TMVI vs TEER for functional MR

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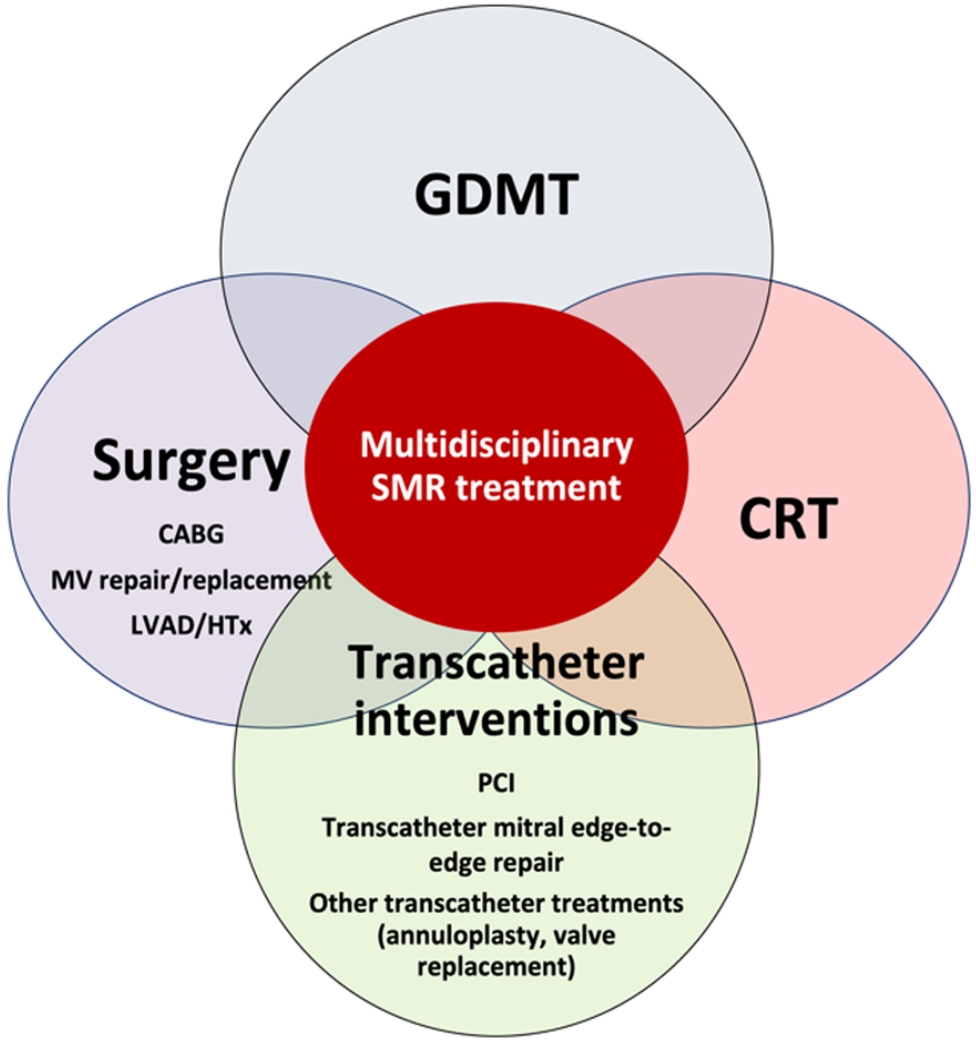
Disclosures

- Steering committee member of HIGHLIFE clinical study

Funtional Mitral Regurgitation: Background

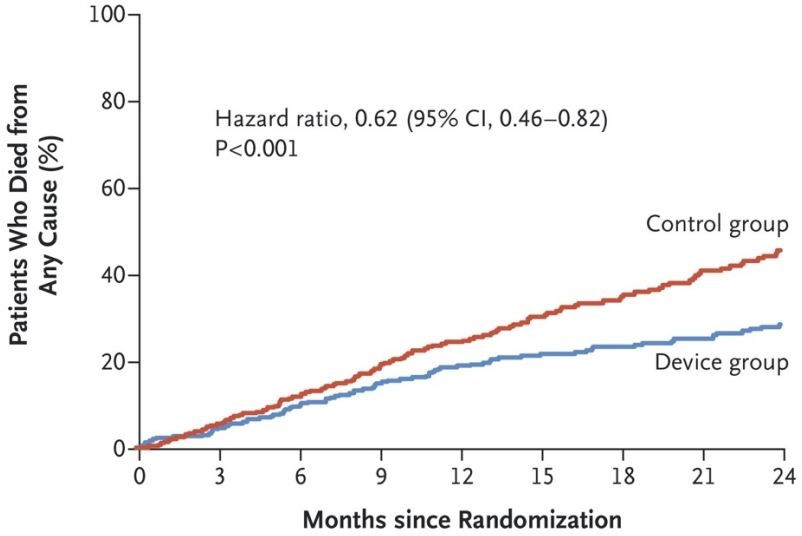
- Mitral regurgitation secondary to LV remodelling (= secondary/functional MR or SMR/FMR) affects one-third of patients with heart failure (HF).[1]
- SMR is associated with progression of symptoms, clinical deterioration and adverse clinical events.[2,3]
- Guidelinesrecommend a multidisciplinary approach for the treatment of SMR.[4]

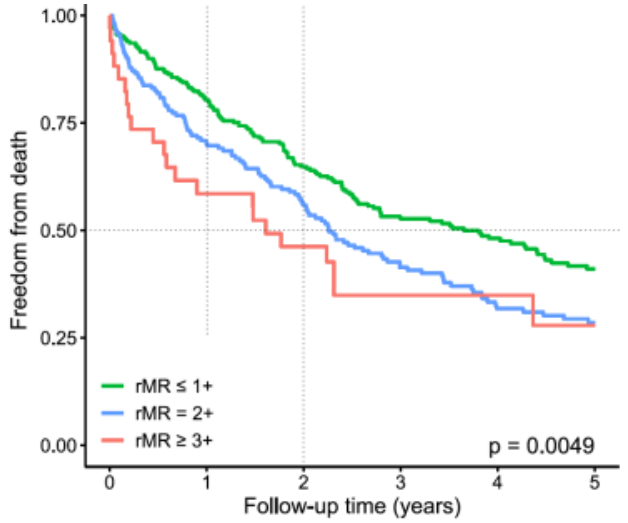


[1]Varadarajan et al., J Am Soc Echocardiogr 2006 [2]Bursi et al., Eur J Heart Fail 2010 [3]Goliasch et al., Eur Heart J 2018 [4]Coats et al., Eur Heart J 2021

