

# Tricuspid Intervention

# Treatment options of intervention

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

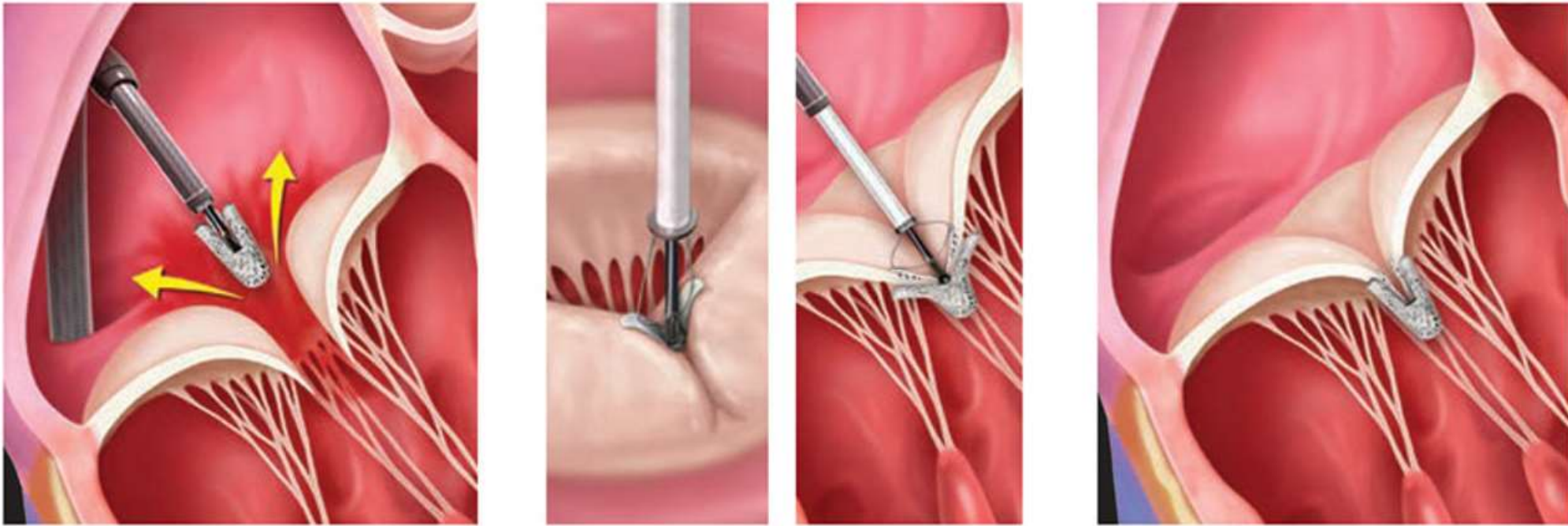
# 2020 AHA/ACC Guideline Indication of Tricuspid intervention

- **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



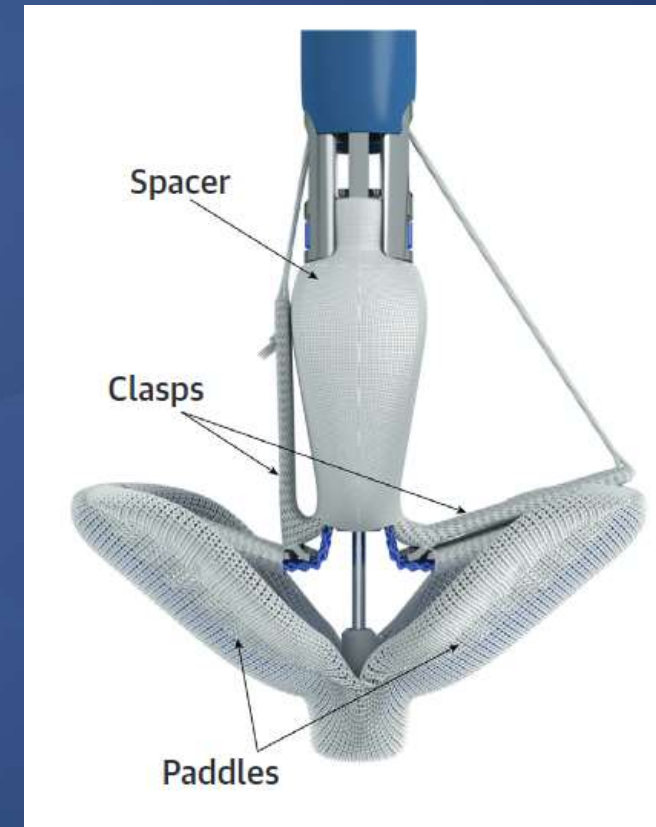
*Repairing a tricuspid valve through a TriClip procedure (Image courtesy of [Abbott](#))*

# 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

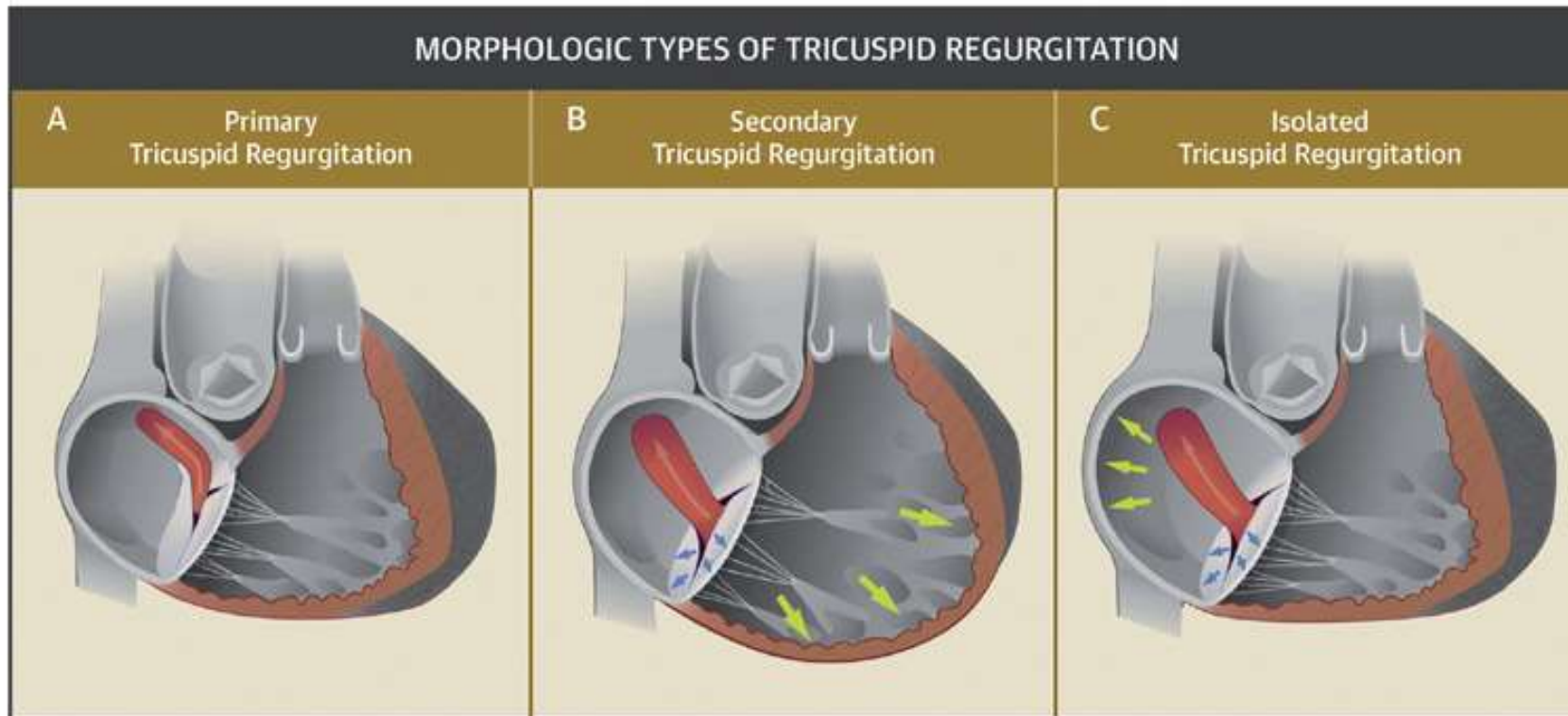
FDA approval of  
TriClip

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)

