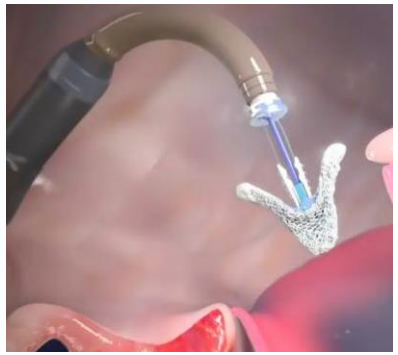
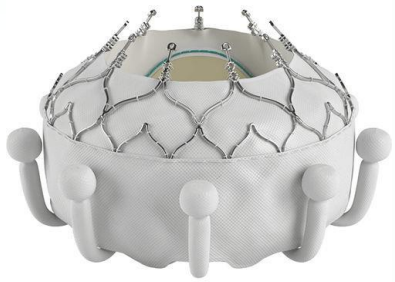
Catheter-Based Strategies to Treat Tricuspid Valve Disease





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Disclosure

- Co-investigator for CLASP and TRISCEND trials

Functional Tricuspid Regurgitation is a Progressive Disease

- Time to TR progression
  - Trivial/mild to mod/severe 5.3 ± 3 yrs

- Independent Risk factors for TR progression:
  - PASP change (p<0.0001)
  - Permanent AF OR=14.3 (p <0.0001)
  - CAD OR (p =0.015)

- Progression-to-severe TR independently predicted subsequent mortality.

1-year survival with severe TR 64%

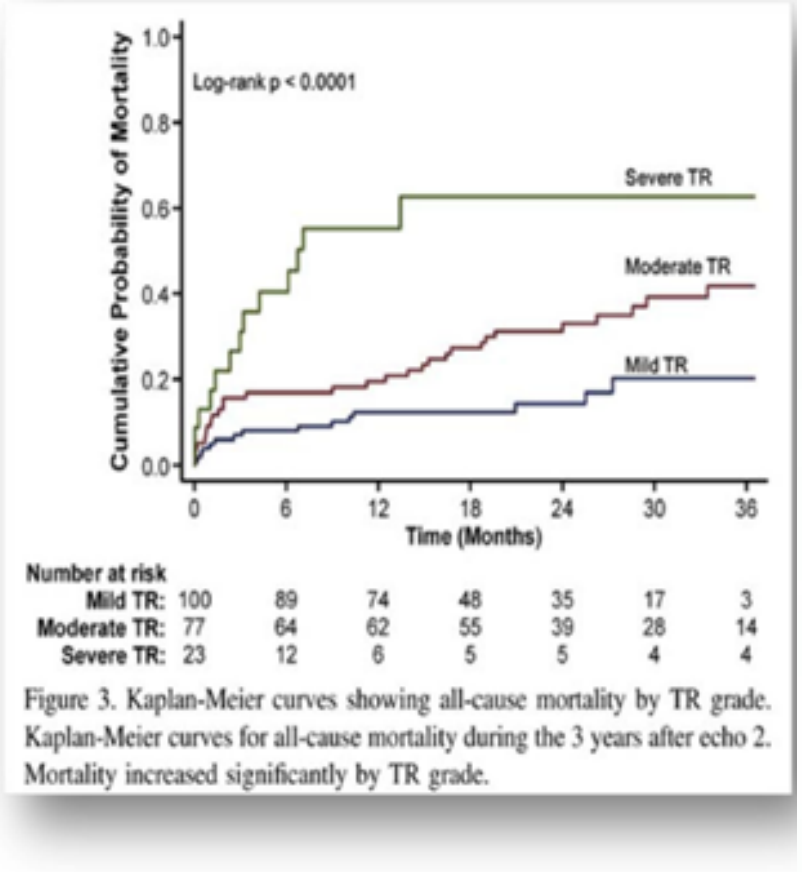


Figure 3. Kaplan-Meier curves showing all-cause mortality by TR grade. Kaplan-Meier curves for all-cause mortality during the 3 years after echo 2. Mortality increased significantly by TR grade.

Shiran A et al *Am J Cardiol* 113:995-1000; 2014

Tricuspid Valve Operations (2002-2014)
STS Database

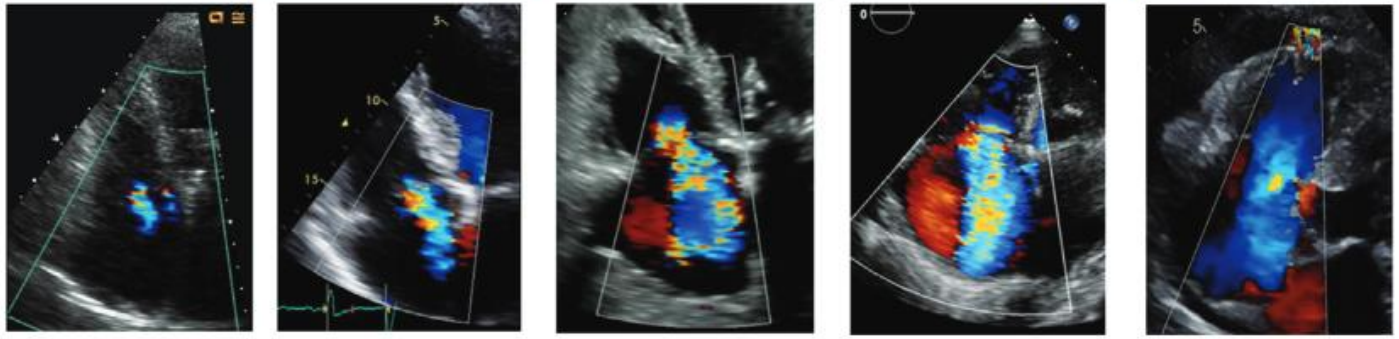
- Isolated Tricuspid Valve Operations n=2,050

  - ® Operative Mortality (9%)
  - ® 170 Cases Per Year in US
  - ® Major Morbidity (42%)

Courtesy of Charles Davidson, MD

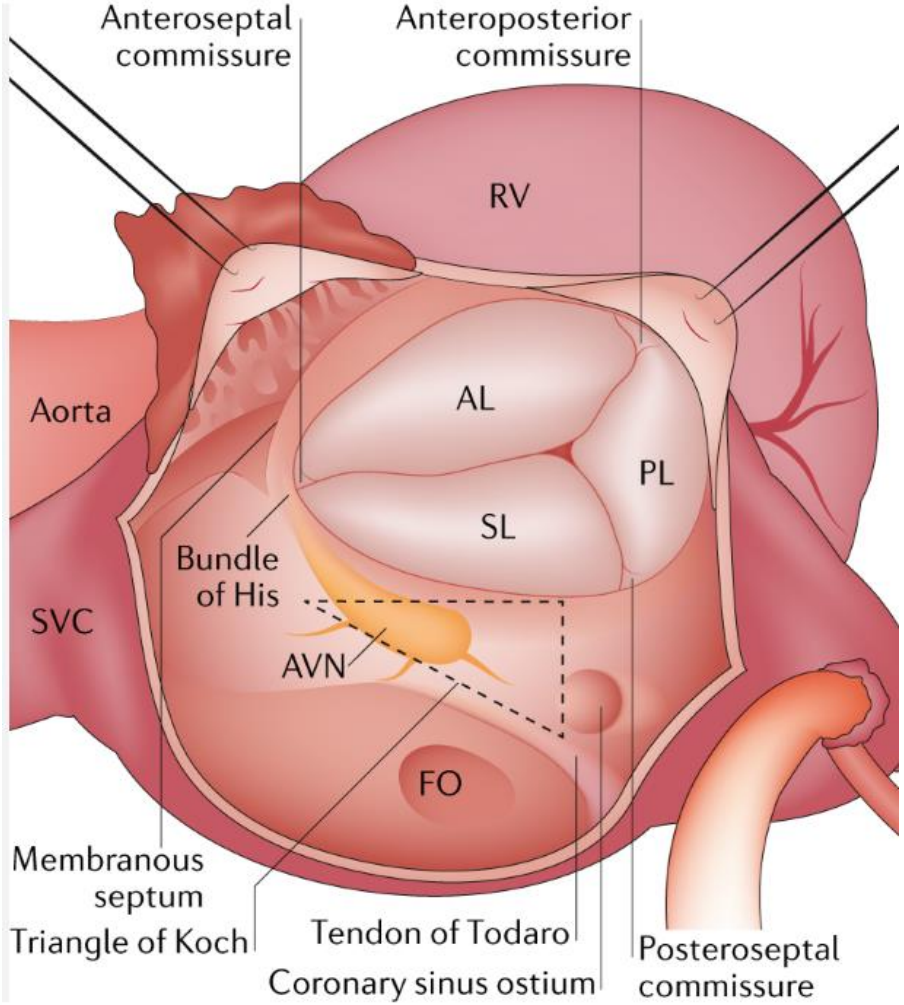
Imaging Assessment of Tricuspid Regurgitation Severity

