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ORIGINAL RESEARCH

Real-World Experience in Tricuspid Transcatheter Edge-to-Edge Repair: Transcatheter Tricuspid Valve Repair in Spain Registry

Antonio Sisinni, MD*; Manuel Barreiro-Perez, MD, PhD*; Xavier Freixa, MD, PhD; Dabit Arzamendi, MD, PhD; Vanessa Moñivas, MD, PhD; Fernando Carrasco-Chinchilla, MD, PhD; Manuel Pan, MD, PhD; Luis Nombela-Franco, MD, PhD; Isaac Pascual, MD, PhD; Tomás Benito-González, MD; Ruth Perez, MD; Iván Gómez-Blázquez, MD; Ignacio J. Amat-Santos, MD, PhD; Ignacio Cruz-González, MD, PhD; Ángel Sánchez-Recalde, MD, PhD; Ana Belén Cid Alvarez, MD, PhD; Laura Sanchis, MD, PhD; Berenice Caneiro-Queija, MD; Chi Hion Li, MD; Maria del Trigo, MD, PhD; Jose David Martínez-Carmona, MD; Dolores Mesa, MD, PhD; Eduardo Pozo, MD, PhD; Pablo Avanzas, MD, PhD; Pedro Cepas-Guillén, MD, PhD; Rodrigo Estévez-Loureiro, MD, PhD

BACKGROUND: Significant tricuspid regurgitation (TR) is associated with increased morbidity and mortality. The development of transcatheter valve repair therapies has opened a wide range of opportunities for treatment of patients with high surgical risk. Real-world data might improve patient selection and outcome. The authors sought to investigate acute and short-term cardiovascular outcomes of tricuspid transcatheter edge-to-edge repair (T-TEER) with dedicated devices in a real-world setting.

METHODS AND RESULTS: This is a retrospective, single-arm, multicenter registry conducted at 15 sites in Spain. The primary end point was a composite of all-cause death, rehospitalization for heart failure, and tricuspid valve re-intervention. Patients included (n=283) were older (76±9 years, 70% female), and showed significant comorbidities. Massive or torrential TR was present in 55% of subjects, with secondary cause being the main mechanism of regurgitation in ≈80% of individuals. Intraprocedural success was achieved in 79% of patients. At 1-year follow-up, significant improvements in TR grade (≥3+, 100% to 25%, P <0.001) and New York Heart Association functional class (I/II, 33%–86%, P <0.001) were observed. Lead-induced cause and single leaflet device attachment emerged as independent predictors of at least severe predischarge residual TR. In-hospital mortality occurred in 4 (1.4%) patients, whereas the Kaplan–Meier estimated 1-year primary end point occurrence rate was 21%. Intraprocedural success (hazard ratio, 0.353 [95% CI, 0.156–0.798]; P=0.012), was found to be an independent predictor of primary end point.

CONCLUSIONS: In a real-world contemporary setting, tricuspid transcatheter edge-to-edge repair with dedicated devices emerged as effective therapeutic option for patients with severe TR.

Key Words: edge-to-edge repair ■ procedural success ■ transcatheter treatment ■ tricuspid regurgitation ■ TRI-SPA

Correspondence to: Manuel Barreiro-Perez, MD, PhD, Department of Cardiology, University Hospital Alvaro Cunqueiro, Vigo, Spain, C/ Clara Campoamor 341, 36213 Vigo, Spain. Email: manuelbarreiroperez@gmail.com

A. Sisinni and M. Barreiro-Perez contributed equally.

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CLINICAL PERSPECTIVE

What Is New?

- In a real-world contemporary cohort, tricuspid transcatheter edge-to-edge repair with dedicated devices proved to be an effective treatment choice, resulting in significant tricuspid regurgitation reduction and symptomatic improvement.
- The study emphasizes the clinical importance of achieving maximum tricuspid regurgitation reduction to optimize outcomes during midterm follow-up.

What Are the Clinical Implications?

- Anatomical features related to procedural failure need to be confirmed in larger all-comers studies with prospective research required to validate clinical results and identify device-specific differences.

Nonstandard Abbreviations and Acronyms

CIED	cardiac-implantable electronic device
NYHA	New York Heart Association
SLDA	single leaflet device attachment
TR	tricuspid regurgitation
T-TEER	tricuspid transcatheter edge-to-edge repair
TV	tricuspid valve

Severe tricuspid regurgitation (TR) is a relatively prevalent valvular heart disease associated with adverse prognosis, in terms of increased risk of hospitalization due to heart failure (HF) and mortality, as well as impaired quality of life.[1] Medical treatment primarily consists of diuretics for symptom relief. Surgical intervention historically carried increased mortality and adverse events,[2] and it is generally reserved for patients with additional indications for cardiac surgery.[3] Over the past few years, growing recognition of TR as an independent predictor of unfavorable clinical outcome reignited the demand for improved treatment alternatives. In this perspective, transcatheter options have broadened the spectrum of potentially treatable patients. Transcatheter repair using the edge-to-edge technique has proven to be a secure and effective approach in reducing the severity of regurgitation and enhancing quality of life.[4,5] In this retrospective, single-arm, multicenter registry, we aim to investigate acute and short-term cardiovascular outcomes of tricuspid transcatheter edge-to-edge repair (T-TEER) with dedicated devices, in a real-world all-comers setting.

METHODS

Study Design

The TRI-SPA (transcatheter tricuspid valve repair in Spain) registry is an ongoing single-arm, multicenter, retrospective registry collecting data of patients submitted to T-TEER, in 15 Spanish hospitals. Inclusion criteria were as follows: (1) symptomatic at least severe TR, despite optimal medical therapy; (2) contraindication to surgery according to local multidisciplinary Heart Team evaluation; and (3) morphological suitability for T-TEER.

