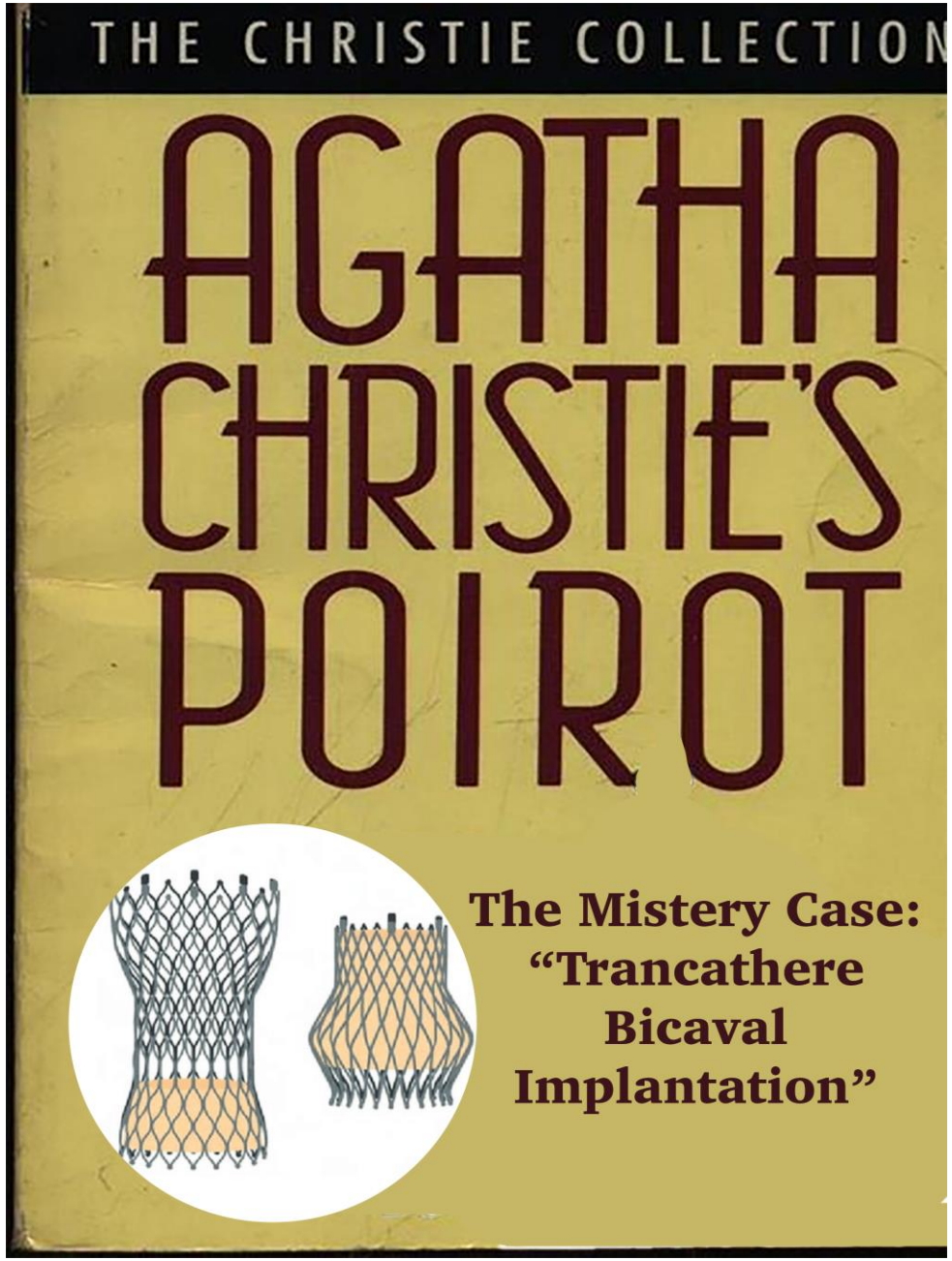

EUROVALVE
& STRUCTURAL CARDIOMYOPATHIES
NH PALERMO

Michele Di Mauro

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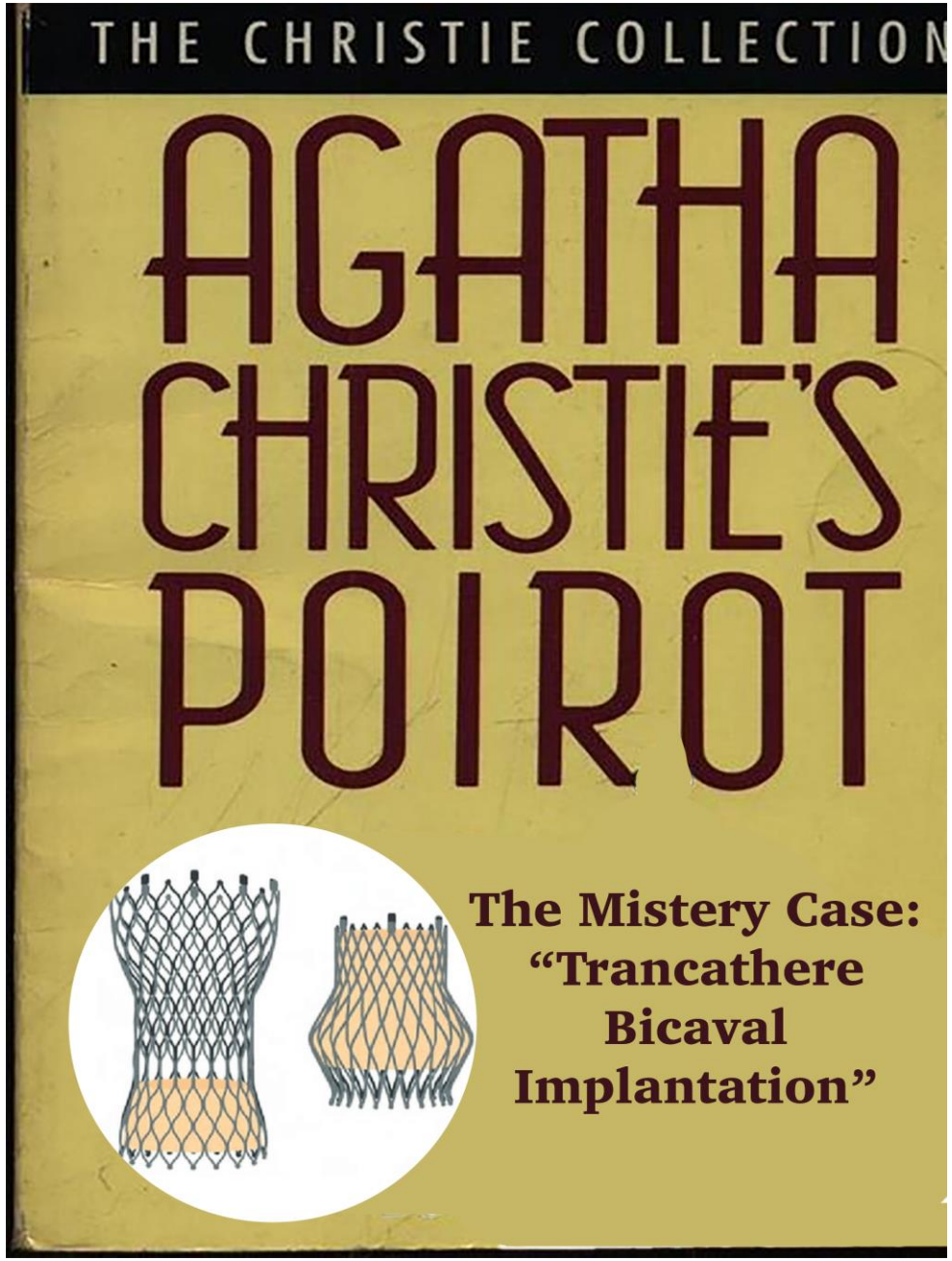

EUROVALVE
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Disclosure

The butler didn't it!

Circulation

ACC/AHA CLINICAL PRACTICE GUIDELINE

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

A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

No PLACE

8.2.3. Timing of Intervention

Recommendations for Timing of Intervention

Referenced studies that support the recommendations are summarized in Online Data Supplement 32.

COR	LOE	Recommendations
1	B-NR	1. In patients with severe TR (Stages C and D) undergoing left-sided valve surgery, tricuspid valve surgery is recommended.[1–8]
2a	B-NR	2. In patients with progressive TR (Stage B) undergoing left-sided valve surgery, tricuspid valve surgery can be beneficial in the context of either 1) tricuspid annular dilation (tricuspid annulus end diastolic diameter >4.0 cm) or 2) prior signs and symptoms of right-sided HF.[3–10]
2a	B-NR	3. In patients with signs and symptoms of right-sided HF and severe primary TR (Stage D), isolated tricuspid valve surgery can be beneficial to reduce symptoms and recurrent hospitalizations.[11–14]
2a	B-NR	4. In patients with signs and symptoms of right-sided HF and severe isolated secondary TR attributable to annular dilation (in the absence of pulmonary hypertension or left-sided disease) who are poorly responsive to medical therapy (Stage D), isolated tricuspid valve surgery can be beneficial to reduce symptoms and recurrent hospitalizations.[11,12,15–19]
2b	C-LD	5. In asymptomatic patients with severe primary TR (Stage C) and progressive RV dilation or systolic dysfunction, isolated tricuspid valve surgery may be considered.[12,20]
2b	B-NR	6. In patients with signs and symptoms of right-sided HF and severe TR (Stage D) who have undergone previous left-sided valve surgery, reoperation with isolated tricuspid valve surgery may be considered in the absence of severe pulmonary hypertension or severe RV systolic dysfunction.[1,2,11,18]

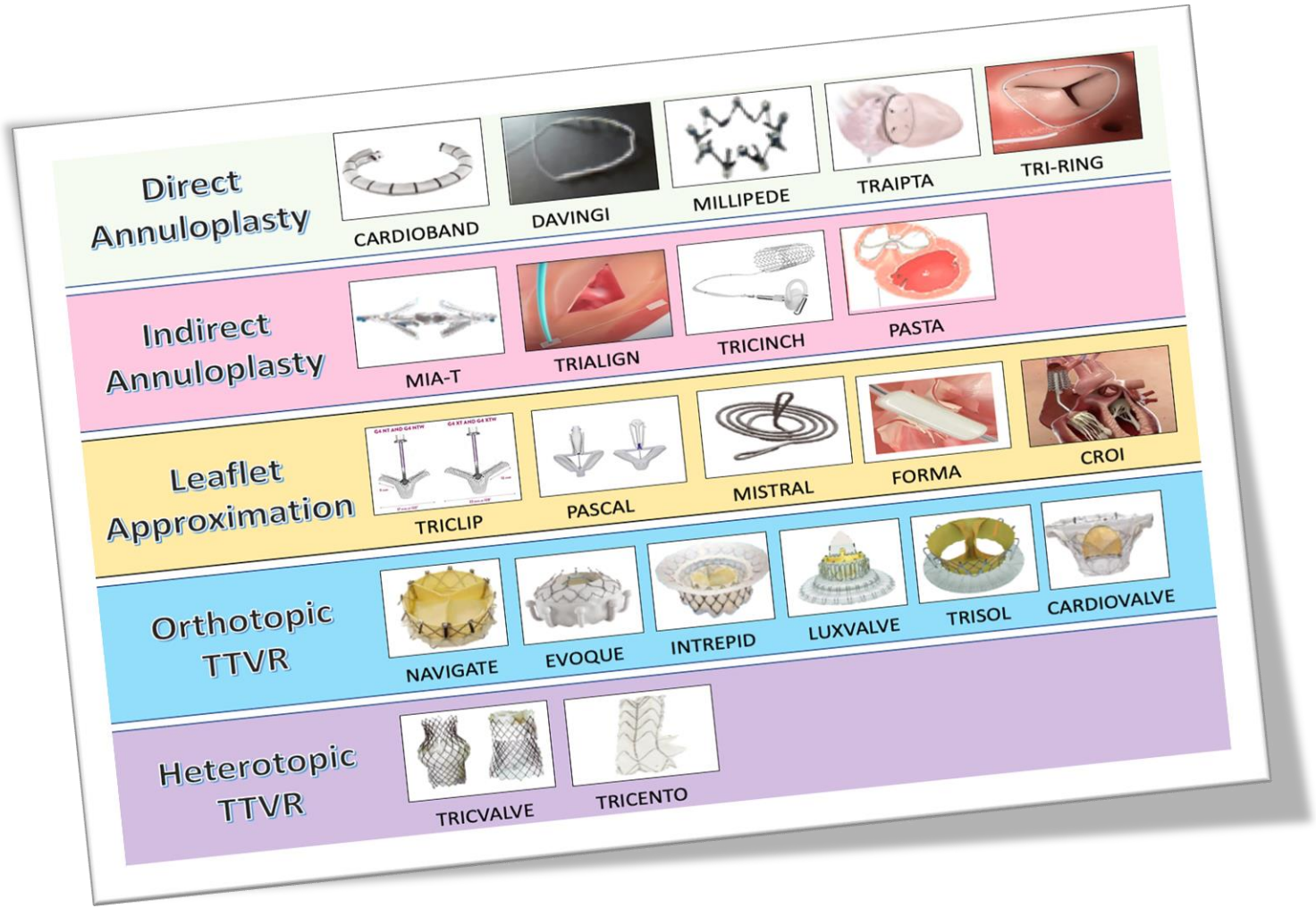
2021 ESC/EACTS Guidelines for the management of valvular heart disease

Developed by the Task Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Recommendations on primary tricuspid regurgitation		
Surgery is recommended in patients with severe primary tricuspid regurgitation undergoing left-sided valve surgery.	I	C
Surgery is recommended in symptomatic patients with isolated severe primary tricuspid regurgitation without severe RV dysfunction.	I	C
Surgery should be considered in patients with moderate primary tricuspid regurgitation undergoing left-sided valve surgery.	IIa	C
Surgery should be considered in asymptomatic or mildly symptomatic patients with isolated severe primary tricuspid regurgitation and RV dilatation who are appropriate for surgery.	IIa	C

