Tricuspid Intervention

Treatment options of intervention

- **Edge-to-edge repair** (Coaptation devices)
  - TriClip
  - PASCAL
- **Direct ring-annuloplasty** (Repair)
  - Cardioband
- **Catheter-based valve replacement**

2020 AHA/ACC Guideline Indication of Tricuspid intervention

- **Severe TR (Stage C, D)**
  - undergoing left-sided valve surgery

    → TV surgery is recommended (**Class I**)
  - combined with signs and symptoms of right-sided HF

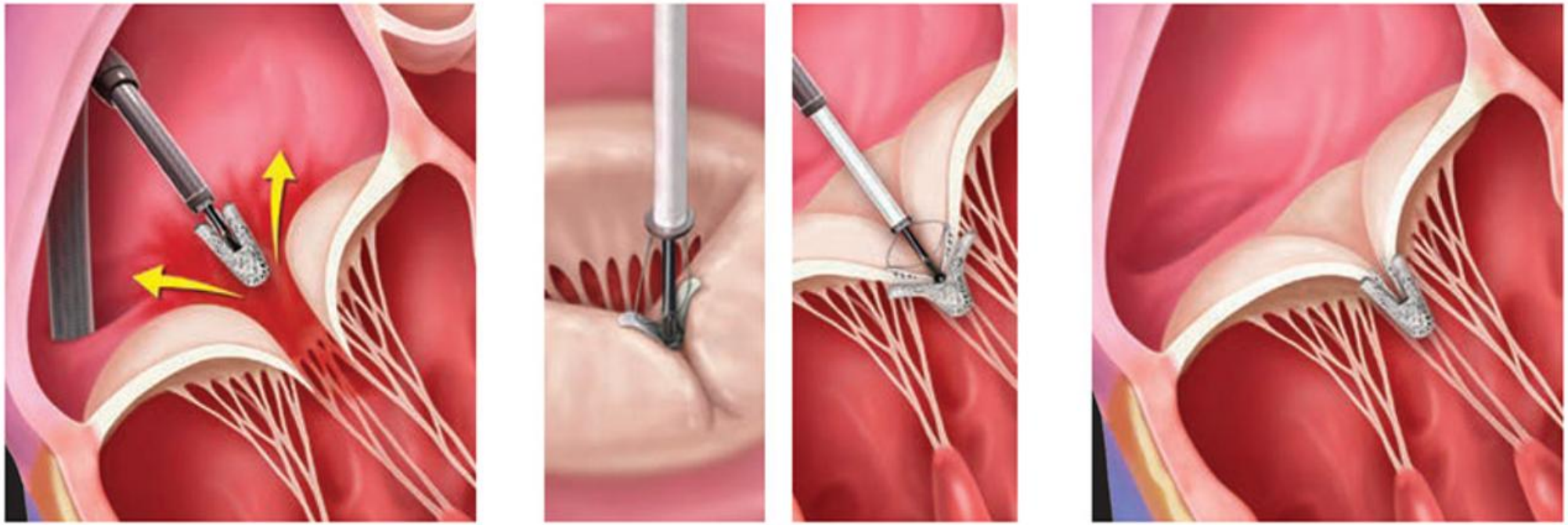
    → isolated tricuspid valve surgery (**Class IIa**)
  - asymptomatic and progressive RV dilation or systolic dysfunction

    → isolated tricuspid valve surgery (**Class IIb**)

2021 ESC/EACTS Guideline Indication of Transcatheter Tricuspid Valve Intervention

- TTVI are under clinical development
- Early registry and study → Coaptation devices, Direct annuloplasty, or Valve replacement can improve symptom and hemodynamics
- **Class IIb (LOE – C)**
  - Transcatheter treatment of symptomatic secondary severe TR may be considered in inoperable patients at a Heart Valve Center

Concept of TEER with TriClip

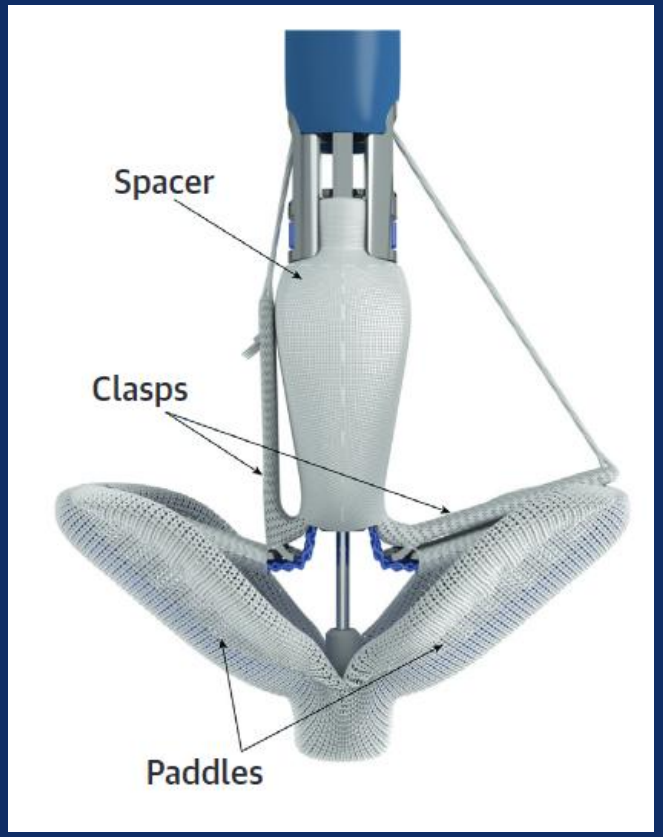


Repairing a tricuspid valve through a TriClip procedure (Image courtesy of Abbott)

Current Devices of TEER

TriClip (Abbott)

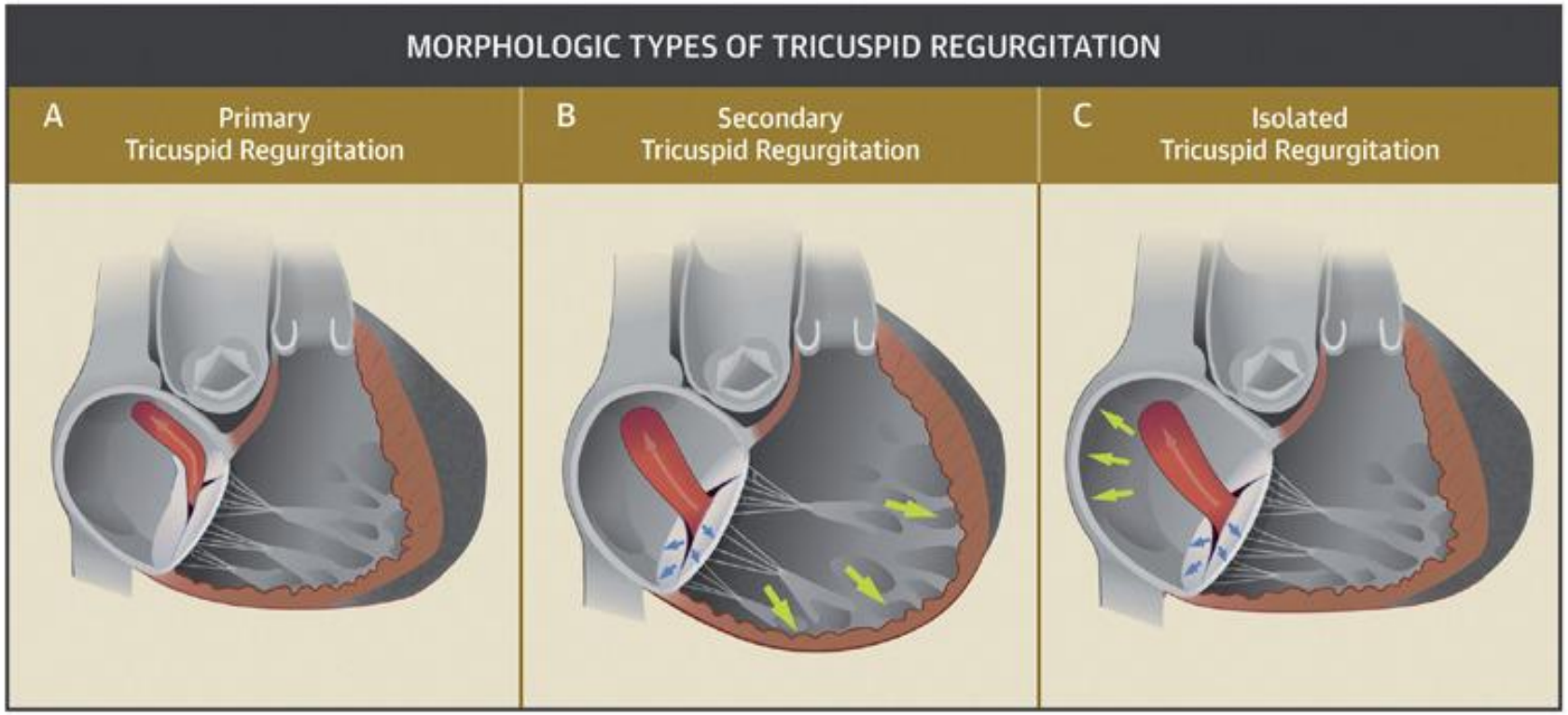
PASCAL (Edwards)



Status of Coaptation Device

Two Types of Tricuspid Regurgitation

CENTRAL ILLUSTRATION: Schematic Drawing of the Different Morphologic Types of Tricuspid Regurgitation



Prihadi, E.A. et al. J Am Coll Cardiol Img. 2019;12(3):491-9.

Evidence of TEER for Severe TR

TriClip
(Abbott Vascular)

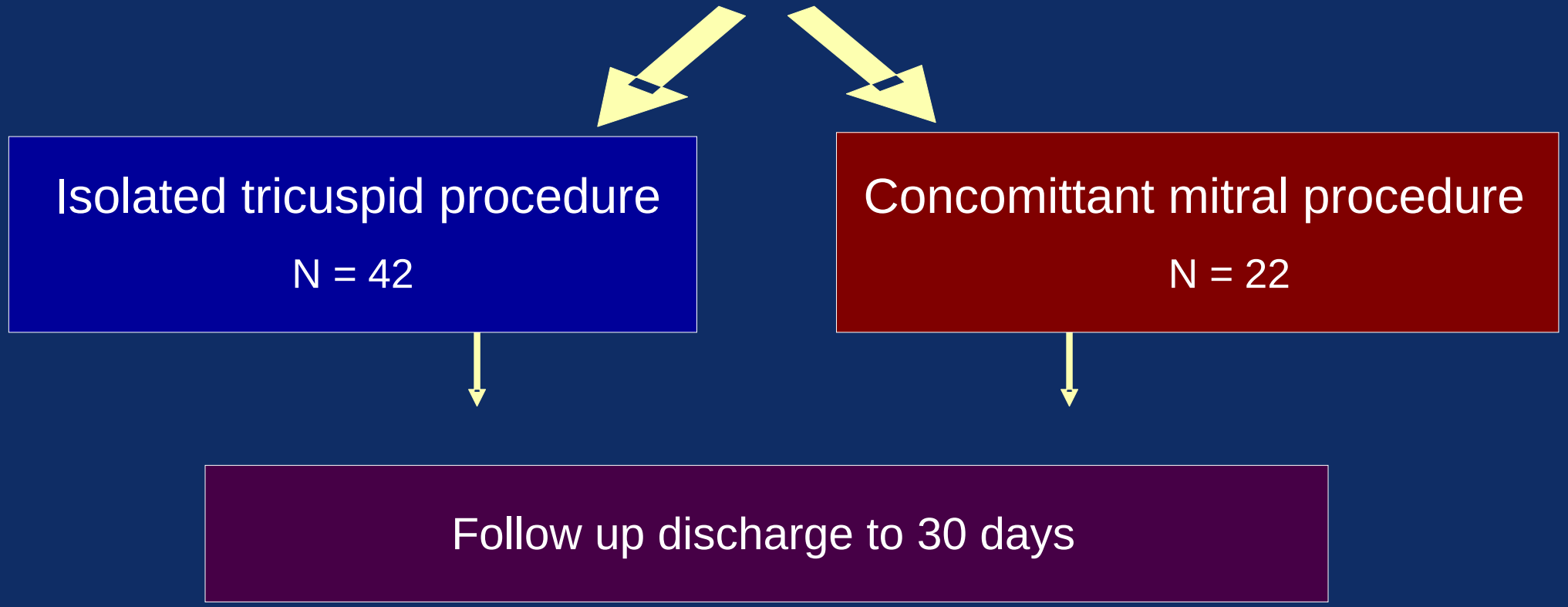
Mitraclip for Severe TR

64 patients enrolled at 10 sites

Severe TR (3+ or 4+)

Exclusion:

sPAP > 60mmHg, severe coaptation defect (>2cm)



Nickenig et al. Circulation 2017;135:1802-1814

MitraClip for Severe TR

64 patients, Single arm study

Baseline characteristics	N = 64
Age	76.6 ± 9.6
Male sex, %	29 (45%)
EuroSCORE, %	27.8 ± 16.7
STS mortality score, %	4.7 ± 4.6
GFR, mL/min	48.7 ± 19.7
AST, U/l	34.5 ± 15.6
ALT, U/l	26.3 ± 20.0
NT-proBNP, ng/l	5528.4±5938.8
NYHA III	47 (73%)
NYHA IV	13 (20%)
Atrial fibrillation / flutter, %	54 (84%)
COPD, %	18 (28%)

Nickenig et al. Circulation. 2017;135:1802-1814.

MitraClip for Severe TR

64 patients, Single arm study

Echo at baseline	N = 64
LV EF, %	46.9 ± 13.9
RA volume, %	117.5 ± 72.4
TAPSE, mm	16.9 ± 5.8
sPAP, mmHg	42.5 ± 15.0
IVC diameter, mm	25.8 ± 8.7
Functional TR, %	56 (88%)
Degenerative TR, %	5 (8%)
Mixed TR	3 (4%)
Moderate TR, %	8 (12%)
Severe TR, %	37 (58%)
Massive TR, %	19 (30%)
TR vena contracta, cm	1.0 ± 0.4
TR EROA, cm^2	0.9 ± 0.4
Septo-lateral diameter, mm	42.4 ± 10.4

Nickenig et al. Circulation. 2017;135:1802-1814.

MitraClip for Severe TR

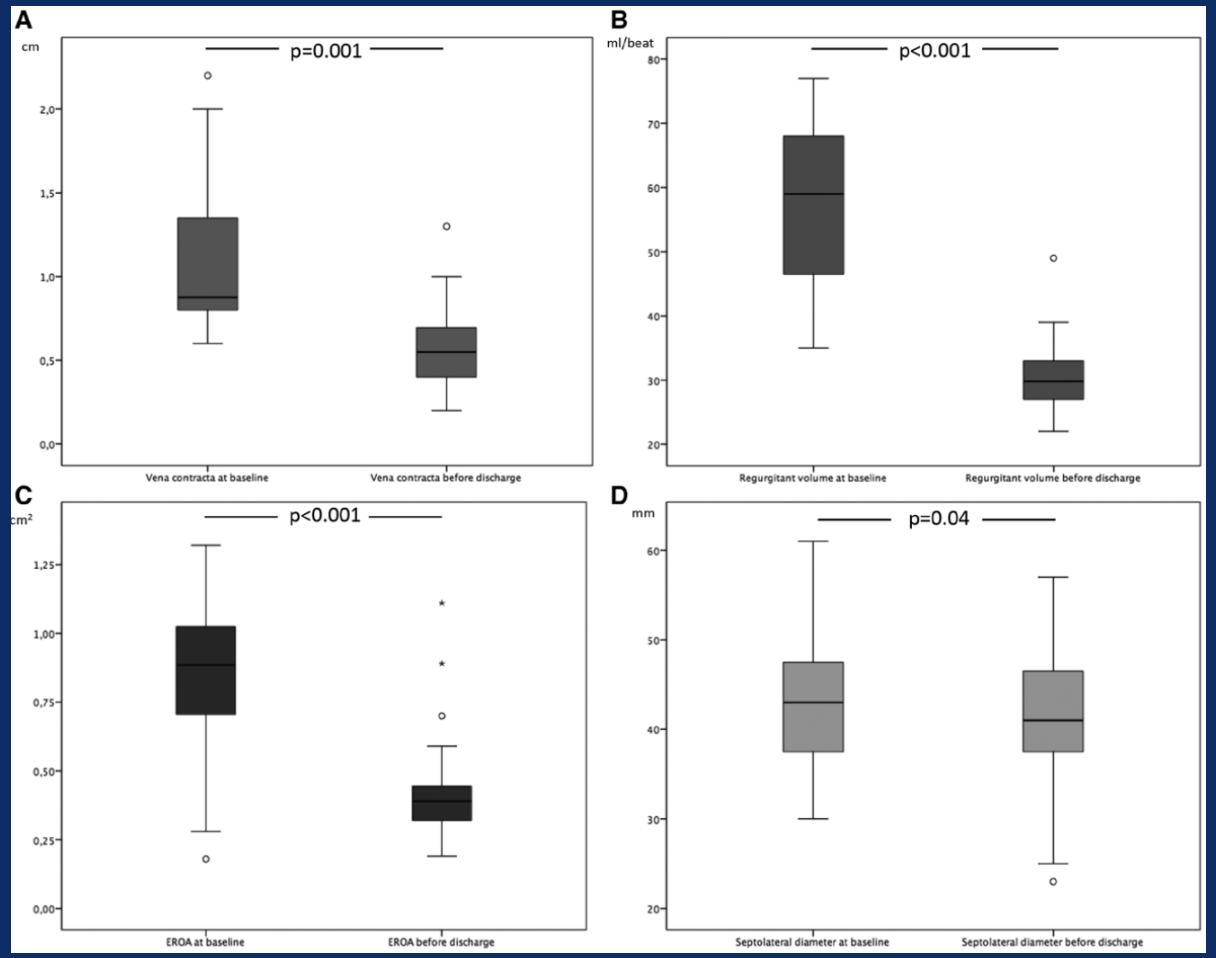
64 patients, Single arm study

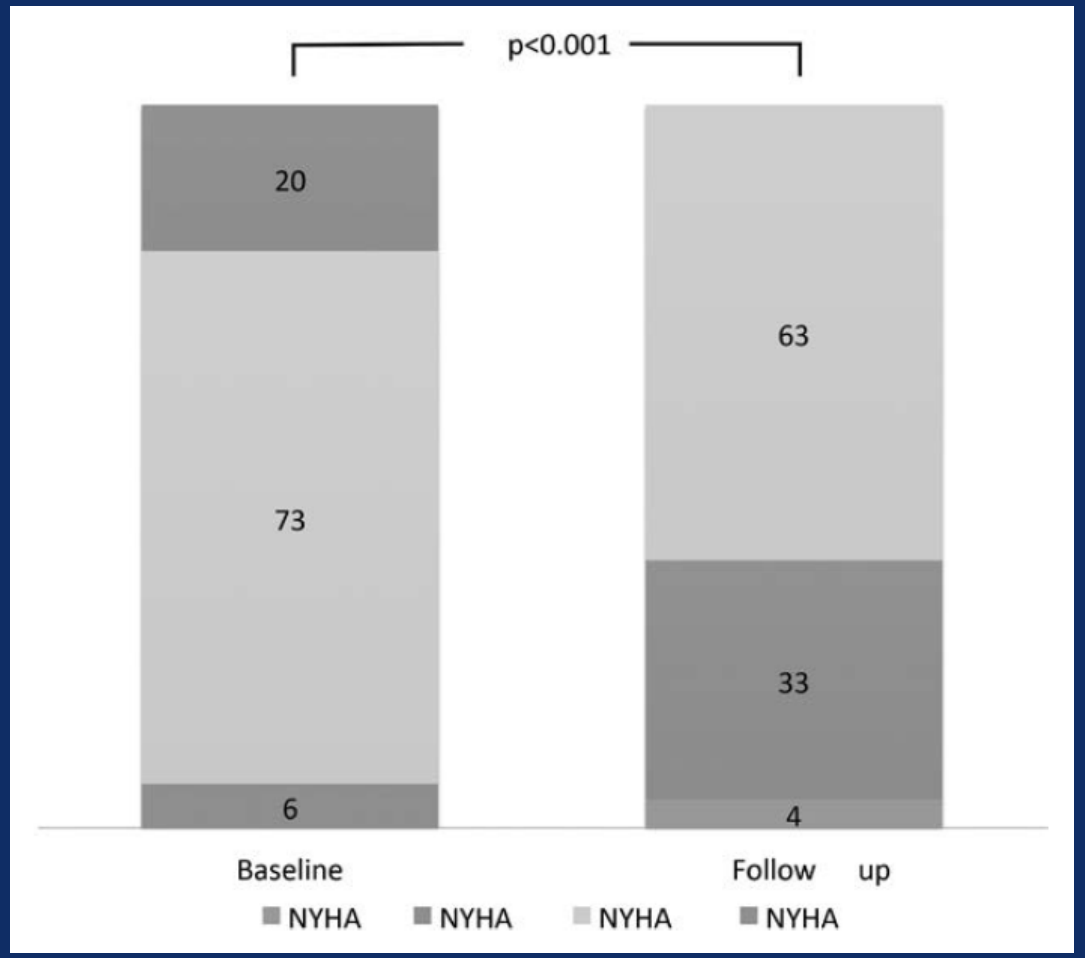
Changes in variables	N	Baseline	Discharge	P value
6MWT, m	21/64	177.4 ± 103.0	193.5 ± 115.9	0.007
GFR, mL/min	64/64	48.7 ± 19.7	49.7 ± 5.4	0.4
NT-proBNP, ng/L	28/64	5528.4 ± 5938.8	5396.8 ± 8191.3	0.9
LV EF, %	50/64	46.6 ± 13.7	48.3 ± 14.1	0.03
RA volume, %	29/64	107.5 ± 61.6	98.1 ± 51.5	0.3
TAPSE, mm	50/64	16.8 ± 5.8	17.1 ± 5.8	0.8
sPAP, mmHg	46/64	44.1 ± 15.4	40.4 ± 12.7	0.02
IVC diameter, mm	23/64	26.1 ± 10.1	24.3 ± 6.9	0.3
TR vena contracta, cm	26/64	1.1 ± 0.5	0.6 ± 0.3	0.001
TR EROA, cm^2	32/64	0.9 ± 0.3	0.4 ± 0.2	< 0.001
Septo-lateral diameter, mm	31/64	41.2 ± 10.6	35.7 ± 16.2	0.04

