Transcatheter Solutions for the Tricuspid Valve

The anatomic challenges of and transcatheter solutions for tricuspid regurgitation.

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Historically considered the forgotten valve, the tricuspid valve (TV) has come front and center in recent years. The true incidence of moderate-to-severe tricuspid regurgitation (TR) is difficult to establish due to its subclinical progression, although contemporary data suggest a prevalence of at least 0.55% in the community setting.[1] Although isolated severe TR serves as an indication for surgical intervention, the majority of patients are managed medically.[2] This is likely a result of the increased morbidity and mortality related to isolated TV surgery, which is often due to late clinical presentation and a high burden of comorbidities that may include left-sided valve and ventricular dysfunction, right ventricular (RV) dysfunction, and pulmonary hypertension.[3,4] It was only in 2014 when the American College of Cardiology/American Heart Association guidelines began to recommend concomitant TV repair in patients undergoing coronary artery bypass grafting or left-sided valvular surgery if there was evidence of at least mild TR and annular dilation.[5]

The exponential growth and success of transcatheter therapies for left-sided valvular heart disease over the last decade have provided a guide for the development of transcatheter tricuspid valve interventions (TTVI). Although intuitively one would think that similar therapies could be applied to both atrioventricular valves, the unique anatomic characteristics of the TV make this more complex than may initially be appreciated. This article summarizes the unique anatomic characteristics that must be considered for TV therapies and the current transcatheter technologies available for TR (Table 1).[6-10]

ANATOMIC CONSIDERATIONS

A thorough understanding of TV anatomy is critical to successfully perform transcatheter therapies. The TV is unique in that its anatomy demonstrates greater variability between individuals than that of the other heart valves. The TV apparatus consists of the annulus, leaflets, papillary muscles, chordae, and the right atrial and ventricular myocardium.

The tricuspid annulus (TA) is a D-shaped, nonuniform ring composed of a combination of the fibrous skeleton, which runs in continuity with the mitral and aortic valves, and the muscular tissue. Its heterogeneous composition results in asymmetric dilatation of the TV under high pressures and/or volume overload. Dilation of the septal segment of the annulus is limited because of its anatomic relation with the fibrous skeleton of the heart. As a result, the annulus will preferentially dilate toward the posterolateral free wall, resulting in a more spherical and planar shape. Unlike the mitral valve, for which the annular plane is nearly orthogonal to the sagittal plane, the TV is almost vertical and so that the annular plane is at a 45° angle to the sagittal plane. This makes achieving coaxiality much more difficult for the TV in terms of both imaging and procedural approach.

The tricuspid leaflets are thinner and more fragile compared to those of the other three cardiac valves. Classic anatomic nomenclature describes the three leaflets as anterior, posterior, and septal leaflets. Attitudinally, the anterior leaflet is more accurately referred to as the anterosuperior leaflet and the posterior leaflet as the inferior leaflet. The anterior leaflet is the largest and most mobile and the septal leaflet is the smallest and most restricted. Furthermore, up to 40% of TVs have four or more leaflets, and up to 10% of people have fusion of the anterior and posterior leaflets.[11] These frequent variations in leaflet anatomy make it difficult to determine universal anatomic landmarks for each leaflet; the most reproducible landmark is the coronary sinus ostium, which is usually located near the posterior and septal leaflet commissure.

The TV usually has two papillary muscles, anterior and posterior. The anterior papillary muscle is typically the larger of the two, providing chordal support for the anterior and posterior leaflets. The posterior papillary muscle is commonly bifid or trifid, providing chordal support to the posterior and septal leaflets. A third septal papillary muscle may be present. Unique to the TV, chordae may arise directly from the interventricular septum and attach to the anterior and septal leaflets. The subvalvular apparatus of the TV is typically much more crowded than that of the mitral valve, which must be taken into consideration when manipulating transcatheter therapy equipment in the right ventricle.

Important anatomic structures within the vicinity of the TV must also be recognized during transcatheter therapies. The AV node and right bundle of His course through the membranous septum. The right coronary artery follows the right atrioventricular groove, which is in closest proximity to the septal and posterior leaflets. The noncoronary sinus of Valsalva is adjacent to the anteroseptal commissure.

