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ORIGINAL RESEARCH

STRUCTURAL

Cardiac Remodeling Following Transcatheter Tricuspid Valve Annuloplasty for Tricuspid Regurgitation

A Real-World, Multicenter Analysis

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ABSTRACT

BACKGROUND Transcatheter tricuspid valve annuloplasty (TTVA) with the Cardioband has proved to be safe and effective in acutely reducing tricuspid regurgitation (TR). However, long-term outcomes, especially regarding right heart remodeling (RHR), are scarce.

OBJECTIVES The aim of this study was to assess long-term efficacy as well as RHR following TTVA.

METHODS This retrospective, multicenter study included consecutive patients undergoing TTVA for severe TR at 2 German high-volume centers from 2019 to 2023. Right atrial and right ventricular (RV) parameters and NYHA functional class were assessed at baseline and follow-up.

RESULTS A total of 156 patients were included, and the median time to follow-up was 435 days (Q1-Q3: 156-704 days). TR reduction to ≤2+ was observed in 71% and NYHA functional class improved to ≤II in 68% ($P < 0.001$ for both). Compared with baseline, right atrial area (36.0 ± 10.1 cm^2 vs 30.4 ± 10.7 cm^2), RV length (67.5 ± 9.4 mm vs 63.7 ± 9.1 mm), RV midventricular dimension (42.6 ± 8.6 mm vs 35.6 ± 7.8 mm), and RV basal dimension (47.8 ± 6.8 mm vs 42.6 ± 7.5 mm)were significantly reduced at follow-up ($P < 0.001$ for all). Notably, torrential to severe TR reduction still yielded remodeling (RV basal diameter 50 ± 8.1 mm vs 44 ± 8 mm; $P = 0.007$). RHR was associated with a decrease in vena contracta width (OR: 1.14; 95% CI: 1.03-1.30; $P = 0.015$).

CONCLUSIONS TTVA is associated with a significant and sustained reduction of TR for more than 1 year. Additionally, patients demonstrated distinct positive cardiac remodeling and functional improvement. (JACC Cardiovasc Interv. 2025;18:2911-2921) © 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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ABBREVIATIONS AND ACRONYMS

FAC = fractional area change

LV = left ventricle/ventricular

LVEDD = left ventricular end-diastolic diameter

PASP = pulmonary artery systolic pressure

PISA = Proximal isovelocity surface area

RA = right atrial/atrium

RHR = right heart remodeling

RV = right ventricle/ventricular

TAPSE = tricuspid annular plane systolic excursion

TR = tricuspid regurgitation

TTE = transthoracic echocardiography

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

TTVA = transcatheter tricuspid valve annuloplasty

TVARC = Tricuspid Valve Academic Research Consortium

The prevalence of tricuspid regurgitation (TR) is increasing with age, resulting in a 4% prevalence of moderate and severe TR among patients 70 years and older.[1,2] Mortality rate rises with increasing TR severity, reaching a 1-year all-cause mortality rate of 36% for severe TR.[3,4] Progressive TR contributes to volume overload, resulting in systemic manifestations and leading to edema, chronic renal failure, ascites, and liver disease, partly associated with coagulopathy and bleeding risk and digestive dysfunction with loss of appetite and nausea. Consequently, TR evolves as a complex syndrome with extracardiac manifestations resulting in a poor quality of life.[5] Notably, TR is increasingly acknowledged as a contributor to adverse clinical outcomes and increased mortality, independent of systolic left ventricular (LV) function, elevated pulmonary artery systolic pressure (PASP) or right ventricular (RV) dysfunction.[6,7] Nevertheless, TR is remarkably undertreated compared with left heart diseases.[8] Addressing this unmet treatment need and considering the multimorbidity and advanced age as well as the high perioperative mortality rate when undergoing open heart surgery, transcatheter tricuspid therapies, such as transcatheter tricuspid valve annuloplasty (TTVA), tricuspid transcatheter edge-to-edge repair (T-TEER), and orthotopic and heterotopic valve implantation have opened up promising new perspectives and provide a viable alternative compared with conservative treatment for patients with severe TR.[9,10] Following the surgical annuloplasty approach, the Conformité Européenne-certified Cardioband (Edwards Lifesciences) reduces TR via direct annular reduction. The technique proved to be safe and effective in several small and selected study cohorts.[11,12] Nevertheless, real-world data on long-term outcomes, and especially right heart remodeling (RHR), in larger patient numbers remain limited.

METHODS

STUDY DESIGN AND PATIENT POPULATION. Consecutive patients with symptomatic, at least severe, secondary TR undergoing TTVA with the Cardioband at 2 German high-volume centers (the Heart Center of the University of Cologne and the Clinic for General and Interventional Cardiology/Angiology in Bad Oeynhausen) between 2019 and 2023 were retrospectively analyzed. Preprocedural assessment included transthoracic echocardiography (TTE) and transesophageal echocardiography, multislice computed tomography, and, according to patients' comorbidities, right and left heart catheterization. The individual decision to perform TTVA was made considering anatomical features that made patients unsuitable for a leaflet-based approach (including leaflet morphology and geometry, interactions of leads with potential leaflet grasping zone, extent of coaptation gap, and annular size). All patients were discussed by the local heart team and were deemed inoperable or at prohibitive surgical risk. Follow-up assessments were performed using clinical visits or telephone interviews. The study was approved by the local ethics committee.

