

EMOCLINIC SYMPOSIUM
SULLE SPONDE DEL TICINO

“Cardiologia
ieri, oggi
e domani”



NOVARA, 7 e 8 Giugno 2018

AUDITORIUM
BANCA POPOLARE DI NOVARA
VIA NEGRONI, 11

INSUFFICIENZA TRICUSPIDALICA: STRATEGIE DI TRATTAMENTO

Roberta Rosso
SCDO Cardiologia 2
AOU Maggiore della Carità

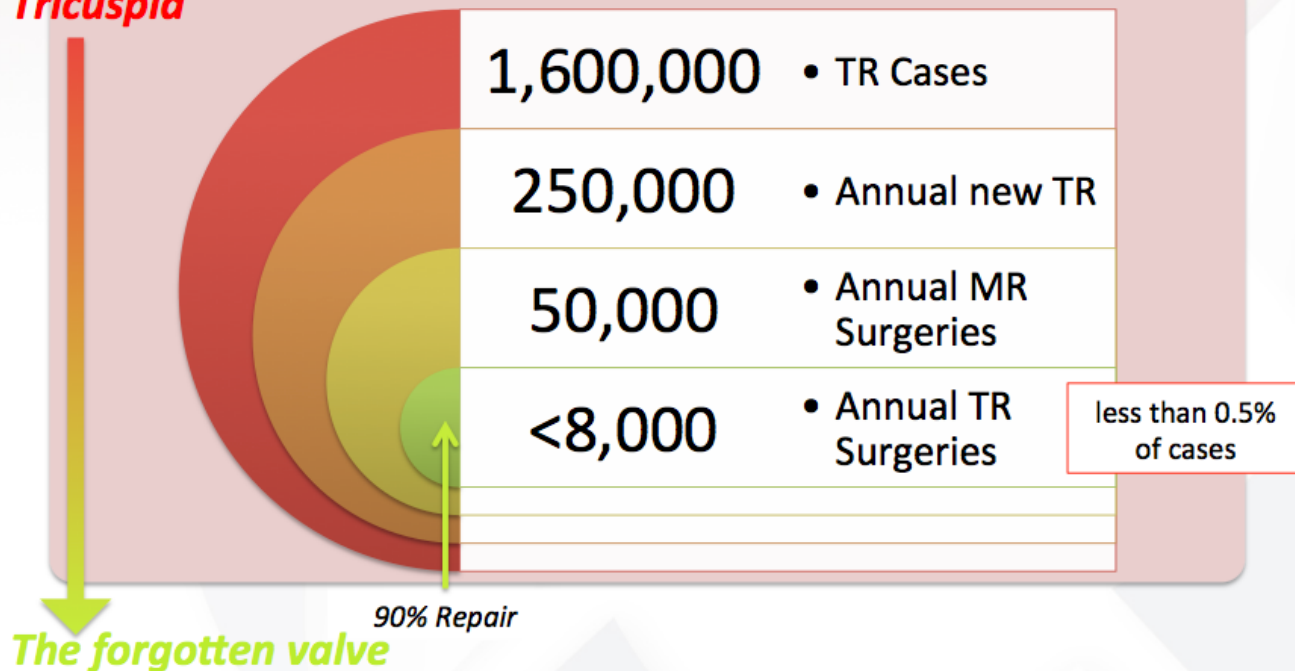
TRICUSPIDE: LA VALVOLA DIMENTICATA

Clinical background

Tricuspid Regurgitation and Low penetration of cardiac surgery

Estimated structural heart disease opportunity: US

Tricuspid

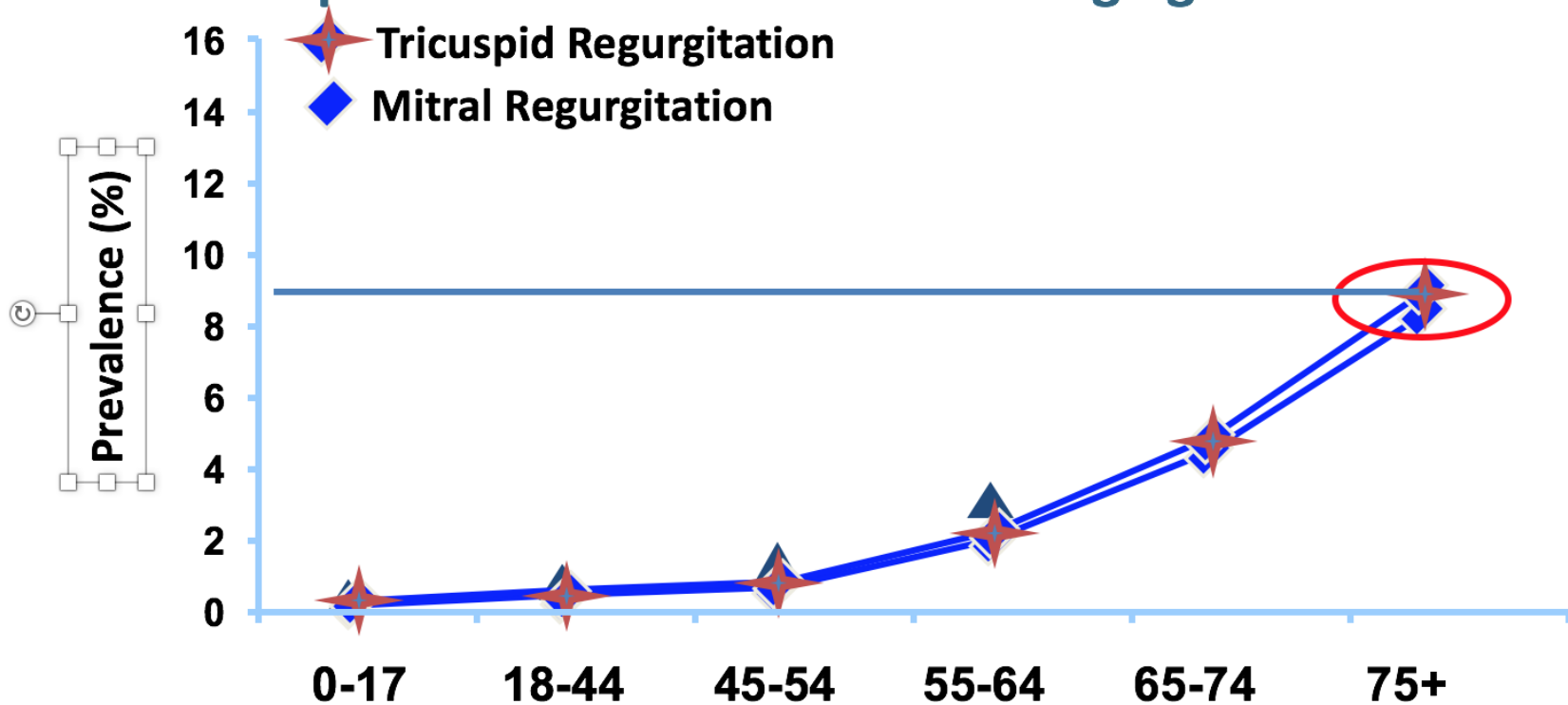


Agarwal et al. *Circ Cardiovasc Interv* 2009;2:565-573

Stuge O, Liddicoat J. *J Thorac Cardiovasc Surg*. 2006 Dec;132(6):1258-61

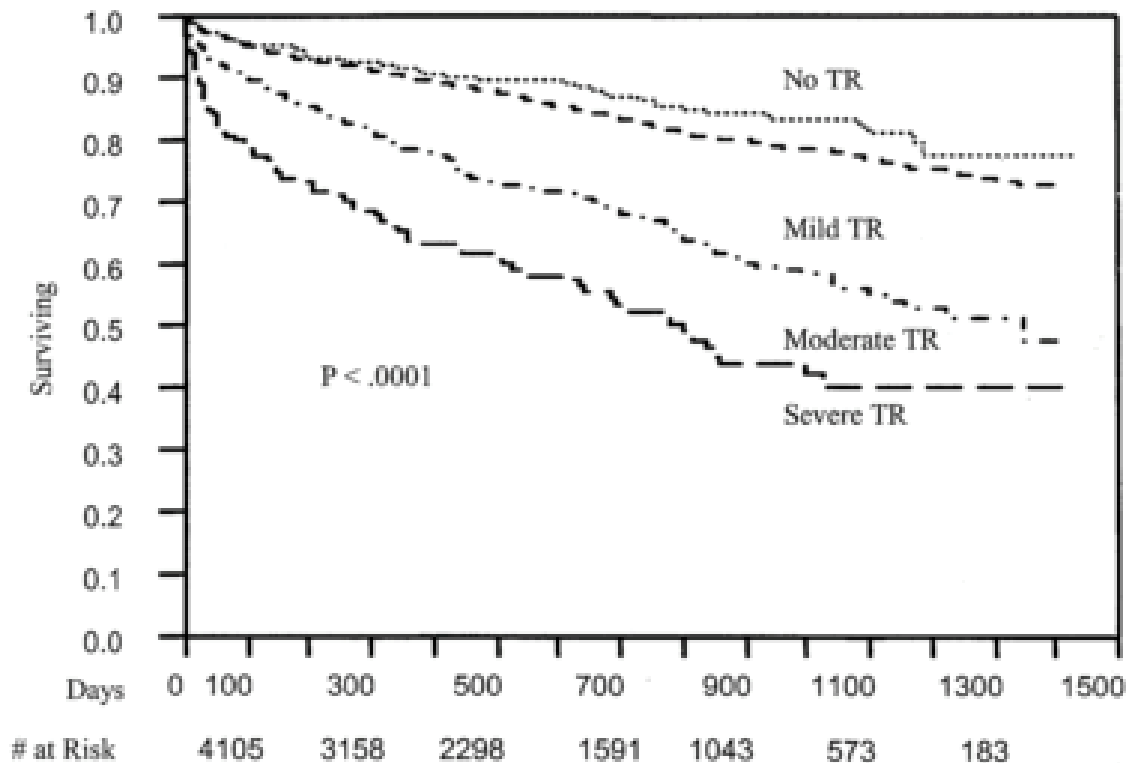
TRICUSPIDE: LA VALVOLA DIMENTICATA

Functional Tricuspid and Mitral Regurgitation have the same incidence & prevalence and are related to aging*



* Diagnosed in Olmsted County, MN, USA Data presented by Prof. M. Enriquez-Sarano - Mayo Clinic
CONFIDENTIAL

