Transcatheter Tricuspid Valve Therapy: The Next Frontier in Structural Heart Disease

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
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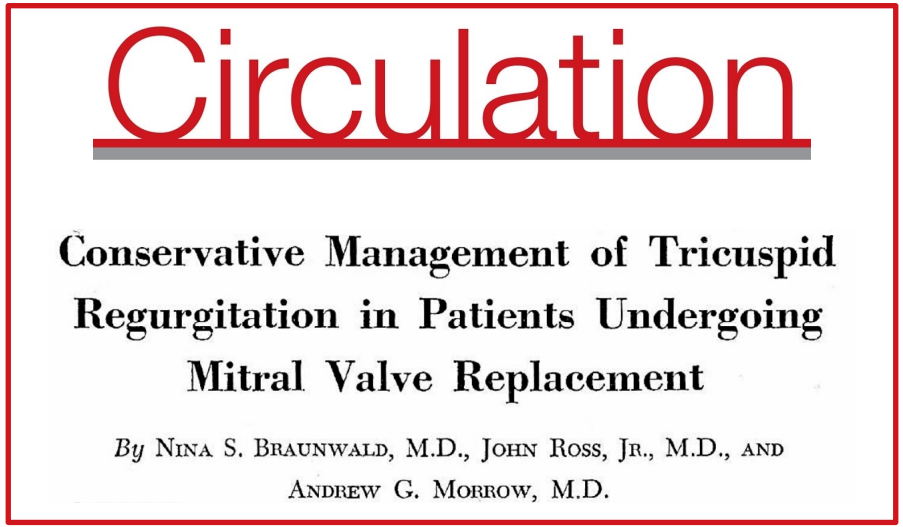
Equity/Investment	Dura Biotech, MicroInterventional Devices, Thubrikar Aortic Valve Inc, Supira, Anteris, Adona, Tioga, X-Dot, Cardiomech, Akura, Reniva, Meacor, Relief Cardiovascular, Bonaparte, Triflo, V2V, Nyra, Trajectory, Helix Valve Repair, Veritas, CLOC

Tricuspid Regurgitation I *Why We Should Care*


Circulation

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.

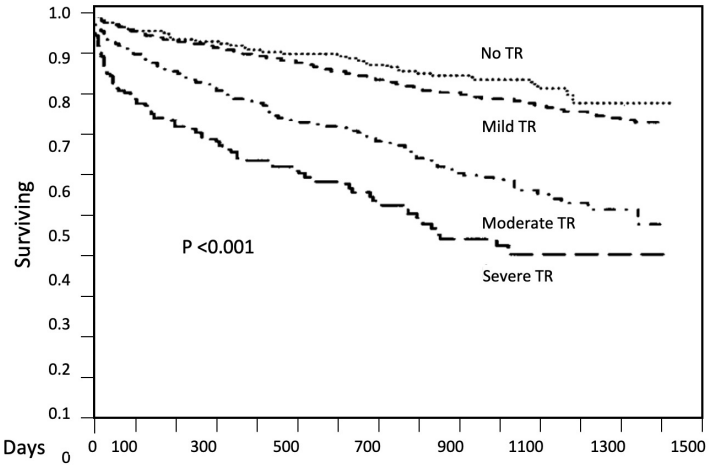
The historical narrative was…

- **"TR is secondary to left sided diseases"**
- **"Treat the left side, leave the right alone and it will follow to get better"**

Tricuspid Regurgitation I *Why We Should Care*

But new data taught us…

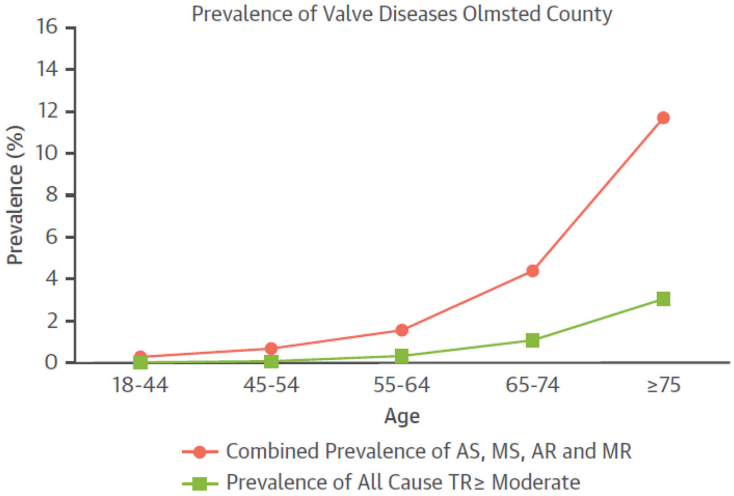
… TR is relevant



- Increasing TR is associated with worse survival;

Nath J. et al. JACC. 2004

… and highly prevalent



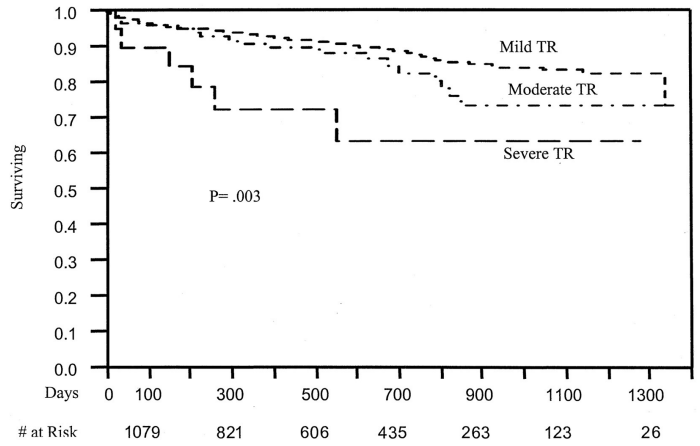
- Severe TR is as prevalent as severe AS, warranting similar attention

Enriquez-Sarano M. et al. Progr. In CV Disease. 2019

Tricuspid Regurgitation I *Why We Should Care*

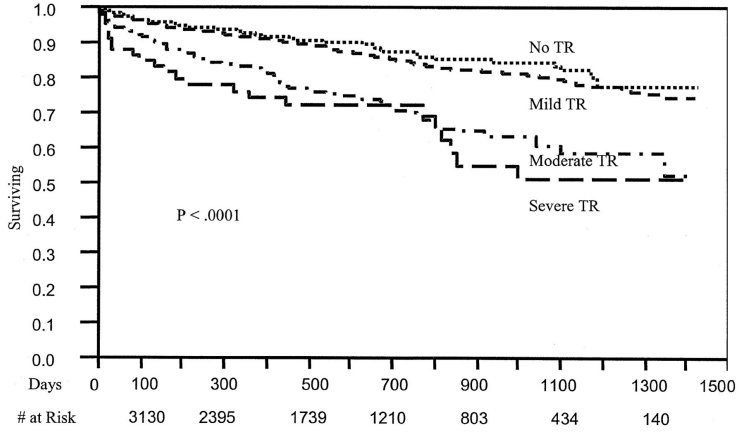
TR is relevant…

… independent of sPAP



Patients with sPAP < 40mmHg

… and independent of LVEF

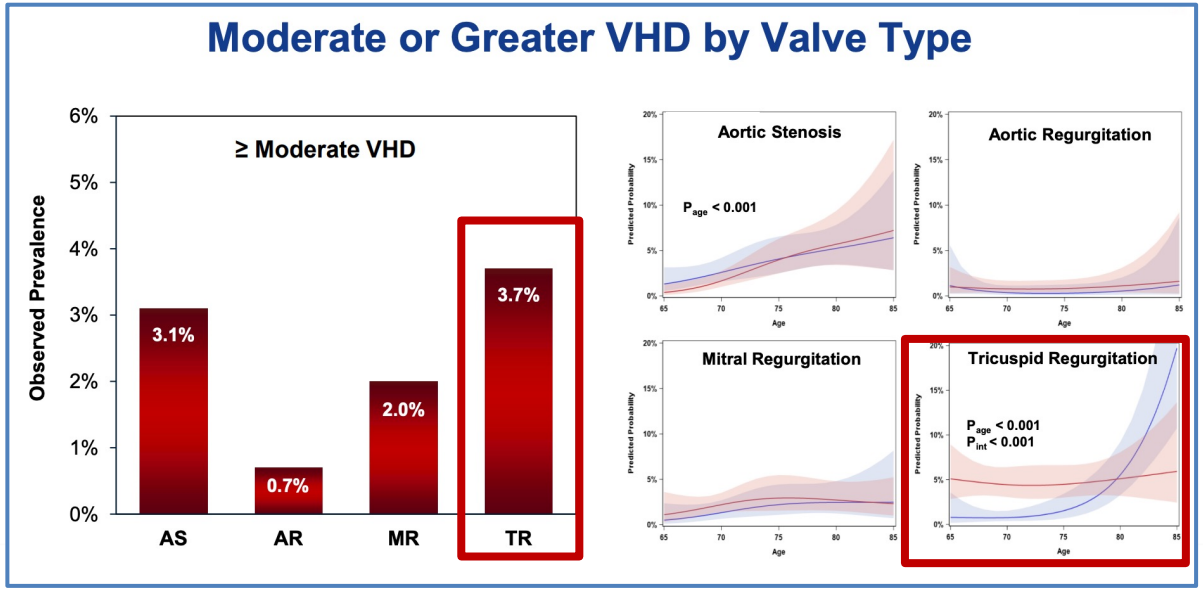


Patients with an LVEF ≥ 50mmHg

Nath J. et al. JACC. 2004

Tricuspid Regurgitation I *Why We Should Care*

TR is prevalent…



Cohen DJ. et al. TCT. 2025

Where Do We Stand Regarding TR?

Should we treat?

When should we treat?

How should we treat?

What are goals of treatment?

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CLINICAL PRACTICE GUIDELINE: FULL TEXT

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease

A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

Developed in collaboration with and endorsed by the American Association for Thoracic Surgery, American Society of Echocardiography, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons

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Otto CM et al J Am Coll Cardiol. 2021;77(4):450-500.

ESC European Society of Cardiology
European Heart Journal (2025) **46**, 4635–4736
https://doi.org/10.1093/eurheartj/ehaf194

ESC GUIDELINES

2025 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)

Authors/Task Force Members: Fabien Praz *†, (ESC Chairperson) (Switzerland), Michael A. Borger *†, (EACTS Chairperson) (Germany), Jonas Lanz ‡, (ESC Task Force Co-ordinator) (Switzerland), Mateo Marin-Cuartas ‡, (EACTS Task Force Co-ordinator) (Germany), Ana Abreu (Portugal), Marianna Adamo (Italy), Nina Ajmone Marsan (Netherlands), Fabio Barili (Italy), Nikolaos Bonaros (Austria), Bernard Cosyns (Belgium), Ruggero De Paulis (Italy), Habib Gamra (Tunisia), Marjan Jahangiri (United Kingdom), Anders Jeppsson (Sweden), Robert J.M. Klautz (Netherlands), Benoit Mores (Belgium), Esther Pérez-David (Spain), Janine Pöss (Germany), Bernard D. Prendergast (United Kingdom), Bianca Rocca (Italy), Xavier Rossello (Spain), Mikio Suzuki (Serbia), Holger Thiele (Germany), Christophe Michel Tribouilloy (France), Wojtek Wojakowski (Poland), and ESC/EACTS Scientific Document Group

Praz F, et al. Eur Heart J. 2025; 46: 4635-4736.

FIRST: Defining OMT

2020 ACC/AHA Guidelines Medical Therapy:

- **CLASS IIa**
- **1. In patients with signs and symptoms of right-sided HR attributable to severe TR (stages C and D), diuretics can be useful. (Level of Evidence: C)**
- **CLASS IIa**
- **1. In patients with signs and symptoms of right-sided HR attributable to severe TR (stages C and D), therapies to treat the primary cause of HF (eg, pulmonary vasodilators to reduced elevated pulmonary artery pressures, GDMT for HF with reduced LVEF or rhythm control of AF) can be useful. (Level of Evidence: C)**

Otto CM et al. J Am [illegible] 2020

2025 ESC/EACTS Guidelines Medical Therapy:

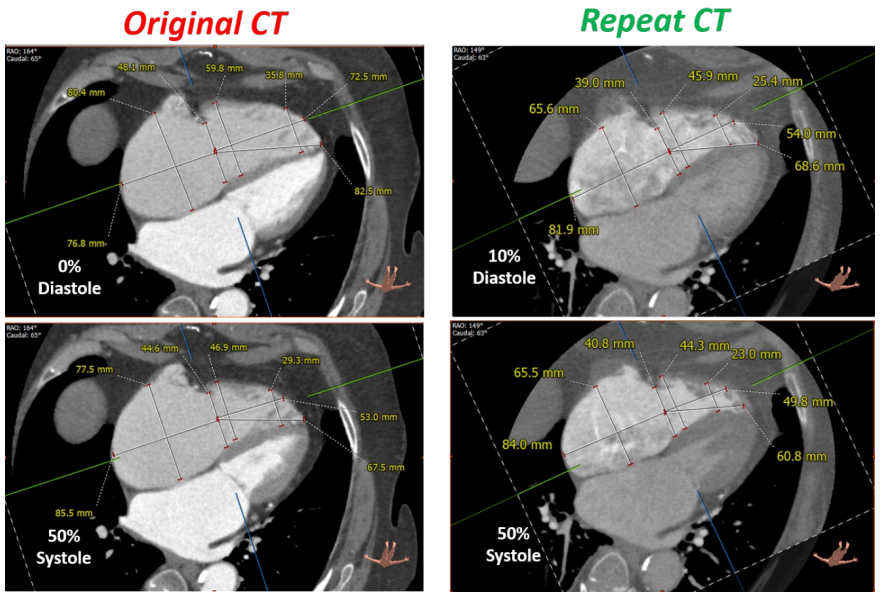
- **Diuretics are useful** in the presence of right heart failure. …the addition of an aldosterone antagonist may be considered.
- **Dedicated treatment of pulmonary hypertension** is indicated in specific cases.
- Although data are limited, **rhythm control may help** to decrease tricuspid regurgitation and contain annular dilatation in patients with chronic AF.
- **Importantly, in the absence of advanced RV dysfunction or severe pulmonary hypertension, none of the above-mentioned therapies should delay referral for surgery or transcatheter therapy.**

Vahanian A, et al. Eur Heart J. 2022 Feb

Major Problem:
Lack of evidence-based data to guide therapy

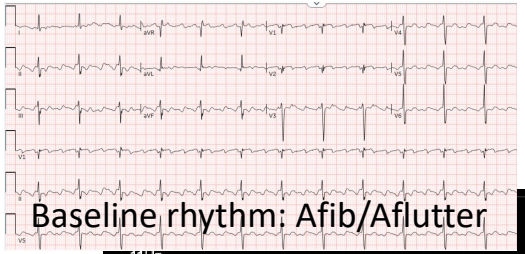
TR is a dynamic disease and volume dependent

- Optimizing patients with OMT can decrease RV dimensions and improve TR
- Consider RHC to guide management
- May require hospitalization for optimization

