Differenzierte interventionelle Therapie der AV-Klappeninsuffizienz – ab wann behandeln, edge-to-edge versus Transkatheter-Ersatz

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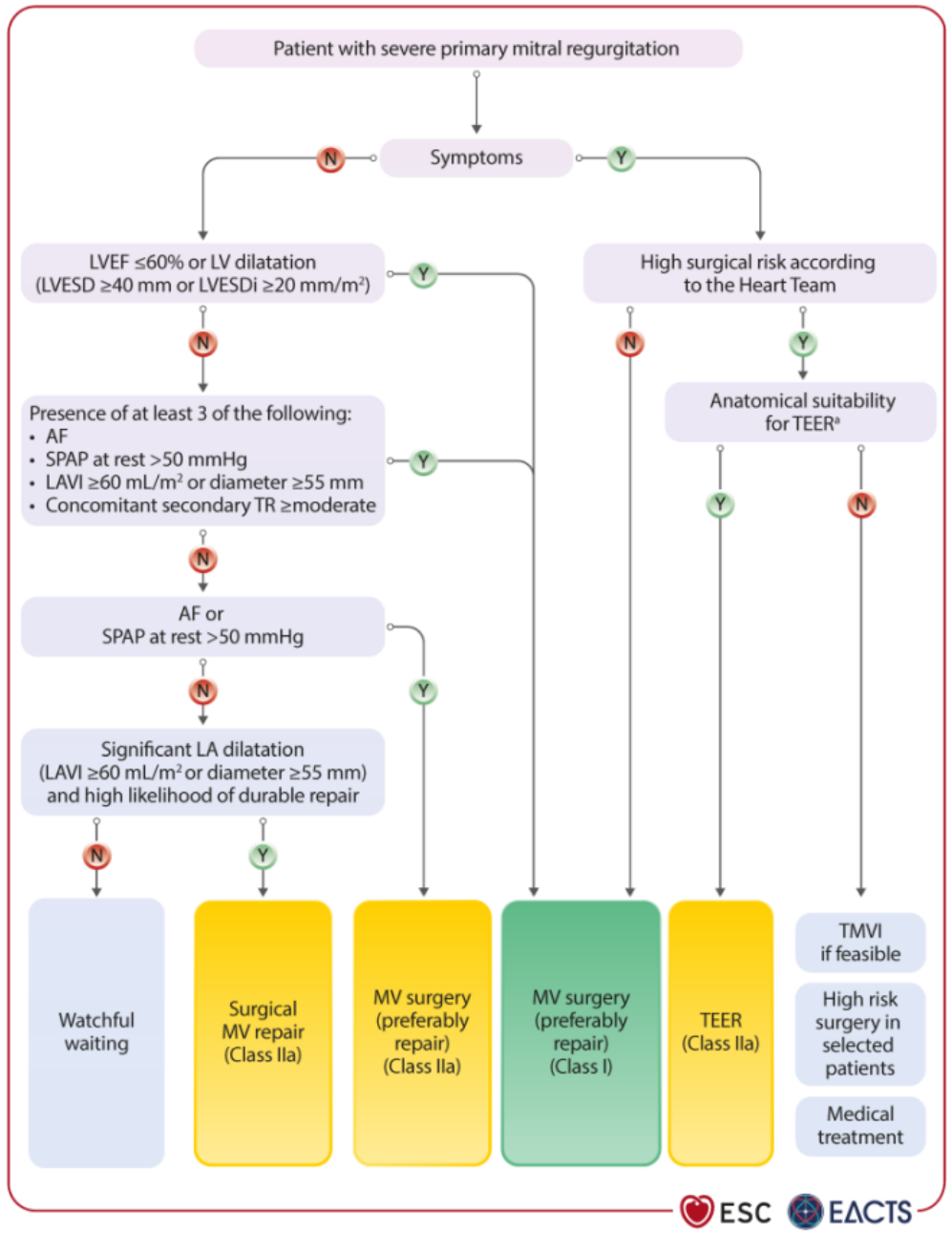
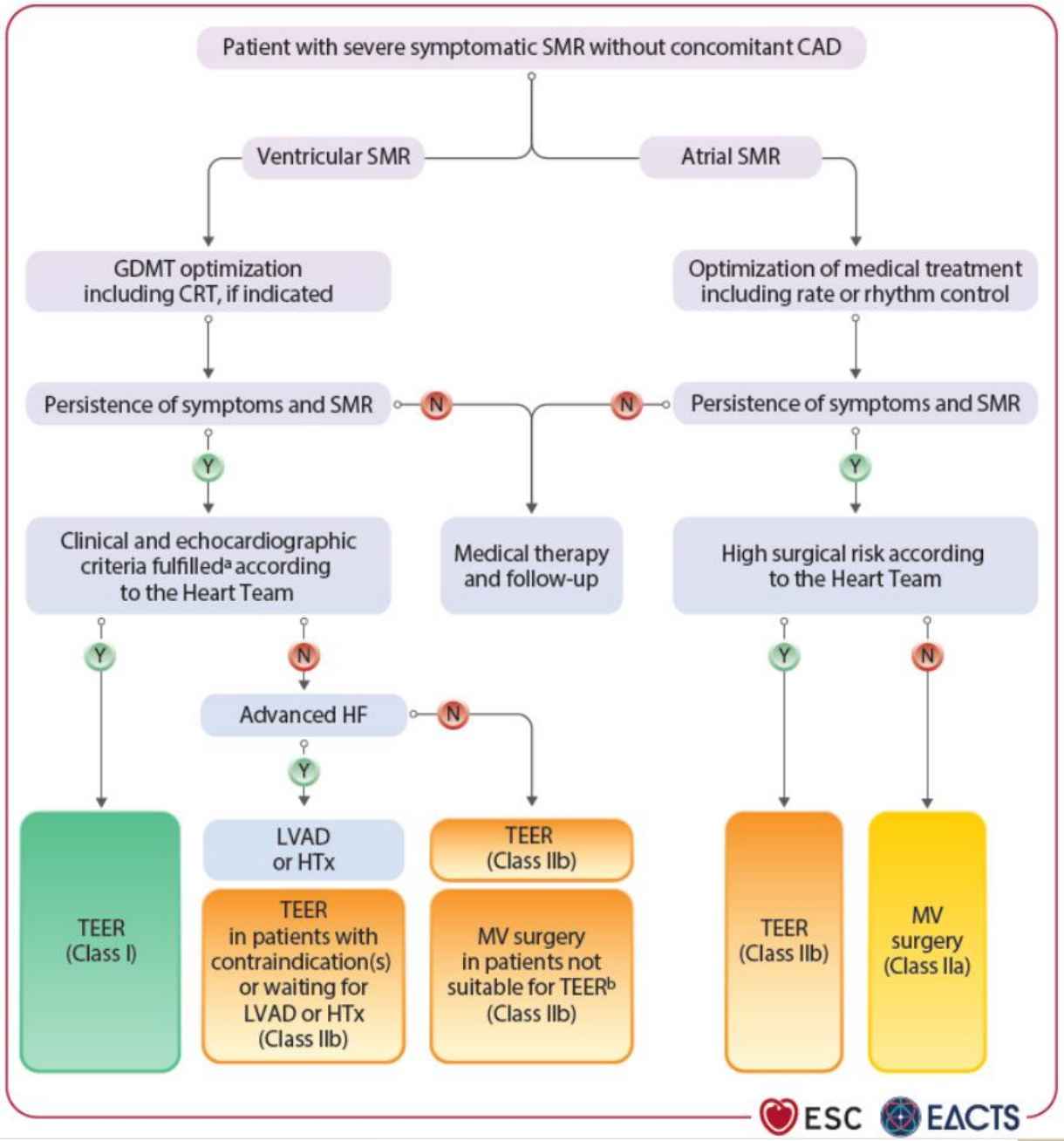
Universitätsklinikum Tübingen

Interessenskonflikte bezogen auf den Vortrag

Firmenname	***Zusammenhang***
Abbott	*Honorar: Vorträge*
Boston Scientific	*Reisekostenerstattung*
Edwards Lifescience	*Honorar: Vorträge, Beratung, Reisekostenerstattung*
Medtronic	*Honorar: Vorträge, Reisekostenerstattung*

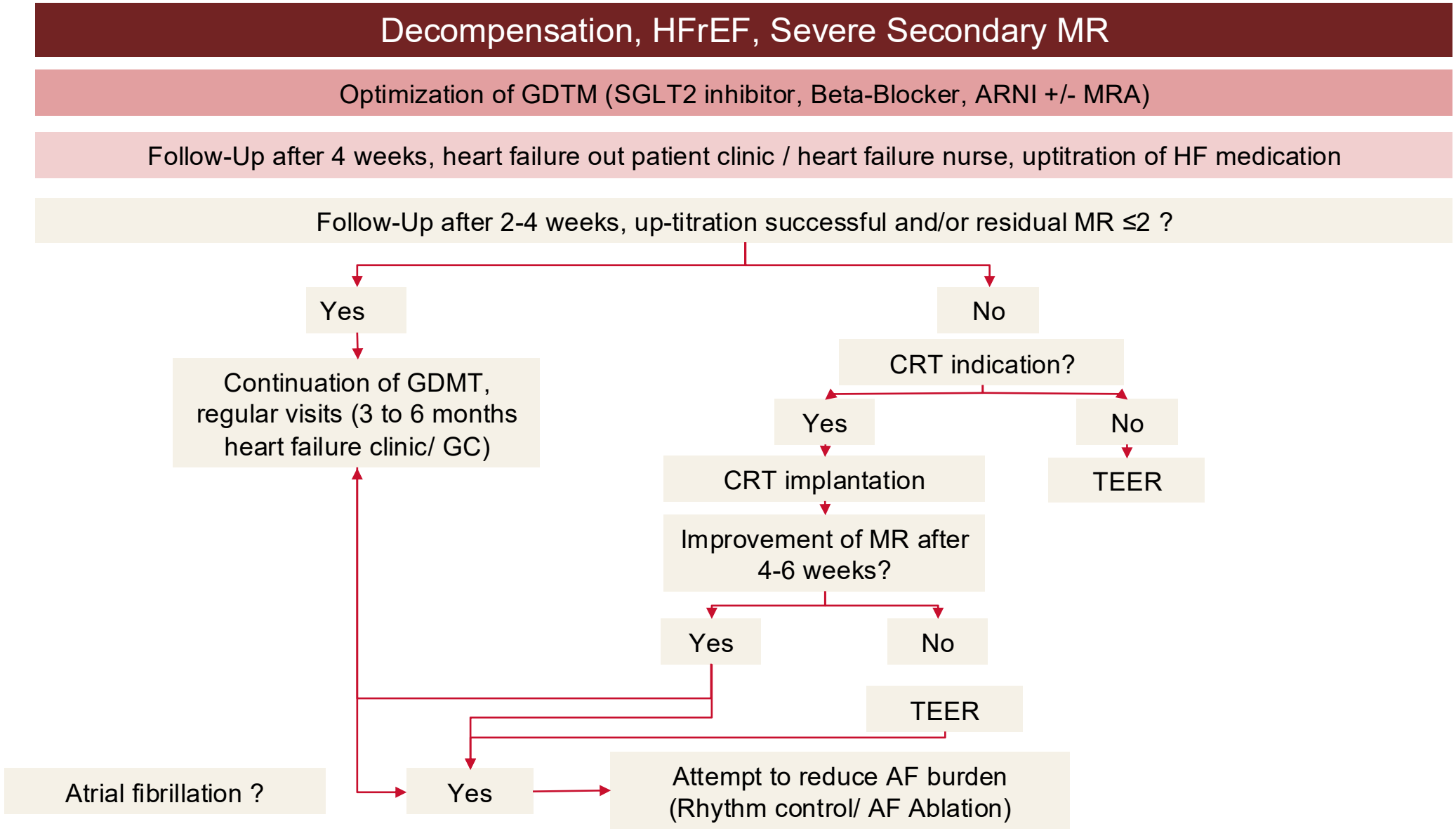


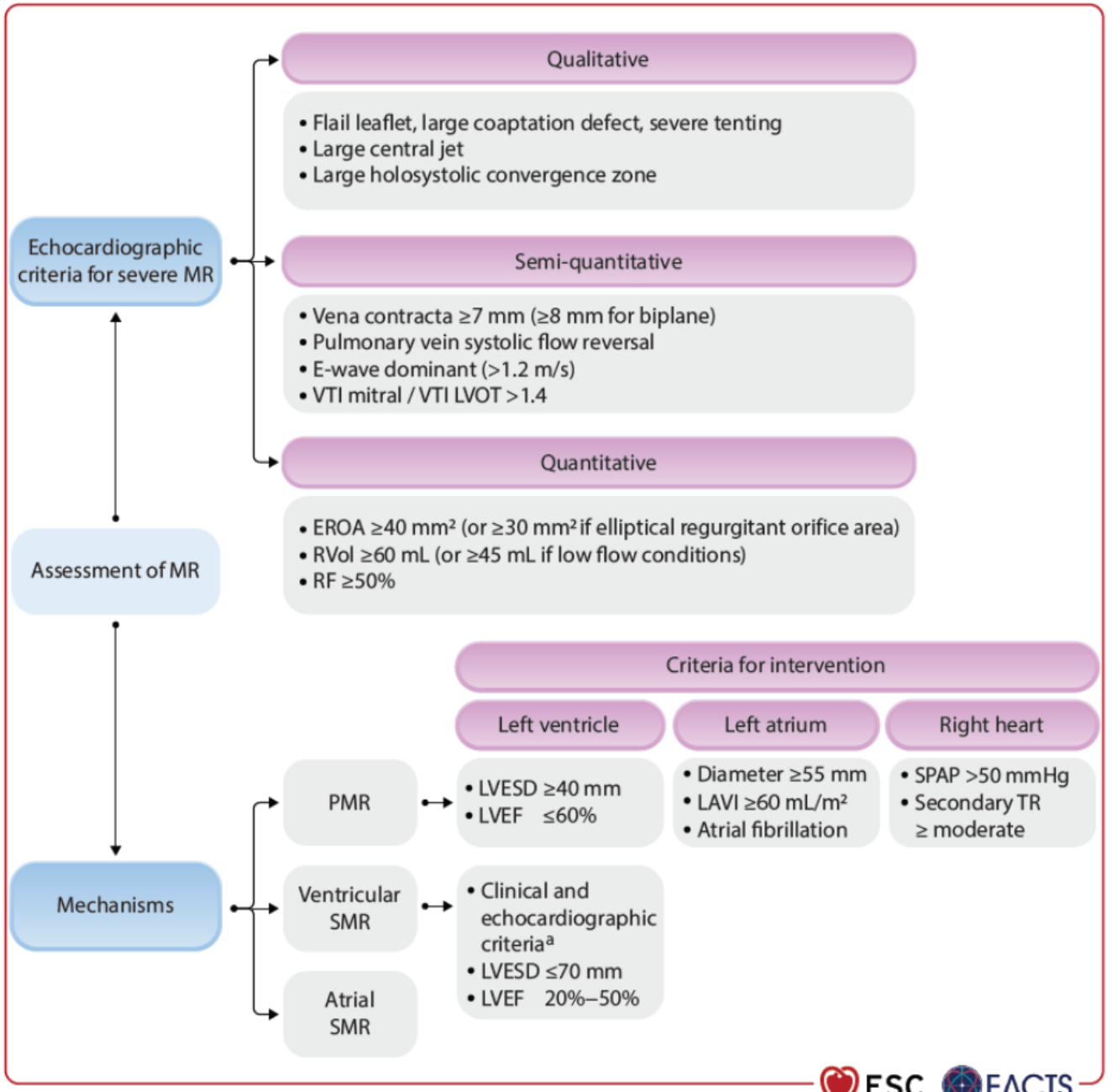


ESC Guidelines for the management of valvular heart disease
(European Heart Journal; 2025 – doi: 10.1093/eurheartj/ehaf194)

Recommendations	Class	Level
Severe ventricular secondary mitral regurgitation without concomitant coronary artery disease		
TEER is recommended to reduce HF hospitalizations and improve quality of life in haemodynamically stable, symptomatic patients with impaired LVEF (<50%) and persistent severe ventricular SMR, despite optimized GDMT and CRT (if indicated), fulfilling specific clinical and echocardiographic criteria.	I	A
TEER may be considered for symptom improvement in selected symptomatic patients with severe ventricular SMR not fulfilling the specific clinical and echocardiographic criteria, after careful evaluation of LVAD or HTx.	IIb	B
MV surgery may be considered in symptomatic patients with severe ventricular SMR without advanced HF who are not suitable for TEER.	IIb	C

Tübinger Algorithmus, sekundäre MI





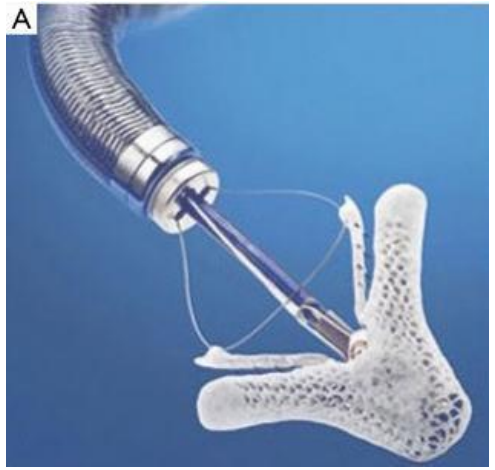
ESC Guidelines for the management of valvular heart disease
(European Heart Journal; 2025 – doi: 10.1093/eurheartj/ehaf194)

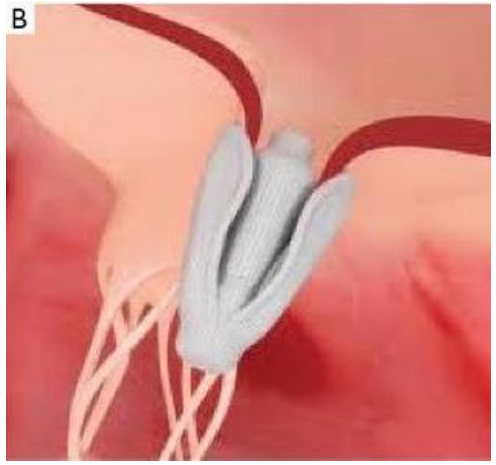
Clinical and echocardiographic criteria predicting outcome improvement in patients with severe ventricular secondary mitral regurgitation undergoing mitral transcatheter edge-to-edge repair

Anatomy deemed suitable for M-TEER
NYHA class ≥II
LVEF 20%–50%
LVESD ≤70 mm
At least one HF hospitalization within the previous year or increased natriuretic peptide levels (BNP ≥300 pg/mL or NT-proBNP ≥1000 pg/mL)
SPAP ≤70 mmHg
No severe RV dysfunction
No Stage D or advanced HF
No CAD requiring revascularization
No severe AV and/or TV disease
No hypertrophic, restrictive, or infiltrative cardiomyopathies

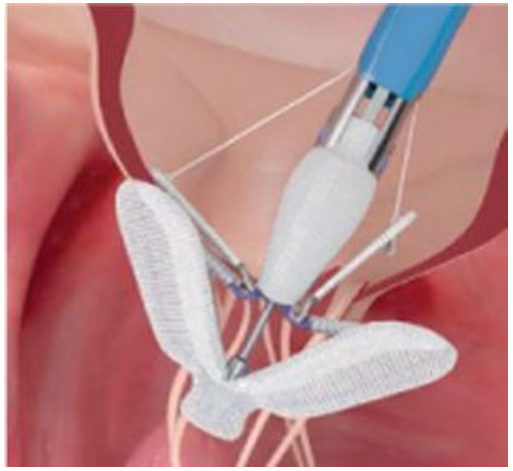
Perkutane Mitralklappenrekonstruktion – verschiedene Optionen

Edge-to-Edge MitraClip® (Abbot)

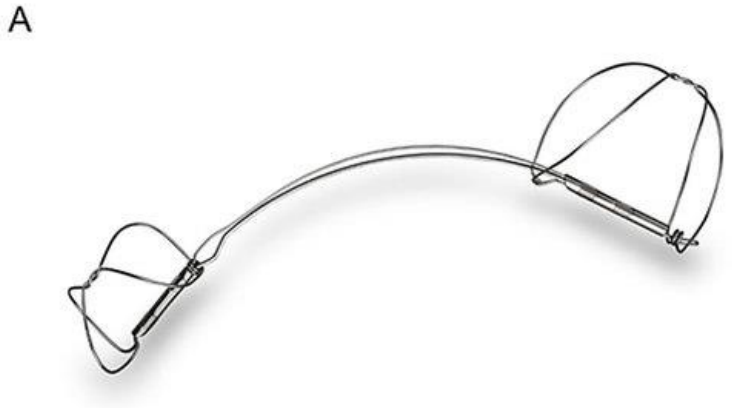


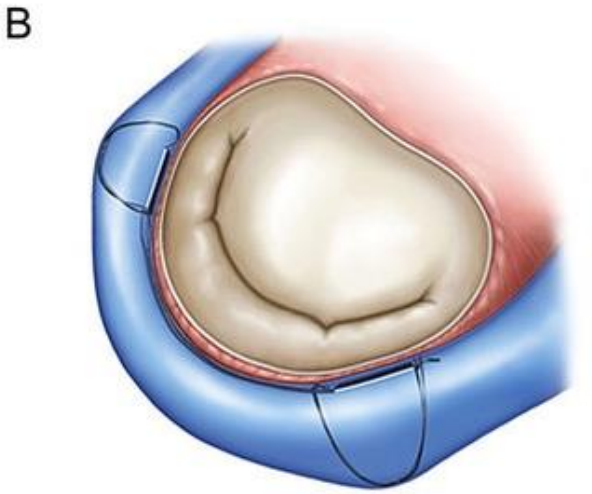


Edge-to-Spacer Pascal® (Edwards)



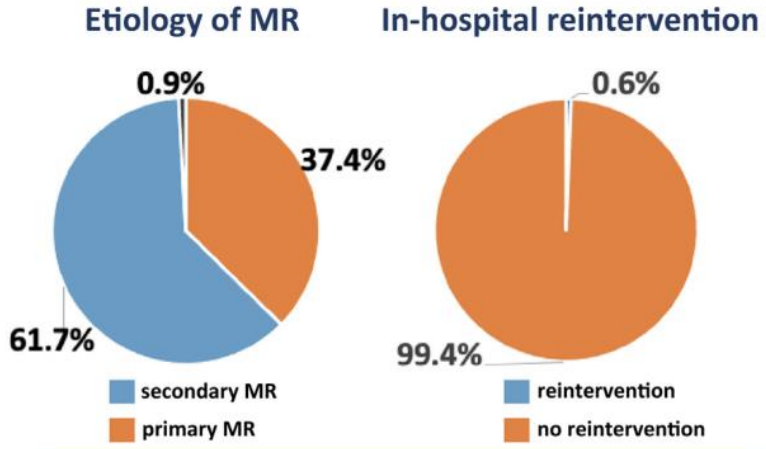
Interventionelle Mitralklappen-Annuloplastie (Carillon®, Cardiac Dimensions)

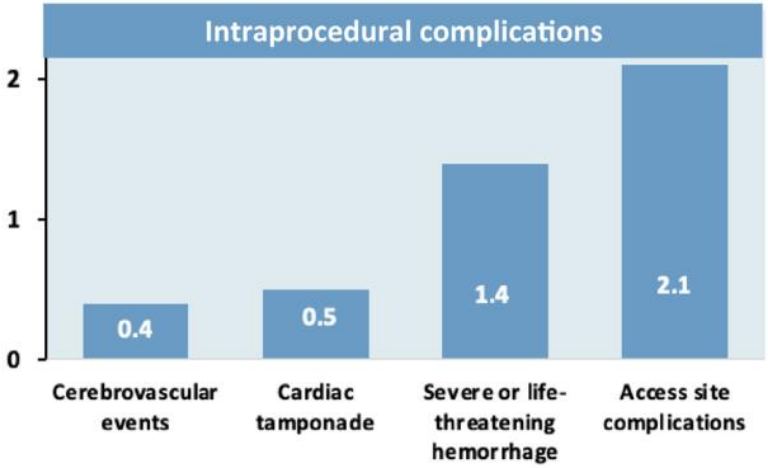




Contemporary Safety Outcomes of Mitral Edge-to-Edge Repair in Germany

IQTiG registry Germany
legally mandated quality assurance registry
2020 - 2021





8,454 patients
184 hospitals
Mitraclip™ approved in 2009
PASCAL approved in 2019
PASCAL Ace approved in 2020
all approved for primary and secondary MR in high surgical risk patients

mean age **78.3 ± 7.9 years**
48% female patients
Creatinine 1.4±1.1 mg/dL
21% pulmonary disease
25% previous cardiac surgery
70% atrial fibrillation
45% coronary artery disease

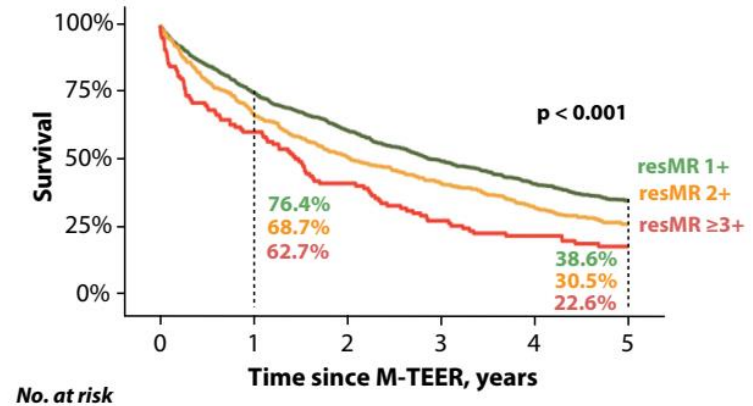
90.3% NYHA III/IV
LVEF 45.3±13.7%
sPAP **48.1±18.9** mmHg

IQTiG = Institute for Quality Assurance and Transparency in Healthcare; LVEF = left ventricular ejection fraction; MR = mitral regurgitation; sPAP = systolic pulmonary artery pressure.

