Aortic Complex Rupture After Transcatheter Aortic Valve Implantation

A Clinical Case Series

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Summary

Aortic complex rupture is one of the most critical complications associated with transcatheter aortic valve implantation (TAVI). Its incidence is rare, and its mechanism varies by case; therefore, it is difficult to identify the predictors of complex rupture. Herein, we report a clinical case series of aortic complex rupture. Within our cohort, the frequency of complex rupture was 0.8% (4/497 consecutive patients) with an in-hospital mortality of 0. Among these four patients with complex rupture, two underwent emergent thoracotomy and surgical hemostasis without a heart-lung machine and surgical aortic valve replacement, whereas the other two were conservatively managed. The case overview revealed the following similarities: all the patients were elderly, small women; balloon-expandable valves were used; the annulus area was small with heavily calcified leaflet; and aggressive treatment strategy was used (i.e., oversizing and post-dilatation). In such cases, TAVI should be performed with a careful strategy. Once aortic complex rupture occurs, damage can be minimized through cooperation with an institutional heart team and calm management.

(Int Heart J 2019; 60: 772-777)

Key words: Aortic stenosis, Aortic complex rupture

Transcatheter aortic valve implantation (TAVI) is an alternative approach for the treatment of patients with severe aortic stenosis (AS) who are considered ineligible or high risk for surgical aortic valve replacement (SAVR).¹⁻⁴⁾ Although the number of TAVI procedures has increased rapidly worldwide as a consequence of the super-aging society,⁵⁾ TAVI can be sometimes associated with critical procedural complications such as aortic complex rupture, coronary occlusion, and access vascular rupture. Although new-generation devices have reduced these complications, the mortality associated to catastrophic complications remains high. According to the European Registry on Emergent Cardiac Surgery (EuRECS)-TAVI, the in-hospital mortality associated with annulus rupture is 62.2%, which is the highest mortality rate of TAVI-related life-threatening complications requiring emergent cardiac surgery.⁶⁾

The incidence of aortic complex rupture is rare, and its mechanism varies by case, making it difficult to identify the predicting factors of this complication.

Herein, we report the cases of four patients with

TAVI-related aortic complex rupture, who were successfully managed and discharged from the hospital without further complications.

Case Report

Between October 2013 and March 2018, 497 patients underwent TAVI in Kokura Memorial Hospital. Among these, 493 received either the Edwards balloon-expandable valve (Edwards Lifesciences Irvine, CA, USA; SAPIEN XT, $n = 214$; SAPIEN3, $n = 208$) or the Medtronic self-expandable valve (Medtronic, Minneapolis, MN, USA; CoreValve, $n = 17$; Evolut R, $n = 54$). Four patients presented with aortic complex rupture after TAVI.

Case 1: An 86-year-old woman was referred to our institution from another center for TAVI. Transthoracic echography (TTE) revealed severe AS with an aortic valve area (AVA) of 0.6 cm², mean pressure gradient (mPG) of 54.6 mmHg, and ejection fraction (EF) of 50.0%. The annulus area was 411.2 mm² (24.9 × 22.3 mm) as measured by multi-detector computed tomography (MDCT). The aortic

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Received for publication August 10, 2018. Revised and accepted October 29, 2018.

Released in advance online on J-STAGE April 25, 2019.

doi: 10.1536/ihj.18-484

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Figure 1. Distribution of annulus calcification, aortic annulus area, and diameter in the pre-procedural multi-detector computed tomography. **A:** Case 1; **B:** Case 2; **C:** Case 3; **D:** Case 4.

valve was a severely calcified bicuspid valve, presenting fusion of the right-coronary and non-coronary cusps. In the left-coronary cusp, the calcification extended into the left ventricular outflow tract (LVOT) (Figure 1A).

The patient underwent transfemoral TAVI using SAPIEN XT 26 mm with 1-mL under balloon volume (oversizing ratio, 1.29; Figure 2A). One day after TAVI, TTE revealed no problems. However, a pre-discharge TTE at 1 week after TAVI revealed a continuous shunt between the aorta and the right ventricle, and aortography showed blood flow from the aortic annulus to the right ventricle (Figure 3A).⁷⁾ Because the patient was asymptomatic and presented a normal hemodynamic status, we carefully proceeded without any intervention. More than 1 year after TAVI, the patient was doing well without heart failure (Table I).