Transcatheter Edge-to-Edge Repair (TEER)

- Transcatheter Edge-to-Edge Repair (TEER) is an established endovascular therapy for SMR, which has shown
  - high procedural safety,
  - functional improvement and
  - improved survival and reduced HF hospitalisations compared to GDMT alone (in selected patients).[5]

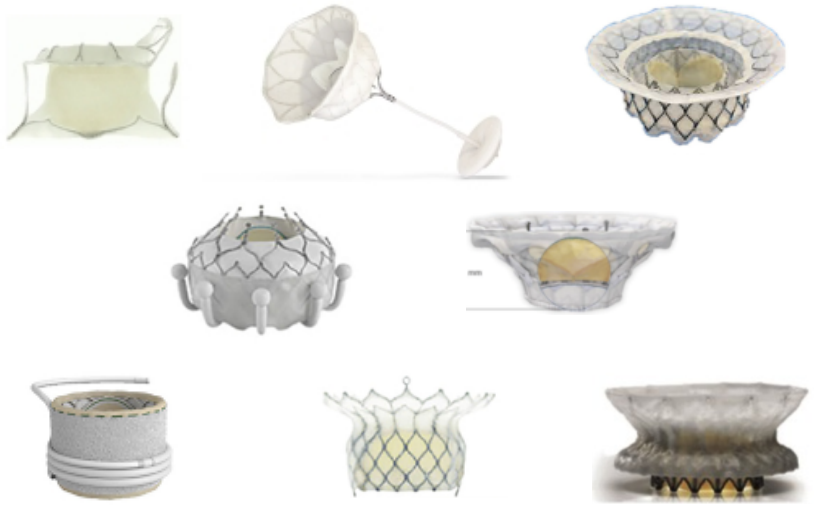




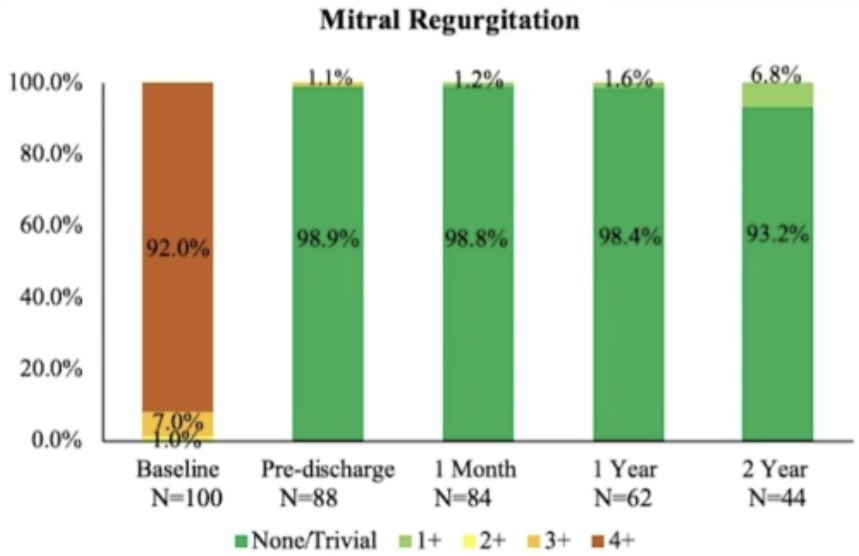
[5]Stone et al., NEJM 2018 [6]Reichart et al., Eur J Heart Fail 2020

Transcatheter Mitral Valve Implantation (TMVI)

- Transcatheter Mitral Valve Implantation (TMVI) is a novel treatment alternative for patients with severe SMR, who are considered ineligible for TEER and mitral valve surgery.



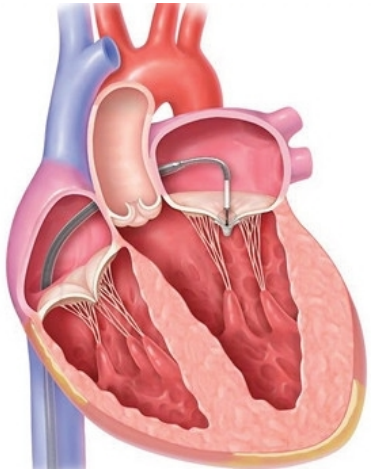
- Several studies have demonstrated favourable procedural and short-term outcomes with different dedicated TMVI systems.[7-11]



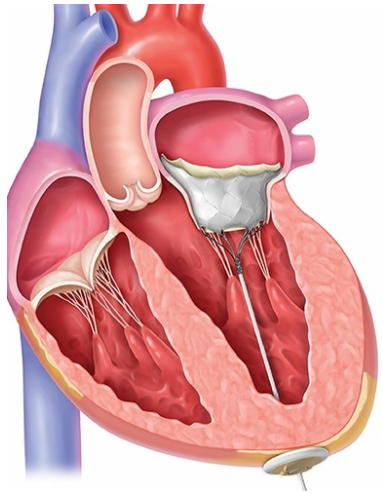
- One central aspect of TMVI seems to be complete and predictable elimination of MR.

[7]Bapat et al. JACC 2018 [8]Sorajja et al. JACC 2019 [9]Ludwig et al. Clin Res Cardiol 2020 [10]Conradi et al. PCR eCourse 2020 [11]Muller et al. PCR eCourse

Study Design



vs.



