Trikuspidální Chlopeň
Včera, Dnes a Zítra?!

ň

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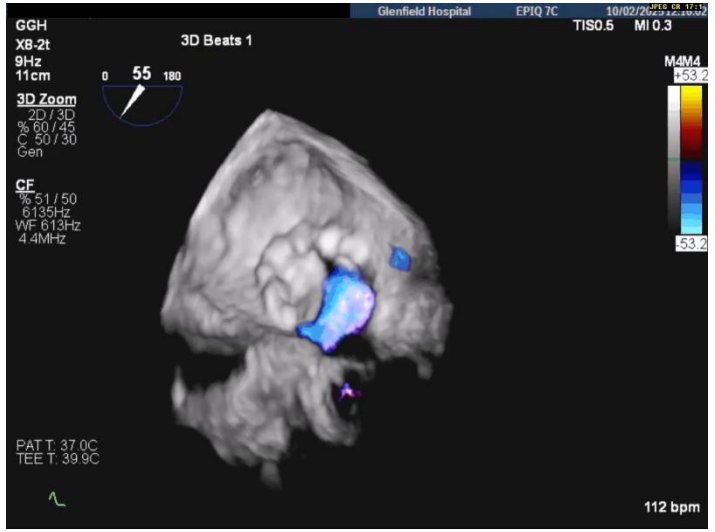
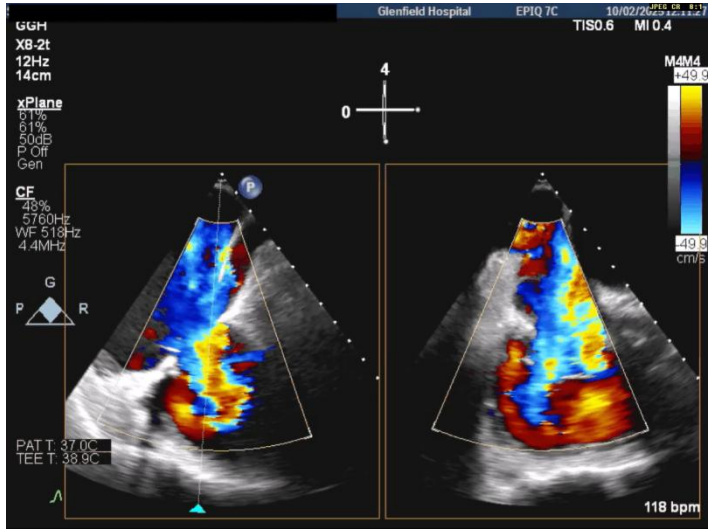
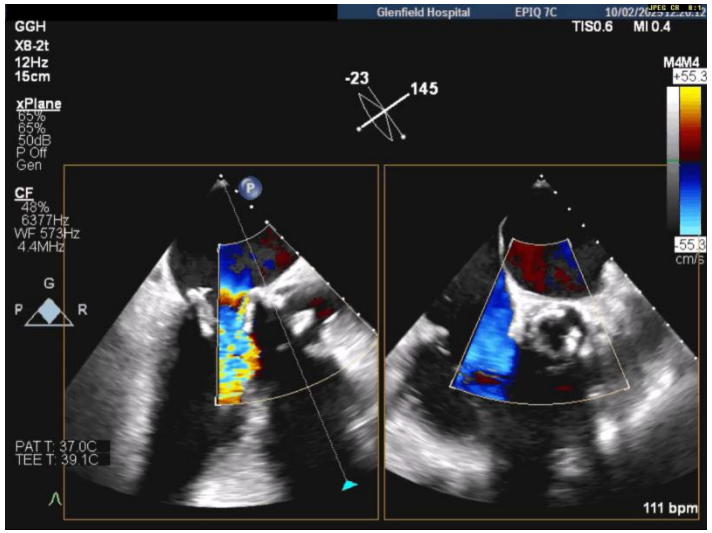
Glenfield Hospital, NIHR BRU Leicester
Leicester
United Kingdom

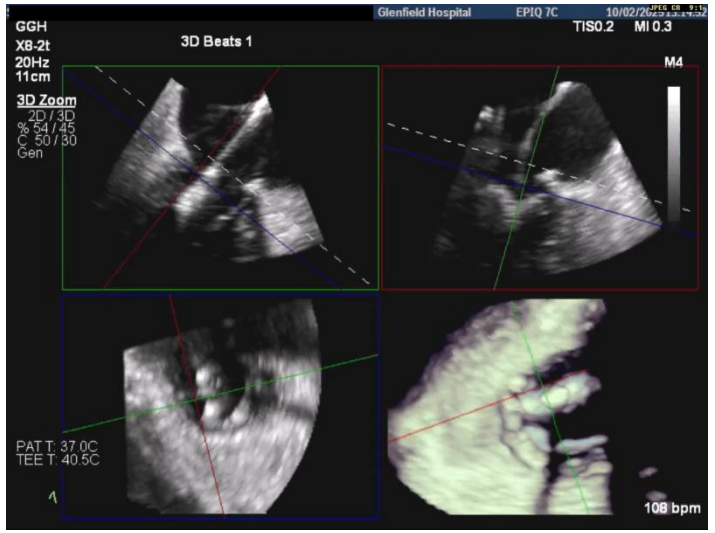
ČAIK 2025, Praha

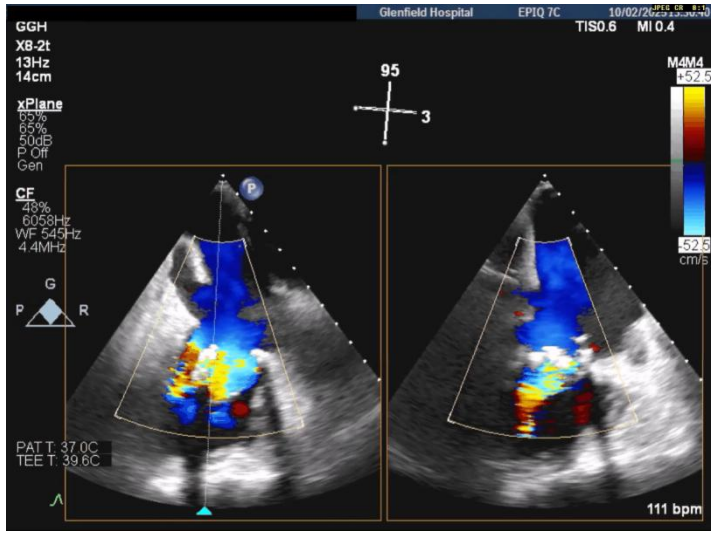
AVR(Mosaic 23mm)
MVR(Mosaic 29mm)
Tricuspid repair(Cosgrove Edwards annuloplasty band 34mm) 2010
AF
T2DM
Previous endocarditis
Depression
Pneumonitis











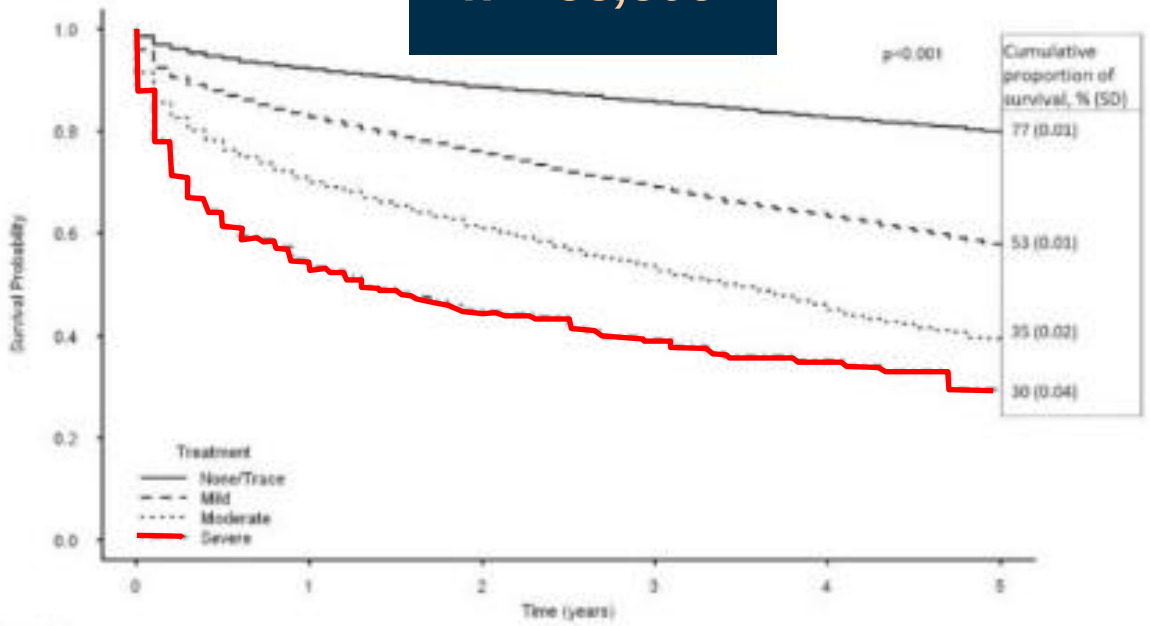
Tricuspid regurgitation and long-term clinical outcomes

FREE

Ehud Chorin, Zach Rozenbaum, Yan Topilsky, Maayan Konigstein, Tomer Ziv-Baran, Eyal Richert, Gad Keren, Shmuel Banai ✉ Author Notes

European Heart Journal - Cardiovascular Imaging, Volume 21, Issue 2, February 2020, Pages 157–165, https://doi.org/10.1093/ehjci/jez216

n = 33,305



Canadian Journal of Cardiology
Volume 37, Issue 7, July 2021, Pages 1078-1085

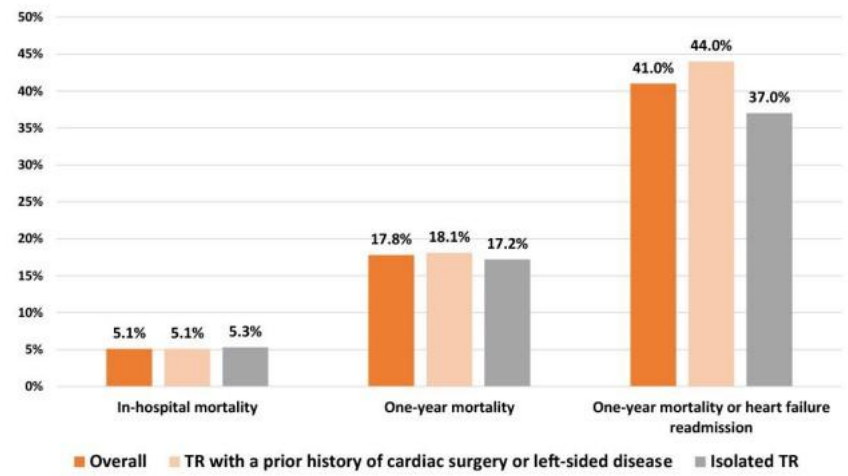
Clinical Research

Management and Outcome of Patients Admitted With Tricuspid Regurgitation in France

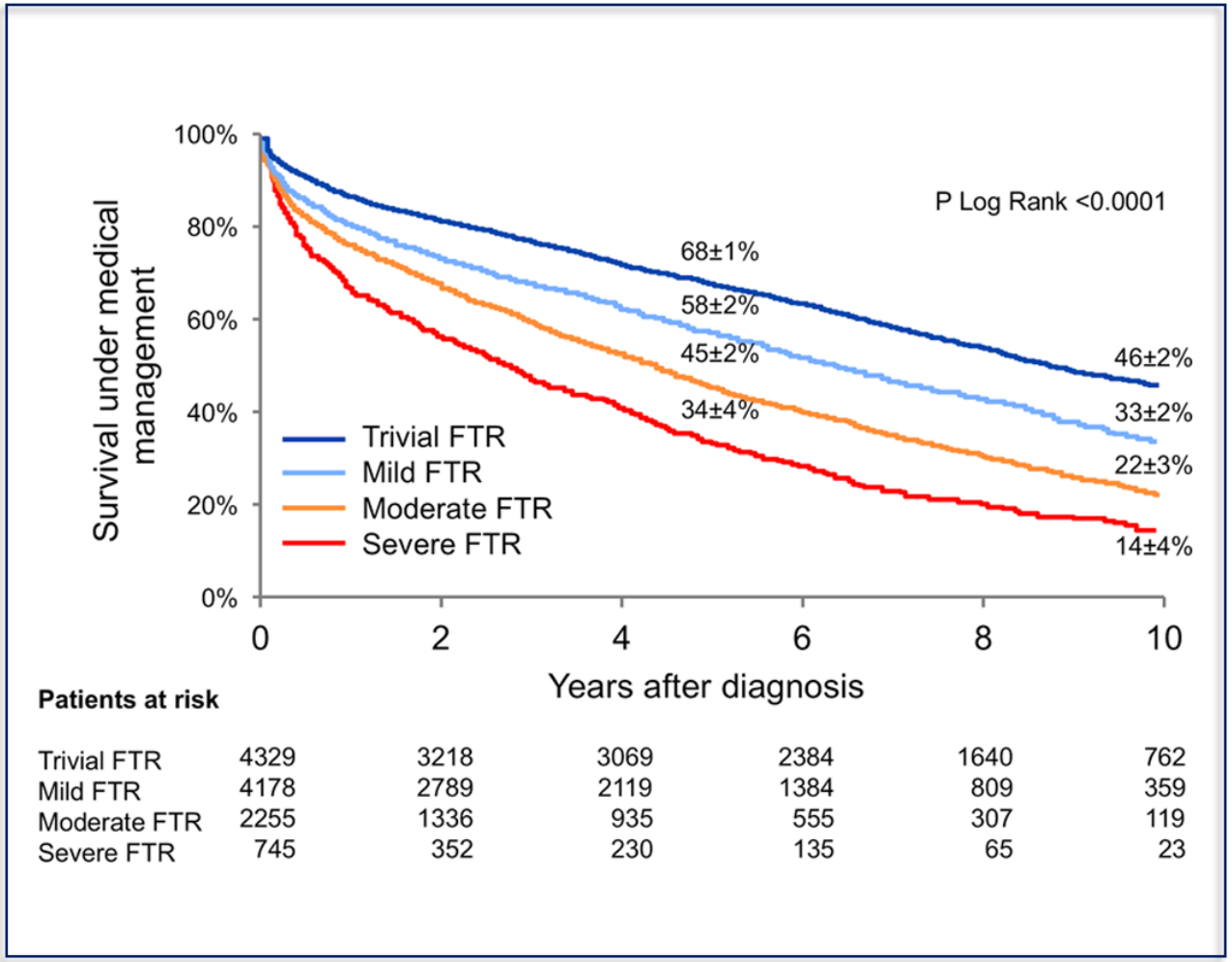
David Messika-Zeitoun MD, PhD [a] ✉, Pascal Candolfi PhD [b], Julien Dreyfus MD [c], Ian G. Burwash MD [a], Bernard Iung MD [d e f], Jean-François Philippon MD [g], Jean-Manuel Toussaint MSc [h], Patrick Verta MS Stat, MD [i], Ted E. Feldman MD [i], Jean-Francois Obadia PhD [j], Alec Vahanian MD [e f], Thierry Mesana MD [a], Maurice Enriquez-Sarano MD [k]

n = 17,676

Event rates in patients with tricuspid regurgitation managed conservatively in a nationwide cohort from France



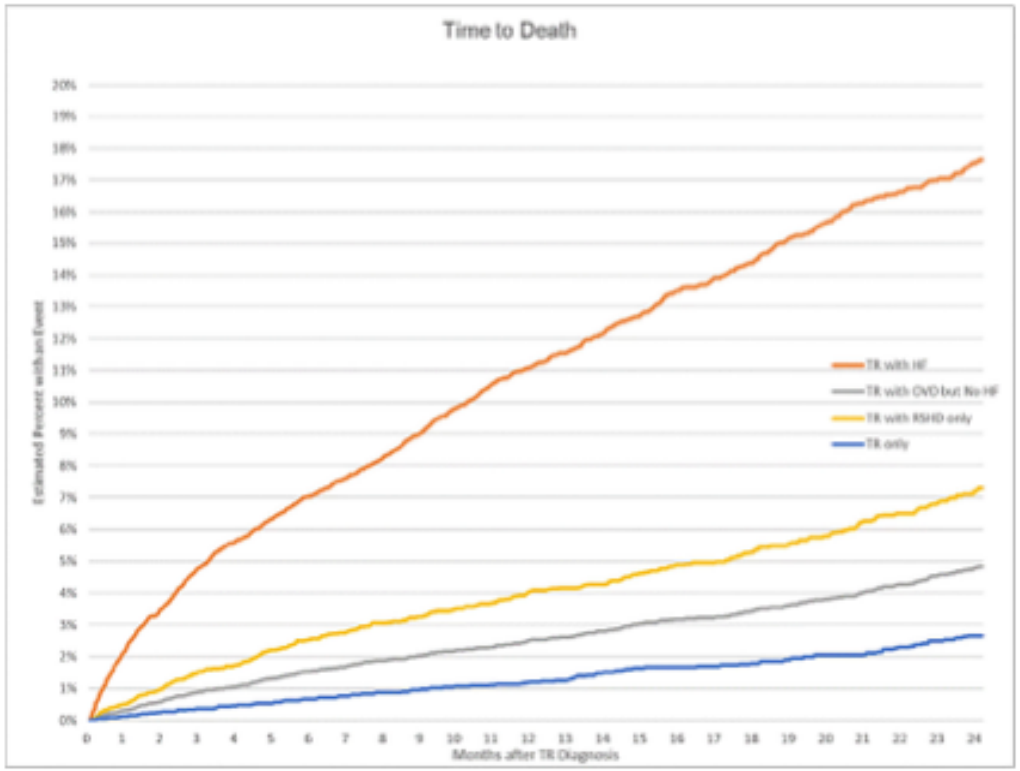
Tricuspid Regurgitation & Mortality



Patients at risk

Trivial FTR	4329	3218	3069	2384	1640	762
Mild FTR	4178	2789	2119	1384	809	359
Moderate FTR	2255	1336	935	555	307	119
Severe FTR	745	352	230	135	65	23

Data from the US Optum Integrated File (2007-18)

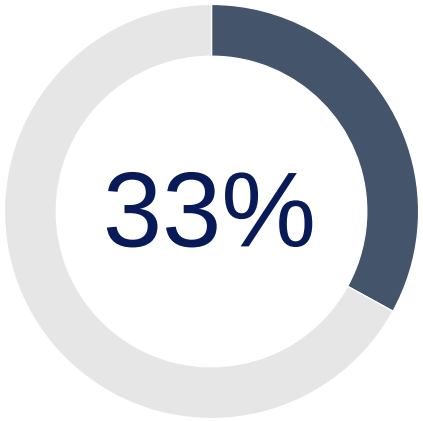


HF=heart failure
OVD=other valve disease
RSHD=right-sided heart disease

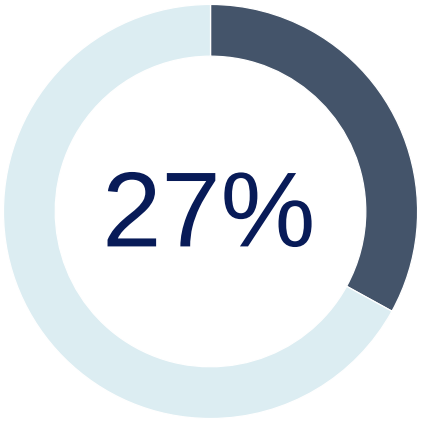
Benfari, et al. *Circulation* 2019;**140**:196-206 Enriquez-Sarano, et al. *Prog Cardiovasc Dis*,2019;**62**:447-51 Barker CM, et al. *Am J Cardiol* 2021;**144**:125-30

Patients with Heart Failure have High Rates of Tricuspid Regurgitation

- **TR is present in up to 60% of patients with HF[1]**



of patients with HF have mild TR[1]



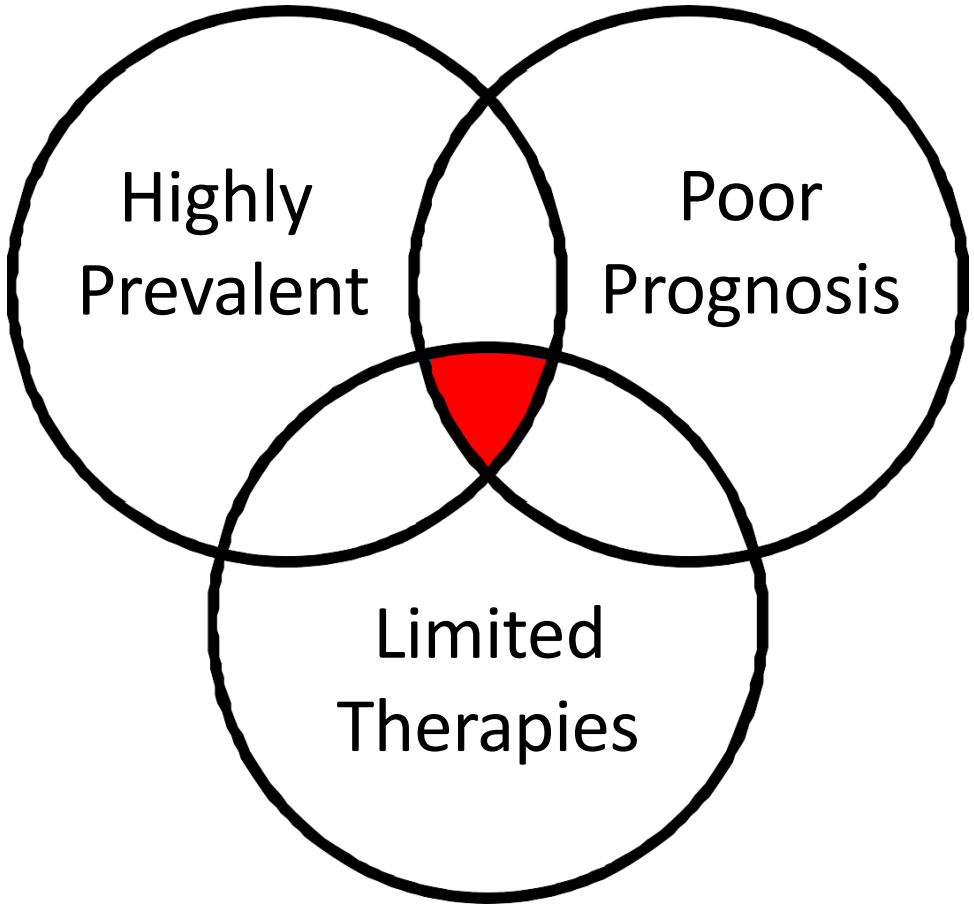
of patients with HF have moderate-to-severe TR[1]