PROCEDURE. The Cardioband tricuspid valve reconstruction system is a Conformité Européenne-certified tool for transvenous direct annuloplasty in patients with secondary TR. The procedure has been described previously.[12] Under fluoroscopic and transesophageal echocardiographic guidance, anchors are placed along the atrial part of the tricuspid annulus starting in the anterior-septal commissure. This is followed by a contraction procedure (cinching) aiming to downsize the annular diameter. During the procedure, a guidance catheter and coronary wire is placed as a marker into the right coronary artery.

CLINICAL OUTCOME. The clinical outcome was defined as all-cause mortality at follow-up. The functional outcome was measured using NYHA functional class at baseline and follow-up. We defined intraprocedural success according to the Tricuspid Valve Academic Research Consortium (TVARC) definitions for TR.[13]

ECHOCARDIOGRAPHIC PARAMETERS. Echocardiographic parameters were assessed using 2-dimensional TTE at baseline and follow-up. Tricuspid valve annular diameter was measured as the distance between the intraventricular septum and the lateral annulus at end-diastole in the apical 4-chamber view. Right atrial (RA) area was quantified at end-systole. Fractional area change (FAC) was quantified by measuring RV area at systole and diastole. RV diameters were measured according to current guidelines.[14] Vena contracta and effective regurgitant orifice area were quantified via color and pulsed-wave Doppler on TTE and divided into 5 grades as proposed by Hahn and Zamorano.[15] The modified biplane Simpson's method was used to assess LV ejection fraction.[16] Using M-mode imaging, tricuspid annular plane systolic excursion (TAPSE) was

TABLE 1 Baseline Characteristics

	Total (N = 156)	Positive RHR (n = 44)	Minimal or No RHR (n = 82)	*P* Value
Age, y	76.5 ± 8.3	79.2 ± 5.5	74.7 ± 9.5	0.004
Female	119 (76.3)	40 (90.9)	55 (67.1)	0.003
TR severity				0.16
Severe	48 (31.2)	11 (25.0)	30 (36.6)	
Massive	41 (26.6)	12 (27.3)	22 (26.8)	
Torrential	65 (42.2)	21 (47.7)	30 (36.6)	
Heart failure with reduced ejection fraction	7 (4.5)	1 (2.2)	4 (4.9)	0.43
Atrial fibrillation	139 (89.1)	42 (95.5)	70 (85.4)	0.39
Diabetes mellitus type 2	38 (24.4)	9 (20.5)	23 (28.0)	0.35
Prior stroke	29 (18.6)	5 (11.4)	17 (20.7)	0.19
Prior left-sided transcatheter valve replacement or repair	18 (11.5)	6 (13.6)	8 (9.8)	0.51
Prior pacemaker/ICD/CRT	32 (20.5)	6 (13.6)	18 (22.0)	0.26
Prior open heart surgery (except cardiac pacer)	25 (16.0)	6 (13.6)	13 (15.9)	0.74
EuroSCORE II, %	4.1 (2.7-7.3)	3.7 (2.7-7.4)	5.6 (2.9-7.3)	0.39
TRI-SCORE (range: 0-12)	5 (3-6)	4.6 (3-6)	5 (3-6)	0.46
PASP (noninvasive), mm Hg	39.6 ± 13.5	34.7 ± 11.6	40.3 ± 14.8	0.03
NT-proBNP level, pg/mL	2,074.5 (1,343.75-3,833.25)	1,970 (1,292-3,080)	2,134 (1,420/4,197)	0.08
Estimated glomerular filtration rate (CKD-EPI), mL/min	48.3 ± 20.3	49.6 ± 13.7	47.1 ± 22.8	0.51
Dialysis	8 (5.1)	0	5 (6.1)	0.096
Loop diuretic agents, mean furosemide-equivalent dose, mg/d	70 (20-80)	30 (20-40)	40 (20-100)	0.008
Aldosterone antagonist	82 (52.6)	25 (56.8)	42 (51.2)	0.60
Oral anticoagulation, total	109 (69.9)			
With non-vitamin K antagonist	65 (41.7)	10 (22.7)	24 (29.3)	
INR	1.2 (1.1-1.4)	1.4 (1.1/1.42)	1.15 (1.1/1.4)	0.39
TAPSE/PASP ratio	0.57 ± 0.31	0.62 ± 0.28	0.52 ± 0.30	0.49
NYHA functional class				0.35
I	0	0	0	
II	11 (7.1)	4 (9.1)	7 (8.5)	
III	133 (85.3)	39 (88.6)	68 (82.9)	
IV	12 (7.7)	1 (2.3)	7 (8.5)	

Values are mean ± SD, n (%), or median (Q1-Q3).

CKD-EPI = Chronic Kidney Disease Epidemiology Collaboration; CRT = cardiac resynchronization therapy; EuroSCORE = European System for Cardiac Operative Risk Evaluation; ICD = implantable cardioverter-defibrillator; INR = international normalized ratio; NT-proBNP = N-terminal pro-brain natriuretic peptide; PASP = pulmonary artery systolic pressure; TAPSE = tricuspid annular plane systolic excursion; TR = tricuspid regurgitation; RHR = right heart remodeling.

measured as excursion of the lateral tricuspid annulus concordant with validated methods.[14,17]

CLASSIFICATION SCHEME FOR RHR. Patients were stratified according to RHR, defining patients achieving greater than or equal to the median reduction of RV basal diameter and those achieving greater than equal to the median RA area reduction at follow-up as positive RHR (RHR+) and those failing to meet these criteria as minimal or no RHR (RHR−).