EuroSMR Registry

- N=1676 patients
- TEER for SMR
- 11 European high-volume centers

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CHOICE-MI Registry

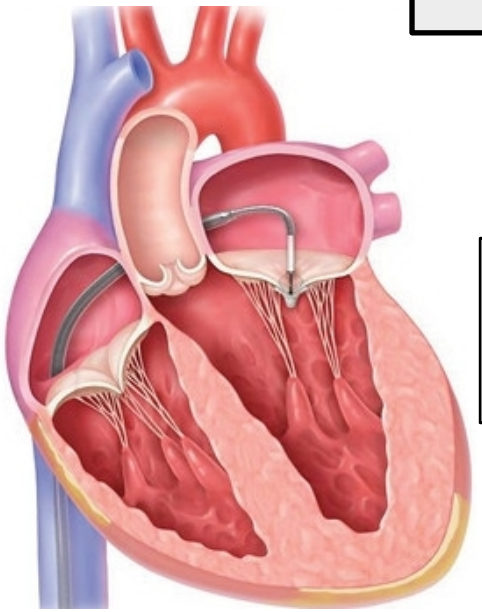
- N=229 patients (N=156 with SMR)
- TMVI for severe MR with eight different devices
- 26 centers from Europe, North America and Australia

NCT04688190

Study Design

EuroSMR Registry
(N=1676)

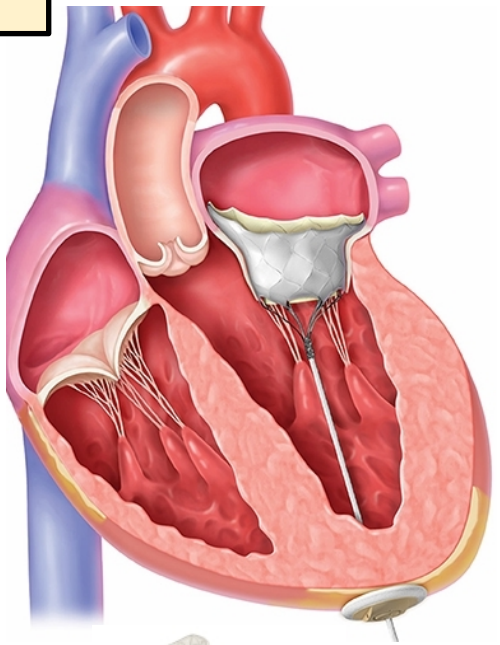
CHOICE-MI Registry
(N=156)



Excluded (N=296)
- pts. lost to FU
- non-severe MR

TEER
(N=1383)

TMVI
(N=153)



Propensity Score Matching
(11 parameters)

TEER
(N=499)

TMVI
(N=144)

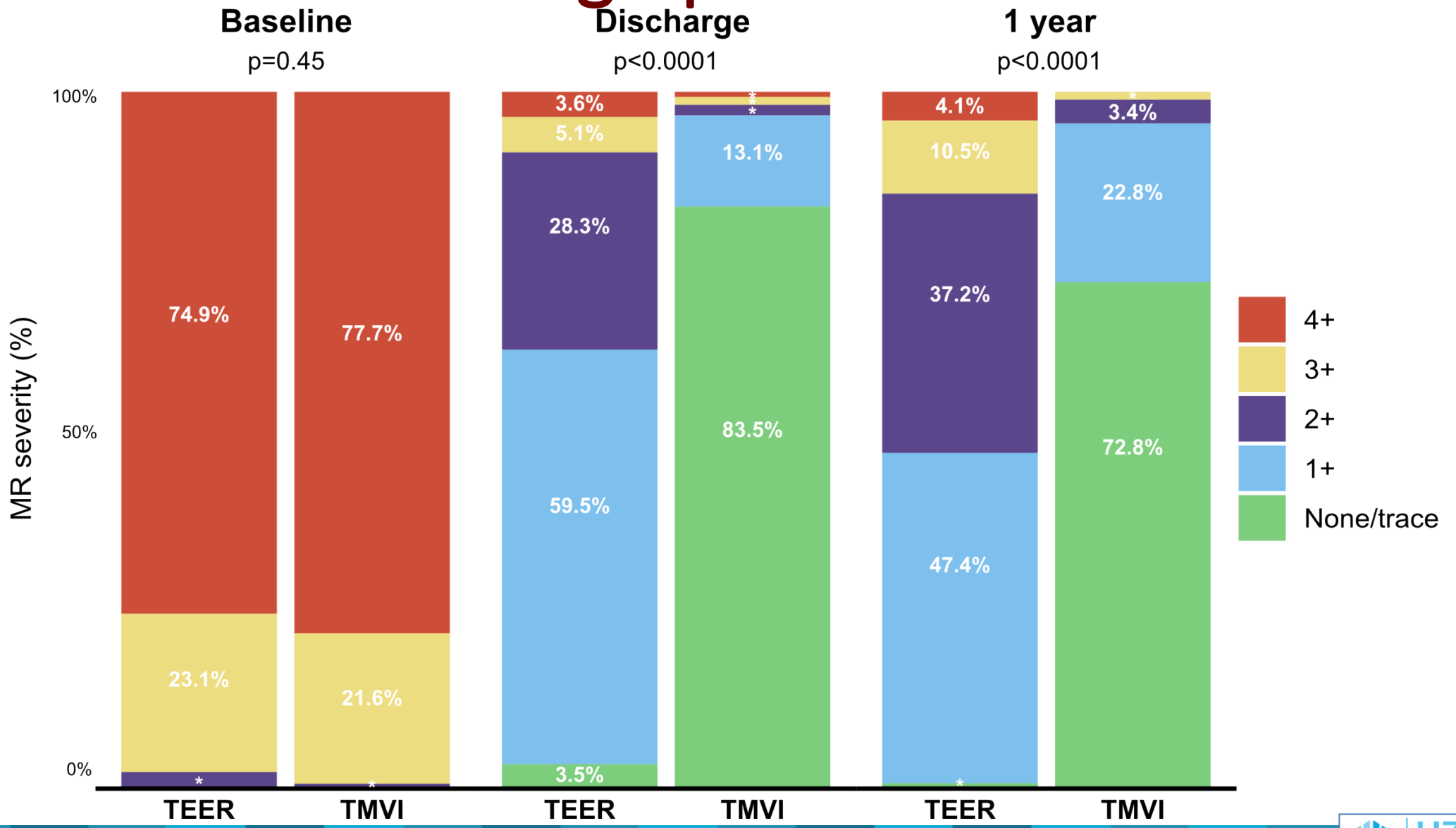
Investigated Outcomes

- Baseline clinical and echocardiographic parameters
- Echocardiographic outcome (residual MR)
- Functional outcome (NYHA functional Class)
- All-cause Death after 30 days and 2 years
- Combined Endpoint: All-cause Death or HF Hospitalisation after 2 years
- Subgroup analysis for the Combined Endpoint

