Transcatheter Annular Approaches for Tricuspid Regurgitation (Cardioband and Others)

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**KEYWORDS**  
- Tricuspid regurgitation  
- Cardioband  
- Transcatheter tricuspid annuloplasty

**KEY POINTS**  
- Growing evidence supports the independent influence of tricuspid regurgitation (TR) on patient outcomes.  
- The postoperative course of isolated tricuspid valve surgery in high-risk patients is associated with poor outcomes.  
- Both transcatheter valve replacement and valve repair have emerged as feasible and efficacious, low-risk interventions for TR correction.

**INTRODUCTION**  
The tricuspid valve (TV) often is referred to as “the forgotten valve” because it frequently is managed with only medical therapy due to poor prognostic outcomes with conventional surgical intervention. Nevertheless, a paradigm shift has occurred in recent years, due to a growing evidence base supporting the independent prognostic influence of tricuspid regurgitation (TR) on patient outcomes and the development of lower-risk transcatheter therapies. Functional TR (FTR), the most prevalent form of TR, seen in approximately 80% of cases, may be a consequence of excessive pulmonary pressure loads (pressure overload) on the right ventricle (RV), causing progressive RV dilatation and dysfunction. Alternatively, long-standing volume overload, as seen in systemic-to-pulmonary shunts, also can induce RV remodeling. RV deformation with subsequent annular dilation and leaflet tethering ultimately lead to FTR. Annular dilatation, typically the dominant mechanism involved in FTR, occurs predominantly along the anteroposterior valve plane, corresponding to the free wall of the RV. Alternatively, in atrial FTR, the right atrium (RA) undergoes progressive dilatation with subsequent annular expansion and leaflet malcoaptation in the absence of pulmonary hypertension (PH). Primary TR results from abnormalities of the
valve leaflets themselves, such as prolapse, flail, perforation, fibrosis, retraction, and congenital abnormalities.

Annular reconstruction frequently is utilized in surgical TV repair. Surgical annular reshaping can be achieved by suture-based or ring-assisted techniques. Suture bicuspidization (Kay procedure) is performed by applying pledget-protected sutures to the posterior annulus with subsequent plication and obliteration of the corresponding segment. Alternatively, surgical annular reduction is performed by the implantation of an undersized, typically incomplete, prosthetic ring. This currently is considered the preferred repair procedure, especially during left-sided valve surgery.3

Unfortunately, the postoperative course of isolated TV surgery in high-risk patients, such as redo cardiac surgery, in the presence of severe RV failure, severe PH, or increased surgical risk due to multiple comorbidities, is associated with poor outcomes.4,5 Therefore, novel transcatheter techniques that replicate surgical annuloplasty are evolving as potentially lower-risk alternatives.

TRICUSPID ANNULAR ANATOMY: IMPLICATIONS FOR THE USE OF PERCUTANEOUS TECHNOLOGIES

The D-shaped tricuspid annulus (TA) is a nonplanar structure and instead has a saddle-shaped 3-dimensional conformation and is devoid of a well-defined annulus fibrosus. The RV free wall attaches to the anterolateral portion of the TA, and the interventricular septum attaches to the relatively shorter septal aspect of the annulus. Histologically, the RV free wall segment contains small amounts of supportive connective tissue whereas the septal segment is in close proximity to the fibrous skeleton of the heart and is more robust. Consequently, annular remodeling is especially pronounced along the axis with less resistance to dilation, along the lateral RV free wall, corresponding to the anteroposterior annulus.

Both transcatheter valve replacement and valve repair have emerged as feasible and efficacious interventions for TR correction. Percutaneous repair techniques that target the leaflets (leaflet-directed) or the TV annulus (annular reshaping therapies) are used most widely and constitute the majority of published evidence.5 Effective transcatheter tricuspid repair must overcome multiple potential anatomic obstacles:

- The TV and TA area is dynamic in response to variable loading conditions, positive pressure ventilation, respiratory phase, and cardiac cycle. Thus, the anatomic details obtained during baseline evaluation using transesophageal echocardiography (TEE) or cardiac-gated computed tomography (CT) may differ from the time of intervention. This is due to factors, such as general anesthesia, the supine position of the patient, and intravascular volume status after fasting and preprocedural diuresis, if performed.
- The TV proximity to the right coronary artery (RCA) and conduction system potentially can increase procedure-related risk of iatrogenic injury, causing myocardial ischemia or conduction disease.
- The thin RV free wall is delicate and can be injured or perforated by device manipulation.
- The hinge point of the TV is not demarcated as clearly as in the mitral valve and often is more difficult visualize by TEE due to a lack of fibrous tissue and thick myocardium.
- There often are multiple mechanisms involved in FTR that rarely can be addressed fully using a single repair device. Even if annular dilatation is the predominant mechanism of FTR, associated leaflet coaptation defects, fibrosis, and tethering may result in residual TR despite successful percutaneous annuloplasty. The presence of cardiovascular implantable electronic device (CIED) wires across the TV also may restrict leaflets physically in some situations and reduce the efficacy of annular-directed therapies.7–10

IMAGING FOR PATIENT SELECTION AND PROCEDURAL PLANNING

The ideal patients for transcatheter TA reshaping are those with predominantly mild to moderate TA dilatation. Presence of specific disease patterns that may limit the benefit of annular reshaping, therefore, must be evaluated during preprocedural evaluation for appropriate patient selection (Fig. 1):

- Severe leaflet tethering (coaptation depth beyond 10 mm), which occurs as a consequence of advanced RV
remodeling, substantially increases annuloplasty failure rates. Annular reshaping techniques effectively stabilize the annular diameter but usually are not sufficient to compensate for leaflet malcoaptation caused by severe leaflet tethering (see Fig. 1). A tenting height greater than 0.51 cm and tenting area greater than 0.80 cm² also are strong indicators to predict annular reshaping failure, regardless of the device used. CIED lead-induced TR due to physical constraint of leaflet mobility may not be associated with significant annular dilatation and thus may not benefit as much from annuloplasty alone. In long-standing CIED-lead induced TR, however, annular dilatation frequently is present. Primary TR due to severe anatomic leaflet defects cannot be addressed effectively by annuloplasty alone.

Fig. 1. Example of patient selection considerations for Cardioband (and other annuloplasty devices). TEE images of the TV demonstrating (A) annular dilatation with a large coaptation gap and mild leaflet tethering and (B) TV septal leaflet tethering (arrow) after Cardioband implantation, resulting in (C) moderate residual TR.
• FTR due to severe TA dilatation (>120 mm) may be difficult to treat with transcatheter annular reshaping due to current device size limitations and reduced annular reduction ability in these cases. Patients with large annuli were excluded from some trials.11,16,17

If transcatheter annular reshaping is appropriate for a patient's anatomy, it is important to recognize that a standardized anatomic and functional evaluation of the TA for transcatheter TV interventions has been described.15 Preprocedural evaluation and planning are needed to achieve an optimal result and are based predominantly on echocardiography and cardiac-gated CT.

TA dimensions typically are measured at maximal diastolic opening (end diastole) for optimal device sizing. This can be performed using 3-dimensional TEE or cardiac-gated CT, with CT recognized as the gold standard due to better reproducibility and accuracy. In addition, the evaluation of the anatomic relationship between the RCA and TA is important to understand and minimize the risk of iatrogenic injury during device fixation. This is performed better by CT. Device implantation may be contraindicated if the RCA courses in close proximity to the anchoring site and there is a high risk of vessel injury.19,20

During a procedure, device positioning and implantation typically are guided by real-time TEE, ideally using 3-dimensional techniques, such as multiplanar reconstruction, to optimize anatomic and device visualization. Therefore, evaluation of TEE image quality and windows in the supine position, including the entire TA, is needed before a procedure. Low-quality TEE imaging would hinder a successful and safe procedure substantially if alternative imaging techniques are not available.

THE CARDIOBAND SYSTEM

The Cardioband system (Edwards Lifesciences, Irvine, California) for TV repair, the first Conformité Européenne (CE) mark–approved transcatheter therapy for TR, is a variant of its mitral counterpart (Table 1). It consists of a sutureless contraction band covered by a polyester sleeve that is fixed on the annulus using a series of helical anchors implanted under live imaging guidance along the anterior, lateral, and posterior segments of the TA.

Following implantation, a size-adjustment tool (SAT) facilitates device contraction and annular perimeter reduction. This is performed under live TEE guidance to evaluate the immediate effect of cinching on TR severity. The Cardioband repair system targets the septolateral diameter with a resultant increase in coaptation area between the TV leaflets (Fig. 2) after device deployment.

