

Immediate Tricuspid Annular Geometric Remodeling After Transcatheter Leaflet Approximation for Tricuspid Regurgitation

Bruno Martins^{1*}, Lucas Pereira¹, Renata Azevedo², Pedro Costa¹

¹Department of Clinical Investigation and Research Systems, University of Minho, Braga, Portugal.

²Department of Medical Sciences and Innovation, University of Porto, Porto, Portugal.

Abstract

A range of transcatheter devices have been introduced for tricuspid valve procedures in recent times. The present investigation sought to examine acute tricuspid annular reshaping following percutaneous leaflet repair with a device designed to bring leaflets together and diminish tricuspid regurgitation (TR). This retrospective cohort analysis included 26 consecutive subjects managed across two institutions. Intraprocedural three-dimensional transesophageal echocardiography was employed to evaluate tricuspid annular geometry. The cohort's average age was 79.3 years, with 88.5% of participants being women. Every patient exhibited severe or worse TR before the intervention, principally resulting from annular enlargement. The procedure was successful in all subjects, as documented by an improvement in TR of at least 1 grade before discharge from the hospital. Marked decreases were recorded for the mean septal-lateral dimension (4.09 ± 0.44 cm vs. 3.54 ± 0.53 cm, $P < 0.0001$), mean major diameter (4.65 ± 0.63 cm vs. 4.28 ± 0.65 cm, $P = 0.0002$), planimetric area (14.00 ± 2.91 cm² vs. 11.25 ± 2.91 cm², $P < 0.0001$), and perimeter (13.62 ± 1.43 cm vs. 12.42 ± 1.62 cm, $P < 0.0001$) of the tricuspid annulus. Within this limited real-world series, transcatheter edge-to-edge repair appeared both efficacious and safe. Deployment of a leaflet approximation device not only lessened TR magnitude but also brought about meaningful contractions in annular measurements. To the best of our understanding, this work provides further confirmation of acute tricuspid annular remodeling following edge-to-edge repair, a finding with noteworthy therapeutic implications.

Keywords: Tricuspid regurgitation, Transoesophageal echocardiography, Edge-to-edge repair, Tricuspid annulus

Corresponding author: Bruno Martins
E-mail: bruno.martins@gmail.com

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Introduction

Hemodynamically significant tricuspid regurgitation (TR) is a widespread valvular disorder affecting approximately 3.0 million people across Europe and 1.6 million in the United States [1]. Based on the causative mechanism, TR is subdivided into primary, secondary, and isolated types. Advanced TR is burdened by serious prognostic weight,

entailing an adverse influence on survival and the progression of heart failure [1, 2]. A retrospective review of an extensive patient database indicates one-year death rates of 29.5% for moderate TR and 45.6% for severe TR, irrespective of possible confounding variables. Likewise, the incidence of heart failure-related hospitalization rises in parallel with TR severity [3].

Transthoracic echocardiography is indispensable for establishing the diagnosis of TR, quantifying regurgitant severity, distinguishing primary from secondary etiologies, assessing concomitant left-sided abnormalities, and measuring right ventricular (RV) dimensions and function [3, 4]. The categorization of TR, historically classified as mild, moderate, and severe, demands an integrative, multiparametric strategy. The traditional three-tiered scheme has been extended through the introduction of two further grades: “massive” and “torrential,” terms now routinely applied in clinical investigations to gauge the effect of catheter-based treatments [5]. Evidence from several studies suggests that a drop in TR of at least one grade is clinically relevant and associated with gains in quality of life [6]. More recently, findings from the Triluminate Trial revealed a notable decline in heart failure hospitalizations among patients receiving T-TEER relative to those managed with pharmacological therapy alone [7].

The tricuspid valve (TV) exhibits intricate anatomy, and the reciprocal relationship between TV and RV underlies the pathophysiological drivers of most TR variants. The tricuspid annulus (TA) constitutes a nonplanar configuration, possessing a more apically displaced posteroseptal segment and a more atrially situated anteroseptal segment, in proximity to the RV outflow tract and the aortic valve. One investigation found that, among individuals with functional TR, the TA acquires a rounder contour due to enlargement along the septal-lateral and posteroseptal-anterolateral axes. Furthermore, the TA tends to flatten as TR worsens [8].

