

# PLACE



PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

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Centro Congressi  
di Confindustria

**Auditorium  
della Tecnica**

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**1 Ottobre**

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## **Cardiochirurgia**

# **Il trattamento della valvulopatia tricuspidalica**

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Direttore del Valve Center Ospedale San Raffaele Milano

# Disclosure Statement of Financial Interest and Potential for Conflicts of Interest

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I, Francesco Maisano, have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation

Grant and/or Research Support                      Abbott; Medtronic; Edwards Lifesciences; Biotronik; Boston Scientific Corporation, NVT, Terumo

Consulting fees, Honoraria:    Abbott; Medtronic; Edwards Lifesciences;; Perfect; Xeltis; Transseptal solutions; Cardiovalve. Magenta

Royalty Income/IP Rights                              Edwards Lifesciences (FMR surgical annuloplasty)

Shareholder (incl. stock options)                      Cardiovalve, Magenta, Transseptalsolutions, 4Tech, Perfect , Coregard

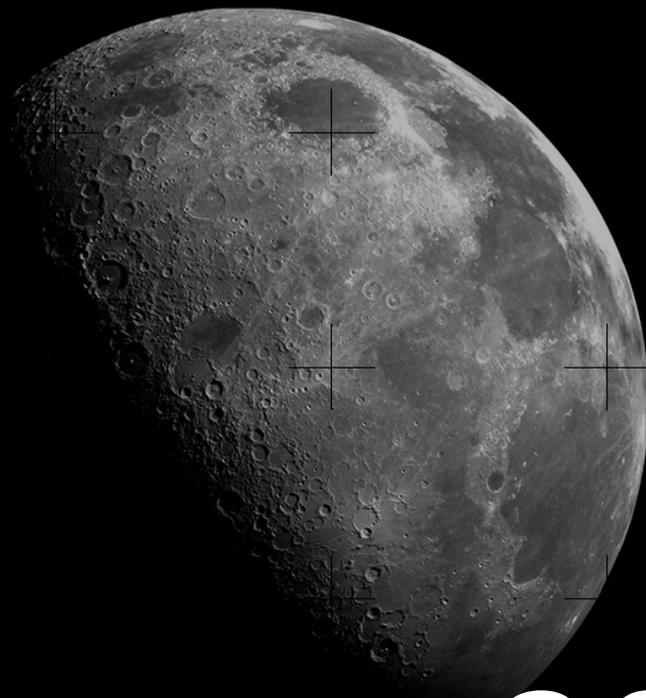
## Conservative Management of Tricuspid Regurgitation in Patients Undergoing Mitral Valve Replacement

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

### Summary:

In many patients with advanced mitral valve disease, associated tricuspid regurgitation is of a functional nature and secondary to right ventricular hypertension and dilatation of the tricuspid annulus. The present results indicate that in such patients tricuspid regurgitation will improve or disappear after mitral replacement and that tricuspid valve replacement is seldom necessary.

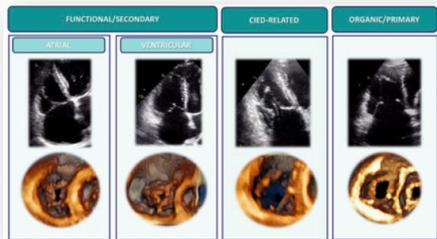
Circulation 1967;35:1-63



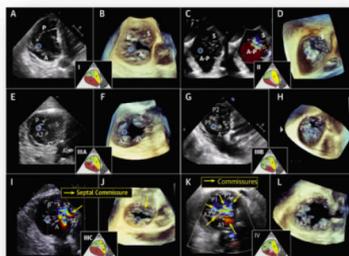
# 2015

# Nuove evidenze, nuove strategie e target terapeutici

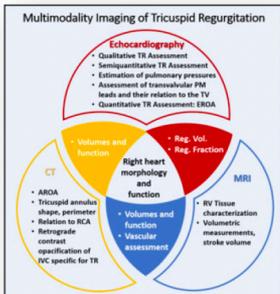
## Novel Tricuspid Regurgitation Classification



## Novel Tricuspid Leaflet Nomenclature



## Novel Tricuspid Valve Approach to Imaging



## Novel Tricuspid Regurgitation Quantitation Methods

Quantitation Method	Measurements Required	Example	Calculation
<b>PCFA</b>	<ol style="list-style-type: none"> <li>PSA radius (r)</li> <li>PSA aliasing velocity (v) (approximately 2R cm/s)</li> <li>TR peak velocity (v<sub>2</sub>)</li> <li>TR velocity time integral (TR<sub>vti</sub>)</li> </ol>		$Q = 2\pi r^2 v$ $RDA = QJ/v_2$ $RegVol = RDA \times TR_{vti}$
<b>Quantitative Doppler</b>	<ol style="list-style-type: none"> <li>TV velocity time integral (TV<sub>vti</sub>)</li> <li>RV Doppler sample volume at the annulus</li> </ol>		$Diastolic\ Stroke\ Volume = TV_{vti} \times Area \times TV_{max}$ $RegVol = Diastolic\ Stroke\ Volume - Forward\ Stroke\ Volume$ $RDA = RegVol \div TR_{vti}$
<b>3D color Doppler</b>	<ol style="list-style-type: none"> <li>3D Color Doppler planimetered area (contracted area) (VC<sub>cont</sub>)</li> <li>TR velocity time integral (TR<sub>vti</sub>)</li> </ol>		$RDA = VC_{cont}$ $RegVol = VC_{cont} \times TR_{vti}$

Abbreviations: PSA = proximal isovelocity surface area, TR = tricuspid regurgitation, Q = flow, RDA = regurgitant orifice area, TV = tricuspid valve, PW = pulsed wave, 3D = three dimensional, RegVol = regurgitant volume, VC = area contracta

Heightened interest in tricuspid regurgitation (TR) has led to a novel classification of the aetiology of TR, novel leaflet nomenclature, novel ways of quantifying TR, and novel methods for imaging the tricuspid valve complex.



Hahn et al, European Heart Journal - Cardiovascular Imaging (2022)

# Le domande, intorno alle nuove evidenze

screening e diagnosi precoce

lifetime management e device/drug interaction

quantificazione e classificazione

chirurgia/interventistica

timing e piano di cura, selezione e futilità

**Novel Tricuspid Classification**

FUNCTIONAL/SECONDARY	CEU-RELATED	ORGANIC/PRIMARY

**Nomenclature**

**Novel Tricuspid Valve Approach to Imaging**

Multimodality Imaging of Tricuspid Regurgitation

- Echocardiography
  - TR Assessment
  - Valve TR Assessment
  - Subvalvular process
  - Tricuspid Annulus
  - TR Assessment: EROA
- CMR
  - TR Assessment
  - TR Assessment: EROA
  - TR Assessment: EROA
- 3D Color Doppler
  - TR Assessment
  - TR Assessment: EROA
  - TR Assessment: EROA

**Novel Tricuspid Regurgitation Quantitation Methods**

Quantitation Method	Measurements	Example	Calculation
PSA	1. PSA velocity 2. PSA velocity (cm/s) 3. TR peak velocity (m/s) 4. TR velocity time integral (cm)		$Q = 2\pi r^2 v$ $ROA = Q/v_r$
Quantitative Doppler	1. TR velocity time integral (cm) 2. Quantitative TR area (cm²) 3. TR velocity (m/s) 4. TR velocity time integral (cm)		$ROA = Q/v_r$
3D color Doppler	1. 3D Color Doppler measurement area (cm²) 2. TR velocity time integral (cm)		$ROA = Q/v_r$

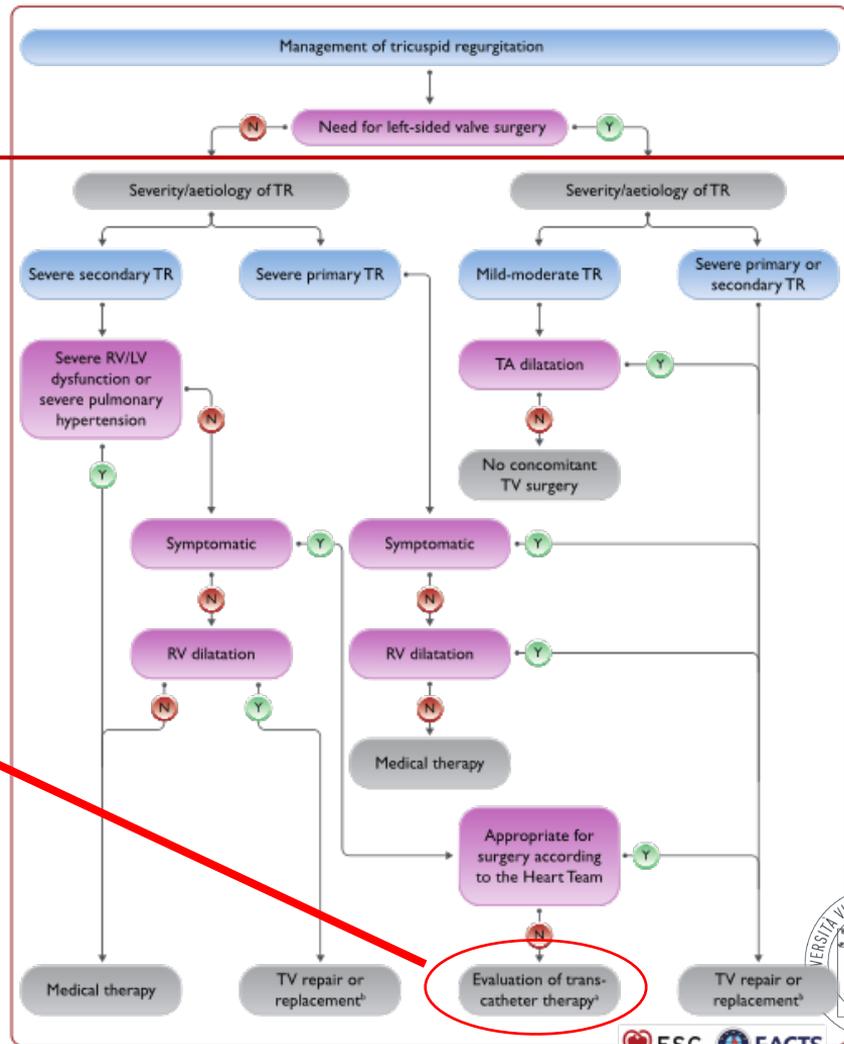
# 2021 ESC/EACTS Guidelines for the management of valvular heart disease

