Insufficienza Tricuspidalica

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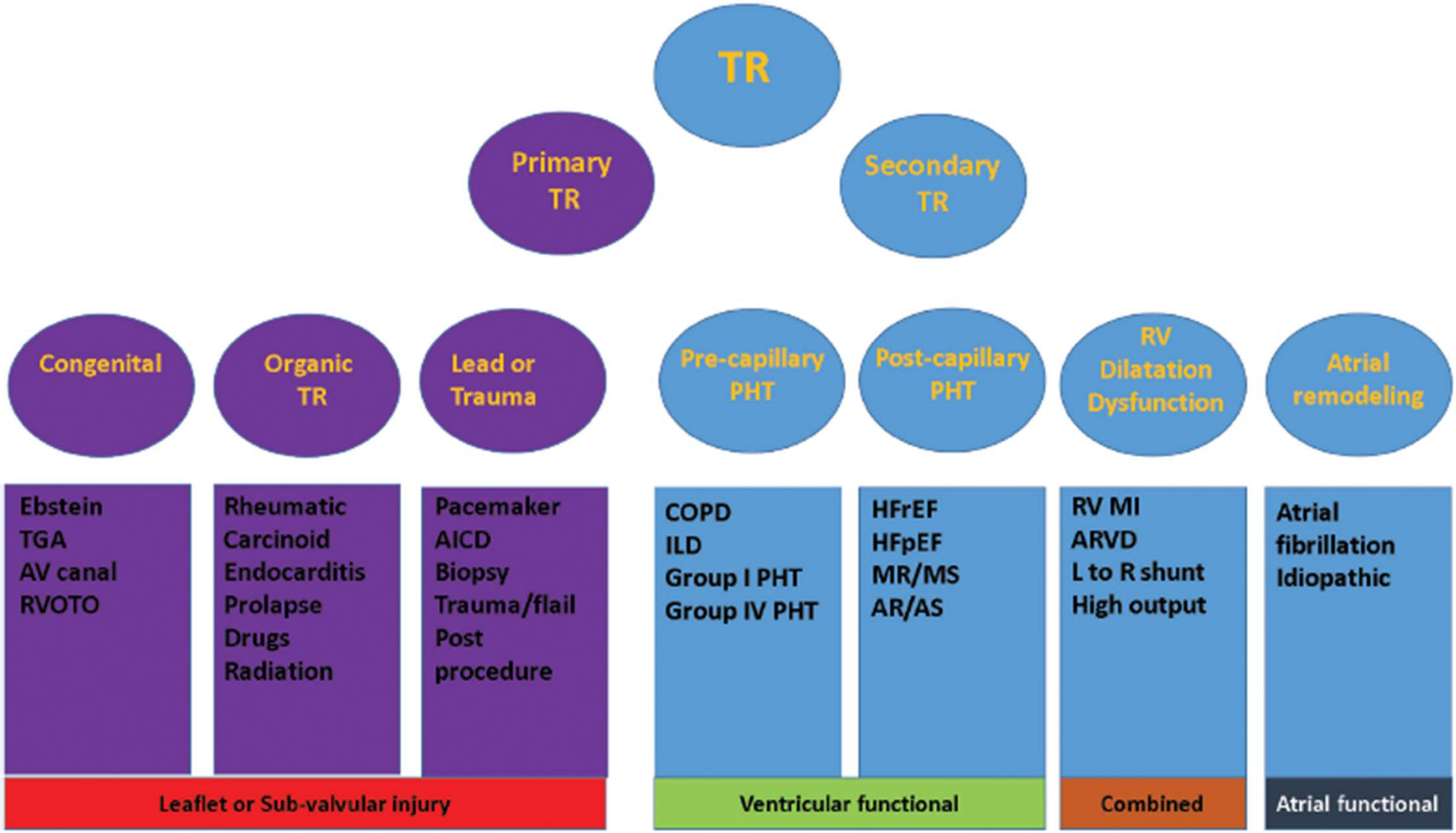
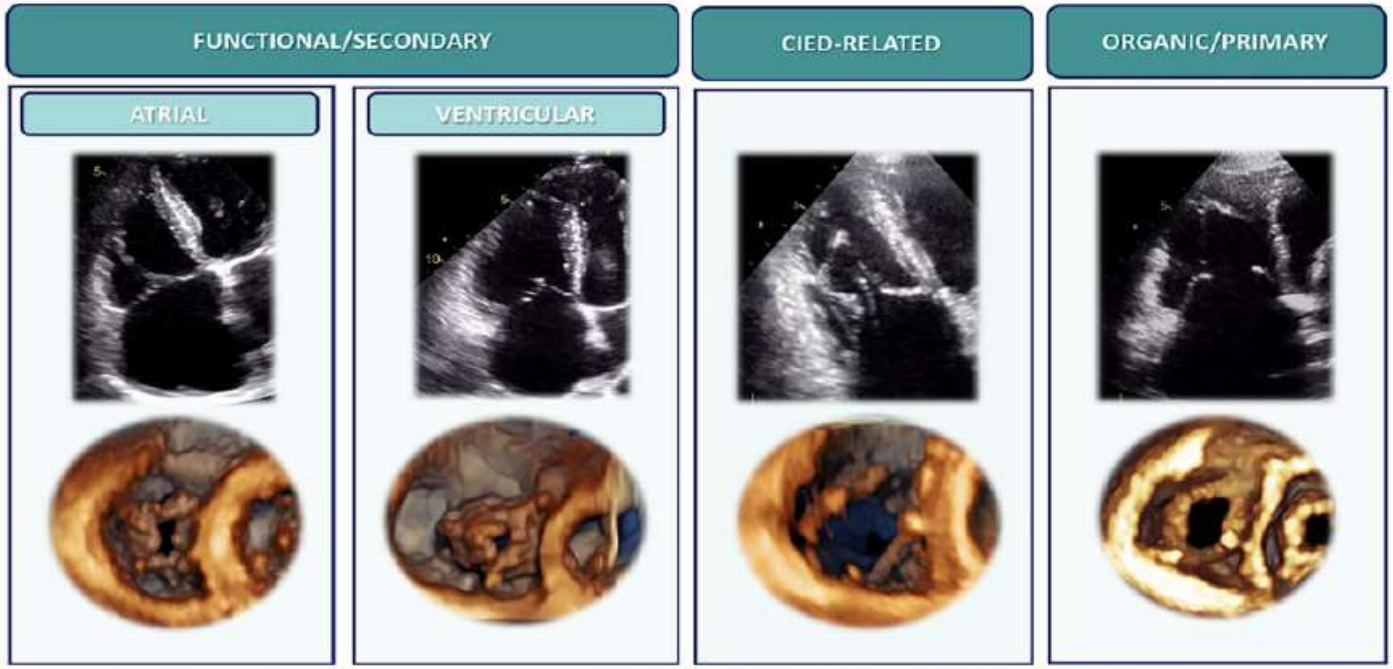
The vast majority of TR patients suffer from secondary TR

Classification	Etiologies
Structural abnormality of the tricuspid valve apparatus	
Primary TR: ~10-15% of patients	
Degenerative Disease	• Prolapse • Flail
Congenital	• Ebstein's Anomaly • Leaflet clefts

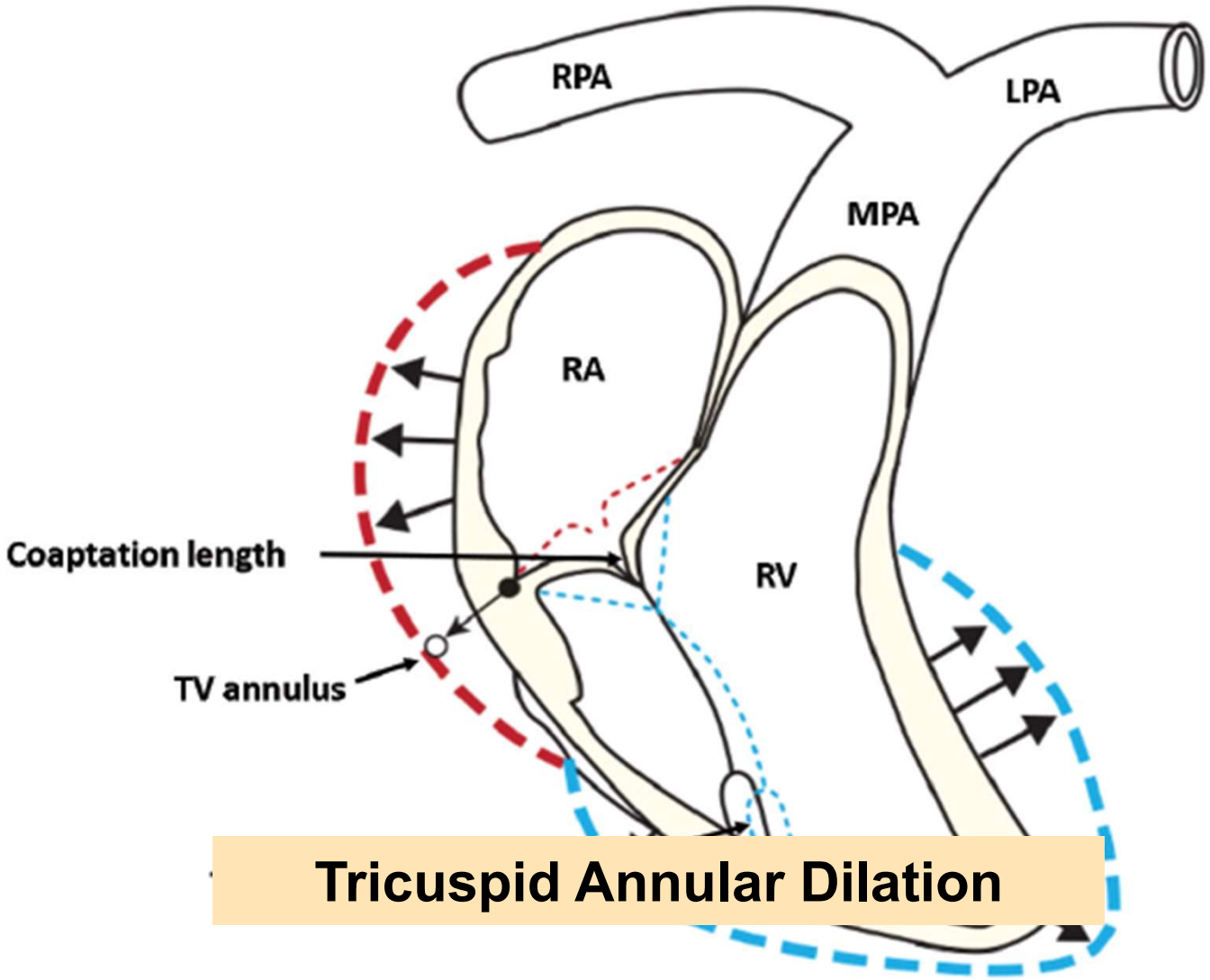
Acquired	• Rheumatic disease (usually with left-side disease)
	• Infective endocarditis
	• Endomyocardial fibrosis
	• Carcinoid disease, serotonin active drugs
	• Traumatic (blunt chest injury, laceration)
	• Iatrogenic
	  ◦ Right ventricular biopsy
	  ◦ Drugs (e.g. exposure to fenfluramine-phentermine, or methysergide)
	Radiation therapy of the mediastinum

Morphological normal leaflets with annular dilatation and/or leaflet tethering	
Functional TR: ~ 80% of patients	
Ventricular secondary TR	• Left heart diseases (left ventricular dysfunction or left heart valve diseases) resulting in pulmonary hypertension • Primary pulmonary hypertension • Secondary pulmonary hypertension (e.g. chronic lung disease, pulmonary thromboembolism, left-to-right shunt) • Right ventricular dysfunction from any cause (e.g. myocardial diseases, ischemic heart disease, chronic right ventricular pacing)
Atrial secondary TR	• Atrial fibrillation • Heart Failure with preserved ejection fraction
Cardiac tumors (particularly right atrial myxomas)	• Right atrial myxomas
Cardiac implantable electronic device (CIED) induced TR (~ 5% of patients)	
Primary CIED-induced TR	• CIED caused by direct interaction of the lead on the valve leaflets)
Secondary CIED-induced TR	• Incidental CIED, with TR due to functional etiologies or pacing related remodeling


TR
Primary TR
Secondary TR
Congenital
Organic TR
Lead or Trauma
Pre-capillary PHT
Post-capillary PHT
RV Dilatation Dysfunction
Atrial remodeling
Ebstein
TGA
AV canal
RVOTO
Rheumatic
Carcinoid
Endocarditis
Prolapse
Drugs
Radiation
Pacemaker
AICD
Biopsy
Trauma/flail
Post procedure
COPD
ILD
Group I PHT
Group IV PHT
HFrEF
HFpEF
MR/MS
AR/AS
RV MI
ARVD
L to R shunt
High output
Atrial fibrillation
Idiopathic
Leaflet or Sub-valvular injury
Ventricular functional
Combined
Atrial functional



Parameter	Atrial FTR	Ventricular FTR	CIED-Related	Primary TR	
				Prolapse (I)	RHD (IIIA)
Leaflet Tethering	-	+++	++	-	-
Leaflet Restriction	-	Systole	Systole/Diastole	-	Diastole
RA/TA Dilatation	+++	++	+/-	++	++
RV Dilatation	+/-	+++	+/-	+/-	+/-
RV Dysfunction	+/-	+++	+/-	+/-	+/-



Tricuspid Annular Dilation

The red arrows show the direction of dilation of atrial wall, annulus, and leaflets in the setting of idiopathic (atrial remodeling) secondary TR.

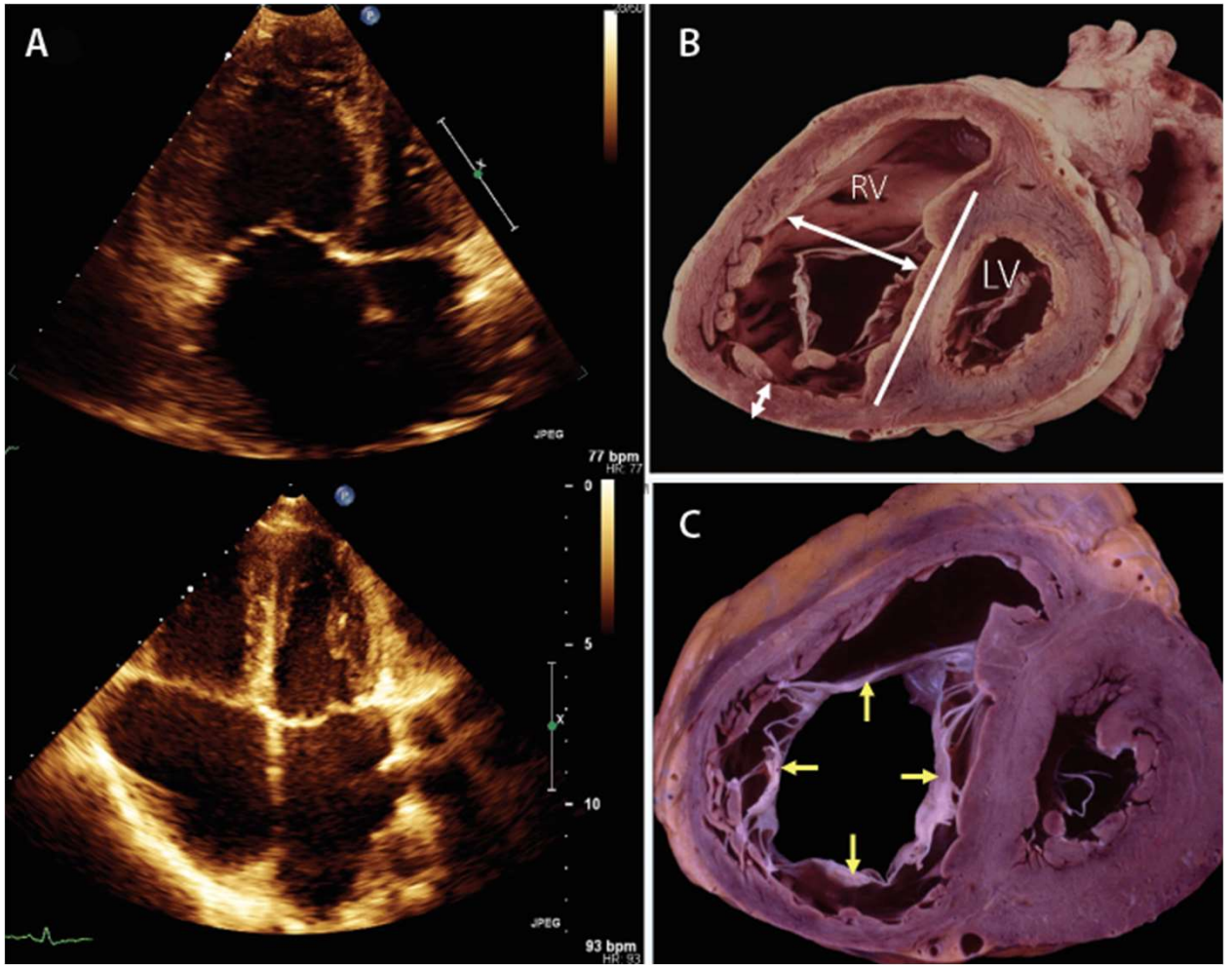
The blue arrows show the direction of dilation of lateral and septal RV walls, papillary muscles, and leaflets in the setting of secondary TR related to pulmonary hypertension (RV remodeling).

In numerous etiologies for secondary TR, these processes can be combined. LPA, left pulmonary artery; MPA, main pulmonary artery; RPA, right pulmonary artery.

