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Tricuspid breakthroughs: Better outcomes are possible

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BRAZIL

2025

Potential conflicts of interest

Speaker's name: Marcio Montenegro

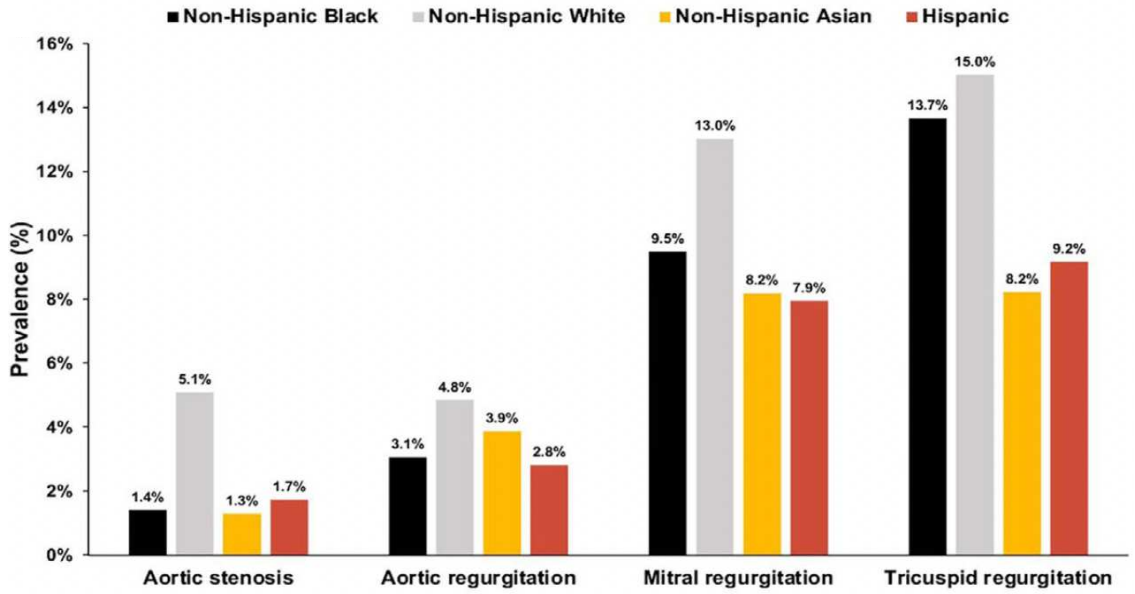
☑ I have the following potential conflicts of interest to report

- Receipt of honoraria or consultation fees – Products & Features

US Population TR Prevalence

Burden of Valvular Heart Diseases in a Racially and Ethnically Diverse Population: The Bronx-Valve Registry

