

Transcatheter Tricuspid Technologies

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Tricuspid Valve "The Forgotten Valve"

Conservative Management of Tricuspid Regurgitation in Patients Undergoing Mitral Valve Replacement

By NINA S. BRAUNWALD, M.D., JOHN ROSS, JR., M.D., AND
ANDREW G. MORROW, M.D.

A SIGNIFICANT proportion of patients with severe, acquired mitral valvular disease also have physical findings and hemodynamic evidence of associated tricuspid regurgitation.¹ Indeed, in many such patients the principal symptoms are attributable to tricuspid regurgitation, rather than to elevated pulmonary venous pressure or reduced cardiac output. Therefore, when operative correction of the mitral malformation becomes necessary in a patient with severe associated tricuspid regurgitation, the important question arises as to whether a concomitant operation on the tricuspid valve is advisable. When the tricuspid valve has been the site of acute rheumatic valvulitis, regurgitation usually results from anatomical deformities of the valve leaflets and their supporting structures. When such a deformed valve is responsible for severe tricuspid regurgitation, it has been the experience of most surgeons that symptoms will persist unless effective function is restored, and almost invariably replacement of the tricuspid valve rather than a reconstructive operation is required.^{2,3} In many patients with mitral valve disease and associated tricuspid regurgitation, however, the tricuspid valve has no functionally significant anatomical abnormality, and regurgitation is the result of right ventricular hypertension and dilatation of the tricuspid annulus. The optimal management of patients with this functional form of tricuspid regurgitation is less well defined since little objective information has been available concerning the course of tricuspid regurgitation after effective correction of mi-

tral stenosis or regurgitation. Such information is provided by the present report, which describes the results of appropriate preoperative and postoperative clinical and hemodynamic assessments in 28 patients with mitral valve disease and tricuspid regurgitation in whom mitral valve replacement was performed.

Patients Studied

The 28 patients, who ranged in age from 15 to 34 years, were selected for study from a consecutive series of 100 patients in whom isolated mitral valve replacement was performed. The preoperative and operative findings were those of pure or predominant mitral stenosis in seven patients and pure or predominant mitral regurgitation in 21. In addition, every patient manifested characteristic clinical and hemodynamic evidence of severe tricuspid regurgitation. Patients with hemodynamic evidence of tricuspid stenosis as well as regurgitation were excluded from the analysis, as were patients in whom the diagnosis of tricuspid regurgitation could not be established by the criteria outlined below.

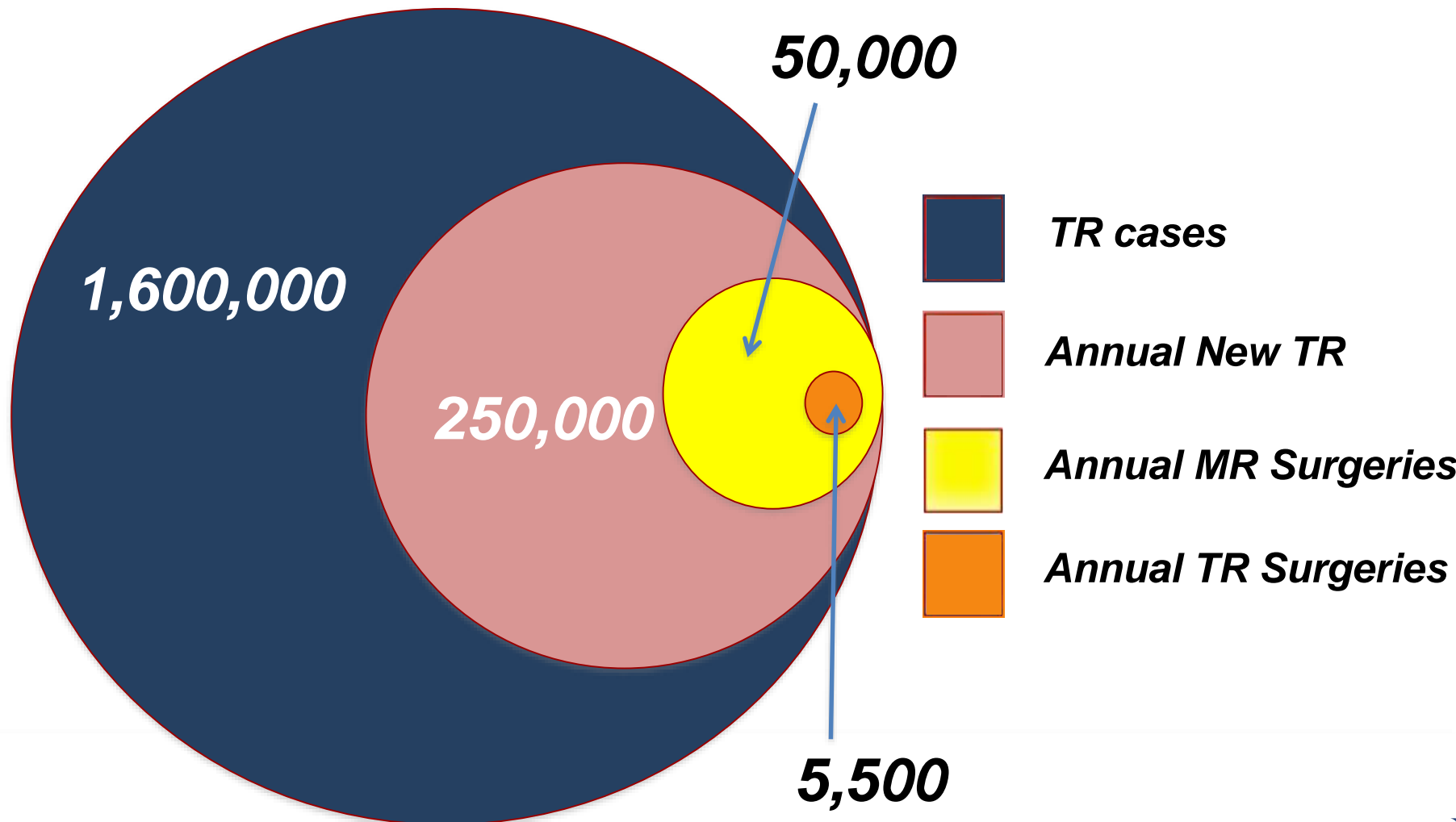
On admission 11 patients were considered in functional class III and 17 in class IV (New York Heart Association). A pansystolic murmur, which varied with respiration, was audible over the lower sternum in 27 of the 28 patients; distended neck veins and prominent v waves in the jugular venous pulse were evident in 25; in 27 patients the liver was enlarged two fingerbreadths or more below the costal margin and was pulsatile; 14 had peripheral edema and seven abdominal ascites. Six patients in the group had the triad of peripheral edema, ascites, and gross hepatomegaly. All of the physical findings list-

In 1967, Braunwald et al advised a conservative approach to TR. *“The present results indicate that in such patients [functional TR in patients with mitral valve disease] tricuspid regurgitation will improve or disappear after mitral replacement and that tricuspid valve replacement is seldom necessary.”*

From the Clinic of Surgery and Cardiology Branch, National Heart Institute, Bethesda, Maryland.

Supplement 1 to *Circulation*, Vol. XXXV and XXXVI, April, 1967

TR is currently undertreated



Challenges with Tricuspid Regurgitation

- Assessment of symptoms
 1. Decreased CO – fatigue, decreased exercise tolerance
 2. Right Heart Failure – Ascites, LE edema
- Assessment of TR Severity

Diagnostic Challenges with TR

- Regurgitation can be dynamic and very volume dependent
- Volume overload is well-tolerated for years
- Medical and surgical therapies are limited
- Poor understanding about grading the severity of TR on Echo

Extended Grading Scheme

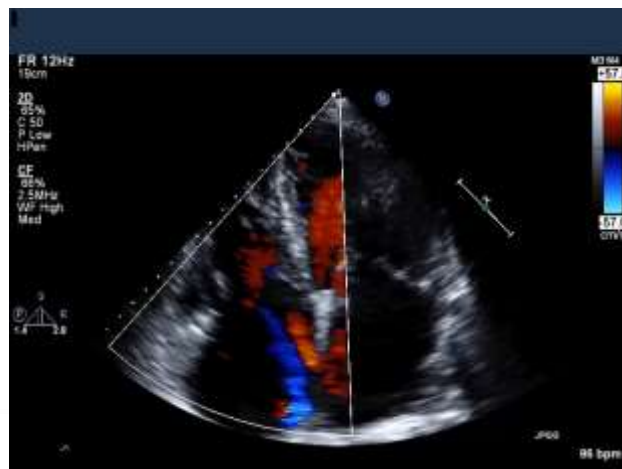
Table 1 Proposed expansion of the 'Severe' grade

Variable	Mild	Moderate	Severe	Massive	Torrential
VC (biplane)	<3 mm	3-6.9 mm	7-13 mm	14-20 mm	≥21 mm
EROA (PISA)	<20 mm ²	20-39 mm ²	40-59 mm ²	60-79 mm ²	≥80 mm ²
3D VCA or quantitative EROA ^a			75-94 mm ²	95-114 mm ²	≥115 mm ²

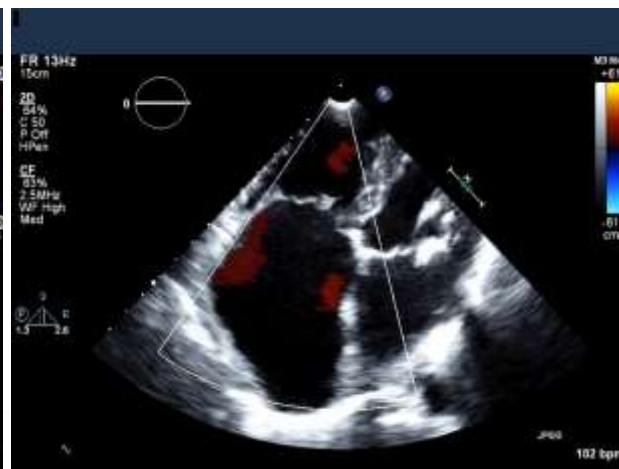
VC, vena contracta; EROA, effective regurgitant orifice area; 3D VCA, three-dimensional vena contracta area.

^a3D VCA and quantitative Doppler EROA cut-offs may be larger than PISA EROA.

Rebecca T. Hahn, and Jose L. Zamorano. "The Need for a New Tricuspid Regurgitation Grading Scheme." *European Heart Journal - Cardiovascular Imaging*, 2017



Severe

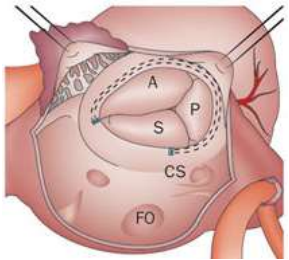


Massive



Torrential

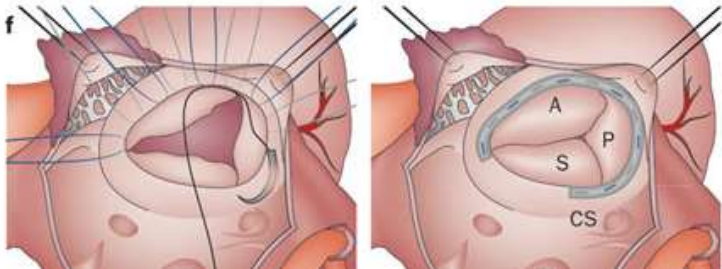
Surgical Approaches to Tricuspid Regurgitation



