



Emerging Transcatheter Tricuspid valve Therapies

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Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a relevant financial relationship(s) with an ineligible company(ies) listed below.

Nature of Financial Relationship

Grant/Research Support

Consultant Fees/Honoraria

Individual Stock(s)/Stock Options

Other

Ineligible Company

Edwards Lifesciences, Medtronic,
Neovasc, Abbott Vascular

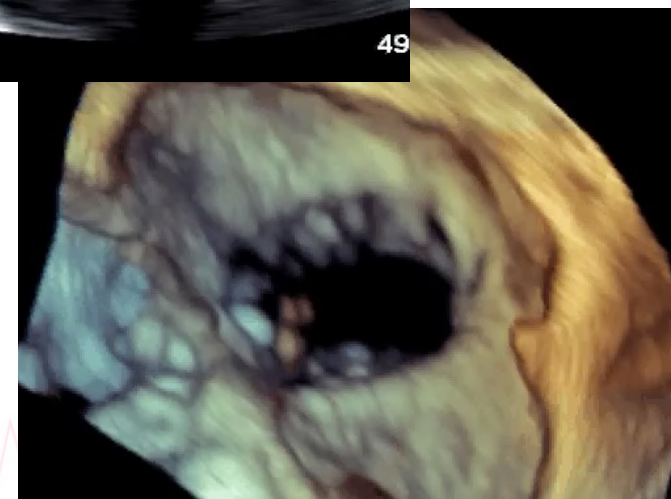
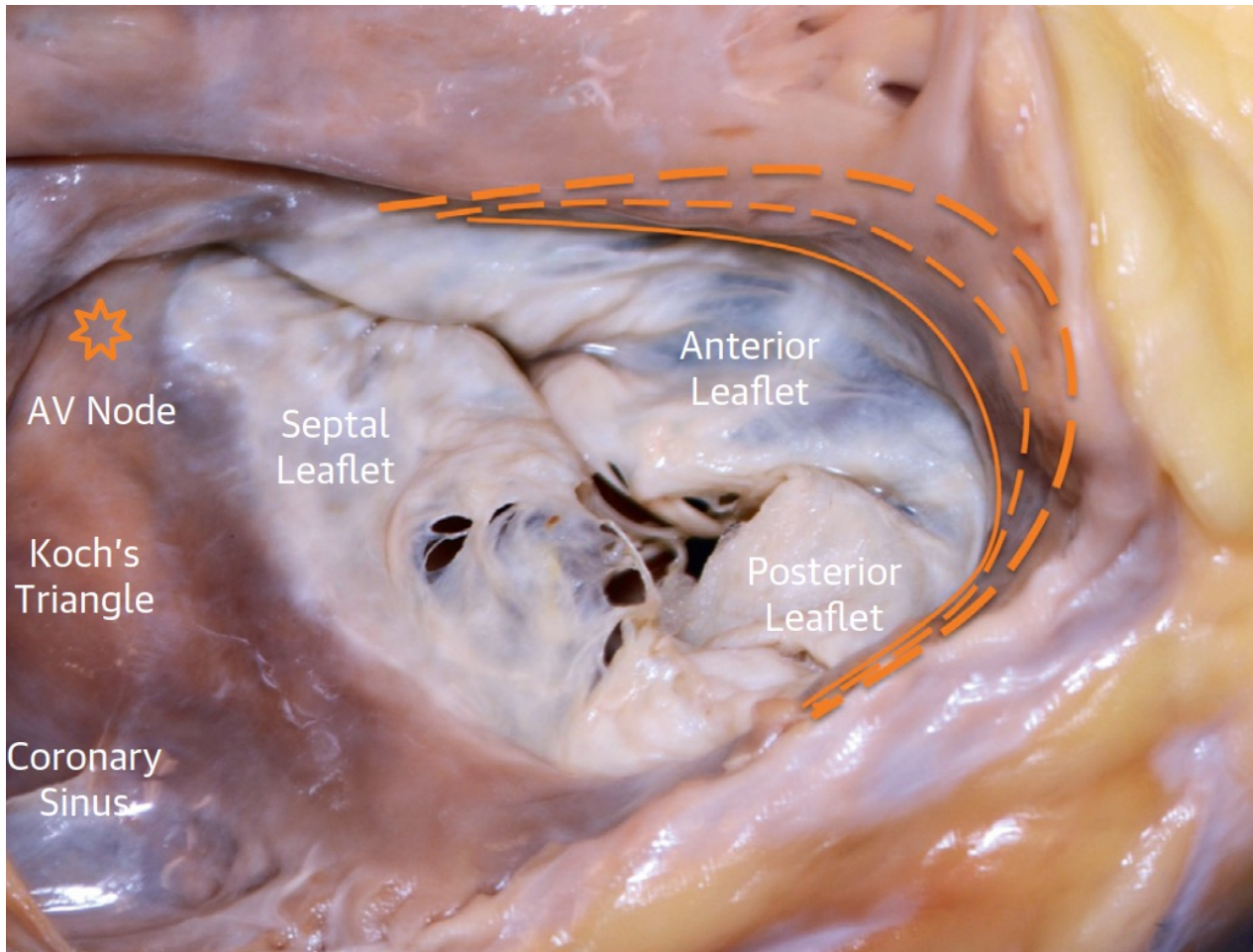
Medtronic, Edwards Lifesciences,
Abbott Vascular, Boston Scientific,
Jenscare

Total Flow Medical
Neovasc Inc

Eligibility Committee Board Member
(TRINITY Trial)



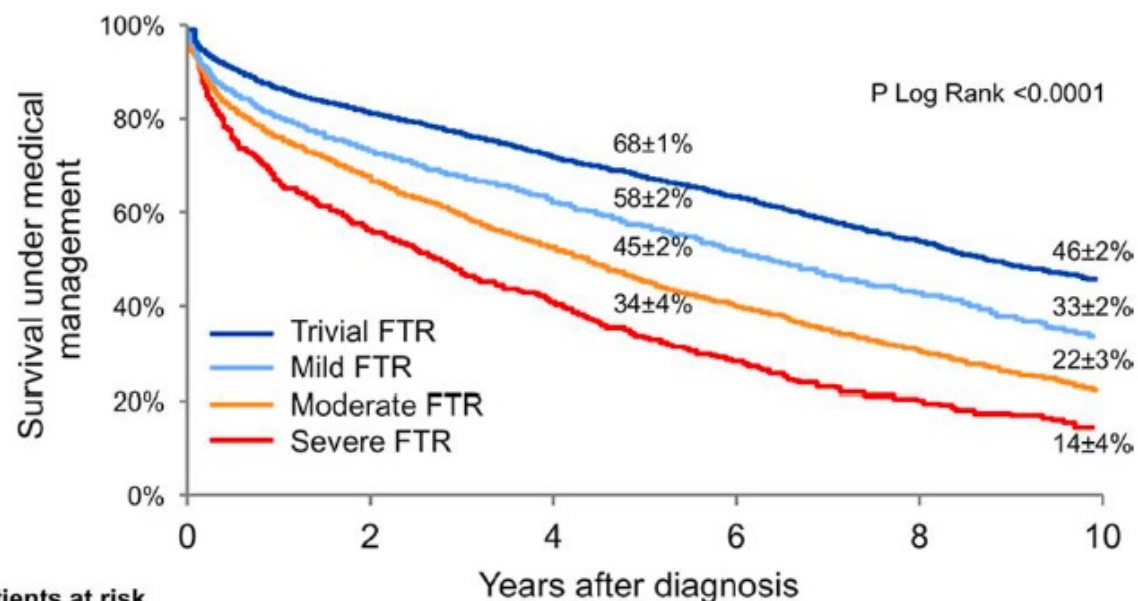
The "Forgotten Valve"



Tricuspid Regurgitation Negatively Impacts Survival

Survival is significantly worse in patients with moderate and severe tricuspid regurgitation

Especially in patients with chronic heart failure



Patients at risk

Trivial FTR	4329	3218	3069	2384	1640	762
Mild FTR	4178	2789	2119	1384	809	359
Moderate FTR	2255	1336	935	555	307	119
Severe FTR	745	352	230	135	65	23

Benfari et al. Excess Mortality Associated with Functional TR Complicating Heart Failure with Reduced EF; Circulation 2019; 140: 196-206

Tricuspid Regurgitation is Prevalent but Rarely Treated with Surgery

1.6M

Moderate to severe TR prevalence

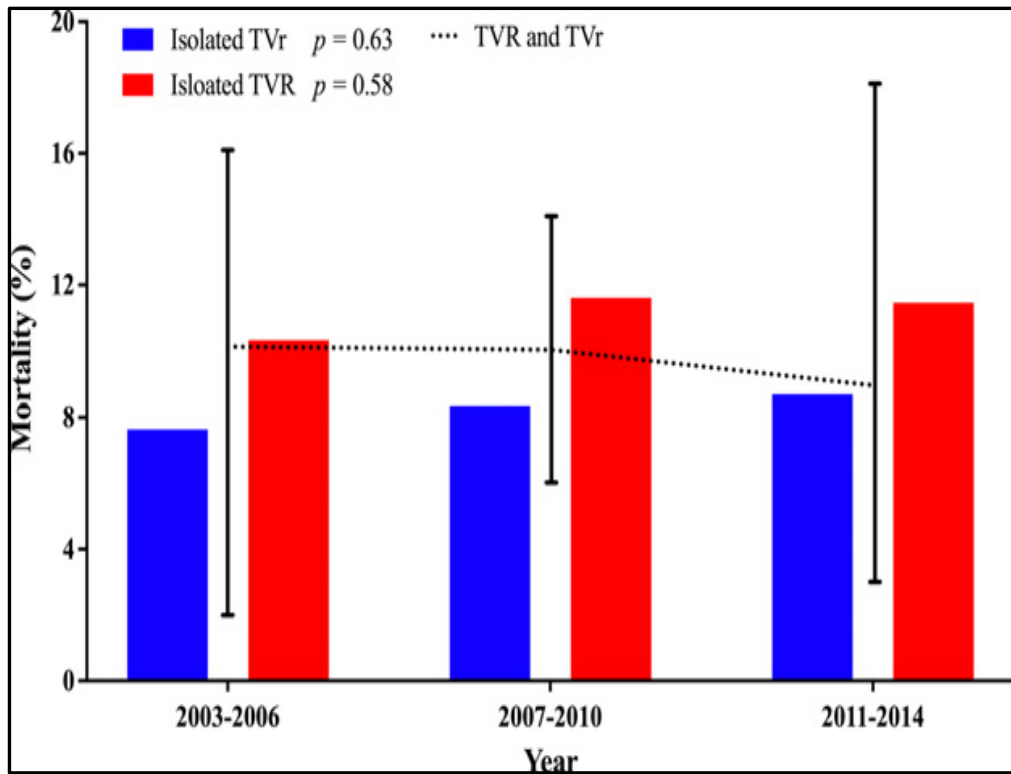


<8k

Surgical procedures annually

Reflective of US data
Stuge et al. *J Thorac and Cardiovasc Surg* 2006;1258-61
McCarthy et al. *Curr Treat Options Cardiovasc Med* 2010;587-597

High Mortality in Isolated TV Surgery



JAHA 2017;6:e007597

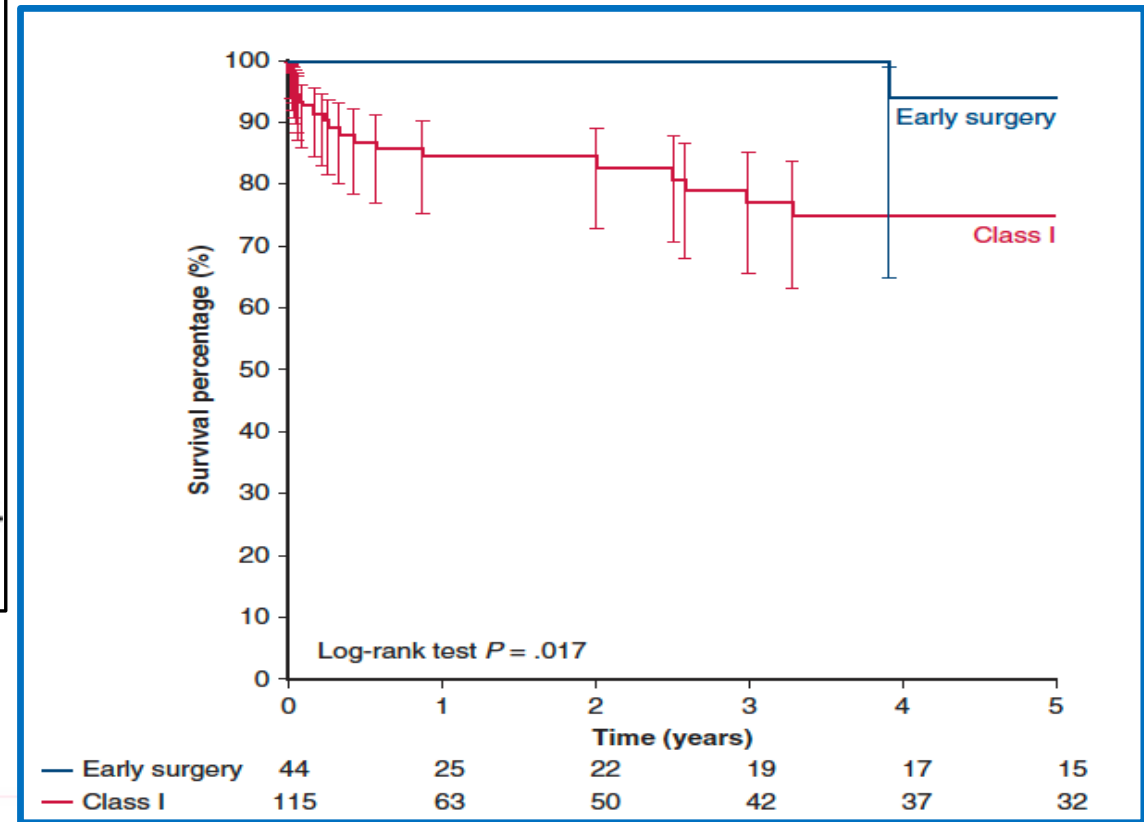


Outcomes of Isolated Tricuspid Valve Surgery Have Improved in the Modern Era



Mohanad Hamandi, MD, Robert L. Smith, MD, William H. Ryan, MD, Paul A. Grayburn, MD, Anupama Vasudevan, PhD, Timothy J. George, MD, J. Michael DiMaio, MD, Kelley A. Hutcheson, MD, William Brinkman, MD, Molly Szerlip, MD, David O. Moore, MD, and Michael J. Mack, MD

Departments of Cardiovascular Research, Cardiothoracic Surgery, and Cardiology, Baylor Scott & White-The Heart Hospital, Plano, Texas