330 570 patients

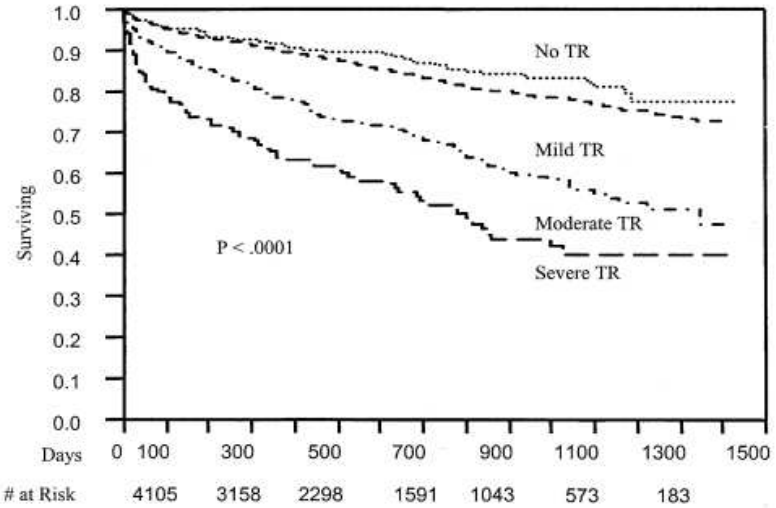


Scotti, et al. J Am Heart Assoc. 2025

Patients with moderate to torrential TR have increased mortality

Impact of Tricuspid Regurgitation on Long-Term Survival

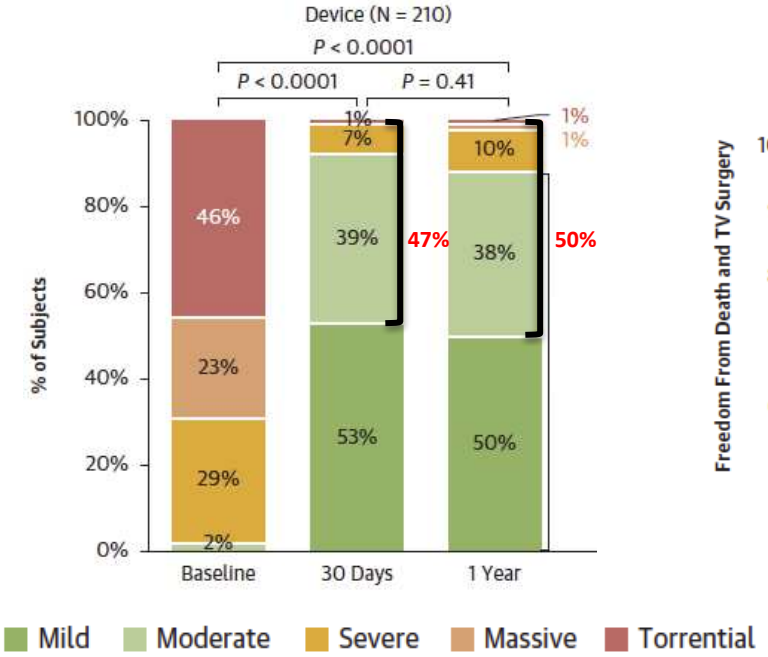
Jayant Nath, MD,* Elyse Foster, MD, FACC,† Paul A. Heidenreich, MD*
Palo Alto and San Francisco, California

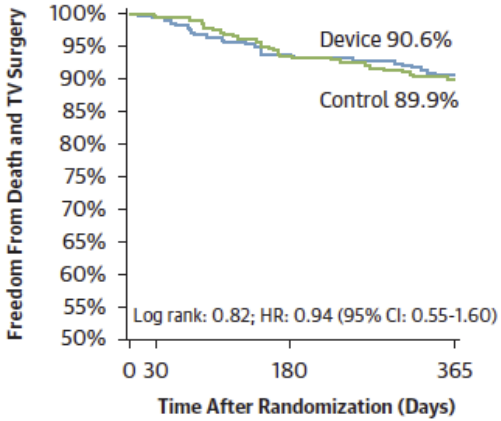


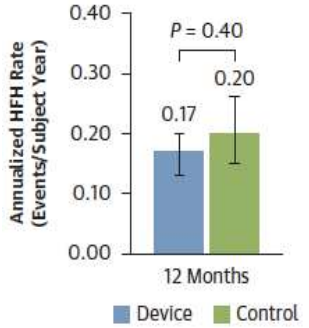
Nath J, et al. J Am Coll Cardiol. 2004

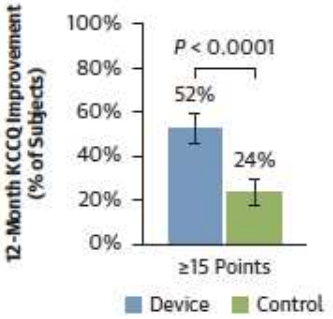
Tricuspid Transcatheter Edge-to-Edge Repair for Severe Tricuspid Regurgitation

1-Year Outcomes From the TRILUMINATE Randomized Cohort









New Guideline ESC

ESC European Society of Cardiology
European Heart Journal (2025) **00**, 1–102
https://doi.org/10.1093/eurheartj/ehaf194

ESC GUIDELINES

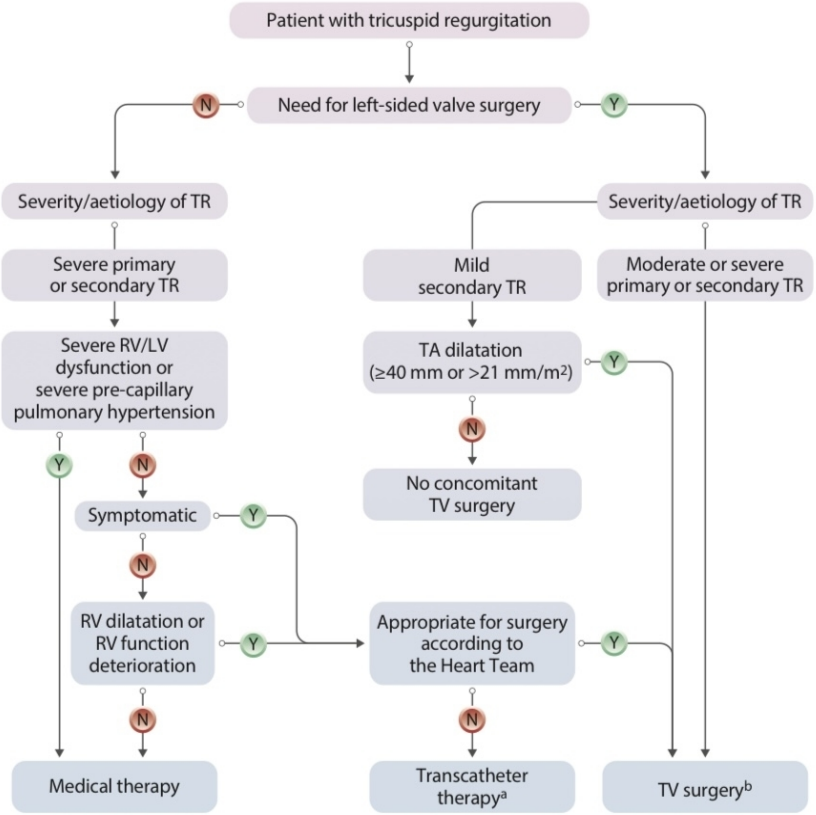
2025 ESC/EACTS Guidelines for the management of valvular heart disease