Overall, the TV apparatus has numerous unique features that must be considered during transcatheter procedural planning. These unique features include the lack of annular calcium to provide scaffolding support, the angulation of the valve in relation to the superior and inferior vena cavae, trabeculation, and relative thinness of the right ventricle hindering a transapical approach, and oftentimes the presence of preexisting cardiac leads through the TV.

PATIENT SELECTION

Appropriate patient selection is critical for procedural and clinical success of TTVI. Patients will often have concomitant left-sided valvular heart disease, atrial fibrillation, or pulmonary hypertension that should be addressed prior to or alongside their TR. The complexity of both the patient population and TTVI procedures warrants a multidisciplinary approach to patient selection and treatment, colloquially termed the "heart team." The heart team is usually composed of interventional cardiologists, cardiothoracic surgeons, cardiac imaging specialists, and heart failure specialists and often requires referral to a tertiary care center. Dedicated valvular imaging with transesophageal echocardiography (TEE) and CT are necessary to determine whether a procedure is anatomically feasible.

Ideally, patients with TR can be treated with TTVI before there is irreversible myocardial damage, such as RV dilatation and dysfunction. In reality, this can be challenging due to the subclinical presentation of TR, with many patients remaining minimally symptomatic until significant RV remodeling and dysfunction are evident. With the recent breakthrough of encouraging data in the TTVI arena, it may be prudent to focus on early patient referral to allow for expedited intervention and, ultimately, prevention of the detrimental downstream effects of untreated TR.

TRANSCATHETER REPAIR APPROACHES

Coaptation Devices

MitraClip in the tricuspid position. The MitraClip (Abbott) is a transcatheter mimic of the surgical Alfieri stitch whereby two leaflets are clasped together to achieve edge-to-edge repair. Given its success for treatment of both primary and secondary mitral regurgitation (MR), its feasibility for TR is now being studied.[12,13] The multicenter TriValve registry recently reported on 249 patients who underwent edge-to-edge repair for severe TR with compassionate or off-label use of the MitraClip system.[14] The 1-year results were promising in terms of both durability and clinical response, with 72% of patients having TR < 2+ and 69% with New York Heart Association (NYHA) class < II. Notably, procedural failure was an independent predictor of 1-year mortality (hazard ratio, 2.12; 95% CI, 1.12-4.02; $P = .014$), reiterating the importance of appropriate patient selection as well as the suggestion of mortality benefit for those patients with successful TR reduction. The TriClip system is a modification of the MitraClip delivery system (although the clip itself is the same) and is currently being investigated in the TRILUMINATE early feasibility trial (NCT03227757). Preliminary clinical outcomes data were released in late 2019, including 85 patients with a 91.6% procedural success rate and 87% achieving TR reduction at 30 days.[10]

The MitraClip system is best operated via a transfemoral venous approach. Although the transjugular approach is appealing to optimize coaxiality with the TV, it has been largely abandoned with the current iterations of MitraClip due to the extraneous length of the steerable guide catheter (SGC) and suboptimal operator positioning near the head of the bed and image intensifier. The TriClip system has an SGC that has been specifically adapted for the right side of the heart but at this time is still recommended to be used via a transfemoral approach.

The optimal clip positioning strategy for management of TR has yet to be established. Two techniques have predominated the recent literature: (1) the triple orifice technique, which is essentially a modification of the Alfieri stitch in which clips are placed centrally to create three separate orifices; and (2) the bicuspidalization technique, in which clips are placed along one commissure to effectively create a bicuspid valve. A small, retrospective analysis by Braun and colleagues showed comparable 30-day outcomes between these two techniques,