Nickenig et al. Circulation. 2017;135:1802-1814.

MitraClip for Severe TR

64 patients, Single arm study





Nickenig et al. Circulation. 2017;135:1802-1814.

Univariate and Multivariate analysis of procedural failure TriValve Registry

249 patients, from 14 centers in Europe and North America

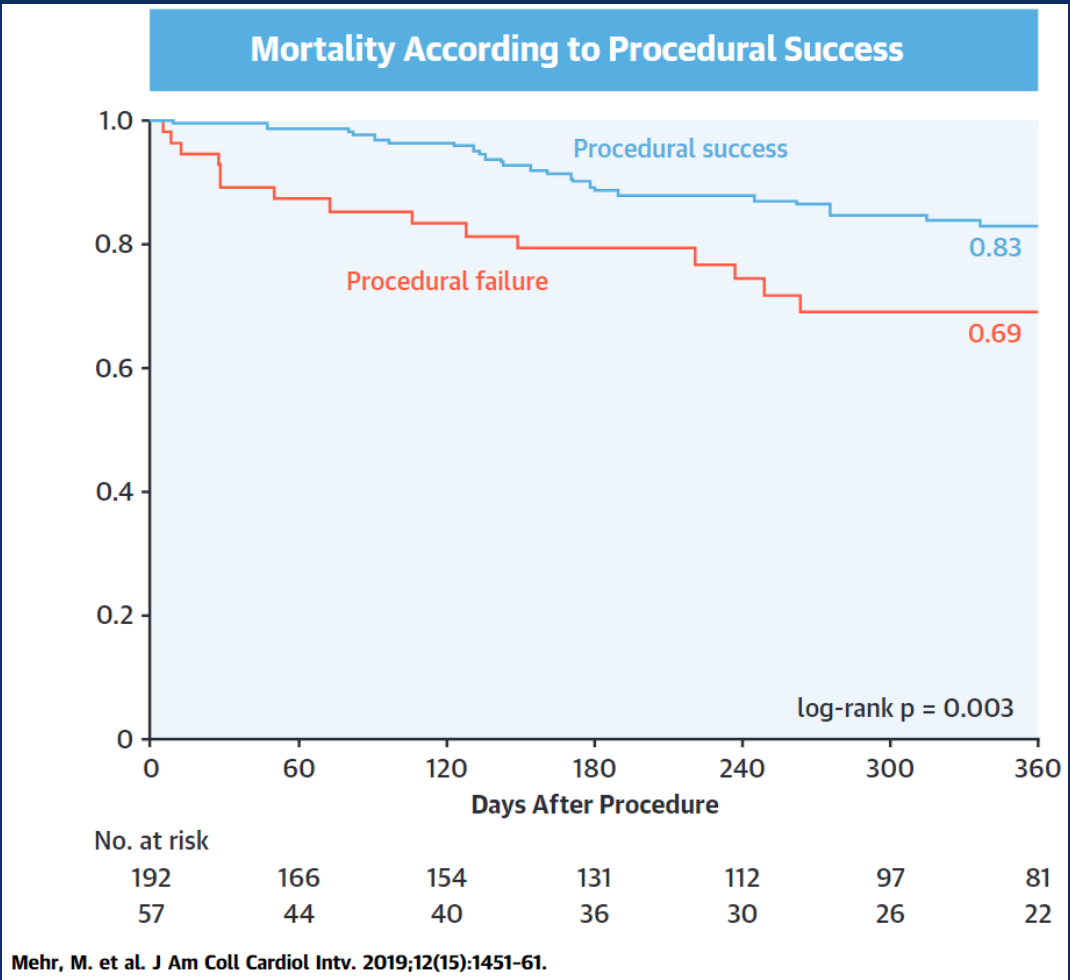
Variables	Univariate		Multivariate	
	OR (95% CI)	P value	OR (95% CI)	P value
Pacemaker or ICD lead	1.53 (0.81-2.84	0.18		
LVEF	1.00 (0.98-1.02)	0.95		
TAPSE	1.02 (0.95-1.10)	0.55		
MR grade	1.10 (0.84-1.44)	0.48		
TR vena contracta	1.76 (0.87-3.53)	0.11		
TR coaptation gap > 6.5 mm	6.16 (3.19-12.18)	<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 TEER	0.66 (0.36-1.20)	0.17		
Number of clips	0.81 (0.57-1.12)	0.20		

Mehr, M et al. JACC. 2019;12(15):1451-61

1-Year Outcomes after TEER with MitraClip

TriValve Registry

249 patients, from 14 centers in Europe and North America

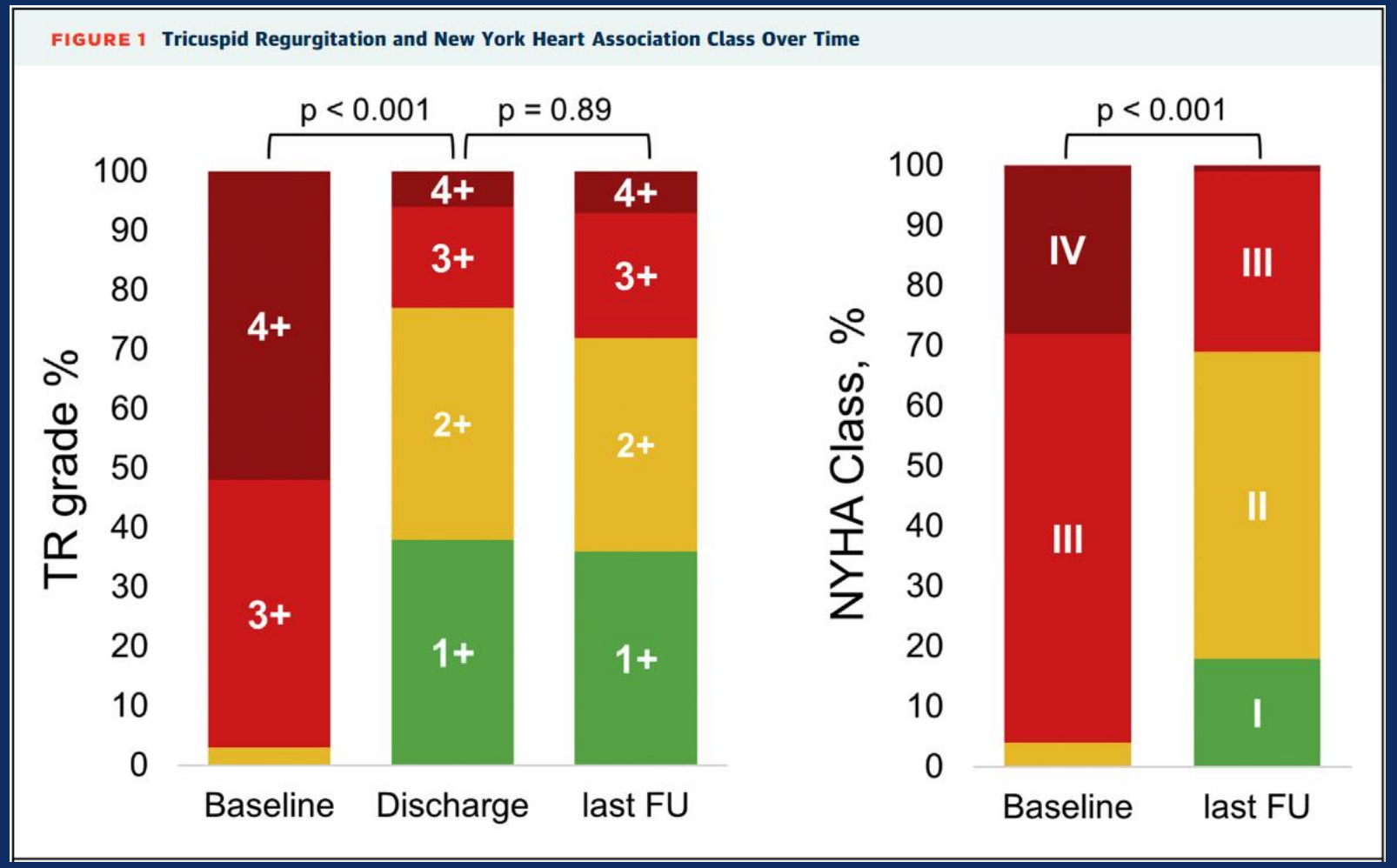


Mehr, M et al. JACC. 2019;12(15):1451-61

1-Year Outcomes after TEER with MitraClip

TriValve Registry

249 patients, from 14 centers in Europe and North America



Mehr, M et al. JACC. 2019;12(15):1451-61

1-Year Outcomes after TEER with MitraClip

TriValve Registry

249 patients, from 14 centers in Europe and North America

Outcomes at Last F/U	N = 249
Estimated mortality at 1 yr	20.3 (14.6-25.8)
Estimated combined mortality and unplanned rehospitalization for HF at 1 yr	34.7 (27.3-41.0)
Tricuspid surgery	7 (2.8)
Decreased of ≥ 1 NYHA functional class (n=175/212)	130 (72.0)
Peripheral edema (n=169/212)	45 (26.6)
Ascites (n=179/212)	37 (20.7)
TAPSE, cm (n=140/212)	15.9 ± 4.3
LVEF, % (n=157/212)	49.6 ± 14.1
sPAP, mmHg (n=141/212)	39.3 ± 14.8
TR severity grade (n=167/212)	
1+, mild	61 (36.5)
2+, moderate	60 (35.9)
3+, severe	35 (21.0)
4+, massive	11 (6.6)

Mehr, M et al. JACC. 2019;12(15):1451-61

Univariate and Multivariate analysis of 1-year Mortality TriValve Registry

249 patients, from 14 centers in Europe and North America

Variables	Univariate		Multivariate	
	OR (95% CI)	P value	OR (95% CI)	P value
Age	1.02 (0.98-1.06)	0.31		
EuroSCORE II	0.99 (0.97-1.02)	0.57		
COPD	0.49 (0.21-1.16)	0.103		
Pacemaker / ICD	1.52 (0.83-2.79)	0.18		
Absence of sinus rhythm	3.85 (1.19-12.43)	0.024	4.40 (1.34-14.49)	0.015
Decrease of 10 ml/min in eGFR	1.29 (1.07-1.55)	0.007	1.25 (1.02-1.51)	0.018
NYHA functional class	2.08 (1.20-3.62)	0.009	1.73 (0.96-3.13)	0.069
Decrease of 10% in LVEF	1.25 (1.02-1.52)	0.028	1.20 (0.98-1.47)	0.084
TAPSE	0.97 (0.90-1.04)	0.42		
TR grade	1.16 (0.67-2.00)	0.59		
MR grade	1.13 (0.86-1.50)	0.39		
Concomitant MV TEER	1.07 (0.59-1.94)	0.83		
Procedure failure	2.43 (1.33-4.46)	0.004	2.12 (1.12-4.02)	0.014

Mehr, M et al. JACC. 2019;12(15):1451-61

TriClip for Severe TR

1-year outcomes of the TRILUMINATE study

84 patients, Single arm study

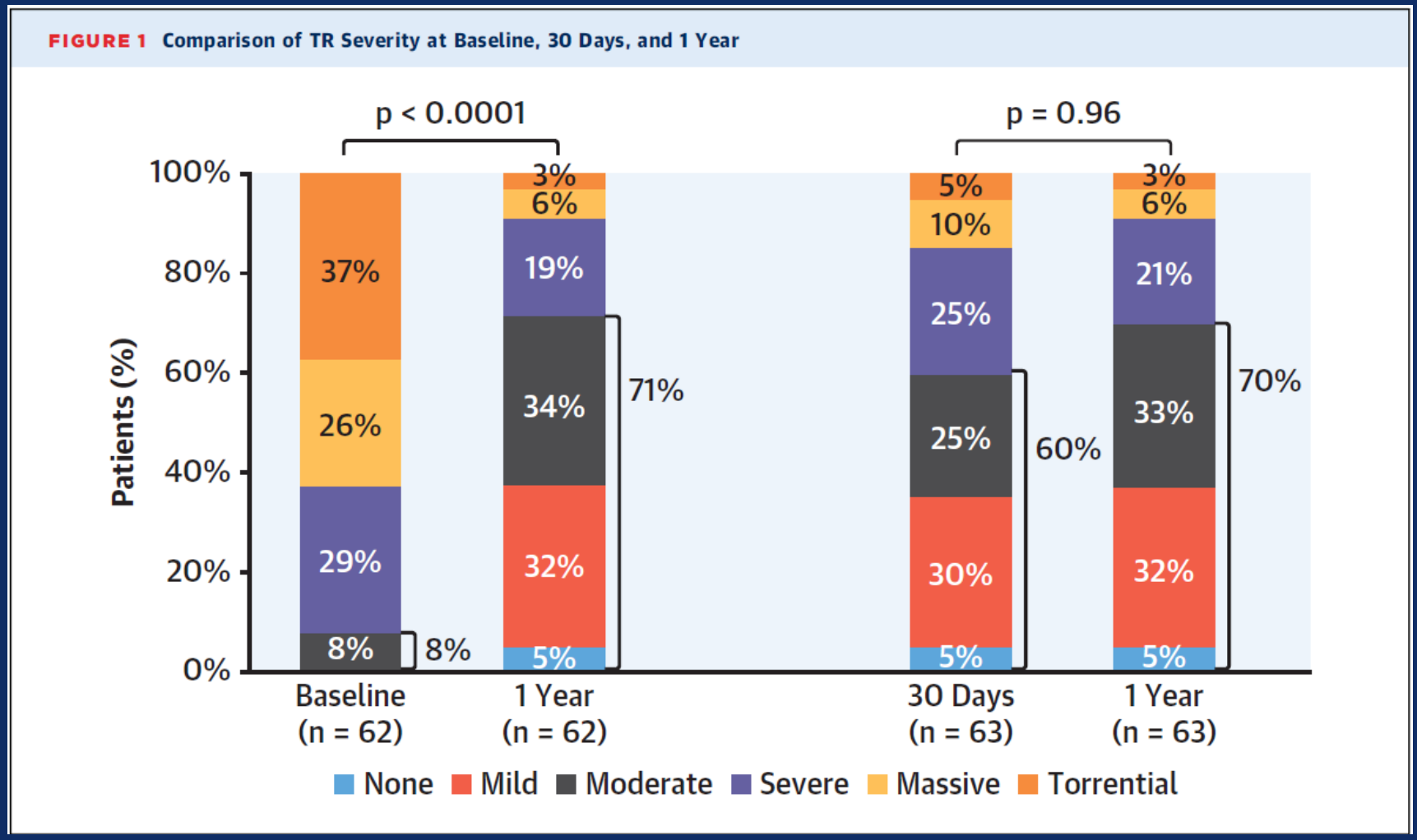
Variables	Baseline (n=85)	30 Days (n=83)	1 Year (n=70)		
			Result	P value (base vs 1 year)	P value (30 days vs 1 year)
EROA, cm² (SE)	0.65 (0.03)	0.40 (0.03)	0.32 (0.05)	<0.0001	0.1053
Regurgitant volume, mL/beat (SE)	52.20 (2.35)	34.83 (2.92)	27.68 (3.08	<0.0001	0.0607
TR jet area, cm² (SE)	14.28 (0.69)	9.18 (0.64	7.55 (0.56)	<0.0001	0.0007
TR vena contracta width, cm (SE)	1.73 (0.07)	1.00 (0.06)	0.78 (0.05)	<0.0001	<0.0001
PISA radius, cm (SE)	0.91 (0.03)	0.68 (0.03)	0.63 (0.04)	<0.0001	0.2092
IVC diameter, cm (SE)	2.29 (0.06)	2.20 (0.06)	2.06 (0.06)	0.0014	0.0216
RV end diastolic dimension, cm (SE)	5.28 (0.07)	4.93 (0.08)	4.79 (0.08)	<0.0001	0.0319
RA volume, mL (SE)	129 (5.84)	117 (6.03)	116 (6.55)	0.0166	0.8536
RV systolic pressure, mmHg (SE)	42.7 (1.08)	42.0 (1.49)	43.9 (2.30)	0.5727	0.4525
TAPSE, cm (SE)	1.44 (0.03)	1.49 (0.03)	1.59 (0.04)	0.0002	0.0069

