EMO GVM CENTRO CUORE COLUMBUS s.r.l.

EMOCLINIC SYMPOSIUM SULLE SPONDE DEL TICINO
"CARDIOLOGIA IERI, OGGI E DOMANI"

Novara, 7 - 8 giugno 2018

OSPEDALE SAN RAFFAELE

Lettura

L'ultima frontiera: la tricuspide

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Centro Cuore Columbus and
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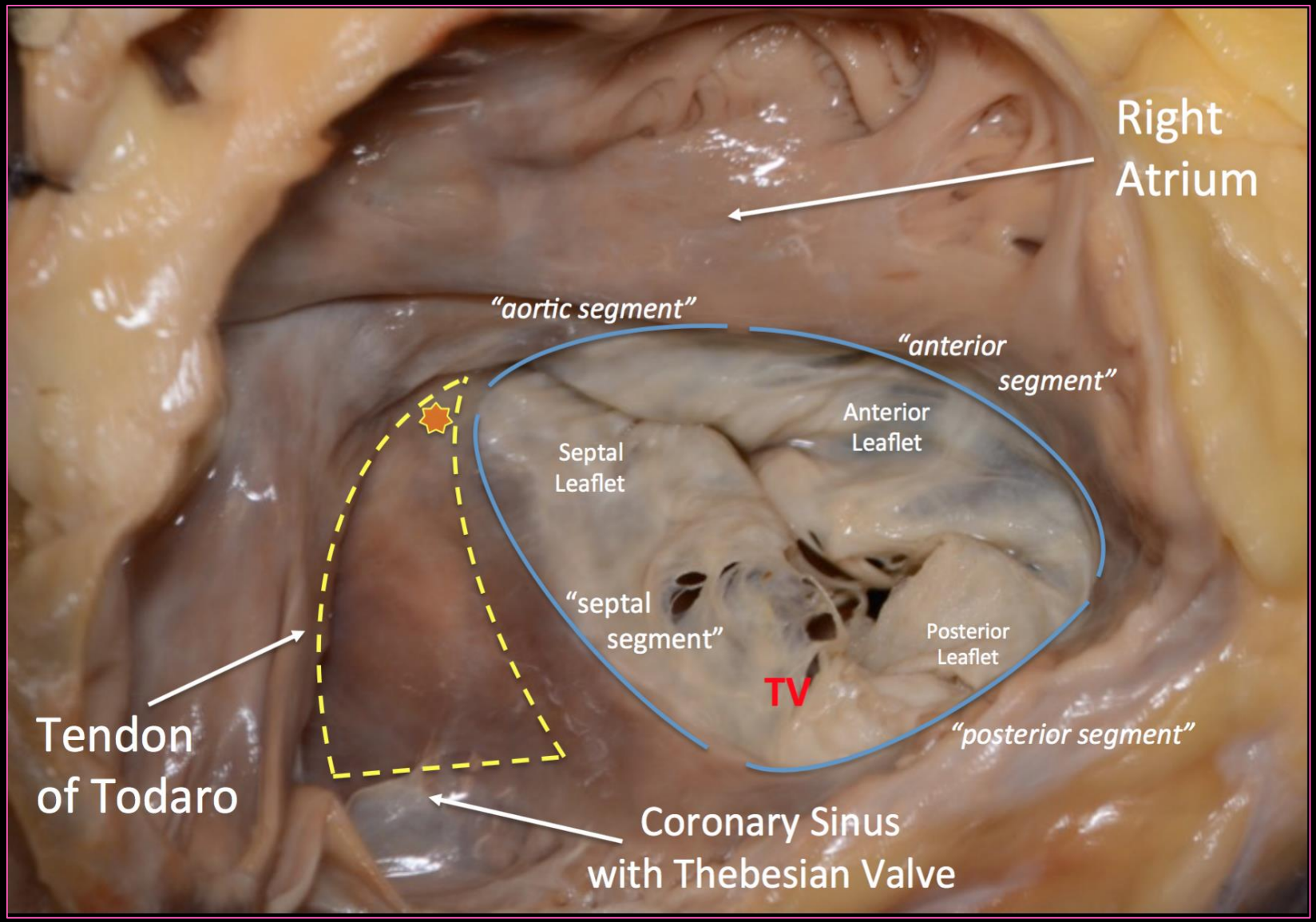
Tricuspid Regurgitation
Etiology

Primary Valvular
- Rheumatic
- Congenital
- Endocarditis
- Carcinoid
- Pacemaker leads

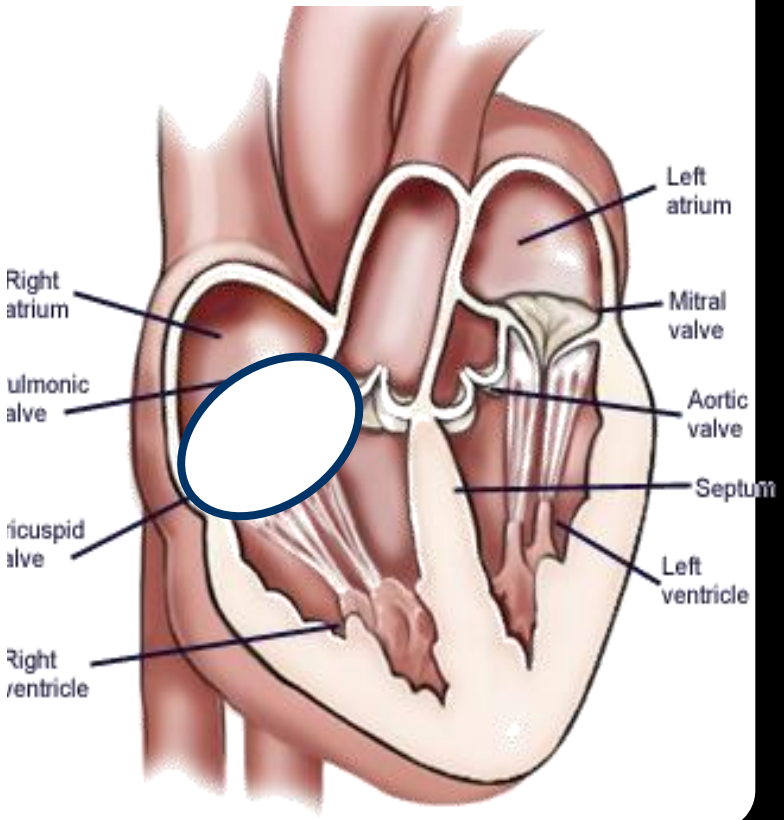
Secondary
- Dilated Cardiomyopathies
- Pulmonary hypertension
- Atrial fibrillation with annular dilatation


Right
Atrium
"aortic segment"
"anterior
segment"
Anterior
Leaflet
Septal
Leaflet
"septal
segment"
Posterior
Leaflet
TV
"posterior segment"
Tendon
of Todaro
Coronary Sinus
with Thebesian Valve

The Forgotten Valve

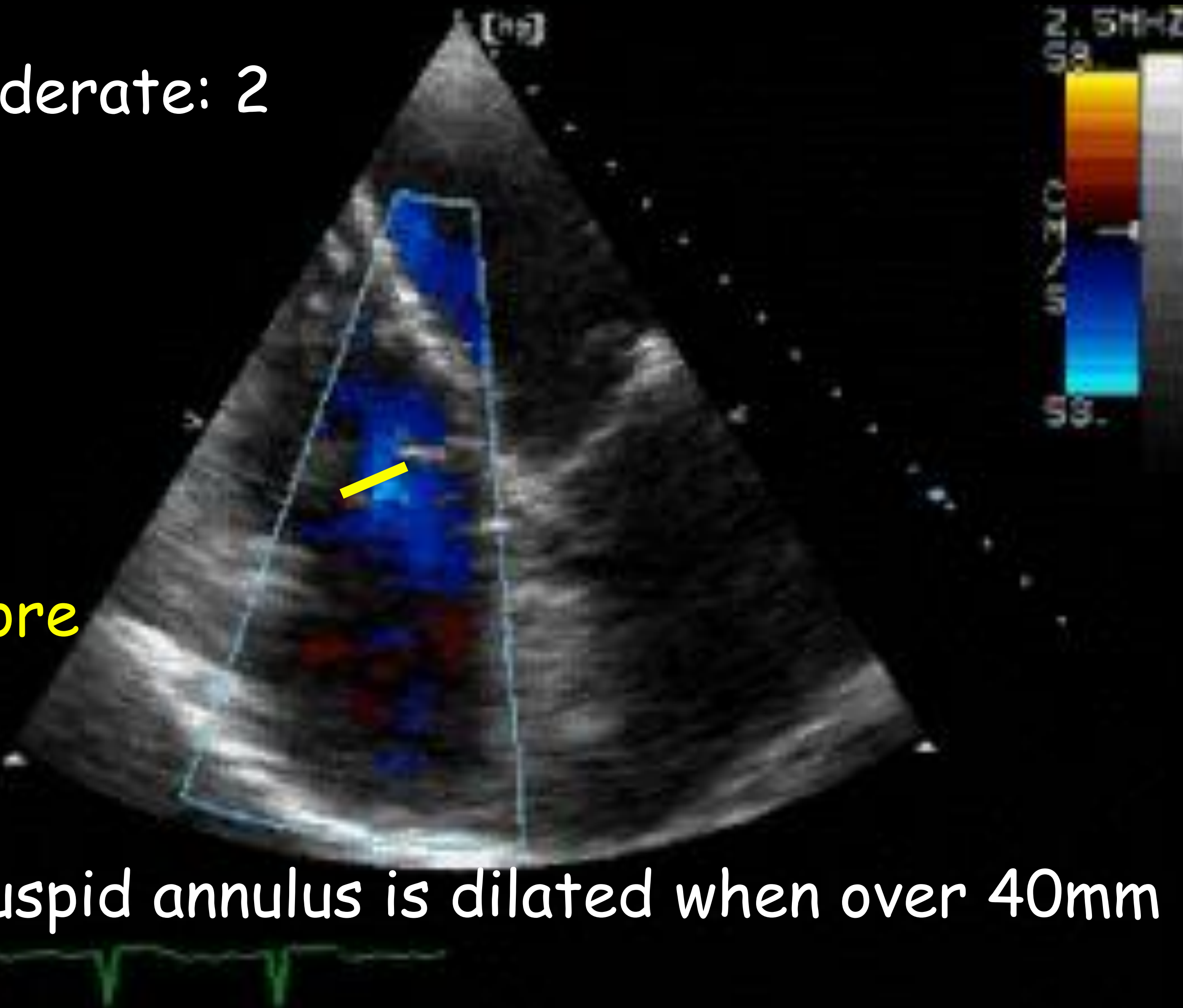
TR Etiology

- Isolated primary (organic) TR
- Secondary (functional) TR in patients undergoing left-sided valve surgery
- Late TR following left-sided valve surgery