In contemporary practice, the right atrial and ventricular geometry in TR patients is meticulously characterized to more precisely delineate the pathophysiology and clinical ramifications of the valve lesion.

Although TR has long been substantially undertreated, enhanced understanding of its pathophysiology and prognostic impact has driven a shift from watchful waiting toward more interventional approaches. Over recent decades, numerous catheter-based devices for TV procedures have been engineered and are now regarded as worthwhile therapeutic alternatives for anatomically suitable individuals deemed high-risk for surgery. Percutaneous systems replicate techniques akin to those of surgical reconstruction, and a contemporary analysis indicates meaningful quality-of-life gains accompanied by fewer periprocedural adverse events [9]. Effectiveness and clinical results appear encouraging [10, 11], though the impact on RV reverse remodeling remains under discussion.

Currently available percutaneous modalities for managing tricuspid regurgitation derive largely from surgical concepts and encompass the leaflet-approximation approach, which seeks to curb TR by coaptating leaflets,

and transcatheter annuloplasty. The most thoroughly investigated system for percutaneous annuloplasty is the CardioBand™ (Edwards Lifesciences, Irvine, CA, USA) device, which directly addresses the pathological substrate of annular dilatation and secures an adjustable band to the TA via multiple screw-type anchors.

The TriClip (Abbott Vascular, Santa Clara, CA, USA) and the PASCAL (Edwards Lifesciences, Irvine, CA, USA) are transcatheter leaflet-repair platforms that work by drawing the tricuspid leaflets together; their outcomes appear comparable in a propensity-matched comparison [12]. The procedural strategy comprises approximations between the anterior and septal leaflets, the posterior and septal leaflets, or a blend of both. In uncommon circumstances, a “clover technique” may be employed [13]. Real-world observational series report high rates of technical success accompanied by a TR decrease of one grade or more in the majority of treated individuals [14, 15]. Data on RV remodeling following transcatheter TV procedures are still sparse, yet existing evidence remains promising [9, 16]. Exploration of the hemodynamic repercussions of transcatheter tricuspid edge-to-edge repair in a subject with isolated TR reveals that lowering the regurgitant volume alleviates RV volume overload, yielding reductions in RV diastolic dimensions and total RV stroke volume [17]. On the other hand, this phenomenon enhances forward pulmonary flow, thereby boosting left ventricular filling and the cardiac index. A decline in external RV work is also observed, coinciding with improved RV performance and reduced oxygen utilization [18].

The purpose of this study is to appraise acute TA remodeling following percutaneous leaflet repair. The authors aimed to examine whether the leaflet approximation method can additionally trigger reverse TA remodeling, serving as a possible mechanism underlying TR reduction.

Materials and Methods

Study population

A total of 31 consecutive symptomatic patients presenting with TR of severe or greater grade, all treated with the TriClip System, were included in this retrospective cohort analysis across two sites—Maria Cecilia Hospital in Cotignola and the University Hospital of Verona—between December 2017 and February 2023. Of these, four individuals had to be excluded because a full 3D acquisition of the tricuspid valve from both before and immediately after the procedure was unavailable. A further patient was removed owing to insufficient 3D image quality, precluding reliable annular measurement. Consequently, the final analytic sample consisted of 26 subjects. The procedures were performed by two

interventional cardiologists, with one serving as the first operator. Demographic, cardiovascular risk factor, and laboratory data were collected at admission (**Table 1**).

Table 1. Demographic variables, cardiovascular risk factors, and blood samples at admission.