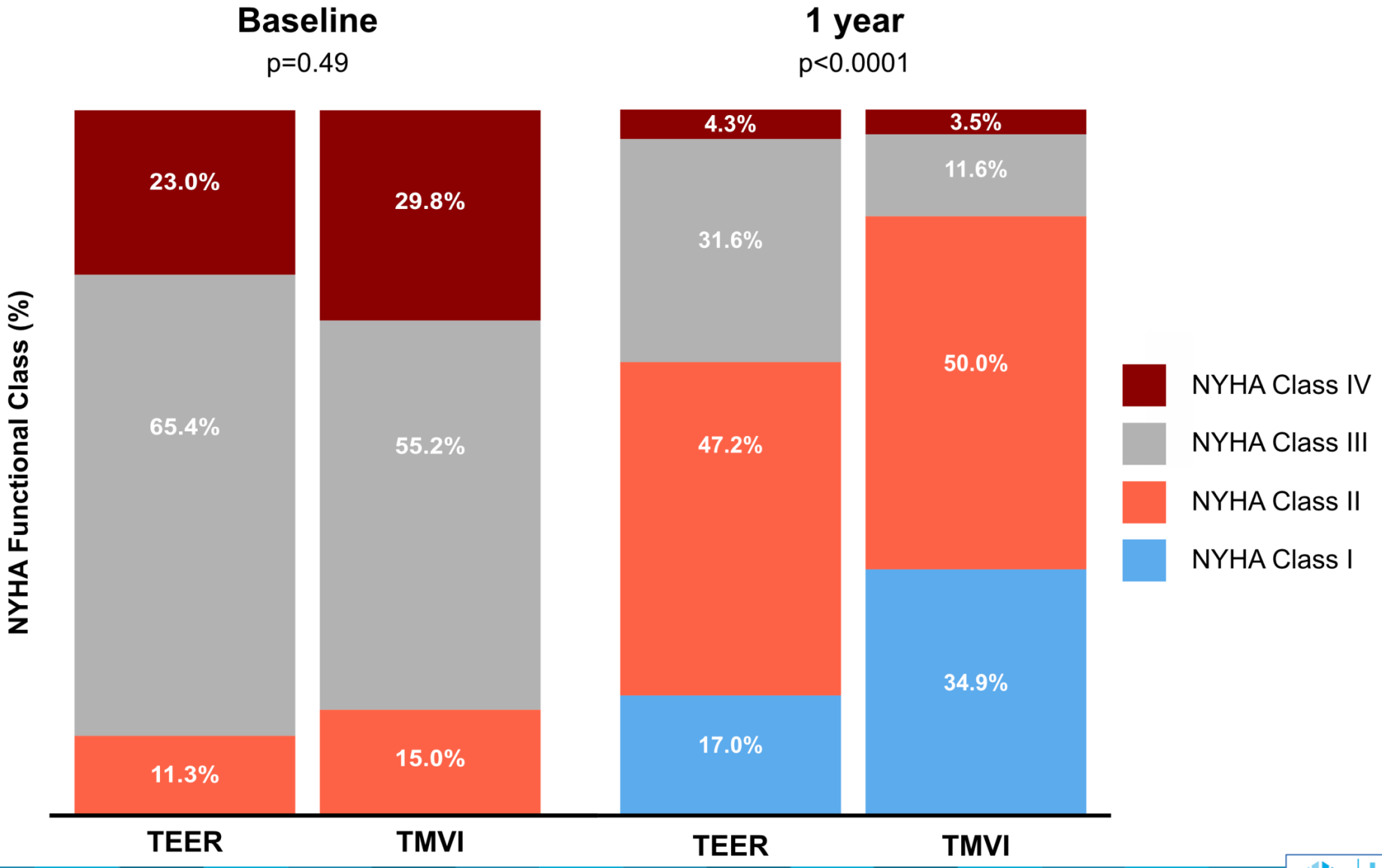
Baseline Characteristics

Propensity Score-matched	TEER (N=499)	TMVI (N=144)	p-value
Age (years)	76.7 (70.0, 80.8)	75.0 (70.3, 80.0)	0.64
Male sex	322 (64.4)	93 (64.7)	0.93
EuroSCORE II (%)	7.5 (3.9, 14.1)	6.3 (3.7, 13.6)	0.32
Diabetes mellitus	157 (34.2)	38 (26.8)	0.15
COPD	85 (17.1)	24 (17.0)	1.00
Prior myocardial infarction	208 (41.6)	67 (46.5)	0.37
Prior CABG No. (%)	137 (27.5)	46 (32.3)	0.34
eGFR (mL/min/1.73 m^2)	45.8 (33.0, 60.4)	45.3 (34.8, 64.1)	0.51
LVEF (%)	36.1 (31.7, 44.9)	38.9 (32.0, 45.1)	0.21
LVEDV (mL)	162.0 (119.0, 210.4)	167.4 (130.1, 218.7)	0.37
EROA (cm^2)	0.32 (0.22, 0.43)	0.30 (0.21, 0.41)	0.20
MVPG (mmHg)	3.0 (2.1, 5.1)	2.9 (2.0, 3.8)	0.35
TAPSE	16.6 (14.0, 19.8)	15.1 (12.1, 19.2)	0.070
≥ moderate TR	248 (49.6)	72 (49.9)	0.94
PASP (mmHg)	46.7 (38.0, 56.8)	49.3 (39.2, 58.4)	0.27

