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CASE REPORT

CLINICAL CASE

Transcaval Transcatheter Aortic Valve Replacement for Pure Aortic Regurgitation Using a Dedicated Self-Expanding Device

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ABSTRACT

Novel dedicated devices allow transcatheter treatment of pure aortic regurgitation (AR). The JenaValve Trilogy Heart Valve System was introduced as the first dedicated and on-label AR transcatheter aortic valve replacement system, implementing a locator-based and calcium-independent anchoring mechanism. Here, we present the first-in-human transcatheter aortic valve replacement for pure AR via a transcaval access in a patient with prohibitive alternative arterial accesses. (J Am Coll Cardiol Case Rep 2024;29:102320) © 2024 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Moderate or severe aortic regurgitation (AR) affects around 2.2% of the population aged 70 years or older.[1] Surgical aortic valve replacement often represents the treatment of choice.[2] Because AR, mainly due to its noncalcific nature, is anatomically very different from aortic stenosis (AS), transcatheter aortic valve replacement (TAVR) for pure AR remains challenging. Recently, the JenaValve Trilogy System (JenaValve) as a novel dedicated self-expanding clippable device has been introduced as on-label option in Europe. It features a novel fixation mechanism with 3 dedicated locators that clip the prosthesis to the aortic cusps. Apart from initial transapical experience with an earlier device generation, in pure AR only transfemoral TAVR has been reported so far.

Here, we demonstrate the first-in-human transcaval TAVR for pure AR case, highlighting important technical aspects.

LEARNING OBJECTIVES

- To understand the role and importance of alternative access routes for TAVR in pure AR.
- To learn how transcaval TAVR can be performed with the JenaValve Trilogy, a dedicated device for treatment of pure AR.

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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ABBREVIATIONS AND ACRONYMS

AR = aortic regurgitation

AS = aortic stenosis

STJ = sinotubular junction

TAVR = transcatheter aortic valve replacement

HISTORY OF PRESENTATION

A 65-year-old man was referred to our center following recurrent cardiac decompensation, suffering from relevant exhaustion and dyspnea (NYHA functional class III), due to valvular heart failure with preserved left ventricular function. Echocardiography revealed severe AR as the only valvular pathology.