The present analysis included only consecutive patients undergoing tricuspid valve (TV) repair with dedicated devices, including TriClip (Abbott Vascular, Santa Clara, CA) and PASCAL (Edwards Lifesciences, Irvine, CA) systems, treated between June 2020 and May 2023 (Figure 1).

All patients included in the study signed a written informed consent after receiving an oral and written explanation of issues concerning the procedure, data collection, and subsequent analysis. Given the retrospective nature of the analysis, Internal Review Board approval was not required. The investigation conforms with the principles outlined in the Declaration of Helsinki. Data that support the findings of this study are available from the corresponding author upon reasonable request.

Echocardiographic Evaluation

Before the procedure, patients underwent transthoracic and transesophageal echocardiography to evaluate TV leaflet morphology according to a recently proposed nomenclature classification scheme,[6] anatomical suitability for T-TEER and to quantify TR, which was graded by means of a multiparametric approach according to a classification system ranging from none to torrential.[7] Considering a leaflet involvement-based classification, TR was defined as (1) primary, resulting from abnormality of the TV apparatus; (2) secondary, characterized by the structural integrity of the TV leaflets in the presence of leaflet tethering or annular dilatation as the main mechanism of regurgitation; and (3) cardiac-implantable electronic device (CIED)–induced, related to interference of the device lead with the TV leaflets.[8] Among other parameters, current guidelines-based biventricular dimensions and function, as well as atrial sizing,[9] mitral regurgitation degree,[3] and pulmonary pressure estimates were provided.[10] Leaflet-to-annulus index was defined as the ratio of the sum of the anterior and septal tricuspid leaflet length relative to the septolateral tricuspid annulus diameter, in the midsystole phase.[11]

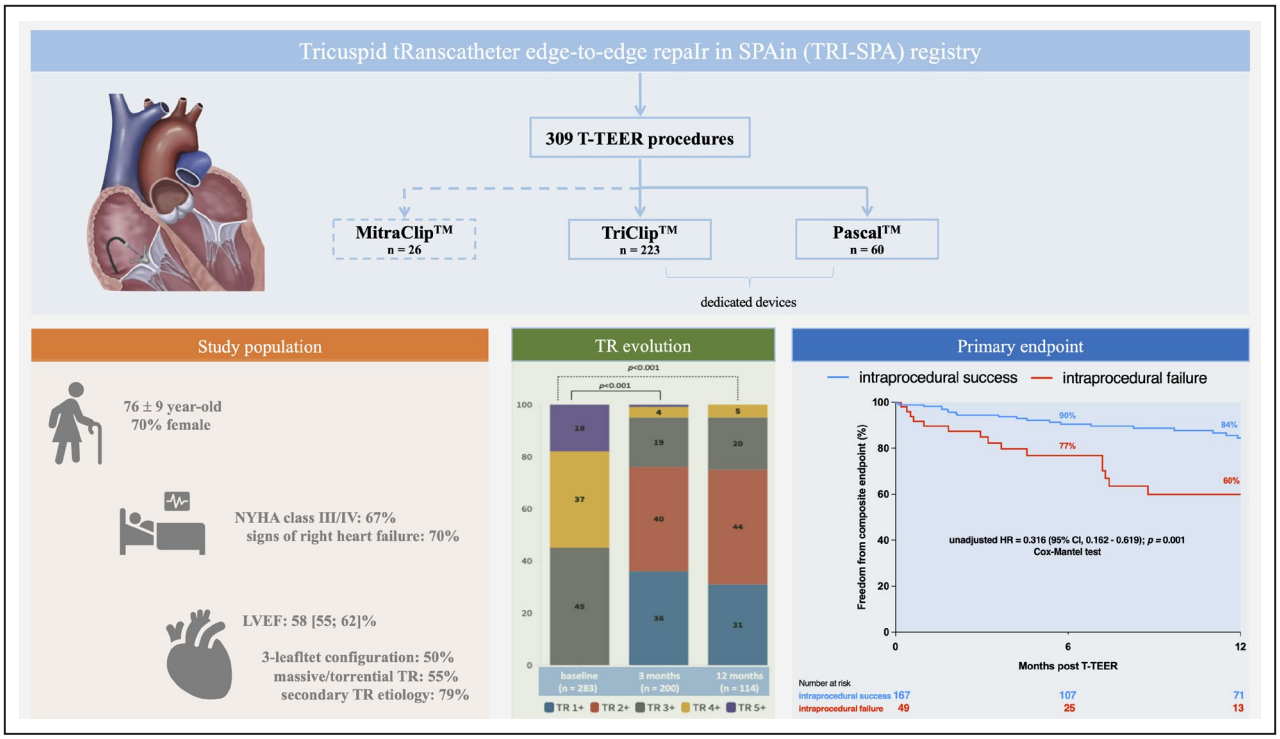

Figure 1. Real-world experience of T-TEER: Transcatheter tricuspid valve repair in Spain (TRI-SPA) registry.
Study design, main clinical and echocardiographic features of study population, and TR severity evolution in entire study cohort at 3- and 12- month follow-up, and Kaplan–Meier survival estimates for the occurrence of the primary end point are presented. HR indicates hazard ratio; LVEF left ventricular ejection fraction; NYHA, New York Heart Association; TR, tricuspid regurgitation; and T-TEER, tricuspid transcatheter edge-to-edge repair.

