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ORIGINAL RESEARCH

STRUCTURAL

Tricuspid Valve Transcatheter Edge-to-Edge Repair in Patients With Cardiac Implantable Electronic Devices

Insights From EuroTR

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ABSTRACT

BACKGROUND Tricuspid valve transcatheter edge-to-edge repair (T-TEER) is increasingly used in patients with severe tricuspid regurgitation (TR) at high surgical risk. Long-term outcomes in those with transvalvular cardiac implantable electronic devices (CIEDs) remain insufficiently characterized.

OBJECTIVES The aim of this study was to evaluate procedural and clinical outcomes of T-TEER in patients with CIED leads in a real-world cohort.

METHODS Among 3,025 patients undergoing T-TEER at 26 centers (2016-2024), 851 (28.1%) had transvalvular CIED leads. Residual TR at discharge and follow-up and the composite of all-cause mortality or heart failure hospitalization at 2 years were assessed. CIED function was evaluated preprocedure and postprocedure. Propensity score matching (1:1) was conducted to compare outcomes between patients with and those without CIEDs.

RESULTS CIED function remained stable, and no lead revision was required. At discharge, TR ≤1+ and ≤2+ was achieved in 39.9% and 79.8%, respectively; at follow-up (median 269 days; Q1-Q3: 63-423 days), TR ≤1+ and ≤2+ persisted in 29.3% and 69.1%. In 385 matched pairs, residual TR, functional status, and 2-year heart failure hospitalization–free survival were comparable between patients with and those without CIEDs (67.1% [95% CI: 62.1%-72.5%] vs 73.6% [95% CI: 68.9%-78.6%]; $P = 0.176$). CIED presence showed a nonsignificant association with more adverse outcomes (HR: 1.31; 95% CI: 0.99-1.74; $P = 0.063$) but was not associated with residual TR >2+ (OR: 0.98; 95% CI: 0.70-1.38; $P = 0.915$). Achieving residual TR ≤2+ conferred significantly better survival irrespective of CIED presence ($P < 0.001$).

CONCLUSIONS T-TEER is safe and effective in selected patients with transvalvular CIED leads. Effective TR reduction remains prognostically relevant, even in this high-risk real-world population. (JACC Cardiovasc Interv. 2025;18:2878-2891) © 2025 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).

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Tricuspid valve transcatheter edge-to-edge repair (T-TEER) has become the predominant transcatheter treatment modality in Europe for patients with symptomatic tricuspid regurgitation (TR) at prohibitive surgical risk because of advanced age and comorbidities. Among these patients, the prevalence of cardiac implantable electronic devices (CIEDs) ranges from 21% to 34%.[1-4]

Right ventricular (RV) leads traversing the tricuspid valve (TV) may impair leaflet coaptation and contribute to lead-induced TR, which has been reported in approximately 10% to 15% of patients.[5] In many others, leads are incidentally present without causing significant valvular dysfunction.

Lead position and interaction with the TV apparatus critically influence both the feasibility and strategy of transcatheter treatment. In some cases, alternative approaches such as transcatheter TV replacement (TTVR), which entails jailing the RV lead between the prosthesis and native annulus, or transvenous lead extraction (TLE) may be considered. However, the long-term impact of lead jailing remains uncertain, and the isolated therapeutic effect of TLE on chronic lead-induced TR appears limited, although outcomes may be more favorable when performed before annular dilatation occurs. Accordingly, TLE should be considered when the lead is clearly causal for TR or interferes with the feasibility of T-TEER or when the risk of jailing is deemed high (eg, in patients with implantable cardioverter-defibrillators or pacemaker dependency).[6]

Recent observational studies suggest that T-TEER is safe and effective in patients with CIEDs, with procedural and clinical outcomes up to 1 year comparable with those without CIEDs.[2,7] A subgroup analysis of the TRILUMINATE randomized controlled trial further supports these findings.[1] Although more recent data suggest less favorable outcomes in patients with RV leads,[3] existing cohorts were limited by small sample sizes and insufficient power.

Despite these insights, long-term data on outcomes after T-TEER in patients with CIEDs remain scarce. Moreover, the impact of RV leads on procedural efficacy and

ABBREVIATIONS AND ACRONYMS

CIED = cardiac implantable electronic device

HFH = heart failure hospitalization

LTR-A = lead-associated tricuspid regurgitation type A

LTR-B = lead-associated tricuspid regurgitation type B

PSM = propensity score matching

RV = right ventricle/ventricular

SLDA = single-leaflet device attachment

TLE = transvenous lead extraction

TR = tricuspid regurgitation

T-TEER = tricuspid valve transcatheter edge-to-edge repair

TTVR = transcatheter tricuspid valve replacement

TV = tricuspid valve

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prognosis, and the effect of T-TEER on CIED function, are not fully understood.

Accordingly, the aims of this study were to evaluate the effect of RV leads on procedural and clinical outcomes following T-TEER and to examine whether T-TEER affects CIED function, leveraging data from the large, multicenter EuroTR (European Registry of Transcatheter Repair for Tricuspid Regurgitation).

METHODS

STUDY DESIGN AND POPULATION. EuroTR is an ongoing, investigator-initiated, observational, retrospective multicenter registry including TR patients treated with T-TEER between 2016 and 2024 at 26 European centers. The present analysis was focused on patients with CIEDs. All patients underwent evaluation by a local multidisciplinary heart team prior to T-TEER. The recommendation was based on an integrated assessment of comorbidities, symptom severity, anatomical feasibility, and anticipated life expectancy.

T-TEER was performed with either the MitraClip or TriClip (Abbott Structural Heart) or the PASCAL (Edwards Lifesciences) T-TEER system, following established protocols.[8] The study was conducted in accordance with the principles outlined in the Declaration of Helsinki, received approval from the respective ethics committees, and is registered at ClinicalTrials.gov (NCT06307262).

Echocardiographic assessments were performed by experienced clinicians at each center adhering to respective guidelines.[9,10] TR severity was graded following the 6-grade quantification scheme, including the grades none (0+), mild (1+), moderate (2+), severe (3+), massive (4+), and torrential (5+).[11]

STUDY DEFINITIONS. CIED presence was defined as at least 1 RV transvalvular lead at the time of T-TEER. Patients with leadless pacemakers or subcutaneous implantable devices were excluded. Lead-related single-leaflet device attachment (SLDA) was defined as SLDA in the presence of a transvalvular lead where lead-device interaction was considered the likely cause by the respective site.

