JACC: CARDIOVASCULAR INTERVENTIONS VOL. 4, NO. 2, 2011

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC. DOI: 10.1016/j.jcin.2010.10.010

Outcome of Patients After Transcatheter Aortic Valve Embolization

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Objectives This study aims to assess the mid- to long-term follow-up of patients after valve embolization at the time of transcatheter aortic valve implantation (TAVI).

Background Transcatheter heart valve (THV) embolization is a rare but serious complication during TAVI. Although various techniques have been developed to manage acute complications and reduce periprocedural morbidity/mortality, long-term clinical and hemodynamic consequences after these events are unknown.

Methods Patients who developed THV embolization after TAVI were prospectively assessed. Clinical and echocardiographic characteristics were recorded at baseline and after successful TAVI/surgical aortic valve replacement. The THV migration and strut fractures/degeneration were assessed by computed tomography.

Results A total of 7 patients had THV embolization, all of which occurred immediately after valve deployment. The embolized THV was repositioned in the aortic arch proximal to the left subclavian artery (n = 2), immediately distal to the left subclavian artery (n = 2), and in the abdominal aorta (n = 3). A second THV was implanted successfully at the same sitting in 4 patients and at the time of a second procedure in 2 patients. Elective conventional aortic valve replacement was performed in 1 patient. Median follow-up was 1,085 days. One patient died during follow-up from an unrelated cause. The remaining 6 survivors were in New York Heart Association functional class I or II at final follow-up. Mid-term computed tomography follow-up (n = 4,591 to 1,548 days) showed that the leaflets of the embolized THV remain open in all phases of the cardiac cycle. There was also no strut fracture or migration of these valves.

Conclusions Clinical outcomes remain good when THV embolization is managed effectively. There are no apparent hemodynamic consequences of a second valve placed in the series. These embolized valves remain in a stable position with no evidence of strut fractures at mid-term follow-up. (J Am Coll Cardiol Intv 2011;4:228–34) © 2011 by the American College of Cardiology Foundation

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Manuscript received September 2, 2010; revised manuscript received October 8, 2010, accepted October 15, 2010.

Embolization of transcatheter aortic valves has been previously described (1). This rare but important complication might occur due to poor positioning of the transcatheter heart valve (THV) or valve ejection after effective ventricular contraction. The potential causes, acute management, and management of this complication have been previously described (2,3). We sought to examine the late outcomes and implications of valve embolization.

Methods

All patients undergoing transcatheter aortic valve implantation (TAVI) between January 2005 and November 2009 for severe symptomatic aortic stenosis complicated by embolization of the THV were prospectively followed in 2 heart centers. Embolization was considered to have occurred when a THV became freely mobile in the aorta after attempted implantation in the aortic annulus. In all patients, TAVI was performed under general anesthesia with transesophageal and fluoroscopic monitoring.

Baseline clinical and procedural characteristics were recorded. Transthoracic echocardiography was performed at baseline, 1 month, 6 months and annually. Follow-up was performed at clinics, by chart reviews and telephone calls to patients or their families/physicians. Computed tomography (CT), to evaluate the position, structural integrity, and leaflet function of the embolized THV, was performed at 3 years or earlier if clinically indicated.

Results

Seven patients were identified with THV embolization.

The median age was 82 years (range 71 to 86 years). All patients were in New York Heart Association functional class III or III at baseline. The median aortic annulus size was 22 (20 to 25) mm (Table 1).

In all cases, embolization occurred immediately after THV deployment. There were no cases of late embolization. Embolization was a feature of the early experience, at which time the principles of correct positioning and deployment were not established. All of these cases occurred in the first half of the experience. There has only been 1 case of embolization in the latter half of the TAVI experience (i.e., 6 cases of embolization in the first 150 TAVIs at Vancouver, and 1 in the next 159 patients).