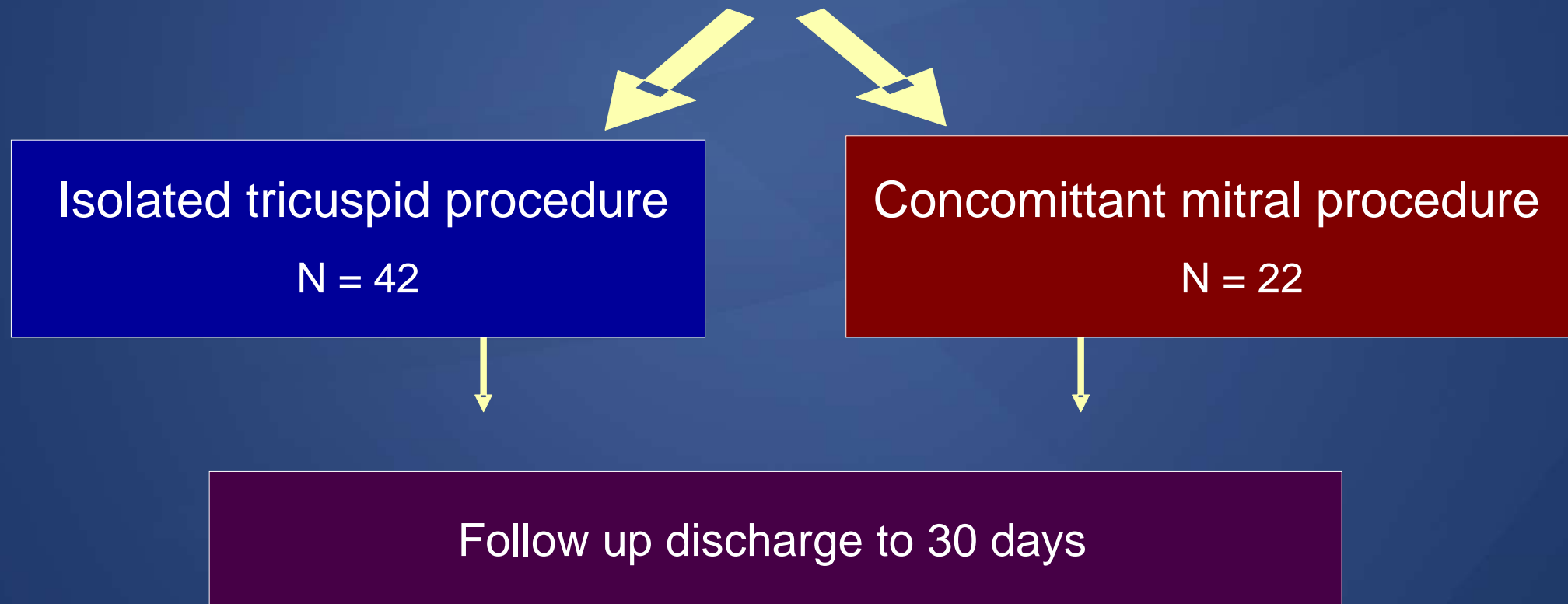
# Mitraclip for Severe TR

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 <sup>2</sup>	0.9 ± 0.4
Septo-lateral diameter, mm	42.4 ± 10.4

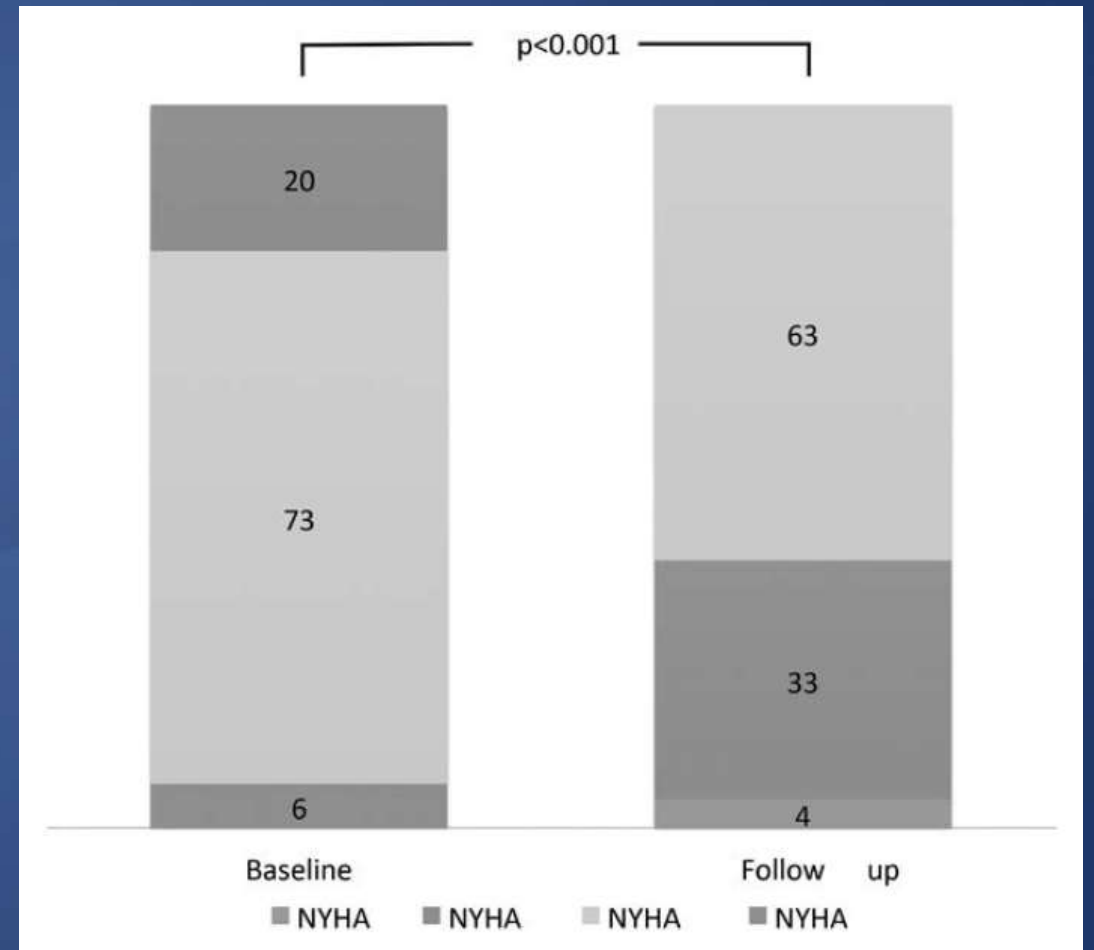
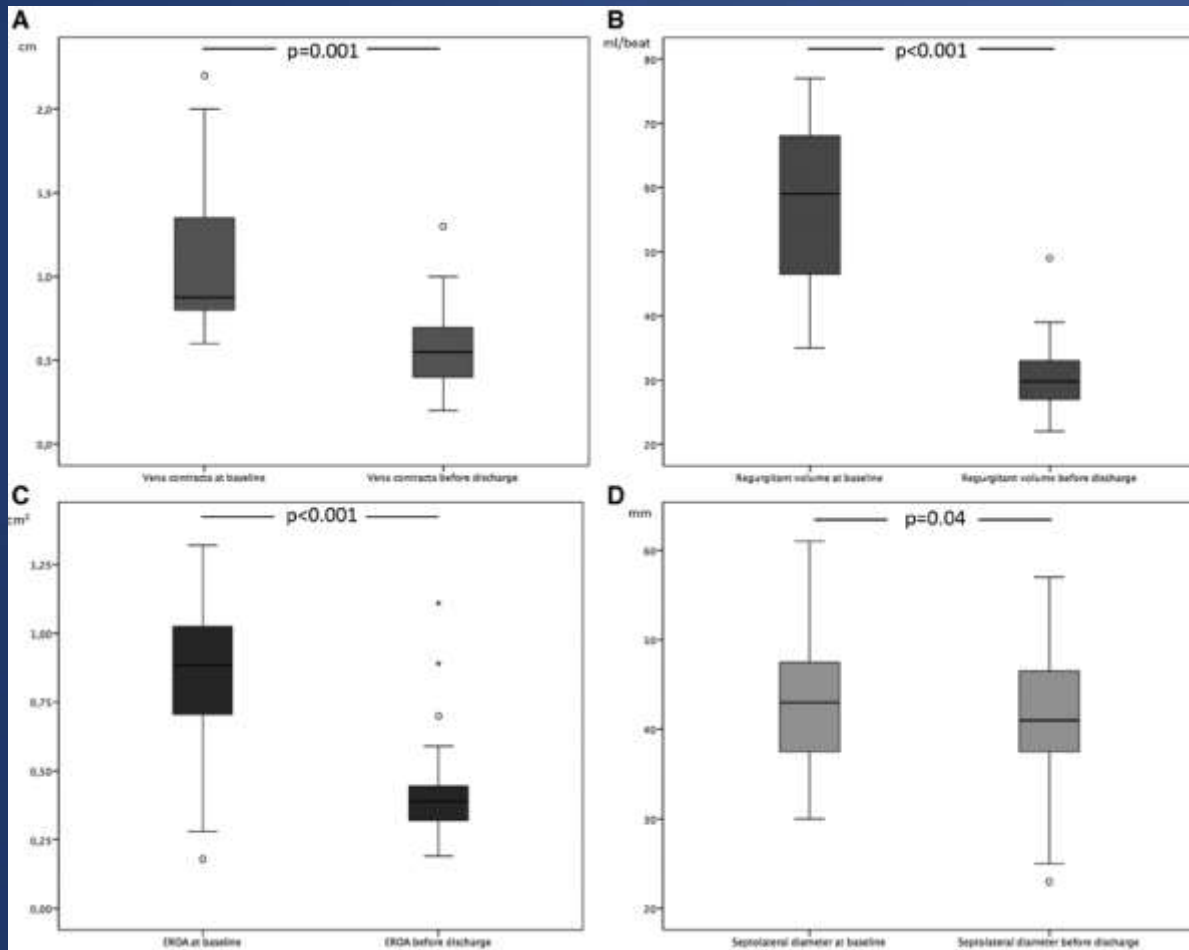
# MitraClip for Severe TR

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 <sup>2</sup>	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