Rudolph V, et al. JACC CVI https://doi.org/10.1016/j.jcin.2023.09.013

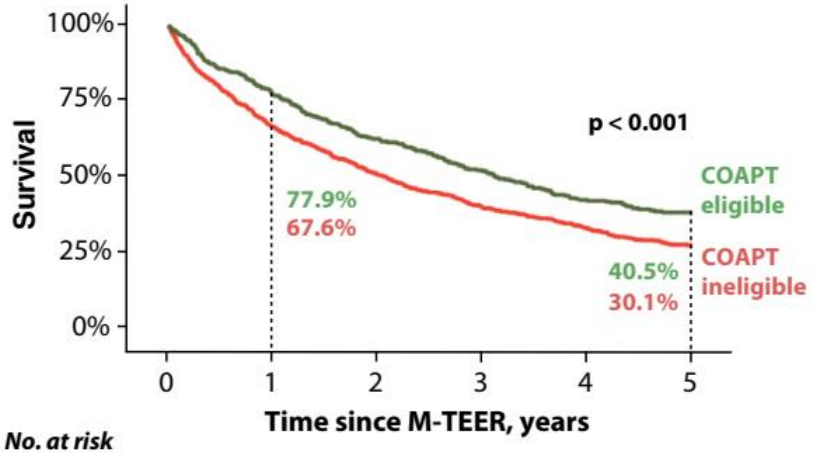
Bedeutung des prozeduralen Ergebnisses und der Nachbehandlung nach M-TEER

EuroSMR Register 1628 Patienten 5 Jahres Follow-Up



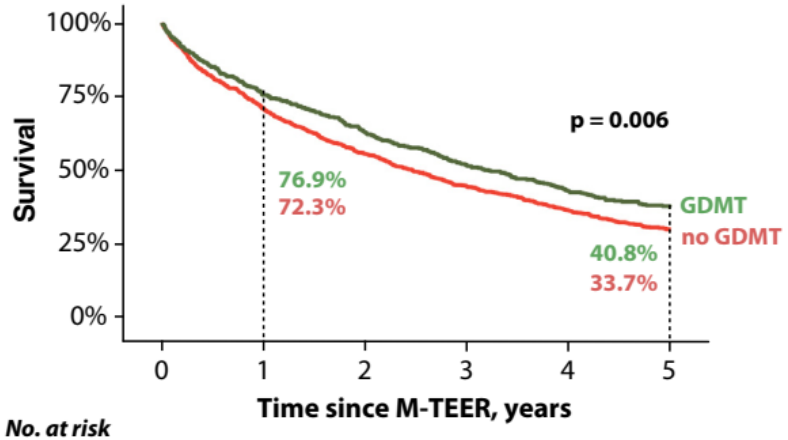
No. at risk

resMR 1+	999	734	598	496	421	274
resMR 2+	492	328	250	204	166	105
resMR ≥3+	125	73	52	36	30	20



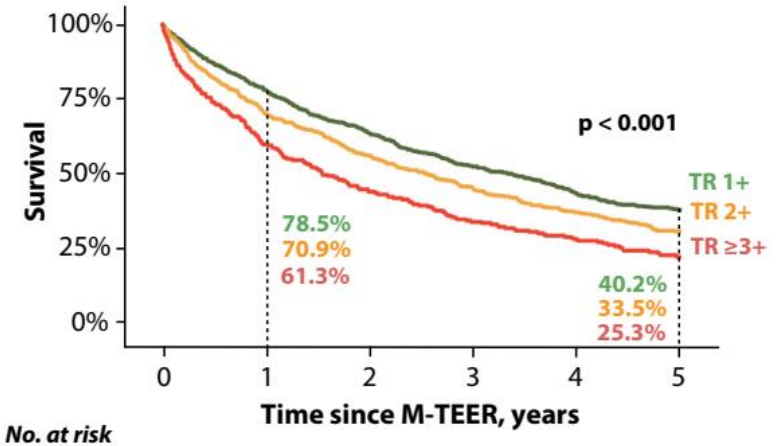
No. at risk

COAPT eligible	217	158	133	112	92	60
COAPT ineligible	1044	775	616	505	434	279



No. at risk

GDMT	967	697	545	444	372	231
no GDMT	470	359	301	249	212	153

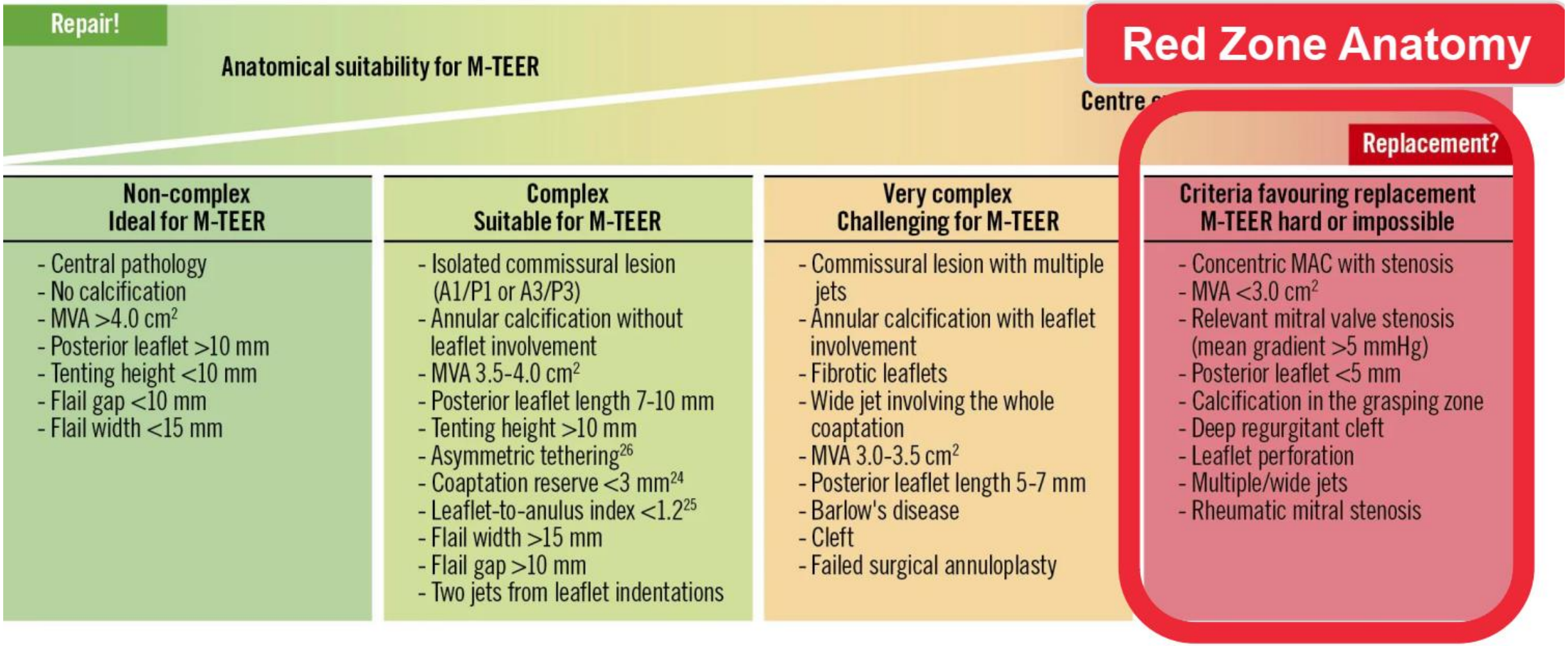


No. at risk

TR 1+	687	522	423	352	295	188
TR 2+	608	417	333	270	228	155
TR ≥3+	277	159	117	91	77	46

Stocker, et al. JACC Cardiovasc Interv. 2024;17:2543–2554.

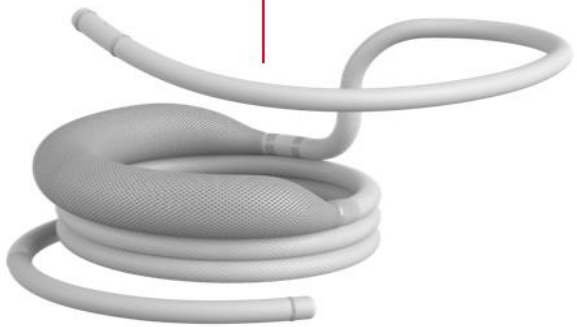
Anatomische Eignung für TEER



Hausleiter J et al. EuroIntervention 2023;18:957-976

SAPIEN M3 System

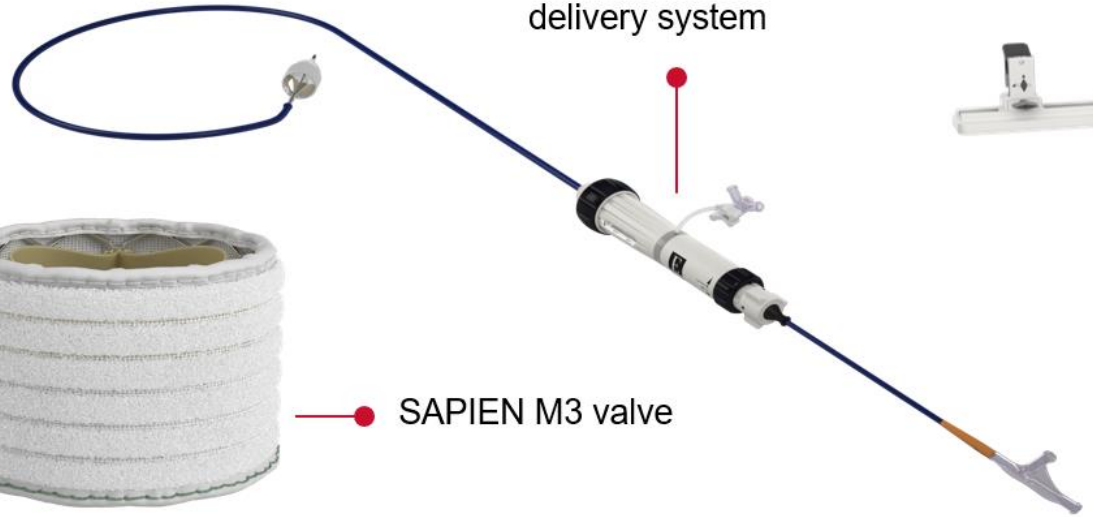
SAPIEN M3 dock



SAPIEN M3 Dock Steerable Catheter

Edwards 23F guide sheath

Edwards Commander M delivery system



SAPIEN stabilizer rail system

SAPIEN M3 valve

– or –

Edwards reusable accessories

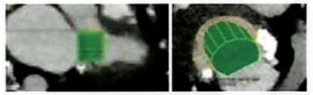
Edwards table

Common Reasons for Screen Failure

Anatomical suitability

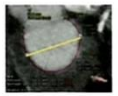
Significant risk of LVOT obstruction

- Neo-LVOT < 150 mm² measured in end-systole is an automatic screen fail



Large commissure-to-commissure diameters

- Com-to-com measurement ≥ 50 mm is an automatic screen fail

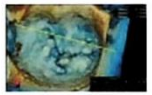


Small LV diameters 1 cm below the annulus

- < 30 mm is an automatic screen fail

Commissural pathology (i.e., calcification, jets, prolapse, flail)

- Flail located at medial commissure is an automatic screen fail
- Flail located at P3 is a screen fail if the com-to-com is ≥ 42 mm



Exclusion criteria within the ENCIRCLE clinical trial

THE ENCIRCLE TRIAL

- MR < 3+
- EF < 25%
- LVEDD ≥ 75 mm
- Severe RV dysfunction

Edwards Lifesciences • One Edwards Way, Irvine CA 92614 USA | Sàrl • Route de l'Etraz 70, 1260 Nyon, Switzerland • edwards.com

Edwards

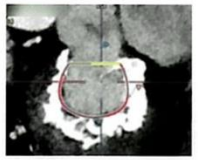
Ideal First SAPIEN M3 Patient Selection

Recommended **FIRST cases** for M3 implant patients

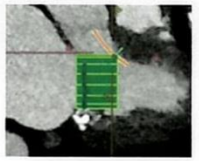
FMR

Annular size < 45 mm

1 cm below annulus dimensions ≥ 35 mm



No MAC/rings



Suitable Neo-LVOT

NOTE

The above parameters are considerations for initial SAPIEN M3 patient selection to allow for familiarization with the devices and implant techniques.

Edwards

Patient (70 Jahre)

- Rezidivierende kardiale Dekompensationen bei hochgradiger Mitralklappeninsuffizienz, sowie koronarer 3-Gefäßerkrankung mit leichtgradig eingeschränkter systolischer LV-Funktion
- Intravenöse Rekompensation
- PTCA/1xDES-Implantation der mittleren LCX im Bereich des R. marginalis ('culotte') am 11.06.2025
- Z. n. akutem Hinterwandinfarkt mit einem Akutverschluss der RCX sowie chronischem Verschluss 10/2019, PTCA /2 DES-RCX sowie Rekanalisation RIVA/ 2 DES Segment 6 - 8
- CVRF: Obstruktives Schlafapnoesyndrom, Adipositas, arterielle Hypertonie, Hypercholesterinämie
- Chronische Niereninsuffizienz, aktuell GFR 29 ml/min/1,73m2
- Z. n. ED Vorhofflimmern 06/25, Z.n. embolischen Schlaganfällen
- CHADS-VA-Score: 5, OAK mit Apixaban (red. Dosis) + Clopidogrel nach PCI

Patientenreport

Relevant Clinical Hx: MR Severity: Severe / 3+.
No other info.

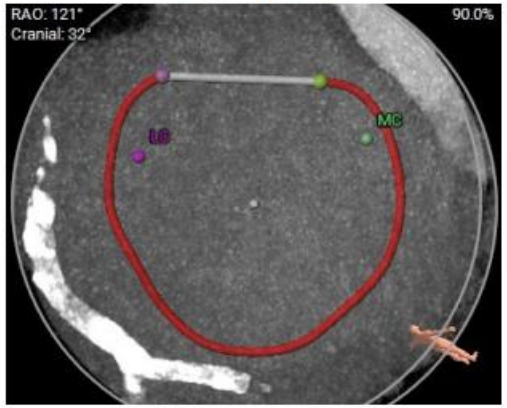
Screening Results: Suitable

Parameter	
C-C (ED)	44.7 mm
Neo-LVOT (ES)	284.6 mm²
1 cm Below (ES)	55.9 mm
MAC Score	N/A
MC Flail or Prolapse?	No
Mid P3 Flail or Prolapse?	No

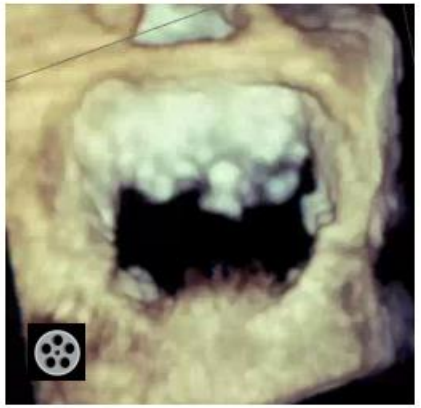
Comments

-No MC and no Mid P3 prolapse.
-Cleft at Med P2 - Lat P3.
-MR jet location extending from Med P1 to Lat P3.
-?fibrinous strand at Lat P3.

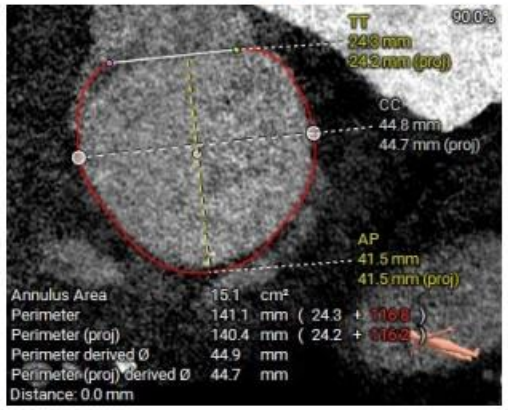
MIP View



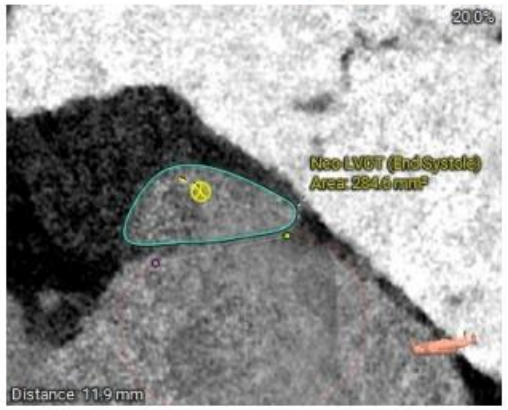
3D TEE En Face



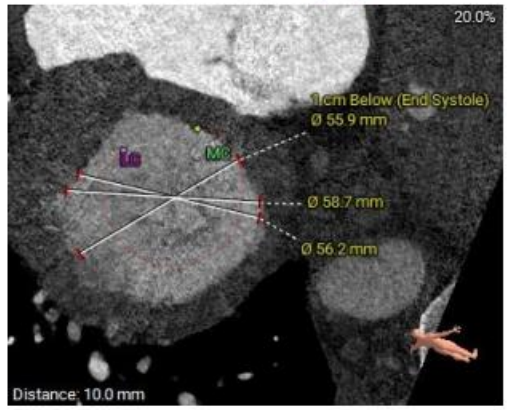
C-C (ED)



Neo-LVOT (ES)

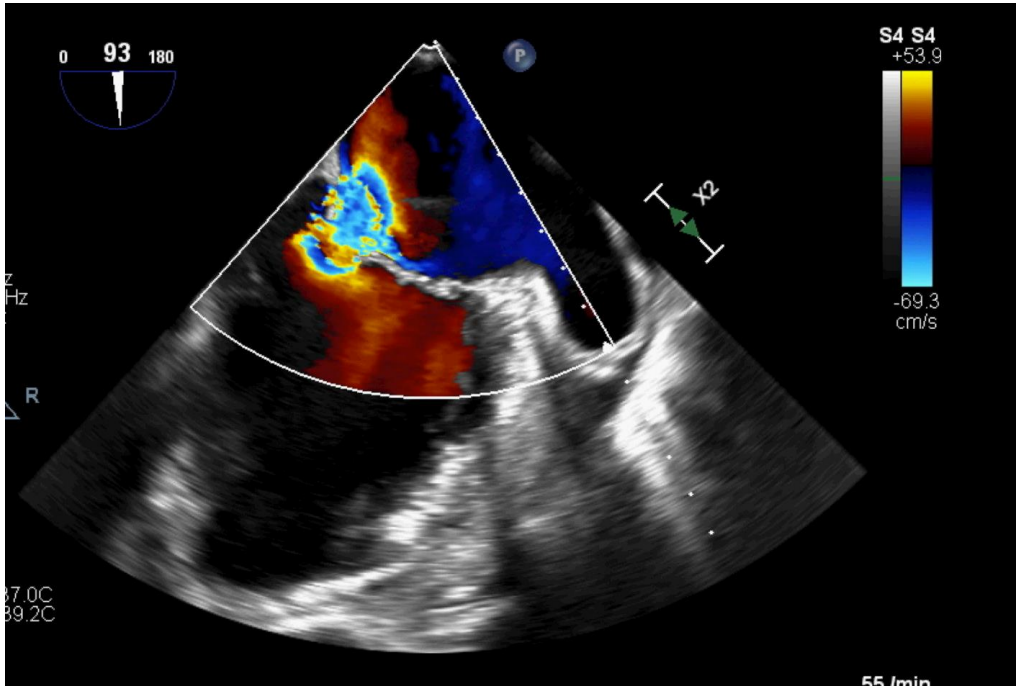


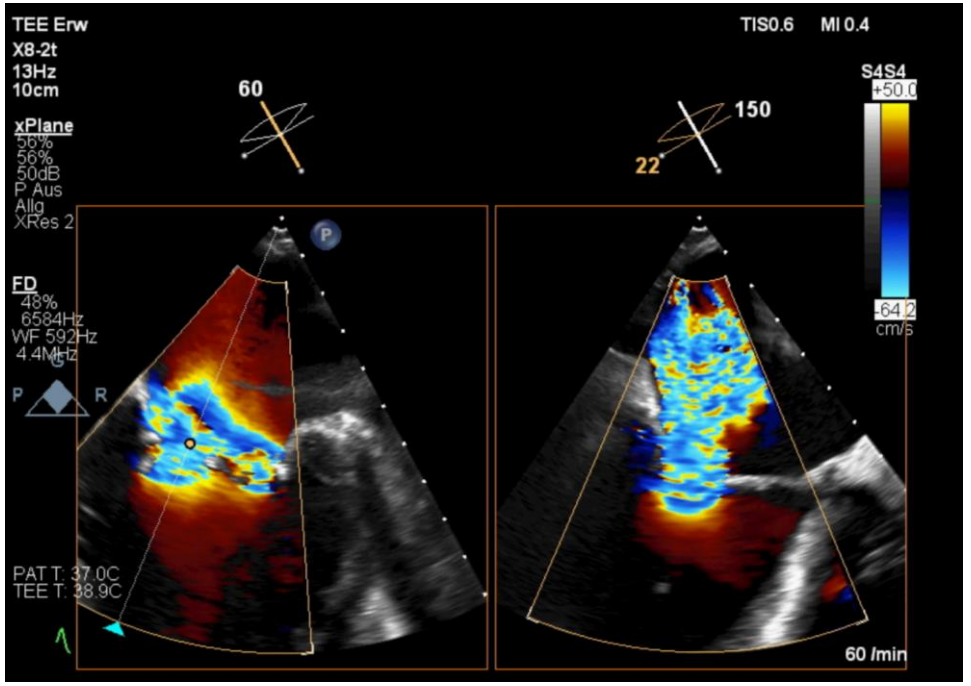
1 cm Below (ES)



Other Relevant Image(s)

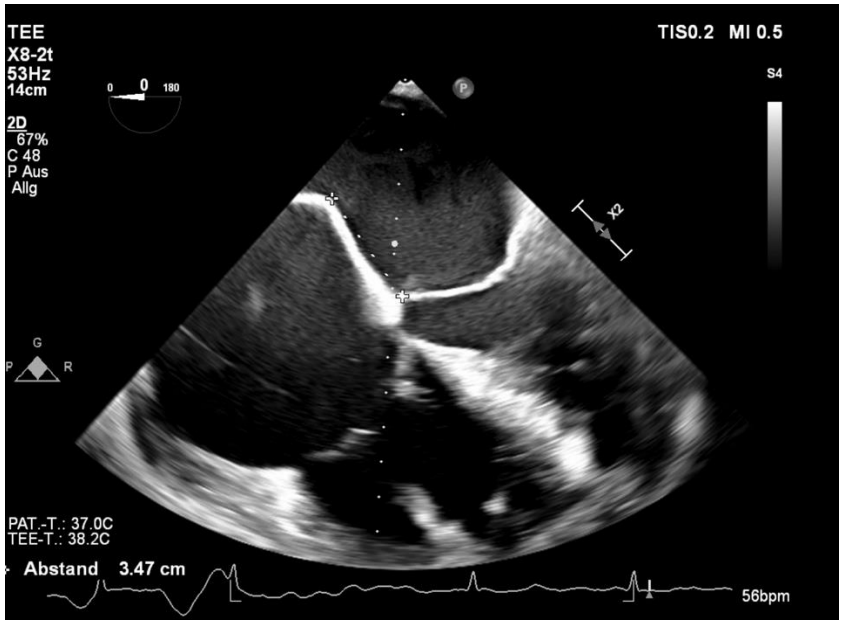
Other Relevant Image

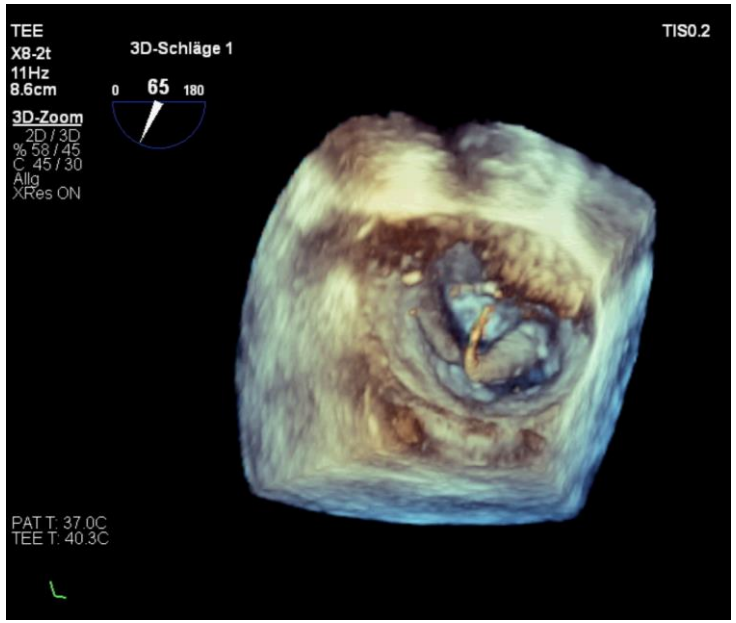

0 93 180
S4 S4
+53.9
-69.3
cm/s
X2
R
55 /min

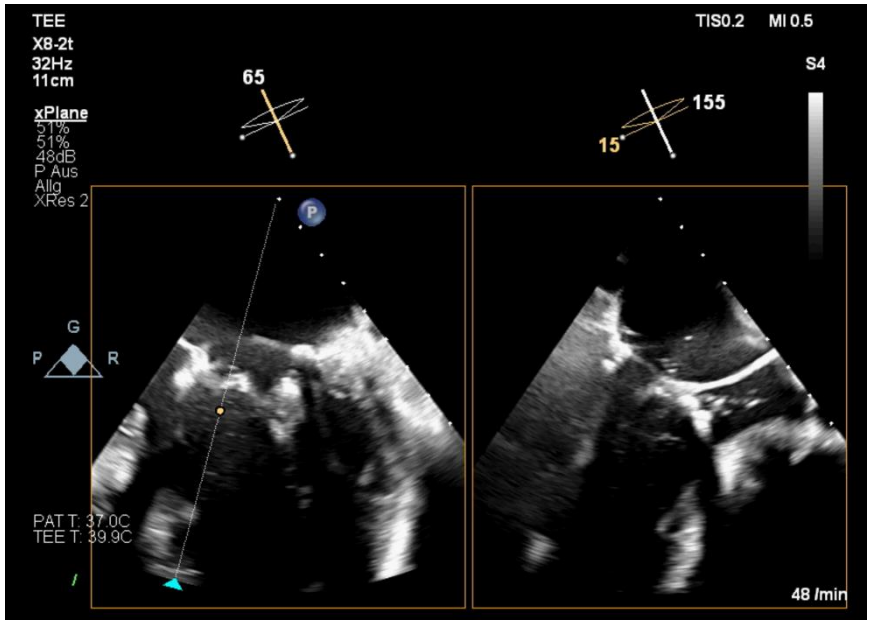

TEE Erw
X8-2t
13Hz
10cm
xPlane
56%
56%
50dB
P Aus
Allg
XRes 2
FD
48%
6584Hz
WF 592Hz
4.4MHz
TIS0.6 MI 0.4
60
150
22
S4S4
+50.0
-64.2
cm/s
P
R
PAT T: 37.0C
TEE T: 38.9C
60 /min

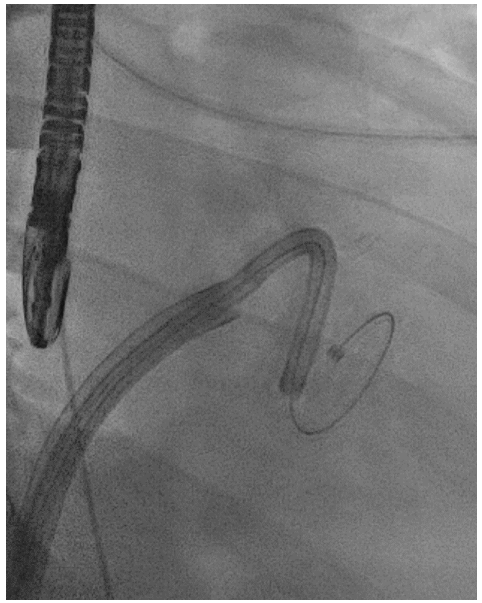

TEE Erw
X8-2t
25Hz
9.1cm
3D-Zoom
2D / 3D
% 55 / 45
C 43 / 30
Allg
XRes ON
3D-Schläge 2
0 60 180
TIS0.2 MI 0.2
PAT T: 37.0C
TEE T: 39.4C
Verzögerung 0ms
56 /min

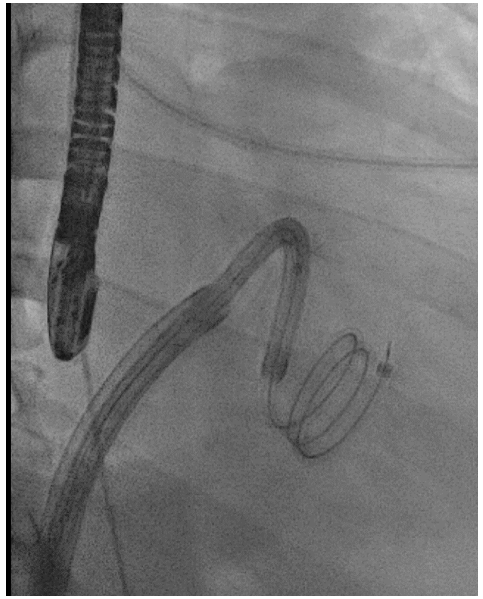

TEE Erw
X8-2t
6Hz
9.1cm
3D-Zoom
2D / 3D
% 62 / 45
C 43 / 30
Allg
XRes ON
FD
% 51 / 50
6998Hz
WF 699Hz
4.4MHz
3D-Schläge 1
0 60 180
TIS0.5 MI 0.3
S4S4
+53.1
-68.3

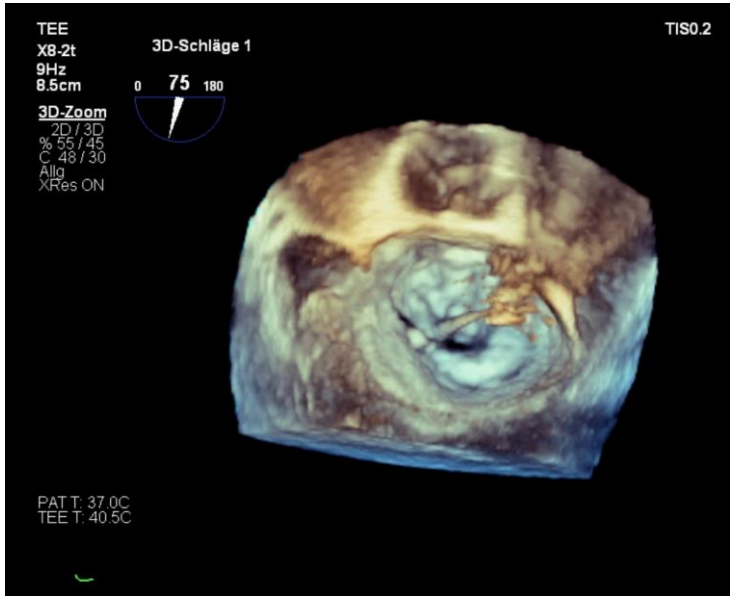

TEE
X8-2t
53Hz
14cm
2D
67%
C 48
P Aus
Allg
TIS0.2 MI 0.5
S4
PAT.-T.: 37.0C
TEE-T.: 38.2C
Abstand 3.47 cm
56bpm