TR is a significant clinical problem affecting >300,000 patients per year in Europe[2]

1. Santas E, Chorro FJ, Miñana G, *et al. Circ J* 2015;**79**:1526-33.

2. Asmarats L, Puri R, Latib A, Navia JL, Rodés-Cabau J. *J Am Coll Cardiol* 2018**;71**:2935-56

∼ 1.6 million in the US
with > moderate TR



>50% three-year mortality
with > moderate TR

Operative mortality ∼ 9%

Tricuspid Regurgitation Management

Medical management represents the current standard treatment but **is often ineffective** in reducing symptoms

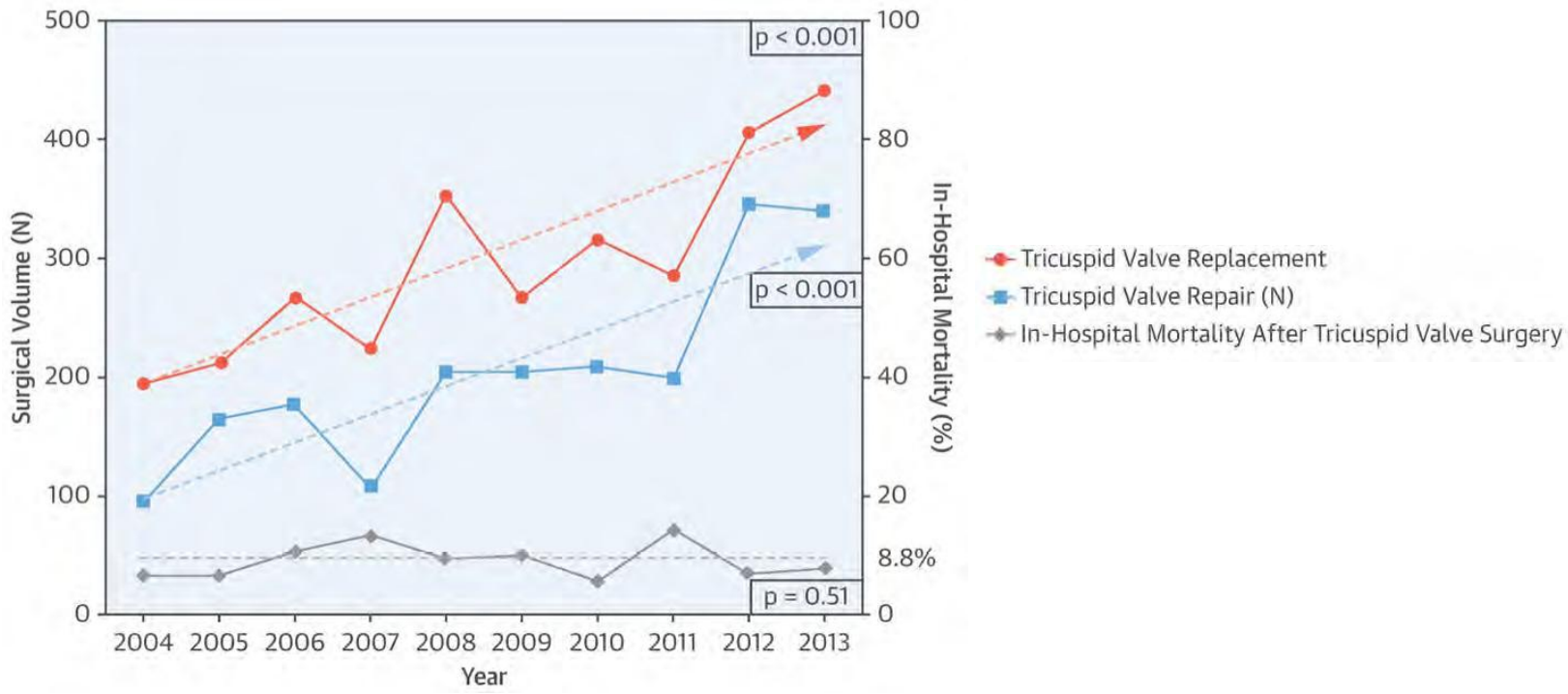
Medical management is not associated with a mortality reduction or **a positive long-term effect**. There are no other drug options after diuretics and mineralocorticoid receptor antagonists (MRAs)

Medical management is still associated with a poor prognosis: in one study, 29% patients treated medically died during the follow-up period and the 5-year survival rate was 74%.

Isolated tricuspid valve surgery is rarely performed / offered to patients due to:

- poor results in terms of survival benefit
- a high level of procedural mortality (9% in-hospital)

Operative Mortality for TR remains high



C.J. Zack, E.A. Fender, P. Chandrashekar, et al. National trends and outcomes in isolated tricuspid valve surgery
J Am Coll Cardiol, 70 (2017), pp. 2953-2960

2021 ESC Valvular Heart Disease & Heart Failure Guidelines:
Secondary Tricuspid Regurgitation

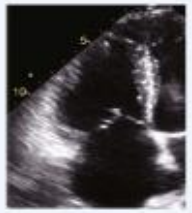
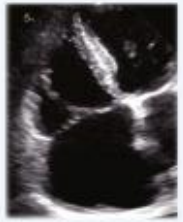
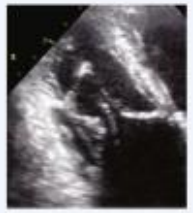
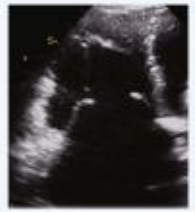
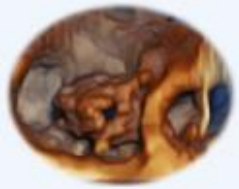
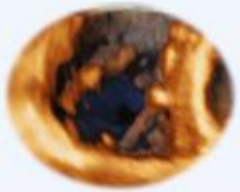
Recommendations on secondary tricuspid regurgitation		
Surgery is recommended in patients with severe secondary tricuspid regurgitation undergoing left-sided valve surgery.[423–427]	I	B
Surgery should be considered in patients with mild or moderate secondary tricuspid regurgitation with a dilated annulus (≥40 mm or >21 mm/m^2 by 2D echocardiography) undergoing left-sided valve surgery.[423,425–427]	IIa	B
Surgery should be considered in patients with severe secondary tricuspid regurgitation (with or without previous left-sided surgery) who are symptomatic or have RV dilatation, in the absence of severe RV or LV dysfunction and severe pulmonary vascular disease/hypertension.[418,433 e]	IIa	B
Transcatheter treatment of symptomatic secondary severe tricuspid regurgitation may be considered in inoperable patients at a Heart Valve Centre with expertise in the treatment of tricuspid valve disease.[f]	IIb	C

2021 ESC/HFA HF Guidelines: TTVI…..

- Tricuspid valve surgery is recommended in patients with severe TR requiring left-sided cardiac surgery
- It should be also considered in patients with moderate TR and tricuspid annulus dilatation requiring left-sided cardiac surgery and in symptomatic patients with isolated TR
- However, surgery in isolated TR is burdened by high in-hospital mortality (8.8%) although the advanced stage of HF may have influenced these data.
- Transcatheter techniques have recently emerged as potential treatment options for TR
- Preliminary results show improvement in TR severity and symptoms with low complication rates. Further prospective studies are needed to show the prognostic impact of these treatment in HF patients

In secondary TR, the ESC guidelines consider transcatheter intervention in inoperable patients

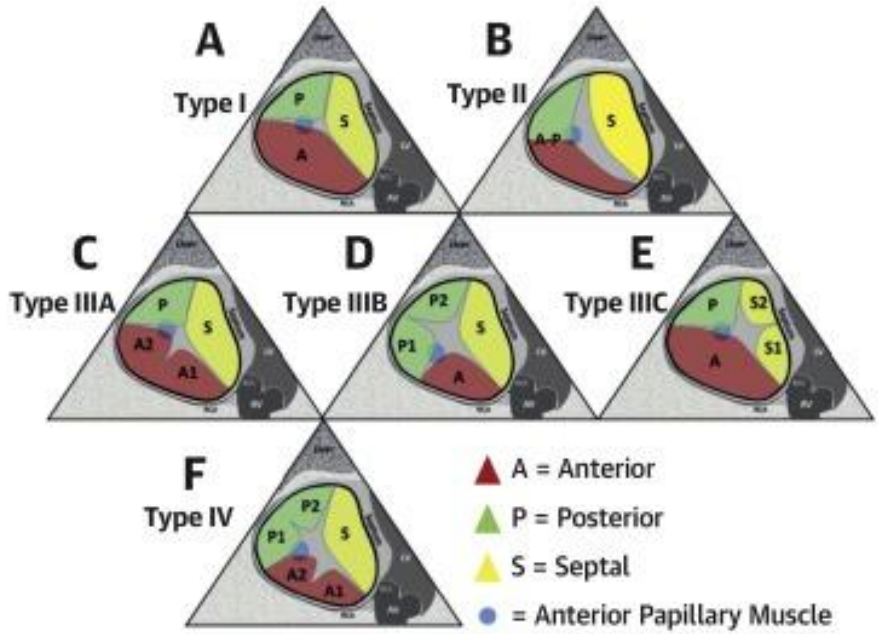
TR classification

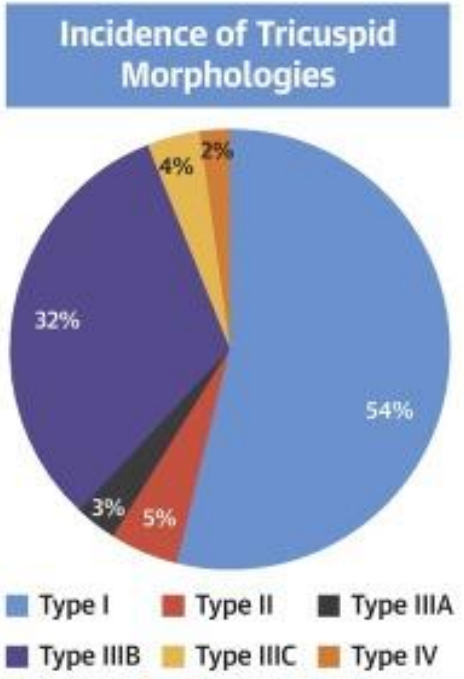
	Secondary		CIED (A)	Primary	
2D TTE					
3D TTE					
Parameter	**Ventricular**	**Atrial**	**CIED Type A**	**Primary TR**	
Carpentier Class	*IIIb*	*I*	*I, IIIa, IIIb*	*Prolapse II*	*RHD IIIa*
TV Tethering	++++	+/−	++	−	−
Leaflet Restriction	Systole	−	Systole/Diastole	−	Diastole
RA/TA Dilatation	++	++++	+/−	++	+++
RV Dilatation	+++	+/−	+/−	+/−	+/−
RV Dysfunction	+++	+/−	+/−	+/−	+/−

Hahn et al., EHJ Card Imaging 2022

TV morphologies

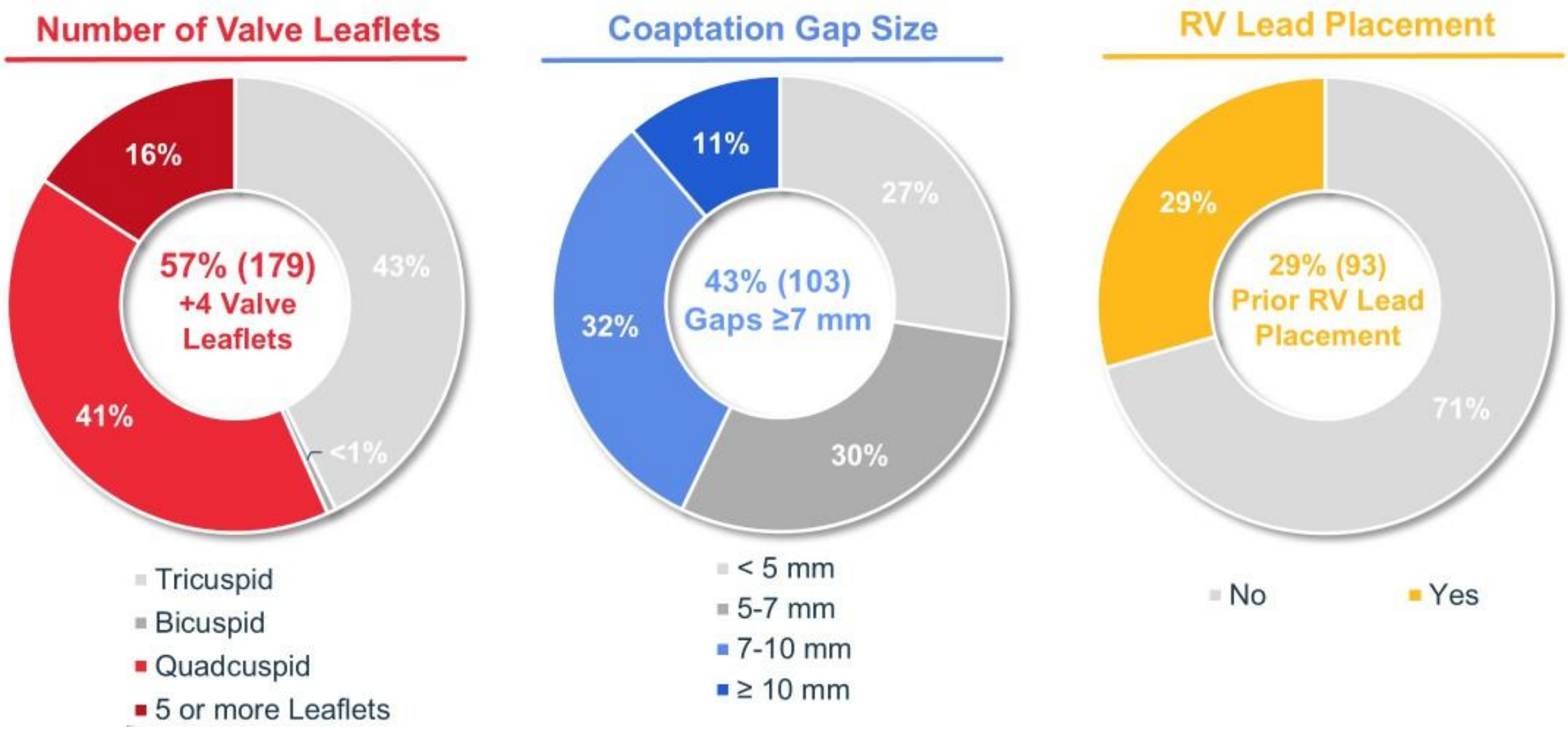
CENTRAL ILLUSTRATION: Tricuspid Valve Nomenclature
Classification Scheme



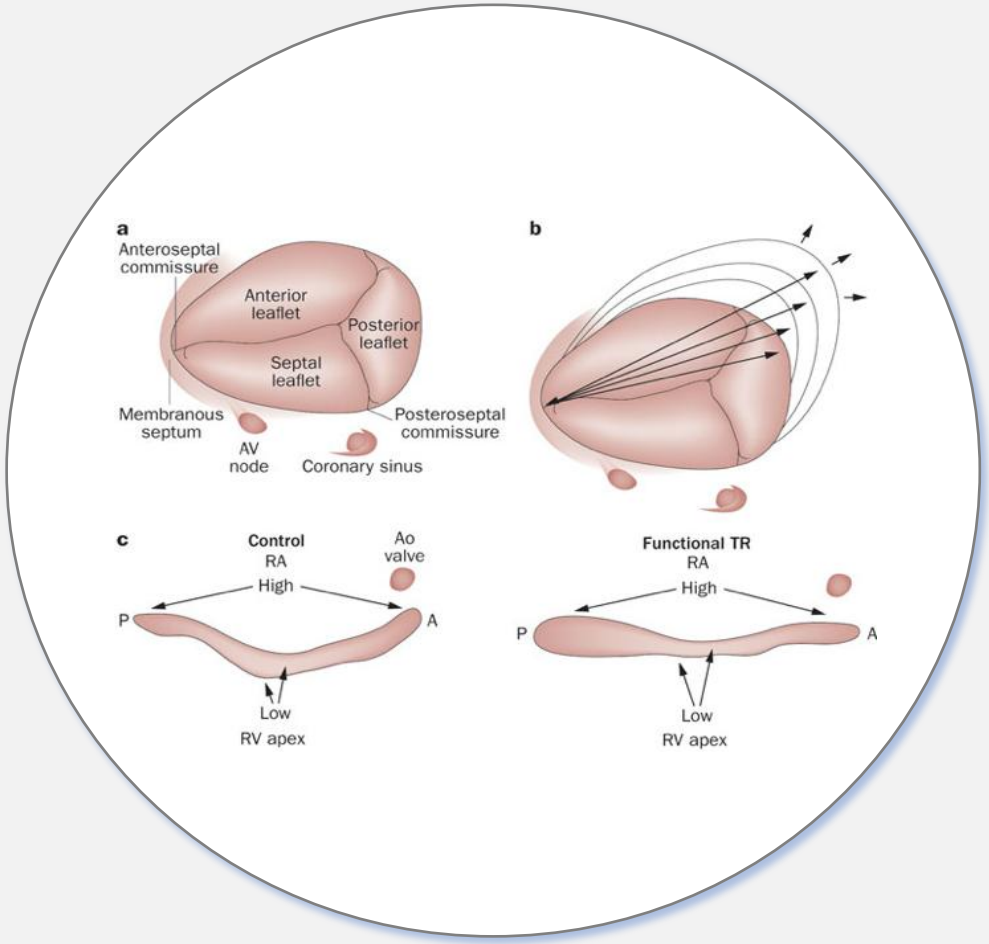


Hahn, R.T. et al. J Am Coll Cardiol Img. 2021;14(7):1299-305.

Wide Range of Anatomies



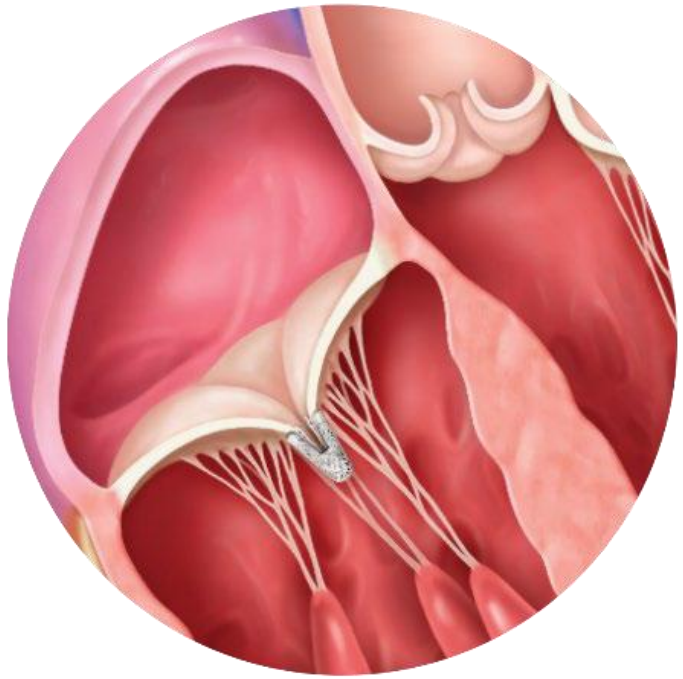
Current Challenges for Tricuspid Valve Technologies



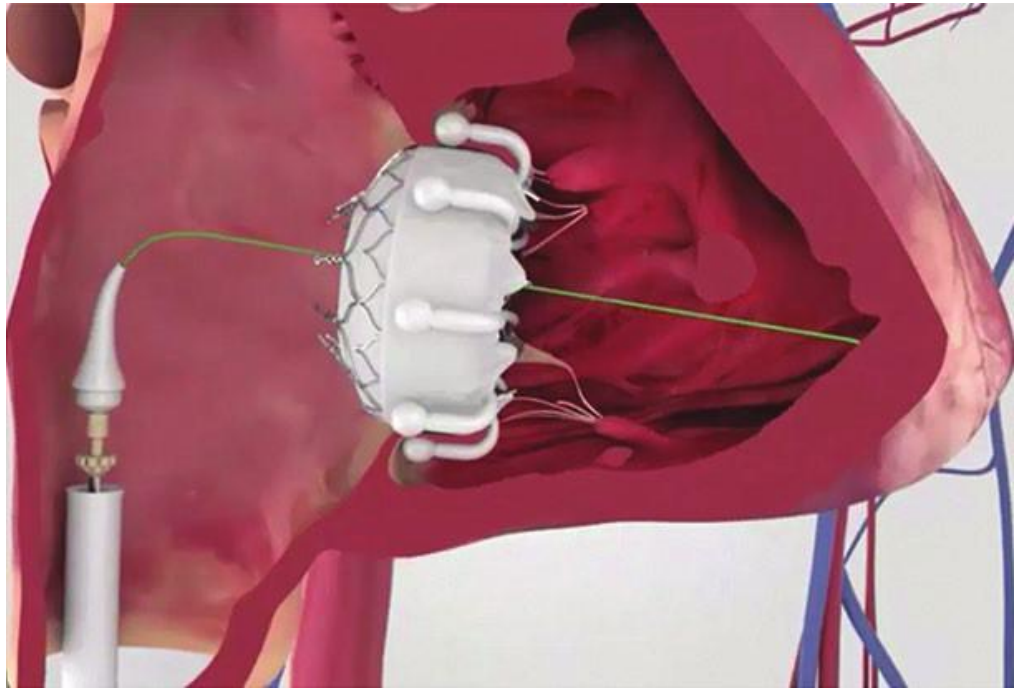
- Position/size of the **regurgitant jet**
- **Number of leaflets**
- Presence of **pacemaker leads**
- Variable shape & size of **tricuspid annulus**
- **Variable & complex leaflet anatomy**
- Difficulty capturing **tethered leaflets**
- Proximity of **RCA**
- Proximity to **AV node**

Bapat V. Making the Case for Transcatheter Tricuspid Valve Replacement: Theory and Outcomes to Date, TCT 2019

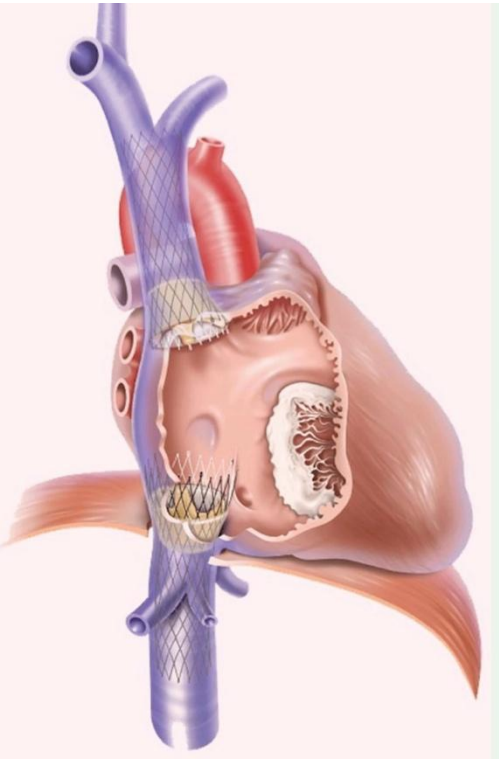
Transcatheter Approaches to Symptomatic TR



