

Transcatheter Tricuspid Valve Interventions (TTVI)

Dr Kathy Lau

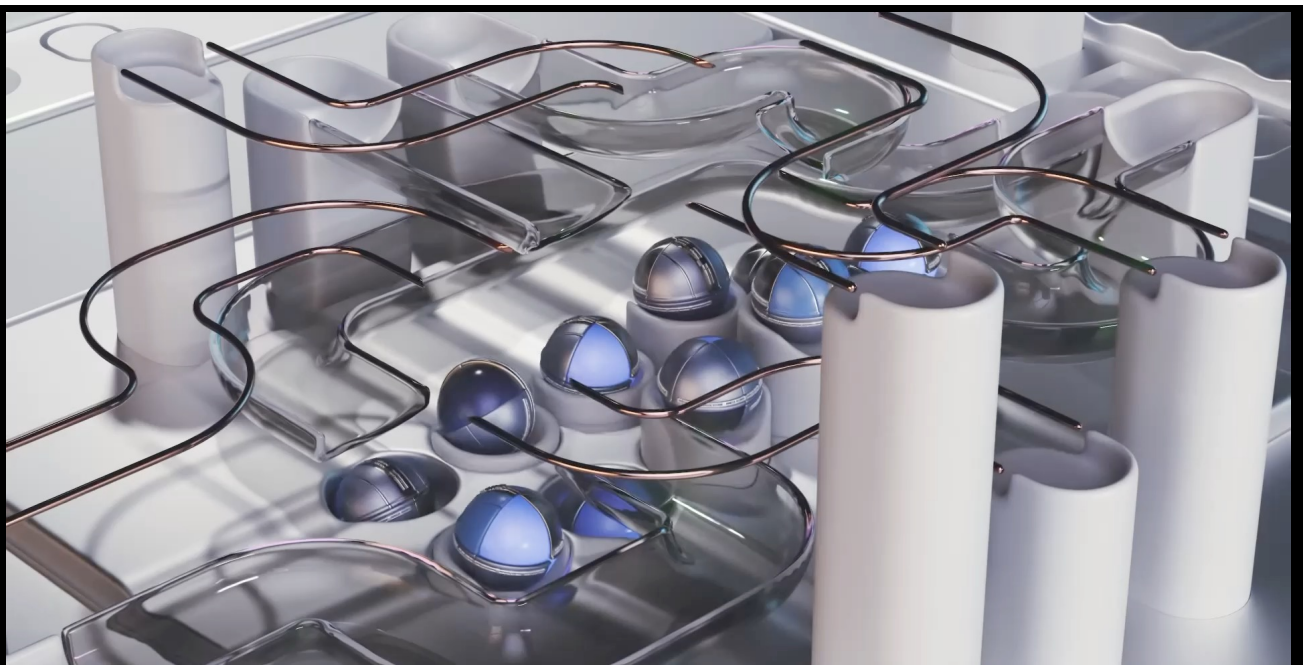


ECHO
AUSTRALIA

17-19 March 2025



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Disclosure

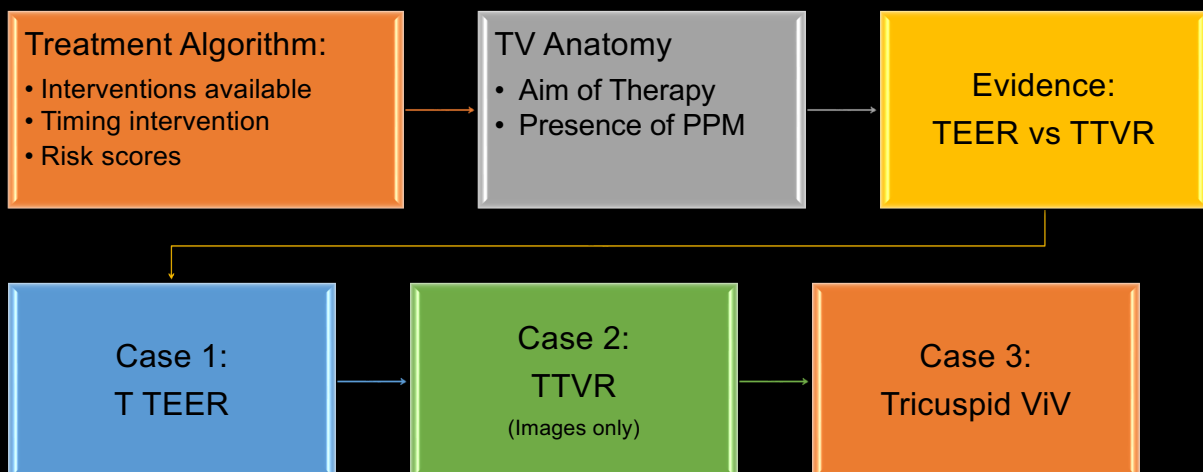
No Financial disclosure

Declaration: The contents of this presentation may not represent the ideas and beliefs of the employer.



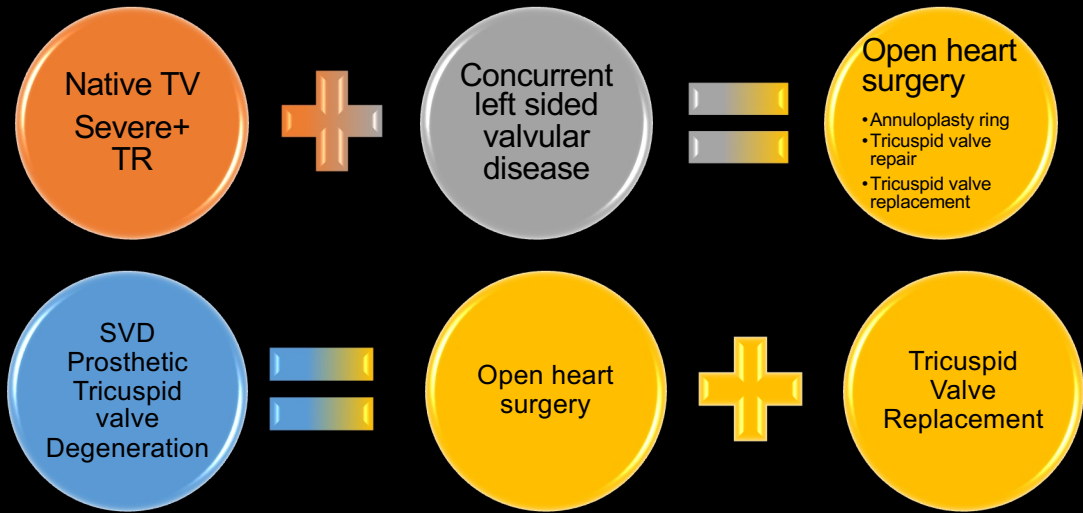
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Transcatheter Tricuspid Valve Interventions (TTVI)



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Changing landscape for TR interventions

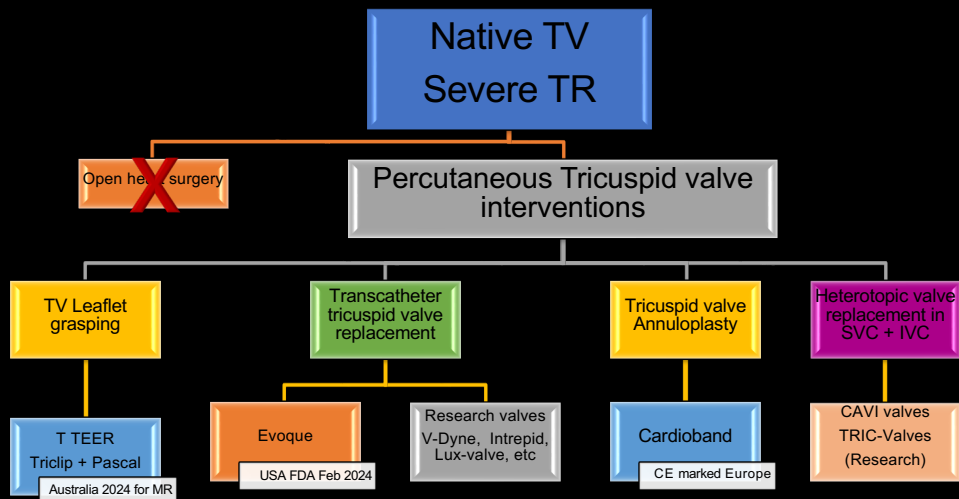


Treatment



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Changing landscape for TR interventions



Treatment



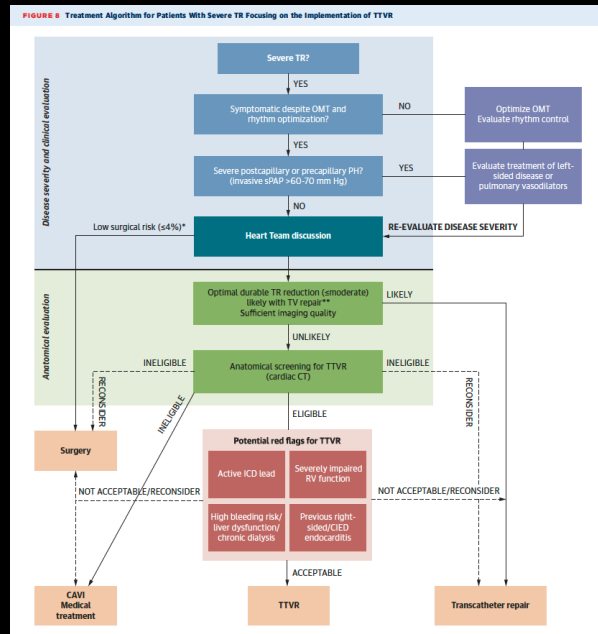
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JACC STATE-OF-THE-ART REVIEW

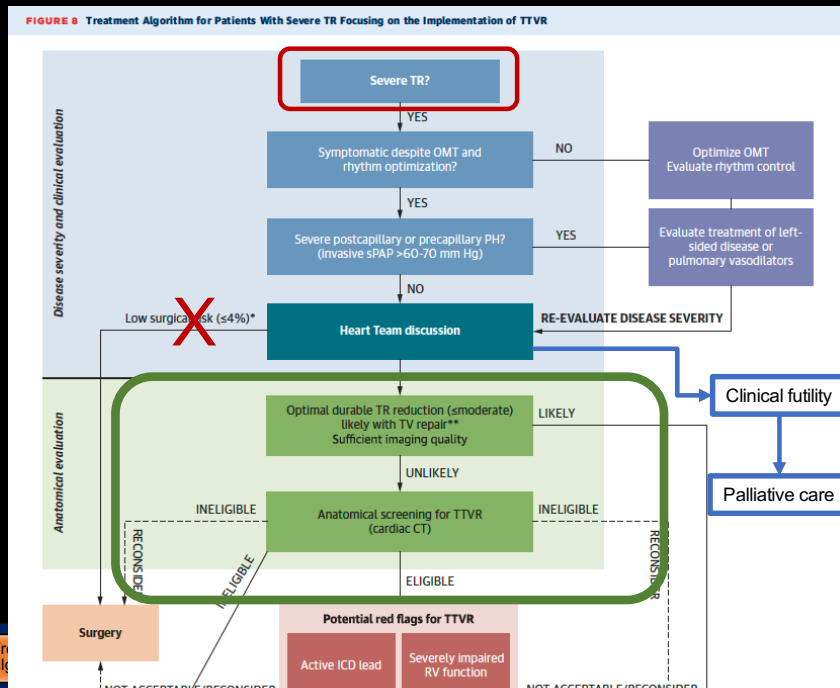
JACC VOL. 85, NO. 1, 2025
JANUARY 28, 2025:265-291

Transcatheter Tricuspid Valve Replacement

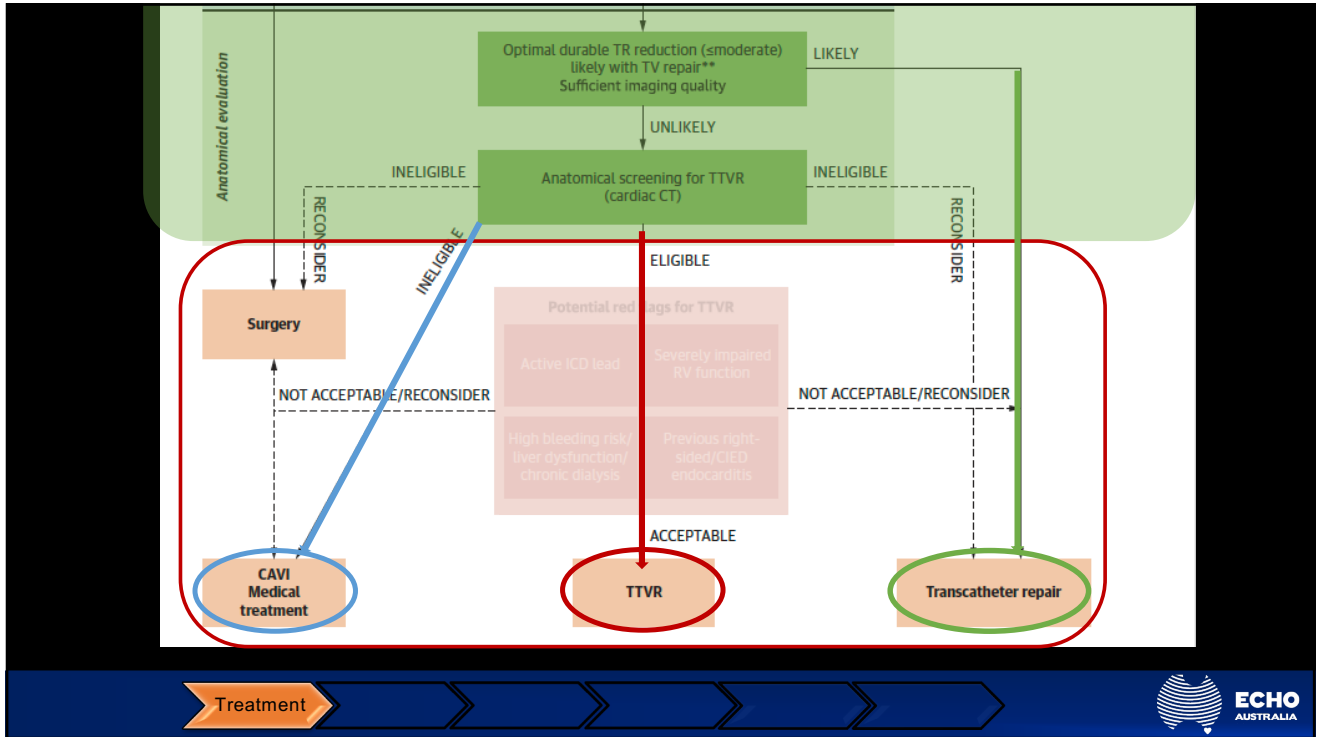
Jörg Hauleiter, MD,^{1,2,3,4} Lukas Stolz, MD,^{1,2,3,4} Philipp Lurz, MD,¹ Volker Rudolph, MD,² Rebecca Hahn, MD,⁴
Rodrigo Estévez-Loureiro, MD,^{5,6} Charles Davidson, MD,⁶ Firas Zaher, MD,¹ Saïmel Kodali, MD,⁷ Raj Makkar, MD,⁸
Anson Cheng, MD,⁹ Renato D. Lopes, MD, PhD,^{10,11} Francesco Maisano, MD,¹² Neil Fan, MD,¹³ Azem Lutfi, MD,¹⁴
Stephan Windecker, MD,¹⁵ Fabien Prus, MD¹⁶



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ESC
European Society of Cardiology

European Heart Journal (2022) 43, 561–632
<https://doi.org/10.1093/eurheartj/ehab395>

ESC/EACTS GUIDELINES

Vahanian, A. et al.

2021 ESC/EACTS Guidelines for the management of valvular heart disease

Recommendations on primary tricuspid regurgitation

Surgery should be considered in patients with moderate primary tricuspid regurgitation undergoing left-sided valve surgery. **IIa C**

Surgery should be considered in asymptomatic or mildly symptomatic patients with isolated severe primary tricuspid regurgitation and RV dilatation who are appropriate for surgery. **IIa C**

Recommendations on secondary tricuspid regurgitation

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. **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**

CLINICAL PRACTICE GUIDELINE

Otto et al.

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

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

JACC VOL. 77, NO. 4, 2021
FEBRUARY 2, 2021:450–500

8.2.3. Timing of Intervention

Recommendations for Timing of Intervention
Referenced studies that support the recommendations are summarized in Online Data Supplement 32.