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)

11.4.2. Transcatheter techniques

Several transcatheter approaches for the treatment of TR have been developed, including TEER, direct annuloplasty, and orthotopic and heterotopic TV replacement. Data from large multicentre registries, single-arm clinical trials, and two recent RCTs in patients with severe TR at intermediate and high risk for surgery have shown the safety of trans-

Clinical Decision Flowchart



Patients with severe tricuspid regurgitation without left-sided valvular heart disease requiring surgery		
TV surgery[c] is recommended in symptomatic patients with severe primary TR without severe RV dysfunction or severe PH.	I	C
TV surgery[c] should be considered in asymptomatic patients with severe primary TR who have RV dilatation/RV function deterioration, but without severe LV/RV dysfunction or severe PH.	IIa	C
TV surgery[c] should be considered in patients with severe secondary TR who are symptomatic or have RV dilatation/RV function deterioration, but without severe LV/RV dysfunction or PH.[685,720,745–747]	IIa	B
Transcatheter TV treatment should be considered to improve quality of life and RV remodelling in high-risk patients with symptomatic severe TR despite optimal medical therapy in the absence of severe RV dysfunction or pre-capillary PH.[713,733,735,738,748–751]	IIa	A

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TricValve clinical evidence

2025

ORIGINAL RESEARCH

STRUCTURAL

Bicaval TricValve Implantation in Patients With Severe Tricuspid Regurgitation

1-Year Outcomes From the TricBicaval Registry

The TricBicaval study is a real-world investigator-initiated multicenter registry that retrospectively and consecutively included 204 patients from 27 hospitals

Indication: all patients with **symptomatic severe, massive, or torrential TR** who were deemed to be at **high surgical risk**.

Tricuspid Regurgitation Treatment Made Easy

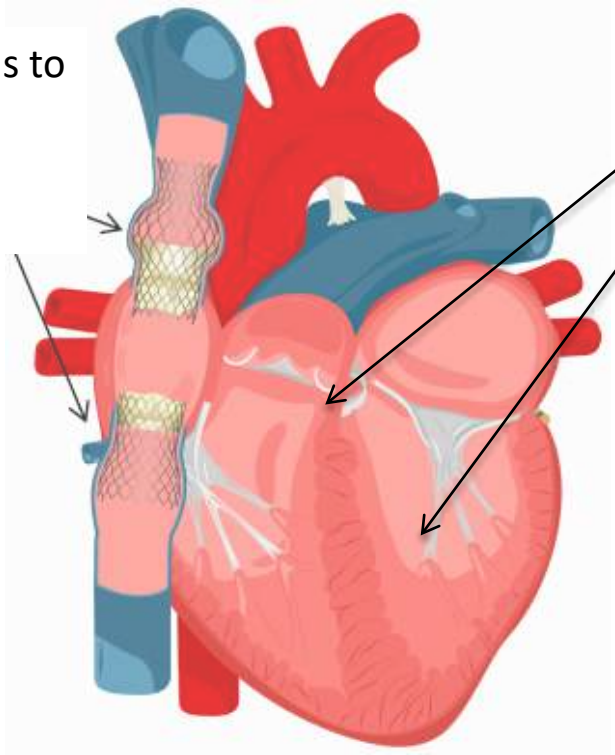
Two independent mechanisms to **control the right ventricle backflow**

Compatible with

pre-existing pacemaker

Right atrium acting as a **reservoir**

No touch the **native valve**



Recovered right ventricular pressure and joint work of atrium and ventricle

Possibility of **multiple future heart interventions**

Minimally invasive procedure with the possibility of **conscious sedation**

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TRICVALVE BICAVAL SYSTEM MULTICENTER REGISTRY (TRIC-BICAVAL)

Multicenter registry initiated by investigators and not supported by any external funding

27 hospitals
204 patients

RHF due to severe TR

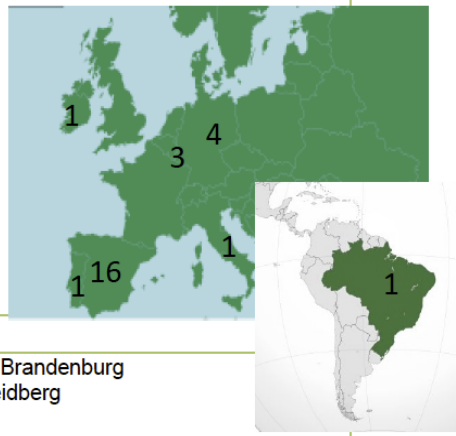
Inoperable and unsuitable for transcatheter orthotopic repair/replacement