Procedural Aspects

Details regarding T-TEER with TriClip and PASCAL system have been previously described.[12,13]

Study End Points

We defined intraprocedural success based on Tricuspid Valve Academic Research Consortium (TVARC) criteria. Success was characterized by the absence of intraprocedural mortality or stroke; successful device access, delivery, and retrieval; proper deployment and positioning of the device without needing additional unplanned devices; effective transcatheter device performance (in terms of TR reduction and absence of TV stenosis); no device-related obstruction of forward flow or pulmonary embolism; and no need for emergency surgery or reintervention within the first 24 hours.[14] The primary study end point was a composite of all-cause mortality, first rehospitalization for HF and TV re-intervention (percutaneous or surgical), over a 1-year follow-up period. Secondary end points were all-cause death, first rehospitalization for HF, and re-intervention on the TV, considered singularly.

Statistical Analysis

Distribution of continuous data was tested with the Shapiro–Wilk test. Normally distributed variables are expressed as mean±SD, whereas non-normally distributed variables are presented as median and interquartile range. Categorical variables are reported as absolute values and corresponding percentages. Differences in continuous variables were tested using independent-sample Student *t* test; categorical variables were compared with the χ^2 test. Paired comparison between baseline and follow-up variables was performed with the paired-sample Student *t* test or Wilcoxon signed-rank test, as appropriate. Binary logistic regression-based univariable and stepwise model selection multivariate analysis were used to identify predictors of significant (>2+) residual TR at the time of discharge. Adverse events were reported as observed number of events and as Kaplan–Meier estimated rates. Event-free survival up to 1 year was evaluated according to the unadjusted Kaplan–Meier method and survivals among subgroups were compared using the log-rank test (Cox-Mantel test). Cox proportional hazards regression analysis was used to determine significant predictors of primary and secondary clinical end points. Variables with a univariable statistical significance of <0.1 were selected for inclusion into the multivariable model. Multivariate analysis, using stepwise forward selection, was finally performed to analyze the association of baseline characteristics

with study end points, expressed as hazard ratio with 95% CI and *P* values. All statistical tests were 2-sided, and *P* values <0.05 were considered statistically significant. The statistical analyses were performed using SPSS software version 28.0.0 (SPSS Inc, Chicago, IL) and GraphPad Prism software version 8 (GraphPad, Inc, San Diego, CA).

RESULTS

Baseline clinical and echocardiographic characteristics of enrolled subjects are summarized in Table 1 and Table 2, respectively. In the present analysis, a total of 283 patients were included. Overall, 67% of patients were in New York Heart Association (NYHA) functional class ≥3; meanwhile, signs of right heart failure were present in 70% of the entire study cohort. Enrolled subjects showed relevant comorbidities. Previous mitral and tricuspid surgery were performed in 25% and 5% of patients, respectively. History of hospital admission for HF within 1 year before the index procedure was present in 37% of subjects. TRI-SCORE-based surgical risk assessment identified 67% of patients as having intermediate or high risk following isolated TV surgery. On average, left ventricular dimensions and systolic function were preserved, whereas significant bi-atrial dilation was observed. Concerning TV anatomy, 3-leaflet configuration (type I) was the most prevalent (50%), followed by 4-leaflet with multiple posterior leaflets (type IIIb, 28%). At least massive degree TR was recognized in 55% of participants, in the presence of a maximum coaptation gap of 6±2 mm, and prevalent anteroseptal (66%) origin of the main regurgitant jet. Secondary cause of TV regurgitation was the most frequently observed, accounting for 79% of cases. Finally, approximately one third of patients exhibited right ventricular dilation (defined as right ventricular end-diastolic area ≥ 25 mm^2), while the study population as a whole displayed preserved right ventricular contractility, a slight increase in estimated pulmonary pressure, and appropriate right ventricular-to-pulmonary artery coupling. Of note, patients showing baseline NYHA functional class ≤2 were significantly younger (73±11 versus 77±8, *P* <0.001), whereas presenting a higher rate of previous MV surgery (30% versus 22%, *P*=0.045) and CIED-related TR (10% versus 7%, *P*=0.040), if compared with more symptomatic individuals.

All procedural data are presented in Table 3. Median procedural time was 137 [99–184] minutes, and 1.8±0.7 clips were deployed. Out of the total cases of procedural complications, 11 involved single leaflet device attachment. Of the 283 subjects, 259 (92%) had evaluable postprocedure TR severity. Intraprocedural success was achieved in 79% of patients. Univariable analysis of predictors for intraprocedural success is reported in Table 4. A 3-leaflet

Table 1. Baseline Clinical Characteristics of the Entire Study Cohort

	Entire study cohort, (n=283)
Demographic and clinical features	
Age (y)	76±9
Female sex, n (%)	198 (70)
Previous or current smoker, n (%)	22 (8)
NYHA class III–IV, n (%)	188 (67)
History of peripheral edema/ascites, n (%)	195 (70)
Hemoglobin (g/dL)	13±2
eGFR (mL/min per 1.73 m^2)	58±20
Bilirubin (mg/dL)	0.89±0.42
GPT (U/L)	23±11
GOT (U/L)	27±10
NT-proBNP (pg/mL)	1435 [707–2732]
EuroSCORE II (%)	4 [2–6]
TRI-SCORE	
Low (≤3)	93 (33)
Intermediate (4, 5)	119 (2)
High (≥6)	71 (25)
Comorbidities, n (%)	
Arterial hypertension	192 (68)
Diabetes	54 (19)
Dyslipidemia	132 (47)
Coronary artery disease	51 (18)
Previous CABG	20 (7)
Previous heart valve surgery	
Aortic	41 (15)
Mitral	70 (25)
Tricuspid	15 (5)
Previous TAVI	9 (3)
Previous M-TEER	18 (6)
Atrial fibrillation	257 (91)
Previous hospitalization for HF	101 (37)
CKD	109 (39)
COPD	40 (14)
PAD	22 (8)
Previous stroke/TIA	40 (14)
Devices, n (%)	
PM/ICD	33 (12)
CRT	2 (1)
Drugs, n (%)	
ACEi/ARB/ARNI	118 (42)
β-blockers	181 (64)
K^+-sparing diuretics	162 (57)
Daily loop diuretics dosage ≥125 mg	29 (10)
Anticoagulant therapy	245 (87)

Data are presented as n (%) or mean±SD or median [interquartile range].