De Vega Plasty



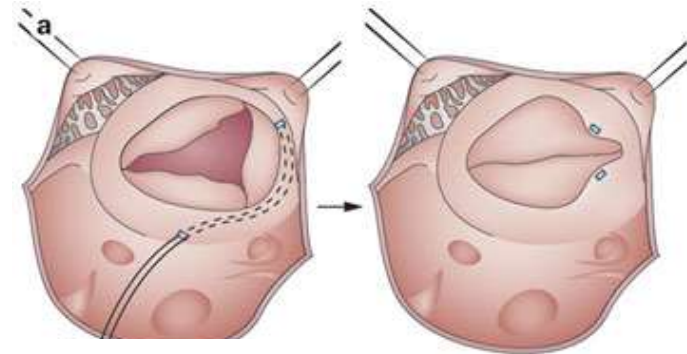
Modified De Vega Plasty



Ring Annuloplasty












Clover



Kay Plasty



New tricuspid therapies

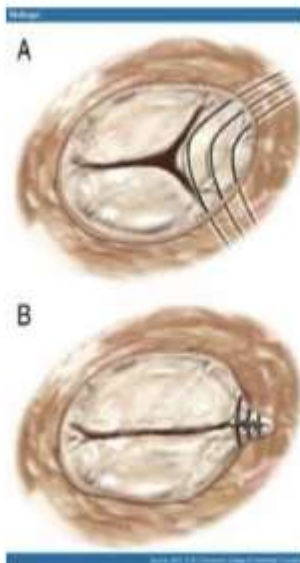
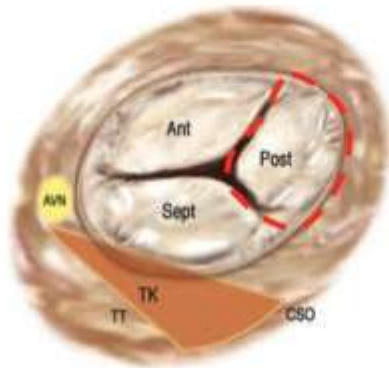
Mechanism	New Technologies			
Annuloplasty (Direct and Indirect)	 <p>TriAlign</p>	 <p>Cardioband</p>	 <p>4Tech</p>	 <p>Millepede</p>
Leaflet Devices	 <p>Forma</p>	 <p>MitraClip</p>	<p>Approaches:</p> <ol style="list-style-type: none"> 1. Superior vena cava 2. Inferior vena cava 3. Transapical 4. Transatrial 	
Stented Valves in IVC/SVC	 <p>Trinity /Sapien</p>	 <p>NVT</p>		
Valve Replacement	 <p>Navigate</p>			

- Approaches:**
1. Superior vena cava
 2. Inferior vena cava
 3. Transapical
 4. Transatrial

Annular Devices



Kay converts an incompetent tricuspid into a competent bicuspid valve



- Pledget is placed at the Antero-Posterior Commissure
- Pledget is placed at the Septo-Posterior Commissure
- Pledgets are cinched together excluding the posterior leaflet and bicuspidizing the valve



Investigational Device: Not Available for Commercial Use.

Bicuspidization of the TV with the Trialign System

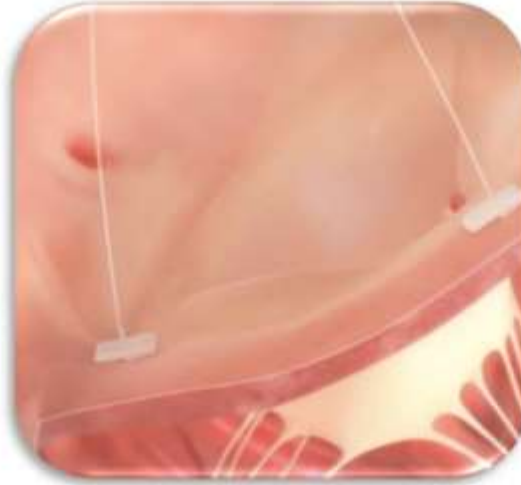
KEY ADVANTAGES:

- Based on Surgical Predicate (Modified Kay Annuloplasty)
- Small footprint leaves future clinical options on the table

Wire Placement



Pledget Delivery



Plication & Lock



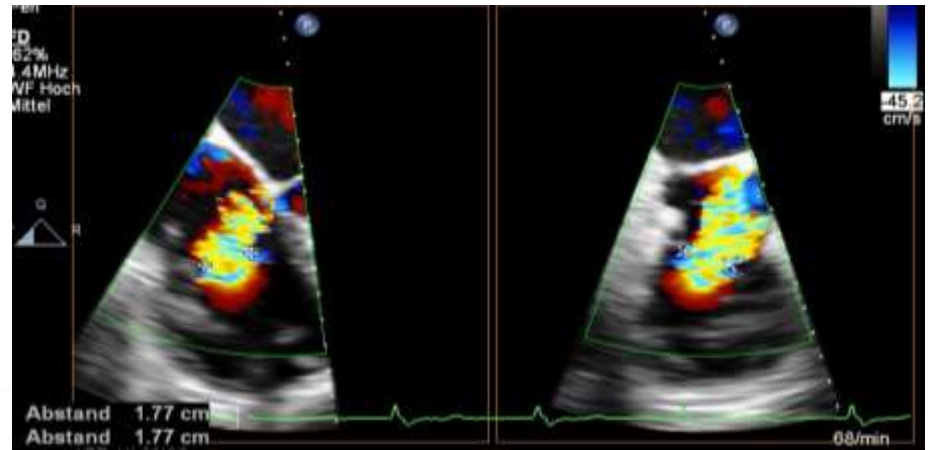
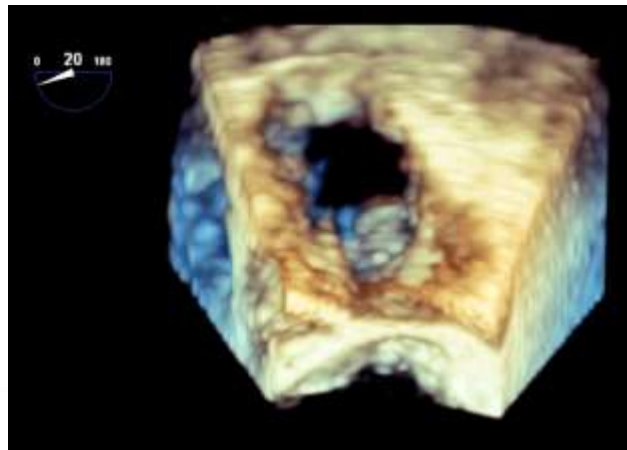
ign



First-in-Human Transcatheter Tricuspid Valve Repair in a Patient With Severely Regurgitant Tricuspid Valve

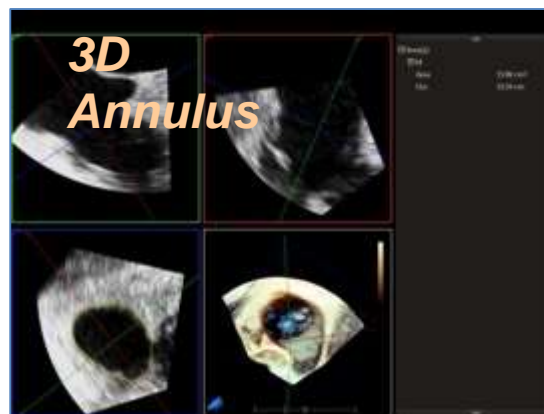
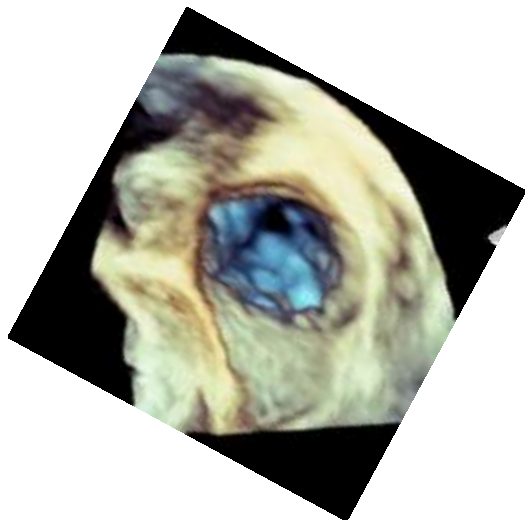
Joachim Schofer, MD,* Klaudija Bijuklic, MD,* Claudia Tiburtius, MD,* Lorenz Hansen, MD,* Adam Groothuis, PhD,†
Rebecca T. Hahn, MD‡

J Am Coll Cardiol 2015;65:1190–5

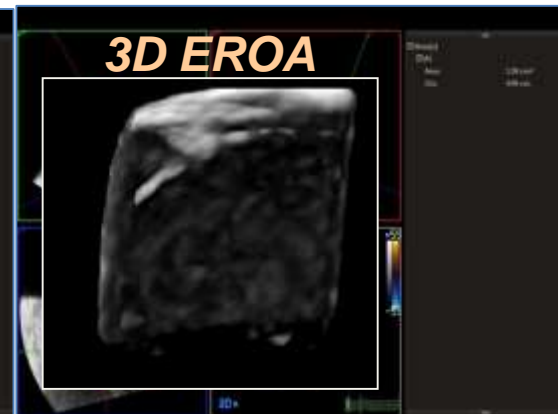


Severe Isolated Primary Tricuspid Regurgitation

◆ **Baseline**

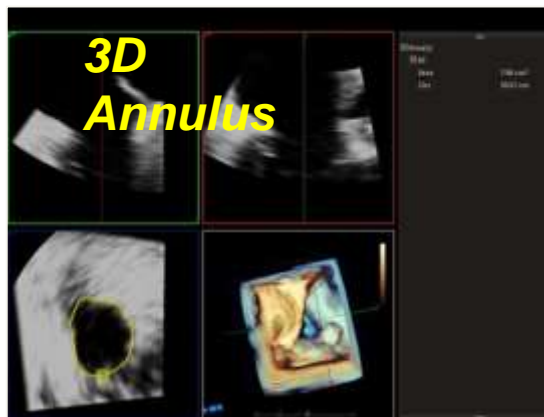


13.9 cm²

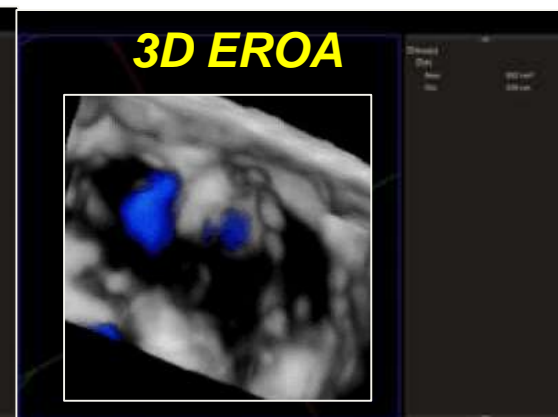


0.99 cm²

◆ **Post-Trialign**



7.6 cm²
(45% reduction)

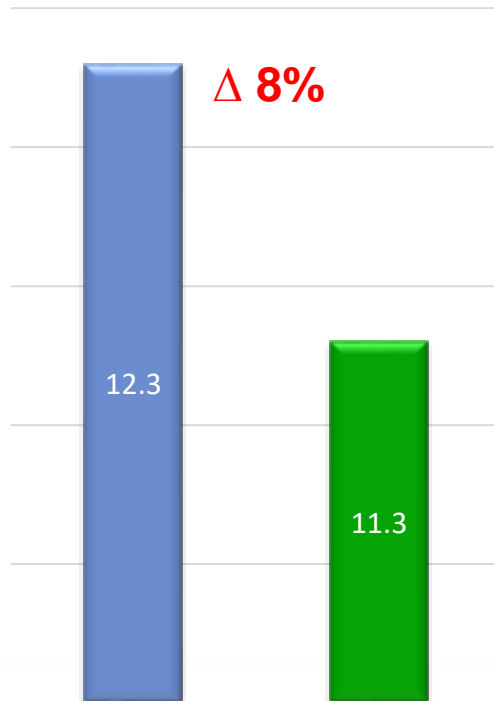


0.43 cm²
(55% reduction)

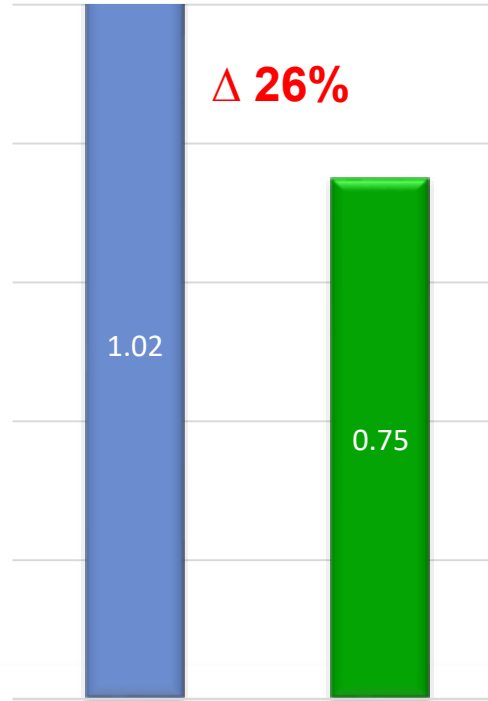
SCOUT 30 Day Data

As-Treated^{‡*}

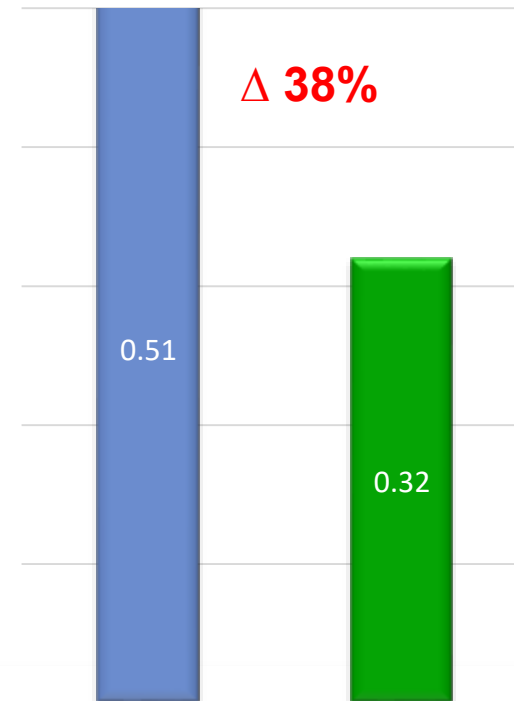
Tricuspid Annular Area (cm²)
(n=15)
p = 0.019