Mild: 1

Moderate: 2

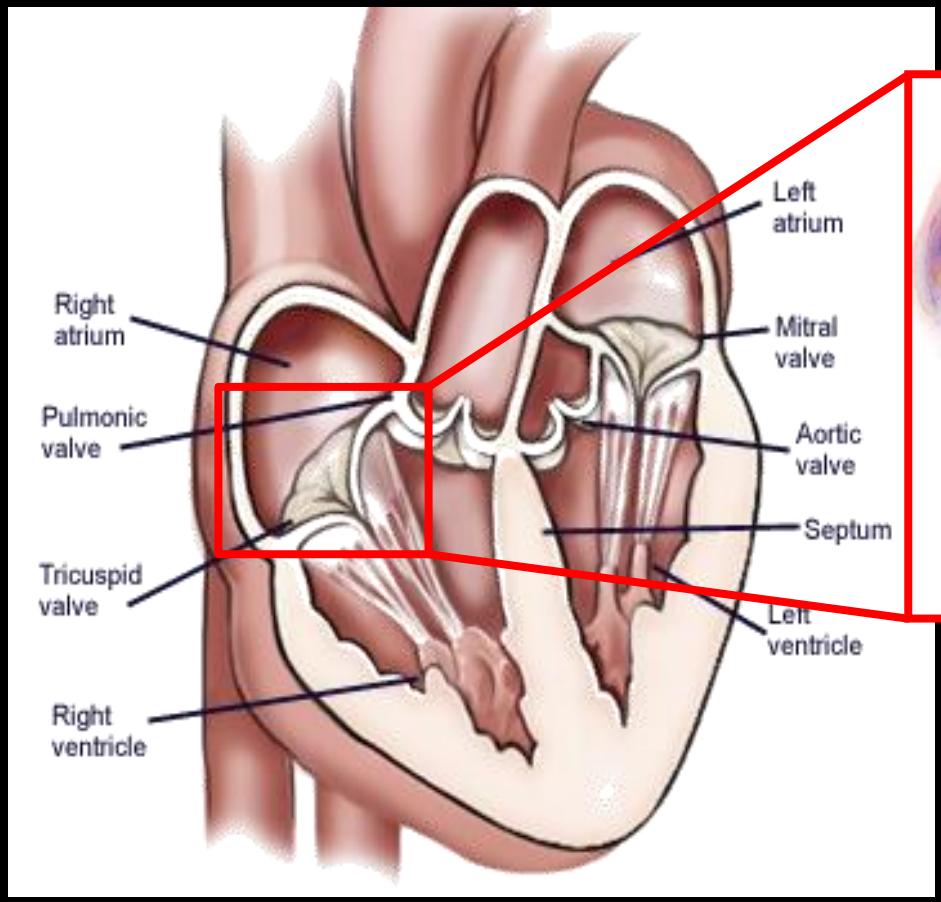


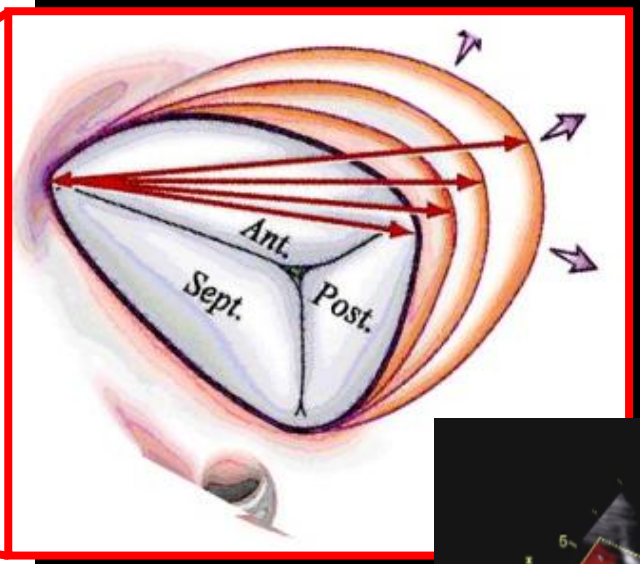
SEVERE:3
Vena
Contracta
7mm or more

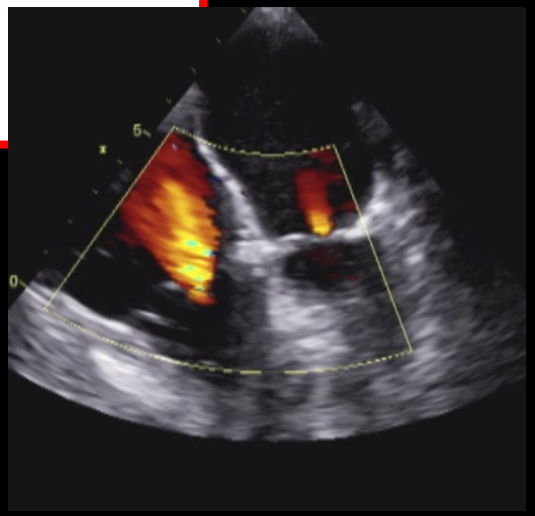
The Tricuspid annulus is dilated when over 40mm

Functional Tricuspid Regurgitation failure mode

Annular dilatation, inducing an increase of the septo-lateral distance resulting in lack of leaflets coaptation and consequent TR.

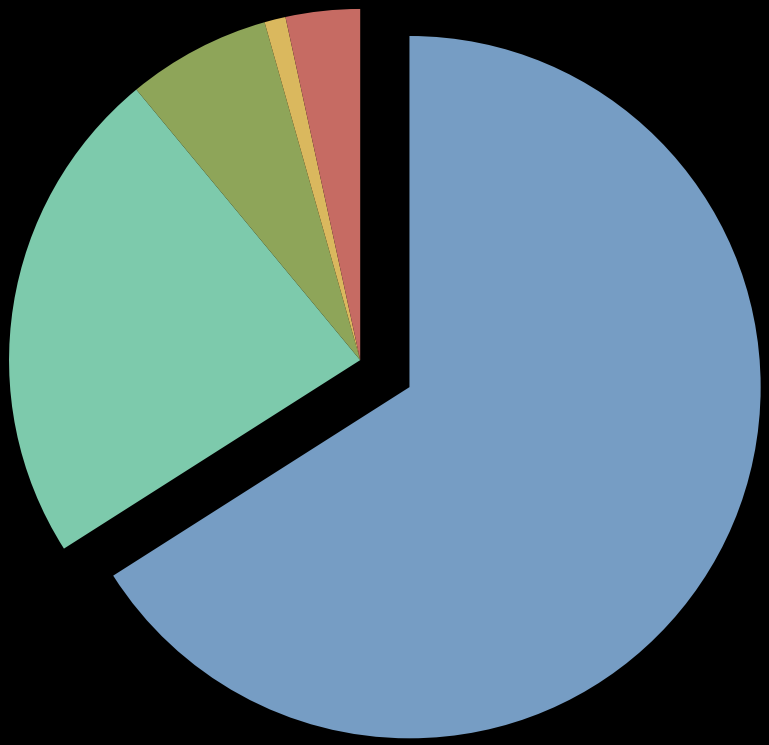






In San Raffaele Hospital from Oct 2014 till Sept 2015, 6906 echo performed,

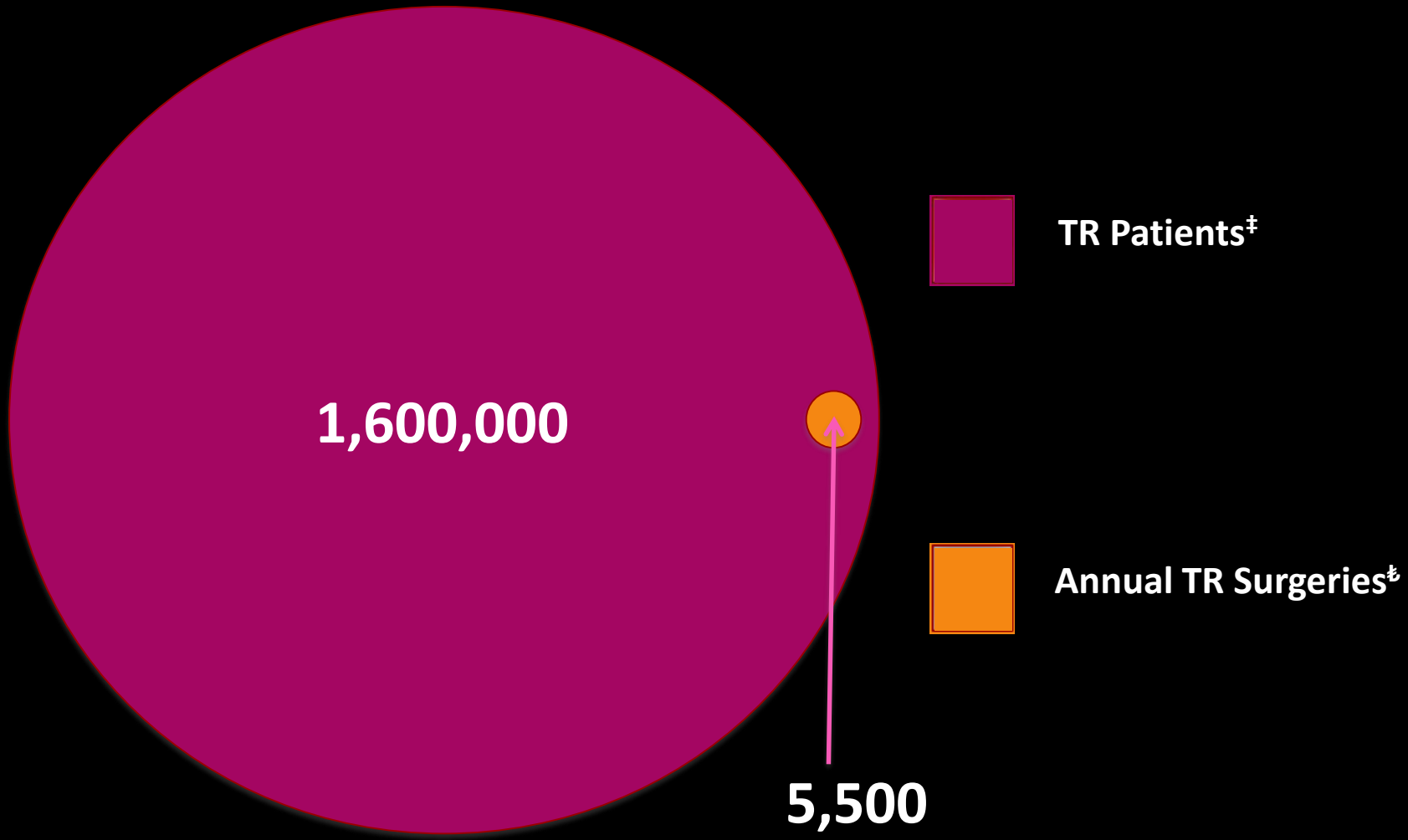
Tricuspid Regurgitation in 2022



	n°	%
NO IT	3922	66
IT 1	1368	23
IT 2	393	7
IT 3	58	1
IT 4	203	3

Considering patients with Tricuspid Regurgitation grade 2-4, only 2% had surgical correction

Tricuspid Regurgitation is largely untreated by surgery (US numbers)