ACEi indicates angiotensin-converting enzyme inhibitors; ARB, angiotensin 1 receptor blocker; ARNI, angiotensin receptor-neprilysin inhibitor; CABG, coronary artery bypass graft; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; CRT, cardiac resynchronization therapy; eGFR, estimated glomerular filtration rate; EuroSCORE, European System for Cardiac Operative Risk Evaluation; GOT, glutamic oxaloacetic transaminase; GPT, glutamic-pyruvic transaminase; HF, heart failure; ICD, implantable cardioverter-defibrillator; K^+, potassium; M-TEER, mitral transcatheter edge-to-edge repair; NT-proBNP, N-terminal prohormone of brain natriuretic peptide; NYHA, New York Heart Association; PAD, peripheral artery disease; PM, pacemaker; TAVI, transcatheter aortic valve implantation; and TIA, transient ischemic attack.

Table 2. Baseline Echocardiographic Characteristics of the Entire Study Cohort

Characteristics	Entire study cohort, (n=283)
LVEDV (mL)	74 [59–101]
LVESV (mL)	31 [22–45]
LVEF (%)	58 [55–62]
Moderate-to-severe MR, n (%)	77 (28)
LAV (mL)	80 [54–114]
RAA (mm^2)	29 [24–36]
TV anatomy, n (%)	
Type I	116 (50)
Type II	19 (8)
Type IIIa	18 (7)
Type IIIb	65 (28)
Type IIIc	11 (5)
Type IV	4 (2)
Septal leaflet length (mm)	15 [12–17]
Anterior leaflet length (mm)	20 [18–23]
Posterior leaflet length (mm)	20 [18–23]
Septal leaflet restriction, n (%)	75 (34)
Anteroposterior TA diameter (mm)	38 [34–43]
Septolateral TA diameter (mm)	38 [34–43]
TR degree, n (%)	
Severe	128 (45)
Massive	105 (37)
Torrential	50 (18)
EROA (cm^2)	0.72±0.48
VC (mm)	11 [9; 12]
Max coaptation gap (mm)	6±2
Main regurgitant jet origin, n (%)	
Anteroseptal	178 (66)
Posteroseptal	55 (20)
Anteroposterior	38 (14)
TR cause, n (%)	
Primary	38 (13)
Secondary	222 (79)
CIED lead-induced	22 (8)
RV EDA (mm^2)	22 [18–27]
RV FAC (%)	41 [34–48]
TAPSE (mm)	18±4
sPAP (mm Hg)	41±11
IVC (mm)	23 [20–27]
TAPSE/sPAP (mm/mm Hg)	0.49±0.19

Data are presented as n (%) or mean±SD or median [interquartile range].

CIED indicates cardiac implantable electronic device; EROA, effective regurgitant orifice area; IVC, inferior vena cava; LAV, left atrial volume; LVEDV, left ventricular end-diastolic volume; LVEF, left ventricular ejection fraction; LVESV, left ventricular end-systolic volume; MR, mitral regurgitation; RAA, right atrium area; RV EDA, right ventricular end-diastolic area; RV FAC, right ventricular fractional area change; sPAP, systolic pulmonary arterial pressure; TA, tricuspid annulus; TAPSE, tricuspid annular plane systolic excursion; TR, tricuspid regurgitation; TV, tricuspid valve; and VC, vena contracta.

Table 3. Procedural Outcome of the Entire Study Cohort

Variables	Entire study cohort, (n=259)
Procedural time (min)	137 [99–184]
Device implanted, n (%)	
TriClip	
NT/NTW	26 (9)
XT/XTW	197 (70)
PASCAL	
P10	7 (2)
ACE	53 (19)
Implanted clips, n	1.8±0.7
First clip location, n (%)	
Anteroseptal	231 (83)
Posteroseptal	41 (15)
Anteroposterior	5 (2)
Single leaflet device attachment, n (%)	11 (4)
Acute myocardial infarction, n (%)	1 (0.4)
Major bleeding, n (%)	4 (2)
Major access site and vascular complications, n (%)	5 (2)
Postprocedure TR severity ≤2+, n (%)	204 (79)
Postprocedure TV gradient	1 [1–;2]
In-hospital death, n (%)[†]	4 (2)
Admission days	3 [2– 4]

TR indicates tricuspid regurgitation; and TV, tricuspid valve.

[†]*P* values are generated by Cox–Mantel analysis.

configuration (type I) did not demonstrate a predictive value when compared with the presence of a 4-leaflet TV anatomy (odds ratio, 0.810 [95% CI, 0.420–1.561]; *P*=0.528). Similarly, leaflet-to-annulus index and anteroseptal origin of the main regurgitant jet were not associated with procedural outcome (odds ratio, 0.551 [95% CI, 0.075–4.029]; *P*=0.557 and odds ratio, 0.658 [95% CI, 0.351–1.236]; *P*=0.193, respectively). The results of the multivariate logistic regression analysis, incorporating all variables identified in the univariable analysis, revealed that CIED-related TR cause and SLDA emerged as independent predictors of procedural failure. In-hospital mortality occurred in 4 participants (1.4%). Of note, the observed death rate was lower than expected according to TRI-SCORE risk groups (Table 5).