TABLE 1. CURRENT DEVICES FOR TRANSCATHETER TRICUSPID VALVE REPAIR

Device (manufacturer)	TriClip (Abbott)	Pascal repair system (Edwards Lifesciences)	
Study name	TRILUMINATE[10]	First-in-Human[6]	
Patients, n	85	28	
Success rates†	85 (100%)	24 (86%)	
Periprocedural complications (30 d unless otherwise noted)	SLDA, 5 (7%); myocardial infarction, 1 (1%); renal failure, 1 (1%)	SLDA, 2 (7%)	
All-cause mortality	6 mo, 4 (5%)	30 d, 2 (7.1%)	
Serial echocardiogram changes (EROA by PISA method)	▪ 71 (86%) patients with TR severity reduced by > 1 grade at 30 d ▪ TA diameter: 43.3 to 41.6 mm at 6 mo (P = .0034) ▪ EROA: 0.65 to 0.35 cm^2 at 6 mo (P < .0001)	▪ 22 (85%) patients with < 3+ TR at 30 d (P < .001) ▪ TA diameter: 47.4 ± 7.3 mm to 40.3 ± 7.1 mm (P < .001)	
Clinical success	63/73 (86%) patients reported NYHA class I/II at 6 mo from 21/83 (25%) at baseline (P < .001); 6MWT: + 61.9 m at 6 mo (P < .0003)	23/26 (88%) patients reported NYHA class I/II at 30 d from 0% at baseline; 6MWT: + 95 m (P < .001)	
Ongoing studies	TRILUMINATE	CLASP TR EFS, CLASP II TR	

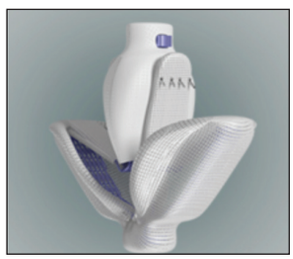
Abbreviations: 6MWT, 6-minute walk test; CAVI, caval valve implantation; EROA, effective regurgitant orifice area; NYHA, New York Heart Association; OMT, optimal medical therapy; SLDA, single leaflet device attachment; TA, tricuspid annulus.
*Randomized controlled trial versus optimal medical therapy.
†Technical success defined as successful access, delivery, and retrieval of the system except for the PREVENT trial and PASCAL First-in-Human whereby only procedural success was reported.
‡TRICAVAL study recruitment was stopped early due to four major complications after the procedure.

with significant increase in 6-minute walking distances and improved quality of life.[15] Most importantly, operators should work closely with their imaging colleagues to understand the origin of the TR, as it may be possible to isolate the jet to a specific location between two leaflets (rather than at the central coaptation of all three) and target the clip(s) to that area.

Unique technical obstacles that have arisen from TTVI include the reduced subvalvular space in the right ventricle, which makes it much easier to entangle clips within the leaflets and chords and the relatively larger coaptation gaps between TV leaflets compared to that of the mitral valve. Data have suggested that procedural failure may be predicted by nonanteroseptal/noncentral jet location, TR effective regurgitant orifice area (EROA) > 0.70 cm^2, TV tenting area > 3.15 cm^2, and TR coaptation gap > 0.65 cm.[14] The customized TriClip system SGC may provide more control in accessing the TV, and contemporary use of the MitraClip XTr with longer arms has proven useful for tricuspid repair.

We recently showed the critical role of TEE with three-dimensional (3D) capability and multiplanar reconstruction (MPR) in successfully performing challenging MitraClip cases for MR.[16] Live MPR allows for real-time cross-referencing of multiple two-dimensional (2D) high-resolution planes alongside a 3D volumetric model. These features are equally valuable for transcatheter tricuspid repair, but the TV can be difficult to image even at baseline. As such, we have dedicated structural imaging specialists who perform our intraprocedural TEE.

Pascal transcatheter repair system. The Pascal repair system (Edwards Lifesciences; Figure 1) is another transcatheter repair device designed to reduce TR. It consists of a 1-cm central "spacer" to reduce the regurgitant orifice area and provide a zone of minimal leaflet coaptation that is held in place by paddles. The paddles can also independently grasp leaflets. Similar to the MitraClip, it was initially developed for treatment of MR but more recently is being studied for feasibility in TR with the CLASP TR EFS trial (NCT03745313) and CLASP II TR



Courtesy of Edwards Lifesciences.

Figure 1. Pascal transcatheter repair system.