STATISTICAL ANALYSIS. Statistical analyses were performed using SPSS Statistics version 29.0.2.0 (IBM). Data are presented as mean ± SD if normally distributed and as median (Q1-Q3) if not normally distributed. Categorial variables are presented as percentages and frequencies. Normal distribution of data was assessed using the Kolmogorov-Smirnov test. For comparisons of means, Student's paired *t*-test for dependent samples was performed if normally distributed and the Wilcoxon test if not normally distributed. All-cause mortality was determined using the Kaplan-Meier method. To determine statistical significance between groups due to survival, the log-rank test was used. Furthermore, we performed a binary logistic regression analysis after testing for multicollinearity using condition indexes (CI <30) and variance proportions (<0.5). Changes in RV dimensions over time (baseline, discharge, and follow-up) were analyzed using linear mixed models with time as a fixed effect. Estimated marginal means and pairwise comparisons with 95% CIs were calculated. All visualizations were conducted using

TABLE 2 Procedure-Associated Values Concerning Feasibility and Safety

Procedure time, min	183 (151-216)
Contrast medium volume, mL	89 (67-142)
TR severity at discharge	2.18
0	3 (2.0)
I	42 (27.8)
II	50 (33.1)
III	39 (25.8)
IV	15 (9.9)
V	2 (1.3)
Pericardial effusion with intervention	6 (3.8)
Intraprocedural success (TVARC)	93 (61.6)
RCA stenting	7 (4.5)
Bleeding, life threatening (TVARC)	4 (2.6)
30-d events	
Hemodynamically relevant arrhythmia	6 (3.8)
Stroke	2 (1.3)
Myocardial infarction	1 (0.6)

Values are median (Q1-Q3) or n (%).

RCA = right coronary artery; TR = tricuspid regurgitation; TVARC = Tricuspid Valve Academic Research Consortium.

TABLE 3 Echocardiographic Values at Baseline and Follow-Up (n = 156)

	Baseline	Follow-Up	*P* Value
Tricuspid annular diameter, SL, mm	43.7 ± 5.8	34.5 ± 6.8	<0.001
RA area, cm^2	36.0 ± 10.1	30.4 ± 10.7	<0.001
FAC, %	36.8 ± 2.2	40.2 ± 8.3	<0.001
TAPSE, mm	18.2 ± 4.2	15.6 ± 4.3	<0.001
PASP, mmHg	39.6 ± 13.5	42.4 ± 14.9	0.085
LVEF, %	55.1 ± 8.8	57.7 ± 9.1	<0.001
RV length, mm	67.5 ± 9.4	63.7 ± 9.1	<0.001
RV midventricular diameter, mm	42.6 ± 8.6	35.6 ± 7.8	<0.001
RV basal diameter, mm	47.8 ± 6.8	42.6 ± 7.5	<0.001
TR severity, grade	4.1 ± 0.9	2.1 ± 1.1	<0.001
0	0	2 (1.6)	
I	0	37 (30.3)	
II	0	47 (38.5)	
III	48 (31.2)	23 (18.9)	
IV	41 (26.6)	8 (6.6)	
V	65 (42.2)	5 (4.1)	
TR vena contracta width, mm	14.7 ± 6.7	7.3 ± 6.5	<0.001
EROA, cm^2	0.80 ± 0.35	0.32 ± 0.35	<0.001
IVC, mm	26.2 ± 6.5	20.6 ± 5.7	<0.001
LVEDD, mm	46.8 ± 6.1	48.7 ± 7.5	0.003
TAPSE/PASP ratio	0.51 ± 0.21	0.42 ± 0.20	0.31

Values are mean ± SD or n (%).

EROA = effective regurgitant orifice area; FAC = fractional area change; IVC = inferior vena cava; LVEF = left ventricular ejection fraction; LVEDD = left ventricular end-diastolic diameter; RA = right atrial; RV = right ventricular; SL = septolateral; other abbreviations as in Table 1.

R version 4.3.2 (R Foundation for Statistical Computing) with ggplot2 version 3.5.2 or Prism version 8 (GraphPad Software) or using SPSS Statistics version 29.0.2.0. Statistical significance was assumed at a 2-tailed *P* value <0.05.