Lurz et al. JACC. 2021;77:229-39

TriClip for Severe TR

1-year outcomes of the TRILUMINATE study

84 patients, Single arm study

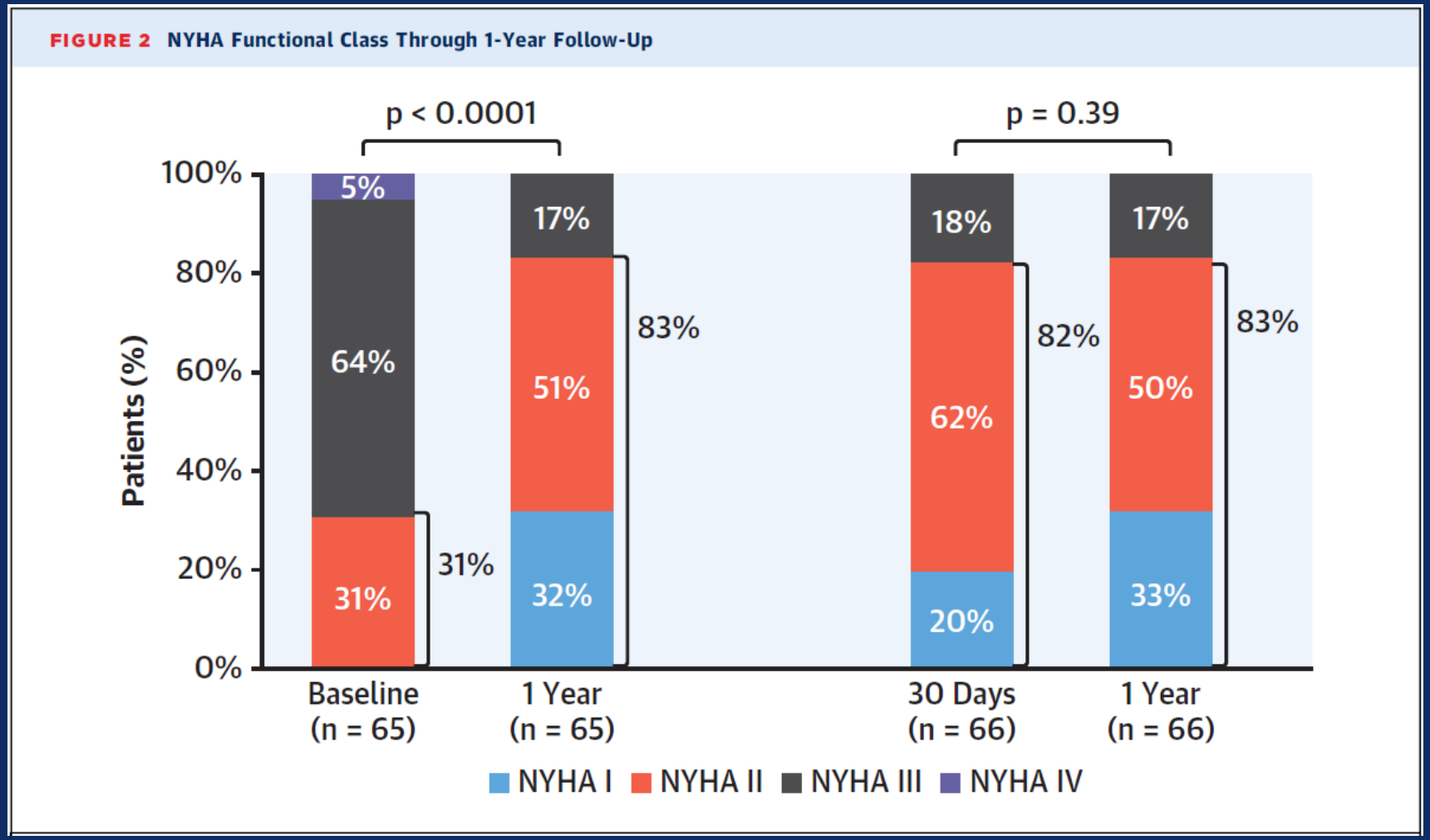


Lurz et al. JACC. 2021;77:229-39

TriClip for Severe TR

1-year outcomes of the TRILUMINATE study

84 patients, Single arm study

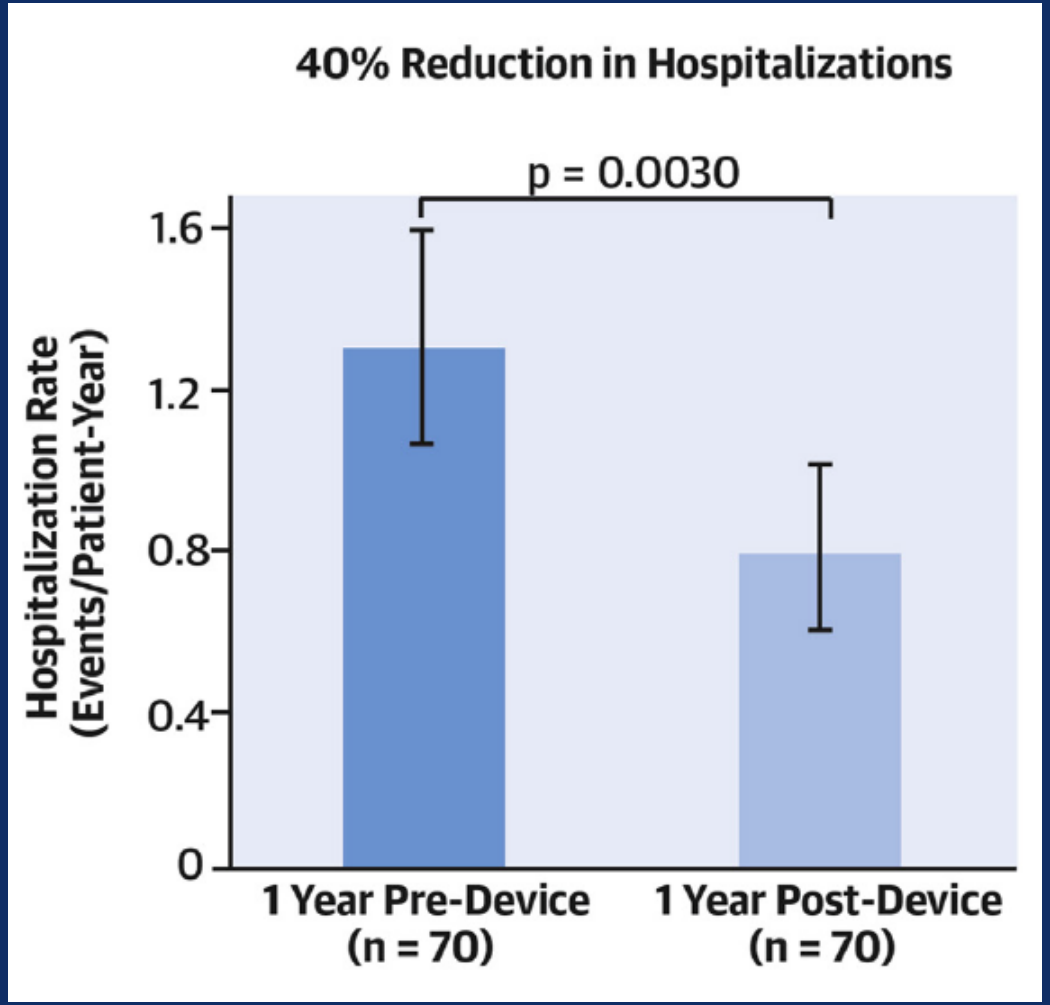


Lurz et al. JACC. 2021;77:229-39

TriClip for Severe TR

1-year outcomes of the TRILUMINATE study

84 patients, Single arm study

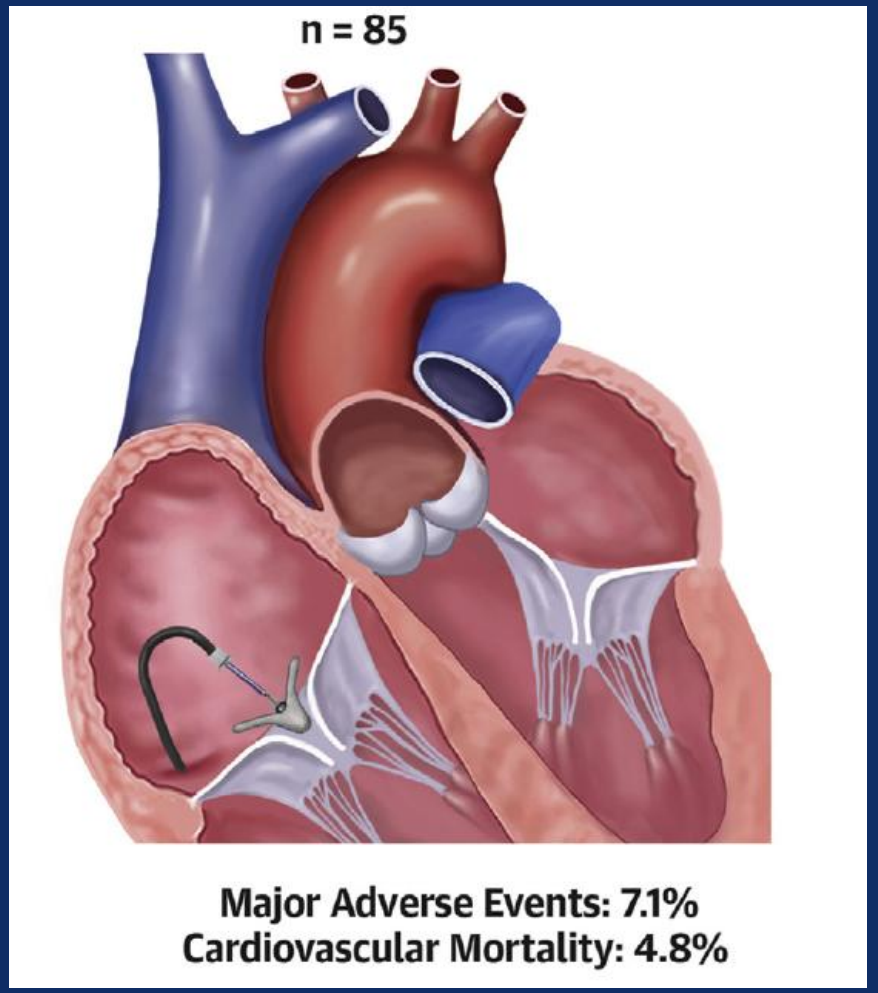


Lurz et al. JACC. 2021;77:229-39

TriClip for Severe TR

1-year outcomes of the TRILUMINATE study

84 patients, Single arm study



Lurz et al. JACC. 2021;77:229-39

TriClip for Severe TR

1-year outcomes of the TRILUMINATE study

84 patients, Single arm study

Safety outcomes	N = 84
MACE through 1 year	6 (7.1%)
CV mortality	4 (4.8%)
Myocardial infarction	1 (1.2%)
Stroke	1 (1.2%)
New onset renal failure	1 (1.2%)
Non-elective CV surgery or Tricuspid valve repair system	0 (0%)
Device-related adverse event	0 (0%)
Other safety endpoints	
All-cause mortality	6 (7.1%)
Major bleeding (BARC type 3a)	10 (11.9%)
New onset AF	1 (1.2%)
Pulmonary thromboembolism	0 (0.0%)
Single leaflet device attachment	5/65 (7.7%)
Mean tricuspid gradient ≥ 5 mmHg	4/64 (6.3%)

Lurz et al. JACC. 2021;77:229-39

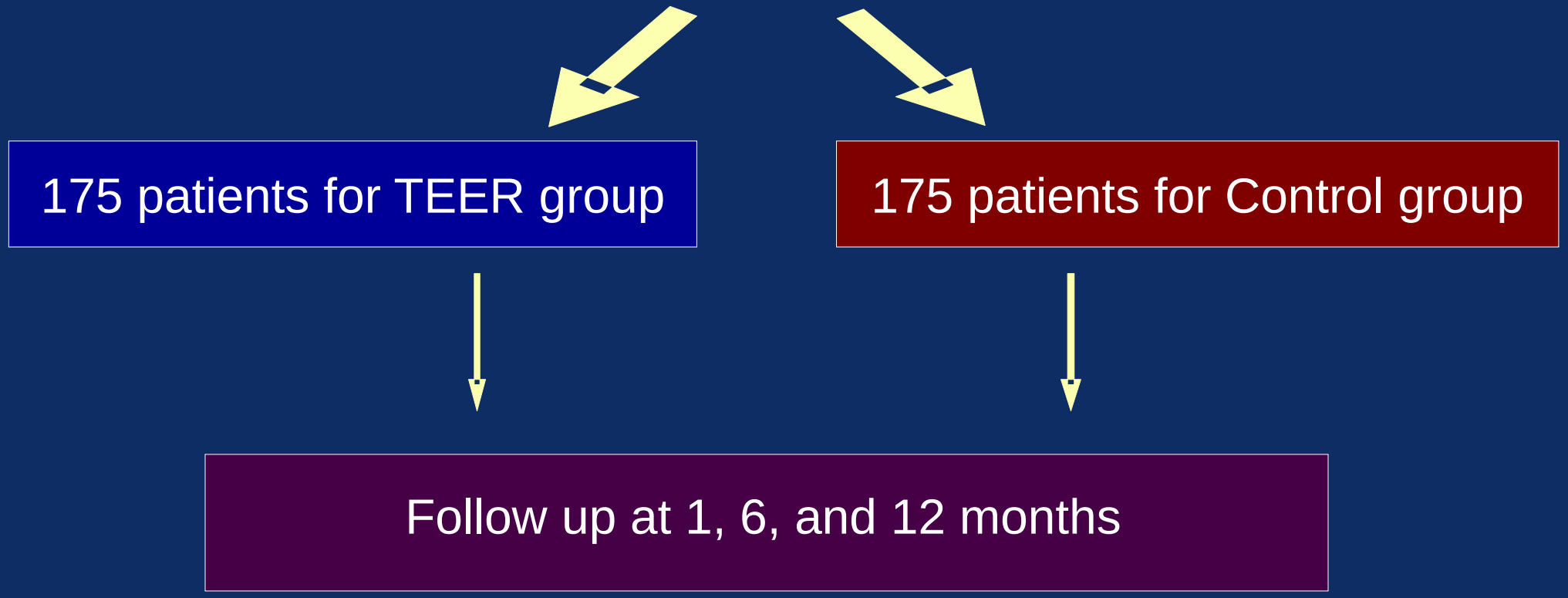
TriClip for Severe TR

TRILUMINATE Pivotal trial (TEER vs Medical Therapy)

84 patients, RCT

Symptomatic Severe TR

sPAP < 70 mmHg, ≥ 30 days GDMT, ≥ intermediate Op risk,
no other CV diseases in need of intervention or surgery



Sorajja et al. NEJM. 2023

TriClip for Severe TR

TRILUMINATE Pivotal trial (TEER vs Medical Therapy)

84 patients, RCT

Baseline Characteristics	TEER Group (N=175)	Control Group (N=175)
Age	78.0 ± 7.4	77.85 ± 7.2
Female sex	98 (56.0%)	94 (53.7%)
NYHA III or IV	104 (59.4%)	97 (55.4%)
Atrial fibrillation	153 (87.4%)	162 (92.6%)
Hypertension	142 (81.1%)	141 (80.6%)
Stroke	11 (6.3%)	19 (10.9%)
Diabetes mellitus	28 (16.0%)	27 (15.4%)
Peripheral vascular disease	16 (9.1%)	18 (10.3%)
Renal disease	62 (35.4%)	62 (35.4%)
Liver disease	11 (6.3%)	16 (9.1%)
Cardiac implantable device	28 (16.0%)	24 (13.7%)
Hospitalization for HF within 1 year	44 (25.1%)	44 (25.1%)
NT-proBNP	382.0 ± 347.5	355.4 ± 283.4

Sorajja et al. NEJM. 2023

TriClip for Severe TR

TRILUMINATE Pivotal trial (TEER vs Medical Therapy)

84 patients, RCT

Primary and Secondary End Points	TEER Group (N=175)	Control Group (N=175)	Difference (95% CI)	P value
Primary				
Hierarchical composite of death from any cause or TV surgery; hospitalization for HF; and improvement of ≥ 15 points in KCCQ score at 1 yr – no. of wins	11,348	7643	1.48 (1.06 – 2.13)	0.02
Secondary, listed in hierarchical order				
KM 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	12.3 ±1.8	0.6 ±1.8	11.7 (6.8 – 16.6)	<0.001
TR of no greater than moderate severity at 30-day f/u	140/161 (87.0%)	7/146 (4.8%)	—	<0.001
Change in 6-min walk distance	-8.1 ± 10.5	-25.2 ± 10.3	17.1 (-12.0 – 46.1)	0.25

Sorajja et al. NEJM. 2023

TriClip for Severe TR

TRILUMINATE Pivotal trial (TEER vs Medical Therapy)

84 patients, RCT

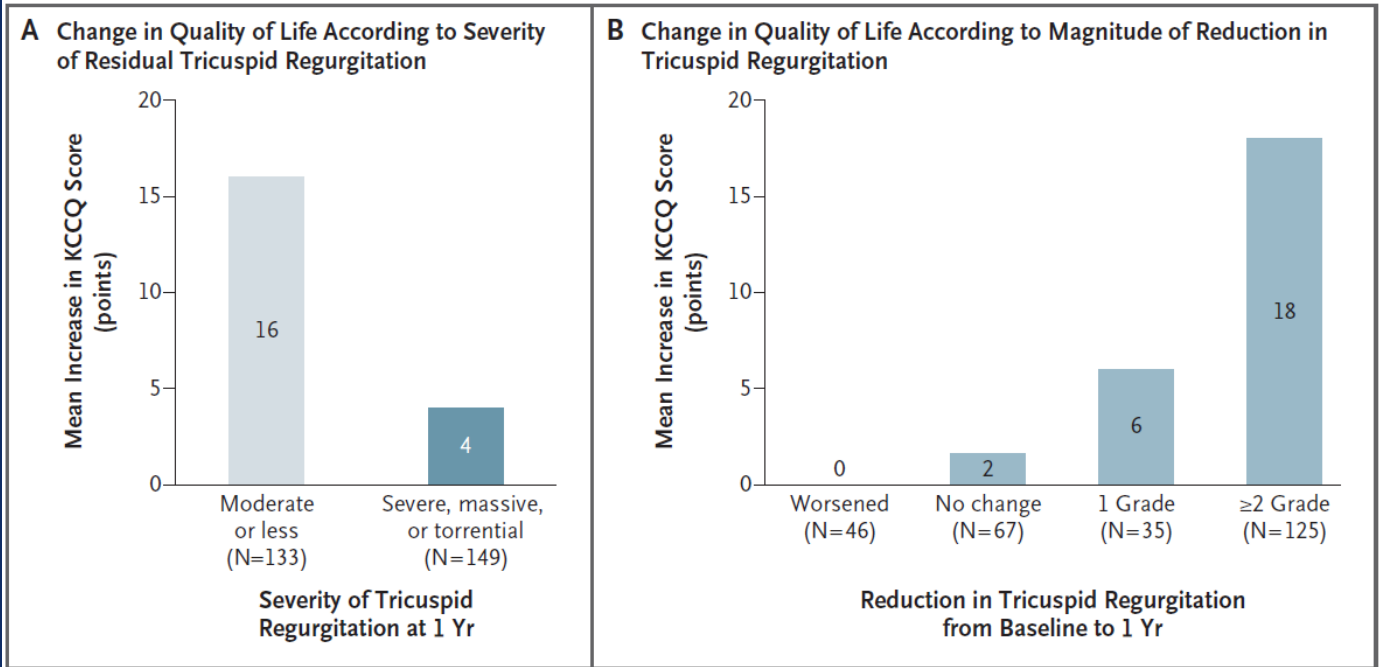


Figure 2. Changes in Quality of Life from Baseline to 1 Year, Stratified According to the Severity of Residual Tricuspid Regurgitation and the Magnitude of the Reduction in Tricuspid Regurgitation.

