

Tricuspid Intervention

Treatment options of intervention

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

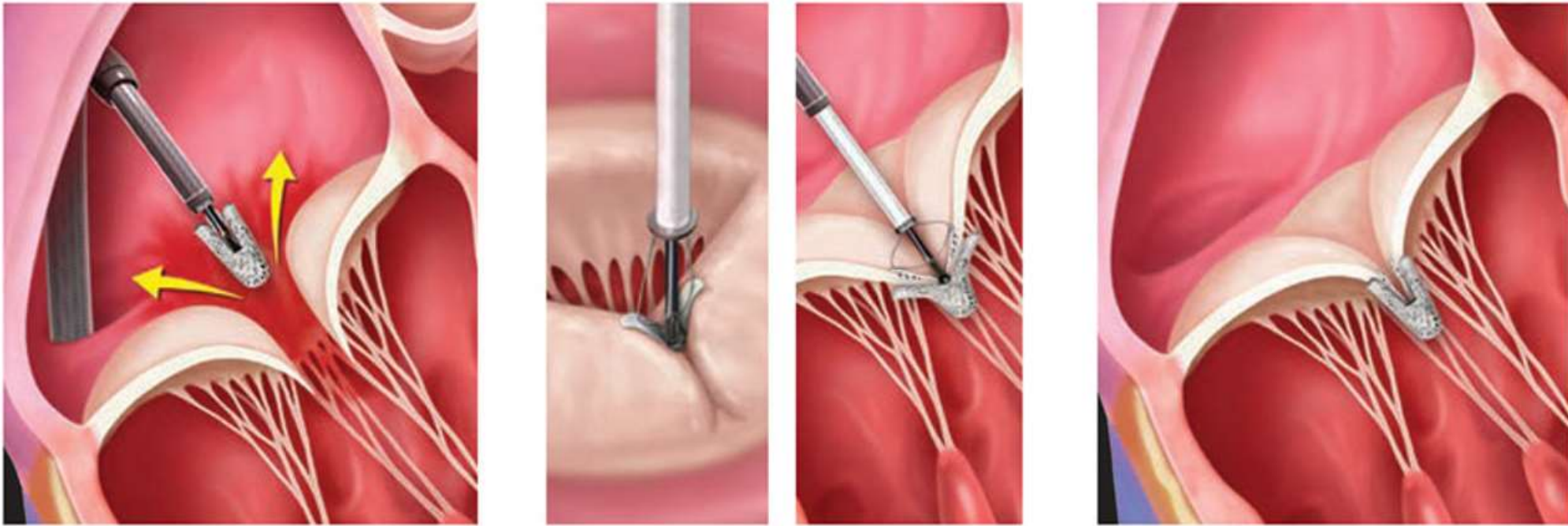
2020 AHA/ACC Guideline Indication of Tricuspid intervention

- **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



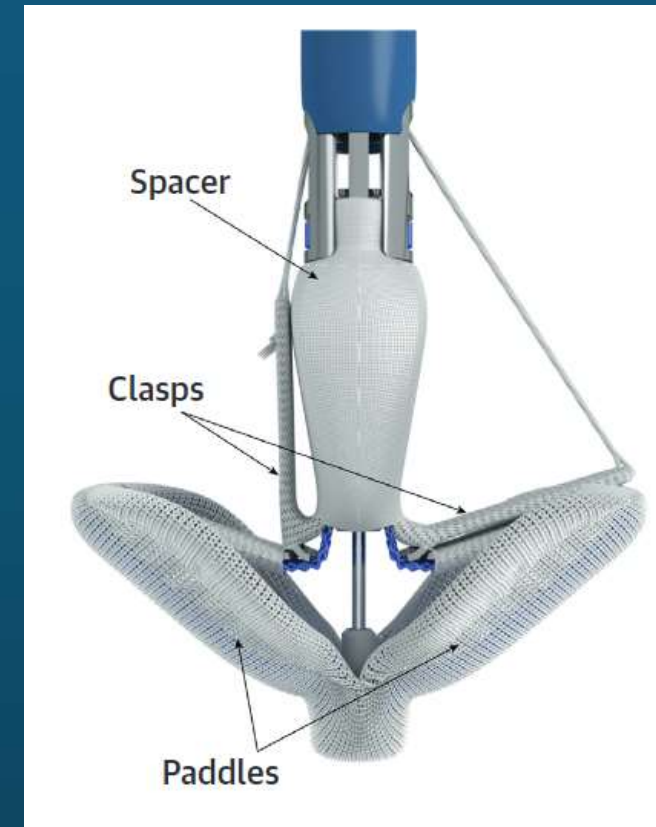
Repairing a tricuspid valve through a TriClip procedure (Image courtesy of [Abbott](#))

Current Devices of TEER

TriClip (Abbott)



PASCAL (Edwards)



Status of Coaptation Device

2016

2018

2019

2020

2021

2023



First in man
of MitraClip
for TR

CE Mark of
Cardioband

First in man
of PASCAL
for TR

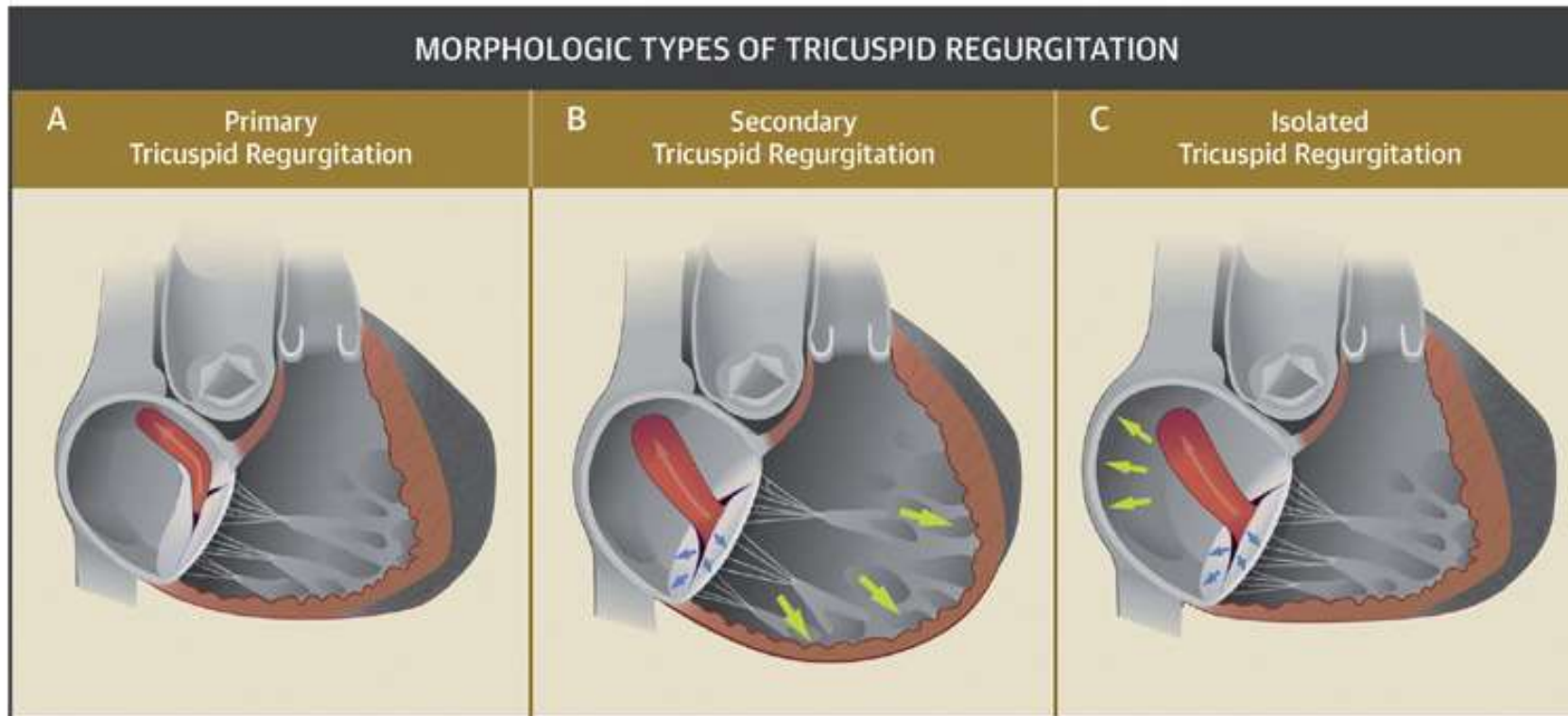
CE Mark of
TriClip, PASCAL

FDA approval of
TriClip

First RCT
of TEER with
medical therapy

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)

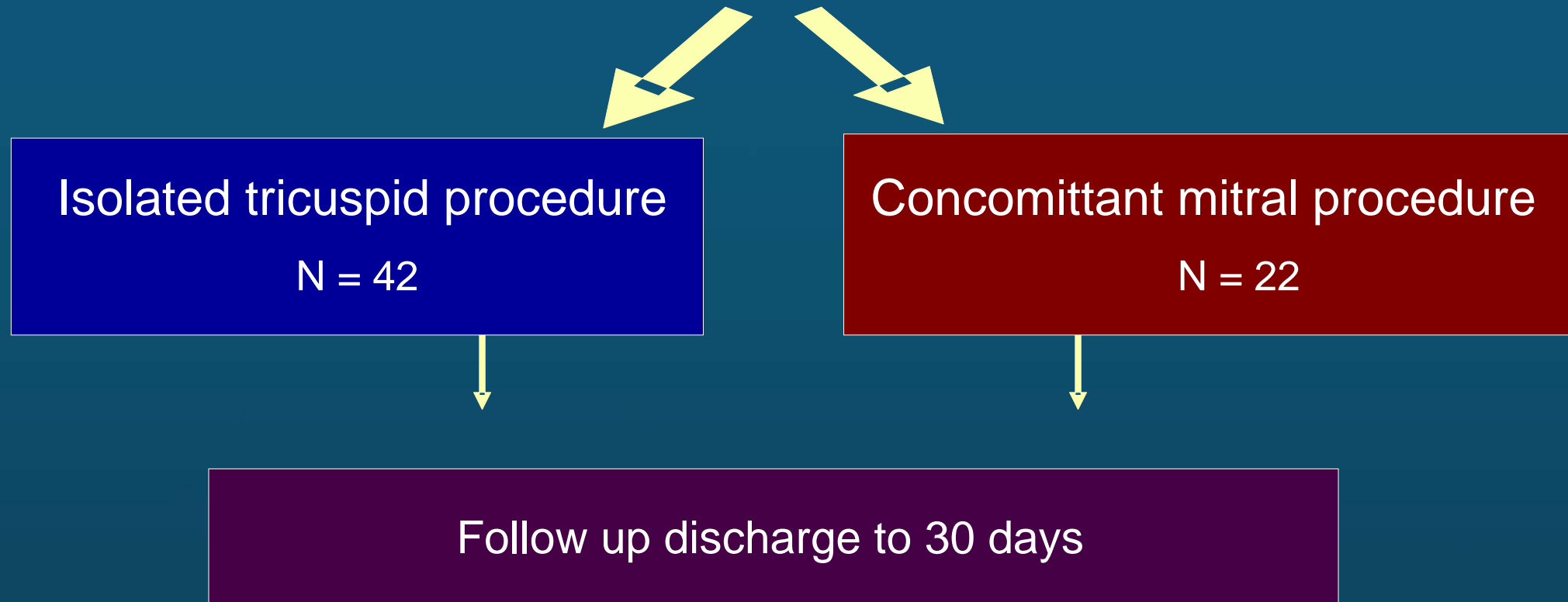
Mitraclip for Severe TR

64 patients enrolled at 10 sites

Severe TR (3+ or 4+)

Exclusion:

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



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%)