RA and RV remodeling

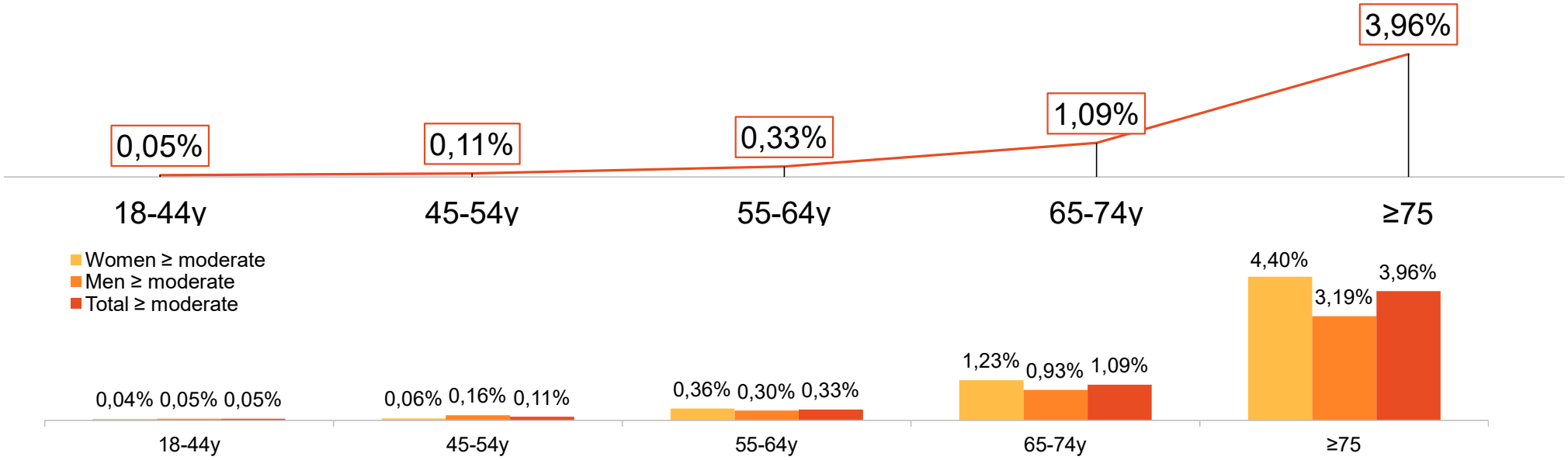
RV remodeling of pulmonary hypertension
RV dilates mostly in the middle area, resulting in spherical appearance of the RV

Atrial remodeling



TR prevalence increases with age

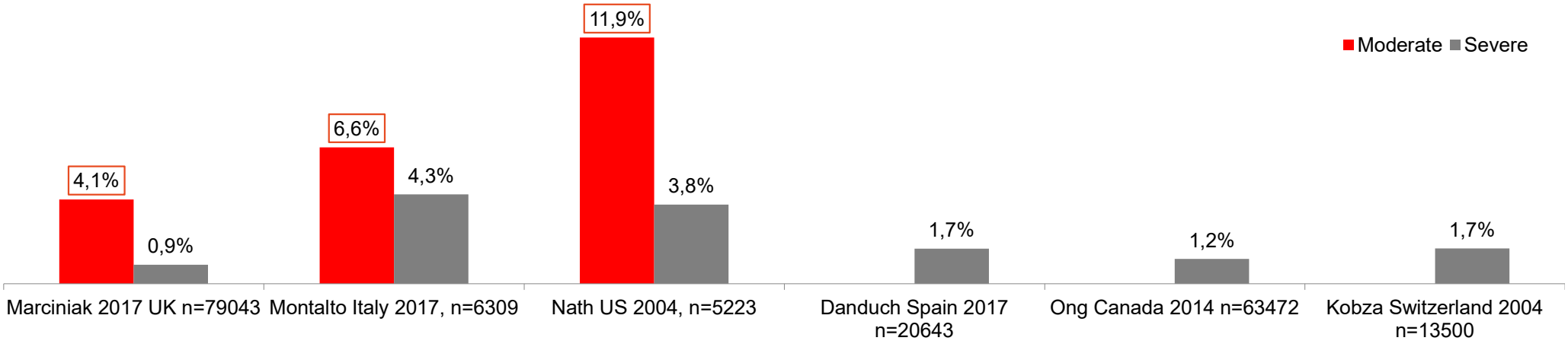
Community-based study (US) – White Population



- Toplisky et al. report prevelence of ≥ moderate TR in 1.1% of patients aged 65-74 years and it increases to 4% in patients aged ≥ 75years
- The prevalence is strongly correlated with age, and higher in women than men

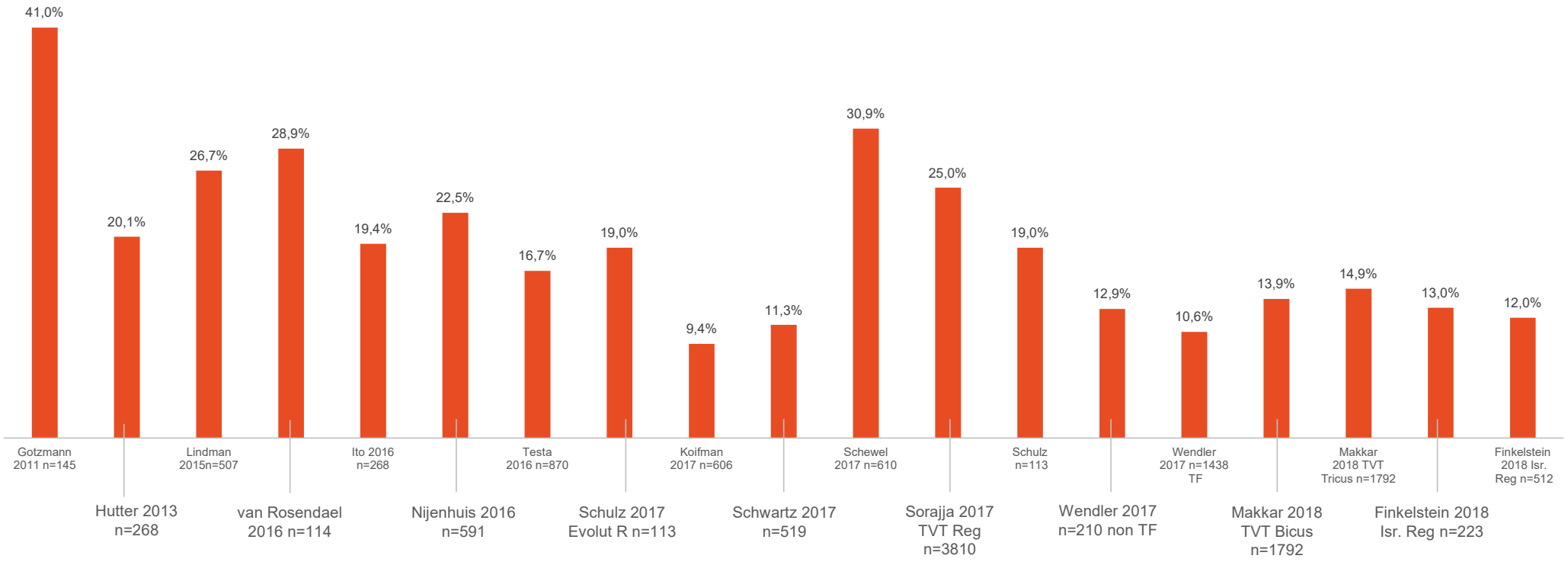
Toplisky Y et al. Burden of Tricuspid Regurgitation in Patients Diagnosed in the Community Setting. J Am Coll Cardiol Img 2019

Prevalence of moderate-severe TR based on echo in tertiary hospitals

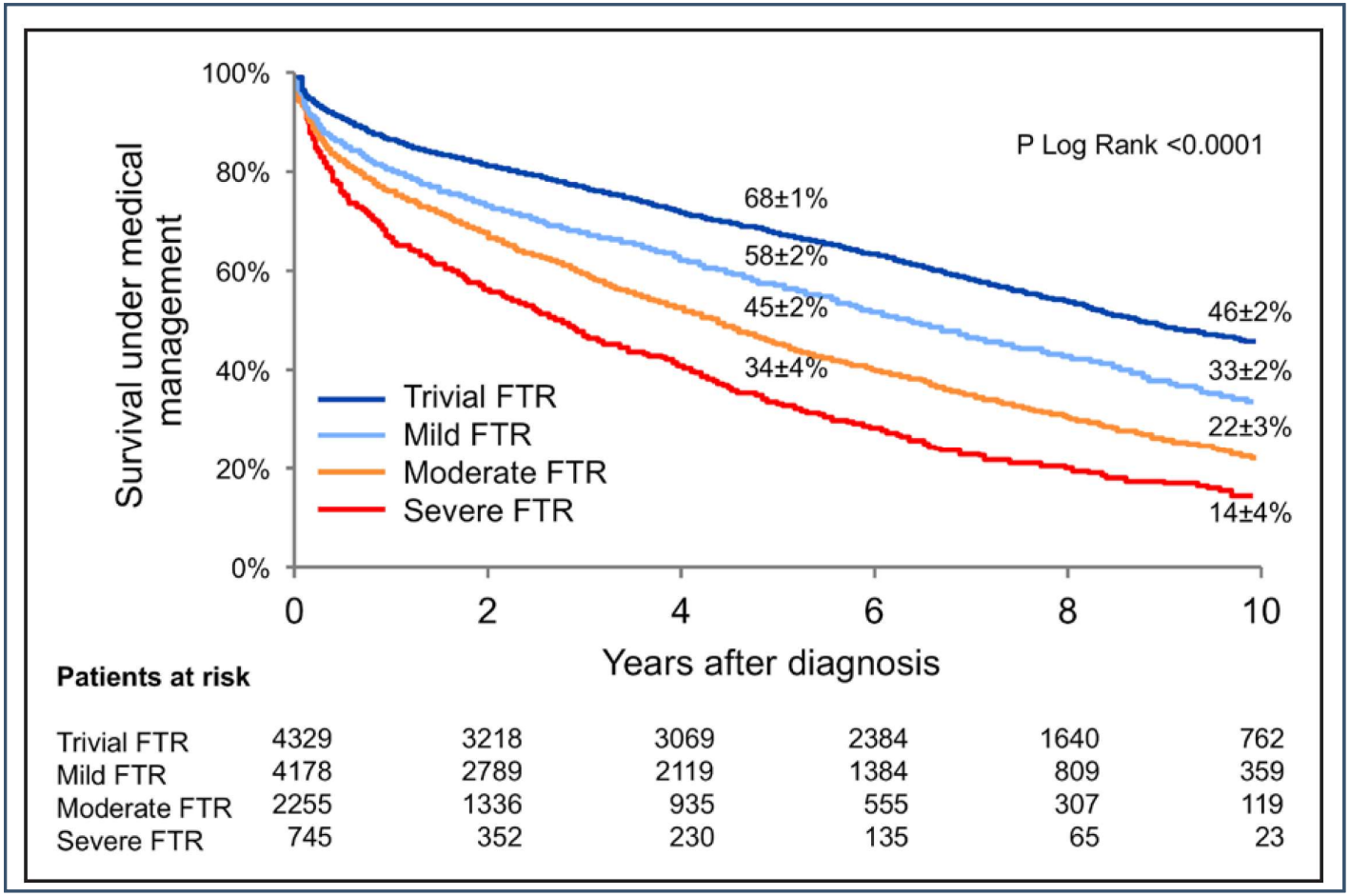


- **Severe TR prevalence varies from 0.9% to 4.3%**
- **≥ Moderate TR ranges from 5% to 15.5%**

10%-41% of TAVI patients suffer from ≥ moderate TR



TR Survival under OMT



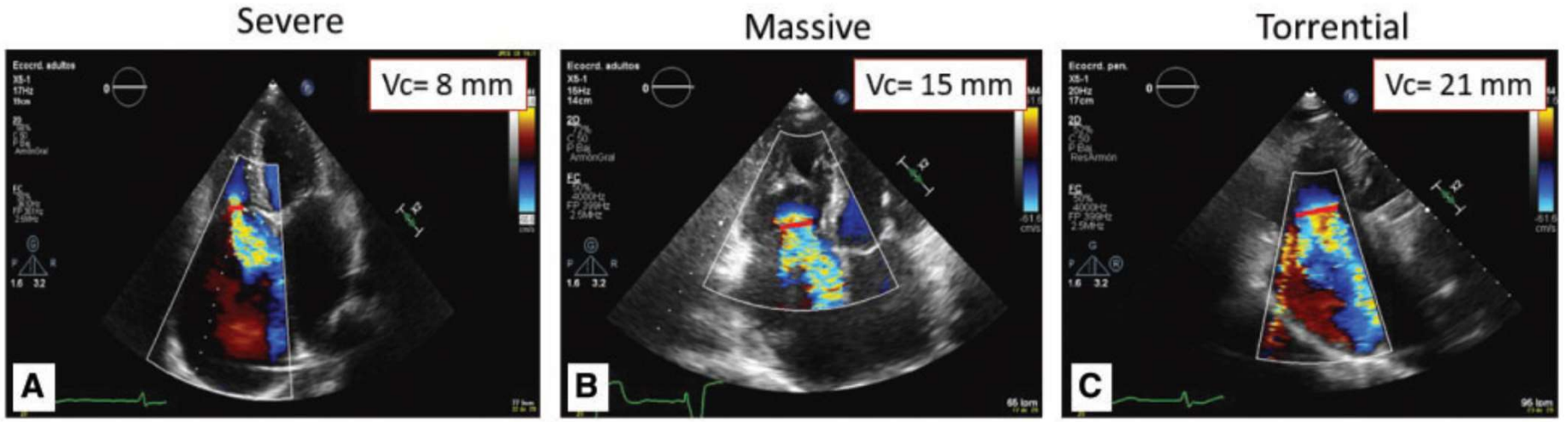
Bernard, Samuel, and Judy Hung. heartjnl-2019

Proposed expansion of the “severe” TR grade

Table I Proposed expansion of the ‘Severe’ grade

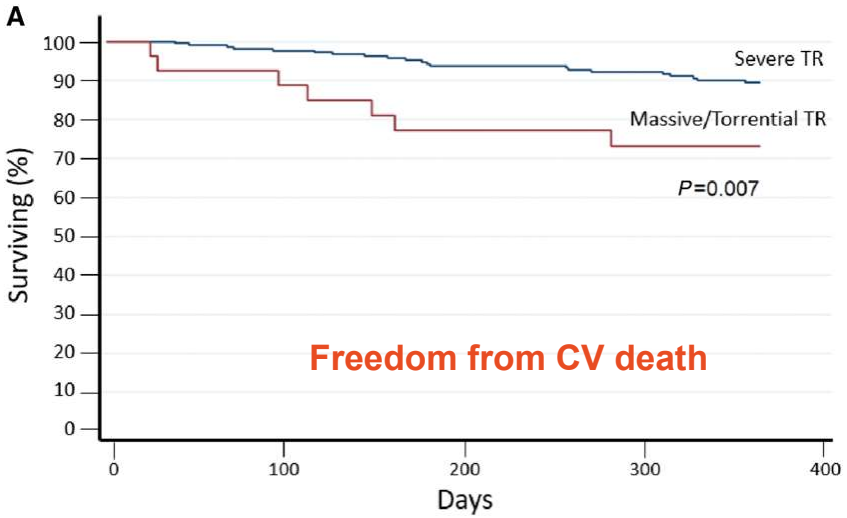
Variable	Mild	Moderate	Severe	Massive	Torrential
VC (biplane)	<3 mm	3-6.9 mm	7–13 mm	14–20 mm	≥21 mm
EROA (PISA)	<20 mm^2	20–39 mm^2	40–59 mm^2	60–79 mm^2	≥80 mm^2
3D VCA or quantitative EROA[a]			75–94 mm^2	95–114 mm^2	≥115 mm^2

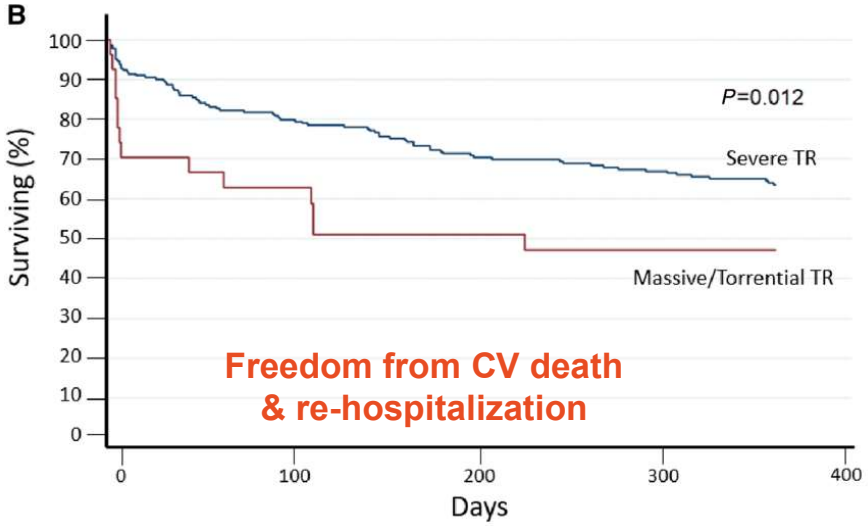
VC, vena contracta; EROA, effective regurgitant orifice area; 3D VCA, three-dimensional vena contracta area.
[a]3D VCA and quantitative Doppler EROA cut-offs may be larger than PISA EROA.



Hahn, R. et al European Heart Journal - Cardiovascular Imaging (2017) 18, 1342–1343; Santoro, C. et al, European Heart Journal - Cardiovascular Imaging (2019) 0, 1–8

Mid-term impact for Severe, Massive and Torrential TR





Patients with massive/torrential TR and patients with comorbidities, especially pulmonary disease, were identified as populations at higher risk of death and readmission for HF compared to patients with severe TR.

