Catheter-Based Tricuspid Intervention

A review of current leaflet, annular, and valve replacement device technologies.

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According to the American Heart Association/American College of Cardiology guidelines, the only class I indication for functional tricuspid regurgitation (TR) intervention is for severe disease at the time of left heart valve surgery.[1] Despite the benefits of concomitant tricuspid repair,[2,3] the majority of eligible patients undergoing left heart valve surgery do not undergo treatment of their significant TR, resulting in a large population of patients with increased reoperative mortality.[4-7] In addition, an increasing number of high-surgical-risk patients are being treated with transcatheter therapies for aortic[8,9] as well as mitral valve disease[10] but have worse outcomes due to severe TR.[11-13] Isolated tricuspid valve (TV) surgery is rarely performed; however, a clearer understanding of the poor natural history of the disease[14-16] has led to an increase in surgical interventions.

The goals of TV surgery are restoration of full leaflet mobility, correction of prolapse, provision of a large leaflet coaptation surface, and annular stabilization.[17] The morphologic abnormalities associated with functional TR include: (1) tethering or tenting of the tricuspid leaflets, (2) dilatation of the annulus and/or right atrium, (3) right ventricular dysfunction, and (4) displacement of the papillary muscles.[18] Because significant tricuspid annular dilatation may be a better predictor of severe late TR after mitral valve surgery,[3,19,20] measurement of the annular diameter has been used as an indication for TV surgery in the absence of severe TR. Significant annular dilatation is defined by a diastolic diameter ≥ 40 mm or > 21 mm/m^2 in the four-chamber transthoracic view,[3] or > 70 mm on intraoperative inspection.[20] Although annuloplasty techniques address this morphologic abnormality, tenting or tethering of the leaflets is a marker for recurrent TR after repair. Tenting areas and volumes correlate with TR severity and with poor outcomes after surgical repair.[21-24] If the TV tethering distance is > 0.76 cm or the tethering area is > 1.63 cm^2, the use of adjunctive surgical techniques with tricuspid annuloplasty or TV replacement should be considered.[17,22,25]

Unfortunately, the in-hospital mortality rate for isolated TV surgery is approximately 9%, with no significant improvement over a 10-year study period.[26,27] Zack et al also showed that the adjusted in-hospital mortality for TV replacement was significantly higher than for TV repair (odds ratio, 1.91; 95% confidence interval, 1.18–3.09; *P* = .009).[26] Alqahtani et al confirmed that after rigorous propensity matching, TV replacement was associated with significantly higher rates of in-hospital death (12% vs 6.9%; *P* = .009) and permanent pacemaker implantation (33.7% vs 11.2%; *P* < .001).[27]

Given the high in-hospital risk associated with isolated TV surgery, a number of transcatheter devices to treat functional TR are being investigated.[28,29] These devices attempt to treat different targets of the TV apparatus (annulus, leaflets, and chordae). Replacement devices are also under investigation.

LEAFLET GRASPING AND SPACERS

Several technologies aiming to reduce the severity of TR by reducing the total regurgitant area are under clinical validation, and we discuss a few of them in the following sections.

TriClip

TriClip (Abbott Structural Heart) is composed of a steerable sleeve and delivery catheter, purposely designed to access the TV. The clip component is the same as in MitraClip (Abbott Structural Heart). Early first-in-human clinical studies validated the potential efficacy profile of the MitraClip device in the treatment of severe TR. The TRILUMINATE trial tested the safety and effectiveness of TV repair using the MitraClip NT device (Abbott Structural Heart). The study included 85 patients at 21 centers in the United States and Europe. Acute device success was 100%. At 30 days, 86.6% had at least one

grade reduction in TR, 25% had residual moderate TR, and 28% had mild residual TR. More than 80% of patients were New York Heart Association (NYHA) class I/II at 30 days.[30]

The recently initiated TRILUMINATE pivotal study aims to validate the TriClip device in improving clinical outcomes in symptomatic patients with severe TR, who are at intermediate or greater estimated risk for mortality with TV surgery. This randomized controlled trial will compare the investigational device (TriClip device) to the control (optimal medical therapy).