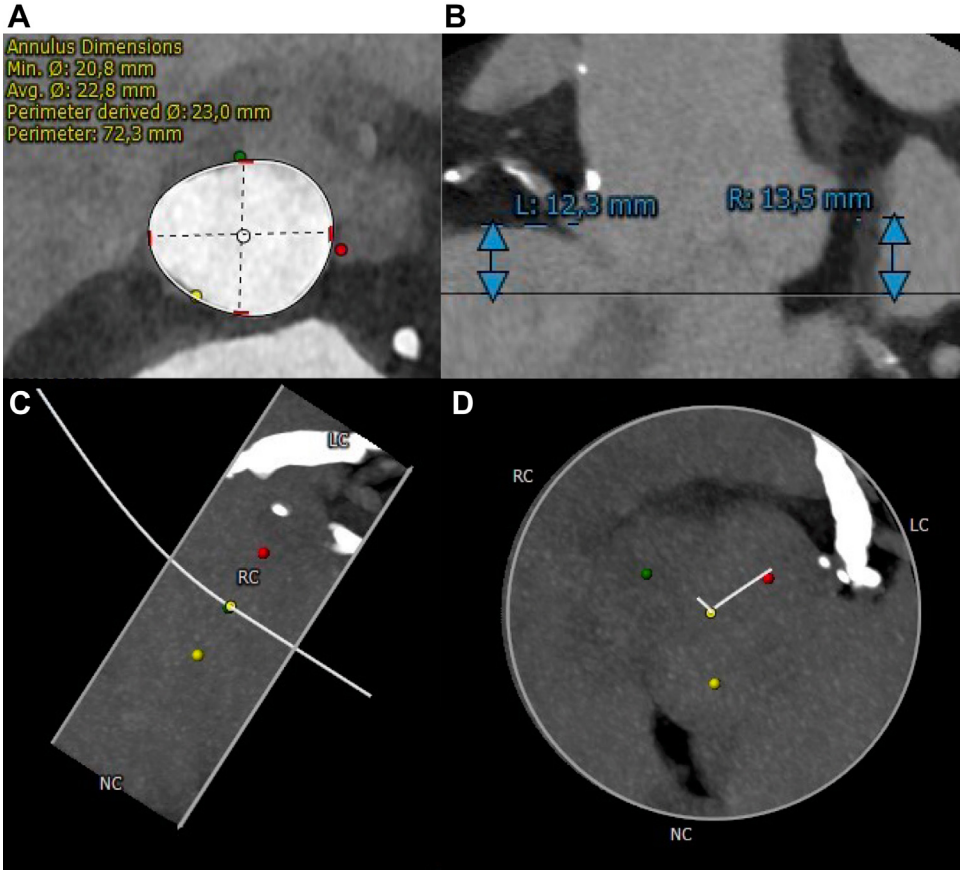
PAST MEDICAL HISTORY

The patient had a history of single-vessel coronary artery disease. Considering the pre-existing comorbidities (ie, peripheral arterial disease, chronic obstructive pulmonary disease [forced expiratory volume in 1 second/forced vital capacity: 67%, forced expiratory volume in 1 second: 65% of predicted value], history of heart failure hospitalizations, impaired mobility requiring a 4-wheeled-walker), EuroSCORE (European System for Cardiac Operative Risk Evaluation) II score of 6.81% (STS [Society of Thoracic Surgeons] score: 5.32%), and the patient's preference, the local heart team considered the patient not suitable for surgery and consensus was reached to perform TAVR using the self-expanding clippable device. Importantly, peripheral arterial disease had been treated with bi-iliac stenting, resulting in a Y-stenting of the aorto-iliac bifurcation.

DIFFERENTIAL DIAGNOSIS

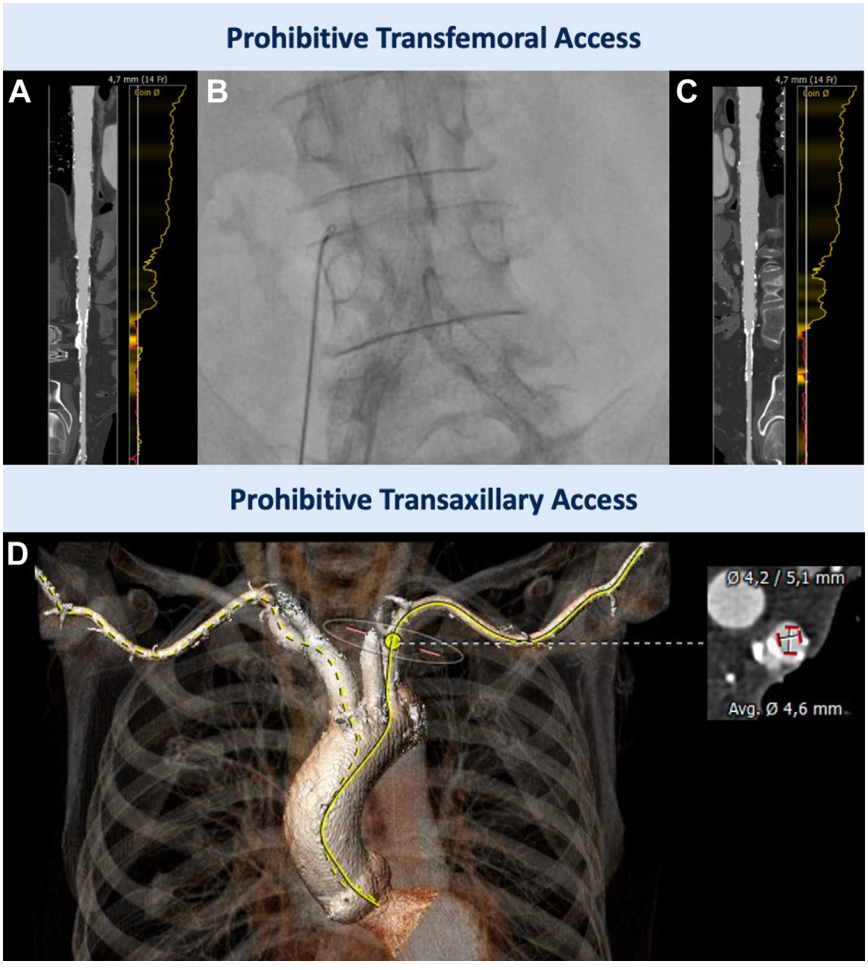
Left- and right-heart catheterization ruled out progression of coronary artery disease and the presence of relevant pulmonary hypertension, respectively.

FIGURE 1 Preprocedural Assessment



Aortic valve in transversal view (A), assessing the aortic root (B), and a hockey-puck projection (C, D), all highlighting the noncalcific aspect.