STUDY ENDPOINTS AND OUTCOMES. The primary endpoint was the proportion of patients achieving TR ≤1+ and TR ≤2+ at discharge. Secondary endpoints included Tricuspid Valve Academic Research Consortium-defined intraprocedural success (successful device implantation with TR reduction by ≥1 grade to ≤2+ without major complications), TR ≤1+ and ≤2+ at the latest available follow-up, the composite of all-cause mortality and first heart failure hospitalization (HFH) analyzed as time to first event with Kaplan-Meier estimates at 2 years, and changes in NYHA functional class at latest available follow-up. To assess the independent association of CIED presence with procedural and clinical outcomes, a propensity score-matched analysis was performed. The matched cohort was further stratified into 4 groups according to CIED status (present vs absent) and residual TR (≤2+ vs >2+), and 2-year outcomes for the composite endpoint were compared.

Additional outcomes included preprocedure and postprocedure CIED function—specifically RV lead pacing threshold, sensing capability, and impedance—as well as temporal trends in procedural experience. Subgroup analyses according to lead-related TR classification (lead-associated TR type A [LTR-A], in which the lead is causative for TR, vs lead-associated TR type B [LTR-B], in which the lead is not directly involved in TR), as well as lead position (commissural vs noncommissural), were conducted to explore differences in procedural outcomes.

STATISTICAL ANALYSIS. Data are presented as mean ± SD, median [Q1-Q3], or frequency (%). Between-group comparisons were performed using the chi-square test, Student's *t*-test, or Mann-Whitney *U* test as appropriate. Temporal trends in procedural outcomes were performed in 2 independent patient cohorts stratified by early (2016-2021) and late (2022-2024) experience. Paired comparisons were assessed using the Wilcoxon signed rank test or the McNemar test. Time-to-event analysis for the composite endpoint of all-cause mortality and first HFH was conducted using Kaplan-Meier estimates, with rates of freedom from the composite endpoint reported at 2 years.

One-to-one nearest neighbor propensity score matching (PSM) was performed without replacement and using a caliper of 0.2. Matching variables included age, sex, body mass index, left ventricular ejection fraction, baseline TR grade, tricuspid annular plane systolic excursion, estimated glomerular filtration rate, RV basal diameter, and N-terminal pro-B-type natriuretic peptide. Covariate balance after matching was assessed using standardized mean differences. Binary outcomes were compared between groups using chi-square or Fisher exact tests as appropriate. Kaplan-Meier analysis was used to evaluate freedom from the composite endpoint at 2 years. The association between CIED presence and procedural failure (residual TR >2+) and the composite endpoint was

evaluated using a logistic regression model and Cox regression model, respectively, in the matched population. The proportional hazards assumption was assessed using Schoenfeld residuals, with no significant violations detected. The assumption of missing completely at random was evaluated using Little's test, which did not indicate significant violations. A 2-sided P value <0.05 was considered to indicate statistical significance. Analyses were conducted using R version 4.4.0 (R Foundation for Statistical Computing).

RESULTS

BASELINE CHARACTERISTICS. Among 3,025 patients undergoing T-TEER, 851 (28.1%) had CIEDs and were included in the present analysis. The median age was 80 years (Q1-Q3: 76-83 years), and 44.6% were woman. Most patients presented with advanced symptoms (NYHA functional class III or IV in 86%) and relevant comorbidities, including atrial fibrillation or flutter, coronary artery disease, and chronic kidney disease.

Pacemakers were the predominant device type (72.0%). Most patients had single RV leads (88.5%), while 8.8% had 2 leads and 2.8% had 3 leads. The median time since CIED implantation was 4.0 years (Q1-Q3: 1.3-7.5 years). Baseline characteristics of patients with and without CIED are displayed in Table 1.

BASELINE ECHOCARDIOGRAPHIC ASSESSMENT. Patients exhibited dilated right heart chambers with preserved RV function. TR severity was classified as 5+ in 23.1%, 4+ in 33.7%, 3+ in 41.2%, and 2+ in 2%.

The RV lead was most commonly positioned in the posteroseptal commissure (45.9%) or adjacent to the posterior leaflet (17.8%). An LTR-A mechanism was reported in 53.8% of classified cases (n = 141 of 262). The main lead-valve interactions were impingement (48.5%) and adhesion (40.4%), with subvalvular entanglement (9.1%) and perforation (2.0%) being less frequent. Baseline echocardiographic characteristics by CIED status are summarized in Table 2.

PROCEDURAL OUTCOMES. Intraprocedural success was achieved in 78.9% of patients. TR severity was significantly reduced ($P < 0.001$). Residual TR ≤1+ and ≤2+ was observed in 39.9% and 79.8% of cases, respectively. Reductions in TR severity of ≥1 and ≥2 grades were achieved in 93.3% and 69.0% of patients, respectively.

In the subgroup of patients with transvalvular leads classified as LTR-A or LTR-B, residual TR ≤1+ at discharge was observed in 39.7% (n = 56 of 141) of patients with LTR-A and 51.8% (n = 57 of 110) of those with LTR-B, while TR ≤2+ was seen in 80.9% (n = 114 of 141) and 76.4% (n = 84 of 110), respectively ($P = 0.074$ and $P = 0.479$).

In the subgroup of patients stratified by commissural and noncommissural lead positions, residual TR ≤1+ was achieved in 42.9% (n = 69 of 161) vs 48.2% (n = 55 of 114) of patients and residual TR ≤2+ in 80.7% (n = 130 of 161) vs 82.5% (n = 94 of 114), respectively ($P = 0.446$ and $P = 0.840$).

Among patients with available CIED-related procedural data, lead-induced shadowing occurred in 23.7% (n = 37 of 156) and impeded leaflet grasping in 18.1% (n = 29 of 160), and lead mobilization was feasible in 47.3% (n = 70 of 148). The final lead position was altered in 17.5% (n = 52 of 297). SLDA occurred in 11 patients (1.3%), including 5 intraprocedural events that were attributed to lead interaction (median time from procedure to SLDA detection 0 days; Q1-Q3: 0-71 days; range: 0-475 days; n = 9). Procedural outcomes are shown in Table 3.

CIED FUNCTION AFTER T-TEER. Device interrogation before and after T-TEER demonstrated overall stable CIED function (Table 4). Although impedance showed a modest but statistically significant decrease, other parameters remained unchanged.

TEMPORAL TRENDS IN PROCEDURAL SUCCESS AMONG PATIENTS WITH CIEDs. Among 693 patients with available procedural dates, the annual number of CIED cases increased steadily from 2016 to 2021 and remained high thereafter. Patients were stratified into an early experience group (2016-2021, n = 398) and a late experience group (2022-2024, n = 295). Rates of TR ≤1+ improved significantly ($P = 0.002$), whereas rates of TR ≤2+ did not differ ($P = 0.058$). The overall distribution of residual TR shifted toward lower severity in the late period ($P = 0.006$) (Figure 1), despite comparable baseline TR ($P = 0.112$).

