

# 11° CONGRESSO NAZIONALE



*Quello che le Linee  
Guida Non Dicono*

**Napoli**  
**5-6 aprile 2024**

**HOW TO SESSION 2**  
**CARDIOLOGIA INTERVENTISTICA CORONARICA E VALVOLARE**

# 11° CONGRESSO NAZIONALE



*Quello che le Linee  
Guida Non Dicono*

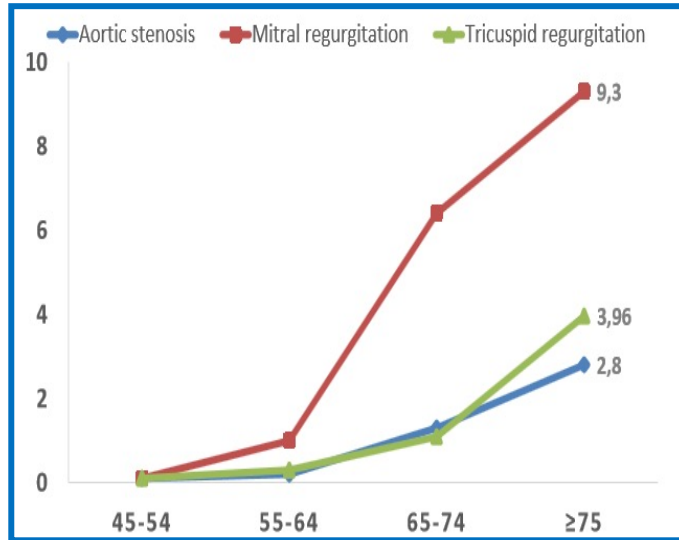
**Napoli**  
**5-6 aprile 2024**

**Trattamento dell'insufficienza tricuspidalica per via percutanea:  
identificazione del fenotipo clinico ideale**

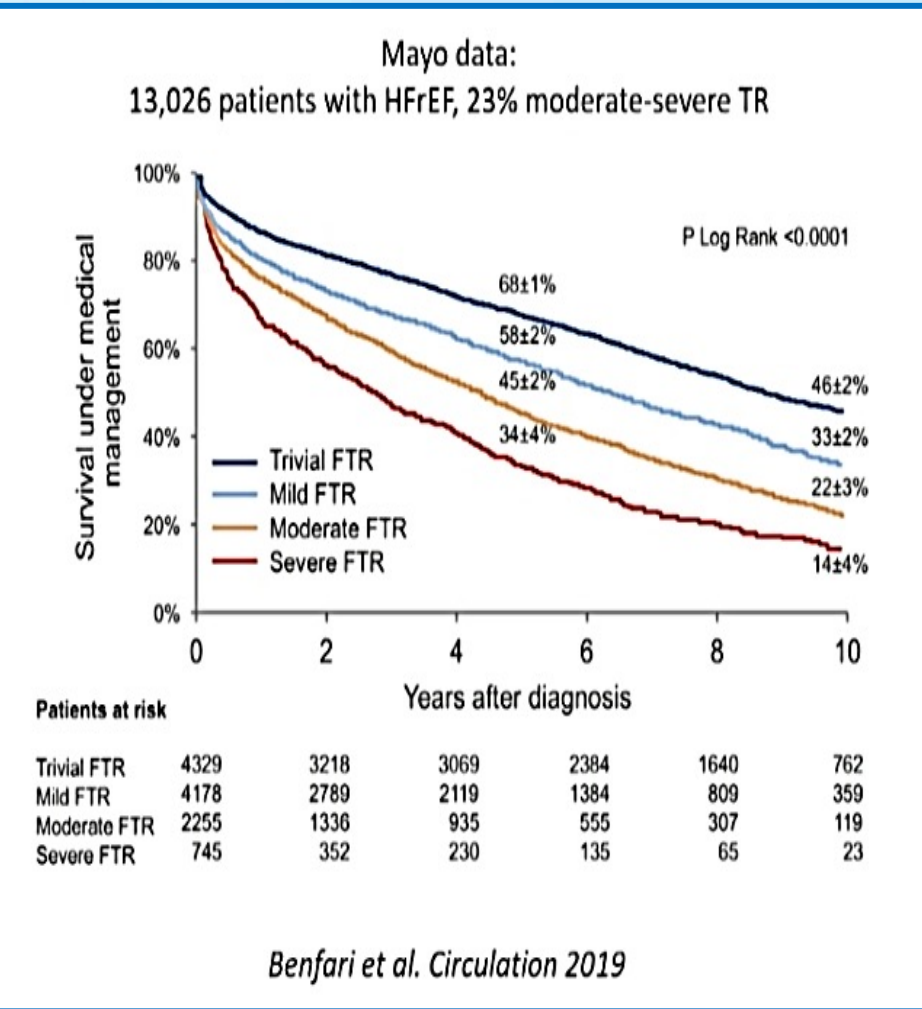
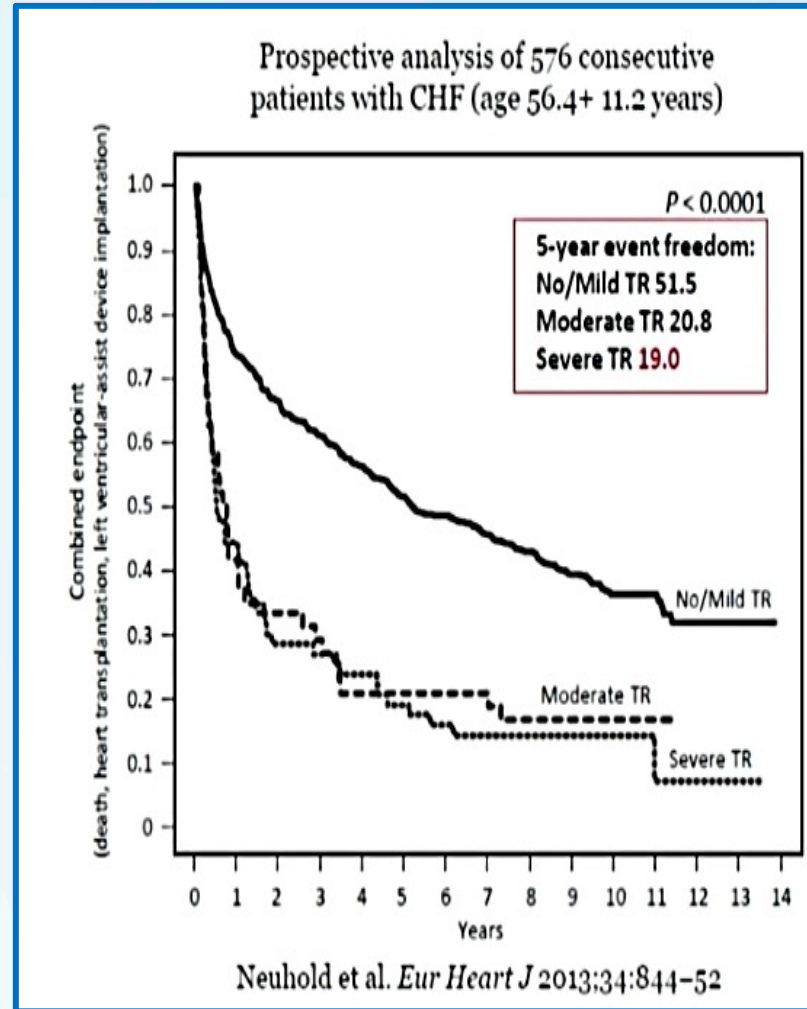
**Dr. M. Cappelli Bigazzi**

