Mitral- und Trikuspidal Edge-to Edge Therapie-

Was ist neu?

Nina C. Wunderlich, MD, FACC, FESC

M-TEER & T-TEER- was ist neu?

PubMed®

mitral regurgitation; edge-to edge repair

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Transcatheter **Edge-to-Edge Repair** for **Tricuspid Regurgitation**-A Systematic Review and Meta-Analysis.

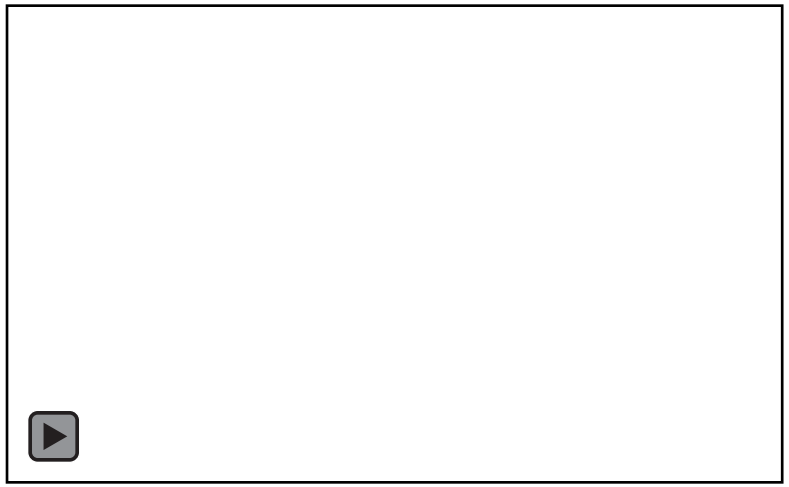
Rehan ST, Eqbal F, Ul Hussain H, Ali E, Ali A, Ullah I, Ullah W, Ahmed J, Brailovsky Y, Rajapreyar IN, Asghar MS.

Curr Probl Cardiol. 2024 Jan;49(1 Pt B):102055. doi: 10.1016/j.cpcardiol.2023.102055. Epub 2023 Aug 29. PMID: 37652111 Review.

Transcatheter **edge-to-edge repair** (TEER) has emerged as a widely accepted procedure for **tricuspid regurgitation** (TR) as gauged by echocardiographic parameters and clinical outcomes. ...No significant differences in left ventricular ejecti ...

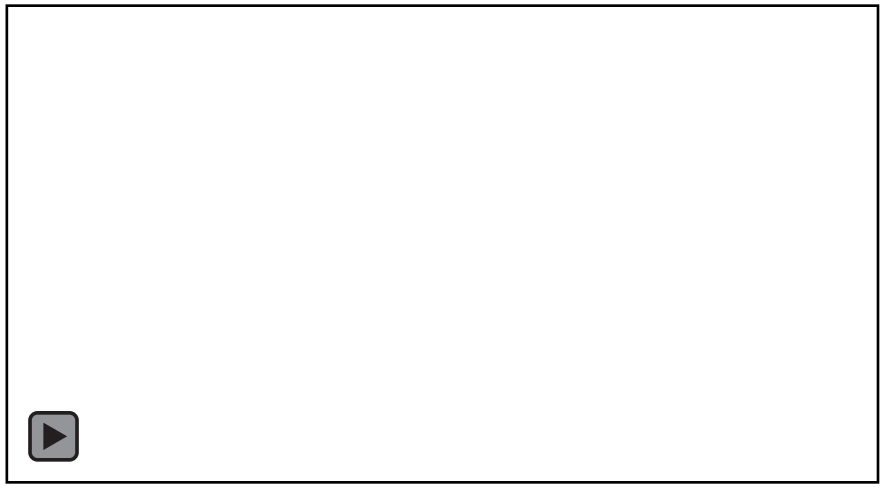
A new player in the field

MitraClip Gen 4 (Abbott)



- 4 different sizes
- Independent leaflet grasping

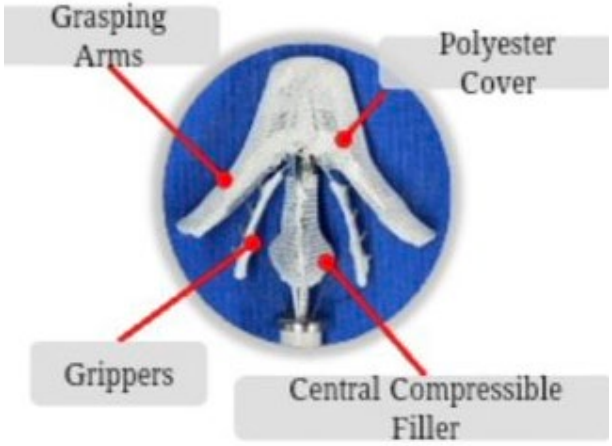
PASCAL (Edwards Lifesciences)



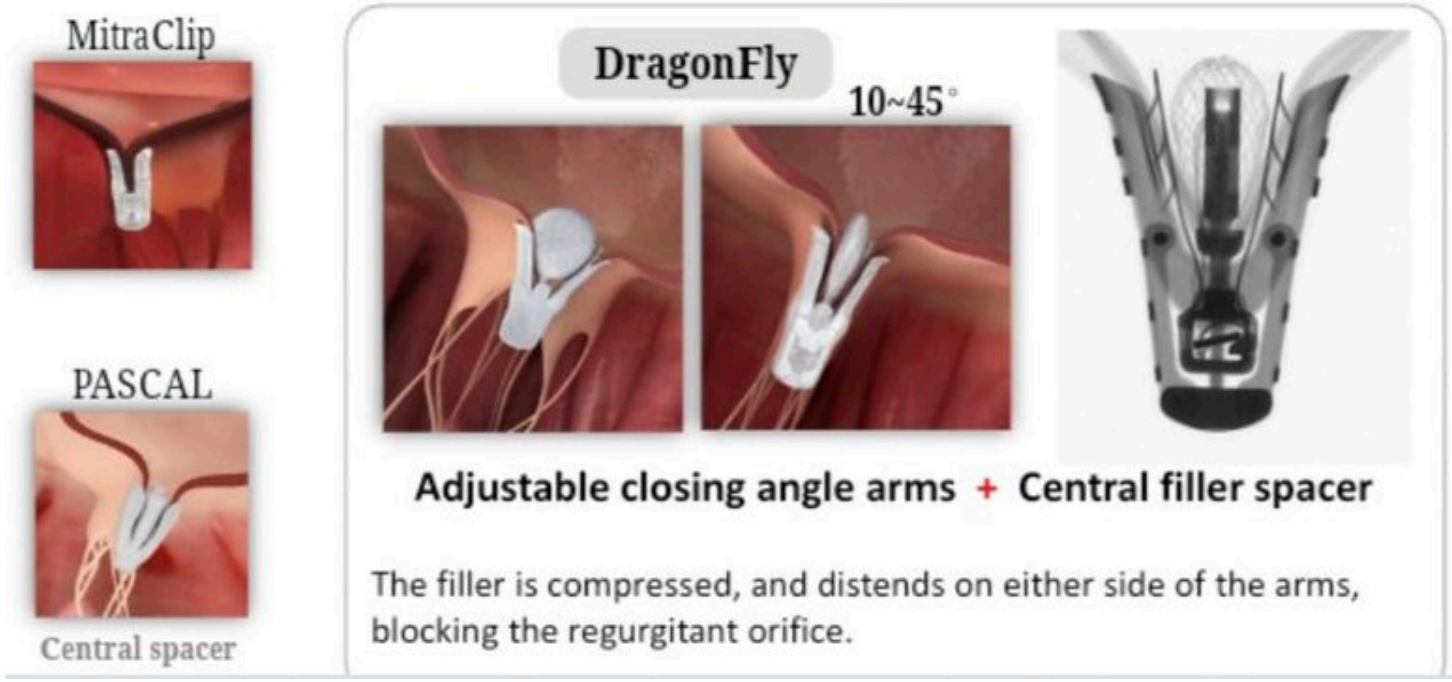
- 2 different sizes (ACE/ PASCAL 10)
- Independent leaflet grasping
- Central spacer

A new player in the field

DragonFly (Valgen Medtech, China)



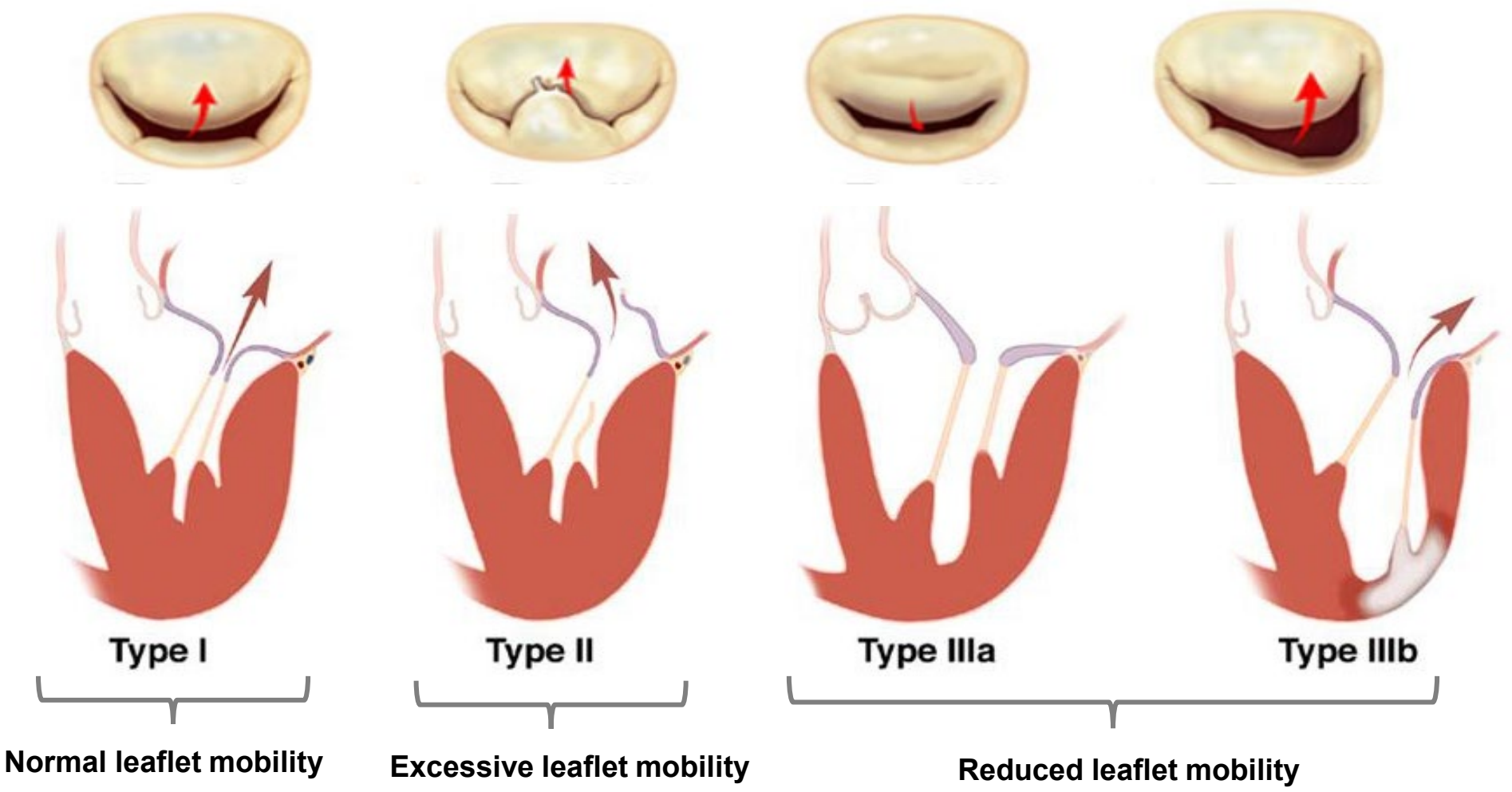
- 4 different sizes
- Independent leaflet grasping
- **Central compressible filler**
- **Adjustable closing angle**