The Cardioband adjustable annuloplasty system includes 4 main components:

• The implant: consists of a contraction wire covered by a polyester sleeve imprinted with radiopaque markers spaced 8 mm apart. The contraction wire is connected to an adjustment spool that facilitates implant shortening. Implant contraction is performed under live echocardiographic monitoring. Various device sizes are available: 89 mm to 96 mm, 97 mm to 104 mm, 105 mm to 112 mm, and 113 mm to 120 mm; they are matched to the TA size.11

• Transfemoral delivery system: the Cardioband delivery system consists of the implant delivery system and the 24F steerable sheath (TSS). The IDS includes a steerable guide catheter and an implant catheter with the Cardioband implant mounted on its distal end.

• Implantable metal anchors and anchor delivery shafts: the Cardioband is fixed to the native TA using 12 to 17 stainless steel helical anchors, deployed in a sequential fashion. The anchors are fully repositionable and retrievable until they are deployed.

• SAT: the SAT distal tip is connected over the implant wire and is used to control the implant adjustment spool and the implant size.

Procedural Steps

After femoral vein access is obtained, the 26F steerable Cardioband sheath is introduced and advanced over a guide wire into the RA. A coronary wire is advanced via arterial access into the RCA to delineate its course and to help demarcate the anterolateral aspect of the annulus on fluoroscopy. This helps facilitate device orientation and implant landing zone localization.

The implant delivery system, consisting of the steerable guide catheter and the implant catheter with the Cardioband device premounted on its distal end, then is introduced to engage the annulus. Band deployment is executed in a stepwise fashion on the atrial side of the annulus in an anterior to posterior, clockwise direction. Initial anchoring at the anterosetal commissure
<table>
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<tr>
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<th>Device Type</th>
<th>Description</th>
<th>Current Clinical Experience</th>
<th>Special Considerations</th>
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<tbody>
<tr>
<td>Cardioband system (Edwards Lifesciences, Irvine, CA)</td>
<td>Direct annuloplasty</td>
<td>TA reconstruction via suture-less polyester contraction band delivered and fixed by a series of anchors along the anteroposterior segments of the TA</td>
<td>Clinical trials and real-world data. TRI-REPAIR study (30 patients), US early feasibility study (30 patients), and the international multicenter TriValve registry (13 patients): effective and durable (up to 2 y follow-up) TR reduction and improvement in patients’ functional status</td>
<td>Risk of RCA injury</td>
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<tr>
<td>TRAIPTA (National Institutes of Health and Cook Medical, Bloomington, Indiana)</td>
<td>Indirect annuloplasty</td>
<td>The system is introduced in the pericardium through the RA appendage and acts extrinsically at the level of the atrioventricular groove to contract the anterolateral portion of the TA.</td>
<td>Preclinical animal experience showed increases leaflet coaptation.</td>
<td>Challenging procedure with need of pericardial space Risk of coronary injury</td>
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<td>TriCinch Coil System (4Tech, Galway, Ireland)</td>
<td>Indirect annuloplasty</td>
<td>The system is secured across the pericardial space using a nitinol coil anchor deployed on the TA (near the anteroposterior commissure) which is connected to a nitinol stent</td>
<td>PREVENT trial (24 patients) showed successful procedure in 85% of patients (2 hemopericardium). Four cases of late anchor detachment</td>
<td>Single anchor with risk of anchor detachment Incomplete plasty with risk of TR recurrence Risk of RCA recurrence</td>
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<tr>
<td>The DaVing TR system</td>
<td>Direct annuloplasty</td>
<td>Two-stage procedures: ring anchoring to the atrial aspect of the TA favoring tissue healing and a second step of annular size contraction through an adjustment connector fixed to the jugular vein</td>
<td>Currently enrolling for first-in-human study (NCT03700918)</td>
<td>Approximately 90-d interval between procedure stages are required for tissue healing. Risk of RCA injury Risk of atrioventricular block</td>
</tr>
<tr>
<td>(Cardiac Implants, Wilmington, DE)</td>
<td>Direct annuloplasty</td>
<td>A complete, semirigid, direct annuloplasty nitinol ring delivered to engage the TA with 8 anchors preattached to the base of the implant. Device contraction reduces annular dimensions.</td>
<td>2 patients treated (surgical device implantation): 36% of TA diameter reduction with complete TR abolishment seen immediately after the procedure and sustained for 12 mo. Furthermore, positive remodeling of left ventricle and RV also was noted.</td>
<td>Complete annuloplasty with potential reduced risk for TR recurrence Risk of RCA injury Risk of atrioventricular block</td>
</tr>
<tr>
<td>The Millipede IRIS</td>
<td>Direct annuloplasty</td>
<td>placed in the inferior vena cava through a tensioning band.</td>
<td>and 1 case of RCA damage. Currently ongoing early feasibility study in the US (NCT03632967)</td>
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<tr>
<td>The MIA-T system (Micro Interventional Devices, PA)</td>
<td>Direct annuloplasty</td>
<td>The annular reduction is achieved without sutures due to the compliant, self-tensioning, MIA implant. Once delivered, traction is applied to anchors, via a connection band, and creates a bicuspidization of the valve by obliterating the posterior leaflet.</td>
<td>STTAR trial (31 patients) showed significant and durable reduction in TA dimensions and TR. No device-related or procedure-related deaths, strokes, or myocardial infarctions reported for any patient throughout the 12-mo follow-up period. The company recently has submitted the required technical documentation for CE mark approval for its MIA-T percutaneous tricuspid annuloplasty system.</td>
<td>Reliable and rapid deployment Replicate the surgical sutures Risk of RCA injury Risk of dehiscence Limited published data</td>
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<td>Trialign percutaneous TV annuloplasty system (Mitralign, Tewksbury, MA)</td>
<td>Direct annuloplasty</td>
<td>Two pledgets are placed at the anteroposterior and septal-posterior commissures and then cinched together using a plication lock device thus obtaining a plication of the posterior leaflet Mimics the Kay surgical procedure</td>
<td>Clinical investigations of the Trialign percutaneous TV annuloplasty system were evaluated in 15 patients in SCOUT</td>
<td>Risk of midterm failure (incomplete plasty), which can be mitigated by placing 2 pairs of sutures Risk of RCA injury</td>
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Abbreviation: TriValve, transcatheter tricuspid valve therapies.