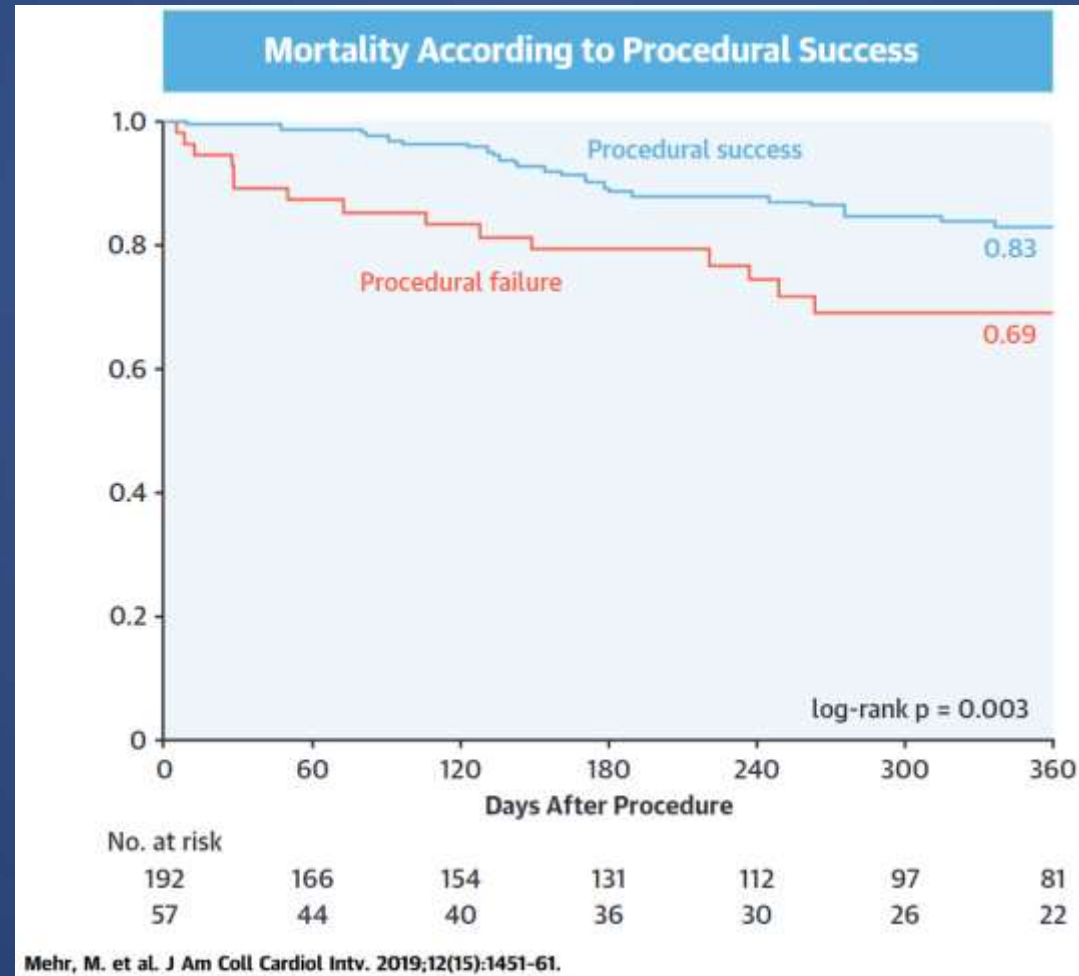
# Univariate and Multivariate analysis of procedural failure TriValve Registry

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 <sup>2</sup>	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 <sup>2</sup>	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

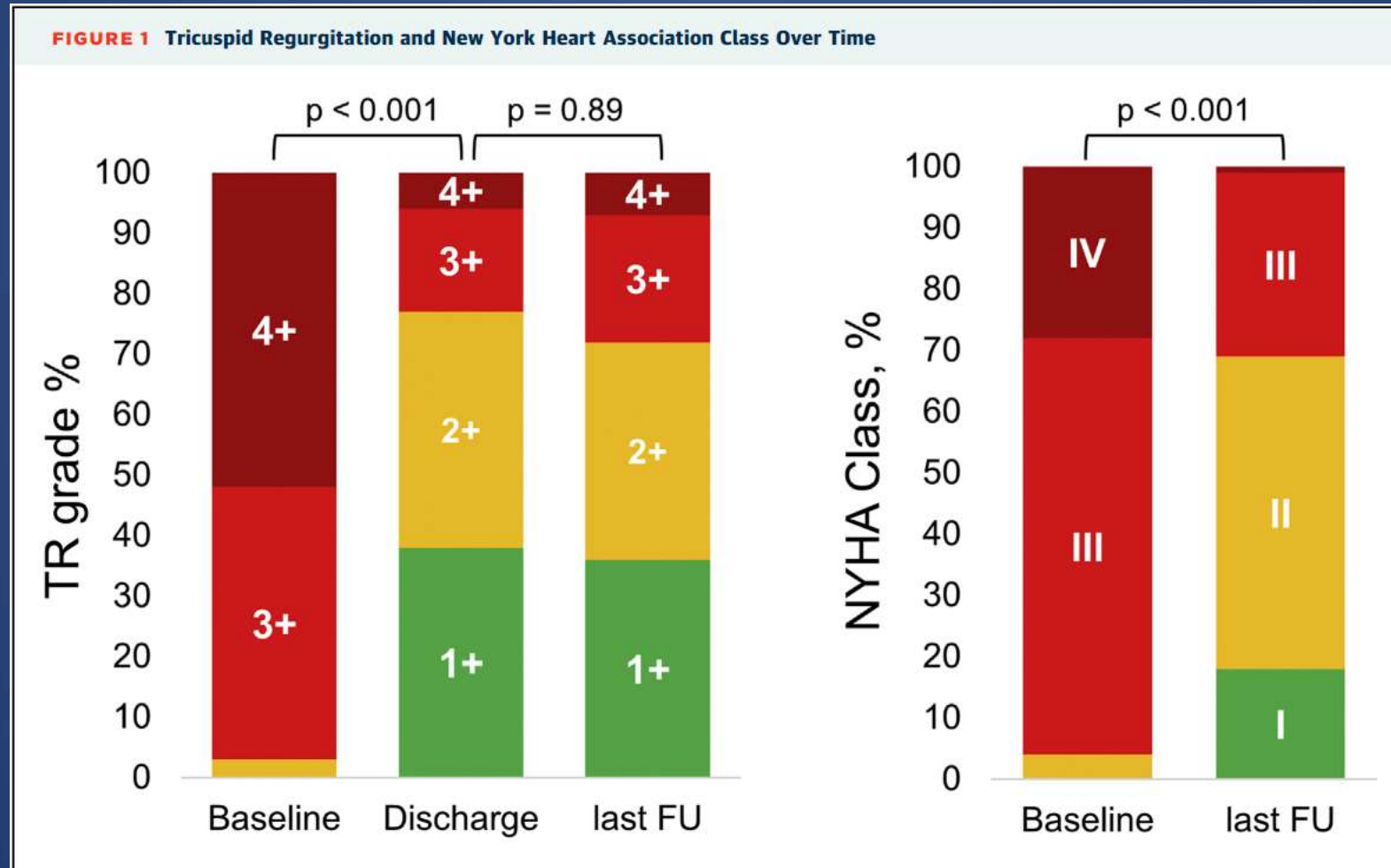
249 patients, from 14 centers in Europe and North America



# 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 $\geq 1$ 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

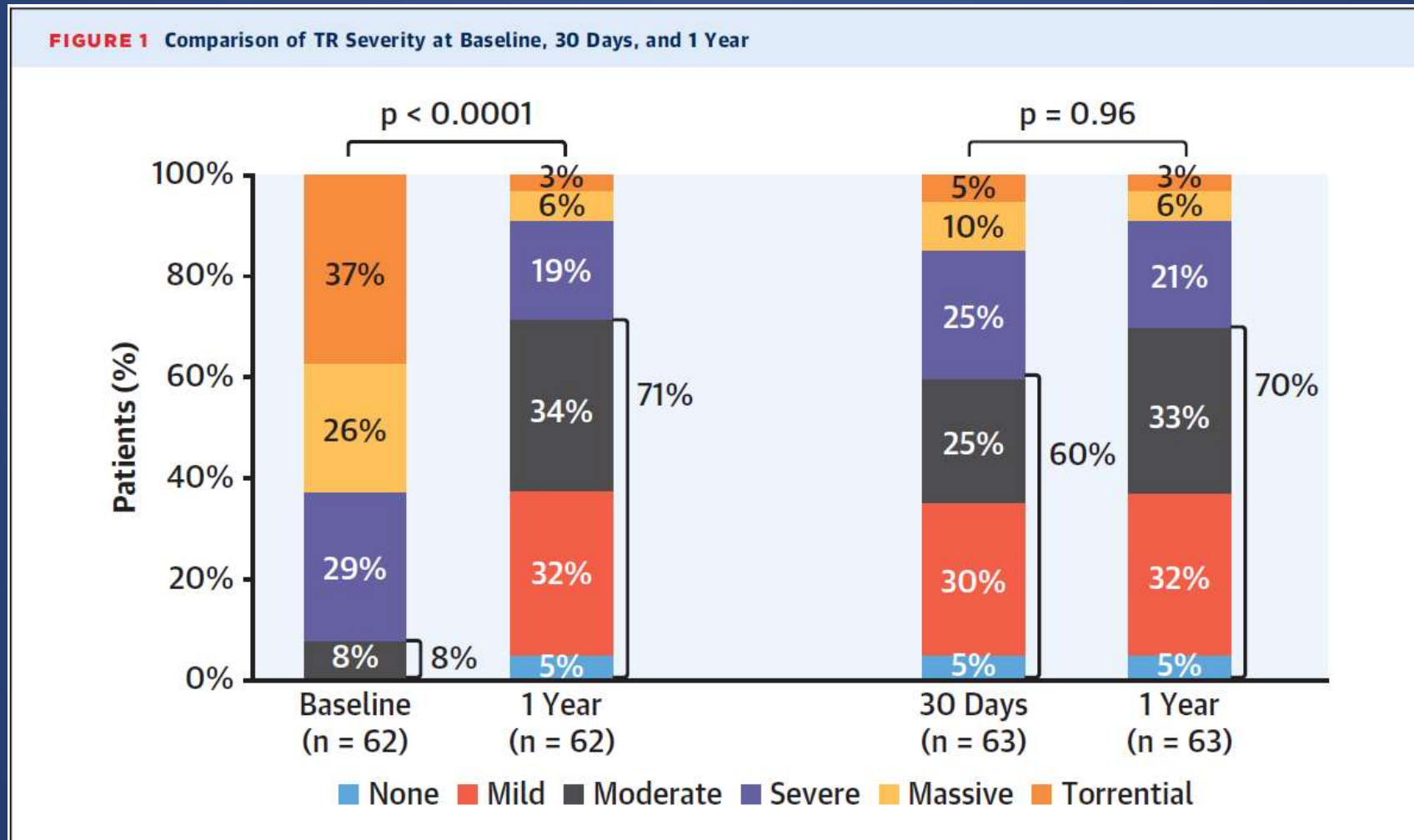
### 84 patients, Single arm study

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 <sup>2</sup> (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 <sup>2</sup> (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