Surgical Treatment



Annuloplasty



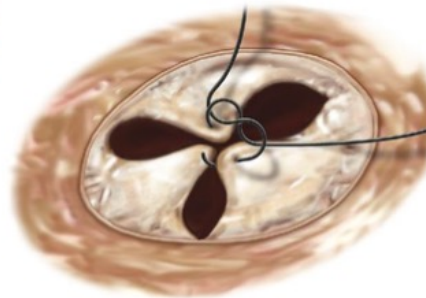
Annular Dilatation



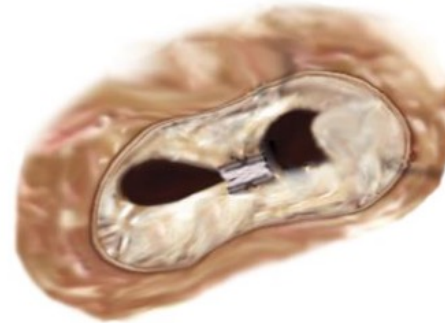
Kay Repair Technique



De Vega Repair



Clover Technique

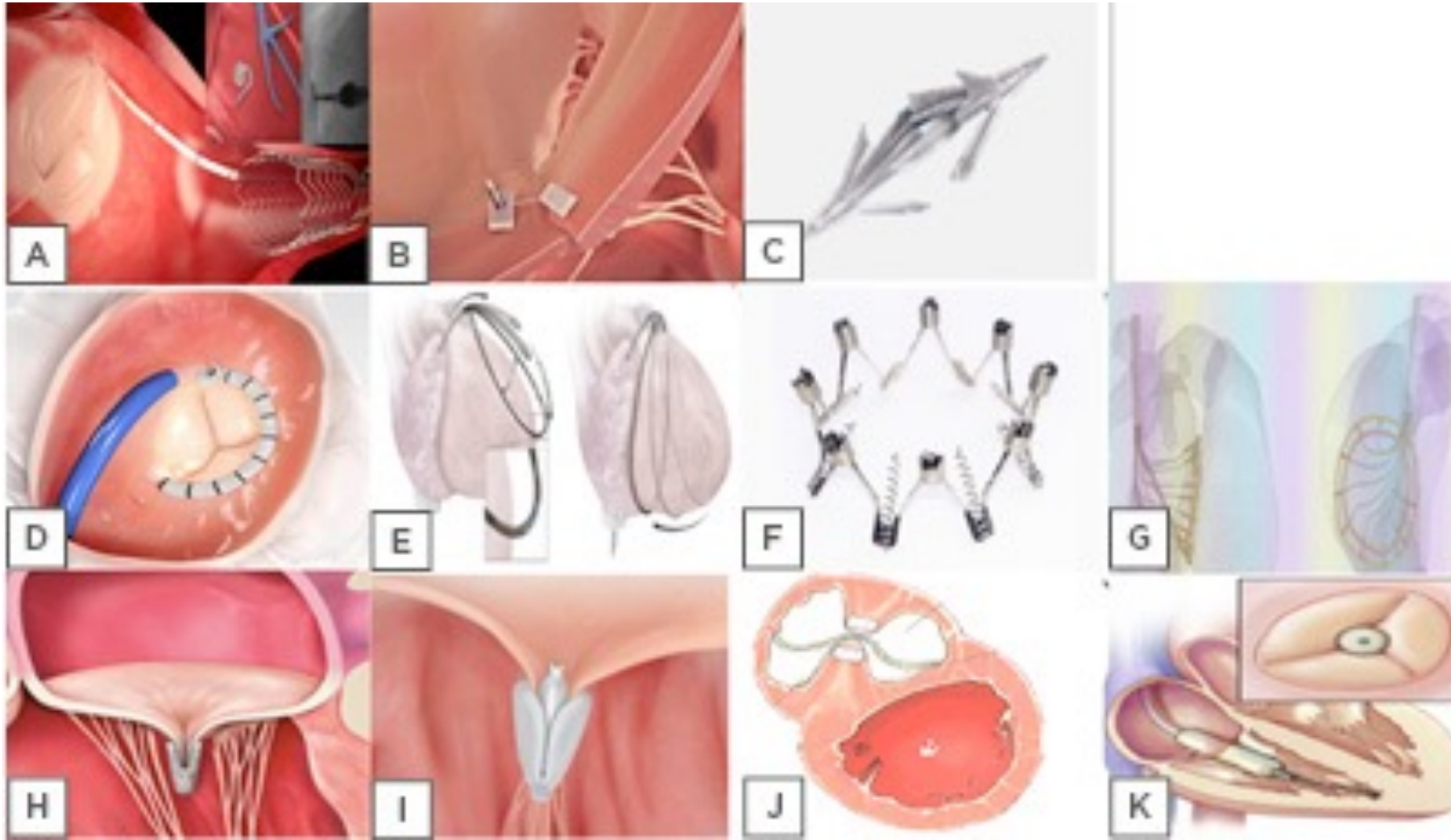


Hetzer Repair

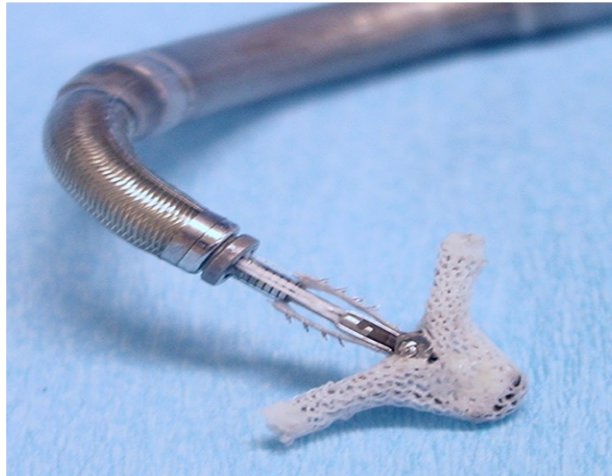
Tricuspid Valve Replacement



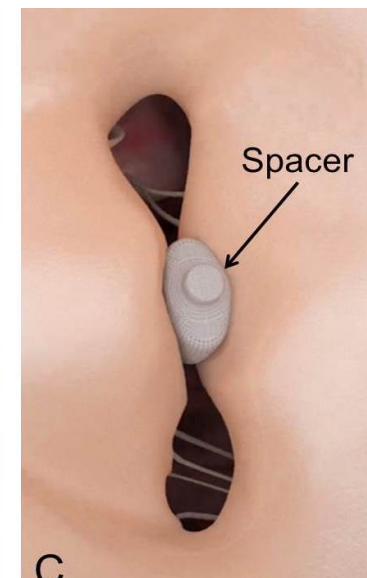
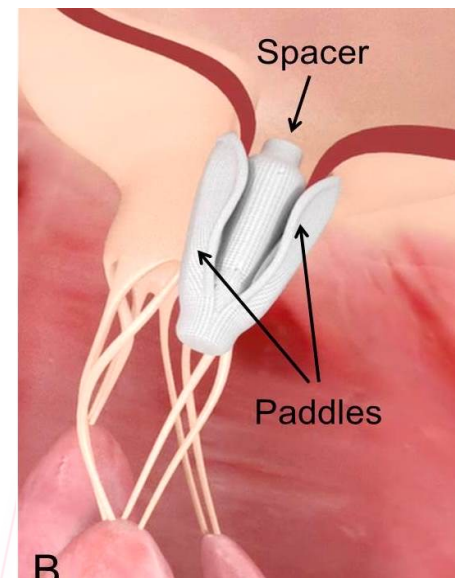
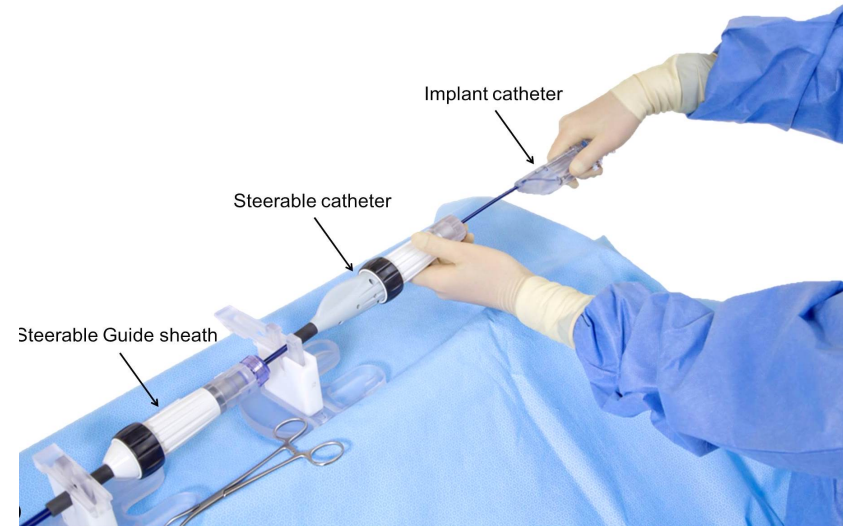
Transcatheter Tricuspid Valve Repair Solutions



