The Texas Heart Institute® Journal

Case Reports

Successful Management of Myval Transcatheter Heart Valve Embolization Into Abdominal Aortic Aneurysm During Transcatheter Aortic Valve Replacement

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Abstract

Transcatheter heart valve embolization is a serious and rare complication of transcatheter aortic valve replacement. Having a strategy for promptly managing transcatheter heart valve embolization is crucial to avoid emergency conversion from transcatheter aortic valve replacement to open-heart surgery. Many cases of transcatheter heart valve embolization occurring with balloon-expandable prostheses such as the SAPIEN 3 (Edwards LifeSciences Corporation) valve and self-expandable prostheses such as the ACURATE neo (Boston Scientific Corporation) valve have been reported in the literature. Here, for the first time (to the authors' knowledge), the case of a Myval (Meril Life Sciences Pvt Ltd) transcatheter heart valve embolization during transcatheter aortic valve replacement, which was treated percutaneously with favorable outcomes, is reported.

Keywords: Transcatheter aortic valve replacement; aortic aneurysm, abdominal; heart valve prosthesis

Case Report

Presentation and Physical Examination

An 83-year-old man with severe, symptomatic aortic valve stenosis (New York Heart Association class II, Canadian Cardiovascular Society angina grade 1) was referred to the reporting institution for transcatheter aortic valve replacement (TAVR). Transthoracic echocardiography revealed severe aortic valve stenosis (maximum velocity, 3.9 m/s; mean gradient, 37 mm Hg; aortic valve area, 0.61 cm^2), a tricuspid aortic valve with severe calcification, mild aortic valve regurgitation, moderate left ventricular hypertrophy with preserved left ventricular ejection fraction, mild mitral valve regurgitation, an ascending aorta with mild dilation (39 mm), and an abdominal aortic aneurysm with a maximum diameter of 38.5 mm. A cardiac computed tomographic scan showed an aortic valve annulus with a perimeter-derived diameter of 27.7 mm, an annulus area of 591 mm^2, no left ventricular outflow tract calcification, an aortic valve calcium score of 4304, and nonobstructive coronary artery disease.

Citation: García-Escobar A, Galeote G, Jurado-Román A, Jiménez-Valero S, Cabrera JA, Moreno R. Successful management of Myval transcatheter heart valve embolization into abdominal aortic aneurysm during transcatheter aortic valve replacement. *Tex Heart Inst J*. 2024;51(2):e227997. doi:10.14503/THIJ-22-7997
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Medical History

The patient had a medical history of hypertension, type 2 diabetes, dyslipidemia, persistent atrial fibrillation on chronic oral anticoagulation (apixaban 5 mg twice daily), iron deficiency anemia treated with oral iron replacement, coronary artery disease treated with percutaneous coronary intervention and drug-eluting stent placement in the right coronary artery, and renal cell carcinoma treated with left radical nephrectomy.

Differential Diagnosis

The symptoms of severe aortic valve stenosis, such as chest pain and dyspnea, overlap with the symptoms of angina. Coronary artery disease as a cause of angina was therefore ruled out.

Technique

During the TAVR procedure, the patient was sedated. A 6F catheter sheath was introduced into the left femoral artery, and the right femoral artery was punctured under fluoroscopy guidance. A regular diagnostic Judkins Right 4 catheter (Medtronic Inc) was crossed through the aortic bifurcation into the opposite femoral artery. A 300-cm 0.018-in Hi-Torque Steelcore guidewire (Abbott Cardiovascular) was left in place in the right femoral artery to provide quick access in case of a major vascular access–related complication. A transvenous pacing wire was then placed in the apex of the right ventricle through a 6F catheter sheath in the right femoral vein. A diagnostic Amplatz Left 1 catheter (Merit Medical Systems, Inc) over a 0.035-in hydrophilic guidewire was used to cross the aortic valve, and was then exchanged for a Safari guidewire (Boston Scientific). The valve was predilated with a 26-mm balloon (Atlas Gold, BD). A 29-mm Myval prosthesis (Meril Life Sciences Pvt Ltd) was crimped to the TAVR delivery system and advanced through the aorta. The Myval transcatheter heart valve was accidentally released at the thoracic aorta (Fig. 1), but by inflating the balloon catheter slightly at low atmospheric pressure, the Myval prosthesis was stabilized. Aortography was performed to identify the site of the abdominal aorta with the least dilation and to assess side-branch occlusion. The Myval transcatheter heart valve was subsequently withdrawn using the balloon catheter and pulled from the thoracic aorta into the abdominal aorta. The Myval prosthesis was progressively dilated using 16-mm, 26-mm, and 29-mm balloons (Fig. 2) and deployed in the abdominal aorta with good apposition and expansion and without side-branch occlusion. Afterward, a new 29-mm Myval transcatheter heart valve was advanced through the aorta and successfully deployed. Finally, a MANTA large-bore closure device (Telefax Inc) was applied for vascular access-site closure at the right femoral artery, and an Angio-Seal vascular closure device (Terumo Interventional Systems) was used to close the left femoral artery.