Tricuspid TEER

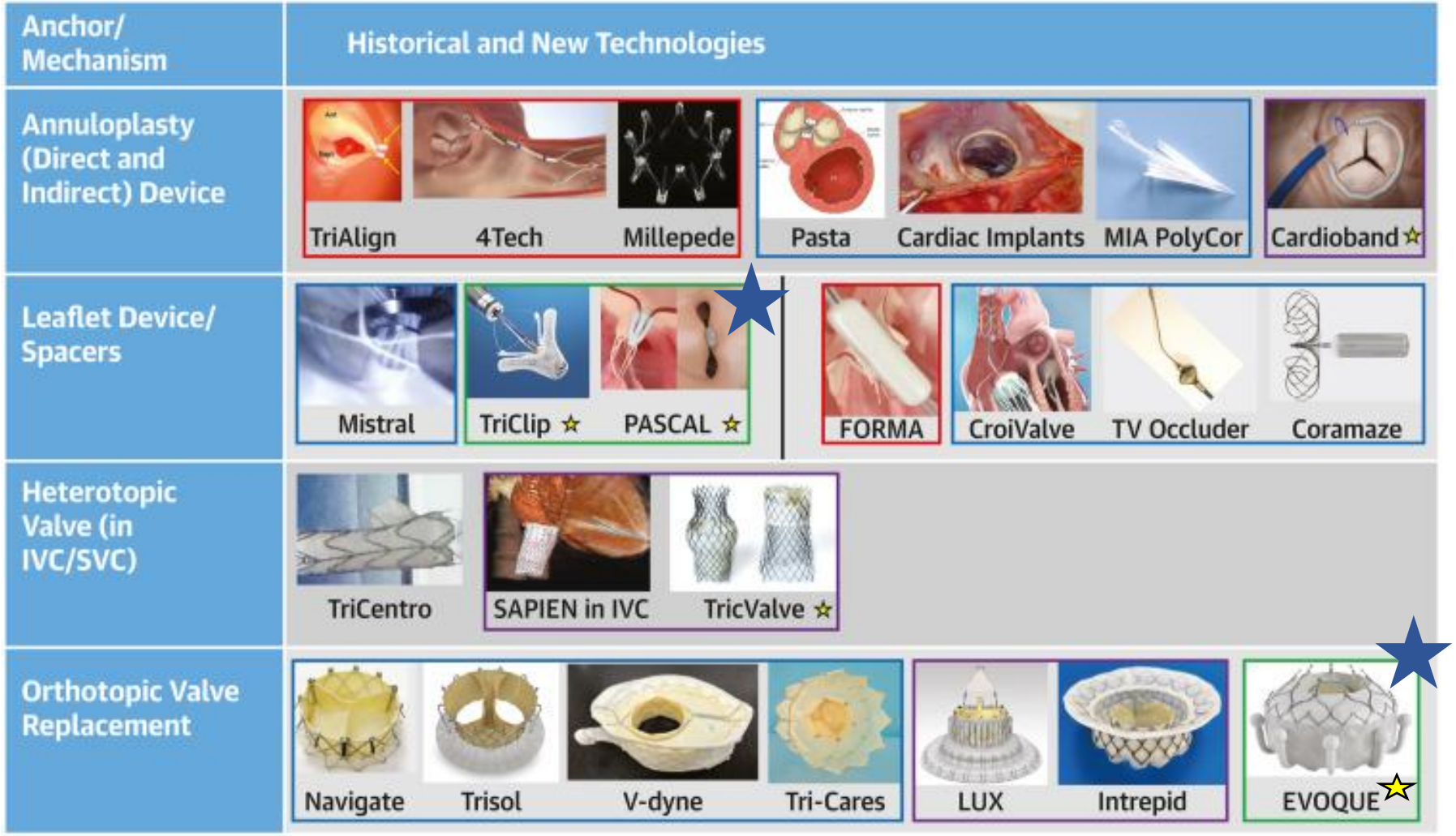


TTVR

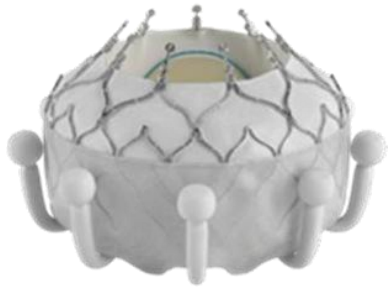


Heterotopic bicaval stenting
Tricuspid Annuloplasty

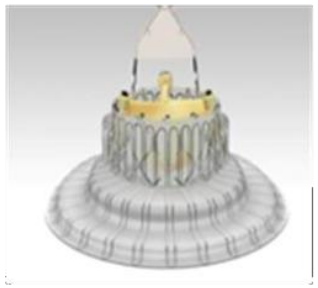
Devices Spectrum



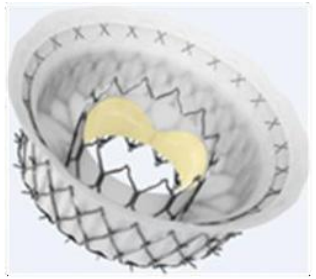
The Landscape of TTVI/R



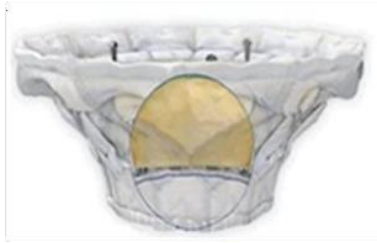
EVOQUE



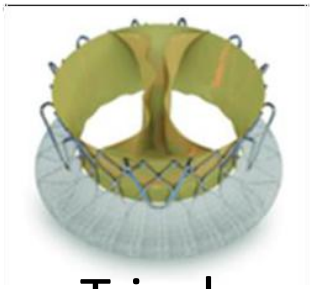
Lux



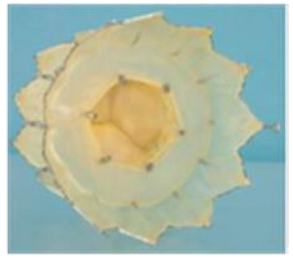
Intrepid



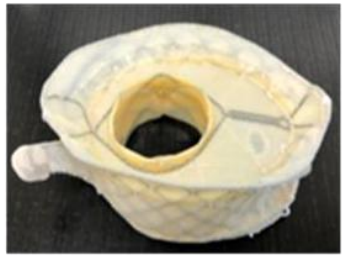
Cardiovalve



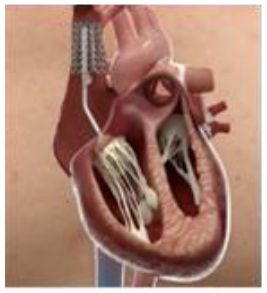
Trisol



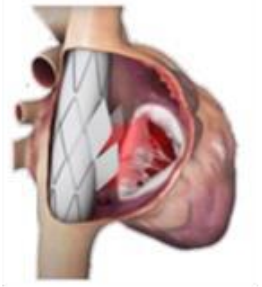
Tricares



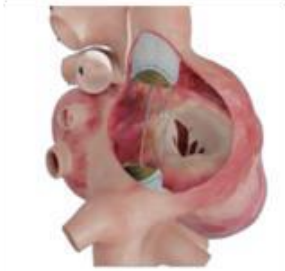
V-dyne



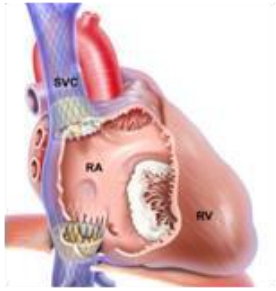
CroiValve



Trillium



Unica

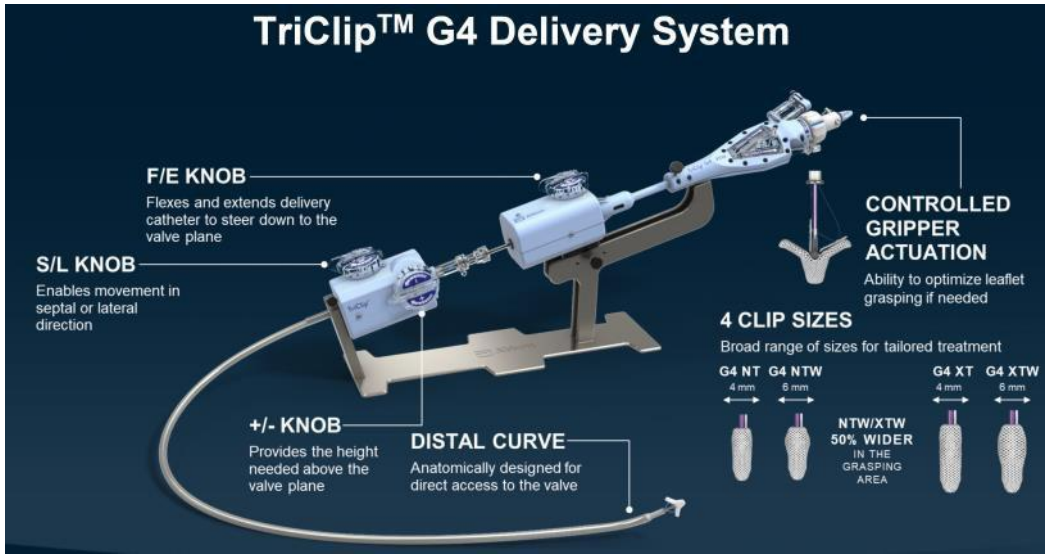


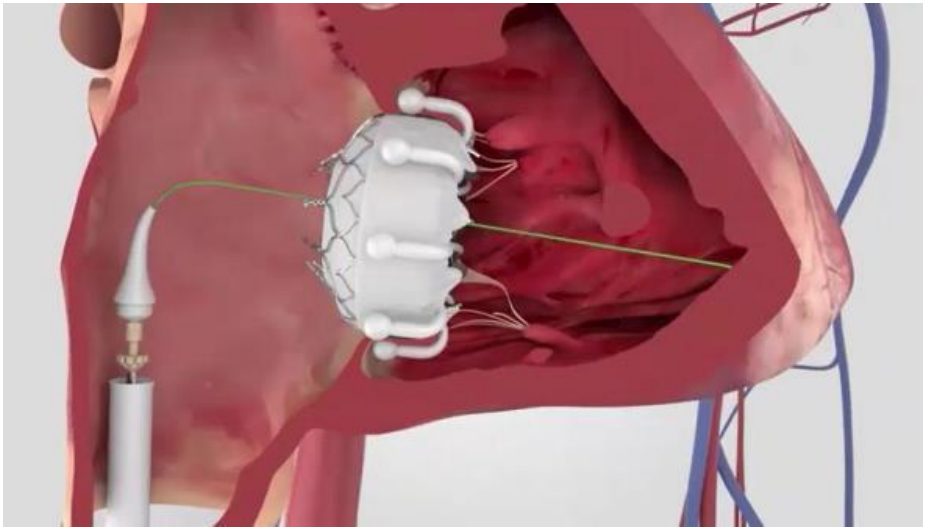
TricValve

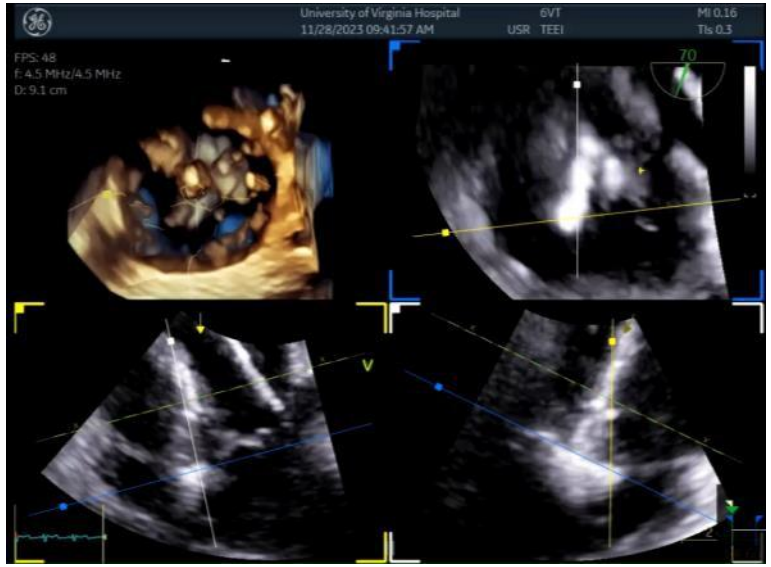
Pivot

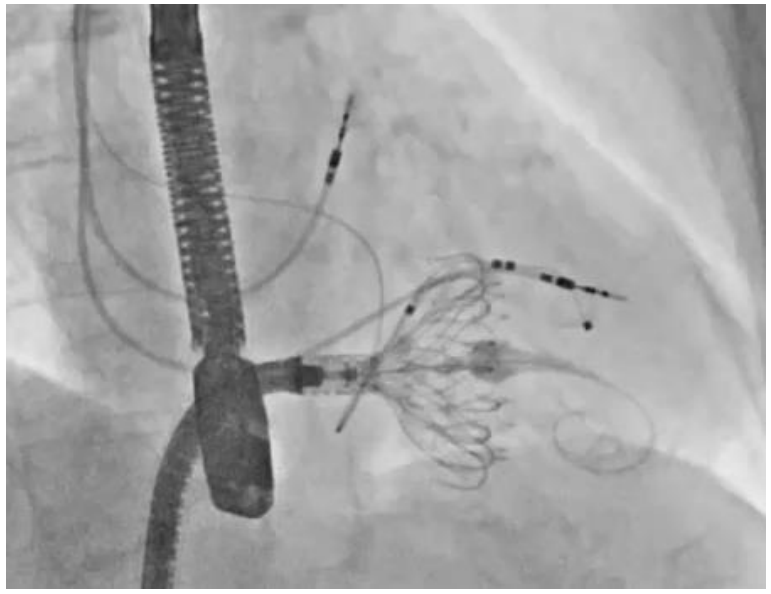
TriFlow

CE Approved TriClip, Pascal & Evoque





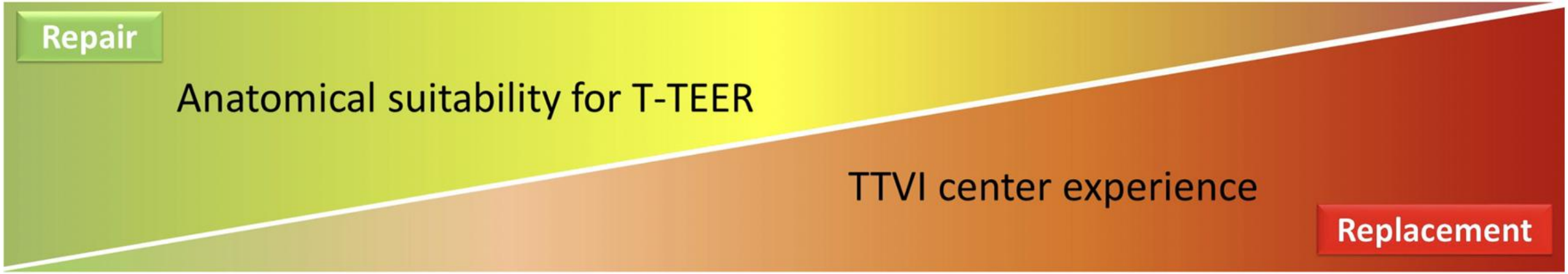




Anatomical Criteria for Device Selection in TTVI

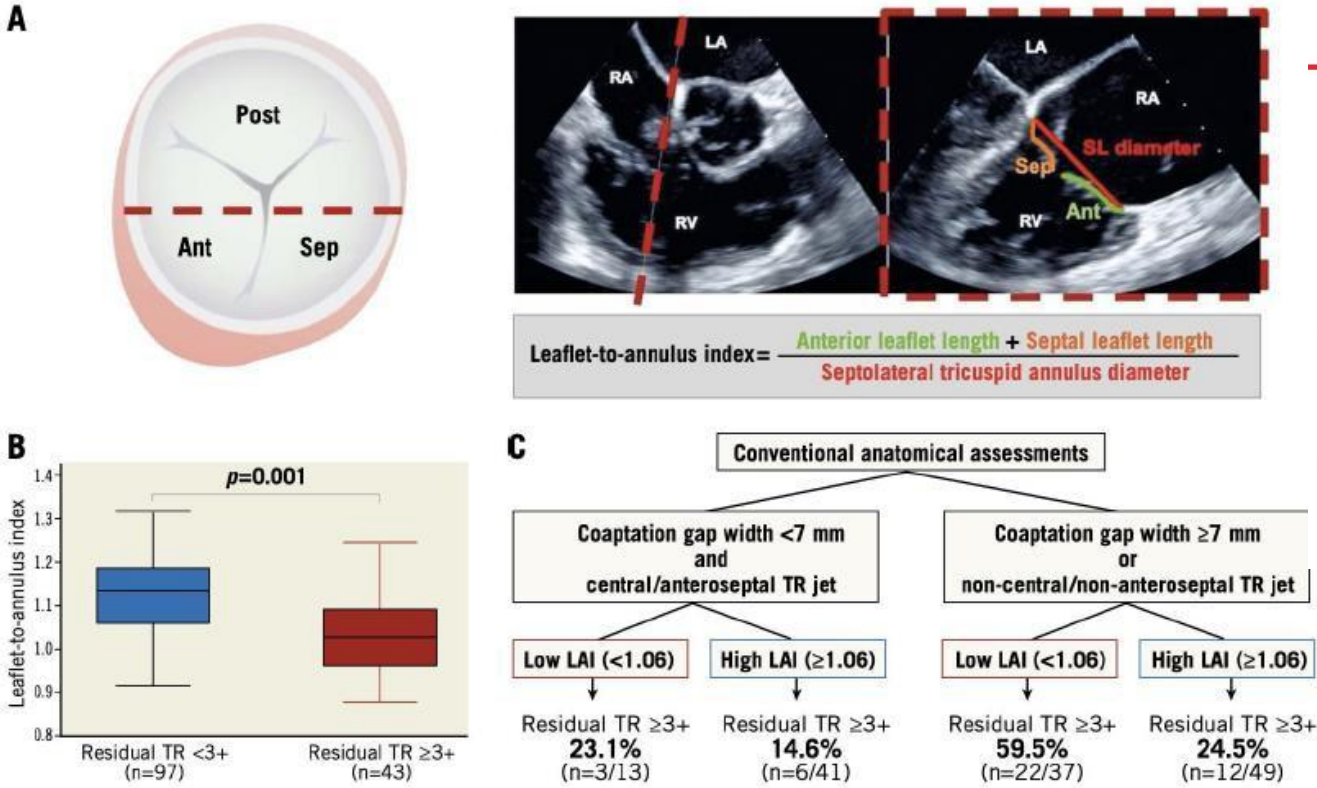
Strategy	Favorable Anatomy	Feasible Anatomy	Unfavorable Anatomy
Leaflet approximation	Small septolateral gap ≤7 mm[100] Anteroseptal jet location Confined prolapse or flail Trileaflet morphology	Septolateral coaptation gap >7 but ≤8.5 mm[101] Posteroseptal jet location Nontrileaflet morphology Incidental CIED RV lead (ie, without leaflet impingement)	Large septolateral coaptation gap >8.5 mm[101] Leaflet thickening/shortening (rheumatic, carcinoid)/perforation Dense chordae with marked leaflet tethering Anteroposterior jet location Poor echocardiographic leaflet visualization CIED RV lead leaflet impingement Unfavorable device angle of approach
Annuloplasty	Annular dilation as primary mechanism of TR Mild tethering (tenting height <0.76 cm, tenting area <1.63 cm^2, tenting volume [3D] <2.3 mL)[102,103] Central jet location Sufficient landing zone for anchoring	Moderate tethering (tethering height at ≥0.76 cm but <1.0 cm, tenting area >1.63 but <2.5 cm^2, tenting volume [3D] ≥2.3 mL but ≤3.5 mL)[102,103] Incidental CIED RV lead (ie, without definite impingement)	Excessive annular dilation (exceeding device size) Severe tethering (tethering height >1.0 cm, tenting volume >3.5 mL) Poor echocardiographic annular visualization[102,103] Annular proximity of RCA CIED RV lead leaflet impingement
Orthotopic valve implantation	Previous surgical repair or bioprosthetic valve replacement Leaflet thickening/shortening (rheumatic, carcinoid) Incidental CIED RV lead (ie, without leaflet impingement) Any leaflet morphology	Large coaptation gap CIED RV lead leaflet impingement	Excessive annular dilation (exceeding device size) Unfavorable device angle of approach Severe RV dysfunction
Heterotopic valve implantation	Appropriate caval diameters (and intercaval distance) No option for direct valve treatment		Proximity of the RA to the orifice of the hepatic veins (<10-12 mm) Severely increased pulmonary artery and RA pressures due to the risk of fracture of bicaval valved stents

Anatomical Factors in TTVI Decision-making

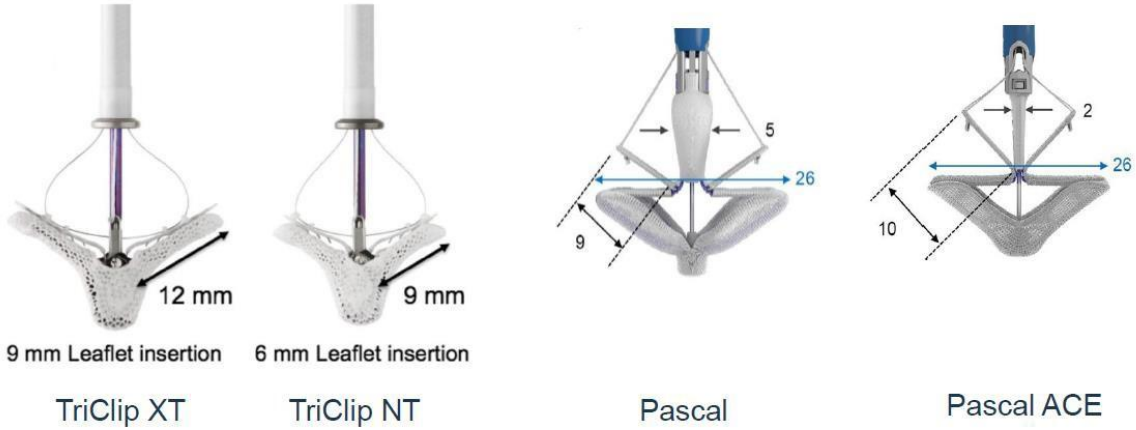


Favorable anatomy for T-TEER	Feasible anatomy for T-TEER	Criteria favouring replacement
• Small septolateral coaptation gap ≤7mm • Anteroseptal jet location • Localized prolapse or flail • Bi- or trileaflet morphology • No CIED lead • Good echocardiographic window for leaflet visualisation	• Septolateral coaptation gap >7 but ≤8.5 mm • Posteroseptal jet location • Multiple leaflets (>3) • Lead-associated TR without permanent leaflet interaction • Sufficient echocardiographic window for leaflet visualisation	• Large septolateral coaptation gap >8.5 mm • Anteroposterior jet location • Multiple leaflets (>3) and identations • Leaflet thickening/shortening (rheumatic, carcinoid)/perforation • Pronouced leaflet tethering • CIED-related TR (impingement, adhesion, perforation, subvalvular entanglement) • Insufficient echocardiographic leaflet visualization

Need Enough Leaflet to Work With



How Much Leaflet do you Need?