Abbott TriClip® System

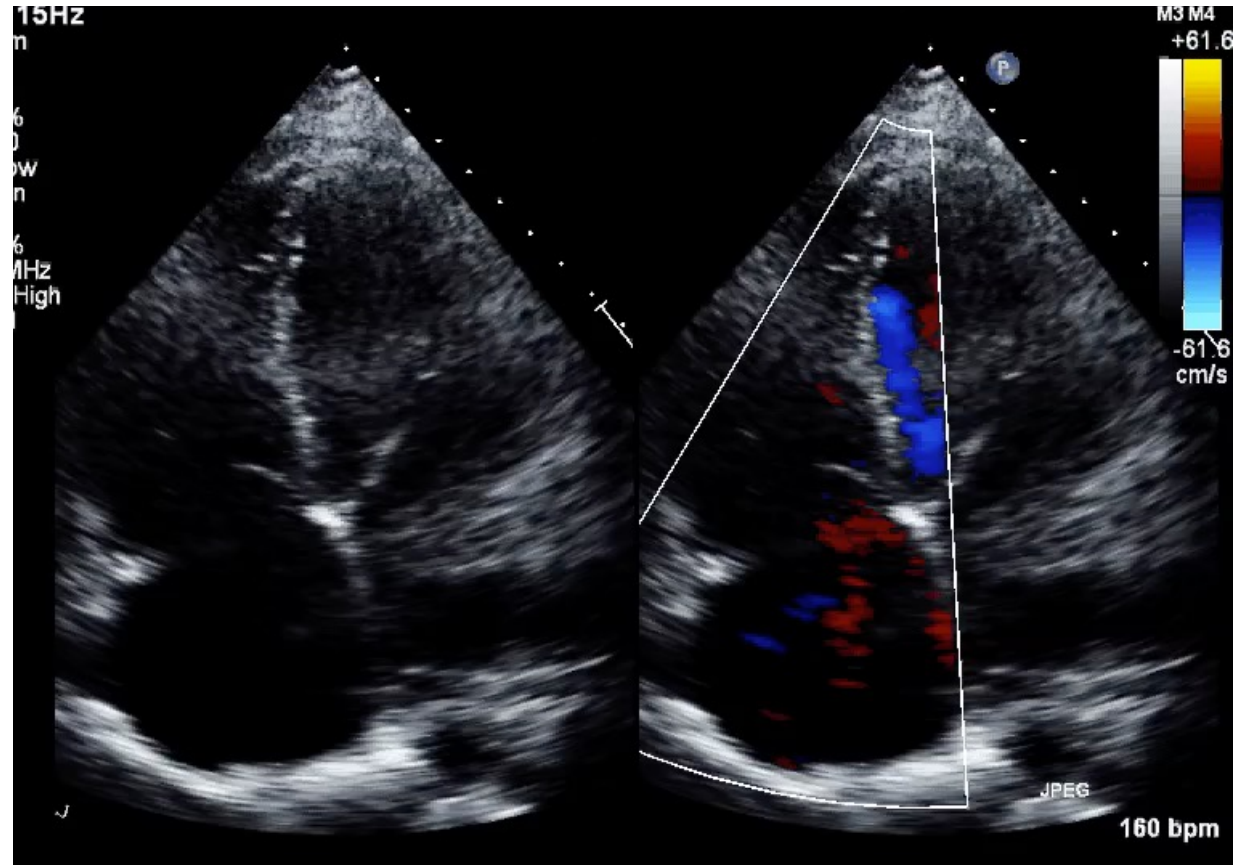


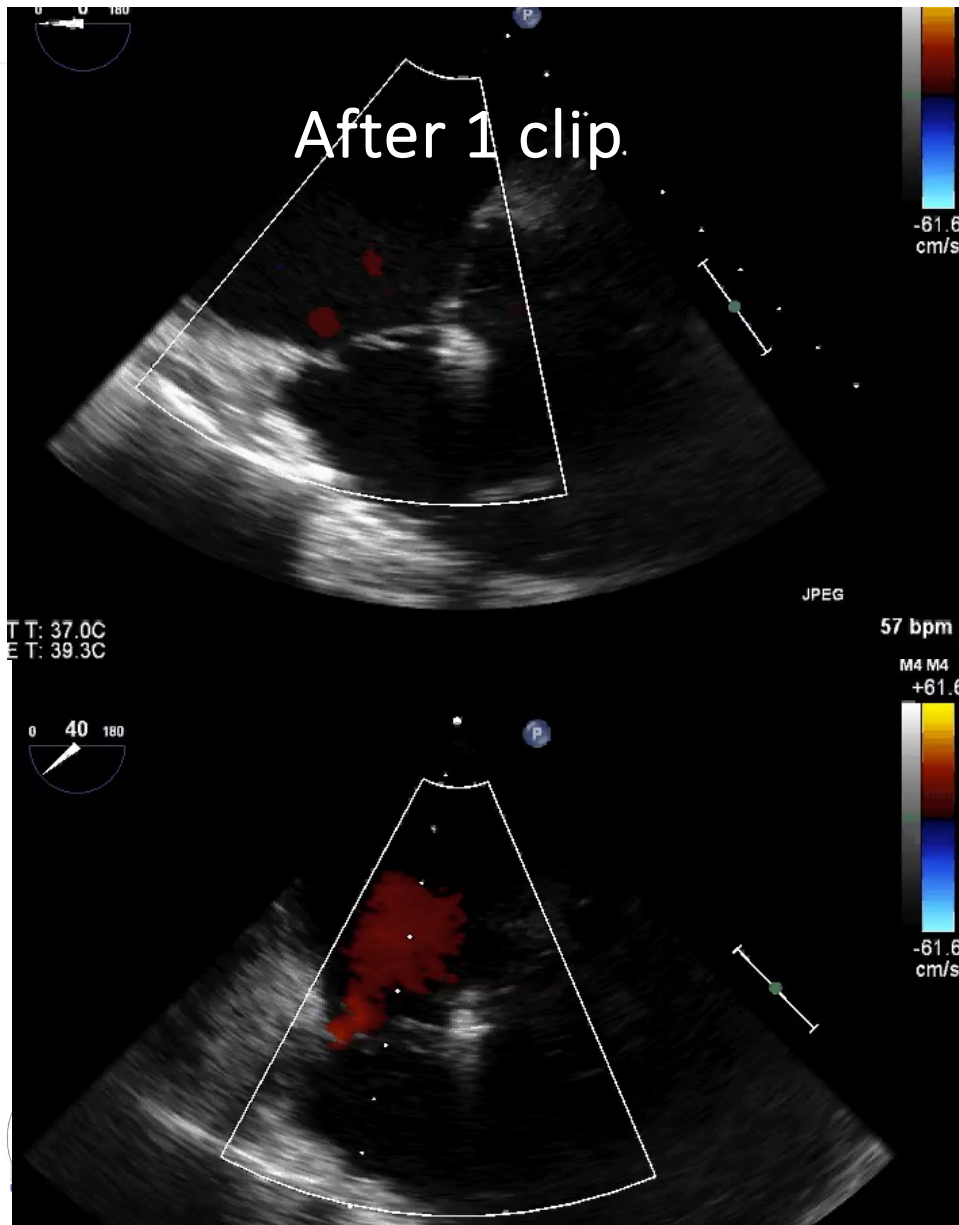
Edwards Pascal System



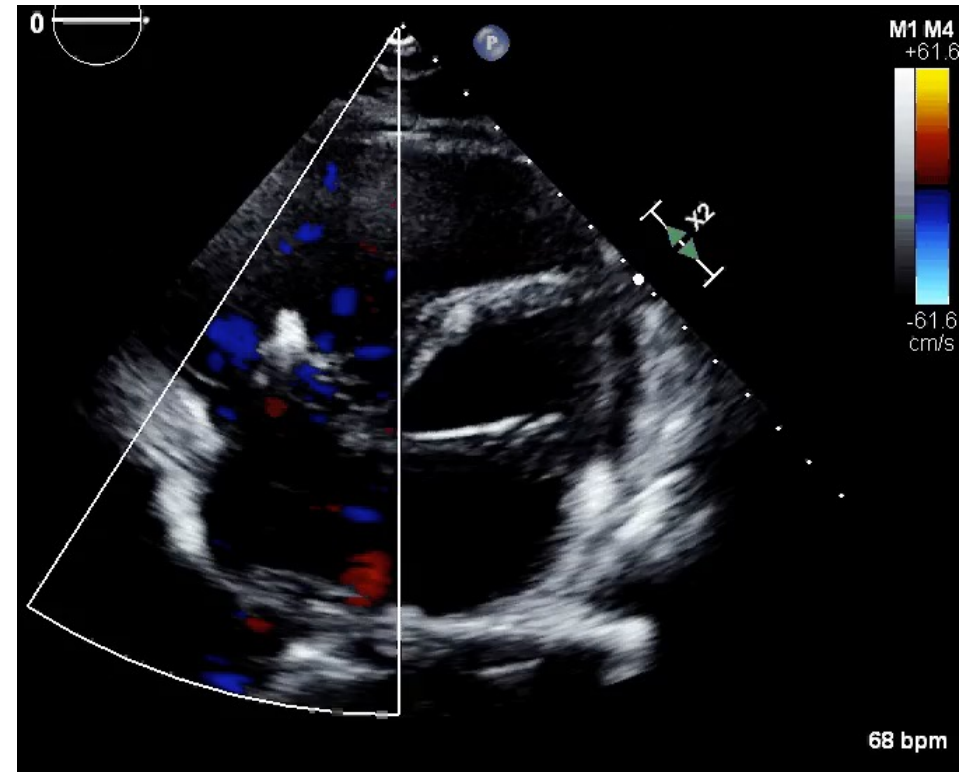
TriClip Case

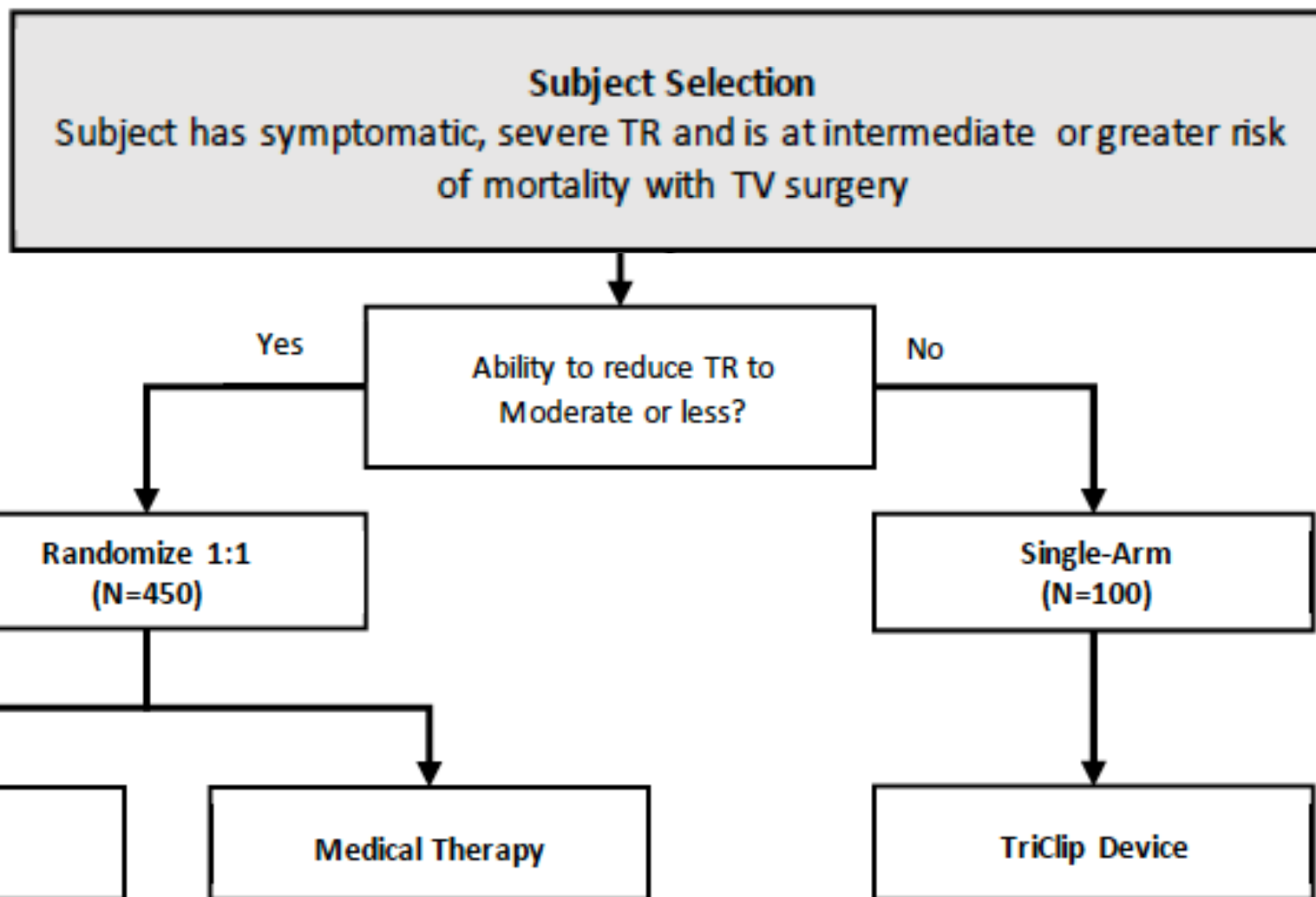
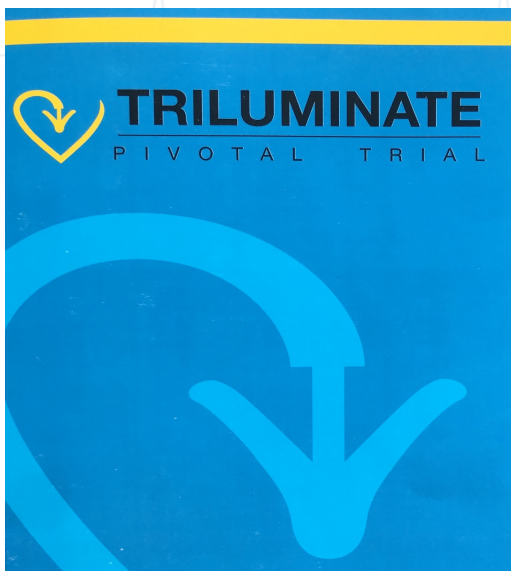
- 75 Male
- Inferior STEMI 2011 – PCI to RCA and LCx
- Further NSTEMI 2011 – CABG (LIMA to OM, RIMA to LAD, SVG to PDA)
- Atrial fibrillation, CVA
- Severe TR with recurrent admissions for heart failure





After 2 clips





Optimal medical therapy for the treatment of TR has not been well defined. Medical treatment primarily revolves around the use of diuretics; however, a proportion of patients continue to progress and suffer from the symptoms of TR. Current treatment options for TR are surgical



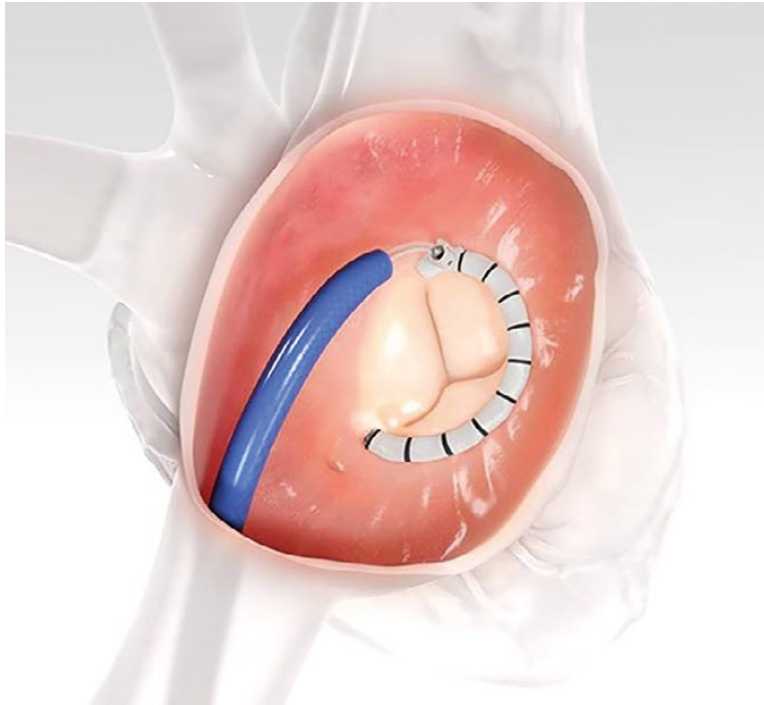
Limitations of TV TEER

- Presence of pacemaker or ICD leads
- Calcification in the grasping area
- Presence of a severe coaptation defect (> 2cm)
- Severe leaflet defect preventing proper device placement
- Ebstein Anomaly
- Poor TEE images
- Limited reduction of TR post clipping



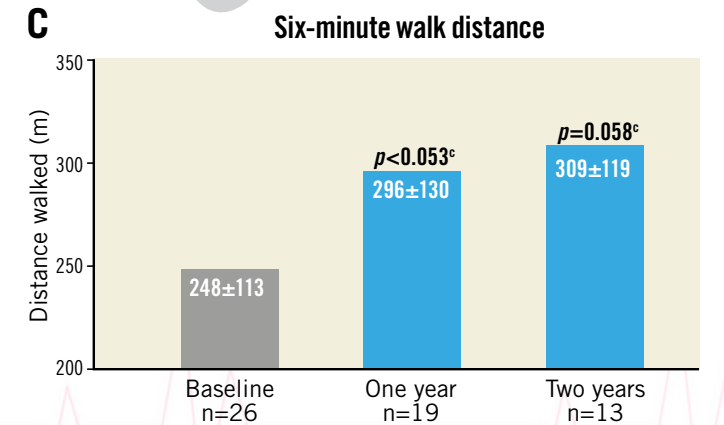
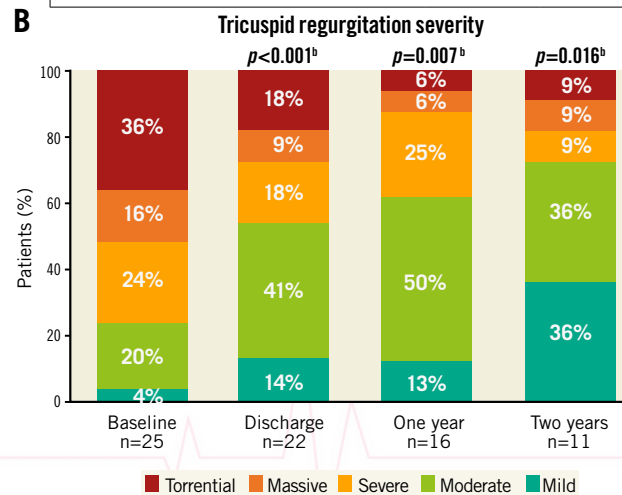
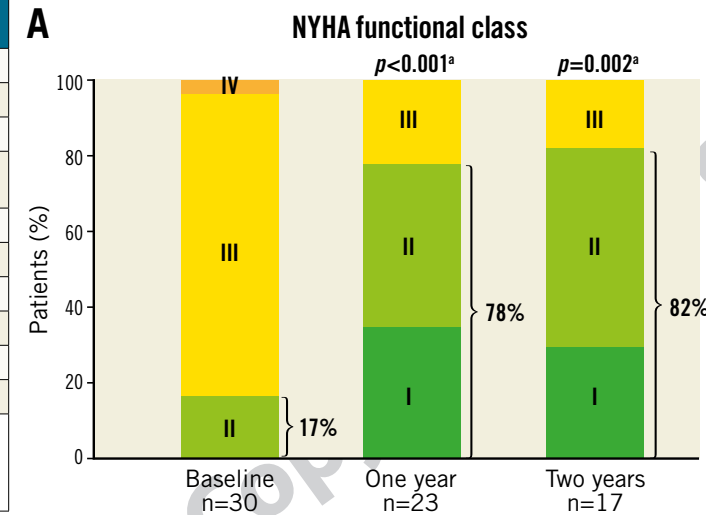
Tricuspid valve repair with the Cardioband system: two-year outcomes of the multicentre, prospective TRI-REPAIR study

Georg Nickenig¹*, MD; Marcel Weber¹, MD; Robert Schüler¹, MD; Jörg Hausleiter², MD;

