Advances in Cardiovascular Arrhythmias –
Great Innovations in Cardiology

Torino, 13-15 ottobre 2016

Heart Failure Session

Treatment of severe tricuspid regurgitation: the interventional cardiologist point of view

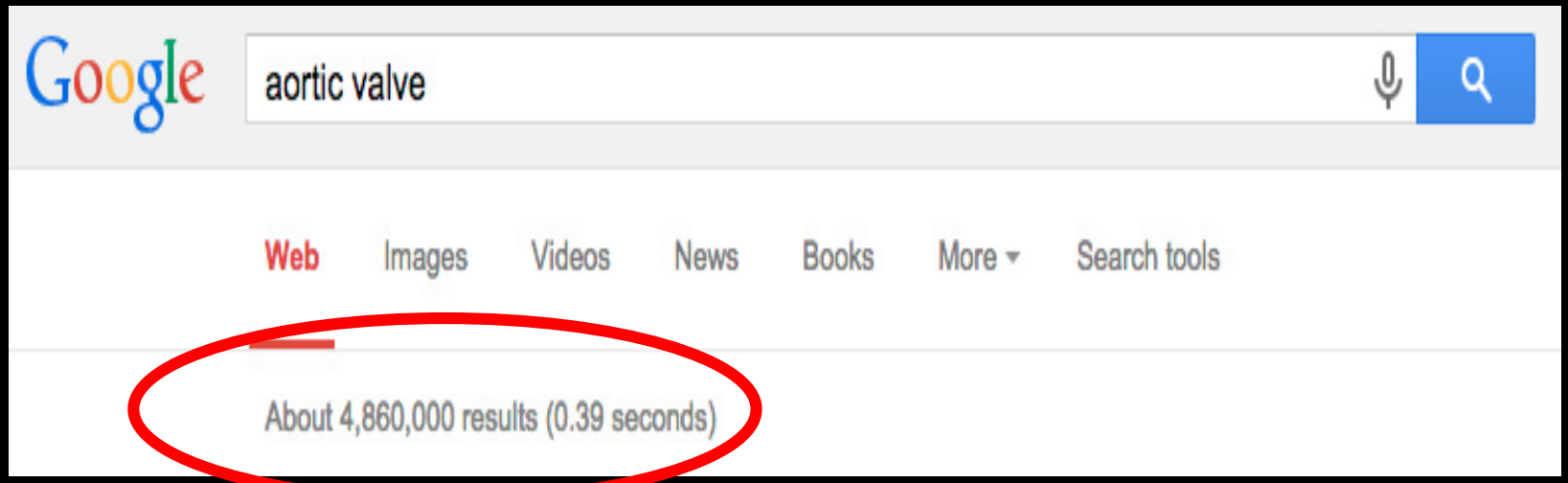
Speaker – 20'

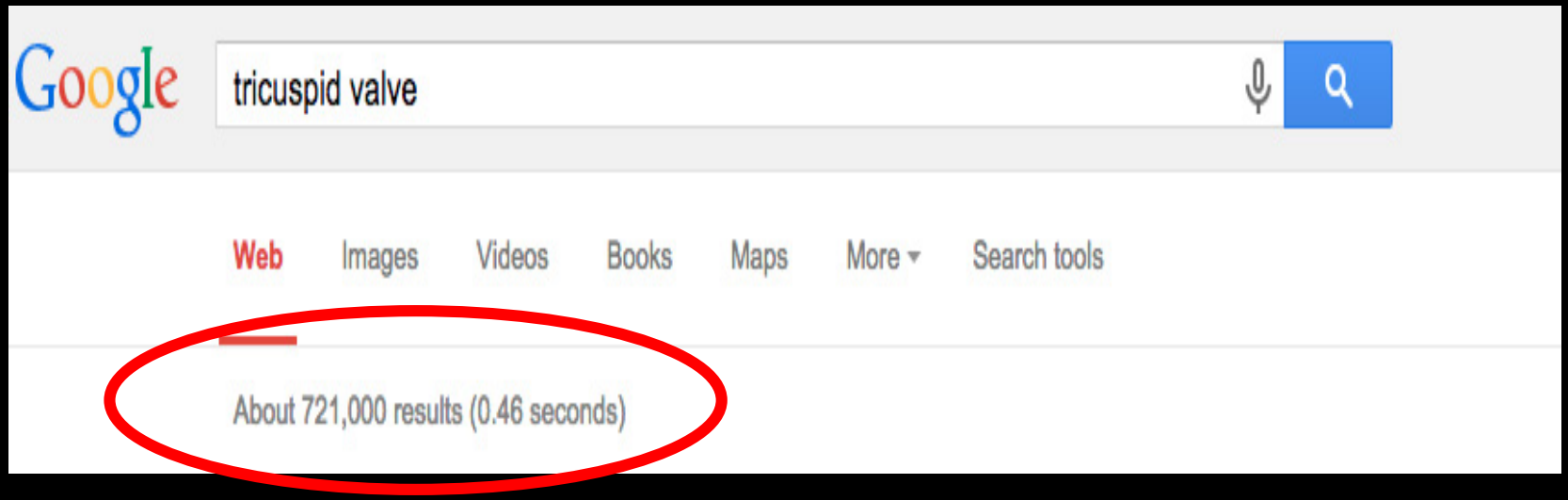
Antonio Colombo

Centro Cuore Columbus and
S. Raffaele Scientific Institute, Milan, Italy

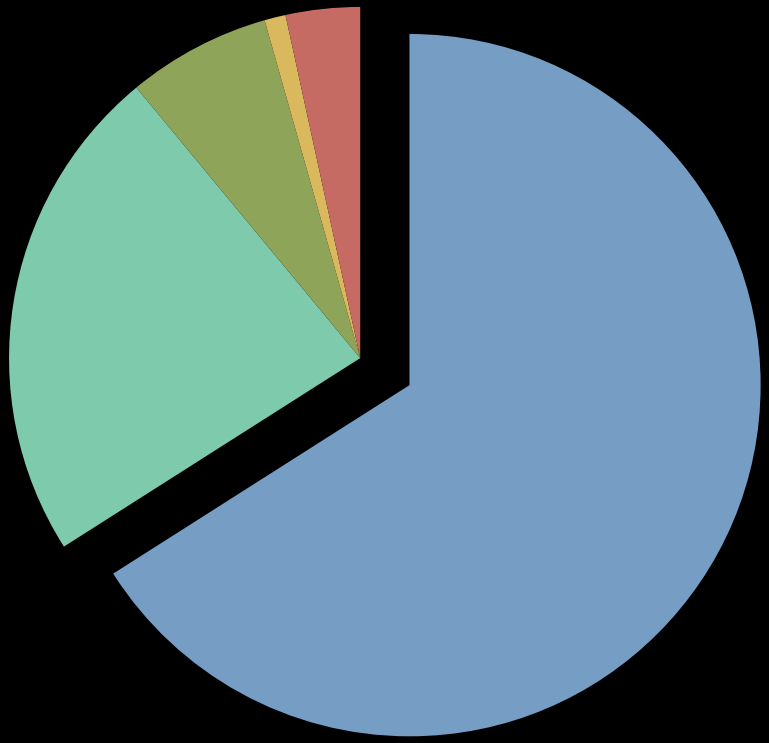
Mild: 1

Still a forgotten valve





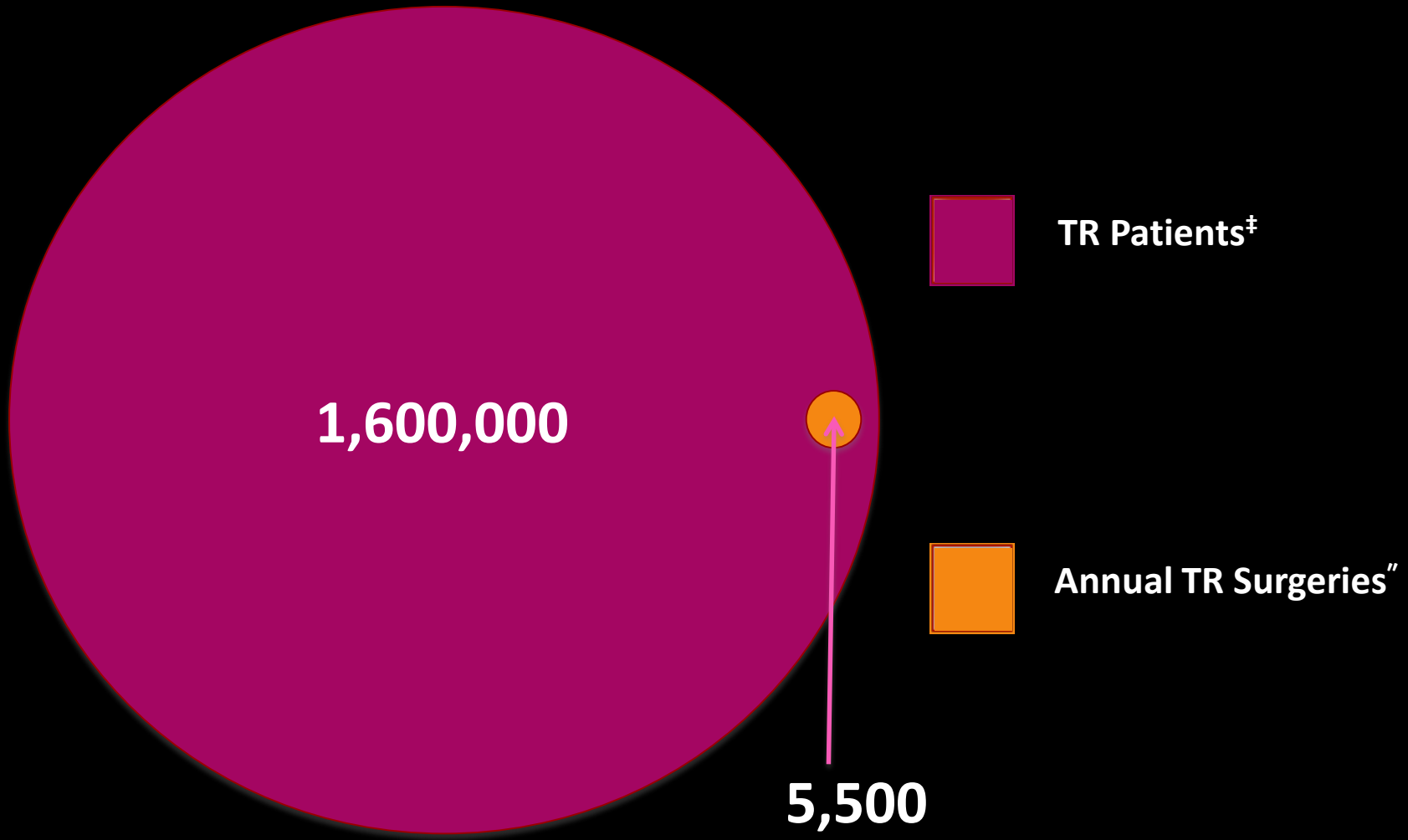
In San Raffaele Hospital from Oct 2014 till Sept 2015, 6906 echo performed, Tricuspid Regurgitation in 2022



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

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

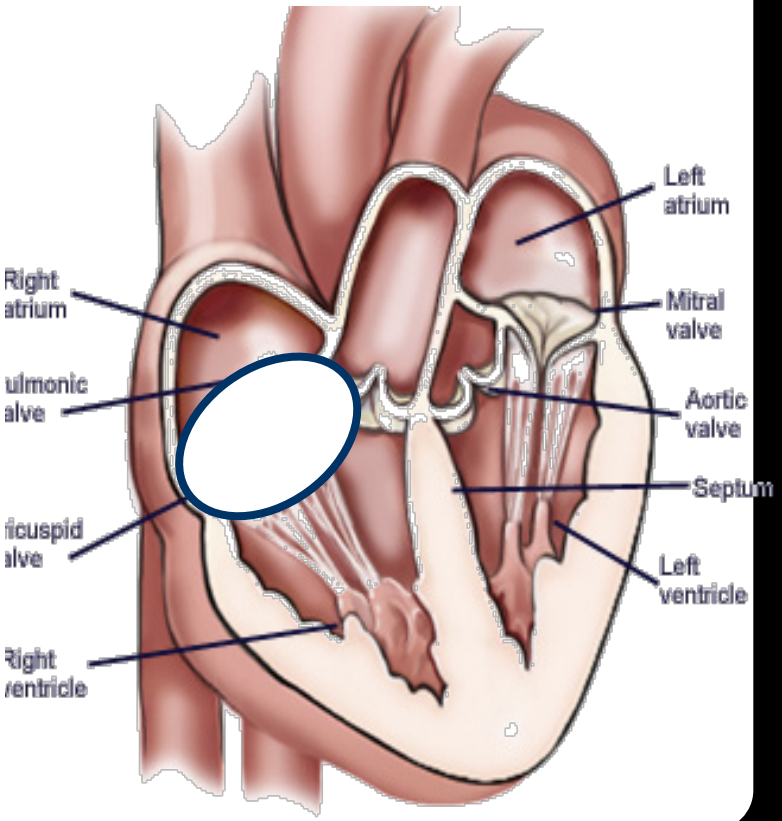
Tricuspid Regurgitation is largely untreated by surgery (US numbers)



