CASE REPORT

# Achieving Accurate Valve Deployment in Complex Anatomies

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The Portico valve (Abbott) is a transcatheter, self-expanding, resheathable device with intra-annular positioning of the bovine leaflets, which has proven safety and performance in several studies.[1,2] The major advantages of this device include its low profile and flexibility, making it easier to overcome potential challenges related to tortuous and calcified vessels, as well as horizontal aortic anatomy. The next-generation delivery system (FlexNav, Abbott) recently took its first step into the clinical arena, offering additional improvements in deliverability and accurate valve deployment in complex anatomies.

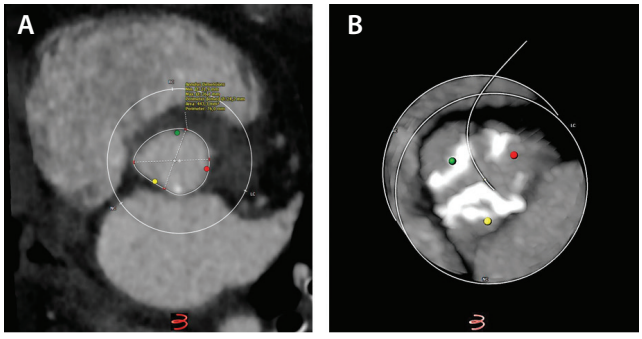


**Figure 1. Aortic annulus dimensions (A) and "hockey-puck" view of valvular calcifications (B).**

## PATIENT PRESENTATION

An 81-year-old woman was referred for evaluation of a severe symptomatic aortic stenosis that was detected several months ago but her symptoms rapidly progressed. The patient reported exertional dyspnea (New York Heart Association [NYHA] class III) that limited daily activities that she had previously undertaken without problems. Her clinical history included systemic hypertension, chronic obstructive pulmonary disease, recurrent pyelonephritis, and previous deep vein thrombosis and stroke. Moreover, the patient had undergone left mastectomy and radiation therapy for breast cancer and subsequent reoperation for relapse.

Her physical examination revealed obesity (body mass index, 31.1 kg/m$^2$) but no signs of cardiac decompensation or renal impairment. An electrocardiogram (ECG) showed normal sinus rhythm. A transthoracic echocardiogram confirmed the diagnosis of severe calcific aortic stenosis (peak gradient, 95 mm Hg; mean gradient, 64 mm Hg; aortic valve area, 0.6 cm$^2$) with preserved left ventricular ejection fraction but concentric left ventricular hypertrophy. The coronary arteries showed mild atherosclerotic disease without obstructive lesions.

## TREATMENT SELECTION

The case was discussed in the multidisciplinary heart team meeting. Taking into consideration the overall risk profile (age, obesity, lung disease, previous thoracic radiation therapy), the patient was scheduled for transcatheter aortic valve implantation (TAVI).

The preprocedural CT scan showed an elliptical aortic annulus with a perimeter-derived diameter of 24.2 mm, valvular calcifications (Figure 1), and horizontal aortic angulation (Figure 2). The abdominal aorta and aortic arch were calcified, but the iliofemoral vessels were otherwise deemed suitable for a transfemoral approach (Figure 3). Due to the calcified aortic arch and horizontal aorta, the flexible Portico transcatheter heart valve (THV) was chosen and delivery was planned with the FlexNav system.