Rejected for CAVI:
TAPSE < 13
LVEF < 40%
PSP > 65 mmHg
V-wave < 15 mmHg

Bicaval suitable Anatomy (CT-scan)

Participating Centers

SPAIN	• University Hospital Ramon y Cajal • University Hospital Clinico San Carlos • University Hospital Valladolid • University Hospital Salamanca • University Hospital Doce Octubre • University Hospital Clinic Barcelona • University Hospital Badajoz • University Hospital Reina Sofia Cordoba • University Hospital La Paz • University Hospital Alvaro Cunqueiro. Vigo • University Hospital Puerta de Hierro • University Hospital Valdecilla Santander • University Hospital Toledo • University Hospital Navarra • University Hospital Germans Trias i Pujol • University Hospital La Coruña
PORTUGAL	• University Hospital Santa Marta. Lisboa
GERMANY	• University Hospital Immanuel Heart Center Brandenburg • University Hospital Asklepios Klnik Nord Heidberg • University Hospital Heart Center Cologne • University Hospital Heart Center Munster
ITALY	• University Hospital Pierangeli Pescara
BELGIUM	• University Hospital ASZ Aalts • University Heart Center St. Antonius • University Hospital Maria Middelares
IRELAND	• University Hospital Galway
BRASIL	• Valve Center IECAC. Rio de Janeiro. Brasil.



Baseline Characteristics (N=204)

Female	133 (65.2) (204)
Age, y	77.8 ± 7.5 (204)
Height, cm	163.8 ± 10.0 (184)
Weight, kg	70.4 ± 15.1 (183)
BMI, kg/m^2	26.2 ± 4.8 (183)
Hypertension	135 (66.2) (204)
Diabetes mellitus	41 (20.1) (204)
Previous stroke/TIA	29 (14.2) (204)
eGFR < 60 mL/min/m^2	145 (71.1) (204)
Dialysis	5 (2.5) (204)
COPD	31 (15.2) (204)
Peripheral artery disease	7 (3.4) (204)
Coronary artery disease	41 (20.1) (204)
Prior myocardial infarction	17 (8.3) (204)
Prior percutaneous coronary intervention	24 (11.8) (204)
EuroSCORE II	5.3 (3.4-8.8) (191)
STS score	7.0 (4.1-12.1) (104)
TRI-SCORE-predicted in-hospital mortality	14.0 (8.0-34.0) (204)
TRI-SCORE	(n = 204)
Low risk (0-3 points)	36 (17.6)
Intermediate risk (4 or 5 points)	75 (36.8)
High risk (≥6 points)	93 (45.6)

Prior cardiac surgery	102 (50.0) (204)
Isolated valve surgery	79 (77.5)
Isolated CABG	12 (11.8)
Both valve surgery and CABG	7 (6.9)
Heart transplantation	1 (1.0)
Other cardiac surgery	3 (2.9)
Prior surgical intervention on tricuspid valve	20 (9.8) (204)
Surgical tricuspid valvuloplasty	19 (95.0)
Biologic tricuspid valve replacement	1 (5.0)
Prior percutaneous tricuspid valve intervention	19 (8.8) (204)
TV TEER	12 (63.2)
Tricuspid annuloplasty	7 (36.8)
Prior percutaneous left heart valve intervention	21 (10.3) (204)
MV TEER	13 (61.9)
TAVR	3 (14.3)
Mitral valvuloplasty	5 (23.8)
Prior pacemaker/ICD (RV lead)/CRT device	70 (34.3) (204)
CRT device	11 (15.7)
HF hospitalization in the past year	113 (60.8) (186)
1	53 (46.9)
≥2	60 (53.1)
Heart rhythm	(n = 203)
Sinus rhythm	11 (5.4)
Paroxysmal atrial fibrillation	25 (12.3)
Permanent atrial fibrillation	167 (82.3)