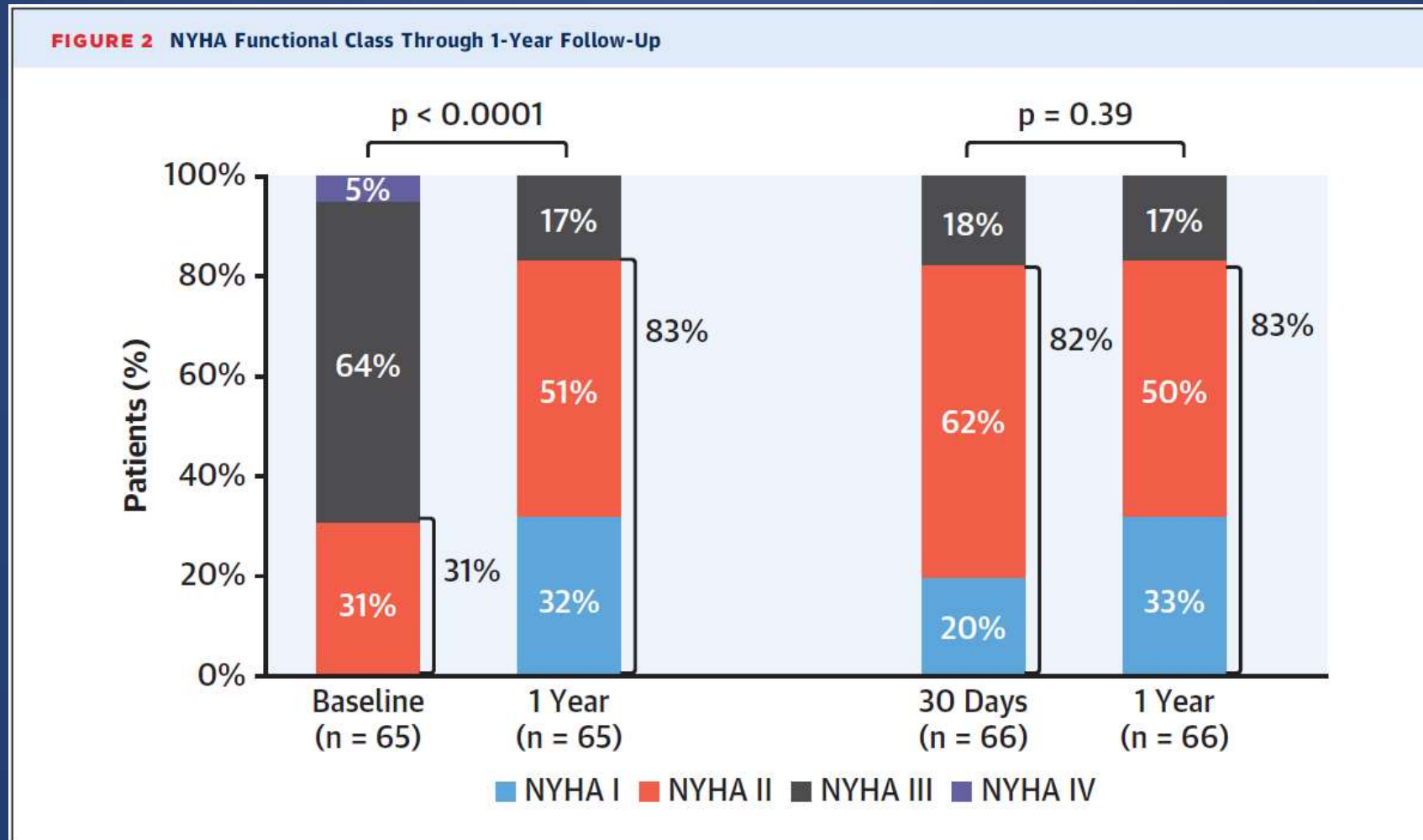




# TriClip for Severe TR

## 1-year outcomes of the TRILUMINATE study

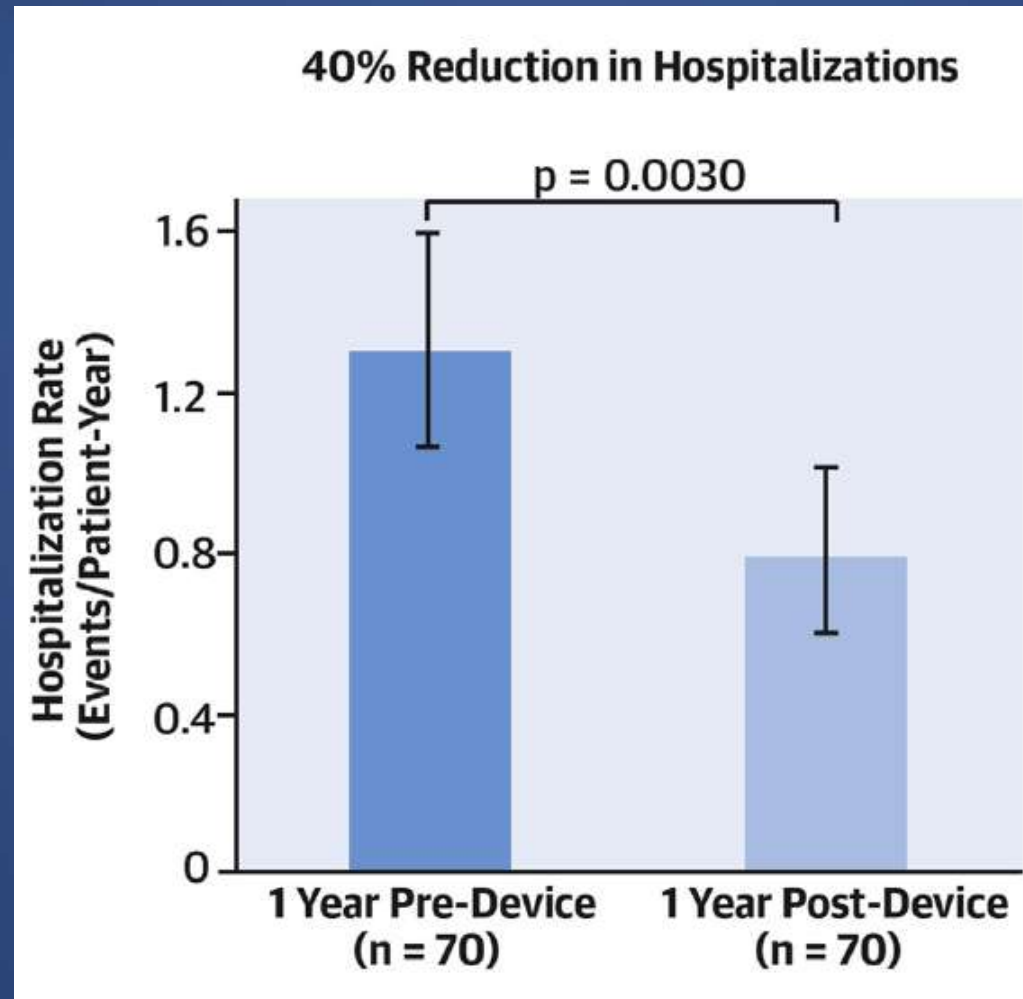
84 patients, Single arm study



# TriClip for Severe TR

## 1-year outcomes of the TRILUMINATE study

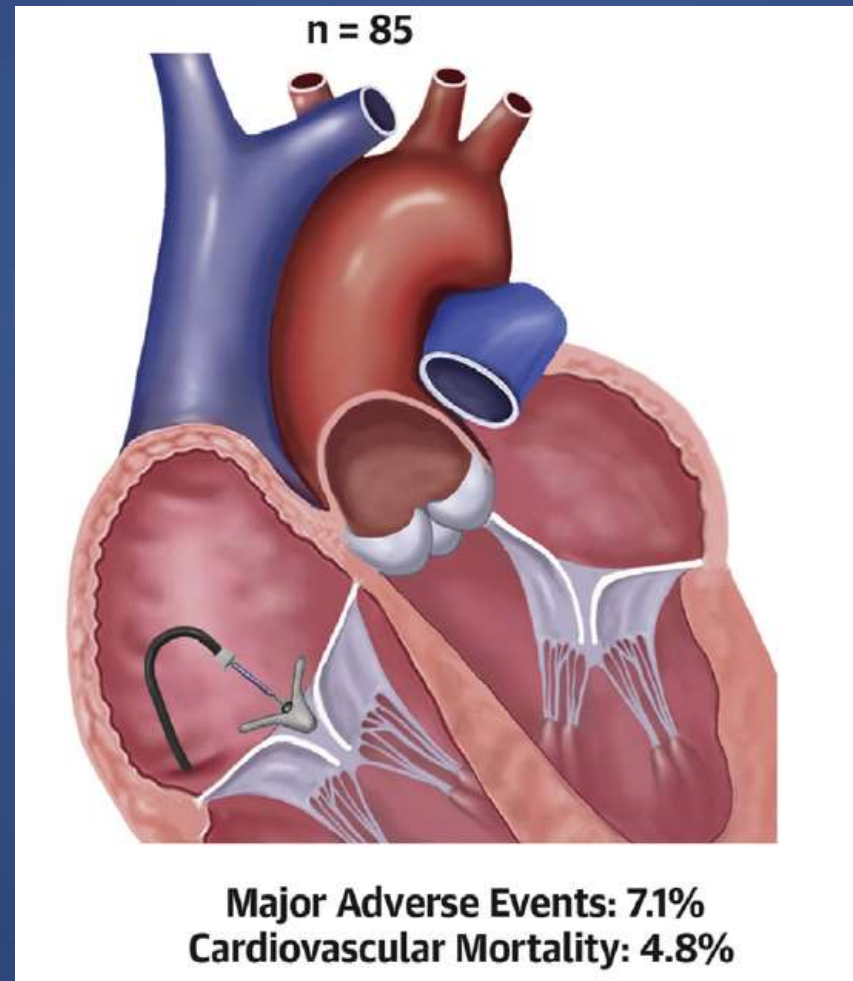
84 patients, Single arm study



# 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
<b>MACE through 1 year</b>	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%)
<b>Other safety endpoints</b>	
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%)

