Editorial

Caval Valve Implantation
Are 2 Valves Better Than 1?

Brian P. O'Neill, MD

The management of patients with severe symptomatic tricuspid regurgitation (TR) remains extremely challenging for cardiologists and cardiovascular surgeons alike. Medical therapy, consisting primarily of escalating doses of diuretics, becomes ineffective in the long term as patients develop increasing diuretic resistance because of worsening renal function. Although in the United States the use of surgery for TR has shown a slight increase during the past decade, only a small portion of eligible patients undergo surgery.[1] This is for several reasons. As patients usually are only referred for surgery late in the disease process when they have severe end-organ compromise, the procedure can be more high risk. In addition, there can be a significant rate of late recurrence of TR post-surgery.[2] It is in this setting that the field of transcatheter tricuspid valve intervention has blossomed during the past 5 years, with multiple devices in early stages of development. In this issue of *Circulation: Cardiovascular Interventions*, Lauten et al[3] describe their experience with one of these techniques: caval valve implantation (CAVI).[3]

See Article by Lauten et al

The concept of CAVI centers around the heterotopic placement of a valve in the inferior vena cava (IVC) alone or in combination with a second valve in the superior vena cava (SVC) to redirect the regurgitant jet from the failing tricuspid valve. Protection of the hepatic and renal veins from the effects of this chronic volume overload may help mitigate the symptoms of right heart congestion, principally ascites and lower extremity edema. In the largest published case series to date of CAVI, 3 patients deemed to be at prohibitive surgical risk demonstrated improvements in New York Heart Association of at least 1 grade at 30 days.[4] Accompanying this improvement, the authors also noted decreases in right ventricular and right atrial volumes. In the current article, Lauten et al[3] expound on these initial findings.

Thirty-one patients were treated, predominantly with IVC valve implant only. The majority of the implantations were performed with a balloon expandable valve. One third of patients had some degree of right ventricular dysfunction, and one third of patients had previous pacemaker placement. Most patients had no more than mild left ventricular dysfunction. The authors demonstrated a high degree of procedural success with 96% of successful implants. In-hospital mortality was 16%, highlighting the higher risk nature of the patients studied. Reverse caval flow was eliminated in all patients on the basis of reduction of the IVC v-wave, and intact valve function was seen in all patients at follow-up. A total of 84% of patients showed improvement in at least 1 New York Heart Association heart failure class.

CAVI represents an intriguing percutaneous option for the treatment of patients with severe TR. It has several characteristics that make it an attractive potential therapy. The first is the ability to treat patients with pre-existing pacemaker implantation. As seen in the study, one third of patients had pre-existing pacemakers. Single-center studies have shown increases in moderate and severe TR post-pacemaker implant,[5] and lead-induced TR is associated with poor outcomes long term.[6] Although an SVC valve implantation may potentially interfere with pacemaker leads, the majority of patients in this study had IVC implant only which would allow implantation below the leads traversing the tricuspid valve. The implant technique has a shallow learning curve utilizing technology from transcatheter aortic valve replacement of which many structural heart disease operators are familiar. This would accelerate the dissemination of the technique over a completely new device. By not directly intervening on the tricuspid valve, CAVI does not preclude the combination of additional therapies to achieve further direct reduction of TR if needed and also does not necessarily eliminate a surgical option. Finally, as the authors describe, patients with right ventricular dysfunction may also be candidates for treatment, something which would make them particularly high risk for a surgical approach.

The main limitation for CAVI remains cava size, both distances from the superior most hepatic vein to right atrium/cava junction, and cava diameter of the IVC or SVC. Similar to dilatation of the tricuspid valve annulus which occurs with long-standing severe TR, the IVC and SVC also dilate from the effects of chronic volume overload. In the current study, patients with an IVC diameter >30 mm were excluded. This is due largely to the limitations in sizing with current transcatheter valve technology. One potential solution is a hybrid approach, with surgical downsizing of the IVC to facilitate valve implant.[7] However, in the highest risk patients, this may not be feasible. More importantly, as in all percutaneous options for severe TR, early treatment is paramount in those patients with severe TR to avoid this dilatation of the cava that would exclude them from treatment. Early treatment may also help to avoid irreversible liver fibrosis or cirrhosis from long-standing venous congestion may also attenuate the effects of decreased IVC pressure.

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association.

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The current study serves as an important first step in defining the field of CAVI. Several issues will need to be addressed for the field to grow. Most importantly, dedicated devices for CAVI are needed. Currently, the Tric Valve (P&F Products & Features Vertriebs GmbH, Vienna, Austria) is the only device designed specifically for CAVI. A docking scaffold that could accommodate current transcatheter valves would be another option because a tight seal as the right atrium/cava junction is important to prevent residual caval flow. Future studies will need to better clarify the role of bicaval implantation versus IVC implant only and their effect on hemodynamics and patient outcomes.[8] Some of these questions will be answered in current trials of CAVI, such as the HOVER trial (Heterotopic Implantation of the Edwards Sapien Transcatheter Valve in the Inferior Vena Cava for the Treatment of Severe Tricuspid Regurgitation)[9] in the United States and TRICAVAL (Treatment of Severe Secondary Tricuspid Regurgitation in Patients With Advance Heart Failure With Caval Vein Implantation of the Edwards Sapien XT Valve; NCT02387697) in Germany. Standardized trial end points, similar to transcatheter aortic valve replacement, are needed to allow reliable comparison between therapies. It is likely improvements in quality of life will be the most reliable metric of success, and trial design should focus on this. A unique risk assessment score for TR is also needed to help aid in patient selection and determine which patients are unlikely to benefit from treatment. Finally, imaging remains critical for CAVI. Accurate sizing in CAVI relies on computed tomographic reconstruction to assess cava size at the superior most hepatic vein, where the skirt of the valve will prevent venous back flow.[10] However, many patients with severe TR have underlying chronic kidney disease, which would make contrasted computed tomography problematic. Magnetic resonance imaging has shown promise in sizing for transcatheter aortic valve replacement, and noncontrasted magnetic resonance imaging has also been used.[11] Further research into magnetic resonance imaging for cava sizing in CAVI is warranted. As these questions are answered, it may be that 2 valves really are better than 1.

Disclosures

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