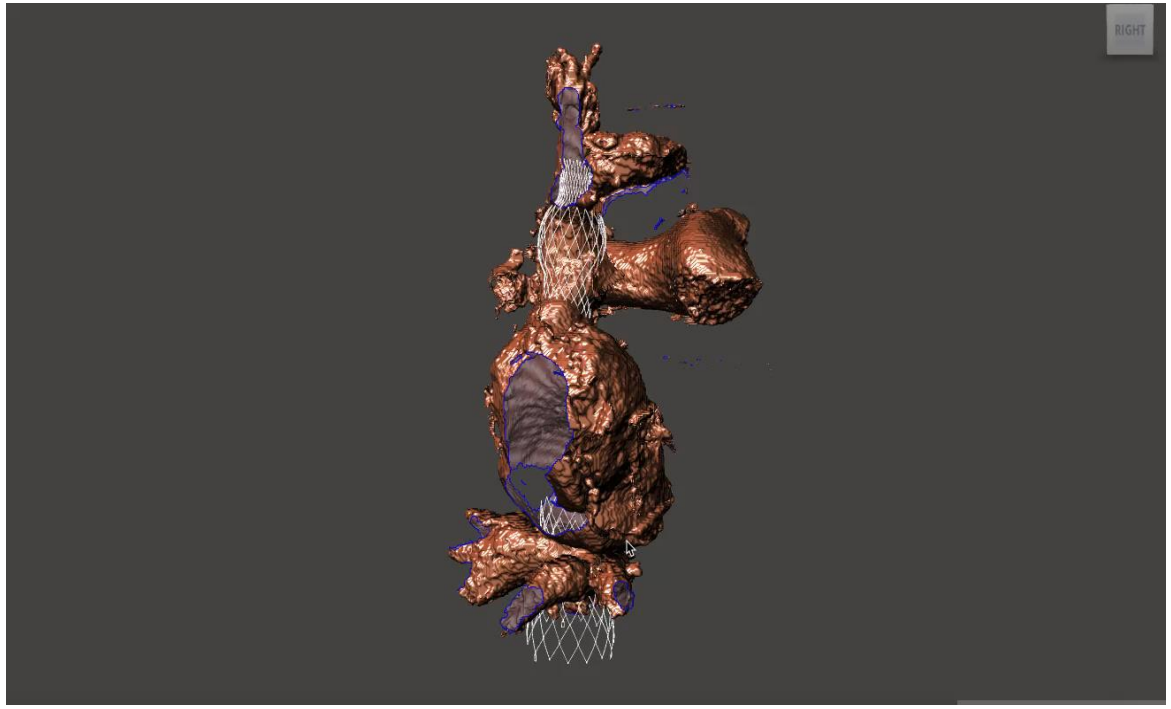
Recommendations on secondary tricuspid regurgitation		
Surgery is recommended in patients with severe secondary tricuspid regurgitation undergoing left-sided valve surgery.[423–427]	I	B
Surgery should be considered in patients with mild or moderate secondary tricuspid regurgitation with a dilated annulus (≥40 mm or >21 mm/m^2 by 2D echocardiography) undergoing left-sided valve surgery.[423,425–427]	IIa	B
Surgery should be considered in patients with severe secondary tricuspid regurgitation (with or without previous left-sided surgery) who are symptomatic or have RV dilatation, in the absence of severe RV or LV dysfunction and severe pulmonary vascular disease/hypertension.[418,423]	IIa	B
Transcatheter treatment of symptomatic secondary severe tricuspid regurgitation may be considered in inoperable patients at a Heart Valve Centre with expertise in the treatment of tricuspid valve disease.[f]	IIb	C

Di Mauro M, Bonalumi G, Giambuzzi I, Masiero G, Tarantini G. ***Isolated tricuspid regurgitation. A new entity to face with*** *. Minerva Cardiology Angiology 2023* [10.23736/S2724-5683.23.06294-4](https://doi.org/10.23736/S2724-5683.23.06294-4)



TRICVALVE® TRANSCATHETER BICAVAL VALVES

The TRICVALVE® TRANSCATHETER BICAVAL VALVES are made of a tubular metallic structure of nitinol which is self-expandable and radiopaque with three valve leaflets of bovine pericardium sutured and complemented by a skirt of polyester to avoid paravalvular leaks. The bioprosthesis leaflets are processed with anti-calcification as well as chemical dehydration. It is designed to treat severe tricuspid regurgitation without removal of the defective tricuspid valve.



- **Available Sizes:** 25 mm and 29 mm Valves
- **Treatment Range SVC 25:** superior vena cava from 22 mm to 31 mm
- **Treatment Range SVC 29:** superior vena cava from 27 mm to 34 mm
- **Frame Height (at relaxed state) SVC 25:** 67 mm
- **Frame Height (at relaxed state) SVC 29:** 69 mm
- **Leaflet Material:** Bovine pericardium
- **Skirt Material:** Bovine pericardium - long skirt to prevent para valvular leak (PVL)
- **Frame Material:** Nitinol

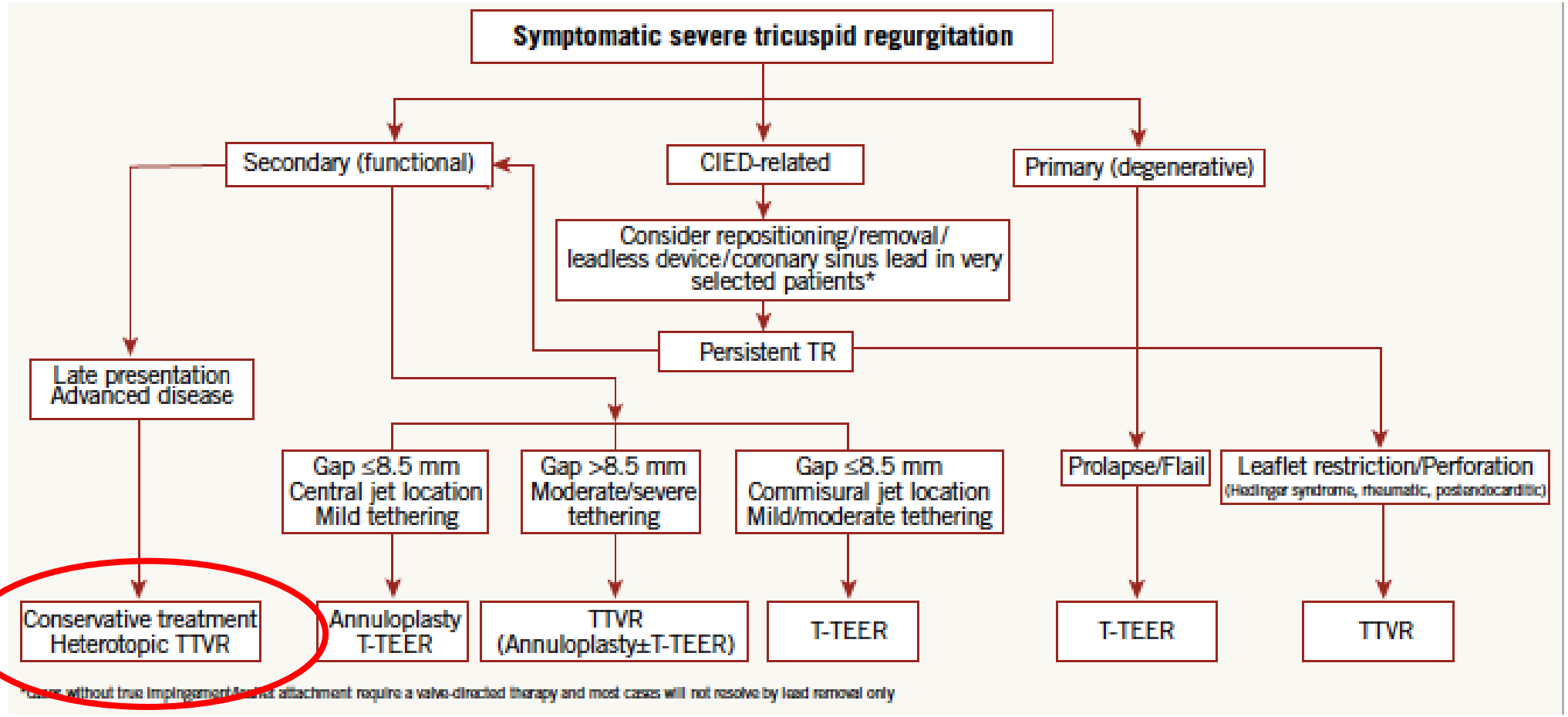
- **Available Sizes:** 31 mm and 35 mm valves
- **Treatment Range IVC 31:** inferior vena cava from 24 mm to 31 mm
- **Treatment Range IVC 35:** inferior vena cava from 28 mm to 35 mm
- **Frame Height (at relaxed state) IVC 31:** 65 mm
- **Frame Height (at relaxed state) IVC 35:** 65 mm
- **Leaflet Material:** Bovine pericardium
- **Skirt Material:** Bovine pericardium + PET - short skirt to prevent hepatic vein occlusion
- **Frame Material:** Nitinol

State of the Art
by EuroIntervention

EuroIntervention 2021;17:791-808

Transcatheter treatment for tricuspid valve disease

Fabien Praz[1*], MD; Denisa Muraru[2], MD; Felix Kreidel[3], MD; Philipp Lurz[4], MD; Rebecca T. Hahn[5], MD; Victoria Delgado[6], MD; Michele Senni[7], MD; Ralph Stephan von Bardeleben[3], MD; Georg Nickenig[8], MD; Jörg Hausleiter[9], MD; Antonio Mangieri[10], MD; Jose L. Zamorano[11], MD; Bernard Prendergast[12], MD; Francesco Maisano[13], MD



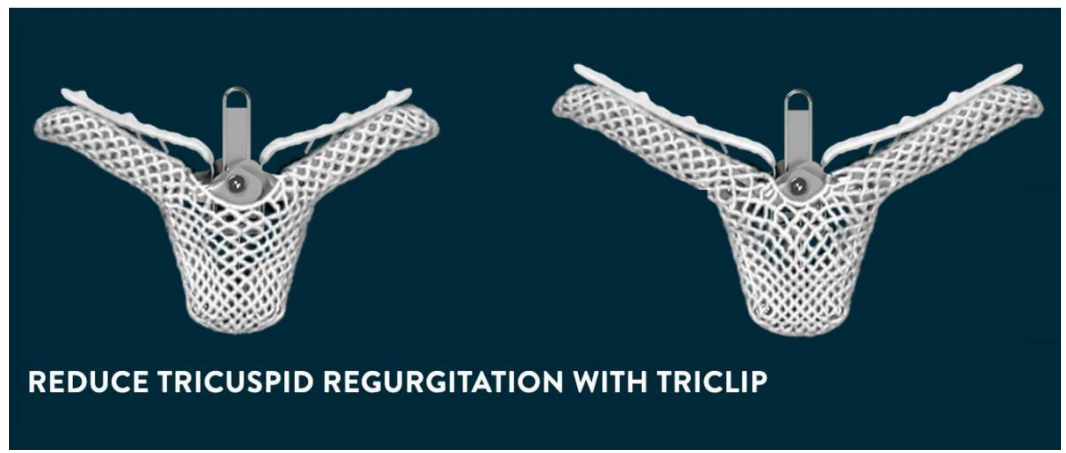
The NEW ENGLAND JOURNAL of MEDICINE

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

Transcatheter Repair for Patients with Tricuspid Regurgitation

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

ABSTRACT



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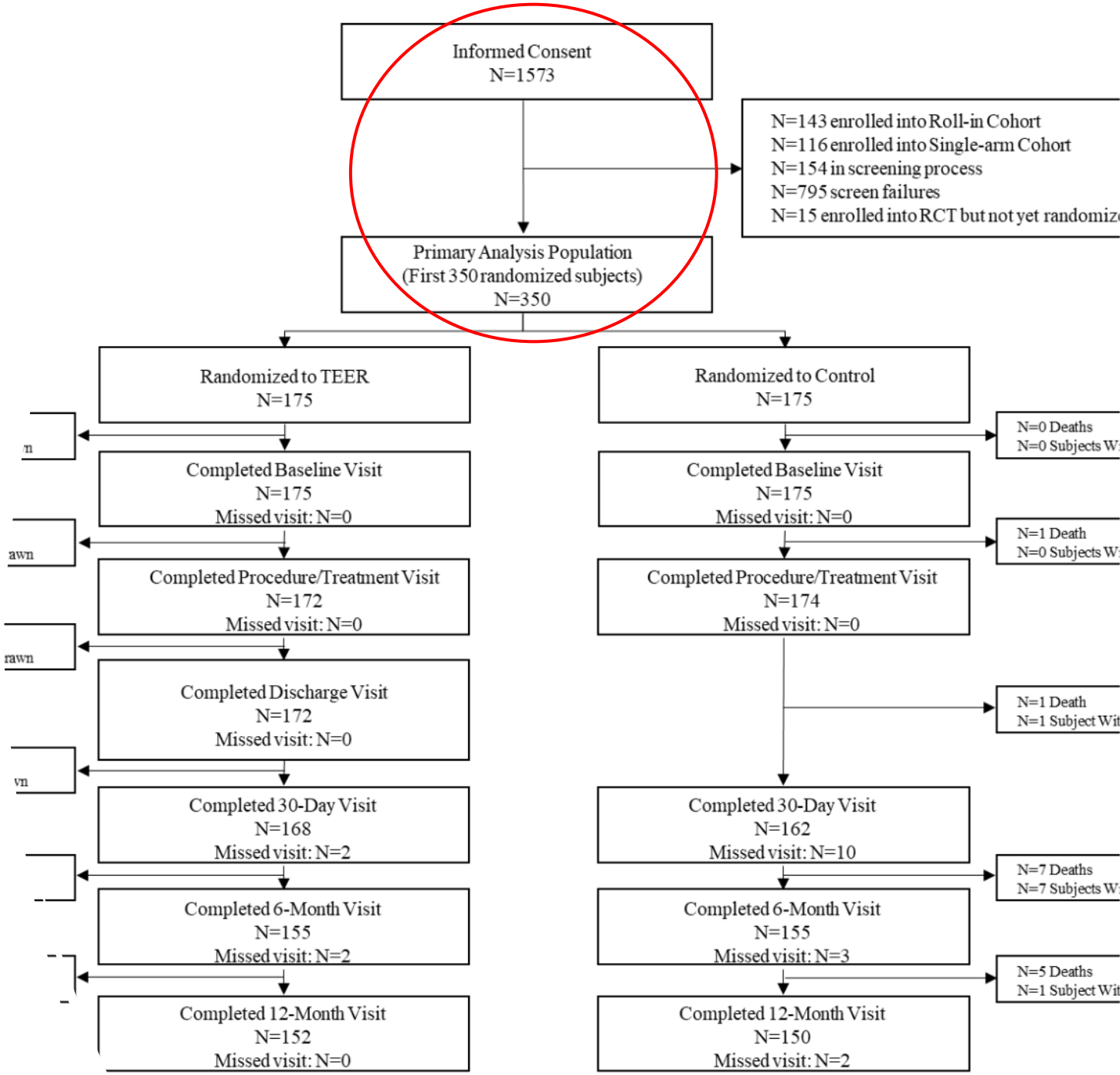
ABSTRACT

- The screening failure rate in the TRILUMINATE trial was approximately 50%, with ultimately **22% of the consented patients randomized**



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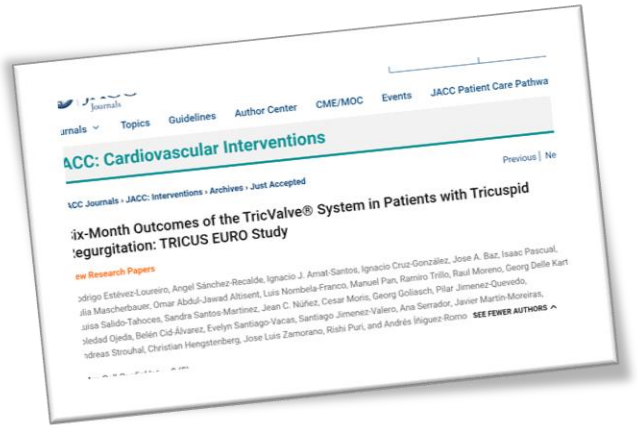
N=143 enrolled into Roll-in Cohort
N=116 enrolled into Single-arm Cohort
N=154 in screening process
N=795 screen failures
N=15 enrolled into RCT but not yet randomized

Six-Month Outcomes of the TricValve® System in Patients with Tricuspid Regurgitation: TRICUS EURO Study