RESULTS

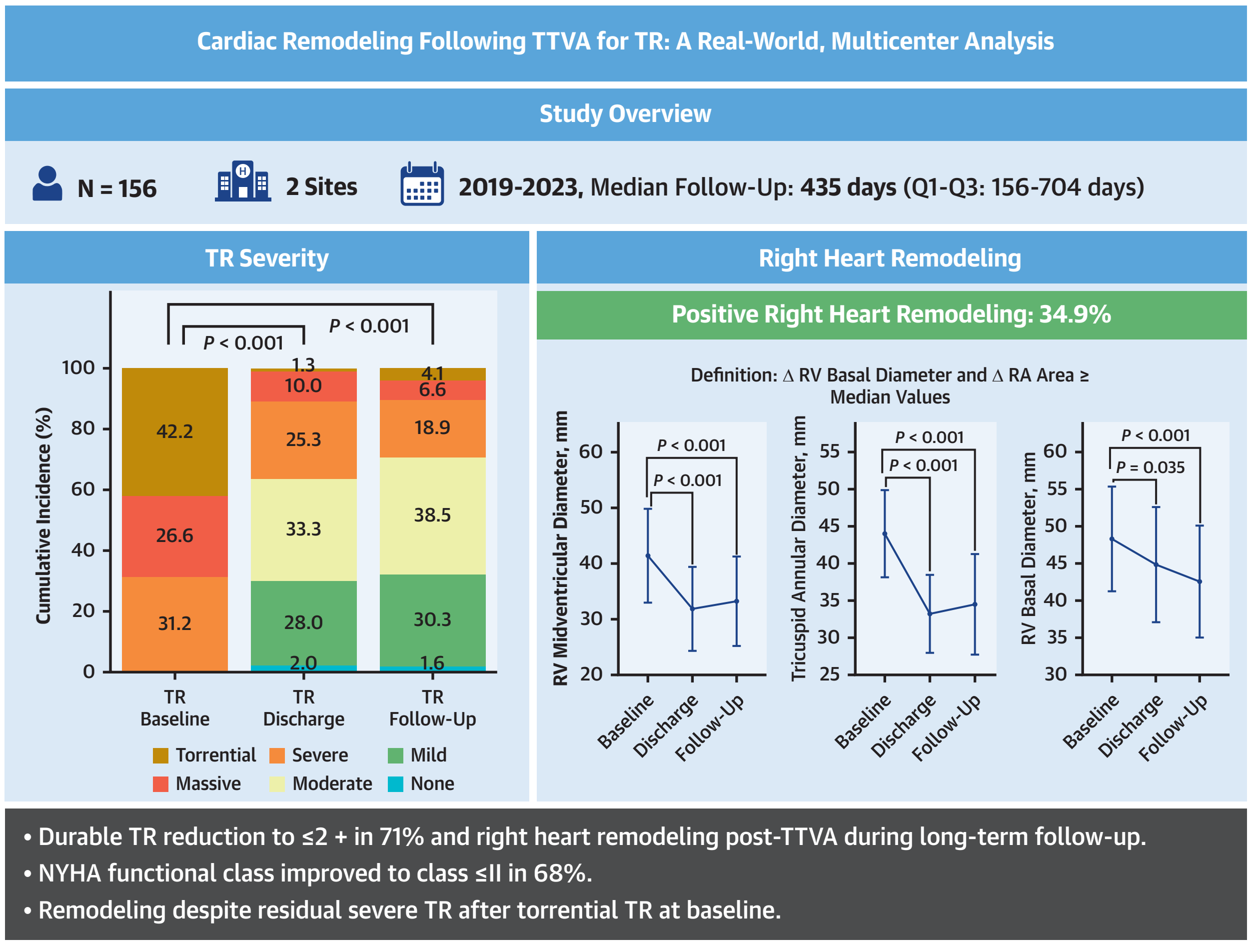
BASELINE CHARACTERISTICS. Baseline characteristics are presented in Table 1.

A total of 156 patients were included. The median age was 79 years (Q1-Q3: 73-82 years), and 76.3% were women (119 of 156). Patients were at increased risk for surgery, with a median European System for Cardiac Operative Risk Evaluation II score of 4.1% (Q1-Q3: 2.7%-7.3%) and a median TRI-SCORE of 5 (Q1-Q3: 3-6). The majority of patients had atrial fibrillation (89.1% [139 of 156]), 16% (25 of 156) underwent prior open heart surgery, and 18.6% (29 of 156) had experienced cerebrovascular events. Prior left-sided transcatheter valve replacement or repair had been performed in 18 patients (11.5%). N-terminal pro-brain natriuretic peptide levels were elevated at baseline (2,075 pg/mL; Q1-Q3: 1,344-3,833 pg/mL), and most of the patients were severely symptomatic, presenting in NYHA functional class III or IV at baseline (93% [145 of 156]). Diuretic therapy with loop diuretic agents was established in 147 patients (94.8% [147 of 155]), with a median furosemide-equivalent dose of 40 mg/d (Q1-Q3: 20-80 mg/d). Median clinical follow-up duration was 435 days (Q1-Q3: 156-704 days). Median procedure duration was 183 minutes, with a minimum of 151 minutes and a maximum of 216 minutes (Table 2). TVARC intraprocedural success was achieved in 61.6% of patients (93 of 151), whereas technical success (successful Cardioband deployment, alive, no need for emergency open heart surgery) was met in 97.4% (152 of 156).[13]

ECHOCARDIOGRAPHIC RESULTS. Echocardiographic data are shown in Table 3.

