MITRAL TRANSCATHETER EDGE TO EDGE REPAIR (TEER)

A CURRENT STATUS AND FUTURE DIRECTION

Olympic Peninsula Medical Conference

11/07/2025

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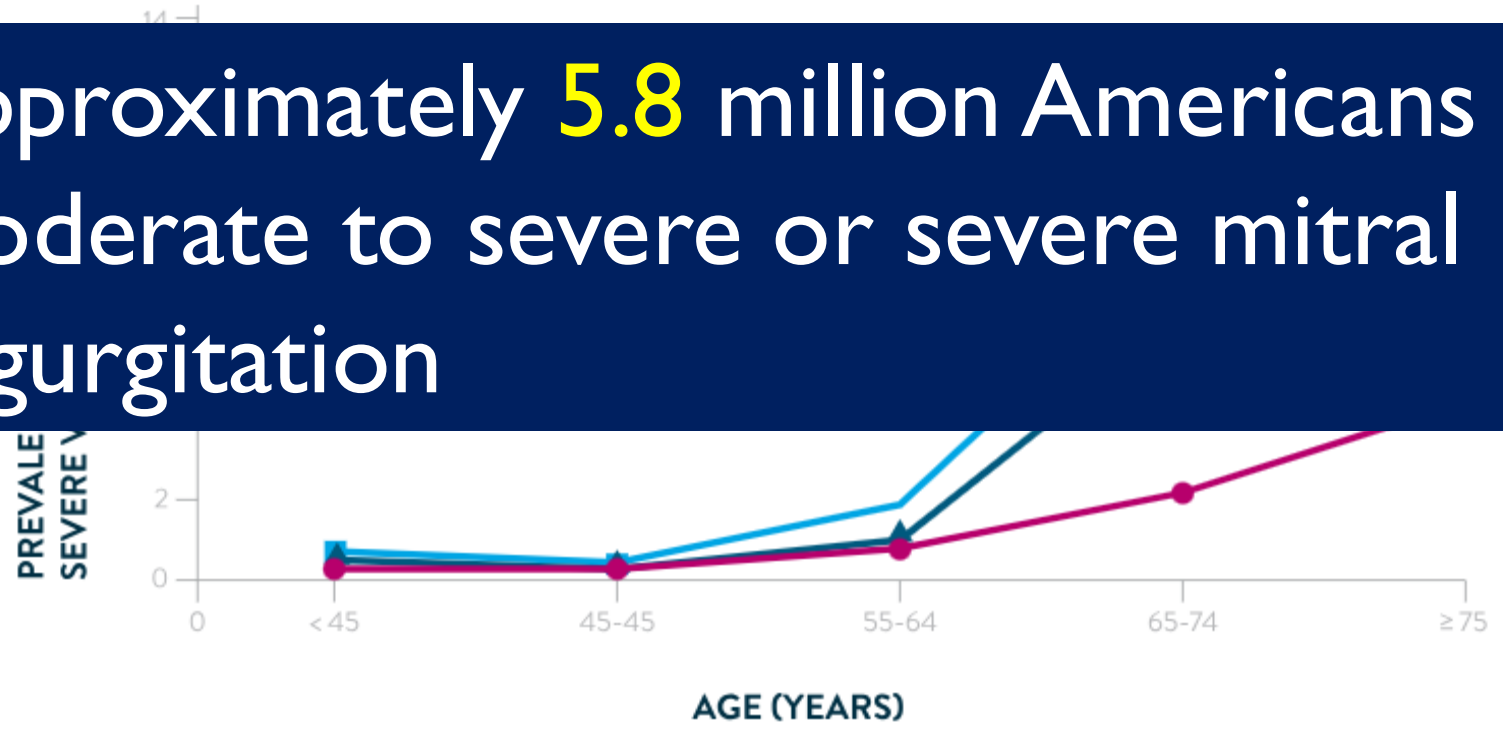
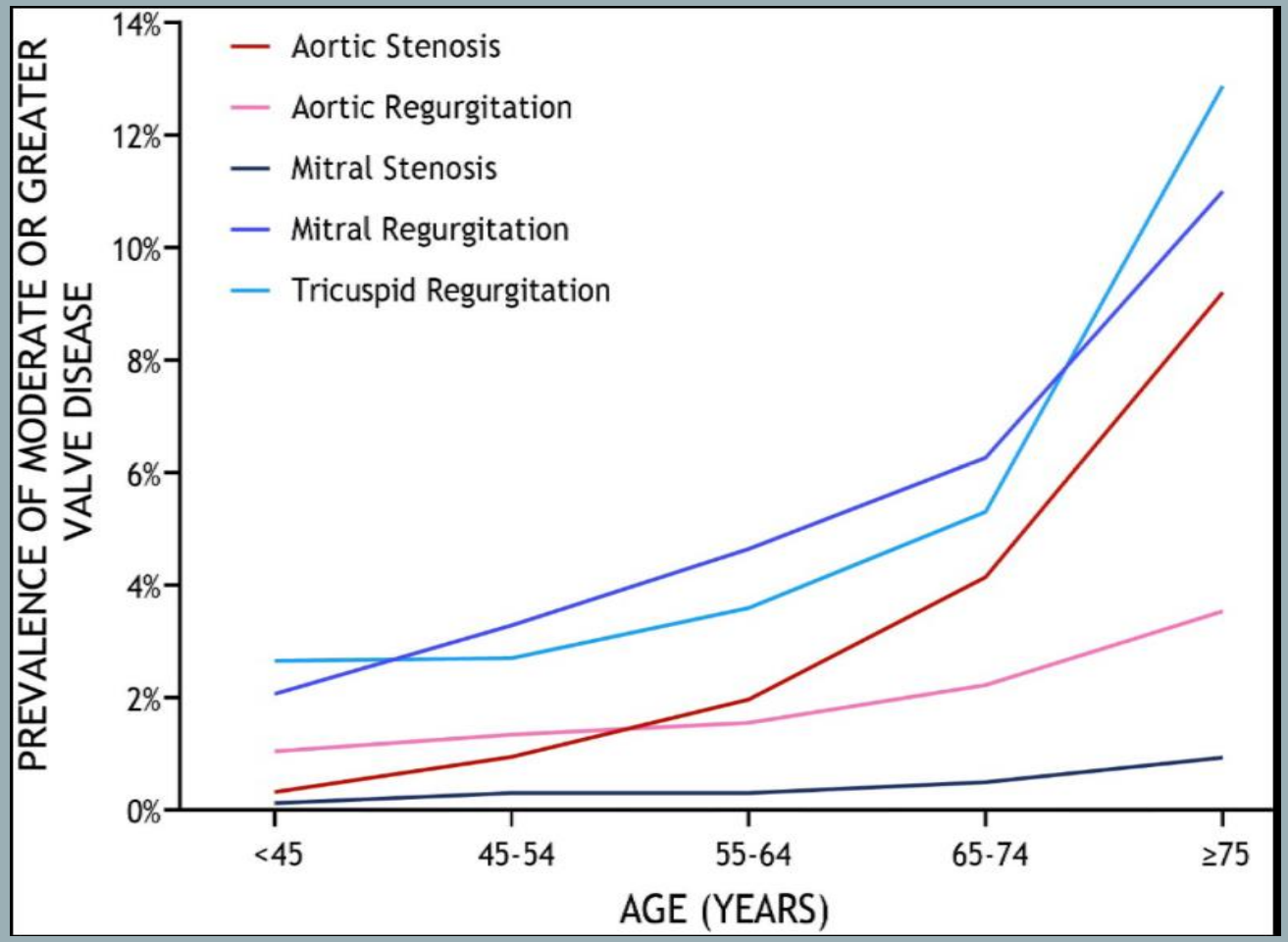
MITRAL VALVE REGURGITATION PREVALENCE

Approximately 5.8 million Americans have moderate to severe or severe mitral regurgitation



Lancet 2006:368: 1005-11

MITRAL VALVE REGURGITATION PREVALENCE



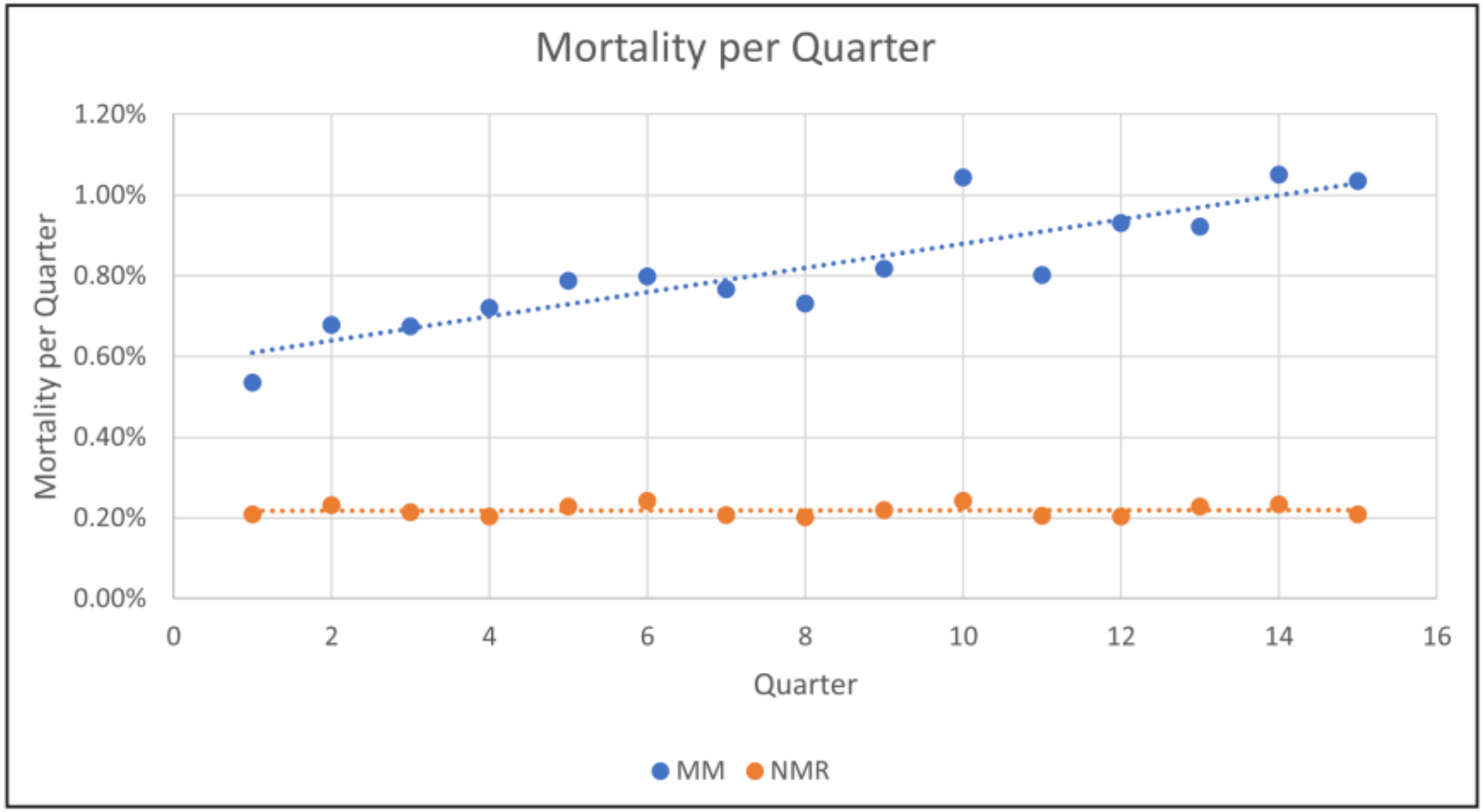
MITRAL VALVE REGURGITATION
" IF LEFT UNTREATED"

Heart failure (systolic and diastolic)

Poor quality of life

Increase mortality

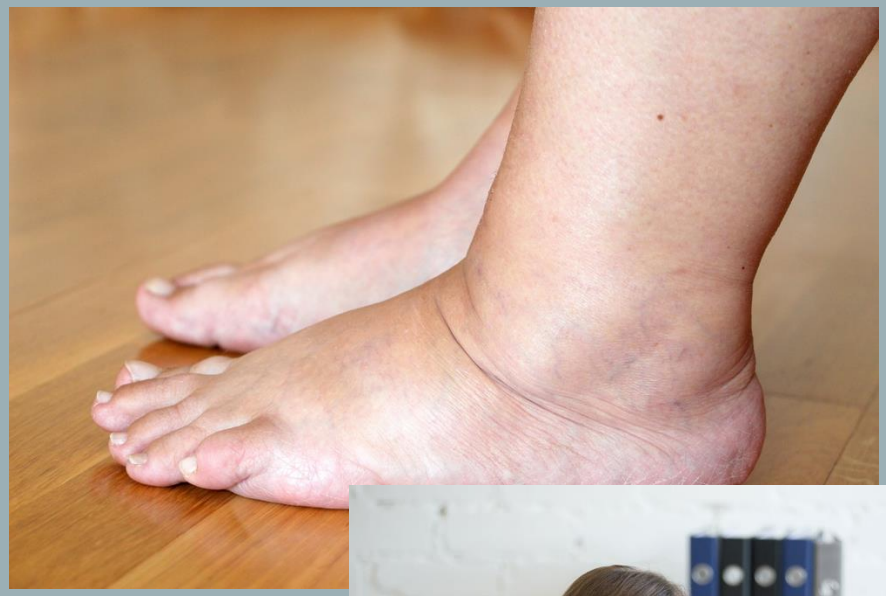
MITRAL VALVE REGURGITATION HIGH MORTALITY RATE



