



Universidad de Oviedo

Congreso de la **SAC24** Sociedad Asturiana de Cardiología **17 y 18 de mayo**



Reparación transcatéter borde a borde mitral y tricúspide

Llanes, 18 de Mayo de 2024

Isaac Pascual MD, PhD, MSc, FESC.

Structural Transcatheter Heart Interventions.

Hospital Universitario Central de Asturias.

Associate Professor. University of Oviedo. Spain.

ipascua@live.com

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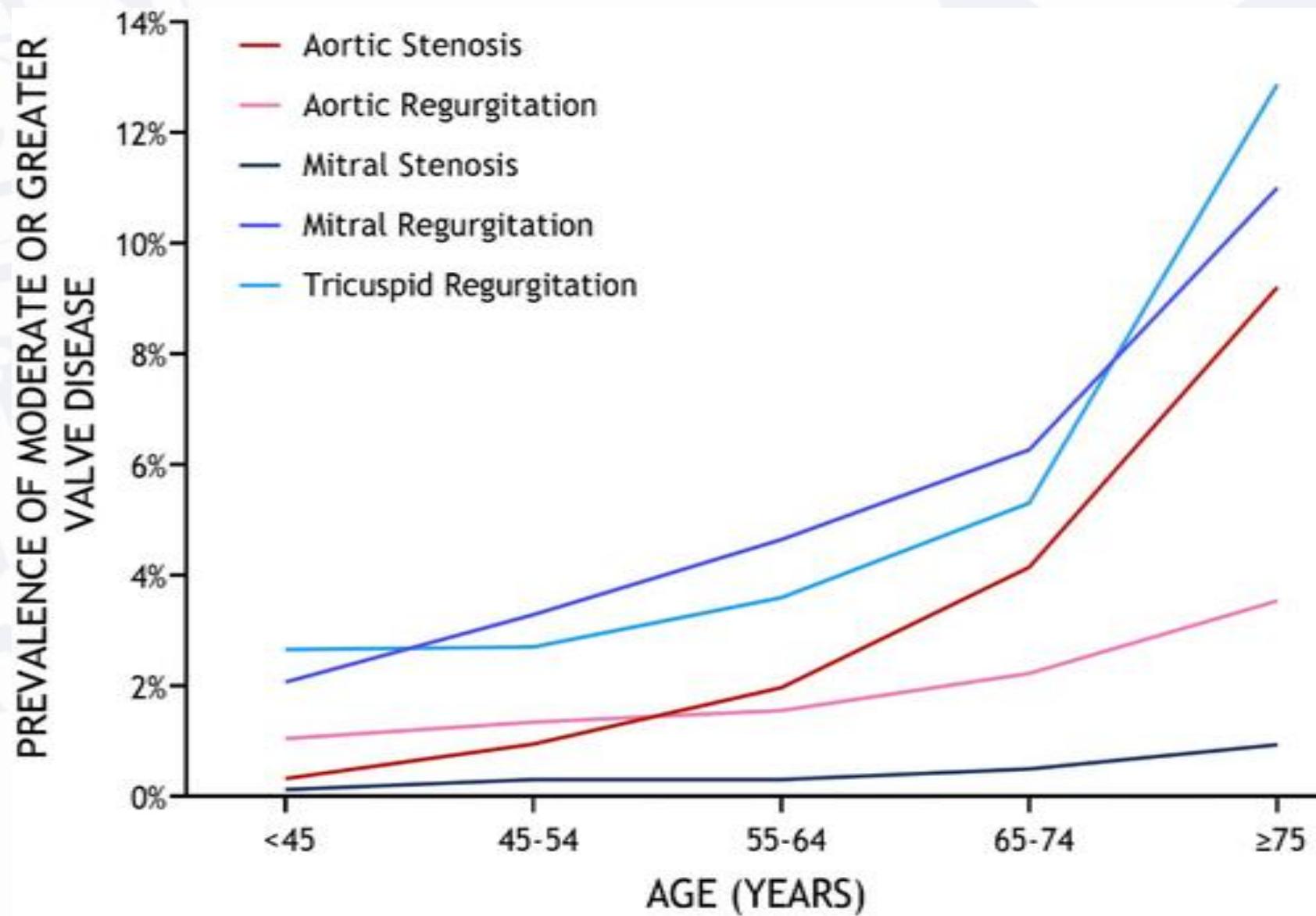
or

not to Clip

1

Introduction

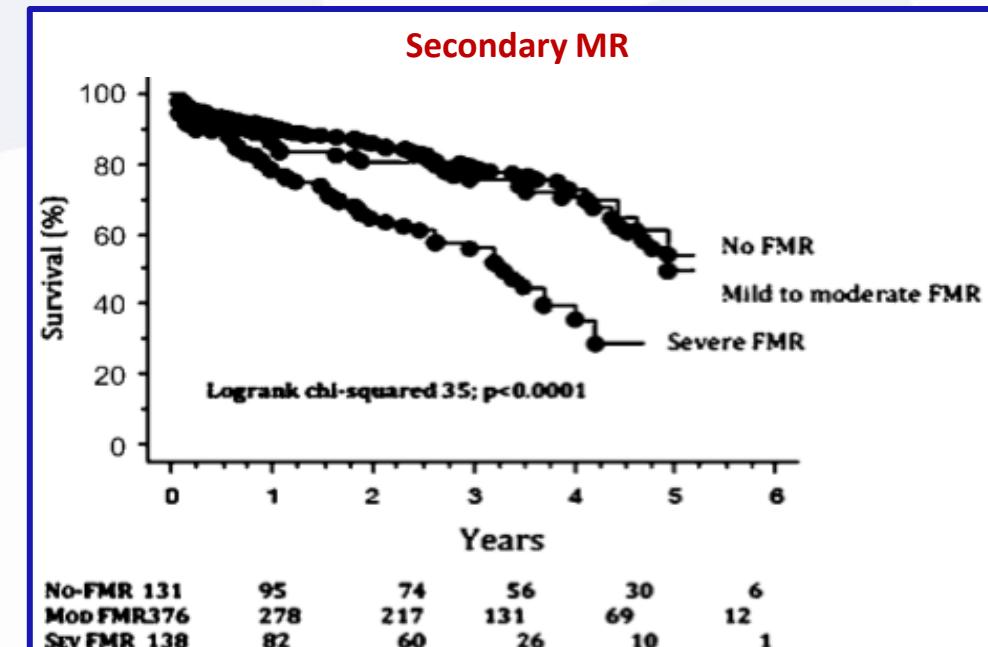
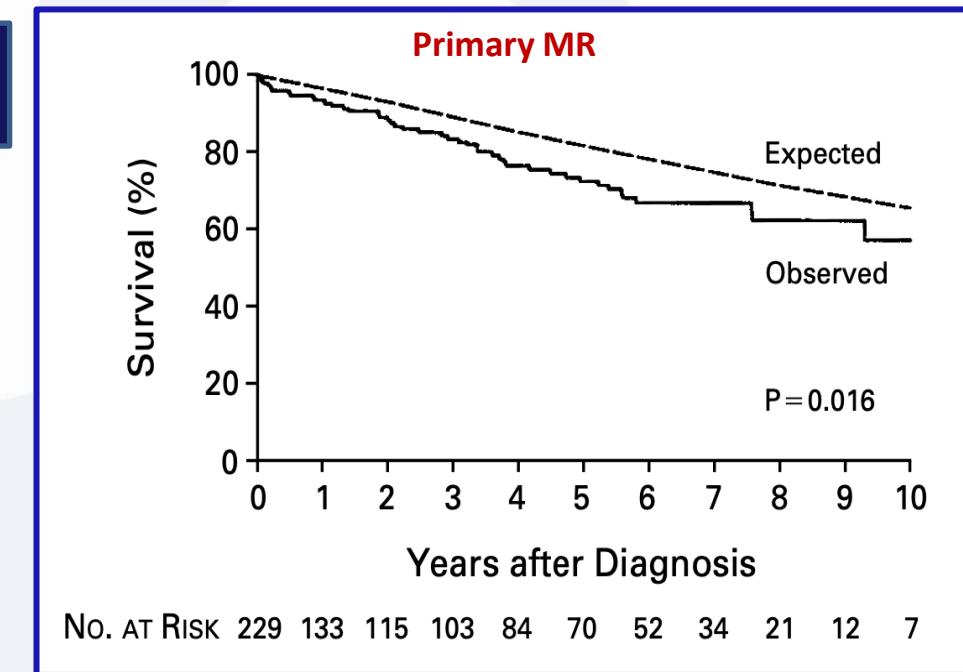
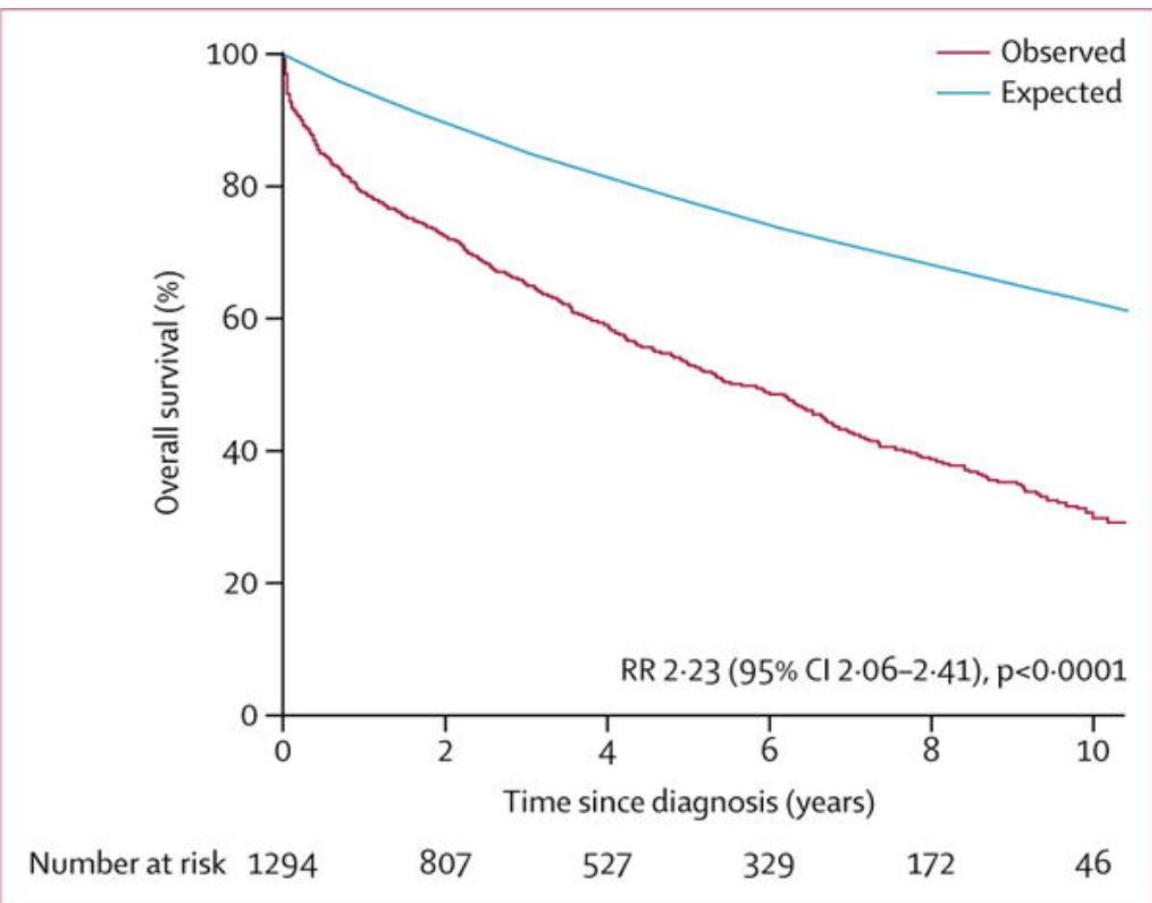
Moderate/severe MR and TR prevalence



Isolated MR

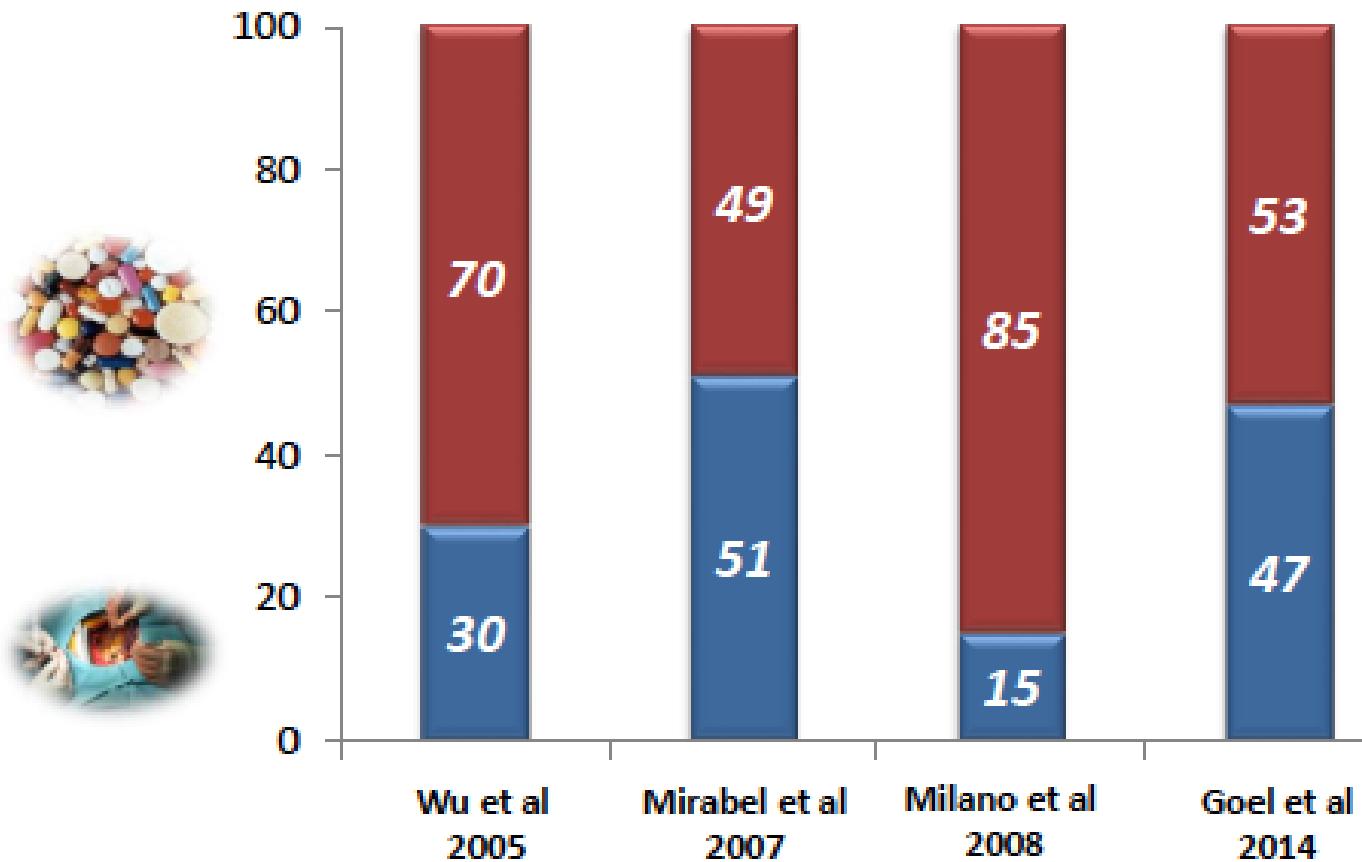
Outcome and undertreatment of mitral regurgitation: a community cohort study

Volha Dziadzko, Marie-Annick Clavel, Mikhail Dziadzko, Jose R Medina-Inojosa, Hector Michelena, Joseph Maalouf, Vuyisile Nkomo, Prabin Thapa, Maurice Enriquez-Sarano



Patients with MR are undertreated

Proportion of patients with severe MR receiving surgical or medical treatment



- Elderly
- Co-morbidities
- LV dysfunction
- Limited acces to high volumen centres.

Moderate or Severe MR in the Community

OMR 32%

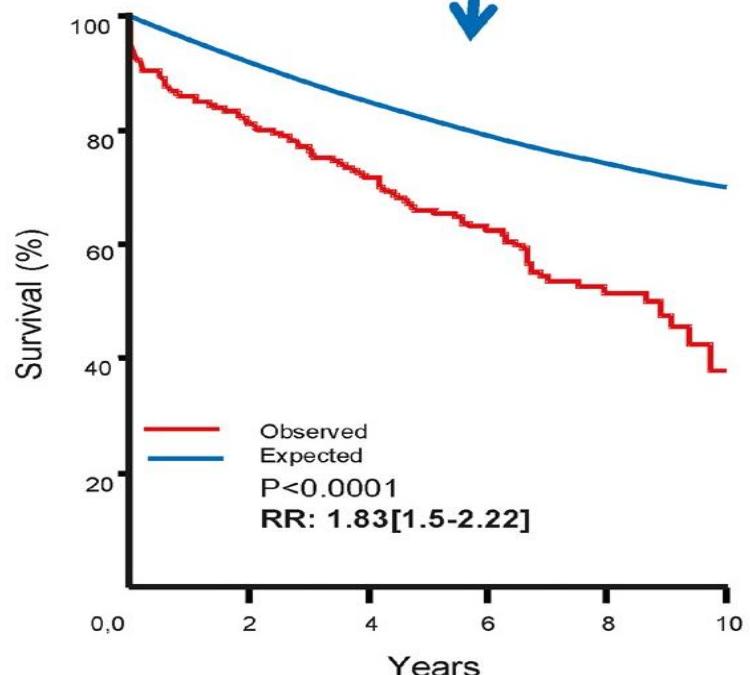
FMR 65%

Mixed 2%

OMR: 32%

Age 68, male 51%, Degenerative 72%
EF 61%, LV 51 mm, RVol 51 mL

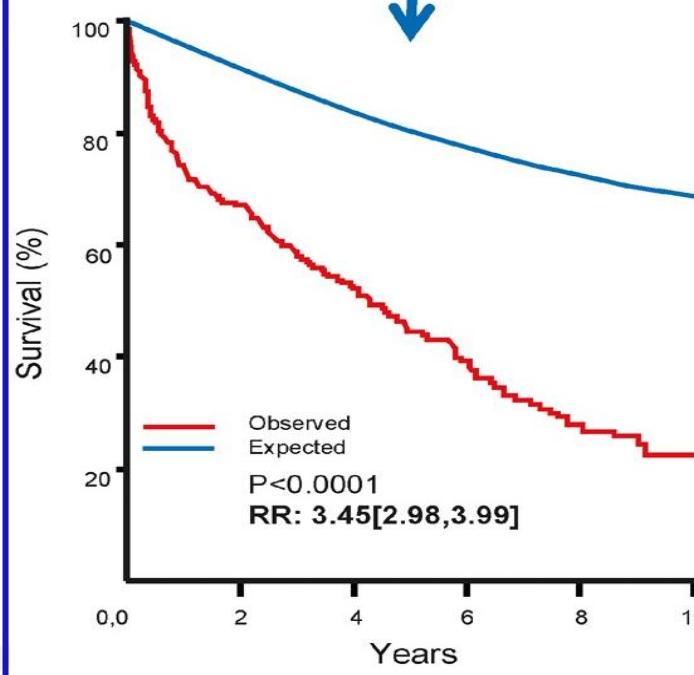
Mitral Surgery
In lifetime: 37%



FMR-v (LV remodeling): 38%

Age 73, male 59%, ischemic 62%
EF 33%, LV 59 mm, RVol 38 mL

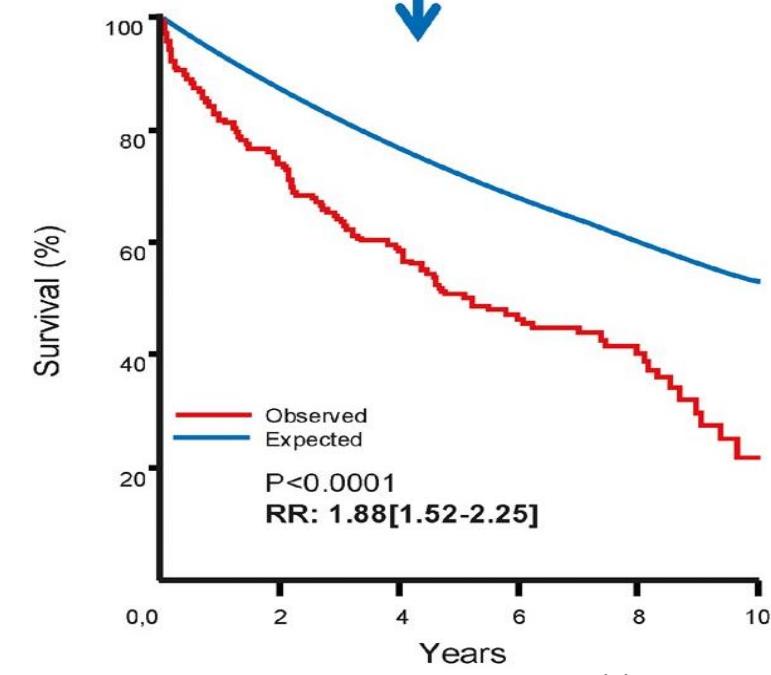
Mitral Surgery
In lifetime: 4%



FMR-a (LA remodeling) : 27%

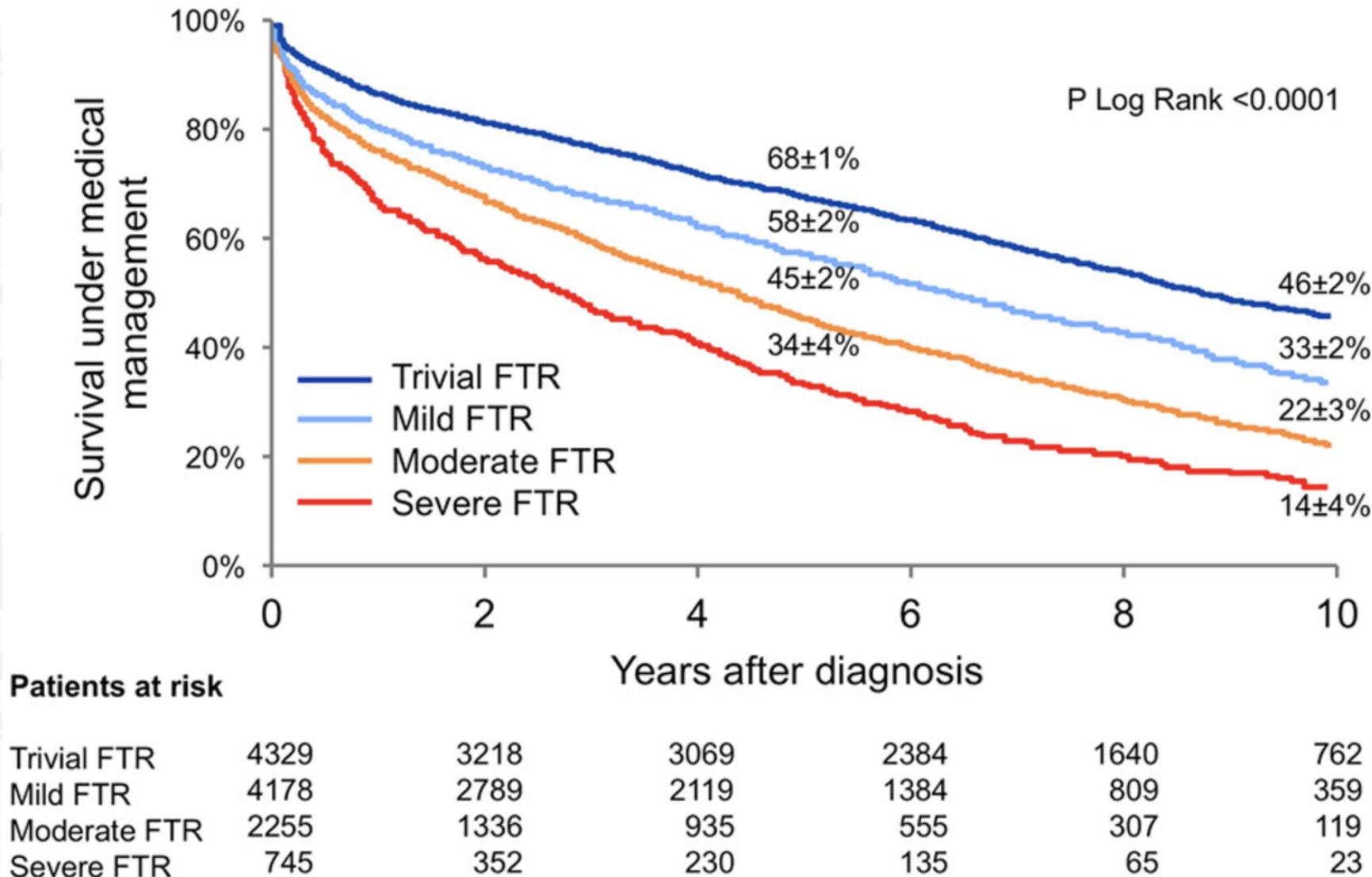
Age 80, male 33%, AF 57%
EF 57%, LV 48 mm, RVol 37 mL

Mitral Surgery
In lifetime: 3%



Excess Mortality Associated With Functional Tricuspid Regurgitation Complicating Heart Failure With Reduced Ejection Fraction

Bad prognosis of TR

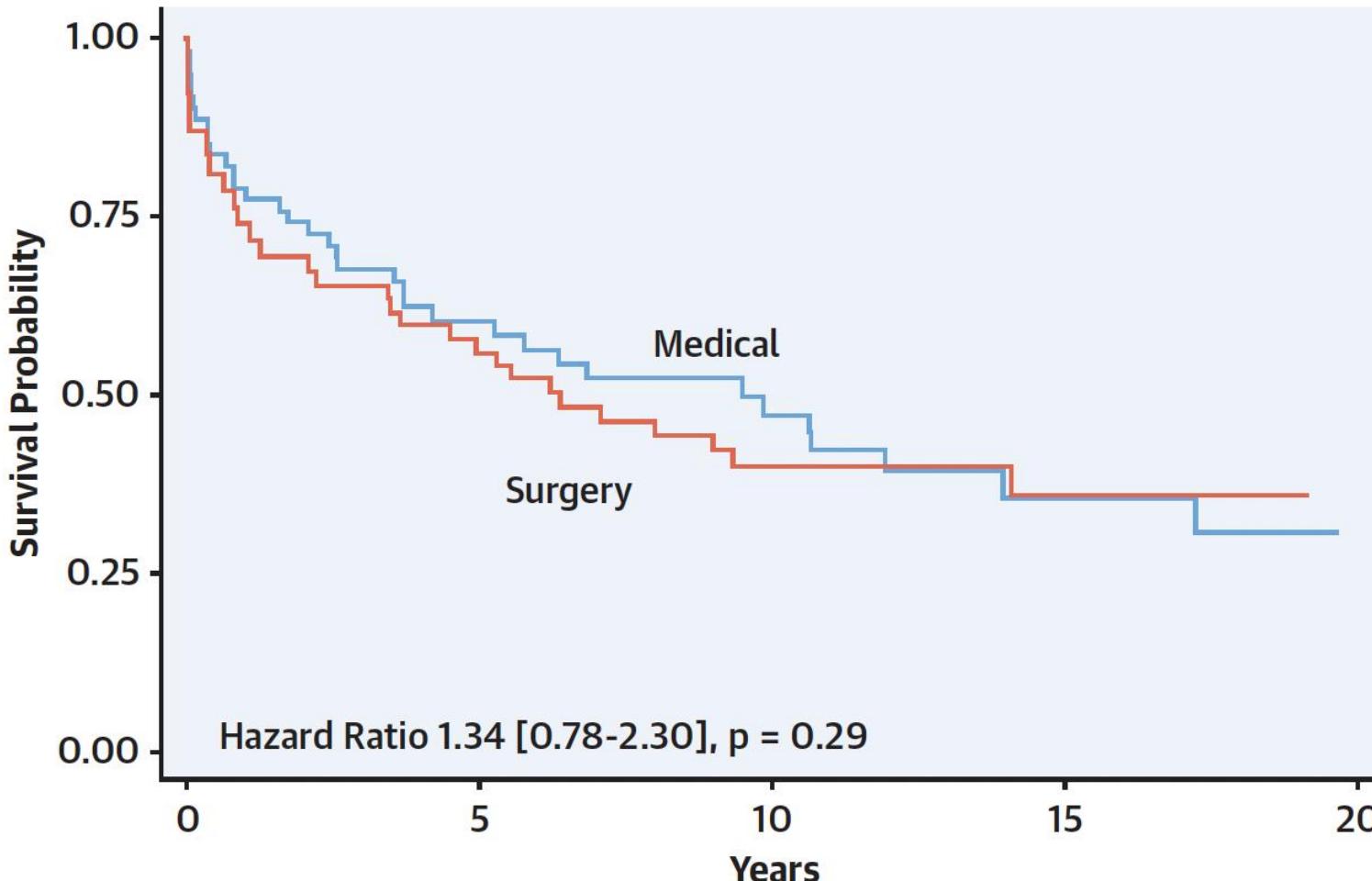


Surgery Does Not Improve Survival in Patients With Isolated Severe Tricuspid Regurgitation