Parameters	MILD	MODERATE	SEVERE	MASSIVE	TORRENTIAL
Vena Contracta width (biplane average)	<3 mm	3-6.9 mm	7 mm - 13 mm	14-20 mm	≥21 mm
EROA by PISA	<20 mm^2	20-39 mm^2	40-59 mm^2	60-79 mm^2	≥80 mm^2
3D Vena Contracta Area or Quantitative Doppler EROA	-	-	75-94 mm^2	95-114 mm^2	≥115 mm^2



Hahn JACC Imaging 2019;12:469-90

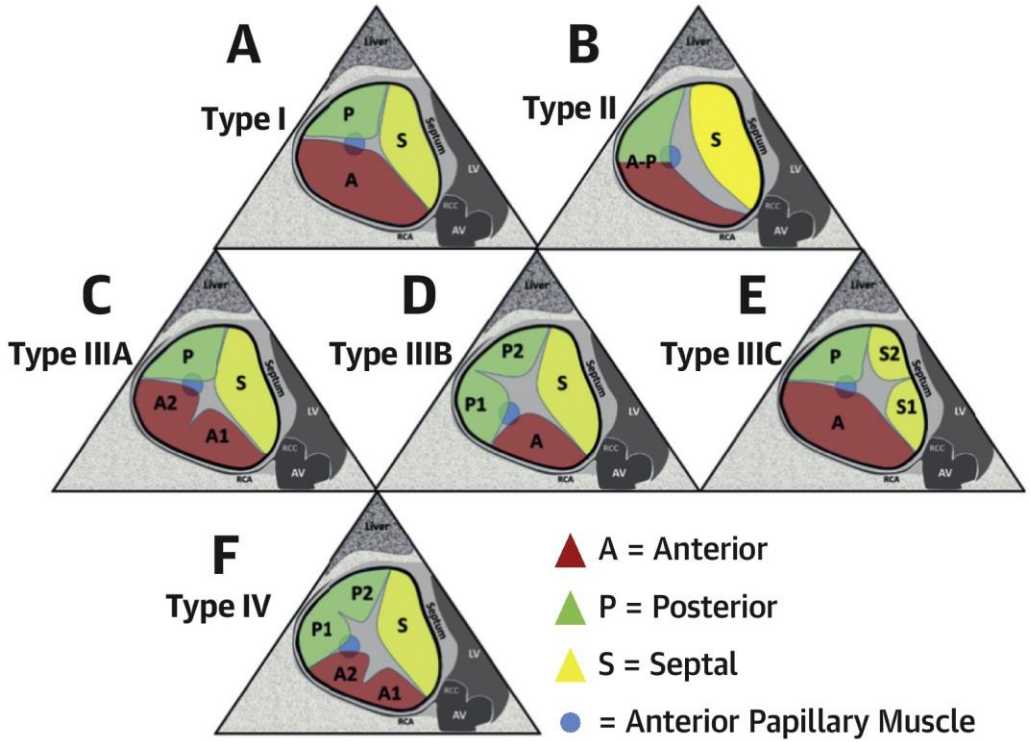
Tricuspid Valve Anatomy

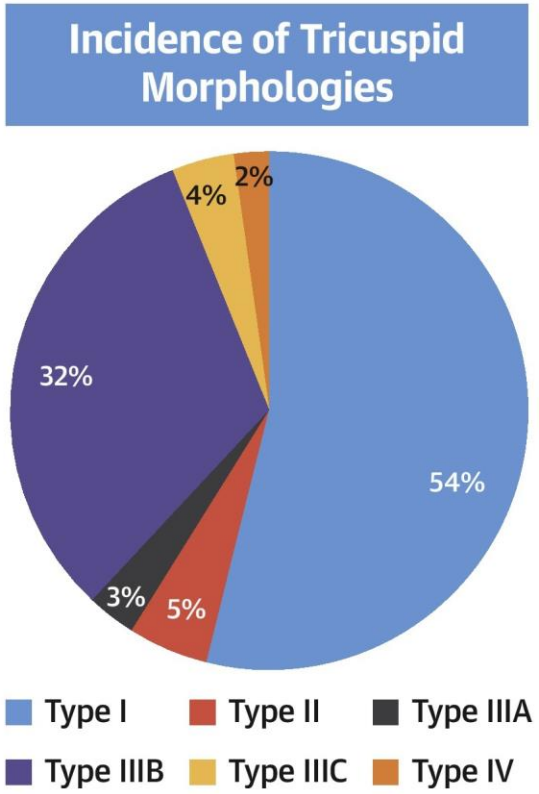


Asmarats et al *Nat Rv Card* 2019;16:538-54

The Tricuspid Valve Has Great Variability

CENTRAL ILLUSTRATION: Tricuspid Valve Nomenclature
Classification Scheme



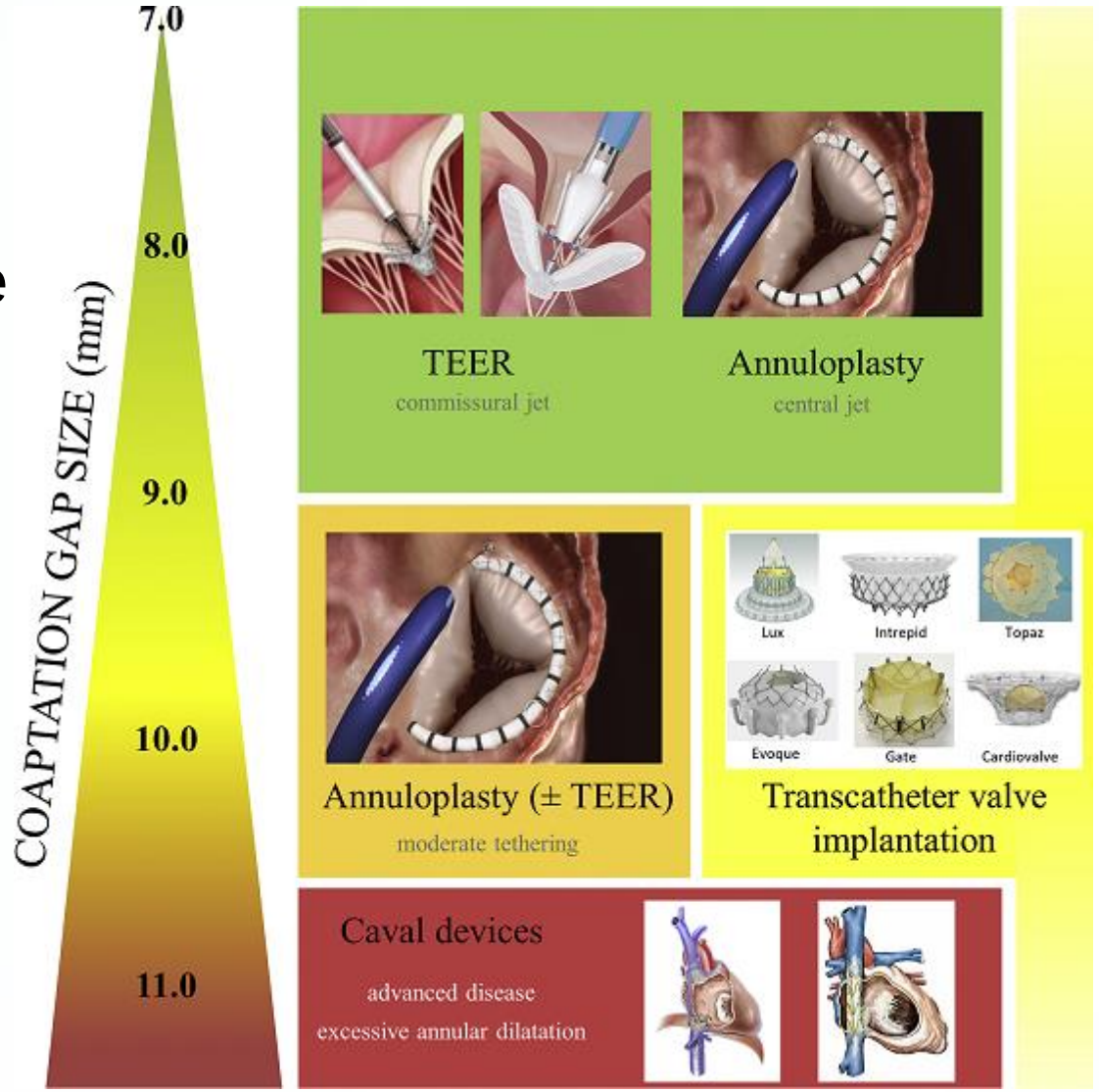


Hahn, R.T. et al. J Am Coll Cardiol Img. 2021;14(7):1299-305.