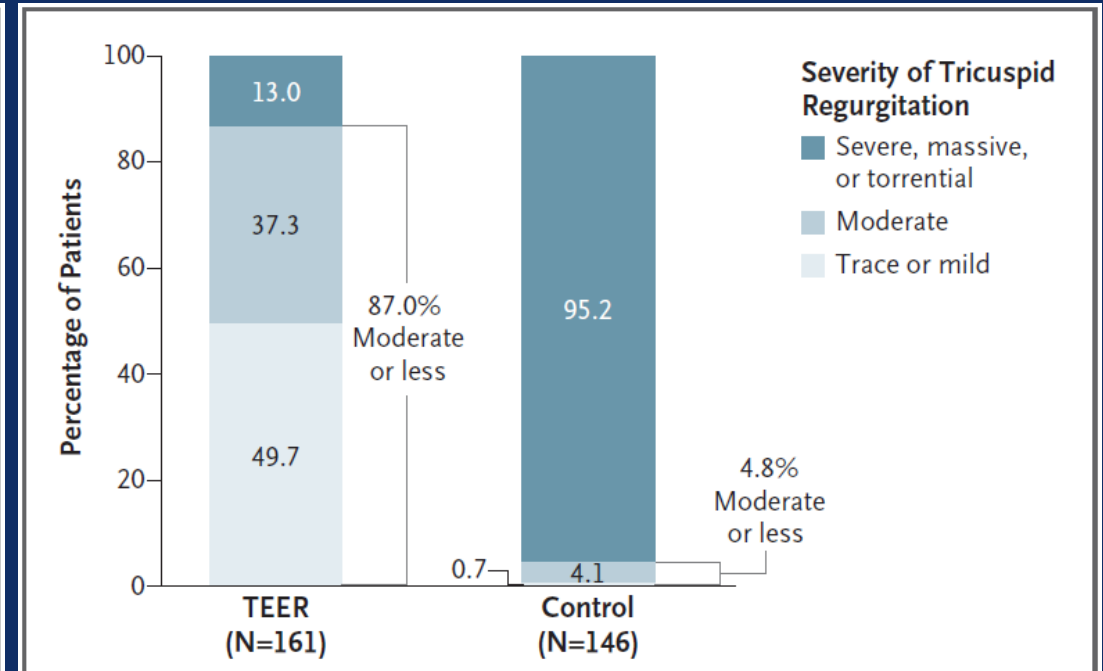
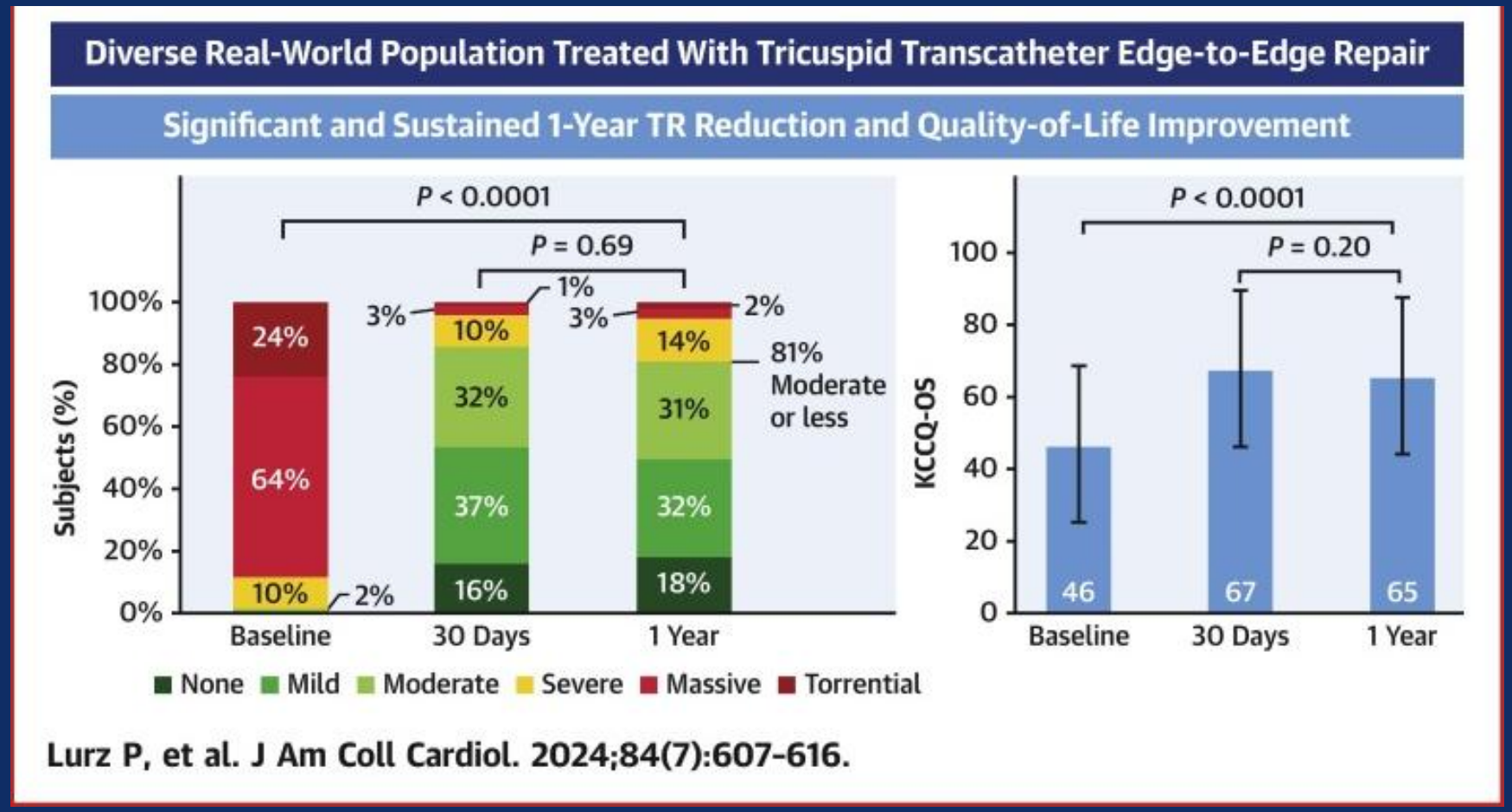


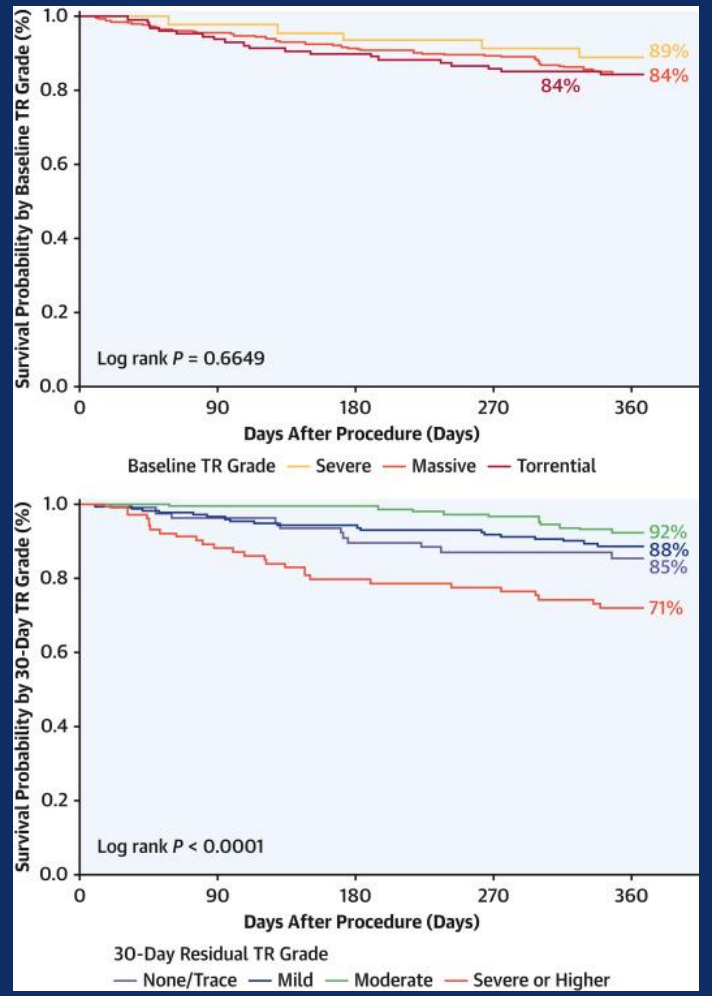
Figure 3. Severity of Tricuspid Regurgitation at 30 Days.

Sorajja et al. NEJM. 2023

bRIGHT Study



Lurz P, et al. J Am Coll Cardiol. 2024;84(7):607-616.



Journal of the American College of Cardiology Volume 84, Issue 7, 13 August 2024, Pages 607-616

PASCAL
(Edwards Lifesciences)

PASCAL for Severe TR

Multicenter, Prospective, Observational, First-in-Human study

23 patients, 7 Centers from 5 Countries

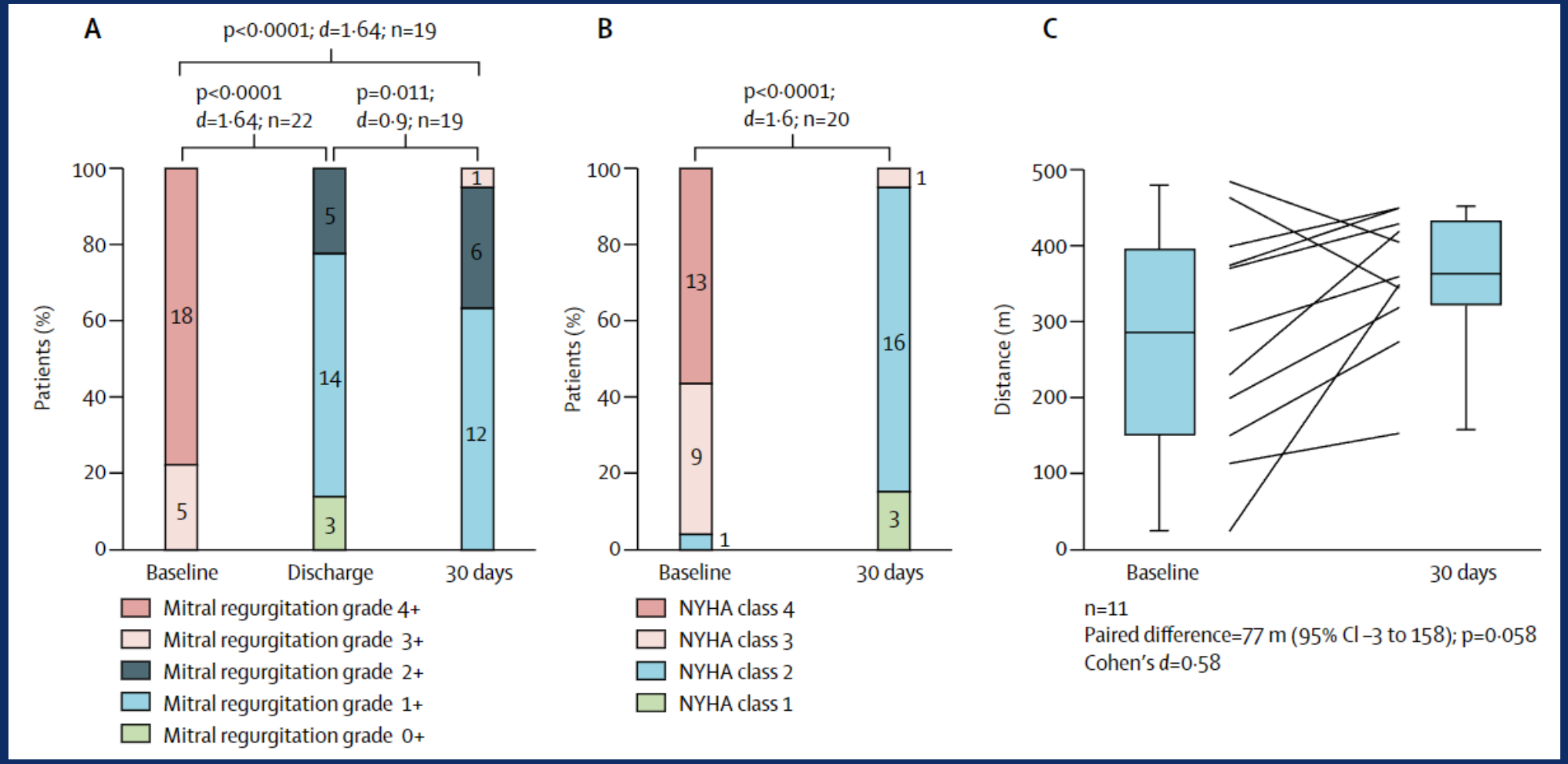
Clinical outcomes at 30 day F/U	N = 23
Device success	18 (78.0%)
All cause mortality	3 (13.0%)
CV mortality	3 (13.0%)
Hospital admission for HF	0 (0.0%)
Reintervention for MV dysfunction	0 (0.0%)
Minor access site bleeding	1 (4.0%)
Major access site bleeding	0 (0.0%)
TIA	1 (4.0%)
Stroke	0 (0.0%)
Myocardial infarction	0 (0.0%)
Renal failure requiring dialysis	0 (0.0%)
Thrombus formation on device	0 (0.0%)

Fabien, P. et al. Lancet; 390:773-80

PASCAL for Severe TR

Multicenter, Prospective, Observational, First-in-Human study

23 patients, 7 Centers from 5 Countries



Fabien, P. et al. Lancet; 390:773-80

PASCAL for Severe TR

Multicenter, Observational, First-in-Human experience

28 patients, Compassionate-use, 6 Centers

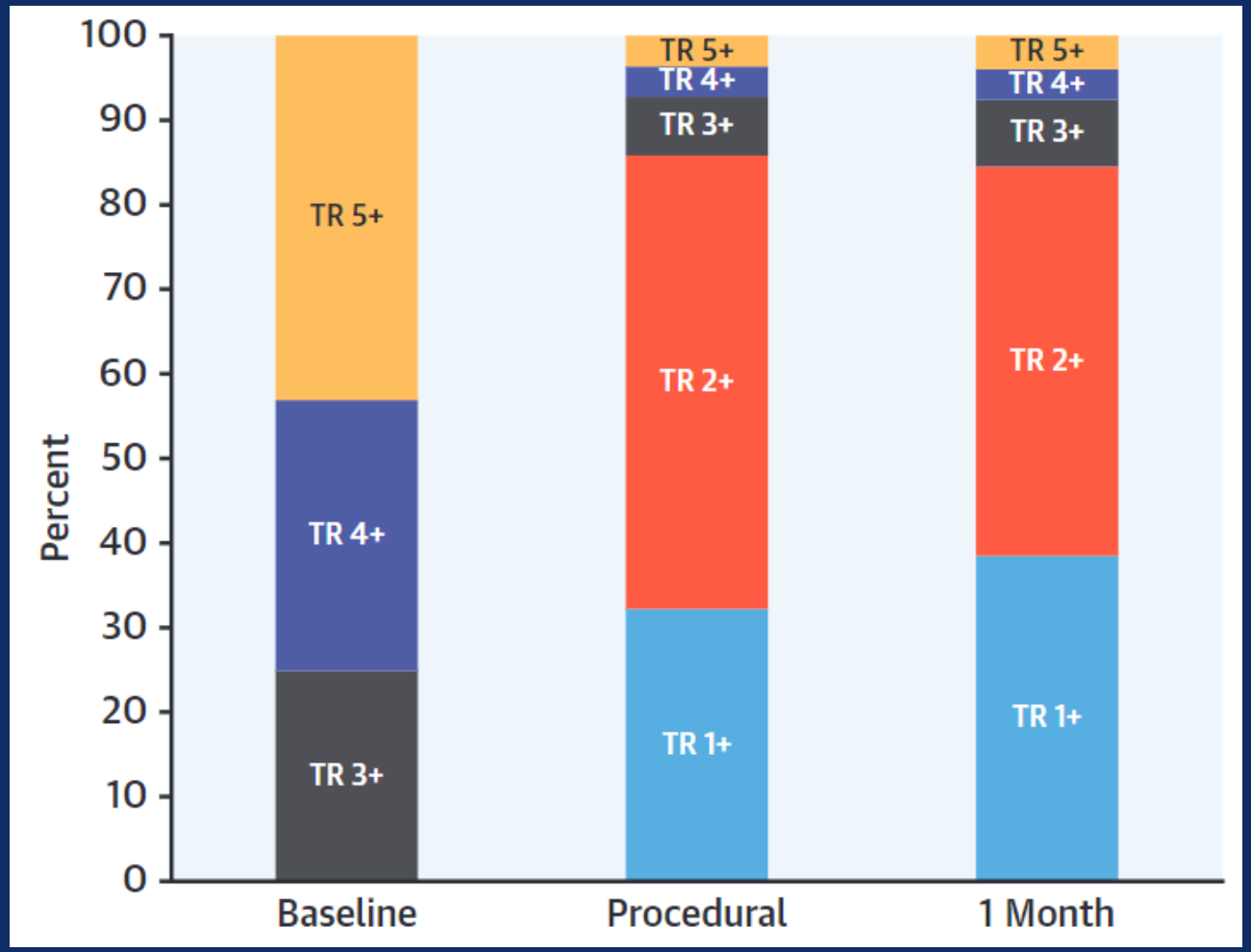
Clinical outcomes at 30 day F/U	N = 28
Mortality	2 (7.1%)
Myocardial infarction	0 (0.0%)
Stroke	0 (0.0%)
Major bleeding	0 (0.0%)
Tamponade	0 (0.0%)
Acute kidney injury	0 (0.0%)
Conversion to surgery	0 (0.0%)
Reintervention	0 (0.0%)
HF hospitalization	1 (3.5%)
Single-leaflet device attachment	2 (7.1%)