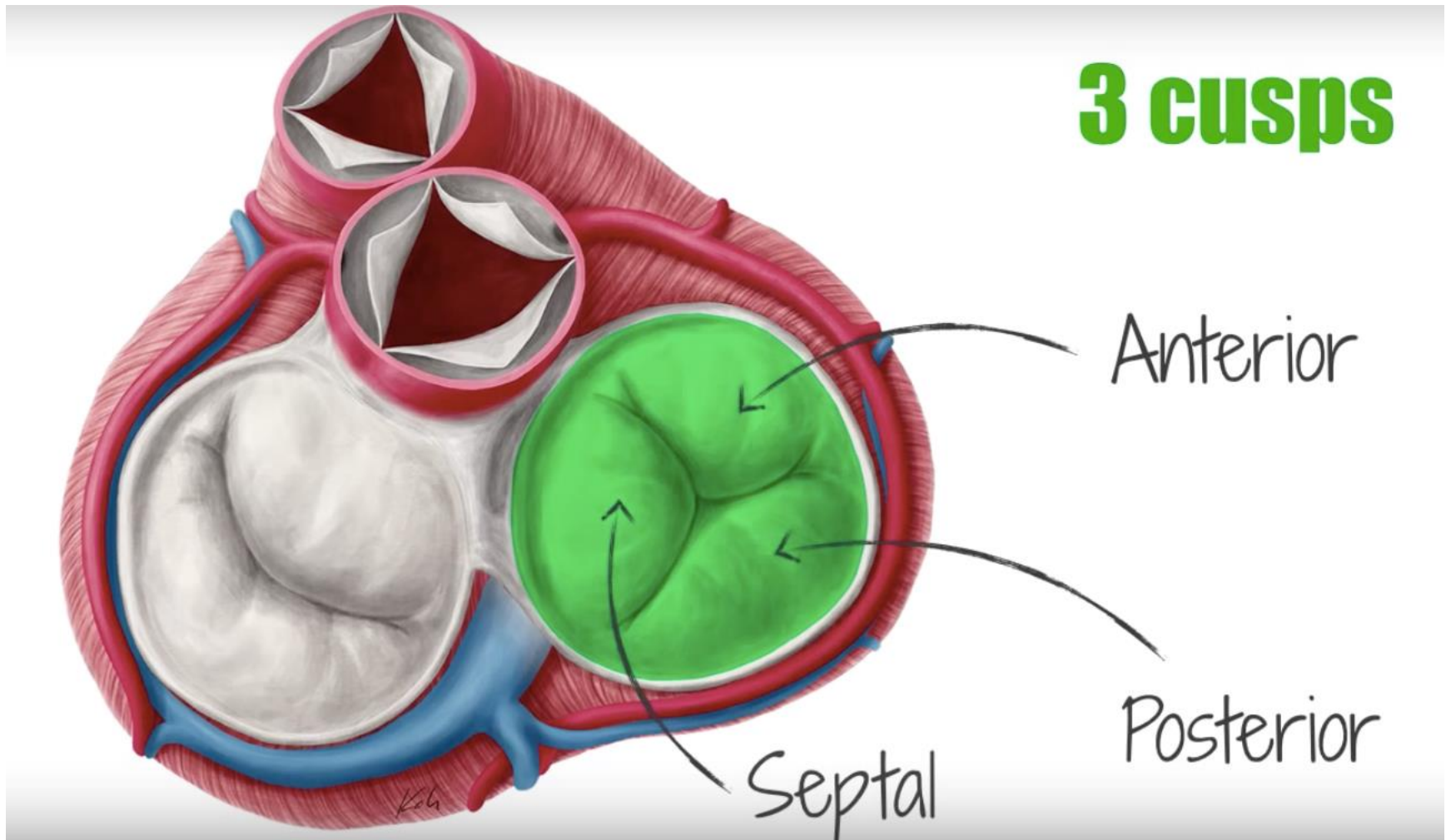
TRICUSPIDE: LA VALVOLA DIMENTICATA



Nath et al. JACC 2004;43:405-9

Stuge and Liddicoat J. Thorac Cardiovasc Surg. 2006;132:1258-61

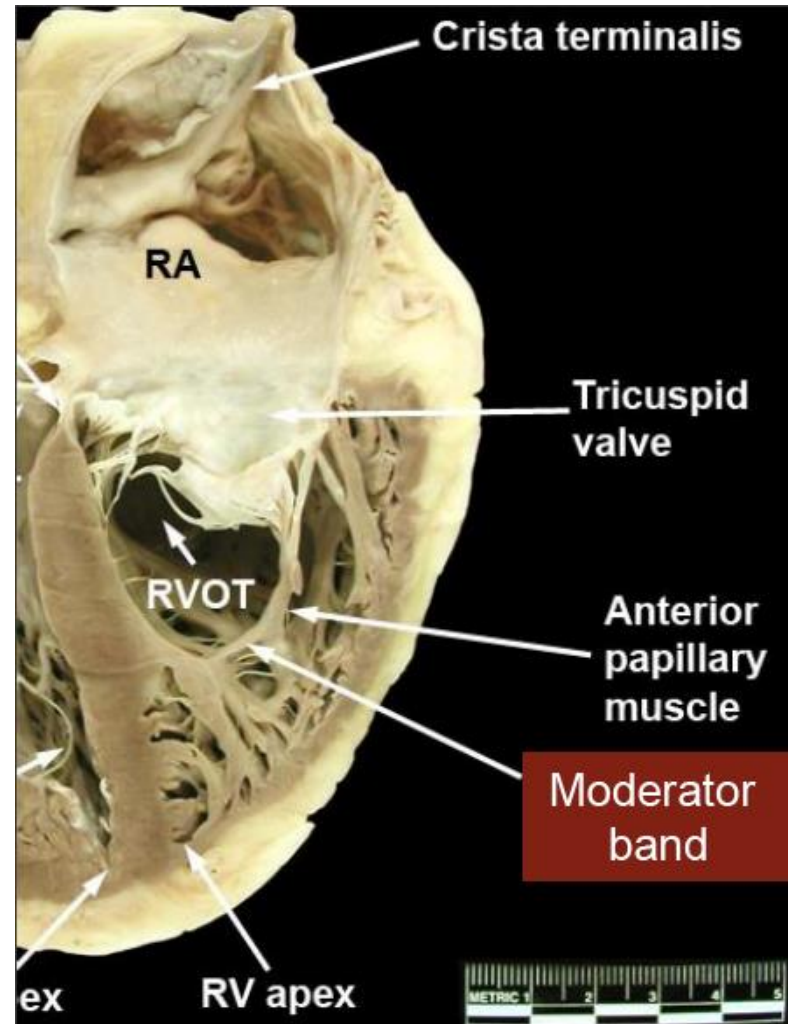
ANATOMIA VALVOLA TRICUSPIDE



ANATOMIA VALVOLA TRICUSPIDE



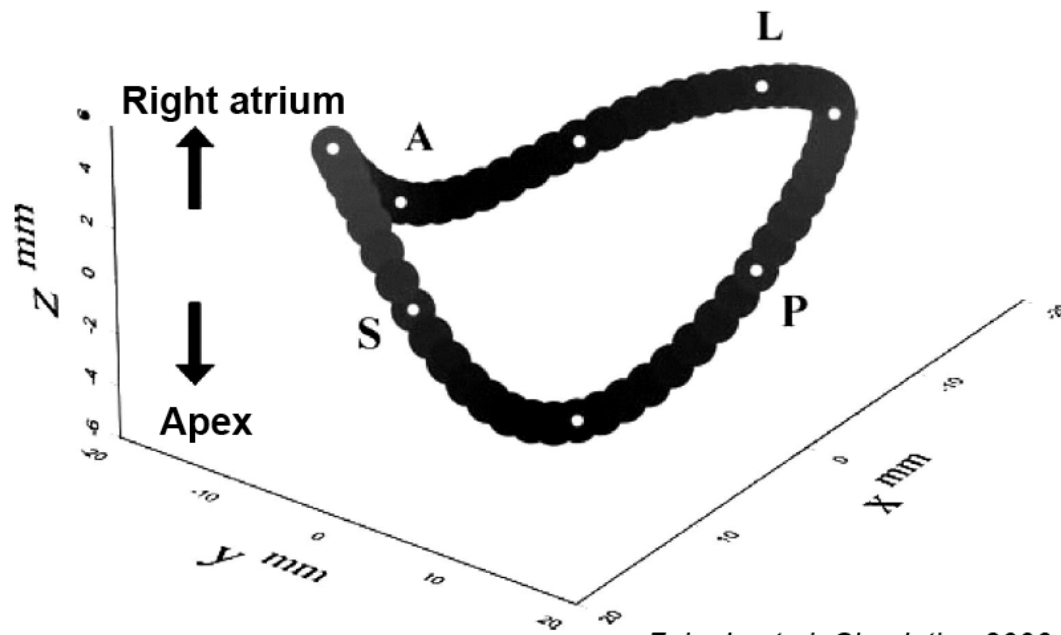
**Valve Area
4-6 cm²**



ANATOMIA VALVOLA TRICUSPIDE

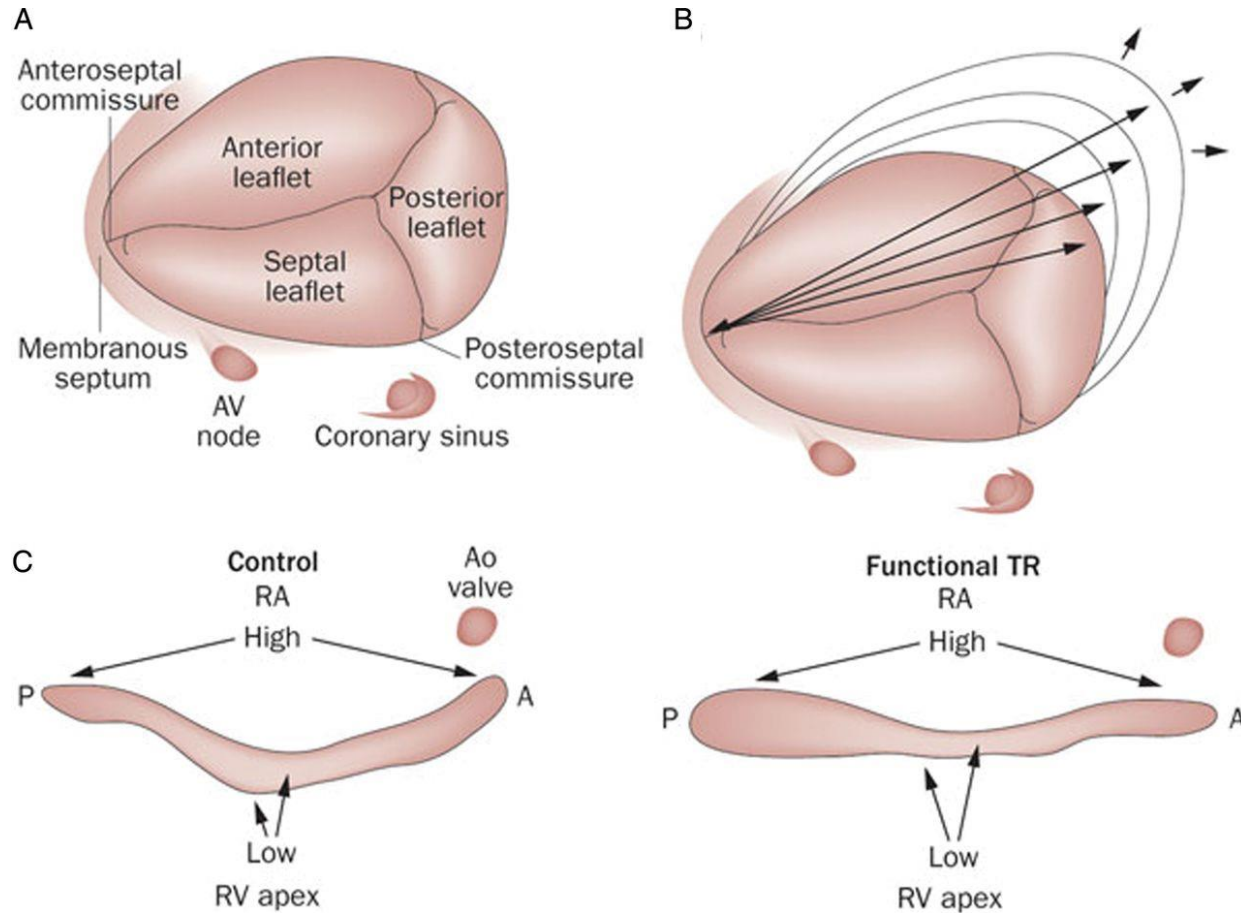
3D shape of the tricuspid annulus

- **Nonplanar, elliptical structure**
 - AS portion is the highest, PS portion is the lowest point
- **Influenced by RV function and loading conditions**
 - ≈ 19% reduction in circumference with atrial systole



Fukuda et al. Circulation 2006;114:1492-98.

ANATOMIA VALVOLA TRICUSPIDE



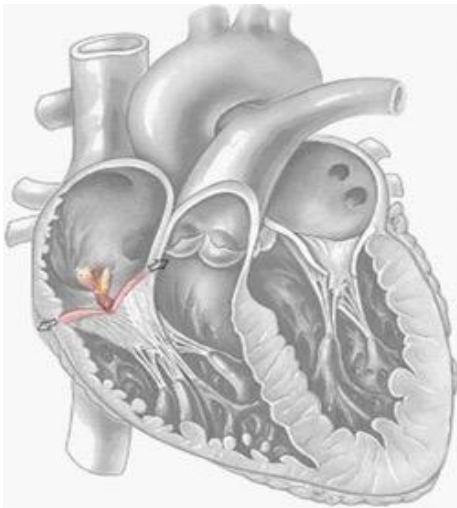
INSUFFICIENZA TRICUSPIDALICA

TABLE 1 Etiologies of TR

Morphological Classification	Disease Subgroup	Specific Abnormality
Primary leaflet abnormality: 25%	Congenital	Ebstein's anomaly Tricuspid valve tethering associated with perimembranous VSD and VSA Other (giant right atrium)
	Acquired disease	Carcinoid Degenerative (myxomatous) Endocarditis Endomyocardial fibrosis Iatrogenic (pacing leads, RV biopsy) Rheumatic Toxins Trauma Other (e.g., ischemic papillary muscle rupture)
Secondary ("functional"): 75%	Left heart disease	LV dysfunction or valve disease
	Right ventricular dysfunction	RV cardiomyopathy (e.g., ARVD) RV ischemia RV volume overload
	Pulmonary Hypertension	Chronic lung disease Left-to-right shunt Pulmonary thromboembolism
	Right atrial abnormalities	Atrial fibrillation
Other	Post-operative	Recurrent TR post-surgical intervention

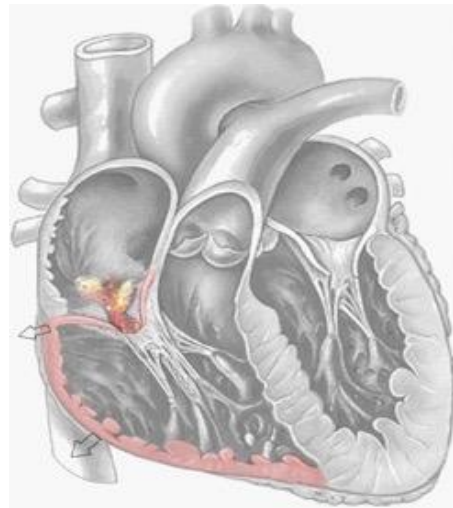
ARVD = arrhythmogenic right ventricular dysplasia; LV = left ventricle; RV = right ventricle; TR = tricuspid regurgitation; VSA = ventricular septal aneurysm; VSD = ventricular septal defect.

INSUFFICIENZA TRICUSPIDALICA



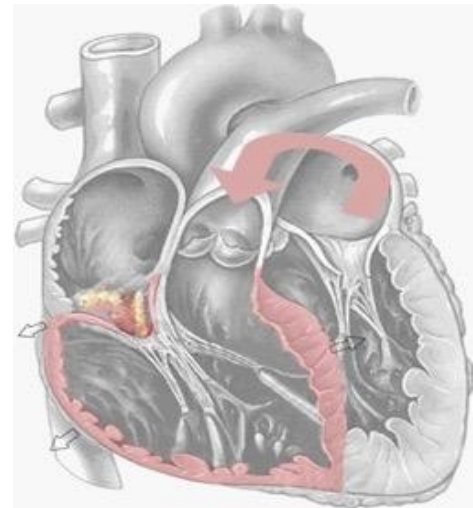
Phase I

Initial dilation of RV
results in TA dilation



Phase II

Progressive RV
and TA dilation
results in lack of coaptation



Phase III

Progressive RV distortion
tethering of the leaflets,
TA dilation, pulm hypertension

INSUFFICIENZA TRICUSPIDALICA

AHA and ACC (2014)³

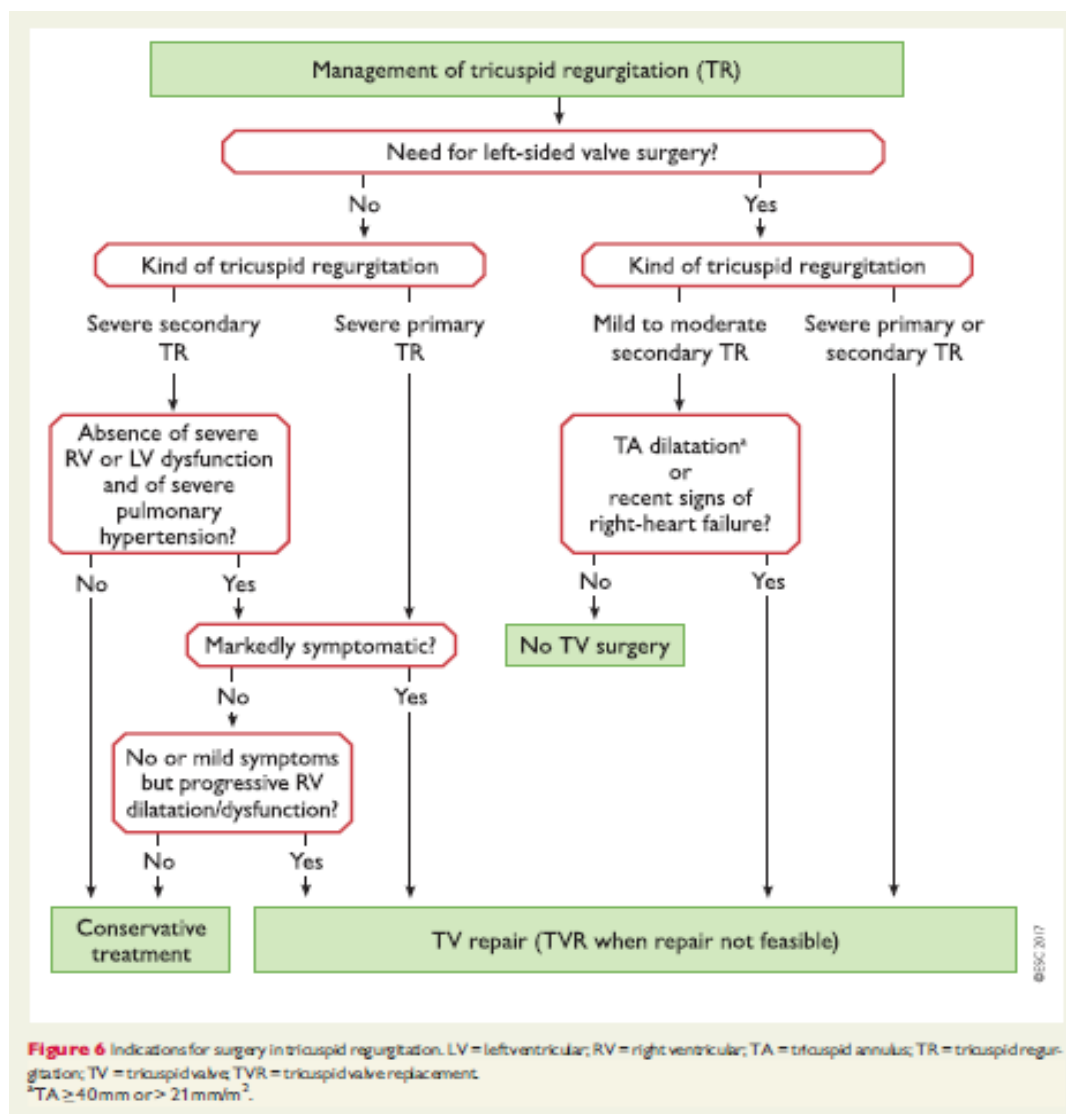
Primary TR

Severe TR at the time of left-sided valve surgery	I	C
Symptoms caused by severe TR not responsive to medical therapy	IIa	C
Asymptomatic or minimally symptomatic severe TR and progressive right ventricular dilatation and/or dysfunction	IIb	C