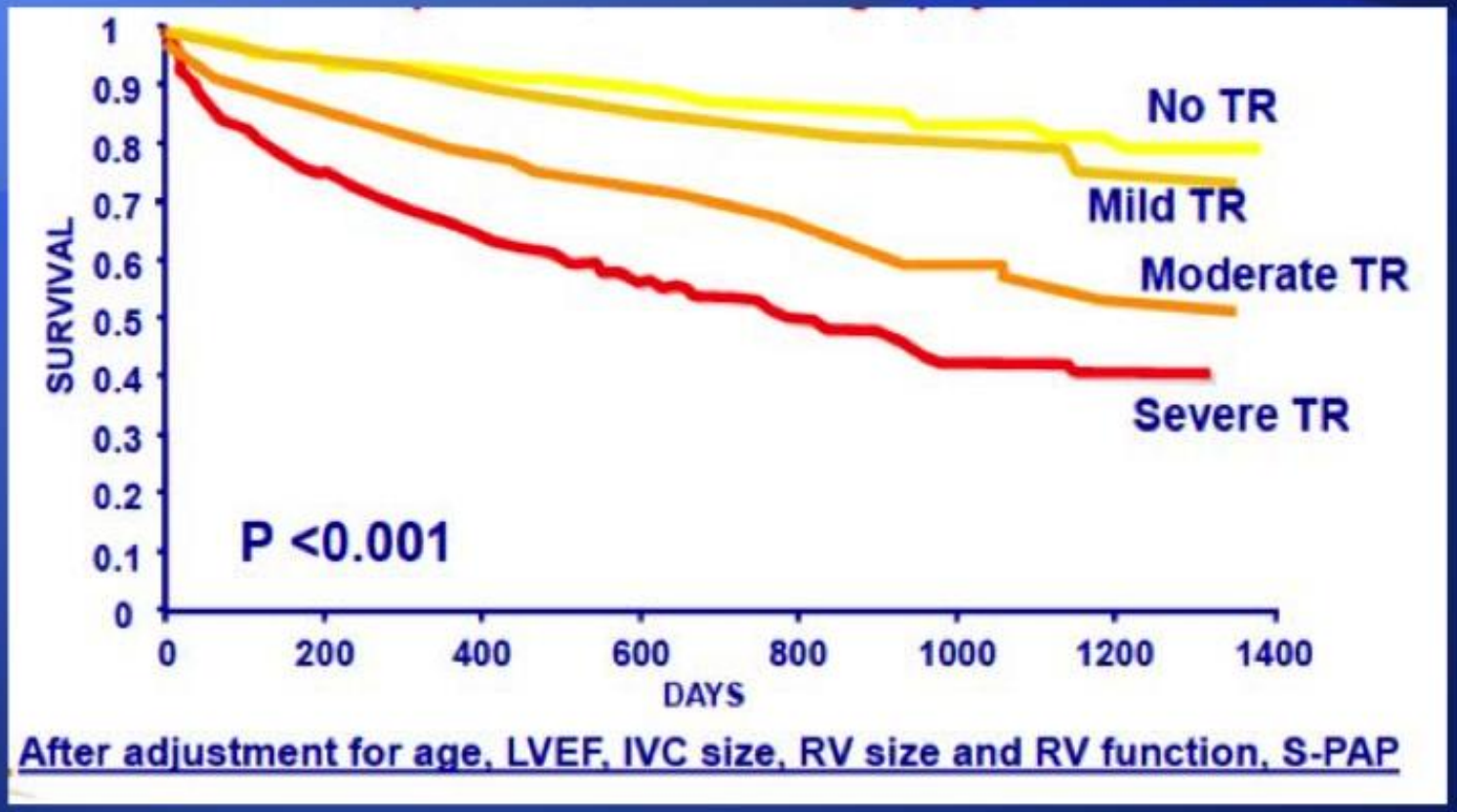
Clinical Presentation of TR

- Decreased CO
  - Fatigue, decreased exercise tolerance
- "Right-sided" Heart Failure
  - Ascites, edema, decreased appetite, abdominal fullness

…Patients feel terrible

Valve repair for functional tricuspid valve regurgitation: anatomical and surgical considerations
Rogers JH, Bolling SF Semin Thorac Cardiovasc Surg. 2010 ;22(1):84-9

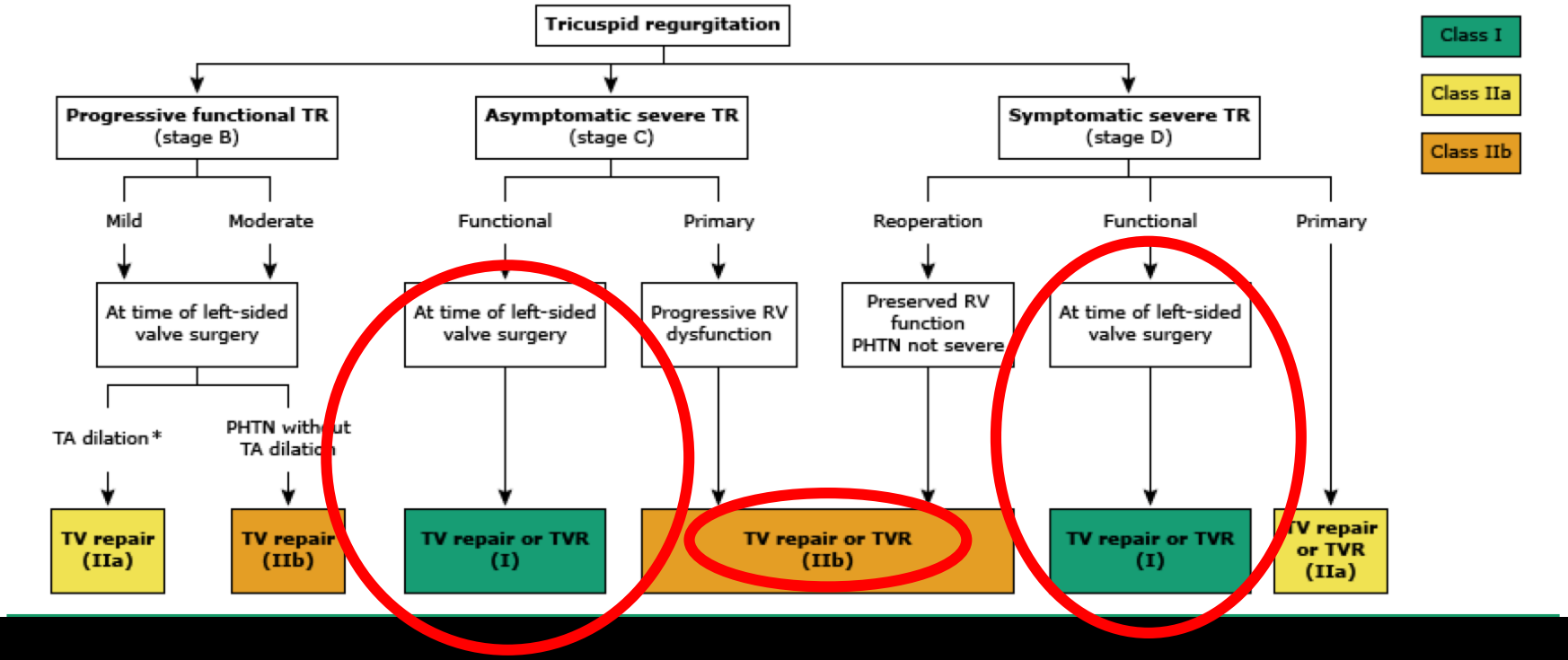
...and they die! TR Increases Mortality !



5223 subjects : Mod-Sev TR increased mortality *independent of* PASP, LVEF, IVC size, RV size/ function.

Nath. JACC 2004;43:405

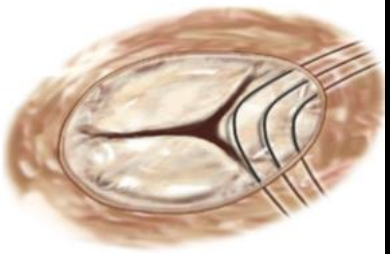
Indications for surgery for TR



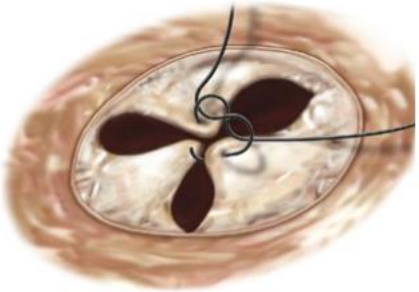
Nishimura RA, et al. 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A. J Am Coll Cardiol 2014; 63:e57.

Surgical Treatment options

Annuloplasty



De Vega Repair

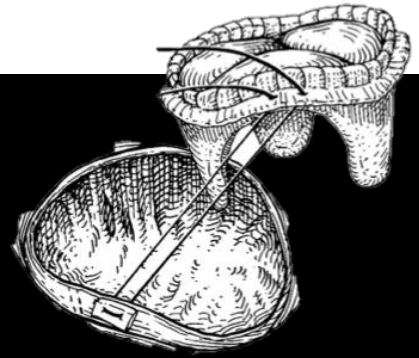


Clover Technique

Hetzer Repair

Kay Repair Technique

In-hospital mortality post-cardiac surgery for TR can go up to 37%



Surgical indications for tricuspid surgery

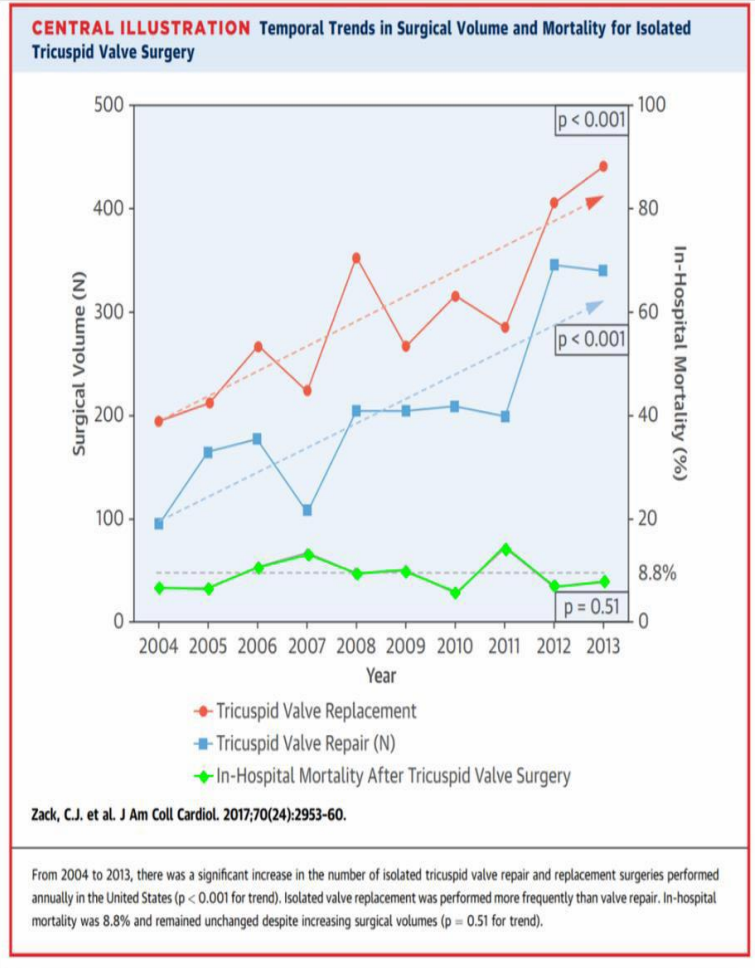
A cardiac operation is considered, especially at the time of left-sided valve surgery.

Functional TR is severe, particularly based on quantitative criteria such as ERO ≥40 mm2.

The patient is symptomatic from the TR, especially with congestive signs directly related to the TR, or marked reduction of functional capacity measured without other cause than the TR.