Andrea L. Axtell, MD, MPH,^{a,b} Vijeta Bhambhani, MS, MPH,^c Philicia Moonsamy, MD,^{a,d} Emma W. Healy, BS,^c
Michael H. Picard, MD,^c Thoralf M. Sundt III, MD,^a Jason H. Wasfy, MD, MPH^{b,c}

CENTRAL ILLUSTRATION Surgery Versus Medical Therapy for Severe Tricuspid Regurgitation

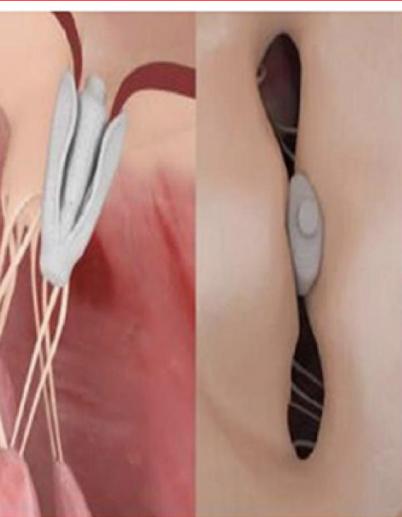


Transcatheter AV valve Therapies

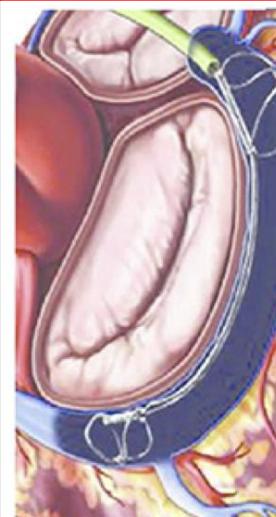
Edge-to-edge repair



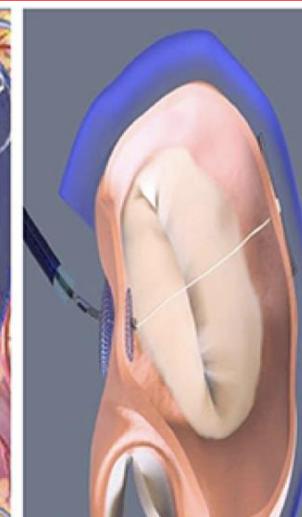
Newer generation MitraClip



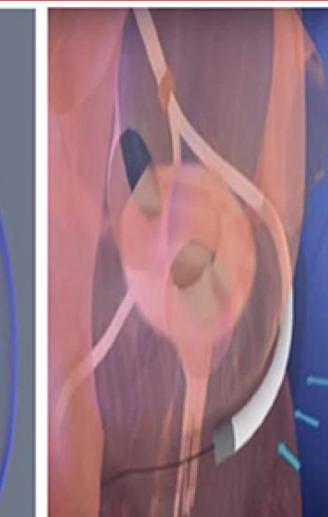
Pascal



Carillon



MVRx ARTO



Mitral Loop Cerclage

Direct annuloplasty



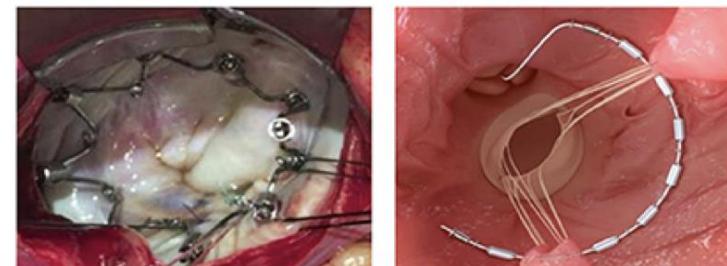
Cardioband



Mitralign



Millipede



Accucinch

Chordal replacement

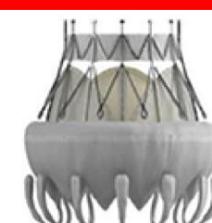


NeoChord

Transcatheter replacement



Sapien 3



Intrepid



CardiaQ



Tendyne



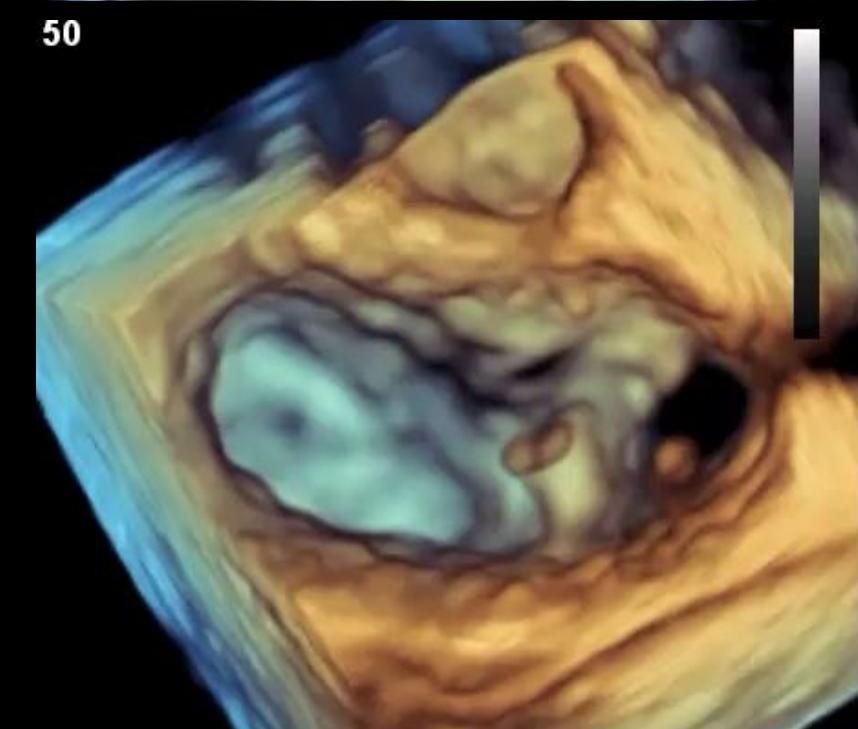
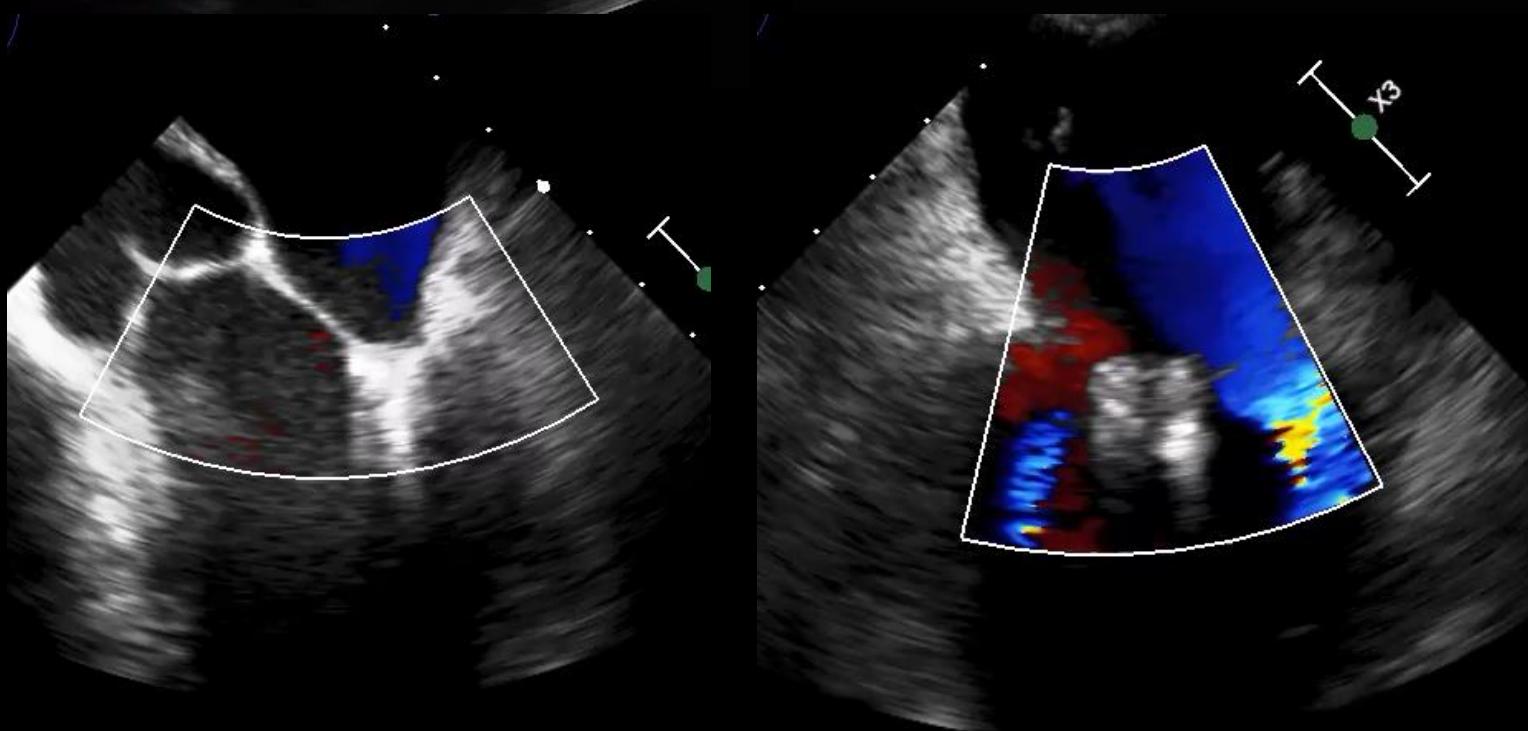
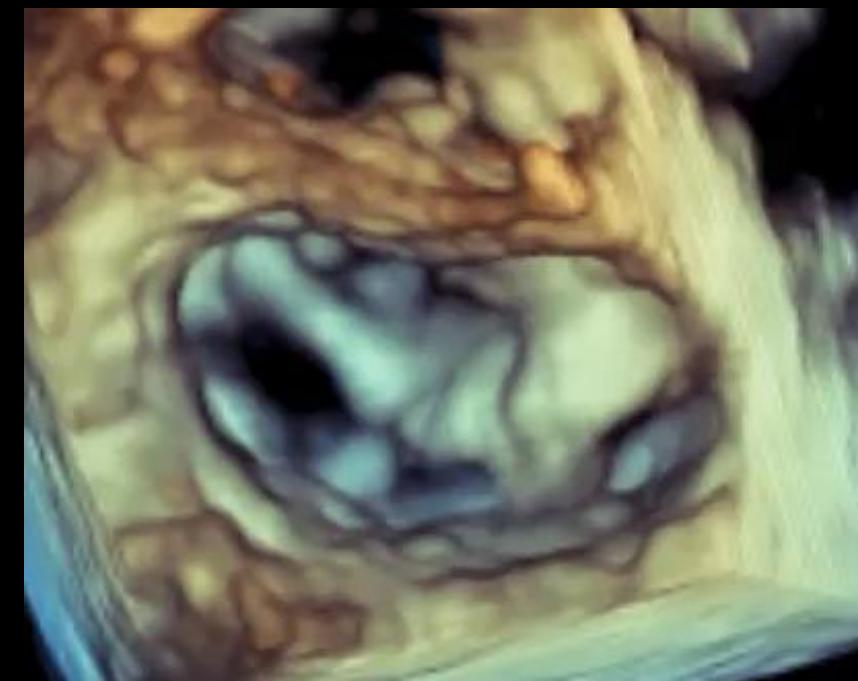
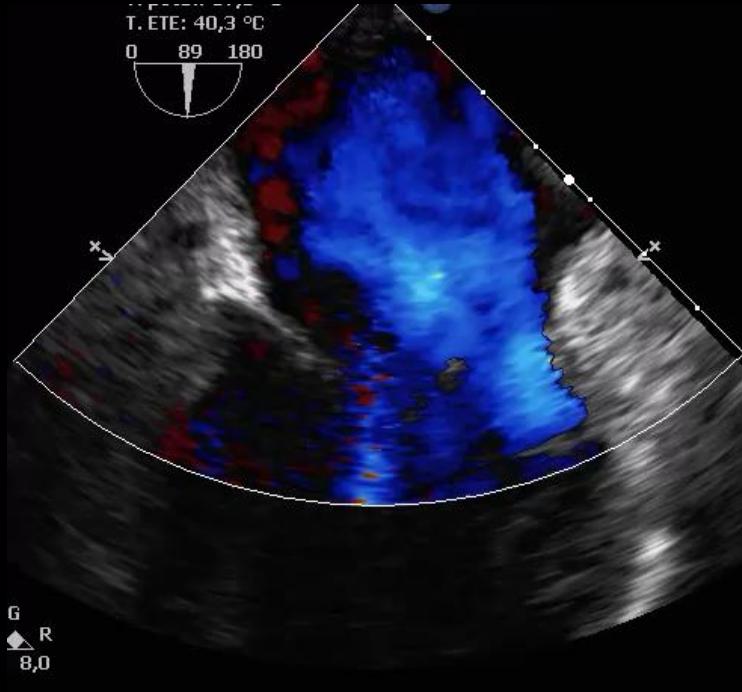
Tiara



Caisson

2

DMR



Evidence in DMR

Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation 5-Year Results of EVEREST II

OBJECTIVE

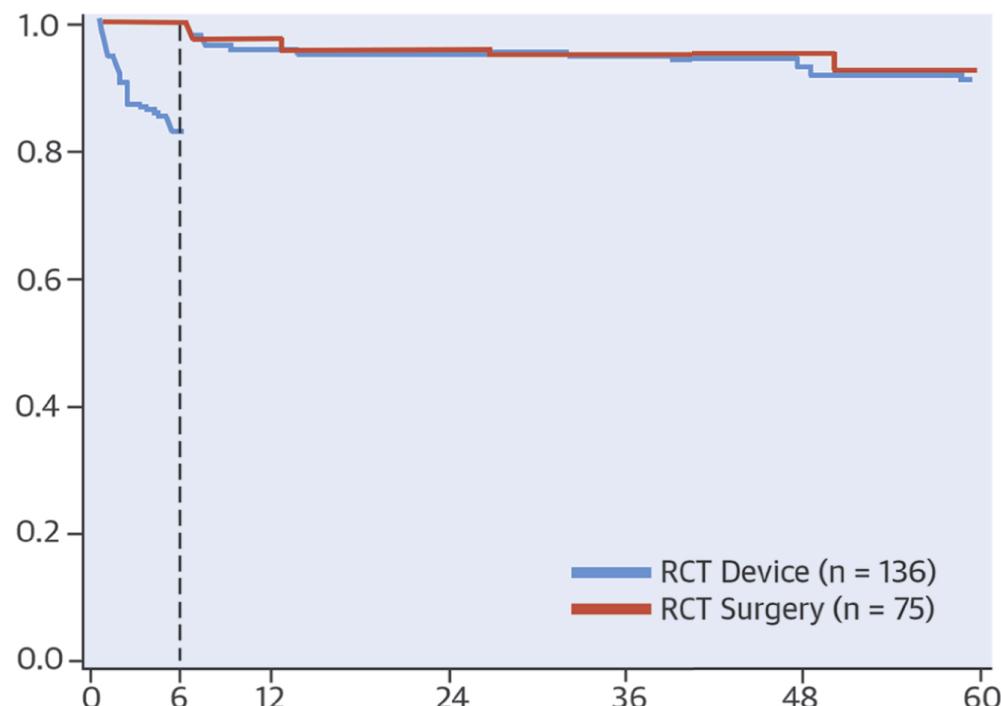
Final 5-year clinical outcomes and durability of TEER MV repair with MitraClip device compared with MV surgery.

TABLE 1 Baseline Characteristics: All-Treated Cohort

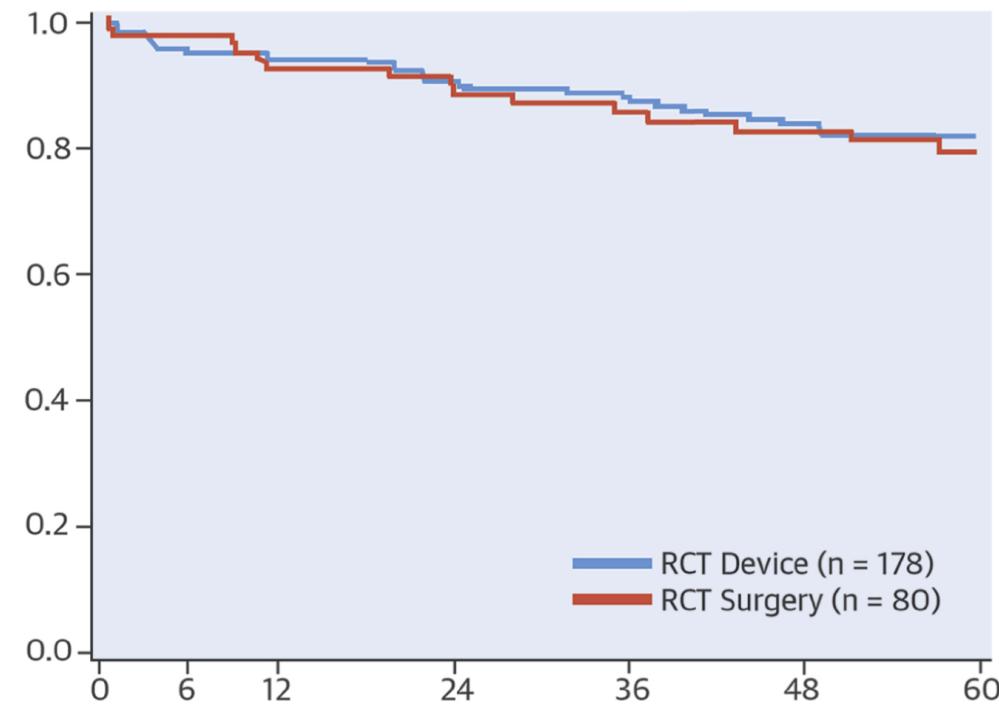
	Percutaneous Repair	Surgery
MR etiology		
Functional	27.0 (48/178)	22.5 (18/80)
Degenerative	73.0 (130/178)	77.5 (62/80)
Degenerative with anterior/bileaflet flail/prolapse	32.6 (58/178)	27.5 (22/80)
Degenerative with posterior flail/prolapse	37.6 (67/178)	47.5 (38/80)
Degenerative with neither flail nor prolapse	2.8 (5/178)	2.5 (2/80)

Evidence in DMR

D. Landmark Analysis of Freedom From MV Surgery or Reoperation Beyond 6 Months



B. Freedom From Death



Patients At Risk		Months						
Device Group	178	136	128	117	109	98	45	
Control Group	80	75	69	63	54	49	21	

Patients At Risk		Months						
Device Group	178	165	158	143	133	119	58	
Control Group	80	76	70	65	57	52	24	

Transcatheter or surgical repair for degenerative mitral regurgitation in elderly patients: A propensity-weighted analysis

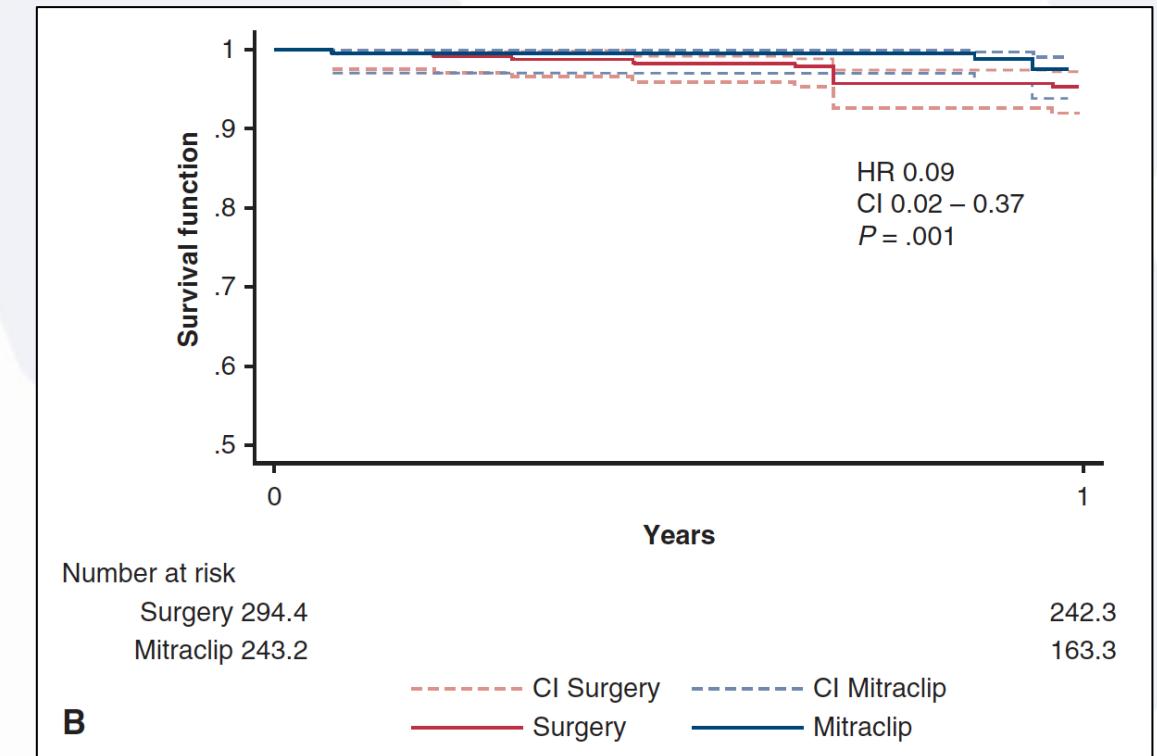


Nicola Buzzatti, MD,^a Mathias Van Hemelrijck, MD,^b Paolo Denti, MD,^a Stefania Ruggeri, MS,^a Davide Schiavi, BS,^a Iside Stella Scarfò, MD,^a Diana Reser, MD,^b Maurizio Taramasso, MD,^b Alberto Weber, MD,^b Giovanni La Canna, MD,^a Michele De Bonis, MD,^a Francesco Maisano, MD,^t Ottavio Alfieri, MD^a

STS Surgery 1.91 [1.43; 3.24]
MitraClip 2.48 [1.91; 3.49]

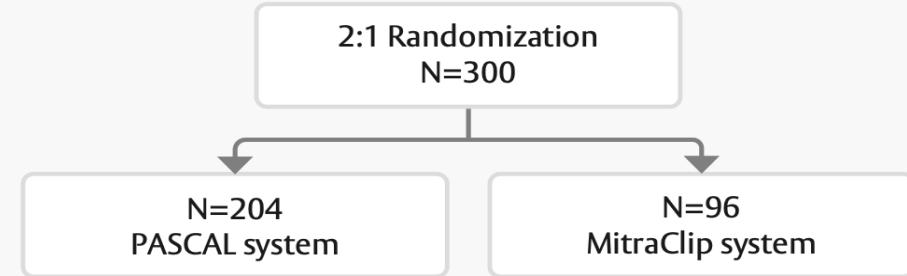
TABLE 4. Weighted Cox model for all-cause death

	HR	P value	95% CI
STS-PROM	1.18	<.001	1.12-1.24
MitraClip (t < 1 y)	0.09	.001	0.02-0.37
MR ≥3+ recurrence	2.19	.033	1.07-4.48

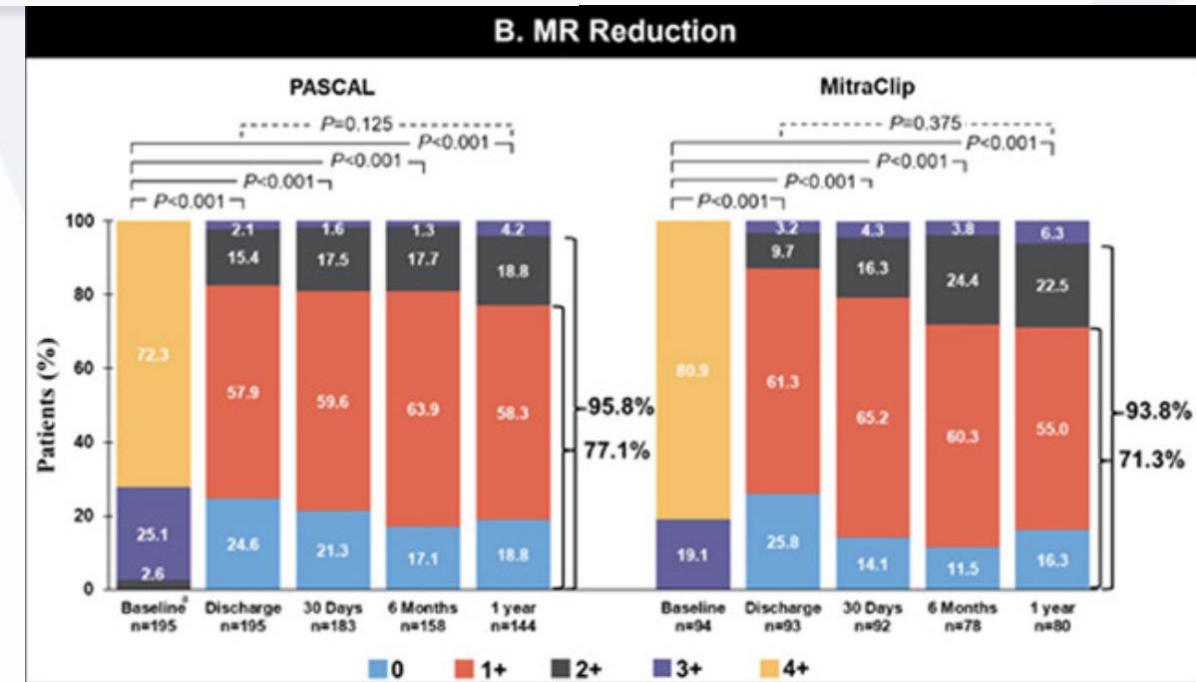
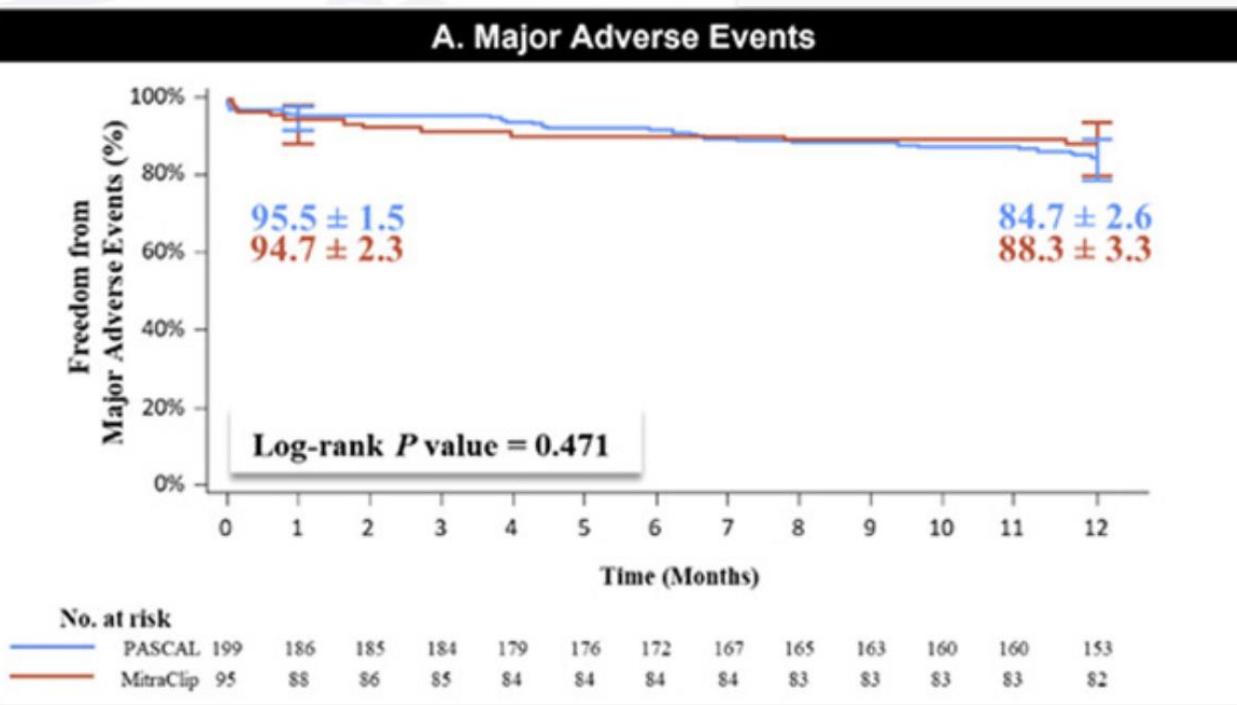


1-y Outcomes from the CLASP IID Randomized Trial for DMR

Patients who are symptomatic, have **3+ or 4+** degenerative mitral regurgitation (DMR) and are deemed **prohibitive risk** for surgery.

