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MINI-FOCUS ISSUE: PROCEDURAL COMPLICATIONS: PART 2

ADVANCED

CASE REPORT: CLINICAL CASE

Sapien 3 Embolization From Ventricle to Aorta in the Setting of Noncalcified Aortic Regurgitation

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ABSTRACT

Transcatheter aortic valve replacement is currently used off-label for noncalcified aortic valve regurgitation and therefore is restricted to selected cases. In this setting we describe a rare complication of Sapien 3 (Edwards Lifesciences, Irvine, California) embolization from the left ventricle to the descending aorta. Given their technical challenges, such procedures require specific considerations and management. (**Level of Difficulty: Advanced.**) (J Am Coll Cardiol Case Rep 2021;3:64–8) © 2021 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/).

A 70-year-old woman was admitted for acute dyspnea. The patient was stable hemodynamically, but she presented with signs of left-sided heart failure with a holodiastolic murmur at the right sternal border.

PAST MEDICAL HISTORY

The patient had obesity and metabolic syndrome. She had undergone percutaneous revascularization 1 year earlier for silent coronary artery disease with preserved left ventricular (LV) ejection fraction.

LEARNING OBJECTIVES

- To understand the major role of appropriate BE valve oversizing, in inoperable patients with severe regurgitation and a noncalcified valve who are undergoing transcatheter aortic valve replacement.
- To be able to evaluate treatment options for an embolized BE valve in the left ventricle and in the aorta.

INVESTIGATIONS

A transthoracic echocardiogram showed a severely reduced LV ejection fraction of 20% in the setting of LV dilation up to 68 mm that was complicating massive aortic regurgitation (AR). A subsequent transesophageal echocardiogram showed a tricuspid aortic valve with right coronary leaflet prolapse without other associated lesions (Video 1).

MANAGEMENT

The patient was in theory eligible for a single surgical aortic valve replacement, but her condition was finally considered inoperable. Therefore, the heart team decided to adopt a percutaneous approach. A

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pre-operative computed tomography scan demonstrated an aortic annulus area of 443 mm^2, without any calcification (**Figure 1**).

Transfemoral transcatheter aortic valve replacement was performed with a balloon-expandable (BE) bioprosthesis (Edwards Sapien 3, 26 mm, Edwards Lifesciences, Irvine, California). Loss of capture during rapid pacing required emergency device repositioning before full inflation to a nominal diameter (Video 2). Given the low implantation height (**Figure 2A**) and the unsatisfactory bioprosthesis shape, post-dilation with 2 ml additional volume was achieved (Video 3). A few minutes after stiff wire removal, intraprocedural echocardiography (**Figure 2B**) showed progressive migration of the device until complete embolization in the left ventricle (**Figures 2C and 2D**). Despite the acute complication, the patient's hemodynamics remained stable while she was under conscious sedation. Because of the formal contraindication to cardiac surgery, the interventional approach was maintained without mechanical assistance.

The first step consisted of recapturing the valve to reposition it into the LV outflow tract to enable the subsequent implantation of a larger device. This was attempted by re-crossing the wire into the valve, underinflating a Z-MED II 28-mm valvuloplasty balloon (Numed Inc., Hopkinton, New York) inside the stent, and retrieving the valve gently. The bioprosthesis was successfully placed into the initial part of the LV outflow tract, but partially upside down. Moving forward could not be achieved because of insufficient support. As a result of hemodynamic disruption, the guidewire was retrieved, and when trying to re-cross, the device jumped into the aorta and stopped in an inverted position just after the origin of the left subclavian artery (**Figures 2E and 2F**). At this point, the patient was intubated, and inotropic drugs were administered. Blood flow to the lower part of the body was compromised, and despite the use of a snare to reorient the device, it was still partially obstructing the aortic cross. As a first step, we decided to restore favorable hemodynamic conditions by treating the AR. An Edwards Sapien 3 29-mm valve at a nominal diameter was implanted on an emergency basis by passing through the valved portion of the first device. The final result was satisfactory, with

ABBREVIATIONS AND ACRONYMS

AR = aortic regurgitation
BE = balloon-expandable
LV = left ventricular
SE = self-expandable