Pascal

The Pascal tricuspid valve repair system (TVRS; Edwards Lifesciences) integrates the advantages of leaflet grasping plus the physical properties of a spacer to further reduce the total regurgitant area. The Pascal TVRS is a 22-F system and that has been used to treat 12 patients in an international compassionate use experience. Acute procedural success (TR reduction by 1+ grade) was achieved in 92% of the patients. A feasibility study has been initiated in the United States and is ongoing.

Forma

The Forma TVRS (Edwards Lifesciences) is positioned within the regurgitant orifice, providing surface for the native leaflets to coapt. Early clinical outcomes from the United States FORMA EFS trial and an international compassionate use series have been reported.[31] In the FORMA EFS trial, out of 29 enrolled patients, technical success was achieved in 93.1%. All-cause mortality was 6.9% at 30 days and 31% at 1 year. A 31% reduction in TR as measured by vena contracta and 41% reduction of the proximal isovelocity surface area–derived effective regurgitant orifice area (PISA EROA) were observed at 30 days, and these reductions were maintained up to 1 year. Clinically significant improvements in functional status were also observed and maintained at 1 year.

Other Emerging Leaflet Technologies

The Mistral TVRS (Mitralix, Ltd.) consists of an 8.5-F delivery system and a spiral-shaped repair device. The device improves leaflet coaptation by gently grasping chords from two adjacent leaflets and bringing them together. The ongoing first-in-human MERIT study (NCT02948231) is investigating the clinical performance of this device.

Cerclage-TR block technique is being developed academically with funding from the National Institutes of Health for implantation of an artificial leaflet extension at the septal location based on a technological platform designed for mitral regurgitation (MR). This device, while still in an early stage of investigation, may have the potential to treat both MR and TR at the same time.

ANNULAR DEVICES

A number of annular devices are currently being studied or are in preclinical evaluation (Table 1), and some of these are described in the following sections.

Cardioband

The Cardioband TVRS (Edwards Lifesciences) has been successfully used to treat severe functional TR.[32,33] Using the surgical incomplete annuloplasty ring as a predicate, the device is an annuloplasty band designed to reduce annular dilatation and improve leaflet coaptation and TR severity. The Cardioband implant consists of a polyester sleeve containing a size-adjustable contraction wire. Under transesophageal echocardiographic (TEE) guidance with adjunctive intracardiac echocardiographic (ICE) imaging, anchors are deployed through the sleeve to secure the implant to the annulus. After implantation, the device is shortened by a contraction wire mounted on the Cardioband's sleeve. Under TEE guidance, the annular reduction (typically in the septolateral dimension) can be adjusted to optimize the final result.

Six-month data from the TRI-REPAIR study were recently published.[33] The study included 30 symptomatic patients (mean age, 75.6 years) from nine European centers who had chronic severe functional TR, tricuspid annulus diameter ≥ 40 mm, and systolic pulmonary arterial pressure ≤ 60 mm Hg. Technical success was achieved in all patients and there were no periprocedural deaths or severe major adverse events. At 6-month follow-up, results showed a 50% relative reduction in the PISA EROA ($P < .01$) and a 28% reduction in vena contracta measurements ($P < .12$), as well as a significant improvement in functional status as measured by 6-minute walk test and NYHA class (all $P < .01$). Although many patients achieved a TR grade of moderate or less at 6 months, many others remained with severe or even torrential TR.

The Cardioband TVRS is currently the only CE Mark–approved transcatheter device to treat patients with TR, and it is undergoing further study in an early feasibility study (NCT03382457), which has begun enrollment in the United States.

