



Transcatheter treatment options for tricuspid regurgitation

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Submitted Jun 17, 2021. Accepted for publication Aug 25, 2021.

doi: 10.21037/acs-2021-tviv-24

View this article at: <https://dx.doi.org/10.21037/acs-2021-tviv-24>

Tricuspid pathology, specifically tricuspid regurgitation (TR), is a recognized independent risk factor for increased morbidity and mortality. Patients with tricuspid valve (TV) problems often present late, with significant right ventricular (RV) dysfunction, a risk factor for open heart surgery. This paper reviews the important anatomic considerations and current landscape of transcatheter tricuspid valve interventions (TTVI), a rapidly evolving field with unique challenges.

Anatomic considerations

Unlike the mitral valve the TV has a septal leaflet with chordal attachments to the interventricular septum (IVS), rendering it incompetent when the IVS is flattened or shifted leftwards. The absence of a fibrous skeleton and distinct annulus renders the TV more susceptible to dilation, even in the short-term. Annular dilation predominantly occurs along the free wall, affecting the anterior and posterior leaflets.

The ill-defined annulus has a complex three-dimensional shape that varies slightly throughout the cardiac cycle. The TV typically has three (four or more in 40% of patients) leaflets, with a dense network of primary and secondary chordae attaching to an inconsistent number and configuration of papillary muscles. The leaflets of the TV vary greatly in height and annular circumference and are typically extremely thin. Lastly, the atrioventricular (AV) node and His bundle are near the TV. These anatomic peculiarities pose unique challenges for transcatheter solutions to repair or replace the TV.

Devices, outcomes and ongoing trials

TTVI encompasses four main categories: edge-to-edge

repair (TEER), annuloplasty, transcatheter TV replacement (TTVR) and bi-caval valve implantation (CAVI). Annuloplasty devices appear most promising in early disease stages, while TEER is limited by the size of the coaptation gap and variability in TV leaflet anatomy. Replacement may be the best option for very large annuli and when RV function is reasonably preserved. Replacement has been performed successfully in patients with previously implanted bioprosthetic surgical valve (valve-in-valve; VIV TTVR) or surgical ring (valve-in-ring; VIR TTVR) using a transcatheter aortic valve prosthesis. CAVI and other technology may offer a palliative solution in patients with advanced disease and limited options.

In the TriValve registry, 249 patients with severe TR undergoing TEER (MitraClip, Abbott, Santa Clara, CA, USA) were studied and 77% had a reduction in TR grade to $\leq 2+$. Unsuccessful TEER was an independent predictor of one-year mortality, which was 20% overall. Procedural failure was predicted by eccentric jets and markers of increased annular dilation and coaptation defect (1). The single-arm TRILUMINATE study reported similar success rates and outcomes in TR reduction (2). Comparable results have also been described with another device (PASCAL, Edwards Lifesciences, Irvine, CA) in the CLASP TR early feasibility study (EFS), along with improved functional status, exercise capacity and quality of life (QoL) after TEER (3). The ongoing TRILUMINATE and CLASP II TR pivotal trials randomize patients with severe TR to TEER (TriClip, Abbott, Santa Clara, CA) versus medical therapy alone and will be the first randomized study of TEER for TR. Cardioband (Edwards Lifesciences, Irvine, CA) is an annuloplasty device that has been evaluated in a small study and an EFS, both showing promising results in terms of TR reduction and QoL at two years (4,5).

Given the often severe annular enlargement, complex leaflet configuration and wide coaptation gap, significant research and development efforts are also expanded on TV replacement to offer an alternative strategy for TR. Additionally, valve-in-valve (ViV) and valve-in-ring (ViR) TTVR using a Sapien (Edwards Lifesciences, Irvine, CA, USA) or Melody (Medtronic, Minneapolis, MN, USA) valve has emerged as a treatment option for high-risk patient with degenerated bioprosthetic TV or recurrent TR after a surgical repair. The largest reported series is from the VIVID registry, suggesting TTVR in this setting can be performed safely, with reasonable short-term results (6). Given the asymmetric and often incomplete ring design, ViR is technically more challenging and associated with a higher rate of paravalvular leak (PVL). Existing trans-tricuspid pacemaker leads are typically jailed during this procedure and infrequently affects lead function; however, it may cause additional PVL and precludes removal of these leads at a later time. Dedicated TTVR valves and delivery systems for placement in native or surgically repaired TVs include: EVOQUE (Edwards Lifesciences, Irvine, CA, USA); NaviGate (NaviGate Cardiac Structures, Inc, Lake Forest, CA, USA), LUX valve (Jenscare Biotechnology, Ningbo, China), Interpid TTVR (Medtronic, Minneapolis, MN, USA), TriSol (TriSol Medical, Yokneam, Israel), TriCares (Aschheim, Germany), VDyne (VDyne Inc., Maple Grove, MN, USA), and CardioValve (Valtech, Yehuda, Israel). All systems are at various stages of pre-clinical, first-in-man (FIM) or EFS studies, some with early and promising results in terms of TR elimination. While delivery of TTVR is often tolerated extremely well from a hemodynamic standpoint, unique challenges for the TV exist. These include the size of the valves needed, large (up to 36 Fr) delivery systems, limited room for maneuvering from the inferior vena cava (IVC) to the tricuspid annulus and the uncertainty as to what extent complete resolution of TR (afterload increase) is tolerated by an impaired RV.

Other devices that have only been studied as FIM applications include the FORMA device, which acts as a spacer that is placed across the TV to reduce regurgitation; and Mistral, a helix-shaped nitinol device designed to pull together the chordae of the TV, thereby reducing TR.

The TriAlign (Mitralign, Tewksbury, MA, USA) device frames the posterior leaflet by deploying two anchors through the TV annulus, which are then pulled together and secured, effectively resulting in bicuspidization of the TV. SCOUT-II is an EFS currently investigating this device. Limited data on caval implantation of valves (CAVI)

to reduce systemic venous congestion has been rather disappointing. TRICAVAL (TricValve, P&F Products Features, Vienna, Austria), a recently published randomized controlled trial failed to show any meaningful improvement in patient outcomes.

Conclusions

TR is an established independent risk factor for morbidity and mortality at all stages. As a common etiology, either in isolation, secondary to other cardiopulmonary disease or following previous valve surgery, it poses unique challenges. Patients with RV failure are commonly high-risk for surgical interventions and would benefit greatly from less-invasive alternatives. TTVI is an active field of investigation with many ongoing trials. Early results with both repair and replacement technologies are promising.

Acknowledgments

Funding: None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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Cite this article as: Wyler von Ballmoos MC, Reardon MJ. Transcatheter treatment options for tricuspid regurgitation. *Ann Cardiothorac Surg* 2021;10(5):694-696. doi: 10.21037/acs-2021-tviv-24