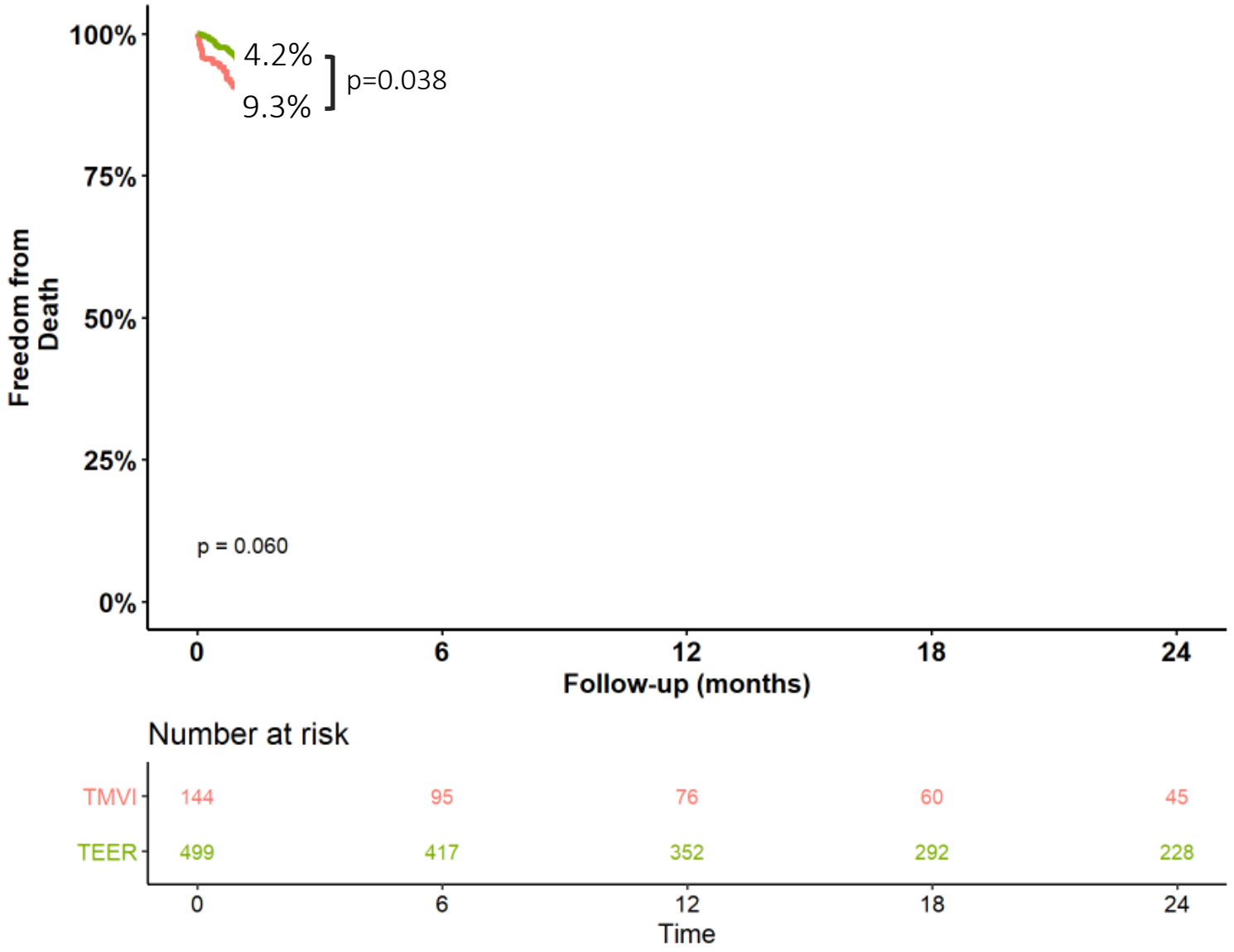
Echocardiographic Outcome



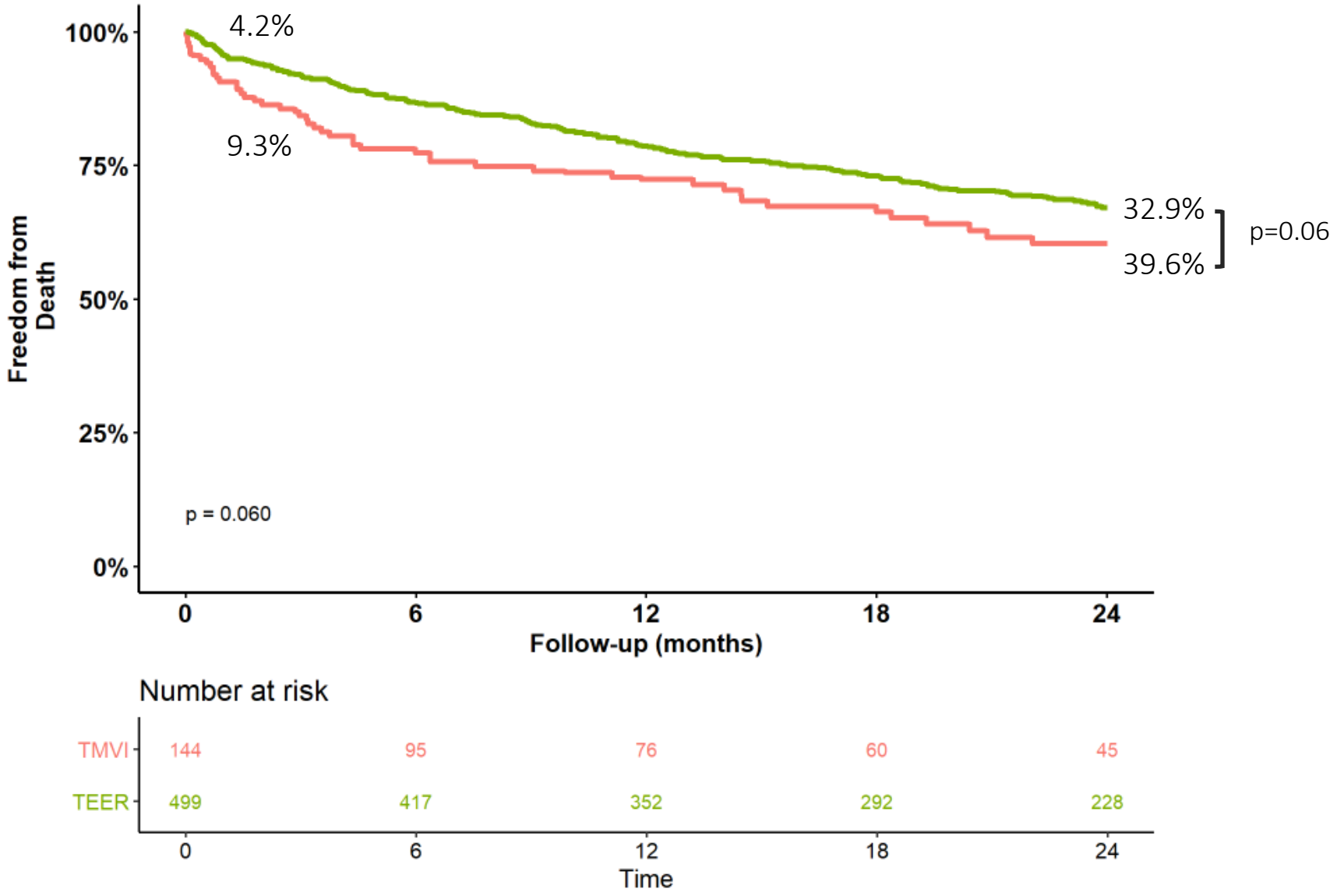
Functional Outcome



All-cause Death

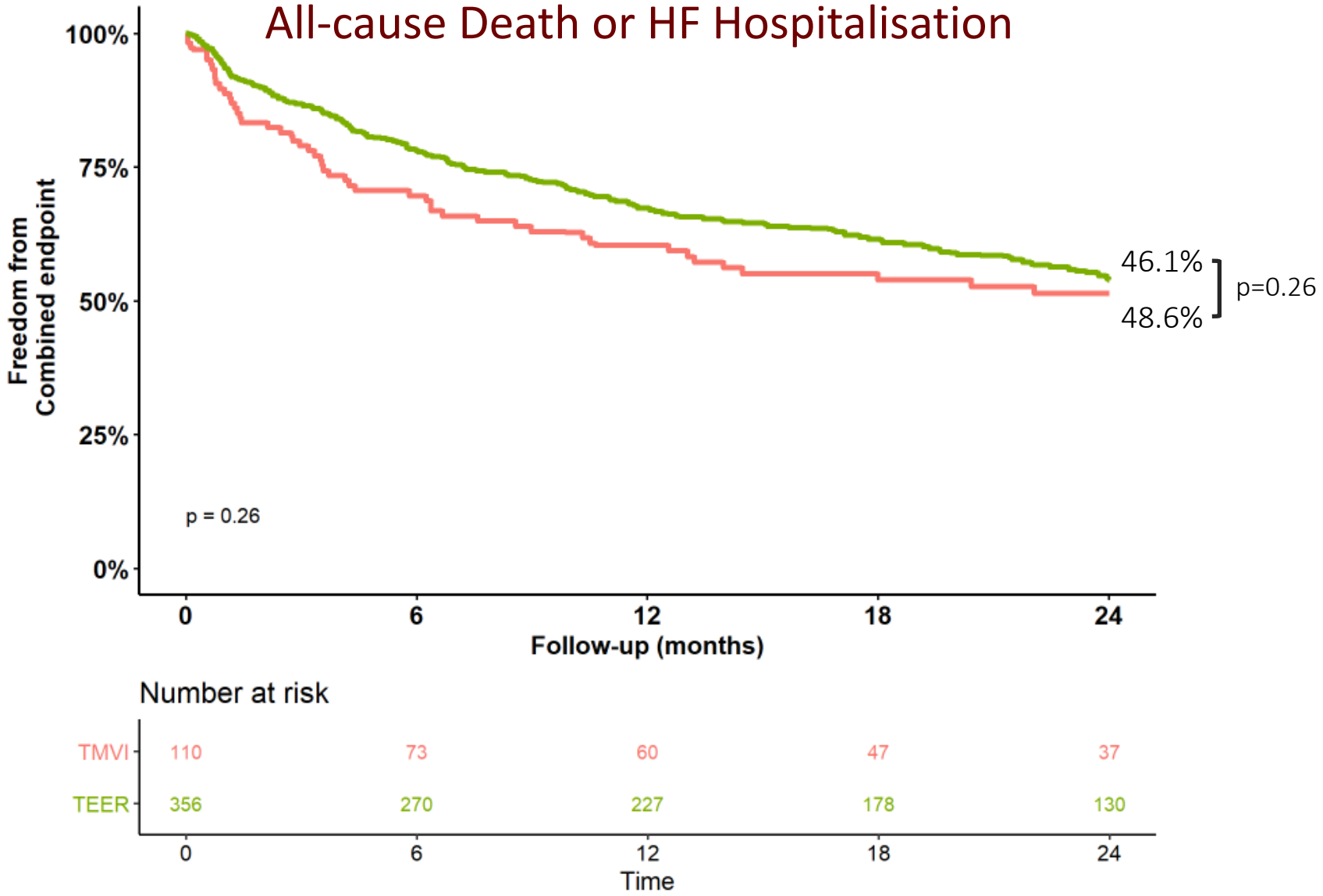


All-cause Death



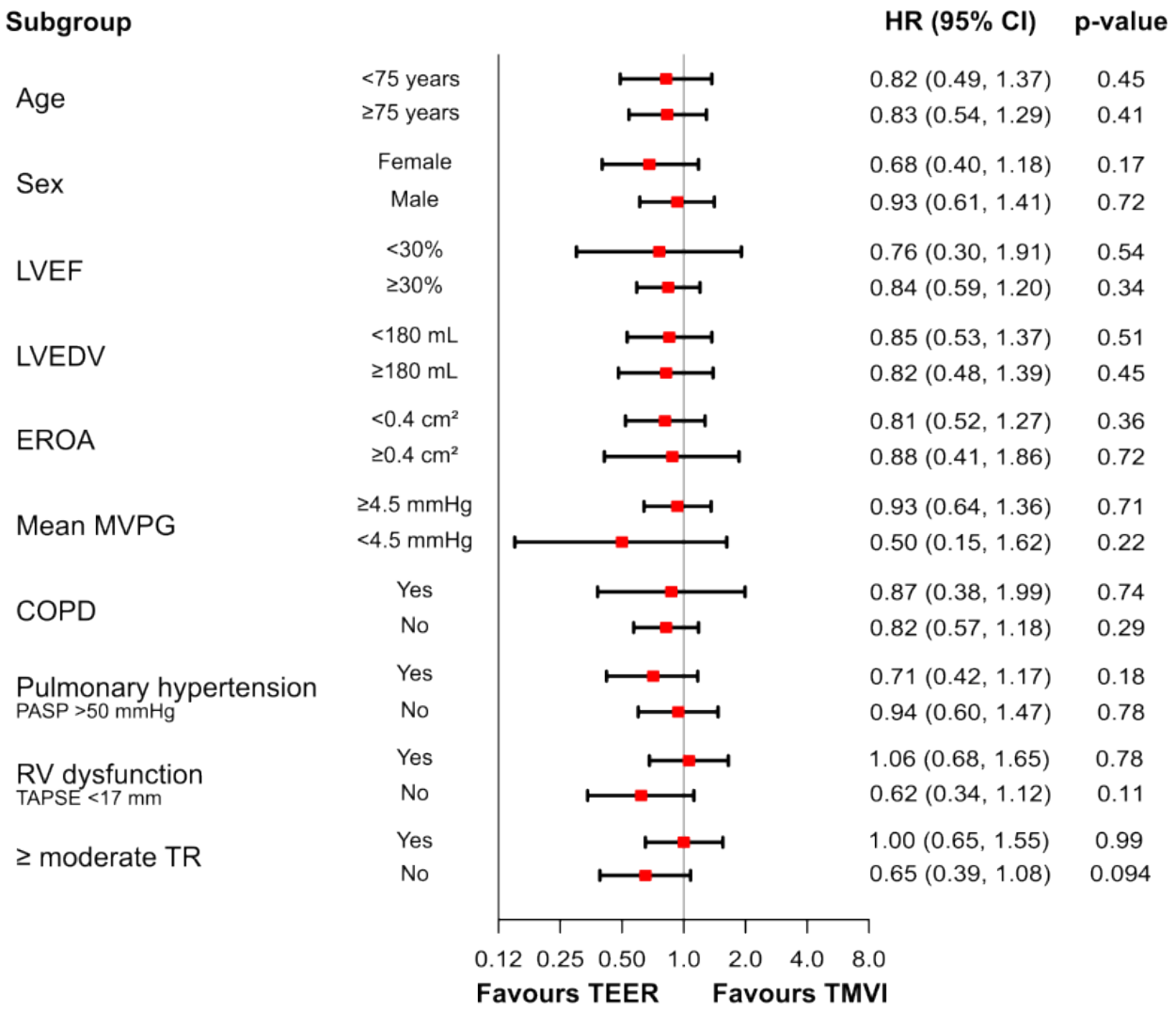
Combined Endpoint

All-cause Death or HF Hospitalisation

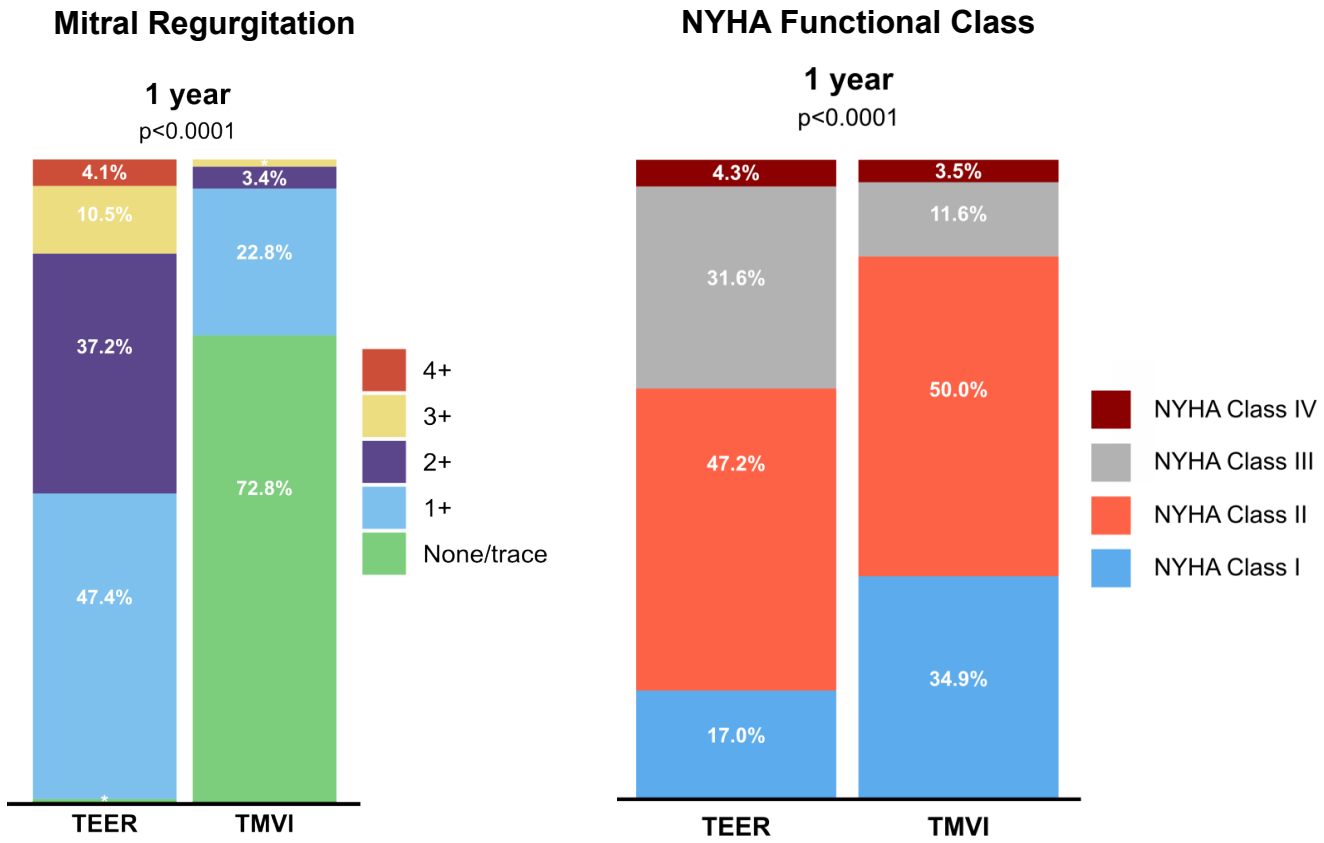


Subgroup Analysis