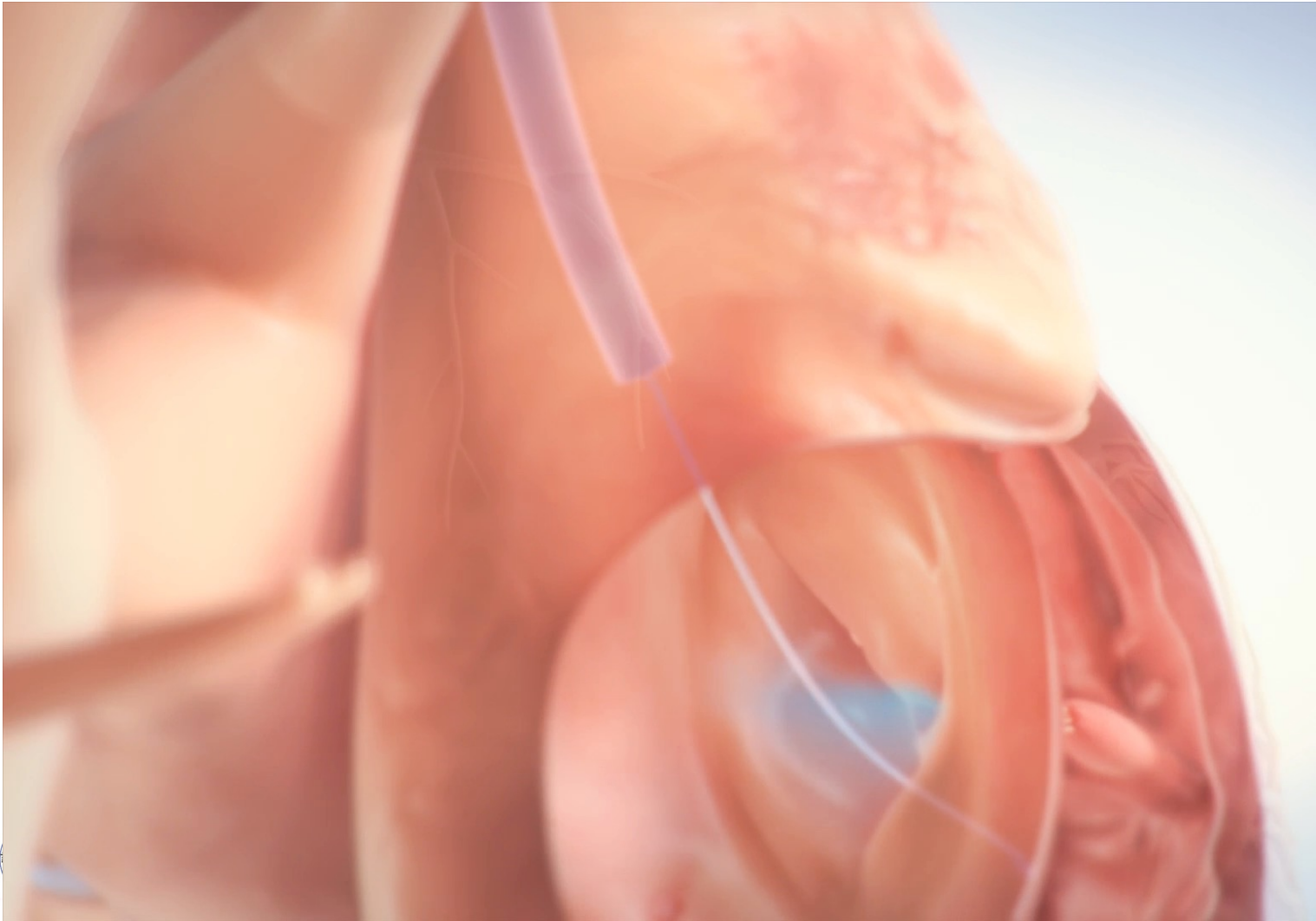


	One year n (%)	Two years n (%)
Death	5 (16.7) ^a	8 (26.7) ^a
Stroke	1 (3.3)	2 (6.7)
Myocardial infarction	0	0
Bleeding complications (extensive, life-threatening, or fatal) [*]	6 (20.0) ^b	7 (23.3)
Coronary complications	3 (10.0)	3 (10.0)
Device-related secondary intervention	1 (3.3) ^b	2 (6.7)
Device-related cardiac surgery	0	0
Renal failure ^c	1 (3.3)	1 (3.3)
Conduction system disturbance	1 (3.3)	2 (6.7)
Ventricular arrhythmia	3 (10.0)	3 (10.0)

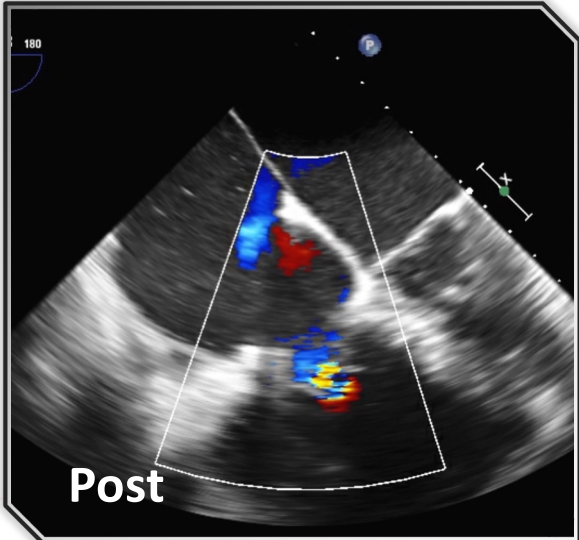
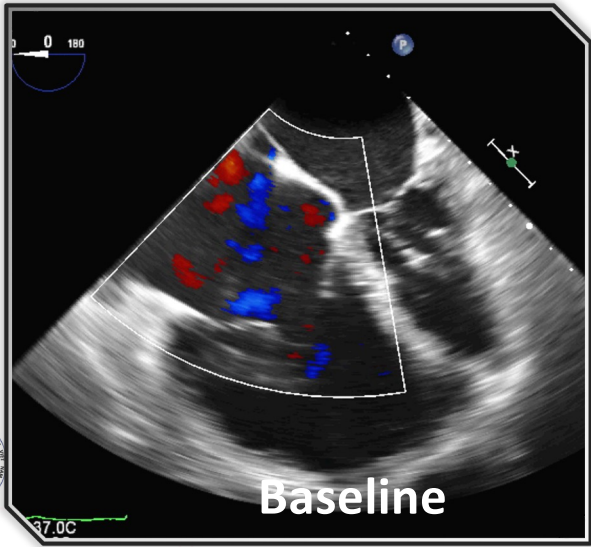
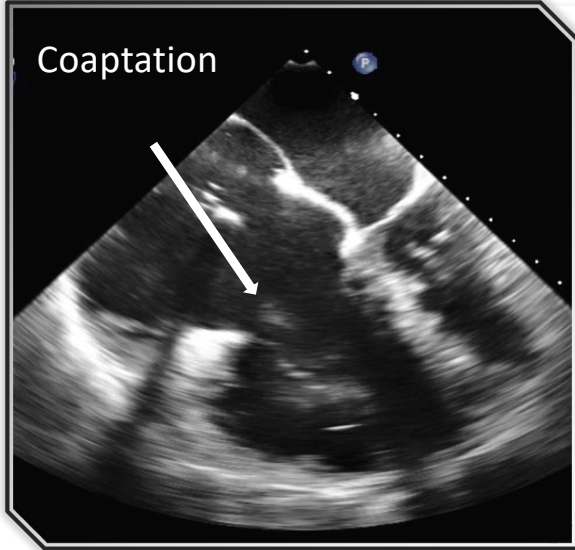
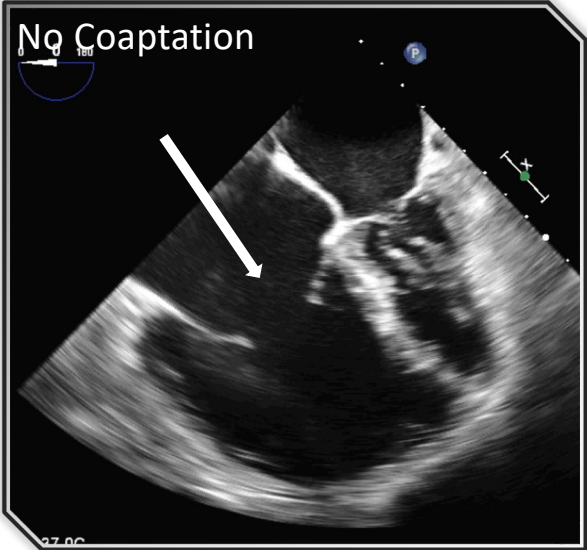
¹ CEC adjudicated. ^{*} Defined according to MVARC guidelines. ^c Occurrence in the first week post procedure and required haemodialysis. ^a None of the deaths between 30 days and two years were cardiovascular-related. ^b Patient experienced bleeding after secondary intervention.



Trialign Transcatheter Tricuspid Repair

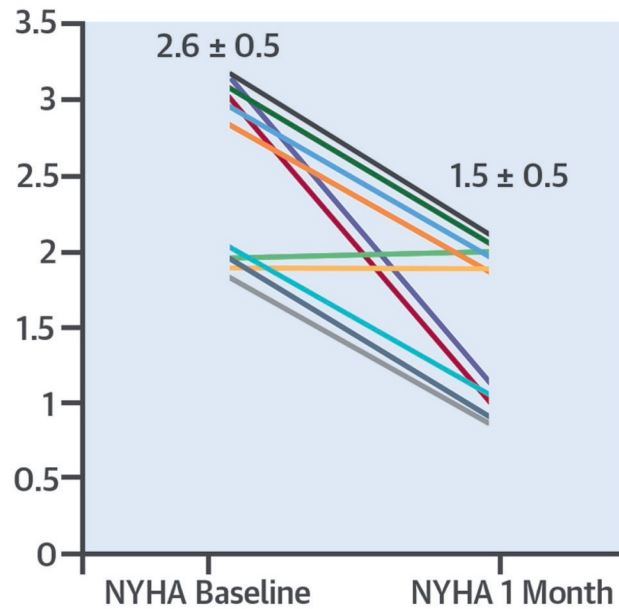


Trialign Procedure

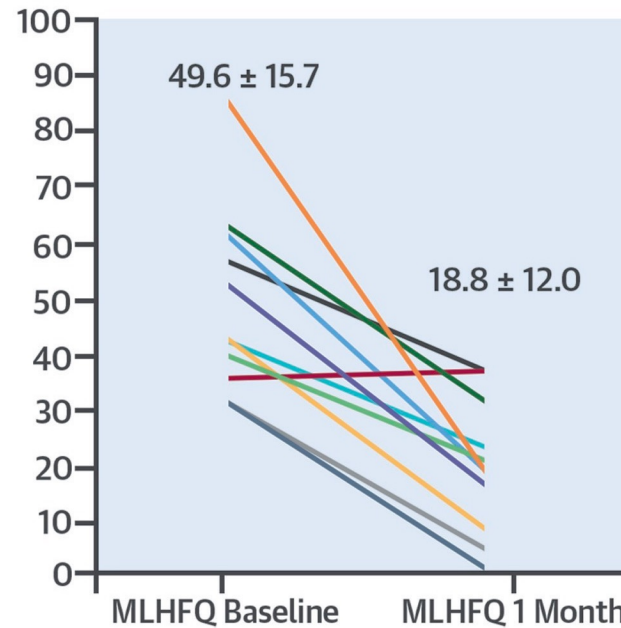


Early Feasibility Study of a Transcatheter Tricuspid Valve Annuloplasty: SCOUT Trial 30-Day Results

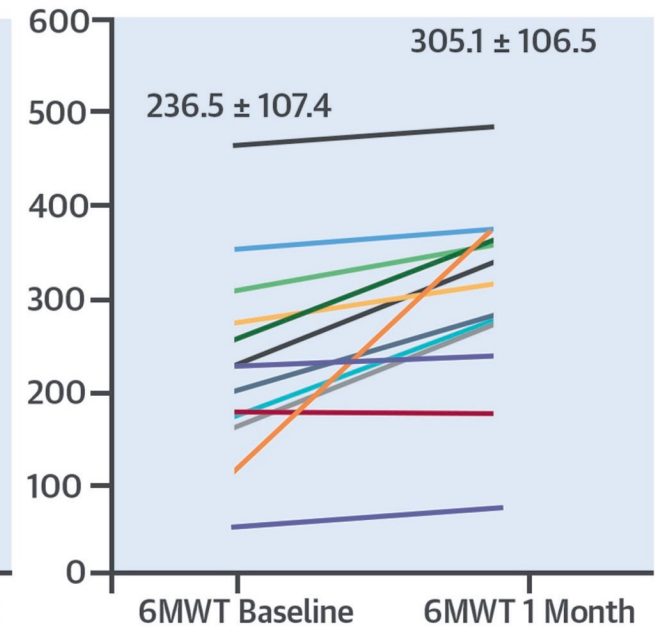
A. NYHA (AT)



B. MLHFQ (AT)



C. 6MWT (AT)



Hahn, R.T. et al. J Am Coll Cardiol. 2017;69(14):1795-806.



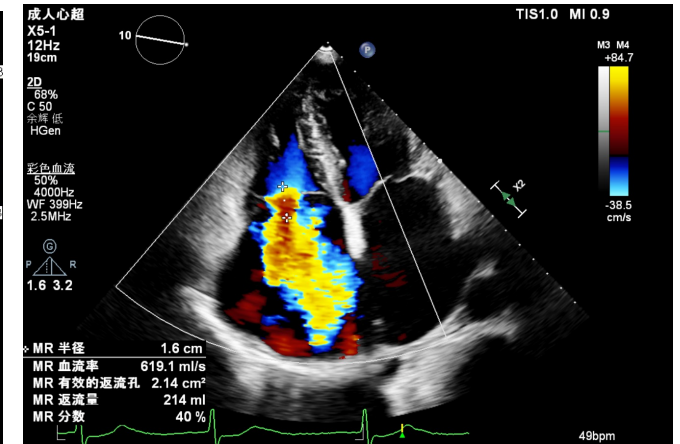
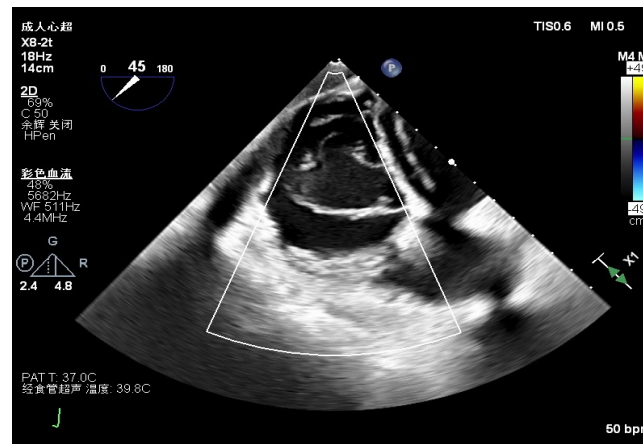
K-Clip[®]: A Novel Designed Annuloplasty Device



Clinical Case

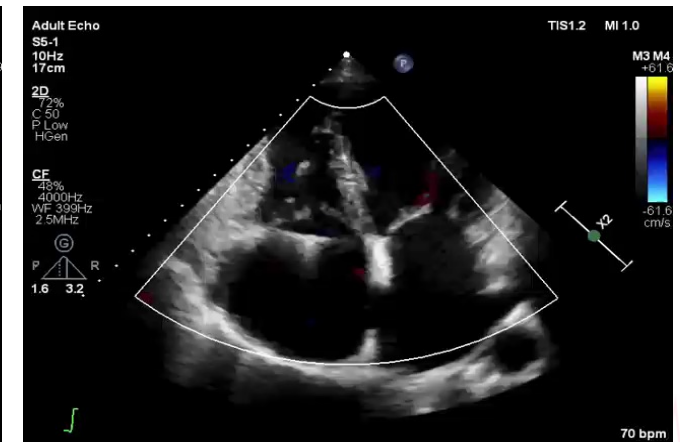
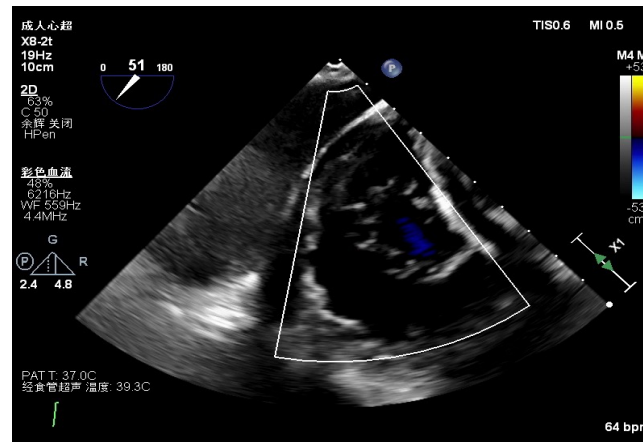
Preoperative Baseline