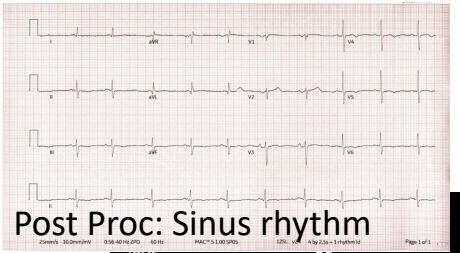


Septal-Lateral Dimension Reduced by 9mm

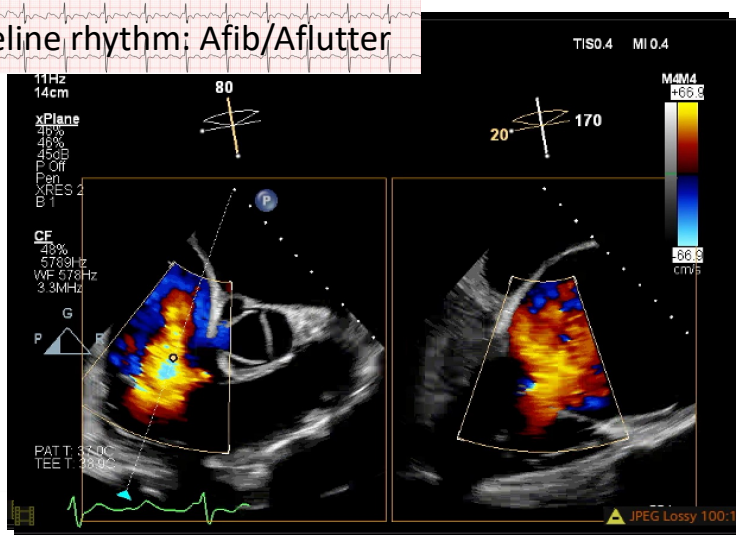
Don’t forget rhythm management



Baseline rhythm: Afib/Aflutter

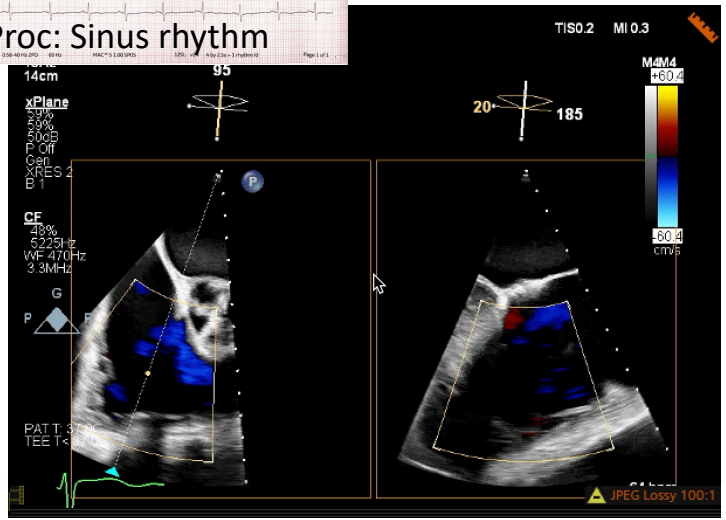


Post Proc: Sinus rhythm



Torrential TR

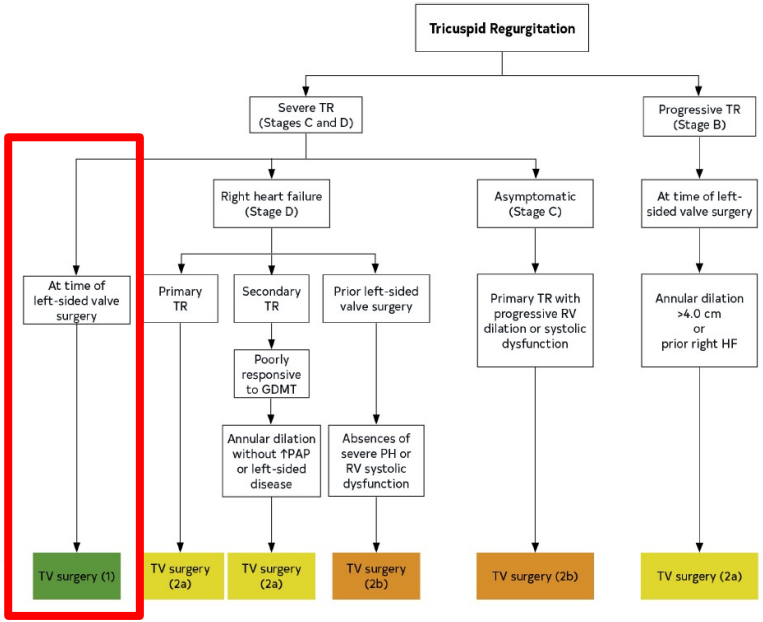
Underwent ablation



Moderate to Severe TR

What about surgery?

Recommendations for Intervention



Recommendations for Medical Therapy

COR	LOE	RECOMMENDATIONS
2a	C-EO	1. In patients with signs and symptoms of right-sided HF attributable to severe TR (Stages C and D), diuretics can be useful.
2a	C-EO	2. In patients with signs and symptoms of right-sided HF attributable to severe secondary TR (Stages C and D), therapies to treat the primary cause of HF (eg, pulmonary vasodilators to reduce elevated pulmonary artery pressures, GDMT for HF with reduced LVEF, or rhythm control of AF) can be useful (1,2)

Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Journal of the American College of Cardiology (JACC)*. 2021;77(4):e25-e197.

Tricuspid Regurgitation I *The Recent State of Care*

TR historically remained vastly undertreated

USA Population

1.6 Mio patients with moderate to severe TR

(250k new cases per year)

BUT: < 8000 TR surgeries performed per year

Wang N. et al. Eur Heart J. 2019

Tricuspid Regurgitation I *The Recent State of Care*

TR historically remained vastly undertreated

Isolated Tricuspid Valve Surgery on Native Valve (N=466)

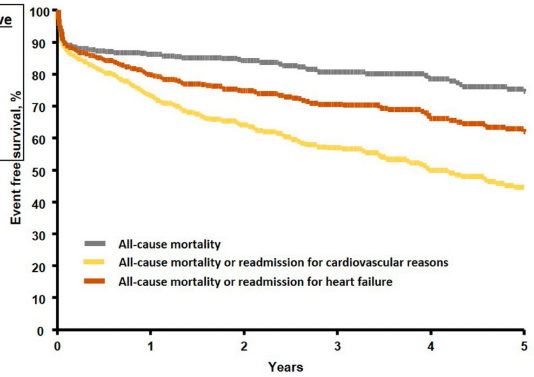
- **Functional tricuspid regurgitation (N=229)**
  - Prior left-sided heart valve surgery (N=101)
  - Isolated (N=128)
- **Organic tricuspid regurgitation (N=237)**
  - Infective endocarditis (N=142)
  - Other (N=95)

Pre-operative presentation

- **Clinical** (NYHA class III/IV, right heart failure signs)
- **Biological** (lower prothrombin time, lower glomerular filtration rate)
- **Echocardiography** (moderate/severe RV dysfunction or dilatation)

Outcome

- **In-hospital death: 10%**
- **In-hospital major complications: 31%**
- **Overall survival, survival free of cardiovascular readmission and survival free of heart failure readmission at 5 years were 75%, 44% and 62%.**



Isolated tricuspid valve surgery is associated with high mortality and morbidity, both in-hospital and during follow-up, predicted by the severity of the pre-operative clinical, biological and echocardiographic presentation but not by etiology or the mechanism tricuspid regurgitation mechanism

Dreyfus J. et al. Eur Heart J. 2020

A meta-analysis of 35 studies (5,316 patients)

Isolated surgery

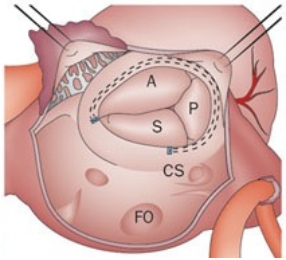
Bioprosthetic & mechanical valves

Operative mortality 12% (9-15)

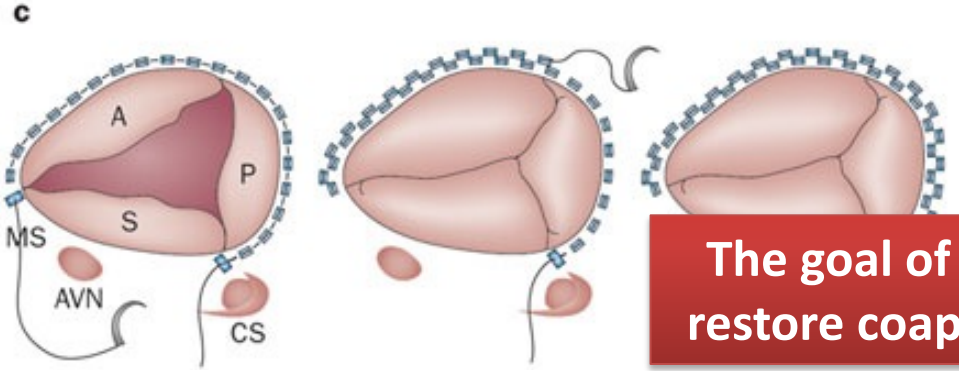
Years 1995-2019: 11% (8-14)

Scotti A, Latib A. et al. EuroIntervention. 2022

Surgical Approaches to Tricuspid Regurgitation

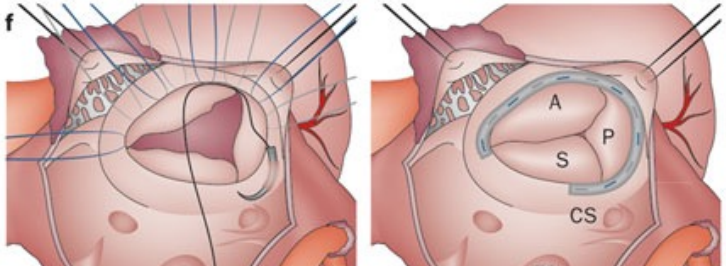


De Vega Plasty

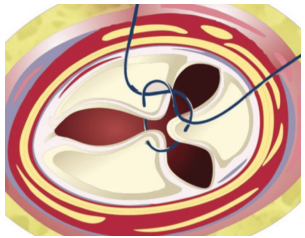


Modified De Vega Plasty

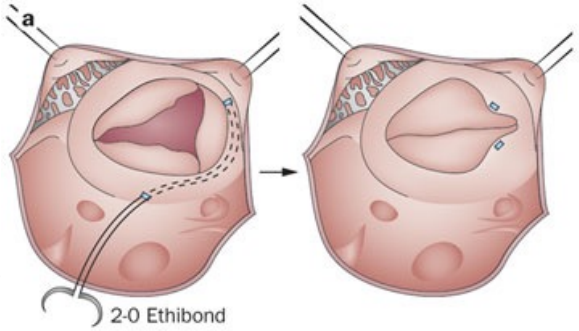
The goal of surgery is to restore coaptation planes



Ring Annuloplasty



Clover



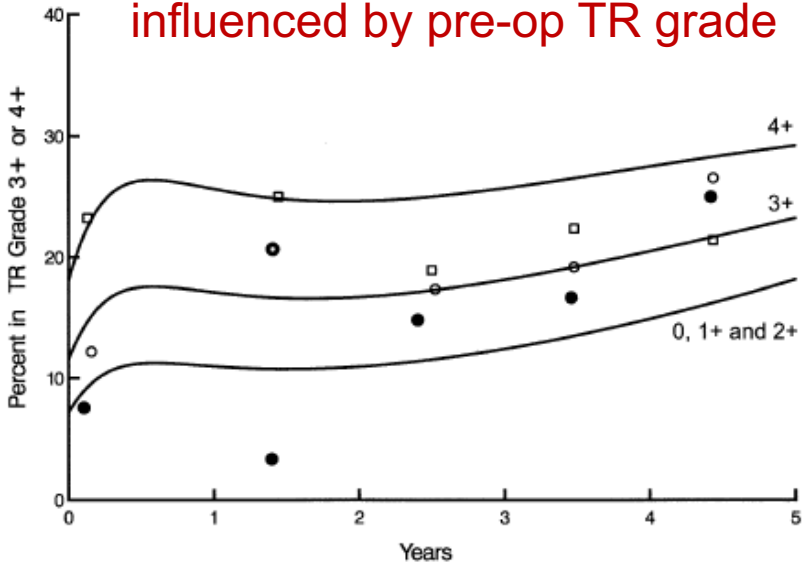
Kay Annuloplasty

Recurrent TR after TV Surgery: Insights From Surgery

Factor	Estimate ± SE	*P* value
Overall		
Higher grade of preoperative TR	0.46 ± 0.062	<.0001
Female	0.71 ± 0.12	<.0001
Mitral valve replacement	0.40 ± 0.11	.0003
Early phase		
Surgical management of TR (compared with rigid ring)		
Flexible ring alone	0.41 ± 0.13	.02
Peri-Guard alone	0.011 ± 0.35	>.9
De Vega alone	6.9 ± 3.02	.02
Kay procedure alone	7.5 ± 3.02	.03
Annulus + leaflet	−0.47 ± 0.404	.2
Kay + leaflet	6.7 ± 3.04	.03
Larger annuloplasty ring size*	5.7 ± 2.7	.03
Lower LVEF†	−0.78 ± 0.14	<.0001
African American	0.52 ± 0.19	.005
History of heart failure	0.43 ± 0.14	.002
Lower body surface area‡	1.4 ± 0.78	.07
Late phase		
Surgical management of TR (compared with rigid ring)		
Flexible ring alone	0.72 ± 0.21	.0007
Peri-Guard alone	2.3 ± 0.40	<.0001
De Vega alone	−0.64 ± 5.6	.9
Kay procedure alone	−1.7 ± 5.6	.8
Larger annuloplasty ring size*	−1.7 ± 4.9	.7
Lower GFR§	0.81 ± 0.21	.0002
Preoperative permanent pacemaker	1.3 ± 0.29	<.0001
At least one coronary artery system diseased	0.97 ± 0.22	<.0001
Larger LV mass index‖	0.38 ± 0.087	<.0001

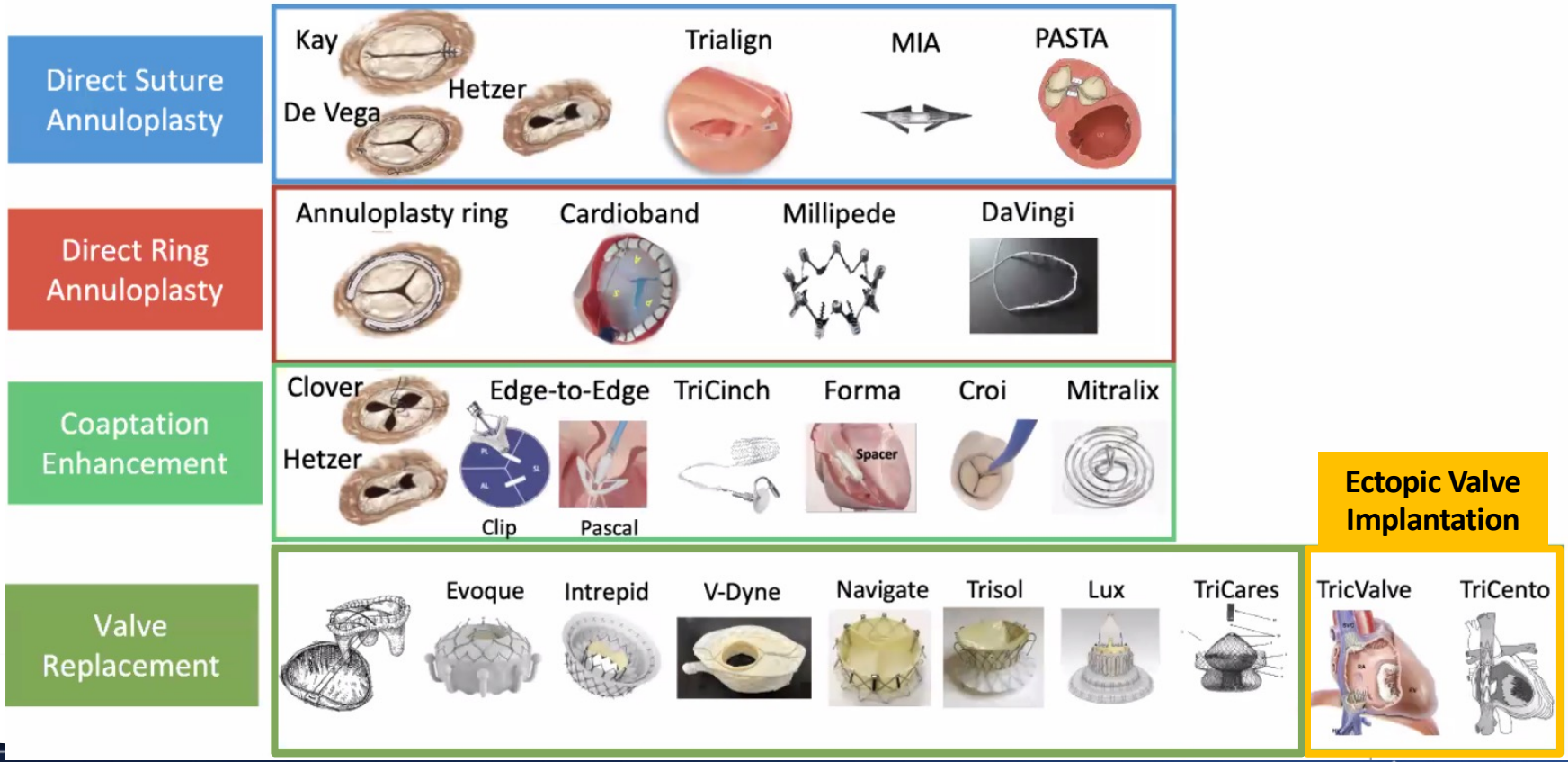
- ↑TR grade pre-op
- Non-rigid annuloplasty ring approach
- Small ring size
- Low LVEF
- CAD
- Pacemaker