Santoro, C. et al, European Heart Journal - Cardiovascular Imaging (2019) 0, 1–8

Tricuspid regurgitation: recent advances in understanding pathophysiology, severity grading and outcome

Rebecca T. Hahn [1]*, Luigi P. Badano[2,3], Philipp E. Bartko[4], Denisa Muraru [2,3], Francesco Maisano[5], Jose L. Zamorano[6] and Erwan Donal [7]

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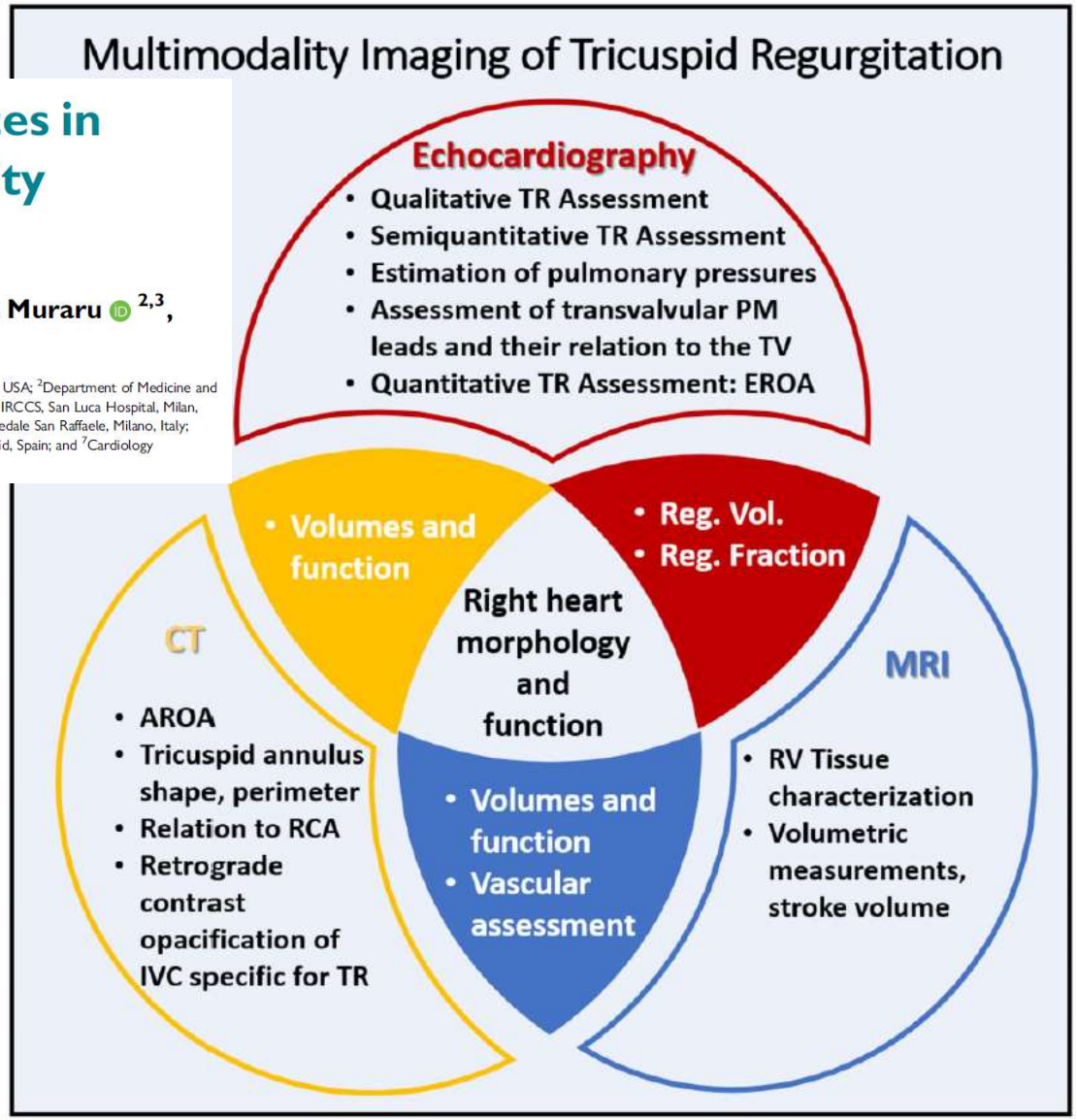
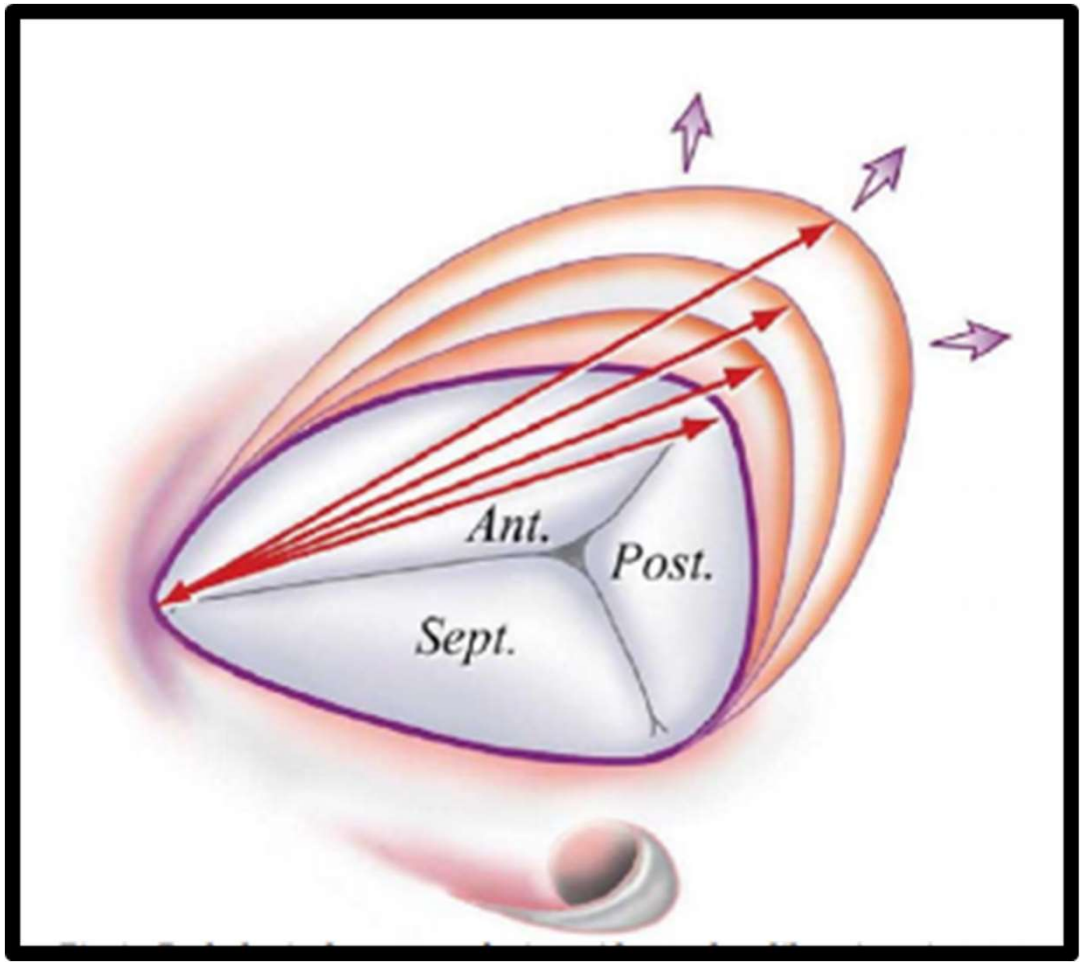


Tricuspid annular dilatation may be a more reliable indicator of tricuspid valve pathology compared with TR…



Dreyfus, Gilles D., et al. 2005

Functional TR and Left Heart Surgery

Diagnosis and Treatment

Stage 1	Stage 2	Stage 3
None or Mild	**Mild or moderate**	**Severe or Torrential**
Annular diameter: **<40mm**	Annular diameter: **>40mm**	Annular diameter: **>40mm**
Coaptation mode: Normal (body-to-body), with no leaflet tethering	Coaptation mode: Abnormal (edge-to-edge), with or without tethering of <8 mm below the annular plane	Coaptation mode: No coaptation, with or without tethering of >8 mm below the annular plane

Dreyfus G et al. Functional Tricuspid Regurgitation. J Am Coll Cardiol 2015;65:2331–6

Functional TR and Left Heart Surgery

Diagnosis and Treatment

Stage 1	Stage 2	Stage 3
None or Mild	**Mild or moderate**	**Severe or Torrential**
Annular diameter: **<40mm**	Annular diameter: **>40mm**	Annular diameter: **>40mm**
Coaptation mode: Normal (body-to-body), with no leaflet tethering	Coaptation mode: Abnormal (edge-to-edge), with or without tethering of <8 mm below the annular plane	Coaptation mode: No coaptation, with or without tethering of >8 mm below the annular plane
OMT NO Surgery	**Concomitant tricuspid annuloplasty is recommended**	**Concomitant tricuspid valve annuloplasty and leaftet augmentation (if tethering is present), Replacement**

Dreyfus G et al. Functional Tricuspid Regurgitation. J Am Coll Cardiol 2015;65:2331–6

Secondary Tricuspid Regurgitation or Dilatation: Which Should Be the Criteria for Surgical Repair?

Gilles D. Dreyfus, MD, Pierre J. Corbi, MD, K. M. John Chan, AFRCS, and Toufan Bahrami, MD

Department of Cardiothoracic Surgery, Royal Brompton and Harefield NHS Trust, Harefield Hospital, Harefield, Middlesex, United Kingdom

Treatment of the MV alone does not correct Tricuspid Dilatation nor does it affect preload or RV function…

Once the annulus is dilated, its size cannot spontaneously return to normal…not just “go away” after MVr… and may continue to dilate

	Before Surgery		After Surgery	
	Group 1 (MVR)	Group 2 (MVR + TVR)	Group 1 (MVR)	Group 2 (MVR + TVR)
Grade 0	54	38	8	102
Grade 1	102	92	33	41
Grade 2	7	16	67	4
Grade 3	0	2	40	1
Grade 4	0	0	15	0
Mean TR grade	0.7 ± 0.5[a]	0.9 ± 0.6[a]	2.1 ± 1.0[b]	0.4 ± 0.6[b]

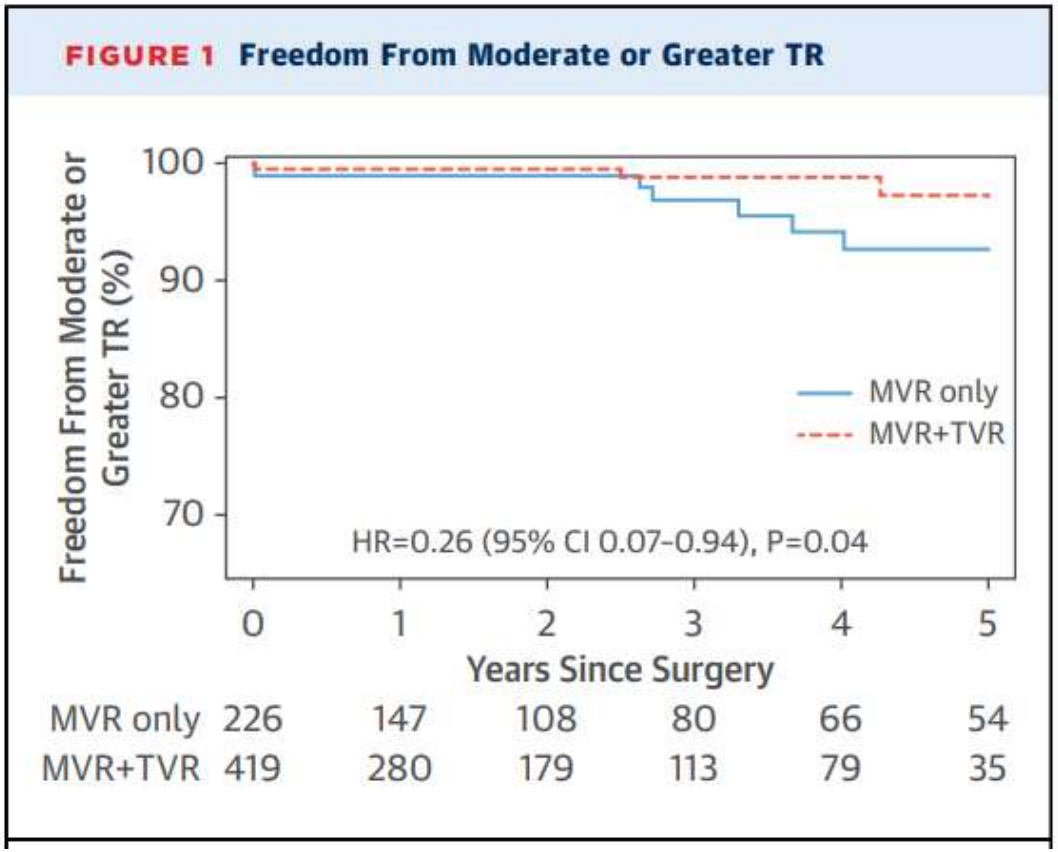
[a] $p = 0.027$ Mann–Whitney. [b] $p < 0.001$ Mann–Whitney.

MVR = mitral valve repair; TR = tricuspid regurgitation; TVR = tricuspid valve repair.

The mean TR grade increased in group 1 and decreased in group 2

Dreyfus, Gilles D., et al. The Annals of thoracic surgery 2005: 127-132.

Long-term Improvement of Freedom from moderate TR



Chikwe, Joanna, et al. " Journal of the American College of Cardiology 65.18 (2015): 1931-1938.

Recovery of RV function

FIGURE 4 Longitudinal Change in the Proportion of Patients With RV Dysfunction

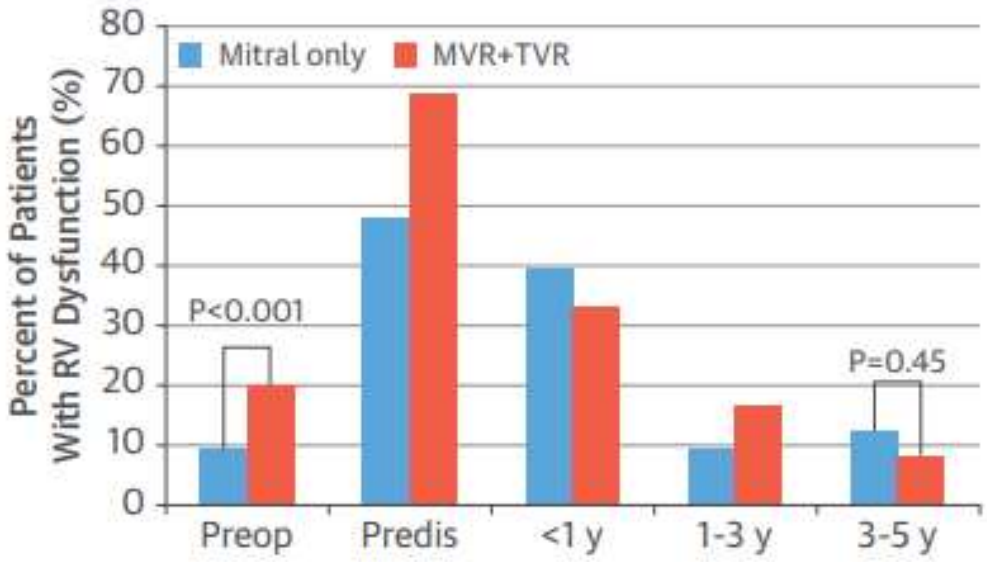
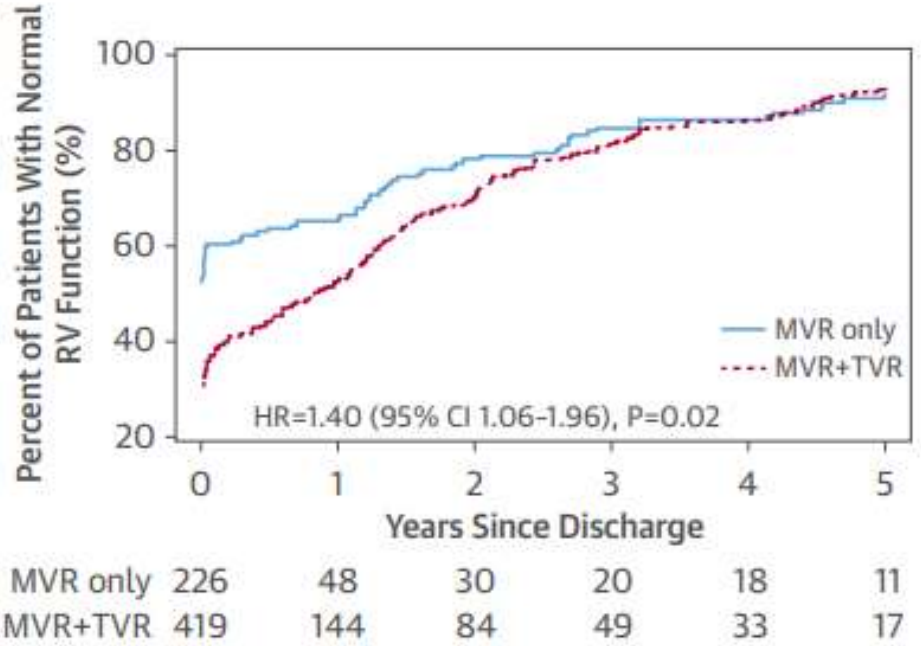
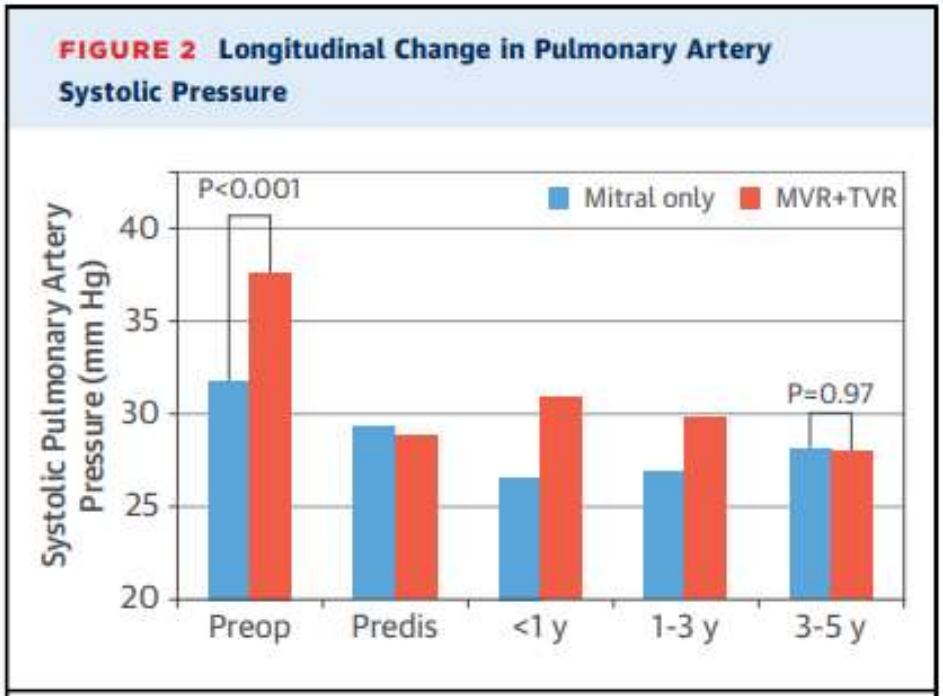


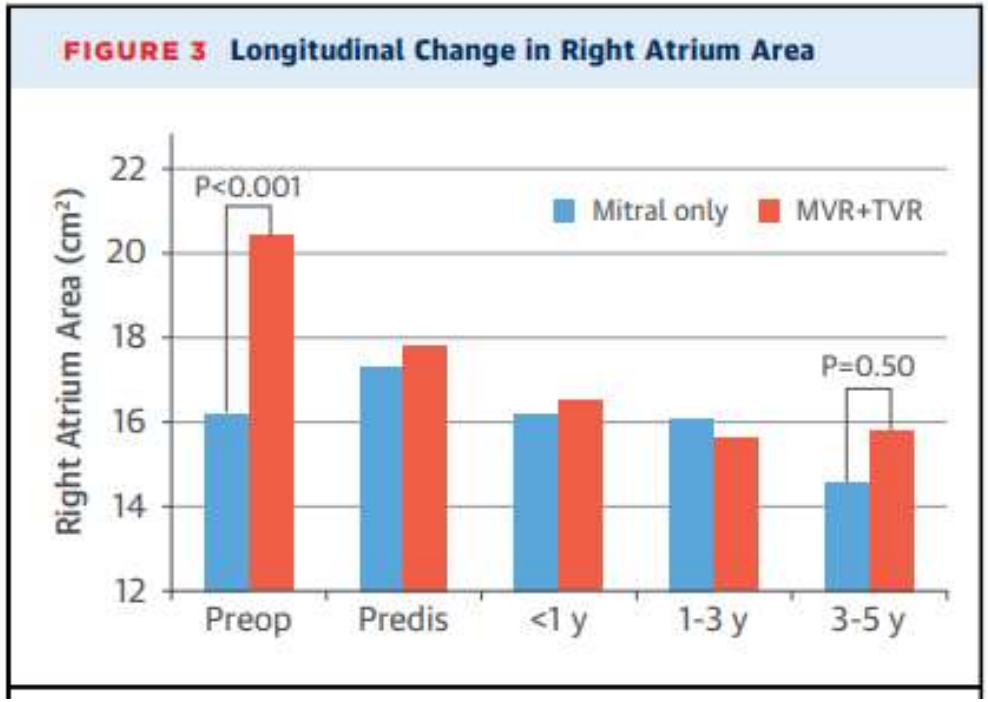
FIGURE 5 Recovery of RV Function



Chikwe, Joanna, et al. Journal of the American College of Cardiology 65.18 (2015): 1931-1938.