With 51 (18%) patients lost to follow-up, 232 were followed for a median of 9 [4–15] months. Baseline clinical and echocardiographic characteristics in 2 study groups identified according to 1-year follow-up data availability are presented in Table S1 and Table S2. Durability of TR severity reduction was observed over a short-term follow-up period, with 76% and 75% of individuals being classified as having moderate

Table 4. Univariable and Multivariable Binary Logistic Regression Analysis for Intraprocedural Success

Variables	Univariable analysis*			Multivariable analysis		
	HR	95% CI	*P* value	HR	95% CI	*P* value
Baseline TR severity (torrential vs severe/massive)	0.477	0.317–0.719	<0.001	0.508	0.150–1.721	0.277
Septal leaflet restriction	0.325	0.172–0.617	0.001	0.618	0.192–1.987	0.419
Max coaptation gap ≥8.5 mm	0.241	0.087–0.668	0.006	0.939	0.802–1.101	0.440
CIED lead-induced TR cause	0.229	0.090–0.584	0.002	0.095	0.017–0.520	0.007
RV EDA ≥25 mm^2	0.439	0.208–0.926	0.031	0.701	0.212–2.316	0.561
Single leaflet device attachment	0.303	0.089–1.033	0.056	0.065	0.006–0.766	0.030

Data are presented as hazard ratio (HR) with 95% CI and *P* values.
*Only statistically significant covariates are reported.
CIED indicates cardiac implantable electronic device; RV EDA, right ventricular end-diastolic area; and TR, tricuspid regurgitation.

or less TR after 3- and 12-month follow-up, respectively (Figure 1). When analyzing TR severity at 3- and 12-month follow-up based on baseline TR degree, it becomes evident that as the preprocedural severity increases, the percentage of residual at least severe TR increases (Figure 2).

At 1-year follow-up, the primary end point occurred in 35 patients (21%). After stratifying the entire study cohort according to procedural outcome, freedom from composite end point occurrence was significantly higher in patients with intraprocedural success (84%), compared with subjects with procedural failure (60%) (Figure 1). Likewise, all-cause death, short-term rehospitalization for HF, and TV re-intervention rates were significantly lower in patients with procedural success (4% versus 14%, *P*=0.040, 12% versus 27%, *P*=0.036, and 2% versus 11%, *P*=0.013, respectively) (Figure 3). At univariable Cox regression analysis, TRI-SCORE, chronic obstructive pulmonary disease, left ventricular end-systolic volume, TR cause, type of implanted device, and intraprocedural success were able to predict the primary end point occurrence. Intraprocedural success was found to be the only independent predictor of primary end point on multivariable analysis (Table 6).

The proportion of individuals classified as NYHA functional class I to II significantly increased from 33% at baseline to 89% at 3 months and 86% at 12 months (*P* <0.001, both), (Figure 4).

Table 5. Observed Versus Predicted In-Hospital Mortality According to TRI-SCORE

TRI-SCORE	Number of patients	Predicted mortality (%)	Observed mortality, n (%)
Low (≤3)	93	1–5	0 (0)
Intermediate (4, 5)	119	8–14	0 (0)
High (≥6)	71	22–65	4 (7)

Device-Specific Analysis

Overall, baseline clinical and echocardiographic parameters were similar between the 2 device groups. However, history of transcatheter mitral valve repair and pacemaker rates was higher in the PASCAL group (Table S3). Additionally, TriClip patients showed lower baseline MR and TR degree, as well as fewer cases of TR related to CIED (Table S4). Intraprocedural success, as well as periprocedural complications rates, did not significantly differ among subgroups, whereas the PASCAL group showed a lower number of implanted devices. Compared with baseline, significant improvement in TR degree was observed in both groups at 3- and 12-month follow-up (Figure 5).

DISCUSSION

In a contemporary, real-world multicenter experience of symptomatic patients with at least severe TR treated with dedicated transcatheter edge-to-edge devices, our results indicate a substantial reduction in TR severity, as well as noteworthy enhancements in NYHA functional class following the T-TEER procedure, in the presence of low-rate procedural complications and in-hospital mortality. Our analysis underscores the importance of achieving the maximum degree of intraprocedural TR reduction, given the associated clinical benefits within a midterm follow-up period.

Interpretation of the study findings requires consideration of the context of a challenging patient population with multiple comorbidities, not suitable for surgical treatment. The bRIGHT postapproval study was the first registry specifically designed to assess the safety and efficacy of the T-TEER with a dedicated device, TriClip system, within a nonselected, real-world patient population.[15] On average, compared with bRIGHT participants, our study cohort exhibited a relatively younger age, with lower baseline symptomatic burden. However, we observed a higher prevalence of atrial fibrillation and more than moderate baseline mitral

Figure 2. Improvement of TR severity at short-term follow-up.
Variations from baseline to 3- and 12-month follow-up of TR degree according to baseline TR severity. TR indicates tricuspid regurgitation.

regurgitation as well as broader range of TR causative mechanisms. When considering subjects enrolled into the T-TEER group of the randomized TRILUMINATE Pivotal trial,[16] our patient population showed a higher rate of previous mitral and tricuspid surgery and hospitalization for HF within 1 year before enrollment.

The intraprocedural success rate was similar to the bRIGHT study (79% versus 80%), despite a significantly lower rate of at least massive TR in our study cohort (55% versus 88%). This implies a TR reduction of lesser magnitude than bRIGHT, likely related to the effect of a learning curve of less experienced centers and increasingly complex TV anatomies, accounting for CIED lead-related regurgitation. Consistently, in our cohort that variable was identified as an independent predictor of procedural failure. Meanwhile, the larger coaptation gap failed to predict it, perhaps as a consequence of using dedicated devices with independent grasping.

