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Case Report

Zero-contrast Balloon-expandable Transcatheter Aortic Valve Implantation With Embolic Protection in Pure Aortic Regurgitation

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Transcatheter aortic valve implantation (TAVI) in pure aortic regurgitation (AR) remains challenging. The Trilogy valve (JenaValve, Irvine, CA) is currently the only approved device for this indication, but restricted to specific annular dimensions. In anatomically challenging situations, alternative options may be considered, albeit off-label.[1] The present case describes the use of a balloon-expandable Myval OctaPro (Meril Life Sciences, Vapi, India) transcatheter heart valve (THV) in a high-risk patient with a very large annulus and a floating valvular structure requiring full embolic protection and a zero-contrast strategy due to manifest hyperthyroidism.

A 63-year-old man was admitted for severe symptomatic AR with recurrent heart failure hospitalizations. Auscultation revealed a faint diastolic heart murmur, and diastolic blood pressure was low (120/50 mm Hg). On electrocardiography, a first-degree atrioventricular block and left bundle branch block were noted. Echocardiography demonstrated a severe AR with a floating structure at the right coronary cusp—most likely of degenerative origin (Fig. 1). Repeated blood cultures were negative, and positron emission tomography scan ruled out any hypermetabolic activity in the aortic area. Left ventricular ejection fraction was preserved, and moderate mitral regurgitation was present. Preprocedural computed tomography angiography showed a large aortic root (systolic annulus area 677 mm^2) without any calcification (Fig. 1); coronary artery disease was ruled out and transfemoral access was considered feasible. Due to limiting comorbidities, including advanced malignancy and frailty, surgical aortic valve replacement was considered prohibitive (Society of Thoracic Surgeons score 2.5%) and, after heart team evaluation, the patient was considered a candidate for TAVI.

The annulus size was out of range for the Trilogy system,[2] so off-label use of the OctaPro 32-mm THV was considered a suitable option, with an acceptable risk of ventricular migration due to the flared left ventricular outflow tract shape.[3] Regarding the floating structure, compassionate use of a full-body embolic protection device (Emboliner; Emboline, Inc, Santa Cruz, CA; investigational—not approved for clinical use) was undertaken. At admission, manifest hyperthyroidism persisted despite thyreostatic therapy. Given the urgency of the intervention, a zero-contrast strategy was chosen to minimize potential complications.

The procedure was performed under mild analgosedation and local anesthesia. Ultrasound-guided vascular access was obtained in both femoral arteries. We inserted 0.035-inch J-tip wires in each cusp to verify the coplanar view (Fig. 2, A and B). The Emboliner system was positioned in the ascending aorta through the left femoral access (Fig. 2C). The OctaPro 32-mm system was introduced via a 14Fr Python sheath in the right groin and was advanced through the protection device (Fig. 2D) over a Safari S-wire (Boston Scientific, Marlborough, MA). After positioning in the aortic annulus (Fig. 2E), the valve was deployed under rapid pacing with an additional +5-mL volume (Fig. 2F; Video 1, view video online), corresponding to 25% oversizing. Immediately after hemodynamic recovery, postdilatation with the same filling volume was performed to ensure

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See page 721 for disclosure information.