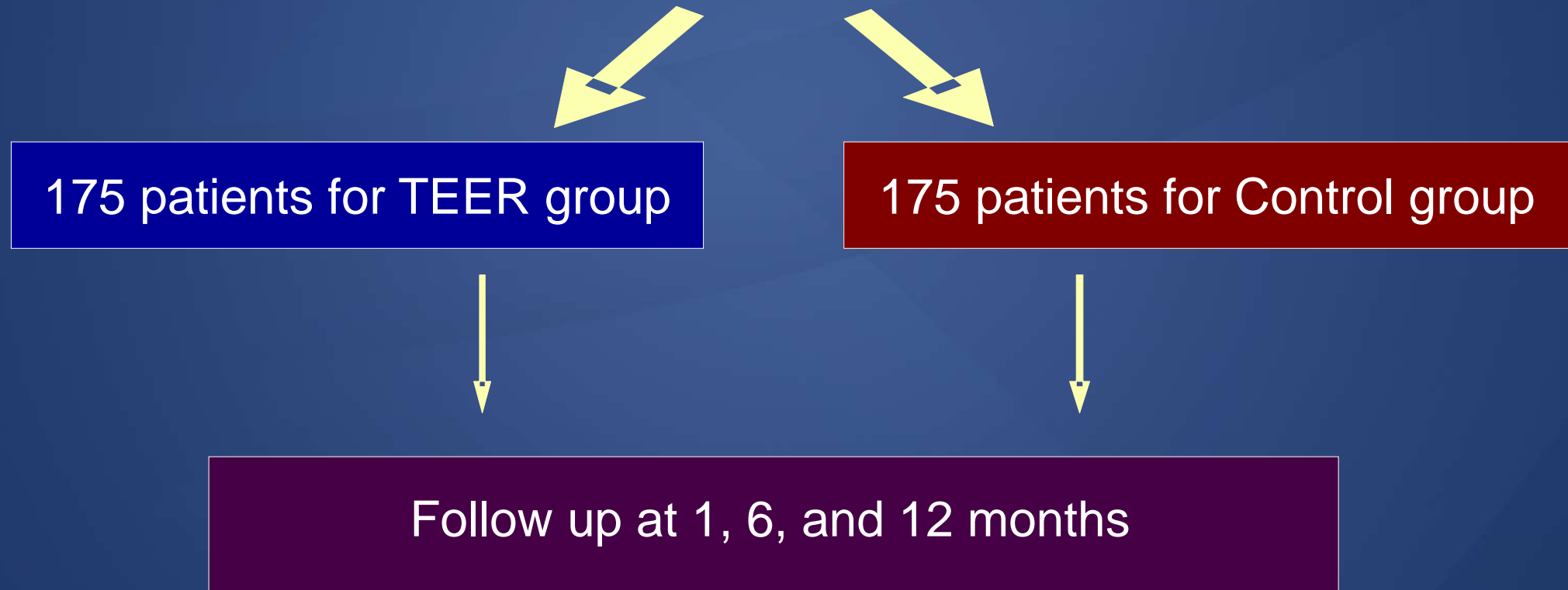
# TriClip for Severe TR

## 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

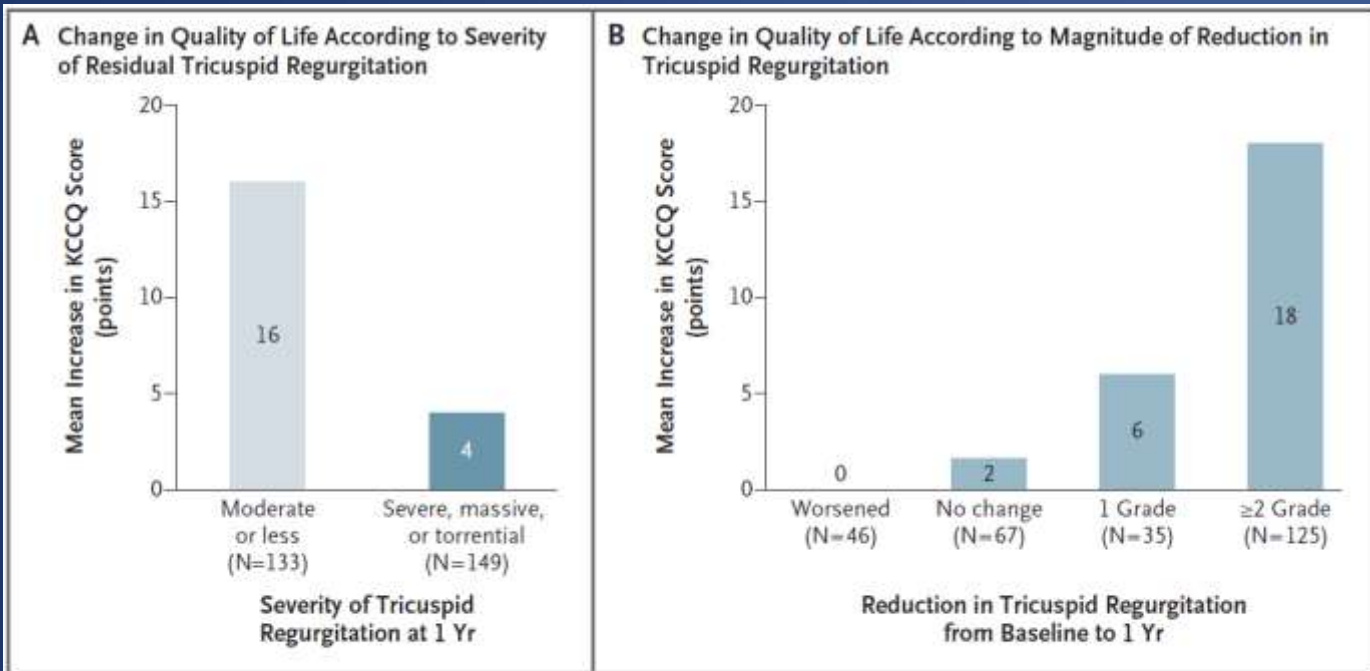
Primary and Secondary End Points	TEER Group (N=175)	Control Group (N=175)	Difference (95% CI)	P value
<b>Primary</b>				
Hierarchical composite of death from any cause or TV surgery; hospitalization for HF; and improvement of $\geq 15$ points in KCCQ score at 1 yr – no. of wins	11,348	7643	1.48 (1.06 – 2.13)	0.02
<b>Secondary, listed in hierarchical order</b>				
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