Developed by the Task Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Transcatheter treatment of symptomatic secondary severe tricuspid regurgitation may be considered in inoperable patients at a Heart Valve Centre with expertise in the treatment of tricuspid valve disease.<sup>f</sup>

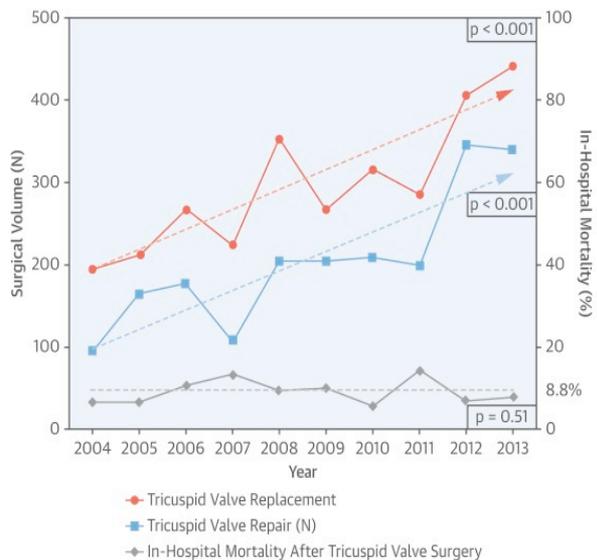
**IIb**

**C**

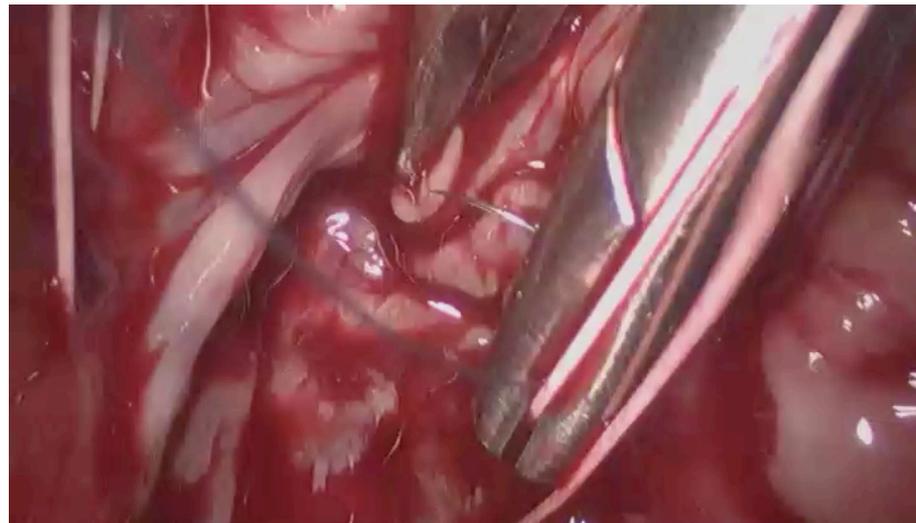


# Chirurgia per la patologia tricuspидale

**CENTRAL ILLUSTRATION: Temporal Trends in Surgical Volume and Mortality for Isolated Tricuspid Valve Surgery**

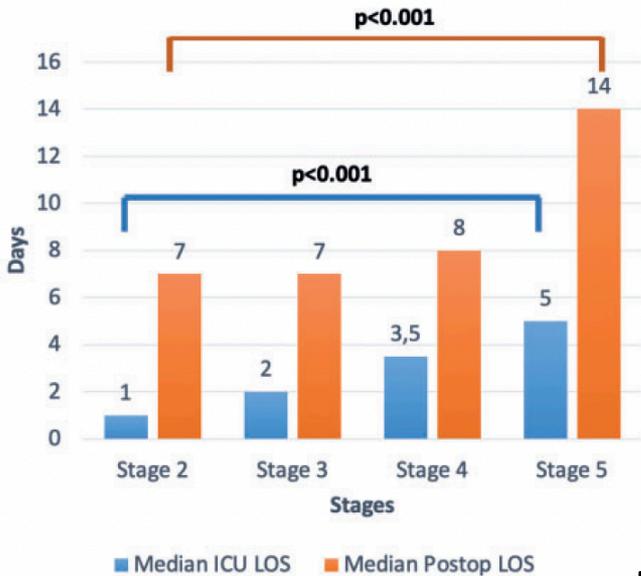


Zack, C.J. et al. *J Am Coll Cardiol.* 2017;70(24):2953-60.



# Ma la chirurgia è veramente ad alto rischio?

Graph showing median intensive care unit stay and postoperative length-of-stay according to each stage



## Stage 1

- No symptoms
- TR < 2+
- Normal RV function, no remodelling
- No treatment

## Stage 2

- No symptoms
- TR > 2+
- Normal RV function, mild remodelling
- None/low-dose diuretics

## Stage 3

- Vague symptoms
- Severe TR
- Mild RV dysfunction/remodelling
- Diuretics

## Stage 4

- Previous RHF episodes
- Severe TR
- > moderate RV dysfunction/remodelling
- moderate-high dose diuretics

## Stage 5

- Overt RHF and/or organ damage
- Torrential TR
- Severe RV dysfunction
- high-dose diuretics/IV diuretics

