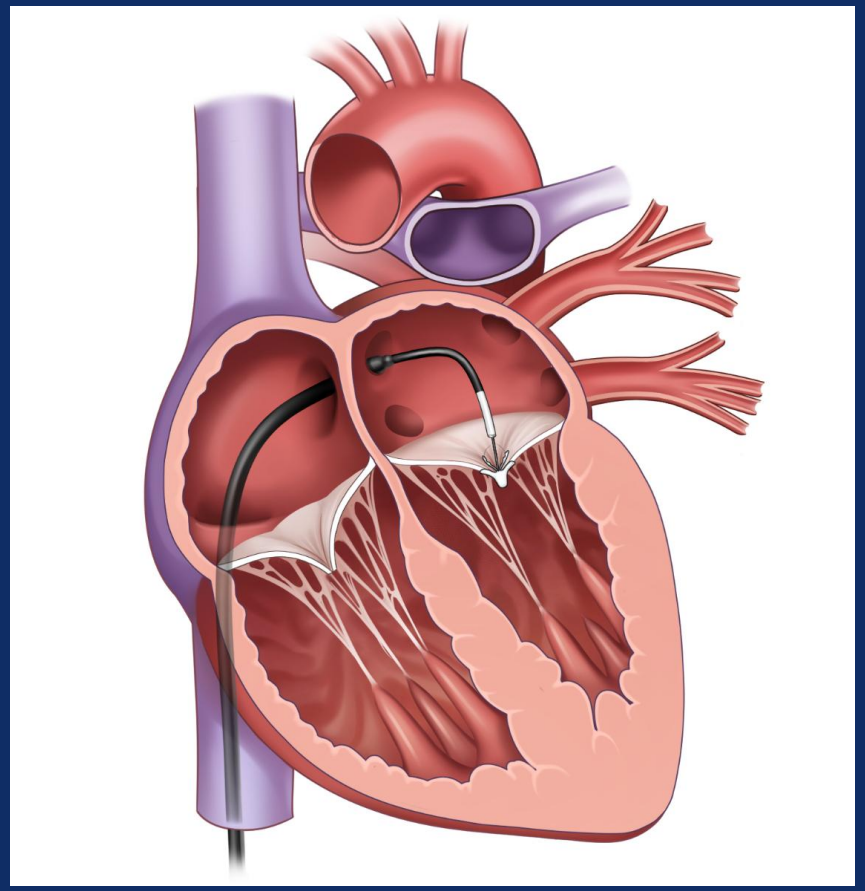
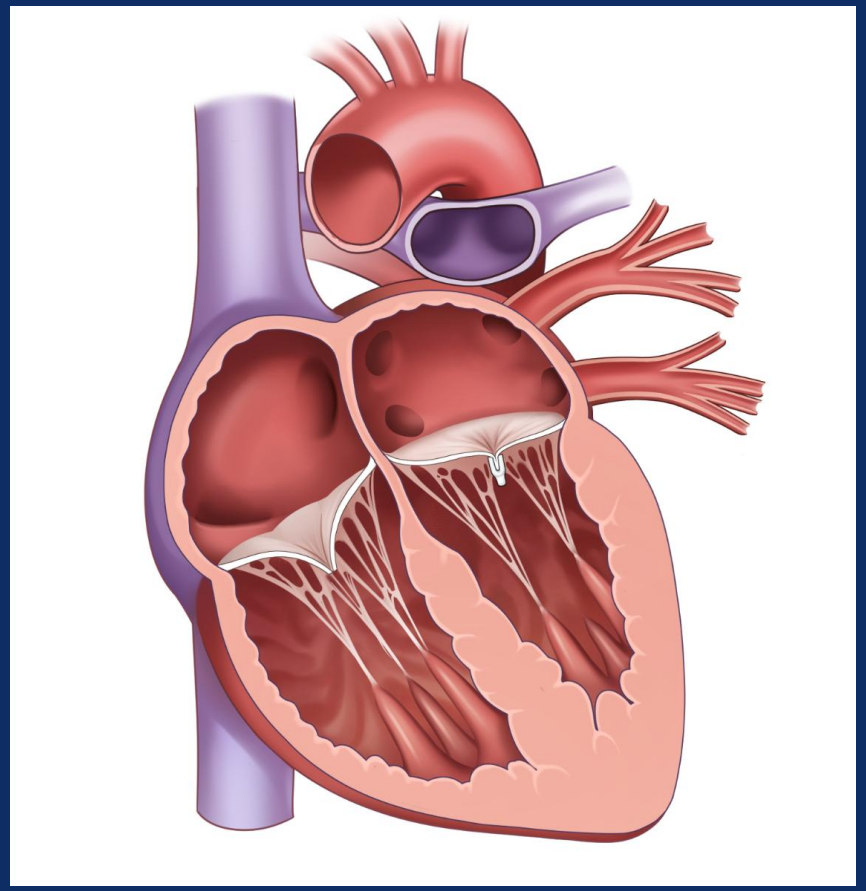
Transcatheter Edge-to-Edge Repair (TEER)

Concept of TEER with MitraClip



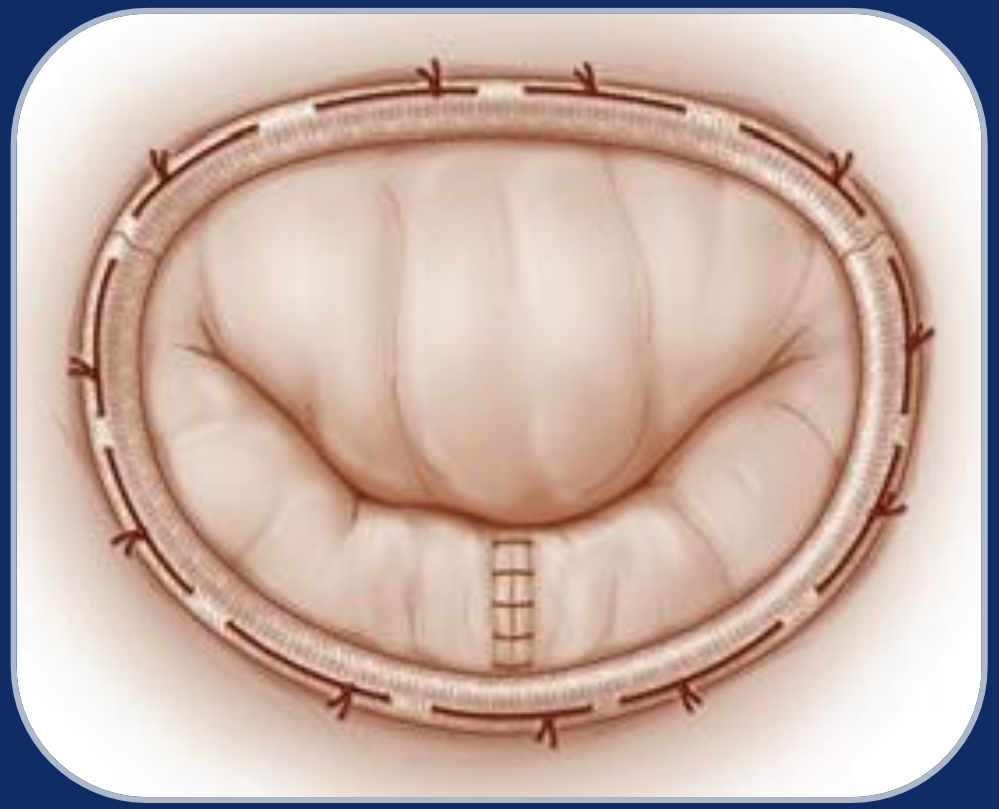


Current Devices of TEER

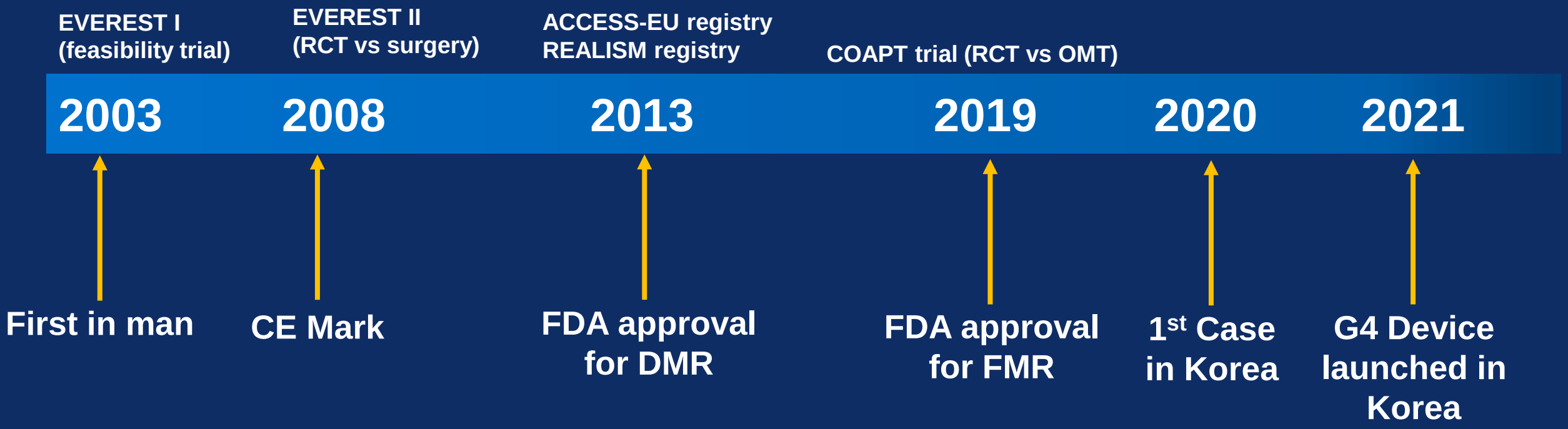
MitraClip (Abbott)
FDA, CE, KFDA approved

PASCAL (Edwards)
CE approved

MitraClip vs. Surgery



Status of MitraClip



2020 AHA/ACC Guideline Indication of TEER

- **Primary MR (IIA, B)**
  - Severely symptomatic MR (NYHA III-IV)
  - High or prohibitive surgical risk
  - Favorable anatomy

- **Secondary MR (IIA, B)**
  - Chronic severe symptomatic MR after optimal GDMT (NYHA II-IV)
  - LVEF 20-50% & LVESD ≤70 mm & PASP ≤70 mmHg
  - Appropriate anatomy

Two Types of Mitral Regurgitation

Primary (degenerative) MR: Prolapse/Flail

Secondary (functional) MR: Ventricular Problem

Evidence of TEER for Primary MR

Mitraclip for Primary MR : EVEREST II RCT

279 patients enrolled at 37 sites

Severe MR (3+ or 4+)

73% DMR, 27% FMR

Specific anatomical criteria

Randomized 2:1

Device Group
MitraClip System
N=184

Control Group
Surgical Repair or Replacement
N=95

Echocardiography Core Lab and Clinical Follow
Baseline, 30 days, 6 months, 1 year, 18 months, and annually through 5 years

Feldman T et al. NEJM 2011;364:1395-406

EVEREST II Trial

279 patients 2:1 Randomization to Mitraclip vs Surgery

	Percutaneous Repair N=184	Surgery N=95	P value
Age	67.3 ± 12.8	65.7 ± 12.9	0.32
> 75 yr	55 (30%)	26 (27%)	0.68
Male sex	115 (62%)	63 (66%)	0.60
Congestive heart failure	167 / 184 (91%)	74 / 95 (78%)	0.005
Coronary artery disease	86 / 183 (47%)	44 / 95 (46%)	0.99
Atrial fibrillation	59 / 175 (34%)	35 / 89 (39%)	0.42
Diabetes	14 / 184 (8%)	10 / 95 (11%)	0.50
COPD	27 / 183 (15%)	14 / 95 (15%)	0.99
Previous CABG	38 / 184 (21%)	18 / 95 (19%)	0.87
LV ejection fraction, %	60.0 ± 10.1	60.6 ± 11.0	0.65

Feldman T et al. N Engl J Med. 2011 Apr 14;364(15):1395-406.

EVEREST II Trial

279 patients 2:1 Randomization to Mitraclip vs Surgery

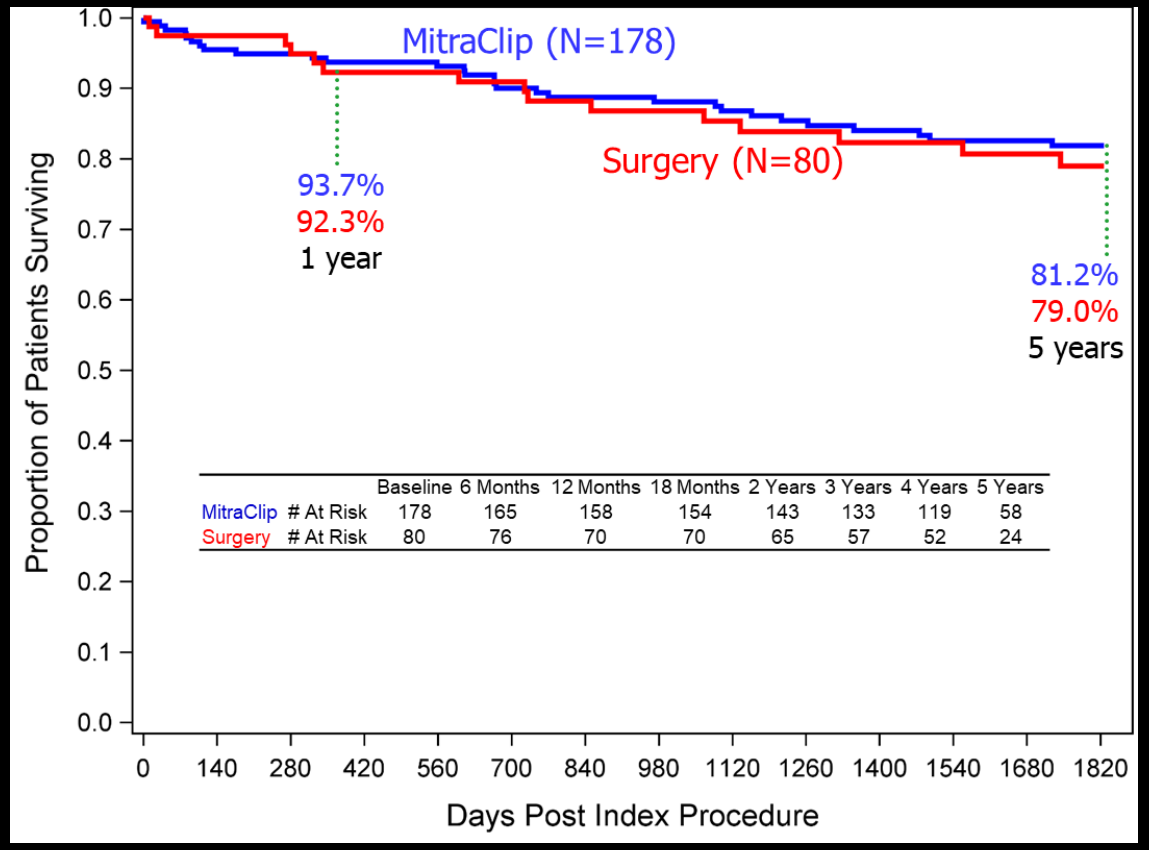
	Percutaneous Repair N=184	Surgery N=95	P value
Primary Efficacy Endpoint at 12 months			
Freedom from death, surgery for MV dysfunction, grade 3+/4+ MR	100 (55%)	65 (73%)	**0.007**
Death	11 (6%)	5 (6%)	1.00
Surgery for MV dysfunction	37 (20%)	2 (2%)	**<0.001**
Grade 3+/4+ MR	38 (21%)	18 (20%)	1.00
Major Adverse Event at 30 days	27 (15%)	45 (48%)	<0.001
Any major adverse event excluding transfusion	9 (5%)	9 (10%)	0.23

Feldman T et al. N Engl J Med. 2011 Apr 14;364(15):1395-406.

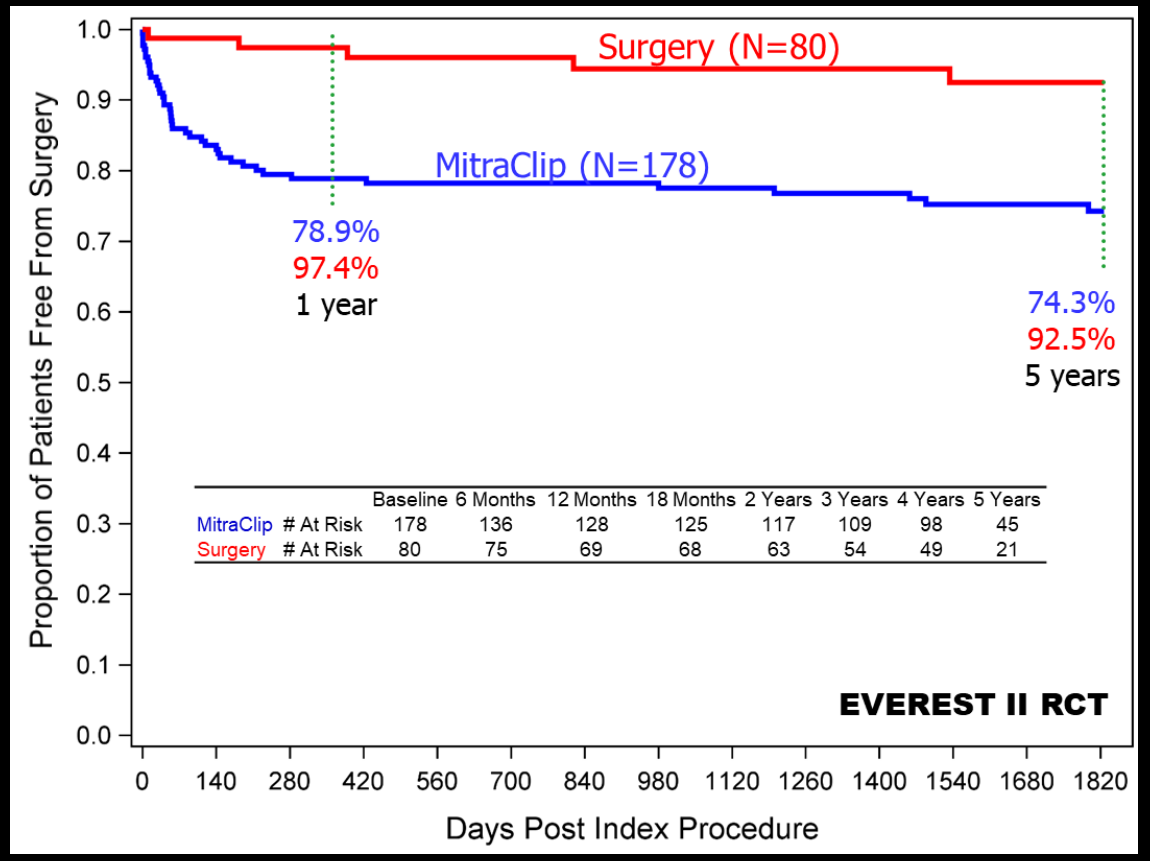
EVEREST II Trial

279 patients 2:1 Randomization to Mitraclip vs Surgery

Freedom from Mortality



Freedom from MV Surgery or Re-operation

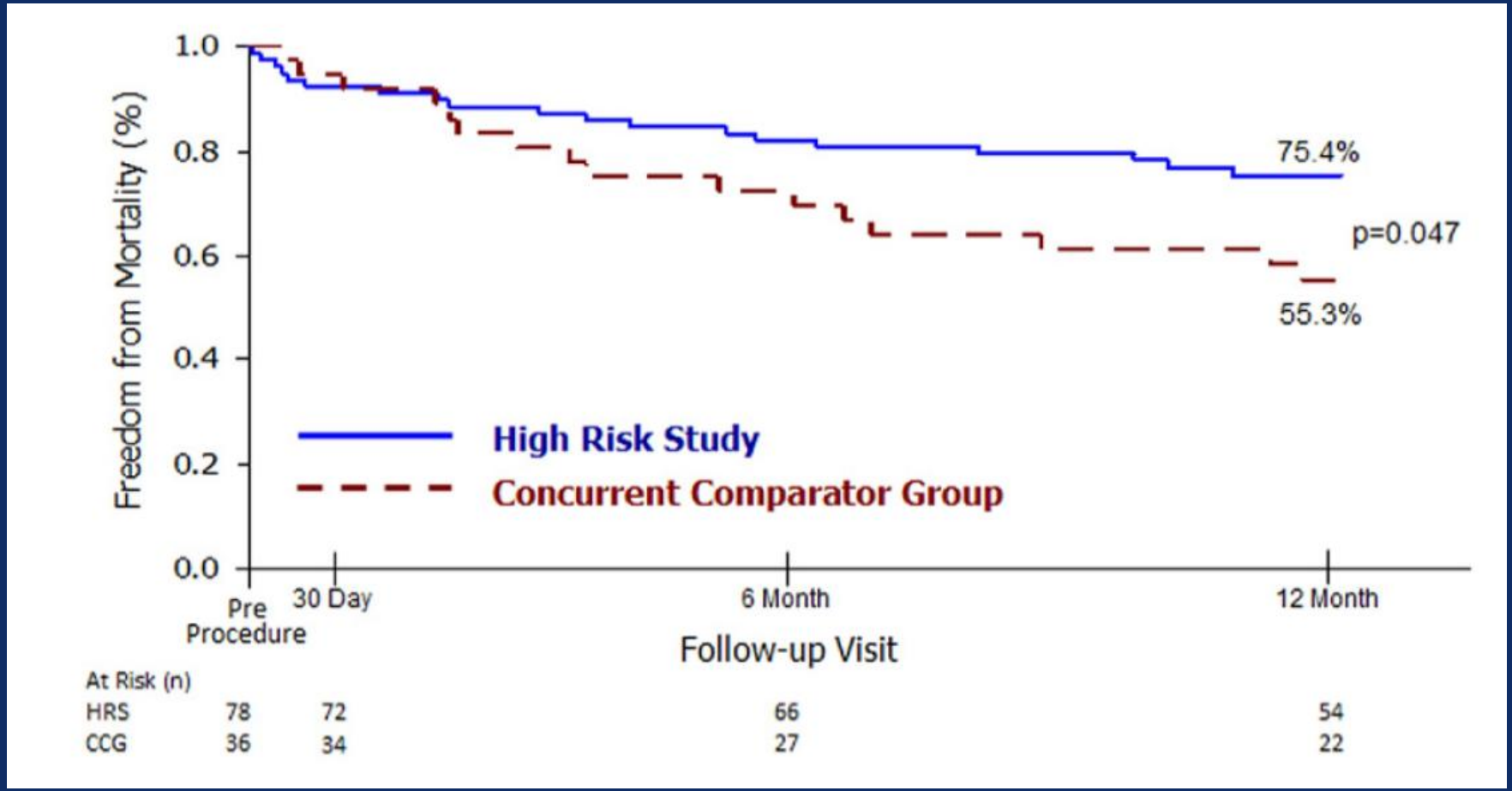


Feldman T et al. N Engl J Med. 2011 Apr 14;364(15):1395-406.

EVEREST II High-Risk Study

76 High Risk Patients compared with 36 Patients with Standard Care

Freedom from Mortality



Whitlow P et al. J Am Coll Cardiol. 2012;59(2):130-9.

2014 & 2017 AHA/ACC Guideline, TMVR for Primary MR

COR	LOE
IIb	B-NR

- Transcatheter mitral valve **repair may be considered** for **severely symptomatic** patients (NYHA class III to IV) with chronic severe primary MR (stage D) who have favorable anatomy for the repair procedure and **a reasonable life expectancy but who have a prohibitive surgical risk** because of severe comorbidities and remain severely symptomatic despite optimal GDMT for heart failure (HF)

Nishimura R et al. Circulation. 2014.

2020 AHA/ACC Guideline, TEER for Primary MR

COR	LOE
IIa	B-R

- In severely symptomatic patients (NYHA class III or IV) with primary severe MR and high or prohibitive surgical risk, transcatheter edge-to-edge repair (TEER) is reasonable if mitral valve anatomy is favorable for the repair procedure and patient life expectancy is at least 1 year

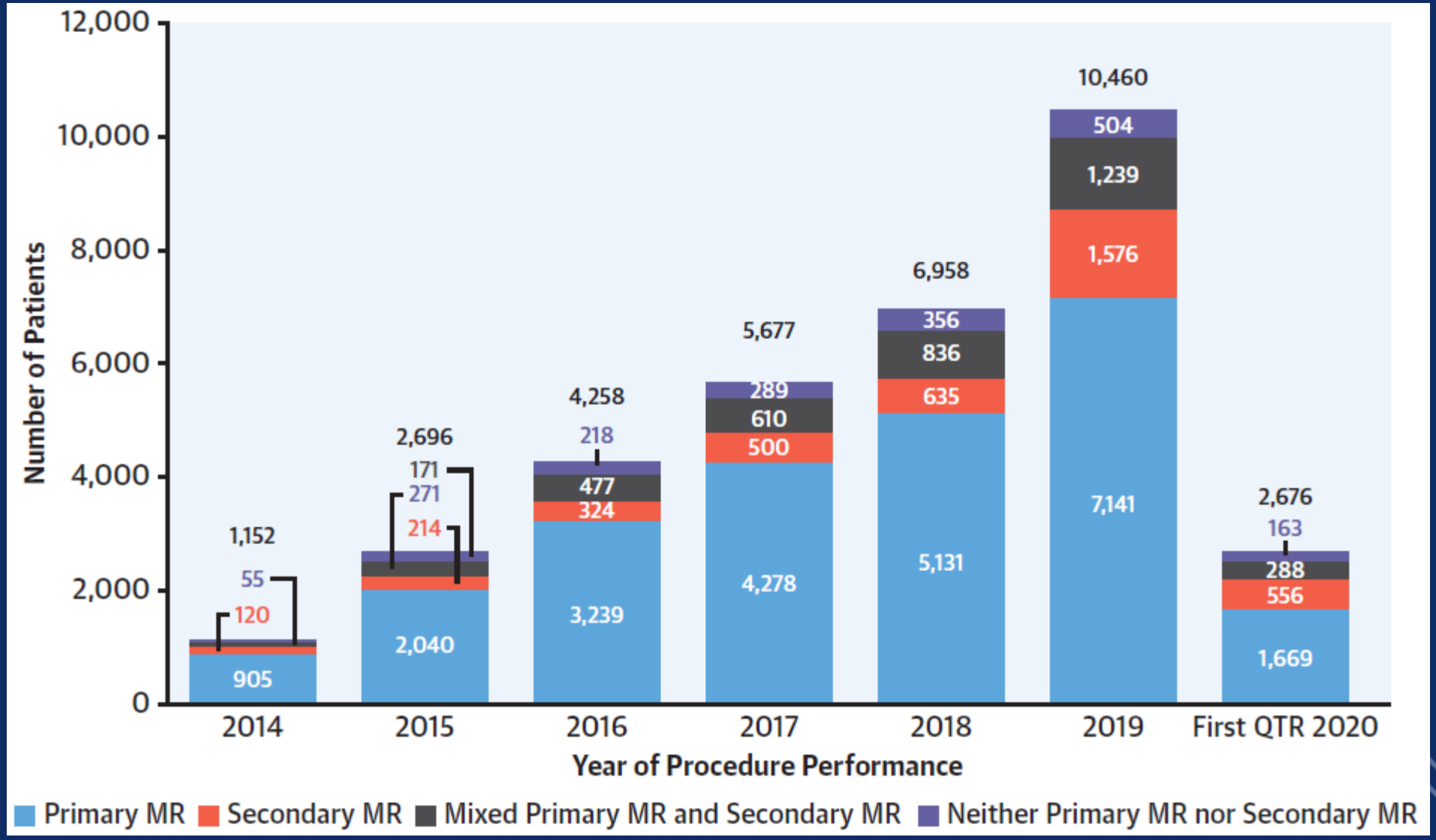
Otto CM et al. J Am Coll Cardiol 2020 Dec 17

Real-World outcome of TEER
: 2021 STS/ACC TVT Registry Report

	In-hospital	30-day
Death	2.2%	4.5%
Stroke	0.7%	1.3%
MV reintervention	0.6%	1.1%
Single leaflet device attachment	1.0%	1.3%
Atrial fibrillation	2.1%	2.9%
Major bleeding	2.2%	4.7%
Major vascular access site complications	0.4%	0.5%
Moderate-severe / Severe mitral insufficiency	8.7%	
MV mean gradient > 5 mmHg	26.3%	

Mack M et al. J Am Coll Cardiol. 2021;78(23):2326-2353.

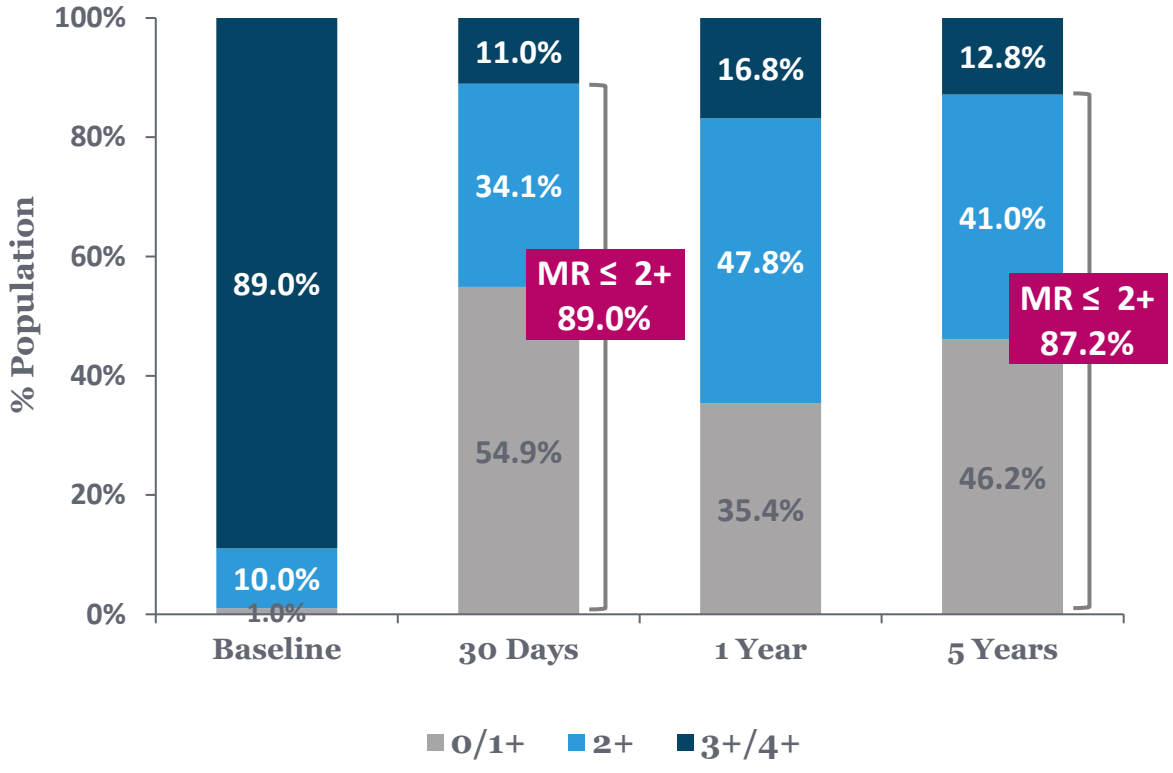
Annual TEER Volume in US
: 2021 STS/ACC TVT Registry



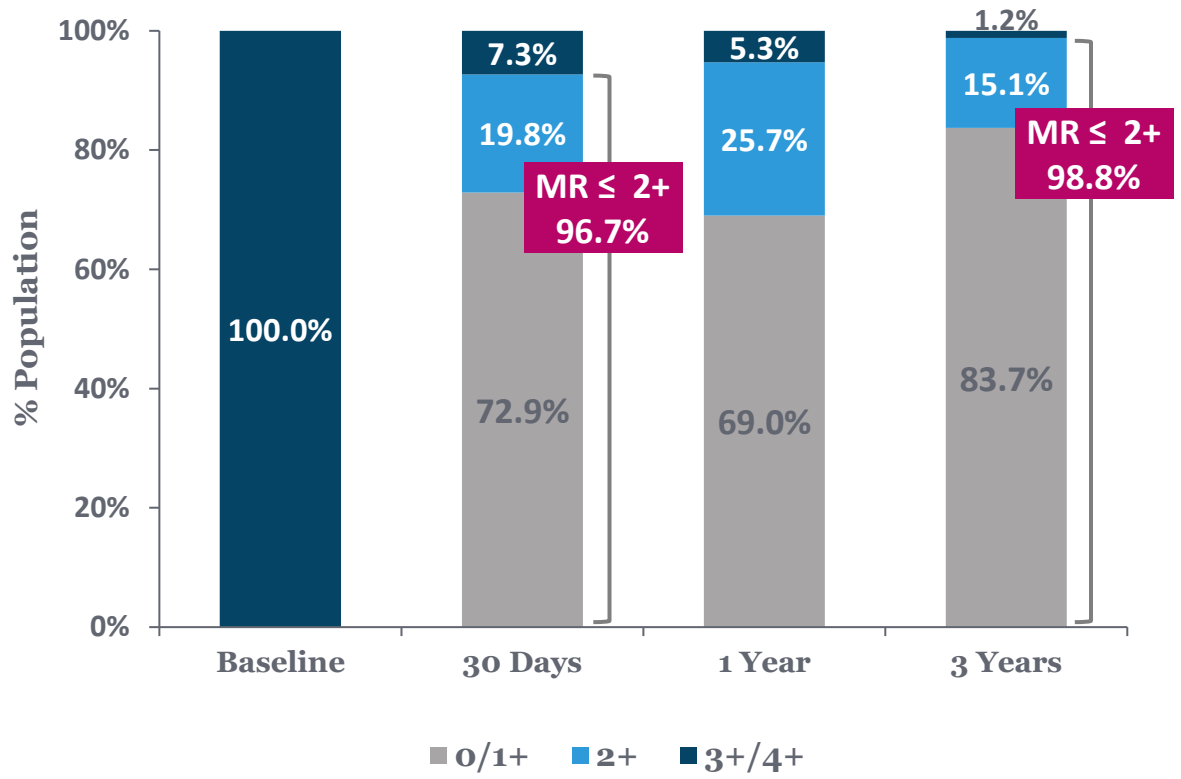
Mack M et al. J Am Coll Cardiol. 2021;78(23):2326-2353.