Causes of embolization. The reasons for embolization were identifiable in all patients (Table 2). The most common reason was placing the valve too aortic (Fig. 1) (4 of 7 cases). This was followed by inadequate visualization of the valve plane and the inability to recognize that the valve was not coaxial to the valve plane before deployment (the concept of perpendicularity of the valve plane was not well-understood in the early experience; it is now well-established that all 3 sinuses of the aorta must lie on a line on fluoroscopy with the long axis of the valve positioned perpendicular to this line to ensure coaxiality). Three cases were caused by inadequate ventricular pacing (2 occurred from transient loss of ventricular capture by the pacing lead, and 1 from premature termination of ventricular pacing) during deployment of the valve, resulting in an increase in stroke volume ejecting the valve (Fig. 2). Other causes were less common. Embolization in Case #1 occurred because of prior mitral valve replacement surgery: the struts of the bioprosthesis displaced the valve-balloon toward the aorta (superiorly) during deployment. Because of this, a successful TAVI was performed in this patient 4 years later with a shorter balloon and a transapical route. Case #3 demonstrated the importance of prior balloon aortic valvuloplasty. The operator initially felt that balloon aortic valvuloplasty was not necessary, because the valve could be crossed easily and the patient had prior strokes. This omission made crossing and positioning dif-

Abbreviations and Acronyms

CT = computed tomography

TAVI = transcatheter aortic valve implantation

THV = transcatheter heart valve

Table 1. Clinical Characteristics

Case #	Age, yrs	Sex	STS Score	NYHA Functional Class Baseline	Aortic Valve Area	Baseline Mean Transaortic Gradient, mm Hg	Left Ventricular Function, %	Annulus Size, mm	Valve Size Selected, mm
1	84	Female	6.4 (porcelain aorta)	3	0.6	34	60	22	23
2	85	Female	8.7	3	0.9	20	65	22	23
3	71	Male	3.8 (left internal mammary graft adherent to chest wall)	3	0.6	57	65	22	26
4	82	Female	5.1 (frailty)	3	0.3	65	65	22	23
5	86	Male	11.9	3	0.7	26	30	25	26
6	76	Male	3.4 (colonic carcinoma)	3	0.6	64	65	20	23
7	82	Male	10.6	3	0.6	35	35	23	26

NYHA = New York Heart Association; STS = Society of Thoracic Surgeons (parentheses denote unscored comorbidities).

Table 2. Causes of Embolization and Final Outcomes

Case #	Reasons for Embolization				Size of Second Valve Deployed During the Index Procedure, mm	Position of Embolized Valve	Final Management of Native Valve	NYHA Functional Class (Follow-Up)
	Not-Coaxial to Valve Plane	Too Aortic	Pacing	Others				
1	X			X (struts of mitral bioprosthesis displaced the deployment balloon during inflation)	Not implanted	Transverse aorta	Repeat TAVI 4 yrs later (transapical 23 mm ES valve)	II
2		X	X (premature termination)		23	Distal to left subclavian artery	Repeat TAVI same sitting	I
3				X (lack of prior aortic balloon valvuloplasty before TAVI)	26	Abdominal aorta	Repeat TAVI same sitting	II
4	X	X			23	Abdominal aorta	Repeat TAVI same sitting	II
5		X	X (loss of capture)		Not implanted	Transverse aorta	Repeat TAVI 7 months later (transapical 26 mm ES valve)	Died
6	X	X			Not implanted	Distal to left subclavian artery	Conventional aortic valve replacement (4 months later)	II
7			Inadequate reduction of pulse pressure at 160/min		26	Abdominal aorta	Repeat TAVI same sitting	I

ES = Edwards-SAPIEN; NYHA = New York Heart Association; TAVI = transcatheter aortic valve implantation.

ficult. The valve was partially dislodged while maneuvering from the balloon and had to be repositioned in the aorta.

Importantly, in all these 7 patients, the Amplatz extra-stiff exchange length wire (Cook Medical, Bloomington, Indiana) was kept in place (within the THV) to prevent inversion of the THV. The deployment balloon was then reinflated partially within the valve with the balloon shoulder as a leading edge to reposition the valve atraumatically.

Most patients (n = 6) were discharged without further in-hospital complications. One patient (Case #4) was noted to have a mobile mass attached to the embolized THV suggestive of a thrombus. She was anticoagulated, and subsequent imaging showed resolution.