AHA Volume 13, Issue 2, 16 January 2024

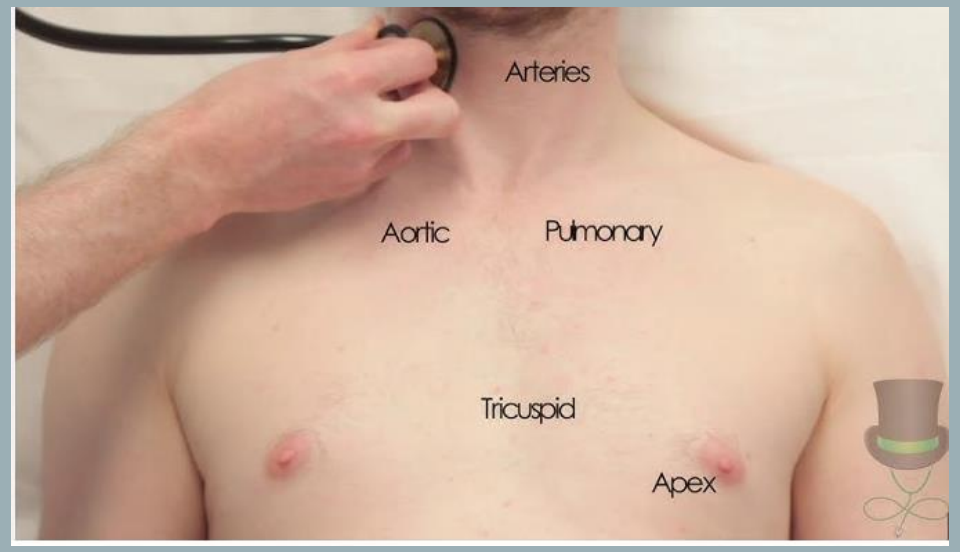
EARLY DIAGNOSIS IS KEY

MITRAL VALVE REGURGITATION SYMPTOMS



MITRAL VALVE REGURGITATION PHYSICAL EXAM

Holosystolic murmur in the apex.. blowing high pitched murmur in the apex

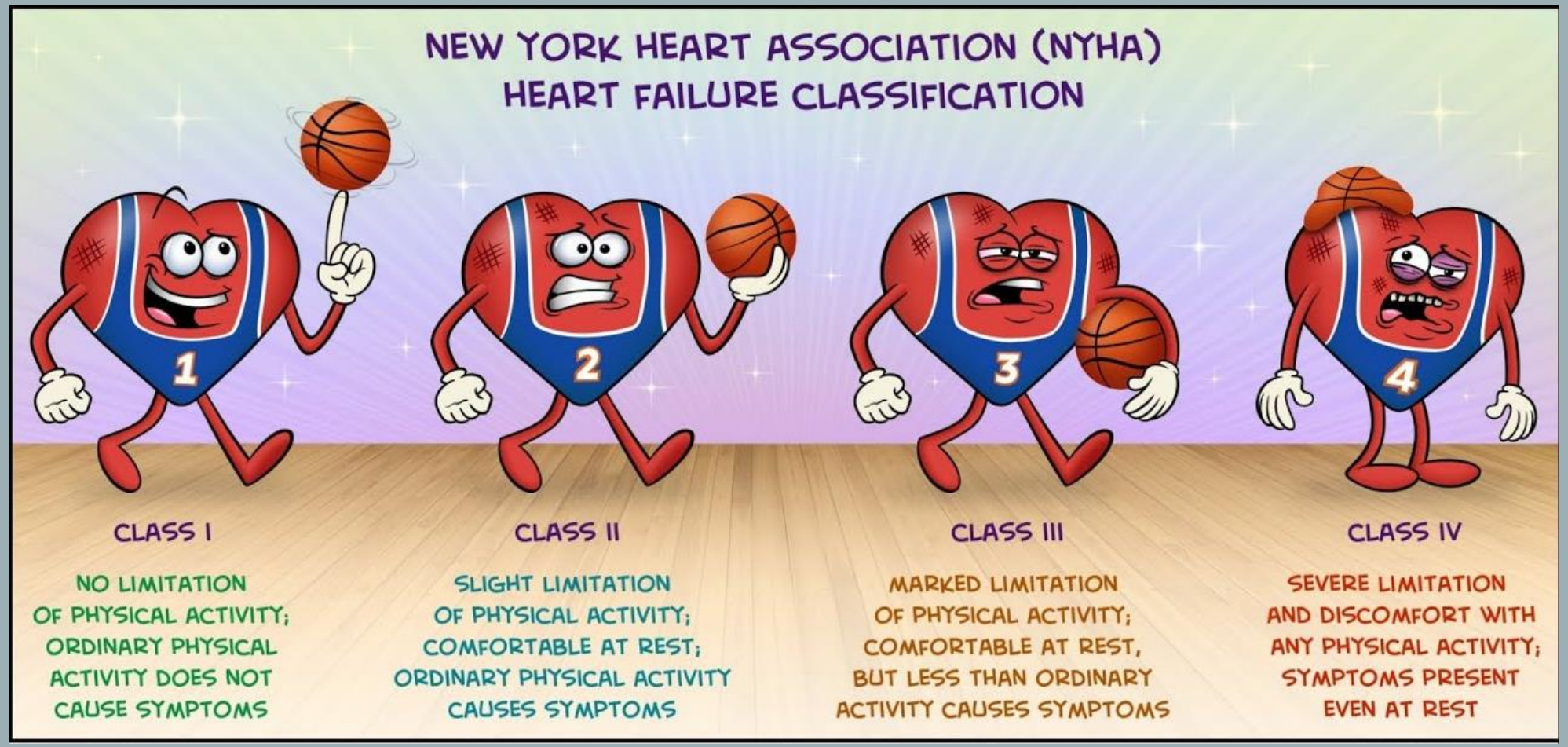


EARLY REFERRAL TO THE HEART TEAM IS CRUCIAL

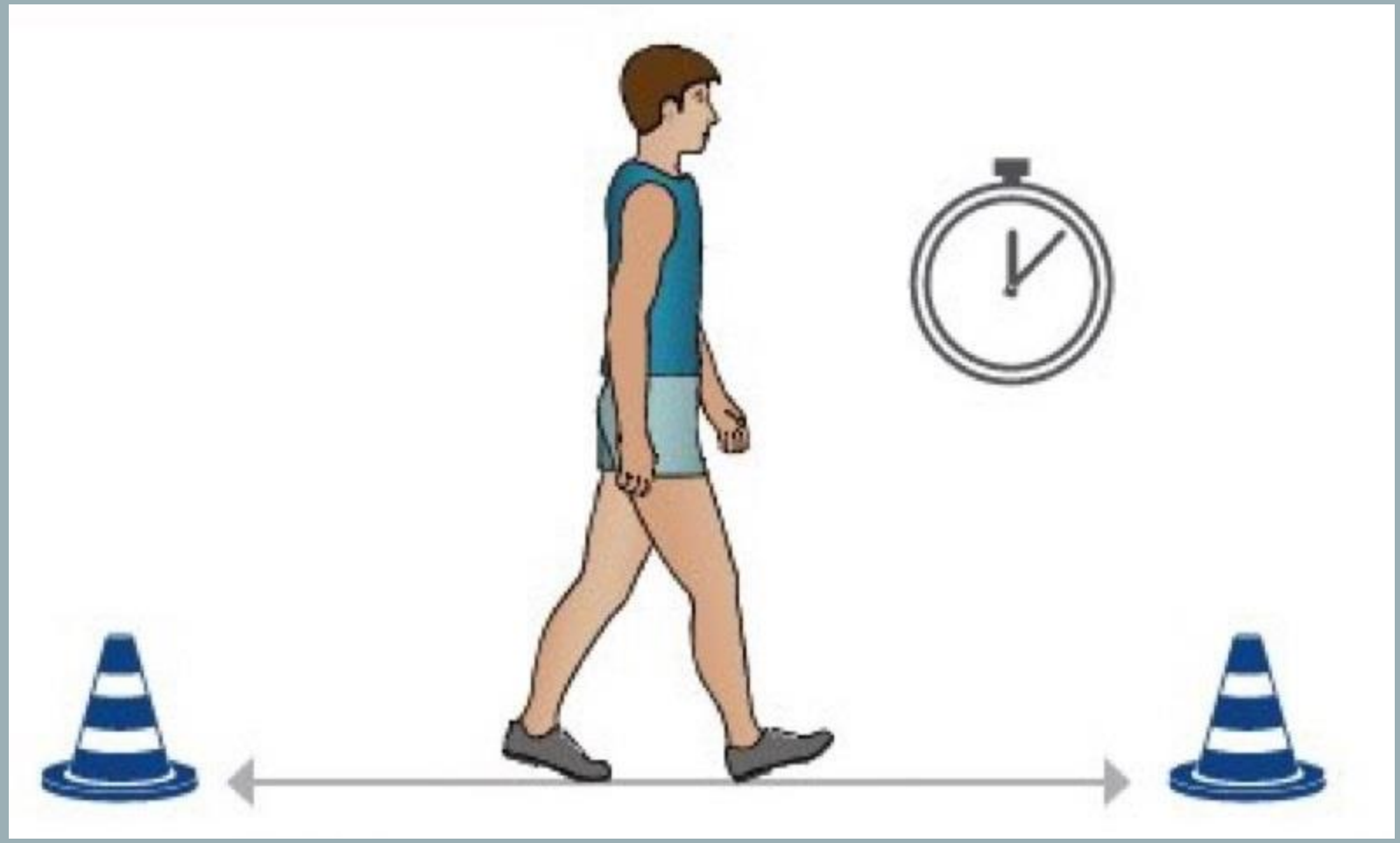
MITRAL VALVE REGURGITATION
" HEART TEAM APPROACH"

- Interventional cardiologist with structural heart experience
- Cardiothoracic surgeon
- Heart failure cardiologist
- Imaging cardiologist
- Structural heart coordinator
- Supporting staff

MITRAL VALVE REGURGITATION "INITIAL ASSESSMENT"



MITRAL VALVE REGURGITATION "INITIAL ASSESSMENT"



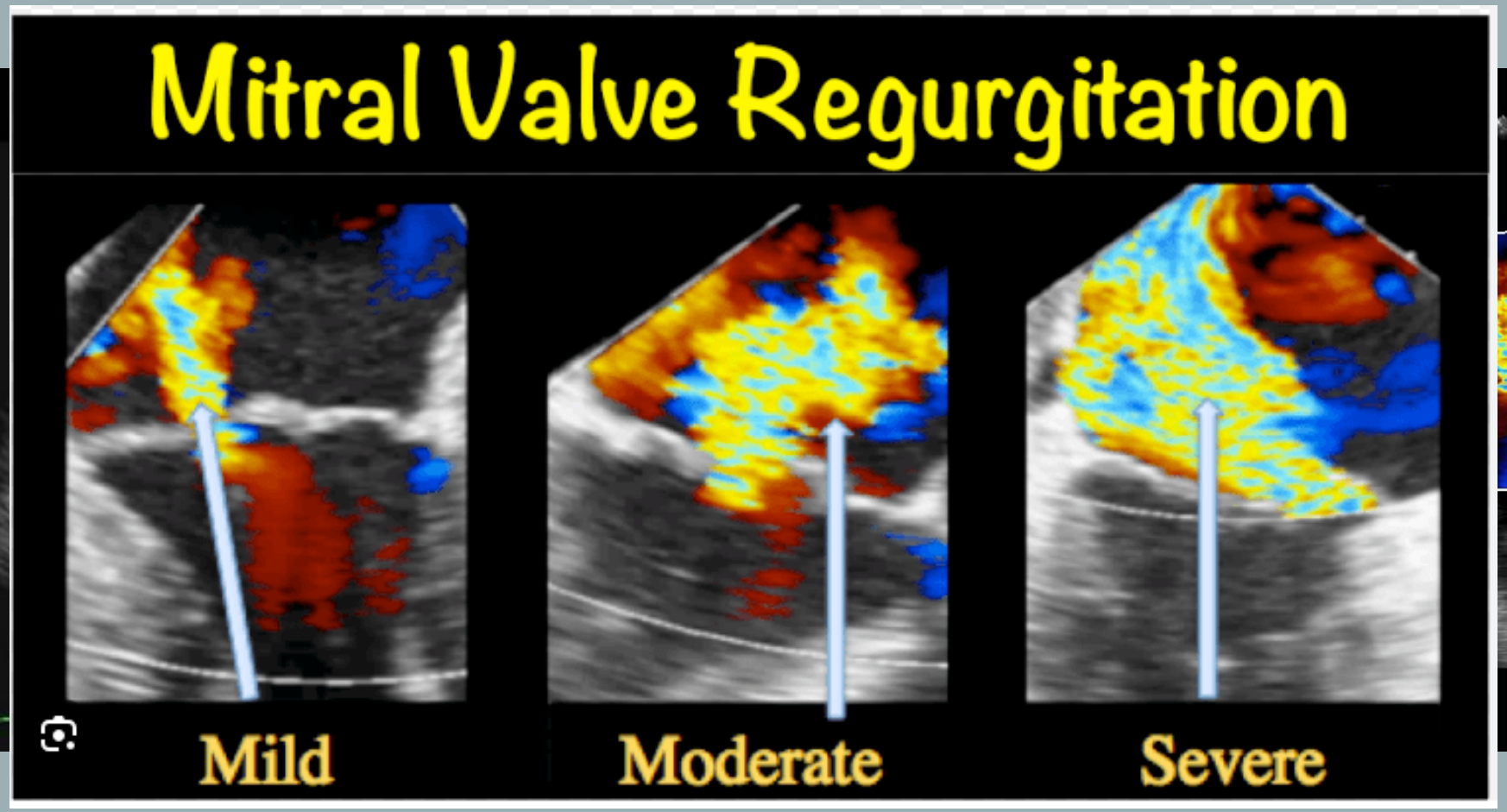
MITRAL VALVE REGURGITATION "INITIAL ASSESSMENT"

- History of hospitalization for heart failure
- Type of heart failure (systolic vs. diastolic)
- Treatment of heart failure

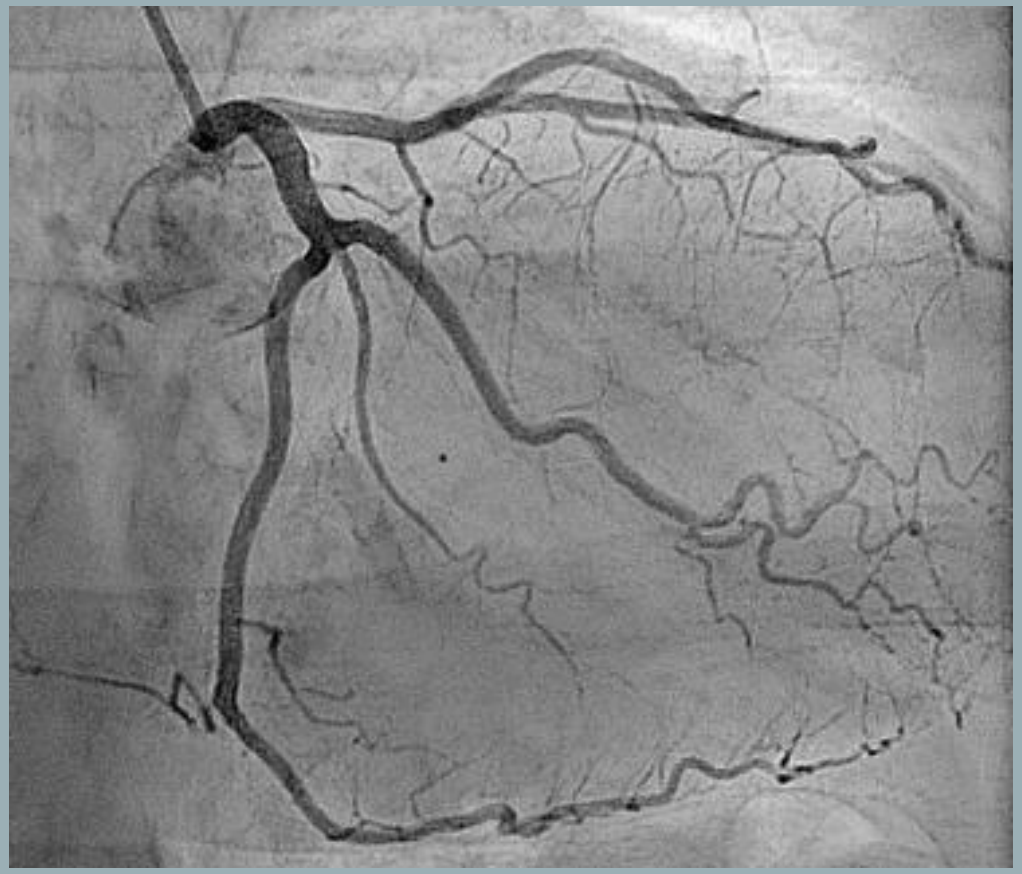
MITRAL VALVE REGURGITATION "INITIAL ASSESSMENT"

- Kidney function
- Liver function
- Quality of life
- Dementia

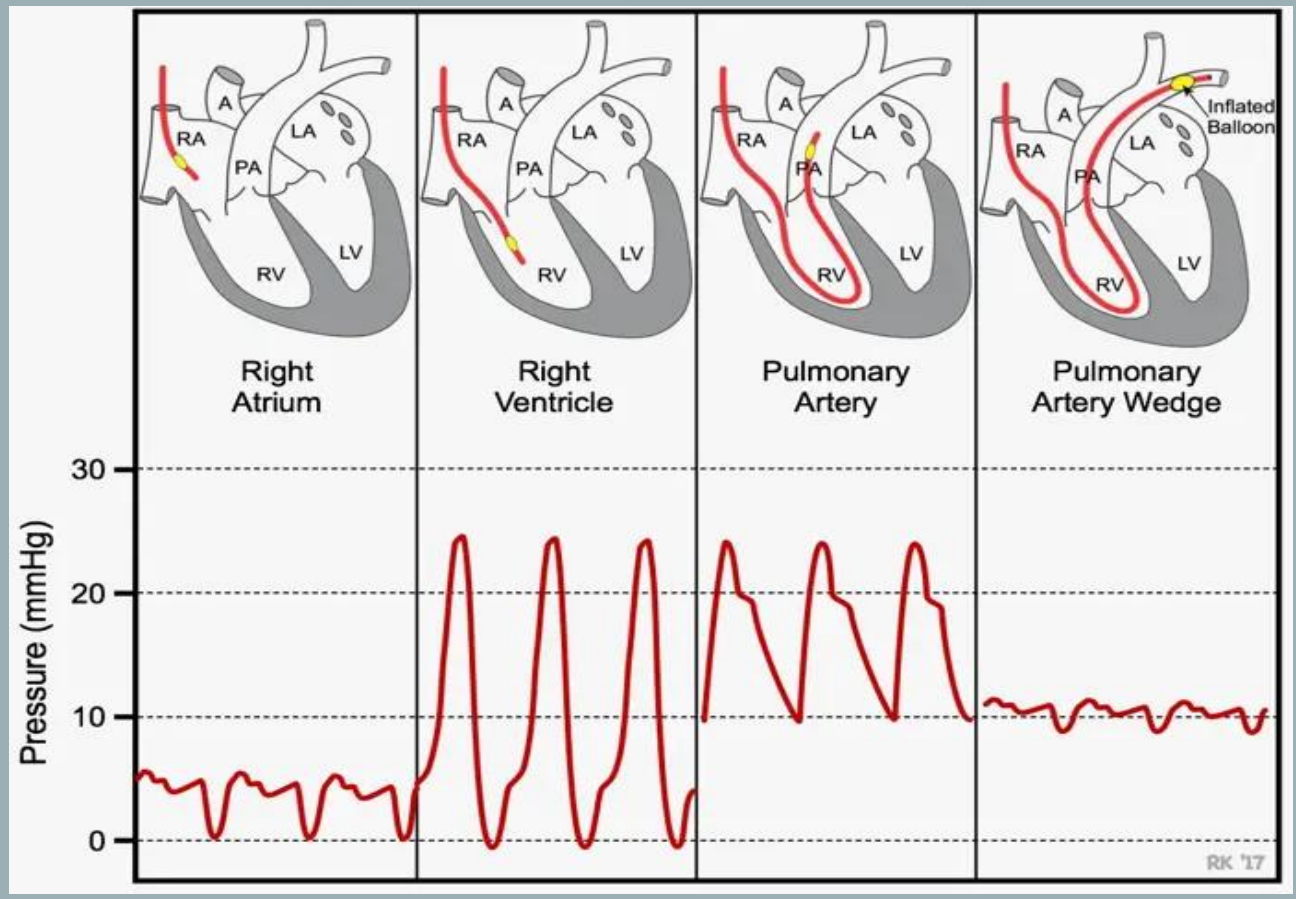
MITRAL VALVE REGURGITATION
"INITIAL ASSESSMENT"



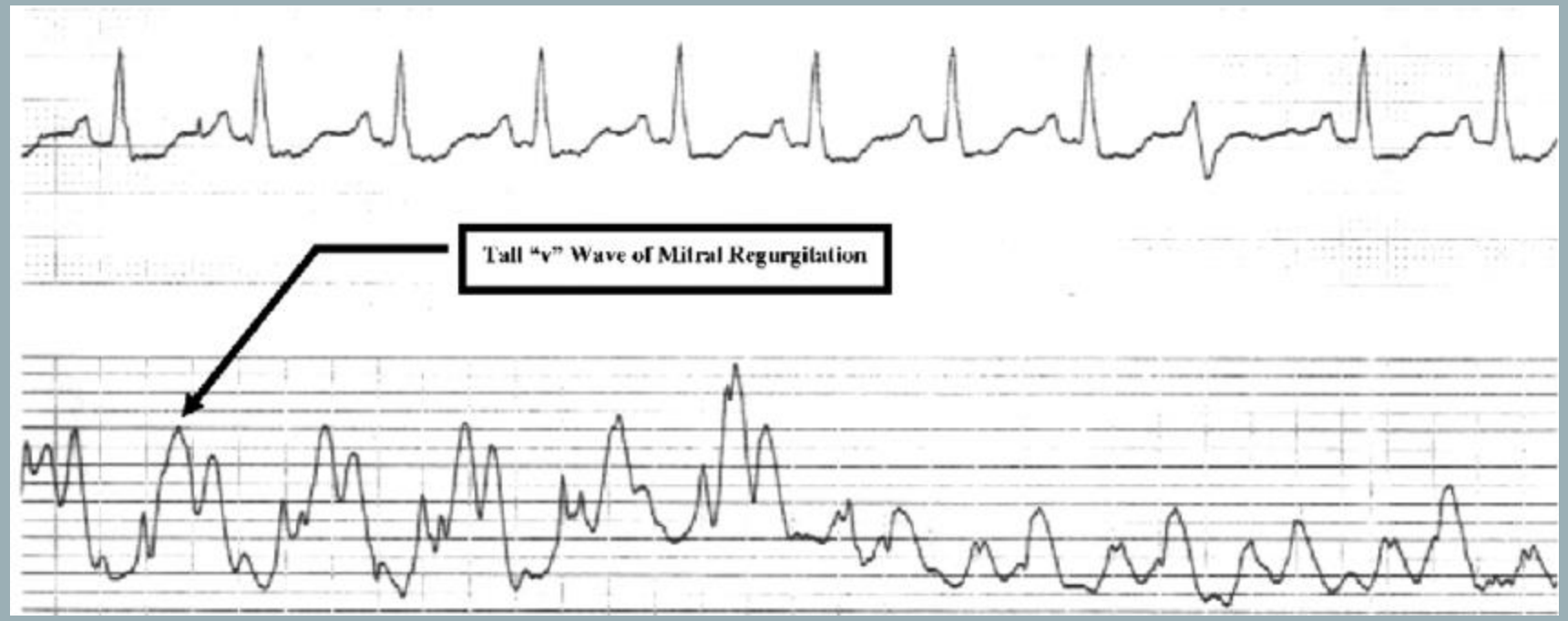
MITRAL VALVE REGURGITATION "INITIAL ASSESSMENT"