FOLLOW-UP AND CLINICAL OUTCOMES. At latest available follow-up (median 269 days; Q1-Q3: 63-423 days), residual TR ≤1+ was observed in 29.3% (n = 146 of 498) and TR ≤2+ in 69.1% (n = 344 of 498) of patients with available echocardiographic data. Freedom from the composite endpoint of all-cause mortality and first HFH at 2 years was 56.3% (95% CI: 52.3%-60.5%). NYHA functional class improved significantly from baseline to latest follow-up ($P < 0.001$), with 53.9% of surviving patients in functional class I or II at follow-up (Figure 2).

OUTCOMES IN MATCHED PATIENTS WITH AND WITHOUT CIEDs. To specifically assess the impact of CIEDs on outcomes, a 1:1 PSM analysis was

TABLE 1 Baseline Characteristics of Patients With and Without CIEDs

	No CIED (n = 2,174)	CIED (n = 851)	*P* Value
Age, y	80 (76-83)	80 (76-83)	0.475
Female	1,267/2,172 (58.3)	378/848 (44.6)	**<0.001**
BMI, kg/m^2	25.1 (22.5-28.4)	25.0 (22.7-28.3)	0.817
TRI-SCORE	5 (4-7)	6 (4-7)	**<0.001**
EuroSCORE II, %	4.3 (2.5-7.4)	5.0 (2.9-8.3)	**<0.001**
6MWD, m	250.0 (168.0-335.0) (n = 739)	244.5 (140.0-327.3) (n = 306)	0.189
NYHA functional class			**<0.001**
I	0/0 (0.0)	0/0 (0.0)	
II	380/2,162 (17.6)	118/845 (14.0)	
III	1,535/2,162 (71.0)	595/845 (70.4)	
IV	247/2,162 (11.4)	132/845 (15.6)	
Prior HFH	604/1,092 (55.3)	273/450 (60.7)	**0.035**
Comorbidities			
Atrial fibrillation/flutter	1,934/2,145 (90.2)	757/839 (90.2)	>0.999
Dyslipidemia	927/2,001 (46.3)	428/794 (53.9)	**<0.001**
Coronary artery disease	832/2,120 (39.2)	393/843 (46.6)	**<0.001**
Prior MI	177/1,951 (9.1)	116/769 (15.1)	**<0.001**
History of cardiac surgery	537/2,088 (25.7)	259/825 (31.4)	**0.002**
Arterial hypertension	1,594/2,030 (78.5)	641/807 (79.4)	0.629
Prior stroke	182/1,602 (11.4)	82/634 (12.9)	0.334
Diabetes mellitus	450/2,006 (22.4)	209/806 (25.9)	0.054
COPD	317/2,082 (15.2)	133/817 (16.3)	0.517
Dialysis	48/1,808 (2.7)	30/724 (4.1)	0.067
Laboratory data			
NT-proBNP, pg/mL	2,340.0 (1,301.0-4,301.0) (n = 1,621)	2,677.0 (1,520.5-5,359.5) (n = 667)	**<0.001**
Bilirubin, mg/dL	0.8 (0.6-1.2) (n = 1,638)	0.8 (0.6-1.2) (n = 637)	0.185
AST, U/L	28 (23-35) (n = 1,903)	29 (24-36) (n = 752)	0.052
ALT, U/L	19 (14-25) (n = 1,826)	19 (14-25) (n = 713)	0.862
GGT, U/L	90 (47-175) (n = 1,745)	109 (55-206) (n = 677)	**<0.001**
Platelets, $\times 10^9$/L	192.0 (154.0-238.0) (n = 1,439)	177.0 (143.0-216.5) (n = 559)	**<0.001**
INR	1.2 (1.1-1.5) (n = 1,009)	1.29 (1.1-1.6) (n = 405)	0.074
eGFR, mL/min/1.73 m^2	46.0 (33.0-60.0) (n = 1,899)	41.0 (30.0-55.0) (n = 735)	**<0.001**
eGFR < 60 mL/min/1.73 m^2	1,401/2,181 (64.2)	592/851 (69.6)	**0.006**
Medications			
RAS inhibitors	1,005/1,762 (57)	388/689 (56.3)	0.780
Beta-blockers	1,680/2,022 (83.1)	679/798 (85.1)	0.353
Loop diuretic agents	1,813/1,978 (91.7)	746/779 (95.8)	**<0.001**
MRAs	803/1,960 (41.0)	392/780 (50.3)	**<0.001**
SGLT2 inhibitors	332/1,373 (24.2)	154/549 (28.1)	0.088
Furosemide equivalent, mg	30 (10-60) (n = 1,463)	30 (20-80) (n = 600)	**<0.001**
Device-specific characteristics			
CIED type			NA
PM	–	508/706 (72.0)	
ICD	–	131/594 (22.1)	
CRT	–	114/581 (19.6)	
Number of RV leads			NA
1	–	161/182 (88.5)	
2	–	16/182 (8.8)	
3	–	5/182 (2.8)	
Time since implantation, y	–	4.0 (1.3-7.5) (n = 252)	NA
Prior RV lead extraction	–	16/198 (8.1)	NA

Values are median (Q1-Q3) or n/N (%). Loop diuretic doses were expressed as furosemide equivalents using standard conversion factors (torsemide × 4). Device-specific characteristics were available only for the CIED cohort, so no comparison was performed for these variables. *P* values in **bold** denote statistical significance.

6MWD = 6-minute walk distance; ALT = alanine aminotransferase; AST = aspartate aminotransferase; BMI = body mass index; CIED = cardiac implantable electronic device; COPD = chronic obstructive pulmonary disease; CRT = cardiac resynchronization therapy; eGFR = estimated glomerular filtration rate; EuroSCORE = European System for Cardiac Operative Risk Evaluation; GGT = gamma-glutamyl transferase; HFH = heart failure hospitalization; ICD = implantable cardioverter-defibrillator; INR = international normalized ratio; MI = myocardial infarction; MRA = mineralocorticoid receptor antagonist; NA = not applicable; NT-proBNP = N-terminal pro-B-type natriuretic peptide; PM= pacemaker; RAS = renin-angiotensin system; RV = right ventricular; SGLT2 = sodium-glucose cotransporter-2.