Transcatheter Tricuspid Landscape

Dozens of devices

Some in trials …
some already gone



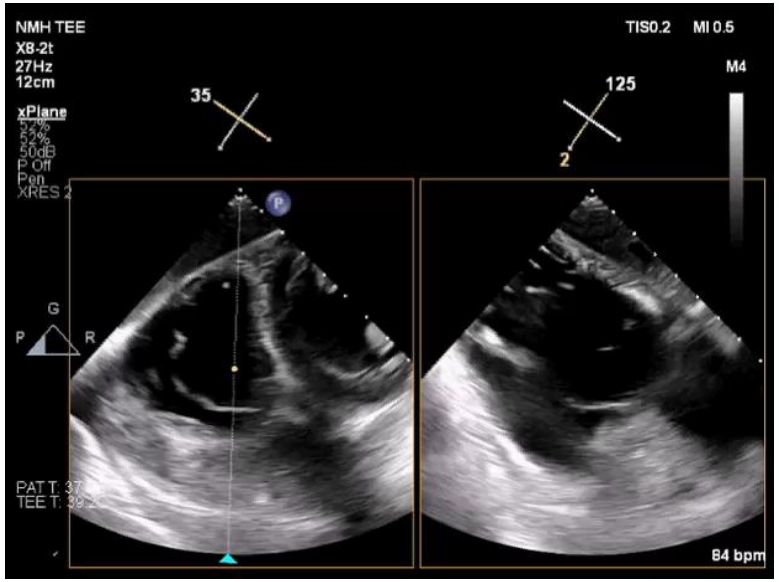
No options “options”

Spacers
Caval devices

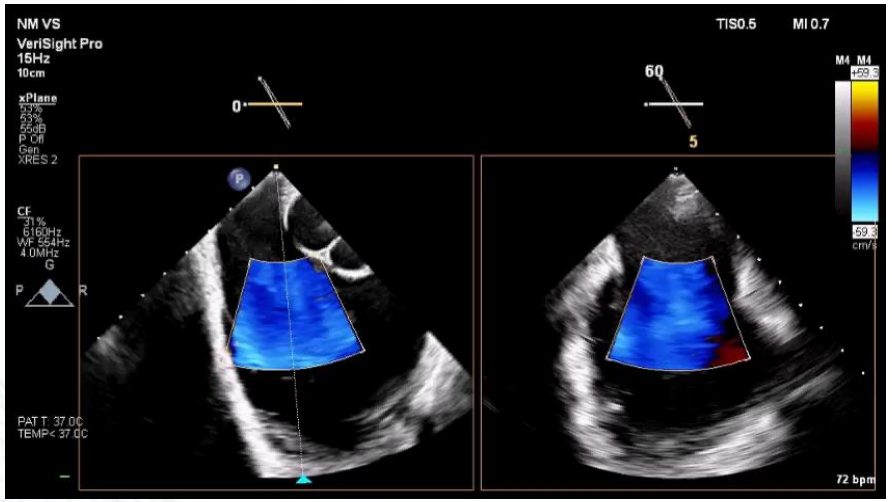
Wild and Praz JACCInt 13:1378-81; 2022

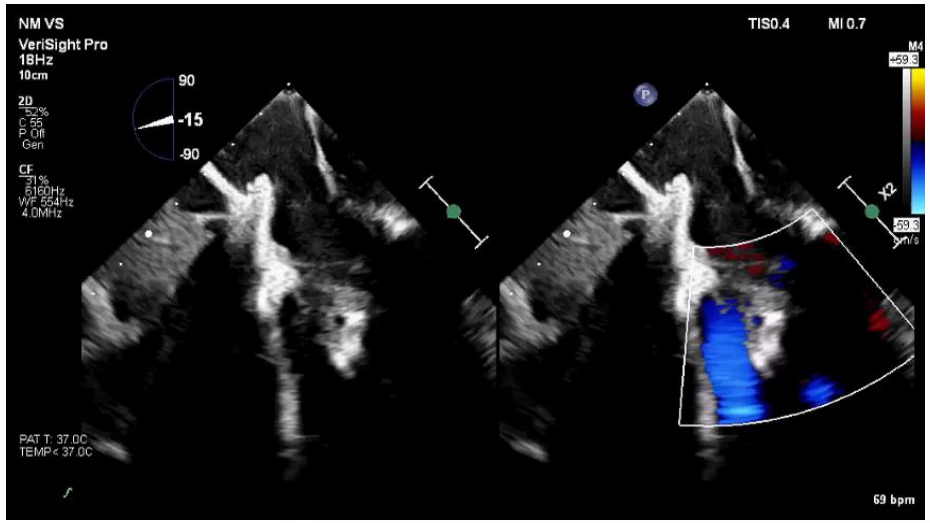
Case 1

- 61 y/o man s/p OHT
- Posterior-septal flail
- Torrential TR (ROA-PA 123, RV 56)
- Good leaflet length, narrow gap
- Annulus mildly dilated



