Latest in Transcatheter Tricuspid Valve Intervention

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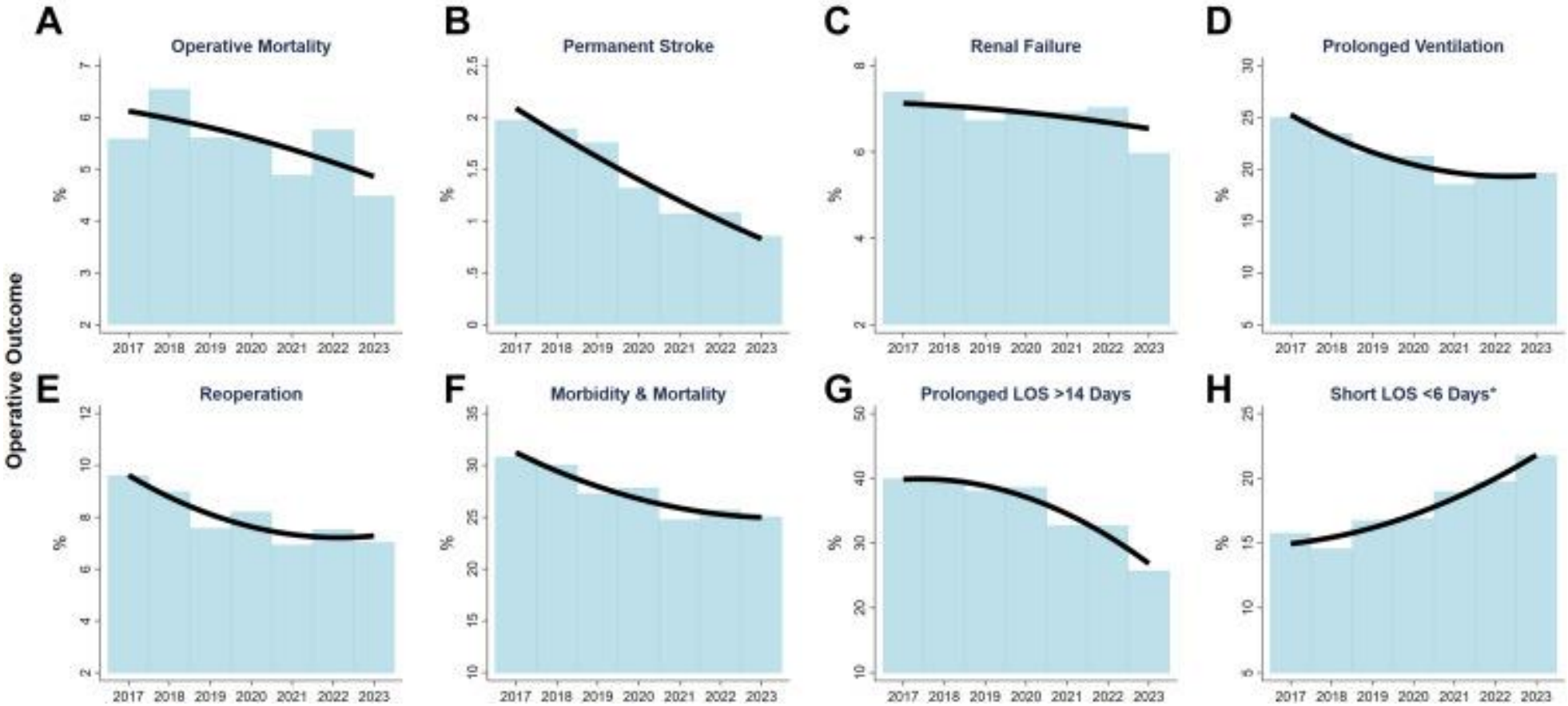
ACC/AHA Guidelines for Medical Therapy for TR

Recommendations for Medical Therapy for TR		
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 et al., Circulation 2021;1433: e7-e227

Contemporary Outcomes of Isolated Tricuspid Surgery in the United States: STS Data (2017-2023)

Operative Mortality: 5.6%

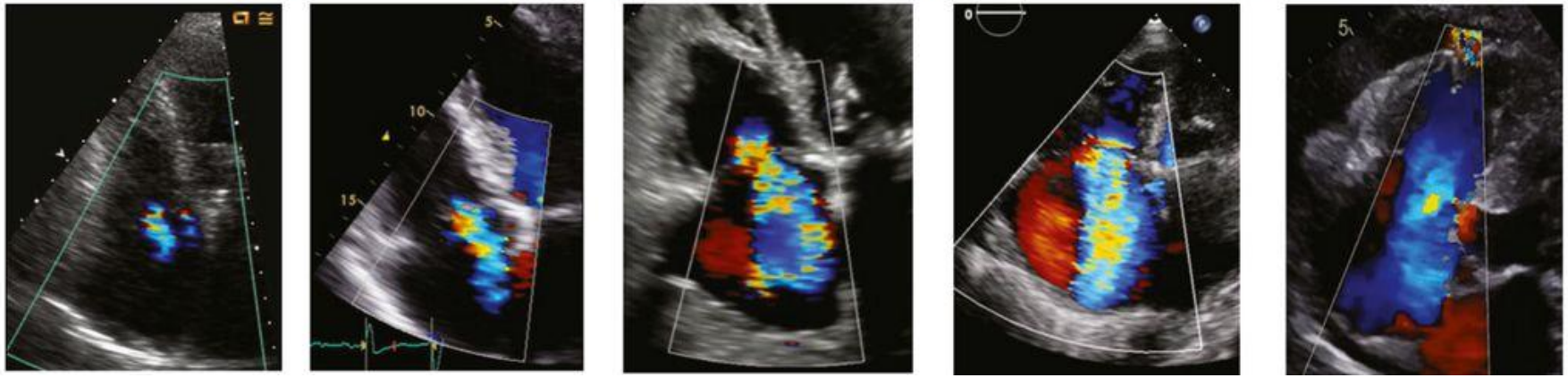


Thourani et al, Ann Thorac Surg. 2024 Oct;118(4):873-881

Extended Grading Scheme for TR

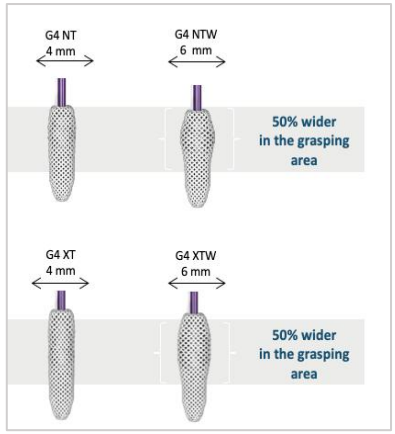
Parameters	MILD	MODERATE	SEVERE	MASSIVE	TORRENTIAL
Vena Contracta width (biplane average)	<3 mm	3-6.9 mm	7 mm - 13 mm	14-20 mm	≥21 mm
EROA by PISA	<20 mm^2	20-39 mm^2	40-59 mm^2	60-79 mm^2	≥80 mm^2
3D Vena Contracta Area or Quantitative Doppler EROA	-	-	75-94 mm^2	95-114 mm^2	≥115 mm^2

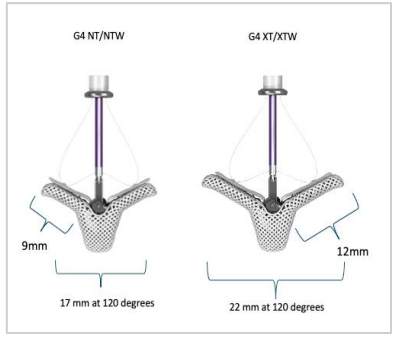
Example:



Hahn RT et al. *JACC Cardiovascular imaging.* 2019;12:469-490

Triclip T-TEER System





TRICLIP G4 DELIVERY SYSTEM

- Steering optimized to position over **tricuspid** valve
  - SGC has 2 Knobs (+/- , S/L)
  - CDS has 1 Knob (F/E)
- Distal curve moved 1 cm more distal than MitraClip

Case: 75 Yr Old Female With NYHA Class IV Symptoms

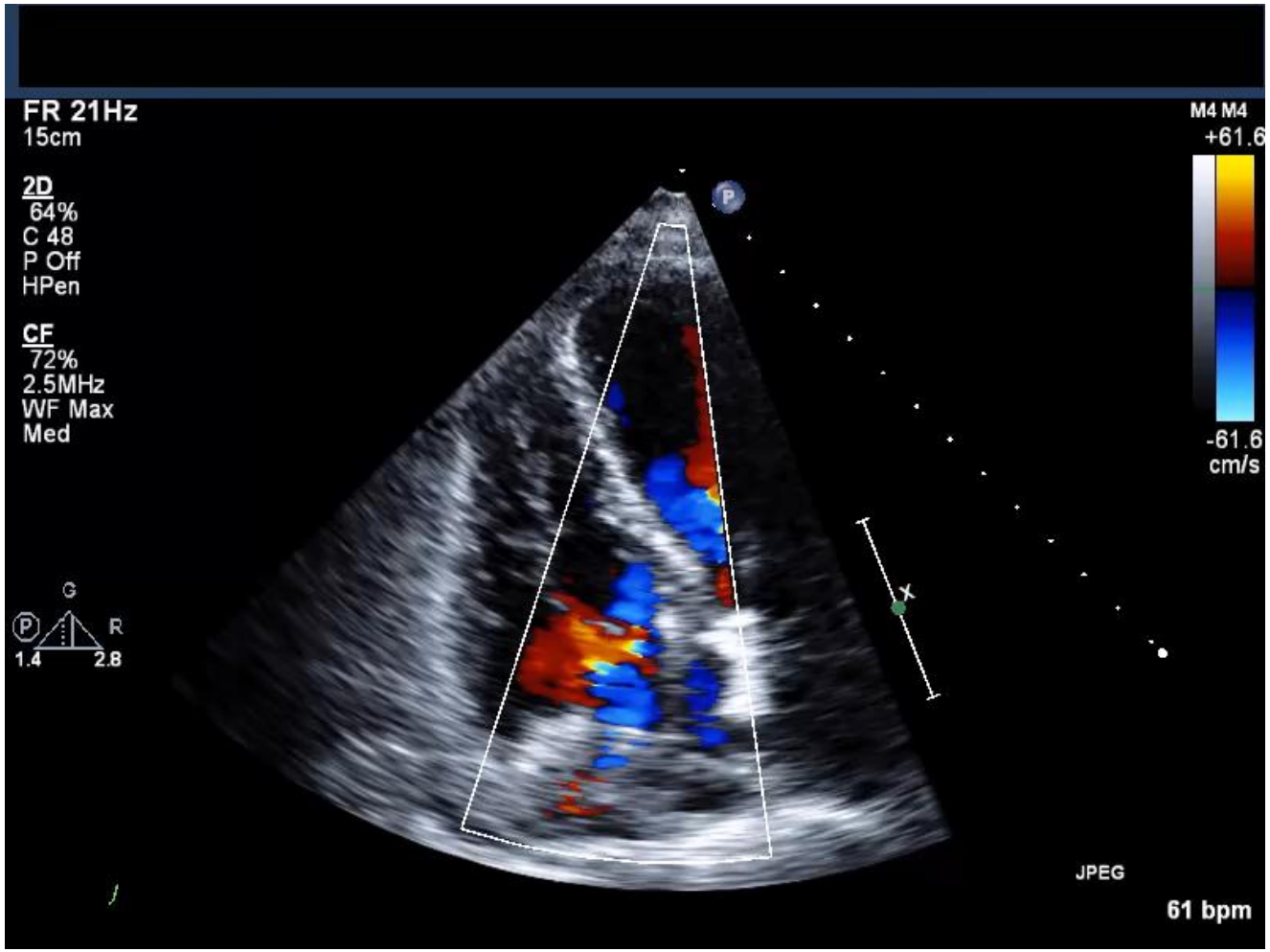
75 yr old female with fatigue, edema, and NYHA Class IV symptoms