Other benefits…





Chikwe, Joanna, et al. "Impact of concomitant tricuspid annuloplasty on tricuspid regurgitation, right ventricular function, and pulmonary artery hypertension after repair of mitral valve prolapse." Journal of the American College of Cardiology 65.18 (2015): 1931-1938.

Treatment of moderate TR or tricuspid annular dilation at the time of MV repair

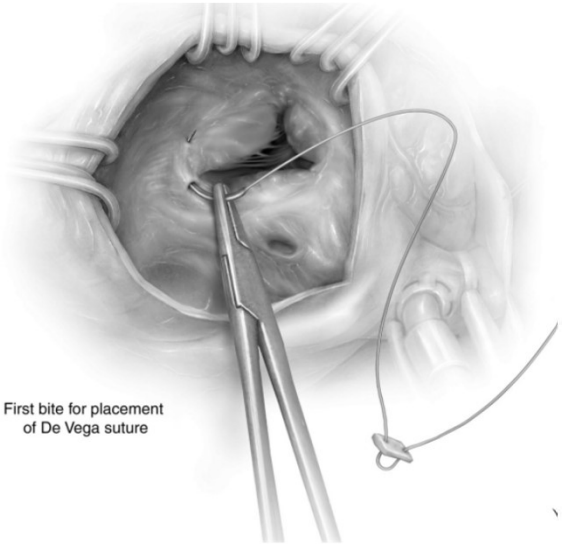
- ✓ Safe
- ✓ Effective
- ✓ Improve long-term right-sided remodeling

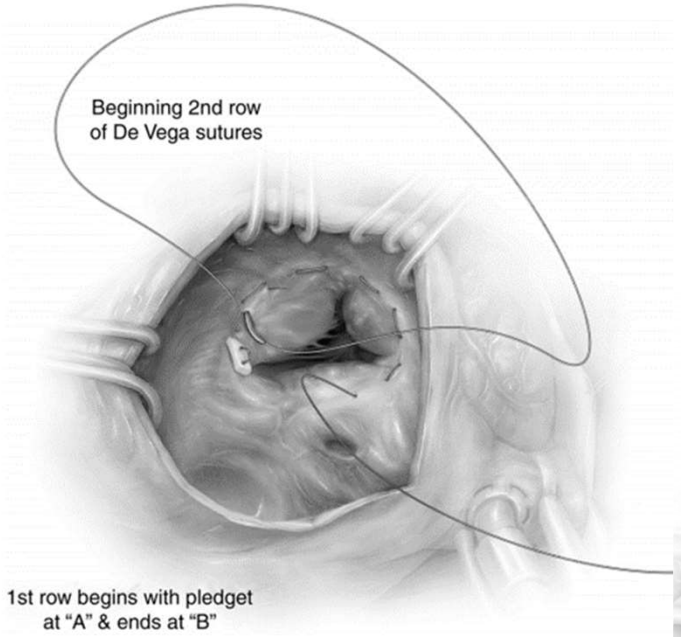
Chikwe, Joanna, et al. Journal of the American College of Cardiology 65.18 (2015): 1931-1938.

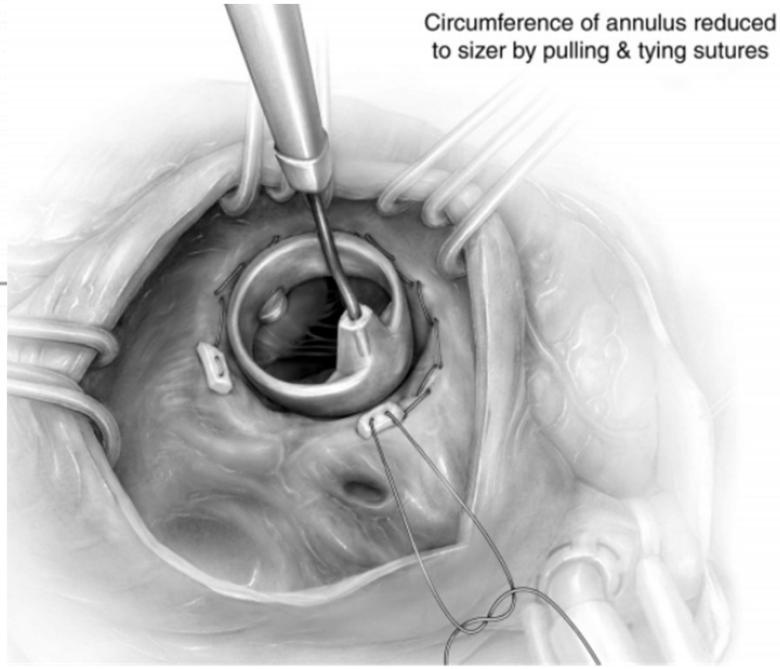
SURGICAL THERAPY

- Since 1960's several annuloplasty methods have been described including suture, band and rings.
- TV Repair with annuloplasty is the first-choice treatment for functional TR in patients with suitable anatomy, preserved RV function and acceptable surgical risk.
- TV repair is associated with lower perioperative mortality as compared to valve replacement in patients with functional TR.

De Vega Annuloplasty

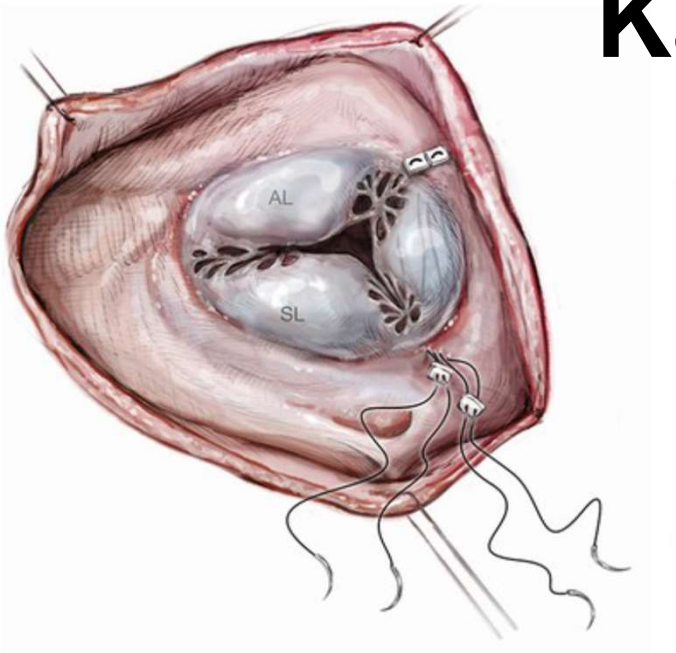


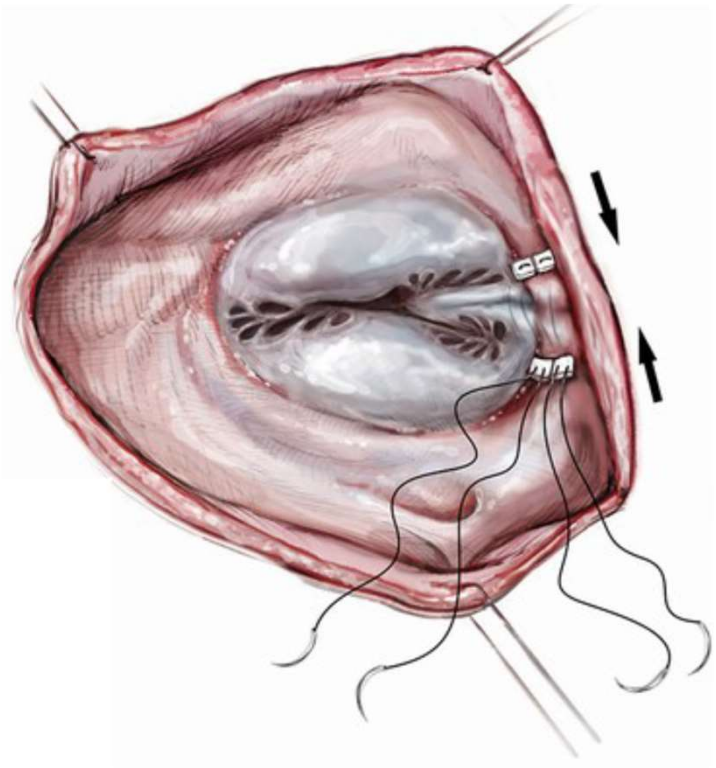


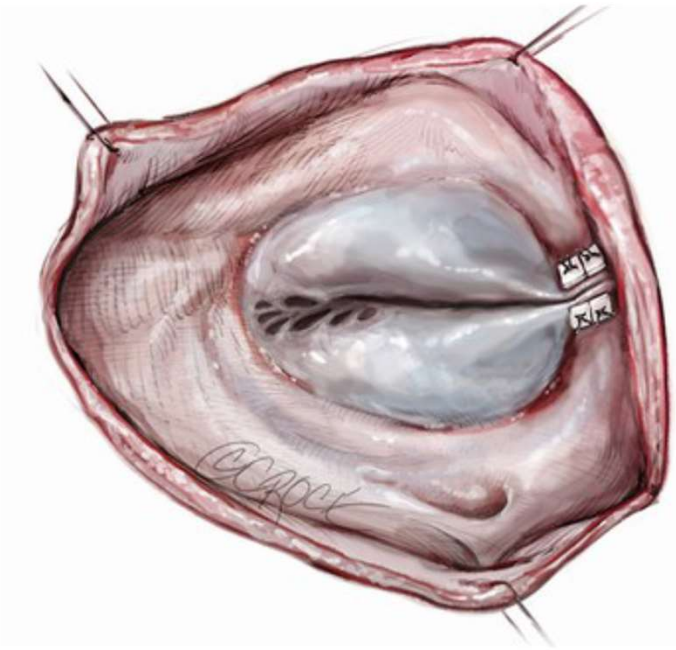


Calafiore, Antonio Maria, and Michele Di Mauro. "Tricuspid Valve Repair—Indications and Techniques: Suture Annuloplasty and Band Annuloplasty." Operative Techniques in Thoracic and Cardiovascular Surgery 16.2 (2011): 86-96.

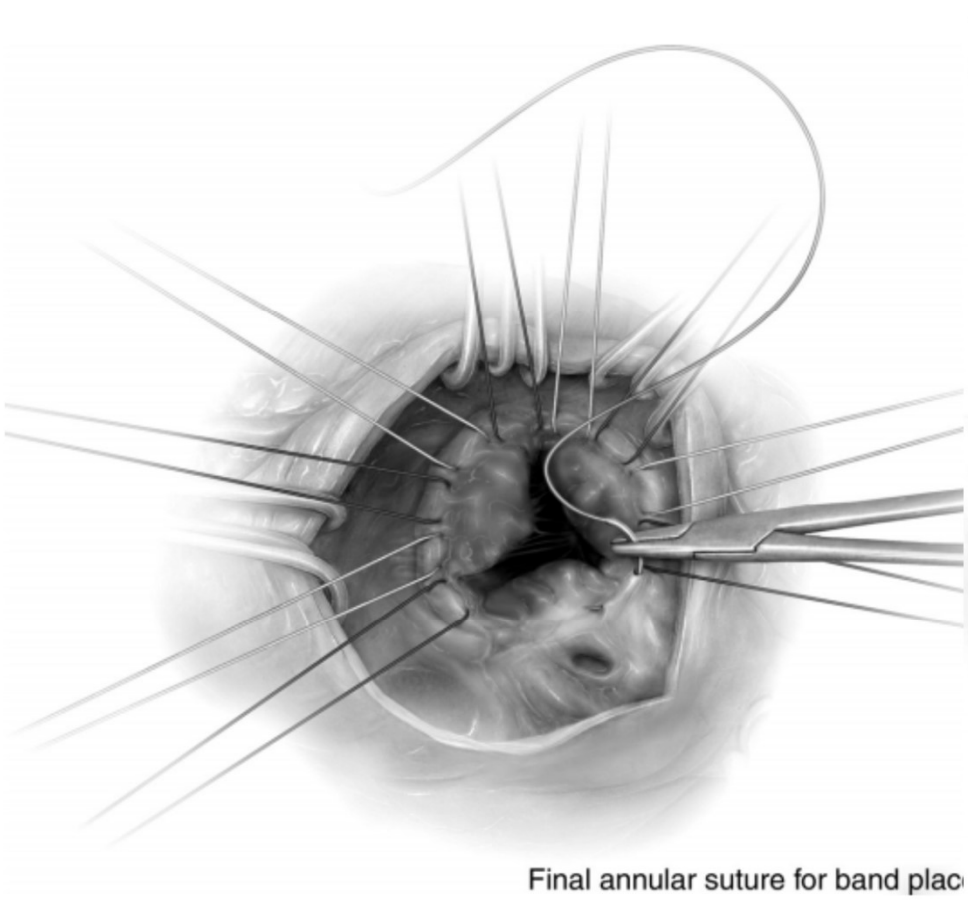
Kay Annuloplasty



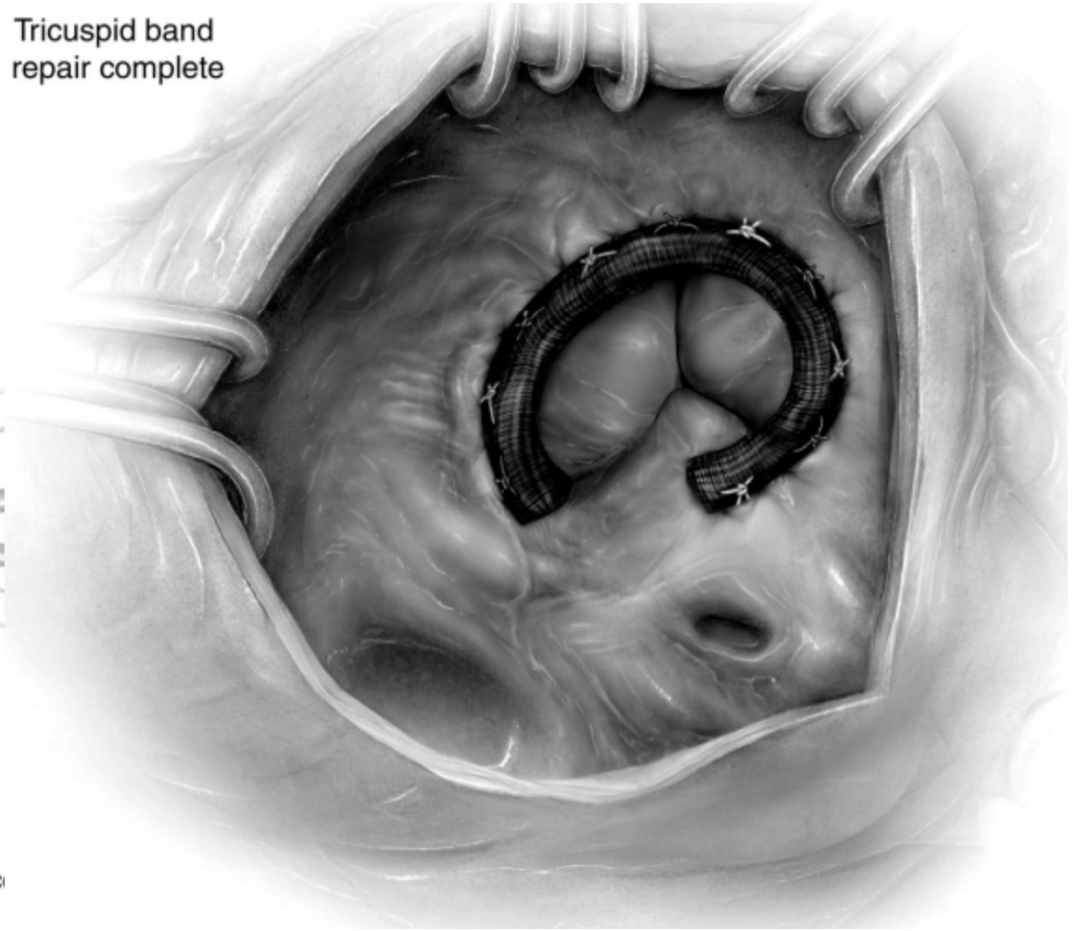




TV Annuloplasty



Final annular suture for band plac



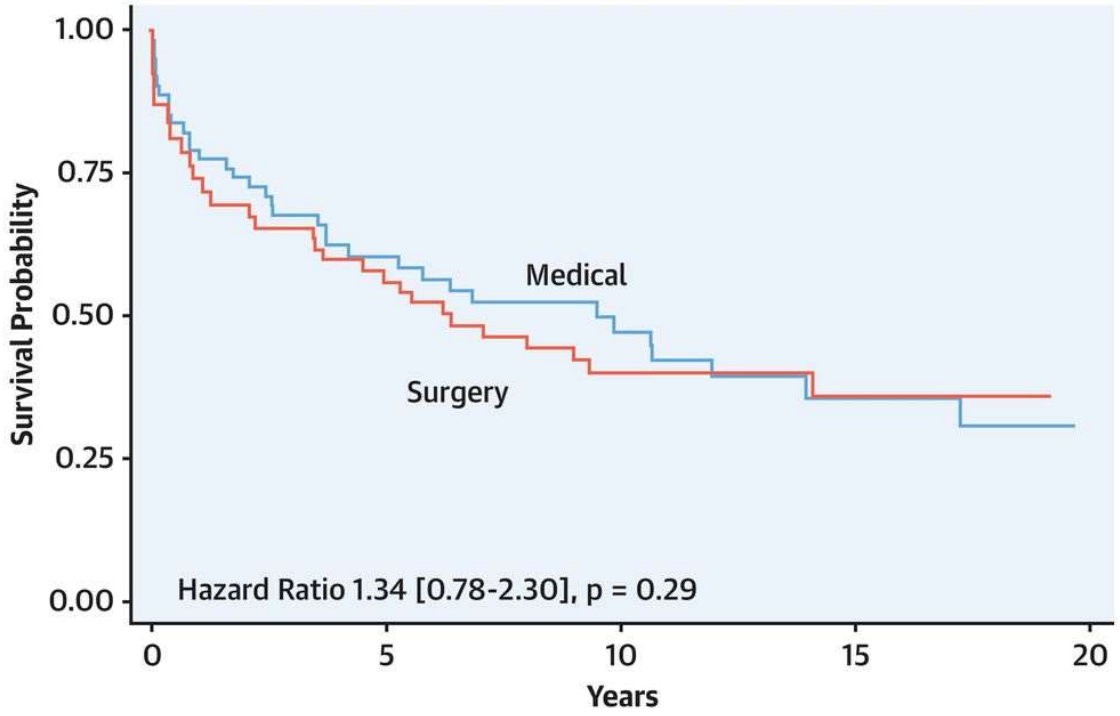
Tricuspid band
repair complete

TV Replacement…rare to be used

Replacement should be considered when valve repair is technically not feasible or predictably not durable because of presence of severe RV dilatation with significant leaflet tethering and papillary muscle dislocation