Choice: TEER

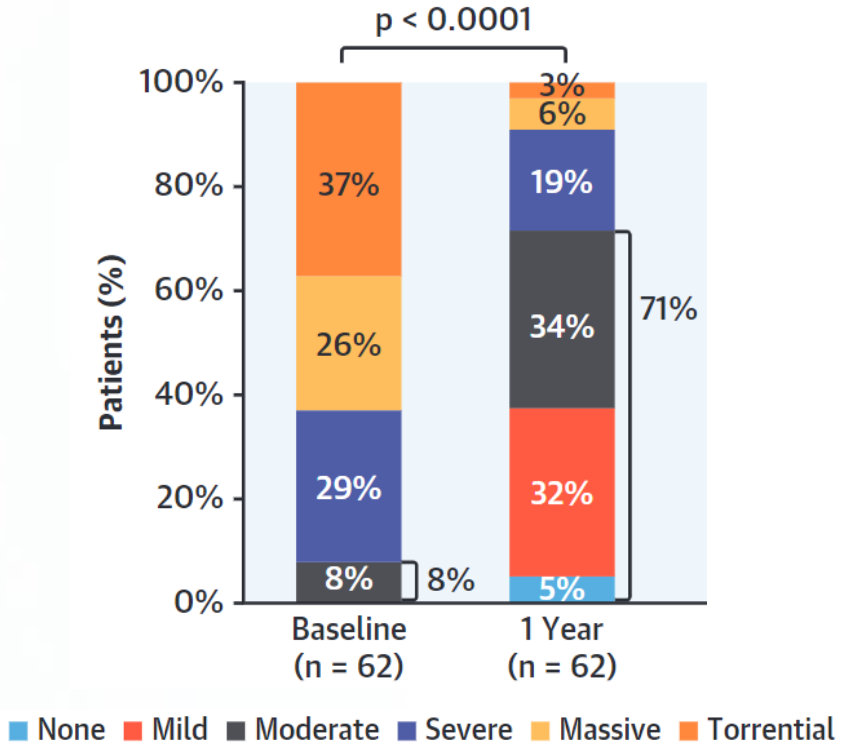


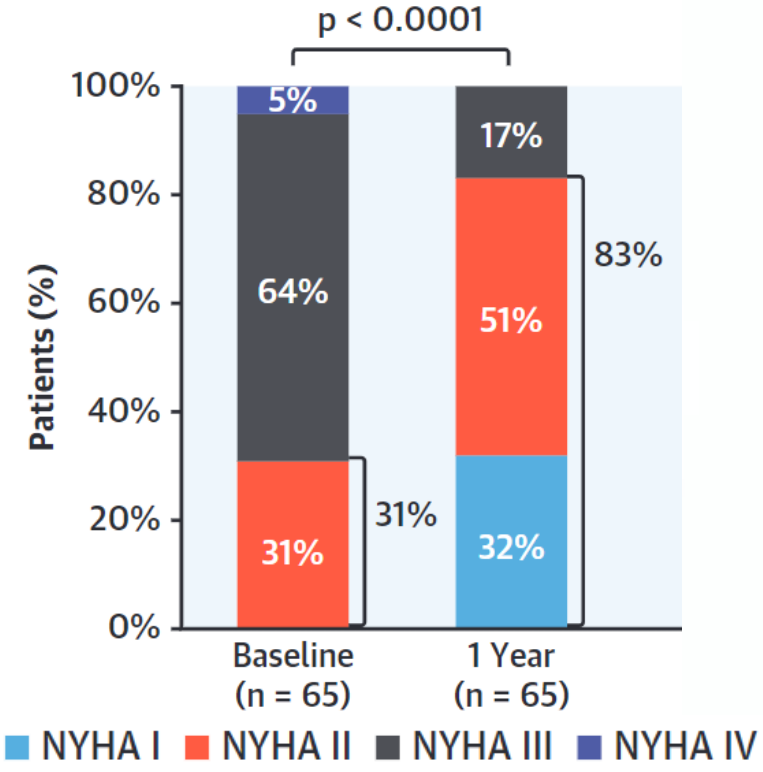


TEER for Tricuspid Regurgitation

TRILUMINATE (“*MitraClip*” for TR)

Transcatheter Edge-to-Edge Repair for Treatment of Tricuspid Regurgitation



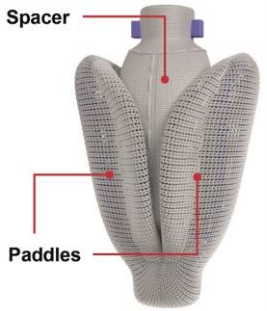


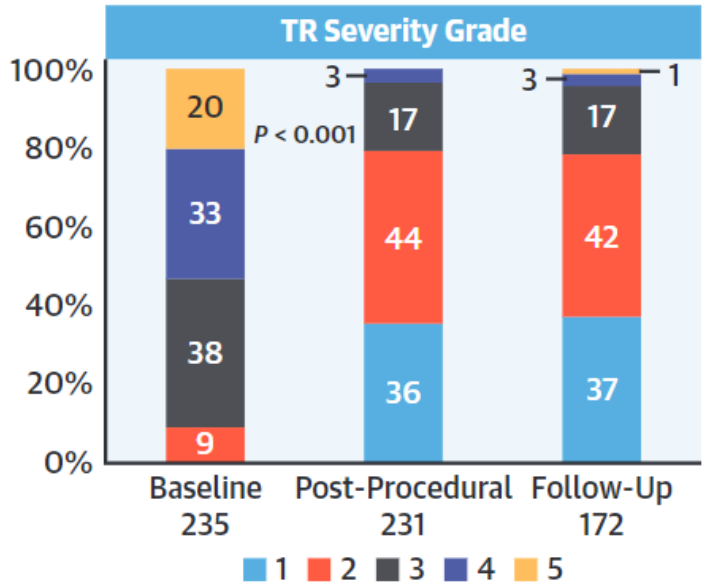
P Lurz et al JACC 77:229-39; 2021

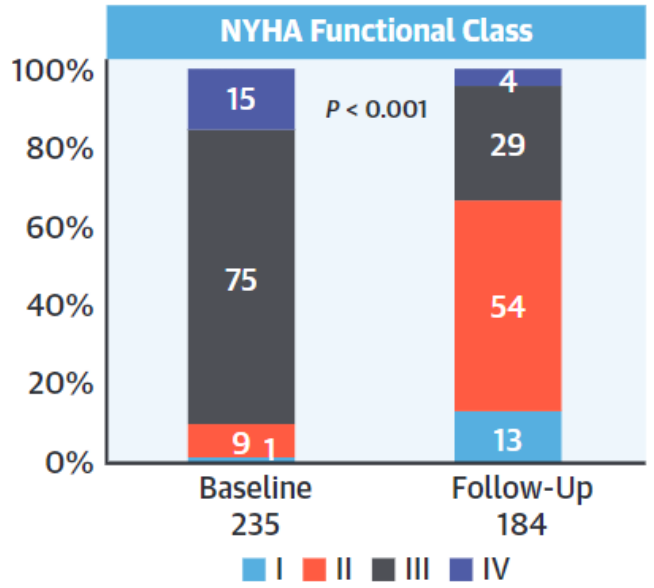
TEER for Tricuspid Regurgitation

PASTE (and CLASP TR - *PASCAL* for TR)

Multicenter Experience With the Transcatheter Leaflet Repair System for Symptomatic Tricuspid Regurgitation







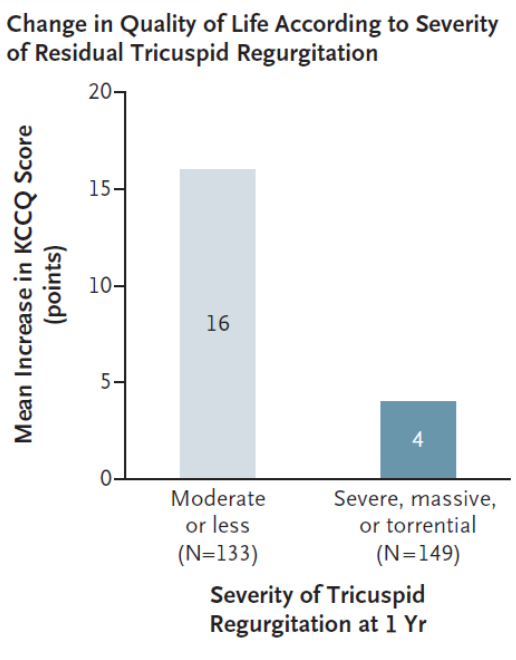
MG Wild et al JACCInt 15:1352-63; 2022

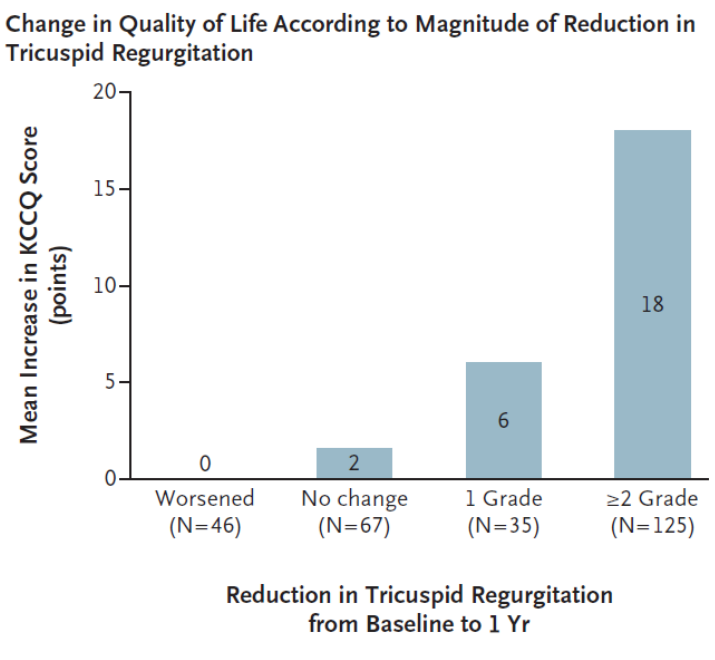
The NEW ENGLAND JOURNAL of MEDICINE

Transcatheter Repair for Patients with Tricuspid Regurgitation

TRILUMINATE

- 350 patients: TEER vs. Med Tx alone
- Composite primary end point: Death/TV surg/HF hosp/+15 KCCQ
- At 30 days, 87% TEER group ≤ moderate TR (vs. 4.8%)
- Win ratio 1.48 (1.06-2.13, p=0.02) for TEER
- Driven entirely by QoL (KCCQ +12.3% vs. +0.6%)





Sorajja et al online March 4, 2023

The NEW ENGLAND JOURNAL of MEDICINE

Transcatheter Repair for Patients with Tricuspid Regurgitation

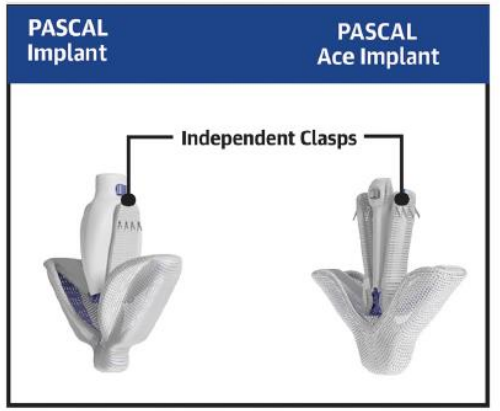
- Is this a Win?
- Too selective? (1573 consented, 795 screen failures)
- Is a sham arm necessary for a QoL trial?
- Hawthorne effect?
- Is one-year enough follow-up (planned for 5 years)?

