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Bicaval Tricvalve in severe tricuspid regurgitation: 1-year outcomes from Tricbicaval registry

Angel Sánchez-Recalde, MD, PhD

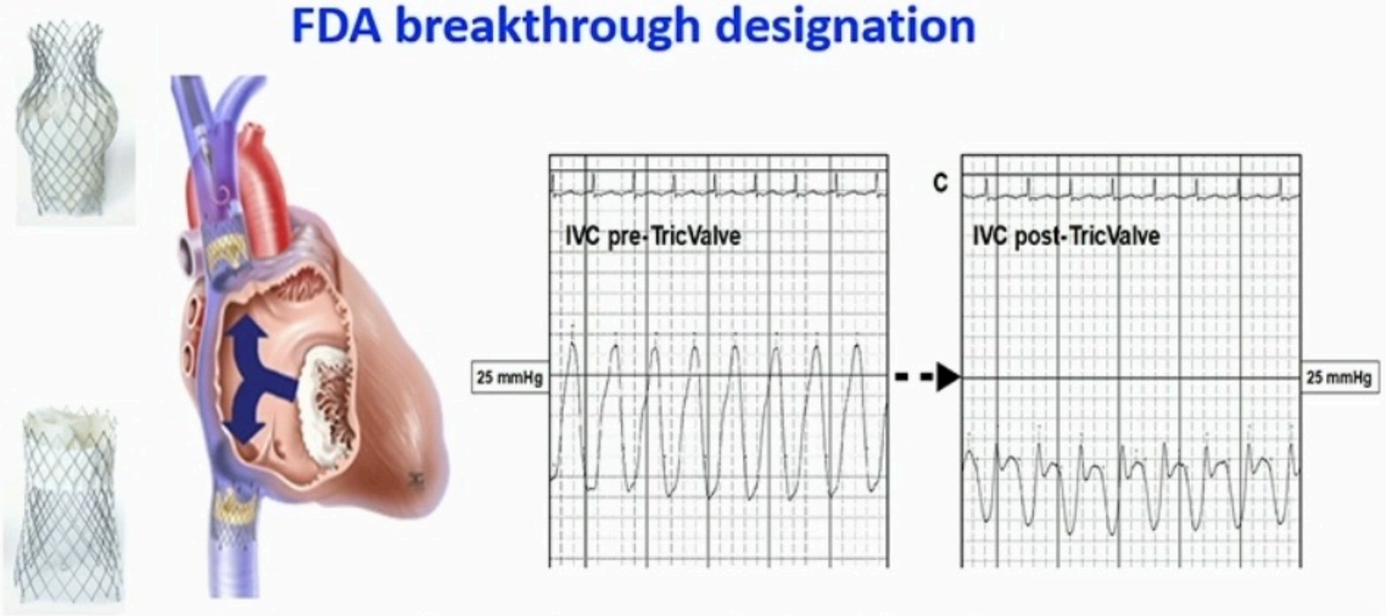
University Hospital Ramón y Cajal, Madrid, Spain on behalf to Tricbicaval registry investigators

PCR

EAPCI
European Society of Cardiology

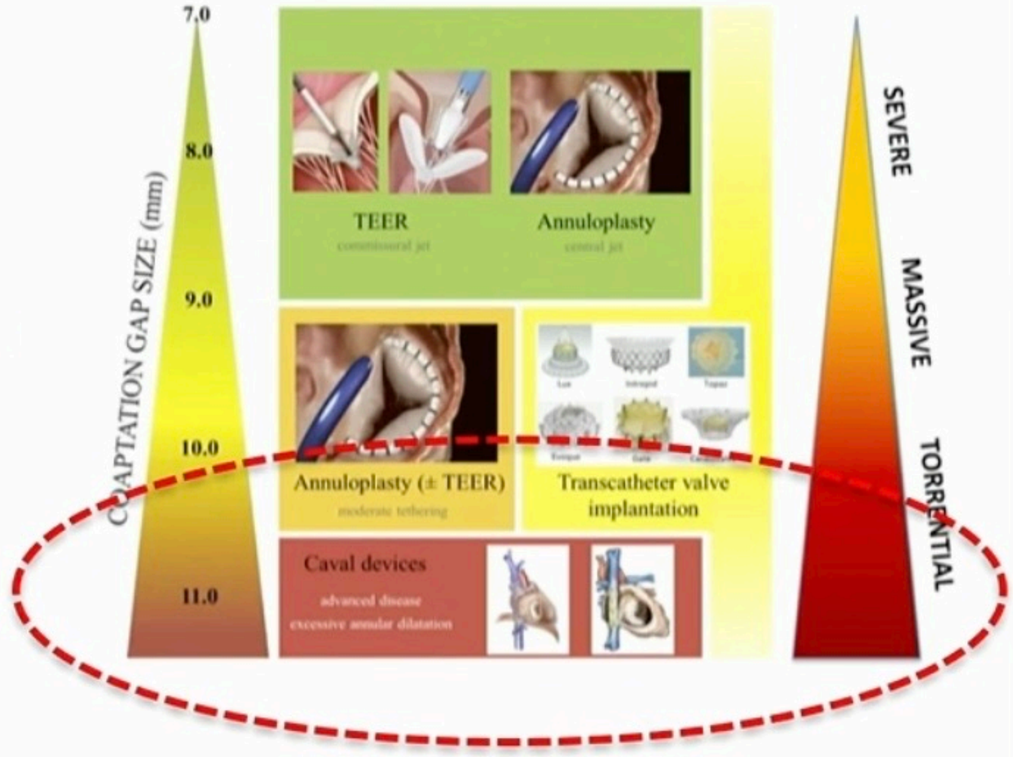
Why this study?