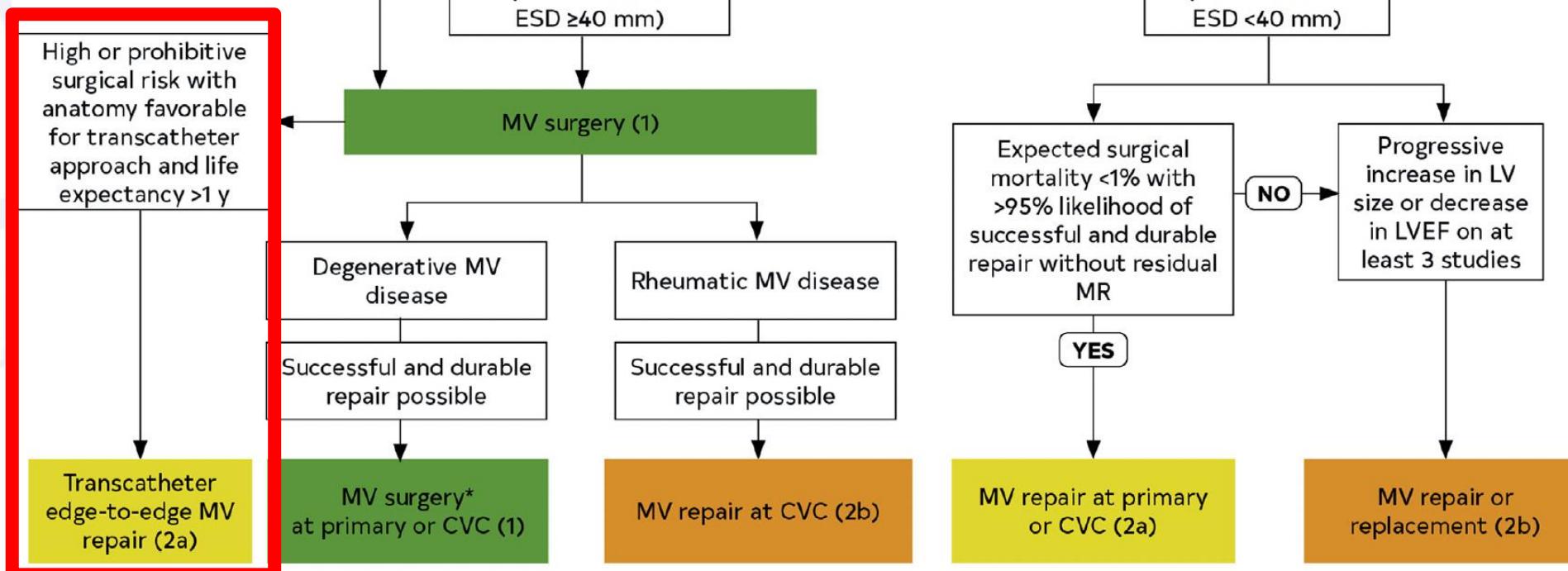


Powered for non-inferiority of the PASCAL system to the MitraClip system

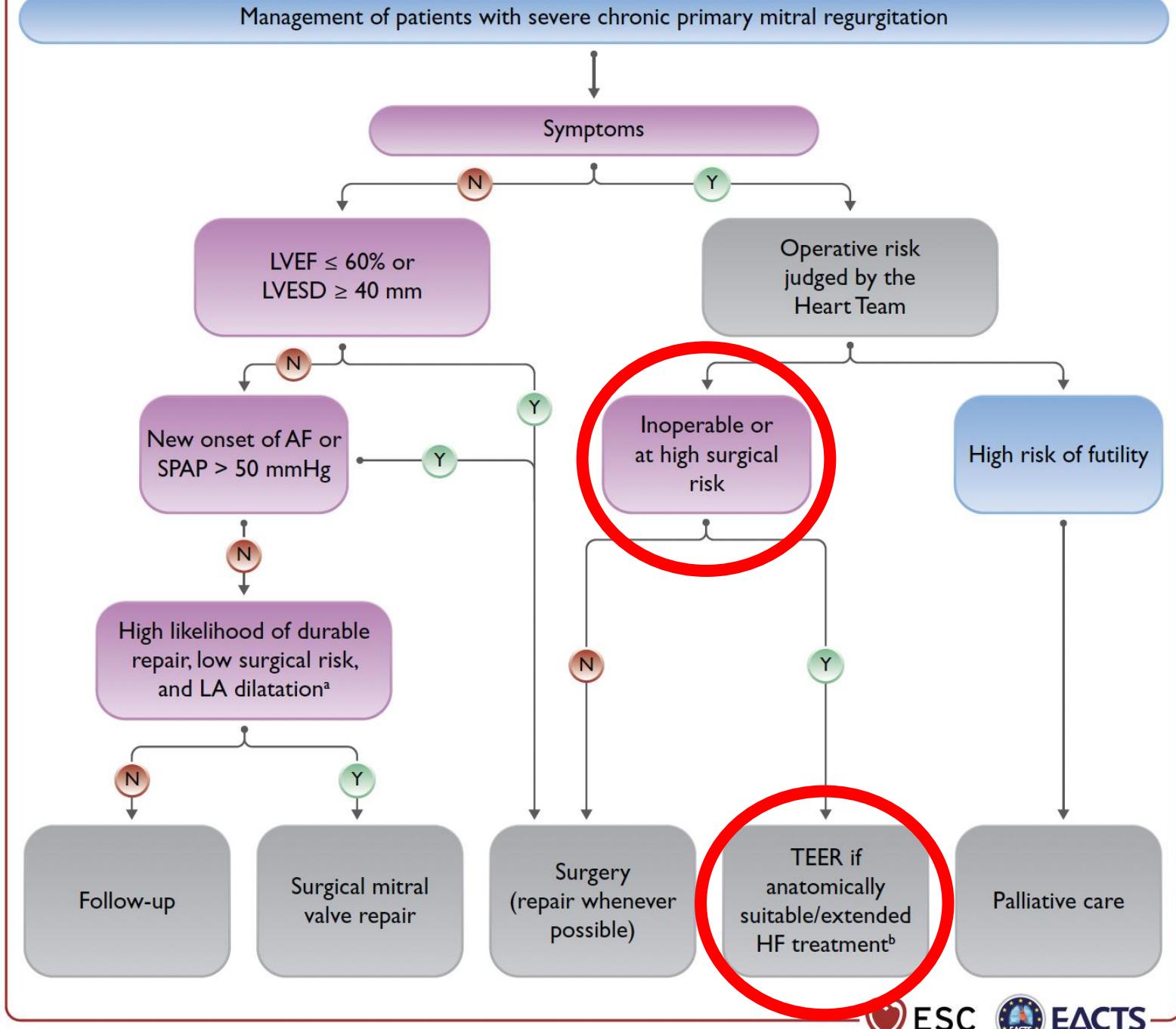


2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease

2a

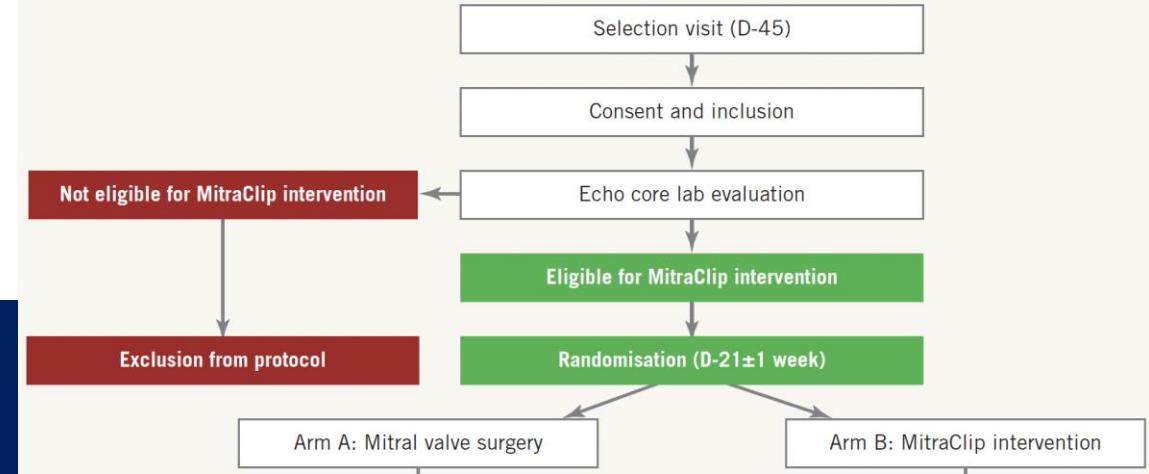


IIb



Randomized Clinical Trials in DMR

The MITRA-HR study: design and rationale of a randomised study of MitraClip transcatheter mitral valve repair in patients with severe primary mitral regurgitation eligible for high-risk surgery



MitraClip REPAIR MR Study

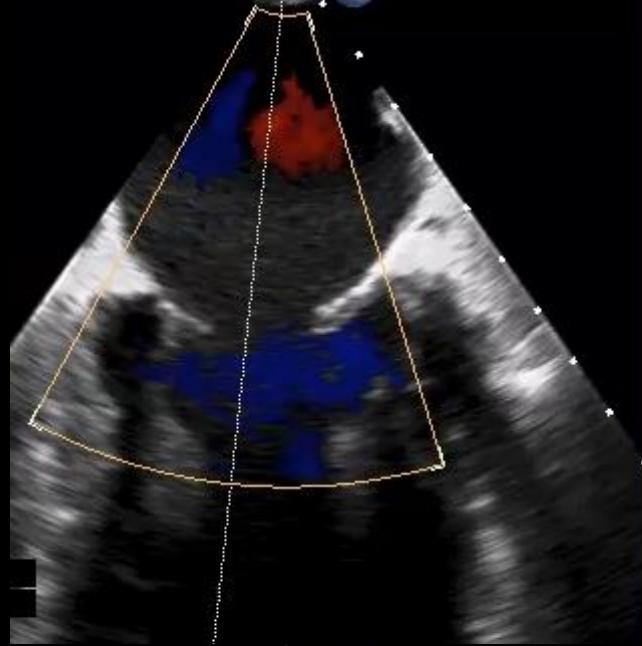
Percutaneous MitraClip Device or Surgical **Mitral Valve** REpair in PAients With Primary **Mitral Regurgitation** Who Are Candidates for Surgery (REPAIR MR)

ClinicalTrials.gov ID  NCT04198870

- Objective: to compare the clinical outcome of **MitraClip™** versus **surgical repair** in patients with **severe primary MR** who are at moderate surgical risk

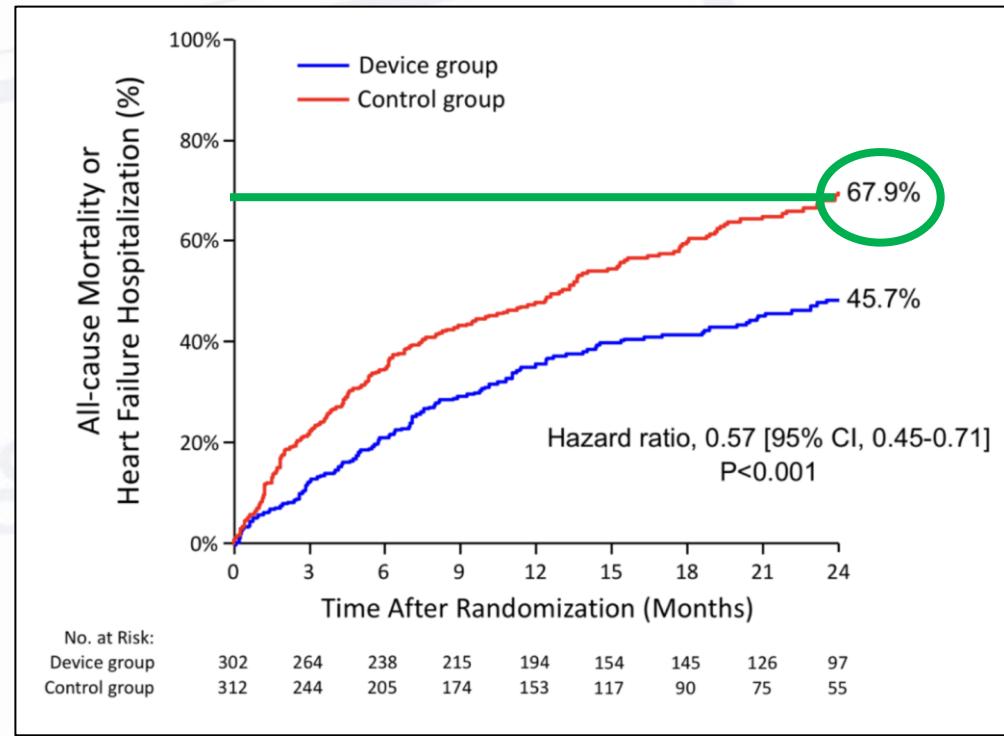
3

FMR

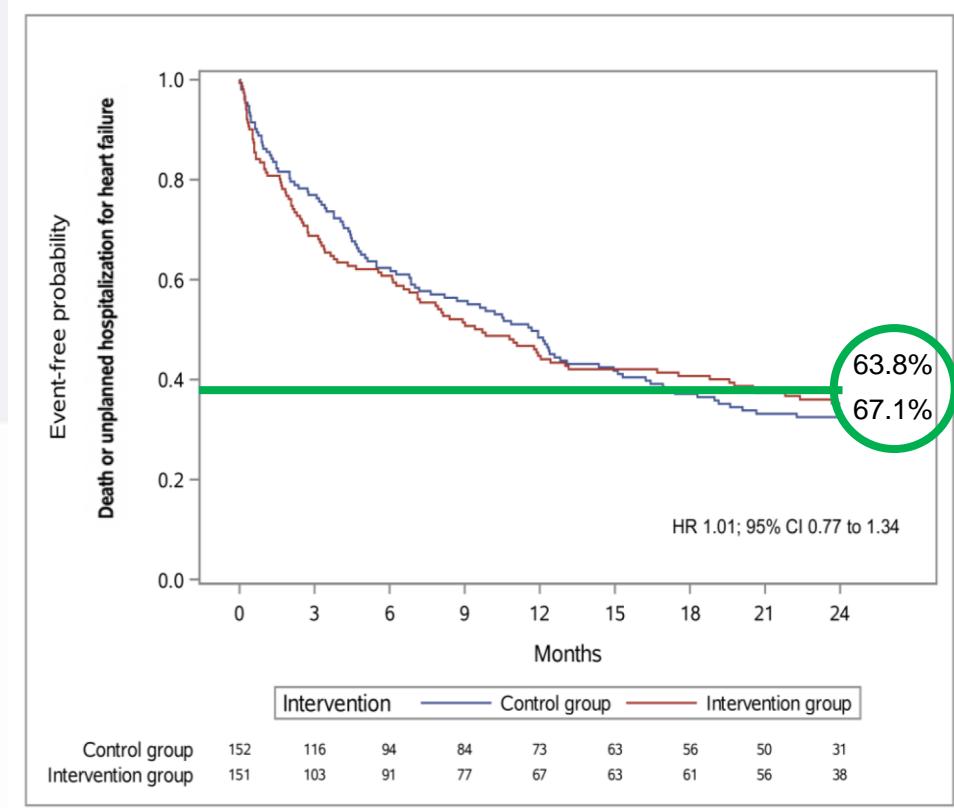


Evidence in FMR

COAPT



2y MITRA-FR





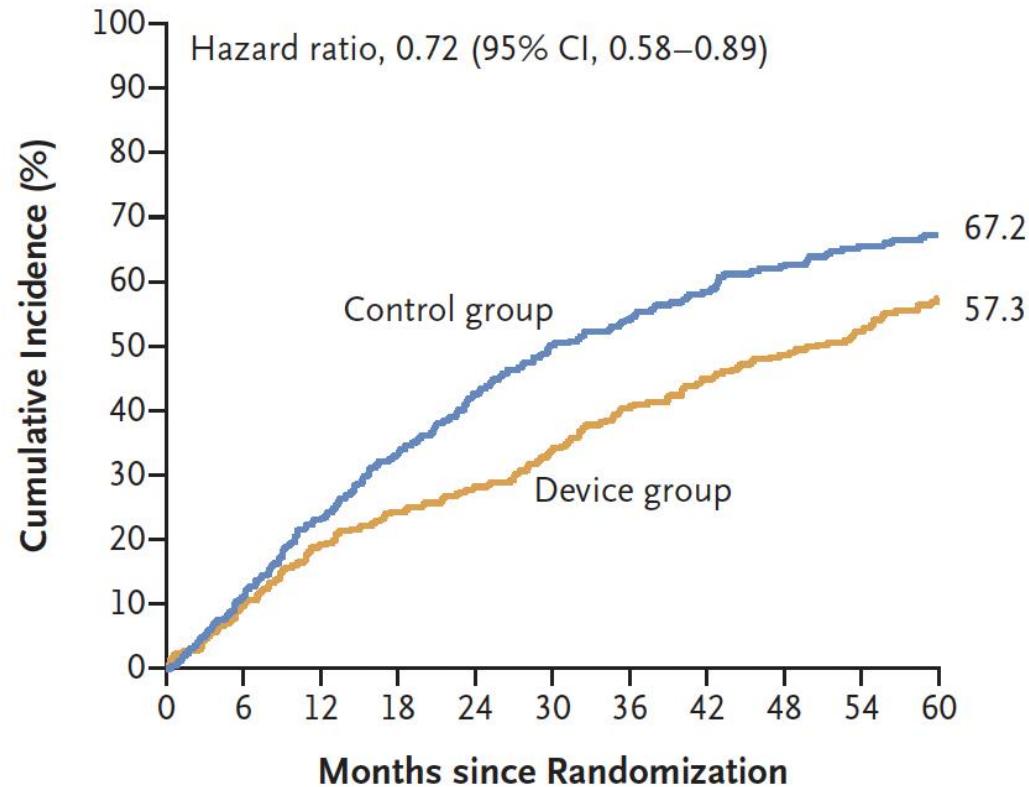
Universidad de Oviedo

ORIGINAL ARTICLE



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

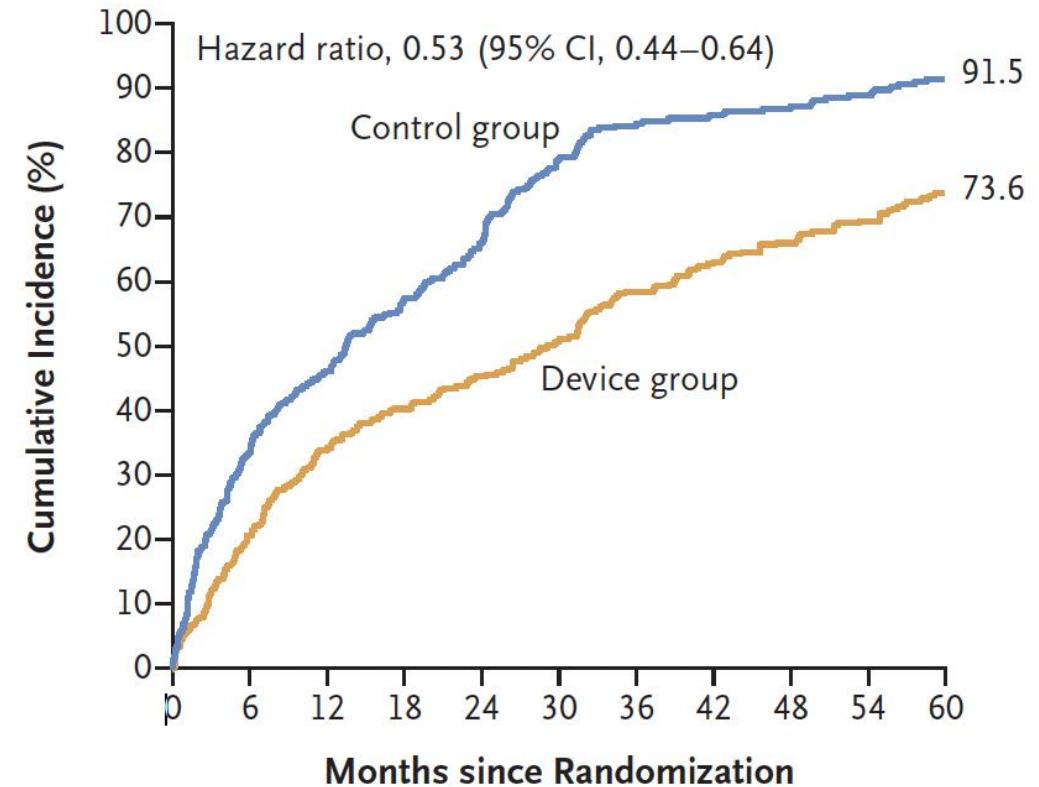
C Death from Any Cause



No. at Risk

Control group	312	272	224	189	157	135	122	107	94	84	59
Device group	302	269	238	219	205	186	167	151	138	124	79

D Death from Any Cause or First Hospitalization for Heart Failure



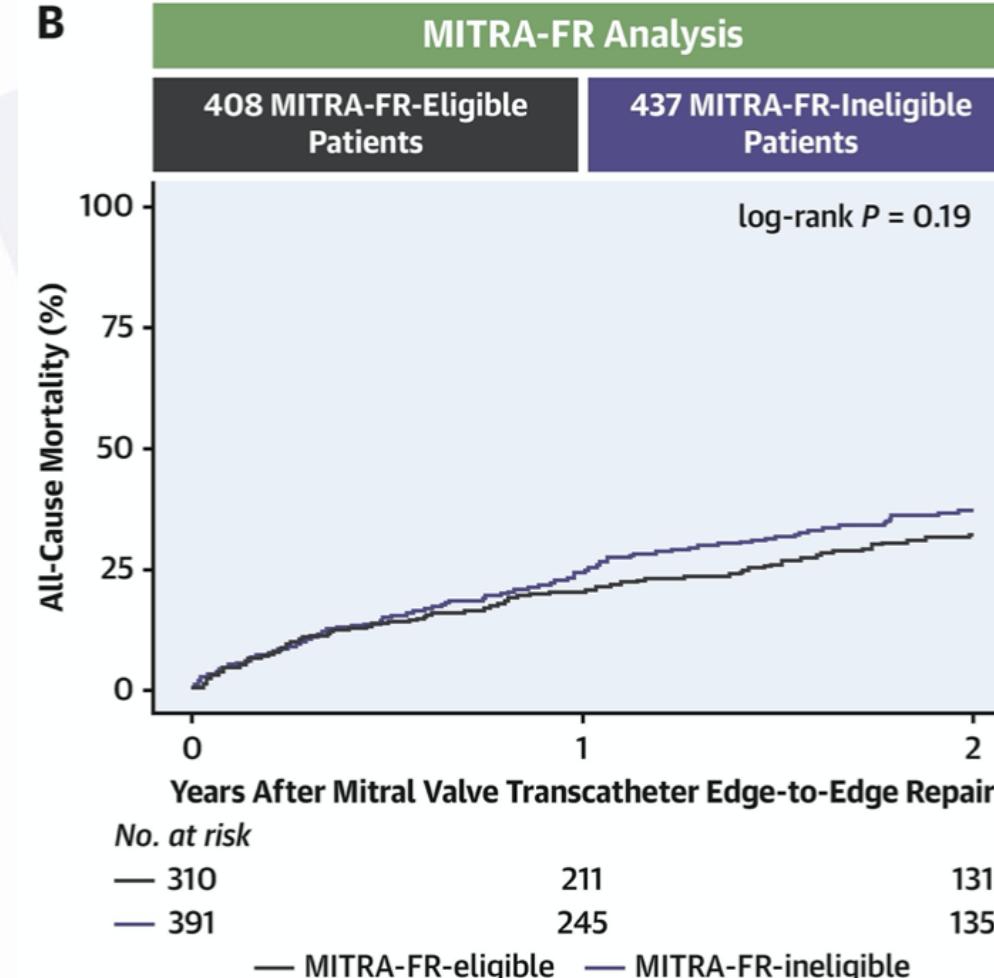
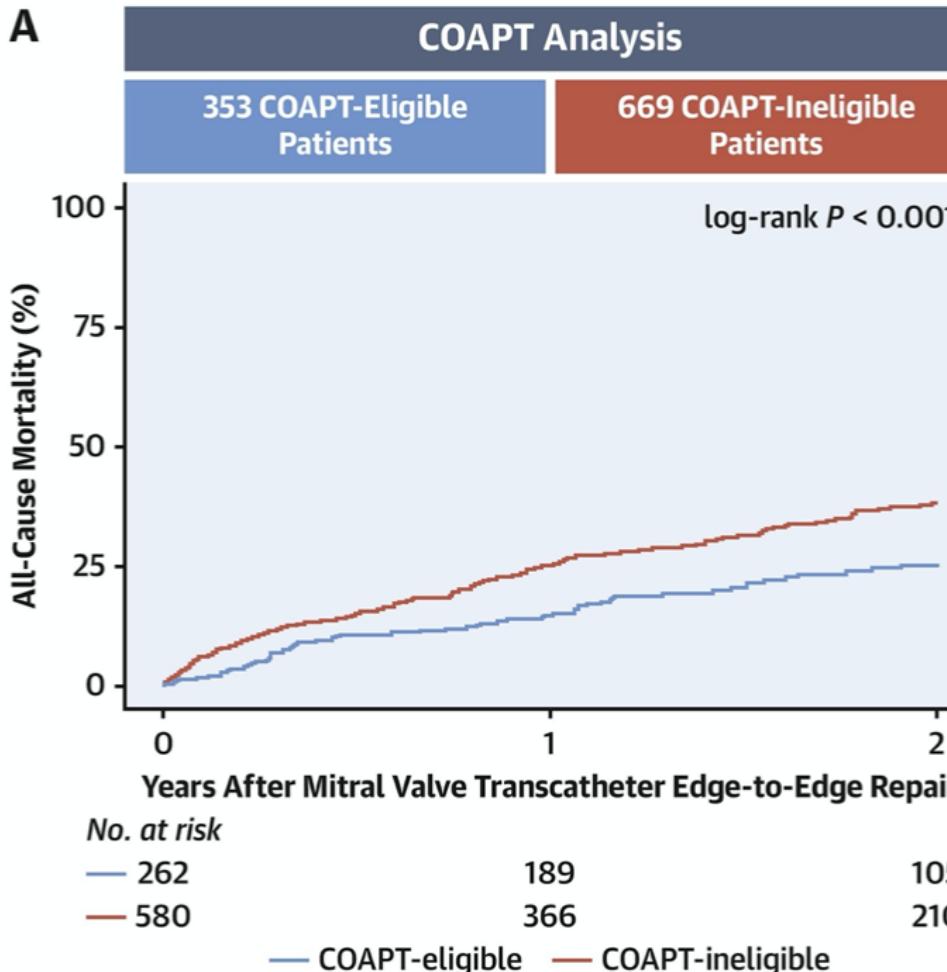
No. at Risk

