Efficacy and Safety of TricValve Bicaval Implantation in patients with Pacemakers

Ángel Sanchez-Recalde on behalf of TricBicaval Registry

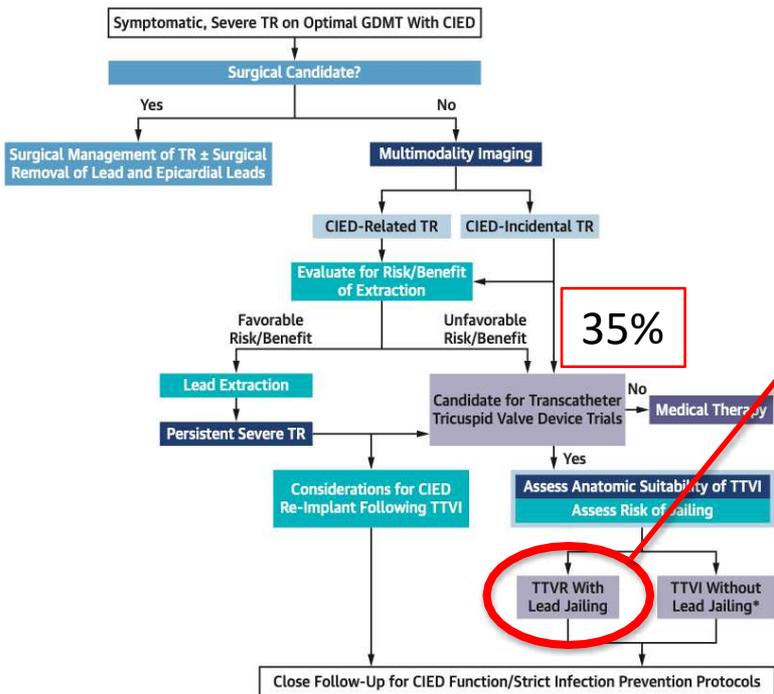*University Hospital Ramón y Cajal*

Madrid. Spain

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Potential conflicts of interest

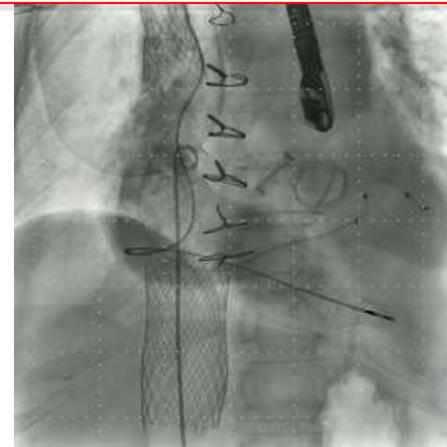**Speaker's name: Ángel Sánchez Recalde**

☑ I have the following potential conflicts of interest to declare:

Honoraria (proctoring) & consultation fees: Products & Features, Edwards Lifesciences, Abbott, Medtronic.

Symptomatic, Severe TR on Optimal GDMT With CIED

Surgical Candidate?

Yes — Surgical Management of TR ± Surgical Removal of Lead and Epicardial Leads

No — Multimodality Imaging

CIED-Related TR | CIED-Incidental TR

Evaluate for Risk/Benefit of Extraction

Favorable Risk/Benefit — Lead Extraction — Persistent Severe TR

Unfavorable Risk/Benefit — **35%**

Candidate for Transcatheter Tricuspid Valve Device Trials — No → Medical Therapy

Yes → Assess Anatomic Suitability of TTVI / Assess Risk of Jailing

Considerations for CIED Re-Implant Following TTVI

TTVR With Lead Jailing | TTVI Without Lead Jailing*

Close Follow-Up for CIED Function/Strict Infection Prevention Protocols

Key Member of MDT Involved in Shared Decision-Making
- Electrophysiologist
- Cardiothoracic Surgeon
- Structural Imager
- Structural Proceduralist
- Clinical Cardiologist/Heart Failure Specialist

Hahn RT, et al. J Am Coll Cardiol. 2024;83(20):2002-2014.

Risks { device-related infection / lead fracture

➤ To determine outcomes of patients with jailed leads following CAVI

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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.