Image of the Davign TR system reproduced with permission from Cardiac Implants LLC, Tarrytown, NY; and Image of the Millipede IRIS provided courtesy of Boston Scientific. © 2021 Boston Scientific Corporation or its affiliates. All rights reserved.
is terminated after posteroseptal commissure, demarcated by the coronary sinus ostium. Up to 17 anchors are utilized to safely secure the device to the annulus, with the number of required anchors corresponding to device size.

Once the Cardioband is anchored to the TA, the size-adjustment tool is introduced over a wire to cinch the implant and reduce the septolateral diameter of the TA. Device anchoring and contraction are monitored carefully by real-time 3-dimensional TEE and fluoroscopy (see Fig. 2).²¹

TEE imaging can be challenging during this procedure due to the position of the TA in relation to the esophagus, acoustic shadowing of left-sided implants or calcification, and catheter-associated shadowing of the posterior region of the annulus. In such circumstances, the use of advanced 3-dimensional TEE techniques, such as live multiplanar reconstruction, or alternative modalities, such as intracardiac echocardiography, can help improve visualization of annular hinge points for safe anchor deployment.¹⁷ Finally, fusion imaging combining real-time fluoroscopic and echocardiographic imaging may help facilitate a faster and safer procedure.²¹

Once there is satisfactory restoration of leaflet coaptation and TR reduction, the delivery system is detached and removed from the body.¹⁷

**Early Clinical Results**

After early device experience on a compassionate use basis,²² the safety and the efficacy of the Cardioband implant for the treatment of TR have been evaluated in the TRIcuspid Regurgitation RePAIR With CaRdioband Transcatheter System (TRI-REPAIR) study.¹¹ Thirty patients with moderate to massive TR (76% had severe to torrential TR) and significant annular septolateral dilatation (>40 mm) who were deemed prohibitive risk for cardiac surgery were enrolled in this single-arm, multicenter, prospective trial.

The Cardioband device was implanted successfully in all patients. At 30 days, 20 of 28 patients (71%) had improved functional status, as assessed by New York Heart Association (NYHA) functional class, to a lower NYHA functional class (P<.0001). At 6 months, patients had a significant improvement of their functional status, as assessed by the Kansas City Cardiomyopathy Questionnaire (KCCQ) score (+24 points.

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**Fig. 2.** Cinching of a tricuspid Cardioband with real-time echocardiographic evaluation. Simultaneous fluoroscopy (top row) and TEE (middle and bottom rows) demonstrating sequential degrees of device cinching and associated gradual improvement in septolateral annular diameter and severity of FTR.
change), and the mean 6-minute walk distance increased by 60 m.