Follow-up. Median follow-up was 1,085 days (365 to 1,747 days), at which time 6 of 7 patients remained alive and in New York Heart Association functional class I or II. One patient (Case #5) died on day 221 from unrelated complications of diverticulitis. Another (Case #6) had an asymptomatic, limited dissection of the ascending aorta adjacent to the embolized THV detected 5 months after the index

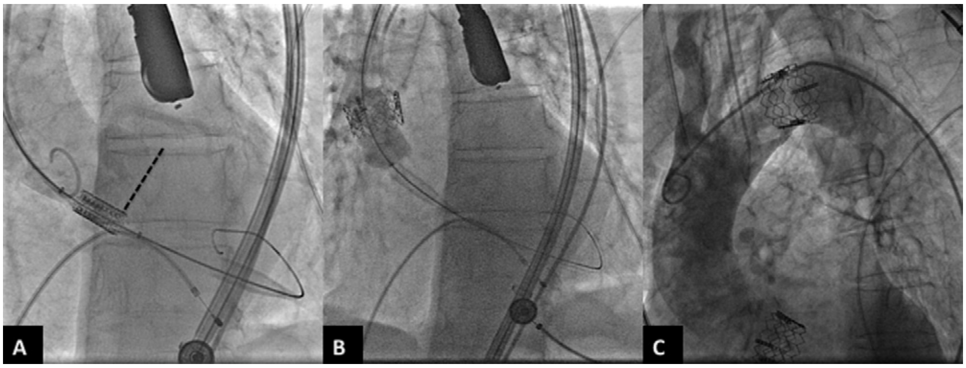

Figure 1. Fluoroscopic Imaging of the Aortic Root and the Importance of Identifying the Valve Plane

(A) Superior positioning of the transcatheter heart valve (THV) (valve plane is shown with **dashed lines**). **(B)** Repositioning of the valve with the balloon. **(C)** Final position of both the embolized valve and anatomically placed valve.

