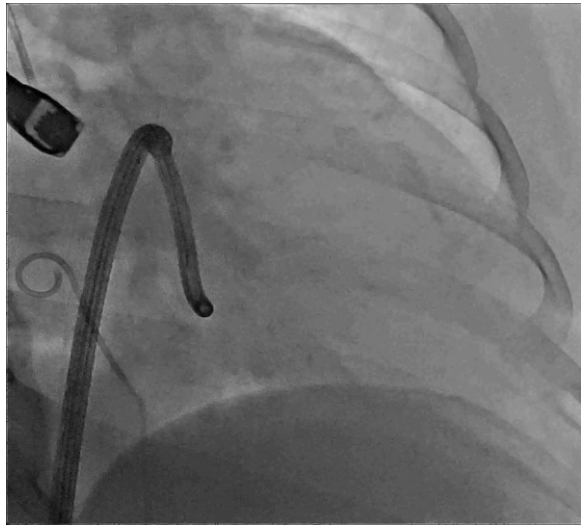
Pre-procedure

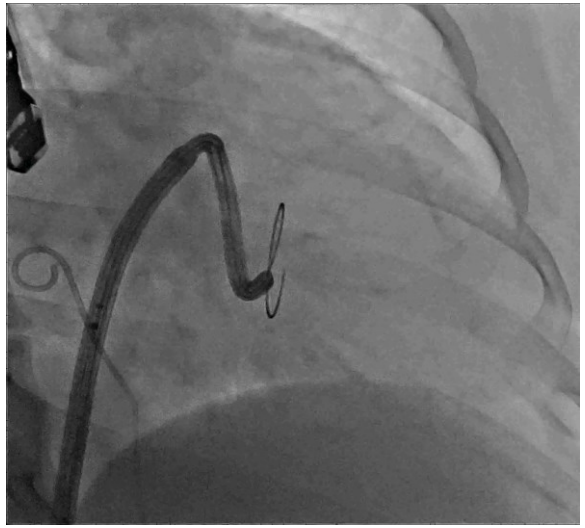


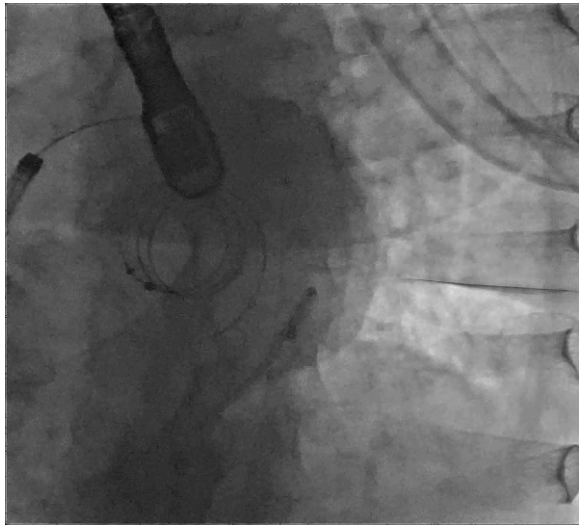


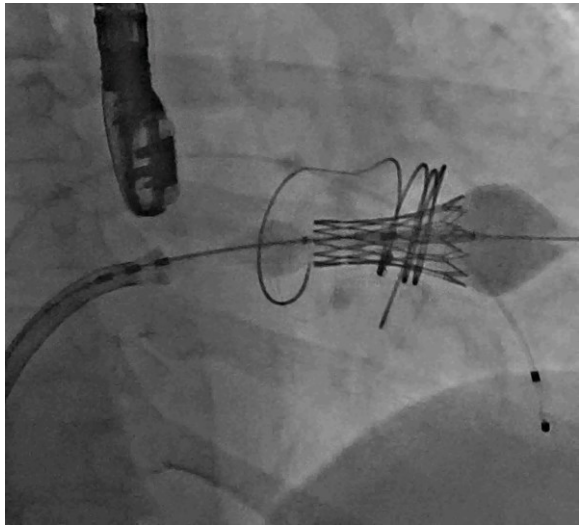
Post-Procedure







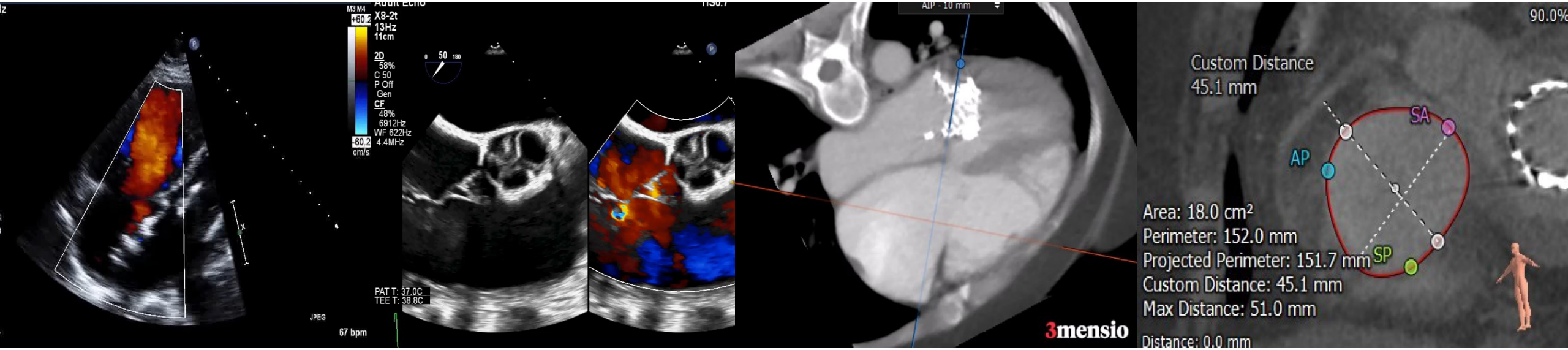




M3 & EVOQUE Example

Excellent symptomatic response
1 year later returns with peripheral oedema