Vcw / mm	21
EROA / cm ²	2.2
RVol/ml	214
Annulus Area / cm ²	18.9



Postoperative Analysis

Vcw/mm	1
EROA / cm ²	0.05
RVol/ml	5
Annulus Area / cm ²	11.2



Baseline Characteristics, procedural and safety results

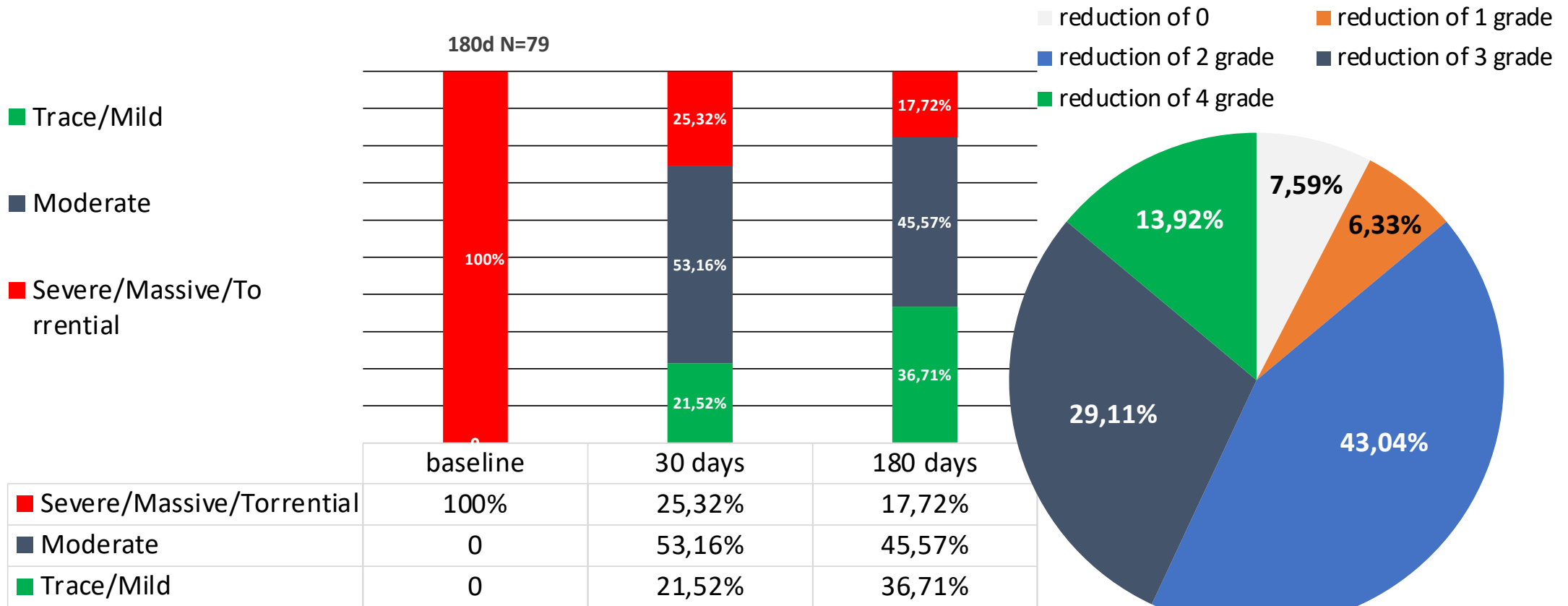
Characteristics	N=96
Age, mean (years)	72.53±4.5
Sex, female (%)	37(38.54)
EuroScore II, %	5.31±0.94
Etiology	100% FTR
NYHA III/IV (%)	68.75%
KCCQ Score	66.04±17.36
LVEF	61.93±6.77%

Variables	N=96
Device success(n,%)	94(97.91)
Operation time(min)	59.89±20.05
Fluoroscopic time(min)	23.84±8.17

Implanted Clips	N=94
1 Clip	51(54%)
2 Clips	40(43%)
3 Clips	3(3%)
Sum:140 Clips, Average: 1.49 Clips	

Endpoint (n,%)	30 Day (n=96)	6 months (n=96)
All-cause mortality	0	2.08%
CV death	0	2.08%
MACCE	1	4.17%

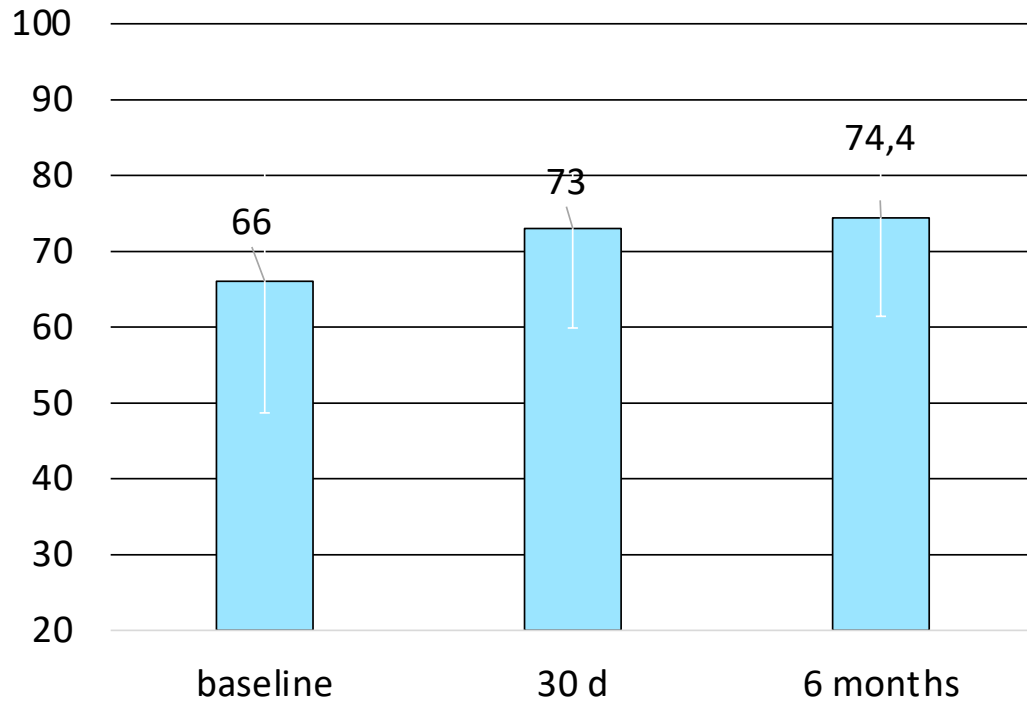
Efficacy Results of 180-day-Follow up



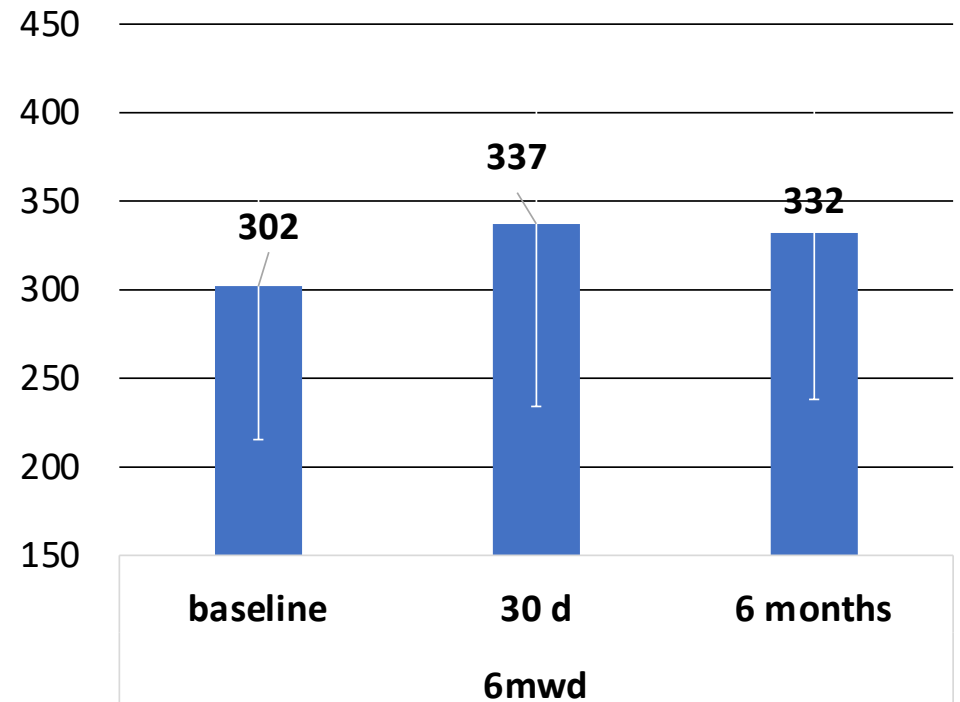
TCT - Oct. 2023 - Cheung

Functional and QoL results of 180-day-Follow up

KCCQ



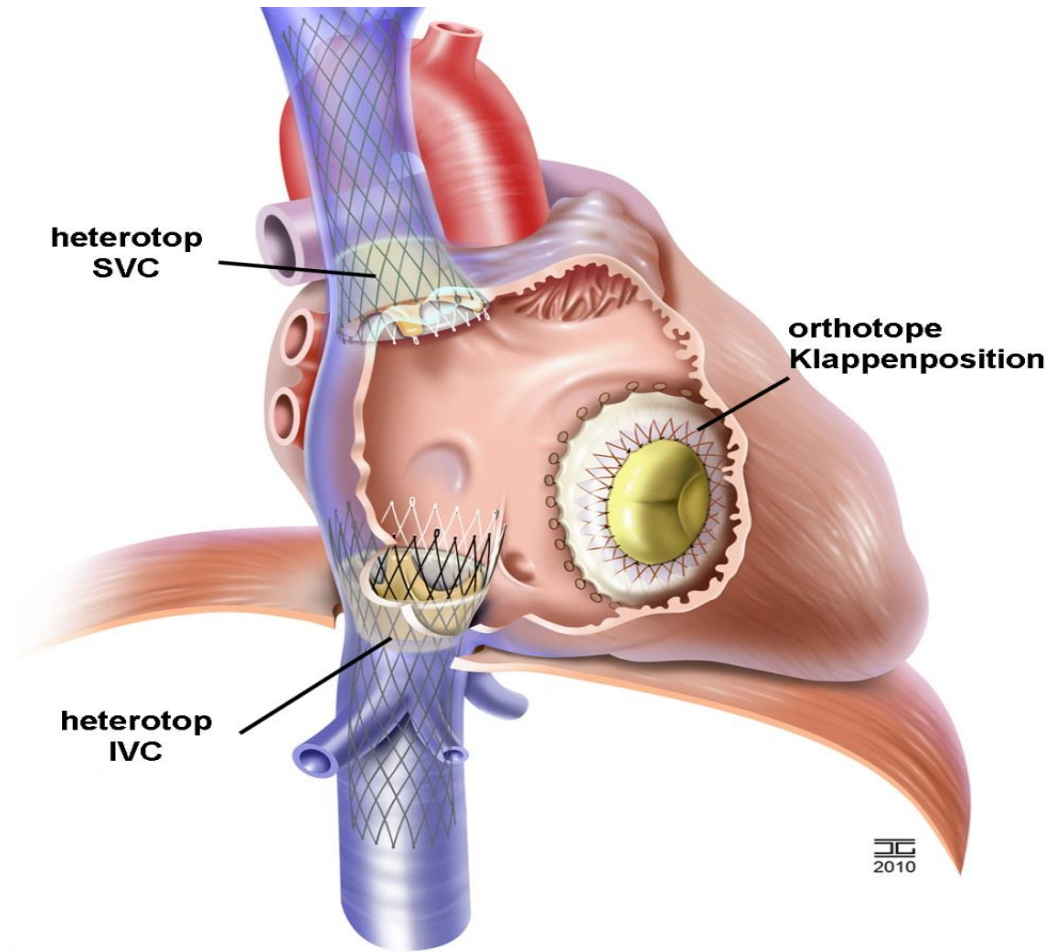
6mwd



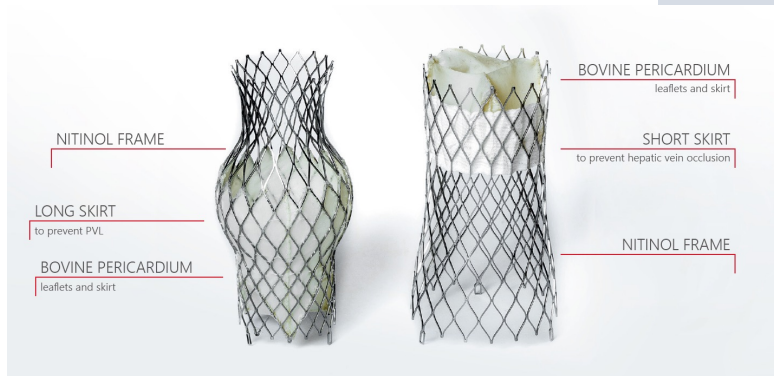
TCT - Oct. 2023 - Cheung



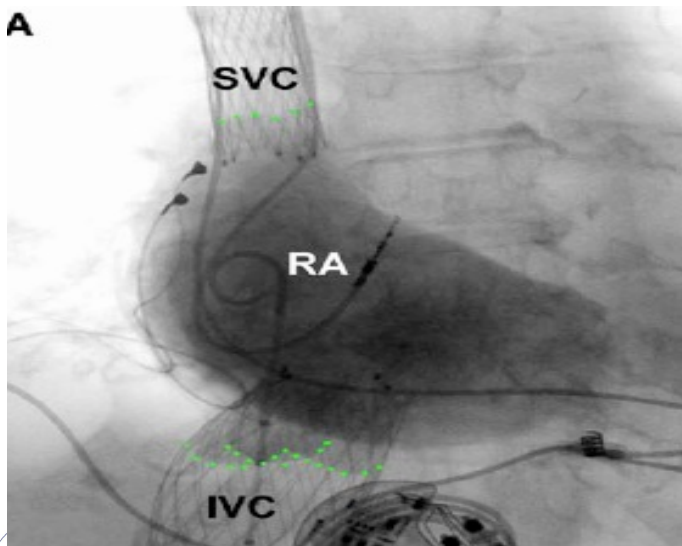
Transcatheter Valve implantation for TR



TricValve



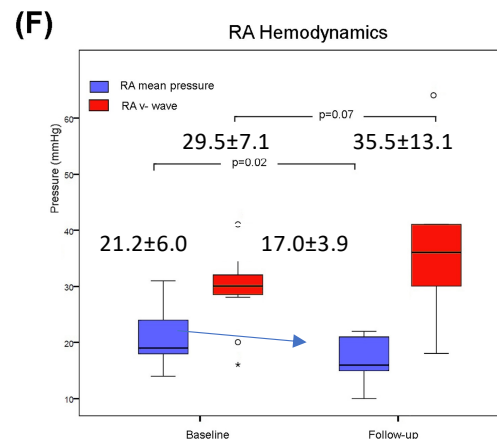
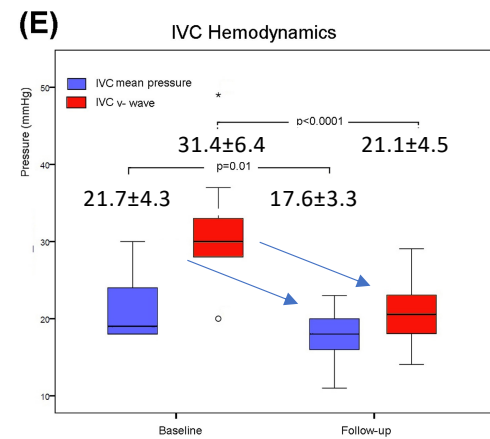
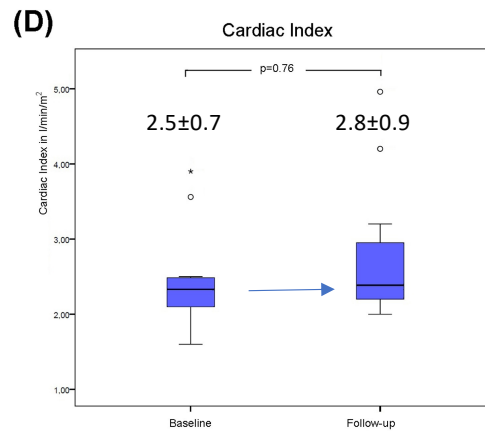
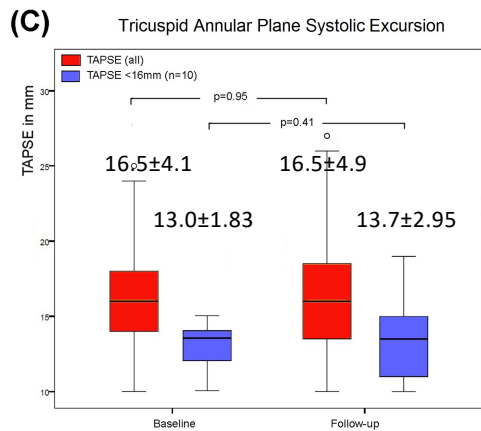
- Patients with hemodynamically relevant tricuspid insufficiency and caval reflux who are high surgical risk
- Two self-expanding biological valves SVC and IVC
- Does not disturb the native tricuspid valve