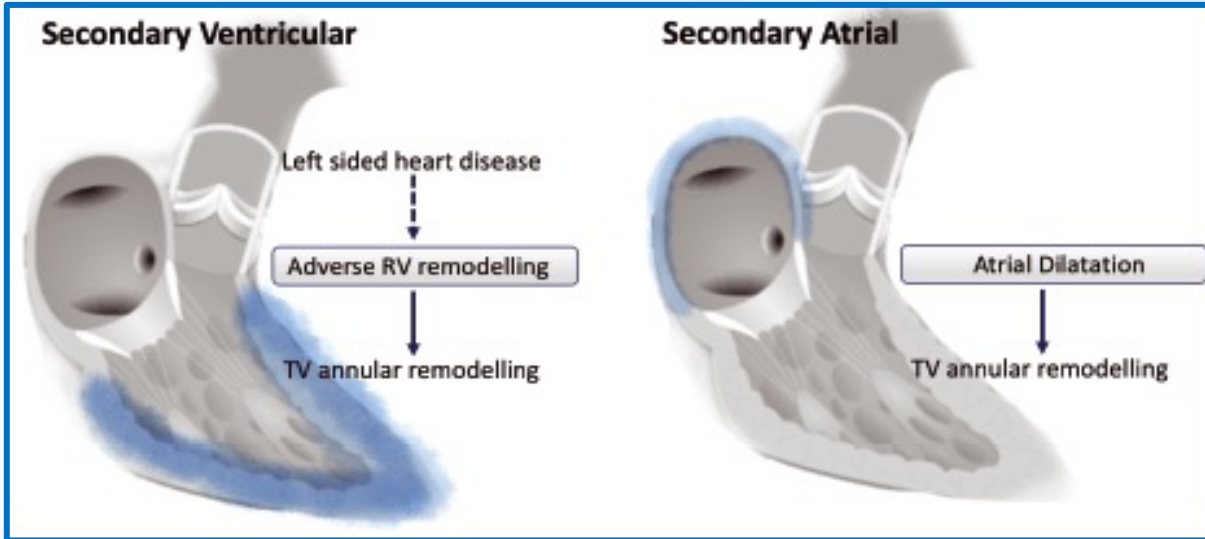
Cardiologia Vanvitelli - A.O.R.N. dei Colli – Ospedale Monaldi

# Prevalence and Prognosis of Tricuspid Regurgitation



Adapted from Nkomo VT et al. Lancet 2006  
Topilsky Y et al., JACC Cardiovasc Imaging 2018





# Pathophysiology of tricuspid regurgitation

**Atrial TR**

**Non-atrial TR**

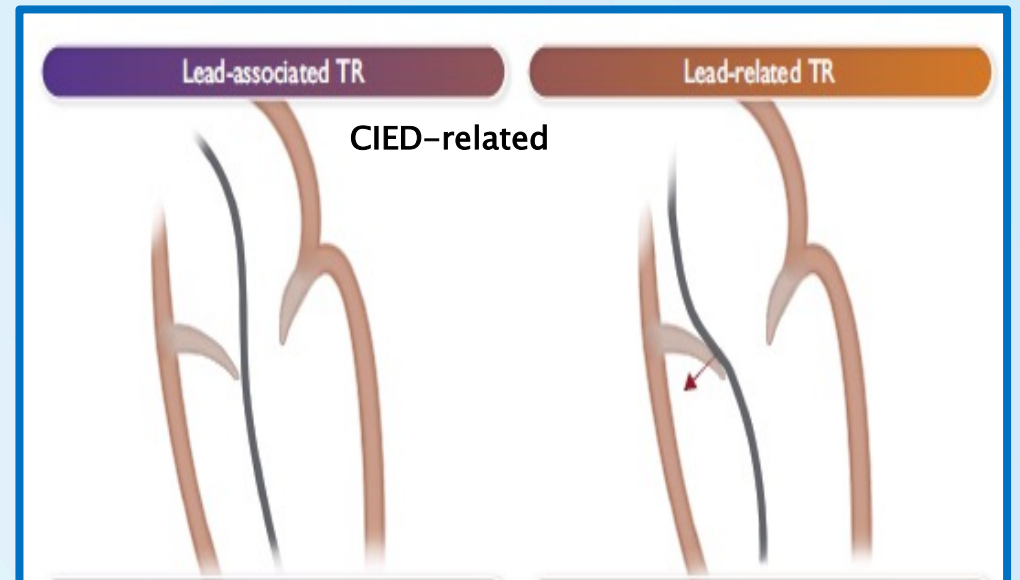
Right atrium  
 Tricuspid valve  
 Right ventricle  
 M  
 L

Healthy subject    A-FTR    V-FTR

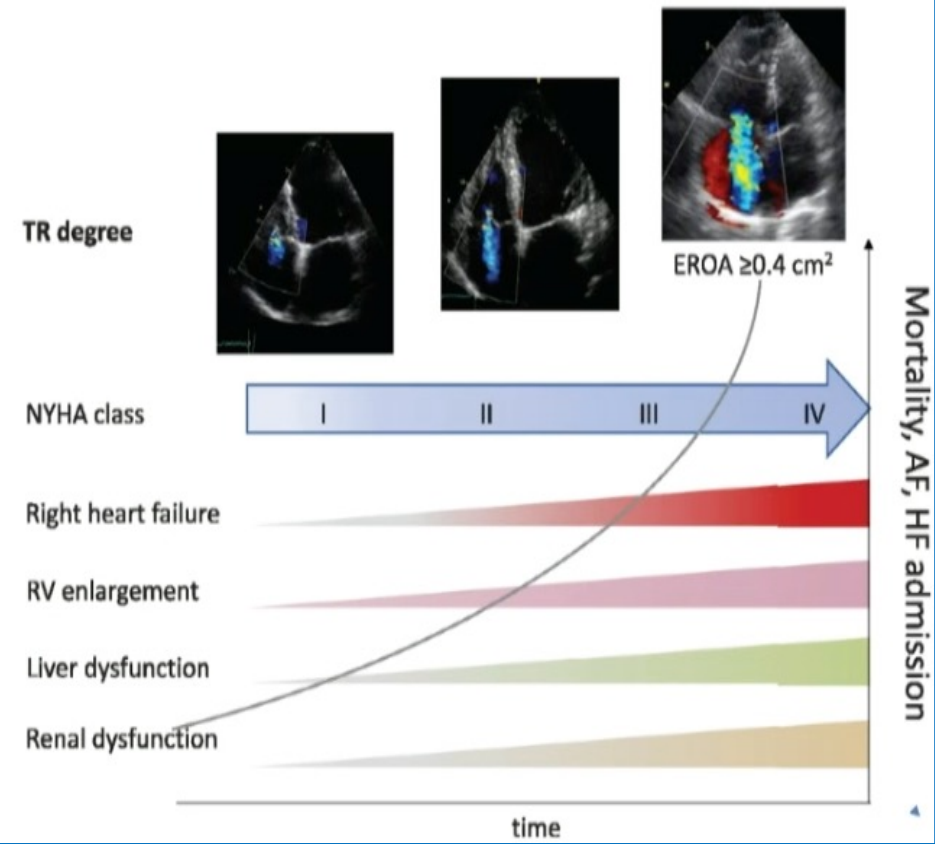
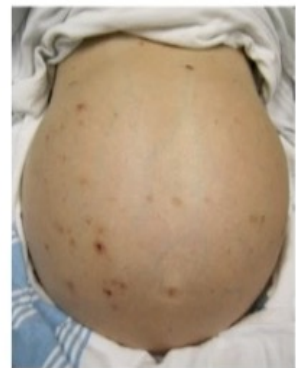
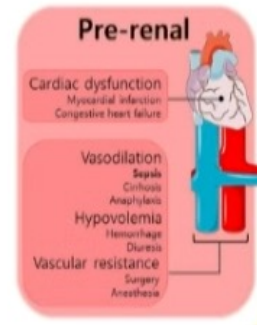
TR