N= 0  
 Death: /  
 Tot: 172

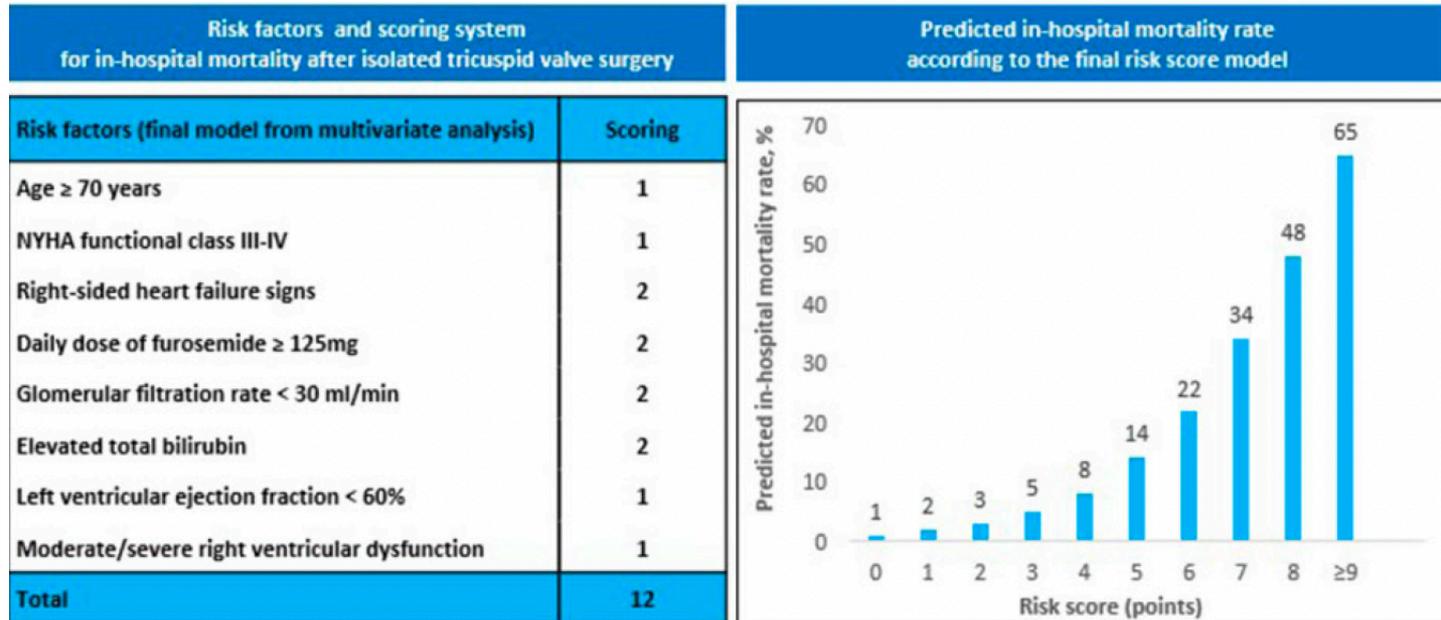
27  
 0%

80  
 0%

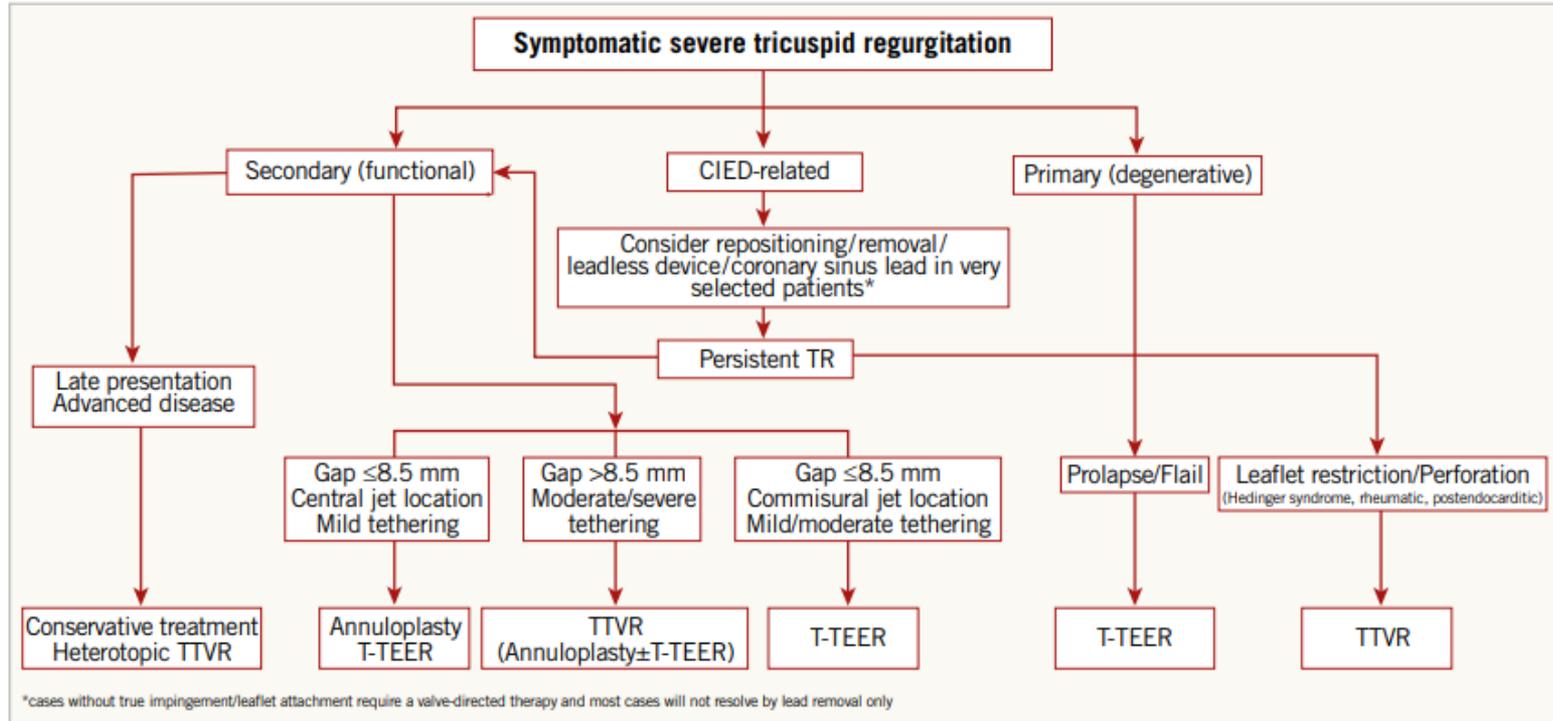
62  
 16%

3  
 0%

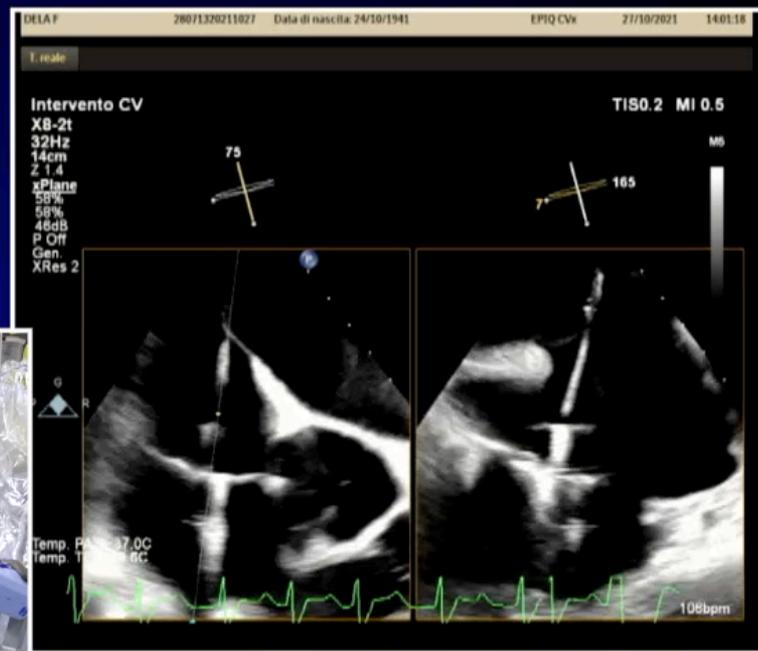
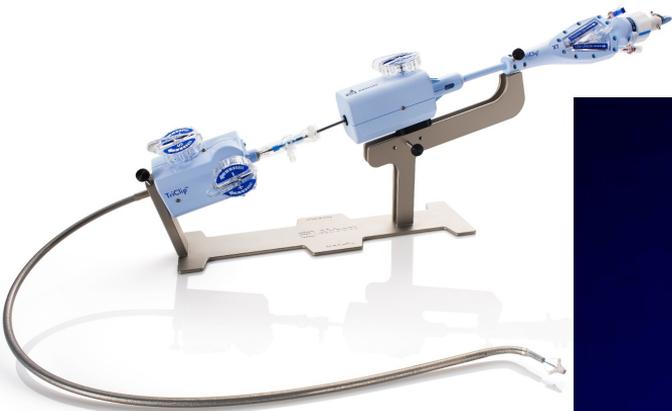
# Risk stratification



# which transcatheter therapy?

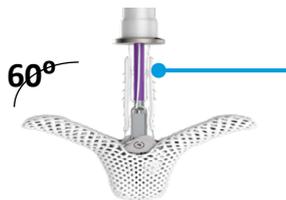


# Triclip

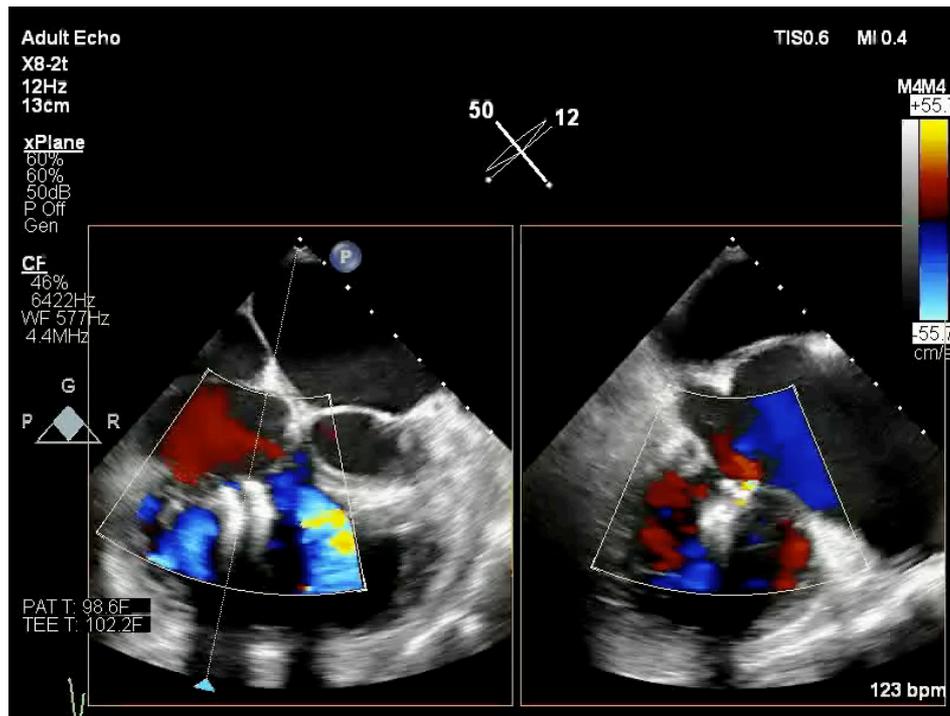


# Improved outcomes with G4...

- Dedicated delivery system obtaining coaxial alignment
- Longer and larger devices to tackle advanced anatomies
- Independent gripper system to improve leaflet insertion
- Improved expertise



**GRIPPERS  
DESIGNED TO  
DISTRIBUTE  
RETENTION  
FORCE<sup>3</sup>**



# bRIGHT: real world last generation tricuspid TEER

71% discharged with less than severe TR

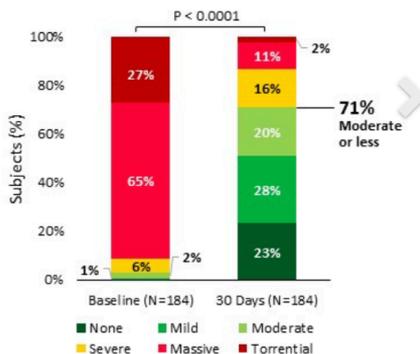
## Procedural outcomes and TR reduction

 High rate of implant success with majority of subjects achieving moderate or less TR at 30 days

### PROCEDURAL OUTCOMES

METRIC	N=300
Implant Success	98%
Acute Procedural Success	91%
Device Time (min)	78 ± 41
Total Procedure Time (min)	101 ± 48

### TR GRADE (CORE LAB)

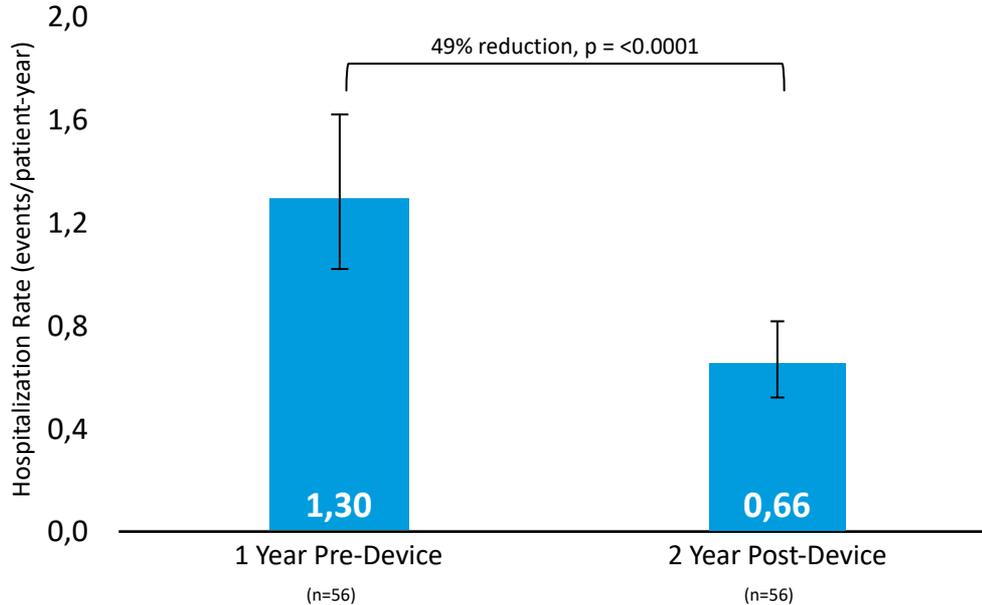


99% freedom from MACE

## Conclusions

-  bRIGHT is the first real-world tricuspid TEER study evaluating TriClip™ across a broad range of tricuspid anatomies.
-  Early TriClip™ G4 experience showed improved TR reduction despite worse TR severity at baseline.
-  The TriClip procedure was safe, with only 1% of subjects experiencing a major adverse event through 30 days.
-  Majority of subjects experienced clinically meaningful improvements in functional status and quality of life at 30-day follow-up.
-  The bRIGHT study will continue to enroll up to 500 subjects to further evaluate TriClip™ G4 Delivery System.