The independent core laboratory echocardiographic results reported a significant reduction of the septolateral annular dimensions from 41.6 mm ± 4.9 mm to 36.2 mm ± 4.7 mm (P < .01) at discharge. The reduction remained stable at 30 days (42.2 mm ± 5.1 mm to 37.8 mm ± 3.3 mm; P = .0004) and at 6 months (41.6 mm ± 5.3 mm to 37.8 mm ± 3.4 mm; P = .0014). The effective regurgitant orifice area (EROA) showed a progressive reduction from 0.78 mm² ± 0.49 mm² at baseline to 0.41 mm² ± 0.26 mm² at 6 months. Furthermore, only 5 patients (28%) had severe or greater TR at 6 months compared with 14 patients (78%) at baseline (P = .0020).

In light of these positive results, Cardioband has since received the CE mark approval for the treatment of FTR and is being implanted commercially in Europe.

Recently, 2-year follow-up data from the TRI-REPAIR was published. Annular diameter was reduced significantly at discharge and was sustained at 1 year and 2 years. End-diastolic septolateral annular diameter was 41.9 mm ± 4.6 mm (n = 26) at baseline, 36.5 mm ± 3.3 mm (n = 19) at 1 year (P < .001), and 35.2 mm ± 4.6 mm (n = 14) at 2 years (P < .001; paired analysis compared with baseline). Parallel to annular reduction, TR severity improved significantly. Whereas 24% of patients were with less than or equal to moderate TR at baseline, this progressively increased to 63% (P = .007; paired analysis compared with baseline) at 1 year and 72% at 2 years (P = .016; paired analysis compared with baseline). Similarly, the statistically significant reductions in proximal isovelocity surface area (PISA), EROA, and vena contracta (VC) that were seen after the procedure compared to baseline were maintained at 1 year and 2 years.

Functional status also was improved significantly: 17% of patients were classified as NYHA class I–II at baseline, which increased to 78% (P < .001; paired analysis compared with baseline) and 82% (P = .002; paired analysis compared with baseline) at 1 year and 2 years, respectively. In addition, 6-minute walk distance was increased by 42 m at 1 year (P = .053; paired analysis) and 73 m at 2 years (P = .058; paired analysis) compared with baseline. Similarly, the overall KCCQ score was increased by 19 points at 1 year (P < .001; paired analysis) and 14 points at 2 years (P = .046; paired analysis) compared with baseline.

Cardioband experience in the United States also recently was published. A single-arm, multicenter, prospective early feasibility study evaluated the 30-day outcomes of the Cardioband device in 30 patients with symptomatic severe TR despite medical therapy. At baseline, 27% had severe TR, 20% massive TR, and 53% torrential TR. Furthermore, 70% of patients had NYHA functional class III or class IV at enrollment. The device was implanted successfully in 93% of cases. After 30 days, the annular septolateral diameter was reduced by 13% (P < .001) compared with baseline, with associated significant TR reduction and improvement in functional capacity and quality of life. At 1 month, 75% of patients were NYHA functional class I to class II (P < .001). No significant increase in 6-minute walk distance was found. Average reductions of 38% in PISA EROA (0.77 cm² vs 0.48 cm², respectively; P = .003) and 35% in mean VC (1.4 cm vs 0.9 cm, respectively; P < .001) were seen by echocardiography during the study period. Moreover, indices of RV remodeling, such as mid-RV end-diastolic diameters and RA volume, also were improved significantly 1 month after annular reshaping (Table 2).

Given the promising results thus far, recruitment for the prospective, multicenter Transcatheter Repair of Tricuspid Regurgitation With Cardioband TR System Post-Market Clinical Follow-Up Study (TriBAND) (NCT03779490) currently is ongoing in Europe. The trial is planned to include 150 patients with symptomatic severe FTR who will be treated with the Cardioband system. Device safety and effectiveness will be evaluated during 5 years of follow-up.

Potential Complications
A relatively low rate of complications was reported in the available clinical experience with Cardioband implantation (Table 3).

In TriRepair, 8 deaths occurred during the 2-year follow-up period; 2 cases occurred within the first 30 days (1 was adjudicated as device-related complication). Six deaths that occurred during follow-up were not related to the implant. Two patients underwent device-related secondary interventions as a result of worsening TR. Anchor detachments occurred in 2 patients with subsequent torrential TR.