Surgical vs Medical for Isolated TR

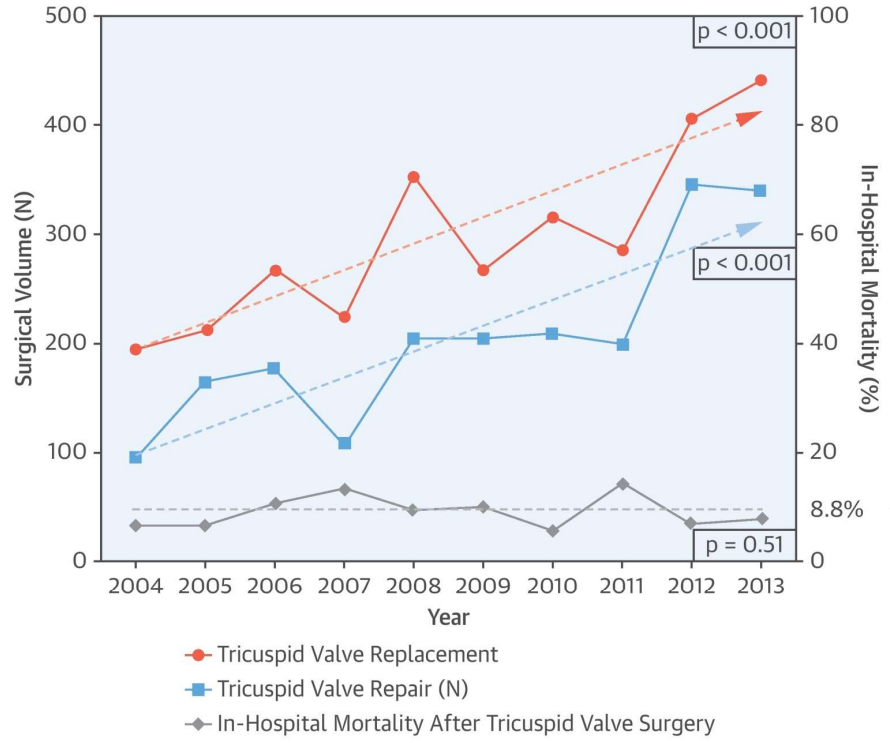
CENTRAL ILLUSTRATION: Surgery Versus Medical Therapy for Severe Tricuspid Regurgitation



Axtell, A.L. et al. J Am Coll Cardiol. 2019;74(6):715-25.

In-Hospital Mortality after TV surgery

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.

In-hospital mortality for isolated TR was 8.8%, being stable over the past 10 years

Patients arrive… LATE … TOO LATE!

- ✓ Volume overload is well-tolerated for years
- ✓ No reduction in RV function
- ✓ Few symptoms

Poor outcomes are due to the late referral of patients, which is linked to comorbidities such as coagulopathy, hepatic failure, kidney impairment and end-stage chronic HF

Right ventricular function in patients with significant tricuspid regurgitation

Doctor Bombace S, Doctor Viggiani G, Doctor Meucci MC, Professor Esposito G, Professor Condorelli G, Doctor Von Roeder M, Professor Lurz P, Doctor Grayburn PA, Professor Sannino A

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Policlinico Agostino Gemelli, Roma, Italy
Università Federico II , Napoli, Italy
Clinical Institute Humanitas IRCCS, Rozzano, Italy
Baylor Scott & White Health, Dallas, United States of America

Funding Acknowledgements: Type of funding sources: None.

Aim: The aim of this meta-analysis was to systematically investigate the prognostic value of right ventricular (RV) function in all-comers patients with significant (at least moderate, ≥ 2+) tricuspid regurgitation (TR).

Background: Chronic significant TR imposes a volume overload to the RV leading to a progressive RV dilatation and dysfunction. A comprehensive assessment of RV function is of paramount importance to guide the therapeutic management of these patients; however, it remains challenging, particularly in presence of altered loading conditions.

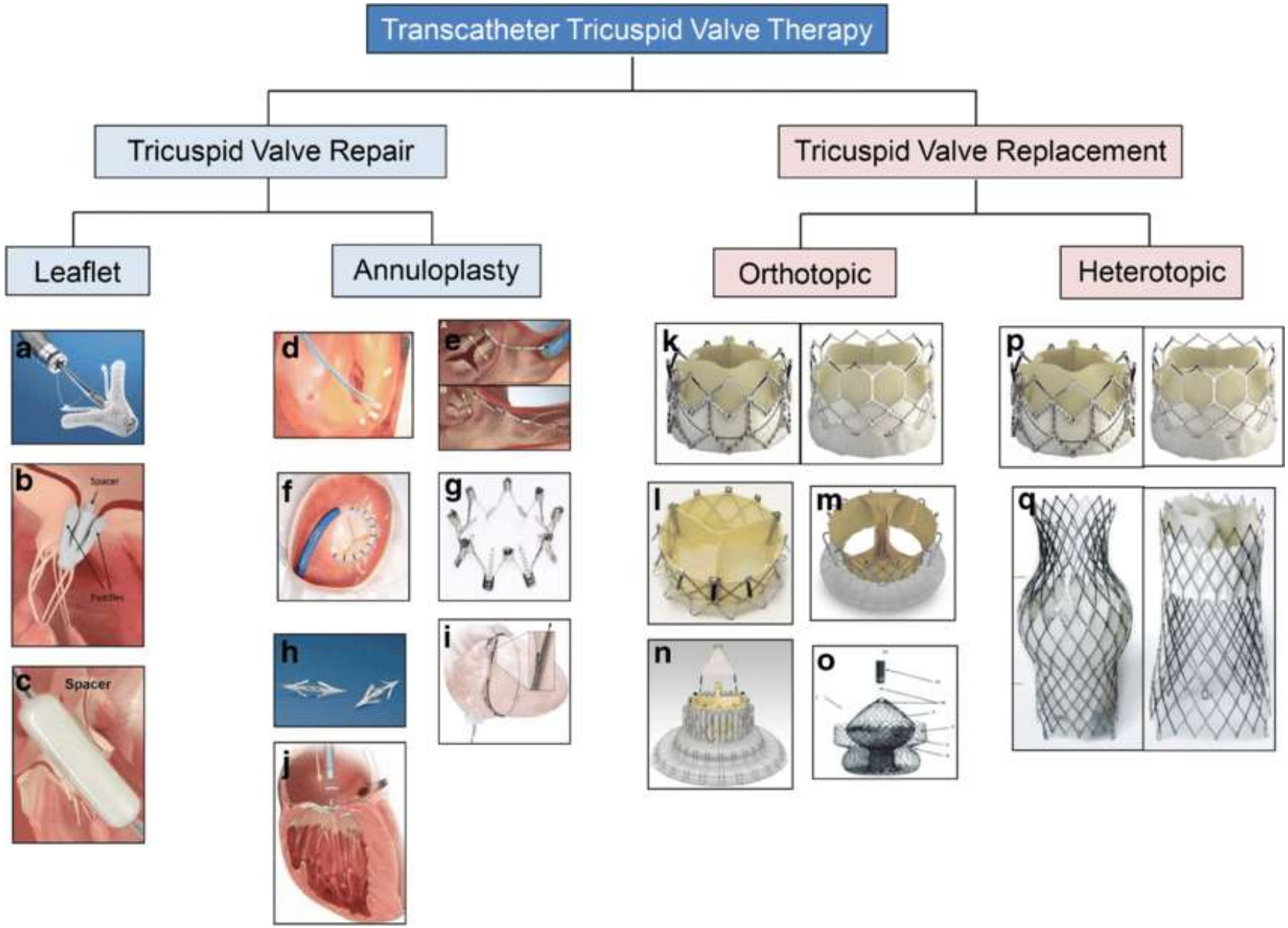
Methods: MEDLINE, ISI Web of Science, and SCOPUS databases were searched for studies published up to July 2022. Studies reporting data on at least one echocardiographic RV function parameter and outcome in patients with significant TR were included. This study was designed according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) requirements. The primary endpoint was all-cause long-term mortality (more than one year).

Results: Out of 3,152 studies, a total of 10 were included in the analytic synthesis, enrolling 3435 subjects. The median follow-up in our study population was 28 [22 – 70] months. All-cause long-term mortality was 40% (95% confidence interval [CI]: 32–49%, p = 0.028; Figure 1). To explore the potential impact of effect size modifiers on all-cause long-term mortality, we performed a meta-regression analysis of the baseline characteristics of the included studies. At long-term, a significant relation was found between RV fractional area change (RV-FAC), tricuspid annular plane systolic excursion (TAPSE), tricuspid annular tissue doppler imaging systolic velocity (TDI s') and mortality. In particular, RV-FAC was associated with reduced incidence of all-cause mortality [7 studies enrolling 2,611 subjects, intercept 5.18, slope –0.15, P = 0.007; Figure 2]; whereas both TAPSE and TDI s' were unsatisfactory to predict the outcome in these patients [TAPSE 9 studies enrolling 2,891 subjects, intercept 1.73, slope –0.12, P = 0.36; TDI s' 5 studies enrolling 1429 subjects, intercept –2.06, slope 0.15, P = 0.78]. Interestingly, diabetes mellitus (DM) and hyperlipidaemia were associated with an increased risk of mortality [DM 9 studies enrolling 3371 subjects, intercept –2.62, slope 0.09, P = 0.004; hyperlipidaemia 6 studies enrolling 2338 subjects, intercept –2.91, slope 0.05, P = 0.01].

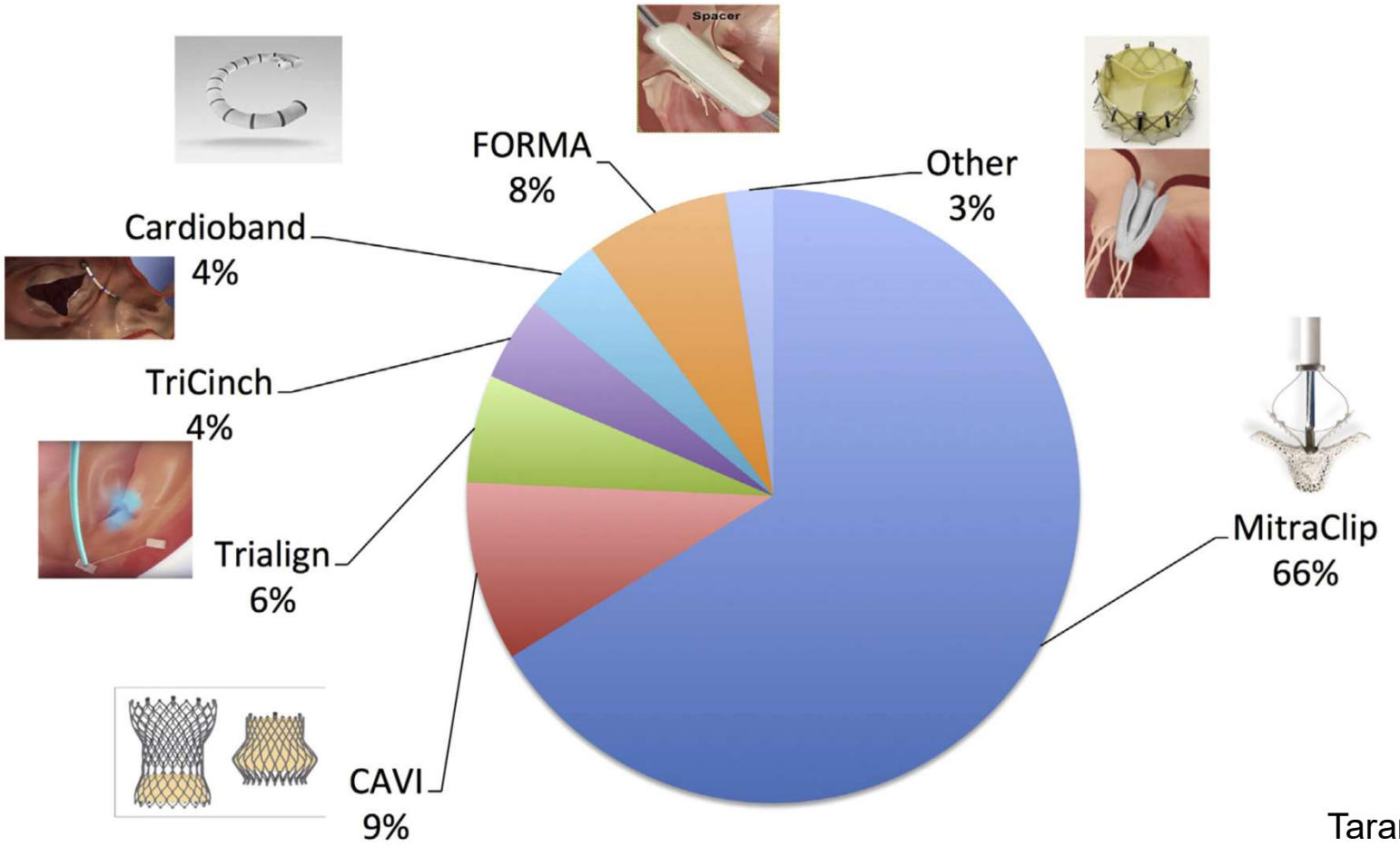
Conclusions: Significant TR is associated with increased risk of all-cause. To our knowledge, this is the first study to demonstrate that only RV-FAC, and not conventional echocardiographic indexes of RV longitudinal function, correlates with adverse outcomes in patients with significant TR.

Given the overall increase in life expectancy and expanding transcatheter intervention for MV disease in patients at increased surgical risk,

the number of patients presenting with relevant TR will increase in the coming decades

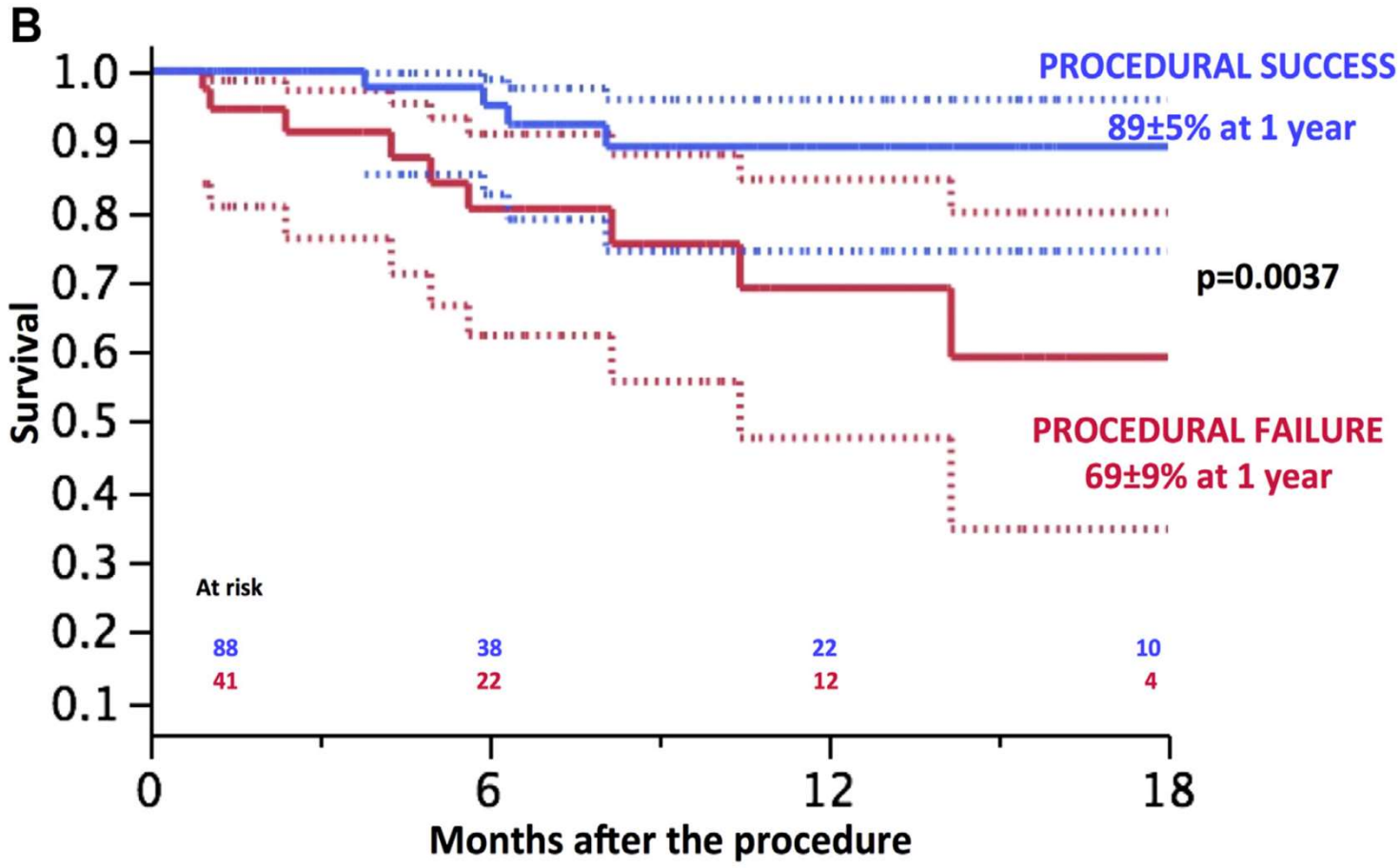

Transcatheter Tricuspid Valve Therapy
Tricuspid Valve Repair
Tricuspid Valve Replacement
Leaflet
Annuloplasty
Orthotopic
Heterotopic
a
b
Spacer
c
Spacer
d
e
f
g
h
i
j
k
l
m
n
o
p
q

