36. Berliner Dialyse Seminar

01. - 02. Dezember 2023

Klappeninterventionen bei Patienten mit CKD



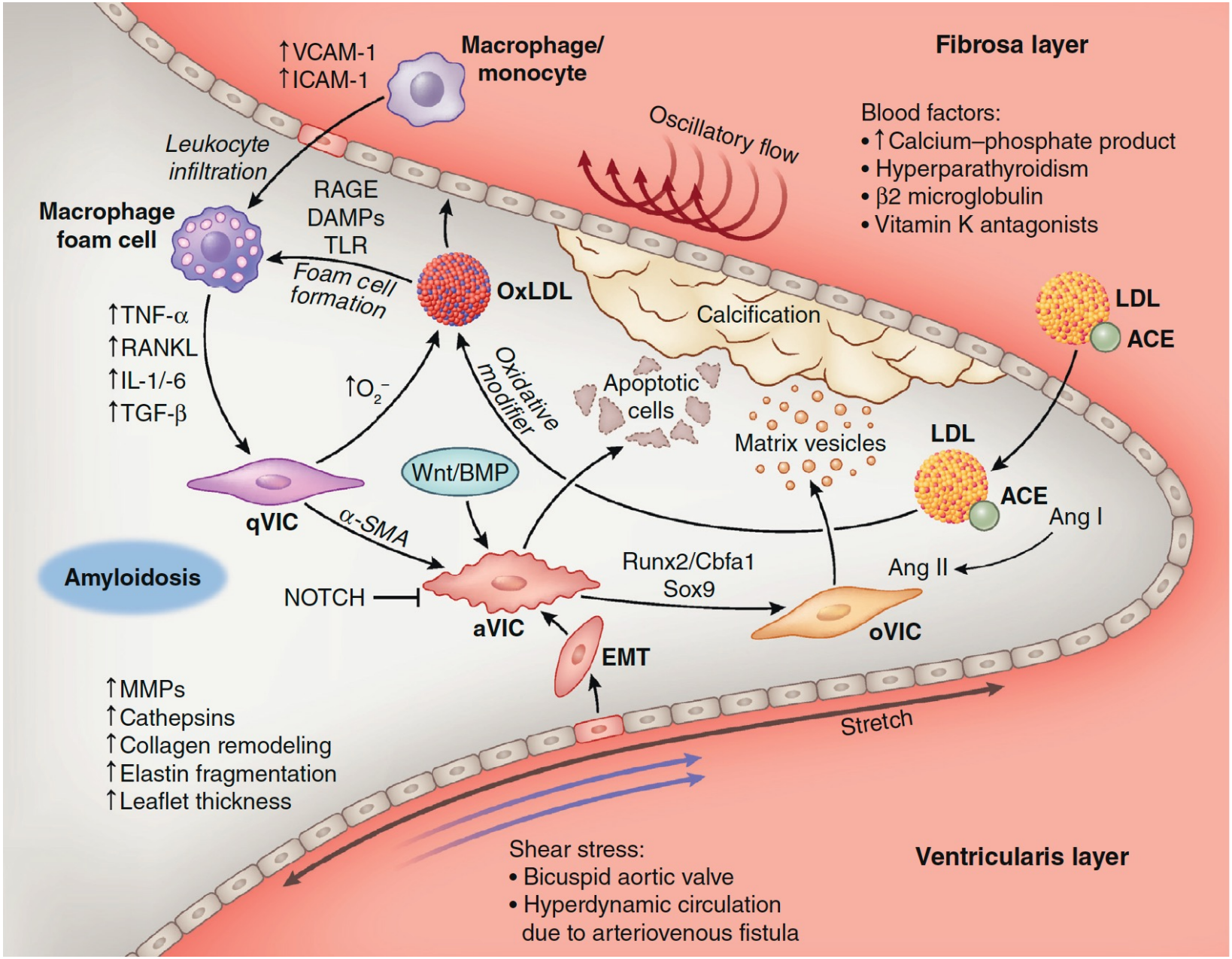
Univ.-Prof. Dr. med. H. Ince

Universitätsmedizin Rostock

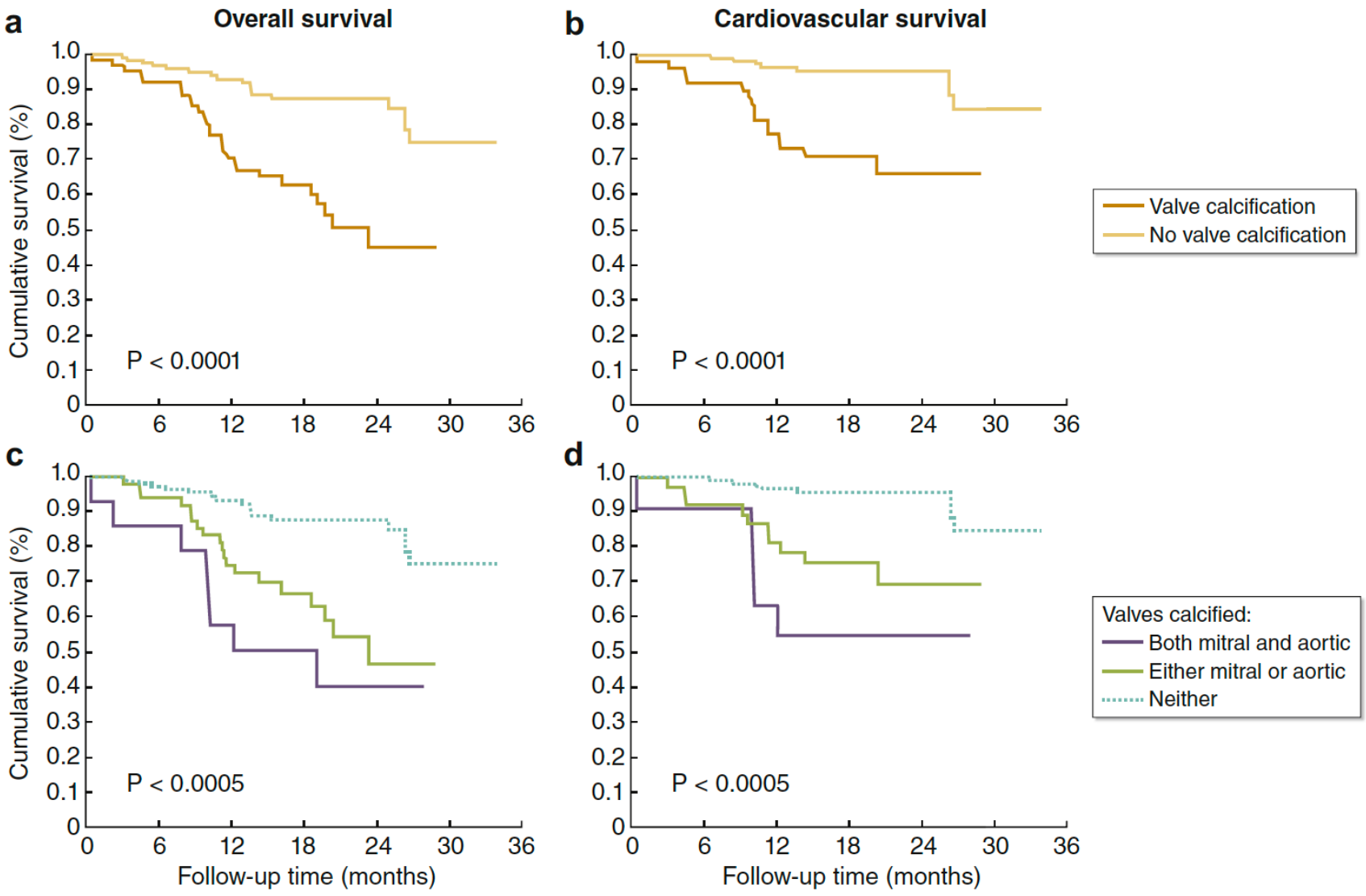
Vivantesklinikum Am Urban und Neukölln, Berlin

COI

- Vortragshonorare: Amgen, BMS, Pfizer, Astra Zeneca, Abbott, Daichi Sankyo



Marwick TH et al., Kidney Int. 2019 Oct;96(4):836-849



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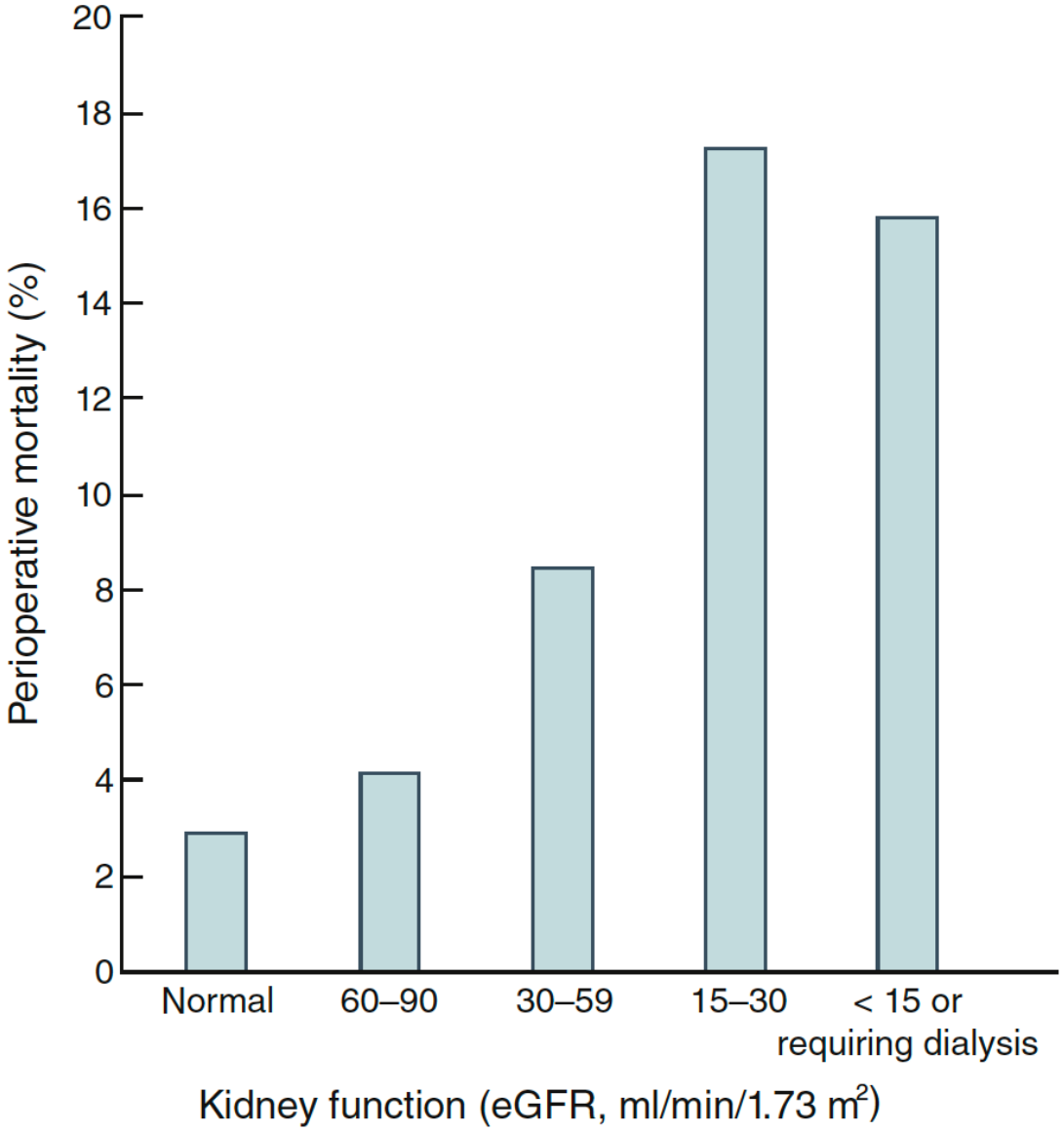
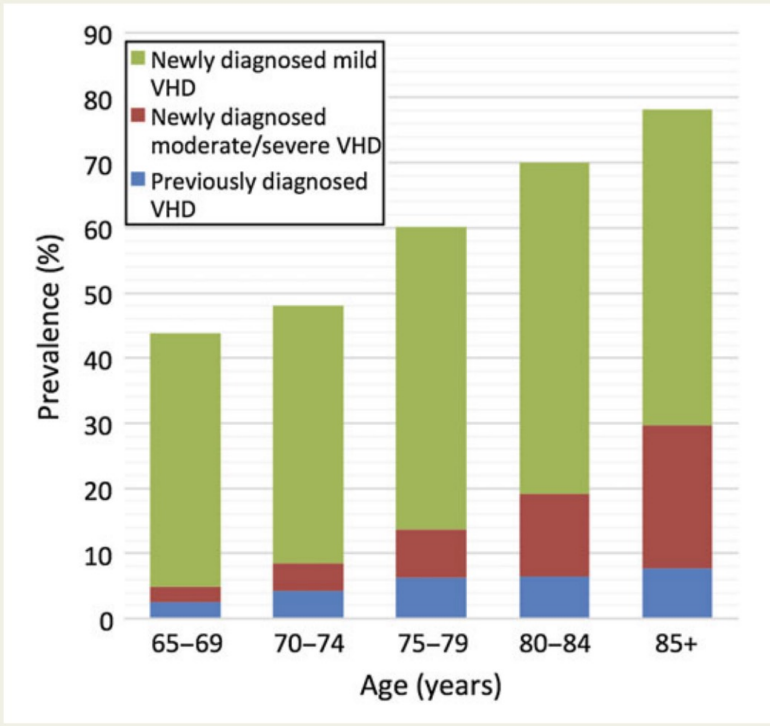


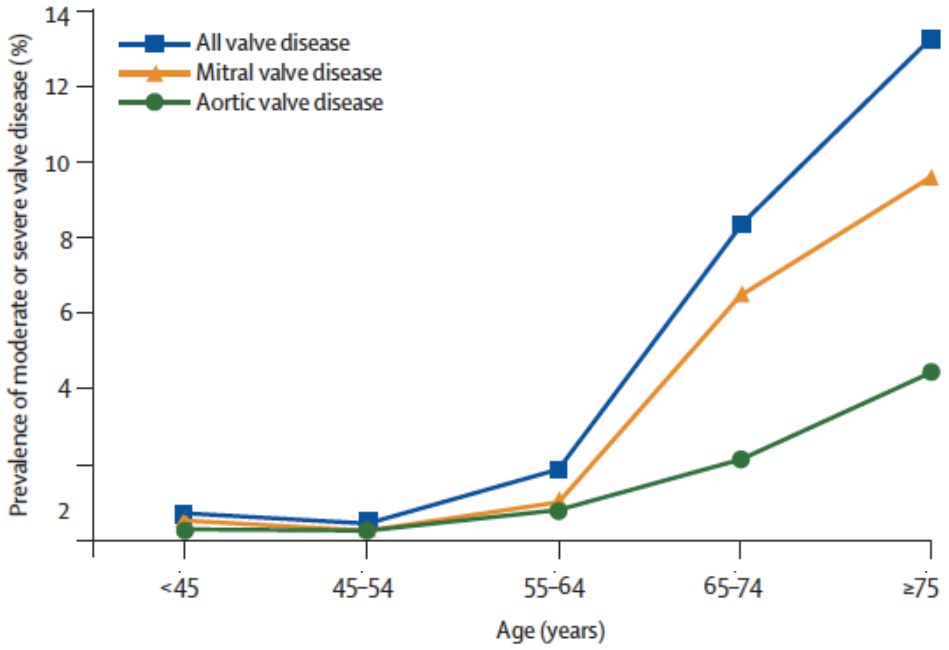
Marwick TH et al., Kidney Int. 2019 Oct;96(4):836-849

Mitralklappe

Prevalence of valvular heart disease

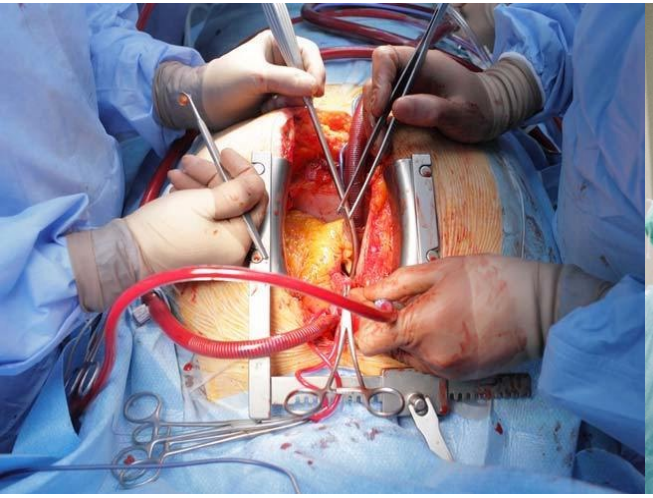


d´Arcy J et al., Eur Heart J 2016



Nkomo VT et al., Lancet 2006

Behandlungsoptionen



PCR
london valves
2015

LIVE demonstration from

Deutsches Herzzentrum Berlin &
the Vivantes Klinikum im Urban
and the Vivantes Klinikum im
Friedrichshain

Berlin, Germany

DEUTSCHES HERZZENTRUM BERLIN

Behandlung der sekundären MI

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

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Vahanian A et al., Eur Heart J 2021

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Five-Year Follow-up after Transcatheter Repair of Secondary Mitral Regurgitation

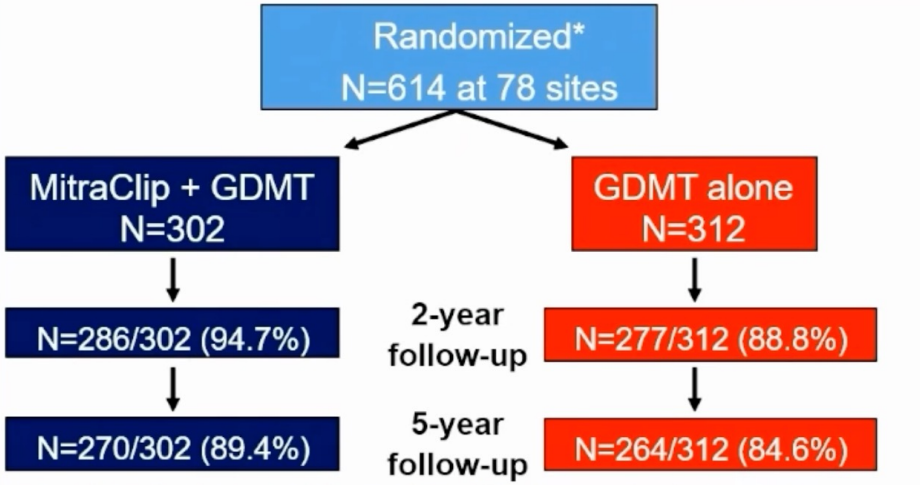
Gregg W. Stone, M.D., William T. Abraham, M.D., JoAnn Lindenfeld, M.D., Saibal Kar, M.D., Paul A. Grayburn, M.D., D. Scott Lim, M.D., Jacob M. Mishell, M.D., Brian Whisenant, M.D., Michael Rinaldi, M.D., Samir R. Kapadia, M.D., Vivek Rajagopal, M.D., Ian J. Sarembock, M.B., Ch.B., M.D., Andreas Brieke, M.D., Steven O. Marx, M.D., David J. Cohen, M.D., Federico M. Asch, M.D., and Michael J. Mack, M.D., for the COAPT Investigators

COAPT Trial Design

Mack et al. Am Heart J 2018; Stone et al. N Engl J Med 2018; Mack et al. J Am Coll Cardiol 2021; Stone et al. N Engl J Med 2023

A parallel-controlled, open-label, multicenter trial in ~610 patients with heart failure and moderate-to-severe (3+) or severe (4+) secondary MR who remained symptomatic despite maximally-tolerated GDMT

Do patients with heart failure and moderate-to-severe (3+) or severe (4+) secondary MR who remain symptomatic despite maximally-tolerated GDMT benefit from MR reduction?