New Research Papers

Rodrigo Estévez-Loureiro, Angel Sánchez-Recalde, Ignacio J. Amat-Santos, Ignacio Cruz-González, Jose A. Baz, Isaac Pascual, Julia Mascherbauer, Omar Abdul-Jawad Altisent, Luis Nombela-Franco, Manuel Pan, Ramiro Trillo, Raul Moreno, Georg Delle Karth , Luisa Salido-Tahoces, Sandra Santos-Martinez, Jean C. Núñez, Cesar Moris, Georg Goliasch, Pilar Jimenez-Quevedo, Soledad Ojeda, Belén Cid-Álvarez, Evelyn Santiago-Vacas, Santiago Jimenez-Valero, Ana Serrador, Javier Martín-Moreiras, Andreas Strouhal, Christian Hengstenberg, Jose Luis Zamorano, Rishi Puri, and Andrés Íñiguez-Romo SEE FEWER AUTHORS

J Am Coll Cardiol Intv. , 0 (0)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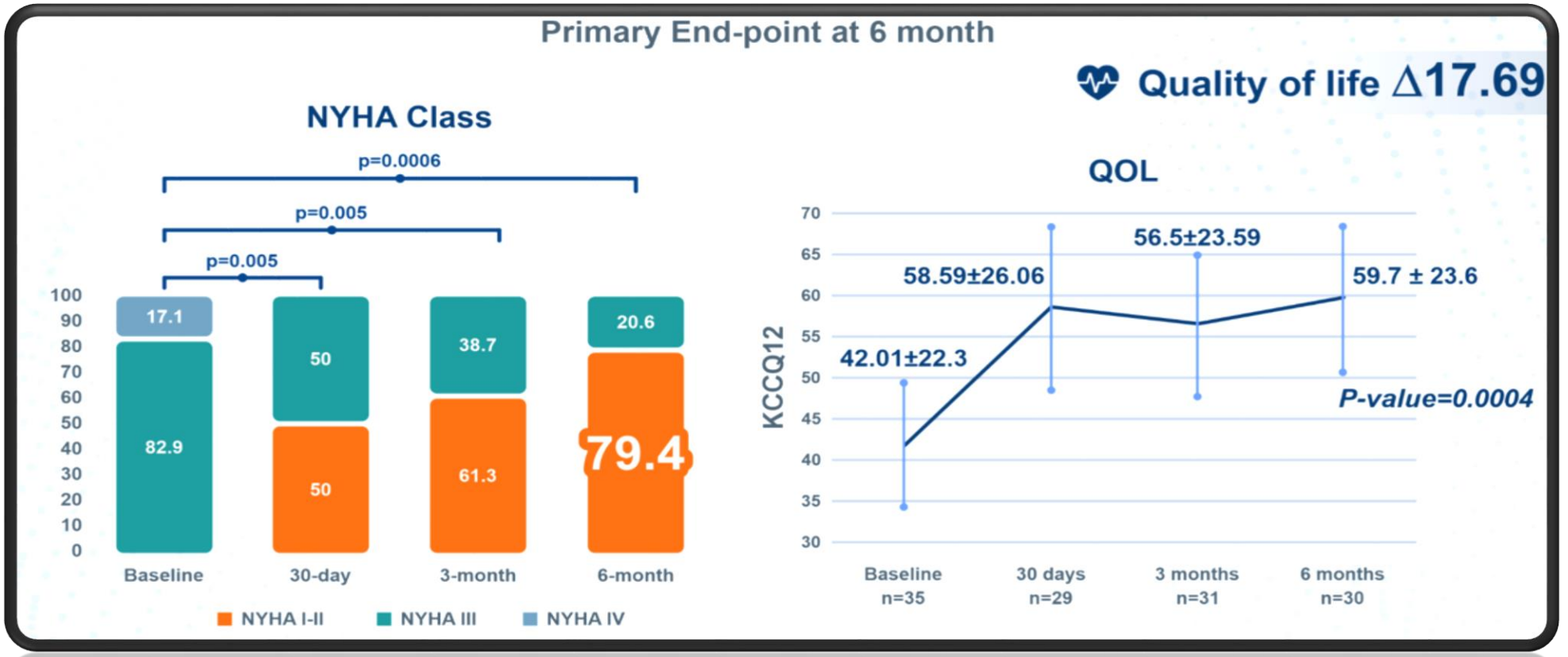
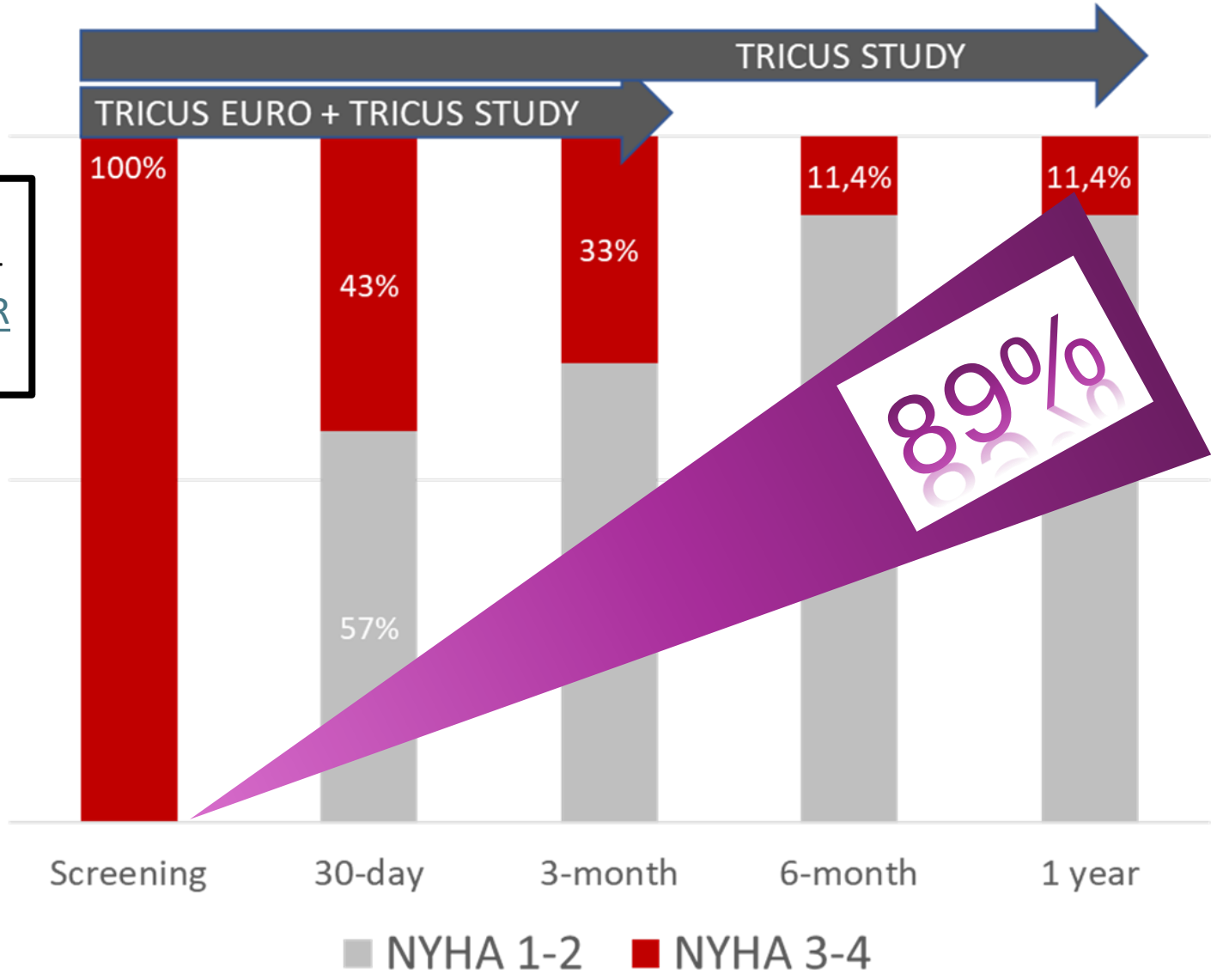


BICAVAL TRICVALVE IMPLANTATION IN PATIENTS WITH SEVERE SYMPTOMATIC TRICUSPID REGURGITATION: 1-YEAR FOLLOW-UP OUTCOMES. JACC: CARDIOVASCULAR INTERVENTIONS VOLUME 17, ISSUE 1, 2024: 60-72



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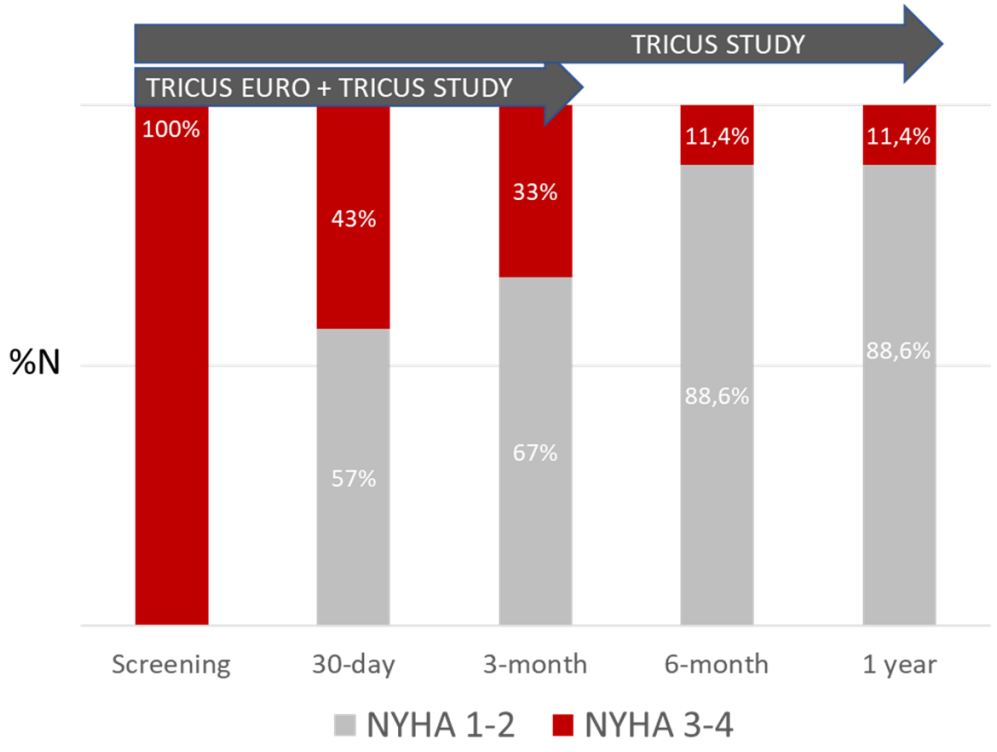

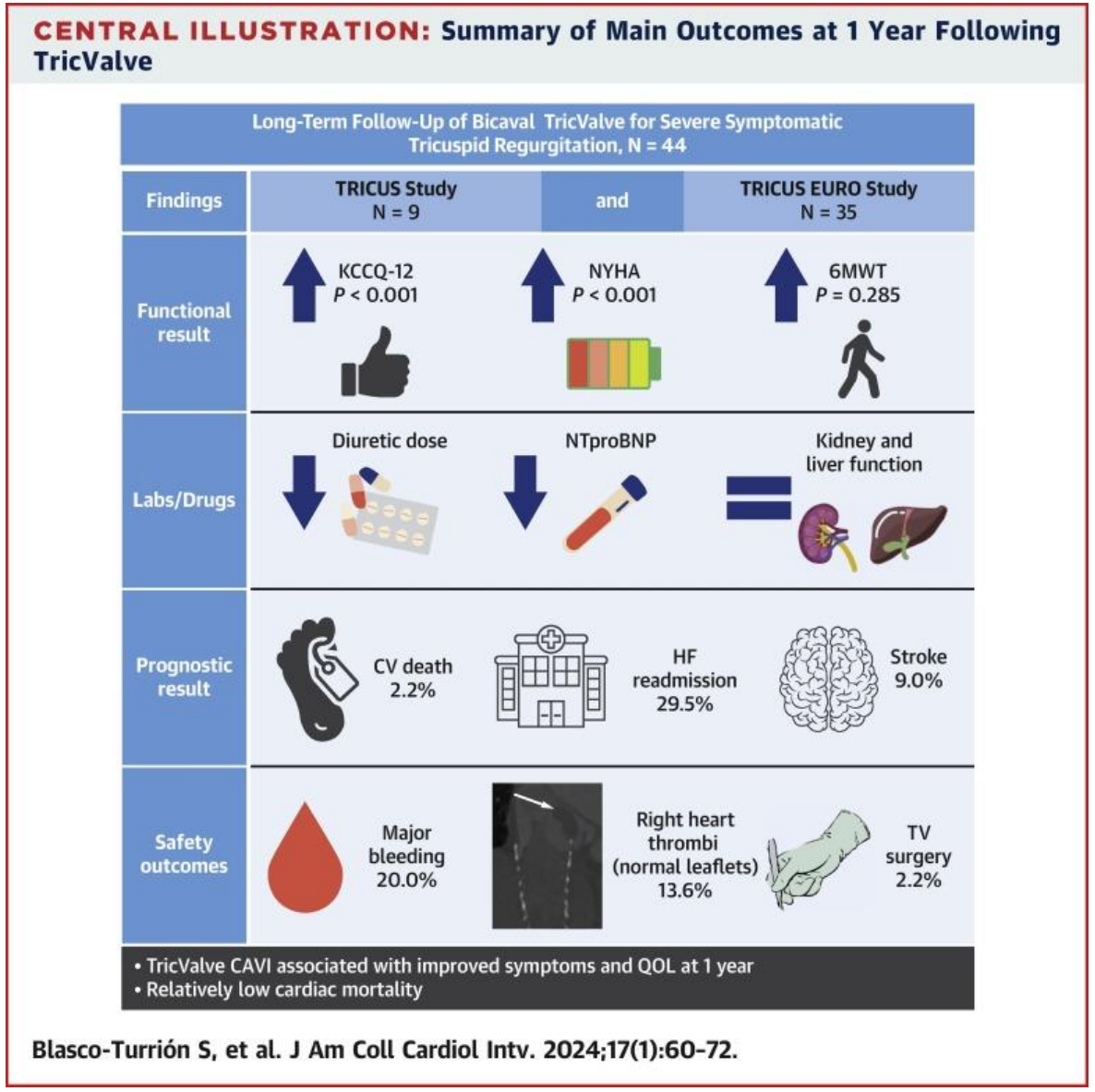

International Journal of Cardiology 402 (2024) 131864

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Transcatheter bicaval valve system for the treatment of severe isolated tricuspid regurgitation. Features from a single-Centre experience

Michele Di Mauro [a,c,1,*], Stefano Guarracini [a,1], Lorenzo Mazzocchetti [a], Donato Capuzzi [a], Lorenzo Salute [a], Massimo Di Marco [b], Roberto Lorusso [c,d,2], Antonio M. Calafiore [e,2]

Baseline clinical, echocardiographic and technical characteristics.

Variables	$N = 13$
Age (years)	81 (77–87)
Gender	
Female	5 (38%)
Male	8 (62%)
Causative Disease Process[§]	
Atrial secondary TR	10 (77%)
CIED-related TR	3 (23%)
Ventricular secondary TR *	3 (23%)
NYHA class	
III	4 (31%)
IV	9 (69%)
LVEF (%)	50 (41–58)
No. of previous hospital admission for RHF	
1	3 (23%)
2	7 (54%)
3	2 (15%)
4	1 (8%)
CRD	10 (77%)
Liver congestion	6 (46%)
Bilirubine mg/dL)	1.49 (1.02–1.86)
AST (U/L)	40 (30–76)
ALT (U/L)	31 (21–55)
PAL (U/L)	212 (113–324)
Ascites	5/6
Peripheral oedema	13 (100%)
RHF	13 (100%)
TR grade	
Severe	3 (23%)
Massive	6 (46%)
Torrential	4 (31%)
RVD	6 (46%)
sPAP (mmHg)	39 (30–45)
Furosemide dosage	125 (125–250)
EuroSCORE II (%)	9 (5–15)
TriSCORE	8 (6–9)
MELD SCORE	14 (9–16)
End-stage condition	2 (16%)
SVC/IVC prosthesis size	
25/31	6 (46%)
25/35	7 (54%)

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Echocardiographic data at baseline and follow up.