COR	LOE	RECOMMENDATIONS
1	B-NR	1. In patients with severe TR (Stages C and D) undergoing left-sided valve surgery, tricuspid valve surgery is recommended (375,389–395).
2a	B-NR	2. In patients with progressive TR (Stage B) undergoing left-sided valve surgery, tricuspid valve surgery can be beneficial in the context of either 1) tricuspid annular dilation (tricuspid annulus end diastolic diameter >4.0 cm) or 2) prior signs and symptoms of right-sided HF (375,391–397).
2a	B-NR	3. In patients with signs and symptoms of right-sided HF and severe primary TR (Stage D), isolated tricuspid valve surgery can be beneficial to reduce symptoms and recurrent hospitalizations (398–401).
2a	B-NR	4. In patients with signs and symptoms of right-sided HF and severe isolated secondary TR attributable to annular dilation (in the absence of pulmonary hypertension or left-sided disease) who are poorly responsive to medical therapy (Stage D), isolated tricuspid valve surgery can be beneficial to reduce symptoms and recurrent hospitalizations (398,399,402–406).

Treatment

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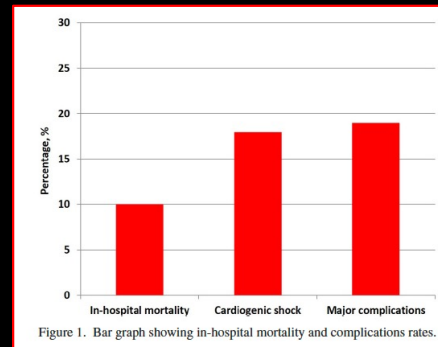
Experience from surgical isolated TVR

- 2013-2014 France Series
- High in-hospital mortality 10% + morbidity major complication rate 19%
- Durability of right-sided valves hindered by:
 - High occurrence of functional stenosis, thrombosis + early structural deterioration.

Timing of Referral of Patients With Severe Isolated Tricuspid Valve Regurgitation to Surgeons (from a French Nationwide Database)

Julien Dreyfus, MD^{1,2}, Nicolas Ghalem, MD³, Eric Garbarz, MD⁴, Claire Cimadevilla, MD⁵, Patrick Nataf, MD⁶, Alec Vahanian, MD⁷, Gilbert Caranhac, MS⁴, and David Messika-Zeitoun, MD, PhD^{2,4,8}

(Am J Cardiol 2018;122:323-326)



Treatment



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Outcomes of Isolated Tricuspid Valve Surgery: A Society of Thoracic Surgeons Analysis and Risk Model

Ann Thorac Surg
2024;118:873-81

Vinod H. Thourani, MD,¹ Levi Bonnell, PhD,² Moritz C. Wyler von Ballmoos, MD, PhD,³ J. Hunter Mehafeey, MD,⁴ Michael Bowdish, MD,⁵ Paul Kurlansky, MD,⁶ Jeffrey P. Jacobs, MD,⁷ Sean O'Brien, PhD,⁸ David M. Shahian, MD,⁹ and Vinay Badhwar, MD⁴

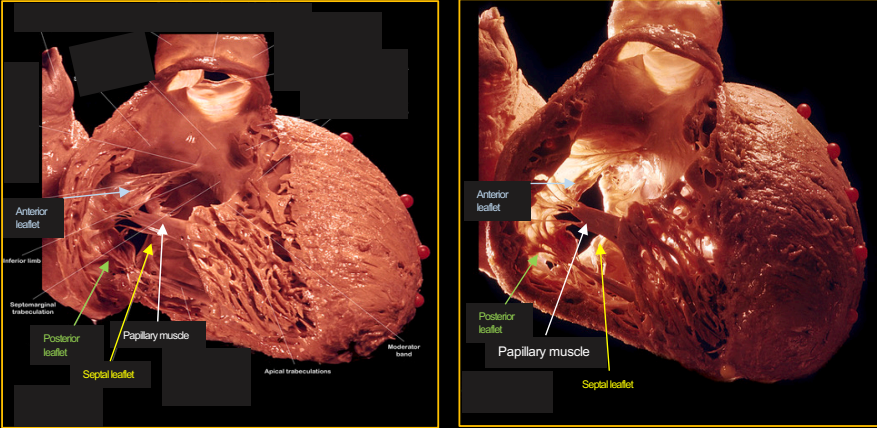
- STS Adult Cardiac Surgery Database (USA) 2017-2023 N= 13,587, age 48.3 ± 18.4 years.
- Isolated TV: 41.1% repairs, 58.9% replacements
- Risk of operative mortality 5.6%
 - TV repairs (5.5%) + replacements (5.7%)
- Mortality of isolated TV operations lower than previously observed.

Treatment



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TV anatomy



The diagrams illustrate the tricuspid valve anatomy. The left diagram shows the valve from a perspective view, highlighting the anterior leaflet, posterior leaflet, septal leaflet, papillary muscle, and chordae tendineae. The right diagram shows the valve from a more detailed perspective, highlighting the anterior leaflet, posterior leaflet, septal leaflet, and papillary muscle. A small inset diagram in the top right corner shows the valve from a cross-sectional view, with labels for the anterior (A), septal (S), and posterior (P) leaflets, and the coronary sinus (CS).

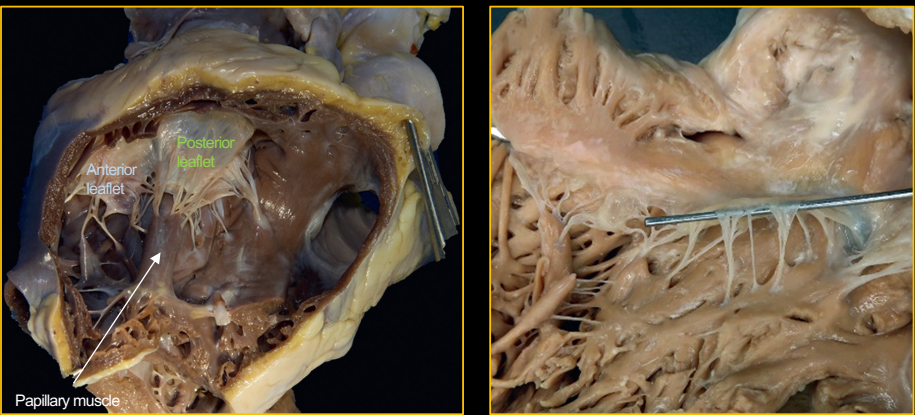
Dahou et al. (2019) Tricuspid Valve Anatomy, J A C C : Cardiovascular imaging, 12 (3), p. 458-68
Kalyanam Shivkumar et al. (2025) JACC; 85, p. 295-296.

Treatment algorithm:

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TV anatomy



The diagrams illustrate the tricuspid valve anatomy. The left diagram shows the valve from a perspective view, highlighting the anterior leaflet, posterior leaflet, papillary muscle, and chordae tendineae. The right diagram shows the valve from a more detailed perspective, highlighting the complex chordal apparatus. A small inset diagram in the top right corner shows the valve from a cross-sectional view, with labels for the anterior (A), septal (S), and posterior (P) leaflets, and the coronary sinus (CS).

Dahou et al. (2019) Tricuspid Valve Anatomy, J A C C : Cardiovascular imaging, 12 (3), p. 458-68
Kalyanam Shivkumar et al. (2025) JACC; 85, p. 295-296.

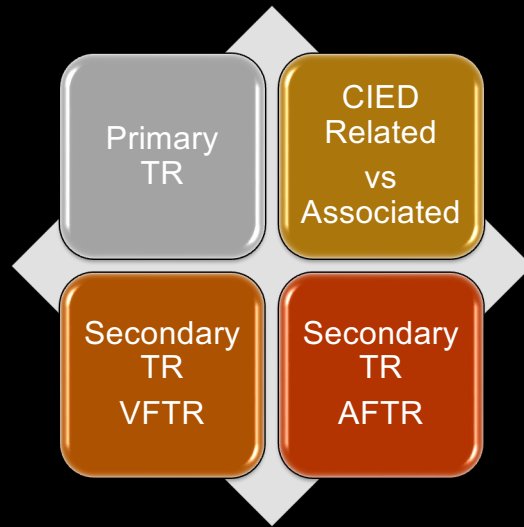
Complex Chordal Apparatus

Anatomy

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Etiology of Tricuspid Regurgitation



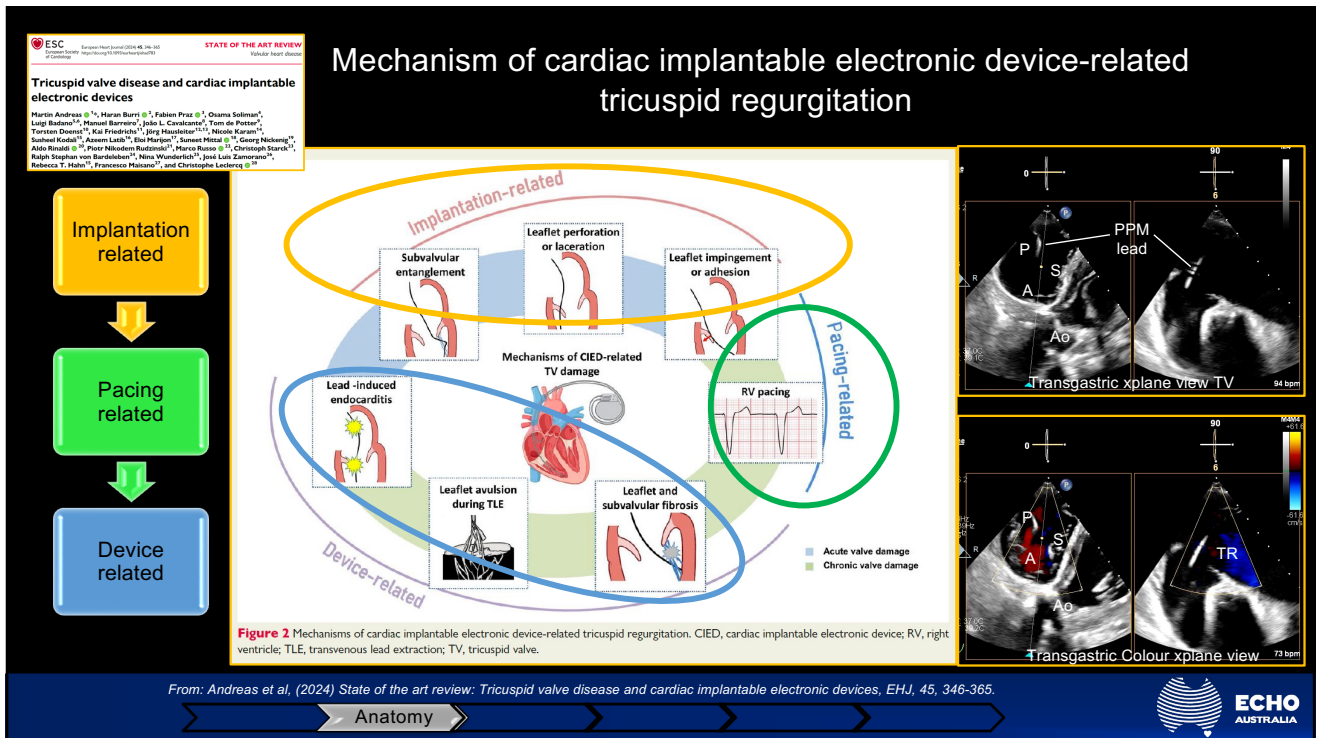
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Etiology of TR

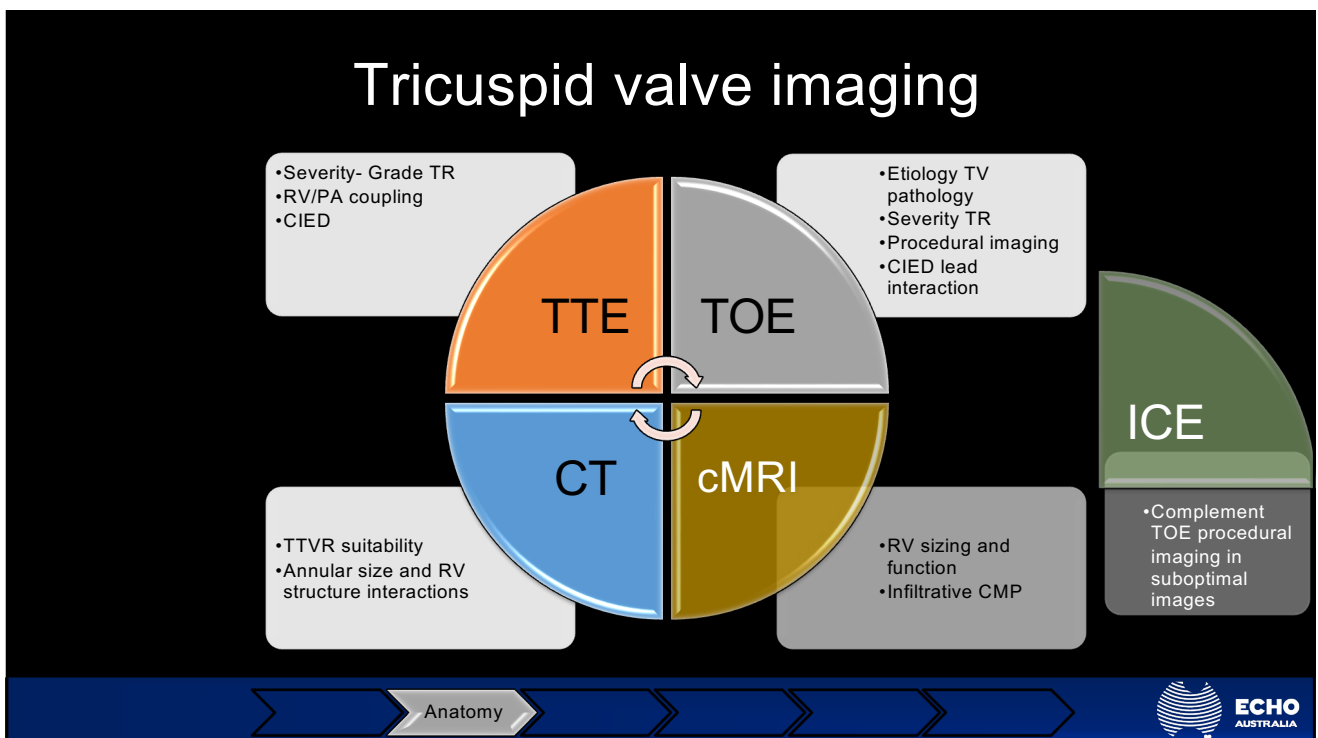
Parameter	Primary TR	Secondary TR VFTR	Secondary TR AFTR	CIED related
Incidence	5-10%	80%		10-15%
Right Atrial Size	Normal to ↑	↑↑	↑↑	↑
Left Atrial Size	Normal	↑↑	↑	Normal to ↑
Tricuspid Annular Size	Normal to ↑	↑	↑↑	Normal to ↑
Leaflet Tethering	-	↑↑	-	↑
Leaflet Restriction	-	Systole	-	Systole/Diastole
Right Ventricle Size	Normal to ↑	↑↑	Normal to ↑	Normal to ↑
Pulmonary Artery Systolic Pressure	Normal to ↑	(≥50 mmHg)	Normal to ↑	Normal to ↑
Right Ventricle Function	Normal to ↓	↓	Normal to ↓	Normal to ↓
Left Ventricular Ejection Fraction	↔	Often reduced (<50%)	Usually normal (>60%)	↔

From: Welle et al (2024), New Approaches to Assessment and Management of TR Before Intervention, JACC: Cardiovascular Interventions, (17), 837-858.

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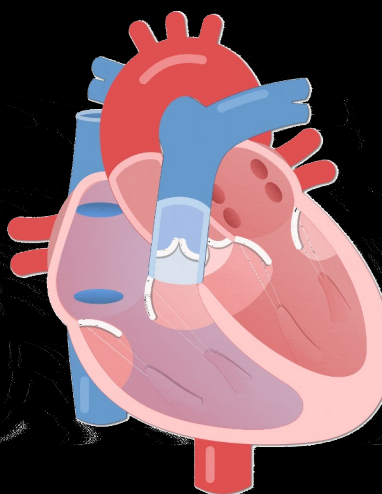
18

Transcatheter TV therapy options

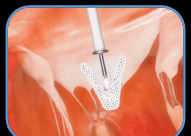
T TEER received regulatory approval in Australia
-Not listed on Commonwealth prostheses list.
-Not eligible for private health insurance rebates.