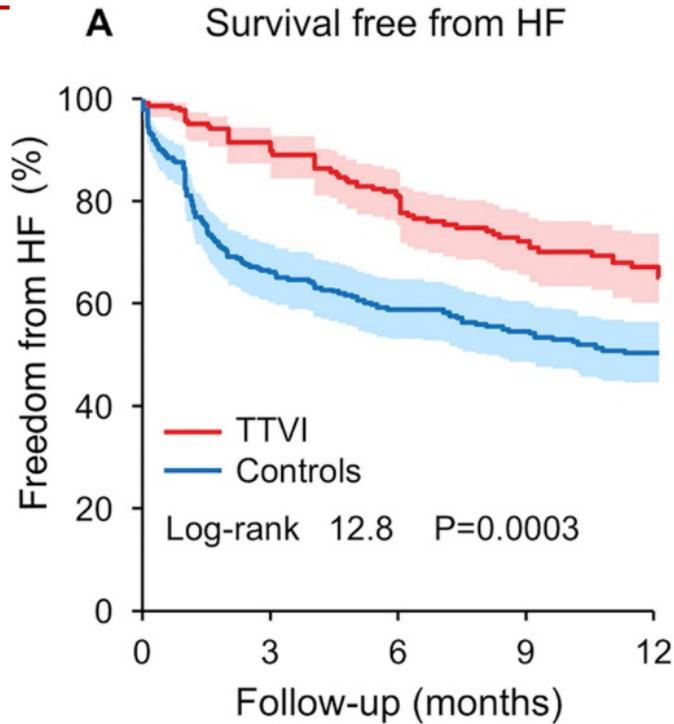
# TRILUMINATE - Reduction in Hospitalizations



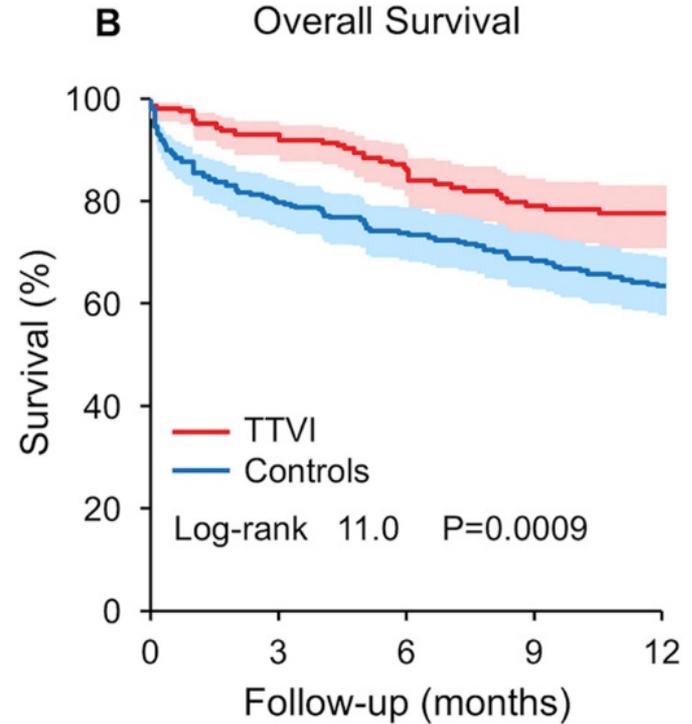
A significant reduction in hospitalization rate was seen at 2 years (49%)\*.

\*Dropout due to death, withdrawal, missed visits

# The TriValve Registry



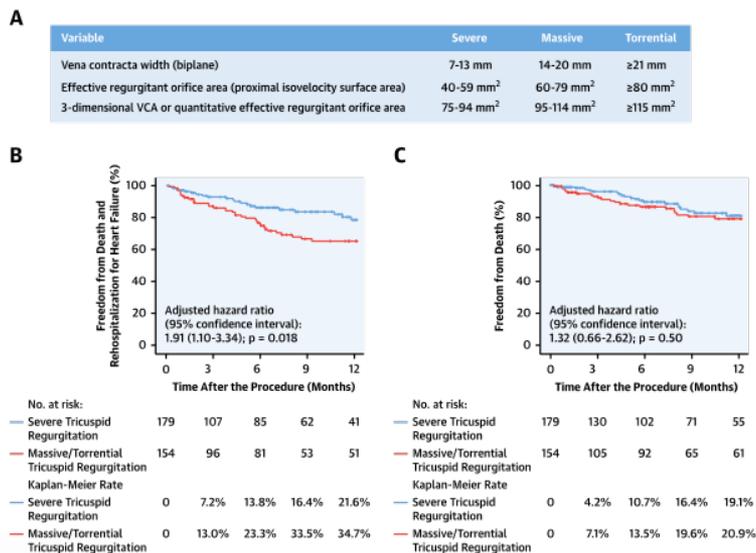
—	268	169	157	107	81
—	268	181	160	148	136



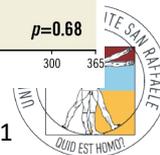
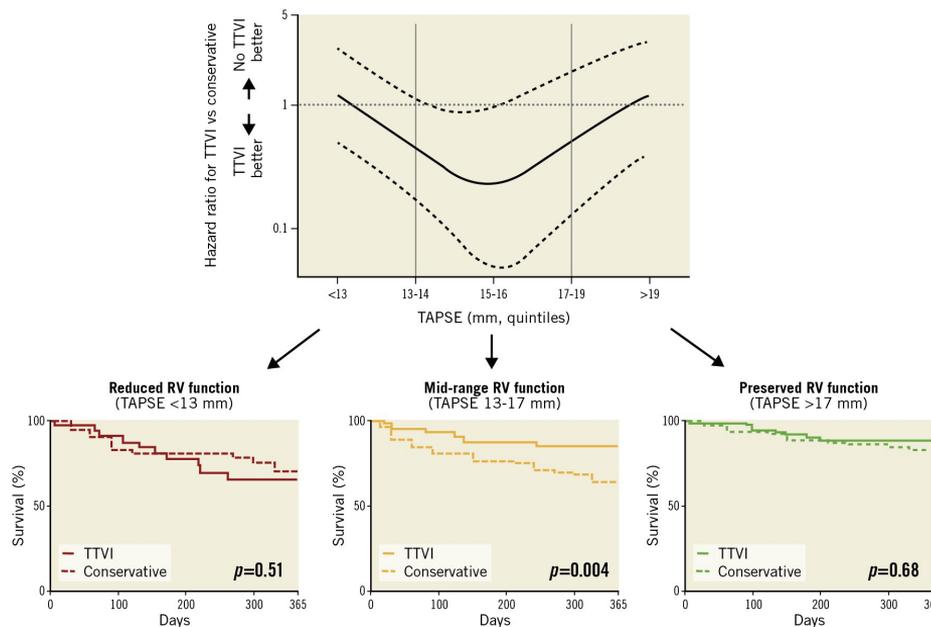
—	268	192	156	104	79
—	268	215	199	184	170

### Impact of Massive or Torrential Tricuspid Regurgitation in Patients Undergoing Transcatheter Tricuspid Valve Intervention

**CENTRAL ILLUSTRATION** Clinical Outcomes of Massive or Torrential Tricuspid Regurgitation



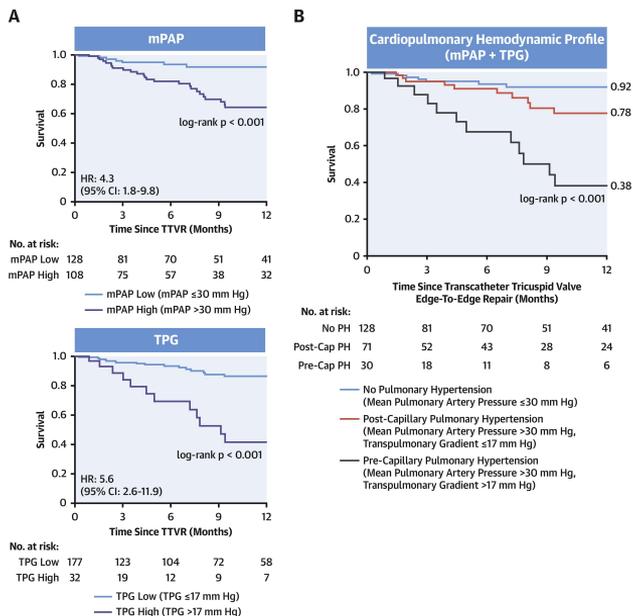
### Impact of RV function



# predittori clinici

From the TriValve Registry

## CENTRAL ILLUSTRATION: Assessment of the Cardiopulmonary Hemodynamic Profile Predicts Survival After Transcatheter Tricuspid Valve Edge-to-Edge Repair



Stocker, T.J. et al. J Am Coll Cardiol Interv. 2021;14(1):29-38.

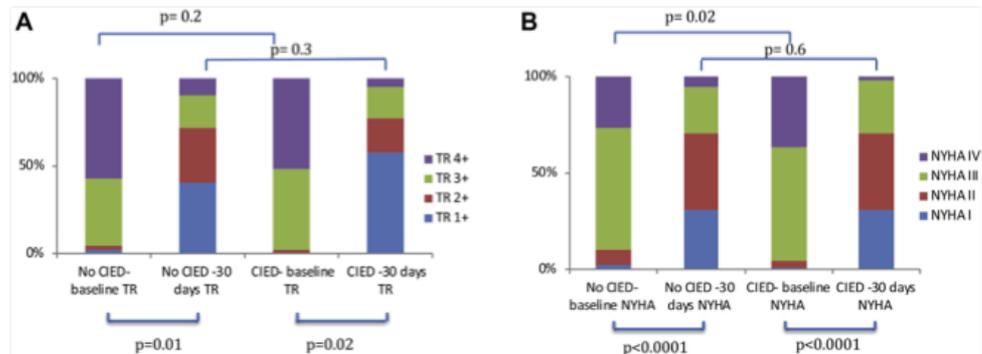
OSPFDAIF

Stocker, T.J. et al. J Am Coll Cardiol Interv. 2021;14(1):29-38.