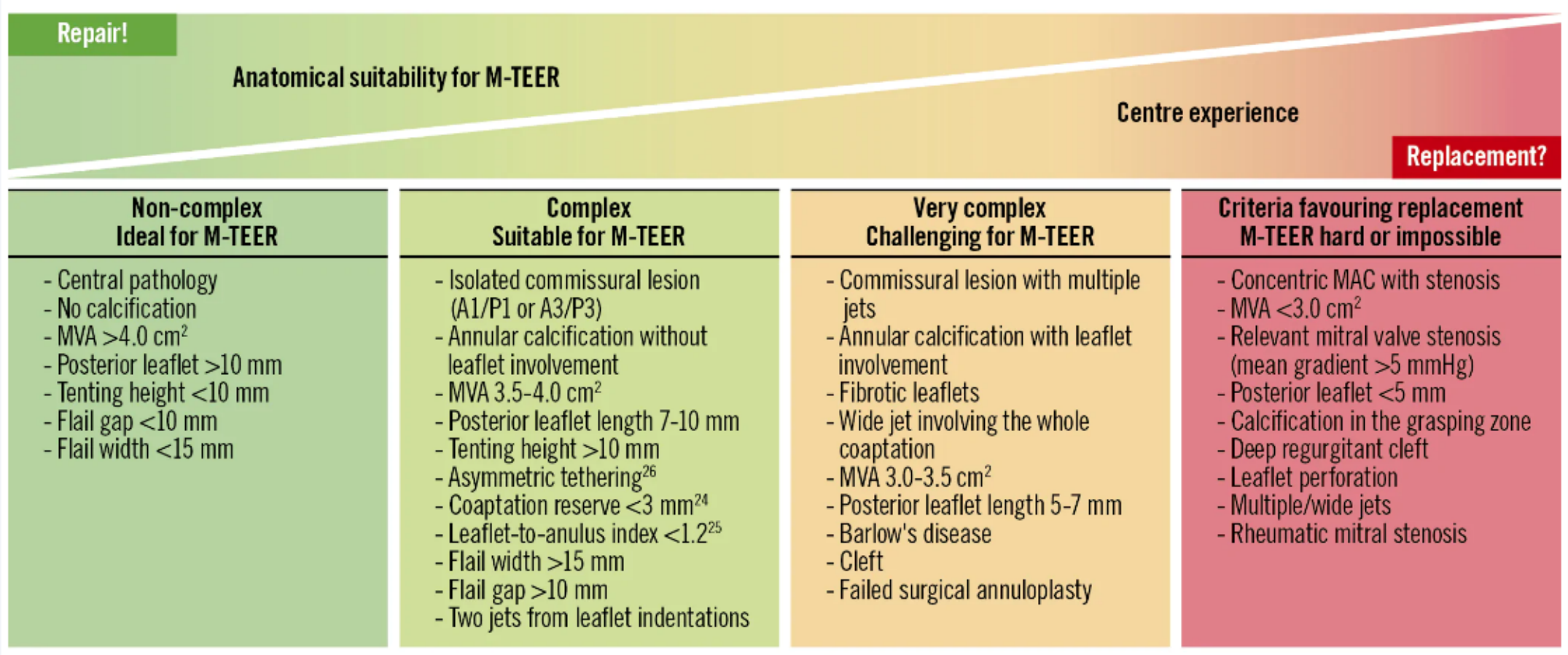
Muhammad Shuaib Abid presented at TCT 2023

Where are we coming from?

Functional classifcation based on leaflet motion

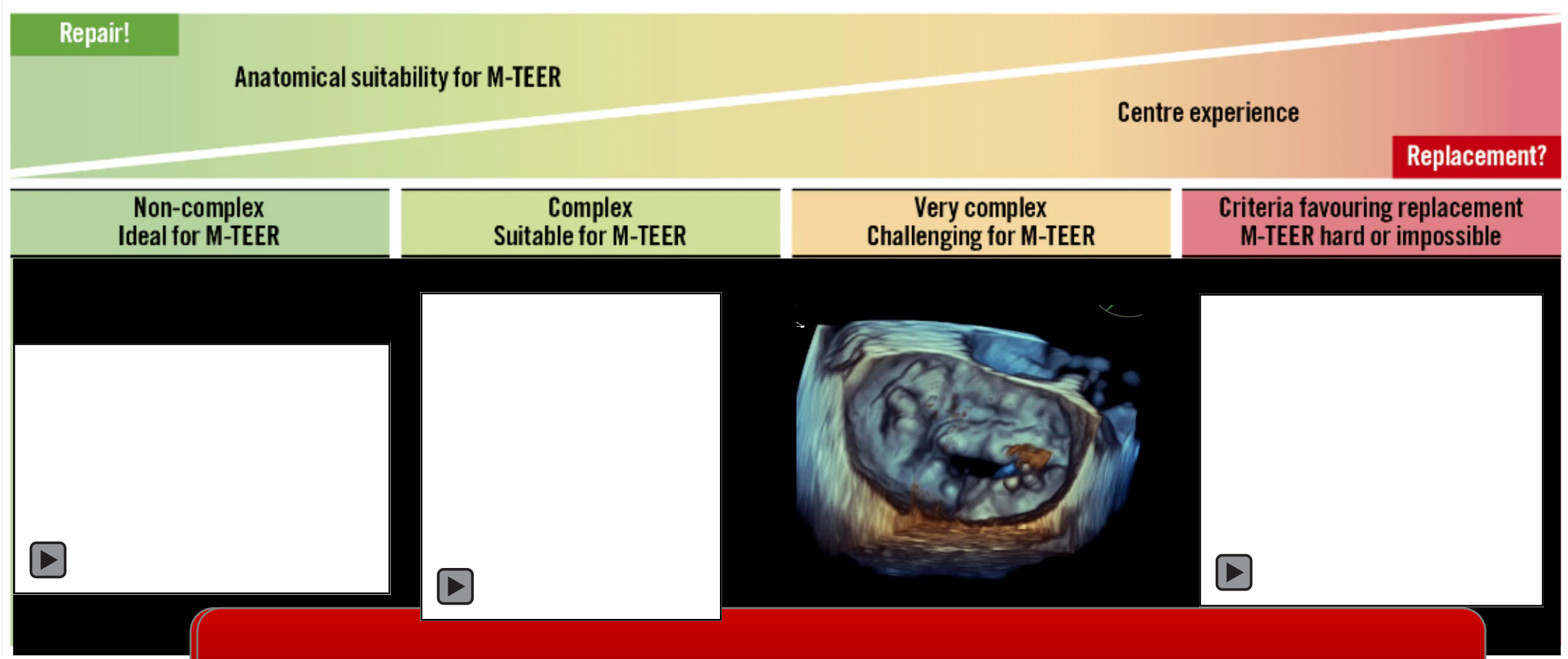


Anatomical/ mechanistic classification



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

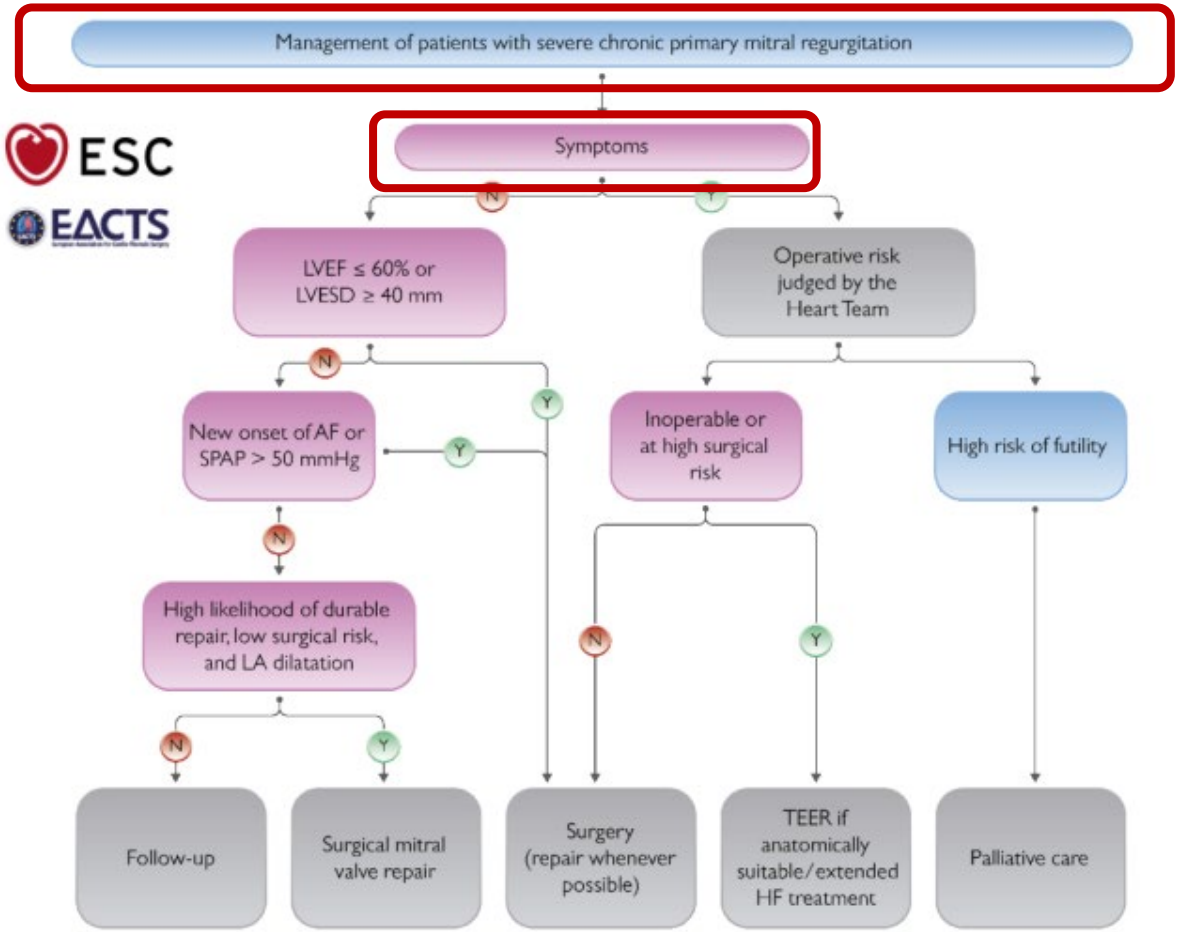
Anatomical/ mechanistic classification



3D imaging is crucial!

Hausleiter J et al. EuroInterv

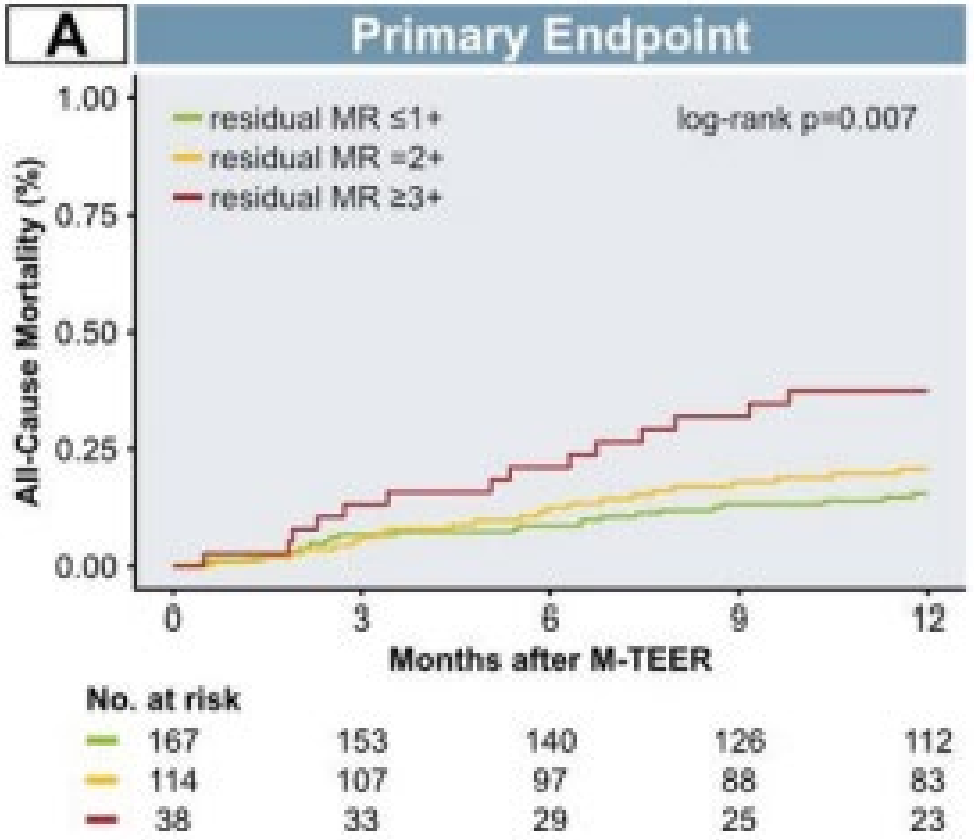
Indications for treatment in pts with PMR



TEER may be considered in symptomatic patients who fulfil the echocardiographic criteria of eligibility, are judged inoperable or at high surgical risk by the Heart Team and for whom the procedure is not considered futile [299–302].	IIb	B

How important is residual MR after M-TEER in PMR pts?