The Forgotten Valve

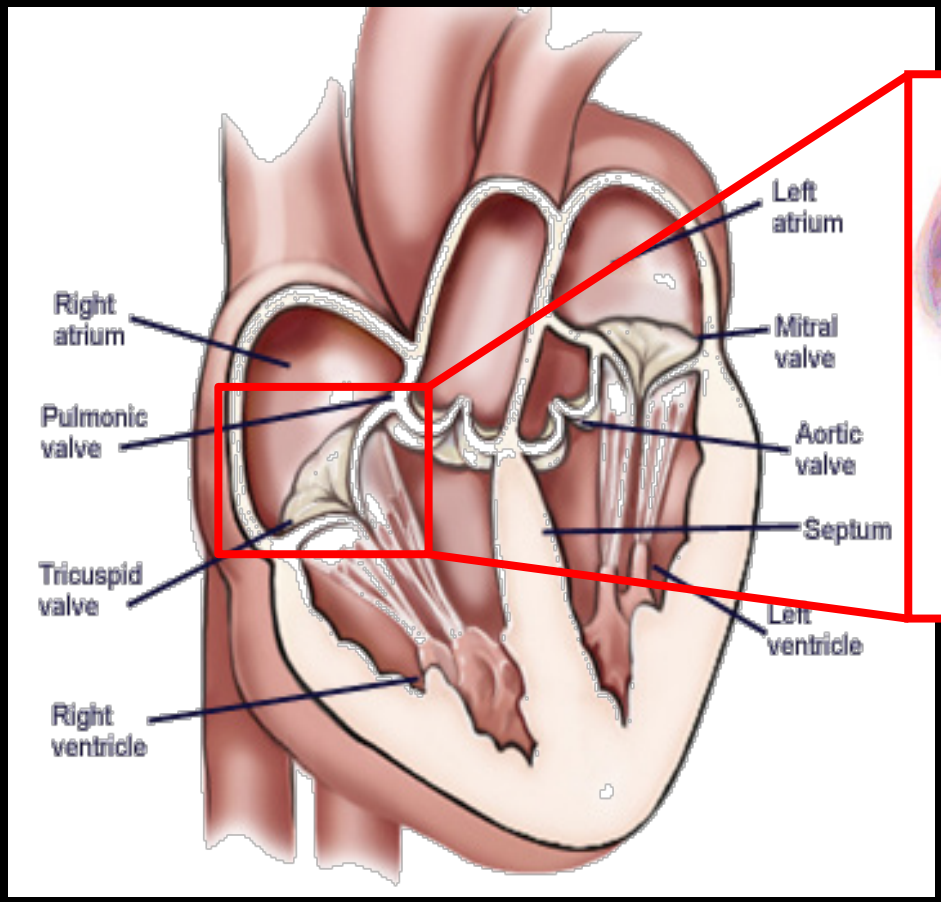
TR Etiology

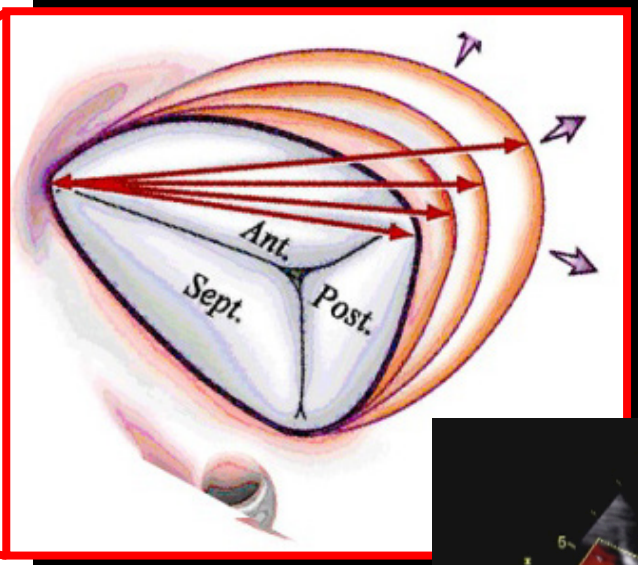
- Isolated primary (organic) TR
- Secondary (functional) TR in patients undergoing left-sided valve surgery
- Late TR following left-sided valve surgery

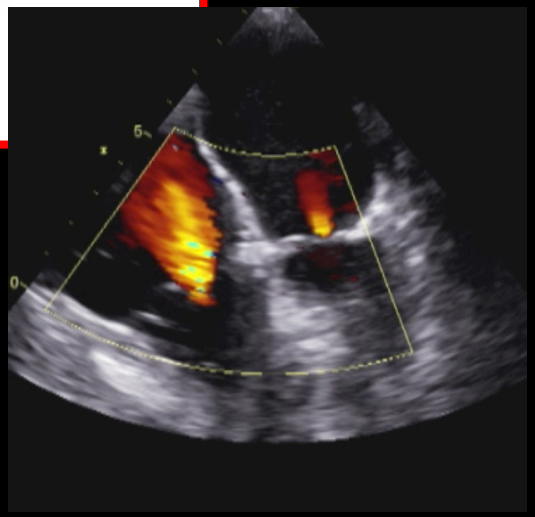


Functional Tricuspid Regurgitation failure mode

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







Clinical Presentation of TR

Decreased CO

Fatigue, decreased exercise tolerance

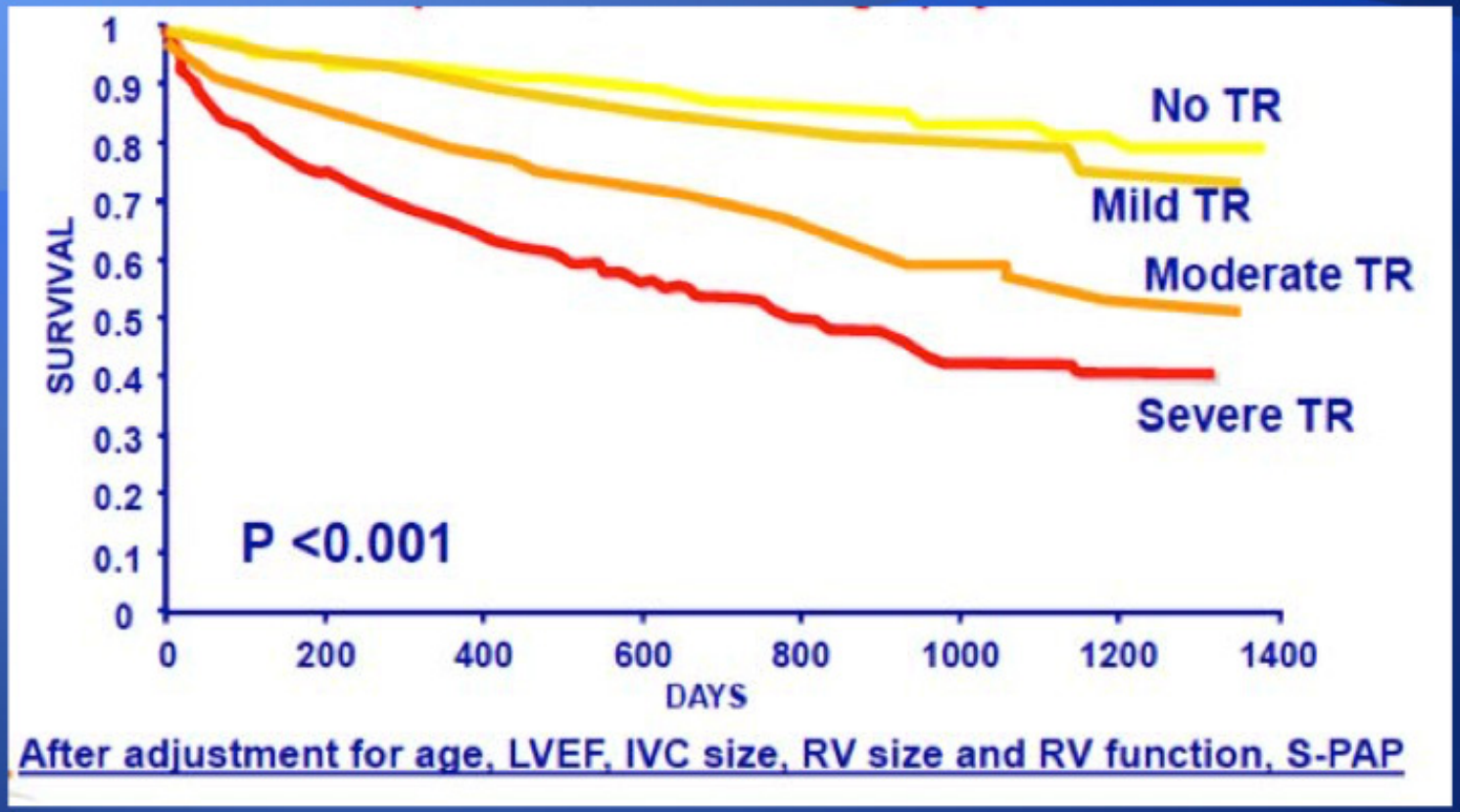
"Right-sided" Heart Failure

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.

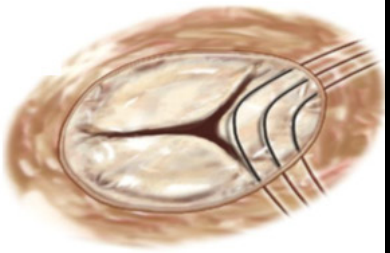
Indications for surgery in tricuspid disease

	Class	Level
Surgery is indicated in symptomatic patients with severe TS.	I	C
Surgery is indicated in patients with severe TS undergoing left-sided valve intervention.	I	C
Surgery is indicated in patients with severe primary, or secondary, TR undergoing left-sided valve surgery.	***I***	***C***
Surgery is indicated in symptomatic patients with severe isolated primary TR without severe right ventricular dysfunction.	I	C
Surgery should be considered in patients with moderate primary TR undergoing left-sided valve surgery. .	IIa	C
Surgery should be considered in patients with mild or moderate secondary TR with dilated annulus (≥ 40 mm or > 21 mm/m²) undergoing left-sided valve surgery.	IIa	C
Surgery should be considered in asymptomatic or mildly symptomatic patients with severe isolated primary TR and progressive right ventricular dilation or deterioration of right ventricular function.	IIa	C
After left-sided valve surgery, surgery should be considered in patients with severe TR who are symptomatic or have progressive right ventricular dilatation/dysfunction, in the absence of left-sided valve dysfunction, severe right or left ventricular dysfunction, and severe pulmonary vascular disease.	IIa	C

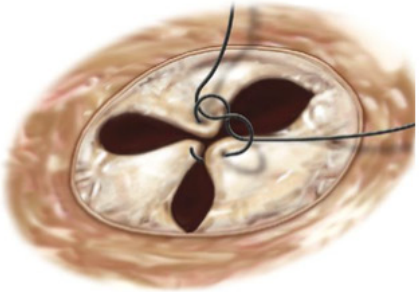
European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 & European Journal of Cardio-Thoracic Surgery 2012 - doi:10.1093/ejcts/ezs455).