FIGURE 1 **Computed Tomography Scan Showing the Aortic Annulus Measurement**

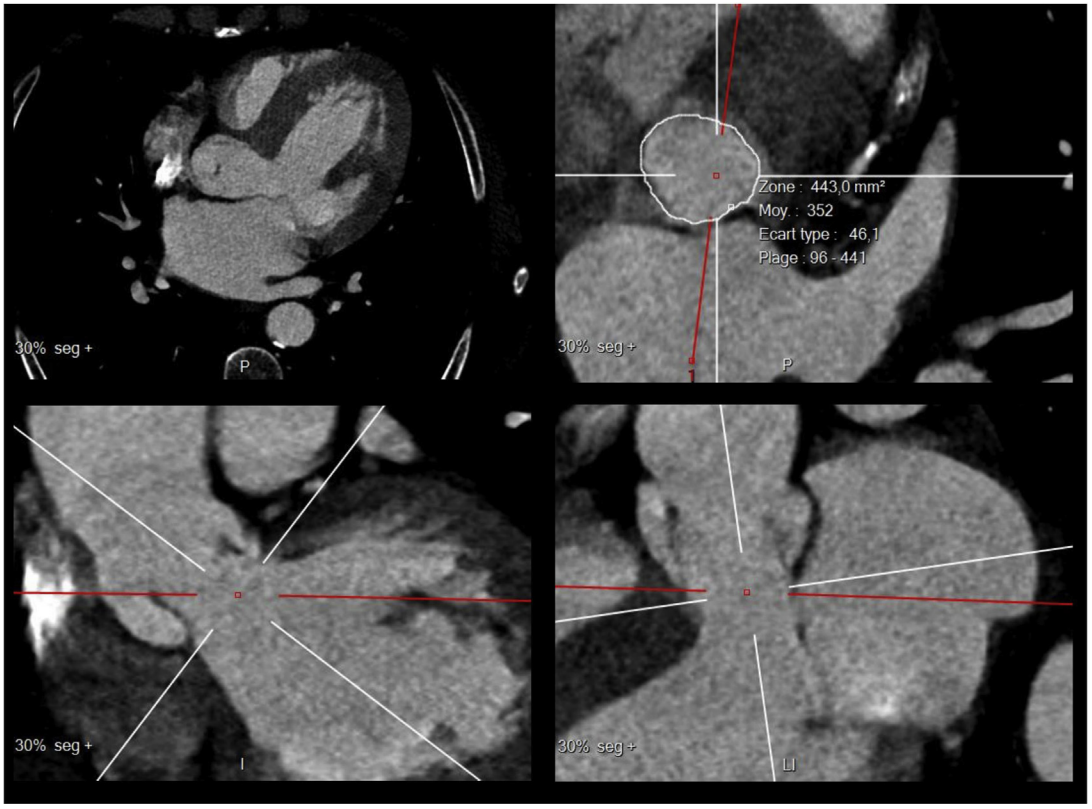

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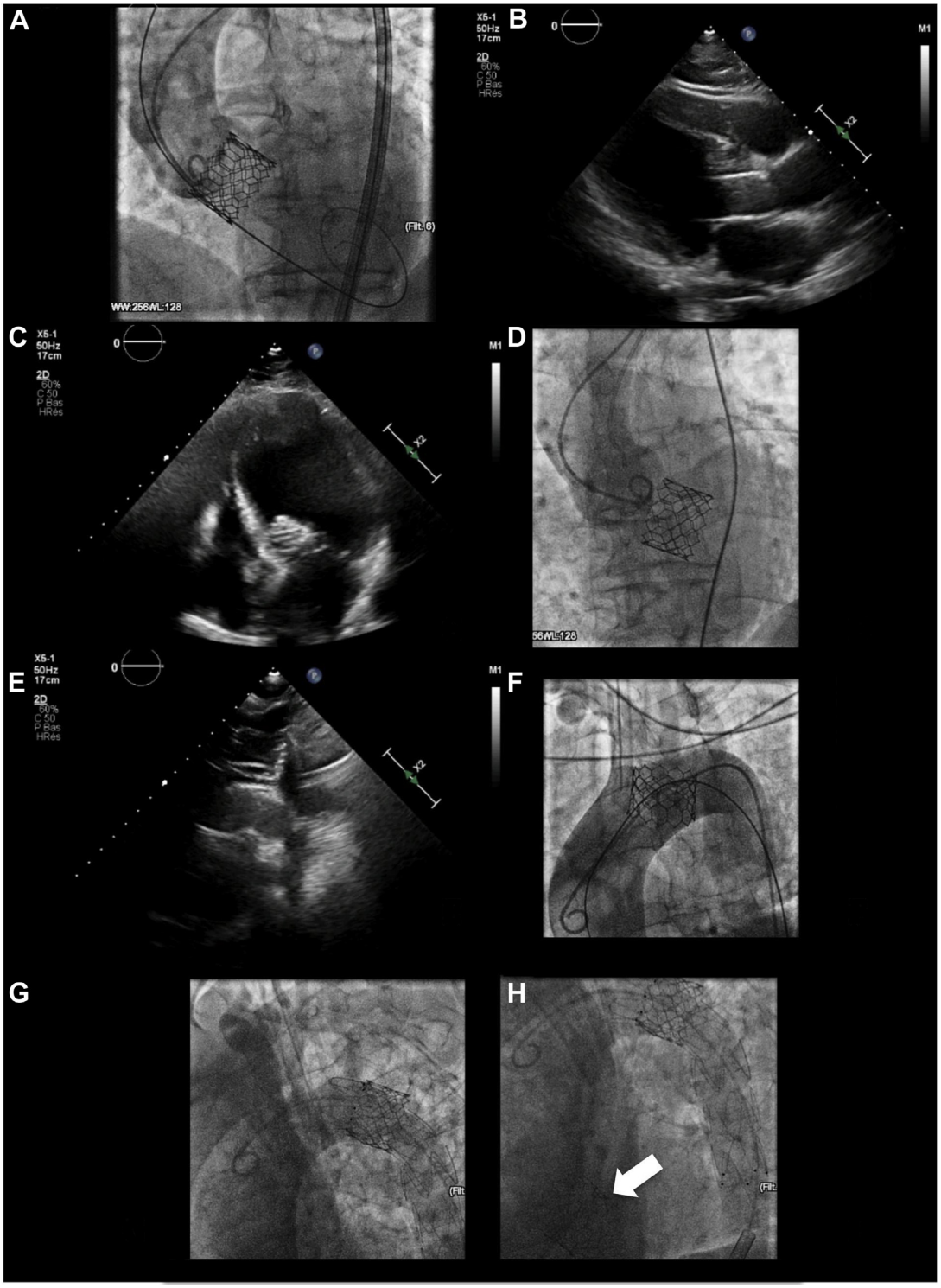
FIGURE 2 Echocardiography and Angiography Illustrating Progressive Embolization of the Sapien 3 26-mm Valve and its Subsequent Management



(A) Initial low implantation height. **(B)** Device migration. **(C and D)** Subsequent left ventricular embolization. **(E and F)** Embolization in the descending aorta. **(G)** Endovascular graft implantation. **(H)** Final result showing the Edwards Sapien 3 29-mm valve (Edwards Lifesciences, Irvine, California) in the aortic annulus **(arrow),** with the Sapien 26-mm device distally in the descending aorta, covered by the endovascular graft.

no residual regurgitation (Video 4). As a second step, a Zenith Alpha Thoracic Endovascular Graft 26 X 105 mm (Cook Medical, Bloomington, Indiana) was placed and deployed inside the Edwards Sapien 3 26-mm valve, thereby relieving the obstruction efficiently (**Figures 2G and 2H**).

DISCUSSION

The incidence of device migration or embolization in the setting of pure native AR has been reported to be up to 19.7% (1), greatly exceeding the embolization rate of 0.1% for aortic stenosis (2). Excessive oversizing and undersizing have been suggested to induce a higher risk of such complications, particularly regarding self-expandable (SE) devices (1). In some cases, an association has also been observed between procedural success and the degree of aortic valve calcification: the less the calcification, the worse the final result (3). Both findings highlight the complexity of accurate device sizing in the situation of a paucity of annular calcification, thus further compromising the correct anchoring of the transcatheter valves. Therefore, to limit device malpositioning and postprocedural AR, a specific oversizing cutoff of 15% or more has been proposed for SE devices (3) and for BE valves (4) by using up to 3 ml additional volume. In our case, the Edwards 26-mm device deployed with 2 ml additional volume and the 29-mm device at a nominal diameter corresponded to 29% and 49% oversizing, respectively. This underlines the unpredictable annular distensibility, which may require, in some cases, higher oversizing rates than those recommended to provide reliable anchoring. Device dimension is not the only factor to be considered in the occurrence of embolization. The increased stroke volume caused by AR, the low implantation height favored by the absence of fluoroscopic calcific landmarks, and pacing failure are other well-known risk factors. Identifying these risk factors is particularly useful to adopt some precautions after valve implantation, such as a prolonged observation time without removing the wire to avoid valve inversion in case of embolization and to allow subsequent balloon recapture maneuvers.