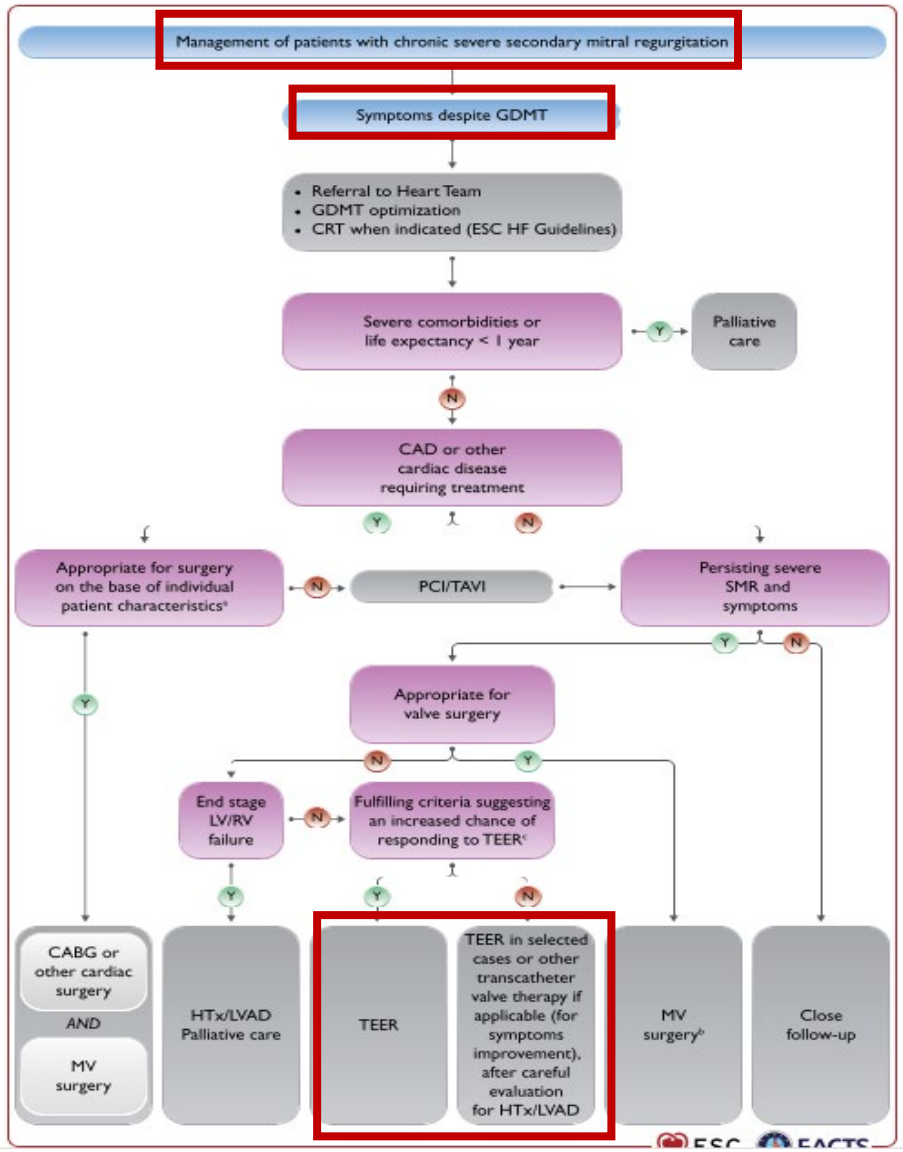
N= 364 pts with PMR, retrospective, single center



Achieving optimal procedural result (rMR ≤ 1+) associated with lower rate of mortality and HFH compared to acceptable result (rMR≤ 2+)

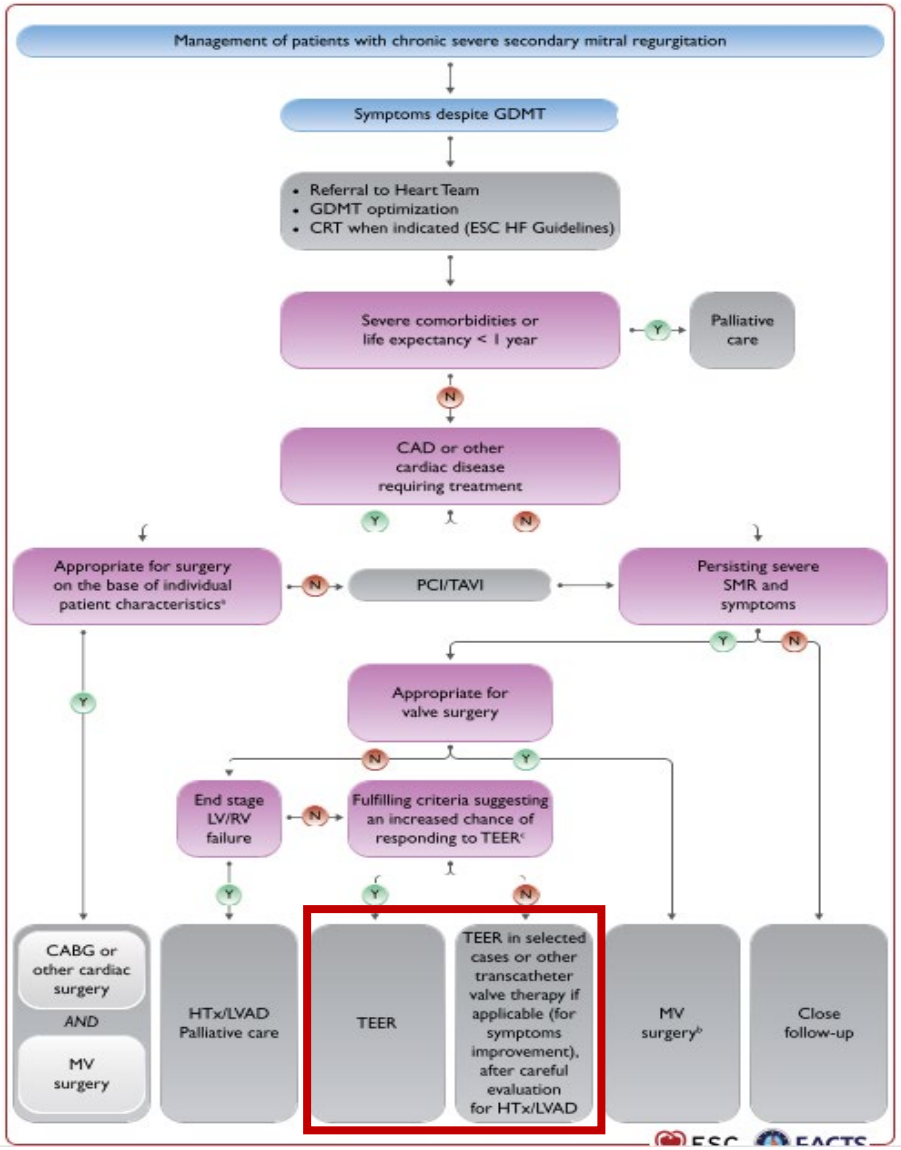
Waldschmidt L et al. Eur Heart J, Vol 43, October 2022, ehac544.1589

Indications for treatment in pts with secondary MR



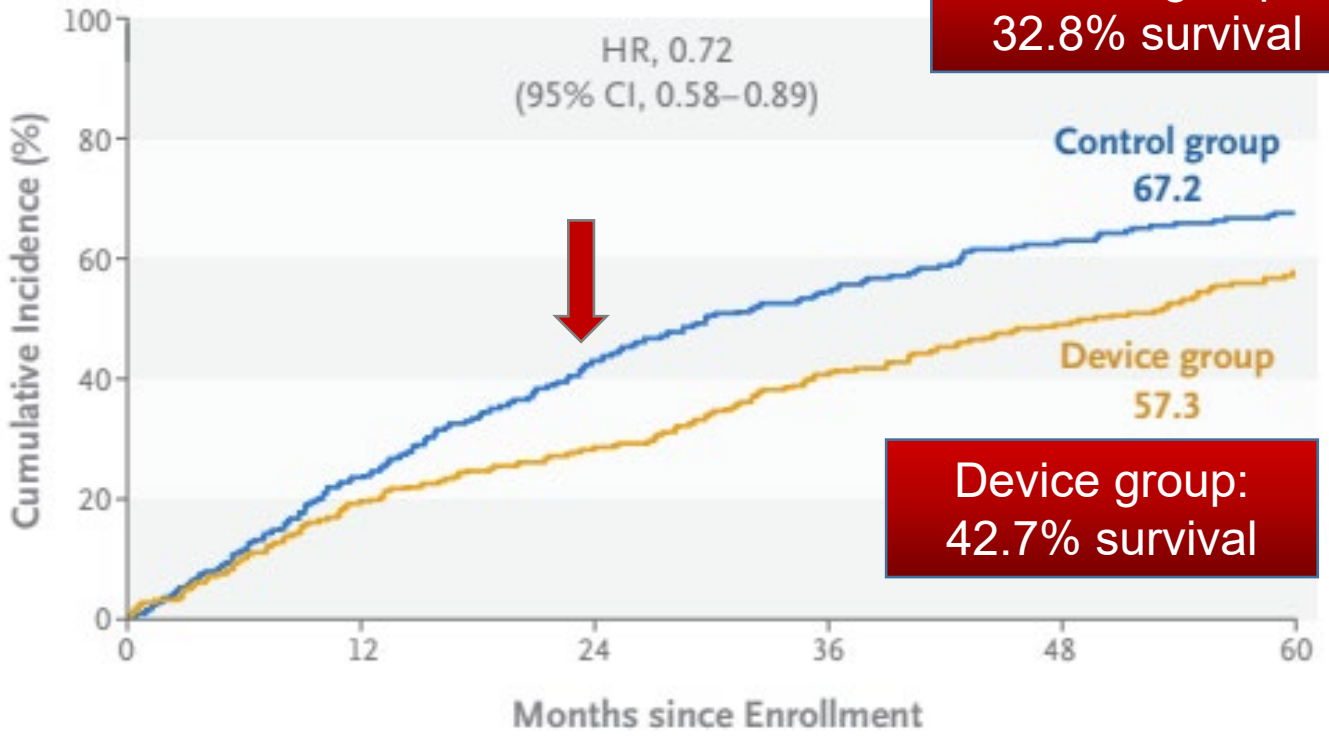
Patients without concomitant coronary artery or other cardiac disease requiring treatment		
TEER should be considered in selected symptomatic patients, not eligible for surgery and fulfilling criteria suggesting an increased chance of responding to the treatment [337, 338, 356, 357]. [e]	IIa	B
Valve surgery may be considered in symptomatic patients judged appropriate for surgery by the Heart Team.	IIb	C
In high-risk symptomatic patients not eligible for surgery and not fulfilling the criteria suggesting an increased chance of responding to TEER, the Heart Team may consider in selected cases a TEER procedure or other transcatheter valve therapy if applicable, after careful evaluation for ventricular assist device or heart transplant.[e]	IIb	C

Indications for treatment in pts with secondary MR



5-year resultes from the COAPT trial

Death from any cause



Control group: 32.8% survival

Device group: 42.7% survival

Stone GW et al. N Engl J Med 2023;388:2037-2048

2018

FOCUS

M-TEER vs GDMT: Key Learnings from COAPT[1] and MITRA-FR[2]

COAPT patients had more MR with less dilated LV, whereas MITRA-FR patients had less MR with more dilated LV[1]

	COAPT (+)	MITRA-FR (-)
MR grade	EROA >0.3 cm^2 or RVol >45 ml	EROA >0.2 cm^2 or RVol >30 ml
LVEDD inclusion criteria	≤7.0 cm	No limit
LVEF inclusion criteria	≥20 and ≤50%	≥15 and ≤40%
Mean EROA	0.41 ± 0.15 cm^2	0.31 ± 0.10 cm^2
Mean LVEDV	192 ± 67 ml	252 ± 67 ml

We need long term FU data after M-TEER from routine clinical practice!