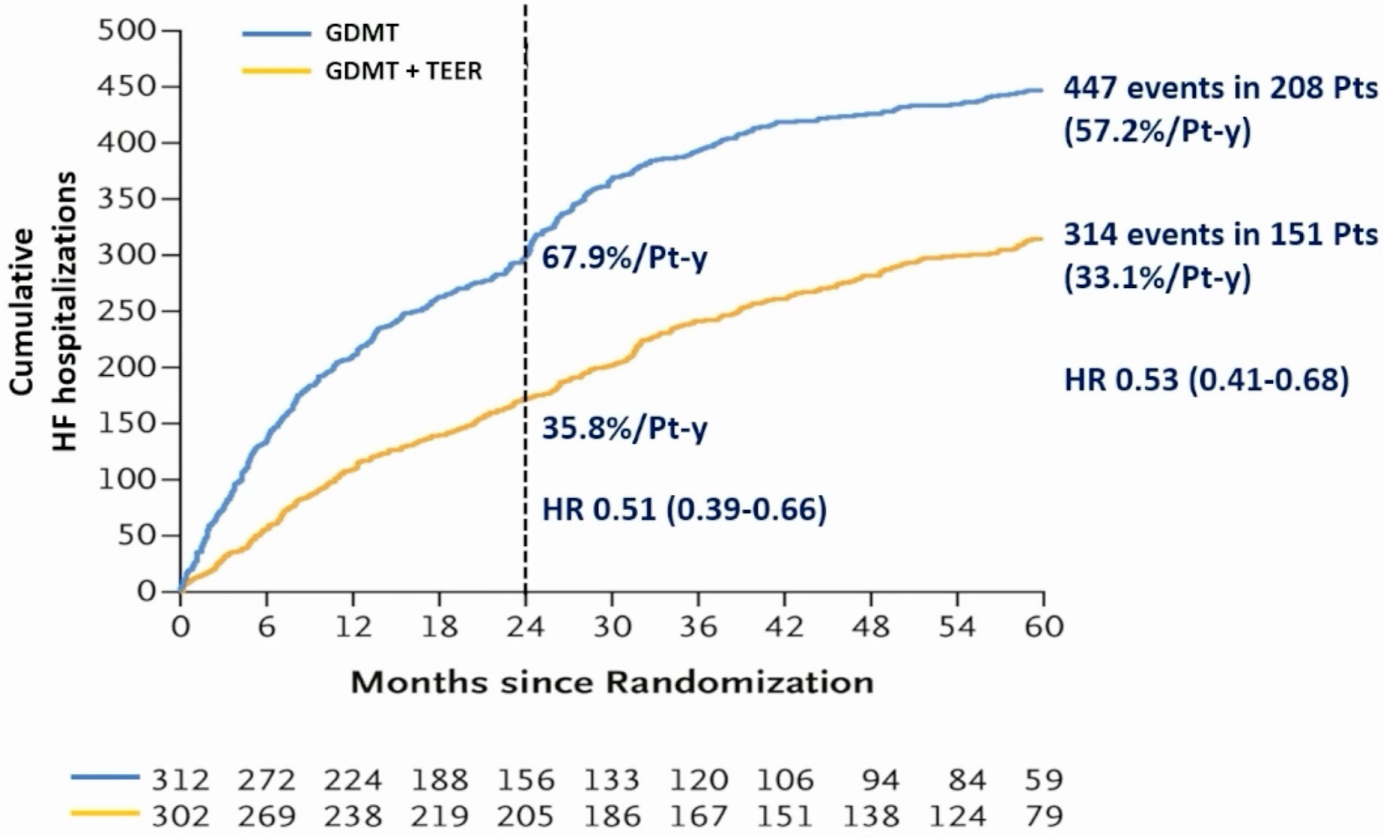


*Use of Maximal tolerated doses of GDMT before randomization and treatment with CRT, defibrillators, and revascularization before randomization.

Key inclusion criteria	Key exclusion criteria
1. LVEF 20%-50% and LVESD ≤70 mm 2. Moderate-to-severe (3+) or severe (4+) secondary MR 3. NYHA class II-IVa despite a stable maximally-tolerated GDMT regimen and CRT, ICD, and/or revascularization 4. HF hospitalzation within 12 months and/or weight-adjusted BNP ≥300 pg/ml* or NT-proBNP ≥1500 pg/ml* 5. IC believes MR can be successfully treated by the MitraClip	1. ACC/AHA stage D HF 2. CAD requiring revascularization 3. COPD requiring continuous home O_2 or chronic oral steroid use 4. Severe PH or moderate or severe RVD 5. Aortic or tricuspid valve disease requiring intervention 6. MV orifice area <4.0 cm^2 by site-assessed TTE 7. Anatomy not suitable for MitraClip therapy
Primary effectiveness endpoint	**Primary safety endpoint**
All HF hospitalizations through 24 months* *Analyzed when the last subject completes 12 months of follow-up	Freedom from device-related complications at 12 months: Single leaflet device attachment, device embolization, endocarditis requiring surgery, severe mitral stenosis (valve area <1.5 cm^2) requiring surgery, LVAD or heart transplant, or any device-related complication requiring non-elective cardiovascular surgery

PRIMARY EFFECTIVENESS ENDPOINT - ALL HF HOSPITALIZATIONS THROUGH 5-YEAR FOLLOW-UP

Gregg W Stone et al. *N Engl J Med* 2023



COAPT TRIAL: FINAL 5-YEAR CLINICAL OUTCOMES

Gregg W Stone et al. *N Engl J Med* 2023

Key outcomes:

	Expected		2 years		3 years		5 years	
	Device group	Control group	Device group	Control group	Device group	Control group	Device group	Control group
Annualized all HF hospitalization, %/patient-year	42.0%	60.0%	35.8%	67.9%	35.5%	68.8%	33.1%	57.2%
			HR 0.53 (0.40-0.70)		HR 0.49 (0.37-0.63)		HR 0.53 (0.41-0.68)	
HF hospitalization, %	-	-	35.7%	56.7%	46.5%	81.5%	61.0%	83.0%
			HR 0.52 (0.40-0.67)		HR 0.43 (0.34-0.54)		HR 0.49 (0.40-0.61)	
All-cause death, %	22.0%*	27.0%*	29.1%	46.1%	42.8%	55.5%	57.3%	67.2%
			HR 0.62 (0.46-0.82)		HR 0.67 (0.52-0.85)		HR 0.72 (0.58-0.89)	
Death or first HF hospitalization, %	-	-	45.7%	67.9%	59.0%	88.0%	73.6%	91.5%
			HR 0.57 (0.45-0.71)		HR 0.48 (0.39-0.59)		HR 0.53 (0.44-0.64)	

* At 1 year

COAPT TRIAL

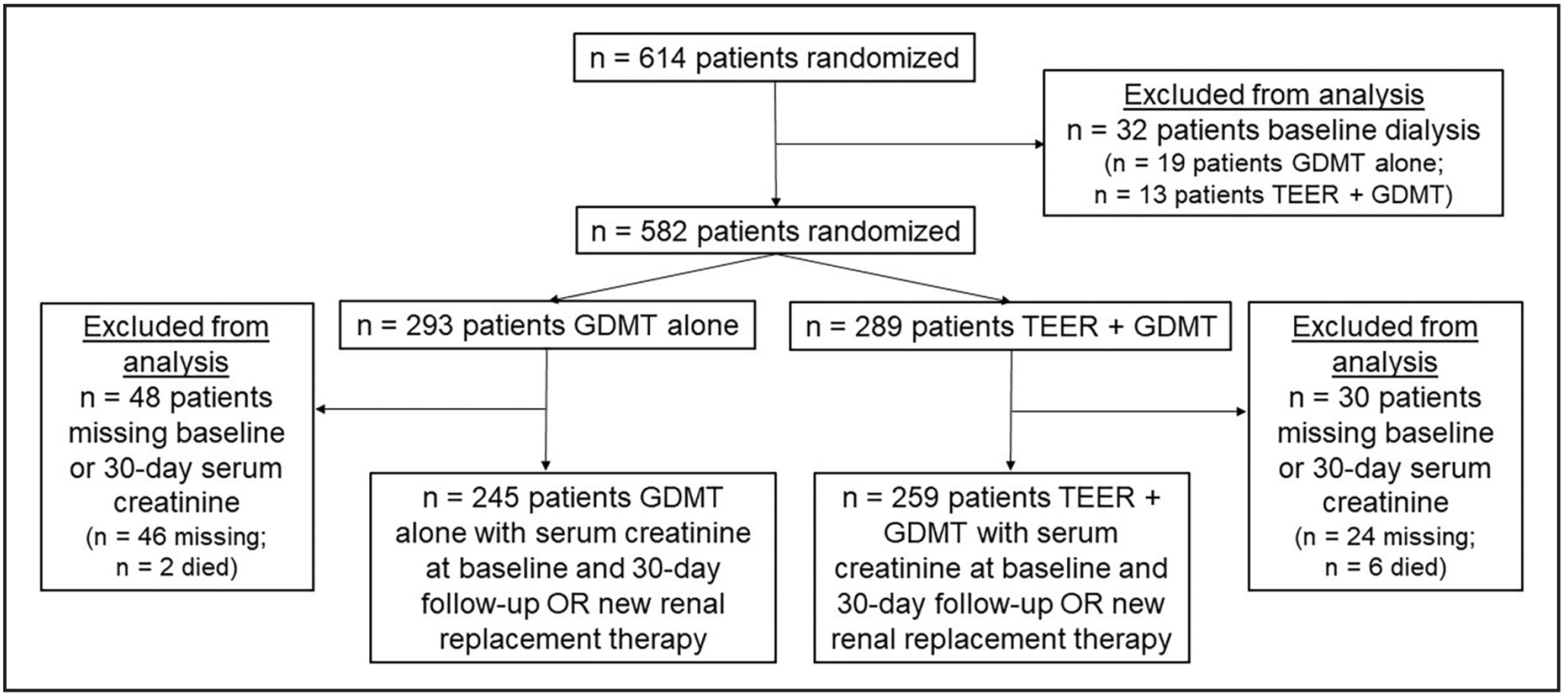
PRIMARY SAFETY ENDPOINT:
FREEDOM FROM DEVICE-RELATED COMPLICATIONS

Gregg W Stone et al. *N Engl J Med* 2023

	Baseline	30 Days	12 Mo	24 Mo	36 Mo	48 Mo	60 Mo
Any safety events, n %	-	4 (1.4)	9 (3.3)	13 (5.2)	20 (8.8)	22 (10.1)	23 (10.8)
Device-specific events, n (%)	-	4 (1.4)	4 (1.4)	4 (1.4)	4 (1.4)	4 (1.4)	4 (1.4)
SLDA	-	2 (0.7)	2 (0.7)	2 (0.7)	2 (0.7)	2 (0.7)	2 (0.7)
Device embolization	-	1 (0.3)	1 (0.3)	1 (0.3)	1 (0.3)	1 (0.3)	1 (0.3)
Endocarditis requiring surgery	-	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mitral stenosis* requiring surgery	-	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Any device-related complication leading to nonelective cardiovascular surgery	-	1 (0.3)	1 (0.3)	1 (0.3)	1 (0.3)	1 (0.3)	1 (0.3)
MR severity ≤2, %	0%	92.7%	94.8%	99.4%	98.3%	97.5%	94.7%

* Mitral stenosis was defined as a mitral-valve area of less than 1.5 cm according to the criteria of the echocardiographic core laboratory.

Einfluss der Nierenfunktionseinschränkung



Kong J et al., J Am Heart Assoc. 2023;12:e029504

Characteristic	WRF (N=57)	No WRF (N=447)	*P* value
Age, y	73.9±8.6	71.9±11.6	0.21
Sex, male	57.9 (33/57)	64.9 (290/447)	0.30
Race, White	78.9 (45/57)	70.7 (316/447)	0.19
Hypertension	91.2 (52/57)	79.2 (354/447)	0.03
Diabetes	50.9 (29/57)	34.7 (155/447)	0.02
Renal disease	71.9 (41/57)	51.9 (232/447)	0.004
Previous transient ischemic attack	14.0 (8/57)	6.7 (30/447)	0.05
Coronary artery disease	89.5 (51/57)	69.4 (310/447)	0.002
Ischemic cardiomyopathy	64.9 (37/57)	59.3 (265/447)	0.41
New York Heart Association class			
I	0 (0/56)	0.2 (1/447)	0.72
II	37.5 (21/56)	40.5 (181/447)	0.67
III	48.2 (27/56)	52.3 (234/447)	0.56
IV	14.3 (8/56)	6.9 (31/447)	0.053
Heart failure hospitalization within 12 mo	61.4 (35/57)	57.3 (256/447)	0.55
Guideline-directed medical therapy			
Angiotensin converting-enzyme inhibitor, angiotensin receptor blocker, angiotensin receptor-neprilysin inhibitor	63.2 (36/57)	69.6 (311/447)	0.32
Aldosterone antagonist	47.4 (27/57)	53.7 (240/447)	0.37
Beta-blockers	93.0 (53/57)	91.1 (407/447)	0.63
Diuretic	94.7 (54/57)	92.8 (415/447)	0.60

Kong J et al., J Am Heart Assoc. 2023;12:e029504

Characteristic	WRF (N=57)	No WRF (N=447)	*P* value
Guideline-directed medical therapy			
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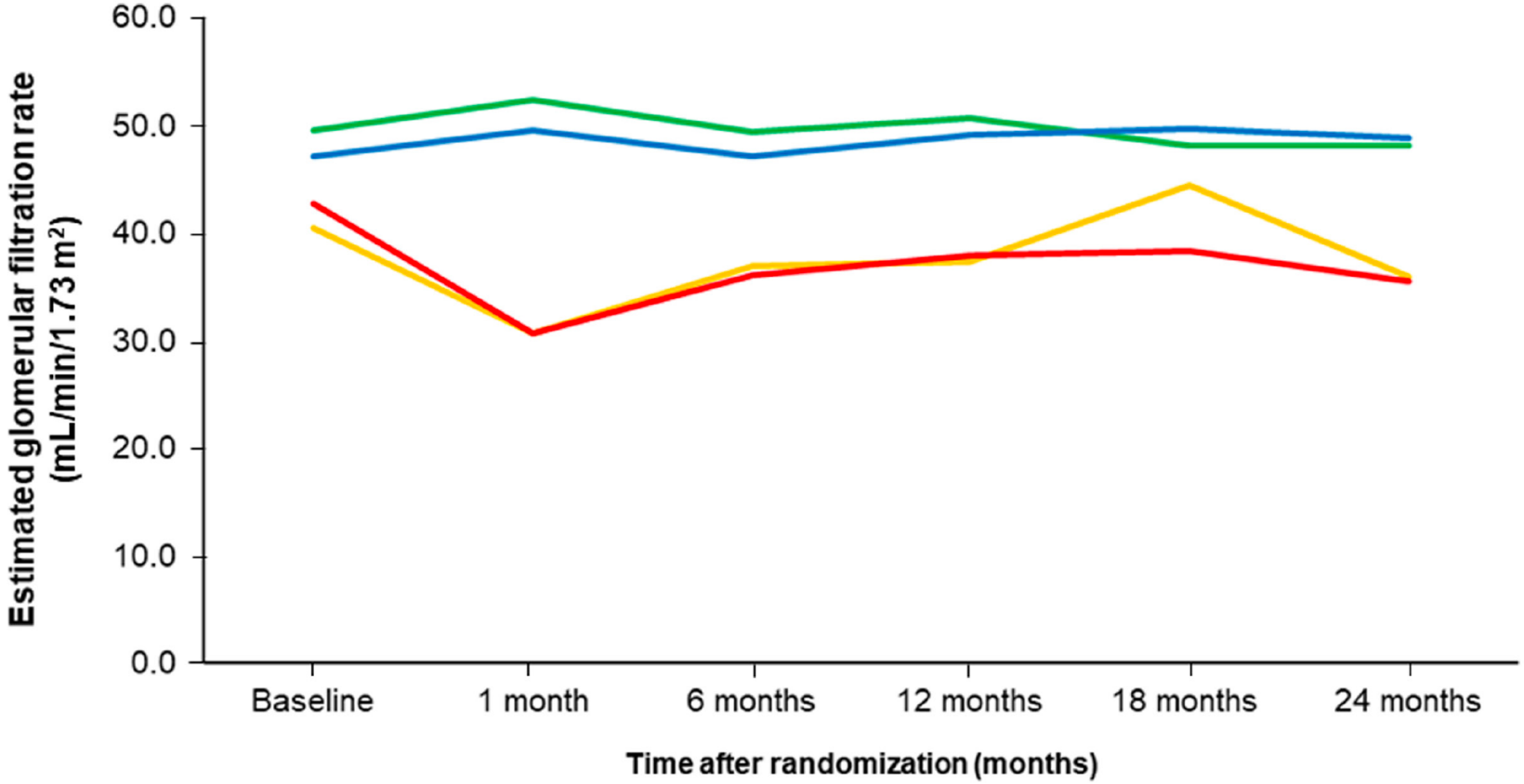
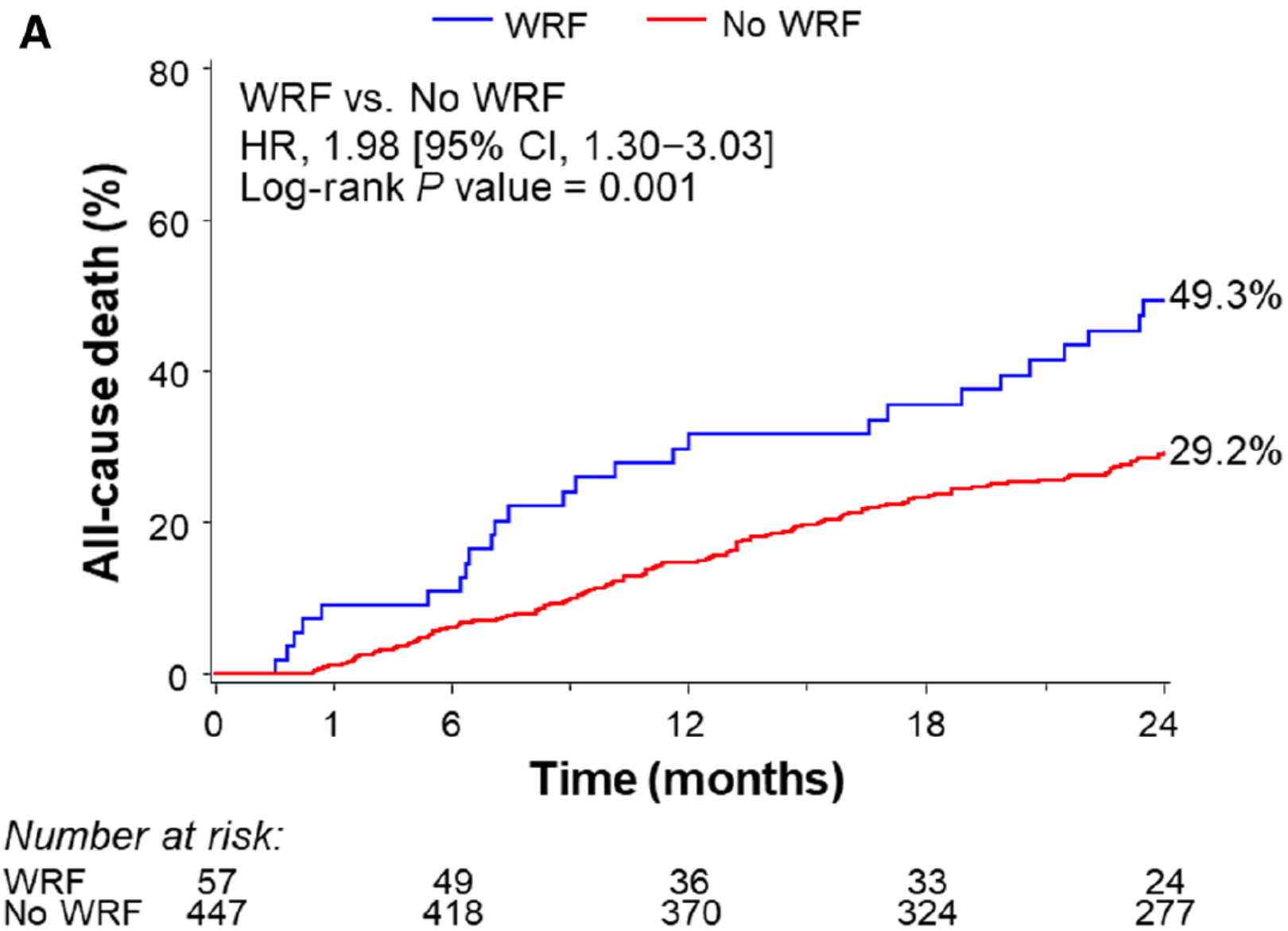
Beta-blockers	93.0 (53/57)	91.1 (407/447)	0.63
Diuretic	94.7 (54/57)	92.8 (415/447)	0.60
Prior device implantation			
Implantable cardioverter-defibrillator	14.0 (8/57)	35.3 (158/447)	0.001
Cardiac resynchronization therapy	45.6 (26/57)	36.2 (162/447)	0.17
Vital signs			
Systolic blood pressure, mm Hg	113.5±14.5	110.6±16.5	0.21
Heart rate, bpm	75.7±13.3	74.1±12.3	0.34
Laboratory findings			
Estimated glomerular filtration rate, mL/min per 1.73 m^2	41.6±15.3	48.3±20.6	0.02
≤60 mL/min per 1.73 m^2	89.5 (51/57)	75.2 (336/447)	0.02
BNP or NT-proBNP converted, pg/mL*	1106.0±1339.8	823.2±994.9	0.057