Control group	312	206	157	122	95	58	43	37	33	26	17
Device group	302	236	194	174	158	141	118	105	93	81	52

Outcomes Stratified by Adapted Inclusion Criteria After Mitral Edge-to-Edge Repair

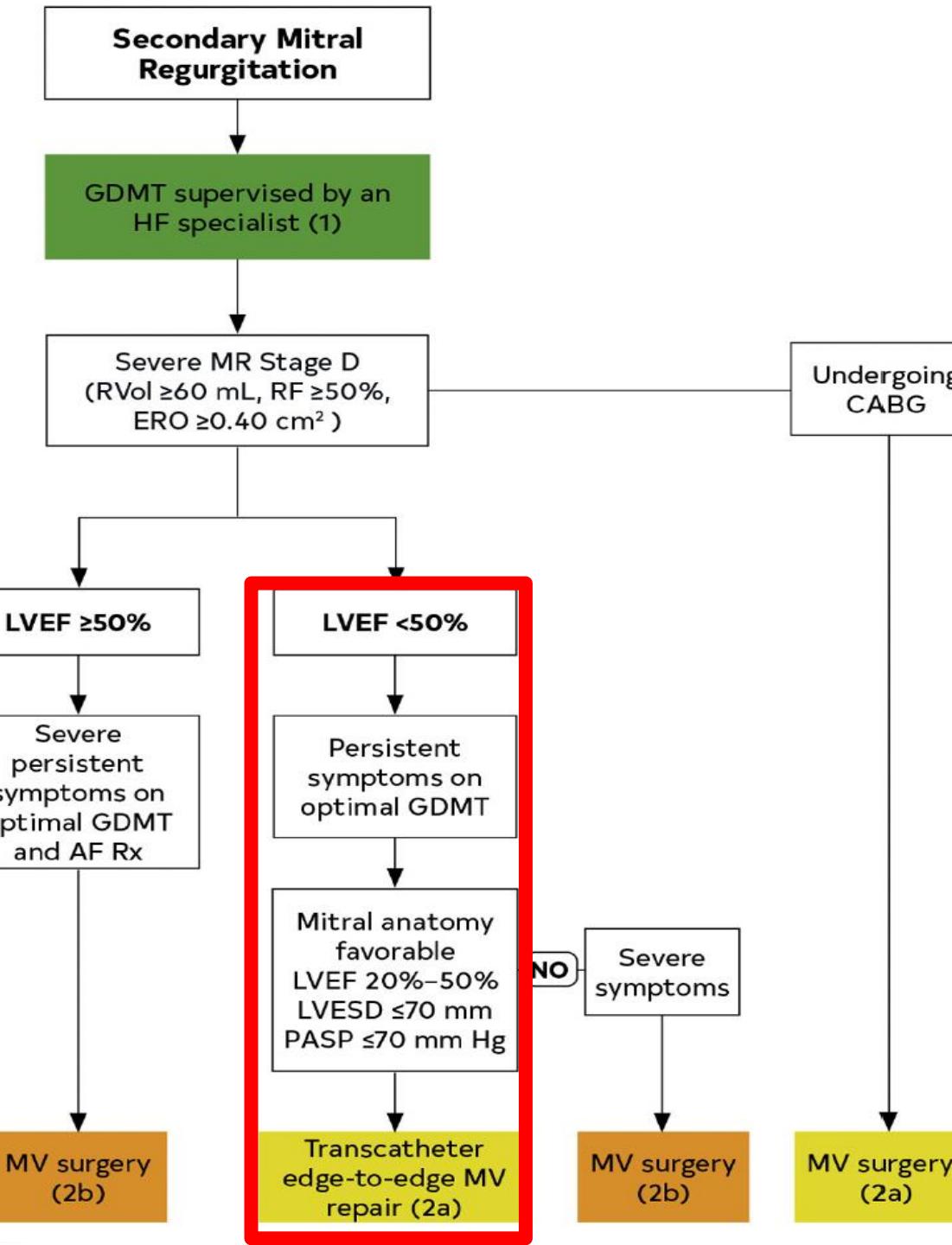
Benedikt Koell MD^{a, b} , Mathias Orban MD^c, Jessica Weimann MSc^a, Mohammad Kassar MD^d, Nicole Karam MD^e, Michael Neuss MD^f, Aniela Petrescu MD^g, Christos Iliadis MD^h, Matthias Unterhuber MD

1,022 patients included in the EuroSMR
(European Registry of Transcatheter Repair for SMR)



2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease

2a



2a

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

Patients with concomitant coronary artery or other cardiac disease requiring treatment

In symptomatic patients, who are judged not appropriate for surgery by the Heart Team on the basis of their individual characteristics,^d PCI (and/or TAVI) possibly followed by TEER (in case of persisting severe SMR) should be considered.

IIa

C

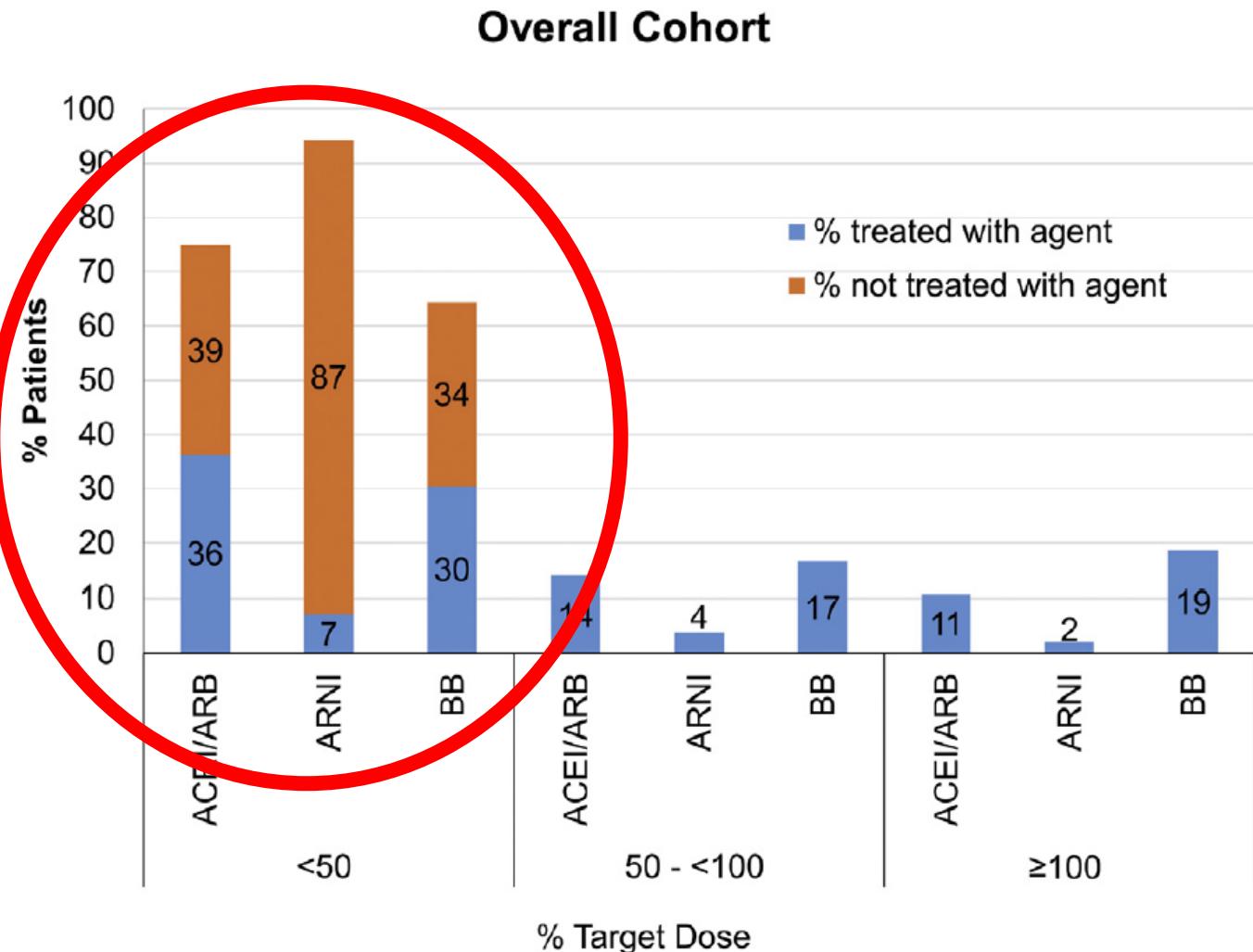
Guidelines

vs

real life?

Optimal
Medical
Treatment

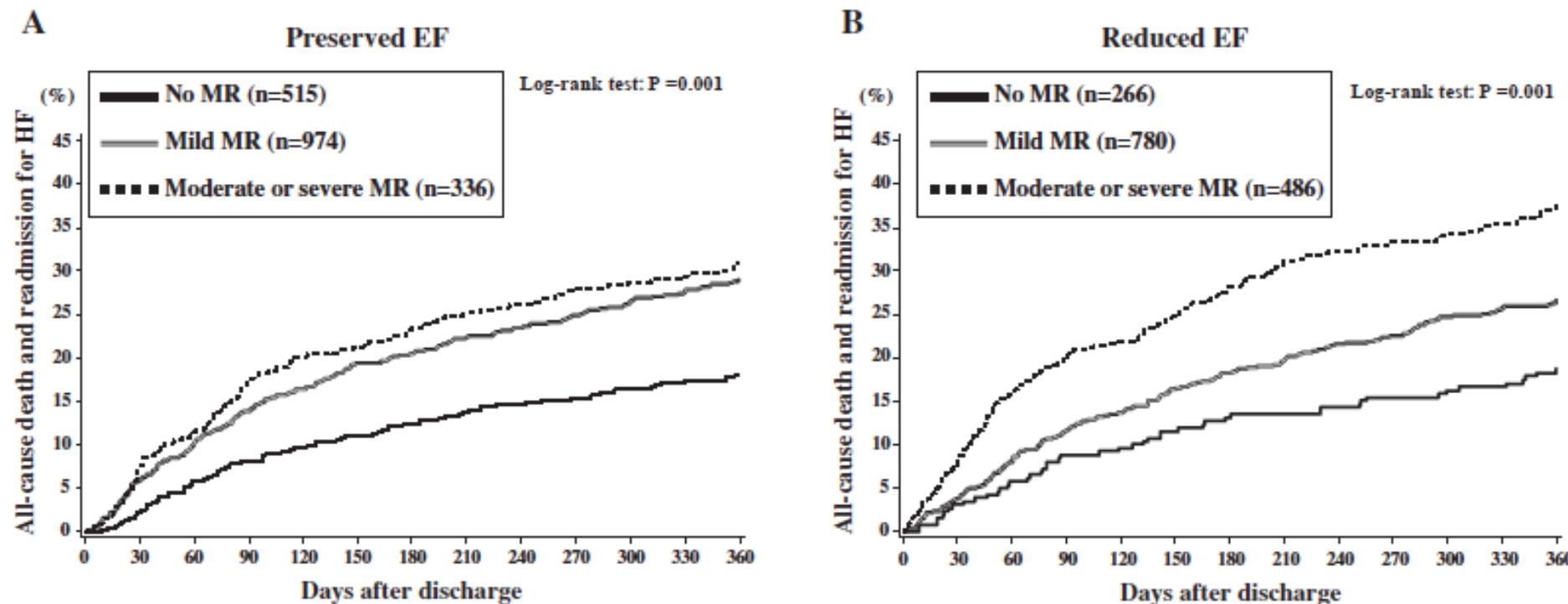
FIGURE 1 Distribution of Percent Target Doses for Each Medication Class in the Overall Cohort



Target dose
 $\leq 30\%$

undertreated
 $\approx 70\%$

Persistent FMR after a HF admission

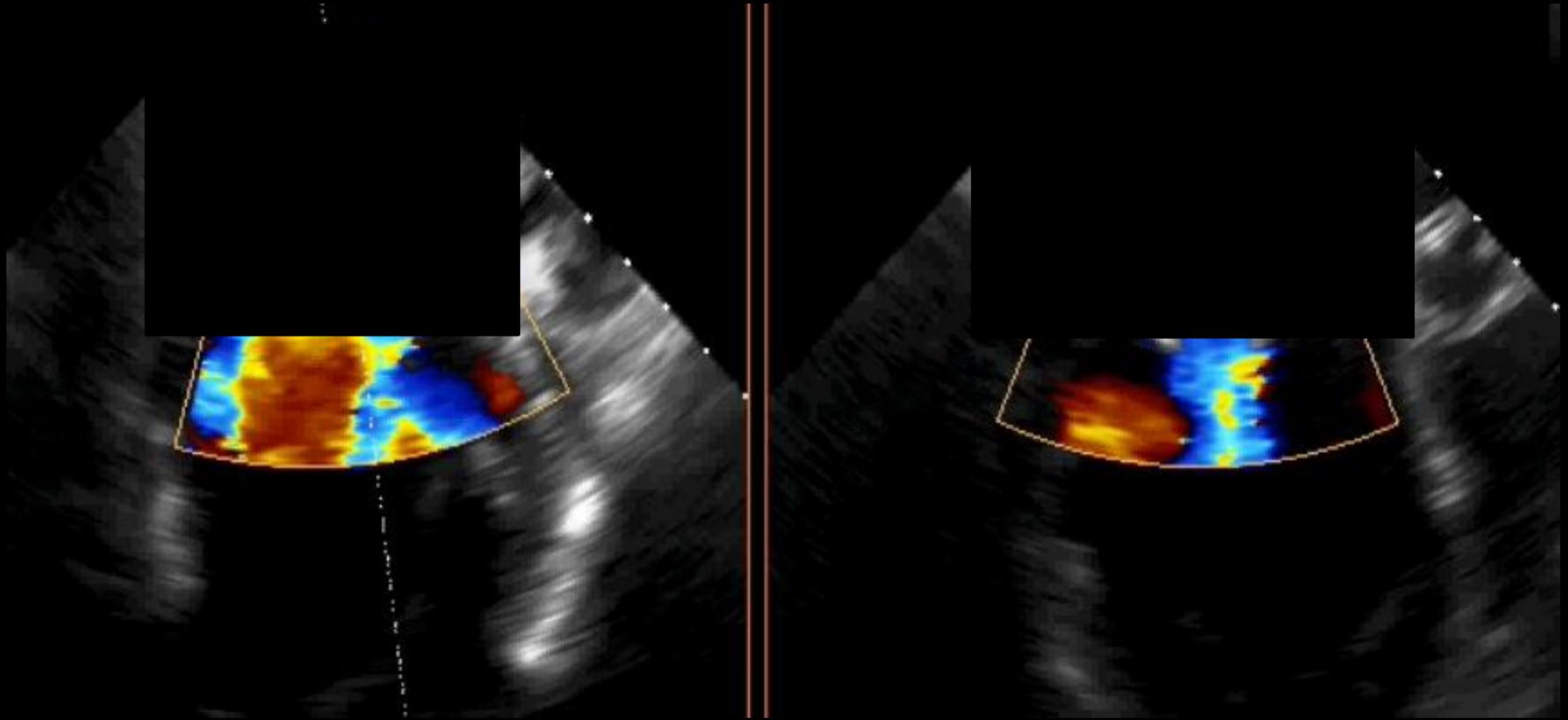


Number at risk

No MR	515	484	462	447	424	409	396
Mild MR	974	866	804	763	720	688	657
Moderate/ Severe MR	336	295	266	255	240	231	221

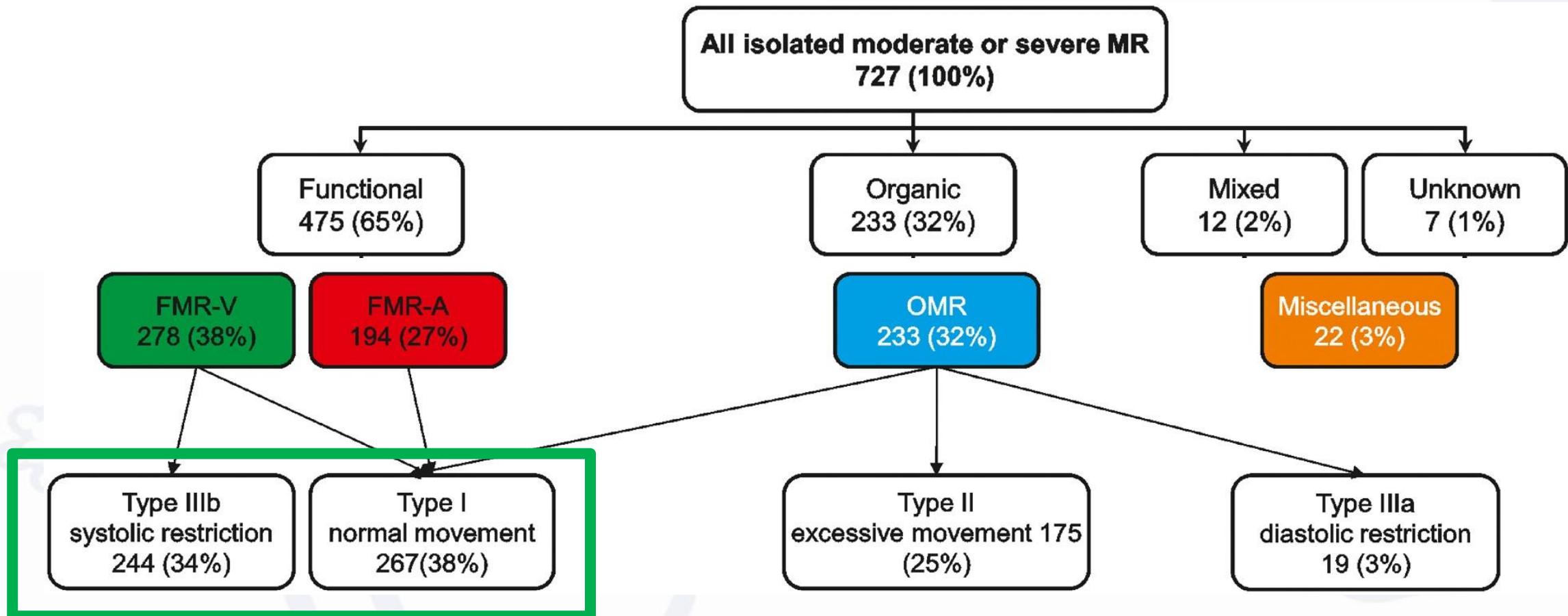
Number at risk

No MR	266	246	234	223	215	208	201
Mild MR	780	707	661	624	587	557	539
Moderate/ Severe MR	486	405	374	342	312	300	281

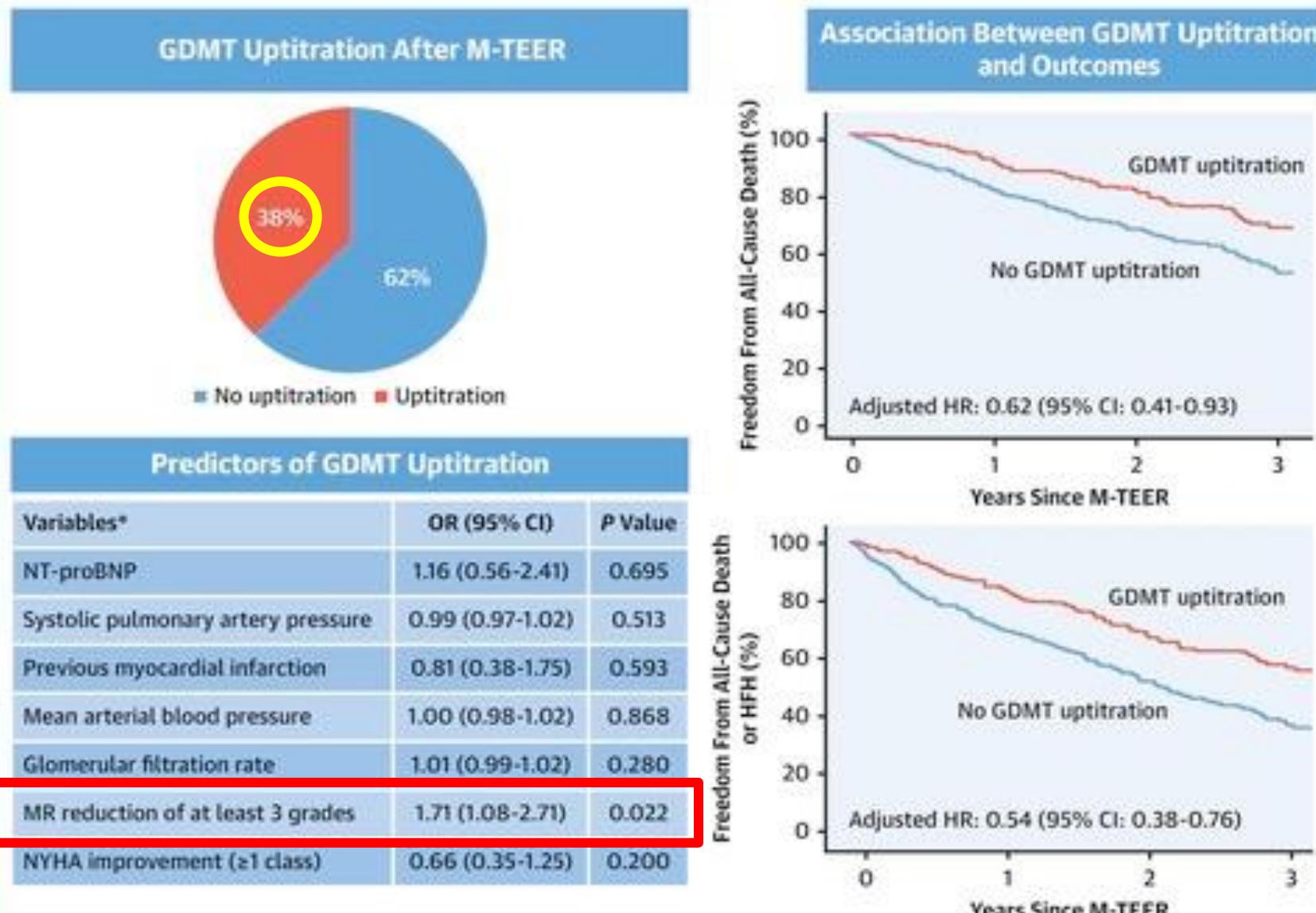


Causes and mechanisms of isolated mitral regurgitation in the community: clinical context and outcome

Volha Dziadzko, Mikhail Dziadzko , Jose R. Medina-Inojosa, Giovanni Benfari,
Hector I. Michelena, Juan A. Crestanello, Joseph Maalouf, Prabin Thapa, and
Maurice Enriquez-Sarano*



Impact of Mitral TEER Mitral on GDMT Uptitration.

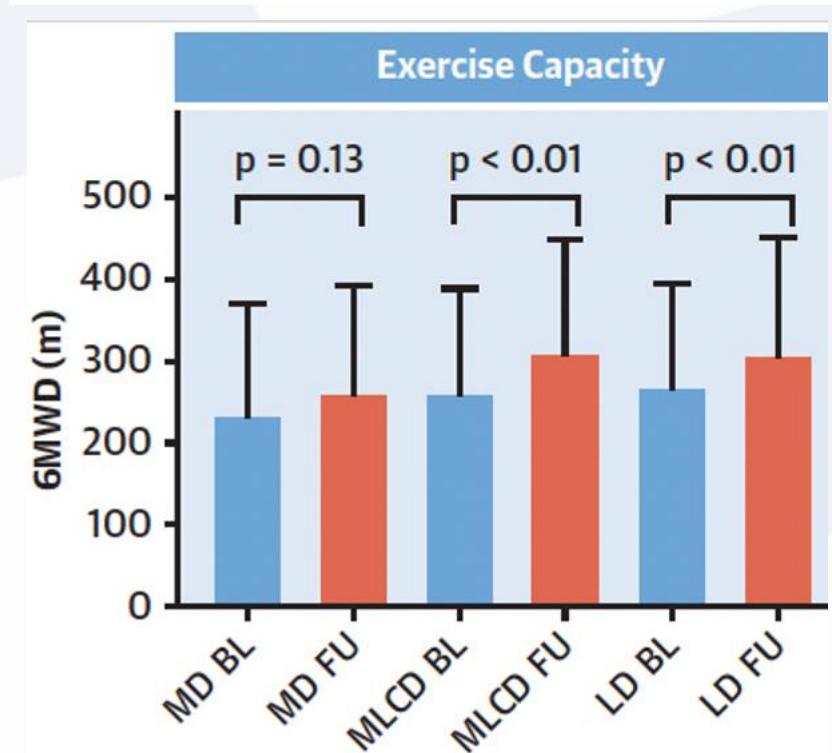
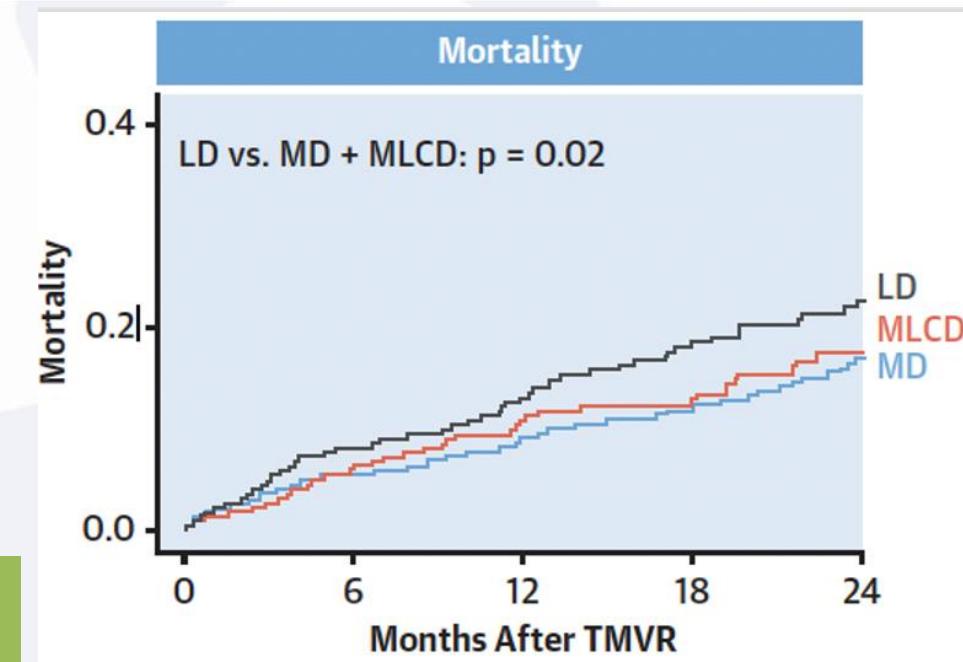
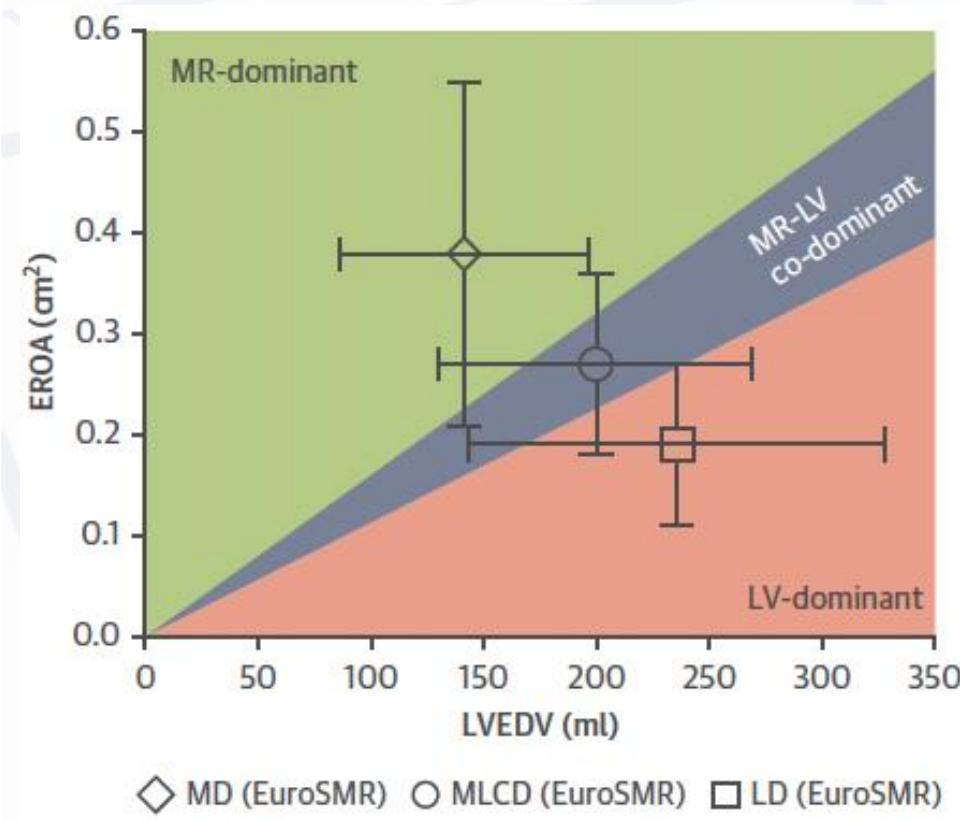