The investigators reported 3 coronary artery complications: 1 patient had an occlusion of a secondary branch of the RCA, which was left untreated; another patient had worsening of a pre-existing lesion of the distal RCA, which was successfully treated with the implantation of a drug-eluting stent; and 1 patient experienced...
Table 2
Changes in echocardiographic and clinical variables between baseline and 30 days

<table>
<thead>
<tr>
<th>Echocardiographic and clinical variables</th>
<th>TRI-REPAIR 30 Days</th>
<th>Baseline</th>
<th>P Value</th>
<th>TRI-REPAIR 30 Days</th>
<th>Baseline</th>
<th>P Value</th>
<th>United States Study 30 Days</th>
<th>Baseline</th>
<th>P Value</th>
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<tr>
<td>Echocardiographic variables</td>
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<tr>
<td>TA septolateral diameter, mm</td>
<td>37.8 ± 3.3</td>
<td>42.2 ± 0.5</td>
<td>.0004</td>
<td>39.5 ± 7.4</td>
<td>.0004</td>
<td>&lt;.001</td>
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<td>PISA EROA, cm²</td>
<td>0.39 ± 0.32</td>
<td>0.79 ± 0.51</td>
<td>.0003</td>
<td>0.55 ± 0.41</td>
<td>.0003</td>
<td>&lt;.001</td>
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<td>Mean VC, cm</td>
<td>0.90 ± 0.39</td>
<td>1.26 ± 0.45</td>
<td>&lt;.0001</td>
<td>0.91 ± 0.44</td>
<td>&lt;.0001</td>
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<td>Mid-RV end-diastolic diameter, cm</td>
<td>3.74 ± 0.58</td>
<td>3.81 ± 0.62</td>
<td>.4943</td>
<td>3.7 ± 0.5</td>
<td>.0003</td>
<td>&lt;.001</td>
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<td>Systolic pulmonary artery pressure, mm Hg</td>
<td>39.6 ± 10.7</td>
<td>35.8 ± 10.6</td>
<td>.0980</td>
<td>40.3 ± 12.0</td>
<td>.259</td>
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<tr>
<td>LV ejection fraction, %</td>
<td>57.7 ± 8.0</td>
<td>57.2 ± 10.5</td>
<td>.7664</td>
<td>58.5 ± 7.1</td>
<td>.904</td>
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<tr>
<td>LV stroke volume, mL</td>
<td>64.5 ± 12.1</td>
<td>59.2 ± 19.7</td>
<td>.0716</td>
<td>64.1 ± 16.4</td>
<td>.660</td>
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<td>Clinical variables</td>
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<td>Severe, massive, or torrental TR, %</td>
<td>24</td>
<td>71</td>
<td>P&lt;.0001</td>
<td>56</td>
<td>P&lt;.001</td>
<td></td>
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<tr>
<td>Functional status class NYHA</td>
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<td>71% of patients with functional status improvement (NYHA) by 1 or more categories</td>
<td>P&lt;.0001</td>
<td>32% of patients had an NYHA functional status of class I or II</td>
<td>P&lt;.001</td>
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<td>6MWD, m</td>
<td>292 ± 123</td>
<td>261 ± 110</td>
<td>P = .0759</td>
<td>—</td>
<td>—</td>
<td>Nonsignificant change was reported</td>
<td></td>
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<tr>
<td>KCCQ score</td>
<td>57 ± 24</td>
<td>45 ± 23</td>
<td>P = .0063</td>
<td>69 ± 24</td>
<td>P&lt;.001</td>
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</table>

Values are mean ±SD, unless otherwise indicated. The P values were calculated by a Student t test or Wilcoxon signed rank test for paired analyses comparing baseline and 30 d.

Abbreviations: 6MWD, 6-minute walk distance; LV, left ventricular.
pericardial tamponade secondary to penetration of 1 anchor into the successfully CA. The perforation was managed successfully with prolonged balloon inflation and pericardial drainage. This complication potentially can be mitigated with the use of advanced echocardiographic techniques, such as live 3-dimensional multiplanar reconstruction and echocardiographic-fluoroscopic fusion to better visualize the anchor implant zone. In the early feasibility trial performed in the United States, 1 episode of iatrogenic RCA deformation that was treated with 2 drug-eluting stents.