MITRAL VALVE REGURGITATION "INITIAL ASSESSMENT"



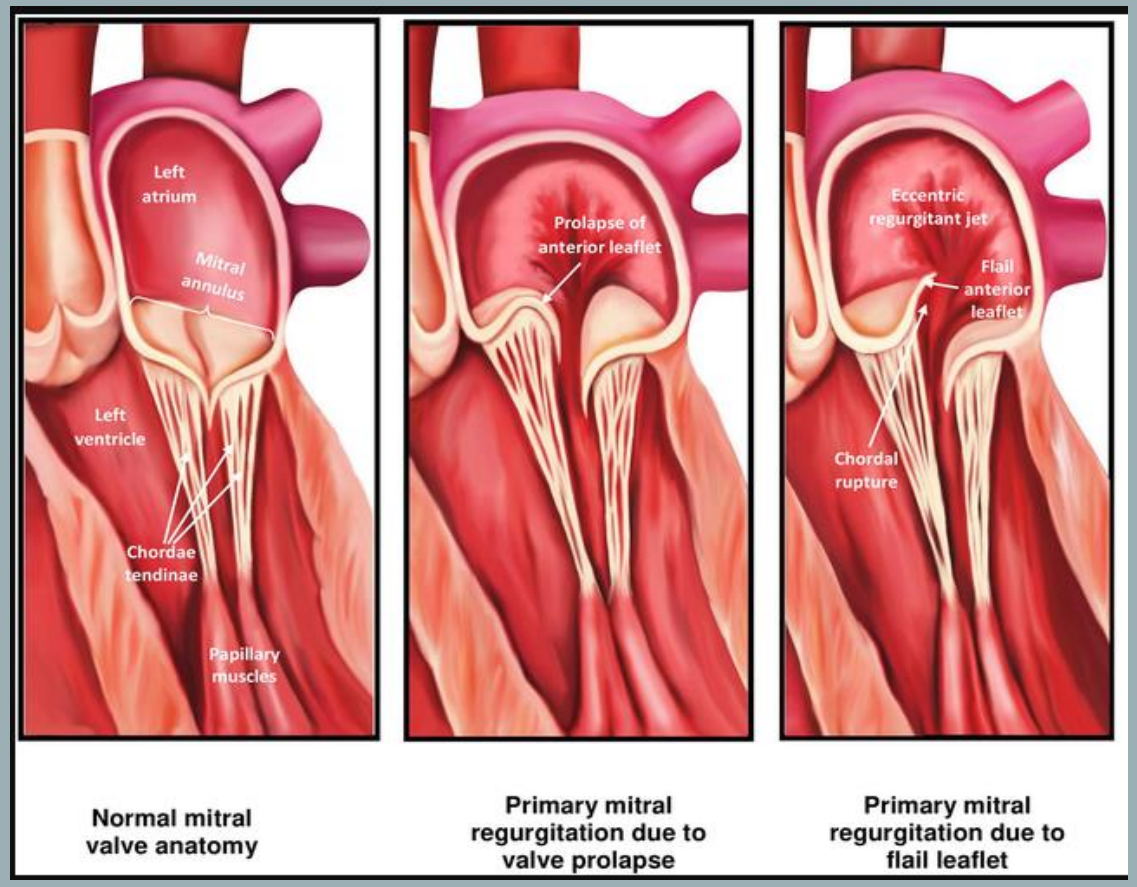
MITRAL VALVE REGURGITATION "INITIAL ASSESSMENT"




CAUSES
Adobe Stock | #264573470

MITRAL VALVE REGURGITATION TYPES " **DEGENERATIVE**"

- Leaflets "prolapse or flail" or perforation in endocarditis
- Chordae and papillary muscle "myocardial infarction"
- Rheumatic , post inflammatory , post-radiation

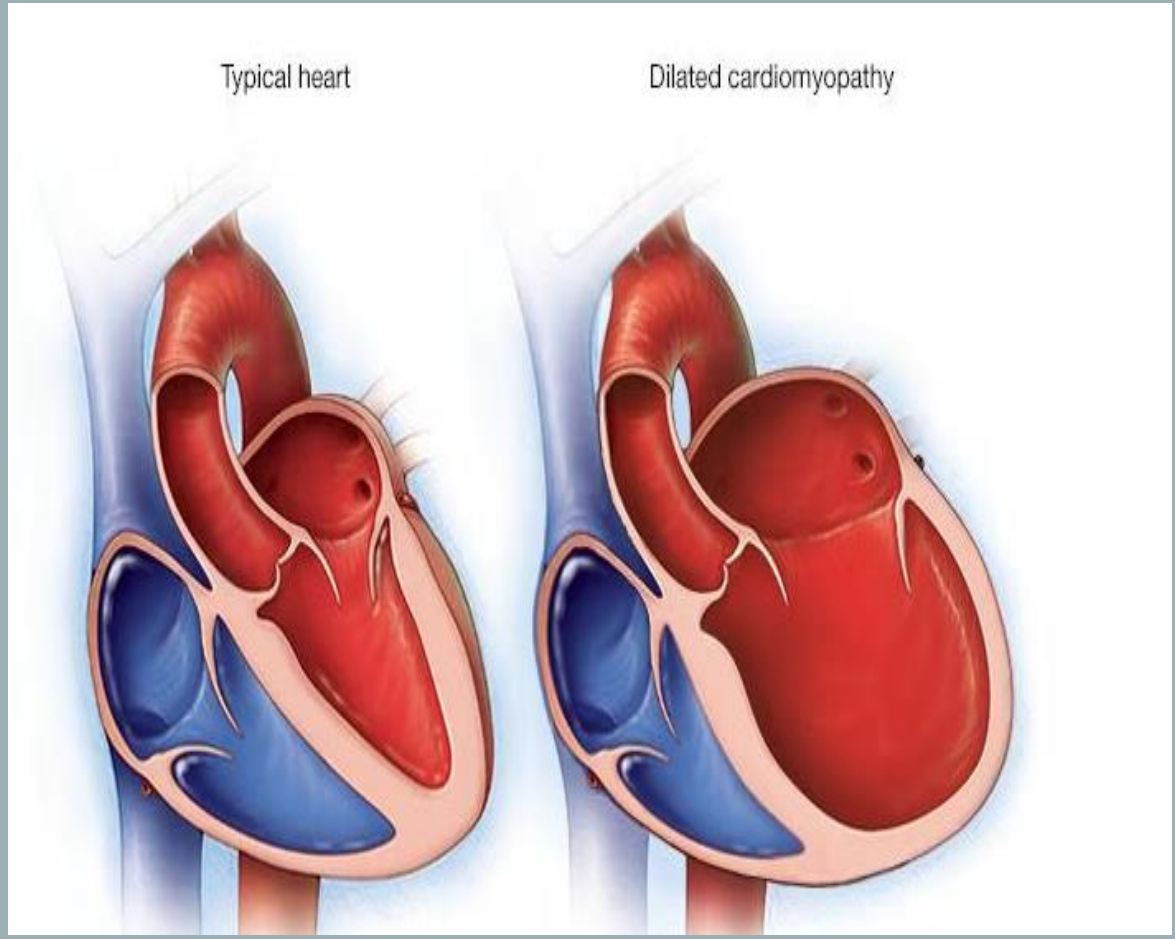


MITRAL VALVE REGURGITATION TYPES " **FUNCTIONAL**"

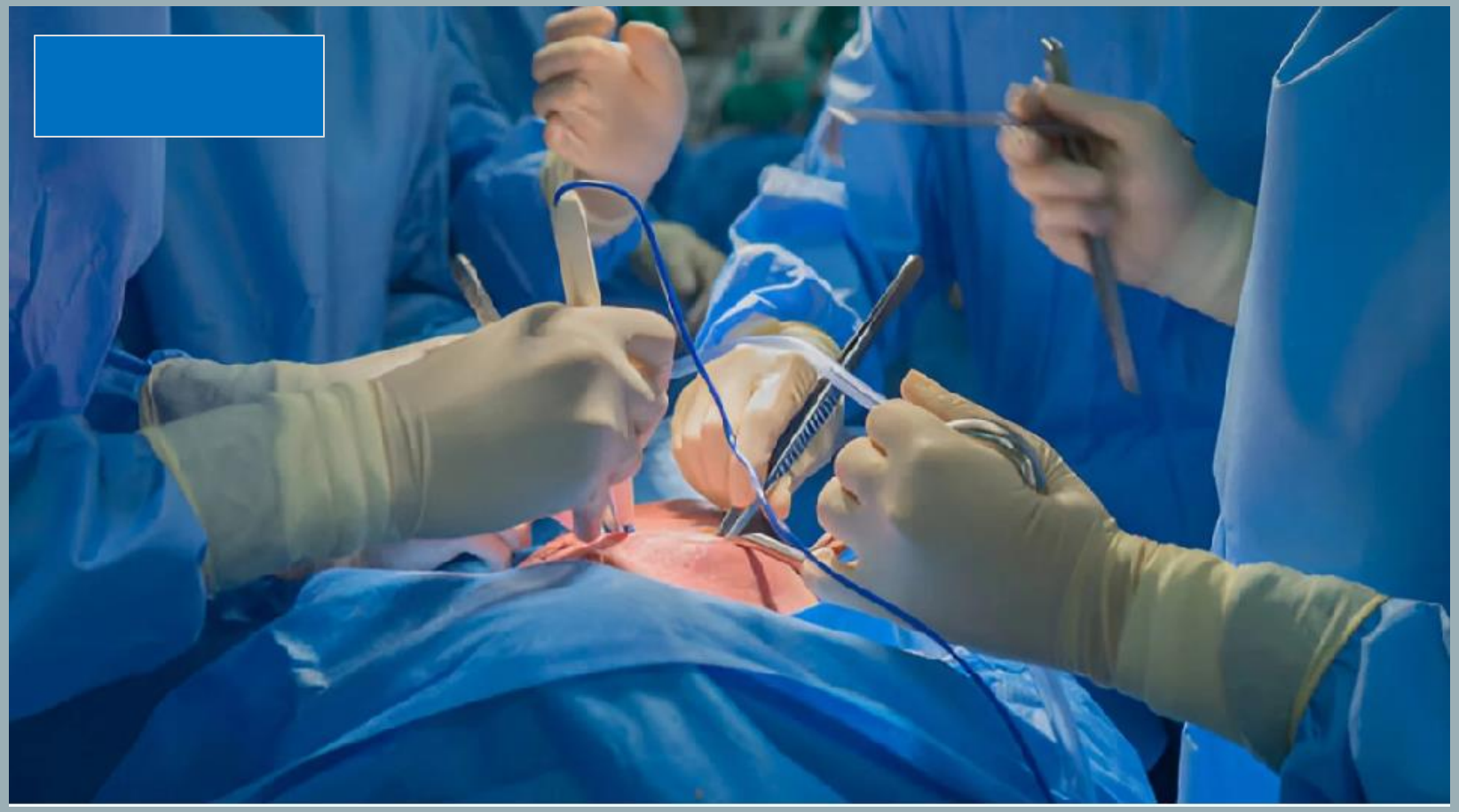
- Left atrium enlargement

  (atrial fibrillation)

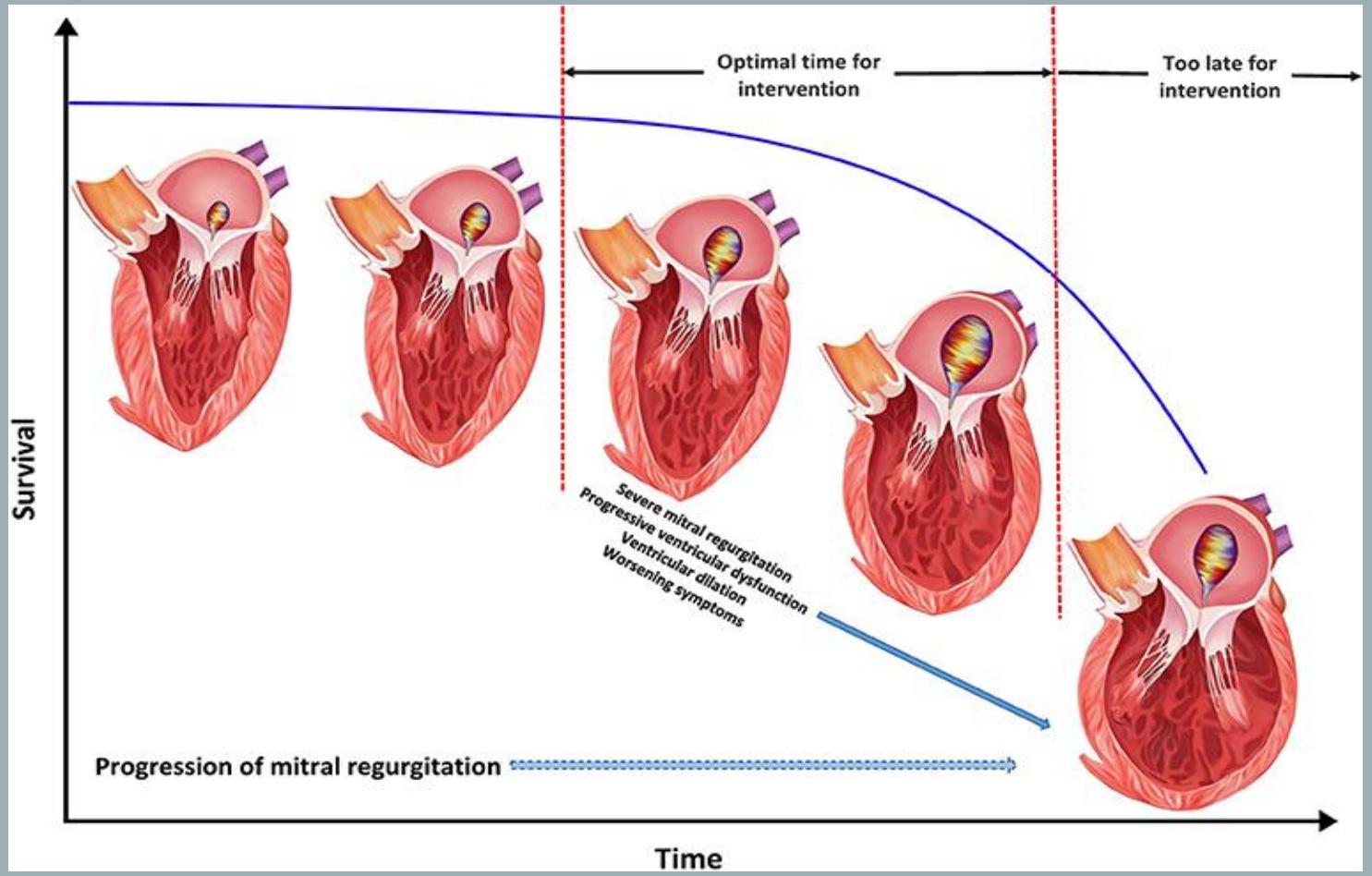
- Left ventricular enlargement (heart failure)