Tricvalve – First CAVI device CE mark approval (May 21)
FDA breakthrough designation



Heterotopic approach: to eliminate TR backflow into venous system reducing peripheral venous congestion and over time increasing forward flow (CO)

But… knowledge of the efficacy and safety of CAVI with Tricvalve remains limited



RHF // Organ failure

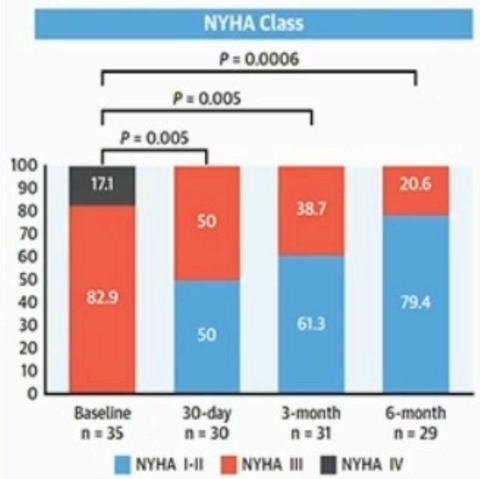
Will MG, Praz F. J Am Coll Cardiol Intv 2022;15:1378-81

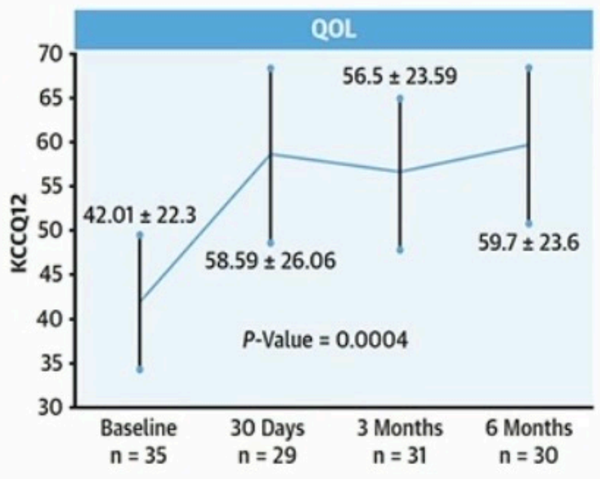
Why this study?

QOL improvements 6-12 months are equivalent to any other TTV therapies (TRICUS EURO N=35 patients)

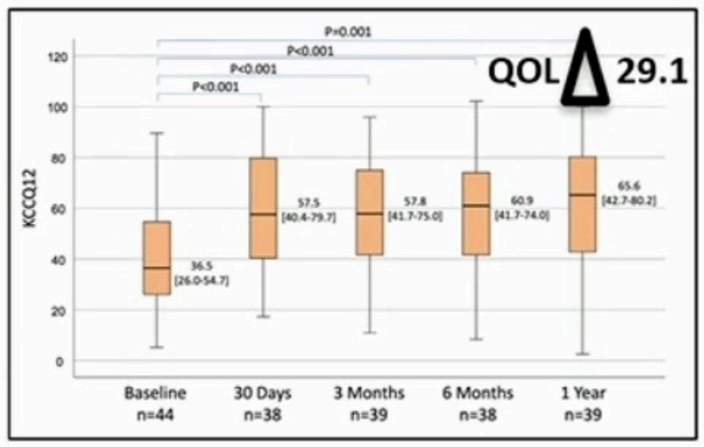
Primary End-point at 6-month

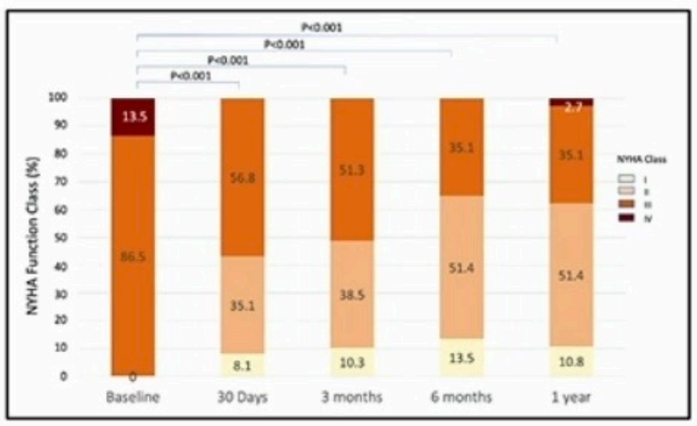
QOL Δ 17.69





Primary End-point at 1-year





But …real-world data are currently lacking to determine the role of this therapy in patients with severe symptomatic TR

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How was the study executed? – Tricbicaval Registry

Retrospective multicenter registry initiated by researchers and not supported by any external funding

204 patients
27 hospitals
(Jan 20-Dec23)

- Severe-Torrential TR
- Refractory RHF
- Inoperable and mostly unsuitable for orthotopic repair/replacement
- Appropriate bicaval Anatomy (CT-scan)

Clinical, analytical, imaging, hemodynamic, and CT characteristics, as well as adverse events, were collected at baseline, 1 month, and 12 months of follow-up.