TR Vena Contracta (cm)
(n=15)
p = 0.048



PISA EROA (cm²)
(n=15)
p = 0.020



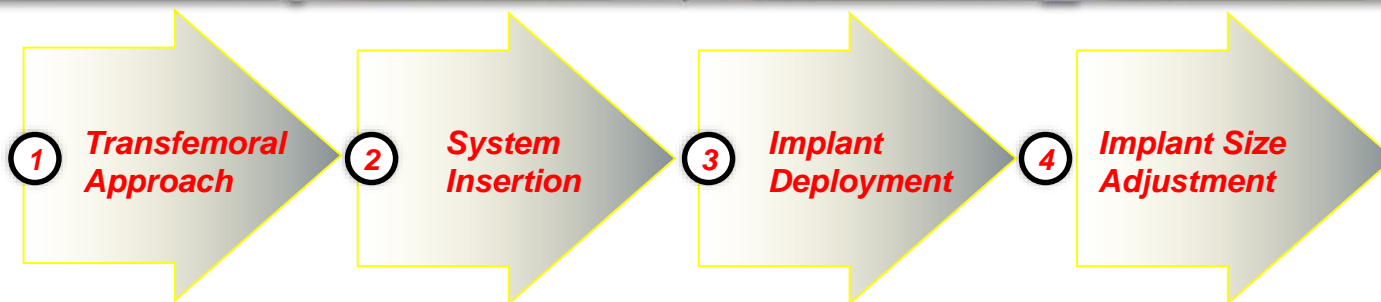
‡ Change from baseline to 30 days computed on paired data
* p-value by paired t-test or Wilcoxon as appropriate

Edwards Lifesciences Cardioband

- Percutaneous band for developed mitral annulus to treat MR
- A series of 15-18 anchors implanted in annulus
- Performed a series of compassionate use cases in patients with tricuspid regurgitation

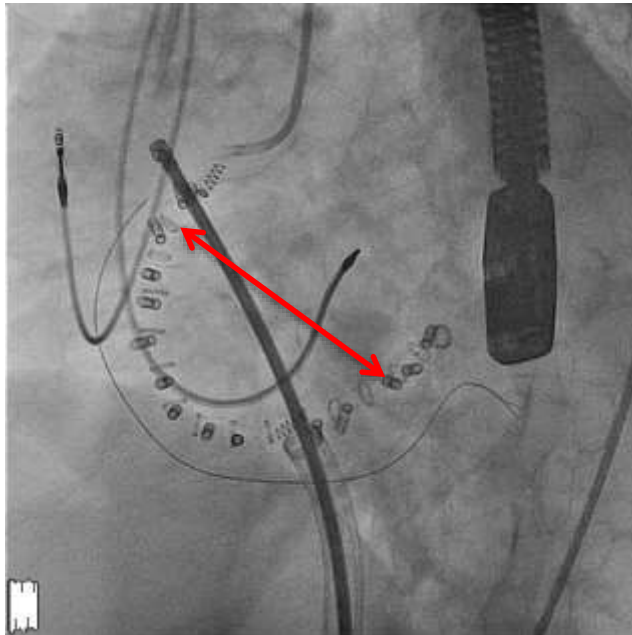


Edwards Cardioband Tricuspid Repair Procedure

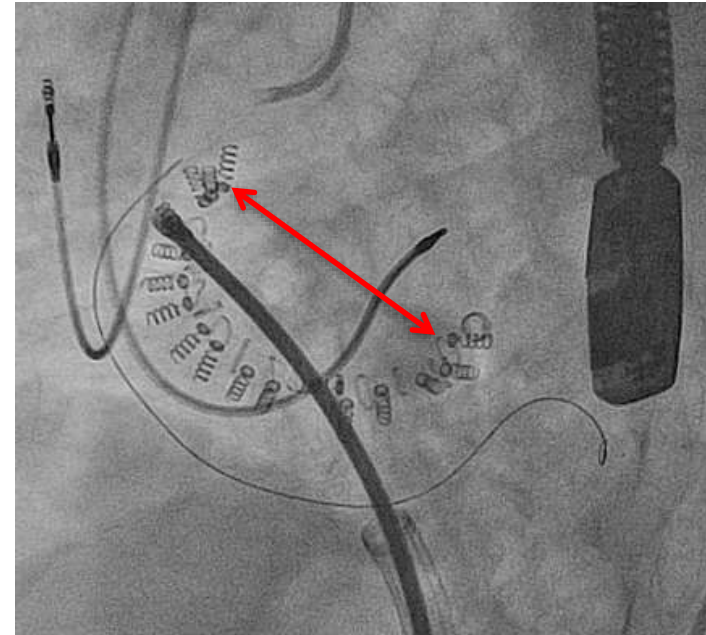


Cardioband Tricuspid Fluoroscopic View

Pre-Reduction



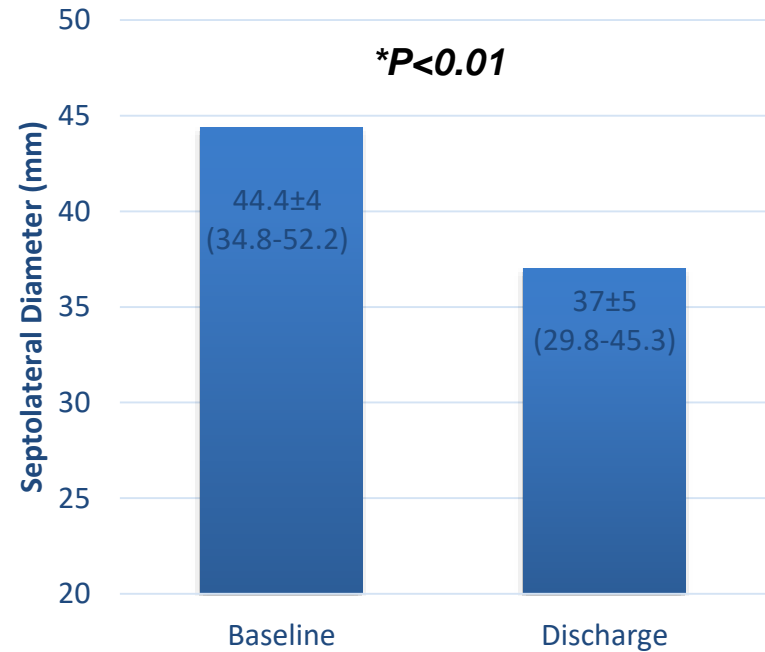
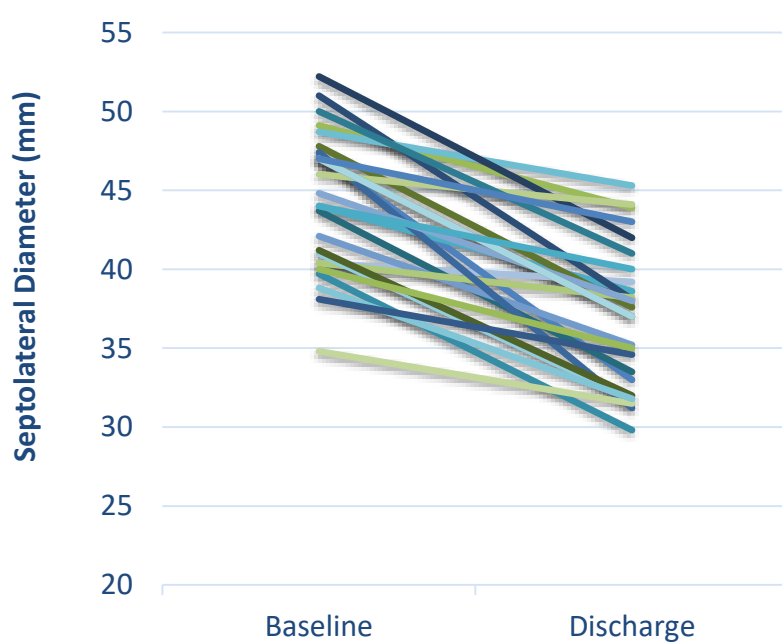
Post-Reduction



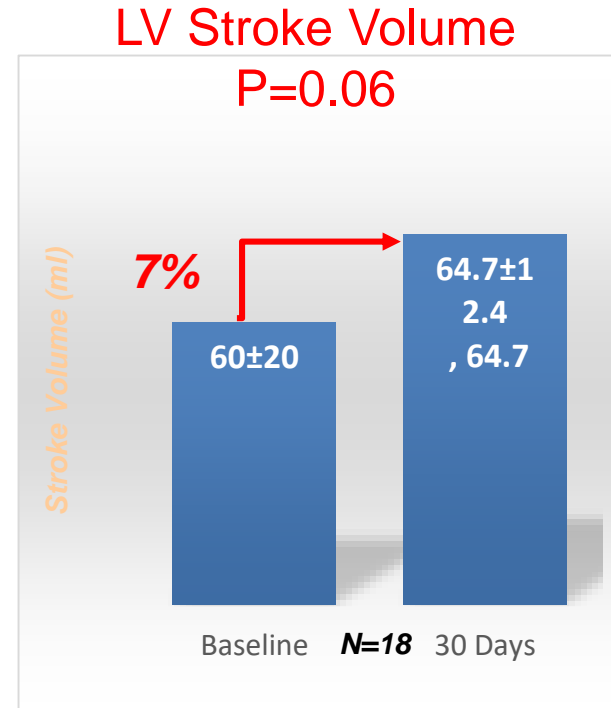
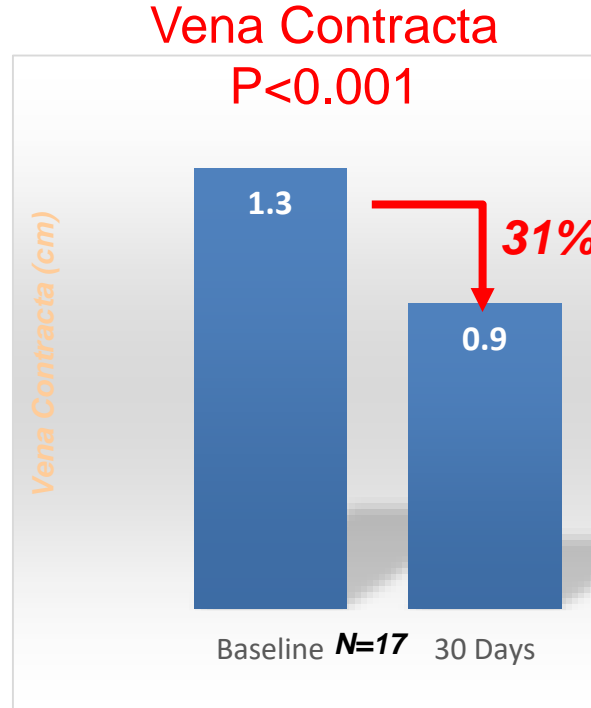
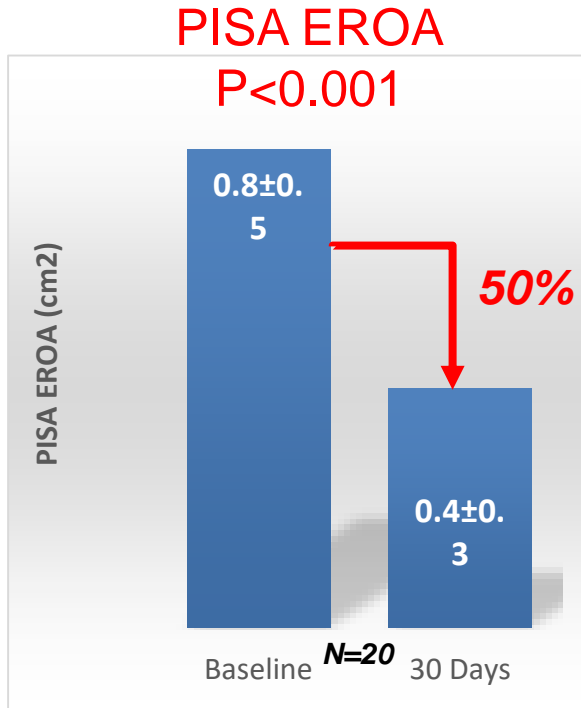
Bonn University Hospital