Secondary TR

Severe TR at the time of left-sided valve surgery	I	C
Mild, moderate, or greater TR at the time of left-sided valve surgery with either a dilated annulus (≥ 40 mm or ≥ 21 mm/m ²) or evidence of previous right heart failure	IIa	B
Moderate TR and pulmonary hypertension at the time of left-sided valve surgery	IIb	C
Reoperation for persistent symptoms caused by isolated severe TR after previous left-sided valve surgery in absence of severe pulmonary artery hypertension or right ventricular dysfunction	IIb	C

INSUFFICIENZA TRICUSPIDALICA



INSUFFICIENZA TRICUSPIDALICA

Indications for tricuspid valve surgery

Recommendations	Class ^a	Level ^b
Recommendations on tricuspid stenosis		
Surgery is indicated in symptomatic patients with severe tricuspid stenosis. ^c	I	C
Surgery is indicated in patients with severe tricuspid stenosis undergoing left-sided valve intervention. ^d	I	C
Recommendations on primary tricuspid regurgitation		
Surgery is indicated in patients with severe primary tricuspid regurgitation undergoing left-sided valve surgery.	I	C
Surgery is indicated in symptomatic patients with severe isolated primary tricuspid regurgitation without severe RV dysfunction.	I	C
Surgery should be considered in patients with moderate primary tricuspid regurgitation undergoing left-sided valve surgery.	IIa	C
Surgery should be considered in asymptomatic or mildly symptomatic patients with severe isolated primary tricuspid regurgitation and progressive RV dilatation or deterioration of RV function.	IIa	C

Recommendations on secondary tricuspid regurgitation

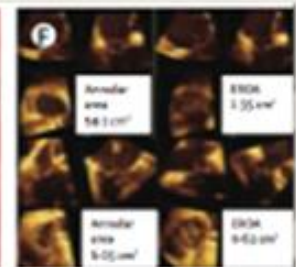
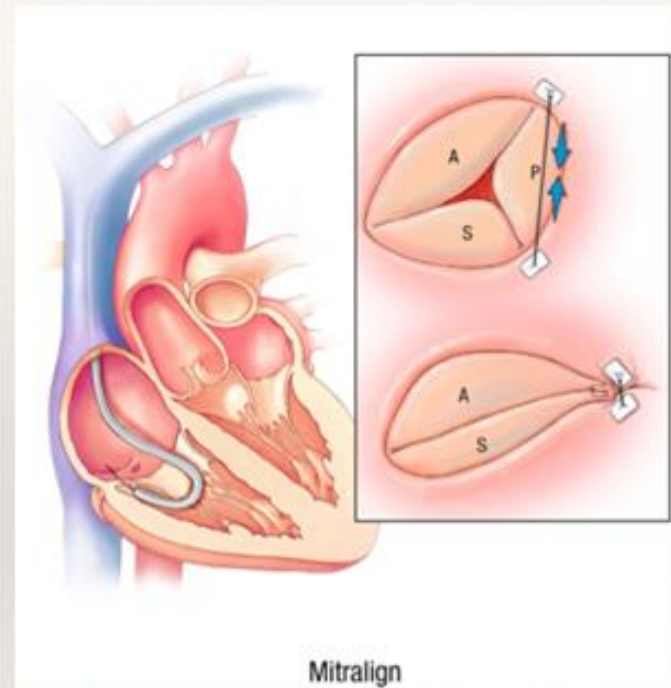
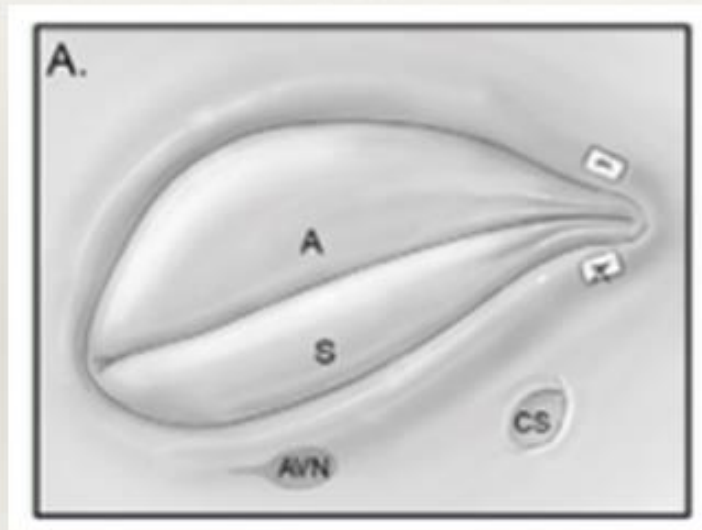
Surgery is indicated in patients with severe secondary tricuspid regurgitation undergoing left-sided valve surgery.	I	C
Surgery should be considered in patients with mild or moderate secondary tricuspid regurgitation with a dilated annulus (≥ 40 mm or > 21 mm/m ² by 2D echocardiography) undergoing left-sided valve surgery.	IIa	C
Surgery may be considered in patients undergoing left-sided valve surgery with mild or moderate secondary tricuspid regurgitation even in the absence of annular dilatation when previous recent right-heart failure has been documented.	IIb	C
After previous left-sided surgery and in absence of recurrent left-sided valve dysfunction, surgery should be considered in patients with severe tricuspid regurgitation who are symptomatic or have progressive RV dilatation/dysfunction, in the absence of severe RV or LV dysfunction and severe pulmonary vascular disease/hypertension.	IIa	C

TIPI DI TRATTAMENTO

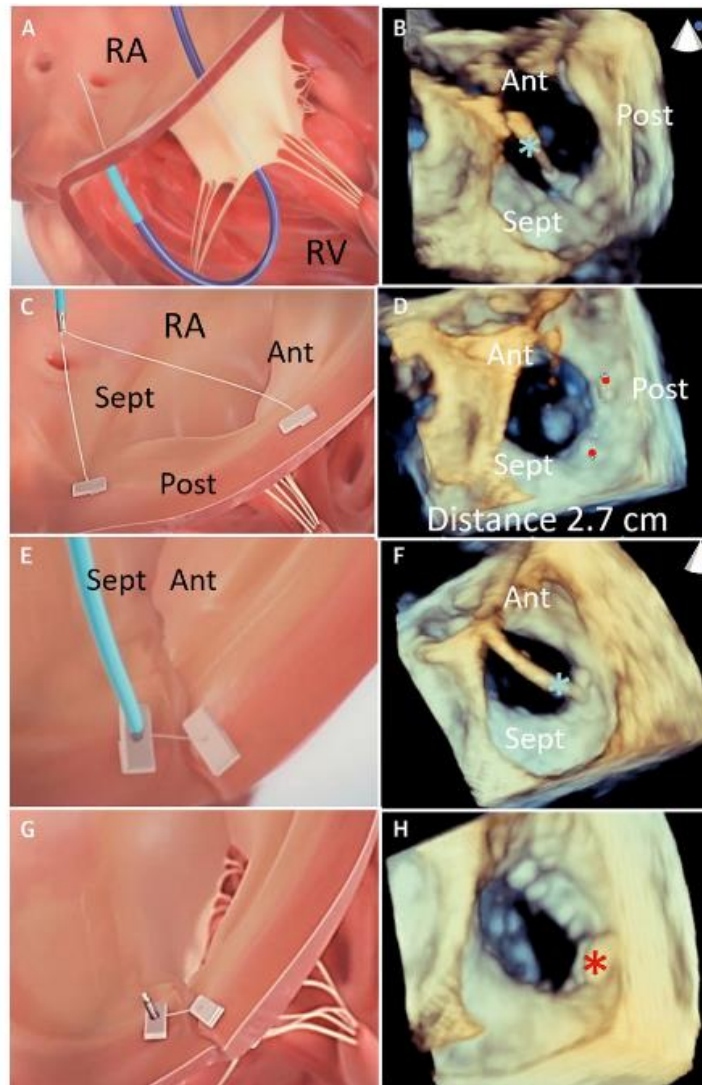
Table 2. Overview of the treatments for tricuspid regurgitation

Mechanism	Surgical technique	Transcatheter technique
Cinching the apparatus	• Ring annuloplasty • Suture annuloplasty	• Mitralign • Tricinch • Millipede • Cardioband
Coaptation of the valve	• Anterior leaflet enlargement • Double-orifice technique	Forma
Edge to edge repair	Clover	MitraClip
Replacement	Orthotopic valve implantation	Heterotopic caval vein implantation (CAVI)

TIPI DI TRATTAMENTO: MITRALIGN



TIPI DI TRATTAMENTI: MITRALIGN



TIPI DI TRATTAMENTO: MITRALIGN

SCOUT I Safety

Safety Profile and Implant Success

	n/N	(%)
Acute Procedure		
Implant Success	15/15	100%
Unplanned intervention	1/15	7%
Intraprocedural stenting of RCA		
30 Day Follow Up		
Freedom from death	15/15	100%
Technical Success	12/15	80%
3 single pledget dehiscence		
Major Adverse Events	0/15	0%

TIPI DI TRATTAMENTO: MITRALIGN

SCOUT I Echocardiographic Outcomes

Echocardiographic Outcomes at 30 Days

Per Protocol^{‡*}

TTE Outcome	Baseline mean +/- SD (n=12)	30 Day mean +/- SD (n=12)
PISA EROA cm ²	0.51 ± 0.2	0.32 ± 0.2
Quantitative EROA cm ²	0.9 ± 0.2	0.6 ± 0.3
TR regurgitant volume ml	79.6 ± 17.5	57.1 ± 29.0
LVOT stroke volume ml	63.6 ± 17.9	71.5 ± 25.7

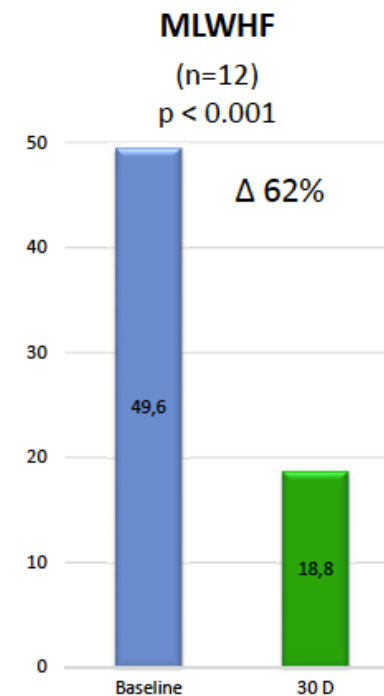
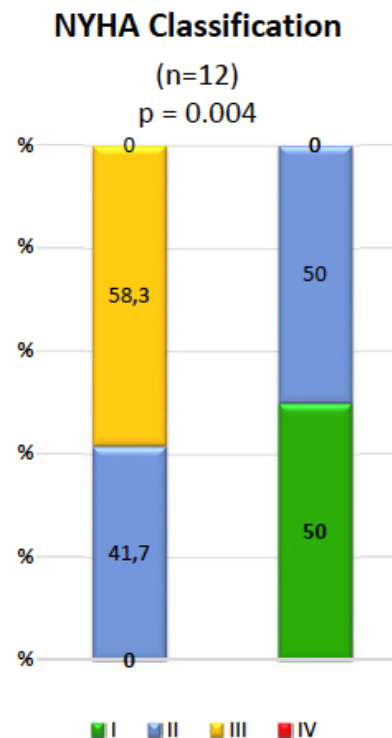
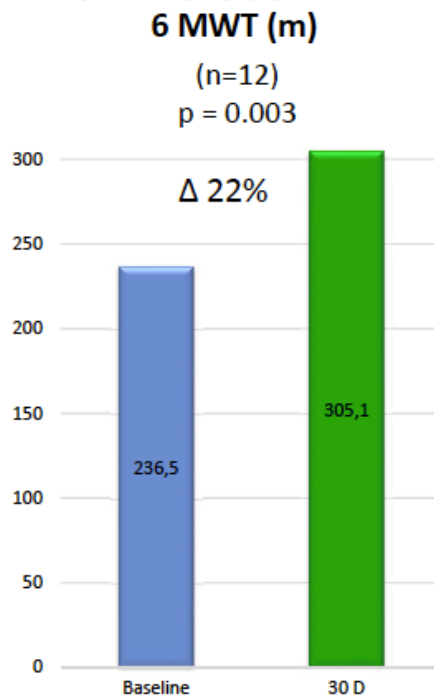
[‡] Change from baseline to 30 days computed on paired data
^{*} p-value by paired t-test or Wilcoxon as appropriate