1. *Grayburn*

Are there some news? EuroSMR registry

EuroSMR registry

M-TEER patients of 14 European high-volume sites (Germany, Switzerland, France, Italy, Portugal) in 2008 - 2020

→

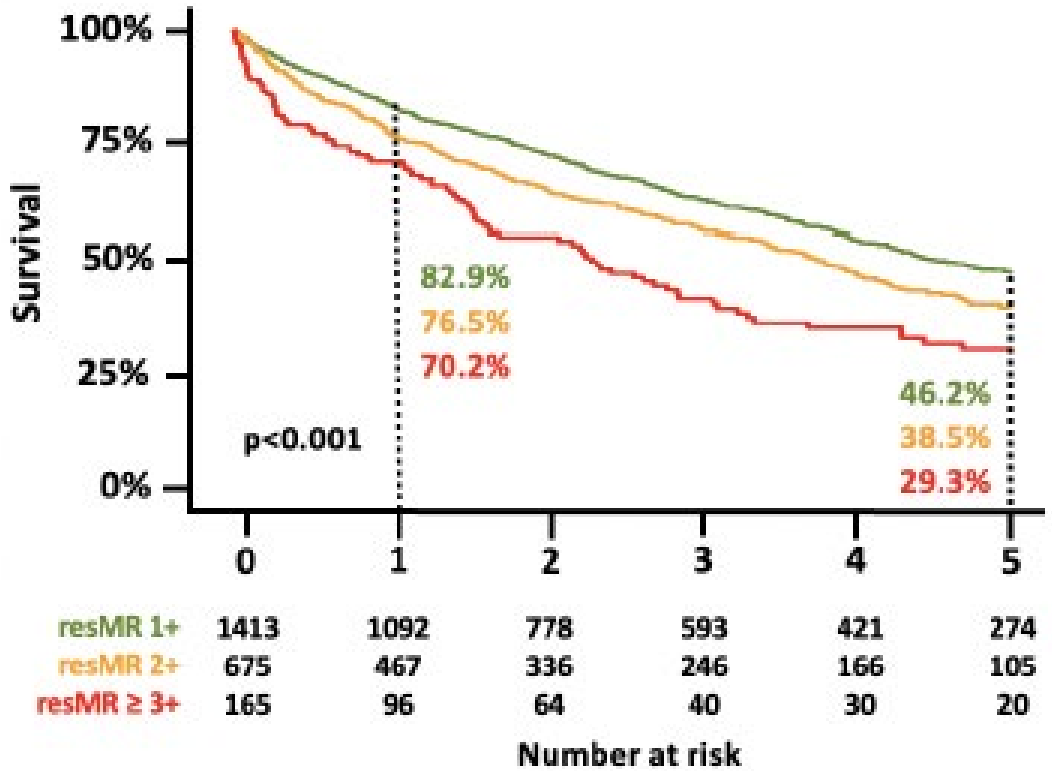
Analysis

- long-term MR reduction
- long-term functional outcomes
- long-term survival rate

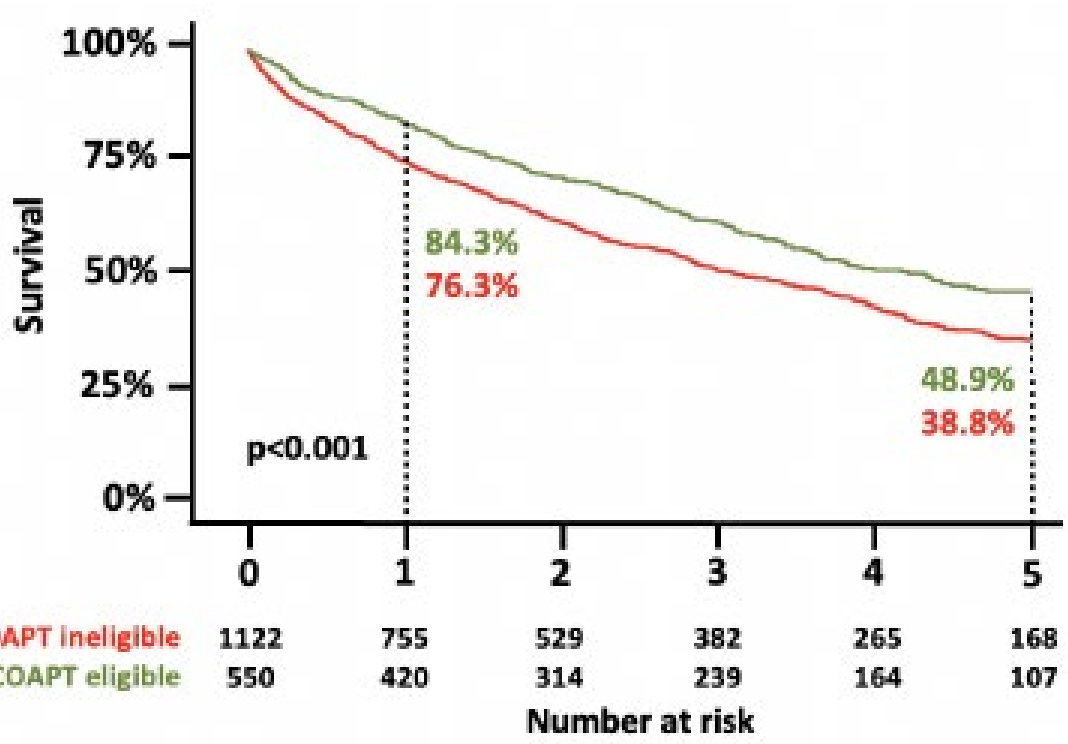
Are there some news? EuroSMR registry

Survival analysis after M-TEER

Impact of MR reduction after M-TEER

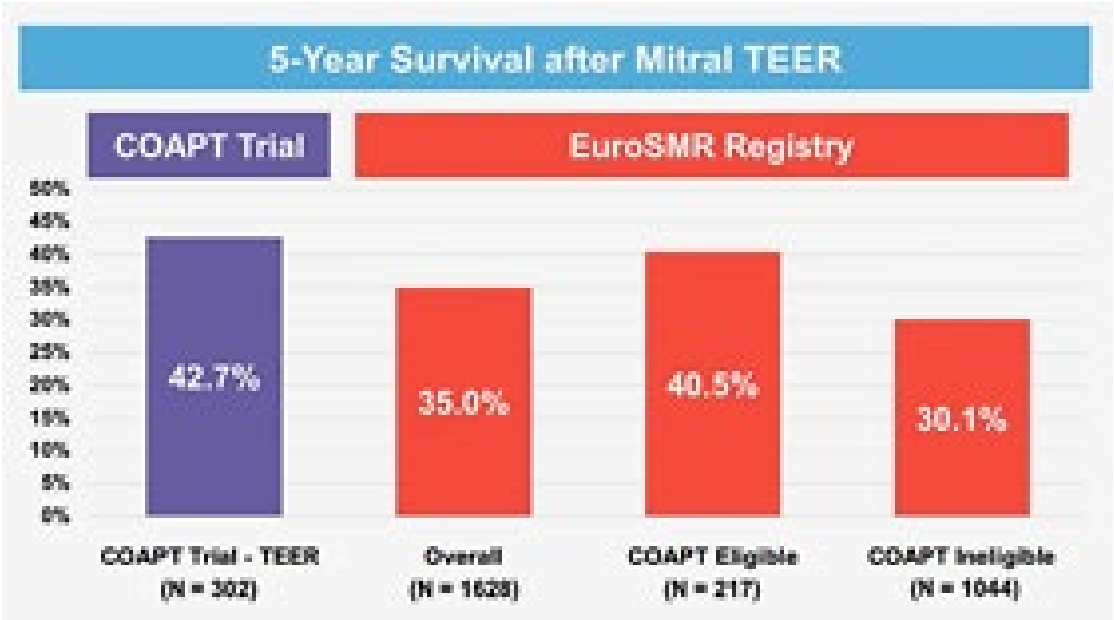


COAPT vs. Non-COAPT patients



Are there some news? EuroSMR registry

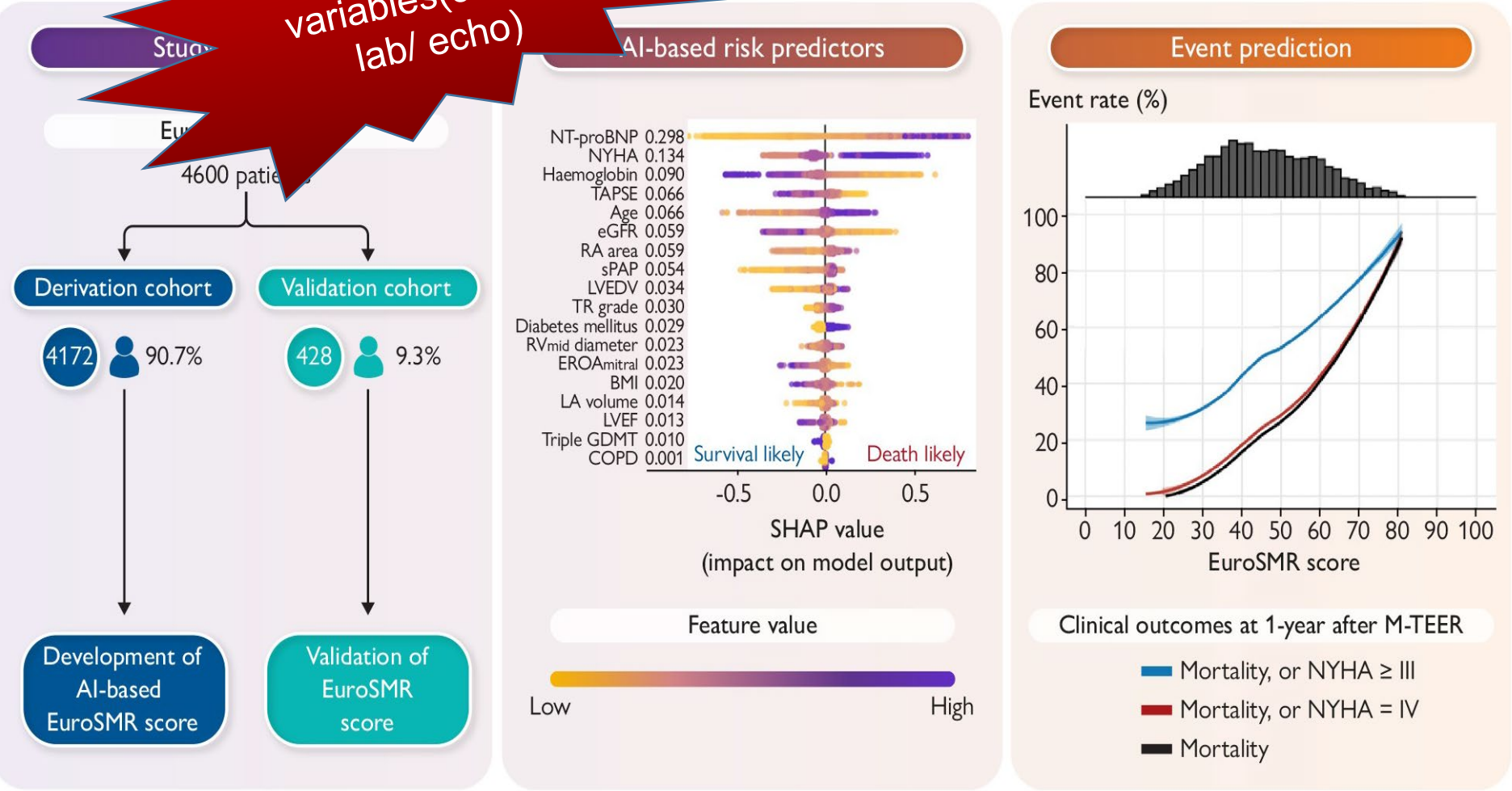
Survival analysis after M-TEER



Jörg Hausleiter, presented at TCT 2024

SMR risk Score

18 variables(clinical/ lab/ echo)



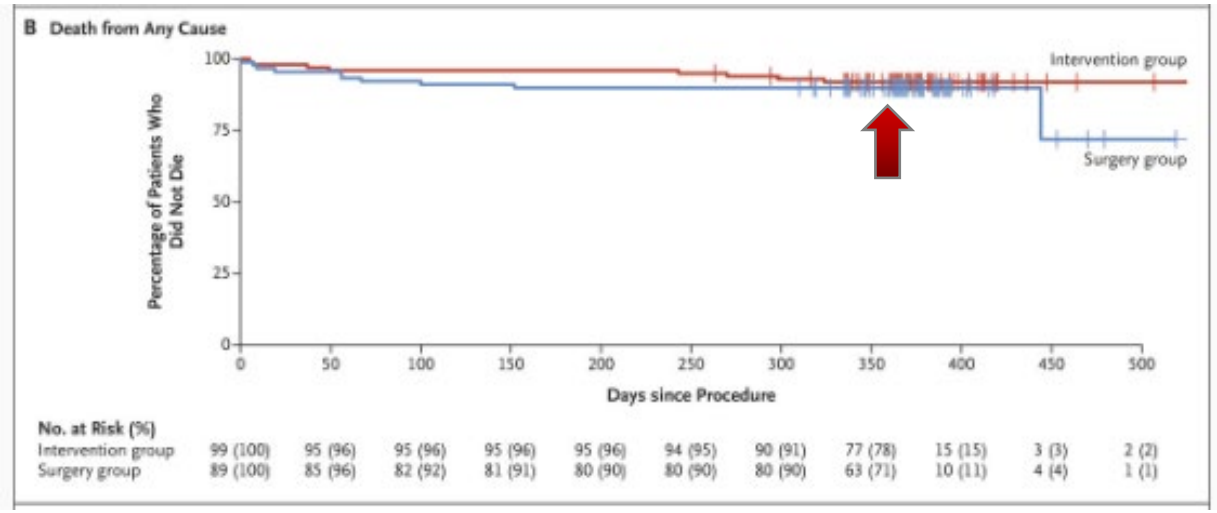
Online risk calculator available at www.eurosmr.com

Hausleiter J et al. Eur Heart J, Volume 45, Issue 11, 14 March 2024, Pages 922–936,

Are there some news? Matterhorn

- Non-inferiority trial conducted in Germany
- N= 210 pts with HF and SMR with symptoms despite GDMT
- Pts were randomly assigned, in a 1:1 ratio, to undergo either M-TEER (intervention group) or surgical MV repair or replacement (surgery group).