Durable Results in Longer-term FU

EVEREST II REALISM 5 Year Outcomes[1]
(n=264)

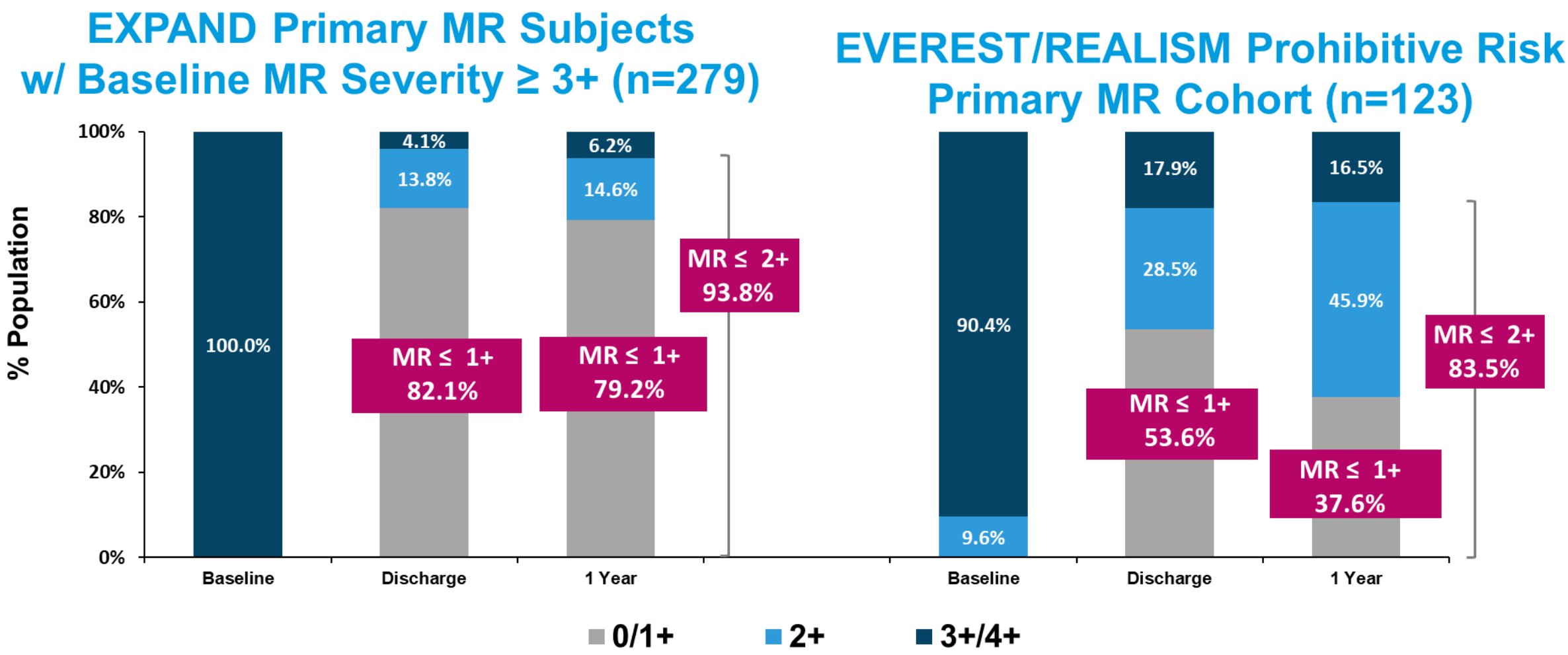


COAPT 3 Year Outcomes[2]
(n=302)



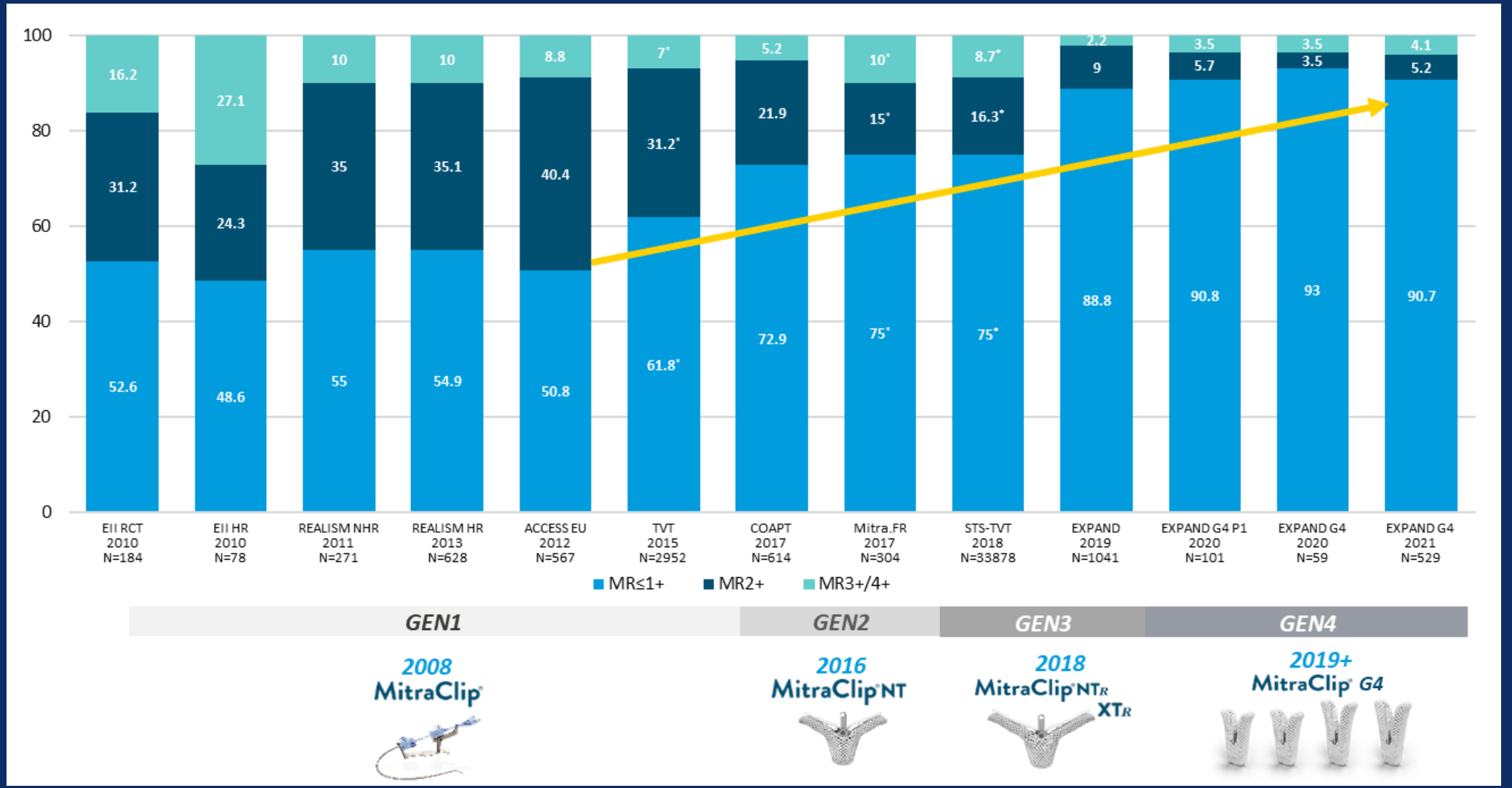
1. EVEREST II REALISM Non High Risk (HR) Cohort, Abbott Internal Data
2. Mack, M.J. et al. J Am Coll Cardiol. 2021;77(8):1029–40.

Higher MR Reduction (about 80% MR ≤1+ at 1-year)



Kar et al. TCT 2020, Presentation, Lim et al. ACC 2018 Presentation

Significant Improvement in MR at 30-days post-TEER Implant Over The Past Years



Rinaldi M. TVT 2022 Presentation

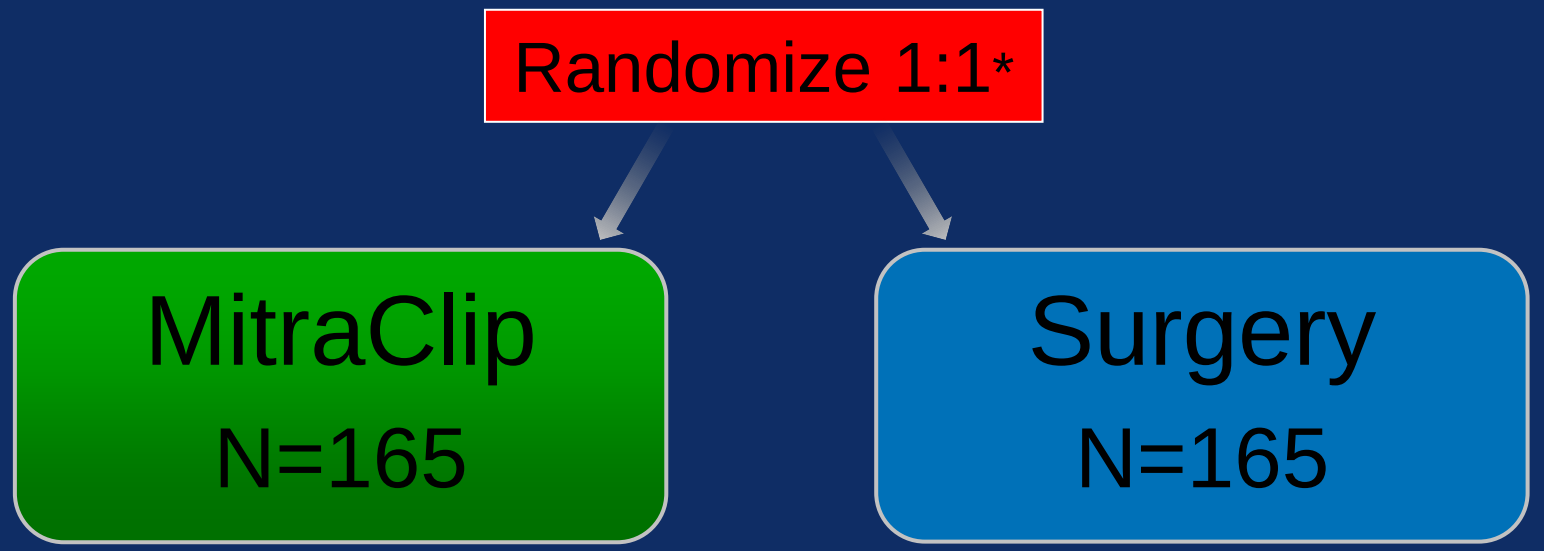
MITRA-HR Trial

MitraClip vs. Surgery for High Surgical Risk Primary MR

Primary Endpoint: All-cause mortality, unplanned hospitalizations for HF and MV reintervention at 12 month (non-inferiority)

Table 1. Inclusion criteria of the MITRA-HR trial.

Primary mitral regurgitation grade 3+ or 4+
New York Heart Association Class II to IV
Mitral valve anatomy appropriate to MitraClip therapy and mitral valve surgery (repair or replacement)
High surgical risk defined by the local Heart Team as: – age ≥75 years and an intermediate MVARC risk (STS score [repair] ≥6%, or one frailty index [mild][1], or one compromised major organ system[2], or one possible procedure-specific impediment[3]) or – age <75 years and a high MVARC risk (STS score [repair] >8%, or two frailty indices [moderate to severe][1], or no more than two compromised organ systems[2], or one possible procedure-specific impediment[3])
Isolated mitral valve pathology
If revascularisation procedures are required, they must be performed more than 30 days from the intervention (day 0)
Affiliation to French social security
[1,2,3] details in Supplementary Appendix 1



PI : Patrice Guerin MD. NCT03271762.
Piriou N et al. EuroIntervention 2019;15:e329-e335.

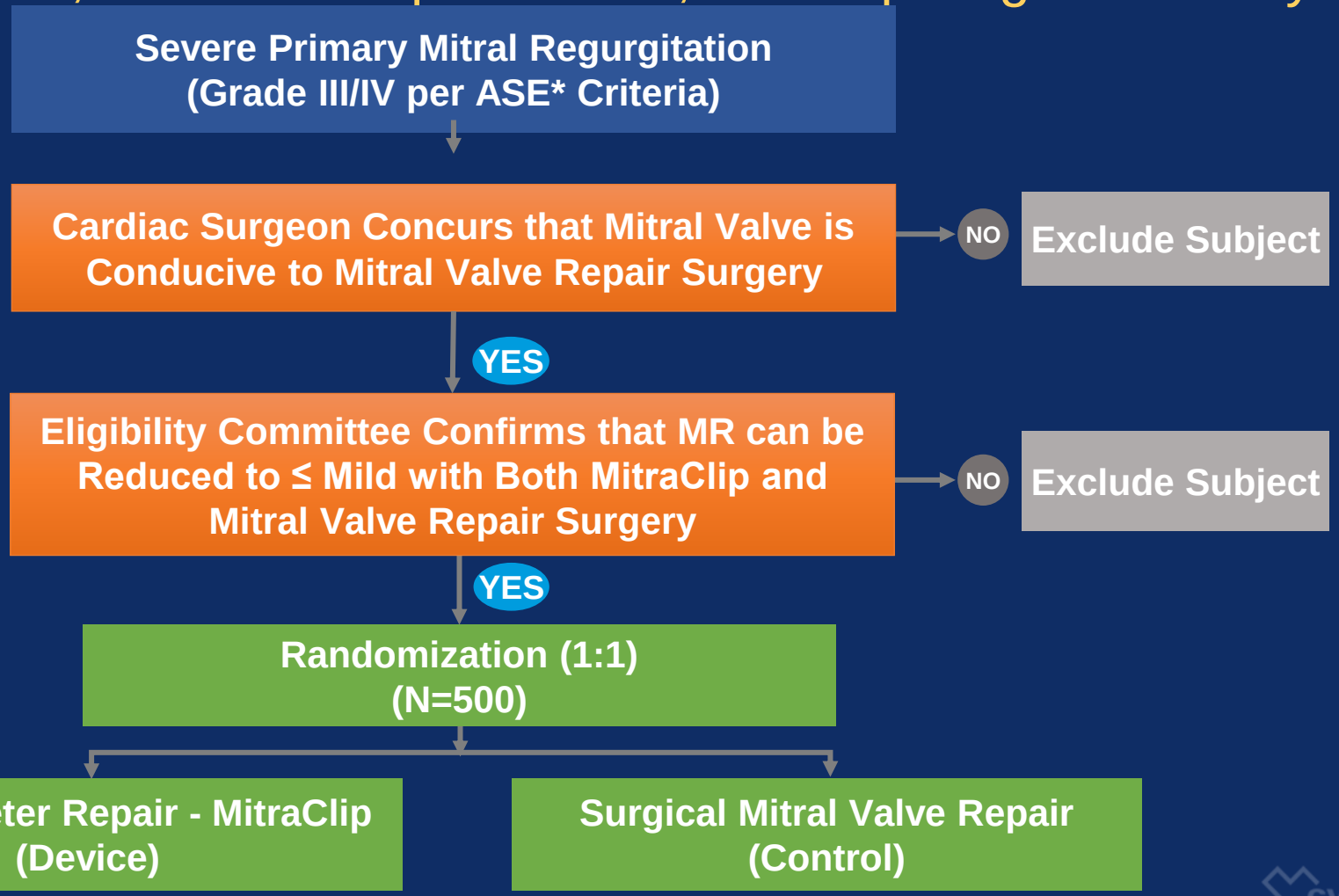
REPAIR-MR Trial

MitraClip vs. Surgery for Moderate Surgical Risk Primary MR

Primary Endpoint: Death, Stroke, Cardiac Hospitalization, AKI requiring RRT at 2 yrs

Patient Population

- Subject is symptomatic (NYHA Class II/III/IV) or asymptomatic (LVEF ≤ 60%, Pulmonary Artery Systolic Pressure > 50 mmHg, or LVESD > 40 mm)
- Subject is at least 75 years of age, OR if younger than 75 years, then has:
  - STS-PROM Score ≥ 2%, OR
  - Presence of other comorbidities which may introduce a potential surgical specific impediment

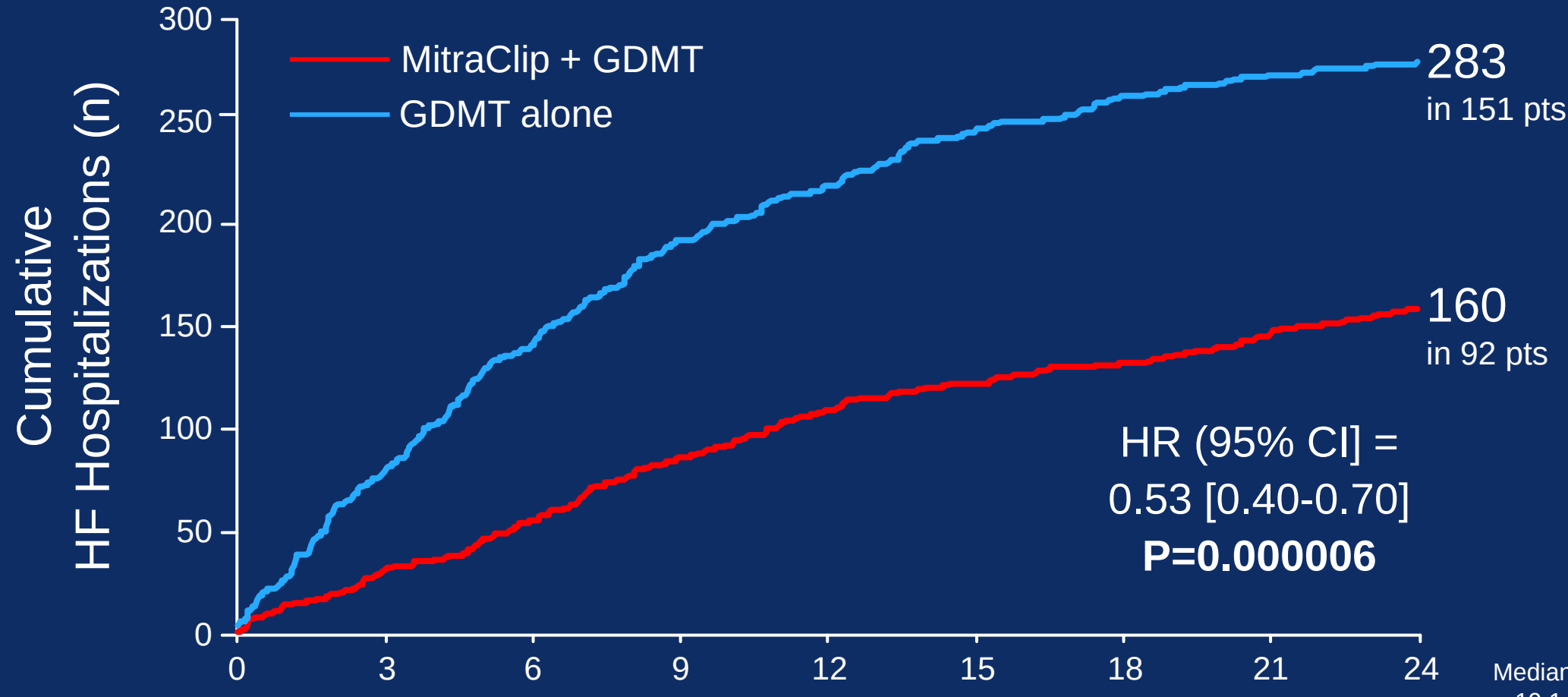


PI : Patrick McCarthy MD, Saibal Kar MD. NCT04198870.

TEER for Secondary MR

COAPT opened a New Era of Mitral Intervention

All Hospitalizations for HF within 24 months



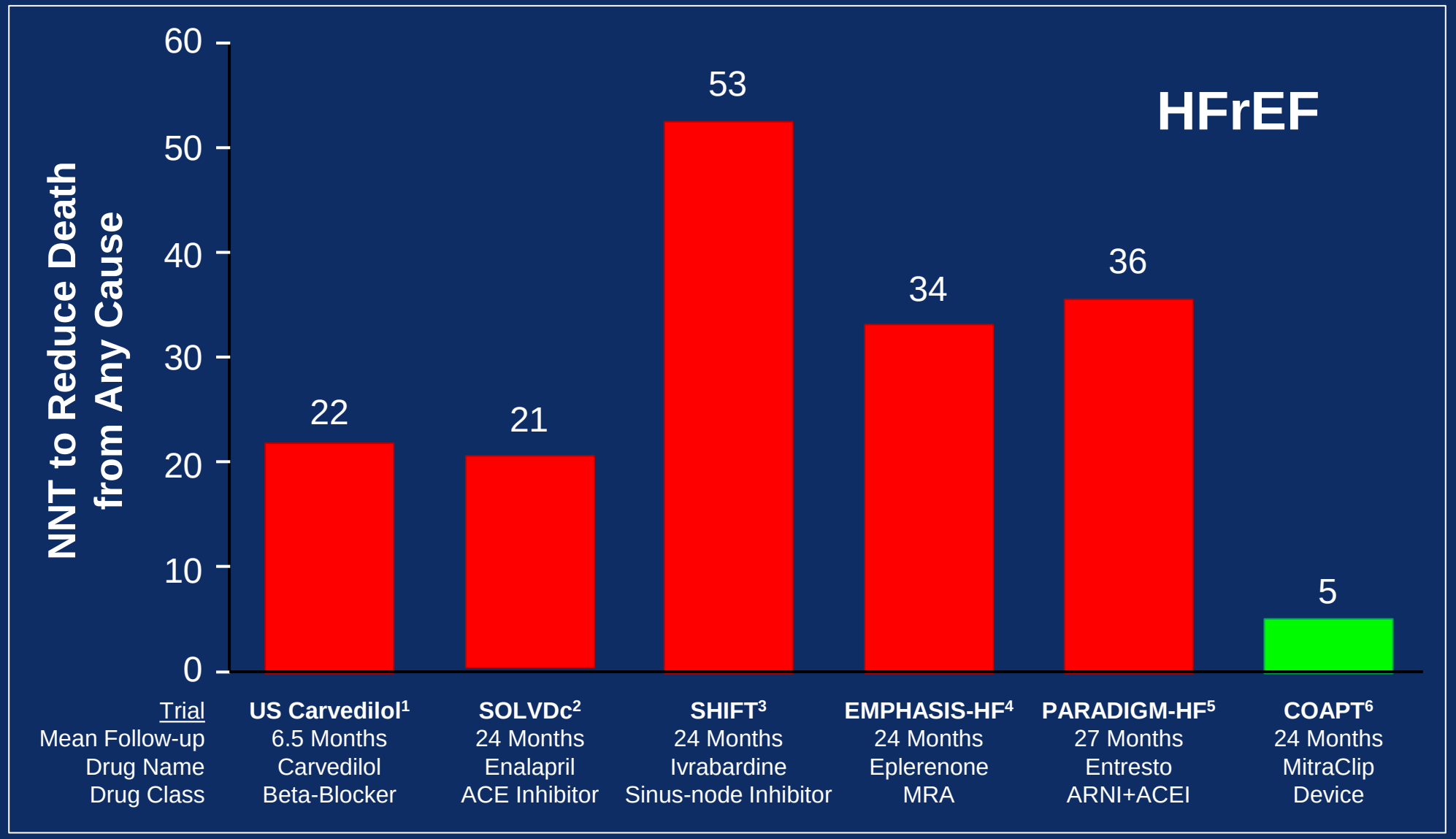
Median [25%, 75%] FU = 19.1 [11.9, 24.0] mos

No. at Risk:

MitraClip	302	286	269	253	236	191	178	161	124
GDMT	312	294	271	245	219	176	145	121	88

Stone GW et al. N Engl J Med. 2018;379:2307-18

COAPT : Number Needed to Treat to Prevent 1 Death

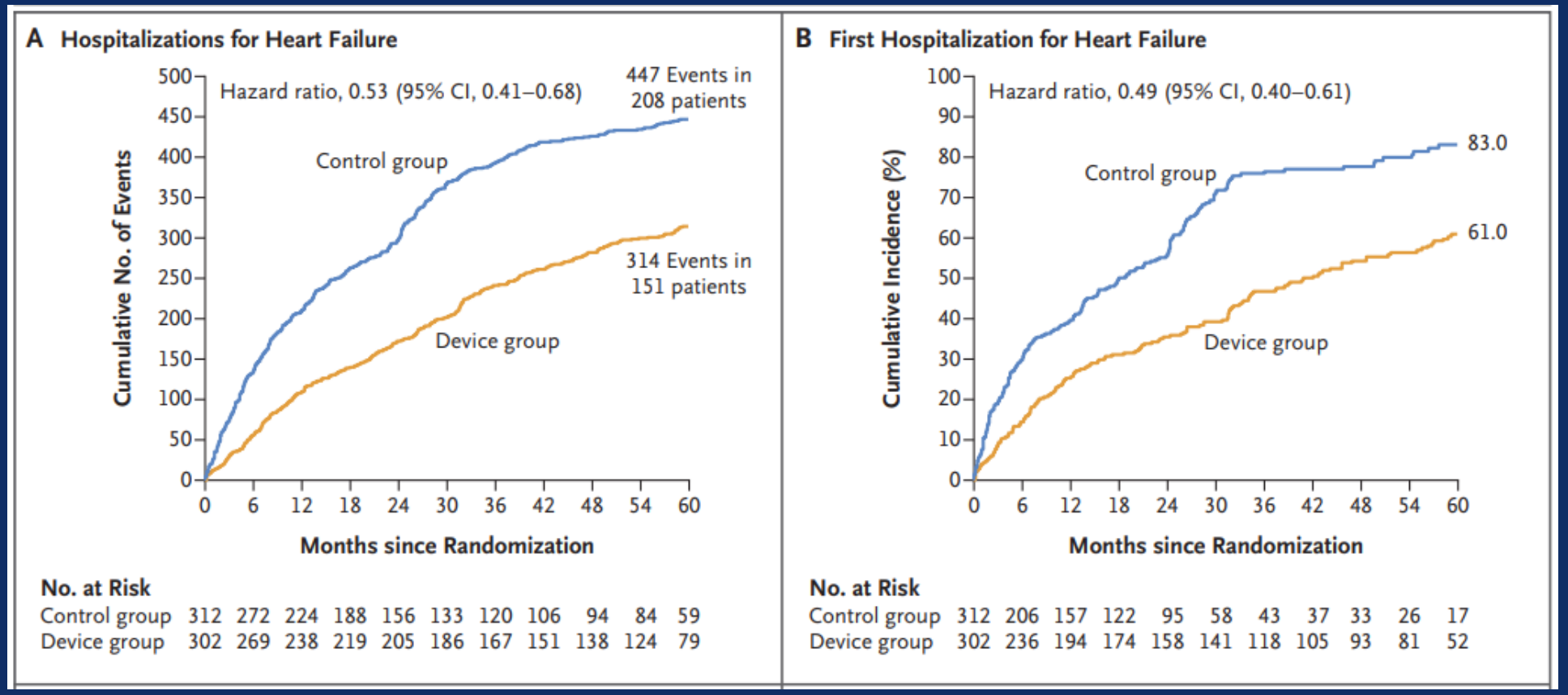


1. Packer M et al. NEJM 1996;334:1349-1355; 2. SOLVD Investigators. NEJM 1991;325:293-302; 3. Swedberg K et al. Lancet 2010;376:1988; 4. Zannad F et al. NEJM 2011;364:11-21; 5. McMurray JJV et al. NEJM 2014;371:993-1004; 6. Stone GW et al. NEJM 2018;379:2307-18.