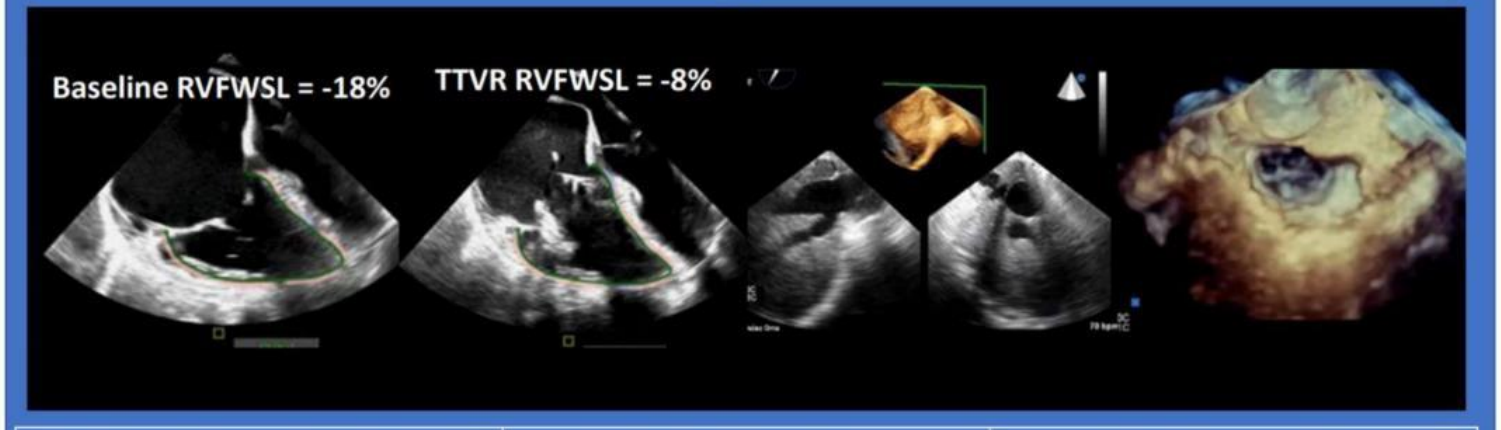
9 mm Leaflet insertion | 6 mm Leaflet insertion

TriClip XT | TriClip NT | Pascal | Pascal ACE

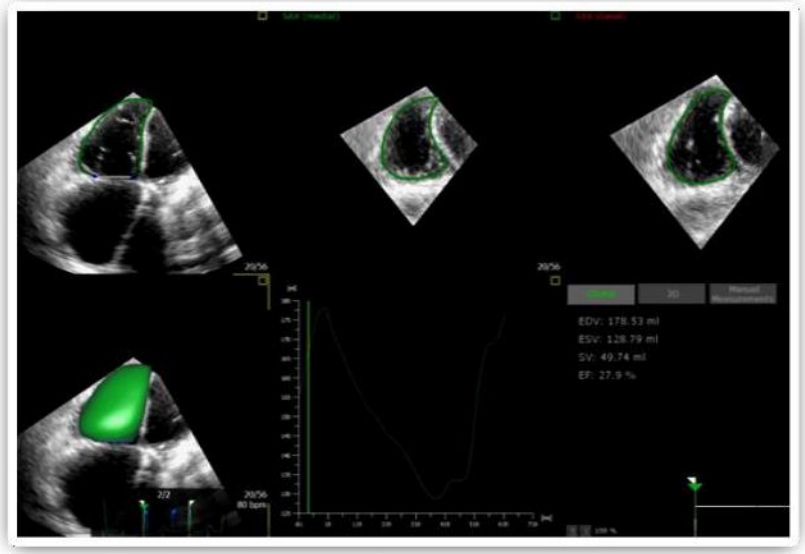
Orthotopic valve replacement anatomic limitations

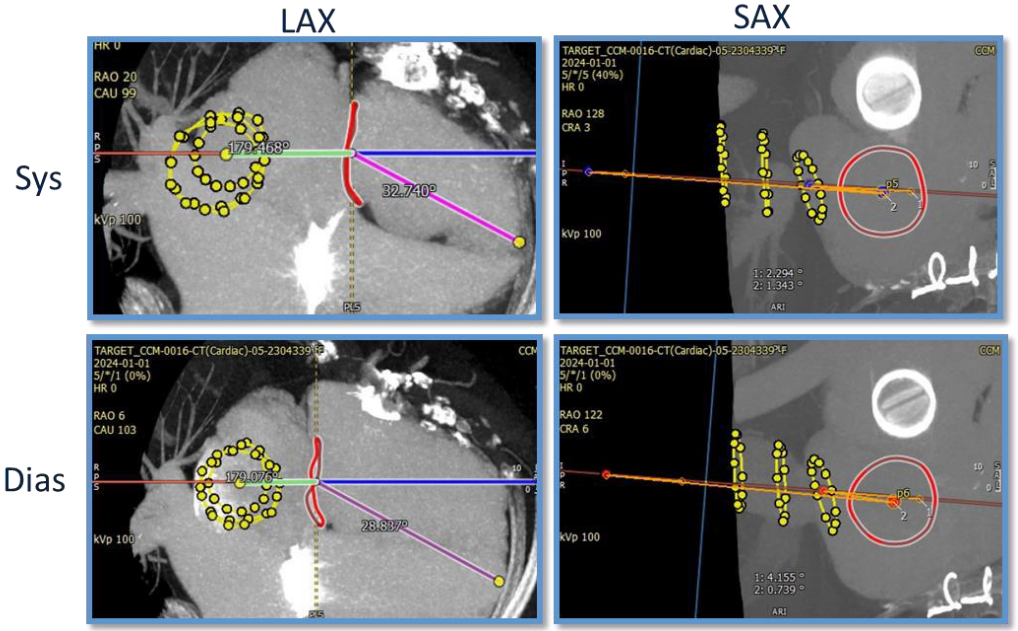
Right Ventricular Dysfunction

Unfavorable Approach Angle

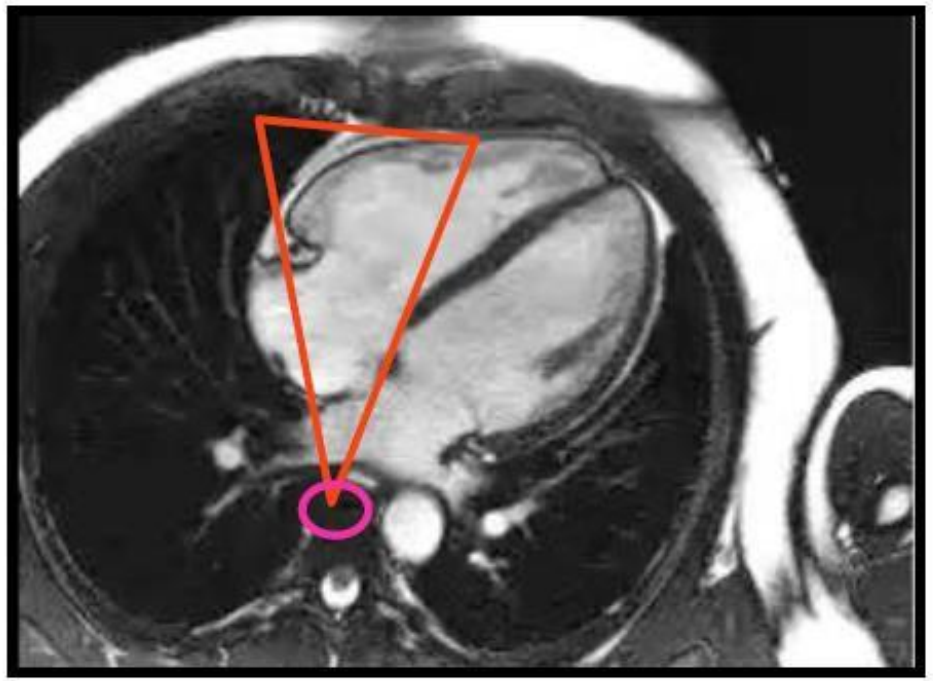


Favorable anatomy	Feasible anatomy	Unfavorable anatomy
• Previous surgical repair or bioprosthetic valve replacement • Leaflet thickening/shortening (rheumatic, carcinoid) • Incidental CIED RV lead (i.e., without leaflet impingement) • Any leaflet morphology	• Large coaptation gap • CIED RV lead leaflet impingement	• Excessive annular dilation (exceeding device size) • Unfavorable device angle of approach • Severe right ventricular dysfunction

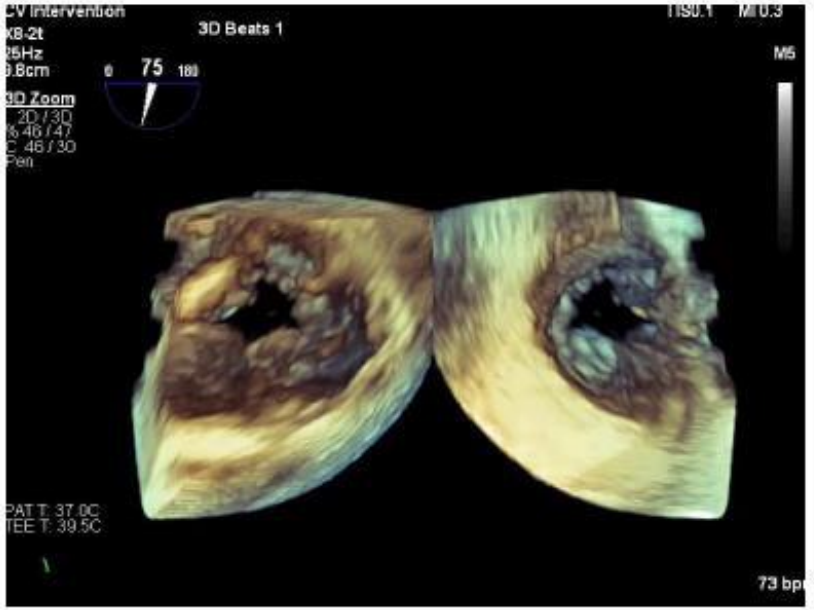




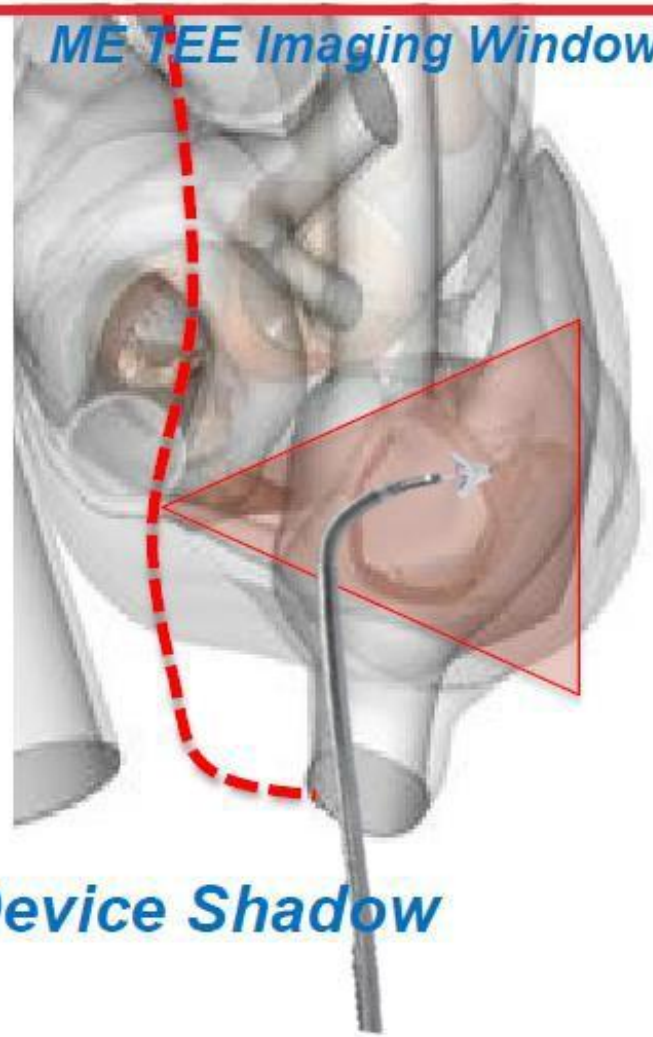
Imaging Tricuspid Valve with TEE is challenging



Farthest away from probe



Anatomy is variable
3D is essential



Questions in the Treatment of Severe TR

Is the any cinical benefit from transcatheter tricuspid valve intervention (TTVI)?

The best time to intervene?

Does transcatheter tricuspid valve replacement (TTVR) confer additional benefit over transcatheter edge-to-edge repair (TEER) by removing TR completely?

Transcatheter Tricuspid Valve Intervention RCTs- 2025

	Industry-sponsored RCTs			Government / industry-supported RCTs		
	CLASP IITR Pivotal	**TRILUMINATE Pivotal**	**TRISCEND II**	**TRI-FR**	**TRIC-i-HF**	**TRACE-NL**
Type of Transcatheter Therapy	**REPAIR**	**REPAIR**	**REPLACEMENT**	**REPAIR**	**REPAIR**	**REPAIR**
Countries	US, Canada	US, Canada, Europe	US & Europe	France, Belgium	Germany	The Netherlands
Sponsor	Edwards	Abbott	Edwards	CHU Rennes, F	LMU Munich, D	St. Antonius Hospital, Nieuwegein, NL
Design	RCT	RCT	RCT 2:1	RCT	RCT 2:1	RCT 2:1
Treatment	PASCAL + OMT	TriClip + OMT	EVOQUE + OMT	TriClip + OMT	PASCAL/TriClip + OMT	PASCAL/TriClip + OMT
Control group	OMT	OMT	OMT	OMT	OMT	OMT
Sample Size	825	700	820	300	360	150
Start / Completion**	Dec 2019 / Mar 2029	**Aug 2019 / Mar 2027**	**Apr 2021 / Jun 2024**	**Feb 2021 / Aug 2025**	Feb 2022 / Mar 2027	Jan 2023 / 2025
Primary Endpoint	Death, TV surgery, HFH at 24 months, QoL at 12 months	Death or TV surgery, HFH, QoL at 12 months	Death and RVAD /Hrt tx and TV surgery, HFH, QoL, NYHA and 6MW at 12 months	Milton Packer Composite Score[a] at 12 months	Death or HFH at 12 months	All-cause mortality, HFH and change in QoL (KCCQ) at 12 months
Key Inclusions	Symptomatic, severe or greater TR, ≥intermediate risk	Symptomatic, severe TR, ≥intermediate risk	Symptomatic, severe or greater TR, ≥intermediate risk	Symptomatic, severe TR, ineligible for surgery	Symptomatic, severe TR, ≥intermediate risk	Symptomatic (NYHA III-IV), severe TR

TEER

TRILUMINATE Pivotal Study

	Patients with severe TR who remain symptomatic despite medical therapy
	Randomized
Patient Population	Ability to reduce TR to Moderate or less
Randomization	1:1 TriClip: Control (Medical Therapy)
Endpoint	Hierarchical composite of all-cause mortality or tricuspid valve surgery, HFH, and KCCQ improvement ≥ 15 points at 12 months
Primary Analysis	**350**
Total Enrolled (Randomized)	**589 (572)**

Baseline Characteristics

Characteristic	Device N=285	Control N=287
Age (years)	78.1 ± 7.9 (285)	78.1 ± 7.6 (287)
Female sex	58.9% (168)	58.9% (169)
BMI	26.8 ± 5.8 (285)	27.1 ± 5.5 (287)
Atrial fibrillation	82.8% (236)	92.7% (266)
Dyslipidemia	62.8% (179)	54.0% (155)
Hypertension	81.1% (231)	81.5% (234)
Diabetes	17.2% (49)	15.7% (45)
Peripheral vascular disease	7.7% (22)	9.4% (27)
CABG	16.8% (48)	17.8% (51)
Prior percutaneous coronary intervention	15.1% (43)	14.3% (41)
Kidney disease	31.9% (91)	34.8% (100)
Liver disease	7.0% (20)	7.3% (21)
COPD	13.0% (37)	15.7% (45)
CRT, CRT-D, ICD, or permanent pacemaker	16.5% (47)	16.4% (47)
Previous aortic/mitral intervention	37.9% (108)	34.5% (99)
HFH within 1 year before enrollment	24.9% (71)	22.6% (65)
NT-proBNP (pg/mL)	1871.1 ± 1483.9 (121)	2420.7 ± 3416.1 (113)
NYHA Class III/IV	56.1% (160)	54.0% (155)
KCCQ score	55.6 ± 22.9 (285)	54.6 ± 23.8 (286)
6-minute walk distance (m)	240.5 ± 116.4 (272)	249.6 ± 125.5 (279)

Echocardiographic and Hemodynamic Characteristics

Characteristic	Device N=285	Control N=287
TR Etiology		
Functional	95.7% (270/282)	93.9% (263/280)
Degenerative	2.1% (6/282)	1.8% (5/280)
Mixed	2.1% (6/282)	3.9% (11/280)
CIED lead-related	0% (0/282)	0.4% (1/280)
Baseline TR Severity		
Moderate	2.2% (6/279)	1.5% (4/274)
Severe	25.1% (70/279)	28.5% (78/274)
Massive	24.0% (67/279)	18.6% (51/274)
Torrential	48.7% (136/279)	51.5% (141/274)
Coaptation gap (mm)	5.3 ± 1.8 (219)	5.2 ± 1.8 (229)
RV TAPSE (cm)	1.7 ± 0.4 (279)	1.6 ± 0.4 (271)
RVEDD, mid (cm)	3.7 ± 0.7 (278)	3.7 ± 0.8 (274)
Right atrial volume (mL)	140.9 ± 81.2 (279)	146.7 ± 78.0 (278)
Tricuspid annulus diameter (cm)	4.3 ± 0.8 (280)	4.4 ± 0.8 (274)
Cardiac output (L/min)	4.6 ± 1.4 (285)	4.6 ± 1.4 (285)
Left ventricular ejection fraction (%)	59.4 ± 9.0 (267)	59.7 ± 9.2 (260)

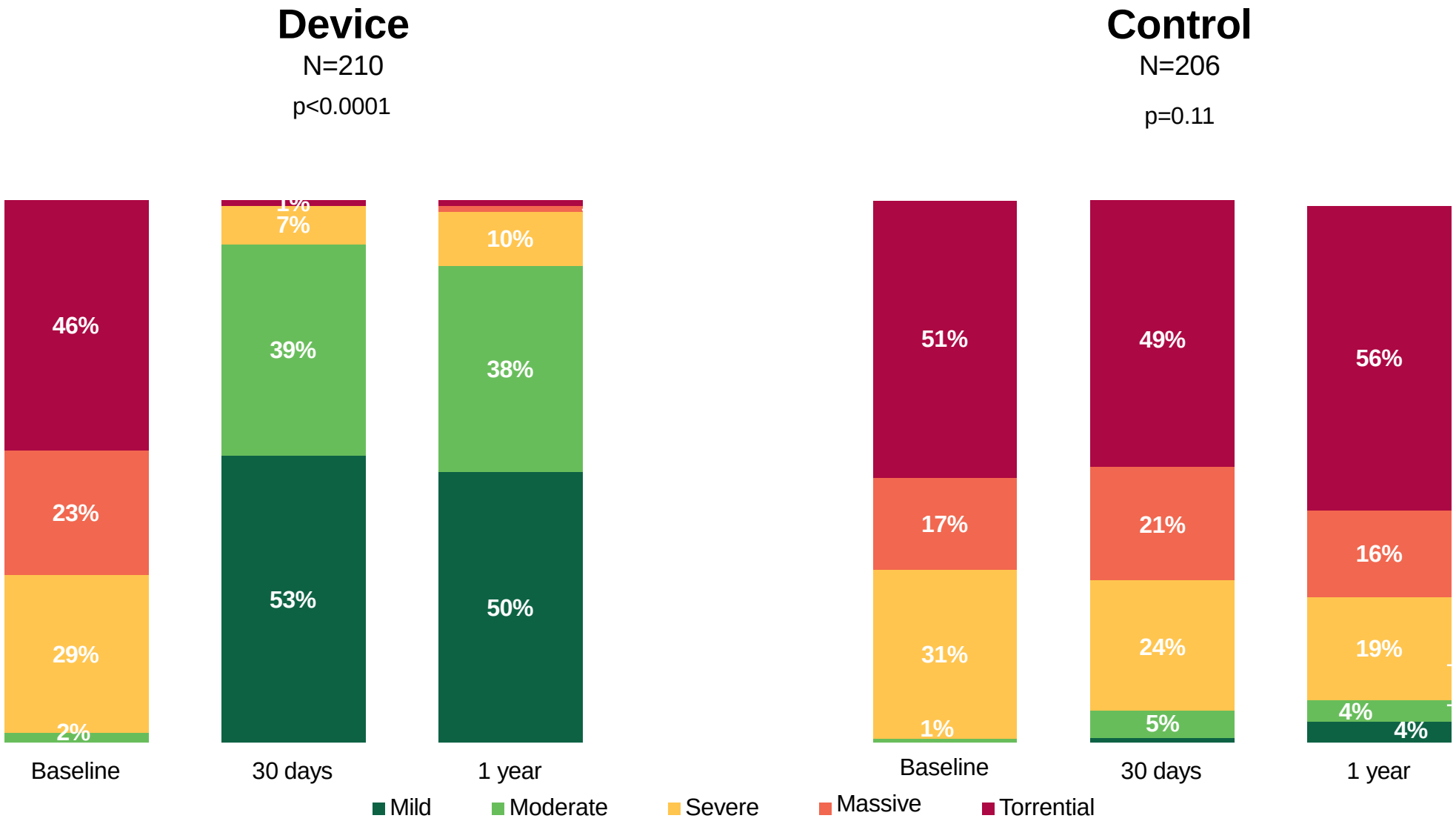
Procedural Characteristics (Device Only)