TIPI DI TRATTAMENTO: MITRALIGN

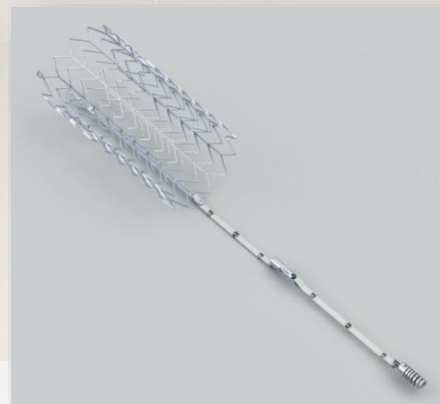
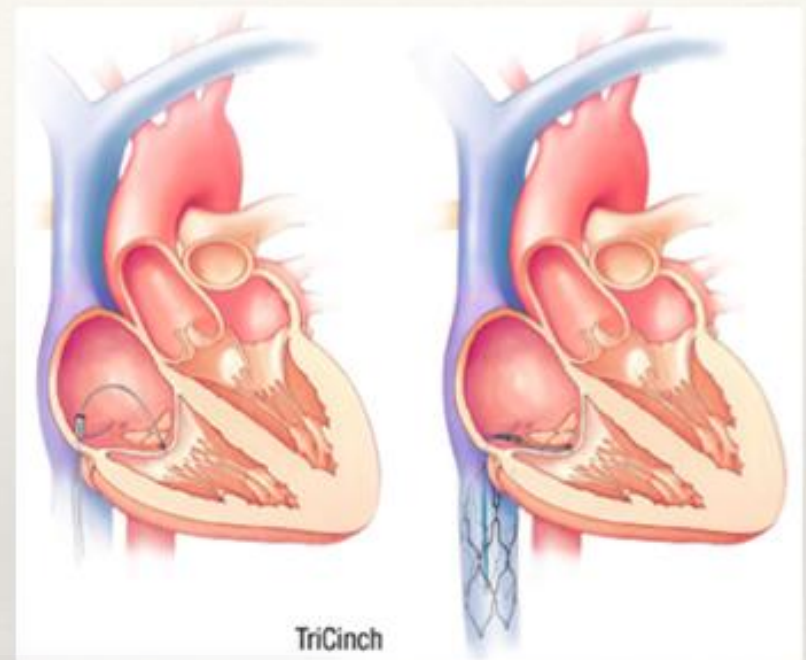
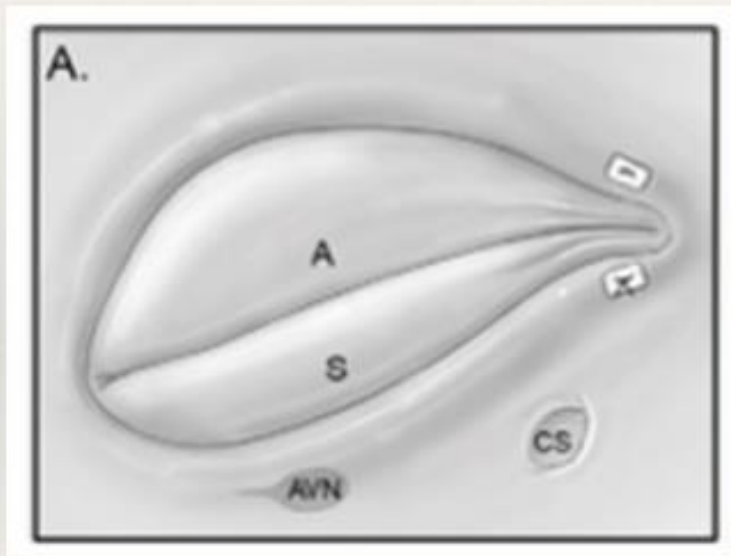
SCOUT I Clinical Outcomes

Clinical Outcomes at 30 Days

Per Protocol^{†*}



TIPI DI TRATTAMENTO: TRI-CINCH



TIPI DI TRATTAMENTO: TRI-CINCH

Early Clinical outcomes from TriCinch™ Gen 1

Baseline characteristics - Patients Enrolled: 24

- Age 71±7yo
- NYHA class ≥III 17 [71%]
- LogES median 12
- Signs of right HF 24 [100%]

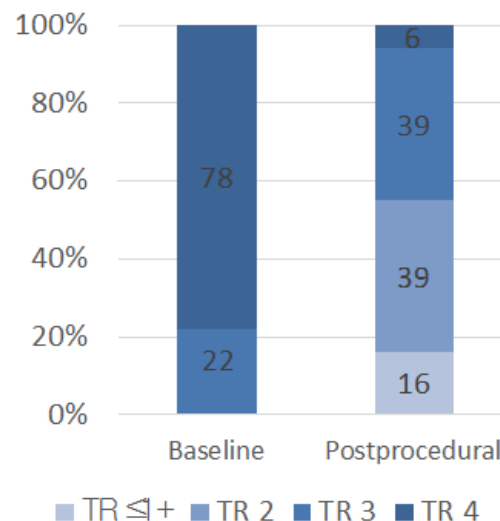
Procedural and post-procedure

Patient Treated (successful implantation)	18 [75%]
Perioperative complications	
hemopericardium	2 [8%]
Post-operative complications	
annulus anchor late detachment	4 [17%]
(no SAE/AE related to detachment)	
30-day all-cause mortality	0 [0%]

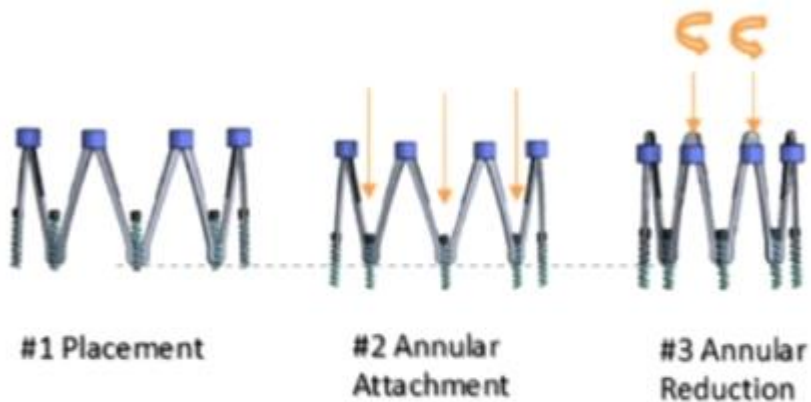
6 Months Follow-up data (n=4)

Accumulated implant time	43 months
Median follow-up time	1 month [1-6]
NYHA class	I - II 75% III 25% IV 0%
Quality of Life Improvement	6MWT (m) +53% - MLHFQ +38% - SF36-physical +42%
All-cause mortality	0 [0%]

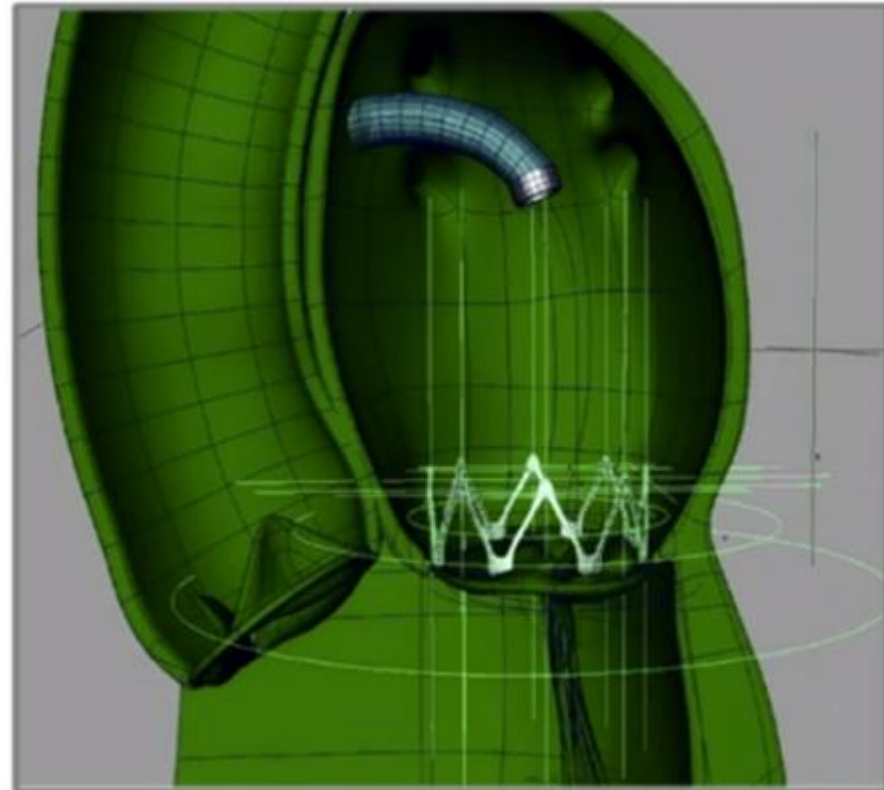
TR Reduction in 94% of the patients



TIPI DI TRATTAMENTO: MILLEPIEDI

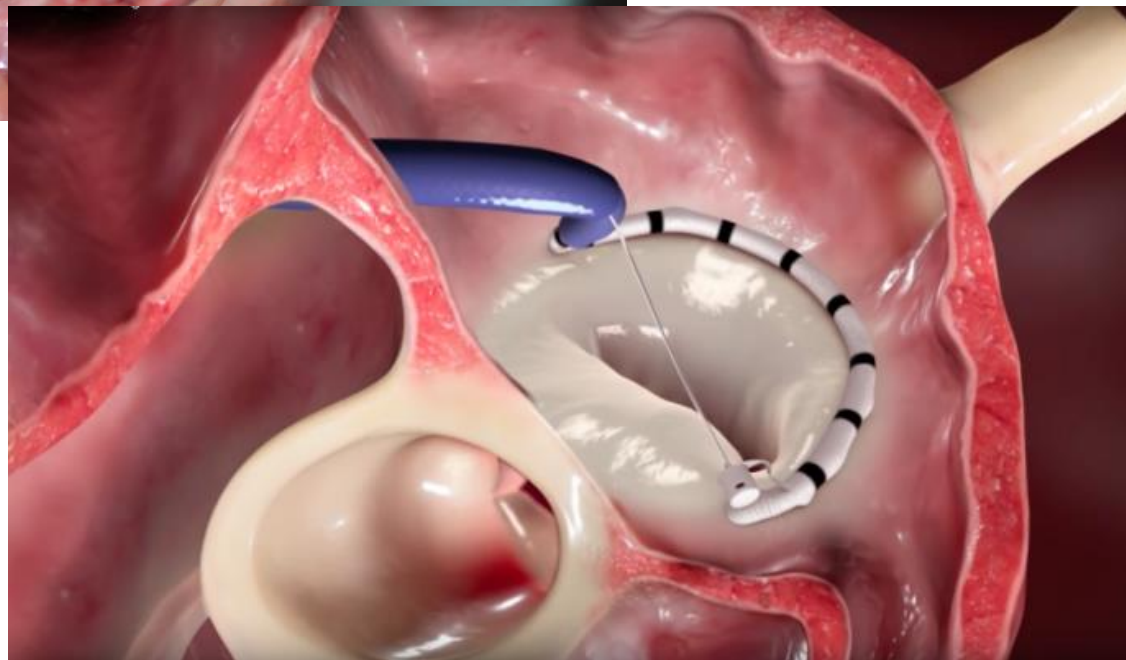
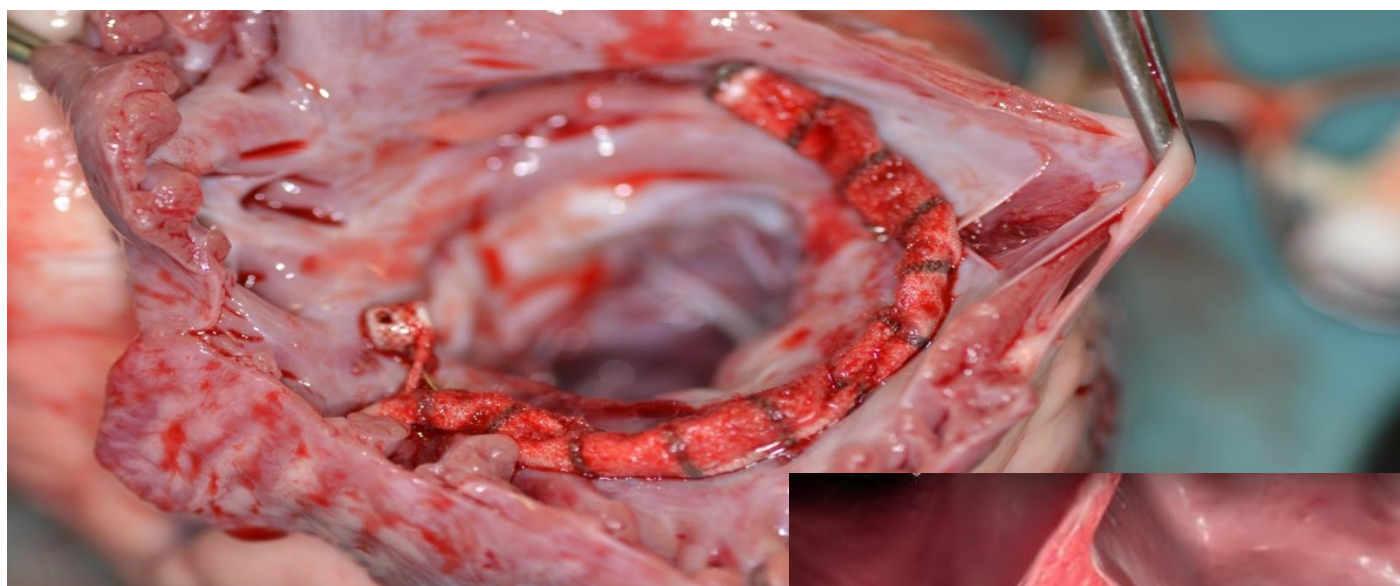