FIGURE 2 **Preprocedural Assessment of Access Sites**



Right (A) and left (C) iliac arteries, extremely narrowed due to the bi-iliac stented Y-prosthesis (B), prohibiting transfemoral access. Given the small profile of the subclavian artery, transaxillary access was also unfeasible (D).

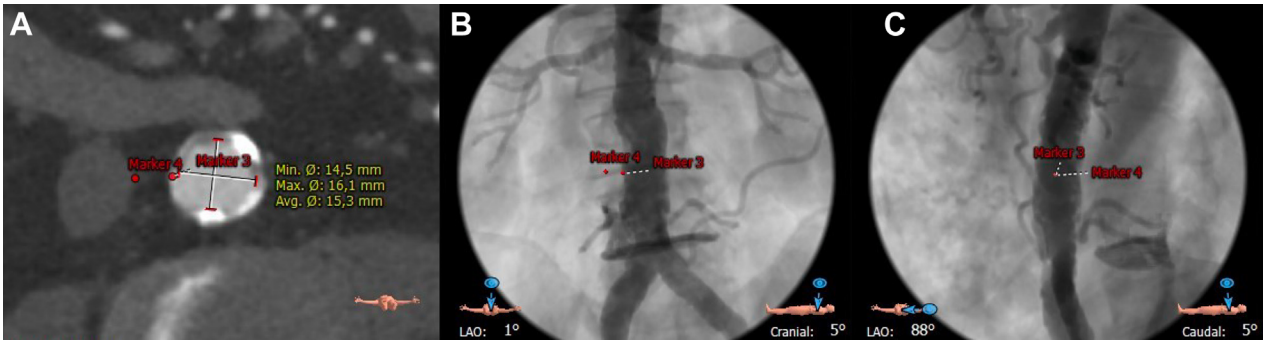
INVESTIGATIONS

Echocardiography showed severe AR (jet width/left ventricular outflow tract diameter: 87%) and confirmed preserved left ventricular dimensions with an ejection fraction of 52%. Given an aortic root dimension of 43 mm, a central coaptation gap of the 3 aortic valve leaflets, and an ascending aorta of 39 mm, AR was classified as secondary to aortic root expansion (Figure 1).

Computed tomography angiography showed unfeasible transfemoral access, primarily due to the previously implanted bi-iliac stents (Figure 2). A transaxillary approach was abandoned as vessel diameters on both sides were too small (4.6 mm) and calcified. Transcarotid access was considered suboptimal owing to moderate stenotic disease of the vessel potentially bearing an increased stroke risk, leaving a transcaval access as a reasonable option. Importantly, with the delivery system of the novel self-expanding clippable device, alternative access must be considered carefully because the valve is implanted via a preshaped and 85-cm-long extended sheath. The preshaped distal sheath part must be placed just above the sinotubular-junction (STJ). Transcaval access might therefore be favorable over other alternative accesses, mimicking transfemoral sheath placement.

To plan a transcaval approach, a calcium-free target zone on the right aortic wall was identified

FIGURE 3 Planning of Transcaval Access and Radiosurgical Crossover



Identification of an aortic puncture site free from calcium (A) and frontal (B) as well as lateral (C) angiographic views of the intended puncture site for transcaval crossover.

(**Figure 3**). The trajectory of the sheath at this location was free of interposed bowel tissue, and the identified aortic entry spot was far from crucial arterial branches, allowing bailout implantation of a covered-stent-graft if necessary.