Meds: furosemide, valsartan, dapagliflozin

Echo: Torrential (**5+**) TR, LVEF 70%, normal LA size, nl TAPSE

RHC: PCWP 10mmHg

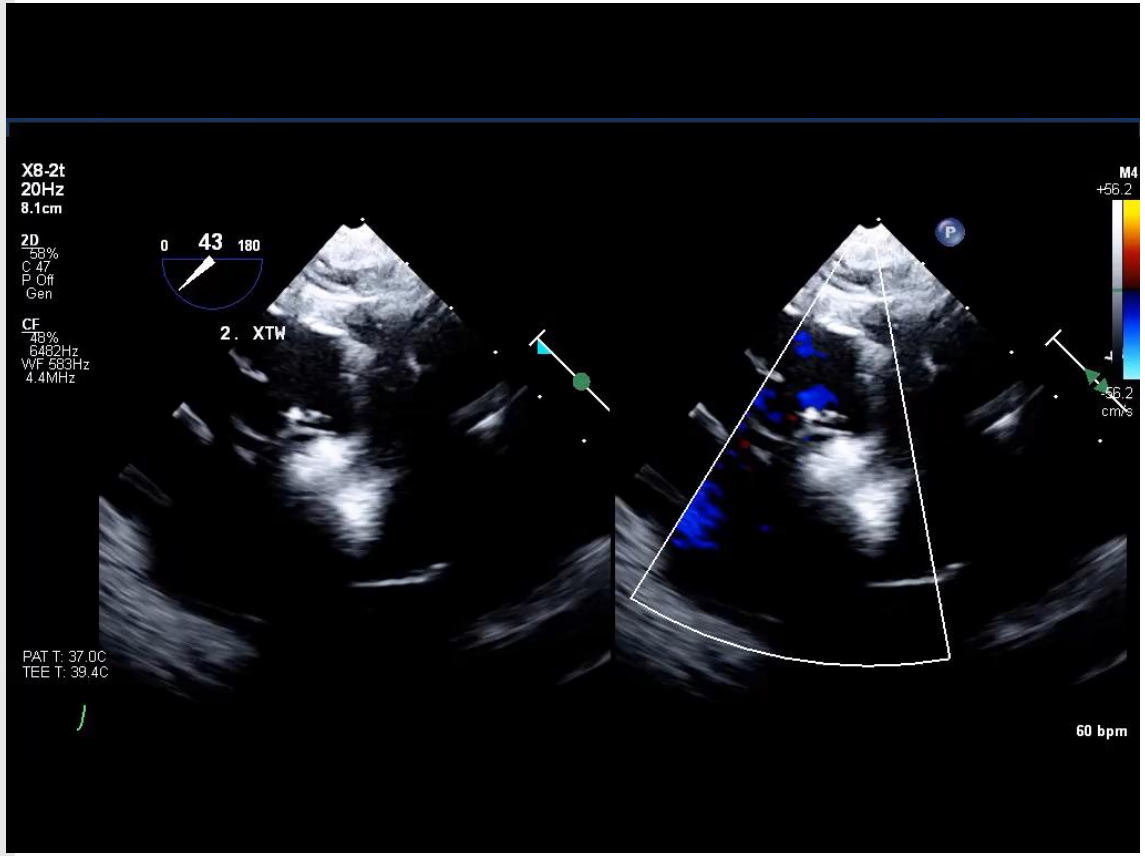
LABS: GFR 37, NT-ProBNP 1230 pg/ml



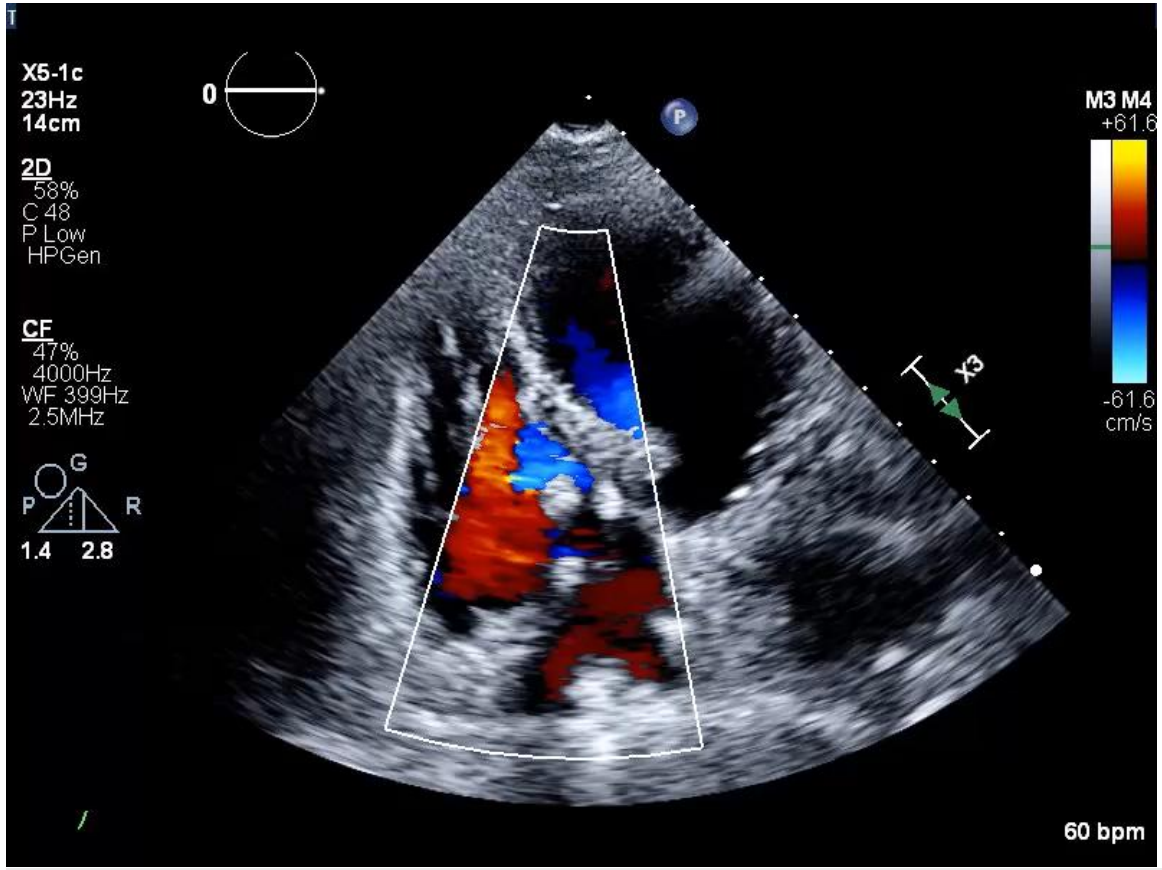
Price MJ, TVT 2023

Treatment: Tricuspid TEER

2 TriClips to restore septal-anterior leaflet coaptation



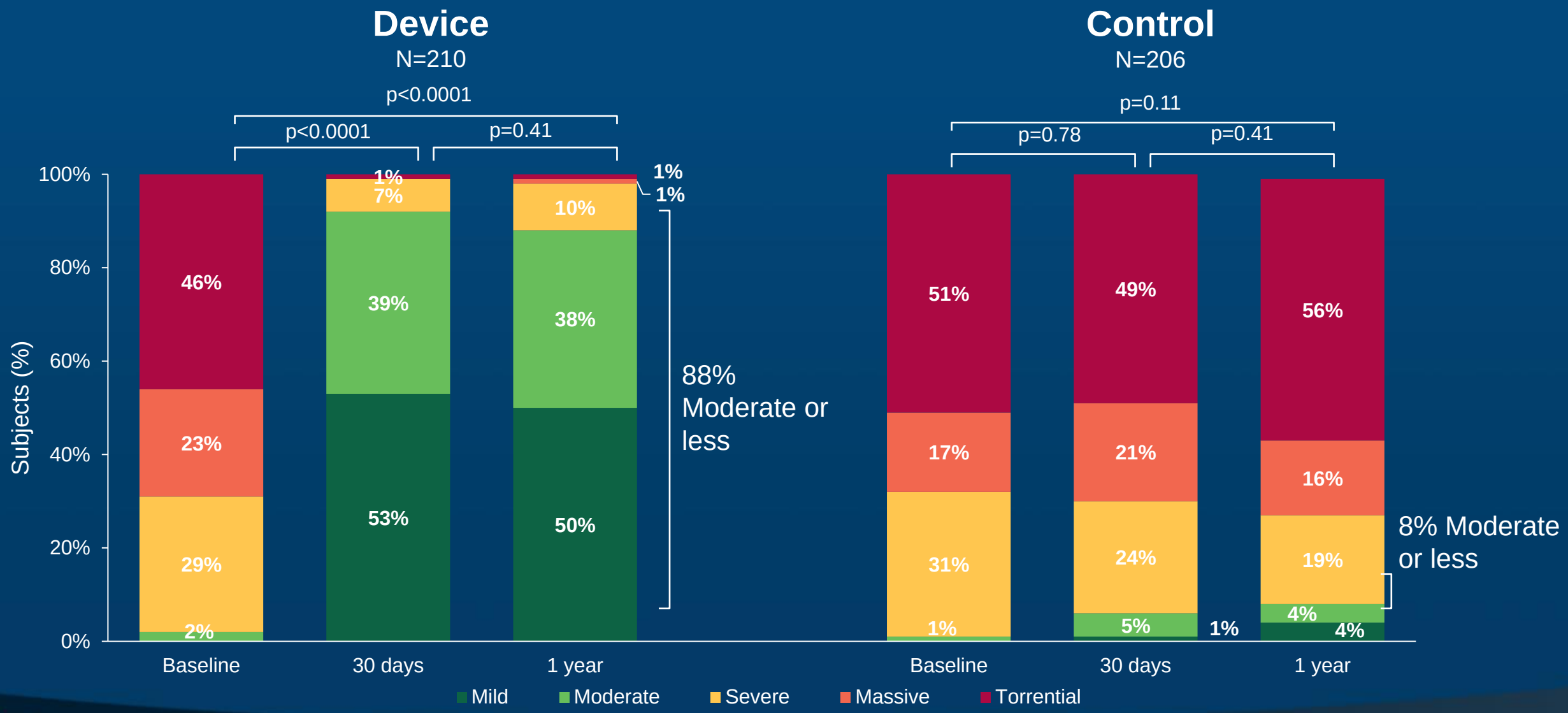
6-month follow-up



1+ TR, NYHA Class I, NT proBNP 117pg/ml, GFR 65

Price MJ, TVT 2023

TRILUMINATE RCT of TriClip vs OMT: TR Severity



Paired data shown.