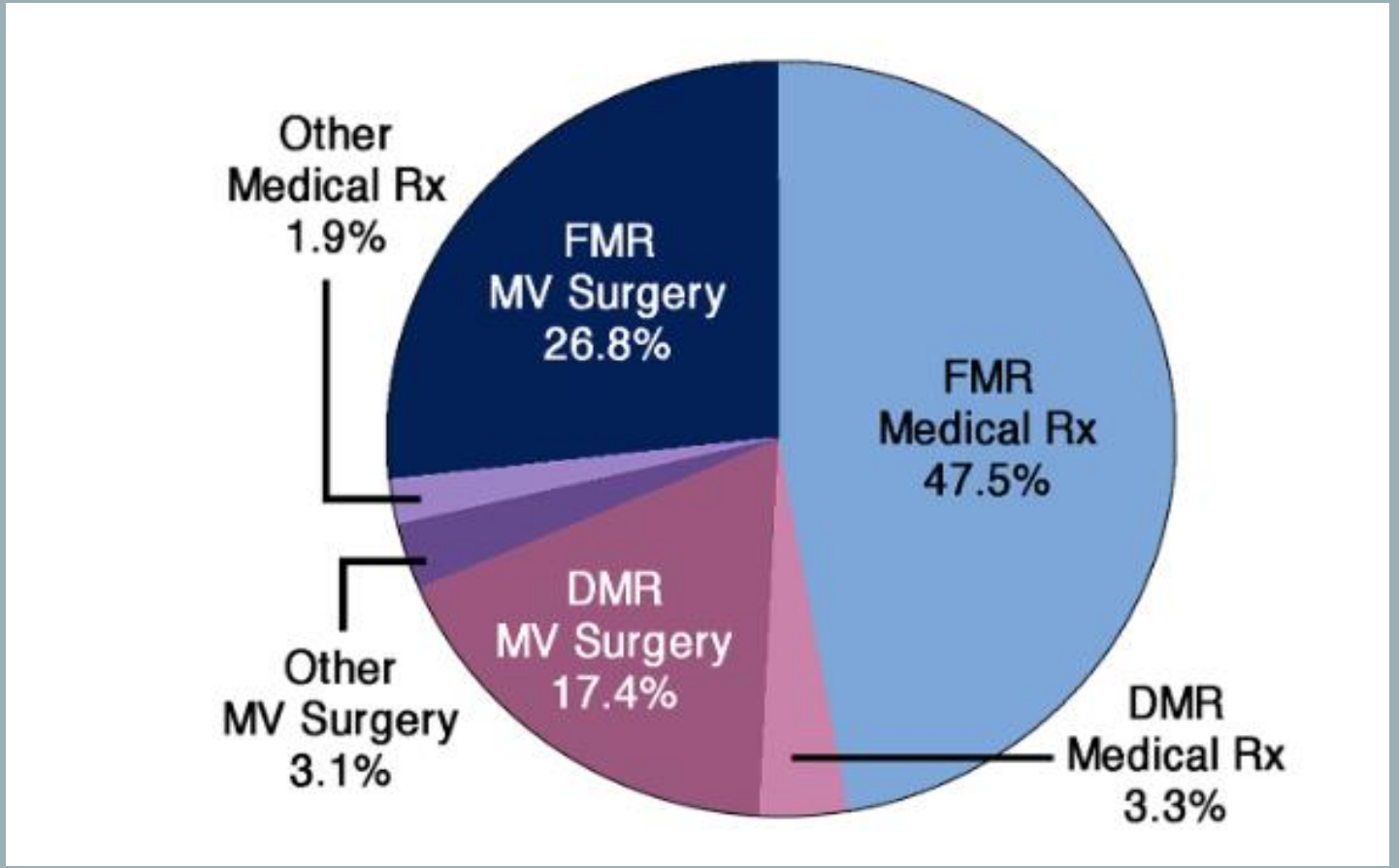
MIRAL VALVE REGURGITATION
“ TREATMENT”



MITRAL VALVE REGURGITATION TIMING FOR INTERVENTION

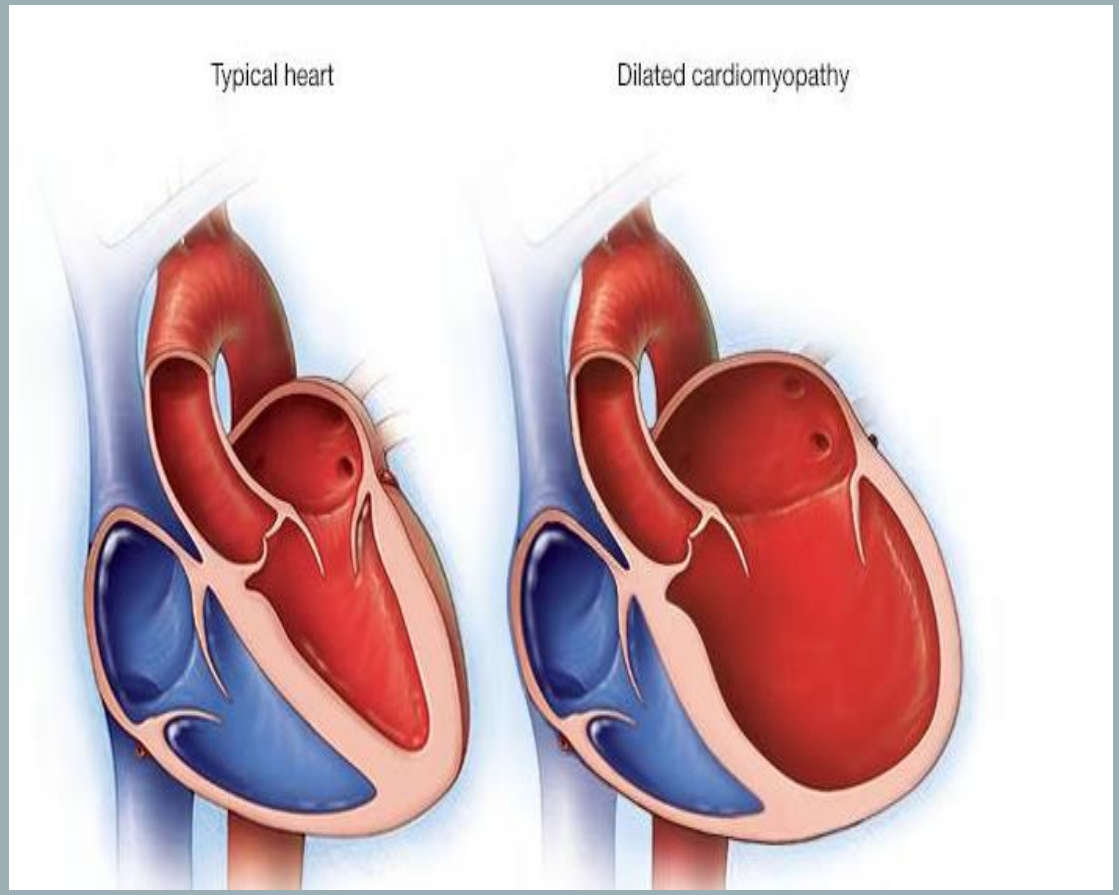


MITRAL VALVE REGURGITATION PATIENT POPULATION



JACC Vol. 63, No. 2, 2014

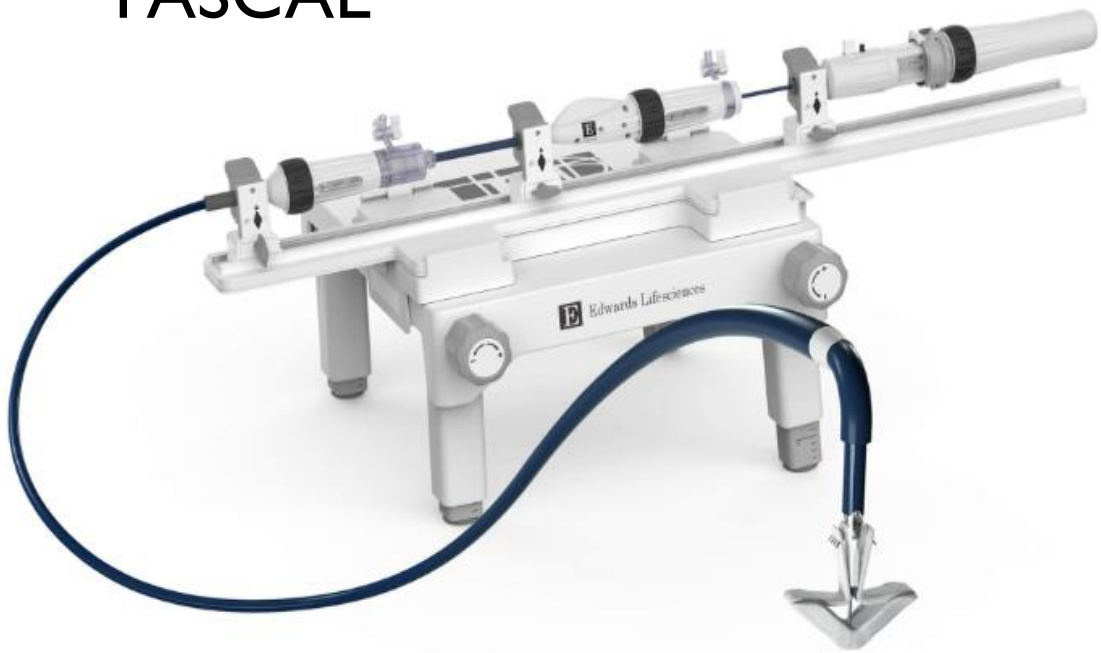
MANAGEMENT OF MITRAL VALVE REGURGITATION
" **SECONDARY MR**"



MITRAL TRANSCATHETER EDGE TO EDGE REPAIR (TEER)

Abbott

PASCAL



COAPT TRIAL

- Total 614 patients randomized
- Moderate to severe mitral valve regurgitation
- 1:1 randomization to device group with medical management and to medical management only
- Primary effectiveness endpoint: All hospitalizations (HF) at 24 months
- Primary safety endpoint: Free from device related complications at 12 months

NEJM 2018 ;379:2307-18

COAPT TRIAL

Characteristic	Device Group (N=302)	Control Group (N=312)
Clinical		
Age — yr	71.7±11.8	72.8±10.5
Male sex — no. (%)	201 (66.6)	192 (61.5)
Diabetes — no. (%)	106 (35.1)	123 (39.4)
Hypertension — no. (%)	243 (80.5)	251 (80.4)
Hypercholesterolemia — no. (%)	166 (55.0)	163 (52.2)
Previous myocardial infarction — no. (%)	156 (51.7)	160 (51.3)
Previous percutaneous coronary intervention — no. (%)	130 (43.0)	153 (49.0)
Previous coronary-artery bypass grafting — no. (%)	121 (40.1)	126 (40.4)
Previous stroke or transient ischemic attack — no. (%)	56 (18.5)	49 (15.7)
Peripheral vascular disease — no. (%)	52 (17.2)	57 (18.3)
Chronic obstructive pulmonary disease — no. (%)	71 (23.5)	72 (23.1)
History of atrial fibrillation or flutter — no. (%)	173 (57.3)	166 (53.2)
Body-mass index†	27.0±5.8	27.1±5.9
Creatinine clearance		
Mean — ml/min‡	50.9±28.5	47.8±25.0
≤60 ml/min — no./total no. (%)	214/299 (71.6)	227/302 (75.2)
Anemia — no./total no. (%)§	180/301 (59.8)	192/306 (62.7)
STS risk score¶		
Mean — %	7.8±5.5	8.5±6.2
≥8% — no. (%)	126 (41.7)	136 (43.6)
Risk of surgery-related complications or death — no./total no (%)‖		
High	205/299 (68.6)	218/312 (69.9)
Not high	94/299 (31.4)	94/312 (30.1)
Related to heart failure		
Cause of cardiomyopathy — no. (%)		
Ischemic	184 (60.9)	189 (60.6)
Nonischemic	118 (39.1)	123 (39.4)

NEJM 2018 ;379:2307-18

COAPT TRIAL

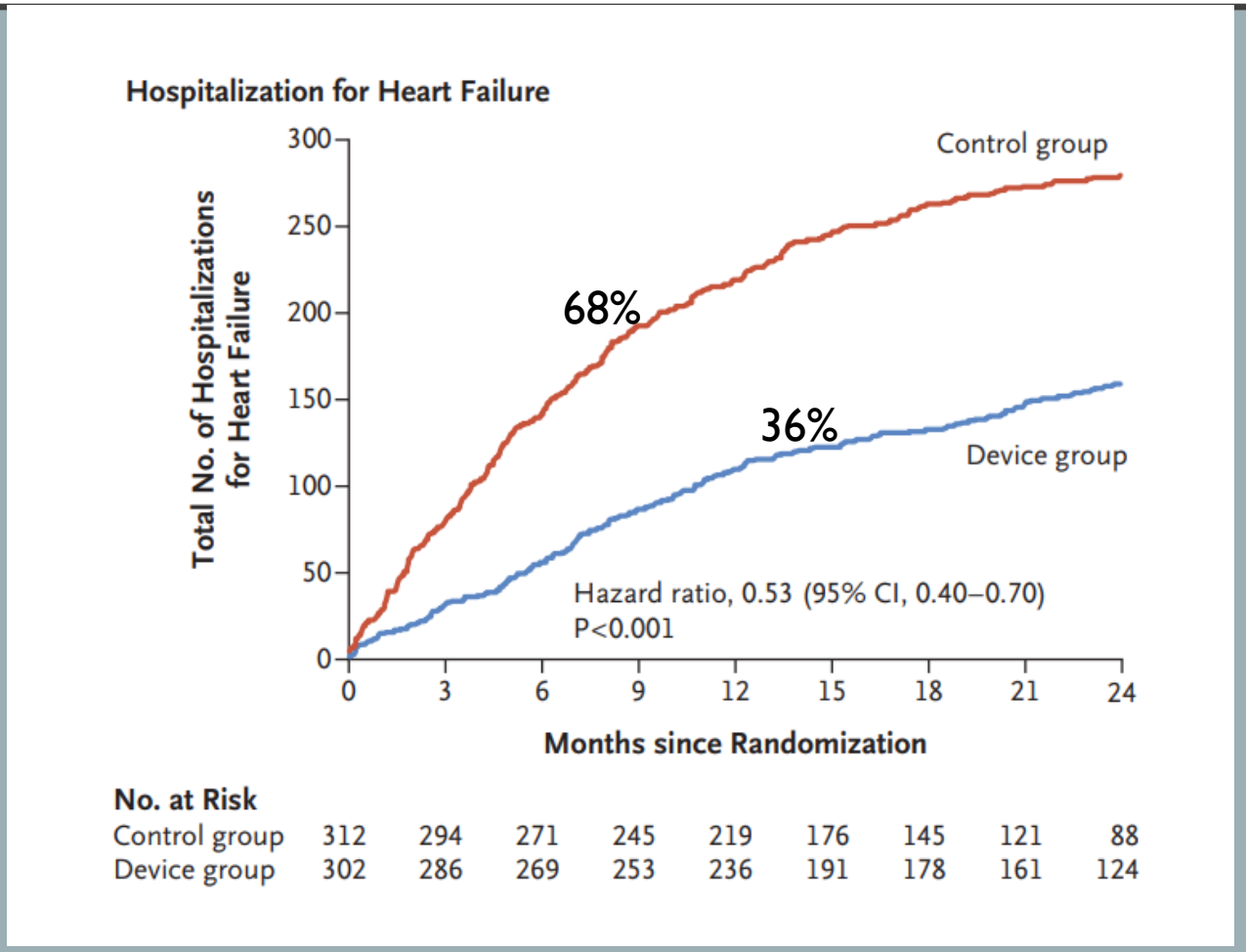
NYHA class — no./total no. (%)		
I	1/302 (0.3)	0/311 (0)
II	129/302 (42.7)	110/311 (35.4)
III	154/302 (51.0)	168/311 (54.0)
IVa, ambulatory	18/302 (6.0)	33/311 (10.6)
Hospitalization for heart failure within previous 1 yr — no. (%)	176 (58.3)	175 (56.1)
Previous cardiac resynchronization therapy — no. (%)	115 (38.1)	109 (34.9)
Previous implantation of defibrillator — no. (%)	91 (30.1)	101 (32.4)
B-type natriuretic peptide level — pg/ml	1014.8±1086.0	1017.1±1212.8
N-terminal pro–B-type natriuretic peptide level — pg/ml	5174.3±6566.6	5943.9±8437.6
Assessed at the echocardiographic core laboratory		
Severity of mitral regurgitation — no./total no. (%)		
Moderate-to-severe, grade 3+	148/302 (49.0)	172/311 (55.3)
Severe, grade 4+	154/302 (51.0)	139/311 (44.7)
Effective regurgitant orifice area — cm^2	0.41±0.15	0.40±0.15
Left ventricular end-systolic dimension — cm	5.3±0.9	5.3±0.9

COAPT TRIAL

Characteristic	Device Group (N=302)	Control Group (N=312)
Left ventricular end-diastolic dimension — cm	6.2±0.7	6.2±0.8
Left ventricular end-systolic volume — ml	135.5±56.1	134.3±60.3
Left ventricular end-diastolic volume — ml	194.4±69.2	191.0±72.9
Left ventricular ejection fraction		
Mean — %	31.3±9.1	31.3±9.6
≤40% — no./total no. (%)	231/281 (82.2)	241/294 (82.0)
Right ventricular systolic pressure — mm Hg	44.0±13.4 (253)	44.6±14.0 (275)