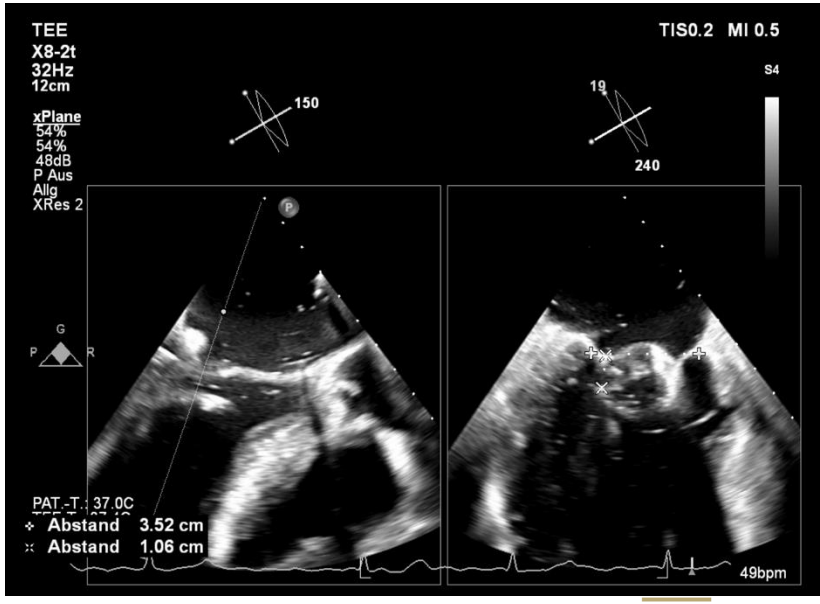

TEE
X8-2t
11Hz
8.6cm
3D-Schläge 1
3D-Zoom
2D / 3D
% 58 / 45
C 45 / 30
Allg
XRes ON
TIS0.2
PAT T: 37.0C
TEE T: 40.3C

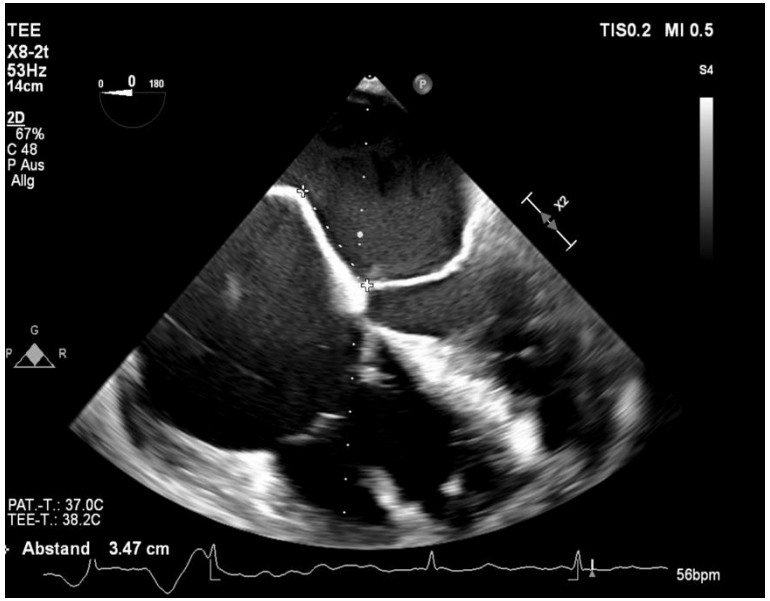

TEE
X8-2t
32Hz
11cm
xPlane
51%
51%
48dB
P Aus
Allg
XRes 2
TIS0.2 MI 0.5
S4
65
155
15
PAT T: 37.0C
TEE T: 39.9C
48 /min

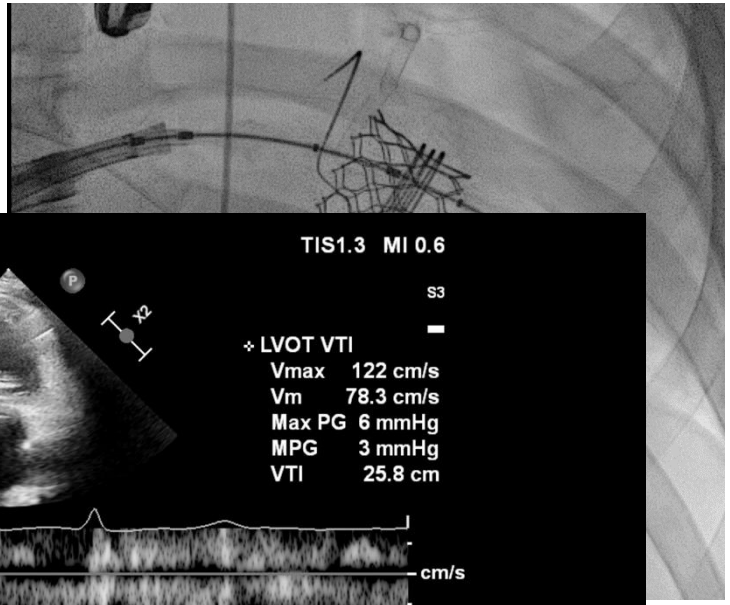




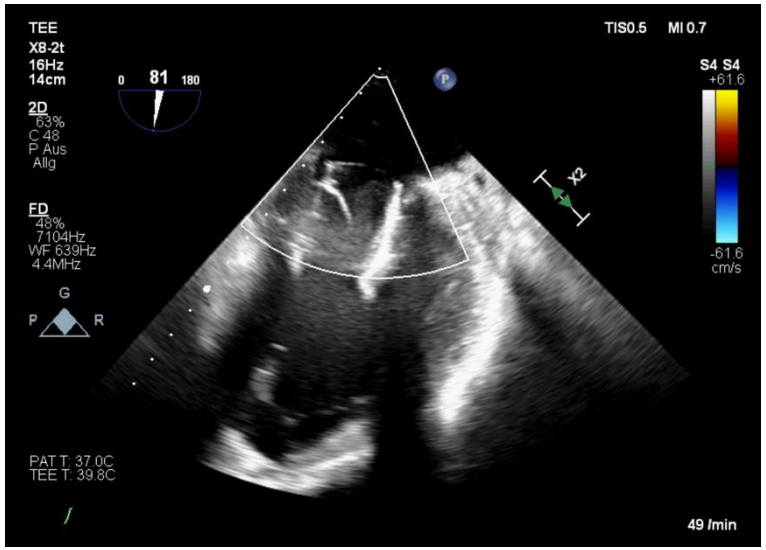

TEE
X8-2t
9Hz
8.5cm
3D-Schläge 1
3D-Zoom
2D / 3D
% 55 / 45
C 48 / 30
Allg
XRes ON
TIS0.2
PAT T: 37.0C
TEE T: 40.5C

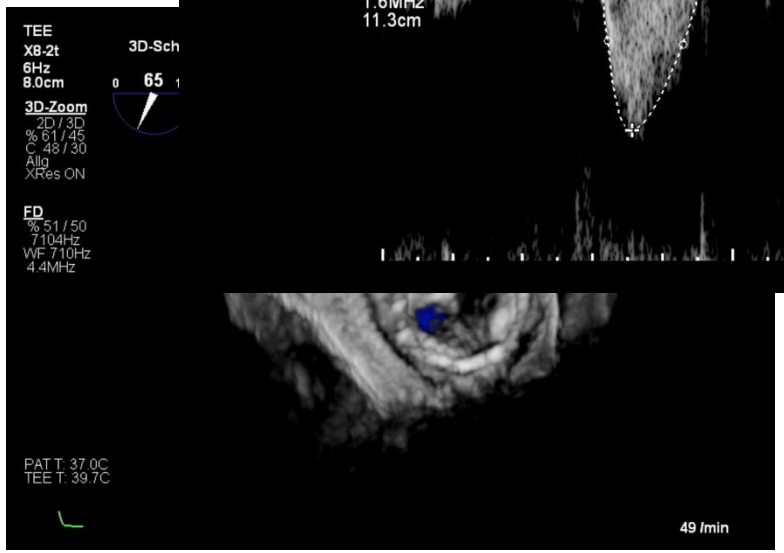

TEE
X8-2t
32Hz
12cm
xPlane
54%
54%
48dB
P Aus
Allg
XRes 2
TIS0.2 MI 0.5
S4
150
19
240
PAT.-T.: 37.0C
Abstand 3.52 cm
Abstand 1.06 cm
49bpm

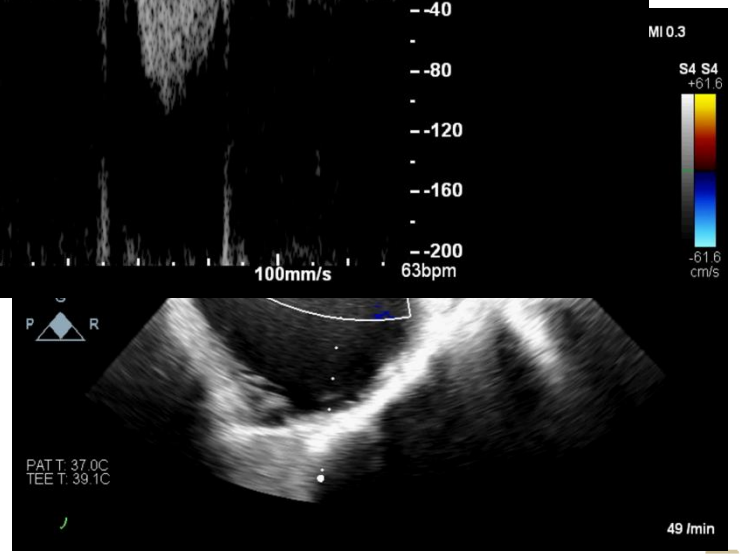

TEE
X8-2t
53Hz
14cm
2D
67%
C 48
P Aus
Allg
TIS0.2 MI 0.5
S4
PAT.-T.: 37.0C
TEE-T.: 38.2C
Abstand 3.47 cm
56bpm



Erw. Echo
S5-1
45Hz
18cm
2D
81%
C 50
P Min.
HAllg
TIS1.3 MI 0.6
S3
LVOT VTI
Vmax 122 cm/s
Vm 78.3 cm/s
Max PG 6 mmHg
MPG 3 mmHg
VTI 25.8 cm
PW
50%
WF 150Hz
DV4.0mm
1.6MHz
11.3cm
cm/s
-40
-80
-120
-160
-200
100mm/s
63bpm

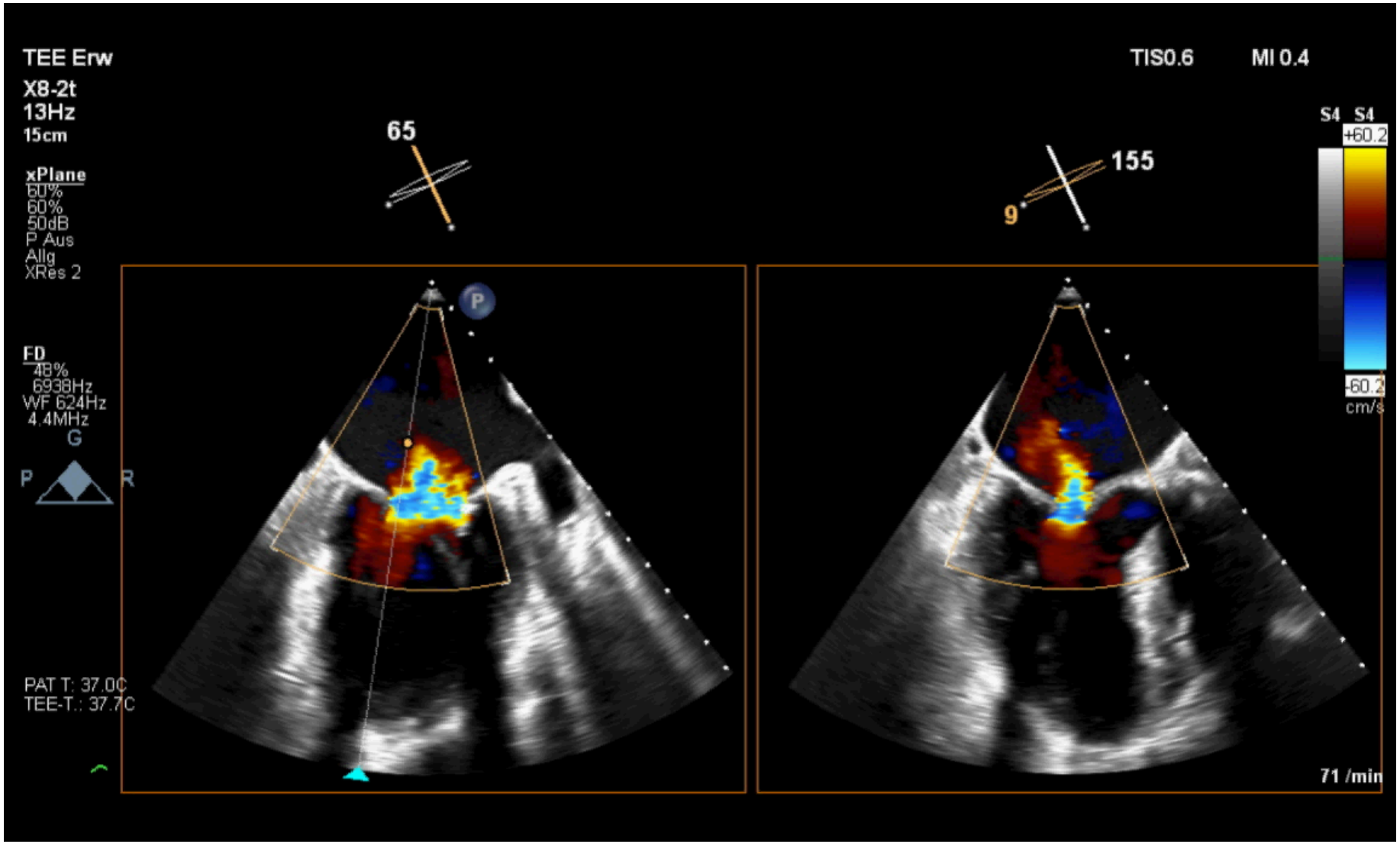

TEE
X8-2t
16Hz
14cm
2D
63%
C 48
P Aus
Allg
FD
48%
7104Hz
WF 639Hz
4.4MHz
TIS0.5 MI 0.7
S4 S4
+61.6
-61.6
cm/s
PAT T: 37.0C
TEE T: 39.8C
49 /min


TEE
X8-2t
6Hz
8.0cm
3D-Zoom
2D / 3D
% 61 / 45
C 48 / 30
Allg
XRes ON
FD
% 51 / 50
7104Hz
WF 710Hz
4.4MHz
PAT T: 37.0C
TEE T: 39.7C
49 /min

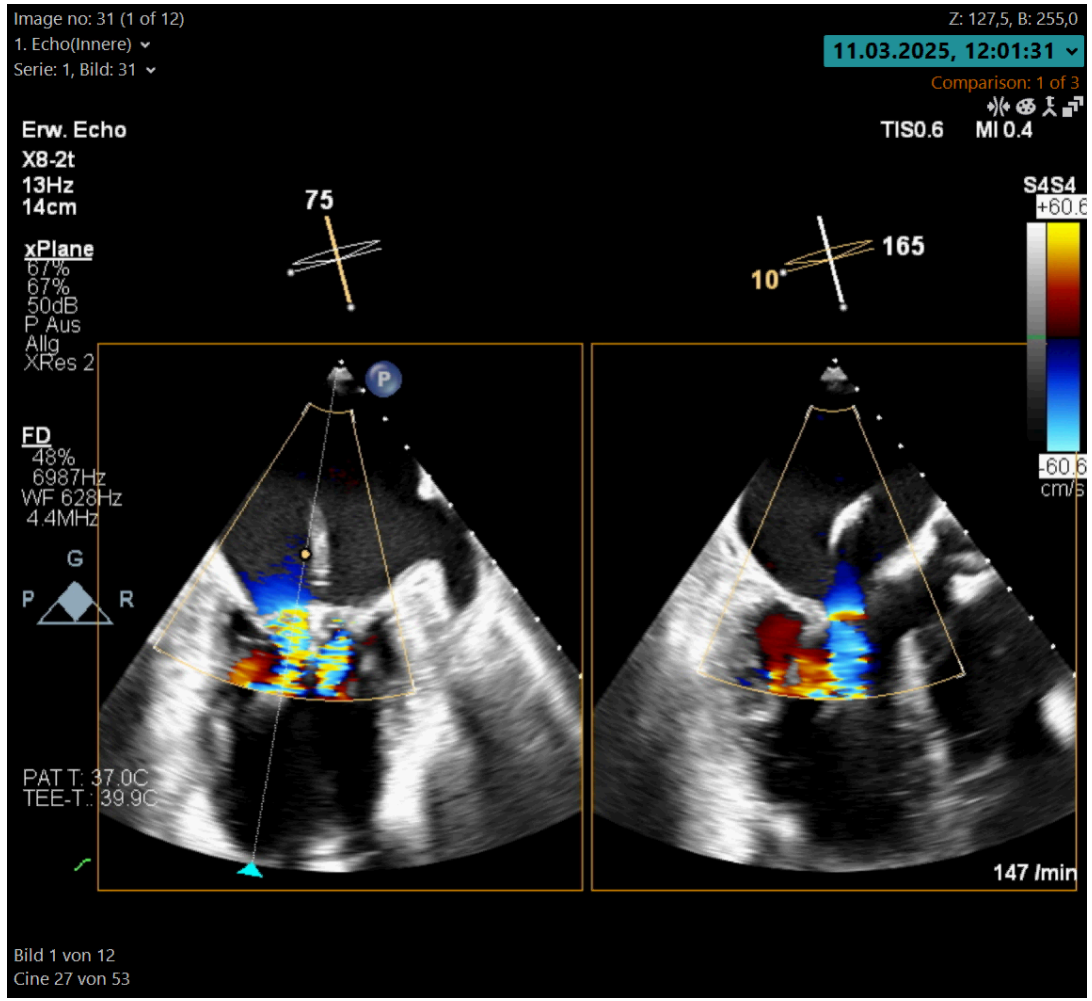

MI 0.3
S4 S4
+61.6
-61.6
cm/s
PAT T: 37.0C
TEE T: 39.1C
49 /min

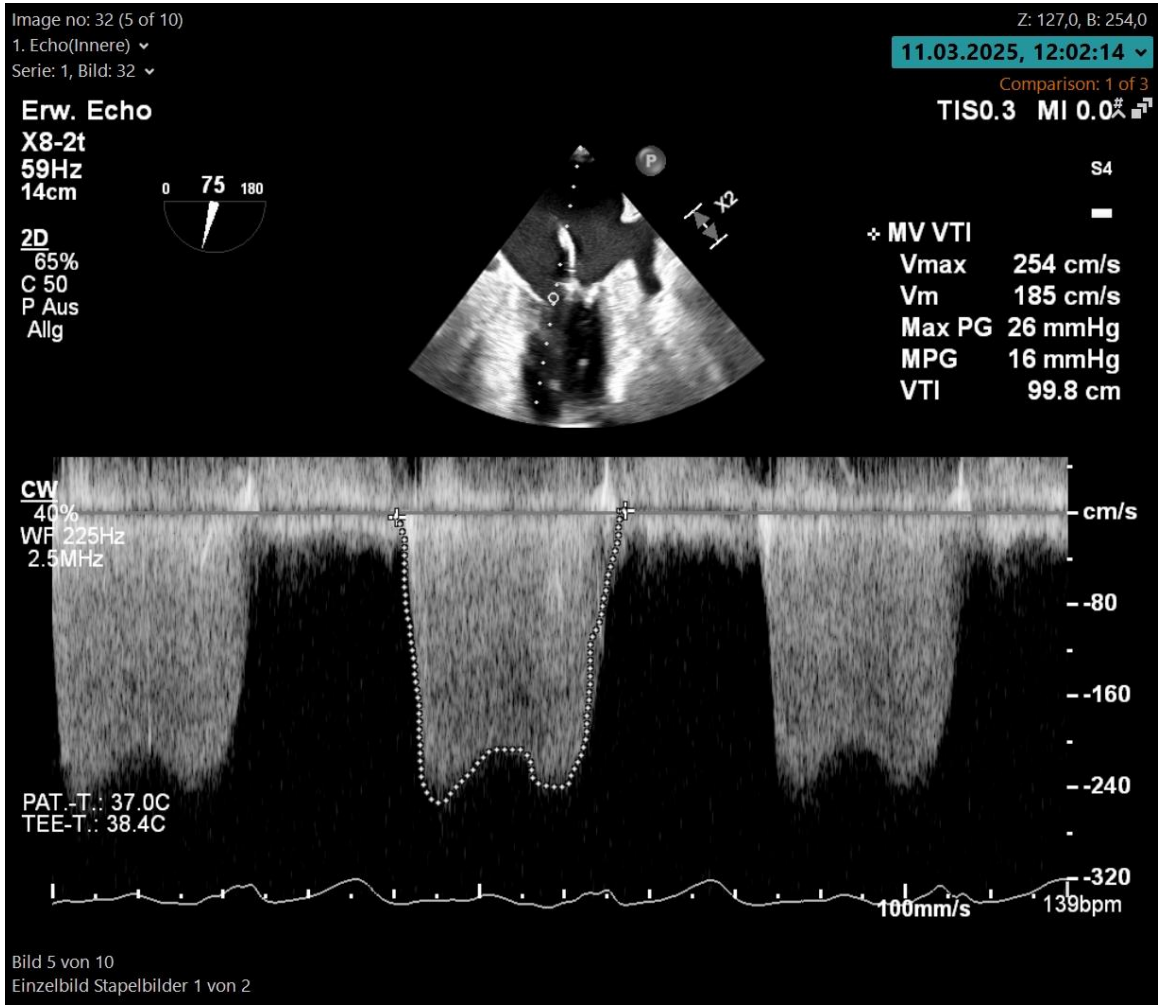
71 jähriger Patient

1. Mitralklappeninsuffizienz III°
   - Z.n. frustranem Versuch der edge-to-edge Therapie (MitralClip NTW), Abbruch wegen hohem Gradienten sowohl zentral als auch lateral (mittlerer Gradient 16mmHg) am 11.03.2025
   - Z.n. Pleuraergüsse bds.
2. Koronare 2-Gefäßererkrankung (LAD; CX) mit normaler systolischer LV-Funktion
   - Z.n. 2-fache Aortokoronare Bypässe mit Anastomosierung der linken A. mammaria auf den R. interventricularis anterior und single Venen Bypass auf den R. marginalis
   - Linksschenkelblock
   - cvRF: arterielle Hypertonie
3. Vormals hochgradige Aortenklappenstenose
   - Z.n. Biologischer Ersatz der Aortenklappe mit einer 23mm (Edwards Perimount) Prothese
4. intermittierendem AV-Block III° 04/23
   - Z.n. Zweikammerschrittmacher Implantation (Enitra 8 DR-T pro MRI)
5. Ektasie der Aorta ascendens (41 mm)
6. Asthma bronchiale
7. Schlaf-Apnoe-Syndrom mit CPAP-Gerät
8. Rheumatische Erkrankung


TEE Erw
X8-2t
13Hz
15cm
xPlane
60%
60%
50dB
P Aus
Allg
XRes 2
FD
48%
6938Hz
WF 624Hz
4.4MHz
G
P
R
PAT T: 37.0C
TEE-T.: 37.7C
TIS0.6
MI 0.4
65
155
9
S4 S4
+60.2
-60.2
cm/s
71 /min

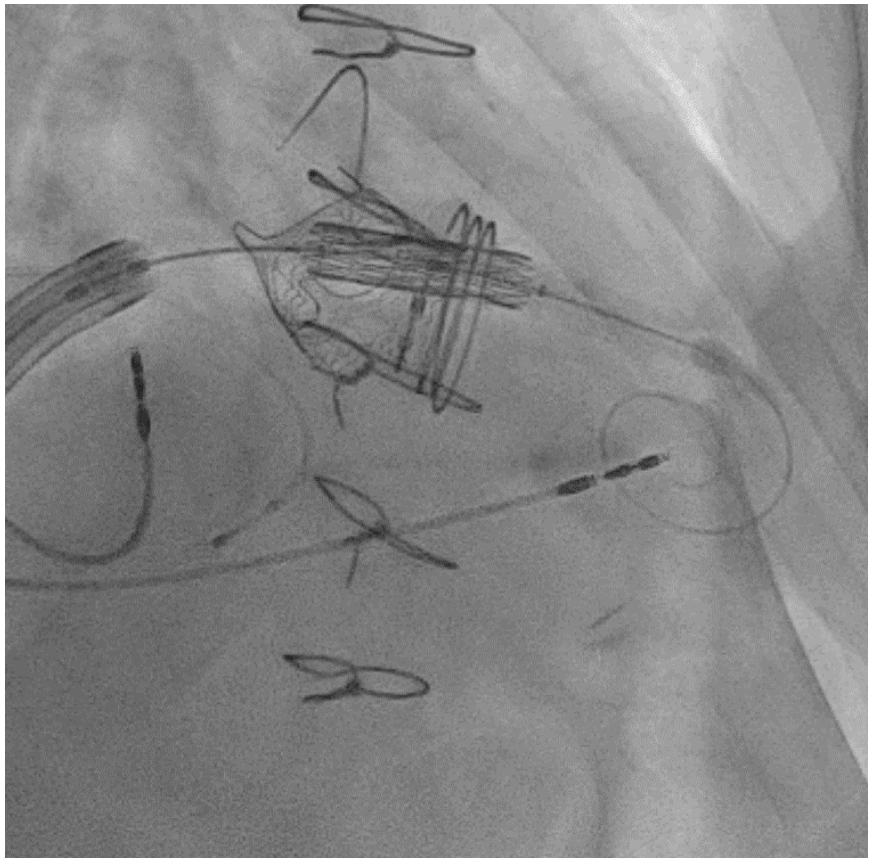
Previous TEER



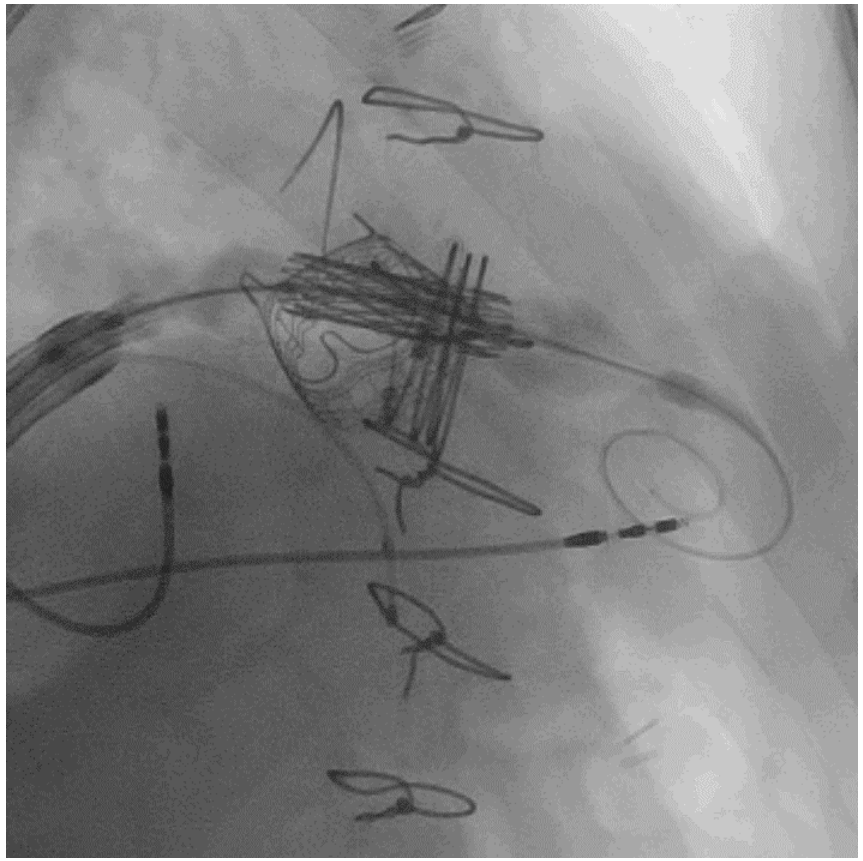


Valve Delivery

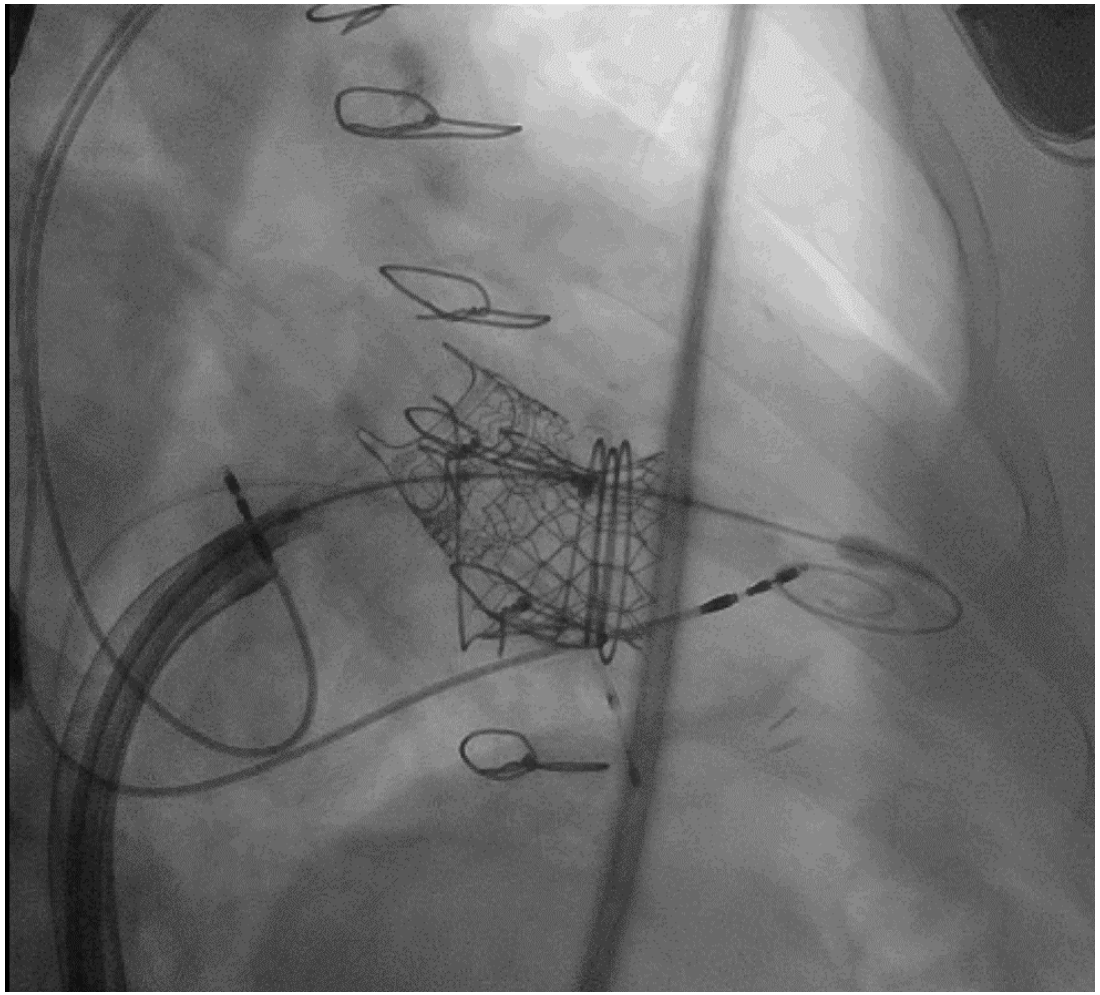
SM3 valve at least 3 mm more ventricular than ventricular most functional turn