Surgical Treatment options

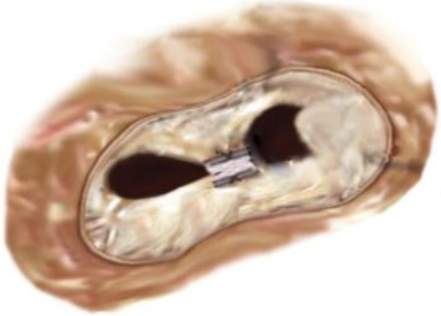
Annuloplasty



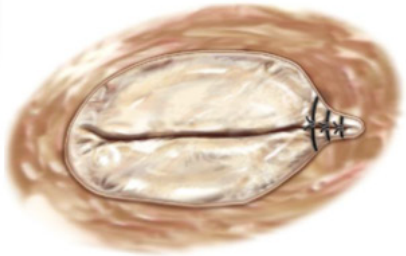
De Vega Repair



Clover Technique

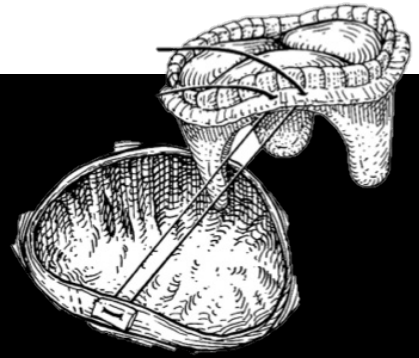


Hetzer Repair



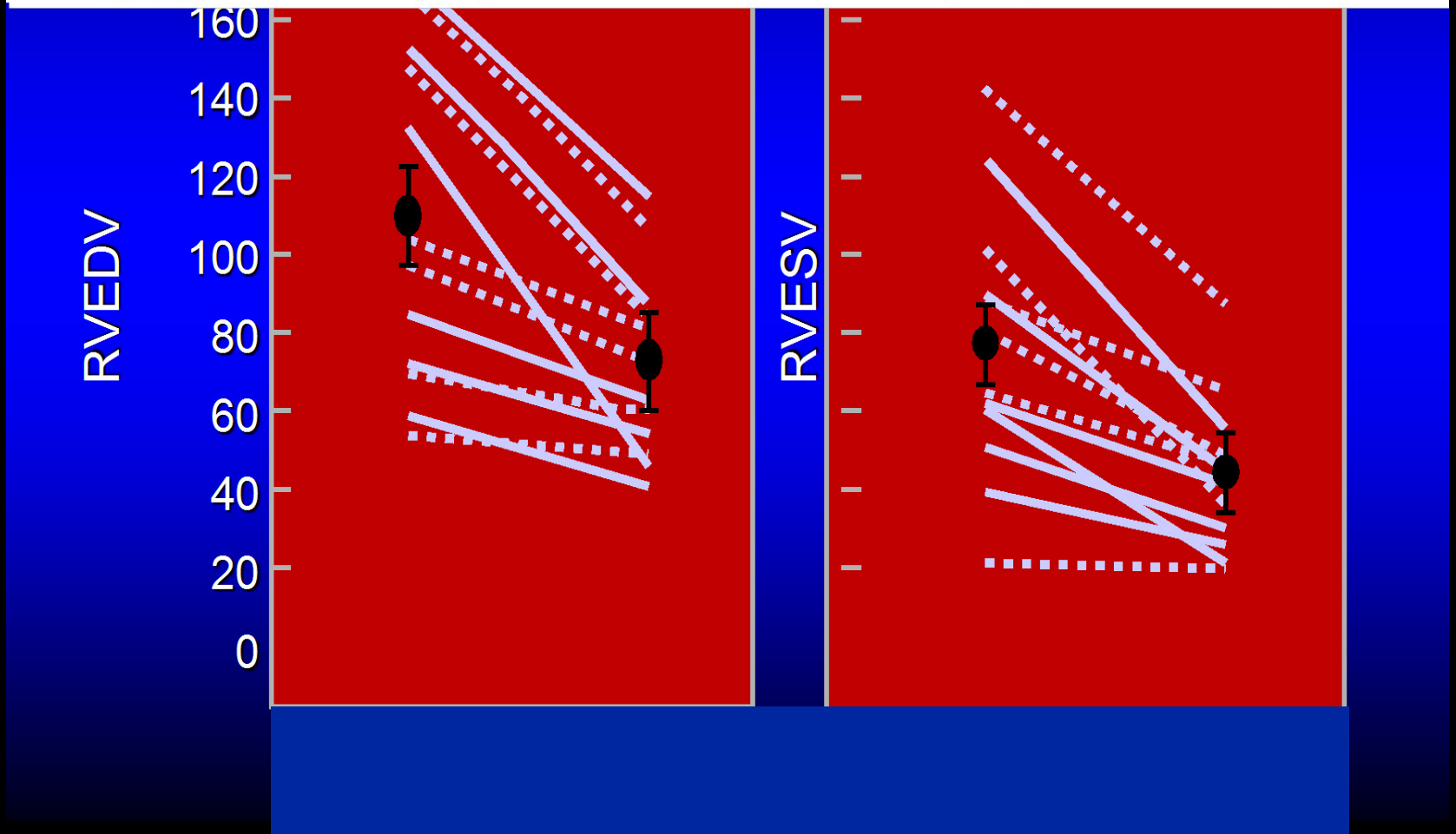
Kay Repair Technique

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

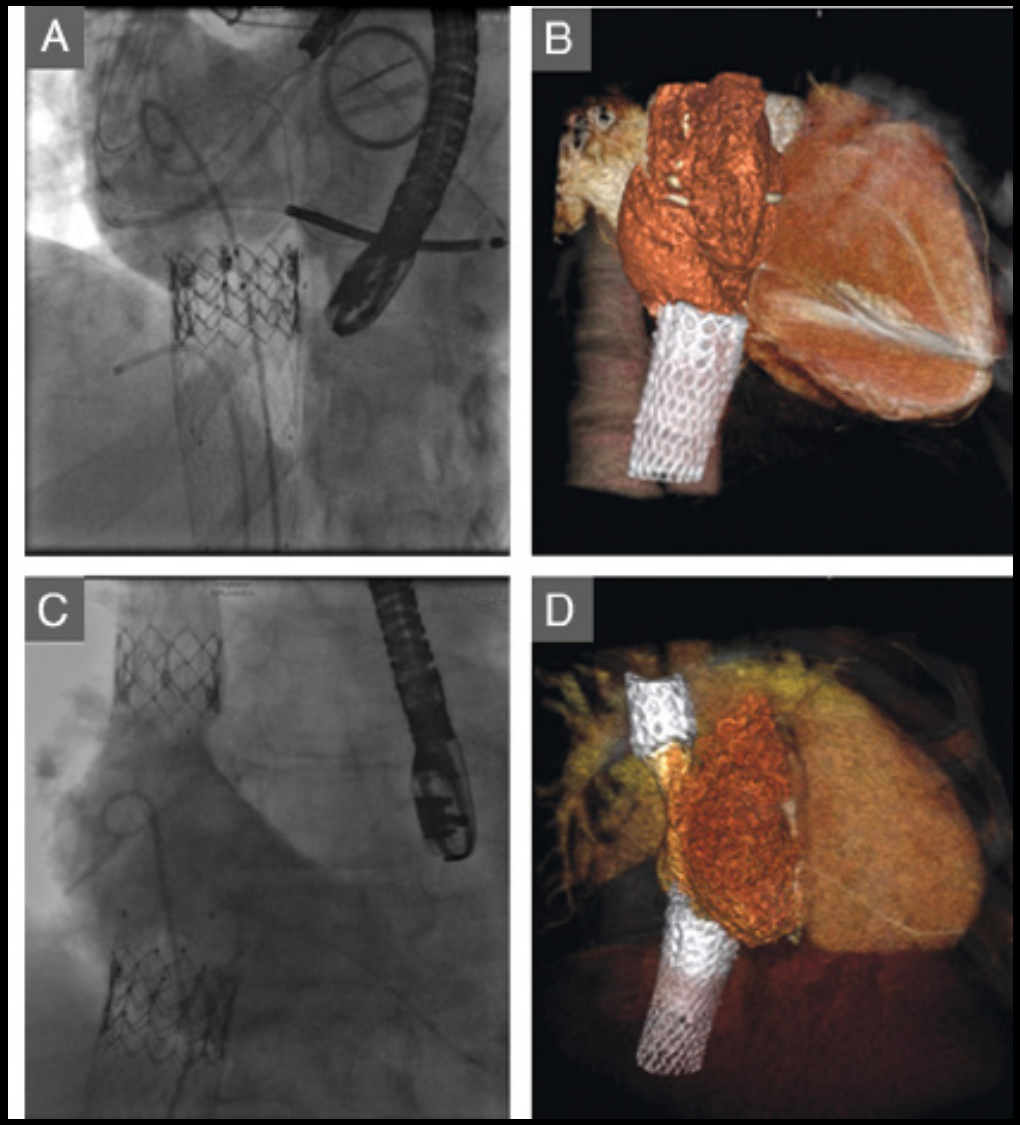


Improvement in Right Ventricular Systolic Function After Surgical Correction of Isolated Tricuspid Regurgitation

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



Heterotopic Valve Implantation



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

Heterotopic Valve Implantation

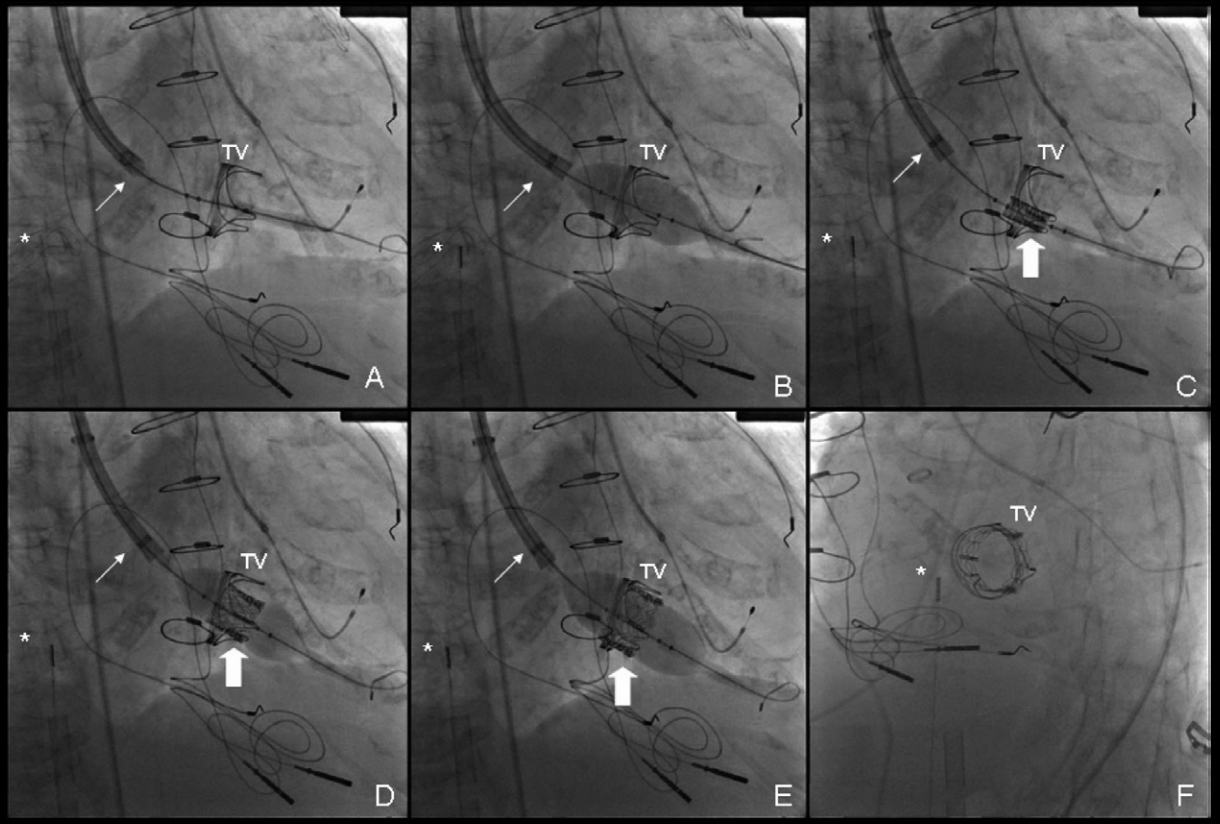
- 3 high-risk patients. EuroScore >40%
- 2 with Valve implantation in IVC, 1 in IVC+SVC
- At 30 days:
  - functional improvement
  - less peripheral oedema, ascites
  - mild decrease in RVEDV
  - stable RVEF

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

Valve in valve

Percutaneous Transcatheter Valve-in-Valve Implantation in Stenosed Tricuspid Valve Bioprosthesis

Leen A.F.M. Van Garsse, MD; Rachel M.A. ter Bekke, MD; Vincent G.V.A. van Ommen, MD, PhD