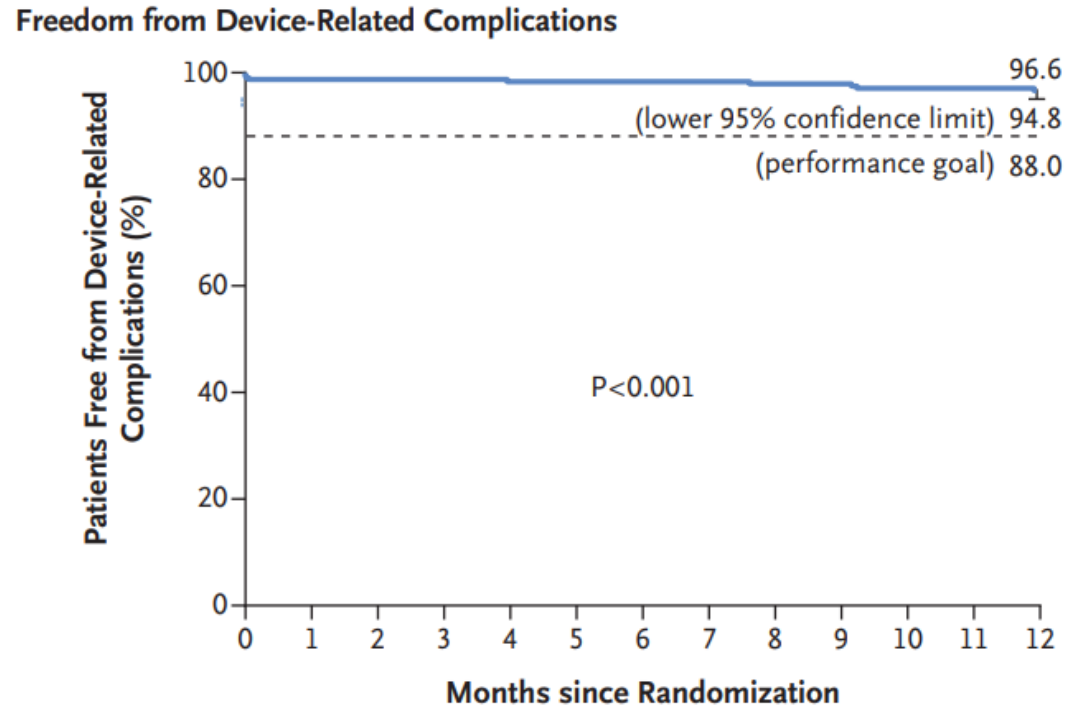
NEJM 2018 ;379:2307-18

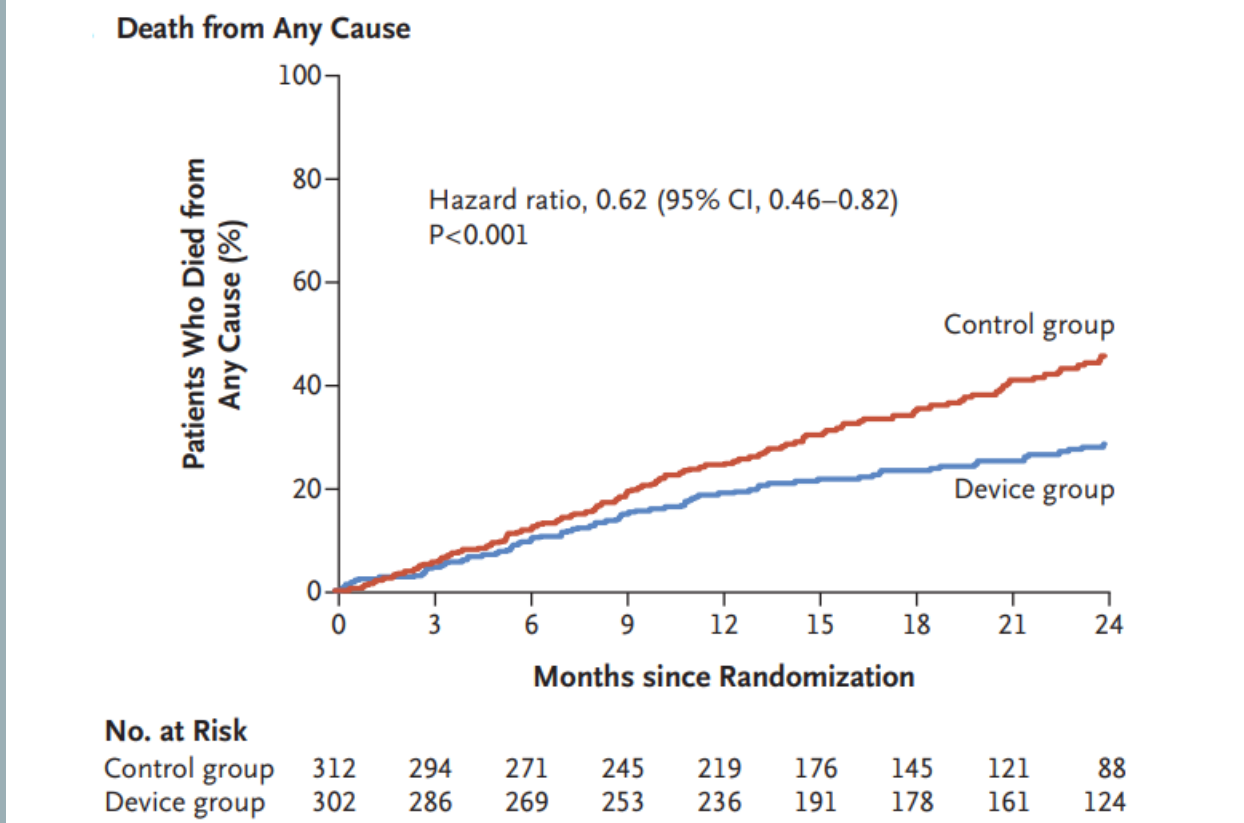
COAPT TRIAL



NEJM 2018 ;379:2307-18

COAPT TRIAL


Freedom from Device-Related Complications
Patients Free from Device-Related Complications (%)
100
80
60
40
20
0
96.6
(lower 95% confidence limit) 94.8
(performance goal) 88.0
P<0.001
0 1 2 3 4 5 6 7 8 9 10 11 12
Months since Randomization
No. at Risk
Device group 293 283 282 277 272 269 261 258 251 245 241 236 221


Death from Any Cause
Patients Who Died from Any Cause (%)
100
80
60
40
20
0
Hazard ratio, 0.62 (95% CI, 0.46–0.82)
P<0.001
Control group
Device group
0 3 6 9 12 15 18 21 24
Months since Randomization
No. at Risk
Control group 312 294 271 245 219 176 145 121 88
Device group 302 286 269 253 236 191 178 161 124

COAPT TRIAL

Conclusion

Patients with heart failure and moderate to severe or severe mitral valve regurgitation who remained symptomatic despite optimal medical management, mitral TEER resulted in a lower rate of hospitalization for heart failure and lower all cause mortality within 24 months than medical therapy alone

NEJM 2018 ;379:2307-18

MITRA FM TRIAL

- Total of 307 patients were randomized
- Severe secondary mitral valve regurgitation and symptomatic systolic heart failure with LVEF 15-40%
- 1:1 randomization to medical therapy vs. mitral TEER
- Primary endpoint : All cause mortality of unplanned hospitalization at 12 months

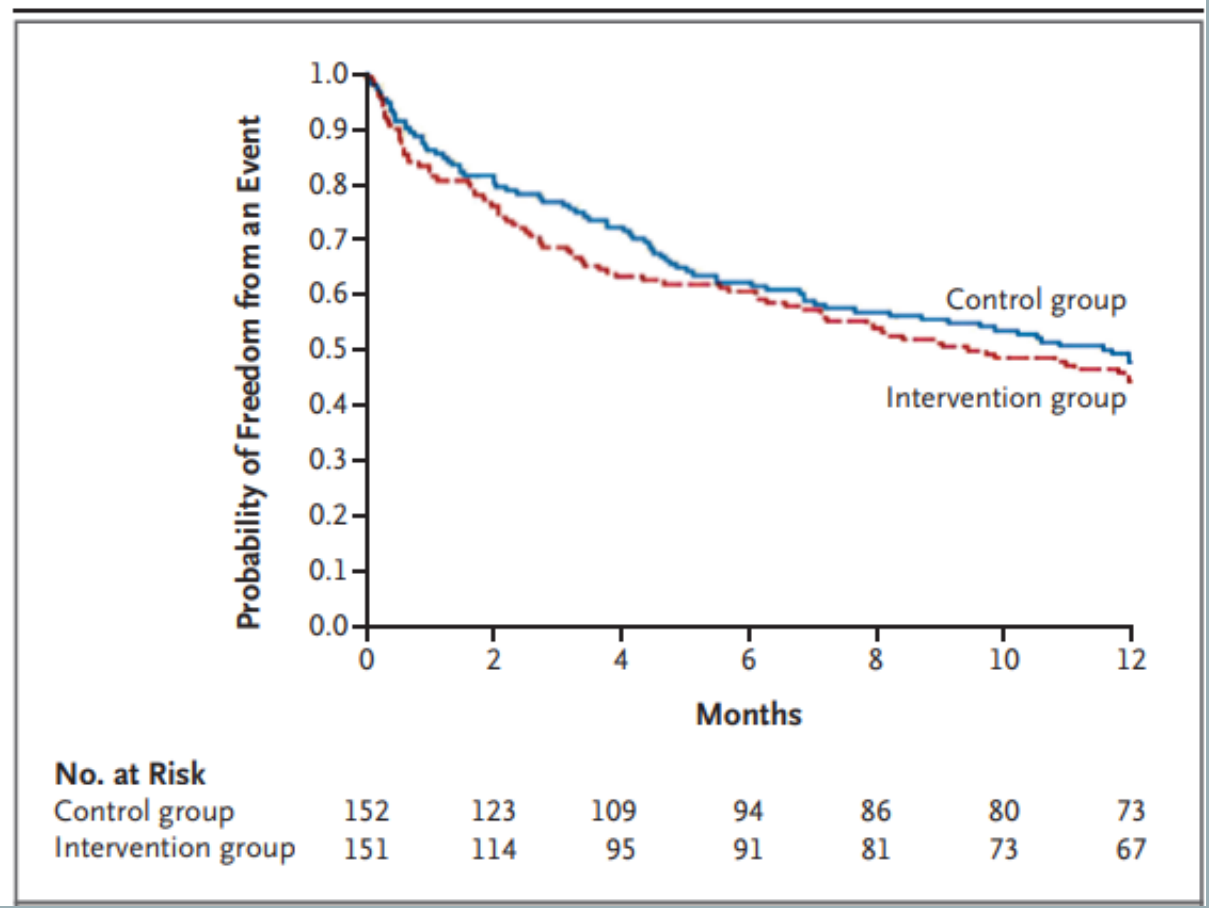
NEJM 2018; 379:2297-306

MITRA FM TRIAL

Characteristic	Intervention Group (N=152)	Control Group (N=152)
Age — yr	70.1±10.1	70.6±9.9
Age >75 yr — no. (%)	51 (33.6)	59 (38.8)
Male sex — no. (%)	120 (78.9)	107 (70.4)
Medical and surgical history – no./total no. (%)		
Ischemic cardiomyopathy	95/152 (62.5)	85/151 (56.3)
Nonischemic cardiomyopathy	57/152 (37.5)	66/151 (43.7)
Previous myocardial infarction	75/152 (49.3)	52/152 (34.2)
Previous coronary revascularization	71/152 (46.7)	64/151 (42.4)
Atrial fibrillation	49/142 (34.5)	48/147 (32.7)
Diabetes	50/152 (32.9)	39/152 (25.7)
Renal insufficiency	22/152 (14.5)	19/152 (12.5)
NYHA class — no. (%)		
II	56 (36.8)	44 (28.9)
III	82 (53.9)	96 (63.2)
IV	14 (9.2)	12 (7.9)
Systolic blood pressure — mm Hg	109±16	108±18
Heart rate — beats/min	73±13	72±13
Median EuroSCORE II (IQR)†	6.6 (3.5–11.9)	5.9 (3.4–10.4)
Left ventricular ejection fraction — %	33.3±6.5	32.9±6.7
Left ventricular end-diastolic volume — ml/m^2	136.2±37.4	134.5±33.1
Effective regurgitant orifice area — mm^2	31±10	31±11
Regurgitant volume — ml	45±13	45±14
Median NT-proBNP (IQR) — ng/liter‡	3407 (1948–6790)	3292 (1937–6343)
Median brain natriuretic peptide (IQR) — ng/liter‡	765 (417–1281)	835 (496–1258)
Glomerular filtration rate — ml/min	48.8±19.7	50.2±20.1

NEJM 2018; 379:2297-306

MITRA FM TRIAL



NEJM 2018; 379:2297-306

MITRA FM TRIAL

Conclusion

The rate of death or unplanned hospitalization for heart failure at one year did not differ significantly between patients who underwent mitral teer in addition to medical therapy and those who received medical therapy alone

NEJM 2018; 379:2297-306

MITRA FM TRIAL VS. COAPT TRIAL

- Patients' characteristics

- Quality of guideline directed medical therapy

COAPT criteria
Indication CoR IIa LoE B for M-TEER in SMR

YES

- Severe SMR
- Optimised HF treatments according to 2021 ESC guidelines
- NYHA Class II, III or ambulatory IV
- LVEF 20-50%
- LV end-systolic diameter ≤70 mm
- At least one HF hospitalisation within the previous year or increased NP levels[a]
- Anatomy judged suitable for M-TEER[b]

NO

- Haemodynamic instability[c]
- Stage D HF[d]
- Moderate or severe RV dysfunction
- Systolic pulmonary pressure >70 mmHg
- COPD requiring oxygen or steroid
- Coronary, aortic or tricuspid valve disease requiring surgery
- Hypertrophic, restrictive or infiltrative cardiomyopathy

SUITABILITY FOR MITRAL TEER

Repair!

Anatomical suitability for M-TEER

Centre experience

Replacement?

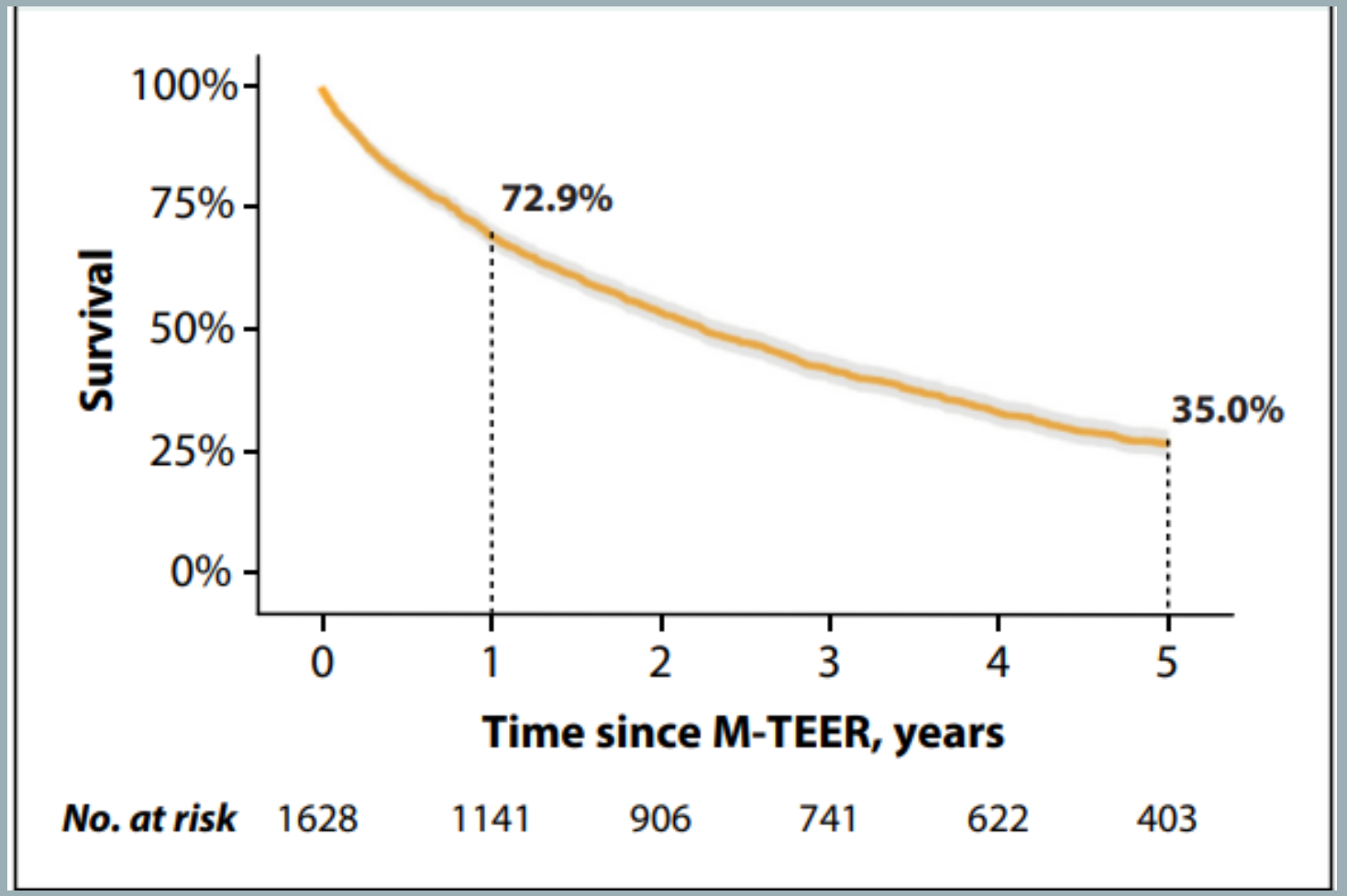
Non-complex Ideal for M-TEER	Complex Suitable for M-TEER	Very complex Challenging for M-TEER	Criteria favouring replacement M-TEER hard or impossible
- Central pathology - No calcification - MVA >4.0 cm^2 - Posterior leaflet >10 mm - Tenting height <10 mm - Flail gap <10 mm - Flail width <15 mm	- Isolated commissural lesion (A1/P1 or A3/P3) - Annular calcification without leaflet involvement - MVA 3.5-4.0 cm^2 - Posterior leaflet length 7-10 mm - Tenting height >10 mm - Asymmetric tethering[26] - Coaptation reserve <3 mm[24] - Leaflet-to-anulus index <1.2[25] - Flail width >15 mm - Flail gap >10 mm - Two jets from leaflet indentations	- Commissural lesion with multiple jets - Annular calcification with leaflet involvement - Fibrotic leaflets - Wide jet involving the whole coaptation - MVA 3.0-3.5 cm^2 - Posterior leaflet length 5-7 mm - Barlow's disease - Cleft - Failed surgical annuloplasty	- Concentric MAC with stenosis - MVA <3.0 cm^2 - Relevant mitral valve stenosis (mean gradient >5 mmHg) - Posterior leaflet <5 mm - Calcification in the grasping zone - Deep regurgitant cleft - Leaflet perforation - Multiple/wide jets - Rheumatic mitral stenosis

EUROSMR REGISTRY

- Evaluate long term efficacy and survival after M-TEER in a large real-world registry
- Total of 1628 patients with secondary MR treated with M-TEER
- MR reduction, functional outcomes, survival rate, all cause mortality