Variable	Overall cohort (n = 26)
Age, years (range)	79.3 (64–88)
Female patients	23 (88.5%)
Body mass index, kg/m ² (range)	25.2 (16.7–32.9)
Hypertension	18 (69.2%)
Diabetes mellitus	2 (7.7%)
Dyslipidemia	14 (53.8%)
Current or former smokers	1 (3.8%)
NYHA functional class	
Class I	0 (0%)
Class II	8 (30.8%)
Class III	17 (65.4%)
Class IV	1 (3.8%)
Coronary artery disease	8 (30.8%)
Prior percutaneous coronary intervention (PCI)	5 (19.2%)
Prior coronary artery bypass grafting (CABG)	1 (3.8%)
Previous valvular procedures	8 (30.8%)
– Aortic valve replacement	2
– Mitral valve replacement	4
– Mitral valve repair	2
– Tricuspid valve repair	1
– MitraClip implantation	1
Atrial fibrillation	24 (92.3%)
Pacemaker or ICD implantation	4 (15.4%)
Chronic obstructive pulmonary disease (COPD)	3 (11.5%)
History of heart failure hospitalization	8 (30.8%)
Peripheral edema	11 (42.3%)
Use of diuretics	26 (100.0%)
Hemoglobin, g/dL (mean ± SD)	12.51 ± 1.49
Chronic kidney disease (eGFR < 60 mL/min)	15 (57.7%)
Serum creatinine, mg/dL (mean ± SD)	1.08 ± 0.40
NT-proBNP, pg/mL (mean ± SD)	3234 ± 2948

Abbreviations: NYHA = New York Heart Association, PCI = percutaneous coronary intervention, CABG = coronary artery bypass graft, PMK = Pacemaker, ICD = Intracardiac Defibrillator, COPD = Chronic Obstructive Pulmonary Disease, HF = Heart Failure, CKD = Chronic Kidney Disease, and eGFR = Glomerular Filtration Rate.

Echocardiographic evaluation

Echocardiographic variables were captured before and after the intervention using both transthoracic and transesophageal windows (**Table 2**). All studies were conducted on either an IE33 or EpiqCVX platform (Philips Medical System, Andover, MA, USA) in compliance with the applicable recommendations from the European

Association of Cardiovascular Imaging and the American Society of Echocardiography.

Table 2. Preoperative echocardiographic examination.

Variable	Total population (n = 26)
Sinus rhythm	3 (11.5%)
Atrial fibrillation/flutter	22 (84.7%)
Paced rhythm	1 (3.8%)
End-diastolic area (EDA), cm ²	21.15 ± 6.06
Fractional area change (FAC), %	41.43 ± 5.69
Tricuspid annular plane systolic excursion (TAPSE), mm	18.08 ± 2.07
Pulmonary artery systolic pressure (PASP), mmHg	49.65 ± 16.59
Ejection fraction (EF), %	58.67 ± 7.14
Severity of tricuspid regurgitation	
Mild	0 (0%)
Moderate	0 (0%)
Severe	12 (46.2%)
Massive	3 (11.5%)
Torrential	11 (42.3%)
Underlying mechanism	
Atrial functional	21 (80.8%)
Ventricular functional	2 (7.7%)
Primary (organic)	1 (3.8%)
Device/lead-related	2 (7.7%)
Mitral regurgitation severity	
Mild	11 (42.3%)
Moderate	7 (26.9%)
Moderate-to-severe	3 (11.5%)
Aortic regurgitation severity	
Mild	13 (50.0%)
Moderate	4 (15.4%)
Severe	0 (0%)

TR burden was graded by integrating qualitative, semiquantitative, and quantitative parameters into a five-class scale. TR etiology was assigned to one of four categories: primary, functional atrial, functional ventricular, or lead-associated.

In each case, a Zoom-3D echocardiographic volume was recorded, with adjustments to depth and sector width intended to include as much of the TV apparatus as possible within the dataset while optimizing spatial detail. A single-beat capture strategy was applied universally to avoid stitching artifacts linked to atrial fibrillation, breathing, or probe motion. No minimum frame rate threshold was enforced.

Every transesophageal 3D study used for TA appraisal was performed by a designated echocardiographer with specific training, both before and after TriClip insertion. These assessments took place during the procedure, with patients in a fasting state after general anesthesia had been induced. Reconstructions were subsequently processed offline using the QLab v.10 software environment (Philips Medical Systems, Andover, MA, USA) from archived recordings by an experienced reader who remained

blinded to the procedural specifics. Procedure-related data were also tabulated (**Table 3**).

Table 3. Operative outcomes.

Parameters	All patients (n = 26)
Clip (n)	
1	2 (7.7%)
2	22 (84.6%)
3	2 (7.69%)
A-S	76.9%
P-S	15.4%
A-P-S	7.7%
A-P	0%
Success	26 (100%)
Complications	2 (7.7%)
Death	0
Hospitalization Length (days)	5

A = anterior leaflet, S = septal leaflet, P = posterior leaflet.