TriValve International Registry for Isolated TR



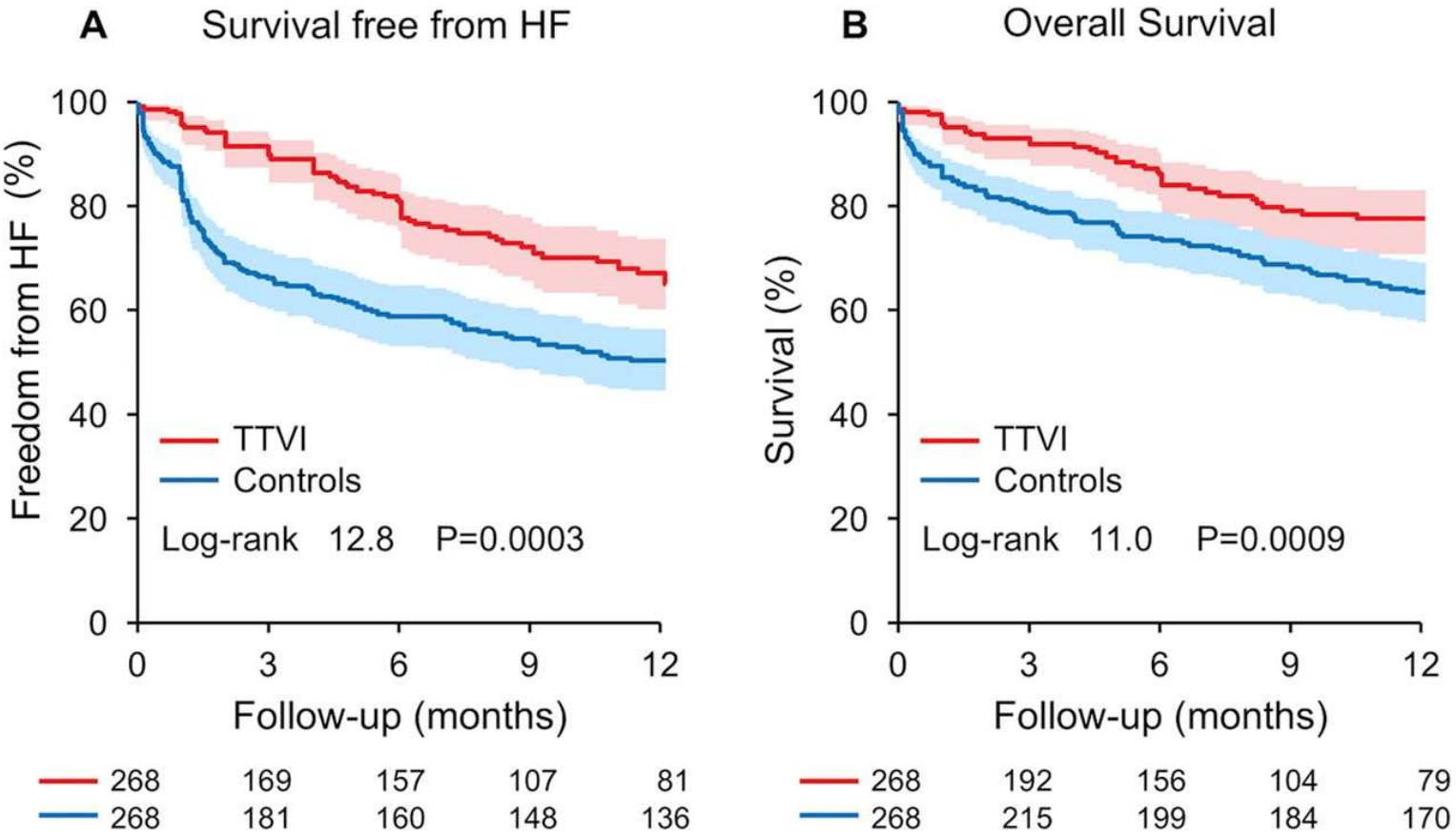
Taramasso 2019

Actuarial Survival after TTVI



Taramasso et al, *Journal of the American College of Cardiology 2019*

TTVI vs Medical Therapy



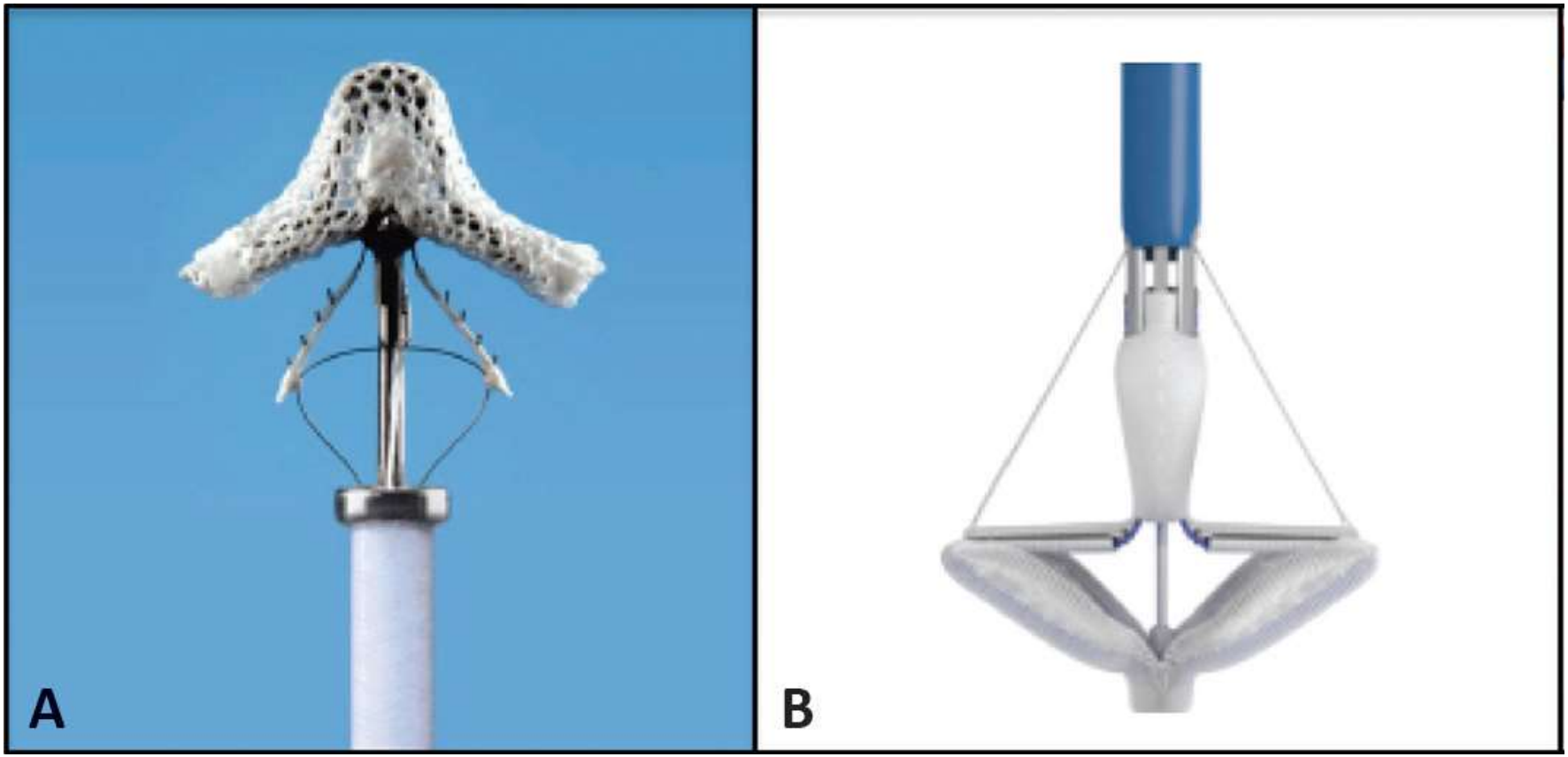
Taramasso et al, *Journal of the American College of Cardiology 2019*

Transcatheter solutions

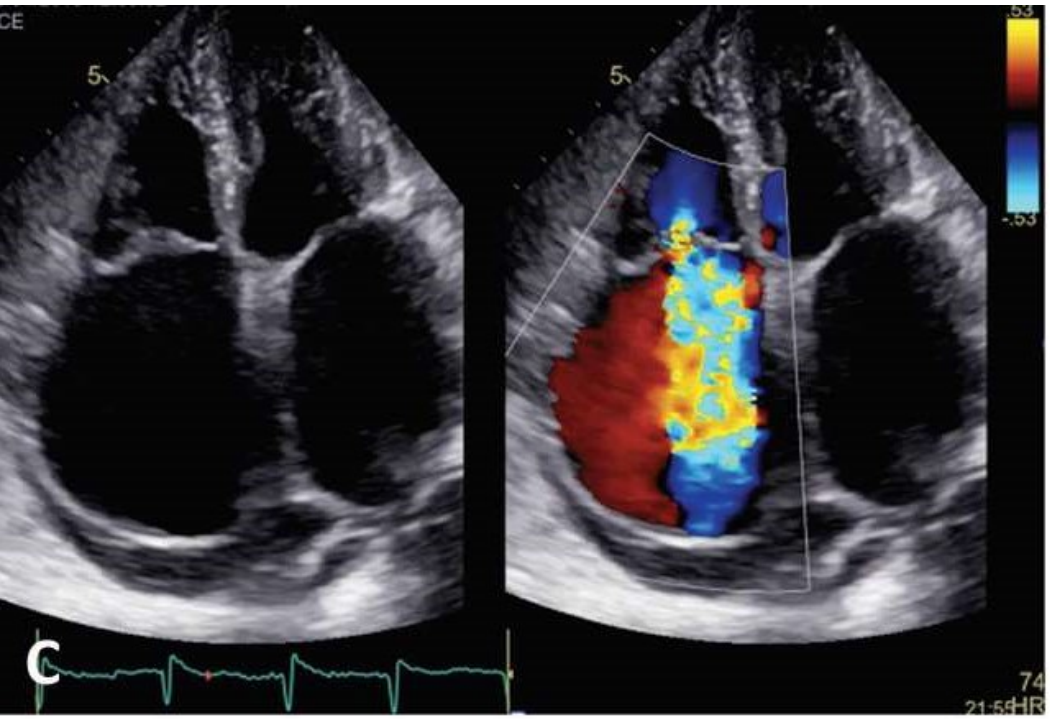
- ✓ Steerability of the catheters
- ✓ Retrievable/repositionable devices
- ✓ Transfemoral approach

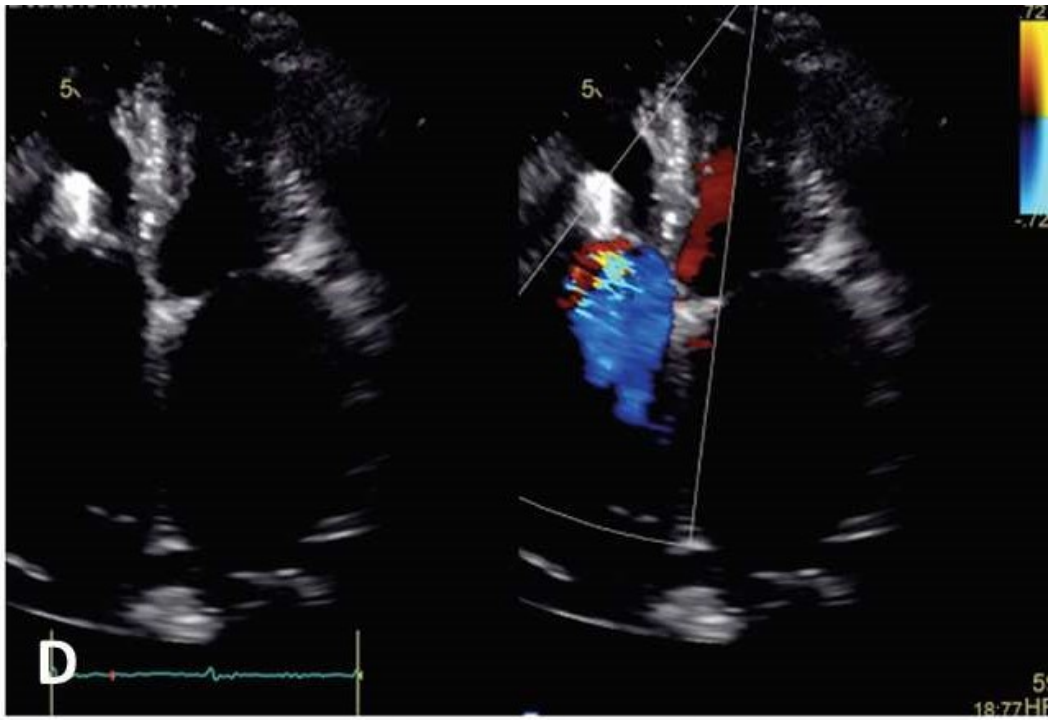
LEAFLET DEVICES

MitraClip System **PASCAL System**



MitraClip…TriClip





Feature	Ideal pathoanatomy for optimal tricuspid TEER outcomes	Challenging pathoanatomy for optimal tricuspid TEER outcomes	Relative pathoanatomic contraindications for tricuspid TEER
Leaflet length and mobility	Good leaflet lengths (≥7 mm) and primary TR with prolapse only (no flail), or secondary TR with normal appearing leaflet mobility	Primary TR with leaflet prolapse or flail gap <10 mm, or secondary TR with reduced leaflet mobility but tethering height <9 mm,	Severe leaflet thickening (i.e. rheumatic) or shortening (length <7 mm) or destruction (i.e. perforation) or large flail gap (≥10 mm), severe leaflet tethering (tethering height ≥9 mm)
Coaptation gap[a]	Significant TR with small coaptation gap (<3–7 mm)	Moderate coaptation gap (>7 to <8.5 mm)	Large coaptation gap (≥8.5 mm)
TR location and severity	Central TR jet within the anteroseptal commissure with clear grasping zones	Central TR jet extending into multiple commissures (i.e. in patients with >3 leaflets) with possible grasping zone	Non-central or very eccentric jets or jets originating from multiple commissures (i.e. in patients with >3 leaflets) with dense chordae (i.e. no clear grasping zone), with massive or torrential disease (i.e. VC width ≥14 mm, EROA by PISA >60–70 mm^2)
Intra-procedural imaging	Good TEE windows[b] for leaflet visualization	Sufficient echocardiographic windows[b] for leaflet visualization or availability of alternative imaging (i.e. intra-cardiac echocardiography)	Insufficient echocardiographic windows† for leaflet visualizations
Presence of CIED	No CIED	Presence of CIED lead, no significant leaflet interaction and no interaction with clip	CIED-induced TR
Right ventricular remodelling[c]	Normal to mildly reduced RV function, normal to mild RV dilatation	Moderately or severely reduced RV function and/or moderate or severe RV dilatation, attributable to volume overload[d]	Severely reduced RV function or severe RV dilatation not primarily attributable to TR[d]
Pulmonary vascular haemodynamics	Normal peak and mean PAP, transpulmonary gradient and normal TAPSE/PASP (>0.41)	PASP ≤60–65 mmHg, pulmonary capillary resistance ≤4 WU, mean PAP ≤30 mmHg, transpulmonary gradient ≤17 mmHg	PASP >60–65 mmHg and/or pulmonary capillary resistance >4 WU, and/or mean PAP >30 mmHg and transpulmonary gradient >17 mmHg, TAPSE/PASP ≤0.41
Concomitant left heart disease	No significant left heart disease	Moderate left heart ventricular or valvular dysfunction which fail to meet criteria for GDMT or intervention	Severe left ventricular or valvular dysfunction amenable to GDMT or intervention

Transcatheter repair for severe tricuspid regurgitation: are we going in the right direction?

Daniela Pedicino [1]* and Rocco Vergallo [2,3]

- The TRILUMINATE Pivotal is the first RCT in symptomatic patients with at least severe TR; it shows that T-TEER is safe and effective in reducing TR and improving QoL at 1 year

- Despite a significant TR reduction, only a modest decrease in diuretic dosage was recorded over 1 year.

- This might suggest that, in more advanced disease, percutaneous treatment no longer impacts prognosis.

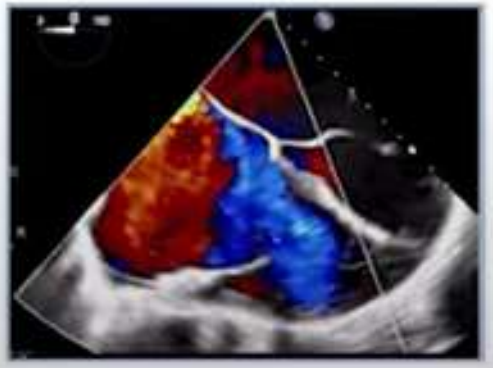
TTVR
Significant Unmet Need

Well-known predictors of TEER procedural failure in TR regurgitation (in functional, high-risk patients)

- Clefts at the leaflets
- Significant leaflet tethering
- Large coaptation gap
- Short coaptation length
- Massive or torrential TR
- Risk for recurrence of a significant TR
- Problematic with future treatment options