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

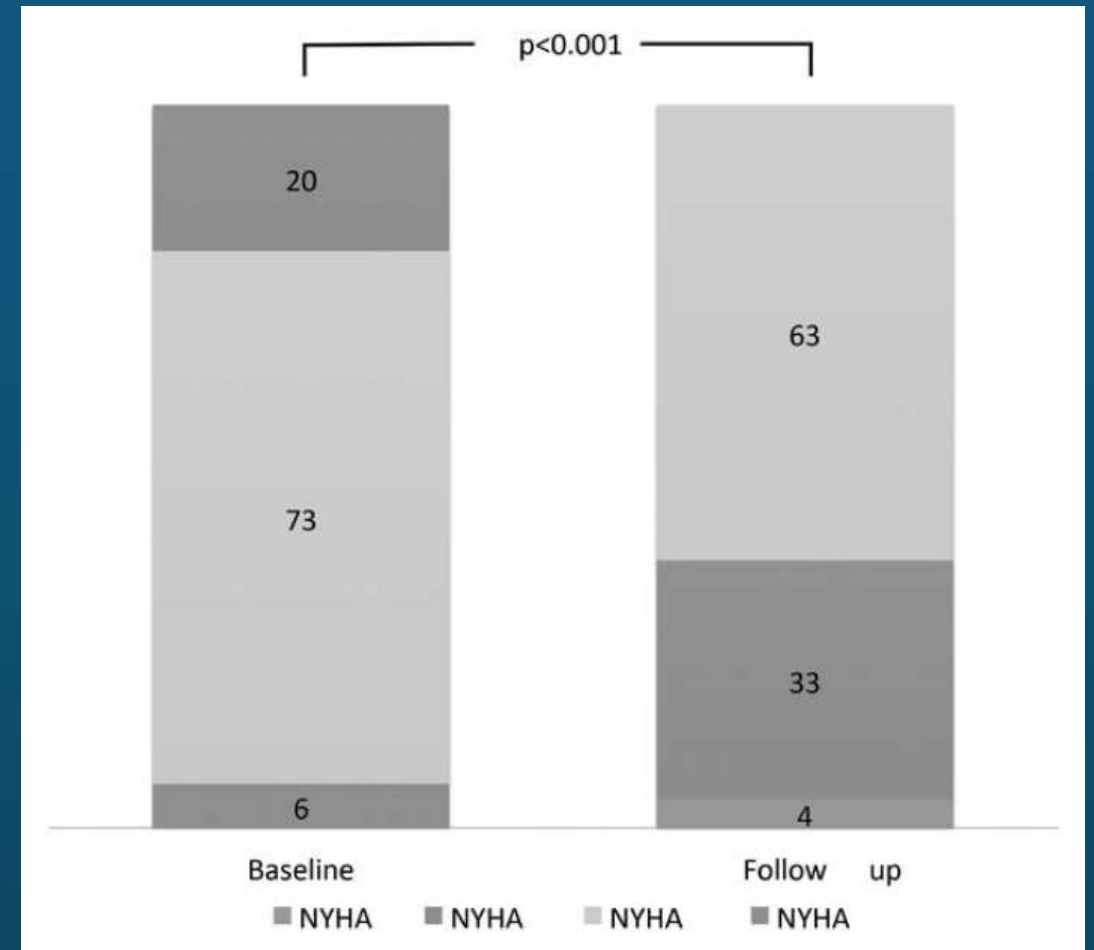
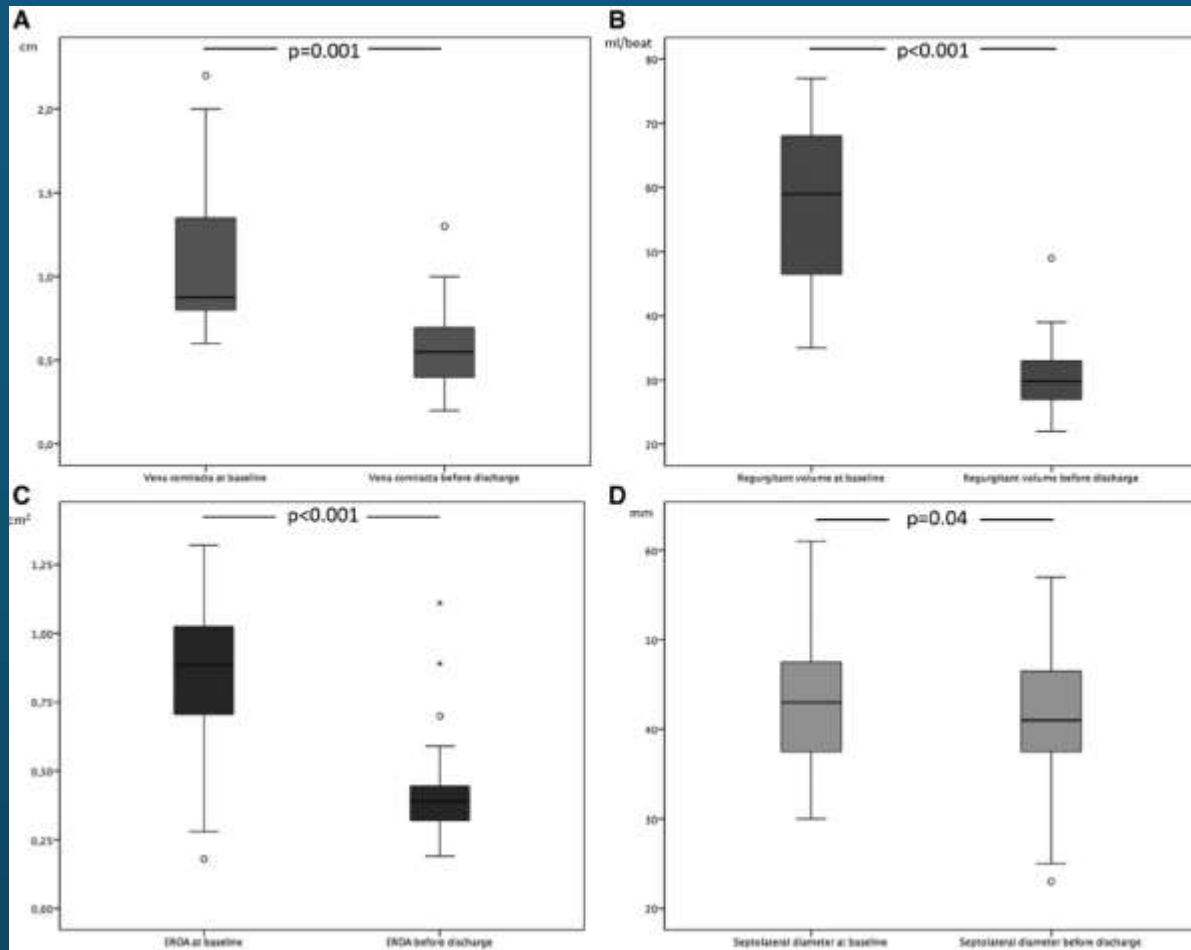
MitraClip for Severe TR

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

MitraClip for Severe TR

64 patients, Single arm study



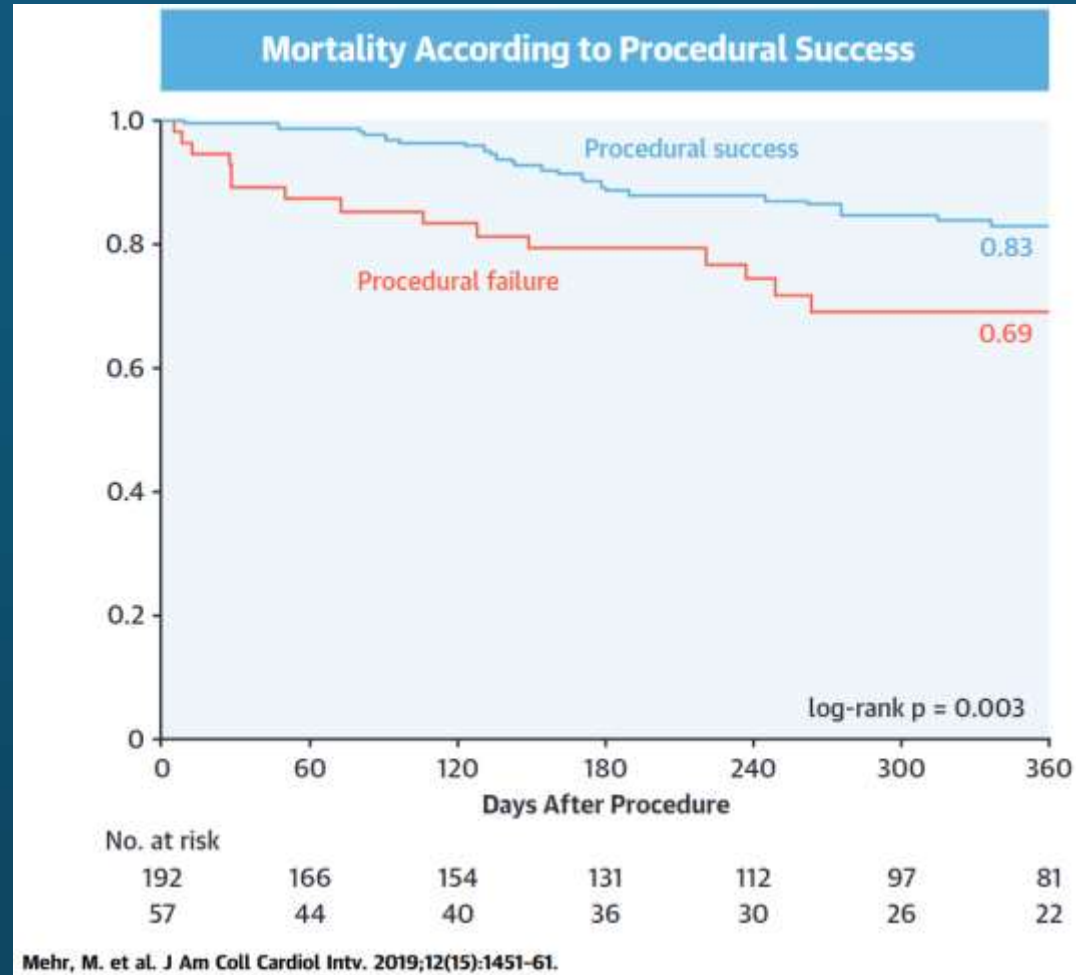
Univariate and Multivariate analysis of procedural failure TriValve Registry

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		

1-Year Outcomes after TEER with MitraClip TriValve Registry

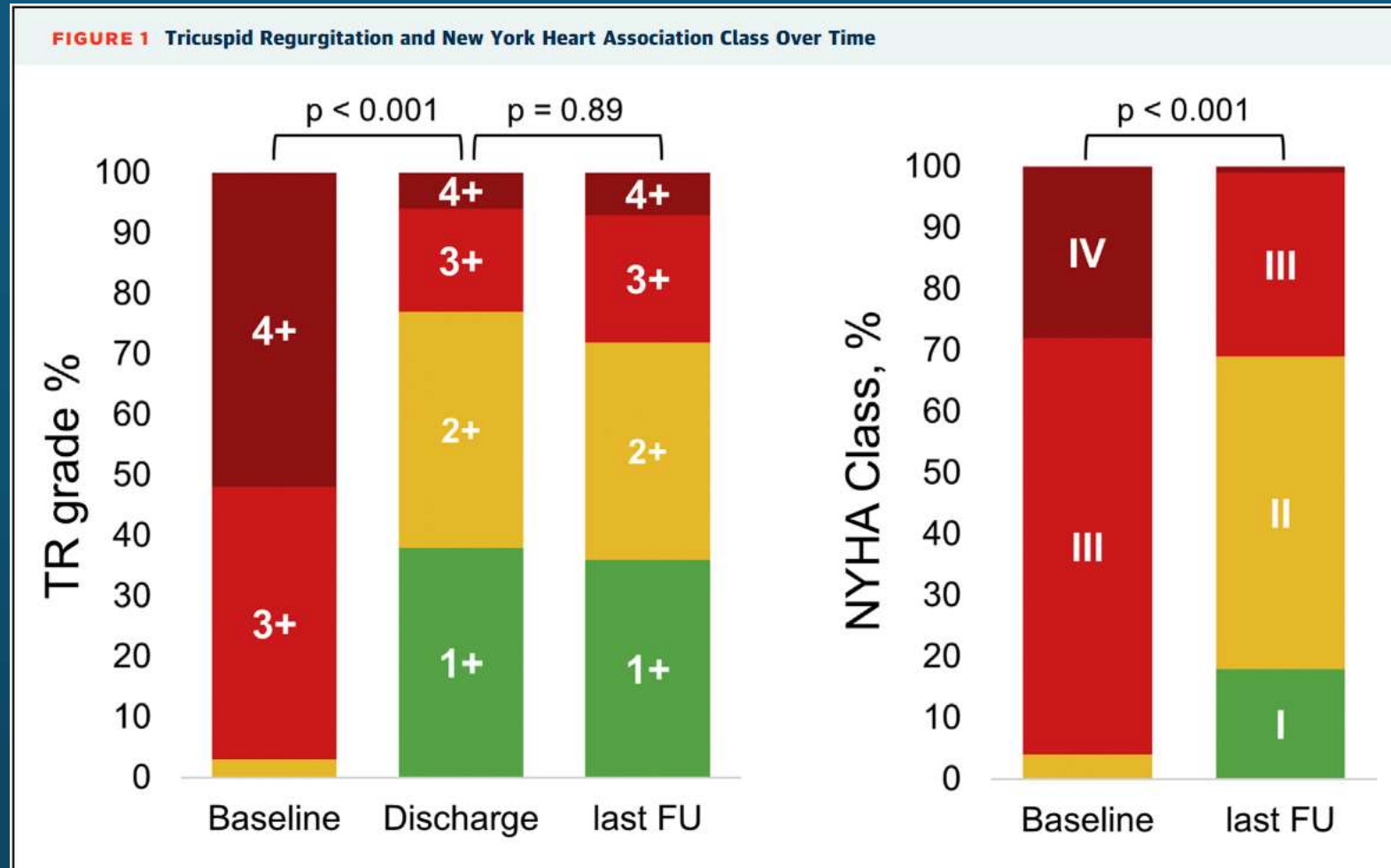
249 patients, from 14 centers in Europe and North America