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BASELINE CHARACTERISTICS

Baseline characteristics	No Pacemaker / ICD / CRT (n=134)	Pacemaker / ICD / CRT (n = 70)	p value
Female sex: n (%)	90 (67.2)	43 (61.4)	0.414
Age, years: mean (SD)	77.9 ± 6.7	77.6 ± 8.8	0.799
eGFR <60ml/min/m^2: n (%)	89 (66.4)	56 (80.0)	**0.042**
Coronary artery disease: n (%)	19 (14.2)	22 (31.4)	**0.004**
TRI-SCORE: n (%)			0.337
Low risk (0-3 points)	23 (17.2)	13 (18.6)	
Intermediate risk (4-5 points)	54 (40.3)	21 (30.0)	
High risk (≥ 6 points)	57 (42.5)	36 (51.4)	
Prior cardiac surgery: n (%)	64 (47.8)	38 (54.3)	0.376
Prior surgical intervention on tricuspid valve: n (%)	12 (9.0)	8 (11.4)	0.573
Prior percutaneous tricuspid valve intervention: n (%)	14 (10.5)	5 (7.1)	0.441
CRT device: n (%)	-	11 (15.7)	-
HF hospitalization in the last year	80 (65.0)	33 (52.4)	0.094
TR etiology: n (%)			**<0.001**
Secondary Atrial	54 (45.0)	14 (22.6)	
Secondary Ventricular	56 (46.7)	20 (32.3)	
Lead related	0 (0.0)	**22 (35.5)**	
Primary	10 (8.3)	6 (9.7)	

Population of 204 patients. 70 patients with **RV lead (34,3%)**

- In 35,5% of cases with **lead-related TR**

- Higher prevalence of **chronic kidney disease** and **coronary artery disease**

- 51,4% of patients had **high risk TRI-SCORE** (≥ 6 points)

- 52,4% had been admitted for HF in the last year

Baseline characteristics	No Pacemaker / ICD / CRT (n=134)	Pacemaker / ICD / CRT (n = 70)	p value
Clinical parameters			
Weight, Kg	70.1 (15.2)	71.1 (15.0)	0.669
NYHA functional class			0.592
II	24 (18.0%)	16 (23.2%)	
III	91 (68.4%)	46 (66.7%)	
IV	18 (13.5%)	7 (10.1%)	
Peripheral edema, n [%]	101 (75.4%)	48 (68.6%)	0.299
Ascites, n [%]	41 (30.6%)	22 (31.4%)	0.903
Laboratory			
eGFR	**51.5 (24.7)**	**44.0 (17.2)**	**0.023 ***
Creatinine, mg/dL	1.4 (1.0)	1.5 (0.6)	0.534
NTproBNP, pg/mL	4092.6 (8226.6)	3659.7 (5017.0)	0.705
Total Bilirubin, mg/dL	1.2 (0.7)	1.1 (0.5)	0.443
AST U/l	29.3 (19.7)	32.1 (20.8)	0.419
ALT U/l	21.2 (18.9)	24.3 (14.5)	0.286
GGT U/l	**129.8 (123.2)**	**176.1 (151.7)**	**0.058**

PM patients had poor functional class (76,8% NYHA III-IV).

High prevalence of **signs of right heart failure**, similar to non-PM patients.

Worse renal function and numerically higher liver enzyme levels **(GGT)**

BASELINE CHARACTERISTICS

Echocardiogram			
LVEF, %	**57.7 (8.5)**	**51.5 (11.7)**	**<0.001 ****
LVEDD, mm	45.7 (7.1)	46.8 (8.7)	0.403
TR-Grade basal			0.280
Severe (III)	13 (10.0%)	12 (17.9%)	
Massive (IV)	51 (39.2%)	25 (37.3%)	
Torrential (V)	66 (50.8%)	30 (44.8%)	
RV basal diameter, mm	51.5 (8.8)	53.9 (9.9)	0.101
TAPSE, mm	17.5 (3.8)	16.7 (4.4)	0.166
Right catheterization			
Pulmonary hypertension (mPAP ≥25)	77 (67.5%)	38 (64.4%)	0.679
mPAP, mmHg	27.1 (6.4)	26.9 (6.8)	0.896
RA V-wave, mmHg	24.7 (7.1)	25.2 (8.5)	0.727
RA mean, mmHg	16.2 (5.4)	16.4 (6.4)	0.830
PCW, mmHg, mmHg	18.3 (5.2)	18.3 (5.5)	0.957
PVR basal, Wood units	2.4 (1.4)	2.0 (1.0)	0.133
Cardiac output, l/min	4.2 (1.4)	4.6 (1.8)	0.164
Treatment			
Loop diuretic dose (equivalent dose of furosemide, mg)	89.1 (70.9)	105.8 (73.3)	0.139
MRA, n [% of use]	84 (62.7%)	53 (75.7%)	0.060
Mean MRA dose (mg)	27.2 (29.6)	32.2 (26.3)	0.283
SGLT2i, n [% of use]	29 (21.6%)	21 (30.0%)	0.188

