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EDITORIAL COMMENT

Functional Tricuspid Regurgitation

Percutaneous Therapies Needed*

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Tricuspid regurgitation (TR) can arise from structural leaflet changes (primary TR) as a result of a variety of causes. More commonly, TR is secondary (functional TR [FTR]) and occurs when there is impaired coaptation of normal tricuspid valve leaflets in the setting of right ventricular enlargement and tricuspid annular dilation. Mild-to-moderate tricuspid regurgitation is commonly seen in clinical practice and is generally well tolerated. More severe TR can develop insidiously and is a consequence of late-stage myocardial, pulmonary, and valvular disease. Patients with significant FTR often have multiple comorbidities, and suffer from reduced cardiac output, congestive hepatopathy, ascites, peripheral edema, and failure to thrive.

Medical therapy for FTR consists primarily of intravascular volume management and has limited efficacy. Surgical correction of FTR is most often performed during operations for functional mitral regurgitation (MR) in the setting of left ventricular heart failure, which results in secondary right ventricular enlargement, unfavorable geometric remodeling, and tricuspid annular dilation. Despite the fact that surgical FTR correction has risen and operative mortality has decreased over the last decade, surgical correction of TR remains underutilized (1). Aggressive treatment of FTR at the time of initial surgery is important, because reoperation for recurrent TR in patients with heart failure can have an in-hospital mortality up to 35% (2). Surgical correction of FTR consists of reducing the tricuspid annular area with ring or suture annuloplasty, thereby moving the leaflets closer together. Despite studies showing more stable and durable outcomes with rigid ring annuloplasties, suture and rigid annuloplasties are still both employed in the surgical treatment of TR (3). Current recommendations from the 2012 European Society of Cardiology and the European Association for Cardio-Thoracic Surgery (4) and 2014 American College of Cardiology/American Heart Association guidelines (5) strongly encourage the surgical correction of TR in patients undergoing left-sided valve surgery. Despite the enthusiasm of these recommendations, the supporting level of evidence is no higher than Level of Evidence: C, highlighting the lack of prospective randomized trials. Because many patients develop recurrent TR over time, and reoperation is not often performed for recurrent TR, emerging minimally invasive and transcatheter methods of FTR correction have the potential to expand therapeutic options and improve safety.

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In this issue of *JACC: Cardiovascular Interventions*, Rogers et al. (6) from the National Institutes of Health describe a highly innovative approach to the treatment of FTR using trans-auricular intra-pericardial tricuspid annuloplasty (TRAIPTA). This transcatheter procedure consists of performing a controlled puncture into the pericardial space through the anterior aspect of the right atrial appendage. A "hoop" made of braided nitinol wire is then deployed within the pericardial space around the base of the heart and tensioned to reduce tricuspid annular dimensions, thereby reducing FTR. TRAIPTA is a novel technique that is similar to an encircling-type concept (mitral cerclage) previously reported by this group for the mitral valve (7). The authors report the technique and results of TRAIPTA in 16 swine (12 healthy and 4 with experimentally induced FTR), with high procedural success and significant favorable changes in the tricuspid annular geometry. The procedure was

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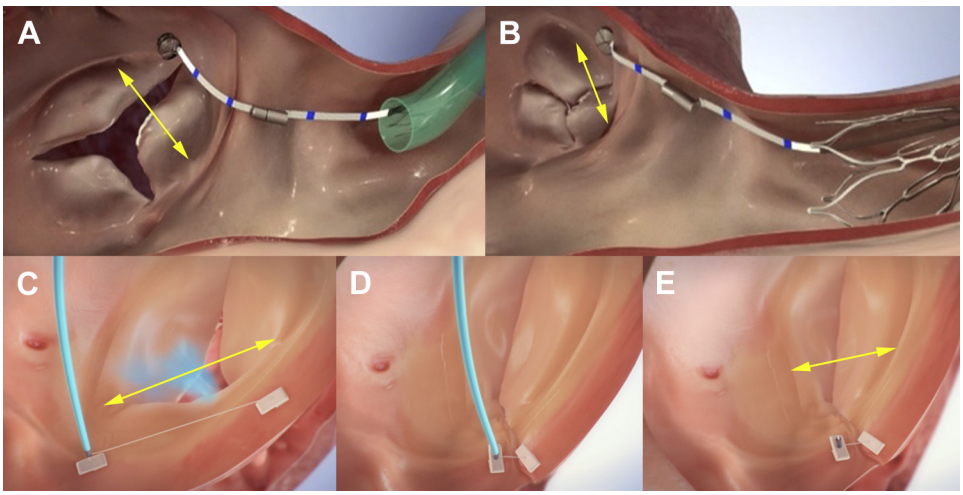
FIGURE 1 Transcatheter Therapies for FTR