The distribution of leaflet configurations closely mirrored the original proposal by Hahn et al., underscoring the consistency in the frequencies of TV anatomies within a distinct cohort.[6] Interestingly, in our study 3-leaflet configuration (type I) was not associated with a reduced risk of procedural failure, if compared with 4-leaflet TV anatomy. This appears to contrast with the findings of Sugiura et al., who provided a single-center analysis of 145 consecutive patients undergoing T-TEER with second and third generation MitraClip (71.7%), TriClip (11.7%), or PASCAL (16.5%) systems,

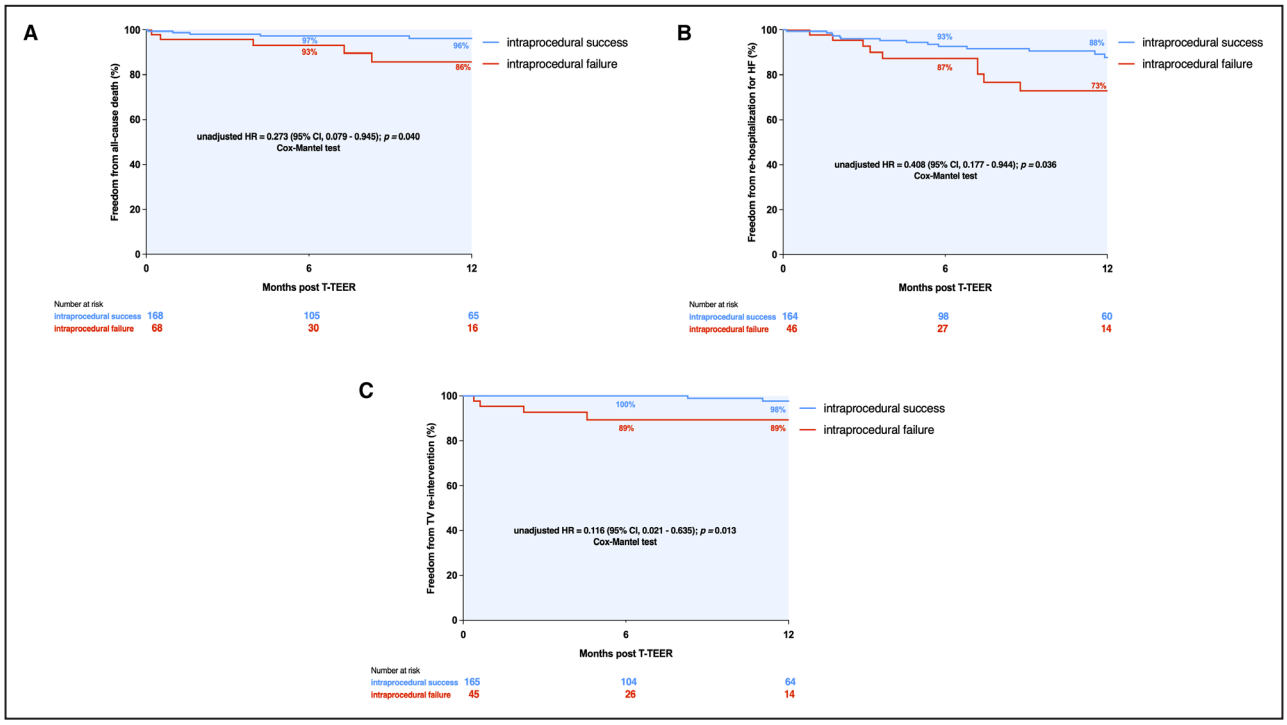

Figure 3. Unadjusted Kaplan–Meier survival estimates for the occurrence of the secondary end points.
Plot of survival free from all-cause death **(A)**, rehospitalization for heart failure (HF) **(B)**, and tricuspid valve (TV) re-intervention **(C)**, in patients stratified according to intraprocedural success. HR indicates hazard ratio; and T-TEER, tricuspid transcatheter edge-to-edge repair.

between 2015 and 2020, and identified 4-leaflet configuration (27.5% of patients) as a predictor of an increased risk of residual TR ≥3+ (odds ratio, 2.65 [95% CI, 1.15–6.10]; *P*=0.022).[17] A possible explanation relies on growing experience of the operators coupled with a wider availability of devices. Utilizing dedicated T-TEER system of varying sizes with independent grasping features, it is currently possible to fit a broader spectrum of TV morphologies and achieve satisfactory outcomes in terms of TR reduction, even in cases with multiple-leaflet anatomies.

T-TEER was performed across the entire study cohort, and a low intraprocedural complications rate was reported. Accordingly, in-hospital mortality was <2%, relevantly lower than expected based on TRI-SCORE assessment. The TRI-SCORE was developed as a risk assessment model composed of 8 easily assessable parameters, aimed at providing valuable insights into the risk associated with isolated TV surgery.[18] While initially developed to predict in-hospital mortality, it also exhibited a significant association with 1-year death rate, ranging from 3% to 60%, for a value of 0 to a score

Table 6. Univariable and Multivariable Cox Regression Analysis for Primary End Point Occurrence in Entire Study Cohort

	Univariable analysis*			Multivariable analysis		
Variables	HR	95% CI	*P* value	HR	95% CI	*P* value
TRI-SCORE, per 1 category-increase	1.612	1.033–2.517	0.036	1.181	0.989–1.394	0.054
COPD	1.965	0.954–4.050	0.067	1.665	0.740–3.749	0.218
LVESV	1.016	1.000–1.032	0.045	1.001	0.999–1.003	0.330
TR cause, secondary vs primary/CIED lead-induced	1.916	1.252–2.931	0.003	1.272	0.777–2.084	0.339
Device implanted, PASCAL vs TriClip	2.019	0.910–4.482	0.084	1.161	0.455–2.959	0.755
Intraprocedural success	0.316	0.162–0.619	0.001	0.353	0.156–0.798	0.012

Data are presented as hazard ratio (HR) with 95% CI and *P* values.
CIED indicates cardiac implantable electronic device; COPD, chronic obstructive pulmonary disease; LVESV, left ventricular end-systolic volume; and TR, tricuspid regurgitation.
*Only covariates with *P* values <0.1 are reported.