## Outcomes of TTVI in Patients With Pacemaker or Defibrillator Leads

### Data From the TriValve Registry

FIGURE 1 Tricuspid Regurgitation and NYHA Functional Class at Baseline and 30 Days



Clinical and echocardiographic outcomes: New York Heart Association (NYHA) functional class (A) and tricuspid regurgitation (TR) (B) at baseline and after 30 days in the 2 groups. CIED = cardiac implantable electronic device.

Taramasso M. et al. JACC Cardiovasc Interv. 2020 Mar 9;13(5):554-564



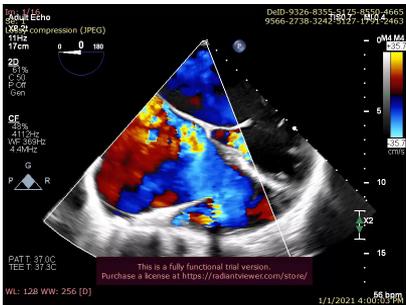
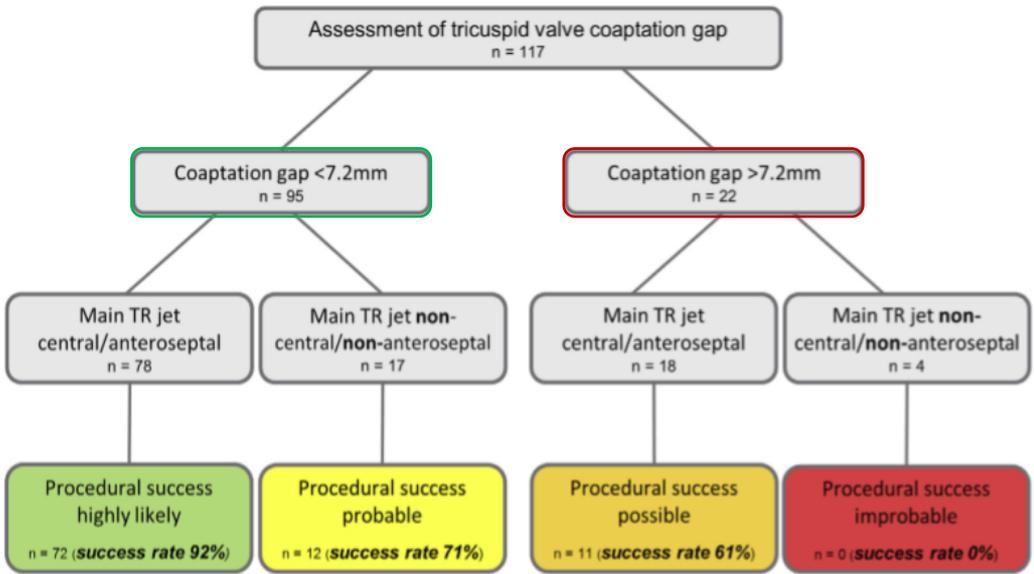
# Predittori anatomici

**TABLE 4 Predictors of Procedural Transcatheter TV Repair Success**

	Univariate		Multivariate	
	Odds Ratio	p Value	Odds Ratio	p Value
TR EROA (PISA)	0.21 (0.06–0.73)	0.01	–	–
TV tenting area	0.65 (0.45–0.94)	0.02	–	–
TR vena contracta	0.87 (0.77–0.99)	0.04	–	–
TV coaptation gap	0.74 (0.63–0.87)	<0.01	0.73 (0.62–0.88)	<0.01
TR jet non-central/ non-anteroseptal	0.22 (0.08–0.62)	<0.01	0.18 (0.06–0.56)	<0.01

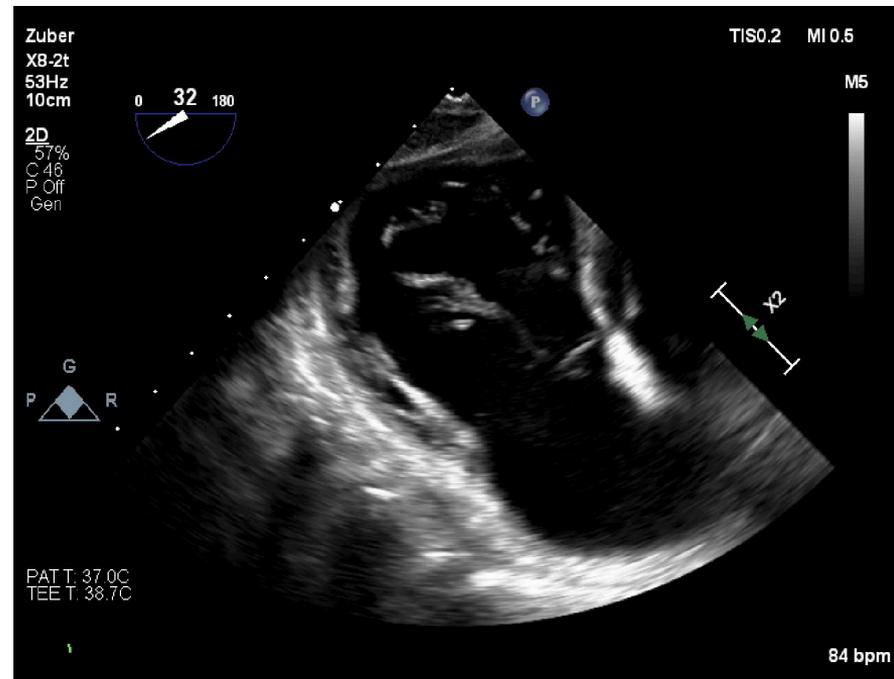
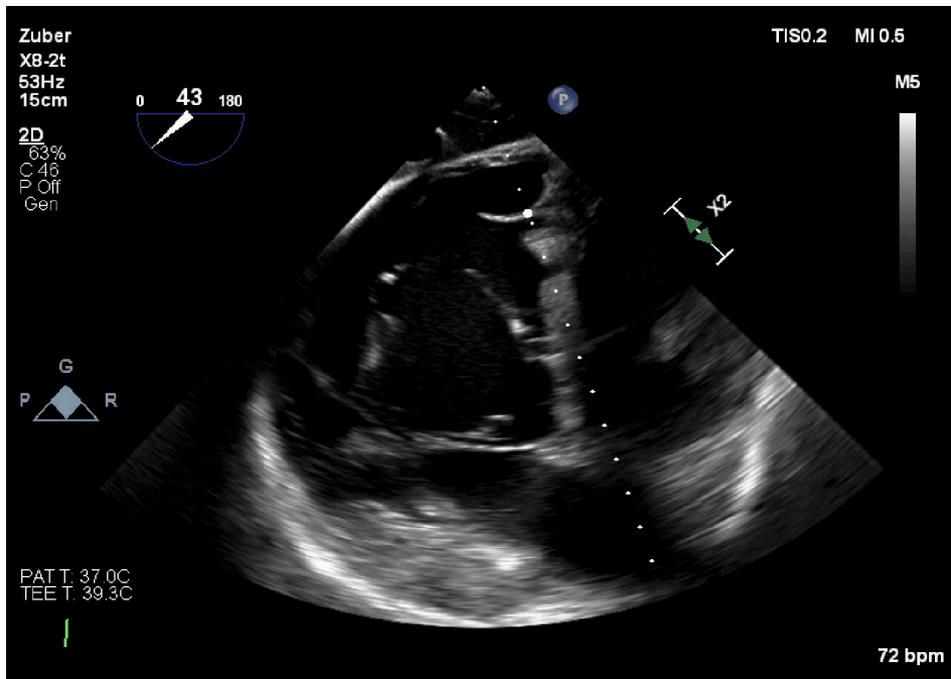
Univariate and multivariate logistic regression for procedural TTVR success, displaying only significant univariate predictors. Univariate predictors were subsequently tested in a multivariate stepwise model.

Abbreviations as in Tables 1, 2, and 3.