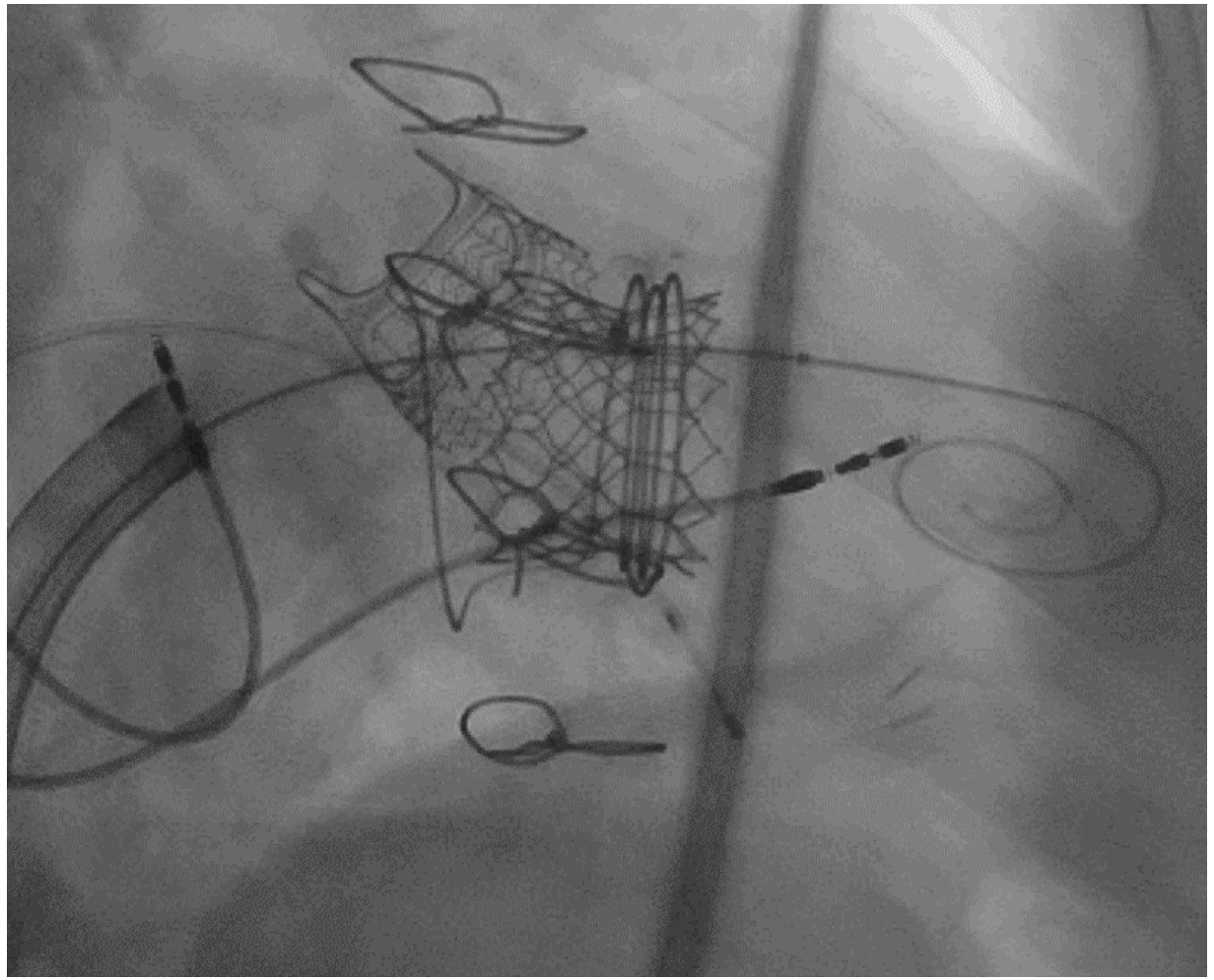


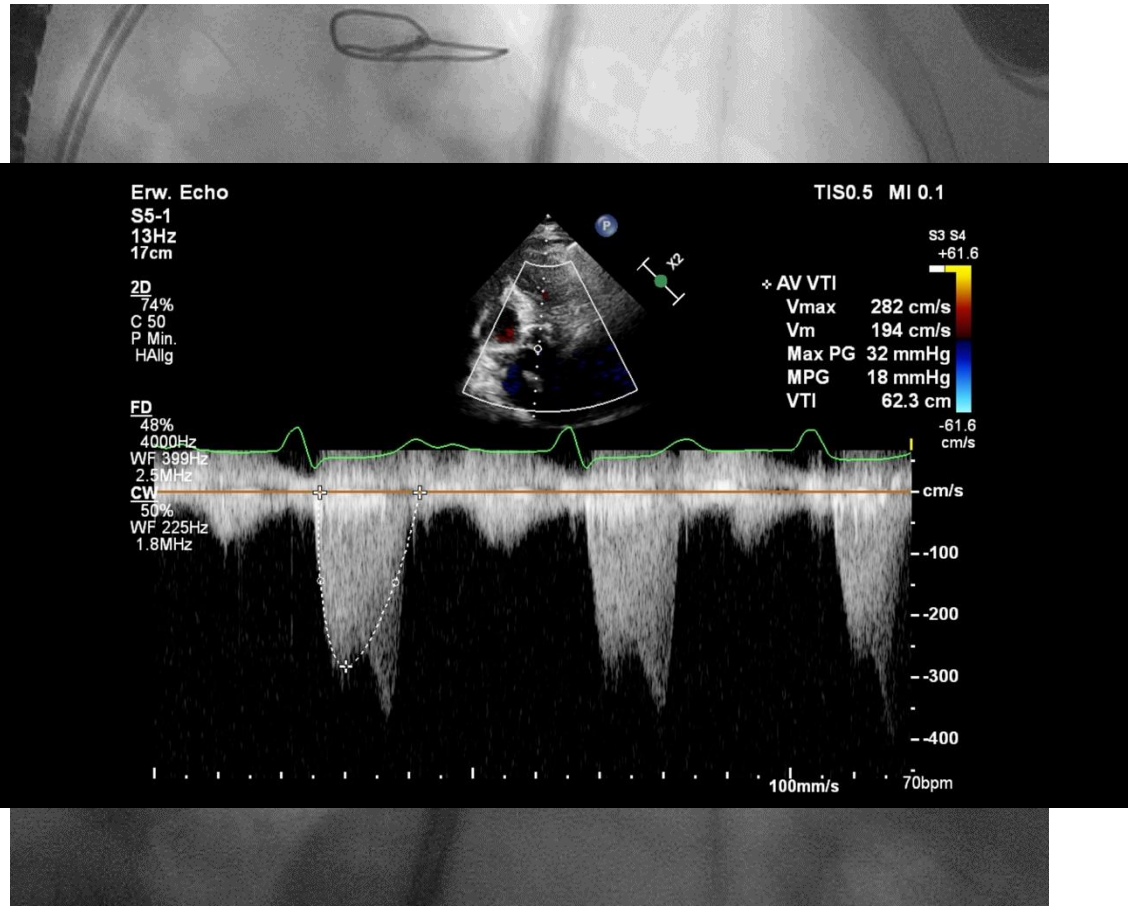
Target final position of 80% atrial / 20% ventricular

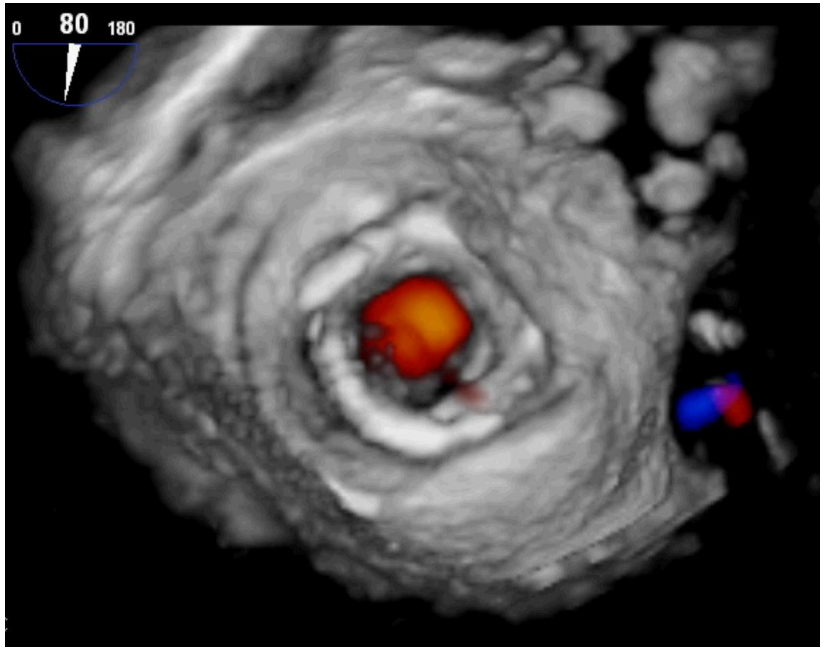


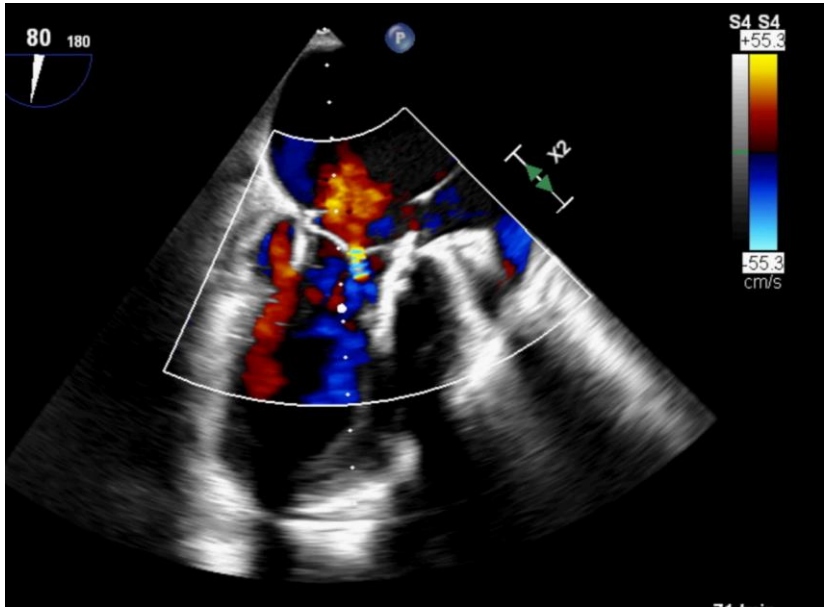
Valve Delivery - Postdilatation



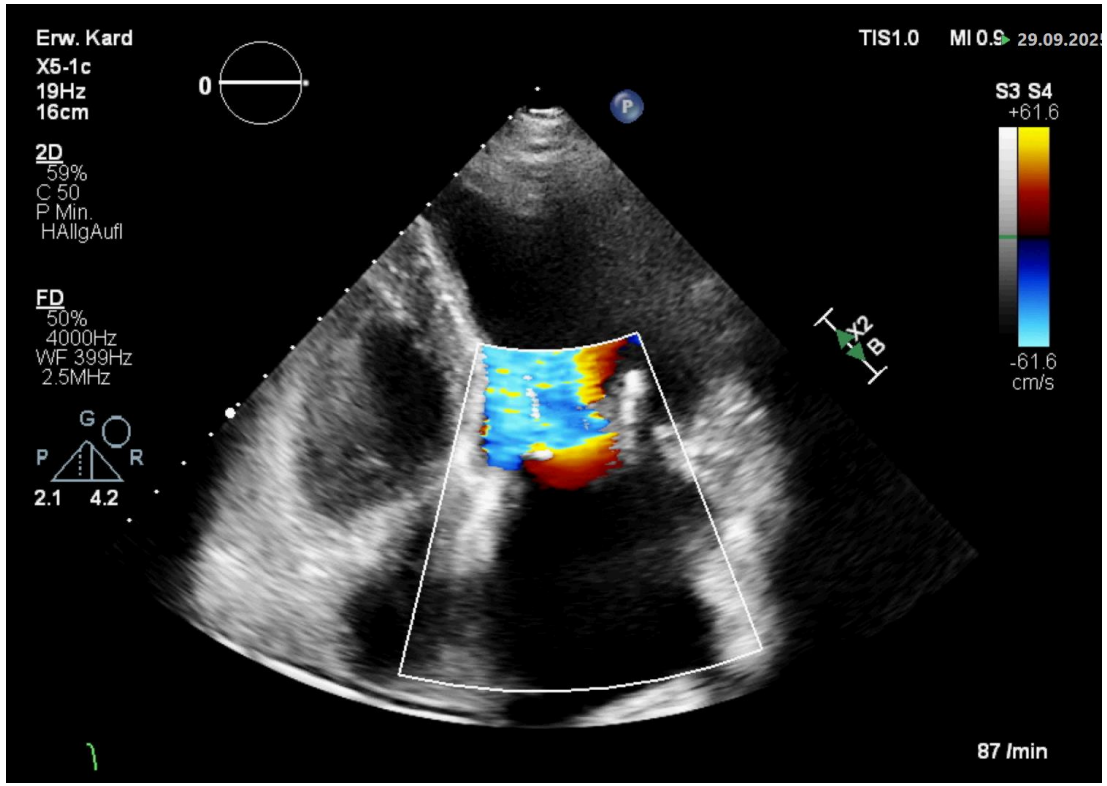


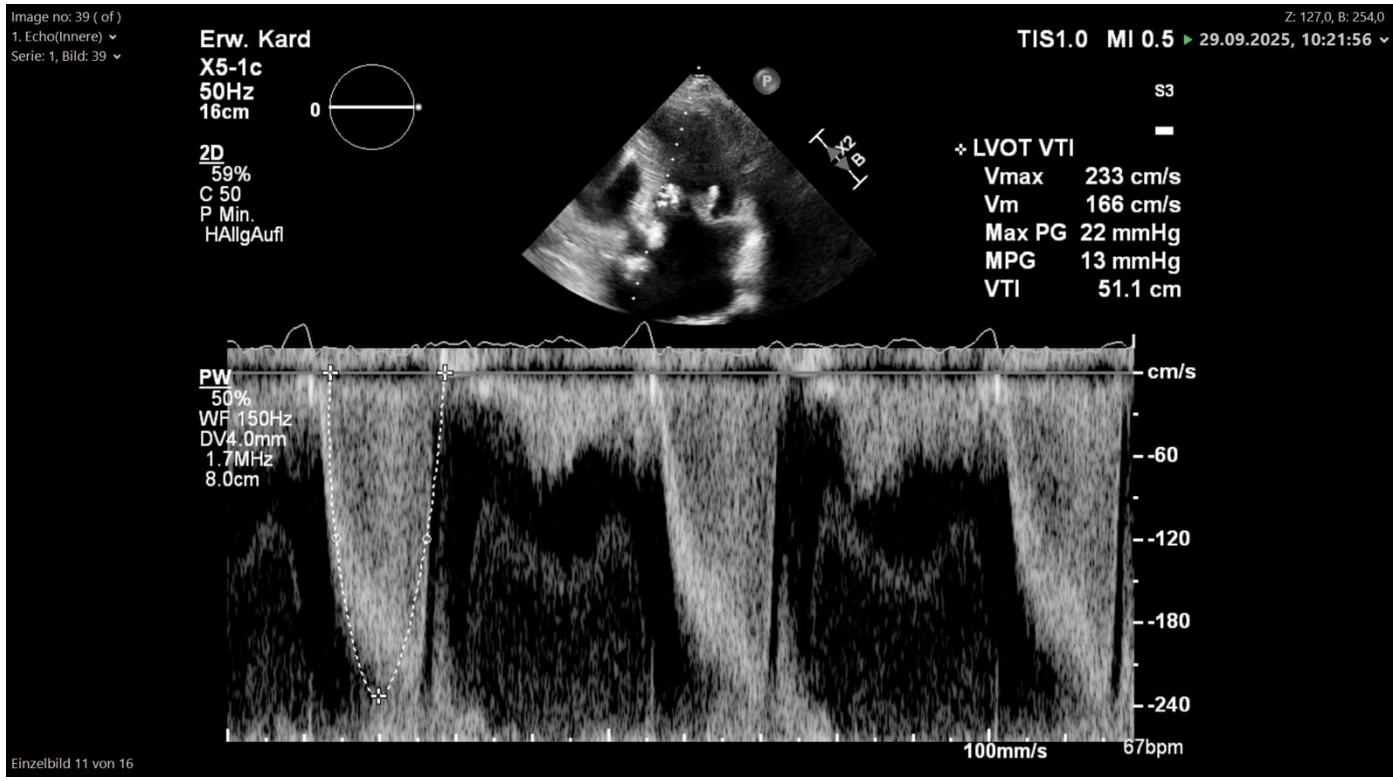

Erw. Echo
S5-1
13Hz
17cm
2D
74%
C 50
P Min.
HAllg
FD
48%
4000Hz
WF 399Hz
2.5MHz
CW
50%
WF 225Hz
1.8MHz
TIS0.5 MI 0.1
S3 S4
+61.6
AV VTI
Vmax 282 cm/s
Vm 194 cm/s
Max PG 32 mmHg
MPG 18 mmHg
VTI 62.3 cm
-61.6
cm/s
cm/s
-100
-200
-300
-400
100mm/s
70bpm


0
80
180


80
180
S4 S4
+55.3
-55.3
cm/s

Follow-Up 3 Monate





The ENCIRCLE Trial

Patients with MR ≥ 3+, NYHA Class ≥ II, and Unsuitable for Commercial Options as Assessed by Heart Team

Commercial Unsuitable (n = 300)	MAC Registry* (n = 100)	Failed TEER Registry (n = 100)

PRIMARY ENDPOINT:
Death & HF Rehospitalization at 6 Months

Follow-up: 30 Days, 6 Months, 1 Year, and Annually Through 5 Years

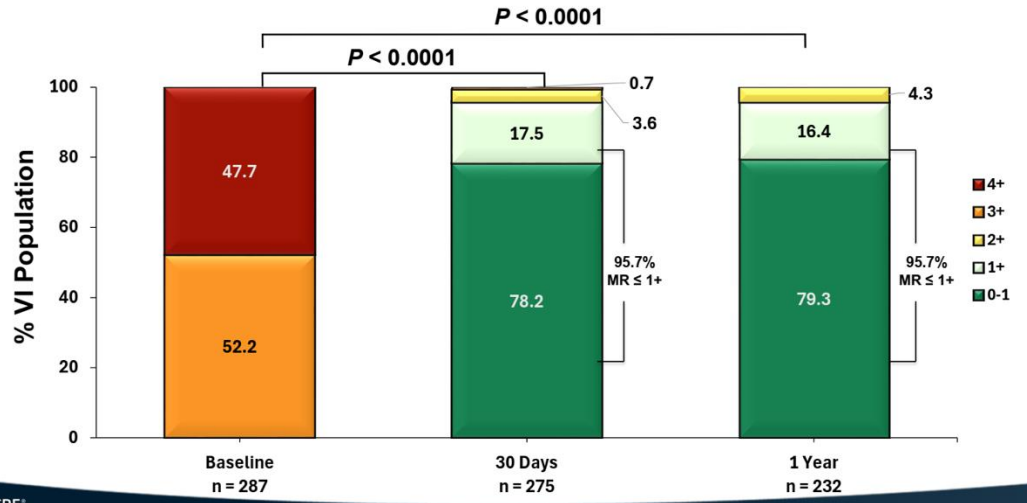
**Additional inclusion criteria for MAC registry: moderate MR and ≥ moderate MS*

Baseline Characteristics

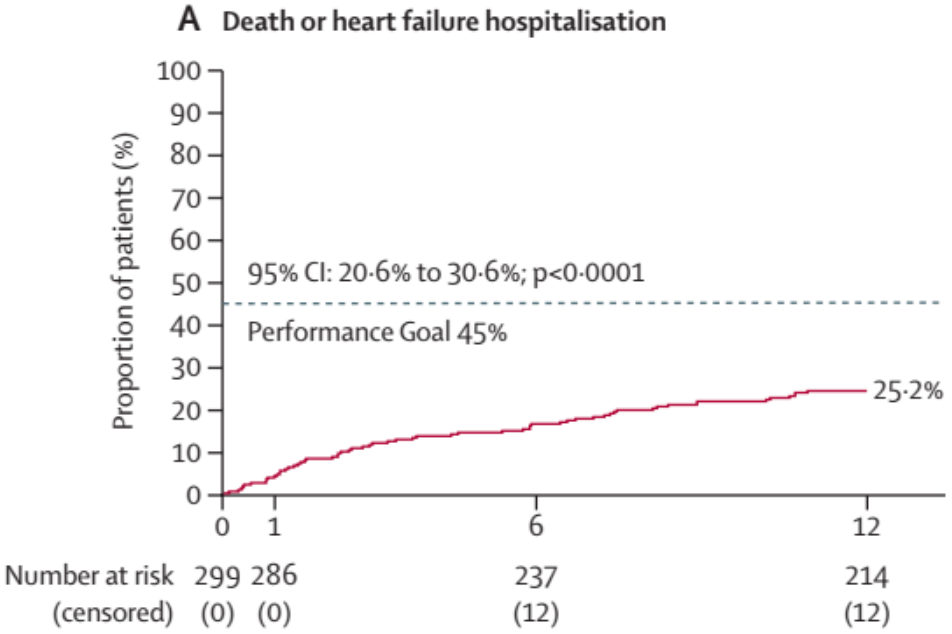
Characteristic	N=299	Characteristic	N=299
Age, y	**75.5 ± 9.35**	Hypertension	84.3%
Male sex	50.8%	Peripheral Vascular Disease	15.1%
BMI, kg/m²	27.6 ± 6.08	**Congestive Heart Failure**	**75.3%**
STS score for mitral valve replacement	**6.6 ± 4.09**	**Atrial Fibrillation**	**69.9%**
STS score ≥ 8	**28.8%**	Prior Pacemaker or ICD	35.8%
KCCQ Score	57.0	Prior MI	30.1%
NYHA Class		**Prior Stroke or TIA**	**18.7%**
I/II	28.8%	Prior PCI	35.5%
III/IV	**71.2%**	Prior CABG	30.4%
Diabetes	34.4%	**Prior Mitral Repair***	**8.7%**
eGFR, mL/min/1.73m²	58.2 ± 19.16	Prior Aortic Valve Replacement	15.7%
NT-proBNP, pg/mL	**2758.9 ± 2996.03**	Mitral Annular Calcification	24.4%

Values presented as %, mean ± SD
* Prior Mitral Repair included 12 prior rings, 11 prior bands, 2 repairs by Alfieri stitch, and 1 not-reported type of repair

Mitral Regurgitation Severity



>95% patients had ≤1+ total MR at 30 days sustained to 1 year



Procedural Characteristics

Characteristic	N=299
Procedure Time*, min	117.0 [50.0, 308.0]
Device Time, min	**90.0 [39.0, 289.0]**
Dock Deployment Time, min	57.0 [13.0, 227.0]
Valve Implant Time, min	9.0 [2.0, 158.0]
Total Fluoroscopy Time, min	46.0
Intra-Procedural Death	**0.0%**
Intra-Procedural Stroke†	0.3%
Procedure Aborted§	4.0%
Conversion to Surgery	**0.0%**

Characteristic	N=299
Valve Embolization	**0.0%**
Multiple Valves Implanted	0.0%
Clinically significant LVOT obstruction	**0.0%**
Pericardial Effusions leading to cardiac tamponade	0.7%
Iatrogenic Ventricular Septal Defects	0.7%
Ventricular Perforation	0.3%
Percutaneous PVL closure	**5.0%**
ASD Closure¶	17.4%
Routine	12.4%
Clinically Significant	5.0%

* Times shown as Median [min, max]
† In a patient that received argatroban due to HIT
§ 12 aborted cases due to 5 encircling difficulties, 5 low dock, 1 mobile echodensity, 1 unable to gain medial commissure access
¶ Routine closures include all that were not clinically significant or were performed under standard clinical practice (i.e., preventative or planned based on patients' history). Clinically significant reasons include hemodynamic instability, multiple ASDs, significant left to right shunt, significant right to left shunt

Guerrero M, Daniels V D and Webb J presentet at TCT 2025 and published Lancet 2025; 406: 2541–50

Additional Clinical Outcomes

Characteristic	30-Days	1 Year
Stroke	2.7%	9.3%
Disabling	**1.7%**	**3.9%**
Non-Disabling	1.0%	5.5%
MV Reintervention*	2.3%	6.4%
Major Bleeding or above, MVARC	8.7%	18.5%
Clinically significant LVOT obstruction	0.0%	0.0%
MI requiring revascularization	0.0%	0.3%
Cardiac Structural Complications	2.3%	2.7%
Major Access Site Vascular Complications	3.0%	5.6%
Clinically Significant Device Thrombosis	**2.3%**	**6.7%**
Hemolysis requiring intervention†	**4.3%**	**7.1%**
Atrial fibrillation, new onset	7.9%	11.5%
New Permanent Pacemaker	2.6%	5.5%
Endocarditis	0.0%	1.5%
AKI requiring renal replacement therapy	1.7%	---§

Values are shown as Kaplan Meier Estimates - %
* Includes PVL Closure (12), Valve in Valve (3), and Surgical Mitral Valve Replacement (4)
† Required blood transfusion or mitral valve reintervention
§ AKI adjudicated up to 30 days, therefore no value for 1-year reported

Anticoagulation Status and Stroke Incidence

		Stroke Rate at 1 Year*		
	Number of Subjects	Adequate Anticoagulation	Inadequate Anticoagulation†	All
Direct oral anticoagulation	221	7.1%	13.4%	9.0%
Vitamin K antagonist	58	6.9%	10.3%	8.6%
No anticoagulation‡	8	---	12.5%	12.5%
Total	287	**7.1%**	**12.5%**	9.1%

Patients with inadequate anticoagulation, irrespective of type, had higher stroke risk

* Observed rate,%
† Inadequate anticoagulation is defined as a gap greater than 1 day in anticoagulation or subtherapeutic INR (<2.5) if taking Vit. K antagonist
‡ Number of subjects with no anticoagulation at time of stroke identification or no anticoagulation within 30 days from index procedure

Anticoagulation Status and Clinically Significant Device Thrombosis Incidence

		Clinically Significant Device Thrombosis Rate at 1 Year*		
	Number of Subjects	Adequate Anticoagulation	Inadequate Anticoagulation†	All
Direct oral anticoagulation	223	6.1%	8.0%	6.7%
Vitamin K antagonist	54	0.0%	10.0%	5.6%
No anticoagulation	10	---	10.0%	10.0%
Total	287	**5.2%**	**8.7%**	6.6%

Patients with inadequate anticoagulation, irrespective of type, had higher rate of thrombosis

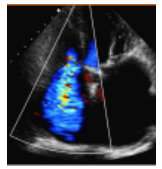
* Observed rate,%
† Inadequate anticoagulation is defined as a gap greater than 1 day in anticoagulation or subtherapeutic INR (<2.5) if taking Vit. K antagonist
‡ Number of subjects with no anticoagulation at time of stroke identification or no anticoagulation within 30 days from index procedure

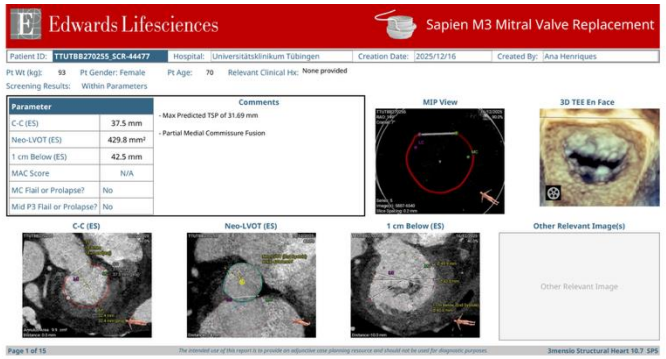
Guerrero M, Daniels V D and Webb J presentet at TCT 2025 and published Lancet 2025; 406: 2541–50

Differenciated Device Selection Transcatheter Mitral Therapy

Valve Coordinator

Primary/ secondary MR + high surgical risk, HEART TEAM discussion





TEER eligble ?