SPAIN	• University Hospital Ramon y Cajal. Madrid • University Hospital Clinico San Carlos. Madrid • University Hospital Valladolid • University Hospital Salamanca • University Hospital Doce Octubre. Madrid. • University Hospital Clinic Barcelona • University Hospital Badajoz • University Hospital Reina Sofia Cordoba • University Hospital La Paz. Madrid • University Hospital Alvaro Cunqueiro. Vigo • University Hospital Puerta de Hierro. Madrid • 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 Hospital Maria Middelares
NETHERLANDS	• St. Antonius, Nieuwegein, Netherlands
IRELAND	• University Hospital Galway
BRASIL	• Valve Center IECAC. Rio de Janeiro. Brasil.

What are the essential results? Baseline characteristics

Most subjects had multiple comorbidities, were highly symptomatic, had high risk TRI-SCORE, and had massive/torrential TR

Age, years: mean (SD)	77.8 ± 7.5
Female, n (%)	133 (65.2%)
Hypertension, n (%)	335 (66.2%)
Stroke/TIA, n (%)	29 (14.2%)
GFR <60 ml/min/m2, n (%)	145 (71.1%)
Dialysis, n (%)	5 (2.5%)
COPD, n (%)	31 (15.2%)
CAD, n (%)	41 (20.1%)
PAD, n (%)	7 (3.4 %)
Cardiac valve surgery, n (%)	102 (50%)
Transcatheter valve intervention, n (%)	39 (19%)
Pacemaker/ICD/-CRT, n (%)	70 (34.2%)
Atrial fibrillation, n (%)	192 (94.1%)

EuroScore II, mean (SD)	6.9 ± 5.4
STS score, MVR, %, mean (SD)	9.5 ± 7.9
TRI-SCORE, predicted in-hospital mortality,%, mean SD	23.2 ± 19.1
TRI-SCORE 0-3 (Low Risk), n (%)	36 (17%)
TRI-SCORE 4-5 (Intermediate Risk), n (%)	75 (36.8%)
TRI-SCORE ≥ 6 (High Risk), n (%)	93 (45.6%
Peripheral edema, n (%)	149 (73%)
Ascitis, n (%)	63 (31 %)
NYHA class III-IV, (%)	158 (80%)
HF hospitalization in past 12 months, n (%)	113 (60.8%)
TR Severity	
Severe	25 (12.7%)
Massive	76 (38.6%)
Torrential	92 (48.7%)

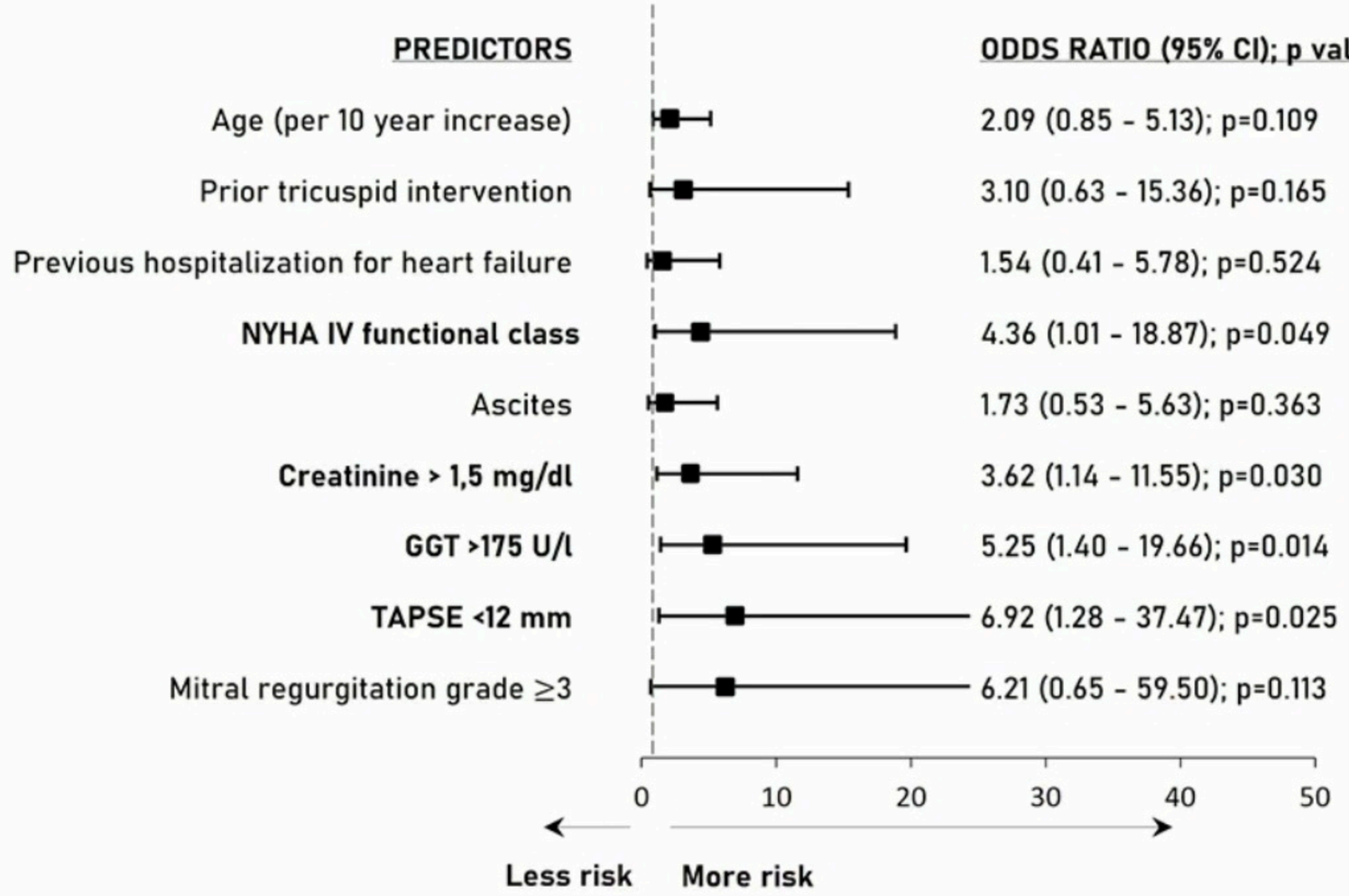
What are the essential results? In-hospital outcomes