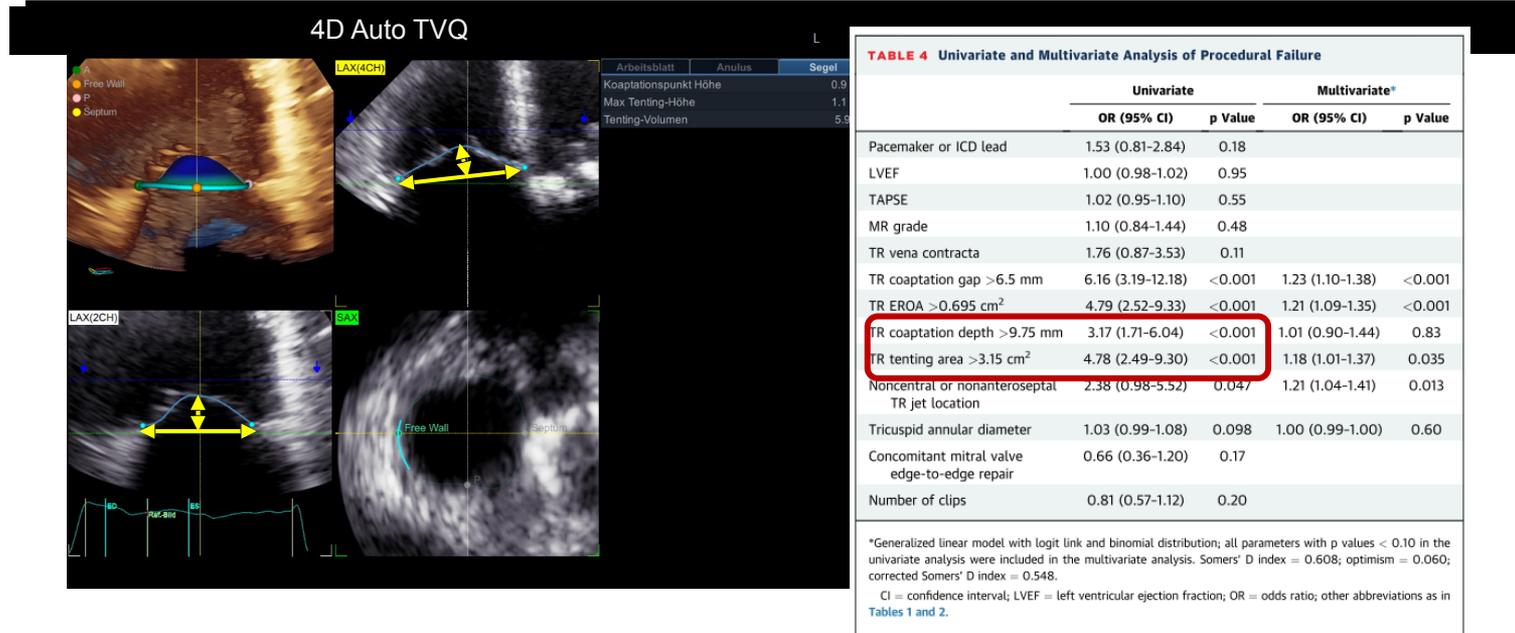


# Not a good case...

# Ideal case



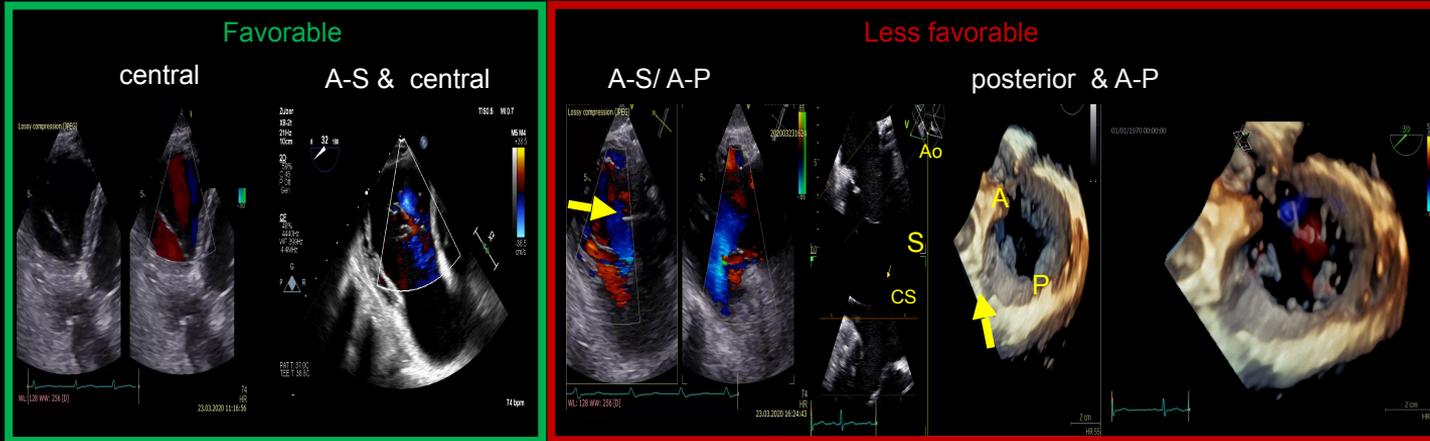
# Leaflet tethering



Severe tethering (tenting area  $\geq 3.15\text{cm}^2$  ; TR coaptation depth  $> 9.75\text{mm}$ ) predict procedural failure (edge-to-edge approach)

# Localization of the regurgitant jet(s) -Predictors of procedural success (e-2-e)

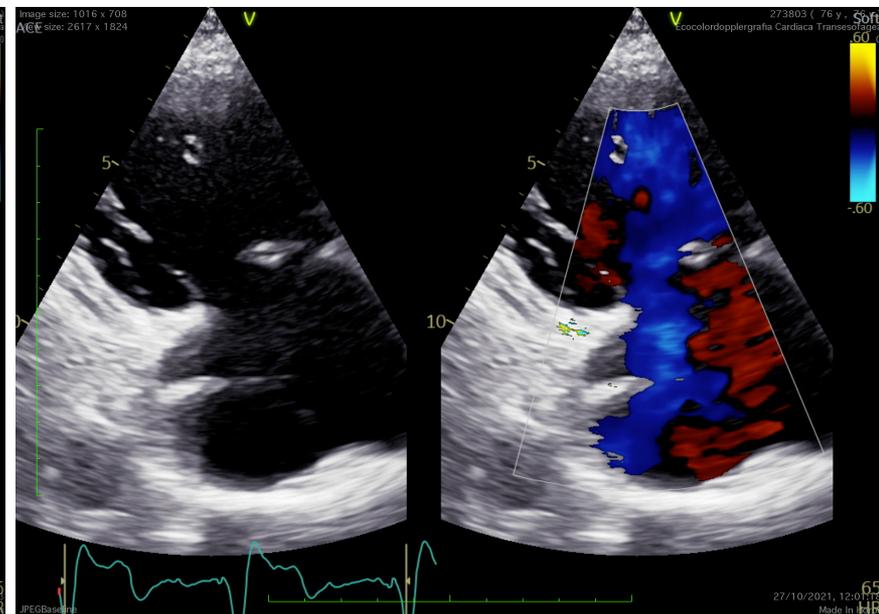
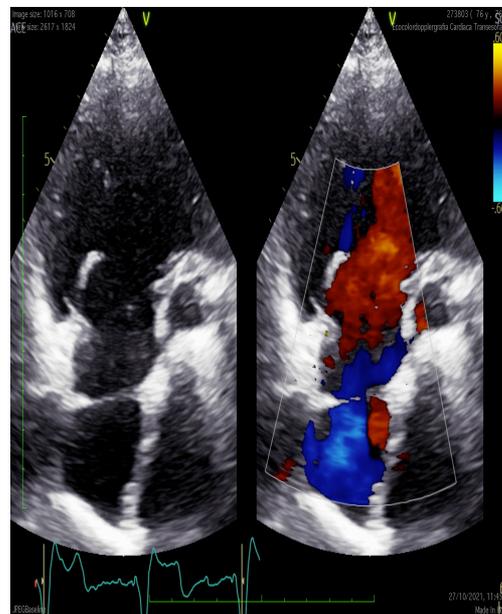
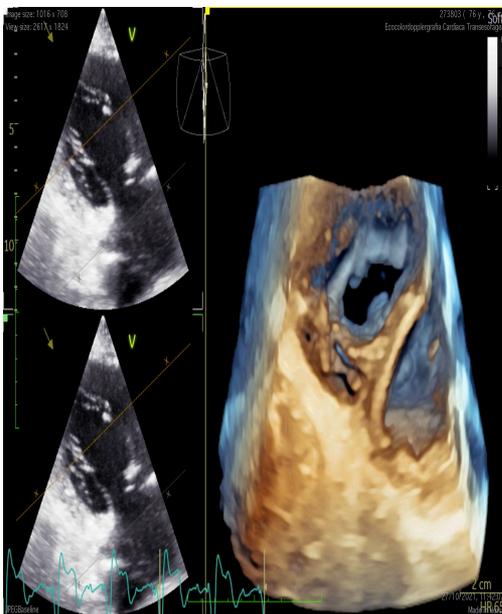
## Jet origin



A predominant central / antero-septal jet predicts procedural success

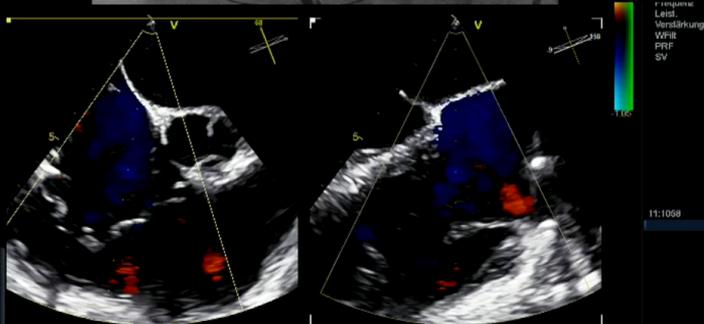
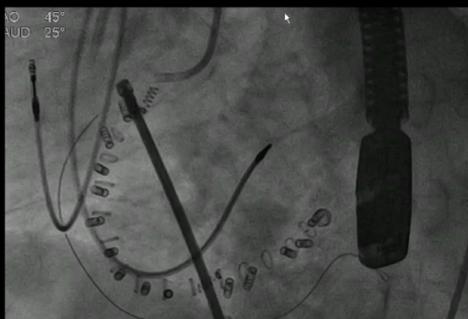
(1) Lurz P et al. Eurointervention 2018; 14(3): e290-e297; 19-28 ; (2) Besler C et al. JACC Intv 2018;11:11; (3) Mehr M et al. J Am Coll Cardiol Intv 2019;12:1451-61

# Quali opzioni nei pazienti con controindicazioni anatomiche?



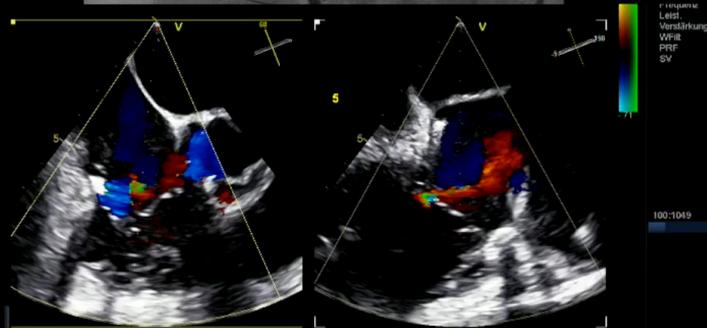
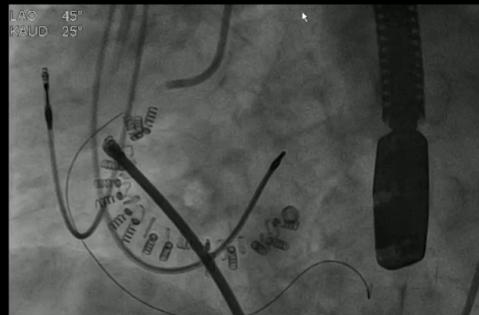
# Cardioband