Durability of surgical TV repair influenced by pre-op TR grade



Navia JL et al. J Thorac Cardiovasc Surg 2010; McCarthy PM et al. JTCVS 2004

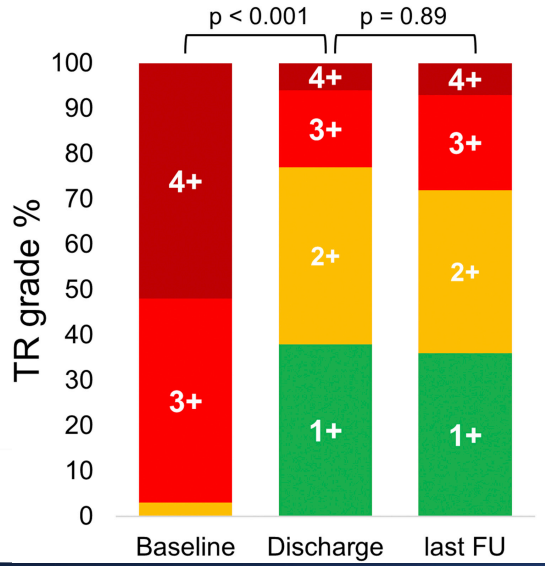
Transcatheter Tricuspid Valve Intervention

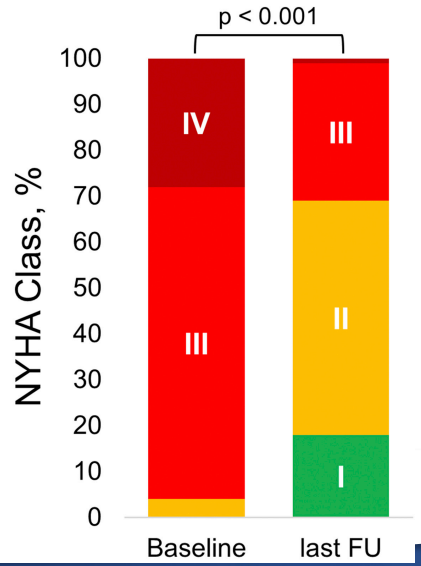


Arrival of First Devices I *M-TEER → T-TEER*

Adoption of the well-established M-TEER technology to the right side moved the field forward

- **Off-label use of the MitraClip on the tricuspid valve according to the early TriValve registry experience proved effective in reducing TR and improving NYHA class**





Mehr M et al. JACC Interv. 2019

Arrival of First Devices I *M-TEER → T-TEER*

Adoption of the well-established M-TEER technology to the right side moved the field forward

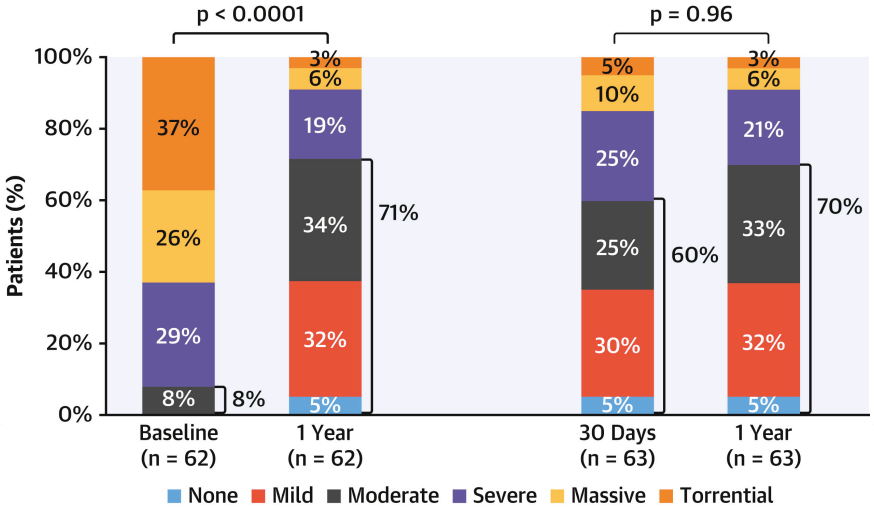
This encouraging first experience led to the development of a dedicated TriClip T-TEER system, enhancing maneuverability & effectiveness

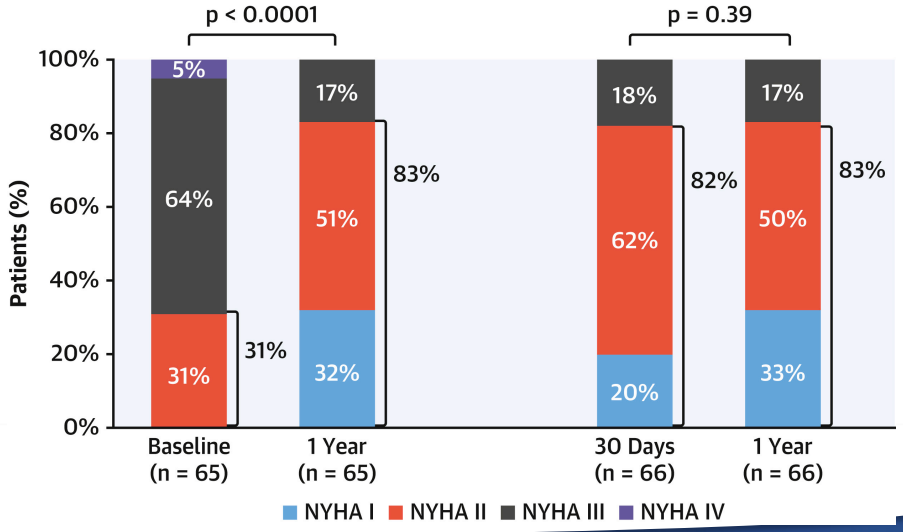
Baseline Discharge last FU Baseline last FU

Arrival of First Data I *T-TEER*

The TRILUMINATE Study…

Non-randomized single arm study (n=85) demonstrated stable TR reduction and significant NYHA class improvement at 1-year.





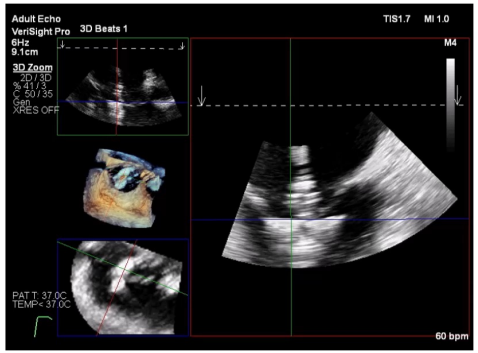
Lurz P et al. JACC. 2021

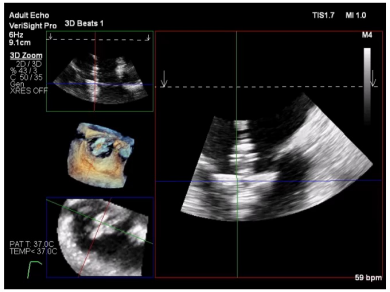
Challenges With Leaflet Devices

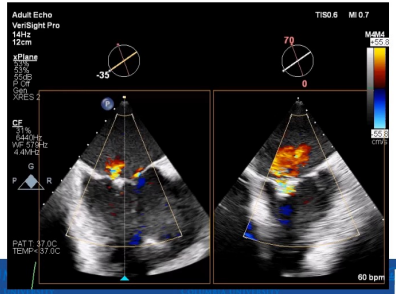
Imaging the leaflets is challenging

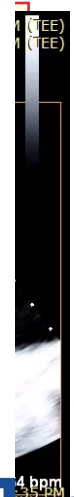
- TV more difficult to image than the mitral valve
- 4D ICE will be a game changer
- Regurgitant orifice is often broad
- Catheter navigation difficult
- Anatomy is challenging
  - Leaflet tissue
  - Multiple chords
  - Large gaps
  - Multiple leaflets

ICE Leaflet Grasp



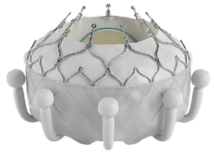




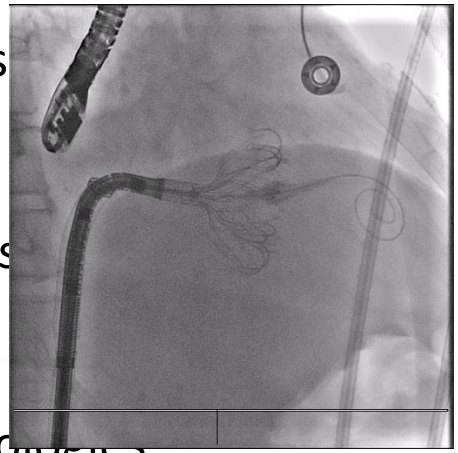


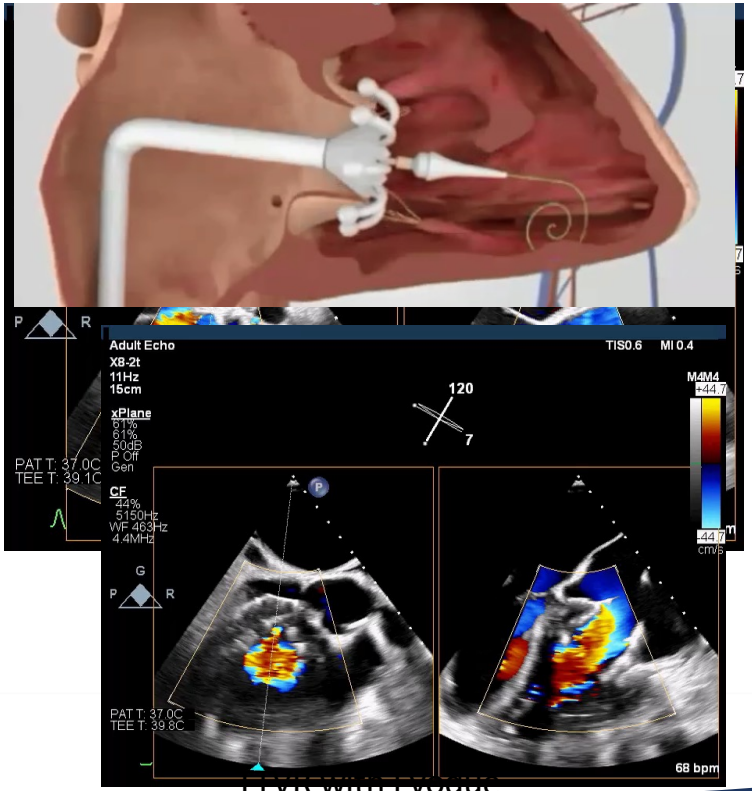
@hahn_rt

When repair is not feasible…



- In cases of torrential TR, repair may not be an option due to anatomic limitations
- Transcatheter replacement may provide a better option for these patients provided the RV can tolerate an acute increase in afterload
- TTVR is not the same as replacement
  - No CPB
  - No massive volume s
  - No RV ischemia
- Early studies with TTVR promise of these technologies



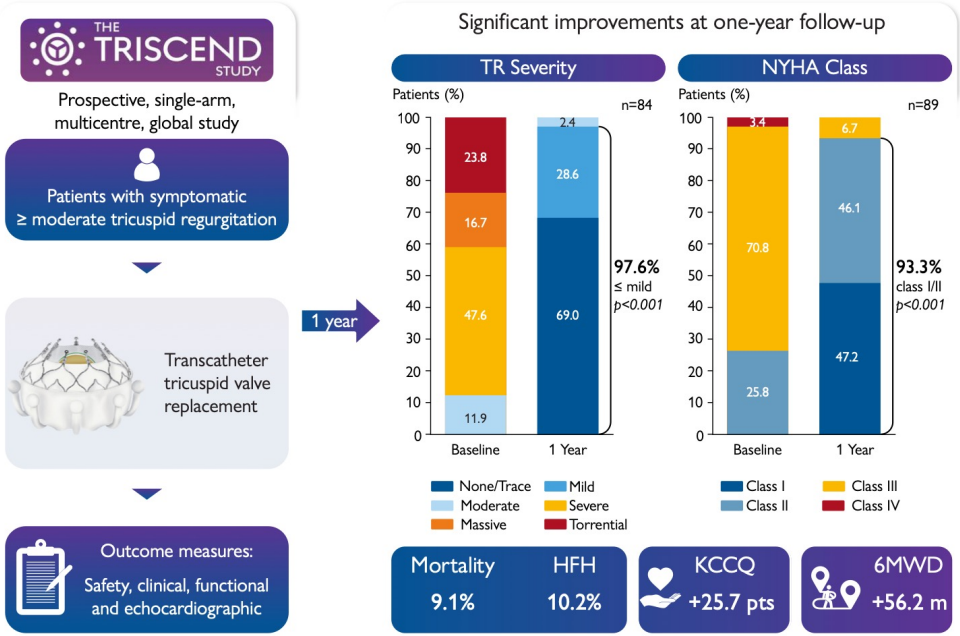


TTVR with Evoque

Arrival of First Data I *TTVR*

Table 2 **Major adverse events adjudicated by the clinical events committee at 30 days and one year**

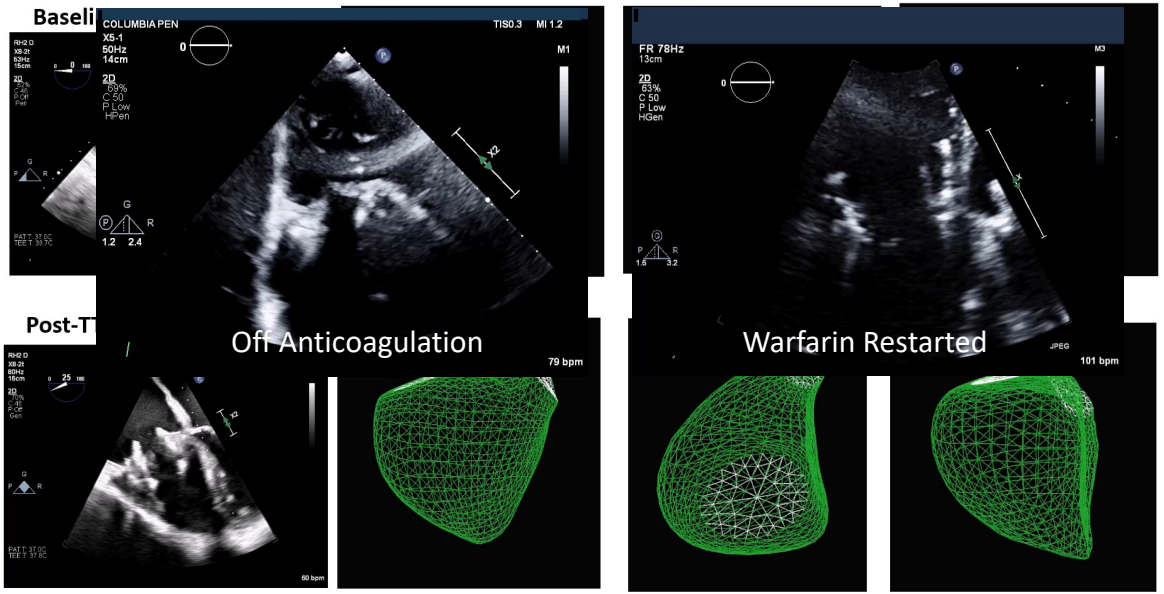
CEC-adjudicated MAEs	30 days ($n = 172$)[a]	1 year ($n = 149$)[a]
Cardiovascular mortality	1.7 (3)	9.4 (14)
Myocardial infarction	0.0 (0)	0.0 (0)
Stroke	0.6 (1)	1.3 (2)
Major cardiac structural complications	0.0 (0)	0.0 (0)
Renal complications requiring unplanned dialysis or renal replacement therapy	1.7 (3)	3.4 (5)
Non-elective tricuspid valve re-intervention	2.3 (4)	4.0 (6)
Major access site and vascular complications	2.3 (4)	2.7 (4)
Severe bleeding[b]	16.9 (29)[c]	25.5 (38)[d]
Major	8.1 (14)	10.7 (16)
Extensive	7.0 (12)	10.7 (16)
Life threatening	1.7 (3)	4.7 (7)
Fatal	0.6 (1)	0.7 (1)
Device-related pulmonary embolism	0.0 (0)	0.0 (0)
Composite MAEs	**18.6 (32)[e]**	**30.2 (45)[e]**