Iatrogenic RCA deformations were evaluated in a recent analysis of 51 patients treated with Cardioband. RCA distortion was evident in 14 of 51 (36.5%) implantations. In 12 cases, although angiographically severe (estimated visually as ≥80% stenosis), no flow impairment or signs of dissection, perforation, or occlusion were observed. Moreover, no signs of ischemia were evident on electrocardiography and no biochemical markers of myocardial injury were evident. A conservative approach was chosen and follow-up angiography (mean of 5.36 days ± 7.73 days after implantation) revealed complete reversal of RCA abnormalities, whereas 2 deformations were treated by stenting. Thus, postimplantation lesions without flow limitations associated with Cardioband implantation often are self-resolving over time and can be managed conservatively if there is no clear indication for immediate stent implantation.

Periprocedural bleeding occurred in 4 patients (13.3%) in the TRI-REPAIR and 7 patients (23.3%) in the early feasibility US study. Two patients, 1 in each study, developed cardiac tamponade during the procedure. In TRI-REPAIR, 1 fatal case of subarachnoid hemorrhage was reported.

OTHER TRANSCATHETER TRICUSPID ANNULOPLASTY SYSTEMS

There currently are several transcatheter devices, which aim to replicate complete or incomplete surgical tricuspid annuloplasty that are in the preclinical or clinical investigational phase of development (see Table 1).

### Transatrial Intrapericardial Tricuspid Annuloplasty

The transatrial intrapericardial tricuspid annuloplasty (TRAIPTA) (National Institutes of Health and Cook Medical, Bloomington, Indiana) is an indirect annuloplasty system delivered through the pericardial space and across the atrioventricular groove. The system is introduced in the pericardium through the right appendage to externally reduce the anterolateral portion of the TA. The system has been tested in 16 Yorkshire swine with successful delivery in all cases without complications. Implantation resulted in a reduction of annular dimensions, annular perimeter and TV area. In 4 animal models with baseline TR, TRAIPTA achieved a significant and stable reduction of the insufficiency. The first-in-human implantation is pending.

### TriCinch

The TriCinch Coil System (4Tech Cardio, Galway, Ireland) is an indirect annuloplasty device in its second generation. Contrary to the first-generation

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>TRI-REPAIR No (%)</th>
<th>US Study No (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>2 (6.7)</td>
<td>0</td>
</tr>
<tr>
<td>Stroke</td>
<td>1 (3.3)</td>
<td>0</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Bleeding complications (extensive, life-threatening, or fatal)</td>
<td>4 (13.3)</td>
<td>7 (23.3)</td>
</tr>
<tr>
<td>Coronary complications</td>
<td>3 (10.0)</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td>Anchor detachment</td>
<td>0</td>
<td>2 (6.7)</td>
</tr>
<tr>
<td>Device-related secondary intervention</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Device-related cardiac surgery</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Conduction system disturbance</td>
<td>1 (3.3)</td>
<td>0</td>
</tr>
<tr>
<td>Ventricular arrhythmia</td>
<td>2 (6.7)</td>
<td>0</td>
</tr>
</tbody>
</table>
device, which was anchored directly to the hinge point of the lateral TA using a corkscrew-shaped anchor, the second-generation device is secured in the pericardial space using a nitinol coil with a hemostasis seal anchor. This anchor is connected to a nitinol stent placed in the inferior vein cava through a tensioning band, which pulls the lateral annulus toward the septum. These modifications to the second-generation device were designed to overcome the main limitation of the previous TriCinch system, that is, dehiscence and loss of efficacy.

In the Percutaneous Treatment of Tricuspid Valve Regurgitation With the TriCinch System (PREVENT) trial (NCT02098200), implantation of the first-generation TriCinch was successful in 18 cases and a reduction of TR by at least 1 grade occurred in 94% of the cases. Two patients had hemopericardium after the procedure and late detachment of the corkscrew shaped anchor was observed in 4 patients.8

After 2 successful procedures in the United States and many in Europe, the TriCinch coil system is under investigation in the Early Feasibility Study of the Percutaneous 4Tech TriCinch Coil Tricuspid Valve Repair System (NCT03632967). This study aims to treat patients with at least moderate TR in 7 centers across the United States.25 Device development since has been interrupted because of financial reasons.

