Caval Valve Implantation

Alexander Lauten, MD[a,*], Henryk Dreger, MD[a], Michael Laule, MD[a], Karl Stangl, MD[a], Hans R. Figulla, MD[b]

KEYWORDS

• Caval valve implantation • Tricuspid valve regurgitation • Tricuspid valve insufficiency
• Right heart failure • Functional tricuspid regurgitation

KEY POINTS

- Severe Tricuspid Regurgitation is associated with backflow into the caval veins which can result in significant morphologic alterations.
- Caval valve implantation (CAVI) results in resolution of venous backflow into the caval veins.
- Devices used for CAVI include the self-expandable TricValve and the ballon-expandable Edwards Sapien 3.

INTRODUCTION

Recently, transcatheter therapy has expanded the treatment options for patients with heart valve disease. Interventional therapy for aortic, mitral, and pulmonic valve disease is well established; however, catheter-based approaches to tricuspid regurgitation (TR) are still in early stages of development.[1–5] Traditionally, TR assumed a lower priority than other valve disease, also driven by less commercial interest in such developments in the past. Nevertheless, the prevalence and the functional impact of moderate to severe TR are high, and this disease is currently vastly undertreated.[6] With increasing severity of TR, 1-year mortality increases, reaching greater than 36% in those with severe TR.[7] Furthermore, the increasing number of patients at advanced age and high-risk profile undergoing successful treatment of left heart disease may contribute further to the growing need for effective interventional approaches of TR, because many of these potentially develop right heart disease at a later stage.[8,9]

For some of the interventional concepts to TR, including the edge-to-edge repair, transcatheter annuloplasty, the tricuspid spacer, and caval valves, procedural feasibility and favorable early clinical outcome have been demonstrated in small compassionate case series.[10–13] However, there is still a lack of evidence and data from randomized trials to demonstrate the functional impact of these treatment approaches. Furthermore, a better understanding of clinical and anatomic selection criteria for these approaches is needed as well as a uniform definition of achievable endpoints, which may differ depending on the subgroup of patients and treatment approaches.[14–16] This article reviews the pathophysiologic background and current evidence for caval valve implantation (CAVI) and examines the potential role of this approach for the treatment of severe TR.

Transcatheter Treatment of Tricuspid Regurgitation: Orthotopic versus Heterotopic Replacement

Although percutaneous repair concepts are conceptually attractive because they restore native tricuspid valve (TV) function, it remains arguable to which extent repair concepts can be implemented on the TV with durable long-term results. A repair procedure has to yield

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[a] Department of Cardiology, Charité – Universitaetsmedizin Berlin, German Centre for Cardiovascular Research (DZHK), University Heart Center, Charitéplatz 1, Berlin D-10117, Germany; [b] University Heart Center Jena, Erlanger Allee 101, 07747 Jena, Germany
* Corresponding author.
E-mail address: alexander.lauten@charite.de

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predictable and reproducible results in the hands of a wide range of interventional cardiologists to be adopted in clinical practice. Because of the above-mentioned unmet need for an effective treatment, transcatheter valve implantation may be an alternative and easier-to-achieve treatment option.

From the interventional perspective, there are 2 basic principles depending on the site of valve implantation: an *orthotopic* versus *heterotopic*, CAVI. For *orthotopic* valve replacement, the prosthetic valve is implanted in an anatomically correct position in the TV annulus, thus restoring the functional separation of the right ventricle (RV) and right atrium (RA). Although repair and heterotopic replacement tend to only partially correct TR, thus reducing the hemodynamic burden of acute complete correction to the RV, the orthotopic approach will most likely lead to complete correction of ventricular regurgitation. It remains arguable whether this is necessary to achieve clinical improvement or is hemodynamically desirable in patients with RV dysfunction.

Furthermore, the orthotopic approach is associated with particular challenges in patients with severe and long-standing TR. It was only recently that this approach was successfully performed for compassionate human treatment with an investigational device. Compared with the aortic annulus, the TV annulus offers a greater variability and less resistance for device fixation because of its larger diameter and lower proportion of fibrous tissue. Size and flexibility of the TV and the surrounding myocardium hamper positioning and long-term fixation of transcatheter devices, and there are no adjacent structures to facilitate implantation of such devices. Annulus dilatation may reach greater than 70 mm in functional TR and is associated with the loss of anatomic landmarks between RV and RA. A device intended for orthotopic TV replacement would require unique solutions for stent and catheter design as well as tissue valve engineering (eg, a 70-mm tissue valve would require a leaflet height of >40 mm to avoid prolapsing into the RA). In 2005, Boudjemline and colleagues[17] experimentally investigated this approach by means of implanting a double-disc nitinol stent with a semilunar valve into the TV annulus. Although in this study technical feasibility was demonstrated to some degree in healthy sheep, several difficulties relating to sufficient fixation of the self-expanding valve in the highly dynamic tricuspid annulus were observed.

Heterotopic CAVI is an obviously attractive alternative. Compared with the orthotopic approach, the heterotopic procedure benefits from the advantage of a straightforward implantation technique because of the distance to vulnerable cardiac structures. The introduction of foreign material in the RV inflow tract is avoided, permitting a potentially lower risk of injury to ventricular structures and making this an attractive approach to the interventional cardiologist. Devices do not interfere with any preexisting trans-tricuspid pacemaker or defibrillator leads, which might represent a limitation for orthotopic procedures on the TV.

The Caval Valve Implantation Approach: From Preclinical Proof-of-Concept to First Human Application

The CAVI concept was first investigated in an experimental study in animals demonstrating function and hemodynamic effects of the caval valves. After creation of acute TR in sheep, self-expanding valves were implanted in the inferior vena cava (IVC) and superior vena cava (SVC) using a transjugular approach (**Fig. 1**A). In this study, the onset of TR resulted in a significant reduction of cardiac output and a ventricular wave in the IVC. After implantation of the IVC and SVC valves, cardiac output and systolic backflow in the caval veins recovered to baseline value.[16,18] Chronic animal data demonstrated device function for a period of up to 6 months after implantation (see **Fig. 1**B, C).[19]

After demonstration of feasibility, CAVI was first applied for compassionate treatment in a human patient in 2010.[14] In this patient with severe functional TR after multiple preceding open-heart procedures, a self-expanding valve was implanted into the IVC at the cavoatrial junction to reduce regurgitant backflow. In this experience, excellent valve function was observed after deployment, resulting in a marked reduction of caval pressure and an abolition of backflow to the IVC (see **Fig. 1**D, E). The patient was discharged home and experienced an improvement of physical capacity and symptoms of right heart failure within the 3-month follow-up period.[20] The first series of patients treated with caval implantation of the Edwards Sapien XT valve (Edwards Lifesciences Inc, Irvine, CA, USA) was published by Laule and colleagues[21] in 2013, reporting the experience with IVC-implantation of balloon-expandable valves (BEV) in 3 patients with severe functional TR (see **Fig. 1**F, G).

Clinical Evidence

With the growing understanding of TR and its natural history, it becomes more and more obvious that this patient population is actually a heterogeneous cohort presenting for treatment in different stages of a continuous disease