	TriCinch (4Tech Cardio)	Cardioband tricuspid system (Edwards Lifesciences)	CAVI (Sapien XT, Edwards Lifesciences)
	PREVENT[7]	TRI-REPAIR[8]	TRICAVAL[9]*
	24	30	14
	85%	30 (100%)	14 (100%)
	Hemopericardium, 2 (8%); coronary injury, 1 (4%); late anchor detachment, 4 (17%)	At 6 mo, stroke, 1 (3%); bleeding, 4 (13%); coronary injury, 3 (10%); conduction disease, 1 (3%)	Urgent open heart surgery, 4/14 (28.5%)‡
	Not reported	30 d, 2 (6.7%); 6 mo, 3 (10%)	In-hospital, 3 (21%)
	Not reported	▪ Reduction from 14/18 (78%) with ≥ 3+ TR at baseline to 5/18 (28%) at 6 mo (P = .0020) ▪ TA diameter: 41.6 ± 5.3 mm at baseline to 37.8 ± 3.4 mm at 6 mo (P = .0014)	Normal caval function at 1, 3, 6, 12 mo
	Not reported	22/25 (88%) patients reported NYHA class I/II at 6 mo; 6MWT: + 60 m (P = .0035)	Change in VO_2 max: -1.0 + 1.6 mL/kg/min in CAVI vs -0.1 + 1.8 mL/kg/min for OMT (P = .299); change in NYHA class: -0.3 + 0.9 OMT vs -0.6 + 0.5 (P = .401); 6MWT, OMT -2.8 + 71.3 m vs CAVI + 18.9 + 47 m (P = .494)
	PREVENT	TriBAND; Cardioband TR EFS	TRICUS (TriValve, P+F Products Features)

(NCT04097145). The short-term results for the compassionate use of the Pascal repair system in 28 patients with severe TR were recently published by Fam and colleagues.[6] The primary outcome of procedural success was achieved in 86%. Two patients were found to have single-leaflet device attachments during their hospital stay and were medically managed, with one patient dying at 29 days of a presumed cardiac cause. Eighty-eight percent of patients reported significant improvement in NYHA class at 30 days, with the incidence of NYHA class > III reduced from 100% at baseline to 12% and TR grade reduction from 100% ≥ 3+ to ≤ 2+ in 85% of patients at 30 days (P < .001). There was associated improvement in 6-minute walk test distance from 240 m to 335 m (P < .001). Following these promising results, the Pascal repair system received CE Mark approval for treatment of patients with TR in May 2020.

Suture-Based Tricuspid Annuloplasty Devices

TriCinch. The TriCinch system (4Tech Cardio) is another transcatheter tricuspid annuloplasty device for secondary TR. Delivered via a 24-F femoral vein introducer sheath, a corkscrew anchor is fixated within the anteroposterior annulus. The corkscrew is connected to a self-expanding nitinol stent via a Dacron band. Once fixated, the system is pulled toward the inferior vena cava and the stent is fixated to maintain tension, ultimately remodeling the anteroposterior annulus.

Although the device has been successfully implanted in a number of patients with secondary TR, no published results are currently available. A second generation of the TriCinch system was developed after five patients were found to have late annular anchor detachment using the first-generation system. The anchor system is now intentionally delivered into the pericardial space to improve stability. The PREVENT trial has completed enrollment to determine feasibility and safety in patients with secondary TR and the results are eagerly anticipated.[7]

Ring-Based Annuloplasty Devices

Cardioband tricuspid valve reconstruction system. The Cardioband tricuspid repair system (Edwards Lifesciences; Figure 2) was adapted from the Cardioband mitral system. It is a sutureless, adjustable fabric-covered band that is fixated to the atrial side of the anteroposterior annulus by up to 17 anchors.

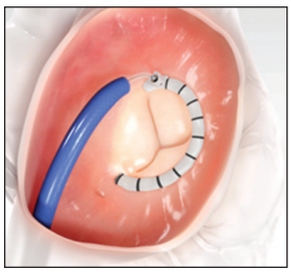

Courtesy of Edwards Lifesciences.

Figure 2. Cardioband tricuspid system.

The system is delivered via a 24-F transfemoral venous access sheath. Once fixated, a size adjustment tool is used to reshape the annulus bidirectionally, ultimately allowing for real-time controlled reduction of the annular diameters.

Six-month outcomes data from the TRI-REPAIR trial were recently published, including 30 patients with a 100% technical success rate.[8] Two patients died within the 30-day periprocedural period, one of which was device-related. The authors found a significant reduction in septal-lateral annular diameter, with a reduction in TR and improved symptoms and 6-minute walk test.

Caval Valve Implantation

Heterotopic caval valve implantation (CAVI) was one of the first transcatheter therapies conceived for severe symptomatic TR and has a goal of palliation rather than cure. Although Sapien XT valves (Edwards Lifesciences) were used to initially test the concept, the TricValve (P&F Products Features) has been developed as two self-expanding bioprosthetic valves designed specifically for the inferior and superior vena cavae. The TRICUS study is currently enrolling patients to establish the safety and efficacy of the TricValve device (NCT03723239).