CE Mark Europe 2020
FDA USA April 2024

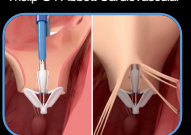
CE-Marked USA, Europe



Edge to Edge repair




Triclip G4 Abbott Cardiovascular




Pascal Ace Edwards Lifesciences

TVVR Replacement




EVOQUE system Edwards Lifesciences

TVVR Replacement



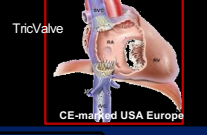
VDyne

Direct annuloplasty



CE-marked USA Europe

Heterotopic caval valve implantation



TricValve

CE-marked USA Europe

Videos from You-tube

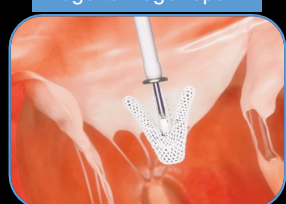
Evidence

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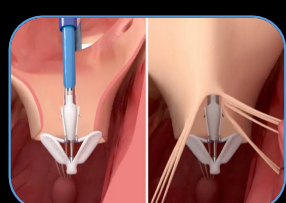
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Europe: CE-marked devices for transcatheter tricuspid valve intervention.

Edge to Edge repair

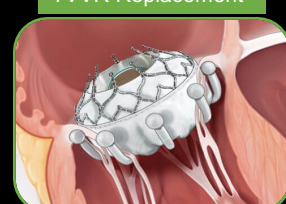


Triclip G4 Abbott Cardiovascular




Pascal Ace Edwards Lifesciences ®

TVVR Replacement




EVOQUE Edwards Lifesciences

Direct annuloplasty



Cardioband Edwards Lifesciences ®

Heterotopic caval valve implantation



TricValve

Videos from You-tube


Evidence

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Investigational devices for transcatheter tricuspid valve intervention.

Direct annuloplasty




K-Clip Huihe Medical Technology

Edge to Edge repair




DragonFly-T Valgen Medtech

TVVR Replacement




VDyne

TVVR Replacement




Intrepid valve Medtronic

TVVR Replacement



LuX-Valve Plus

TVVR Replacement



Cardiovalve

Videos from You-tube

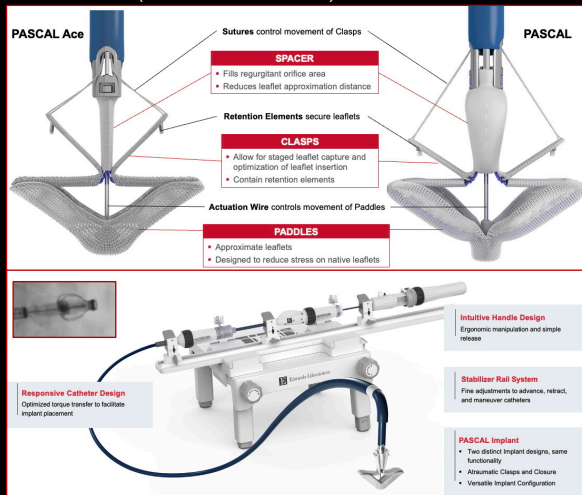
Evidence

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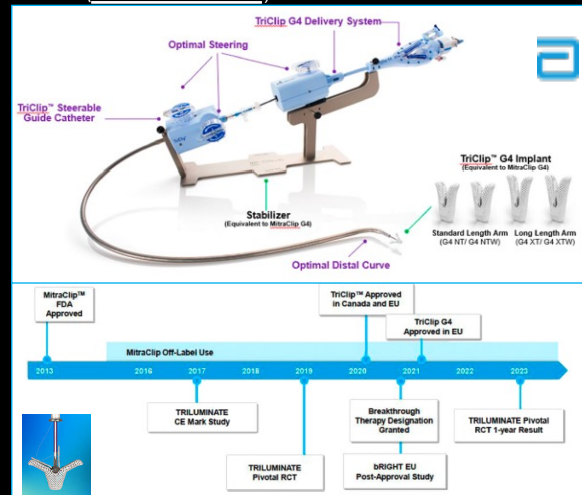
Tricuspid Edge to Edge Repair Systems

PASCAL device (Edwards Lifesciences)



(a) From Edwards Lifesciences- procedure manual

TRICLIP (Abbott Cardiovascular)



(b) Lupu et al, (2024) Overview of 2024 FDA Advisory Panel Meeting on the TriClip transcatheter tricuspid valve repair system, AHJ, Vol. 275, p 21-34

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TRIVALVE Score

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 17, NO. 18, 2024
SEPTEMBER 23, 2024:2170-2179

A Risk Score for Mortality/Hospitalization Prediction in Patients Undergoing Transcatheter Tricuspid Valve Intervention

Giulio Russo, MD, PhD,^{1,4*} Daniela Pedicino, MD, PhD,^{1,4*} Denise Pires Marafon, MD,² Marianna Adamo, MD,⁴ Hannes Alessandrini, MD,¹ Martin Andreas, MD,² Daniel Braun, MD,³ Kim A. Connelly, MD,¹ Paolo Denti, MD,¹ Rodrigo Estevez-Loureiro, MD,¹ Neil Fam, MD,² Rebecca T. Hahn, MD,¹ Claudia Harr, MD,¹ Jörg Hausleiter, MD,¹ Dominique Humbert, MD,¹ Daniel Kalbacher, MD,¹ Edwin Ho, MD,² Azeem Latib, MD,³ Nicolò Lentini, MD,⁴ Edith Lubos, MD,¹ Sebastian Ludwig, MD,¹ Philipp Lurz, MD,¹ Marco Metra, MD,⁴ Vanessa Monivas, MD,⁴ Georg Nickenig, MD,² Roberta Pastorino, PhD,² Giovanni Pedrazzini, MD,^{1,2} Alberto Pozzoli, MD,² Fabien Praz, MD,¹ Joseph Rodes-Cabau, MD,² Christian Besler, MD,¹ Karl-Philipp Rommel, MD,² Joachim Schofer, MD,¹ Andrea Scotti, MD,² Kerstin Playda, MD,¹ Horst Sievert, MD,¹ Gilbert H.L. Tang, MD, MSc, MBA,¹ Holger Thiele, MD,¹ Florian Schlotter, MD,¹ Ralph Stephan von Bardeleben, MD,¹ John G. Webb, MD,¹ Stephan Windecker, MD,¹ Martin Leon, MD,¹ Maurice Enriquez-Sarano, MD,^{1b} Francesco Maisano, MD,¹ Filippo Crea, MD,^{1,4*} Maurizio Taramasso, MD, PhD^{1,4*}

CENTRAL ILLUSTRATION Proposed Risk Score for TTVI Patients

A Dedicated Risk Score for Patients With Severe TR Undergoing TTVI

Parameter	Points
Atrial fibrillation	1
GFR <30 mL/min	1
Elevated GGT or bilirubin	1
Signs of right HF	1
LVEF <50%	0.5

B Predicted 12-Month Death/Rehospitalization According to Risk Score

Risk Score (Points)	Predicted Death/Rehosp <12 mo, %
0	3.4
0.5	5.1
1	7.5
1.5	11.1
2	16.0
2.5	22.6
3	30.8
3.5	40.5
4	51.0
4.5	61.4

C Survival According to Risk Score Category

No. at risk:

Strata	Low Risk	High Risk
0-2	201	125
3-4.5	92	70
5-6	48	20

Evidence

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GLIDE Score for Prediction of Mild Tricuspid Regurgitation following Transcatheter Edge-to-Edge Repair

The GLIDE Scoring System

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

GLIDE Score	TR Reduction ≥2 Grades (%)	TR Grade Moderate or Less (%)
0-1	~95	~95
2-3	~55	~65
4+	~15	~25

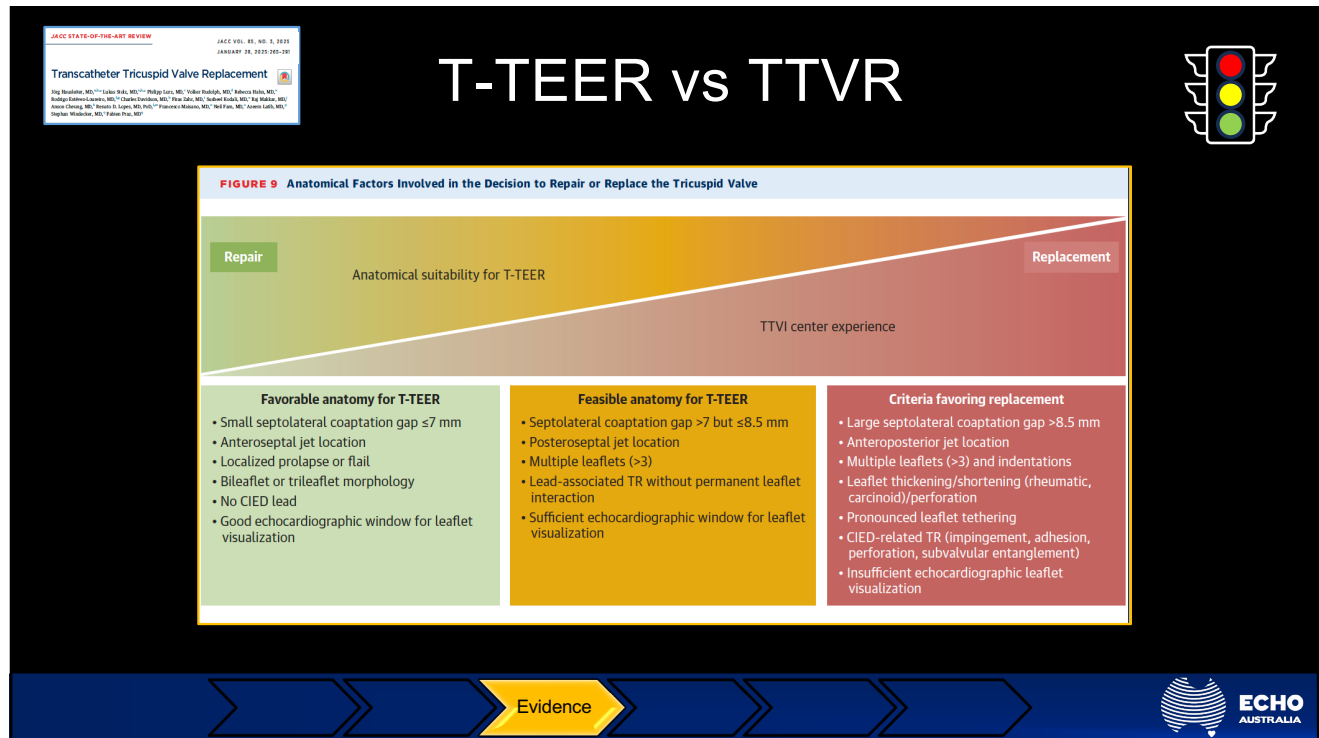
TABLE 1 The GLIDE Scoring System^a

Parameters	Straightforward	Complex
G. Septolateral gap	0 points	1 point
L. Predominant jet location	0-5 mm	>5 mm
I. Image quality	Good	Limited
D. Chordal structure	Modest	High
E. En-face TR jet morphology	Oval or linear	Star-shaped

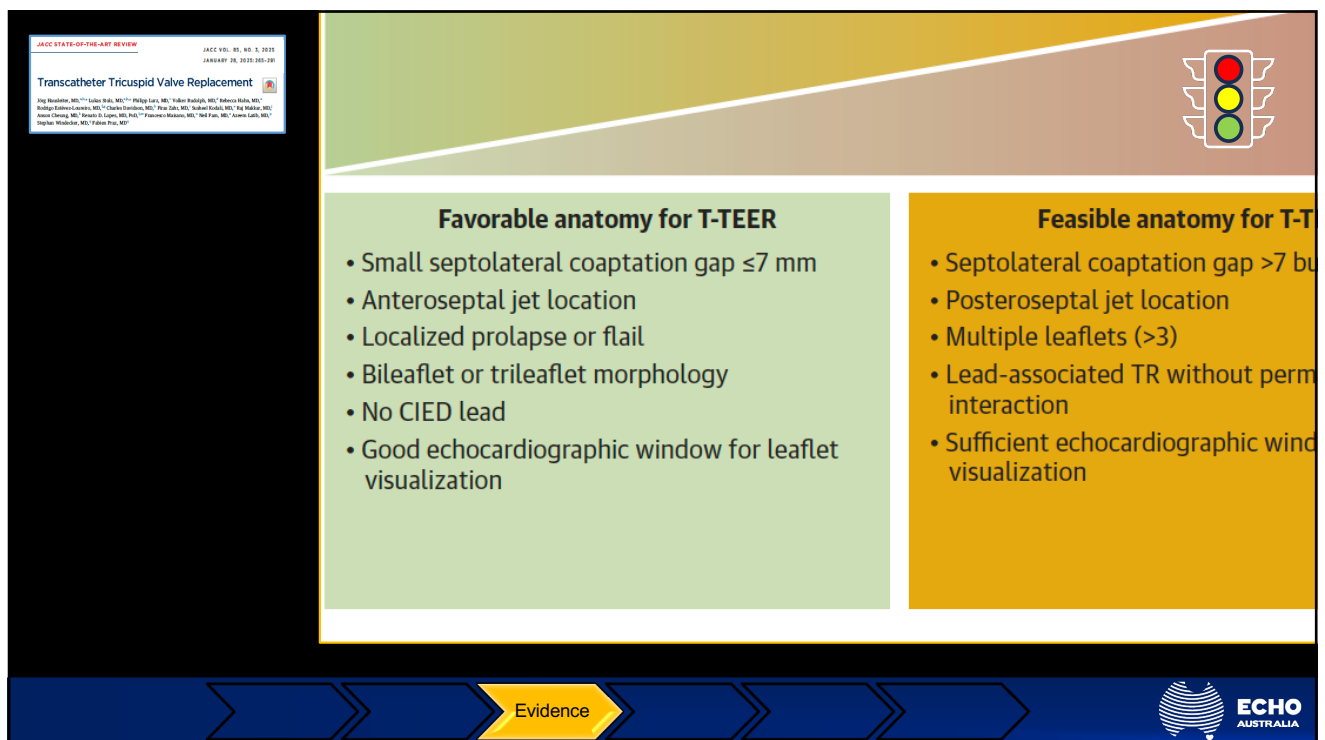
TR = tricuspid regurgitation.

Evidence

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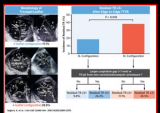
TTVI center experience

Feasible anatomy for T-TEER


- Large septolateral coaptation gap >7 but ≤8.5 mm
- Septal jet location
- Multiple leaflets (>3)
- Associated TR without permanent leaflet on
- Echocardiographic window for leaflet visualization

Criteria favoring replacement

- Large septolateral coaptation gap >8.5 mm
- Anteroposterior jet location
- Multiple leaflets (>3) and indentations
- Leaflet thickening/shortening (rheumatic, carcinoid)/perforation
- Pronounced leaflet tethering
- CIED-related TR (impingement, adhesion, perforation, subvalvular entanglement)
- Insufficient echocardiographic leaflet visualization

Evidence

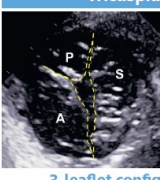


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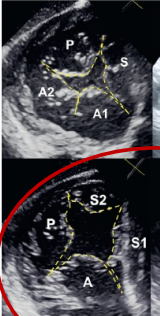
Feasible anatomy for

- Large septolateral coaptation gap >7
- Septal jet location
- Multiple leaflets (>3)
- Associated TR without pe
- on
- Echocardiographic w
- tion

Morphology of Tricuspid Leaflet

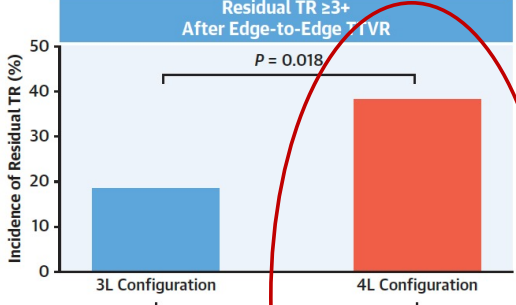


3-leaflet configuration 71.1%




4-leaflet configuration 28.9%

Residual TR ≥3+ After Edge-to-Edge TTVR




Larger coaptation gap (>7 mm) or TR jet from non-central/anterosseptal commissure?			
No		Yes	
3L Configuration	Residual TR ≥3+ 9.8%	Residual TR ≥3+ 24.2%	4L Configuration
			Residual TR ≥3+ 11.1%
			Residual TR ≥3+ 45.5%



Sugiura, A. et al. J Am Coll Cardiol Interv. 2021;14(20):2260-2270.