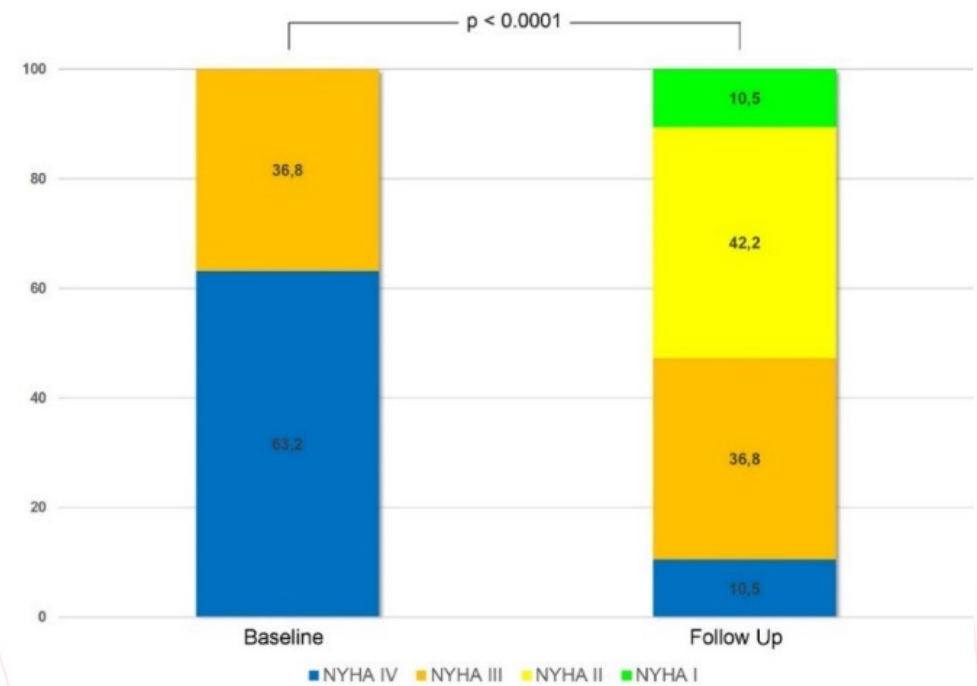
TRICVALVE® MODEL	VALVE SIZE	PROXIMAL DIAMETER	DISTAL DIAMETER	LENGTH AFTER DEPLOYMENT
SVC 25	25	25	20	66,60
SVC 29	29	29	20	69,10
IVC 31	31	34	38	65
IVC 35	35	38	47	65

Results

- FIM CAVI 08/2010 - Inclusion 08/2010 – 02/2017, 7 centers (6 in Germany, 1 in Canada)
- 100% compassionate cases („last resort“, non-randomized treatment with ethical consent)



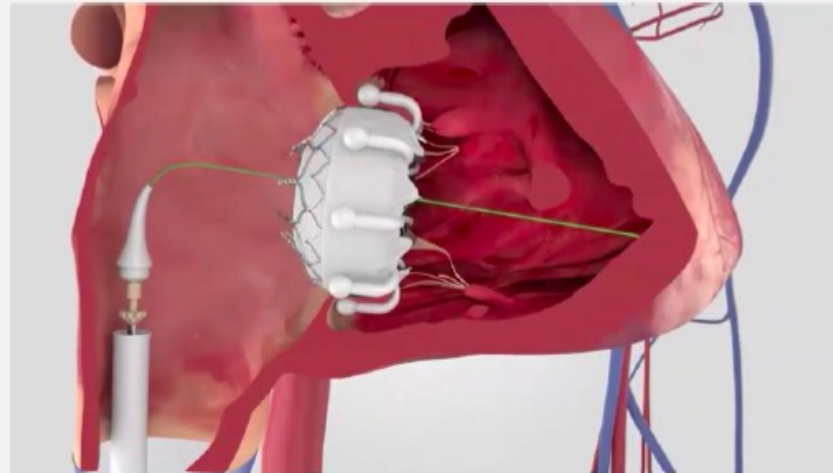
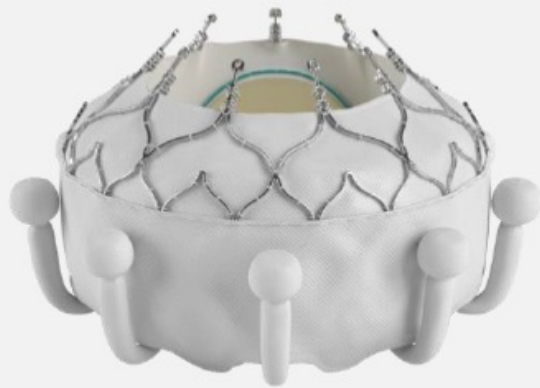
NYHA-Class Baseline vs. Discharge



EVOQUE Tricuspid Valve Replacement System

EVOQUE CU

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



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

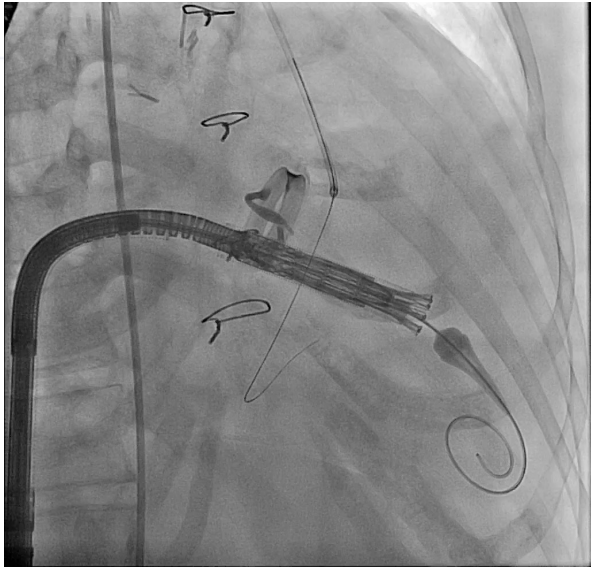
Conforming frame designed to achieve optimal retention force

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

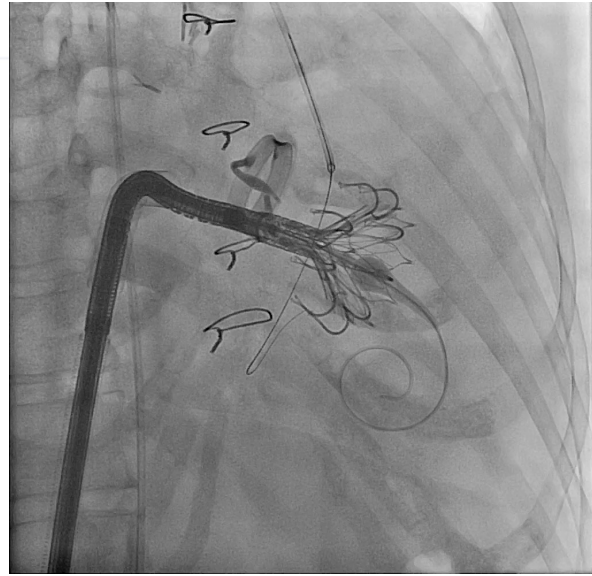
28F transfemoral delivery system with multiple planes of flexion and depth control

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

CRF
TVT
THE
STRUCTURAL
HEART
SUMMIT



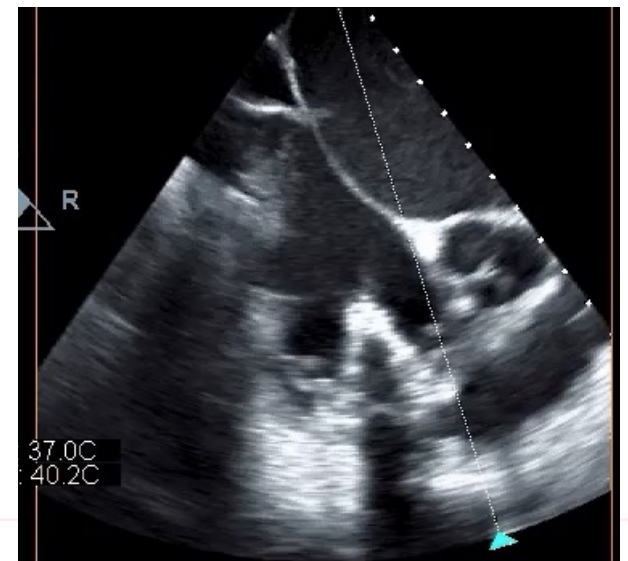
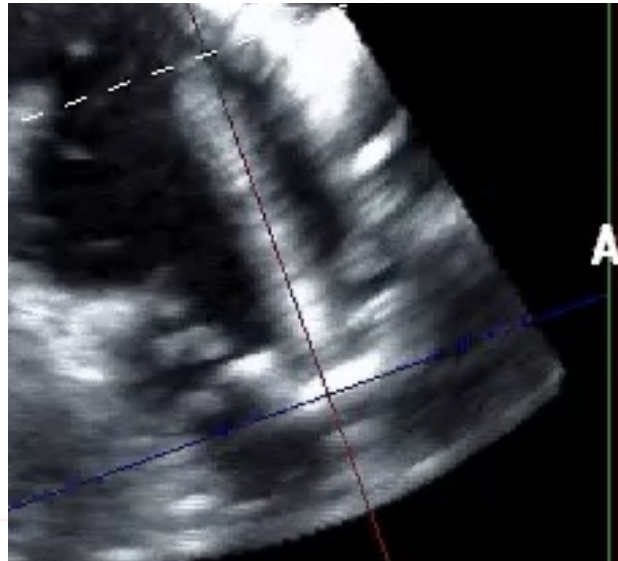
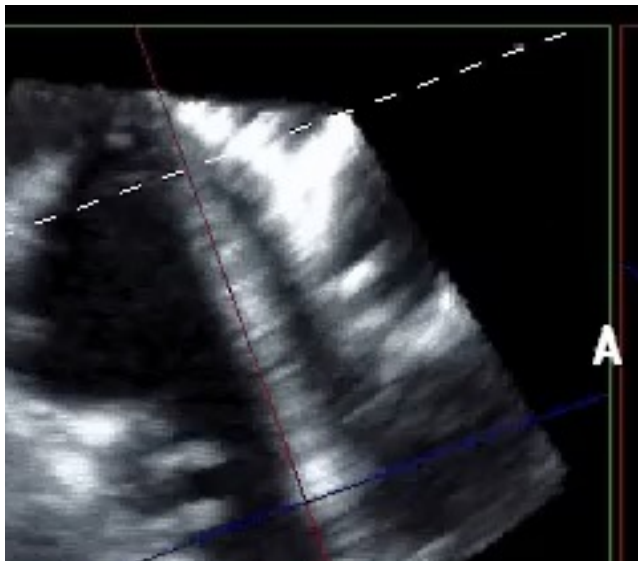
Exposed in LV