Results of the TRICAVAL randomized control trial were recently published, showing no difference in functional outcomes in patients randomized to CAVI with the Sapien XT valve versus medical management.[9] However, patients did report improved symptoms after the procedure. The trial was stopped early for safety concerns after four patients required urgent open heart surgery for valve dislodgement. With a surge of alternative transcatheter options for TR, CAVI may be reserved for those high-risk, inoperable patients with preexisting pacemaker leads that prohibit alternative transcatheter options. It should be kept in mind that the TR will persist, and thus long-term effects of right atrial ventricularization and persistent right atrial volume overload may be of concern.

Transcatheter Tricuspid Valve Replacement

The large annular dimensions of the TV, along with its lack of a solid foundation to anchor a bioprosthetic valve, serve as the largest challenges of transcatheter tricuspid valve replacement technology.

GATE system. The GATE system (Navigate Cardiac Structures Inc.) is a trileaflet bioprosthetic atrioventricular valve nitinol stent that can be delivered via a transcatheter approach. It is currently available in four sizes ranging from 36 to 52 mm with a maximal profile height of 23 mm, which minimizes extension of the frame into the right atrium or ventricle. Although it can be delivered via a transjugular approach, one of its major limitations at this point is the need for a 42-F introducer sheath. As such, an important part of preprocedural planning includes assessment of jugular vein dimensions on CT with a cutoff of < 15 mm. Alternatively, a direct transatrial approach can be taken. The GATE system's first published use was in 2017 and since then has been deployed in just over 35 patients for compassionate use.[17]

Evoque tricuspid valve replacement system. The Evoque tricuspid system (Edwards Lifesciences; Figure 3) represents the contemporary iteration of the prior CardiAQ valve. Initially developed for the mitral valve, the system was almost completely redesigned to the current device with improved valve anchoring and delivery. Recently, a delivery system created specifically for the right heart anatomy was developed and allows either the 44- or 48-mm valve to be implanted via a 28-F delivery system. The first case was performed by Dr. Neil Fam in Toronto, Ontario in May 2019. The early feasibility study of the Evoque tricuspid system (TRISCEND study; NCT04221490) is currently in its early stages with plans to establish device safety as well as functional and echocardiographic outcomes in 15 patients.

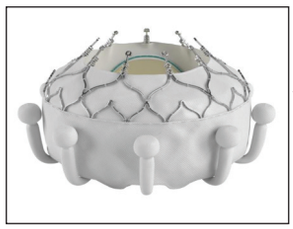
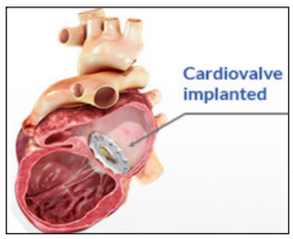

Courtesy of Edwards Lifesciences.

Figure 3. Evoque tricuspid valve replacement system.

Cardiovalve. The Cardiovalve (Figure 4; Valtech) is a transfemoral system designed to replace either the MV or TV via a transcatheter approach. There are three valve sizes available (M, L, XL), with reported plans for an XXL size to be added in the near future. The AHEAD trial is currently underway in both Europe and the United States to test feasibility and safety in patients with severe MR, with successful implantation thus far in five of five patients. Regarding application of the device to patients with TR, United States clinical sites began activation for an early feasibility study in early 2020,



Courtesy of Valtech.

Figure 4. Cardiovalve.

with plans to include 15 patients in this initial evaluation (NCT04100720).

CONCLUSION

Transcatheter therapies for the TV are still in their early stages, but the data available thus far are promising with significant improvement in quality of life, functional status, and degree of TR with several different devices. The variable and complex anatomy of the TV means that a thorough understanding of each individual patient's anatomy is crucial for procedural success. Although many of the leaflet and annular repair strategies have demonstrated promising early results, the aforementioned considerations regarding TV anatomy imply the potential benefit in some patients of a valve replacement system. Numerous devices initially designed for mitral application are being redeveloped for the tricuspid position, and clinical trials are underway. In the future, it will also be important to better understand which patients may benefit most from TTVI and the optimal timing of these treatments. ■

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