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IMAGING VIGNETTE

CLINICAL VIGNETTE

First-in-Human Treatment of Severe Tricuspid Regurgitation Using a Novel Cross-Caval Heterotopic Device

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ABSTRACT

A 79-year-old woman, previously surgically treated for mitral and aortic valve replacement, experienced recurrent torrential tricuspid regurgitation after 2 transcatheter edge-to-edge repair procedures. Heart team assessment deemed the patient high risk for redo surgery and excluded transcatheter edge-to-edge repair and orthotopic replacement. The patient was then scheduled for a novel cross-caval device implantation. (J Am Coll Cardiol Case Rep 2023;28:102103)

A 79-year-old woman with a history of permanent atrial fibrillation and rheumatic valvular heart disease, previously treated with surgical mechanical mitral and aortic valve implantation, was submitted to 2 transcatheter edge-to-edge repair procedures with the TriClip system (Abbott Vascular) for torrential tricuspid regurgitation (TR). The initial attempt involved placing 3 clips in the anteroseptal position, and it was complicated by 2 single-leaflet device attachments (Video 1). Due to a persistent massive TR at 1-year follow-up, a redo procedure was performed with a single-clip implantation in posteroseptal position. Three months later, the patient experienced recurrent torrential symptomatic (NYHA functional class III, Kansas City Cardiomyopathy Questionnaire score 38.54) TR (**Figure 1A**, Video 2) with 1 admission caused by heart failure.

Other echocardiographic findings included preserved left ventricular systolic function, normal functioning of the prostheses, and severely dilated right ventricle, with preserved contractility. Right heart catheterization revealed increased right atrial pressure and mild postcapillary pulmonary hypertension with preserved cardiac output.

Heart team assessment deemed the patient not suitable for surgical redo and excluded transcatheter edge-to-edge repair and orthotopic replacement. Based on cardiac computed tomography, the inferior vena cava (IVC) diameter was 46.1 mm; meanwhile, the superior vena cava (SVC) was 57.0 mm, both at the level of RA inlet. Dimension of the IVC below the hepatic vein exceeded the dimensions of currently available devices, resulting in high risk of migration. Therefore, patient was scheduled for implantation of the novel Unica caval valve (Innoventric).