Challenges With TTVR

- TTVR delivery
- RV function
- Conduction disturbance
- Leaflet thrombosis
- Durability

Change in Right Ventricular Physiology following TTVR



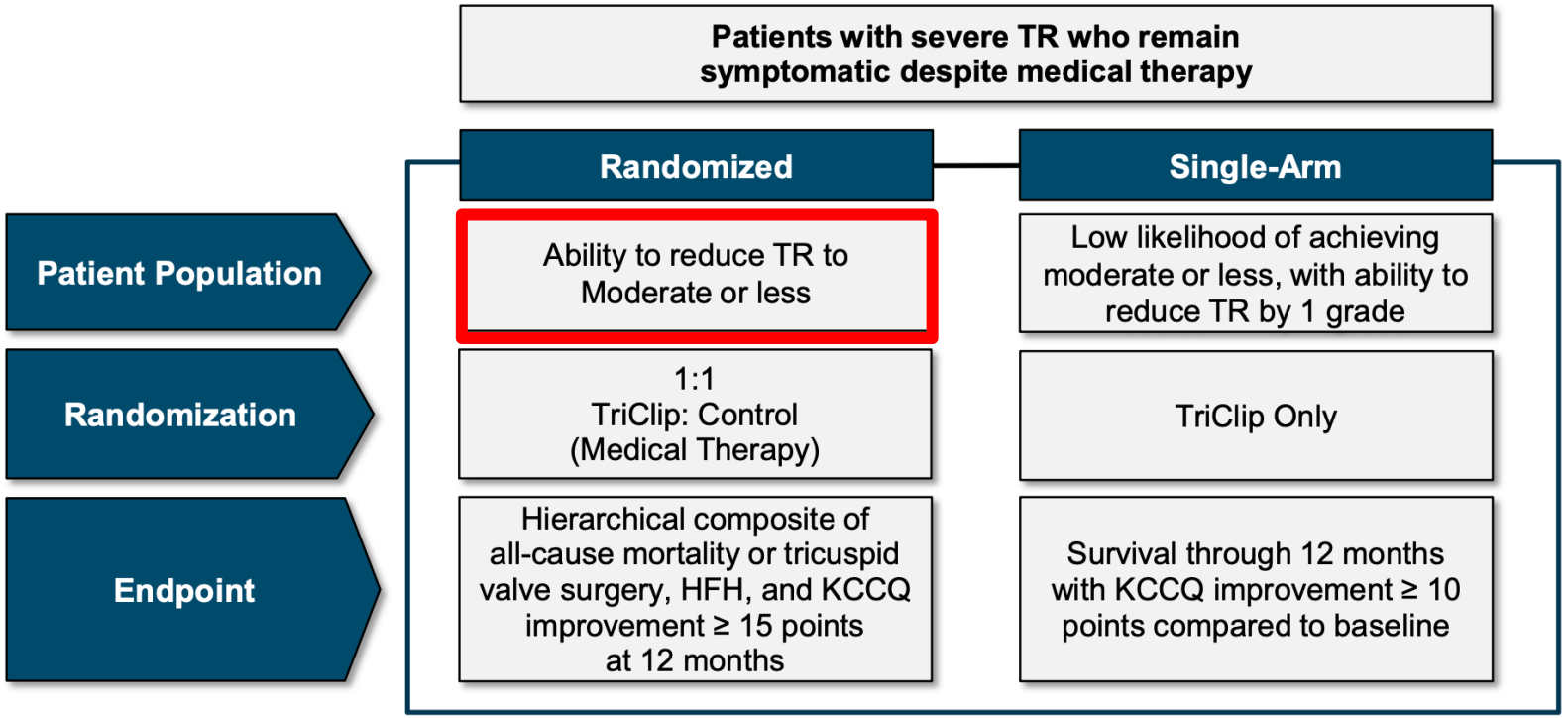
Courtesy R. Hahn

Ranard et al, CCI 2022

• Courtesy of Susheel K. Kodali, MD.

Randomized Trial Data I *T-TEER*

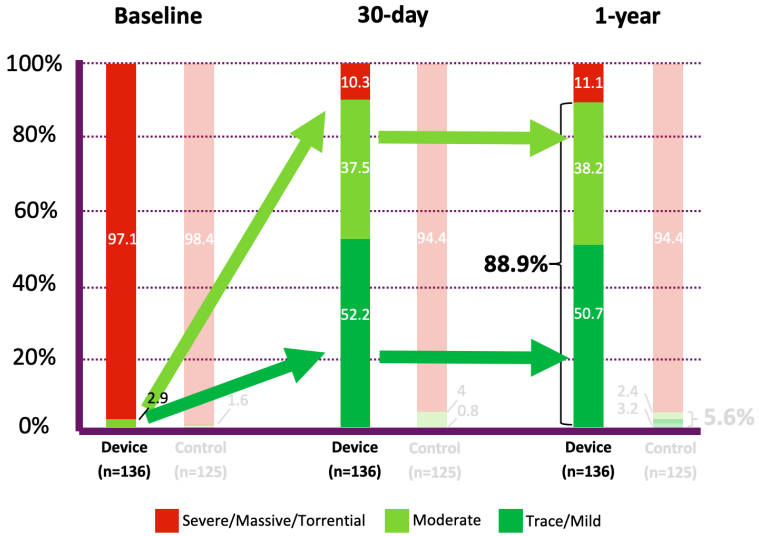
TRILUMINATE Study Design

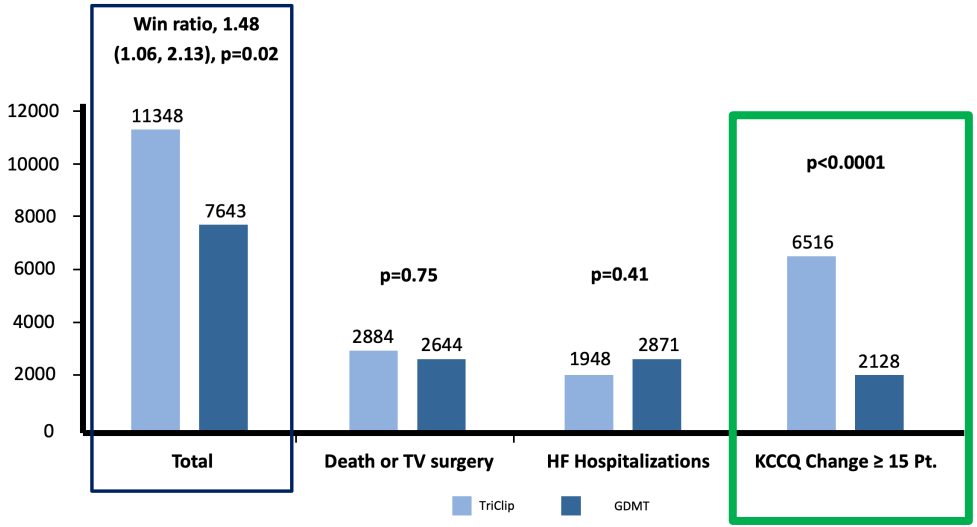


Randomized Trial Data I *T-TEER*

The TRILUMINATE Pivotal Trial…

First randomized trial (n=350) of T-TEER vs. GDMT demonstrated significant benefit of continued TR reduction, mainly driven by QoL benefits, at 1-year.





Randomized Trial Data I *T-TEER*

The TRILUMINATE Pivotal Trial…

Demonstrated that T-TEER is very safe, with 98.3% freedom from MAEs at 30-days.

Secondary Endpoint Analysis

	Device N=175	Control N=175	p-value
Freedom from MAE at 30d	98.3%	-	
TR ≤ moderate at 30d	87.0%	4.8%	<0.001
Change in 6MWTD	-8.1	-25.2	0.25

*MAE: CV mortality, myocardial infarction, stroke, renal failure, endocarditis requiring surgery, non-elective CV surgery T-TEER related

Sorajja P et al. NEJM. 2023

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Repair for Patients with Tricuspid Regurgitation

Paul Sorajja, M.D., Brian Whisenant, M.D., Nadira Hamid, M.D., Hursh Naik, M.D., Raj Makkar, M.D., Peter Tadros, M.D., Matth
Gagan Singh, M.D., Neil Fam, M.D., Saibal Kar, M
Jonathan G. Schwartz, M.D., Shamir Mehta, M.D., Richard
Nishant Sekaran, M.D., Travis Warner, M.D., Moody Ma
George Zorn, M.D., Erin M. Spinner, Ph.D., Phillip M. Tru

No difference in mortality, heart failure r 6MWD

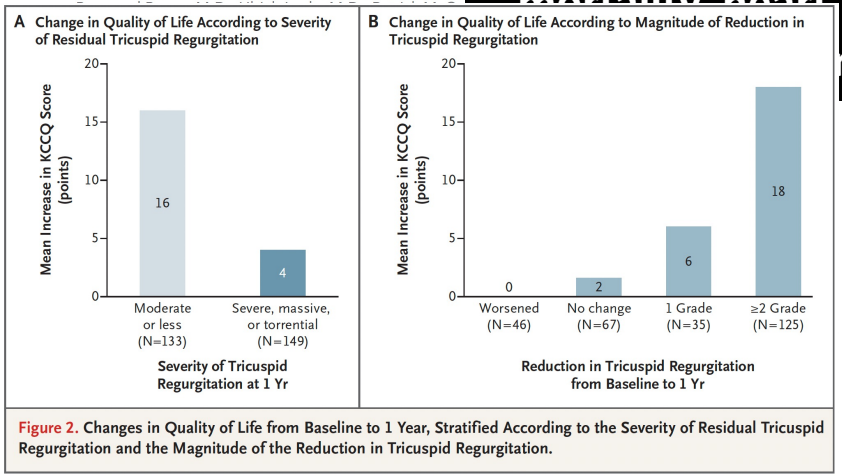


Figure 2. Changes in Quality of Life from Baseline to 1 Year, Stratified According to the Severity of Residual Tricuspid Regurgitation and the Magnitude of the Reduction in Tricuspid Regurgitation.

WHY?

Wrong patient population
- Too sick
- Not sick enough

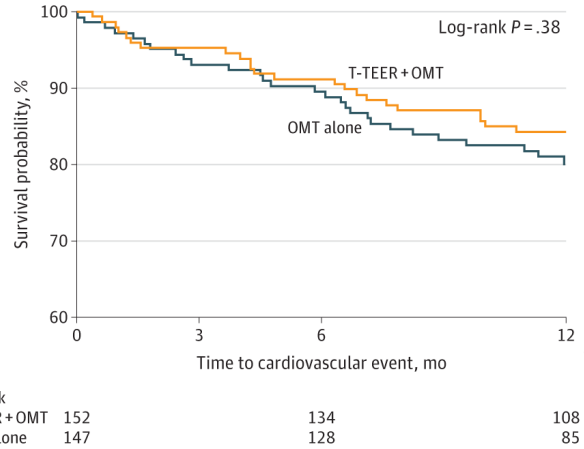
- Not enough reduction in TR
- Heart failure management impacted medical therapy arm
- Mortality in TR overestimated
- One year not long enough to demonstrate benefit

Randomized Trial Data I *T-TEER*

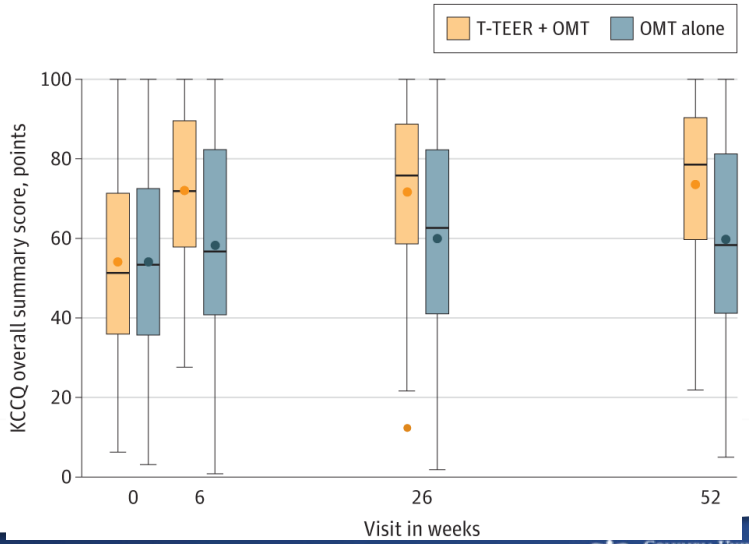
The Tri.Fr Randomized Clinical Trial…

allocated 300 patients to TEER or GDMT & demonstrated TR reduction and as well as a reduced composite, driven primarily by quality of life improvements

Survival



KCCQ Quality of Life



Randomized Trial Data I TTVR

THE TRISCEND II PIVOTAL TRIAL

Screening and Enrollment

Eligibility Confirmed by Independent Review Committee

R 2:1

EVOQUE + OMT

- Pre-procedure OMT continued ≥ 3 months post-implant
- Concomitant procedures not permitted

OMT Alone[a]

- Pre-study OMT continued (primarily oral diuretics)

Annual Follow-up Through 5 Years

0	Day 30	Month 3	Month 6	Year 1
	Primary Safety		Primary Effectiveness	Hierarchical Outcomes

CRF TCT

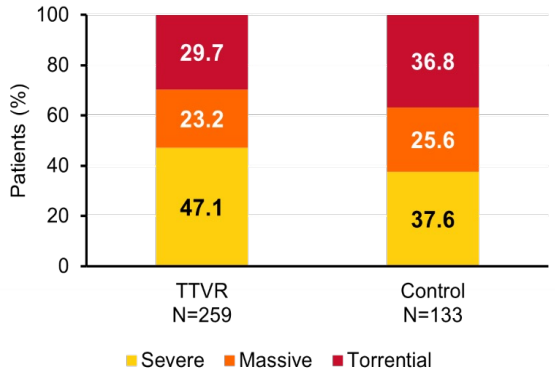
[a]Patients randomized to OMT alone may be eligible for treatment with the EVOQUE system following 1- or 2-year follow-up visits.
OMT, optimal medical therapy; *R*, randomization

Randomized Trial Data I *TTVR*

THE TRISCEND II PIVOTAL TRIAL

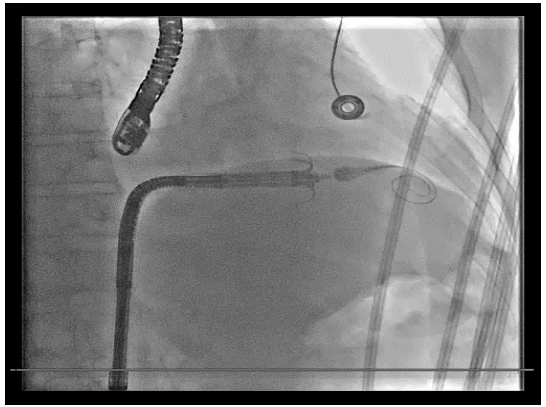
	TTVR N=259 Mean ± SD or %	Control N=133 Mean ± SD or %
Age, years	79.3 ± 7.4	79.1 ± 7.8
Female	74.9%	76.7%
NYHA class III-IV	73.0%	69.2%
KCCQ overall score, points	52.8 ± 22.0	50.6 ± 21.4
STS score, mitral valve replacement, %	9.6 ± 5.1	10.0 ± 5.2
Left ventricular ejection fraction, %	54.4 ± 9.9	54.3 ± 11.1
TAPSE, mm	16.3 ± 4.5	15.6 ± 4.2
Pulmonary artery systolic pressure, mmHg	38.6 ± 10.9	37.6 ± 11.3
Atrial fibrillation	96.1%	92.5%
Stroke	15.1%	9.0%
Chronic kidney disease	54.1%	59.4%
Ascites	18.5%	21.8%
HF hospitalization in past 12 months	34.0%	36.1%
History of pacemaker/CIED	38.2%	39.8%
Prior valve surgery/intervention	33.6%	30.8%

