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CASE REPORT

Late Paravalvular Aortic Regurgitation: Migration of the Valve or Late Recoil?

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ABSTRACT

A 79-year-old man underwent trans-catheter aortic valve replacement for symptomatic severe aortic stenosis with a 26-mm Edwards SAPIEN XT valve. Immediately after valve deployment there was moderate amount of paravalvular leak. Post-dilation was performed with an additional 2 cc of volume, and the paravalvular leak was reduced to trace. Nine months later, trans-thoracic echocardiography revealed moderate to severe paravalvular leak and possible aortic migration of the valve. The patient was brought back for the treatment of the paravalvular leak which was suspected to be due to valve migration. However, fluoroscopy and trans-esophageal echocardiography showed good valve position. Measurement of late valve recoil in the Coplanar view using cine-angiographic analysis software showed that the lower third of the valve had the greatest late recoil (−1.74 mm, 6.55%), which presumably accounted for the progression of the paravalvular leak. Valve-in-valve trans-catheter aortic valve replacement was performed with a 26-mm SAPIEN 3 valve and the paravalvular leak was reduced to trace. This case displays late recoil as a likely mechanism for development of paravalvular leak after SAPIEN XT valve implantation. Our case illustrates that late recoil needs to be systematically evaluated in future studies, especially when trans-catheter aortic valve replacement is being expanded to lower risk and younger patients for whom the longevity and long-term performance of these valves is of critical importance.

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INTRODUCTION

Paravalvular leak (PVL) has been described as the Achilles' heel of trans-catheter aortic valve replacement (TAVR). Moderate or greater degree of PVL has been clearly associated with increased mortality, and some studies have even shown an association between mild PVL and all-cause mortality [1–3]. What happens to PVL during the follow-up period is a matter of debate. Early experience with TAVR raised the concern that progression of PVL could lead to volume overload of the left ventricle resulting in heart failure symptoms or hemolysis and consequent blood transfusion necessitating re-intervention. In the first PARTNER trial, which used the first-generation SAPIEN valve (Edwards Lifesciences Inc., Irvine, CA), PVL had worsened by ≥1 grade at 2 years of follow-up in 22.4% of patients [1, 2]. Like other vascular scaffolds, such as coronary stents, the supporting stent scaffold of the TAVR valves is subject to acute and late recoil, and late recoil has been postulated as a potential mechanism of progression of PVL; however, this mechanism has not yet been described in the literature.

CASE REPORT

A 79-year-old man with a history of hypertension, diabetes, prior coronary bypass, atrial fibrillation, carotid artery stenosis, colon cancer, and frailty who had been turned down for surgical AVR at his referring hospital underwent TAVR for symptomatic severe aortic stenosis with a 26-mm SAPIEN XT valve (Edwards Lifesciences Inc.). Computed tomography prior to the procedure showed minimal amount of aortic annular calcification—the calcium volume was 1670 mm^3 and mainly deposited in the valve leaflets (Fig. 1a). The aortic valve annular area measured 459 mm^2, which corresponded to 15.7% oversizing. Immediately after the SAPIEN XT valve deployment there was moderate amount of PVL (Enhanced Content Video 1). Acute valve recoil was measured at three levels in the Coplanar view by subtracting valve diameters immediately after balloon deflation from the valve diameters at maximum balloon inflation. Measurements were performed with the image processing software from the Philips Xcelera package (Philips Medical Systems, Veenpluis, The Netherlands). Using this software, calibration was performed on a straight segment of a contrast-filled pigtail catheter several centimeters from its tip using the known diameter of the catheter based on its French size. After calibration, the valve scaffold was measured from outer edge to outer edge in the coplanar view at three levels: high, mid, and low level. The numbers were reported as absolute values and as the percentage of the valve diameter at maximum balloon inflation. The valve had –0.45 mm (1.68%) recoil at the higher level, –1.01 mm (3.77%) recoil at the mid-level, and –0.66 mm (2.49%) recoil at the lower level (Fig. 1b). Post-dilation was performed with 2 cc of extra volume, and the PVL was reduced to trace (Enchanced Content Video 2). Acute valve recoil was re-measured and the valve had –1.1 mm (4%) recoil at the higher level, –1.02 mm (3.75%) recoil at the mid-level, and –0.14 mm (0.52%) recoil at the lower level (Fig. 1c). Nine months later, a trans-thoracic echocardiography performed for atypical chest pain showed moderate to severe PVL and possible aortic migration of the valve (Enhanced Content Video 3). The patient was