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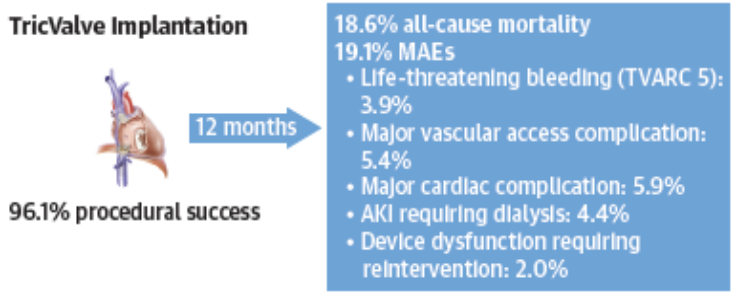
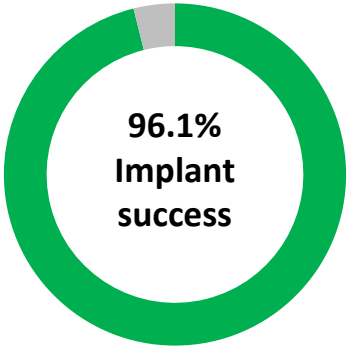
Sánchez-Recalde A, et al. JACC. 2025

Results

In-hospital mortality	17 (8.3)
Cardiovascular	13 (76.5)
Noncardiovascular	4 (23.5)
Conversion to surgery	0 (0.0)
Need for percutaneous tricuspid reintervention	1 (0.5)
Bicaval stenting	1 (100.0)
SVC malposition/migration	2 (1.0)
Valve reposition	1 (50.0)
Second valve implantation (valve-in-valve)	1 (50.0)
Significant leak, not treated	0 (0.0)
IVC malposition/migration	16 (7.8)
Valve reposition	8 (50.0)
Second valve implantation (valve-in-valve)	6 (37.5)
Significant leak, not treated	2 (12.5)





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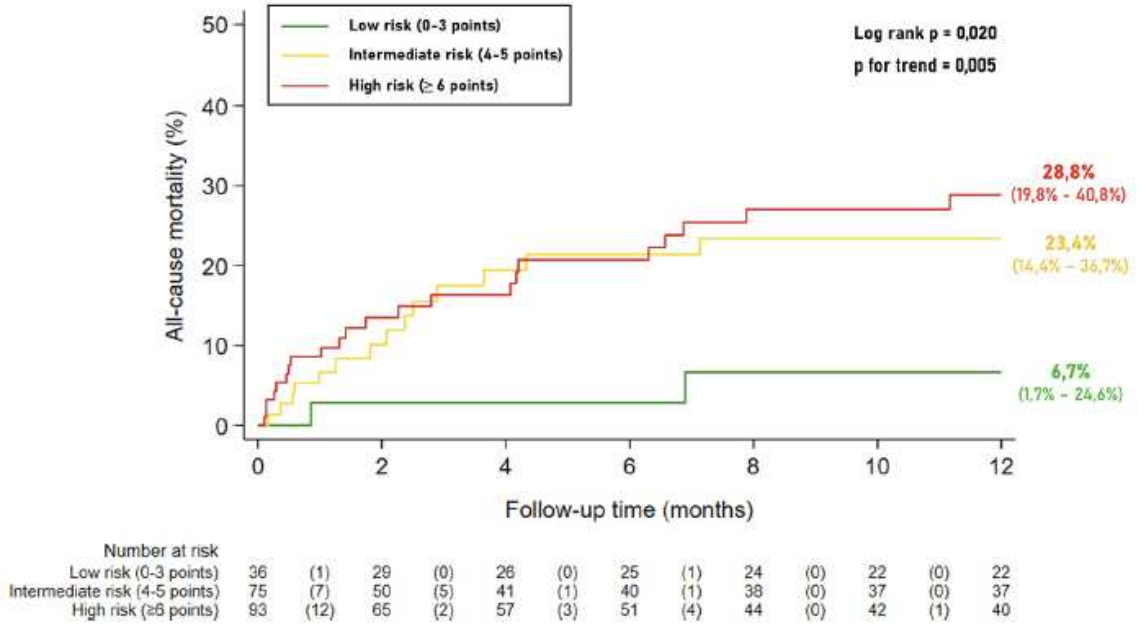
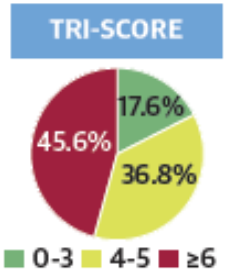
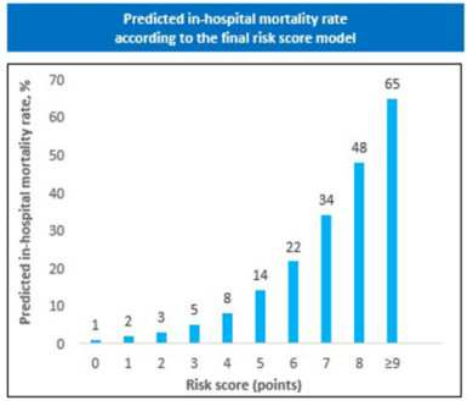
TRI-SCORE as a Predictor of All-Cause Mortality