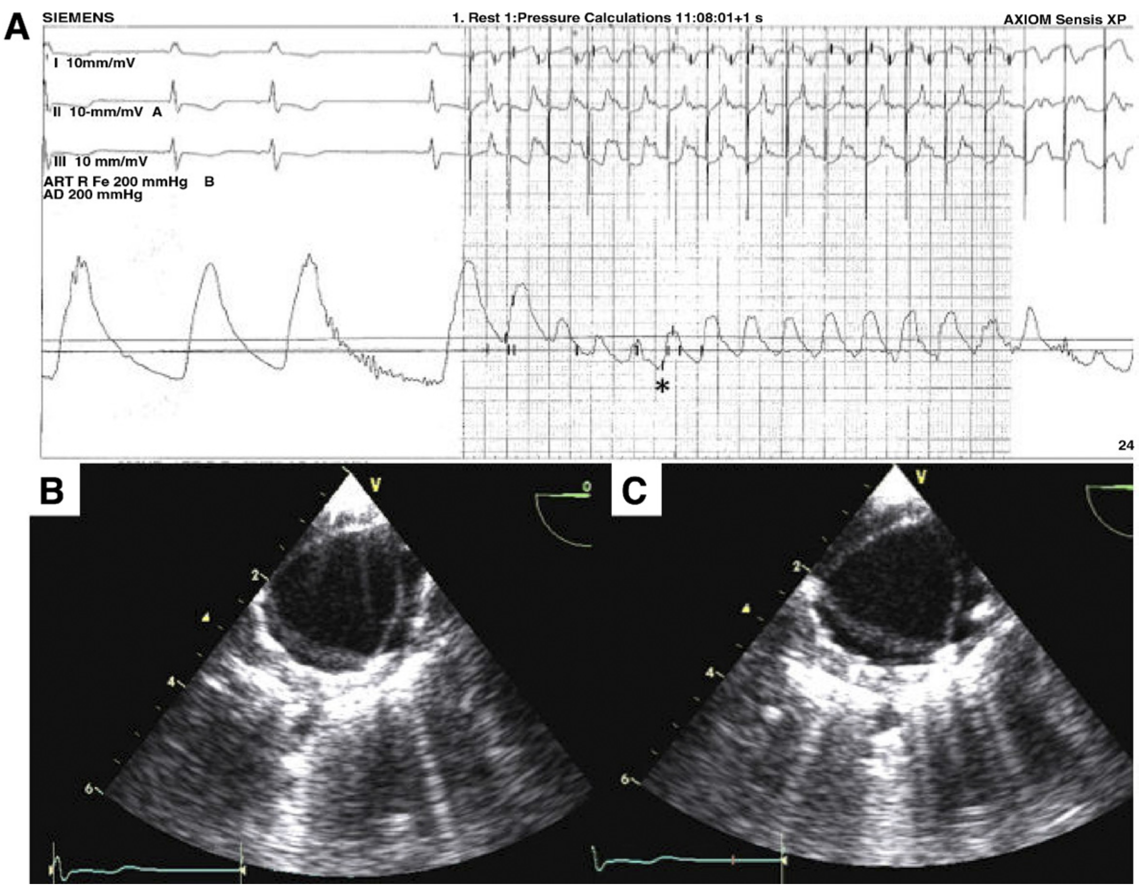

Figure 2. Ineffective Ventricular Pacing Resulting in Valve Embolization

Images from Case #7. **(A)** electrocardiogram and femoral artery pressure tracings showing the lack of adequate reduction in pulse pressure during valve deployment **(*)**. Lower echocardiographic image shows that the valve leaflets of the embolized valve remains in the open position in systole **(B)** and diastole **(C)**.

TAVI during conventional aortic valve surgery. The THV was removed, and the dissection was repaired uneventfully.

Follow-up transthoracic echocardiography after replacement of the anatomical aortic valve (i.e., THV or conventional surgery) showed a significant improvement in aortic valve area with a concomitant reduction of aortic valve gradient from baseline. All patients had mild aortic regurgitation at follow-up. We were unable to measure echocardiographic transvalvular gradients across the embolized THV positioned in the aorta, with the exception of 1 patient in whom there was no gradient (Case #4).

Computed tomography was performed in 4 patients (at 591 to 1,548 days). There was no evidence of any clinically significant migration of the embolized THV in these patients (Fig. 3) on the basis of comparison of the final fluoroscopic images with follow-up CT. The integrity of the THV was preserved with no evidence of strut fracture (Fig. 4). Images of both valves (embolized and anatomically placed THV) were acquired in both systole and diastole. The anatomically placed valves, as expected, were fully open in systole and closed in diastole. However, the embolized valve leaflets remained in the open position during both phases of the cardiac cycle in all 4 cases (Figs. 5 and 6). This is seen in embolized THVs positioned in the proximal or distal (abdominal aorta).

Discussion

Transcatheter heart valve embolization is a largely but not entirely preventable complication with current balloon-expandable valves. We have previously reviewed the factors that predispose to this complication (3). Attention to procedural details, optimal imaging, and an improved understanding of the procedure are making this a relatively rare occurrence. Currently the published rates of valve embolization range from 0.5% to 8% (4–8).

Early outcomes. This experience demonstrates that acute embolization of balloon-expandable valves can be associated with favorable outcomes, if managed appropriately. There were no apparent adverse outcomes because of emboliza-

JACC: CARDIOVASCULAR INTERVENTIONS, VOL. 4, NO. 2, 2011
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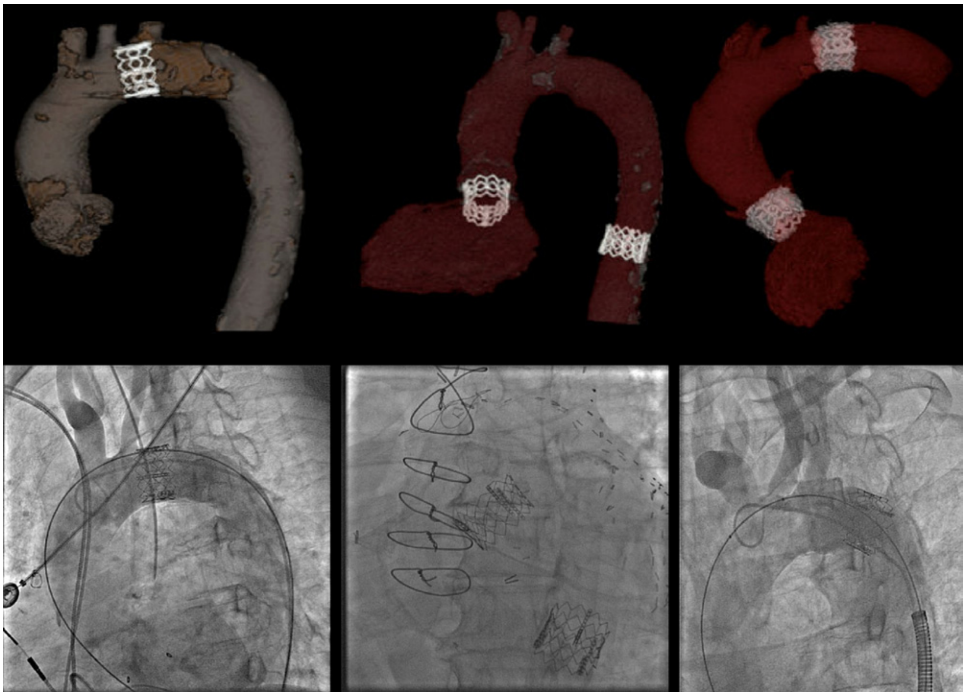