Mean vena contracta width at baseline was 14.7 ± 6.7 mm, and mean effective regurgitant orifice area at baseline was 0.80 ± 0.35 cm^2. Most patients presented with torrential TR (42.2% [65 of 154]), while 31.2% (48 of 154) presented with TR grade III and 26.6% (41 of 154) with TR grade IV (Central Illustration). At baseline, patients exhibited RV dilatation accompanied by annular enlargement of the tricuspid valve (43.7 ± 5.8 mm) (Table 3). Between groups (positive vs no RHR), baseline variables did not differ significantly, apart from PASP (34.7 ± 11.6 mm Hg in those with positive RHR vs 40.3 ± 14.8 mm Hg in

CENTRAL ILLUSTRATION Long-Term Outcomes After Transcatheter Direct Annuloplasty of Secondary TR



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At baseline, all patients were assigned to tricuspid regurgitation (TR) grades III to V, compared with 29.6% at follow-up. Line graphs illustrate improvements in right ventricular (RV) basal diameter, tricuspid annular diameter, and mid-RV diameter between baseline, discharge, and follow-up. RA = right atrial; TTVA = transcatheter tricuspid valve annuloplasty.

those with minimal or no RHR; $P = 0.031$), TR vena contracta (16.4 ± 7.8 mm in those with positive RHR vs 13.8 ± 5.8 mm in those with minimal or no RHR; $P = 0.046$), and LV end-diastolic diameter (LVEDD) (44.4 ± 5.4 mm in those with positive RHR vs 48.1 ± 6.1 mm in those with minimal or no RHR; $P = 0.002$). At follow-up, we ascertained significant declines in RA area, RV length, RV midventricular diameter, and RV basal diameter, demonstrating positive RA and RV remodeling (**Table 3**, **Central Illustration**). Especially for tricuspid annular diameter, we observed a statistically significant reduction from baseline to discharge (mean difference -10.86 mm; 95% CI: -12.37 to -9.35 mm; $P < 0.001$) and from baseline to follow-up (mean difference -9.57 mm; 95% CI: -11.08 to -8.06 mm; $P < 0.001$) (**Central Illustration**, Supplemental Figure 1).

LVEDD increased significantly, as did LV ejection fraction at follow-up compared with baseline values (**Table 3**). At follow-up, 30.3% of patients (37 of 122) exhibited TR grade I, 38.5% (47 of 122) TR grade II, 18.9% (23 of 122) TR grade III, 6.6% (8 of 122) TR grade IV, and 4.1% (5 of 122) TR grade V, demonstrating sustained TR reduction ($P < 0.001$).

In a subgroup analysis limited to patients with torrential TR at baseline exhibiting a reduction of 2 grades at discharge (TR grade V at baseline and TR grade III at discharge), evidence of favorable cardiac

TABLE 4 Subgroup Analysis Including Patients With TR Grade V at Baseline and TR Grade III at Discharge

	Baseline	Follow Up	*P* Value
RV basal diameter, baseline, mm	50.0 ± 8.1	44.0 ± 8.0	0.007
RA area, baseline, cm^2	39.1 ± 13.9	31.8 ± 14.9	<0.001
LVEDD, mm	46. 7 ± 6.2	57.1 ± 17.7	0.028
TR vena contracta, mm	18.6 ± 3.9	8.4 ± 4.6	<0.001
NYHA functional class			<0.001
I	0	3 (12)	
II	2 (7.7)	18 (72)	
III	24 (92.3)	4 (16)	
IV	0	0	

Values are mean ± SD or n (%).
Abbreviations as in Tables 1 and 3.

remodeling was also observed: RV basal diameter, RA area, TR vena contracta, and NYHA functional class decreased significantly (Table 4).

Overall, reduction of TR was an independent predictor of favorable RHR. In binary logistic regression, reduction of TR vena contracta was associated with positive RHR in multivariate analysis (OR: 1.14; 95% CI: 1.03-1.30; $P = 0.015$) (Table 5). In addition, the use of a high dose of a loop diuretic agent at baseline emerged as a negative predictor of positive RHR (OR: 0.98; 95% CI: 0.97-1.00; $P = 0.035$) (Table 5). Forty of 44 patients (90.9%) exhibiting positive RHR were women.

CLINICAL OUTCOME. Kaplan-Meier estimates of all-cause mortality for a subgroup of patients with follow-up ≤100 days were 39.1% (RHR−) and 0% (RHR+) ($P = 0.039$) (Figure 1). An additional survival analysis highlighted the clinical relevance of remarkable residual TR in our cohort: residual TR ≥3 was associated with elevated all-cause mortality compared with residual TR <3 (25.9% vs 13.2%; $P = 0.042$) (Figure 2).

Symptoms were reduced significantly after TTVA (Figure 3, Supplemental Figure 2). At baseline, patients were severely symptomatic according to NYHA functional class and improved at follow-up (NYHA functional class I or II in 7.1% [11 of 156] at baseline vs 67.6% [92 of 136] at follow-up; $P < 0.001$).

Seven of 116 patients (6%) underwent transcatheter tricuspid reintervention, mainly staged edge-to-edge repair. Two patients underwent heterotopic tricuspid valve implantation using the TricValve transcatheter bicaval valve system (Products & Features).

DISCUSSION

To the best of our knowledge, this is the largest real-world, multicenter study to assess long-term efficacy, as well as RHR and clinical outcomes, following TTVA.

The main findings of our study are as follows: 1) following TTVA, TR reduction is sustained at long-term follow-up and is accompanied by positive RHR; 2) TTVA leads to significant symptomatic alleviation at long-term follow-up; and 3) even patients with torrential TR that could be reduced only to severe TR showed positive remodeling at follow-up.