Fluoroscopic Time: **30 min** [20-41]

Intraprocedural success (TVARC)	**96.1 %**
SVC malposition – 2nd valve implantation	**1 (0.49%)**
IVC malposition – 2nd valve implantation	**6 (2.9%)**
In-hospital mortality	**17 (8.3%)**
TVARC bleeding ≥ 3	**20 (9.8%)**
TVARC major access complications	**11 (5.39)**
TVARC major cardiac complications	**8 (3.9%)**
Cardiac tamponade	***3 (1.47%)***
New pacemaker implantation (1 Lead dysfunction pacemaker)	***4 (1.96%)***
Shoulder pain	**96 (47.1%)**
AKI requiring dialysis	**5 (2.4 %)**
Length of hospital stay (days)	**8 (4 - 24)**

What are the essential results?

Predictors of In-Hospital Mortality

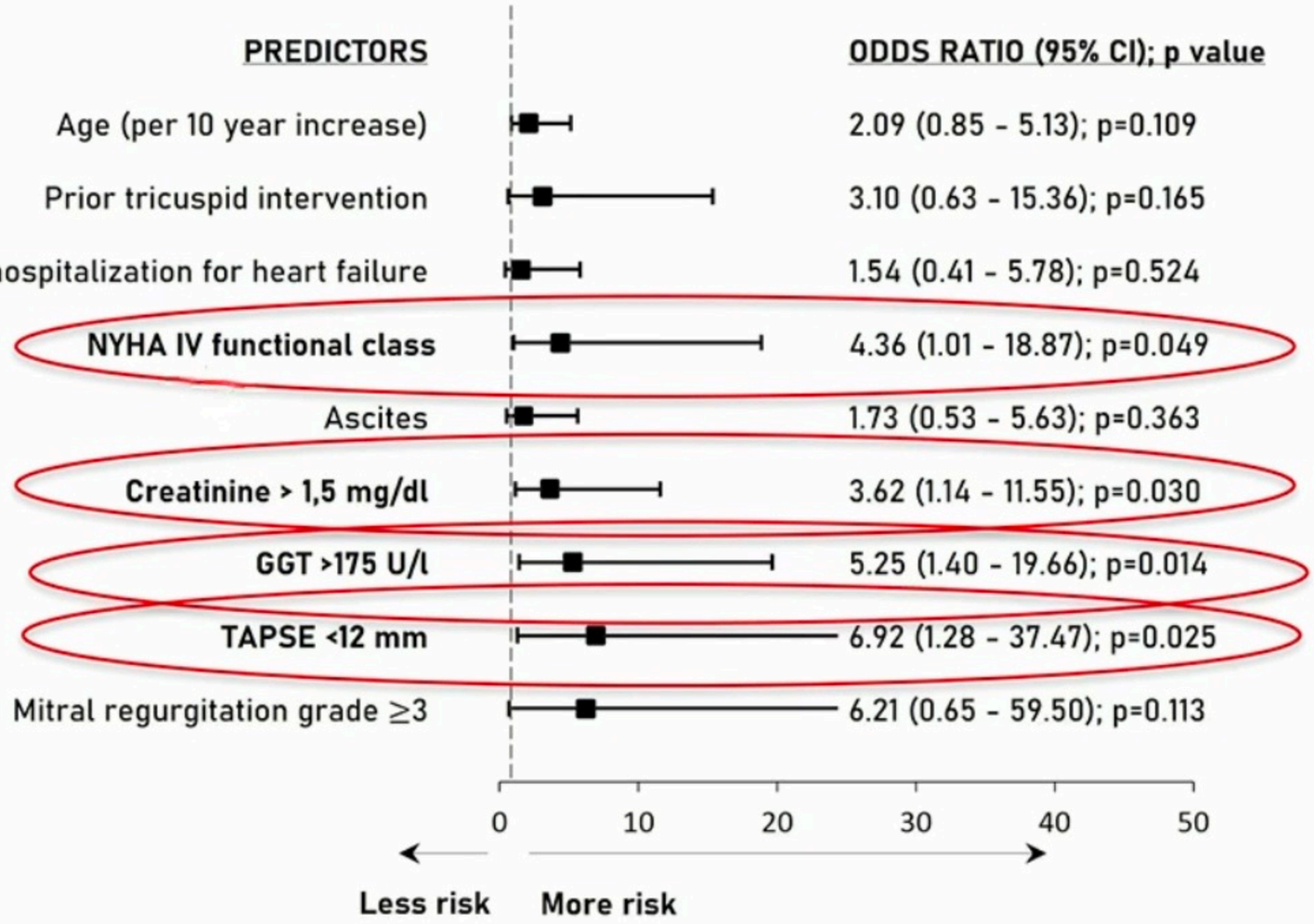


What are the essential results? Safety endpoints

SAFETY ENDPOINTS	Early events (≤30 days) n = 204*	Late events (31 to 365 days) n = 168**	Cumulative events (0 to 365 days) n = 204*
MORTALITY			
Intraprocedural mortality All-cause mortality: n (%)	0 (0.0)	NA	NA
In-hospital mortality	17 (8.3)	NA	NA
All-cause mortality	19 (9.3)	19 (11.3)	**38 (18.6)**
Cardiovascular Mortality	15 (7.4)	17 (10.1)	**32 (15.7)**
TVARC MAJOR ADVERSE EVENTS			
Life threatening bleeding (TVARC 5): n (%)	3 (1.5)	5 (3.0)	8 (3.9)
Major vascular access complication: n (%)	11 (5.4)	0 (0.0)	11 (5.4)
Major cardiac complications: n (%)	9 (4.4)	3 (1.8)	12 (5.9)
Stage 2 or 3 AKI: n (%) Requiring dialysis	9 (4.4) 5 (2.5)	7 (4.2) 4 (2.4)	16 (7.8) 9 (4.4)
Device-related dysfunction requiring for reintervention: n (%)	1 (0.5)	3 (1.8)	4 (2.0)
COMPOSITE MAEs: n (%)	28 (13.7)	11 (6.5)	**39 (19.1)**

What are the essential results?