Figure 3. Comparing the Embolized Valve Position at the End of the Procedure and at Follow-Up

Three-dimensional reconstruction of the aorta and the embolized transcatheter heart valves (THVs). This shows the position of the THVs implanted in the transverse arch **(left)**, the abdominal aorta **(middle)**, and the aorta distal to the left subclavian artery **(right)**. Inserts show the fluoroscopic position of the valves at the end of the procedure.

tion. When embolization does occur, it is important to have a good understanding of the how this is best managed. Maintaining a coaxial wire within the prosthesis prevents it from becoming inverted and obstructing aortic flow. Repositioning can be accomplished by withdrawing the THV on an inflated valvuloplasty balloon to a secure position in the more distal aorta while avoiding aortic injury. Slight overdilation might assist in fixing the THV in an area free of side-branches. The THVs remains acutely stable in their position, and there is no adverse effect on hemodynamic status. In this study, we have not addressed another group of patients who might have an unstable valve in the left ventricular outflow tract or even valves that "embolize" into the left ventricle. Strictly speaking, these should not be classified as embolization. These valves are often treated with a variety of techniques: an overlapping second valve to stabilize the first or inflate a balloon in or distal to the THV and attempt to retrieve or reposition it. Most patients, however, still undergo open surgery to remove the THV.

In this experience, 2 patients had the embolized THV ultimately fixed in the transverse aorta, 2 just distal to the subclavian artery, and 3 in the descending aorta (Fig. 3). Experience gained from thoracic endovascular aortic stent repair suggests an increased risk of strokes when devices are

Figure 4. CT Assessment for Valve Stent Fracture at Follow-Up

Higher magnification of the transcatheter heart valve (THV) on computed tomography (CT) to assess for strut fracture.

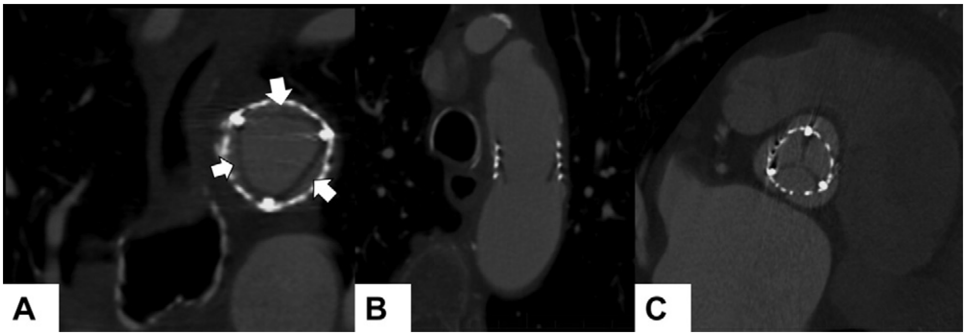

Figure 5. CT of the Embolized THV Demonstrating No Hemodynamic Interaction of the 2 Valves in Series

Computed tomography (CT) of the embolized transcatheter heart valve (THV) in Case #2 showing the hemodynamic interaction of the 2 valves in series. All 3 images were taken during early diastole. The embolized valve is shown en-face in **A** and longitudinally in **B**, demonstrating that the valves are opened **(white arrows)**. **C** shows the valve in the aortic root, which is closed during this phase of the cardiac cycle. The embolized valve remains open throughout systole and diastole.

placed proximally or near the arch (9). No periprocedural strokes were detected in these patients.

The in vivo mechanics of the embolized valve are unknown. Although valved-stents placed in the descending aorta of animal models with severe aortic regurgitation might reduce aortic regurgitation (10,11), it is uncertain whether this physiology is mirrored in humans.

Implantation of a covered or uncovered stent within an embolized valve has been suggested. However, this was not necessary in our experience and might be a source of needless complications. If the guidewire is maintained within the THV during repositioning, it will be maintained oriented in the direction of flow. Our experience suggests there are no important hemodynamic adverse consequences of a correctly oriented THV implanted in the aorta. In contrast, an inverted valve likely would be obstructive, which might be effectively managed with stenting.