Procedural Safety (Device Only)

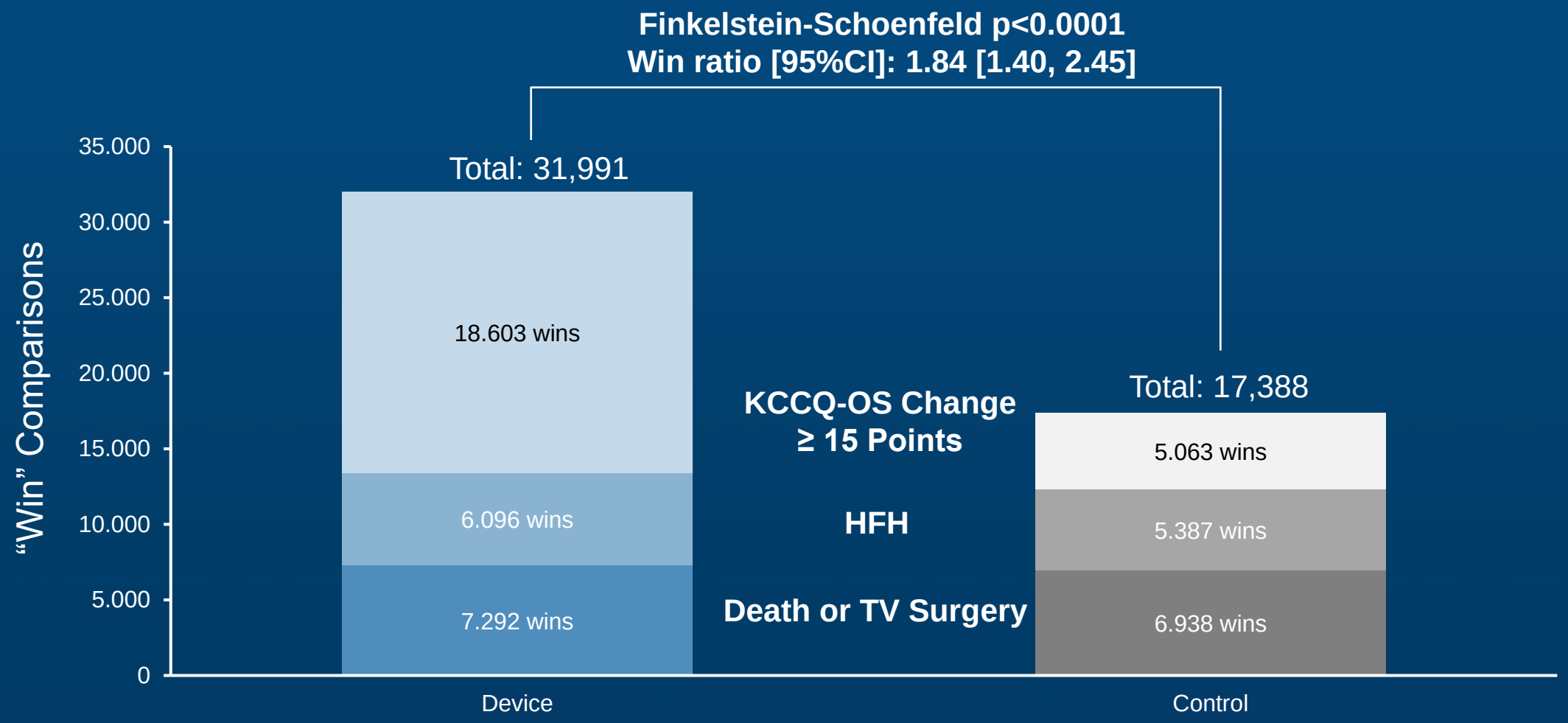
Variable	Device N=281
System	
TriClip	29.9% (84)
TriClip G4	70.1% (197)
Number of devices implanted	
0	1.1% (3)
1	14.9% (42)
2	60.5% (170)
3	20.6% (58)
4	2.8% (8)
Device type	
NT	10.0% (59/588)
XT	32.0% (188/588)
NTW	5.6% (33/588)
XTW	52.4% (308/588)
Device time (minutes)	85.6 ± 63.0 (274)
Procedure time (minutes)	147.2 ± 72.0 (279)
Length of hospital stay (days)	1.5 ± 1.3 (281)
In-hospital death	0% (0)
Home discharge	97.9% (275)

Adverse Events through 30 Days	Device N=281
Major Adverse Events through 30 Days	
Cardiovascular mortality	0.4% (1)
New-onset renal failure	0.7% (2)
Non-elective cardiac surgery	0% (0)
Endocarditis requiring surgery	0% (0)
Other Adverse Events through 30 Days	
Myocardial infarction	0% (0)
Stroke	0.4% (1)
Major bleeding	3.2% (9)
Device embolization	0% (0)
Single leaflet device attachment (SLDA)	5.7% (16)
Device thrombosis	0% (0)

No in-hospital deaths and low rates of adverse events

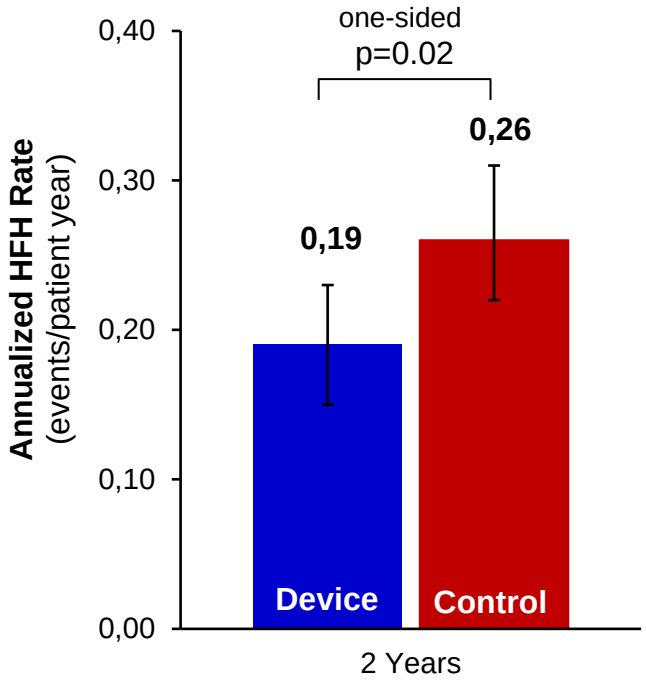
Data shown for attempted procedure population. Data shown as % (n), % (n/N # of total clips), or mean±standard deviation (n).

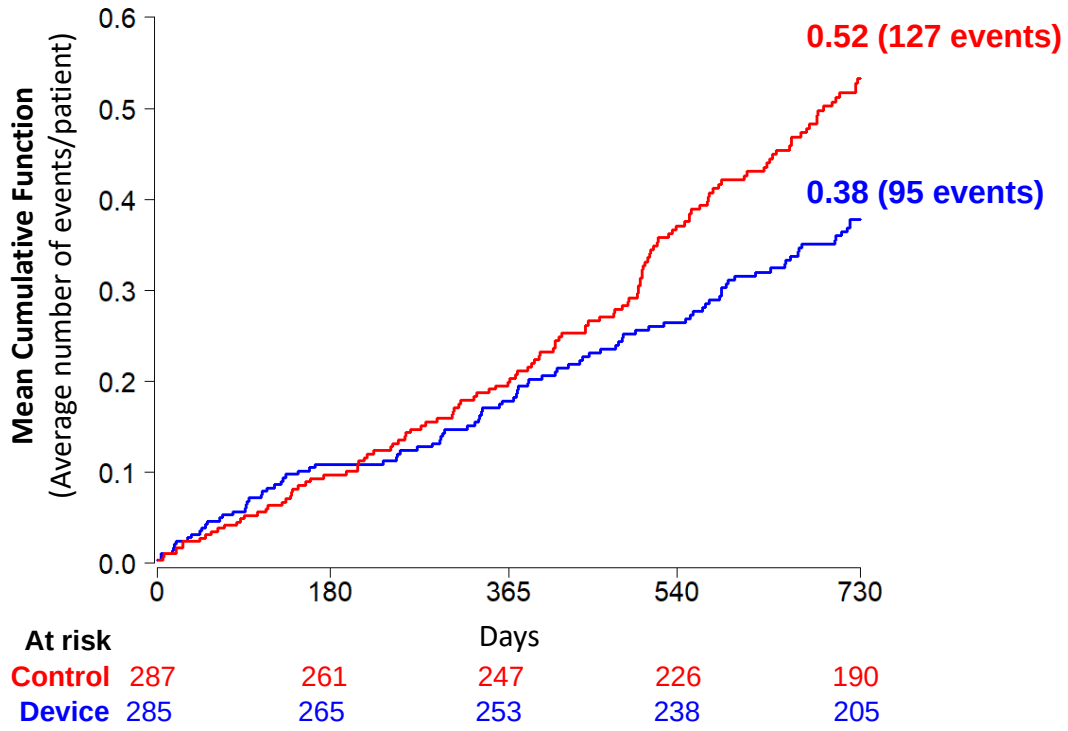
Primary Endpoint for Full Randomized Cohort (N=572)