5-Year follow-up COAPT trial

Mitraclip versus GDMT in patients with heart failure and secondary MR

Clinical Outcomes of 5-Year follow-up

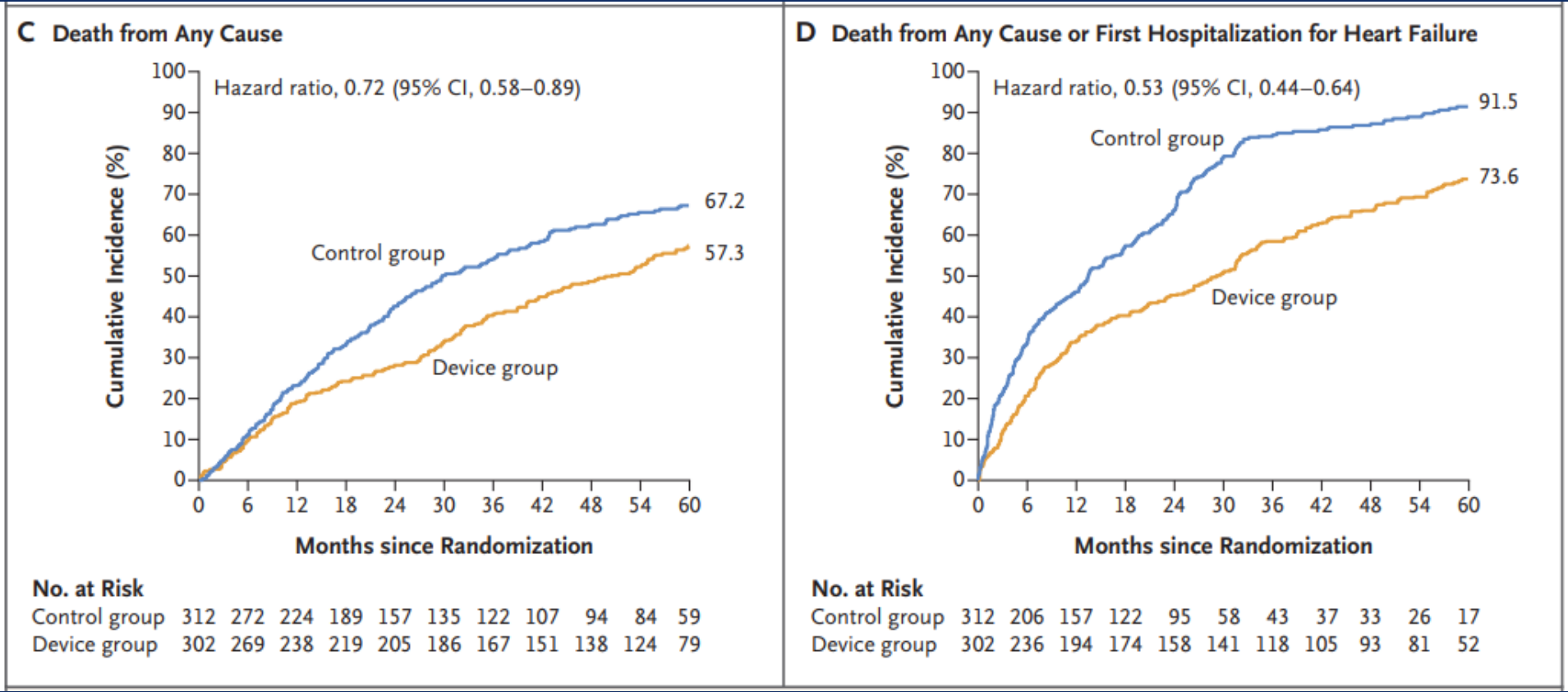


Gregg W. Stone et al. N Engl J Med. 2023; Mar 5.

5-Year follow-up COAPT trial

Mitraclip versus GDMT in patients with heart failure and secondary MR

Clinical Outcomes of 5-Year follow-up



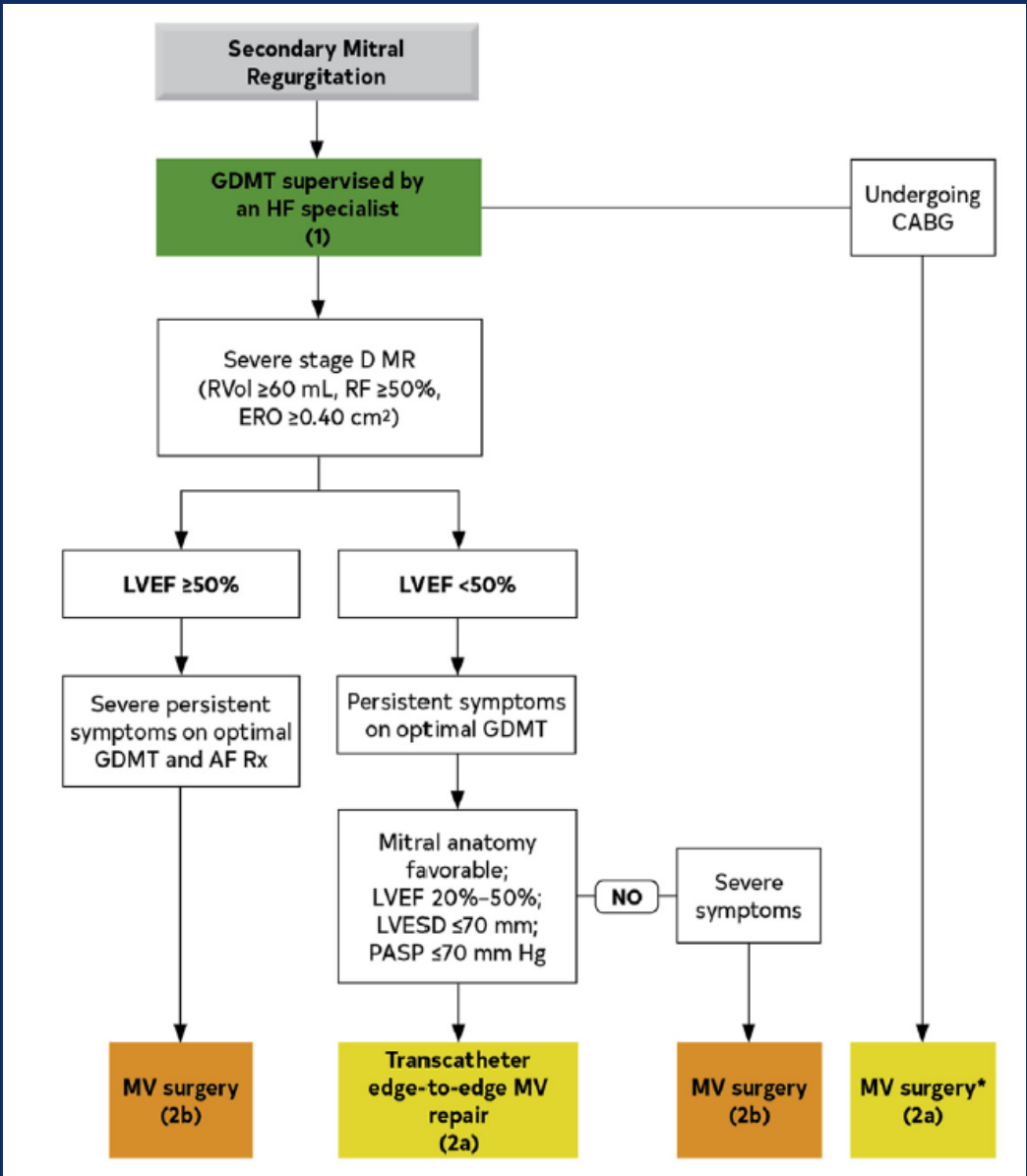
Gregg W. Stone et al. N Engl J Med. 2023; Mar 5.

2020 AHA/ACC Guidelines for Secondary MR

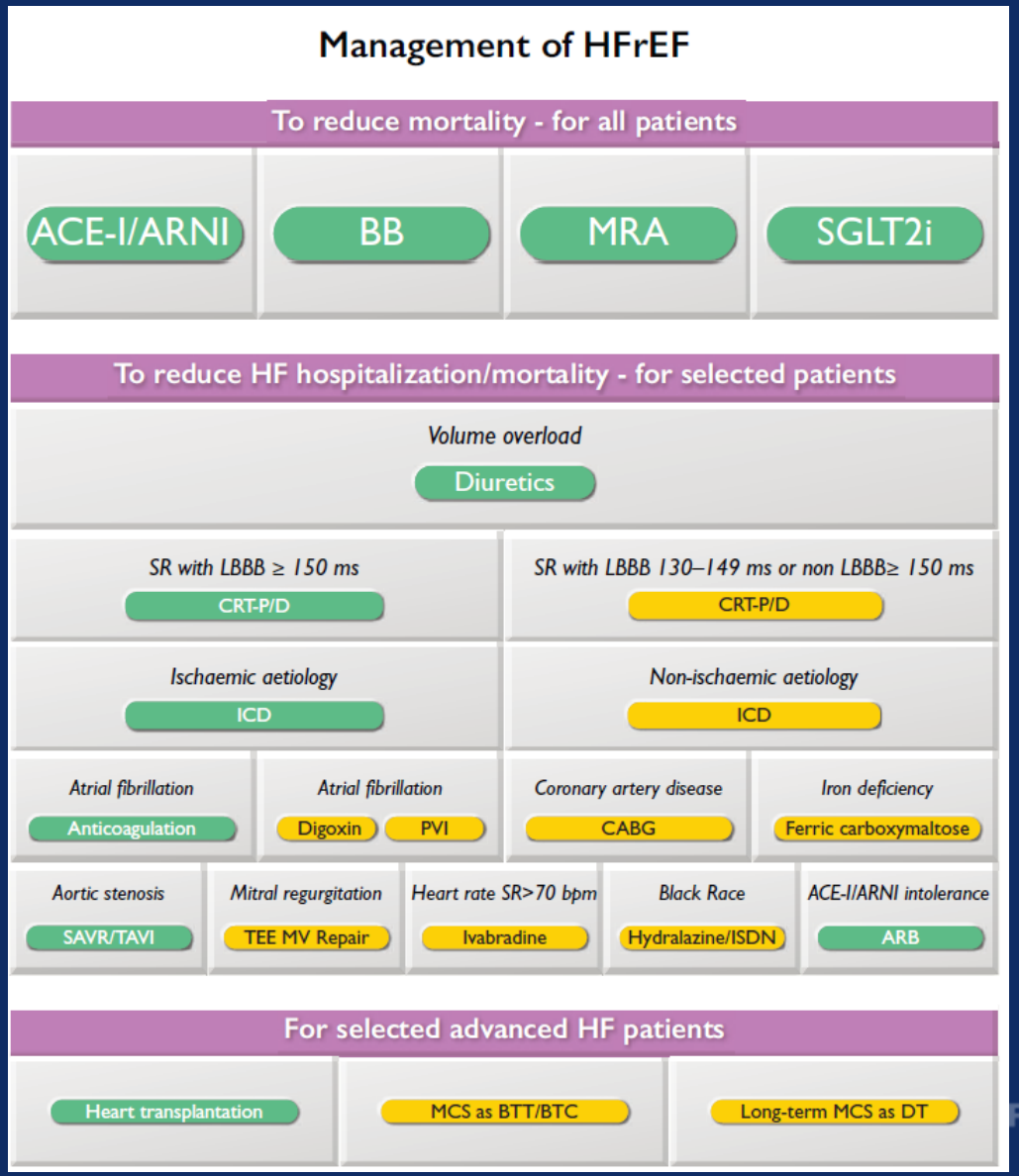
	COR	LOE
➢ In patients with chronic severe secondary MR related to LV systolic dysfunction (LVEF <50%) who have persistent symptoms (NYHA class II, III, or IV) while on optimal GDMT for HF (Stage D), TEER is reasonable in patients with appropriate anatomy as defined on TEE and with LVEF between 20% and 50%, LVESD ≤ 70 mm, and pulmonary artery systolic pressure ≤ 70 mmHg.	**IIa**	**B-R**
➢ In patients with chronic severe secondary MR related to LV systolic dysfunction (LVEF <50%) who have persistent severe symptoms (NYHA class III or IV) while on optimal GDMT for HF (Stage D), mitral valve surgery may be considered	**IIb**	**B-NR**

Otto CM et al. J Am Coll Cardiol 2020 Dec 17

TEER in VHD & HF Guidelines



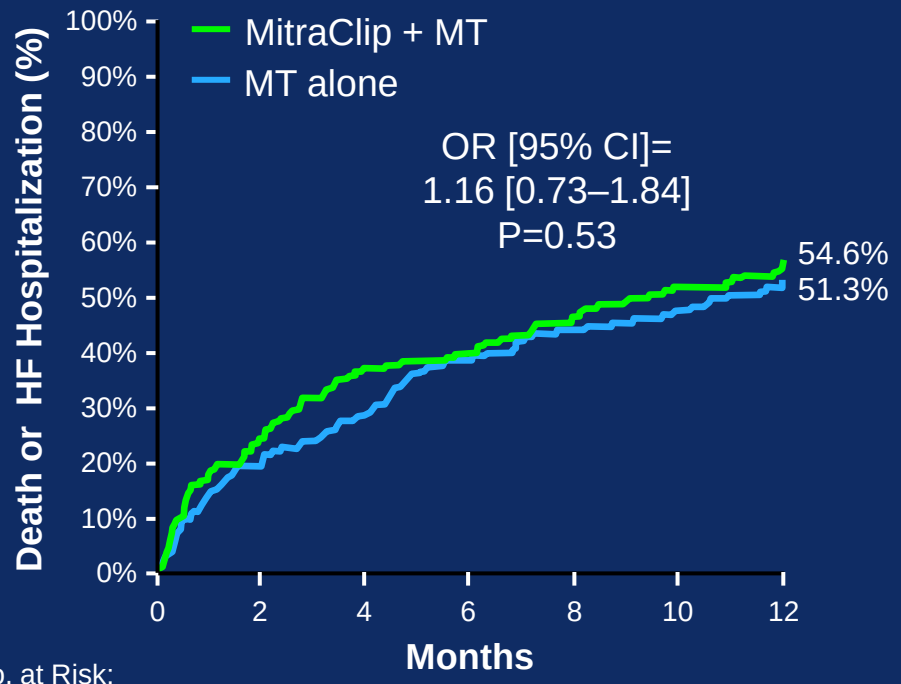
Heidenreich PA et al. J Am Coll Cardiol. 2022;79(17):1757-1780.



McDonagh TA et al. Eur Heart J. 2021;42(36):3599-3726.

Two Contrasting RCTs of TEER for Secondary MR

MITRA-FR

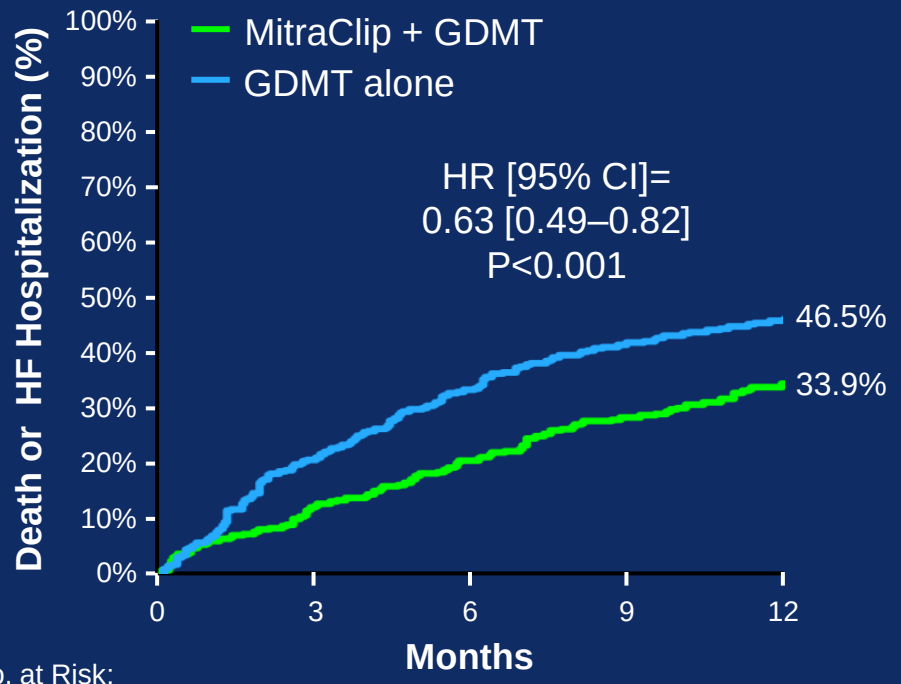


No. at Risk:

Control Group	152	123	109	94	86	80	73
Device Group	151	114	95	91	81	73	67

Obadia JF et al. N Engl J Med. 2018;379:2297-306

COAPT

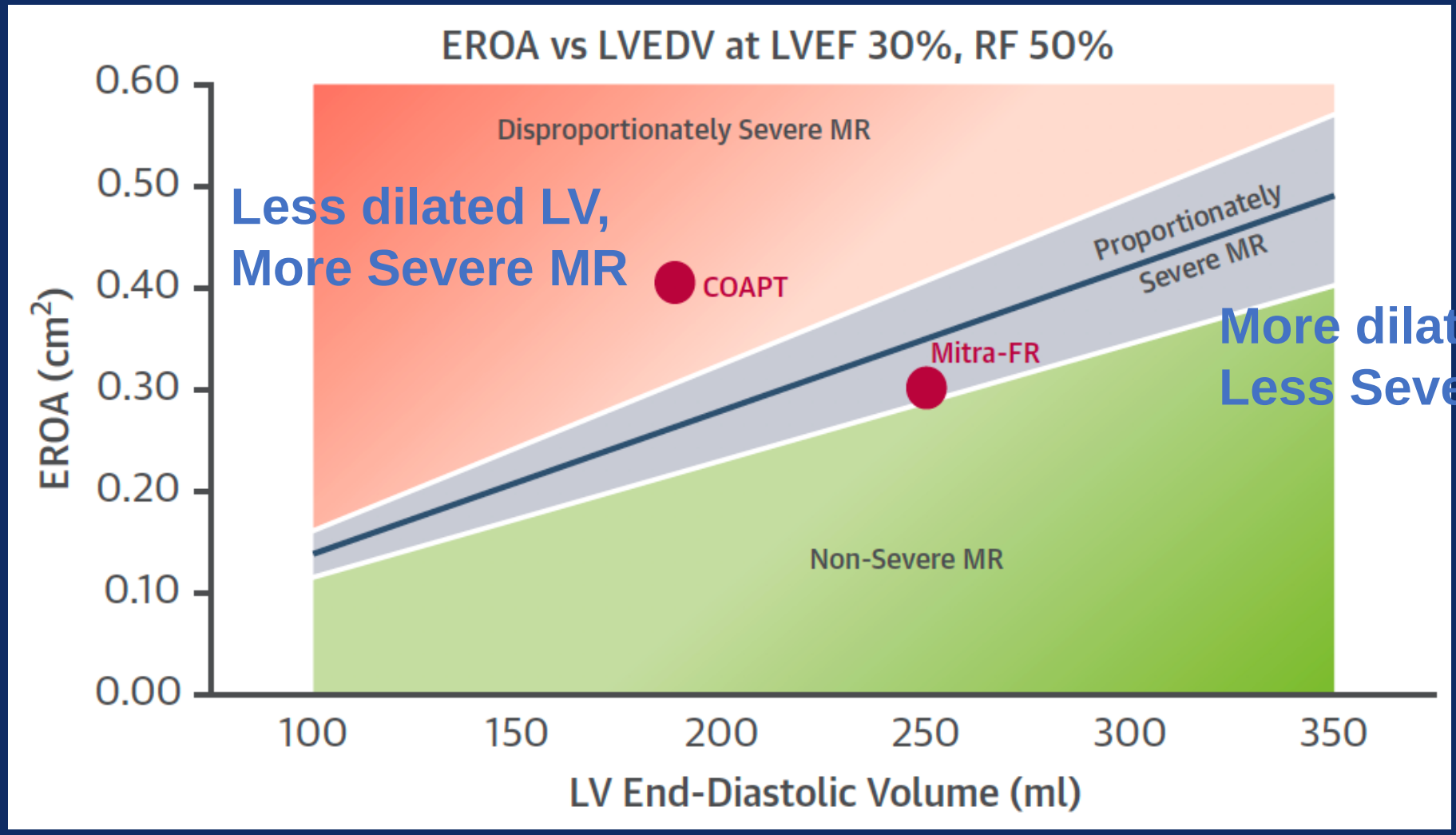


No. at Risk:

Control Group	312	244	205	174	153
Device Group	302	264	238	215	194

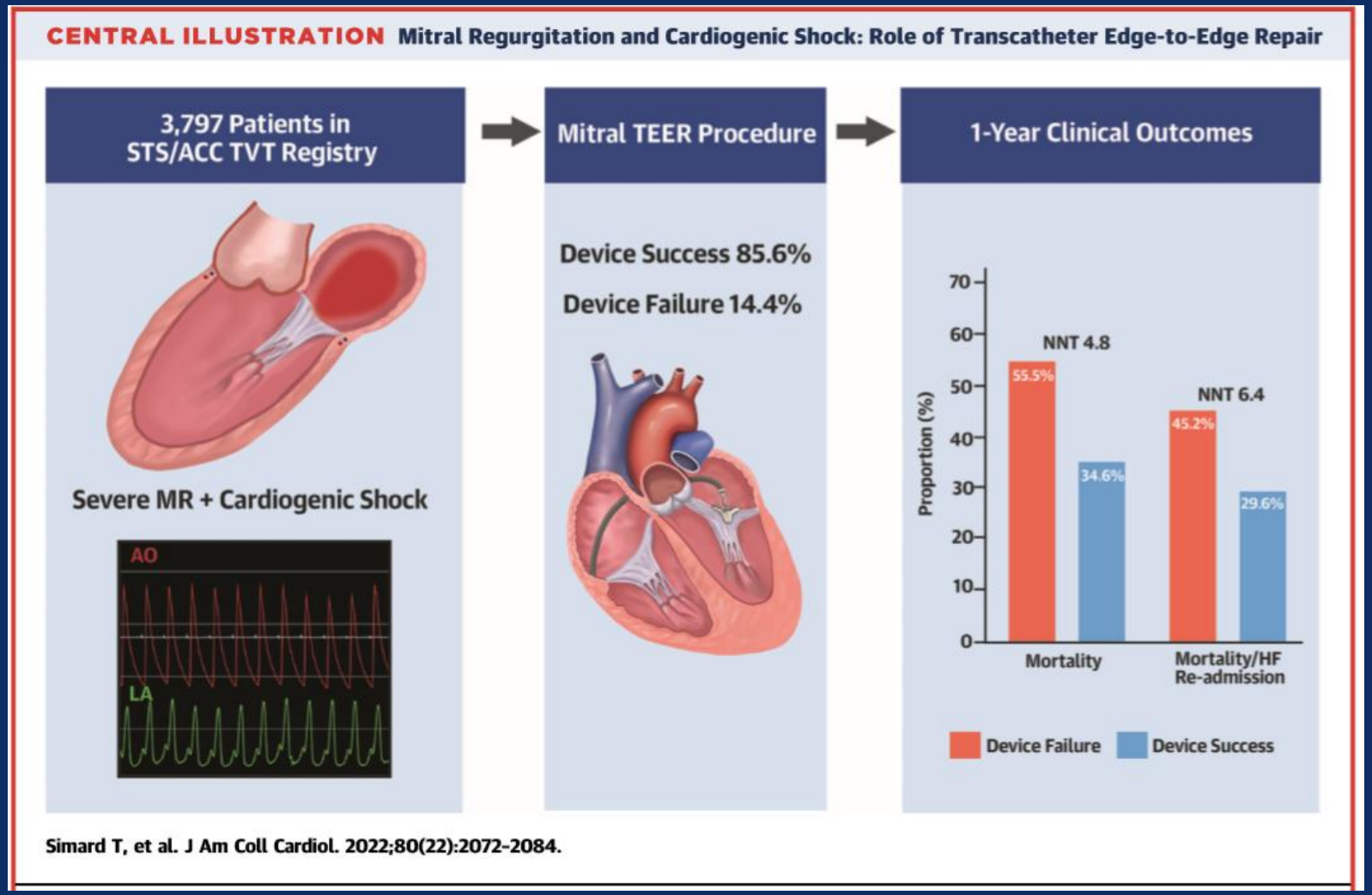
Stone GW et al. N Engl J Med. 2018;379:2307-18

Concept of Disproportionate MR



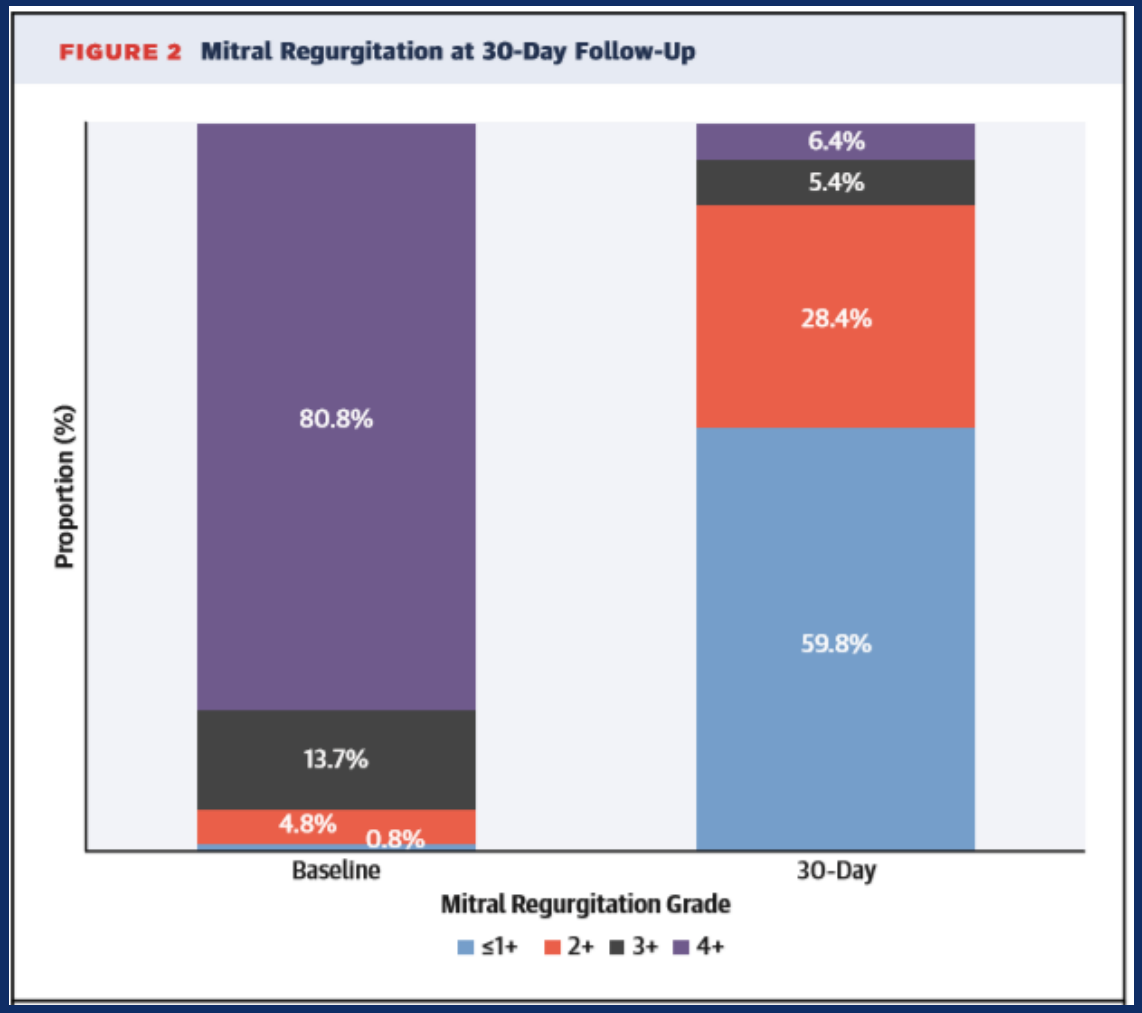
Grayburn PA et al. JACC CV Imaging 2019;12:353–62

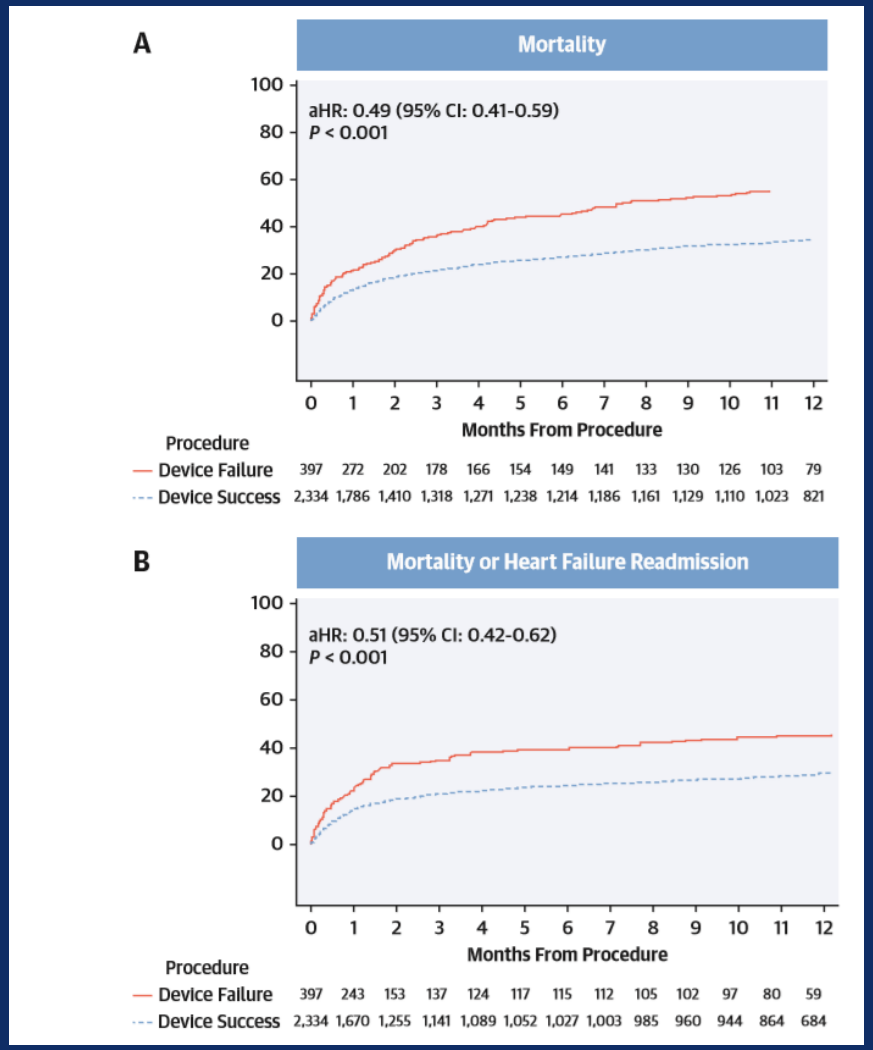
TEER in Patient with Severe MR and Cardiogenic Shock



Simard T et al., J Am Coll Cardiol. 2022 Nov 29;80(22):2072-2084.

TEER in Patient with Severe MR and Cardiogenic Shock





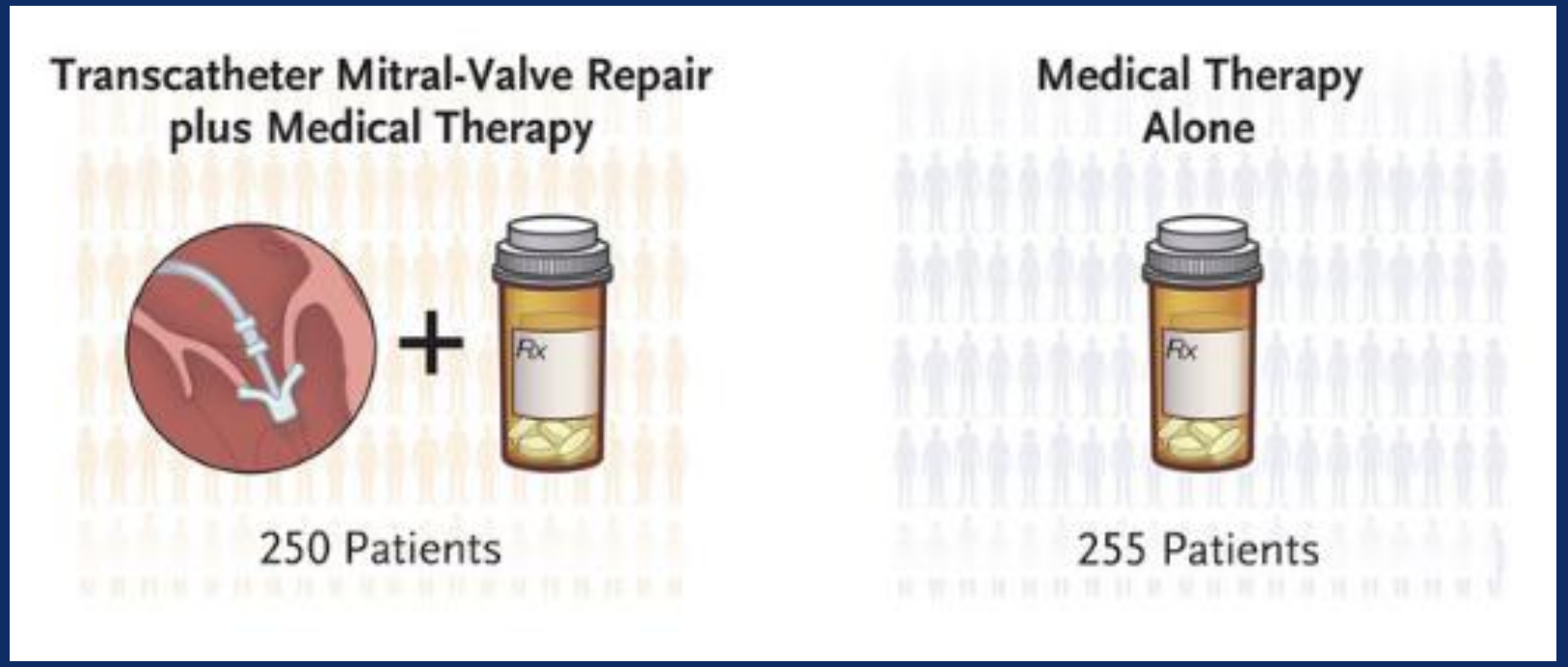
Simard T et al., J Am Coll Cardiol. 2022 Nov 29;80(22):2072-2084.