Right heart dilatation

Florescu D et al. Circ Interventions 2022



## Raise in central venous pressure



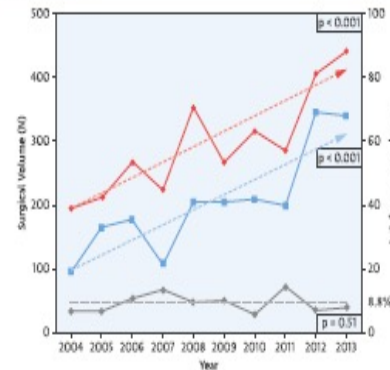
- 4% of patients > moderate TR
- In the USA, this equates to ~ 1,600,000 patients
- CTSNET: TR surgically treated 8,000 per year
- **0.4% of patients with >moderate TR treated**



5,005 isolated TV operations between 2004-2013  
(~20% of cases in US)

TV repair in 40.8%: TV replacement in 59.2%

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



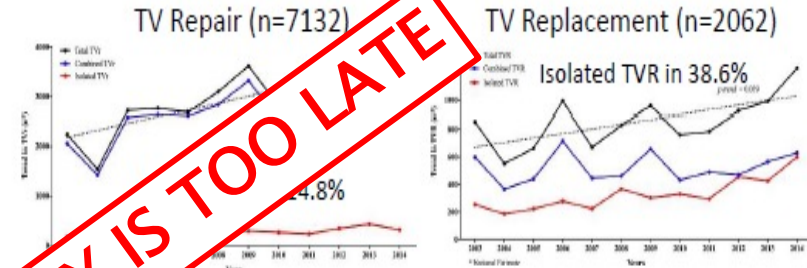
Zelik, C.J. et al. J Am Coll Cardiol. 2017;70(4):2353-60.

**In-Hospital Mortality**

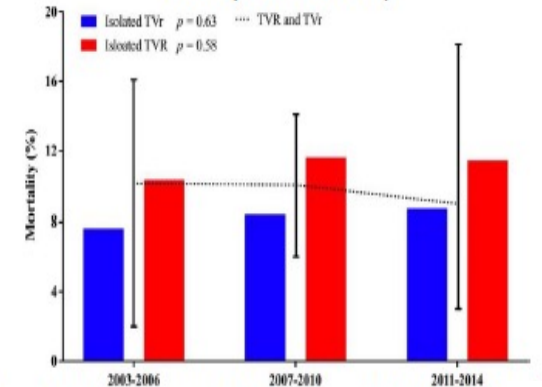
Comorbidity	Odds Ratio	95% CI	p Value
Coagulopathy	2.37	1.44-3.82	<0.001
Hypertension	0.40	0.27-0.63	<0.001
End-stage renal disease	3.15	1.41-7.05	0.005
Age ≥60 yrs	2.02	1.22-3.34	0.006
Tricuspid valve replacement	1.91	1.18-3.08	0.009
Charlson comorbidity index	1.58	0.93-2.67	0.09

12,567 patients undergoing TV Repair & Replacement between 2003-2014

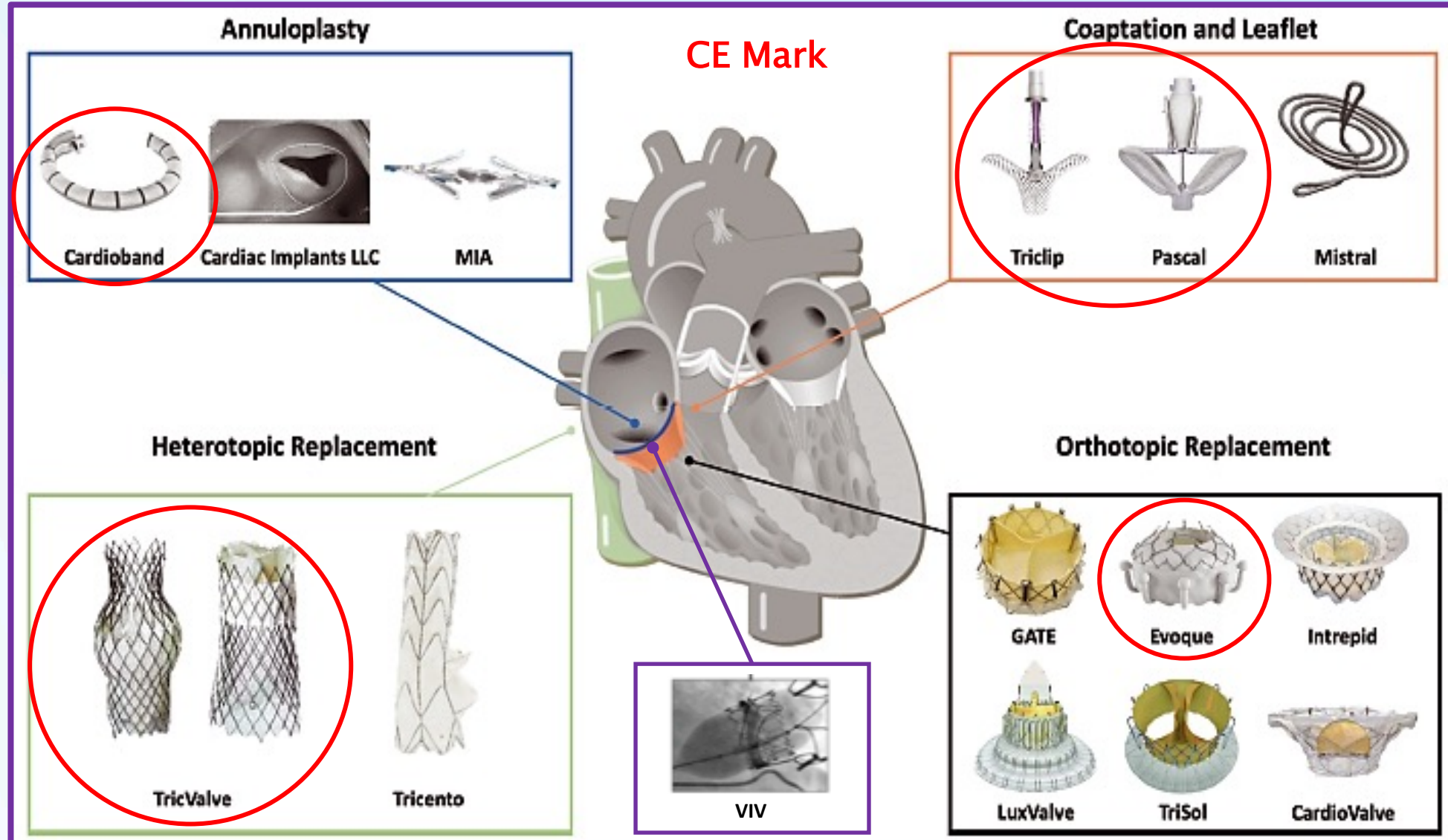
No. of patients undergoing TV surgery for TR increased by 48% from 3100 in 2003 to 4600 in 2014