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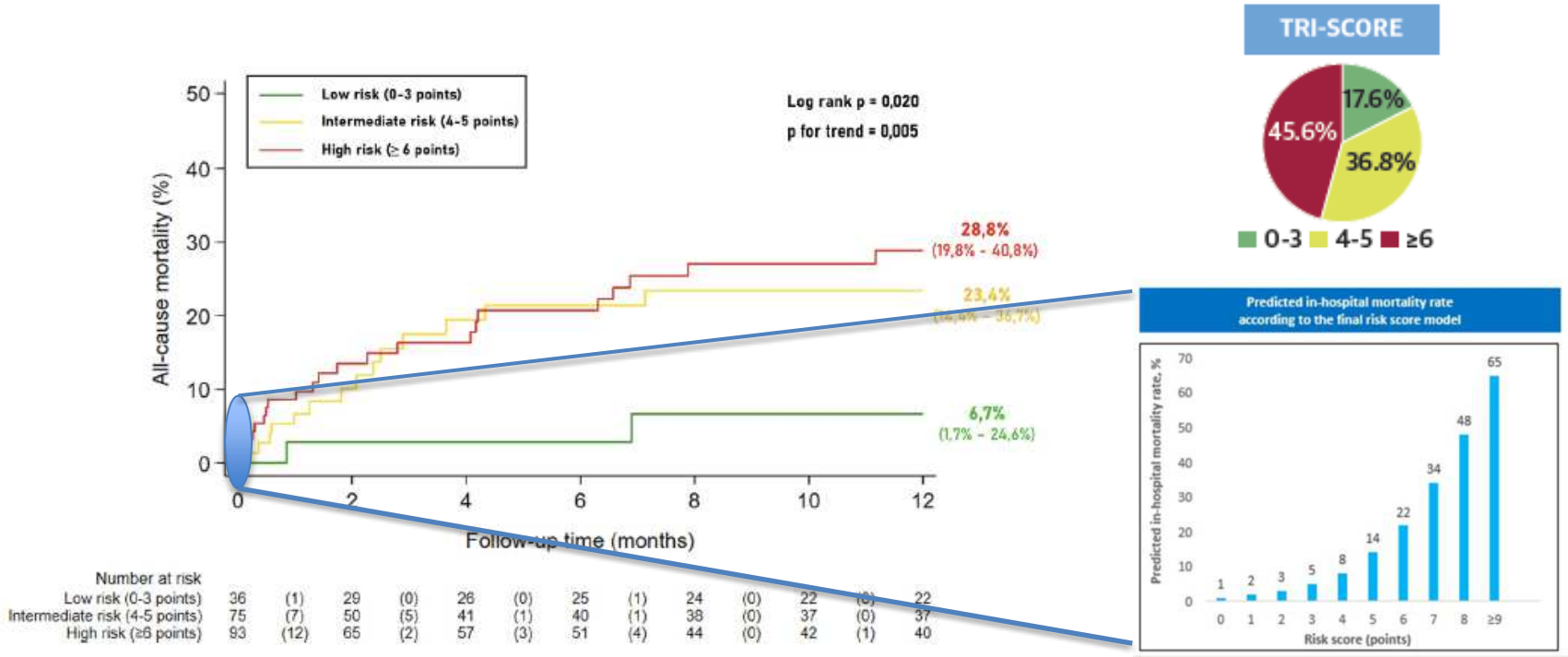
TRI-SCORE as a Predictor of All-Cause Mortality



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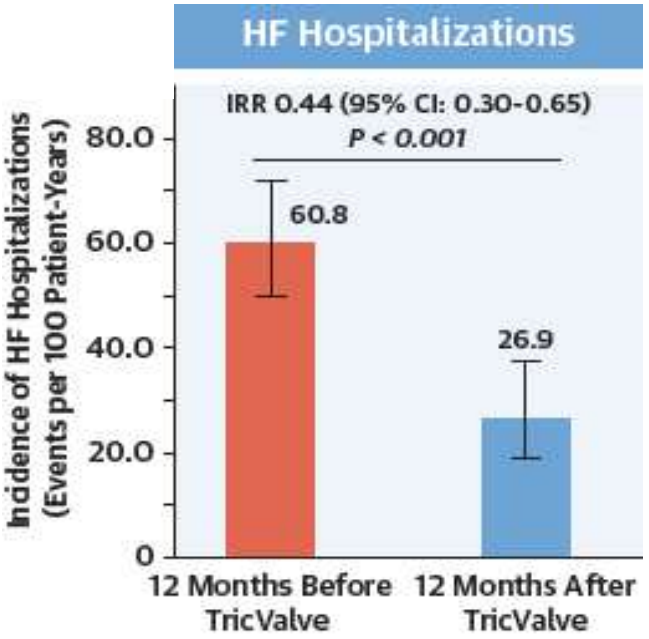
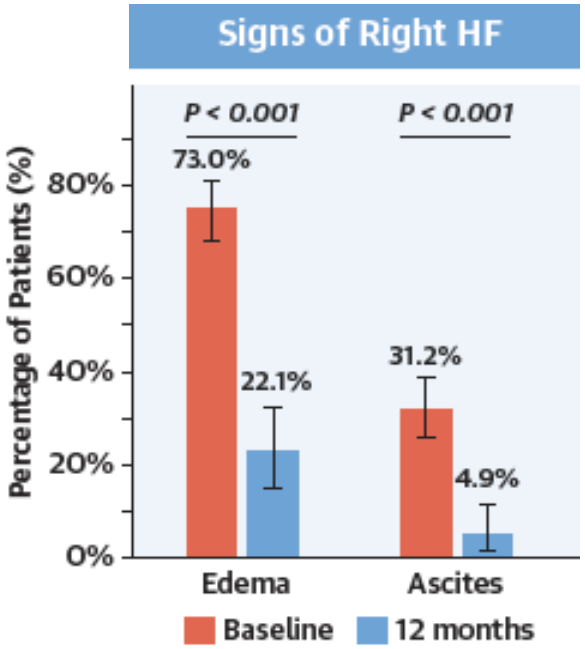
Patients presented reduced signs of right HF and HF hospitalizations