Large coaptation gap

Massive TR

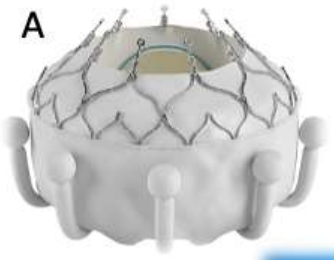


TTVR

Orthotopic valves

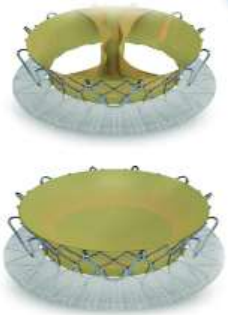
Heterotopic valves

A

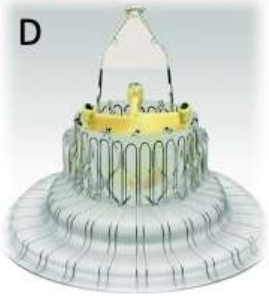


B

C

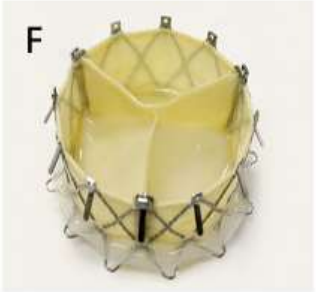


D

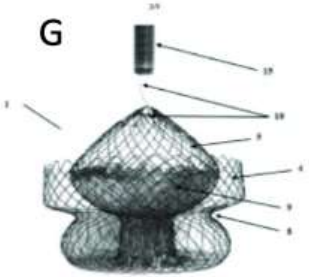


E

F

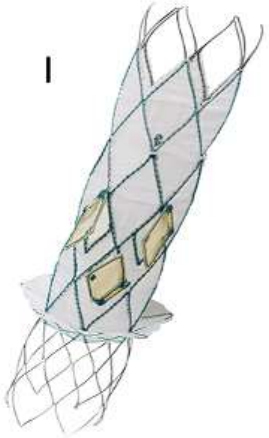


G



H

I

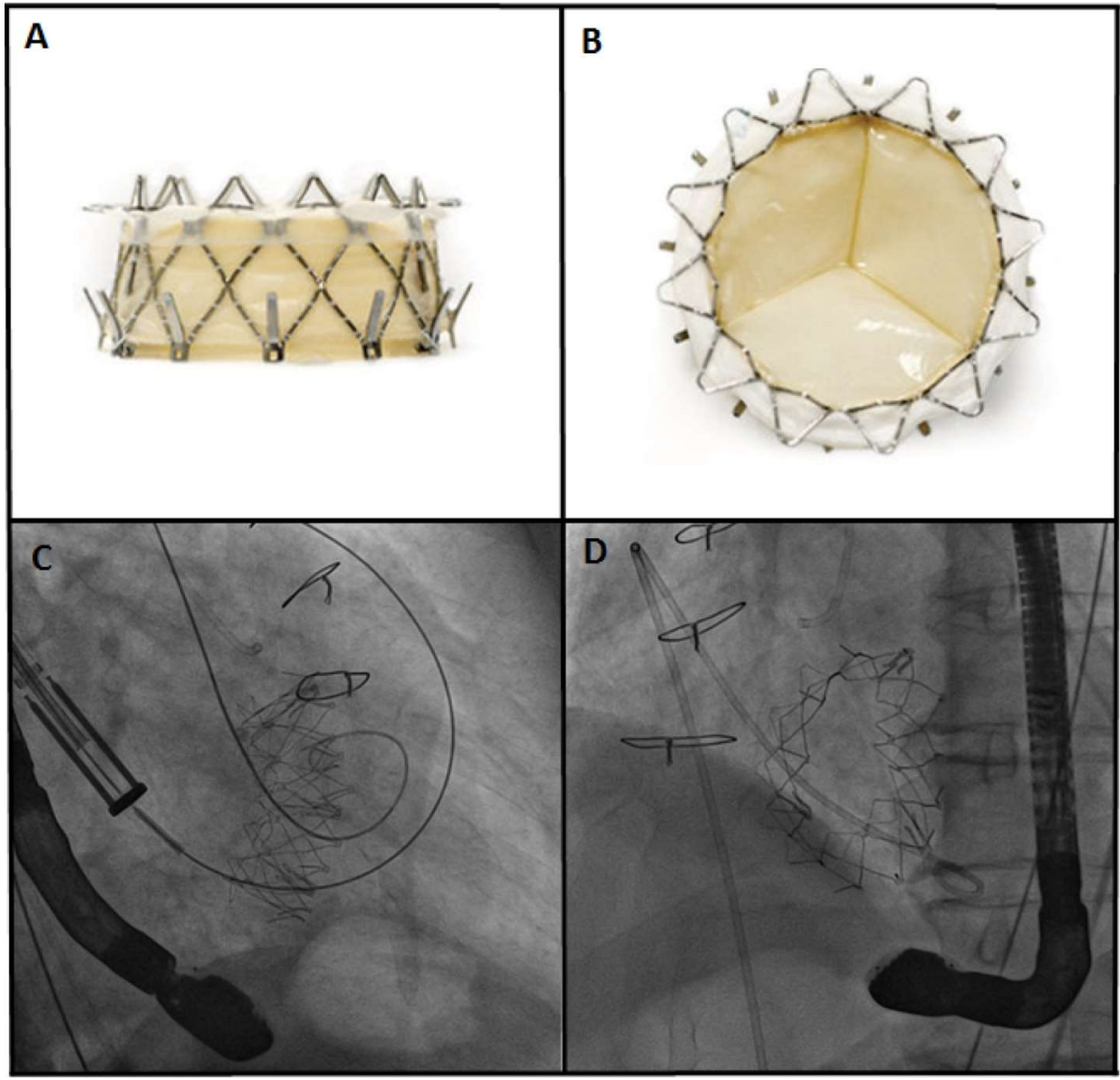


J

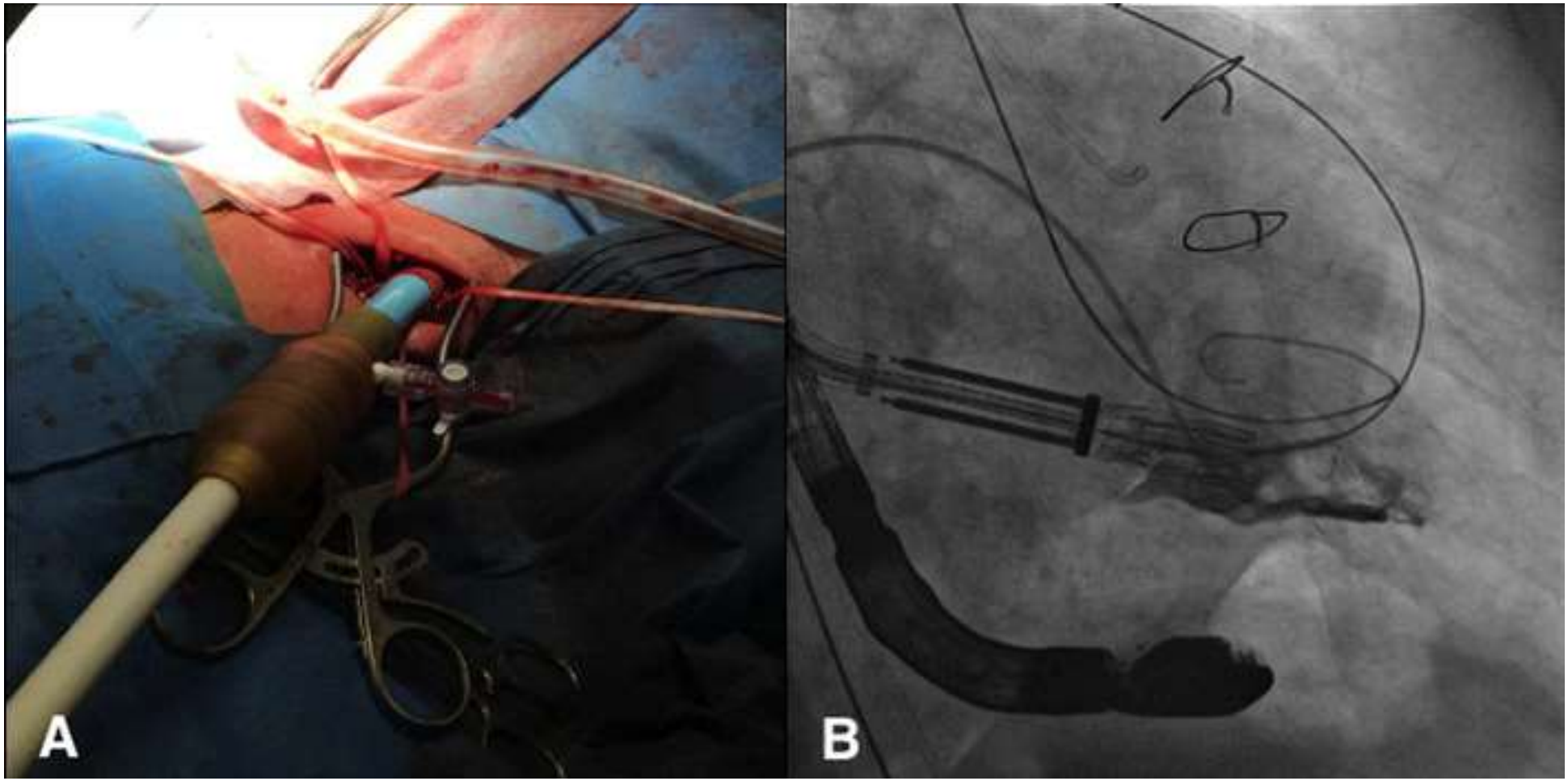
K

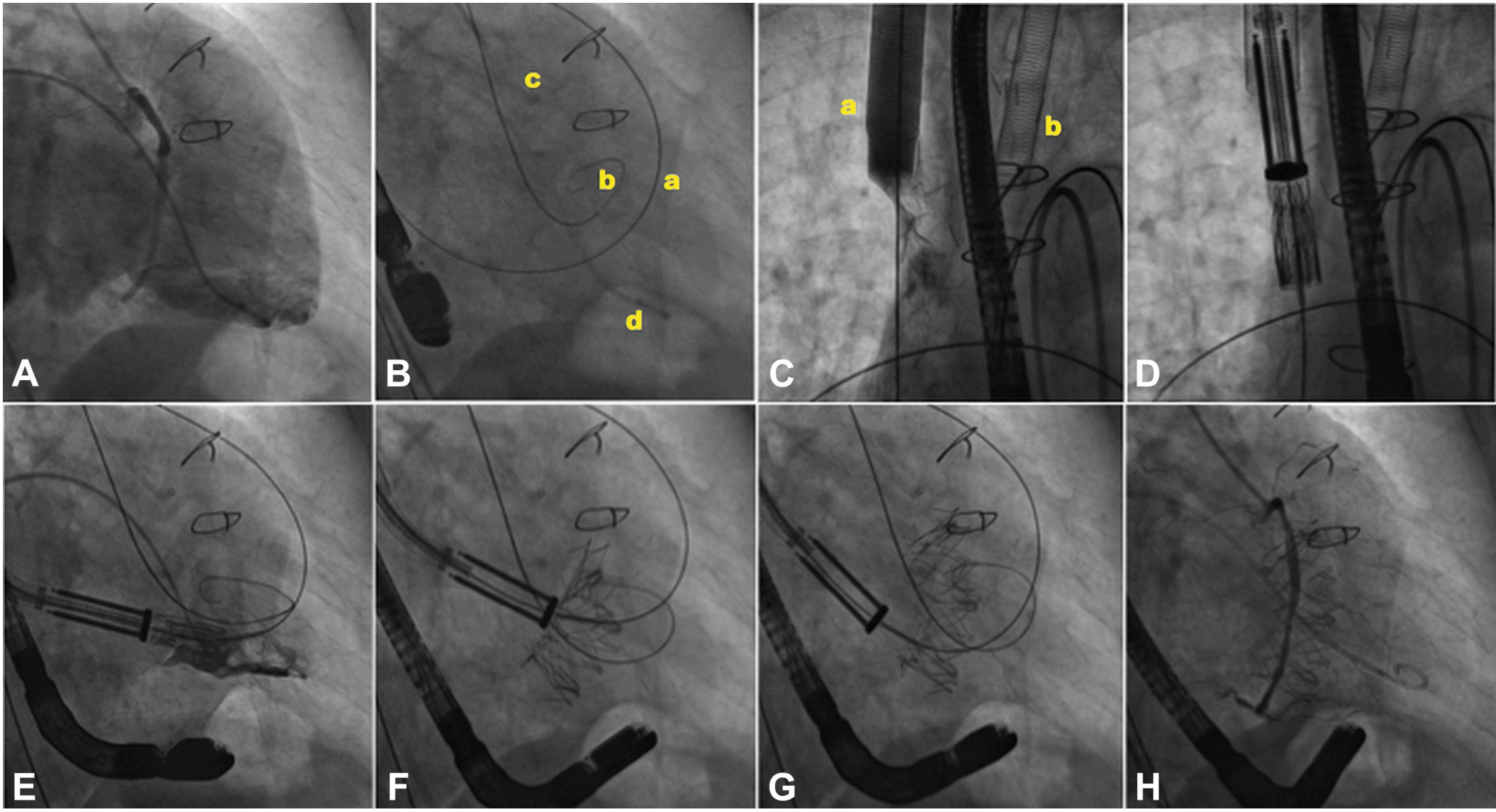
NaviGate

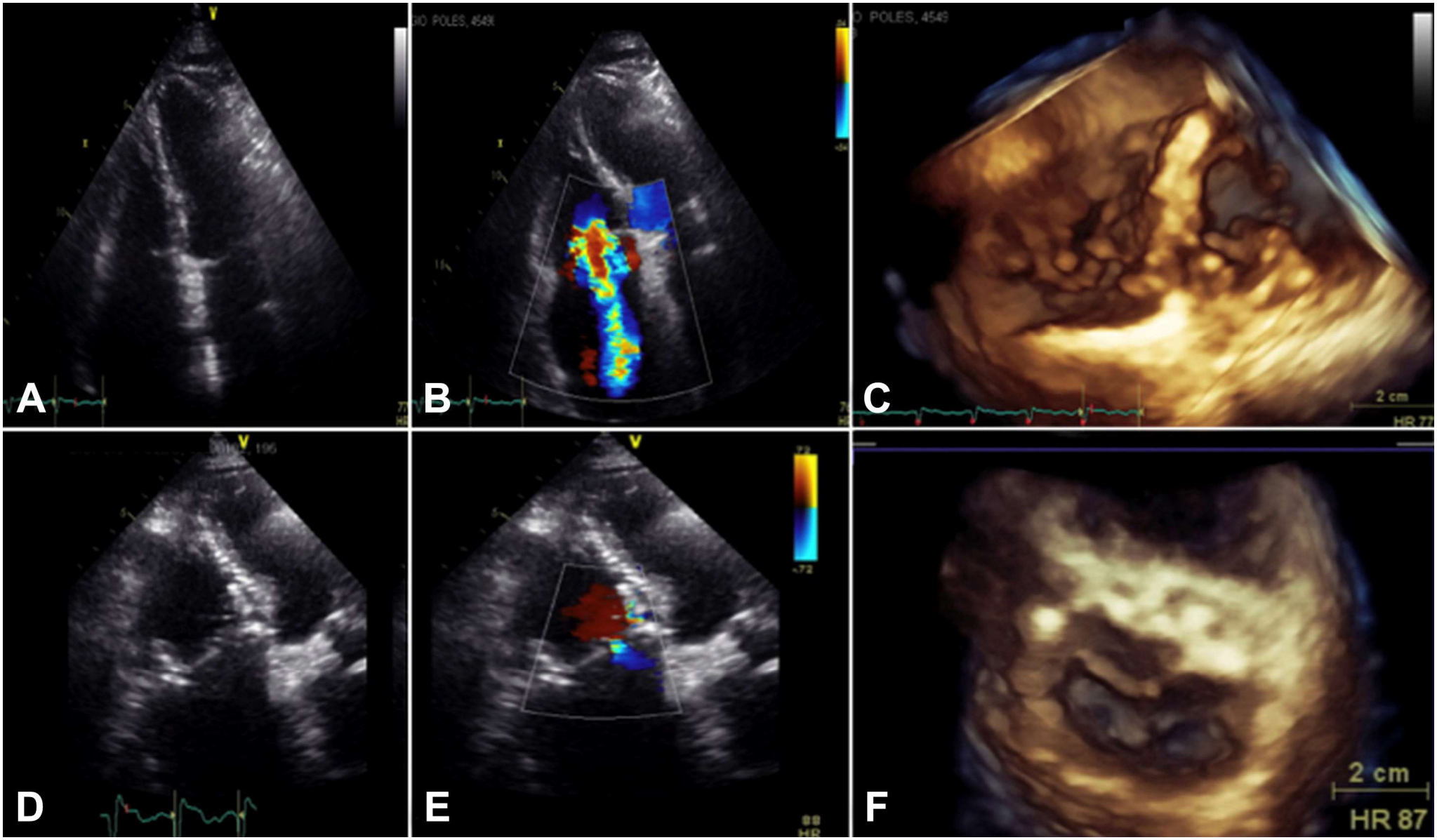
Pericardial
Self-expandable
Nitinol Frame
Sizes 36-54 mm
42Fr Sheath
TransJugular or
Transatrial



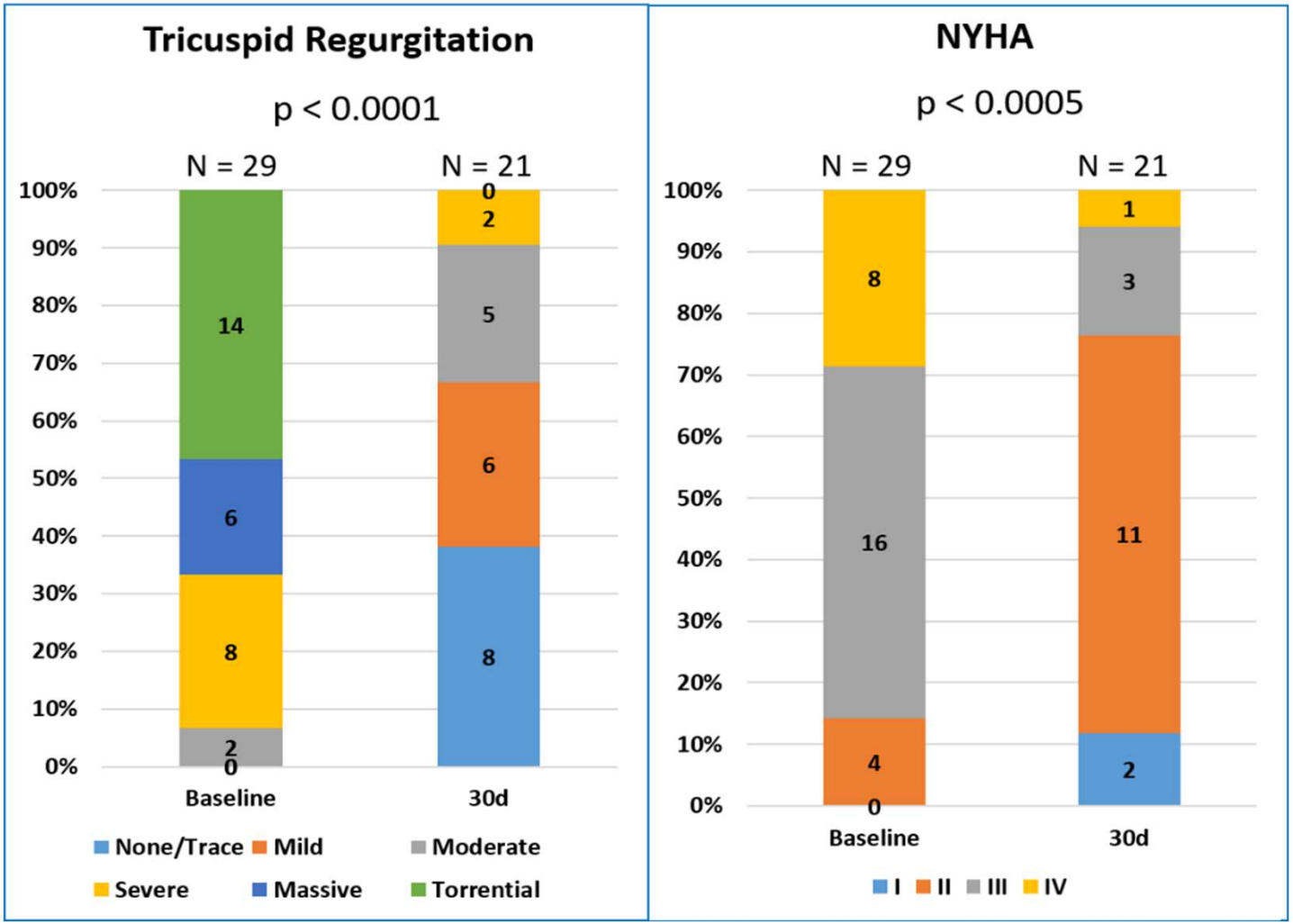
NaviGate




A
B
c
b
a
d
C
a
b
D
E
F
G
H


A
B
C
2 cm
HR 77
D
E
F
2 cm
HR 87

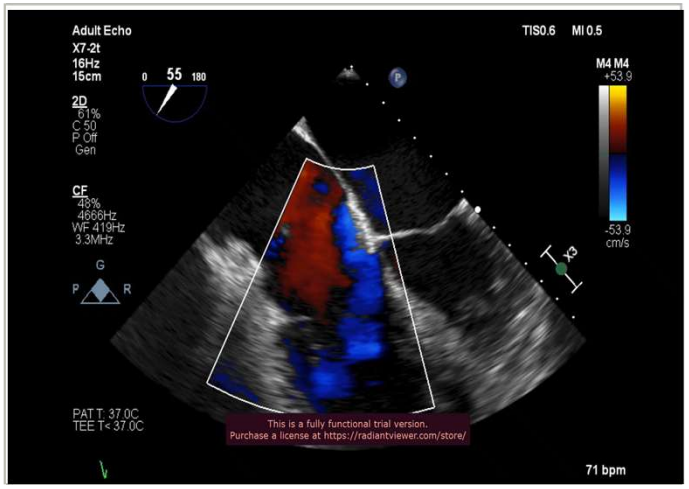
Gate


Tricuspid Regurgitation
p < 0.0001
N = 29
N = 21
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
14
6
8
2
0
2
5
6
8
0
Baseline
30d
None/Trace
Mild
Moderate
Severe
Massive
Torrential
NYHA
p < 0.0005
N = 29
N = 21
8
16
4
0
1
3
11
2
Baseline
30d
I
II
III
IV

