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EDITORIAL COMMENT

Predicting the Future in Tricuspid TEER

Numbers, Colors, or the Wide Space in Between

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The cardiovascular community has long recognized the large burden of moderate to severe tricuspid regurgitation (TR) in the United States, with an estimated 1.6 million affected individuals and estimates of >70 million affected individuals worldwide.[1] Despite this significant disease burden, treatment options have included medical therapy with diuretic agents and rarely surgical valve repair or replacement in the United States because transcatheter tricuspid valve repair options were available only in Europe. Recently, the U.S. Food and Drug Administration approved the use the EVOQUE system (Edwards Lifesciences) on the basis of results from TRISCEND II (Edwards EVOQUE Tricuspid Valve Replacement II) for transcatheter tricuspid valve replacement (TTVR) and approved the use of the TriClip system (Abbott Vascular) on the basis of the results of TRILUMINATE (Trial to Evaluate Treatment With Abbott Transcatheter Clip Repair System in Patients With Moderate or Greater Tricuspid Regurgitation) for transcatheter tricuspid valve repair (T-TEER).[2,3] As such, the TR disease burden of patients has now become the treatment challenge for the cardiovascular community and, more specifically, the treatment decision dilemma for heart teams.

Several challenging factors must be accounted for when considering what physicians believe may be the best treatment option for a patient with severe symptomatic TR. Broadly, these factors can be categorized as follows: 1) patient-specific risk factors: age, renal function, liver function, diuretic agent dosing, atrial fibrillation, long-term anticoagulation, left ventricular function, and pulmonary hypertension; 2) right ventricular (RV) anatomical features: RV size, depth, and function; papillary muscle location and height; and pacemaker or defibrillator leads; and 3) tricuspid valve morphologic characteristics: degree and location of TR, tricuspid leaflet morphology, scallop size, density of chordal structures, gap width, and imaging quality. The goal in the assessment of all of these factors is to choose the right therapy by eliminating TR without subjecting the patient to undue risk for the potential of an improved quality of life and future morbidity and mortality benefit.

The TRI-Score is a risk model that has been developed to try to understand the mortality benefit of medical therapy, T-TEER, or surgical interventions on the basis of 8 separate patient-specific risk factors, as well as outcomes associated specifically with T-TEER but that have been suboptimal in predicting outcomes except for those patients at the highest risk.[4,5] Alternatively, in this issue of *JACC: Cardiovascular Imaging,* Gerçek et al[6] aim to develop a predictive score on the basis of tricuspid valve morphologic characteristics as an anatomical and image-guided means to predict procedural outcomes in T-TEER.

Gerçek et al[6] have presented sound methods for the development of this T-TEER score given that 2 centers and 168 patients were recruited to develop the score, and a separate cohort of 126 patients at 2 different centers was recruited to validate the score. An independent echocardiography core laboratory was used to evaluate all the variables. Endpoints were immediate postprocedural TR reduction ≥2 grades and a residual TR grade of moderate or less. The 5 most predictive variables were septolateral coaptation gap, chordal structure density, en face TR jet configuration, TR jet location, and image quality. This study has many strengths, including the use of both PASCAL (Edwards Lifesciences) and TriClip repair systems, as well as a derivation and validation cohort with a sound statistical method. A total of 80% of the treated patients had a ≥2 grade reduction in TR with procedural times of <2 hours. The success rate was

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97% for a score of 0 and 85% for a score of 1. However, with more complex anatomical and imaging features, the success rate dropped to 64% with a score of 2, had a further drop to 30% with a score of 3, and fell to as low as 12.5% with a score of 4.

Although colors and numbers can potentially help heart teams make treatment decisions for patients with severe TR, most patients and teams will find themselves in the wide space in between, surrounded by many moving targets:

- The endpoints of this study were immediate post-procedural TR reduction of ≥2 grades and residual TR grade moderate or less on procedural transesophageal echocardiography. This is different from TRILUMINATE and PASCAL TR (Edwards PASCAL TrAnScatheter Valve RePair System in Tricuspid Regurgitation), which used baseline and 30-day transthoracic echocardiograms. The limitation of this endpoint will become even more relevant as we continue our aspiration to achieve greater and more durable TR reduction after T-TEER.
- Although functional TR remains the most common cause in this and many other T-TEER studies, it is critically important to analyze the tricuspid valve anatomy and the origin of TR because cardiac implantable electronic device lead-induced TR and primary TR are often overlooked. These leads often pose significant challenges in T-TEER, especially if they cause leaflet impingement and/or are in the grasping zone. Long-term outcomes of jailing the leads with the tricuspid valve replacement devices also remain unclear.
- Current practices have incorporated multiple techniques already to address some of the scored challenges, including positive end-expiratory pressure ventilation, preprocedural diuresis, and table tilting to decrease the leaflet gap. Moreover, the use of 3-dimensional intracardiac echocardiography has been instrumental in improving procedural imaging and in helping execute preprocedural planning. Computed tomography can also help us understand the inferior cava offset and predict challenges in navigating the delivery system to deliver the TEER device on the desired valve segments.
- Different times, different valve, but many attempts were made to have a unifying scoring system for mitral TEER.[7] This has been proven challenging given variations in patients' anatomy and operators' experience. Rapid evolution in devices and procedural techniques have made it difficult to protect these scores from obsolescence. The closest we reached was by using a color-based scale that experienced heart teams quickly challenged in various registries, such as the EXPAND G4 (A Post-Market Study Assessment of the Safety and Performance of the MitraClip G4 System) and PASCAL IID Registry (PASCAL IID Registry Within the Edwards PASCAL TrAnScatheter Valve RePair System Pivotal Clinical Trial [CLASP IID]) and by raising the bar on mitral regurgitation reduction goals.[8,9]

The primary lesson from these score predictors for outcomes of T-TEER is that we are capable of identifying both high-risk patient cohorts by patient-specific risk factors and low-risk patient cohorts by tricuspid valve morphologic characteristics, but it is the widening gap in between that we need to understand more fully. Finally, as we further broaden our thinking on tricuspid valve intervention, and looking at it with a futuristic eye, it becomes more evident that we need a dynamic assessment tool that adapts to various causes of TR, degrees of TR and RV function, evolution in imaging, heart team learning curve, and meaningful endpoints. We also need to incorporate TTVR and other devices that are not necessarily leaflet based and maybe even combinations of therapies to achieve the ultimate results at various stages of the disease process and in various forms of tricuspid valve anatomy.

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