Percutaneous Bicaval Valve Implantation for Transcatheter Treatment of Tricuspid Regurgitation

Clinical Observations and 12-Month Follow-Up

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Severe tricuspid regurgitation (TR) frequently constitutes a high risk for surgical correction.[1] For inoperable patients with TR, transcatheter caval valve implantation has been suggested.[2] Herein, we report the human application and 12-month follow-up after first bicaval implantation of self-expanding valves into the superior (SVC) and inferior (IVC) vena cava as interventional concept for severe TR.[3]

Patient and Procedure

The procedure was performed as compassionate treatment in an 83-year-old female with severe, long-standing functional and structural TR after University Hospital Jena institutional review board approval. At admission, she was in New York Heart Association-stage IV and presented symptoms of chronic right heart failure with peripheral edema, ascites, and orthopnea. Synthetic liver function was impaired with reduced serum albumin and cholinesterase because of congestive hepatopathy, echocardiography demonstrated right ventricle enlargement with preserved systolic function. Right heart catheterization confirmed severe TR with a ventricular wave (v-wave) in the right atrium (RA), the SVC, and the IVC of 32, 27, and 28 mm Hg, respectively, as well as a slightly elevated pulmonary artery pressure and vascular resistance. Hemodynamics, laboratory, and clinical parameters are detailed in the Table.

Based on computed tomography-angiographic images, 2 self-expanding percutaneous heart valves were custom-made with 10% to 20% oversizing to fit the anticipated implantation site in the SVC and IVC.[4] The IVC valve was designed with the upper segment protruding into the RA with the biological valve located above the diaphragm to protect the abdominal vasculature from systolic backflow and avoid occlusion of hepatic veins (Figure 1). For the SVC valve, the stent frame was funnel shaped with the upper and lower segments tapered to facilitate sufficient fixation at the cavo-atrial inflow. The proximal stent segment was mounted with a trileaflet bovine pericardial valve and a sleeve covering the inside down to the base of the leaflets to prevent paravalvular leakage (Figure 2). Both devices were implanted in one single procedure. The SVC valve was loaded into a 27F catheter and advanced in over-the-wire-technique through the right femoral vein to the SVC, aligned with the inflow of the brachiocephalic vein and deployed in a stepwise fashion. Second, the IVC valve was implanted as previously described (see the Data Supplement).[4]

After deployment, IVC pressure decreased from 28/19 to 16/14 mm Hg with a reduction of mean pressure from 19 to 14 mm Hg. In the SVC, pressure decreased from 27/14/19 to 21/13/18 mm Hg. In contrast, in the RA an increase from 32/7 to 37/11 mm Hg with nearly unchanged mean pressure (20 versus 21 mm Hg; Figure 3) was observed. Cardiac output estimated by Fick calculations slightly increased from 3.9 to 4.2 L/min immediately after valve implantation. The patient experienced an obvious improvement of heart failure symptoms and physical capacity improved to New York Heart Association II to III. She was discharged home after an uneventful postoperative course.

During follow-up visits she reported further improvement of physical capacity ≤12 months after implantation. Symptoms of right ventricle failure including ascites and peripheral edema had fully resolved with an associated loss of 9 kg body weight and synthetic liver function had normalized. After 3 months, right heart catheterization confirmed a further reduction of pressure in the SVC (21/7 mm Hg, mean 11 mm Hg) and IVC (13/6 mm Hg, mean 9 mm Hg), mean RA pressure had decreased from 21 to 16 mm Hg suggesting a chronic decrease in right ventricle volume load. During chronic follow-up, SVC pressure remained at a higher level than IVC pressure, possibly because of an increased resistance caused by the use of a large prosthetic device in this first human application. An unchanged position of both devices was confirmed and valve function without paravalvular leakage was documented echocardiographically and by computed tomography angiogram (Figure 4).

At 12 months after implantation the patient remains well in New York Heart Association-class II and without clinical signs of right heart failure. No visible fracture or change in the impedance or function of the transvenous pacemaker

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Table. Clinical and Hemodynamic Parameters Before and After Caval Valve Implantation