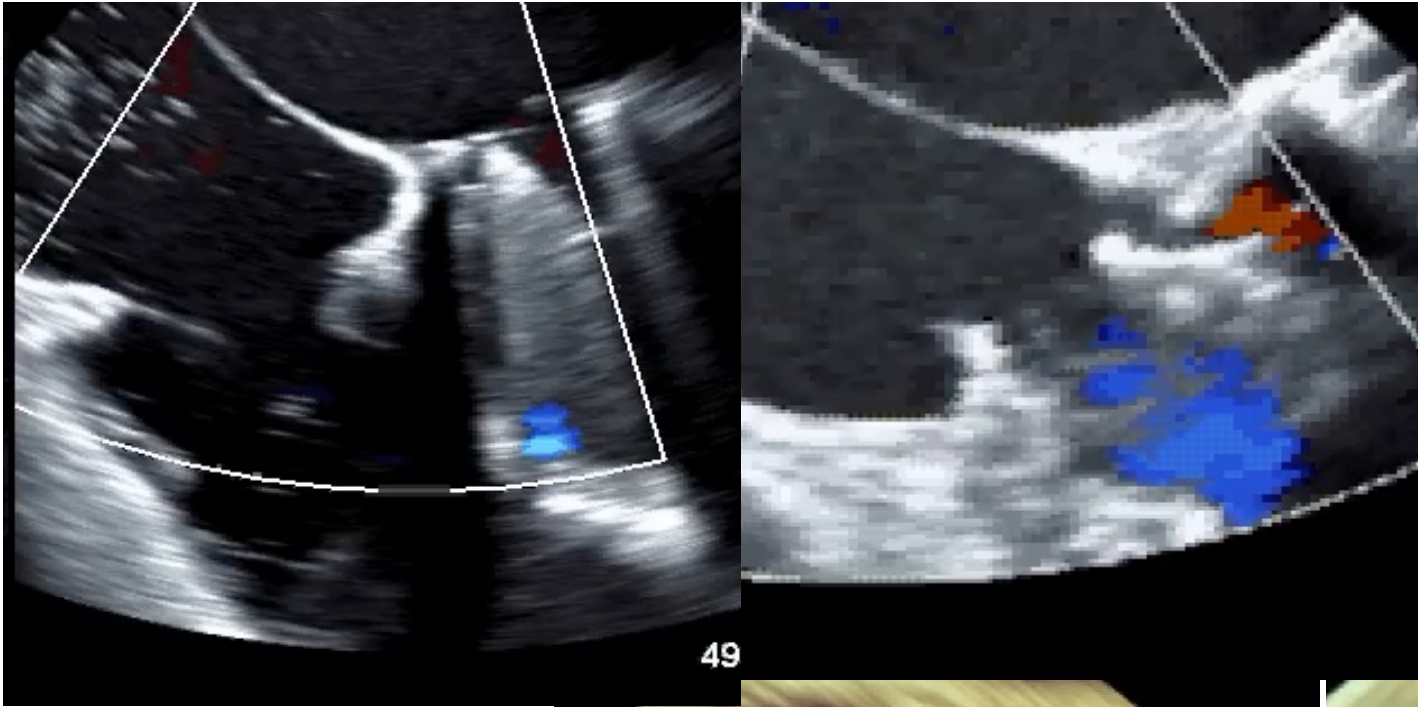


Grasping

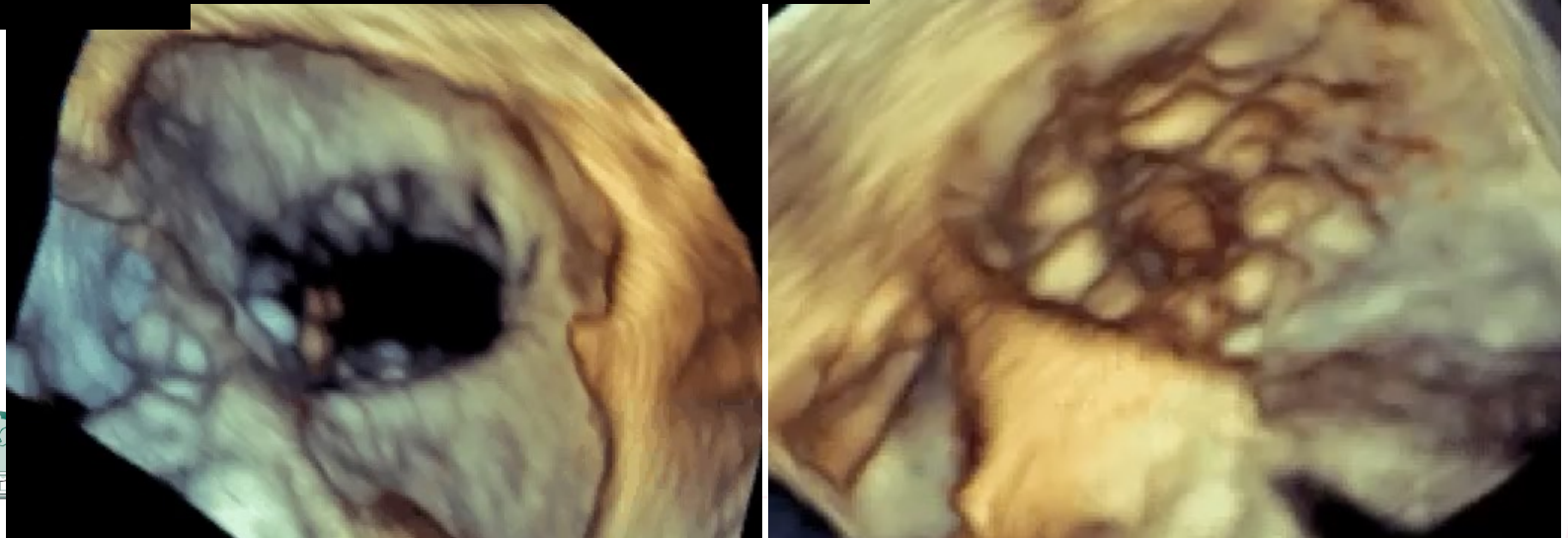


Leaflet capture





49



Clinical outcomes

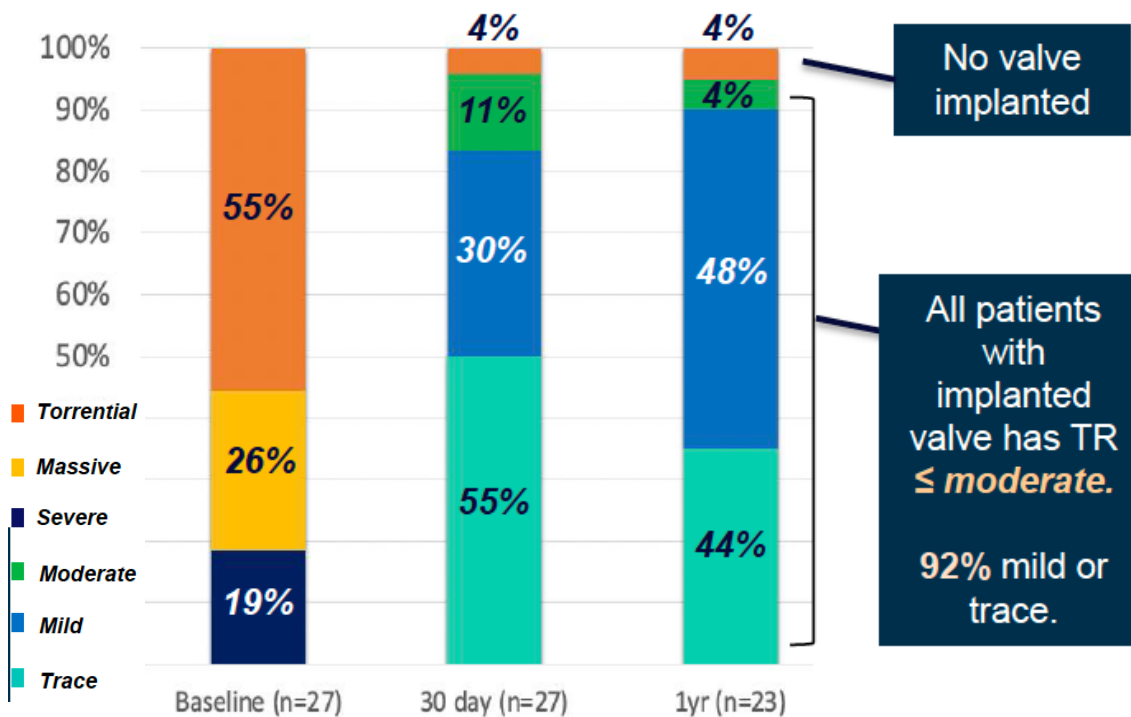
30 day	N (%) or Mean \pm SD
Procedural success ¹	25 (93%)
Procedural time (skin-skin) (mins, mean/min/max)	68 (37, 101)
Mortality	0 (0%)
Stroke	0 (0%)
Reintervention	0 (0%)
HF hospitalization	0 (0%)
Dialysis requirement	1 (4%)
Anticoagulation	25 (93%)
New PPM	2 (8%)

30 day to 1 year	N (%) or Mean \pm SD
Mortality	2 (7%)
Valve-related mortality	0 (0%)
Stroke	0 (0%)
Re-intervention	0 (0%)
HF Hospitalization	2 (7%)
Dialysis requirement	0 (0%)
New PPM	1 (4%)
HALT	3 (12%)

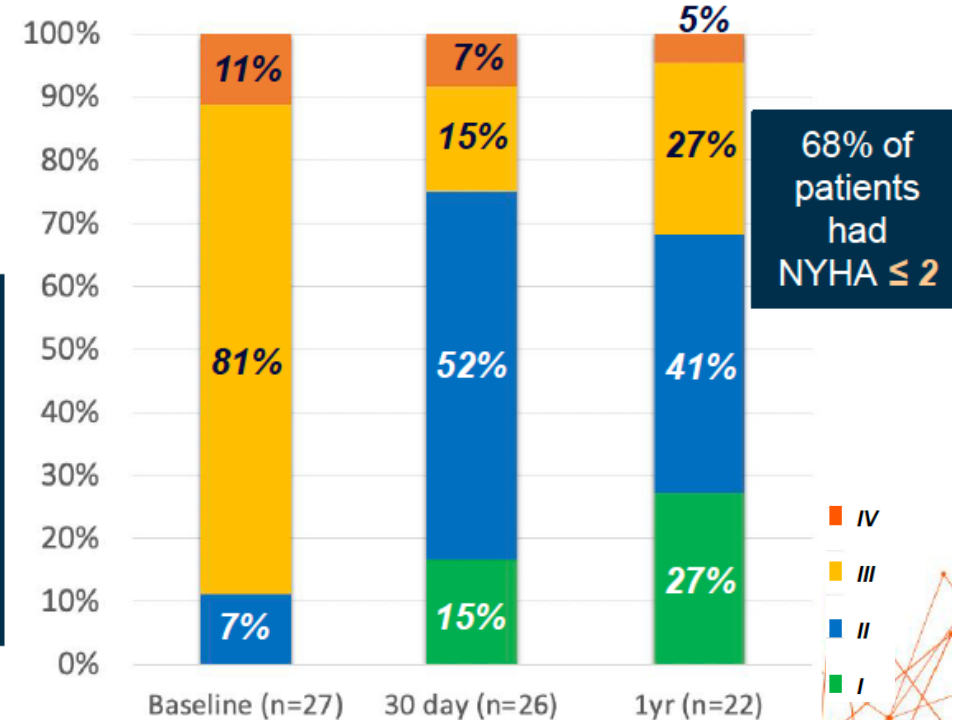
¹Defined as ability to deliver and deploy the valve to the intended location with the absence of major device or procedural related serious adverse events
Fam NP, Webb JG et al. Transfemoral Transcatheter Tricuspid Valve Replacement With the EVOQUE System: A Multicenter, Observational, First-in-Human Experience. JACC Cardiovasc Interv. 2021 Mar 8;14(5):501-511.

Echocardiographic and clinical outcomes

TR Severity

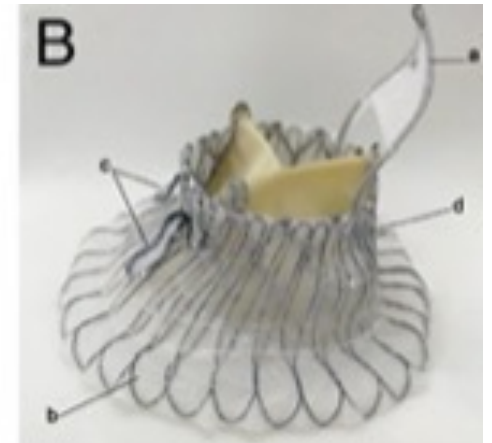
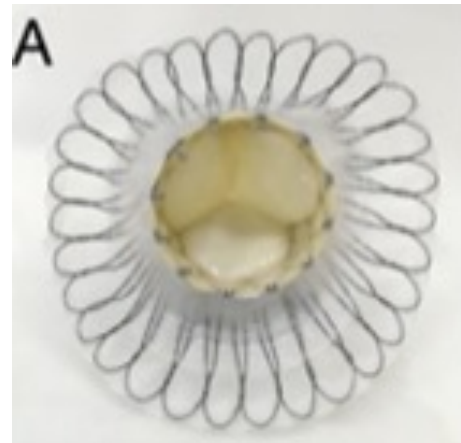