Variables	Baseline	Follow up	*p*-value
LVEF (%)	50 (41–58)	55 (41–58)	0.075
RV dysfunction	4 (36%)	2 (18%)	0.555
RV diameter, basal (mm)	43 (40–45)	38 (36–41)	0.011
RA diameter, major (mm)	60 (53–65)	60 (54–66)	0.534
RA diameter, minor (mm)	51 (44–56)	52 (45–56)	0.058
Hepatic vein backflow	10 (91%)	5 (45%)	0.054

Legend. LVEF = left ventricular ejection fraction, RV = right ventricle, RA = right atrium.

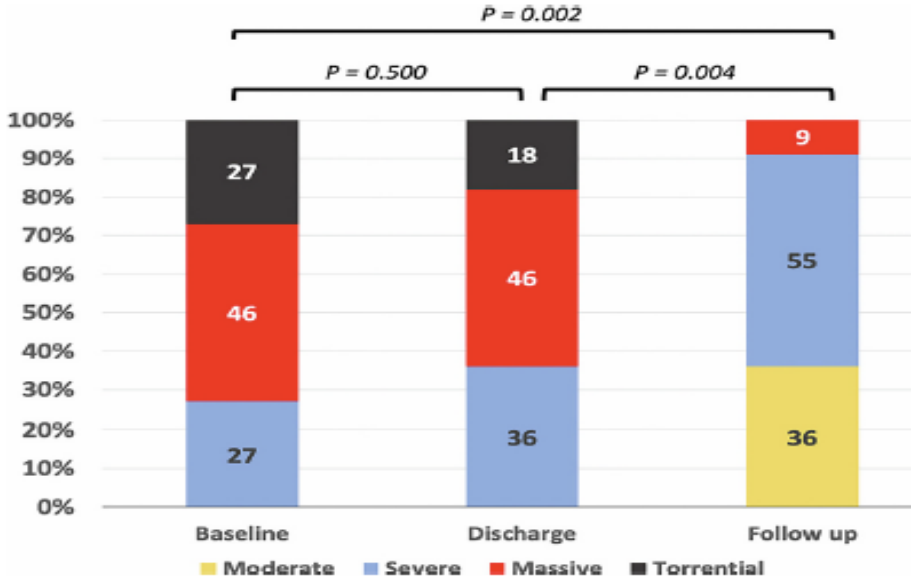
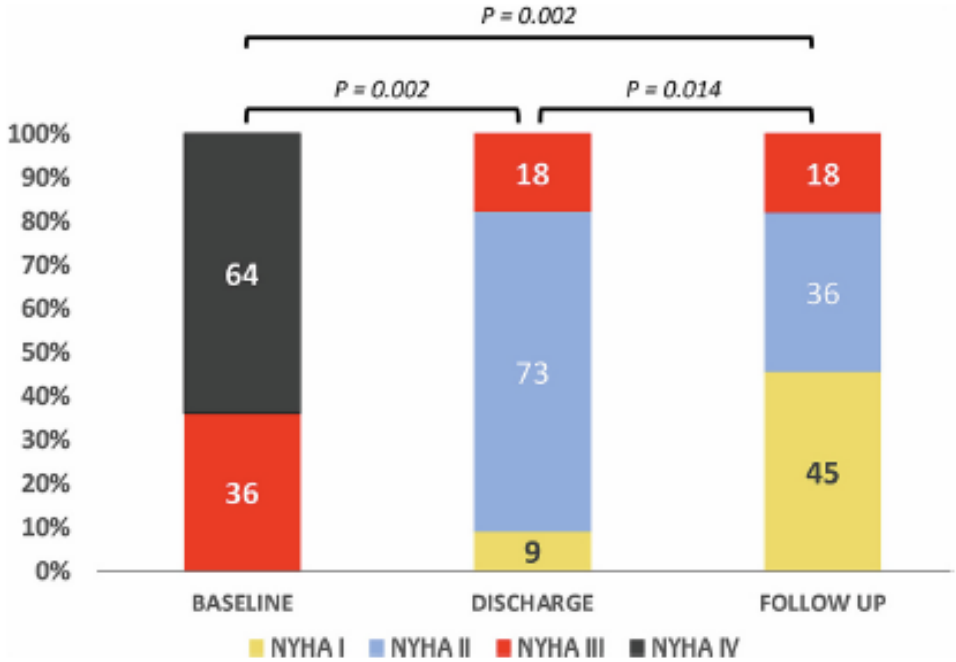
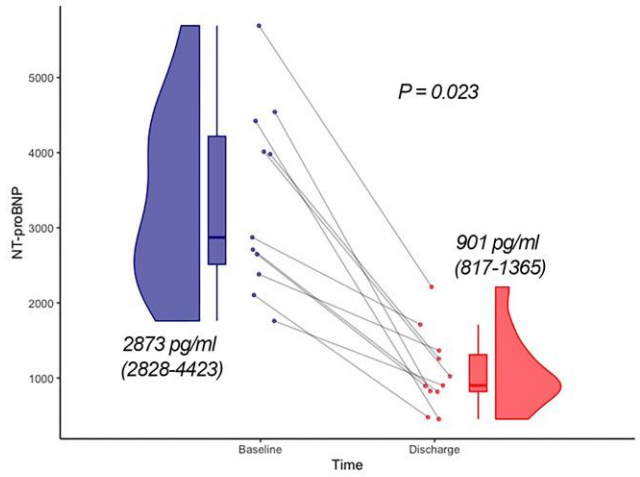
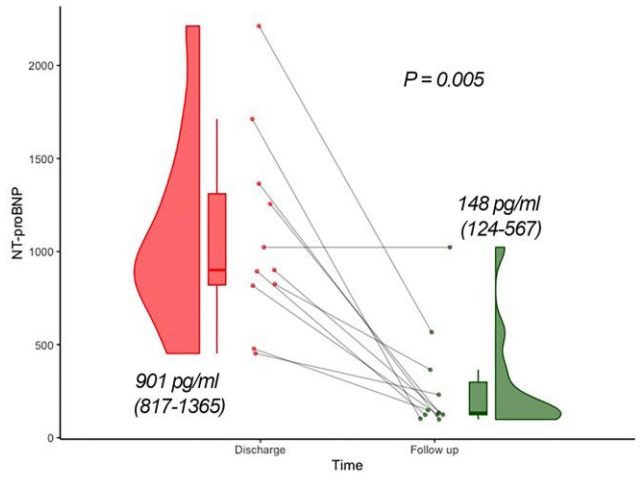
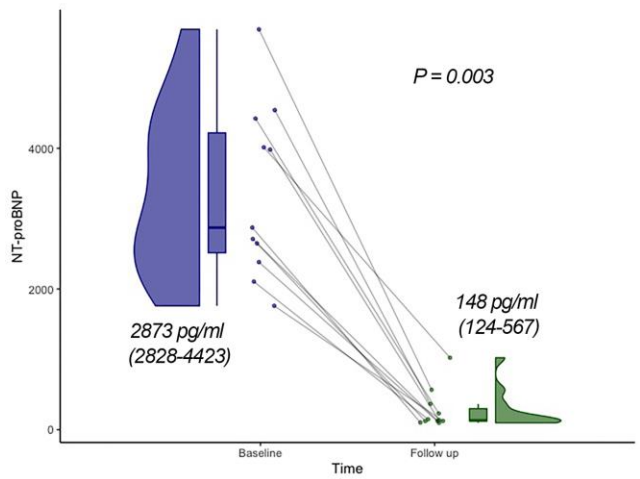


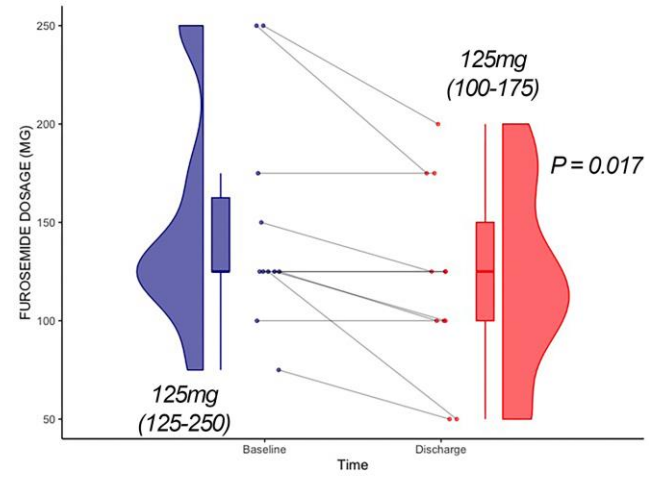
Fig. 2. Modification of Tricuspid grade (TR) class across time.

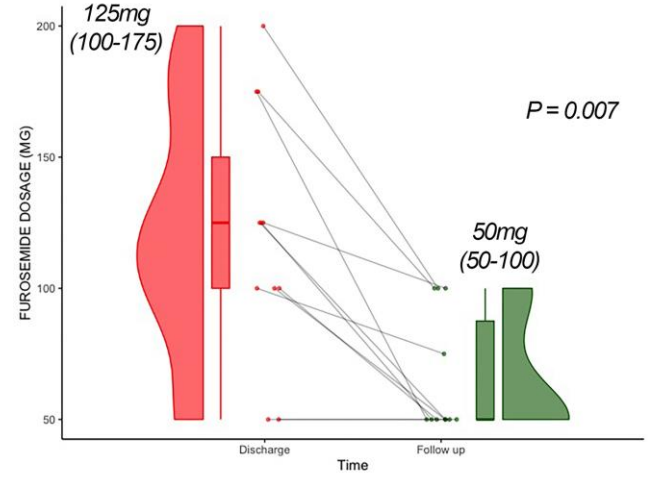


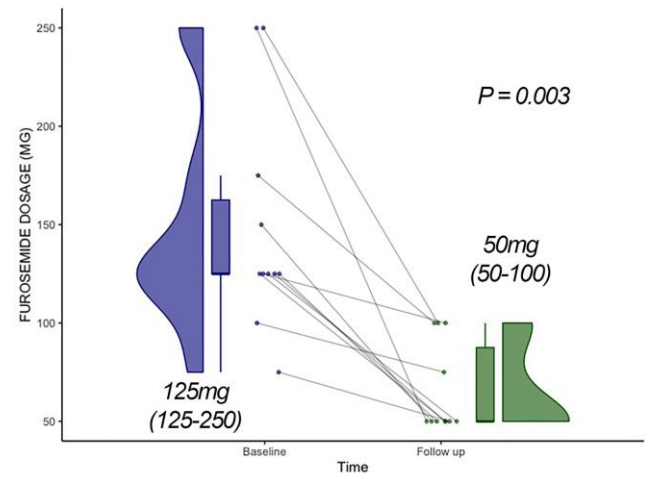












EUROVALVE
& STRUCTURAL CARDIOMYOPATHIES
NH PALERMO

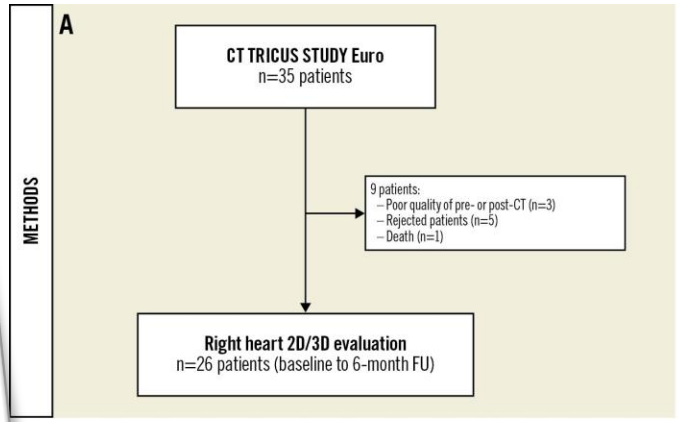
RESEARCH CORRESPONDENCE

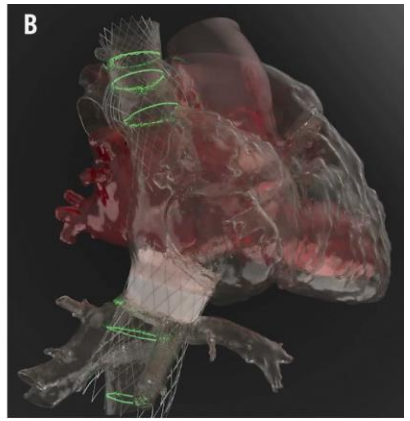
DOI: 10.4244/EIJ-D-23-00077

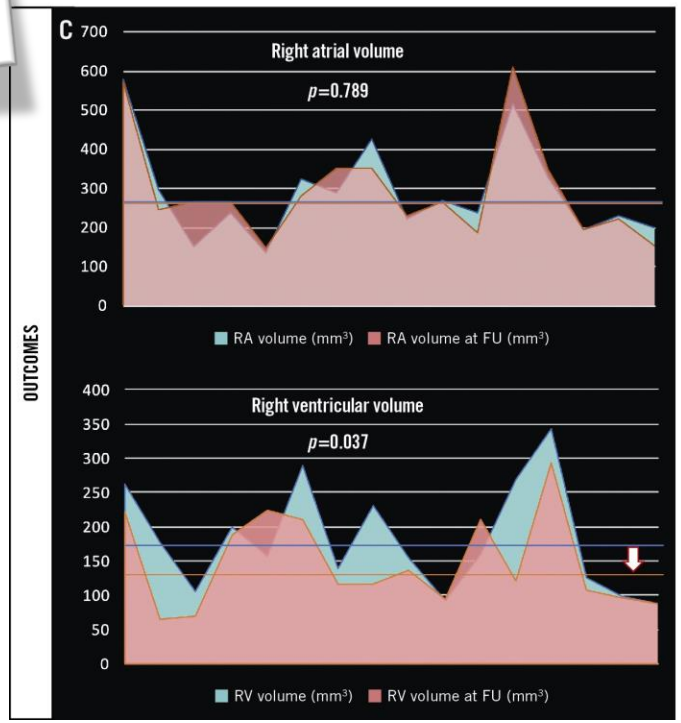
Right heart remodelling after bicaval TricValve implantation in patients with severe tricuspid regurgitation