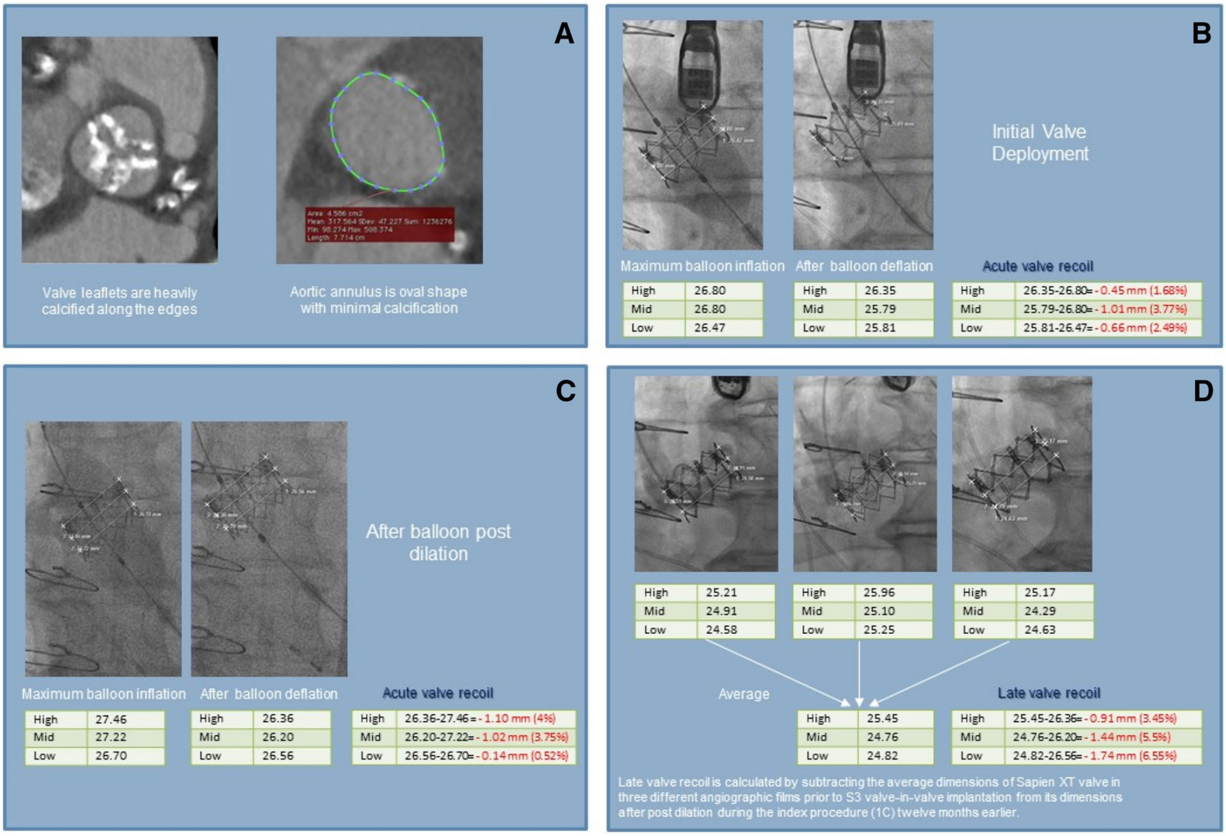

Fig. 1 Native valve morphology and acute and late recoil of the SAPIEN XT valve. **a** Computed tomography showing heavily calcified native aortic valve leaflets with no calcification of the aortic valve annulus, **b** acute recoil of the 26-mm SAPIEN XT valve after initial deployment, **c** acute recoil after post-dilation with 2 cc of extra volume, **d** late recoil 12 months after valve implantation, which displays the greatest recoil along the lower third of the valve