MANAGEMENT

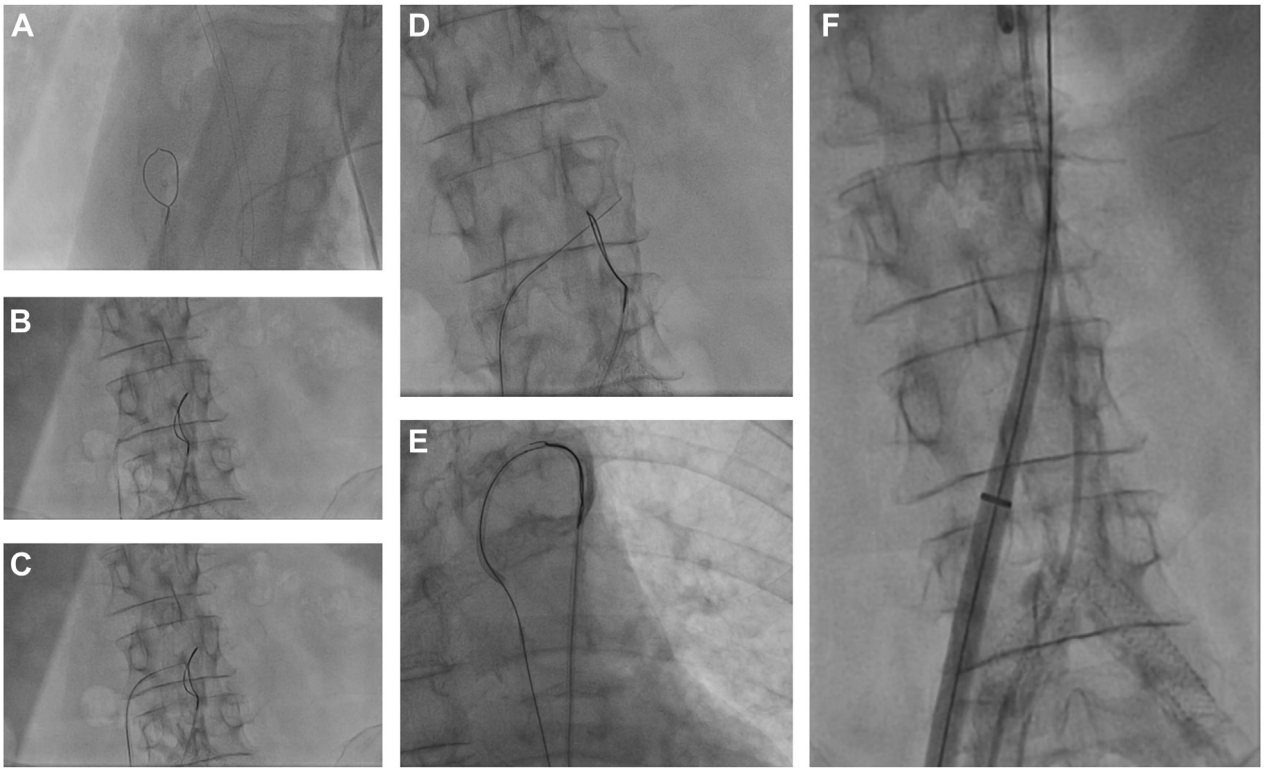
The supra-annular self-expanding clippable system comprises a self-expanding nitinol stent frame with a trileaflet porcine pericardial valve. Integrated "locators" attached to the valve frame are intended to sit at the bottom of each cusp and clip the self-expandable device onto the native valve leaflets. Owing to this anchoring mechanism, the self-expanding clippable system has been proven a reliable implant in pure, noncalcific AR.[3] Owing to the locators, correct commissural and axial alignment is automatically achieved, leading to a low risk for coronary obstruction. Transfemoral implantation has been proven feasible.[3] However, a transcaval implantation using the self-expanding clippable device has not been performed to date.

Heparin was administered for an activated clotting time >250 s. A loop snare (ONE Snare, Endovascular Snare System, 20 mm, Merit Medical Systems) was positioned in the aorta at the height of the previously identified calcium-free segment to serve as a target (**Figures 4A and 4B**, Video 1). Then a coaxial crossing system consisting of a 0.014-inch × 300 cm coronary guidewire (Astato XS 20, Asahi Intecc) inside a 0.035 inch × 145 cm wire convertor (Piggyback, Vascular Solutions), inside a braided 0.035-inch × 90 cm microcatheter (CXI Support Catheter, Cook Medical), all inside a 6-F, 55-cm renal guiding catheter (RDC, Cordis) was positioned in the vena cava as described before.[4]

After meticulous positioning of the caval guiding catheter toward the aortic snare, the coaxial crossing system was electrified using a monopolar electrosurgery pencil at 50 W during guidewire advancement across the vascular walls. Once snared, the guidewire and the snare were advanced toward the thoracic aorta (**Figures 4C and 4D**). The system was exchanged for a stiff guidewire (Back up Meier, 0.35 inches, 300 cm, Boston Scientific). The introducer sheath (Sentrant introducer sheath, 18-F, 28 cm, Medtronic) was then advanced from the femoral vein into the aorta (**Figure 4F**). After crossing the aortic valve and placement of a Safari wire in the left ventricle, the 18-F Sentrant sheath was exchanged to the 18-F equivalent long sheath of the self-expanding clippable device and placed just above the STJ. The delivery system with the loaded prosthesis (Trilogy-S, size 23) was advanced to the STJ. First the 3 locators were carefully maneuvered to the base of the aortic cusps (**Figure 5**, Video 2). After confirming correct anatomical alignment, the prosthesis was deployed under fast pacing at 120 beats/min. Angiographic control showed good valve placement and no sign of paravalvular leakage.