RESHAPE-HF2 Trial

Mitraclip versus GDMT in patients with heart failure and secondary MR

PATIENTS

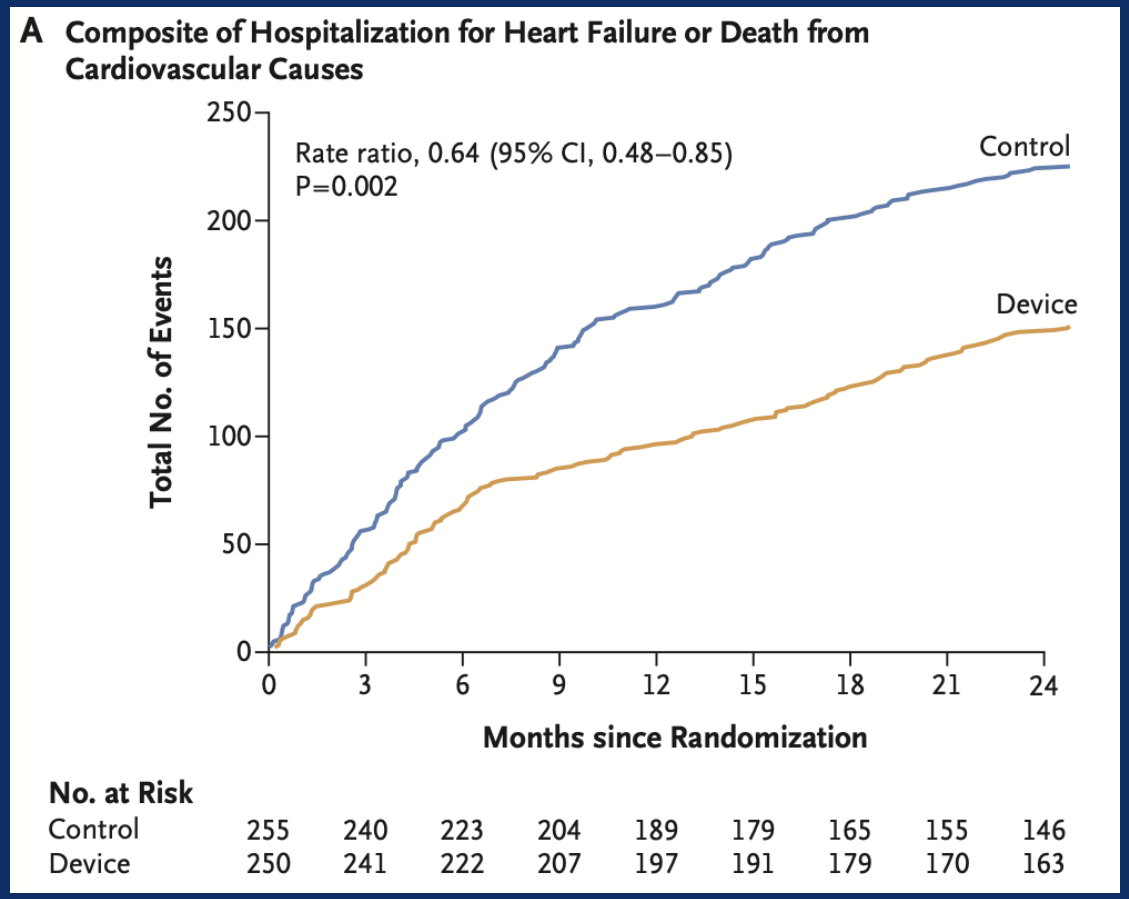
WHO	505 patients
	Mean age, 70 years
	Men: 80%; Women: 20%
CLINICAL STATUS	Symptoms and signs of heart failure
	Grade 3+ or 4+ functional mitral regurgitation
	Left ventricular ejection fraction of 20 to 50%
	Either hospitalization for heart failure or elevated plasma natriuretic peptide level in previous 90 days

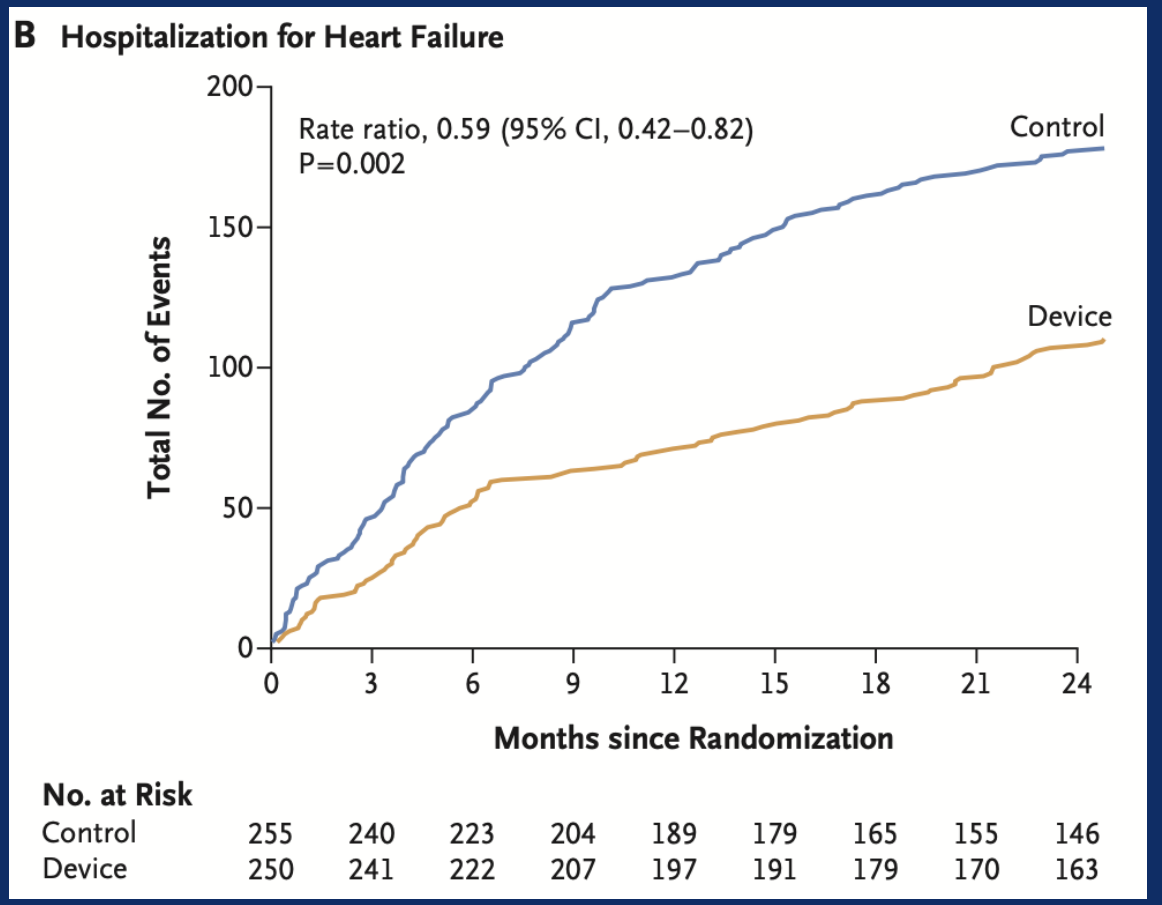


N Engl J Med 2024;391:1799-1809

RESHAPE-HF2 Trial

Mitraclip versus GDMT in patients with heart failure and secondary MR





N Engl J Med 2024;391:1799-1809

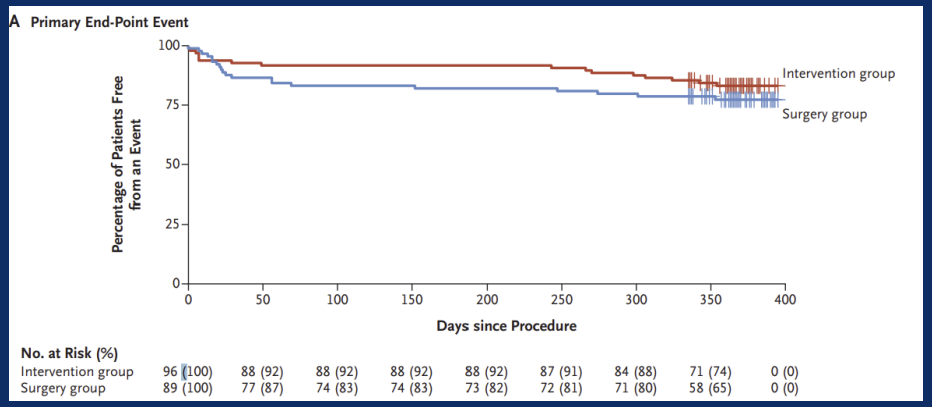
MATTERHORN Trial

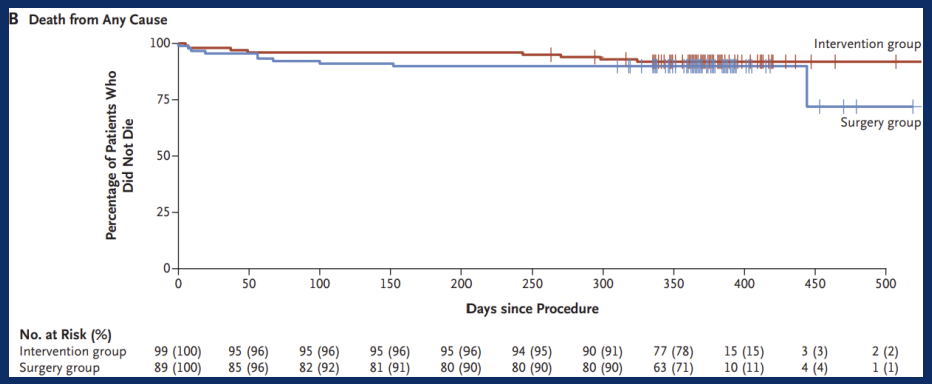
- Transcatheter edge-to-edge repair versus Surgical mitral-valve repair or replacement

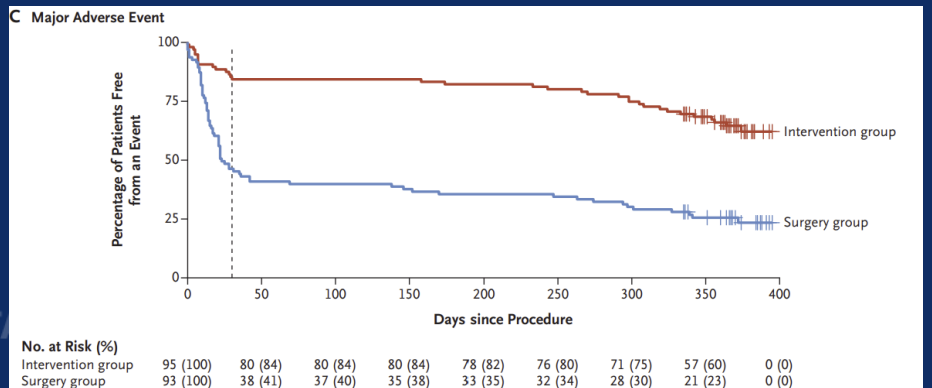
- Secondary mitral regurgitation
  - ERO area of at least 20 mm^2
  - Biplane vena contracta width of more than 8 mm
  - Regurgitant volume of at least 30 ml,
  - Regurgitant fraction of at least 50%
  - At least two hospitalizations for acute heart failure during the 12 months before enrollment.

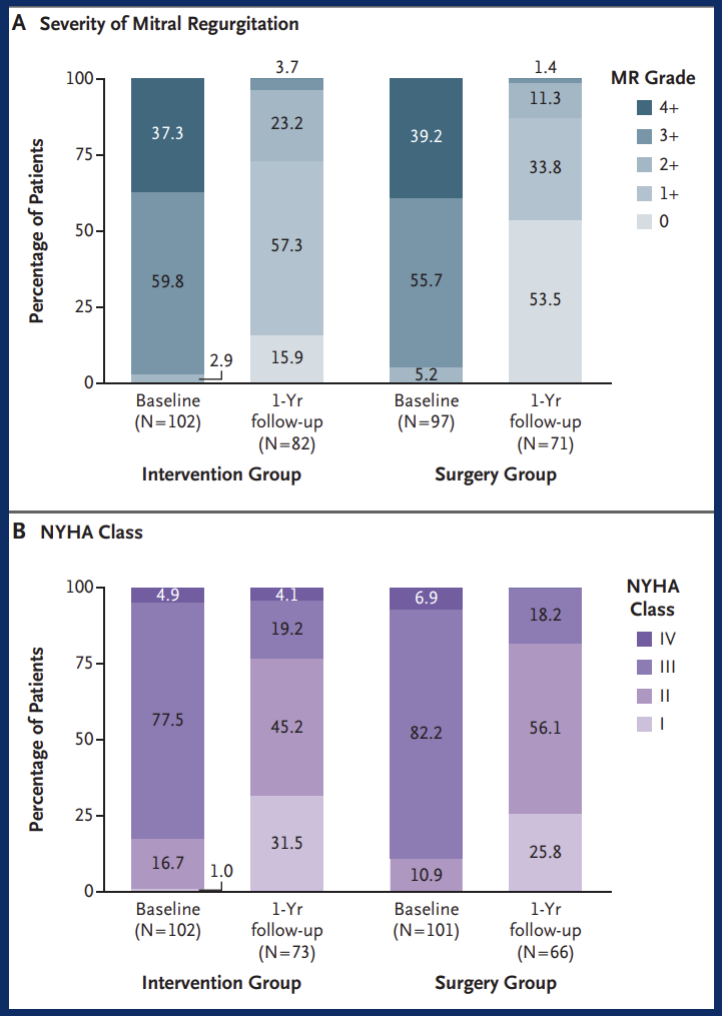
N ENGL J MED 391;19 NEJM.ORG NOVEMBER 14, 2024

MATTERHORN Trial





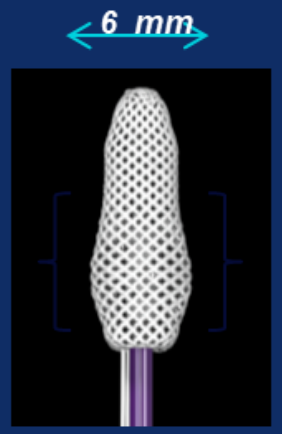




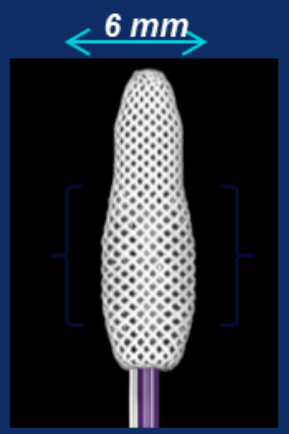
N ENGL J MED 391;19 NEJM.ORG NOVEMBER 14, 2024

Device Update to G4 Mitraclip

Mitraclip™ G4 : Various Length & Width of Clips



50% wider in the grasping area

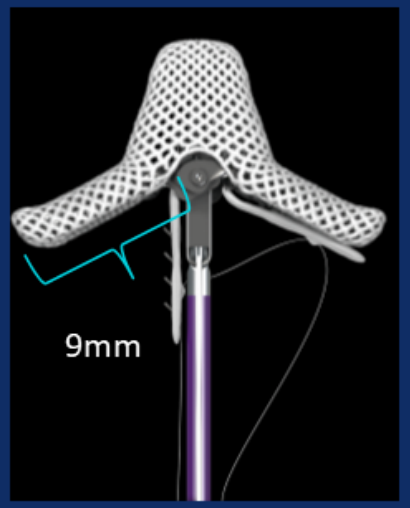


50% wider in the grasping area

NT/XT **NTW/XTW**

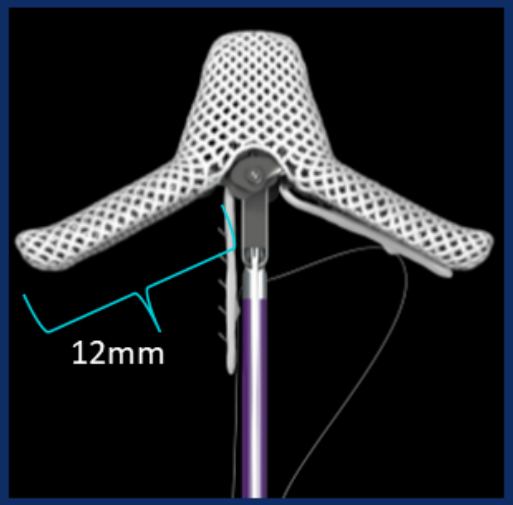
MitraClip™ G4

4 Clip sizes



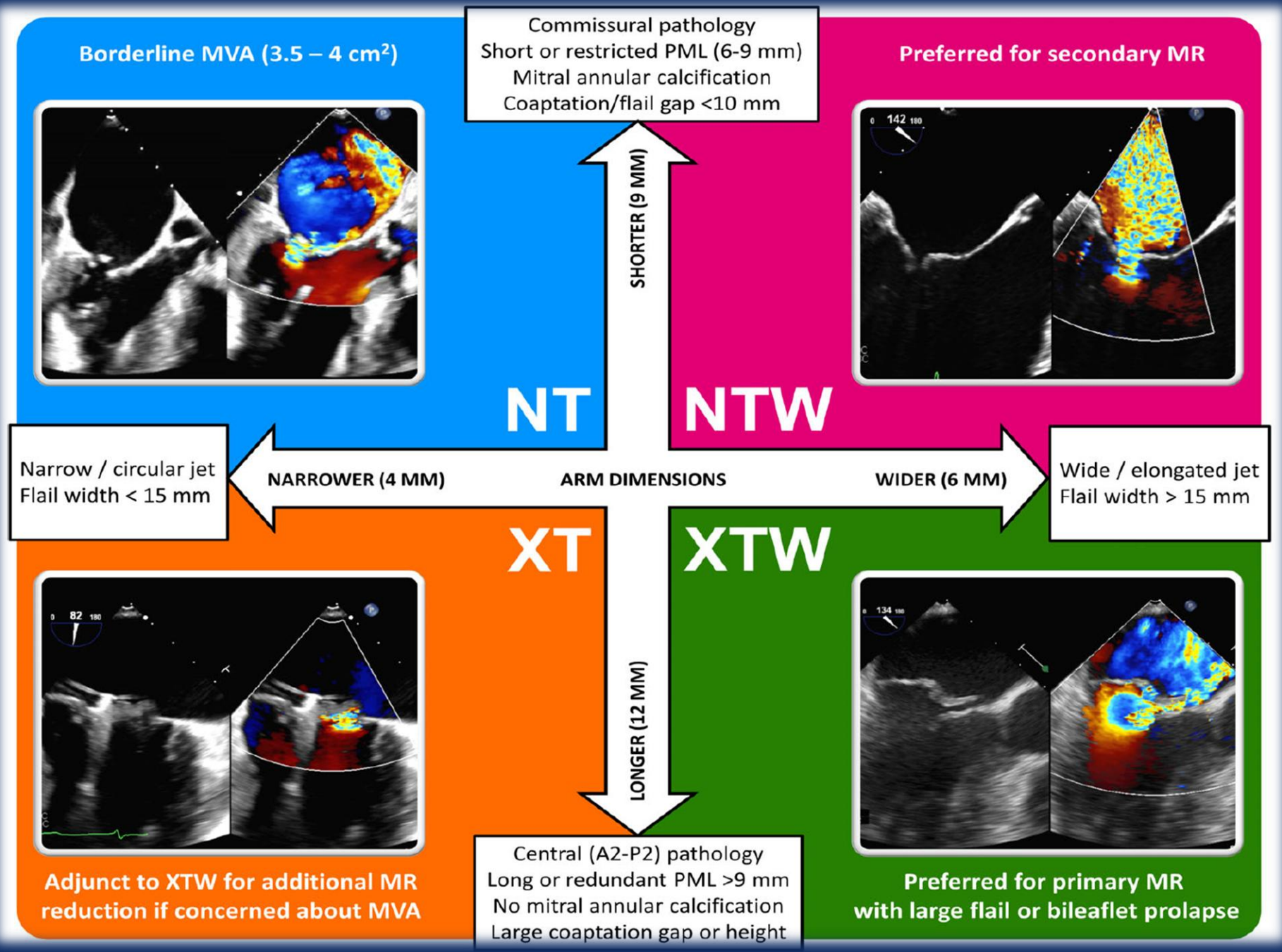
17 mm at 120 degrees
20 mm at 180 degrees

NT/NTW



22 mm at 120 degrees
25 mm at 180 degrees

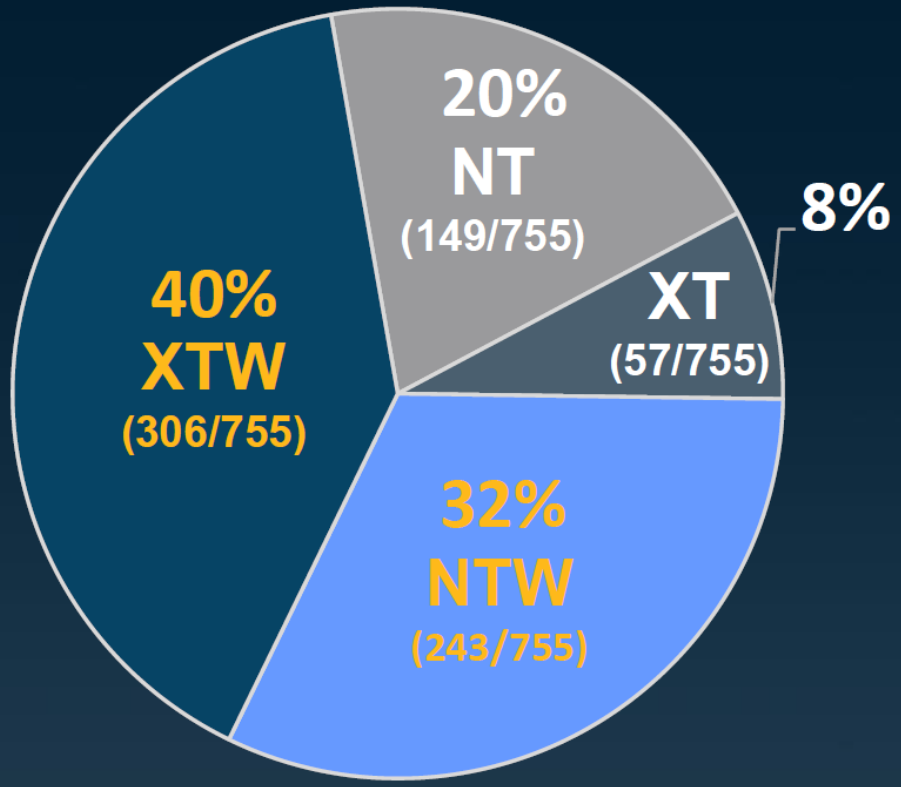
XT/XTW



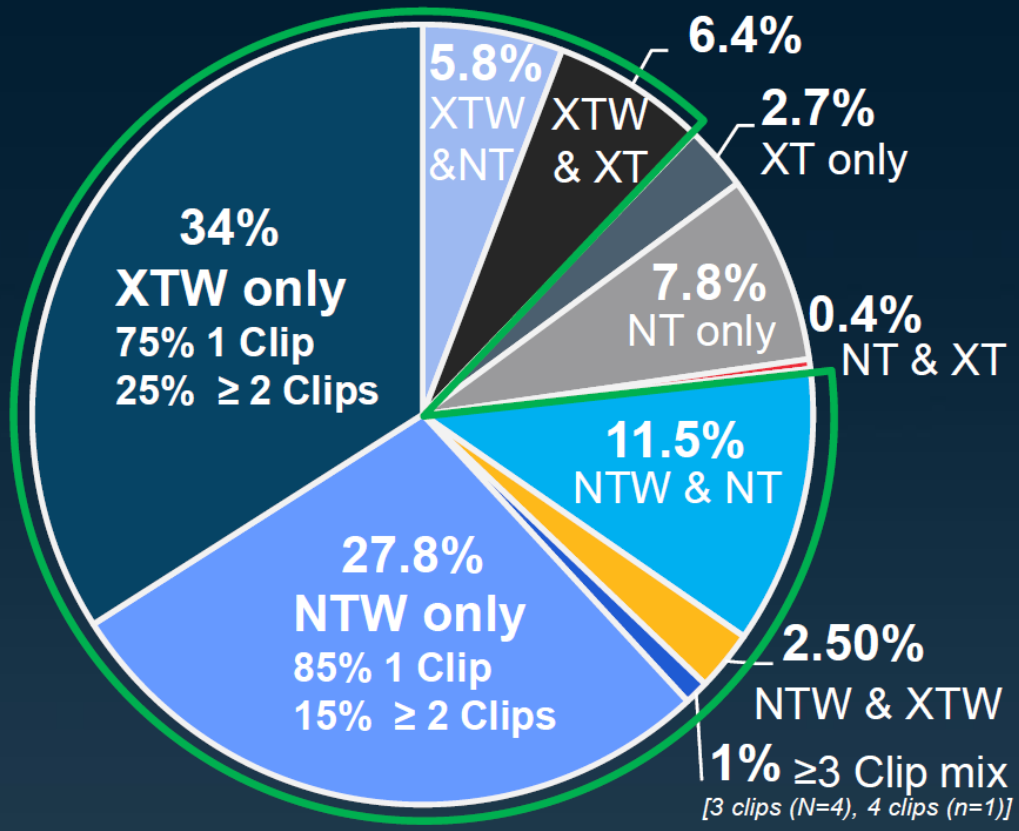
Garcia-Sayan E et al. Catheter Cardiovasc Interv. 2021;98(4):E626-E636.

Clips Used in EXPAND G4 Registry (N=529)

Clip Size Usage (total clips implanted = 755)

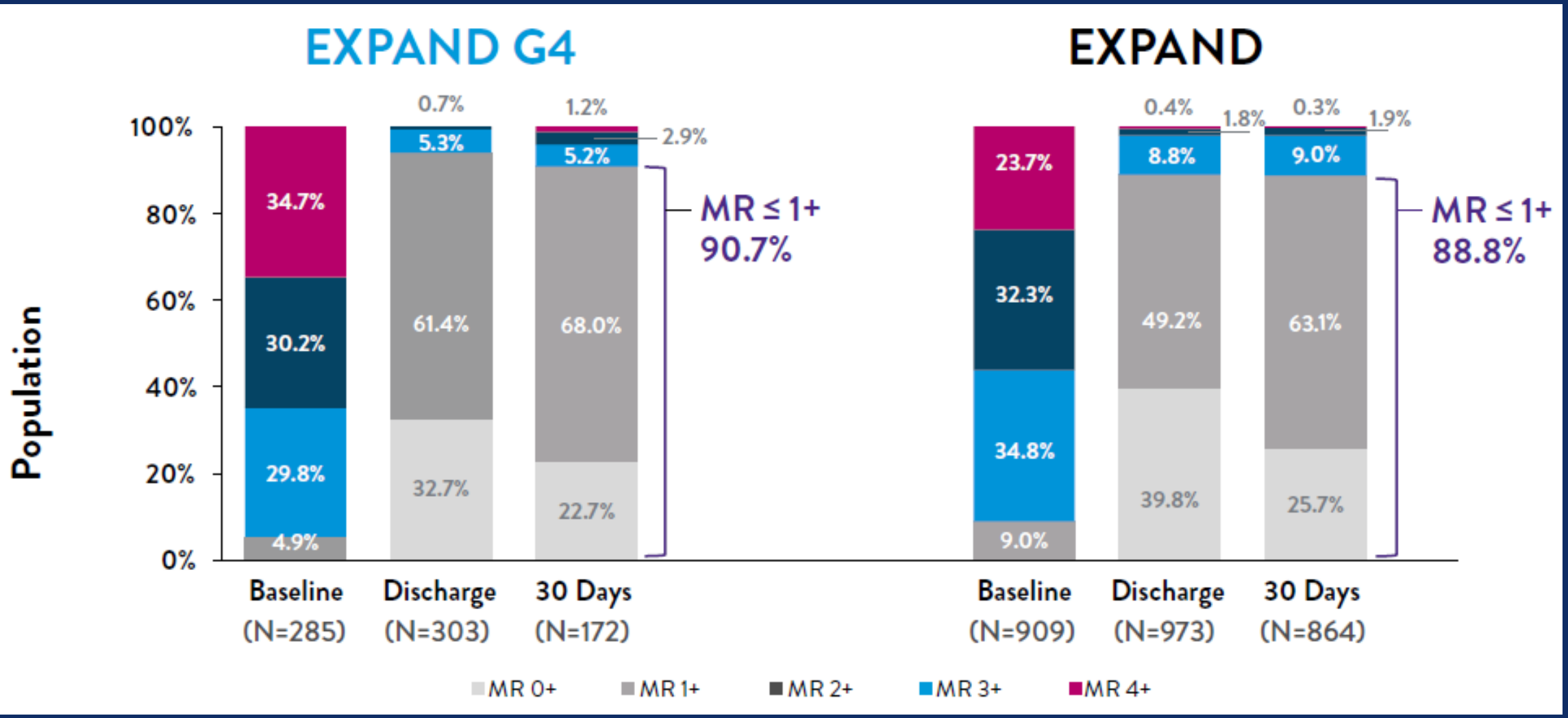


Clip Mix (N=514, 13 Clip combinations)



Rodriguez E. Presented at TCT 2021

MR Severity in EXPAND G4 Registry



Rodriguez E. Presented at TCT 2021.