DaVingi
The DaVingi TR system (Cardiac Implants, Wilmington, Delaware) is a transcatheter tricuspid annuloplasty system that is implanted in a 2-step procedure. The device is first delivered through a 22F catheter from the jugular vein and positioned on the atrial aspect of the TA. It is fixed to the annulus by simultaneously firing a set of anchors. The presence of a prosthesis ring favors a healing process so that, in a second step procedure done approximately 3 months later, the annular size is adjusted through an adjustment connector fixed to the jugular vein. The first 5 patients of a first-in-human study have been enrolled (NCT03700918).8

Millipede IRIS
The Millipede IRIS device (Boston Scientific, Marlborough, Massachusetts) is a complete, semirigid, nitinol ring that is attached to the TA with 8 helical anchors that are pretached to the base of the implant. It functions as a direct annuloplasty device. The upper portion of the device has 8 sliding collars, which, when advanced, decreases the distance between 2 adjacent anchoring elements. Each ring segment (consisting of 1 sliding collar and 2 anchors) can be adjusted independently, allowing selective remodeling of the most dilated portions of the annulus. The ring is completely retrievable for optimal repositioning prior to deployment. The 3 basic steps of the Millipede IRIS procedure are (1) placement, (2) anchoring, and (3) adjustment.8,26

The Millipede IRIS has been implanted during open heart surgery as proof-of-concept in 3 patients during a combined procedure to treat both TR and MR. After placement and anchoring, the collars were advanced to reduce the size of the device and attached annulus until leaflet coaptation was achieved and there was no TR by surgical bulb testing. Significant reduction in TR to trace was noted, with an average TA septolateral diameter reduction of 36% that was stable at 6-month and 12-month follow-up. A dedicated delivery catheter for transcatheter deployment to the TA is under development.26

MIA-T System
The MIA-T system (Micro Interventional Devices, Newtown, Pennsylvania) consists of a series of low-mass, polymeric, self-tensioning PolyCor anchors and a thermostatic elastomer, MyoLast, for tensioning of the anchors inducing annular plication. A dedicated 12F delivery catheter is used for anchor deployment. Once delivered, the anchors are linked using a connection band, which then is tightened to bicuspidize the valve by obliterating the posterior leaflet. A total of 31 patients supposedly have been enrolled thus far in the percutaneous arm of the Study of Transcatheter Tricuspid Annular Repair (STTAR) trial (NCT03692598). The company has reported significant reductions in annular dimensions and TR with MIA-T system and durable results at 1-year follow-up. There are no published data, however, on these patients. The company recently has submitted the required technical documentation for CE mark approval based on these data.8

Trialign
The Trialign percutaneous TV annuloplasty system (Mitralign, Tewksbury, Massachusetts) is a transcatheter incomplete direct annuloplasty system designed to mimic the Kay surgical procedure. Using a transjugular approach, 2 pledgets are placed at the anteroposterior and posteriorseptal commissures, followed by cinching using a plication lock device to eliminate the posterior leaflet to bicuspidize the valve. The performance of the device has been tested in the
Transcatheter Annular Approaches for Tricuspid Regurgitation

Percutaneous Tricuspid Valve Annuloplasty System for Symptomatic Chronic Functional Tricuspid Regurgitation (SCOUT) I and SCOUT II trial. Device development has since been interrupted because of financial reasons.

SUMMARY

Transcatheter tricuspid interventions are progressively gaining importance in the undertreated TR patient population, especially in the setting of those at high surgical risk. Several devices aiming to achieve TA remodeling, by direct or indirect annuloplasty, have been designed to treat 1 of the primary mechanisms for FTR. These devices require specific preprocedural assessment to ensure appropriate patient selection and to maximize the likelihood of success by designing through careful procedural planning. Because many of these devices still are in the early stages of development, further experience with larger cohorts of patients are under way to better evaluate procedural and clinical outcomes.

CLINICS CARE POINTS

- FTR is the most prevalent form of TR, arising in the setting of RV remodeling.
- Severe TR is associated with poor patient outcomes.
- Available drug therapy specific for TR is highly limited and is based mainly on diuretics. Treating the underlying etiologies associated with secondary TR is strongly recommended.
- Surgical annuloplasty currently is considered the preferred repair procedure, especially during left-sided valve surgery.
- Surgical repair of isolated TR in high-risk patients with evidence of end-organ damage is associated with poor outcomes. Thus, treatment should be pursued early, before the onset of severe PH and/or severe RV failure.
- Novel transcatheter techniques that replicate surgical annuloplasty are evolving as effective and lower-risk alternatives.

REFERENCES