(A) The TriCinch Gen 1 System (4 Tech, Dublin, Ireland) is a percutaneous approach in which anchors are placed in the inferior vena cava and on the tricuspid valve annulus. **(B)** Tension is then applied between the 2 points with a Dacron band leading to a reduction of the tricuspid valve area and decreased functional tricuspid regurgitation (FTR). **(C)** The Mitralign device (Tewksbury, Massachusetts), which is used for functional mitral regurgitation, has been adapted for the treatment of FTR. Two pledgeted anchors are placed. **(D)** The anchors are tensioned, which plicates the posterior annulus. **(E)** The sutures are locked, resulting in bicuspidalization of the tricuspid valve and reduction in FTR. **Yellow arrows** show reduction of tricuspid annular dimensions pre- and post-procedure for both devices.

reported to be safe in these animals, with no adverse events and no coronary artery compromise.

Most transcatheter valve therapies have been targeted at patients who are high risk for conventional surgery. This paradigm has been successful and led to Food and Drug Administration approval for transcatheter aortic valve replacement and percutaneous edge-to-edge mitral valve correction. Because these target populations are frail and have multiple comorbid conditions, procedural safety must be a cardinal concern, followed by efficacy. Although the TRAIPTA approach is promising, it is fairly invasive and carries an as yet undefined risk in humans. The investigators reviewed 14 human cardiac computed tomography scans, and all met anatomic criteria for transatrial pericardial access, although all subjects had at least 1 epicardial coronary artery that crossed the projected course of the TRAIPTA implant. TRAIPTA involves circumferential compression of the heart near the atrioventricular groove, and coronary artery compression would certainly be possible, although this was not seen in the animal studies. Other transcatheter devices in the coronary sinus for the treatment of functional MR have shown us that coronary artery compression is not predictable, and that compression can occur intraprocedurally and in follow-up (8,9).

The TRAIPTA procedure involves planned puncture of the right atrial appendage. There have not been any other previously described structural heart procedures using this access route. Clinical experience with the fragile left atrial appendage (LAA) has led operators to a "minimal touch" approach for LAA occlusion procedures. In a multicenter series describing real-world outcomes of transcatheter LAA ligation, a procedure that requires "dry" pericardial access, clinically significant pericardial effusions (10.4%) and major bleeding (9.1%) were not uncommon (10). Patients at high surgical risk with FTR are fragile as a rule, and procedural complications will not be well tolerated. Also, given that TRAIPTA will not be possible in patients with prior pericardiotomy or pericarditis (and therefore any patient with prior cardiac surgery), the applicability of this procedure to a "high-risk population" (many of whom have had prior sternotomy) could be limited.

There are currently no reports of native transcatheter tricuspid valve replacement, but other emerging transcatheter procedures to address TR have been reported. For patients with degenerated tricuspid surgical bioprostheses, tricuspid "valve-in-valve" therapy can be performed. The most commonly used devices have been the Melody valve (Medtronic, Minneapolis, Minnesota), and Edwards Sapien or Sapien XT valves (Edwards Lifesciences, Irvine, California). Both valves have comparable

efficacy and safety in the short term, but longer-term data are limited.

