Both de

base of the leaflets to prevent paravalvular leakage (Figure

pericardial valve and a sleeve covering the inside down to the

proximal stent segment was mounted with a trileaflet bovine

to facilitate sufficient fixation at the cavo-atrial inflow. The

was funnel shaped with the upper and lower segments tapered

vasculature from systolic backflow and avoid occlusion of

valve located above the diaphragm to protect the abdominal

the upper segment protruding into the RA with the biological

site in the SVC and IVC. The IVC valve was designed with

self-expanding percutaneous heart valves were custom-made

10% to 20% oversizing to fit the anticipated implantation

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 mmHg with a reduction of mean pressure from 19 to

14 mmHg. In the SVC, pressure decreased from 27/14/19
to 21/13/18 mmHg. In contrast, in the RA an increase from

32/7 to 37/11 mmHg with nearly unchanged mean pressure

(20 versus 21 mmHg; 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 fail-

ure 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 improve-

ment 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 normal-

ized. After 3 months, right heart catheterization confirmed a

further reduction of pressure in the SVC (21/7 mmHg, mean

11 mmHg) and IVC (13/6 mmHg, mean 9 mmHg), mean

RA pressure had decreased from 21 to 16 mmHg suggest-

ing 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 resis-

tance 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 clini-

cal signs of right heart failure. No visible fracture or change

in the impedance or function of the transvenous pacemaker

Severe tricuspid regurgitation (TR) frequently consti-
tutes 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 orthop-

nea. 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, lab-

oratory, and clinical parameters are detailed in the Table.

Based on computed tomography-angiographic images, 2

d-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

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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.

Acknowledgments
We thank Mr Jens Geiling, Institute of Anatomy, Friedrich-Schiller University, Jena, for his artwork contributions to this article.

Disclosures
None.

References

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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Before Implantation</th>
<th>Immediately After Implantation</th>
<th>At 3 Mo After Implantation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systemic hemodynamics</td>
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<td></td>
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<tr>
<td>Arterial blood pressure, mm Hg</td>
<td>114/62/83</td>
<td>110/67/83</td>
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<td>Systemic vascular resistance, dyn-cm⁻¹</td>
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<td>1180</td>
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<tr>
<td>PCWP, mm Hg</td>
<td>16</td>
<td>16</td>
<td>13</td>
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<tr>
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<td>45</td>
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<tr>
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<td>4.2</td>
<td>4.3</td>
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<tr>
<td>Pulmonary vasculature</td>
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<tr>
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<td>36/18/25</td>
<td>34/9/21</td>
</tr>
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<td>197</td>
<td>145</td>
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<tr>
<td>Transpulmonary gradient, mm Hg</td>
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<td>9</td>
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</tr>
<tr>
<td>Right ventricle</td>
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<td></td>
<td></td>
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<tr>
<td>RV pressure, mm Hg</td>
<td>39/7/13</td>
<td>34/8/12</td>
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<tr>
<td>TAPSE, cm</td>
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<td>v-Wave, mm Hg</td>
<td>32</td>
<td>37</td>
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<td>y-Decent, mm Hg</td>
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<tr>
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<td>21</td>
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<tr>
<td>y-Decent, mm Hg</td>
<td>14</td>
<td>13</td>
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<tr>
<td>Mean pressure, mm Hg</td>
<td>19</td>
<td>18</td>
<td>11</td>
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<tr>
<td>Body weight, kg</td>
<td>60</td>
<td>57*</td>
<td>51</td>
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<tr>
<td>Hepatic synthetic function</td>
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<td></td>
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<tr>
<td>Albumin (range, 31–45 g/L)</td>
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<td>24*</td>
<td>36</td>
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<tr>
<td>Cholinesterase (range 65–180 μmol/L-s)</td>
<td>45</td>
<td>42*</td>
<td>89</td>
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<tr>
<td>Right atrium, mm×mm†</td>
<td>50×59</td>
<td>50×62*</td>
<td>52×48‡</td>
</tr>
</tbody>
</table>

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.

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 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 mmHg, of 27 and 28 mmHg 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.
Percutaneous Bicaval Valve Implantation for Transcatheter Treatment of Tricuspid Regurgitation: Clinical Observations and 12-Month Follow-Up
Alexander Lauten, Torsten Doenst, Ali Hamadanchi, Marcus Franz and Hans R. Figulla

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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