PM patients had **worse LVEF** and received numerically **higher doses of diuretics**.

High prevalence of **pulmonary hypertension** and **high RA pressures** in both groups.

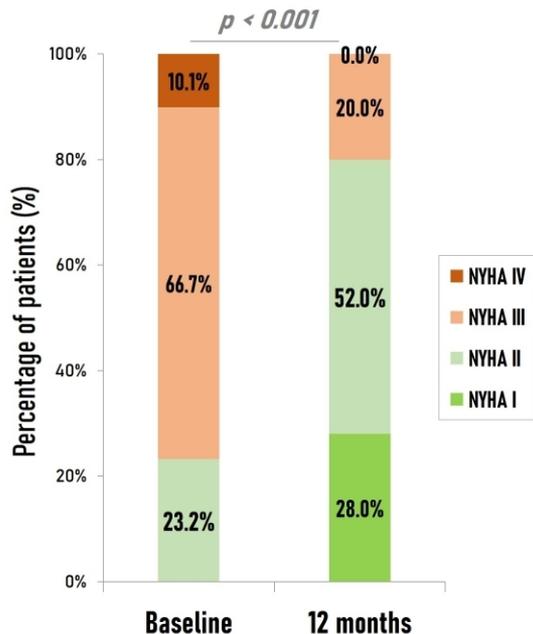**Procedure-Related, In-Hospital, and Follow-Up Adverse Events**
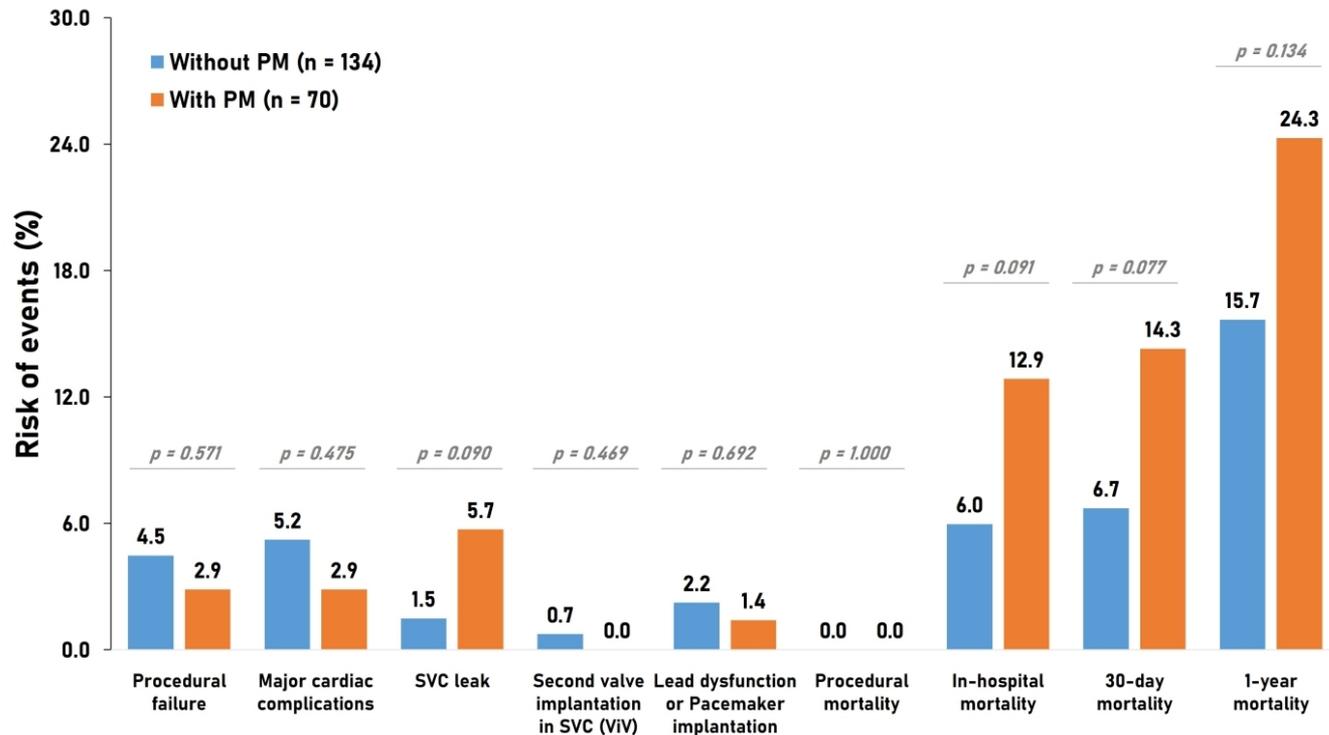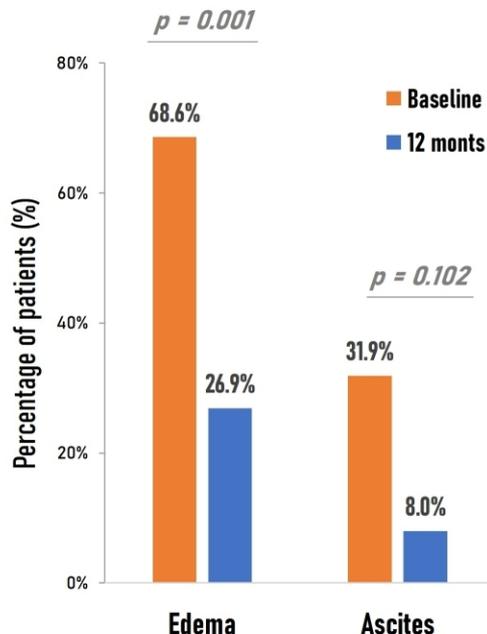