Intraprocedural success was defined in accordance with the Tricuspid Valve Academic Research Consortium (TVARC) standards [19]. In brief, acute procedural success (APS) required that the device be deployed successfully with a resultant TR grade no higher than moderate ($\leq 2+$).

The study adhered to the ethical standards outlined in the Declaration of Helsinki, and every included patient was enrolled in the prospective clinical registry and provided written consent for the anonymized use of their data.

Tricuspid annulus analysis

TA dimensions were assessed from intraprocedural 3D datasets using the QLab v.10 software package. Offline manipulation of the 3D volumes was performed via multiplanar reconstruction (MPR). By manual post-processing, the full-volume datasets were oriented to extract 2D cut planes equivalent to transverse, coronal, and sagittal cross-sections passing through the tricuspid annulus. This allowed precise determination of the maximal septal-lateral (SL) and antero-posterior (AP) diameters, as well as computation of the annular perimeter and area. In addition, the major diameter was measured on the planimetered TA. Every measurement was made in end-diastole. The SL and AP dimensions were derived from the coronal and sagittal planes, respectively, with anatomical references, such as the aortic root, used to guide correct alignment. The TA was then planimetered in the transverse plane to yield the perimeter, area, and major diameter (**Figure 1**). An identical analytic protocol was applied uniformly to the datasets obtained before and after TV repair for all subjects. The eccentricity index was computed as the SL diameter divided by the AP diameter. All values were determined at end-diastole, both pre- and post-intervention.

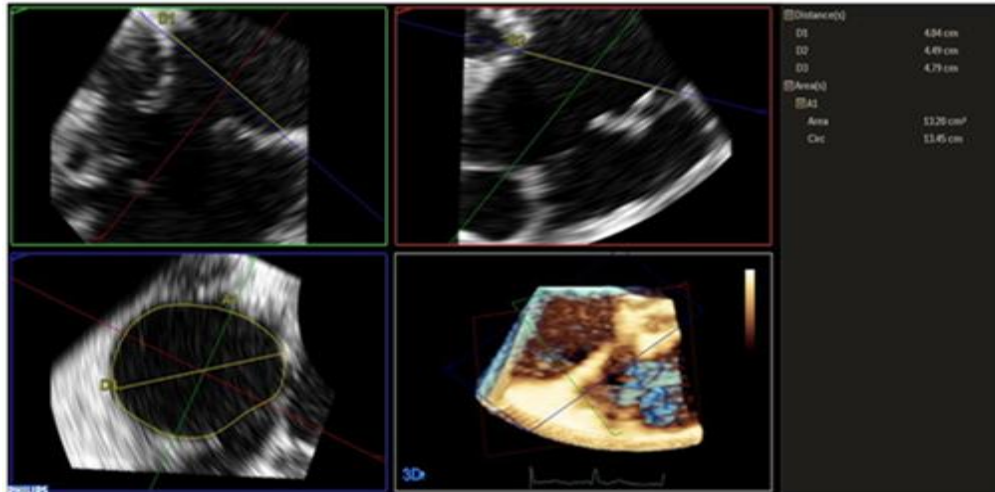


Figure 1. Tricuspid annular measurement, Tricuspid annular measurements using multiplanar reconstruction (MPR) from 3D transesophageal echocardiography. The septal-lateral and antero-posterior diameters, as well as annular area and perimeter, were assessed at end-diastole using orthogonal planes and planimetric tracing.

Statistical analysis

Categorical variables in the descriptive summaries are shown as frequencies with corresponding percentages, while continuous variables are displayed as mean \pm standard deviation. Pre-implantation and post-implantation measurements of the AP diameter, SL diameter, major diameter, TA area, and TA perimeter were compared by means of a paired t-test. The same test was applied to the eccentricity index. All statistical work was

performed using the Statistical Package for Social Sciences, version 24 (SPSS, Chicago, IL, USA).