No

YES

Conditionally feasible (yellow group)

Screening for alternate approach (TMVR), Contraindications Bleeding risk/GA with TMVR?

TMVR

TEER

In case of insufficient reduction of MR, t → Conversion/two stage approach

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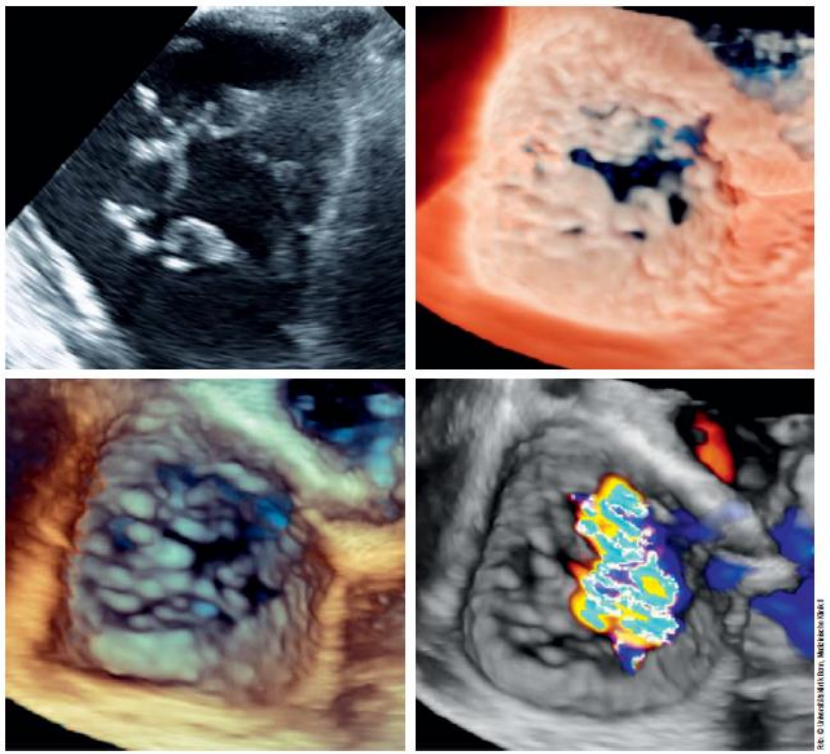
sadija.dzaferovic@med.uni-tuebingen-de

Klinische Bedeutung der Trikuspidalklappeninsuffienz



TRIKUSPIDALINSUFFIZIENZ

Die vernachlässigte Klappe

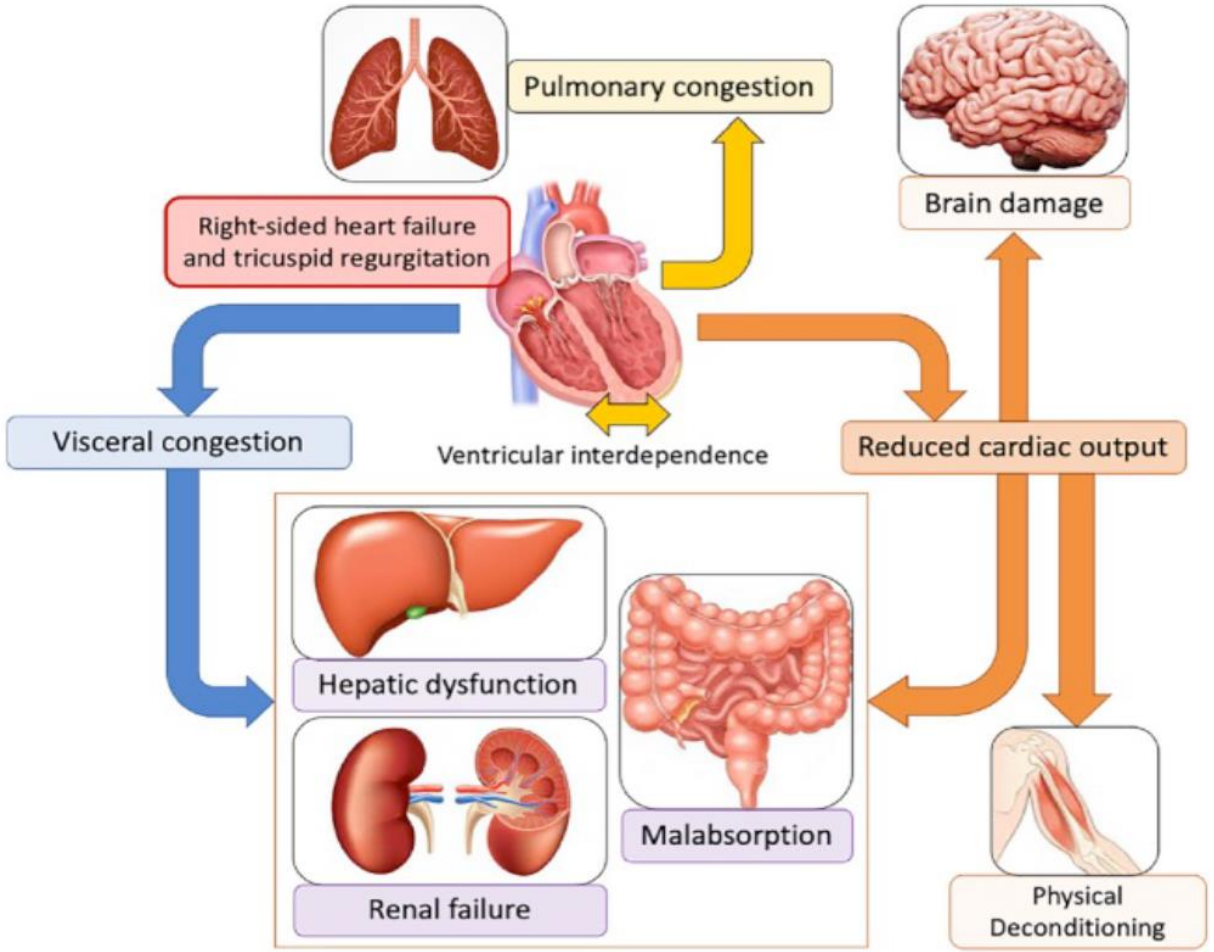
Angesichts der demografischen Entwicklung sind unterschiedliche minimalinvasive Verfahren zur interventionellen Therapie in Erprobung. Erste klinische Studien sind vielversprechend.

Abbildung 1 (oben): Trikuspidalklappenaufsicht in der transösophagealen und transgastralen Echokardiografie (2-D- und 3-D-Rekonstruktion +/- Farbdoppler)

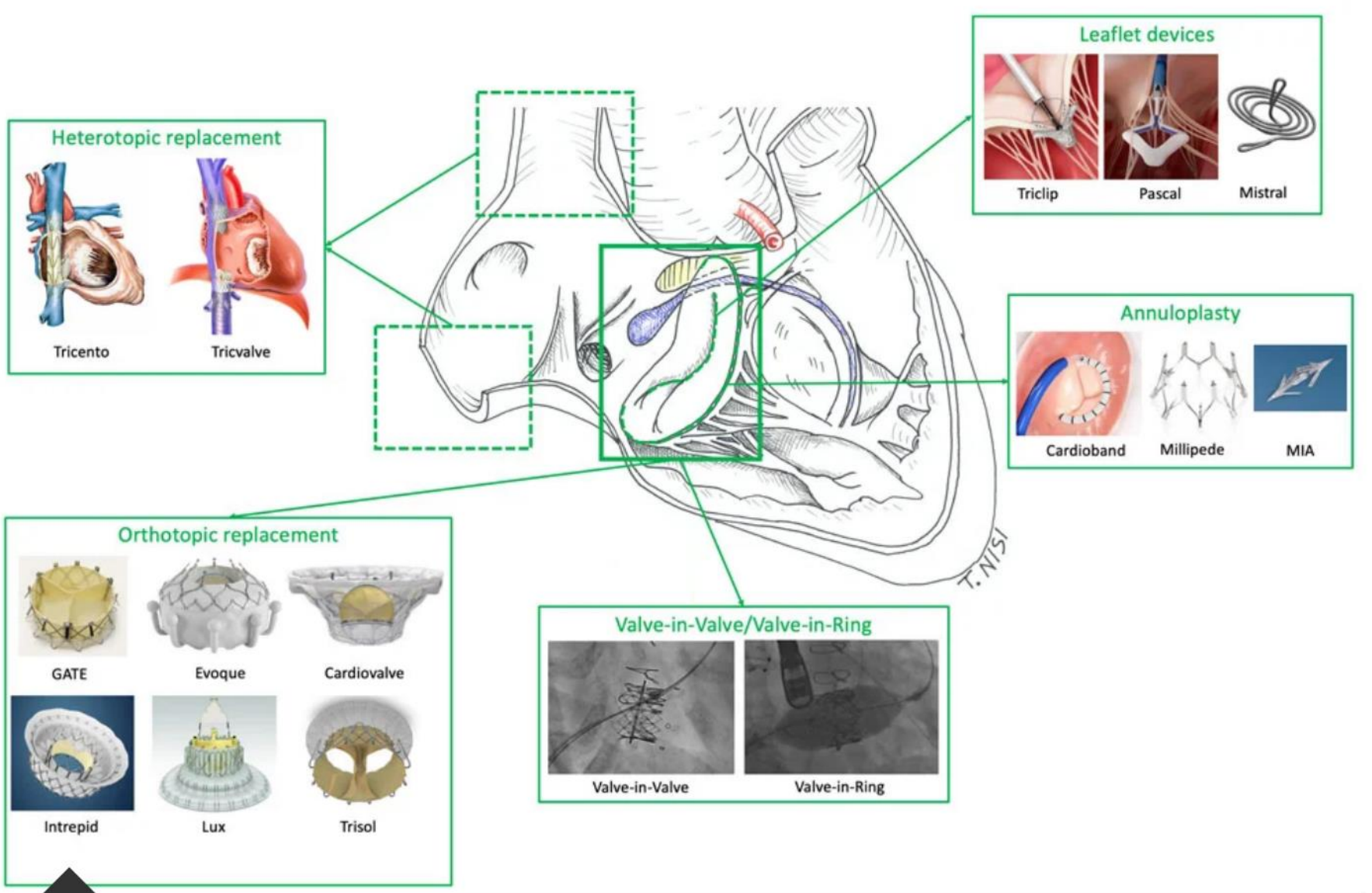
Eine milde Trikuspidalklappeninsuffizienz (TI) wird in der klinischen Praxis häufig beobachtet – meist als Zufallsbefund im Rahmen einer Routine-Echokardiografie oder bei symptomatisch führender Linksherzerkrankung (sekundäre TI). Sie gilt als benigne und kann trotz Progress lange klinisch inapparent und kompensiert bleiben (1).

Die Prävalenz einer klinisch relevanten, höhergradigen TI nimmt mit circa 5 % in der Population der > 70-Jährigen (schätzungsweise 3 Mio. Menschen europaweit) zu und wird durch Alter und weibliches Geschlecht begünstigt (2–4).

Bei der vergleichsweise selteneren **primären TI** (8–10 % der Fälle) liegt die Pathologie in der Trikuspidalklappe (TK) selbst, die Ursachen sind – auch aufgrund der komplexen Klappenanatomie – vielfältig *(Grafik 1)*. Weitaus häufiger (> 90 % der Fälle) liegt eine **sekundäre (funktionelle) TI** vor; sie ist

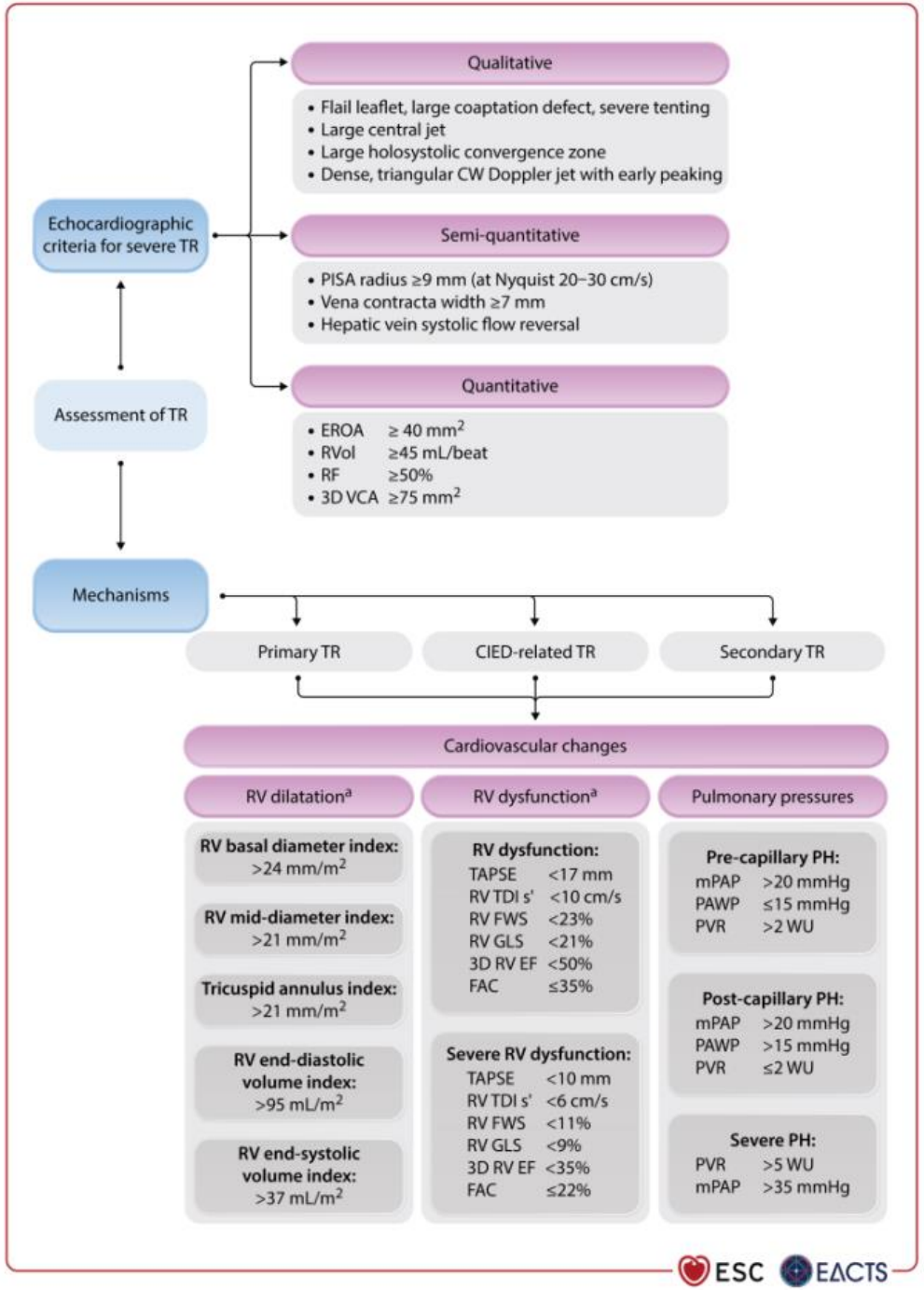


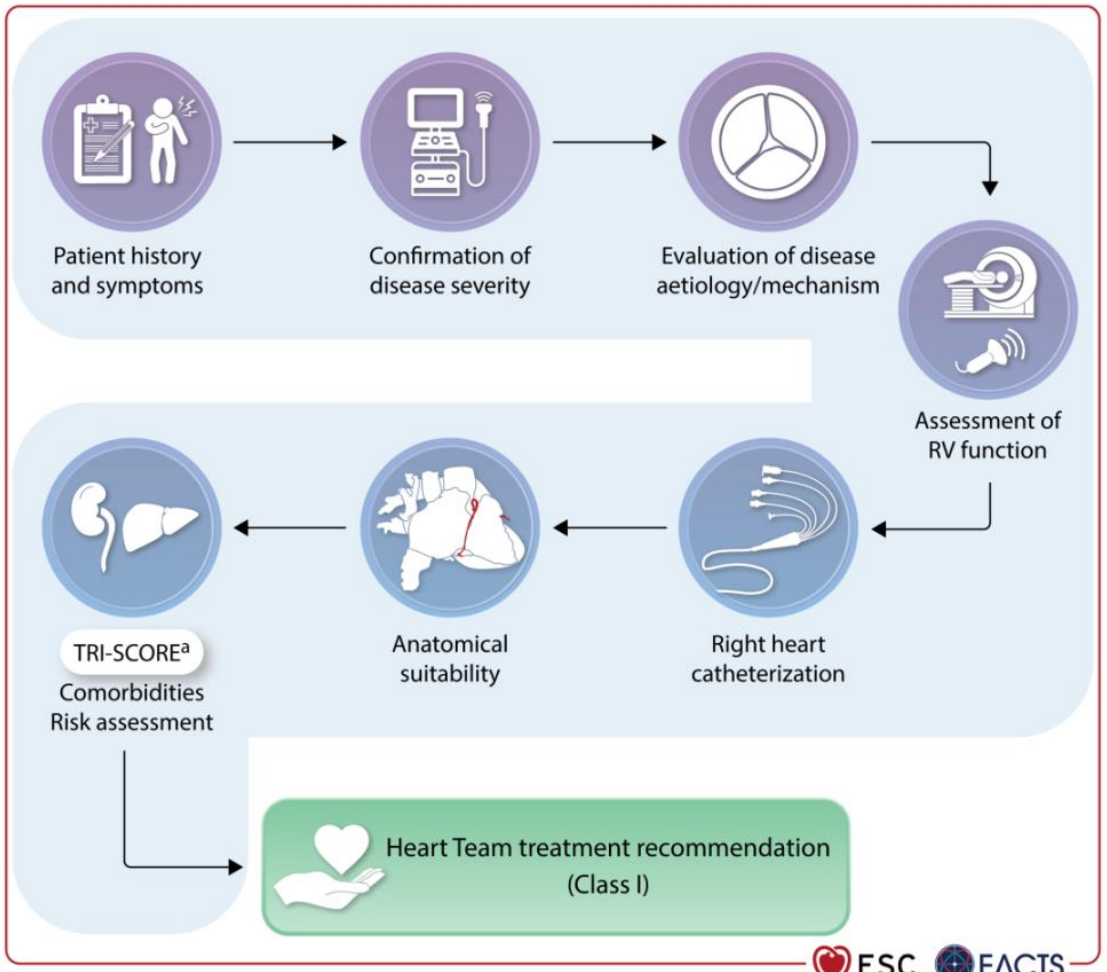
Adamo M. et al, *Eur J Heart Fail* 2024



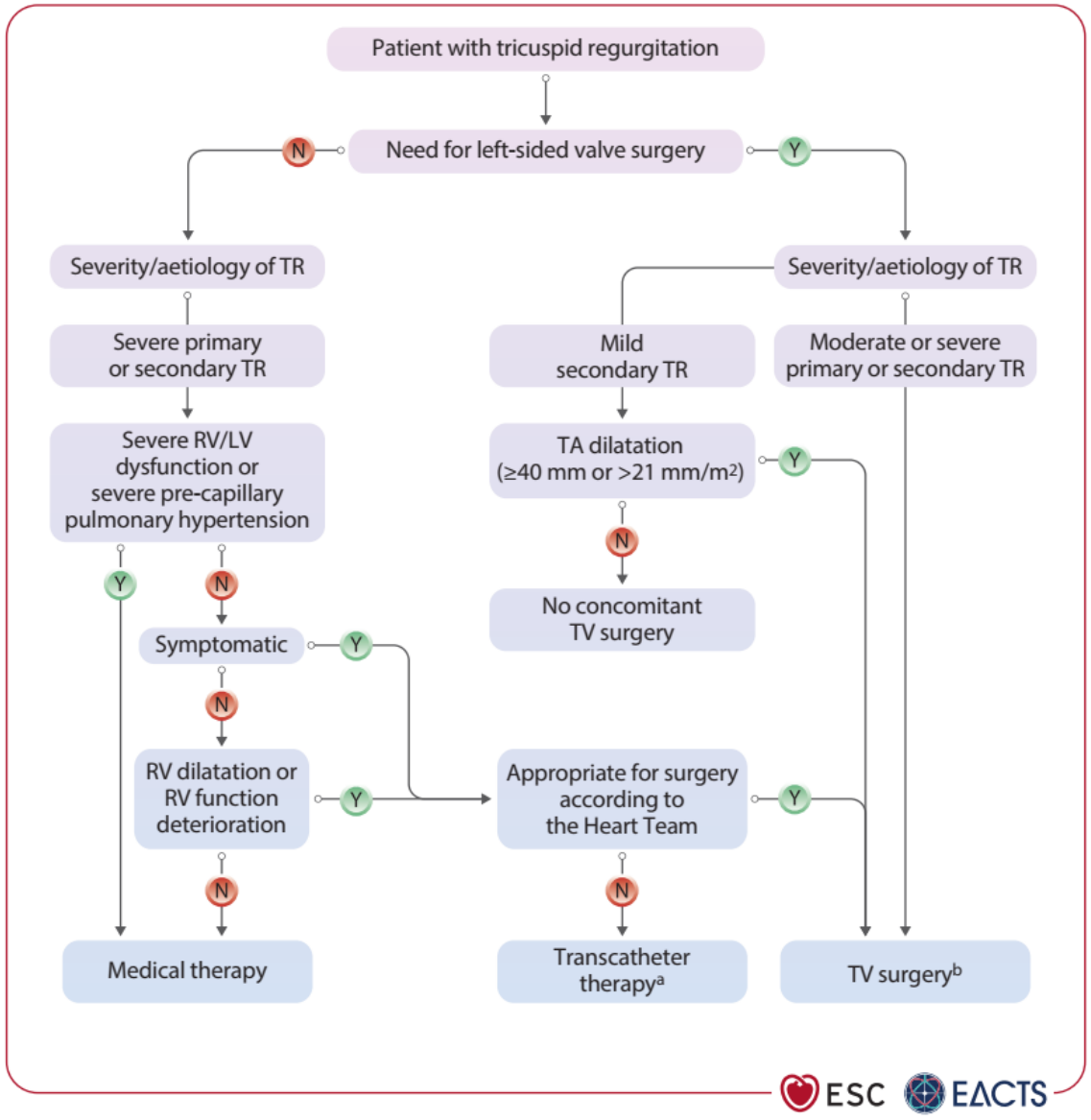
Landscape of currently most important transcatheter tricuspid devices.

Nicola Buzzatti, Jean-Michel Juliard, Fabien Praz, Alec Vahanian, Azeem Latib, Eric Brochet, Phalla Ou, Dominique Himbert, Mirjam Wild, Domenico Angellotti, The PCR-EAPCI Textbook.





Transcatheter TV treatment should be considered to improve quality of life and RV remodelling in high-risk patients with symptomatic severe TR despite optimal medical therapy in the absence of severe RV dysfunction or pre-capillary PH.[713,733,735,738,748–751]	IIa	A



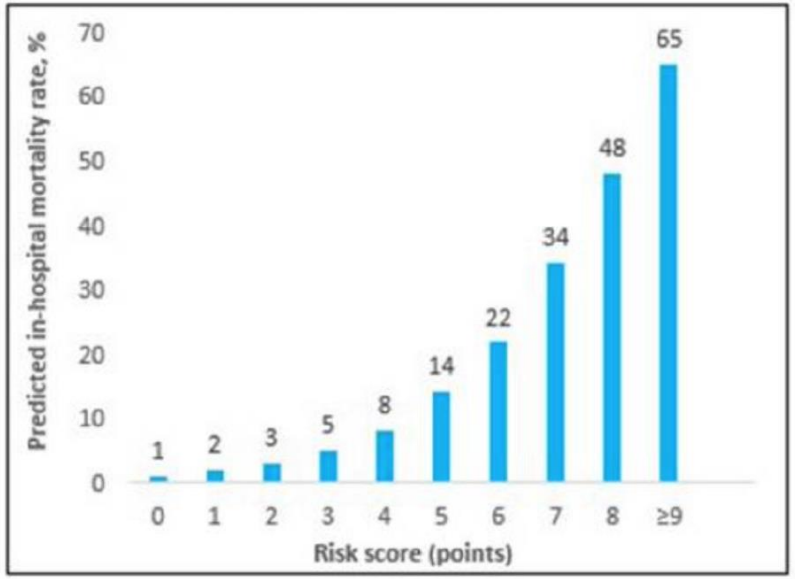
TRISCORE

Risk factors and scoring system for in-hospital mortality after isolated tricuspid valve surgery

Risk factors (final model from multivariate analysis)	Scoring
Age ≥ 70 years	1
NYHA functional class III-IV	1
Right-sided heart failure signs	2
Daily dose of furosemide ≥ 125mg	2
Glomerular filtration rate < 30 ml/min	2
Elevated total bilirubin	2
Left ventricular ejection fraction < 60%	1
Moderate/severe right ventricular dysfunction	1
Total	12

Dreyfus J. et al, *Eur Heart J* 2023

Predicted in-hospital mortality rate according to the final risk score model



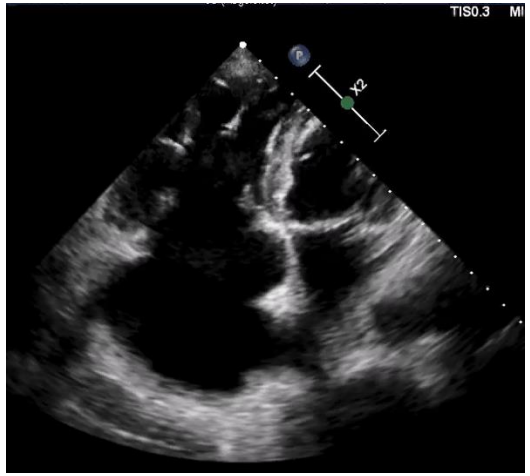
The 5-grade system

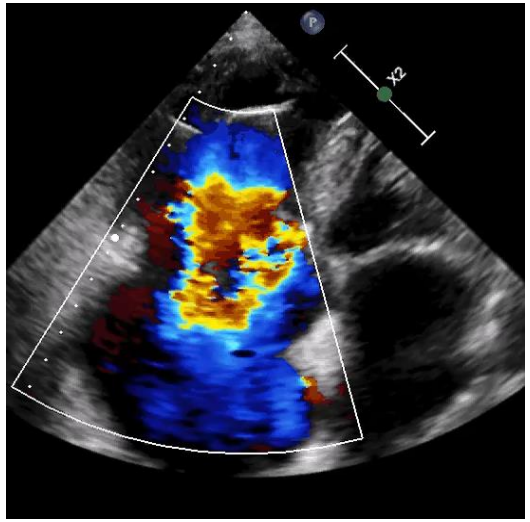
Table I Proposed expansion of the 'Severe' grade

Variable	Mild	Moderate	Severe	Massive	Torrential
VC (biplane)	<3 mm	3-6.9 mm	7–13 mm	14–20 mm	≥21 mm
EROA (PISA)	<20 mm^2	20–39 mm^2	40–59 mm^2	60–79 mm^2	≥80 mm^2
3D VCA or quantitative EROA[a]			75–94 mm^2	95–114 mm^2	≥115 mm^2

VC, vena contracta; EROA, effective regurgitant orifice area; 3D VCA, three-dimensional vena contracta area.
[a]3D VCA and quantitative Doppler EROA cut-offs may be larger than PISA EROA.