- **High procedural success rate (97,1%).**

- Very **low risk of cardiac complications or lead dysfunction**.

- **Non-significant increase in mortality** at 30 days and at 1-year follow-up.

# 1-YEAR OUTCOMES: Clinical improvement

NYHA Functional Class

p < 0.001

Percentage of patients (%)

Baseline: NYHA IV 10.1%, NYHA III 66.7%, NYHA II 23.2%
12 months: NYHA IV 0.0%, NYHA III 20.0%, NYHA II 52.0%, NYHA I 28.0%

- NYHA IV
- NYHA III
- NYHA II
- NYHA I

Signs of Right Heart Failure

- Baseline
- 12 monts

p = 0.001
p = 0.102

Edema: Baseline 68.6%, 12 months 26.9%
Ascites: Baseline 31.9%, 12 months 8.0%

Improvement in **NYHA functional class** and **right heart failure signs**, are comparable to those observed in non-pacemaker patients.

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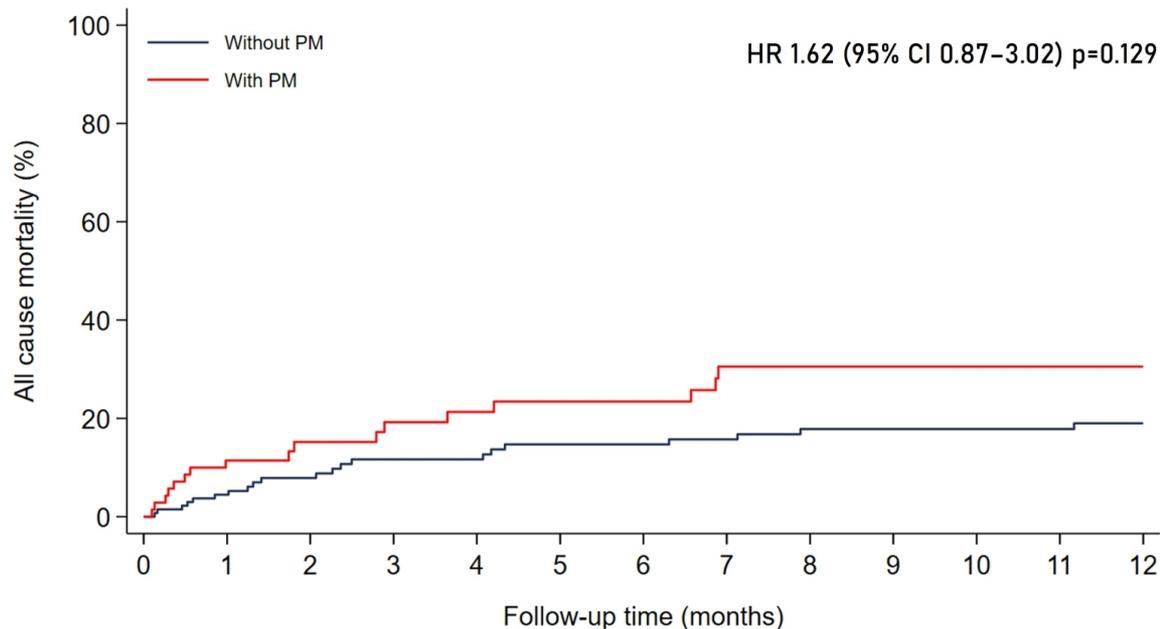# 1-YEAR OUTCOMES: HF Hospitalization