INTENTION-TO-TREAT

Prespecified Endpoint: Heart Failure Hospitalizations

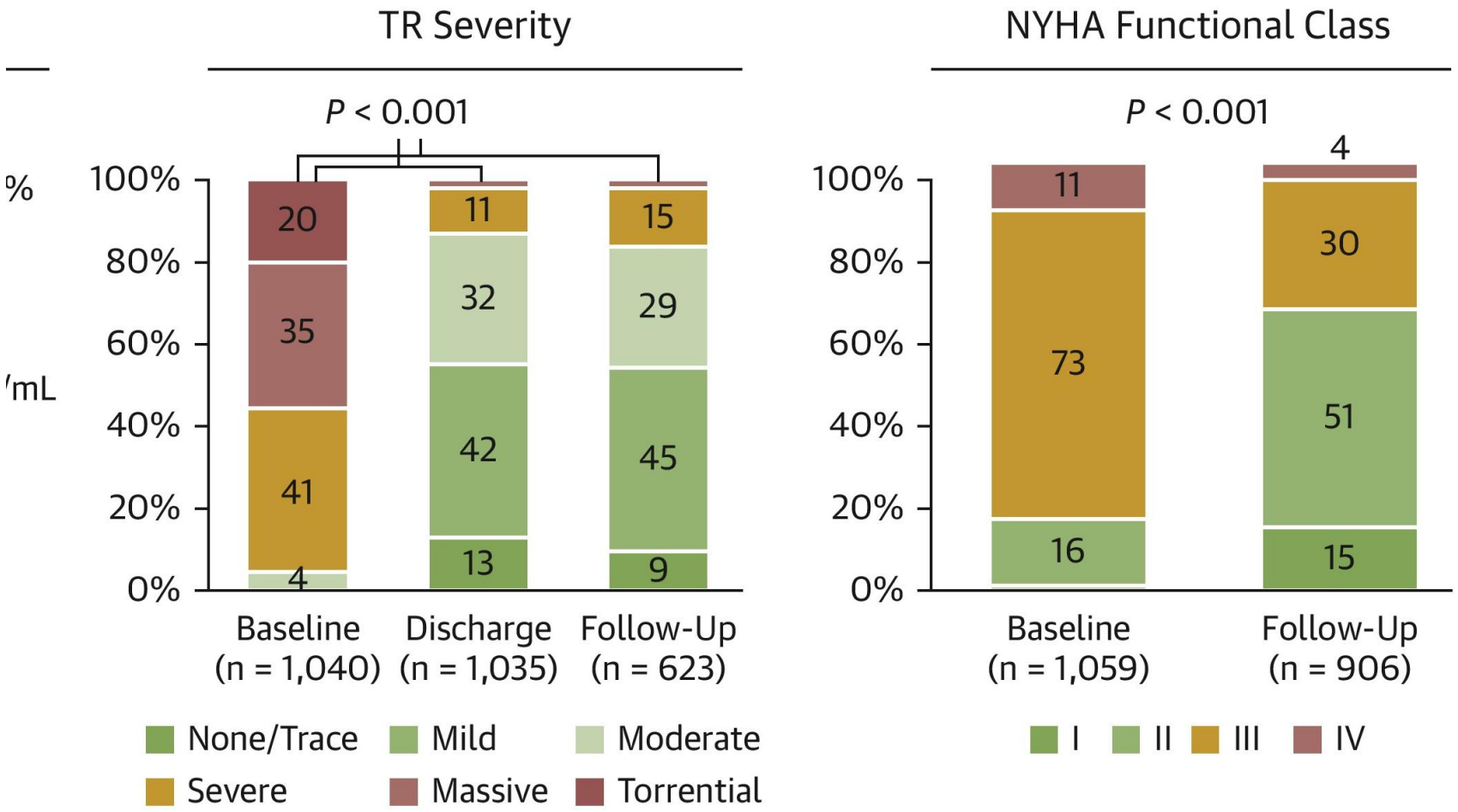




28% relative risk reduction in HFH with TriClip device treatment,
HR 0.72 (two-sided 95%CI [0.53, 0.98])

Prespecified secondary endpoint from joint frailty model; intention-to-treat (ITT) analysis shown. *CI*, confidence interval, *HFH*, heart failure hospitalization, *HR*, hazard ratio. HFH does not include hospitalization for crossover procedure.

PASTE Registry: PASCAL for Severe TR



Wild MG et al, JACC 2025; 83(3):220-231

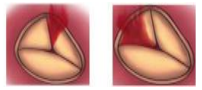
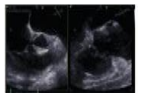
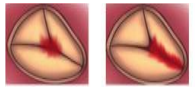
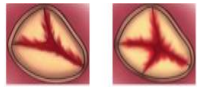
Anatomical Predictors of Tricuspid-TEER Success: Expert Consensus

- **Complex interplay of anatomical factors:** gap width, location of primary jet, # of leaflets, degree of leaflet restriction, echo visualization, lead-leaflet interaction

EASY	MEDIUM	HARD
Small (≤ 6 mm) gaps	Moderate (≥ 7mm but ≤ 8.5mm) gaps	Large (>8.5mm) gaps
Septal-anterior jet location	Septal-posterior jet location	Antero-posterior jet location
Three (or less) leaflets	More than 3 leaflets	Thick and multiple leaflets
No leaflet restriction	Minimal leaflet restriction	Severely restricted leaflet
Good echo visualization (TEE)	CIED lead in commissure and/or not at jet location	Complex CIED lead scenarios
Favorable leaflet annular index	Focal primary disease	Horizontal Heart (role for ICE)

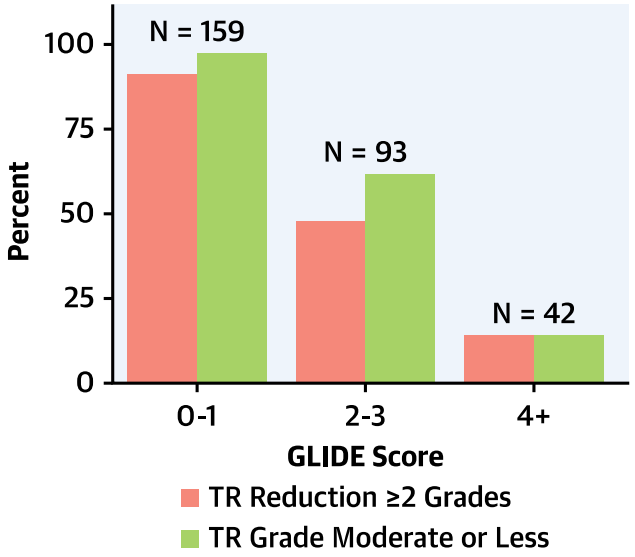
Tricuspid TEER Success Dictated by Leaflet Anatomy and TEE Imaging Quality

The GLIDE Scoring System

Parameters	Straightforward (0 points)	Complex (1 point)
Septolateral Gap	0-5 mm 	≥6 mm 
Predominant Jet Location	Anteroseptal/ Central 	Posteroseptal/ Anteroposterior/Diffuse 
Image Quality	Good 	Limited 
Chordal Structure Density	Modest 	High 
En Face TR Jet Morphology	Oval/Linear 	Star-Shaped 

Gerçek M, et al. J Am Coll Cardiol Img. 2024;17(7):729–742.

Procedural Success in Each GLIDE Score Group



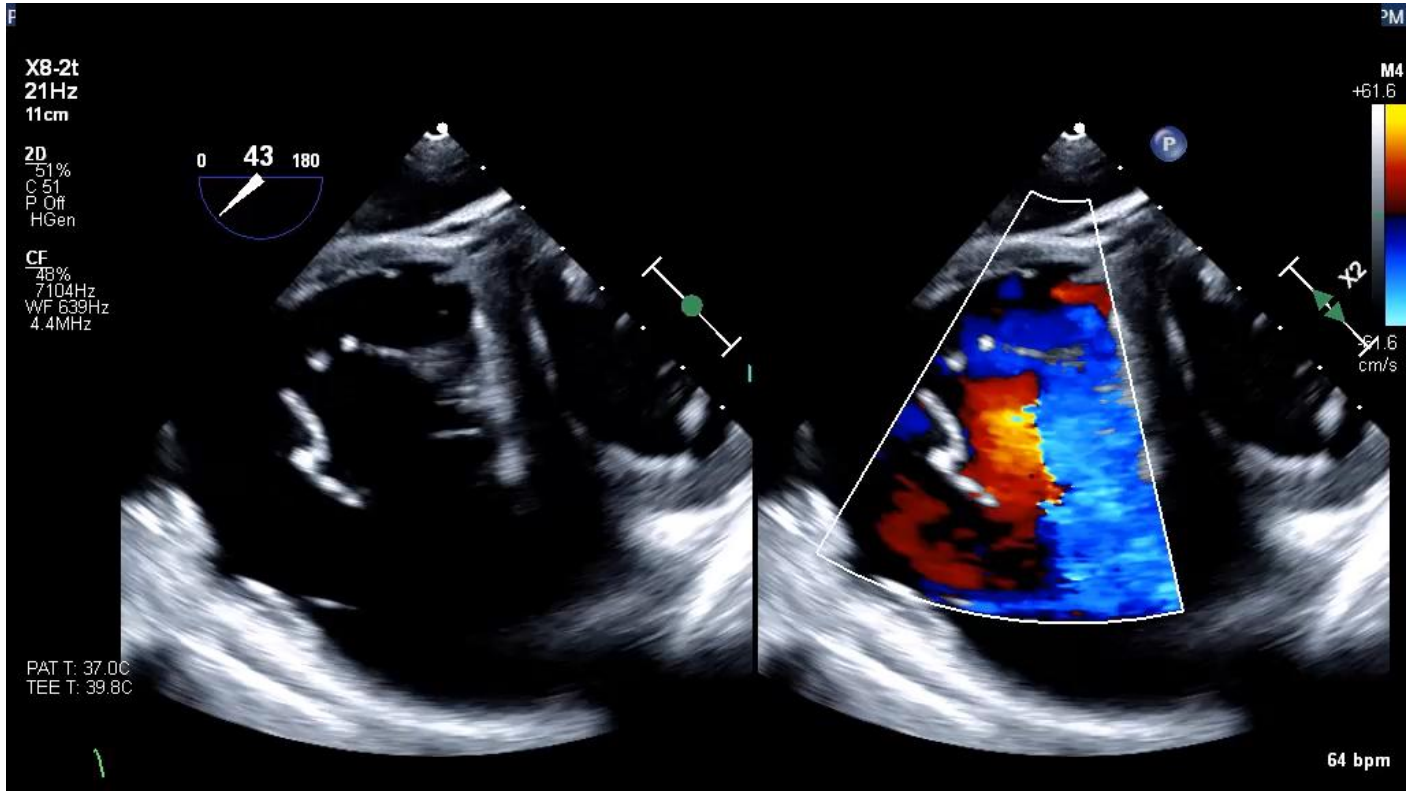
The GLIDE (Gap, Location, Image quality, density, en-face TR morphology) score is a simple, 5-component score that is readily obtained during patient imaging and can predict successful T-TEER. T-TEER = tricuspid valve transcatheter edge-to-edge repair; TR = tricuspid regurgitation.

TRILUMINATE: Baseline Factors Associated with HFH in First Year of Enrollment for Control Patients

- Lower eGFR
- Higher MELD-XI score
- Having HFH in the prior year
- Frequent and/or bothersome swelling in the feet, ankles, or legs
- Lower KCCQ scores
- Elevated diuretics usage
- Elevated sPAP
- Lower RV/PA coupling (RV TAPSE/sPAP)
- More severe TR

CASE: 70 Yr-old With DOE, Severe LE Edema, Early Satiety/Weight Loss

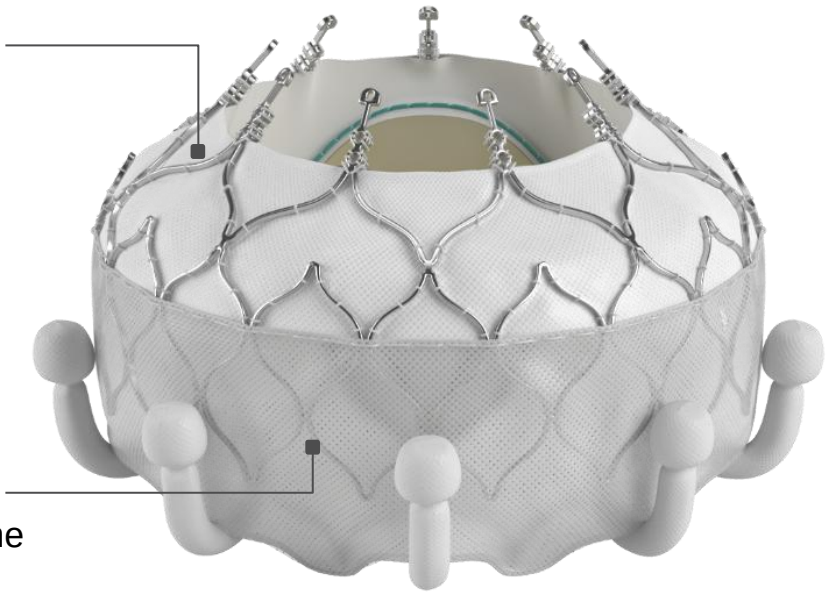
- Parkinson's disease
- NYHA class II
- Carcinoid syndrome
- Weight loss & severe LE edema despite diuretics
- Torrential (5+) TR
- LVEF 65%,PASP 31mmHg, RV dilated with nl function