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)

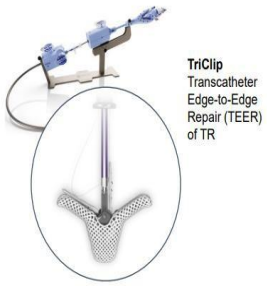
Adverse Events through 30 Days	Device N=281
Major Adverse Events through 30 Days	
Cardiovascular mortality	0.4% (1)
New-onset renal failure	0.7% (2)
Non-elective cardiac surgery	0% (0)
Endocarditis requiring surgery	0% (0)
Other Adverse Events through 30 Days	
Myocardial infarction	0% (0)
Stroke	0.4% (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

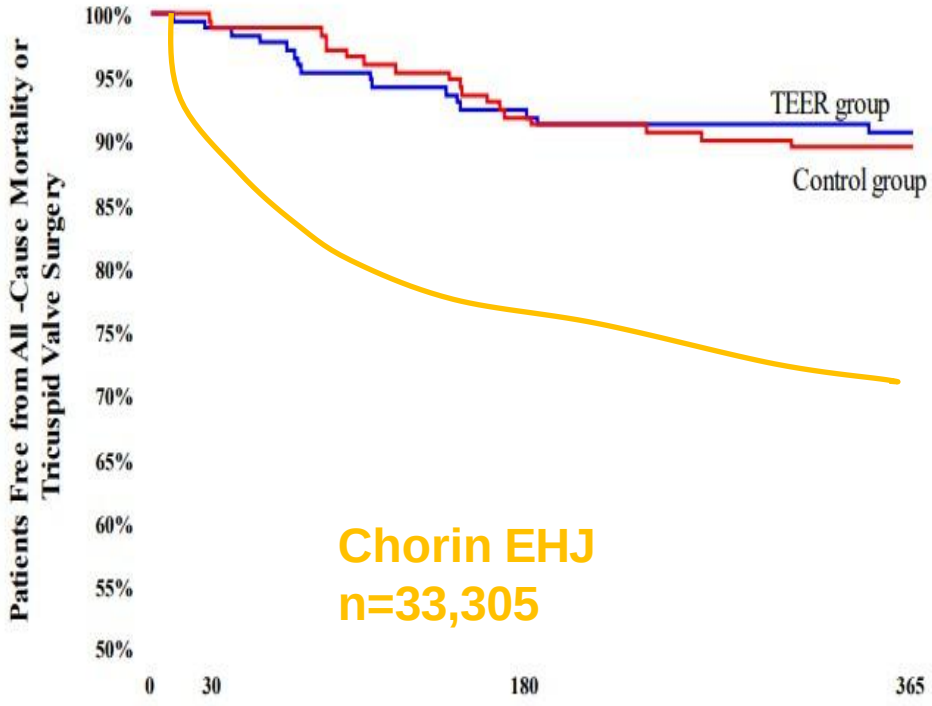
Tricuspid Regurgitation Severity



TRILUMINATE
PIVOTAL TRIAL

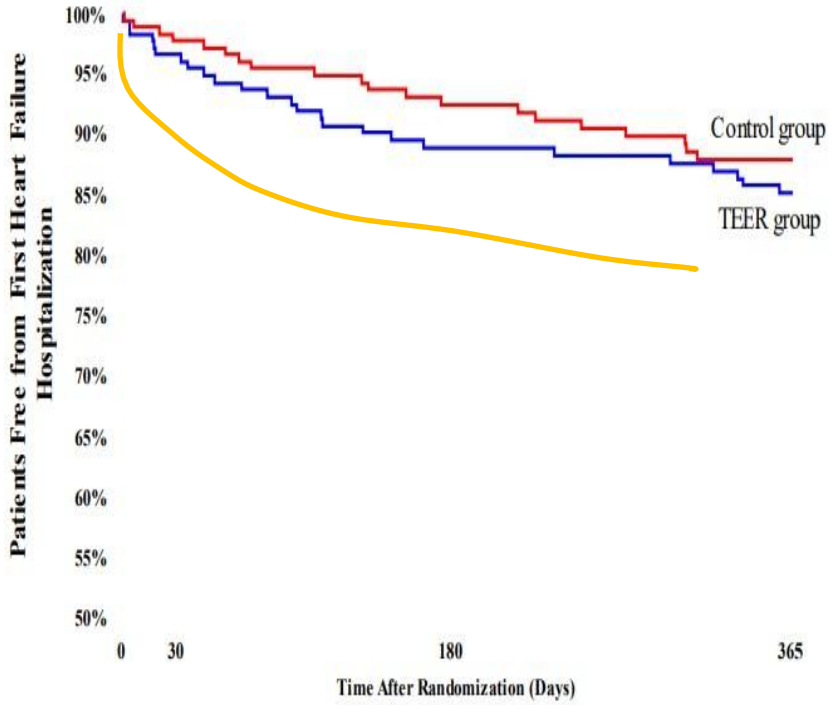


Mortality



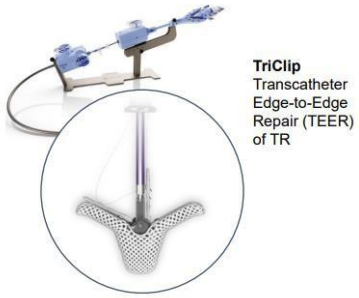
Chorin EHJ
n=33,305

Impact on HF



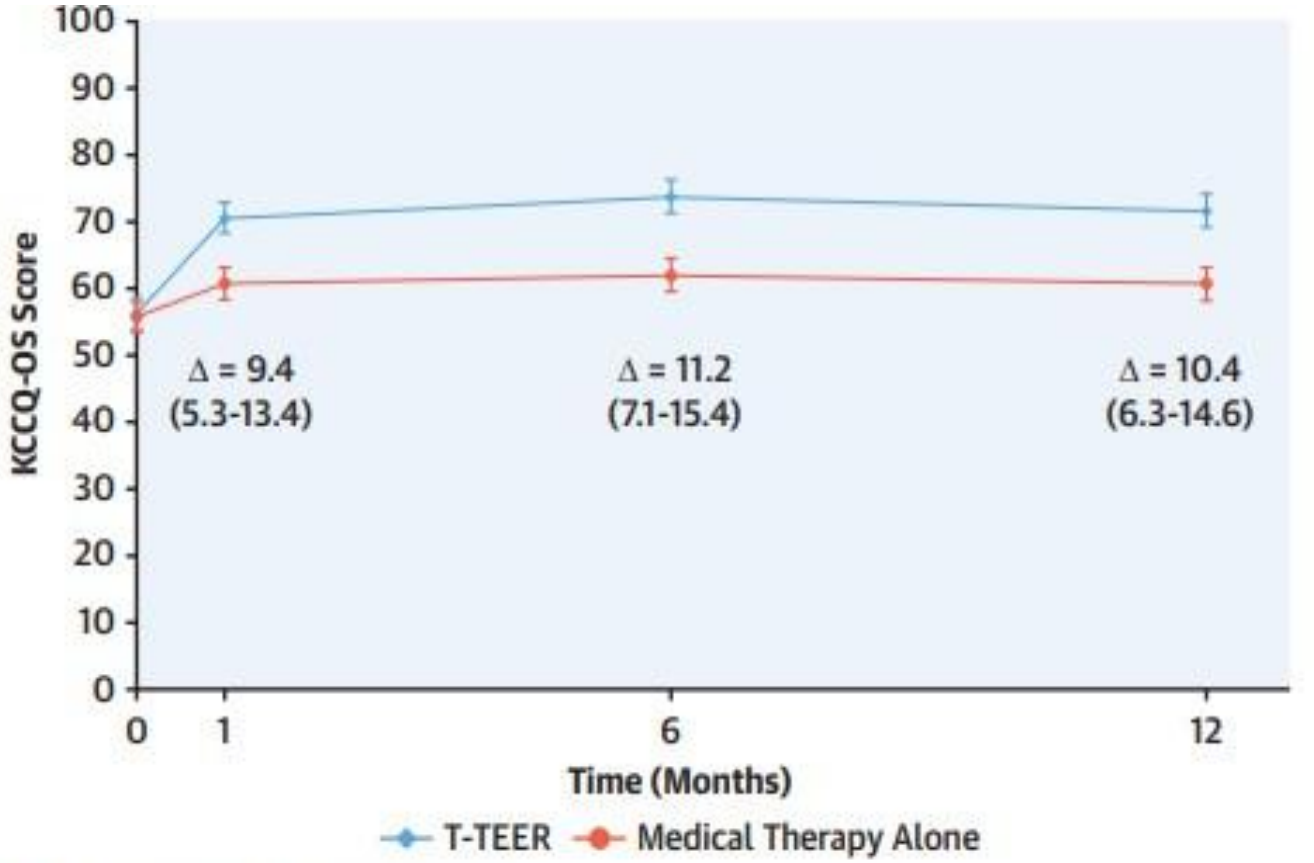
www.accessdata.fda.gov/cdrh_docs/pdf23/P230013C.pdf

TRILUMINATE
PIVOTAL TRIAL



TriClip
Transcatheter Edge-to-Edge Repair (TEER) of TR

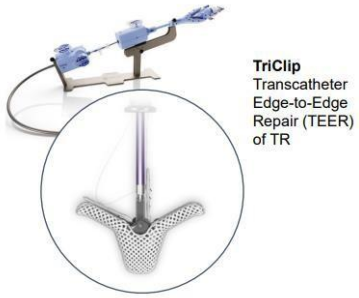
KCCQ Scores



Arnold SV, et al. J Am Coll Cardiol. 2024;83(1):1-13.

www.accessdata.fda.gov/cdrh_docs/pdf23/P230013C.pdf

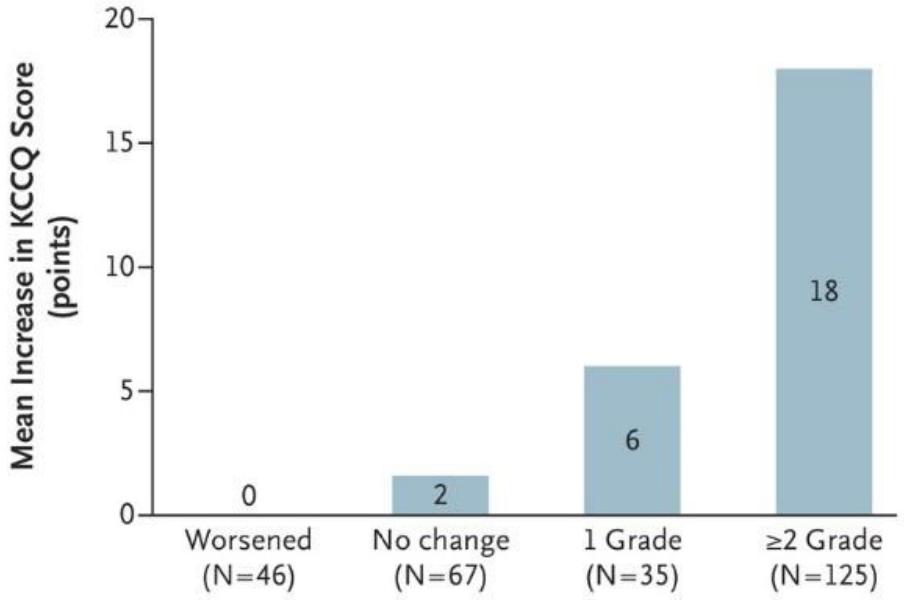
TRILUMINATE
PIVOTAL TRIAL



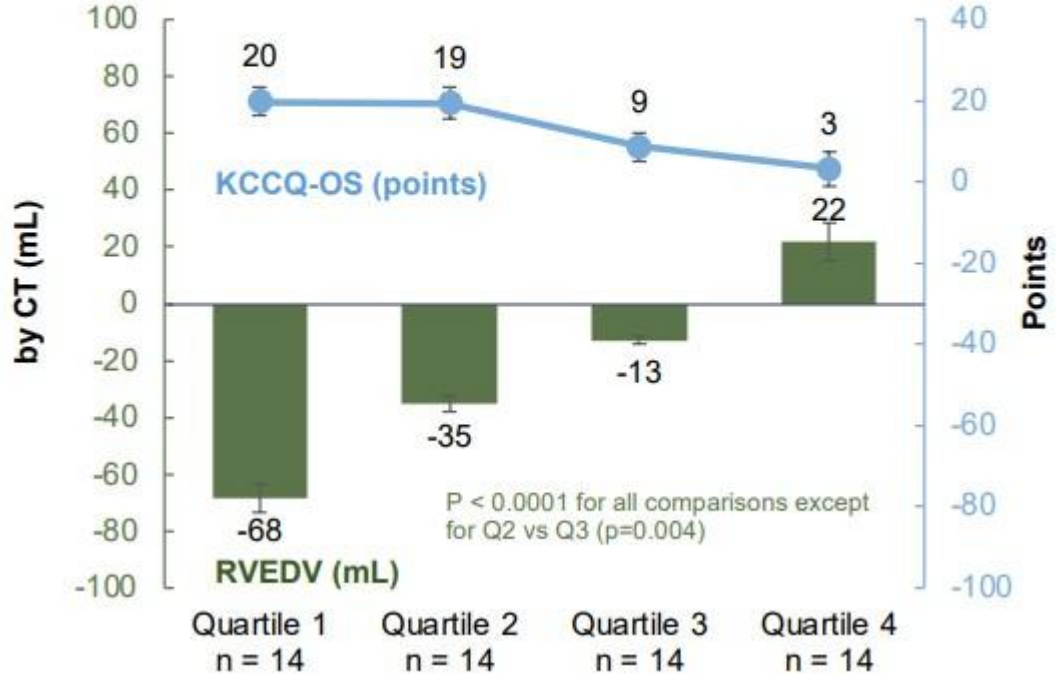
TriClip
Transcatheter Edge-to-Edge Repair (TEER) of TR

KCCQ Scores

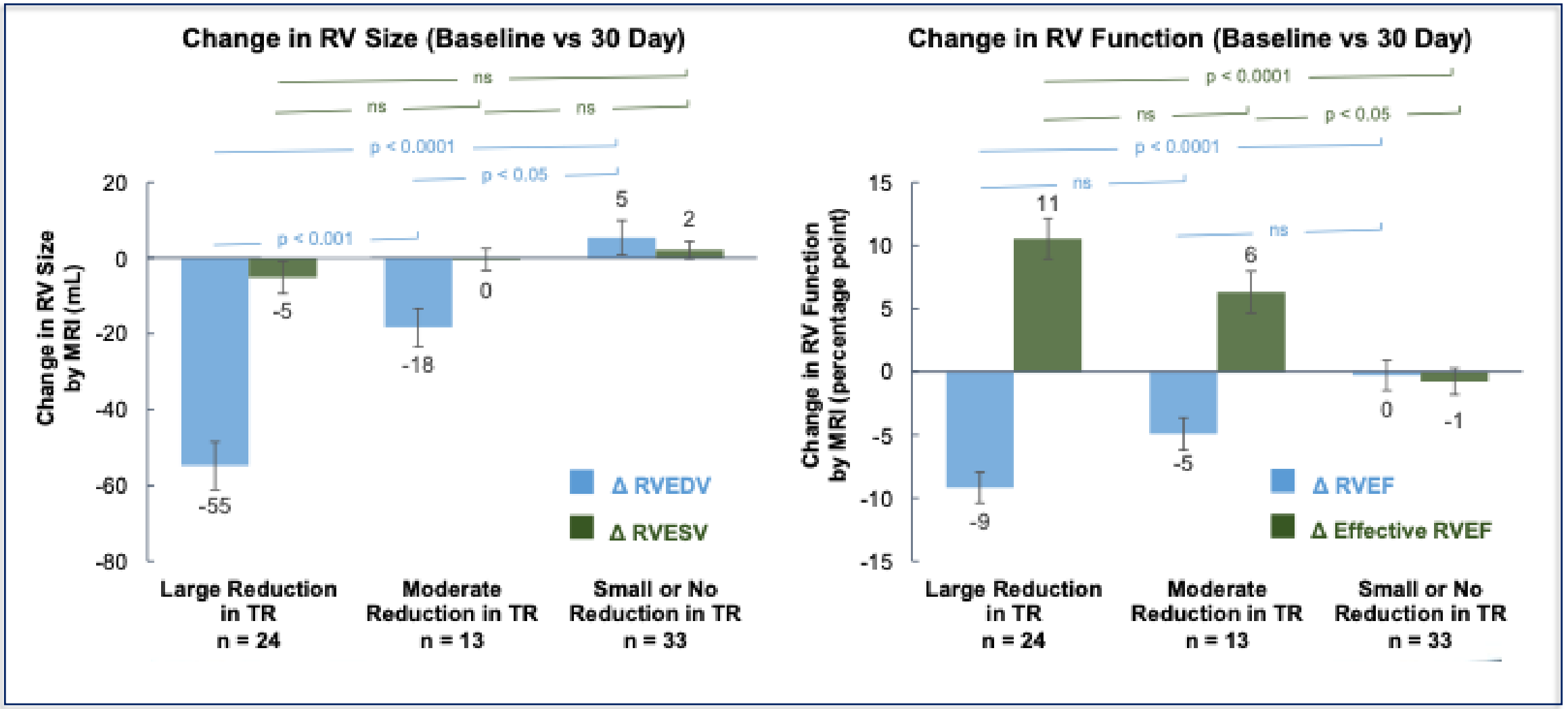
Change in Quality of Life According to Magnitude of Reduction in Tricuspid Regurgitation



Change in RVEDV vs Change in KCCQ-OS (Baseline vs 12 Month)



RV Remodeling is Associated with TR Reduction



Cavalcante J, et al. *TVT* 2024

The TRILUMINATE Pivotal Trial

- The **first randomized controlled trial** to evaluate **tricuspid Transcatheter Edge to Edge Repair (TEER) in patients with symptomatic, severe TR** despite optimized medical therapy.
- The primary endpoint (evaluated at 1 year follow-up) showed **tricuspid TEER with the TriClip device was superior to medical therapy alone**, driven by improvements in health status with no differences in mortality or heart failure hospitalization (HFH).[1]
- However, a favorable trend in HFH was seen in the later enrollment at 1 year.[2]

The TriClip device (Abbott)

[1] Sorajja P, Whisenant B, Hamid N, et al. *N Engl J Med*. 2023;388(20):1833-1842.
[2] Tang GHL, Hahn RT, Whisenant BK, et al.. *J Am Coll Cardiol*. 2025;85(3):235-246.

Two-year Outcomes Of Transcatheter Tricuspid Valve Edge-to-Edge Repair For Tricuspid Regurgitation:

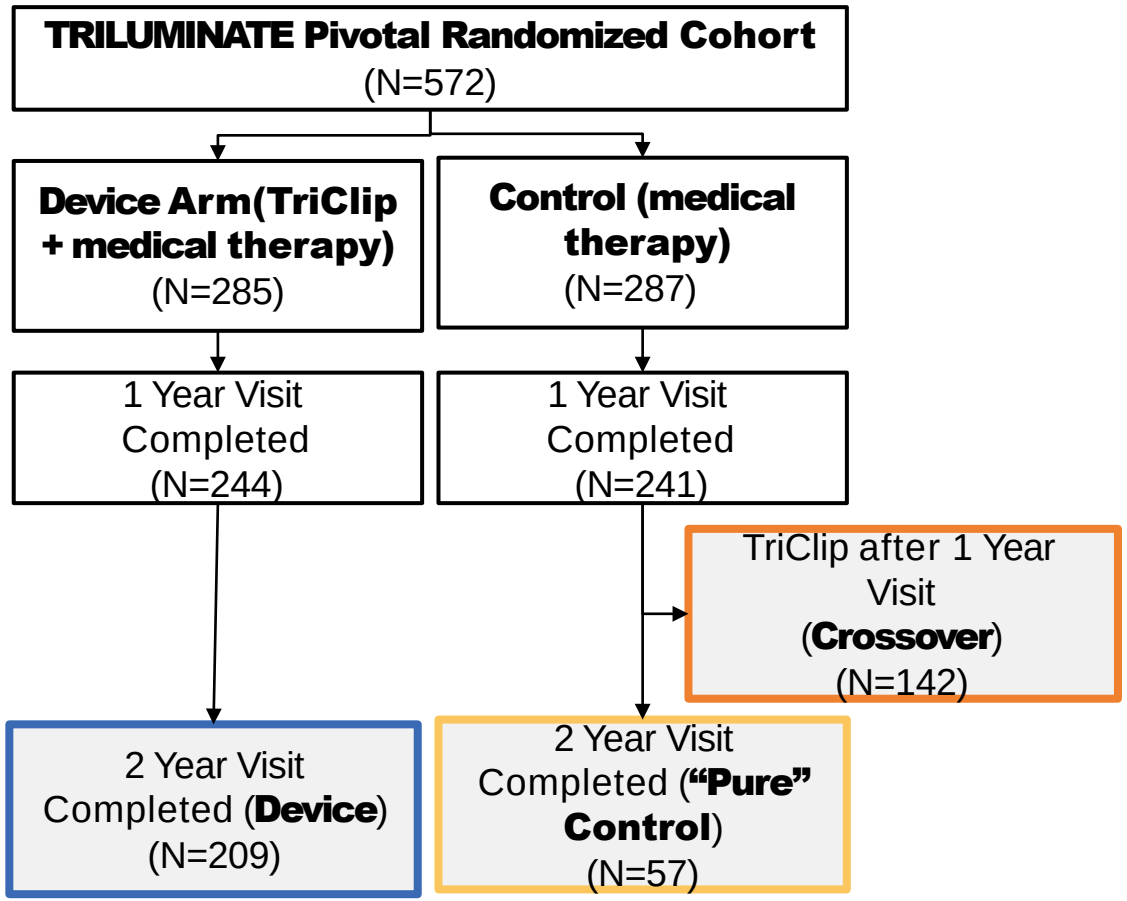
The TRILUMINATE Pivotal Trial

Saibal Kar, MD, on behalf of the TRILUMINATE Pivotal Trial investigators

Program Director, Cardiovascular disease fellowship
Los Robles Regional Medical Center, Thousand Oaks, CA
National Physician Leader, Interventional Cardiology,
HCA Healthcare, USA

ACC 2025

Study Design



Prespecified 2-year Endpoints (ITT)

1. Recurrent Heart Failure Hospitalizations (HFH) at 24 months
2. Freedom from all-cause mortality, tricuspid valve surgery, and tricuspid valve intervention at 24months