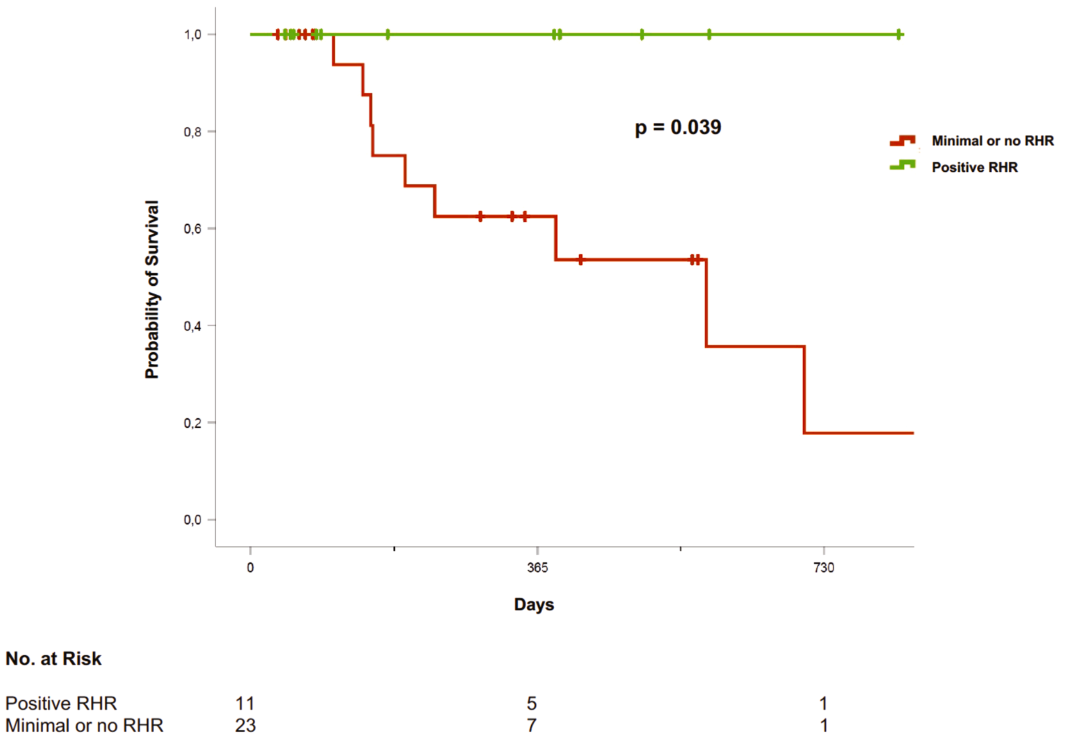
Although reverse RV remodeling is often present in patients with chronic right heart disease, a release of prolonged RV stress may be able to invert it: in patients with chronic thromboembolic pulmonary hypertension, performing pulmonary endarterectomy leads to RV afterload reduction followed by improvements in RV diameters and FAC, suggesting a promising remodeling capacity of the RV in general.[18] There is also some evidence on positive RHR

TABLE 5 Logistic Regression Analysis to Identify Predictors of Positive Right Heart Remodeling Defined as Improvements in Right Atrial Area and RV Basal Diameter at Follow-Up

	Univariate Analysis			Multivariate Analysis		
	OR (95% CI)	β	*P* Value	OR (95% CI)	β	*P* Value
RV basal diameter, baseline, mm	1.02 (0.97-1.08)	0.023	0.41	–	–	–
NT-proBNP, baseline, ng/L	1 (1-1)	0	0.086	1 (1-1)	0	0.27
TR severity, baseline, grades I-V	1.38 (0.89-2.14)	0.32	0.16	–	–	–
Delta TR VC, baseline/discharge	1.09 (0.99-1.19)	0.082	0.081	1.14 (1.03-1.30)	0.13	0.015
TAPSE/PASP ratio, baseline	3.03 (0.83-11.07)	1.11	0.093	0.99 (0.23-4.29)	−0.10	0.99
Loop diuretic agents, furosemide-equivalent dose, mg/d, baseline	0.98 (0.97-0.99)	−0.01	0.015	0.98 (0.97-1.0)	−0.02	0.035

Key clinical and echocardiographic variables were included in the model, and ORs with 95% CIs are displayed. Statistically significant predictors are highlighted (statistical significance was assumed at *P* values <0.1 for univariate analysis and <0.05 for multivariate analysis).
VC = vena contracta; other abbreviations as in Tables 1 and 3.

FIGURE 1 Kaplan-Meier Curves for Positive vs Minimal or No RHR



Kaplan-Meier curves for all-cause mortality stratified according to the classification scheme of right heart remodeling (RHR). Positive RHR was defined as changes in right ventricular basal diameter and right atrial area between baseline and follow-up equal to or greater than the median values. Patients with echocardiographic follow-up ≤100 days after transcatheter tricuspid valve annuloplasty were selected. The stratification highlights the impact of RHR on long-term survival outcomes.

following T-TEER,[19] but data on RHR following TTVA remain scarce. So far, dedicated studies included only very selected patients, and numbers at follow-up were limited.[20,21]