Evidence



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Case 1

83 yo male presented with NYHA 3 on OMT

Background:

- Atrial fibrillation
- Osteoarthritis knees

Medications:

- Apixaban 5mg BD
- Metoprolol 50mg BD
- Frusemide 40mg BD

Surgical risk TRI-score:

- 5/12
- Predicted in-hospital mortality 14%

TRI-SCORE CALCULATOR

Age ≥ 70 years ☒ Female ☐ NYHA functional class III or IV ☒ Right-sided heart failure signs ☐ Prior left-sided heart valve intervention ☐ Permanent pacemaker / defibrillator ☐ Atrial fibrillation / flutter ☐ Daily dose of furosemide ≥ 125 mg ☐ Glomerular filtration rate < 30 mL/min ☐ Elevated total bilirubin ☐ Left ventricular ejection fraction < 40% ☒ Moderate/severe right ventricular dysfunction ☐ Mechanism of tricuspid regurgitation

Left ventricular ejection fraction < 40% ☐ Moderate/severe right ventricular dysfunction ☐ Mechanism of tricuspid regurgitation

Secondary ☒ Primary ☐ Mixed ☐

Prediction

TRI-SCORE

5/12

Predicted in-hospital mortality after isolated tricuspid valve surgery

14%

Risk

Low ☒ Moderate ☐ High ☐

The TRI-SCORE calculator is a tool to help predict the risk of in-hospital mortality after isolated tricuspid valve surgery.

(Affix patient identification label here)

URN: _____
Family Name: _____
Given Names: _____
Address: _____
Date of Birth: _____ Sex: ☐ M ☐ F ☐ I

Assessment of Tricuspid Edge to Edge Investigations

☐ DTR ☐ AFTR ☐ VFTR ☐ PPM

Transthoracic Echocardiogram (TTE) date: ____/____/____

RV size	RV function	RV GLS (%)	LV EF (%)
TAPSE (mm)	RV S (cm/s)	RVSP (mmHg)	LV GLS (%)
TR grade	TR direction	Lead	MR grade
Comment:	AS	AR	LA

Transoesophageal Echocardiogram (TOE) date: ____/____/____

TV type: ☐ Type I ☐ Type II ☐ Type IIIA ☐ Type IIIB ☐ Type IIIC ☐ Type IV

TR Grade: ☒ J4 TR direction: _____ ERO (mm²): _____ 3D VCA (mm³): _____

Reg Vol (mLs): _____ Reg Frac (%): _____ Coaptation gap (mm): _____ Lead: _____

3D Image Quality: ☐ Adequate ☐ Poor
Trans-gastric quality: ☐ Adequate ☐ Poor

Comments:

COMMENTS:

Imaging issues:

STATUS: ☐ Feasible ☐ Difficult

me: _____

Patient selection criteria sheet
Designed by Professor Scalia

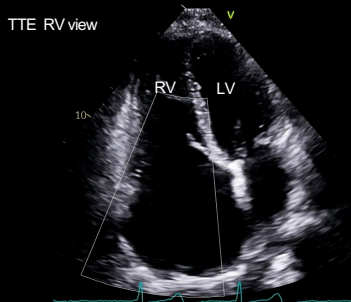
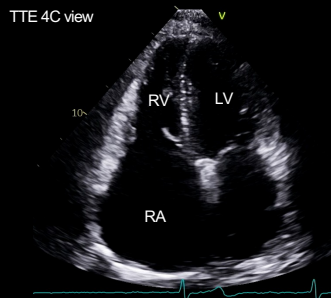
ASSESSMENT OF TRICUSPID EDGE TO EDGE INVESTIGATIONS

Case 1

TTEER



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(Affix patient identification label here)

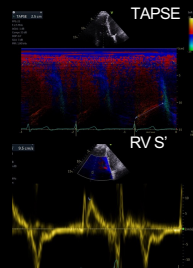
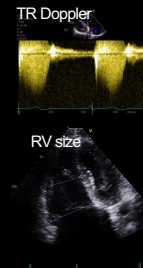
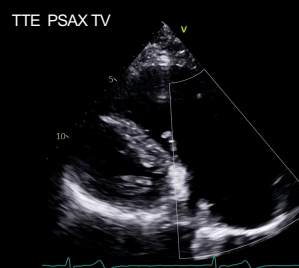
URN: _____
Family Name: _____
Given Names: _____
Address: _____
Date of Birth: _____ Sex: ☐ M ☐ F ☐ I

Assessment of Tricuspid Edge to Edge Investigations

☐ DTR ☒ AFTR ☐ VFTR ☐ PPM

Transthoracic Echocardiogram (TTE) date: ____/____/____

RV size	Mildly dilated	RV function	Normal	RV GLS (%)	13%	LV EF (%)	53	
TAPSE (mm)	25	RV S (cm/s)	9.5	RVSP (mmHg)	40	LV GLS (%)	-	
TR grade	4 /4	TR direction	Central	Lead	N	MR grade	2 /4	
Comment:	RA dilation 131ml/m ² ; TV tenting < 3mm; FAC 28%; TAPSE/RVSP 0.23mmHg/mmHg						AS	No
						AR	1 /4	

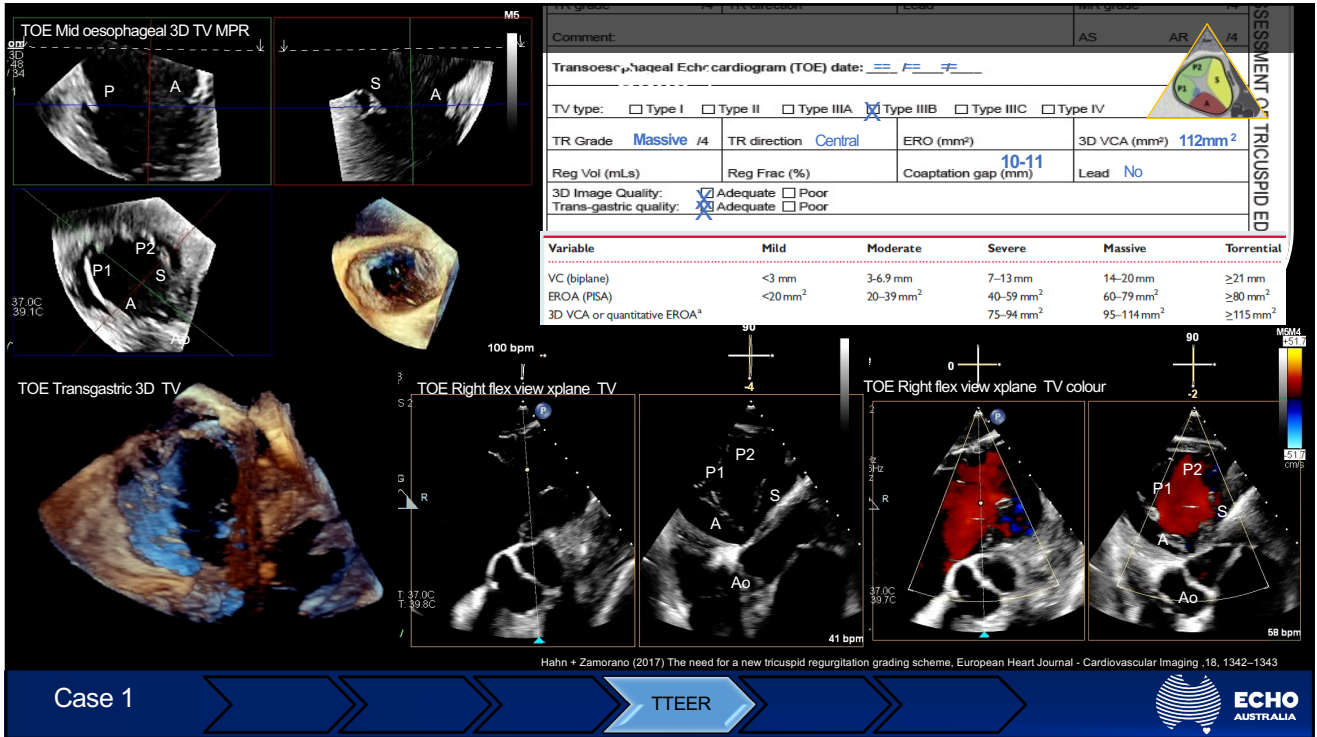


Case 1

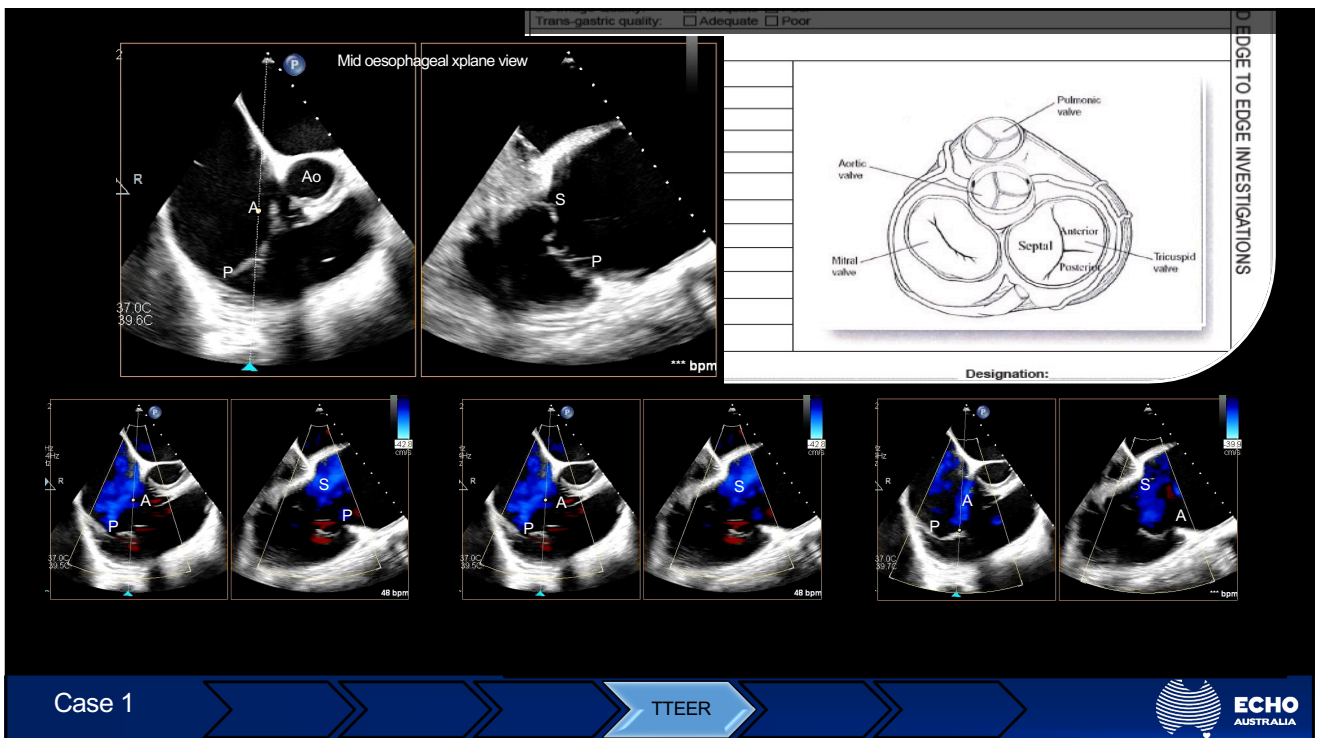
TTEER



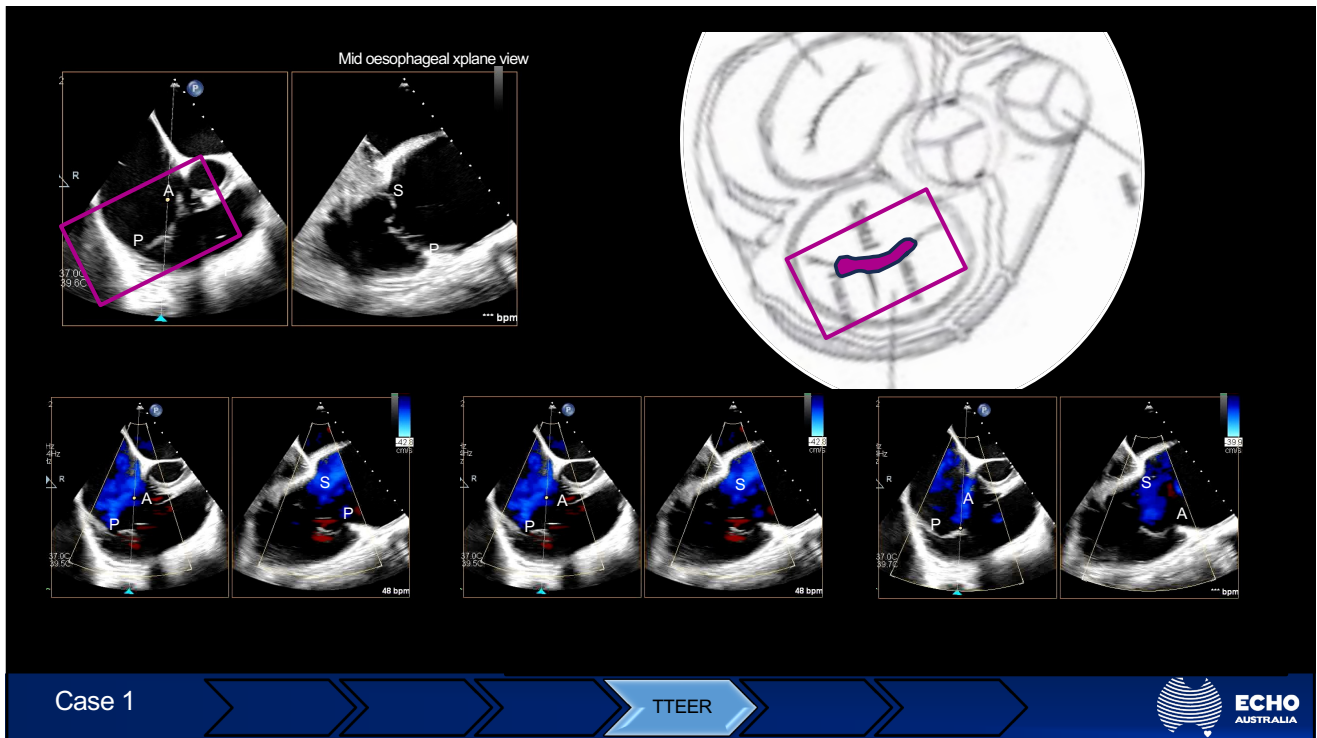
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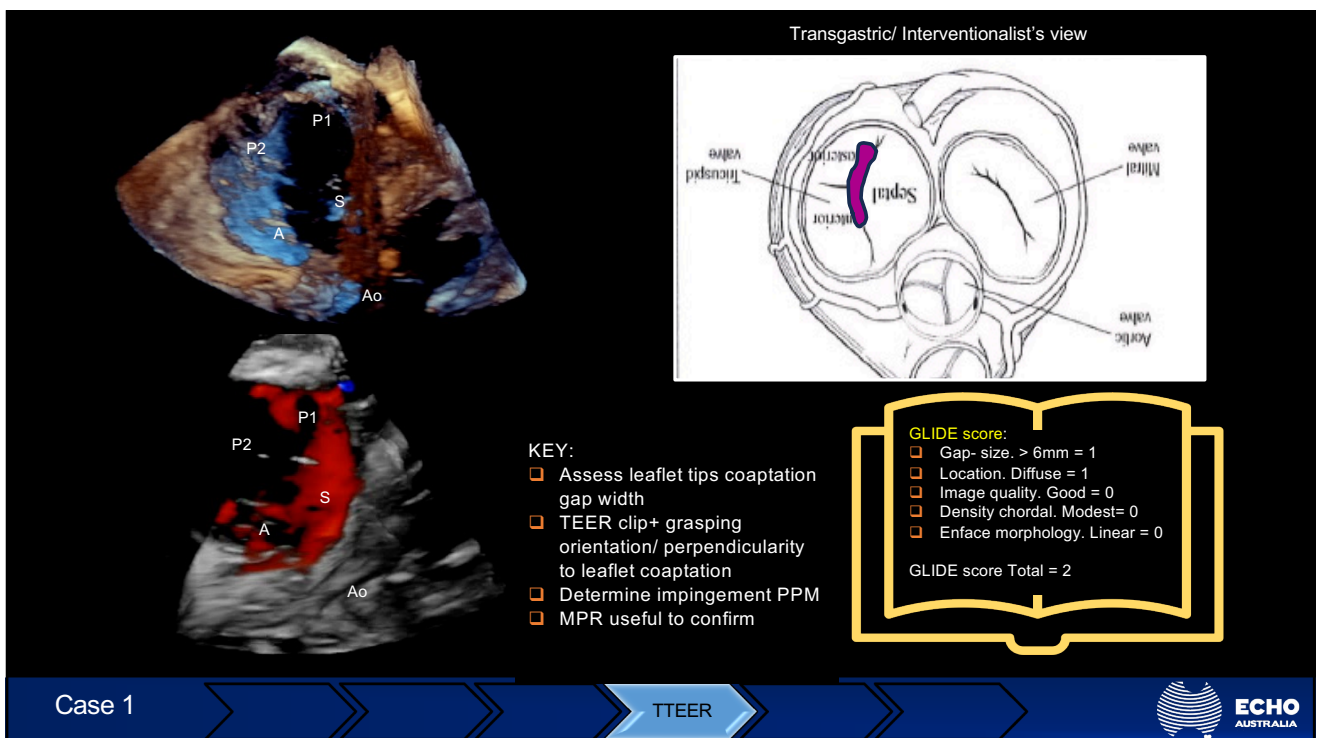
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32