National Trends and Outcomes in Isolated Tricuspid Valve Surgery

Chad J. Zack, MD,[a] Erin A. Fender, MD,[a] Pranav Chandrashekar, MBBS,[a] Yogesh N.V. Reddy, MBBS,[a] Courtney E. Bennett, DO,[a,b] John M. Stulak, MD,[c] Virginia M. Miller, PhD,[c,d] Rick A. Nishimura, MD[a]

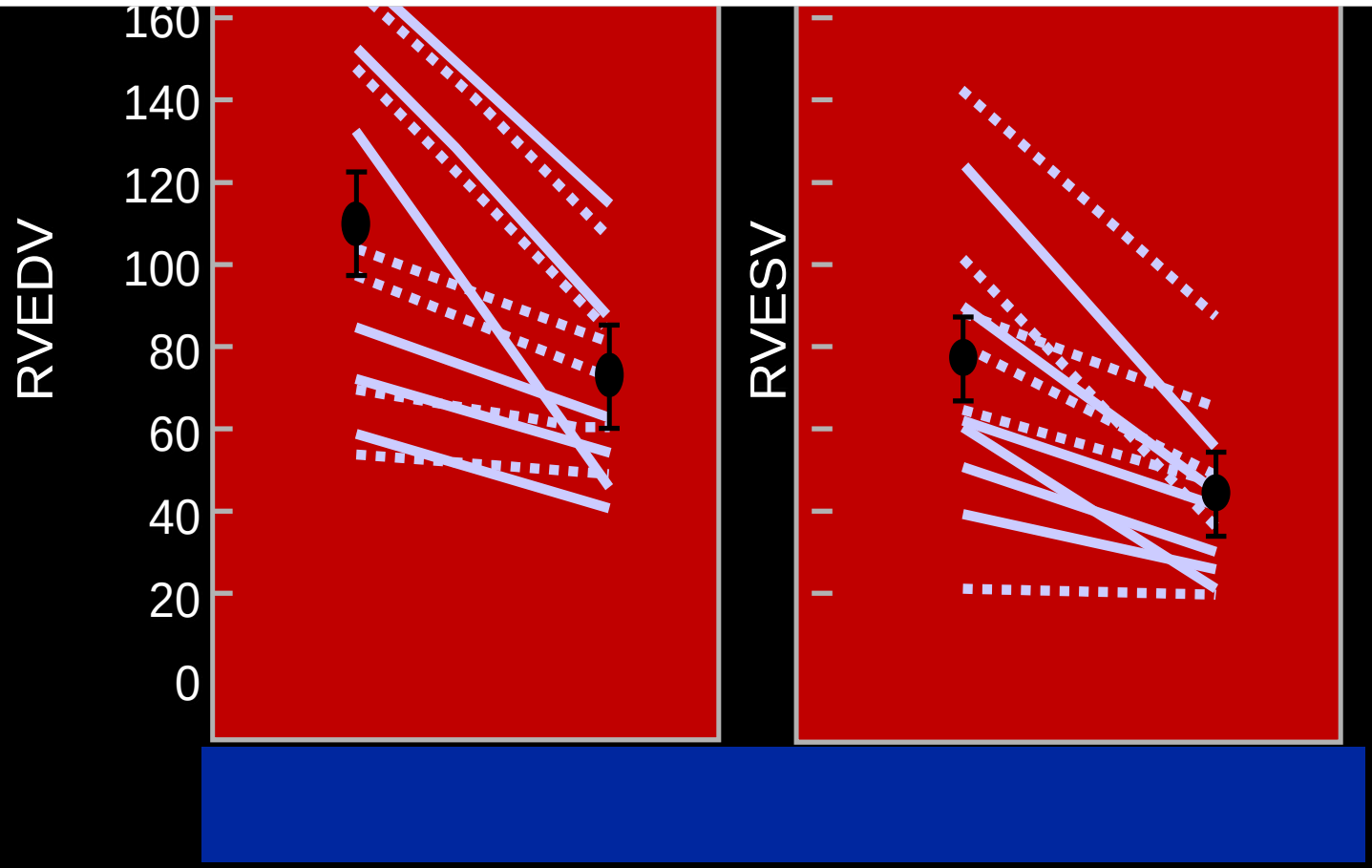


- TV replacement was performed in 59.2% of patients, whereas TV repair was performed in 40.8%.
- From 2004 to 2013, the proportion of TV replacements significantly decreased from 67.2% to 57.1% (p ¼ 0.003).

- **In-hospital mortality = 8.8% and did not vary across the study period**

Improvement in Right Ventricular Systolic Function After Surgical Correction of Isolated Tricuspid Regurgitation

Debabrata Mukherjee, MD, Simone Nader, MD, Arrel Olano, MD, Mario J. Garcia, MD, and Brian P. Griffin, MD, *Cleveland, Ohio*



When it is better not to intervene

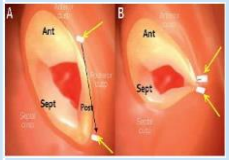
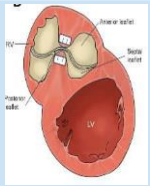
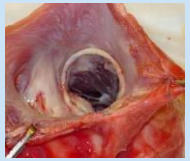
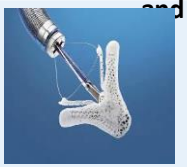
Severe right ventricular dysfunction

Severe pulmonary hypertension (>60 mmHg)

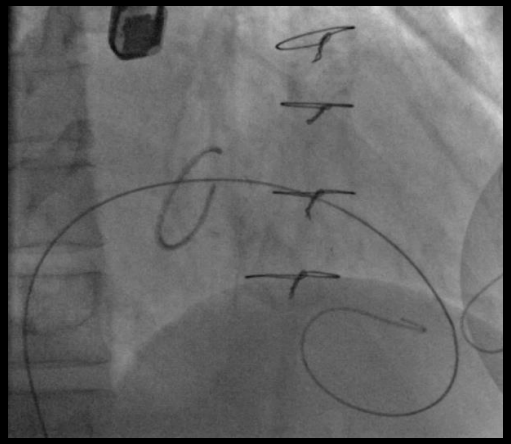
Severe disease of a left sided valve that cannot be treated

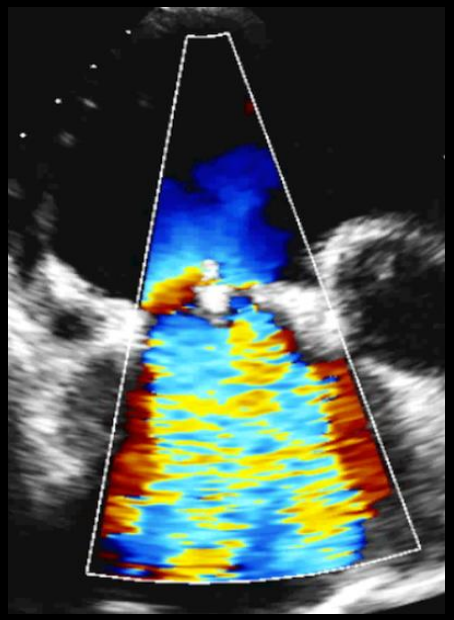
New tricuspid therapies

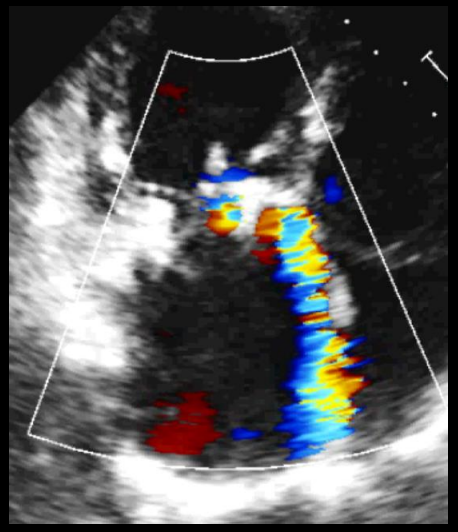
TRANSCATHETER TECHNOLOGIES

Annuloplasty (Direct and Indirect)						
	TriAlign	Cardioband	4Tech	Millepede	Pasta	Cardiac Implants
Leaflet Devices						
	Forma	MitraClip	PASCAL			
Stented Valves in IVC/SVC						
		TriCentro	SAPIEN in IVC			
Valve Replacement						
	Navigator	Tristar				

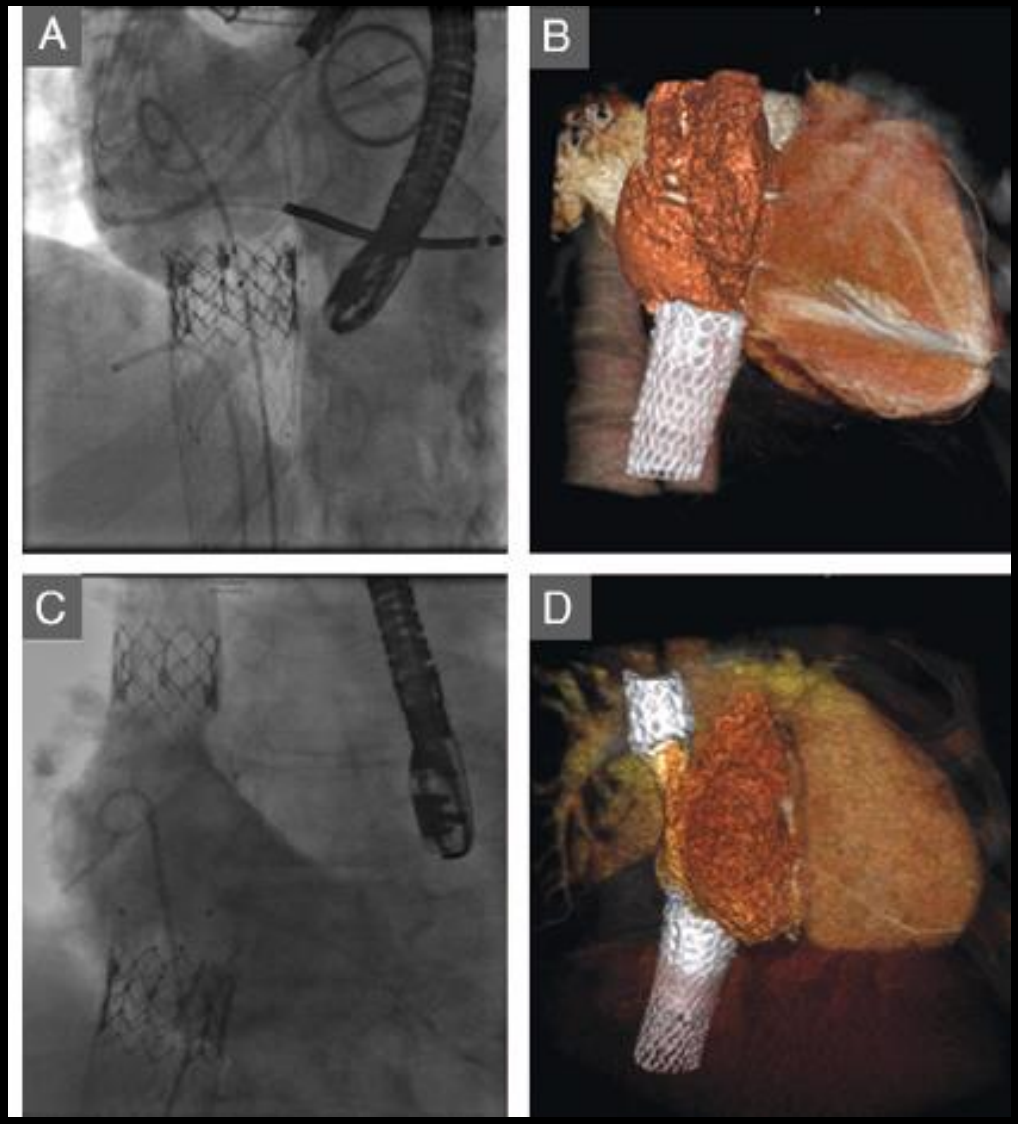
Valve in Ring







Heterotopic Valve Implantation



(Laule et al. J Am Coll Cardiol 2013;62:B41-2.)

