

EDITORIAL COMMENT

Bicaval Valve Implantation for Severe Tricuspid Regurgitation



Thinking Outside the Valve Box*

Philippe B. Bertrand, MD, PhD, Judy Hung, MD

Despite a more profound interest in tricuspid valve anatomy and pathophysiology over this past decade, the management of severe symptomatic tricuspid regurgitation (TR) remains most challenging. Chronic systemic congestion and systolic venous backflow in the setting of severe TR is known to cause symptoms of peripheral edema and ascites, and over time they may lead to irreversible liver cirrhosis and renal dysfunction with an adverse prognosis (1,2). Medical management is limited to optimizing diuretic drug regimens as far as tolerated by renal function. Alternatively, surgical treatment of severe TR is associated with high operative mortality, likely a reflection of the significant comorbidities that coexist with severe TR (3). Moreover, because TR is most commonly “secondary” to right ventricular and/or right atrial dilation in the setting of left-sided heart disease, pulmonary hypertension, and/or atrial fibrillation, its presence is also a marker of the underlying cardiovascular disease. To overcome these issues, a wide range of transcatheter solutions to treat TR are currently being developed, comprising coaptation devices (e.g., edge-to-edge repair), suture or ring annuloplasty techniques, transcatheter tricuspid valve replacement devices, and heterotopic caval valve implantation to relieve central venous congestion in the presence of severe inoperable TR (4).

In this issue of *JACC: Case Reports*, Werner et al. (5) report on the successful implantation of a novel bicaval valve prosthesis in a 75-year-old patient with severe inoperable TR. The patient had a history of multiple valve operations, including a De Vega tricuspid repair and—during redo surgery—an anterior tricuspid leaflet augmentation. The patient was deemed too high risk for yet another tricuspid valve surgery, had evidence of severe pulmonary hypertension, and was not a good candidate for other percutaneous tricuspid repair techniques currently under investigation. The implanted caval prosthesis (Tricento, New Valve Technology, Muri, Switzerland) consists of a bicavally anchored covered stent with a single bicuspid valve located in the inferior portion of the right atrium (6). The single valve is destined to prevent regurgitant flow into both the superior vena cava and inferior vena cava during ventricular systole while enabling unobstructed systemic venous inflow during ventricular diastole. Pre-procedural image-based planning and periprocedural fusion imaging were essential for the success of this procedure. The patient’s clinical course at 6 months was favorable.

SEE PAGE 720

In concept, caval valve implantation to alleviate the hemodynamic impact of severe inoperable TR represents an interesting outside-the-box approach. The rationale is that any reduction in hepatic, abdominal, or systemic venous congestion may also reduce symptoms of peripheral edema and ascites and hopefully improve clinical outcome. Feasibility of the concept has been demonstrated in the initial clinical experience with deployment of a Sapien transcatheter heart valve (Edwards Lifesciences, Irvine, California) in the inferior vena cava, after pre-stenting the inferior vena cava to provide a landing

*Editorials published in *JACC: Case Reports* reflect the views of the authors and do not necessarily represent the views of *JACC: Case Reports* or the American College of Cardiology.

From the Cardiac Ultrasound Laboratory, Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts. Both authors have reported that they have no relationships relevant to the contents of this paper to disclose.

zone (7,8). Hemodynamic analyses have shown a successful (and durable after 9 months) elimination of systolic flow reversal and systemic congestion, as well as improved intracardiac hemodynamics likely secondary to improved diuretic drug responsiveness (9). On the basis of these initial data, caval valve implantation offers an attractive approach for patients with severely symptomatic TR who are at prohibitive surgical risk.

However, several unknowns remain. The clinical benefit of the caval technique has yet to be proved. The TRICAVAL (Treatment of Severe Secondary TRicuspid Regurgitation in Patients With Advance Heart Failure With CAval Vein Implantation of the Edwards Sapien XT VALve; NCT02387697) trial, randomizing 28 patients toward caval valve implantation (n = 14) versus optimal medical therapy (n = 14), showed no difference in the primary endpoint of maximal oxygen uptake at 3 months. More alarming were the 4 major complications in the caval implantation arm of the study (2 cases of cardiac tamponade secondary to stent migration and 2 valve dislocations) that led to the discontinuation of recruitment for safety purposes (10). It remains to be determined whether higher up on the learning curve,

with dedicated device designs (no need for pre-stenting) and targeting of patients in earlier stages of disease, will provide better results. Additional unknowns are the longer-term impact of right atrial ventricularization (risk of atrial arrhythmia, persistent atrial congestion), the impact of pre-existing pulmonary hypertension on hemodynamics and outcome after the caval approach, the implications for anticoagulation to prevent valve thrombosis in a low-pressure caval system, and whether a bicaval approach (as presented here) would be better than sealing only the inferior vena cava. Finally, the place of the caval technique in the current landscape of percutaneous tricuspid valve devices is largely unclear (11). We look forward to receiving more answers in the near future. This will help decide whether and in whom a strategy outside the valve box should be considered for treatment of severe TR.

ADDRESS FOR CORRESPONDENCE: Dr. Judy Hung, Cardiac Ultrasound Laboratory, Massachusetts General Hospital, Harvard Medical School, 55 Fruit Street, Yawkey 5E, Boston, Massachusetts 02114. E-mail: jhung@mgh.harvard.edu.

REFERENCES

- Nath J, Foster E, Heidenreich PA. Impact of tricuspid regurgitation on long-term survival. *J Am Coll Cardiol* 2004;43:405-9.
- Verbrugge FH, Dupont M, Steels P, et al. Abdominal contributions to cardiorenal dysfunction in congestive heart failure. *J Am Coll Cardiol* 2013;62:485-95.
- Zack CJ, Fender EA, Chandrashekar P, et al. National trends and outcomes in isolated tricuspid valve surgery. *J Am Coll Cardiol* 2017;70:2953-60.
- Asmarats L, Puri R, Latib A, Navia JL, Rodes-Cabau J. Transcatheter tricuspid valve interventions: landscape, challenges, and future directions. *J Am Coll Cardiol* 2018;71:2935-56.
- Werner P, Russo M, Scherzer S, et al. Transcatheter caval-valve implantation of the Tricento valve for severe tricuspid regurgitation using advanced intraprocedural imaging. *J Am Coll Cardiol Case Rep* 2019;1:720-4.
- Toggweiler S, De Boeck B, Brinkert M, et al. First-in-man implantation of the Tricento transcatheter heart valve for the treatment of severe tricuspid regurgitation. *EuroIntervention* 2018;14:758-61.
- 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.
- Lauten A, Hamadanchi A, Doenst T, Figulla HR. Management of tricuspid regurgitation by caval valve implantation: from technical feasibility to evaluation of efficacy. *J Am Coll Cardiol* 2013;62:2258-9.
- Rakita V, Lakhter V, Patil P, O'Neill BP. Intermediate term hemodynamic effects of single inferior vena cava valve implant for the treatment of severe tricuspid regurgitation. *Catheter Cardiovasc Interv* 2017;90:521-5.
- Laule M, Mattig I, Schobel C, et al. Inferior caval valve implantation versus optimal medical therapy for severe tricuspid regurgitation. *J Am Coll Cardiol* 2019;74:473-5.
- Taramasso M, Alessandrini H, Latib A, et al. Outcomes after current transcatheter tricuspid valve intervention: mid-term results from the international TriValve Registry. *J Am Coll Cardiol Intv* 2019;12:155-65.

KEY WORDS right heart failure, transcatheter, tricuspid valve, valve replacement