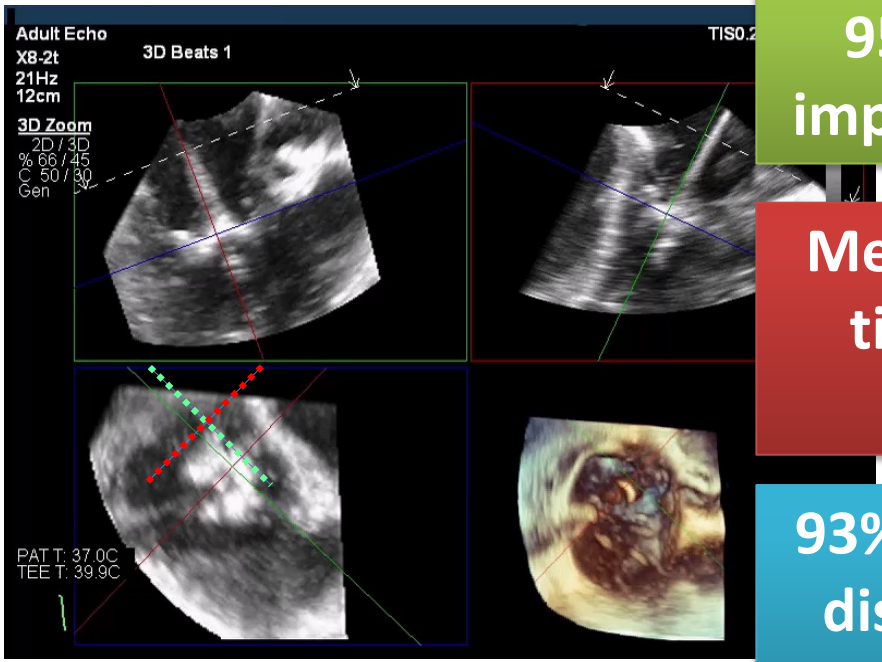
TR Etiology	TTVR N=259	Control N=133
Primary[a]	14.7%	14.3%
Secondary[b]	74.1%	71.4%
Mixed	9.7%	9.0%
Indeterminate	1.5%	5.3%



Baylor Scott and White Research Institute Cardiac Imaging Core Laboratory, Plano, TX, USA. Data from patients with available assessments. [a]Degenerative, organic, structural [illegible]. [b]Functional or nonstructural. CIED, cardiac implantable electronic device; HF, heart failure; KCCQ, Kansas City Cardiomyopathy Questionnaire; NYHA, New York Heart Association; STS, Society of Thoracic Surgeons; TAPSE, tricuspid annular plane systolic excursion; TR, tricuspid regurgitation; TTVR, transcatheter tricuspid valve replacement.

Randomized Trial Data I *TTVR*





95.4% valve implant success

Median device time of <60 minutes

93% of patients discharged to home

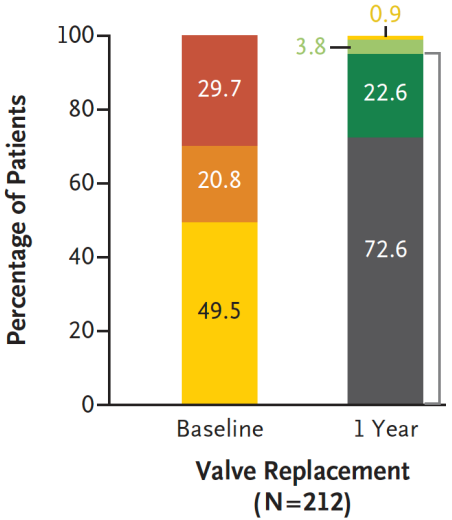
Typically live 3D MPR from a sin
deep esophageal view is enough

Randomized Trial Data I TTVR

TRISCEND II…

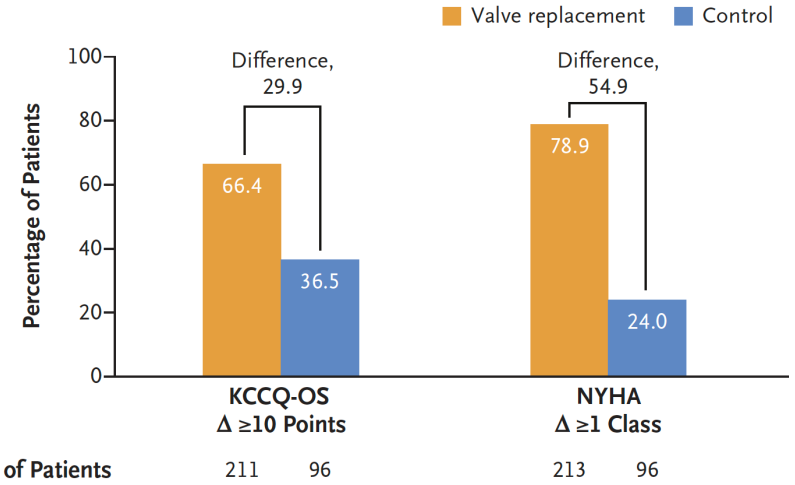
First randomized trial of TTVR vs GDMT (2:1) demonstrated near complete elimination of TR at 1-year along with QoL improvements

TR Reduction



95 % ≤ mild TR

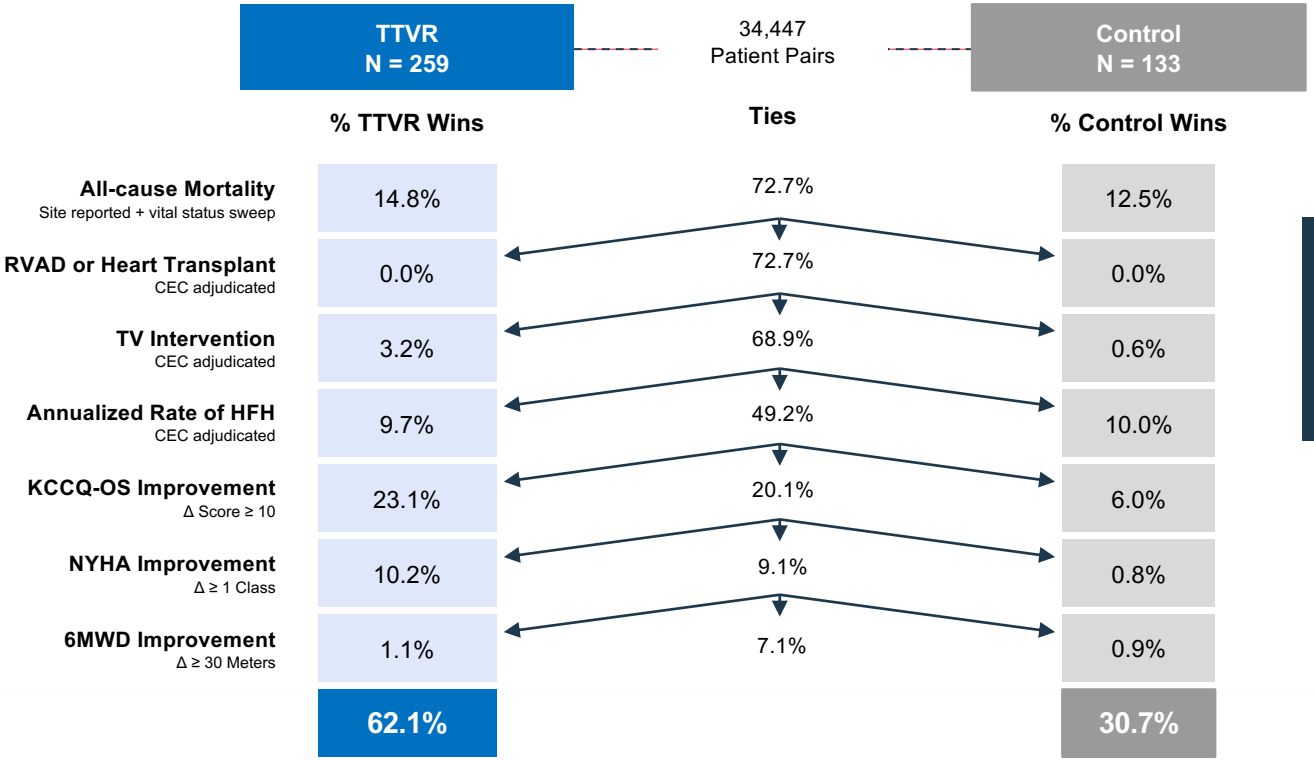
Quality of Life / NYHA Class



Hahn R et al. NEJM. 2025

Randomized Trial Data I *TTVR*

THE TRISCEND II PIVOTAL TRIAL



Win Ratio = 2.02
(95% CI, 1.56, 2.62)

Finkelstein-Schoenfeld:
P<0.001

6MWD, 6-minute walk distance; CEC, clinical events committee; HFH, heart failure hospitalization; KCCQ-OS, Kansas City Cardiomyopathy Questionnaire Overall Summary score; NYHA, New York Heart Association; RVAD, right ventricular assist device; TTVR, transcatheter tricuspid valve replacement; TV, tricuspid valve

CARDIOVASCULAR RESEARCH FOUNDATION
A Passion for Innovation

COLUMBIA UNIVERSITY MEDICAL CENTER
NewYork-Presbyterian
The University Hospital of Columbia and Cornell

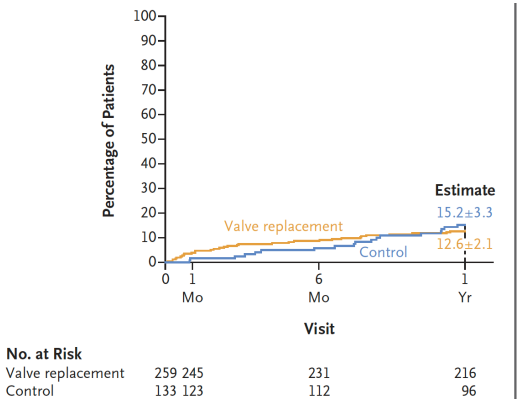
Randomized Trial Data I *TTVR*

TRISCEND II

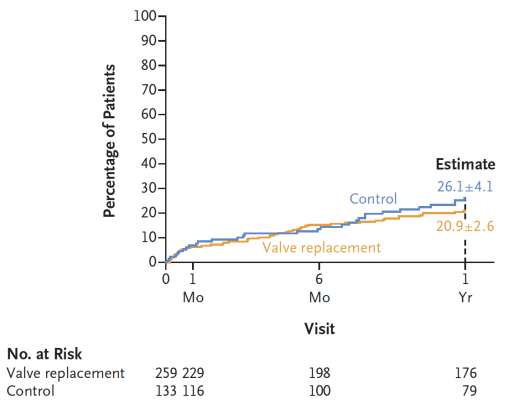
However, again no relevant benefit in terms of survival or HF hospitalization

AND: For TTVR a safety signal emerged, given 3% 30 day mortality 15% bleeding and 17% new PM

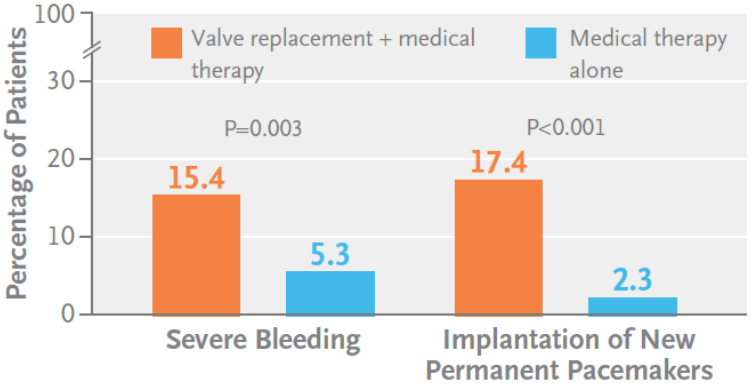
Mortality



HF Hospitalization



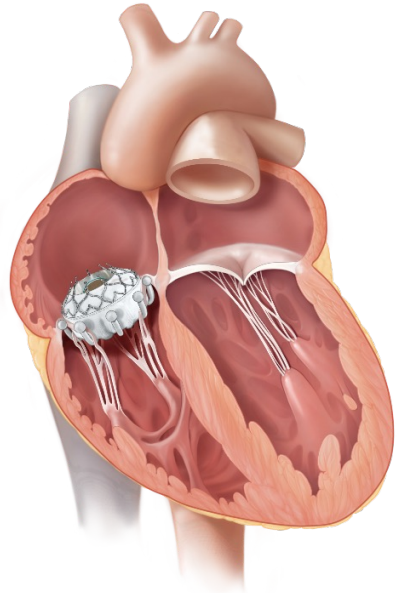
Adverse Events

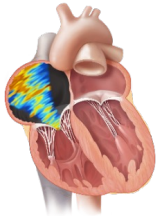


Hahn R et al. NEJM. 2025

TTVR and RV Mechanics

THE TRISCEND II PIVOTAL TRIAL





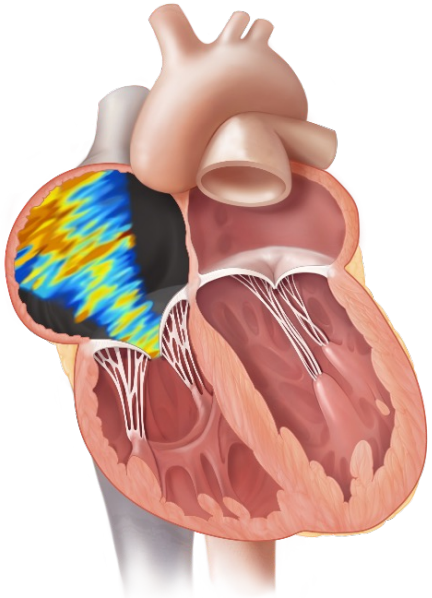
Randomized 2:1

TTVR + Medical Therapy N=267

Medical Therapy Alone N=133

Outcomes at 1 Year

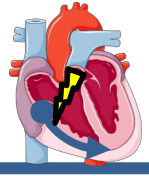
TTVR		Control
↓↓↓↓	TR Grade	↓
↓↓	Venous Congestion	—
↓↓	RV Size	—
↓↓	Preload-dependent RV Systolic Function	—
↓	RV-PA Coupling	—
↑	Forward Flow	—



Greyburn et al, NY Valves 2025

TTVR and Conduction Risk

NOCD+ population characteristics



Hyperdynamic RV longitudinal function

iRVEDV<120mL/m² in 1 out of 2 patients

Type IIIB TV in 1 out of 2 patients

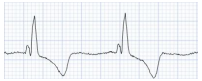
WBC peak over 13G/L in 1 out 2 patients post-procedurally