EVOQUE Transcatheter Tricuspid Valve Replacement System

Designed for anatomical compatibility
Self-expanding shape-memory nitinol frame designed to conform to native valve anatomy

Designed to seal within native tricuspid annulus
Intra-annular sealing skirt and frame



4 sizes treat wide range of anatomies

44mm 48mm 52mm 56mm

Delivery System

Transfemoral

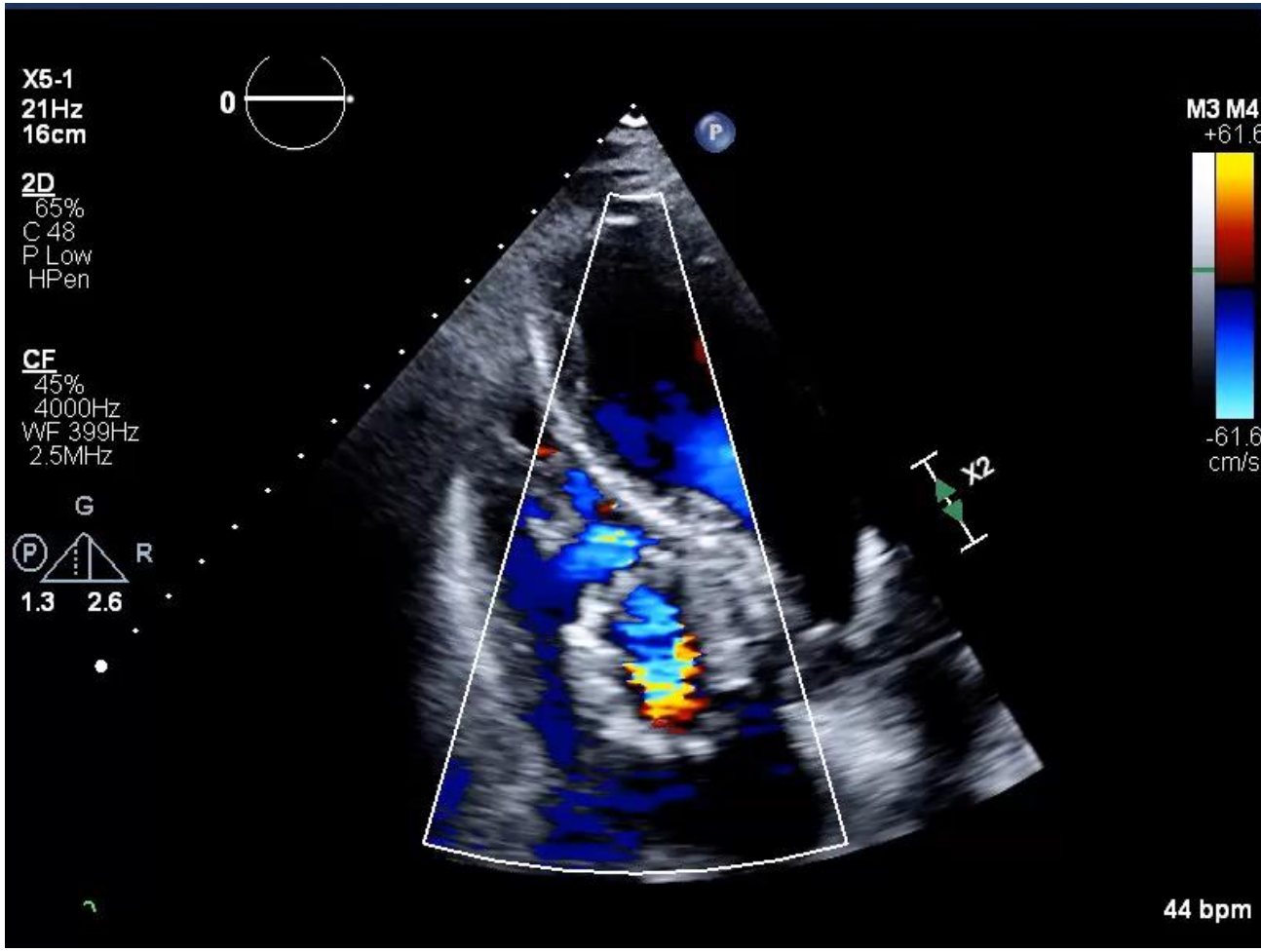
28 Fr outer diameter

3 planes of movement

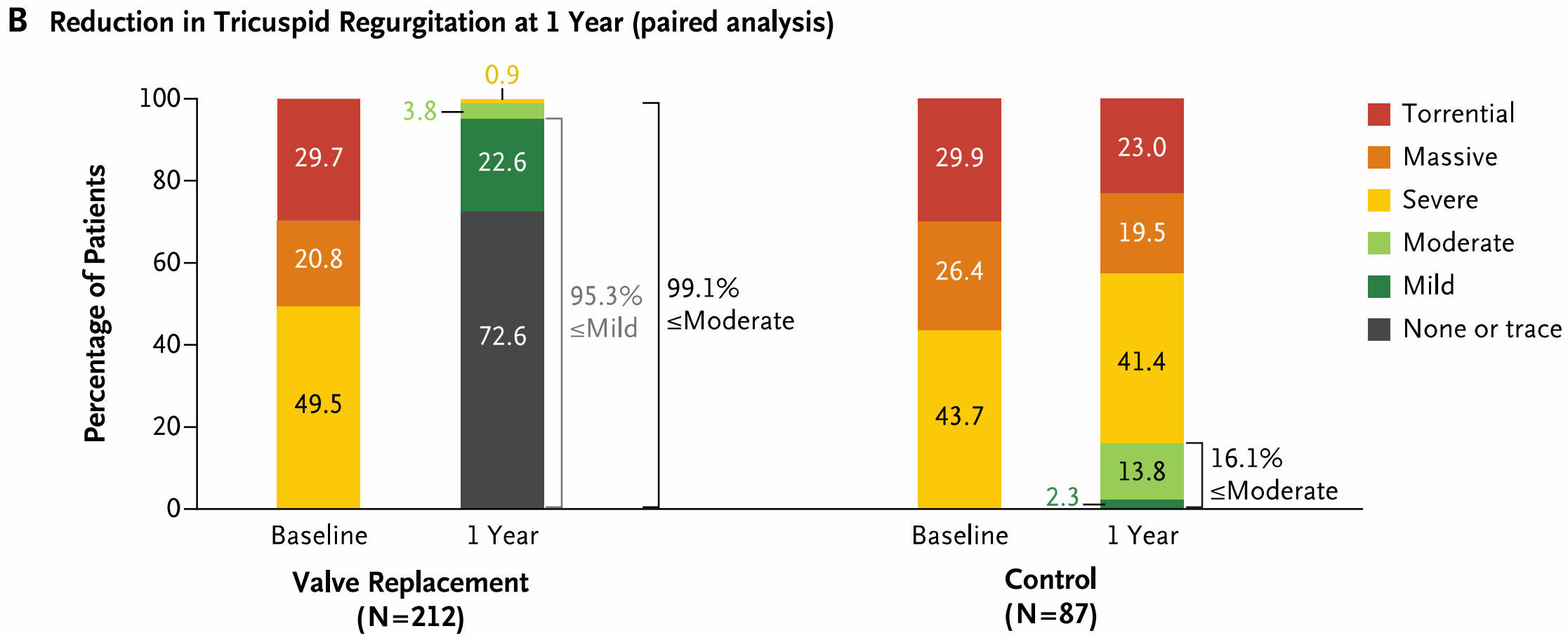
CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information.

CASE: 70 YR-OLD WITH CARCINOID, SEVERE TR

- 48mm Evoque TTVR
- New RBBB after implant, no further block at 1 month FU
- LE edema resolved
- NYHA class I



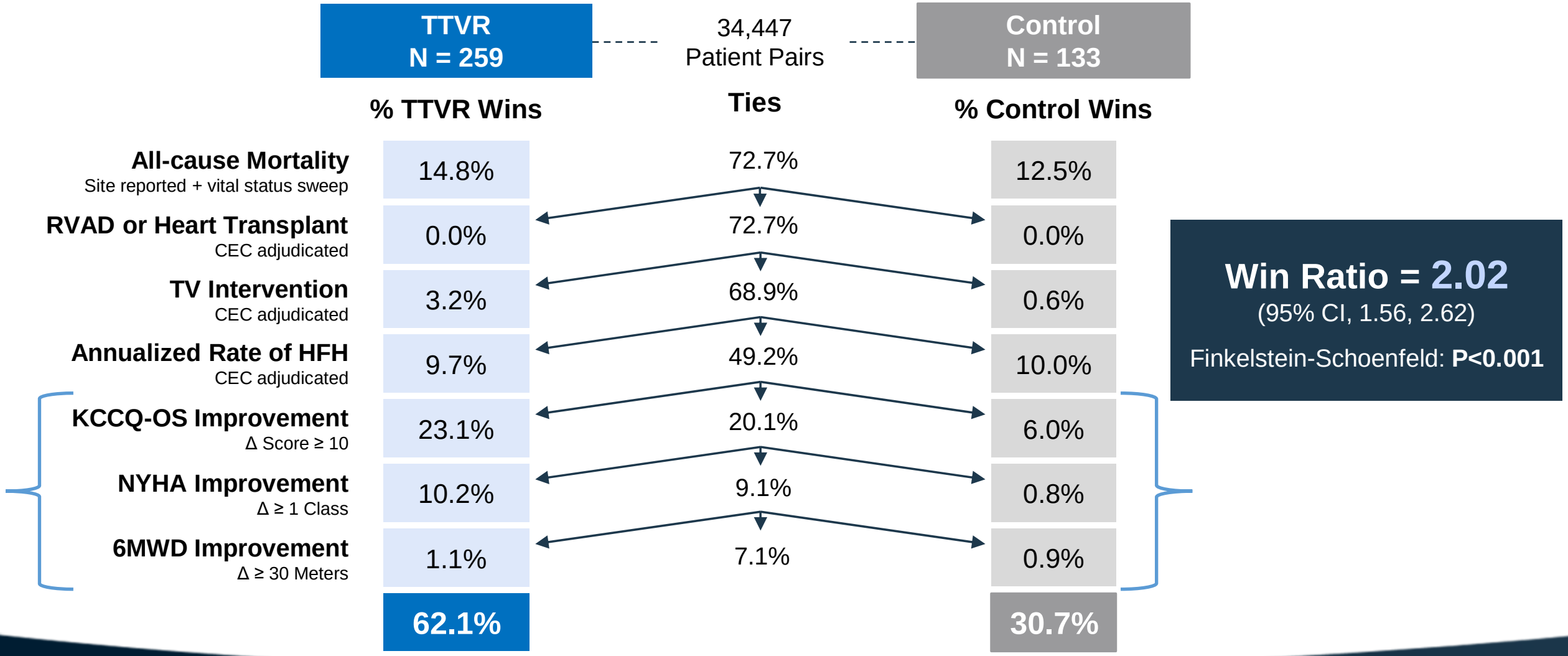
TRISCEND II RCT of Evoque vs OMT: TR Reduction