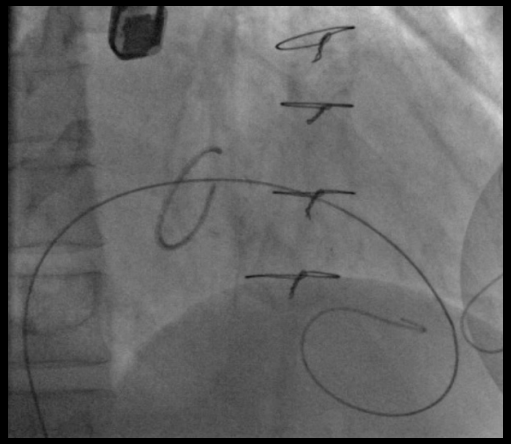


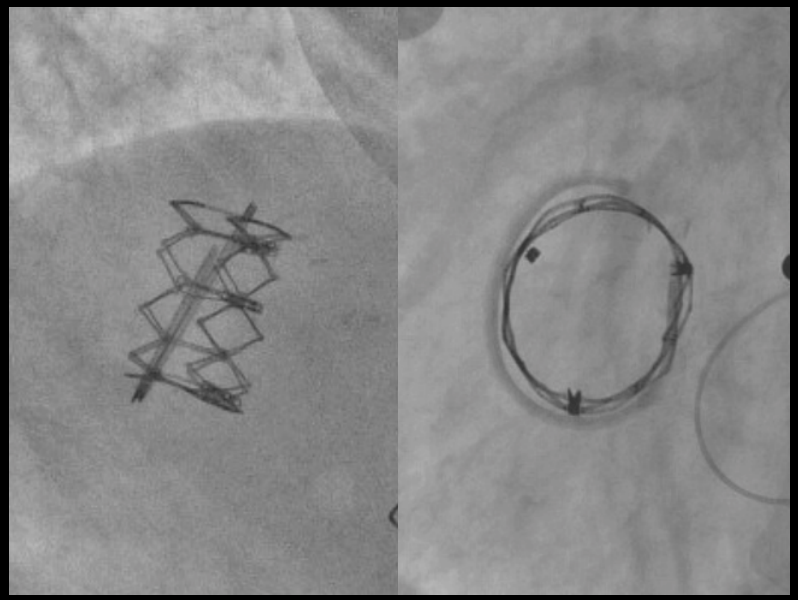
Circulation. 2011;123:e219-e221

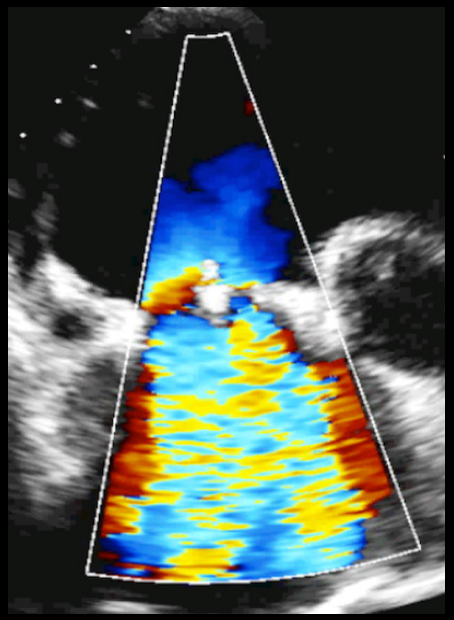
EMO GVM
CENTRO
CUORE COLUMBUS s.r.l.

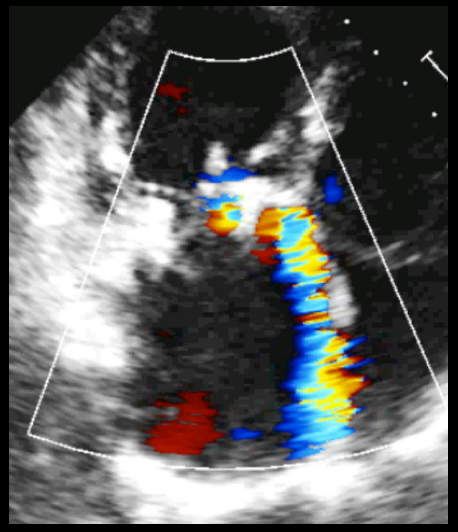
OSPEDALE
SAN RAFFAELE

Valve in Ring









Literature Valve in valve/ring

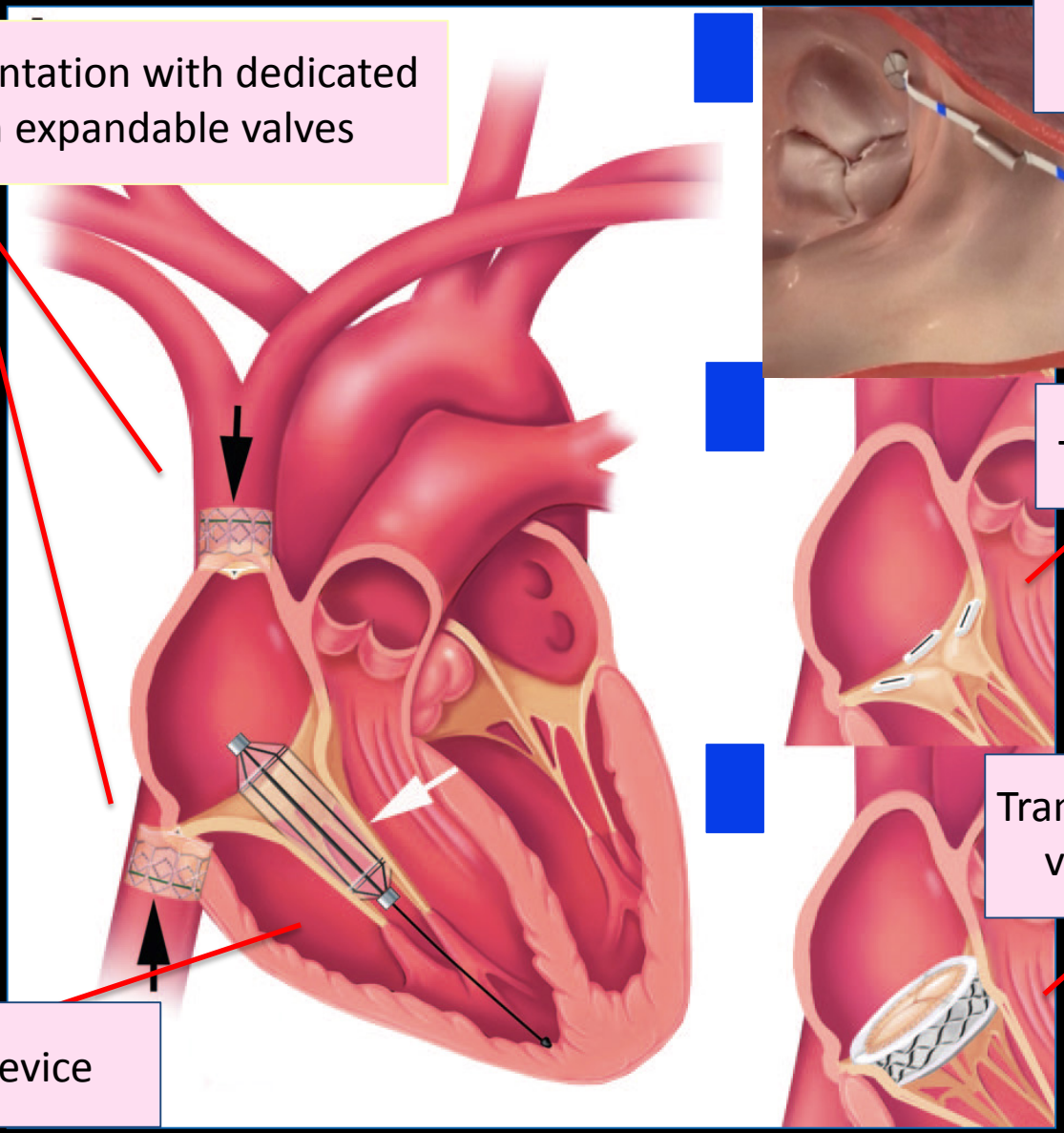
31 Valve in Valve

- 15 Melody V.; 16 Sapien V.
- High procedural success
- 1 death, 1 AV Block, 1 migration, 1 endocarditis
- FU reported in only 4 cases