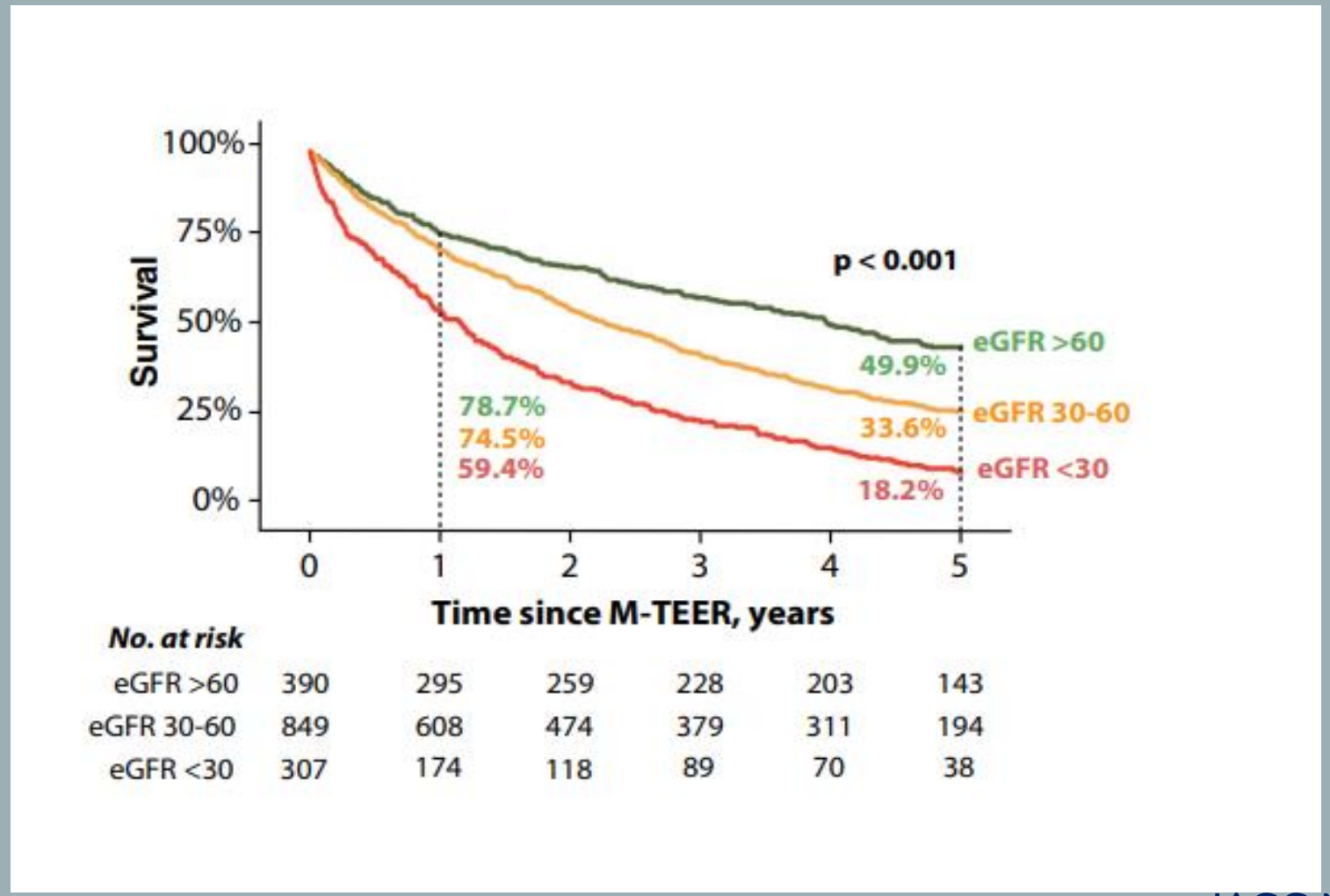
JACC November,2024:2543-2554

EUROSMR REGISTRY



JACC November,2024:2543-2554

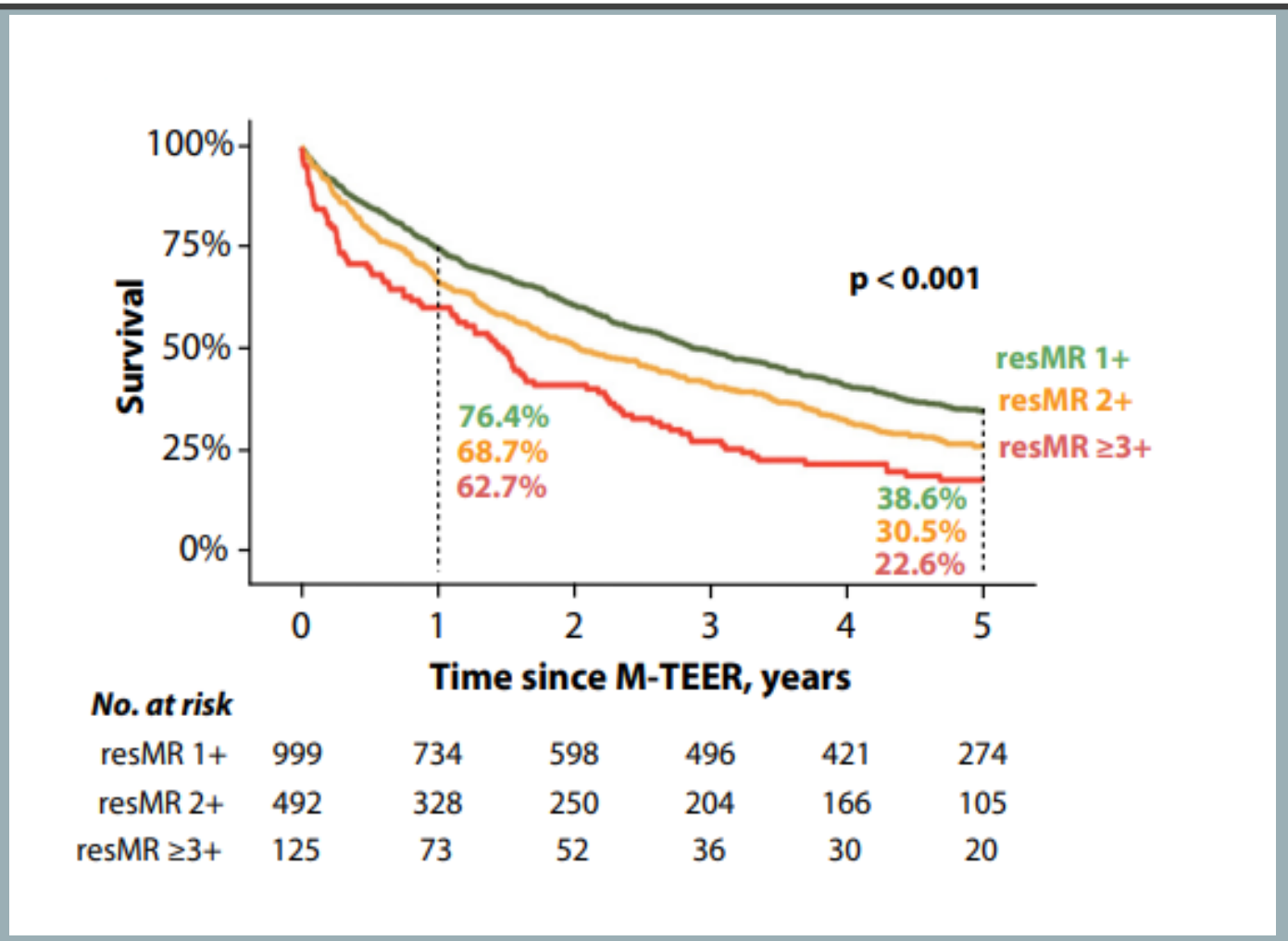
EUROSMR REGISTRY



No. at risk						
eGFR >60	390	295	259	228	203	143
eGFR 30-60	849	608	474	379	311	194
eGFR <30	307	174	118	89	70	38

JACC November,2024:2543-2554

EUROSMR REGISTRY

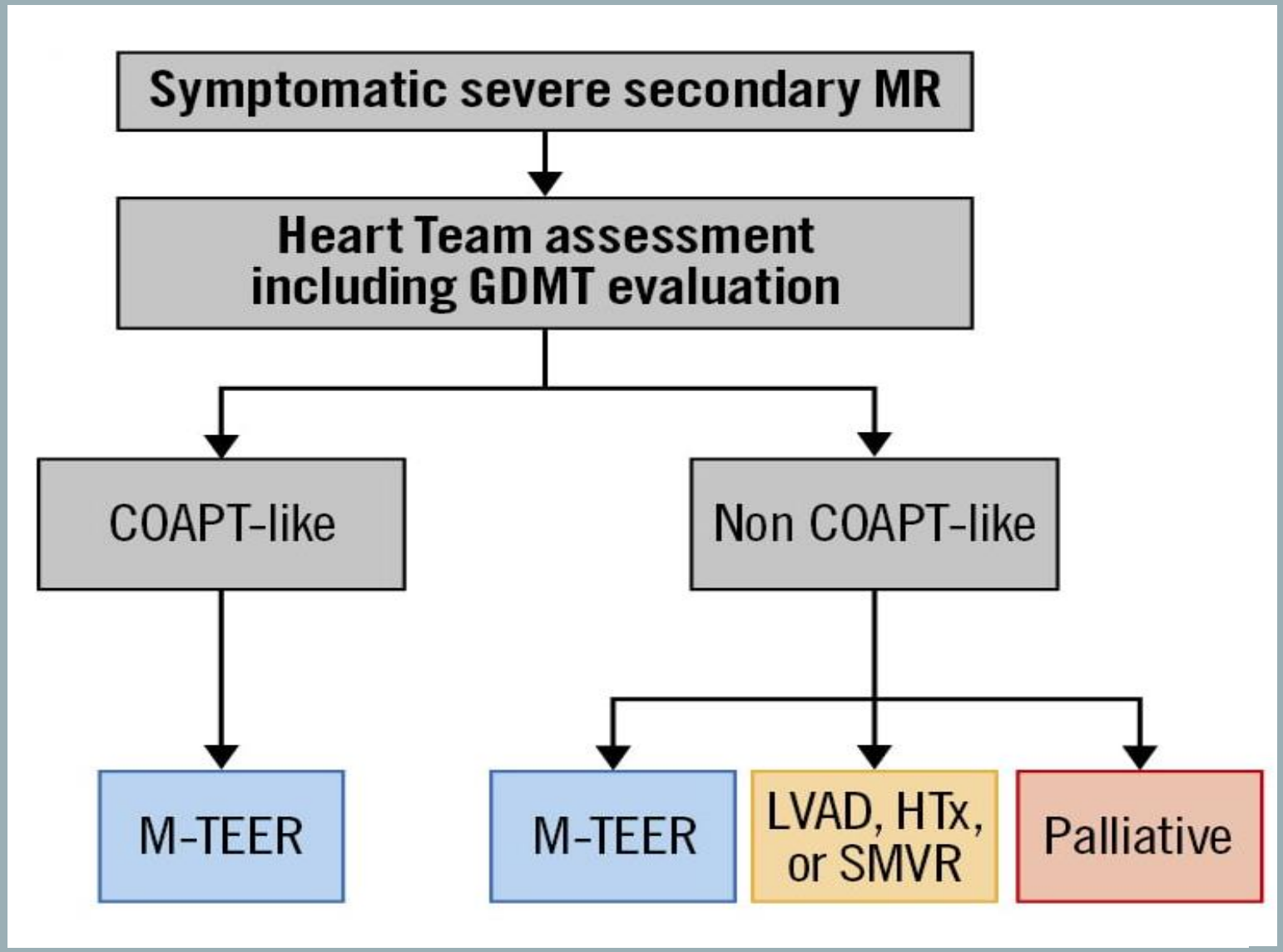


No. at risk

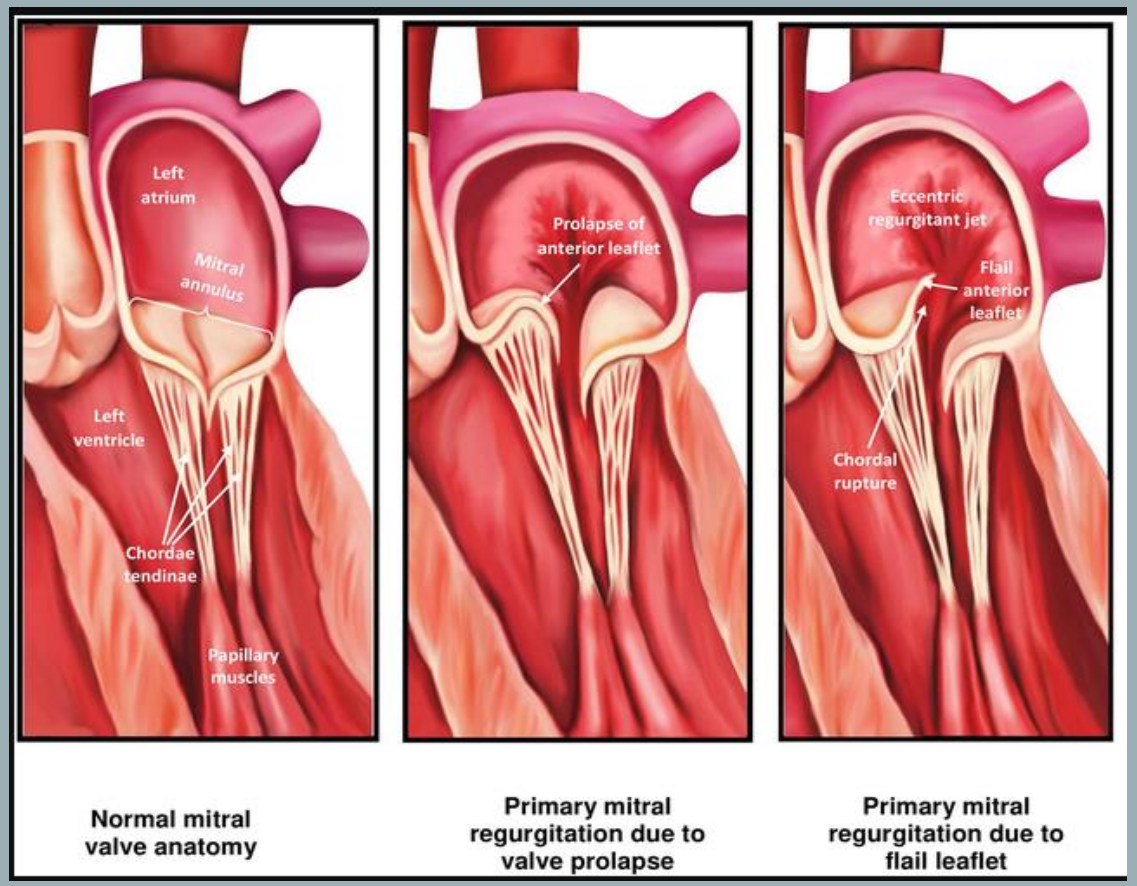
resMR 1+	999	734	598	496	421	274
resMR 2+	492	328	250	204	166	105
resMR ≥3+	125	73	52	36	30	20

JACC November,2024:2543-2554

MANAGEMENT OF MITRAL VALVE REGURGITATION
" SECONDARY MR"



MANAGEMENT OF MITRAL VALVE REGURGITATION
" PRIMARY MR"



MANAGEMENT OF MITRAL VALVE REGURGITATION " PRIMARY MR"

- Mitral valve surgery is the standard of care
- Repair is preferred than replacement
- In patients with prohibitive risk for surgery , mitral TEER may be considered

NEJM 2018 ;379:2307-18

MANAGEMENT OF MITRAL VALVE REGURGITATION
" PRIMARY MR"

EVEREST II TRIAL

NEJM 2018 ;379:2307-18

EVEREST II TRIAL

Total of 279 patients with moderate to severe or severe mitral valve regurgitation
Randomized 2:1
Mitral TEER or surgical mitral valve repair or replacement

Primary efficacy endpoint: Freedom from death, freedom from mitral valve surgery (MV dysfunction or severe MR) at one year
Primary safety endpoint: Major adverse events at 30 days

NEJM 2018 ;379:2307-18

EVEREST II TRIAL

Table 1. Baseline Characteristics of the Patients.*

Severity of mitral regurgitation — no. (%)			0.38
1+ to 2+ (mild to moderate)	0	1 (1)	
2+ (moderate)	8 (4)	6 (6)	
3+ (moderate to severe)	130 (71)	67 (71)	
4+ (severe)	46 (25)	21 (22)	
Regurgitant volume — ml/beat	42.0±23.3	45.2±26.6	0.31
Regurgitant orifice area — cm^2	0.56±0.38	0.59±0.35	0.55
Cause of mitral regurgitation — no. (%)			0.81
Functional	49 (27)	26 (27)	
Degenerative			
With anterior or bileaflet flail or prolapse	58 (32)	25 (26)	
With posterior flail or prolapse	72 (39)	42 (44)	
With no flail and no prolapse	5 (3)	2 (2)	
III	82 (45)	41 (43)	
IV	12 (7)	4 (4)	

EVEREST II TRIAL

Event	Percutaneous Repair	Surgery	P Value
	no. (%)		
Primary efficacy end point			
Freedom from death, from surgery for mitral-valve dysfunction, and from grade 3+ or 4+ mitral regurgitation†	100 (55)	65 (73)	0.007
Death	11 (6)	5 (6)	1.00
Surgery for mitral-valve dysfunction‡	37 (20)	2 (2)	<0.001
Grade 3+ or 4+ mitral regurgitation	38 (21)	18 (20)	1.00
Major adverse event at 30 days§			
Any major adverse event	27 (15)	45 (48)	<0.001¶
Any major adverse event excluding transfusion	9 (5)	9 (10)	0.23
Death	2 (1)	2 (2)	0.89
Myocardial infarction	0	0	NA
Reoperation for failed surgical repair or replacement	0	1 (1)	0.74
Urgent or emergency cardiovascular surgery for adverse event	4 (2)	4 (4)	0.57
Major stroke	2 (1)‖	2 (2)	0.89

EVEREST II TRIAL

Table 3. Secondary End Points at 12 Months in the Intention-to-Treat Population.*