TriCinch

The TriCinch system (4Tech Cardio Ltd.) comprises two components: (1) a stainless steel corkscrew implant to be placed in the anterior annulus of the TV, in proximity to the anteroposterior commissure, and (2) a self-expanding nitinol stent that is deployed below the hepatic region of the inferior vena cava (IVC).[34-36] A delivery system is available for each component. Stent implants are available in four different sizes (27, 32, 37, and 43 mm) to allow for IVC oversizing of 30%.[36]

TABLE 1. TRICUSPID ANNULAR REPAIR AND REPLACEMENT DEVICES AND TECHNIQUES

Target of Therapy	Device/Technique Name	Description	Status
Direct suture annuloplasty	Trialign (Mitralign, Inc.)	▪ Involves delivery of polyester pledgets via right internal jugular approach ▪ Pledget is a polyester implant with a suture attached that serves as a suture-buttressed anchor for plication of the annulus ▪ A stainless steel lock tracks over the sutures and once adequate plication is achieved, locks the pledgeted sutures together	SCOUT US EFS trial completed; SCOUT II CE Mark trial is enrolling
	MIA (Micro Interventional Devices, Inc.)	▪ Designed to replicate tricuspid repair remotely ▪ Customizable number of implants deployed to the target annulus	STTAR FIH study
	PASTA technique (using marketed devices)	▪ Transjugular access ▪ Transannular pledgeted sutures to perform anterioposterior annular plication (double-orifice valve)	Preclinical experience
Direct ring annuloplasty	Cardioband	▪ Adjustable, sutureless annuloplasty band of polyester fabric through which stainless steel anchors (6 X 2.5 mm) are inserted ▪ Utilizes transfemoral access ▪ Reduces the septolateral annular diameter	CE Mark approved in April 2018; US EFS trial is enrolling
	Iris	▪ Complete annular ring ▪ Adjustable	FIH implantation performed under direct surgical view
Indirect ring annuloplasty	TRAIPTA technique	▪ Nitinol wire that is preshaped into a self-expanding loop to encircle the heart from within the pericardial space ▪ Transauricular pericardial approach	Preclinical experience
Valve replacement (heterotopic)	TricValve	▪ Two self-expanding percutaneous heart valves customized to provide 10%–20% oversizing of the SVC and IVC ▪ IVC valve protrudes into the right atrium, preventing backflow, avoiding obstruction of the hepatic vein ▪ SVC is funnel-shaped with a skirt covering the entire base of the valve, preventing paravalvular regurgitation ▪ Caval valve implantation	FIH study completed; ongoing trial in the US and Europe
	TriCento (NVT GmbH)	▪ Bicavally anchored stent with a lateral bicuspid valve element (to the right atrium) made of thin porcine pericardium leaflets ▪ Largest stent diameter available is 48 mm ▪ Layer of noncovered struts added to ensure safe anchoring in the IVC and to avoid endoleak ▪ Reduces backflow in the venous system	FIH study completed

Abbreviations: EFS, early feasibility study; FIH, first in human; IVC, inferior vena cava; MIA, minimally invasive annuloplasty; PASTA, pledget-assisted suture tricuspid valve annuloplasty; SVC, superior vena cava; TRAIPTA, transauricolar intrapericardial tricuspid annuloplasty; US, United States.

The anchor and the stent are connected via a Dacron band. A reduction in tricuspid annulus dimension is obtained by applying tension and shortening the Dacron band. The device is implanted via transfemoral venous access under TEE and ICE guidance, as well as fluoroscopic guidance.

Rosser et al evaluated the safety and efficacy of the device in Europe in patients with functional severe symptomatic TR and significant annular dilatation (≥ 40 mm) and who were inoperable or at high risk for standard surgery.[36] Initial experience showed that the procedure is reproducible, with an expected implantation time of

< 1 hour, and that it is reversible at every step to enhance control and safety. After redesign of the anchor, the Early Feasibility Study of the Percutaneous 4Tech TriCinch Coil Tricuspid Valve Repair System study (NCT03632967) has begun enrollment in the United States.