Kong J et al., J Am Heart Assoc. 2023;12:e029504

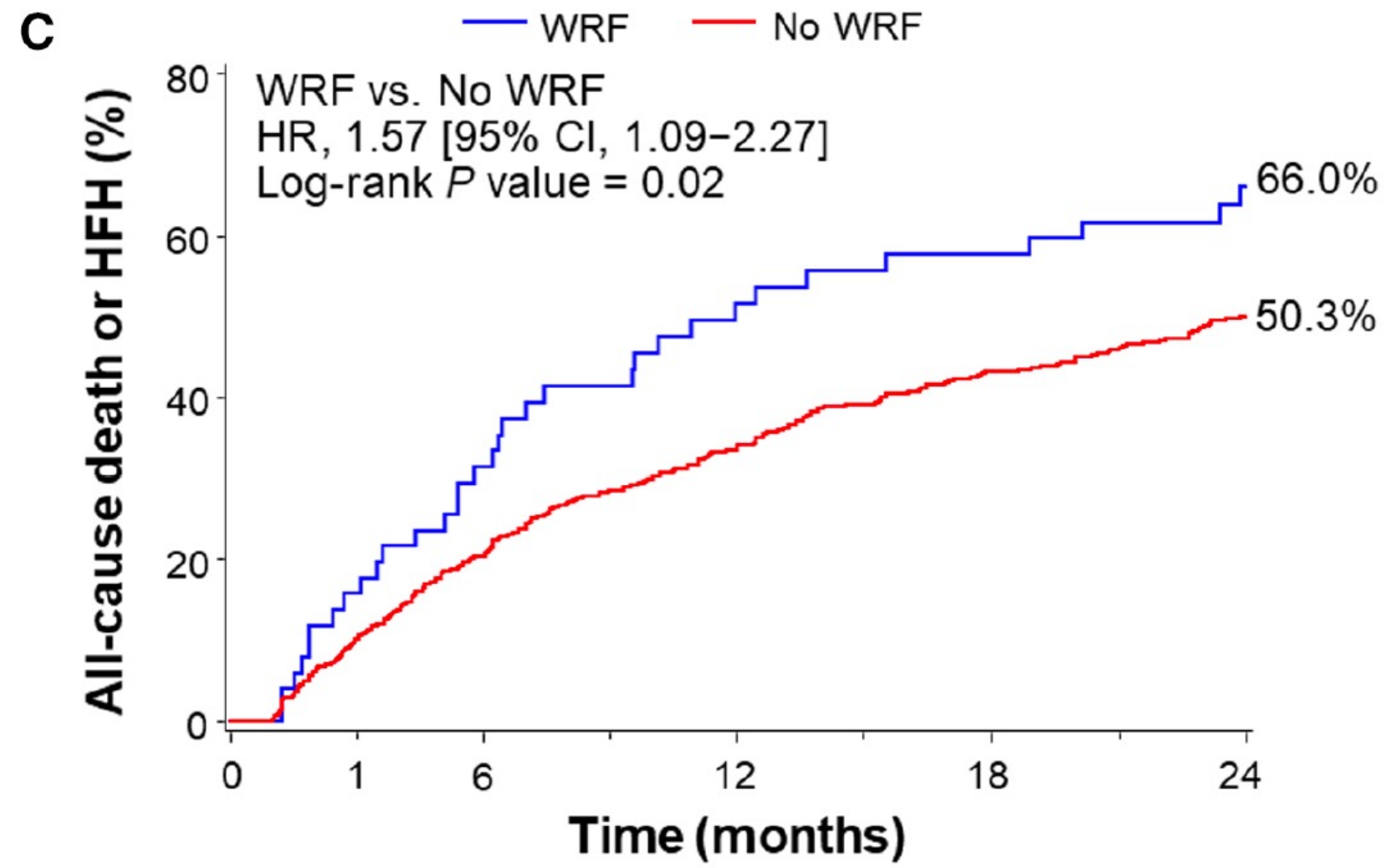


NUMBER OF OBSERVATIONS	Baseline	1 month	6 months	12 months	18 months	24 months
WRF – TEER + GDMT	40.4 ± 12.4 n = 25	30.6 ± 9.7 n = 24	36.9 ± 9.5 n = 17	37.2 ± 7.8 n = 17	44.4 ± 12.7 n = 12	35.9 ± 9.6 n = 11
WRF – GDMT alone	42.6 ± 17.3 n = 32	30.6 ± 10.5 n = 31	36.0 ± 12.6 n = 20	37.8 ± 13.9 n = 15	38.3 ± 11.8 n = 11	35.4 ± 13.7 n = 7
No WRF – TEER + GDMT	49.5 ± 21.1 n = 234	52.3 ± 20.9 n = 234	49.4 ± 19.9 n = 207	50.6 ± 20.1 n = 177	48.1 ± 20.3 n = 134	48.0 ± 21.0 n = 105
No WRF – GDMT alone	47.1 ± 20.1 n = 213	49.5 ± 21.3 n = 213	47.0 ± 20.5 n = 174	49.0 ± 21.8 n = 143	49.6 ± 21.5 n = 95	48.7 ± 22.0 n = 70

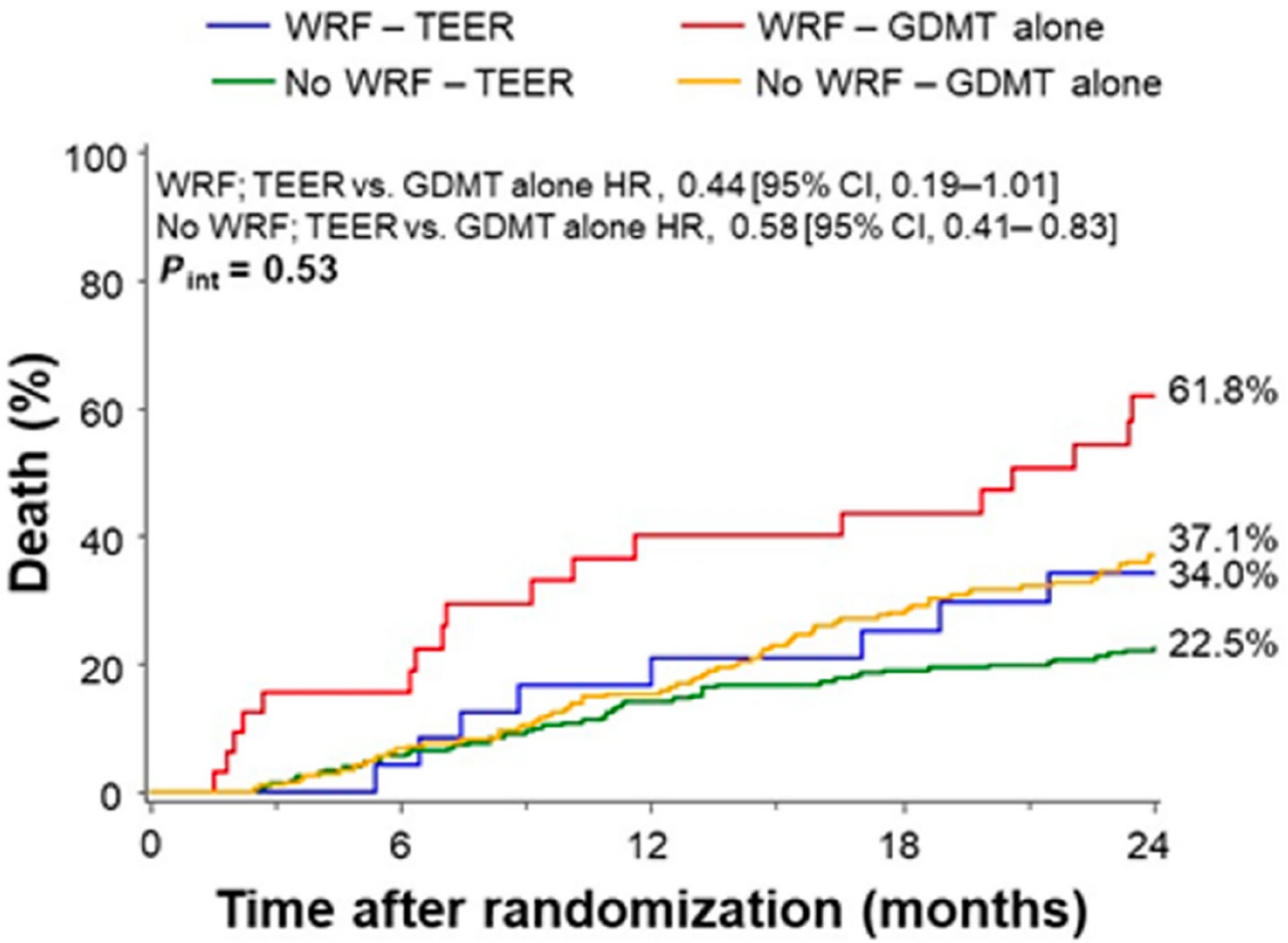
Kong J et al., J Am Heart Assoc. 2023;12:e029504



Kong J et al., J Am Heart Assoc. 2023;12:e029504



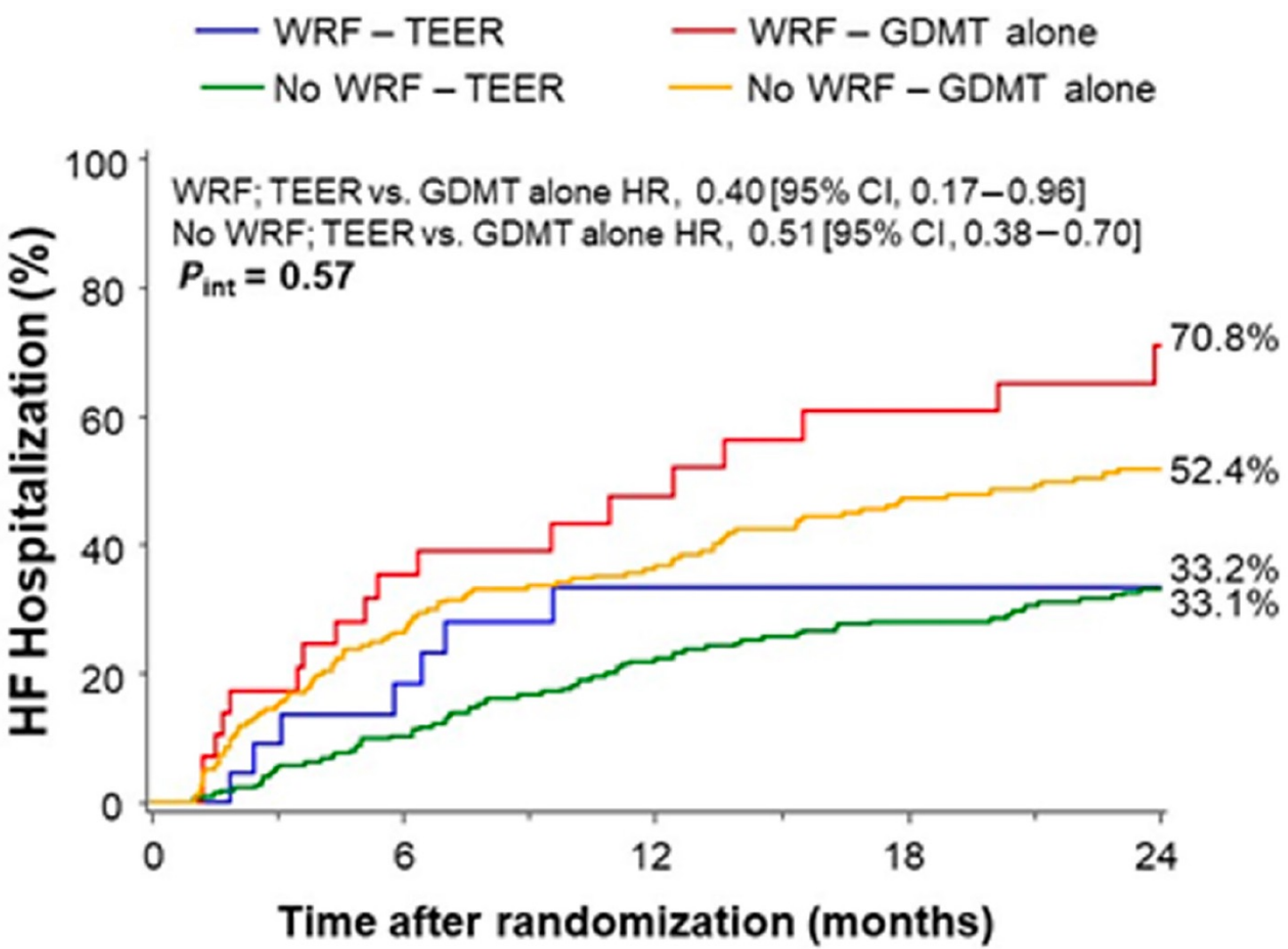
Kong J et al., J Am Heart Assoc. 2023;12:e029504



Number at risk:

WRF – TEER	25	23	19	17	14
WRF – GDMT alone	32	26	17	16	10
No WRF – TEER	234	221	199	185	164
No WRF – GDMT alone	213	197	171	139	113

Kong J et al., J Am Heart Assoc. 2023;12:e029504



Number at risk:

WRF – TEER	25	17	12	12	10
WRF – GDMT alone	32	18	12	9	5
No WRF – TEER	234	197	164	147	126
No WRF – GDMT alone	213	146	114	87	68

Kong J et al., J Am Heart Assoc. 2023;12:e029504

Trikuspidalklappe

Chronic Kidney Disease Modifies the Association of Tricuspid Regurgitation with Overall Survival

Insights from SHEBAHEART big data

Ranel Loutati

Viana Copeland; Robert Klempfner, MD; Sagit Ben-Zekry, MD; Efrat Mazor, MD; Paul Fefer, MD; Israel M. Barbash, MD; Victor Guetta, MD; Amit Segev, MD; Rafael Kuperstein, MD; Elad Maor, MD PhD

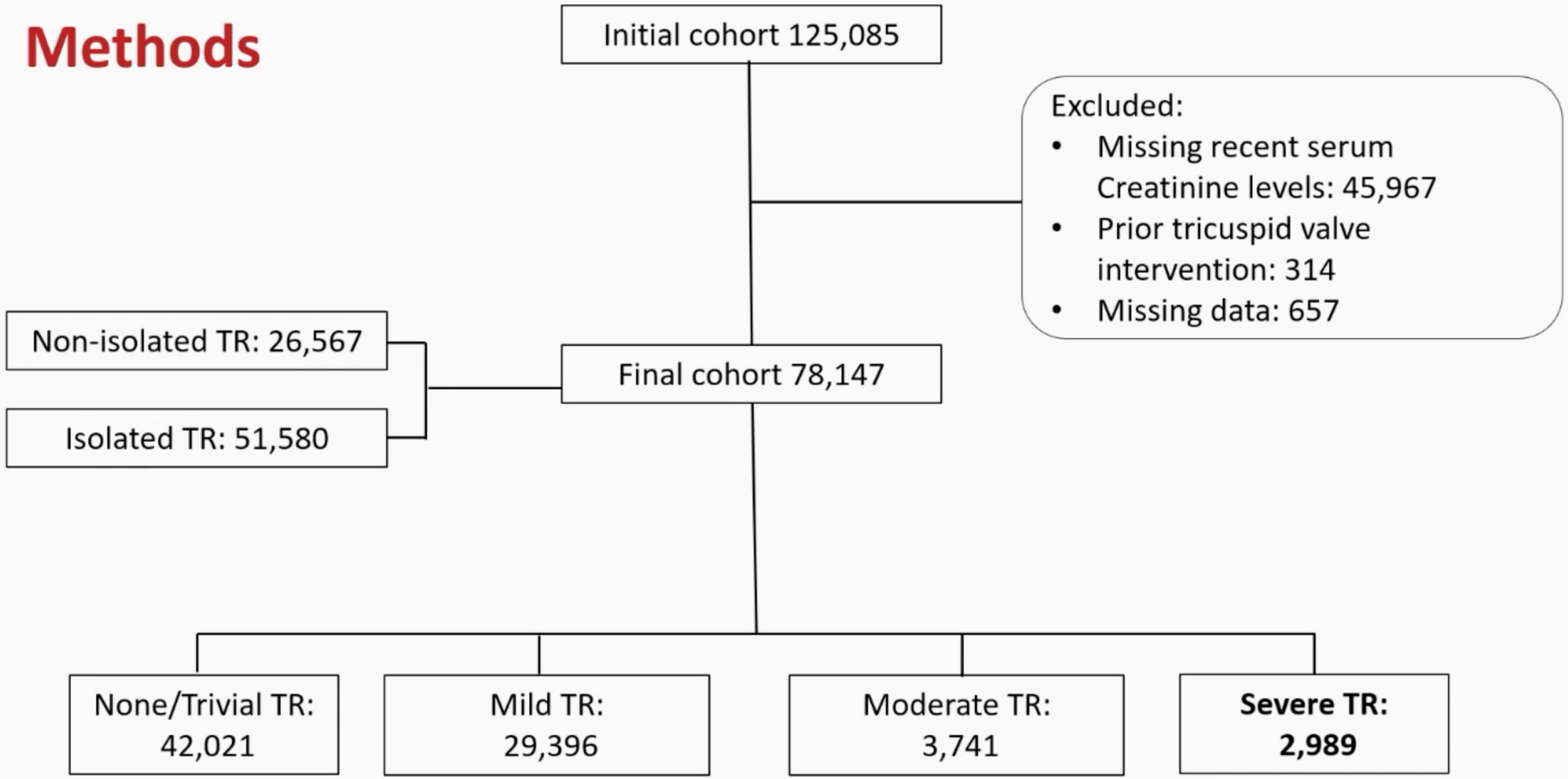
Chaim Sheba Medical Center, Tel Hashomer, Israel; Sackler School of Medicine, Tel Aviv University, Tel Aviv, Israel