End Point	Percutaneous Repair (N=184)			Surgery (N=95)			P Value for Comparison between Study Groups
	No. of Patients	Value	P Value for Comparison between Baseline and 12 Mo	No. of Patients	Value	P Value for Comparison between Baseline and 12 Mo	
Change from baseline in left ventricular measurement							
End-diastolic volume — ml	144	−25.3±28.3	<0.001	66	−40.2±35.9	<0.001	0.004
End-diastolic diameter — cm	148	−0.4±0.5	<0.001	67	−0.6±0.6	<0.001	0.04
End-systolic volume — ml	144	−5.5±14.5	<0.001	66	−5.6±21.0	0.04	0.97
End-systolic diameter — cm	146	−0.1±0.6	0.06	67	−0.0±0.6	0.86	0.38
Ejection fraction — %	144	−2.8±7.2	<0.001	66	−6.8±10.1	<0.001	0.005
Change from baseline in quality-of-life score†							
30 days							
Physical component summary	147	3.1±9.4	<0.001	64	−4.9±13.3	0.004	<0.001
Mental component summary	148	4.4±11.3	<0.001	64	1.8±13.4	0.29	0.14
12 months							
Physical component summary	132	4.4±9.8	<0.001	60	4.4±10.4	0.002	0.98
Mental component summary	133	5.7±9.9	<0.001	60	3.8±10.3	0.006	0.24
Severity of mitral regurgitation at 12 mo — no. (%)	153			69			<0.001
0+ (none)		9 (6)	NA		13 (19)	NA	
1+ (mild)		57 (37)	NA		39 (57)	NA	
1+ to 2+ (mild to moderate)		18 (12)	NA		5 (7)	NA	
2+ (moderate)		41 (27)	NA		9 (13)	NA	
3+ (moderate to severe)		21 (14)	NA		3 (4)	NA	
4+ (severe)		7 (5)	NA		0	NA	

NEJM 2018 ;379:2307-18

EVEREST II TRIAL

Conclusion

Mitral TEER was less effective at reducing mitral valve regurgitation than surgery however it has superior safety and similar improvement in outcome

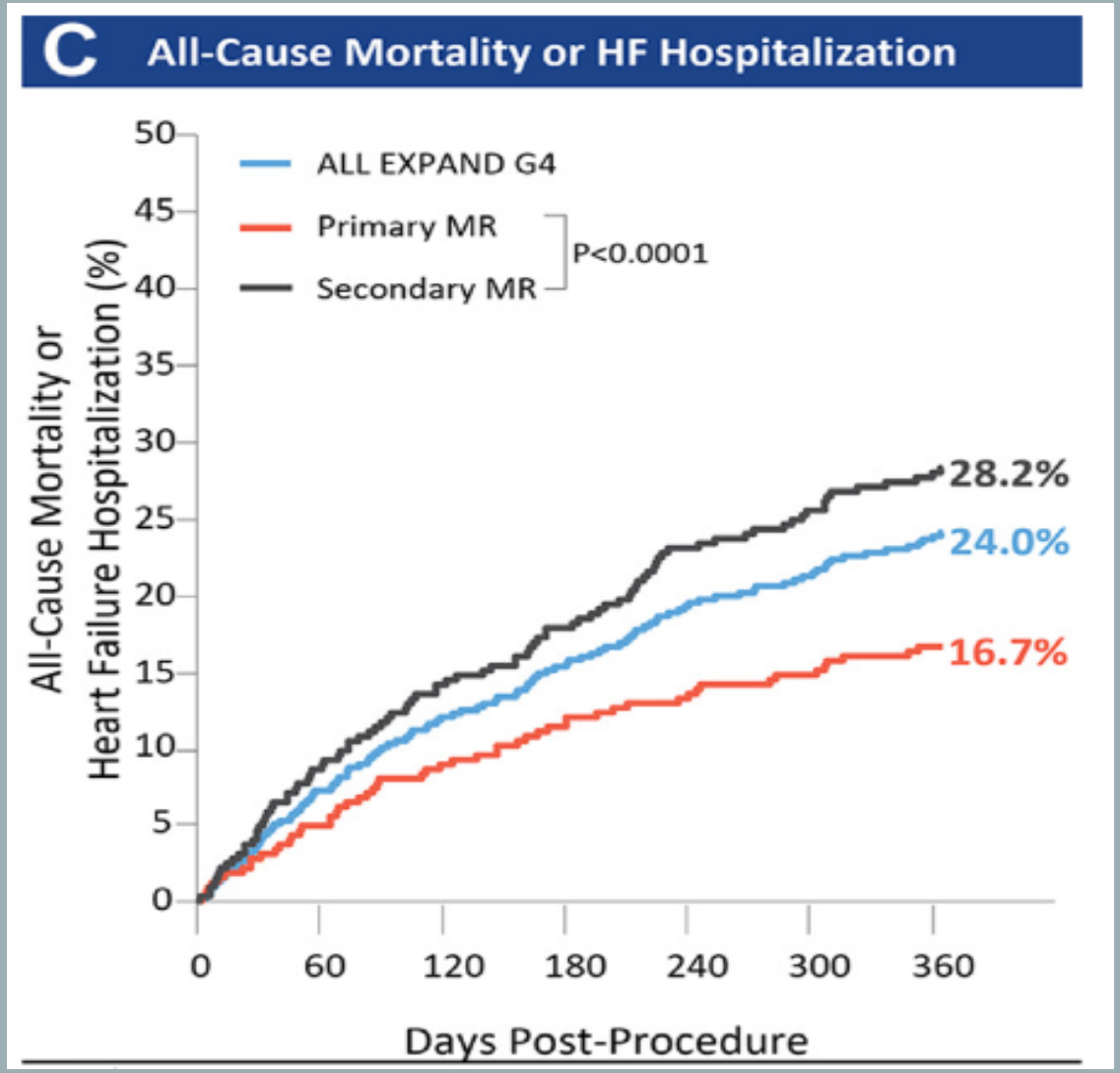
NEJM 2011;364:1395-406

EXPAND REGISTRY

- Evaluate 1-year outcomes in a contemporary , real-world cohort of patients treated with Mitra clip G4 system
- Total of 1164 patients treated with M-TEER from 2020-2022

JACC November 13, 2023:2600-2610

EXPAND REGISTRY



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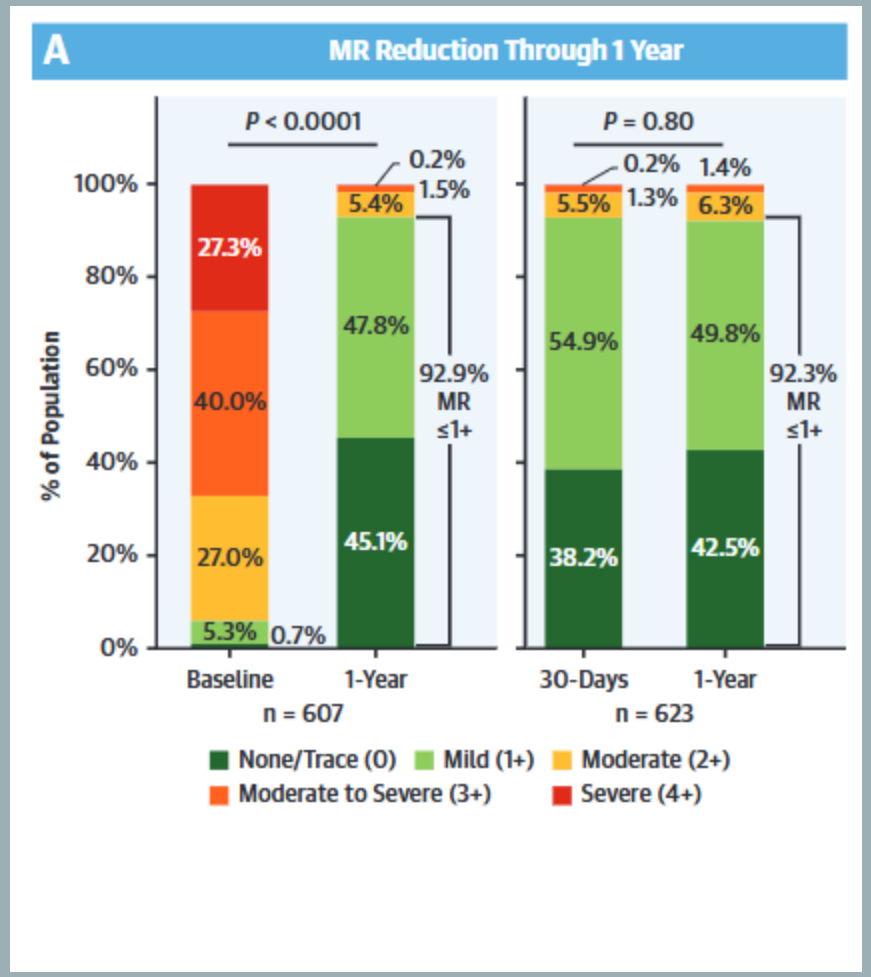

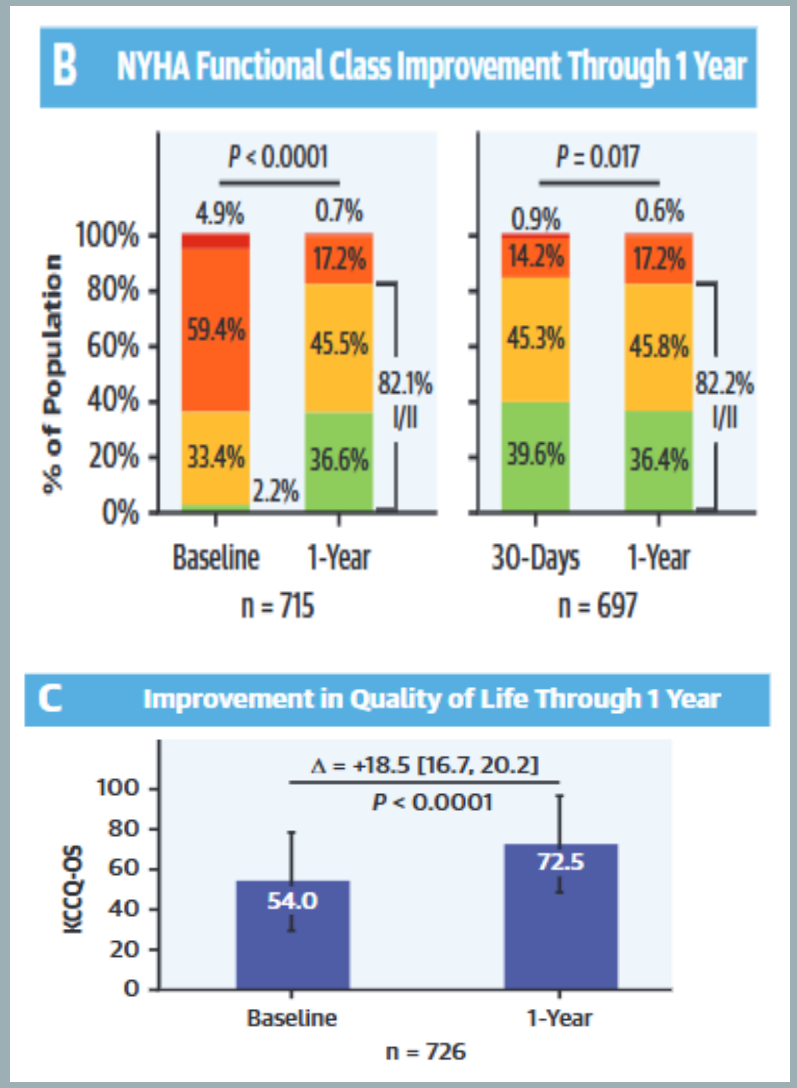

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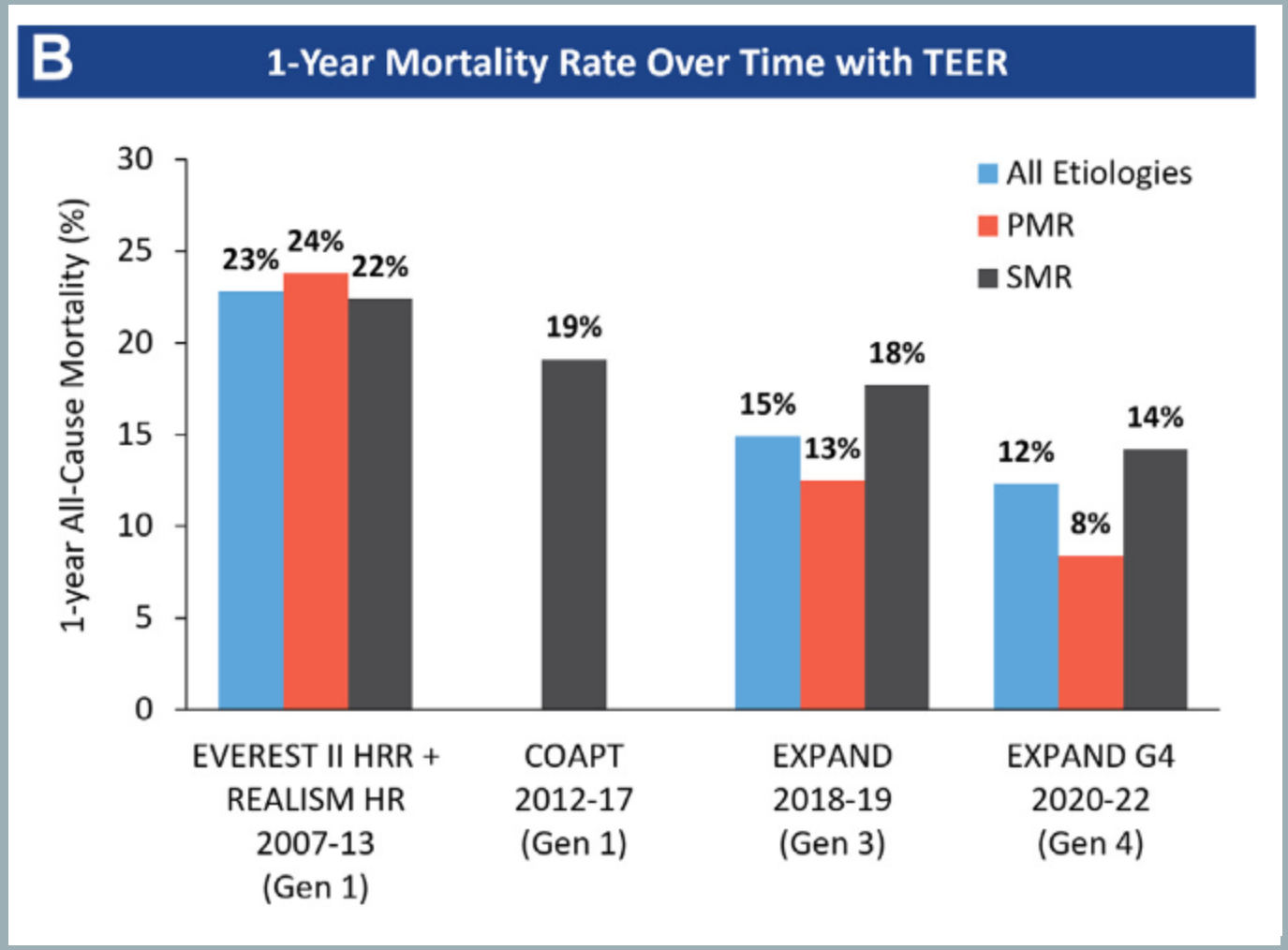
EXPAND REGISTRY



JACC November 13, 2023:2600-2610

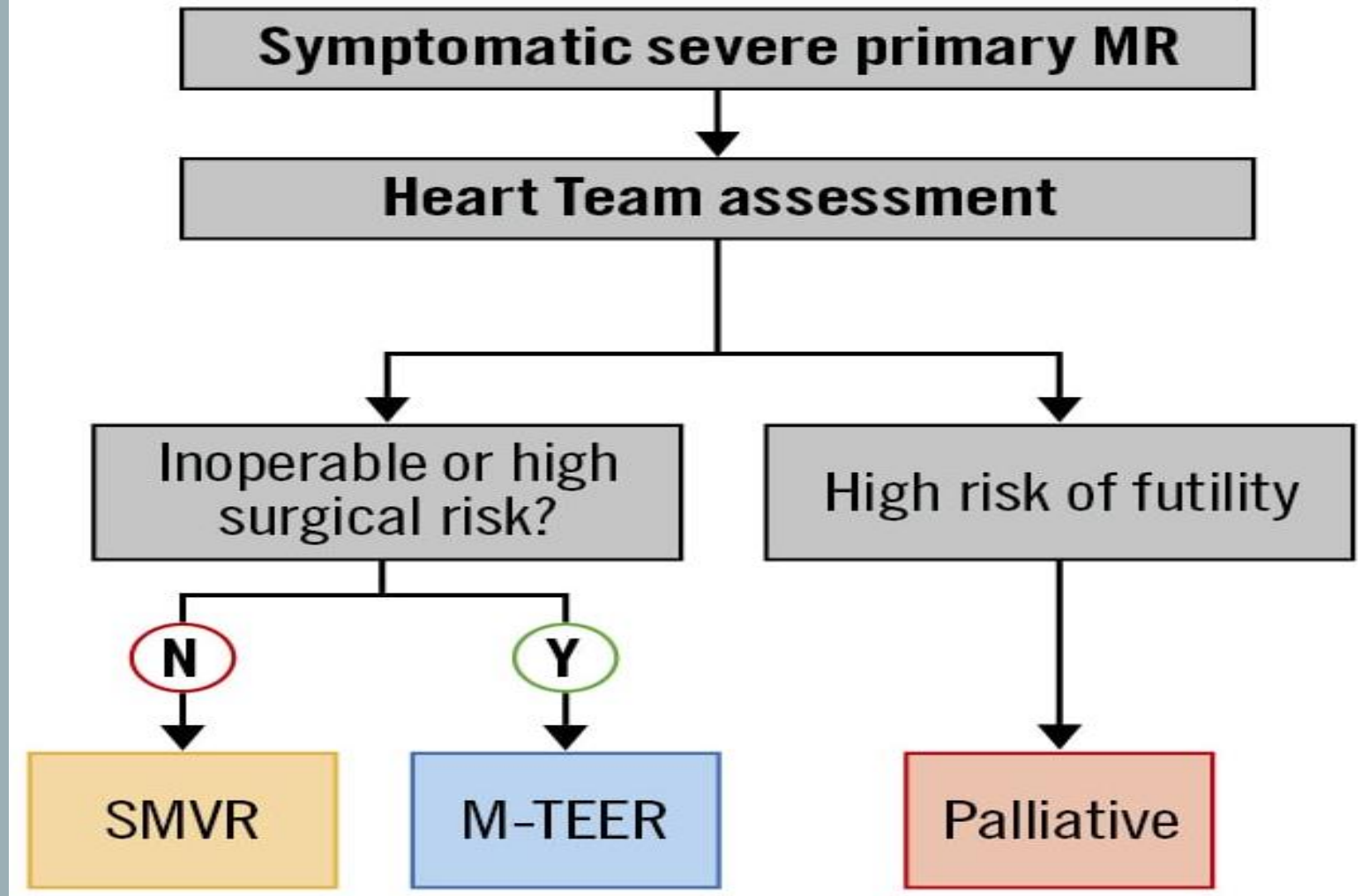
EXPAND REGISTRY

Conclusion

- M-TEER using the fourth-generation M-TEER device was safe and effective at 1 year follow up
- Durable reduction in MR severity in more than 90% of patients
- Concomitant improvement in functional status and quality of life.