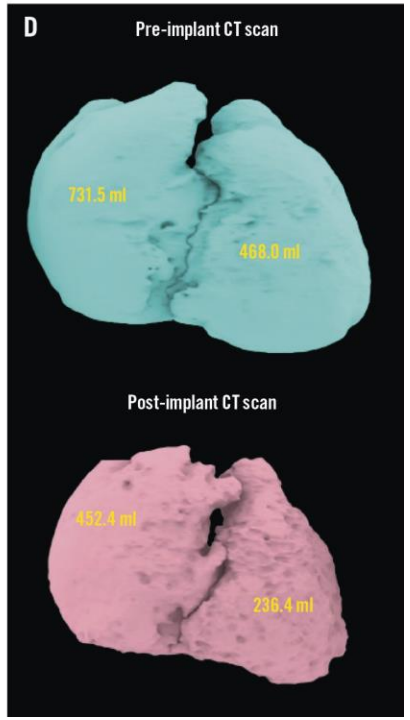
Ignacio J. Amat-Santos[1,2], MD, PhD; Rodrigo Estevez-Loureiro[3], MD, PhD; Ángel Sánchez-Recalde[4], MD, PhD; Ignacio Cruz-González[1,5], MD, PhD; Isaac Pascual[1,6], MD, PhD; Julia Mascherbauer[7], MD, PhD; Omar Abdul-Jawad Altisent[1,8], MD, PhD; Luis Nombela-Franco[9], MD, PhD; Manuel Pan[10], MD, PhD; Ramiro Trillo[1,11], MD, PhD; Raul Moreno[12], MD, PhD; Georg Delle Karth[13], MD, PhD; Sara Blasco-Turrión[2], MD; Juan Pablo Sanchez-Luna[2], MD; Ana Revilla-Orodoea[1,2], MD, PhD; Alfredo Redondo[2], MD; Jose Luis Zamorano[1,4], MD, PhD; Rishi Puri[14], MBBS, PhD; Andrés Íñiguez-Romo[3], MD, PhD; Alberto San Román[1,2], MD, PhD;

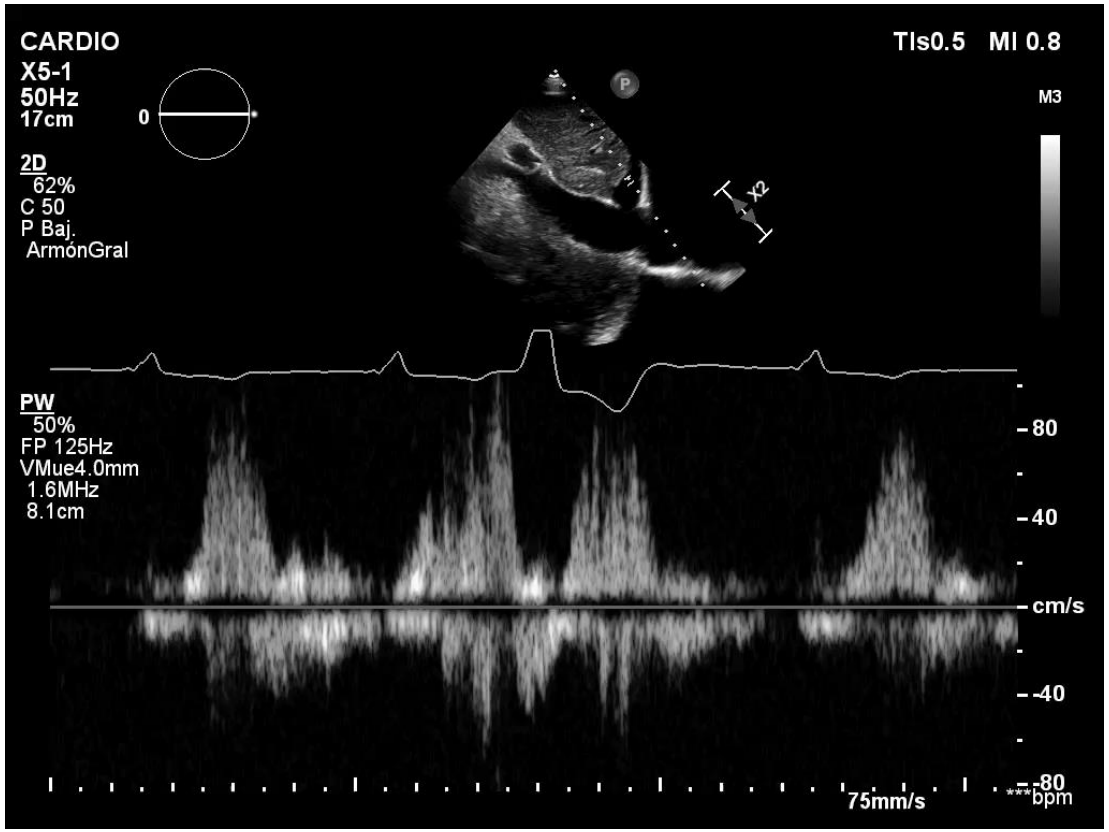
	RAVolume	RVVolume
PreCTscan	731,5 ml	468,0 ml
PostCTscan	452,4 ml	236,4 ml
Reduction %	38,1	49,4

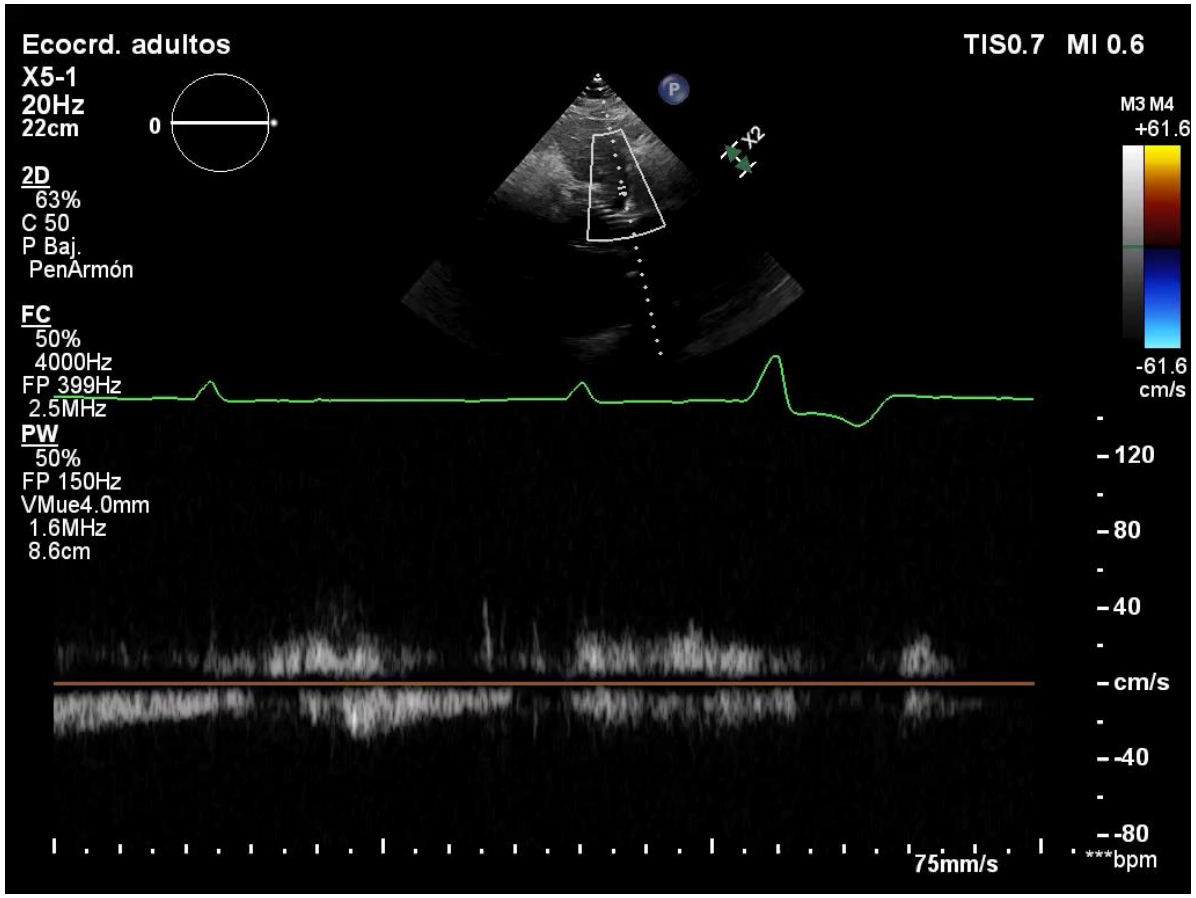




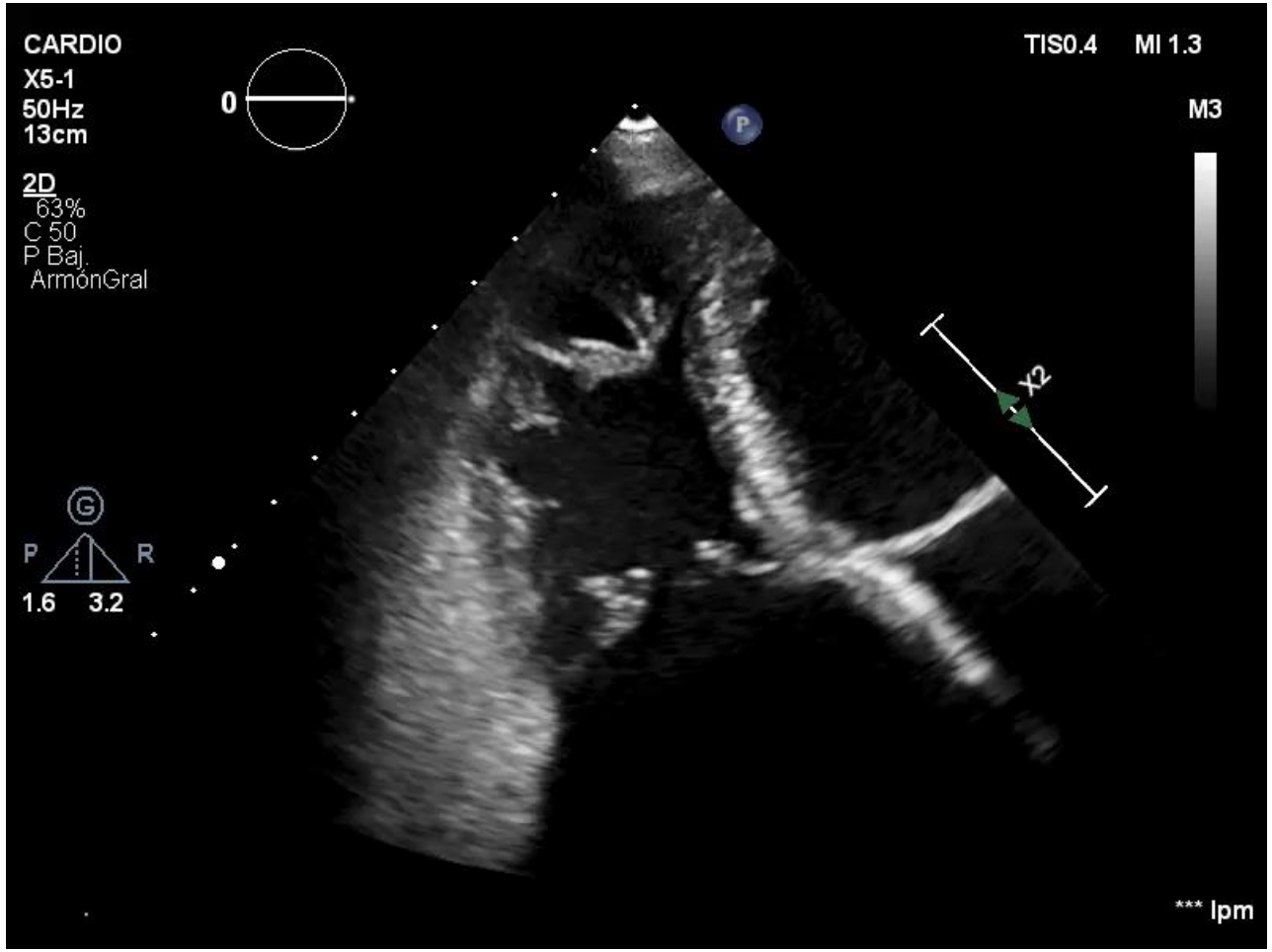


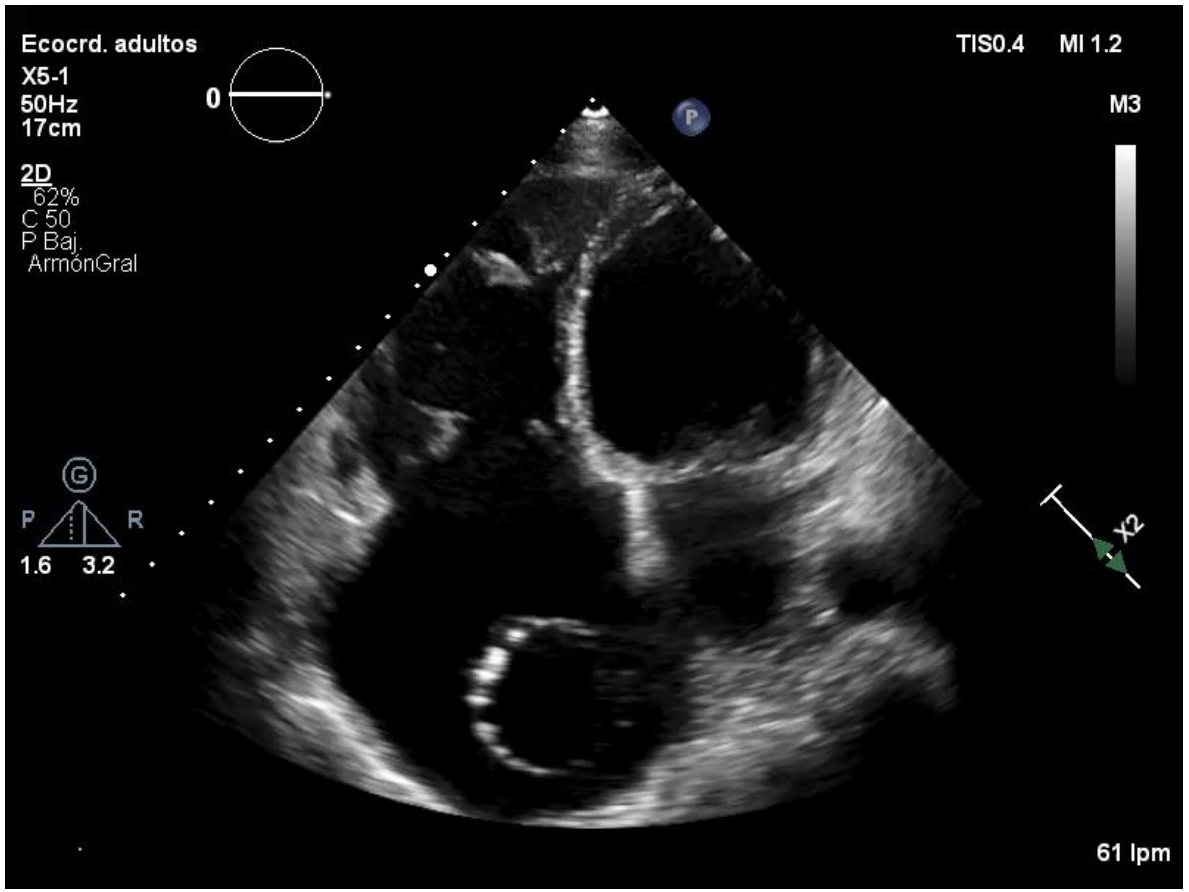






Abolition of backflow


CARDIO
X5-1
50Hz
13cm
2D
63%
C 50
P Baj.
ArmónGral
TIS0.4 MI 1.3
M3
X2
P R
1.6 3.2
*** lpm


Ecocrd. adultos
X5-1
50Hz
17cm
2D
62%
C 50
P Baj.
ArmónGral
TIS0.4 MI 1.2
M3
X2
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1.6 3.2
61 lpm