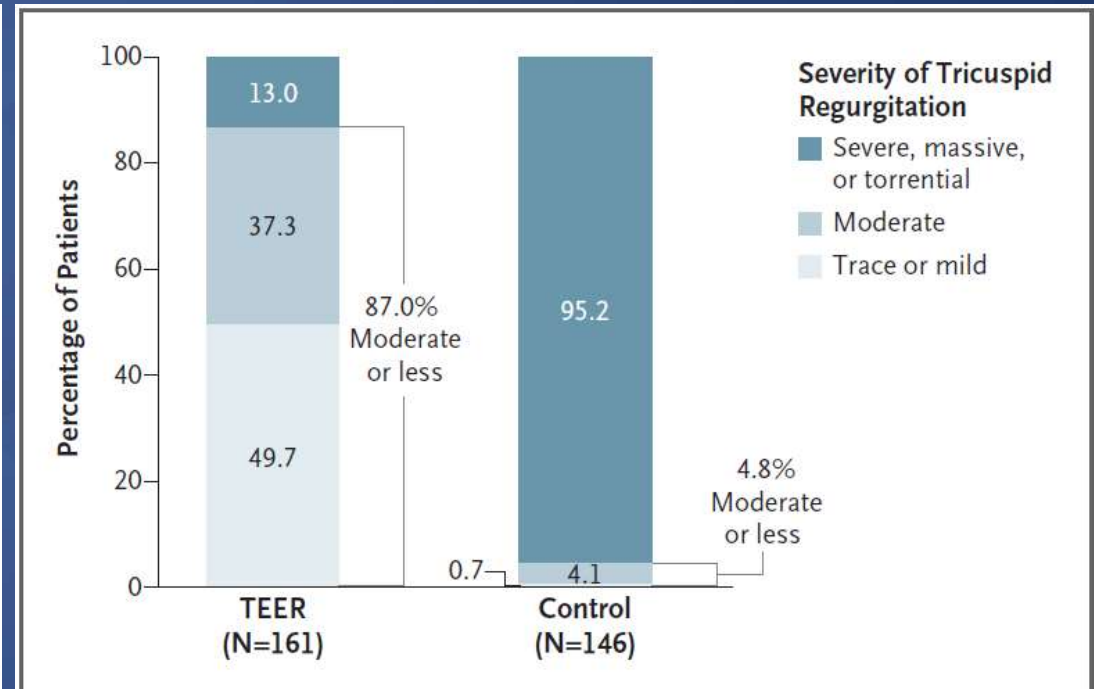
# TriClip for Severe TR

## 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)

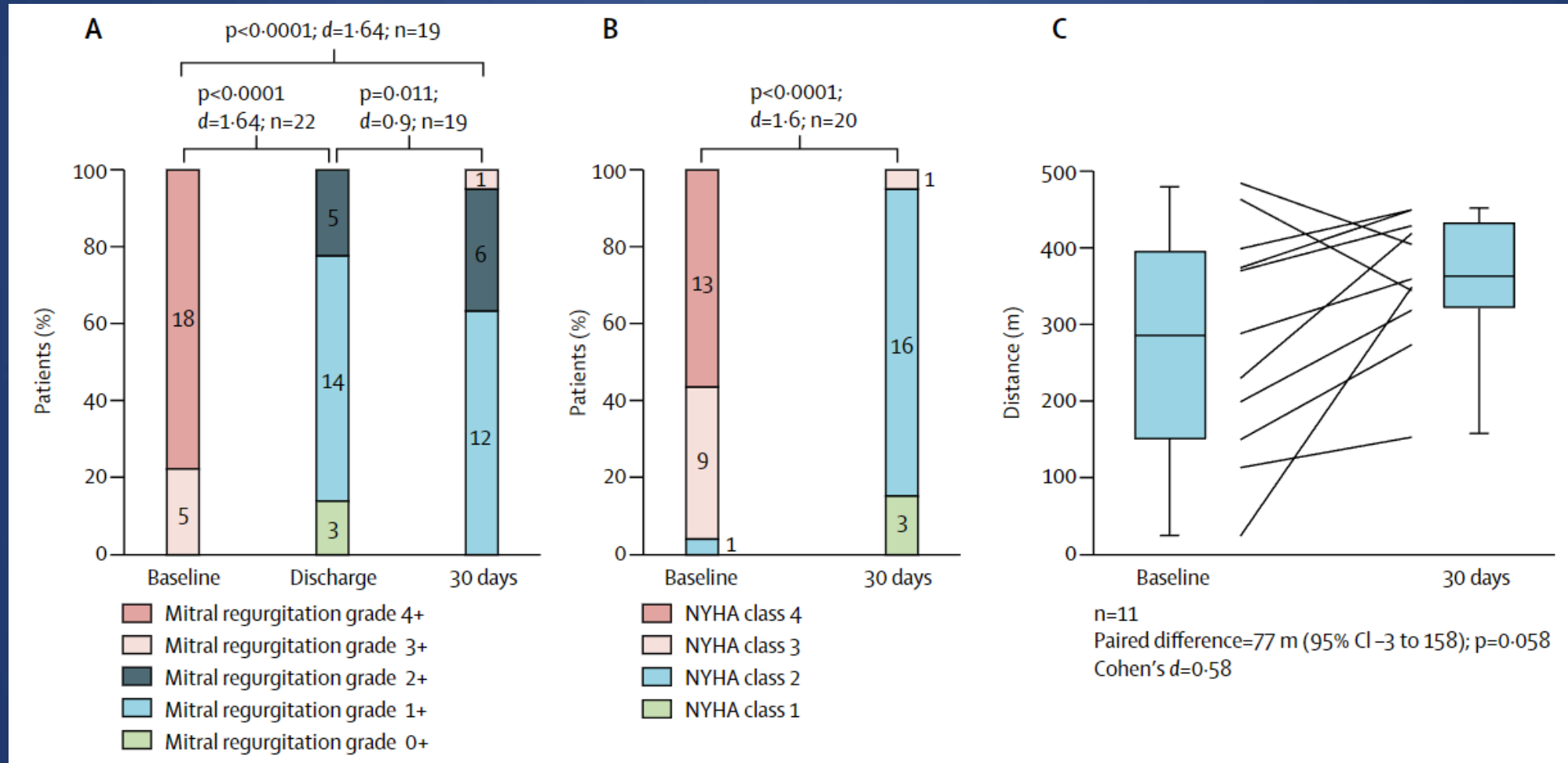
# PASCAL for Severe TR

**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

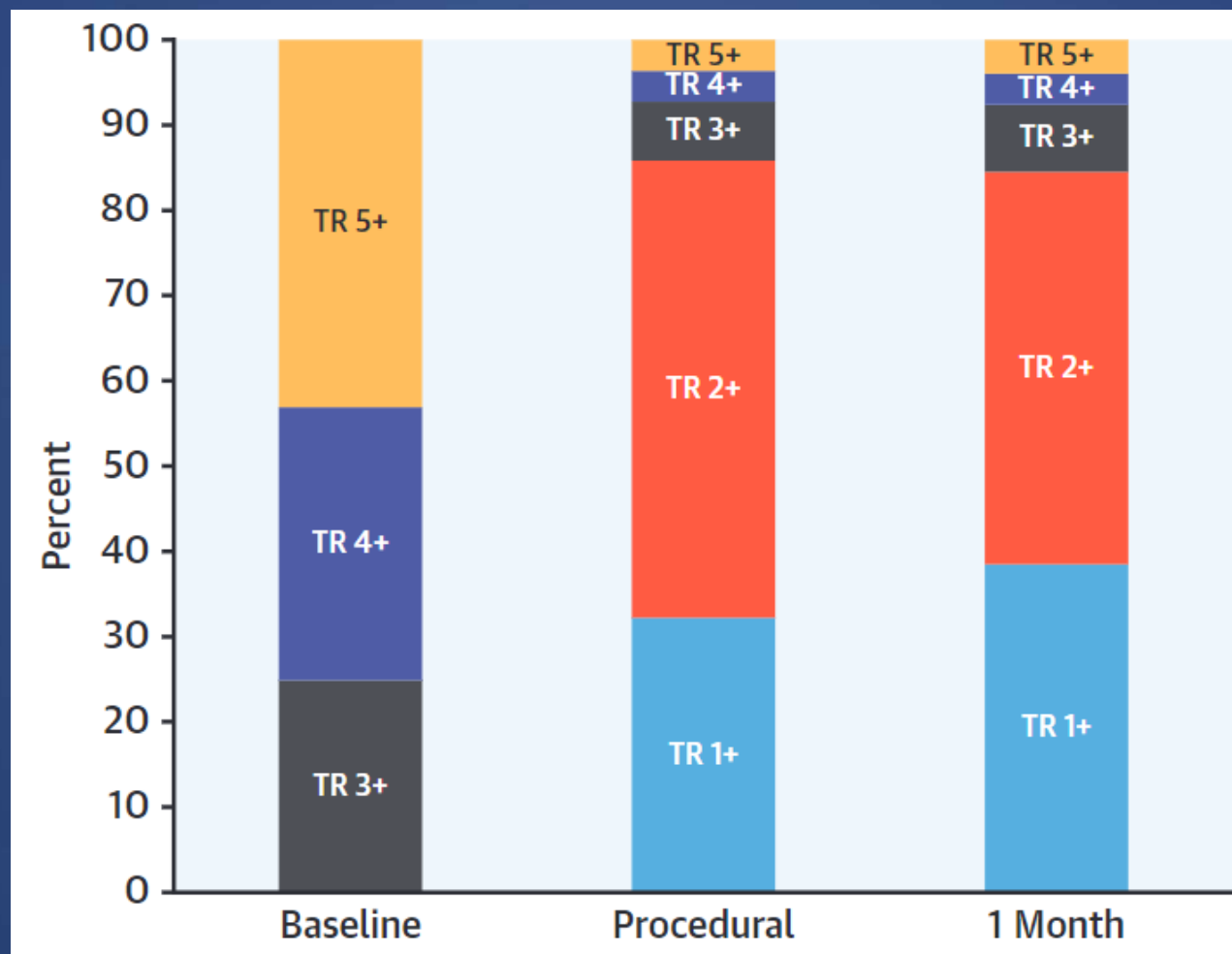
28 patients, Compassionate-use, 6 Centers