TABLE 2 Echocardiographic Assessment at Baseline of Patients With and Without CIEDs

	No CIED (n = 2,174)	CIED (n = 851)	*P* Value
RAA, cm^2	34.0 (28.0-42.7) (n = 1,422)	34.0 (28.0-42.8) (n = 560)	0.964
RV basal diameter, mm	47.0 (42.0-53.5) (n = 1,302)	50.0 (44.0-57.0) (n = 521)	**<0.001**
RV mid diameter, mm	39.0 (33.0-45.0) (n = 1,450)	41.0 (35.0-46.0) (n = 586)	**<0.001**
RV longitudinal diameter, mm	69.0 (61.0-77.3) (n = 1,123)	73.3 (65.0-81.0) (n = 456)	**<0.001**
RVEDA, cm^2	24.7 (19.8-31.0) (n = 1,186)	27.7 (21.6-34.0) (n = 463)	**<0.001**
RVESA, cm^2	15.0 (11.7-19.8) (n = 1,186)	17.0 (12.7-22.0) (n = 463)	**<0.001**
RVFAC, %	40.0 (32.0-48.0) (n = 1,186)	40.0 (32.0-47.0) (n = 463)	0.608
TAPSE, mm	17 (14-20) (n = 1,896)	17 (14-20) (n = 743)	**0.001**
Estimated PASP, mm Hg	42 (34-51) (n = 1,742)	40 (31-50) (n = 680)	**0.001**
Tricuspid valve			
Coaptation gap, mm	5.5 (4.0-7.0) (n = 1,054)	6.0 (4.2-8.0) (n = 395)	**0.001**
Tenting height, mm	7.0 (5.0-9.3) (n = 974)	8.0 (5.4-10.0) (n = 413)	**0.040**
TV inflow gradient, mm Hg	1.0 (0.8-1.3) (n = 620)	1.0 (0.8-1.4) (n = 226)	0.669
Tricuspid regurgitation			
Grade			**0.007**
0	0/0 (0.0)	0/0 (0.0)	
1+	0/0 (0.0)	0/0 (0.0)	
2+	57/2,100 (2.7)	16/821 (2.0)	
3+	979/2,100 (46.6)	338/821 (41.2)	
4+	674/2,100 (32.1)	277/821 (33.7)	
5+	390/2,100 (18.6)	190/821 (23.1)	
Vena contracta width, mm	10 (8-13) (n = 1,822)	10 (8-14) (n = 722)	0.098
EROA, cm^2	0.54 (0.40-0.78) (n = 1,727)	0.60 (0.44-0.80) (n = 698)	**<0.001**
Regurgitant volume, mL	46.0 (35.0-63.0) (n = 1,486)	49.0 (38.0-67.0) (n = 614)	**0.001**
Etiology			**<0.001**
Primary	209/2,019 (10.4)	65/790 (8.2)	
Secondary	1,682/2,019 (83.3)	501/790 (63.4)	
Mixed	128/2,019 (6.3)	224/790 (28.4)	
LTR-A (causative)	–	141/262 (53.8)	NA
LTR-B (incidental)	–	110/262 (42.0)	NA
Left ventricle			
LVEF, %	55 (50-61) (n = 2,034)	50 (41-58) (n = 807)	**<0.001**
LVEDD, mm	47 (42-52) (n = 1,884)	50 (45-56) (n = 733)	**<0.001**
Mitral regurgitation grade			0.096
0	166/2,024 (8.2)	52/799 (6.5)	
1+	1,240/2,024 (61.3)	471/799 (59.0)	
2+	462/2,024 (22.8)	217/799 (27.2)	
3+	127/2,024 (6.3)	45/799 (5.6)	
4+	29/2,024 (1.4)	14/799 (1.8)	
Device-specific characteristics			
Lead position			NA
AS commissure	–	14/281 (5.0)	
PS commissure	–	129/281 (45.9)	
AP commissure	–	21/281 (7.5)	
Middle	–	31/281 (11.0)	
Adjacent to septal leaflet	–	15/281 (5.3)	
Adjacent to anterior leaflet	–	21/281 (7.5)	
Adjacent to posterior leaflet	–	50/281 (17.8)	
Lead-valve interaction			NA
Impingement	–	48/99 (48.5)	
Adhesion	–	40/99 (40.4)	
Subvalvular entanglement	–	9/99 (9.1)	
Perforation	–	2/99 (2.0)	

Values are median (Q1-Q3) or n (%). Device-specific characteristics were available only for the CIED cohort, so no comparison was performed for these variables. *P* values in **bold** denote statistical significance.

AS = anteroseptal; AP = anteroposterior; EROA = effective regurgitant orifice area; LVEDD = left ventricular end diastolic diameter; LVEF = left ventricular ejection fraction; PASP = pulmonary artery systolic pressure; PS = posteroseptal; RAA = right atrial area; RVEDA = right ventricular end-diastolic area; RVESA = right ventricular end-systolic area; RVFAC = right ventricular fractional area change; TAPSE = tricuspid annular plane systolic excursion; TV = tricuspid valve; other abbreviations as in Table 1.

TABLE 3 Procedural Outcomes in CIED Patients (N = 851)

Procedure time, min	115 (78-152) (n = 541)
Number of devices implanted	
1	236/764 (30.9)
2	408/764 (53.4)
3	110/764 (14.4)
4	9/764 (1.2)
5	1/764 (0.1)
Intraprocedural success (TVARC)	617/782 (78.9)
TR grade	
0	0/0 (0.0)
1+	307/769 (39.9)
2+	307/769 (39.9)
3+	128/769 (16.6)
4+	21/769 (2.7)
5+	6/769 (0.8)
TV inflow gradient	1.8 (1.0-2.2) (n = 244)
Change in CIED lead position	52/297 (17.5)
SLDA	11/851 (1.3)

Values are median (Q1-Q3) or n (%).
SLDA = single-leaflet device attachment; TR = tricuspid regurgitation; TVARC = Tricuspid Valve Academic Research Consortium; other abbreviations as in Tables 1 and 2.

performed, resulting in 385 matched pairs of patients with and without CIEDs. Covariate balance was confirmed across all matching variables (Supplemental Figure 1), and no significant differences in baseline or echocardiographic characteristics were observed between groups (Supplemental Tables 1 and 2).

Rates of residual TR ≤1+ and ≤2+ at discharge and latest follow-up were comparable between patients with and those without CIEDs (**Central Illustration**), and the presence of a CIED was not associated with residual TR >2+ (OR: 0.98; 95% CI: 0.70-1.38, $P = 0.915$). Findings were consistent in patients with baseline TR ≥4+ (Supplemental Table 3).

Freedom from the composite endpoint did not differ between groups (**Figure 3**). In Cox regression, the presence of CIED was associated with a nonsignificant HR of 1.31 (95% CI: 0.99-1.74; $P = 0.063$). Stratification by CIED status and residual TR showed markedly better outcomes with TR ≤2+ irrespective of CIED presence (**Figure 4**). No interaction between CIED presence and residual TR was observed ($P = 0.365$), indicating that both factors contributed independently to outcome. Results were consistent when restricting the analysis to residual TR ≤1+ vs >1+ (Supplemental Figure 2) and to all-cause mortality alone (Supplemental Figures 3 and 4).

In terms of functional status, NYHA functional class ≤ II at latest follow-up was observed in 63.7% (n = 121 of 190) of patients with CIEDs and 66.5% (n = 129 of 194) of those without ($P = 0.638$).