Old
Mitral
Treatment

Impact of Proportionality of Secondary Mitral Regurgitation on Outcome After Transcatheter Mitral Valve Repair

1016 ptes
FU 22 meses

EROA / LVEDV



MitraBRIDGE study

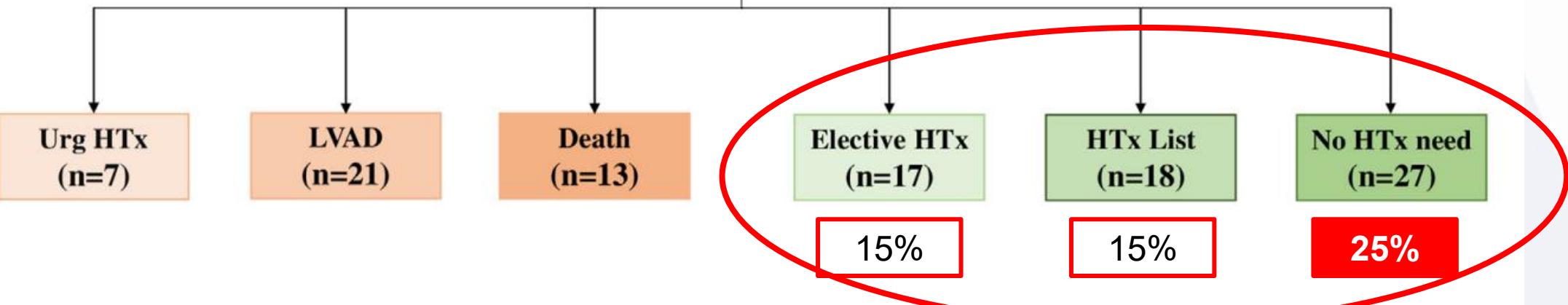
Time of index procedure

Last follow-up
(median 532, IQR:
188-986 days)

MitraClip procedure as «bridge strategy» (n=119)

Lost at follow-up (n=3)

Still waiting for decision (n=13)



Baseline groups

In List (%)	5 (16)	0 (0)	2 (6.5)	8 (26)	10 (32)	5 (16)
BTD (%)	1 (2)	16 (29.5)	8 (15)	5 (9)	4 (7.5)	12 (22)
BTC (%)	1 (3)	5 (15)	3 (9)	4 (12)	4 (12)	10 (29.5)

4

Acute MR



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Endocarditis



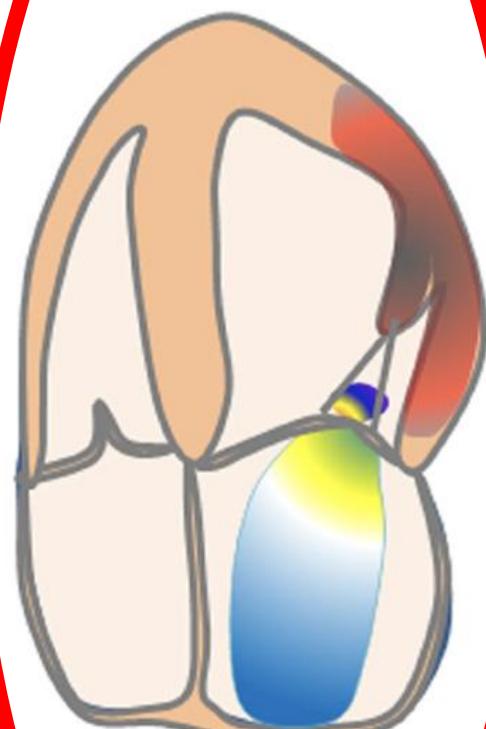
Vegetation
Leaflet prolapse
Leaflet perforation

PM rupture



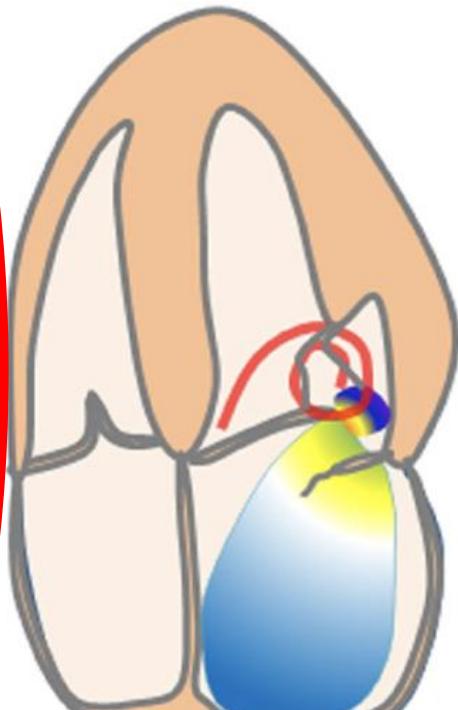
Regional wall motion
abnormality
Ruptured PM head

Ischaemic



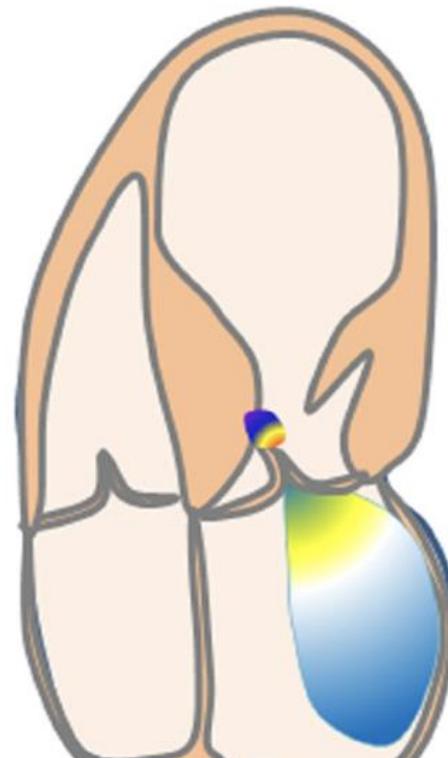
Regional wall motion
abnormality
Leaflet tethering

Device-related



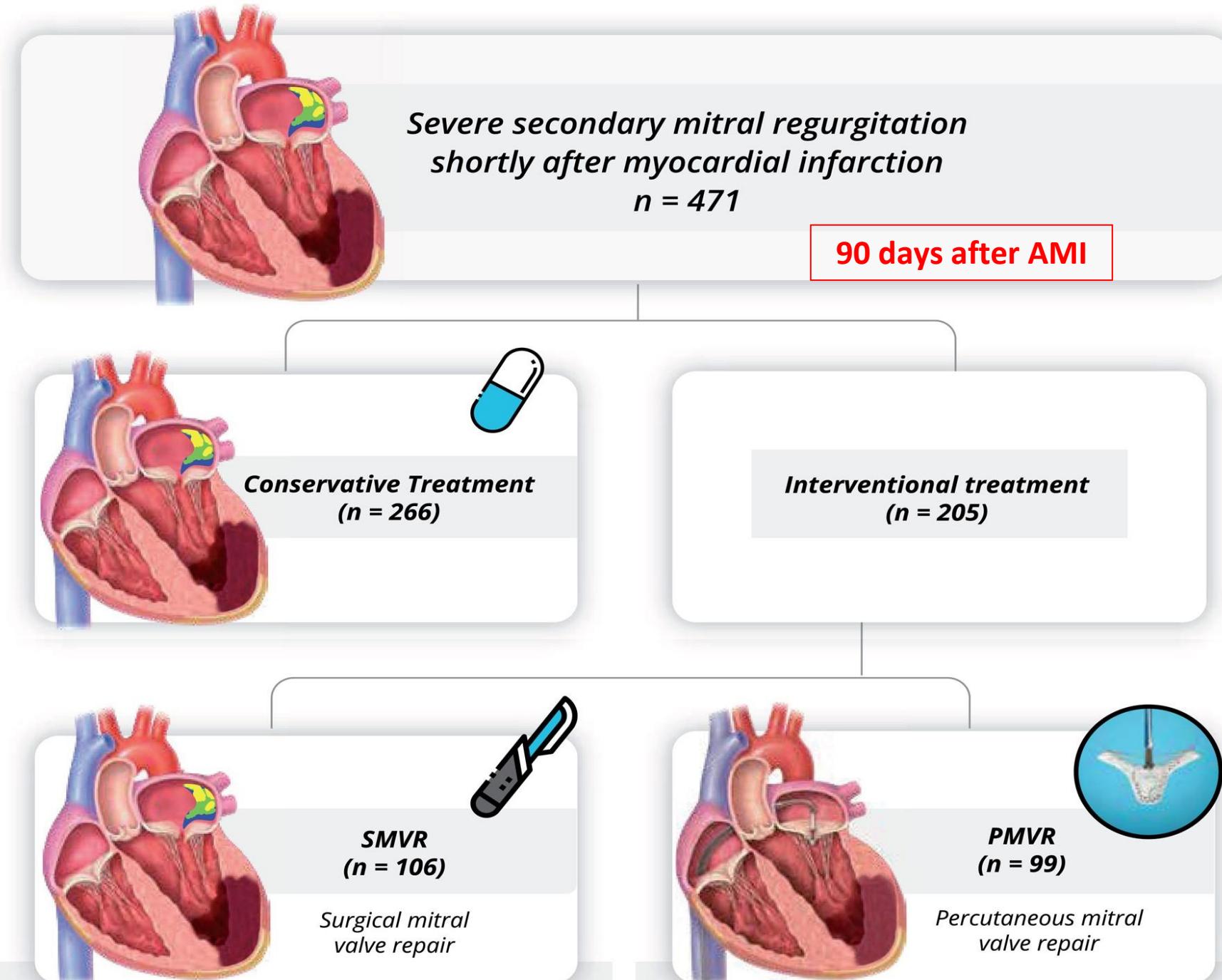
Tethered or ruptured
chordae by tangled
guidewire/catheter

Takotsubo



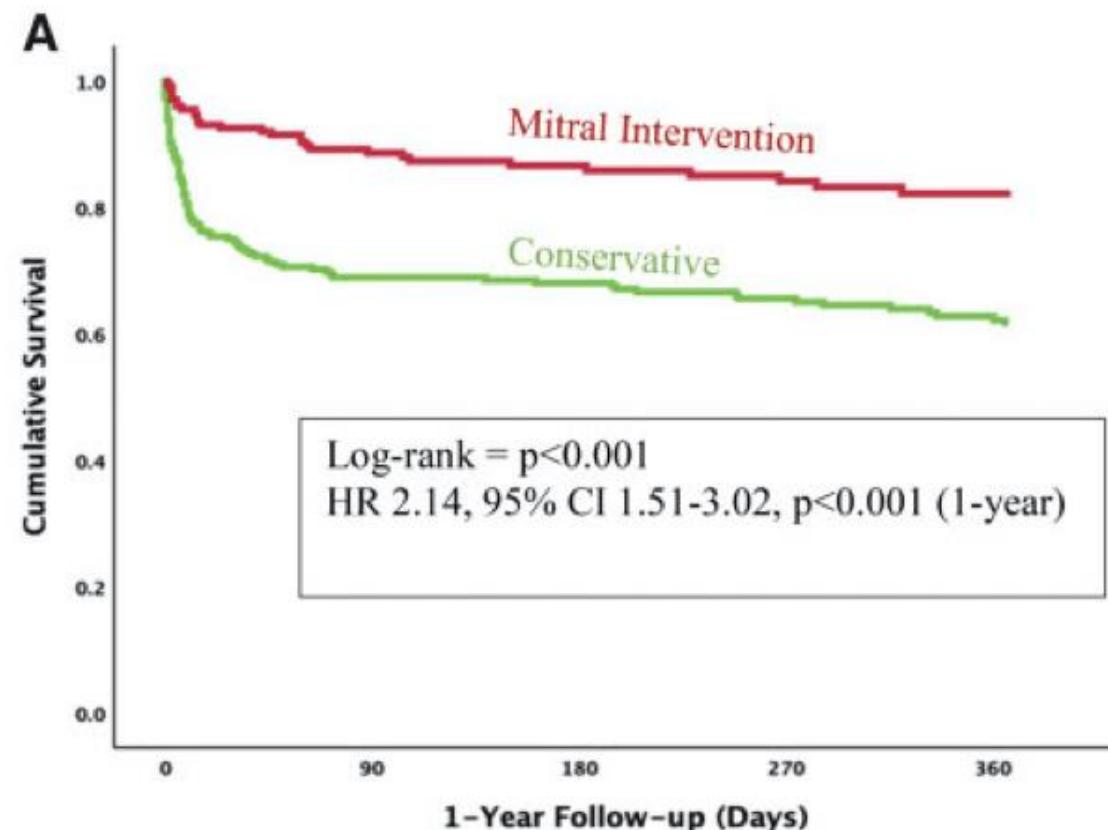
Apical ballooning
Hyperkinetic basal LV
SAM

Conservative, surgical, and percutaneous treatment for mitral regurgitation shortly after acute myocardial infarction





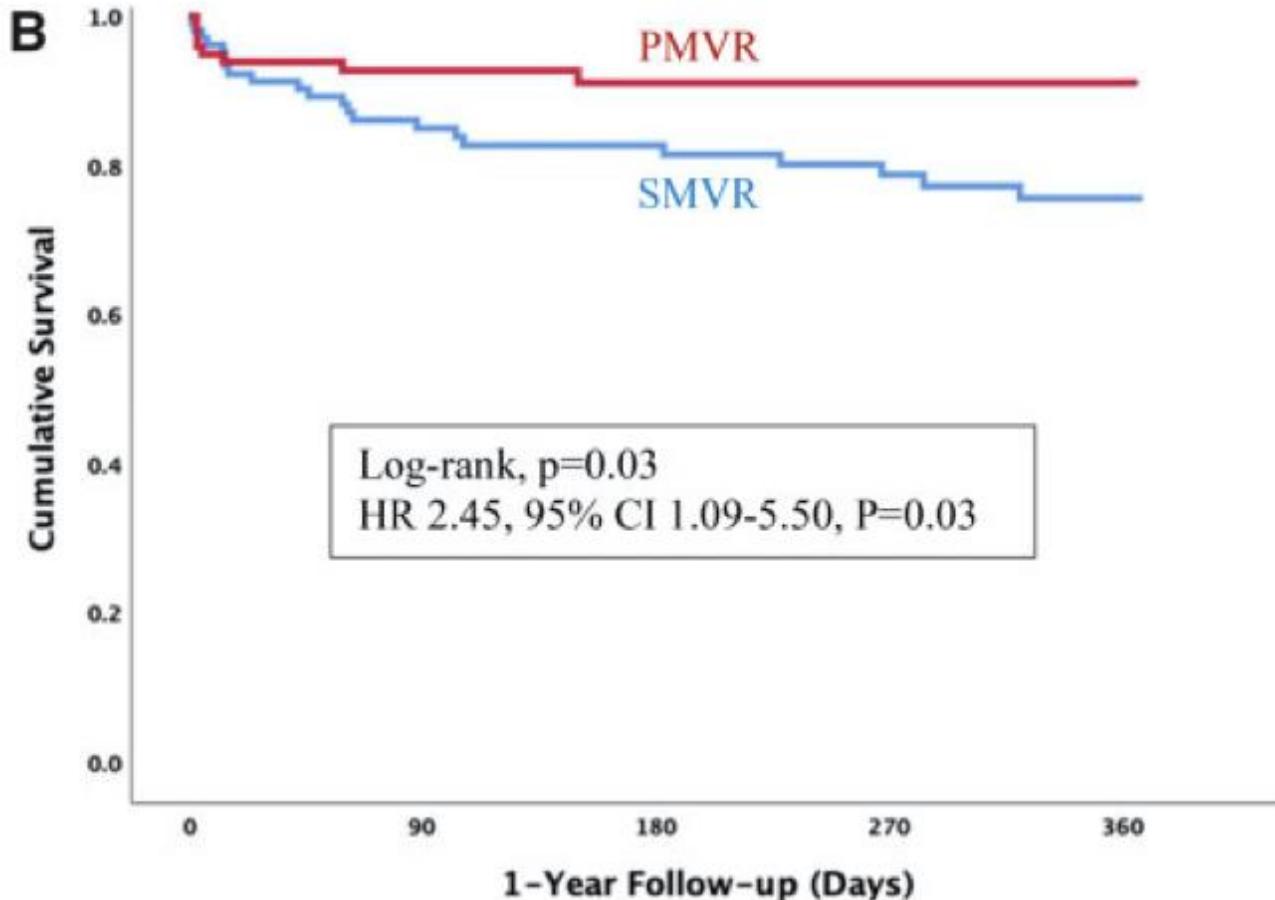
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Risk	Number at	0	3-Month	6-Month	9-Month	1-Year
Conservative	256	161	147	126	90	
Intervention	201	184	139	115	64	



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Number at Risk	0	3-Month	6-Month	9-Month	1-Year
SMVR	103	77	66	53	36
PMVR	98	72	55	38	28



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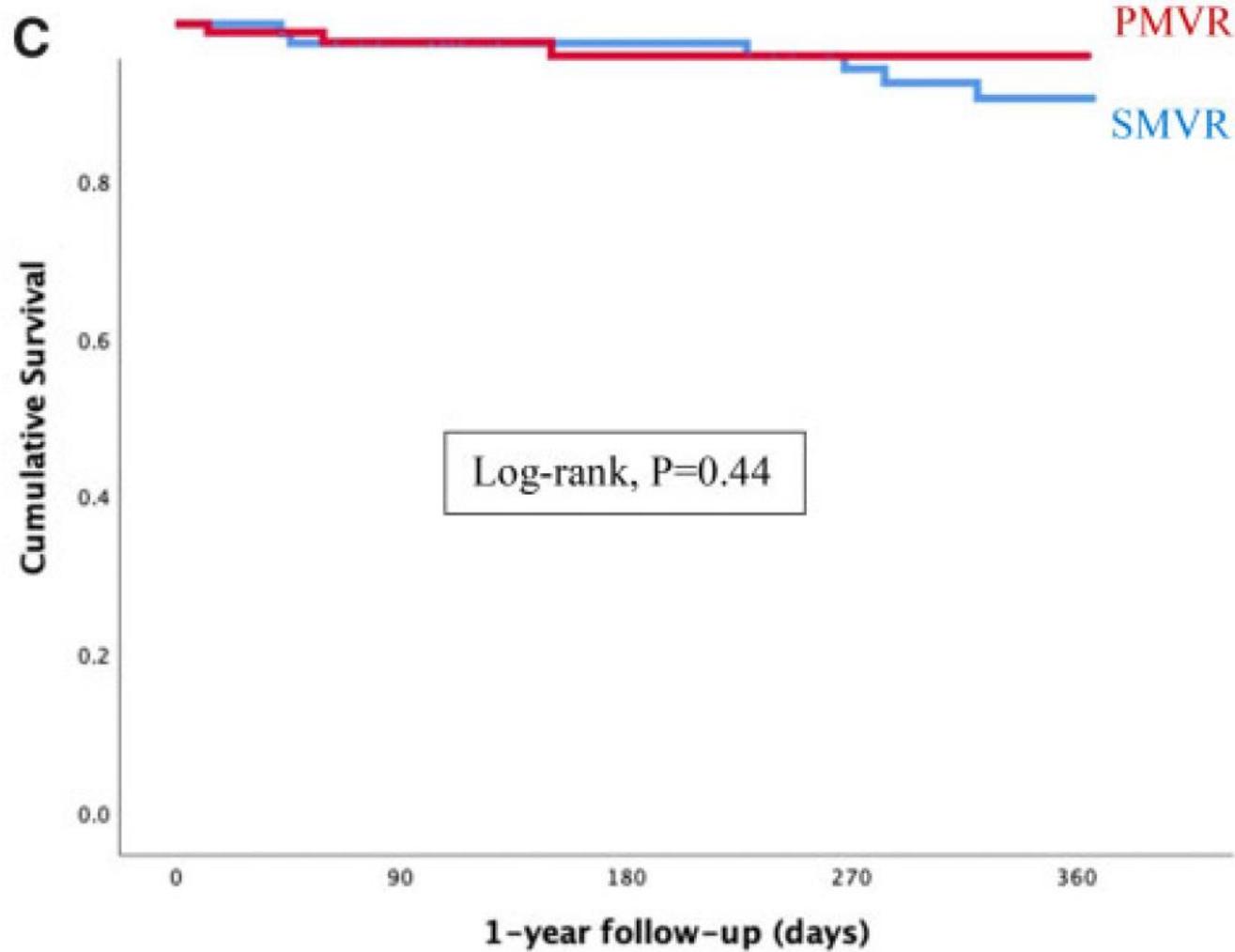
HOSPITAL
UNIVERSITARIO
CENTRAL de
ASTURIAS

Table 2 Procedural details and patient outcomes of surgical mitral valve repair or replacement and percutaneous mitral valve repair

Variable	SMVR <i>(n = 106)</i>	PMVR <i>(n = 99)</i>	P-value
<hr/>			
Procedure			
Procedure time, min	150 [118–240]	90 [60–136]	<0.01
MI to Procedure, days	12 [5–19]	19 [10–40]	<0.01
MR >2 at discharge	9 (8)	8 (8)	0.80
Major complications	36 (34)	6 (6)	<0.01
<hr/>			
Outcomes			
Procedure success	98 (92)	92 (93)	0.53
In-hospital mortality	17 (16)	6 (6)	0.03
Mortality at 3 months	21 (20)	10 (10)	0.13
Rehospitalization at 3 months	6 (6)	13 (13)	0.14
1-year mortality	32 (31)	16 (17)	0.04

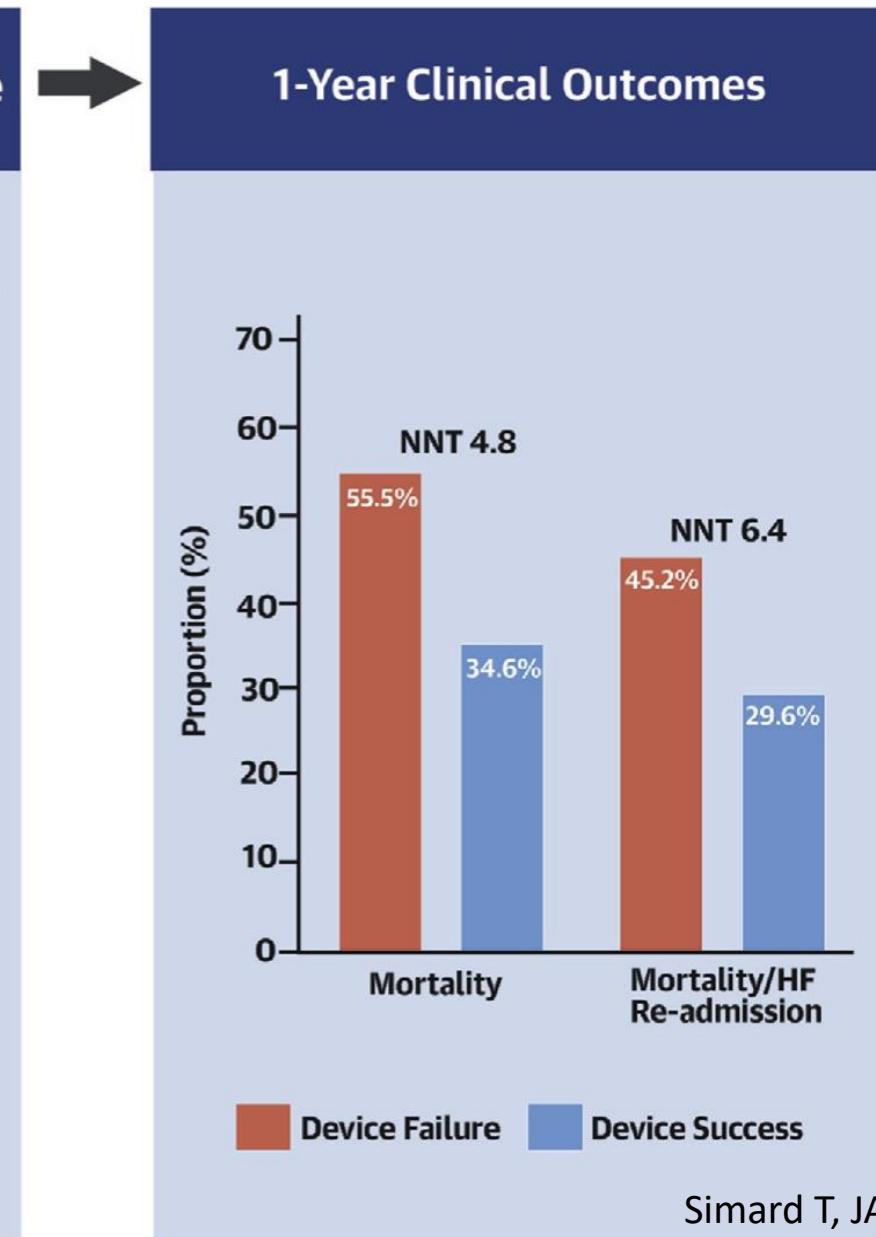
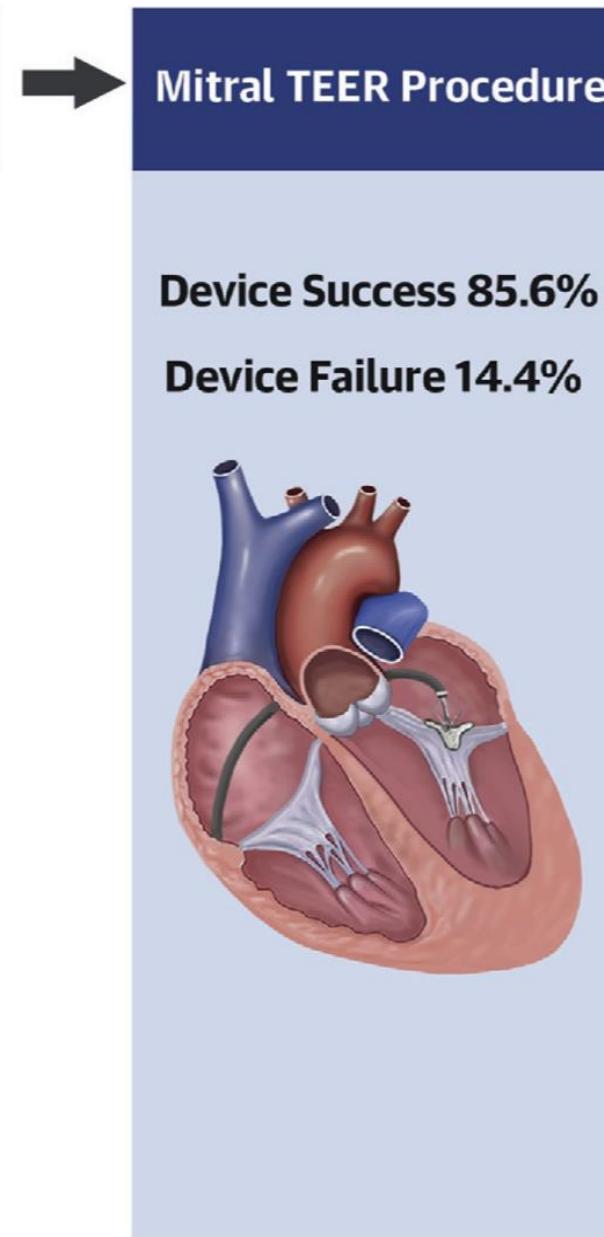
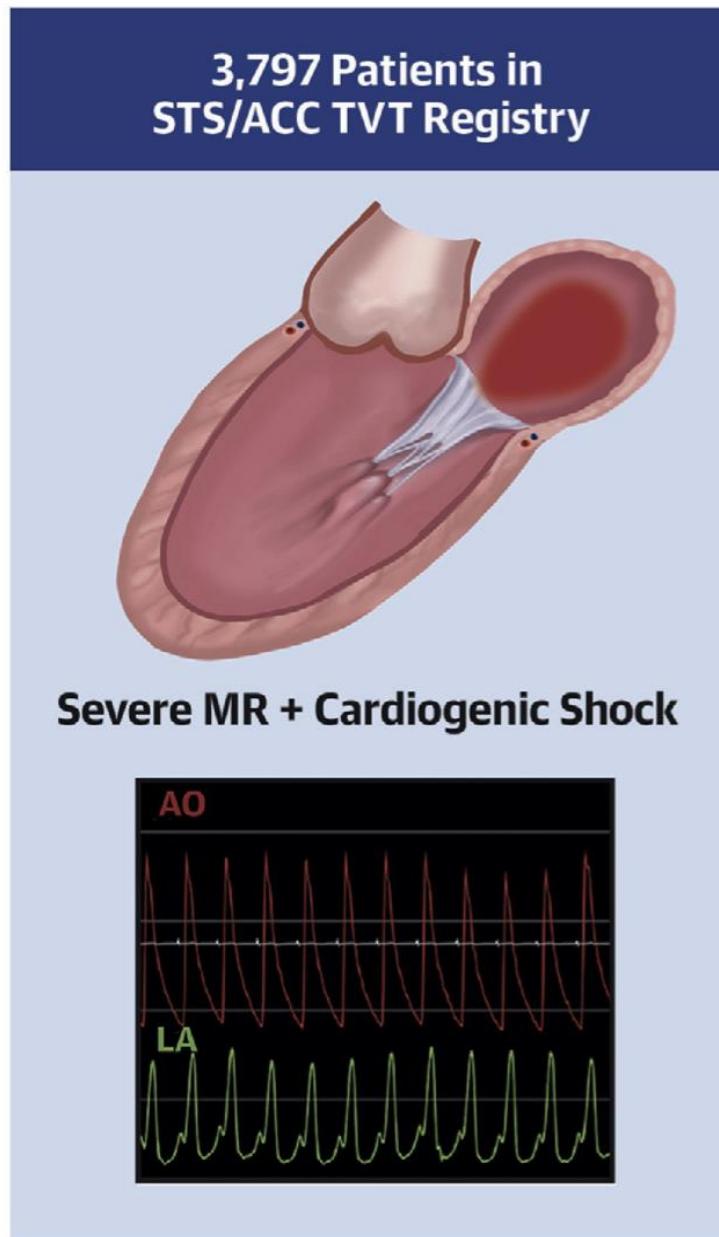