Iris

The Iris system (Boston Scientific Corporation) is a fully repositionable and retrievable complete ring that can be implanted surgically or via transcatheter on the atrial side of the native tricuspid annulus.[37,38] Rotational anchors attach the ring to the annulus at defined intervals.[38] The device has a zigzag appearance (like the top of a crown), with the anchors at the lowest points and collars around the hinge points at the crest. Annular reduction is then accomplished by repositioning the collars further down the crest, effectively reducing the distance between the anchors.[38] A first-in-human implantation in the mitral position was performed surgically in 2015. Among nine patients who underwent mitral valve repair with the Iris system, two had concomitant tricuspid valve repair, with significant annular reduction and no postprocedural residual TR.[39] The device now has an internal channel for an ICE catheter to enhance visualization of anchor deployment. Early feasibility trials are expected by 2020.

TV REPLACEMENT DEVICES

In the presence of marked tethering, typically in association with right ventricular dilatation/dysfunction and with or without pulmonary hypertension, an annular device may not accomplish sufficient reduction in TR and a replacement device may be indicated.

Gate

The Gate valve (NaviGate Cardiac Structures, Inc.) is a transcatheter valve composed of an atrioventricular valved stent, delivery system, compression loading system, and introducer sheath. The conical-shaped valve stent is nitinol alloy, is made in four sizes (40, 44, 48, and 52 mm in diameter), and is intended for native tissue tricuspid annular diameters of 36 to 52 mm. Twelve right ventricular tines grasp the tricuspid leaflets from the right ventricular side. There are 12 right atrial winglets perpendicular to the conical stent and covered by a microfiber polyester cloth designed to provide a seal. The three leaflets and the skirt are made of treated equine pericardium. The delivery system consists of a tip-deflecting catheter designed to go through a 42-F introducer sheath.

More than 40 Gate valves have been implanted in inoperable severe, symptomatic TR patients on a compassionate-use basis. Most of these have been implanted via the transatrial route. Early single-site reports of the compassionate use of the Gate valve have shown that implantation was technically feasible and resulted in a reduction of TR to ≤ 2+.[40,41] This TR reduction was associated with right ventricular remodeling, increased cardiac output, and improvement in NYHA functional class in most patients. Further studies are needed to refine patient population selection for this device and to determine long-term outcomes.

Heterotopic Caval Valve Implantation

A feasible alternative to orthotopic approaches (intervention in the site of the TV) is caval valve implantation, which involves the implantation of stent valves in a heterotopic position into the IVC and superior vena cava (SVC). This concept has been investigated preclinically with encouraging results and has been utilized in compassionate use cases.[42-46] The objective of heterotopic caval TV implantation is to reduce the reflux of severe TR into the venae cavae and thereby improve symptoms and signs of right heart failure, albeit without affecting the magnitude of TR.[35] With the implantation of a one-way valve in the IVC or both the IVC and SVC, the hepatic and renal veins are protected from the transmission of the volume from the right ventricle.[28,29,42,43] As a consequence, the venous pressure decreases and the difference in arteriovenous pressure increases, which may result in improvement in renal and hepatic functions.

From a technical perspective, the large and variable diameters of the IVC and SVC and the length of the landing zone between the hepatic veins and inferior cavo–right atrial junction are major challenges.[28,35] Two valve prototypes, the self-expandable TricValve (P&F Products Features GmbH in cooperation with Braile Biomedica) and the balloon-expandable Sapien 3 and XT valves (Edwards Lifesciences) have been tested in proof-of-concept trials for this purpose in patients who are inoperable or at a high surgical risk for TV replacement.[35] The TRICUS study (NCT03723239) is currently enrolling and seeks to determine the safety and efficacy of the TricValve device.

The TRICAVAL trial (NCT02387697) randomized patients to optimal medical treatment versus transfemoral implantation of the Sapien XT valve into the IVC. The trial was terminated early for safety concerns after enrollment of 28 patients and the future of this solution to TR is unclear.

CONCLUSION

As our understanding of the impact of TR on outcomes expands, the limitations of the current treatment guidelines, as well as the high mortality associated with isolated TV surgery, highlight the need for less invasive options for this undertreated population. A number of transcatheter therapies are currently under investigation with the hope of providing an efficacious, safe option for treatment of this high-surgical-risk population. ■

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