Fam, N.P. et al. JACC intervention. 2019;12(24):2488-95

PASCAL for Severe TR

Symptom and TR grade improvement

28 patients, Single arm study

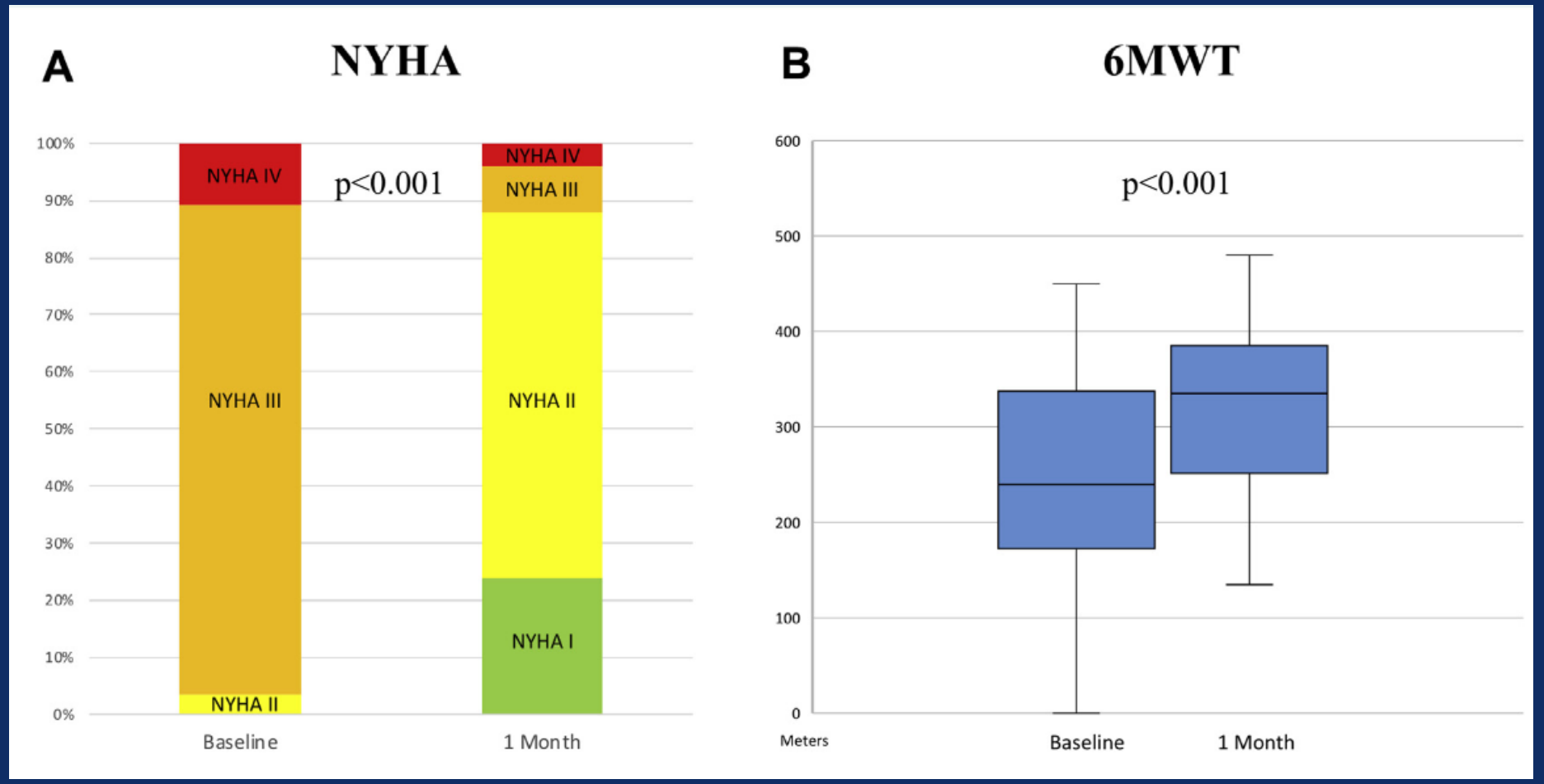


Fam, N.P. et al. JACC intervention. 2019;12(24):2488-95

PASCAL for Severe TR

Symptom and TR grade improvement

28 patients, Single arm study



Fam, N.P. et al. JACC intervention. 2019;12(24):2488-95

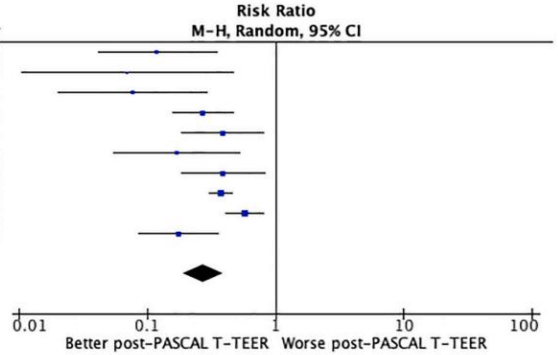
PASCAL for Severe TR

Meta-analysis 10 retrospective studies

A. NYHA 3 or greater

Study or Subgroup	Post-PASCAL Events	Post-PASCAL Total	Pre-PASCAL Events	Pre-PASCAL Total	Weight	Risk Ratio M-H, Random, 95% CI	Year
Fam 2019	3	26	27	28	7.2%	0.12 [0.04, 0.35]	2019
Sugiura 2020	1	15	21	22	3.1%	0.07 [0.01, 0.46]	2020
Kitamura 2021	2	29	27	30	5.3%	0.08 [0.02, 0.29]	2021
Low 2021	10	40	44	48	13.0%	0.27 [0.16, 0.47]	2021
Aurich 2021	4	11	16	16	10.5%	0.39 [0.19, 0.81]	2021
Rottlander 2022	2	14	20	20	6.6%	0.17 [0.05, 0.53]	2022
Volz 2022	4	11	11	11	10.5%	0.39 [0.19, 0.82]	2022
Wild 2022	62	184	211	235	17.3%	0.38 [0.31, 0.46]	2022
Baldus 2022	23	52	40	52	15.8%	0.57 [0.41, 0.81]	2022
Kodali 2023	7	56	46	65	10.8%	0.18 [0.09, 0.36]	2023
Total (95% CI)		**438**		**527**	**100.0%**	**0.27 [0.19, 0.39]**	
Total events	118		463				

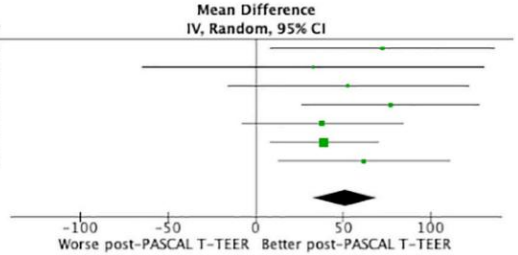
Heterogeneity: $Tau^2 = 0.19$; $Chi^2 = 30.03$, df = 9 (P = 0.0004); $I^2 = 70\%$
Test for overall effect: Z = 6.96 (P < 0.00001)



B. 6MWD

Study or Subgroup	Post-PASCAL Mean	Post-PASCAL SD	Post-PASCAL Total	Pre-PASCAL Mean	Pre-PASCAL SD	Pre-PASCAL Total	Weight	Mean Difference IV, Random, 95% CI	Year
Fam 2019	322.9	104.7	26	250.4	128.9	26	8.5%	72.50 [8.67, 136.33]	2019
Sugiura 2020	223.5	104.1	7	190.6	81.2	7	3.6%	32.90 [-64.90, 130.70]	2020
Kitamura 2021	328	115	23	275	122	23	7.4%	53.00 [-15.52, 121.52]	2021
Low 2021	290	122	42	213	115	42	13.5%	77.00 [26.30, 127.70]	2021
Baldus 2022	285.5	105.1	40	247.3	105.3	40	16.3%	38.20 [-7.91, 84.31]	2022
Wild 2022	303	123	114	264	115	114	36.3%	39.00 [8.09, 69.91]	2022
Kodali 2023	270	152	51	208	107	65	14.4%	62.00 [12.84, 111.16]	2023
Total (95% CI)			**303**			**317**	**100.0%**	**50.96 [32.34, 69.59]**	

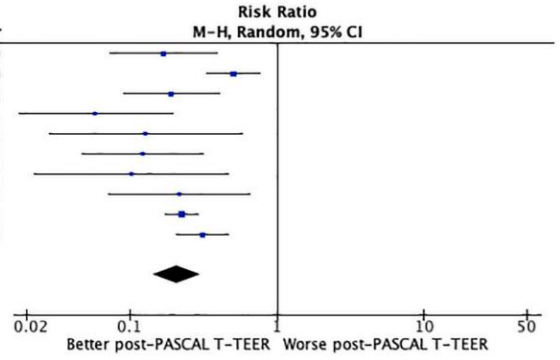
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 2.65$, df = 6 (P = 0.85); $I^2 = 0\%$
Test for overall effect: Z = 5.36 (P < 0.00001)



C. Severe TR or greater

Study or Subgroup	Post-PASCAL Events	Post-PASCAL Total	Pre-PASCAL Events	Pre-PASCAL Total	Weight	Risk Ratio M-H, Random, 95% CI	Year
Fam 2019	4	26	28	28	9.7%	0.17 [0.07, 0.39]	2019
Sugiura 2020	11	22	22	22	15.2%	0.51 [0.34, 0.77]	2020
Kitamura 2021	5	28	28	28	10.7%	0.19 [0.09, 0.41]	2021
Low 2021	2	42	48	48	6.5%	0.06 [0.02, 0.20]	2021
Aurich 2021	1	11	16	16	4.8%	0.13 [0.03, 0.58]	2021
Baldus 2022	4	40	44	54	8.7%	0.12 [0.05, 0.31]	2022
Rottlander 2022	1	14	20	20	4.7%	0.10 [0.02, 0.47]	2022
Volz 2022	2	11	11	11	7.2%	0.22 [0.07, 0.66]	2022
Wild 2022	48	231	213	233	17.2%	0.23 [0.18, 0.29]	2022
Kodali 2023	17	56	63	65	15.4%	0.31 [0.21, 0.47]	2023
Total (95% CI)		**481**		**525**	**100.0%**	**0.21 [0.14, 0.31]**	
Total events	95		493				

Heterogeneity: $Tau^2 = 0.20$; $Chi^2 = 28.27$, df = 9 (P = 0.0009); $I^2 = 68\%$
Test for overall effect: Z = 8.08 (P < 0.00001)



O. Badwan et al. International Journal of Cardiology. 2023

1-year outcomes of Transcatheter Tricuspid valve repair

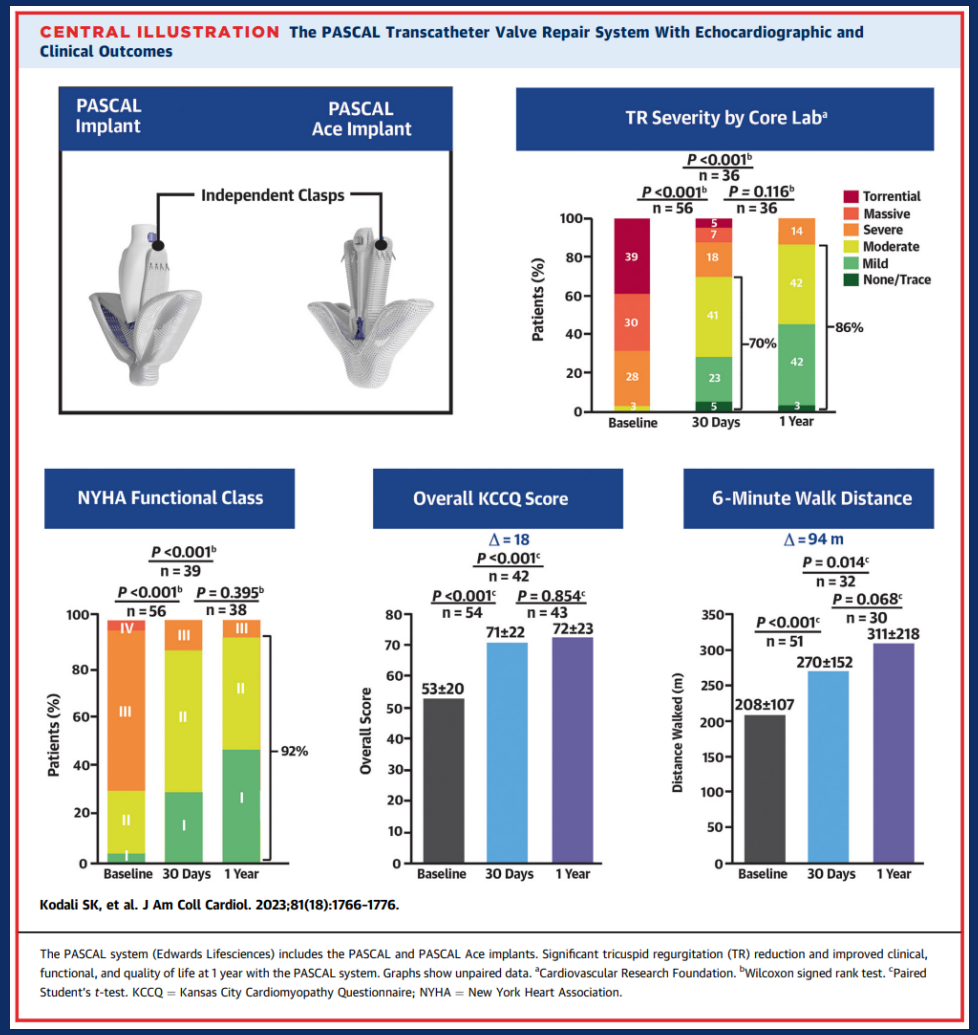


TABLE 3 CEC-Adjudicated and Other Events at 30 Days and 1 Year

	30 Days (n = 65)	1 Year (n = 65)
CEC-adjudicated MAEs		
Cardiovascular mortality	2 (3.1)	5 (7.7)
Myocardial infarction	0 (0.0)	0 (0.0)
Stroke	1 (1.5)	3 (4.6)
Renal complications requiring unplanned dialysis or renal replacement therapy	0 (0.0)	0 (0.0)
Severe bleeding[a]	5 (7.7)	6 (9.2)
Unplanned or emergency reintervention related to the device	0 (0.0)	1 (1.5)
Major access site and vascular complications requiring intervention	2 (3.1)	2 (3.1)
Composite MAE	6 (9.2)	11 (16.9)
Other events		
All-cause mortality	2 (3.1)	7(10.8)
Heart failure hospitalization	0 (0.0)	12 (18.5)
SLDA[b]	3 (4.6)	3 (4.6)

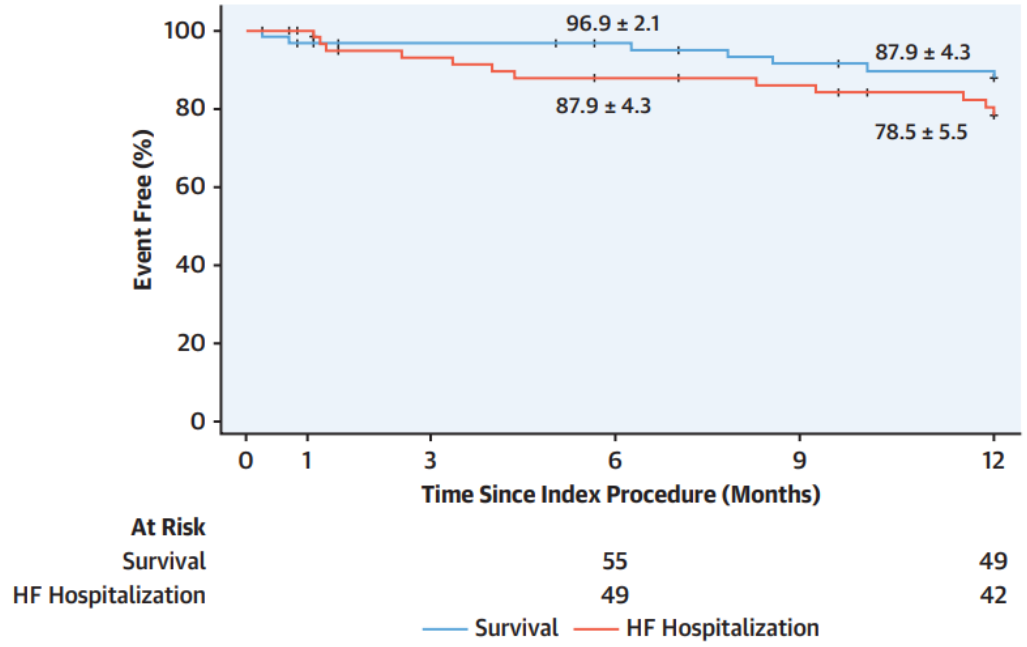
Values are n (%). [a]Severe bleeding is defined as major, extensive, life-threatening, or fatal bleeding according to Mitral Valve Academic Research Consortium criteria. [b]Core laboratory: Cardiovascular Research Foundation.

CEC = clinical events committee; MAE = major adverse event; SLDA = single-leaflet device attachment.

Kodali et al 1-Year Results of the CLASP-TR Study. JACC Vol.81, NO.18.2023.MAY,2023;1766-1776

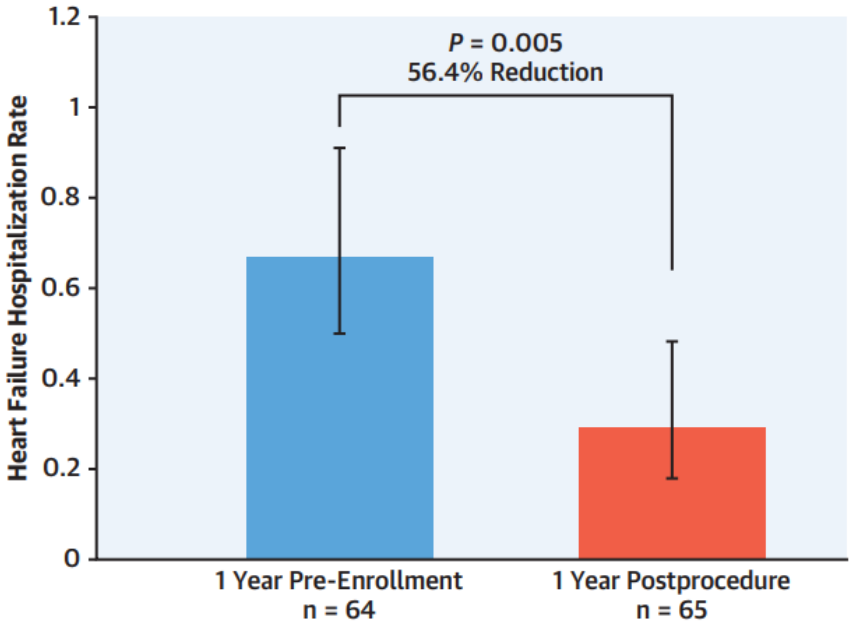
1-year outcomes of Transcatheter Tricuspid valve repair

FIGURE 1 Kaplan-Meier Estimates for Clinical Events Committee-Adjudicated Survival and Freedom From HF Hospitalization



The Kaplan-Meier estimates at 1 year for survival and freedom from heart failure (HF) hospitalization were 87.9% ± 4.3% and 78.5% ± 5.5%, respectively. Kaplan Meier analysis estimate ± SE.

FIGURE 2 Annualized Reduction in Heart Failure Hospitalization Rate

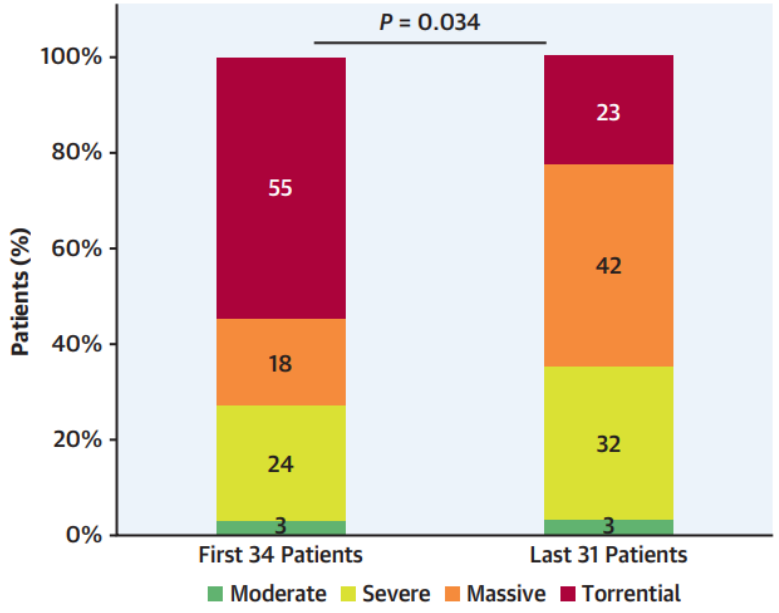


Preprocedure data were collected from site-reported medical history; postprocedure data were adjudicated by the clinical events committee. The annualized heart failure hospitalization rate showed a significant relative reduction of 56.4%. **Error bars** represent 95% CIs.

Kodali et al 1-Year Results of the CLASP-TR Study. JACC Vol.81, NO.18.2023.MAY,2023;1766-1776

1-year outcomes of Transcatheter Tricuspid valve repair

FIGURE 3 Baseline Tricuspid Regurgitation Severity by Patient Subgroup



First 34 Patients and Last 31 Patients refer to when patients were treated among the 65 total patients enrolled and are significantly different between subgroups. The *P* value was determined on the basis of the Fisher exact test.