Predictors of In-Hospital Mortality



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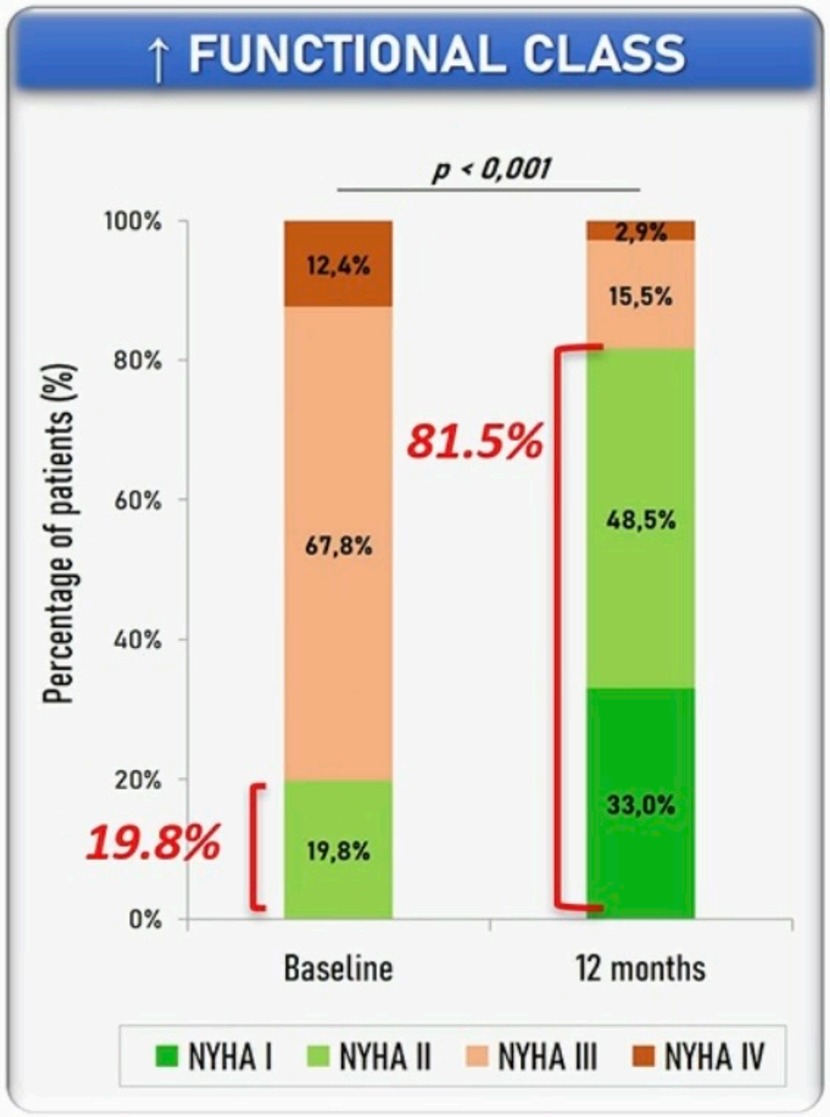
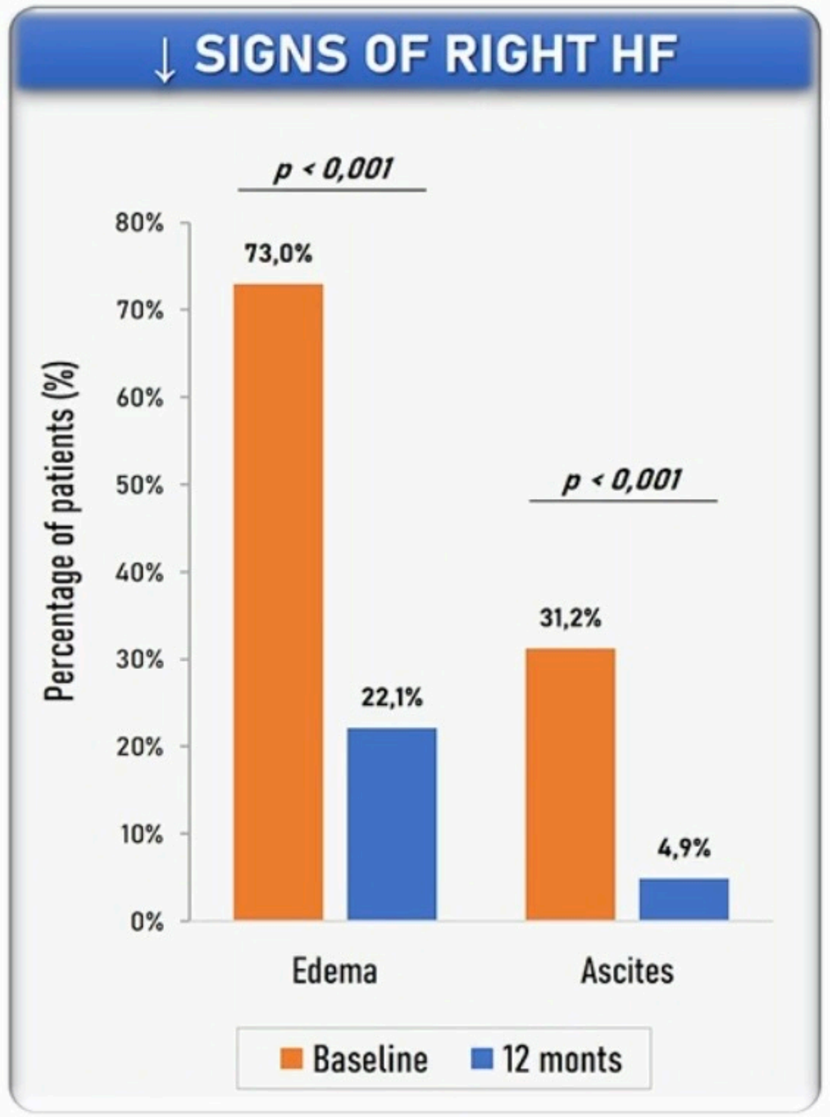
What are the essential results? 1-y clinical outcomes