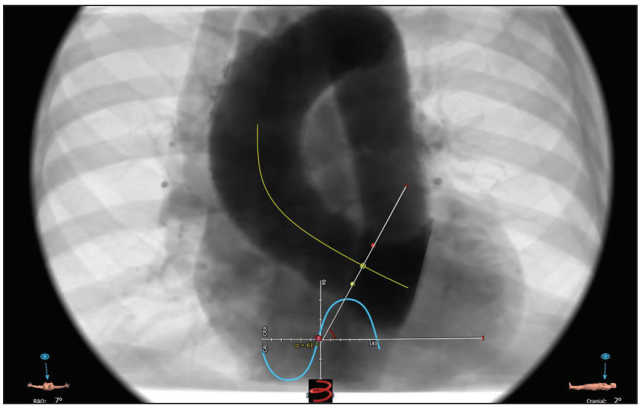

**Figure 2. Aortic root angulation.**

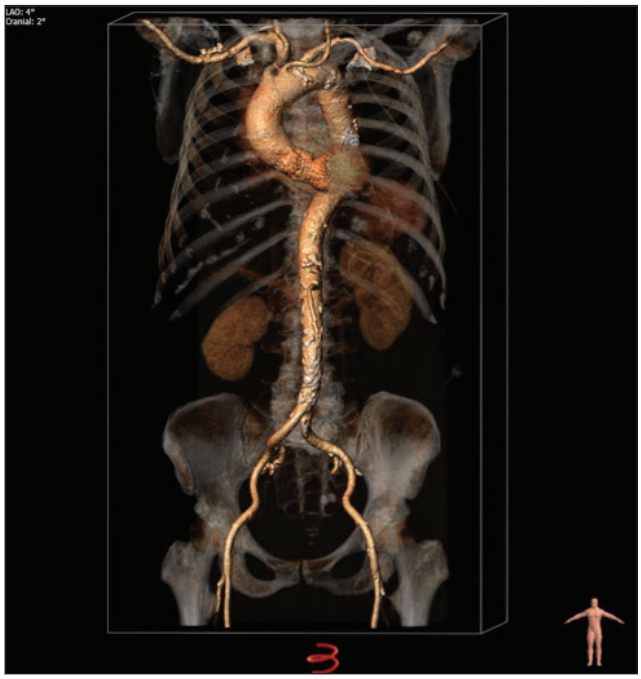

**Figure 3. A three-dimensional volume-rendering reconstruction of the aorta and iliofemoral vessels.**

## PROCEDURE DESCRIPTION AND RESULTS

The procedure was performed using local anesthesia and without sedation. The right femoral artery was chosen as the access route for the THV system. After establishing vascular access in the common femoral artery, a 14-F sheath was inserted over a stiff guidewire. The aortic valve was then crossed with an Amplatz left 2 catheter and a straight standard guidewire. Next, a preshaped stiff guidewire (Safari2, Boston Scientific Corporation) was placed in the left ventricle and predilatation was performed with a 22-mm True balloon (BD Interventional). Subsequently, a 27-mm Portico THV was loaded in the FlexNav delivery system, the 14-F sheath was removed, and the FlexNav delivery system was introduced using the integrated sheath. The flexibility of the delivery system allowed safe passing of the calcified aortic arch, as well as coaxial alignment in the aortic annulus. The Portico THV was successfully deployed without the need for pacing or repositioning. The final aortogram showed only trace paravalvular leak (Figure 4). The ipsilateral arterial access site was successfully closed with a Manta device (Teleflex). An ECG revealed unchanged normal sinus rhythm, and the temporary pacing lead was therefore removed at the end of the procedure. No procedural complications occurred, and the total procedural time was 90 minutes, including 45 minutes of skin-to-skin time.

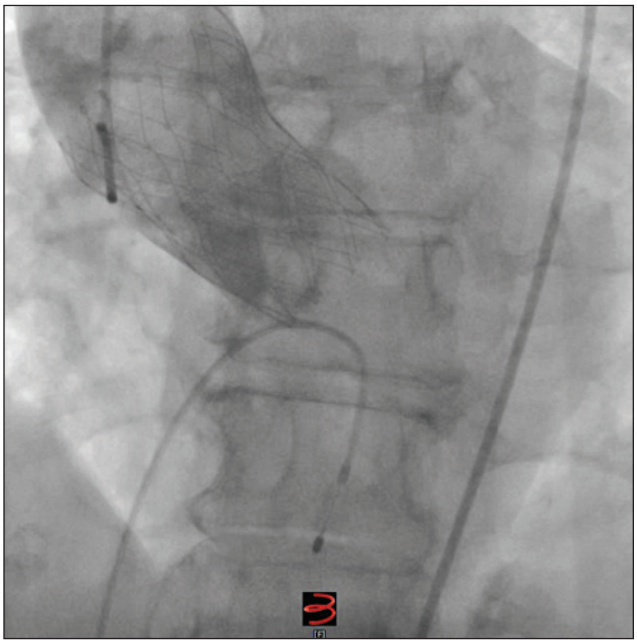

**Figure 4. Final aortogram after implantation of the Portico THV.**

The patient was discharged to home 48 hours after the procedure. A predischarge echocardiogram showed favorable prosthesis performance (mean gradient, 6 mm Hg; effective orifice area, 2.5 $cm^2$) and absence of paravalvular leakage.

At 30-day follow-up, the patient reported a marked improvement in clinical symptoms (NYHA class I), with progressive resumption of normal everyday activities.

## DISCUSSION

TAVI is currently playing an increasing role in the treatment of symptomatic severe aortic stenosis. During

the last decade, the technological evolution and increased learning experience has facilitated streamlining the procedures and simplifying the overall clinical course. This even applies to high-risk patients with diseased peripheral vessels, horizontal aorta, and aortic annulus with unfavorable anatomy. Particularly in these often elderly patients with several comorbidities, it is mandatory to avoid complications that may not only prolong the hospital stay but also trigger a vicious cycle of clinical deterioration. Historically, vascular complications and bleeding have confounded the TAVI journey, leading to increased morbidity and mortality.[3] The presence of a horizontal aorta represents a challenge for accurate THV placement, especially with less flexible systems.[4] Finally, the presence of an elliptic aortic annulus may represent an additional challenge in the setting of self-expandable heart valves.[5]

This high-risk case demonstrates how the development of a new-generation THV system with a low insertion profile and high flexibility allows a simple and safe procedure with accurate THV placement, even in cases with challenging anatomic features. Thus, the Portico THV system allows passage even through severely tortuous and calcified peripheral vessels and overcomes the challenges of unfavorable aortic root angulations. The next-generation FlexNav delivery system promises further enhancement of such features, offering an integrated sheath and a hydrophilic coating. The outcomes of the ongoing FlexNav European Union CE Mark study (NCT03724812) and FlexNav arm of the Portico United States investigational device exemption trial (NCT02000115) will provide information about the safety and efficacy of the new-generation Portico delivery system in larger patient cohorts. ■

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*Disclosures: Consultant fees and institutional research grants from Abbott.*