Transcaval Retrograde Transcatheter Aortic Valve Replacement for Patients With No Other Access
First-in-Man Experience With CoreValve

The first transcatheter aortic valve replacement (TAVR) approach was antegrade transvenous transseptal. This approach obligated transseptal catheterization and a more circuitous path to deploy the valve. The procedural complexities associated with the transseptal approach led to its replacement by the “less complex” and most commonly utilized transfemoral (TF) arterial retrograde approach (1). However, approximately two-thirds of screened patients are not suited for the TF approach because of peripheral arterial disease (2). In addition, the TF approach is associated with a significantly higher rate of vascular complications when compared with other approaches (1,3). The available alternatives are transapical for the Edwards Sapien valve (Edwards Lifesciences, Irvine, California), subclavian/axillary for the self-expandable Medtronic CoreValve ReValving system (CV) (Medtronic, Minneapolis, Minnesota), and transaortic for both prostheses. Despite these options, more than 3% of patients with symptomatic severe aortic stenosis are believed to have anatomic or physiological features making none of these approaches feasible (2). We report our first-in-man experience and demonstrate the intra-procedural safety of the CV percutaneous aortic valve implantation using the novel retrograde caval-aortic approach in a subgroup of inoperable patients with severe aortic stenosis.

All procedures were performed under general anesthesia and with aseptic technique. Vascular access in both right and left femoral arteries and veins was established. Unfractionated heparin was used for anticoagulation for a target activated clotting time between 250 to 300 s. A transvenous pacemaker was placed through the left femoral vein, and a pigtail catheter was introduced through the right femoral artery. Root aortography was performed during rapid ventricular pacing with rotational imaging and computerized tomographic reconstruction in order to confirm the best aortic valve angulation. Through standard right femoral vein access, a stiff 0.014-inch guidewire (Asahi Confianza Pro 12, Abbott Vascular, Santa Clara, California) inside a 0.035-inch wire converter (PiggyBack, Vascular Solutions, Minneapolis, Minnesota) was loaded in a Quick-Cross catheter (Spectranetics, Colorado Springs, Colorado) inside a 5-F Cobra catheter (Terumo, Somerset, New Jersey) (Figure 1). The distal end of the Confianza Pro 12 guidewire was connected to the cautery set in cut mode at 50 to 70 W. A vascular EV3 GooseNeck snare (Covidien, Plymouth, Minnesota) was positioned in the distal aorta and was used to capture the guidewire from the vena cava. Confirmation of the orientation was performed using 15° right anterior oblique and 70° left anterior oblique views at the infrarenal level with the least amount of calcification. Once the entire system was in position, and with the guidewire pointing to the snare in the aorta, the cautery was turned on, and the wire was advanced from the inferior vena cava to the distal aorta through the lumen of the snare. The wire was then captured in the snare and advanced to the ascending aortic curvature; the PiggyBack wire was advanced loaded onto a 0.035-inch Quick-Cross catheter. Once in the aortic arch, the PiggyBack converter and the Confianza Pro 12 guidewire were removed, and the 0.35-inch Quick-Cross catheter was left in the aortic arch to allow the exchange of a 0.35-inch Amplatz Super Stiff guideewire (Boston Scientific, Natick, Massachusetts). An 18-F 40-cm Cook Introducer Sheath (Cook Medical, Bloomington, Indiana) was introduced from the venous access connecting the femoral vein to the aorta. The self-expanding CV, mounted in the catheter system, was then advanced to the left ventricular outflow tract to be deployed using the standard technique. Closure of the aorto-caval fistula was completed with an Amplatzer Muscular VSD Occluder (St. Jude Medical, St. Paul, Minnesota). Arterial hemostasis was achieved using either manual pressure or a vascular closure device: Angio-Seal (St. Jude Medical) or Proglide (Abbott Vascular).

We successfully performed TAVR with caval-aortic access in 4 patients with a mean age of 81.5 ± 8.5 years (3 women and 1 man), mean Society of Thoracic Surgeons predicted risk of mortality of 8 ± 4.8%, and
mean logistic EuroSCORE of $11 \pm 5.8\%$. All patients had severe symptomatic aortic stenosis and were deemed inoperable by cardiac surgeons. All patients had peripheral arterial disease and contraindications for both transaortic and subclavian/transaxillary access. Valve sizes were 26, 29, and 31 mm (2 patients). One patient required permanent pacemaker placement. There were no other complications per Valve Academic Research Consortium criteria (4). The mean New York Heart Association functional class improved from 3.5 to 1.25, and the mean aortic valve area increased from 0.46 to 2.0 cm$^2$. At 6 months follow-up, all patients were free from rehospitalization and noted a significant improvement in functional capacity.

Caval-aortic approach was recently described by Halabi et al. (5) in 14 swine in which access to the abdominal aorta was gained via the femoral vein or inferior vena cava. In that report, the caval-aortic tracts were created by energizing a coronary guidewire with an electrosurgery unit, and the tracts were closed using Amplatzer Duct occluders (St. Jude Medical) or Memopart VSD occluders (Lepu Medical, Shanghai, China) (5). This approach has also been described in humans with the Edwards Sapien valve; however, this option has not been explored for CV (6). This rapid and uncomplicated novel technique incorporates advantages of both venous and arterial approaches without the need of a transseptal puncture and prevents femoral arterial complications. The more compliant and distensible veins can accommodate larger catheter sheaths, thus avoiding any iliofemoral arterial complications; the caval-aortic fistulas did not seem to be acutely life threatening and could easily be closed with the currently available devices (5). The operators should therefore be mindful of the caval-aortic approach, especially for a subgroup of patients with no arterial access because of small-caliber, tortuous, calcific, or otherwise obstructed iliofemoral arteries. Prospective assessment of the safety and efficacy of this approach with TAVR warrants further study with a larger number of patients.
First-in-Human Off-Pump Transcatheter Mitral Valve Replacement

Transcatheter mitral valve replacement (TMVR) faces significant challenges arising from the heterogeneous pathology of the mitral valve and the anatomic complexity of the mitral annulus, leaflets, and subvalvular apparatus (1,2). The Tendyne mitral prosthesis (Tendyne Holdings, Roseville, Minnesota) is a fully retrievable, apically tethered trileaflet porcine pericardial valve sewn onto a nitinol frame (Figure 1).

U.S. Food and Drug Administration Export Permit and international regulatory approvals were obtained before the study. The protocol was approved by the National Ethics Committee of Paraguay. Informed consent was obtained from 2 patients with severe mitral regurgitation (MR). The patients agreed to have the Tendyne valve implanted and observed for up to 2 h before proceeding with conventional mitral valve surgery.

On February 19, 2013, TMVR was performed in a 57-year-old man with severe MR secondary to degenerative mitral valve disease. At a later date, TMVR was also performed in a 55-year-old woman with severe MR and combined rheumatic and...