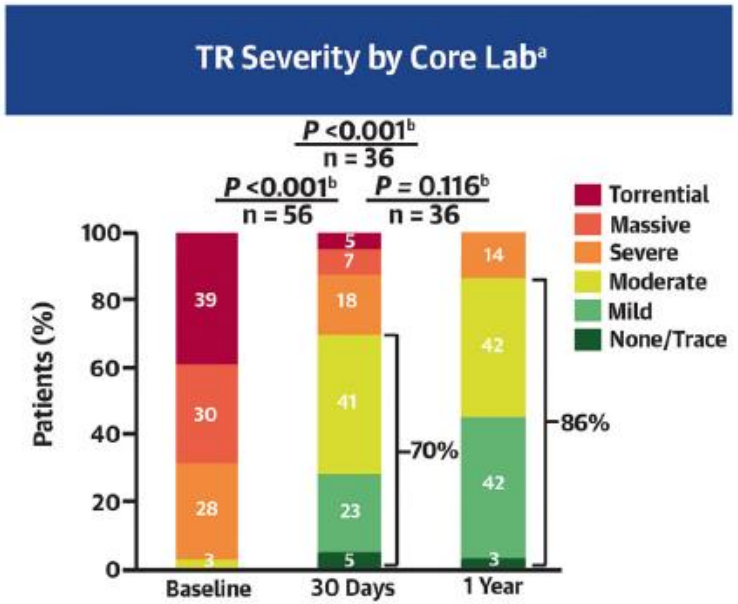
Sorajja et al on line March 4, 2023

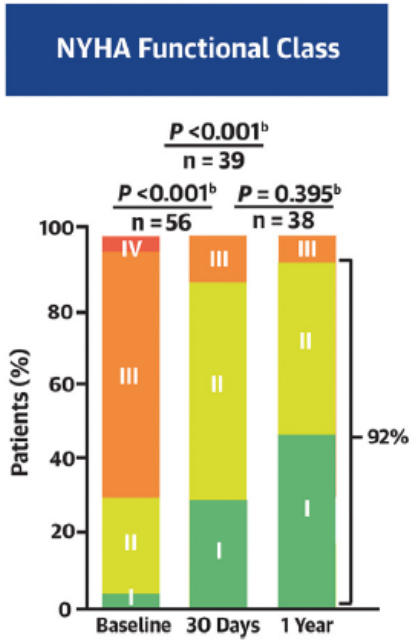
JACC: Cardiovascular Interventions

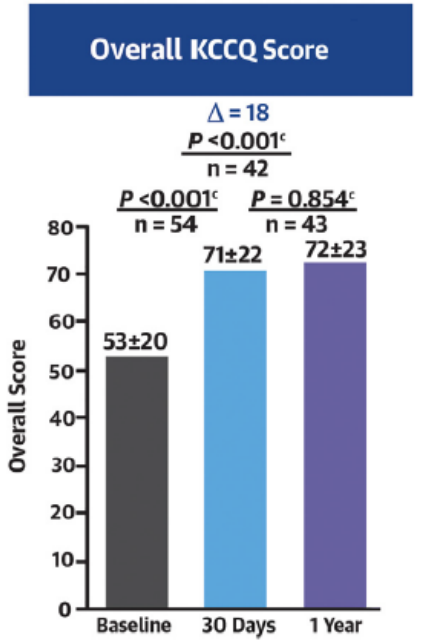
1-Year Outcomes of Transcatheter Tricuspid Valve Repair

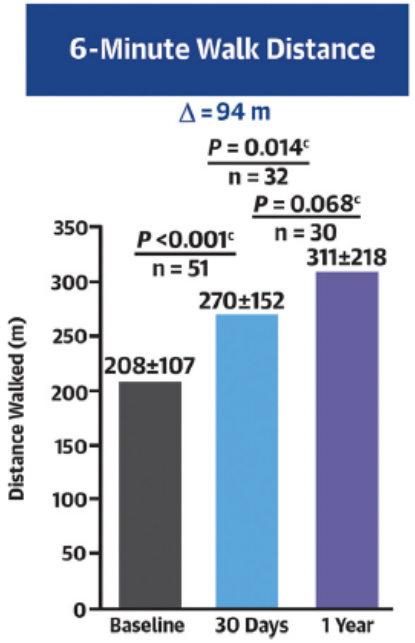
- 65 patients
- 97% with severe to torrential TR
- 86% achieved moderate or less TR









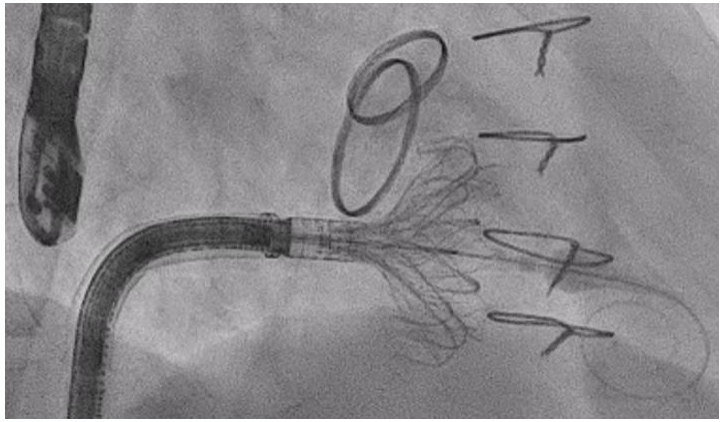


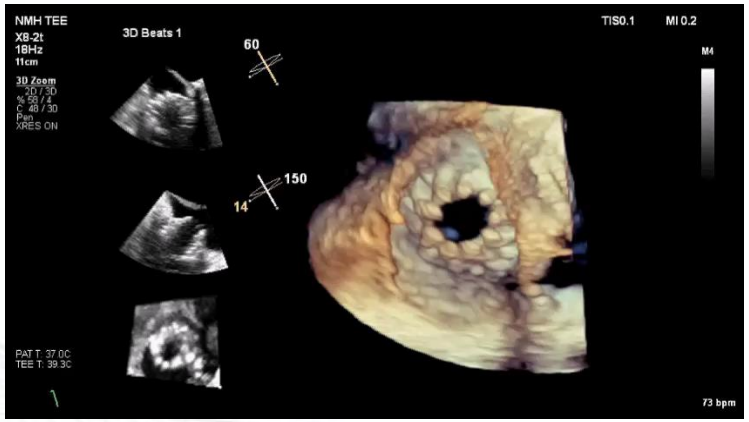
Kodali et al 2023;81:1766-76

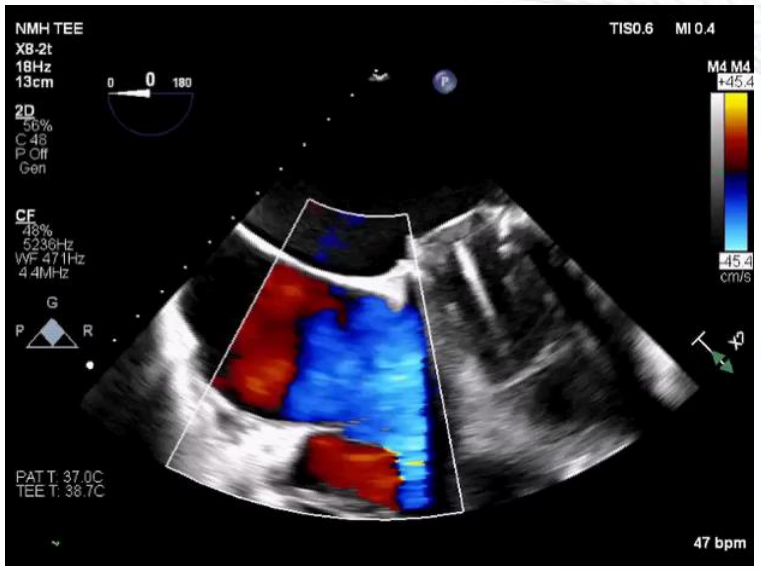
Case 2

- 75 y/o man, persistent A-fib
- Severe Annular Dilation
- Massive TR (ROA-PA 70, RV 45)
- Short restricted septal leaflet