28/08/2023

ESC Congress 2023
Amsterdam & Online

SHEBA Tel HaShomer | The Leviev Cardiothoracic & Vascular Center

Methods



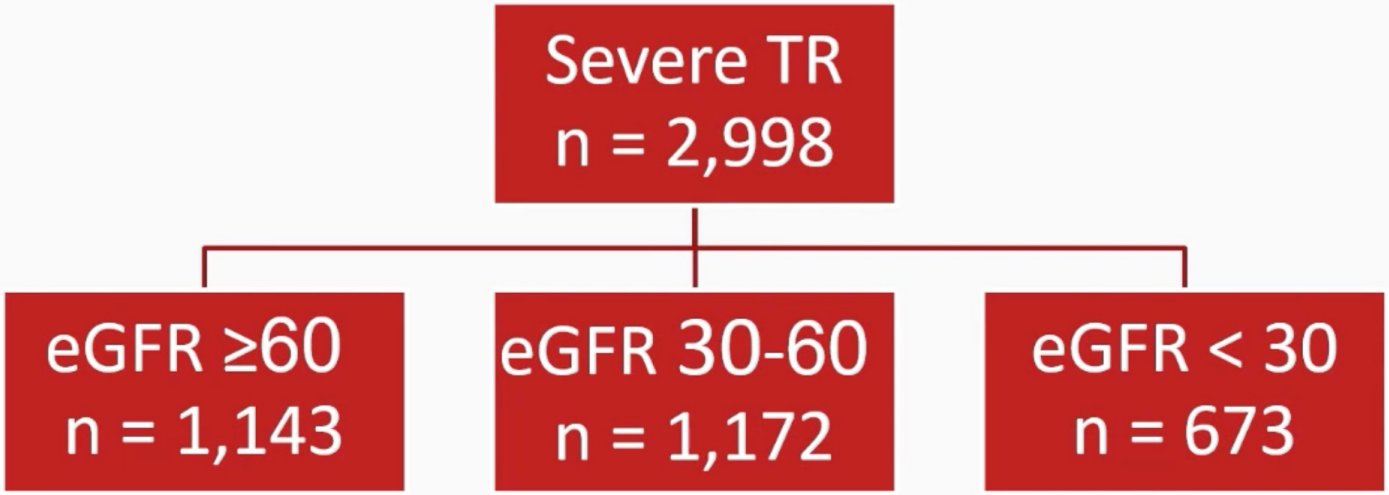
Loutati R et al., ESC 2023

Results

	Severe TR (N=2,989)	All patients (N=78,147)
Age	75.0 ± 14.4	64.9 ± 17.3
Female sex	1,673 (56.0%)	32,561 (41.7%)
Atrial Fibrillation	1,823 (61.0%)	16,904 (21.6%)
LVEF	46.7 ± 16.8	55.2 ± 11.5
CKD (eGFR ≤ 60)	1,845 (61.5%)	19,910 (25.5%)