All-cause Death or HF Hospitalisation



- Based on data from two large multicentre registries, a propensity score-matched comparison between SMR patients treated with either TEER or TMVI allows to conclude:



<u>No difference</u> between TEER and TMVI regarding

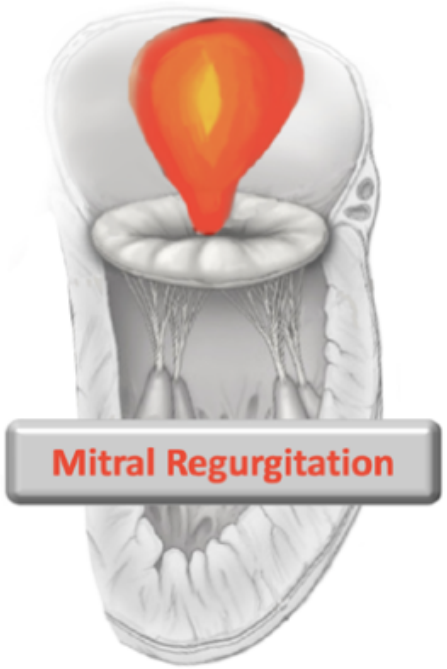
- All-cause Death after 2 years
- Combined Endpoint after 2 years

Limitations

- This is a retrospective analysis of registry data and all results can only be hypothesis-generating.
- Propensity score matching does not equal prospective randomisation.
- Patients treated with TMVI are considered suboptimal candidates for TEER. Therefore, comparability of both groups is limited per se.
- This analysis may have disregarded a potential learning curve effect with TMVI.