Edwards TRI-REPAIR Study

17% average reduction in septolateral diameter by core lab

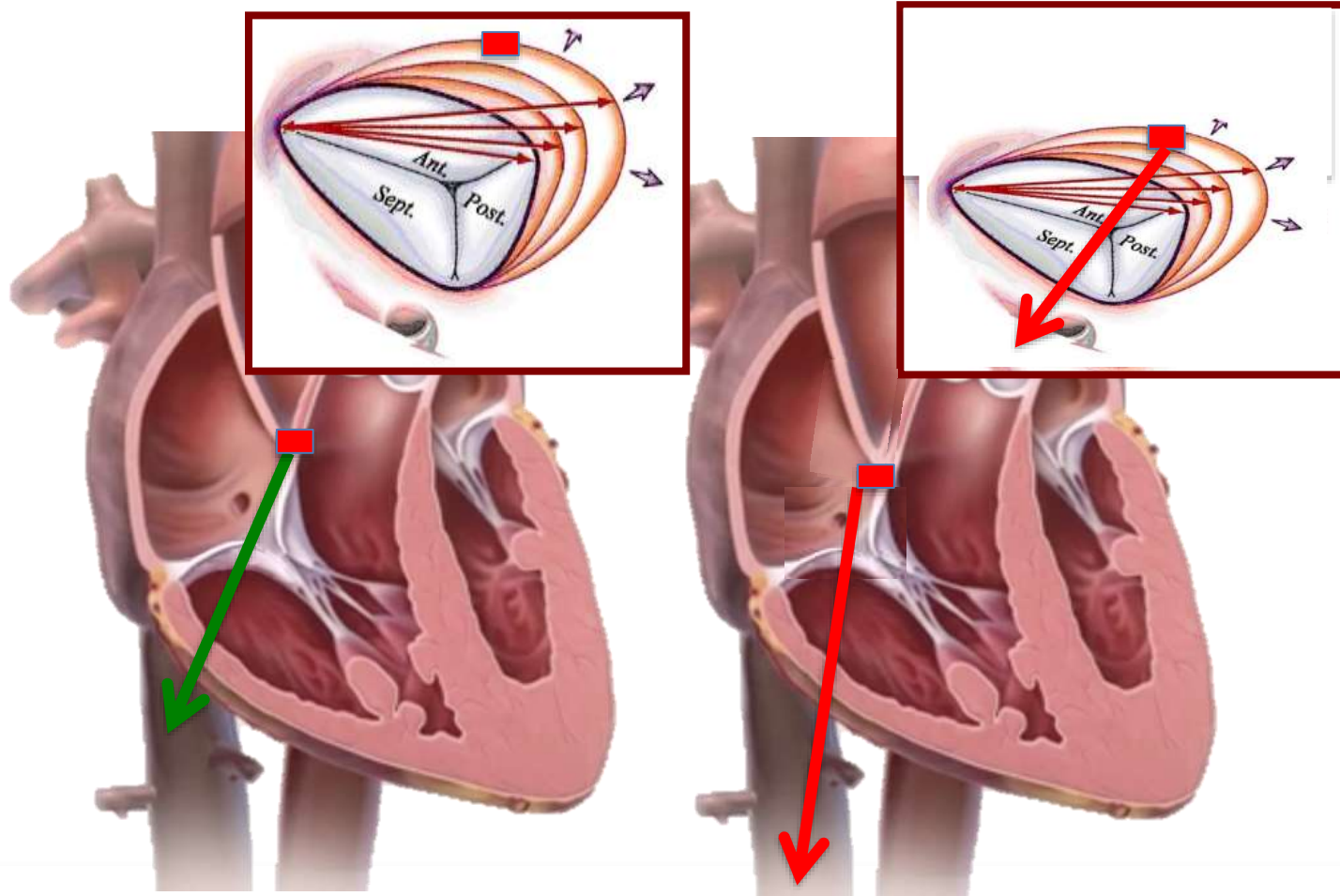


Edwards TRI-REPAIR Study

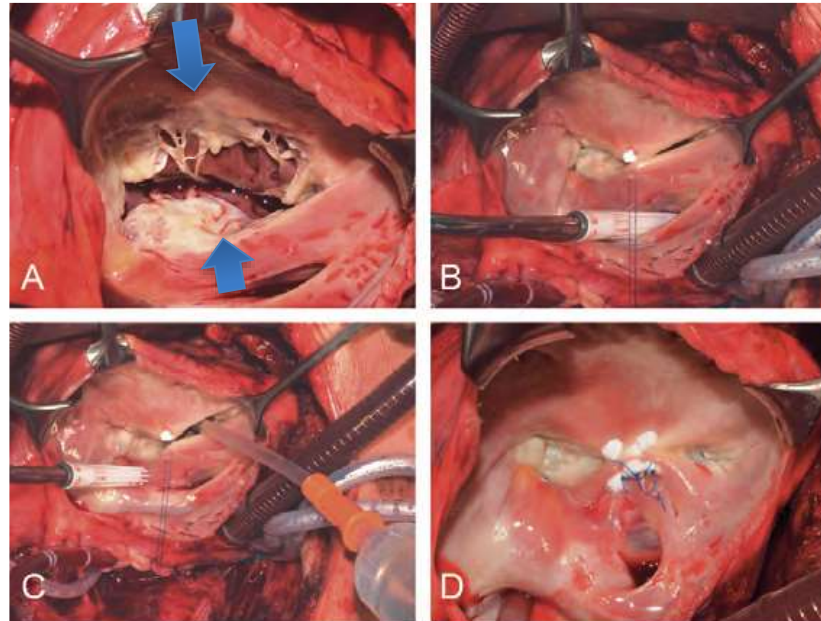
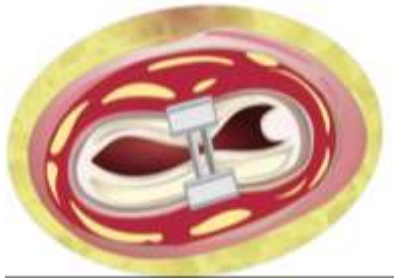


- **Large proportion of patients treated with “torrential TR”**
- **Improvements resulted in most patients achieving lower severity or moderate TR at 30 days.**

The 4TECH TriCinch Concept



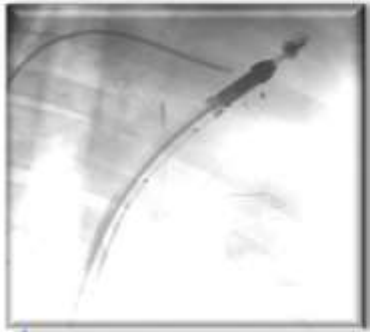
Hetzer Double Orifice Repair



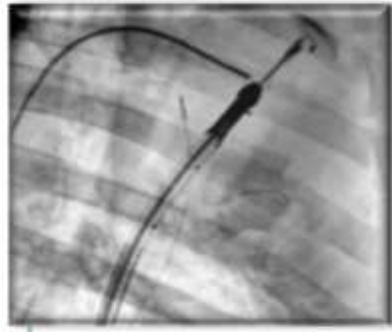
91 patients with severe TR treated; mean follow-up of 4.1 years (range 9 months, 19.4 years), no reoperation for recurrent TR

TriCinch Coil System Procedural Steps

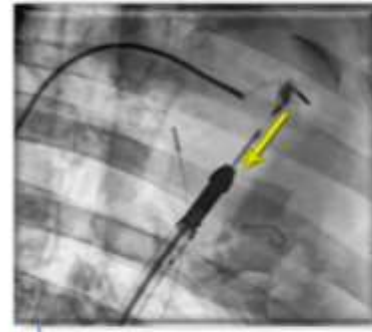
4 procedural steps to deploy the TriCinch Coil System