TTVR for severe and symptomatic TR

44.3% NOCD

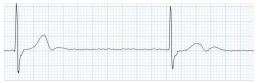
13.8% PPI in naïve-pacemaker patients

41.9% RBBB



19.4% CAVB

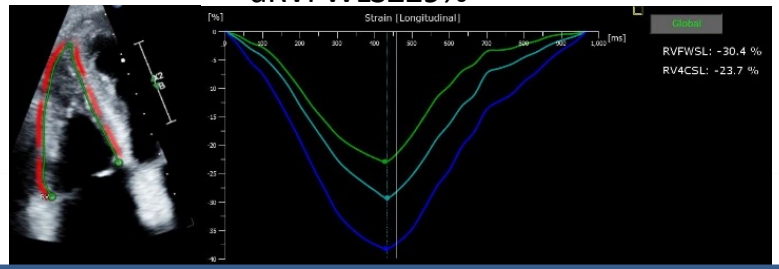
16.1% Slow aFib



Independent predictors for NOCD after TTVR

Model 1: all study population (n=70)

aRVFWLS≥29%



Model 2: post-TTVR CCTA assessment (n=43)

aRVFWLS≥29%

Anchor in MS

TTVR and Conduction Risk

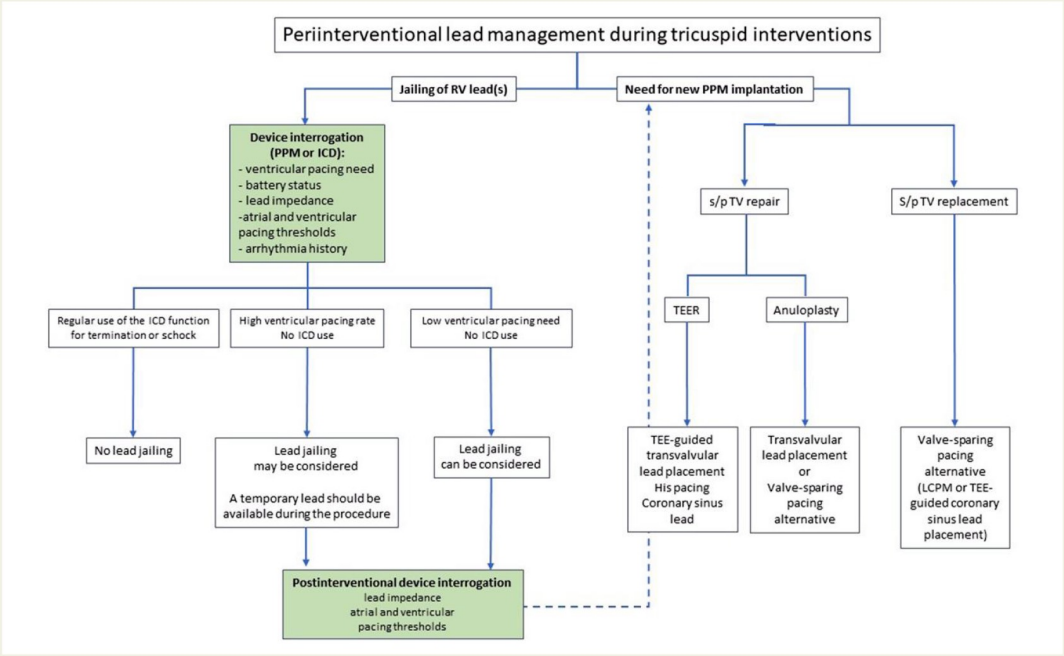


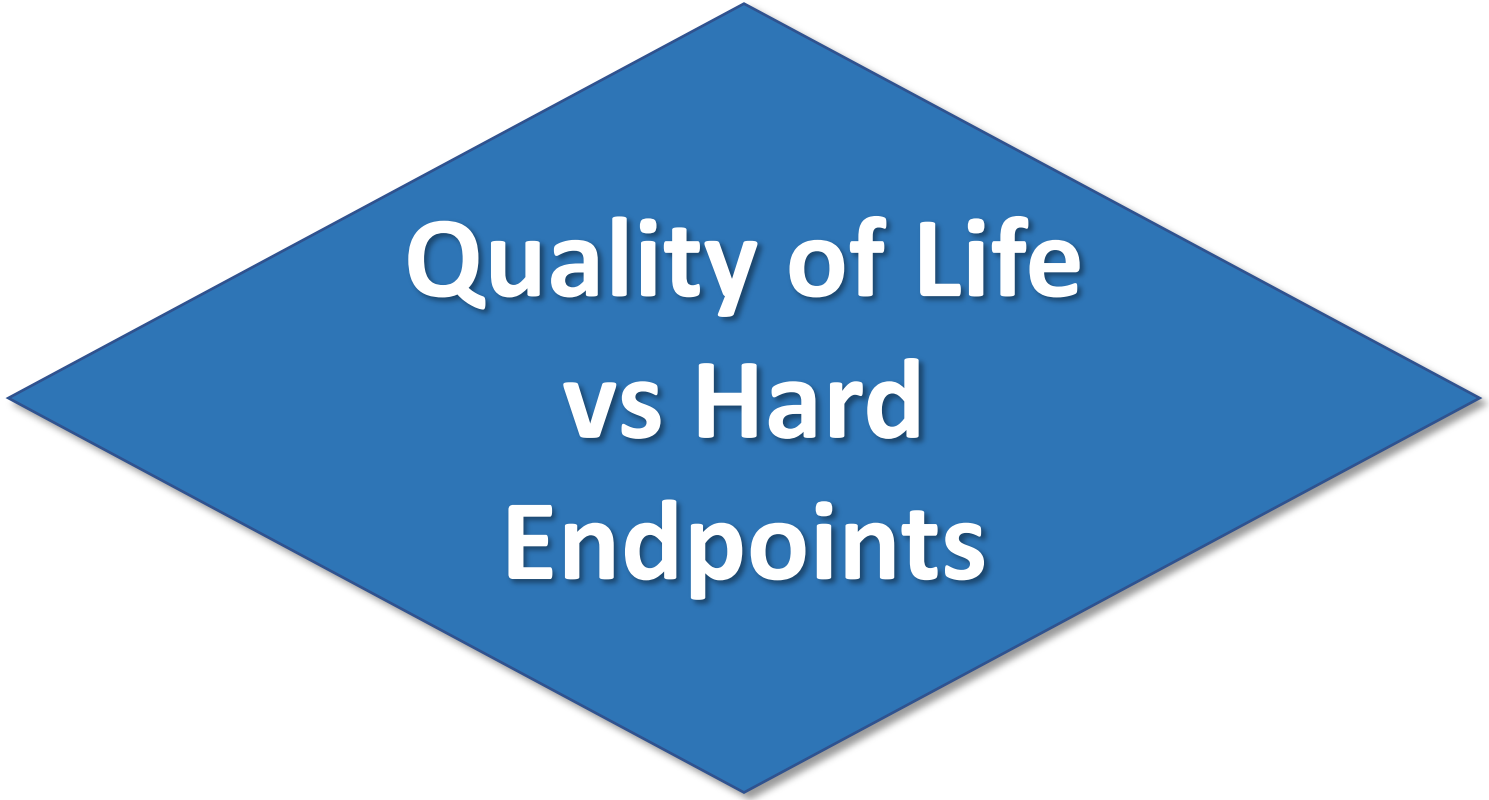
Figure 11 Peri-interventional lead management during tricuspid interventions. ICD, implantable cardioverter defibrillator; LCPM, leadless cardiac pacemaker; PPM, permanent pacemaker; RV, right ventricle; s/p, status post; TEE, transoesophageal echocardiography; TEER, transcatheter edge-to-edge repair; TV, tricuspid valve.

- Lead dysfunction can result from jailing by TTVR (~6% in Triscend II study)
- Lead extraction should be considered if feasible prior to TTVR
- Electrophysiologist should be part of the heart team

Clinical Trial Regrets

- Primary endpoint at one year
- Allowing cross-over at one year
- Lumping heterogenous populations into one trial without prespecified sub-group analyses
- Lack of registries in important subgroups that were excluded to understand limits of therapy

Not the end of the story for TTVI…



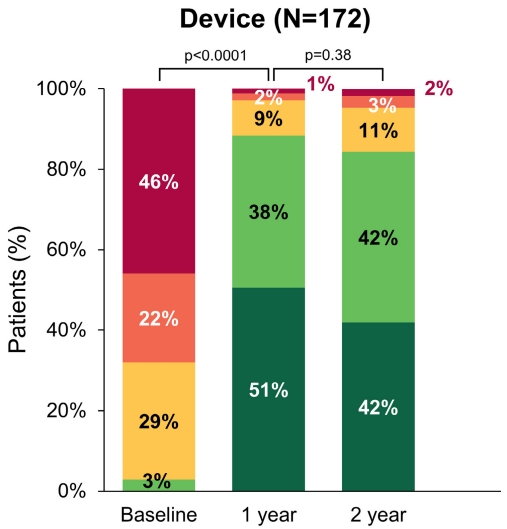
Impact of TTVR I *QoL vs. Hard Endpoints*

The TRILUMINATE Pivotal Trial

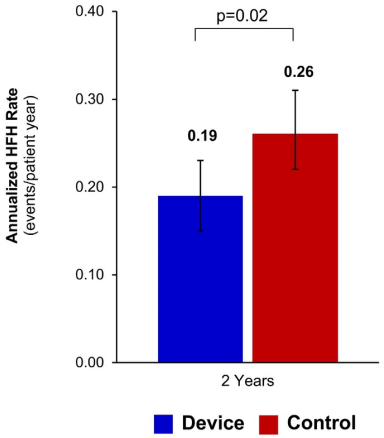
At 2-years TR reduction in the T-TEER group proved stable.

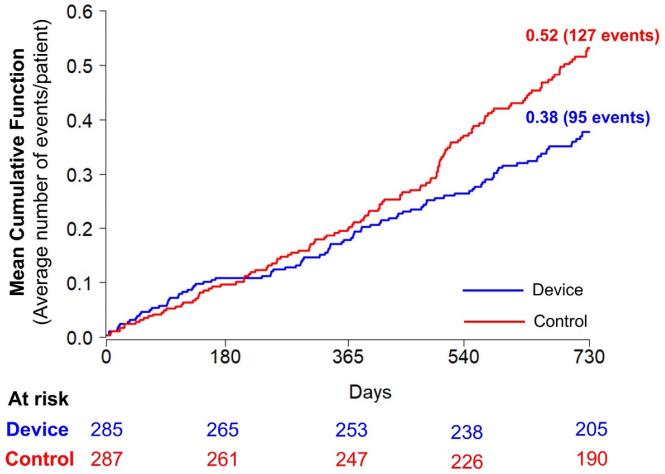
And: **NOW AT 2-YEARS a significant reduction of HFH was observed**

Stable TR Reduction



Significant Reduction of HF Hospitalizations at 2y



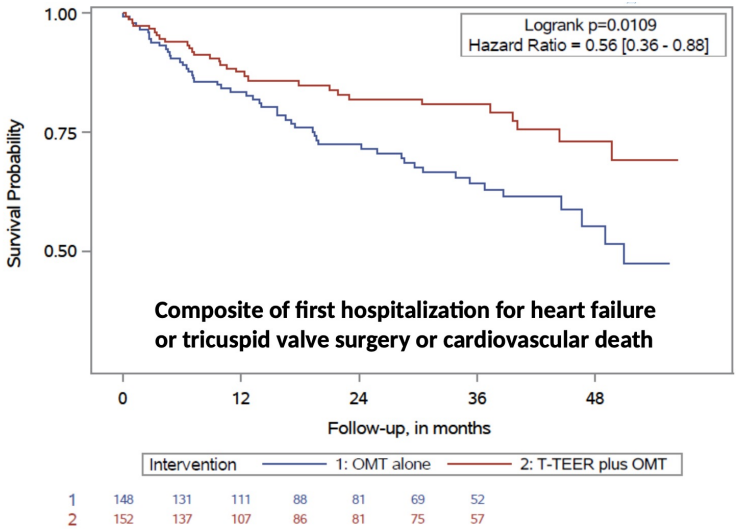


Kar S et al. Circulation. 2025

Impact of TTVR I *QoL vs. Hard Endpoints*

The Tri.Fr Randomized Clinical Trial

Also in Tri.Fr, **NOW AT 2-YEARS**, in the T-TEER group a **significant reduction of Heart Failure hospitalizations** was observed

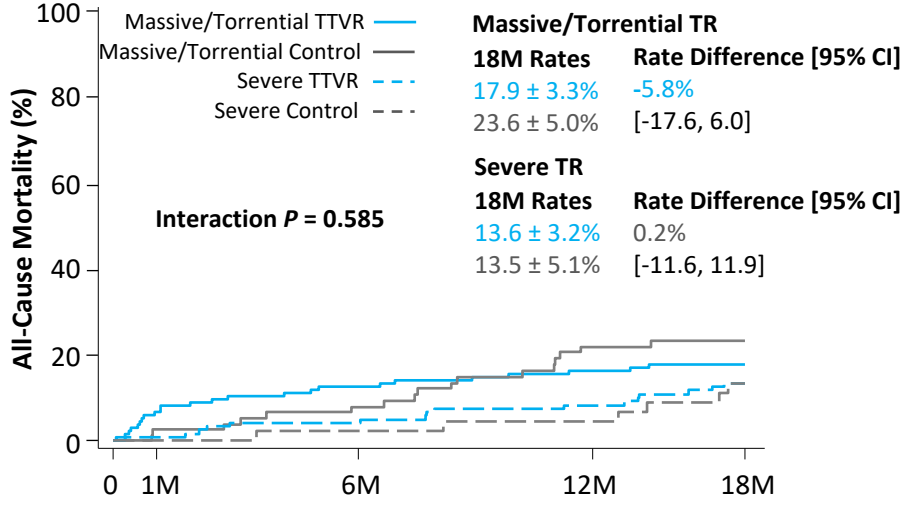


- **44% reduction of composite EP**
- **T-TEER induced a ≈50% reduction of HF-hospitalizations at 2-years**

Donal E et al. ACC 2026

Impact of TTVR I *QoL vs. Hard Endpoints*

All-Cause Mortality



Massive/Torrential TR

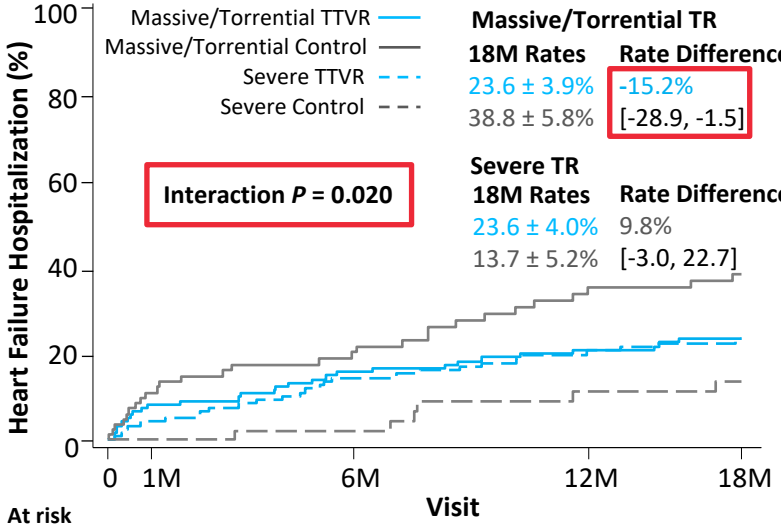
18M Rates	Rate Difference [95% CI]
17.9 ± 3.3%	-5.8%
23.6 ± 5.0%	[-17.6, 6.0]

Severe TR

18M Rates	Rate Difference [95% CI]
13.6 ± 3.2%	0.2%
13.5 ± 5.1%	[-11.6, 11.9]

At risk					
Mass/Torr					
TTVR	137	125	117	111	108
Control	83	75	67	53	51
Severe					
TTVR	122	120	114	106	99
Control	50	48	45	43	38

Heart Failure Hospitalization



Massive/Torrential TR

18M Rates	Rate Difference [95% CI]
23.6 ± 3.9%	-15.2%
38.8 ± 5.8%	[-28.9, -1.5]

Severe TR

18M Rates	Rate Difference [95% CI]
23.6 ± 4.0%	9.8%
13.7 ± 5.2%	[-3.0, 22.7]

At risk					
Mass/Torr					
TTVR	137	114	99	92	86
Control	83	68	56	41	38
Severe					
TTVR	122	115	99	85	80
Control	50	48	44	38	33