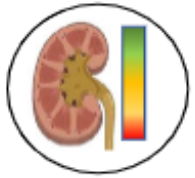
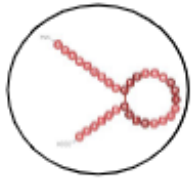
Freedom from Death from any cause



M-TEER (MitraClip) achieved MR reduction comparable to surgery

Are there some news? *RESHAPE –HF2*

Patients in RESHAPE-HF2 form a third distinct population tested with MitraClip, primarily comprising those with moderate-to-severe FMR, unlike the COAPT and MITRA-FR trials, which recruited patients with severe FMR

	Age (years)	eGFR (ml/min/1.73 m²)	NT-proBNP (pg/ml)	LVEF (%)	Mean EROA (cm²)	6MWD (m)
RESHAPE-HF2	70	56 ± 21	Mean: 4185 Median: 2745	31 ± 8	0.25	Mean: 292 Median: 300
COAPT	72	49 ± 26	Mean: 5558	31 ± 9	0.40	Median: 240
MITRA-FR	70	50 ± 20	Median: ≈3400	33 ± 6	0.31	Mean: 310

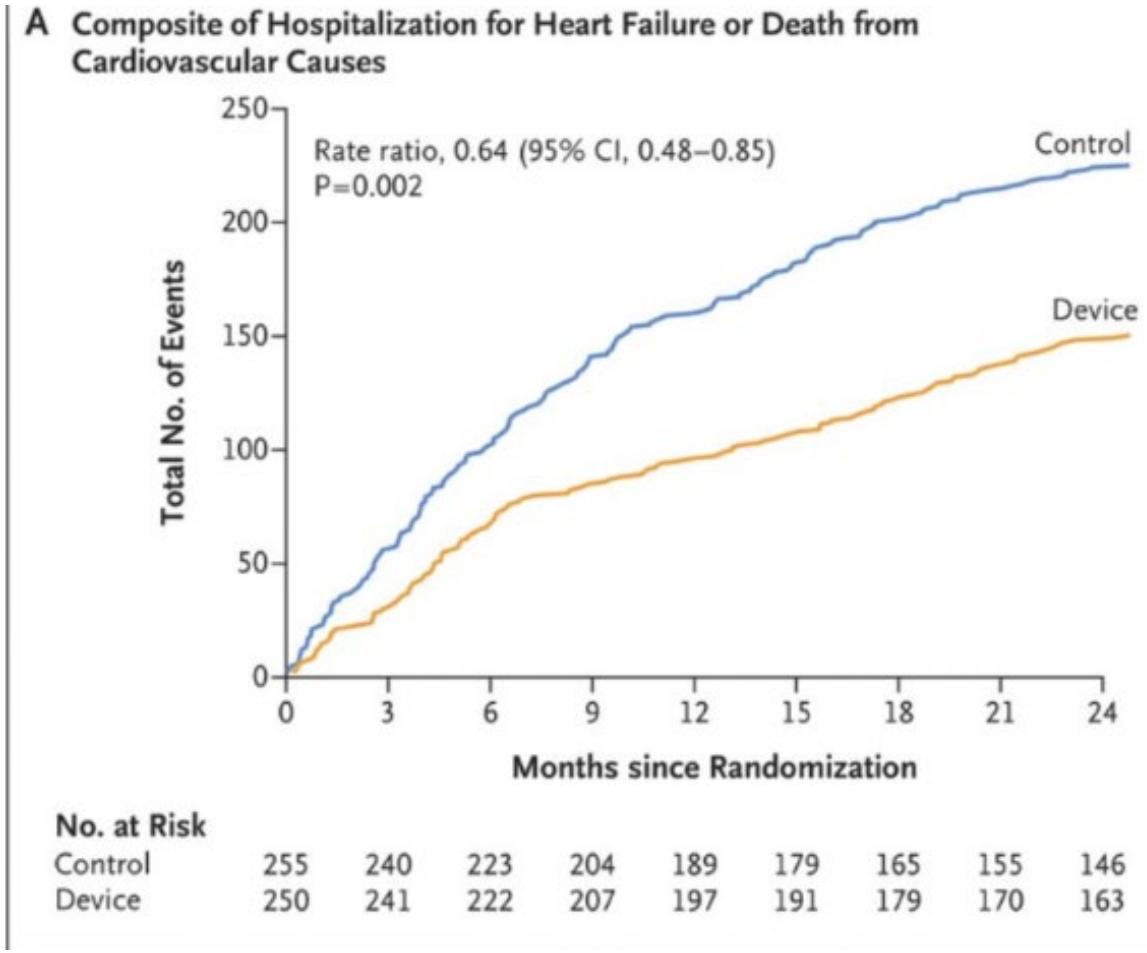
Compared to COAPT and MITRA-FR, RESHAPE-HF2 pts were less likely to have MR grade 4+ and, on average, had lower EROA, and plasma NT-proBNP and higher GFR rate, but otherwise had similar age, comorbidities, CRT therapy and LVEF

Anker SD et al; European Journal of Heart Failure (2024) 26, 1608–1615

Are there some news? *RESHAPE –HF2*

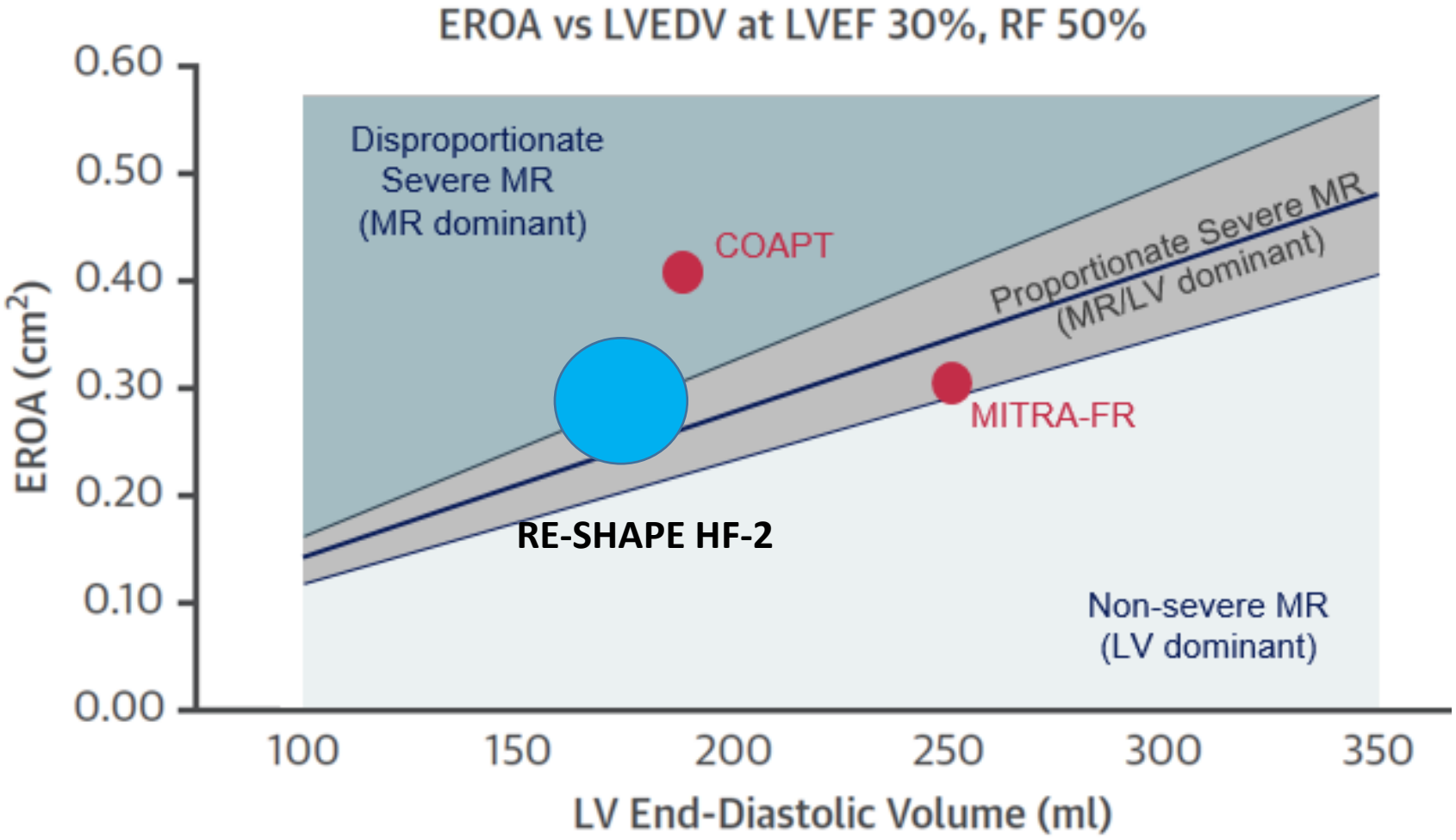
- **Treatment with M-TEER (MitraClip) led to:**
  - 36% risk reduction in 24-months CV death & 41% risk reduction in HF hospitalisation
  - Significant improvement in quality of life : +22 points at 12 months KCCQ-OS

M- TEER should be considered in pts with symptomatic heart failure and *moderate-to-severe* and severe SMR