Direct Vision



Catheter Delivery

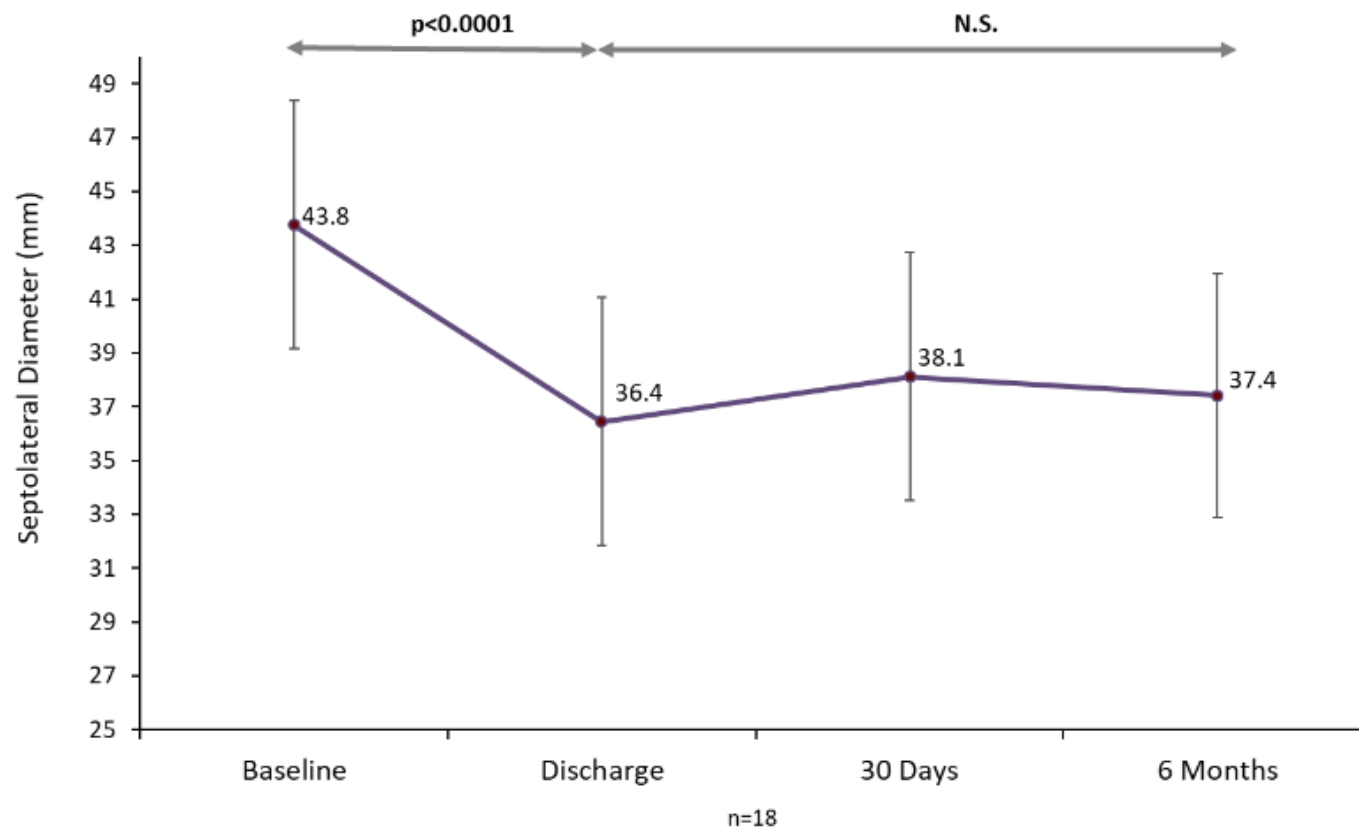
TIPI DI TRATTAMENTO: CARDIOBAND



TIPI DI TRATTAMENTO: CARDIOBAND

2018 | euro
PCR

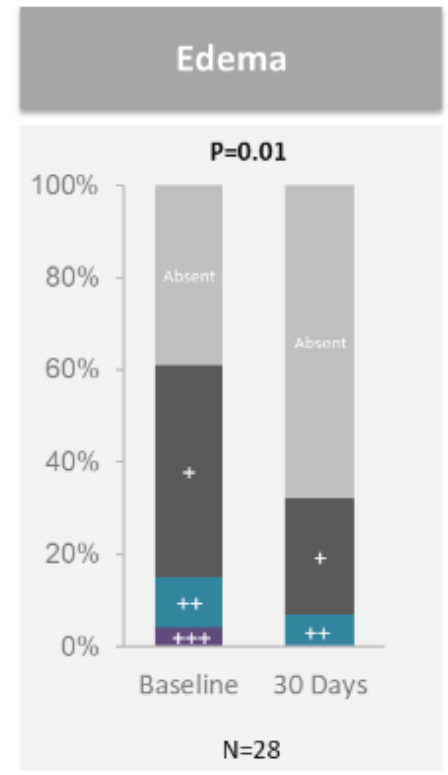
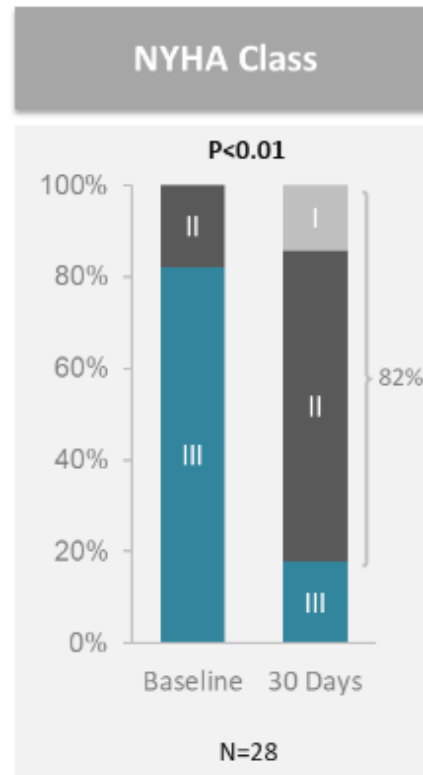
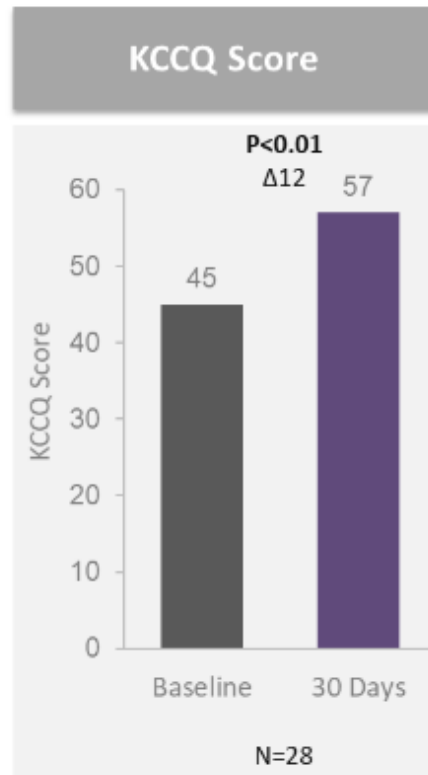
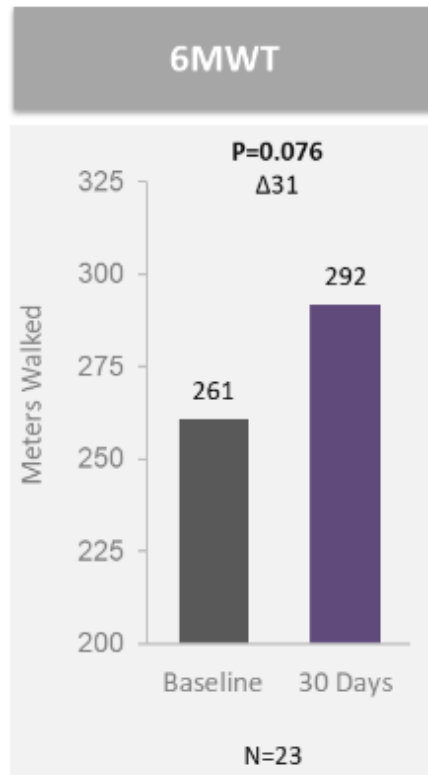
Edwards Cardioband Tricuspid System
TRI-REPAIR Study



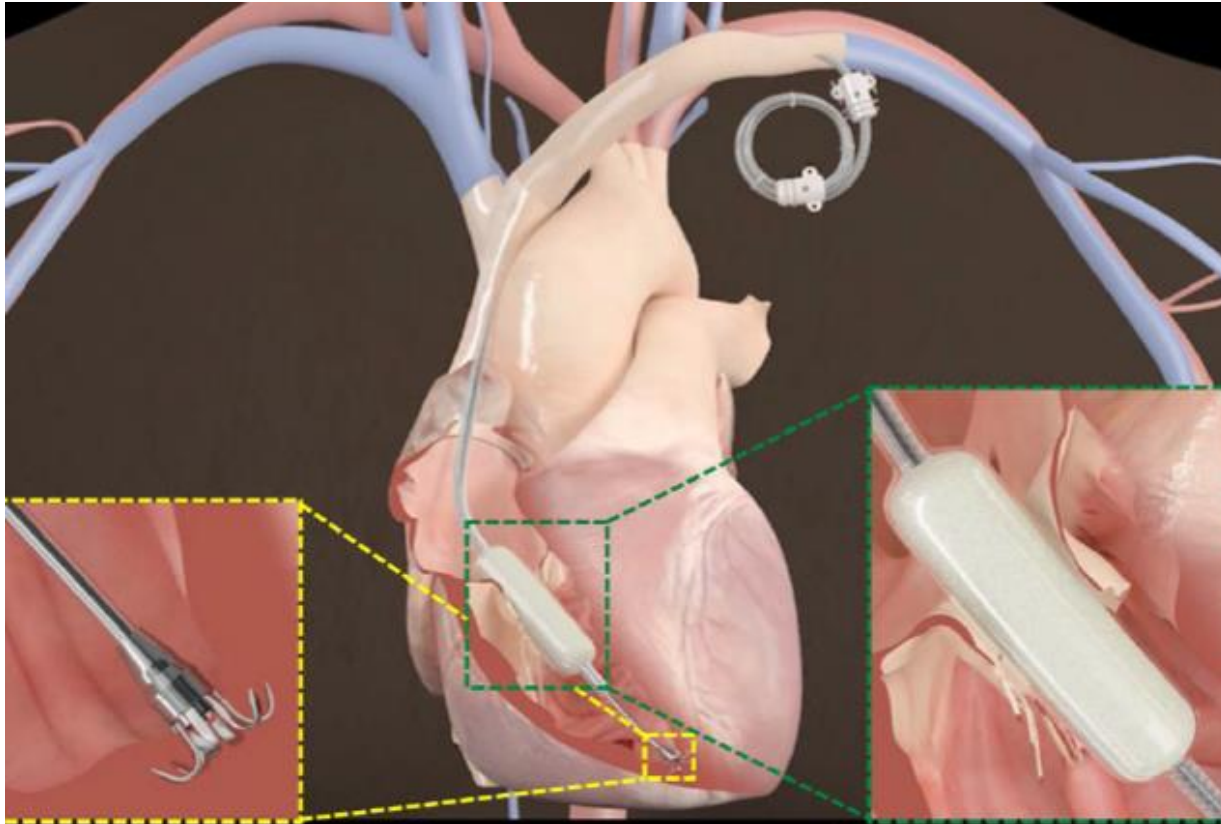
TIPI DI TRATTAMENTO: CARDBIOBAND



TIPI DI TRATTAMENTO: CARDIOBAND

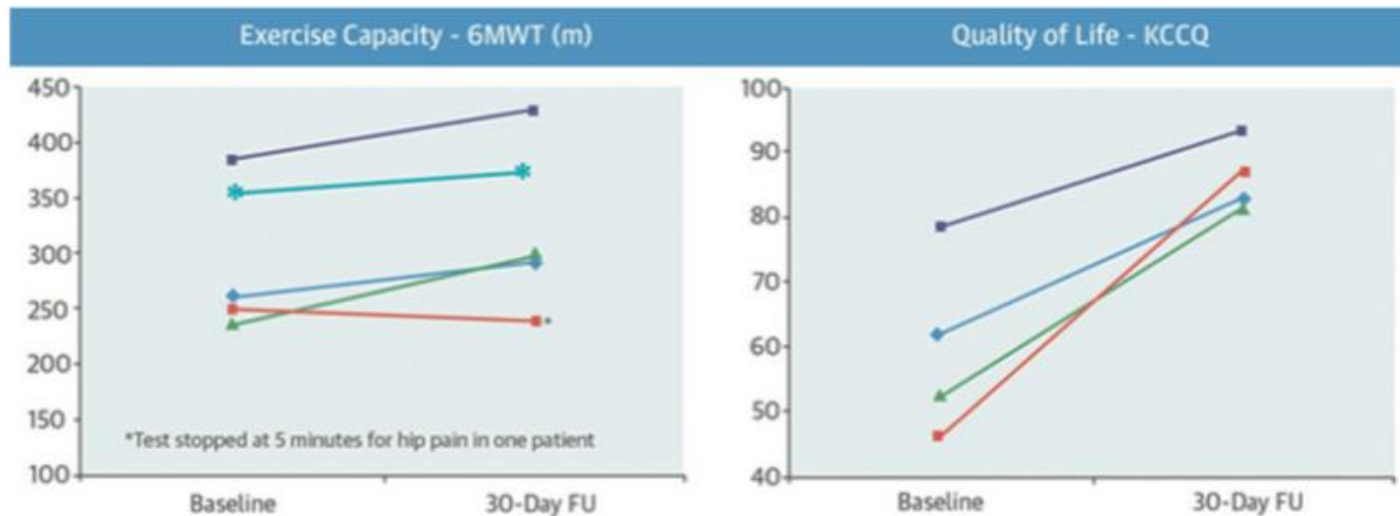


TIPI DI TRATTAMENTO: FORMA



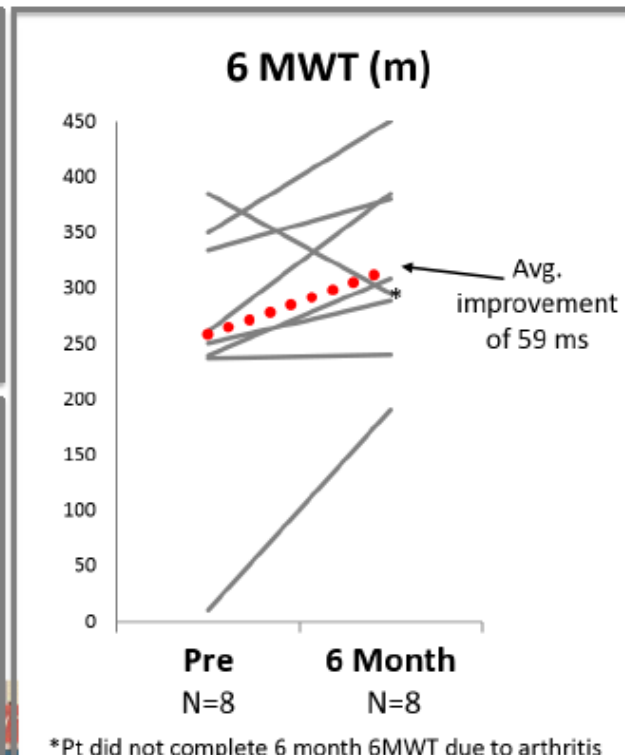
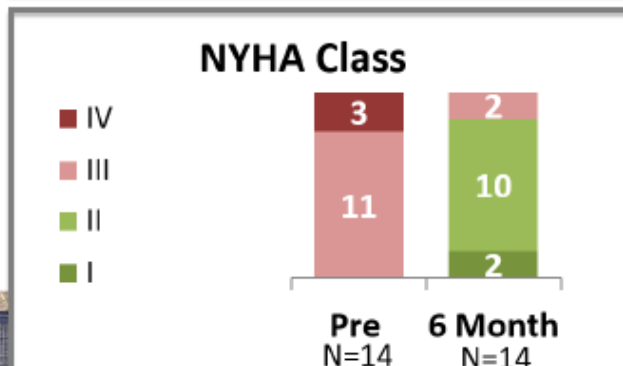
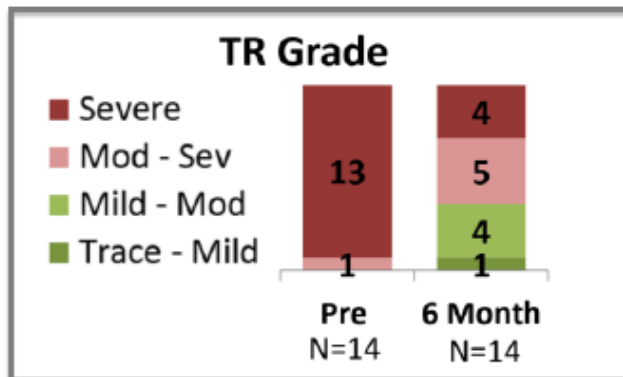
TIPI DI TRATTAMENTO: FORMA

CENTRAL ILLUSTRATION Novel Transcatheter Repair System for Severe Tricuspid Regurgitation: Exercise Capacity and Quality of Life Before and After Device Implantation