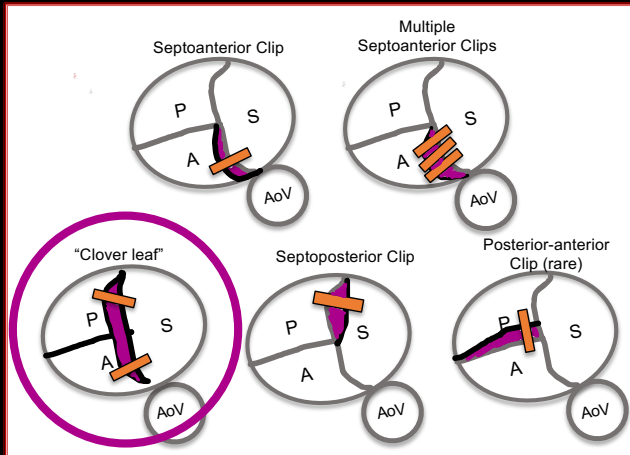
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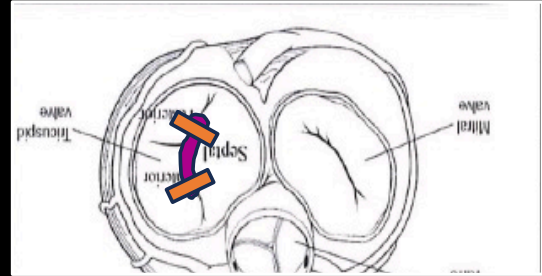
34

Tricuspid TEER Clip placement strategy

Transgastric view



Device image from: Abbott Triclip G4 TEER
https://www.youtube.com/watch?v=CnoUG5OG5_U



Transgastric/ Interventionalist's view

- First TEER clip Septo-anterior close to aortic valve
- Further parallel TEER clip placement or "Clover leaf" configuration (septoposterior)
- RULE- Obey- "Line of coaptation"

Case 1

TTEER



35

Tricuspid TEER Procedure 4-day admission for "Pre-Hab"



TOE Mid oesophageal 3D TV MPR

7.6cm

3D Zoom

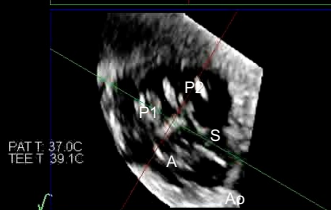
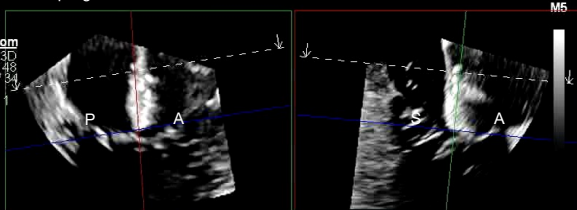
25/30

% 54/48

C 44/34

Pell

XRES

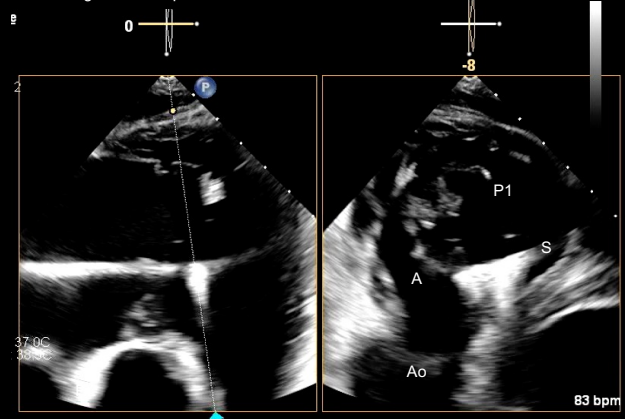


PAT T 37.0C

TEET 39.1C

89 bpm

TOE Right flex view xplane TV



37.0C

83 bpm

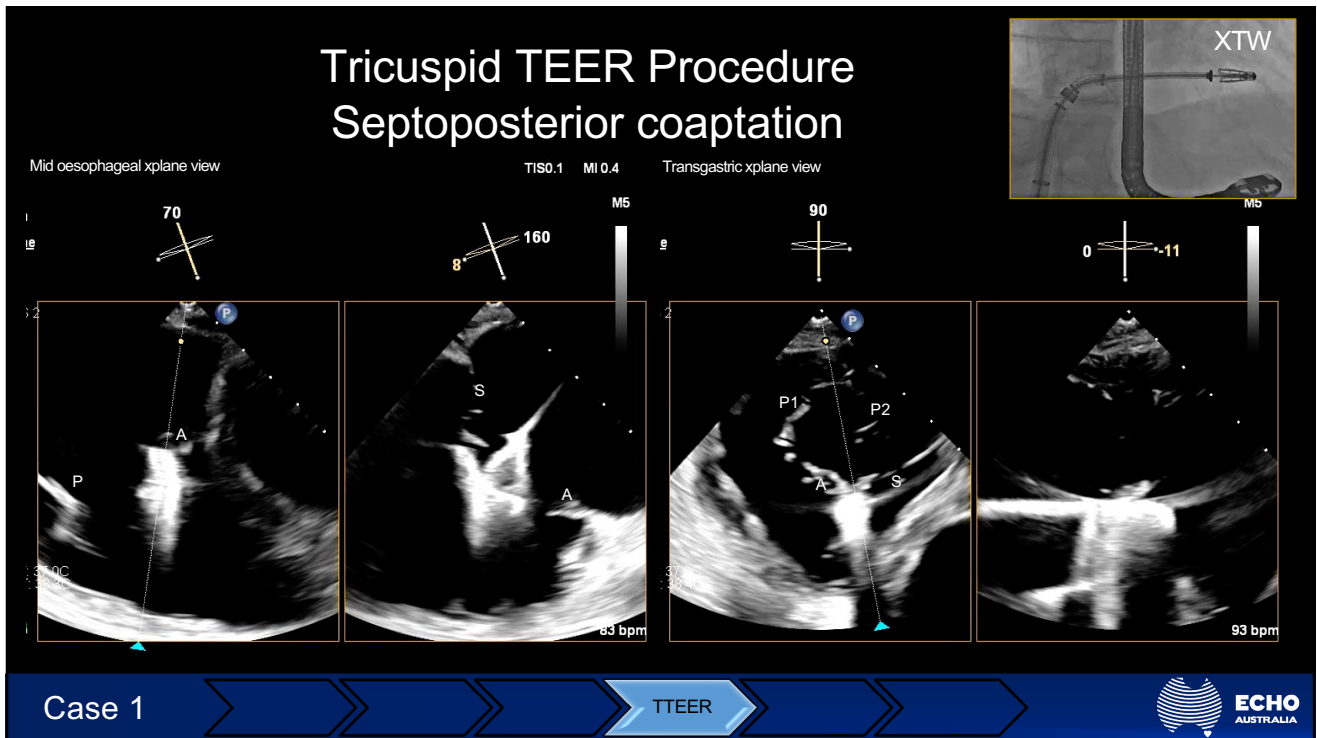
Image: Netter, Atlas of human anatomy

Case 1

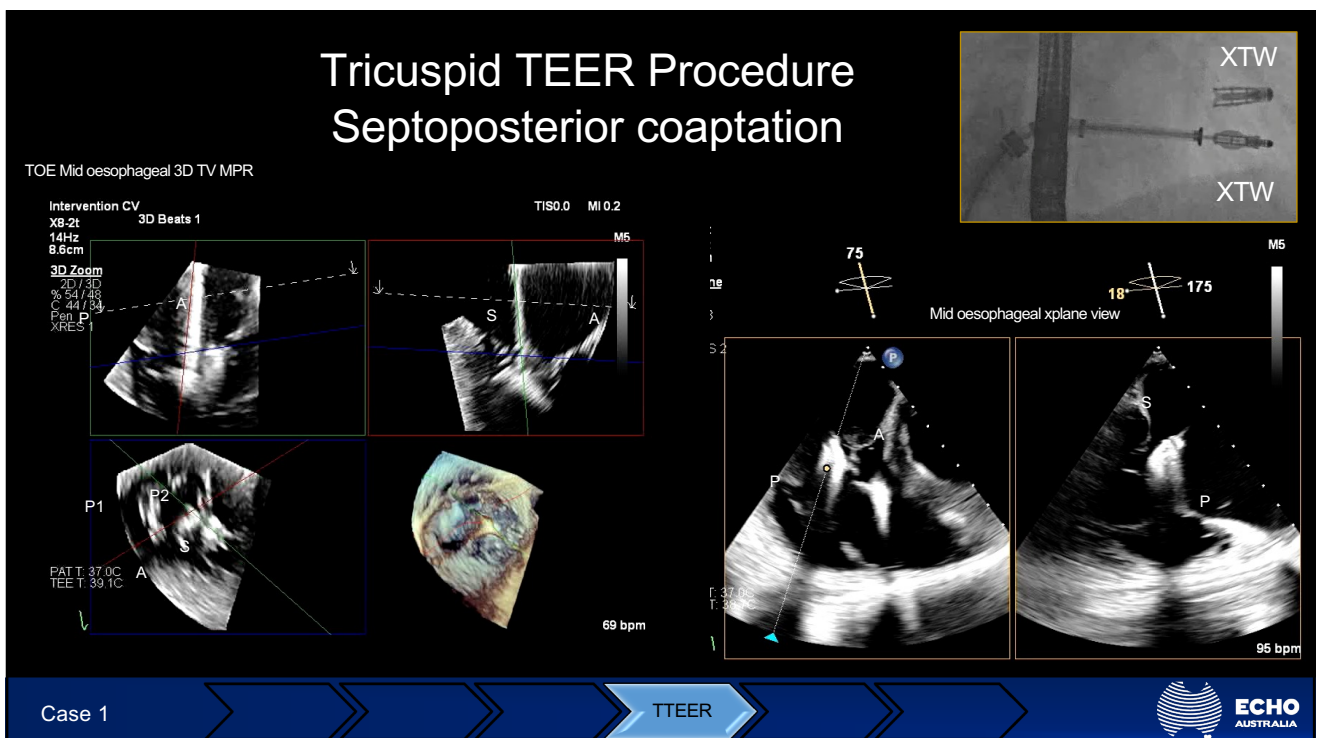
TTEER



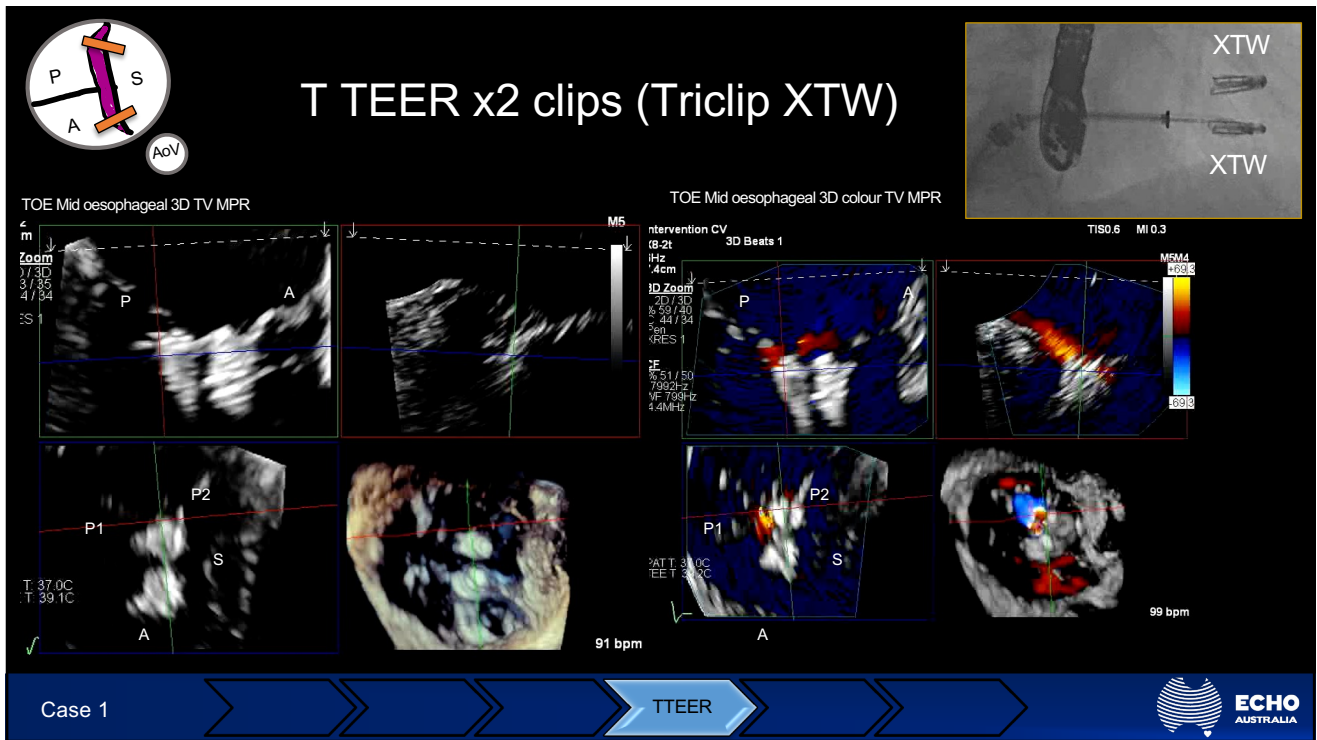
36



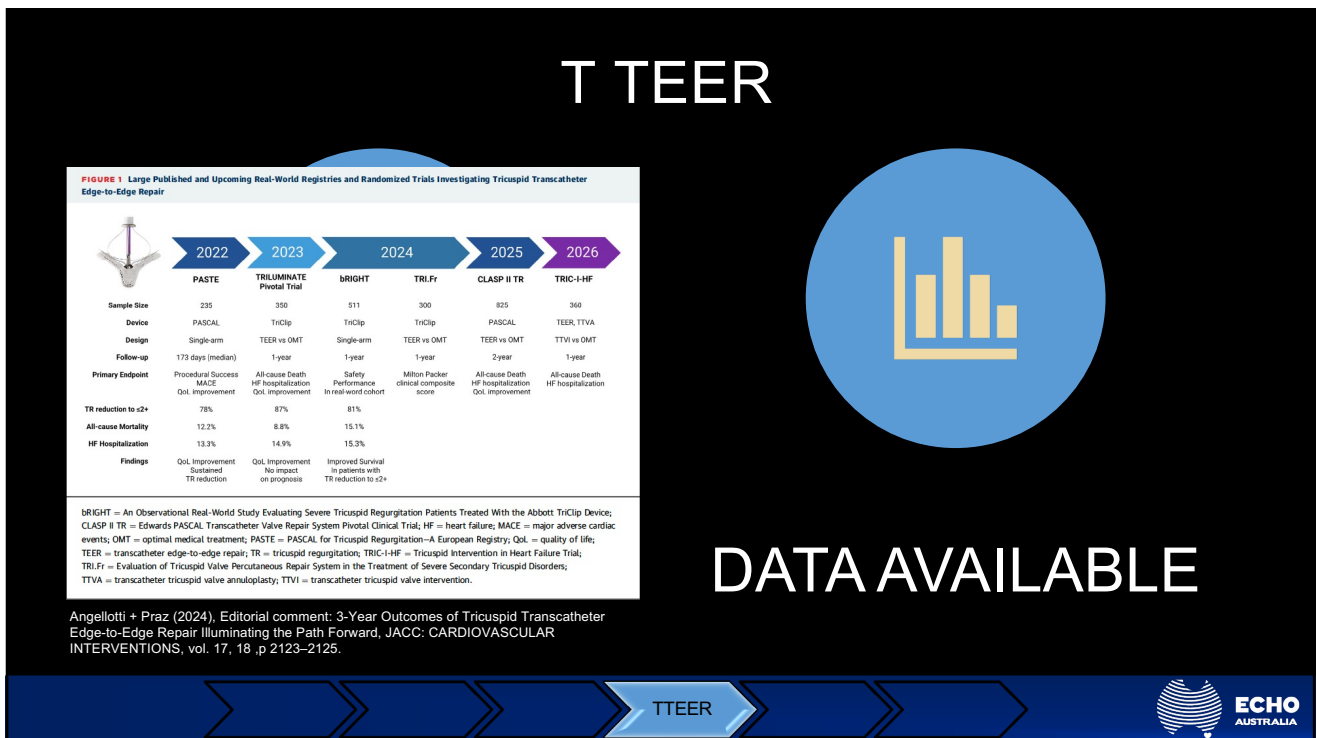
37



38



39



40

Transcatheter Valve Repair for Tricuspid Regurgitation
1-Year Results From a Large European Real-World Registry
PASTE
JACC VOL. 85, NO. 3, 2025
JANUARY 28, 2025:220-231

Real-World 1-Year Results of Tricuspid Edge-to-Edge Repair From the bRIGHT Study
JACC VOL. 84, NO. 7, 2024
AUGUST 13, 2024:607-616

Transcatheter Edge-to-Edge Repair for Severe Isolated Tricuspid Regurgitation
The Tri.Fr Randomized Clinical Trial
JAMA | Original Investigation
JAMA. 2025;333(2):124-132. doi:10.1001/jama.2024.2189
Published online November 27, 2024.