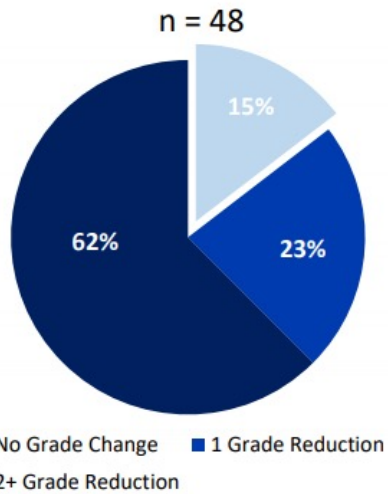
**In-Hospital Mortality**



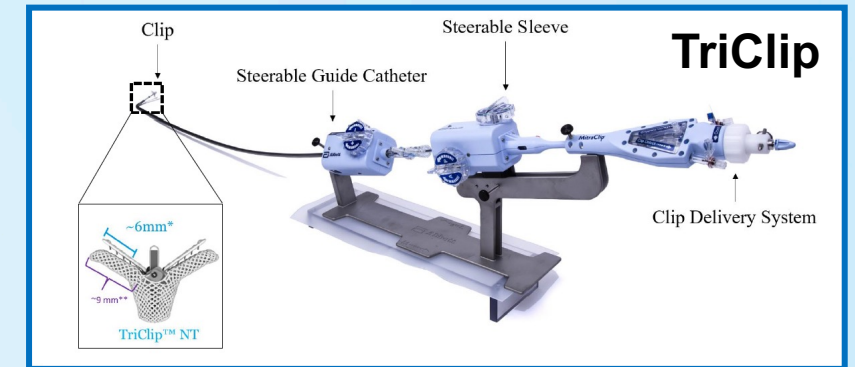
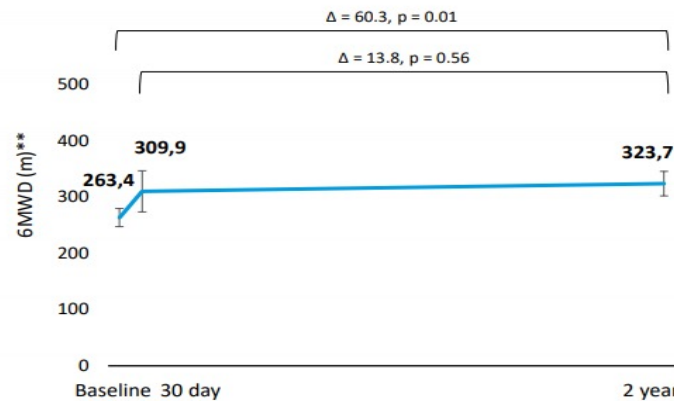
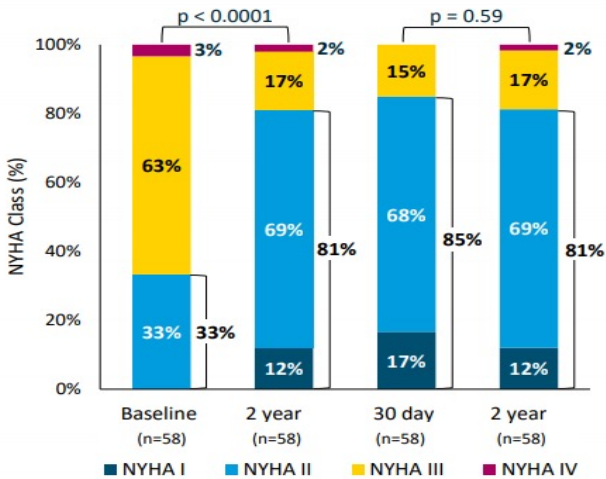
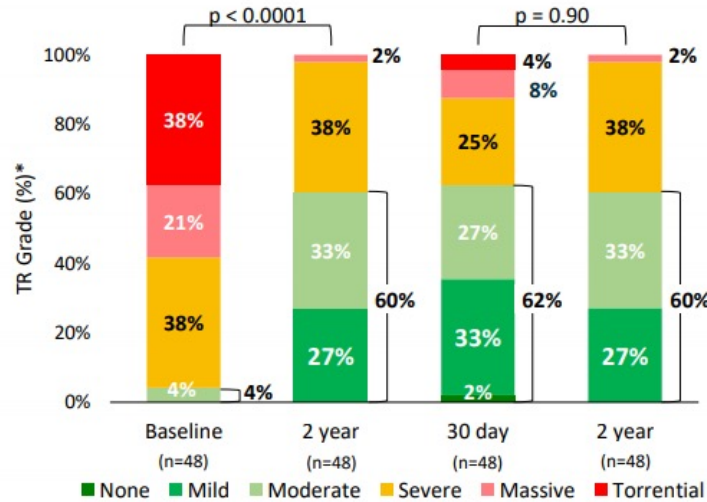
# Transcatheter Tricuspid Solutions



# TRILUMINATE Trial 2 year



TR reduced by  $\geq 1$  grade in 85.4% of subjects, consistent with the



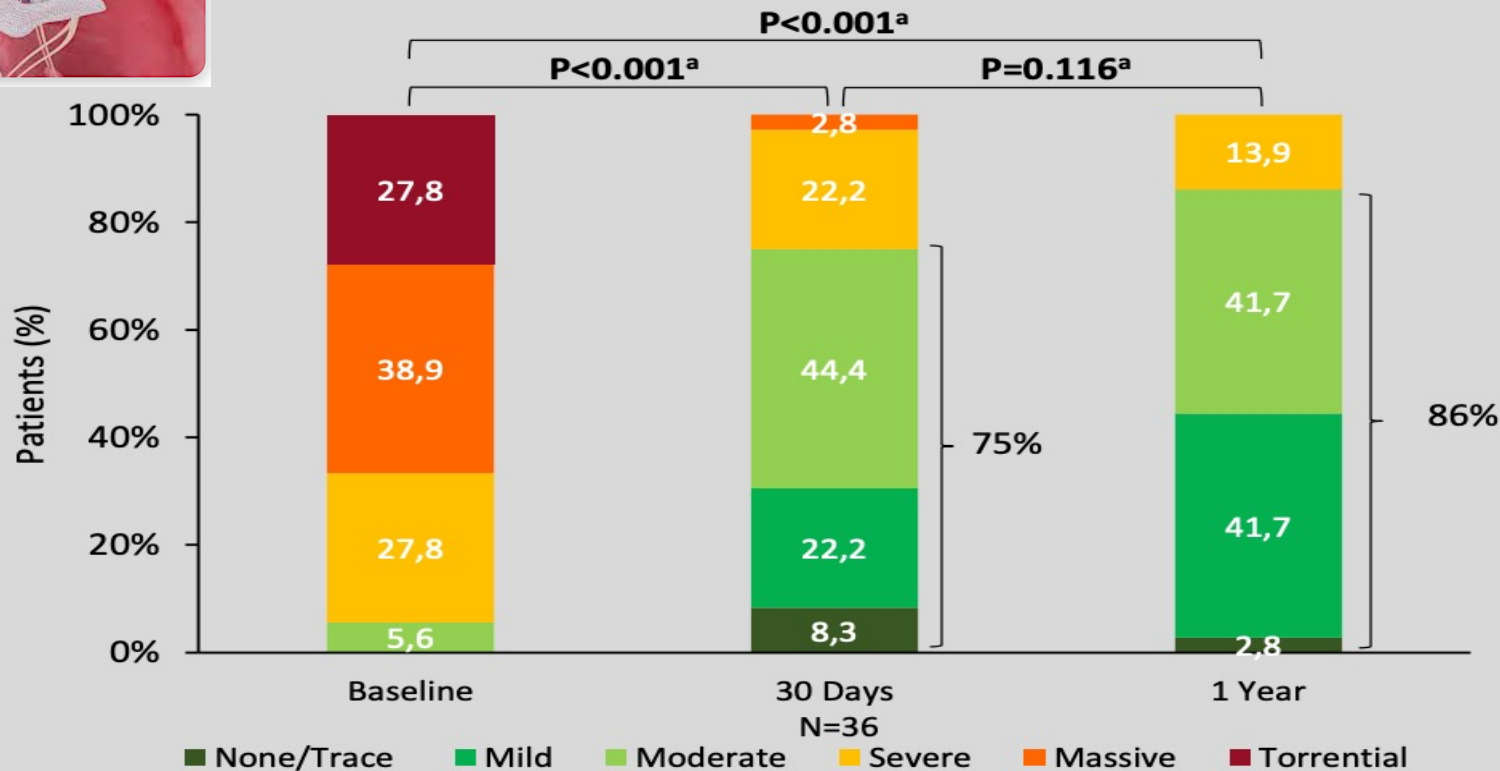
Parameter	TVRS
Implant Success Rate	100%
Acute Device Success	100%
Acute Procedural Success	91.6%
Device Time, min	75.2±49.4
Total Procedure Time, min	152.7±57.8
Fluoroscopy Duration, min	23.3±17.8