TABLE 4 Paired Analysis of Cardiac Implantable Electronic Device Function Before and After T-TEER

	Before T-TEER	After T-TEER	*P* Value	n
Impedance, Ω	459 (399-575)	456 (388-565)	**0.011**	193
Sensing, mV	9.1 (6.1-11.6)	8.8 (6.2-11.6)	0.246	137
Pacing threshold, V	0.75 (0.63-1.00)	0.75 (0.70-1.00)	0.498	194
Threshold duration, ms	0.4 (0.4-0.4)	0.4 (0.4-0.4)	0.755	191

Values are median (Q1-Q3). P values in **bold** denote statistical significance.
T-TEER = tricuspid valve transcatheter edge-to-edge repair.

DISCUSSION

In this large, multicenter, real-world cohort, we demonstrate that T-TEER is safe and effective in patients with CIEDs, with procedural success and clinical outcomes comparable with those in patients without CIEDs. The main findings can be summarized as follows: 1) In this large contemporary cohort, CIEDs were present in 28% of patients undergoing T-TEER, with high procedural success rates sustained at follow-up; 2) T-TEER was safe in patients with CIEDs, with no evidence of procedure-related device dysfunction and a low incidence of SLDA; 3) Among patients with CIEDs, less residual TR was observed over time, suggesting an operator learning curve, better patient selection, and the growing availability and use of dedicated T-TEER devices; and 4) in a matched analysis, procedural efficacy and clinical benefit were comparable regardless of CIED presence, with effective TR reduction remaining the key therapeutic determinant.

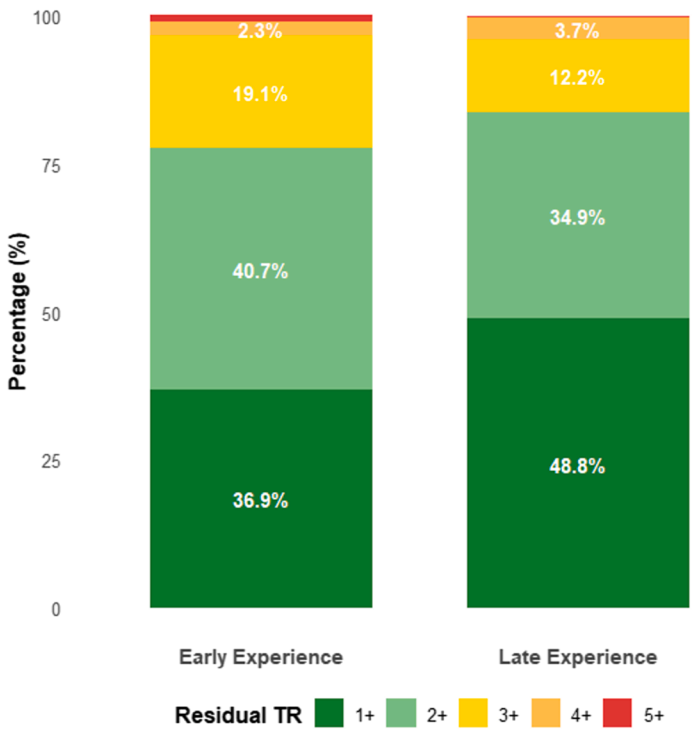
Older patients with severe TR and transvalvular CIED leads who are deemed inoperable because of high surgical risk represent a challenging population with limited treatment options. T-TEER has emerged as the most widely adopted transcatheter strategy for managing TR in these high-risk patients, supported by growing evidence of procedural safety and effectiveness.[1,2] Our analysis represents the largest study to date showing that T-TEER is feasible and effective even in patients with transvalvular CIED leads. In our predominantly male cohort with mostly functional TR, residual TR ≤2+ was achieved in nearly 80% of patients and maintained in 70% at latest follow-up. These results are comparable with those of previous studies, with residual TR ≤2+ observed in 71% of patients in the bRIGHT (Observational Real-World Study Evaluating Severe Tricuspid Regurgitation

Patients With the Abbott TriClip Device) registry and in 84.9% in the TRI-SPA (Transcatheter Tricuspid Valve Repair in Spain) registry.[7,12] A subanalysis of the EuroTR registry demonstrated that achieving procedural success is independently associated with improved long-term survival.[13] Consequently, residual TR ≤2+ remains an established prognostic threshold. However, emerging evidence suggests that further TR reduction beyond this cutoff, although not associated with additional survival benefit according to contemporary data, may translate into greater symptomatic reduction, better quality of life, and more pronounced RV reverse remodeling.[14] In this regard, it is important to note that in this real-world registry, functional improvement was less pronounced compared with TRILUMINATE,[15] in which more than 80% of patients reached NYHA functional class I or II at 1 year. A recent analysis applying the TRILUMINATE eligibility criteria confirmed that symptomatic alleviation occurred irrespective of trial eligibility, yet ineligible patients, who presented with more advanced disease, remained more symptomatic on average despite significant TR reduction, underlining the differences between highly selected trial populations and real-world cohorts.[16]

It is worth noting that in more than 50% of cases, the RV lead was located in the posteroseptal commissure or adjacent to the posterior leaflet, locations that, despite potential anatomical constraints, are generally considered favorable for planning subsequent T-TEER, as these often still allow leaflet grasping between the anteroseptal or posteroseptal leaflets. Indeed, high procedural success rates were achieved in both commissural and noncommissural lead positions, despite cases with significant lead-related shadowing or difficult leaflet grasping. Notably, the rate of lead-related SLDA (0.6%) and overall SLDA (1.3%) was very low, further underscoring procedural safety and operator expertise. At the same time, the site-reported nature of this registry without systematic core laboratory adjudication may have contributed to underrecognition of late events, which are, however, generally considered uncommon.