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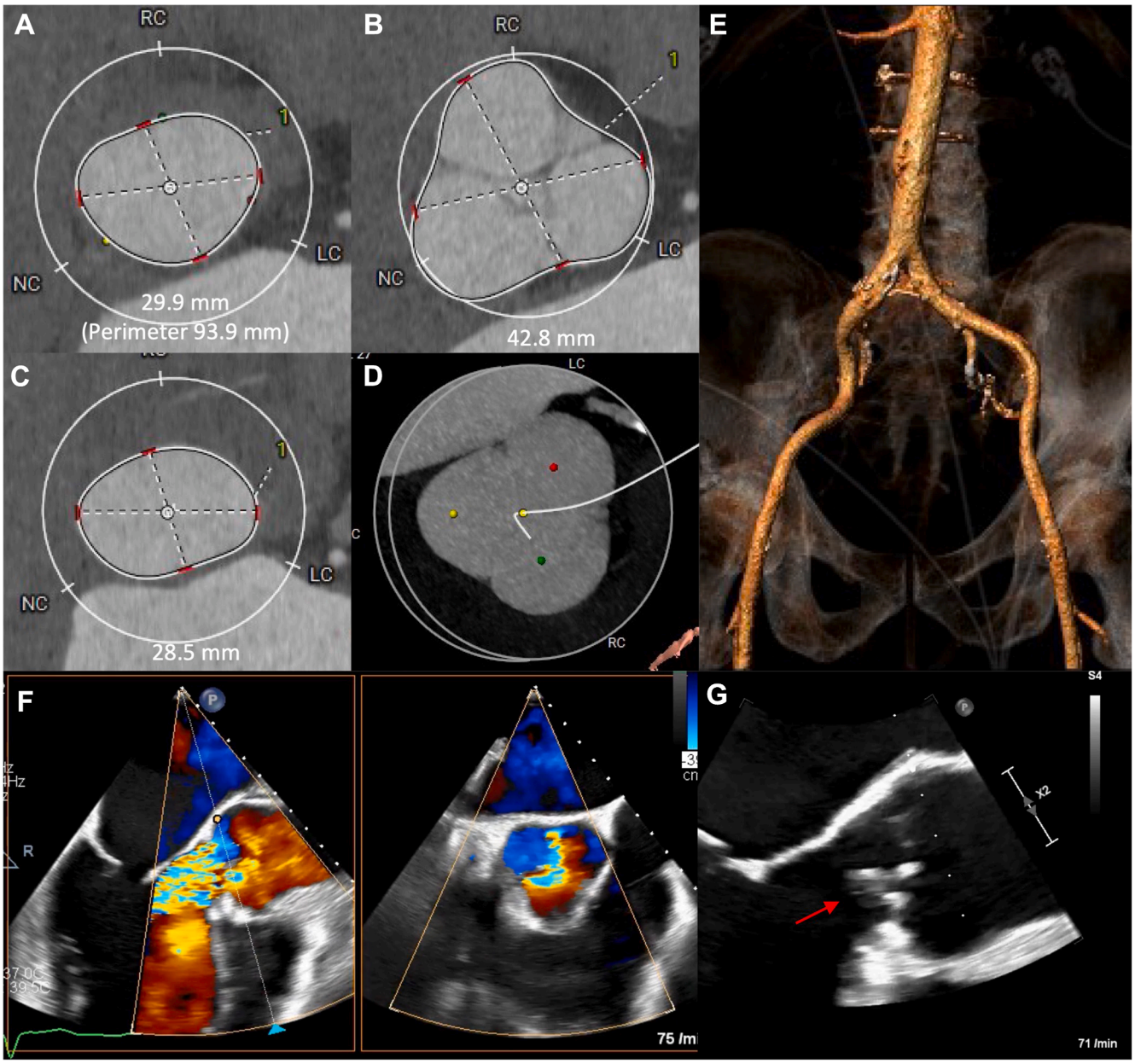

Figure 1. Preprocedural work-up. Computed tomography shows the (**A**) annulus, (**B**) sinus of Valsalva, (**C**) left ventricular outflow tract, (**D**) aortic root without any calcification, and (**E**) femoral access route. Transesophageal echocardiography shows severe aortic regurgitation (**F**) and a floating structure at the right coronary cusp (**G**) (**red arrow**).

optimal frame expansion (double tap). The prosthesis remained in a stable position at an implantation depth of 6 mm. Pressure tracings showed no transaortic gradient (Fig. 2G), and there was no residual AR on echocardiography.

On the second postoperative day, echocardiography showed a mean gradient of 8 mm Hg and no relevant AR, but left ventricular ejection fraction was now moderately decreased, presumably due to worsening left bundle branch block and omission of the severe AR. Thus, guideline-directed medical therapy was established. After 5 days, high-degree atrioventricular block occurred requiring permanent pacemaker implantation. The hospitalization was furthermore prolonged due to intercurrent cardiac decompensation and infections requiring antibiotic therapy, but the patient subsequently recovered and was discharged home in stable condition.

Discussion

This case illustrates 3 key aspects: the feasibility of balloon-expandable TAVI for pure AR in a very large annulus; the first reported use of full embolic protection in this setting; and the application of a zero-contrast strategy in the context of manifest hyperthyroidism.