	Before Implantation	Immediately After Implantation	At 3 Mo After Implantation
Systemic hemodynamics			
Arterial blood pressure, mm Hg	114/62/83	110/67/83	114/56/77
Systemic vascular resistance, dyn·s·cm^{-5}	1292	1180	1134
PCWP, mm Hg	16	16	13
LV ejection fraction, %	45	45	50
Cardiac output, L/min	3.9	4.2	4.3
Pulmonary vasculature			
PA pressure, mm Hg	37/18/25	36/18/25	34/9/21
Pulmonary vascular resistance, dyn·s·cm^{-5}	185	197	145
Transpulmonary gradient, mm Hg	9	9	8
Right ventricle			
RV pressure, mm Hg	39/7/13	34/8/12	32/6/12
TAPSE, cm	2.0	1.6	1.7
TASV, cm/s	9.0	14	12
Right atrium			
v-Wave, mm Hg	32	37	36
y-Decent, mm Hg	7	11	3
Mean pressure, mm Hg	20	21	16
Inferior vena cava			
v-Wave, mm Hg	28	16	13
y-Decent, mm Hg	15	13	6
Mean pressure, mm Hg	19	14	9
Superior vena cava			
v-Wave, mm Hg	27	21	21
y-Decent, mm Hg	14	13	7
Mean pressure, mm Hg	19	18	11
Body weight, kg	60	57*	51
Hepatic synthetic function			
Albumin (range, 31–45 g/L)	23	24*	36
Cholinesterase (range 65–180 μmol/L·s	45	42*	89
Right atrium, mm×mm†	50×59	50×62*	52×48‡

LV indicates left ventricle; PA, pulmonary artery; PCWP, pulmonary capillary wedge pressure; RV, right ventricle; TAPSE, tricuspid annular plane systolic excursion; and TASV, tricuspid annular systolic velocity.

*At hospital discharge; †measured in 4-chamber apical view; and ‡measurement at 12 mo after implantation.

leads that were jailed by the SVC stent occurred during follow-up. At this time point, excellent valve function is continuously documented echocardiographically and the distance covered in 6-minute walk test further improved to 350 m at this time point.

This initial human case demonstrates the technical feasibility using self-expandable valves for caval valve implantation in human cardiac anatomy. The procedure resulted in an immediate and sustained hemodynamic improvement with a complete abolishment of caval backflow as confirmed by invasive pressure measurement post procedure and after 3 months. Mean pressures in the IVC and SVC were permanently lowered, whereas RA mean pressure remained unchanged early postoperatively; however, it decreased during follow-up. The hemodynamic improvement was accompanied by a substantial clinical improvement of heart failure symptoms, normalization of liver function, and improvement of physical capacity.

In summary, caval valve implantation is a promising interventional treatment concept. However, this approach should be limited to the compassionate use for inoperable patients with treatment refractory and symptomatic TR until further evidence of clinical efficacy and long-term results is available.

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Disclosures

None.

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KEY WORDS: tricuspid regurgitation ■ tricuspid valve incompetence ■ tricuspid valve insufficiency

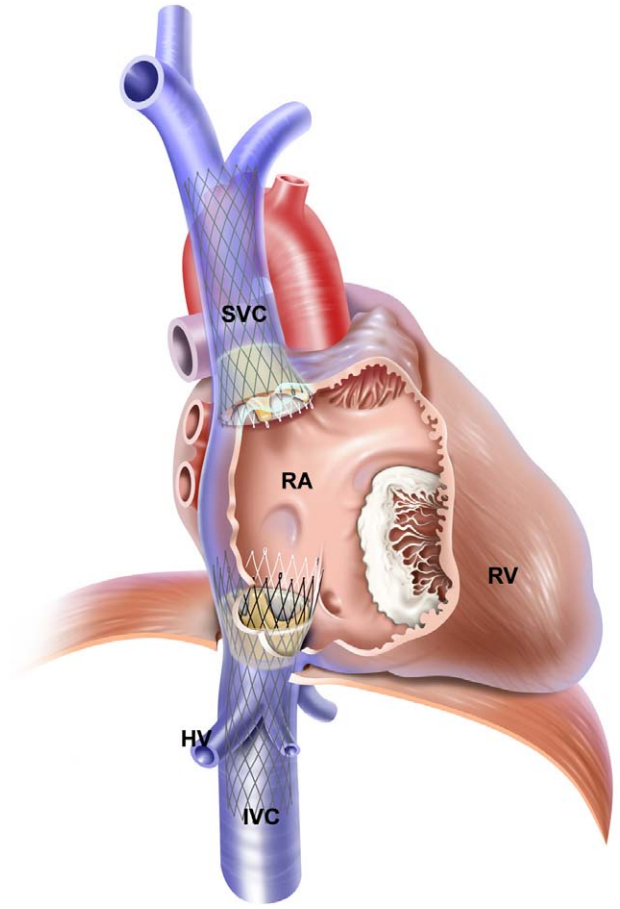

Figure 1. Concept of transcatheter caval valve implantation using self-expandable devices: The inferior vena cava (IVC) valve is designed with the upper segment protruding into the right atrium (RA) and the lower segment for anchoring in the IVC, thus protecting of the hepatic veins from elevated RA pressure. The superior vena cava (SVC) device is funnel shaped to facilitate sufficient fixation at the SVC-cavoatrial junction. Both stents are mounted with a trileaflet bovine pericardial valve and a sleeve covering the inside down to the base of the leaflets. HV indicates hepatic vein; and RV, right ventricle.