Case 2: An 86-year-old woman underwent TAVI for severe, symptomatic AS (AVA of 0.72 cm², mPG of 69.5 mmHg, and EF of 58.6%). MDCT showed that the annulus area was 347.0 mm² (23.4 × 18.7 mm), and the leaflet presented severe calcification (Figure 1B). A 26-mm Evolut R prosthesis was implanted via the subclavian approach under general anesthesia. Transesophageal echography revealed a mild-to-moderate paravalvular leak; therefore, post-dilatation was performed with Z-MED II 20 mm (NuMED, Inc., Denton, TX, USA; Figure 2B). After post-dilatation, aortic complex rupture and pericardial effusion were identified by transesophageal echography (Figure 3B), with an immediate instability of hemodynamic status. Extracorporeal membrane oxygenation, followed by thoracotomy was performed, and eruptive hemorrhage from the anterior wall of the right ventricle

was detected. The patient underwent patch repair and was discharged from our hospital to receive rehabilitation in a different institution (Table I).

Case 3: An 82-year-old woman was referred to our institution for severe AS and acute heart failure. TTE revealed severe AS with an AVA of 0.63 cm², mPG of 39.3 mmHg, and EF of 67.3%. The annulus area was 313.0 mm² (22.2 × 16.9 mm), as measured by MDCT (Figure 1C). Because the aortic valve did not show heavy calcification and because of comorbidity and frailty, transfemoral TAVI using SAPIEN 3 23 mm was performed (oversizing ratio, 1.30).

SAPIEN 3 23 mm was implanted with a 1-mL under balloon volume. TTE showed a mild-to-moderate paravalvular leak; therefore, post-dilatation with nominal volume was performed (Figure 2C).

The patient's condition was stable, and TTE performed immediately and 1 day after the procedure revealed an absence of problems, including cardiac effusion. Although she was asymptomatic, a routine pre-discharge MDCT (4 days after TAVI) revealed pseudoaneurysm and pericardial effusion (Figure 3C). Her hemodynamic status was stable, and the pericardial effusion was small and did not increase thereafter, probably because of the depression caused by the surrounding tissue. She was closely followed, and 1 year after TAVI, she was doing well and remained asymptomatic (Table I).

Case 4: An 85-year-old woman was referred to our institution for the treatment of severe, symptomatic AS. Her symptoms were NYHA IV, and TTE revealed severe AS with an AVA of 0.55 cm², mPG of 71.4 mmHg, and preserved EF of 69.6%. CAG revealed significant coronary

Figure 2. Implantation of transcatheter heart valve or post-dilatation during the procedures. **A:** Case 1, implantation of SAPIEN XT 26 mm with 1-mL underfilling. **B:** Case 2, post-dilatation with Z-MED II 20 mm. **C:** Case 3, post-dilatation with a 23-mm device balloon with nominal volume. **D:** Case 4, post-dilatation with a 23-mm device balloon with nominal volume.

artery stenosis (#6-#7, 90%). Given her age and frailty, the institutional heart team decided to perform TAVI after percutaneous coronary intervention. She first underwent percutaneous coronary intervention for #6-#7 with Ultimaster 3.0 × 38 mm (Terumo Corp., Tokyo, Japan).

The annulus area was 346.4 mm² (22.8 × 18.4 mm), as measured by MDCT (Figure 1D). The leaflet of the aortic valve was heavily calcified, and the left-coronary height was low (9.9 mm). Transfemoral TAVI using a SAPIEN 3 23 mm with coronary protection was performed.

SAPIEN 3 23 mm was implanted with nominal volume under local anesthesia (oversizing ratio, 1.17). The expansion of the implanted valve was insufficient as fluoroscopically evaluated; therefore, post-dilatation with nominal volume was performed (Figure 2D), after which electrocardiography revealed ST elevation and gradually decreasing blood pressure. A subsequent aortography revealed constant leakage at the level of the sinus of Valsalva between the right-coronary and non-coronary cusps (Figure 3D). Although her hemodynamic status was relatively stable, blood pressure gradually decreased due to pericardial tamponade; therefore, surgical hemostasis was performed. Because the bleeding was not severe, it could

be managed with compression hemostasis. The patient was discharged from the hospital on foot (Table I).