Event	(n)
Major Adverse Event (MAE) through 6 months	3
Cardiovascular Mortality	2
Myocardial Infarction	0
Stroke	0
New Onset Renal Failure	1
Non-elective CV surgery, TVRS	0
Device-related AE	0





**TR Severity via Core Lab<sup>1</sup>**

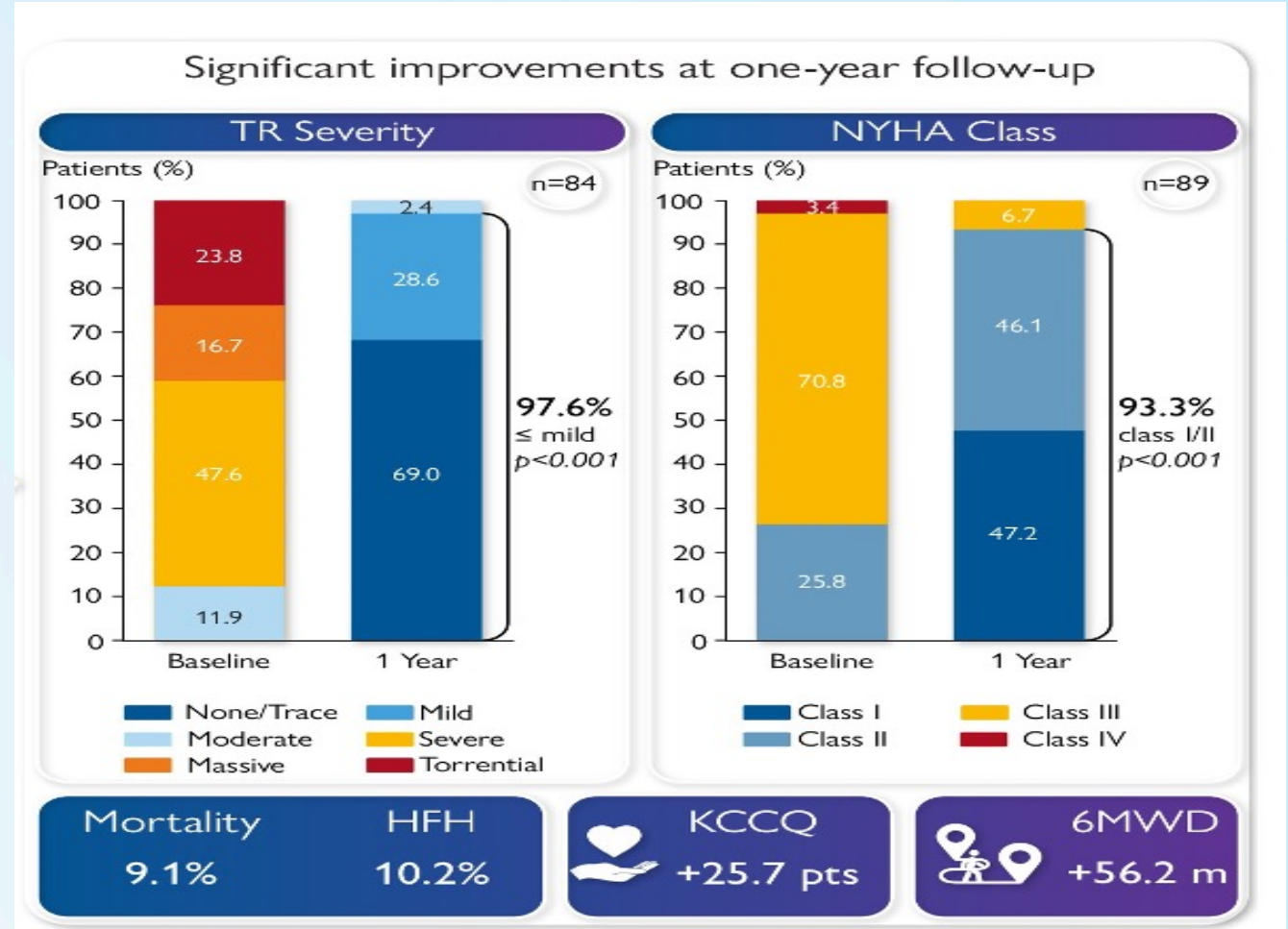
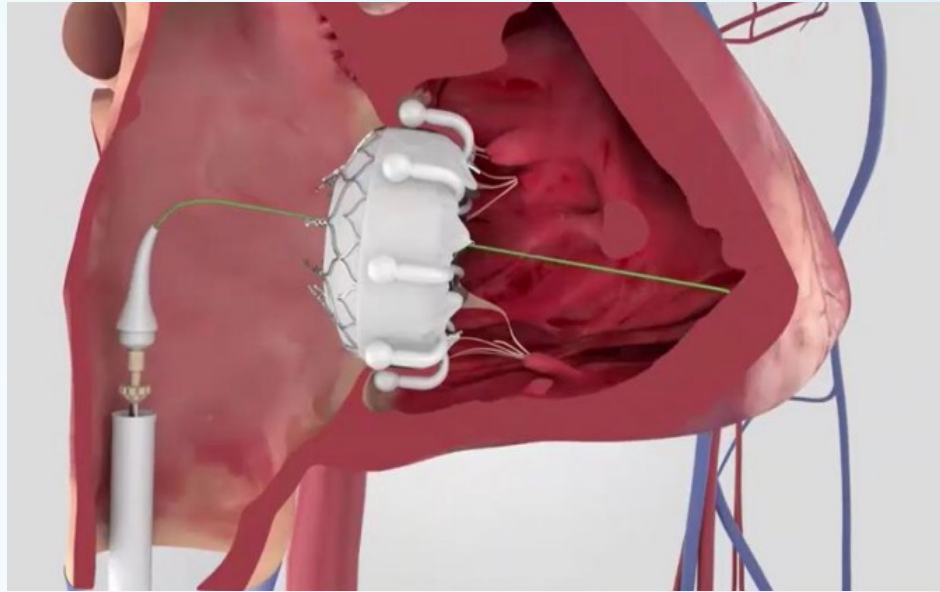