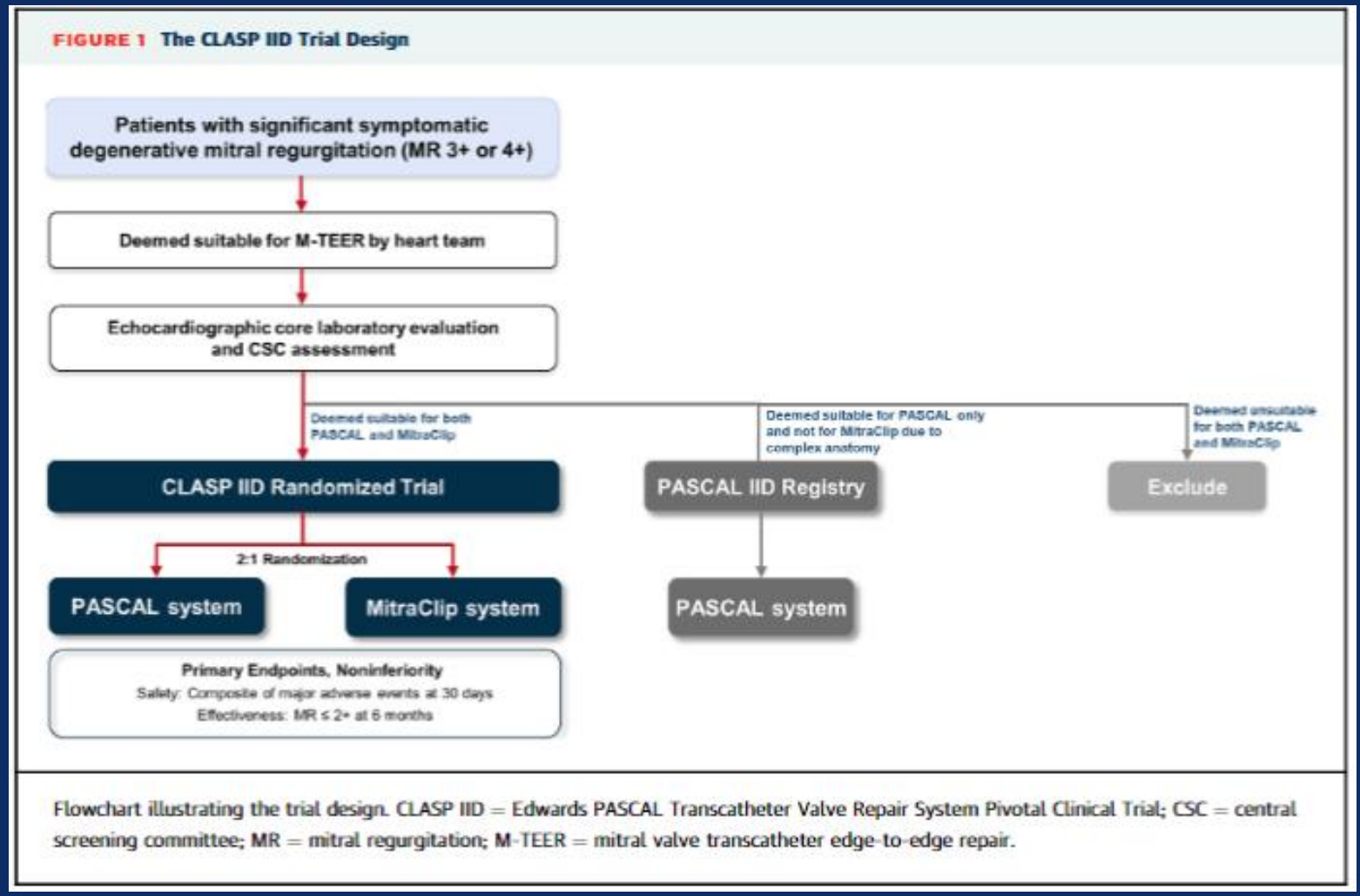
Real-World Safety & Durability of G4 Mitraclip

	TVT Registry 30-Day (N=2,952)	EXPAND 30-Day (N=1,041)	EXPAND 1-Year (N=1,041)	EXPAND G4 30-Day (N=529)
All-cause Death	5.2% (96)	2.3% (24)	14.9% (147)	**1.5% (7)**
MI	0.2% (3)	0.0% (0)	1.2% (12)	**0.0% (0)**
Stroke	1.0% (17)	1.2% (8)	1.7% (18)	**0.0% (0)**
Ischemic stroke	0.6% (11)	1.0% (6)	N/A	**0.0% (0)**
Non-elective CV surgery for device related complications	N/A	1.1% (11)	N/A	**0.8% (4)**
Leaflet Adverse Events	1.5% (17)	2.0% (20)	2% (20)	**1.1% (6)**
SLDA	1.5% (4)	1.7% (18)	1.7% (18)	**1.1% (6)**

Rinaldi M. TVT 2022 Presentation

CLASP IID Trial (PASCAL)

180 patients 2:1 Randomization to PASCAL : Mitraclip



D. Scott Lim et al. JACC Cardiovasc Interv. 2022 Dec 26;15(24):2523-2536.

CLASP IID Trial (PASCAL)

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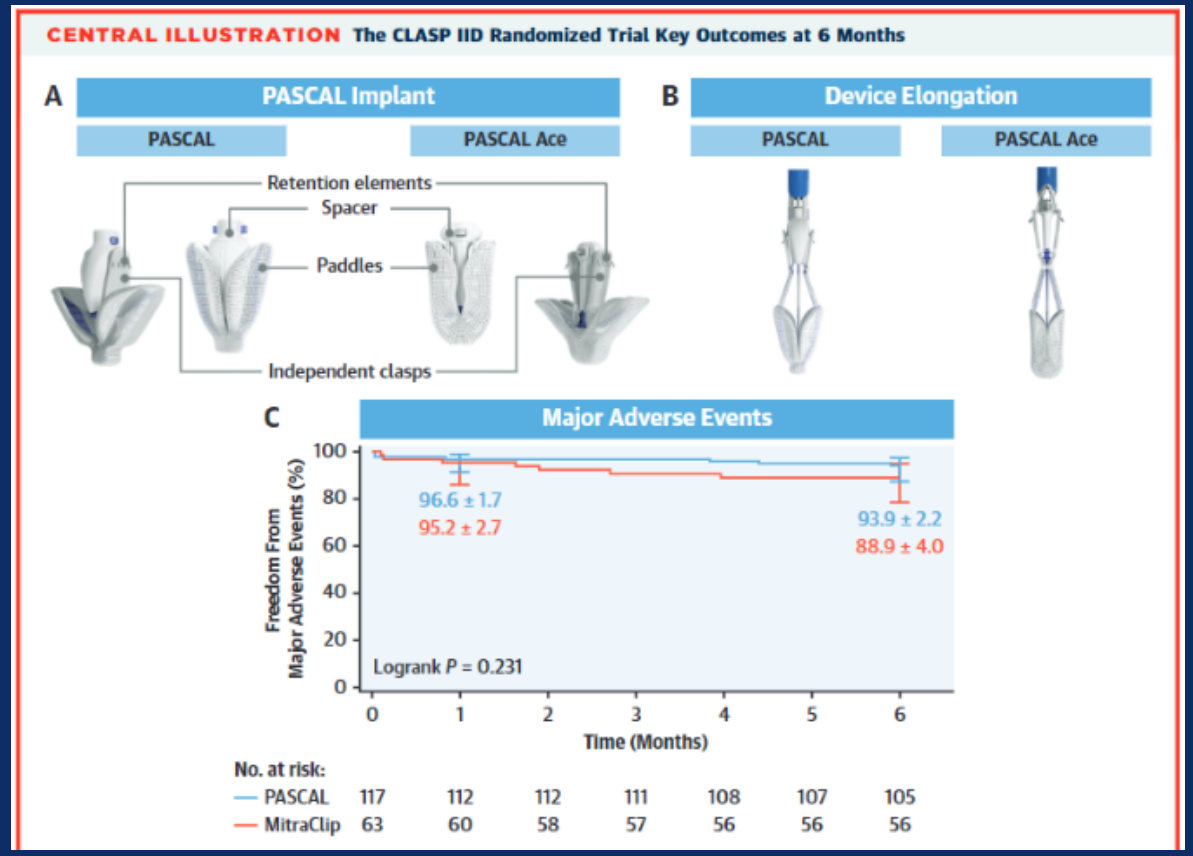

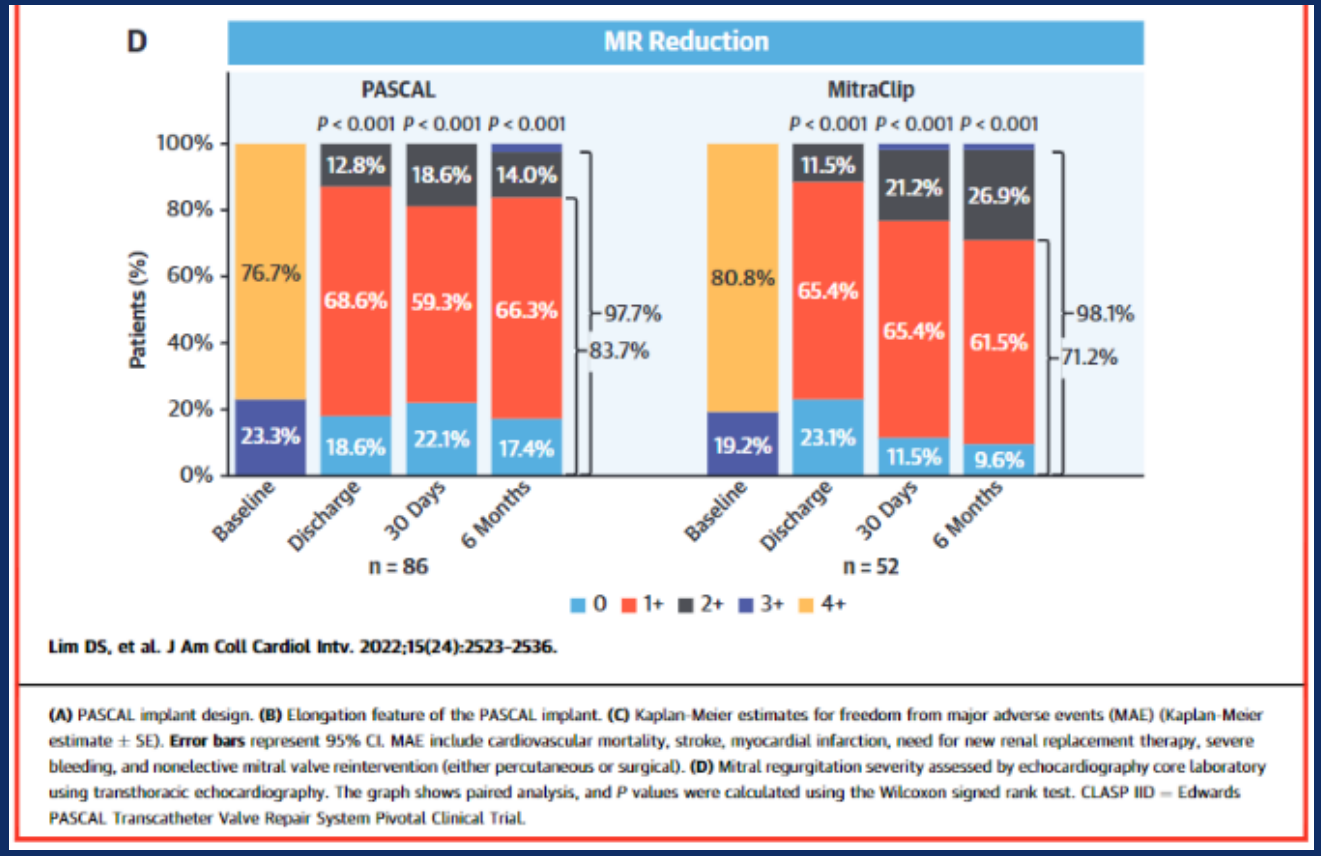

Lim DS, et al. J Am Coll Cardiol Intv. 2022;15(24):2523-2536.

(A) PASCAL implant design. **(B)** Elongation feature of the PASCAL implant. **(C)** Kaplan-Meier estimates for freedom from major adverse events (MAE) (Kaplan-Meier estimate ± SE). **Error bars** represent 95% CI. MAE include cardiovascular mortality, stroke, myocardial infarction, need for new renal replacement therapy, severe bleeding, and nonelective mitral valve reintervention (either percutaneous or surgical). **(D)** Mitral regurgitation severity assessed by echocardiography core laboratory using transthoracic echocardiography. The graph shows paired analysis, and *P* values were calculated using the Wilcoxon signed rank test. CLASP IID = Edwards PASCAL Transcatheter Valve Repair System Pivotal Clinical Trial.

D. Scott Lim et al. JACC Cardiovasc Interv. 2022 Dec 26;15(24):2523-2536.

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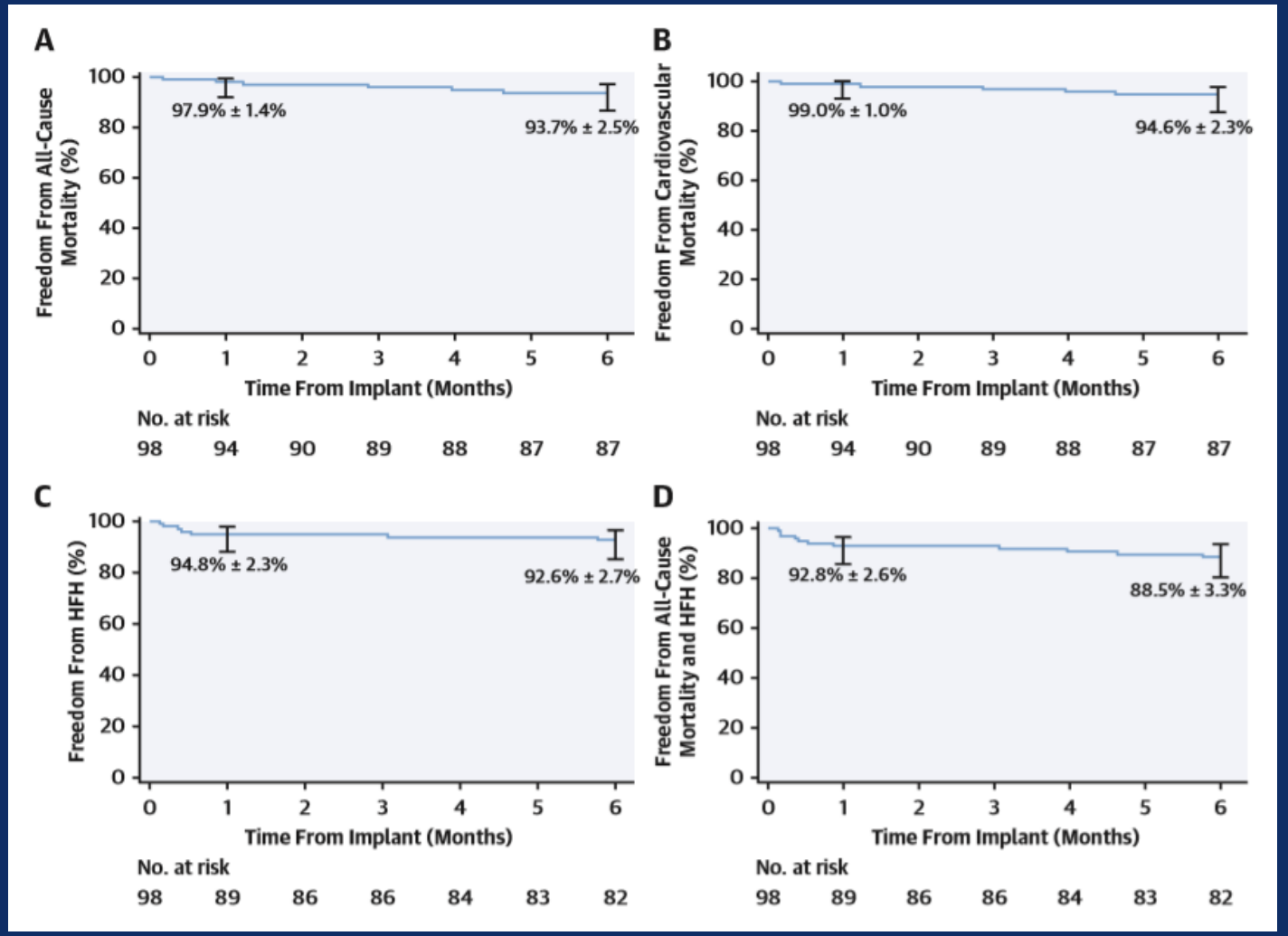


D. Scott Lim et al. JACC Cardiovasc Interv. 2022 Dec 26;15(24):2523-2536.

CLASP IID Trial (PASCAL)

TEER in Patient with Anatomically Complex Degenerative MR

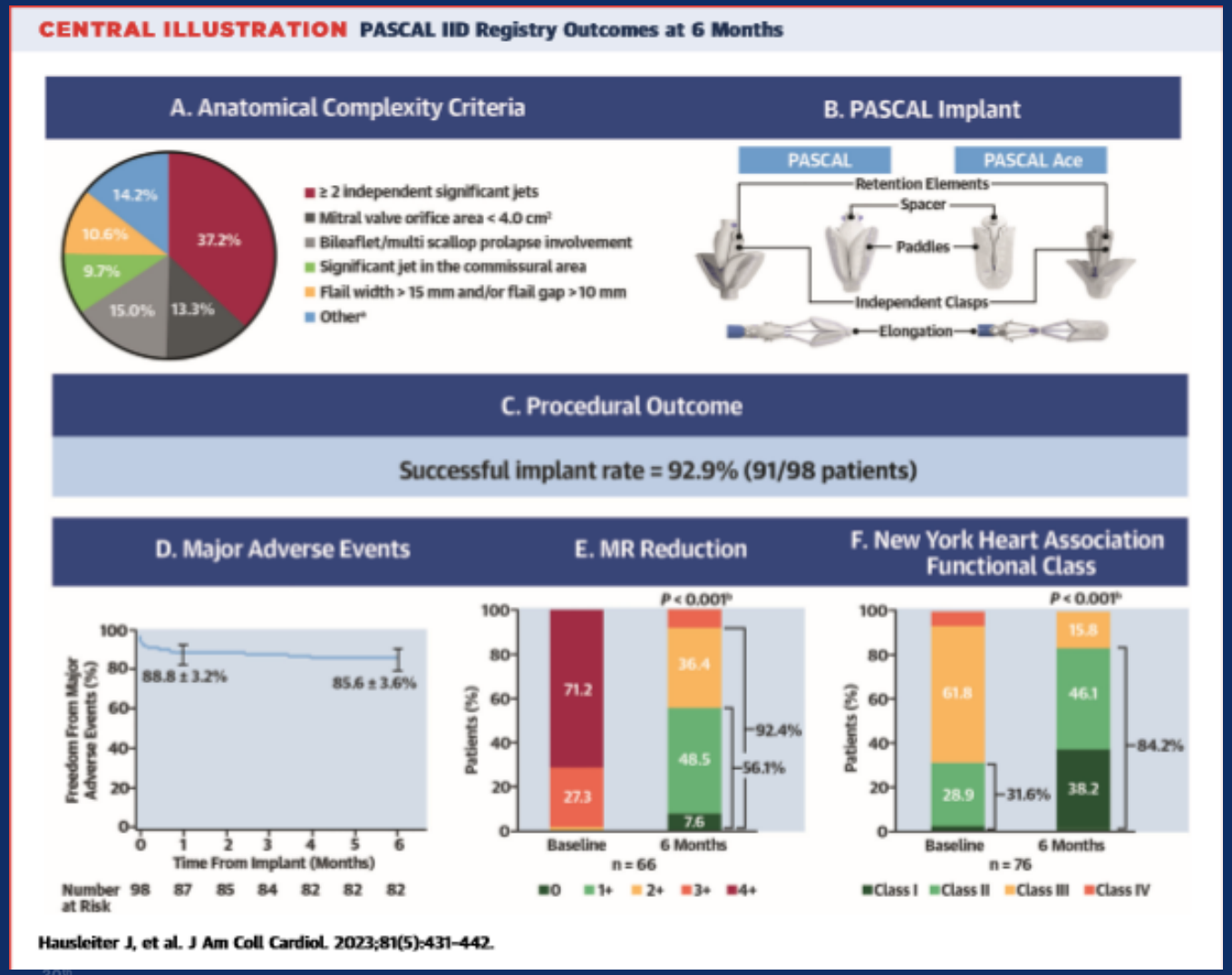


TABLE 2 Anatomical Complexity Criteria

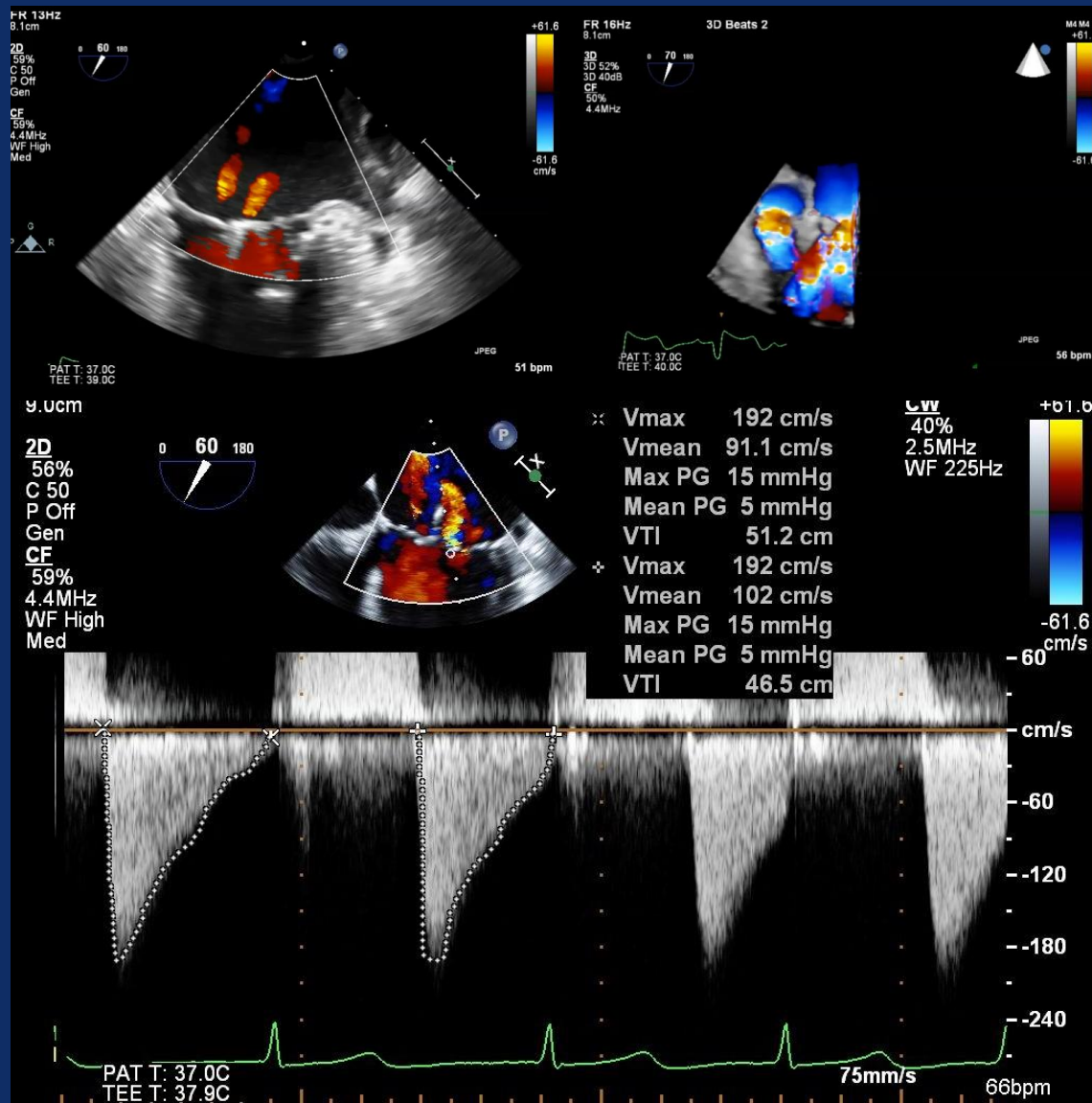
Anatomic Criteria[a]	(N = 113)
Presence of ≥2 independent significant jets	42/113 (37.2)
Evidence of severe bileaflet/multi scallop prolapse involvement	17/113 (15.0)
Mitral valve orifice area <4.0 cm^2	15/113 (13.3)
Large flail gap and/or large flail width[b]	12/113 (10.6)
Presence of 1 significant jet in the commissural area	11/113 (9.7)
Presence of significant cleft or perforation in the grasping area	7/113 (6.2)
Leaflet mobility length <8 mm	4/113 (3.5)
Evidence of moderate to severe calcification in the grasping area	4/113 (3.5)
History of endocarditis and significant tissue defects in the leaflet	1/113 (0.9)
Total Number of Anatomic Criteria Met[c]	**(N = 98)**
1	83/98 (84.7)
2	15/98 (15.3)

Hausleiter J et al., JACC, 2023; 81(5):431-442.

Optimal Procedural Outcomes

How to define TEER success?

- MR reduction (≤ 2+)
  - "achievable" MR result will depend on starting MVA, baseline MR, etc
  - **Acceptable MR reduction ("success") may vary among patients**
- Absence of significant MS
  - Mean gradient ≤ 5 mmHg
  - Increased gradients did OK in COAPT (MG +/- 7 mmHg), in secondary MR…

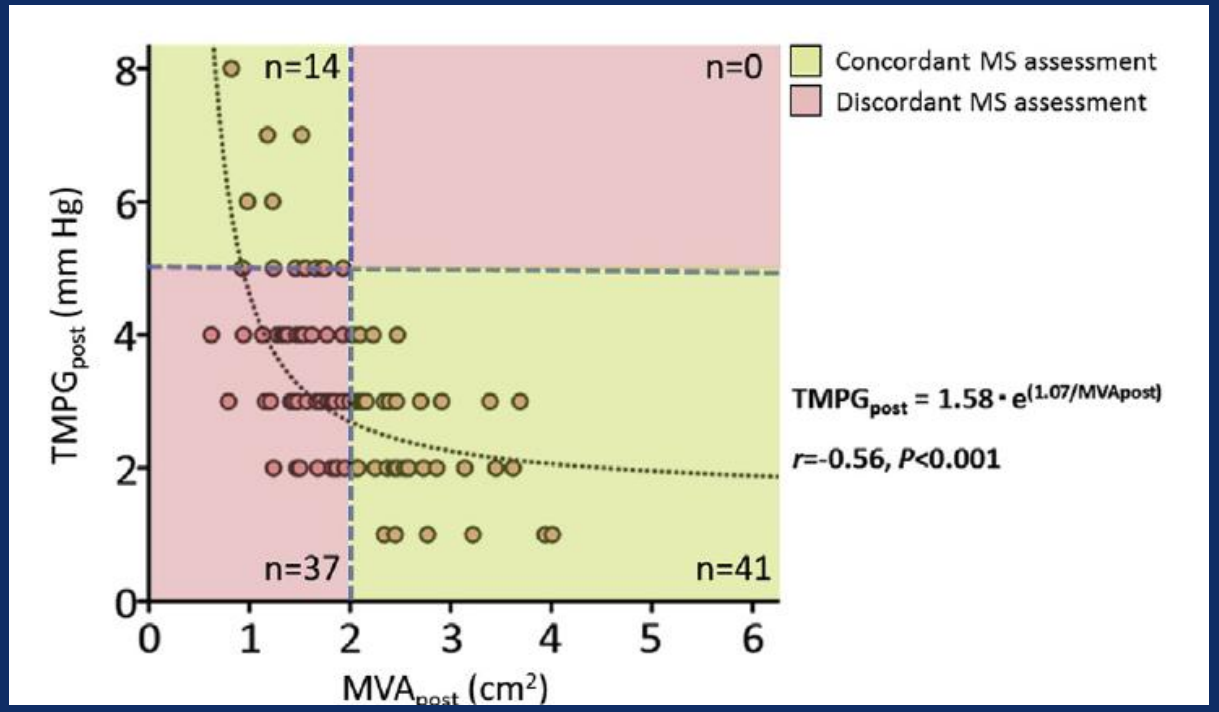


Halaby R et al. JACC CV Interv. 2021

TEER Reduces MV Area, therefore Increase MV Gradient

Double-edged Sword of TEER

MVA & mean MV gradient after Mitraclip



Utsunomiya H et al. Am J Cardiol. 2017;120:662-669.

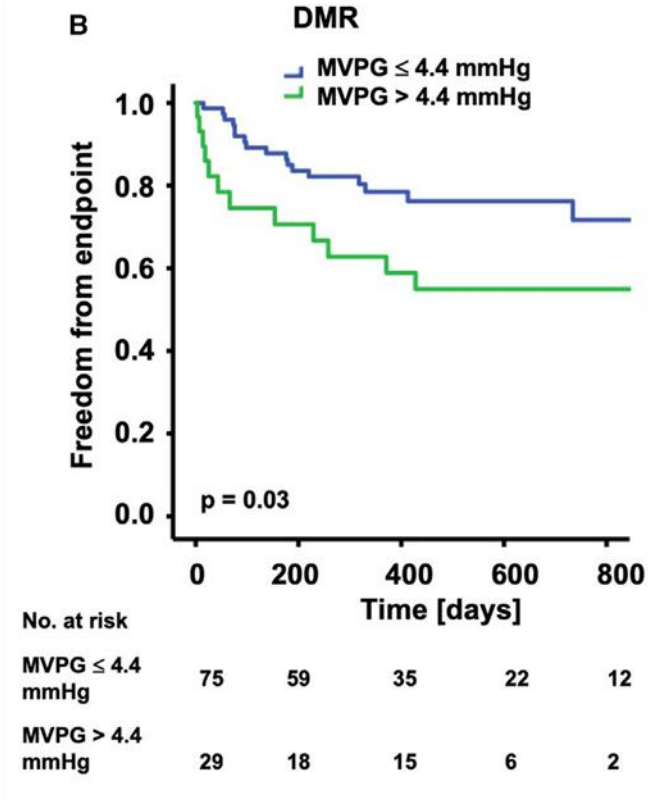
Predictor of Increased MV Gradient after TEER

- MV Orifice Area ≤ 4.0 cm^2
- Baseline Mitral Gradient ≥ 4mmHg
- Mitral Annular Calcification
- Hemodialysis
- More Clips used
- Higher Residual MR (Increased Blood Flow over MV)

Neuss M et al. JACC CV Interv. 2017;10:931-9. Thaden JJ et al. J Am Heart Assoc. 2018;7:e007315.
Oguz D et al. Catheter Cardiovasc Interv. 2021;98:E932-E937.