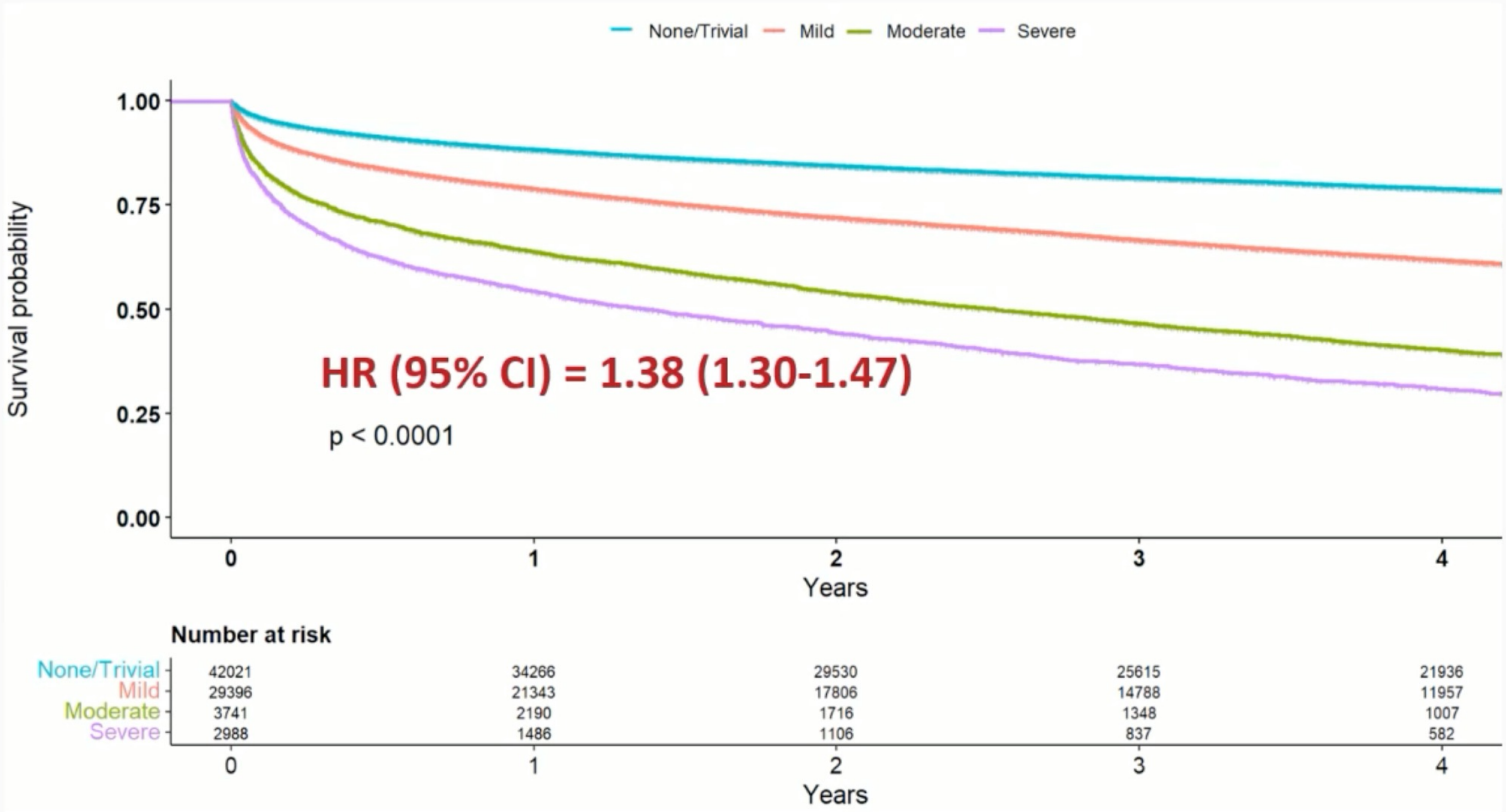
Loutati R et al., ESC 2023

Results



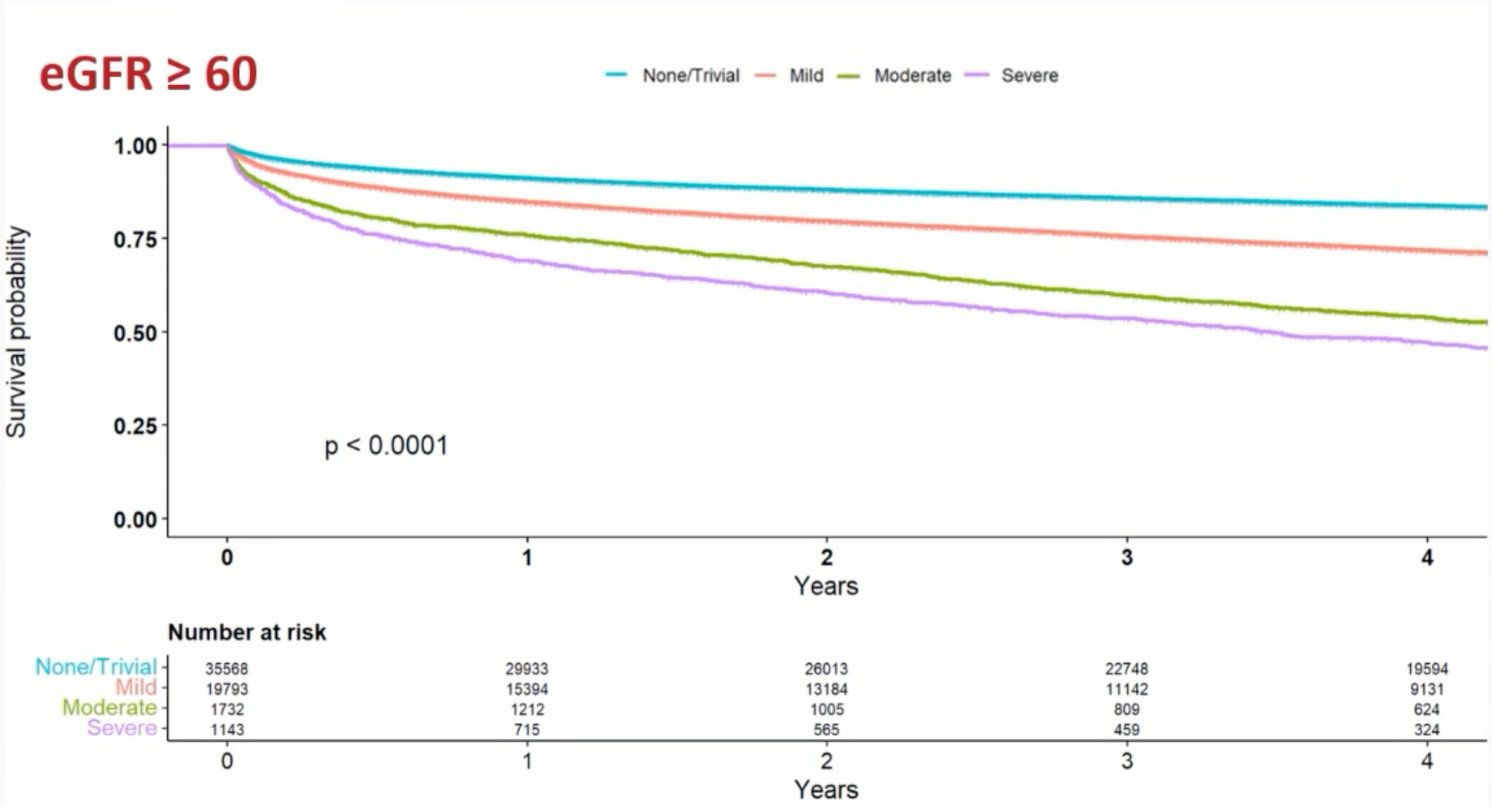
Loutati R et al., ESC 2023

TR Severity and Overall Survival



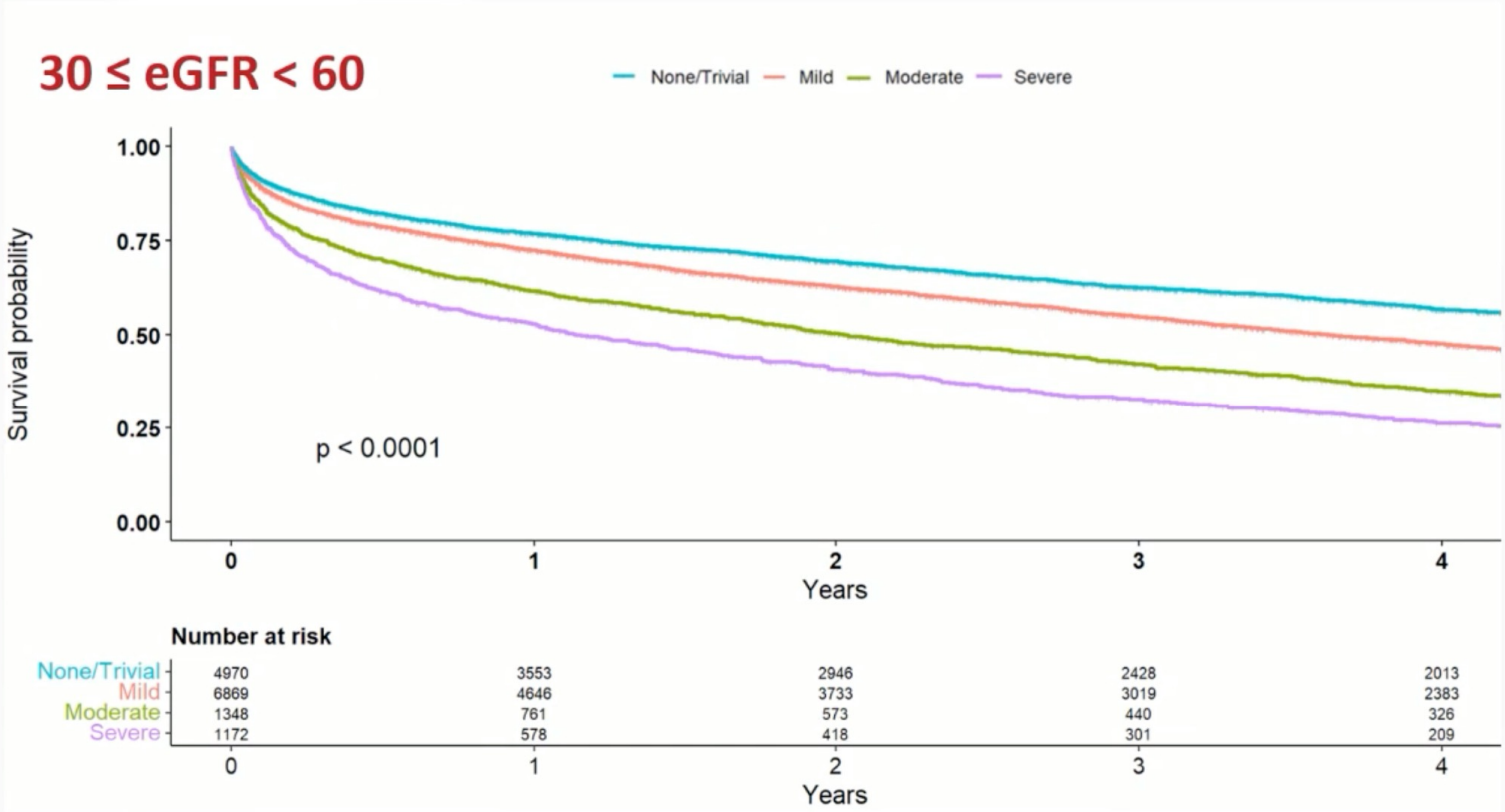
Loutati R et al., ESC 2023

CKD Modification Effect



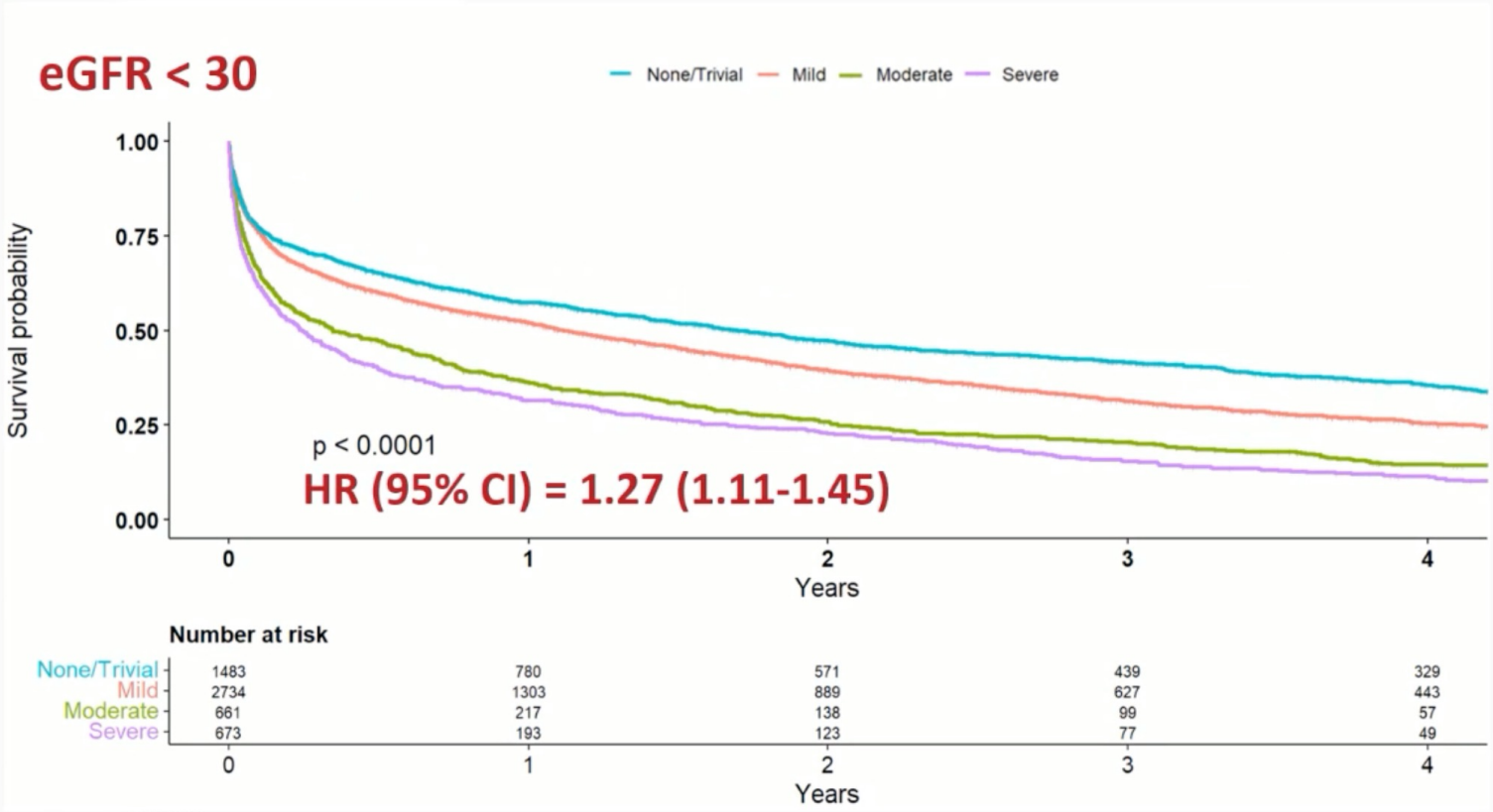
Loutati R et al., ESC 2023

CKD Modification Effect



Loutati R et al., ESC 2023

CKD Modification Effect

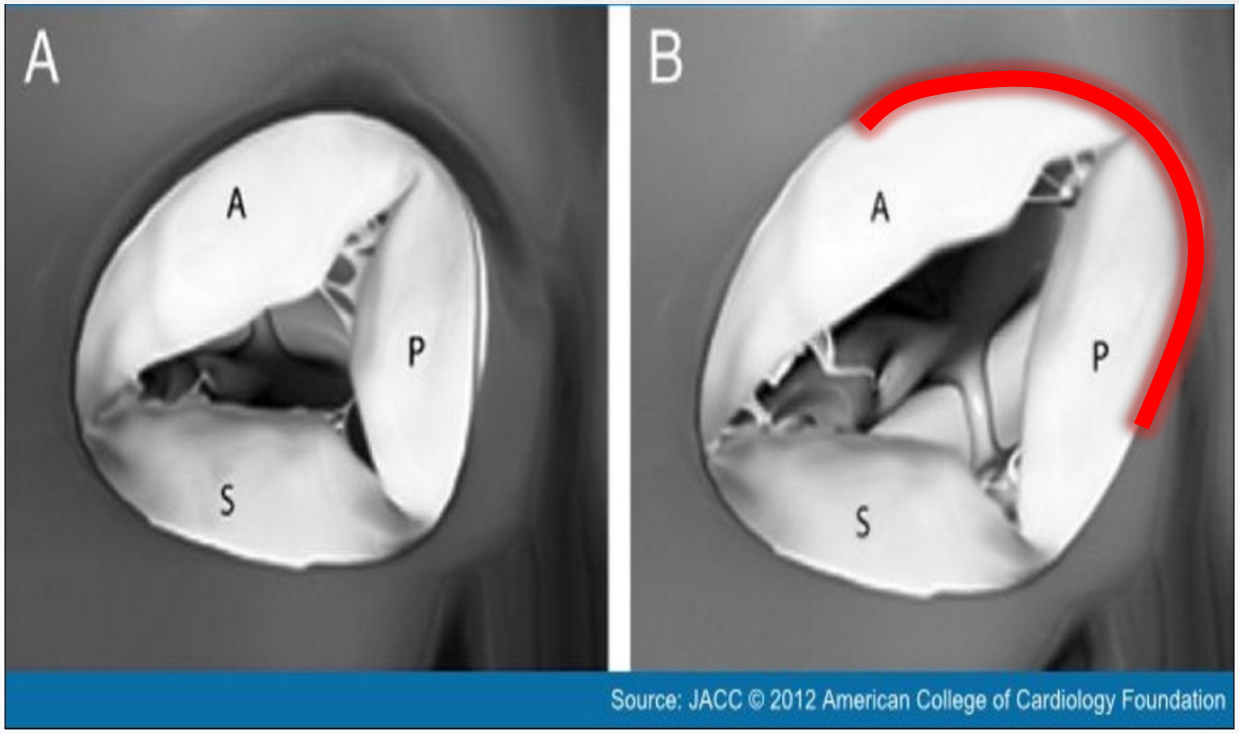


Loutati R et al., ESC 2023

TEER Trikuspidalklappe

Funktionelle Trikuspidalklappeninsuffizienz ist oft die Folge einer annulären Dilatation

Normale Trikuspidalklappe | Antero-Posteriore Dilatation des Annulus



- **TI ist Folge antero-posteriorer Dilatation**
- **TI ist oft sekundär bei Linksherzinsuffizienz**
- **Ca 30% - 50% der Mitralpatienten haben eine signifikante TI**
- **Herzchirurgische Mortalität = 10-15%. Outcome unklar.**

Dreyfus, G. et al. JACC 2015 Vol 65, Issue 21

TriClip für die Trikuspidalklappe

Multi-axis steering enables movement across all lines of coaptation

F/E Knob

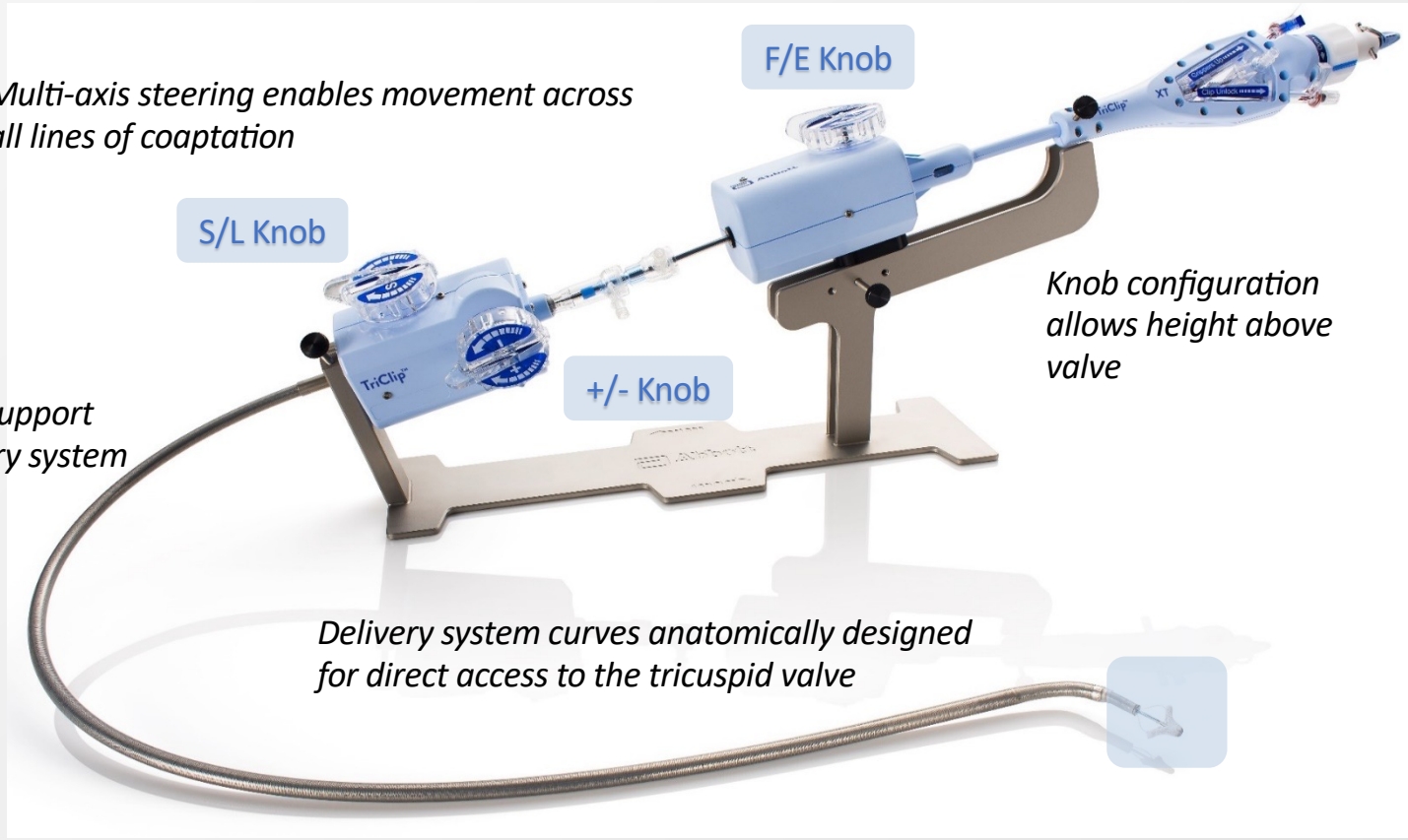
S/L Knob

+/- Knob

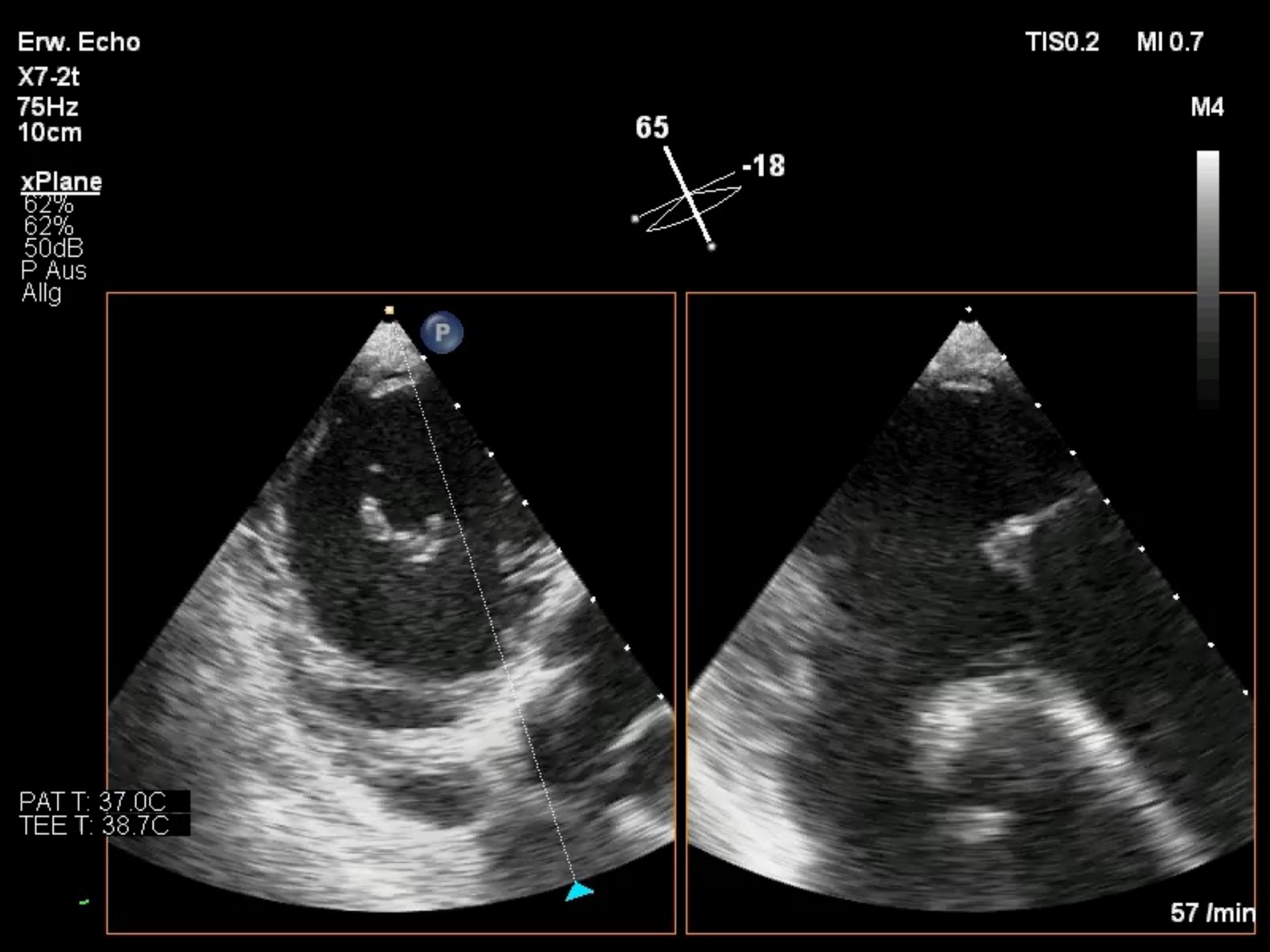
Knob configuration allows height above valve

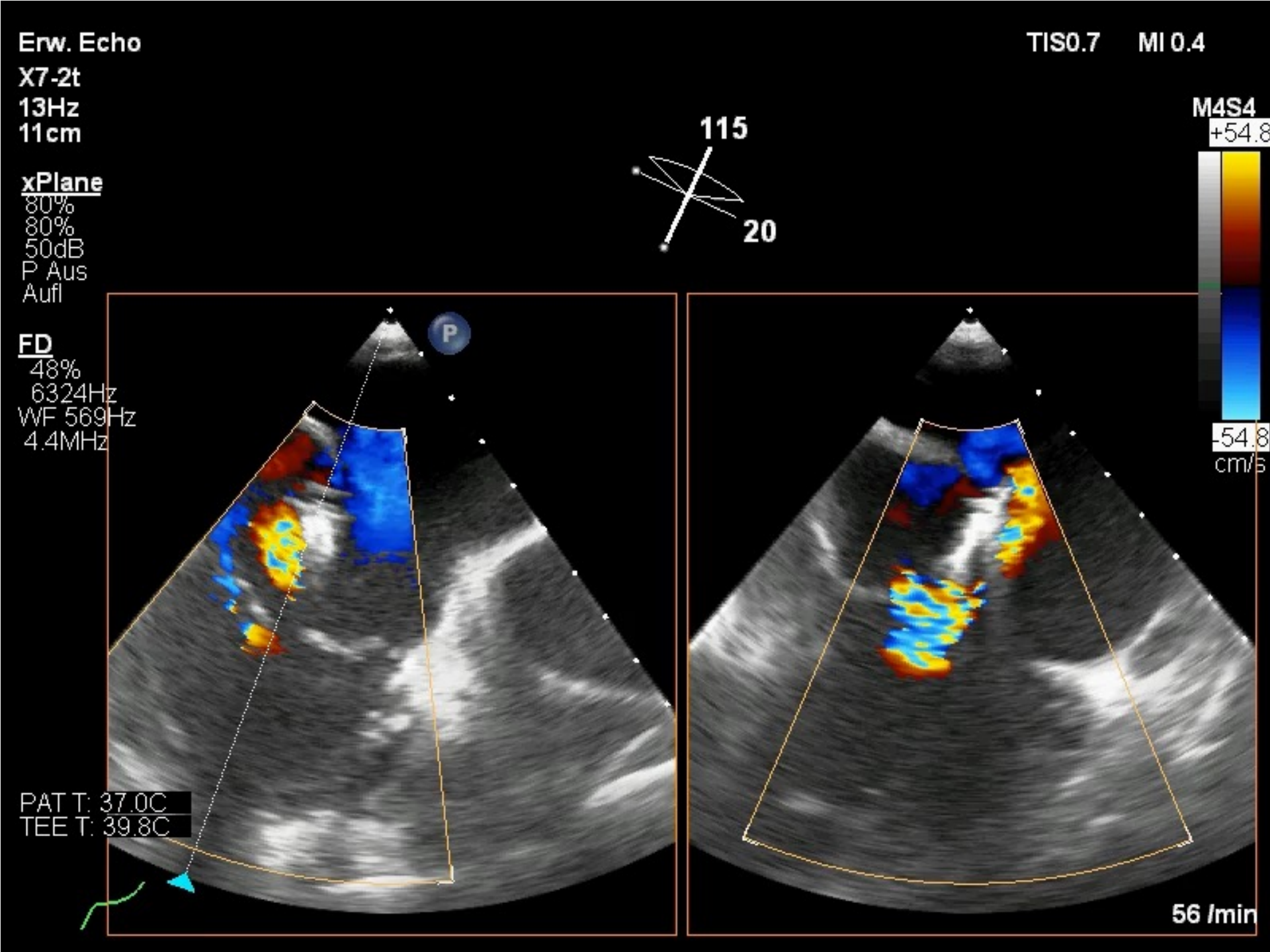
High support delivery system

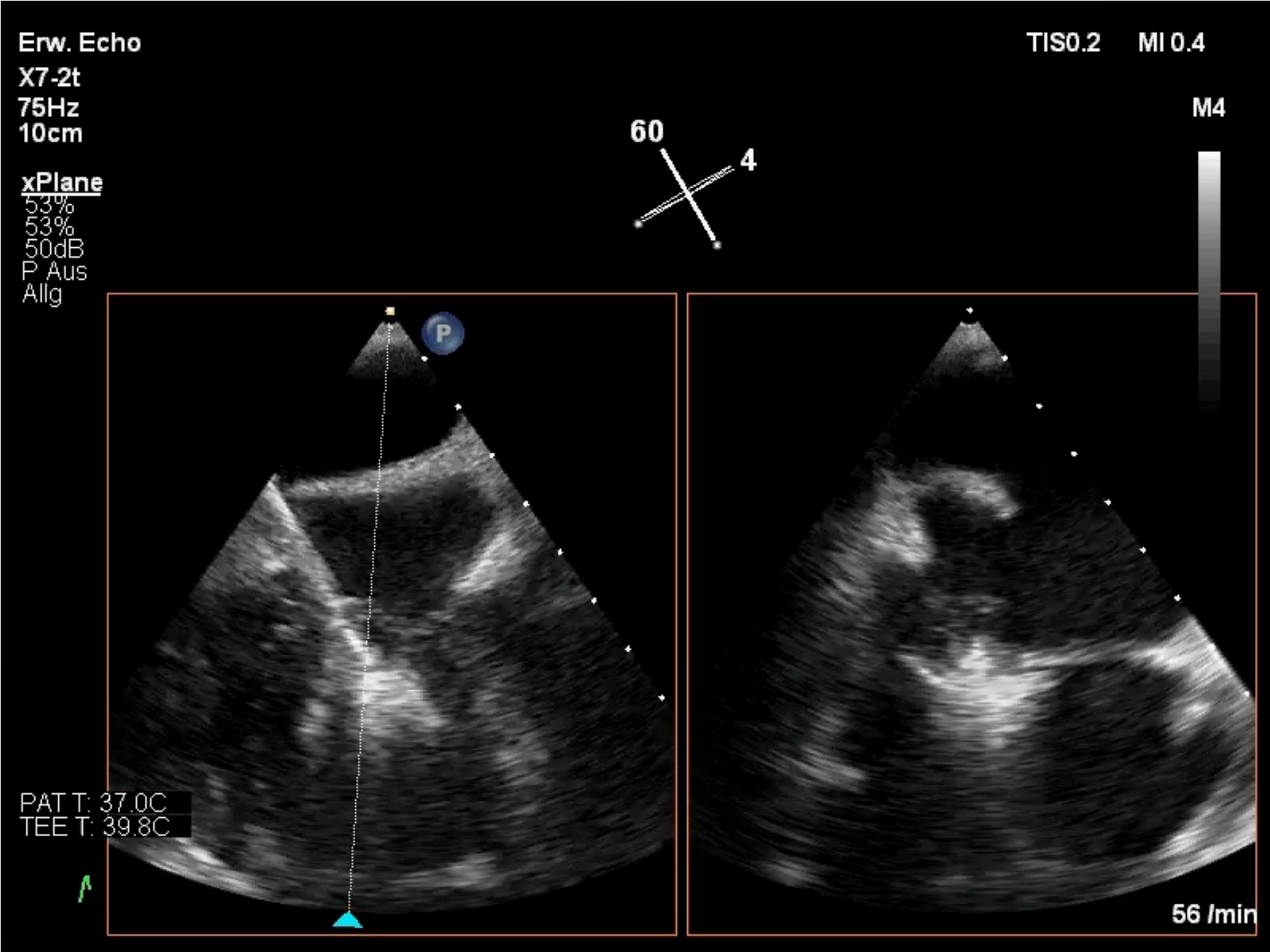
Delivery system curves anatomically designed for direct access to the tricuspid valve