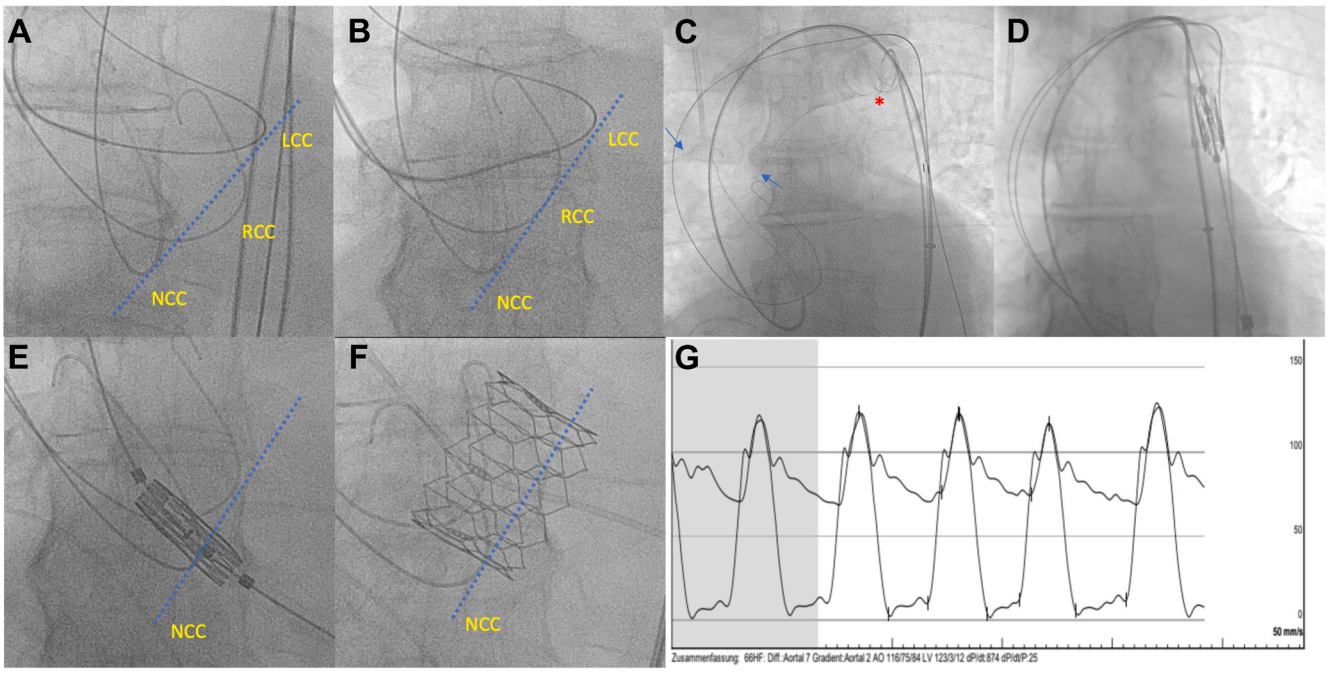

Figure 2. Procedure. Verification of the 3-cusp view by placement of 0.035-inch J-wires in each cusp; the right coronary cusp (RCC) was too low. After adjustment of the angulation, the 3-cusp view was appropriate (**B**). Insertion of the Emboliner system (**C**) shows good apposition of the mesh (blue arrows) in the ascending aorta. Advancement of the valve system across the access port (**red asterisk** in **C** and **D**). With positioning in the annulus, the wire in the noncoronary cusp (NCC) serves as a landmark (**E**). Final valve position (**F**) and pressure tracings (**G**).

The feasibility of balloon-expandable TAVI for pure AR has been demonstrated in observational series including follow-up data of at least 1 year for both the SAPIEN 3 device (Edwards Lifesciences, Irvine, CA) in annuli up to 605 mm^2 and the Myval system in annuli up to 840 mm^2.[4,5] Hence, both platforms may represent alternative options in high-risk patients not suitable for the Trilogy THV, yet feasibility in noncalcified AR with annuli exceeding 605 mm^2 has only been reported for the Myval system. The off-label use of balloon-expandable devices, however, is associated with a slightly higher embolization risk compared with the Trilogy (5%-10% vs 3%), although this risk appears negligible in the presence of a flared left ventricular outflow tract shape.[3,5]

Notably, this is the first ever reported TAVI for pure AR combined with full embolic protection—also demonstrating the compatibility of the Myval THV with the Emboliner system. Although no visible debris was captured by the filter, its use was mandatory given the unclear origin and nature of the floating structure. The full coverage of all supra-aortic branches and the entire distal vasculature made it preferable over the Sentinel system.

Finally, this case suggests that zero-contrast TAVI using balloon-expandable THVs for pure AR may be feasible. Only a few case series with zero-contrast TAVI approaches have been reported, but those studies exclusively used self-expanding THVs in chronic renal failure and not in the context of hyperthyroidism, which precluded the use of contrast agent.

Ethics Statement

The research reported has adhered to the relevant ethical guidelines.

Patient Consent

The authors confirm that patient consent has been obtained for this article.

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Disclosures

The authors have no conflicts of interest to disclose.

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Supplementary Material

To access the supplementary material accompanying this article, visit the online version of the *Canadian Journal of Cardiology* at www.onlinecjc.ca and at https://doi.org/10.1016/j.cjca.2025.10.034