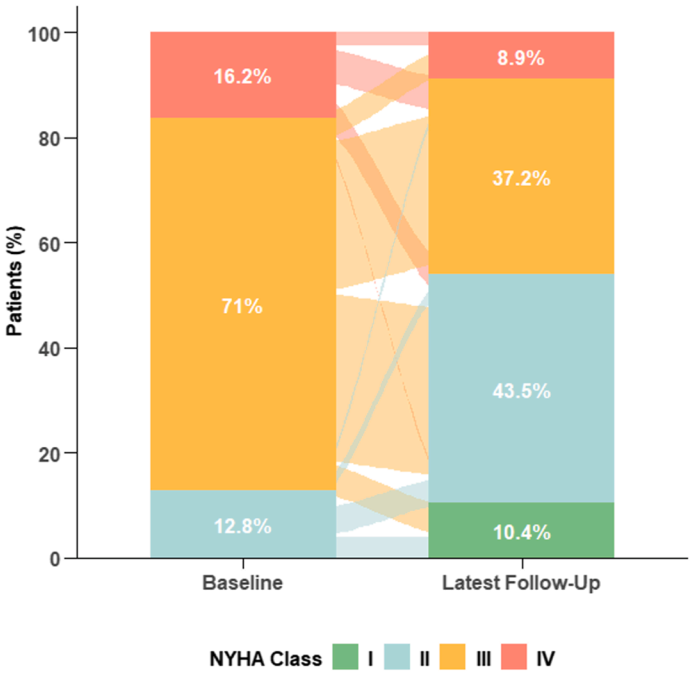
Regarding underlying mechanisms, lead-related TR in our cohort was most commonly attributed to impingement and/or adhesion, mechanisms consistent with prior studies.[17] Remarkably, LTR-A was identified in 54% of patients, a prevalence that contrasts with contemporary studies reporting lower rates, such as 1.4% in the TriValve registry and 15.5% in the core laboratory-adjudicated TRILUMINATE subanalysis. Conversely, the core laboratory-adjudicated PASTE (PASCAL for Tricuspid Regurgitation—A European Registry) and bRIGHT registries reported LTR-A in 67% and 81% of cases, respectively, underscoring the impact of standardized imaging and adjudication.[3,12] These discrepancies likely reflect underdiagnosis in routine clinical practice, particularly in the absence of systematic echocardiographic protocols. Even within the EuroTR registry, comprising predominantly experienced heart valve centers, detailed documentation of lead-valve interaction was available in only about 25% of cases. Importantly, subgroup analyses did not reveal statistically significant differences in procedural success according to lead-related TR classification. Although rates of TR ≤2+ were comparable between patients with LTR-A and LTR-B, numerically lower rates of TR ≤1+ were observed in the LTR-A subgroup, suggesting that achieving complete or near complete TR reduction may be more challenging in lead-induced TR. These findings, however, must be interpreted with caution given the selected nature of patients deemed anatomically suitable for T-TEER.

FIGURE 1 **Temporal Trends in Residual TR Severity at Discharge in Patients With Transvalvular Cardiac Implantable Electronic Device Leads**



Distribution of residual tricuspid regurgitation (TR) at discharge, stratified into early (2016-2021) and late (2022-2024) experience groups.

FIGURE 2 Changes in NYHA Functional Class From Baseline to Latest Follow-Up in Patients With Transvalvular Cardiac Implantable Electronic Device Leads



Paired analysis (n = 462) showed significant improvement in NYHA functional class, with 53.9% in NYHA functional class I or II at follow-up and 55.2% improving by ≥1 class.

Our findings further suggest a trend toward improved procedural results over time, with lower rates of residual TR >2+ in more recent years. This trend may be partly explained by the broader use of nondedicated edge-to-edge devices, particularly the MitraClip, during the earlier years of the study period, before dedicated T-TEER systems became more broadly available. In addition, improved operator experience and more refined patient selection, particularly regarding anatomical suitability for T-TEER, likely contributed to these favorable results. Nonetheless, this trend is consistent with data from the PASTE registry, which demonstrated higher success rates with increasing center experience.[3]

Importantly, we found no deterioration in post-procedural CIED function, as evidenced by stable RV lead thresholds, sensing, and impedance, despite reported cases of lead mobilization and lead position change during the procedure. Furthermore, the absence of any required device revision is particularly noteworthy, emphasizing the safety of T-TEER even in this technically demanding subset, although the lack of systematic follow-up for lead-related complications may limit the generalizability of this finding.

In our cohort, the median RV lead dwell time was 4 years (Q1-Q3: 1.3-7.5 years). Although lead extraction could in principle have been considered, these patients often present with complex anatomy, and the risk for TV injury during TLE, particularly in patients with LTR-A, in whom a thorough assessment of the underlying mechanism is warranted, may be substantial.[18] Even though contemporary data suggest improved safety and efficacy for TLE,[6] our findings support a treatment strategy in which TLE is reserved for cases in which T-TEER is not feasible. In addition, although still technically feasible after T-TEER, extraction in this setting can be particularly challenging and carries the risk for device destabilization or leaflet injury, including SLDA, especially in the context of device-related infection. This underscores the need for careful case-by-case evaluation at expert centers. Another treatment option for such scenarios is now available with the EVOQUE system (Edwards Lifesciences), the first commercially available orthotopic TTVR device. However, in patients with transvalvular leads, the prosthesis inevitably entraps the lead between the native annulus and the valve frame, a configuration that permanently precludes future lead extraction and may raise safety concerns in the event of device-related infection. Moreover, the recently published TRISCEND II trial reported new pacemaker implantation in 15.4% of patients with pre-existing devices and in 24.7% of those without prior CIEDs,[19] rates comparable with those observed with surgical TV interventions.[20] Given these relatively high rates of new pacemaker implantation observed with TTVR, this approach may currently be particularly considered in patients with transvalvular leads who are not suitable candidates for T-TEER. At the same time, randomized evidence from TRISCEND II demonstrated that TTVR achieves near complete elimination of TR in the vast majority of patients, accompanied by significant improvements in quality of life and functional status.[21] However, rates of HFH did not differ significantly between groups at 1 year, highlighting that the long-term clinical implications of TR elimination remain to be established. Ultimately, the presence of a transvalvular lead requires careful, individualized decision making within a multidisciplinary heart team that includes electrophysiologists. This is especially important given the irreversible nature of lead entrapment and the procedural risks associated with TLE, which should be reserved for experienced centers after thorough risk/benefit evaluation.

CENTRAL ILLUSTRATION **Tricuspid Valve TEER in CIED Patients: Results From EuroTR**

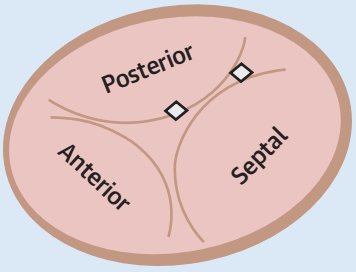
Tricuspid Valve Transcatheter Edge-to-Edge Repair in CIED Patients: Results From EuroTR

Patient Population

EuroTR Registry
2016-2024
N = 3,025
851 (28%) CIED Patients

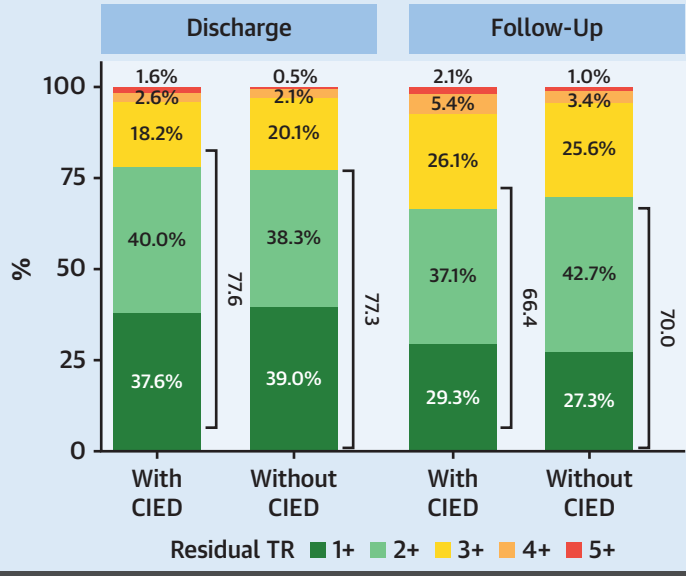
385 Matched Pair
(with versus without CIED)
44% Female, Age 80 Years
81% NYHA Functional Class III/IV
58% TR 4+/5+