- No MR but severe functional TR

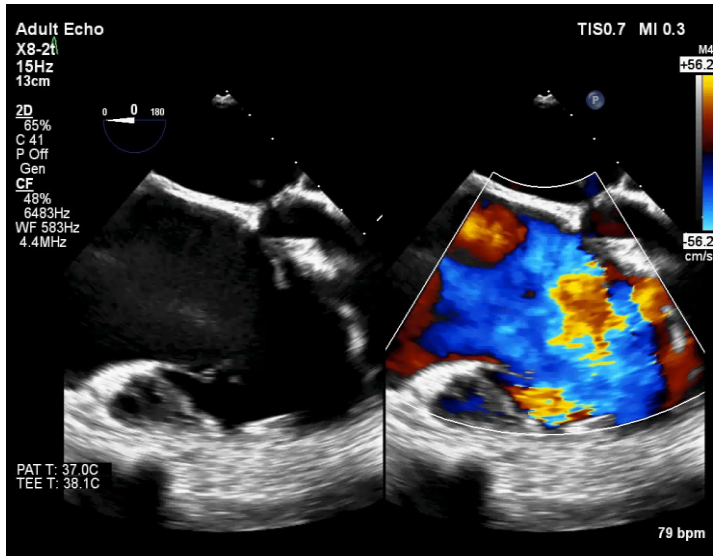
NYHA Class III,
Severe MR s/p MVR with SM3 device
Congestive Heart Failure
A-fib on Eliquis
Severe PAH



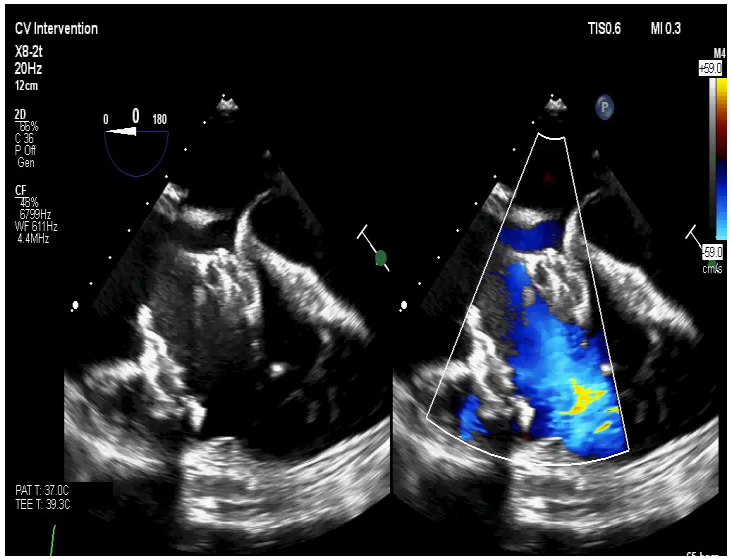
M3 & EVOQUE Example

61-year-old female with severe functional TR
- Treated with 48mm EVOQUE TTVR

TEE Pre-Procedure



TEE Post-Procedure



Day 30 Follow-up