Once bioprosthesis embolization has occurred, its management calls for specific considerations. LV dislodgment is almost exclusively observed with the BE devices because the design of the SE valves precludes their complete migration below the aortic annulus (5). Conversion to surgery is the usual treatment in this situation, although only rare cases of balloon or snare-mediated repositioning have been reported (6–8). The aortic position accounts for the majority of device embolizations; however, recapturability of the newer generation of SE valves decreases this risk considerably. A percutaneous approach, by pulling the valve in a more distal, branch-free segment, is the most commonly attempted treatment. Such bailout measures require the use of balloons, snares, or bioptomes that may expose patients to a higher risk of vessel injury (9). The rare situations of valves embolizing upside down in the aorta require emergency intervention to release obstruction (10). For the first time, we report the use of a thoracic endovascular graft to restore hemodynamic conditions safely in that setting.

FOLLOW-UP

The patient required prolonged mechanical ventilation with inotropic support, and she had multiple complications, such as complete atrioventricular block, right limb ischemia, and ischemic stroke.

CONCLUSIONS

Despite recommended oversizing, embolization of the BE valve is still possible, even from the ventricle to the aorta, with the risk of malposition and obstruction. Given the increased annular distensibility of noncalcified valves, bioprosthesis sizing is challenging and requires further studies to assess the benefit of greater oversizing.

We report here the first case of thoracic endovascular graft implantation for an obstructive embolized BE valve in the descending aorta.

AUTHOR DISCLOSURES

The authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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REFERENCES

1. De Backer O, Pilgrim T, Simonato M, et al. Usefulness of transcatheter aortic valve implantation for treatment of pure native aortic valve regurgitation. Am J Cardiol 2018;6:1028–35.

2. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. N Engl J Med 2016;17:1609–20.

3. Yoon S-H, Schmidt T, Bleiziffer S, et al. Transcatheter aortic valve replacement in pure native aortic valve regurgitation. J Am Coll Cardiol 2017; 22:2752–63.

4. Urena M, Himbert D, Ohlmann P, et al. Transcatheter aortic valve replacement to treat pure aortic regurgitation on noncalcified native valves. J Am Coll Cardiol 2016;15:1705–6.

5. Kim W-K, Schäfer U, Tchetche D, et al. Incidence and outcome of peri-procedural transcatheter heart valve embolization and migration: the TRAVEL registry (TranscatheteR HeArt Valve EmboLization and Migration). Eur Heart J 2019; 38:3156–65.

6. Makkar RR, Jilaihawi H, Chakravarty T, et al. Determinants and outcomes of acute transcatheter valve-in-valve therapy or embolization. J Am Coll Cardiol 2013;5:418–30.

7. Dumonteil N, Marcheix B, Grunenwald E, Roncalli J, Massabuau P, Carrié D. Left ventricular embolization of an aortic balloon-expandable bioprosthesis. J Am Coll Cardiol Intv 2013;3: 308–10.

8. Tiroch K, Schleiting H, Karpettas N, et al. How should I treat dislocation of a TAVI SAPIEN prosthesis into the left ventricle? EuroIntervention 2015;11:1370–2.

9. Alkhouli M, Sievert H, Rihal CS. Device embolization in structural heart interventions. J Am Coll Cardiol Intv 2019;2:113–26.

10. Fankhauser CD, Nietlispach F, Emmert MY, Maisano F. Antegrade valve embolization after transcatheter treatment for pure aortic regurgitation. Eur Heart J 2016;10:856.

KEY WORDS device embolization, native pure aortic regurgitation, transcatheter aortic valve replacement

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