1-Year Outcomes after TEER with MitraClip

TriValve Registry

249 patients, from 14 centers in Europe and North America



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 \pm 4.3
LVEF, % (n=157/212)	49.6 \pm 14.1
sPAP, mmHg (n=141/212)	39.3 \pm 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)

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

TriClip for Severe TR

1-year outcomes of the TRILUMINATE study

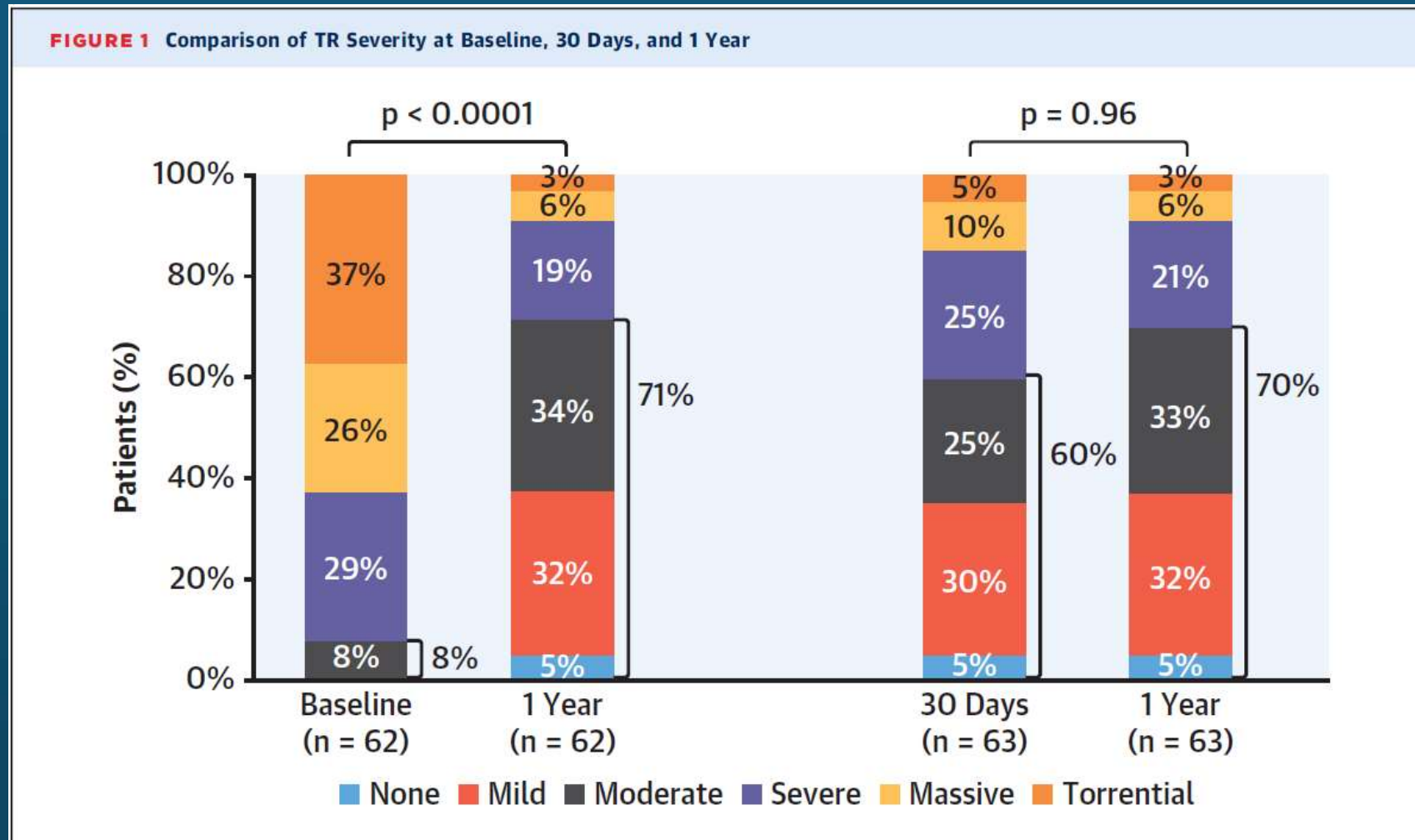
84 patients, Single arm study

Variables	Baseline (n=85)	30 Days (n=83)	Result	1 Year (n=70)	
				P value (base vs 1 year)	P value (30 days vs 1 year)
EROA, cm ² (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, cm ² (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