Heterotopic Valve Implantation

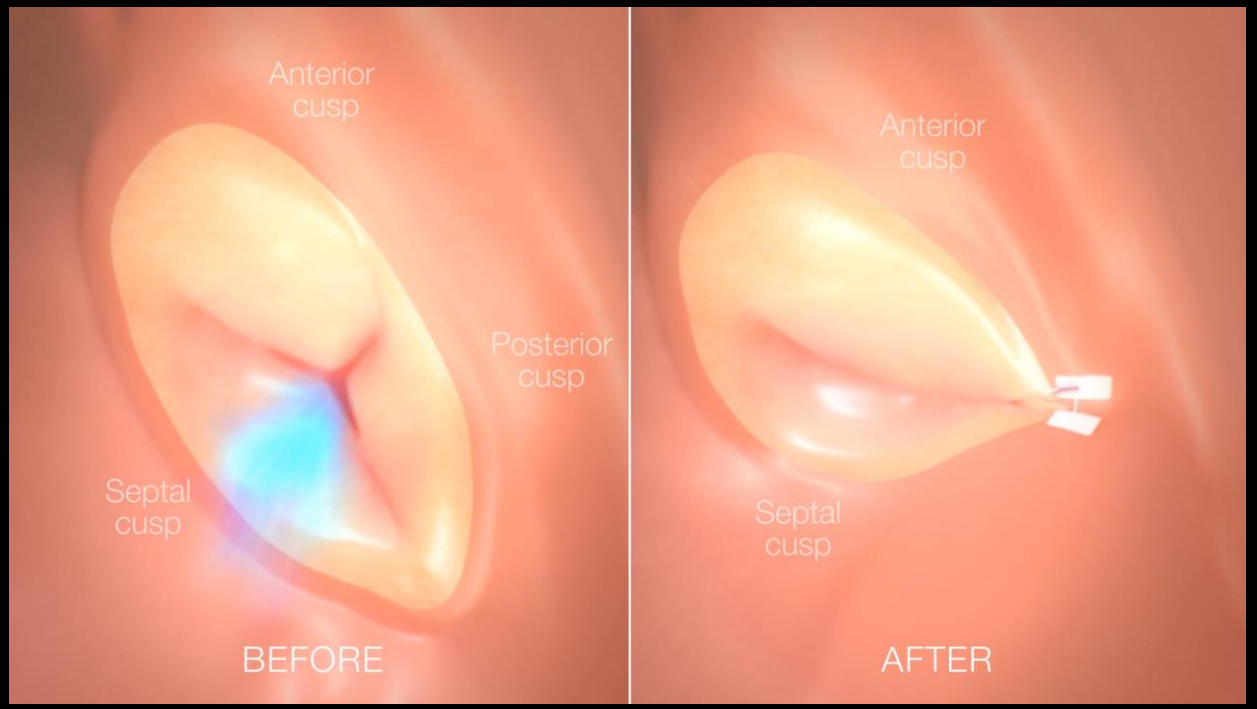
- 3 high-risk patients. EuroScore >40%
- 2 with Valve implantation in IVC, 1 in IVC+SVC
- At 30 days:
  - functional improvement
  - less peripheral oedema, ascites
  - mild decrease in RVEDV
  - stable RVEF

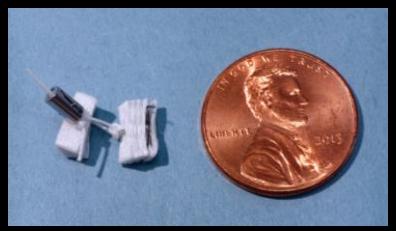
(Laule et al. J Am Coll Cardiol 2013;61:1929-1931)

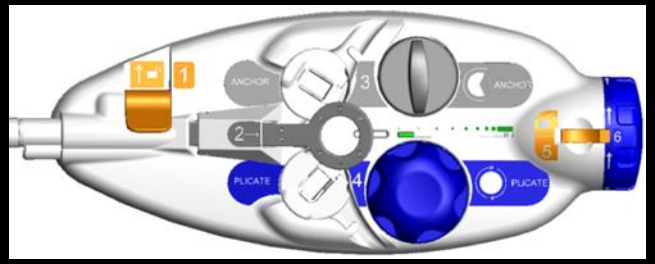
Mitralign System for tricuspid valve repair

Procedural Steps

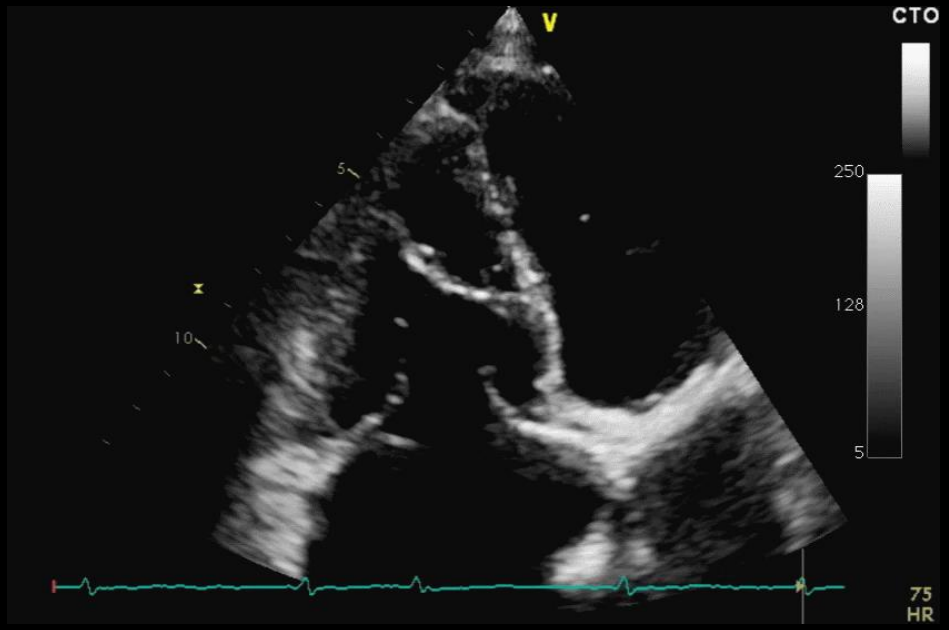
- Jugular Access
- 40cm 14F Sheath
- Hook around wire delivery to deliver 1st pledget (anchor)
- Repeat wire delivery steps to deliver 2nd pledget (anchor)
- Cinch pledgets together to obliterate the posterior leaflet and deliver lock on atrial side

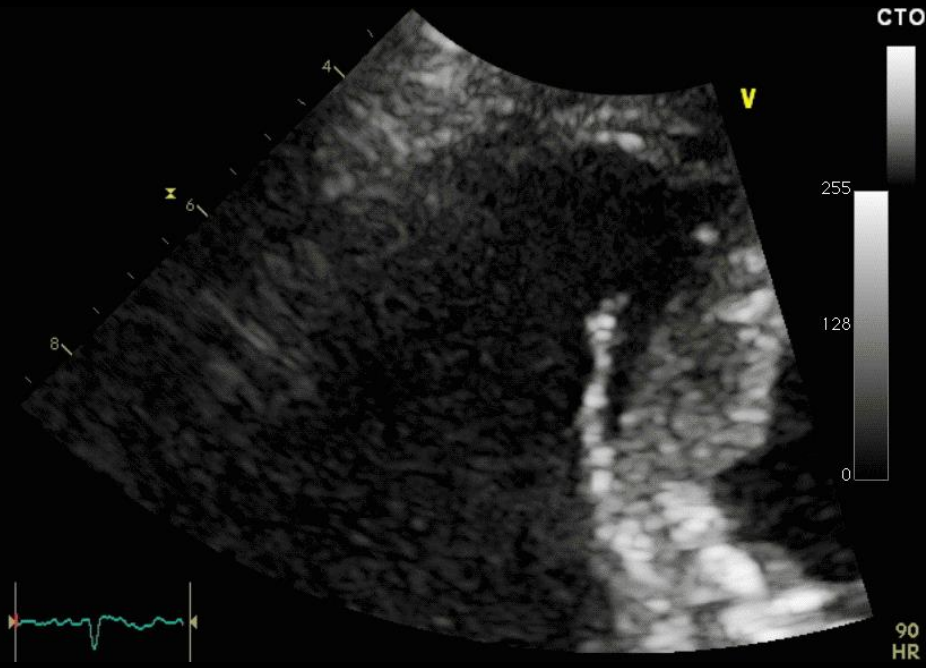






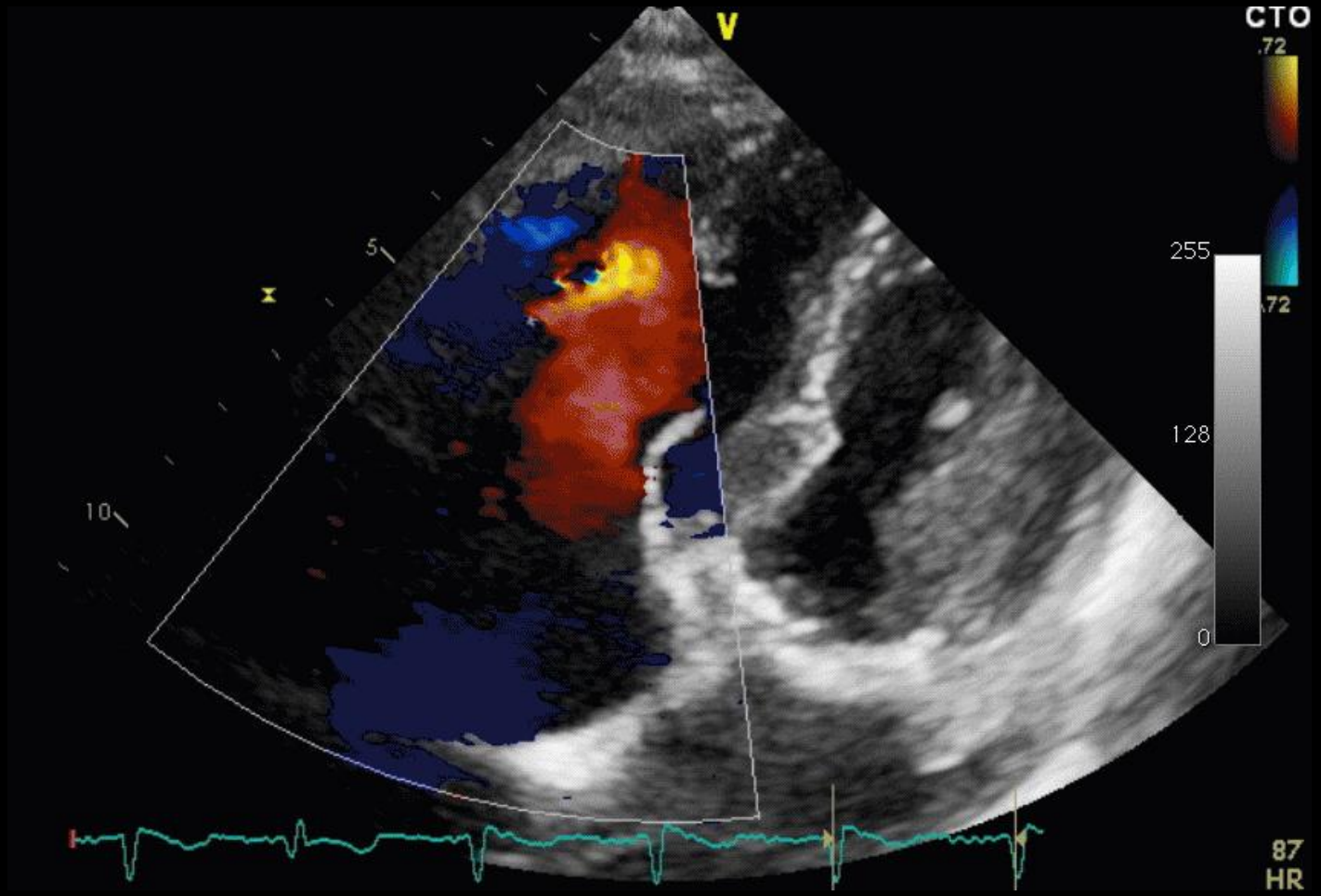
Case done in San Raffaele Hospital
TEE Baseline





