Management of Tricuspid Regurgitation by Caval Valve Implantation
From Technical Feasibility to Evaluation of Efficacy

We congratulate Laule et al. (1) for the first reported use of the 29-mm Edwards Sapien XT balloon-expandable valve (Edwards Lifesciences, Irvine, California) for transcatheter venous implantation to treat tricuspid regurgitation (TR). However, when we first investigated and clinically applied the concept of caval valve implantation (CAVI) as a management option for severe TR, we observed major hemodynamic and anatomic limitations that should be considered when selecting patients for this approach (2–6). First, CAVI does not address TR itself but the regurgitation of blood into the caval veins. Because this condition is present only in a subgroup of patients with severe, often long-standing TR and right ventricular (RV) enlargement, hemodynamic proof of caval regurgitation is essential before valve implantation. Second, CAVI increases RV afterload by exclusion of backward regurgitation. Thus, this novel approach should be reserved for patients with preserved RV systolic function and without elevated pulmonary vascular resistance. In the aforementioned patient group, there is considerable variation in the anatomic diameter of the inferior vena cava (IVC), which may reach up to 45 mm. The diameter of the IVC usually exceeds the suitable range for implantation of current, commercially available devices. Therefore, these patients require specifically designed, potentially individualized devices, which are currently not commercially available. In the series presented by Laule et al., the IVC diameter was within the range to allow implantation of 29-mm balloon-expandable devices, which—from our experience—contradicts “hemodynamically” severe TR.

Further issues in the article by Laule et al. (1) deserve clarification. First, the clinical benefit observed in these patients, particularly the reduction of edema and ascites, is frequently affected by the improved medical therapy and close clinical follow-up they are given. In the data presented, there is no obvious change in echocardiographic parameters to substantiate clinical improvement. Improved RV function as stated in the text is not supported by the data presented and is unlikely for the aforementioned reasons. Lack of documentation of pressure-derived parameters such as RV end-diastolic pressure and mean right atrial pressure further complicates the justification of procedure-related clinical improvement. Improved RV function as stated in the text is not supported by the data presented and is unlikely for the aforementioned reasons.

REFERENCES

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We appreciate the comments by Dr. Lauten and colleagues on our caval vein approaches with the Edwards Sapien XT valve (Edwards Lifesciences, Irvine, California) to treat severe secondary tricuspid regurgitation (STR) (1), and we welcome the opportunity to reply to their letter. Since the publication of our letter, we have performed 4 additional procedures, with the result that our experience now includes 7 patients, with follow-ups ranging between 1 and 14 months.

We agree that caval valve implantation (CAVI) is restricted to STR. Relevant regurgitation into hepatic and caval veins can easily be verified by clinical examination and ultrasound Doppler flow profiles. Indeed, although CAVI does not affect tricuspid regurgitation, the allegedly compromising heterotopic inferior vena cava (IVC) single-vein approach offers a number of important advantages over complete valve replacement in anatomic valve position. First, provided that CAVI primarily represents a tool in advanced heart failure, frequently under conditions of impaired right ventricular (RV) function and pulmonary hypertension (PH), the IVC single-valve approach provides a safety valve by leaving the superior vena cava untreated. Also, the majority of patients with heart failure have transvalvular RV-pacemaker and/or implantable cardioverter-defibrillator leads, a fact that renders catheter-based valve replacement in anatomic position virtually impossible. In heterotopic IVC position, however, the leads do not interfere in any way.

The stipulations voiced by Dr. Lauten and colleagues are correct in stating that in STR, the FCI diameter is actually too large for the available valve types. In our patients, the diameters were between 28 and 33 mm, which meant that direct valve implantation was not possible, primarily for this reason. Therefore, we prepared a landing zone, with 2 stents implanted 1 over the other. This method enables successful stabilization and downsizing, and implantation of the 29-mm Edwards Sapien XT becomes possible. Approximately 10% of the screened patients had larger diameters (>35 mm) and were not able to be treated. The occurrence of large vein diameters should actually prompt design of an appreciably larger dedicated valve.

Dr. Lauten and colleagues request further echo and pressure parameters to support our concept. The space limitation involved here in this Reply prevented their presentation; these data will be included in a publication of ours to appear later.

REFERENCES