## Baseline



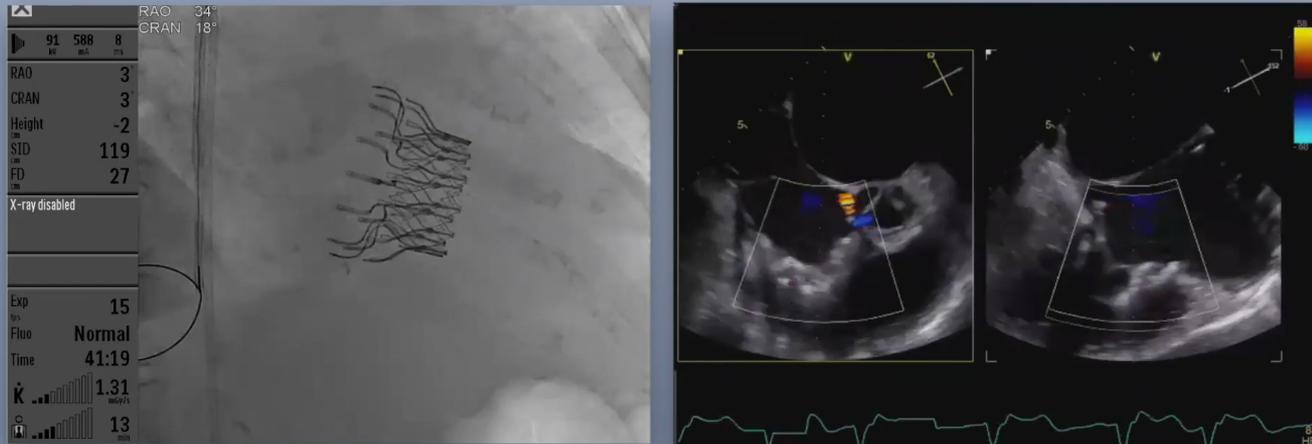
**Severe TR**

## Post Cinching



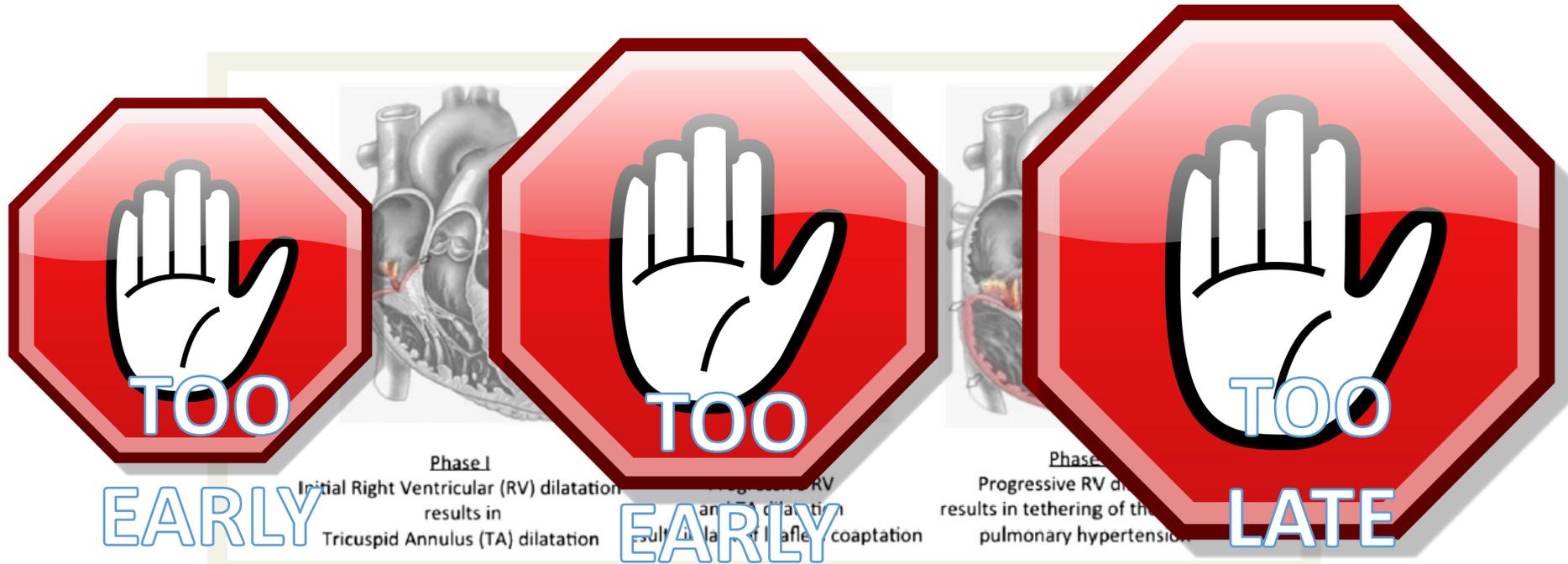
**Trace TR**

# FINAL RESULTS



Cardiovalve implant correctly in place - No Tricuspid Regurgitation

# Quando vs Come

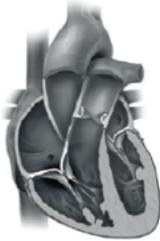
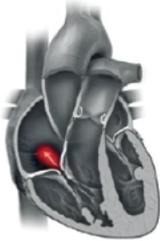
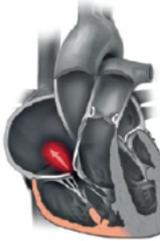
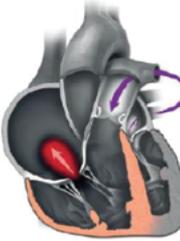
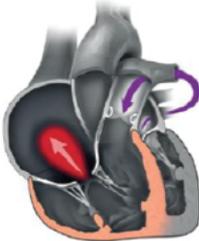


**Figure 2** Pathophysiology of functional tricuspid regurgitation.

# Stadi clinici dei pazienti con insufficienza tricuspидale e timing delle procedure

## Heterogeneity of TR Population

Proposed classification of TR stages and potential treatment options

	Stage 1	Stage 2	Stage 3	Stage 4	Stage 5
					
Percutaneous treatment	No	Potential future target for percutaneous options as minimally invasive option could change natural history with minimal risk	Potential candidates for isolated TR surgery who could be enrolled in upcoming IDE RCTs	Current group of patients being treated in EFS if high-risk for surgery. May require combination of annuloplasty and leaflet device or TVR	Prohibitive risk and potentially futile. (Palliative procedures can be considered in highly selected patients)

### Early

RV: Initial dilatation  
TA: Subsequent initial dilatation

Annuloplasty  
Leaflet Approximation  
Replacement (orthotopic)

### Progressive

RV: Progressive dilatation  
TA: Progressive dilatation → lack of leaflet coaptation

± Annuloplasty  
Leaflet Approximation  
Replacement (orthotopic)

### Late

RV/TA: Progressive distortion and subsequent further leaflet tethering

± Leaflet Approximation  
Replacement (heterotopic)  
Replacement (orthotopic;  
depending on RV function)

Fare diagnosi:

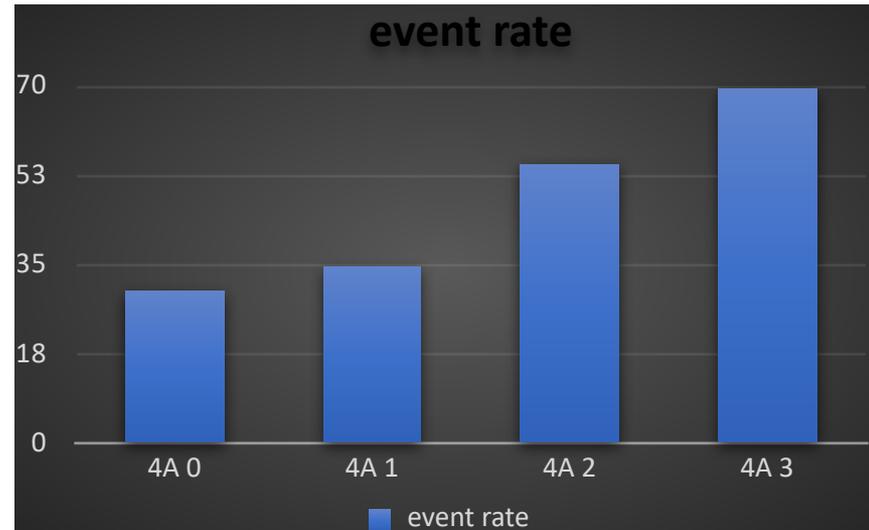
135 pts, 2 yrs median follow-up, combined endpoint CV mortality or HF admission

Asthenia

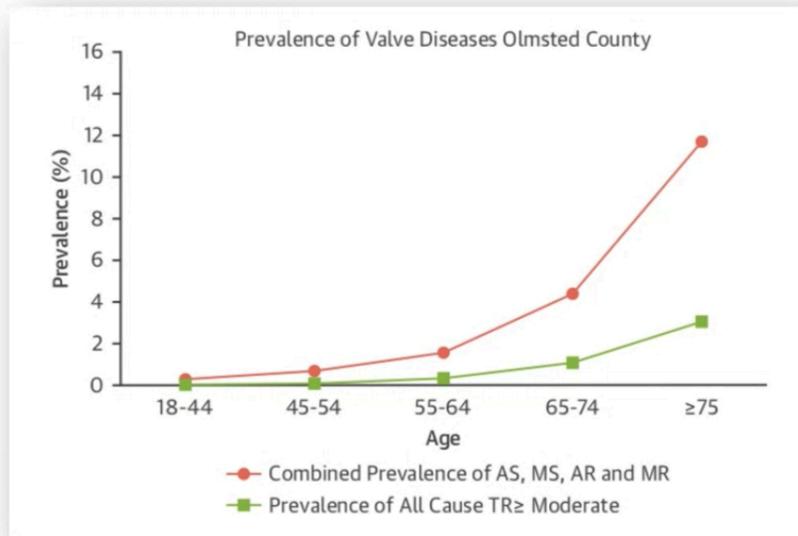
Ankle swelling

Abdominal  
pain or  
distention

Anorexia



# Burden of Significant TR in the Community



- All-cause TR ≥ Moderate = **0.6%**
- Significant increase with **ageing**
- More prevalent in **women**
- As prevalent as **aortic stenosis**
- Prognosis depends on TR **severity** and on **etiology**
- Highest mortality if TR is associated with **LV dysfunction** or **left-sided valvular disease**

**1 in 25 people ≥ 75 years have a moderate or severe TR**

# Moderate / Severe TR Associated with Mortality

## Study description

- Systematic review and meta-analysis (n=32,601 patients) to determine the influence of tricuspid regurgitation (TR) severity on mortality based on 3-level grading of TR
- Primary endpoint: all-cause mortality
- Secondary endpoints: cardiac mortality and hospitalization for heart failure (HF)