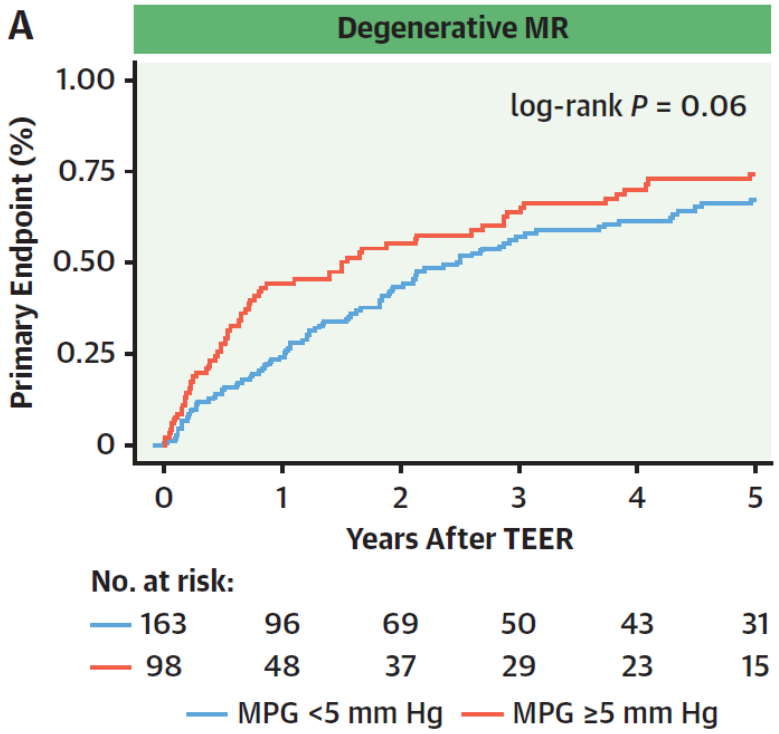
Contrasting Results of Impact of High Transmitral Gradient after TEER for Primary MR

255 from German Single Center
Mortality, MV Surgery, Redo, LVAD



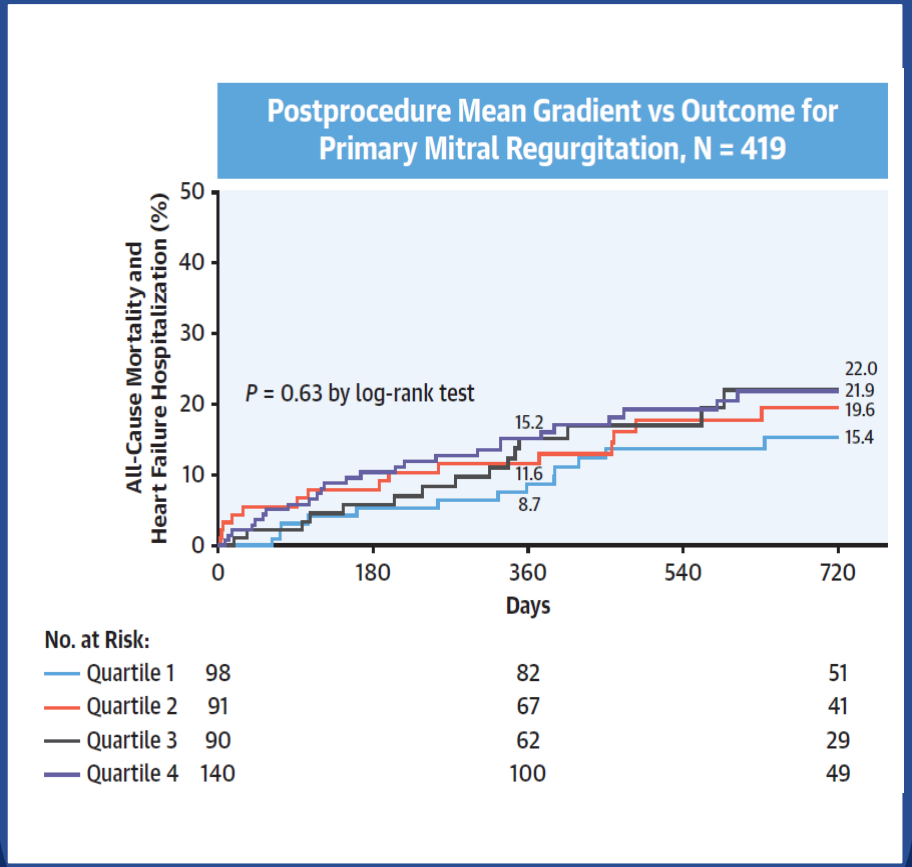
Patzelt J et al. JAHA. 2019;8:e011366.

265 from German Single Center
Mortality, HF Hospitalization



Koell B et al. JACC Interv. 2022;15:922-34.

419 from US Single Center
Mortality

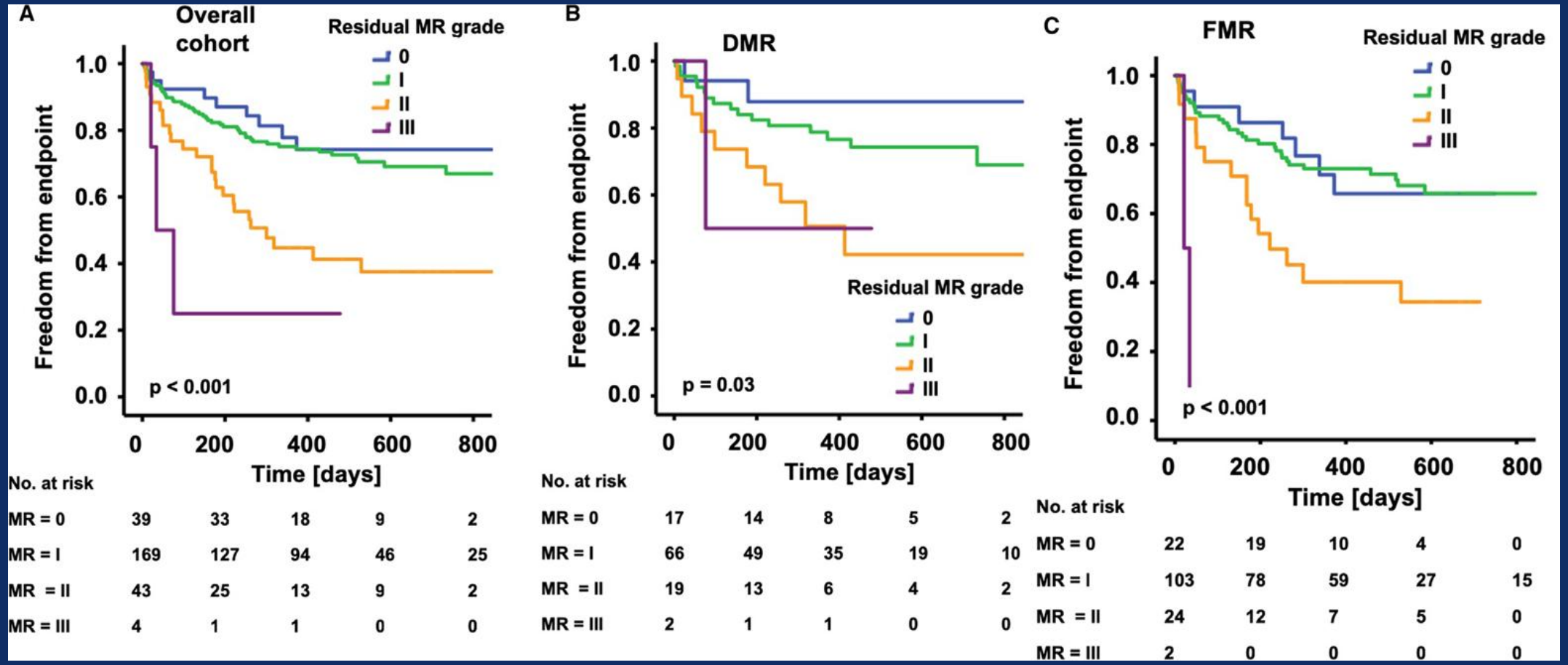


Yoon S et al. JACC Interv. 2022;15:935-45.

Residual MR was Stronger Predictor than MV Gradient

255 Patients from German Single Center from 2014 to 2017, Primary 41%, Secondary 59%

Clinical Outcome: All-cause mortality, MV Surgery, LVAD, or Redo TEER

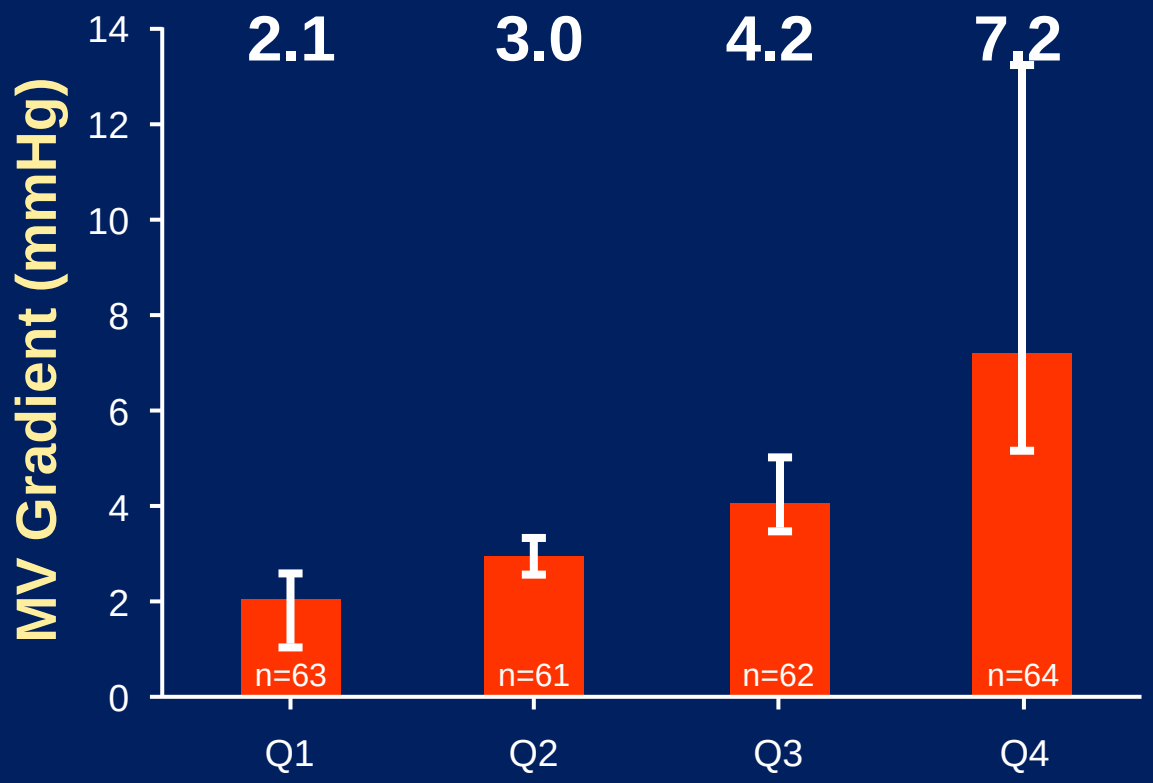


Patzelt J et al. J Am Heart Assoc. 2019;8:e011366.

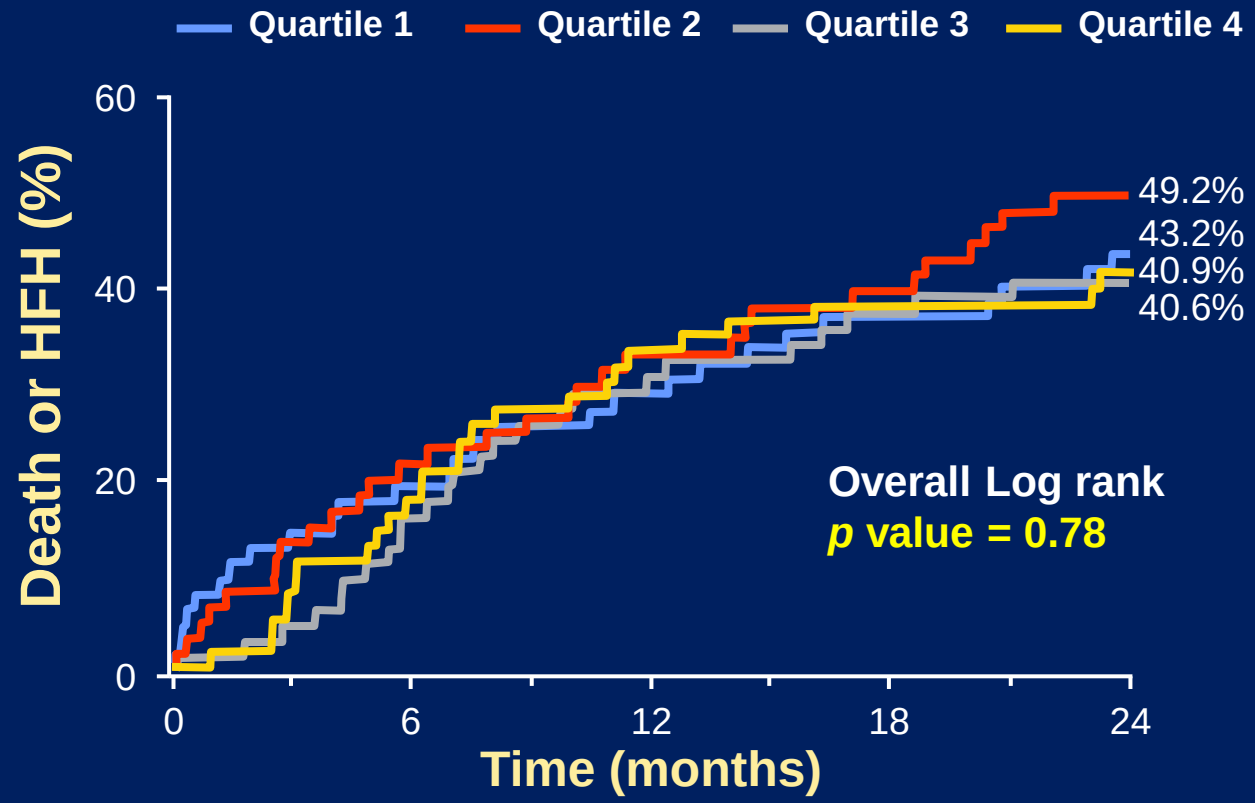
High Transmitral Gradient after TEER was NOT associated with Worse Outcome in COAPT Trial (Secondary MR)

Mean discharge TTE MVG after MitraClip was 4.2 ± 2.2 mmHg (range 1 to 13.2 mmHg)*

Mitral Valve Gradient by Quartile



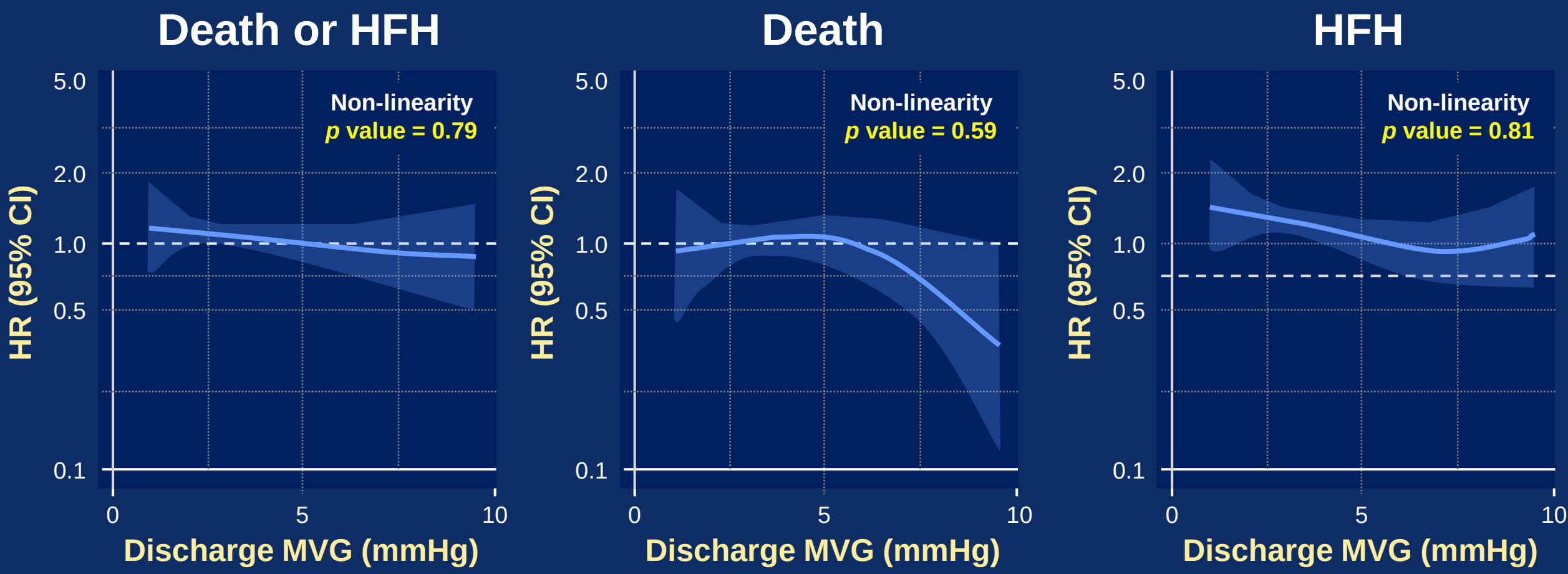
Death or HF Hospitalization



Halaby R et al. JACC Cardiovasc Interv. 2021;14(8):879-889.

*Median [IQR] = 3.5 [2.6, 5.1]

Impact of MV Gradient after TEER in COAPT Trial (Secondary MR)



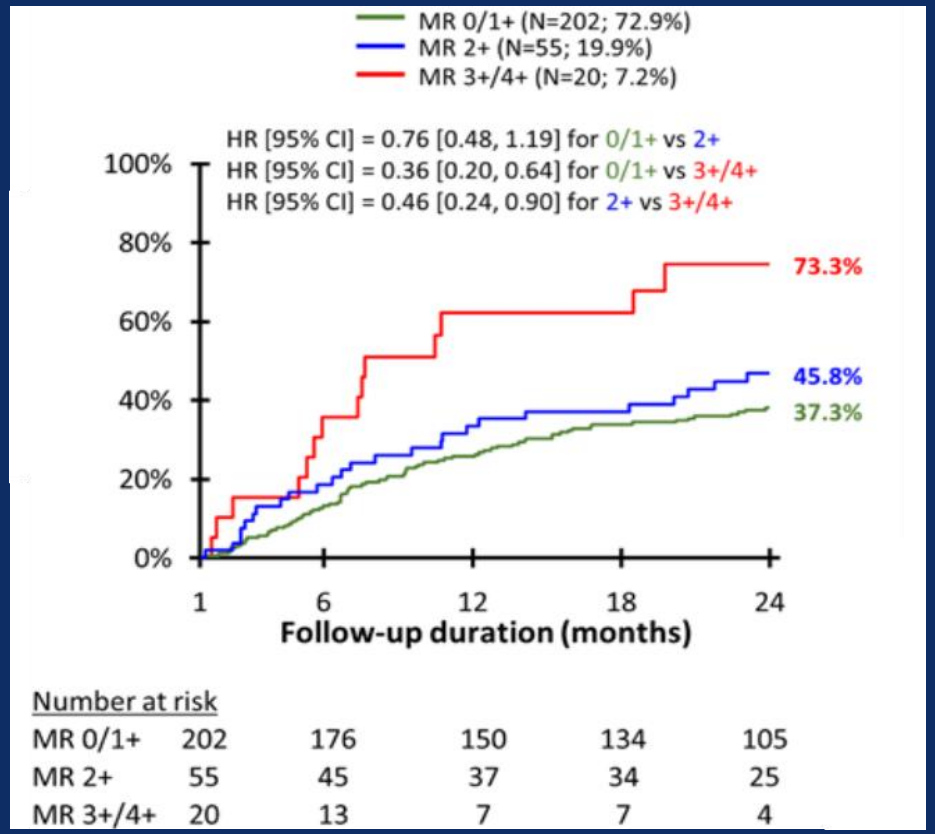
Halaby R et al. JACC Cardiovasc Interv. 2021;14(8):879-889.

*Median [IQR] = 3.5 [2.6, 5.1]

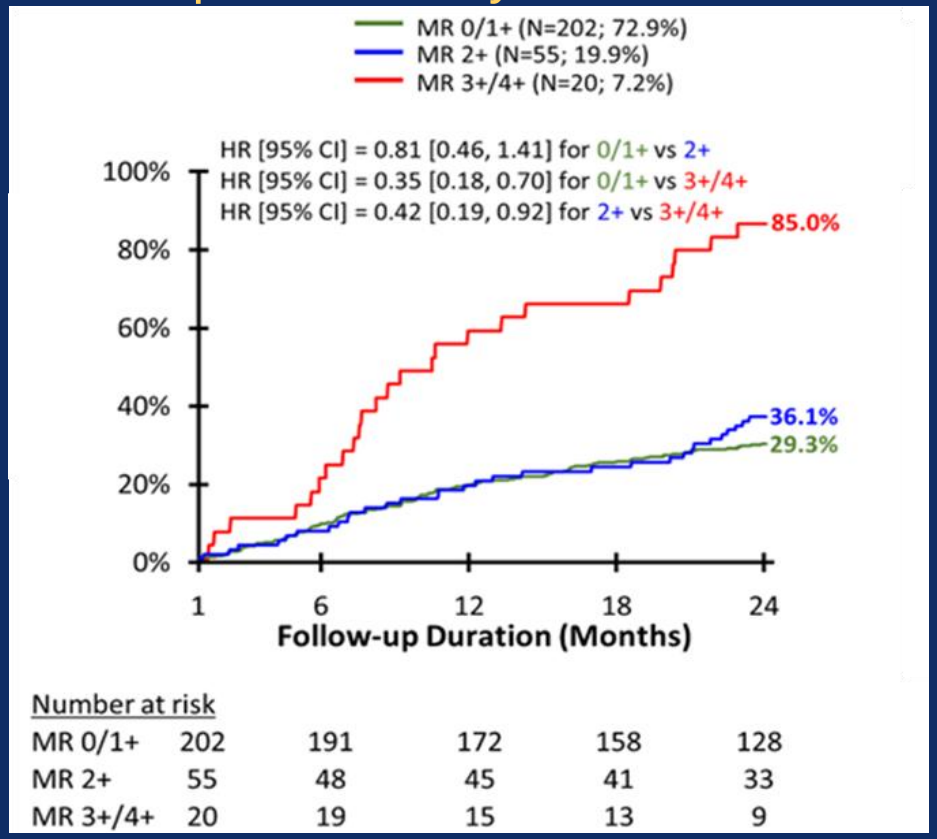
MR Reduction was Strong Predictor of Clinical Outcome

277 Secondary MR Patients after TEER from COAPT Trial
Benefits of MR Reduction Might Outweigh the Adverse Effects of Increased MV Gradient

Death or HFH by Residual MR



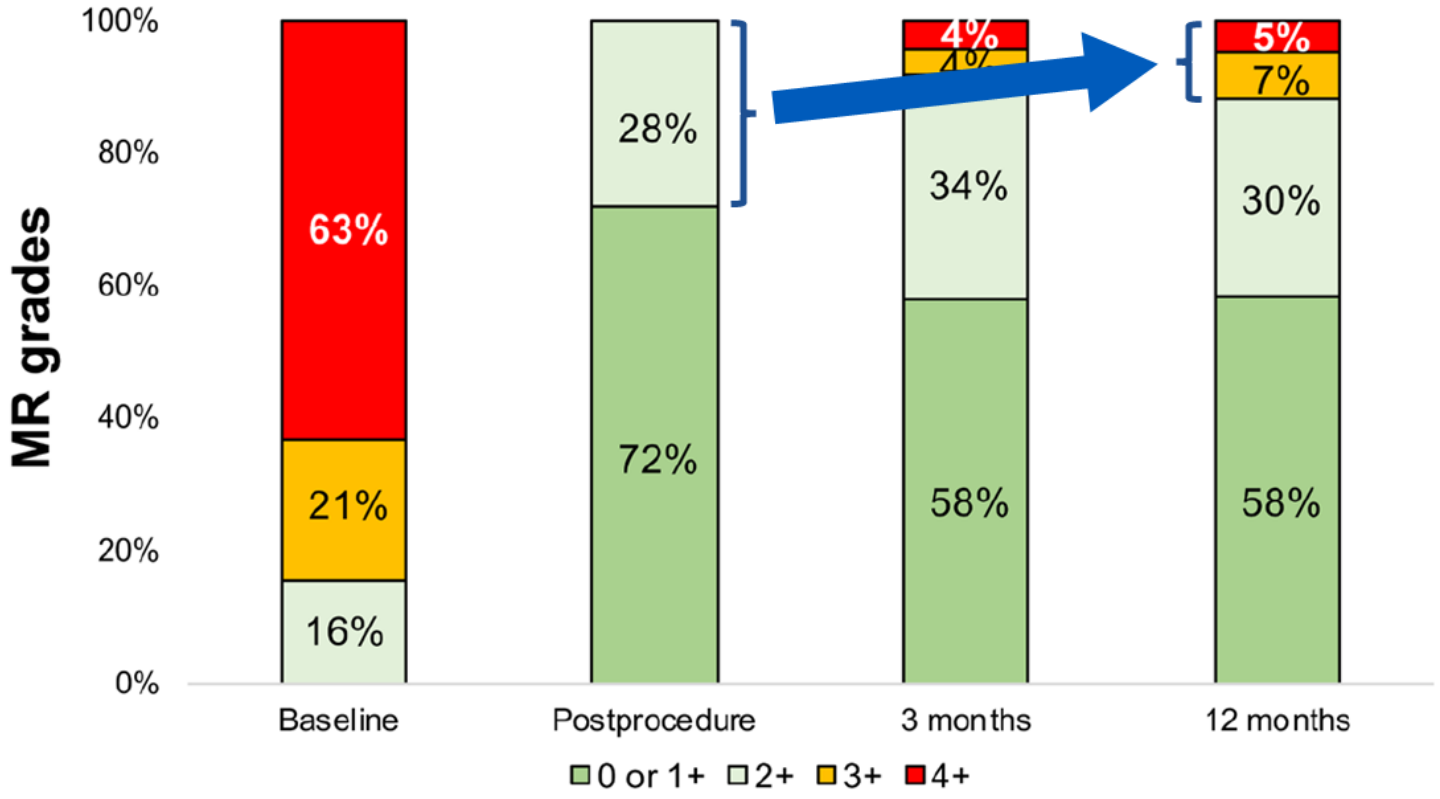
HF Hospitalization by Residual MR

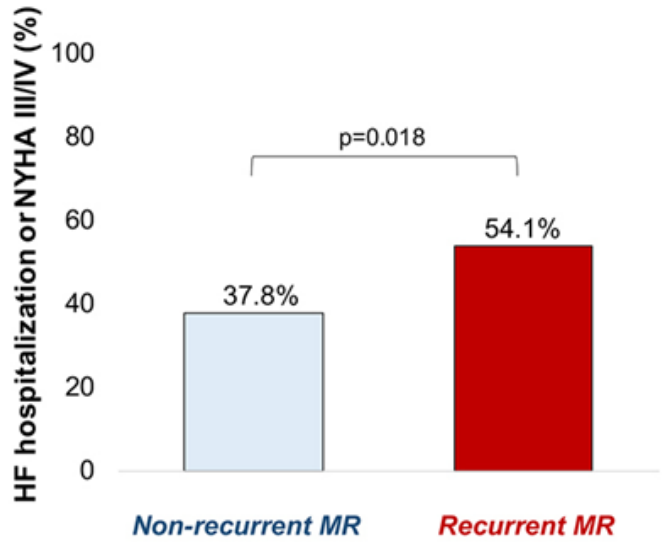


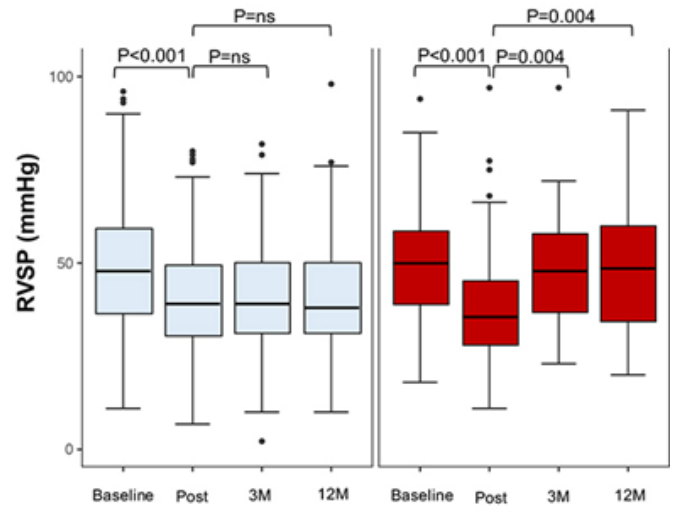
Kar S et al. Circulation. 2021;144:426-37.

Deleterious Hemodynamic Effect of Recurrent MR

- German Single center, MR to ≤2+ after Mitraclip (N=685)
- 61 (8.9%) patients developed recurrent MR within 12 months
- Predictor of Recurrent MR : MR 2+, Flail leaflet



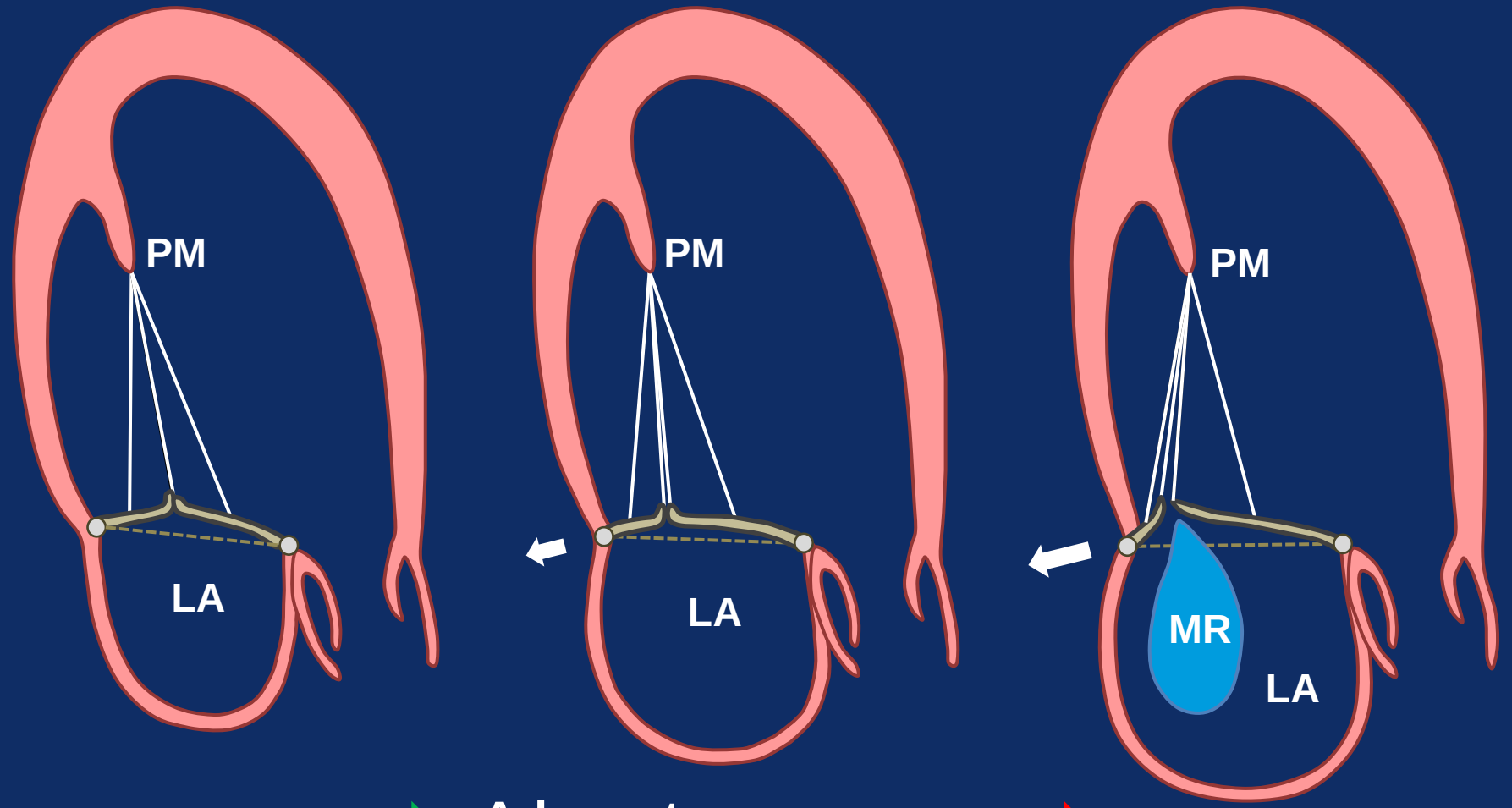




Sugiura A et al. Circ Cardiovasc Interv. 2022;15(3):e010895.