NYHA Functional Class

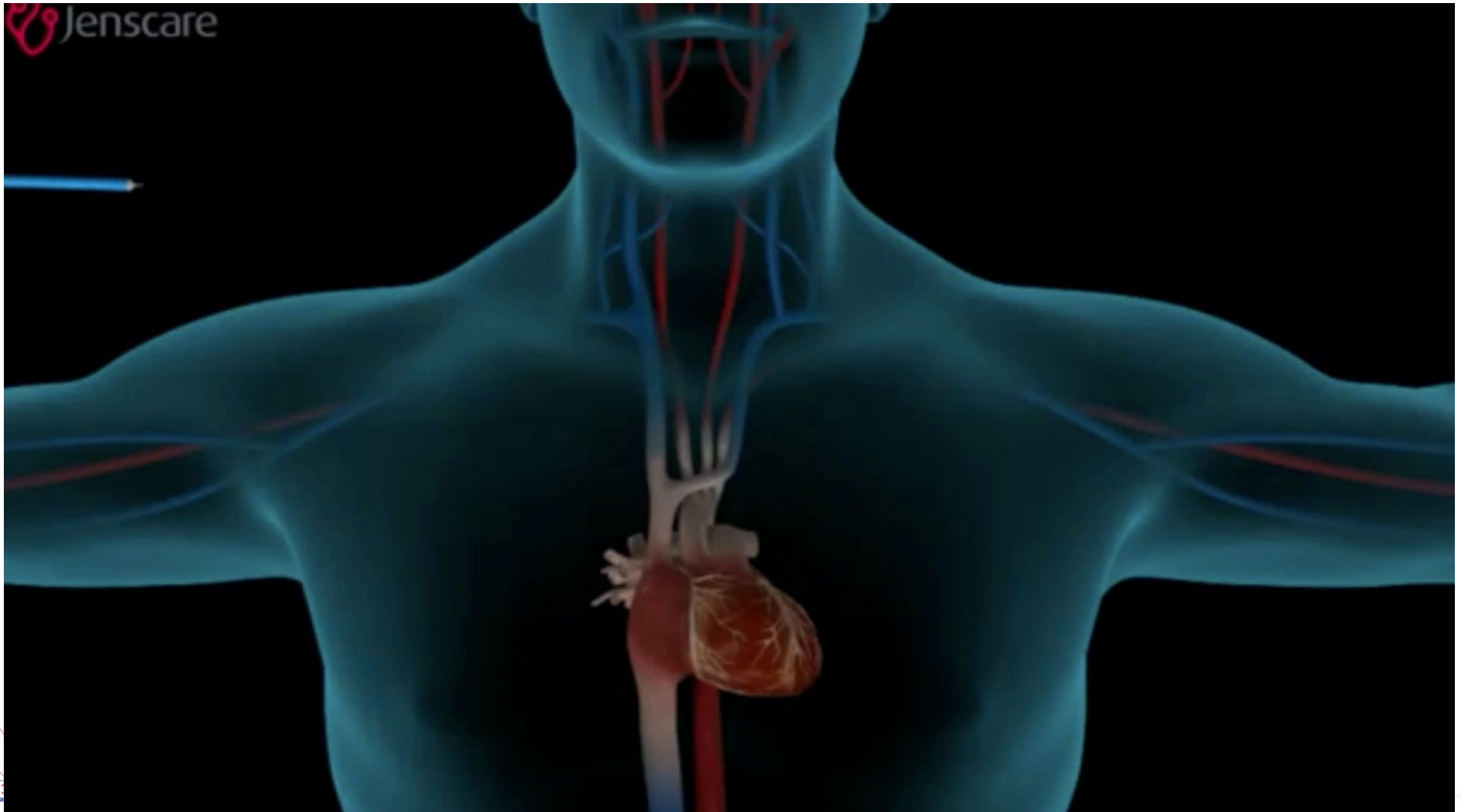


Jenscare Transjugular LuX Tricuspid Valve Implant System

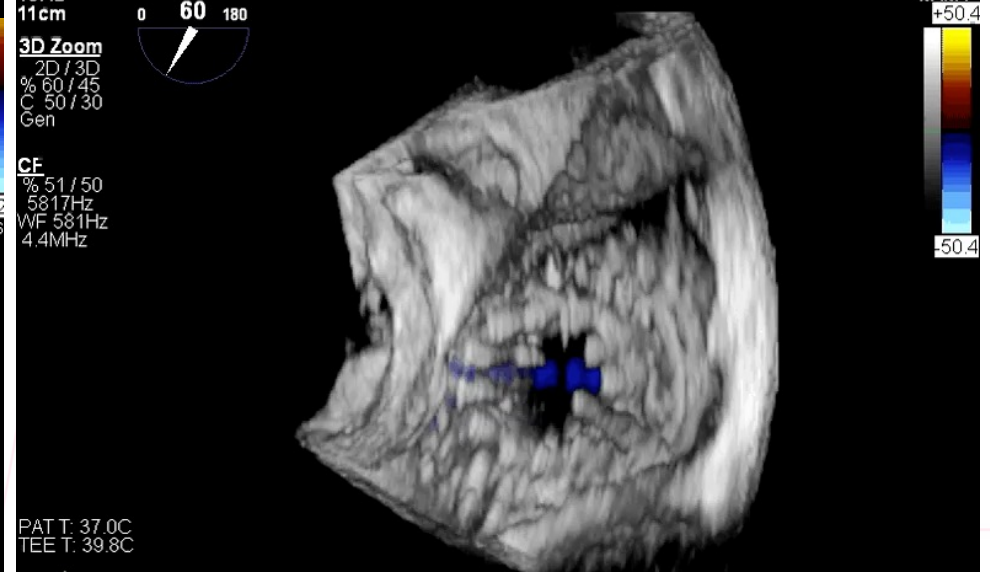
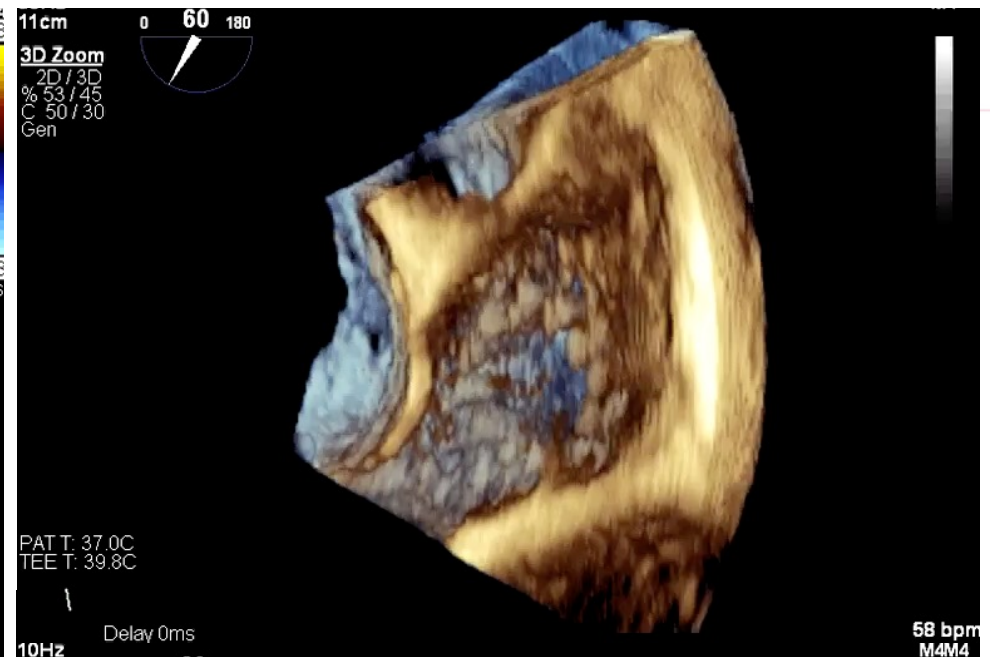
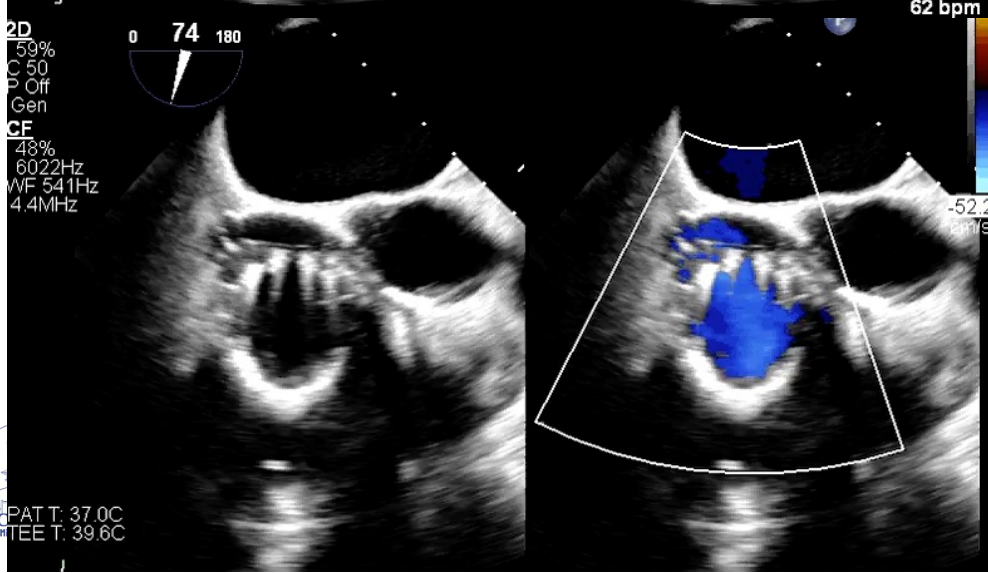
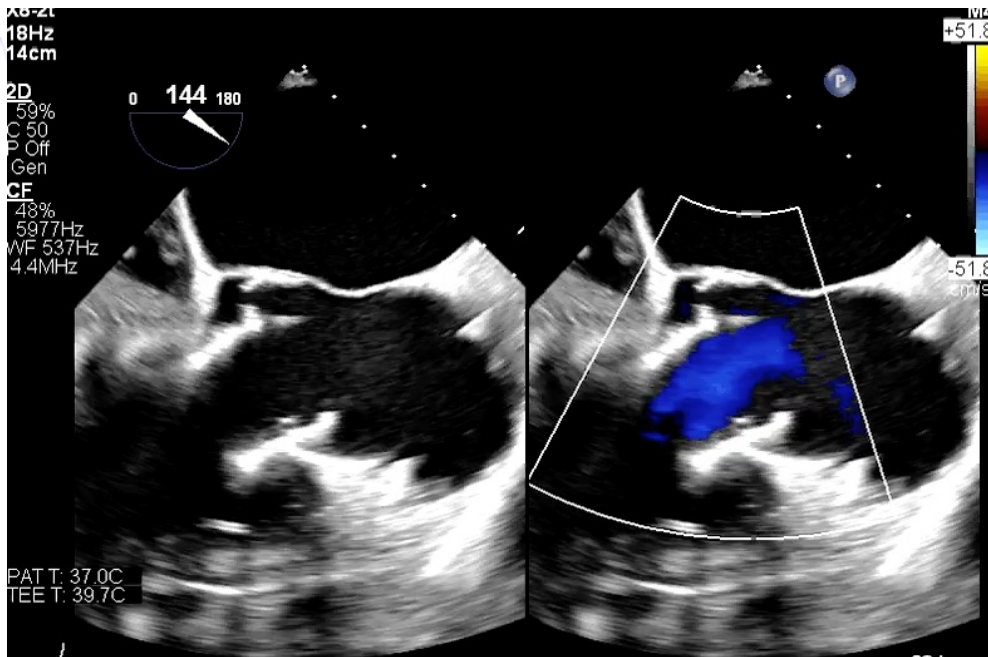
- Nitinol, self expanding tri-leaflets valve
- Anchoring with 2 subannular tabs (ant and post) and a septal anchor
- Multi-plane steerable 32F transjugular delivery catheter
- TEE and fluoroscopic guidance
- No pacing required for implant
- 6 valve sizes (mean annular - 35 - 65mm)



Transjugular LuX TTVR System







N=96 % or mean±SD	
Age	71.35±8.77
Female	71.88%
TR grade	
Severe	38.54%
Massive	27.08%
Torrential	34.38%
NYHA III-IV	100%
Prior left heart valve surgery/intervention	49.51%
Pacemaker/ ICD	
Atrial fibrillation	83.52%
Ascites	8.89%
Stroke	3.30%
mPAP (mmHg)	20.19±6.85
TAPSE (mm)	17.91±3.68
RVFAC (%)	46.42±8.70
LVEF (%)	63.22±6.49
6 MWT (m)	309.91±95.70

N=96 % or mean±SD	
Aetiology	
Primary	13.54%
Secondary	86.46%
Surgery Risk Assessment	
STS score (MV replacement), %	9.09±4.06
EuroScore II, %	4.46±5.57
CRS score	7.51±1.58
Acute clinical outcomes (FAS= 96)	
Device success	98.91%
Procedure success	98.91%
Device time (min)	35.56±20.82



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Clinical outcomes at 30 days



CEC-adjudicated Composite Events	30 days
	N = 93*
All-cause Death	1 (1.08%)
Myocardial Infarction	0 (0.00%)
Stroke	0 (0.00%)
Conversion to surgical tricuspid valve replacement or tricuspid valvuloplasty	0 (0.00%)
New onset III°AVB requiring permanent pacemaker implantation	1 (1.04%)
Requirement of ECMO or IABP	0 (0.00%)
Long-term Mechanical Ventilation (>72 hours)	0 (0.00%)
Acute Renal Failure	1 (1.04%)
Acute Liver Failure	1 (1.04%)
Severe Perivalvar Leakage	1 (1.08%)
Cardiovascular Injury Requiring surgical intervention (heart perforation, vascular injury)	0 (0.00%)
Life-threatening Massive Bleeding	0 (0.00%)
Composite event rate	4 (4.30%)

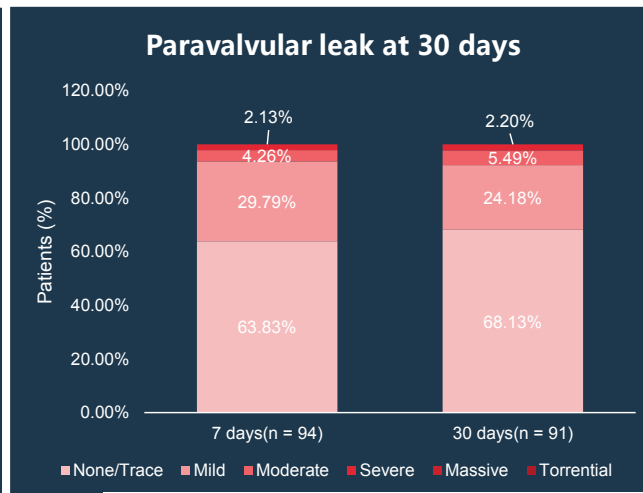
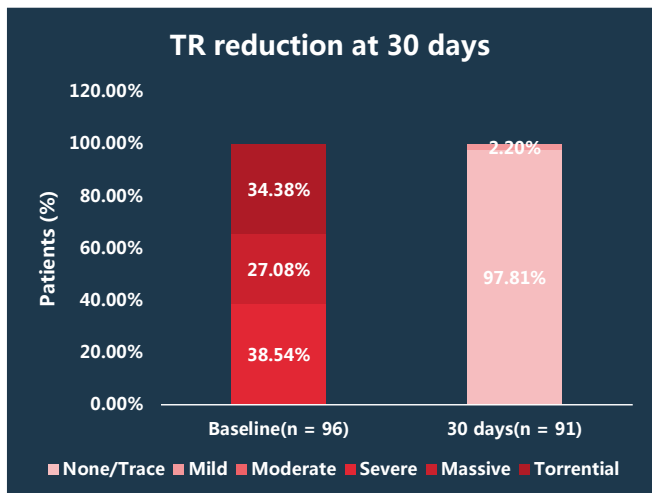
* 2 patients refused follow-up after discharge, and 1 patient met the exclusion criteria.

Clinical outcomes at 30 days

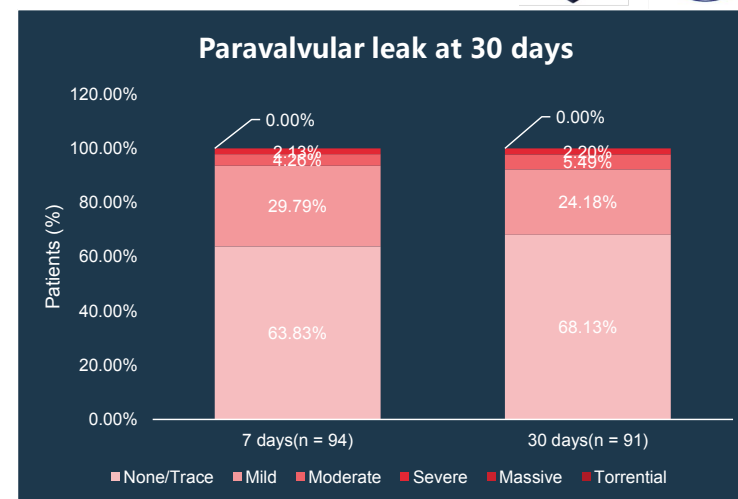
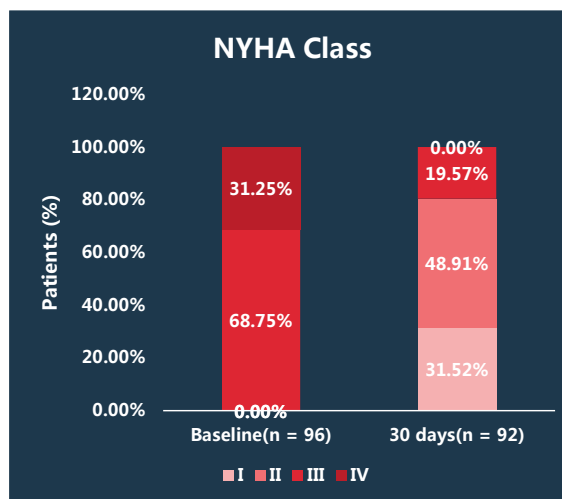


CEC-adjudicated MAEs	30 days N = 96
➤ III°AVB or requiring permanent pacemaker	2 (2.08%)
➤ Severe ventricular arrhythmias	0 (0.00%)
➤ Pulmonary infarction	0 (0.00%)
➤ Renal failure	1 (1.04%)
➤ Respiratory failure	0 (0.00%)
➤ Liver failure	0 (0.00%)
➤ Myocardial infarction	0 (0.00%)
➤ Right cardiac perforation or septal perforation	0 (0.00%)
➤ Thoracic bleeding	0 (0.00%)
➤ Intra-operational conversion to surgical tricuspid valve replacement or tricuspid valvuloplasty	1 (1.04%)
➤ Endocarditis	0 (0.00%)
➤ Stroke	0 (0.00%)
➤ Injury of blood vessel	0 (0.00%)
➤ Device related complications	0 (0.00%)
➤ Valve prosthesis dislocation	0 (0.00%)
➤ Perivalvular leak	2 (2.08%)
➤ Valve stent fracture	0 (0.00%)
Composite MAE rate	5 (5.21%)

Echocardiographic asseesment at 30 days



Clinical, functional and quality-of-life changes from baseline to 30 days





Conclusions

- High prevalence of TR
- TR is not a benign disease, associated with significant morbidities and mortality
- Isolated TR surgery may be beneficial if performed earlier
- Unmet need for less invasive therapy for TR
- Transcatheter tricuspid repair/replacement are good option for high-risk surgical candidate