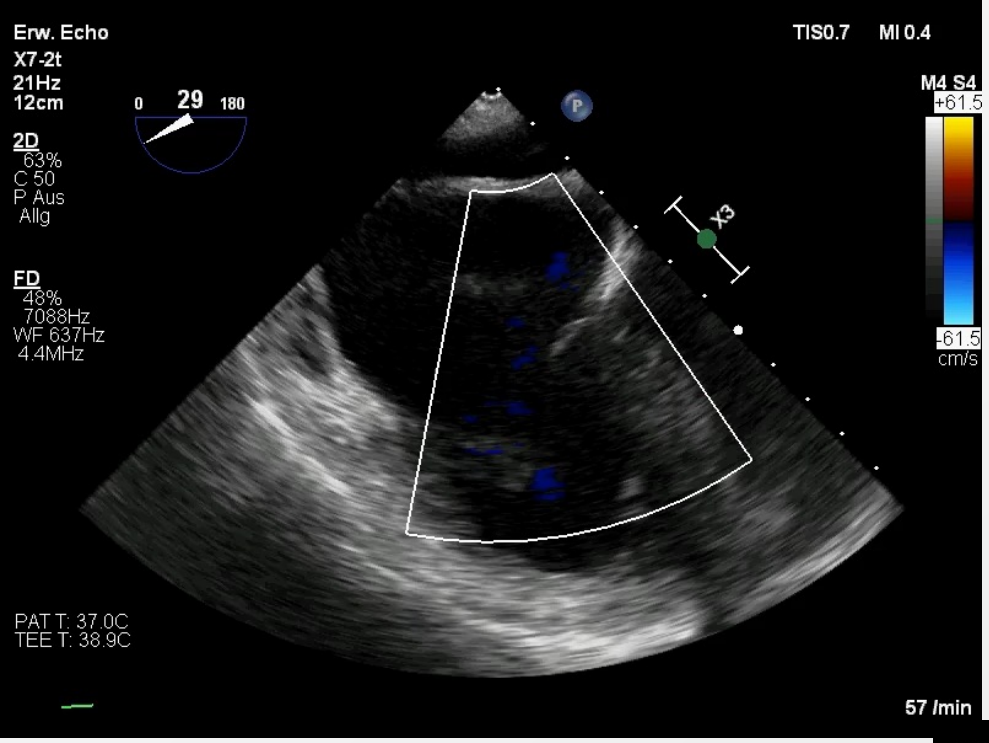


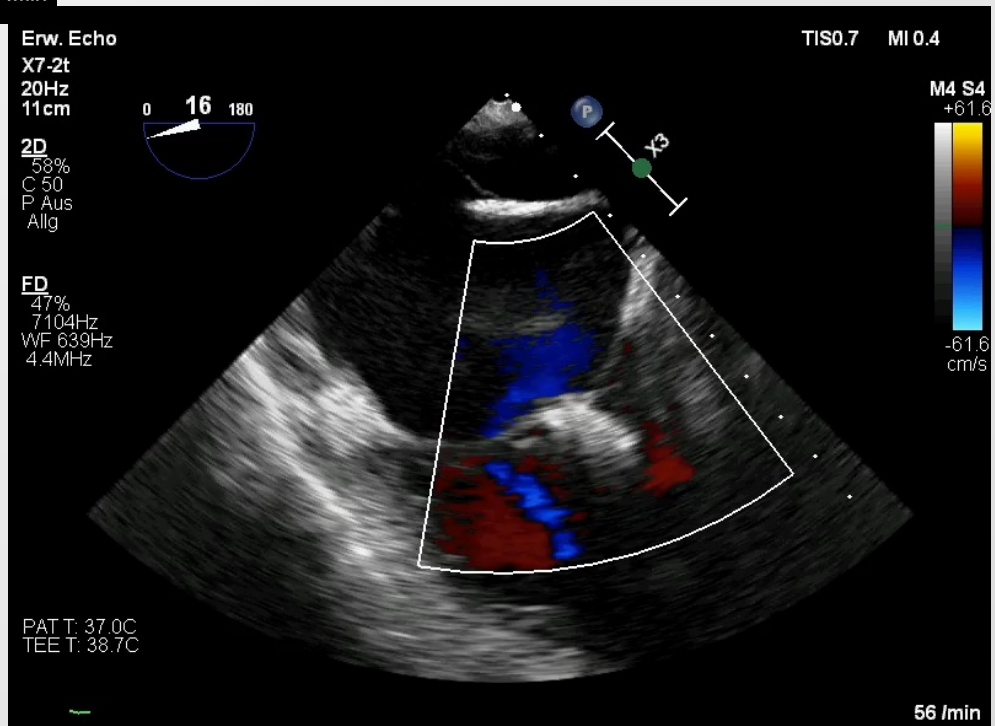
2 GRÖSSEN


Erw. Echo
X7-2t
75Hz
10cm
xPlane
62%
62%
50dB
P Aus
Allg
TIS0.2
MI 0.7
M4
65
-18
P
PAT T: 37.0C
TEE T: 38.7C
57 /min


Erw. Echo
X7-2t
13Hz
11cm
TIS0.7
MI 0.4
M4S4
+54.8
-54.8
cm/s
115
20
xPlane
80%
80%
50dB
P Aus
Aufl
FD
48%
6324Hz
WF 569Hz
4.4MHz
P
PAT T: 37.0C
TEE T: 39.8C
56 /min


Erw. Echo
X7-2t
75Hz
10cm
xPlane
53%
53%
50dB
P Aus
Allg
TIS0.2
MI 0.4
M4
60
4
P
PAT T: 37.0C
TEE T: 39.8C
56 /min


Erw. Echo
X7-2t
21Hz
12cm
0 29 180
2D
63%
C 50
P Aus
Allg
FD
48%
7088Hz
WF 637Hz
4.4MHz
TIS0.7 MI 0.4
M4 S4
+61.5
-61.5
cm/s
X3
PAT T: 37.0C
TEE T: 38.9C
57 /min


Erw. Echo
X7-2t
20Hz
11cm
0 16 180
2D
58%
C 50
P Aus
Allg
FD
47%
7104Hz
WF 639Hz
4.4MHz
TIS0.7 MI 0.4
M4 S4
+61.6
-61.6
cm/s
X3
PAT T: 37.0C
TEE T: 38.7C
56 /min

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 MAY 18, 2023 VOL. 388 NO. 20

Transcatheter Repair for Patients with Tricuspid Regurgitation

Paul Sorajja, M.D., Brian Whisenant, M.D., Nadira Hamid, M.D., Hursh Naik, M.D., Raj Makkar, M.D., Peter Tadros, M.D., Matthew J. Price, M.D., Gagan Singh, M.D., Neil Fam, M.D., Saibal Kar, M.D., Jonathan G. Schwartz, M.D., Shamir Mehta, M.D., Richard Bae, M.D., Nishant Sekaran, M.D., Travis Warner, M.D., Moody Makar, M.D., George Zorn, M.D., Erin M. Spinner, Ph.D., Phillip M. Trusty, Ph.D., Raymond Benza, M.D., Ulrich Jorde, M.D., Patrick McCarthy, M.D., Vinod Thourani, M.D., Gilbert H.L. Tang, M.D., Rebecca T. Hahn, M.D., and David H. Adams, M.D., for the TRILUMINATE Pivotal Investigators*

Baseline Characteristics

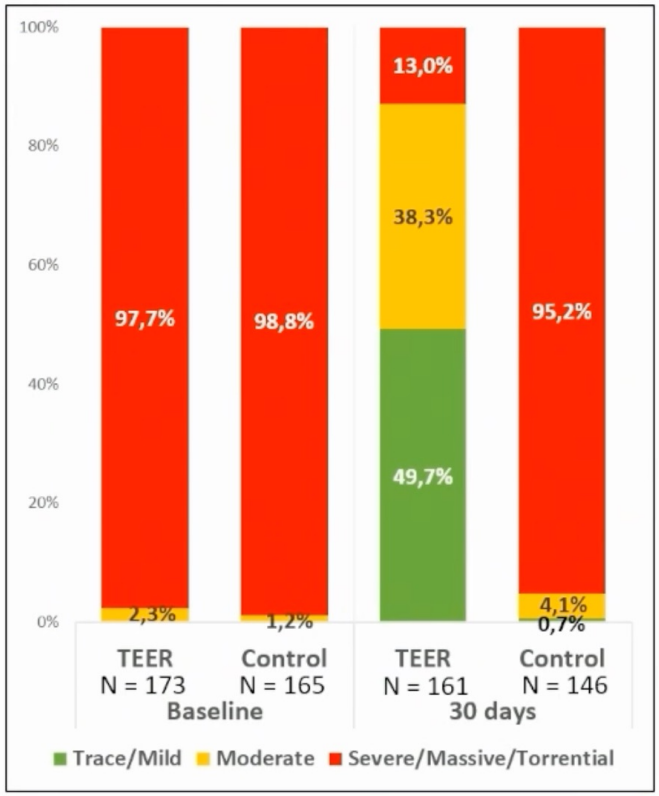
	Device N=175 # (%)	Control N=175 # (%)
Age, Mean (years)	78.0 ± 7.4	77.8 ± 7.2
Sex (Female)	98 (56.0)	94 (53.7)
NYHA class III or IV	104 (59.4)	97 (55.4)
KCCQ Score, mean	56.0 ± 23.4	54.1 ± 24.2
Hypertension	142 (81.1)	141 (80.6)
Renal disease	62 (35.4)	62 (35.4)
Liver disease	11 (6.3)	16 (9.1)
Atrial fibrillation	153 (87.4)	162 (92.6)
Diabetes	28 (16.0)	27 (15.4)
COPD	19 (10.9)	24 (13.7)
CRT/CRT-D/ICD/PPM	28 (16.0)	24 (13.7)
Prior aortic intervention	27 (15.4)	27 (15.4)
Prior mitral intervention	45 (25.7)	42 (24.0)
Prior tricuspid intervention	1 (0.6)	0 (0.0)

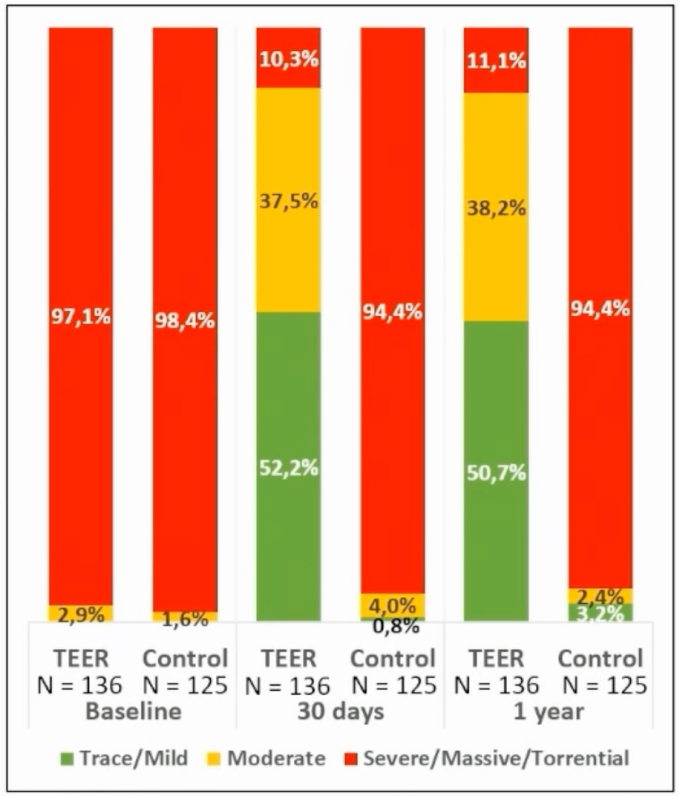
	Device N=175 # (%)	Control N=175 # (%)
TR Severity		
Moderate	4 (2.3)	2 (1.2)
Severe	44 (25.4)	49 (29.7)
Massive	37 (21.4)	30 (18.2)
Torrential	88 (50.9)	84 (50.9)
Etiology (functional)	165 (94.8)	158 (92.9)
Coaptation Gap, Mean (mm)	5.5 ± 1.8	5.2 ± 1.7
Heart size/function, Mean		
RVEDD (base, cm)	5.0 ± 0.8	5.2 ± 0.8
TV annulus diameter (cm)	4.3 ± 0.7	4.5 ± 0.8
RV TAPSE (cm)	1.7 ± 0.4	1.6 ± 0.4
LVEF (%)	59.3 ± 9.3	58.7 ± 10.5
CO (L/min)	4.1 ± 1.2	4.2 ± 1.1

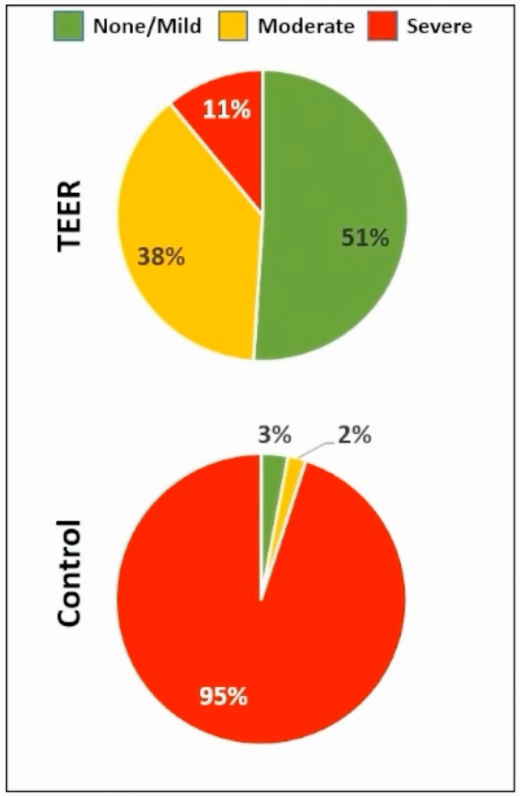
TRILUMINATE™ PIVOTAL TRIAL

ECHOCARDIOGRAPHIC OUTCOMES - TR SEVERITY

Sorajja et al. N Engl J Med 2023;388(20):1833-1842.







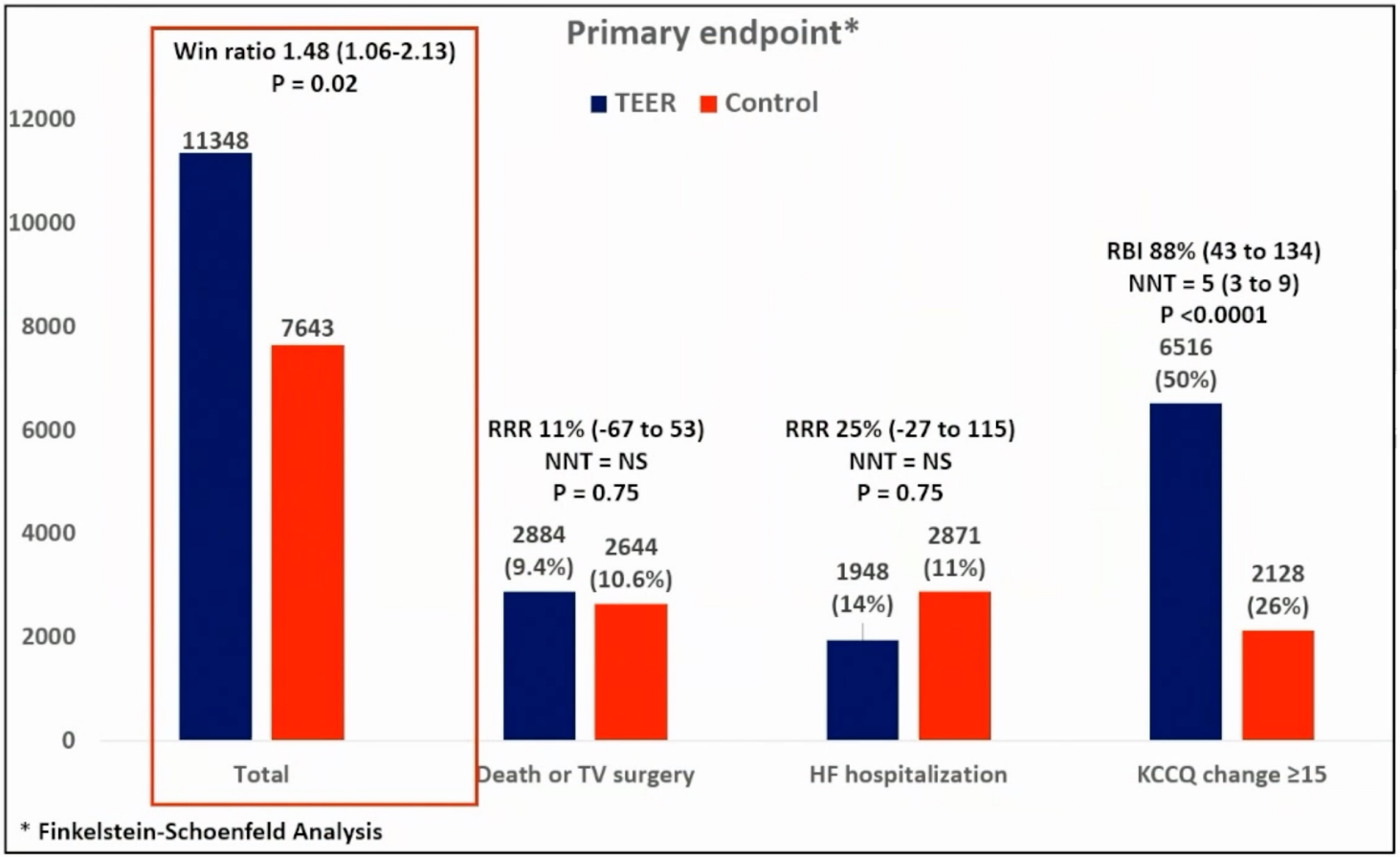
✓ *TR was reduced by TriClip therapy to moderate or less in 87%, vs. 4.8% for the control group, and reductions were sustained througout 1-year F/U, 7% SLDA*

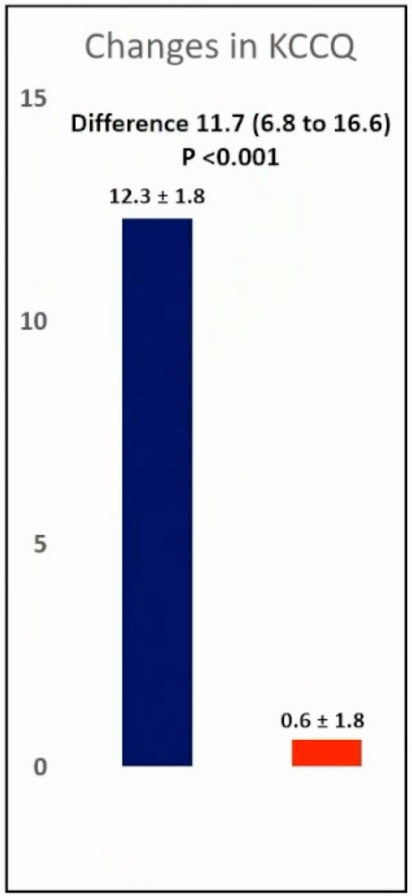
TRILUMINATE PIVOTAL TRIAL

TRILUMINATE
PIVOTAL TRIAL

CLINICAL OUTCOMES - TRILUMINATE PIVOTAL TRIAL

Sorajja et al. N Engl J Med 2023;388(20):1833-1842.