TriClip for Severe TR

1-year outcomes of the TRILUMINATE study

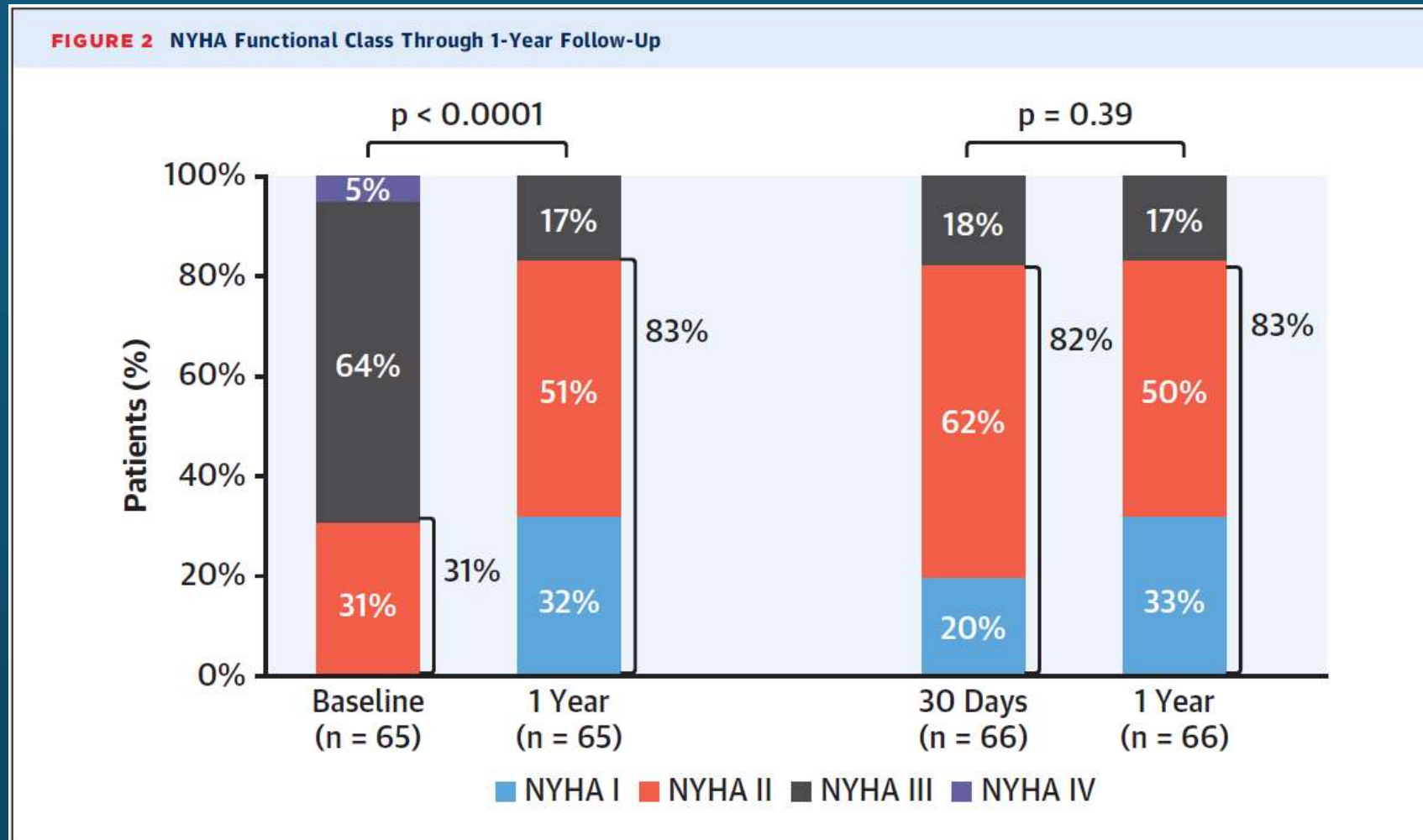
84 patients, Single arm study



TriClip for Severe TR

1-year outcomes of the TRILUMINATE study

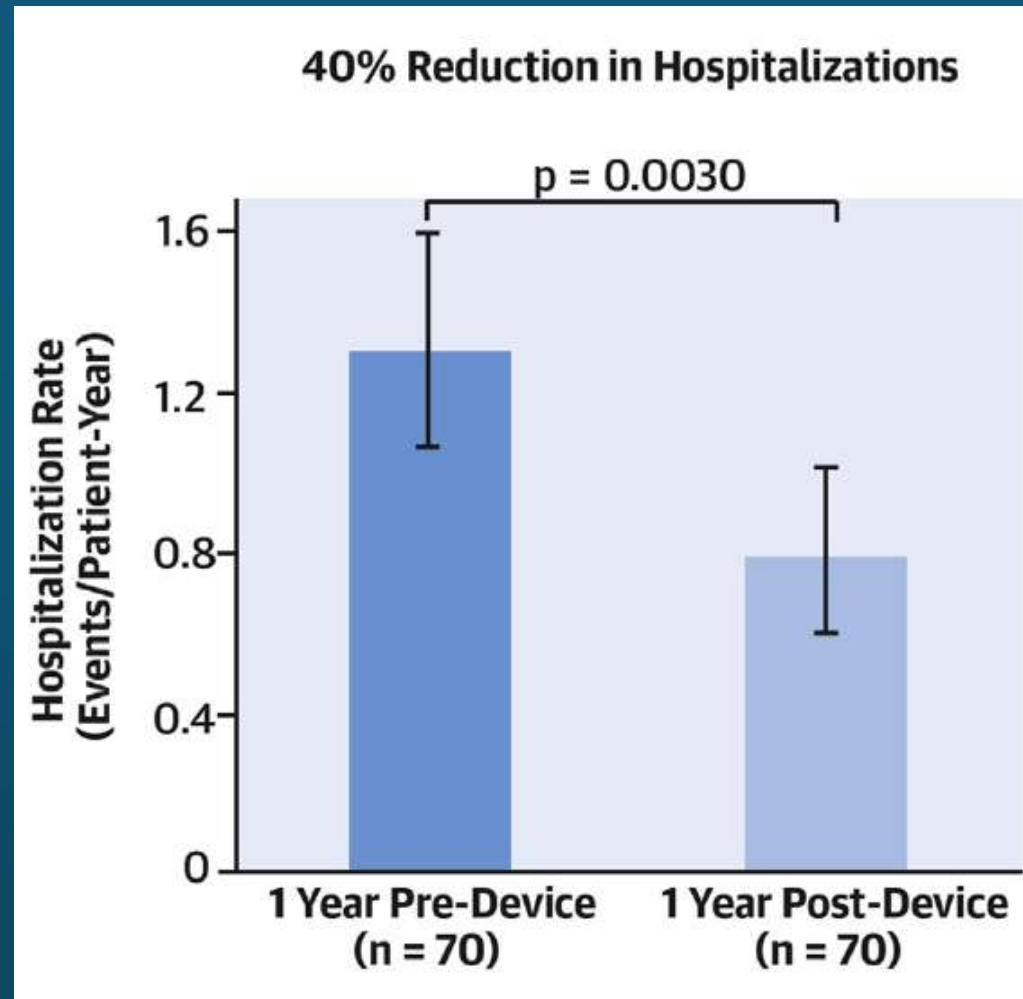
84 patients, Single arm study



TriClip for Severe TR

1-year outcomes of the TRILUMINATE study

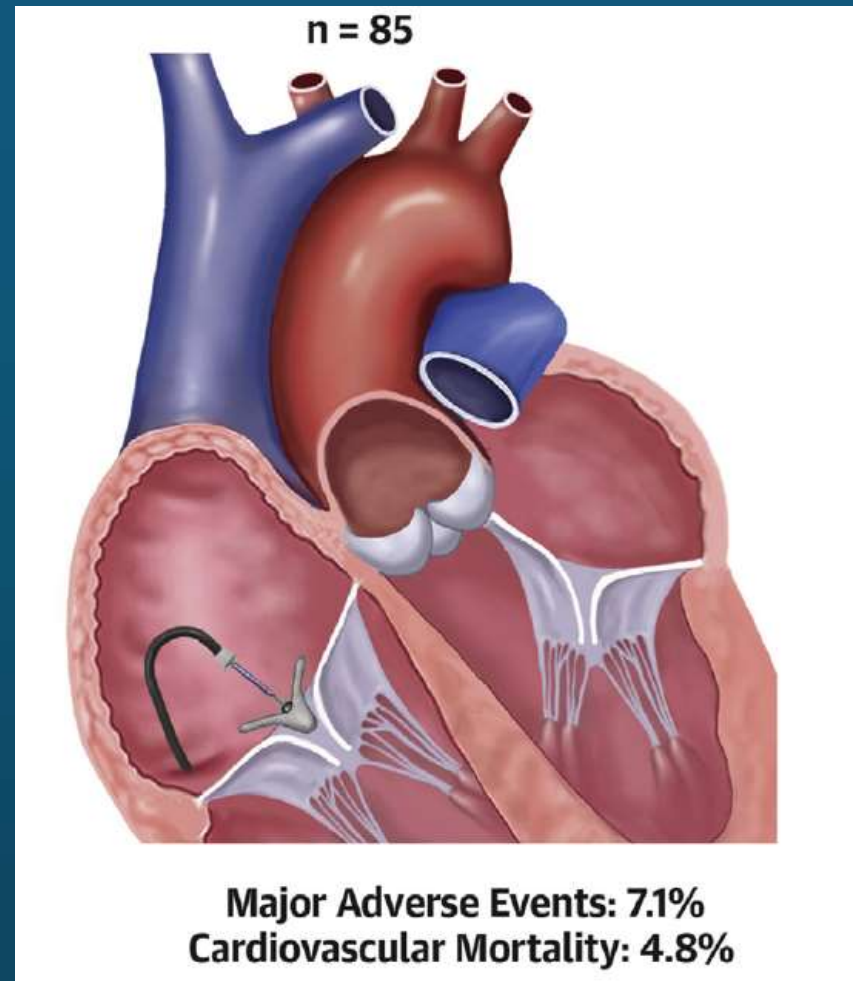
84 patients, Single arm study



TriClip for Severe TR

1-year outcomes of the TRILUMINATE study

84 patients, Single arm study



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 \geq 5 mmHg	4/64 (6.3%)

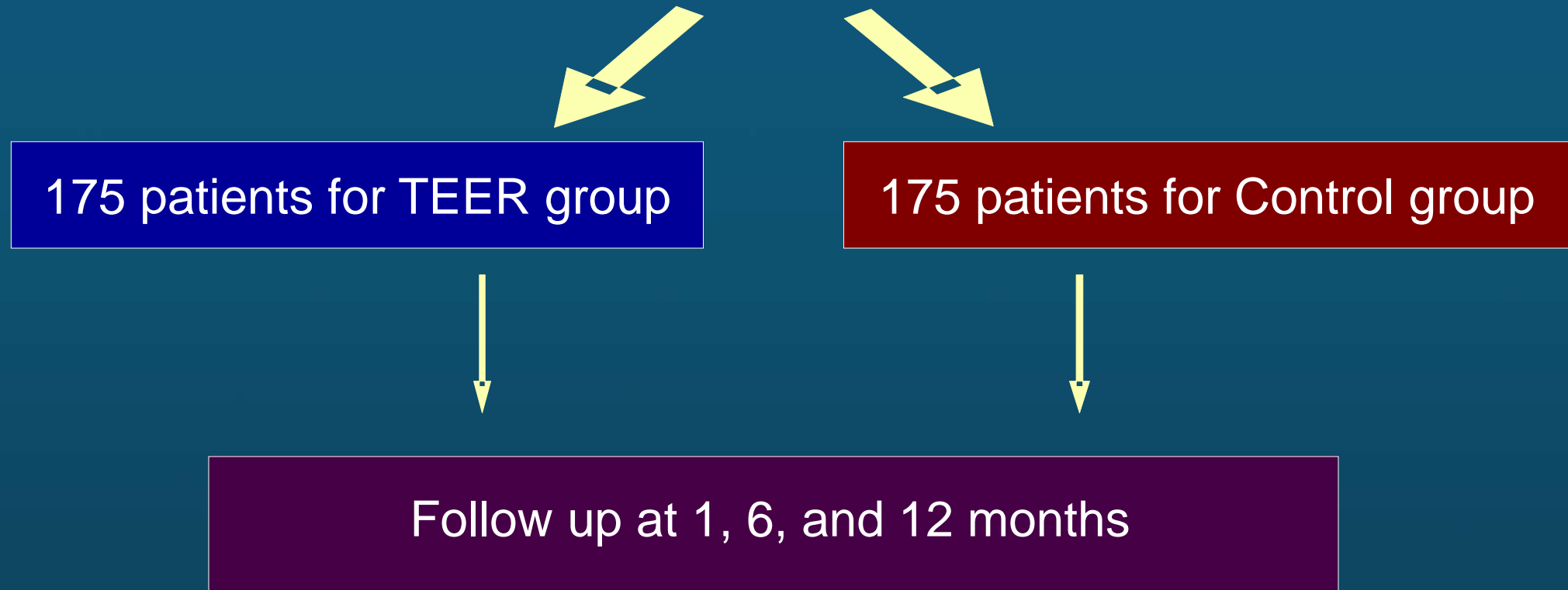
TriClip for Severe TR

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



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

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 \pm 1.8	0.6 \pm 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 \pm 10.5	-25.2 \pm 10.3	17.1 (-12.0 – 46.1)	0.25

TriClip for Severe TR

TRILUMINATE Pivotal trial (TEER vs Medical Therapy)

84 patients, RCT

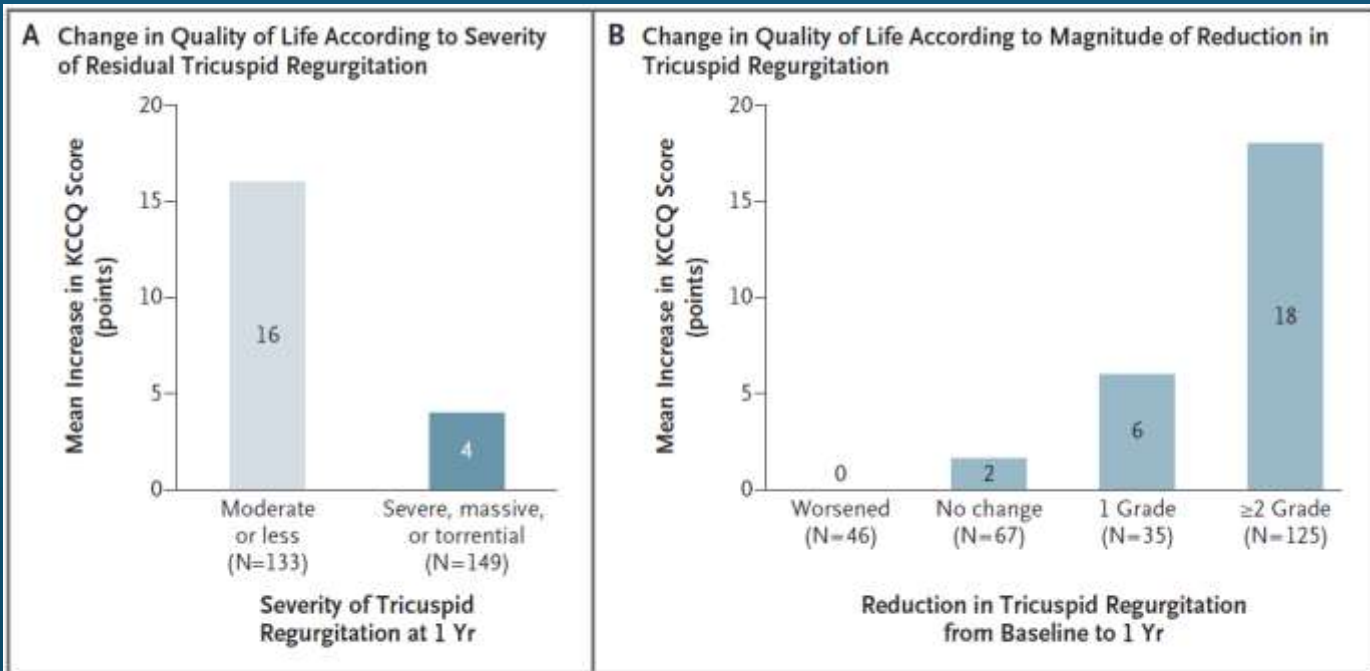


Figure 2. Changes in Quality of Life from Baseline to 1 Year, Stratified According to the Severity of Residual Tricuspid Regurgitation and the Magnitude of the Reduction in Tricuspid Regurgitation.

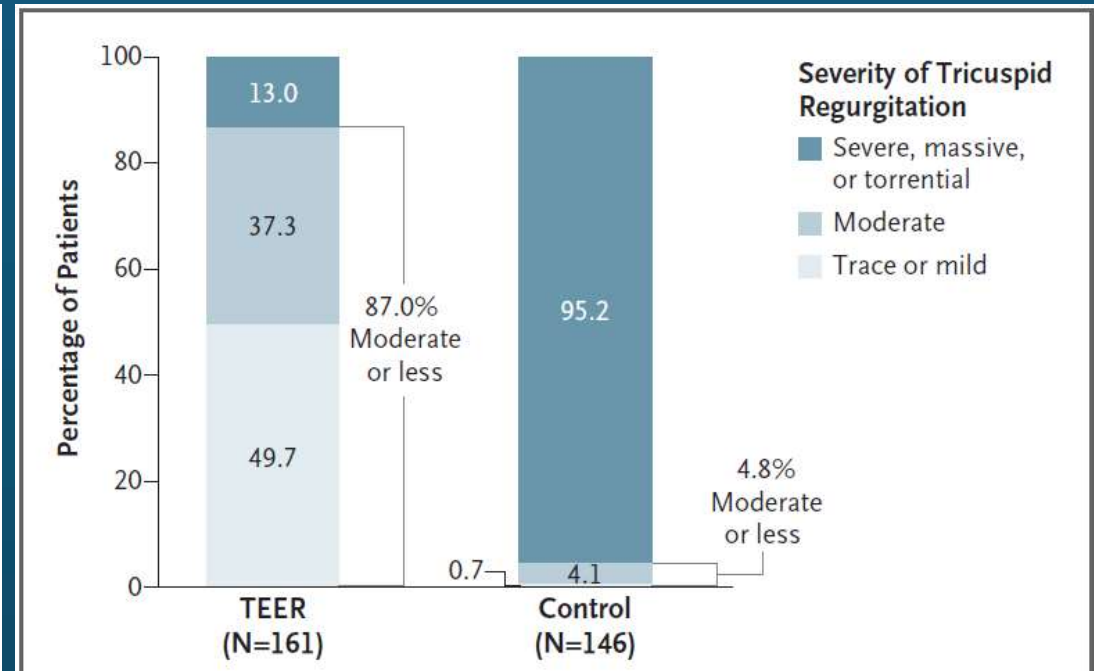


Figure 3. Severity of Tricuspid Regurgitation at 30 Days.