Results and Discussion

Clinical and echocardiographic characteristics

Twenty-six subjects with tricuspid regurgitation of at least severe grade formed the study sample. Their average age was 79.3 years, and female patients accounted for 88.5%

of the group. Breaking down TR severity, 46.2% had severe regurgitation, 11.5% massive regurgitation, and 42.3% torrential regurgitation. With respect to mechanism, atrial functional TR was identified in 21 individuals (80.8%), ventricular in 2 (7.7%), primary in 1 (3.8%), and lead-associated (caused by leaflet impingement) in 2 (7.7%). A central and antero-septal dominant jet was the most common pattern, observed in 18 subjects (69.2%). Six patients (23.1%) presented with a wide jet spanning from the postero-septal to the antero-septal commissure, and only two (7.7%) had a jet that was exclusively postero-septal dominant. Severe functional disability, corresponding to New York Heart Association class III or above, was noted in 69.2% of cases. Previous valve intervention had been performed in 8 patients, and atrial fibrillation (AF) was detected before the procedure in 24 patients (92.3%). Prior PMK/ICD implantation was present in 4 individuals, and established coronary artery disease was found in 8.

On admission, peripheral edema was evident in a meaningful subgroup (11 patients, 42.3%), and all participants were taking diuretic agents. Eight patients (30.8%) had been hospitalized for heart failure at least once before, and the average circulating NT-proBNP level was 3234 pg/mL. Preoperative transesophageal and transthoracic imaging identified RV systolic dysfunction in 3 patients (11.5%), alongside a mean fractional area change of $41.43 \pm 5.69\%$ and a mean tricuspid annular plane systolic excursion of 18.08 ± 2.07 mm. The estimated mean pulmonary systolic pressure reached 49.65 ± 16.59 mmHg. Right heart catheterization was systematically carried out to exclude both severe and pre-capillary pulmonary hypertension. All subjects had a preserved left ventricular ejection fraction, yet moderate-to-severe mitral regurgitation coexisted in 3 of them (11.5%) (Table 2).

Operative outcomes

Edge-to-edge repair was accomplished in all patients (n=26), with a drop of at least 1 TR grade recorded after the intervention. Procedural success, as defined, was met in 24 instances (92.31%). Two clips were deployed in most cases (22 patients, 84.6%). Only 2 individuals (7.7%) received either a single clip or three clips. Leaflet approximation was performed between the anterior and septal leaflets in 76.9% of the cohort, and between the posterior and septal leaflets in 15.4%. A dual approach combining antero-septal and postero-septal clipping was adopted in only 7.7% of subjects.

Insertion of a new permanent pacemaker became necessary in 1 patient who developed a second-degree atrioventricular block, and 1 additional patient sustained a vascular access-site complication. The median postoperative hospital stay was 5 days (Table 3).

Echocardiographic outcomes

At hospital discharge, mild TR was documented in 23.1% (n=6) of the cohort (Table 4). The TR grade was reduced to no more than moderate in all but two patients (7.7%). No newly emerging regurgitant jets were observed, except in the two subjects in whom the procedure was unsuccessful. In one case, marked distortion of the tricuspid valve architecture was the underlying cause, while in the other, a small iatrogenic flail leaflet was responsible. Among all remaining patients, pre-existing jets were diminished without any new jets arising. Every individual in the study (100%, n=26) achieved a TR reduction of at least one grade (Figure 2). The average tricuspid annular plane systolic excursion measured 17.29 ± 3.58 mm, and the mean left ventricular ejection fraction was $59.96 \pm 8.83\%$.

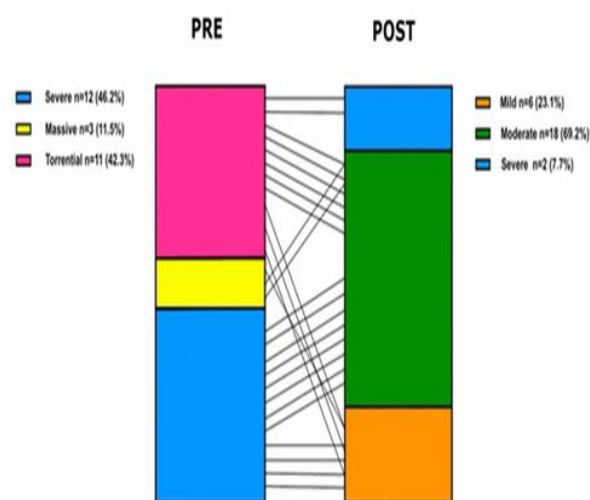


Figure 2. Tricuspid regurgitation quantification pre- and post-intervention. The illustration depicts how TR severity is distributed before and after the procedure, showing the counts of patients classified as severe, massive, or torrential before the procedure, and the counts presenting with mild or greater TR afterward.