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Number at Risk	0	3-Month	6-Month	9-Month	1-Year
SMVR	86	73	66	54	40
PMVR	92	62	48	38	28

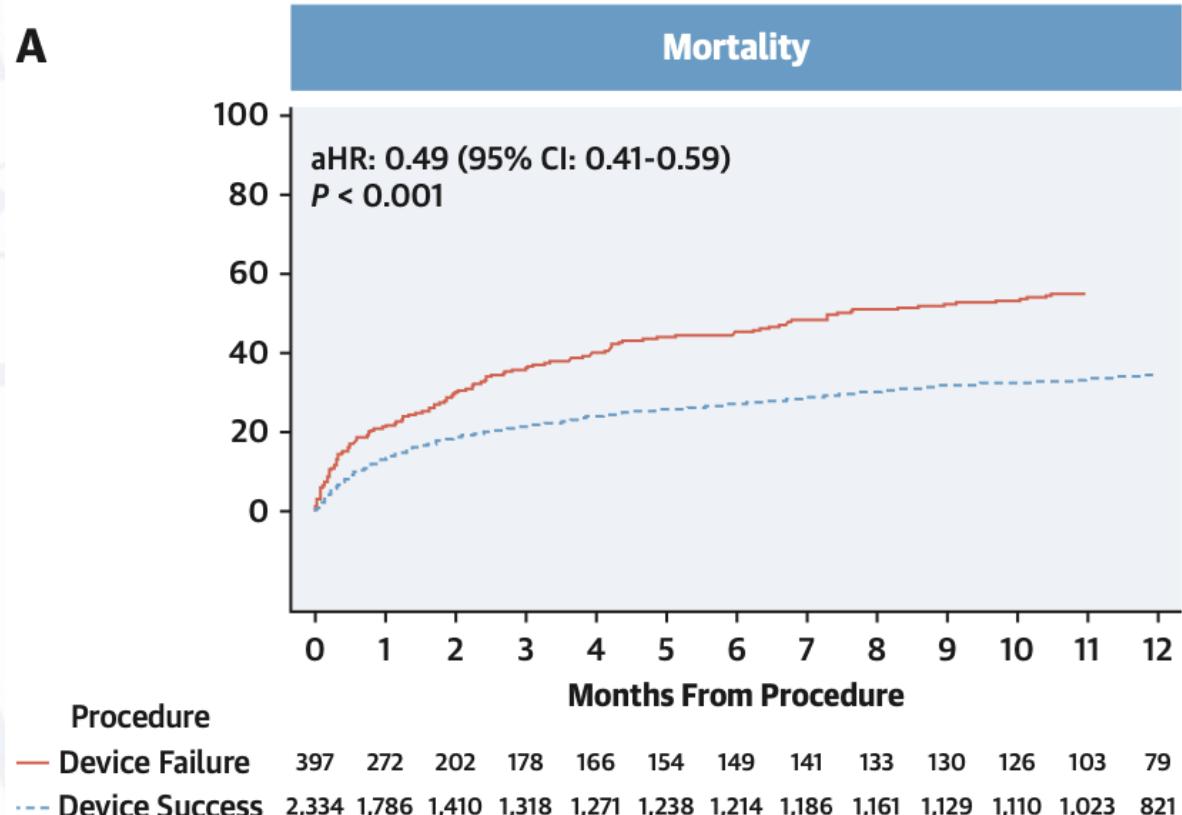
CENTRAL ILLUSTRATION: Mitral Regurgitation and Cardiogenic Shock: Role of Transcatheter Edge-to-Edge Repair





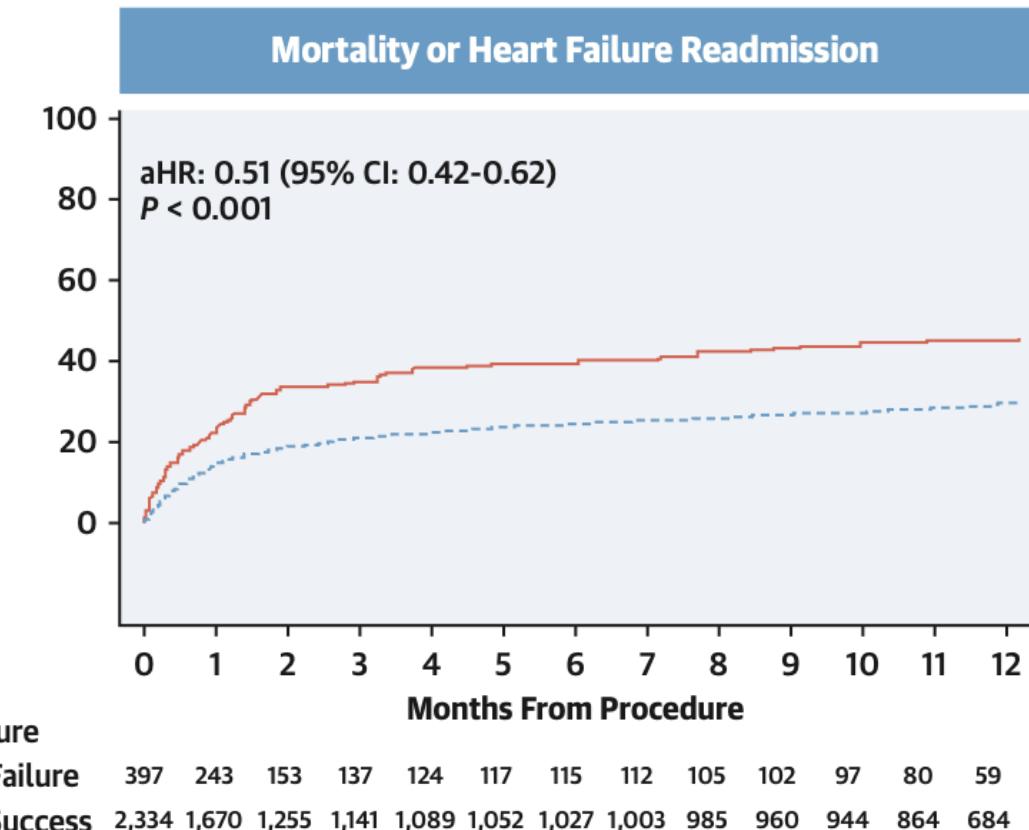
Universidad de Oviedo

A



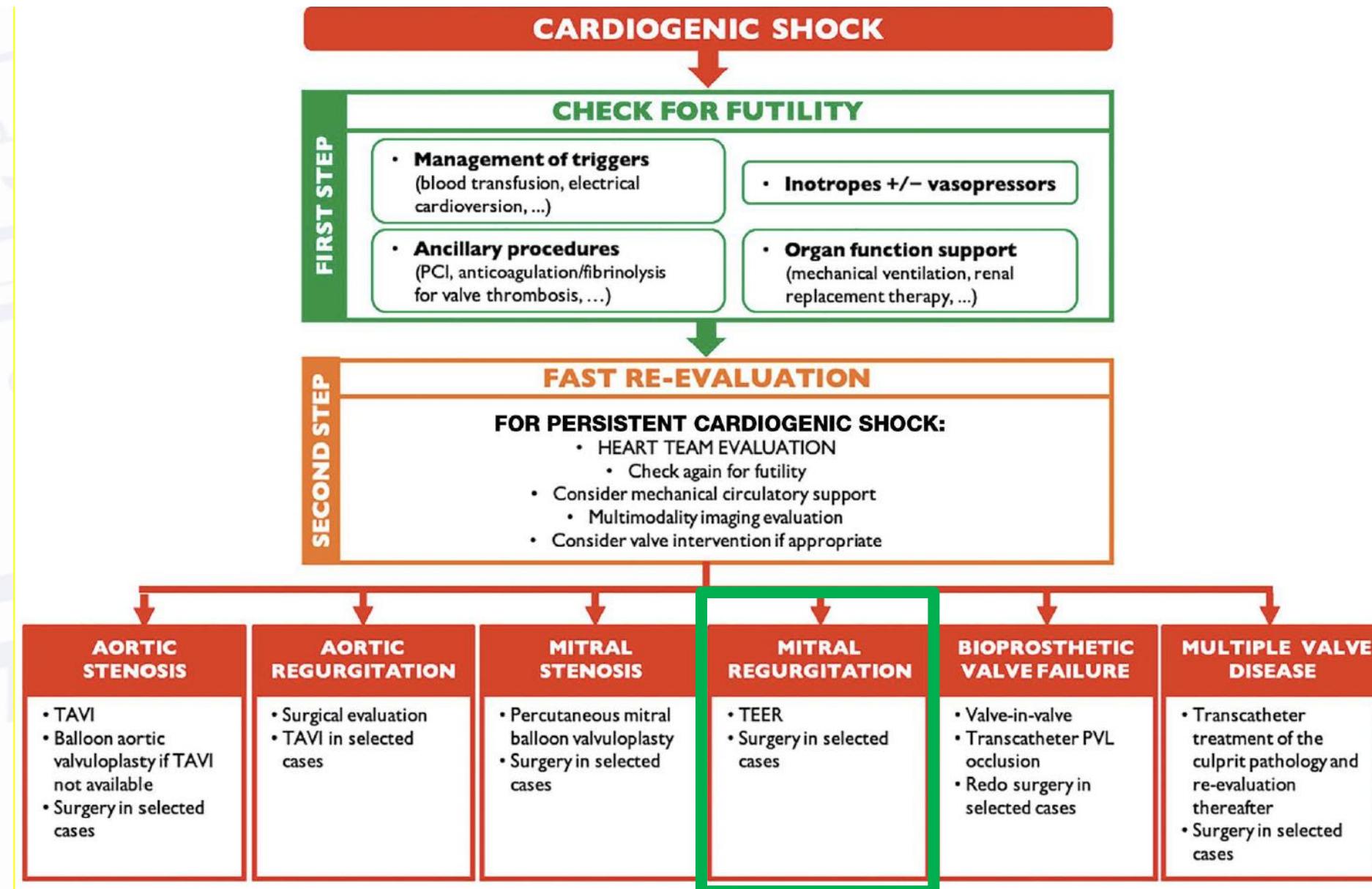
NNT 4.8

B



NNT 6.4

CENTRAL ILLUSTRATION Diagnostic and therapeutic algorithm in cardiogenic shock and valvular heart disease.



Early Transcatheter Mitral Valve Repair after Myocardial Infarction (EMCAMI)

Spain Study Centers

101	Hospital Universitario Central de Asturias
102	Hospital Clinic y Provincial de Barcelona
103	Hospital Universitario Virgen de la Victoria de Málaga
104	Hospital Universitario de Córdoba
105	Hospital Universitario del a Santa Creu i San Pau de Barcelona
106	Hospital Alvaro Cunqueiro de Vigo
107	Hospital Universitario Puerto de Hierro de Madrid
108	Hospital Clínico Universitario San Carlos de Madrid
109	Hospital Clínico Universitario de Valladolid
110	Hospital de la Vall d'Hebron de Barcelona
111	Hospital Universitario Ramón y Cajal de Madrid
112	Hospital Universitario de Gran Canaria
113	Hospital Universitario Marqués de Valdecilla
114	Hospital Universitario de Alicante
115	Hospital Universitario Bellvitge de Barcelona

Netherlands Study Centers

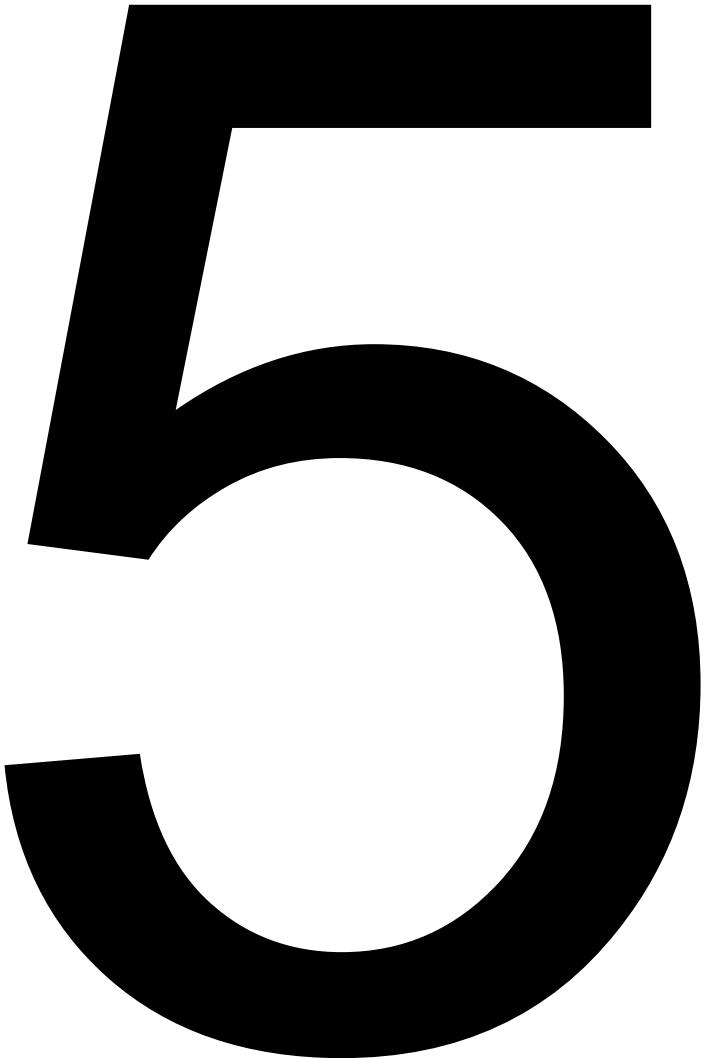
201	Maastricht University Medical Center
202	Amphia Hospital, Breda
203	Amsterdam University Medical Center
204	Catharina Hospital, Eindhoven
205	St. Antonius Hospital, Nieuwegein
206	Isala Hospital, Zwolle
207	Leiden University Medical Center

Israel Study Centers

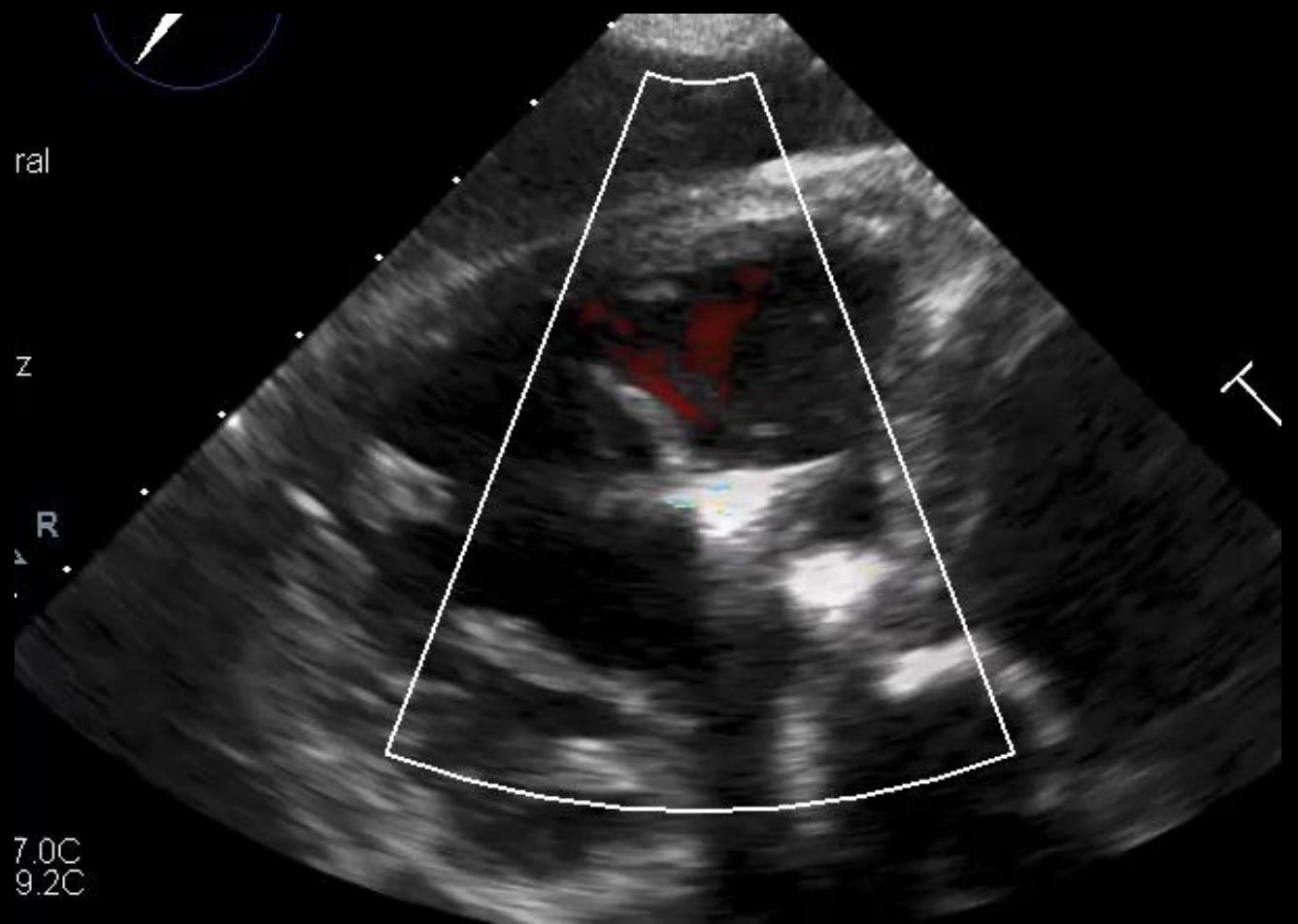
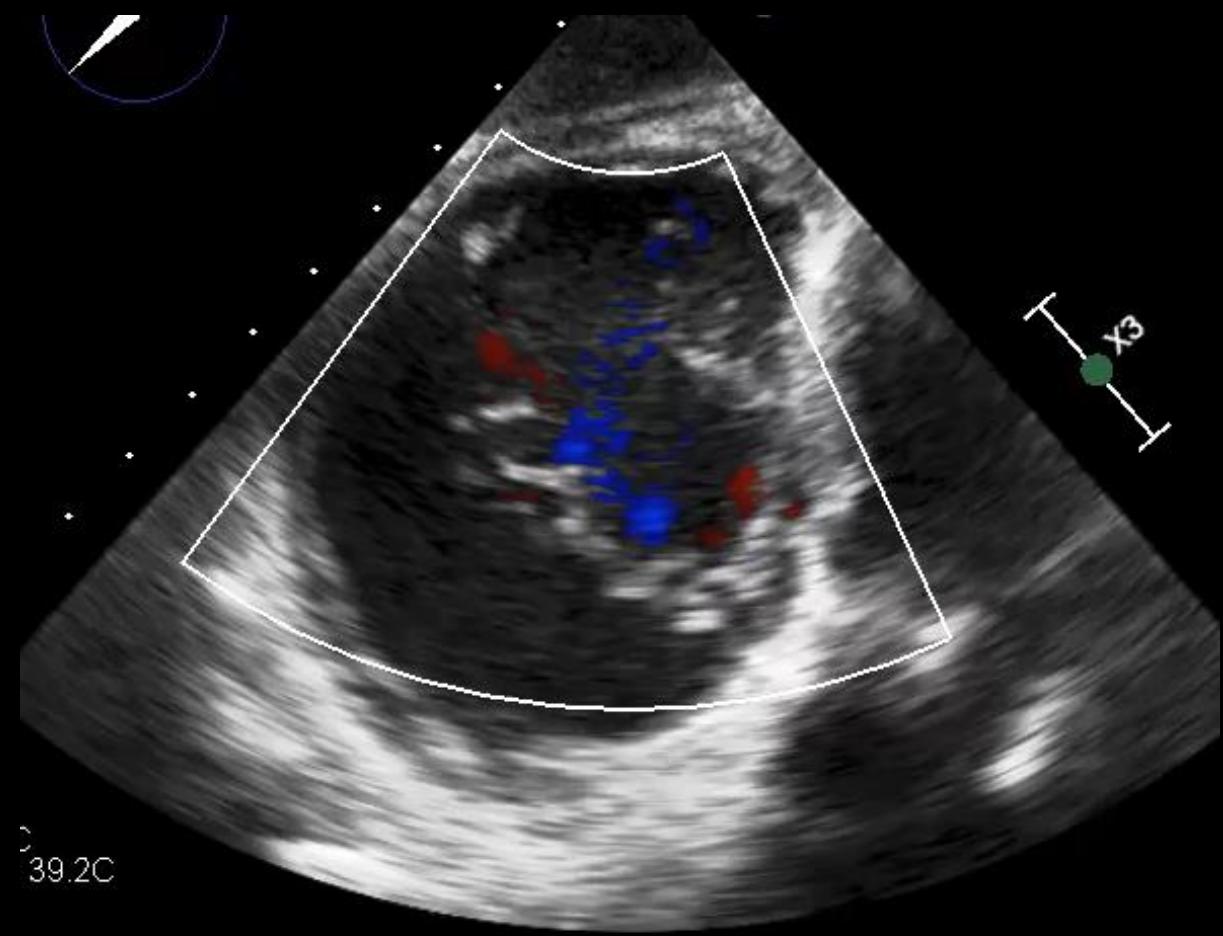
301	Shaare Zedek Medical Center, Jerusalem
302	Rabin Medical Center, Petah Tikva
303	Sheba Medical Center, Tel Aviv

Italy Study Centers

401	Hospital San Raffaele, Milan, Italy
402	San Donato Hospital, Milan, Italy
403	University and Civil Hospitals of Brescia, Italy



TR-TEER



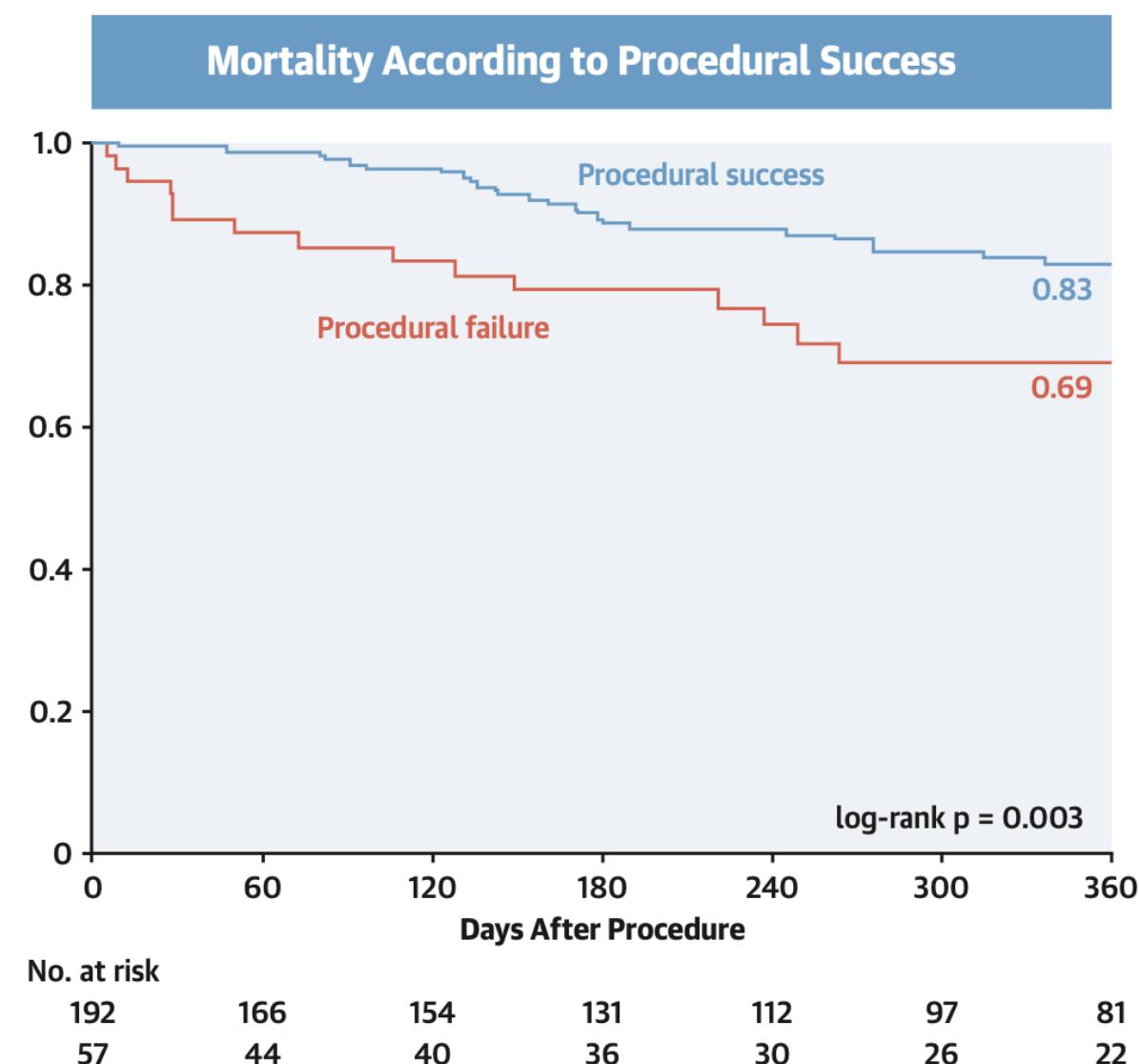
1-Year Outcomes After Edge-to-Edge Valve Repair for Symptomatic Tricuspid Regurgitation