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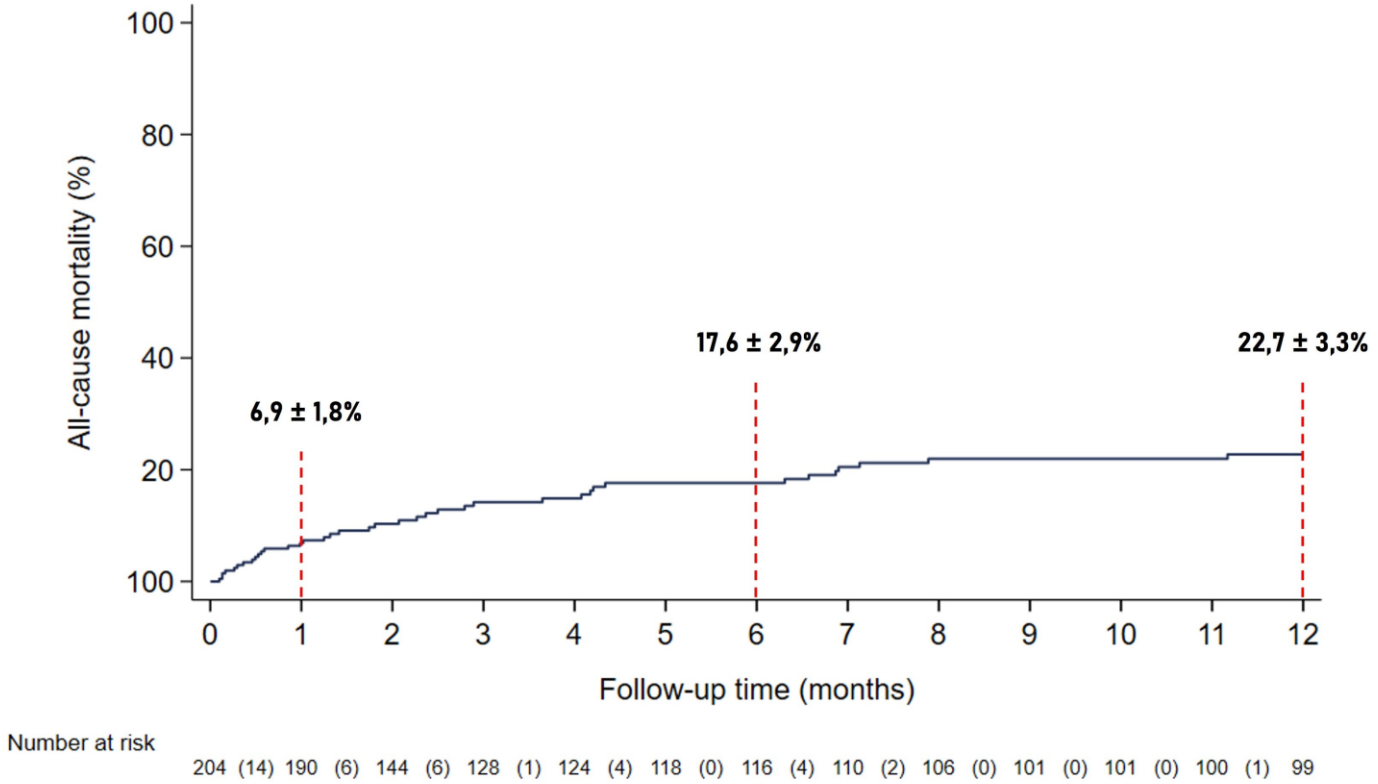
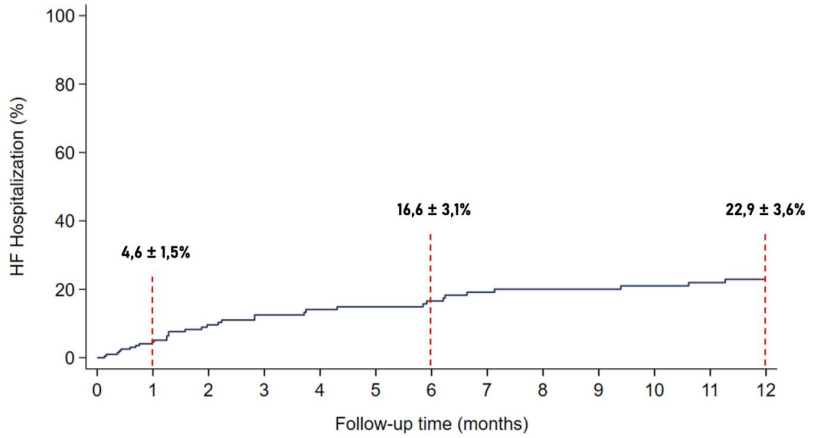
A) All-Cause Mortality



Number at risk

204 (14) 190 (6) 144 (6) 128 (1) 124 (4) 118 (0) 116 (4) 110 (2) 106 (0) 101 (0) 101 (0) 100 (1) 99

B) Heart Failure Hospitalization



Number at risk

204 (9) 182 (8) 133 (4) 115 (2) 109 (1) 102 (2) 98 (3) 91 (1) 88 (0) 83 (1) 82 (1) 81 (1) 79

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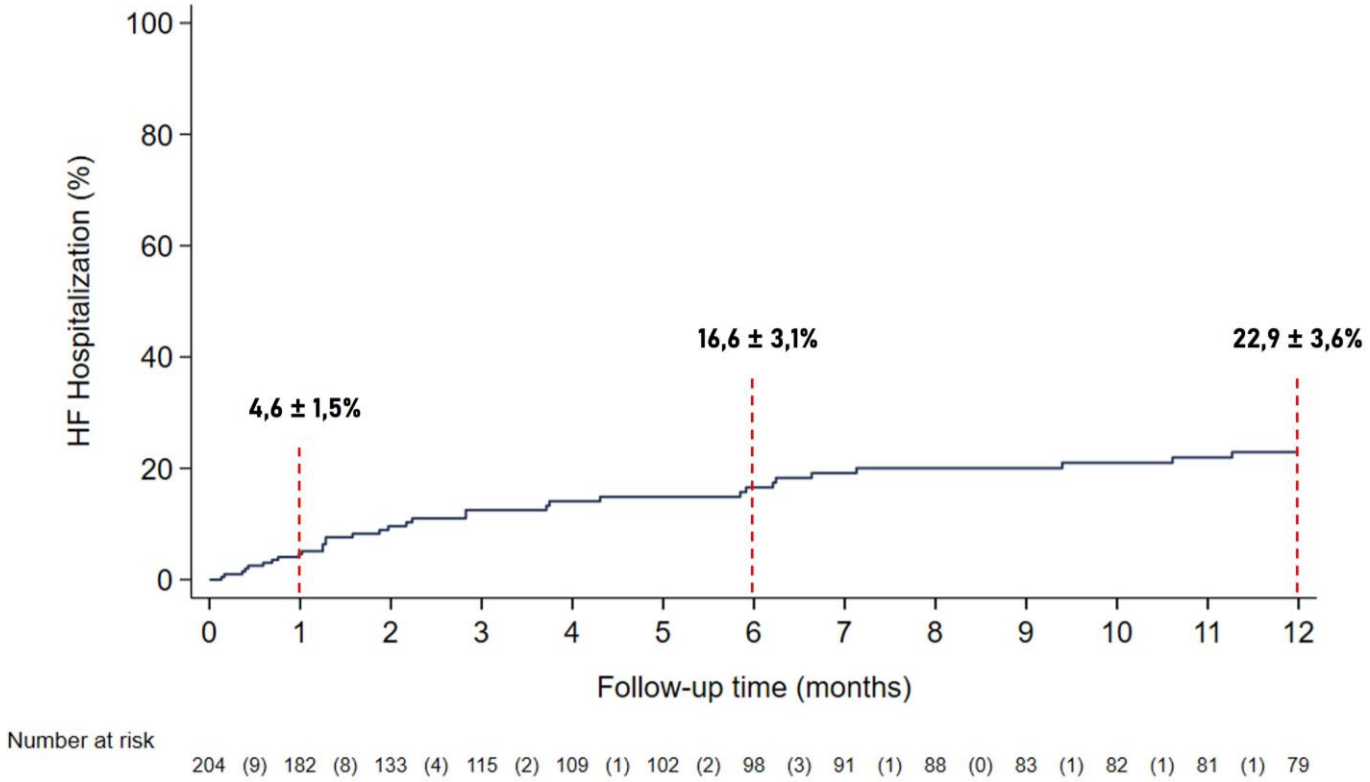
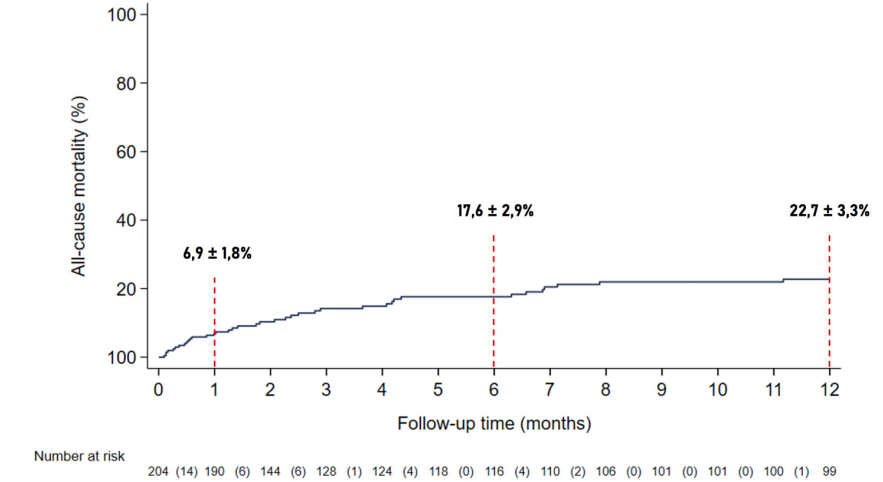
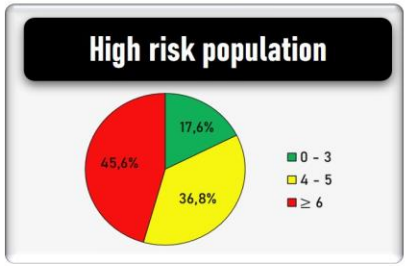


A) All-Cause Mortality

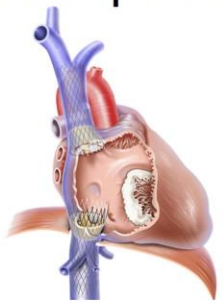


THE TRICBICAVAL REGISTRY

- 204 patients
- 27 hospitals (Europe, Brazil)
- Severe to torrential TR
- Refractory right HF
- Not suitable for other devices



TricValve implantation



96,1% procedural success

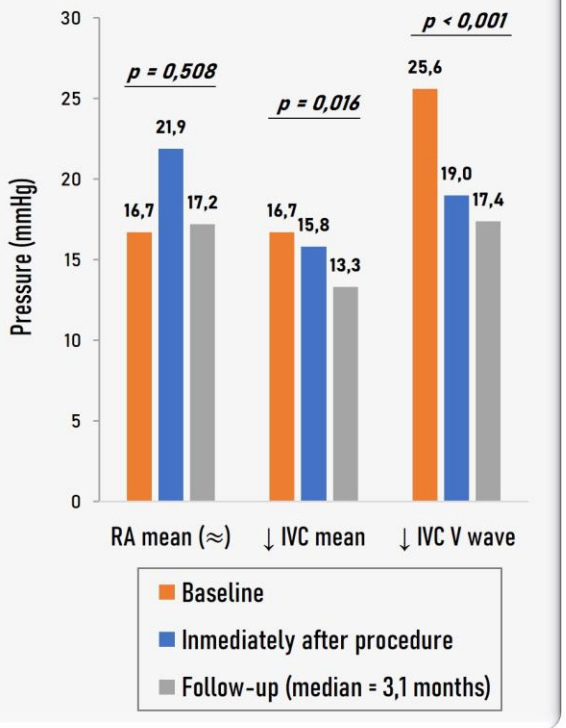
12 months

27,0% all-cause mortality

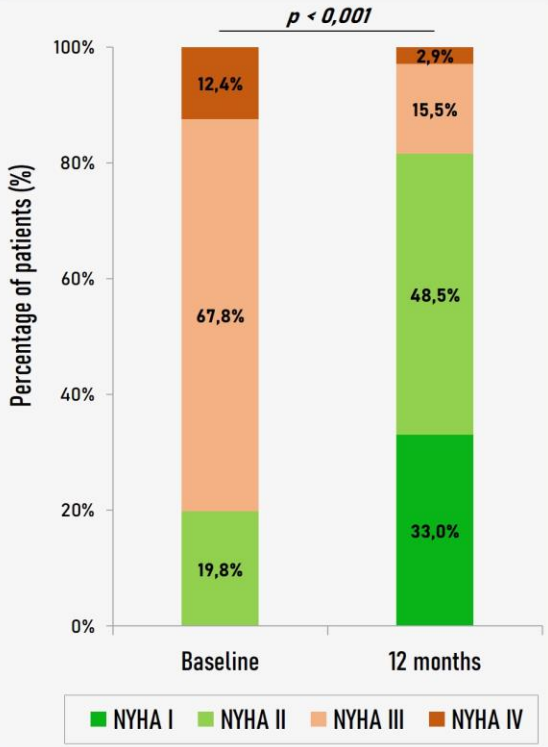
27,7% MAEs

- Life-threatening bleeding (TVARC 5): 5,7%
- Major vascular access complication: 5,4%
- Major cardiac complication: 8,5%
- AKI requiring dialysis: 6,4%
- Device diysfunction requiring reintervention: 2,8%