Hahn R. and Zamorano JL., The need for a new tricuspid regurgitation grading scheme. Eur Heart J Cardiovasc Imaging. 2017 Dec 1;18(12):1342-1343.





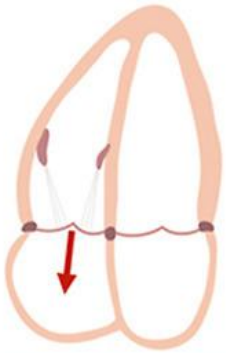
From severe to torrential, when is time to refer a patient?

Mild — Moderate — Severe — Massive — Torrential

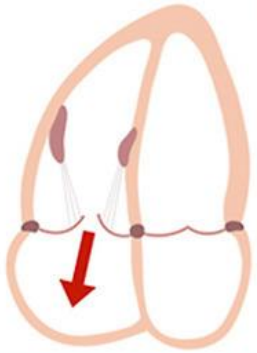
Too early ***Too late***

Early to Timely Treatment	Timely Treatment	Late Presentation

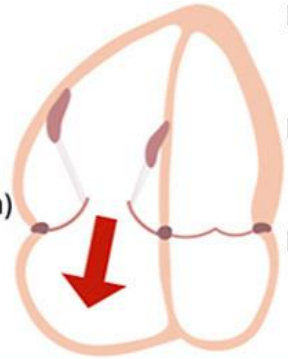
Echocardiographic Characteristics



I. RV function normal with absent or subtle RV/RA remodeling
II. Absent or mild leaflet tethering and annular remodeling
III. Moderate-to-severe/severe TR with absent or small coaptation gaps



I. Mild/moderate RV dysfunction with RV/RA remodeling
II. Varying degrees of leaflet tethering (<1.0 cm) and annular remodeling (≥40 mm)
III. ≥Severe TR with varying degrees of coaptation gaps (<0.8 cm)



I. Severe RV dysfunction with progressive RV/RA remodeling
II. Significant leaflet tethering (≥1.0 cm) and annular remodeling (≥40 mm)
III. Massive/torrential TR with significant coaptation gaps (≥0.8 cm)

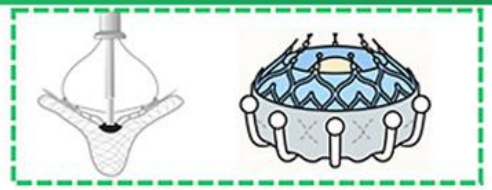
Clinical Characteristics

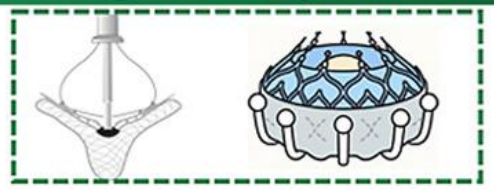
I. Mild or absent symptoms (NYHA I/II)
II. Normal renal/hepatic function
III. Normal or mildly elevated pulmonary artery pressures
IV. Absent or mild edema
V. Normal mobility/ capability to fulfil daily routine

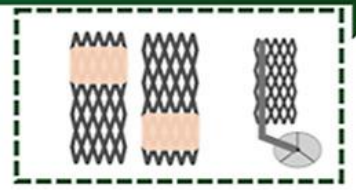
I. Varying degrees of symptoms at exertion (NYHA II/III)
II. Impaired renal/hepatic function
III. Elevated pulmonary artery pressures
IV. Presence of edema/ascites
V. Impaired mobility/ impaired capability to fulfil daily routine

I. Symptoms at rest (NYHA IV)
II. Severely impaired renal/hepatic function
III. Manifest pulmonary hypertension
IV. Presence of edema/ascites
V. Dependent on assistance for mobility and daily routine

Potential Treatment Strategies + Optimal Medical Treatment



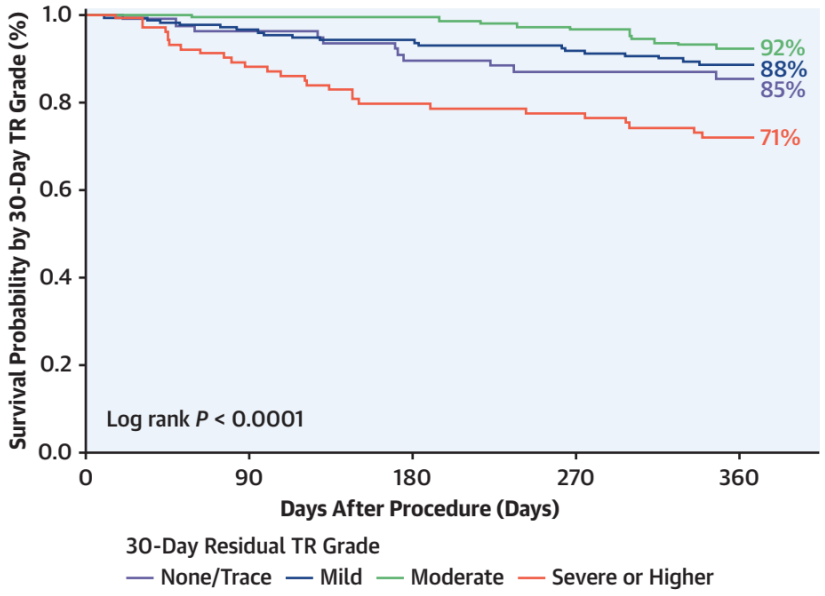




Von Stein J, Structural Heart 10 (2026) 100788

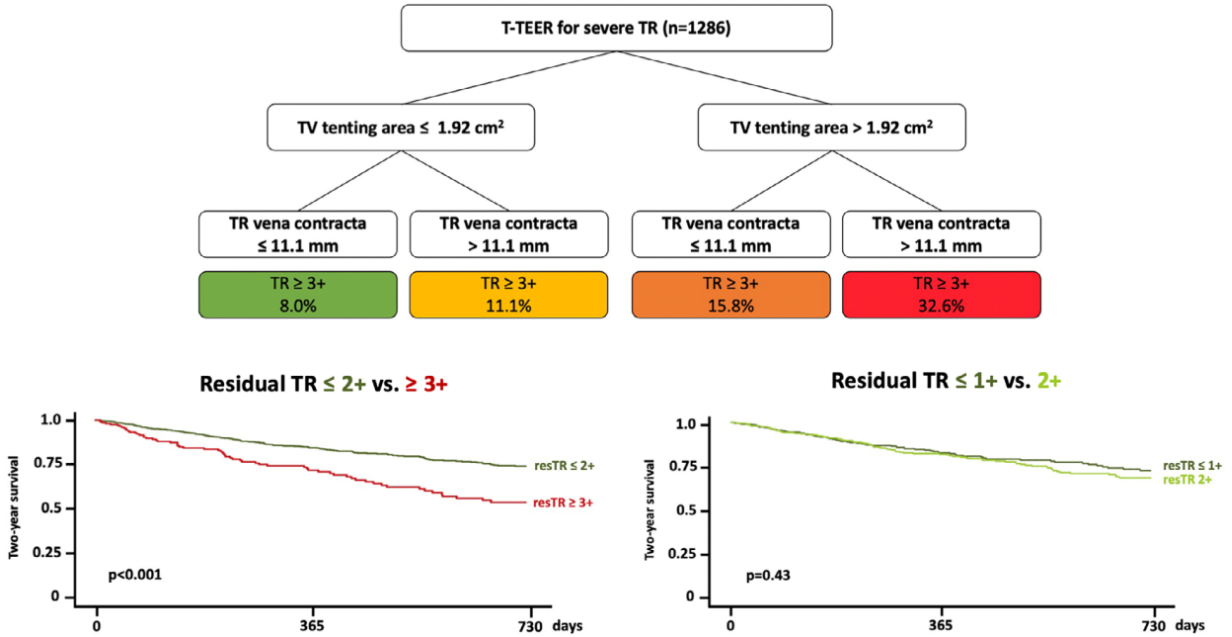
Prognose einer residuellen TI >=3+ ist deutlich schlechter

bRIGHT Register



Lurz P, et al. J Am Coll Cardiol 2024;84:607–616

EuroTR Register



Stolz L, Geisler T, Hausleiter, et al, Eur J Heart Failure (2024) 26, 1850–1860

Prävalenz einer residuellen TR >=3+

Table 1 Tricuspid regurgitation rates at discharge or 30-day follow-up in currently available transcatheter tricuspid valve intervention studies and registries

TR at discharge or 30 days	TRILUMINATE[3]	Tri.Fr[2]	PASTE[9]	bRIGHT[10]	EuroTR[11]	TRISCEND II[12]
≤1+	52%	38%[a]	55%	53%	42.4%	98.1%
2+	38%	41%[a]	32%	32%	40.0%	1.9%
≥3+	10%	21%[a]	13%	15%	17.6%	0.0%

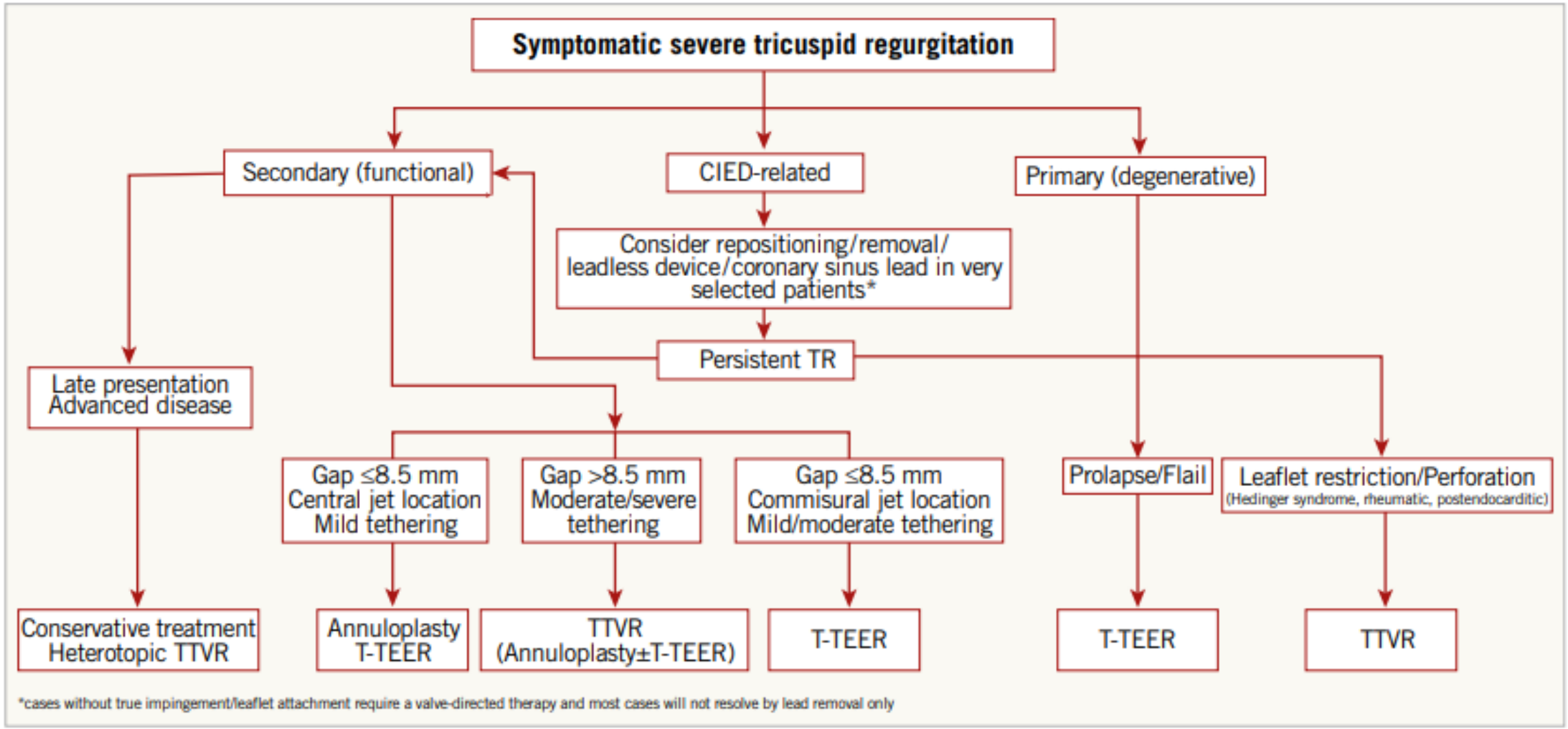
TR, tricuspid regurgitation.
[a]Estimated values derived from supplemental charts of the Tri.Fr study.

T-TEER

TTVR

Stolz L, et al. Eur J Heart Failure (2025) 27, 1496–1499

Differenciated Device Selection Transcatheter Tricuspid Therapy



TR, tricuspid regurgitation; CIED, cardiac implantable electronic device; T-TEER, tricuspid transcatheter edge-to-edge repair; TTVR, tricuspid transcatheter valve replacement
Praz F, Muraru D, Kreidel F, et al. EuroIntervention 2021;17:791-808

GLIDE Score

Scoring System for Prediction of Procedural Success in Tricuspid Valve Transcatheter Edge-to-Edge Repair

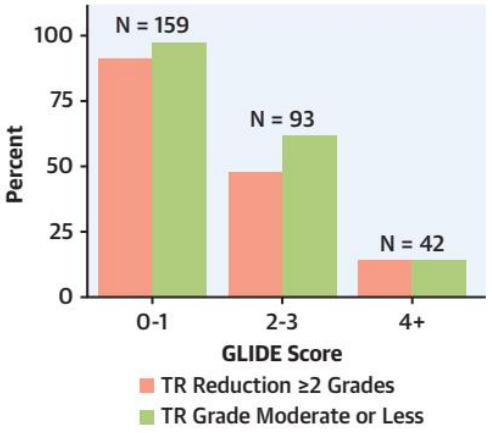
Muhammed Gerçek, MD,[a,b] Akhil Narang, MD,[b] M. Isabel Körber, MD,[c] Kai P. Friedrichs, MD,[a] Jyothy J. Puthumana, MD,[b] Maria Ivannikova, MD,[a] Mohamed Al-Kazaz, MD,[b] Paul Cremer, MD,[b] Abigail S. Baldridge, MS,[b] Zhiying Meng, MS,[b] Peter Luedike, MD,[d] James D. Thomas, MD,[b] Tanja K. Rudolph, MD,[a] Tobias Geisler, MD,[e] Tienush Rassaf, MD,[d] Roman Pfister, MD,[c] Volker Rudolph, MD,[a] Charles J. Davidson, MD[b]

CENTRAL ILLUSTRATION The GLIDE Score

The GLIDE Scoring System

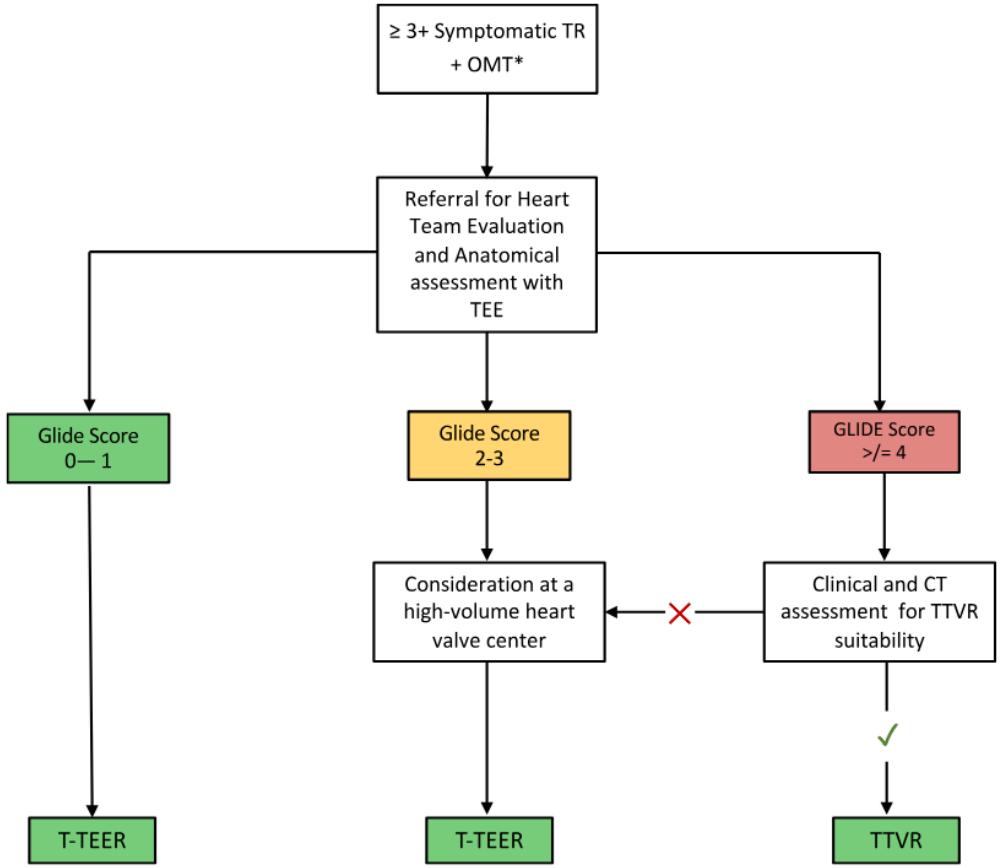
Parameters	Straightforward (0 points)	Complex (1 point)
Septolateral Gap	0-5 mm	≥6 mm
Predominant Jet Location	Anteroseptal/ Central	Posteroseptal/ Anteroposterior/Diffuse
Image Quality	Good	Limited
Chordal Structure Density	Modest	High
En Face TR Jet Morphology	Oval/Linear	Star-Shaped

Procedural Success in Each GLIDE Score Group



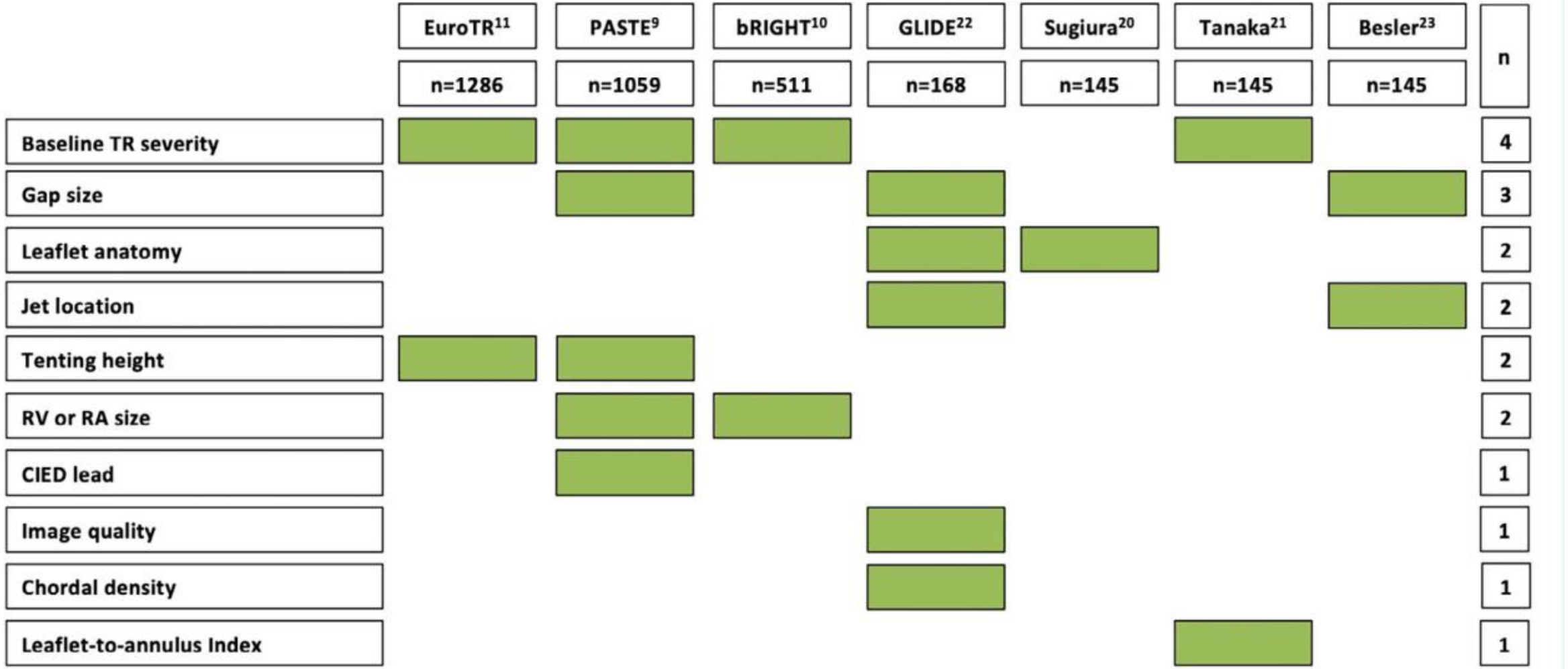
Gerçek M, et al. J Am Coll Cardiol Img. 2024;17(7):729-742.

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



Kempton H et al. Structural Heart 9 (2025) 100732

Prädiktoren eines schlechten prozeduralen Erfolges nach T-TEER

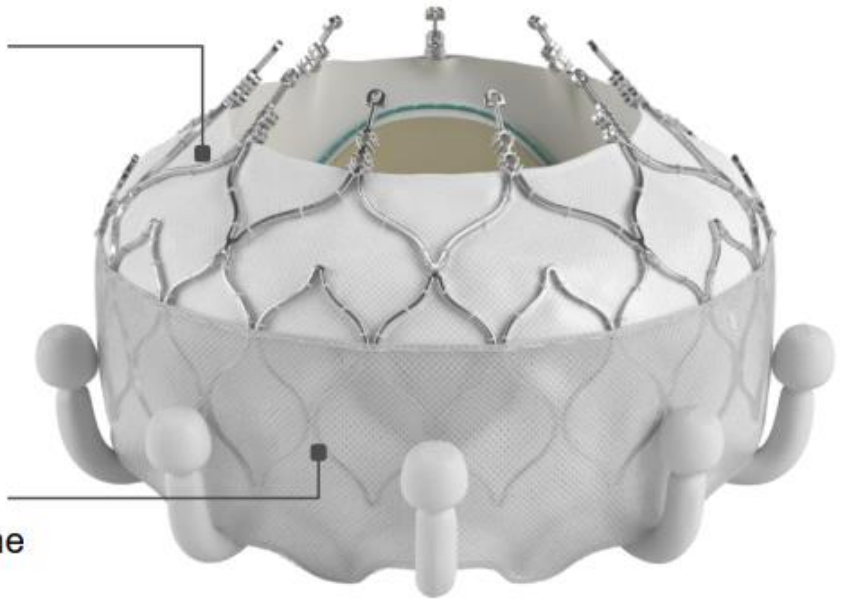


Stolz L, et al. Eur J Heart Failure (2025) 27, 1496–1499

EVOQUE Transcatheter Tricuspid Valve Replacement System

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

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



4 sizes treat wide range of anatomies

44mm 48mm 52mm 56mm

Delivery System

Transfemoral

28 Fr outer diameter

3 planes of movement

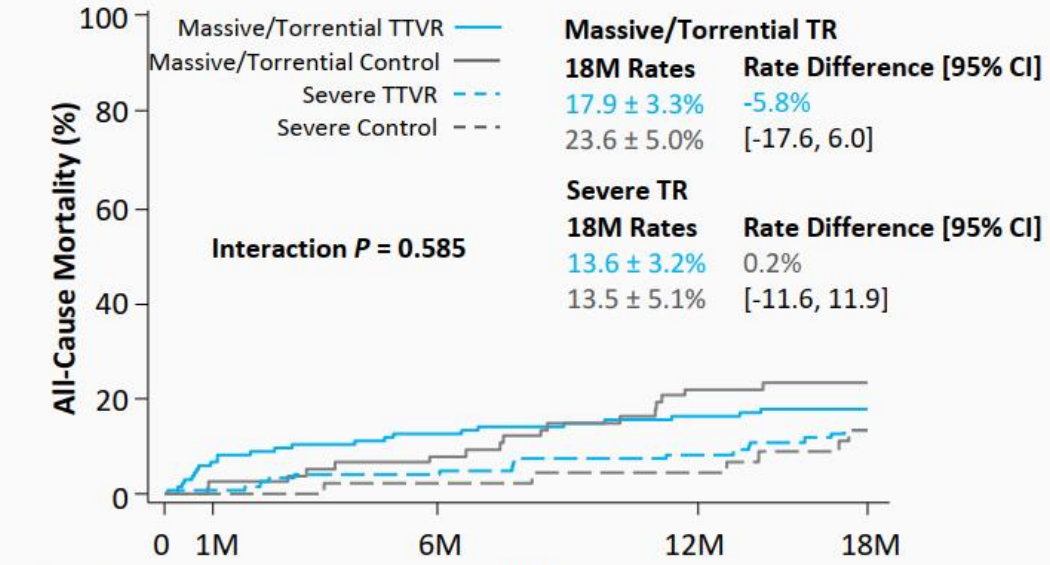
CRF® TCT®

TV replacement outcomes by baseline TR severity: subananalysis of TRISCEND II trial

CEC-adjudicated Kaplan-Meier estimates to 18 months

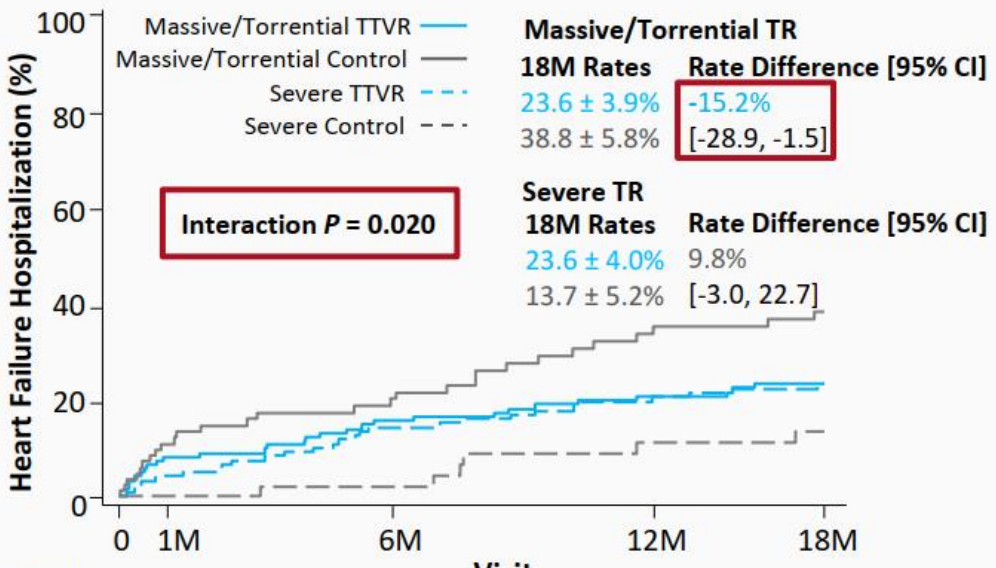
THE TRISCEND II PIVOTAL TRIAL

All-Cause Mortality



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

Heart Failure Hospitalization



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

Kaplan-Meier estimates include standard error. *CEC*, clinical events committee; *TR*, tricuspid regurgitation; *TTVR*, transcatheter tricuspid valve replacement. **Crossover patients were included in the analysis.**

Lurz P, presented at ESC 2025, published European Heart Journal (2025) 00, 1–15

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 18, NO. 15, 2025

ORIGINAL RESEARCH

STRUCTURAL

Early Outcomes of Real-World Transcatheter Tricuspid Valve Replacement

Domenico Angellotti, MD,[a,b] Isabel Mattig, MD,[c] Daryoush Samim, MD,[a,d] Björn Goebel, MD,[e] Charlotte Jantsch, MD,[f] Barbara Rubinic, MS,[g,h] Tobias Ruf, MD,[i] Tobias Geisler, MD,[j] Mirjam Kessler, MD,[k] Matti Adam, MD,[l] Lukas Stolz, MD,[m] Varius Dannenberg, MD,[f] Mohammad Kassar, MD,[a,g,n] Konstantinos Stathogiannis, MD,[o] Vincenzo Cesario, MD,[p] Nicolas Dumonteil, MD,[p] Michael Chrissoheris, MD,[o] Konstantinos Spargias, MD,[o] Stephan Baldus, MD,[l] Wolfgang Rottbauer, MD,[k] Muhammed Gerçek, MD,[g,h] Philippe M. Bartko, MD,[f] Harald Lapp, MD,[e] Henryk Dreger, MD,[c] Jörg Hausleiter, MD,[m] Philipp Lurz, MD,[i] Stephan Windecker, MD,[a] Volker Rudolph, MD,[g,h,*] Fabien Praz, MD[a,*]