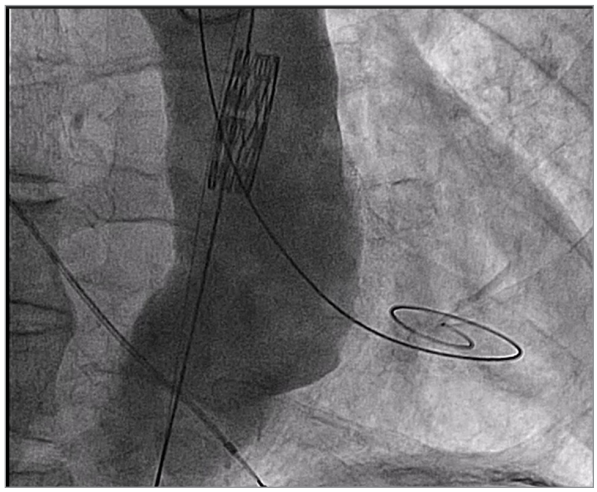

Fig. 1 Aortogram in anterior-posterior projection shows the Myval prosthesis (Meril Life Sciences Pvt Ltd) accidentally released in the thoracic aorta.
Supplemental motion image available for Figure 1.

Key Points

- Expandable sheaths facilitate the implantation of transcatheter heart valves (including large valve sizes) in smaller recipient arteries and may reduce vascular complications over nonexpandable sheaths.
- Transcatheter heart valve embolization is a rare but serious complication during TAVR that requires immediate action, such as snaring the prosthesis to stabilize its position and pulling it to a safe place.
- To the authors' knowledge, this is the first reported case of Myval transcatheter heart valve embolization during TAVR that was managed successfully in a percutaneous procedure with favorable outcomes.

Abbreviation

TAVR, transcatheter aortic valve replacement

Outcome

The patient's stay in the intensive care unit and hospitalization were otherwise uneventful. Before the

patient was discharged home, a transthoracic echocardiogram showed good hemodynamic results, with a mean gradient of 8 mm Hg and minimal paravalvular leak. An abdominal computed tomographic scan revealed a thrombus outside of the Myval prosthesis at the right lateral abdominal aortic wall, located 4 cm from the iliac bifurcation (Fig. 3), similar to the thrombus observed on a previous abdominal computed tomographic scan.

Latest Follow-Up

At 3-month follow-up, a transthoracic echocardiogram confirmed good hemodynamic results. In addition, the patient's aortic stenosis was graded as New York Heart Association class I and Canadian Cardiovascular Society angina grade 0.

Discussion

To date, many cases of transcatheter heart valve embolization have been reported to occur with balloon-expandable prostheses such as the SAPIEN 3 (Edwards Lifesciences) and self-expandable prostheses such as the ACURATE neo (Boston Scientific).[1,2] No cases of transcatheter heart valve embolization, however, were reported in the study of the Myval-1 transcatheter heart valve by Sharma et al[3] or the study by García-Gómez et al[4] of the Myval transcatheter heart valve in patients with low-risk aortic stenosis. To the authors' knowledge, this is the first reported case of Myval transcatheter heart valve embolization.

Expandable sheaths such as the 14F or 16F eSheath introducers (Edwards Lifesciences) and the 14F iSLEEVE introducer (Boston Scientific) are designed to enter the vessel at a low profile and expand upon device delivery, which facilitates the implantation of transcatheter heart valves in smaller recipient arteries. An observational study (N = 192) showed that minor vascular complications occurred less often with expandable sheaths than with nonexpendable sheaths (10% vs 17.1%, respectively; $P = .19$).[5] A 14F expandable sheath can furthermore be used to insert large prosthetic valves, such as the 34-mm CoreValve Evolut R valve (Medtronic Inc), with the exception of the 29-mm SAPIEN 3 valve, which requires an 16F eSheath introducer. In contrast, it is recommended that the Myval transcatheter heart valve be crimped over the Navigator transcatheter heart valve delivery system (Meril Life Sciences Pvt Ltd) (Fig. 4;) before insertion with a 14F expandable Python introducer sheath (Meril Life Sciences Pvt Ltd). The Navigator