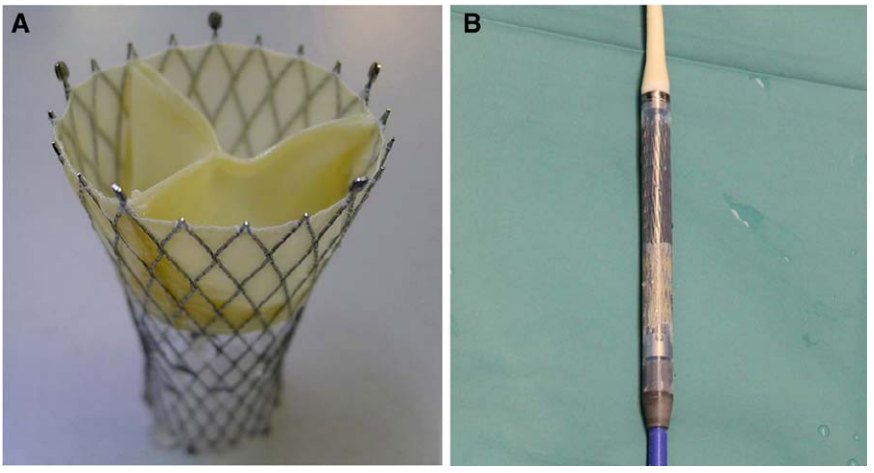

Figure 2. Self-expanding valve for superior vena cava (SVC) implantation. **A**, The stent frame was funnel shaped with the upper and lower segments tapered to facilitate sufficient fixation. The stent was mounted with a trileaflet porcine pericardial valve and an inside sleeve covering to prevent paravalvular leakage. **B**, SVC device loaded into a 27F catheter for implantation.