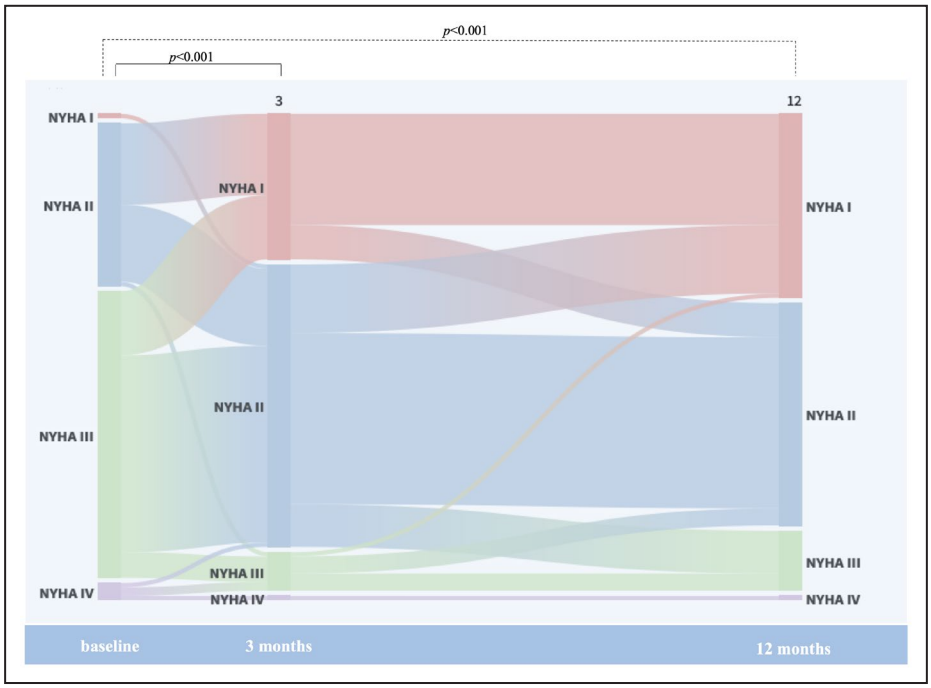

Figure 4. Paired Alluvial Plot of Change in NYHA Functional Class between baseline and 3- and 12-month follow-up (n=110).
NYHA indicates New York Heart Association.

of 9 or more, respectively. In our analysis, mortality rate ranged from 1.5% among patients with TRI-SCORE ≤3 (low risk) to 9.8% in subjects with TRI-SCORE ≥6 (high risk). This once again underscores the profound frailty and the inappropriateness of surgical intervention for individuals included in our study.

A

	TriClip™ (n = 223)	Pascal™ (n = 60)	*p* value
Intraprocedural success, n (%)	170 (79)	34 (76)	0.552
Procedural time (min)	135 [98; 180]	150 [100; 204]	0.158
Implanted clips, n	1.8 ± 0.7	1.6 ± 0.6	**0.019**
Single leaflet device attachment, n (%)	11 (5)	0 (0)	0.128

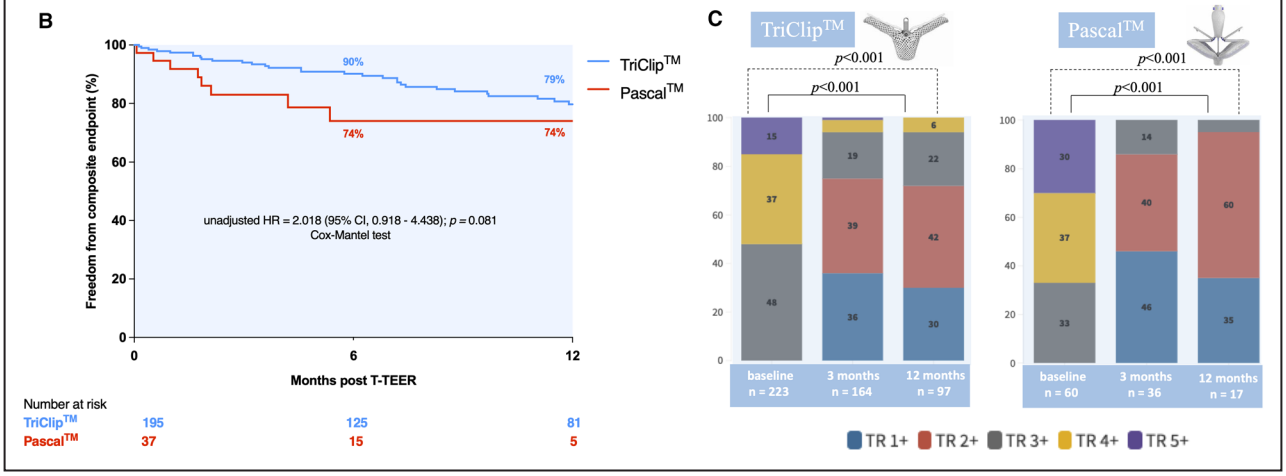

Figure 5. Device-specific analysis.
Dedicated device-based analysis of procedural outcomes **(A)**, primary end point occurrence **(B)**, and TR severity improvement at 3- and 12-month follow-up **(C)**. HR indicates hazard ratio; TR, tricuspid regurgitation; and T-TEER, tricuspid transcatheter edge-to-edge repair.