3 Valve in Ring

Transcatheter solutions: some attempts

Bicaval valve implantation with dedicated self- or balloon expandable valves



The 4Tech system

The Mitralign system

Transcatheter tricuspid valve replacement

The FORMA device

4Tech TriCinch™ Concept

Intended for percutaneous treatment of tricuspid regurgitation

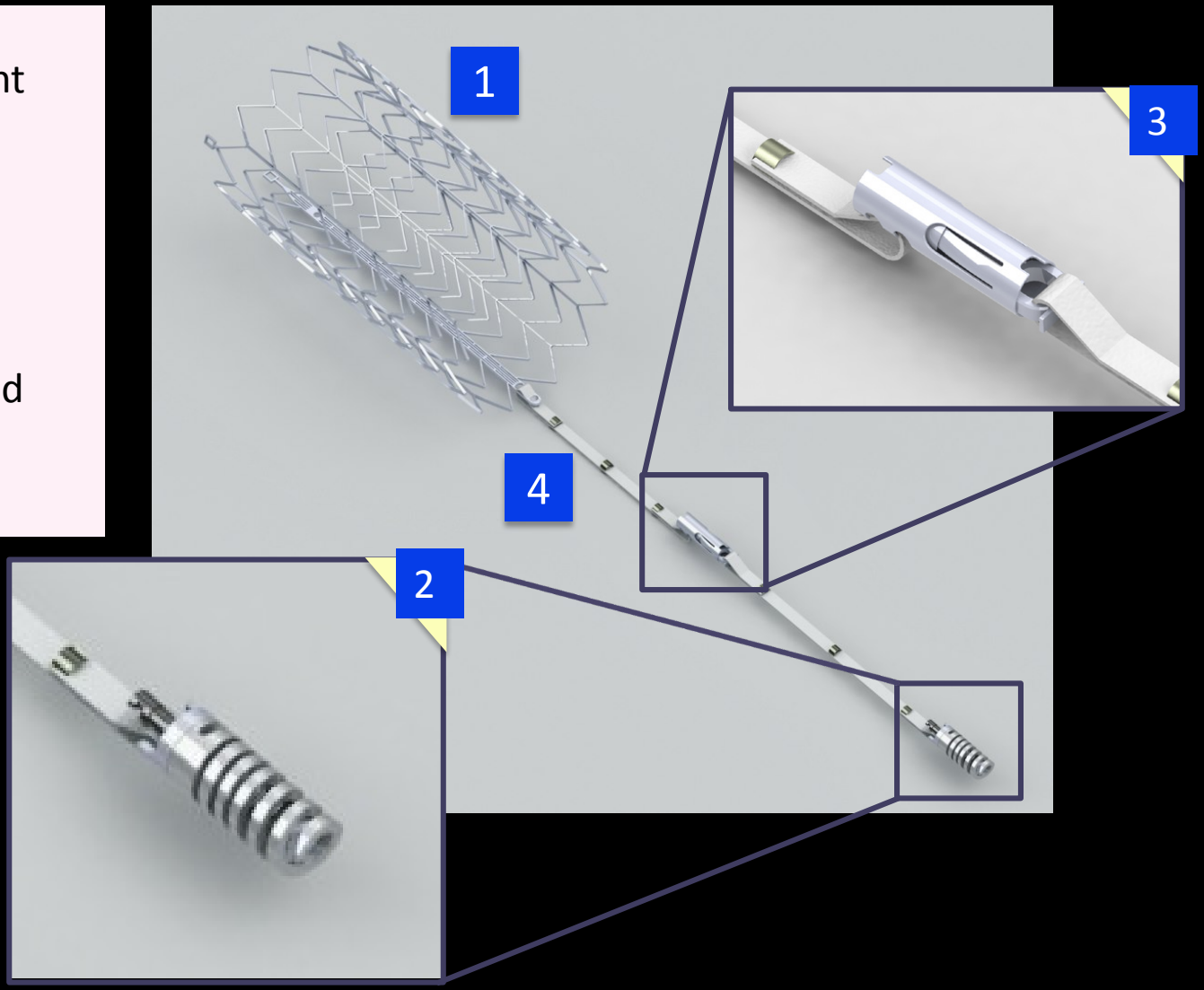
1: Retrievable Nitinol stent

2: Nitinol Corkscrew

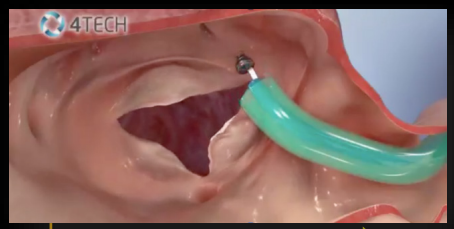
3: Coupling mechanism

4: Fluoroscopically marked

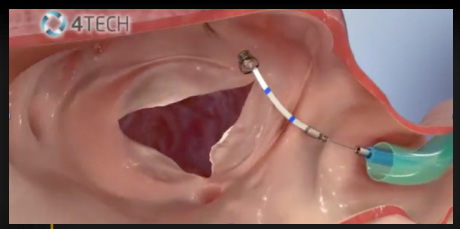
Dacron band



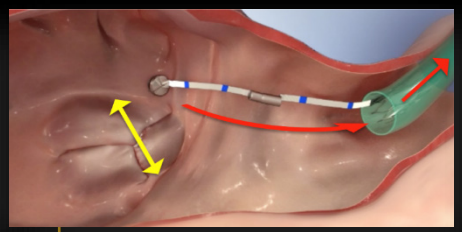
4Tech TriCinch Procedure



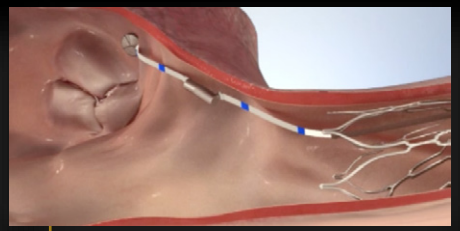
1 Corkscrew implant in APC



2 Coupling mechanism

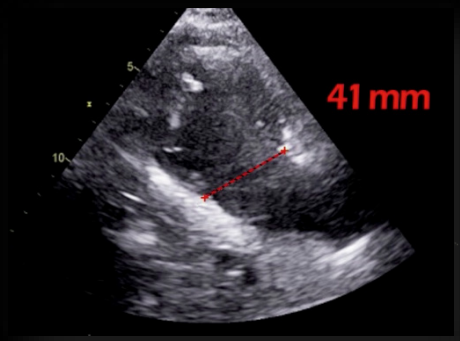


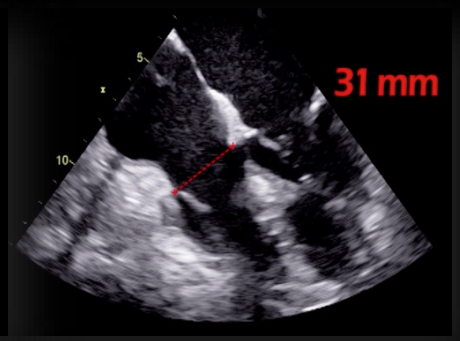
3 Tension applied

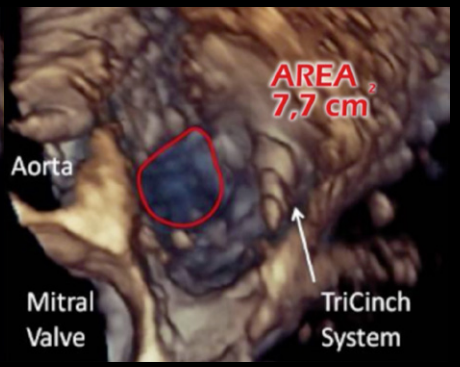


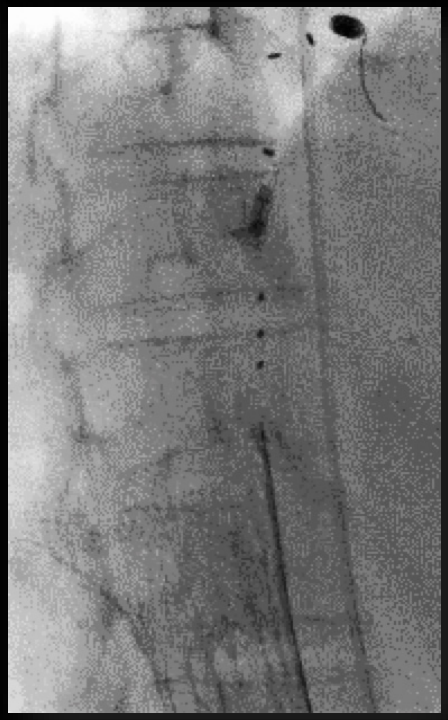
4 Stent deployment in IVC

Echocardiographic results



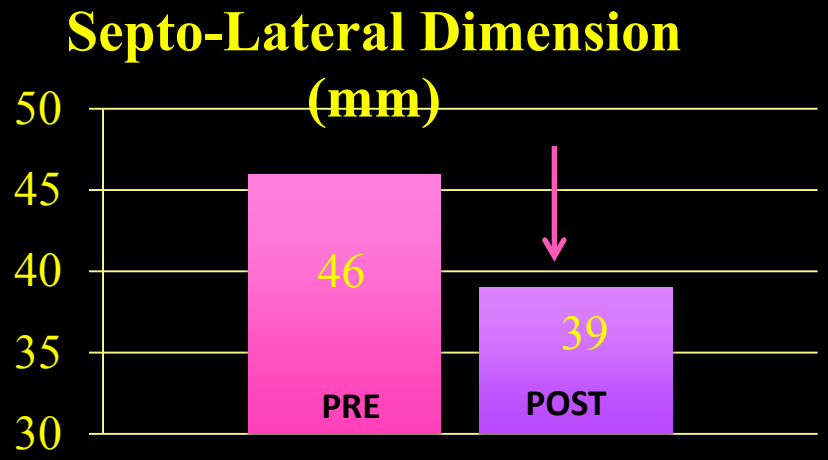


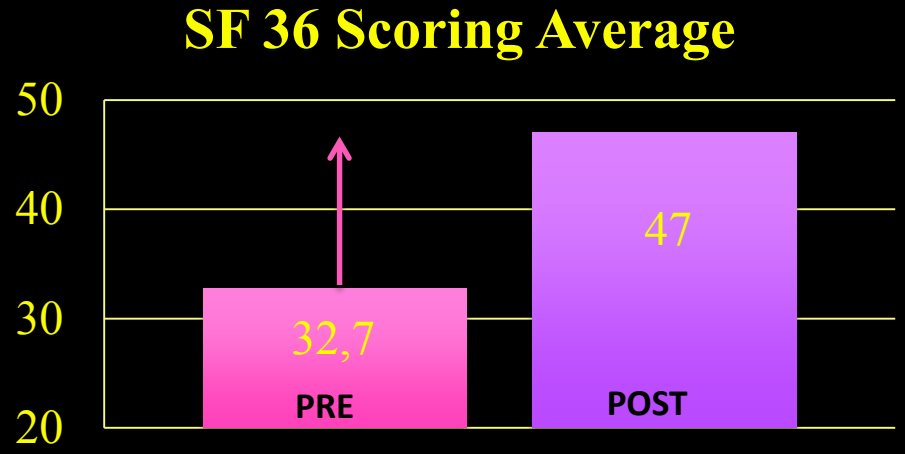


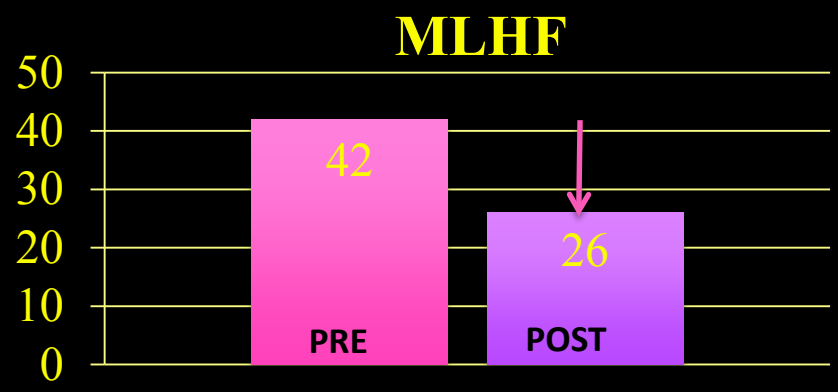


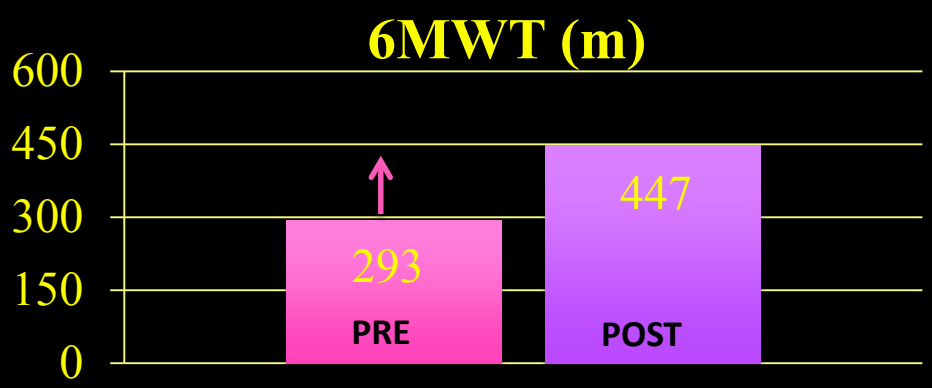
Outcomes highlights

- 9 enrolled, 5 implanted successfully, 3 evaluated at 6 months. Primary and Secondary Endpoints met
- Straightforward procedure *Average procedural time* 72 minutes
- 100% Patient survival





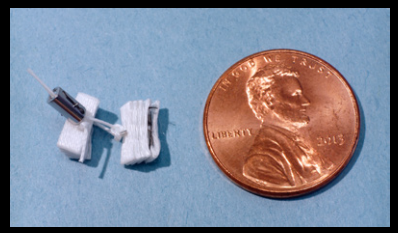


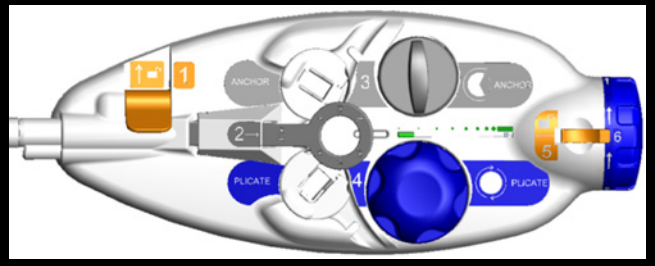


Mitralign System for tricuspid valve repair

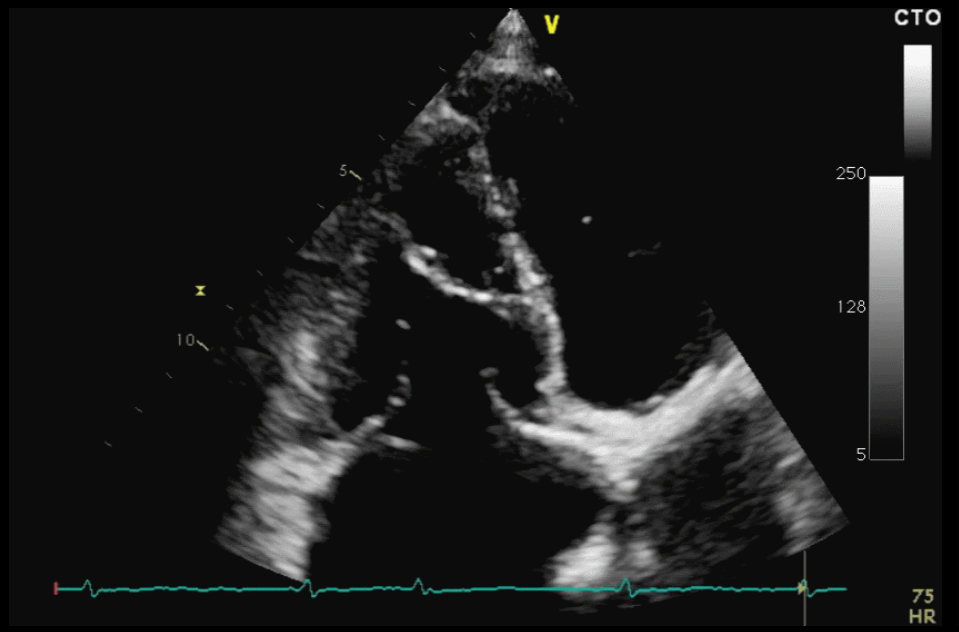
Procedural Steps

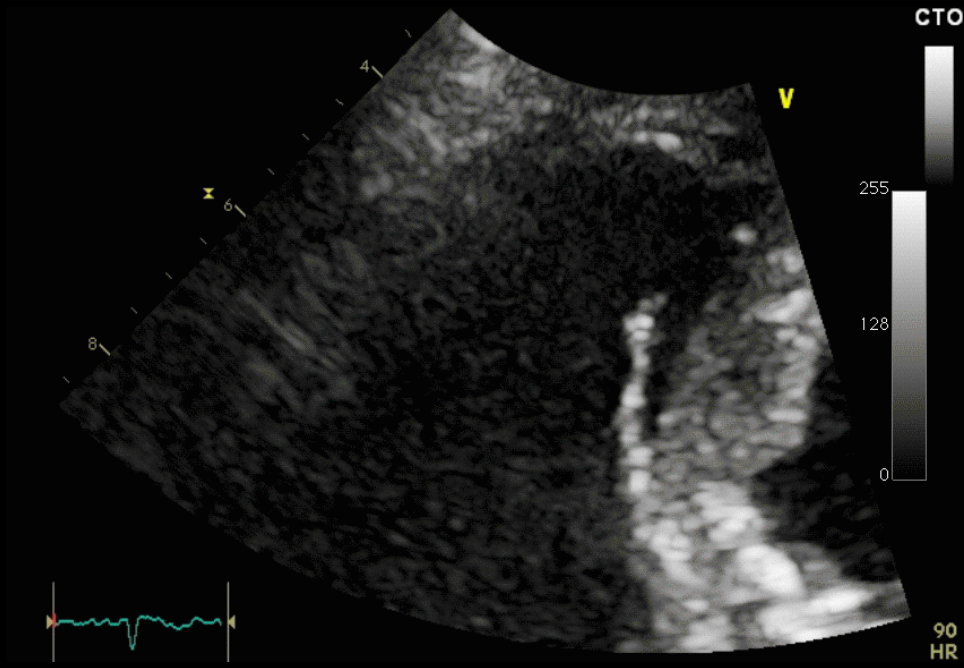
- Jugular Access
- 40cm 14F Sheath
- Hook around wire delivery to deliver 1st pledget (anchor)
- Repeat wire delivery steps to deliver 2nd pledget (anchor)
- Cinch pledgets together to obliterate the posterior leaflet and deliver lock on atrial side