Percutaneous Edge-to-Edge Repair for Tricuspid Regurgitation
3-Year Outcomes From the TRILUMINATE Study
JACC: CARDIOVASCULAR INTERVENTIONS VOL. 17, NO. 18, 2024
SEPTEMBER 23, 2024:2113-2122

TTEER

ECHO AUSTRALIA

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Edwards PASCAL TrAnScatheter Valve RePair System in TR (CLASP TR)

1-Year Outcomes of Transcatheter Tricuspid Valve Repair
JACC VOL. 81, NO. 18, 2023
MAY 9, 2023:1766-1776

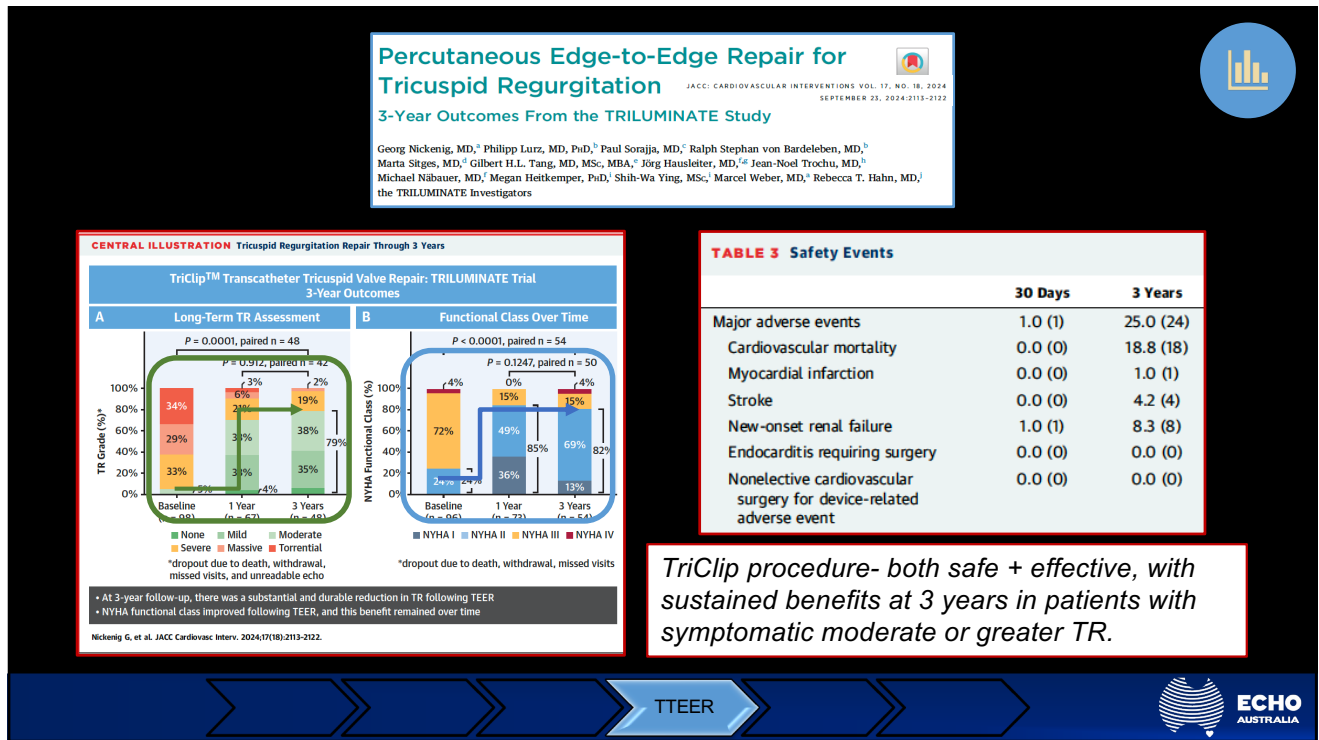
Single-arm, multicenter, prospective CLASP TR 2023 (Edwards PASCAL TrAnScatheter Valve RePair System in Tricuspid Regurgitation [CLASP TR] Early Feasibility Study)

- 1-year outcomes of the PASCAL transcatheter valve repair system to treat TR.
- CONCLUSIONS:** PASCAL system demonstrated low complication + high survival rates, with significant and sustained improvements in TR, functional status, and quality of life at 1 year.

TTEER

ECHO AUSTRALIA

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43



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Transcatheter Valve Repair for Tricuspid Regurgitation

1-Year Results From a Large European Real-World Registry

JACC VOL. 85, NO. 3, 2025
JANUARY 28, 2025:220-231

PASTE

Mirjam G. Wild, MD,^{1,2} Lukas Stolz, MD,^{3,4} Sebastian Roach, MD,^{5,6} Felix Rudolph, MD,⁷ Björn Goebel, MD,⁸ Benedikt Kötter, MD,⁹ Philipp von Stein, MD,¹⁰ Wolfgang Rothbauer, MD,¹¹ Tienash Rassaf, MD,¹² Harald Reucher, MD,¹³ Martin Kraus, MD,¹⁴ Mohammad Kassar, MD,¹⁵ Tobias Geisler, MD,¹⁶ Andreas Ruck, MD,¹⁷ Joao Ferreira-Martins, MD,¹⁸ Stefan Toggweiler, MD,¹⁹ Paula Sagneister, MD,²⁰ Dirk Westermann, MD, PhD,²¹ Thomas J. Stocker, MD,²² Ludwig T. Weckbach, MD,²³ Michael Nábauer, MD,²⁴ Magnus Settergren, MD, PhD,²⁵ Sam Dawkins, MD,²⁶ Tobias Köster, MD,²⁷ Fabien Praz, MD,²⁸ Marc Vorpalil, MD,²⁹ Mathias H. Konstantin, MD,³⁰ Peter Lüdike, MD,³¹ Mojum Kelller, MD,³² Christos Iliadis, MD,³³ David Kolhauer, MD,³⁴ Philip Lauten, MD,³⁵ Mohammed Geryk, MD,³⁶ Christian Besler, MD,³⁷ Philipp Lurz, MD,³⁸ Jörg Hauleiter, MD,³⁹ the PASTE Investigators^a

PASCAL system effectively treats severe TR in high-risk patients, sustained TR reduction + significant clinical improvements at 1-year.

JAMA | Original Investigation

JAMA. 2025;333(2):124-132. doi:10.1001/jama.2024.21899
Published online November 27, 2024.

Transcatheter Edge-to-Edge Repair for Severe Isolated Tricuspid Regurgitation

The Tri-Fr Randomized Clinical Trial

Erwan Donal, MD, PhD,¹ Julien Dreyfus, MD, PhD,² Guillaume Laurent, MD,³ Augustin Colone, MD, PhD,⁴ Pierre-Yves Leroux, MD,⁵ Anne Ganivet, MSc,⁶ Catherine Sportouch, MD, PhD,⁷ Yoan Lavie Badie, MD,⁸ Patricia Guerin, MD, PhD,⁹ Frédéric Rouleau, MD, PhD,¹⁰ Christelle Diakov, MD, PhD,¹¹ Jan van der Heyden, MD,¹² Stéphane Lafitte, MD, PhD,¹³ Jean-François Obadia, MD, PhD,¹⁴ Mohammed Nejari, MD,¹⁵ Nicole Karam, MD, PhD,¹⁶ Anne Bernard, MD, PhD,¹⁷ Antoinette Neylon, MD,¹⁸ Romain Pierrard, MD,¹⁹ Didier Tchetché, MD,²⁰ Said Ghosline, MD,²¹ Gregory Ducrocq, MD, PhD,²² Thiziri Si Moussi, MD,²³ Antoine Jau, MD,²⁴ Marcel Peltier, MD, PhD,²⁵ Bernard Cosyns, MD, PhD,²⁶ Yvan Le Dolley, MD,²⁷ Gilbert Habib, MD, PhD,²⁸ Vincent Auffret, MD, PhD,²⁹ Florent Le Ver, MD, PhD,³⁰ François Picard, MD,³¹ Nicolas Pirou, MD,³² Thierry Laperche, MD,³³ Elena Galli, MD, PhD,³⁴ Sabina Istratoae, MD, PhD,³⁵ Jérôme Jouan, MD, PhD,³⁶ Guillaume Bonnet, MD, PhD,³⁷ Pascal de Groot, MD, PhD,³⁸ Amedeo Anselmi, MD, PhD,³⁹ Jean-Noël Trochu, MD, PhD,⁴⁰ Emmanuel Ogier, MD, PhD,⁴¹ for the Tri-Fr Investigators

T-TEER reduces TR severity + improves composite score driven by improved patient-reported outcome measures in patients with severe, symptomatic TR.

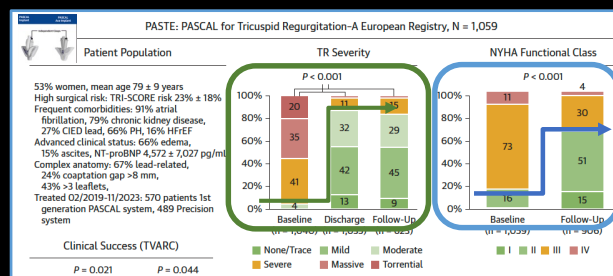


Figure 2. KCCQ Summary Score Over Time and Magnitude of Reduction in Tricuspid Regurgitation

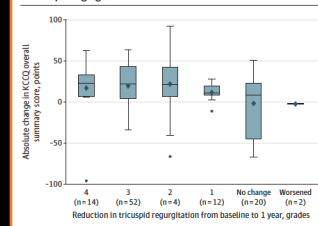
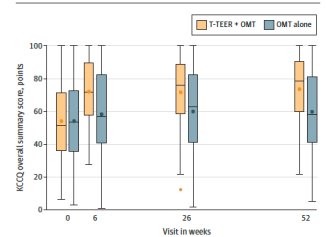


Figure 3. Change in KCCQ Overall Summary Score Over Time



TTEER



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TRIGISTRY

Prognostic Implications of Residual Tricuspid Regurgitation Grading After Transcatheter Tricuspid Valve Repair

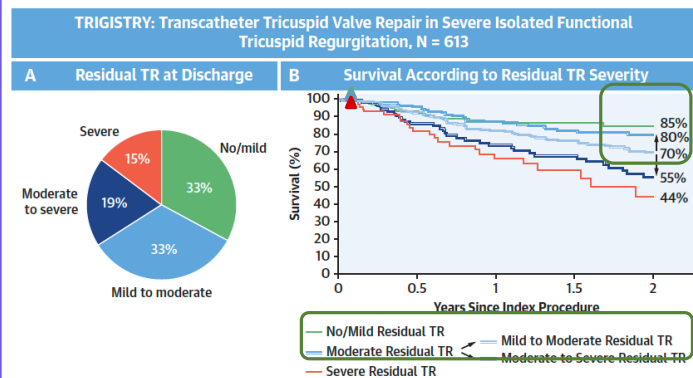
Julien Dreyfus, MD, PhD,¹ Maurizio Taramasso, MD, PhD,² Karl-Patrick Kneissl, MD,³ Hazem Omer, MD,⁴ Christos Iliadis, MD,⁵ Giulio Russo, MD,⁶ Marcel Weber, MD,⁷ Luis Nombela-Panero, MD, PhD,⁸ Rodrigo Esteves Loureiro, MD, PhD,⁹ Jörg Hauleiter, MD,¹⁰ Azeem Latif, MD,¹¹ Lukas Stolz, MD,¹² Fabien Praz, MD,¹³ Stephan Windecker, MD,¹⁴ Jose Luis Zamorano, MD,¹⁵ Ralph Stephan von Bardeleben, MD,¹⁶ Gilbert H.L. Tang, MD, MSc, MBA,¹⁷ Rebecca Hahn, MD,¹⁸ Edith Lubos, MD,¹⁹ John Webb, MD,²⁰ Joachim Schofer, MD,²¹ Neil Fam, MD,²² Alexander Lauten, MD,²³ Giovanni Pedrazzini, MD,²⁴ Josep Rodés-Cabau, MD, PhD,²⁵ Mohammed Nejari, MD,²⁶ Luigi Radano, MD, PhD,²⁷ Hannes Alessandrini, MD,²⁸ Dominique Himbert, MD,²⁹ Horst Sievert, MD,³⁰ Kerstin Playda, MD, MSc,^{31,32} Erwan Donal, MD, PhD,³³ Thomas Modine, MD, PhD,³⁴ Georg Nickenig, MD,³⁵ Roman Pfister, MD,³⁶ Volker Rudolph, MD,³⁷ Jordan Bernick, MSc,³⁸ George A. Wells, MSc, PhD,³⁹ Jeroen Bax, MD, PhD,⁴⁰ Philipp Lurz, MD, PhD,⁴¹ Maurice Enriquez-Sarano, MD, PhD,⁴² Francesco Maisano, MD,⁴³ David Meslekin-Zetoun, MD, PhD,⁴⁴ the TRIGISTRY Investigators

JACC Cardiovascular Interventions VOL. 17, NO. 12, 2024
JUNE 24, 2024:1485-1495

Observational retrospective registry

- 613 patients
- Overall- using 4 grade TR severity classification:
- Achieve mild to moderate or less TR

CENTRAL ILLUSTRATION Impact on Mortality of Residual Tricuspid Regurgitation Grade After Transcatheter Tricuspid Valve Repair



- Survival at 2 years following TEER worse in patients with moderate to severe compared to mild to moderate residual TR ($P = 0.006$) but not different between no/mild and mild to moderate ($P = 0.67$) and between moderate to severe and residual TR ($P = 0.96$)
- Prediction of survival is improved using a more granular 4-grade TR classification (ie, dividing moderate residual TR into 2 subgroups)
- These results highlight the importance of achieving mild to moderate or less residual TR during transcatheter tricuspid valve repair

Dreyfus J, et al. J Am Coll Cardiol Intv. 2024;17(12):1485-1495.

TTEER



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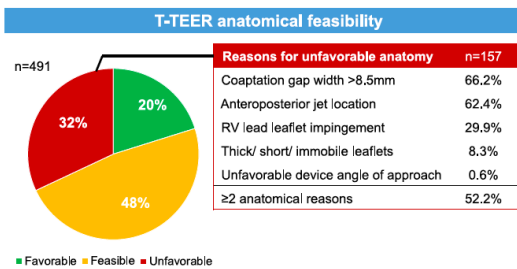
Anatomical Criteria of Feasibility for Transcatheter Tricuspid Edge-to-Edge Repair vs Tricuspid Valve Replacement

TABLE 1 Anatomical Criteria of Feasibility for Tricuspid Transcatheter Edge-to-Edge Repair

Factors	Favorable Anatomy	Feasible Anatomy	Unfavorable Anatomy
Coaptation gap width, mm	≤7	>7 but ≤8.5	>8.5
TR jet location	Central/anteroseptal coaptation line	Posteroseptal coaptation line	Anteroposterior coaptation line
Leaflet morphology	3-leaflet	Non-3-leaflet	
CIED RV lead	—	Incidental	Leaflet impingement
Leaflet degeneration	—	—	Thick/short/immobile/perforated leaflet
Device angle approach	—	—	Unfavorable

CIED = cardiac implantable electronic device; RV = right ventricular; TR = tricuspid regurgitation.