**CLASP TR Study**

**At one year, 100% improved by at least one TR grade,  
75% by at least two grades  
86% reached moderate or lower TR**

# EVOQUE

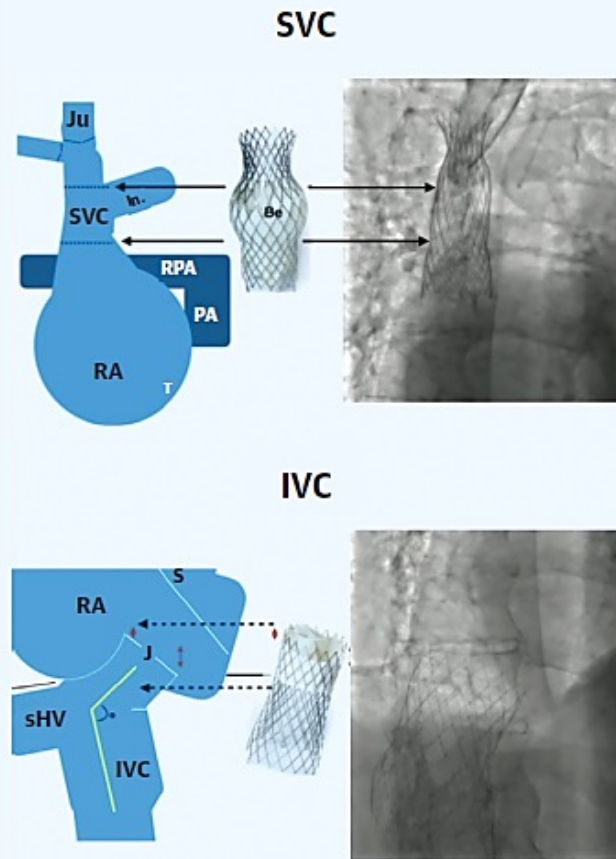
# TRISCEND Study



Need for anticoagulation  
13.3% PMK implantation

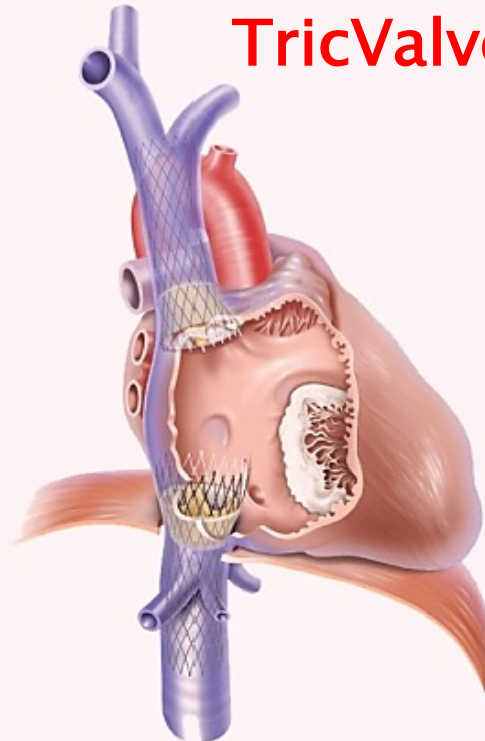


### Device & Procedure

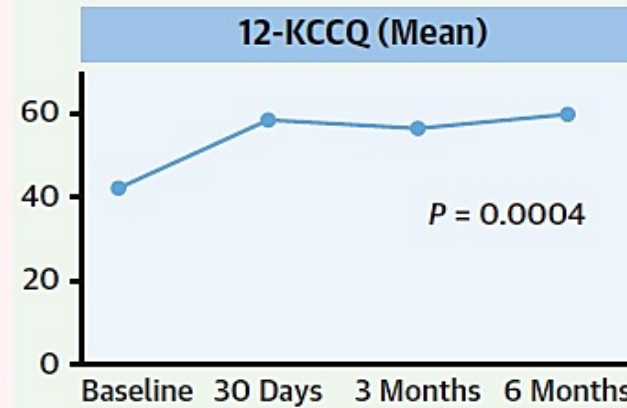


- 97% Technical success
- 0% 6-month cardiac death
- Persistent functional improvement

### TricValve



### Functional



# TRICUS EURO Study

# TRILUMINATE PIVOTAL Trial

The **NEW ENGLAND**  
**JOURNAL of MEDICINE**

ESTABLISHED IN 1812

MAY 18, 2023

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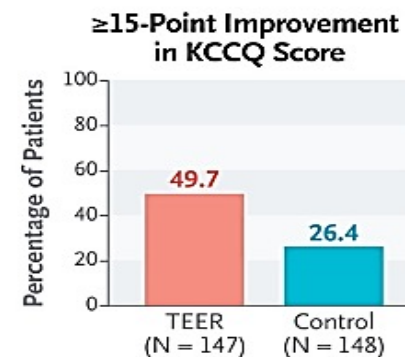
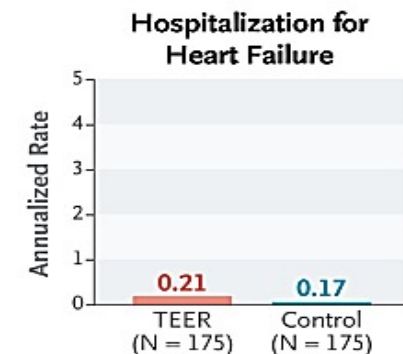
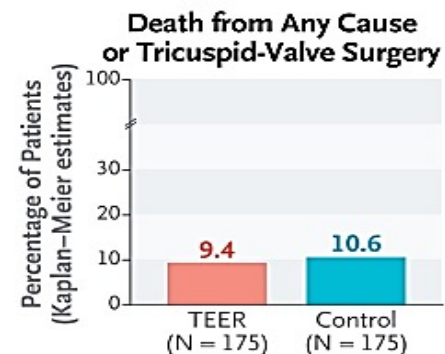
Transcatheter Repair for Patients with Tricuspid Regurgitation

<b>Patient Population</b>	Ability to reduce TR to moderate or less
<b>Randomization</b>	1:1 TriClip: Control (Medical Therapy)
<b>Endpoint</b>	Hierarchical composite of all-cause mortality or tricuspid valve surgery, HFH, and KCCQ improvement $\geq 15$ points at 12 months
<b>Primary Analysis (adaptive design)</b>	350

## Primary End Point

Win ratio, 1.48 (95% CI, 1.06–2.13); P = 0.02

	TEER Group (N = 175)	Control Group (N = 175)
Hierarchical composite — no. of wins	11,348	7643