TEER in Atrial Functional MR

Isolated Annular Dilation Develops Atrial FMR in AF



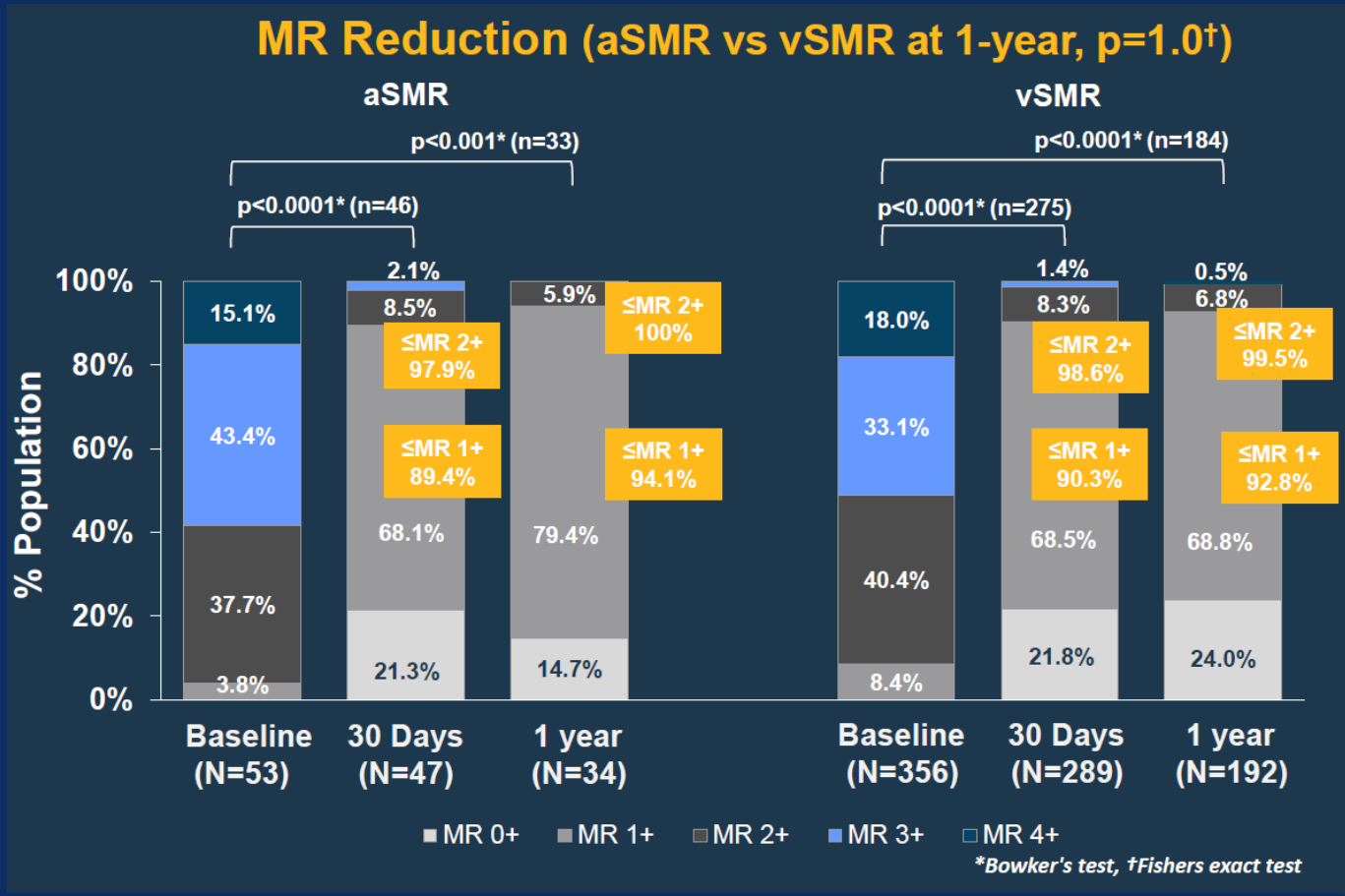
Normal → Adequate Leaflet Adaptation → Inadequate Leaflet Adaptation

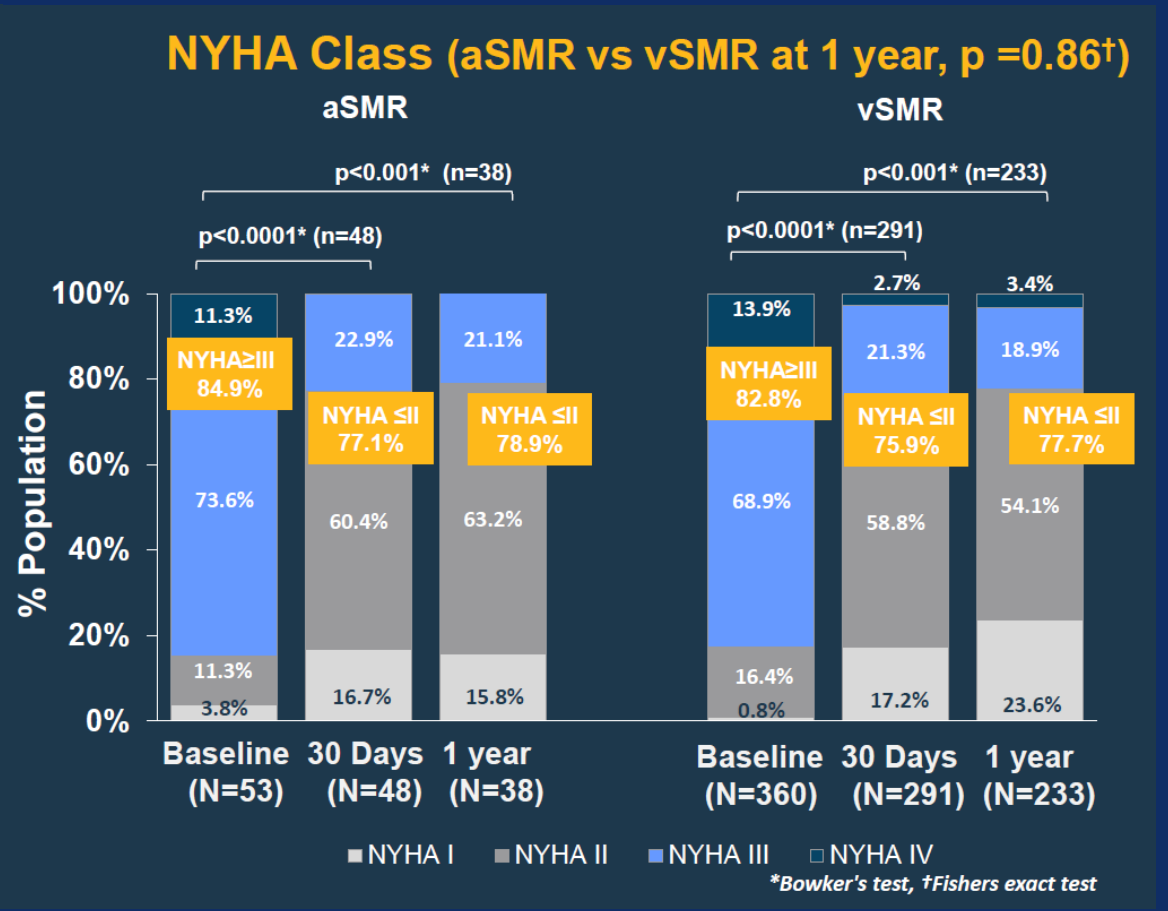
NSR | AF

Kim DH et al. JACC Imaging. 2019;12:665–

TEER in Atrial FMR : Global EXPAND study

N=53, LV EF ≥45% without RWMA, AF with Dilated LA



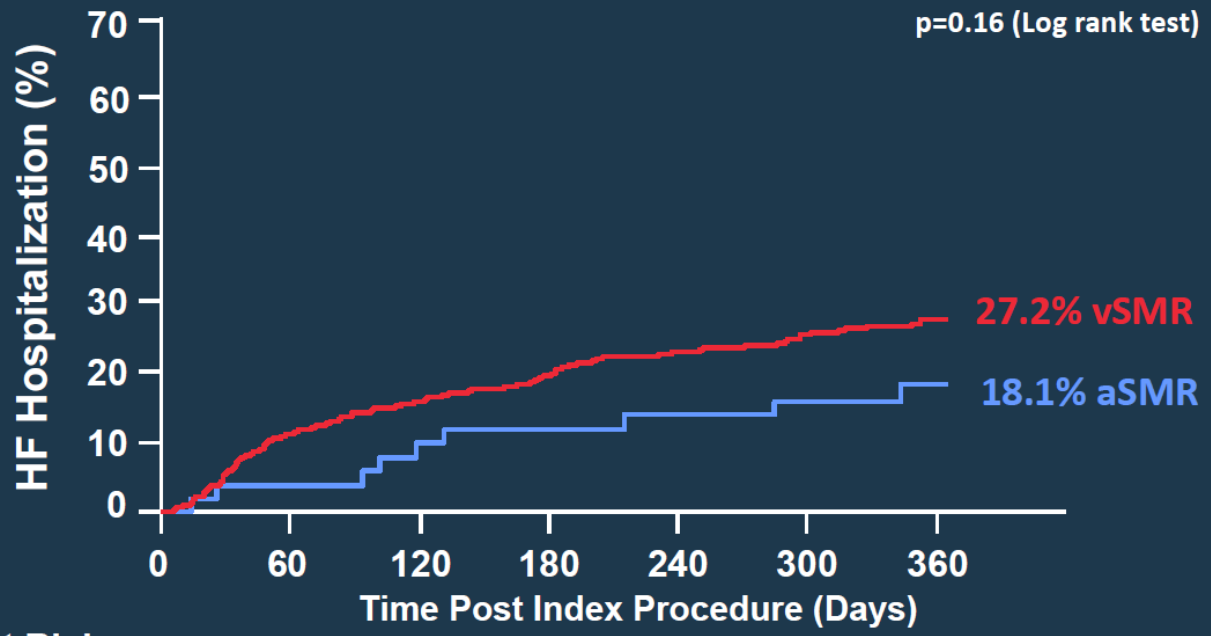


Sodhi et al. Presented at TCT 2021

TEER in Atrial FMR : Global EXPAND study

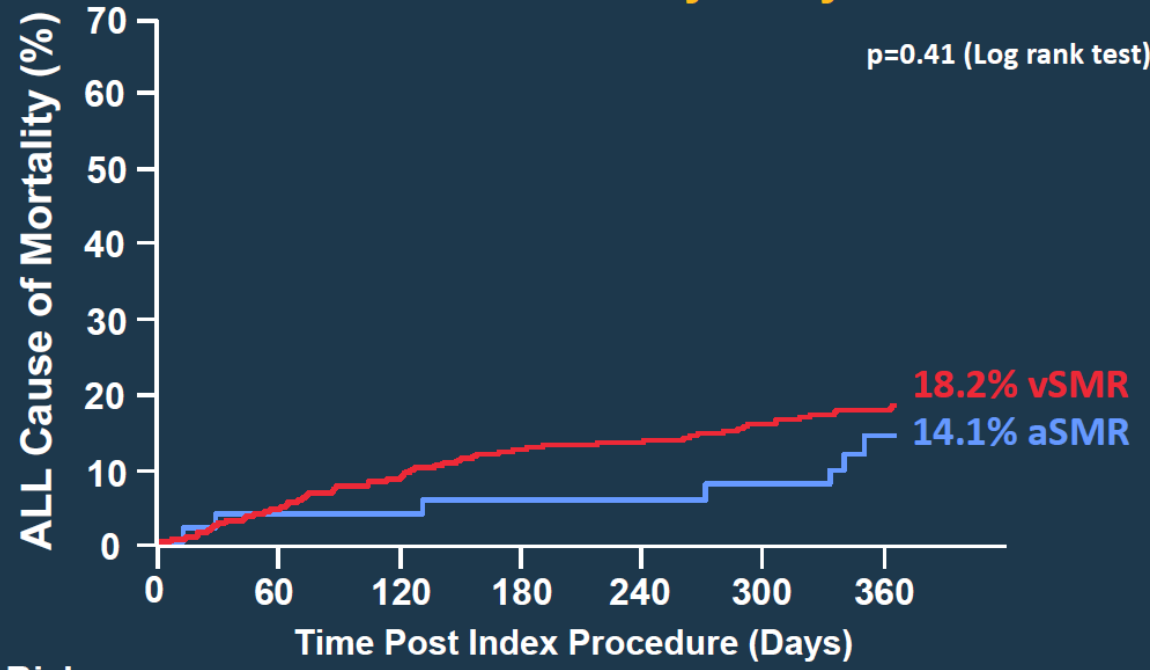
N=53, LV EF ≥45% without RWMA, AF with Dilated LA

HF Hospitalization at 1 year



At Risk				
aSMR	53	49	44	24
vSMR	360	333	251	144

All-Cause mortality at 1 year



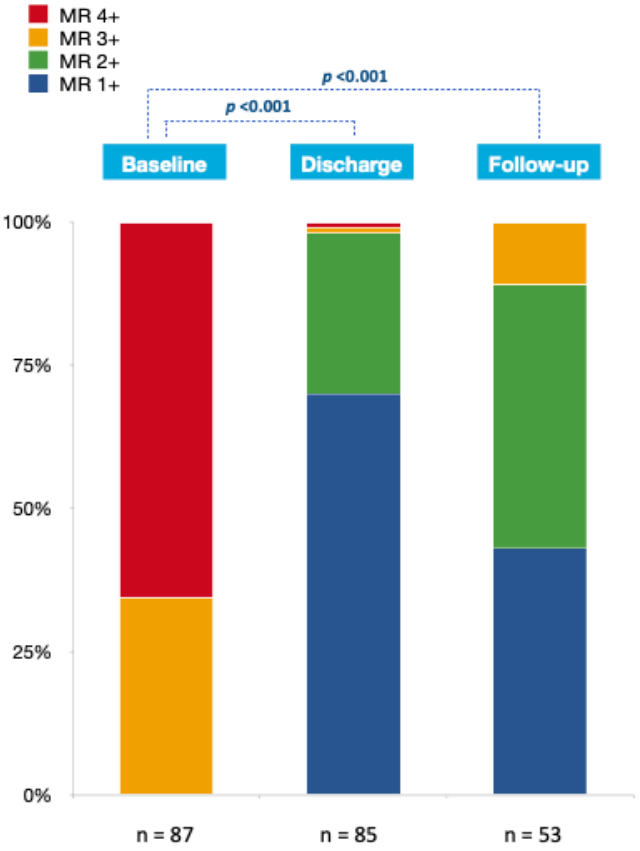
At Risk				
aSMR	53	50	49	29
vSMR	360	349	292	183

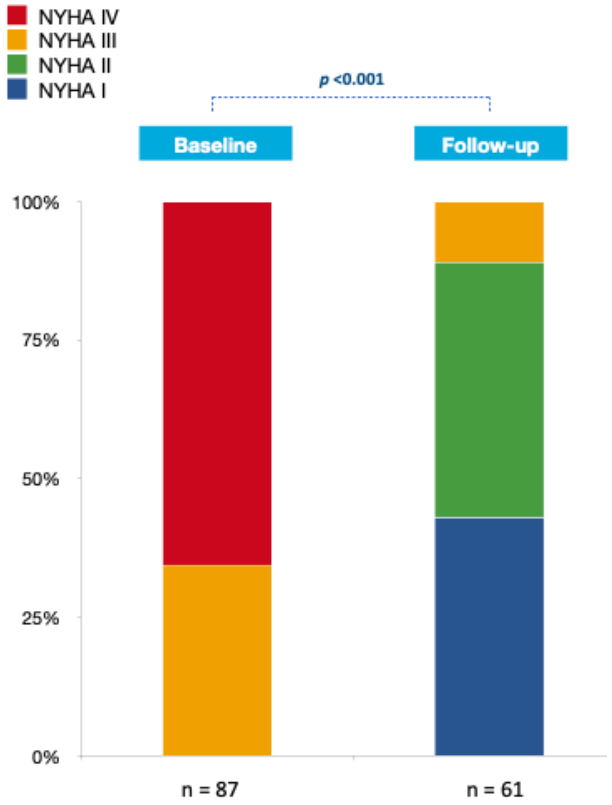
HFH, based on each patient's first occurrence of HF Hospitalization.

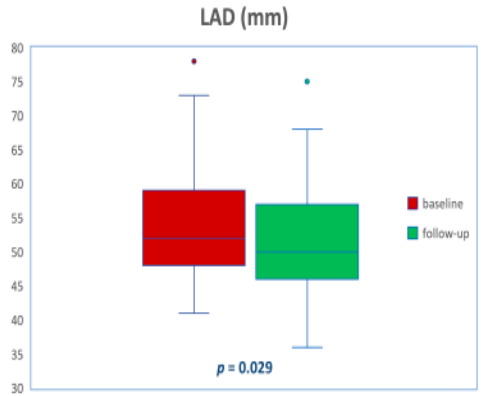
Sodhi et al. Presented at TCT 2021

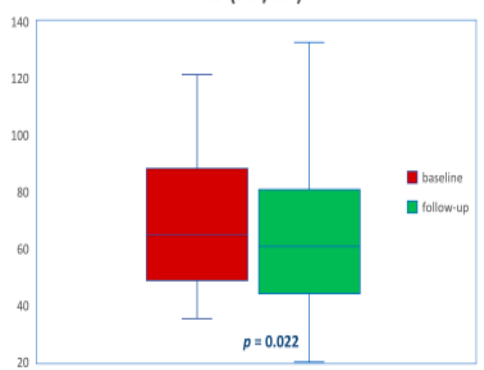
TEER in Atrial FMR : MITRA-TUNE

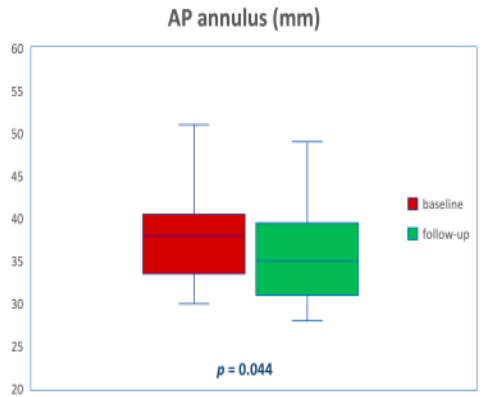
N=87 (7.6% of FMR), LV EF ≥50%, LVEDD <55mm, AF
81 YO, 61% female, STS 4%

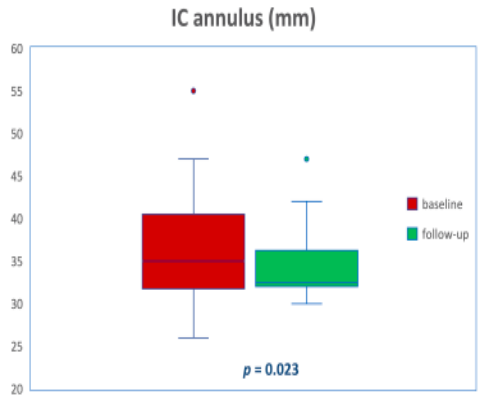








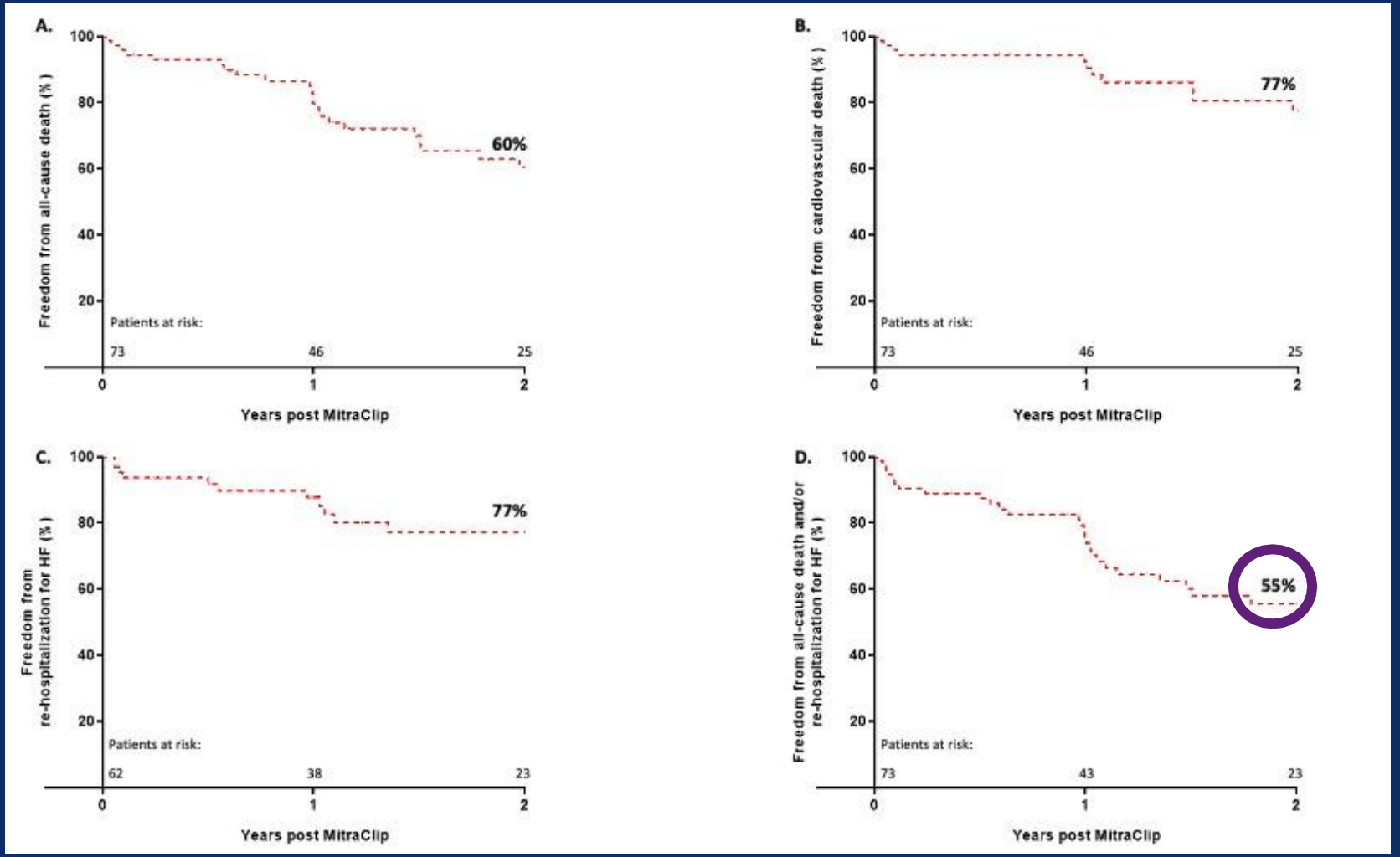




Rubbio AP et al. IJC 2022;349:39-45

TEER in Atrial FMR : MITRA-TUNE

83% device success, 2% in-hospital death, 5% 30-day mortality



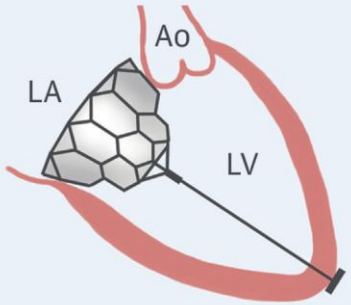
Rubbio AP et al. IJC 2022;349:39-45

Transcatheter Mitral Valve Replacement (TMVR)

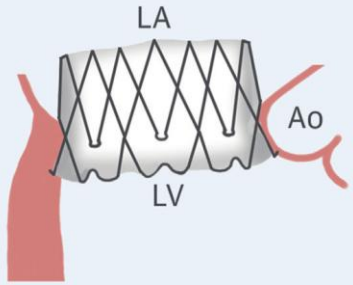
Transcatheter Mitral Valve Replacement for Native Mitral Regurgitation

Anchoring Mechnisms of TMVR

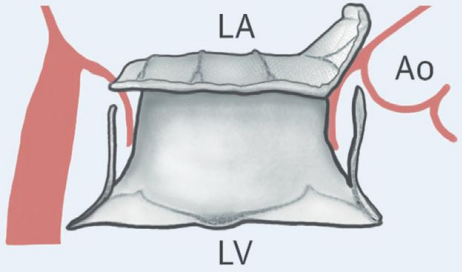
Apical Tether



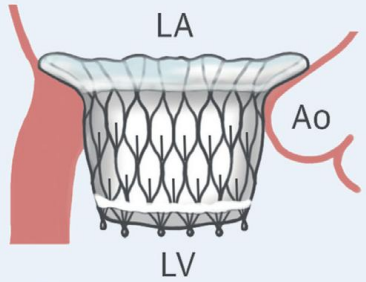
Annular Winglets



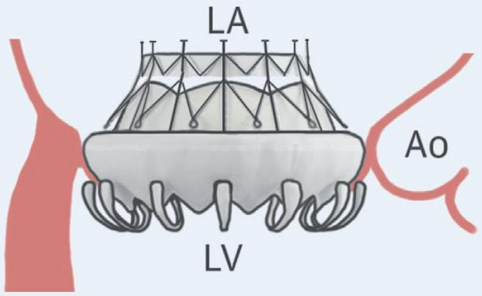
Native Leaflet Engagement



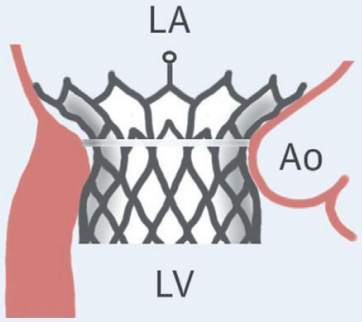
Radial Force



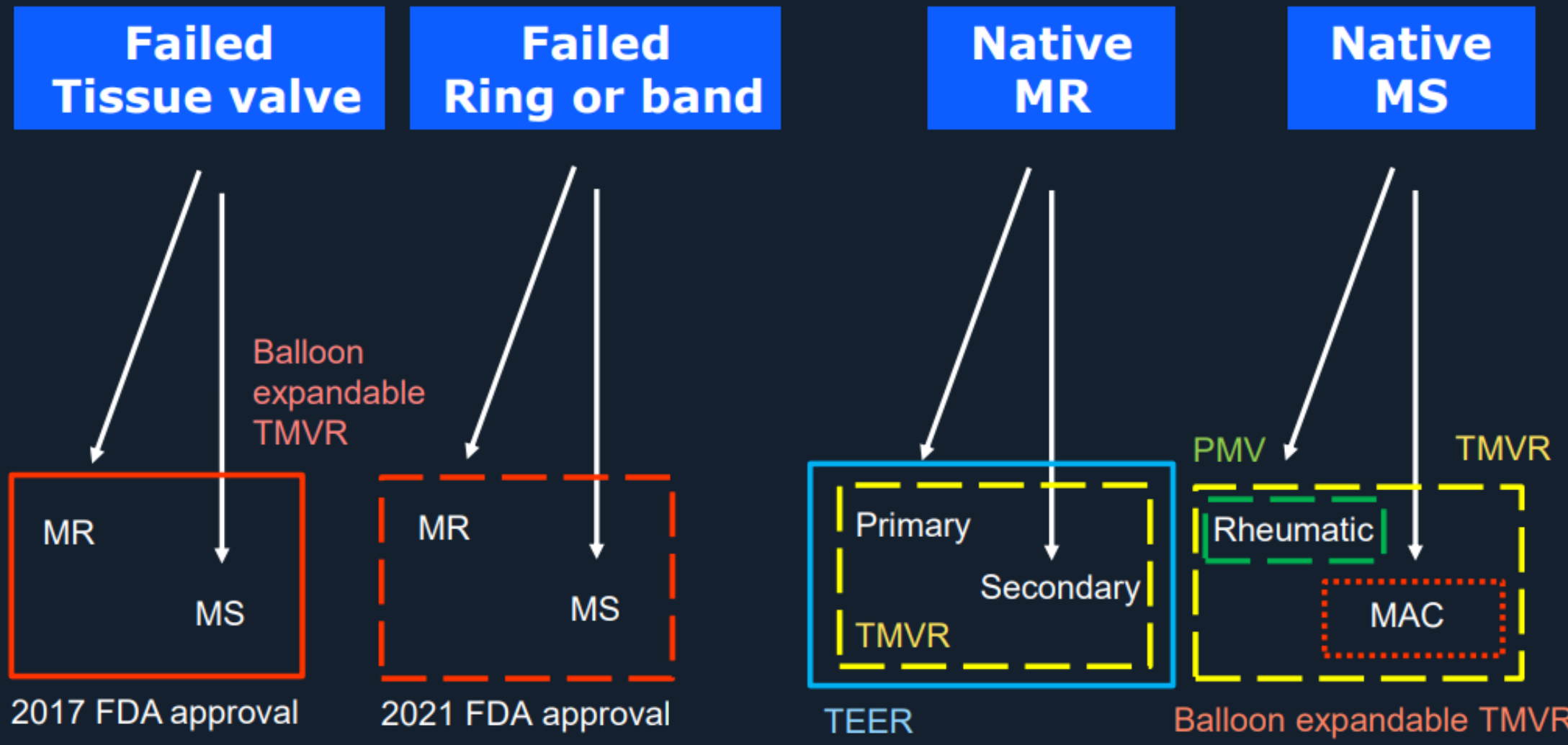
Mitral Annulus Clamping



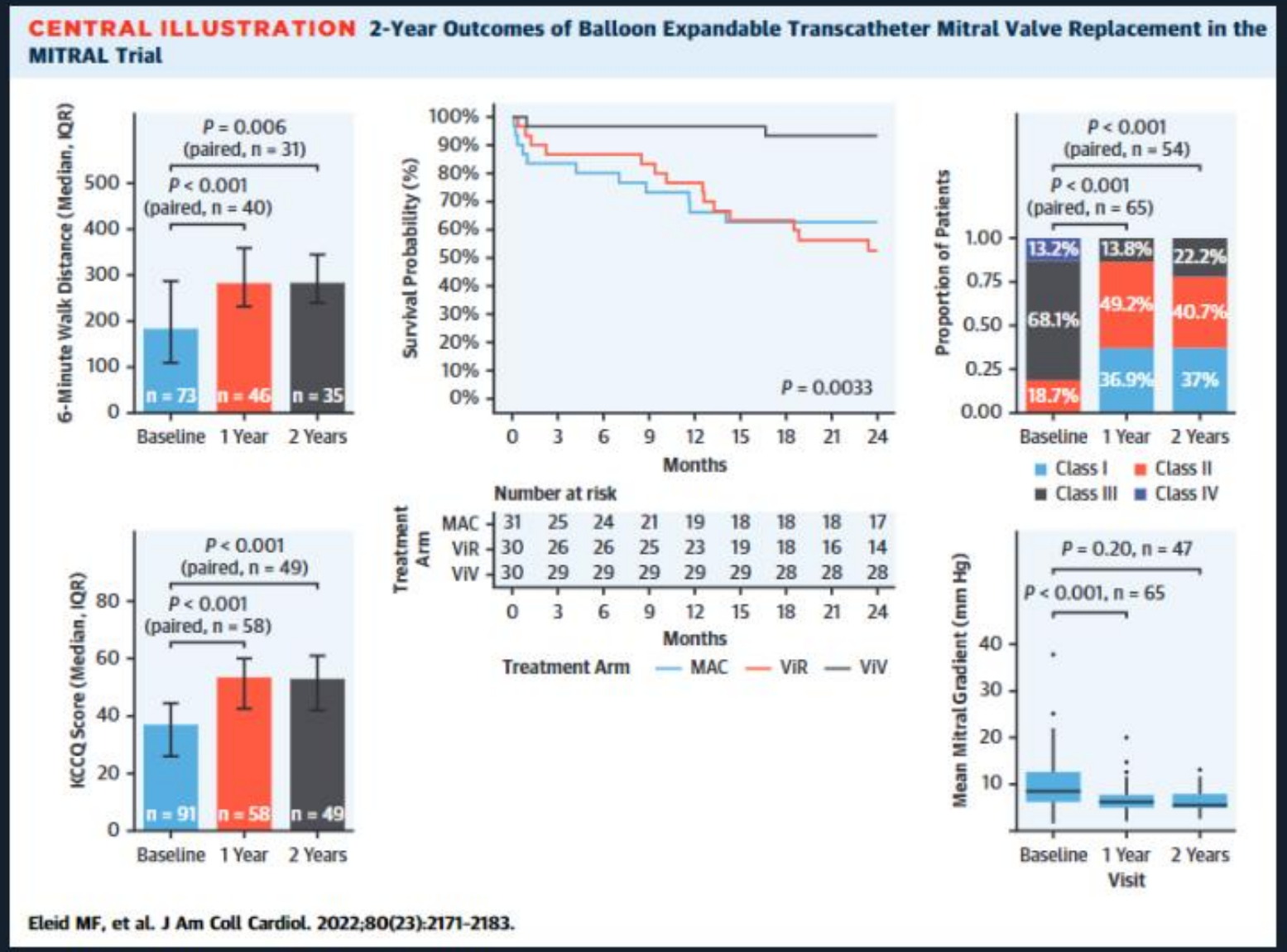
External Anchor



Treatment of trans-catheter mitral valve disease



2-year clinical outcome (MViV, MViR, ViMAC)



Eleid MF, et al. J Am Coll Cardiol. 2022;80(23):2171-2183.