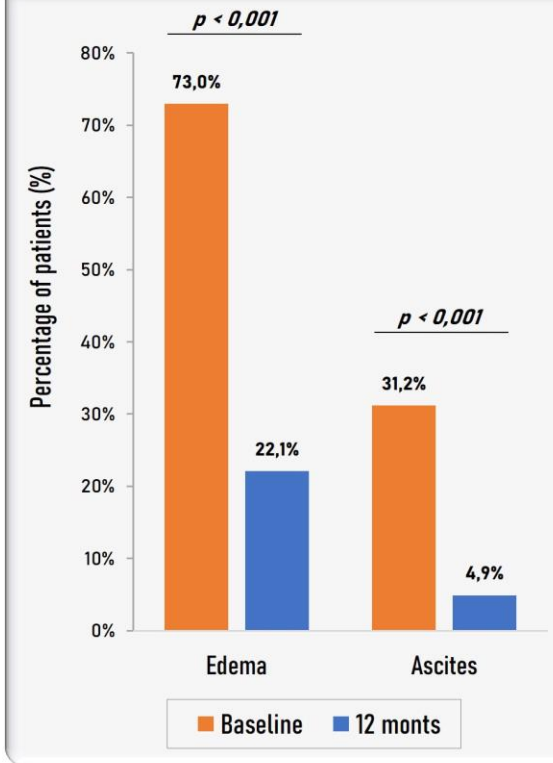
HEMODYNAMIC IMPROVEMENT



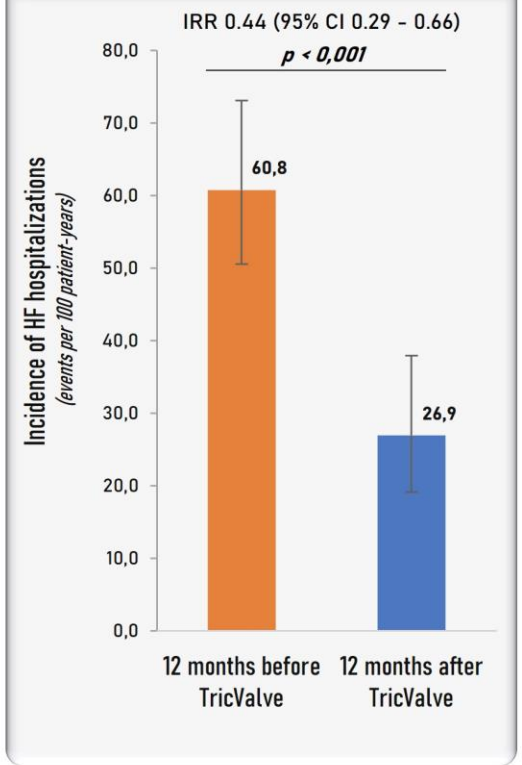
↑ FUNCTIONAL CLASS



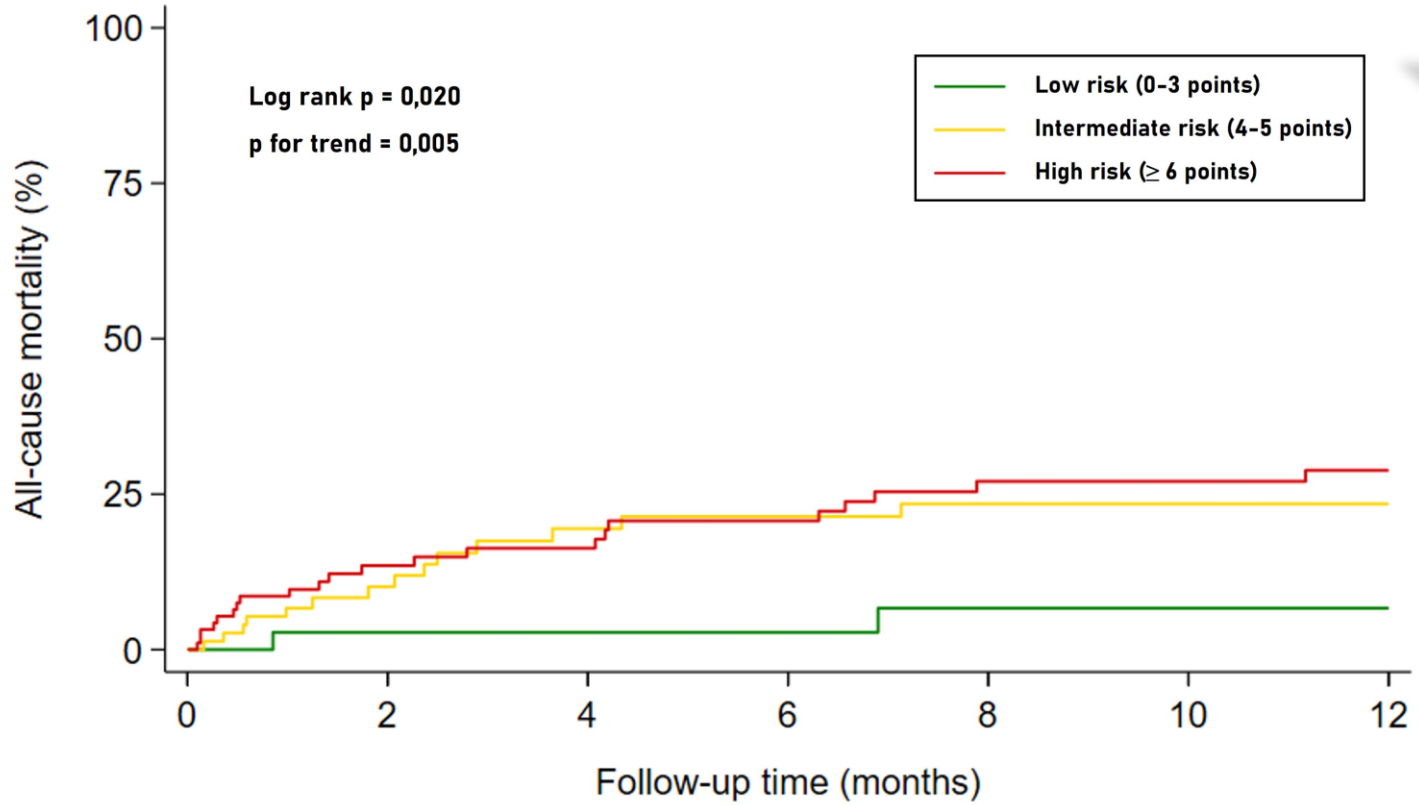
↓ SIGNS OF RIGHT HF



↓ HF HOSPITALIZATIONS



TRI-SCORE as predictor of all-cause Mortality



Number at risk													
Low risk (0-3 points)	36	(1)	29	(0)	26	(0)	25	(1)	24	(0)	22	(0)	22
Intermediate risk (4-5 points)	75	(7)	50	(5)	41	(1)	40	(1)	38	(0)	37	(0)	37
High risk (≥6 points)	93	(12)	65	(2)	57	(3)	51	(4)	44	(0)	42	(1)	40

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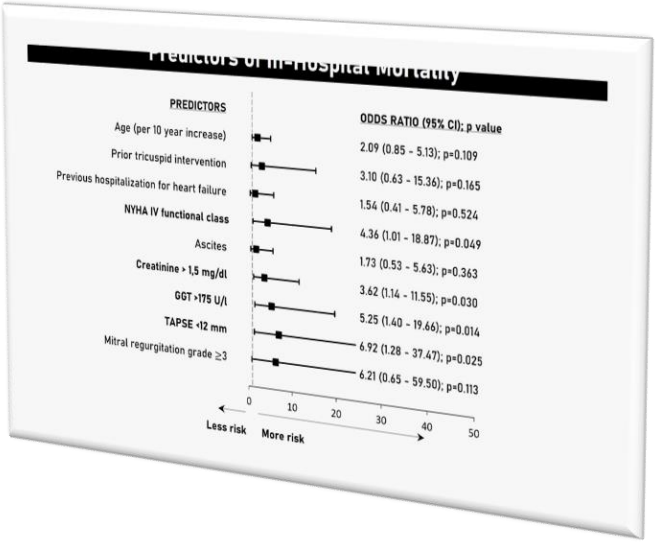
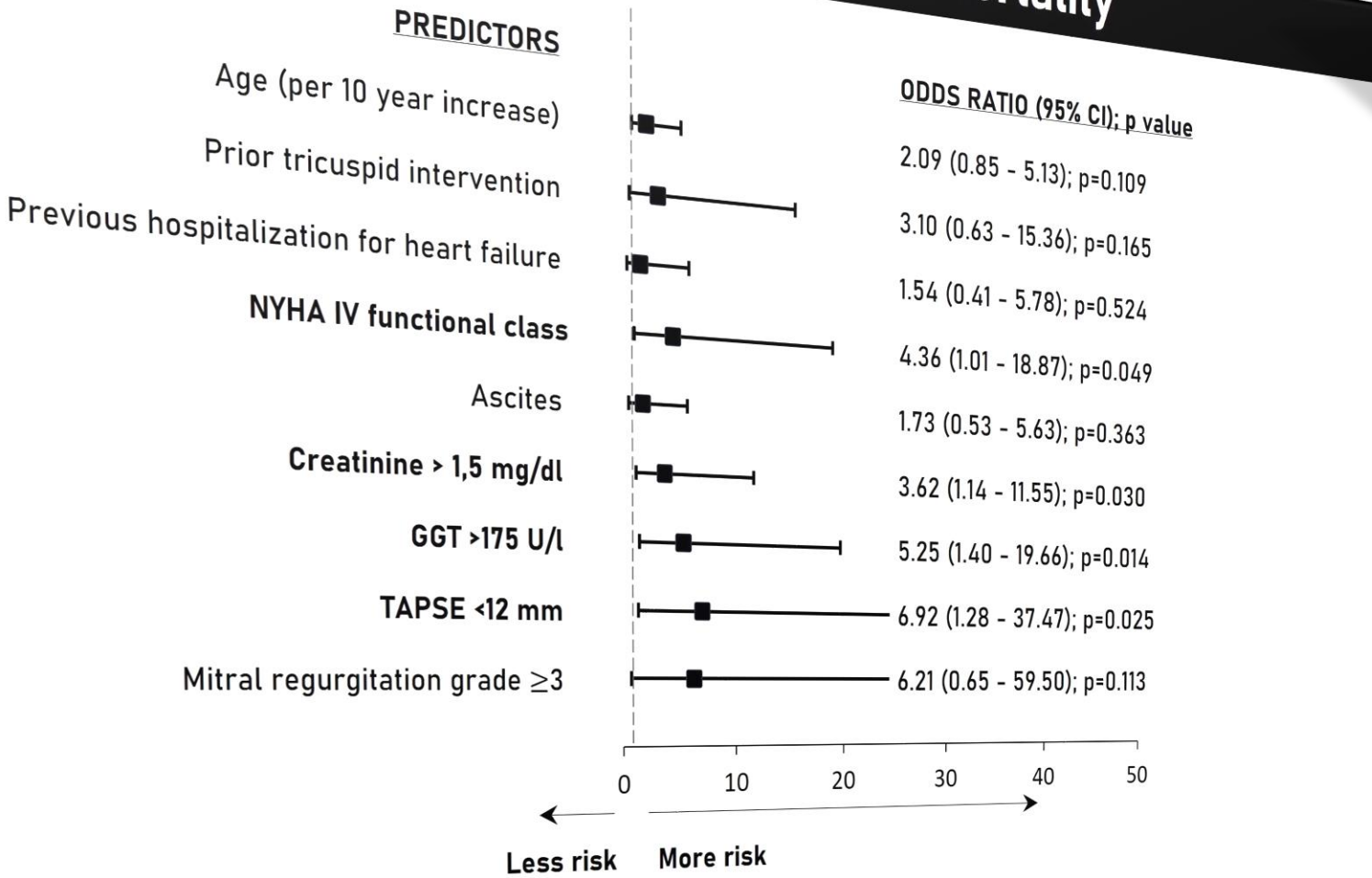