Choice: TTVR



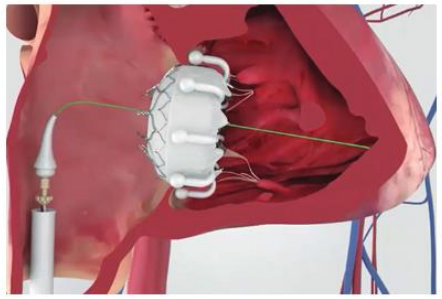


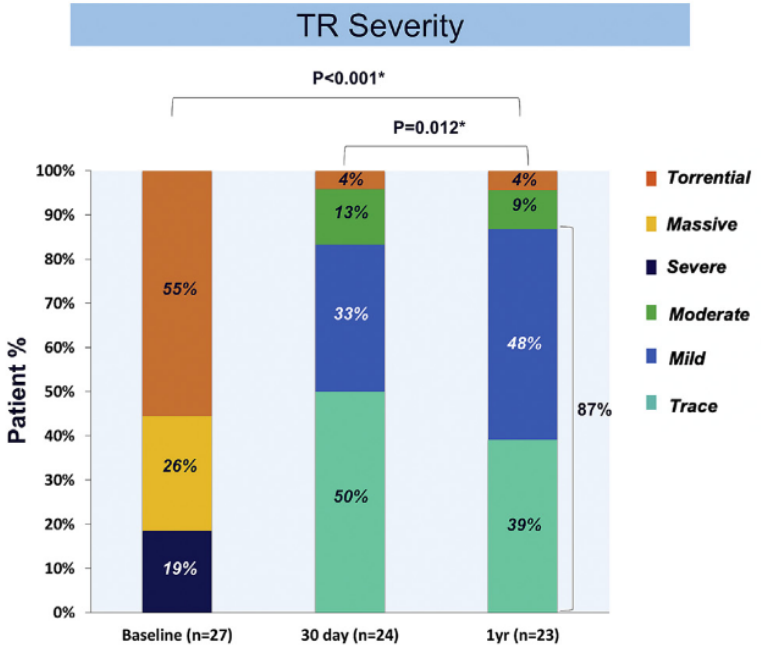


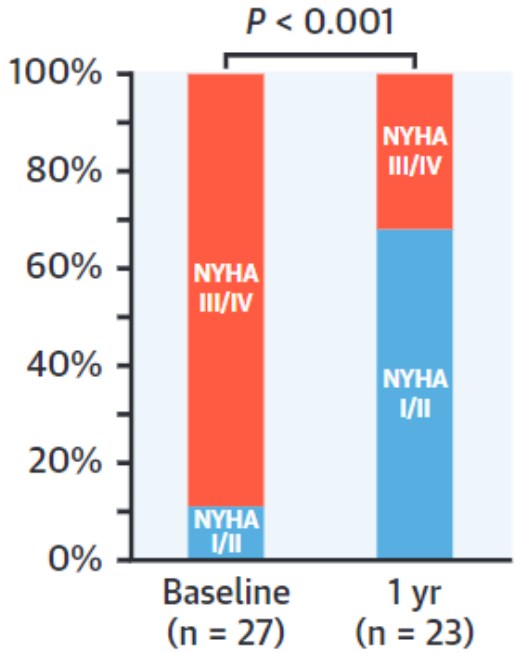
JACC: Cardiovascular Interventions

Transcatheter Tricuspid Valve Replacement With the EVOQUE System

1-Year Outcomes of a Multicenter, First-in-Human Experience







All-cause mortality: 7%
HF hospitalization: 7%
New pacemaker: 7% within 30 days, 4% beyond 30 days

JG Webb et al 15:481-91; 2022

TRISCEND Global Registry

- 176 high-risk patients
- ≥mod TR (40% ≥ massive) & refractory HF
- Implant success 96.2%
- 1 year CV mortality 9.4%
- ~ 12 hospitalization at 1 year
- 97.6% ≤ mild TR
- KCCQ score 46.0 → 71.7
- 6-min walk +56 meters

THE TRISCEND II PIVOTAL TRIAL

250 pts

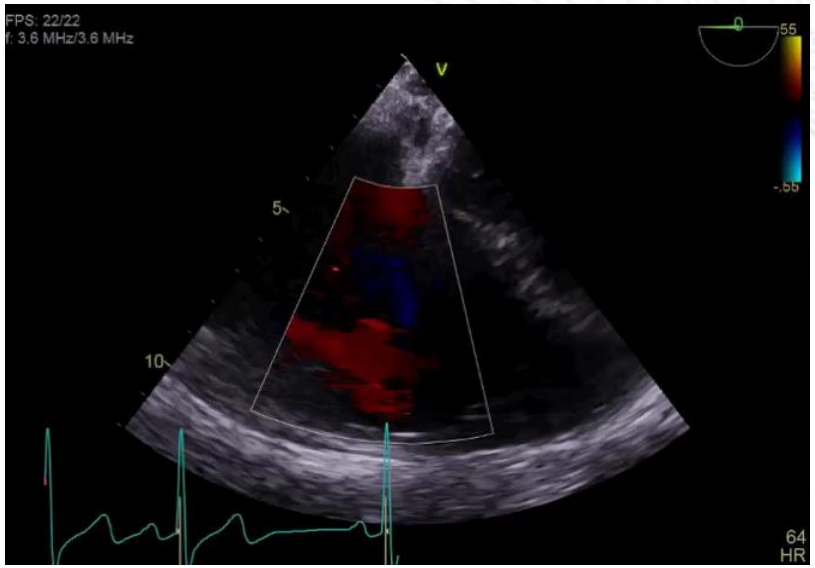
TTVR with EVOQUE + OMT randomized (2:1) vs. OMT alone followed through 5 years.

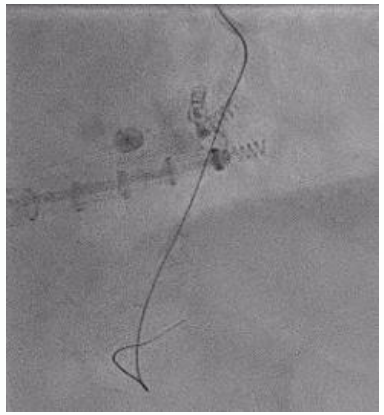
S Windcecker London Valves Nov 2022

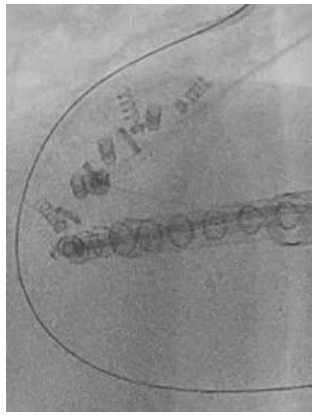
Case 3

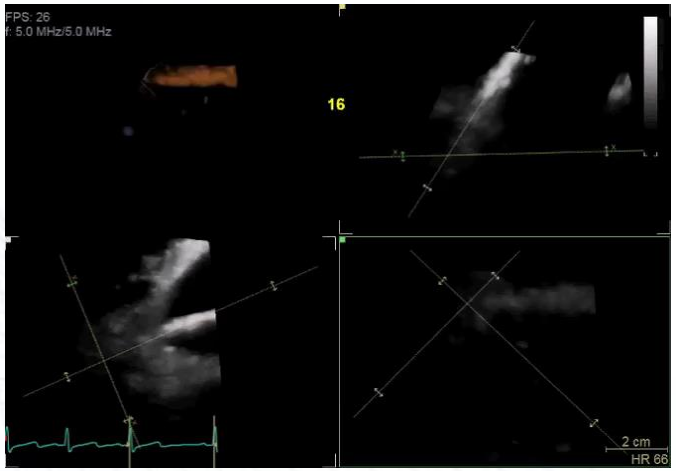
- 71 y/o woman, CAD and A-fib
- Massive Annular Dilation
- Sev-Massive TR (ROA-PA 55, RV 51)
- Large coaptation gap