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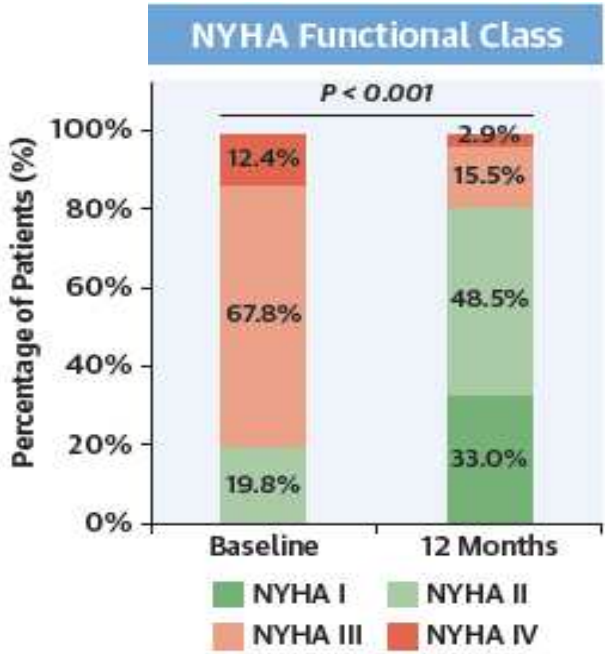
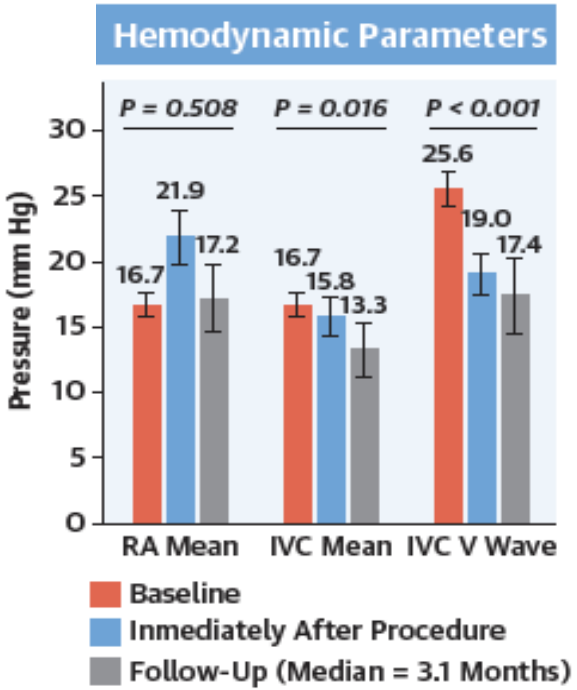
Improvements in hemodynamic status and functional class