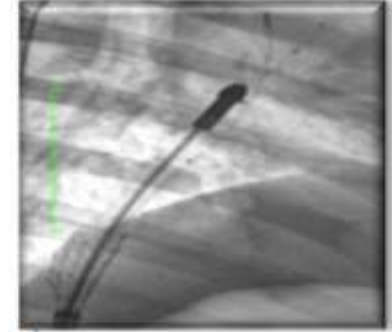
1 Position & puncture APC region



2 Deploy Coil anchor in pericardial space



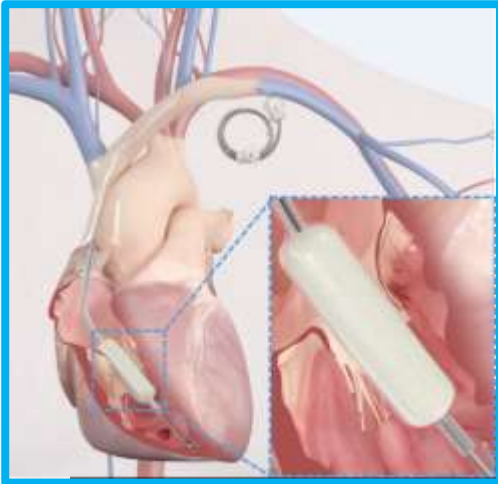
3 Tension applied



4 Stent deployment in IVC

Leaflet Devices

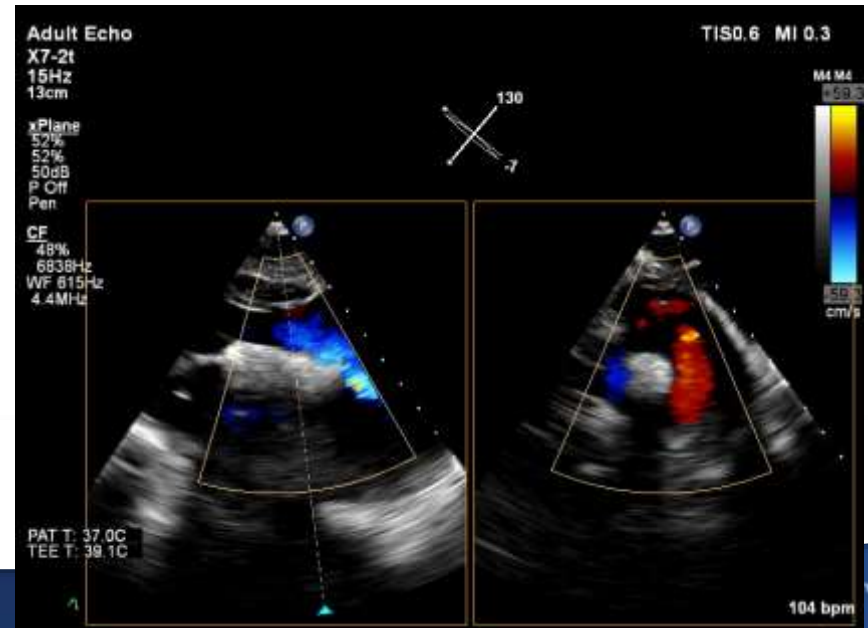
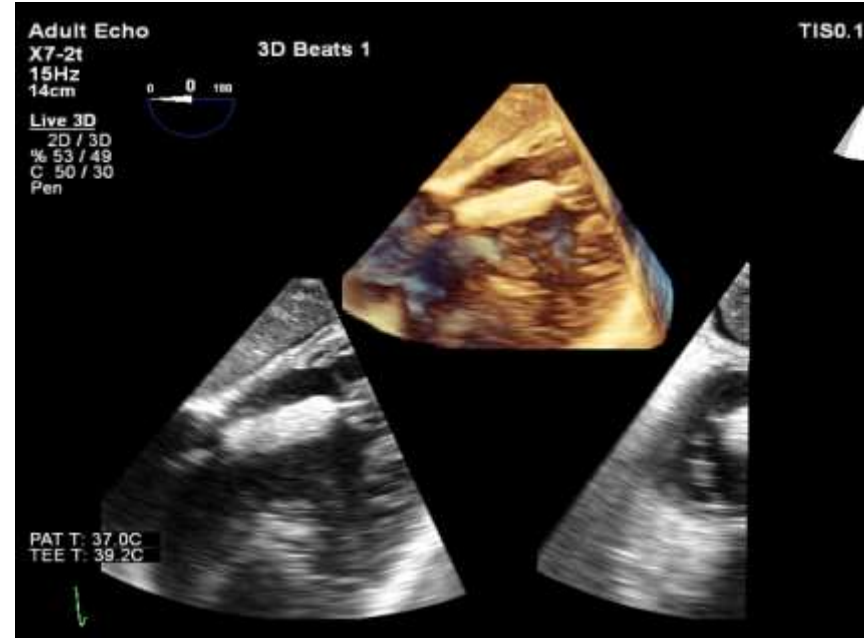
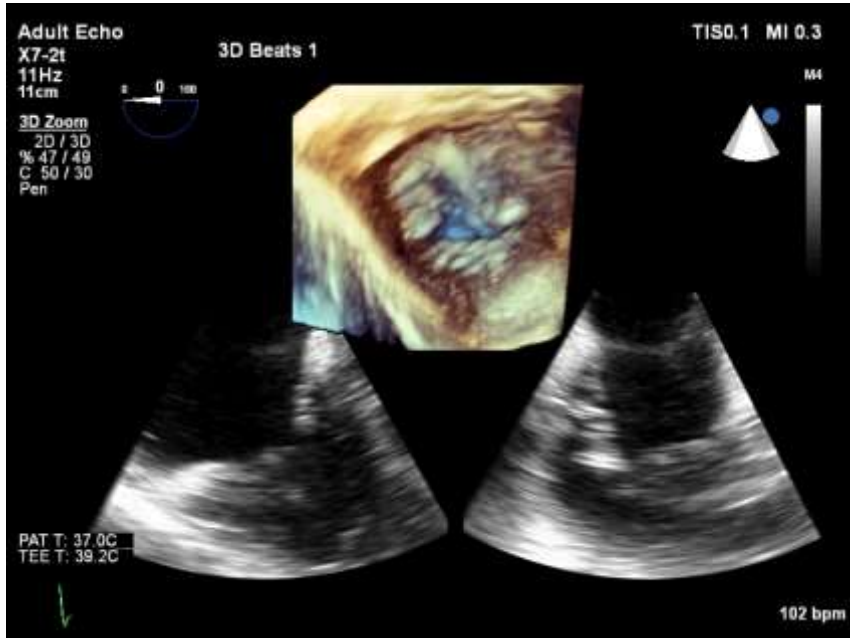
FORMA Tricuspid Valve Therapy System(Edwards Lifesciences)



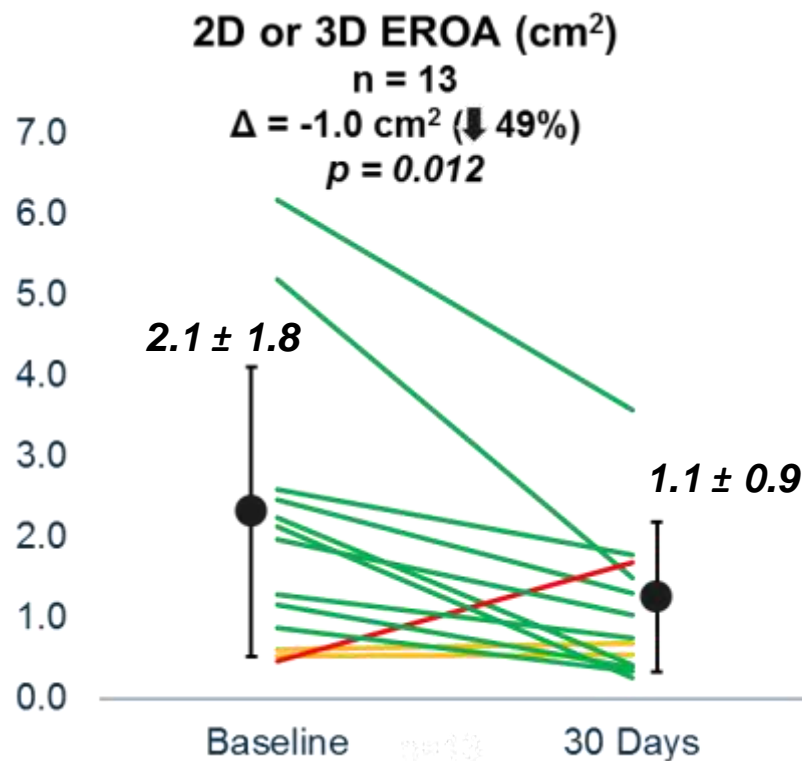
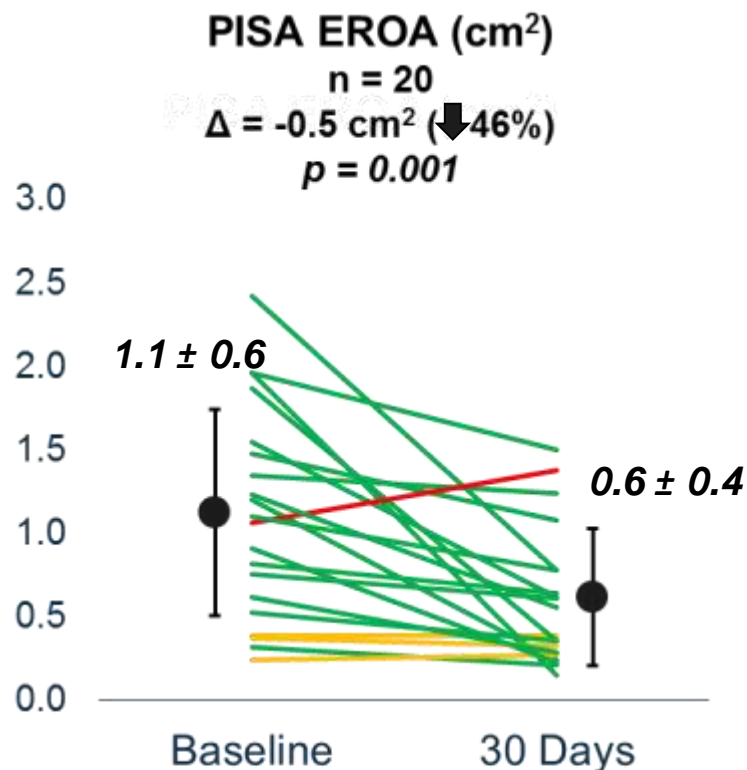
- Spacer
 - Positioned within regurgitant orifice
 - Provides surface for native leaflets to coapt
 - 12, 15 and 18mm sizes
 - Advanced from left subclavian vein
- Rail
 - Tracks Spacer into position
 - Anchored at RV apex and subclavian vein



Case Example Forma



FORMA Early Feasibility Study Echocardiography Outcomes at 30 Days (echo core lab)



Mitraclip for Treatment of Severe Tricuspid Regurgitation

ORIGINAL RESEARCH ARTICLE



Transcatheter Treatment of Severe Tricuspid Regurgitation With the Edge-to-Edge MitraClip Technique

Editorial, see p 1815

BACKGROUND: Current surgical and medical treatment options for severe tricuspid regurgitation (TR) are limited, and additional interventional approaches are required. In the present observational study, the safety and feasibility of transcatheter repair of chronic severe TR with the MitraClip system were evaluated. In addition, the effects on clinical symptoms were assessed.

Georg Nickenig, MD
Marek Kowalski, MD
Jörg Hausleiter, MD
Daniel Braun, MD
Joachim Schofer, MD
Ermela Yzeiraj, MD
Volker Rudolph, MD
Kai Friedrichs, MD

Common Femoral Approach

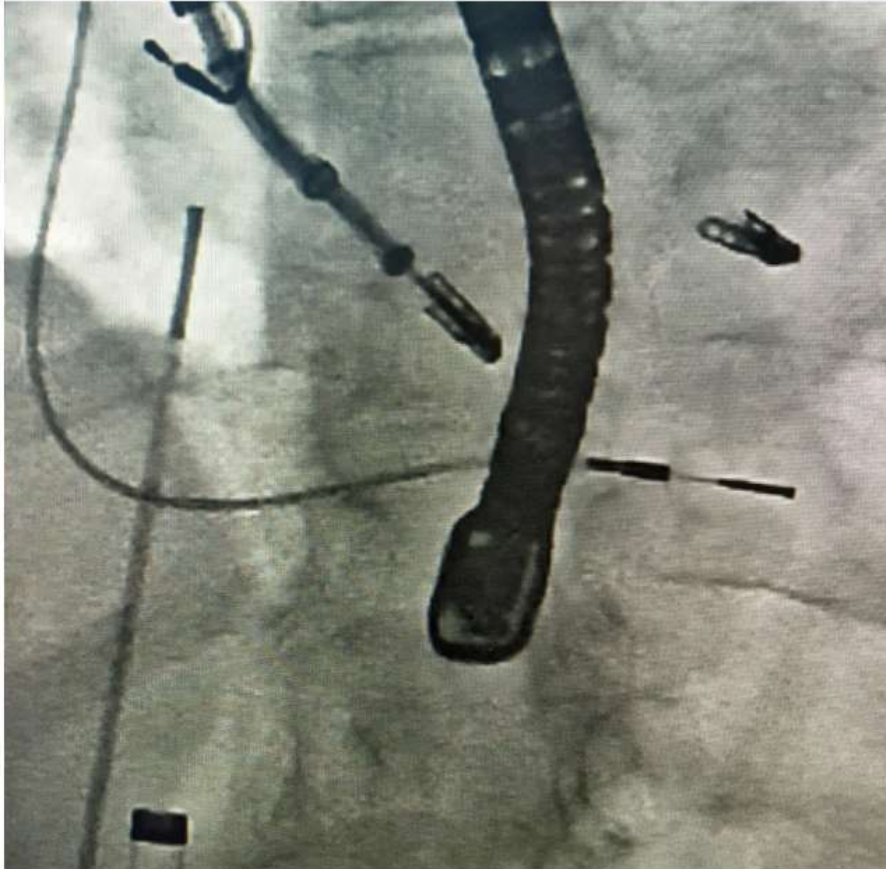


- ◆ **64 consecutive patients (mean age 76.6±10 years)**
- ◆ **Functional TR was present in 88%.**
- ◆ **The degree of TR was severe or massive in 88% of patients before the procedure.**
- ◆ **The MitraClip device was successfully implanted in the tricuspid valve in 97% of the cases.**

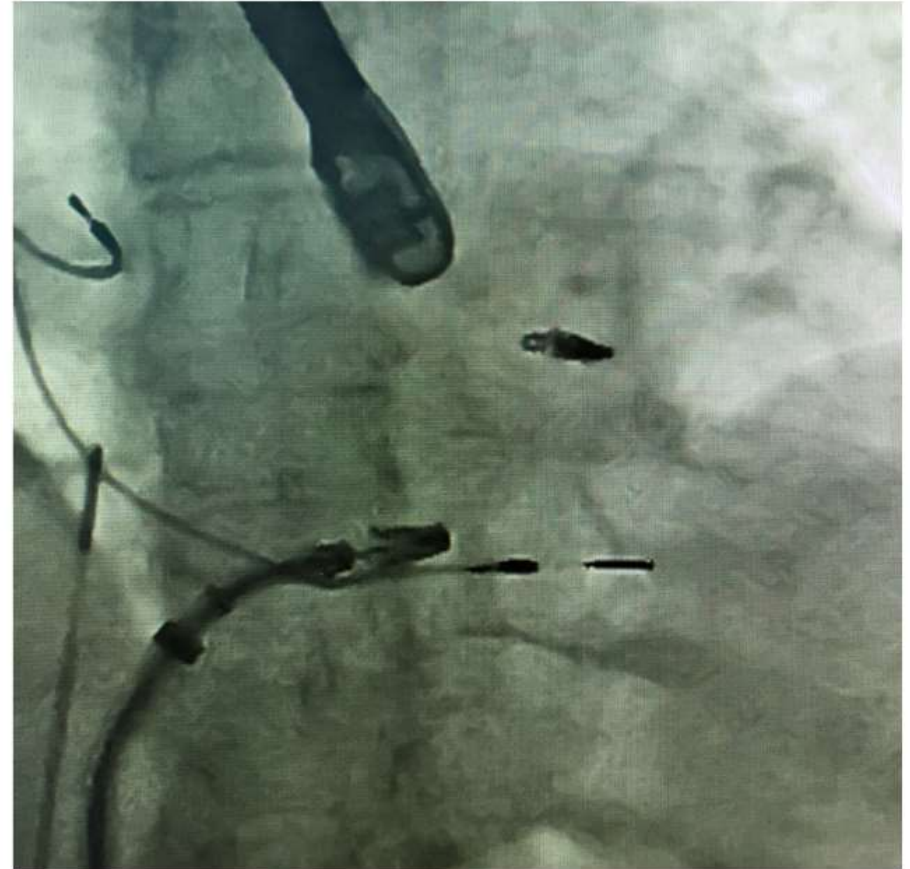
Nickenig G et al Circulation. 2017;135:1802–1814.