FIGURE 3 Prevalence of Anatomical Feasibility for T-TEER



Tanaka et al. (2024) Eligibility for T-TEER and TTVR in Patients With TR, JACC : CARDIOVASCULAR INTERVENTIONS vol. 17 , no. 23 , p. 2732– 2744

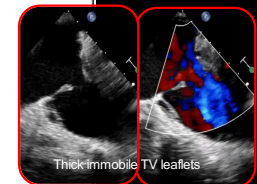
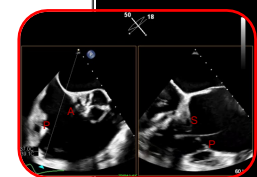
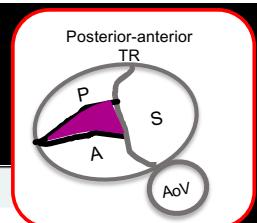
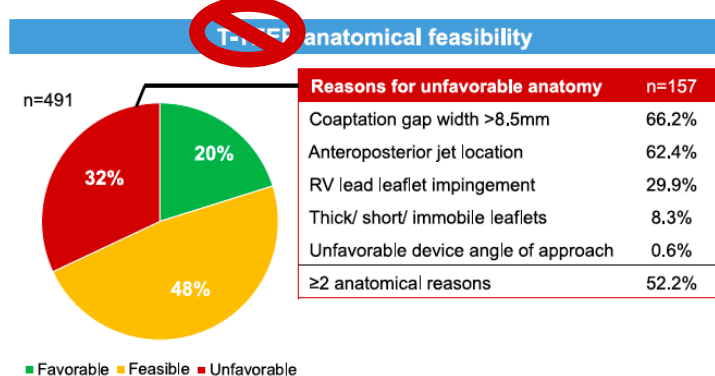
TTVR



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Anatomical Criteria of Feasibility for Transcatheter Tricuspid Edge-to-Edge Repair vs Tricuspid Valve Replacement

FIGURE 3 Prevalence of Anatomical Feasibility for T-TEER



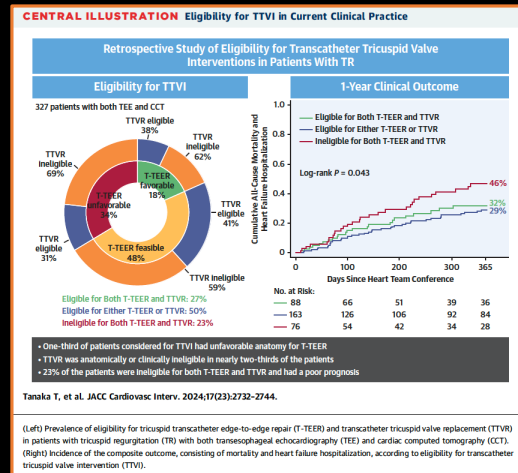
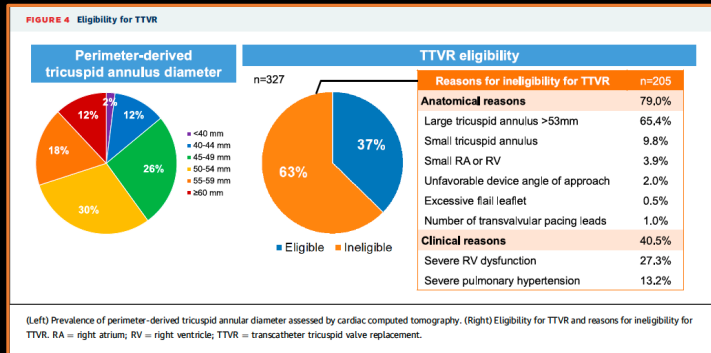
Tanaka et al. (2024) Eligibility for T-TEER and TTVR in Patients With TR, JACC : CARDIOVASCULAR INTERVENTIONS vol. 17 , no. 23 , p. 2732– 2744

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Eligibility TTVR or NOT



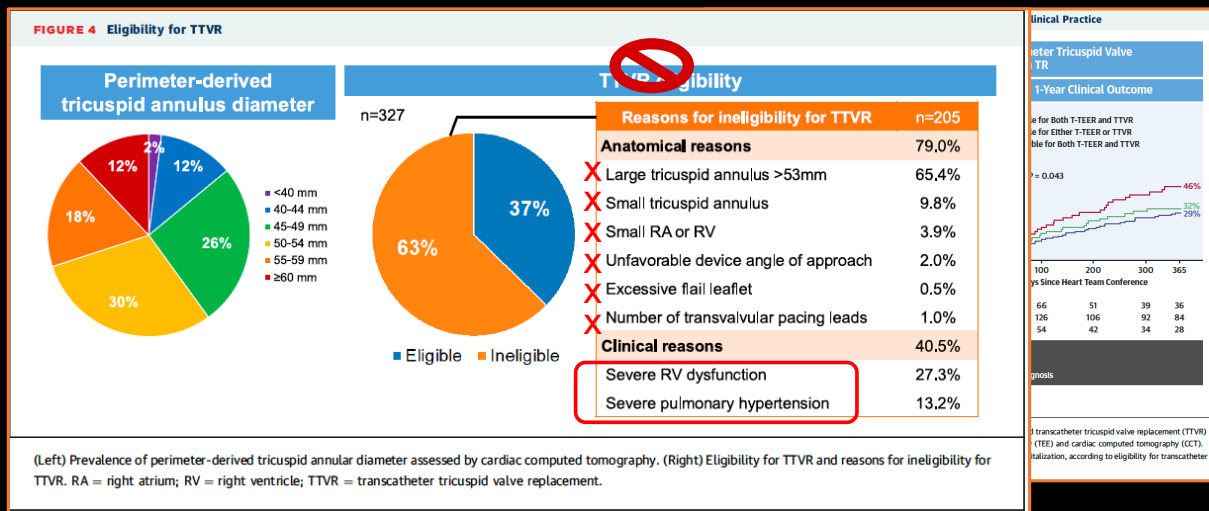
Tanaka et al. (2024) Eligibility for T-TEER and TTVR in Patients With TR. JACC : CARDIOVASCULAR INTERVENTIONS vol. 17 , no. 23 , p. 2732 – 2744

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Eligibility TTVR or NOT



Tanaka et al. (2024) Eligibility for T-TEER and TTVR in Patients With TR. JACC : CARDIOVASCULAR INTERVENTIONS vol. 17 , no. 23 , p. 2732 – 2744

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Transcatheter Tricuspid Valve Replacement

Jörg Hausleiter, MD,^{a,b,h,*} Lukas Stolz, MD,^{a,b,h,*} Philipp Lurz, MD,^c Volker Rudolph, MD,^d Rebecca Hahn, MD,^e Rodrigo Estévez-Loureiro, MD,^{f,g} Charles Davidson, MD,^h Firas Zahr, MD,ⁱ Susheel Kodali, MD,^e Raj Makkar, MD,^j Anson Cheung, MD,^k Renato D. Lopes, MD, PhD,^{l,m} Francesco Maisano, MD,ⁿ Neil Fam, MD,^o Azeem Latib, MD,^p Stephan Windecker, MD,^q Fabien Praz, MD^q

Device	Study Name (Identifier)	N (Study Size)	Age, y	Female, %	STS-PROM	NYHA Functional Class III/IV	Renal Insufficiency, %	AF, %	PPM/ICD, %	TR > Severe, %	TR Etiology, %
EVOQUE	First-in-man study ¹ (NA)	27 (7)	77 ± 8	89	8.6 ± 5.5	89	56	85	33	54	81
	Compassionate use ² (NA)	38 (8)	77 ± 12	74	7.9 ± 6.5 ^a	NA	NA	NA	NA	89	Functional 70 Degenerative 11 Mixed 19 NA
	TRISCEND (NCT04221493) 1-y report ³	176 (29)	79 ± 7	71%	7.4 ± 5.8 (MV repair) 10.0 ± 5.3 (MV replacement)	75	59	92	32	22	43
	2-y report ⁴	208 (29)	79 ± 7	71%	10.0 ± 5.4 (MV replacement)	73	62	90	33	20	48
	TRISCEND IF (only EVOQUE arm is reported) (NCT04482062)	400 (45)	79.2	75.5	9.7% (MV replacement)	70.3	54.5	93	38	19.3	55
											Primary 10% Secondary 68% Mixed 14% CIED 3% Indeterminate 5% Functional/mixed 84.1% Degenerative 8.2% Other 7.7%
CardioValve	Compassionate use ⁵ (NA)	20 (9)	79 ± 6	50	6.2 ± 3.9	60	NA	NA	NA	90	Functional 100
LUX-Valve Plus	First-in-man study ⁶ (NA)	10 (1)	70	70	EuroScore II 11 ± 1	100	NA	40	10	NA	100
	TRAVEL II (NCT05194423)	96 (15)	71 ± 8.8	71.9	9.1 ± 4.1 (MV replacement)	100	NA	83.5	17.5	8.9	61.4
											Secondary 86 Primary 14
Topaz	Early compassionate use and special access experience ⁷ (NA)	11 (NA)	NA	NA	NA	100	NA	NA	NA	NA	54
											NA

TTVR



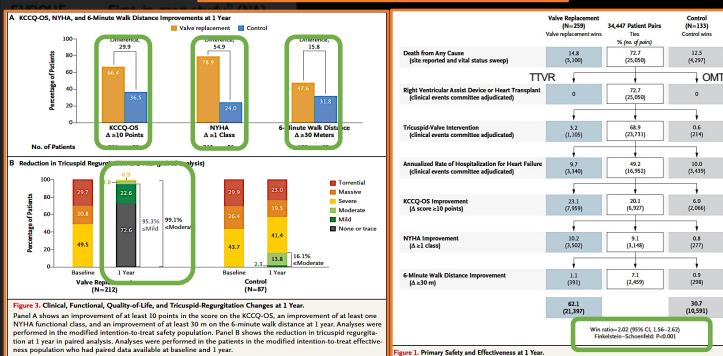
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The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JANUARY 9, 2025 VOL. 382 NO. 2

Transcatheter Valve Replacement in Severe Tricuspid Regurgitation

R.T. Hahn, R. Makkar, V.H. Thourani, M. Mahabadi, S.P. Sharma, C. Haefliger, C.J. Davidson, A. Narang, B. O'Neill, J. Lee, P. Yadav, F. Zahr, S. Chadderdon, M. Elend, S. Pitaru, R. Smith, M. Szemply, B. Whisenand, N.K. Selvaraj, S. Garcia, T. Stewart-Dehnert, H. Thiele, R. Eipperman, K. Kaulgiani, D.S. Lim, D. Fowler, S. Kapadia, S.C. Harb, P.A. Grayburn, A. Sannino, M.J. Meek, M.R. Leon, P. Lurz, and S.K. Kodali, for the TRISCEND II Trial Investigators¹



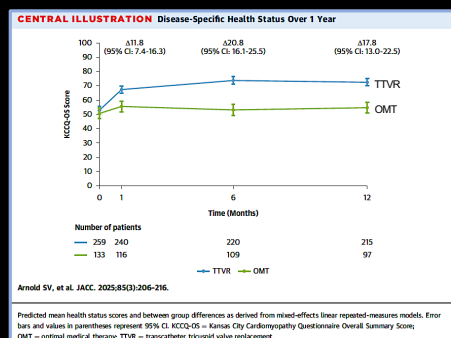
Treatment of patients with symptomatic + severe or greater TR with TTVR+OMT resulted in substantial improvement in symptoms, function, + quality of life. Benefits evident 30 days after TTVR → increase to 6 months → durable through 1 year.

Quality of Life After Transcatheter Tricuspid Valve Replacement

1-Year Results From TRISCEND II Pivotal Trial

JACC VOL. 85, NO. 3, 2025
JANUARY 28, 2025:206-216

Suzanne V. Arnold, MD, MHA,^a Rebecca T. Hahn, MD,^b Vinod H. Thourani, MD,^c Raj Makkar, MD,^d Moody Makkar, MD,^e Rahul P. Sharma, MD,^f Christine Haefele, MD,^g Charles J. Davidson, MD,^h Akhil Narang, MD,ⁱ Brian O'Neill, MD,^j James Lee, MD,^k Pradeep Yadav, MD,^l Firas Zahr, MD,^m Scott Chadderdon, MD,ⁿ Macram Elend, MD,^o Serin Pitaru, MD, PhD,^p Robert Smith, MD,^q Molly Swerlip, MD,^r Brian Whisenand, MD,^s Nishant Sekaran, MD,^t Santiago Garcia, MD,^u Terri Stewart-Dehnert, MD,^v Paul A. Grayburn, MD,^w Anna Sannino, MD, PhD,^x Clayton Snyder, MPH,^y Yinan Zhang, MS,^z Michael J. Mack, MD,^{aa} Martin R. Leon, MD,^{ab} Philipp Lurz, MD, PhD,^{ac} Susheel Kodali, MD,^{ad} David J. Cohen, MD, MSc,^{ae} for the TRISCEND II Pivotal Trial Investigators



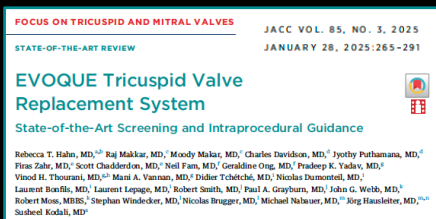
TRISCEND II Pivotal Trial

TTVR



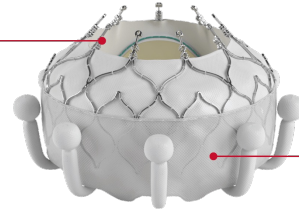
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EVOQUE TTVR



Designed for anatomical compatibility

Self-expanding, shape memory nitinol frame designed to conform to native valve anatomy

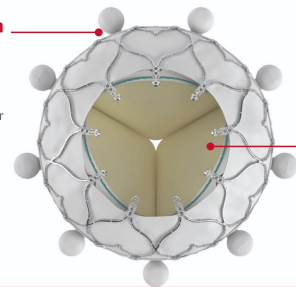


Designed to seal within the native tricuspid annulus

Intra-annular sealing skirt and frame

Designed for a secure implantation

Nine ventricular anchors engage leaflets, subvalvular anatomy and the annulus enabling a secure transcatheter placement



ThermaFix tissue technology*

Same bovine pericardial tissue as Edwards SAPIEN and PERIMOUNT valves†

TTVR

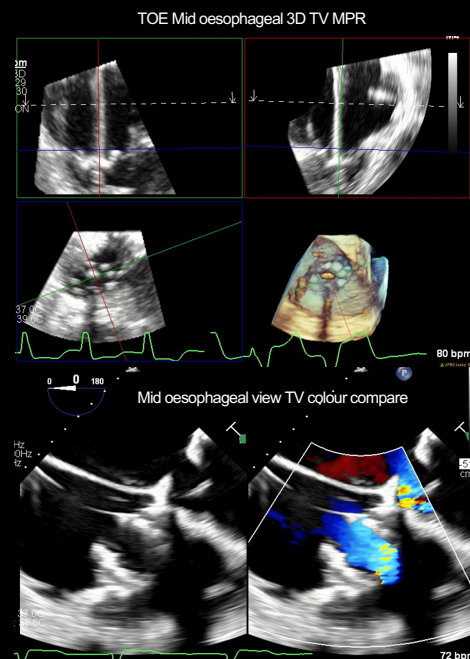


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EVOQUE TTVR (FDA USA + Europe)

- TTVR superior to OMT
- Improvements in QOL
- Event curves for mortality + HF hospitalization favoured device
- Further follow-up needed to confirm
- TTVR associated with significant risk of new pacemakers + severe bleeding.

Evoque TTVR images courtesy Dr. S.Tomlinson.