Transfemoral Trans-septal Valve

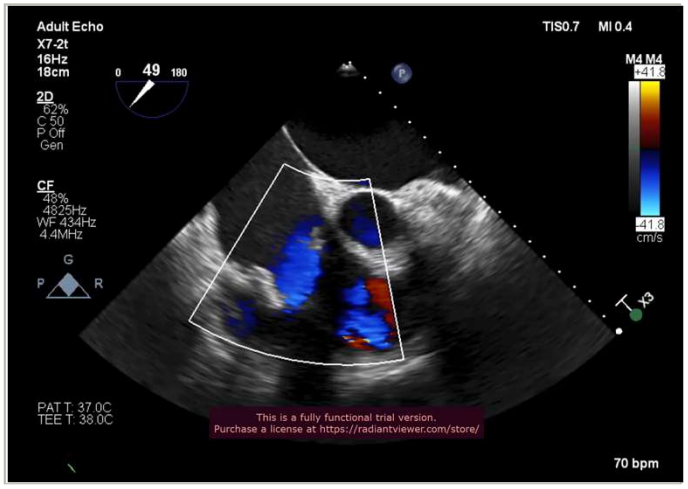
Representative case I

BASELINE



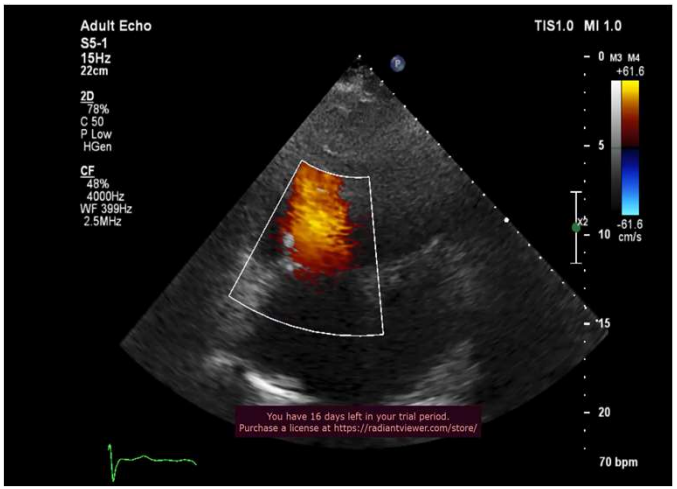
- 78, Male , Severe TR
- CAD , anemia , Afib
- NYHA III
- sPAP 46,PVR 1 wood,
- PM Lead

ACUTE RESULTS



- No TR
- No elevated gradient

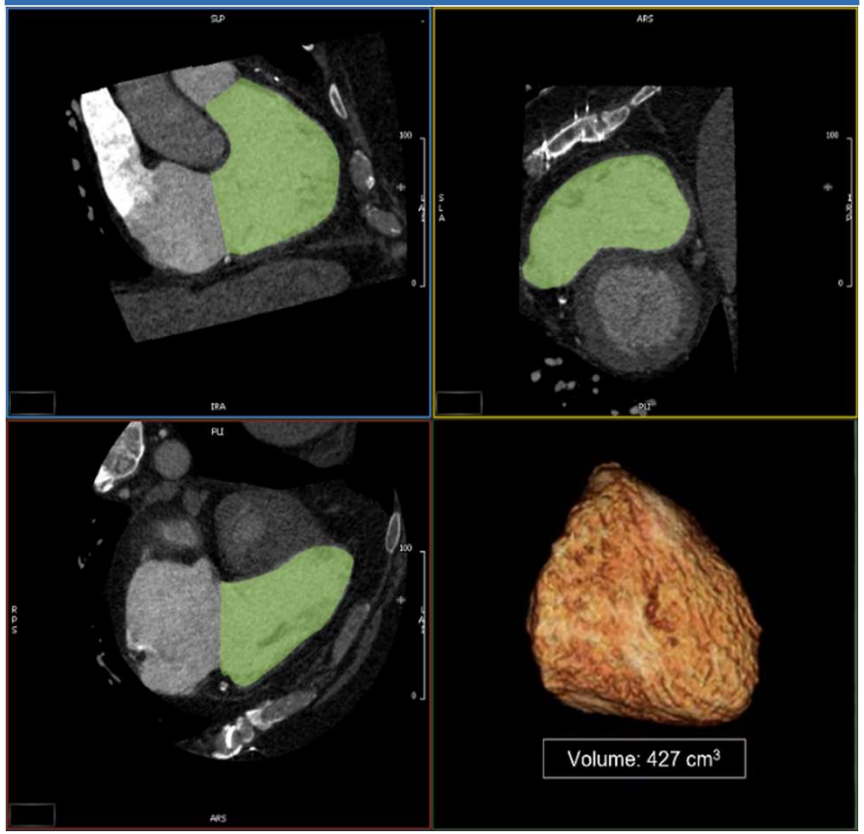
1-YEAR FOLLOW UP



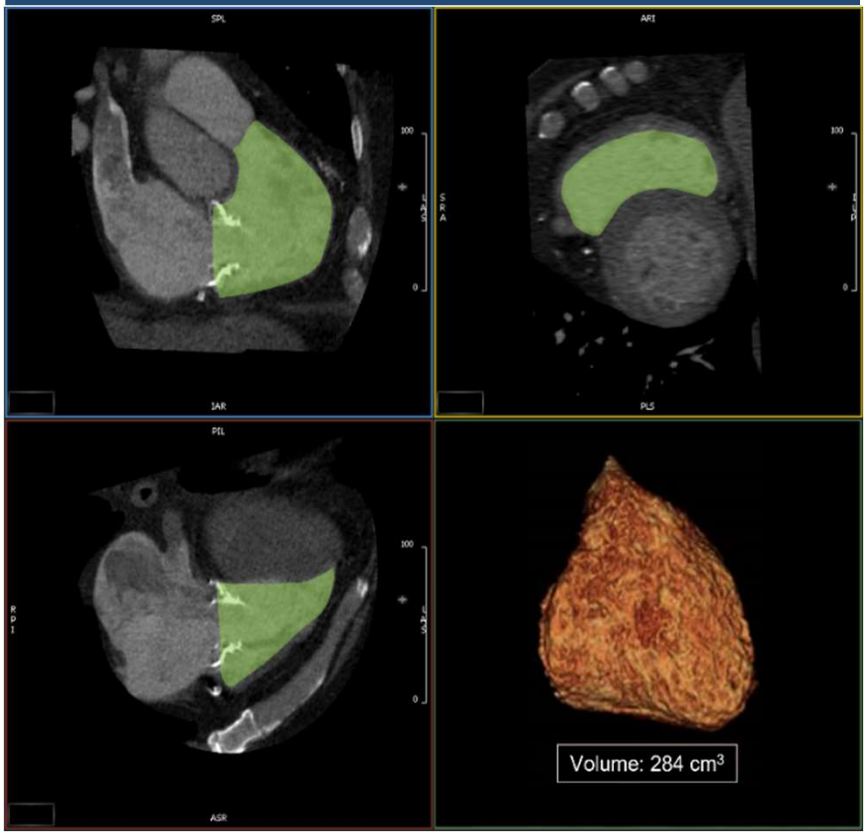
- No TR
- Mean gradient 2 mmHg

Significant reduction in RV volume at 3M post Cardiovalve

Before



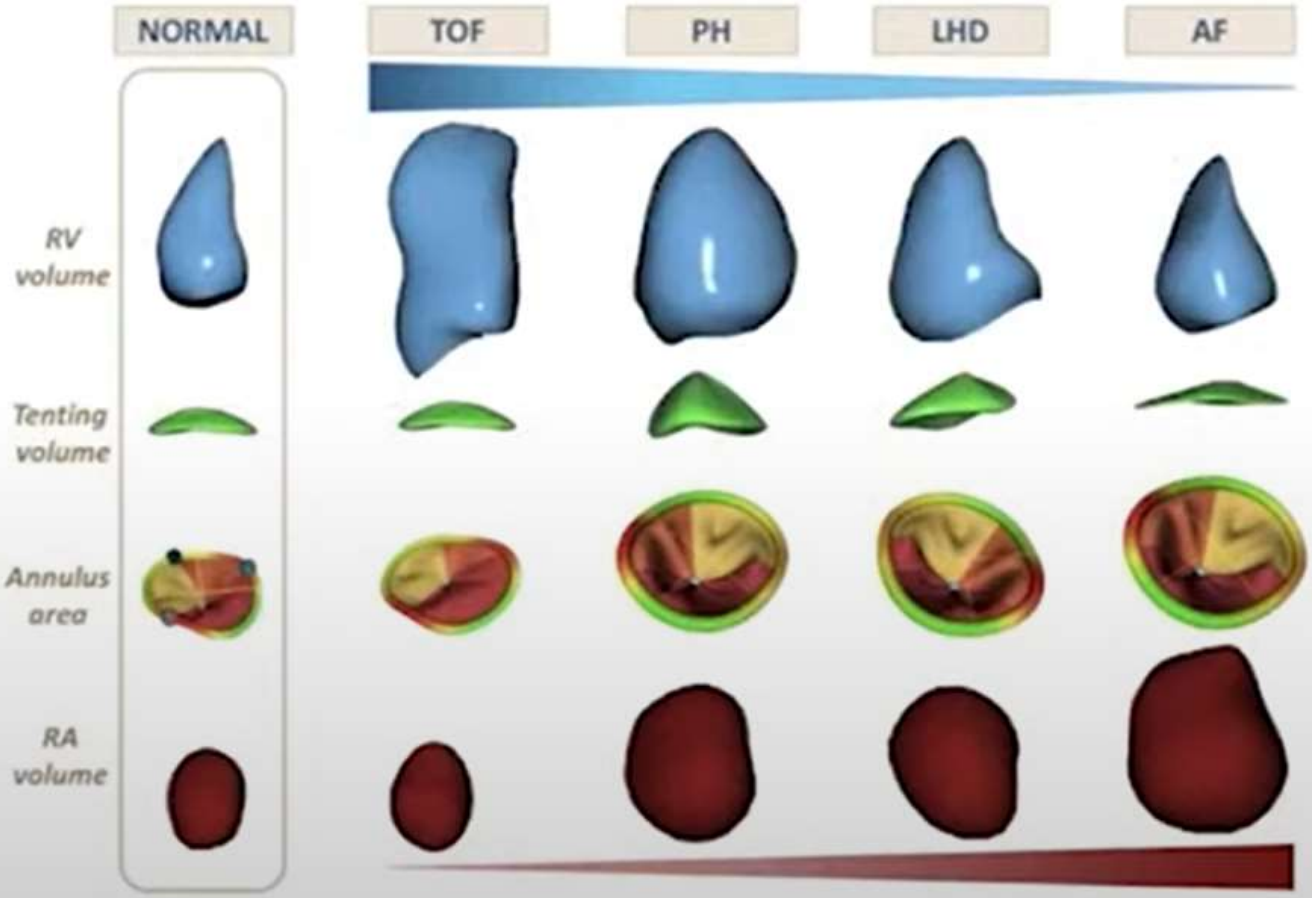
After



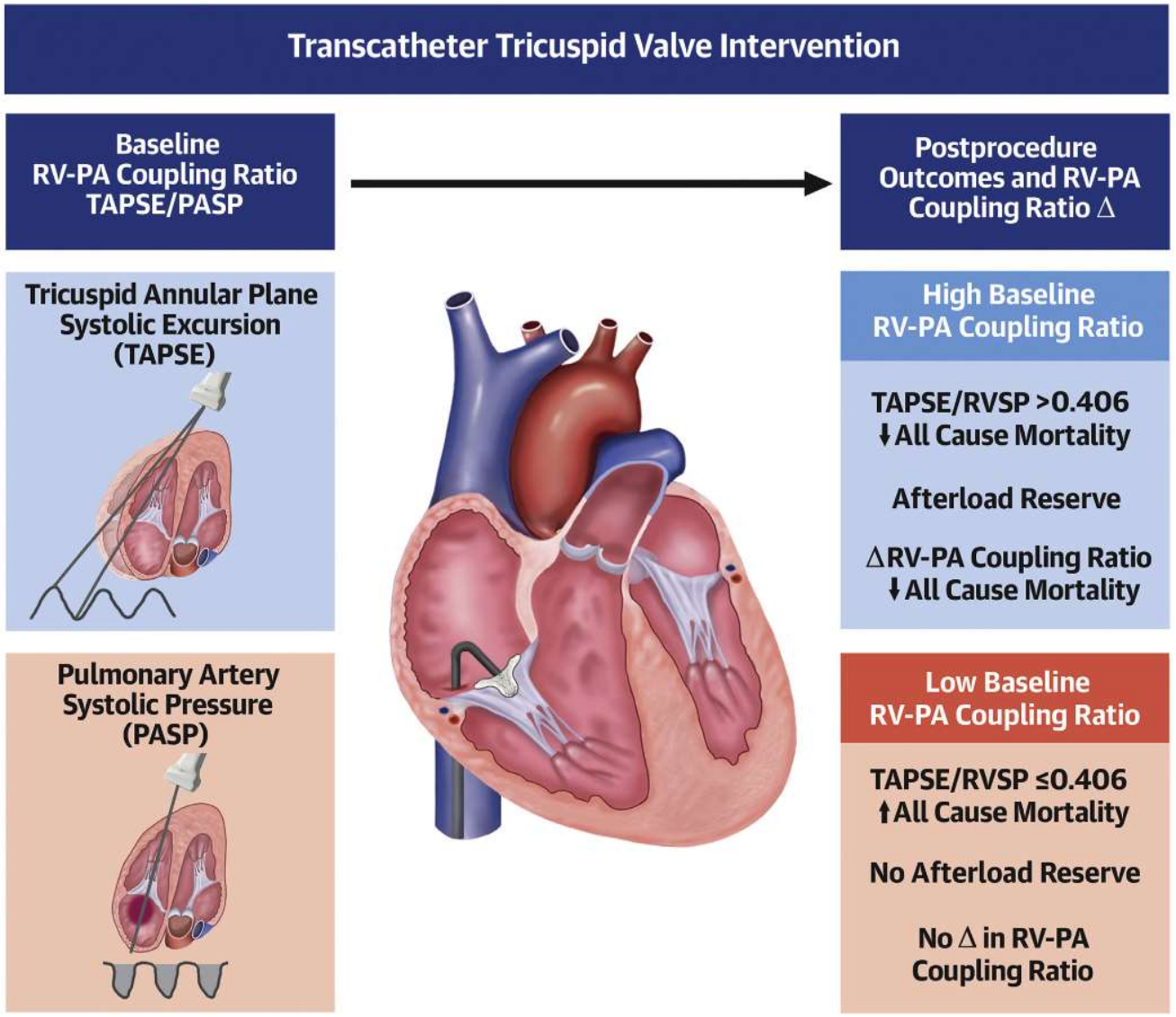
Limitations and grey zones

- Afterload mismatch and futility
- Is it really needed to abolish TR to have improved QoL?
- Anticoagulation
- AV conductance
- Anatomical limitations (screeen failures)
  - Size of the annulus
  - Size of the right ventricle
  - Size of the Right atrium
  - Angle with the IVC
  - Leaflets integrity
  - Papillary muscle distribution and morphology

Heterogeneity of TV and Right Chamber Remodelling in Secondary TR

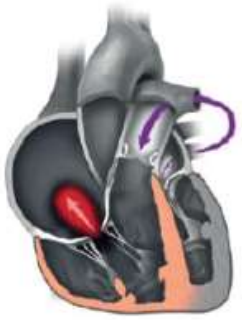
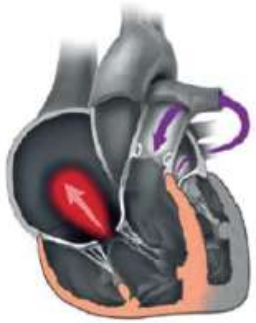


Muraru D et al. EHJCI 2020



Brener, M.I. et al. J Am Coll Cardiol. 2022;79(5):448-461.

TR Stages and suitable transcatheter treatments

	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 reguire combination of annuloplasty and leaflet device or TVR	Prohibitive risk and potentially futile. (Palliative procedures can be considered in highly selected patients)
	Early		**Progressive**		**Late**
	RV: Initial dilatation TA: Subsequent initial dilatation		RV: Progressive dilatation TA: Progressive dilatation → lack of leaflet coaptation		RV/TA: Progressive distortion and subsequent further leaflet tethering
	Annuloplasty Leaflet Approximation Replacement (orthotopic)		± Annuloplasty Leaflet Approximation Replacement (orthotopic)		± Leaflet Approximation Replacement (heterotopic) Replacement (orthotopic; depending on RV function)

TV the forgotten valve… No More

- ✓The evidence on long-term negative effect of unrepaired severe TR
- ✓The unfavorable outcomes of "late" treated TR are clear
- ✓Always indicated to treat moderate or dilated TV during Left Heart Surgery

- ✓ Transcath Repair devices have specific advantage of native valve structure preservation
- ✓Transcath Replacement devices are more reproducibile, easier learning curve and complete elimination of TR
- ✓However, the risk of afterload mismatch, valve thrombosis and the long-term impact on RV function are potential limitations of replacement

CONCLUSIONS

- ✓ Different approaches might be applicable for different TR stages

- ✓However, the risk of afterload mismatch, valve thrombosis and the long-term impact on RV function are potential limitations of replacement