Our data analyzing 156 real-world patients now demonstrate not only sustained TR reduction for more than 1 year (two-thirds of patients exhibiting mild or moderate TR) but also decreased tricuspid annular size by 21% compared with 16% on 2-year follow-up in the TRI-REPAIR (Tricuspid Regurgitation Repair With Cardioband Transcatheter System) study.[20] Furthermore, significant positive alterations in RA area and RV dimensions were noted, accompanied by an improvement in radial RV function (FAC). Interestingly, there was no improvement in TAPSE over time. Systolic RV contraction pattern is complex and composed of several mechanisms: inward movement of the RV free wall, passive LV traction, and longitudinal movement contribute to systolic RV contraction.[22] On the basis of previous studies, the validity of TAPSE, a marker of longitudinal contraction pattern, for analyzing RV dysfunction after transcatheter repair needs to be questioned as well as the potential dominance of alternative contraction patterns.[23] Therefore, future prospective studies should incorporate strain analysis or 3-dimensional echocardiographic parameters to analyze systolic RV function in a more differentiated manner. Previous research has elucidated that a reduction in chronic RV volume overload after TTVR also leads to improved LV preload and LV filling,[24] and a reduced deviation of the interventricular septum after TTVR supports augmented LV filling.[19] The present results support these findings, as LVEDD increased after TTVA, indicating hemodynamic benefits for LV filling. In accordance with previous research, dilated RV and RA dimensions as well as impaired systolic RV function are highly prevalent in patients with severe TR, as pathologic RV volume overload[12] is associated with poor prognosis.[25]

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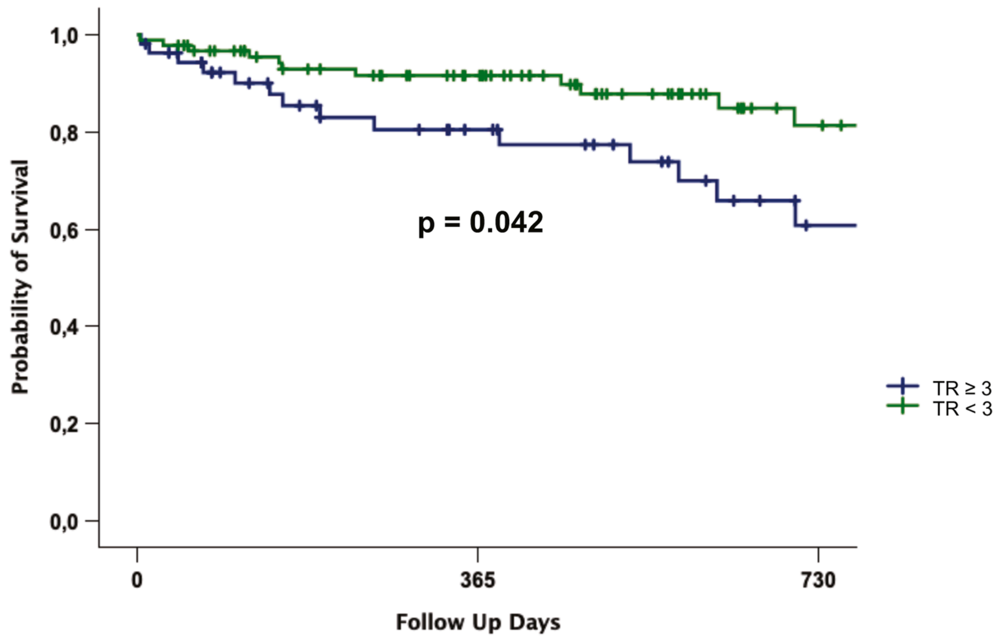
FIGURE 2 Kaplan-Meier Curves for Residual TR After Transcatheter Tricuspid Valve Annuloplasty



No. at risk

	0	365	730
TR < 3	90	60	22
TR ≥ 3	53	28	11

Kaplan-Meier curves for all-cause mortality stratified according to residual tricuspid regurgitation (TR) ≥3 vs TR <3.

We furthermore identified the decrease in vena contracta width from baseline to follow-up as a predictor of positive RHR, underscoring the potential link among procedural success, sustained TR reduction, and positive RHR. The ratio of TAPSE to PASP as a hemodynamic parameter for ventricular/atrial coupling and the complex interaction between contraction and afterload already play an important role in risk stratification among patients with pulmonary hypertension and is implemented in the current European Society of Cardiology guidelines for pulmonary hypertension.[26,27] Higher doses of loop diuretic agents at baseline were negatively associated with RHR, probably indicating a more advanced stage of disease when requiring intensified diuretic therapy, reflecting a limited remodeling capacity in this cohort. TAPSE/PASP ratio values at baseline and follow-up did not differ significantly. However, they consistently remained >0.32 mm/mm Hg, which is the cutoff distinguishing low and intermediate risk for mortality in the 3-stratum model of pulmonary hypertension.[26] These relatively favorable values may explain why TAPSE/PASP ratio did not emerge as an independent predictor for positive RHR in our cohort. In a subgroup analysis with follow-up ≤100 days, positive RHR was associated with a lower all-cause mortality rate compared with patients without RHR. These findings suggest a potential early benefit of reverse remodeling. However, expecting the impact of positive RHR on clinical outcomes to unfold gradually over time, clinical follow-up was initiated after echocardiographic confirmation of remodeling, leading to a relatively small sample size and therefore limited statistical power. Longer follow-up is needed to confirm clinical outcomes in terms of remodeling.