All clinical outcomes included in the study primary end point were driven by intraprocedural success. This is consistent with TRILUMINATE experience, indicating that achieving moderate or lower TR levels within 30 days after the procedure resulted in nearly a 3-fold decrease in mortality and HF hospitalizations at 1-year follow-up.[4]

The improvement of NYHA functional class, as well as decrease in TR severity after T-TEER, appeared to be stable within a 1-year period. Interestingly, the proportion of cases with at least severe residual TR at short-term follow-up increased with increasing baseline TR severity. Nevertheless, baseline TR degree (torrential versus severe/massive) failed to predict procedural outcome (hazard ratio, 0.283 [95% CI, 0.066–1.212]; *P*=0.089) in the multivariate model.

To the best of our knowledge, this is the first study providing a comparison between dedicated devices for T-TEER concerning procedural and short-term follow-up outcomes. Despite fewer clips being implanted, procedural time was significantly longer in the PASCAL group, possibly reflecting the relatively initial experience with this device, which undeniably involves a learning curve, as suggested by the CLASP TR Early Feasibility Study experience.[19] T-TEER resulted in significant improvement in TR degree at 3- and 12-month follow-up in both device groups, even when considering the relevant gaps in follow-up data for the PASCAL population. Primary end point occurrence was similar among device groups.

Study Limitations

The nonrandomized, observational design of this study may have introduced patient selection and ascertainment bias, potentially affecting event rates. Additionally, a uniform protocol for selection criteria for T-TEER was not clearly established and therefore may vary across different centers. An independent core lab to adjudicate echocardiographic data was not available. Finally, the study had a relatively short follow-up period, and longer-term durability of TR reduction and clinical outcomes should be further investigated.

CONCLUSIONS

The present study provides valuable insights into the feasibility and outcomes of T-TEER for patients with significant symptomatic TR who are not candidates for surgery. Our analysis suggests that T-TEER with dedicated devices can be an effective treatment option, leading to reductions in TR severity, and improvements in clinical outcomes driven by predischarge residual TR degree. Further research is needed to confirm these findings and assess the long-term durability of this approach.

ARTICLE INFORMATION

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Affiliations

Department of Cardiology, University Hospital Alvaro Cunqueiro, Vigo, Spain (A.S., M.B.-P., B.C.-Q., R.E.-L.); Department of Cardiology, IRCCS Policlinico San Donato, San Donato Milanese, Milan, Italy (A.S.); Cardiovascular Research Group, Department of Cardiology, University Hospital Alvaro Cunqueiro, Galicia Sur Health Research Institute (IIS Galicia Sur), Servizo Galego de Saude, University of Vigo, Vigo, Spain (A.S., M.B., B.C., R.E.); Department of Cardiology, Cardiovascular Institute, Hospital Clínic, Barcelona, Spain (X.F., L.S., P.C.-G.); Division of Interventional Cardiology, Hospital de la Santa Creu i Sant Pau, Universitat Autónoma de Barcelona, Barcelona, Spain (D.A., C.H.L.); Department of Cardiology, University Hospital Puerta de Hierro-Majadahonda, Madrid, Spain (V.M., M.d.T.); Unidad de Gestión Clínica del Corazón, Hospital Universitario Virgen de la Victoria, CIBERCV, Instituto de Investigación Biomédica de Málaga (IBIMA), Universidad de Málaga (UMA), Málaga, Spain (F.C.-C., J.D.M.-C.); Department of Cardiology, Hospital Reina Sofía, Universidad de Córdoba, Instituto Maimónides de Investigación Biomédica de Córdoba (IMIBIC), Córdoba, Spain (M.P., D.M.); Cardiovascular Institute, Hospital Clínico San Carlos, IdISSC, Madrid, Spain (L.N.-F., E.P.); Heart Area, Hospital Universitario Central de Asturias, Oviedo, Spain (I.P., P.A.); Department of Cardiology, University Hospital of León, León, Spain (T.B.-G.); Department of Cardiology, University Hospital A Coruña, Spain (R.P.); Department of Cardiology, University Hospital 12 Octubre, Madrid, Spain (I.G.-B.); Department of Cardiology, University Clinic Hospital, CIBERCV, Valladolid, Spain (I.J.A.-S.); Department of Cardiology, Hospital Universitario de Salamanca, CIBERCV, IBSAL, Salamanca, Spain (I.C.-G.); Department of Cardiology, Hospital Universitario Ramón y Cajal, Madrid, Spain (Á.S.-R.); and Department of Cardiology, University Clinic Hospital, CIBERCV, Santiago de Compostela, Spain (A.B.A.).

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Disclosures

Manuel Barreiro-Perez is proctor for Abbott Vascular, Edwards Lifesciences, and Venus Medtech. Rodrigo Estévez-Loureiro is a consultant and proctor for Abbott Vascular, Edwards Lifesciences, Boston Scientific, and Venus Medtech. Dabit Arzamendi is a consultant and proctor for Abbott Vascular and Edwards Lifesciences. Xavier Freixa is a consultant and proctor for Abbott Vascular and Edwards Lifesciences. Luis Nombela-Franco is a consultant and proctor for Abbott Vascular. Ignacio Cruz-González is proctor for Abbott Vascular. Fernando Carrasco-Chinchilla is proctor for Abbott Vascular. Laura Sanchis is proctor for Abbott Vascular. Ignacio J. Amat-Santos is consultant and proctor for P&F. Ángel Sánchez-Recalde is proctor for P&F. Chi Hion Li is proctor for Abbott Vascular and Edwards Lifesciences. Isaac Pascual is proctor for Abbott Vascular. The remaining authors have no disclosures to report.

Supplemental Material

Tables S1–S4

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