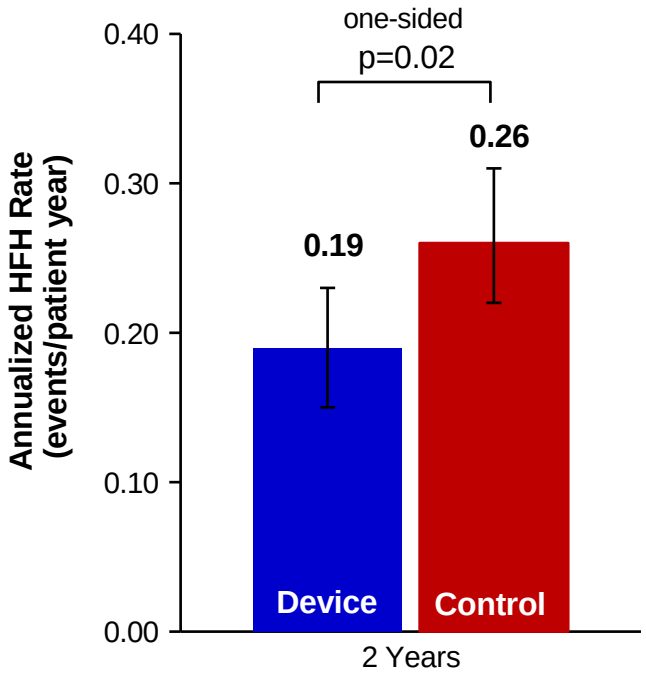
Additional 2 Year Outcomes

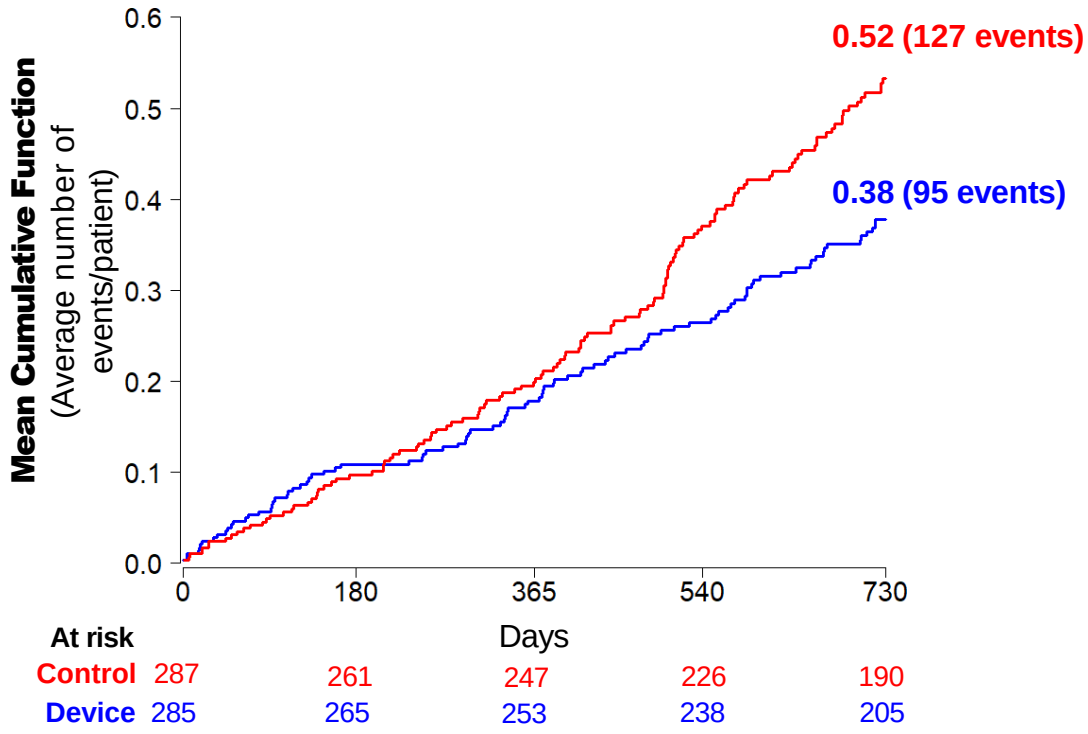
Adverse events, tricuspid regurgitation grade, health status

Prespecified 2-year endpoints were performed intention-to-treat (ITT).

INTENTION-TO-TREAT

Heart Failure Hospitalizations





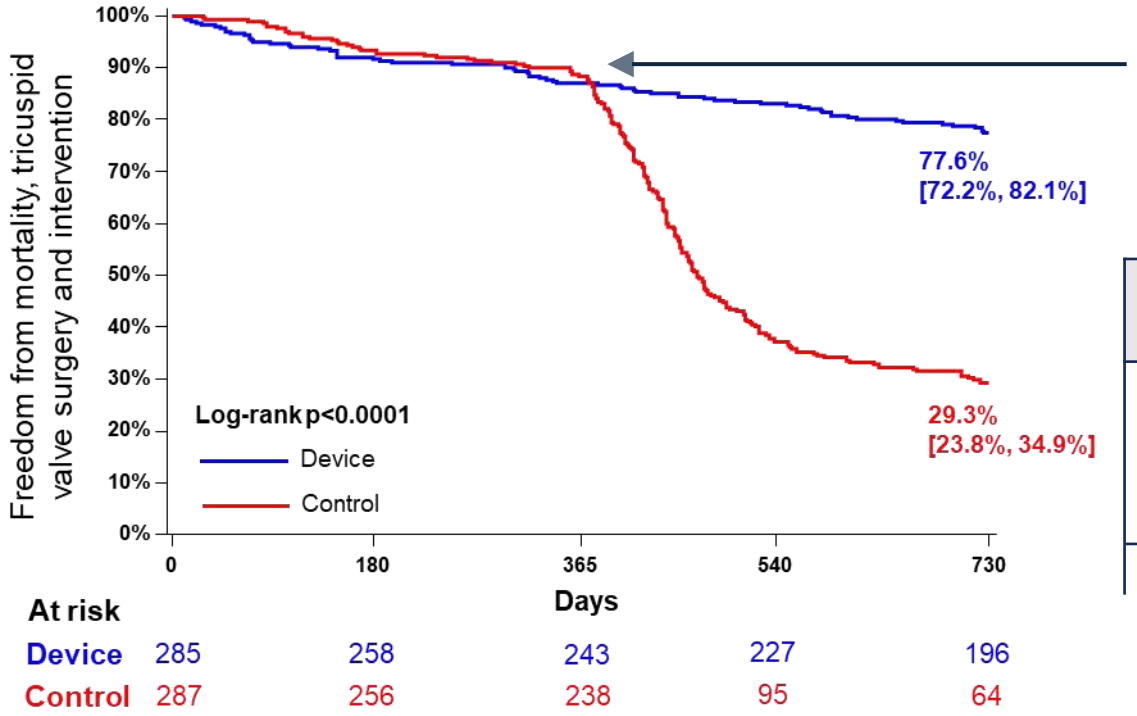
28% relative risk reduction in HFH with TriClip device treatment,

HR 0.72 (two-sided 95%CI [0.53, 0.98])

TRILUMINATE PIVOTAL TRIAL

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.

Freedom from All-cause mortality, TV Surgery, TV Intervention



Difference driven by transcatheter intervention in Control group (crossover procedure) after 1 year. Rates of all-cause mortality and tricuspid valve (TV) surgery not statistically different between groups.

Component	Device N=285	Control N=287	p-value
Composite	**22.4% (62)**	**70.7% (185)**	**<0.0001**
All-cause mortality	17.9% (49)	17.1% (45)	
Tricuspid valve surgery	2.3% (6)	4.3% (11)	
Transcatheter intervention	3.8% (10)	61.5% (142)	

TRILUMINATE PIVOTAL TRIAL

Prespecified secondary endpoint; intention-to-treat (ITT) analysis shown. *TV*, tricuspid valve.

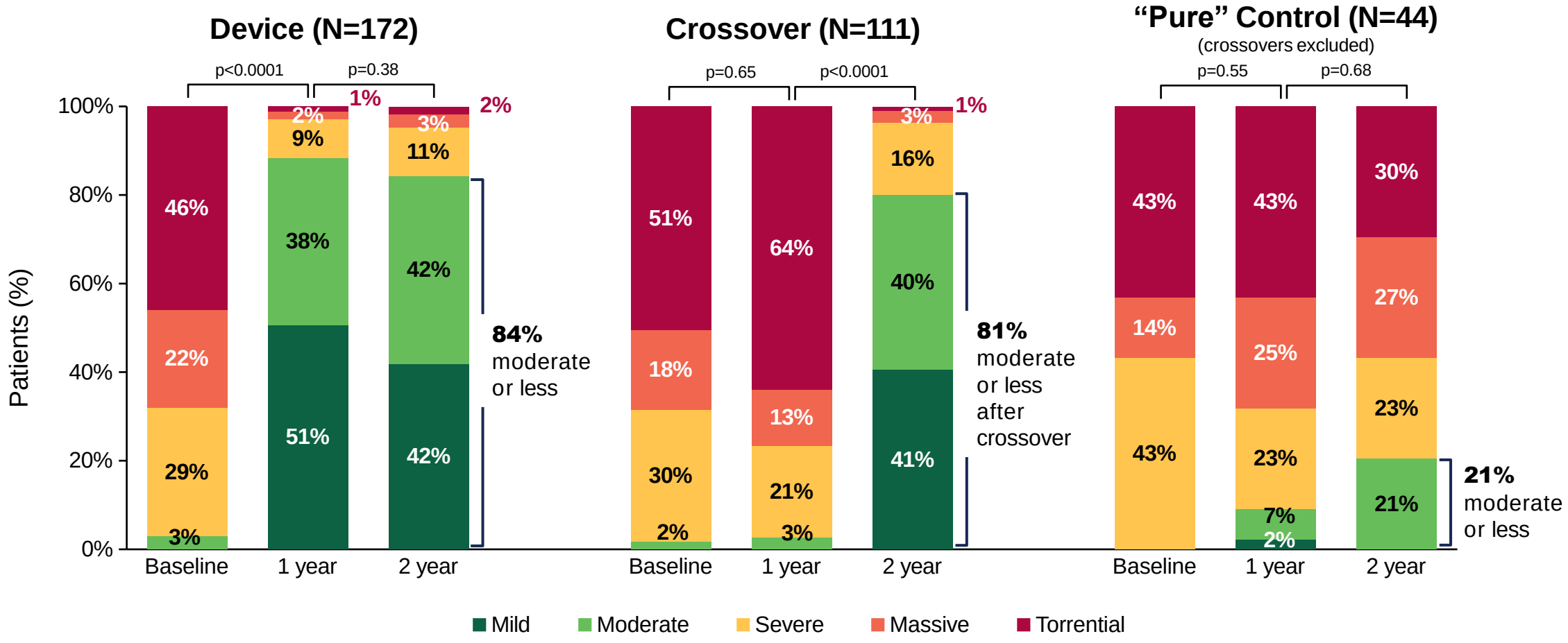
Characteristics Prior to Crossover

Variable at 1 Year (Prior to Crossover)	Patients who Crossed Over N=142	Patients who did not Crossover N=94
Torrential TR	65.2%	41.5%
NYHA III/IV	47.5%	30.4%
KCCQ Change (baseline to 1YR)	0 ± 18	7 ± 18
6MWD Change (baseline to 1YR)	-22 ± 103	-1 ± 90
HFH (events/patient-year)	0.17	0.07
Diuretic Dose Change (baseline to 1YR)	+22 mg	+5 mg

Patients who crossed over were more symptomatic with a higher prevalence of torrential TR and more HFH prior to crossover.

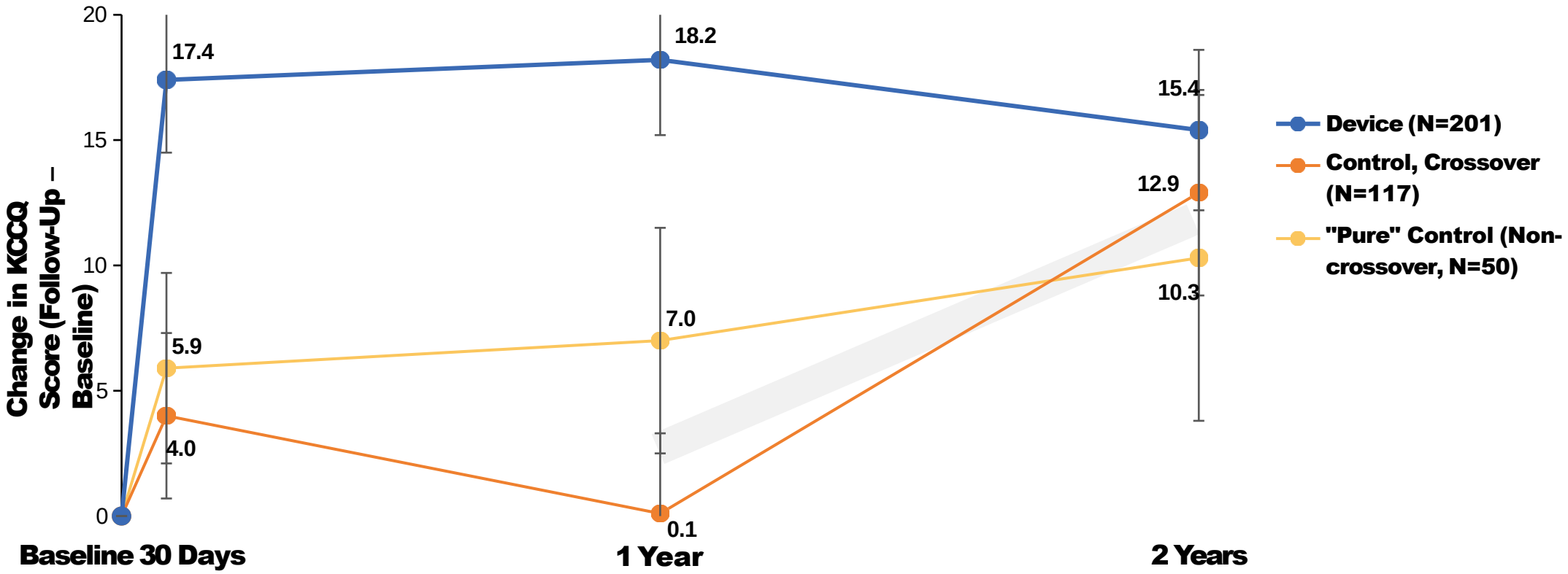
Includes patients eligible for crossover (completed 1-year follow-up), patients with tricuspid valve surgery are excluded. *TR*, tricuspid regurgitation; *NYHA*, New York Heart Association; *KCCQ*, Kansas City Cardiomyopathy Questionnaire; *6MWD*, 6-minute walk distance; *HFH*, heart failure hospitalization.

Tricuspid Regurgitation Grade After Crossover



Paired data shown. "Pure" control includes patients who remain on medical therapy alone. Patients with tricuspid valve surgery are excluded from all groups.

Health Status Through 2 Years



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

Mean and 95%CI and paired data shown. “Pure” control includes patients who remain on medical therapy alone. Patients with tricuspid valve surgery are excluded. KCCQ improvements were sustained in Device patients (changes from baseline to 30 days, 1 year, and 2 years were not significantly different, p=0.06).

The TRILUMINATE Pivotal Trial At 2 Years…

At 2 years, treatment with the TriClip device reduced HFH compared with medical therapy (despite crossovers in the Control group).

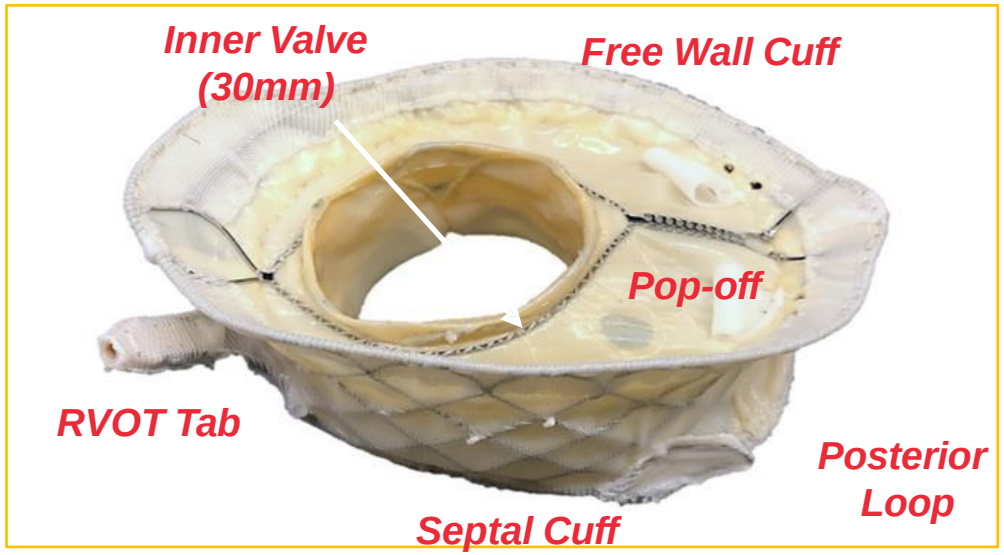
Improvements in TR severity and quality of life were sustained in Device patients through 2 years.

TriClip therapy is safe through 2 years and upon crossover.

Control patients, whose symptoms and health status had worsened prior to crossover, benefited from TriClip device with improvements in TR severity and quality of life.

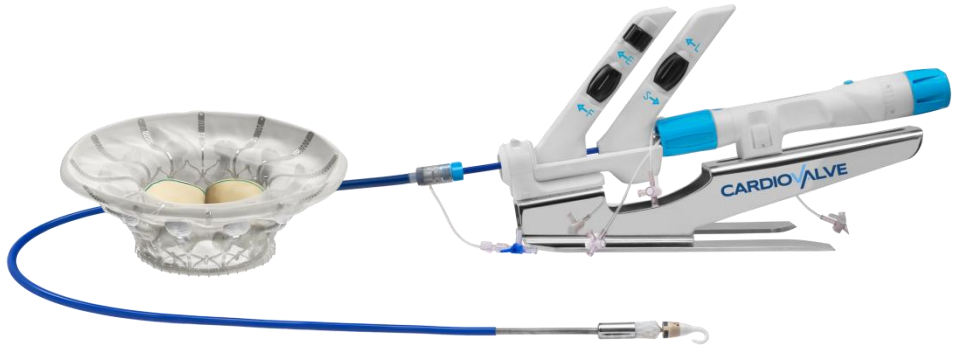
TTVR(I)

VDyne TTVR Technology



- **Valve designed to match the asymmetric tricuspid annulus**
  - **No exclusions for ventricular size/shape**
  - **Atraumatic to the conduction system**
  - **No barbs or paddles for securement**
  - **Pop-off solution, afterload mismatch**
  - **Repositionable and retrievable**
- **Side delivery provides distinct advantages for anatomical flexibility, delivery system size & procedural imaging**

TTVR…Cardiovalve fits both Mitral and Tricuspid anatomies



Transfemoral-Transseptal approach

Reduced risk for LVOT obstruction

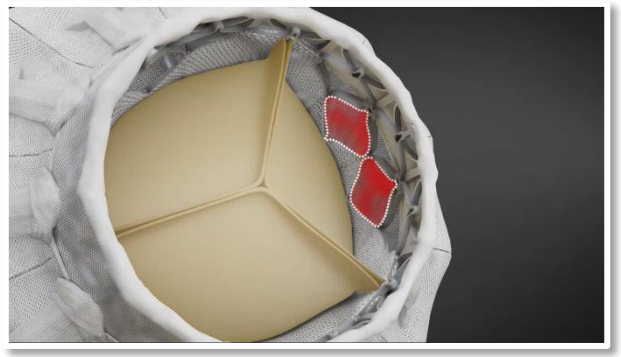
No radial forces
Proprietary anchoring

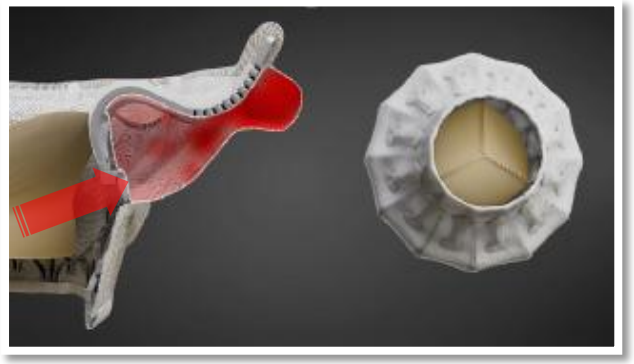
PVL sealing
with inflatable cuff solution

Fits different anatomies, up to 55mm
Vast range of sizes
(M,L,XL)