MitraClip For Functional TR

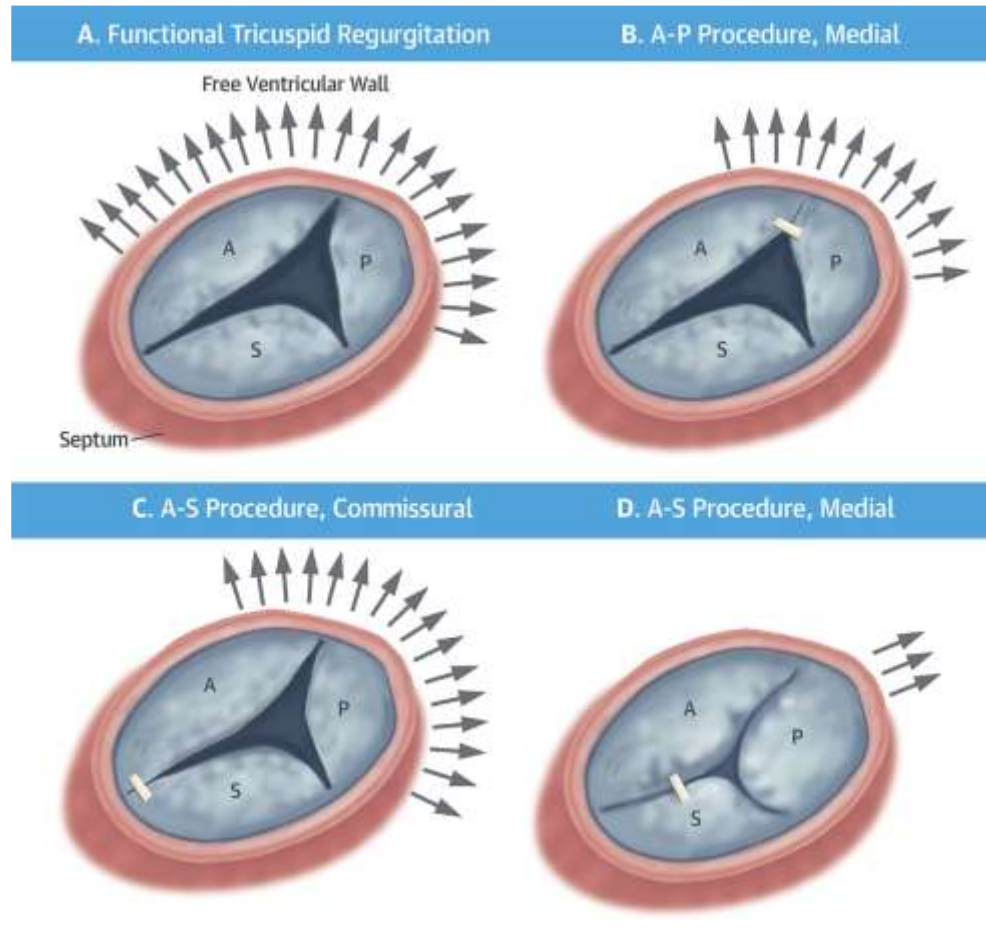
Internal Jugular Approach



Common Femoral Approach



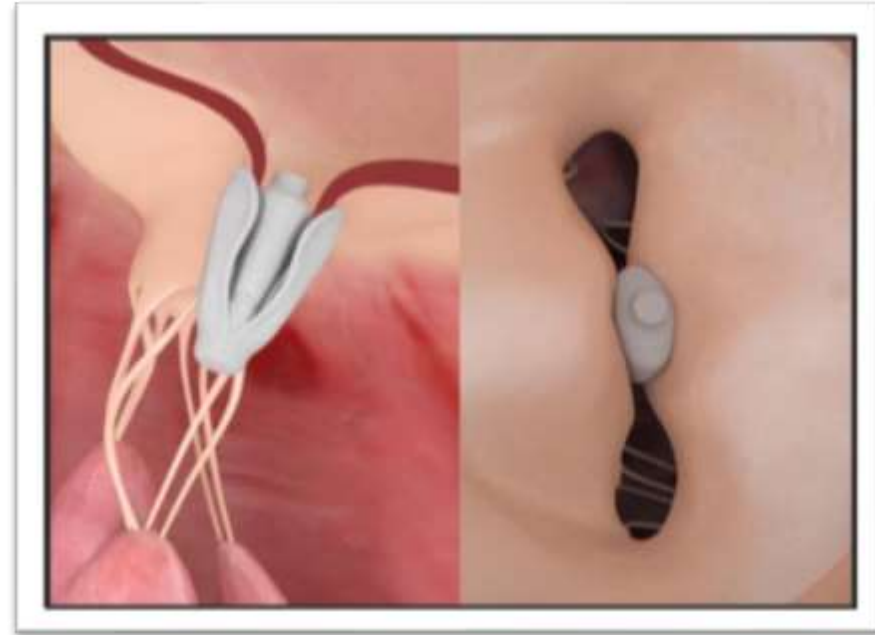
Modeling MitraClip for TR



Vismara, R. et al. J Am Coll Cardiol. 2016;68(10):1024–33.

Edwards Pascal Repair System

- ◆ Spacer is clasped between both Mitral valve leaflets
- ◆ Independent leaflet clasp system
- ◆ Simple “commander-like” delivery system
- ◆ Conventional transfemoral/transseptal approach
 - ◆ Minimal dependence on puncture height



PAdles
Spacers
Clasps
ALfieri

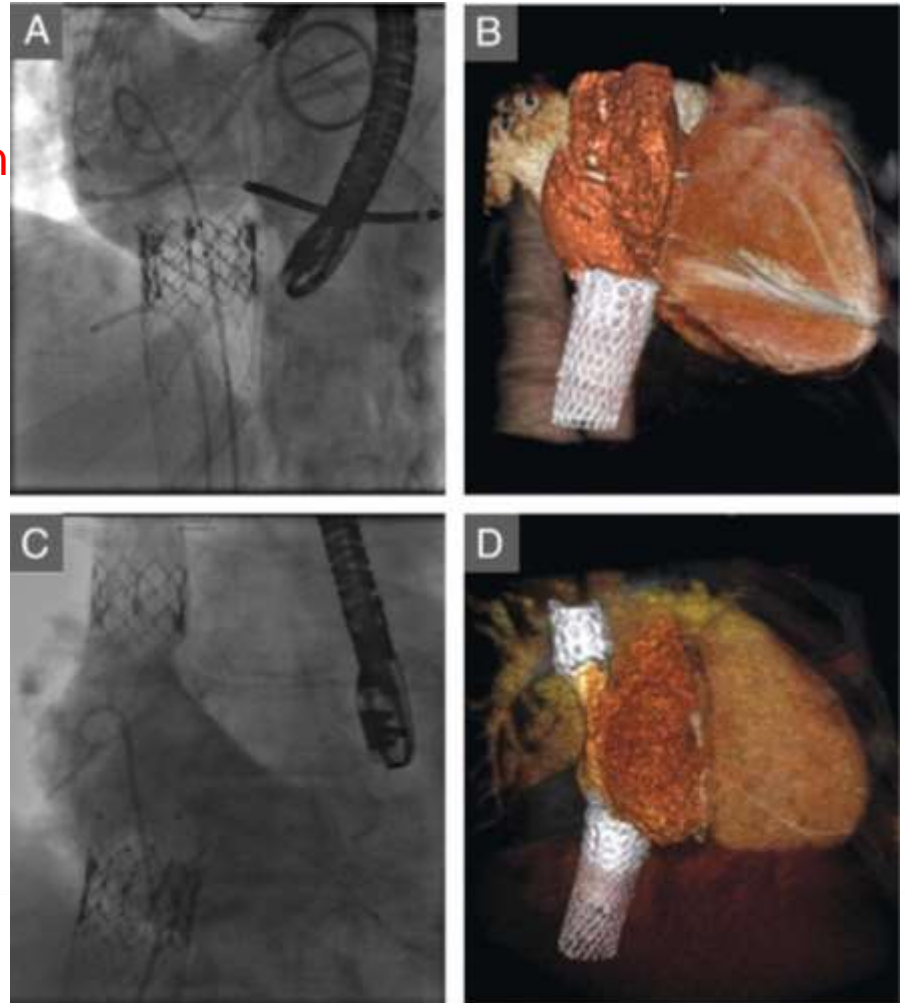
Caval Implants

Sapien XT in IVC and SVC

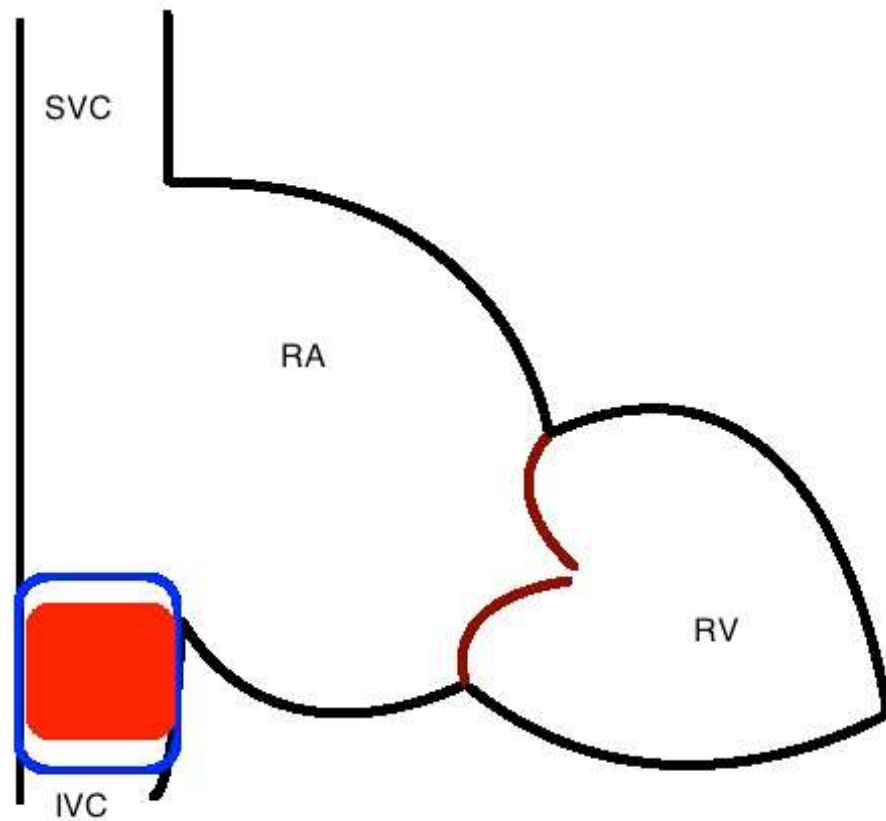
Michael Laule, Charité–Universitätsmedizin
Berlin, Campus Mitte, Germany

J Am Coll Cardiol. 2013;61(18):1929-1931.