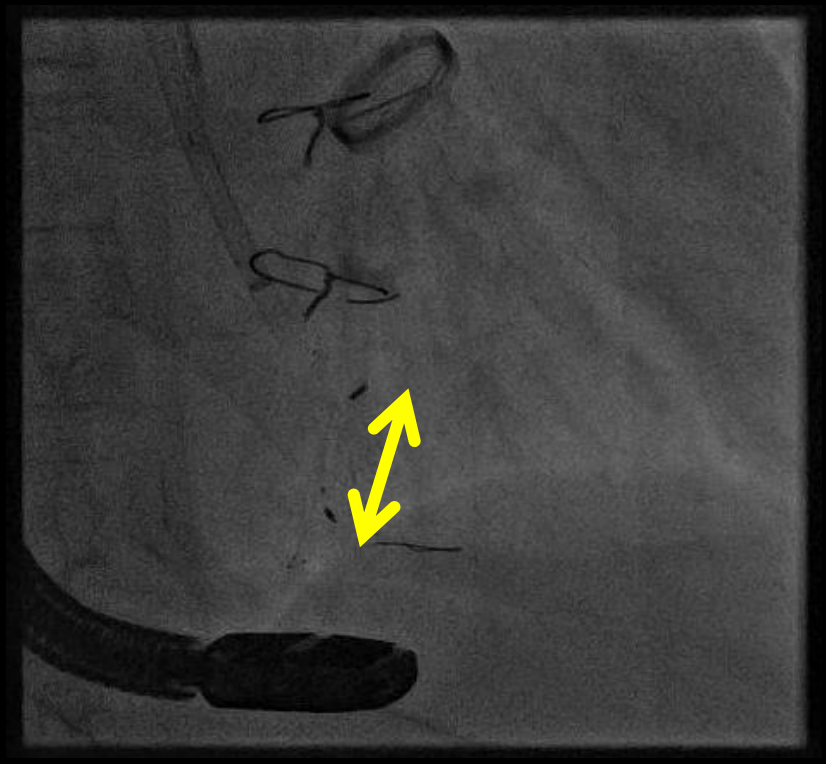
Note complete lack of coaptation!

Baseline Echo



Implant Fluoroscopy

Before treatment



Before plication

After treatment

After plication

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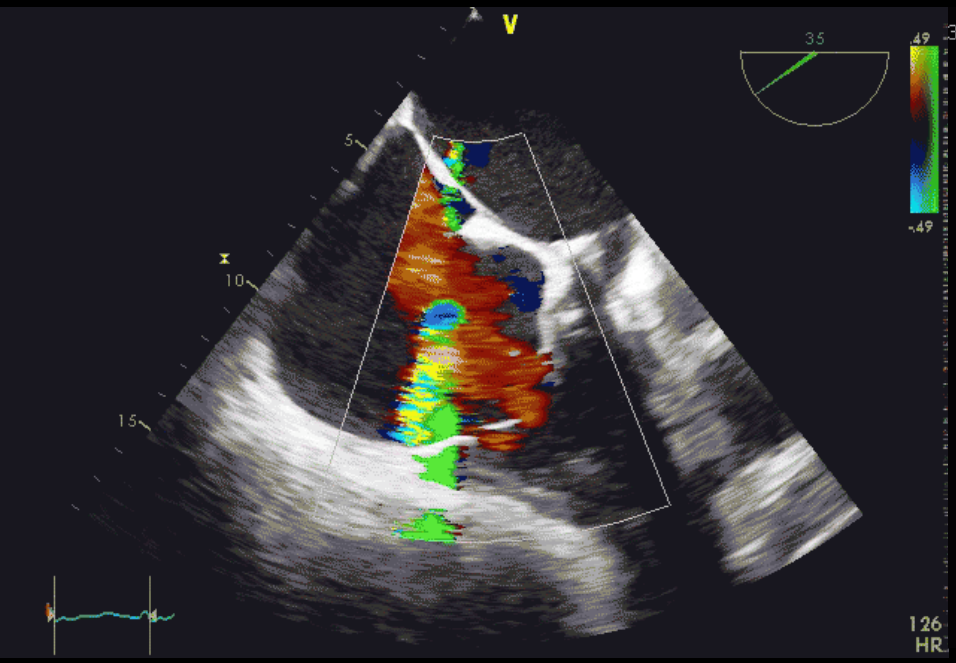
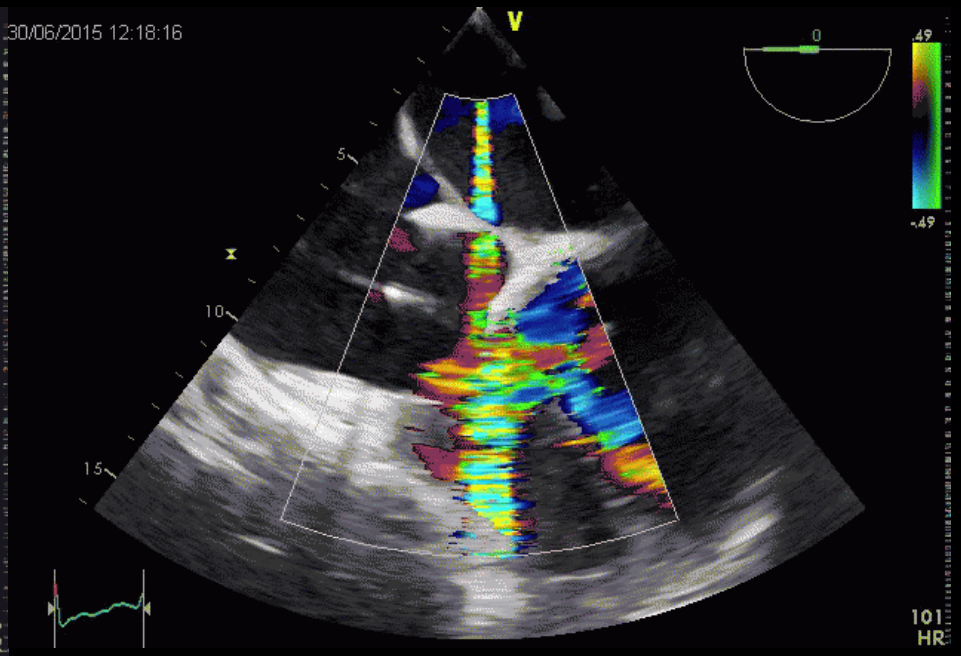
Tricuspid Regurgitation Comparison

Before treatment



Before

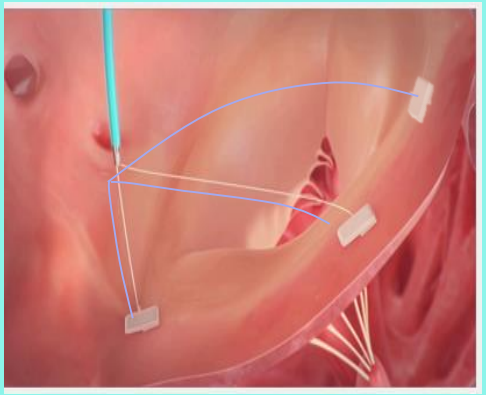
After treatment

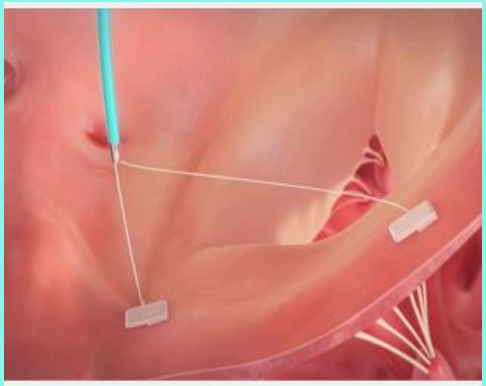


After

Acute Procedural Success

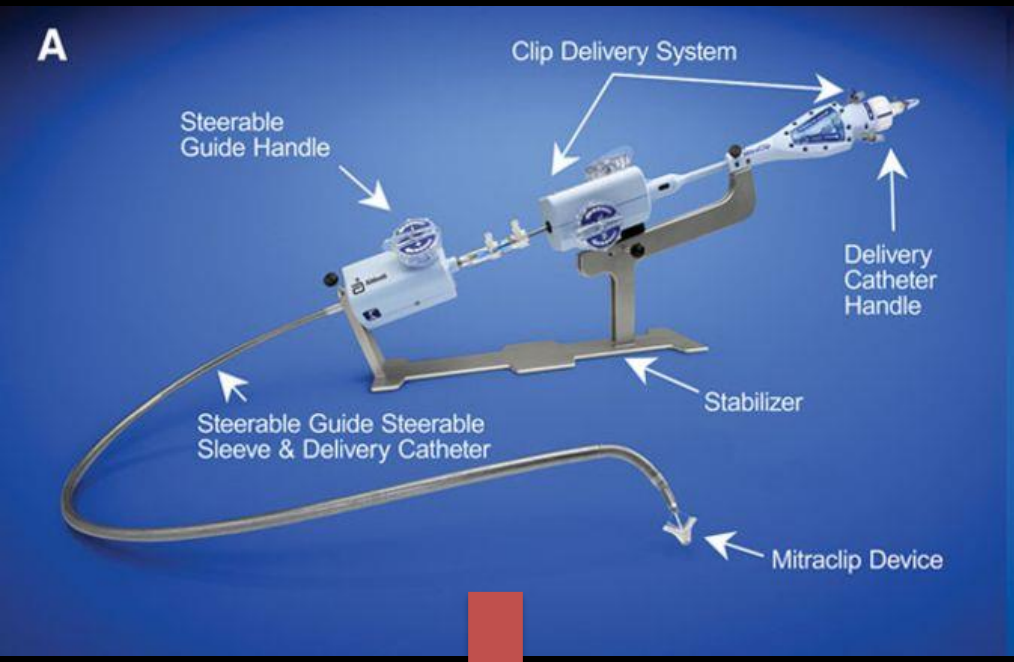
- Device Delivery
  - –8/10 patients received pledget implants
    - •2 patients: annular tissue was fragile
  - –Implant Configuration
    - •2 pledgets: n=6
    - •3 pledgets: n=2
- Procedural Efficacy
  - –Tricuspid regurgitation:
    - •6/8 patients showed TR reduction acutely
    - •1/8 patient showed no TR reduction but had PAP>100
  - –Annular Reduction
    - •8/8 patients demonstrated annular changes
      - –Annular shape
      - –Annular circumference