The potential for aortic dissection because of manipulating a THV in the aorta is an obvious concern. Injury to ascending aorta was observed in 1 patient, although fortunately this responded well to conservative management. Atheroembolism because of aortic injury is likely to occur but was not clinically evident. Occlusion of an aortic side-branch is similarly a concern but was not observed. Thrombus formation on the embolized valve in the descending aorta was observed in 1 case, although the significance of this is unclear.

Late outcomes. In this study, most patients who underwent a successful second procedure derived significant benefit

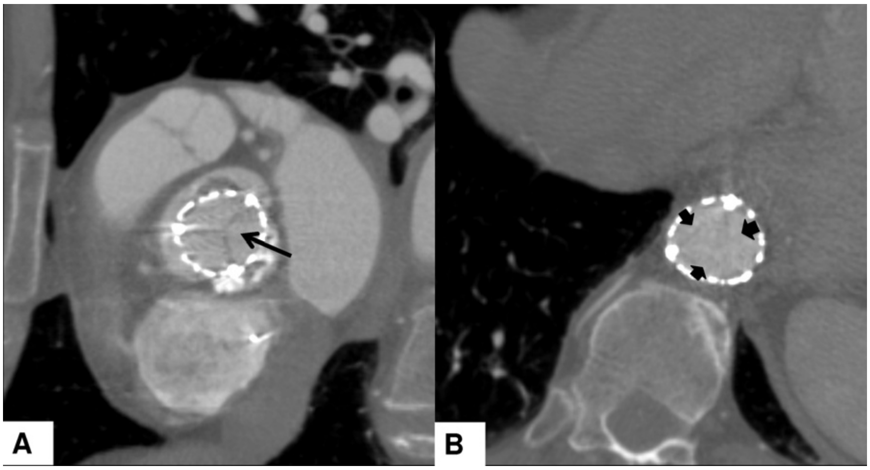

Figure 6. CT of the Embolized THV (Descending Aorta) Showing No Interaction With the Anatomically Placed THV

Case #4. Axial computed tomography (CT) images of transcatheter heart valves (THVs) in the aortic root **(A)** and the descending aorta **(B)**. The THV in the aortic position remains closed in early diastole, whereas the embolized THV in the descending aorta is wide open (**black arrows** show valve leaflets).

with improvements in functional class, aortic valve area, and aortic valve gradients at mid- to long-term follow-up, with no suggestion of adverse impact of the embolized valve on outcomes compared with published studies of TAVI patients (12).

Echocardiography and late CT imaging in 4 patients clearly showed that the valve leaflets remained in the open position during systole and diastole (Figs. 5 and 6). This indicates that the diastolic pressures distal to the valve do not exceed the proximal pressures and there is no significant diastolic flow reversal. It seems that (correctly oriented) embolized THVs functionally behave like a covered stent. Similar findings have been suggested with CoreValve (Medtronic, Inc., Irvine, California) self-expanding prostheses implanted in the descending aorta (13).

Late migration of THVs was not observed. In this series, THVs were withdrawn to a portion of the aorta with a diameter that approximated the THV diameter. At this point, the THV was slightly over-dilated. Late movement might still occur in cases where a THV could not be manipulated into a secure position. A limitation of this study is the lack of CT done immediately after the procedure for comparison with the follow-up CT. The comparison of fluoroscopic imaging and CT is not optimal, but no clinical significance was seen.

Currently available balloon-expandable valve frames are designed to be resistant to fracture or structural failure. Stents implanted within the aorta are not subject to the forces seen with implantation in the heart itself. It is reassuring that stent fracture was not observed on late CT imaging.

Prevention is better than cure. Although embolization can be managed effectively in the acute situation and seems to have good outcomes, prevention remains the key to success. Meticulous attention must be paid to accurately size the valve, derive an optimal plane perpendicular to the valve, and ensure reliable control of ventricular pacing before valve deployment.

Conclusions

Embolization of balloon-expandable valves is a rare acute complication of TAVI but can be managed effectively with good early outcomes. Embolized valves oriented correctly in the direction of flow did not seem to have hemodynamic consequences. When repositioned in the aorta, adverse clinical consequences were not observed at late follow-up.

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Key Words: computed tomography (CT) ■ embolization ■ hemodynamic status ■ percutaneous aortic valve replacement.