Predictors of In-Hospital Mortality



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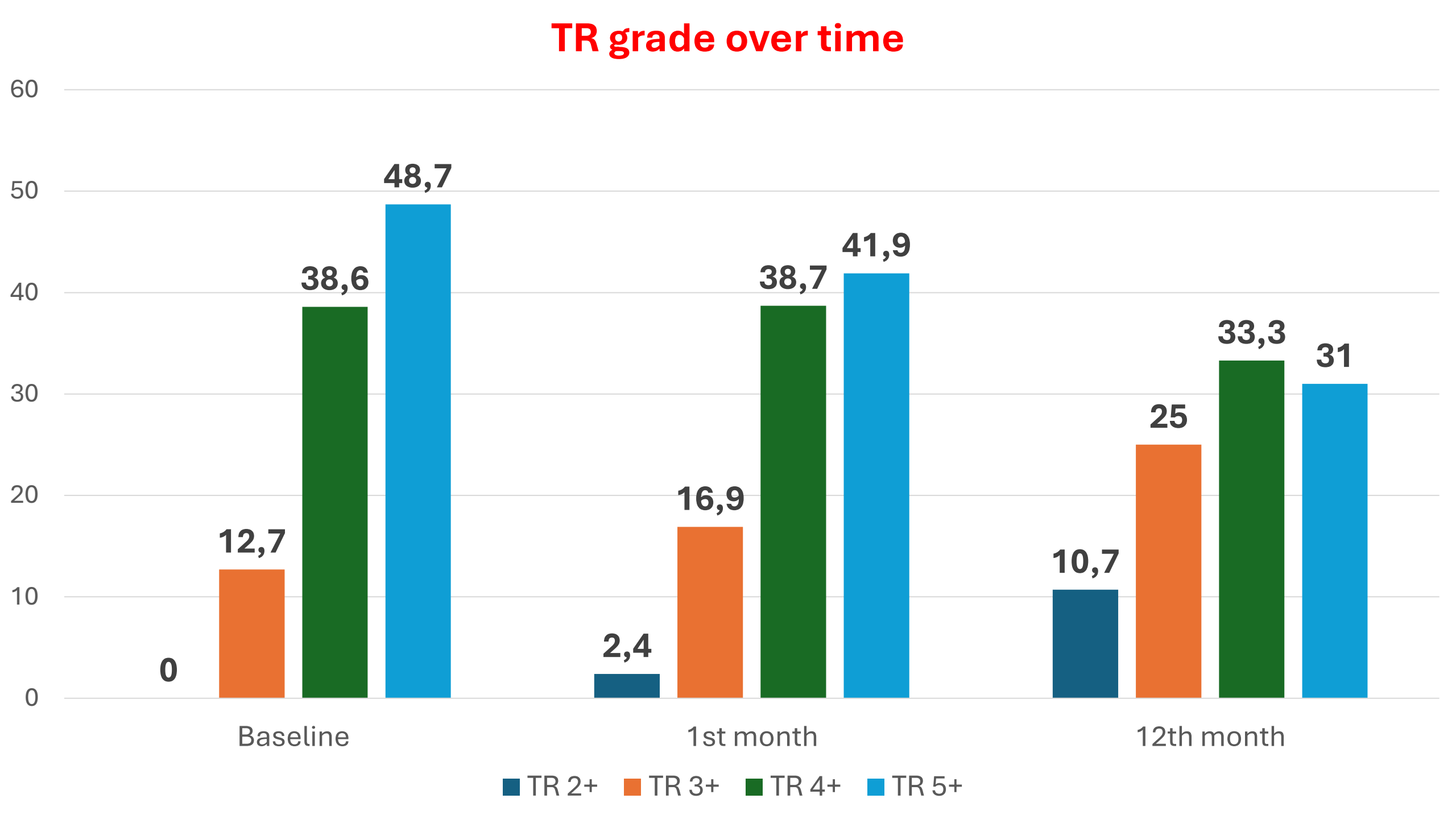
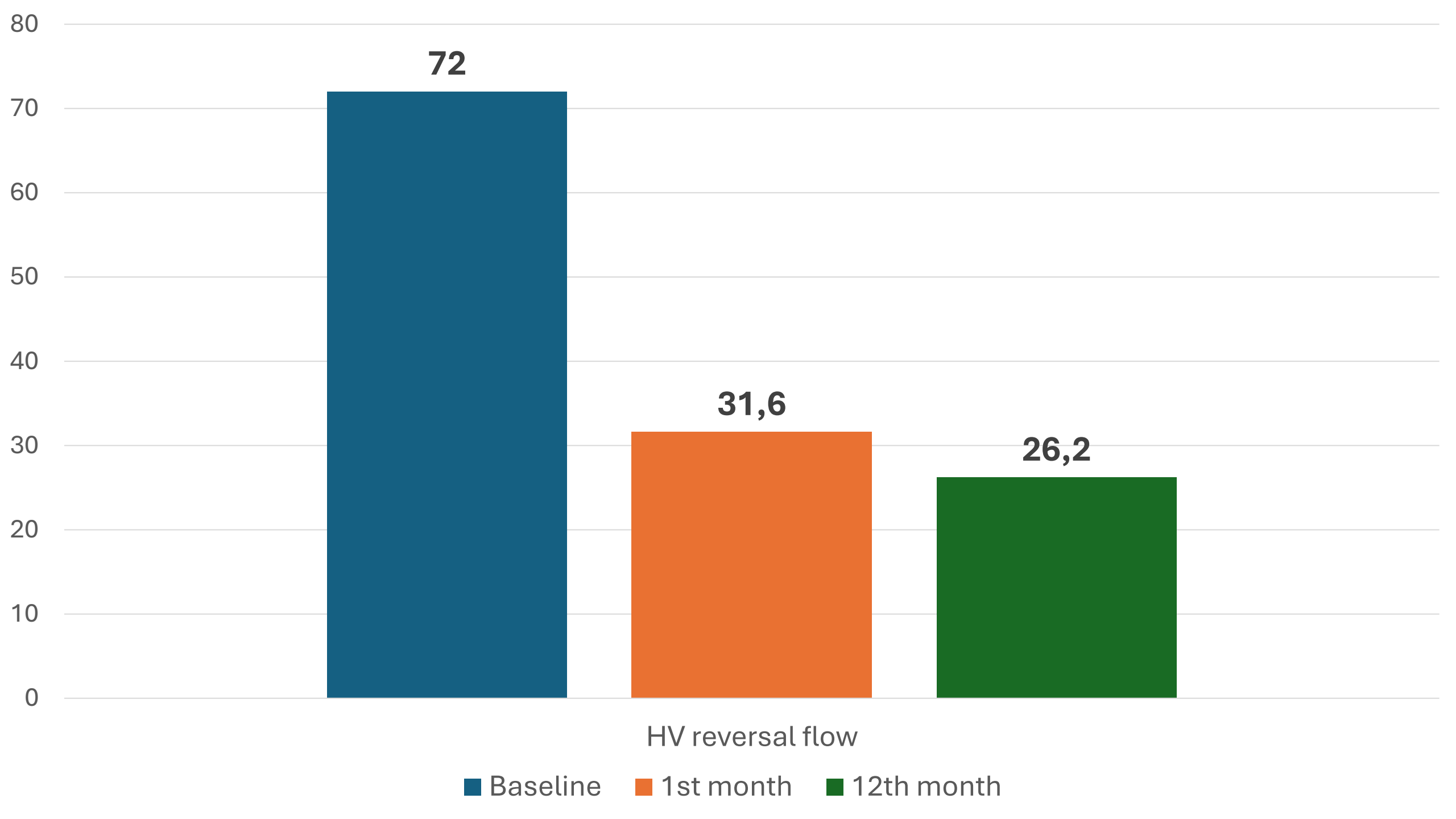
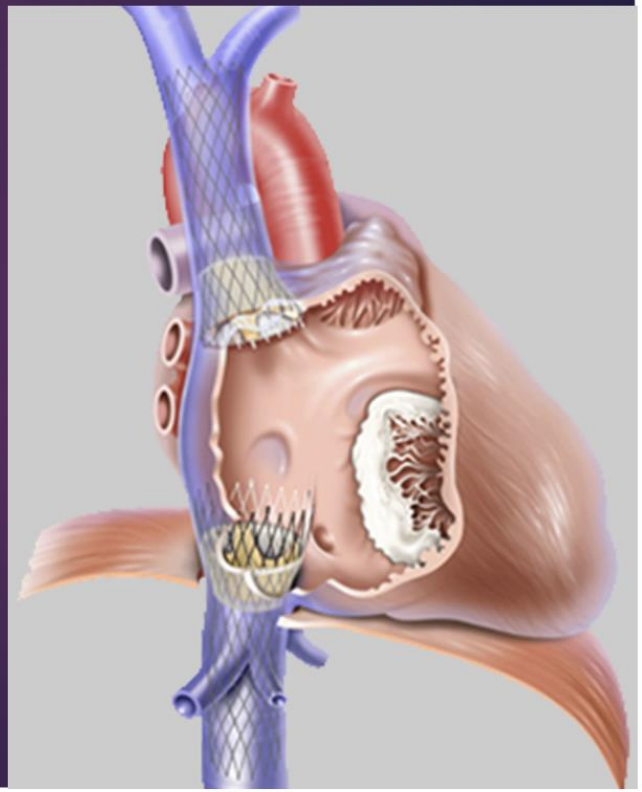
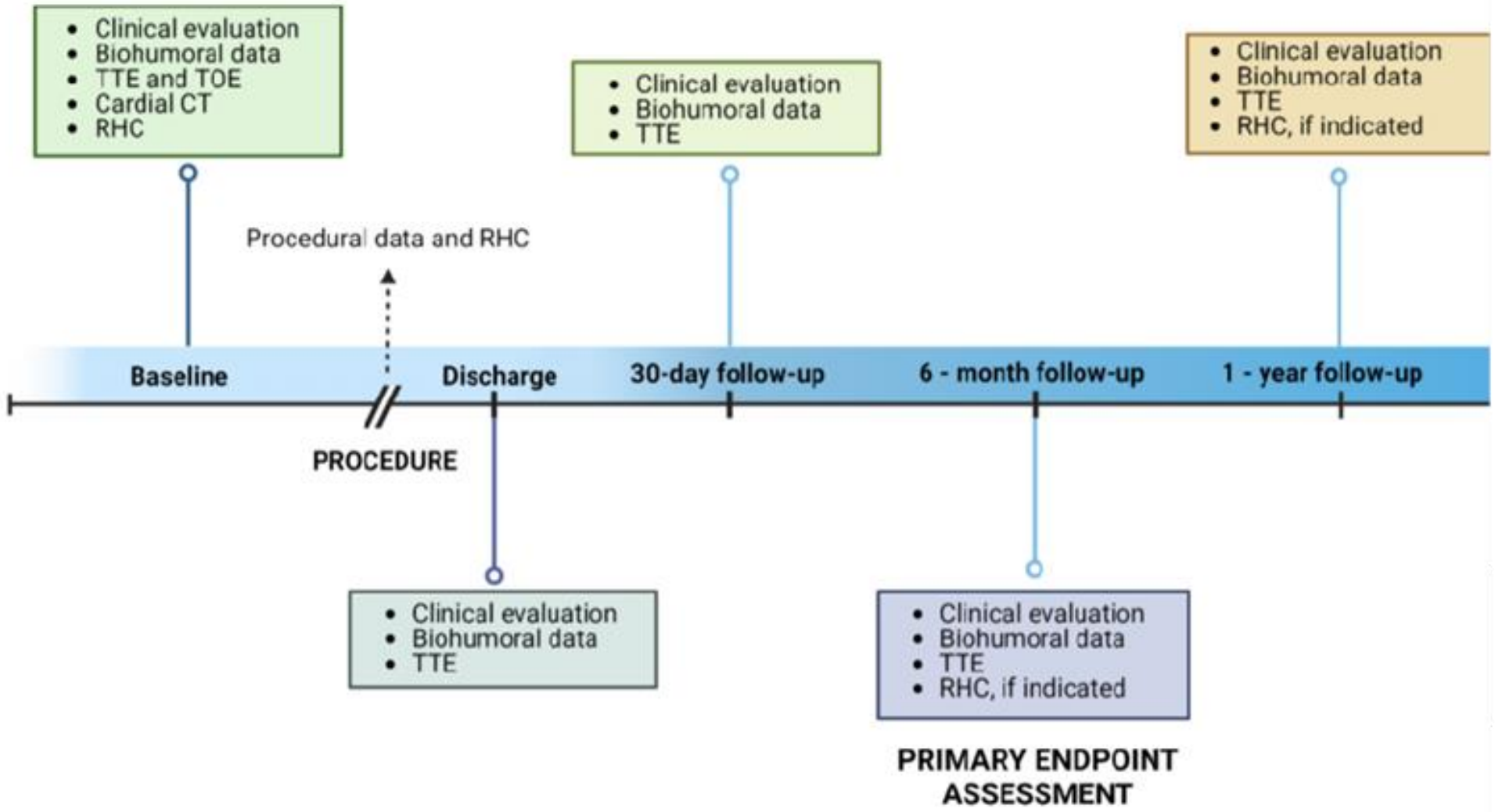

TR grade over time
60
50
40
30
20
10
0
0
12,7
38,6
48,7
2,4
16,9
38,7
41,9
10,7
25
33,3
31
Baseline
1st month
12th month
TR 2+
TR 3+
TR 4+
TR 5+


80
70
60
50
40
30
20
10
0
72
31,6
26,2
HV reversal flow
Baseline
1st month
12th month

Cardiovascular, Renal and haemodynamIc outcomes in patients with severe TrIcuspid regurgitation after triCvALve system implantation: an International Registry

CRITICAL INTERNATIONAL REGISTRY




Clinical evaluation
Biohumoral data
TTE and TOE
Cardial CT
RHC
Procedural data and RHC
Clinical evaluation
Biohumoral data
TTE
Clinical evaluation
Biohumoral data
TTE
RHC, if indicated
Baseline
Discharge
30-day follow-up
6 - month follow-up
1 - year follow-up
PROCEDURE
Clinical evaluation
Biohumoral data
TTE
Clinical evaluation
Biohumoral data
TTE
RHC, if indicated
PRIMARY ENDPOINT ASSESSMENT

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 17, NO. 1, 2024

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EDITORIAL COMMENT

Last, But Not Least

TricValve Implantation Reduces Heart Failure Burden in Severe Tricuspid Regurgitation*

Thomas J. Stocker, MD[a,b]

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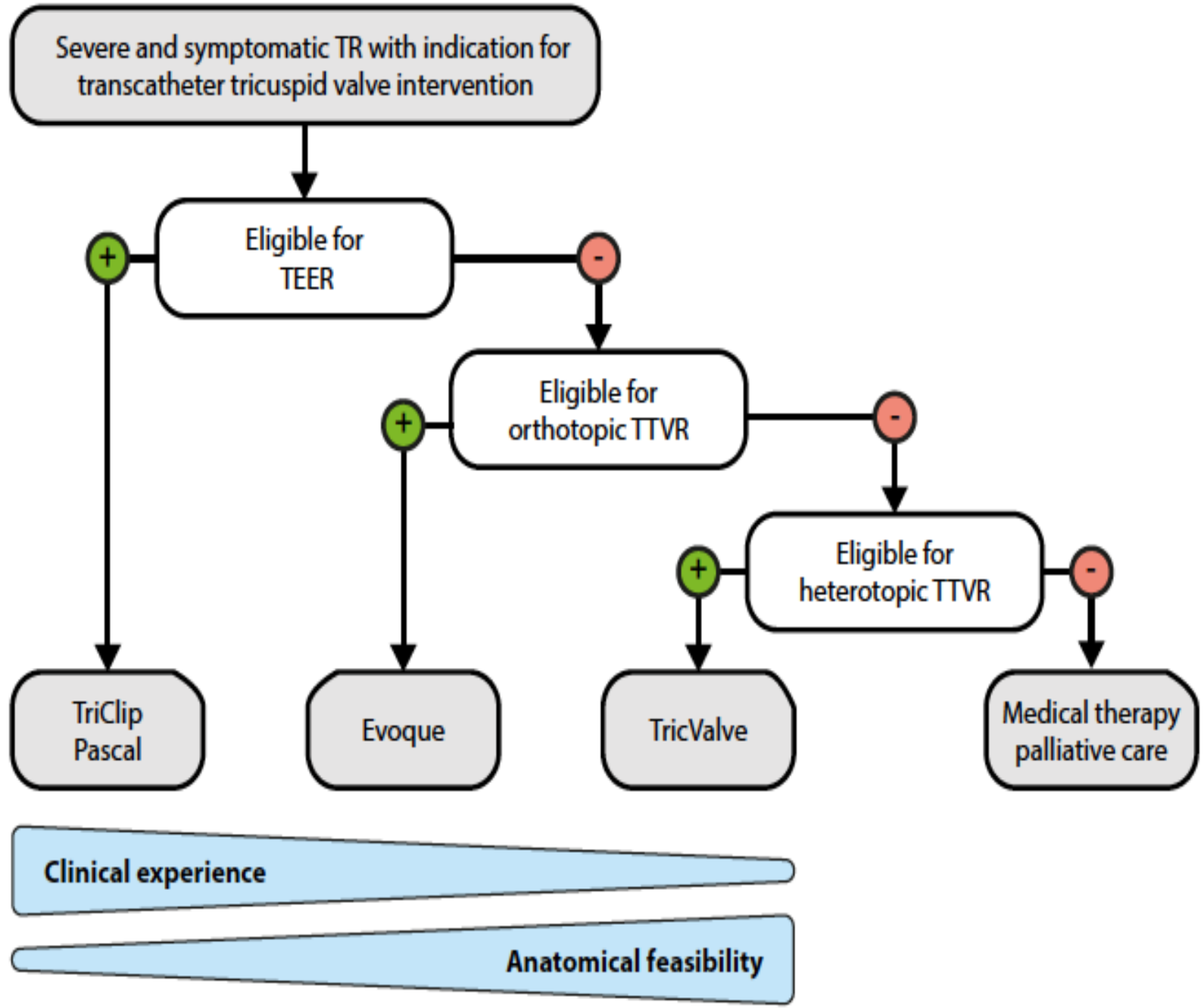

- The CAVI concept is based on the premise that by preventing the regurgitant backflow into the systemic venous system, peripheral congestion improves and over time increases forward RV stroke volume and thus cardiac output

- The improvement in systemic venous peripheral congestion is well explained by the significant decrease of the IVC pressure over time. The reduction of elevated pressures backward to the hepatic and splacnic vasculature may alleviate sympathetically mediated venous constriction, thereby decreasing stressed blood volume, ameliorating organ function (kidney, liver)

- Furthermore, the abrupt rise in right atrial pressure following TricValve implantation appears to diminish over time, as the right atrium accommodates the pressure overload without an increase in size, a phenomenon also demonstrated in a sub-study of the TRICUS EURO trial that volumetrically analyzed pre-procedural and 6-month follow-up CT scans

- The TricValve implantation show a tendency of RV reverse remodeling with a reduction in RV diameters, as corroborated by TRICUS EURO CT substudy and our experience. This could be at the basis of TR grade reduction

Abdul-Jawad Altisent O, Codina P, Puri R, Bayés-Genís A. Transcatheter bi-caval valve implantation (CAVI) significantly improves cardiac output: mechanistic insights following CardioMEMS® and TricValve® implantation. Vol. 111, Clinical Research in Cardiology. Springer Science and Business Media Deutschland GmbH; 2022. p. 966–8.

Fudim M, Kaye DM, Borlaug BA, Shah SJ, Rich S, Kapur NK, et al. Venous Tone and Stressed Blood Volume in Heart Failure: JACC Review Topic of the Week. Vol. 79, Journal of the American College of Cardiology. Elsevier Inc.; 2022. p. 1858–69.

Amat-Santos IJ, Estévez-Loureiro R, Sánchez-Recalde A, Cruz-González I, Pascual I, Mascherbauer J, et al. Right heart remodelling after bicaval TricValve implantation in patients with severe tricuspid regurgitation. EuroIntervention. 2023;19(5):E450–2.

Conclusions

TricValve is capable to:

- **Improve the functional and biochemical status of patients with TR and RHF**
- **Reduce organ dysfunction (liver and kidney)**
- **Reduce the clinical effects and discomfort of taking high-dose diuretics**
- **Reduce RV size with consequent reduction of TR grade over time**

This procedure is very safe and effective, especially if patients are carefully selected.

The procedure is extremely easy with very low clinical impact on the patients

Although Tricuspid TEER remains thew gold standard, TricValve may be used more and more in patients not eligible for TEER or in those with advance RV disease

Further prospective randomized trials comparing the TricValve with standard medical therapy are warranted.

Waiting for Scoopy-Doo to solve the TricValve mystery case

thanks for your attention!!