CIED Details Pre-TEER



- 72% pacemaker
- 89% single RV lead
- lead dwell time 4.0 years
- 64% posteroseptal and posterior lead position
- 54% lead-associated TR (impingement/adhesion)

Tricuspid Regurgitation Reduction

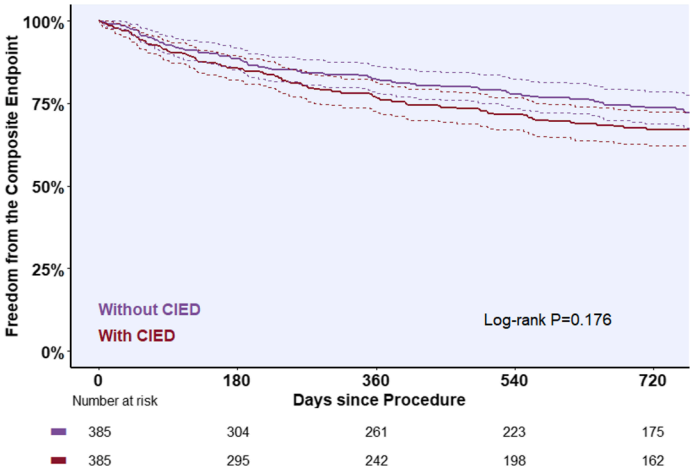


- T-TEER is feasible and safe in CIED patients, with low SLDA-rate (1.3%), stable device function, and no lead revisions at approximately 1-year follow-up.
- CIED presence does not impair outcomes. Matched patients showed similar TR reduction, NYHA functional class improvement, and 2-year HFH-free survival (67.1% with CIED vs 73.6% without CIED; log-rank P = 0.176).
- Effective TR reduction remains key, irrespective of CIED presence.

von Stein J, et al. JACC Cardiovasc Interv. 2025;18(23):2878-2891.

Among 3,025 patients in the EuroTR (European Registry of Transcatheter Repair for Tricuspid Regurgitation) registry, 851 (28%) had cardiac implantable electronic devices (CIEDs). The left panel illustrates the tricuspid valve, highlighting the 2 most frequent lead positions (white boxes) in the posteroseptal commissure and posterior location. In 385 well-balanced matched pairs with and without CIEDs, no differences in tricuspid regurgitation (TR) reduction were observed at discharge (TR ≤1+: 37.6% [143 of 380] vs 39.0% [148 of 379] [P = 0.743]; TR ≤2+: 77.6% [295 of 380] vs 77.3% [293 of 379] [P = 0.984]) or latest follow-up (median 356 days [Q1-Q3: 181-397 days]) (TR ≤1+: 29.3% [82 of 280] vs 27.3% [80 of 293] [P = 0.664]; TR ≤2+: 66.4% [186 of 280] vs 70.0% [205 of 293] [P = 0.413]). HFH = heart failure hospitalization; RV = right ventricular; SLDA = single-leaflet device attachment; TEER = transcatheter edge-to-edge repair.

FIGURE 3 2-Year Freedom From the Composite Endpoint in Matched Patients With and Without Transvalvular CIED Leads

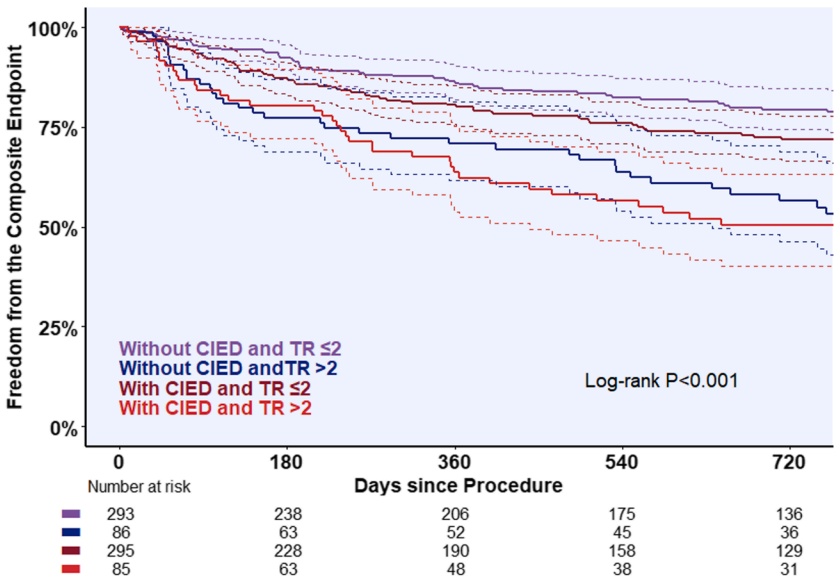


At 2 years, freedom from the composite endpoint was 67.1% (95% CI: 62.1%-72.5%) in patients with transvalvular cardiac implantable electronic device (CIED) leads and 73.6% (95% CI: 68.9%-78.6%) in those without (log-rank $P = 0.176$).

After PSM, no significant differences in baseline characteristics were observed between patients with and without CIEDs, allowing us to isolate the effect of transvalvular leads on procedural and clinical outcomes to the extent possible. In contrast to the PASTE registry, in which CIED leads were independently associated with procedural failure, no such association was found in our matched cohort. This discrepancy may reflect methodological differences: PSM provides a more balanced comparison by aligning key clinical and echocardiographic characteristics, whereas multivariable regression remains more susceptible to residual confounding, especially considering that patients with CIED frequently carry a high comorbidity burden.