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

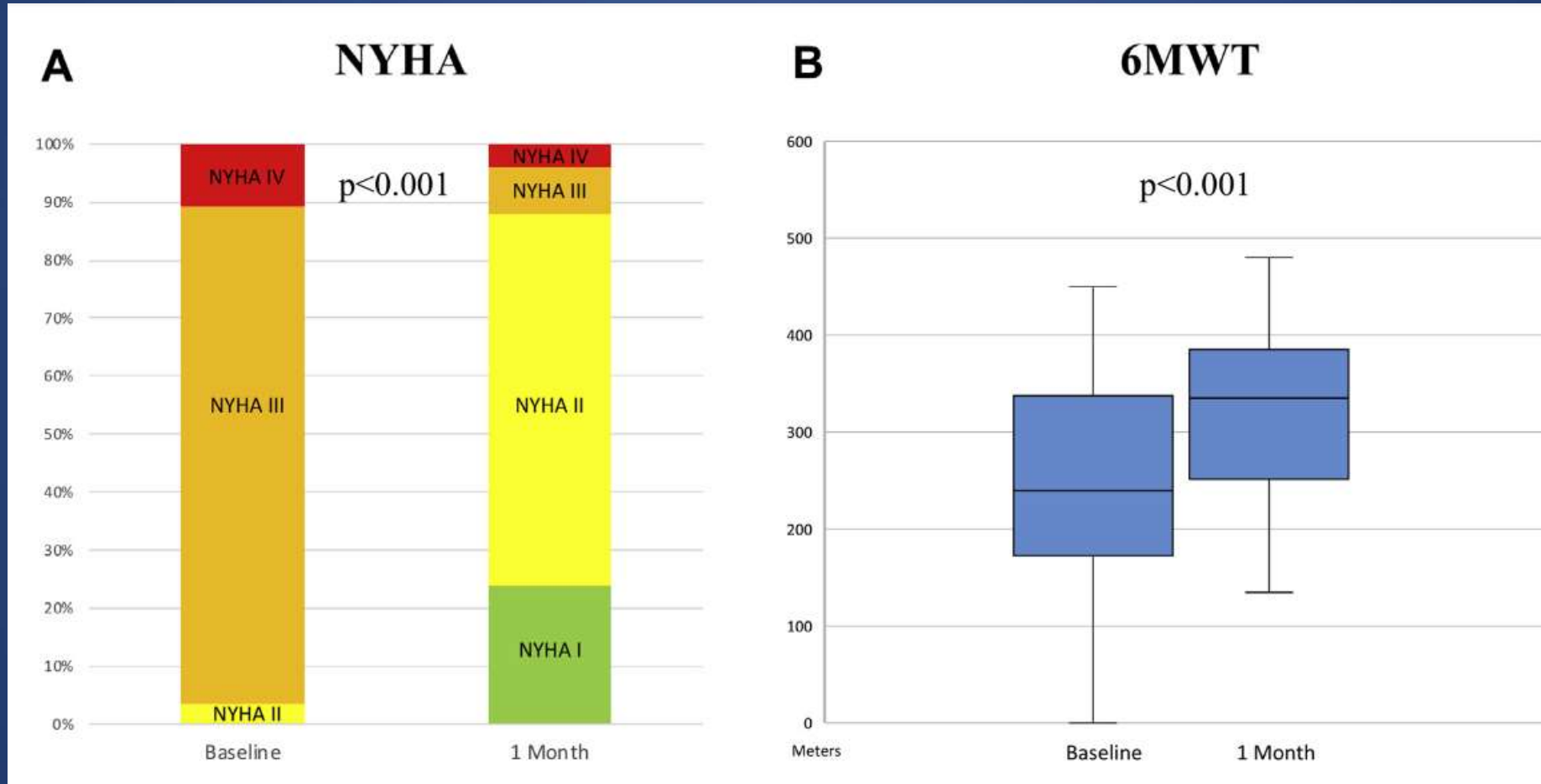
28 patients, Single arm study



# PASCAL for Severe TR

## Symptom and TR grade improvement

28 patients, Single arm study



# 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%)

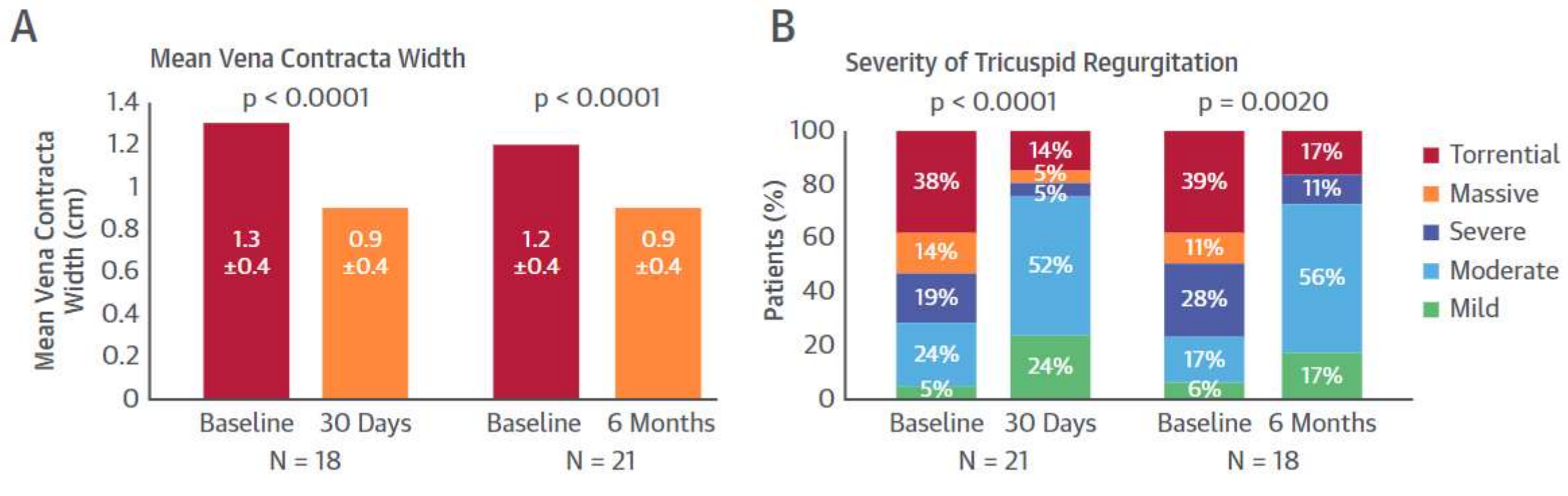
# 6-Month Outcomes of Cardioband for Severe TR

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

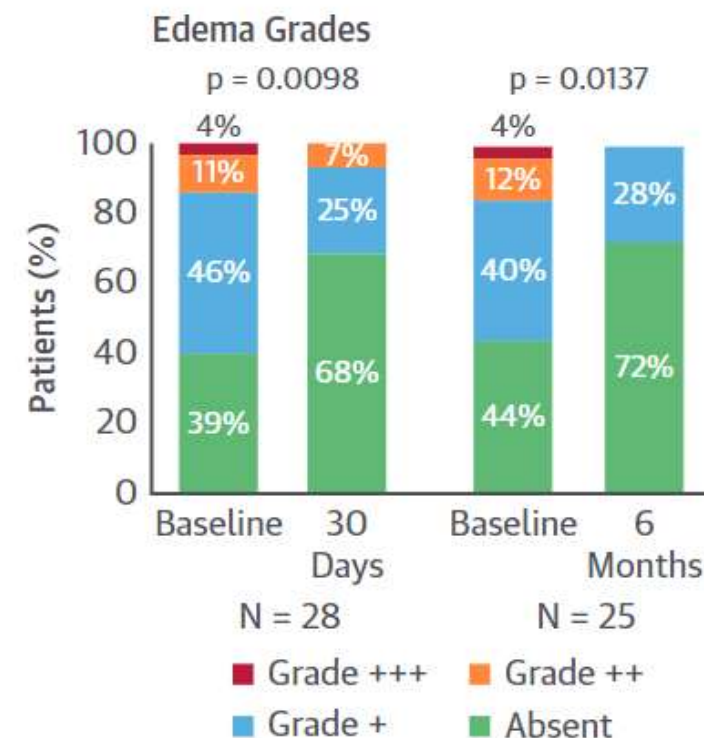
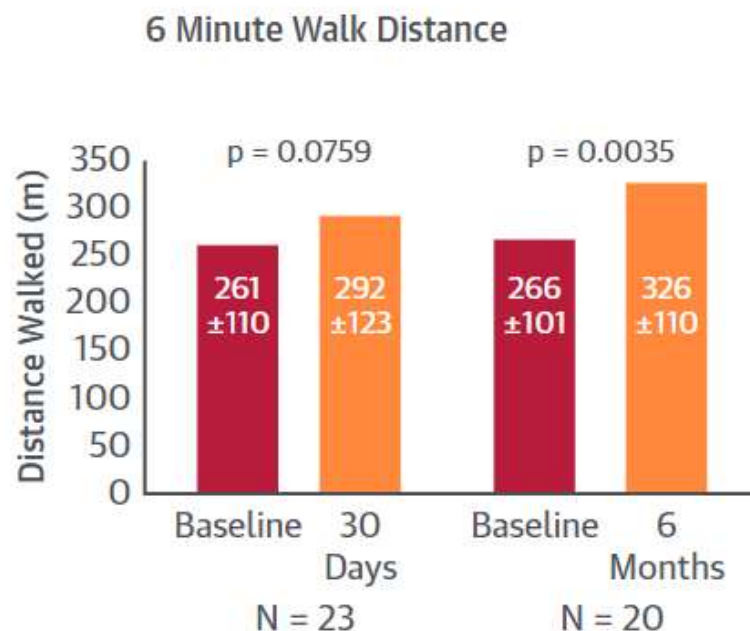
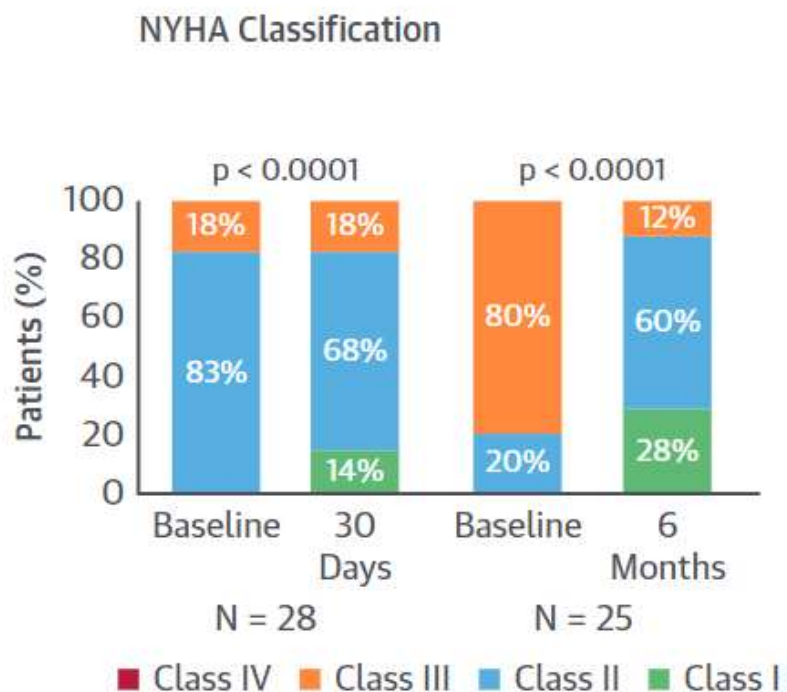
# 6-Month Outcomes of Cardioband for Severe TR