PASCAL

(Edwards Lifesciences)

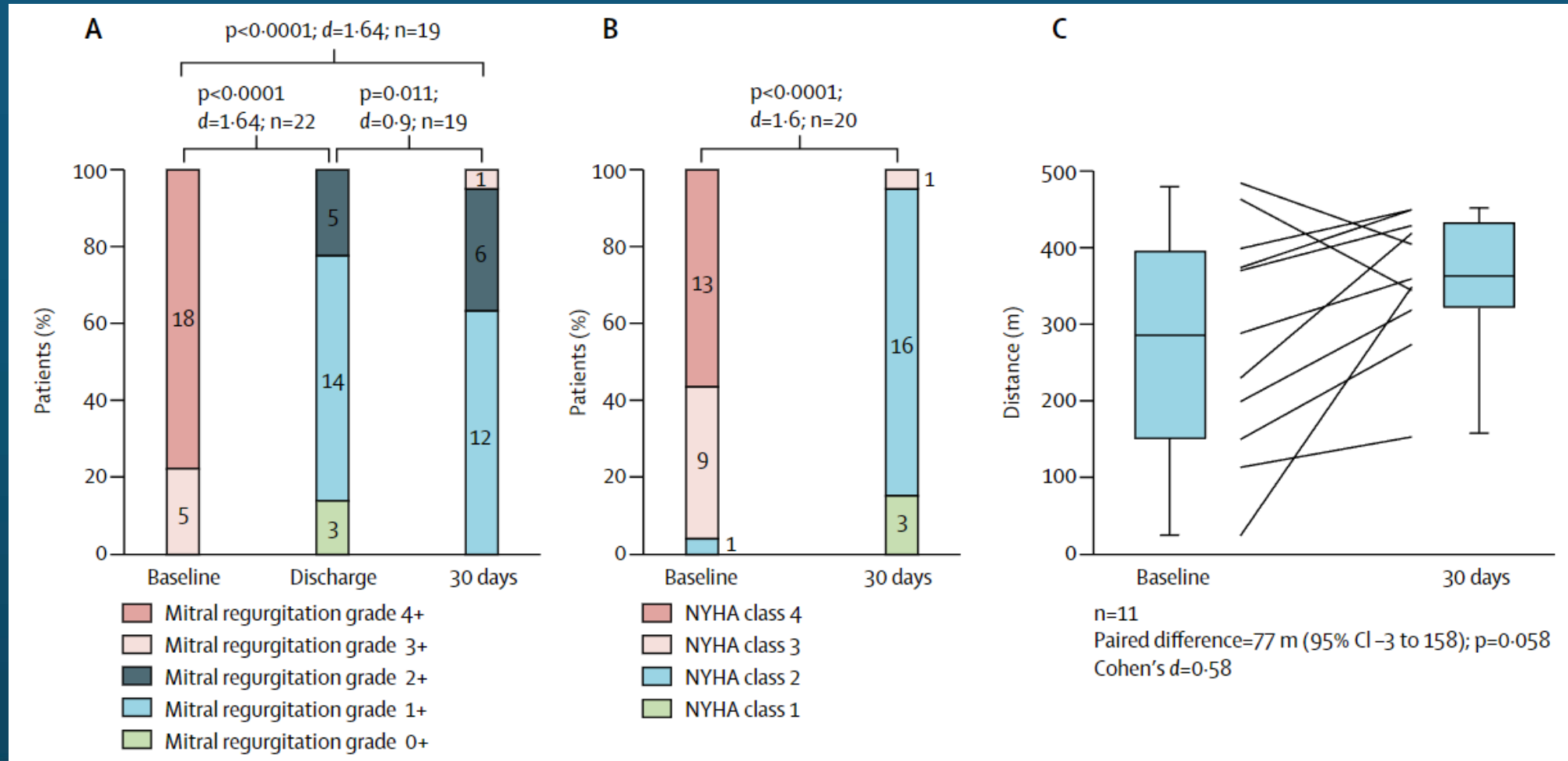
PASCAL for Severe TR

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%)

PASCAL for Severe TR

Multicenter, Prospective, Observational, First-in-Human study
23 patients, 7 Centers from 5 Countries



PASCAL for Severe TR

Multicenter, Observational, First-in-Human experience

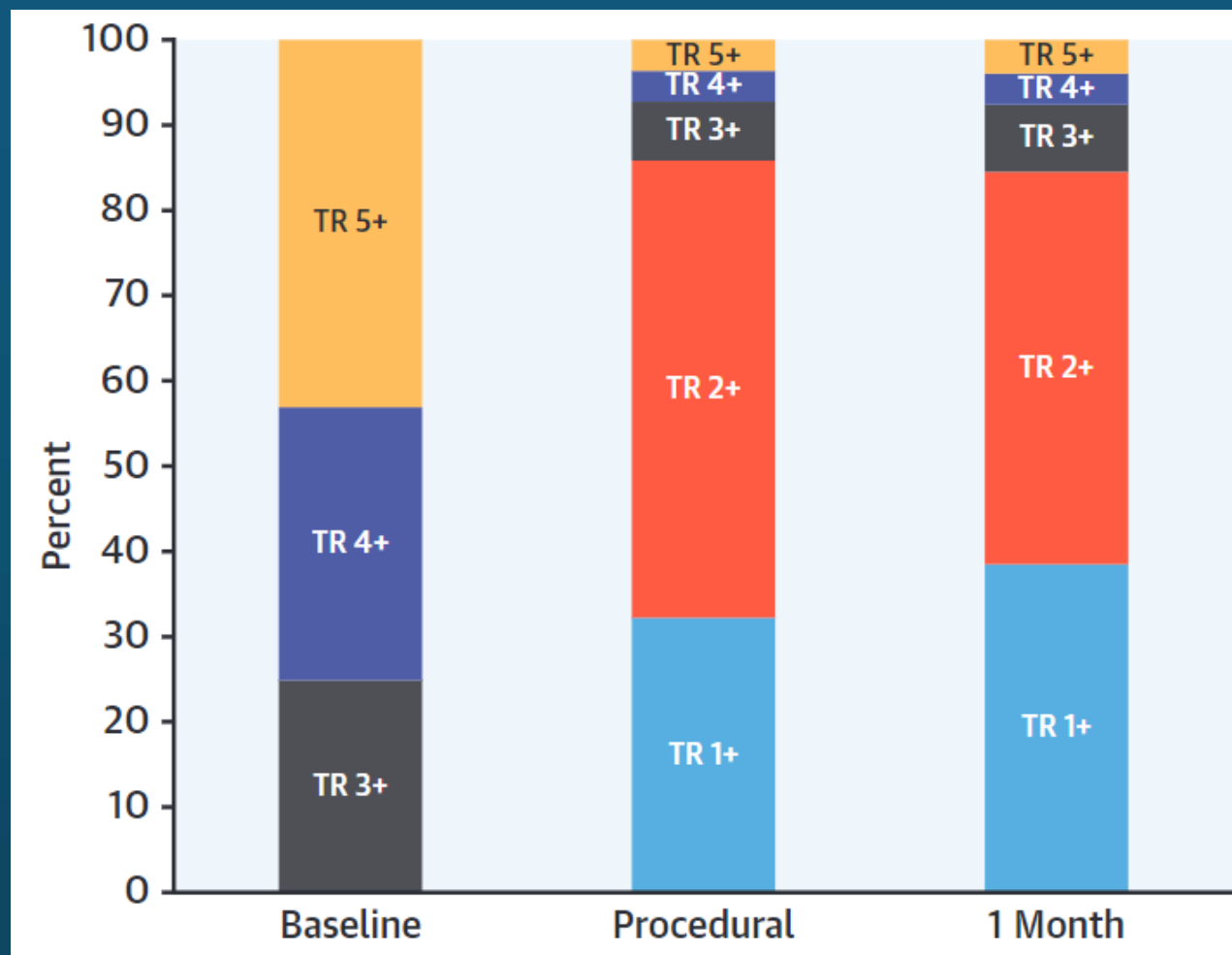
28 patients, Compassionate-use, 6 Centers

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%)