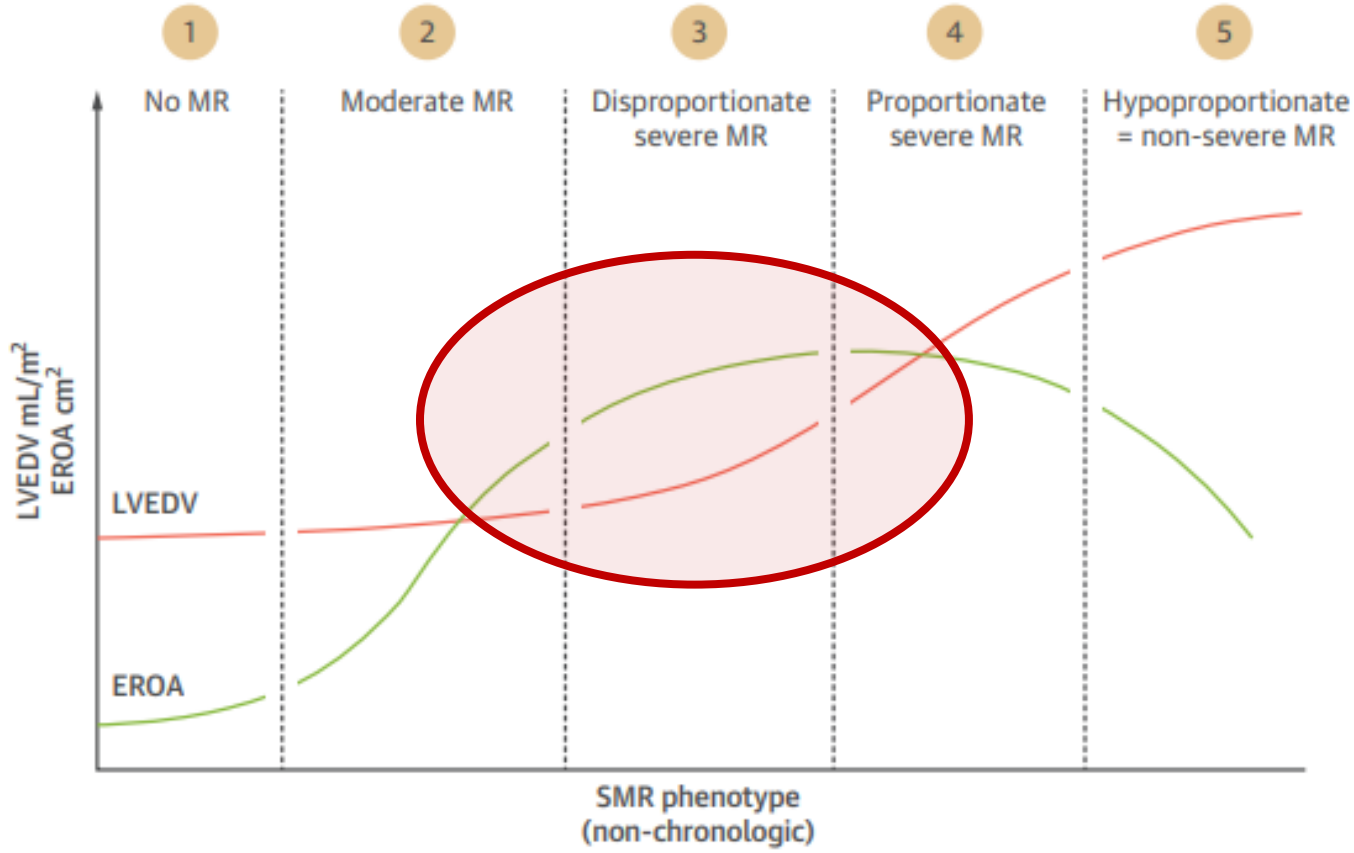


Anker SD et al; presented at ESC 2024

Are there some news? *EXPANDed Studies*



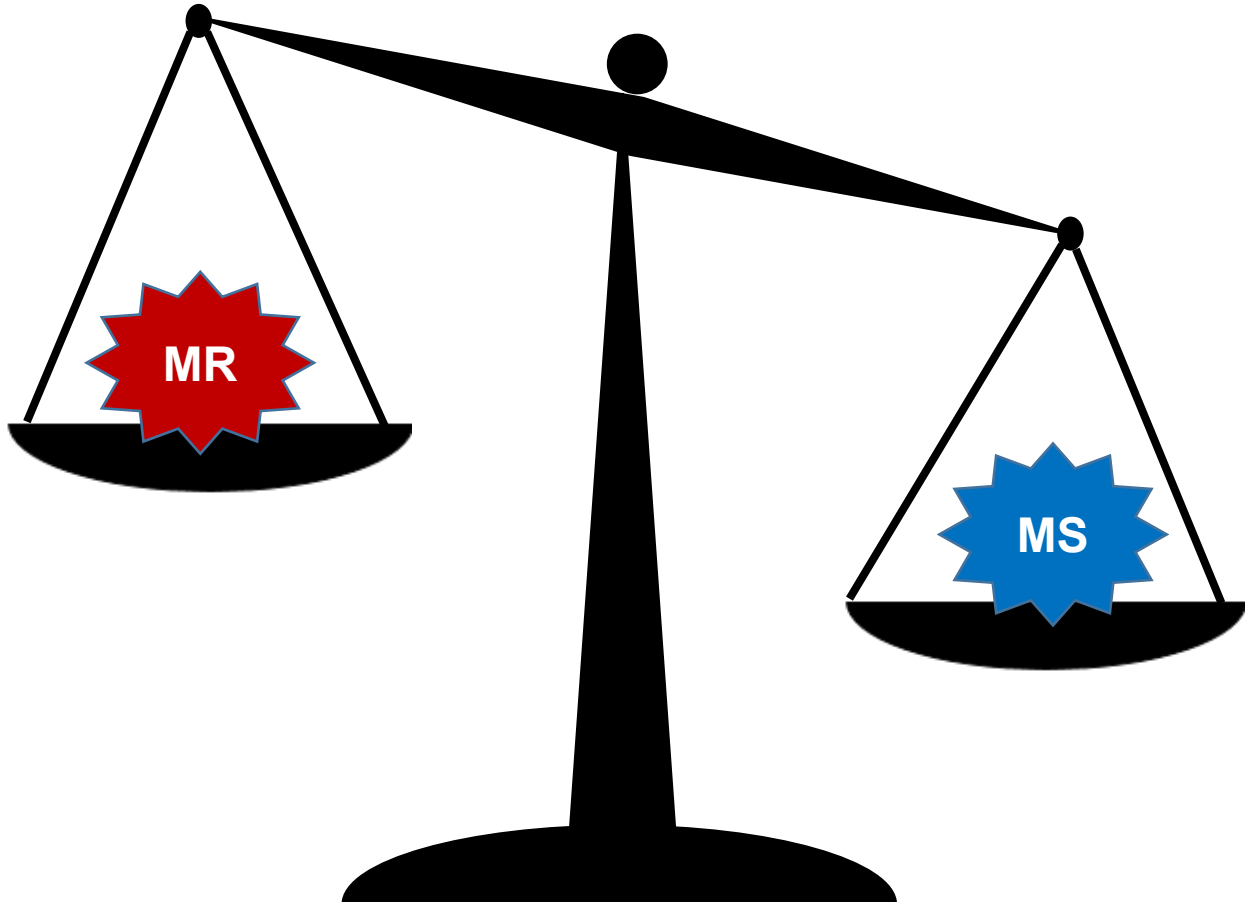
Relationship of MR severity and LV dilation



Description of phenotypes- no chronological description

Stolz L, et al. J Am Coll Cardiol Img. 2024;17(6):659-668.

What about the balance between MR reduction & creating MS?



- The goal is to strike a balance where MR is reduced without causing significant MS

Are there some news? *EXPANDed Studies*

How to balance between rMR and MS?

CENTRAL ILLUSTRATION Impact of Postprocedure MR and MVG After M-TEER

EXPANDed: Impact of Postprocedure MR and MVG on Clinical Outcomes After M-TEER, N = 1,723

A Patients

M-TEER in EXPAND and EXPAND G4 (N = 2,205)

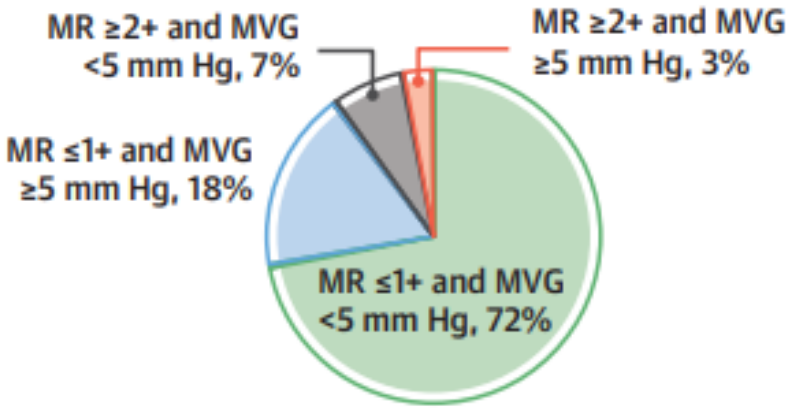
→ 62 deaths
→ 152 missed visits/withdrawals/lost to follow-up
→ 283 nonevaluable MR or MVG

Evaluable MR grade and MVG from 30-day echocardiogram (N = 1,723)

→ 173 deaths
→ 251 missed visits/withdrawals/lost to follow-up

1-year follow-up (N = 1,299)

B 30-Day MR Severity and MV Gradient

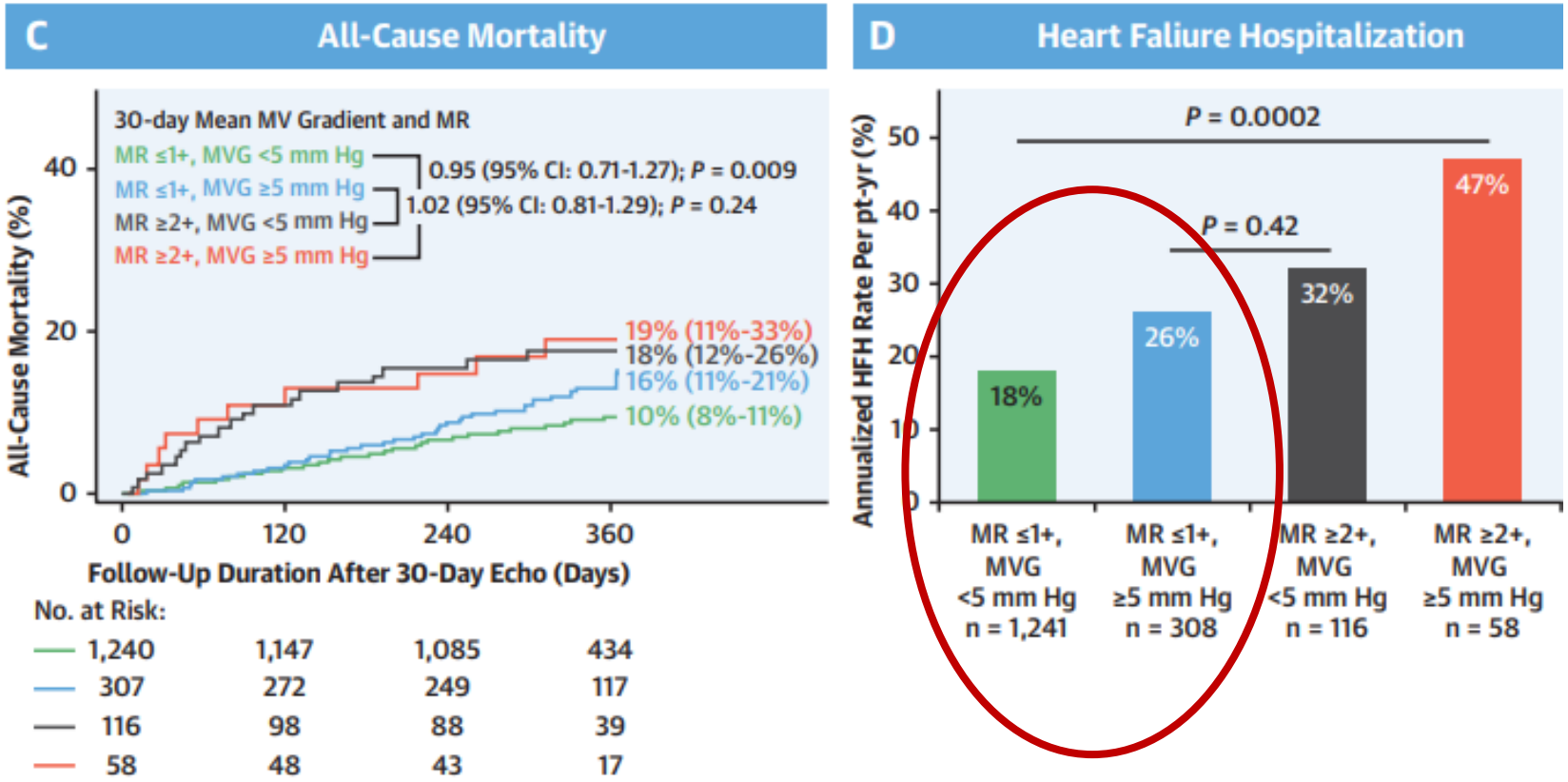


At 30 days after M-TEER, 91% achieved MR reduction to ≤1+ and 72% had mean gradient <5mmHg

Singh DD et al. Ardiovasc Interv.2024; 17(21):2530-2540

Are there some news? *EXPANDed Studies*

How to balance between rMR and MS?



- 1 yr rates of all-cause mortality and HFH were lower for pts who achieved MR≤ 1+, regardless of MVG

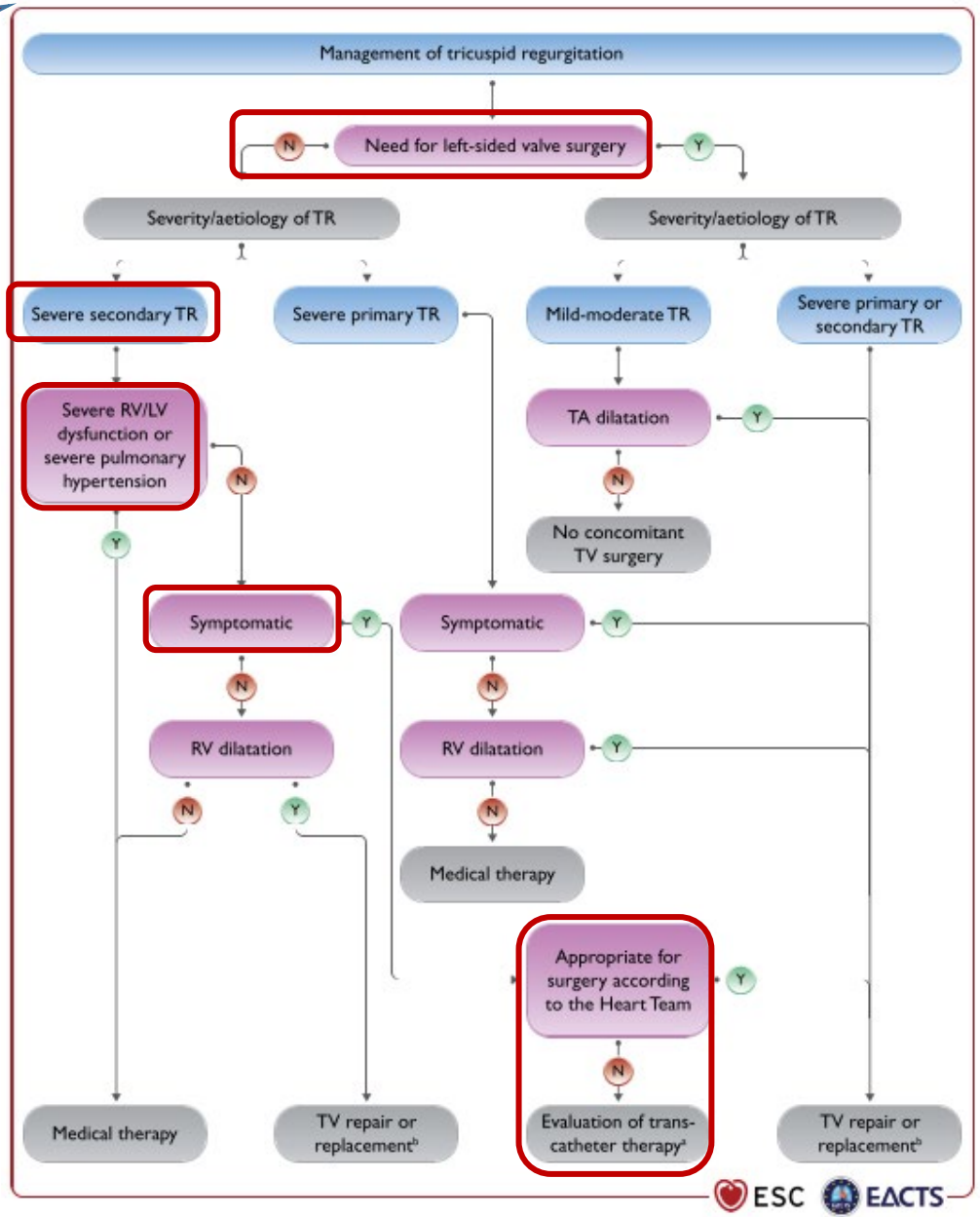
Singh DD et al. Cardiovasc Interv.2024; 17(21):2530-2540

Zusammenfassung: M-TEER- Was ist neu?