Safety Profile

Major Adverse Event (MAE) Through 30 Days Post-Procedure – no.(%)	Device N=172†
Total	**3 (1.7%)**
Cardiovascular mortality	1 (0.6%)
Endocarditis requiring surgery	0 (0%)
New-onset renal failure	2 (1.2%)
Non-elective CV Surgery, TVRS for device-related AE	0 (0%)

Other Clinical Safety Endpoints Through 30 Days Post-Procedure– no.(%)	Device N=172†
Any-cause mortality	1 (0.6%)
Tricuspid valve surgery	1 (0.6%)
Tricuspid valve re-intervention	3 (1.7%)
Major bleeding#	8 (4.7%)
Tricuspid mean gradient ≥ 5mmHg	8 (4.7%)
Single leaflet device attachment (SLDA)*	12 (7.0%)
Stroke	1 (0.6%)
Myocardial Infarction	0 (0%)
Embolization*	0 (0%)
Thrombosis	0 (0%)
New CRT/CRT-D/ICD/perm. pacemaker^	1 (0.6%)

†Attempted procedure population (3 subjects randomized to Device withdrew consent prior to index procedure)
#Defined as bleeding ≥ Type 3 based on a modified Bleeding Academic Research Consortium (BARC) definition
*SLDA and embolization evaluated through 30-day follow-up
^Assessed through adverse event reporting

TRILUMINATE™ PIVOTAL TRIAL

What is new (20)

Indications for intervention in secondary tricuspid regurgitation			
2017 VHD Guidelines	**Class**	**2021 VHD Guidelines**	**Class**
		Transcatheter treatment of symptomatic secondary severe tricuspid regurgitation may be considered in inoperable patients at a Heart Valve Centre with expertise in the treatment of tricuspid valve disease.	**IIb**

©ESC/EACTS

2021 ESC/EACTS Guidelines for the management of valvular heart disease
(European Heart Journal; 2021 – doi: 10.1093/eurheartj/ehab395; European Journal of Cardio-Thoracic Surgery; 2021 – doi: 10.1093/ejcts/ezab389)

TAVI

Aortenklappenstenose – Prognose

Lebenserwartung bei einer symptomatischen Aortenklappenstenose:

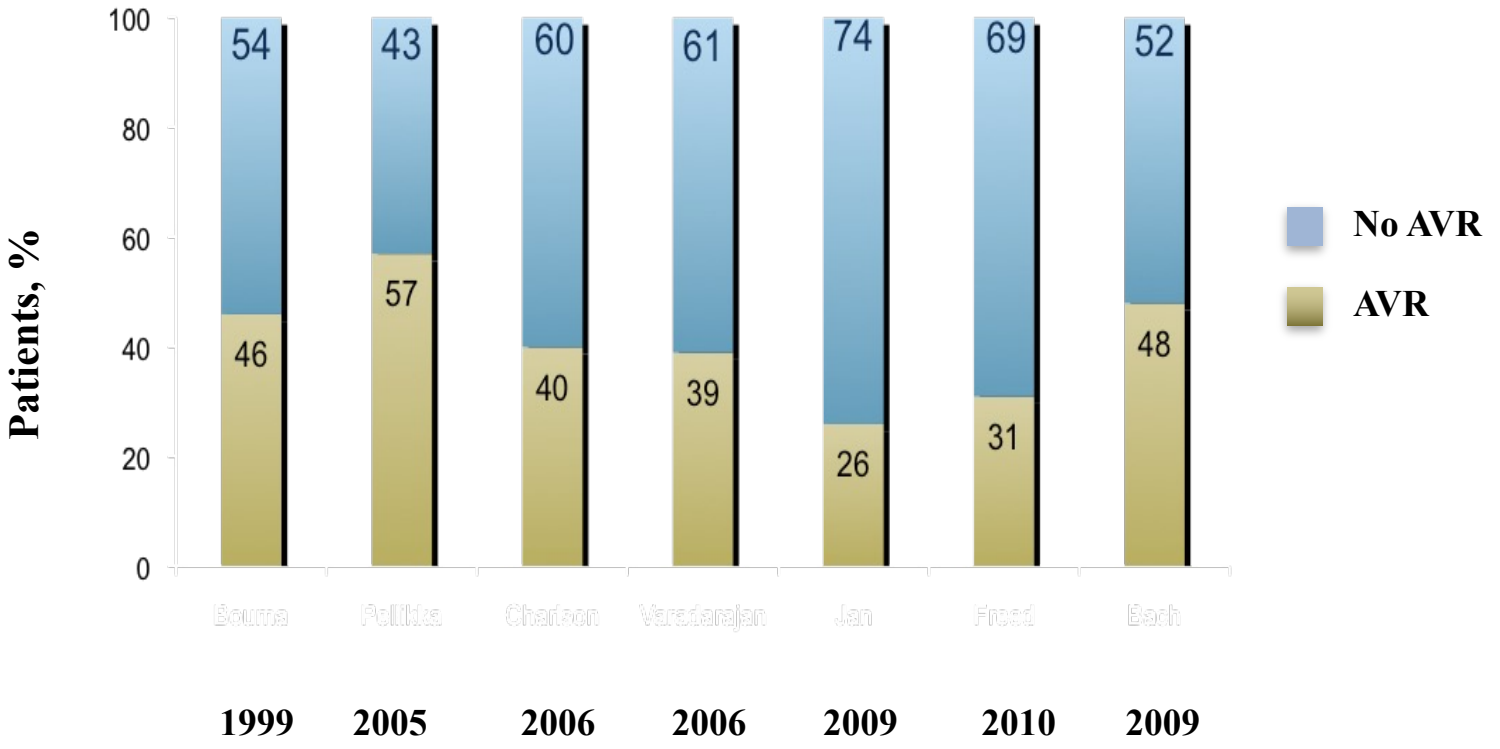
Angina pectoris	1 - 3 Jahre
Synkopen	1 - 3 Jahre
Linksherzdekompensation	1 - 2 Jahre

1-Jahres-Mortalität 50 % [1]

5-Jahres-Mortalität 94 % [1]

[1] Kapadia et al. Lancet 2015

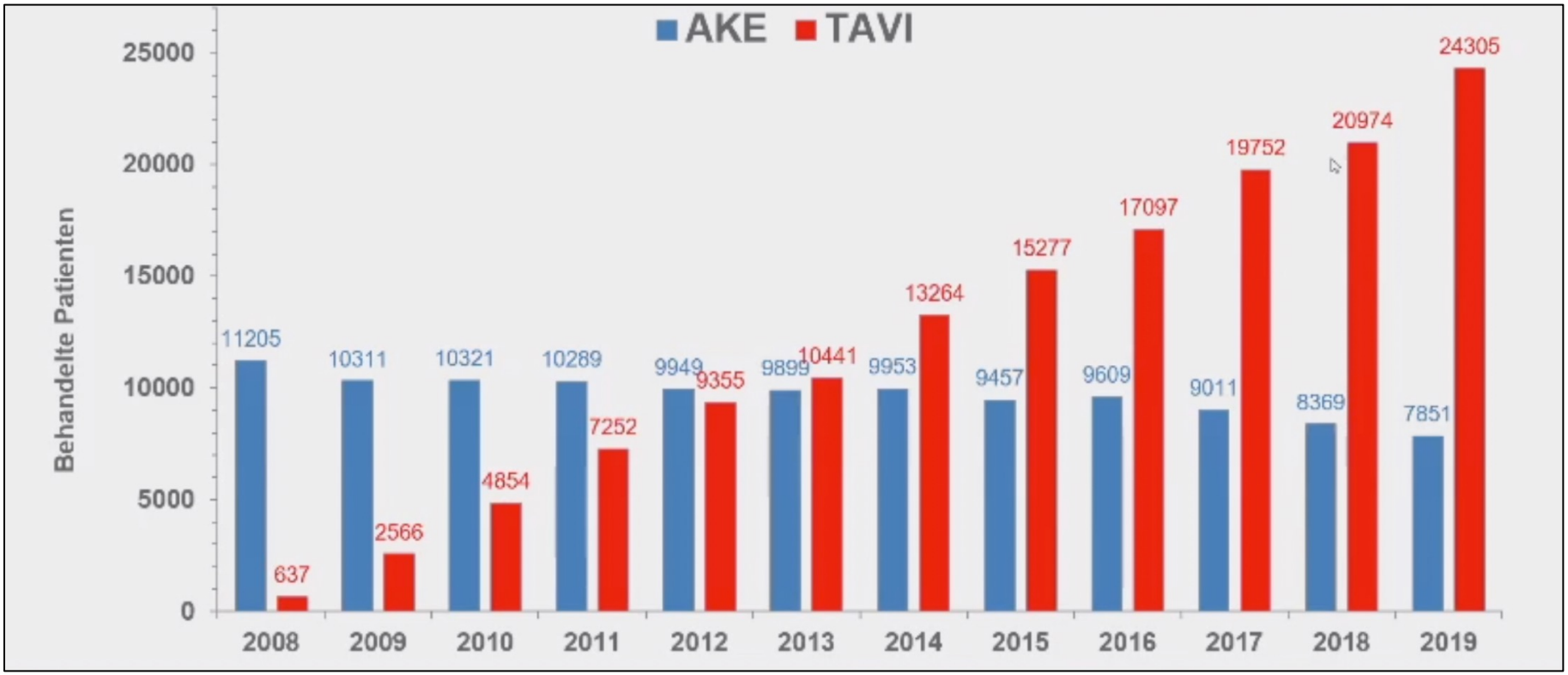
40-50 % der Patienten mit hochgradiger Aortenklappenstenose werden nicht operiert [1-7]



1. Bouma BJ, et al. To operate or not on elderly patients with aortic stenosis: the decision and its consequences. *Heart*. 1999;82:143-148.
2. Pellikka PA, et al. Outcome of 622 adults with asymptomatic, hemodynamically significant aortic stenosis during prolonged follow-up. *Circulation*. 2005;111:3290-3295.
3. Charlson E, et al. Decision-making and outcomes in severe symptomatic aortic stenosis. *J Heart Valve Dis*. 2006;15:312-321.
4. Varadarajan P, et al. Clinical profile and natural history of 453 nonsurgically managed patients with severe aortic stenosis. *Ann Thorac Surg.* 2006;82:2111-2115.
5. Jan F, et al. Unoperated patients with severe symptomatic aortic stenosis. *Circulation.* 2009;120;S753.
6. Freed BH, et al. Reasons for nonadherence to guidelines for aortic valve replacement in patients with severe aortic stenosis and potential solutions. *Am J Cardiol.* 2010;105:1339-1342.
7. Bach DS, et al. Evaluation of patients with severe symptomatic aortic stenosis who do not undergo aortic valve replacement. *Circ Cardiovasc Qual Outcomes.* 2009;2:533-539.

TAVI – Implantationstechnik

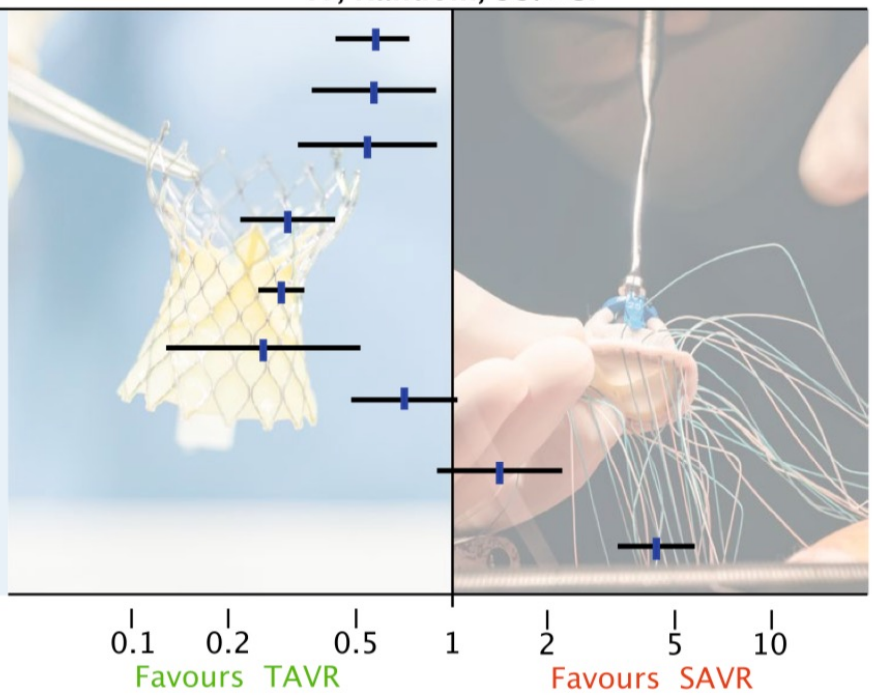
Trend in Deutschland



Daten der QS von AQUA und IQTIG 2020

TAVI vs AKE bei niedrigem Risiko

Outcome	Risk Ratio IV, Random, 95% CI
MACE	0.60 [0.46, 0.78]
Overall Mortality	0.60 [0.38, 0.94]
Cardiovascular Mortality	0.54 [0.33, 0.89]
Life Threatening/ Disabling Bleeding	0.31 [0.22, 0.43]
Atrial Fibrillation	0.25 [0.22, 0.30]
Acute Kidney Injury	0.26 [0.13, 0.52]
Stroke	0.71 [0.48, 1.04]
Major Vascular Complications	1.38 [0.88, 2.16]
Pacemaker Implantation	4.24 [3.21, 5.59]



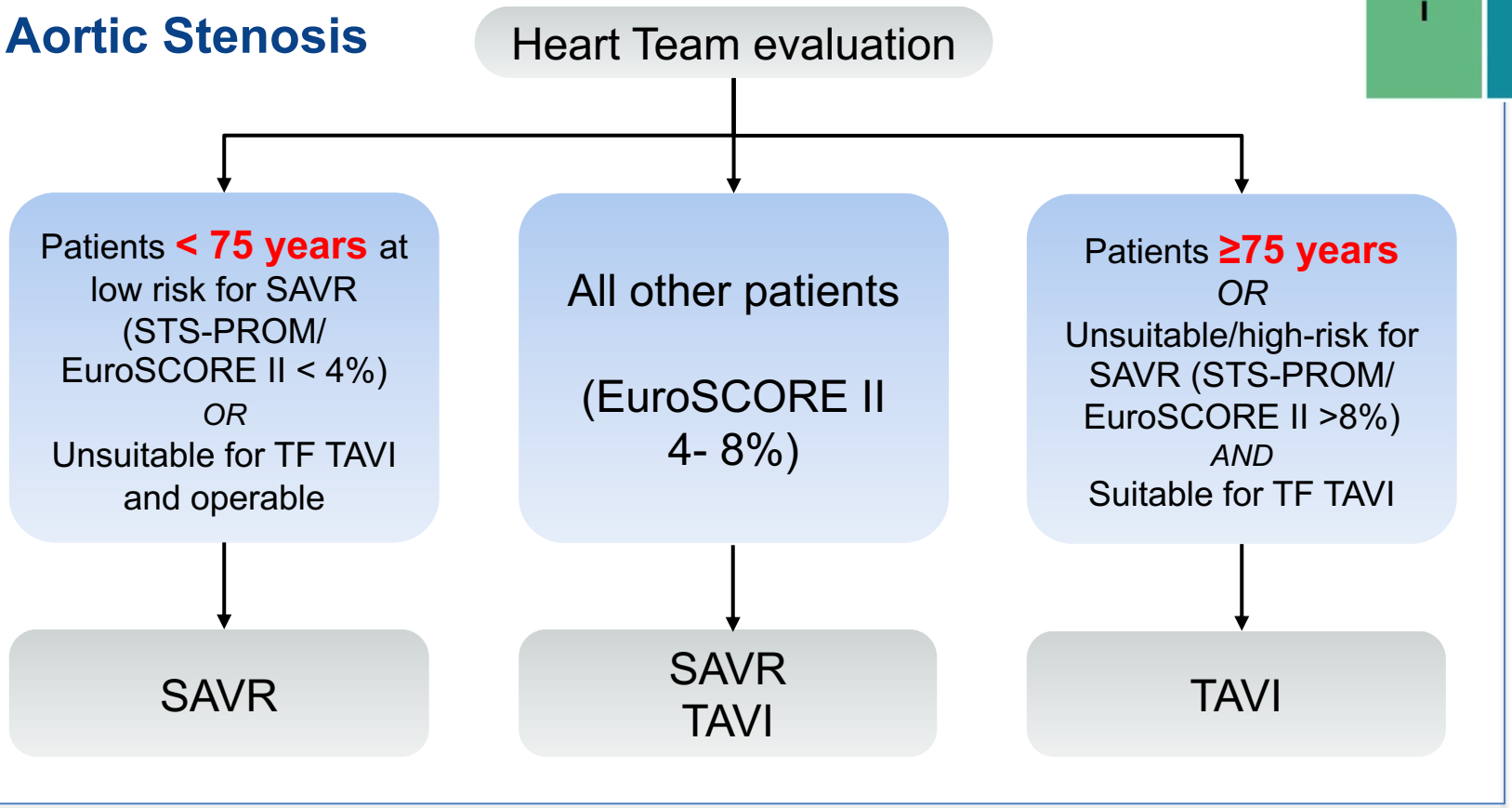
Conclusion: TAVR in low-risk patients is superior to SAVR for the majority of outcomes.

Hofer et al. Clin Res Cardiol. 2020 Jun;109(6):761-775.

2021 ESC/EACTS Guidelines for the management of valvular heart disease

I A

Aortic Stenosis



Vahanian A et al., Eur Heart J 2021

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Transcatheter Aortic Valve Replacement in Patients With End-Stage Renal Disease

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TABLE 1 Baseline Characteristics of the Study Population

	Overall (N = 72,631)	No Dialysis (n = 69,578)	Dialysis (n = 3,053)	p Value
Age, yrs	83 (77-87)	83 (77-88)	76 (68-82)	<0.001
Male	37,925 (52.2)	36,089 (51.9)	1,836 (60.1)	<0.001
Race				<0.001
Caucasian	68,168 (93.9)	65,722 (94.5)	2,446 (80.1)	
African American	2,755 (3.8)	2,311 (3.3)	444 (14.5)	
Asian	859 (1.2)	783 (1.1)	76 (2.5)	
Other	849 (1.2)	762 (1.1)	87 (2.8)	
BSA, m^2	1.85 (1.68-2.02)	1.85 (1.68-2.02)	1.86 (1.70-2.03)	<0.001
Comorbidities				
Atrial fibrillation	29,542 (40.7)	28,301 (40.7)	1,241 (40.6)	0.977
COPD				<0.001
None/mild	52,535 (72.8)	50,559 (73.1)	1,976 (65.0)	
Moderate	9,770 (13.5)	9,262 (13.4)	508 (16.7)	
Severe	9,859 (13.7)	9,305 (13.5)	554 (18.2)	
Diabetes	27,203 (37.5)	25,503 (36.7)	1,700 (55.7)	<0.001
Hypertension	65,163 (89.7)	62,322 (89.6)	2,841 (93.1)	<0.001
PAD	22,162 (30.5)	20,934 (30.1)	1,228 (40.2)	<0.001
Prior MI	18,045 (24.8)	17,085 (24.6)	960 (31.4)	<0.001
Prior CABG	20,290 (27.9)	19,500 (28.0)	790 (25.9)	0.010
Prior PCI	25,369 (34.9)	24,193 (34.8)	1,176 (38.5)	<0.001
Heart failure				<0.001
NYHA functional class I-II	13,018 (17.9)	12,626 (18.1)	392 (12.8)	<0.001
NYHA functional class III-IV	58,908 (81.1)	56,274 (80.9)	2,634 (86.3)	<0.001
Stroke	8,794 (12.1)	8,352 (12.0)	442 (14.5)	<0.001
STS PROM, %	6.4 (4.2-9.9)	6.2 (4.1-9.5)	13.5 (8.9-20.6)	<0.001