PASCAL for Severe TR

Symptom and TR grade improvement

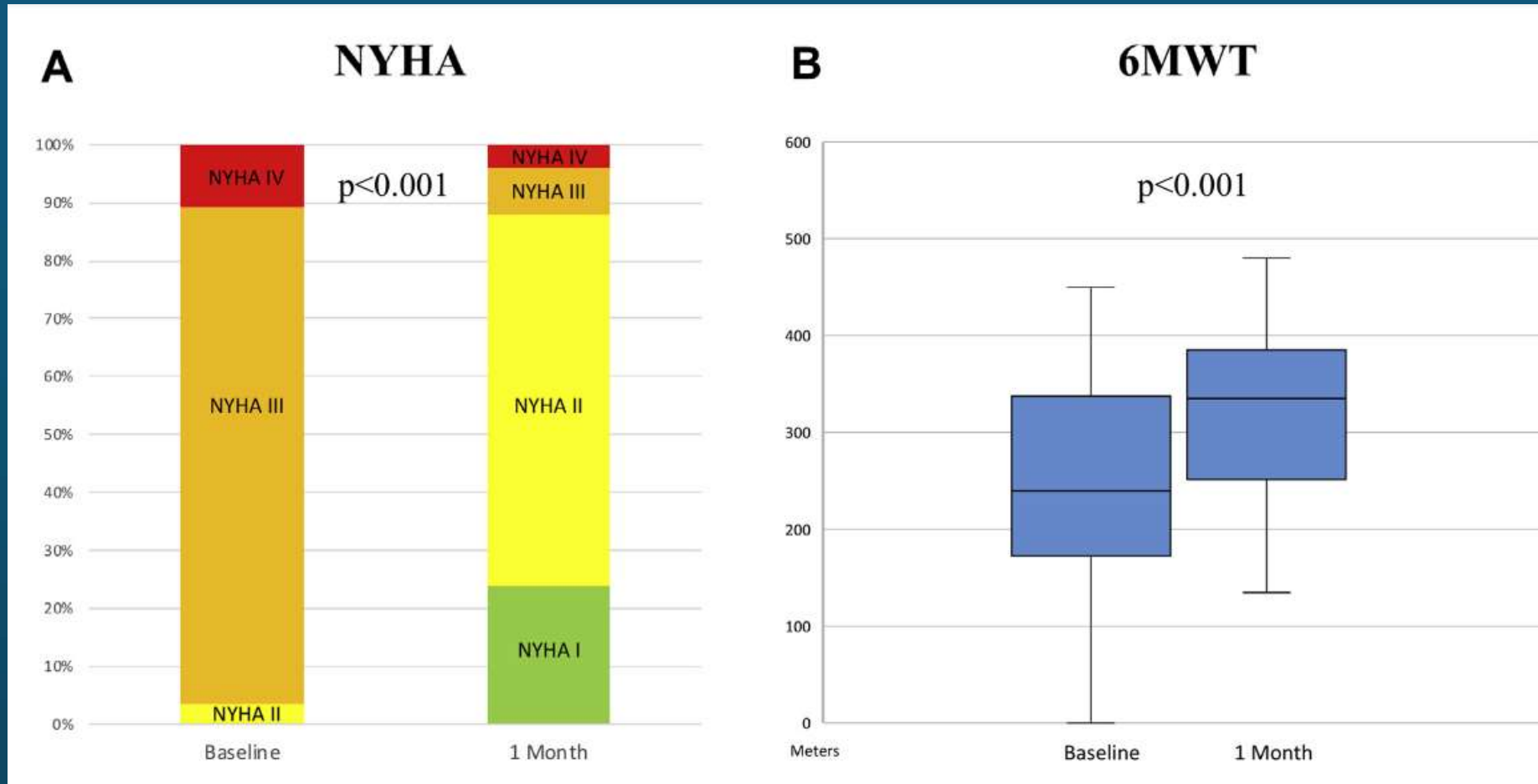
28 patients, Single arm study



PASCAL for Severe TR

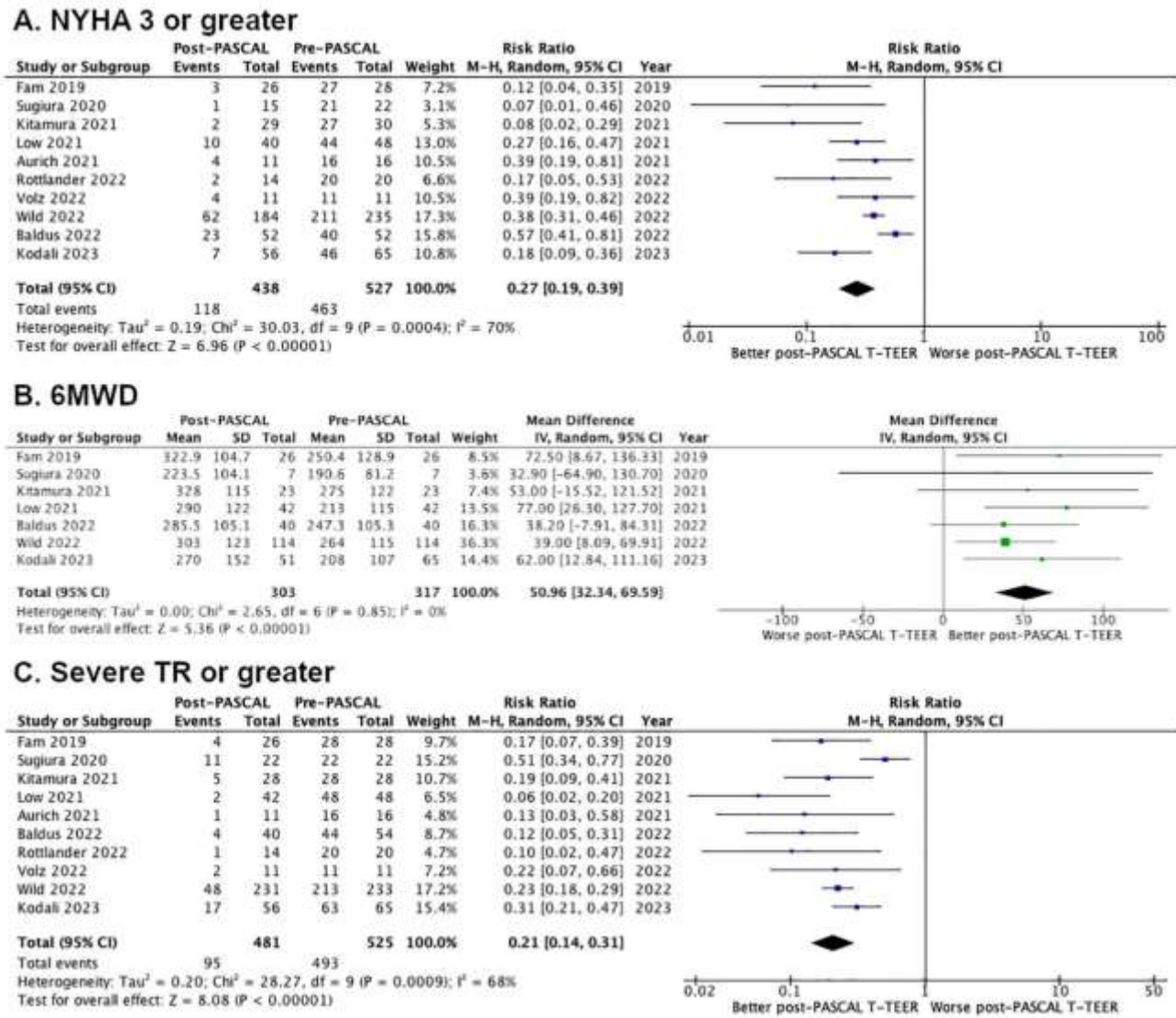
Symptom and TR grade improvement

28 patients, Single arm study



PASCAL for Severe TR

Meta-analysis 10 retrospective studies



1-year outcomes of Transcatheter Tricuspid valve repair

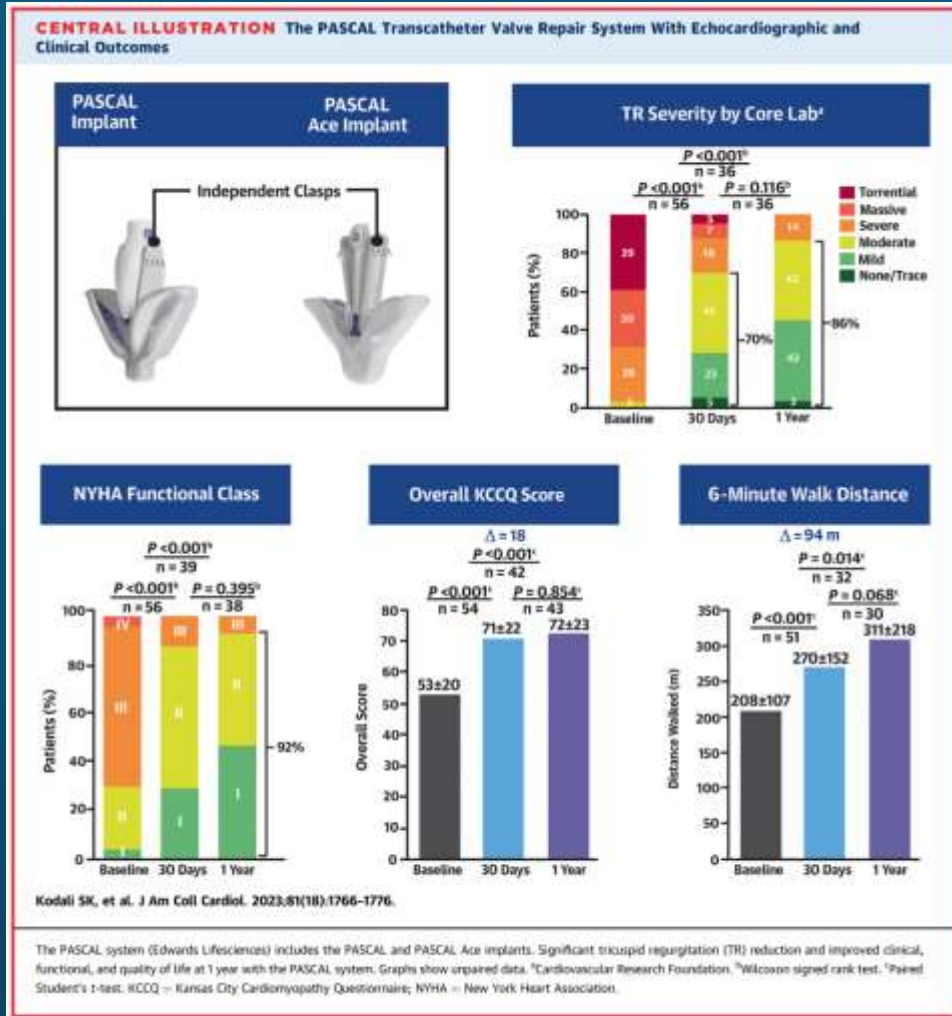


TABLE 3 CEC-Adjudicated and Other Events at 30 Days and 1 Year

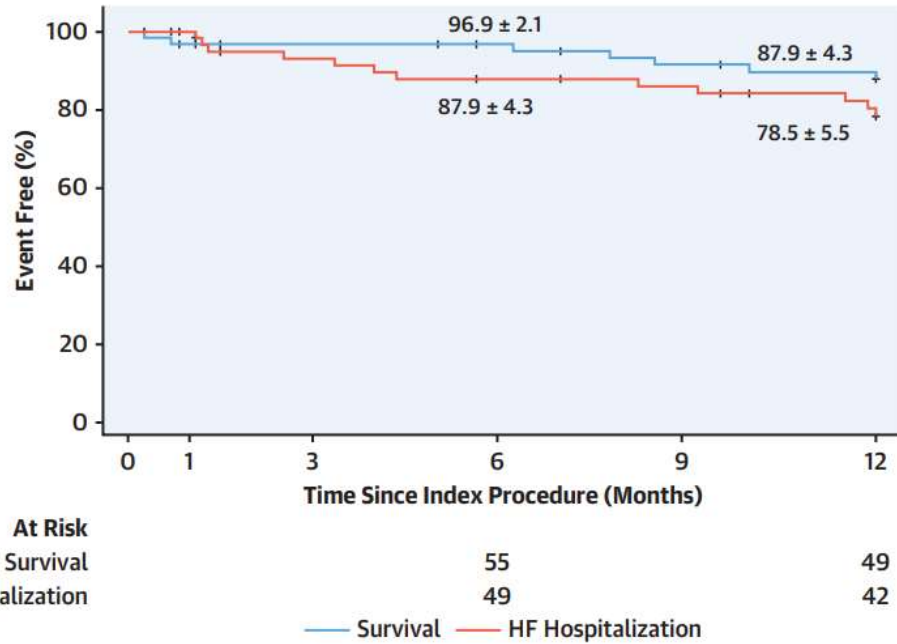
	30 Days (n = 65)	1 Year (n = 65)
CEC-adjudicated MAEs		
Cardiovascular mortality	2 (3.1)	5 (7.7)
Myocardial infarction	0 (0.0)	0 (0.0)
Stroke	1 (1.5)	3 (4.6)
Renal complications requiring unplanned dialysis or renal replacement therapy	0 (0.0)	0 (0.0)
Severe bleeding ^a	5 (7.7)	6 (9.2)
Unplanned or emergency 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 (%). ^aSevere bleeding is defined as major, extensive, life-threatening, or fatal bleeding according to Mitral Valve Academic Research Consortium criteria. ^bCore laboratory: Cardiovascular Research Foundation.

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

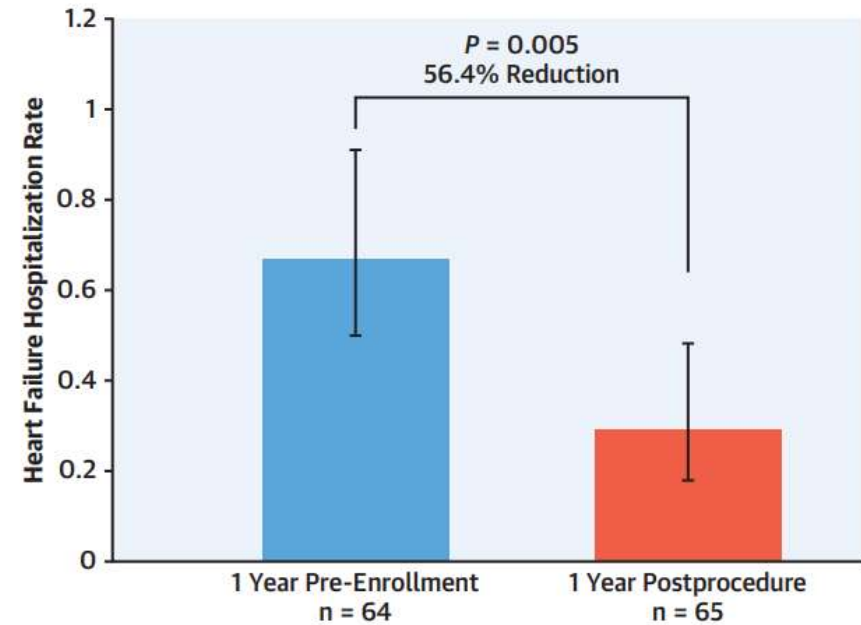
1-year outcomes of Transcatheter Tricuspid valve repair

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.

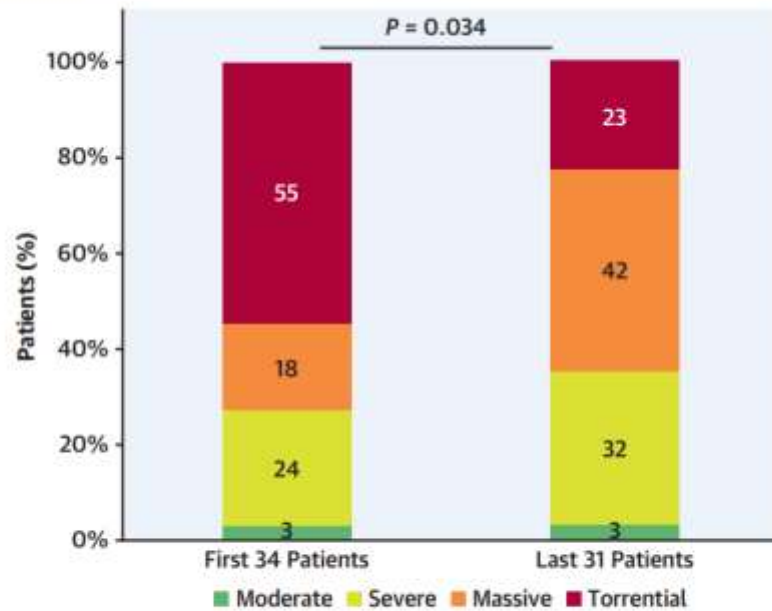
FIGURE 2 Annualized Reduction in Heart Failure Hospitalization Rate



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.

1-year outcomes of Transcatheter Tricuspid valve repair

FIGURE 1 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. ^aP 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.