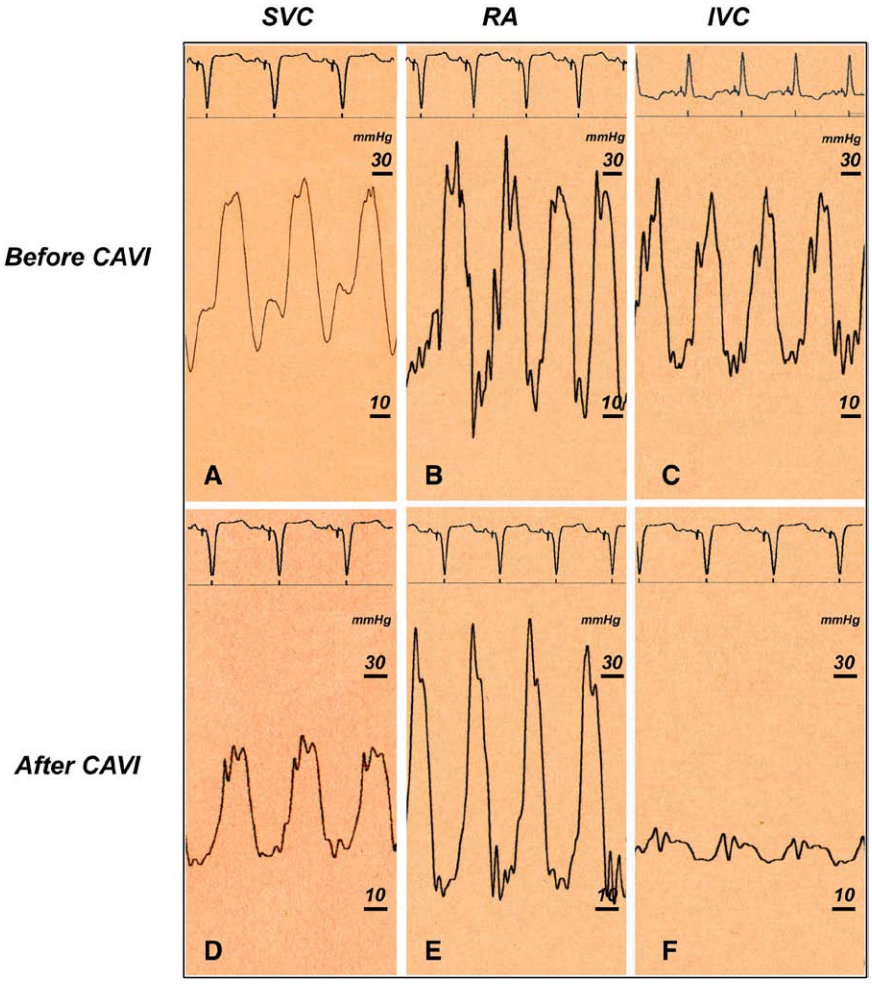

Figure 3. Invasive hemodynamic measurements. **A** to **C**, Right heart catheterization confirms a prominent ventricular wave of 32 mm Hg, of 27 and 28 mm Hg in the right atrium (RA), and the superior vena cava (SVC) and the inferior vena cava (IVC) which is transmitted down to the femoral veins. **D** to **F**, After implantation of both cava valves venous backward flow is reduced, as demonstrated by a reduction of the v-wave in the central veins. CAVI indicates caval valve implantation.

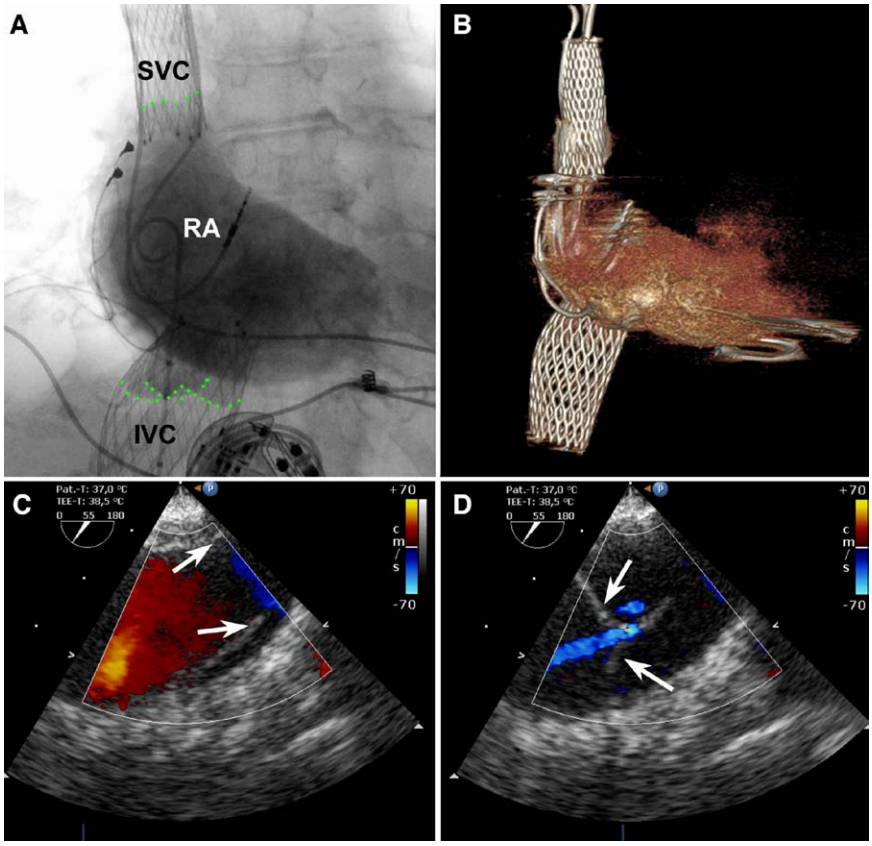

Figure 4. Device position and function 3 months after caval valve implantation. **A**, Right ventricle angiography confirms unchanged position and function of both valves. After right atrium (RA) injection contrast is retained at the level of the leaflets (marked by a green dotted line), thus also protecting of the hepatic veins from elevated RA pressure. **B**, Computed tomography angiography with 3D volume–rendering images confirms the position of both devices in the superior vena cava (SVC) and inferior vena cava (IVC). **C** and **D**, Echocardiographic evaluation of prosthetic valve function demonstrates diastolic opening and systolic closure of the IVC valve at 3 months after implantation. Doppler interrogation confirms valvular competence with trivial central regurgitation. Leaflets marked with white arrows.

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Supplemental Material

Video Legends

Video 1 shows an angiogram of the inferior vena cava demonstrating caval regurgitation in severe tricuspid regurgitation

Video 2 shows an RA angiogram after CAVI demonstrating prosthetic valve function

Video 3 shows an echocardiogram after CAVI demonstrating prosthetic valve function