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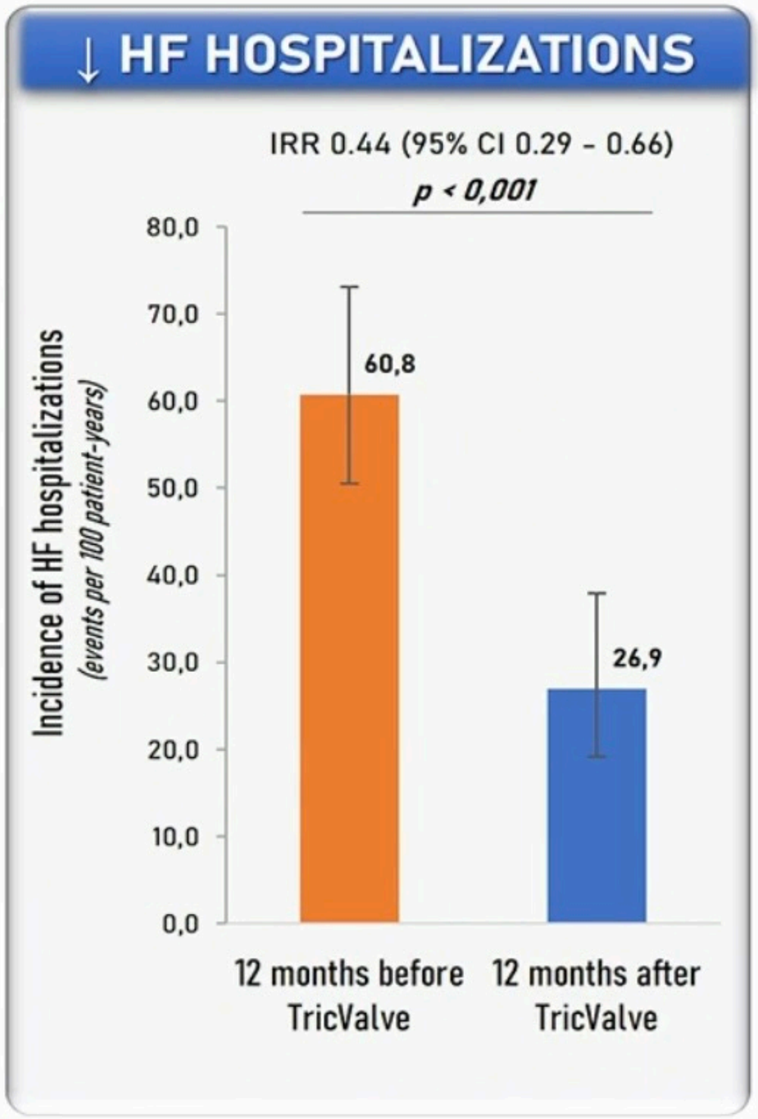