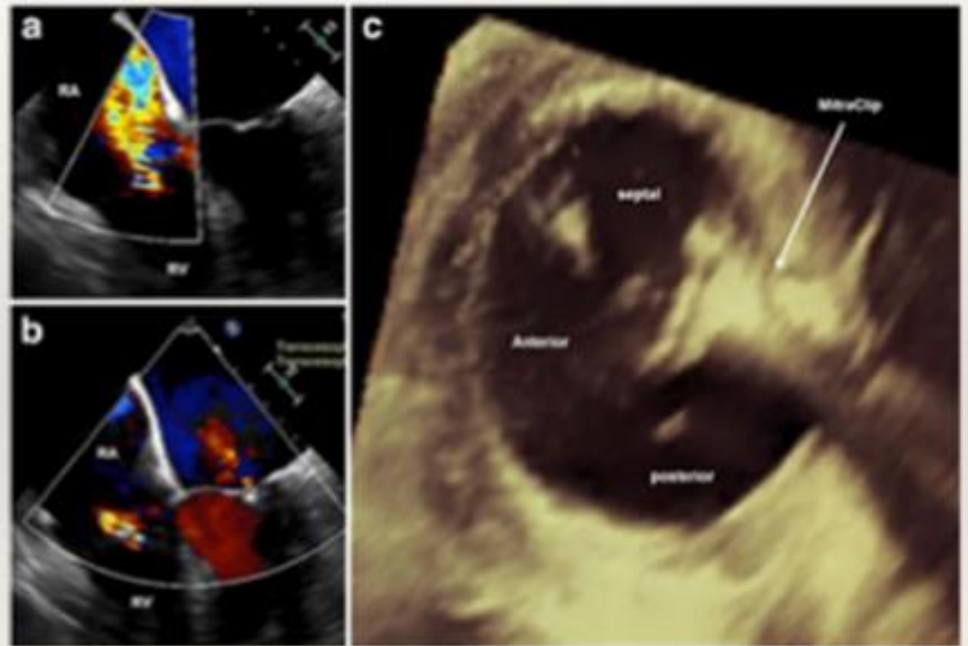
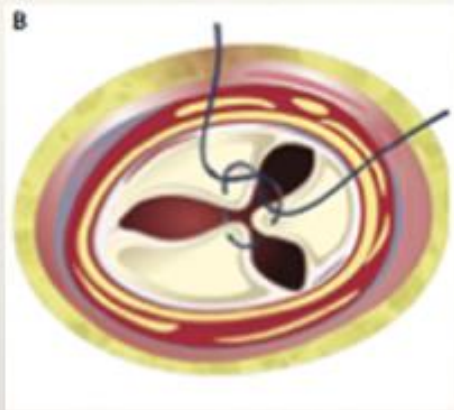


TIPI DI TRATTAMENTO: FORMA

Early FORMA Clinical Results 6 Month Follow Up



TIPI DI TRATTAMENTO: MITRALCLIP



TIPI DI TRATTAMENTO: MITRALCLIP

Circulation



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

Georg Nickenig, Marek Kowalski, Jörg Hausleiter, Daniel Braun, Joachim Schofer, Ermela Yzeiraj, Volker Rudolph, Kai Friedrichs, Francesco Maisano, Maurizio Taramasso, Neil P. Fam, Giovanni Bianchi, Francesco Bedogni, Paolo Denti, Ottavio Alfieri, Azeem Latib, Antonio Colombo, Christoph Hammerstingl and Robert Schueler

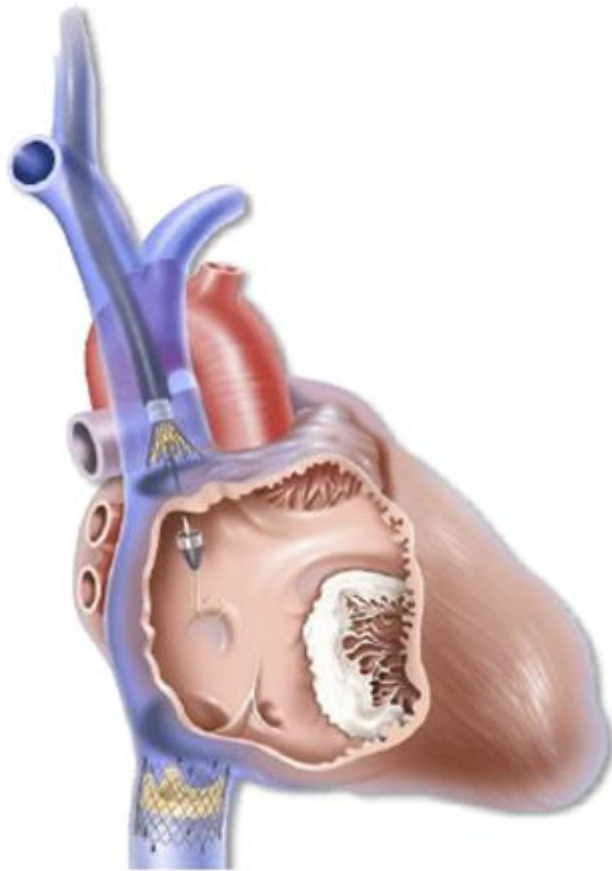
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TIPI DI TRATTAMENTO: MITRALCLIP

EUROPEAN EXPERIENCE IN 64 PATEINTS

	Clip for TR (n=42)			Clip for TR+MR (N=22)		
TR vena contracta, cm	1.0 ± 0.4	0.5 ± 0.1	0.003	1.3 ± 0.6	0.8 ± 0.5	0.06
TR EROA, cm ²	0.8 ± 0.4	0.4 ± 0.2	<0.001	1.0 ± 0.3	0.4 ± 0.1	<0.001
Regurgitant volume, ml/beat	59.9 ± 18.4	30.8 ± 6.9	<0.001	56.3 ± 13.4	29.9 ± 8.2	<0.001
Septo-lateral diameter, mm	43.2 ± 7.6	30.5 ± 8.7	0.02	42.2 ± 9.7	32.7 ± 9.6	0.04
Leaflet tenting area, cm ²	3.4 ± 1.9	3.6 ± 3.1	0.7	4.5 ± 0.7	4.2 ± 0.8	0.5
Leaflet tenting distance, mm	13.6 ± 3.7	15.5 ± 4.9	0.3	13.3 ± 4.5	14.8 ± 6.7	0.5
6MWT, m	181.9 ± 44.1	209.5 ± 59.9	0.006	224.0 ± 143.1	268.2 ± 143.1	0.2

TIPI DI TRATTAMENTO: CAVI



Review:

- Caval Valve Implantation
- Technology ad-hoc designed or Stent as support for TAVI implant
- Transfemoral-tranjugular access
- Risk of ventricularization of the right atrium
- Few clinical cases performed
- Few clinical data available

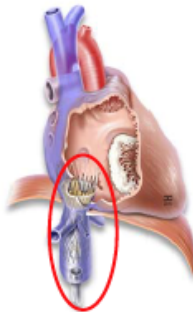
TIPI DI TRATTAMENTO: CAVI



Caval Valve Implantation (CAVI) – Concepts

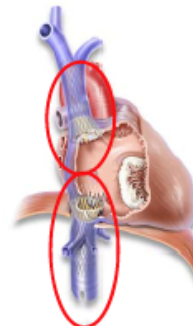
Volume 2016: ~ 40 compassionate cases treated mostly in Germany

IVC-CAVI – *Single* Valve Implantation



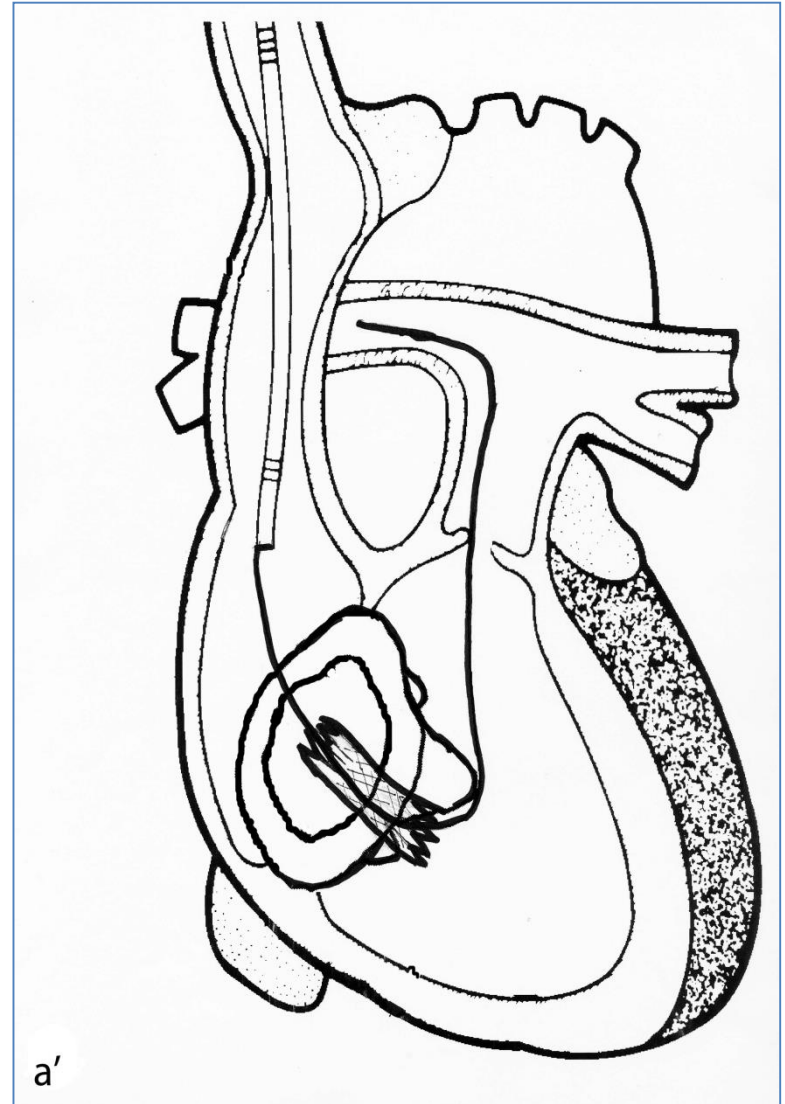
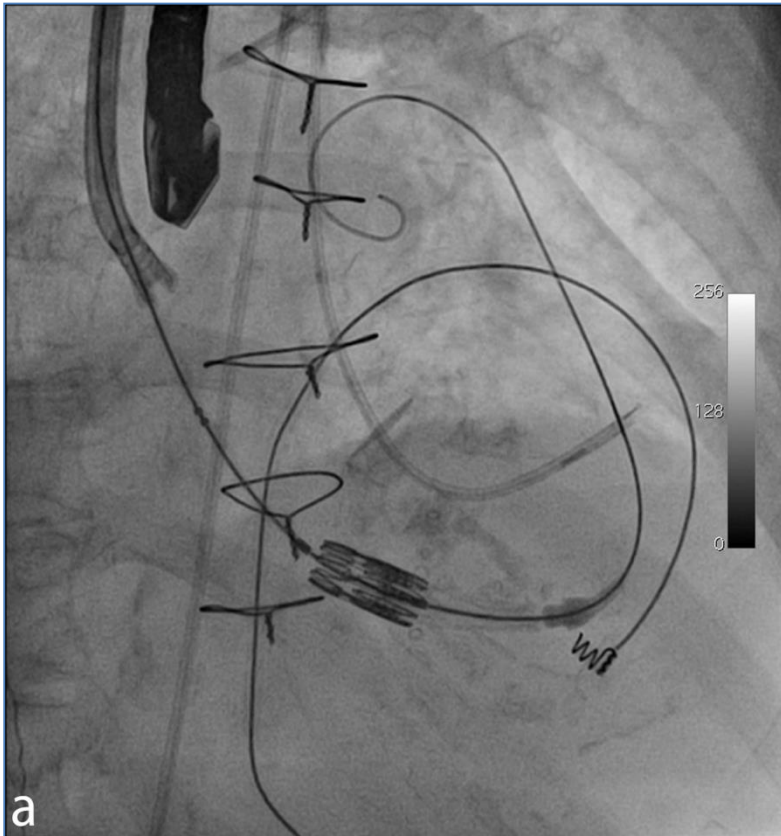
- AIM: - to resolve IVC congestion with limited material and time resources
however:
- partial treatment of ~ 2/3 of caval backflow
- potentially less effective regarding hemodynamic and clinical improvement due to collateral circulation

BiCAVI - Double Valve Implantation



- AIM: to resolve 100% of caval backflow
however:
- includes SVC + IVC Valve Implantation
- more expensive – 2 Valves and catheters
- technically challenging

TIPI DI TRATTAMENTO: VALVE IN VALVE



TIPI DI TRATTAMENTO: VALVE IN VALVE

First Implant of a Transcatheter Tricuspid Valved Stent Marks New Frontier in Percutaneous Valve Care



From ConsultQD

Transcatheter heart valve replacement has just expanded to a new front: A Cleveland Clinic team successfully performed the world's first implantation of a transcatheter tricuspid valved stent.

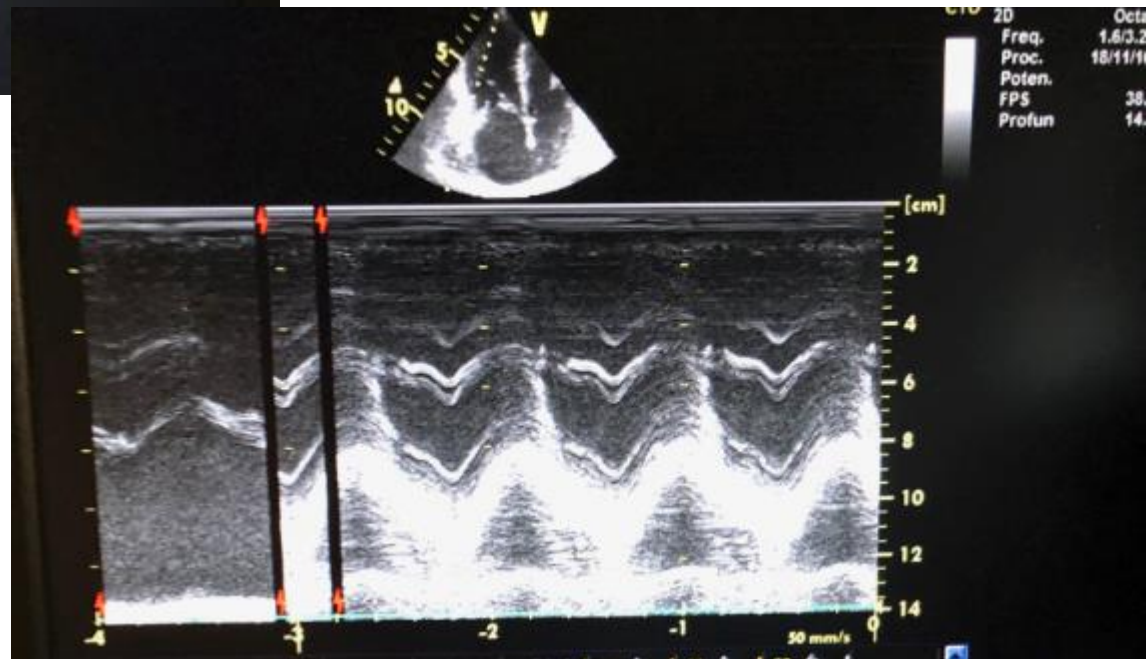
The procedure was done in November 2016 in a 64-year-old woman with a long history of severe tricuspid regurgitation (TR 4+), which invariably leads to lethal right heart failure. Following stent implantation (see Figure below), the new tricuspid valve demonstrated excellent valve performance, indicating significant reduction of the patient's severe valve regurgitation. The patient was stable and faring well 30 days after the procedure.