Prior to closure of the iatrogenic aortocaval connection, the sheath of the self-expanding clippable device was exchanged for the 18-F Sentrant sheath once again. Heparin was reversed with protamine and a soft buddy 0.014-inch guidewire (Asahi Sion blue) was advanced into the aorta through the

FIGURE 4 Transcaval Crossover From Vena Cava to Abdominal Aorta



A loop snare positioned in the aorta and a crossing system placed in the vena cava (A,B). The electrified wire was advanced toward the abdominal aorta (C), where it was snared (D). The snared system was exchanged for a stiff guidewire and the delivery system of the self-expanding clippable device was advanced using the established transcaval access (E, F).

Sentrant sheath. A nitinol duct occluder (Amplatzer Duct Occluder, 12 mm, Abbott Laboratories) was inserted through a deflectable catheter (Agilis NxT dual Reach, Abbott Laboratories). Both were advanced just outside the Sentrant sheath that was then removed fully inside the vena cava. The occluder was turned horizontally and carefully deployed alongside the aortic wall (**Figures 6A to 6C**). Aortic angiography showed a remaining aortocaval fistula that was intentionally accepted, because it resembled no retroperitoneal bleeding.

DISCUSSION

This report describes the first case of transcaval access to treat pure AR with a dedicated self-expanding clippable device, resulting in excellent mid-term outcomes.

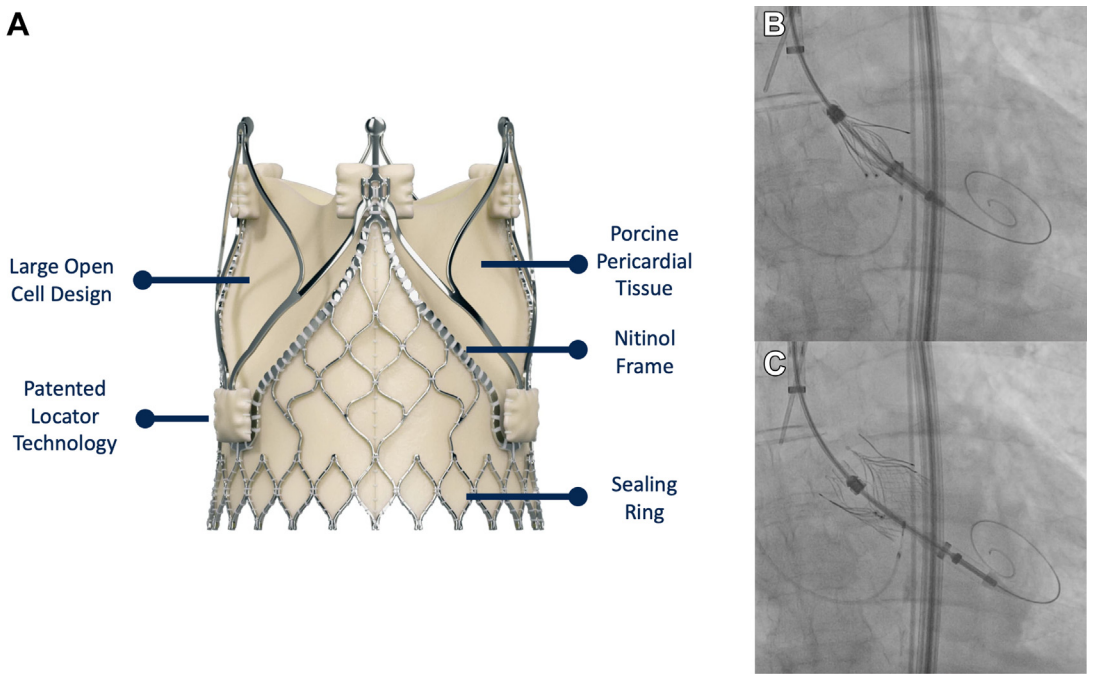
The transcaval approach was recently introduced as safe alternative access option, with low risk of stroke, transient ischemic attack, and similar rates of bleeding compared to an axillary access in the setting of TAVR for AS.[4] The self-expanding clippable device was developed for transfemoral delivery; however, the feasibility of the system even in absence of retrograde arterial access options by a transcaval approach addresses the versatility of newer dedicated devices.