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ABBREVIATIONS AND ACRONYMS

IVC = inferior vena cava

SVC = superior vena cava

TR = tricuspid regurgitation

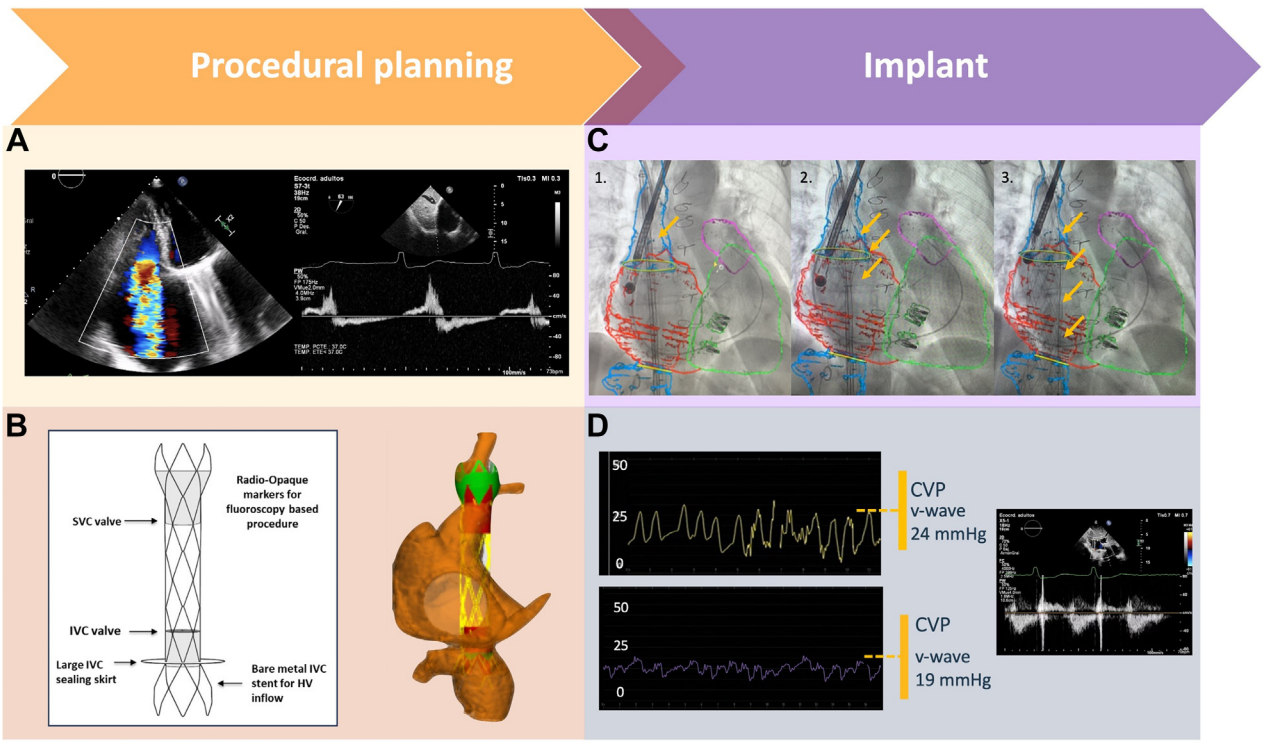
This is a cross-caval stent graft incorporating 2 30 mm-diameter bovine pericardium caval valves and a lower sealing skirt, with a final bare-metal portion for hepatic vein inflow (**Figure 1B**). Currently, 180- and 200-mm length configurations are available. Right atrium-IVC skirt allows to seal against diameters up to 60 mm, whereas upper sealing can be obtained in the majority of anatomies because of the long graft material neck extending into the SVC.

Under conscious sedation, with fluoroscopic and computed tomography fusion guidance (**Figure 1C**), after left femoral vein access for IVC angiography and right jugular vein access for SVC angiography and Swan-Ganz catheter positioning, the device was inserted via right transfemoral venous access with a 24-F capsule delivery system. The inferior radiopaque marker was then positioned across the line marking the atrial floor, and, without the need for any alignment, the device was successfully top-to-base deployed. Immediate significant decrease in venous pressure (IVC v-wave from 24-19 mmHg) occurred, in the absence of significant residual venous backflow (**Figure 1D**, Video 3).

At 6-month follow-up, the patient experienced significant symptomatic improvement (NYHA functional class II, Kansas City Cardiomyopathy Questionnaire score 79.17 points, no peripheral edema), with echocardiographic evidence of adequate device sealing (Video 4) and reduction of systolic hepatic vein backflow from severe to mild. Loop diuretic intake decrease was 20 mg daily, whereas no changes in body weight from discharge were observed. No adverse events occurred. No new hospitalizations were observed.

This first-in-human case demonstrates the possibility of novel device for indirect treatment of the systemic effects of TR. Because of its specific design, it might potentially adapt to a broad range of TR patients, in a predictable, short, simple, and straightforward procedure. More experience and longer-term follow-up are needed to confirm this promising single-case result.

FIGURE 1 Unica Caval Valve Implantation Procedure



(A) Preprocedural torrential tricuspid regurgitation and severe reverse flow in hepatic veins. (B) Cross-caval device implant with device characteristics and computer simulation of the position. (C) Procedural implant (orange arrows) under real-time computed tomography fusion imaging. (D) Significant decrease in v-wave in inferior vena cava (IVC) and venous backflow. CVP = central venous pressure; HV = hepatic vein; SVC = superior vena cava.

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APPENDIX For supplemental videos, please see the online version of this paper.