A step forward in treating tricuspid regurgitation

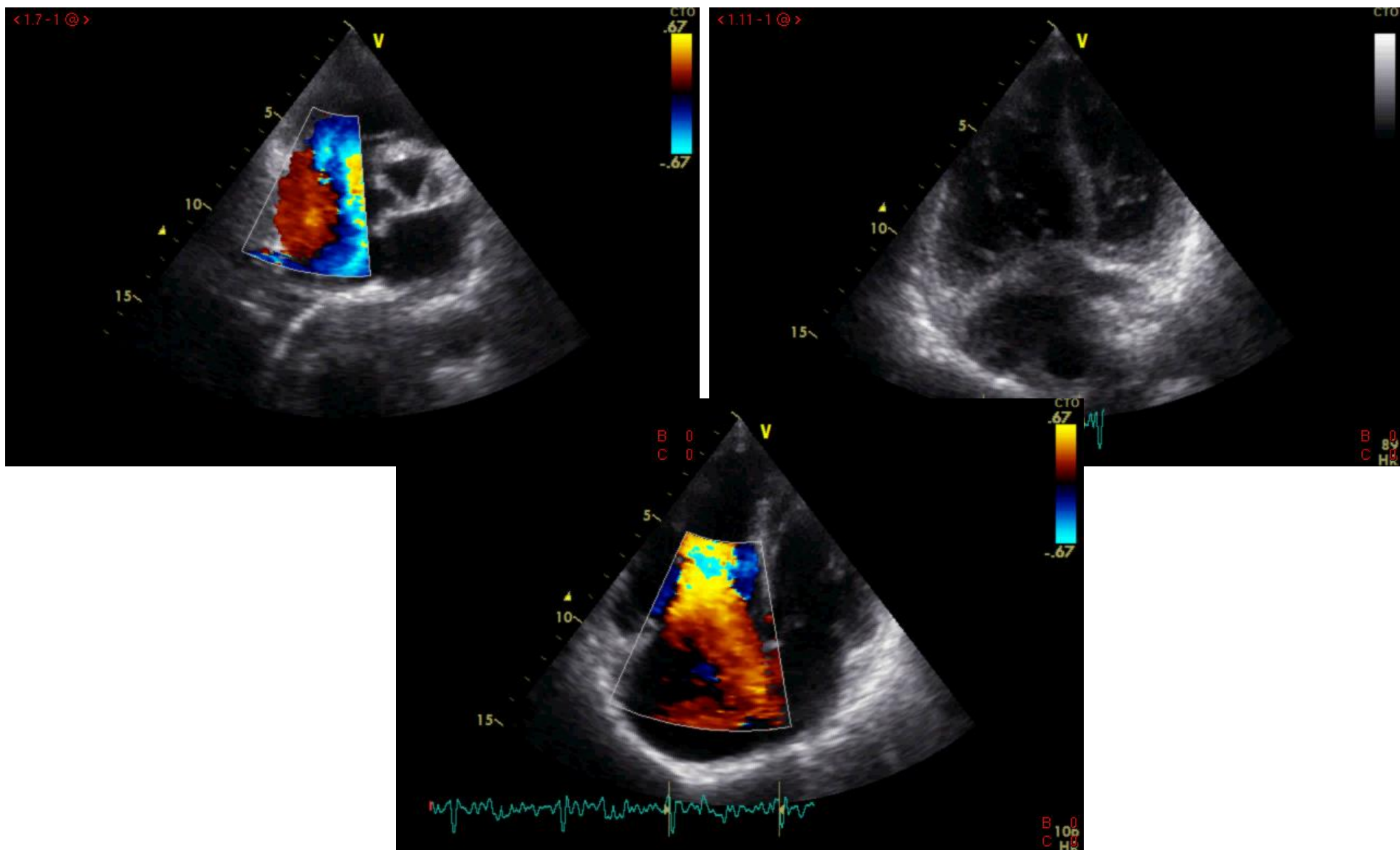
CASO CLINICO

- Uomo di 69 anni
- FdR: ex-tabagismo
- Comorbidità: carcinoma neuroendocrino intestinale sottoposto ad emicolectomia dx + resezione ileo terminale (2003), metastasectomie multiple epatiche (2004). Nel 2018 progressione della malattia a livello epatico per cui inizia terapia con Termozolide.
- Accesso in PS (3/2018) per dolore toracico e dispnea.
- TC torace per escludere TEPA: negativa
- Dispnea progressiva: richiesto ecocardiogramma

CASO CLINICO: ECOCARDIOGRAMMA



CASO CLINICO: ECOCARDIOGRAMMA

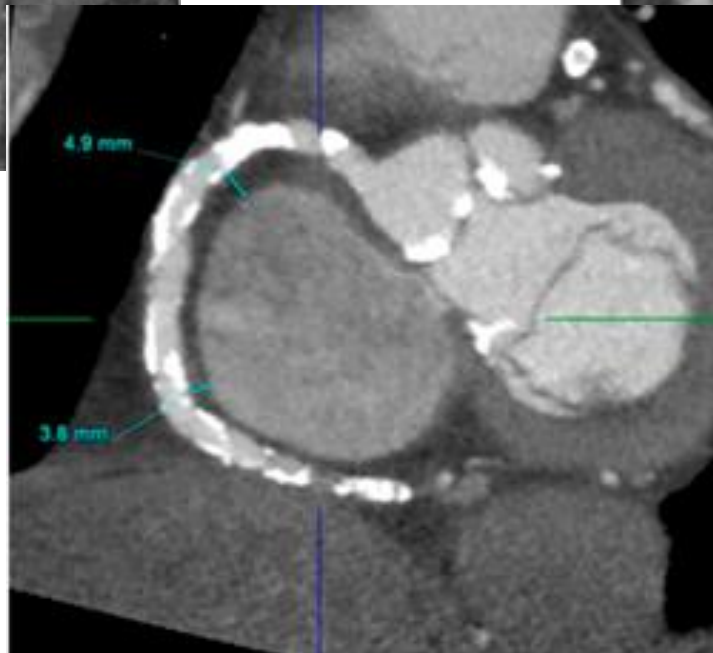
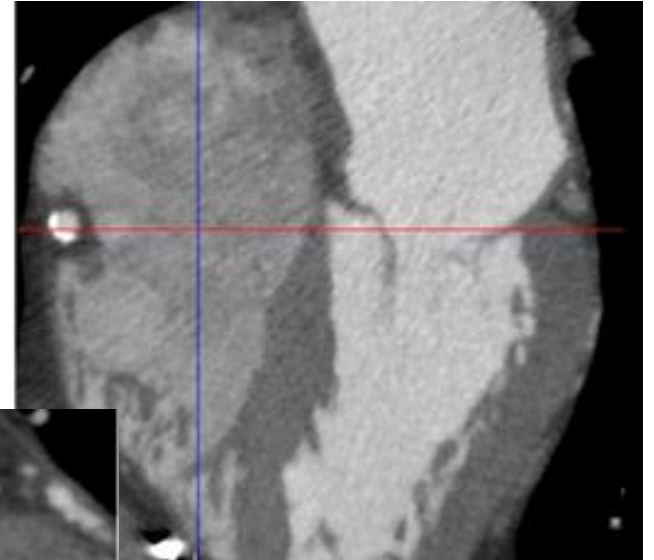
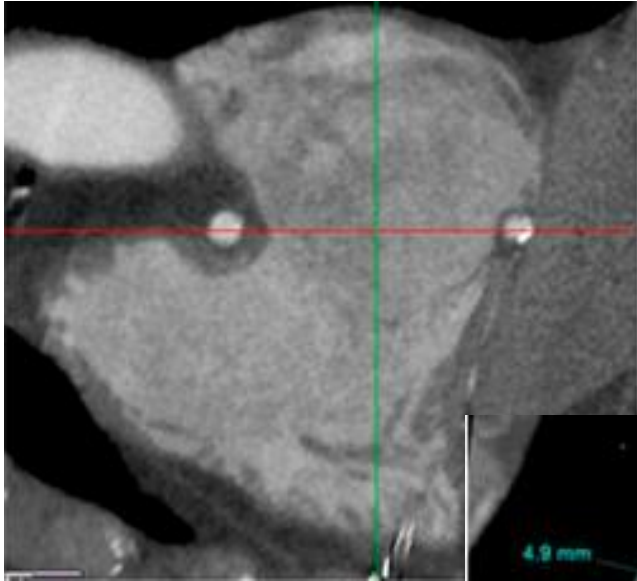


CASO CLINICO: CATETERISMO DESTRO E CORONAROGRAFIA

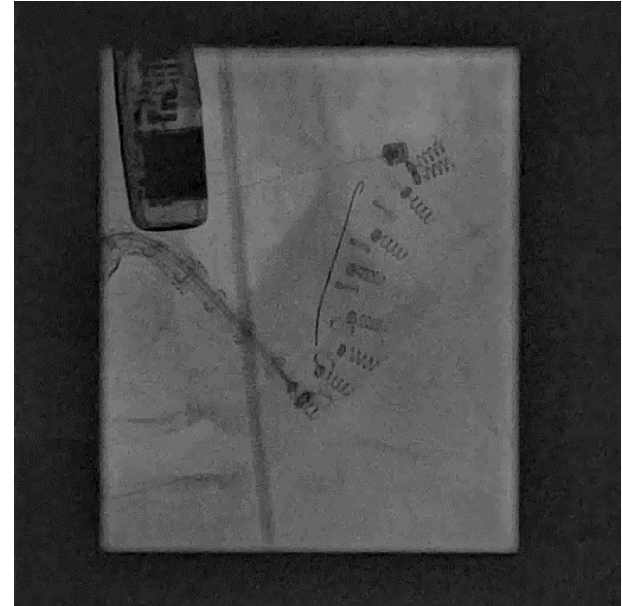
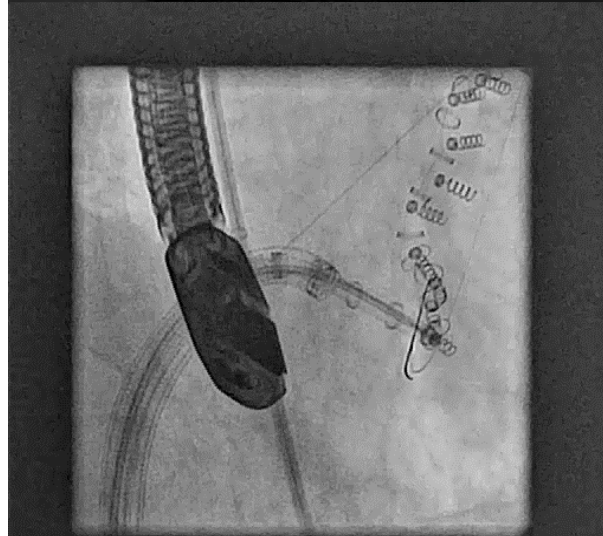
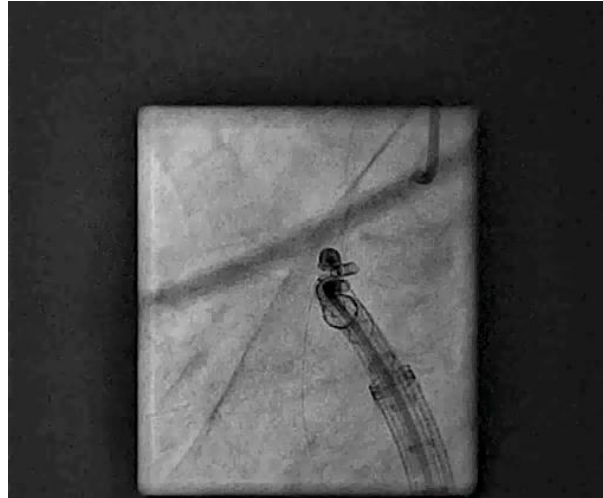
**PAPS 40
MMHG
PCWP 12
MMHG**