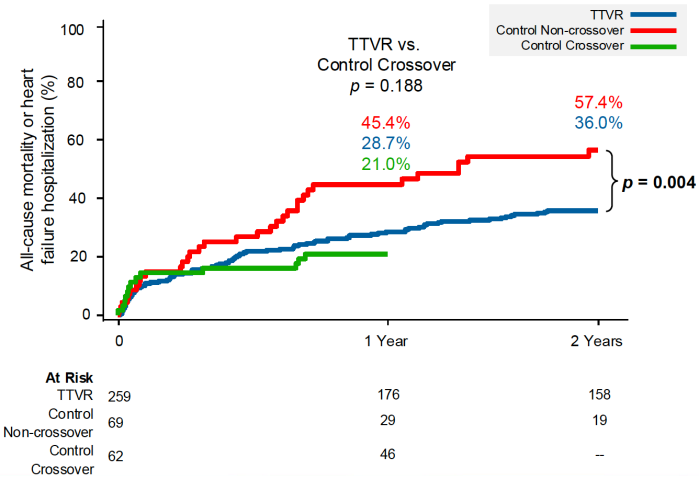
Lurz et al, EHJ 2025

Impact of TTVR I *QoL vs. Hard Endpoints*

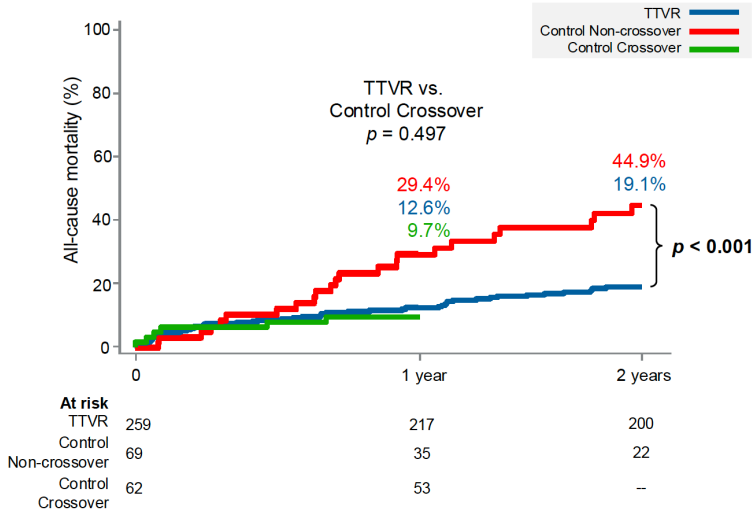
TRISCEND II

And also in TRISCEND II, **NOW AT 2-YEARS, in the TTVR group** (albeit limited by cross-over design) **a signal of significantly reduced mortality emerged**

Composite (Mort / HF Hosp)



Heart Failure hospitalizations



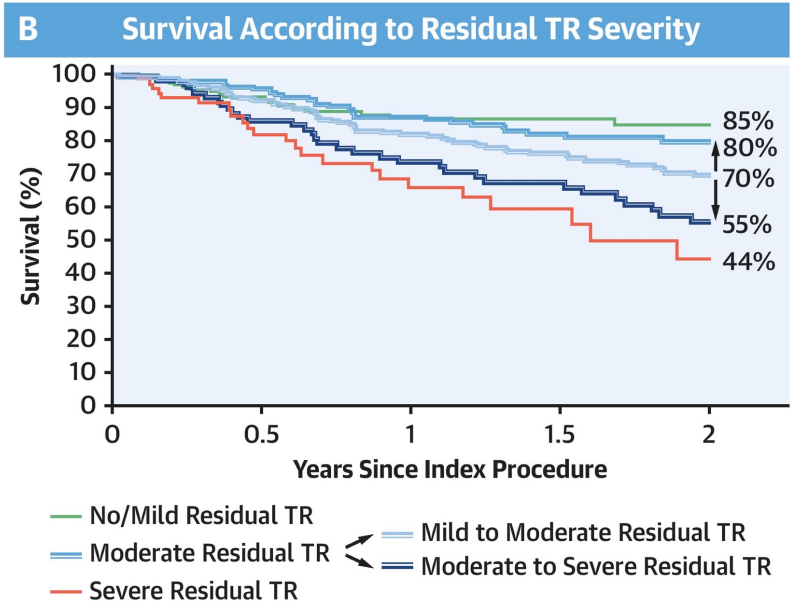
Thourani V et al. ACC 2026

Crossroads of TR Therapy

The Promise of TR Abolition I *Less TR is Better*

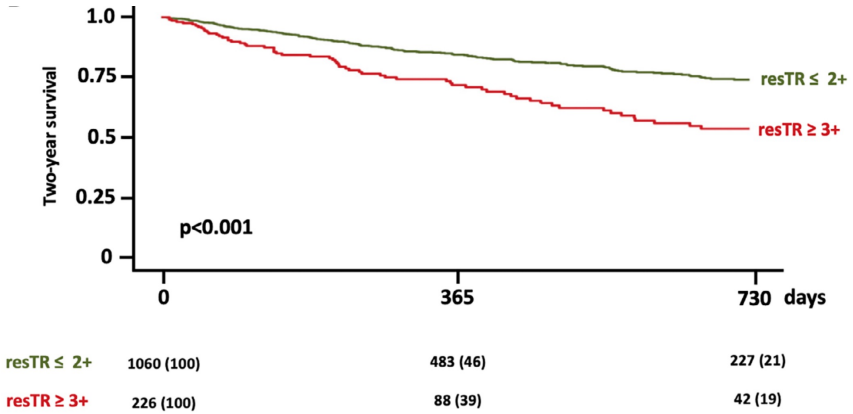
Consistent Data: Less TR post-procedure means better (soft+hard) outcomes

TRIGISTRY



Dreyfus J et al. JACC Interv. 2024

EuroTR Registry

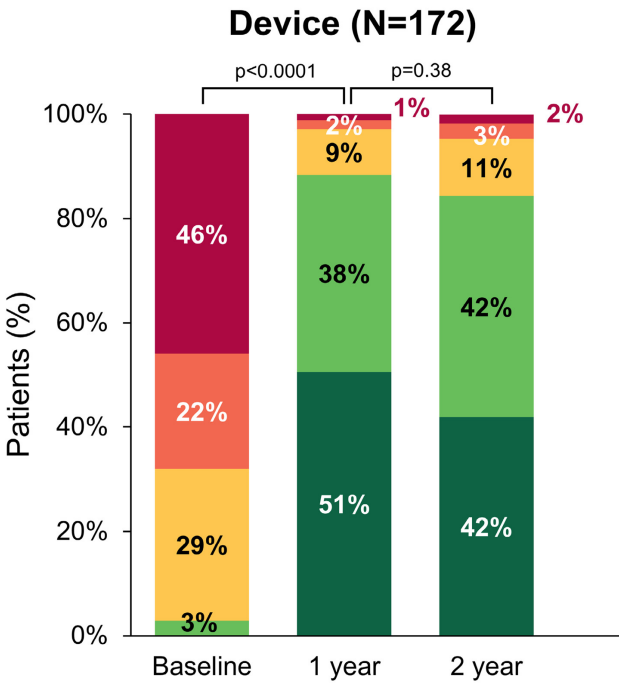


Stolz L et al. Eur J HF. 2024

The Promise of TR Abolition I *TR after T-TEER*

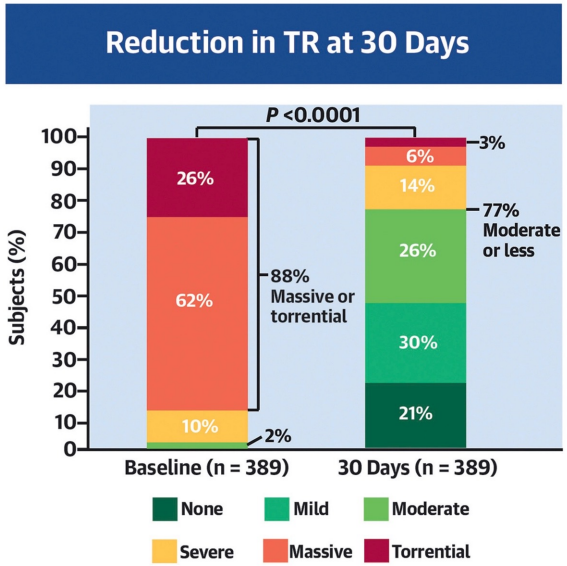
A relevant portion of patients (≈10%-20%) after T-TEER still has relevant TR

TRILUMINATE PIVOTAL



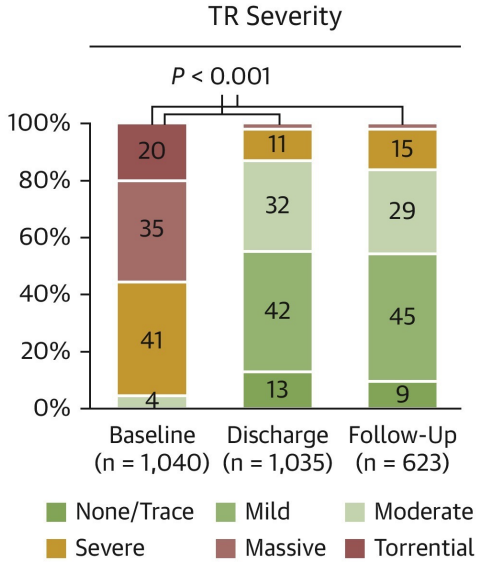
Kar S et al. Circulation. 2025

bRIGHT Registry



Lurz P et al. JACC. 2024

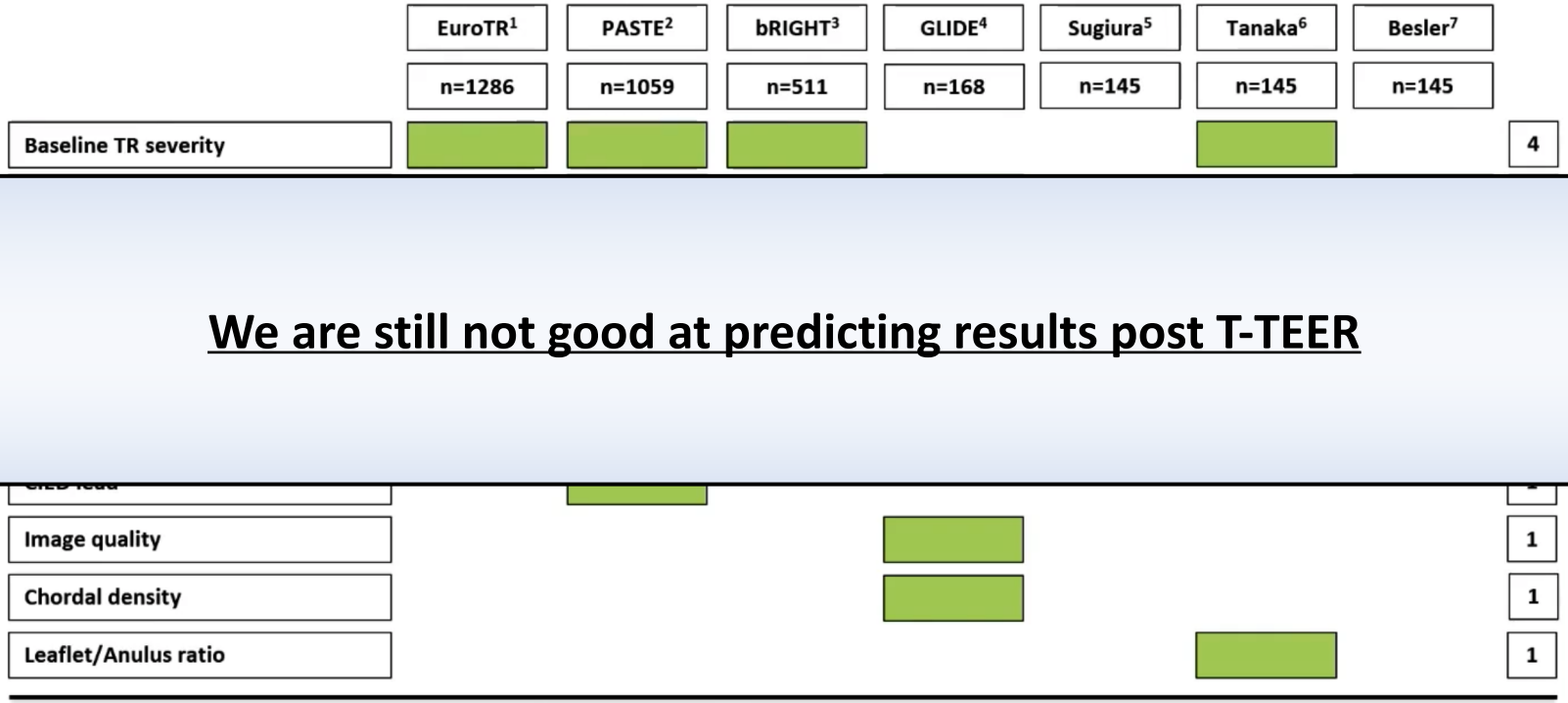
PASTE Registry



Wild M et al. JACC. 2025

The Promise of TR Abolition I

Predictors of residual TR following T-TEER



We are still not good at predicting results post T-TEER

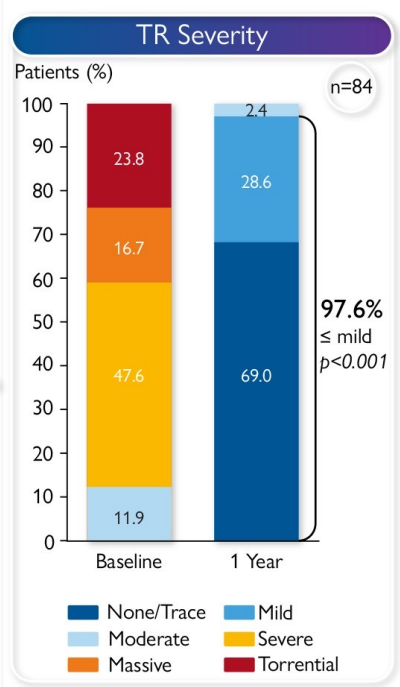
(1) doi: 10.1002/ejhf.3274; (2) doi: 10.1016/j.jacc.2024.10.068; (3) doi: 10.1016/j.jacc.2023.05.008; (4) doi: 10.1016/j.jcmg.2024.04.008; (5) doi: 10.4244/EIJ-D-21-00862; (6) doi: 10.1016/j.jcin.2021.07.048; (7) doi: 10.1016/j.jcin.2018.05.002

Stolz L et al. Eur J HF. 2025

The Promise of TR Abolition I *TR after TTVR*

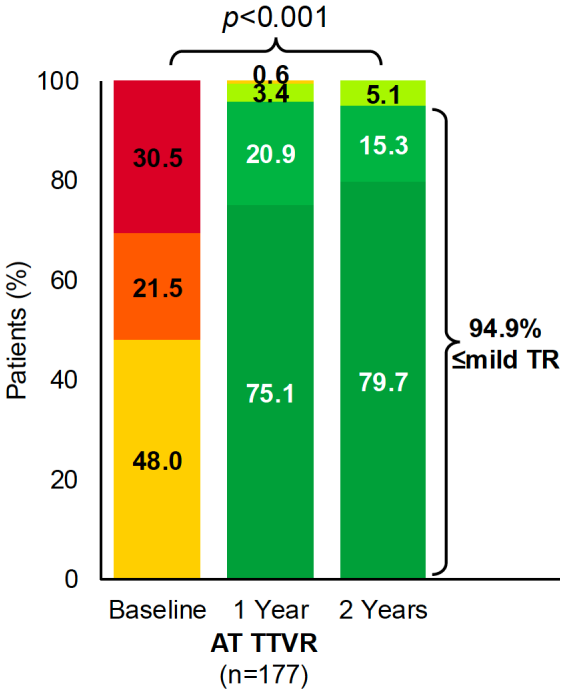
In contrast to T-TEER, TTVR shows consistent near-elimination of TR