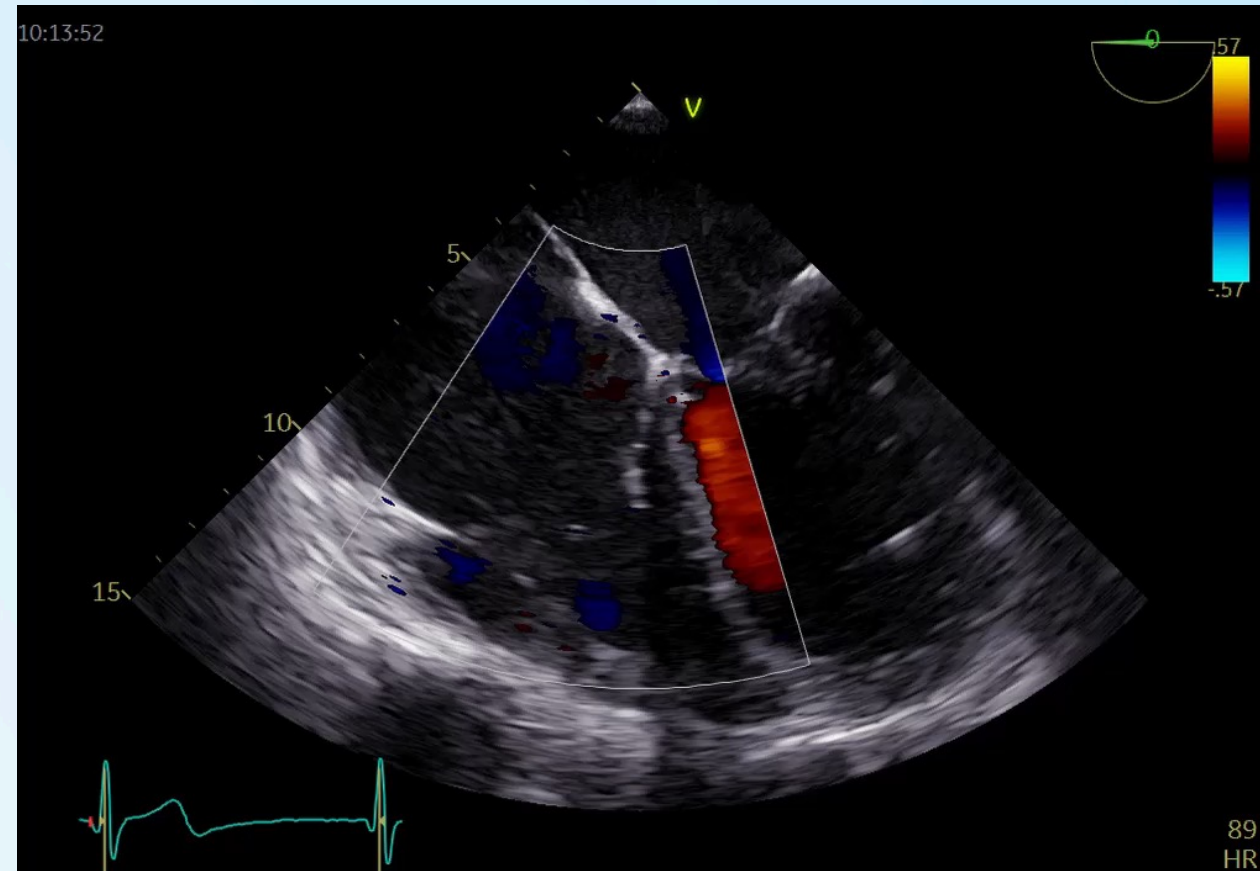
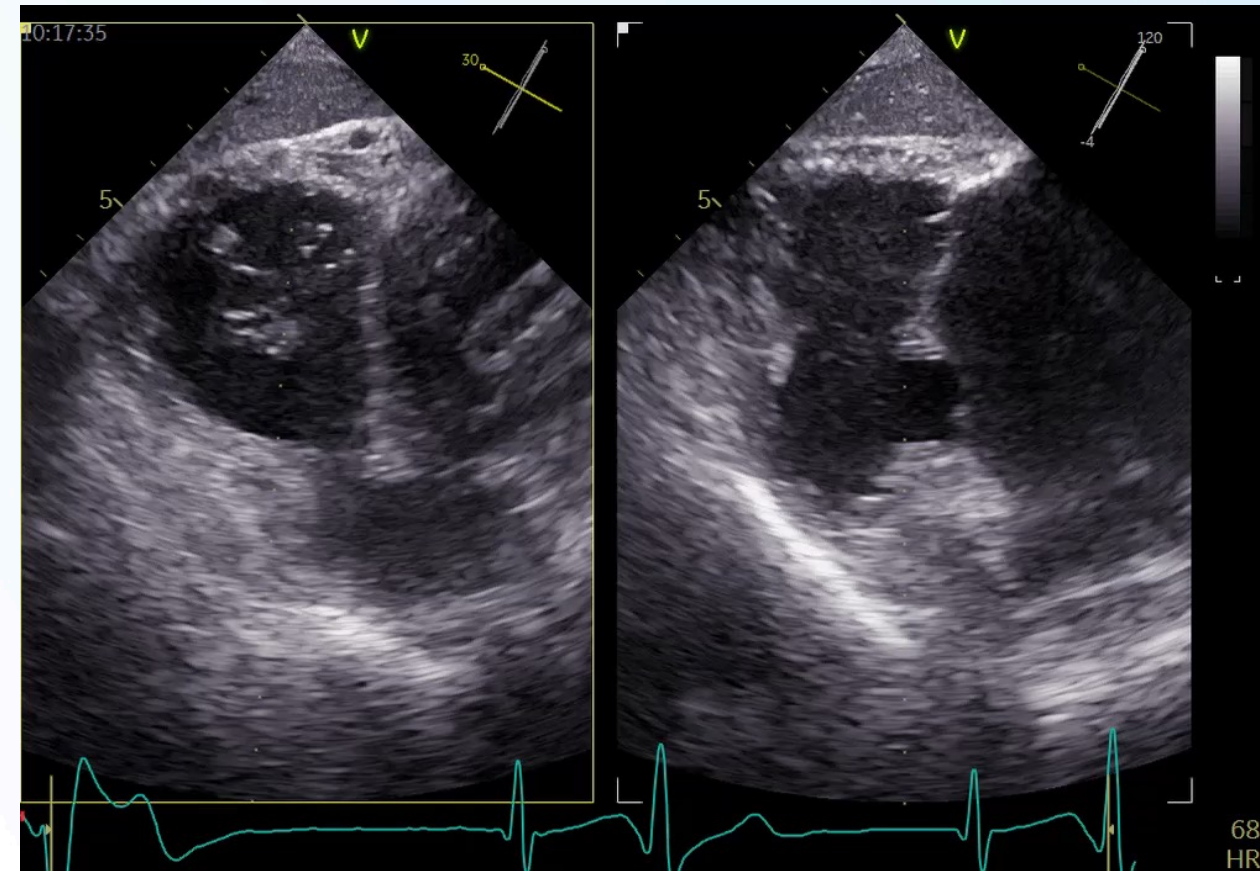


Quale tipo di trattamento percutaneo utilizzare?

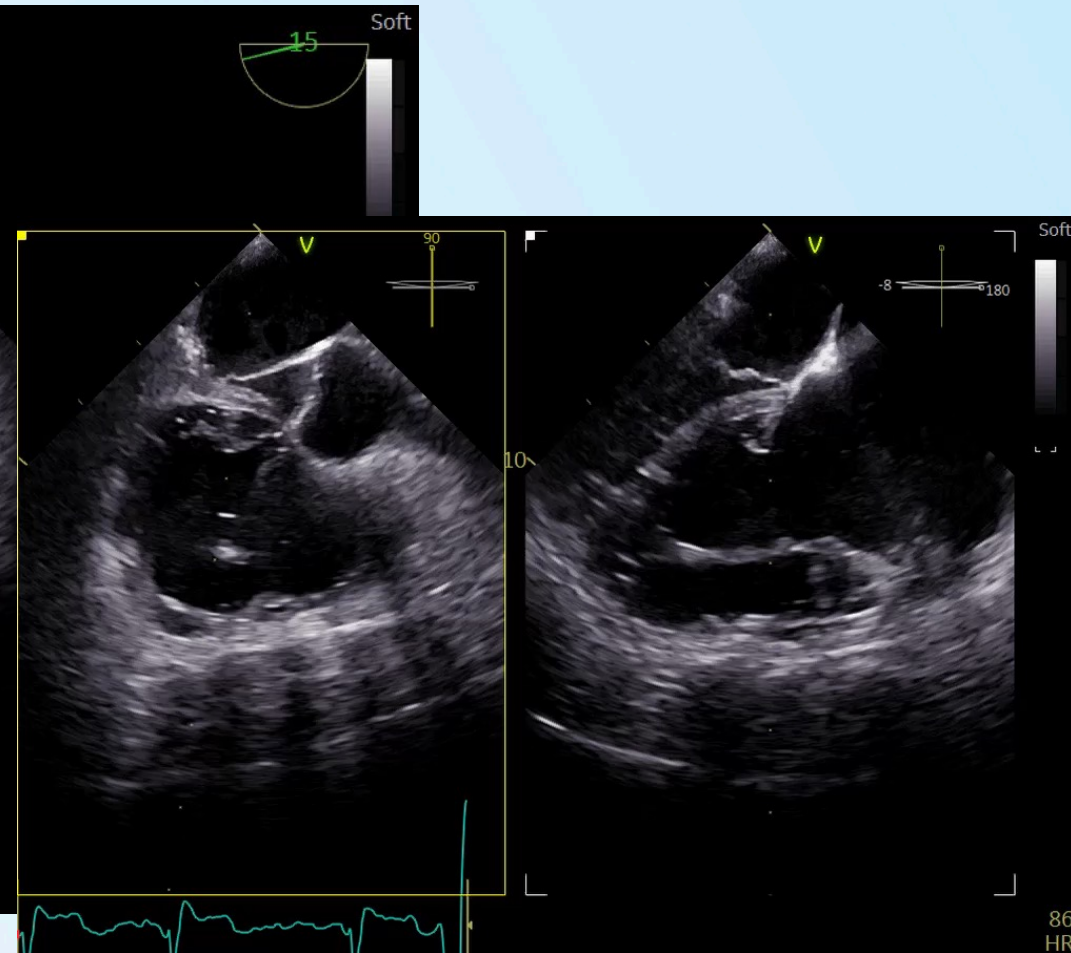
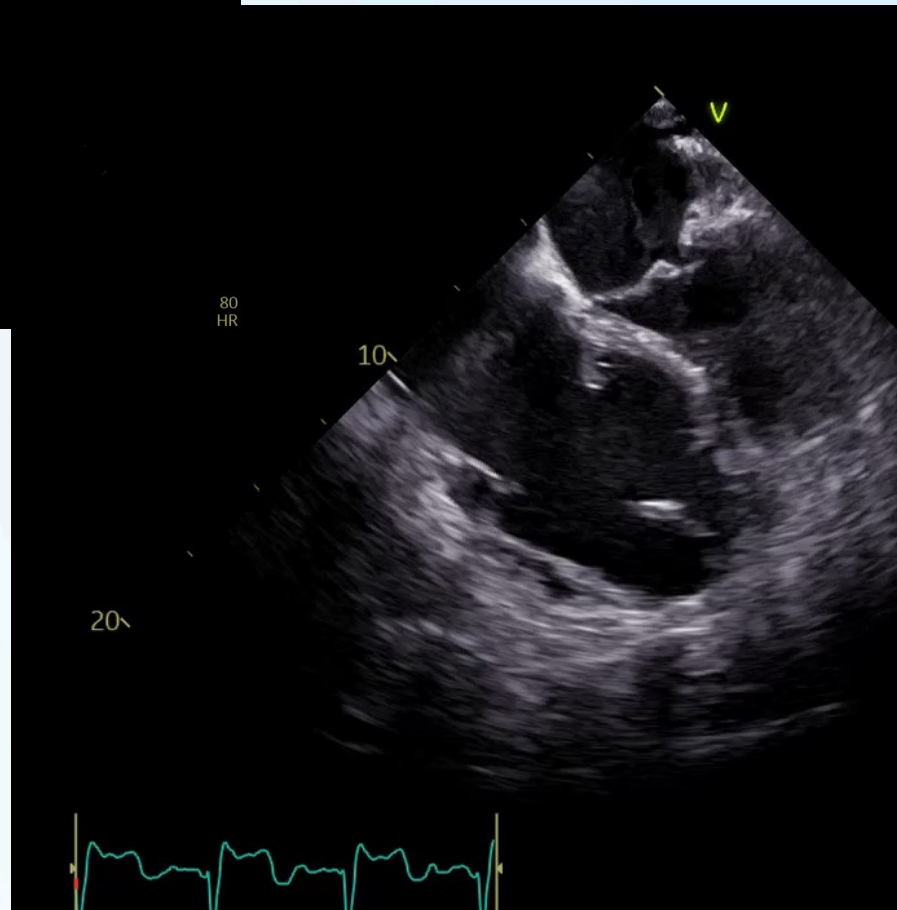
Secondo quali criteri di scelta?

