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EDITORIAL COMMENT

Return of the Tricuspid Spacer

Filling an Unmet Clinical Need*

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The management of patients with severe tricuspid regurgitation (TR) remains a significant clinical dilemma, given the modest efficacy of diuretics and the limited role of isolated tricuspid surgery. The field of transcatheter tricuspid valve intervention (TTVI) has emerged as a less invasive alternative, including transcatheter edge-to-edge repair (TEER), annuloplasty, spacers, and heterotopic and orthotopic valve replacement (TTVR). TEER is the most widely adopted TTVI, with excellent safety and moderate efficacy, and is being studied in multiple randomized controlled trials. More recently, TTVR has made rapid progress through the elimination of TR with an improving safety profile, and it is also being compared with medical therapy in a randomized controlled trial. Despite this remarkable progress over a short time, many patients do not qualify for existing TTVI devices owing to massive annular dilation, huge leaflet coaptation gaps, lead-induced TR, or advanced right ventricular (RV) dysfunction. Furthermore, effective and consistent imaging of the tricuspid valve for procedural guidance remains a barrier for more widespread TTVI adoption. Clearly, there is a need for further innovation and outside-the-box approaches to TTVI to facilitate treatment of the most challenging TR patients, who are often excluded from clinical trials.

In this issue of *JACC: Basic to Translational Science*, Chon et al[1] report the preclinical experience with the novel Pivot TR spacer device. The device consists of an atraumatic C-shaped nitinol anchoring mechanism with a proximal spiral anchor in the inferior vena cava and distal elephant nose in the pulmonary artery. The integrated 3D leaflet spacer traverses the tricuspid valve vertically and obliquely rather than coaxially and is available in 9-, 12-, and 15-mm diameters. The device is implanted via percutaneous transfemoral approach and is repositionable and recapturable, requiring only fluoroscopy and transthoracic echocardiographic guidance, allowing for fast (<30 minutes) and simple implantation. In this study, a swine model of primary TR was used through the creation of flail leaflets. A total of 36 animals were studied, 22 normal and 14 with TR. In the normal animals, there was minimal impact on valve function, with no device migration. In the TR animals, device implantation led to significant TR reduction in all cases, with up to 4-month follow-up. Complications were relatively few and included 2 hepatic vein thrombi, 1 subsegmental pulmonary embolism, and 1 device infection. Minor septal leaflet thickening was noted in the anteroseptal or posteroseptal commissures at the point of spacer contact and was associated with trivial or mild TR. Finally, the authors attempted to validate Pivot TR for clinical use through computed tomographic analysis and 3-dimensional printing of 18 human hearts with TR, with adequate device implantation across a range of right heart anatomy.

Important limitations of this study include the experimental model of acute primary TR with flail leaflets rather than chronic functional TR which accounts for the vast majority of clinical cases. However, as noted by the authors, if the device can effectively treat such large eccentric coaptation gaps with torrential TR, this would seem to bode well for functional TR patients with central gaps. In addition, humans have a much larger and more variable cavotricuspid isthmus than swine, and patients with chronic severe TR often have massive annular

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dilation, suggesting that the device may require further iteration with a larger size matrix before clinical use. Furthermore, although the device is retrievable after deployment, a potentially attractive feature in the patient with TR reduction and subsequent RV reverse remodeling, it is unclear how long after implantation this would remain a safe option.

Where do these preclinical Pivot TR data fit into the current TTVI landscape? Patients currently being offered TTVI represent the tip of the iceberg of the TR population that may benefit, considering delayed diagnosis and referral and a lack of awareness by the cardiovascular community in general. When patients do present to clinical attention, they are often in an advanced disease stage with cardiac cirrhosis, ascites, and cardiorenal syndrome. After heart team assessment, such patients are often excluded from clinical trials or commercially available devices for anatomic reasons or perceived futility. However, there is often a mismatch between a given patient's daunting tricuspid anatomy and clinical phenotype, such that heart teams feel compelled to offer interventional treatment, albeit palliative in some cases. It is in such patients that tricuspid spacers will likely play a role. The Forma device (Edwards Lifesciences) was the earliest spacer prototype, and demonstrated TR reduction and improvements in symptoms and quality of life in the majority of patients treated, but it had safety issues including RV perforation, device dislocation, and late TR recurrence that were poorly tolerated in this comorbid population.[2,3] Currently, spacers under active development for clinical use include Croivalve, Coramaze, and TriFlow, all of which use innovative and unique solutions to improve coaptation. Ultimately, these devices must solve the significant technical issues of stable anchoring, durability, and thrombosis before they will be ready for clinical adoption. In this context, the Pivot TR device is promising, given its apparent ease of use and encouraging safety profile, without the need for advanced procedural imaging or general anesthesia. Although the road from innovative idea to regulatory approval is long and bumpy, the remarkable pace of device development bodes well for our patients suffering from severe TR.

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