Results From the TriValve Registry

CENTRAL ILLUSTRATION Kaplan-Meier Estimates of 1-Year Mortality According to Procedural Failure After Edge-to-Edge Tricuspid Valve Repair

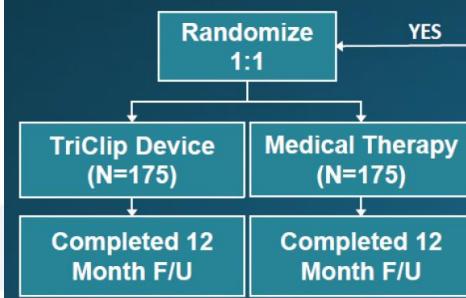
TABLE 4 Univariate and Multivariate Analysis of Procedural Failure

	Univariate		Multivariate*	
	OR (95% CI)	p Value	OR (95% CI)	p Value
Pacemaker or ICD lead	1.53 (0.81-2.84)	0.18		
LVEF	1.00 (0.98-1.02)	0.95		
TAPSE	1.02 (0.95-1.10)	0.55		
MR grade	1.10 (0.84-1.44)	0.48		
TR vena contracta	1.76 (0.87-3.53)	0.11		
TR coaptation gap >6.5 mm	6.16 (3.19-12.18)	<0.001	1.23 (1.10-1.38)	<0.001
TR EROA >0.695 cm ²	4.79 (2.52-9.33)	<0.001	1.21 (1.09-1.35)	<0.001
TR coaptation depth >9.75 mm	3.17 (1.71-6.04)	<0.001	1.01 (0.90-1.44)	0.83
TR tenting area >3.15 cm ²	4.78 (2.49-9.30)	<0.001	1.18 (1.01-1.37)	0.035
Noncentral or nonanteroseptal TR jet location	2.38 (0.98-5.52)	0.047	1.21 (1.04-1.41)	0.013
Tricuspid annular diameter	1.03 (0.99-1.08)	0.098	1.00 (0.99-1.00)	0.60
Concomitant mitral valve edge-to-edge repair	0.66 (0.36-1.20)	0.17		
Number of clips	0.81 (0.57-1.12)	0.20		



TRILUMINATE trial

(TriClip, Abbott Vasc)



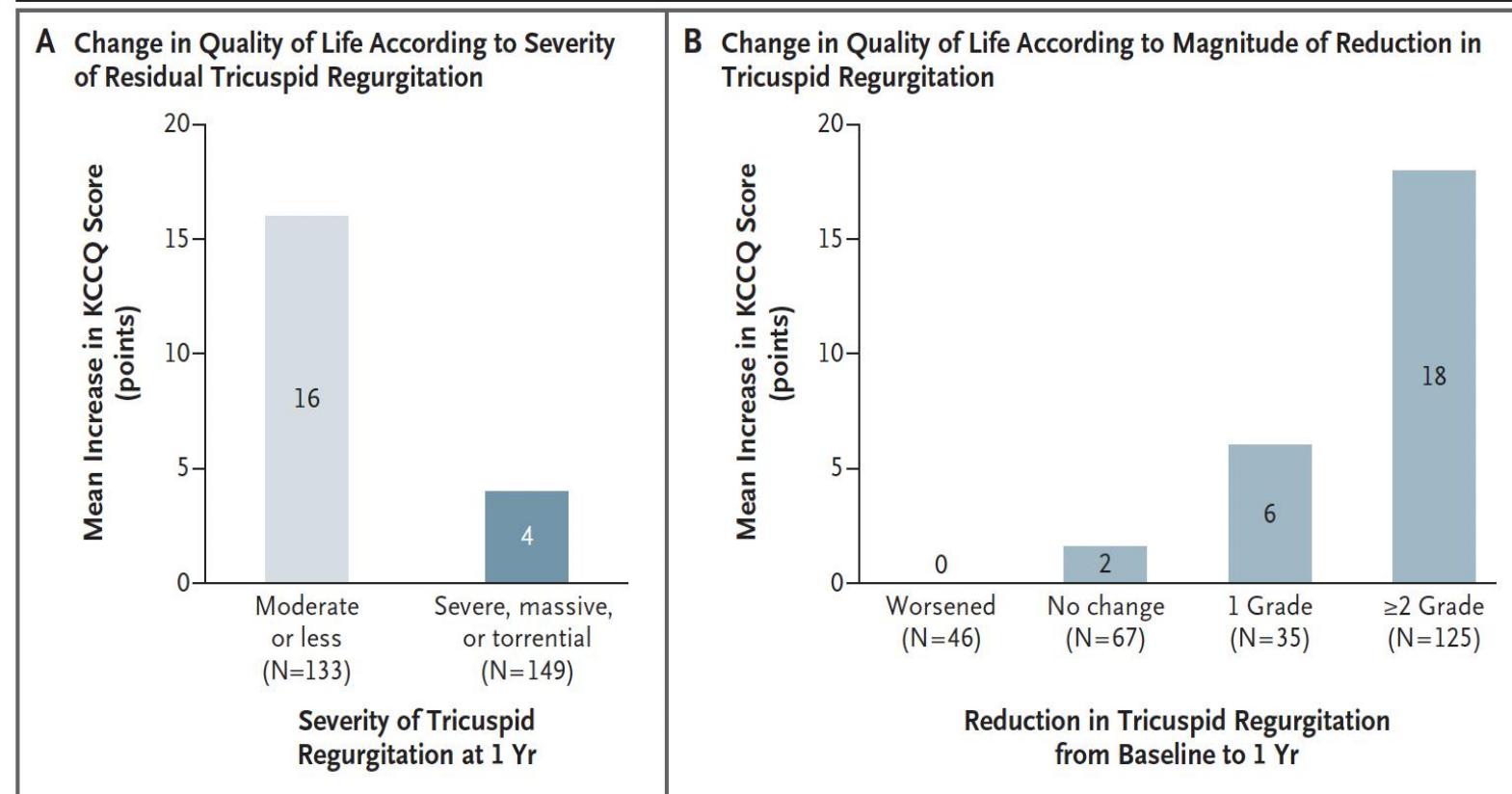
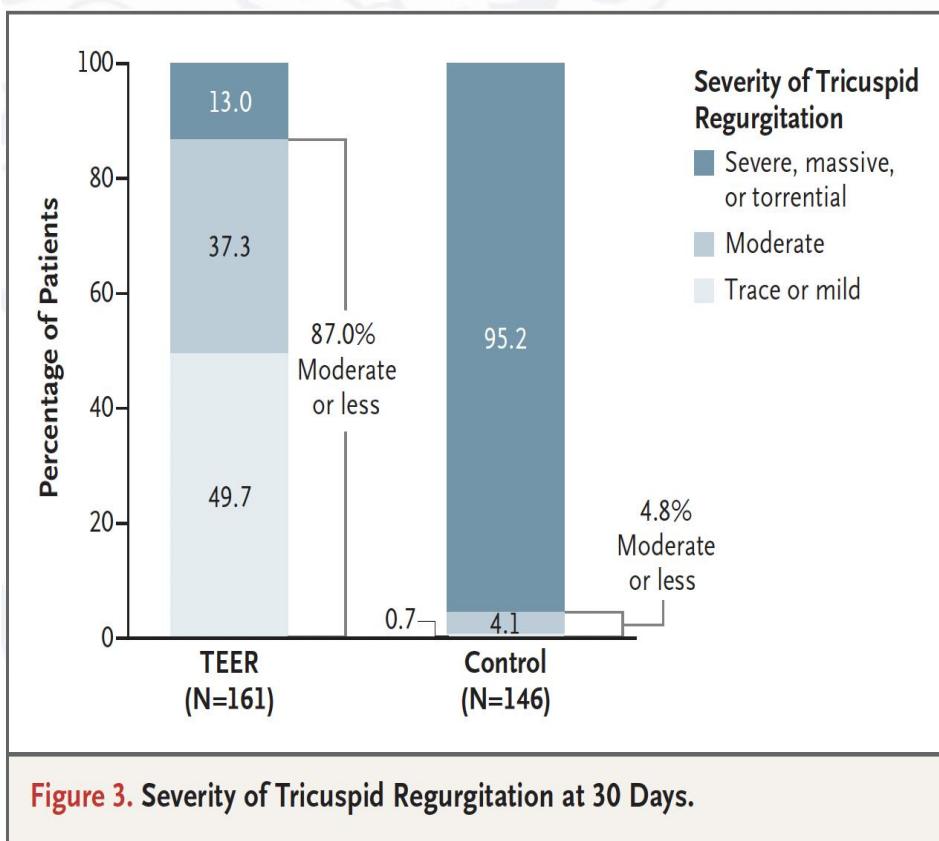
- Primary end point favored the TEER group (win ratio, 1.48; 95% CI, 1.06 -2.13; P = 0.02).
- No effects on HF hospitalizations and survival were observed at 1 year.

Table 2. Primary and Secondary End Points.*

End Point	TEER Group (N=175)	Control Group (N=175)	Difference (95% CI)	P Value
Primary				
Hierarchical composite of death from any cause or tricuspid-valve surgery; hospitalization for heart failure; and improvement of ≥ 15 points in KCCQ score at 1 yr — no. of wins†	11,348	7643	1.48 (1.06 to 2.13)	0.02
Secondary, listed in hierarchical order				
Kaplan-Meier estimate of percentage of patients with freedom from major adverse events through 30 days after the procedure (lower 95% confidence limit)‡	98.3 (96.3)	—	—	<0.001
Change in KCCQ score from baseline to 1 yr — points§	12.3 \pm 1.8	0.6 \pm 1.8	11.7 (6.8 to 16.6)	<0.001
Tricuspid regurgitation of no greater than moderate severity at 30-day follow-up — no. of patients/total no. (%)¶	140/161 (87.0)	7/146 (4.8)	—	<0.001
Change in 6-min walk distance from baseline to 1 yr — m	-8.1 \pm 10.5	-25.2 \pm 10.3	17.1 (-12.0 to 46.1)	0.25

TRILUMINATE trial

(TriClip, Abbott Vasc)



bRIGHT Study

Short-term Outcomes of Tricuspid Edge-to-Edge Repair in Clinical Practice

Philipp Lurz, MD, PhD, Christian Besler, MD, Thomas Schmitz, MD, Raffi Bekeredjian, MD, Georg Nickenig, MD, Helge Möllmann, MD, Ralph Stephan von Bardeleben, MD, Alexander Schmeisser, MD, Iskandar Atmowihardjo, MD, Rodrigo Estevez-Loureiro, PhD, MD, Edith Lubos, MD, Megan Heitkemper, PhD, Dina Huang, PhD, Harald Lapp, MD, Erwan Donal, MD

METRIC

Implant Success

N=511

99%

Procedural Success

91%

Device Time (min)

76 ± 39

Total Procedure Time (min)

96 ± 44

Number of Clips

1.9 ± 0.7

Device Type

NT

1%

XT

56%

NTW

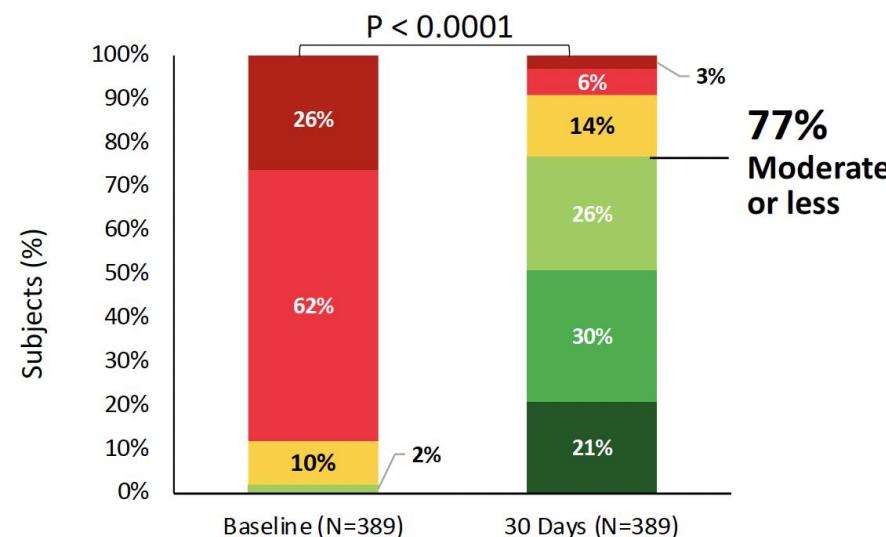
0.1%

XTW

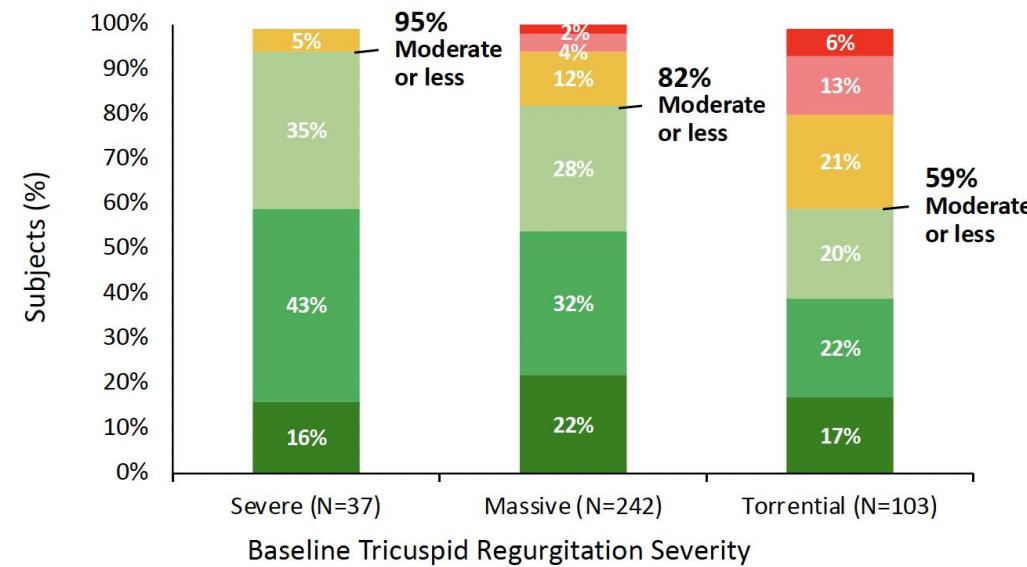
43%

Acute TR Reduction

Paired 30 Day TR Severity



30 Day TR Severity by Baseline TR



■ None ■ Mild ■ Moderate ■ Severe ■ Massive ■ Torrential

Lurz et al. JACC 2023



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bRIGHT Study



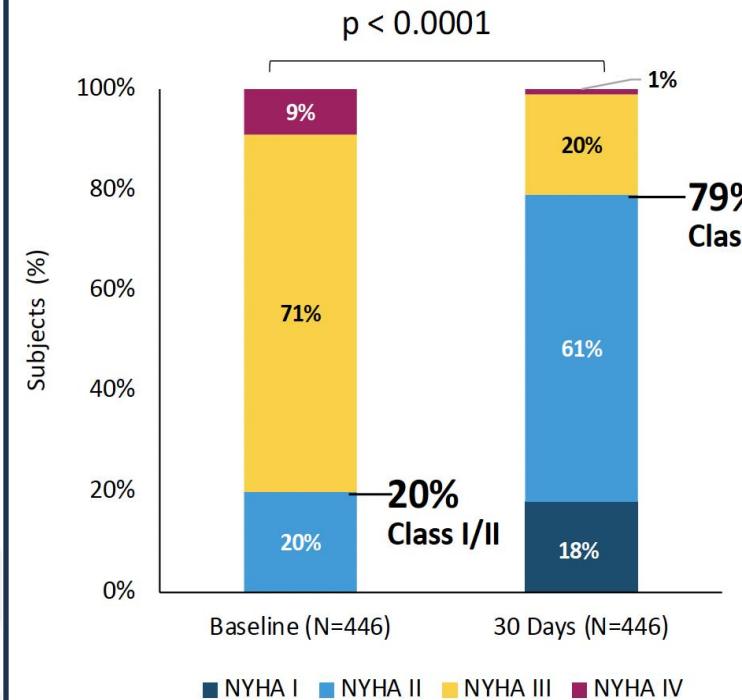
Safety Profile

EVENT n=511

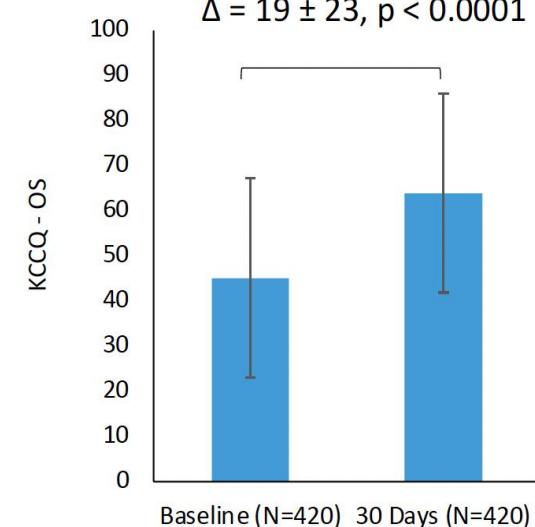
MAEs	2.5% (14)
Cardiovascular Mortality	0.8% (4)
Myocardial Infarction	0.0% (0)
Stroke	0.4% (2)
New Onset Renal Failure	1.4% (7)
Non-Elective Cardiovascular Surgery for Device-Related AE	0.2% (1)

NYHA & QoL

NYHA FUNCTIONAL CLASS

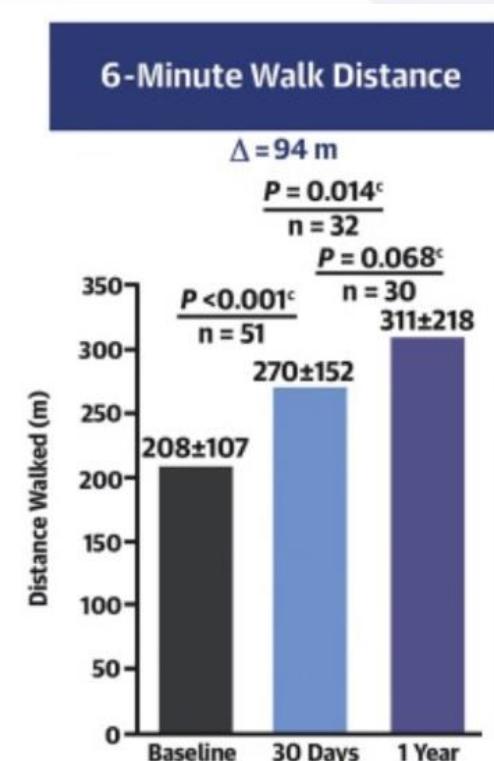
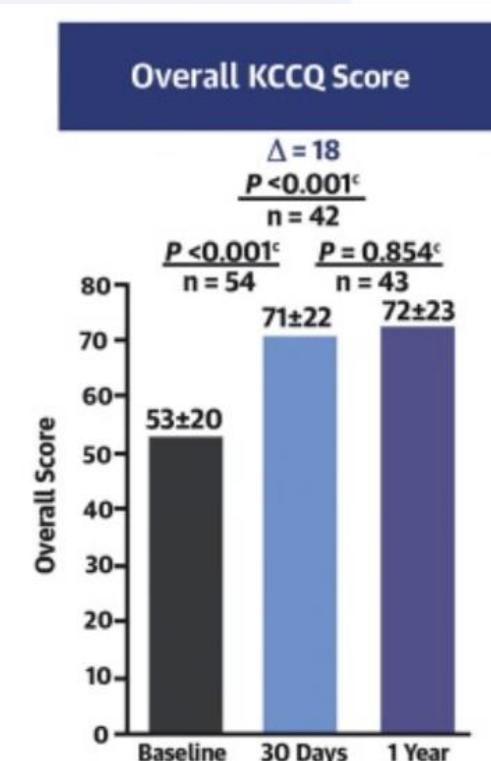
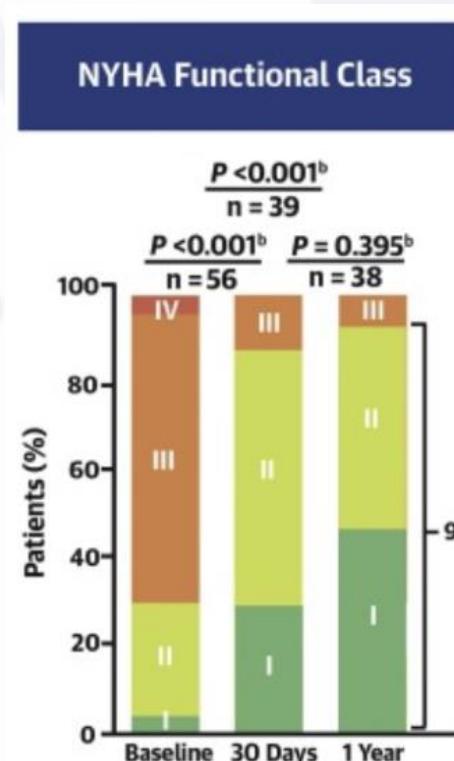
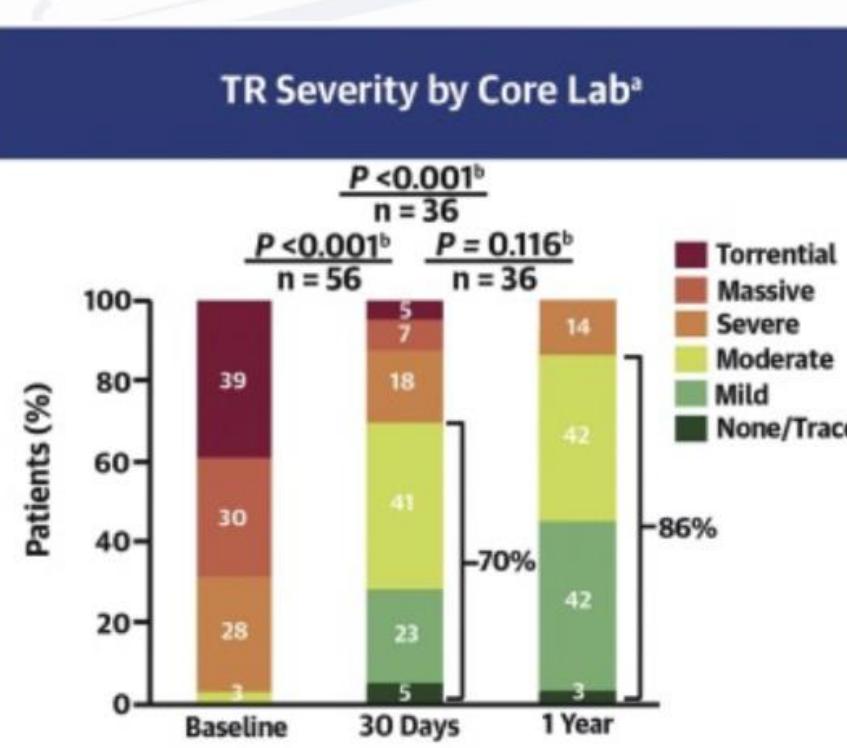
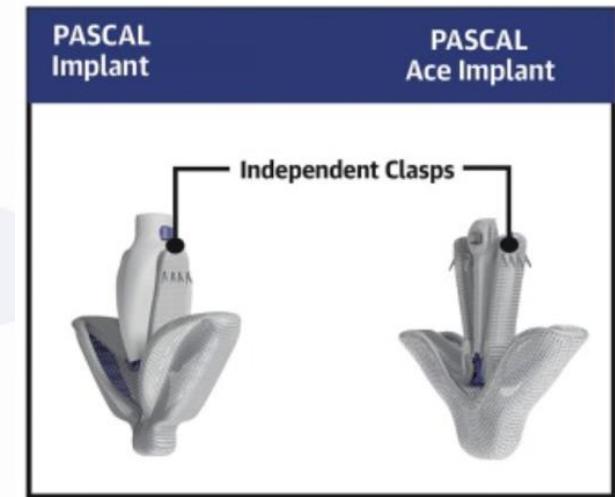


KCCQ
 $\Delta = 19 \pm 23$, p < 0.0001

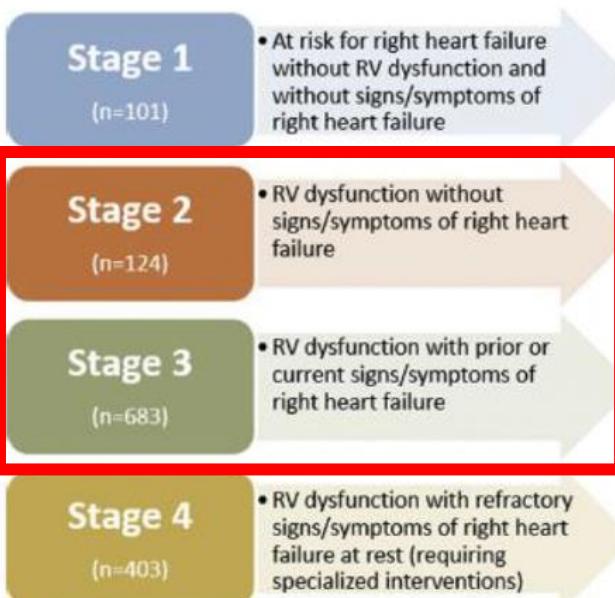


56.2% KCCQ
Improvement ≥ 15 pts

Edwards PASCAL TrAnScatheter Valve RePair System in Tricuspid Regurgitation [CLASP TR] Early Feasibility Study

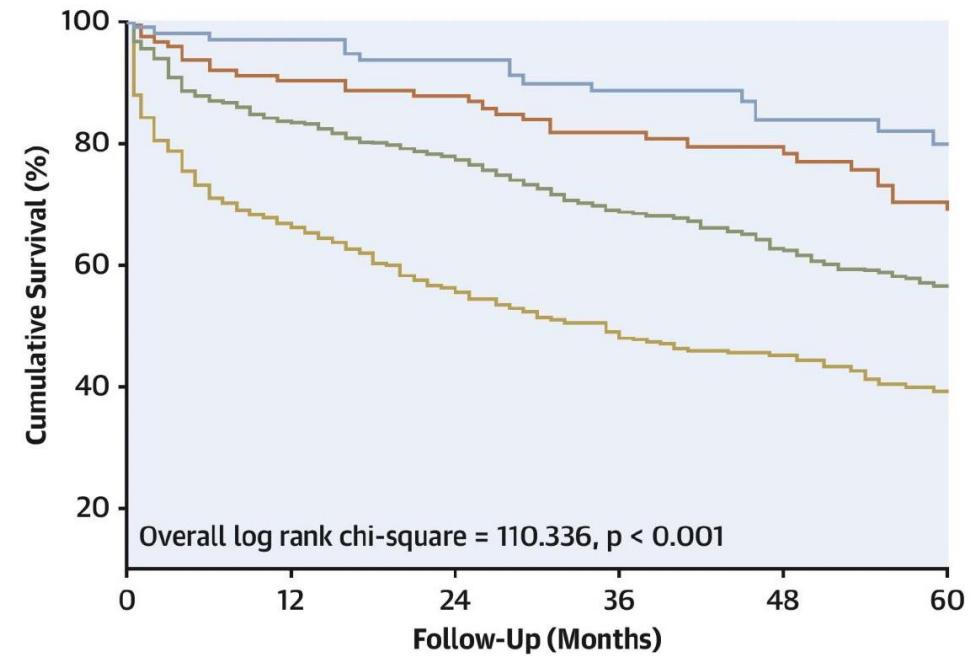


SECONDARY TR



RV-function	NYHA class	Diuretics	Edema
TAPSE \geq 17	I	-	-
TAPSE<17	I	-	-
TAPSE<17	II-III	+	-
TAPSE<17	IV	+	+