Discussion

Our cohort presented a frequency of aortic complex rupture of 0.8% (4/497 consecutive patients), with an in-hospital mortality of 0. Among the four patients with aortic complex rupture, two underwent emergent thoracotomy and surgical hemostasis without a heart-lung machine or SAVR, whereas the other two were conservatively managed. Although a previous study has shown a high mortality associated with aortic complex rupture after TAVI,⁶⁾ a better management may improve the survival (Table I, Table II). All the four patients in the present series were elderly, small women, and balloon-expandable valves were used in three patients. These characteristics are similar to those in previous reports (Table II). In most patients, the MDCT features included a small annulus area and heavily calcified leaflet. Case overview revealed that the most common mechanism of aortic complex rupture was an aggressive treatment strategy (i.e., oversizing and post-dilatation).

Figure 3. Imaging-detected aortic annulus rupture. **A:** Case 1, aortography after the implantation of SAPIEN XT showing blood flow from the aortic annulus to the right ventricle. **B:** Case 2, transesophageal echography after post-dilatation showing pericardial effusion. **C:** Case 3, multi-detector computed tomography at 4 days after the procedure showing pseudoaneurysm and pericardial effusion. **D:** Case 4, aortography after post-dilatation showing constant leakage at the level of the sinus of Valsalva between the right-coronary and non-coronary cusps.

According to the EuRECS-TAVI, the incidence of aortic complex rupture requiring emergent cardiac surgery was under 0.4% during follow-up; however, the associated in-hospital mortality was 62.2%.⁶⁾ Although in our cohort the incidence of aortic complex rupture requiring emergent surgery was similar (0.4%, 2/497 patients), there were no instances of in-hospital mortality. Table I depicts a brief description of these previous cases. In summary, most of the patients were women (5/8 patients) aged between 81 and 93 years, and all the patients were treated with balloon-expandable valves. Most of the patients got pericardial tamponade (7/8 patients) and received surgical treatment (4/8 patients) or pericardial drainage (2/8 patients), whereas in one patient, the rupture was contained and conservatively managed. All the patients survived due to good management.

Surprisingly, all the patients were elderly, small women in this case series. A previous study on patients with acute myocardial infarction showed that the female population is at a higher risk for mortality,⁸⁾ which may be related with older women receiving a less aggressive treat-

ment⁹⁾ or with the incidence of procedural complications, such as vascular and hemorrhagic complications, which are more frequent among women.¹⁰⁾ In contrast, according to the Women's International Transcatheter Aortic Valve Implantation registry, women present good early and mid-term outcomes regarding vascular complications and life-threatening bleeding.^{11,12)} Asian TAVI candidates have smaller bodies than the European candidates,¹³⁾ and among nonagenarian TAVI patients, there are several female patients.¹⁴⁾

Among the patients with aortic complex rupture, the MDCT features included a small annulus area and a heavily calcified leaflet. These features may be more common among elderly, small women. A previous study has reported that patients with annulus rupture present large calcifications in the epicardial fat area of the annulus.¹⁵⁾ In our cohort, only one patient (Case 1) exhibited a huge calcification in such a vulnerable area. Barbanti *et al.* revealed that massive calcifications in the LVOT were the cause of complex rupture.¹⁶⁾ In our cohort, only one patient (Case 1) exhibited severe calcification in the LVOT.

Table I. Patients' Descriptive Data and Clinical Course After Annulus Rupture

Case	Age (years)	Sex	Comor-bidity	CAAA (mm ²)	Access	Implantation	Post-dilatation	Detail	Treatment	Discharge (days)	Last follow-up (days)
1	86	F	Af, COPD	411.2	Trans-femoral	SAPIEN XT 26 mm – 1-mL underfilling	None	Aorto-RV fistula	Conservative management	Alive (POD 19)	Alive (POD 456)
2	86	F	HT	347.0	Trans-subclavian	Evolut R 26 mm	Z-MED II 20 mm	Eruptive hemorrhage	ECMO, Surgical management without HLM	Alive (POD 22)	Alive (POD 502)
3	82	F	HT, Af	313.0	Trans-femoral	SAPIEN 3 23 mm – 1-mL underfilling	Device Balloon 23 mm nominal	Contained rupture	Conservative management	Alive (POD 13)	Alive (POD 375)
4	85	F	HT	346.4	Trans-femoral	SAPIEN 3 23 mm nominal	Device Balloon 23 mm nominal	Pericardial tamponade	Surgical management without HLM	Alive (POD 24)	Alive (POD 196)

CAAA indicates calculated aortic annulus area; F, female; Af, atrial fibrillation; COPD, chronic obstructive pulmonary disease; HT, hypertension; RV, right ventricle; ECMO, extracorporeal membrane oxygenation; HLM, heart lung machine; and POD, postoperative day.