TABLE 5 Paired Echocardiographic Parameters, Baseline to 1 Year

	n	Baseline	1 Year	*P* Value[a]
2D PISA EROA, cm^2	23	0.7 ± 0.3	0.3 ± 0.1	<0.001
PISA regurgitant volume, mL	23	53.3 ± 16.7	22.6 ± 11.0	<0.001
Mean TR vena contracta width 2D, cm	33	1.4 ± 0.4	0.5 ± 0.2	<0.001
Tricuspid annulus diameter (end-diastole, apical 4-chamber), cm	36	4.5 ± 0.8	4.0 ± 0.6	<0.001
CO (LVOT stroke volume × heart rate), L/min	32	4.5 ± 1.2	4.4 ± 1.1	0.810
LVOT Doppler stroke volume, mL	32	59.6 ± 14.7	61.9 ± 14.4	0.292
Left ventricular stroke volume index (LVSV/BSA), mL/m^2	22	33.3 ± 8.5	34.5 ± 8.4	0.385
LVEF, Simpson's method, %	36	56.5 ± 7.1	56.0 ± 8.1	0.644
RV end-diastolic diameter (mid) (4-chamber), cm	36	4.0 ± 0.9	3.5 ± 0.7	<0.001
RV FAC, %	29	36.9 ± 9.4	36.0 ± 8.3	0.531
RA volume (single-plane Simpson) (4-chamber), mL	34	148.9 ± 81.7	130.6 ± 63.9	0.013
RV TAPSE, cm	36	1.4 ± 0.4	1.4 ± 0.3	0.658
IVC diameter, cm	29	2.5 ± 0.6	2.1 ± 0.6	0.002
TR peak velocity, cm/s	36	256.6 ± 41.9	254.5 ± 60.7	0.843
TR jet area (maximum), cm^2	22	15.1 ± 5.0	6.9 ± 3.6	<0.001
TV diastolic mean gradient, mm Hg	34	1.3 ± 0.5	2.1 ± 1.5	<0.001

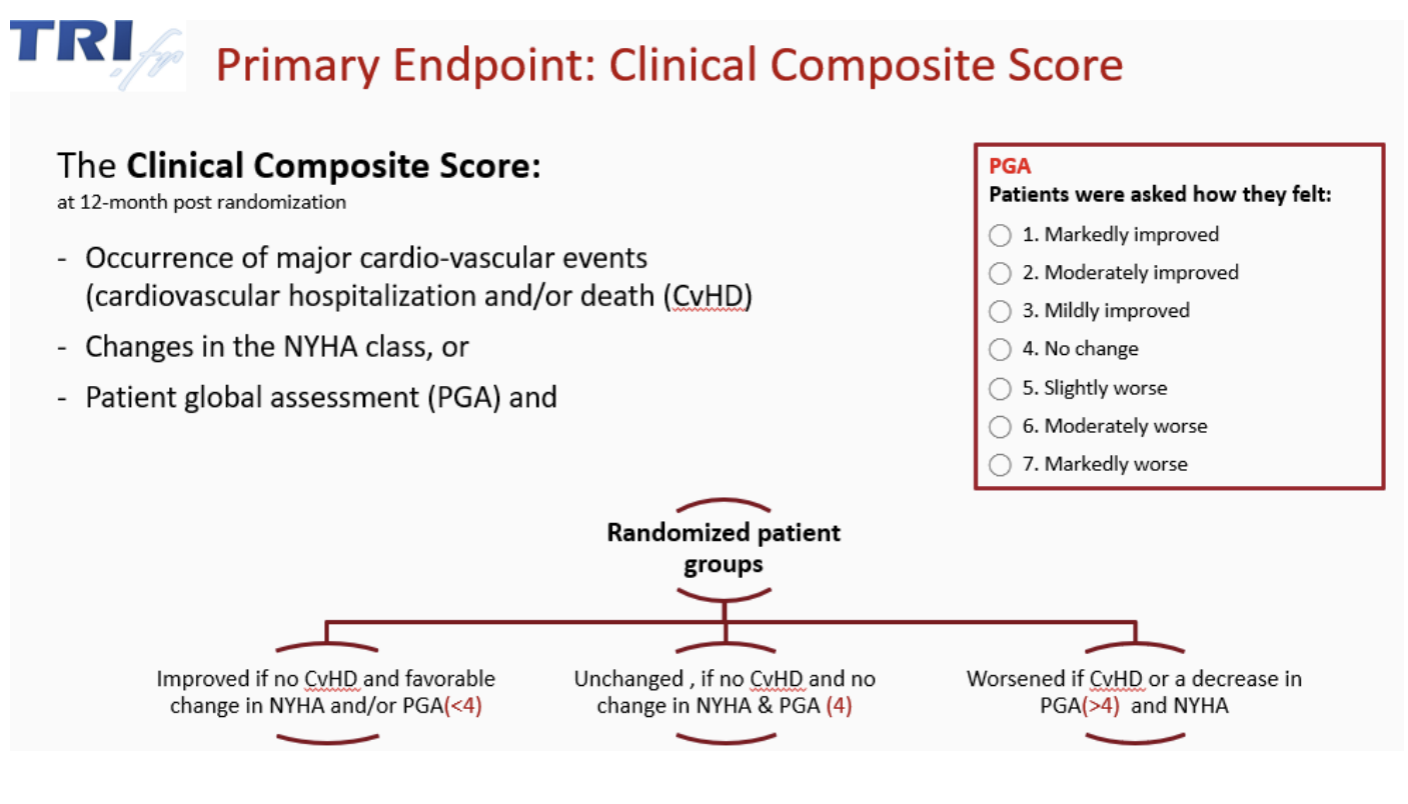
Values are paired mean ± SD unless otherwise indicated. [a]*P* values calculated by Student's *t*-test for paired analysis.

BSA = body surface area; CO = cardiac output; EROA = effective regurgitant orifice area; FAC = fractional area change; IVC = inferior vena cava; LVEF = left ventricular ejection fraction; LVOT = left ventricular outflow tract; LVSV = left ventricular stroke volume; PISA = proximal isovelocity surface area; RA = right atrial; RV = right ventricular; TAPSE = tricuspid annular plane systolic excursion; TR = tricuspid regurgitation; TV = tricuspid valve; 2D = 2-dimensional.

Kodali et al 1-Year Results of the CLASP-TR Study. JACC Vol.81, NO.18.2023.MAY,2023;1766-1776

TRI-FR trial

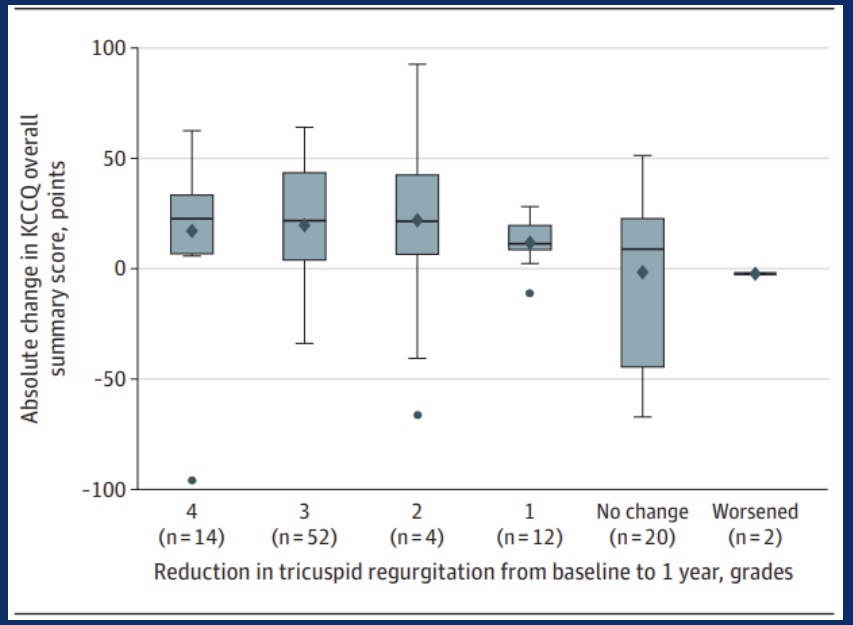
- T-TEER with the TriClip system plus OMT vs OMT alone in patients with severe, symptomatic tricuspid regurgitation

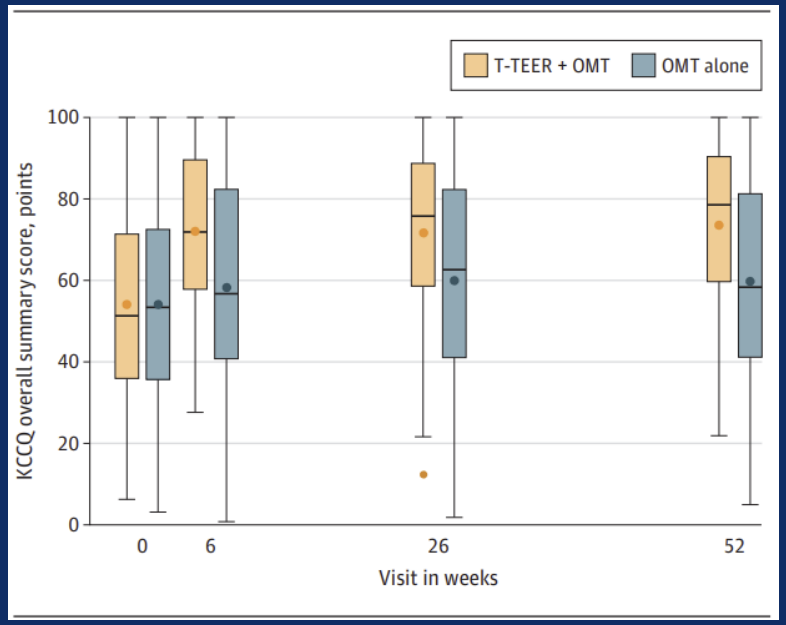


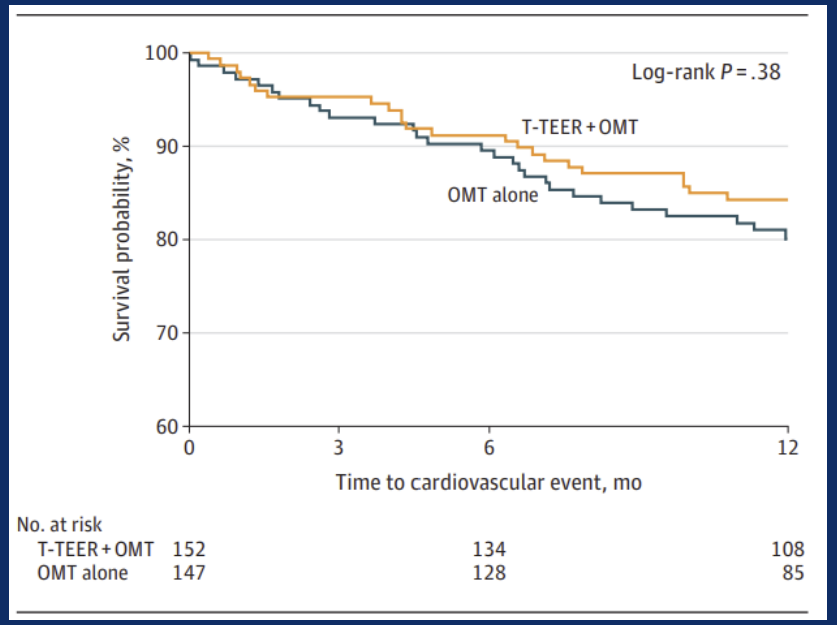
JAMA January 14, 2025 Volume 333, Number 2

TRI-FR trial

T-TEER + OMT reduces tricuspid regurgitation severity and improves the composite clinical outcome comprising NYHA class, PGA, andmajorcardiovascular events at 12months





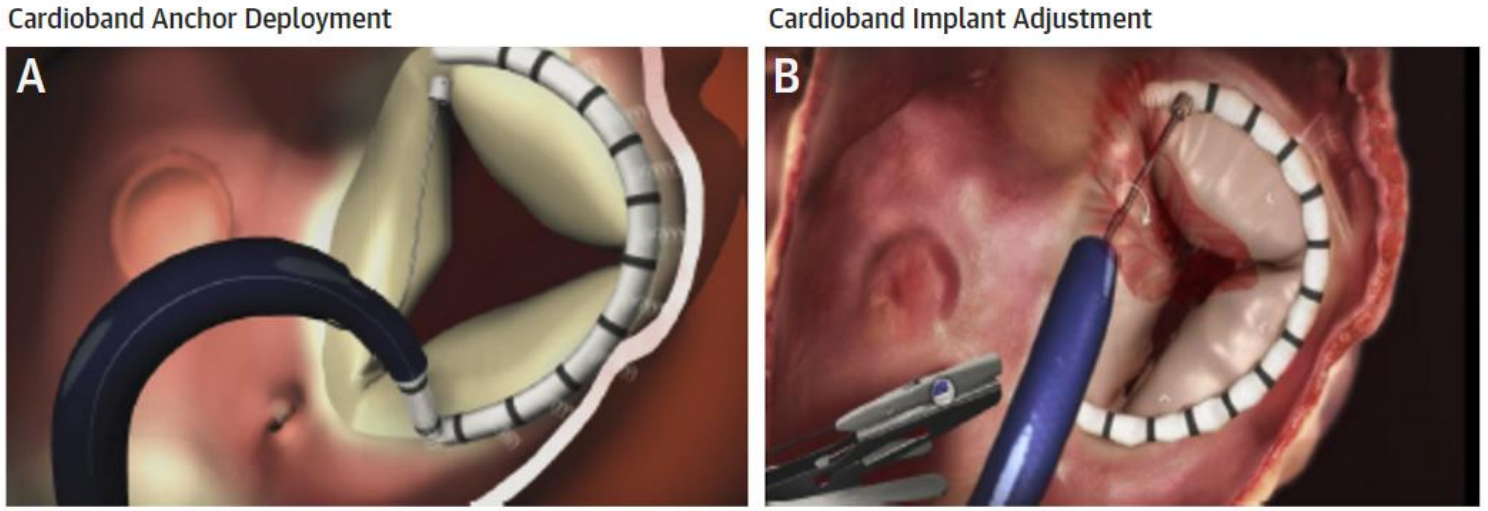


JAMA January 14, 2025 Volume 333, Number 2

Evidence of Direct Annuloplasty for Severe TR

Cardioband (Edwards Lifesciences)

FIGURE 1 The Tricuspid Valve Reconstruction System



(A) Anchor deployment through implant to the tissue. **(B)** Adjustment of implant. Image provided by Edwards Lifesciences.

6-Month Outcomes of Cardioband for Severe TR

30 patients, Single arm study, Multicenter, Prospective trial

Baseline Characteristics	N = 30
Age	75.2 ± 6.6
Female	22 (73.3%)
EuroSCORE II	4.1 ± 2.8
STS score	2.6 ± 1.6
NYHA III or IV	25 (83.3%)
Functional TR, %	30 (100%)
Hypertension	24 (80.0%)
Elevated pulmonary pressure (> 30mmHg)	15 (50.0%)
Atrial fibrillation / flutter	28 (93.3%)
Congestive HF	17 (56.7%)
Prior implanted cardiac device	4 (13.3%)
Prior stroke/TIA	5 (16.7%)
Coronary artery disease	11 (36.7%)
Chronic renal disease	16 (53.3%)

Nickenig. et al. JACC. 2019;73:1905-15

6-Month Outcomes of Cardioband for Severe TR

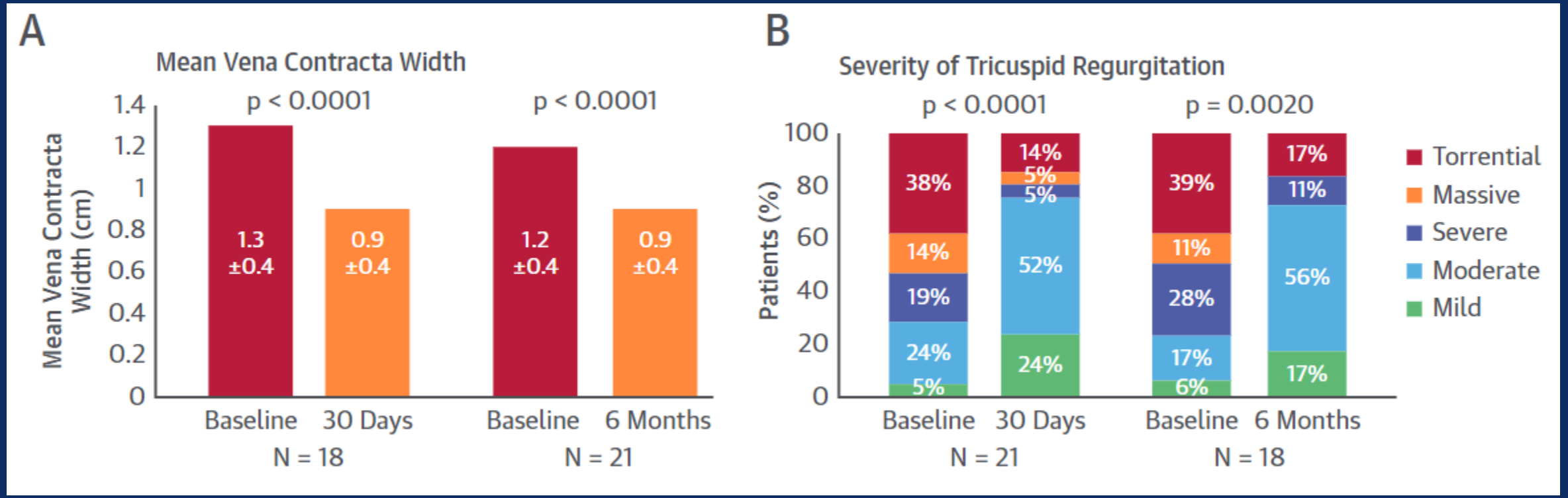
30 patients, Single arm study, Multicenter, Prospective trial

Procedural characteristics	N = 30
In-hospital death	1
Length of stay in hospital, days	8.5 ± 5.6
Length of stay in ICU, days	2.0 ± 1.8
Procedure time, min	254.5 ± 92.8
Implant size, mm (89-96)	2
Implant size, mm (97-104)	4
Implant size, mm (105-112)	6
Implant size, mm (113-120)	18
Adjudicated 30-day events, n	
Death	4 (13.23%)
Stroke	1
Myocardial infarction	0
Bleeding complications	4
Coronary complications	3
Device-related cardiac surgery	0
Renal failure	1
Conduction system disturbance	1