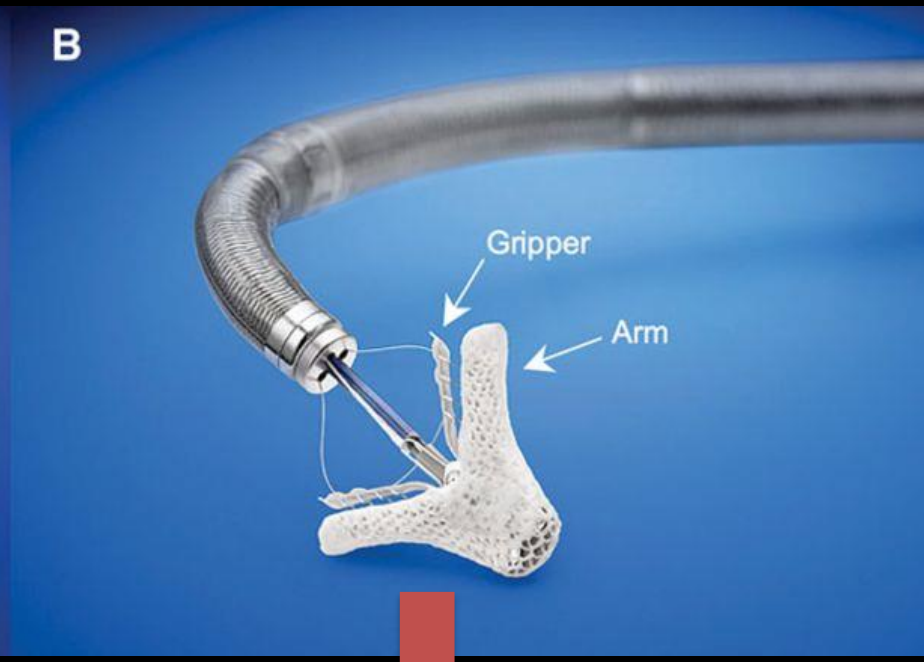


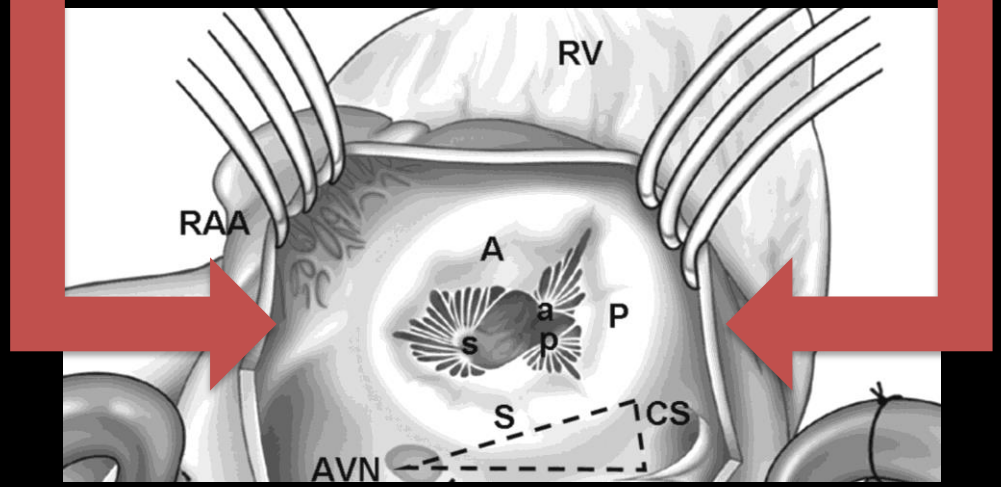


MitraClip on Tricuspid Valve

More than 600 pts. treated world wide



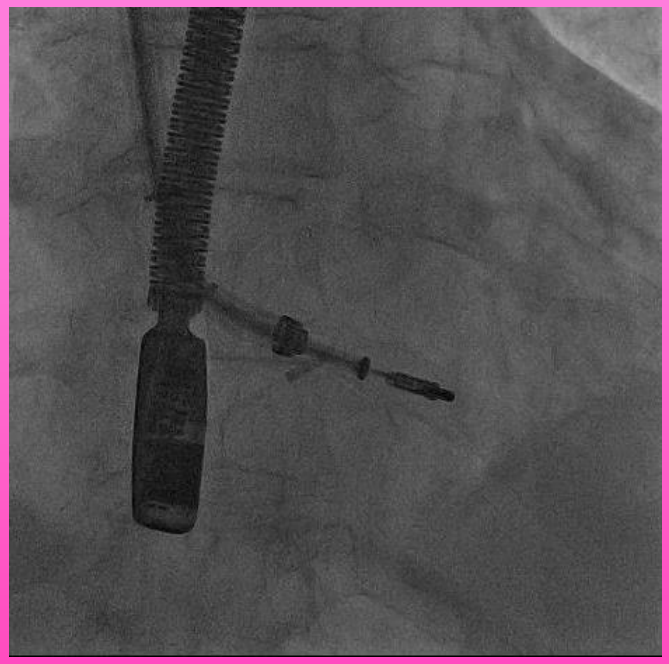


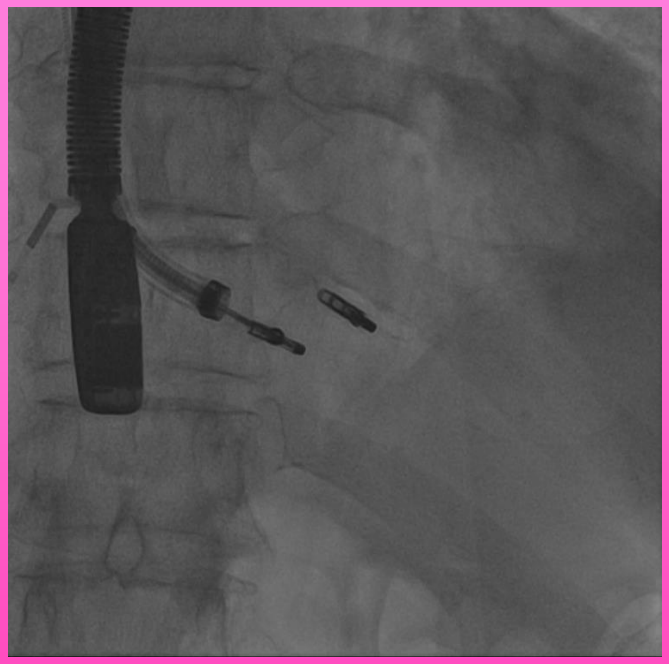


Procedural steps and clips' location

Trans-jugular access, implantation of 2 Mitraclip

- → **First clip**: antero-septal commissure
- → **Second clip:** medial to previously implanted

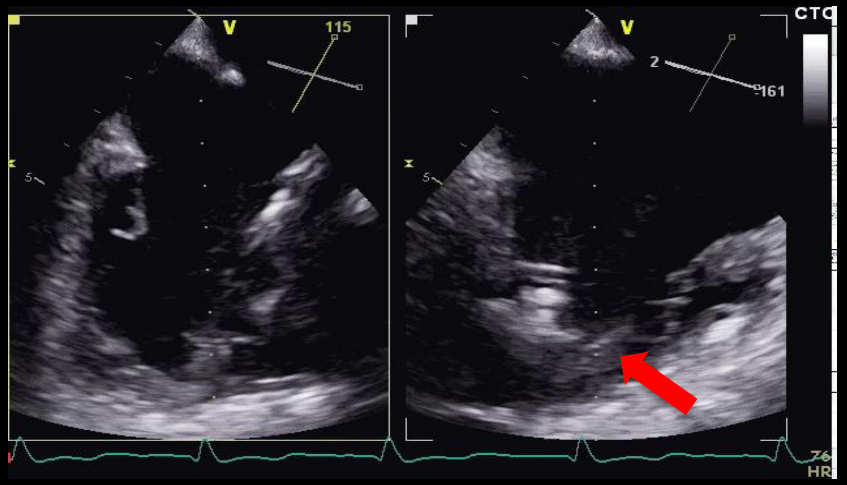




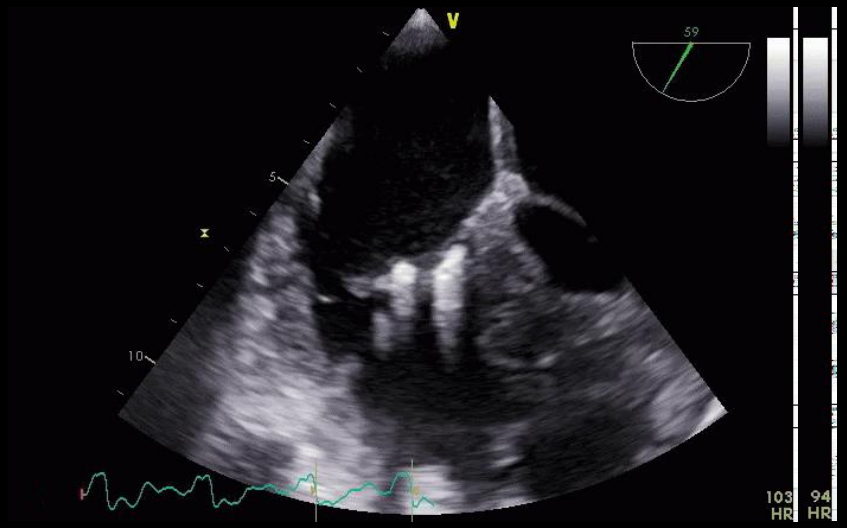
Bicuspidalization of the valve with good echographic result (residual moderate regurgitation)