TRISCEND I



95 % ≤ mild TR

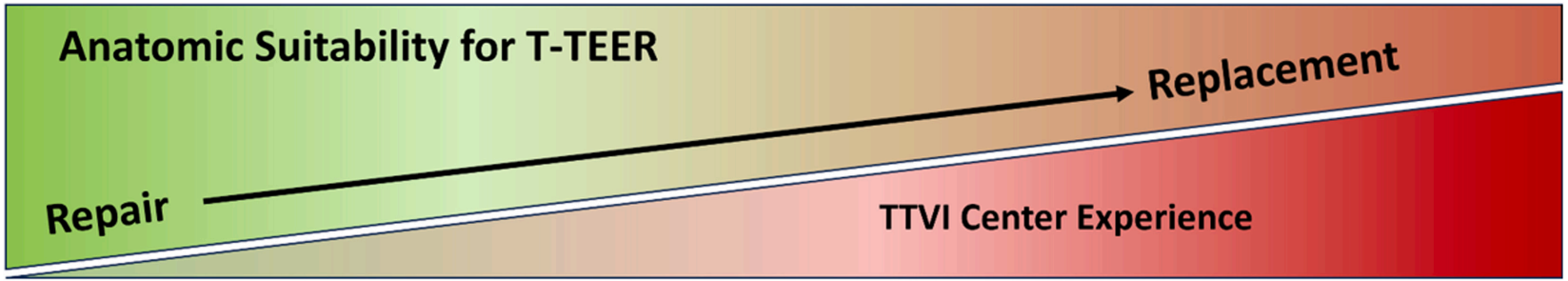
TRISCEND II



Kodali S et al. Eur Heart J. 2023

Thourani V et al. ACC 2026

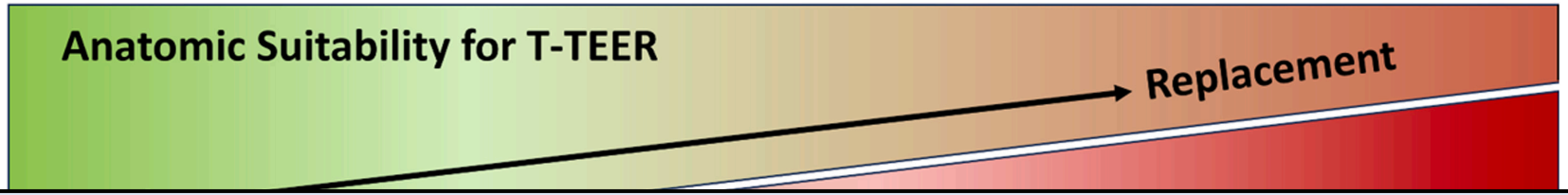
The Promise of TR Abolition I *T-TEER vs. TTVR feasibility*



Favorable anatomy for T-TEER	Feasible Anatomy for T-TEER	Unfavorable anatomy for T-TEER
• Small septolateral gap ≤7 mm • Anteroseptal or central jet location • Confined prolapse or flail • Bileaflet or Trileaflet morphology • TR <torrential • Leaflet-to-annulus ratio <1.06 • Low tethering height • Low RA Volume • No CIED lead • Good TEE imaging of leaflets from multiple views	• Septolateral gap >7 but ≤8.5 mm • Posteroseptal jet location • Complex leaflet morphology (>3) • Incidental CIED (i.e., without leaflet impingement) • CIED-related TR (if ↓TR to optimal or acceptable level is possible) • Acceptable TEE imaging of leaflets from multiple views and/or good 3D ICE imaging	• Large septolateral gap >10-15 mm • Anterior-posterior commissural jet location • Leaflet thickening/shortening/perforation • Dense chordae w/ marked leaflet tethering or immobility • CIED-related TR with <1 grade reduction likely • Torrential TR (EROA >1.5 cm^2) • Poor leaflet visualization by any echocardiographic modality

Hahn RT. JACC HF. 2025

The Promise of TR Abolition I *T-TEER vs. TTVR feasibility*



BUT

It is not just anatomy & imaging … *feasibility* of TTVR also means:

- **Can the patient tolerate life-long OAC?**
- **Is the patient frail, at HBR, or preferring the less invasive/less risky approach?**

• Low RA Volume • No CIED lead • Good TEE imaging of leaflets from multiple views	• Acceptable TEE imaging of leaflets from multiple views and/or good 3D ICE imaging	likely • Torrential TR (EROA >1.5 cm^2) • Poor leaflet visualization by any echocardiographic modality

Hahn RT. JACC HF. 2025

Tricuspid Valve Therapies: The Future?

Anatomic and clinical considerations for device therapies…

Leaflet Technologies

- Mobile leaflets
- Good quality imaging
- Minimal tethering
- Small gaps
- No excessive chords
- Procedural safety

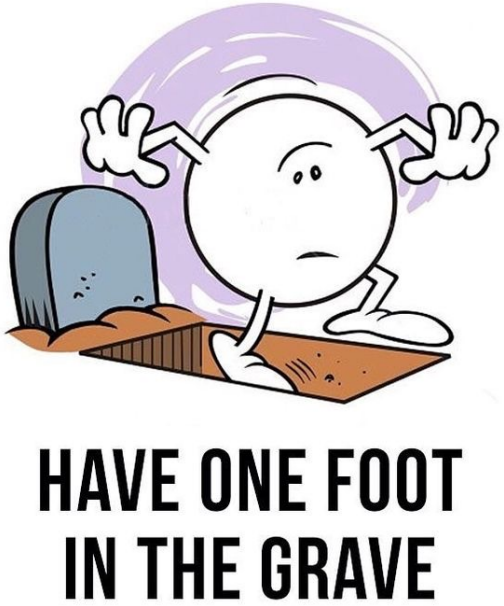
Replacement

- Annular size not excessively large
- RV function
- Pacemaker risk
- IVC location
- Ability to tolerate AC

Etiology of TR will Impact Anatomic Considerations

Tricuspid Valve Intervention I *Who is too sick?*

Defining "Cohort C" in Tricuspid Regurgitation



- The early years of TAVR focused on defining not only on *who to treat* but also *who not to treat*
- Defining "cohort C" in TR is not so simple
  - Patients often present late in disease state with extreme frailty and multiple comorbidities
  - Many patients present with "end-stage" liver and kidney disease - however, removing volume load may reverse those conditions
  - Often unknown whether improving cardiac output with TTVR will help reverse clinical deterioration
- There remains a lot to learn and mistakes will be made

Tricuspid Valve Intervention I *Who is too sick?*

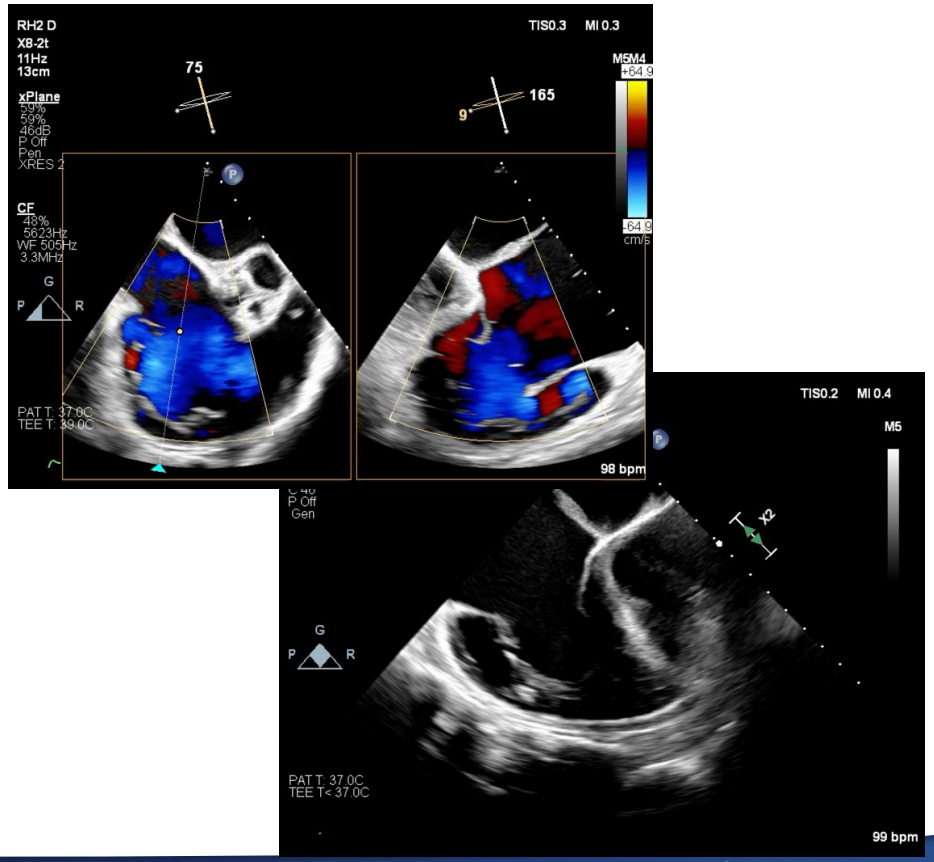
84-year-old male admitted to the hospital with altered mental status and lethargy.

Multiple recent hospital admissions for decompensated cirrhosis with hepatic encephalopathy.

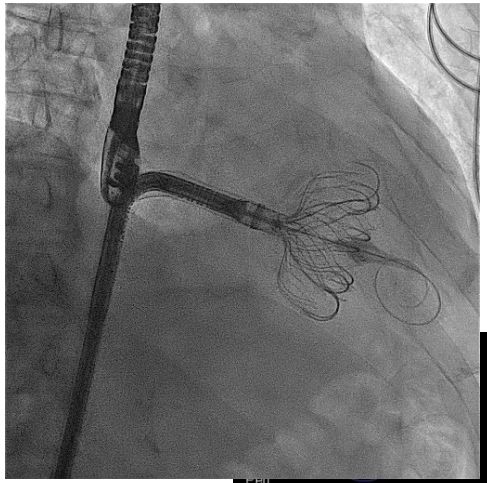
Labs notable for Plt 69, sCr 1.94, T.bili 10.3, Albumin 3.2, ntproBNP 5338, Lactate 6.5

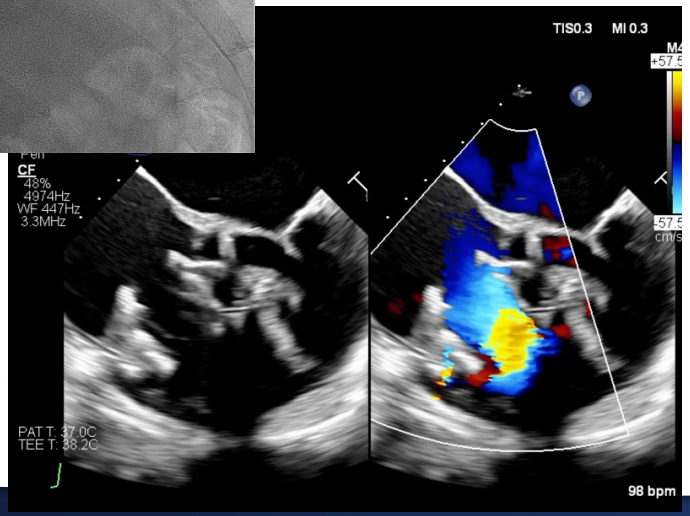
Echo shows torrential TR

Patient extremely frail and bed bound



Tricuspid Valve Intervention I *Who is too sick?*





Underwent TTVR with 56mm Evoque

6 Month Follow up

- Increased exercise tolerance with NYHA Class I symptoms – 6MWT increased to 393m at 6 months
- Ascites and edema resolved and patient off diuretic therapy.
- On eliquis (low dose 2.5 mg BID) for anticoagulation
- Nt-proBNP 628 (normal)
- Echo:
  - RV size moderately increased
  - RV function mildly reduced
  - Well functioning TTVR

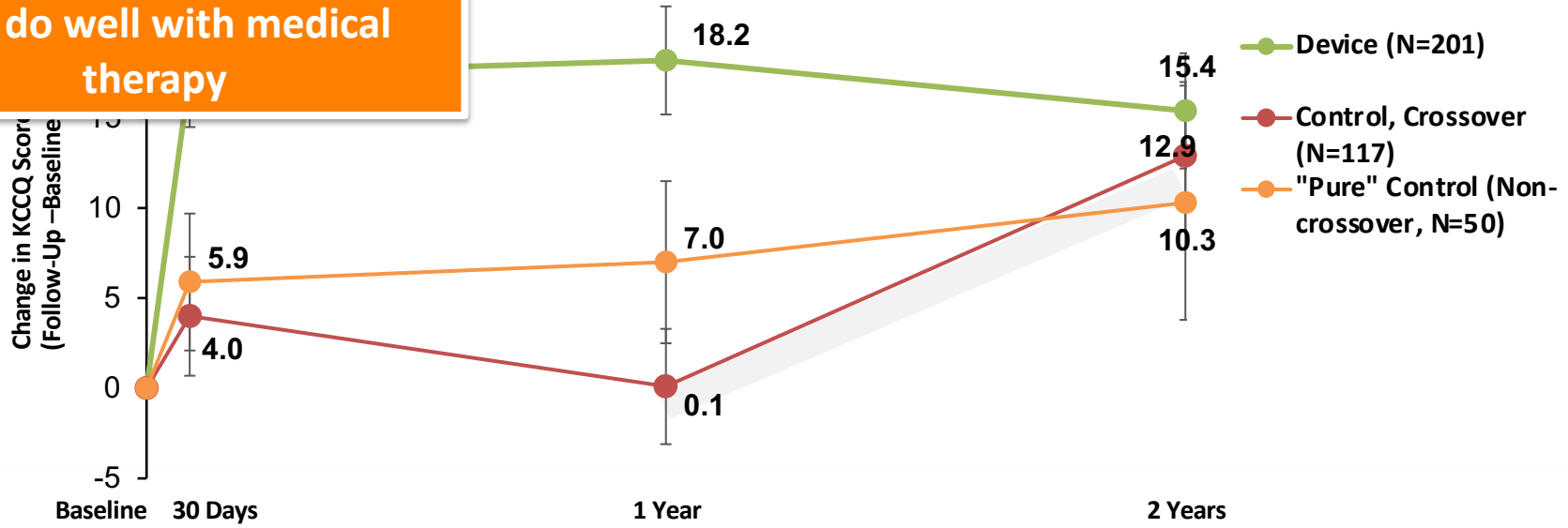
Tricuspid Valve Intervention I *Who is too well?*

TRILUMINATE PIVOTAL TRIAL

Health Status Through 2 Years

ACC.26

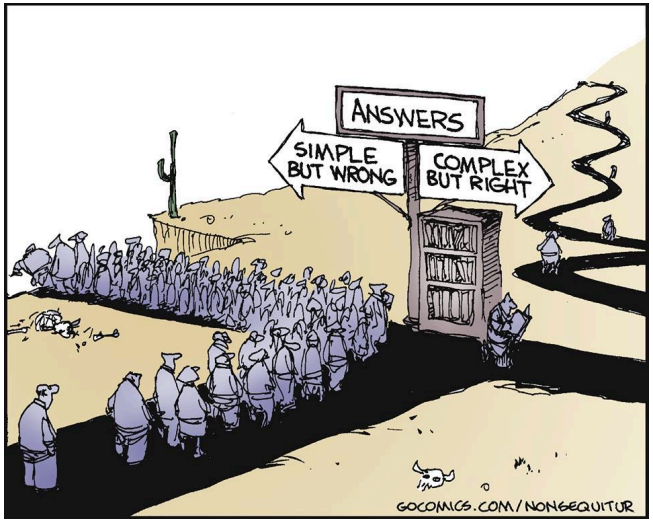
Need to identify those patients that do well with medical therapy



Control eligible for crossover after 1-year follow-up visit

Tricuspid Valve at the Crossroads:
Promising Path Ahead

- Multiple studies have demonstrated that TR is prevalent and has a significant clinical impact
- Undertreatment due to high surgical risk has created an unmet need and led to the development of new therapies
- Initial data has demonstrated clinical effectiveness and improvement in QOL endpoints



Stay tuned for an exciting journey

Tricuspid Valve at the Crossroads:
Promising Path Ahead

- Longer term follow-up has demonstrated a potential impact on hard clinical endpoints including mortality with treatment of tricuspid regurgitation, especially when it is massive/torrential
- Heart teams now have to carefully decide who to treat and how to treat based on clinical and anatomic features

Thank you!

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