Nickenig. et al. JACC. 2019;73:1905-15

6-Month Outcomes of Cardioband for Severe TR

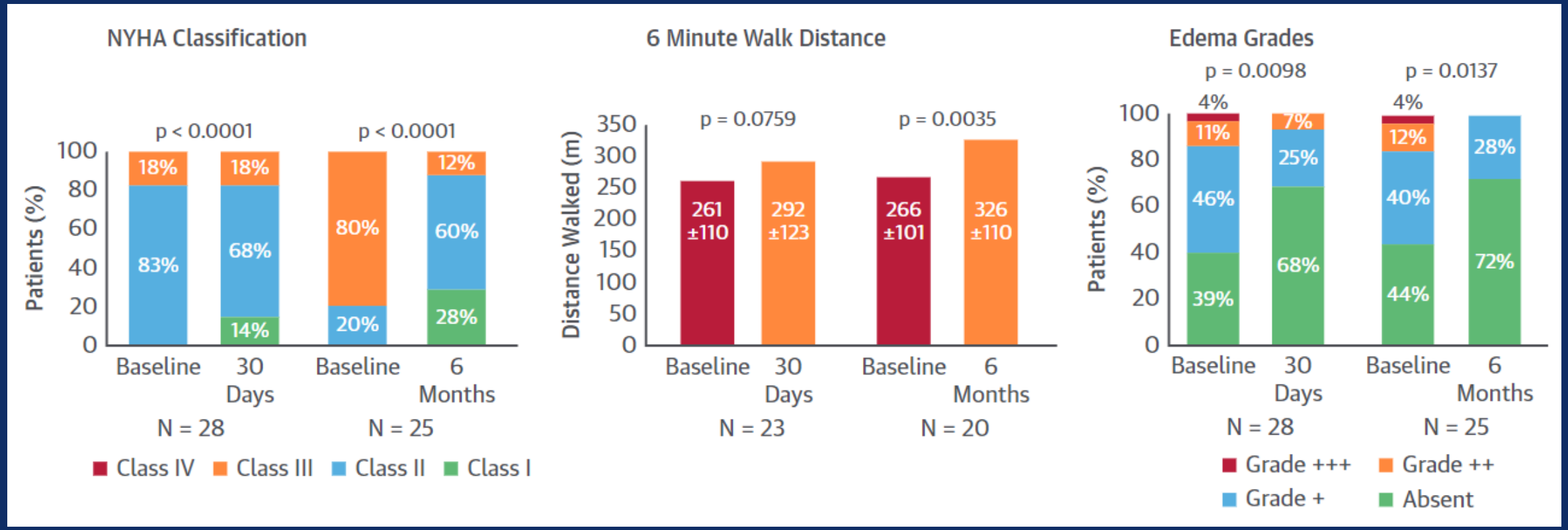
30 patients, Single arm study, Multicenter, Prospective trial



Nickenig. et al. JACC. 2019;73:1905-15

6-Month Outcomes of Cardioband for Severe TR

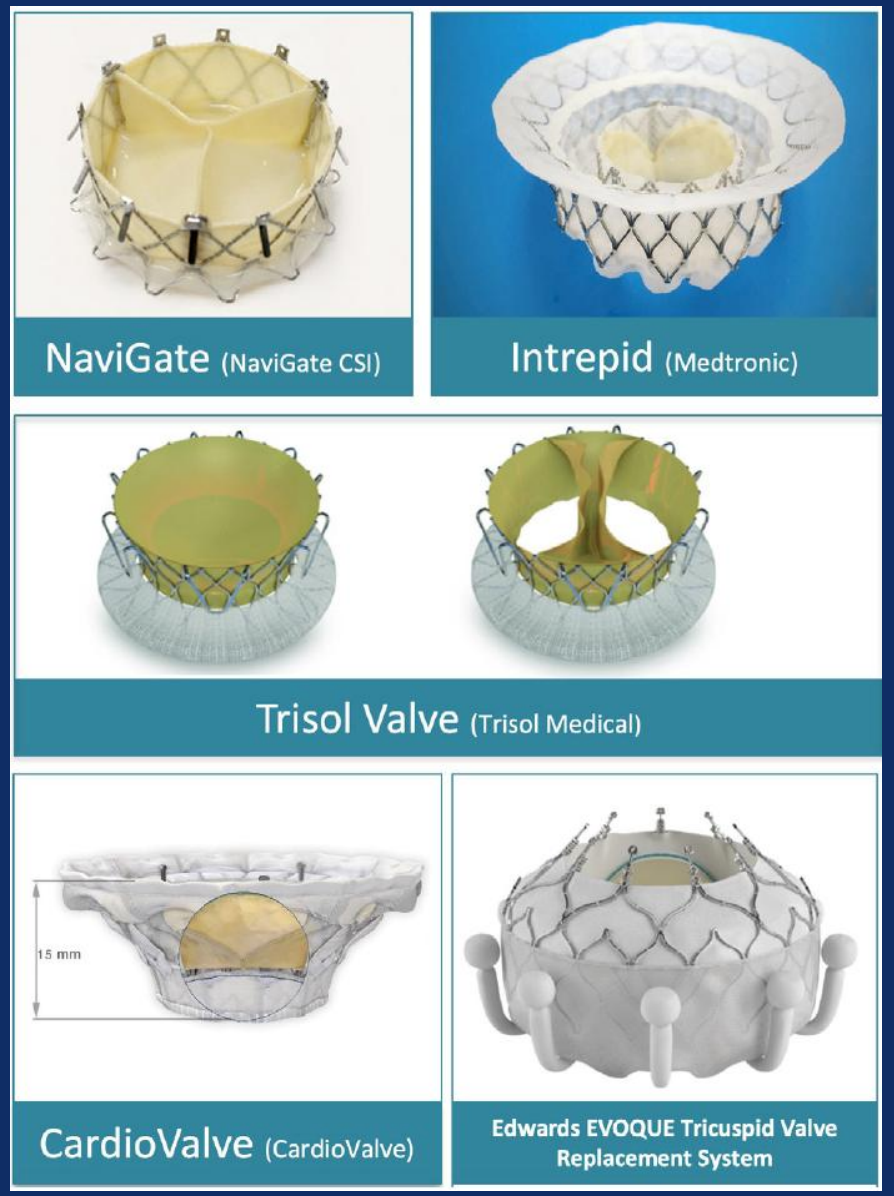
30 patients, Single arm study, Multicenter, Prospective trial



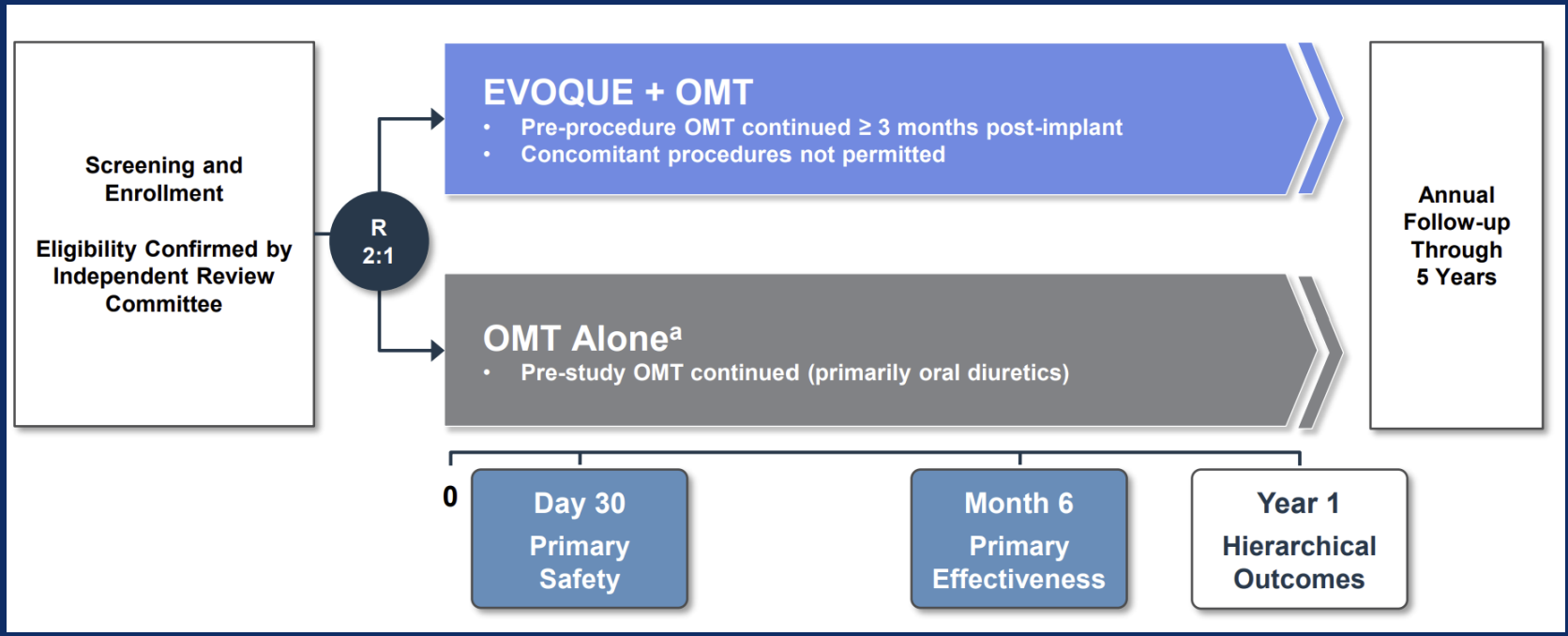
Nickenig. et al. JACC. 2019;73:1905-15

Evidence of Catheter-based Valve Replacement for Severe TR

Transcatheter Tricuspid Valve Replacement



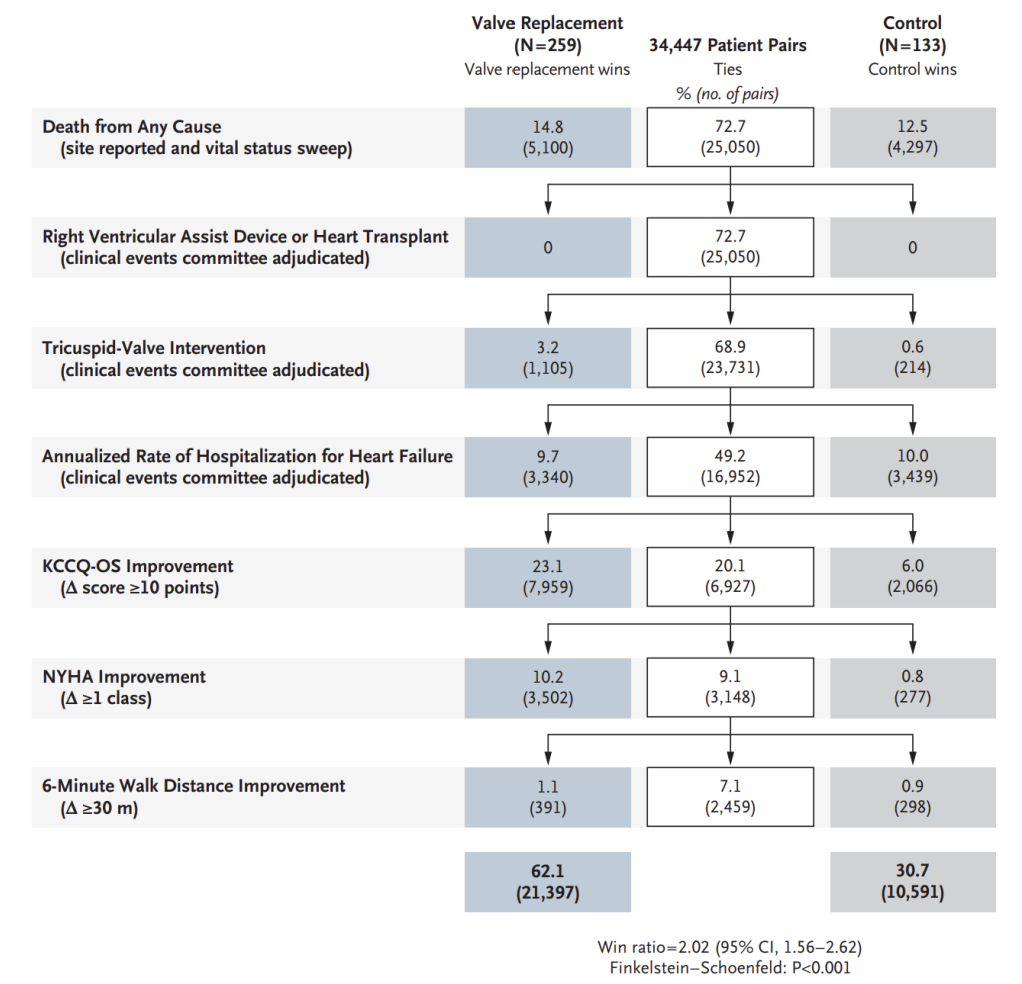
TRISCEND II Trial

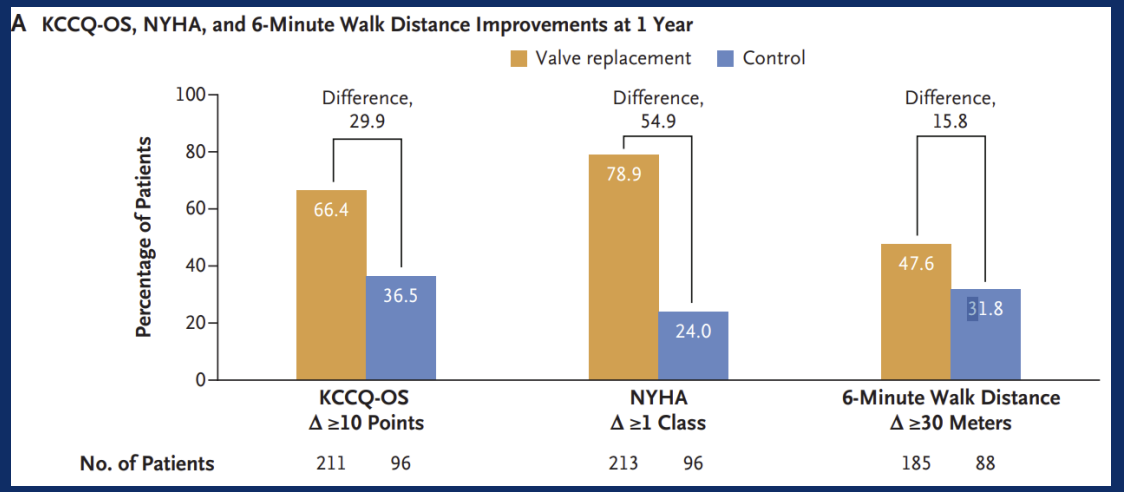


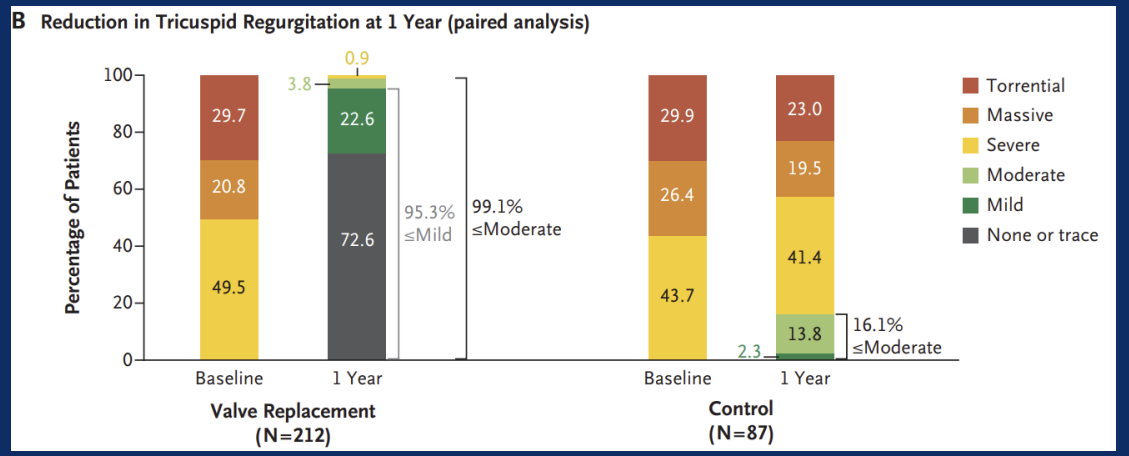
Primary Endpoints
Safety
Composite MAE rate
Effectiveness (6 Months)
TR grade reduction
Hierarchical composite of KCCQ, NYHA and 6MWD
Hierarchical Composite (1 Year)
All-cause mortality
RVAD implant or Heart transplant
TV surgery or Intervention
Annualized heart failure hospitalization
KCCQ, NYHA, 6MWD