Hahn RT et al, NEJM 2024

Primary Safety and Effectiveness Endpoint – Percent Wins

Superior Clinical Benefits with EVOQUE System



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

TRISCEND II: Safety Outcomes

Safety Event	Early Events (≤30 Days)†		Late Events (31 to 365 Days)‡		Cumulative Events (0 to 365 Days)†		P Value§
	Valve Replacement (N=259)	Control (N=133)	Valve Replacement (N=247)	Control (N=128)	Valve Replacement (N=259)	Control (N=133)	
	number of patients (percent)						
Death from any cause¶	9 (3.5)	0	21 (8.5)	14 (10.9)	30 (11.6)	14 (10.5)	0.87
Death from cardiovascular cause	8 (3.1)	0	14 (5.7)	10 (7.8)	22 (8.5)	10 (7.5)	0.85
Myocardial infarction	2 (0.8)	0	3 (1.2)	1 (0.8)	5 (1.9)	1 (0.8)	0.67
Stroke	1 (0.4)	0	3 (1.2)	0	4 (1.5)	0	0.30
New renal-replacement therapy‖	4 (1.5)	NA	4 (1.6)	NA	8 (3.1)	NA	NA
Severe bleeding**	27 (10.4)	2 (1.5)	13 (5.3)	6 (4.7)	40 (15.4)	7 (5.3)	0.003
Nonelective tricuspid-valve reintervention††	2 (0.8)	1 (0.8)	0	3 (2.3)	2 (0.8)	4 (3.0)	0.19
Major access-site and vascular complication‖	8 (3.1)	NA	0	NA	8 (3.1)	NA	NA
Major cardiac structural complication‖	3 (1.2)	NA	0	NA	3 (1.2)	NA	NA
Device-related pulmonary embolism‖	2 (0.8)	NA	1 (0.4)	NA	2 (0.8)	NA	NA
Arrhythmia and conduction disorder resulting in permanent pacing	41 (15.8)	0	5 (2.0)	3 (2.3)	46 (17.8)	3 (2.3)	<0.001
New pacemaker or cardiac implantable electronic device‡‡							
In all patients	40 (15.4)	0	5 (2.0)	3 (2.3)	45 (17.4)	3 (2.3)	<0.001
In patients without pre-existing pacemaker§§	40/162 (24.7)	0/80	5/118 (4.2)¶¶	3/76 (3.9)¶¶	45/162 (27.8)	3/80 (3.8)	<0.001

Hahn RT et al, NEJM 2024

In-Hospital and 30-Day Outcomes After Evoque TTVR in Current Clinical Practice

TABLE 4 Procedural Outcomes (N = 176)

	Value	95% CI
Intraprocedural success	171 (97.2)	94.7-99.6
Femoral vein access	176 (100)	
Procedure time, min	102.5 [48.8]	
Device time, min	45.0 [31.0]	
Device size		
44 mm	26 (14.8)	
48 mm	41 (23.3)	
52 mm	91 (51.7)	
56 mm	16 (9.1)	
Residual TR at the end of the procedure		
None	138 (78.4)	
Mild	35 (19.8)	
Moderate	1 (0.6)	
Severe	2 (1.2)	
TV mean pressure gradient, mm Hg	1.8 [1.2]	
Device malposition	1 (0.6)	0.1-1.7
In-hospital reintervention	1 (0.6)	0.1-1.7
Conversion to cardiac surgery	0 (0)	
In-hospital death	6 (3.4)	0.7-6.1
Acute right heart failure requiring inotropic support	2 (1.1)	0.1-2.7
Periprocedural cardiac decompensation	8 (4.5)	1.5-7.6
Length of hospitalization (from the procedure)	7 (6)	

TABLE 6 Outcomes at 1-Month Follow-Up

	30-d Follow-Up	95% CI
Clinical success	153 (86.9)	82.0-91.9
All-cause death	9 (5.1)	1.9-8.4
HFH	9 (5.1)	1.9-8.4
Composite death or HFH	15 (8.5)	4.4-12.6
New conduction disturbances	42 (23.9)	17.6-30.2
Advanced AV block	17 (40.4)	
Second-degree AV block	5 (11.9)	
RBBB	12 (28.5)	
Slow AF	4 (9.5)	
Other	4 (9.5)	
New PM implantation		
Overall	25/176 (14.2)	9.0-19.4
PM-naive patients	21/111 (18.9)	11.6-26.2
Type of PM		
Leadless	10/25 (40.0)	
Lead across valve	6/25 (24.0)	
Coronary sinus lead	9/25 (36.0)	
New arrhythmias	5 (2.8)	
Bleeding	17 (9.7)	
TVARC type ≥3a	13 (7.4)	
Life threatening	3 (1.7)	
Vascular complication	8 (4.5)	
Major	2 (1.1)	
AKI	22 (12.5)	7.6-17.4
Stage ≥2	9 (5.1)	1.9-8.4
HALT	11 (6.3)	2.7-9.8
RLM	3 (1.7)	0.1-3.6
Major valve thrombosis	3 (1.7)	0.1-3.6

Moderate/Severe RV dysfunction: predictor of mortality

- TAPSE <14 mm and RV s ′ < 9 cm/s or RV fractional area change <33%
- 13.9% vs 0.7% in-hospital, 19.4% vs. 2.4% at 30 days

Massive/Torrential TR (4+/5+): predictor of improvement in NYHA class

Agnellotti et al, JACC CVI 2025

TRIPLACE Registry: Effect of TTVR on Lead Function in Patients Treated with Prior CIED ("Jailed" Leads)

Lead Data

Lead-related outcomes

Median follow-up	181 Days
N = 101	
Confirmed Lead Failure	5.9%
New PPM implanted	6.9%

N = 101	
Pacing dependent	51%
Lead contributing to TR	66%

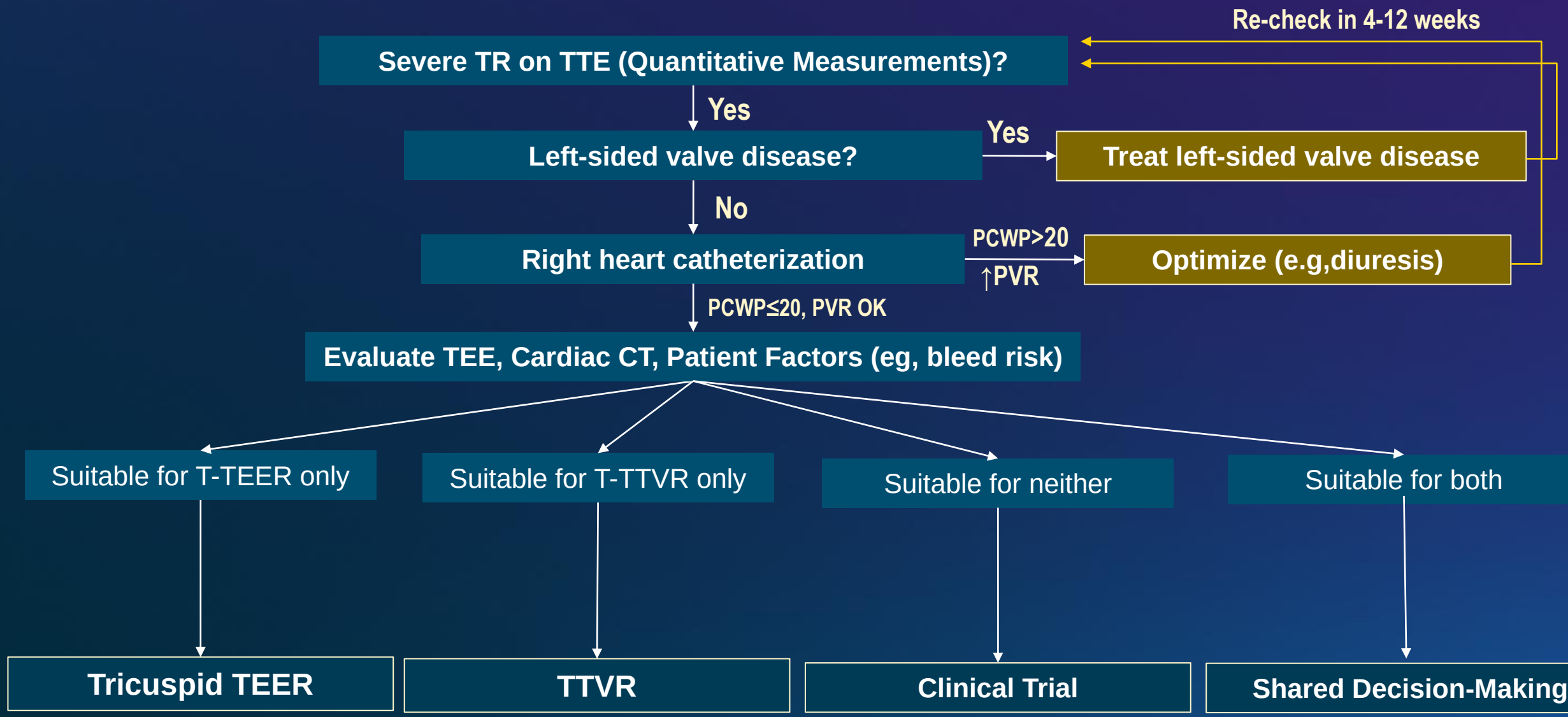
Lead position	%
Central	13.33
A-S	11.67
P-S	50
P-A	3.33
A leaflet	6.67
P leaflet	6.67
S leaflet	8.33

Lead Parameter Changes

N = 60	Baseline	Most recent	P Value
Threshold (V)	0.84	1.04	***0.045***
Sensing Amplitude (mA)	8.69	9.22	NS
RV pacing frequency (%)	68	72	NS
Impedance (Ohms)	511	494	NS

NY Heart Valves, 2025

MY APPROACH TO TRICUSPID INTERVENTION



Can We Do Better With TTVR?