Although data on TR reduction and positive remodeling are very promising in our cohort, it must be mentioned that intraprocedural success according to TVARC was 61.6%, a number generally lower than in recent T-TEER trials.[11,24] This finding is driven mainly by the unmet TR reduction to moderate or less (grade II) included in this new definition. Patients undergoing TTVA usually represent a high-risk cohort with advanced remodeling and higher baseline TR stage (large coaptation gaps and/or leaflet tethering leading to unsuitability of an edge-to-edge strategy) compared with edge-to-edge cohorts.[28]

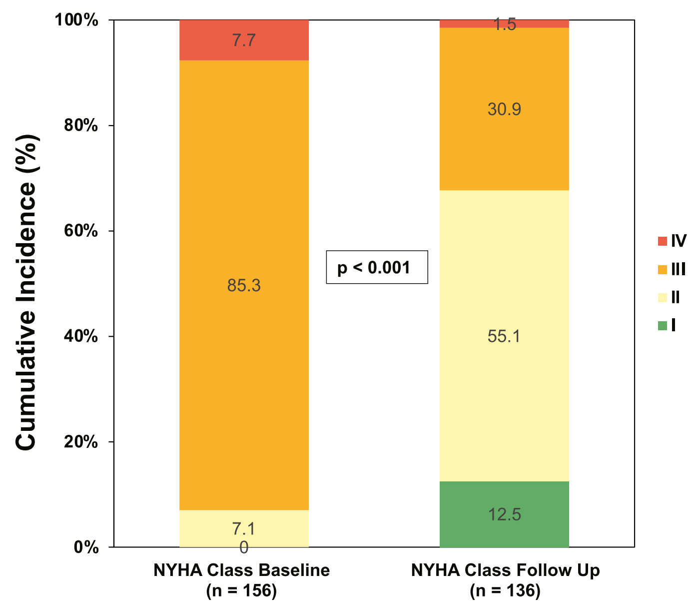
As we have learned from T-TEER cohorts, residual TR ≥3 emerged as an independent predictor of all-cause mortality and heart failure hospitalization.[29,30] Still, 70.5% of patients in our study experienced TR reductions of at least 2 grades, and our findings in the subgroup in which TR was "only" reduced from grade V to III indicate that this reduction was still associated with favorable remodeling as well as clinical benefit. Thus, residual TR ≥3 at discharge was associated with an elevated mortality rate compared with TR <3 (25.9% vs 13.2%; $P = 0.042$). Residual TR therefore must be taken seriously. Close clinical follow-up and the evaluation of further treatment options, such as staged edge-to-edge repair, should be carefully taken into consideration in this vulnerable "high-risk-cohort." Therefore, efforts should be made to treat patients earlier in their course of TR and right heart failure to optimize outcomes.

Interestingly, positive RHR was more often observed in women in our cohort. This might be a bias due to the overall larger representation of female patients in TR cohorts, but still, further studies evaluating gender differences on RHR in patients with TR would be of interest.

Although data indicate differences in RV mass, volumes, and ejection fraction across age and gender, trials comparing or analyzing the underlying mechanisms of reverse RHR in men and women are lacking.[31,32]

STUDY LIMITATIONS. Limitations of our study involve its retrospective study design, while follow-up rates were still very satisfactory. Functional status was assessed by classifying dyspnea by NYHA functional class. Further clinical tests, such as the 6-minute walk test, and heart failure questionnaires should be analyzed in further studies. There was no echocardiographic core laboratory for analyses, leading to potential intercenter and interobserver variability in echocardiographic assessments, but both centers are specialized in imaging analyses of TR and right heart failure. Although both participating centers are highly experienced, TTVA remains a technically more demanding procedure with longer procedure duration than edge-to-edge repair, which currently limits its broader application.

FIGURE 3 Bar Charts Demonstrating Symptomatic Status Classified According to NYHA Functional Class at Baseline and Follow-Up



At baseline, the majority of patients were severely symptomatic (93% in NYHA functional class III or IV). At follow-up, the proportion of patients in NYHA functional class III or IV had decreased substantially to 32.4%, reflecting marked symptomatic reduction over time.

CONCLUSIONS

In this large, multicenter, real-world cohort, TTVA was associated with a significant reduction in TR severity that was sustained for more than 1 year. Furthermore, patients showed distinct positive RA and RV as well as LV remodeling that was accompanied by an improvement in functional status. Reduction of TR was an independent predictor of favorable RHR.

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Dr Hasse has received travel expenses from Boehringer Ingelheim and Lilly Deutschland. Dr Koerber has received travel support and lecture fees from Edwards Lifesciences and Abbott Laboratories. Dr Gerçek has received funding from Ruhr University Bochum (Advanced Clinician Scientist); and has served as a consultant for Edwards Lifesciences. Dr Curio has received research grant support from Boston Scientific; and has received travel support from Laralab Dr J. von Stein has received speaker honoraria from Edwards Lifesciences. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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PERSPECTIVES

WHAT IS KNOWN? TTVA with the Cardioband has proved to be safe and effective in acutely reducing TR.

WHAT IS NEW? In this multicenter, real-world cohort, TTVA was associated with a significant and sustained reduction of TR for more than 1 year. Additionally, patients demonstrated distinct positive cardiac remodeling and functional improvement.

WHAT IS NEXT? Further prospective studies, including functional tests such as the 6 minute walk test, as well as 3-dimensional echocardiography, are needed to improve our current knowledge.

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APPENDIX For supplemental figures, please see the online version of this paper.