Table II. Summary of Previously Published Cases of Annulus Rupture Following Transcatheter Aortic Valve Implantation

Journal	Age (years)	Sex	Comor-bidity	CAAA (mm ²)	Access	Implantation	Post-dilatation	Detail	Treatment	Discharge (days)	Last follow-up (days)
JACC Interv 2013	82	F	Un-known	Un-known	Trans-femoral	Edwards valve 26 mm nominal	none	Pericardial tamponade	Percutaneous drainage	Alive (POD 8)	Alive (POD 8)
CCI 2013	93	M	Un-known	Un-known	Trans-femoral	Edwards valve 26 mm nominal	Device balloon 26 mm + 2-mL overfilling	Pericardial tamponade	Percutaneous drainage	Alive (POD 10)	Alive (POD 365)
	89	F	Un-known	Un-known	Trans-aortic	Edwards valve 26 mm nominal	none	Pericardial tamponade	Surgical management without HLM	Alive (un-known)	Alive (POD 365)
Gen Thorac Cardiovasc Surg 2015	81	F	DL, DM	Un-known	Trans-femoral	Edwards valve 26 mm nominal	none	Pericardial tamponade	Pericardial patching and bypass with HLM	Alive (un-known)	Alive (unknown)
Acta Cardiol 2015	81	M	Un-known	460.0	Trans-femoral	Edwards valve 26 mm nominal	none	Pericardial tamponade	SAVR with HLM	Dead (POD 4)	Dead (POD 4)
JACC Interv 2016	89	F	Un-known	278.0	Trans-femoral	SAPIEN XT 23 mm – 2 mL underfilling	Device balloon 23 mm – 1-mL underfilling	Contained rupture	Conservative management	Alive (POD 30)	Alive (POD 365)
Eurointervention 2017	82	M	Un-known	665.0	Trans-femoral	SAPIEN 3 29 mm nominal	none	Pericardial tamponade	Second SAPIEN 3 implanted	Alive (un-known)	Alive (POD 30)
Wien Klein Wochenschr 2017	80	F	Un-known	475.0	Trans-femoral	SAPIEN XT 26 mm nominal	none	Pericardial tamponade	SAVR with HLM	Alive (POD 14)	Alive (POD 365)

CAAA indicates calculated aortic annulus area; F, female; M, male; DL, dyslipidemia; DM, diabetes mellitus; HLM, heart lung machine; SAVR, surgical aortic valve replacement; and POD, postoperative day.

These factors are widely known factors of aortic complex rupture and clinicians should take care of them. Therefore, paradoxically, severe calcifications in the epicardial fat area of the annulus and LVOT were not the main reason of the complex rupture.

The most common mechanism of aortic complex rup-

ture was an aggressive treatment strategy, such as oversizing and post-dilatation. In the era of SAPIEN XT, excessive oversizing is reported to carry a risk of root injury.¹⁷⁾ TAVI using new-generation devices in intermediate-risk patients is associated with low mortality and no complications, with superiority for composite outcomes, compared

with SAVR.¹⁸⁾ We have rarely experienced fatal complications such as aortic complex rupture and coronary obstruction.⁶⁾ Moreover, better TAVI results, such as paravalvular leakage reduction and prosthesis-patient mismatch, are required. These factors may lead to an aggressive treatment strategy, especially in the case of small annulus size to avoid prosthesis-patient mismatch, and the use of self-expanding valve will potentially avoid rupture and patient-prosthesis mismatch.

Conclusion

Herein, important cases of patients with TAVI-related aortic complex rupture were described, all of whom were successfully managed. The case overview revealed several similarities, including advanced age, female sex, small body size, use of balloon-expandable valves, a small annulus area, heavily calcified leaflet, and aggressive treatment strategy (i.e., oversizing and post-dilatation). In cases with such characteristics, TAVI should be performed according to more careful strategies. Moreover, once aortic complex rupture is observed, cooperation with an institutional heart team and calm management are critical for patient survival.

Disclosure

Conflicts of interest: Miura is a consultant for Japan Lifeline. All other authors declare no conflicts of interest.

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