30 patients, Single arm study, Multicenter, Prospective trial



# 6-Month Outcomes of Cardioband for Severe TR

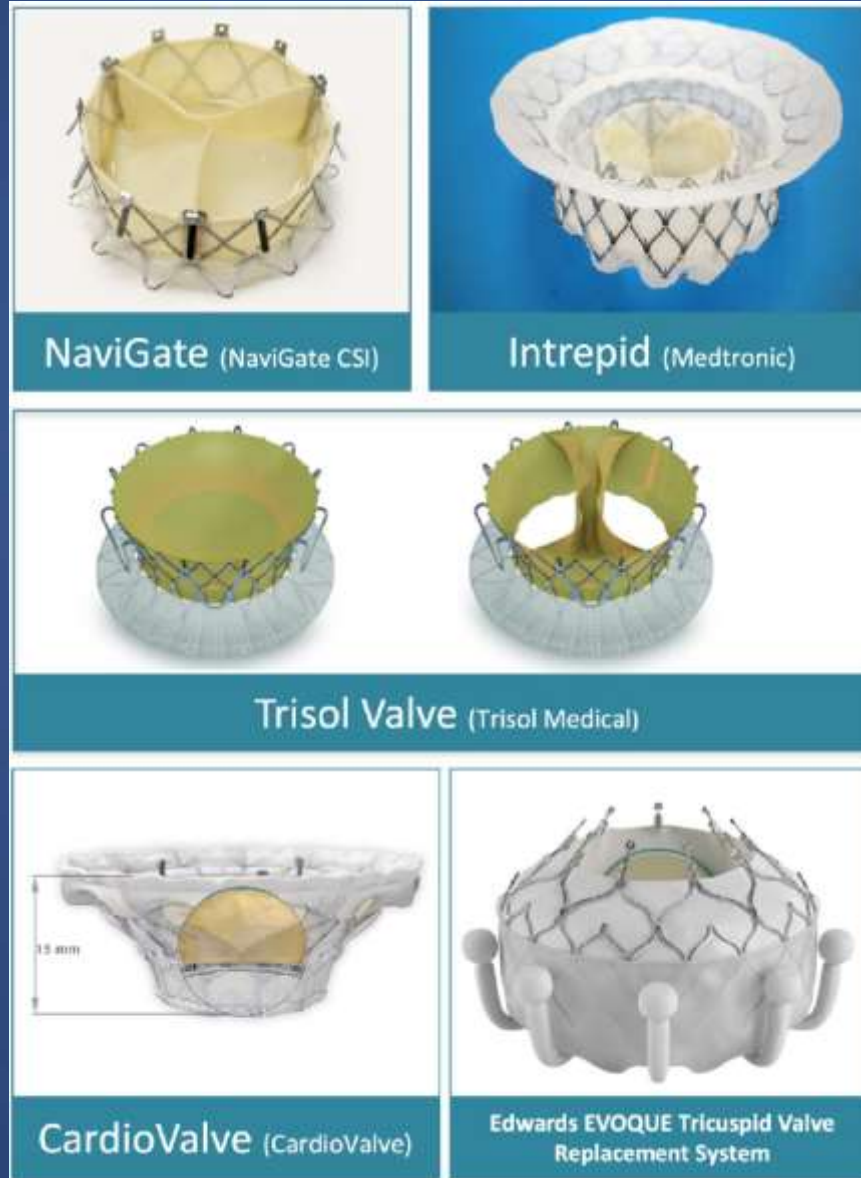
30 patients, Single arm study, Multicenter, Prospective trial



# Evidence of Catheter-based Valve Replacement for Severe TR



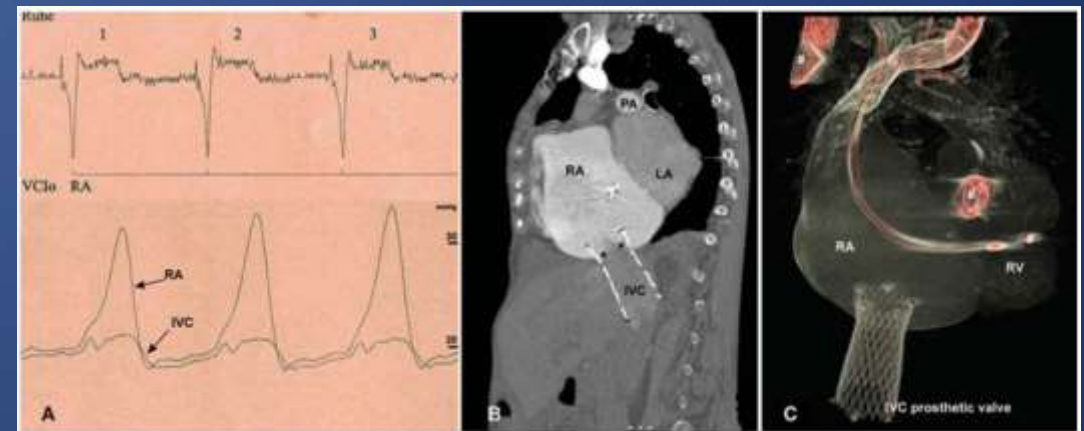
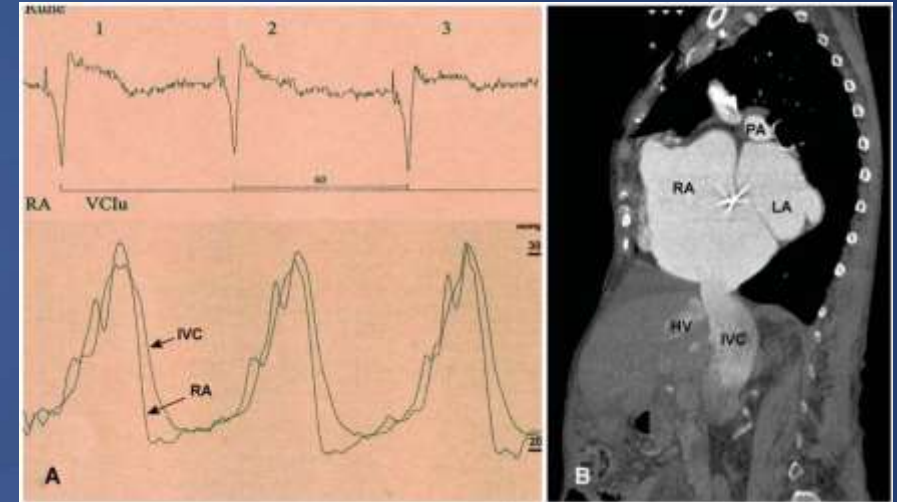
# Transcatheter Tricuspid Valve Replacement



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

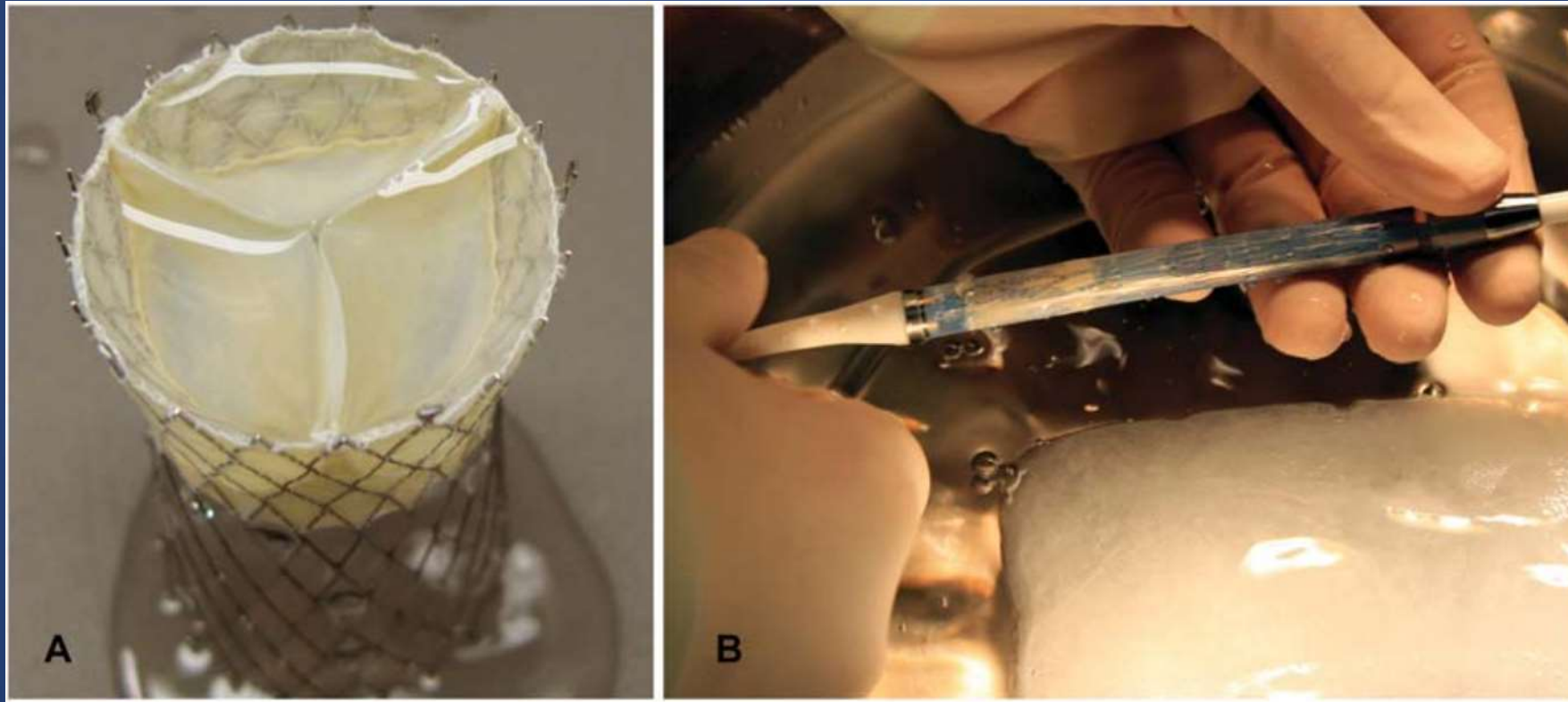
## First-in-Human application

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



# Ongoing Clinical Trials

# Key Ongoing Clinical Trials

Device	Study title	Study design	No. of patients	Description
<b>TriClip (Abbott)</b>	TRI-FR (NCT04646811) Multicenter rancomized trial	Multicenter, Prospective, Interventional, Randomized	300	RCT; aim: demonstrate safety and effectiveness of TTVR with TriClip (TriClip + OMT vs OMT)
<b>TriClip (Abbott)</b>	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
<b>PASCAL (Edwards)</b>	CLASP TR EFS (NCT03745313) Early feasibility study	Multicenter, Prospective, Single-arm, Interventional	65	Aim: evaluate the safety and performance of the Edwards PASCAL
<b>PASCAL (Edwards)</b>	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)
<b>Cardioband (Edwards)</b>	TriBAND (NCT03779490) Cardioband post market	Multicenter, Prospective, Single-arm, Observational, Postmarket registry	150	Aim: assess the safety and the effectiveness of the Cardioband
<b>TTVR with either TriClip, PASCAL, or Cardioband</b>	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
<b>Edwards EVOQUE Tricuspid Valve Replacement System</b>	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