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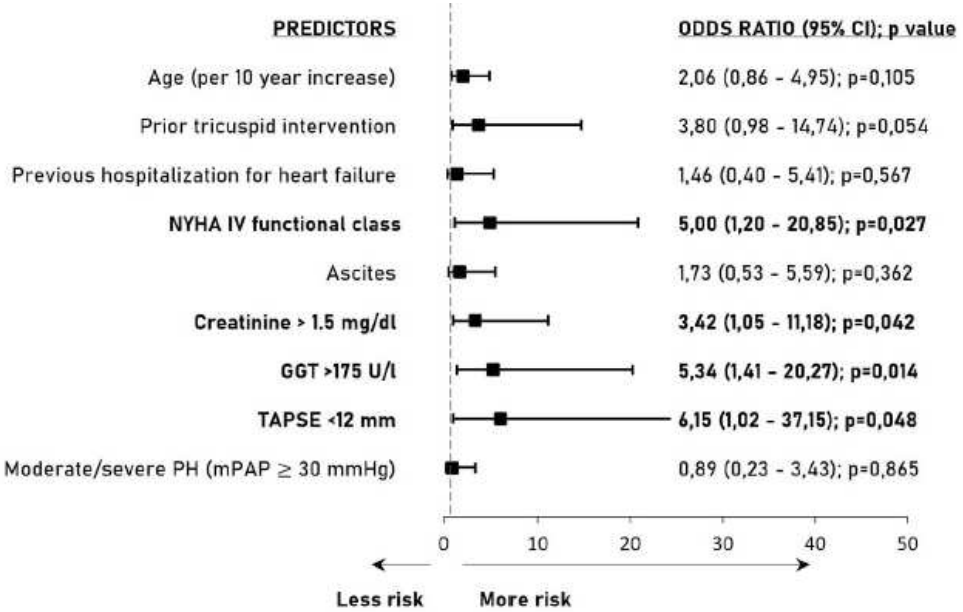
Echo at 1-Month and 12-Month Follow-Up

	Baseline	1 mo	Baseline)	12 mo	(With Respect to Baseline)
LVEF, %	55.6 ± 10.1 (202)	55.8 ± 9.1 (130)	0.240	57.2 ± 9.3 (86)	0.158
LVEDD, mm	46.1 ± 7.7 (168)	46.4 ± 7.7 (103)	0.087	46.8 ± 8.1 (71)	0.292
Significant MR (grade ≥ III)	6 (2.9%) (204)	3 (1.8%) (80)	0.625	3 (2.5%) (41)	0.650
TAPSE, mm	17.0 (14.1-20.0) (188)	16.0 (12.0-18.0) (120)	**<0.001**	17.0 (14.0-18.0) (82)	**<0.001**
RV strain, %	−17.6 (−14.0 to −22.5) (40)	−16.0 (−14.0 to −18.0) (25)	0.867	−16.0 (−14.0 to −22.0) (17)	0.828
RV fractional area change, %	41.6 (34.0-47.4) (116)	36.9 (30.5-44.5) (80)	**<0.001**	36.6 (32.5-46.0) (40)	**0.035**
RV basal diameter, mm	52.3 ± 9.2 (174)	50.8 ± 9.7 (100)	**0.004**	48.5 ± 8.4 (73)	0.184
RV mid diameter, mm	43.9 ± 9.0 (111)	40.6 ± 9.4 (75)	**0.003**	41.2 ± 8.3 (44)	0.421
RA area, mm^2	39.0 ± 15.0 (131)	39.4 ± 13.8 (79)	0.113	37.5 ± 12.1 (49)	0.943
TR grade	(n = 197)	(n = 124)	**0.049**	(n = 84)	**<0.001**
Moderate (II)	0 (0.0)	3 (2.4)		9 (10.7)	
Severe (III)	25 (12.7)	21 (16.9)		21 (25.0)	
Massive (IV)	76 (38.6)	48 (38.7)		28 (33.3)	
Torrential (V)	96 (48.7)	52 (41.9)		26 (31.0)	
RVSP, mm Hg	41.6 ± 13.7 (100)	40.0 ± 16.6 (54)	0.087	34.5 ± 11.0 (38)	0.068
Hepatic vein systolic flow reversal	148 (72.5) (204)	36 (31.6) (114)	**<0.001**	17 (26.2) (65)	**<0.001**
IVC maximum diameter, mm	27.9 ± 6.7 (143)	24.8 ± 6.1 (39)	**0.002**	25.1 ± 7.3 (19)	0.120
IVC inspiratory collapse >50%	23 (11.3) (204)	22 (26.2) (84)	**0.007**	16 (41.0) (39)	**0.004**

Predictors of In-Hospital Mortality



Red flags: **NYHA IV, renal dysfunction, hepatic dysfunction, and TAPSE < 12mm** were **independent predictors of in-hospital mortality** in a multivariate analysis

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Patients followed for one-year demonstrated (Baseline x TricValve)

- Improvement in **NYHA functional class I or II (19.8% vs. 81.6%; p<0.001);** **4X**
- Significant reduction in **peripheral congestion (73% vs. 22%; p<0.001);** **3X**
- Significant reduction in **ascites (31% vs. 5%; p<0.001);** **6X**
- Significant reduction in **diuretic doses (36,4% vs. 8,7%; p=0.002);** **4X**
- Significant reduction in **hospitalization rates (61% vs. 27%; p<0.001);** **2X**
- Significant reduction in **hepatic vein systolic flow reversal (148 vs. 17; p<0.001);** **8X**

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Conclusion

This is the first large registry to demonstrate that **TricValve system effectively reduces IVC pressure** and significantly **improves functional status and peripheral venous congestion at 1 year**, along with a substantial **reduction in hospital readmissions for right HF**

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