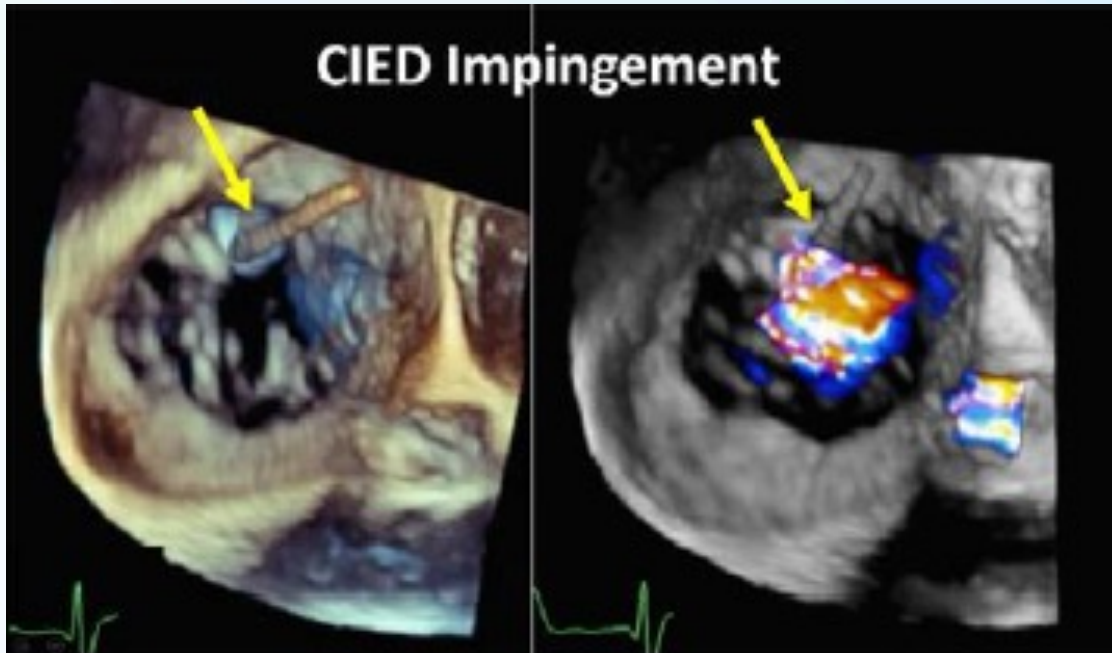
Strategy	Favourable anatomy	Feasible anatomy	Unfavourable anatomy
Leaflet approximation	<p>Small septolateral gap <math>\leq 7</math> mm<sup>10</sup></p> <p>Anteroseptal jet location</p> <p>Confined prolapse or flail</p> <p>Trileaflet morphology</p>	<p>Septolateral coaptation gap <math>&gt;7</math> but <math>\leq 8.5</math> mm<sup>65</sup></p> <p>Posteroseptal jet location</p> <p>Non-trileaflet morphology</p> <p>Incidental CIED RV lead (i.e., without leaflet impingement)</p>	<p>Large septolateral coaptation gap <math>&gt;8.5</math> mm<sup>65</sup></p> <p>Leaflet thickening/shortening (rheumatic, carcinoid)/perforation</p> <p>Dense chordae with marked leaflet tethering</p> <p>Anteroposterior jet location</p> <p>Poor echocardiographic leaflet visualisation</p> <p>CIED RV lead leaflet impingement</p> <p>Unfavourable device angle of approach</p>
Annuloplasty	<p>Annular dilatation as primary mechanism of TR</p> <p>Mild tethering (tethering height <math>&lt;0.76</math> cm, tenting area <math>&lt;1.63</math> cm<sup>2</sup>, tenting volume [3D] <math>&lt;2.3</math> mL)<sup>110,111</sup></p> <p>Central jet location</p> <p>Sufficient landing zone for anchoring</p>	<p>Moderate tethering (tethering height <math>\geq 0.76</math> cm but <math>&lt;1.0</math> cm, tenting area <math>&gt;1.63</math> but <math>&lt;2.5</math> cm<sup>2</sup>, tenting volume [3D] <math>\geq 2.3</math> mL but <math>\leq 3.5</math> mL)<sup>110,111</sup></p> <p>Incidental CIED RV lead (i.e., without leaflet impingement)</p>	<p>Excessive annular dilatation (exceeding device size)</p> <p>Severe tethering (tethering height <math>&gt;1.0</math> cm, tenting volume <math>&gt;3.5</math> mL). Poor echocardiographic annular visualisation<sup>110,111</sup></p> <p>Annular proximity of RCA</p> <p>CIED RV lead leaflet impingement</p>
Orthotopic valve implantation	<p>Previous surgical repair or bioprosthetic valve replacement</p> <p>Leaflet thickening/shortening (rheumatic, carcinoid)</p> <p>Incidental CIED RV lead (i.e., without leaflet impingement)</p> <p>Any leaflet morphology</p>	<p>Large coaptation gap</p> <p>CIED RV lead leaflet impingement</p>	<p>Excessive annular dilatation (exceeding device size)</p> <p>Unfavourable device angle of approach</p> <p>Severe right ventricular dysfunction</p>
Heterotopic valve implantation	<p>Appropriate caval diameters (and intercaval distance)</p> <p>No option for direct valve treatment</p>		<p>Proximity of the RA to the orifice of the liver veins (<math>&lt;10-12</math> mm)</p> <p>Severely increased pulmonary artery and RA pressures due to the risk of fracture of bicaval valved stents</p>

## Anatomia favorevole per riparazione edge-to-edge



## Anatomia non favorevole per riparazione edge-to-edge





Anatomia non favorevole per riparazione edge-to-edge





Quali pazienti si giovano maggiormente del trattamento percutaneo?

Come valutare la severità dell'insufficienza tricuspidalica e la gravità della malattia?