- Für die Patientenselektion hat sich eine anatomisch/ mechanistische Betrachtungsweise durchgesetzt; 3D Bildgebung ist dafür unerlässlich
- **Primäre MI:** die chirurgische Intervention bleibt 1. Wahl; ein MI Grad ≤1+ ist anzustreben
- **Sekundäre MI:** Real-world Daten (EuroSMR) bestätigen die Effektivität einer M-TEER Therapie (TI Reduktion/ funktonelle Verbesserung), auch bezüglich eines Mortalitäts-Vorteils
  - Der Mortalitäts- Vorteil ist abhängig vom Grad an MI Reduktion und dem Patientenprofil (COAPT-like)
  - Der EuroSMR Risko Score kann für eine bessere Patientenselektion genutzt werden
  - Die M-TEER Therapie ist einer chirurgischen Intervention nicht unterlegen
  - Pat. mit sympt. moderater-schwerer MI profitieren ähnlich wie Pat. mit einer schweren MI
- Der Grad an residualer MI nach M-TEER ist prognostisch schwerwiegender als der Grad an MS

Management of TR

2021

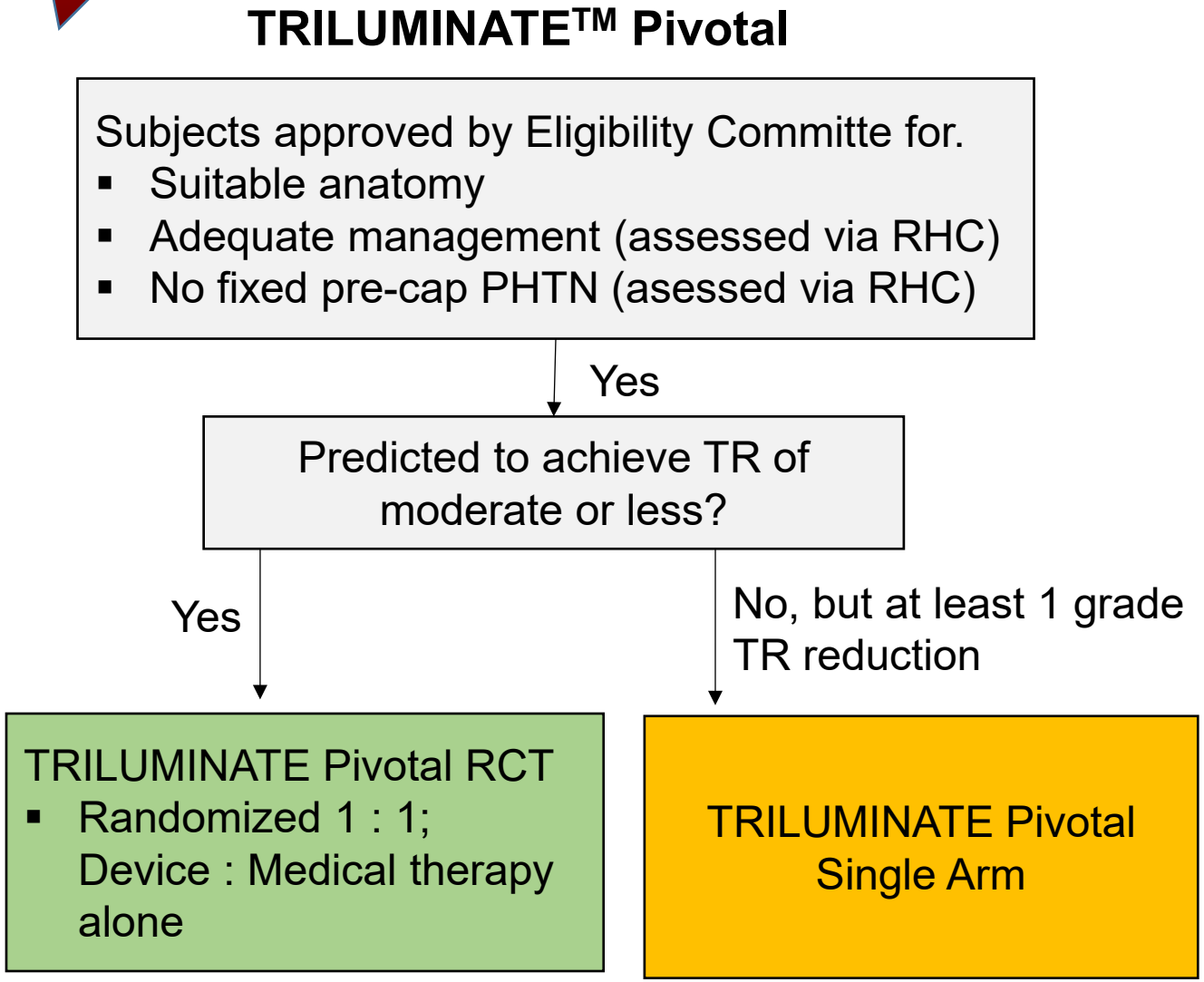


Vahanian A et al. European Journal of Cardio-Thoracic Surgery 00 (2021) 1–74

2024

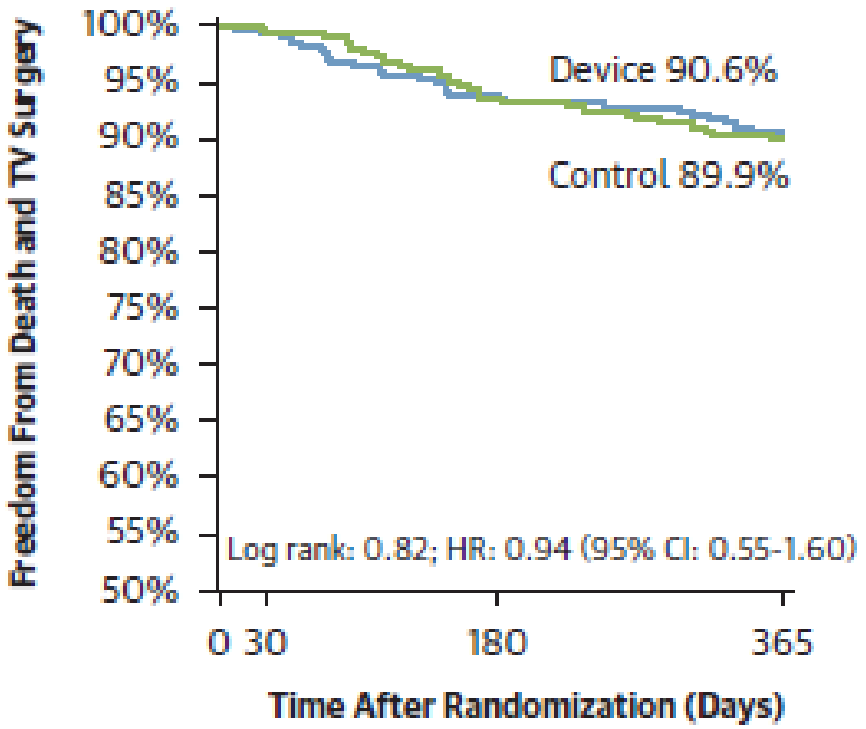
portant T-TEER studies: TRIMLUMINATE™ Pivotal & bRight

Study patient enrollment

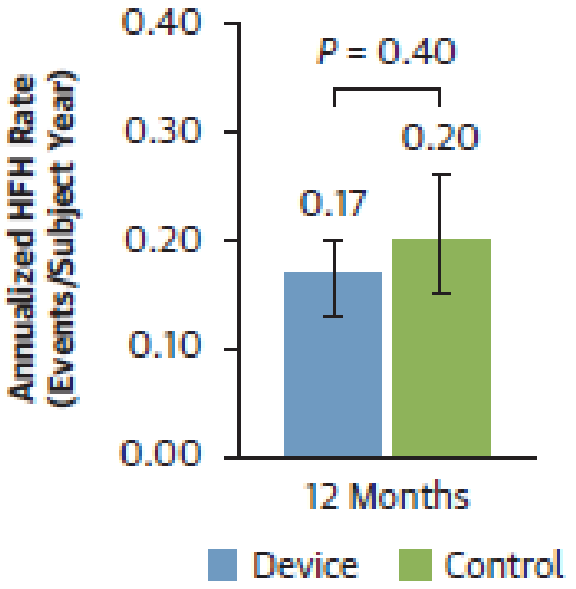


TRILUMINATE: 1 year results

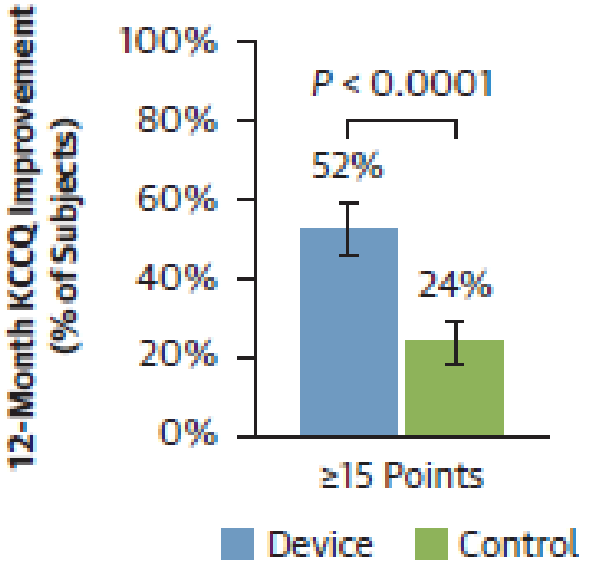
Device: N= 210 Device size; Controls: N= 206



Annualized HFH Rate



Functional improvement

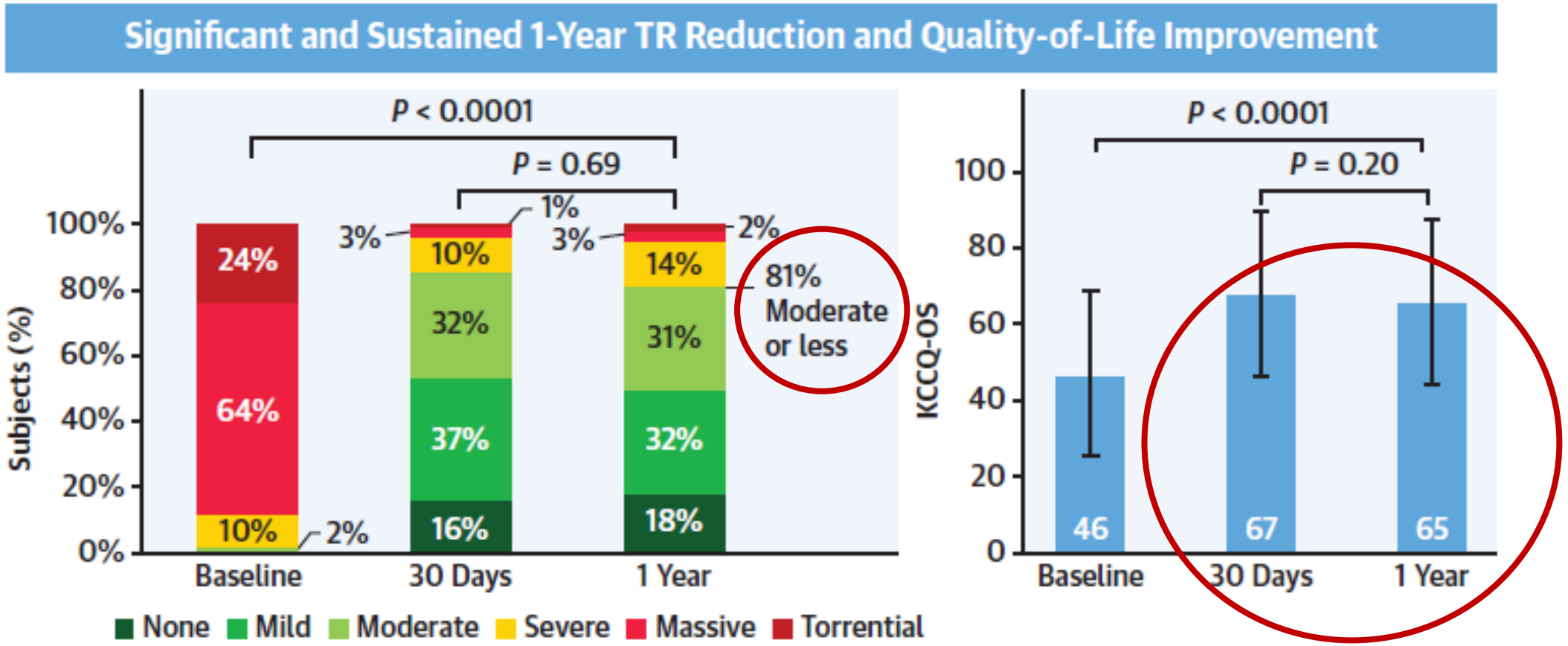


Tang GH

No mortality benefit!

bRight: 1 year results

N= 511 pts

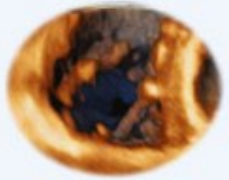


Lurz P, et al. J Am Coll Cardiol. 2024;84(7):607-616.