Evidence of Direct Annuloplasty for Severe TR

Cardioband (Edwards Lifesciences)

FIGURE 1 The Tricuspid Valve Reconstruction System

Cardioband Anchor Deployment



Cardioband Implant Adjustment



(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%)

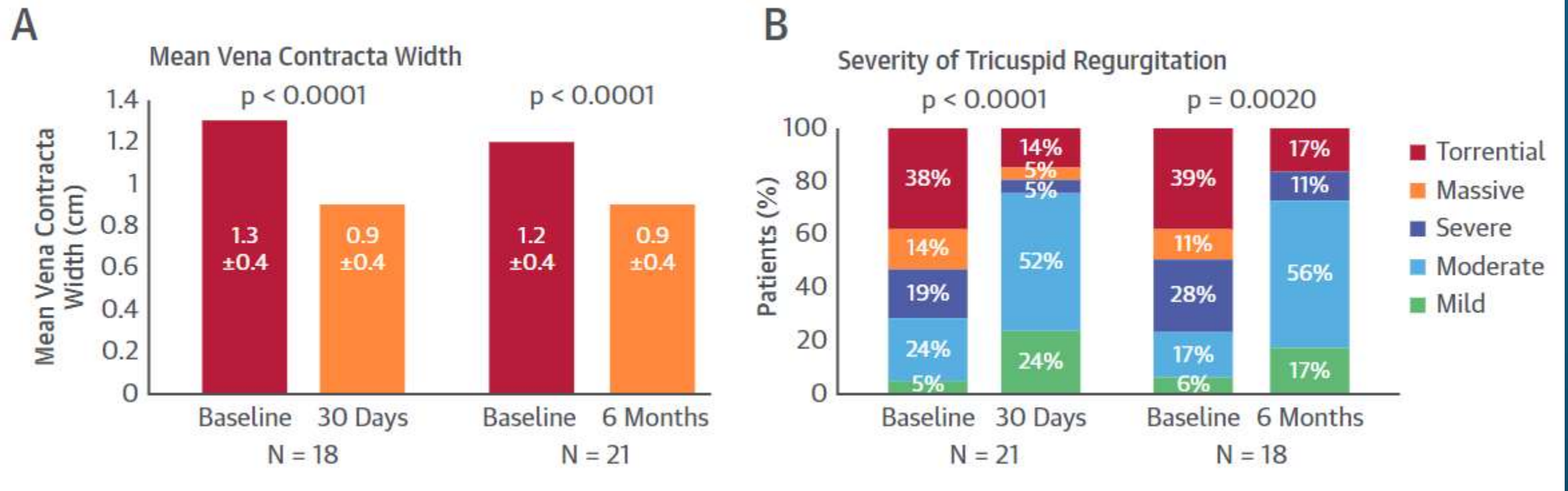
6-Month Outcomes of Cardioband for Severe TR

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

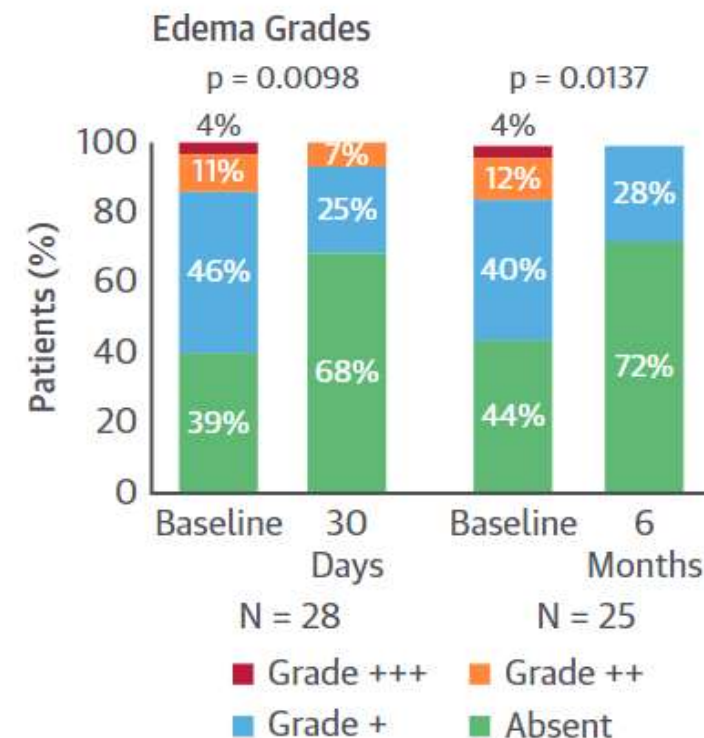
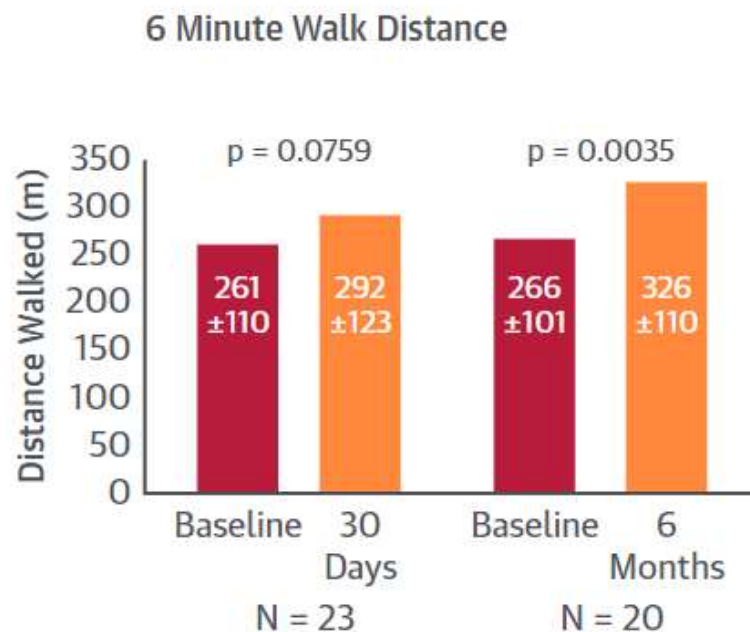
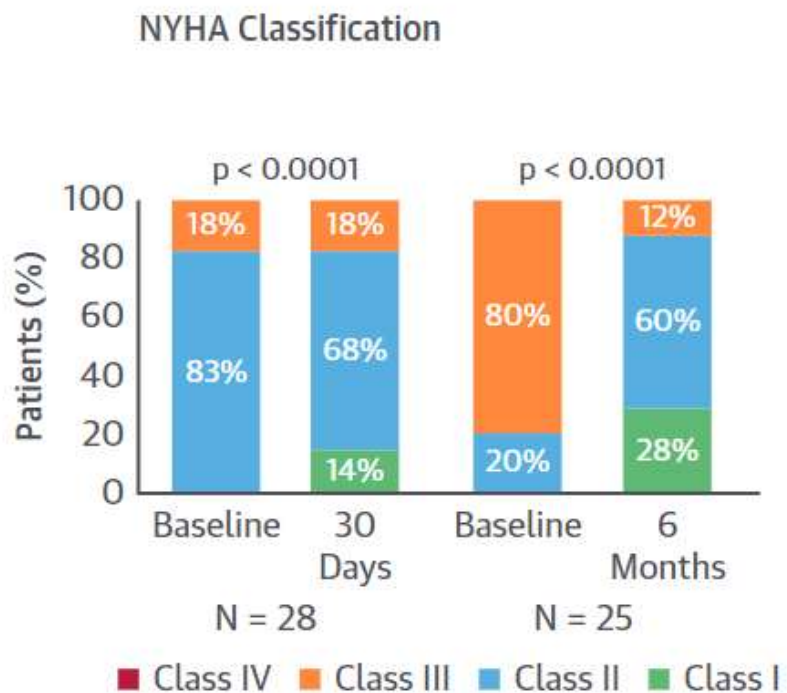
6-Month Outcomes of Cardioband for Severe TR

30 patients, Single arm study, Multicenter, Prospective trial



6-Month Outcomes of Cardioband for Severe TR

30 patients, Single arm study, Multicenter, Prospective trial



Evidence of Catheter-based Valve Replacement for Severe TR

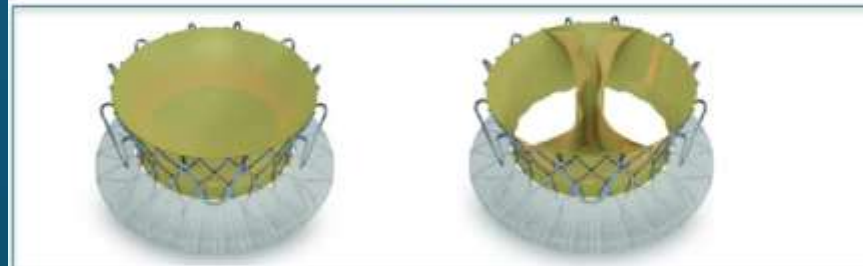
Transcatheter Tricuspid Valve Replacement



NaviGate (NaviGate CSI)



Intrepid (Medtronic)



Trisol Valve (Trisol Medical)



CardioValve (CardioValve)

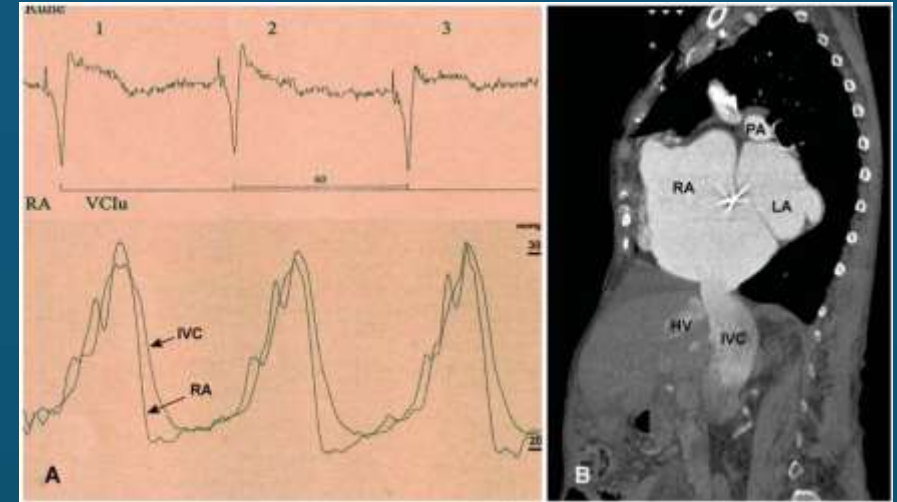


Edwards EVOQUE Tricuspid Valve Replacement System

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

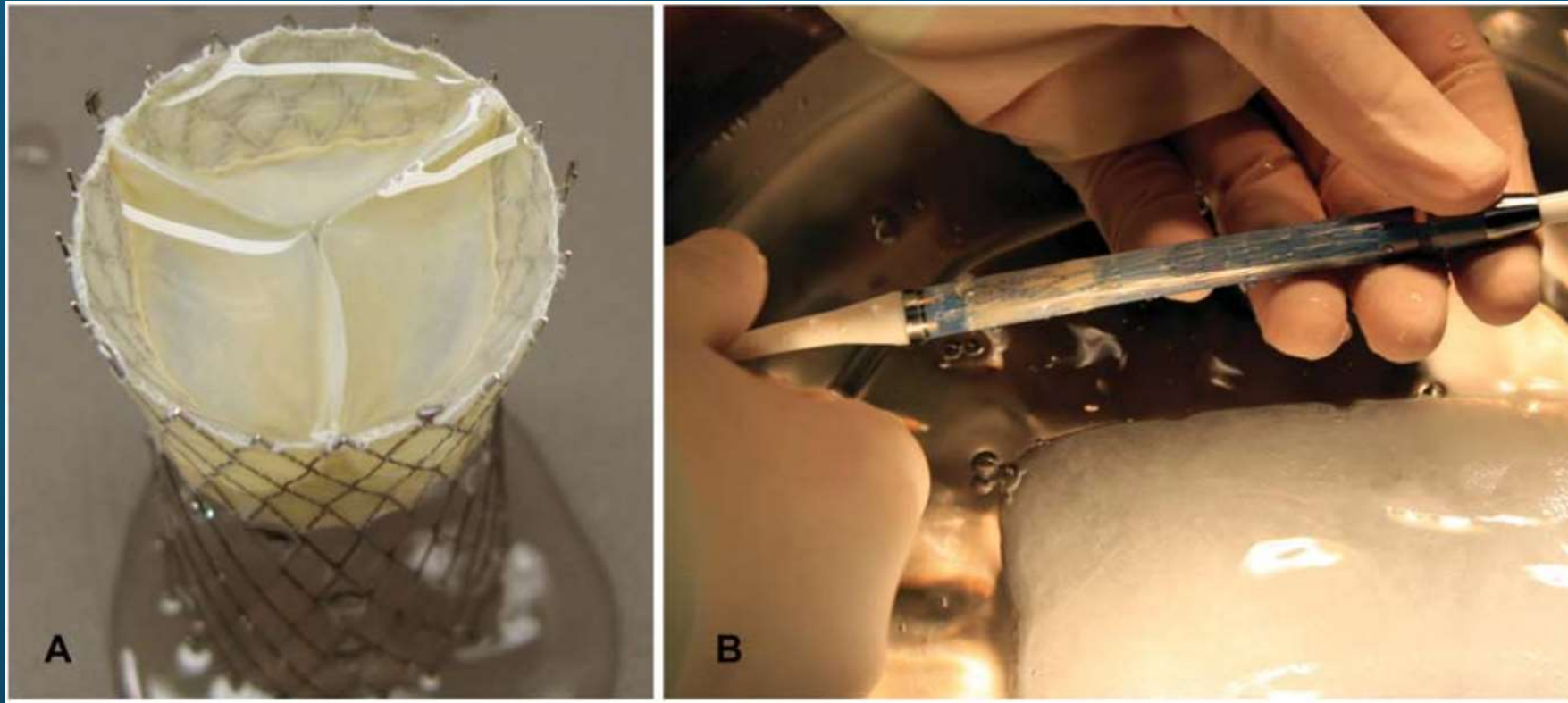
First-in-Human application

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)