N ENGL J MED 392;2 NEJM.ORG JANUARY 9, 2025

TRISCEND II Trial







N ENGL J MED 392;2 NEJM.ORG JANUARY 9, 2025

TRISCEND II Trial

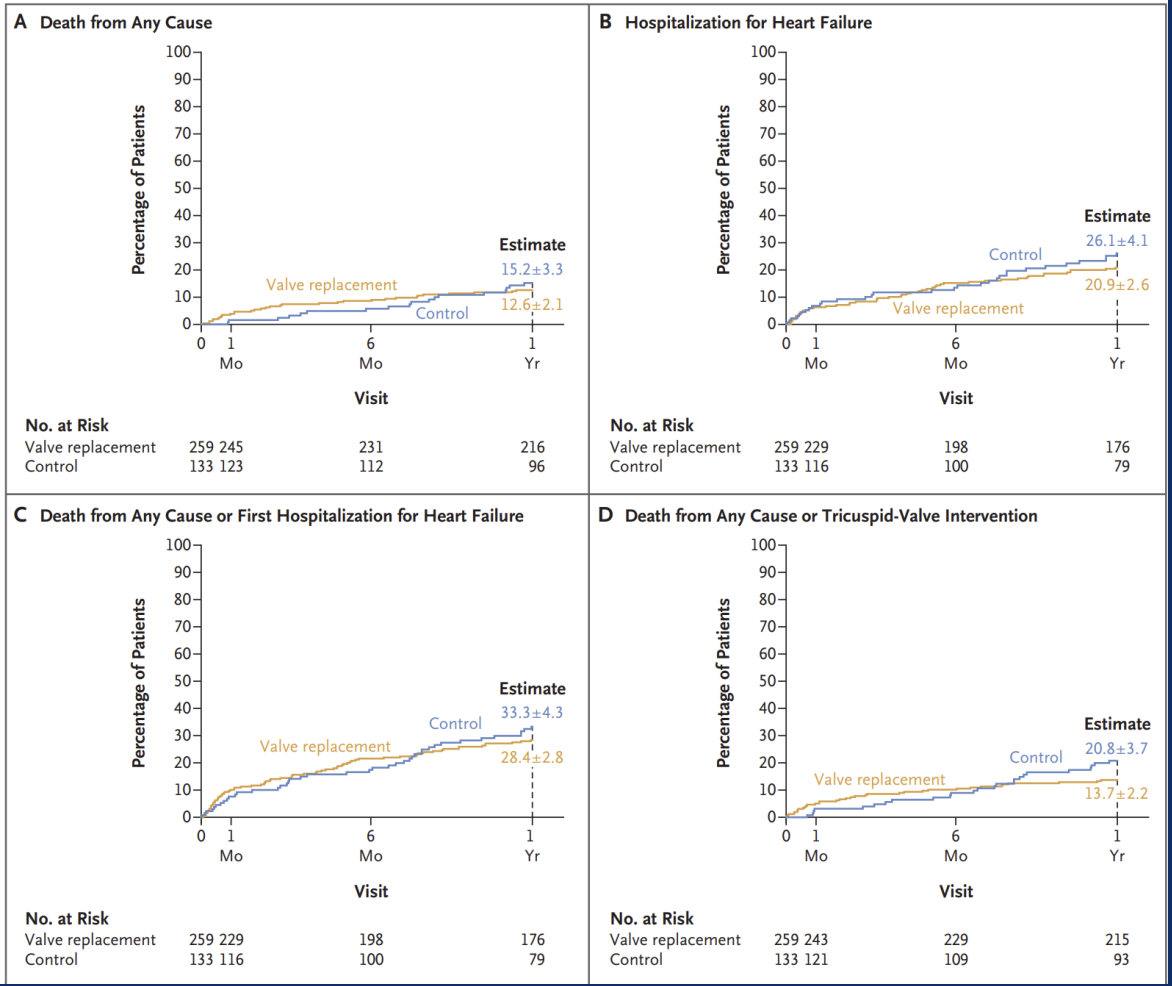


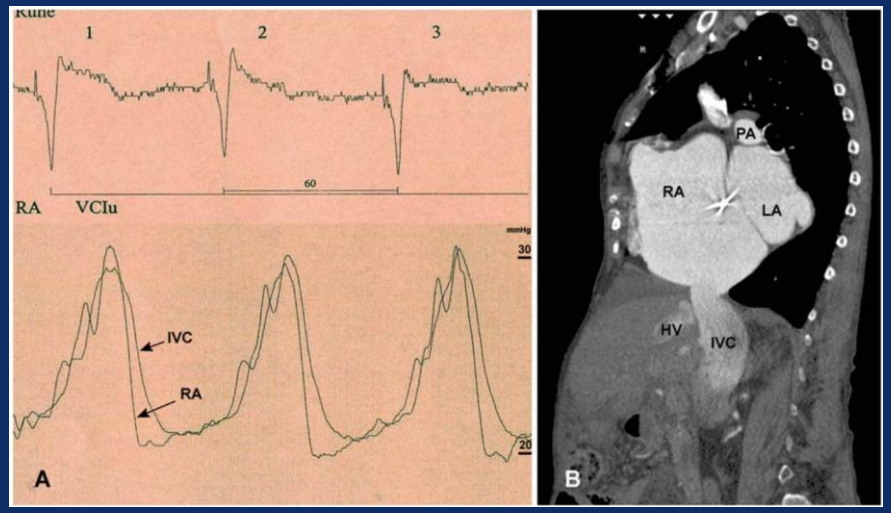
Table 2. Safety Outcomes.*

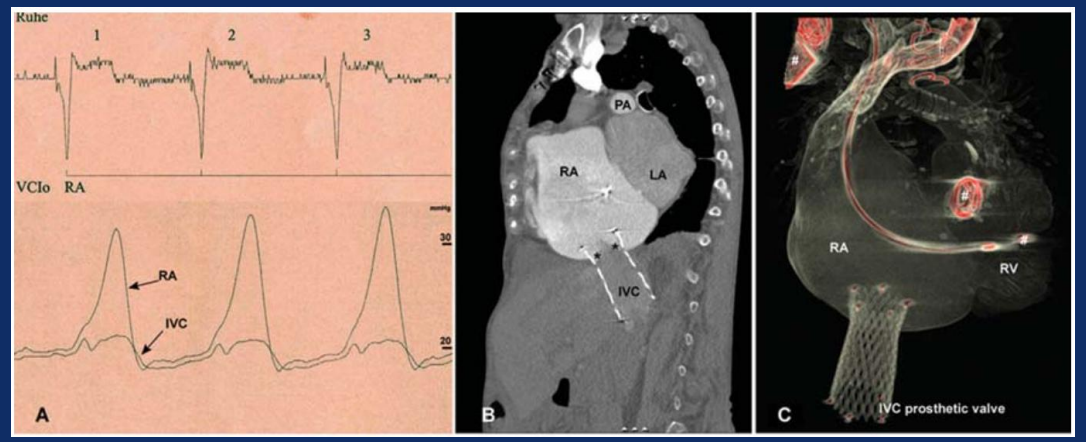
Safety Event	Early Events (≤30 Days)†		Late Events (31 to 365 Days)‡		Cumulative Events (0 to 365 Days)†		P Value§
	Valve Replacement (N=259)	Control (N=133)	Valve Replacement (N=247)	Control (N=128)	Valve Replacement (N=259)	Control (N=133)	
	number of patients (percent)						
Death from any cause¶	9 (3.5)	0	21 (8.5)	14 (10.9)	30 (11.6)	14 (10.5)	0.87
Death from cardiovascular cause	8 (3.1)	0	14 (5.7)	10 (7.8)	22 (8.5)	10 (7.5)	0.85
Myocardial infarction	2 (0.8)	0	3 (1.2)	1 (0.8)	5 (1.9)	1 (0.8)	0.67
Stroke	1 (0.4)	0	3 (1.2)	0	4 (1.5)	0	0.30
New renal-replacement therapy‖	4 (1.5)	NA	4 (1.6)	NA	8 (3.1)	NA	NA
Severe bleeding**	27 (10.4)	2 (1.5)	13 (5.3)	6 (4.7)	40 (15.4)	7 (5.3)	0.003
Nonelective tricuspid-valve reintervention††	2 (0.8)	1 (0.8)	0	3 (2.3)	2 (0.8)	4 (3.0)	0.19
Major access-site and vascular complication‖	8 (3.1)	NA	0	NA	8 (3.1)	NA	NA
Major cardiac structural complication‖	3 (1.2)	NA	0	NA	3 (1.2)	NA	NA
Device-related pulmonary embolism‖	2 (0.8)	NA	1 (0.4)	NA	2 (0.8)	NA	NA
Arrhythmia and conduction disorder resulting in permanent pacing	41 (15.8)	0	5 (2.0)	3 (2.3)	46 (17.8)	3 (2.3)	<0.001
New pacemaker or cardiac implantable electronic device‡‡							
In all patients	40 (15.4)	0	5 (2.0)	3 (2.3)	45 (17.4)	3 (2.3)	<0.001
In patients without pre-existing pacemaker§§	40/162 (24.7)	0/80	5/118 (4.2)¶¶	3/76 (3.9)¶¶	45/162 (27.8)	3/80 (3.8)	<0.001

Interventional Valve Implantion in Caval position (CAVI) for Severe TR

First-in-Human application

Hemodynamic parameters	Before implantation	After implantation
HR, (bpm)	60	60
RA pressure, (mmHg)	28/10	38/13
IVC pressure, (mmHg)	29/19	19/12
TV annulus (mm)	46	46 (after 8 wks)
TAPSE (mm)	16	15 (after 8 wks)
TASV (cm/s)	6.3	6.8 (after 8 wks)

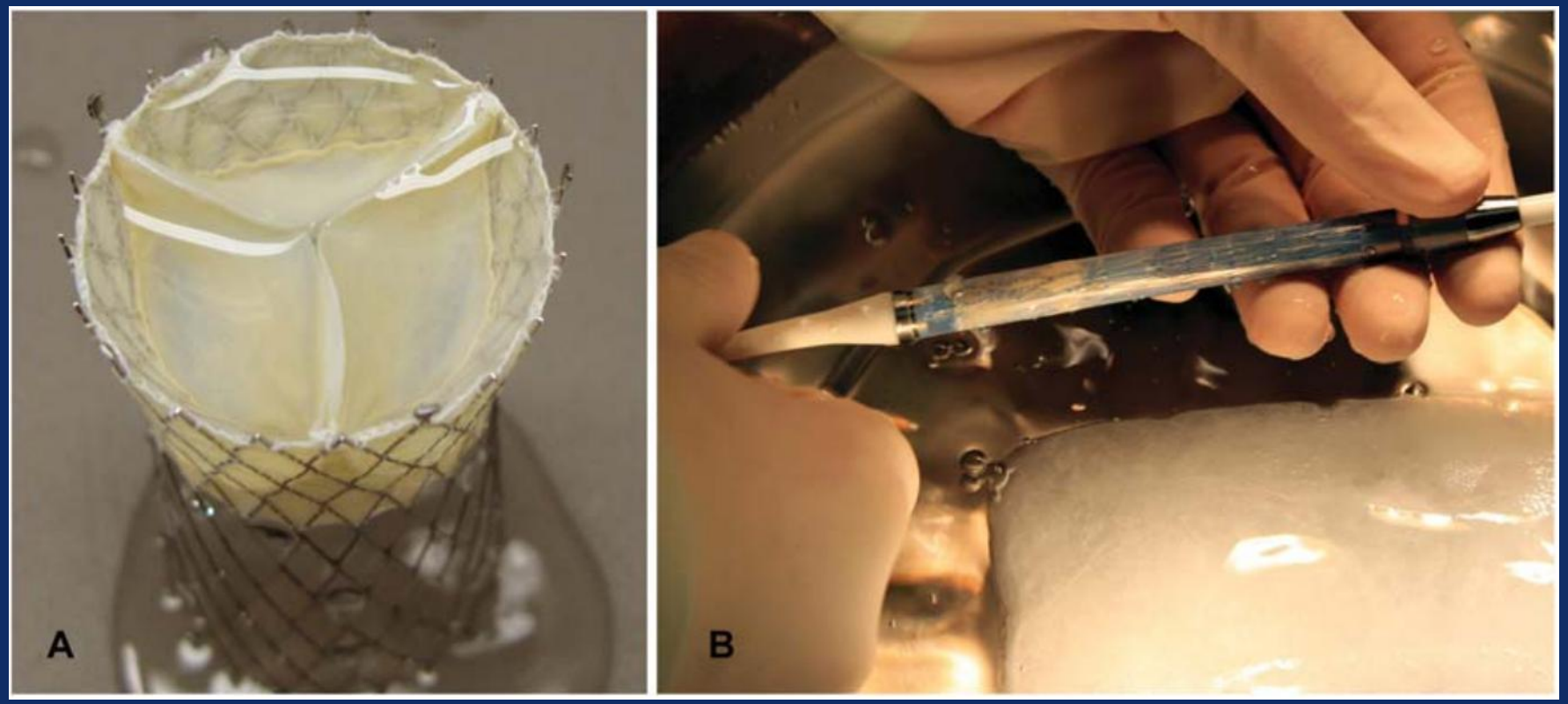




A. Lauten et al. EHJ. 2011;32:1207-1213

Interventional Valve Implantion in Caval position (CAVI) for Severe TR

First-in-Human application



A. Lauten et al. EHJ. 2011;32:1207-1213

Novel Vertical Spacer for Tricuspid Regurgitation

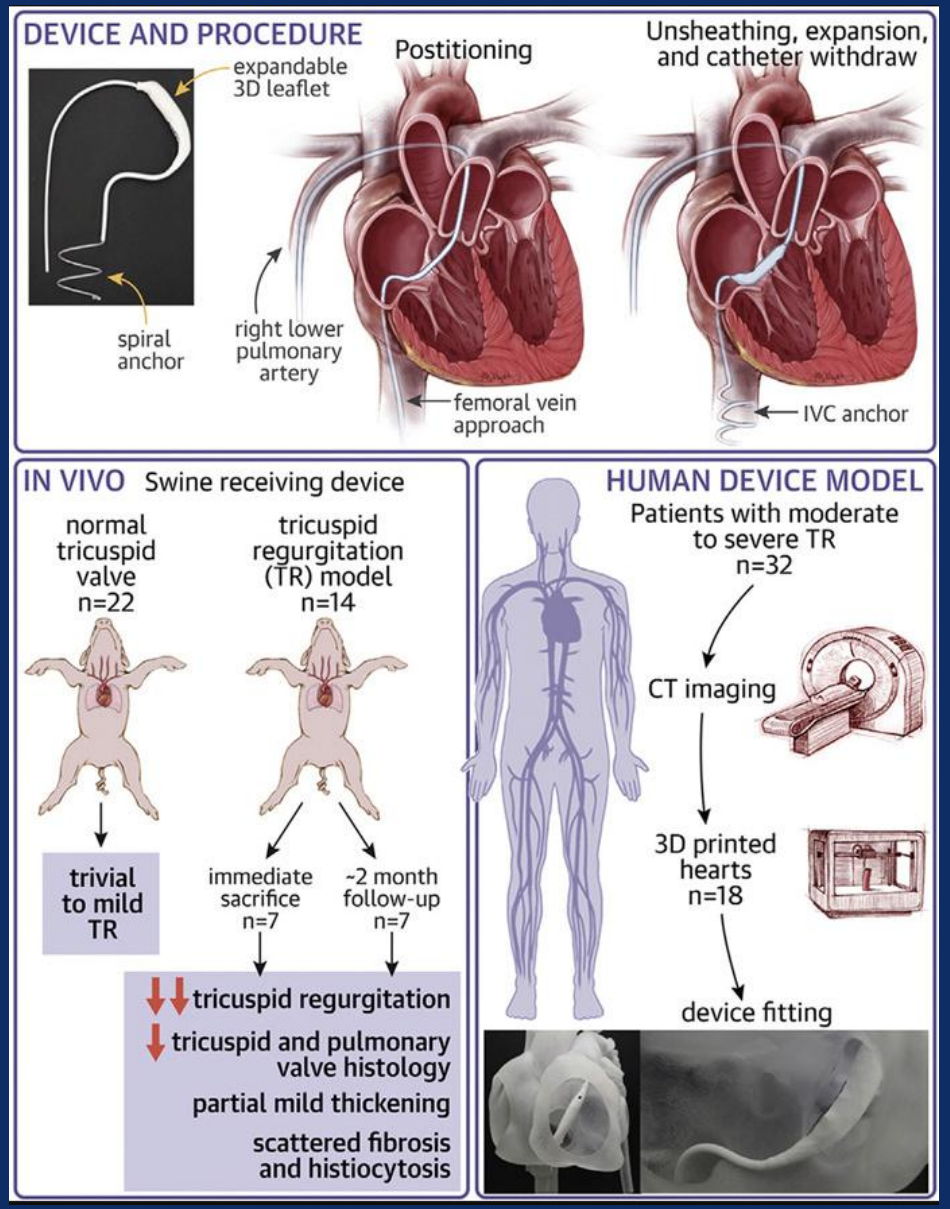
Novel vertical spacer for TR

ORIGINAL RESEARCH - PRECLINICAL

A Novel Device for Tricuspid Regurgitation Reduction Featuring 3-Dimensional Leaflet and Atraumatic Anchor

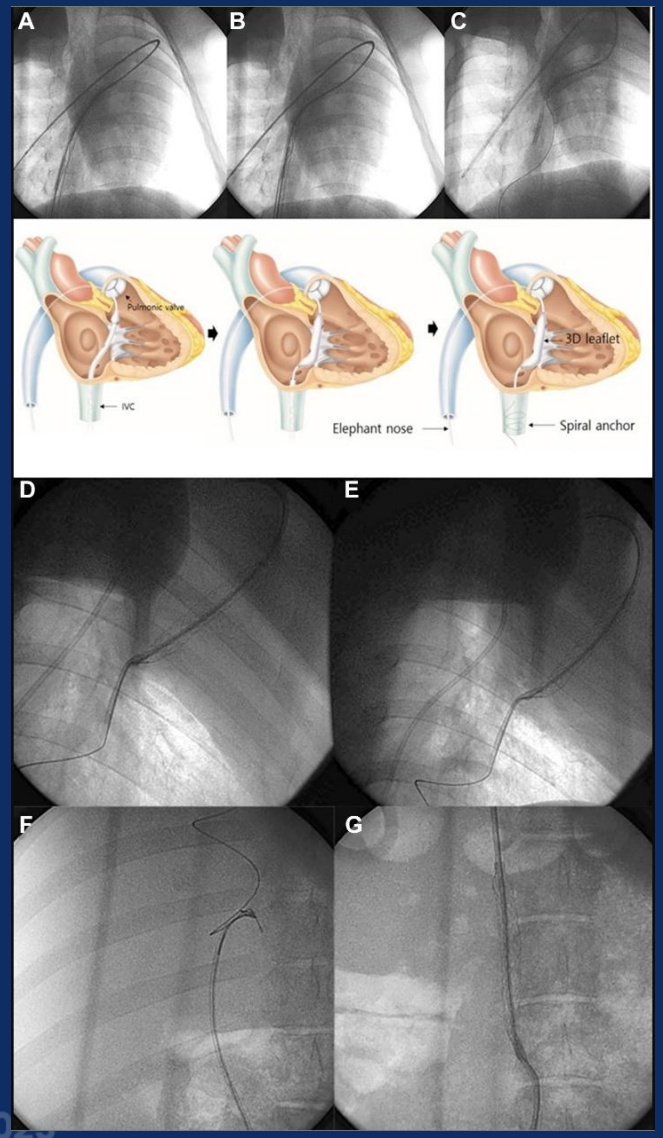
Pivot-TR System

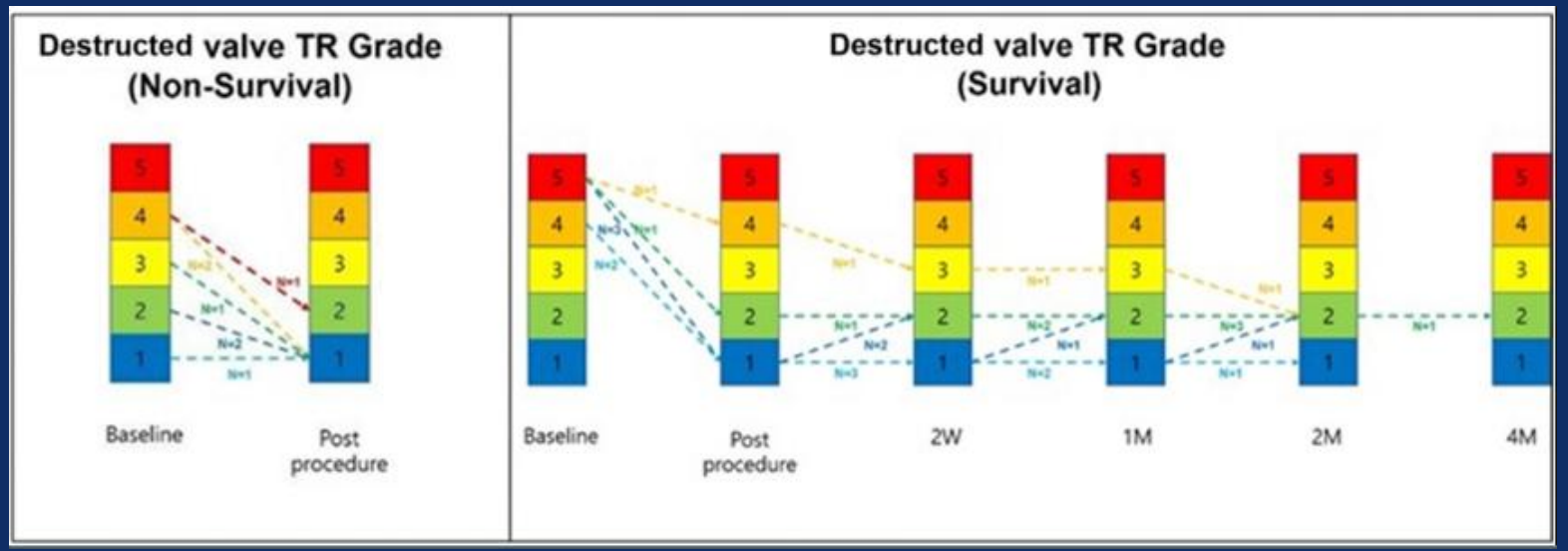
Min-Ku Chon, MD,[a] Seung-Whan Lee, MD,[b] Joo-Yong Hahn, MD,[c] Yong-Hyun Park, MD,[a] Hyun-Sook Kim, MD,[d] Sang-Hyun Lee, MD,[a] Dong-Hoon Shin, MD,[e] Pil Hyung Lee, MD,[b] Eun Kyoung Kim, MD,[c] Jae-Hwan Lee, MD,[f] Jae-Hyeong Park, MD,[g] Young Jin Choi, MD,[h] Markus Reinthaler, MD,[i] Fabian Barbieri, MD,[i] Jai-Wun Park, MD,[j] Junhui Park, PhD,[j] June-Hong Kim, MD[a]



Chon. et al. JACC Basic to Translational Science. 2022;7(12):1249-1261

Novel vertical spacer for TR





Chon. et al. JACC Basic to Translational Science. 2022;7(12):1249-1261

Thank you for your attention!