Case done in San Raffaele Hospital
TEE Baseline



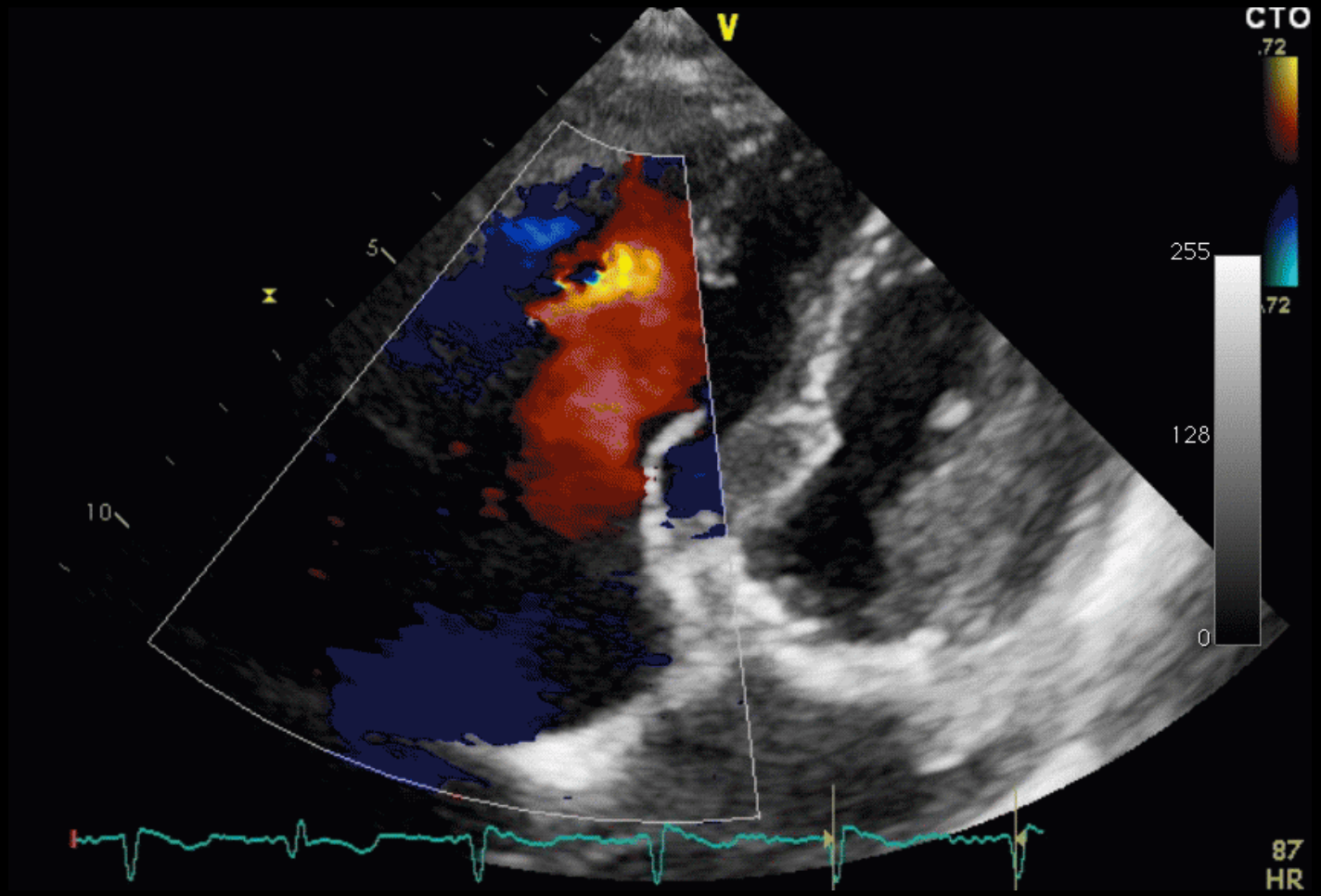


Note complete lack of coaptation!

EMO GVM
CENTRO
CUORE COLUMBUS s.r.l.

OSPEDALE
SAN RAFFAELE

Baseline Echo



Implant Fluoroscopy

Before treatment

Before plication

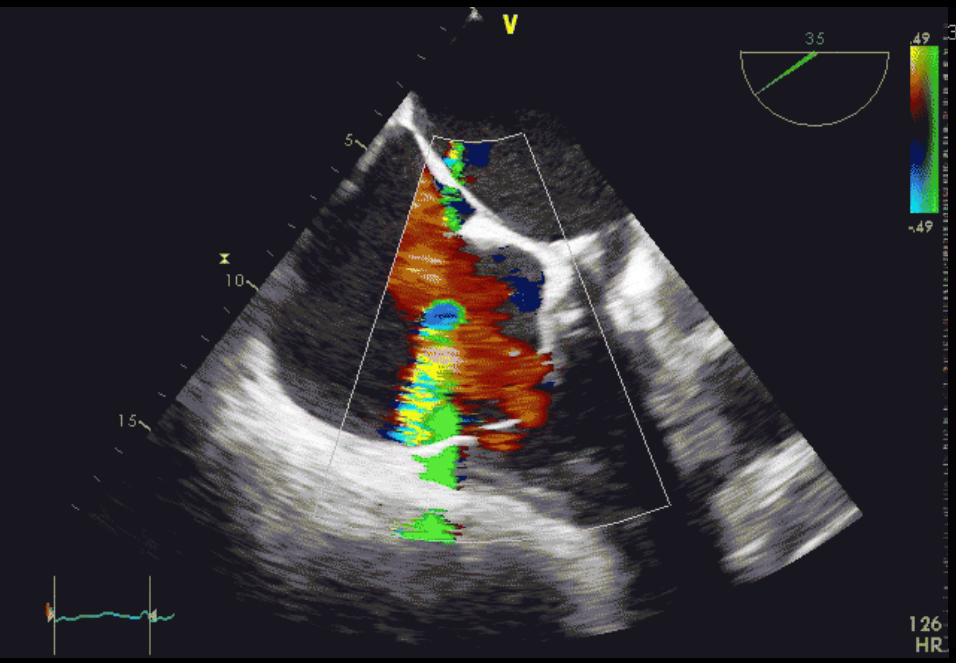
After treatment

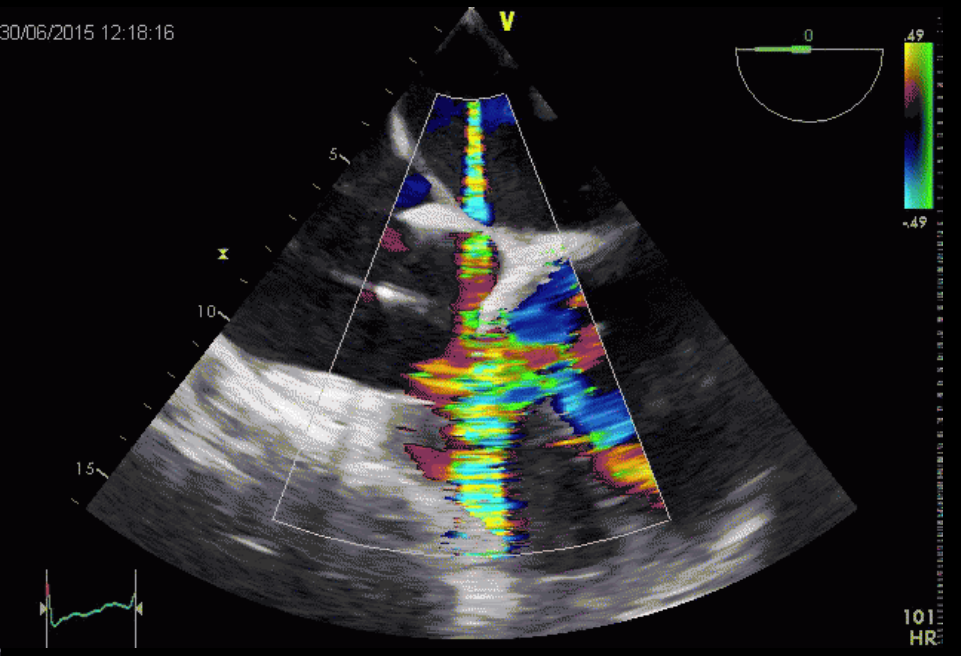
After plication

EMO GVM
CENTRO
CUORE COLUMBUS s.r.l.

OSPEDALE
SAN RAFFAELE

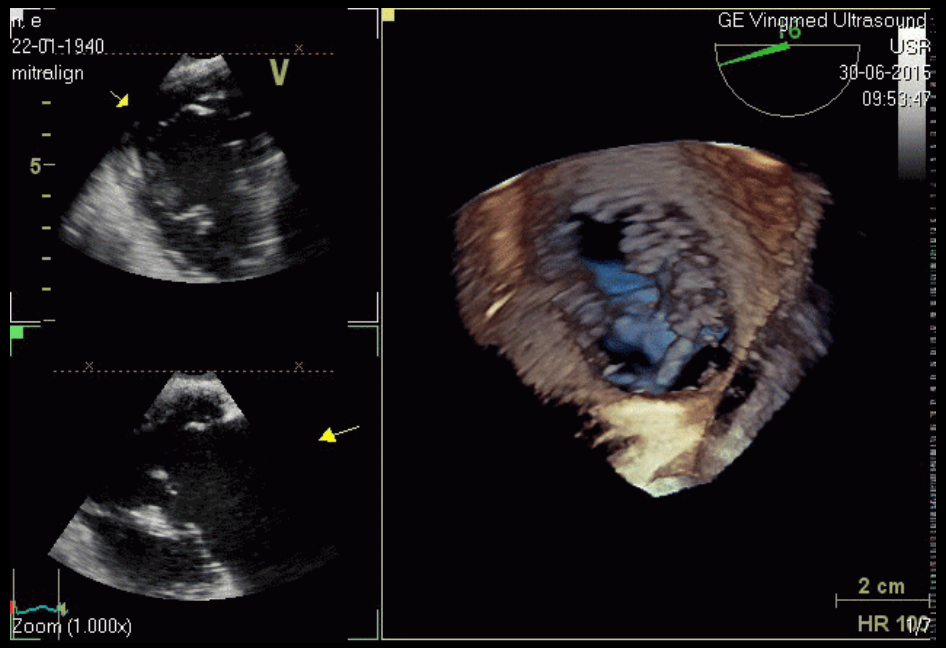
Tricuspid Regurgitation Comparison



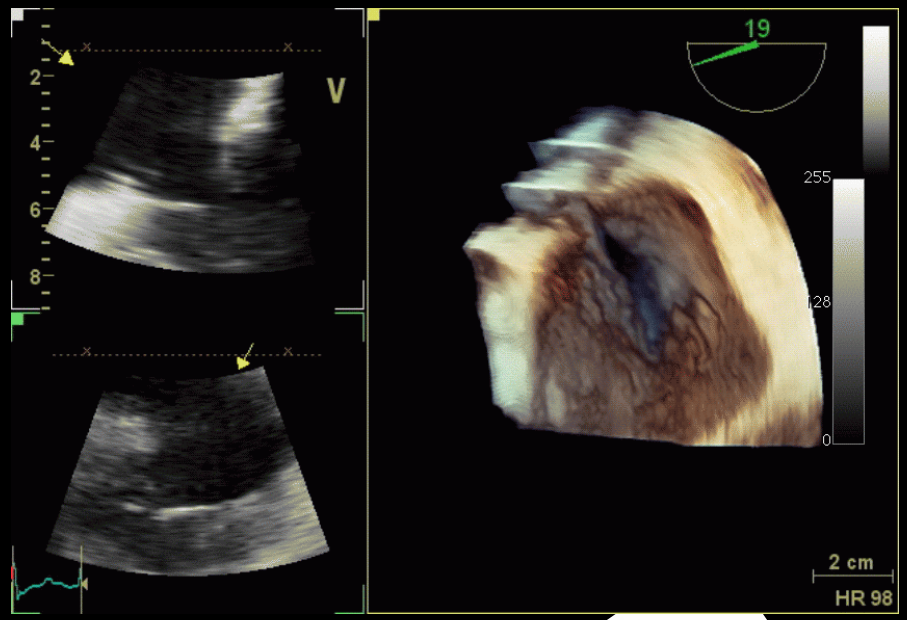


3D TEE

Before treatment

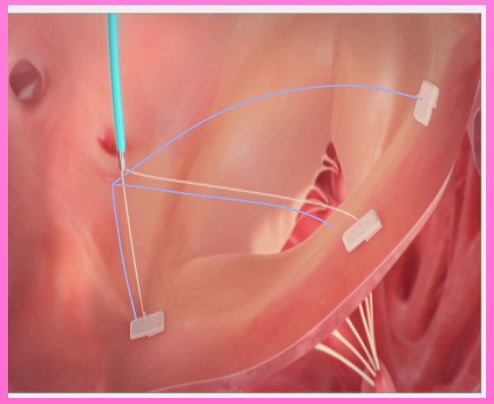


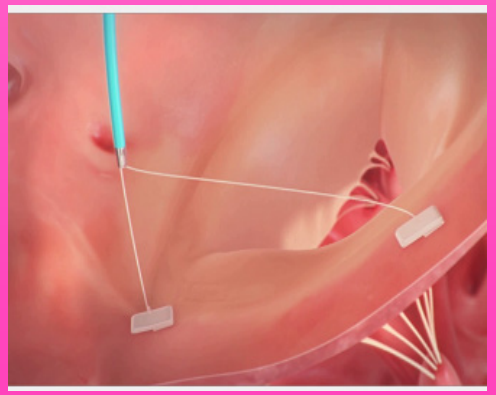
After treatment, the Tricuspid Valve is Bicuspidized!