Severe MV disease with severe MAC or high Echo score MS

Native MR or MS disease

Surgical candidate

Yes

MAC related technical challenges?

No

MVR

Yes

Surgical implantation
Balloon expandable THV (SITRAL trial)

No

Favorable anatomy for trans-septal TMVR with Balloon expandable THV?

Yes

Balloon expandable THV
with or without
1. LAMPOON, ANCHOR
2. Alcohol septal ablation
3. Lithotripsy

No

TMVR
Single arm or Trial
(SUMMIT APPOLO ENCIRCLE)

ViMAC (SITRAL Trial)

Clinical Outcomes at 30 Days and 1 Year		
	30 Days (n=39)	1 Year*(n=22)
All-cause mortality	15.3 (6/39)	40.9 (13/22)
Stroke	5.1 (2/39)	7.4 (2/27)
Atrial fibrillation	15 (3/20)	13.6 (3/22)
Follow-up echocardiography	(n=22)	(n=9)
Paravalvular MR		
None	90.9 (20/22)	88.9 (8/9)
Mild	9.1 (2/22)	11.1 (1/9)

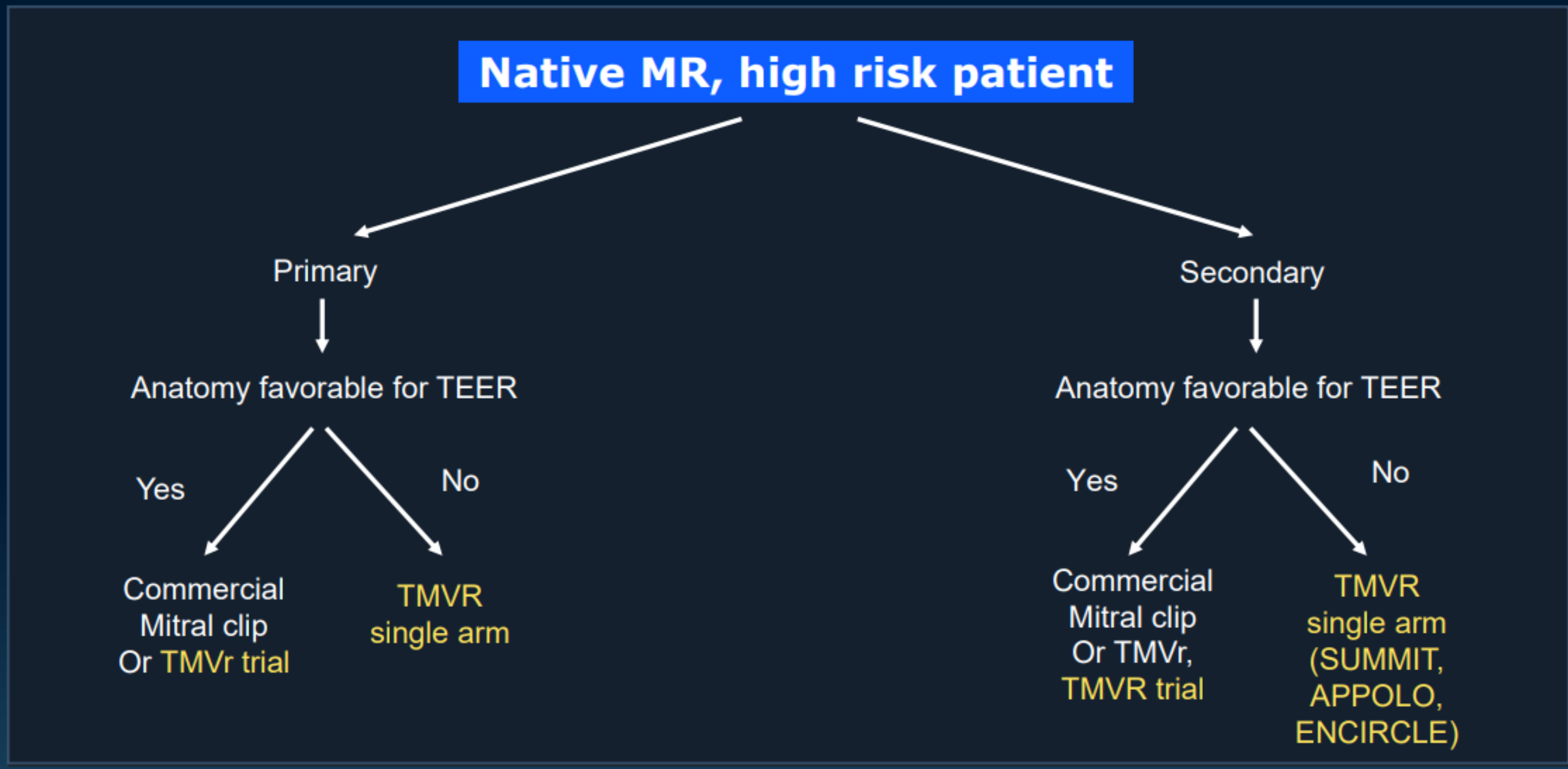
TCT 2019

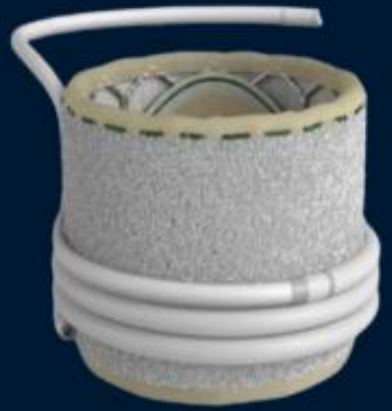
11 patients

Outcome	Result
30-day outcomes	
In-hospital mortality	0 (0)
30-day mortality	0 (0)
Stroke	1 (9.1)
Cardiac surgery reoperation	1 (9.1)
Hemolytic anemia	1 (9.1)
Vascular access complication	1 (9.1)
Arrhythmia	7 (63.6)
Permanent pacemaker implantation	2 (18.2)
New hemodialysis requirement	1 (9.1)
Blood transfusion	3 (27.3)
ICU LOS (d)	10.6 ± 20.6
Hospital LOS (d)	19.1 ± 20.2
Postprocedure echocardiographic outcomes	
Postoperative PVL	
None or trace	8 (72.7)
Mild	3 (27.3)
Moderate or severe	0 (0)
Mean THV gradient <5 mm Hg	9 (81.2)
LVOT gradient ≧30 mm Hg	2 (18.2)

JTCVS Tech. 2021 Oct; 9: 49–56.

Severe MR without severe MAC

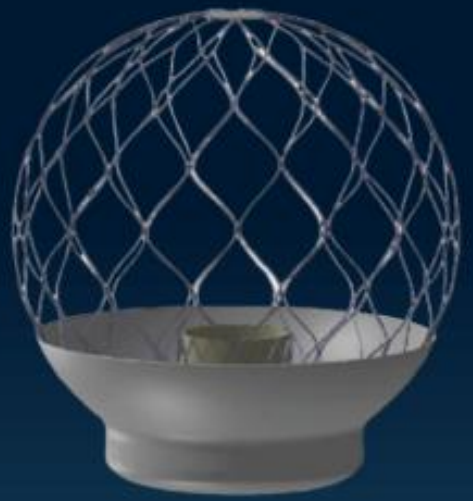




Saphien M3

Interpid

Tendyne



Altavalve

Cephea

Tendyne Valve

- Trans-apical only
- Abbott vascular
- Anchor : Apical pad
- 34 French, recapturable
- >1500 patients treated worldwide (cohort: 100 patients)
- 30 day mortality : 8~9%
- 1 year mortality : 25~27%, 2 year mortality : ~40%
- Disabling stroke : 3%
- Technical success : 97%
- Ongoing study : SUMMIT (MR: TEER vs tendyne / severe MAC)

Tendyne™ Clinical Evidence

Initial Feasibility Study of a New Transcatheter Mitral Prosthesis

The First 100 Patients

Paul Sorajja, MD,[a] Neil Moat, MBBS,[b] Vinay Badhwar, MD,[c] Darren Walters, MBBS,[d] Gaetano Paone, MD,[e] Brian Bethea, MD,[f] Richard Bae, MD,[g] Gry Dahle, MD,[h] Muhaddir Mumtaz, MD,[i] Paul Grayburn, MD,[j] Samir Kapadia, MD,[k] Vasilis Babaliaros, MD,[l] Mayra Guerrero, MD,[l] Lowell Satler, MD,[m] Vinod Thourani, MD,[m] Francesco Bedogni, MD,[n] David Hirsh, MD,[o] Paolo Denti, MD,[p] Nicolas Dumonteil, MD,[q] Thomas Modine, MD,[r] Ajay Sinhal, MBBS,[s] Michael L. Chuang, MD,[t] Jeffrey J. Popma, MD,[u] Philipp Blanke, MD,[v] Jonathon Leipsic, MD,[v] David Muller, MBBS[w]

euro PCR 2019 LATE BREAKING TRIALS

Mitral regurgitation severity predicts one-year therapeutic benefit of Tendyne transcatheter mitral valve implantation

Vinay Badhwar[1*], MD; Paul Sorajja[2], MD; Alison Duncan[3], MD; Vinod Thourani[4], MD; Ulrich Schaefer[5], MD; Paul Grayburn[6], MD; Nicolas Dumonteil[7], MD; Vasilis Babaliaros[8], MD; Andrea Garatti[9], MD; Jonathon Leipsic[10], MD; Michael Chuang[11], MD; Philipp Blanke[10], MD; David Muller[12], MD

ORIGINAL INVESTIGATIONS

Novel Transcatheter Mitral Valve Prosthesis for Patients With Severe Mitral Annular Calcification

Paul Sorajja, MD,[a] Mario Gössl, MD,[b] Vasilis Babaliaros, MD,[c] David Hirsh, MD,[d] Lenard Conradi, MD,[e] Richard Bae, MD,[f] Robert F. Rushe, MD,[g] Ulrich Schäfer, MD,[h] John C. Liuba, MD,[i] Robert D. Riley, MD,[j] Robert Guyton, MD,[k] Nicolas Dumonteil, MD,[l] Pierre Berthoumieu, MD,[l] Didier Tchetche, MD,[l] Philipp Blanke, MD,[l] João L. Cavalcante, MD,[a] Benjamin Sun, MD[a]

2-Year Outcomes of Transcatheter Mitral Valve Replacement in Patients With Severe Symptomatic Mitral Regurgitation

David W.M. Muller, MBBS, MD,[a] Paul Sorajja, MD,[b] Alison Duncan, MBBS, PhD,[c] Brian Bethea, MD,[d] Gry Dahle, MD,[e] Paul Grayburn, MD,[f] Vasilis Babaliaros, MD,[g] Mayra Guerrero, MD,[h] Vinod H. Thourani, MD,[i] Francesco Bedogni, MD,[j] Paolo Denti, MD,[k] Nicolas Dumonteil, MD,[l] Thomas Modine, MD,[m] Paul Jansz, MBBS, PhD,[n] Michael L. Chuang, MD,[o] Philipp Blanke, MD,[p] Jonathon Leipsic, MD,[p] Vinay Badhwar, MD[q]

Early clinical results with the Tendyne transcatheter mitral valve replacement system

Jared P. Beller[1], Jason H. Rogers[2], Vinod H. Thourani[3], Gorav Ailawadi[1]

[1]Division of Thoracic and Cardiovascular Surgery, Department of Surgery, University of Virginia, Charlottesville, VA, USA; [2]Division of Cardiovascular Medicine, Department of Internal Medicine, University of California Davis, Sacramento, CA, USA; [3]Department of Cardiac Surgery, MedStar Heart and Vascular Institute and Georgetown University, Washington, DC, USA

Correspondence to: Gorav Ailawadi, MD. Chief, Cardiac Surgery, Department of Surgery, University of Virginia, PO Box 800679, Charlottesville, VA, USA. Email: Gorav@virginia.edu

RESEARCH CORRESPONDENCE

6-Year Outcomes of First-In-Man Experience With Tendyne Transcatheter Mitral Valve Replacement

A Single Center Experience

follow-up). All patients provided written informed consent, and the study was approved by the local Ethics committee. Clinical and echocardiographic data (baseline, discharge, and follow-up) are presented in accordance with Mitral Valve Academic Research Consortium definitions. The study cohort (74 [range 63-87] years, 80% male) presented with primary (n = 1) and secondary (n = 4) MR. All were symptomatic (NYHA functional class III/IV) with high surgical risk scores (Society of Thoracic Surgeons Predicted Risk of Mortality range 14%-23%, EuroSCORE II [European System for Cardiac Operative

Neo-Left Ventricular Outflow Tract modification With Alcohol Septal Ablation Before Tendyne Transcatheter Mitral Valve Replacement

Anene Ukaigwe, MD, Mario Gössl, MD, João Cavalcante, MD, Sara Olson, BSN, Paul Sorajja, MD

Articles and Issues Available at ScienceDirect

Structural Heart

journal homepage: www.structuralheartjournal.org

Opinion Piece

Multicenter Clinical Management Practice to Optimize Outcomes Following Tendyne Transcatheter Mitral Valve Replacement

Alison Duncan, FRCP, PhD[a,*], Gry Dahle, MD, PhD[b], Lenard Conradi, MD[c], Nicholas Dumonteil, MD[d], John Wang, MD[e], Nimesh Shah, MD[f], Benjamin Sun, MD[g], Paul Sorajja, MD[h,i], Gorav Ailawadi, MD[j], Jason H. Rogers, MD[j], Cesare Quarto, PhD, FRCS[a,c], Brian Bethea, MD[a,k]

Single centre experience with transapical transcatheter mitral valve implantation†

Gry Dahle[a,*], Kjell-Arne Rein[a] and Arnt E. Fiane[a,b]

[a] Department of Cardiothoracic and Thoracic surgery, Oslo University Hospital, Oslo, Norway
[b] Faculty of Medicine, University of Oslo, Oslo, Norway

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ESC European Society of Cardiology

European Journal of Heart Failure (2022) 24, 899–907
doi:10.1002/ejhf.2434

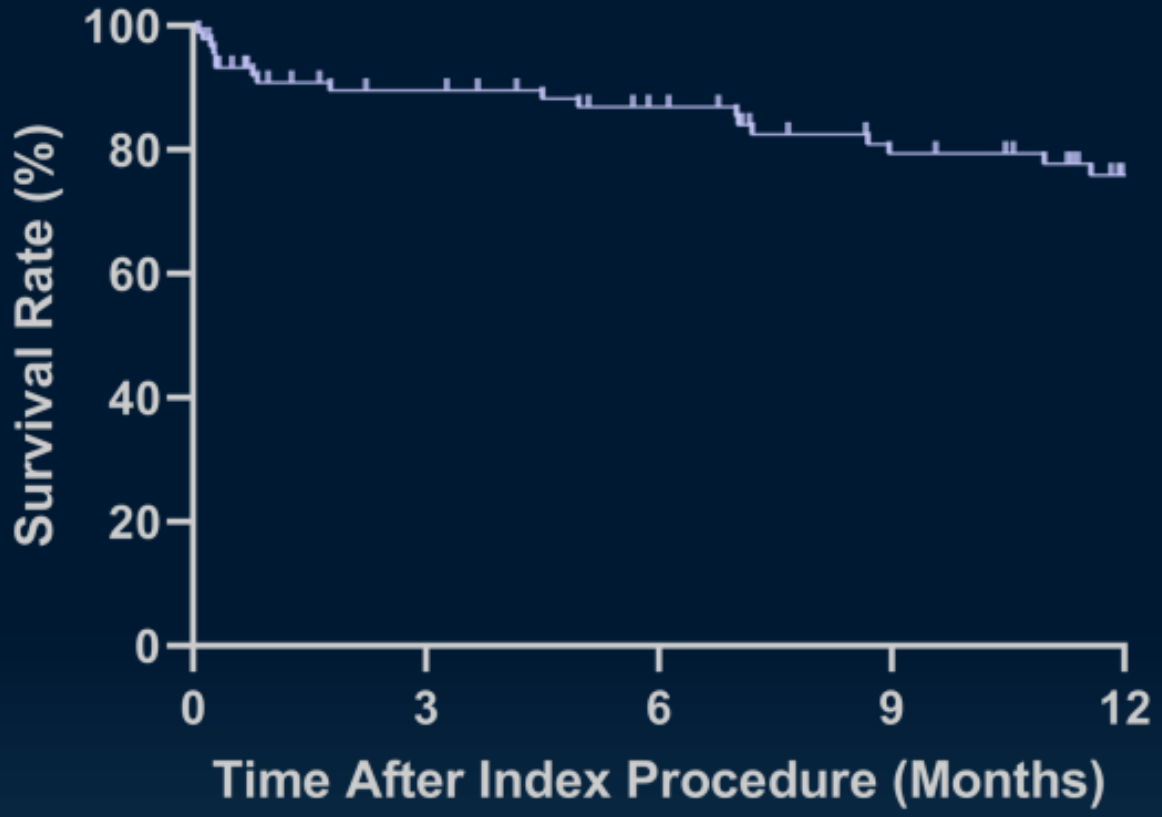
RESEARCH ARTICLE

Transapical mitral valve implantation for treatment of symptomatic mitral valve disease: a real-world multicentre experience

Mirjam G. Wild[1,2†], Felix Kreidel[3†], Michaela M. Hell[1], Fabien Praz[2], Markus Mach[4], Matti Adam[5], David Reineke[6], Hendrik Ruge[7], Sebastian Ludwig[8], Lenard Conradi[8], Tanja K. Rudolph[9], Sabine Bleiziffer[9], Jörg Kellermair[10], Andreas Zierer[10], Georg Nickenig[11], Marcel Weber[12], Anna Sonia Petronio[12], Cristina Giannini[13], Gry Dahle[14], Kjell A. Rein[14], Augustin Coisne[15], André Vincentelli[15], Christophe Dubois[16], Alison Duncan[17], Cesare Quarto[18], Axel Unbehaun[19], Ignacio Amat-Santos[20], Javier Cobiella[21], Nicolas Dumonteil[22], Rodrigo Estevez-Loureiro[23], Andrea Fumero[24], Tobias Geisler[25], Philipp Lurz[26], Antonio Mangieri[24], Vanessa Monivas[27], Thilo Noack[28], Luis Nombela Franco[23], Miguel A. Pinon[23], Lukas Stolz[1], Didier Tchétché[22], Thomas Walter[29], Bernhard Unsöld[30], Stephan Baldus[5], Martin Andreas[4], Jörg Hausleiter[1*†], and Ralph S. von Bardeleben[31], on behalf of the TENDER Investigators

SUMMIT
TENDYNE TRIAL

Results: Survival Through One Year



Time	Day 0	1 mo	3 mo	6 mo	12 mo
At risk	90	74	70	62	36
Event rate	1.1%	10.2%	11.5%	14.1%	25.0%

Interpid

Outer 43-50mm

Inner 27mm

- Trans-apical -> Trans-femoral / Target : mitral / tricuspid
- Medtronic
- Anchor : Perimeter oversizing
- 35 French (->29Fr. Future), recapturable
- >350 patients treated worldwide (TF cohort: >50 patients)
- TF – 30 day mortality : 0% / TA – 14%
- 1 year mortality : 0% (median 7.2 month) / TA – 23.5%
- TF – Disabling stroke : 0%, major bleeding : 8%
- Technical success : 96%, delivery time : 42.5 min
- Ongoing study : APPOLO (MR: TEER vs TF-interpid / severe MAC)

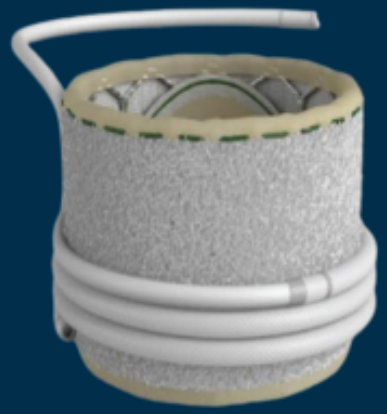
Clinical Outcomes

Clinical Outcomes	Median follow-up: 7.2 (3.1, 12.0)	
KM rate (# of subjects with event)	0-30 days *# pts expected for visit = 30*	0-365 days *# pts expected for visit = 14*
All-cause mortality	0% (0)	0% (0)[1,2]
Stroke or transient ischemic attack	0% (0)	0% (0)
Myocardial infarction	3% (1)	3% (1)
Major vascular complications (procedural)	27% (8)	27% (8)
≥ Stage 2 Acute kidney injury	0% (0)	0% (0)
Reoperation (or reintervention)	3% (1)	3% (1)
New-onset atrial fibrillation/atrial flutter[3]	13% (2)	33% (4)
Valve leaflet thrombosis[4]	0% (0)	7% (1)
Cardiovascular hospitalization	7% (2)	22% (5)
Heart failure	0% (0)	9% (2)

[1]One patient died on day 378 of relapsing lymphoma and worsening heart failure.
[2]The 25th patient in this series died 232 days after their procedure, which was >2 months after this data snapshot was captured. Final source documentation and CEC adjudication are pending.
[3]Patients with baseline AF removed from risk set.
[4]Represents a proportion.

Saphien M3

EVOQUE



Saphien M3

- Trans-femoral
- Edwards Lifescience
- Anchor : Sub-annular nitinol dock, BEV (29 mm)
- 20 French, partially recapturable (only dock system)
- Valve in ring like procedure (docking and then, implantation)
- 35 TF patients treated worldwide
- 30 day mortality: 2.9%
- Technical success : 88.6% (31/35) – 1 (PVL closure), 2 separate trans-septal puncture (dock and valve), 1 (disabling stroke)
- 30 day Mean MVPG : 5.36 mmHg (baseline 3.20 mmHg)
- Ongoing study : EFS, ENCIRCLE (single arm – 3 cohort)

SAPIEN M3 System

Dock Delivery

SAPIEN M3 dock

SAPIEN M3 dock delivery system

Valve Delivery

SAPIEN M3 valve

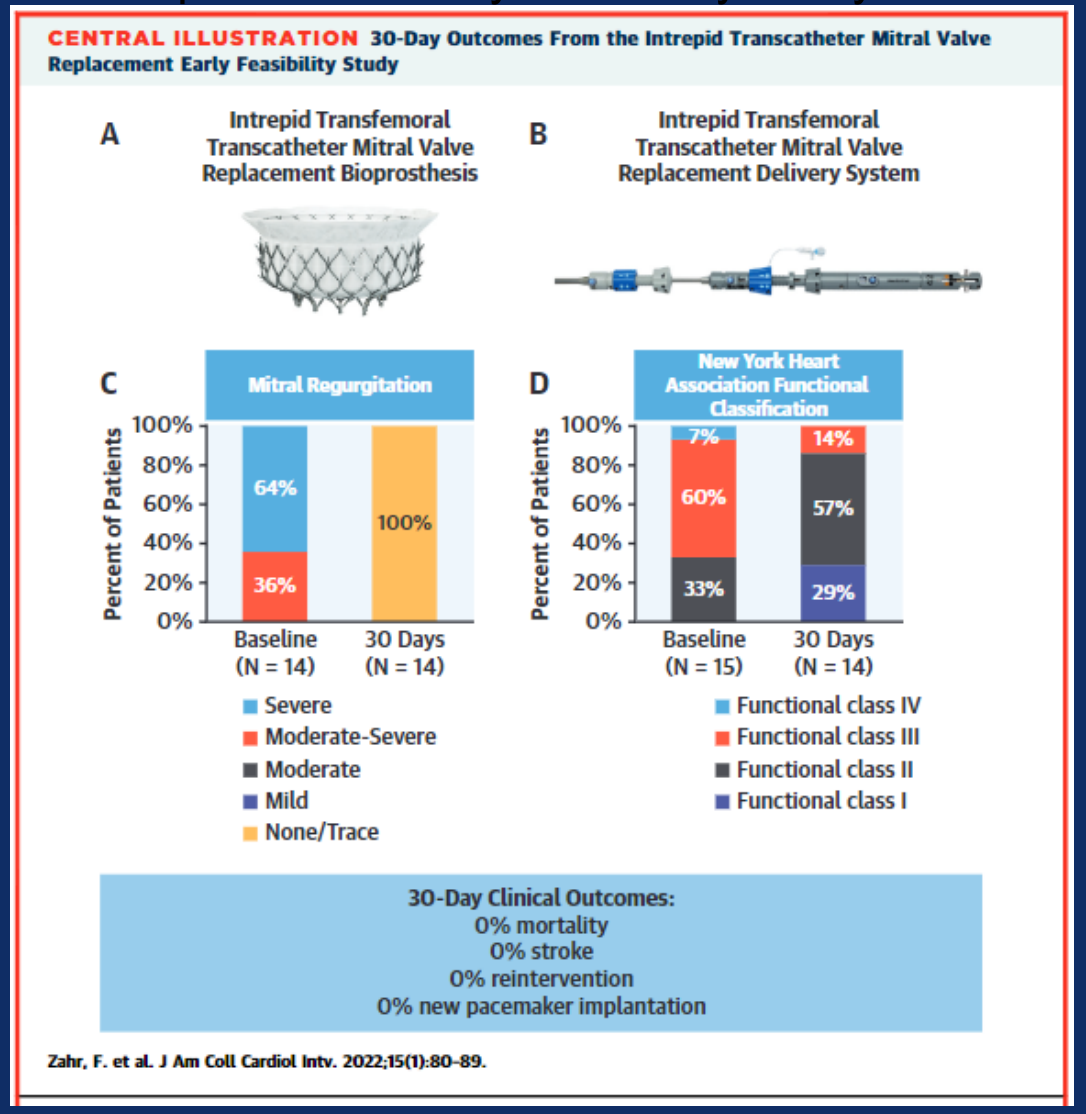
Edwards Commander M delivery system

Final Implant

CAUTION – Investigational device. Limited by Federal (United States) law to investigational use.

APOLLO Trial

30-Day Outcomes Following Transfemoral TMVR
Intrepid TMVR Early Feasibility Study Result

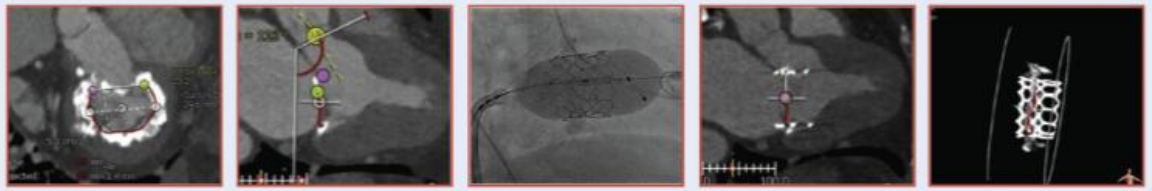


Firas Zahr et al., JACC Cardiovasc Interv. 2022 Jan 10;15(1):80-89.

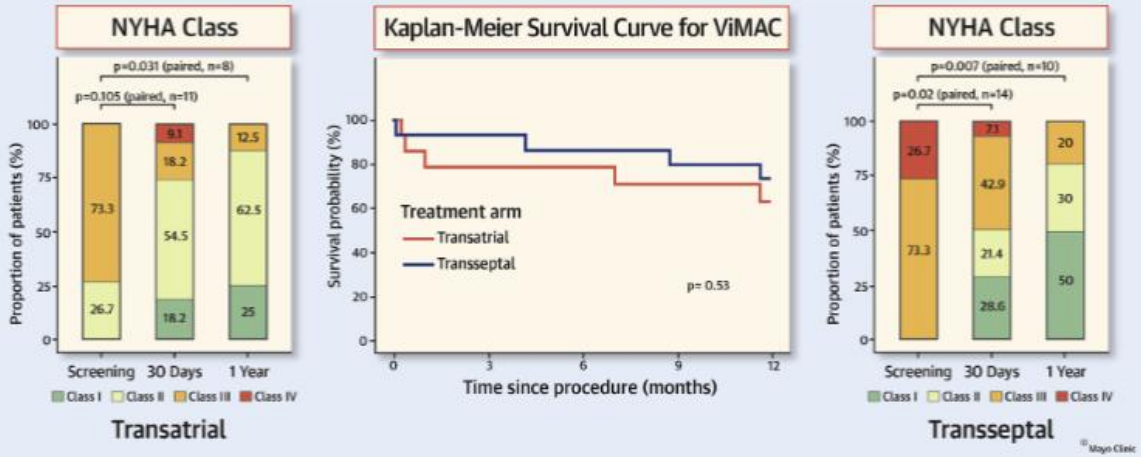
MITRAL Trial

Prospective Study of TMVR Using Balloon-Expandable Aortic Transcatheter Valves in MAC

CENTRAL ILLUSTRATION 30-Day and 1-Year Outcomes of Valve-in-Mitral Annular Calcification in the Mitral Implantation of Transcatheter Valves Trial



Transseptal ViMAC 30-day mortality=6.7%
Transatrial ViMAC 30-day mortality=21.4%
Similar all-cause mortality at 1 year
Sustained improvement of symptoms at 1 year in both groups



Guerrero, M. et al. J Am Coll Cardiol Intv. 2021;14(8):830–45.

Early and late outcomes for functional capacity (New York Heart [NYHA] Association functional class) in the transatrial group **(left)** and transseptal group **(right)** and for survival **(middle)**. ViMAC = valve-in-mitral annular calcification.

Guerrero M et al., JACC Cardiovasc Interv. 2021 Apr 26;14(8):830-845.

Ongoing Clinical Trials

REPAIR MR

MitraClip vs. Surgery for Moderate Surgical Risk

Primary Endpoint: Death, Stroke, Cardiac Hospitalization, AKI requiring RRT at 2 yrs

Patient Population

- Subject is symptomatic (NYHA Class II/III/IV) or asymptomatic (LVEF ≤ 60%, Pulmonary Artery Systolic Pressure > 50 mmHg, or LVESD > 40 mm)
- Subject is at least 75 years of age, OR if younger than 75 years, then has:
  - STS-PROM Score ≥ 2%, OR
  - Presence of other comorbidities which may introduce a potential surgical specific impediment

Severe Primary Mitral Regurgitation (Grade III/IV per ASE* Criteria)

↓

Cardiac Surgeon Concurs that Mitral Valve is Conducive to Mitral Valve Repair Surgery → NO → **Exclude Subject**

↓ YES

Eligibility Committee Confirms that MR can be Reduced to ≤ Mild with Both MitraClip and Mitral Valve Repair Surgery → NO → **Exclude Subject**

↓ YES

Randomization (1:1) (N=500)

↓

Transcatheter Repair - MitraClip (Device)

Surgical Mitral Valve Repair (Control)

PI : Patrick McCarthy MD, Saibal Kar MD. NCT04198870.

Summary : Clinical Update of MitraClip

- Real-world registries showed higher efficacy, safety, and durability with contemporary MitraClip G4 devices.
- Obtaining optimal MR reduction was the key for better long-term clinical outcome.
- Reduction of MR seems more important than reducing transmitral gradient, especially in secondary MR patients.
- MitraClip is trying to widen its indication to moderate-risk primary MR or atrial functional MR.
- Another strong competitor (PASCAL) is coming.

Thank you for your attention!