Investigators have reported placing transcatheter valves in the inferior vena cava (IVC) and in some cases the superior vena cava for the treatment of FTR. The rationale behind this approach is to reduce the regurgitant volume and pressure from TR that refluxes into the IVC. Transcatheter placement of a custom stented valve in the IVC in a patient with symptomatic FTR resulted in clinical improvement in symptoms (11). The Sapien XT valve has also been used in the IVC and superior vena cava positions with clinical success to reduce the systemic hemodynamic effects of severe TR (12). The long-term effects of this caval stenting approach on right atrial size and right ventricular function are not known, and long-term anticoagulation is currently recommended. Despite conceptual promise, the MitraClip procedure (Abbott, Abbott Park, Illinois), which has been effective in the mitral position, has not yet been translated successfully for use in the tricuspid position. Challenges to a tricuspid edge-to-edge repair include the trileaflet nature of the tricuspid valve, wide malcoaptation gaps, and higher chordal density. Other transcatheter therapies for FTR are currently in development (**Figure 1**).

In conclusion, patients with severe FTR are often highly symptomatic, and operations are not commonly performed because of high actual or perceived surgical risk. Many patients undergoing transcatheter correction of MR or aortic stenosis with biventricular heart failure and FTR may also benefit from concomitant TR correction. Randomized, controlled trials of tricuspid correction versus control are needed to solidify the evidence for both current surgical and future transcatheter approaches. TRAIPTA encourages us to consider what is possible, and moves us forward in our efforts to expand tricuspid valve therapies.

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REFERENCES

1. Kilic A, Saha-Chaudhuri P, Rankin JS, Conte JV. Trends and outcomes of tricuspid valve surgery in North America: an analysis of more than 50,000 patients from the Society of Thoracic Surgeons Database. Ann Thorac Surg 2013;96:1546–52, discussion 1552.

2. Bernal JM, Morales D, Revuelta C, Llorca J, Gutierrez-Morlote J, Revuelta JM. Reoperations after tricuspid valve repair. J Thorac Cardiovasc Surg 2005;130:498–503.

3. Navia JL, Nowicki ER, Blackstone EH, et al. Surgical management of secondary tricuspid valve regurgitation: annulus, commissure, or leaflet procedure? J Thorac Cardiovasc Surg 2010;139:1473–82.e5.

4. Vahanian A, Alfieri O, Andreotti F, et al. Guidelines on the management of valvular heart disease (version 2012): the Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). Eur J Cardiothorac Surg 2012;42:S1–44.

5. Nishimura RA, Otto CM, Bonow RO, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2014;63:2438–88.

6. Rogers T, Ratnayaka K, Sonmez M, et al. Transatrial intrapericardial tricuspid annuloplasty. J Am Coll Cardiol Intv 2015;8:483–91.

7. Kim JH, Kocaturk O, Ozturk C, et al. Mitral cerclage annuloplasty, a novel transcatheter treatment for secondary mitral valve regurgitation: initial results in swine. J Am Coll Cardiol 2009;54:638–51.

8. Harnek J, Webb JG, Kuck KH, et al. Transcatheter implantation of the MONARC coronary sinus device for mitral regurgitation: 1-year results from the EVOLUTION phase I study (Clinical Evaluation of the Edwards Lifesciences Percutaneous Mitral Annuloplasty System for the Treatment of Mitral Regurgitation). J Am Coll Cardiol Intv 2011;4:115–22.

9. Siminiak T, Wu JC, Haude M, et al. Treatment of functional mitral regurgitation by percutaneous annuloplasty: results of the TITAN Trial. Eur J Heart Fail 2012;14:931–8.

10. Price MJ, Gibson DN, Yakubov SJ, et al. Early safety and efficacy of percutaneous left atrial appendage suture ligation: results from the U.S. transcatheter LAA ligation consortium. J Am Coll Cardiol 2014;64:565–72.

11. Lauten A, Ferrari M, Hekmat K, et al. Heterotopic transcatheter tricuspid valve implantation: first-in-man application of a novel approach to tricuspid regurgitation. Eur Heart J 2011;32:1207–13.

12. Laule M, Stangl V, Sanad W, Lembcke A, Baumann G, Stangl K. Percutaneous transfemoral management of severe secondary tricuspid regurgitation with Edwards Sapien XT bioprosthesis: first-in-man experience. J Am Coll Cardiol 2013;61:1929–31.

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