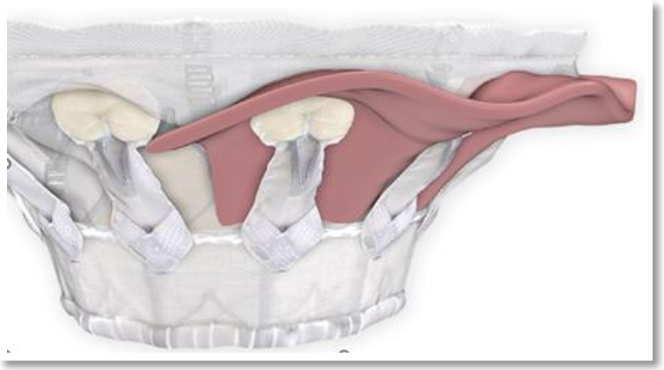
The Cardiovalve Implant

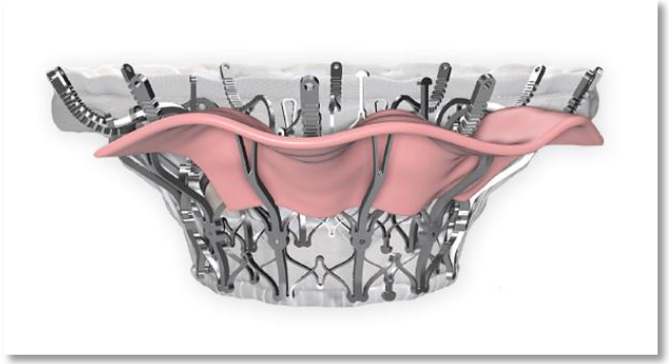
- Active Sealing – Inflatable Cuff



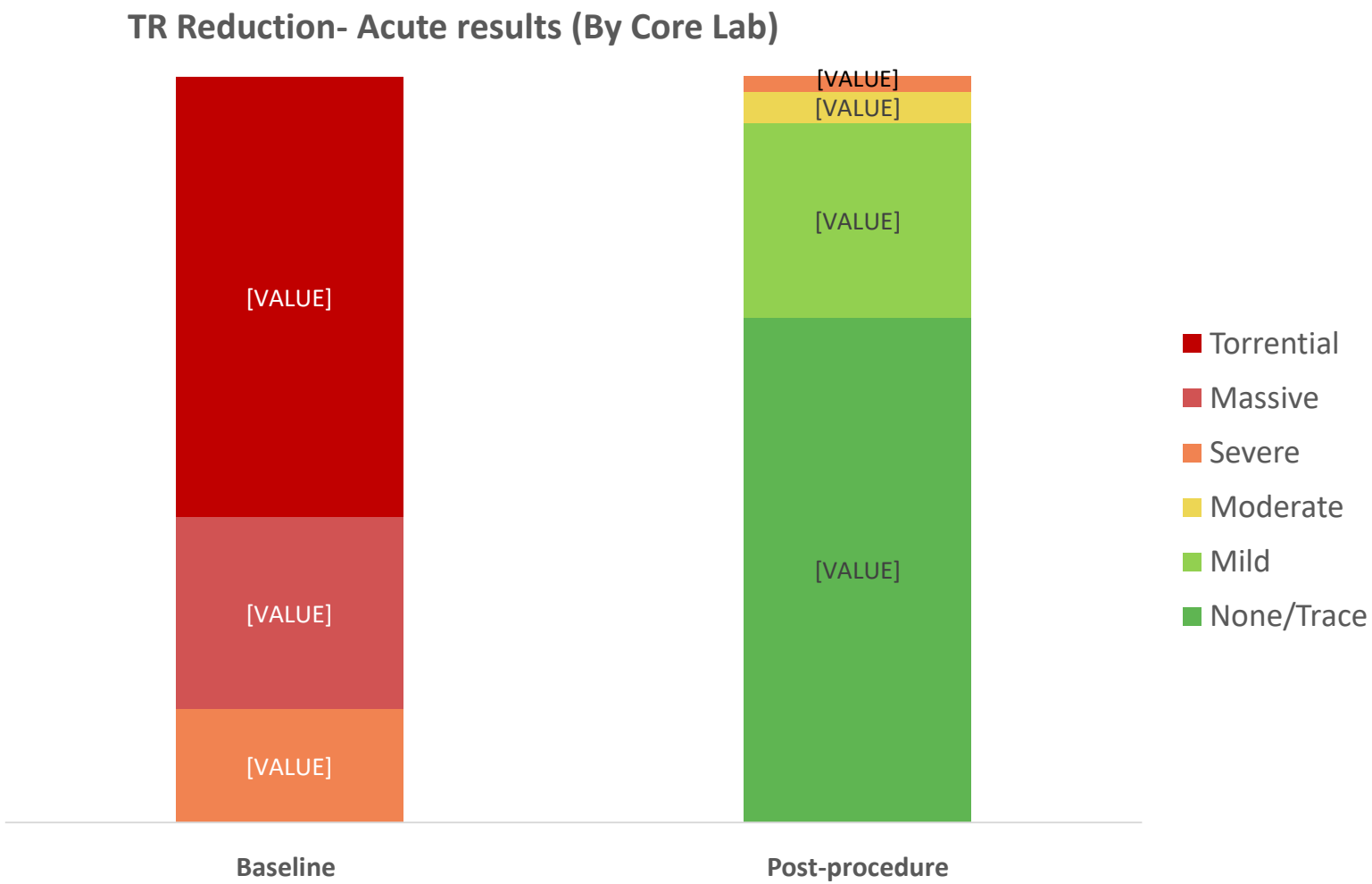


- Grasping “sandwich”- promotes 24 focal grasping points throughout the annular circumference





TARGET Study procedural success (N=115)

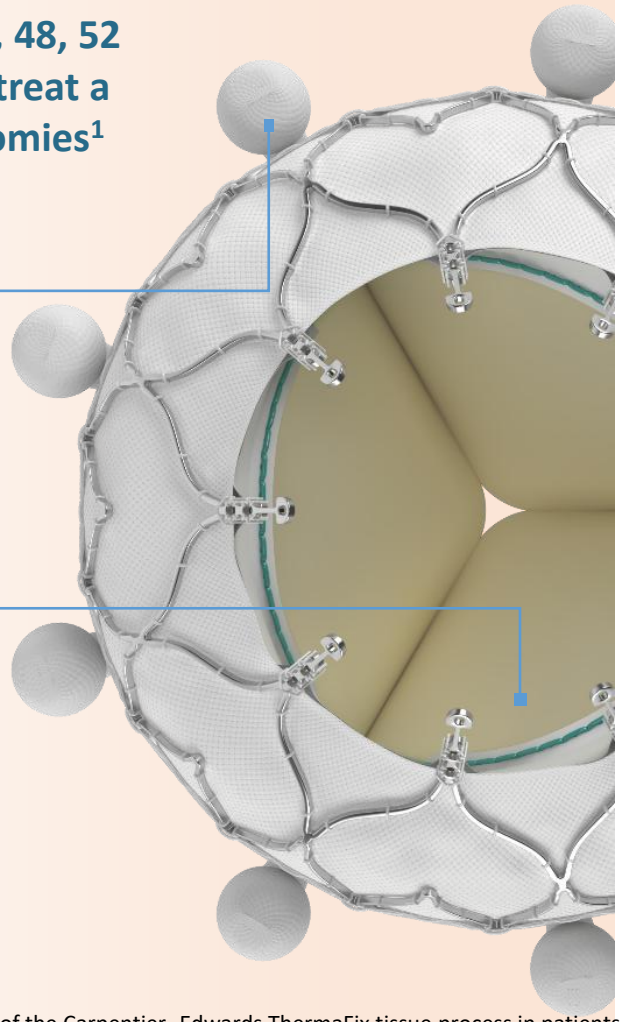


The EVOQUE valve-Transcatheter Tricuspid Valve

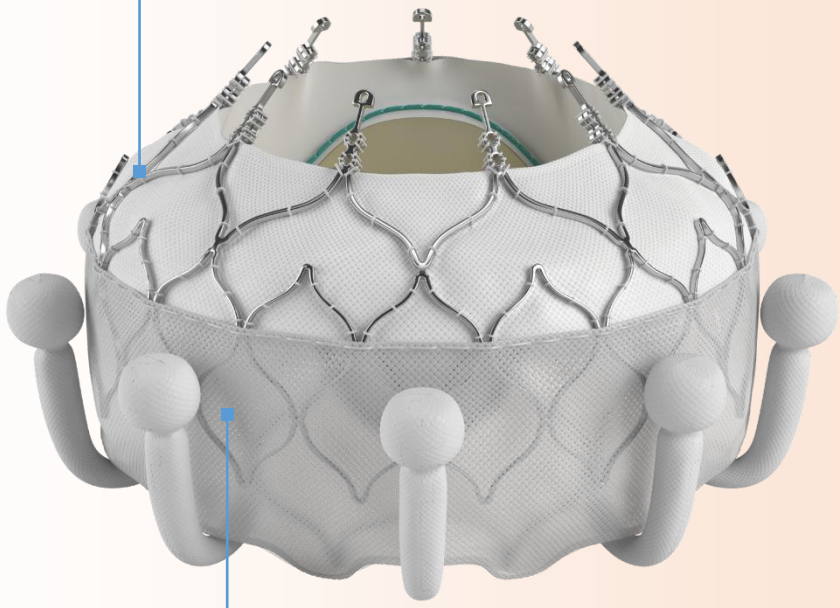
Four different valve sizes (44, 48, 52 and 56 mm) are designed to treat a wide range of tricuspid anatomies[1]

9 ventricular anchors
Engage leaflets, subvalvular anatomy and the annulus

ThermaFix tissue technology†
Same bovine pericardial tissue as Edwards SAPIEN and PERIMOUNT valves



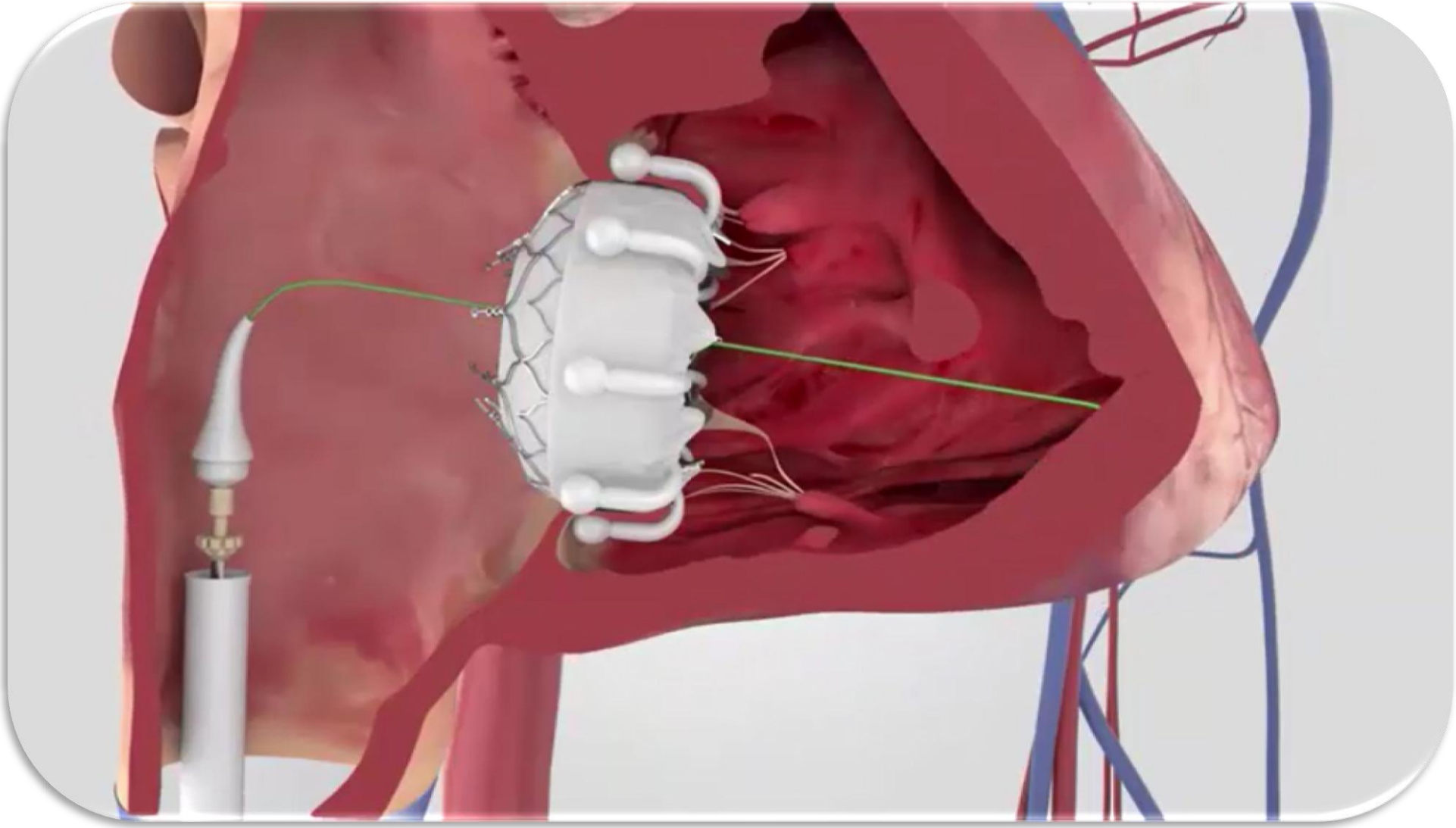
Nitinol self-expanding frame
Designed to conform to native valve anatomy



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

* First-of-its-kind device commercially available (in the EU).
† No clinical data are available that evaluate the long-term impact of the Carpentier- Edwards ThermaFix tissue process in patients.
1.

The EVOQUE valve-Transcatheter Tricuspid Valve Option



CEC Adjudicated Major Adverse Events at 30 Days

Major Adverse Events	N=124[a] N (%)
Cardiovascular mortality	3 (2.4%)
Myocardial infarction	0 (0%)
Stroke	0 (0%)
Renal complications requiring unplanned dialysis or renal replacement therapy	1 (0.8%)
Severe bleeding[b]	22 (17.7%)
Major access site and vascular complications	2 (1.6%)
Non-elective tricuspid valve re-intervention, percutaneous or surgical	2 (1.6%)
Major cardiac structural complications	1 (0.8%)
Device-related pulmonary embolism	0 (0%)
Composite MAE Rate	**23 (18.5%)**
Other Events	**N=124[a]** N (%)
All cause mortality	4 (3.2%)
Site-Reported Events	**N=76[c]** N (%)
New permanent pacemaker	8 (10.5%)

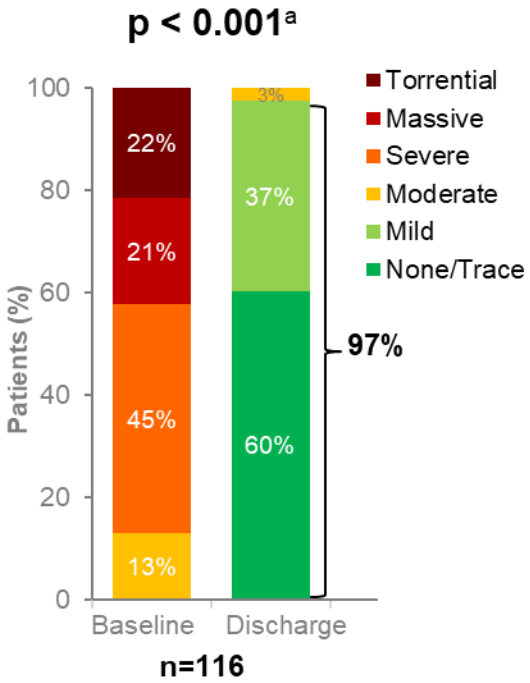
81.5% of patients had no MAEs at 30 days

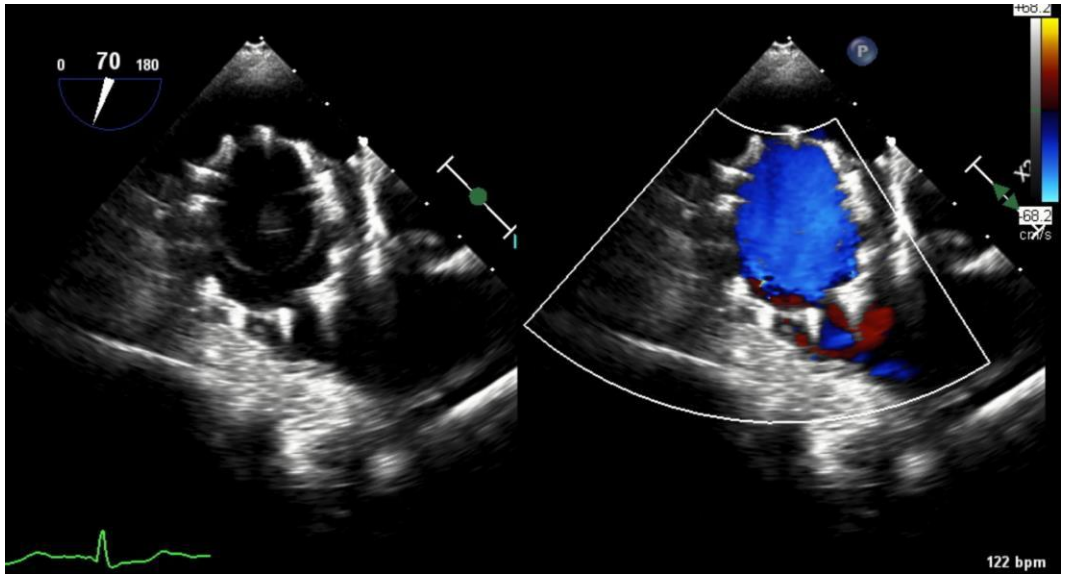
[a]Denominator for % calculation includes all patients who reached 30-day follow-up as well as any patients who experienced an MAE prior to follow-up.

[b]Severe bleeding is defined as major, extensive, life-threatening, or fatal bleeding per Mitral Valve Academic Research Consortium (MVARC).

Significant Reduction in TR Severity by Core Lab[1] at 6 Months

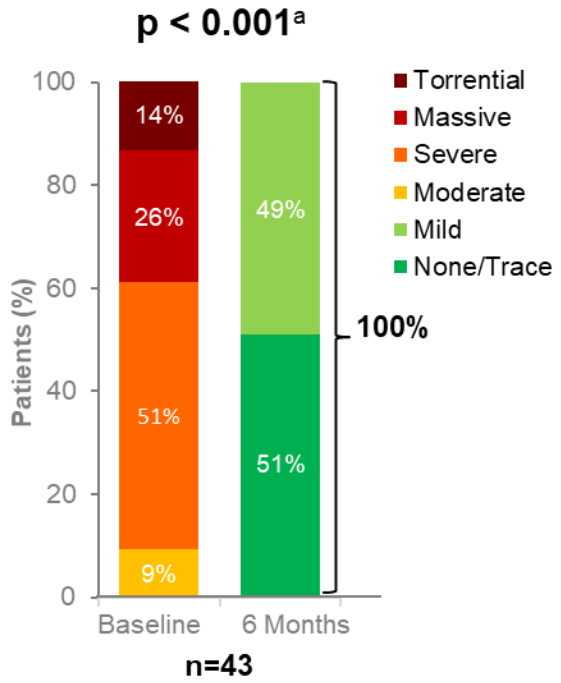
TR Severity at Discharge





No residual TR post implant with EVOQUE valve

TR Severity at 6 Months

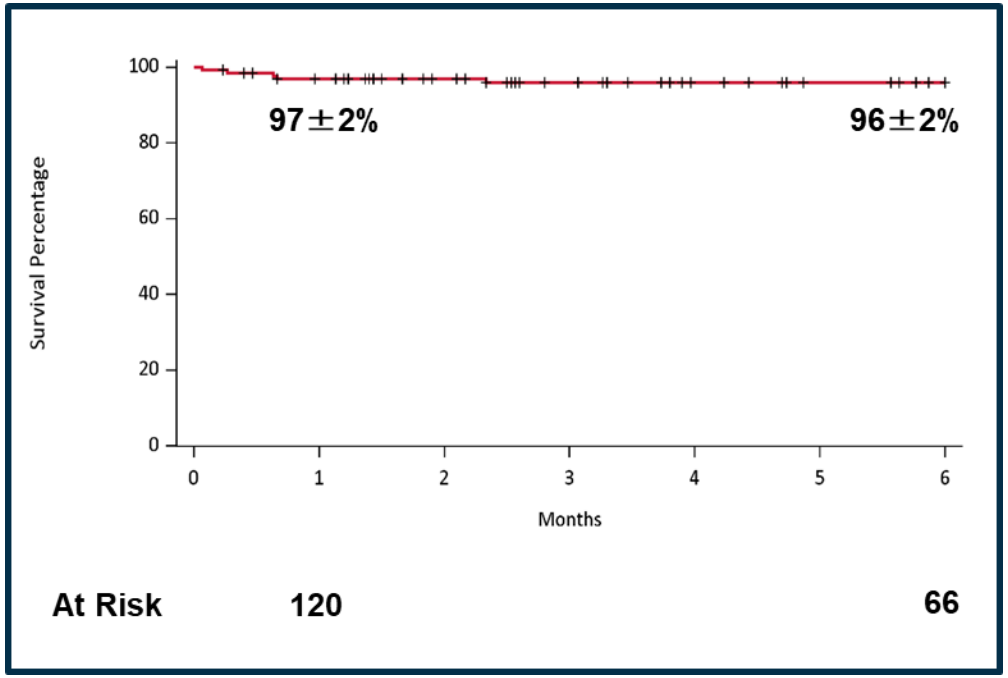


≥1 grade reduction in 100% at discharge and 6 months
≥2 grade reduction in 95% at discharge and 98% at 6 months

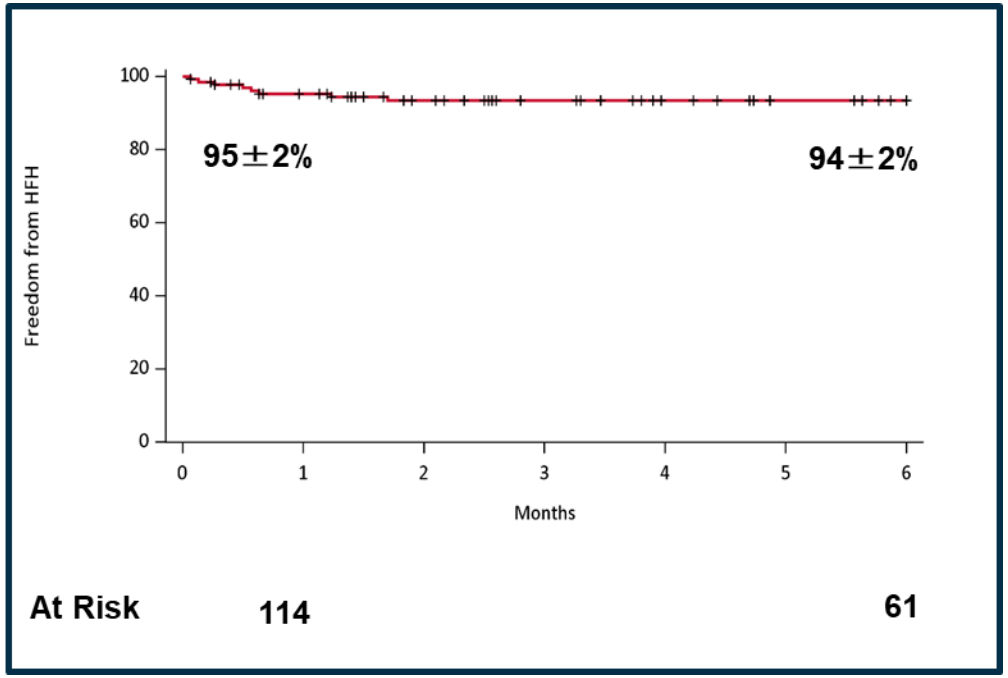
[1]Core lab: Baylor, Scott and White Research Institute; [a]Wilcoxon signed-rank test. TR, tricuspid regurgitation

High Survival Rate and Freedom from Heart Failure Hospitalization to 6 Months

Survival



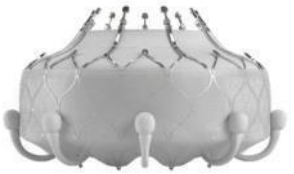
Freedom from Heart Failure Hospitalization