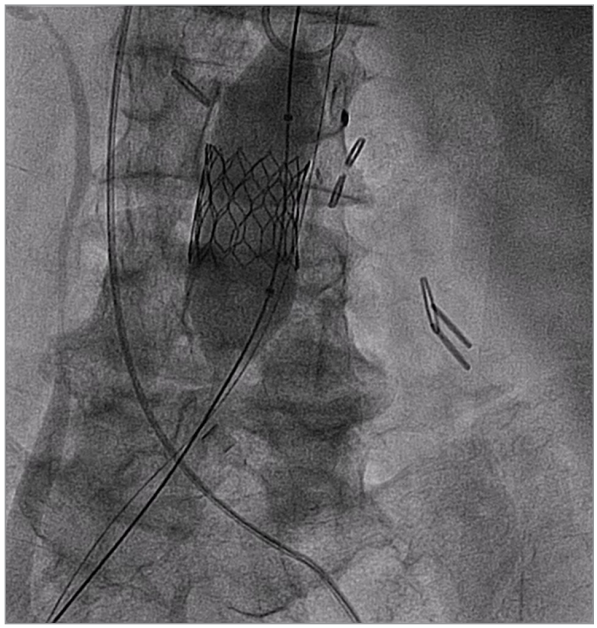

Fig. 2 Aortogram in anterior-posterior projection shows the Myval prosthesis (Meril Life Sciences Pvt Ltd) being dilated with a 29-mm balloon in the abdominal aorta.
Supplemental motion image available for Figure 2.

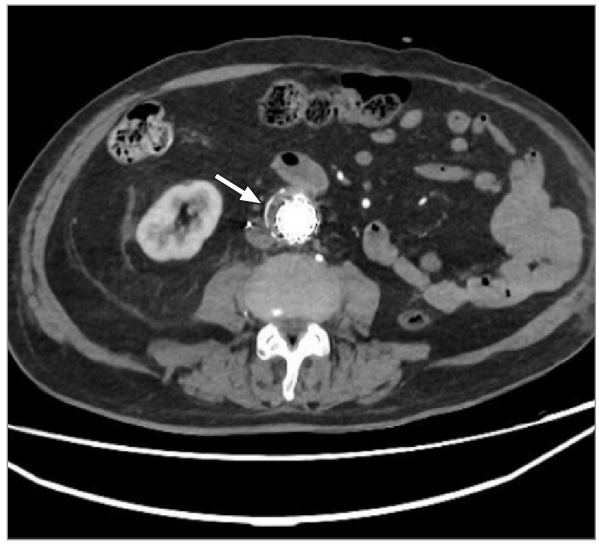

Fig. 3 Axial abdominal computed tomogram before hospital discharge demonstrates a thrombus (arrow) outside the Myval prosthesis (Meril Life Sciences Pvt Ltd) at the right lateral abdominal aortic wall located 4 cm from the iliac bifurcation.