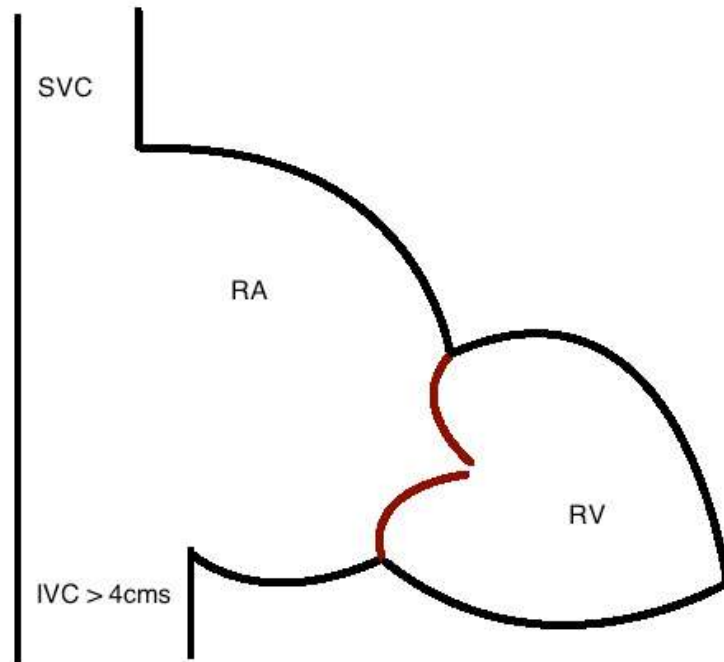
3 Patients



Sapien in IVC

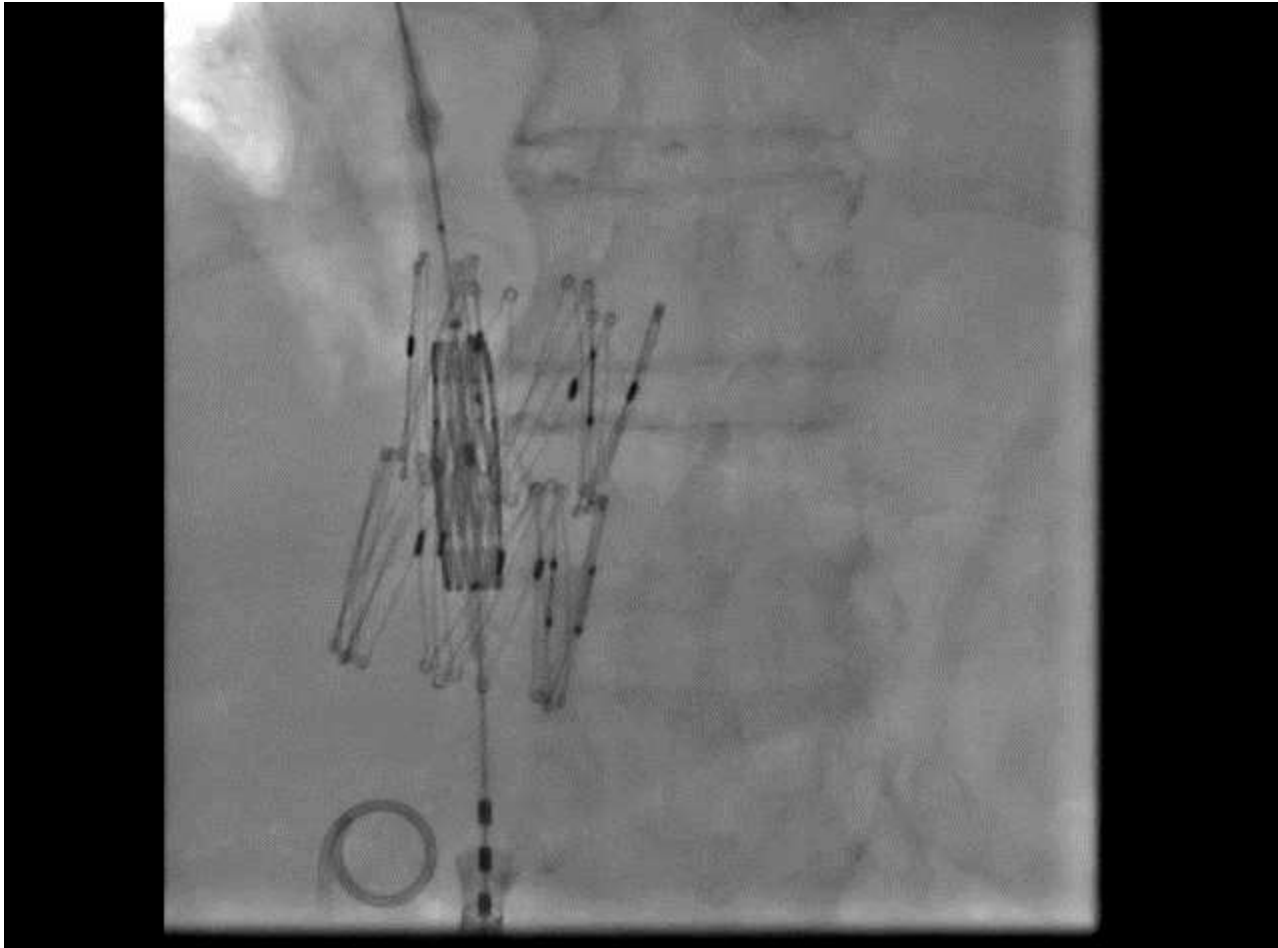


Sapien in IVC



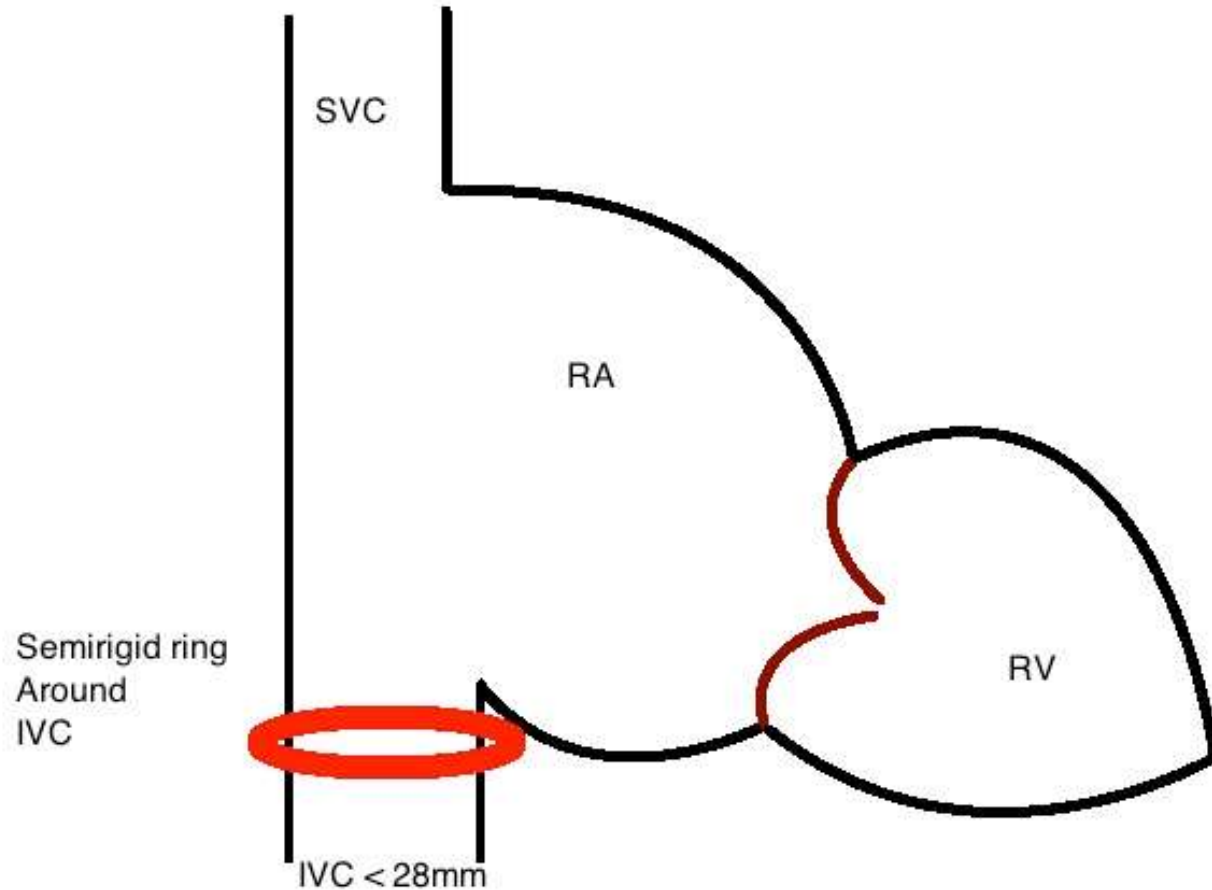
What if the IVC is >30mm

Z stent used as scaffold

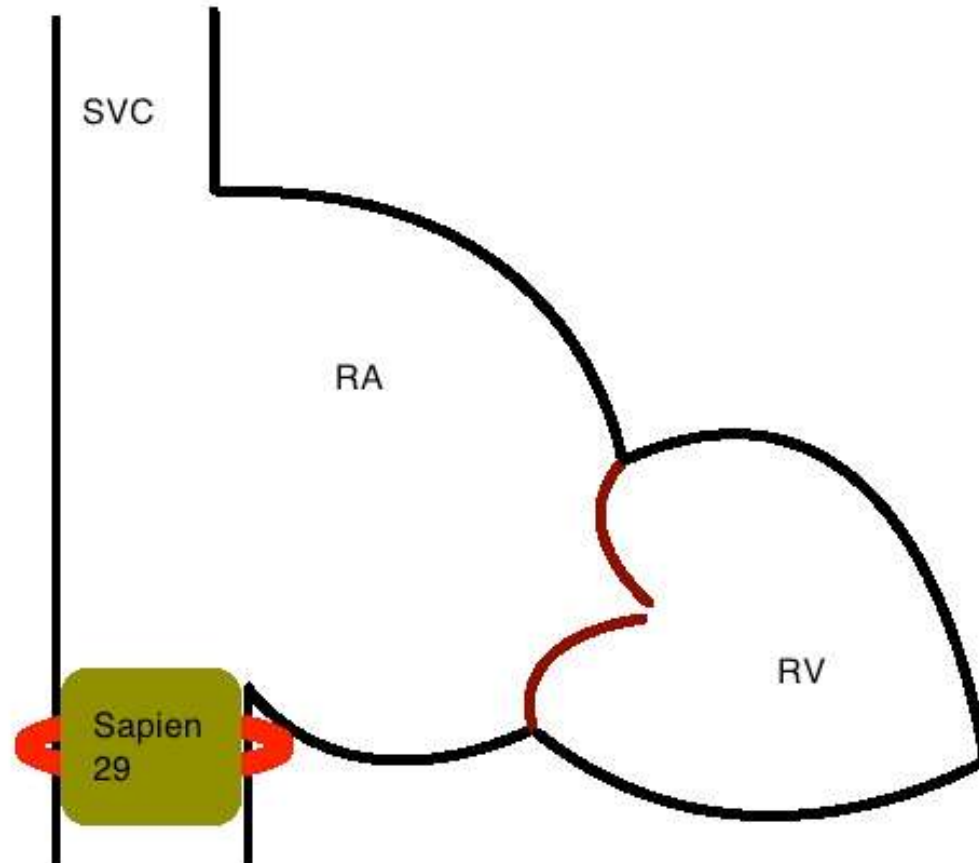


29mm S3 deployed with contrast injection to guide positioning

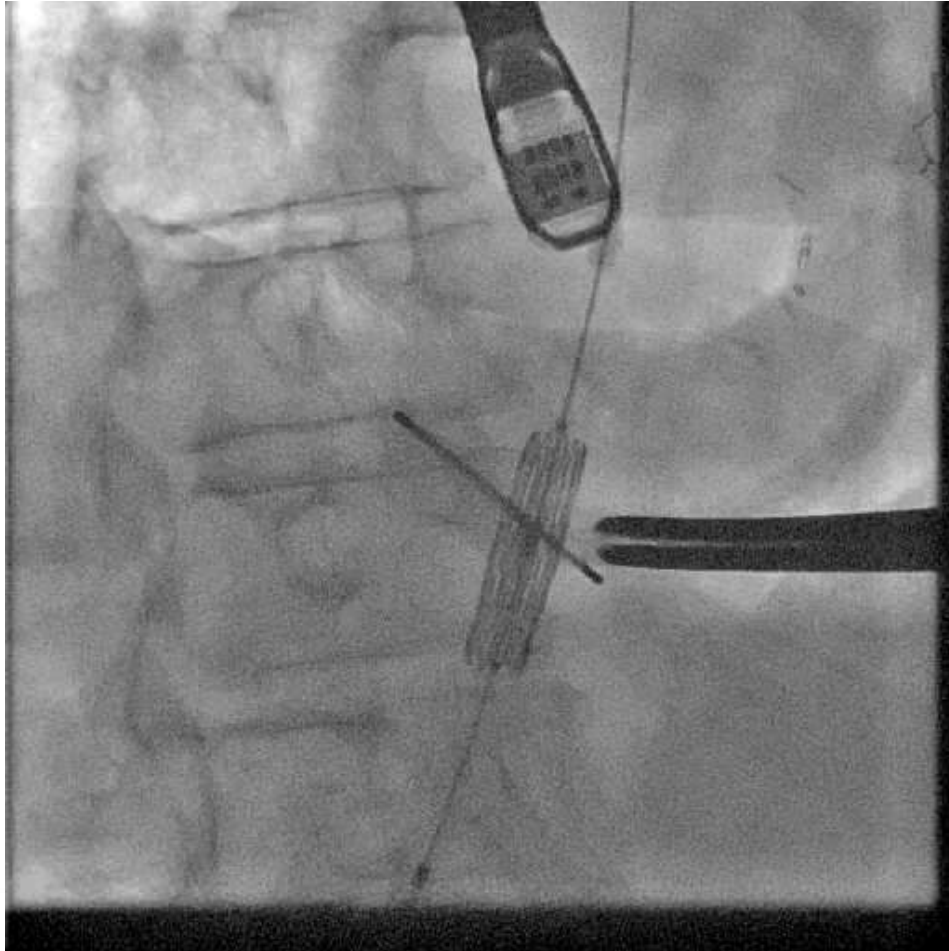
Sapien in IVC



Sapien in IVC



Sapien in IVC



Large IVC >35mm




***External Ring to downsize IVC
Sapien 29 through Femoral Vein***

Transcatheter Tricuspid Valve Replacement



*Navigate Transcatheter
Valve*

VALVED-STENT DIMENSIONS (mm)