Table 4. Echocardiographic outcomes.

Parameters	All Patients (n = 26)
Tricuspid regurgitation	
Mild	6 (23.1%)
Moderate	18 (69.2%)
Severe	2 (7.7%)
TAPSE (mm)	17.29 ± 3.58
PAPS (mmHg)	44.04 ± 12.85
EF (%)	59.96 ± 8.83

Acute tricuspid annulus remodeling

Comparing TA dimensions before and following TriClip deployment (Table 5), a statistically meaningful decrease was found in the mean SL diameter ($P \leq 0.0001$) and in the mean major diameter ($P = 0.0002$). In contrast, the decline in AP diameter did not reach statistical significance ($P =$

0.0626). When planimetric area and annular perimeter were contrasted at the two time points (**Figure 3**), both exhibited significant declines ($P \leq 0.0001$ for each). Lastly, the mean eccentricity index shifted from 0.98 ± 0.17 before device implantation to 0.90 ± 0.17 afterward ($P = 0.0286$).

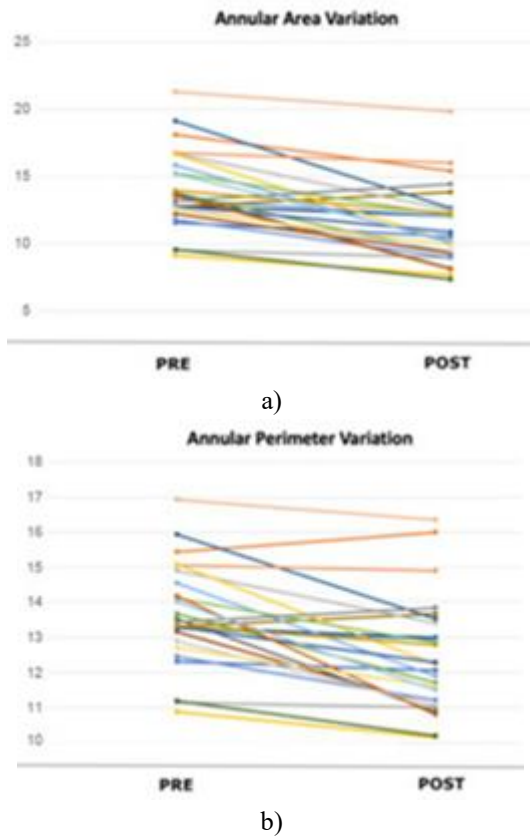


Figure 3. Variation in tricuspid annular area and perimeter pre- and post-procedure in every single patient. The graph plots the individual-level change in both the area and the perimeter of the tricuspid annulus, pairing measurements taken before and after the intervention for each study cohort member.

Table 5. Acute tricuspid annulus remodeling.

Parameters	p Value	After	Before
SL diameter (cm)	<0.0001	3.54 ± 0.53	4.09 ± 0.44
AP diameter (cm)	0.0626	4.01 ± 0.62	4.29 ± 0.79
Major diameter (cm)	0.0002	4.28 ± 0.65	4.65 ± 0.63
Area (cm ²)	<0.0001	11.25 ± 2.91	14.00 ± 2.91
Perimeter (cm)	<0.0001	12.42 ± 1.62	13.62 ± 1.43
Eccentricity index	0.0286	0.90 ± 0.17	0.98 ± 0.17

Findings from both the TRILUMINATE Pivotal (Trial to Evaluate Cardiovascular Outcomes in Patients Treated with the Tricuspid Valve Repair System) and the CLASP TR (Edwards PASCAL Transcatheter Valve Repair System in Tricuspid Regurgitation) investigations extended beyond demonstrating meaningful TR grade

reduction after T-TEER; they also documented a notable contraction of the TV annular SL dimension within the first 30 days following the procedure, with durability of this remodeling observed during continued follow-up [20-22]. Work by Russo *et al.* [23] similarly confirmed significant immediate shifts in TV annular geometry following T-TEER in subjects enrolled in the TriValve registry. A principal shortcoming shared by those analyses is that the SL diameter of the TV annulus was measured solely via 2D TTE, a modality acknowledged to have considerable limitations in capturing the true maximal diameter. In a more recent contribution, a single-center study by Cammalleri *et al.* [24] described tricuspid annular reconfiguration occurring immediately after T-TEER, as assessed by 3D echo.