## Results

### Progressive increase in all-cause mortality risk in patients with TR vs. no TR by grades (3-level grading):

TR grading	Mild	Moderate	Severe
All-cause mortality	1.25*	1.61*	3.44*

p < 0.001

\*Describes the risk increase in all-cause mortality

- It appears to be independent of pulmonary pressures and RV dysfunction

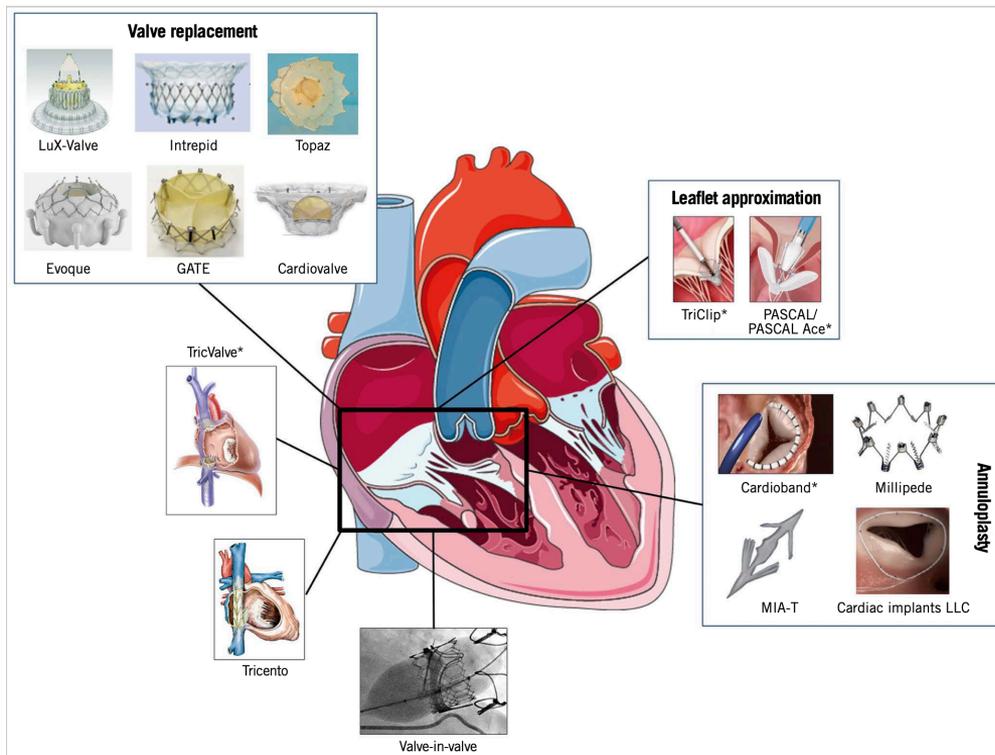
### Moderate / severe TR (3-level grading) vs. no/mild TR patients showed:

↑ **1.95-fold** risk increase of **all-cause mortality**

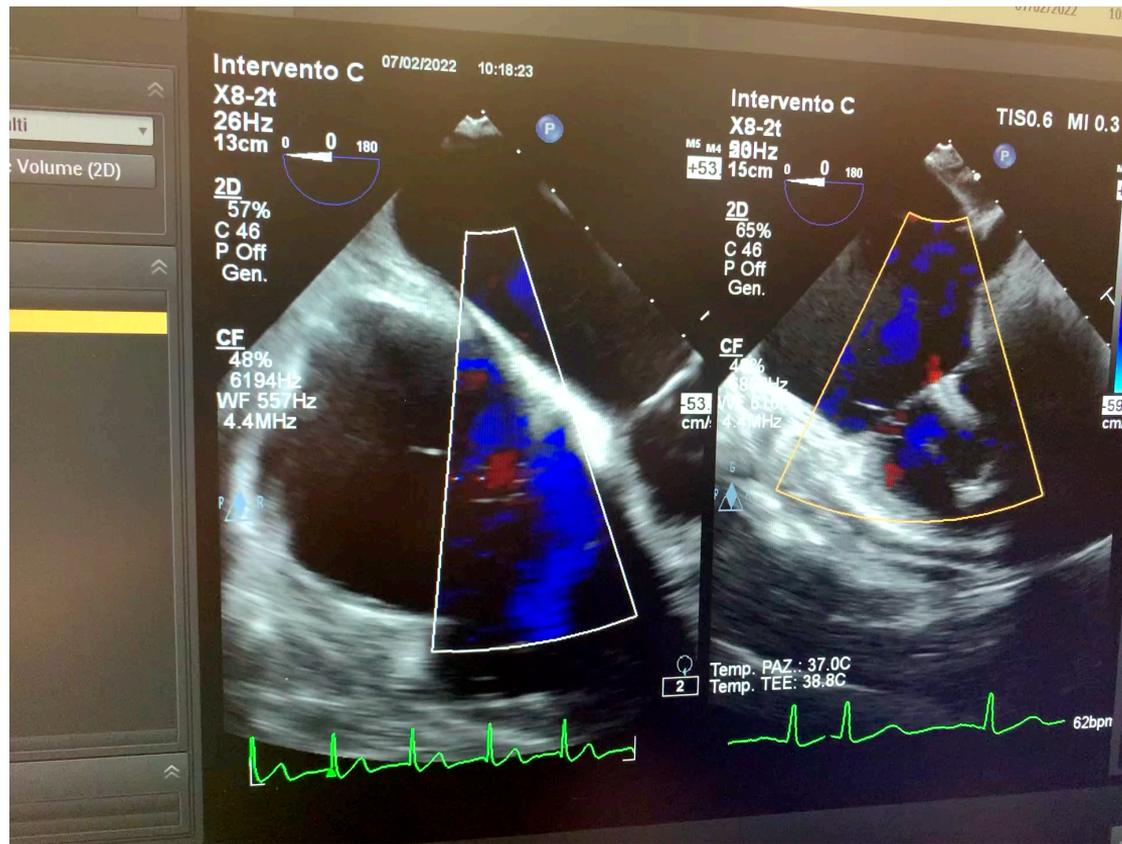
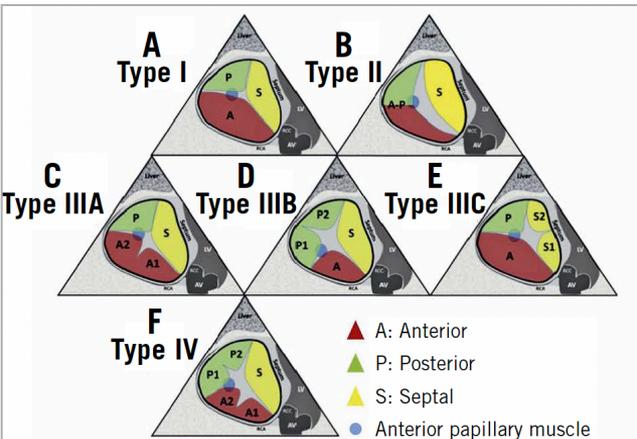
↑ **2.56-fold** risk increase of **cardiac mortality**

↑ **1.73-fold** risk increase of **HF-hospitalization**

# abbiamo una batteria di soluzioni efficaci e sicure per correggere l'insufficienza tricuspидale

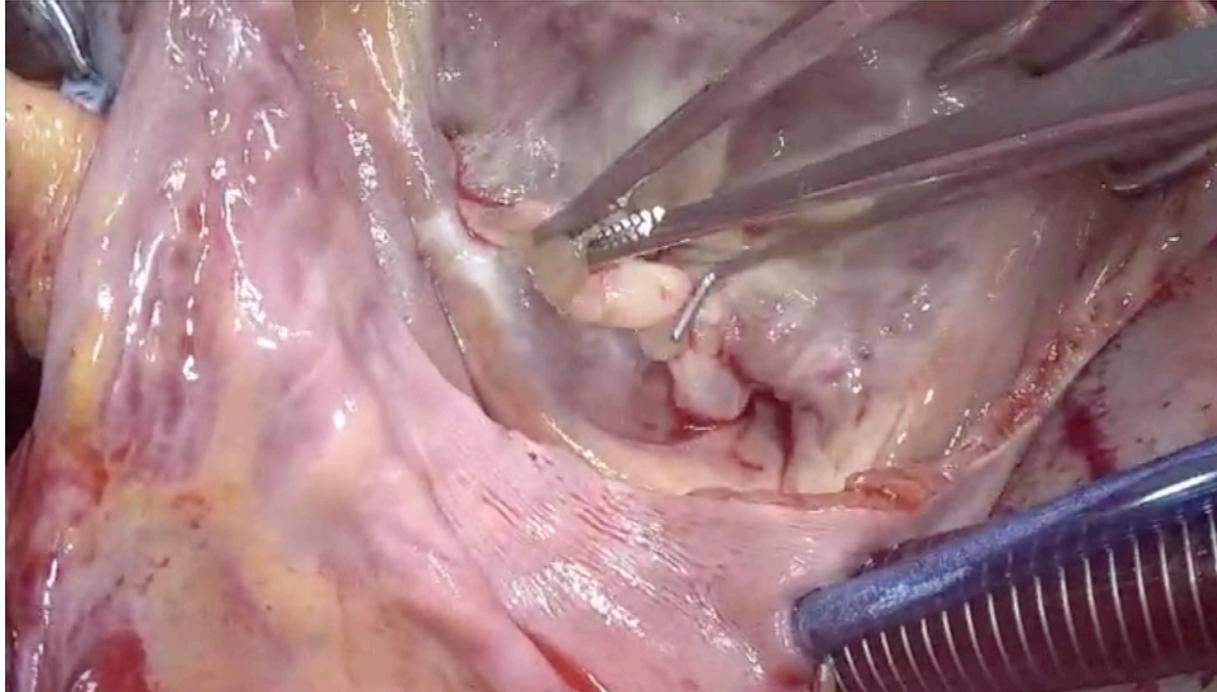


# Type IIIA, euvolemica, indicazione precoce (Dilatazione VD)



# Ebstein con preservata funzione ventricolare

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# Tricuspid Heart Team

## TRICUSPID HEART TEAM