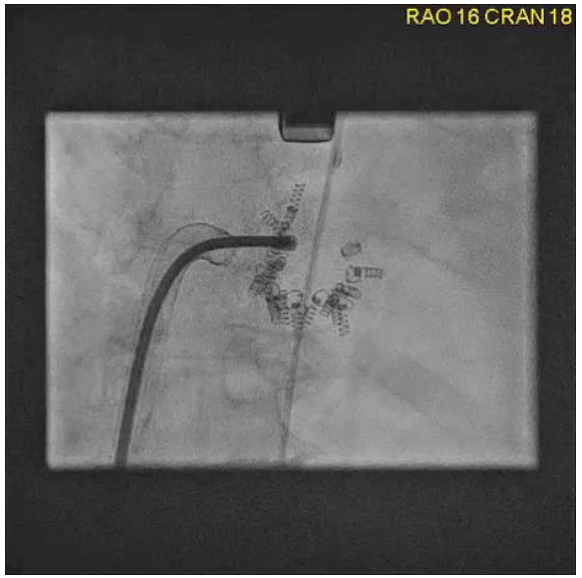
Choice: Annuloplasty





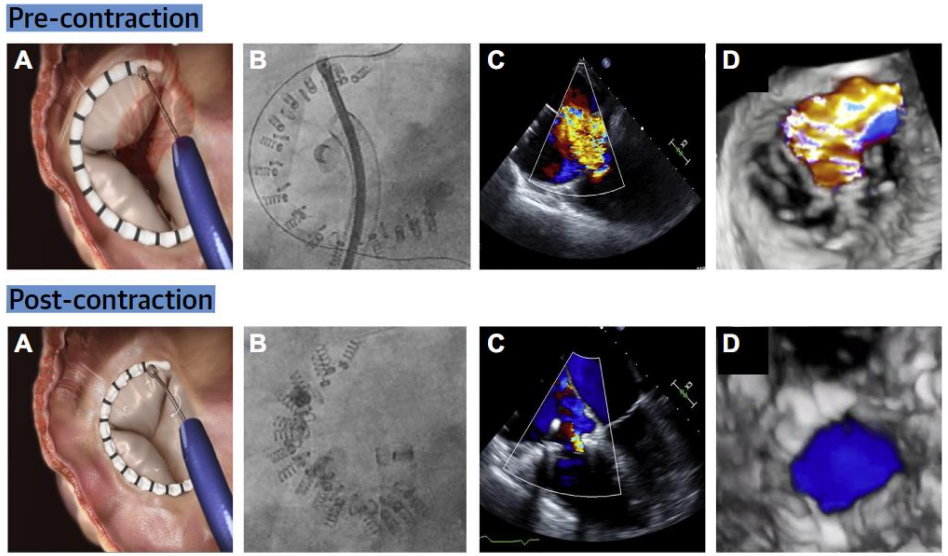


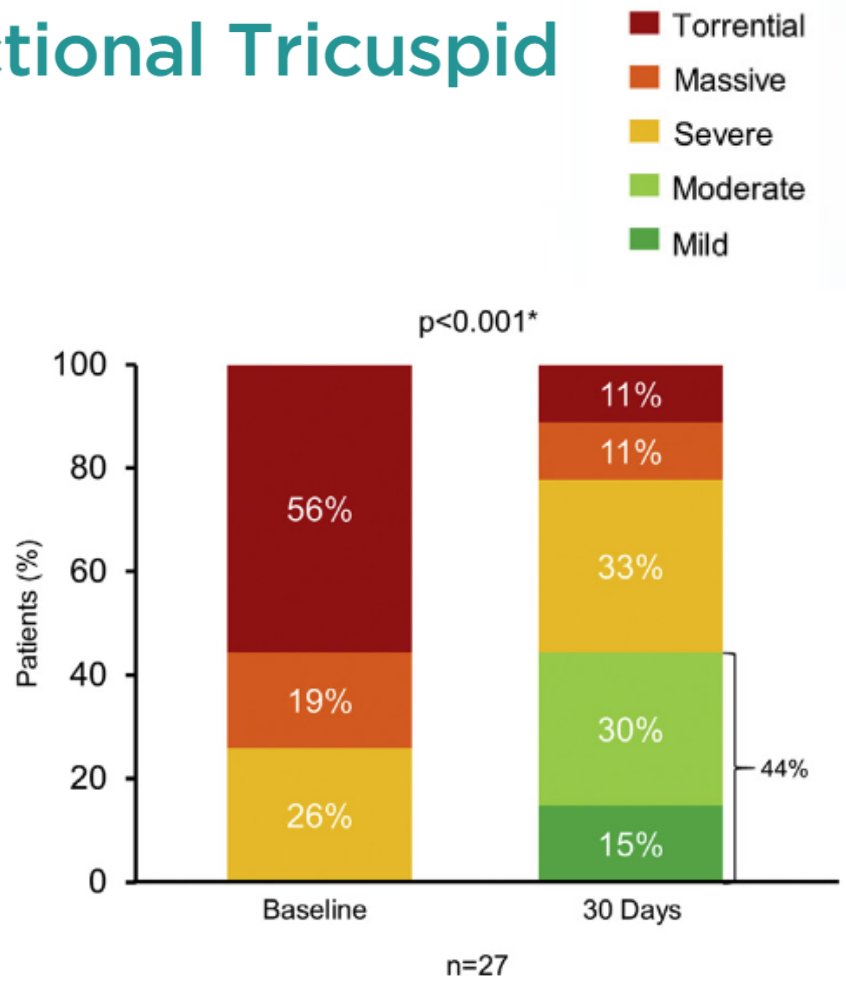




JACC: Cardiovascular Interventions

Early Feasibility Study of Cardioband Tricuspid System for Functional Tricuspid Regurgitation



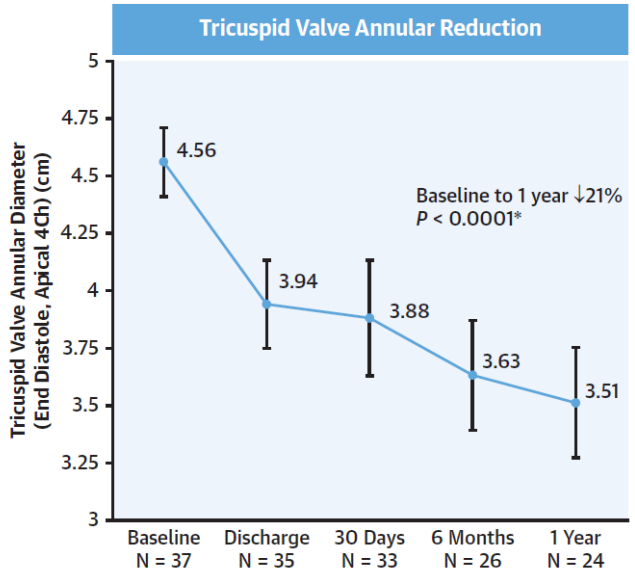


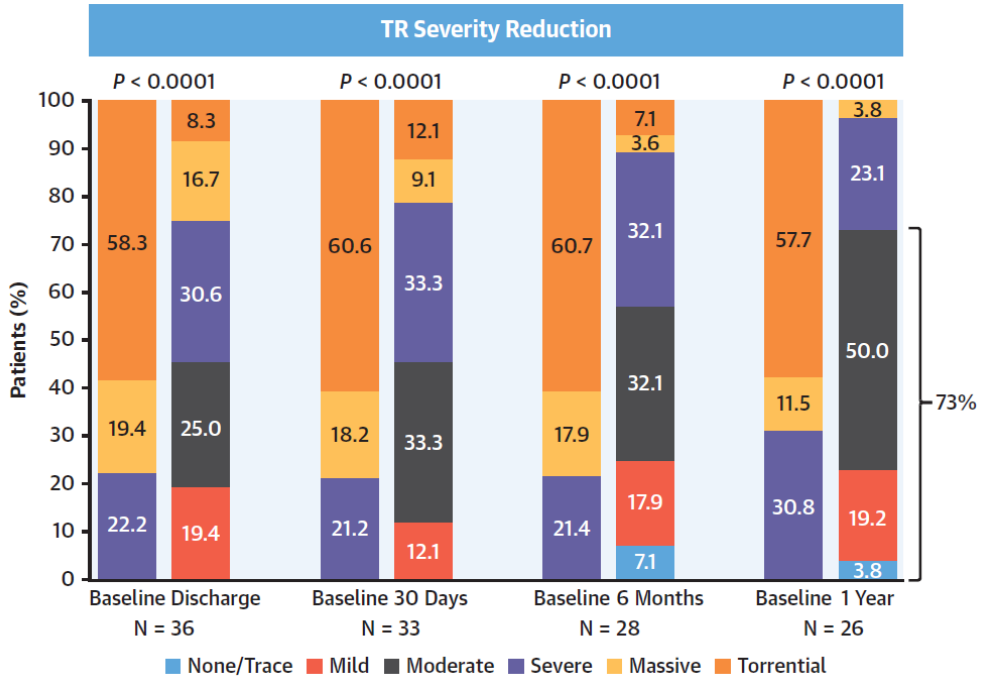
CJ Davidson et al 14:41-50; 2021

JACC: Cardiovascular Interventions

1-Year Outcomes of Cardioband Tricuspid Valve Reconstruction System Early Feasibility Study

