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Letters

Caval Valve Implantation for Treatment of Severe Tricuspid Regurgitation

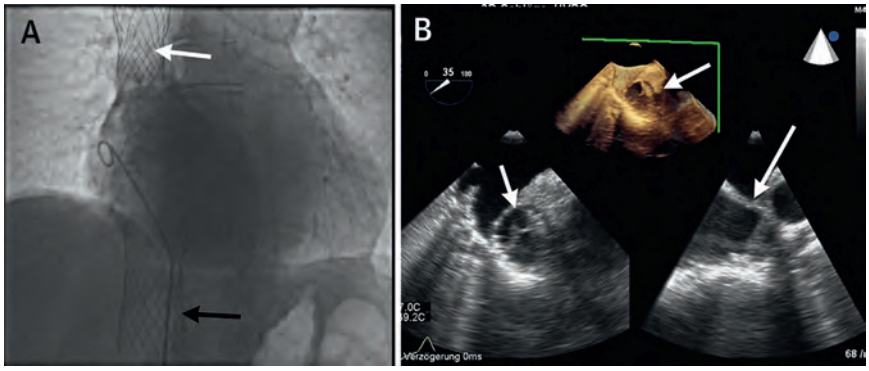
Severe tricuspid regurgitation (TR) is a complex condition of the right ventricle and tricuspid valve apparatus and frequently associated with symptomatic heart failure and significant morbidity and mortality (1). In contrast to other types of valve disease, TR is seldom an isolated valve pathology but rather a marker of an advanced stage of cardiac disease (2).

Currently there are increased efforts to develop interventional approaches to treat severe TR, including the implantation of balloon- and self-expandable valves into the caval veins (3-5). As neither the treatment approach nor the devices are currently approved for this indication, caval vein implantation (CAVI) is mainly applied by many centers as a last-resort option in patients with treatment-refractory and debilitating symptoms of right heart failure and excessive risk profile. As data on safety and efficacy are still missing, we reviewed our current experience with this approach.

Under a compassionate clinical use program, patients (n = 22, male 50%, age 74.9 ± 6.9 years; Society of Thoracic Surgeons mortality score 14.5 ± 12.8) underwent CAVI using either the self-expandable TricValve (P&F, Vienna, Austria) (n = 6; 27.3%) (**Figure 1**), the balloon-expandable valve (Sapien XT/3, Edwards Lifesciences, Irvine, California) (n = 15, 68.2%), or other devices (Directflow, Direct Flow Medical, Santa Rosa, California) (n = 1, 4.5%). Pre-interventional screening included a computed tomographic angiogram and right-heart catheterization for evaluation of hemodynamic and anatomic suitability, the latter depending on device availability. Patients with a systolic pulmonary artery pressure > 60 mm Hg and/or a massively depressed tricuspid annular plane systolic extension (<10 mm) function were excluded.

Depending on anatomic suitability, patients were then treated with either single-valve implantation (n = 17, 77.3%) or bicaval valve implantation (n = 5, 22.7%). Immediate procedural success was achieved in 90.9% (n = 20) of patients, confirming the

FIGURE 1 Bicaval Valve Implantation With the Self-Expandable TricValve



(A) Position of the self-expandable TricValve in the superior vena cava (SVC) **(white arrow)** and inferior vena cava (IVC) **(black arrow).** The TricValve (a set of 2 self-expandable valves) is made of bovine pericardium and the inner part of the atrial stent portion is lined with a polytetrafluoroethylene skirt. The SVC valve is then deployed with the landing zone of the enlarged mid-portion of the stent above the right pulmonary artery. The IVC valve is deployed with the upper, skirt-lined segment of the stent protruding into the right atrium and the device fully anchored in the IVC. **(B)** Echocardiographic evaluation of prosthetic valve function in the SVC visualized by transesophageal echocardiography. Three-dimensional, short-, and long-axis views of the device after deployment are shown.

feasibility and safety of the procedure. Conversion to surgery was required in 1 case following superior vena cava valve migration after deployment. A second patient underwent surgery within 30 days after atrial migration of the inferior vena cava valve.

In all patients, CAVI resulted in full reduction of reverse caval flow as confirmed by a significant reduction of the inferior vena cava v-wave from 30.8 ± 6.7 mm Hg to 20.8 ± 4.7 mm Hg ($p < 0.0001$) and color Doppler investigation. Despite the excessive risk profile of the patient population, the procedure was associated with no intraprocedural mortality. However, in-hospital mortality occurred in 5 of 22 patients (22.7%). Seventeen of 22 (77.3%) patients were discharged alive. In this subgroup, transthoracic echocardiography obtained during follow-up confirmed appropriate function of all implanted devices. The longest follow-up of 51 months is available for a bi-CAVI patient with documented intact valve function. In patients discharged from hospital, symptoms improved in 88.2% (n = 15) by ≥1 New York Heart Association functional class. However, 12-month mortality was 63.6% (14/22), respectively, with the majority of patients dying from non-cardiovascular causes.

In summary, these early results suggest that treatment of severe TR and caval backflow with the CAVI technique is feasible and there are reproducible results in a reduction of caval backflow. This hemodynamic improvement may potentially translate into clinical improvement, as suggested by the present study. However, due to its exclusive compassionate use, the present clinical experience is currently limited to the most severely ill subgroup with a high proportion of patients also experiencing non-cardiovascular comorbidities. Therefore, it remains unclear whether the presented treatment modality results in a sustained clinical improvement or improved patient prognosis. Further studies including randomized trials are required to determine which patients benefit most from interventional treatment, adjusting clinical criteria for patient selection and evaluating long-term safety and efficacy.

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Gut Microbiota Signature in Heart Failure Defined From Profiling of 2 Independent Cohorts

Metabolic and inflammatory disturbances may play a role in the development and progression of chronic heart failure (HF), but the mechanisms are not completely understood. The potential role of the gut microbiota in HF remains elusive, and only small studies with diverse methods and results have been reported so far (1–3).

To define a more robust gut microbiota signature in HF, we investigated 2 independent cross-sectional cohorts of patients with stable systolic HF (discovery, n = 40; and validation, n = 44; all >6 months in New York Heart Association functional class II-IV) and population-based control subjects (n = 266, randomly allocated to the 2 cohorts for comparison).