30-Day Outcomes of Real-World TTVR With Evoque System in Europe, N = 176

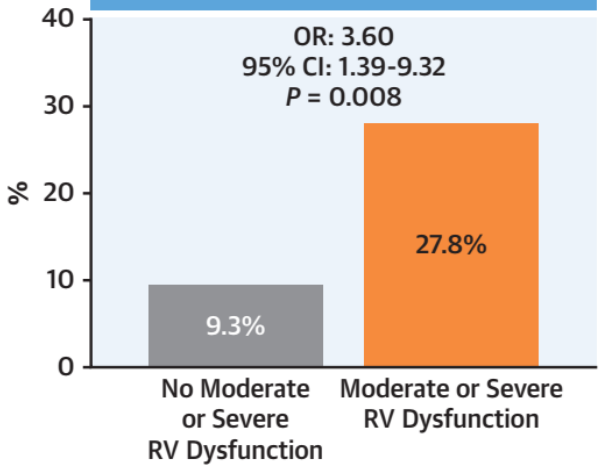
Patient Population

- Mean age 77.8 years
- 72% women
- Median TRI-SCORE 5 (IQR 2)
- Treated with the EVOQUE system October 2023 to February 2025
- 12 Heart Valve Centers

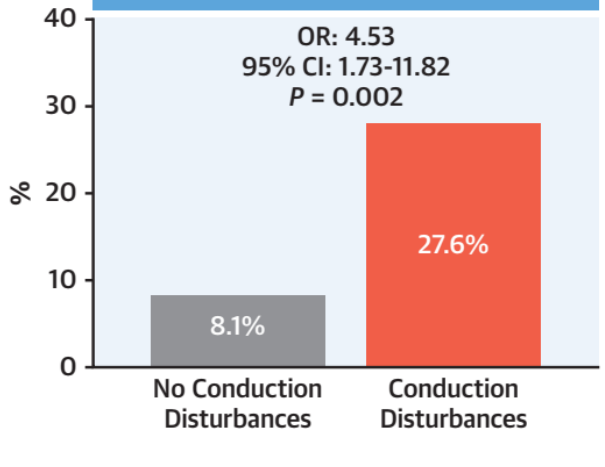
Outcomes at 30 Days

- T-VARC clinical success: 86.9%
- Improvement of ≥1 NYHA functional class: 71%
- Improvement in renal function: eGFR mean difference +6.7 mL/min/1.73 m^2, $P < 0.001$
- Reduction in bilirubin levels: mean difference −3.1 µmol/mL, $P < 0.001$

Frequency of Clinical Failure



Frequency of PPM Implantation

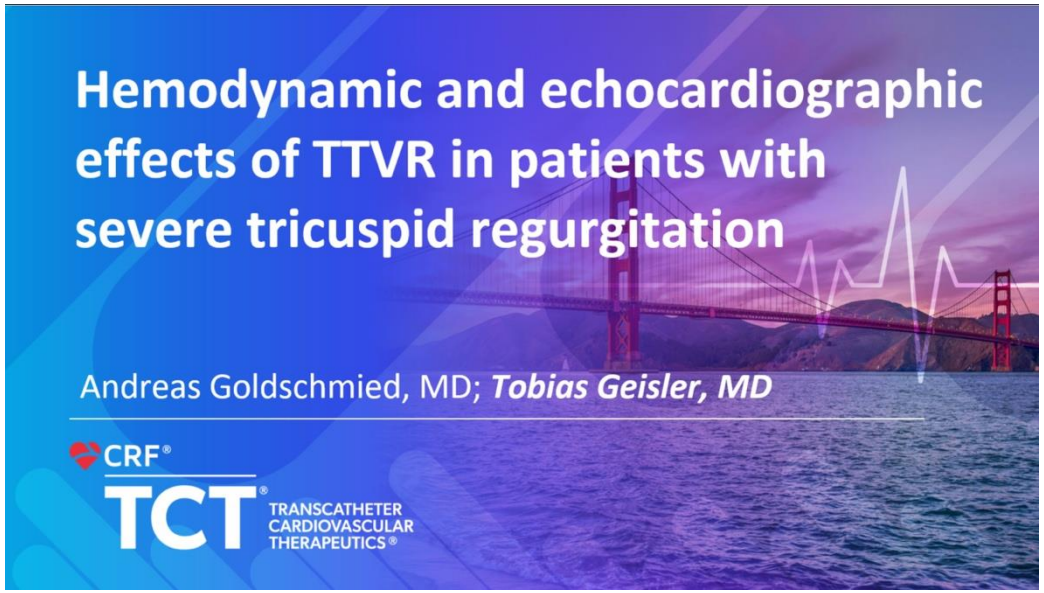


- Successful TR reduction after TTVR was associated with significant improvements in functional status and hepato-renal function.
- Moderate or severe RV dysfunction at baseline (20.5%) predicted clinical failure.
- Conduction disturbances at baseline (32.4%) predicted PPM implantation.

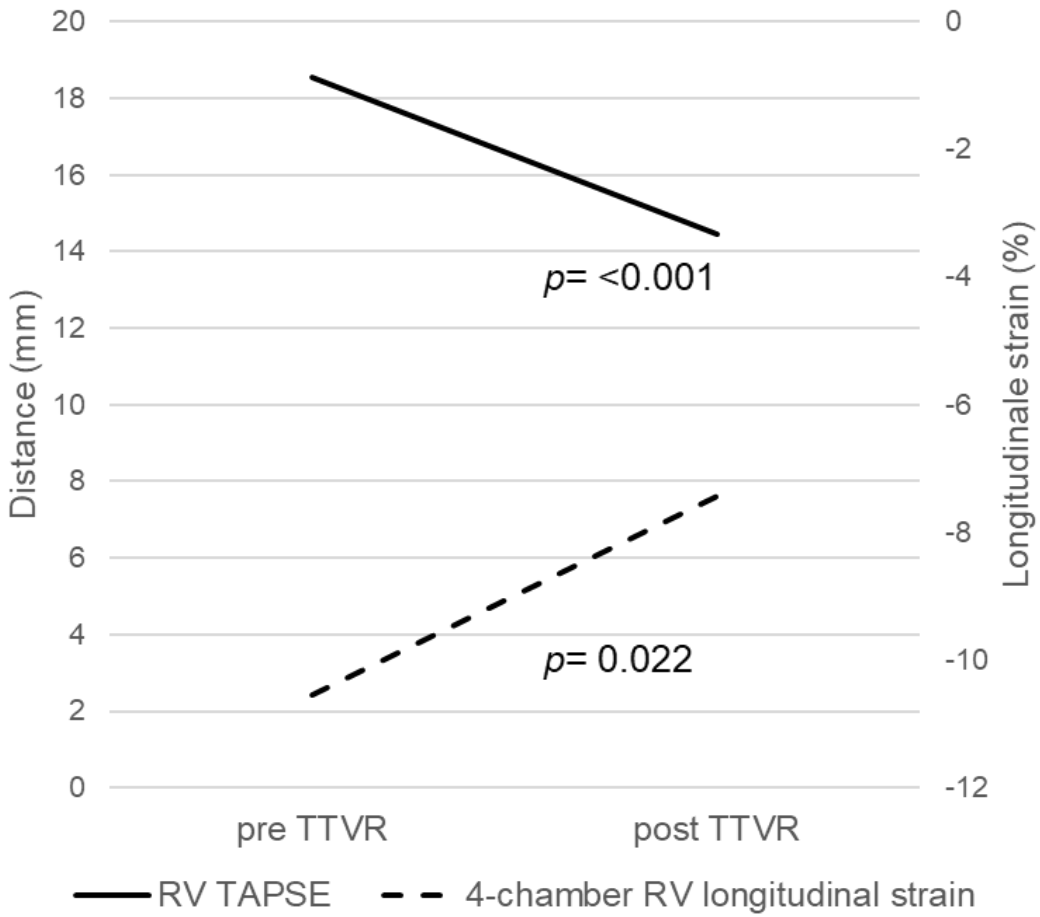
Angellotti D, et al. JACC Cardiovasc Interv. 2025;18(15):1896-1909.

One-month outcomes after transcatheter tricuspid valve replacement (TTVR). eGFR = estimated glomerular filtration rate; PPM = prosthesis-patient mismatch; RV = right ventricular; T-VARC = Tricuspid Valve Academic Research Consortium.

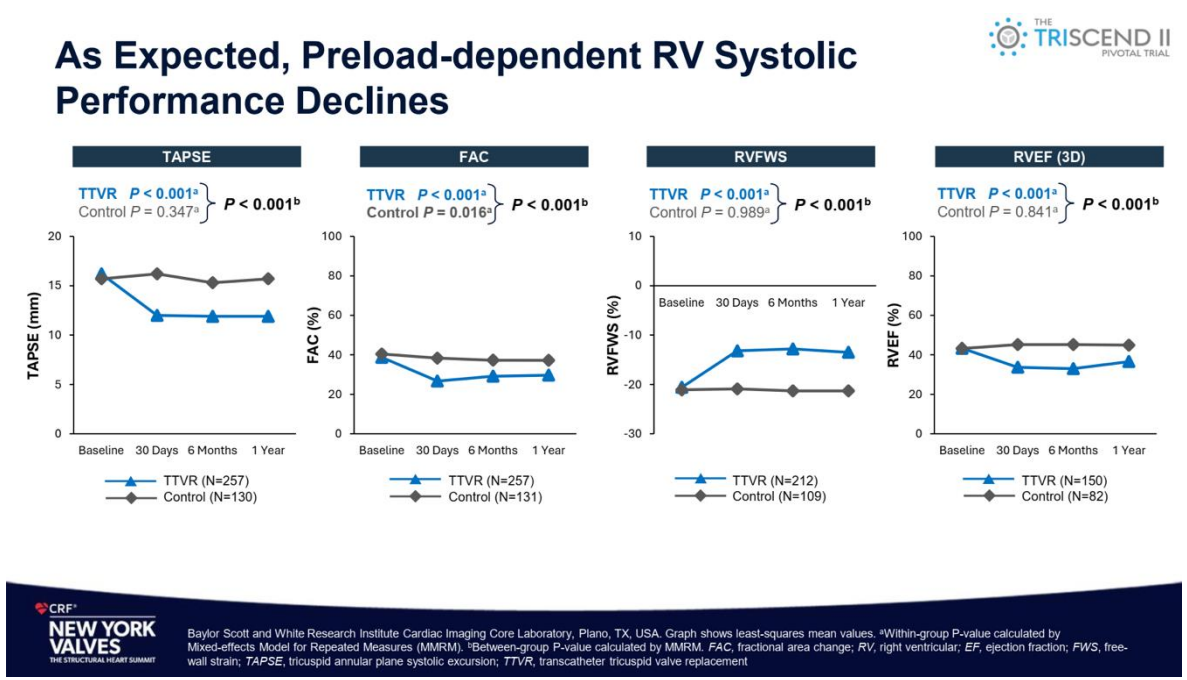
RV contractility after TTVR (EVOQUE)

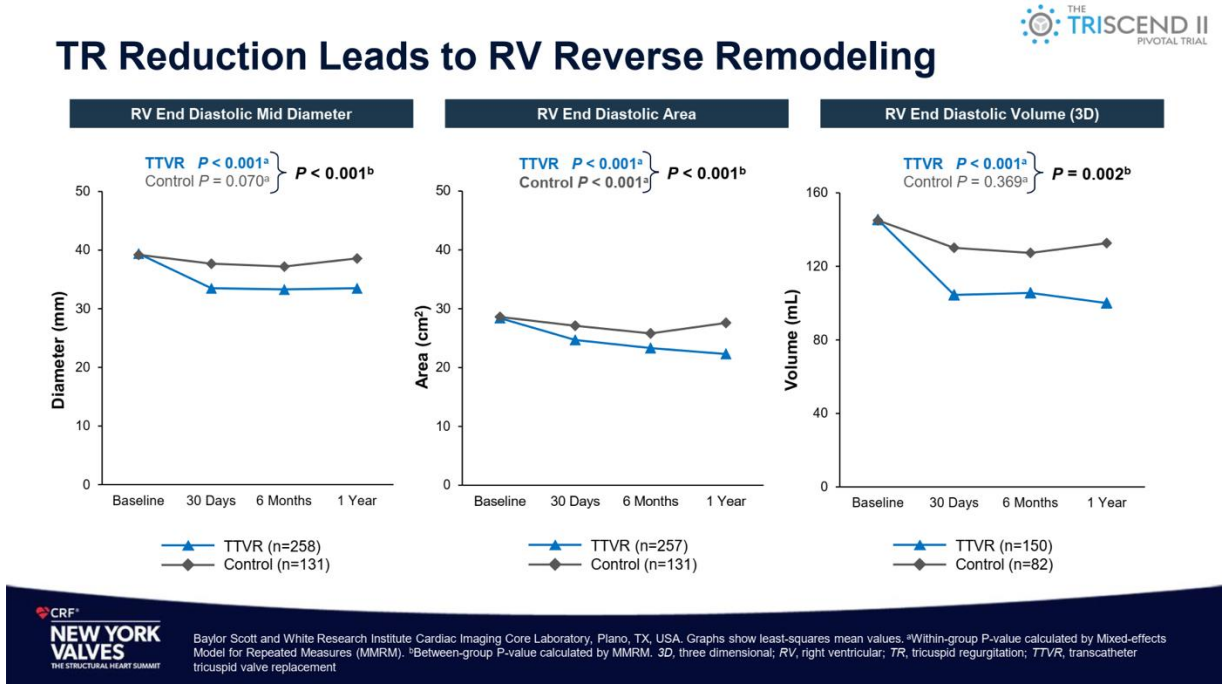


Systolic RV function decreases significantly



Kurz- und langfristige Effekte auf die RV-Funktion und Remodelling nach orthotoper TTVR

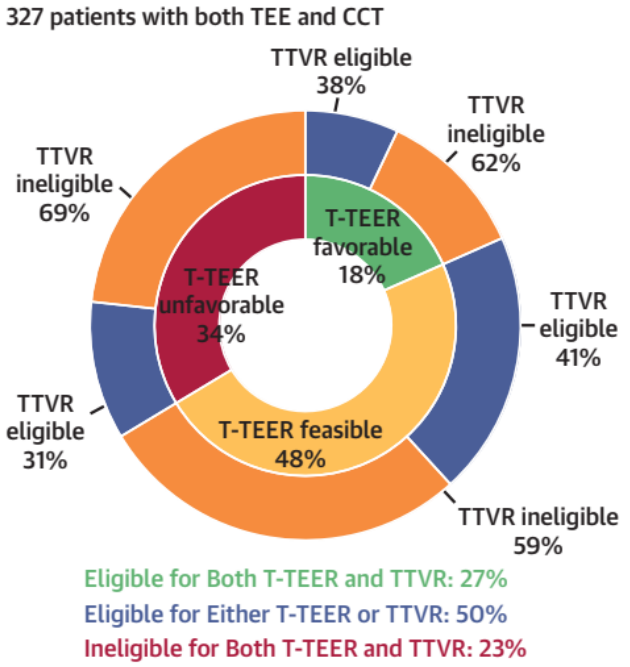




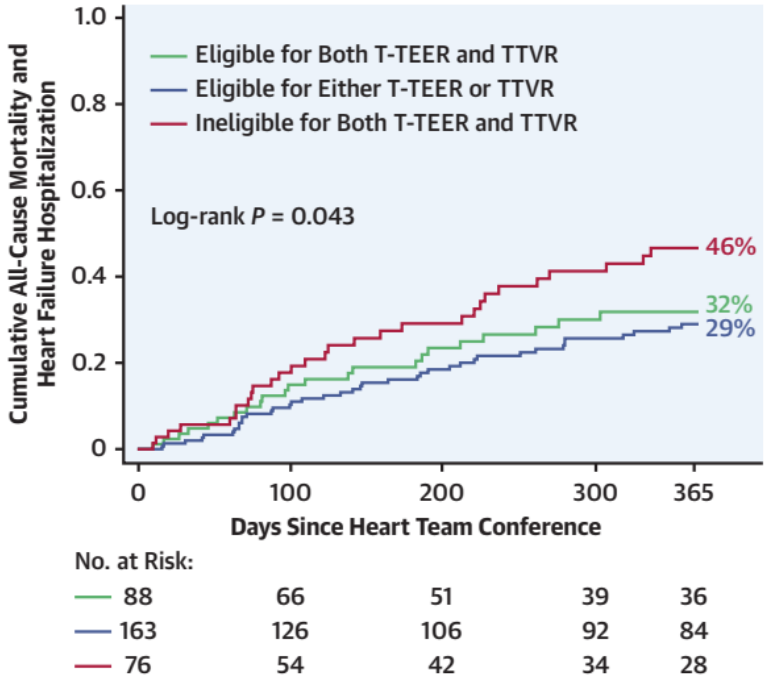
CENTRAL ILLUSTRATION Eligibility for TTVI in Current Clinical Practice

Retrospective Study of Eligibility for Transcatheter Tricuspid Valve Interventions in Patients With TR

Eligibility for TTVI



1-Year Clinical Outcome



- One-third of patients considered for TTVI had unfavorable anatomy for T-TEER
- TTVR was anatomically or clinically ineligible in nearly two-thirds of the patients
- 23% of the patients were ineligible for both T-TEER and TTVR and had a poor prognosis

Tanaka T, et al. JACC Cardiovasc Interv. 2024;17(23):2732-2744.

(Left) Prevalence of eligibility for tricuspid transcatheter edge-to-edge repair (T-TEER) and transcatheter tricuspid valve replacement (TTVR) in patients with tricuspid regurgitation (TR) with both transesophageal echocardiography (TEE) and cardiac computed tomography (CCT). (Right) Incidence of the composite outcome, consisting of mortality and heart failure hospitalization, according to eligibility for transcatheter tricuspid valve intervention (TTVI).

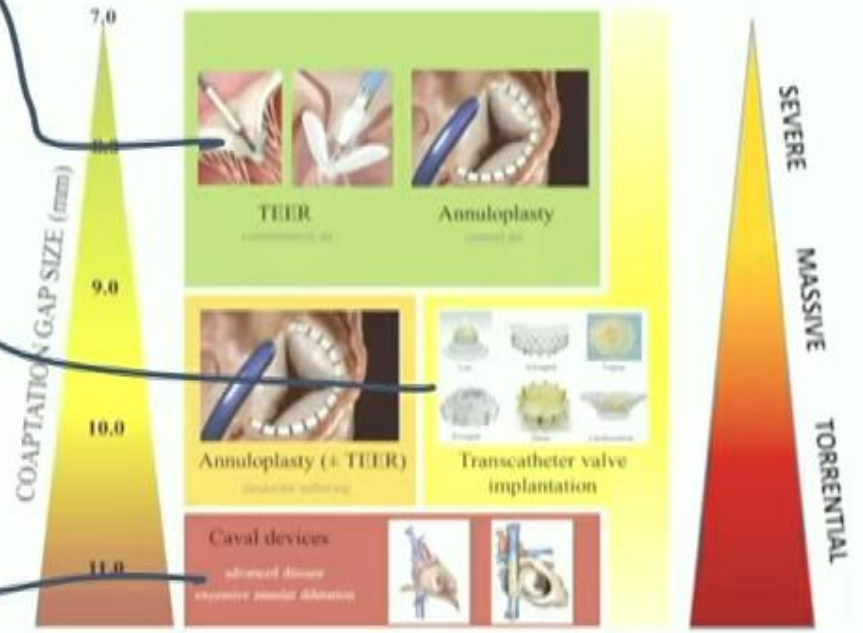
What is the target population for CAVI ?

Baseline characteristics

	TRILUMINATE	TRISCEND II	TRIC-BICAVAL REGISTRY
HF hospitalization (last year)	25.1%	34%	**60.8%**
Renal disease	35.4%	54%	**71.1%**
Massive or Torrential TR	72.3%	53%	**87.3%**
NT-proBNP (pg/ml)		1567	**3937**
NYHA III-IV	59.4%	75.4%	**82.4%**

Very high-risk profile / advanced stage of disease

Preclinical stage



RHF // Organ failure

Will MG, Praz F. J Am Coll Cardiol Intv 2022;15:1378-81

Sanchez-Recalde A, presented at London Valve 2025

How to find the right patient

TR III - V
(symptomatic / sec. organic dysfunction)

pulm. HTN specialist

prekapp. PH
PVR > 3 WU

PH-Safety Margin:
TR IV: + 10mmHg
TR V: + 15mmHg

TAPSE <18mm:
Evalute Type-2-Contr.
(3D-EF / FAC / MRI)

Heart-Team

RV/PA-Coupling > 0,4
PAP_i < 55mmHg

(T-TEER palliative)
periproced. expanded Monitoring

conservative

good result with TriClip predictable?

Full-Cycle-CT
(all-valves-protocol)

surgical approach @ low risk

T-TEER curative

heterotopic valve replacement

orthotopic valve replacement

pcrlondonvalves.com

Nikolai, presented at London Valve 2025

Device selection

	TEER	TTVR	TricValve
Low RV/PA-Coupling	(+)	-	-
Bad imaging conditions	-	-	+
ICD-Leads	+ -	+ -	+
Pacemakers leads	+ -	+	+
Very large annuli (> 60mm)	-	-	+
Complex anatomical situations (GLIDE Score >2)	(+) -	+	+
Failed TEER (partail leaflet detachament)	(+) -	+ -	+

Nikolai, presented at London Valve 2025

Right atrial remodelling orthotopic versus heterotopic replacement

RA Volumes after orthotopic TTVR (EVOQUE)

TABLE 5 Paired Baseline and 30-Day Follow-Up Echocardiographic Parameters

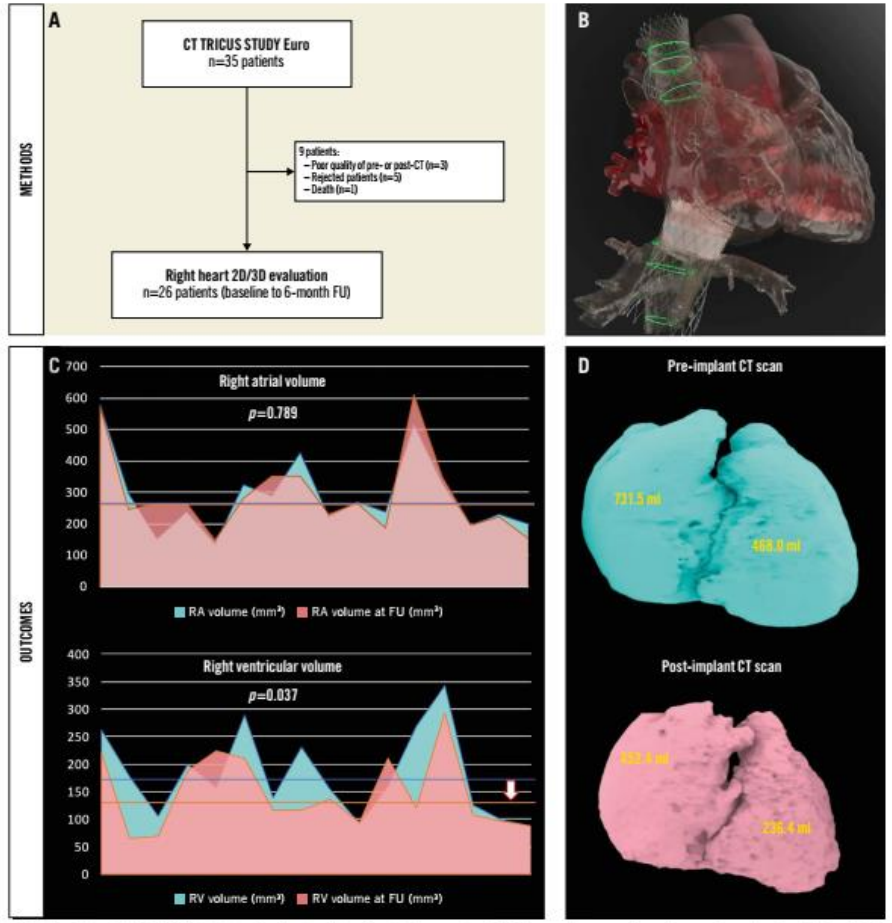
	n	Baseline	30 d	*P* Value[a]
PASP, mm Hg	31	40.1 ± 10.5	32.2 ± 10.2	0.002[b]
RV end-diastolic area, cm^2	45	33.1 ± 7.2	23.4 ± 7.1	<0.001[b]
RV end-systolic area, cm^2	45	20.5 ± 5.1	17.6 ± 5.8	0.001[b]
RV FAC, %	45	37.6 ± 9.3	24.8 ± 9.9	<0.001[b]
IVC diameter, expiration, mm	48	27.0 ± 7.1	21.3 ± 5.6	<0.001[b]
RA volume systolic, mL	52	154.1 ± 66.1	138.2 ± 61.8	0.009[b]
TAPSE, mm	24	14.9 ± 3.9	13.0 ± 3.2	0.035[b]
TV mean gradient, mm Hg	49	1.8 ± 1.1	3.4 ± 1.5	<0.001[b]
LVEF, %	47	53.4 ± 10.2	58.2 ± 10.4	0.014[b]

Values are mean ± SD. [a]*P* values calculated by Student's *t*-test for paired analysis. [b]Statistically significant.
FAC = fractional area change; IVC = inferior vena cava; LVEF = left ventricular ejection fraction; PASP = pulmonary artery systolic pressure; RA = right atrial; RV = right ventricular; TAPSE = tricuspid annular plane systolic excursion; TV = tricuspid valve.

Kodali, et al. J Am Coll Cardiol Intv 2022;15:471–480

RA Volumes after heterotopic TTVR (TRICVALVE)

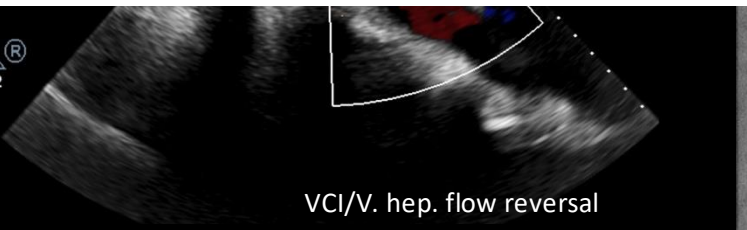
CENTRAL **ILLUSTRATION** Right heart remodelling following TricValve implantation (CT analysis).



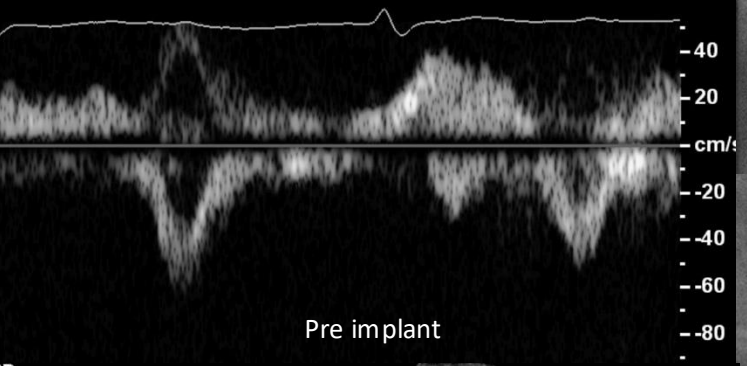
Study flowchart (A). TricValve implant simulation (B) and main changes in right heart volumes, reflected as a patient-level analysis of right atrial and ventricular volumes (C) after 3D reconstruction (the arrow reflects the decrease in mean right ventricular volume). Case example of significant decrease in right chamber volume (D). 2D/3D: two-/three-dimensional; CT: computed tomography; FU: follow-up; RA: right atrial; RV: right ventricular

Amat-Santos IJ EuroIntervention. 2023 Aug 7;19(5):e450-e452. doi: 10.4244/EIJ-D-23-00077. PMID: 37083622; PMCID: PMC10397665.