Intra-procedural TEE monitoring

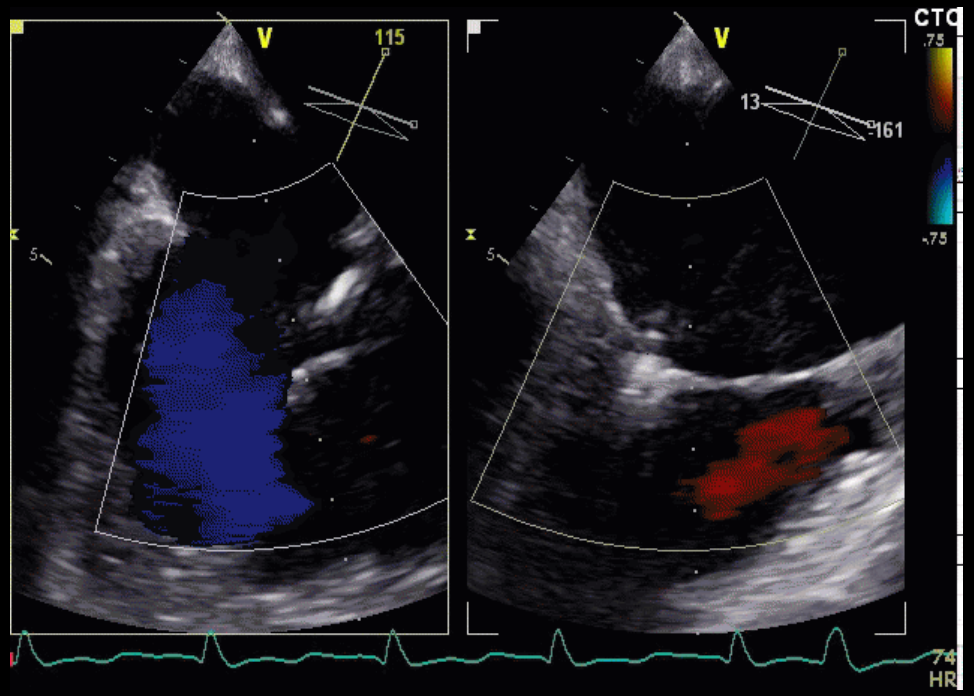
First Clip pre-grasping



Second Clip implanted
First Clip implanted

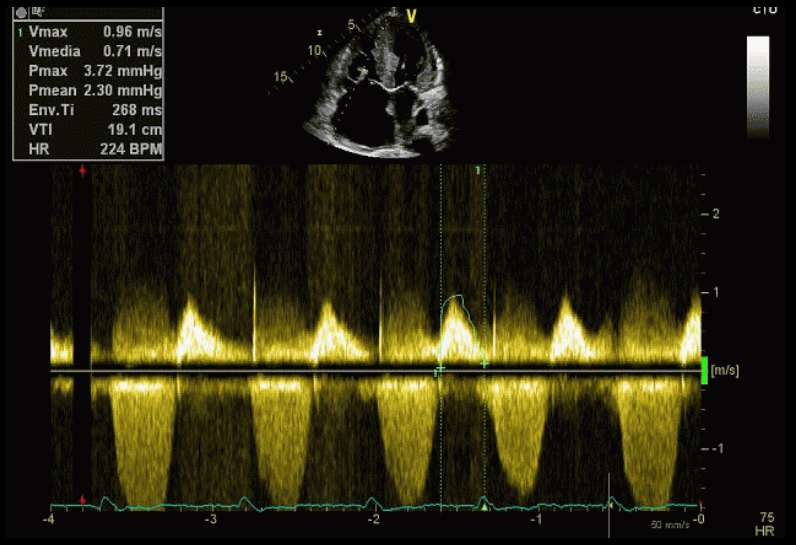


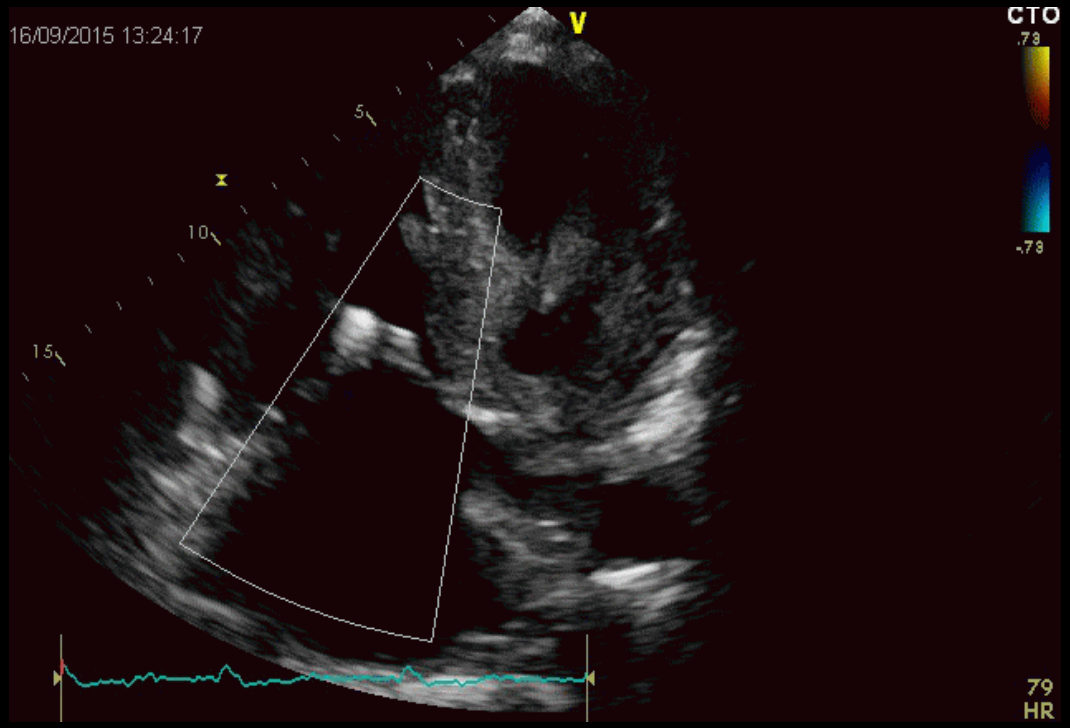
Final result with residual moderate regurgitation and no stenosis

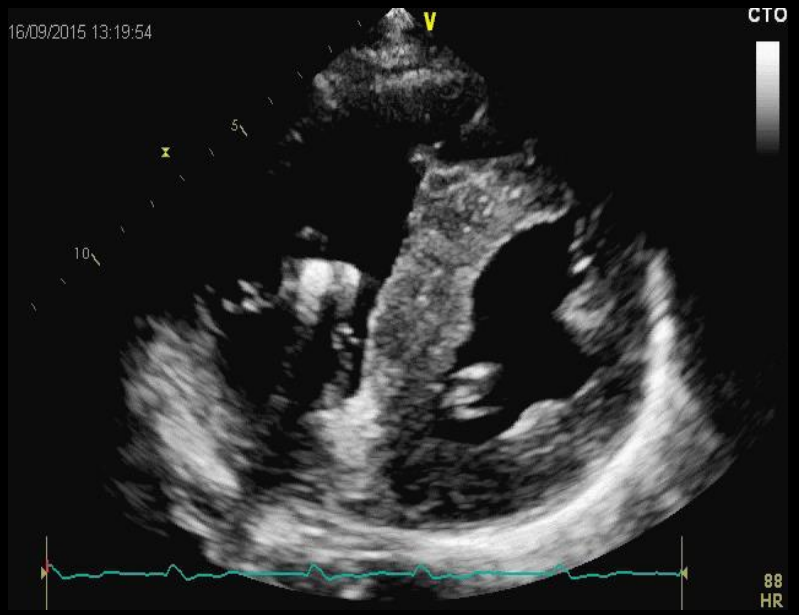


Echocardiographic results at 1 month follow-up

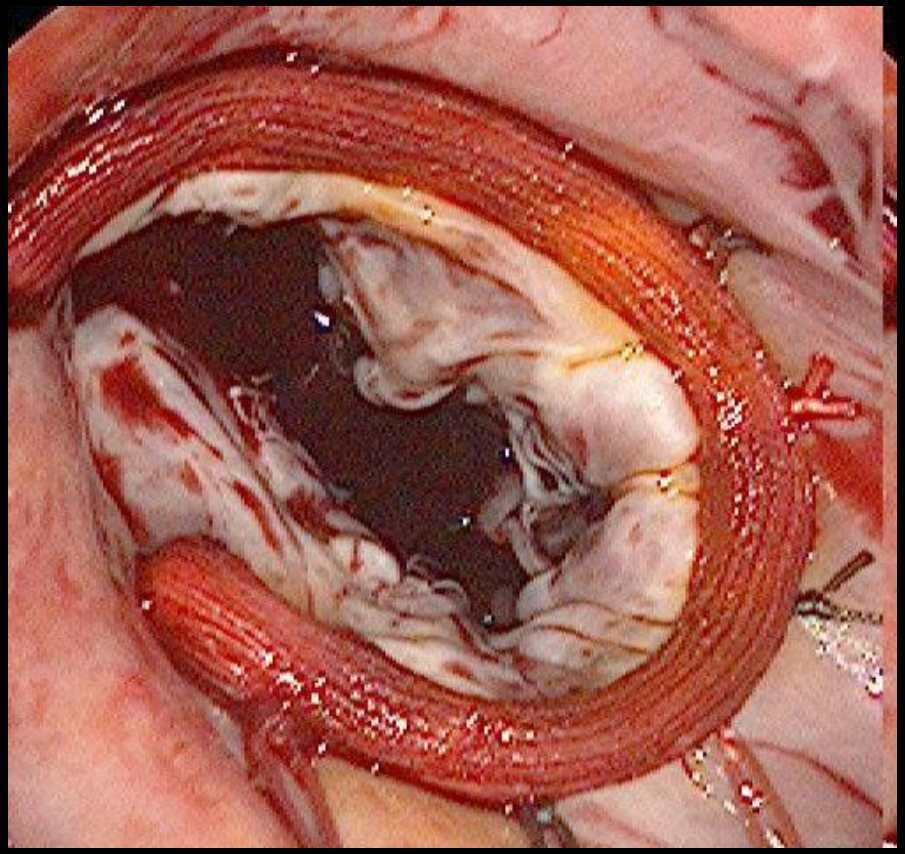
- NYHA class II
- *Normal liver function*
- *moderate renal failure*





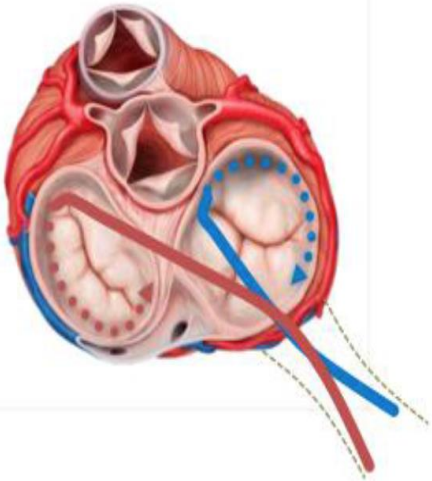


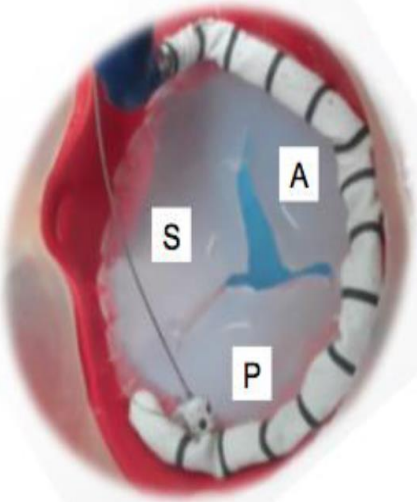
Gold standard surgical treatment: remodelling annuloplasty

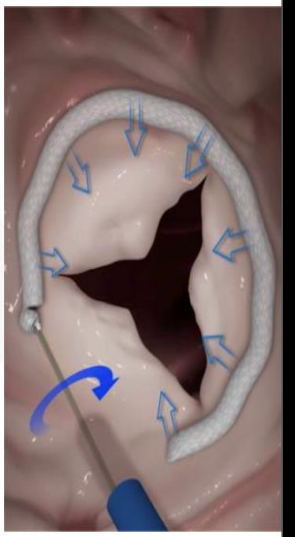


Cardioband Tricuspid

- Cardioband Tricuspid is an adjusted Cardioband Trans Femoral (CBTF – CE approved for mitral regurgitation treatment).
- Proven safety and performance with over 90 mitral patients.
- Quick learning curve to CBTF users.
- Applying the surgical gold standard with a trans femoral approach.







Replacement: 11 human cases reported

BusinessWire
A Berkshire Hathaway Company

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NaviGate Cardiac Structures Inc. ("NCSI") Reports World's First Transcatheter Tricuspid Valved Stent is Successfully Implanted

December 30, 2016 01:04 PM Eastern Standard Time

LAKE FOREST, Calif.--(BUSINESS WIRE)--**NaviGate Cardiac Structures Inc. ("NCSI")** announced today that a novel valved stent that can capture the enlarged annulus in patients suffering from functional tricuspid regurgitation (FTR) was implanted in a patient presenting with massive incompetence of the tricuspid valve.

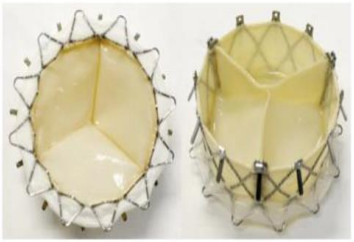
"This patient's annulus measured 49.7 millimeters in diameter, and there are currently no valved stents that can secure such a dimension without extending into any of the chambers and still provide valvular function, yet there are

The patient, a 64-year-old female with an extensive history of severe tricuspid regurgitation (TR 4+) that invariably results in right heart failure (RHF), a lethal condition, was successfully treated with the **GATE™** tricuspid Atrioventricular Valved Stent (AVS) from NCSI. The cardiac team from the Cleveland Clinic, recognized as the number-one cardiac medicine center in the USA for 22 consecutive years, implanted the AVS with catheter-guided technique under a compassionate plea from the patient. (A compassionate plea allows a special

NaviGate

Tricuspid Valved Stent and Delivery Systems

Components Specifications



- Temperature Shape Memory NiTinol Tapered Stent
- Height profile 21 mm, Truncated Cone configuration with a Diffuser Effect
- Annular Winglets for secure anchoring of TV annulus and tricuspid valve leaflet
- Sizes= 36mm, 40mm, 44mm, 48mm, and 52mm
- Chemically Preserved Xenogeneic Pericardium

Delivery System

- Presently 35F profile at the distal capsule
- 24F catheter shaft
- Two degrees of motion at tip
- 90° Articulation
- Controlled Valve Release
- The delivery use the same valve configuration

Take Home Message

- Tricuspid regurgitation is a frequent valvular disease
- Most of the patients with tricuspid regurgitation are left untreated (only medical therapy)
- Effective treatment improves RV dimensions and may affect survival
- Minimally invasive treatment may be instituted with low risk in early phase of Tricuspid Regurgitation with possible long term benefit