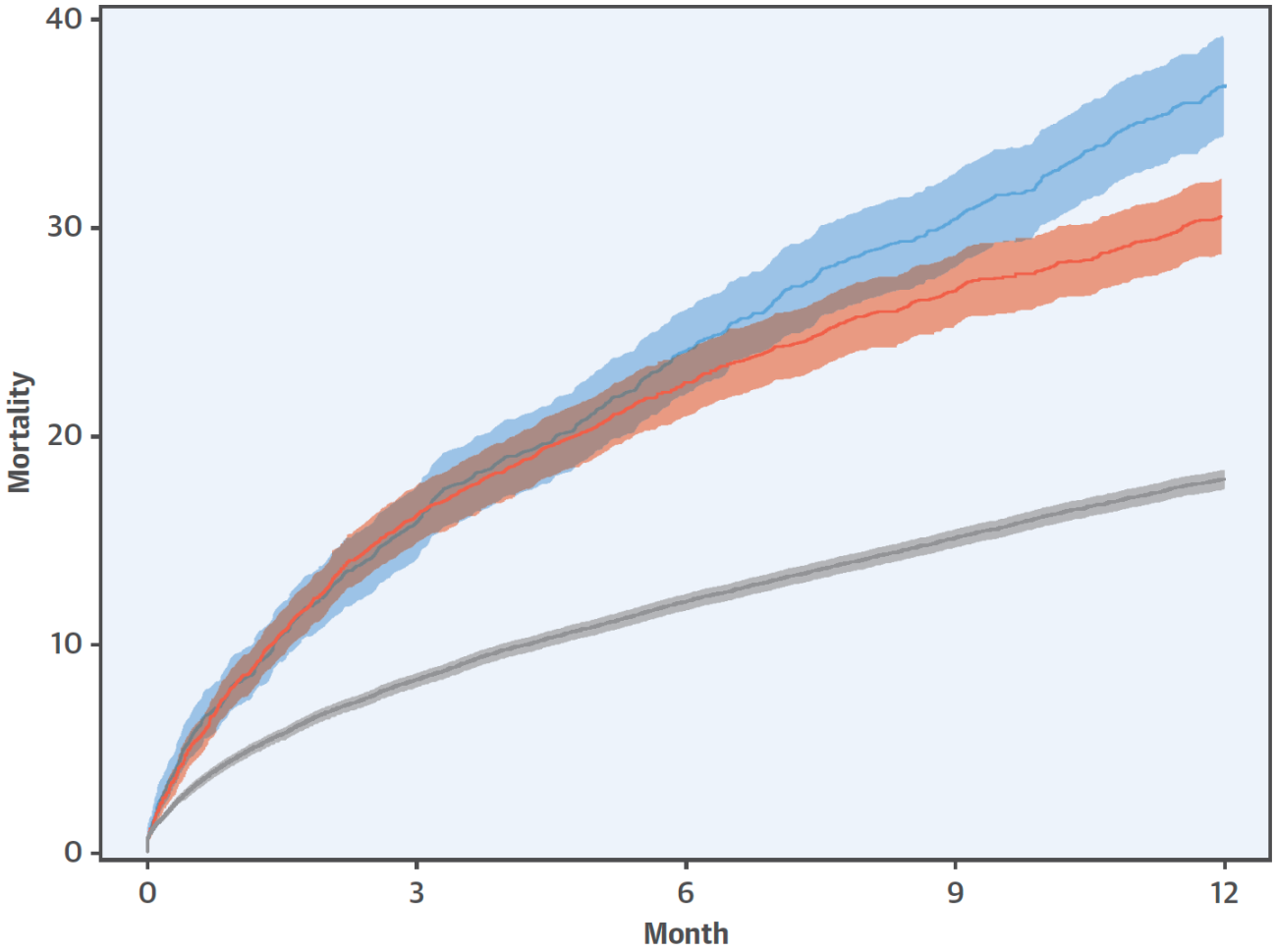
Szerlip M et al., J Am Coll Cardiol 2019 Jun 11;73(22):2806-2815

TABLE 2 Procedural Characteristics and Outcomes

	Overall (N = 72,631)	No Dialysis (n = 69,578)	Dialysis (n = 3,053)	p Value
Procedure status				<0.001
Elective	65,655 (90.4)	63,158 (90.8)	2,497 (81.8)	
Urgent	6,713 (9.2)	6,187 (8.9)	526 (17.2)	
Emergency	159 (0.2)	138 (0.2)	21 (0.7)	
Salvage	31 (0.0)	25 (0.0)	6 (0.2)	
Reason for procedure				<0.001
Inoperable (technique)	2,621 (3.6)	2,519 (3.6)	102 (3.3)	
Prohibitive risk (co-morbid condition)	9,226 (12.7)	8,792 (12.6)	434 (14.2)	
Prohibitive risk (debilitated/deconditioned)	2,789 (3.8)	2,735 (3.9)	54 (1.8)	
Inoperable/extreme risk	13,193 (18.2)	12,560 (18.1)	633 (20.7)	
High risk	41,116 (56.6)	39,356 (56.6)	1,760 (57.6)	
Intermediate risk	2,376 (3.3)	2,342 (3.4)	34 (1.1)	
Other than above reasons	1,310 (1.8)	1,274 (1.8)	36 (1.2)	
Approach				0.008
Transfemoral	56,885 (78.3)	54,553 (78.4)	2,332 (76.4)	
Nontransfemoral	15,746 (21.7)	15,025 (21.6)	721 (23.6)	
Device success	67,539 (93.0)	64,719 (93.0)	2,820 (92.4)	0.170
Second valve	4,517 (6.2)	4,319 (6.2)	198 (6.5)	0.534
Complications				
In-hospital mortality	2,504 (3.4)	2,347 (3.4)	157 (5.1)	<0.001
O:E mortality	0.43	0.44	0.32	<0.001
Access complication	3,329 (4.6)	3,191 (4.6)	138 (4.5)	0.859
Major bleed	754 (1.0)	710 (1.0)	44 (1.4)	0.025
Stroke	2,226 (3.1)	2,143 (3.1)	83 (2.7)	0.255
Unplanned vascular surgery or intervention	2,714 (3.7)	2,601 (3.7)	113 (3.7)	0.912
LOS, days	5.0 (3.0-8.0)	5.0 (3.0-8.0)	6.0 (4.0-12.0)	<0.001

Szerlip M et al., J Am Coll Cardiol 2019 Jun 11;73(22):2806-2815

CENTRAL ILLUSTRATION **1-Year Patient Mortality Stratified by Renal Function Following Transcatheter Aortic Valve Replacement**



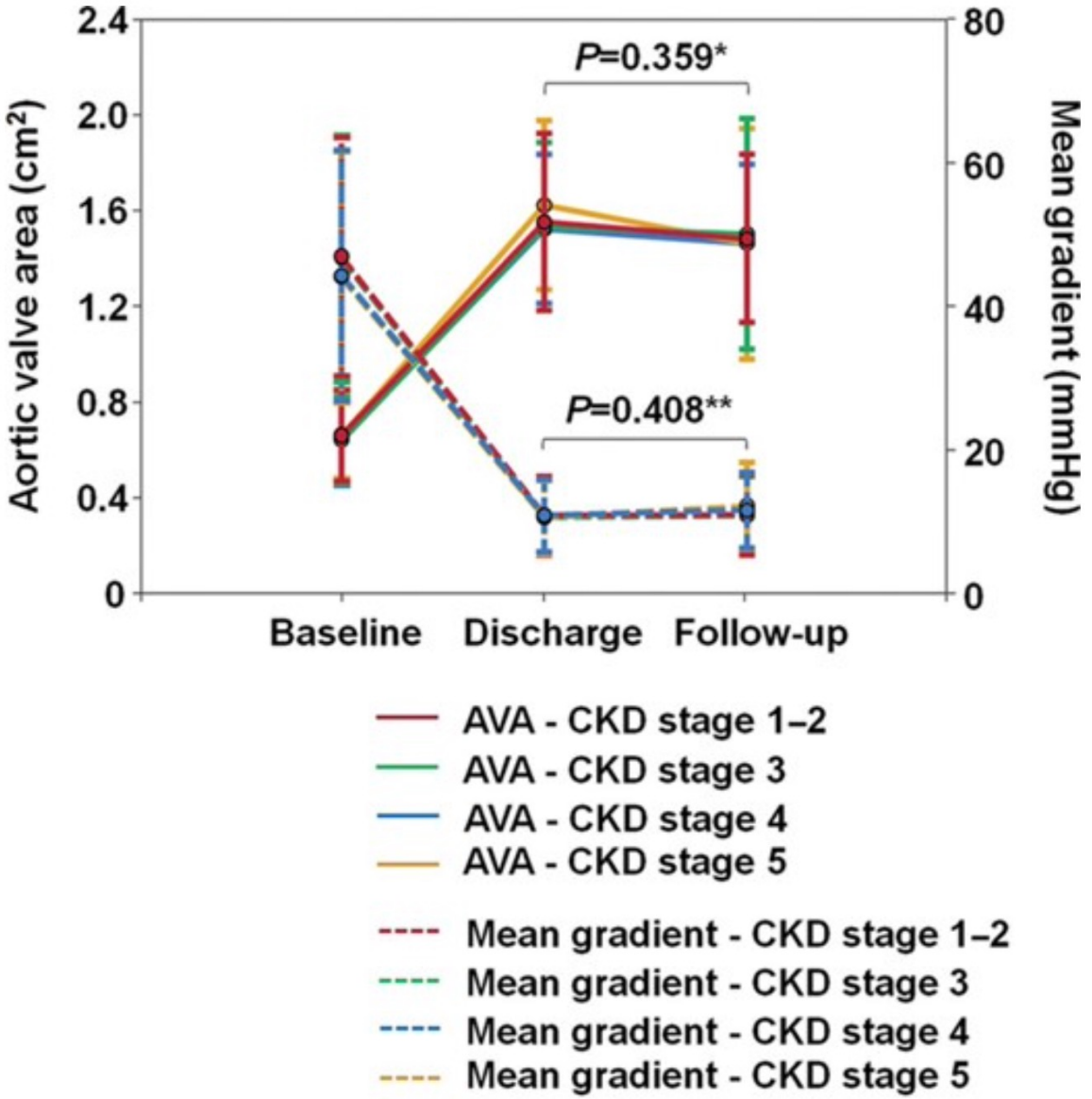
Szerlip M et al., J Am Coll Cardiol 2019 Jun 11;73(22):2806-2815

CKD Stadium und Symptomatik

Table 1 Baseline and procedural characteristics of the study population, according chronic kidney disease severity

eGFR (mL/min/1.72 m^2)	**CKD stage 1–2**	**CKD stage 3**	**Advanced CKD**		***P*-value**
			Stage 4	**Stage 5**	
	≥60	**<60 to ≥30**	**<30 to ≥15**	**<15 or Dialysis**	
	***n* = 950**	***n* = 924**	***n* = 134**	***n* = 67**	
Baseline variables					
Age, years	79.4 ± 8.0	81.9 ± 6.2	81.0 ± 7.5	76.9 ± 8.0	0.001
Male sex	537 (56.5)	404 (43.7)	56 (41.8)	39 (58.2)	0.001
Body mass index (kg/m^2)	26.8 ± 5.1	27.0 ± 5.2	27.1 ± 5.6	25.2 ± 4.9	0.048

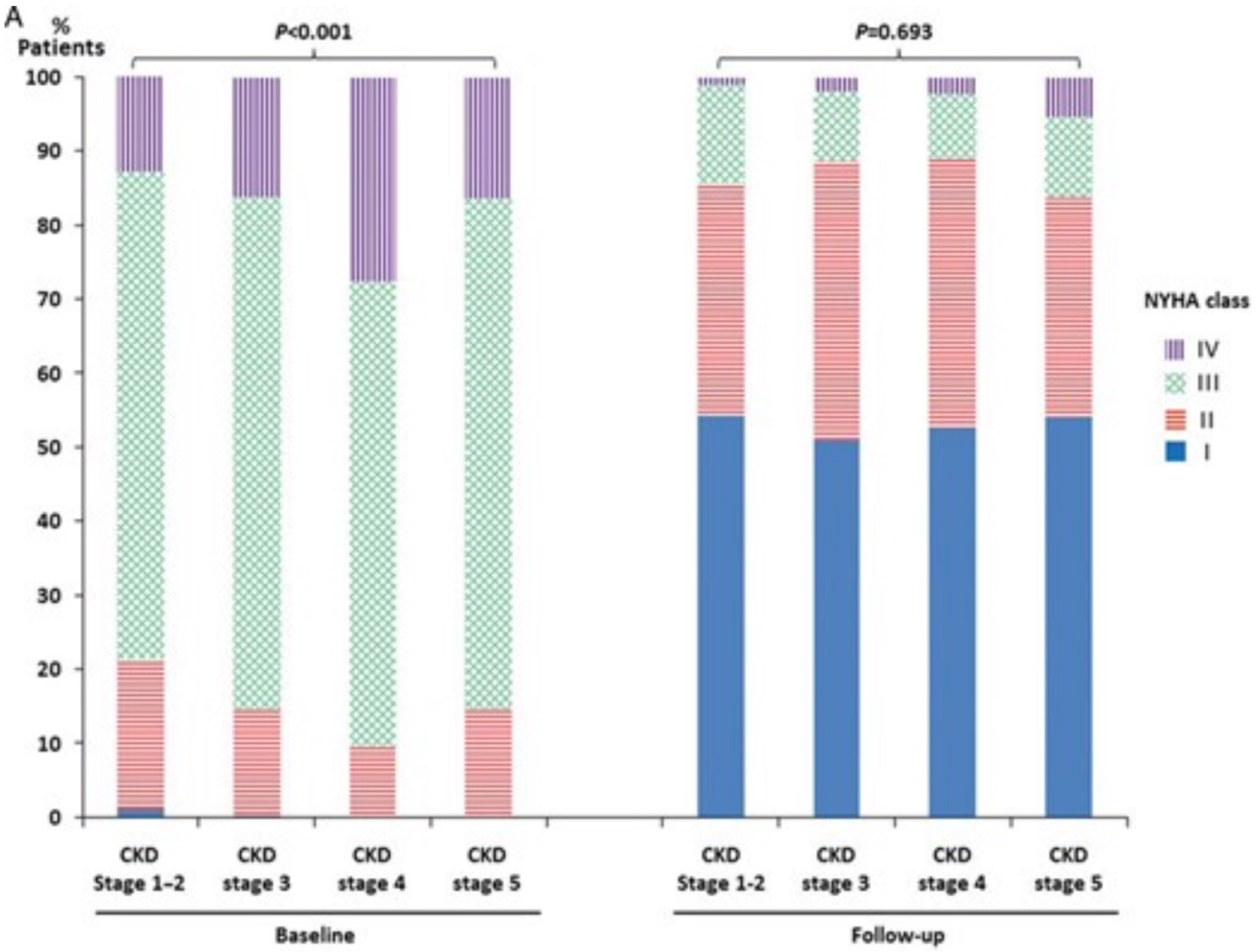
Allende R et al., Eur Heart J. 2014 Oct 7;35(38):2685-96



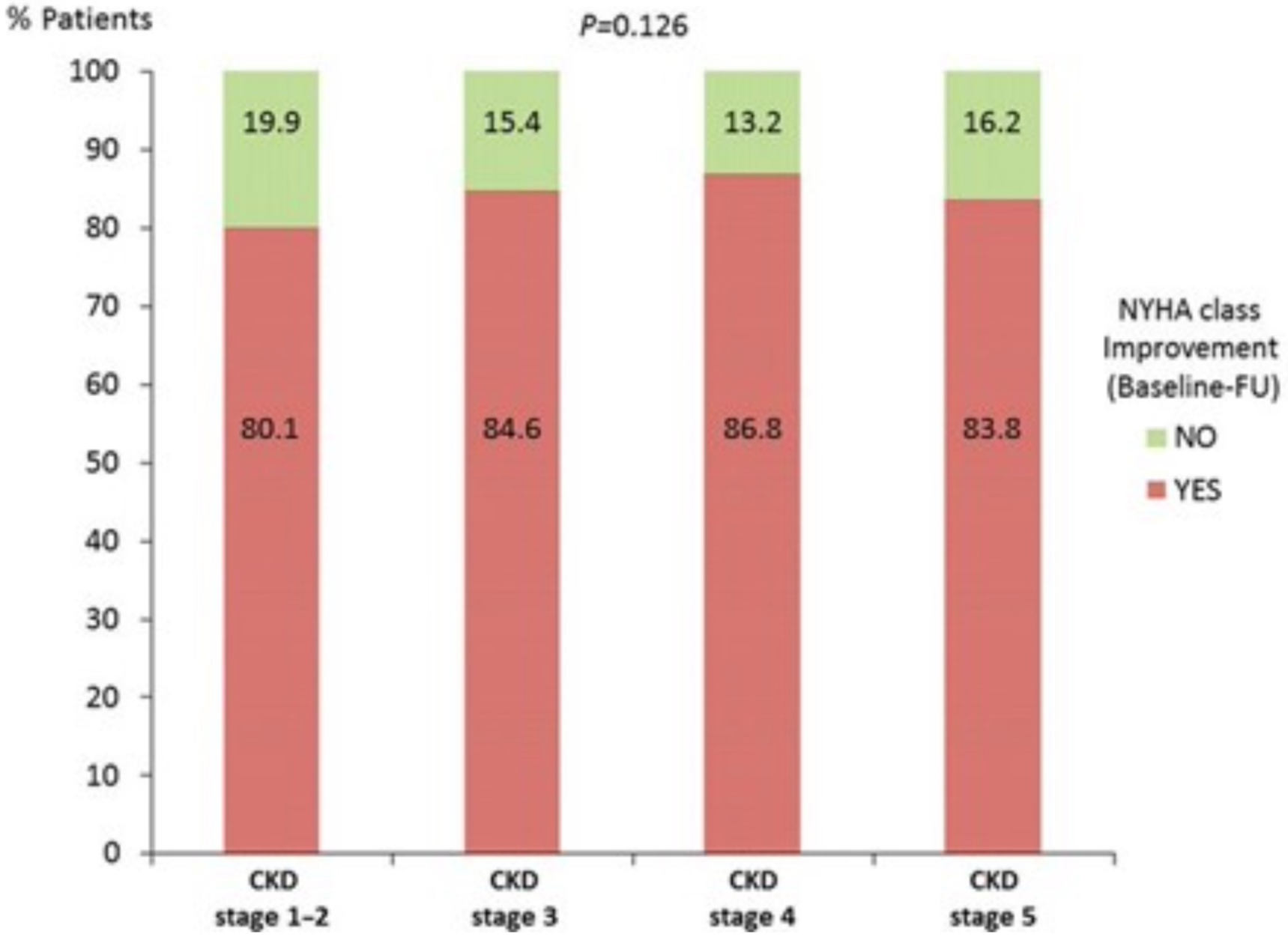
*AVA changes over time between groups

**Mean gradient changes over time between groups

Allende R et al., Eur Heart J. 2014 Oct 7;35(38):2685-96



Allende R et al., Eur Heart J. 2014 Oct 7;35(38):2685-96



Allende R et al., Eur Heart J. 2014 Oct 7;35(38):2685-96

Zusammenfassung

TEER bei FMR führt nicht zur Einschränkung der Nierenfunktion nach 30 Tagen

Patient*innen mit sich reduzierender Nierenfunktion haben eine höhere Mortalität als Patient*innen mit stabiler Nierenfunktion nach TEER

Erfreulicherweise ist der gleiche Benefit nach TEER bezüglich des primären Endpunkts Tod und HHI bei CKD nachweisbar

Patient*innen mit CKD sollte daher eine Klappenintervention nicht vorenthalten werden

TEER der Trikuspidalklappe ist vielversprechend

ESRD ist ein signifikanter Prädiktor für Mortalität nach TAVI, dennoch ist eine signifikante Verbesserung der Symptomatik nachweisbar

Ein interdisziplinärer holistischer Ansatz ist immer empfehlenswert

Vielen Dank für Ihre Aufmerksamkeit