	36	40	44	48	52
Ventricular \emptyset 	36	40	44	48	52
Atrial \emptyset 	30	30	33	36	38
HEIGHT 	20	18.2	19.4	22	21.4

NAVIGATE

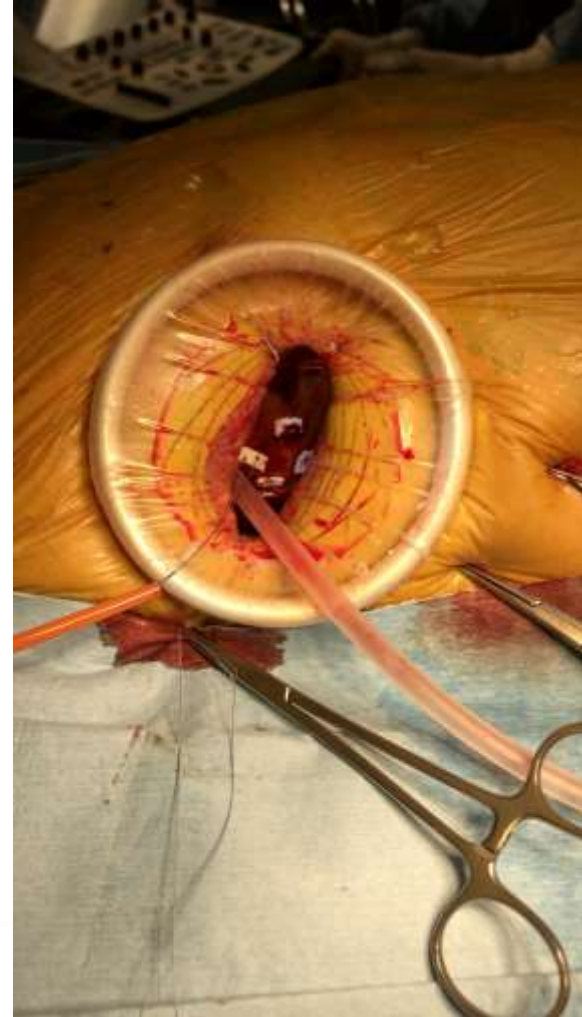
Valved Stent Delivery System



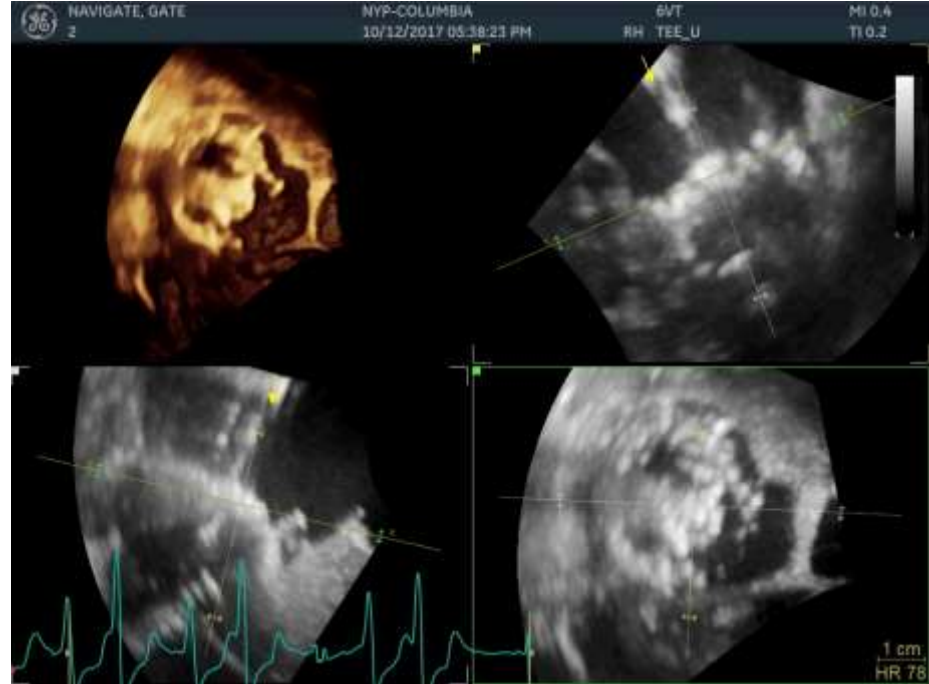
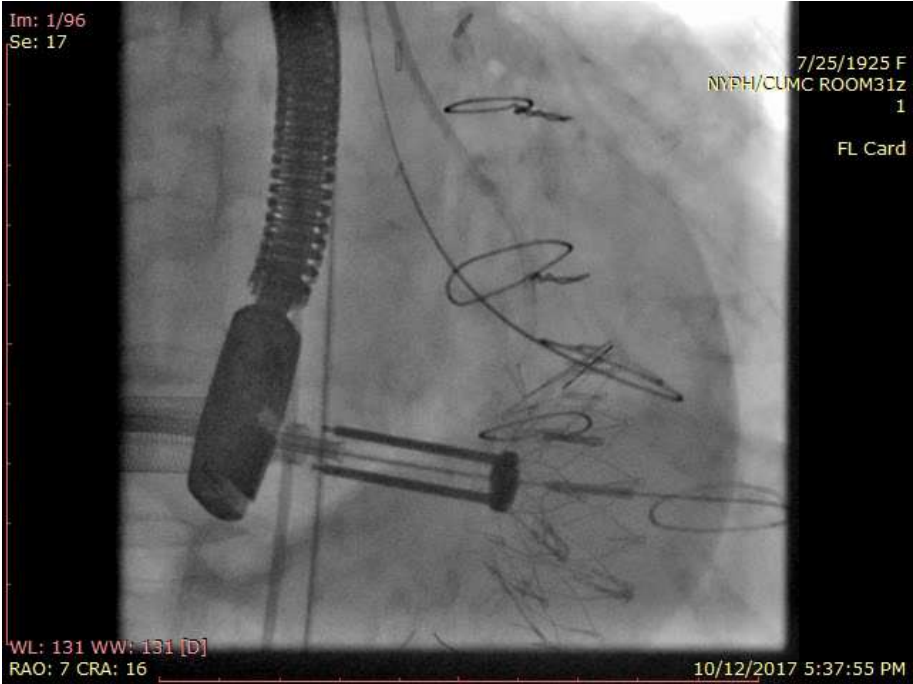
- Presently 35F distal capsule OD
- 24F catheter shaft
- 80° Articulation
- Controlled Valve Release
- All modes of delivery use the same valve configuration

Surgical Access

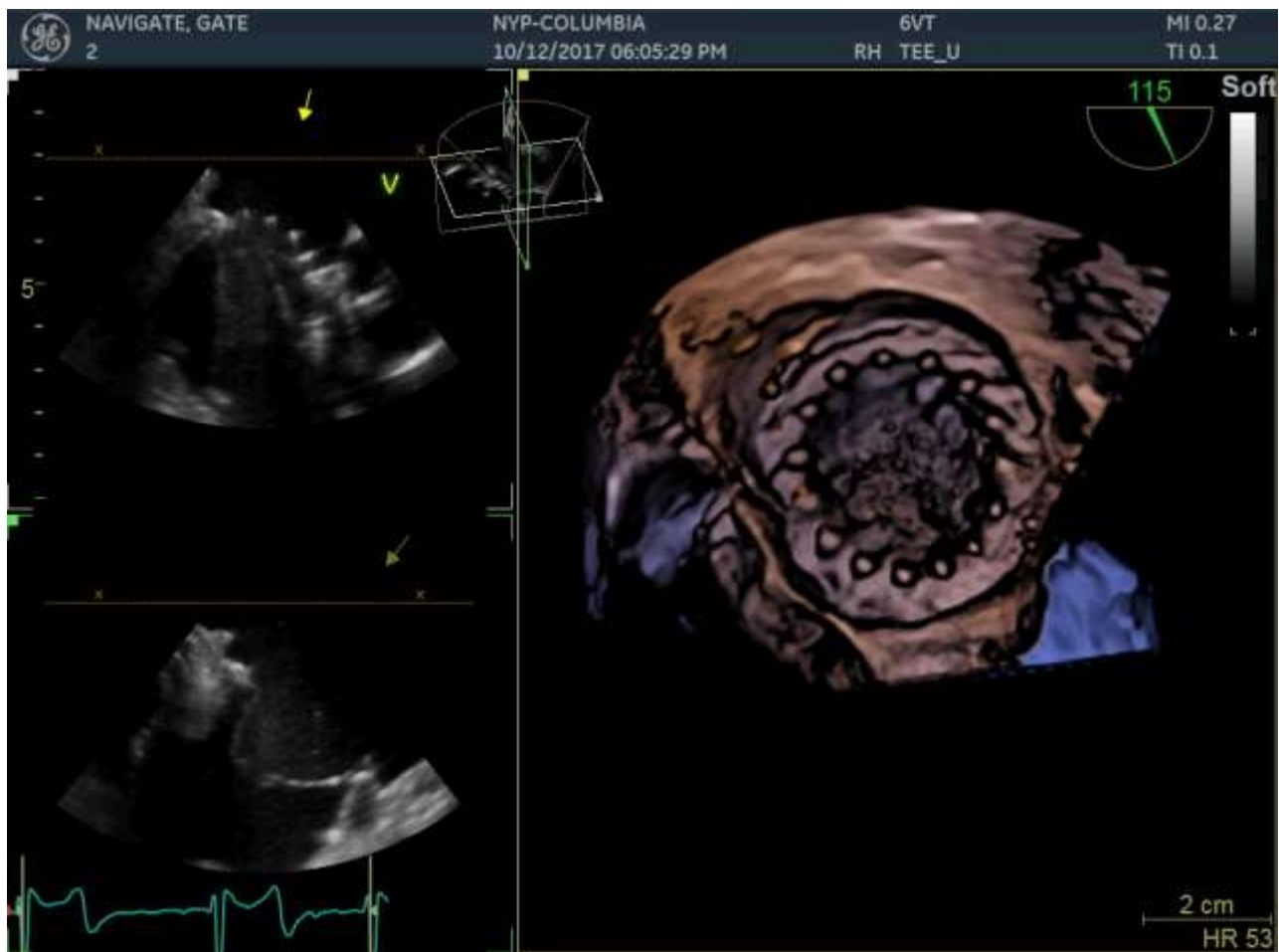
- Right thoracotomy
- Right diaphragm retracted down to expose the site of the pure string



Valve release



Intra-procedural TEE –valve deployed



Right ventriculography post valve deployment



What has the early experience demonstrated?

- Patients often present with torrential TR
- Procedures are relatively safe
- ~50% reduction in EROA
- Improvement in clinical symptoms
- **Durability is unclear**

Next Steps

- Tricuspid Regurgitation Classification
- TR evaluation
- Understanding RV reserve
- Therapy in presence of PPM
- Repair vs Replacement