B) Heart Failure Hospitalization
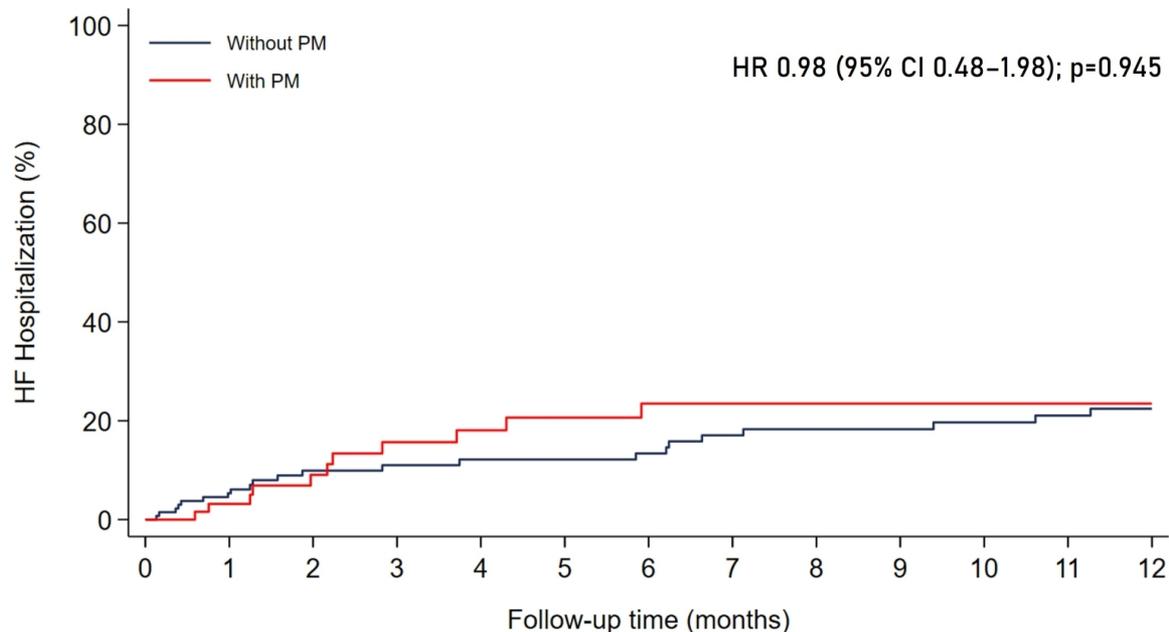
No statistically significant differences in **Heart Failure Hospitalizations** during the first year of follow-up.

A) All–Cause Mortality

No statistically significant differences in **All-Cause Mortality** during the first year of follow-up.

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CONCLUSIONS

- **TricValve bicaval implantation in pacemaker patients is safe**, with high procedural success rate and a very **low risk of cardiac complications** or pacemaker lead damage

- Overall outcomes, including **improvement in NYHA functional class and right heart failure signs**, are **comparable to those observed in non-pacemaker patients**

- **No significant differences in mortality or HF hospitalization** at 30 days and 1-year follow-up

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