Mitral Valve Anatomy

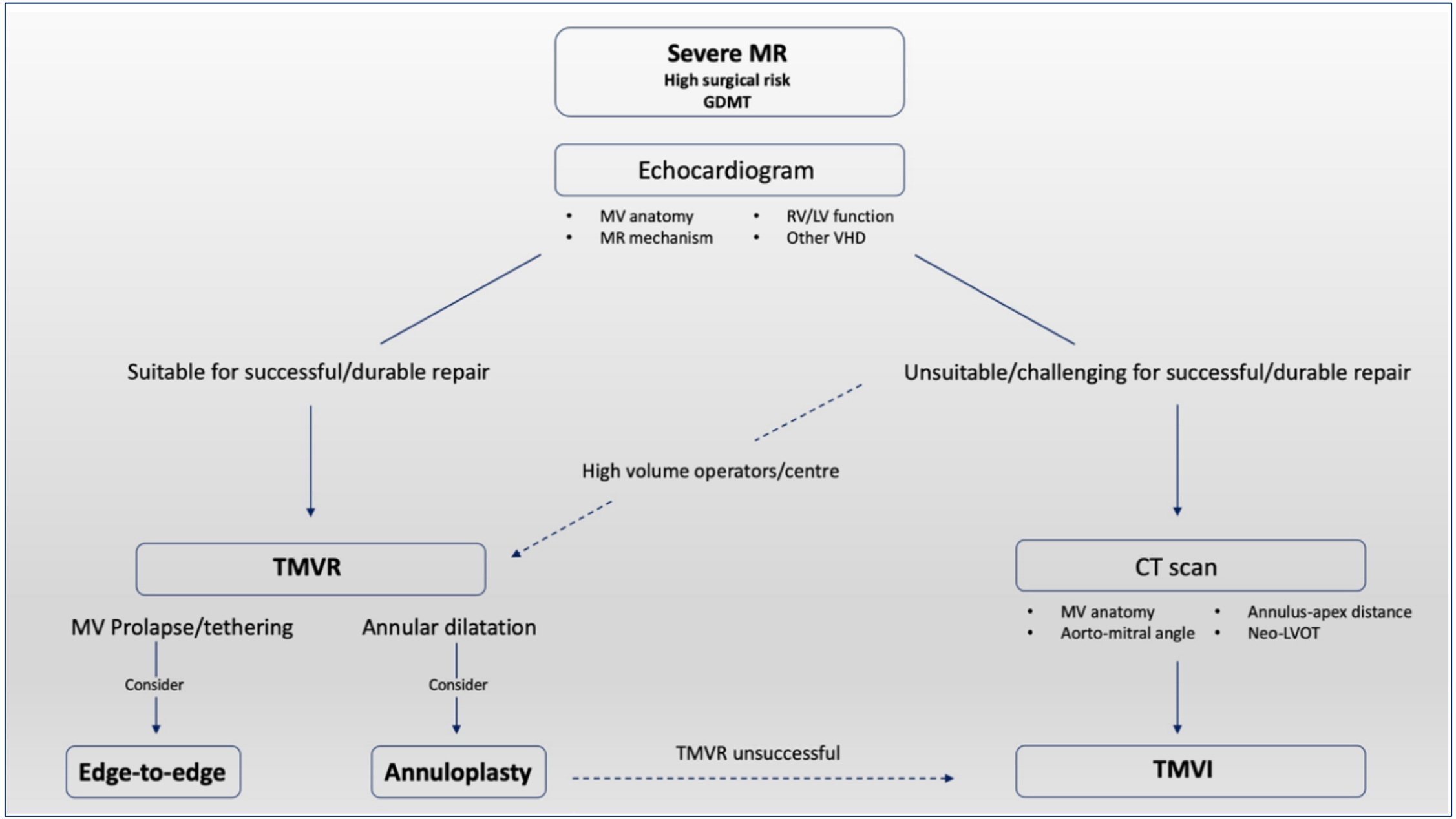
Favouring Repair	Favouring Replacement
A2-P2 lesion	Commissural/complex lesion
Single jet	Multiple jet
No/poor annular/leaflet calcification	Severe annular/leaflet calcification
Large annulus	Device-compatible annulus
No MV baseline gradient	Baseline gradient >4 mmHg
Suitable coaptation depth/length	Large coaptation gap
Adequate MV area (>4 cm^2)	Small MV area (<3.5 cm^2)



Patient

No previous surgery	Previous MV bioprosthesis
Contraindication to lifelong anticoagulation	Low bleeding risk

Russo et al. Circ Cardiovasc Interv. 2021;14:e010628. DOI: 10.1161



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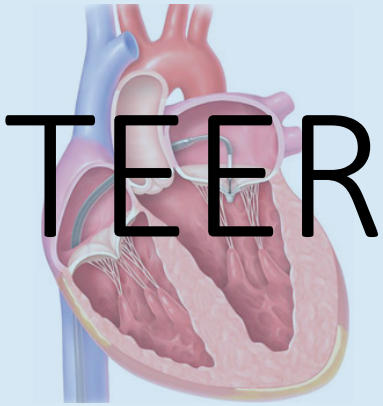
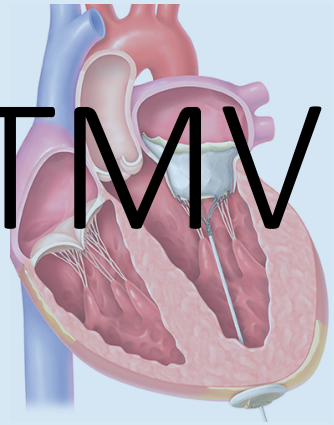
Summary

TEER	TMVI
	
<u>established</u> transcatheter therapy excellent safety profile	**<u>novel</u>** transcatheter therapy predictable MR elimination
residual or recurrent MR	elevated short-term mortality

Prospective randomised trials are needed to define the future role of TMVI among routine SMR treatment options (SUMMIT, APOLLO,…).