brought back for the treatment of PVL which was suspected to be due to valve migration. Trans-esophageal echocardiography confirmed severe PVL and showed three separate regurgitation jets in the mid-esophageal short-axis view (lower left inset of Video 4 in Enhanced Content). However, fluoroscopy and trans-esophageal echocardiography showed good valve position and no evidence of valve migration (Fig. 2, Video 4). To discover the mechanism for PVL progression we decided to measure the amount of late recoil. To this end, we obtained three angiographic cine images in the coplanar view, in the same projection that the initial TAVR had been performed. Valve diameters were measured at three levels from these films and averaged (Fig. 1d). Late recoil was calculated by subtracting the average numbers at each level from valve diameters after balloon deflation at the post-dilation phase of the initial TAVR (middle table in Fig. 1c). Late recoil was measured to be −0.91 mm (3.45%) at the higher level, −1.44 mm (5.5%) at the mid-level, and −1.74 mm (6.55%) at the lower level of the valve (Fig. 1d). Therefore, the lower level of the valve showed the greatest amount of late recoil, which in our opinion was the mechanism for progression of the PVL. The summation of acute and late recoil at 12 months was

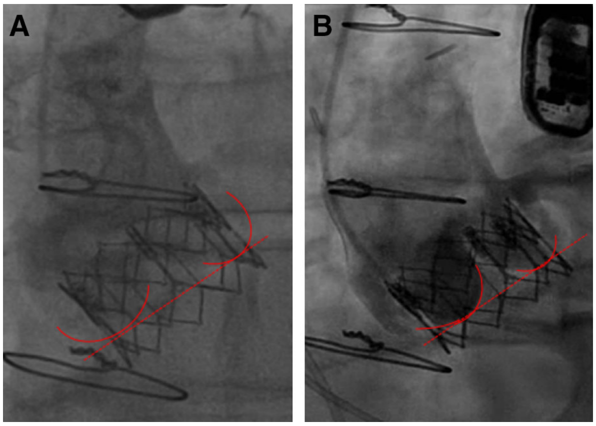

Fig. 2 Stable position of the SAPIEN XT valve with no evidence of valve migration. Root angiography and fluoroscopy show stable valve position: **a** valve position at initial deployment, **b** valve position 12 months later

(4.00 + 3.45 = 7.45%) at the higher level, (3.75 + 5.50 = 9.25%) at the mid-level, and (0.52 + 6.55 = 7.07%) at the lower level of the valve. To treat the PVL, valve-in-valve TAVR was performed with a 26-mm SAPIEN 3 valve (Edwards Lifesciences Inc.) and the PVL was reduced to trace (Enhanced Content Video 5).

Informed consent was obtained from the patient for receiving treatment.

DISCUSSION

The incidence of PVL has been reduced significantly as a result of more accurate valve sizing based on computed tomography measurements, availability of the 29-mm valve in addition to the 23-mm valve, and the 26-mm valve as a third size option, improved operators' skills, and innovative valve designs. The upshot of studies that have reported degree of PVL at different follow-up points is that the incidence of moderate or greater PVL decreases during the follow-up period in most patients [4]. The reduction in incidence of moderate or greater PVL in the follow-up could be due to increased mortality of patients who had or developed moderate to severe PVL or it could be related to remodeling of the aortic valve annulus. Echocardiographic analysis of patients participating in the PARTNER trial, which used the first-generation SAPIEN valve, showed that at 2 years of follow-up PVL remained the same in 46.2% of patients, improved in 31.5%, and worsened by ≥1 grade in 22.4% [1, 2]. Studies have not specifically looked at the progression of PVL with the newer generation SAPIEN XT or SAPEIN 3 valves over time, but PVL remains an important complication of TAVR. In Cohort A of the PARTNER II trial, which used the second-generation SAPIEN XT valve in intermediate-risk patients, moderate to severe PVL was reported in 3.7% of patients at 30 days of follow-up and was associated with a hazard ratio of 2.85 for all-cause mortality in the follow-up period compared to patients with no PVL or trace PVL [5]. In Cohort B of the PARTNER II trial, which compared SAPIEN XT to the first-generation SAPIEN valve in inoperable patients, the reported incidence of moderate to severe PVL with the SAPIEN XT valve was markedly higher than that reported in other studies—24.2% at 30 days of follow-up and 27.5% at 1 year [6]. The higher rate of PVL in that study was speculated to be due to the ambiguity and difficulty in quantifying PVL and the tendency of the echocardiography core laboratory to overestimate its amount. It has however been postulated that acute and late recoil are at least partially responsible for the development and progression of PVL.