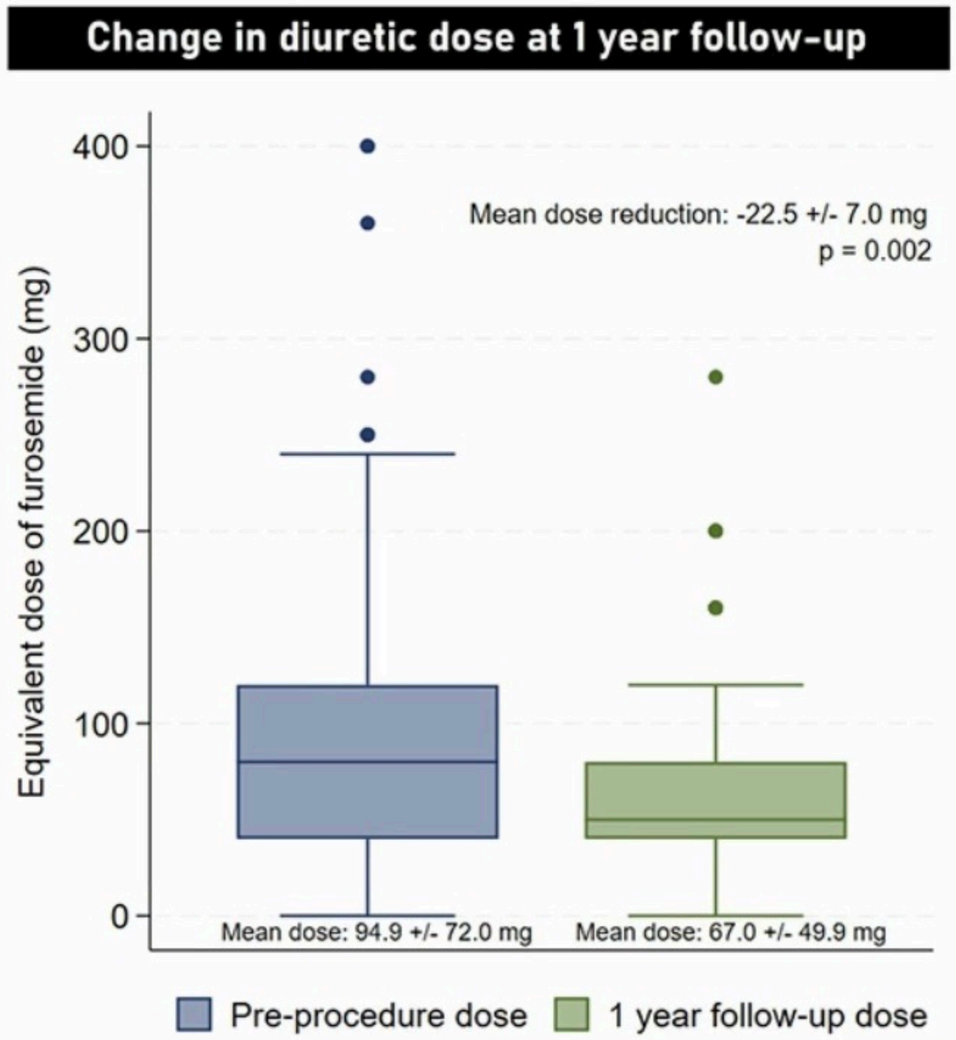
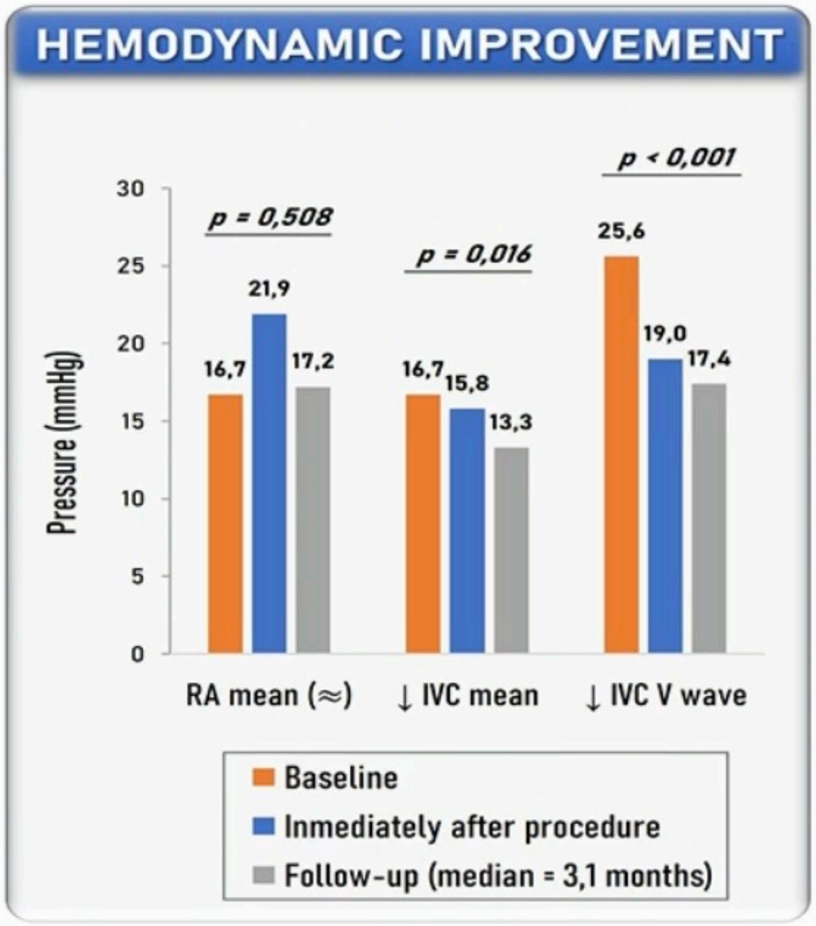