Although no significant differences in 2-year outcomes were observed, numerically lower rates of freedom from the composite endpoint in patients with CIEDs, reflected by a nonsignificant HR in the Cox regression analysis, may suggest residual confounding from disease severity rather than the CIED presence itself. These patients presented with more advanced disease stages prior to matching, which

FIGURE 4 2-Year Freedom From the Composite Endpoint in Matched Patients Stratified by CIED Status and Residual TR Severity



Two-year freedom from the composite endpoint was highest in patients without CIEDs and TR ≤2+ (79.4%; 95% CI: 74.4%-84.7%), followed by those with CIEDs and TR ≤2+ (71.9%; 95% CI: 66.4%-77.9%). Freedom was markedly lower in both TR >2+ groups (56.5% [95% CI: 46.4%-68.9%] without CIEDs and 50.4% [95% CI: 40.2%-63.2%] with CIEDs; log-rank $P < 0.001$). Abbreviations as in Figures 1 and 3.

may not have been entirely mitigated despite covariate balance in the matched cohort. Nevertheless, our findings are in line with previous reports, which also showed no differences in procedural success, HFH, or mortality despite baseline imbalances. In the TriValve registry, patients with CIEDs presented with more advanced clinical heart failure, including worse NYHA functional class, higher N-terminal pro-B-type natriuretic peptide levels, and more frequent prior HFH.[2] Importantly, the TriValve registry encompassed a broad range of transcatheter TV therapies, not limited to T-TEER, and the MitraClip was the only T-TEER device used off label at that time, further distinguishing our current analysis.

Although these early findings offered valuable insights, our study adds to the field by providing the first PSM analysis specifically focused on T-TEER in CIED patients, thereby minimizing confounding and enabling a more balanced assessment of procedural and clinical outcomes. In particular, CIED presence alone does not seem to compromise technical safety and efficacy in T-TEER, as a lead merely crossing the TV does not necessarily interact with T-TEER. However, patients considered unsuitable for T-TEER at the discretion of the local operators were excluded, limiting definitive conclusions on the heterogeneous impact of CIEDs. These facts may explain why procedural success was associated with the lowest 2-year event, irrespective of CIED presence. Ultimately, our findings reinforce the prognostic relevance of procedural success and highlight that favorable outcomes are achievable even in anatomically challenging cases. Nevertheless, meticulous screening of T-TEER suitability prior to intervention is warranted.

STUDY LIMITATIONS. Missing data for several baseline variables and incomplete echocardiographic follow-up may have introduced selection bias, despite systematic assessment of missingness across baseline variables (Supplemental Table 4). Comprehensive imaging evaluation of lead-valve interaction was feasible in only a subset, and information on lead jailing after T-TEER or clip location was unavailable. Although no core laboratory adjudication was performed, all echocardiographic assessments were conducted by experienced imaging specialists at each site. Patient selection was highly specific, as only those deemed technically suitable for T-TEER were included. Furthermore, although no device revision or lead dysfunction was reported, systematic long-term follow-up for CIED-related complications such as lead endocarditis was lacking, limiting definitive safety conclusions. Finally, residual confounding due to unmeasured clinical or anatomical factors cannot be excluded despite PSM adjustment.

CONCLUSIONS

In this large, multicenter real-world cohort, T-TEER proved safe and effective in selected patients with transvalvular CIED leads, yielding procedural success and outcomes comparable with those without CIEDs. Procedural safety was underscored by stable device function and a very low rate of lead-related complications. CIED presence alone did not compromise procedural efficacy or clinical benefit. These findings highlight the prognostic role of effective TR reduction and the importance of careful preprocedural screening in patients with RV leads undergoing T-TEER.

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Among the full cohort of patients in the registry, data collection for the Hamburg patients was supported by a grant from the German Heart Foundation. Dr Stolz has received speaker honoraria from Edwards Lifesciences. Dr Kresoja has received travel expenses from Edwards Lifesciences. Dr J. von Stein has received lecture honoraria from Edwards Lifesciences. Dr Rottbauer has received speaker honoraria from Edwards Lifesciences and Abbott Laboratories. Dr Denti has served as a consultant for InnovHeart, Picardia, HVR, and Approxima; and has received speaker honoraria from Abbott Laboratories and Edwards Lifesciences. Dr Rassaf has received speaker honoraria and consulting fees from AstraZeneca, Bayer, Pfizer, and Daiichi-Sankyo. Dr Barreiro-Perez has received speaker fees from Abbott Vascular, Edwards Lifesciences, and Venus Medtech. Dr Adamo has received consulting fees in the past 3 years from Abbott Structural Heart and Edwards Lifesciences. Dr Toggweiler has received personal honoraria from Medtronic, Boston Scientific, Biosensors, Abbott Vascular, Medira, Shockwave Medical, Teleflex, atHeart Medical, Cardiac Dimensions, Polares Medical, Amarin, Sanofi, AstraZeneca, ReCor Medical, and Daiichi-Sankyo; has received institutional research grants from Edwards Lifesciences, Boston Scientific, Fumedica, Novartis, and Boehringer Ingelheim; and holds equity in Hi-D Imaging. Dr Metra has received consulting fees in the past 3 years from Abbott Structural Heart, AstraZeneca, Bayer, Boehringer Ingelheim, Edwards Lifesciences, and Roche Diagnostics. Dr Geisler has received speaker honoraria and research grants from AstraZeneca, Bayer, Bristol Myers Squibb/Pfizer, Ferrer/Chiesi, Medtronic, and Edwards Lifesciences (all unrelated to this study). Dr Estévez-Loureiro has received speaker fees from Abbott Vascular, Edwards Lifesciences, Boston Scientific, and Venus Medtech. Dr Maisano has received grant and/or research institutional support from Abbott Laboratories, Medtronic, Edwards Lifesciences, Biotronik, Boston Scientific, NVT, Terumo, and Venus; has received consulting fees and personal and institutional honoraria from Abbott Laboratories, Medtronic, Edwards Lifesciences, Xeltis, Cardiovalve, Occlufit, Simulands, Mtex, Venus, Squadra, and Valgen; has received royalty income and intellectual property rights from Edwards Lifesciences; and is a shareholder (including share options) in Magenta,

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PERSPECTIVES

WHAT IS KNOWN? T-TEER is increasingly used in high-risk patients with severe TR. CIEDs are common in this population, but their impact on procedural success and outcomes remains uncertain.

WHAT IS NEW? In the largest cohort to date, T-TEER was found to be safe and effective in patients with transvalvular CIED leads. The presence of a transvalvular CIED lead alone did not compromise procedural success or 2-year clinical outcomes. Achieving residual TR ≤2+ remained prognostically relevant, irrespective of CIED presence.

WHAT IS NEXT? Given the comparable safety and efficacy outcomes, patients with CIEDs should continue to be included in future trials to refine selection criteria and validate long-term outcomes in this growing population. Our findings also underscore the need for standardized echocardiographic protocols and dedicated imaging specialists with expertise in advanced modalities such as 3-dimensional echocardiography to enable detailed assessment of lead-valve interaction and optimize both preprocedure and postprocedure evaluation in patients with transvalvular leads.

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KEY WORDS CIED, EuroTR, leads, tricuspid regurgitation, tricuspid valve transcatheter edge-to-edge repair, T-TEER

APPENDIX For supplemental tables and figures, and a video of the interactive Central Illustration, please see the online version of this paper.