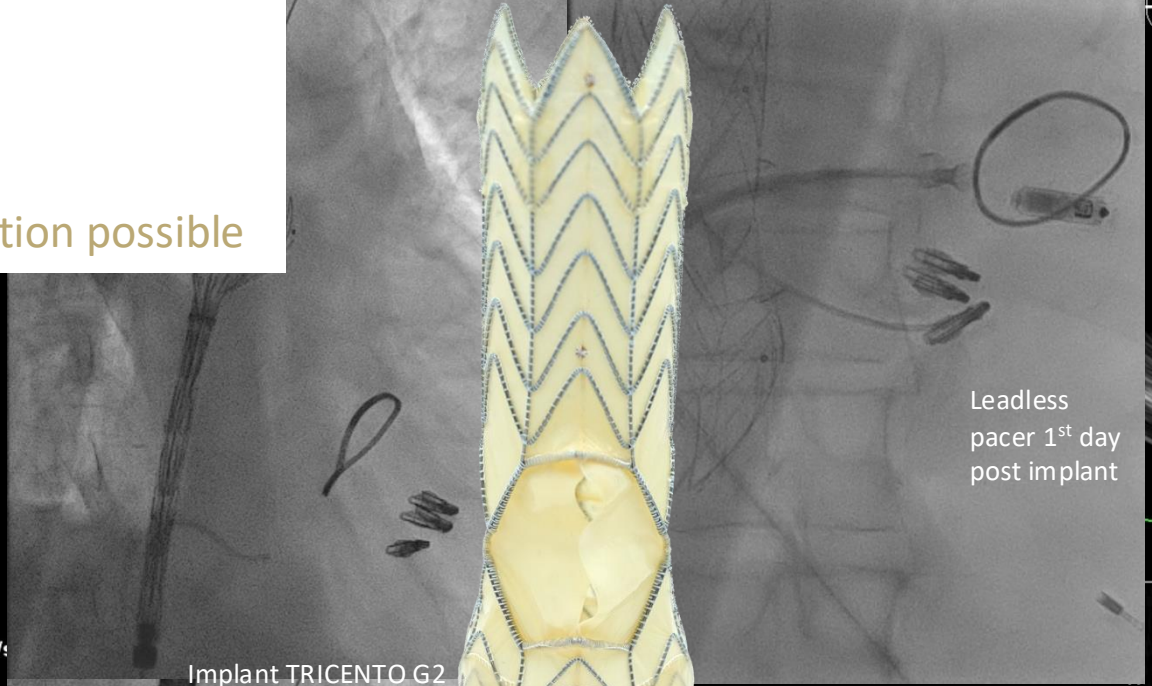
TRISCENTO Gen2
Compassionate Use
No Re-TEER
No orthotopic
No heterotopic (TRICVALVE) Implantation possible



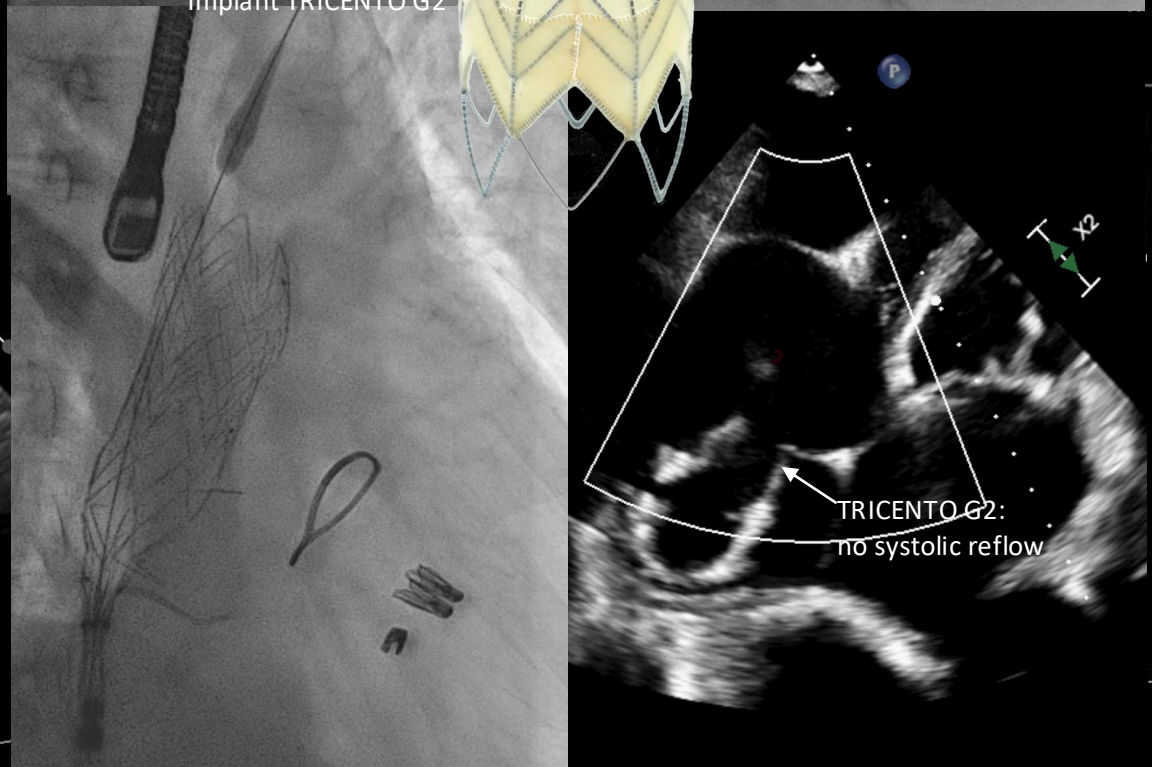
VCI/V. hep. flow reversal

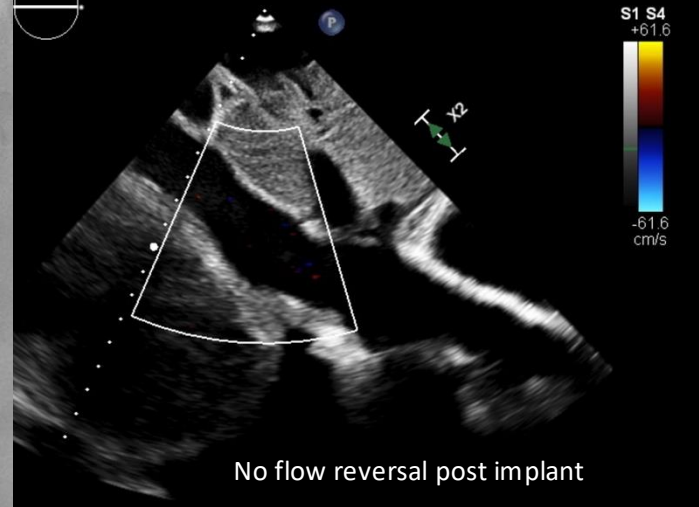


Pre implant



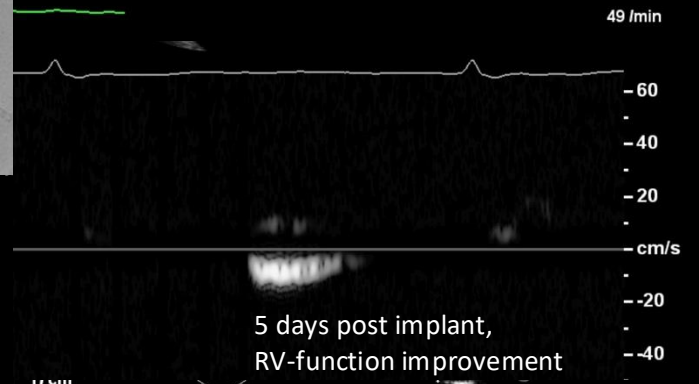
Implant TRICENTO G2



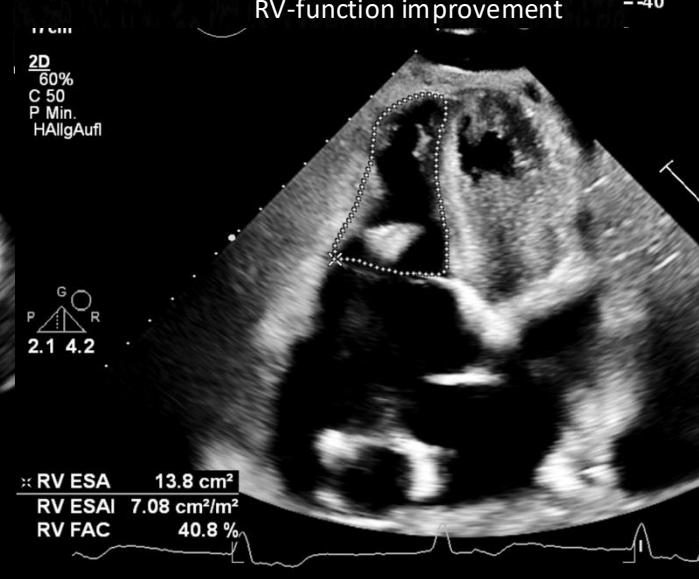


Leadless pacer 1st day post implant

No flow reversal post implant



5 days post implant, RV-function improvement

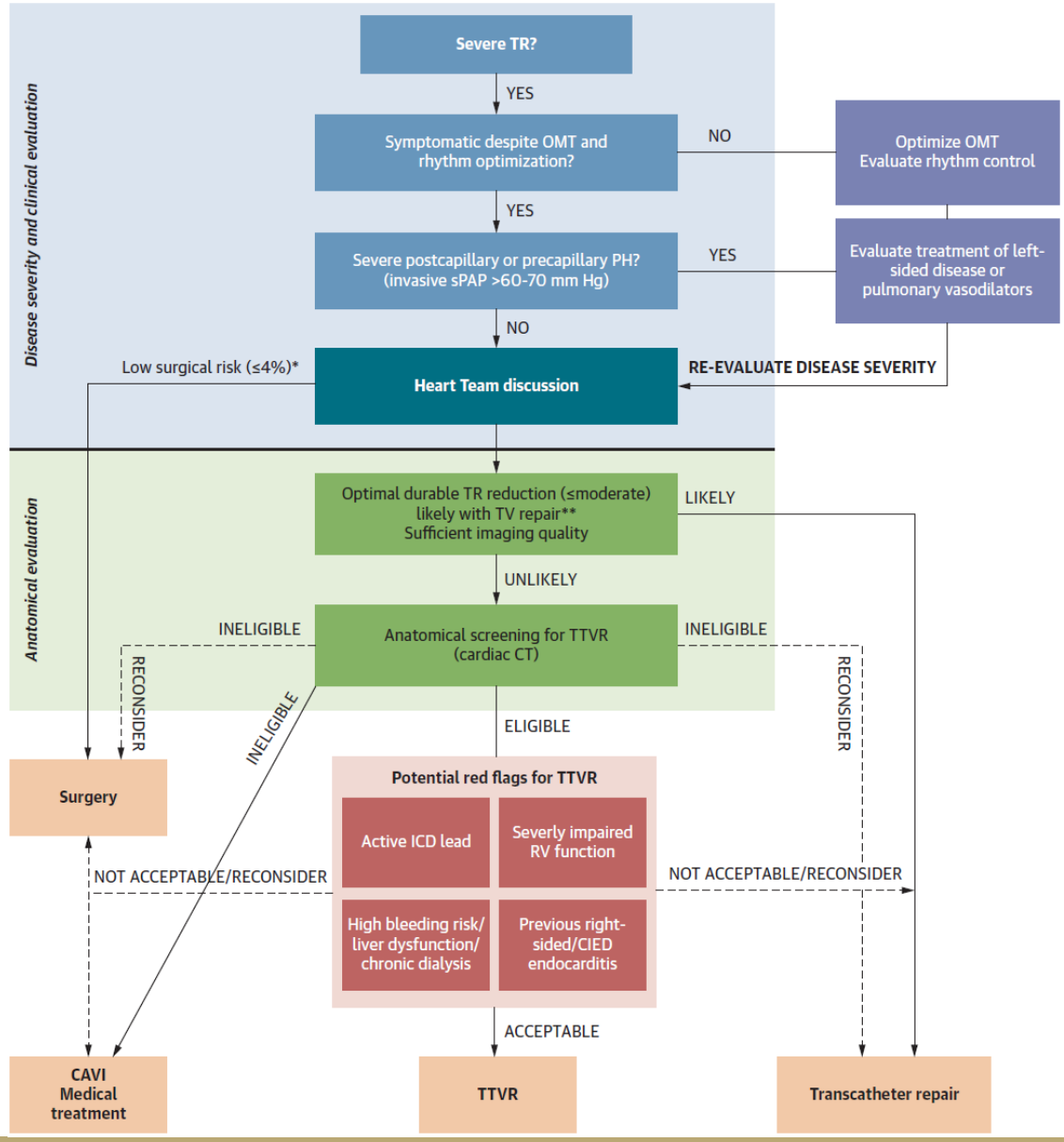


TRICENTO G2:
no systolic reflow

Proposed treatment algorithm for patients with ≥ severe TR focusing on the implementation of TTVR

Device selection should be based on several considerations including:

- Clinical and anatomical factors
- Lifetime management



TTVR: transcatheter tricuspid valve replacement; TR: tricuspid regurgitation; TV: tricuspid valve; CIED: cardiac implantable electronic device; ICD: implantable cardioverter-defibrillator; OMT: optimal medical treatment; PH: pulmonary hypertension; sPAP: systolic pulmonary artery pressure; RV: right ventricle; CAVI: caval valve implantation; CT: computed tomography

Hausleiter J. et al., J Am Coll Cardiol. 2025 Jan 28;85(3):265-291.

Zusammenfassung

- Patientenselektion und Timing spielen für die interventionelle AV-Klappentherapie eine entscheidende Rolle und beeinflussen das Verfahren
- Ziel sollte immer ein optimales Ergebnis mit dem gewählten Verfahren sein (d.h. MI ≤ 1+ und TI ≤ 2+)
- In der Mehrheit der Fälle kommt nach wie vor die edge-to-edge Therapie aufgrund der Sicherheit und auch günstiger Langzeitdaten (bis zu 5 Jahren bzw. 2 Jahren für M-TEER und T-TEER)
- Anatomische Besonderheiten/Bildgebungsqualtität, die mit einem schlechten prozeduralen Outcome verbunden sind, sollten in die Entscheidung für das geeignete Verfahren mit einbezogen werden (GLIDE-Score)
- Ein fortgeschrittener Verlauf und Begleiterkrankungen (LV-Dysfunktion/Dilatation, RV-Dysfunktion) bedürfen einer individuellen Risikoabwägung (erwartbarer Effekt auf die Lebensqualität, M-TEER als Bridging Option, ggf. heterotoper TK-Ersatz zur Symptomverbesserung bei mangelnden Alternativen)

→ Zukünftig werden differenzierter Therapieansätze an Bedeutung gewinnen

Vielen Dank für die Aufmerksamkeit!

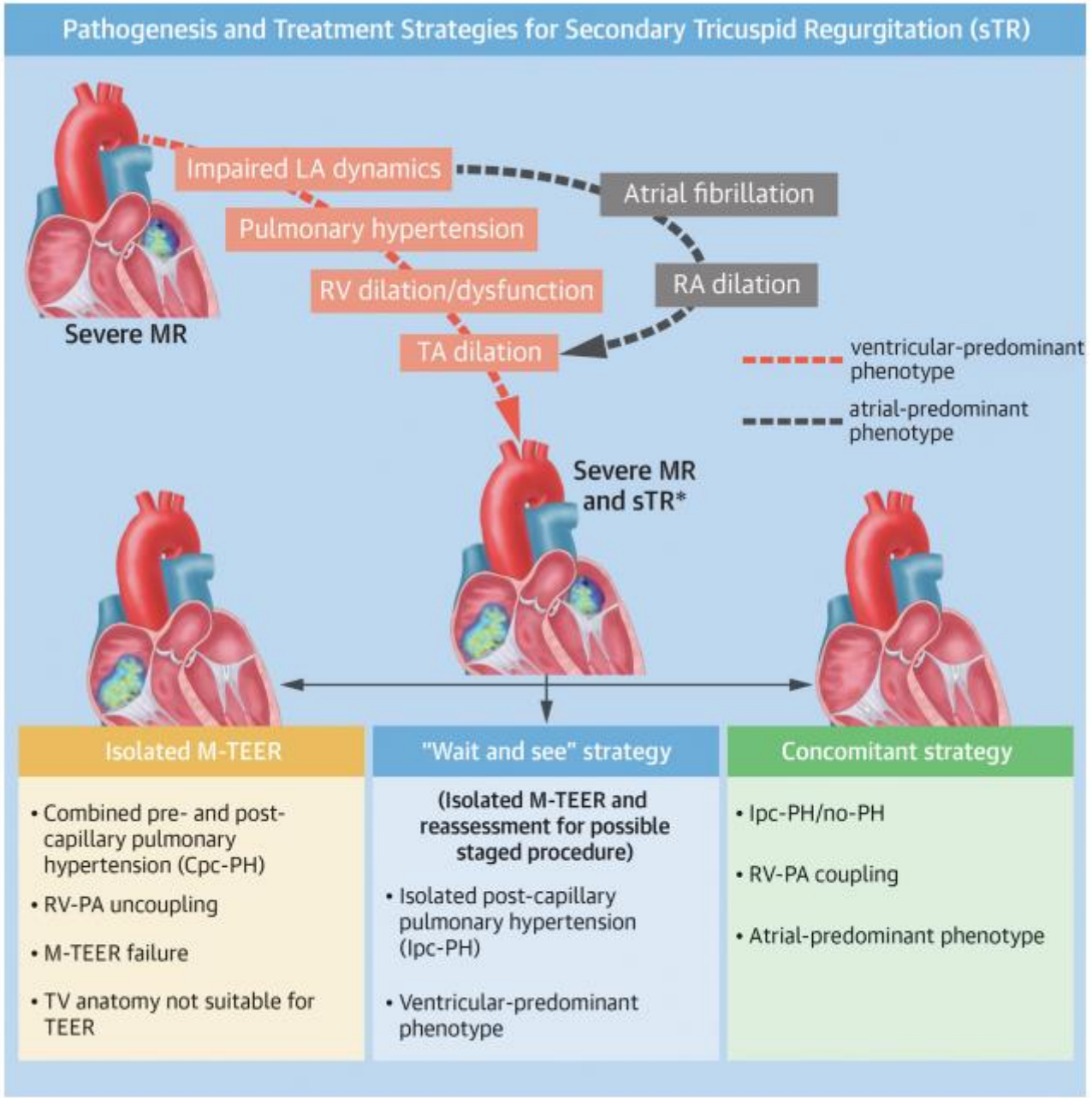
Universitätsklinikum Tübingen

12.03.2026

Backup

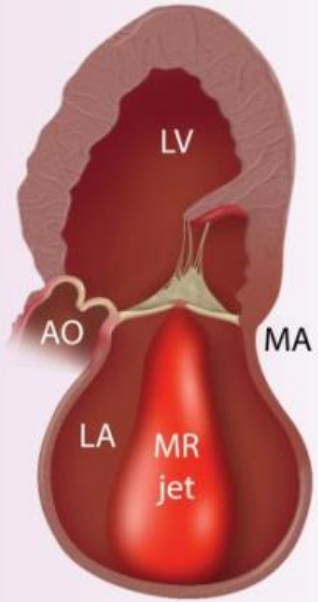
Universitätsklinikum Tübingen

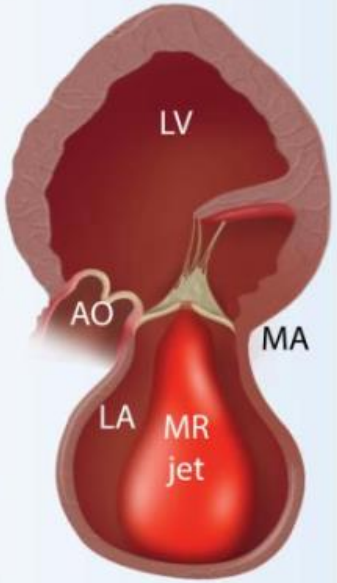
12.03.2026



Sisinni A, et al. J Am Coll Cardiol Intv. 2023;16(2):127-139.

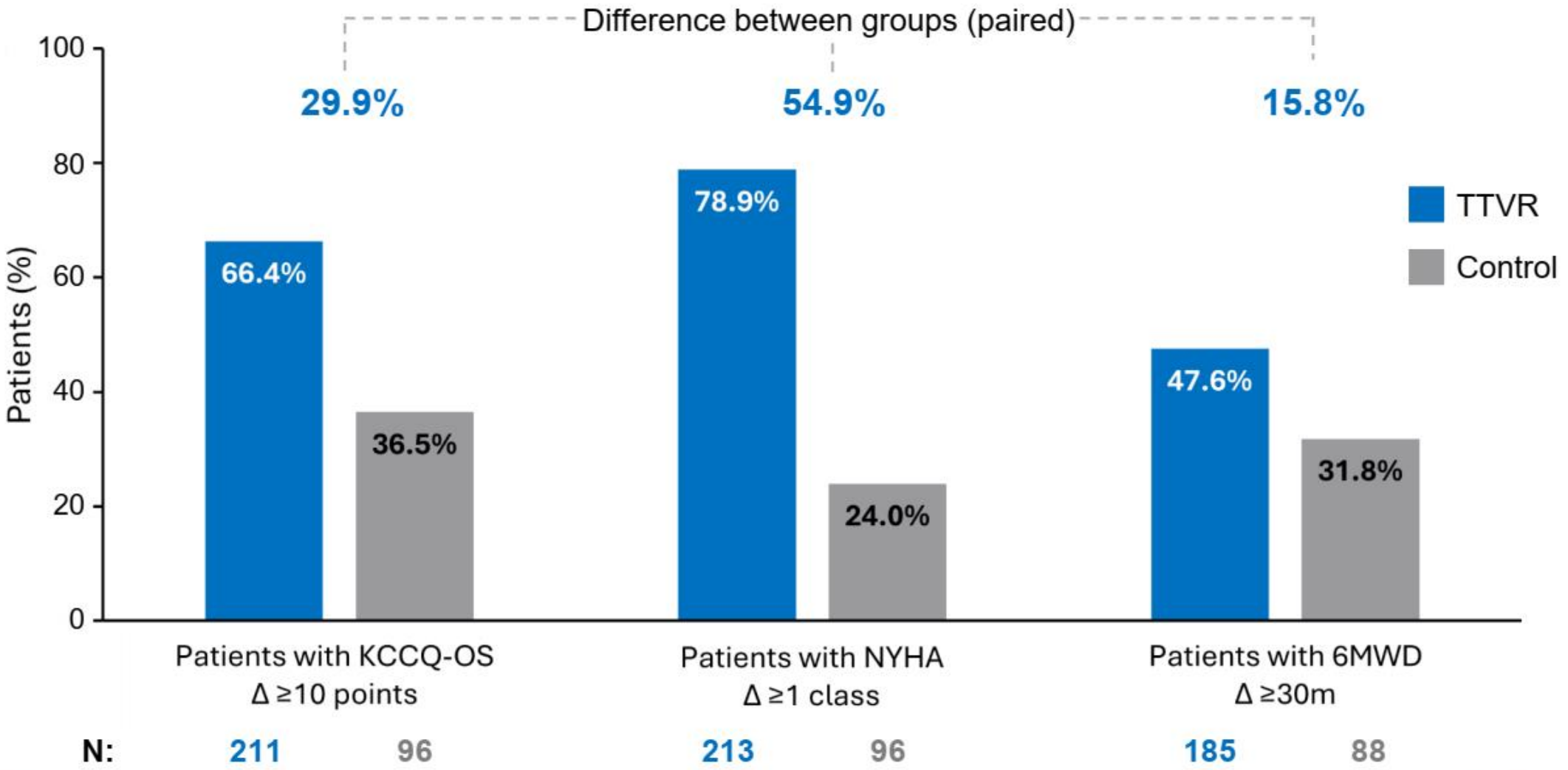
Atrial SMR	Key criteria	Ventricular SMR
	LVEF ≥50% without regional wall motion abnormalities	LVEF <50% with or without regional wall abnormalities
	No or mildly dilated LV cavity[a] without leaflet tethering	Restrictive leaflet motion with tethering
	Mitral annulus dilatation (AP >35 mm)	Normal leaflet morphology
	Enlarged LA (LAVI >34 mL/m^2)	Central or eccentric jet
	Additional echocardiographic criteria[b]	
	Normal leaflet motion	Dilated LV
	Normal leaflet morphology	Dilated LA
	Usually central jet	Dilated MV annulus
	Additional clinical criteria	
	Atrial fibrillation	Ischaemic heart disease
	HFpEF	Dilated cardiomyopathy





ESC EACTS

Functional and Quality-of-Life Improvements at 1 Year



6MWD, 6-minute walk distance; *KCCQ-OS*, Kansas City Cardiomyopathy Questionnaire Overall Summary score; *NYHA*, New York Heart Association; *TTVR*, transcatheter tricuspid valve replacement

Study Aim

Primary MR

Red Zone Anatomy

Which treatment strategy should be preferred?

TEER

TMVR

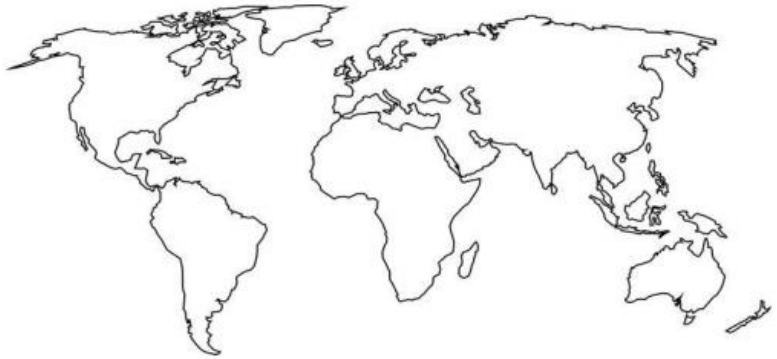
CHOICE-MI

CHoice of OptImal transCatheter trEatment for Mitral Insufficiency

TMVR with dedicated devices

N=436

40 centers



PRIME-MR

MITRAL VALVE EDGE-TO-EDGE REPAIR IN PRIMARY MITRAL REGURGITATION

TEER for primary MR

N=3,083

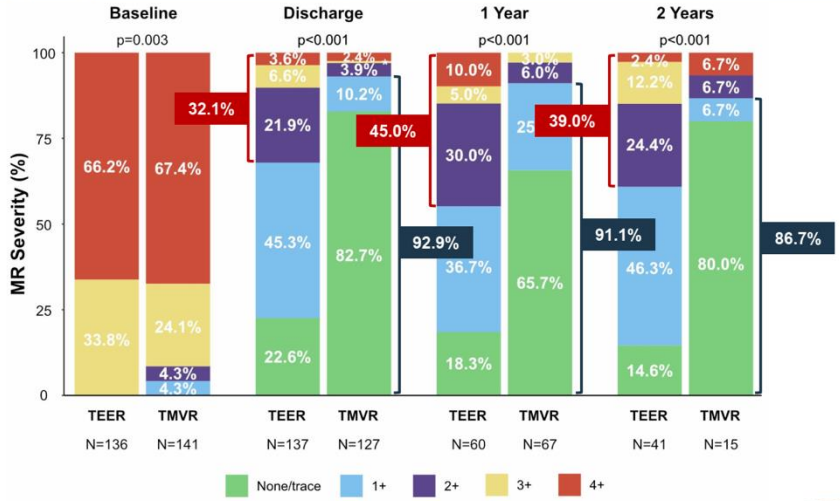
25 centers

2 investigator-initiated, international, retrospective, multi-center registries

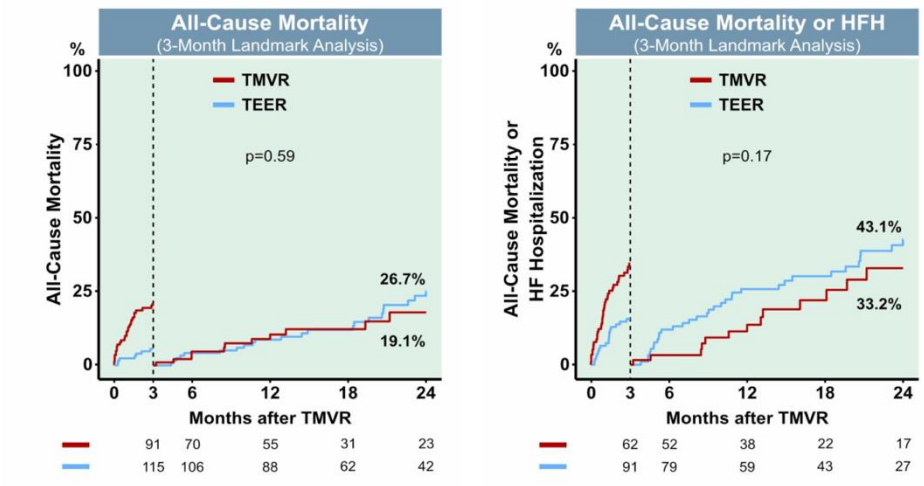
Baseline characteristics

	TEER (N=141)	TMVR (N=141)	*P* value
Age (years)	80.0 (76.0, 83.0)	79.0 (76.0, 82.0)	0.27
Male sex, n (%)	78 (55.3)	82 (58.2)	0.72
BMI (kg/m²)	25.4 (21.8, 28.1)	26.1 (22.7, 29.1)	0.15
EuroSCORE II (%)	4.8 (2.7, 9.5)	6.6 (3.8, 10.4)	0.11
STS PROM (MV repair) (%)	4.0 (2.4, 6.7)	4.0 (2.7, 6.1)	0.78
Atrial fibrillation, n (%)	107 (77.5)	95 (75.4)	0.79
COPD, n (%)	26 (20.5)	23 (16.3)	0.47
Diabetes, n (%)	35 (26.9)	42 (29.8)	0.70
CAD, n (%)	71 (53.0)	79 (62.7)	0.14
Prior myocardial infarction, n (%)	19 (16.4)	29 (21.0)	0.44
Prior CABG, n (%)	23 (18.5)	32 (22.7)	0.50
eGFR (mL/min/1.73m²)	49.1 (34.9, 59.6)	48.0 (36.9, 59.0)	0.76
HF hospitalization (prior 12 months), n (%)	56 (60.9)	88 (63.8)	0.76

Mitral Regurgitation



3-Month Landmark Analysis



30-Day MVARC Outcomes