What are the essential results? Echo parameters

	Baseline	1 month	Paired p value (with respect to baseline)	12 months	Paired p value (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	**17.2 ± 4.0 (188)**	**15.7 ± 4.6 (120)**	**<0.001**	**16.3 ± 3.4 (82)**	**<0.001**
RV Strain, %	-17.9 ± 6.6 (40)	-15.9 ± 3.8 (25)	0.867	-18.0 ± 5.8 (17)	0.828
RV Fractional area change, %	**40.4 ± 10.1 (116)**	**36.9 ± 9.5 (80)**	**<0.001**	**38.9 ± 9.5 (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 II III IV V	n = 197 0 [0.0%] 25 [12.7%] 76 [38.6%] 96 [48.7%]	n = 124 3 [2.4%] 21 [16.9%] 48 [38.7%] 52 [41.9%]	0.049	n = 84 9 [10.7%] 21 [25.0%] 28 [33.3%] 26 [31.0%]	<0.001
RVSP, mmHg	41.6 ± 13.7 (100)	40.0 ± 16.6 (54)	0.087	34.5 ± 11.0 (38)	0.068
Hepatic vein systolic flow reversal, n (%)	**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

Why is this important? Hemodynamic parameters



	Pre intervention (n = 190)	Immediate post-intervention (n = 105)	p Value	On follow-up (n = 26) Median FU 3.1 months	p Value
Systolic PAP, mmHg	41.5 (10.3)	*Not measured*	-	51.0 (26.1)	0.303
Mean PAP, mmHg	27.1 (6.5)	*Not measured*	-	35.5 (21.4)	0.099
PCWP, mmHg	18.3 (5.3)	*Not measured*	-	18.2 (6.0)	0.414
RVf/BA	2.3 (1.4)	*Not measured*	-	2.2 (1.2)	0.677
Cardiac output (l/min)	4.4 (1.5)	*Not measured*	-	4.2 (1.4)	0.810
RA mean pressure, mmHg	**16.7 (6.2)**	**21.9 (9.0)**	**<0.001**	**17.2 (5.8)**	0.508
RA V wave pressure, mmHg	**25.8 (9.1)**	**37.7 (15.2)**	**<0.001**	**32.8 (11.7)**	**0.018**
IVC mean pressure, mmHg	**16.7 (6.0)**	**15.8 (6.2)**	**<0.001**	**13.3 (4.2)**	**0.016**
IVC V wave pressure, mmHg	**25.6 (8.7)**	**19.0 (7.1)**	**<0.001**	**17.4 (6.6)**	**<0.001**
SVC mean pressure, mmHg	16.7 (6.1)	18.1 (9.1)	0.325	15.6 (4.4)	0.865
SVC V wave pressure, mmHg	25.4 (8.7)	22.8 (11.2)	0.176	22.0 (8.0)	0.843

Why is this important?

Tricvalve implantation is feasible with an acceptable safety profile in this highly comorbid patient population and in an advanced stage of the disease

Treatment of severe TR with the Tricvalve system resulted in meaningful improvements in functional status and venous peripheral congestion at 12 months, and in a significant reduction of re-admissions due to RHF

TTVR with the Tricvalve system effectively reduces the IVC pressure and promotes a positive RV remodelling despite the presence of massive or torrential TR at baseline in the vast majority of the patients

The essentials to remember

- **Why?** Real world clinical outcomes of Tricvalve are currently lacking
- **What?** Safety and effective outcomes at 1 year of follow
- **How?** Retrospective analysis from large, international registry
- **What are the results?** TricValve system demonstrated significant overall clinical improvement at 1-year, with a mortality rate commensurate with their baseline TRI-SCORE
- **Why is this important?** This is the first large registry to demonstrate that CAVI with the 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 due to right heart failure