**CORONAROGRAFIA:
CORONARIE
CALCIFICHE ED
ATEROMASICHE MA
SENZA STENOSI
SIGNIFICATIVE**

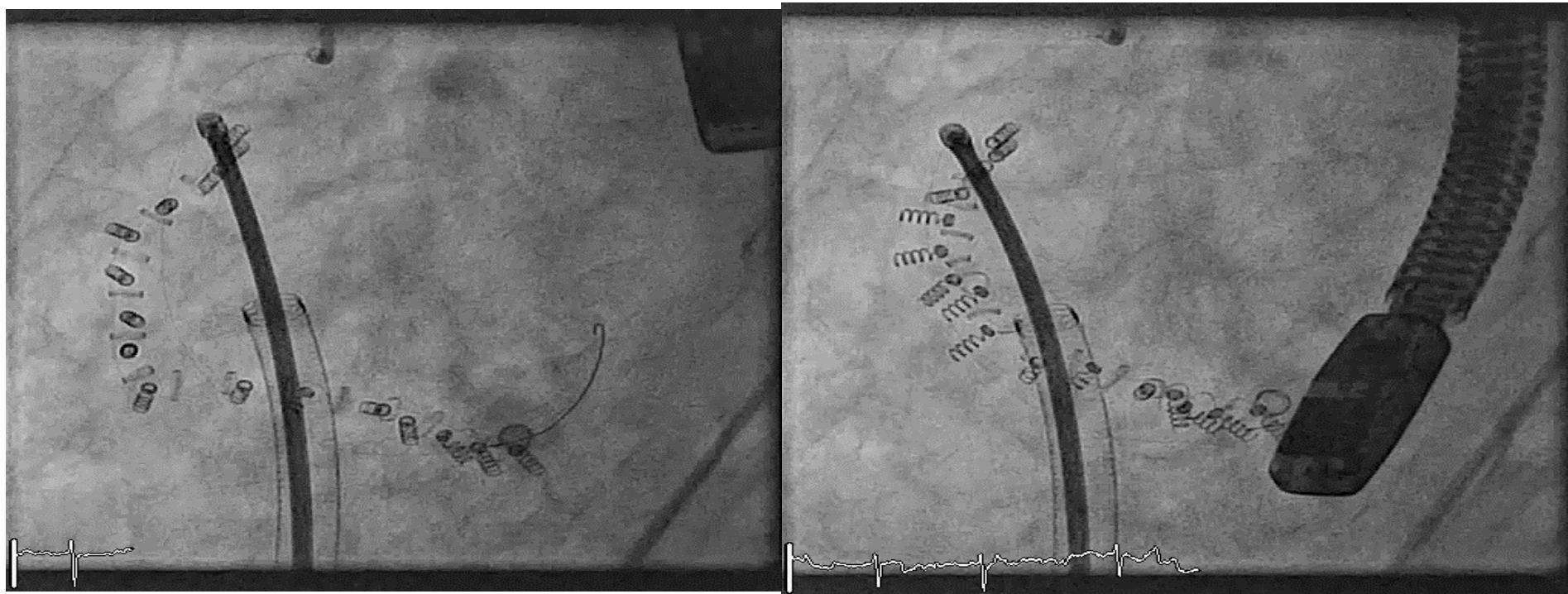
CASO CLINICO: ANGIOTC



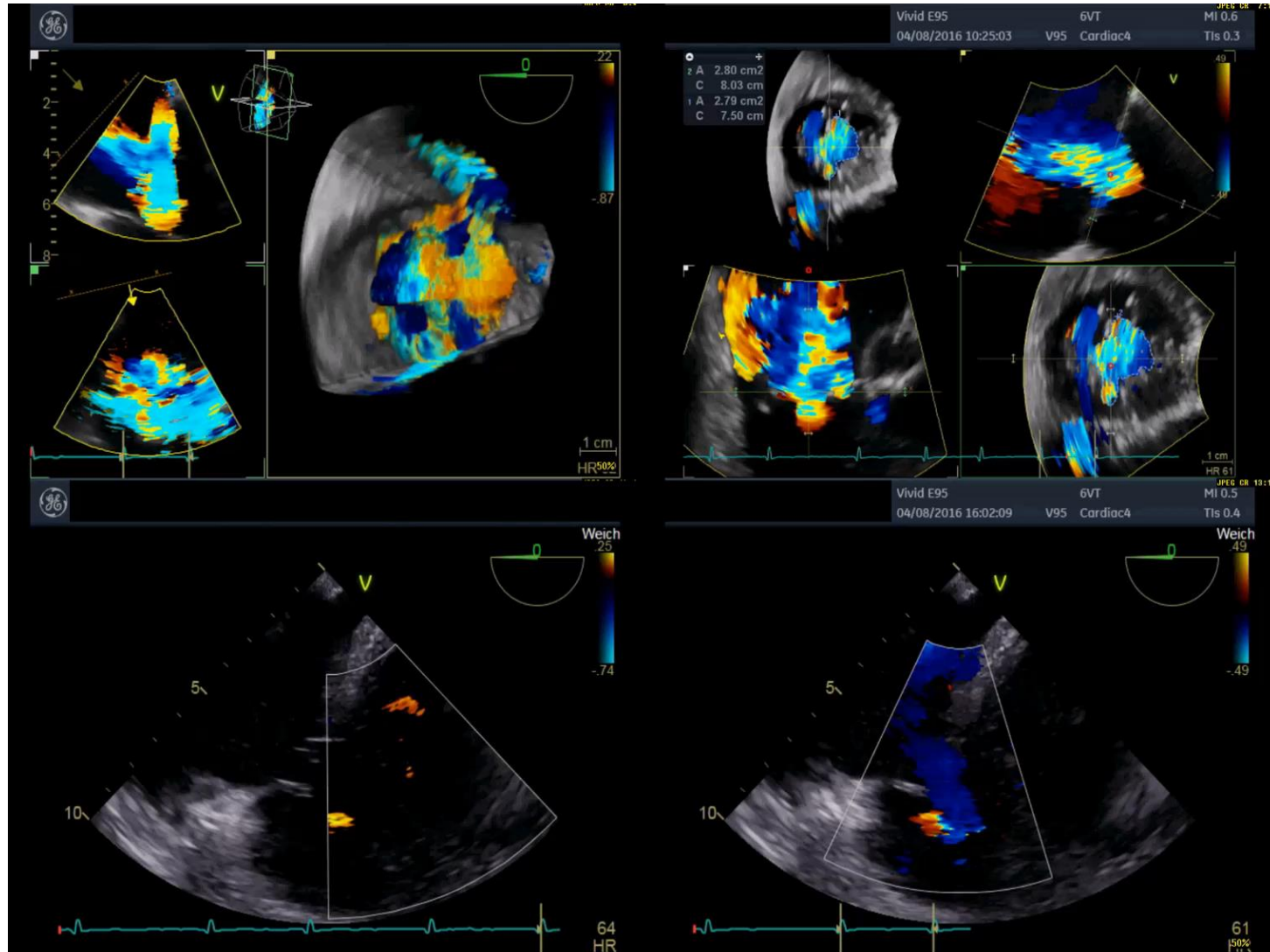
CASO CLINICO: INTERVENTO



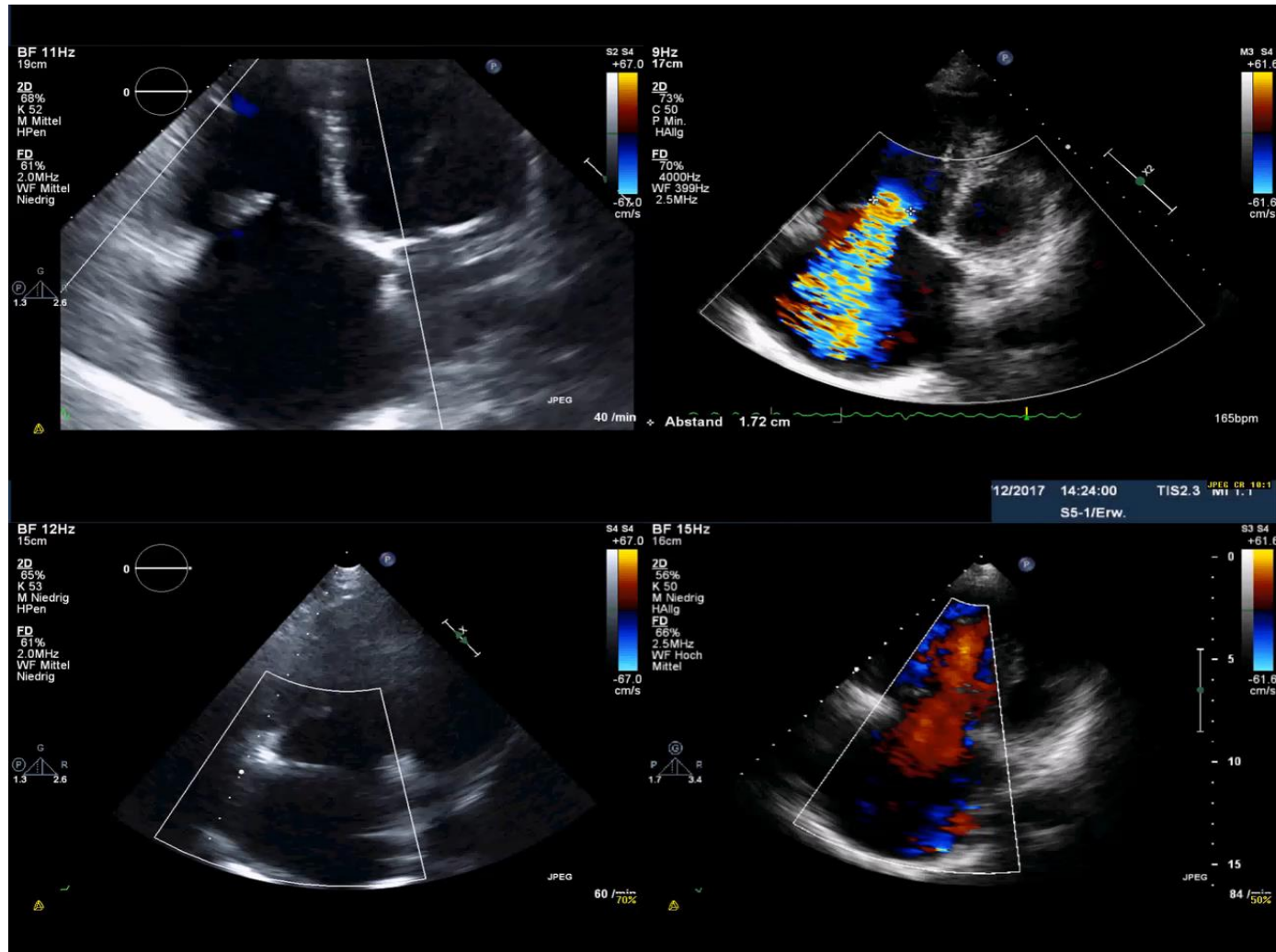
CASO CLINICO: INTERVENTO



CASO CLINICO

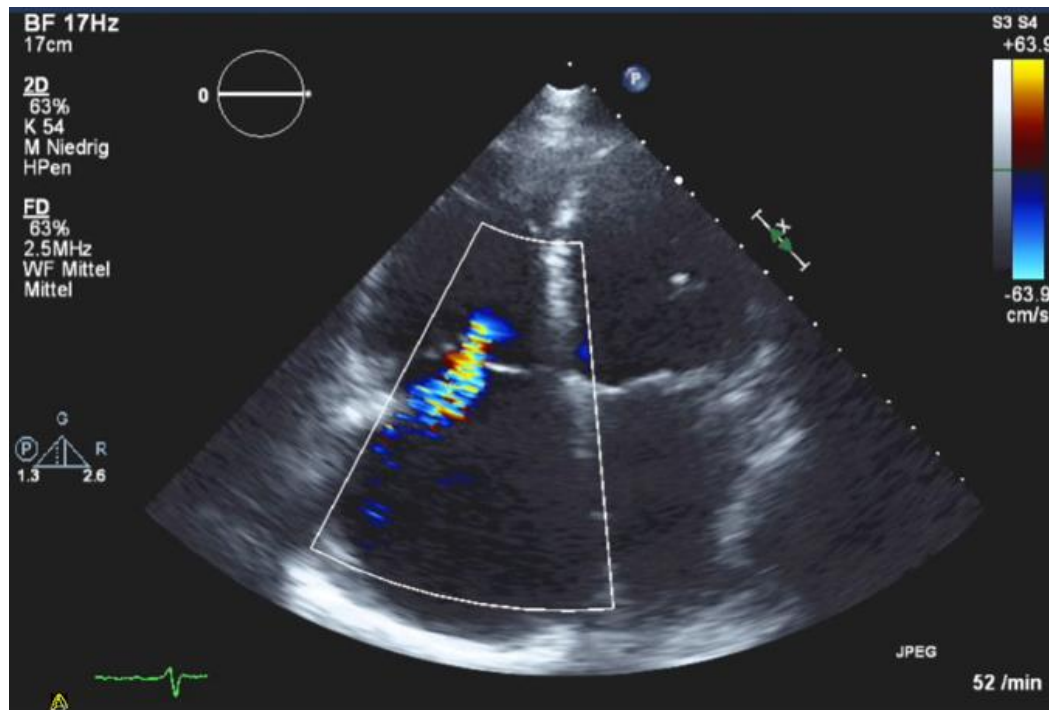


CASO CLINICO



CASO CLINICO: FOLLOW-UP

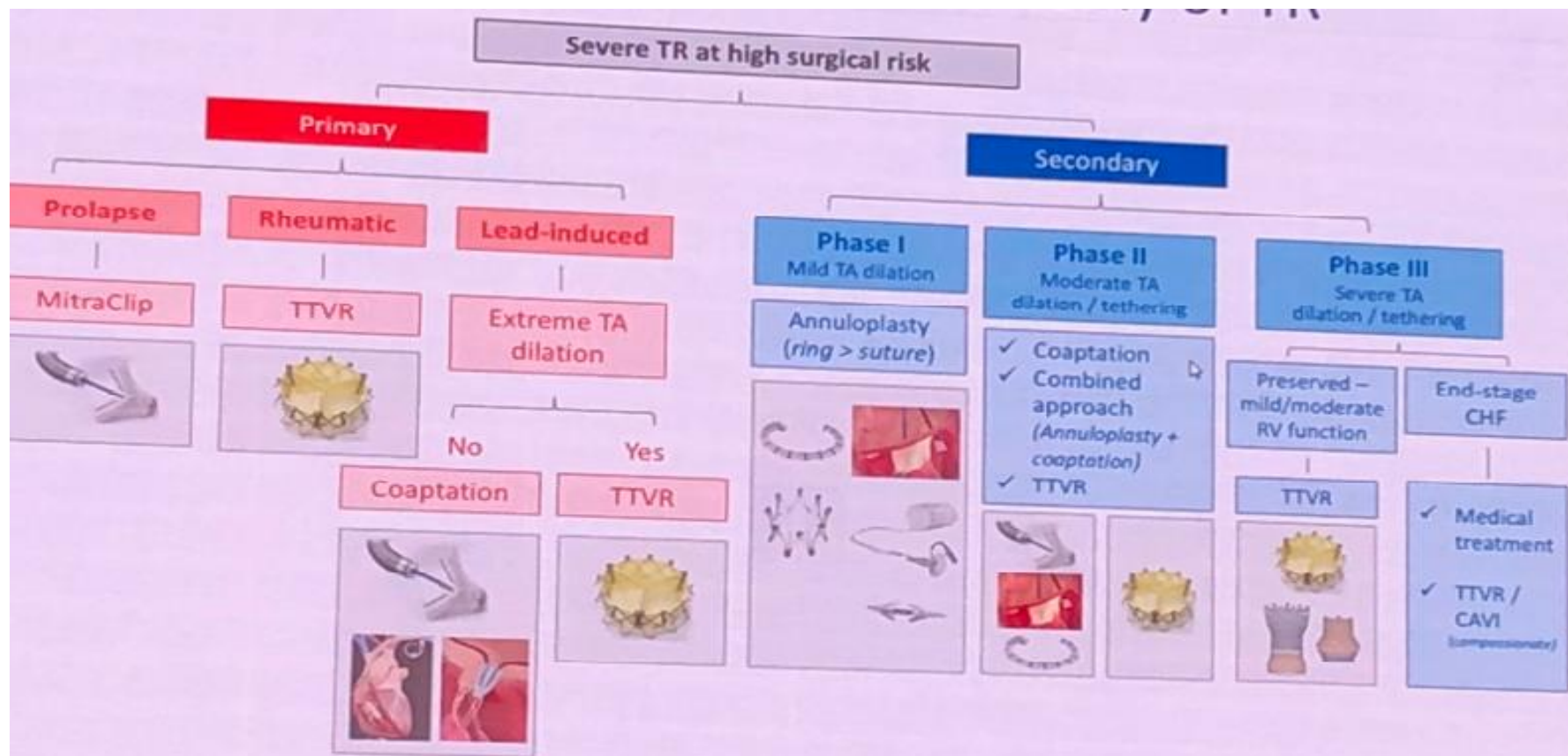
- Miglioramento della sintomatologia dispnoica con una classe NYHA II



CONCLUSIONI

- Il trattamento percutaneo di IT è un tema emergente nel campo delle terapia di tale valvulopatia: grande bisogno clinico insoddisfatto
- Le tecnologie TV percutanee possono essere utili per una grande quantità di pazienti con TR ad alto rischio di chirurgia tradizionale
- E' necessario utilizzare regolarmente nuove modalità di imaging (angioTC, RMN)
- Siamo in una fase iniziale non ancora idonea ad una pratica clinica di routine

Thank
you



Asmarats L, Puri R, Latib A, Navia J, Rodés-Cabau J. JACC 2018 (In press)