Reduction in Tricuspid Valve Annular Diameter and TR Severity at 1 Year With Cardioband System



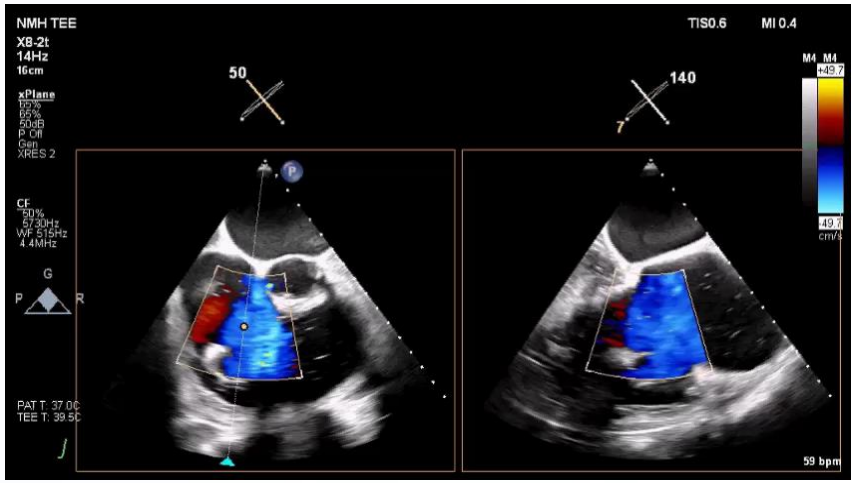


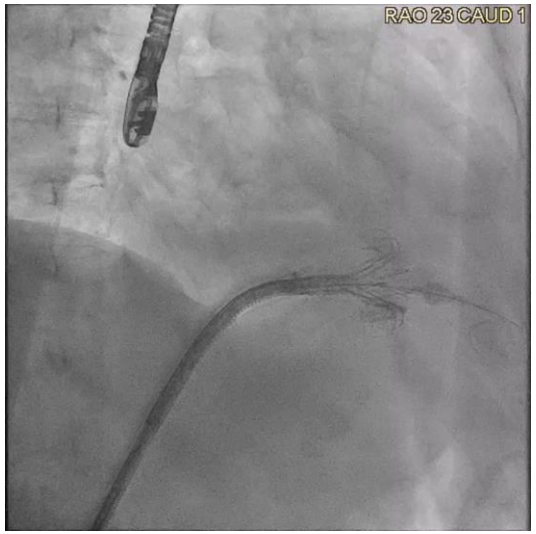
W Gray et al 19:1921-32; 2022

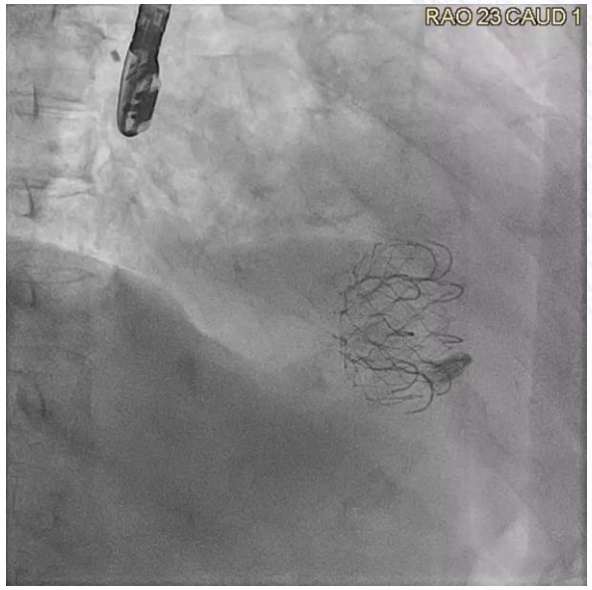
Unanswered Questions About Transcatheter TV Therapies

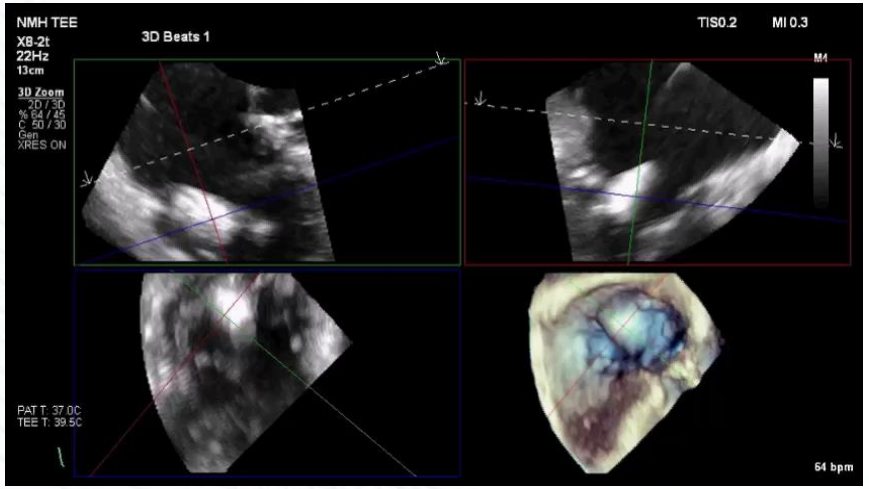
- What is the appropriate outcome target for TV trials?
  - QoL, NYHA class, mortality, rehospitalization
- Are the promising results with TV device therapy durable?
  - How long will anti-coagulation be required for TTVR?
  - Will TEER preclude future TTVR?
- Should we be treating TR earlier?
- Should we be more aggressive treating A-fib and pulmonary HTN and less aggressive placing pacemaker leads across the TV?

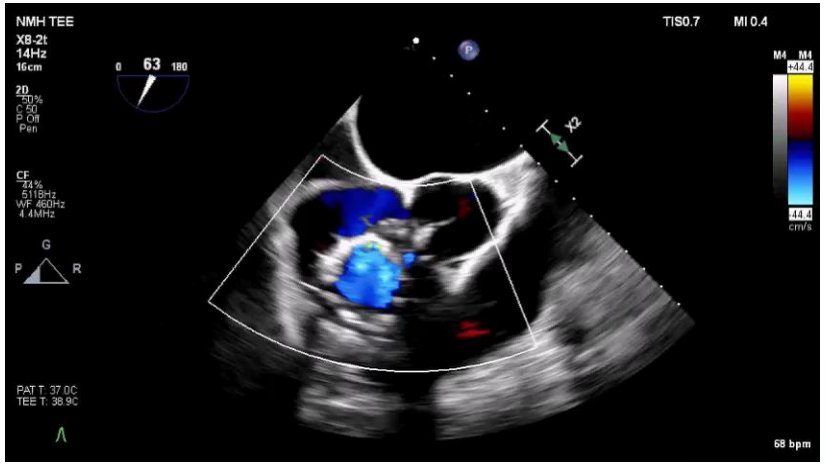
TTVR After Failed TEER











Conclusions

- Tricuspid regurgitation portends a poor prognosis
- Surgical therapy for tricuspid regurgitation is uncommon and is associated with poor outcomes
- An array of percutaneous tricuspid valve therapies has emerged and is showing promise to transform the therapeutic landscape of tricuspid regurgitation and right ventricular failure
- There remain many unanswered questions about TR therapies that will need to be addressed by clinical trials