Effective TR reduction & functional improvement; no mortality benefit!

Was ist noch neu?

New classification of TR

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

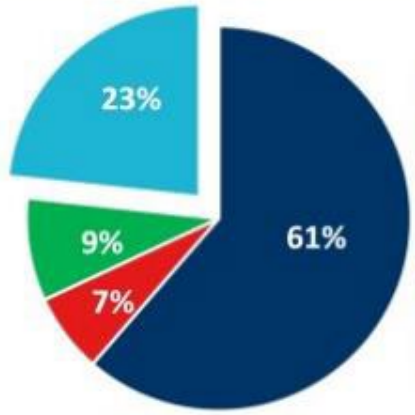
~80%

~20%

Praz et al. EuroIntervention 2021;17:791-808; Hahn RT et al; Eur Heart J 2023 Nov 14; 44(43): 4508–4532

The TR etiology has impact on survival - *aSMR vs vSMR*

Distribution of severe functional TR

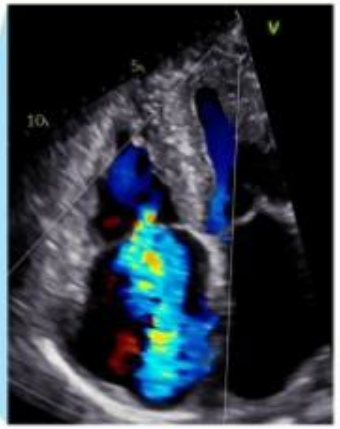


- Left-sided cardiac disease
- Pulmonary hypertension
- RV dysfunction

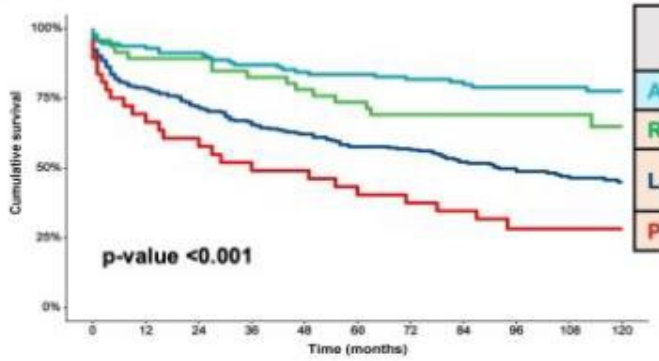
VFTR

- Atrial FTR

AFTR



Overall survival of severe functional TR



	1-year survival	5-year survival	10-year survival
Atrial FTR	94%	84%	78%
RV dysfunction	89%	74%	65%
Left-sided cardiac disease	79%	58%	45%
Pulmonary hypertension	69%	43%	28%

Galloo X et al. European Heart Journal - Cardiovascular Imaging (2023) 24, 733–741

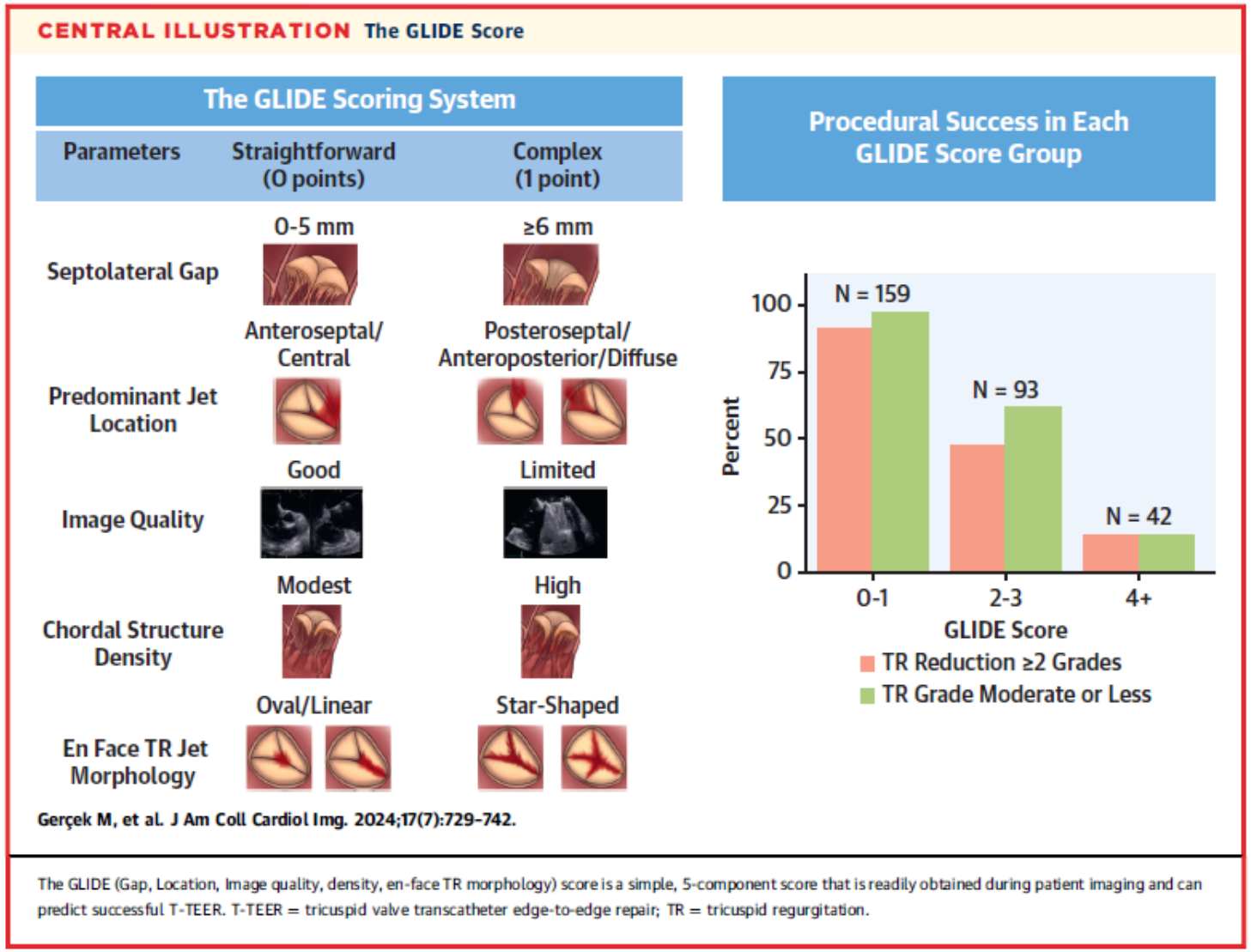
Consider earlier intervention in pts with vSMR

How to define suitable patients for T-TEER?

THE GLIDE SCORE

5 Parameters:

- **G** ap
- **L** ocation of predominant jet
- **I** mage quality
- **D** ensity of chordal structures
- **E** n- face TR Jet morphology



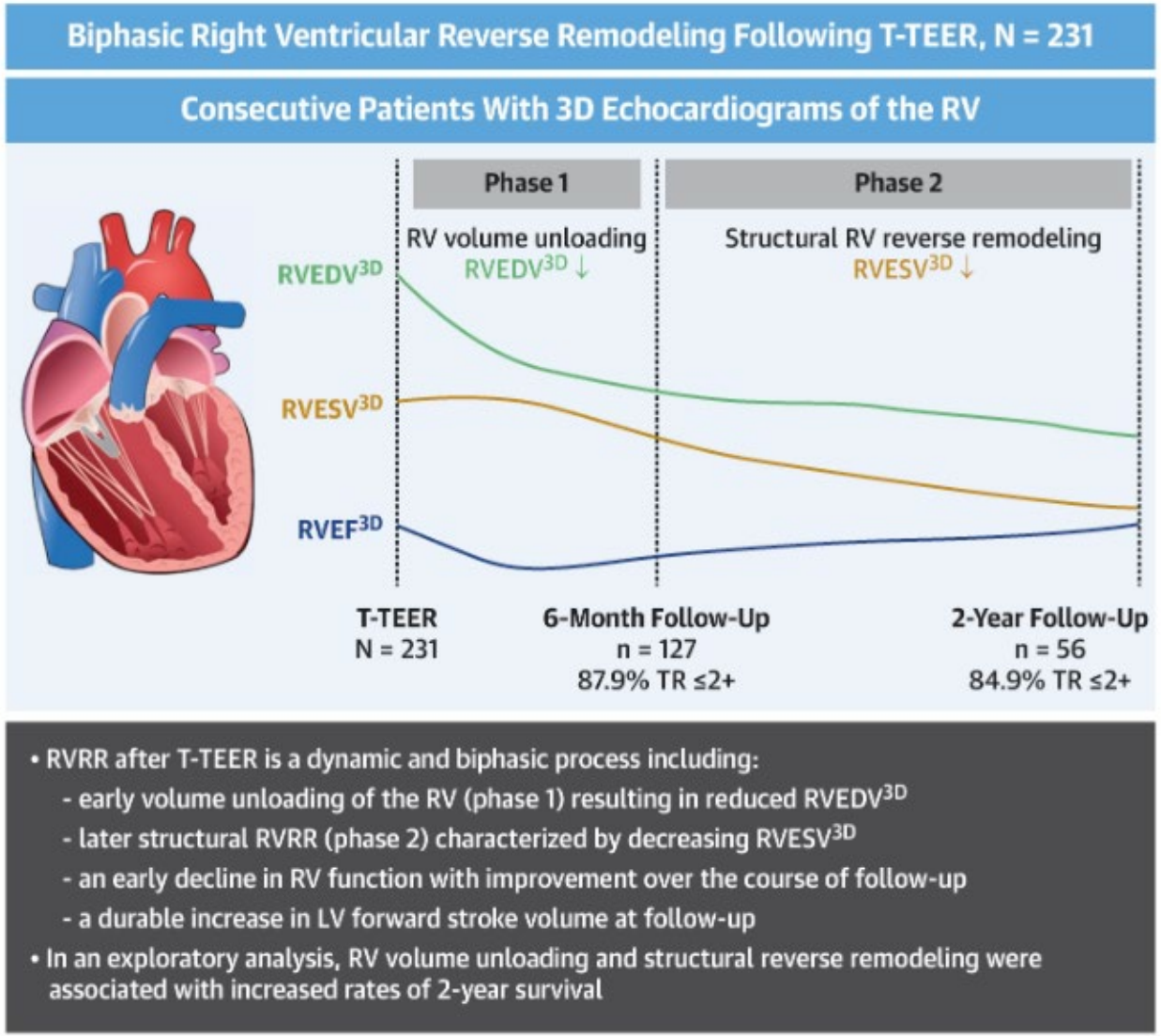
Zusammenfassung: T-TEER- Was ist neu?

- TRILUMINATE & bRIGHT (1-Jahres Ergebnisse)
  - bRight hat eine mehr sympt. Patientenpopulation mit schlechterer QoL eingeschlossen
  - Die 30 Tages adverse event rate war niedrig (~1% all cause mortality or CV mortality)
  - Die TR Reduktion war in beiden Studien effektiv und anhaltend
  - Eine funktionelle Verbesserung war in beiden Studien verifizierbar (NYHA/ KCCQ)
  - Kein Überlebensvorteil in beiden Studien für die Device Therapie (Mortalitätsraten ~8%-11%, ähnlich derer von nicht behandelten Patienten)
- Die neue TI Klassifikation hat prognostische Bedeutung (aFTR > vFTR)
- Der GLIDE Score ist ein einfaches Mittel um den prozeduralen Erfolg einer T-TEER Prozedur vorherzusagen

HERZFOCUS

Vielen Dank!

RV remodeling after T-TEER



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