The minimum access size for this self-expanding clippable system is 18-F, and the delivery sheath needs to be advanced across the aortic arch down to the STJ prior to advancing the unique locators just above the valvular cusps. Hence, it is important to know that handling and rotating of the device as well as sheath placement was not impaired by transcaval access.

The device is available in 3 sizes (small, medium, and large) covering an annular perimeter from 66 to 85 mm, and an annular diameter from 21 to 27 mm, currently limiting applicability in larger anatomies.

Nevertheless, with cavoaortic transition in even more calcified or tortuous anatomies,

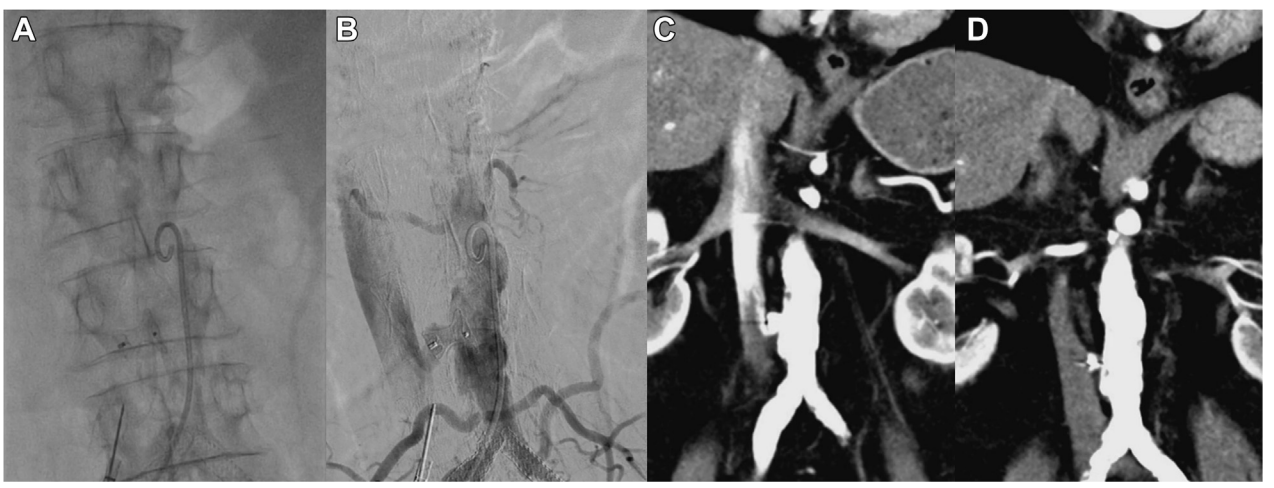
FIGURE 5 Successful Placement of the Self-Expanding Clippable Device Using Transcaval Access



The system allows for placement in noncalcific pure aortic regurgitation (A). Using a transcaval access, the system was positioned above the aortic valve (B). It was then released, clipping itself to the valve using the dedicated locator mechanism (C).

maneuverability of the delivery device may technically be impaired. Importantly, patients with AR often present with more tortuous and dilated aortas than AS patients do, which may also be challenging for transcaval access. Additionally, more experience is needed in occluder closure of aortocaval fistulas in patients with AR. In addition, the need for large-bore 18-F access with this self-expanding clippable device

FIGURE 6 Closure of Transcaval Crossover



The transcaval puncture site was closed using a duct occluder (A), resulting in mild residual leakage (B, C), which fully resolved at 30-day follow-up (D).

includes 2 exchanges from a shorter sheath to the actual sheath of the system and vice versa. This might imply higher bleeding and rupture risks and needs to be carefully evaluated.

FOLLOW-UP

The patient presented for 3-month follow-up, reporting a substantial relief of symptoms and significant improvement in quality of life. Importantly, repeated computed tomography angiography revealed full closure of the aortocaval fistula (**Figure 6D**).

CONCLUSIONS

This first-in-human transcaval TAVR procedure for pure AR, using a dedicated self-expanding clippable system, demonstrates the feasibility of such approach. Transcaval access may further broaden the applicability of TAVR for AR. Therefore, research should be promoted to detect relevant particularities for this access in AR.

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KEY WORDS alternative access, aortic regurgitation, electrosurgery, TAVR, transcaval

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