The current investigation, a retrospective dual-center study, examined TA dimensions before and shortly after edge-to-edge tricuspid leaflet repair with the TriClip device in a real-world setting. The population consisted mainly of older adults, predominantly women, with atrial functional TR as the predominant etiology. Only a handful of individuals had coexisting left-sided valvular or coronary pathology, and none exhibited reduced left ventricular systolic performance. At the same time, virtually all patients carried a diagnosis of AF, suggesting that the predominant TR mechanism in this group is annular enlargement coupled with right atrial remodeling driven by AF. The clinical phenotype of the cohort closely resembles those described in the landmark trials of the TriClip and PASCAL systems, and given the prohibitive operative risk posed by age, multimorbidity, and isolated tricuspid involvement, such patients are well-suited for transcatheter therapeutic options [25, 26].

The present work reports procedural success in the clear majority of subjects, as evidenced by the appropriate deployment of one or more clips. No life-threatening complications were encountered, further attesting to the platform's safety profile. A five-tier classification scheme was used during the preoperative transthoracic and transesophageal echocardiographic workup to grade TR severity. Before discharge, every patient had improved by at least 1 TR grade, and only 4 individuals had severe residual regurgitation. Equally important, acute right ventricular dysfunction did not arise in any participant. For decades, TR, rooted in annular dilation, has been surgically addressed with ring annuloplasty. Edge-to-edge transcatheter approaches were adapted from mitral repair techniques and subsequently translated to the right-sided circulation [22]. The TriClip, along with other available edge-to-edge platforms, mitigates tricuspid valve regurgitation by securing the tricuspid leaflets together and restricting their movement. The consequent alleviation of volume overload triggers favorable reverse remodeling of the RV. This observational study aimed to

characterize the acute TA remodeling induced by direct traction applied to the leaflets during TriClip placement. The retrospective evaluation of intraprocedural 3D echocardiographic acquisitions established that edge-to-edge tricuspid repair via TriClip induces beneficial acute TA remodeling, marked by significant decreases in both the SL and major diameters. This phenomenon is easily rationalized by the anatomical constraint that only the septal-anterior and septal-posterior leaflet couples can be brought into apposition. Planimetric area and perimeter likewise shrank significantly, lending further weight to the echocardiographic observations. Examination of the AP diameter revealed a reduction that did not achieve statistical significance—a finding that may be connected to the concomitant reduction observed in the eccentricity index. Indeed, earlier research has established that TA dilation preferentially affects the lateral aspect, as the septal region is inherently more fibrous and less stretchable. Consequently, the coaptation defect most often occurs between the anterior and septal leaflets, and clips were predominantly positioned along the antero-septal line of coaptation (**Table 3**). This may have altered the TA configuration in select patients, resulting in a more oval contour and reduced eccentricity.

Several constraints deserve recognition. To begin with, the study was retrospective in design and drew from a small cohort without a comparator arm. Thus, these observations await validation in a larger prospective investigation. Additionally, the fidelity of intraprocedural imaging may be suboptimal due to acoustic shadowing from intracardiac implants or the TriClip hardware itself, which could influence analyses performed with the reconstruction software. In this regard, all measurements were undertaken by a single operator, and neither intra-observer nor inter-observer reproducibility was formally evaluated. Finally, no prognostic insights were offered.

Conclusion

In this limited, real-world sample, edge-to-edge repair employing the TriClip system emerged as an approach that is both efficacious and safe. Our findings provide further support for the concept of acute tricuspid annular remodeling driven by direct traction exerted by the deployed clips on the leaflets, as evidenced chiefly by a significant reduction in SL diameter.

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Ethics statement: This study was conducted in accordance with the Declaration of Helsinki, and the Romagna Ethics Committee approved the protocol on 15 February 2017 (protocol number 1149/2017—Rif. I. 5/258).

Patients enrolled provided written consent. Data protection and privacy regulations were strictly observed in the capture, forwarding, processing, and storage of patient data.

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