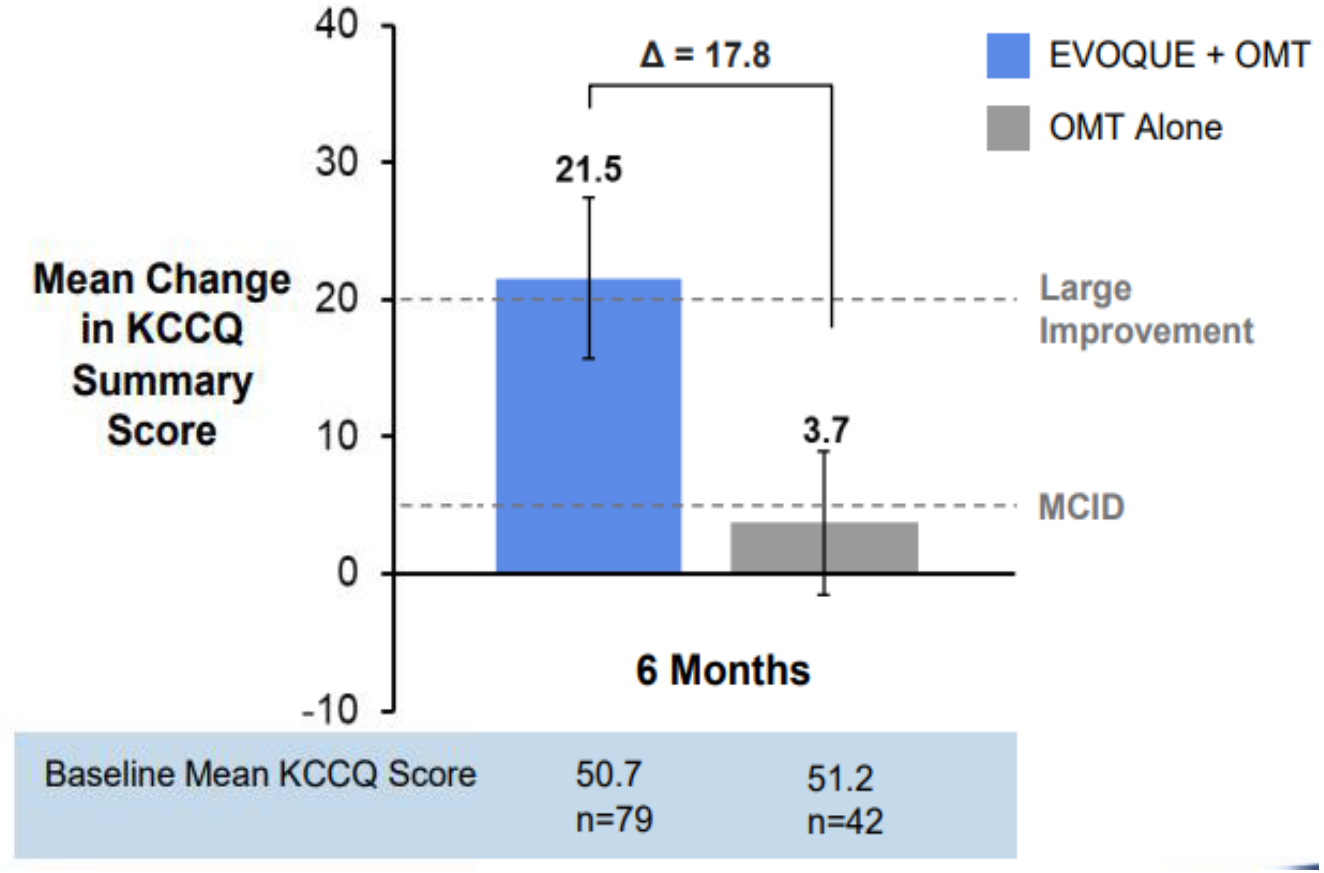


Kaplan-Meier analysis

THE TRISCEND II PIVOTAL TRIAL

KCCQ Scores





Baseline Mean KCCQ Score	50.7 n=79	51.2 n=42

www.accessdata.fda.gov/cdrh_docs/pdf23/P230013C.pdf

EVOQUE Clinical Experience: TRISCEND

THE TRISCEND STUDY

n=207 | ♀: 71% | 20 | 17 | 3 | 3 sizes

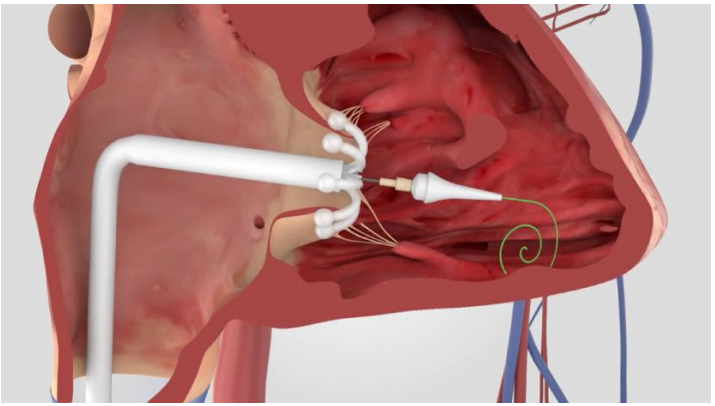
At 2 years,

- 83% survival and 84% freedom from HF hospitalisation (78% reduction in annualised HF hospitalization)
- TR reduction to ≤mild in 95% of patients, with 74% at none or trace
- Significant and sustained improvements in NYHA class (87% in class I/II) ΔKCCQ = 26 points and Δ6MWD = 46 metres)
- Echocardiographic evidence of favourable right heart remodelling

EVOQUE Clinical Experience: TRISCEND II

Consistent TR reduction with a reproducible procedure

- **95% ≤ mild TR at 1 year**
- **Median device time < 60 minutes**



TRISCEND II Pivotal[a] – Additional Clinical Data Highlights

Win Ratio	All-cause mortality	HF hospitalization	KCCQ-OS improvement	NYHA I/II
2.02	**12.6%**	**20.9%**	**+18.4 points**	**91%**
clinical benefit	± 2.6%	± 2.6%		
	15.2%± 3.3% OMT cohort	26.1% ± 4,1 OMT cohort	+3 points with OMT	34% with OMT

Hahn R, et al. *New Engl J Med* 2025;**392**;115-26

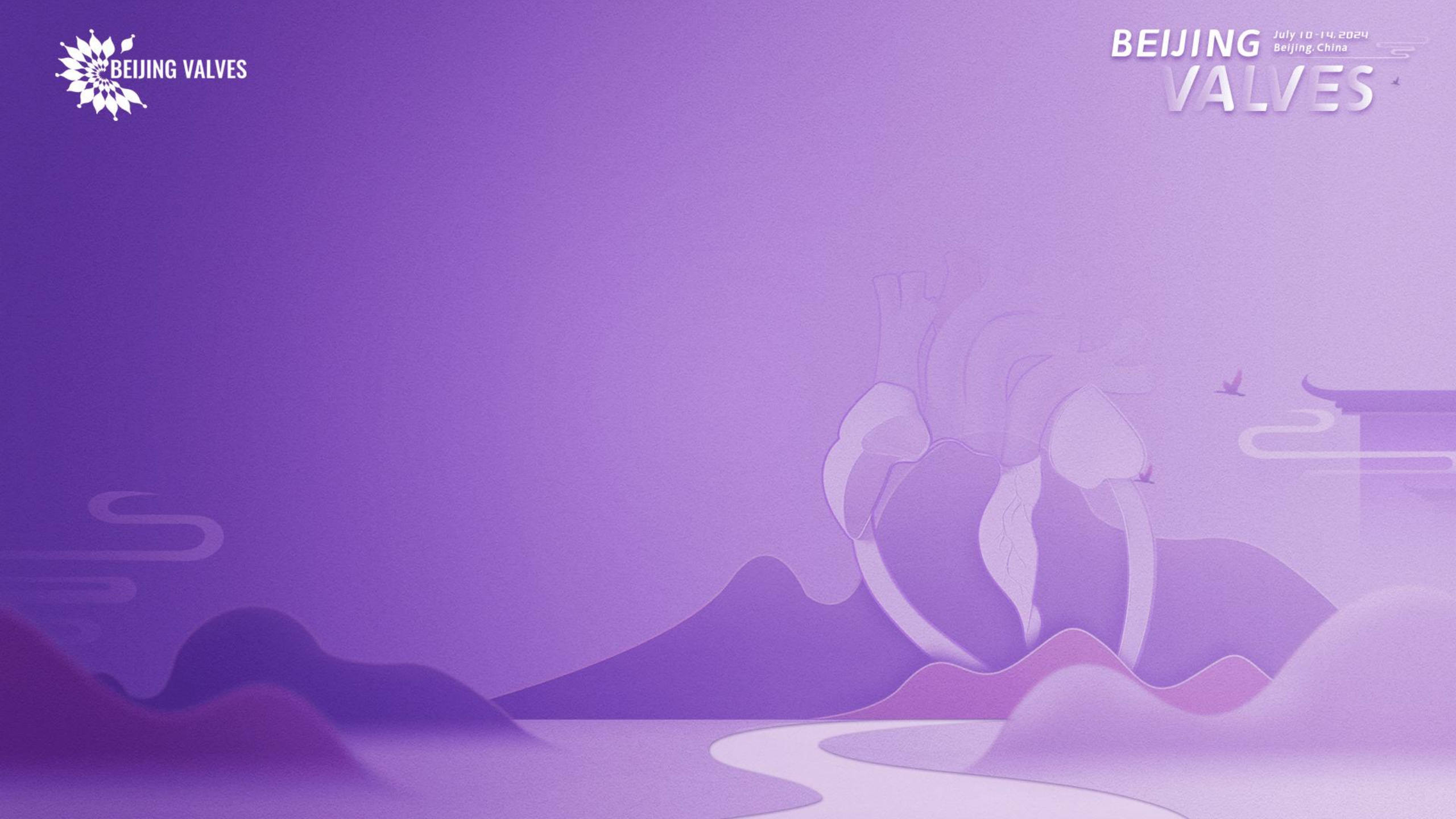
Two Trials….

	TRILUMINATE	TRISCEND II
Study Size/Randomization	572 (**1:1**)	400 (**2:1**)
Study Population (Control HFH rate)	**LESS SICK** • HFH in control arm: 13%	**MORE SICK** • HFH in control arm: 26%
Baseline TR Severity	**MORE SEVERE** (4+/5+, 69%)	**LESS SEVERE** (4+5+, 54%)
Residual TR at 1 year (Device group)	**MORE RESIDUAL TR** • 88% with ≤2+ • 50% with ≤1+	**LESS RESIDUAL TR** • 99% with ≤2+ • 95% with ≤1+
Effect on Hard Endpoints	**NONE**	**NONE**
Procedural Mortality (30d)	**0%**	**3.4%**
PPM at 30 days	**0%**	**25%**
NNT "alive with large QOL improvement"	**3.8**	**5.0**

Caution… Do We Need Sham Controlled Trial?

- There is no question that some of the benefit of TTVI observed in the clinical trials is a placebo effect
- In an ideal world, a sham controlled trial would be performed to remove all doubt and to convince the skeptics
- However, **the available data from the RCTs are reasonably convincing that some component of the observed benefit of TTVI is biologically mediated**– the only question is how much
- While it is reasonable to use our current devices to improve QOL for pts with severe TR, to perform **a sham- controlled trial is essential** for continued progress in treatment of valvular heart disease

Post-TTVI Patient Management


BEIJING VALVES
BEIJING VALVES
July 10-14, 2024
Beijing, China

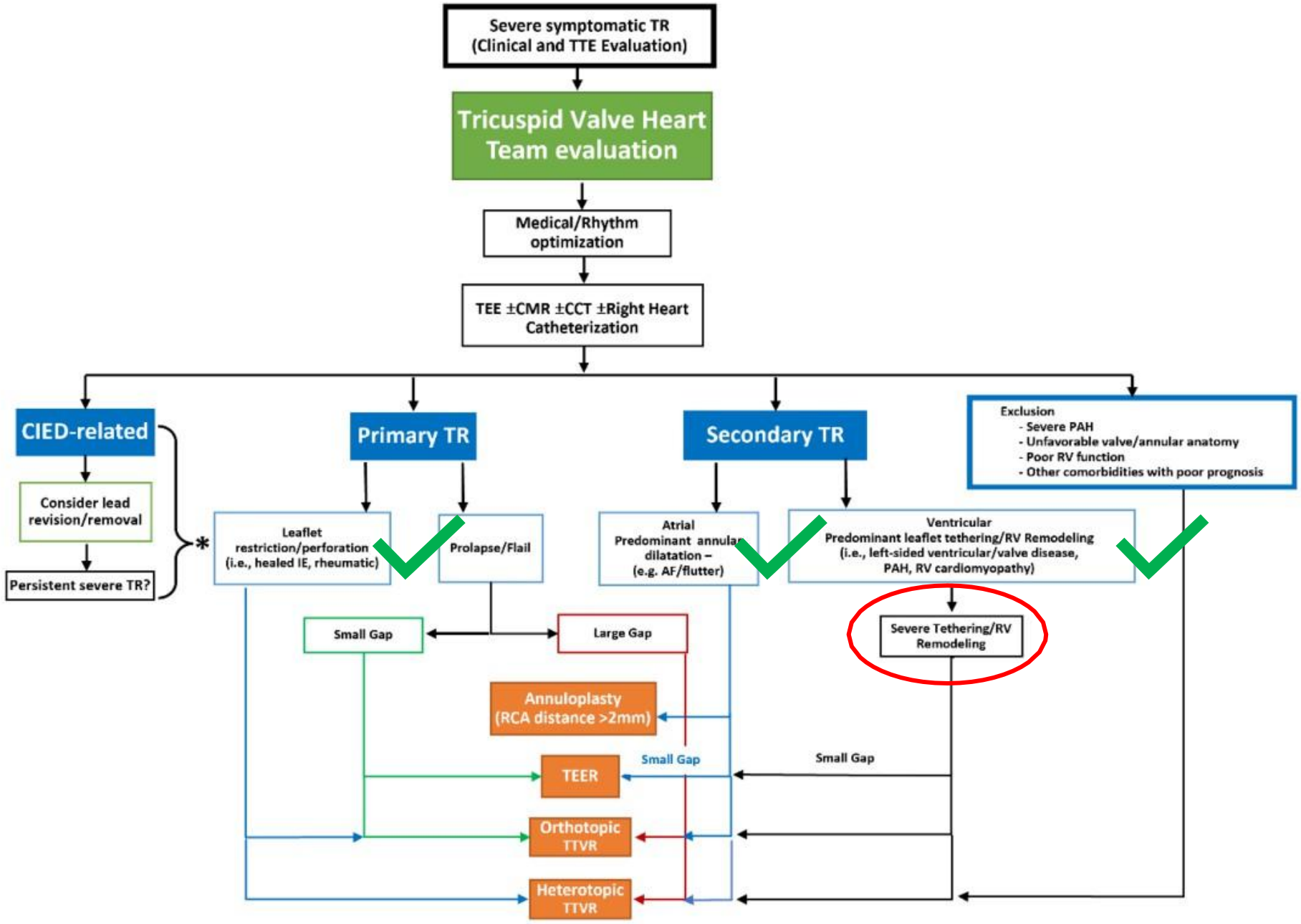
Heart Team Alive And Well..

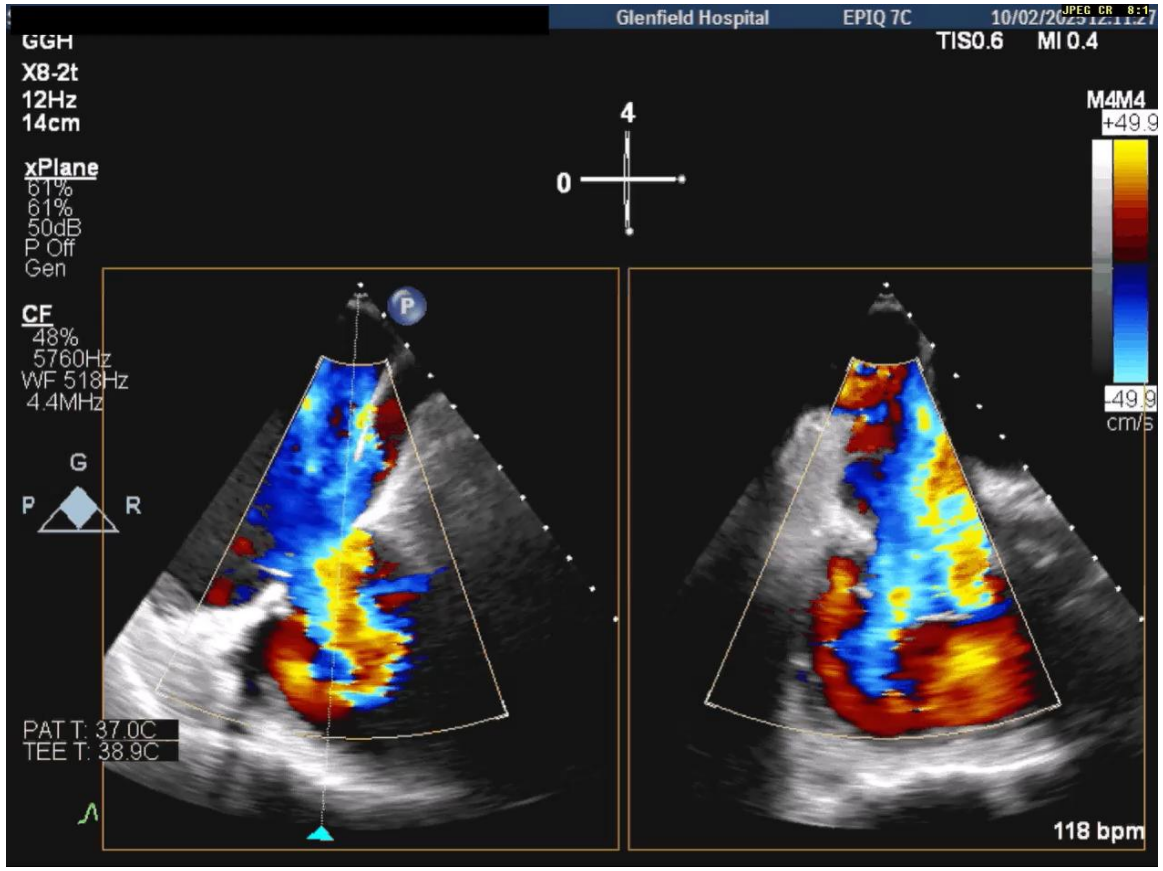
Procedural success in tricuspid intervention is predicted on appropriate device selection for patient specific anatomy and satisfactory imaging for intra-procedural guidance

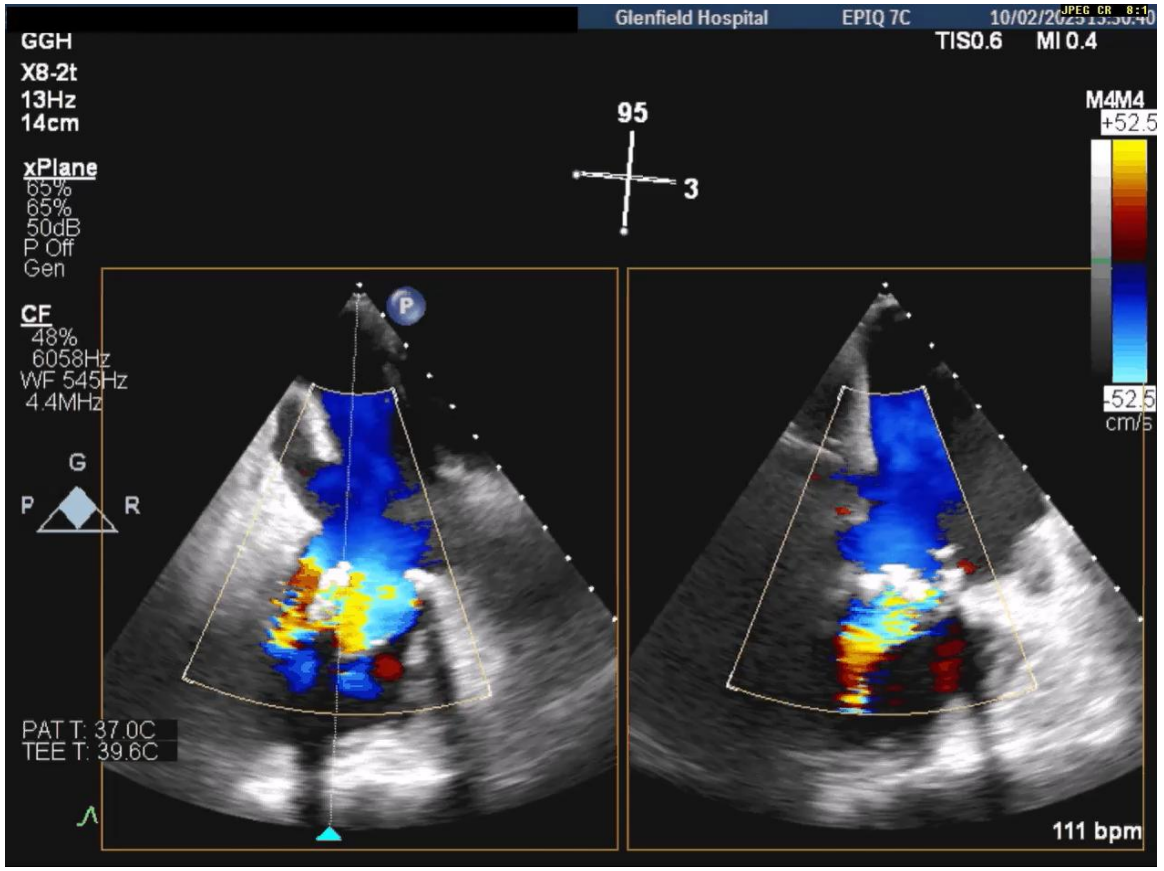
Multimodality imaging is essential in the selection of adequate candidates for TTVR

Echocardiography and CT provide complementary information about anatomy and pathology of the TV, RV function, TV annulus, IVC angles and femoral access.

Optimal Medical Therapy Complements TTVI/R and Vice Versa


Severe symptomatic TR
(Clinical and TTE Evaluation)
Tricuspid Valve Heart Team evaluation
Medical/Rhythm optimization
TEE ±CMR ±CCT ±Right Heart Catheterization
CIED-related
Consider lead revision/removal
Persistent severe TR?
*
Primary TR
Leaflet restriction/perforation (i.e., healed IE, rheumatic)
Prolapse/Flail
Secondary TR
Atrial
Predominant annular dilatation –
(e.g. AF/flutter)
Ventricular
Predominant leaflet tethering/RV Remodeling
(i.e., left-sided ventricular/valve disease,
PAH, RV cardiomyopathy)
Exclusion
- Severe PAH
- Unfavorable valve/annular anatomy
- Poor RV function
- Other comorbidities with poor prognosis
Small Gap
Large Gap
Severe Tethering/RV Remodeling
Annuloplasty
(RCA distance >2mm)
Small Gap
Small Gap
TEER
Orthotopic TTVR
Heterotopic TTVR





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