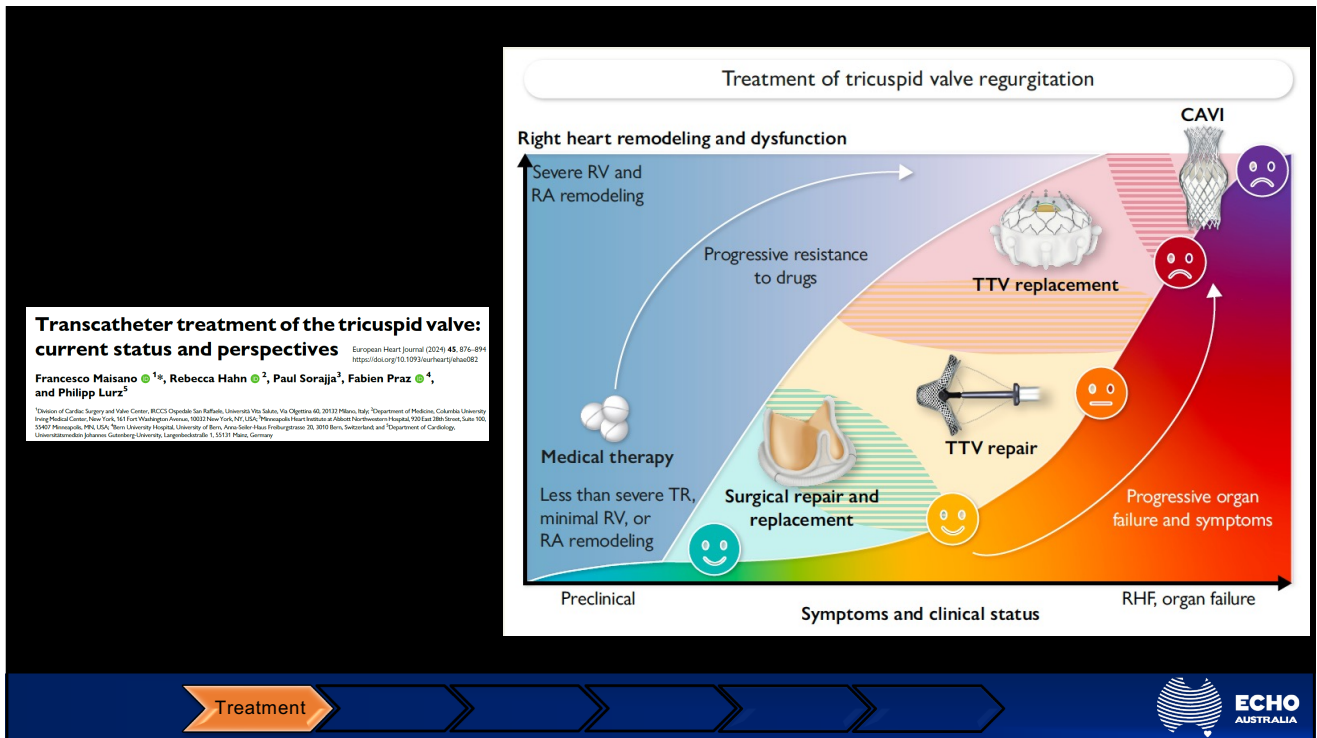


Case 2

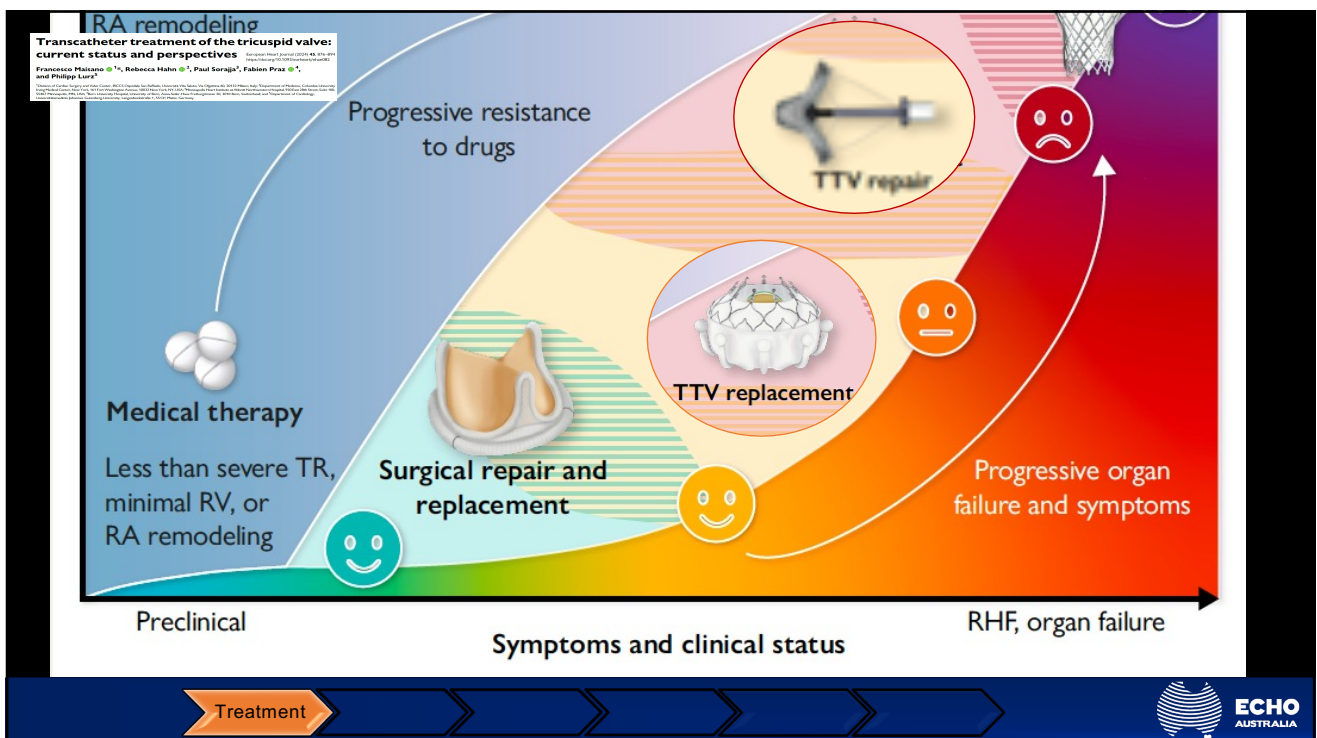
TTVR



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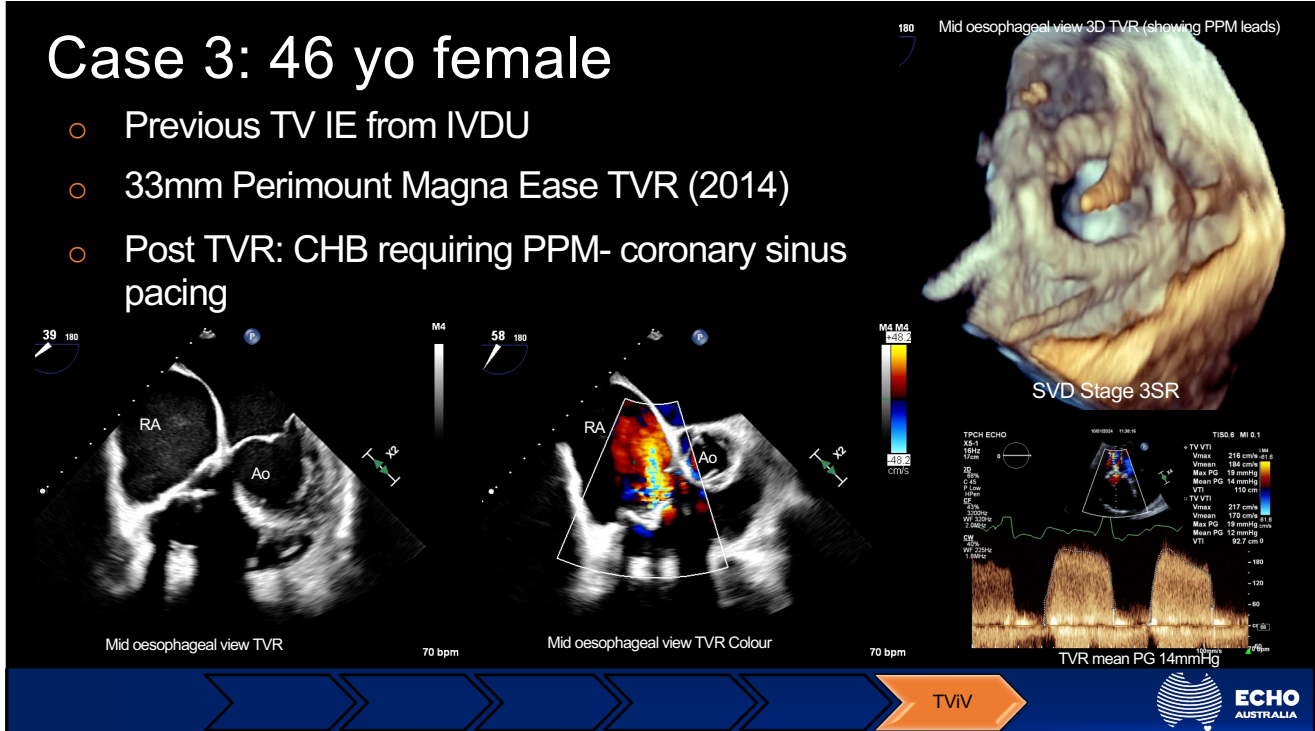
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56

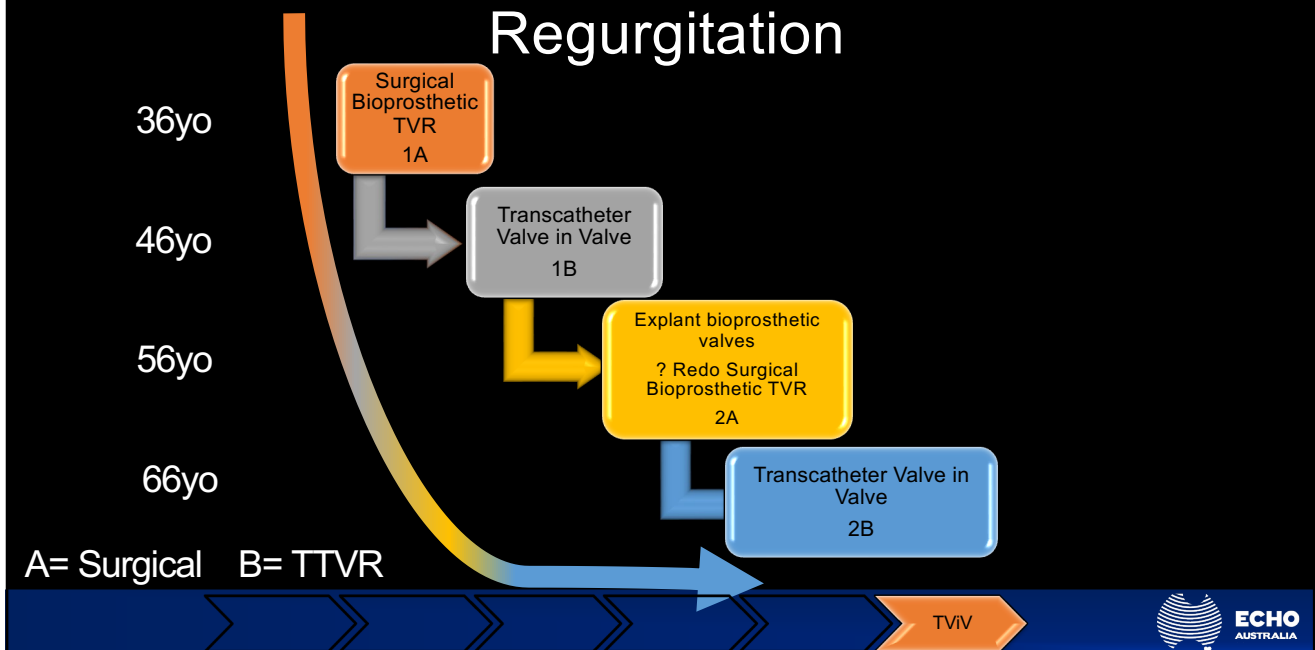
Case 3: 46 yo female

- Previous TV IE from IVDU
- 33mm Perimount Magna Ease TVR (2014)
- Post TVR: CHB requiring PPM- coronary sinus pacing

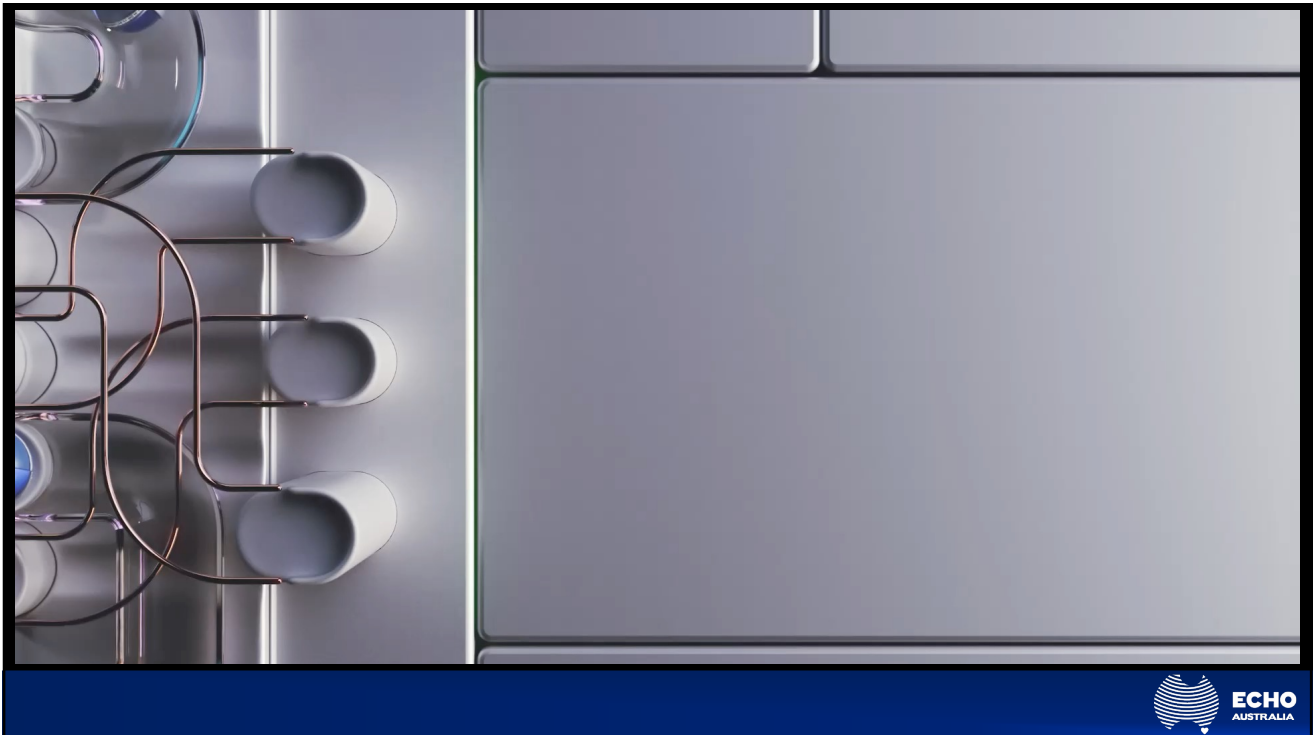


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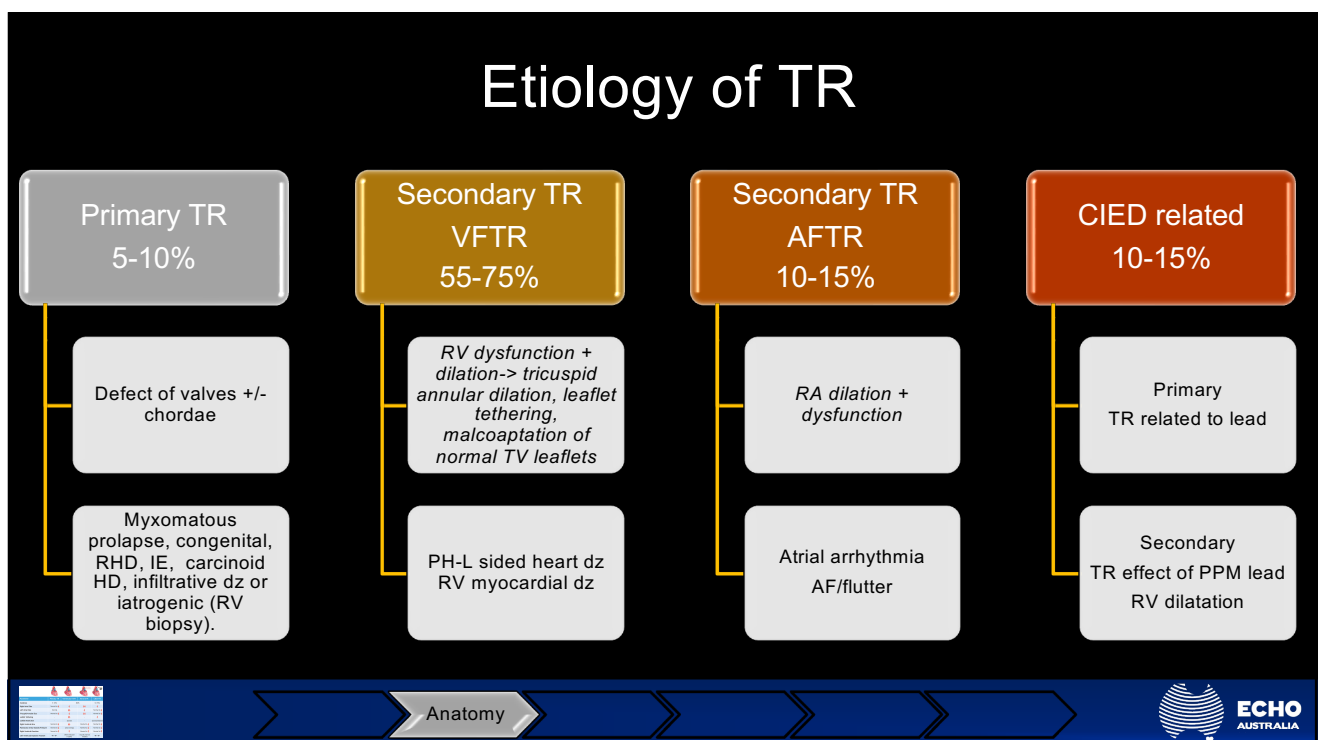
Lifetime Management of Severe Tricuspid Regurgitation



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