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

First-in-Human application



Novel Vertical Spacer for Tricuspid Regurgitation

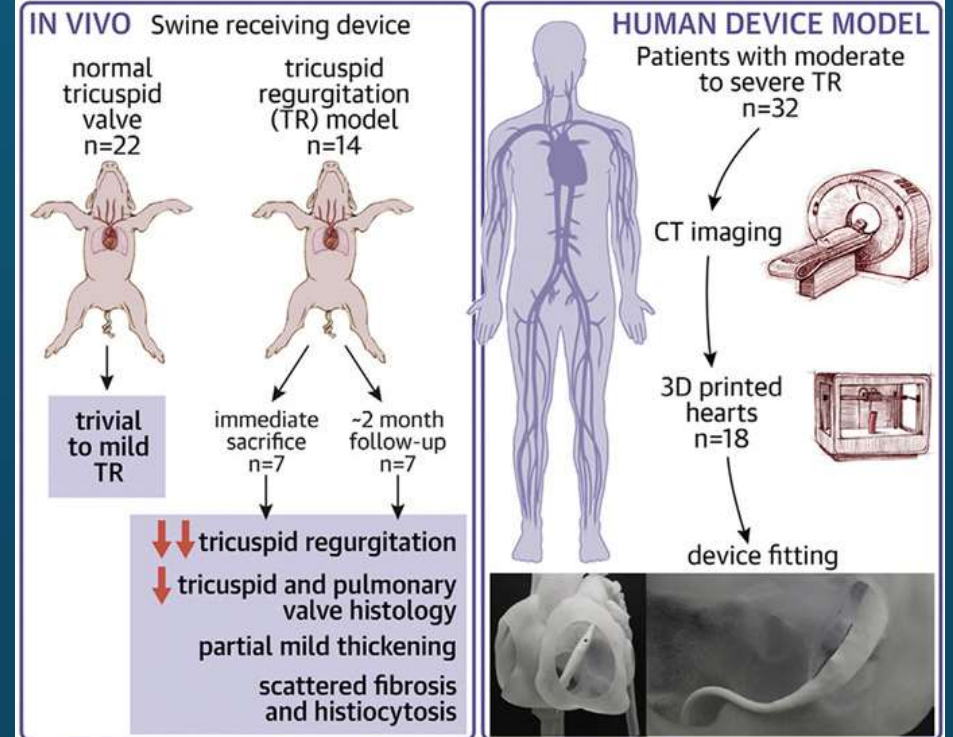
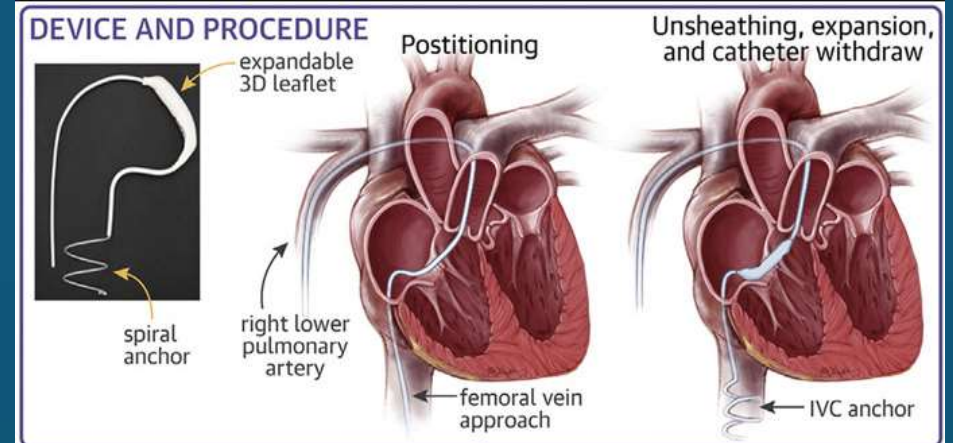
Novel vertical spacer for TR

ORIGINAL RESEARCH - PRECLINICAL

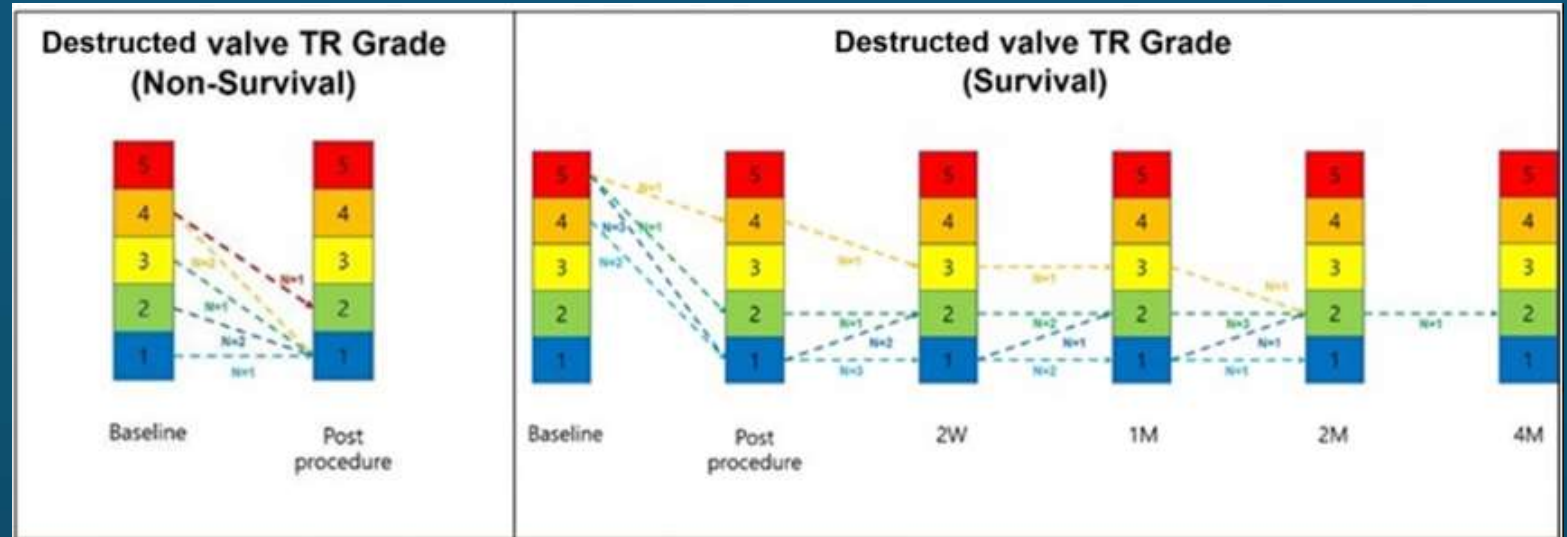
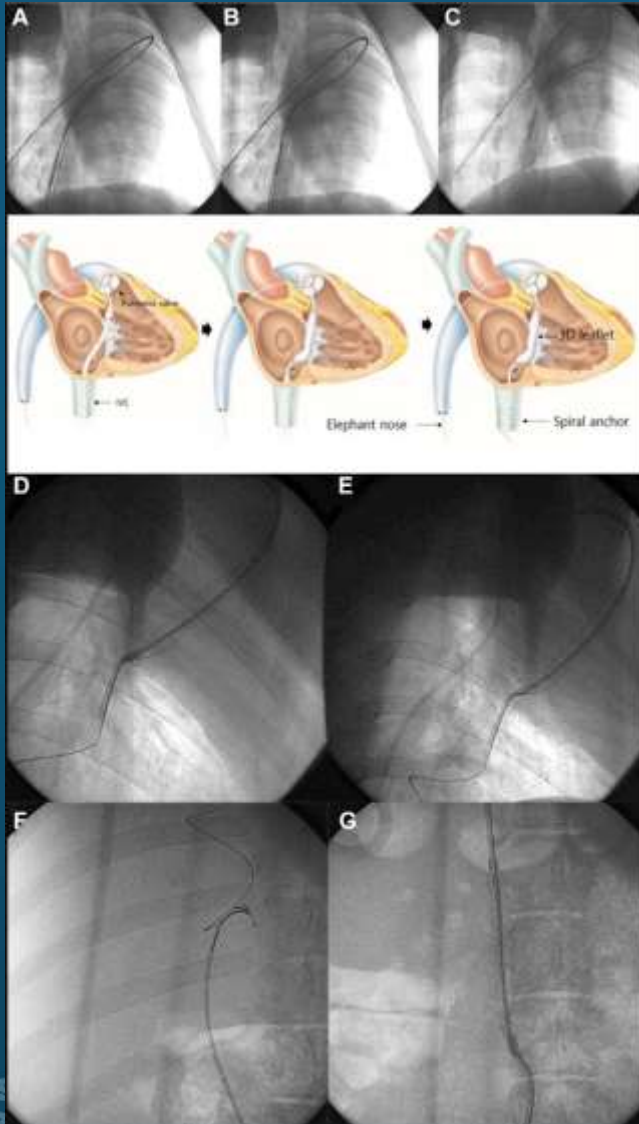
A Novel Device for Tricuspid Regurgitation Reduction Featuring 3-Dimensional Leaflet and Atraumatic Anchor

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



Novel vertical spacer for TR



Ongoing Clinical Trials

Key Ongoing Clinical Trials

Device	Study title	Study design	No. of patients	Description
TriClip (Abbott)	TRI-FR (NCT04646811) Multicenter randomized trial	Multicenter, Prospective, Interventional, Randomized	300	RCT; aim: demonstrate safety and effectiveness of TTVR with TriClip (TriClip + OMT vs OMT)
TriClip (Abbott)	bRIGHT (NCT04483089) Observational real-world	Multicenter, Prospective, Single-arm, Observational, Postmarket registry	200	Postapproval study to confirm safety and performance of the TriClip in a real-world setting
PASCAL (Edwards)	CLASP TR EFS (NCT03745313) Early feasibility study	Multicenter, Prospective, Single-arm, Interventional	65	Aim: evaluate the safety and performance of the Edwards PASCAL
PASCAL (Edwards)	CLASP II TR (NCT04097145) PASCAL Pivotal trial	Multicenter, Prospective, Randomized, Parallel assignment	825	Aim: evaluate the safety and effectiveness of the Edwards PASCAL (PASCAL + OMT vs OMT)
Cardioband (Edwards)	TriBAND (NCT03779490) Cardioband post market	Multicenter, Prospective, Single-arm, Observational, Postmarket registry	150	Aim: assess the safety and the effectiveness of the Cardioband
TTVR with either TriClip, PASCAL, or Cardioband	TRICuspid Intervention in Heart Failure Trial (NCT04634266)	Multicenter, Prospective, Randomized	360	RCT; aim: assess the concept that TTVR will translate into a reduced morbidity and mortality TTVR + OMT vs OMT alone
Edwards EVOQUE Tricuspid Valve Replacement System	TRISCEND II Pivotal Trial (NCT04482062) Edwards EVOQUE TTVR	Multicenter, Prospective, Open-label, Randomized interventional	675	RCT; aim: evaluate the safety and effectiveness of the EVOQUE system + OMT vs OMT

Thank you for your attention!