JACC November 13, 2023:2600-2610

MITRAL VALVE REGURGITATION "TREATMENT"



COMPLICATION

Complications	Rate
Singe leaflet detachment	1-5%
Device embolization	0.5%
Leaflet injury	0-2%
Residual MR (moderate or more)	3-15%
Access complication	1-4%
Pericardial effusion	0.5%
Myocardial infarction	0-3%
Stroke	0.1%

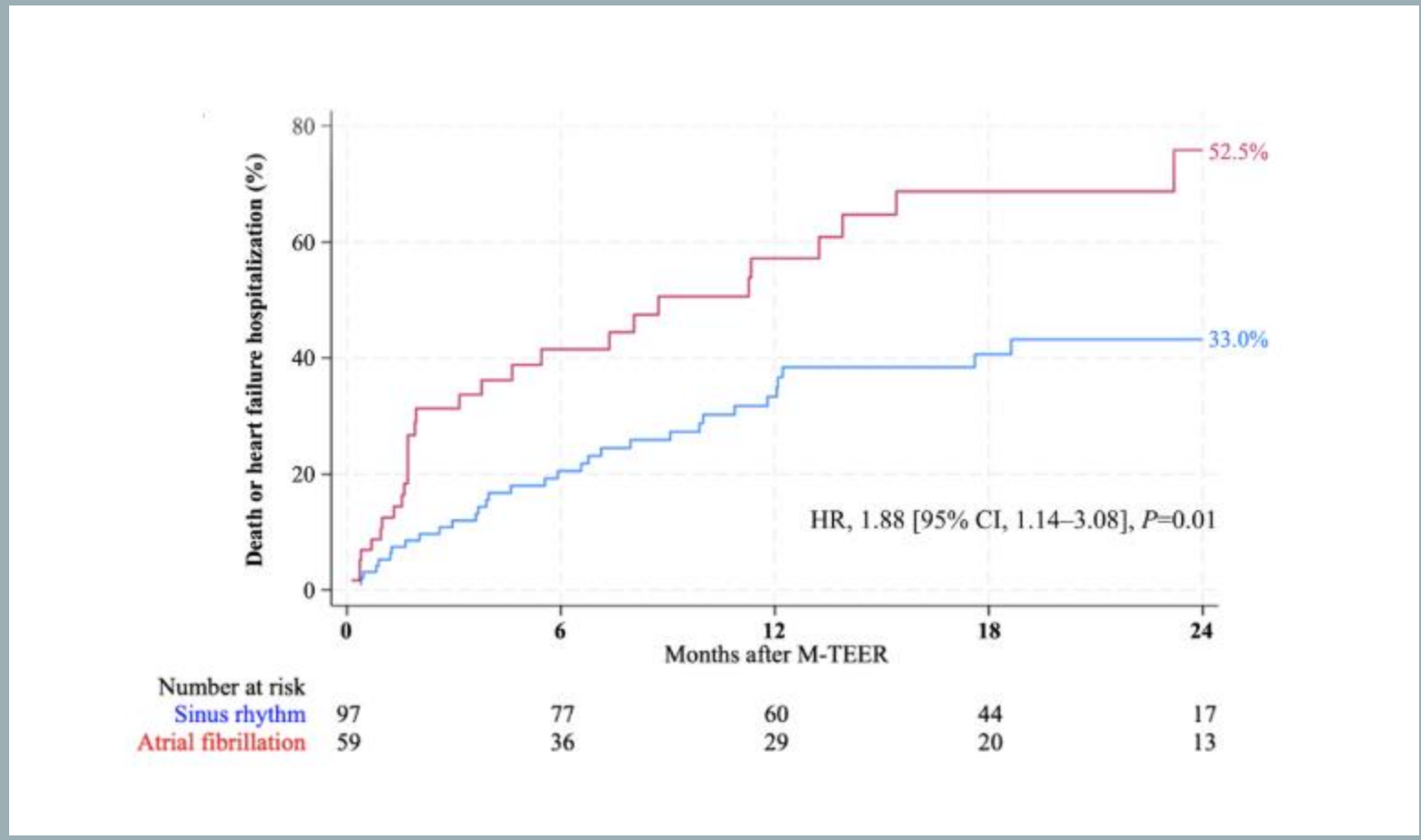
ATRIAL FIBRILLATION AND MITRAL REGURGITATION

- Total of 156 patients enrolled
- Patient with symptomatic HF undergoing Mitral TEER

Primary endpoint : The composite outcome of death or heart failure hospitalization

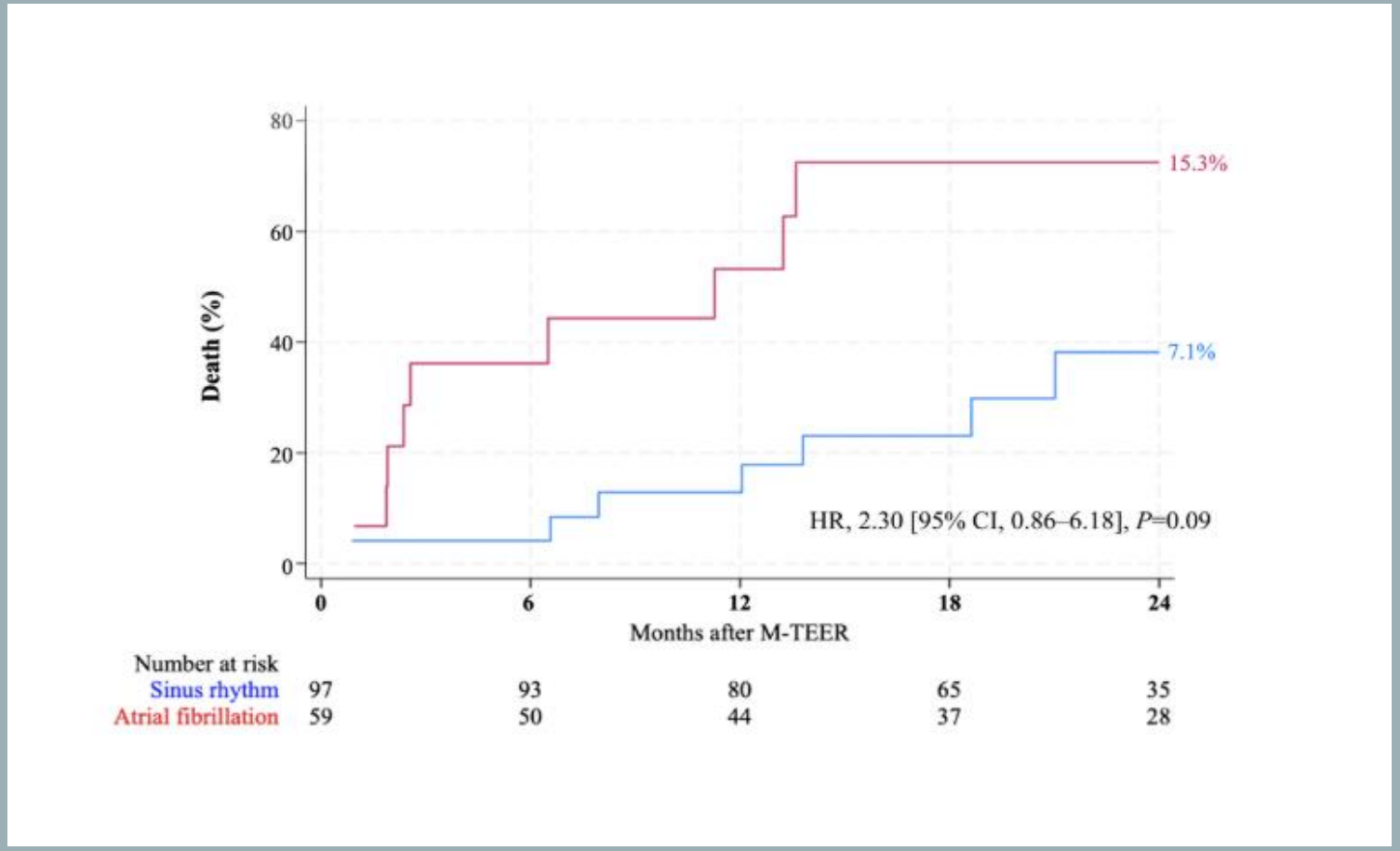
J am heart assoc 2025;14:e 042016

ATRIAL FIBRILLATION AND MITRAL REGURGITATION



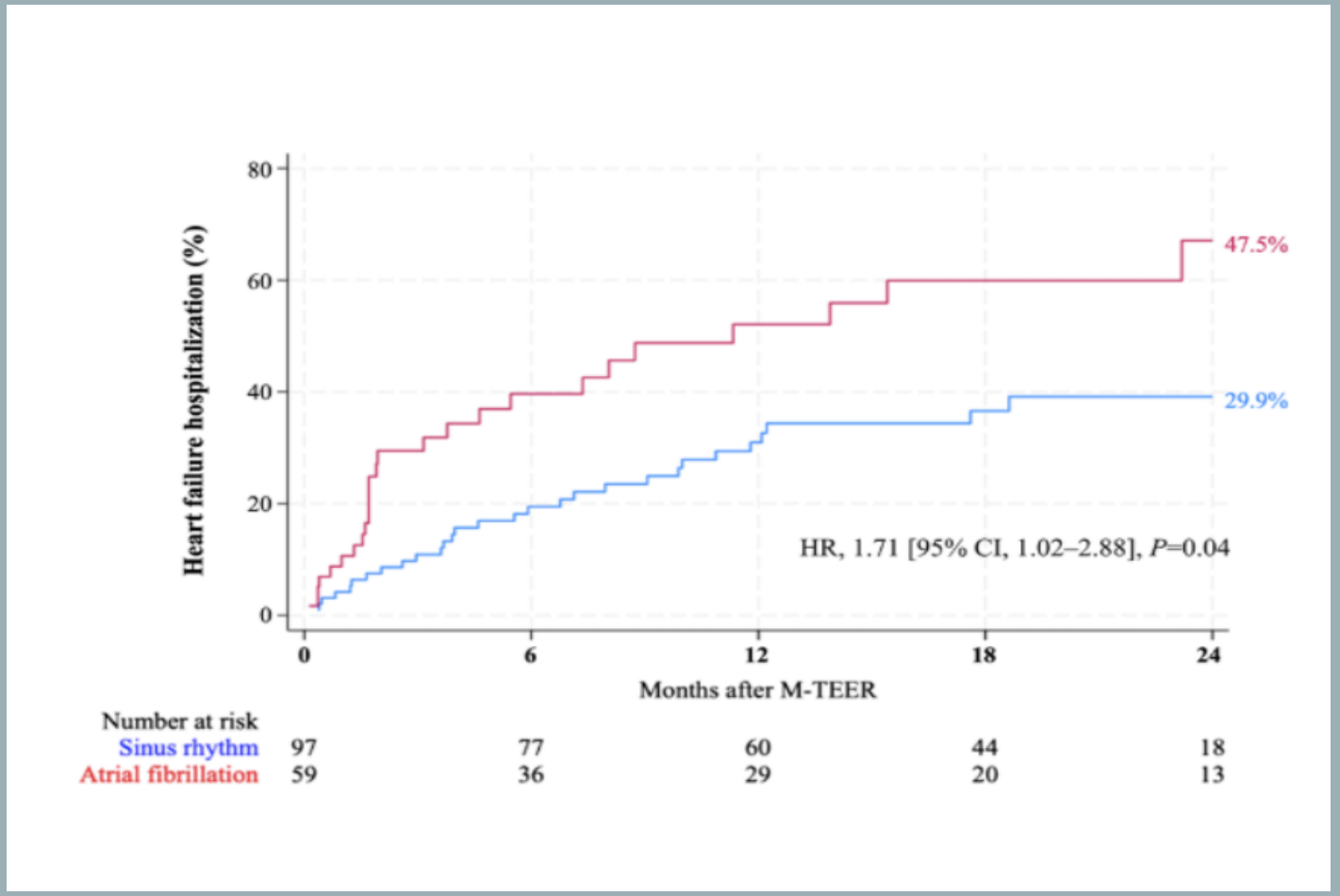
J am heart assoc 2025;14:e 042016

ATRIAL FIBRILLATION AND MITRAL REGURGITATION



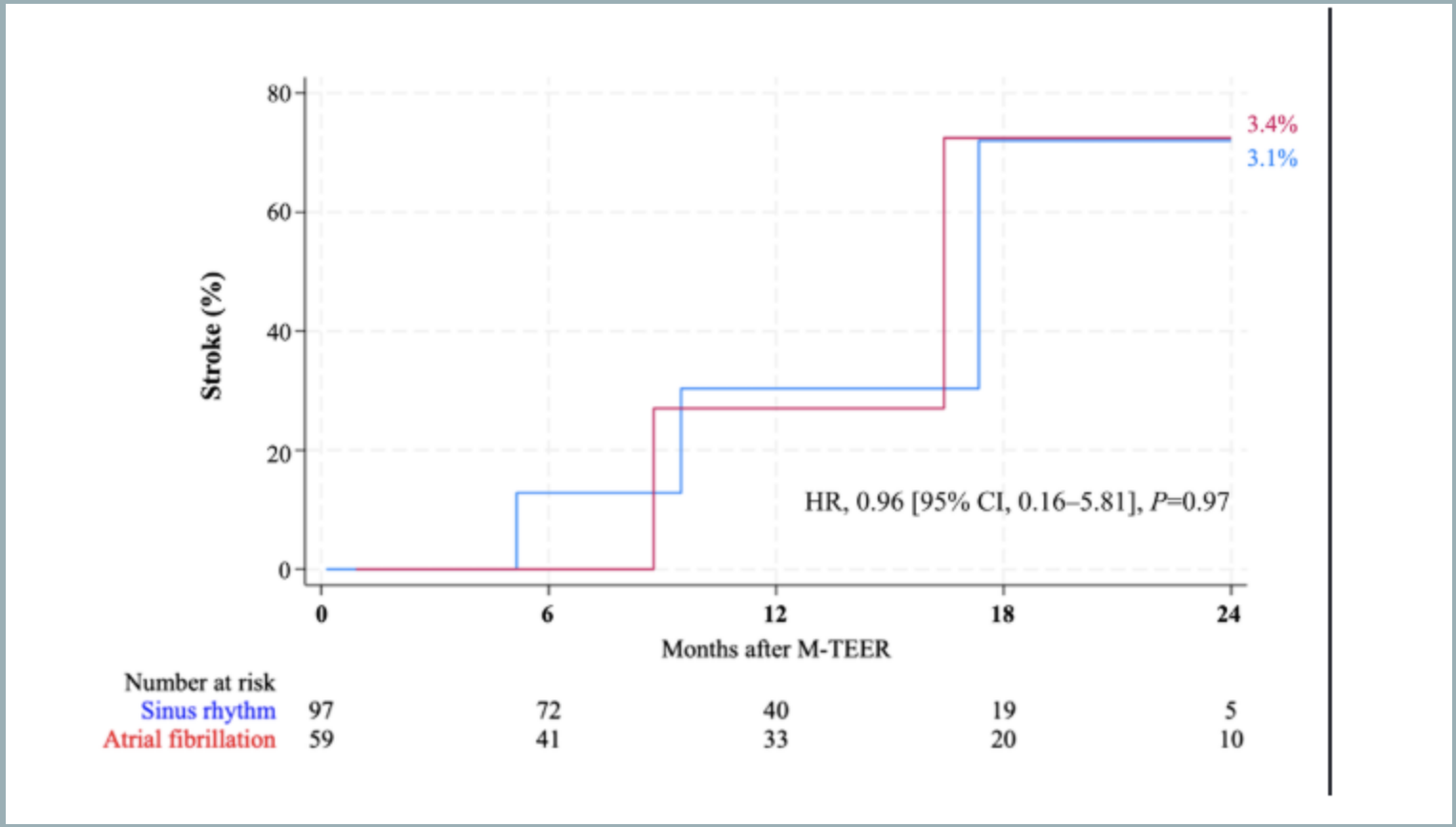
J am heart assoc 2025;14:e 042016

ATRIAL FIBRILLATION AND MITRAL REGURGITATION



J am heart assoc 2025;14:e 042016

ATRIAL FIBRILLATION AND MITRAL REGURGITATION



J am heart assoc 2025;14:e 042016

ATRIAL FIBRILLATION AND MITRAL REGURGITATION

Conclusion

In patients with HF and severe MR treated with mitral TEER, baseline atrial fibrillation was associated with impaired right and left heart remodeling and more frequent MR recurrence and more than doubling of the 2 year risk of death or HF hospitalization

J am heart assoc 2025;14:e 042016

FUTURE DIRECTION

REPAIR MR TRIAL

Will determine the safety and effectiveness of transcatheter edge to edge repair with mitral clip of secondary mitral valve regurgitation in patients who are a good candidate for surgical mitral valve repair

CONCLUSION

Mitral-TEER is an important trans-catheter approach for patients with severe or moderate to severe mitral valve regurgitation

Structural cardiologist growing experience along with device improvements made this strategy a valid option for selected patients with mitral regurgitation and an important alternative to surgery as recommended by the current guidelines.

THANK YOU