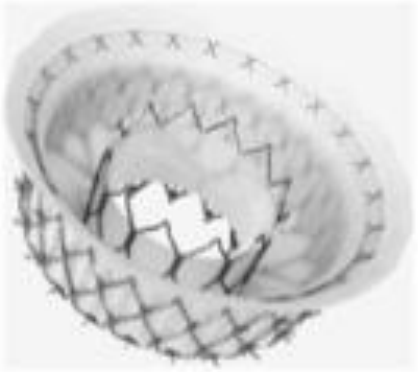
- *Decrease the rate of pacemaker implantation*
  - Reduced radial strength at annulus? Alternative anchoring mechanisms?
- *Improve anatomical screen fails (40-50%)*
- *Improve procedural/30-day safety*
  - Effect on RV afterload
- *Improve leaflet performance*
- *Increase ease of implantation (less intensive MPR imaging)*

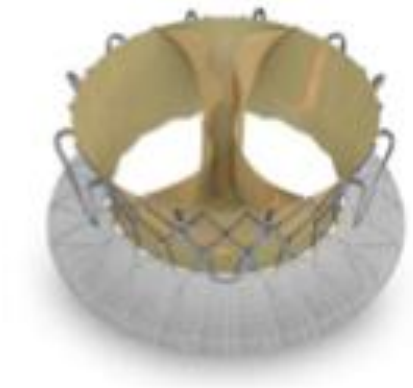
Beyond Evoque: The Coming Parade of TTVR Technology

Several Early Feasibility Studies Ongoing or Completed in US/OUS









Formal, randomized/prospective studies for approval soon

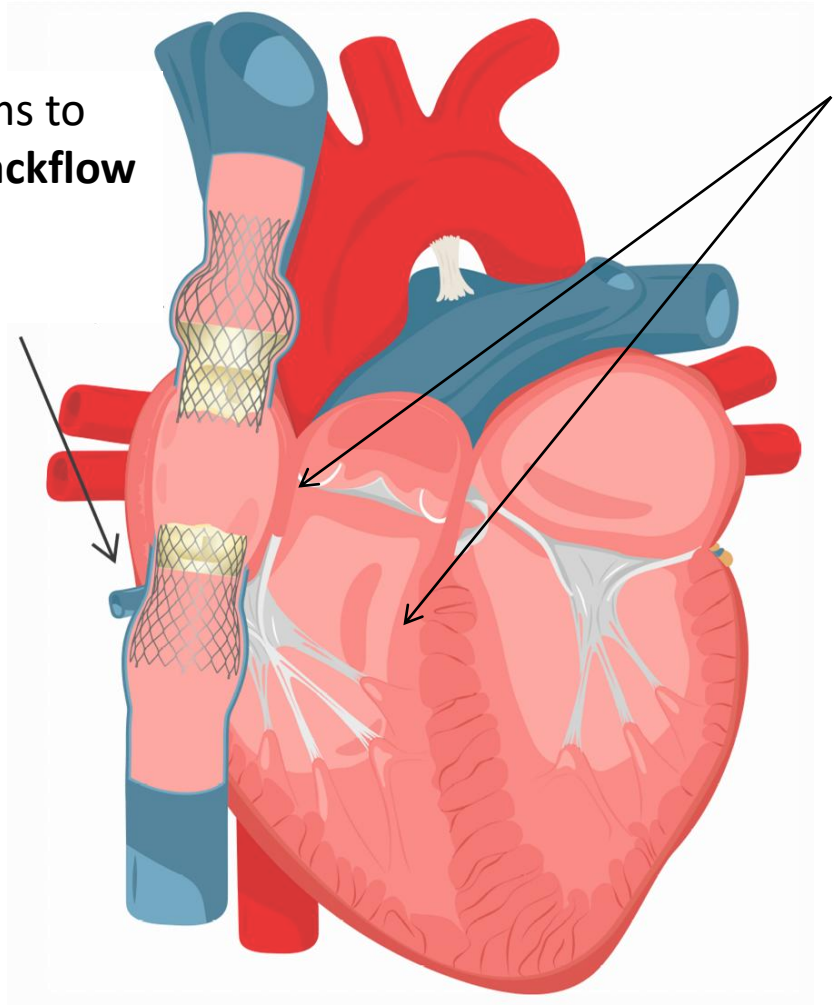
Heterotopic Bicaval Valves System: TricValve

Two independent mechanisms to **control the right ventricle backflow**

Compatible with **pre-existing pacemaker**

Standard **procedure time** between **30-50 min**

Right atrium acting as a **reservoir**



Recovered right ventricular pressure and joint work of atrium and ventricle

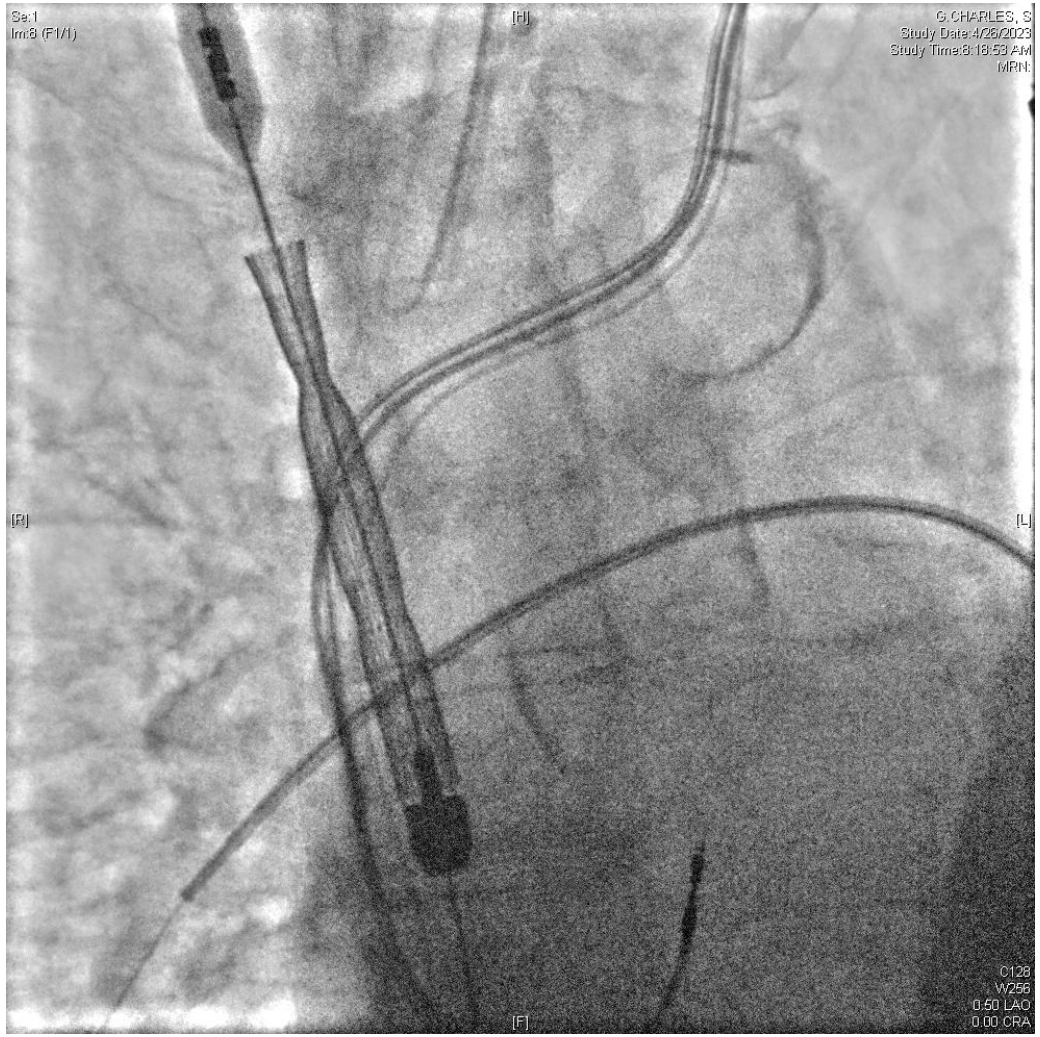
Possibility of **multiple future heart interventions**

Native valve remains **untouched**

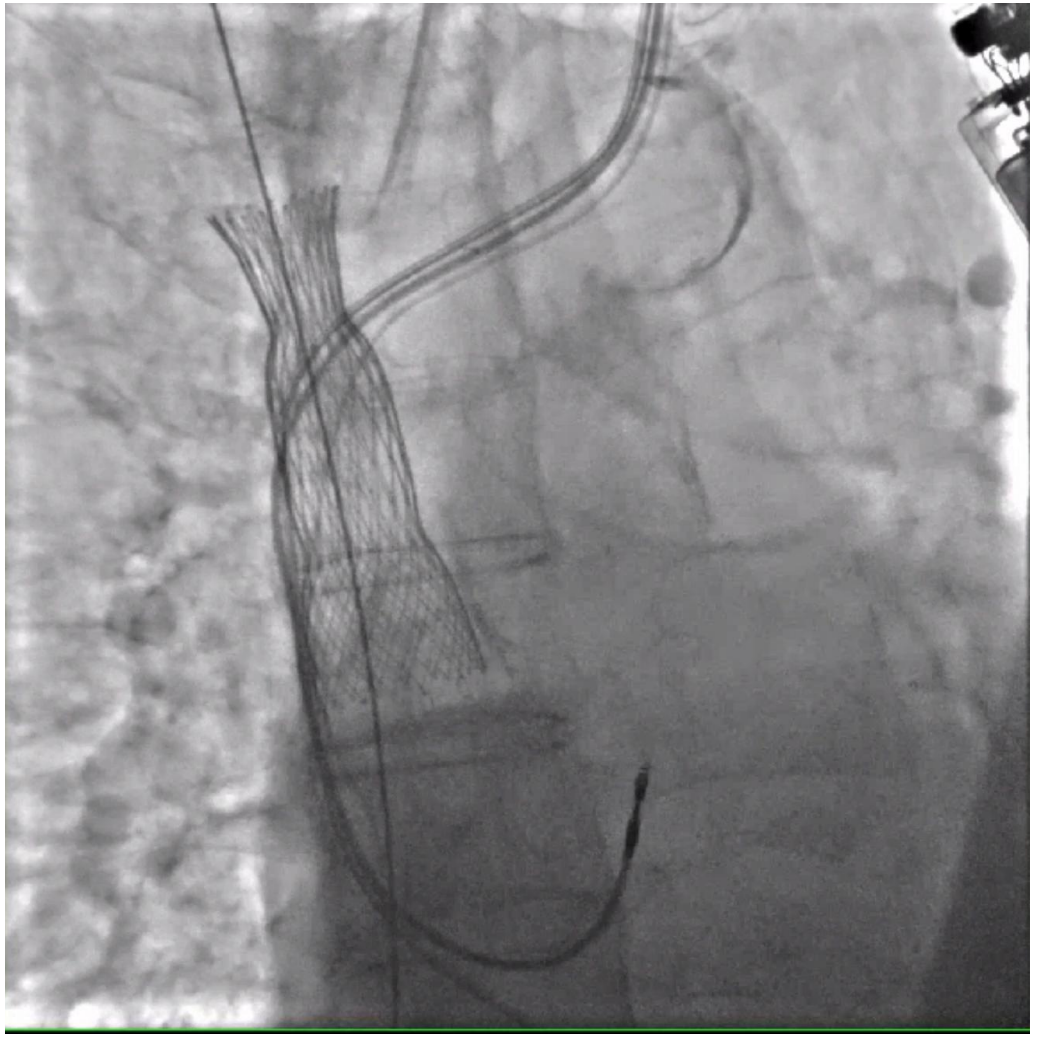
Minimally invasive procedure with the possibility of **conscious sedation**

Heterotopic Caval Valve Implantation (CAVI) with TricValve: SVC valve

SVC valve positioned using *fluoroscopy* (PA cath and carina)