CENTRAL ILLUSTRATION: Kaplan-Meier Curves for Survival According to Stages of Right Heart Failure

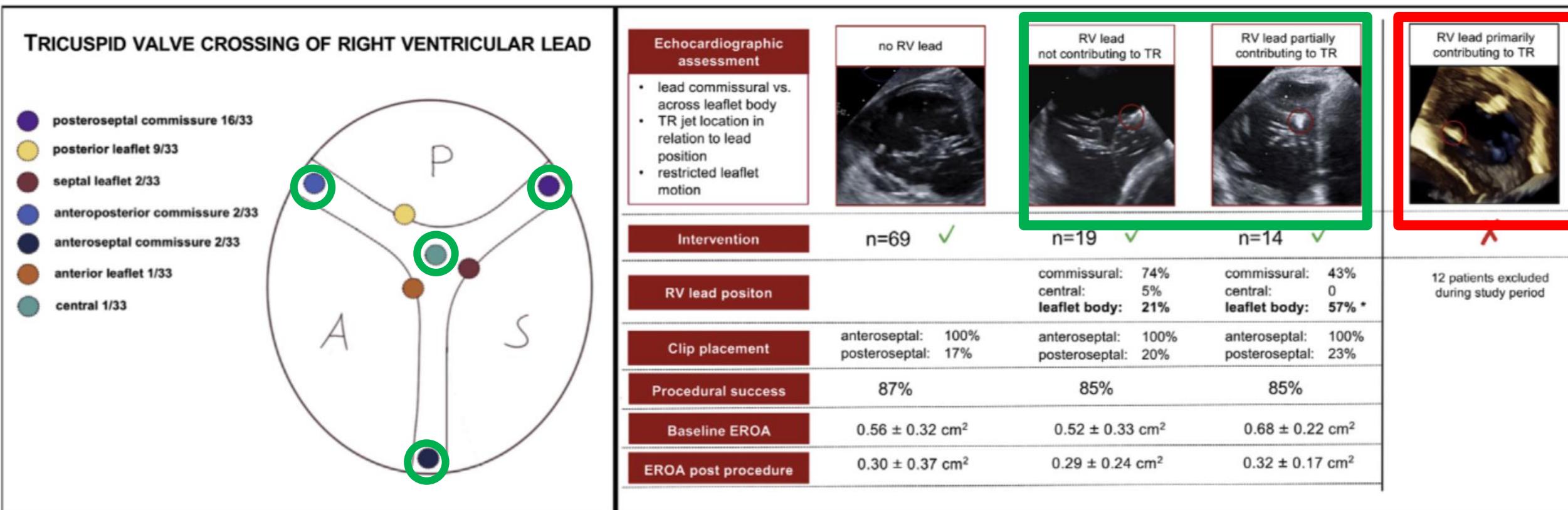


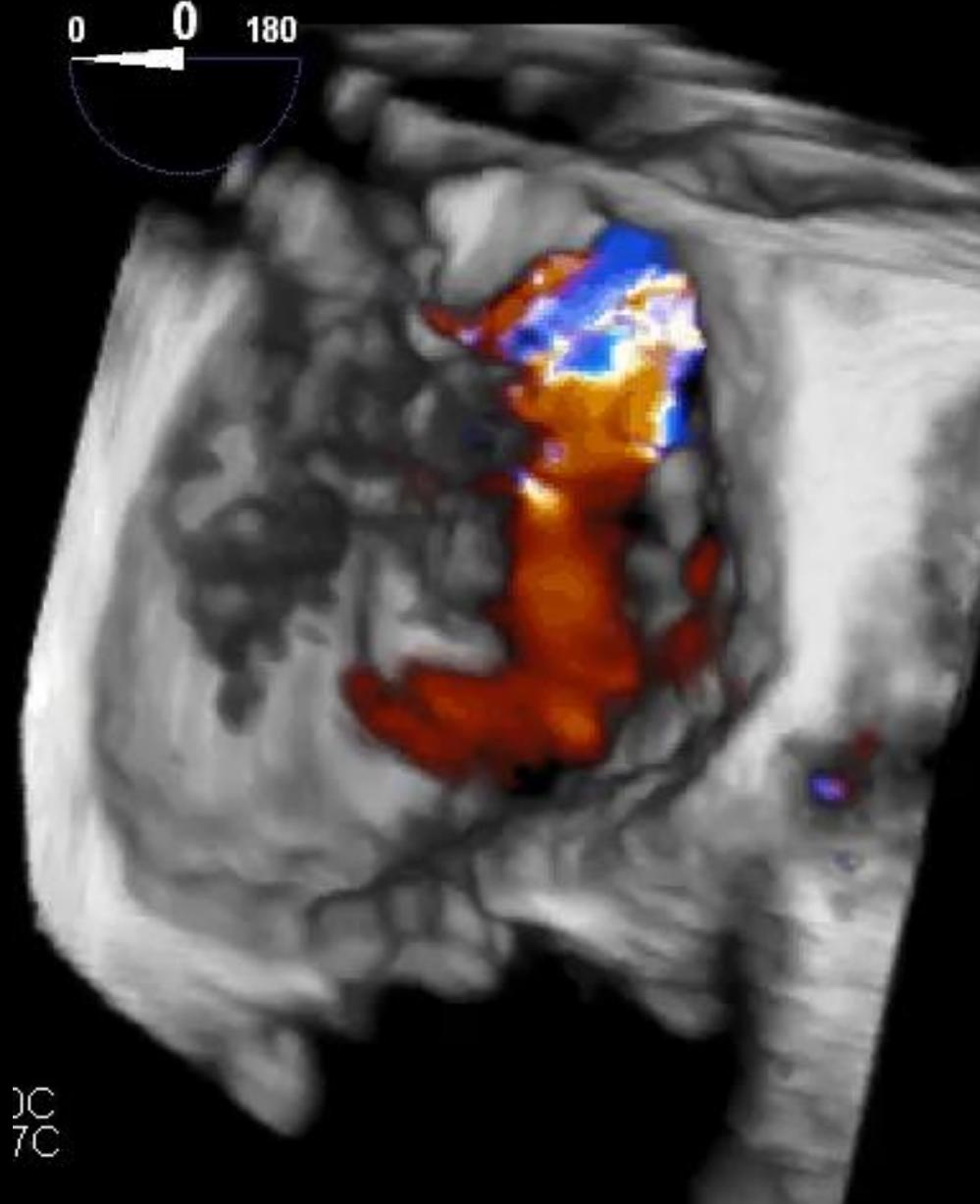
	Number at risk					
Stage 1	101	94	79	63	48	41
Stage 2	124	110	96	77	63	51
Stage 3	683	566	472	356	268	202
Stage 4	403	266	197	146	111	77

Safety and Efficacy of Transcatheter Edge-to-Edge Repair of the Tricuspid Valve in Patients With Cardiac Implantable Electronic Device Leads

TR and electronic device leads

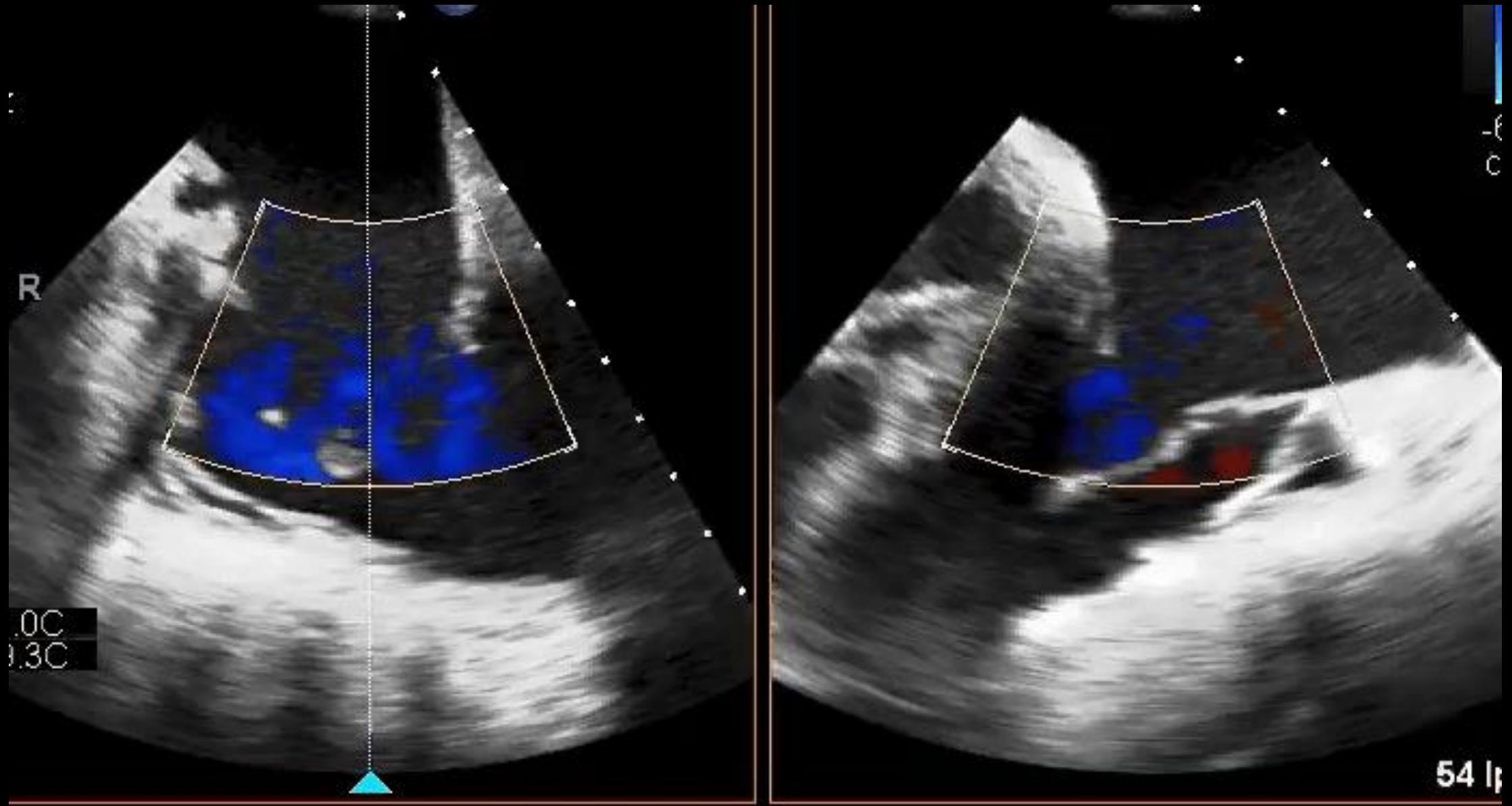
FIGURE 1 Anatomic, Interventional, and Echocardiographic Details



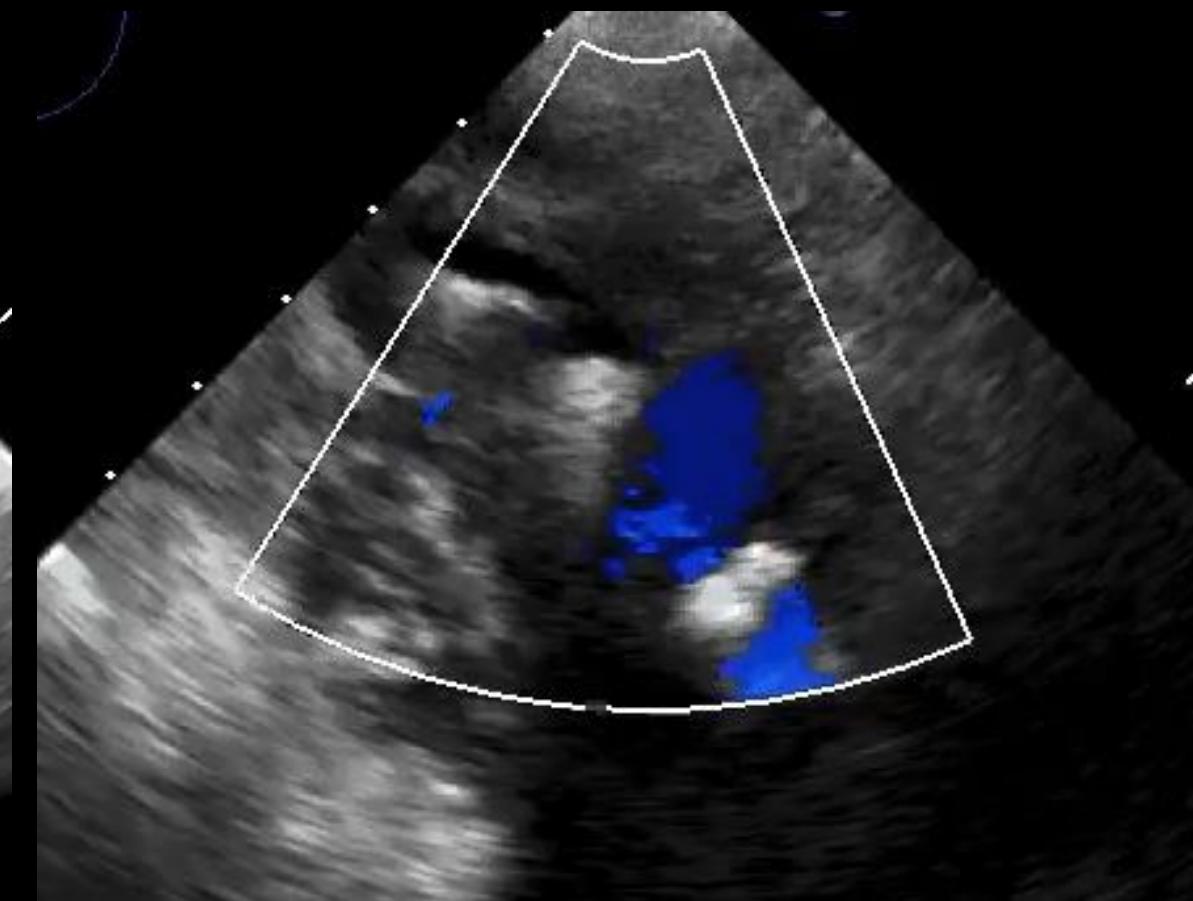
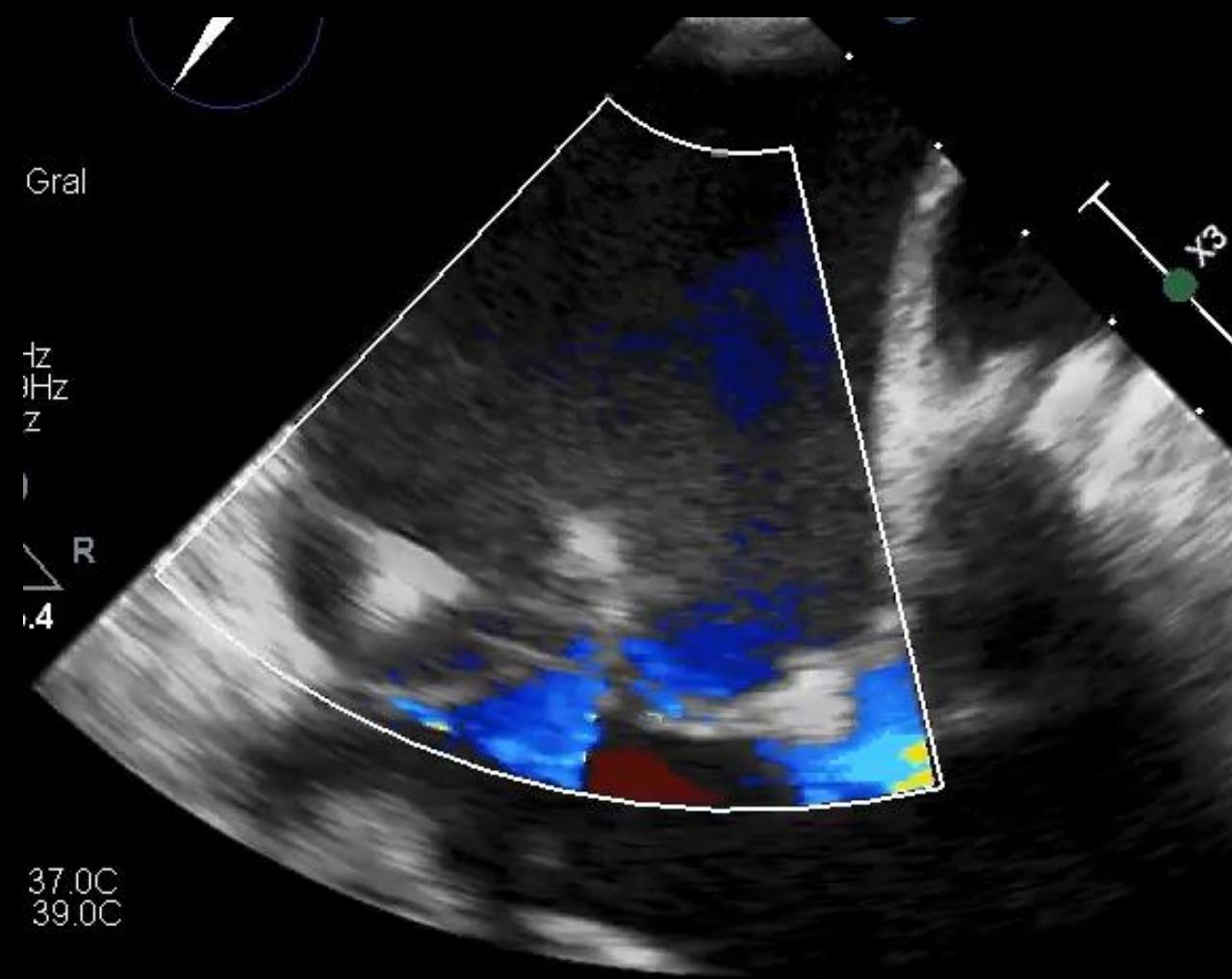




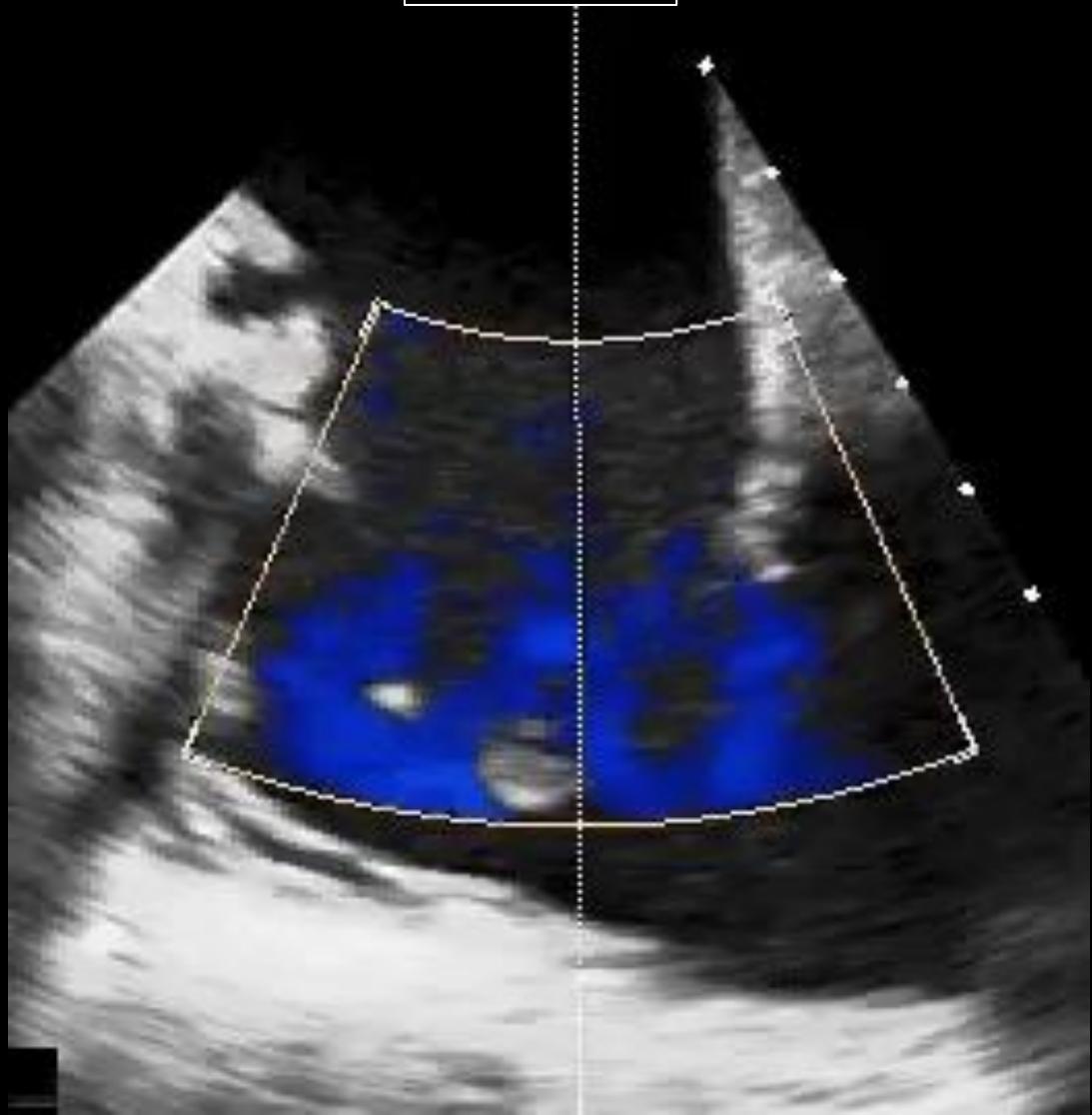
65 lpr



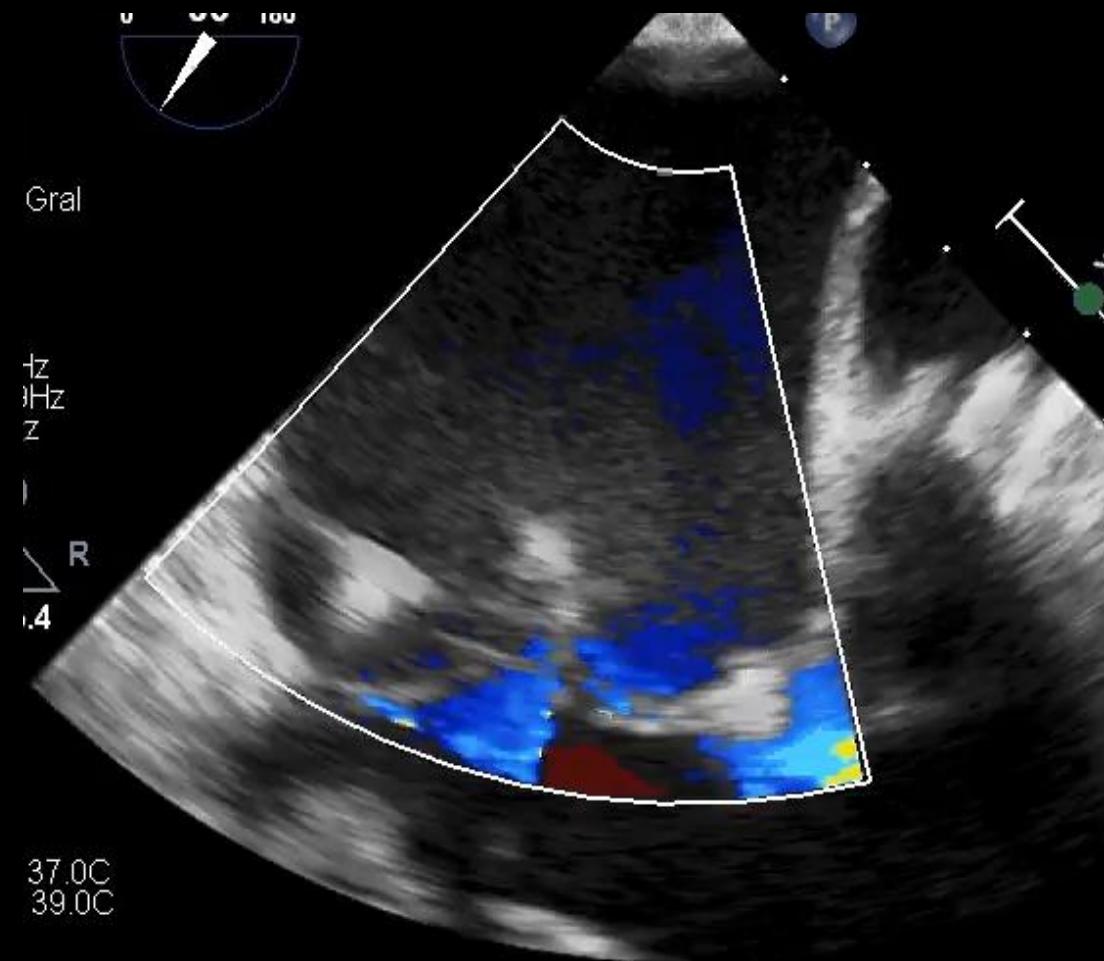
POST XTW + XT

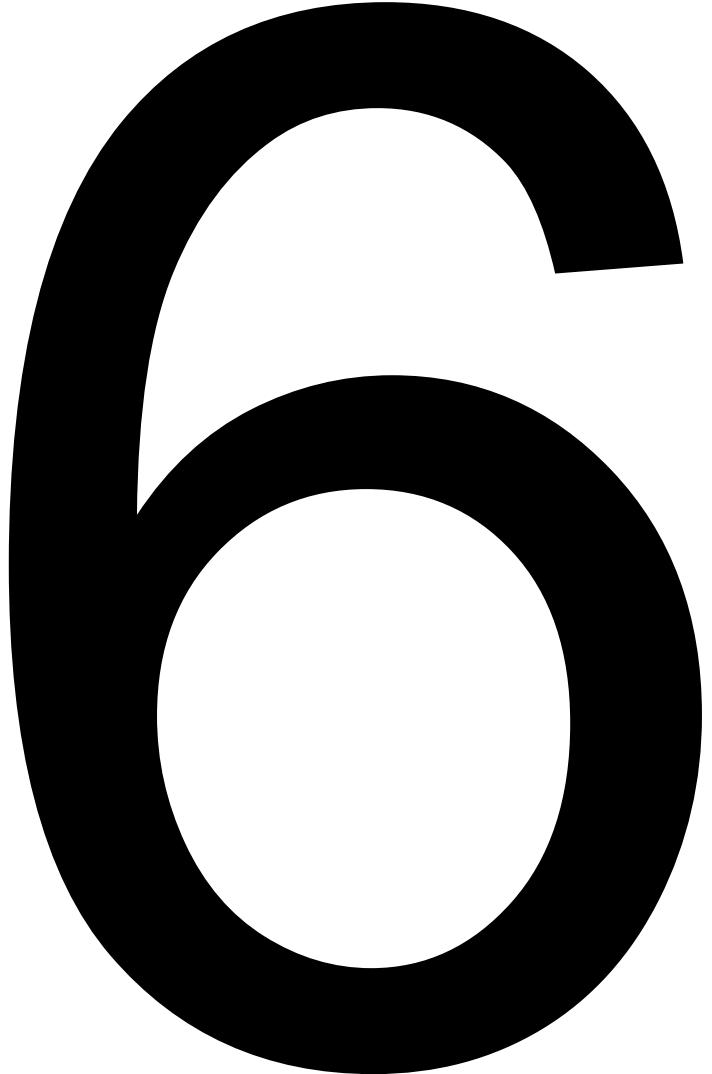


PRE-CLIP



POST XTW + XT





Take Home

1

M-TEER is the treatment of choice for FMR in association with OMT.

1

M-TEER is the treatment of choice for FMR in association with OMT.

2

M-TEER for DMR with high / prohibitive surgical risk.

1

M-TEER is the treatment of choice for FMR in association with OMT.

2

M-TEER for DMR with high / prohibitive surgical risk.

3

M-TEER is a secure and effective solution for severe MR shortly after MI.

1

M-TEER is the treatment of choice for FMR in association with OMT.

2

M-TEER for DMR with high / prohibitive surgical risk.

3

M-TEER is a secure and effective solution for severe MR shortly after MI.

4

T-TEER is an option for selected and symptomatic patients.