Acute Procedural Success

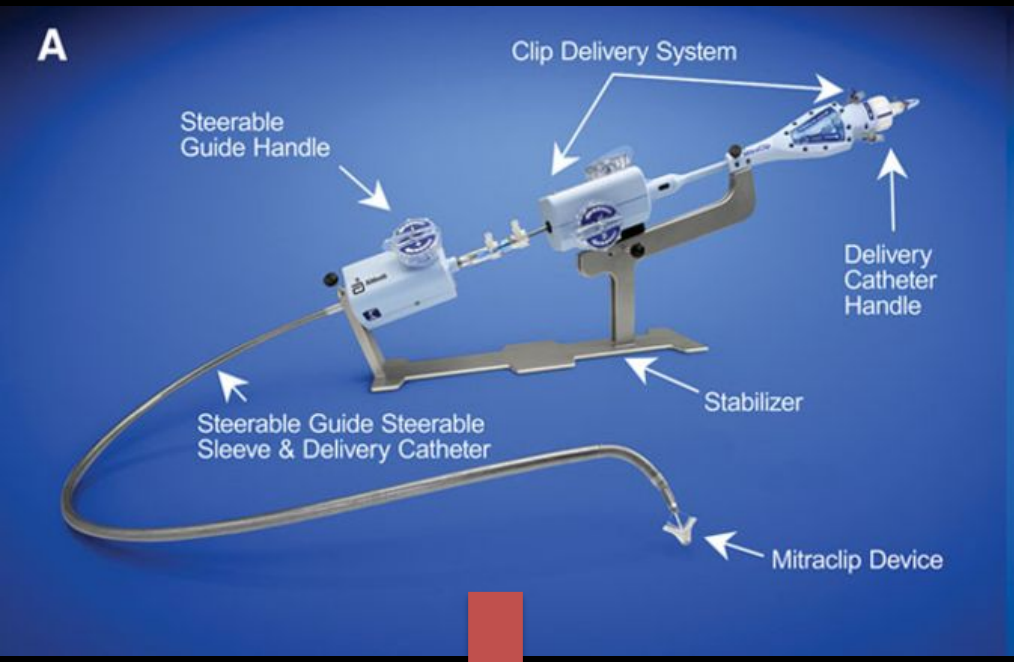
- Device Delivery
  - –8/10 patients received pledget implants
    - •2 patients: annular tissue was fragile
  - –Implant Configuration
    - •2 pledgets: n=6
    - •3 pledgets: n=2
- Procedural Efficacy
  - –Tricuspid regurgitation:
    - •6/8 patients showed TR reduction acutely
    - •1/8 patient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

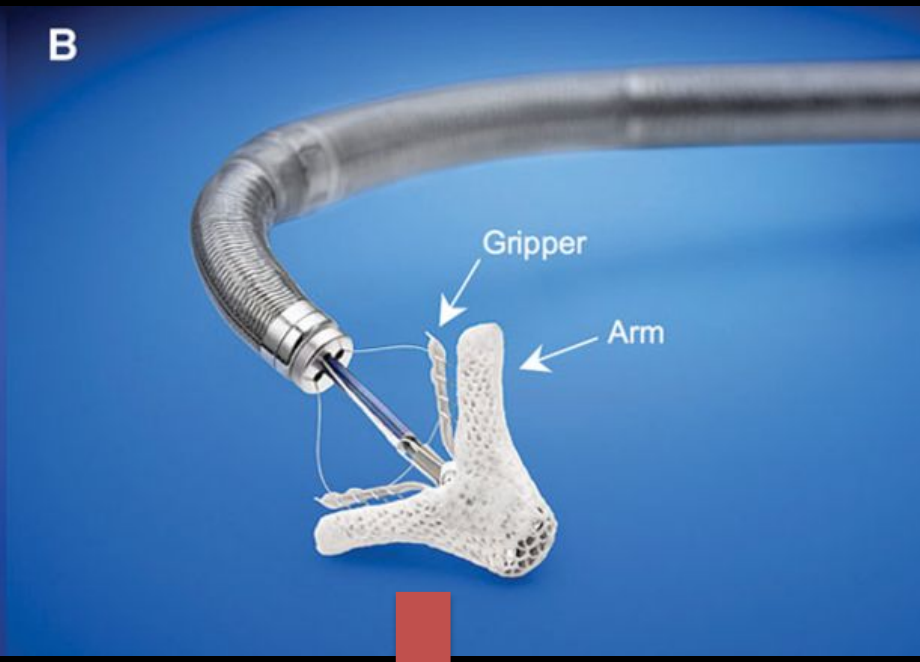


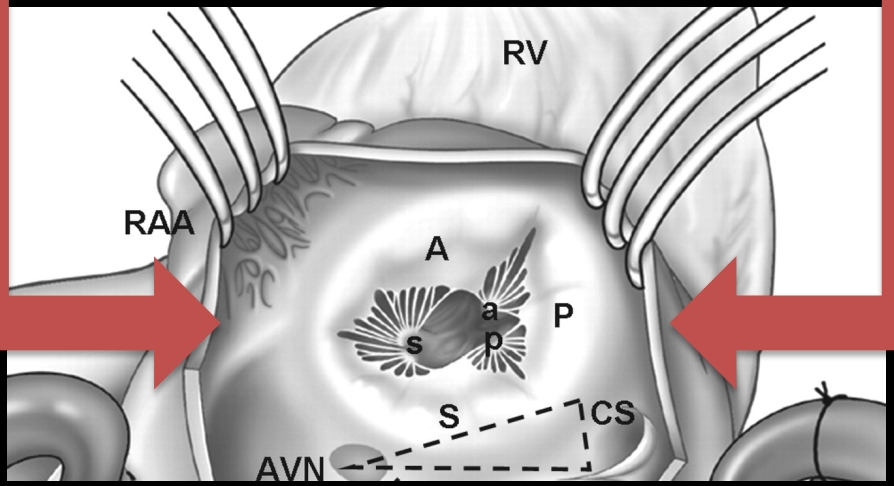


MitraClip on Tricuspid Valve

Is it possible to transfer the Mitral knowledge into the Tricuspid valve?







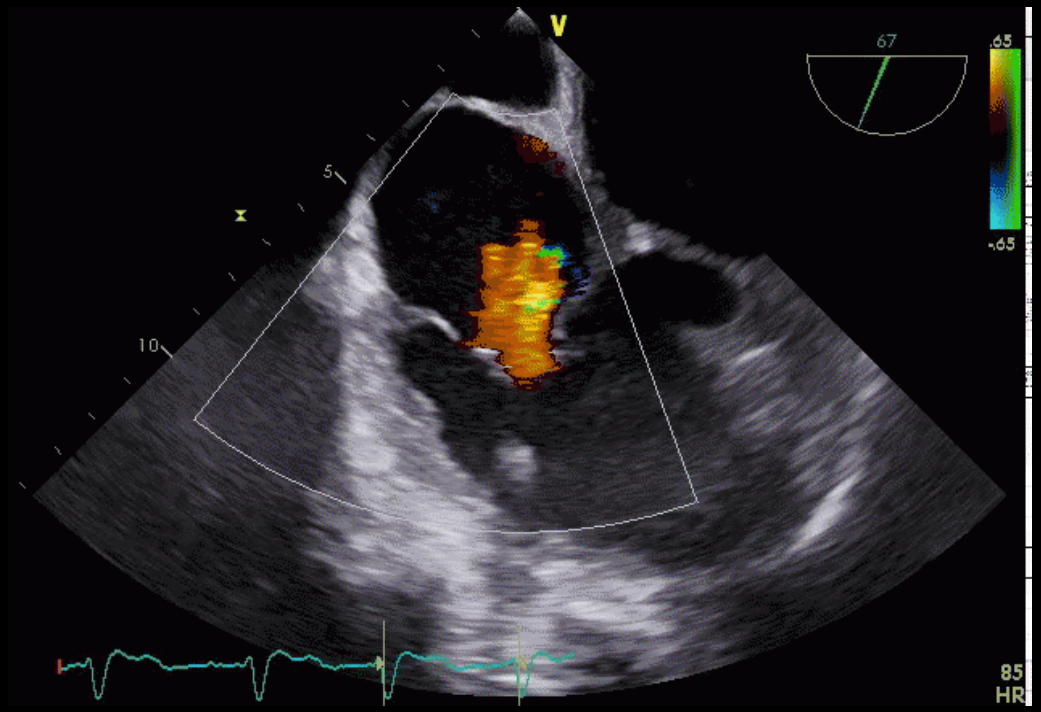
Case done in San Raffaele Hospital- TEE Pre

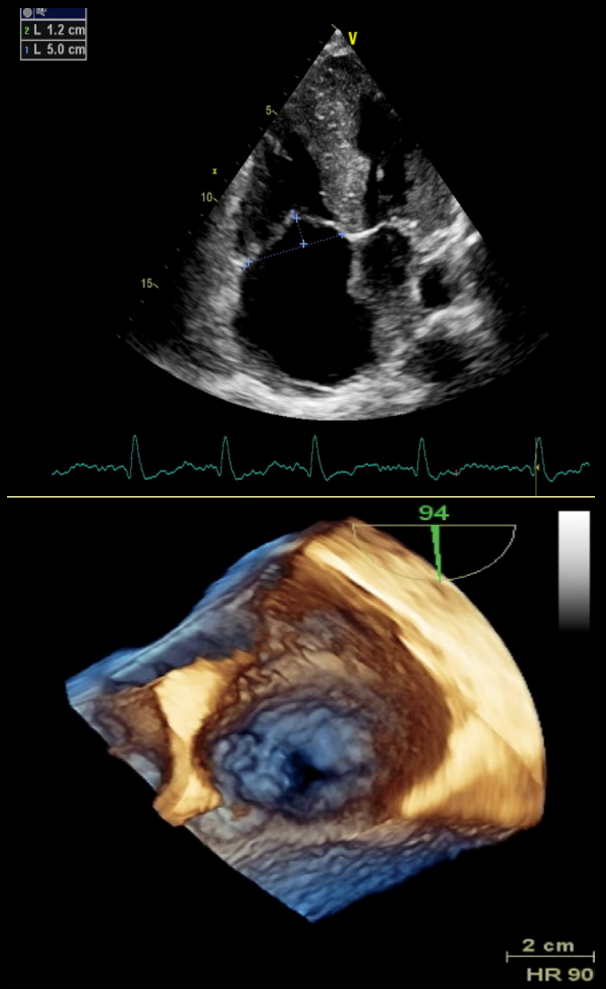
Right ventricle:

- *normal dimensions*
- *reduced systolic function*
  - *TAPSE 16 mm*
  - *s' TDI 9 cm/s*

TTE:

- *severe tricuspid regurgitation*
- *moderate annular dilatation (40 x 48 mm)*

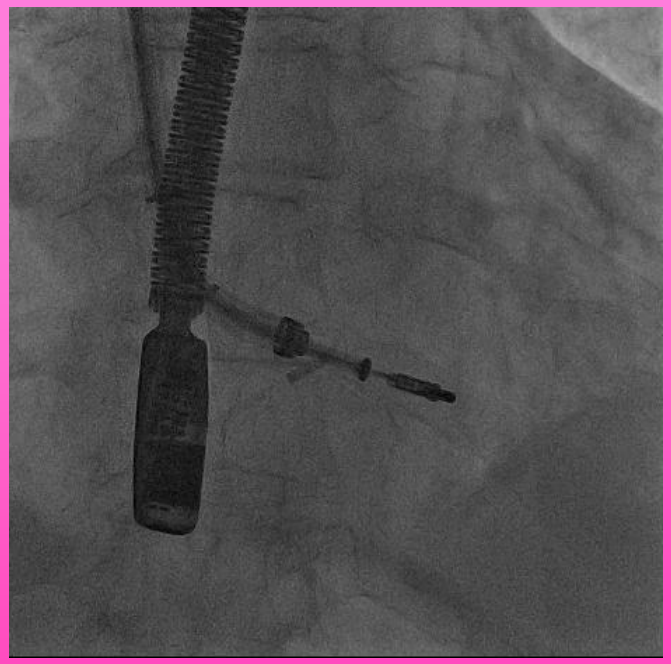


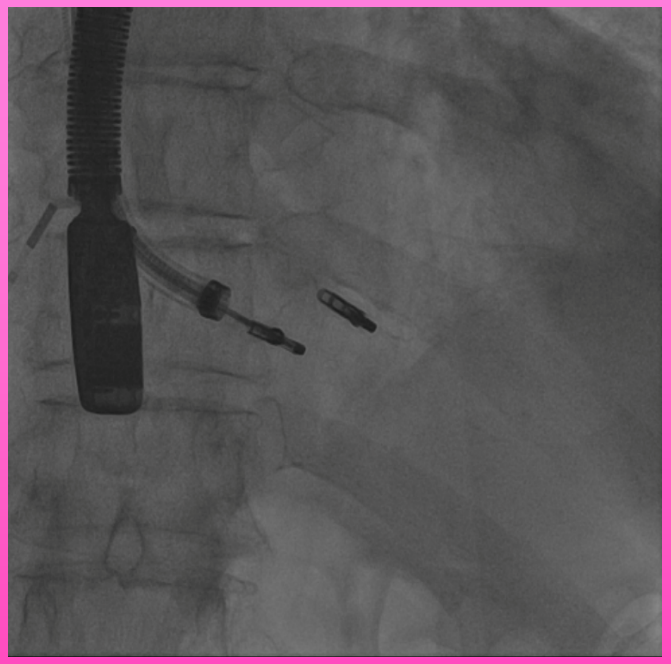


Procedural steps and clips' location

Trans-jugular access, implantation of 2 Mitraclip

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

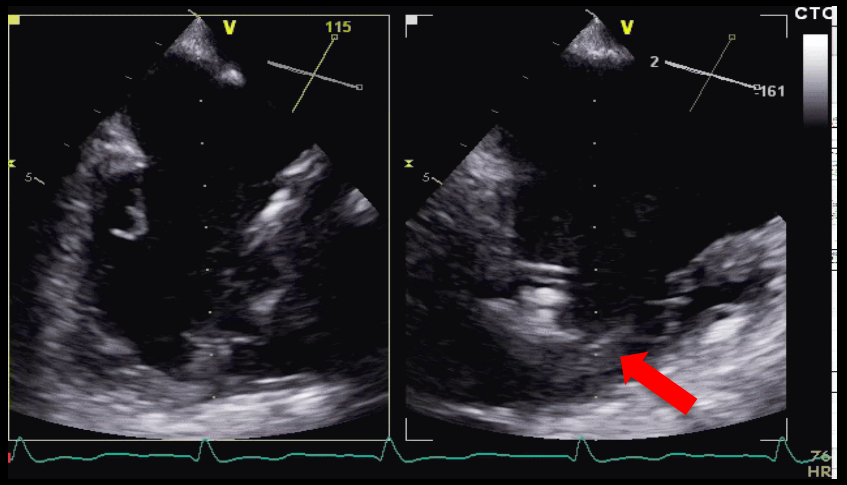




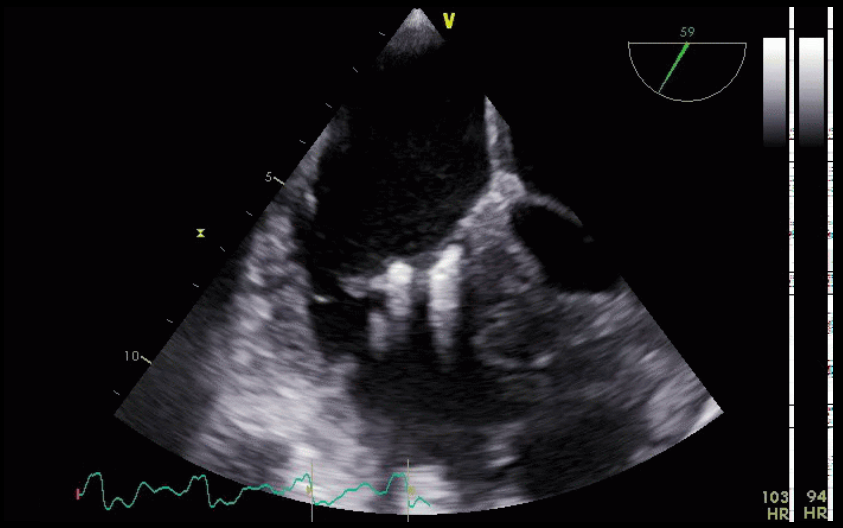
Bicuspidalization of the valve with good echographic result (residual moderate regurgitation)

Intra-procedural TEE monitoring

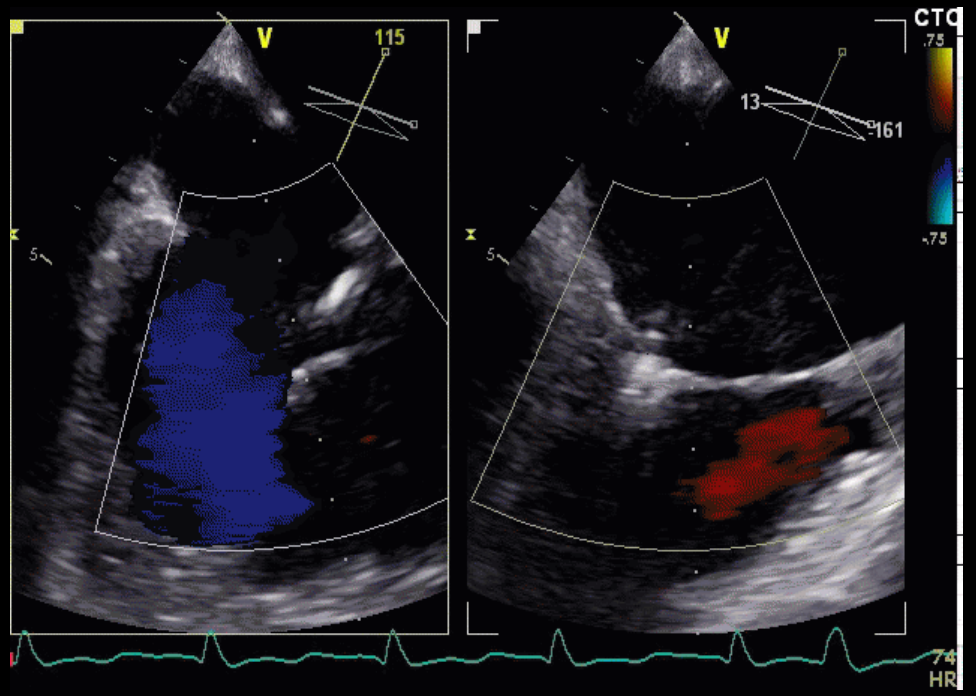
First Clip pre-grasping



Second Clip implanted
First Clip implanted

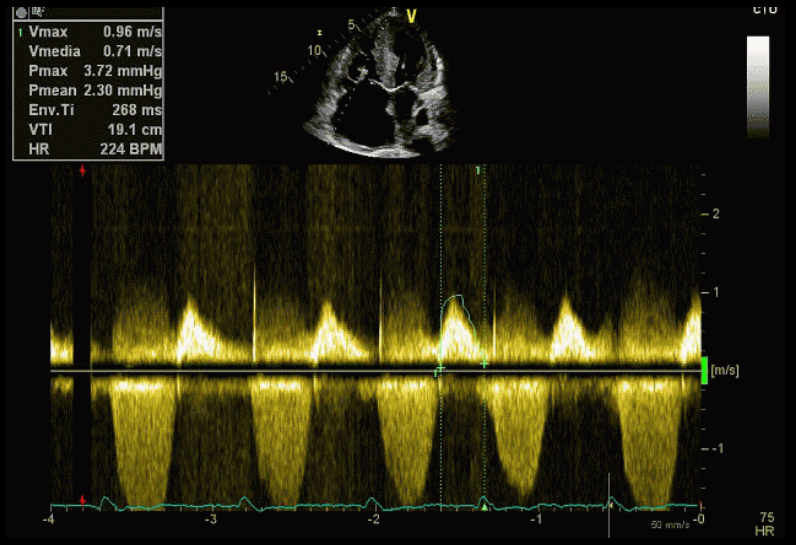


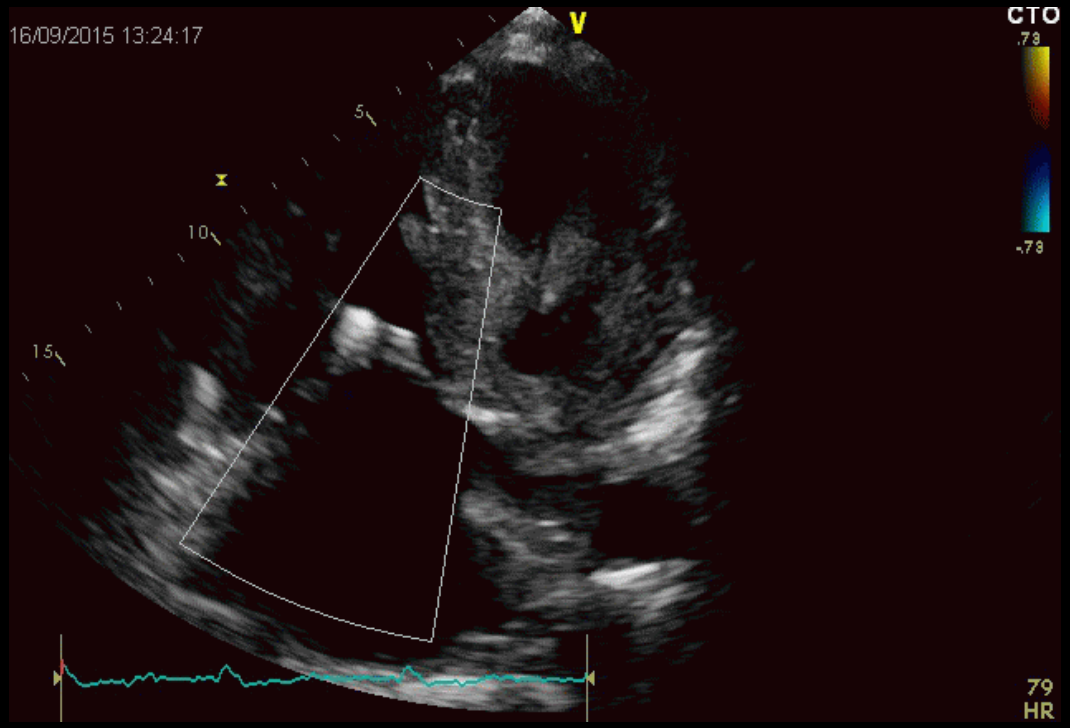
Final result with residual moderate regurgitation and no stenosis

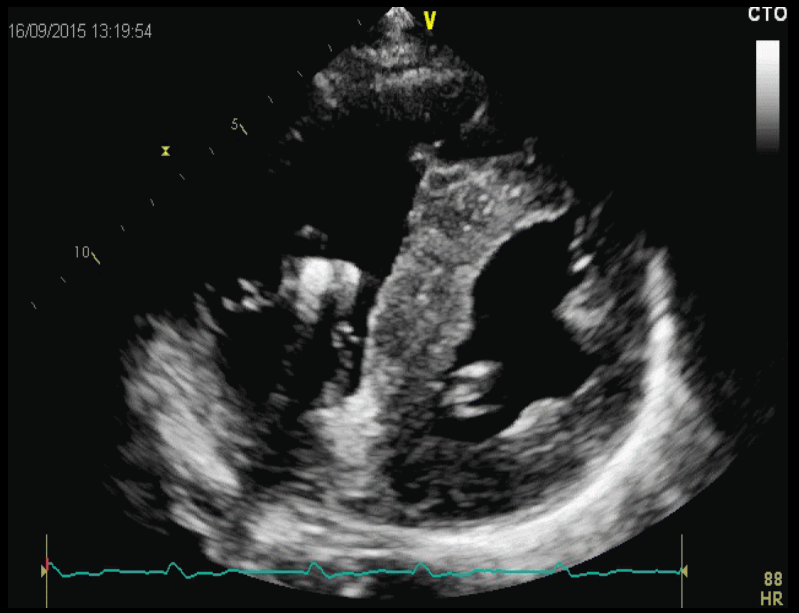


Echocardiographic results at 1 month follow-up

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







Conclusions

- Emerging innovative percutaneous therapies for FTR
- Different pathophysiological basis and mechanism of reducing TR and/or annular dimensions
- Varies from percutaneous Kay to palliative implantation of valves in the cava
- Biggest challenge is patient selection:
  - Which patient is the most appropriate for percutaneous therapy?
  - Importance of PHT and RV function
- If these therapies are shown to be effective, patients with moderate-severe FTR and annular dilatation could be treated earlier even if asymptomatic before they develop PHT and RV dysfunction

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