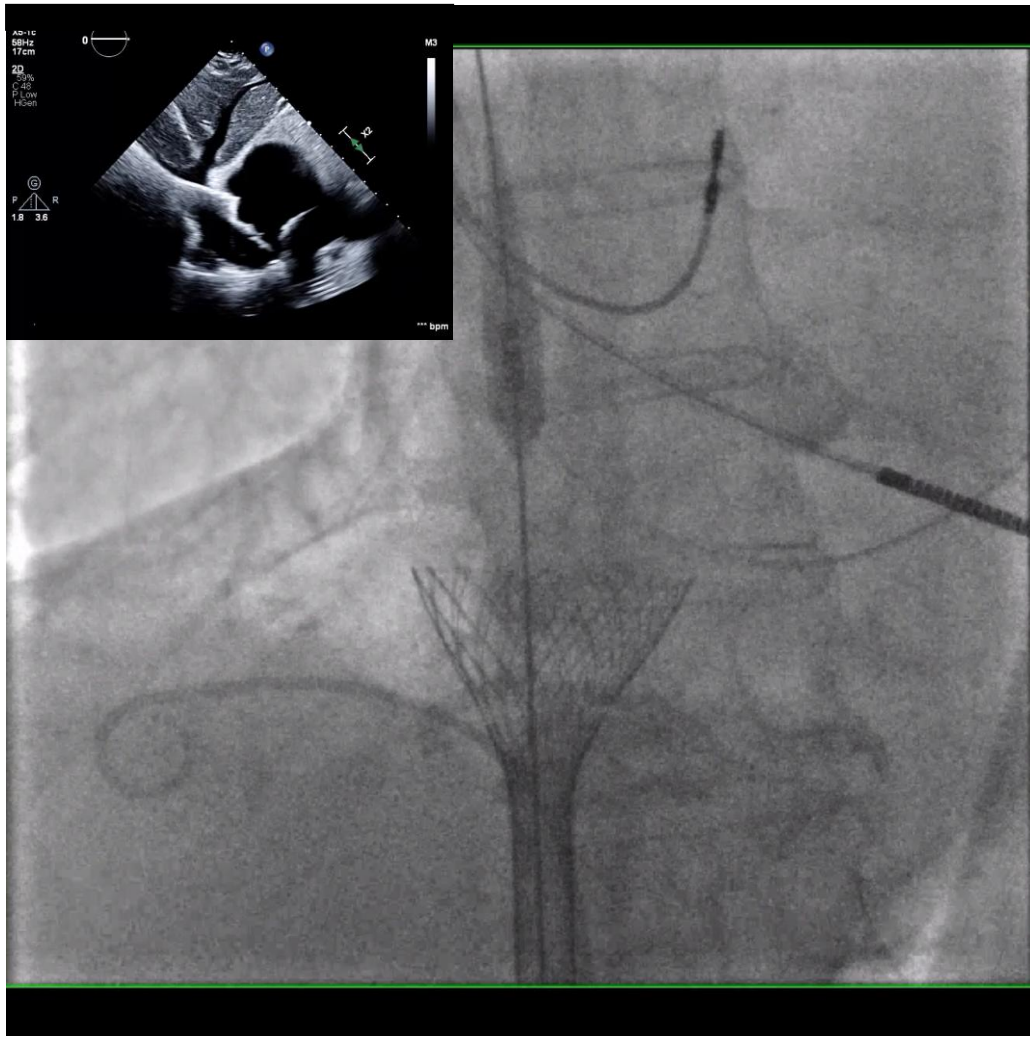


SVC valve fully deployed



TricValve (CAVI): IVC Valve

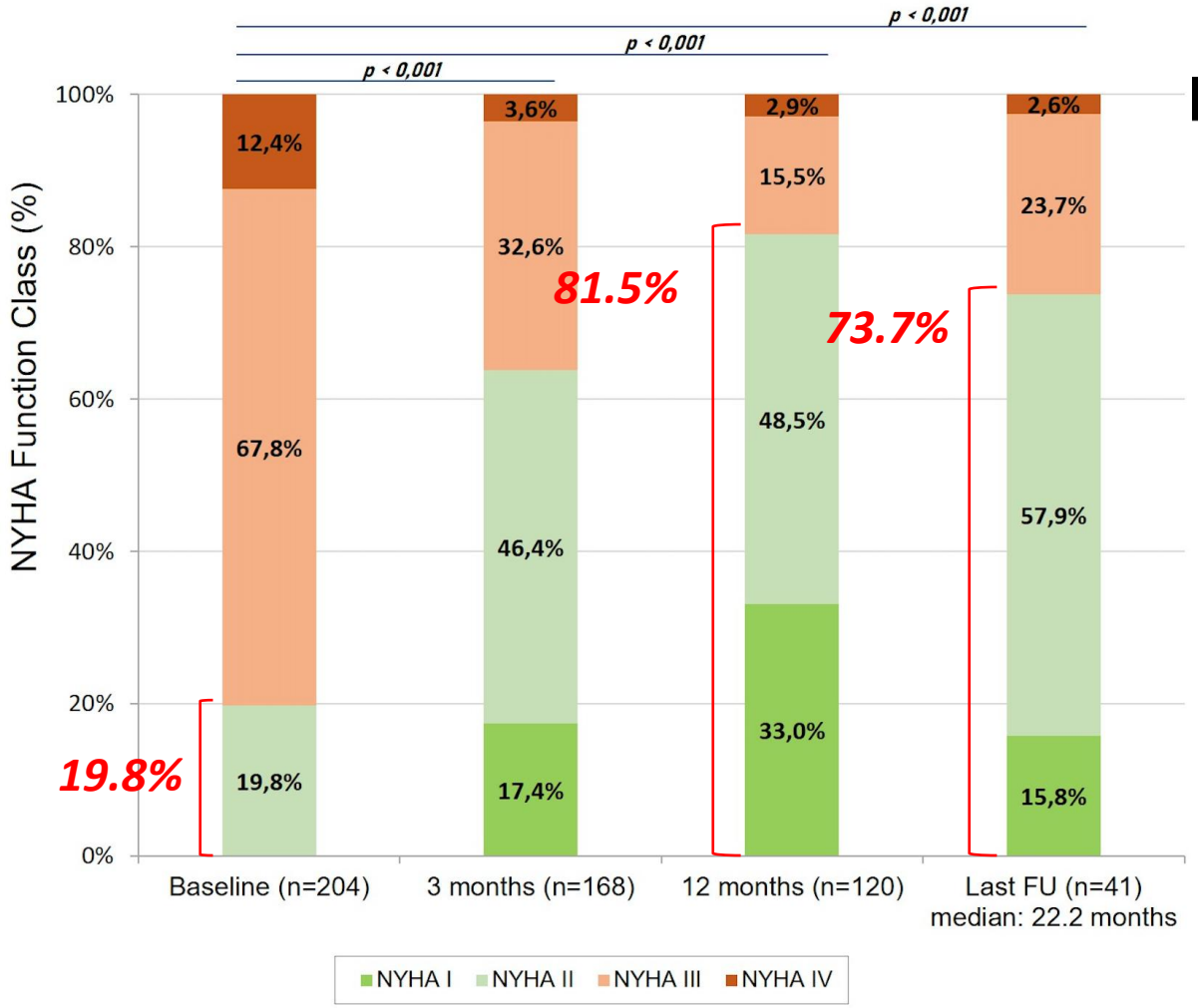
IVC valve positioned/deployed (using angiography and TTE)



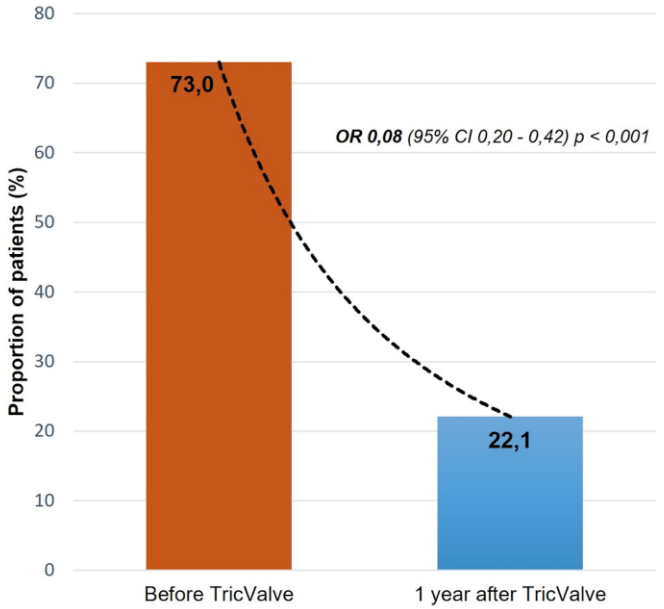
IVC valve fully deployed

TRIC-BICAVAL REGISTRY: Changes NYHA Class & peripheral congestion

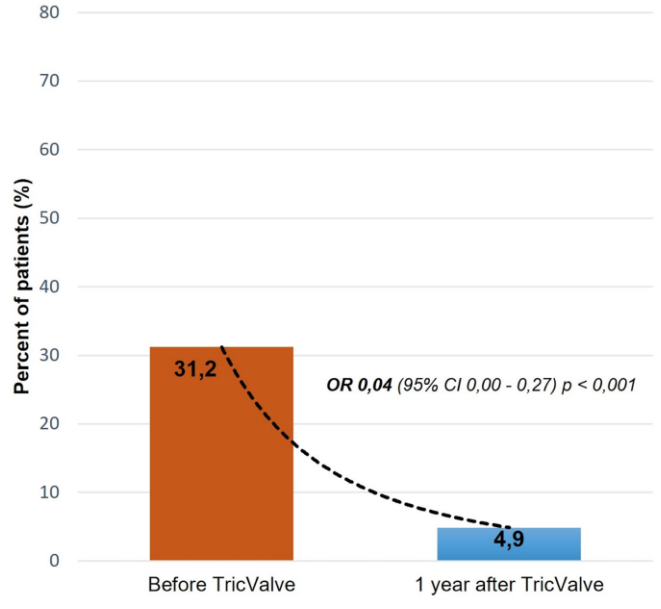
Functional class improvement



Improvement of peripheral edema



Improvement of ascites



TricValve is available in >10 countries across Latin America

Tricus Registry

Brazil: 7 sites

Chile: 2 sites

Uruguay: 1 site

Argentina: 4 sites

FDA Clinical Roadmap

P&F PRODUCTS & FEATURES

Compassionate Use

- **31/36 patients** treated in the US
- Not eligible for **clip or replacement or surgery**
- Data presented at **CRT 2024**

TRICAV-I

- Single Arm
- 50 patients at **50 sites**
- NYHA III-IV
- **Currently enrolling**

TRICAV-II

- 2:1 Randomized vs OMT
- **400 randomized pts** for total of **780 pts at 50 sites**
- NYHA III/IV
- **Crossover at 12 months**
- Includes Registry for pts outside of I/E
- **Currently under review with FDA**

Indication for use:
The TricValve Transcatheter Bicaval Valve System is intended for the treatment of patients with **severe symptomatic tricuspid regurgitation** (hemodynamically relevant) and caval reflux. It is intended for use in patients at **high risk** or **who are inoperable for open surgery**.

Summary

- Work-up of the TR patient should include **recognition and optimization of left-sided disease**
- Only TriClip and Evoque have completed RCTs vs medical therapy
  - Both associated with large improvements in QOL
  - Improvement in HFH at 2 years with TriClip
- Device selection should incorporate TV anatomy, severity of symptoms/TR, ability to tolerate OAC, risk of PPM, RV function, and **patient preference**
- **There is an unmet clinical need for devices** that can safely provide consistent TR reduction across a broad range of anatomies