To date, only two studies have systemically assessed acute recoil of the Edwards balloon-expandable valves. Both studies only included the first-generation SAPIEN valve and the second-generation SAPIEN XT valve, and both reported higher degree of acute recoil with the SAPIEN XT valve [7, 8].

The stent scaffold of the SAPIEN XT valve is made of cobalt–chromium (CoCr) alloy as opposed to stainless steel which is used in the first-generation SAPIEN valve, but the stent struts of the SAPIEN XT valve are thinner than those of the older generation SAPIEN valve. For the same strut thickness, CoCr alloy is stiffer and more resistant to recoil than stainless steel. This quality is exploited to reduce the thickness of the stent struts and the crimped valve profile to allow delivery of the valve through a smaller sheath. Thinner stent struts, however, reduce the stiffness of the valve scaffold, making it more prone to recoil. Additionally, the SAPIEN XT stent scaffold possesses three rungs of struts instead of the four rungs present in the older generation SAPIEN valve, which also makes it more susceptible to recoil. To our knowledge, late recoil has not been previously investigated or measurably reported nor has acute recoil of the SAPIEN 3 valve been studied. The SAPIEN 3 stent scaffold is made of CoCr alloy and consists of five rungs of struts with a wider strut angle. These characteristics provide higher radial strength to keep circularity compared to the SAPIEN XT valve (internal data provided by Edward Lifesciences Inc.) [9, 10] and likely make the SAPIEN 3 valve less prone to recoil compared to the SAPIEN XT valve; however, the degree of acute or late recoil of the SAPIEN 3 valve has not yet been studied in vivo. Nevertheless, we postulate recoil would have less effect on PVL of the SAPIEN 3 valve, given the presence of the outer skirt, and therefore we chose to treat our patient with the SAPIEN 3 valve. In a large observational study of slightly over 1000 patients, the SAPIEN 3 valve was associated with 3.4% incidence of moderate to severe PVL at the 30-day follow-up [11] and only 2% at 1 year [12].

It is also worthwhile mentioning that although we initially suspected aortic migration of the valve as the mechanism for progression of the PVL, late aortic migration of TAVR valves is an extremely rare phenomenon, and late migration of the TAVR valve is most commonly retrograde towards the left ventricle as opposed to towards the aorta. Interestingly, a computational fluid dynamics model showed that the antegrade force exerted on the TAVR valve during ejection is tenfold weaker than the retrograde force applied to it in diastole, which would explain why late migration tends to occur towards the left ventricular outflow tract [13].

CONCLUSION

Acute and late recoil are mechanisms for development and progression of PVL. Studies have shown an average 3.75–5.18% of acute recoil associated with the SAPIEN XT valve depending on the valve size or the study [7, 8]. This case report shows late recoil as the likely mechanism for progression of PVL during follow-up after a 26-mm SAPIEN XT implantation and in summation shows 7.07–9.25% of acute plus late recoil at different valve levels at 1 year of follow-up. The effect of valve recoil on PVL has not been previously studied. Future studies need to systematically evaluate and report acute and late recoil and how they affect PVL.

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Compliance with Ethics Guidelines. Informed consent was obtained from the patient for receiving treatment.

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