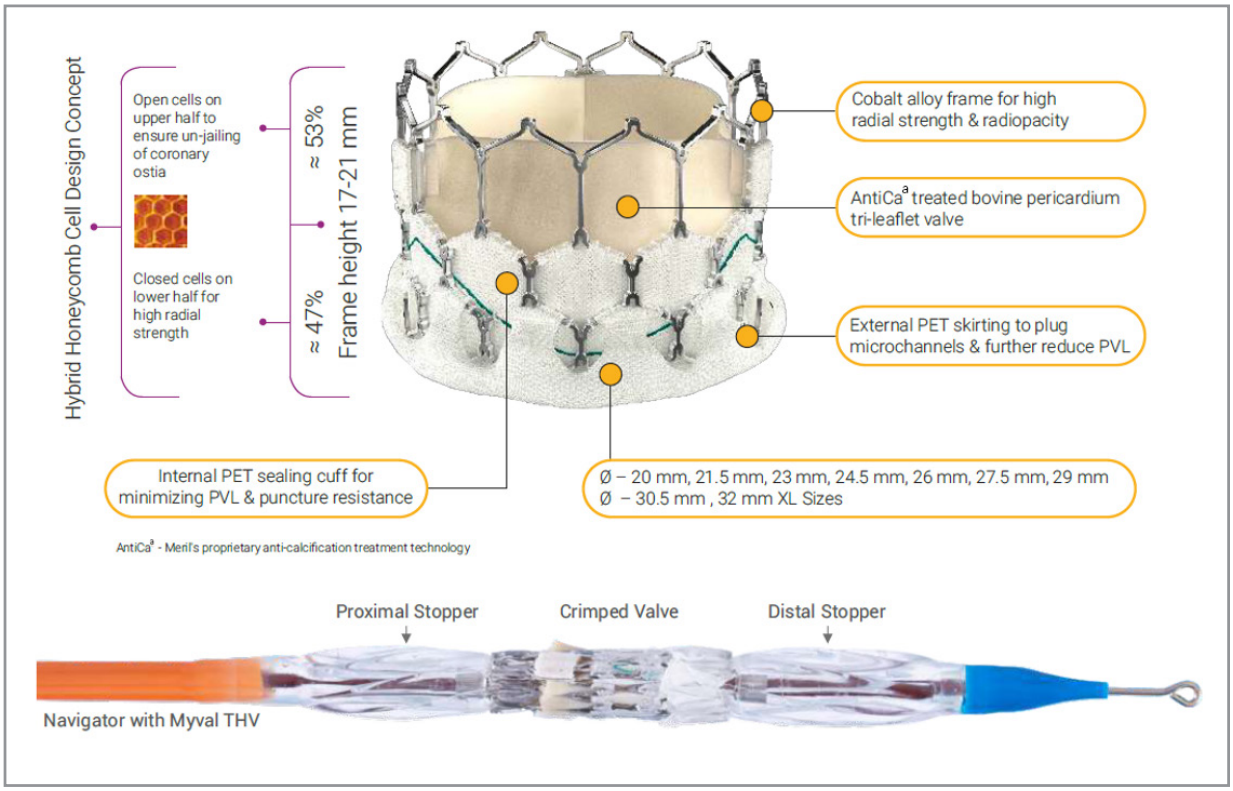

Fig. 4 The Myval valve (Meril Life Sciences Pvt Ltd) crimped over the Navigator transcatheter heart valve delivery system (Meril Life Sciences Pvt Ltd), which has a set of proximal and distal stoppers, making valve crimping precise and snug. Figure courtesy of Meril Life Sciences Pvt Ltd.

PET, polyethylene terephthalate; PVL, paravalvular leak; THV, transcatheter heart valve; XL, extra-large.

delivery system has a set of proximal and distal stoppers, making valve crimping precise and snug.[6] The 14F Python introducer sheath accommodates Myval transcatheter heart valves of all diameters (20 mm to 32 mm); larger-sized transcatheter heart valves, such as 26 mm, 27.7 mm, and 29 mm, require at least a 5.5-mm mean luminal diameter for vascular access, and transcatheter heart valve sizes of 30.5 mm and 32 mm require a mean luminal diameter of at least 6 mm.[6] The 14F Python sheath uses 2 separate calibrated loading tubes that must be assembled to ensure temporary opening of the hemostatic valves in the proximal port, allowing smooth passage of the crimped Myval transcatheter heart valve system.[6] Of note, as with any other expandable sheath, prior use of dilators is required; in this case, an 18F dilator corresponds to the 29-mm Myval transcatheter heart valve. In retrospect, it can be hypothesized that when the Python 14F introducer sheath was assembled, the operators may not have used 1 of the dilators, but the true mechanism of the valve embolization remains unknown. Notably, no reports of valve embolization with other balloon-expandable delivery systems that used expandable sheaths have been described under these circumstances. Given that use of the Myval transcatheter heart valve is relatively scarce outside India, where the device is manufactured, it cannot be determined whether the Myval transcatheter heart valve embolization was related to operator unfamiliarity or device failure. Nonetheless, more clinical trials are required to determine patient outcomes when treated with Myval transcatheter heart valves at long-term follow-up.

Conclusion

Promptly managing transcatheter heart valve embolization during TAVR is crucial to avoiding emergency conversion to open-heart surgery. Most strategies involve snaring and pulling the device to stabilize it without aortic side-branch occlusion. In this case, the Myval transcatheter heart valve was snared using a balloon catheter that was slightly dilated at low atmospheric pressure. Then, the transcatheter heart valve

was pulled to a safe place in the abdominal aorta at the site with the least dilation to deploy the device and ensure good apposition of the transcatheter heart valve to the abdominal aortic wall. Here, the authors report—for the first time, to their knowledge—a case of Myval transcatheter heart valve embolization during TAVR that was treated successfully percutaneously and with favorable outcomes.

Article Information

Published: 5 November 2024

Author Contributions: Artemio García-Escobar was responsible for the concept design, writing, and editing of the entire manuscript, including data curation (figures and videos) and the conclusion. Alfonso Jurado-Román and Santiago Jiménez-Valero wrote and edited the case presentation. Guillermo Galeote, José Ángel Cabrera, and Raúl Moreno wrote and edited the discussion.

Conflict of Interest Disclosure: Raúl Moreno is proctoring support for Meril Life Sciences Pvt Ltd (Myval), Boston Scientific (ACURATE neo), and Biosensors International (Allegra) and receives lecturer fees from Edwards Lifesciences.

Funding/Support: None.

Meeting Presentation: This case was presented at the PCR London Valves course; November 27, 2022; London, United Kingdom.

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