

Three-step surgical management algorithm for annular rupture in transcatheter aortic valve replacement



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ABSTRACT

Objective: Whereas transcatheter aortic valve replacement is widely implemented, annular rupture is a devastating complication and could be highly mortal. However, owing to its rare incidence, the optimal treatment algorithm has not been established. Thus, we evaluated the feasibility and effectiveness of a 3-step algorithm to treat annulus rupture.

Methods: From 2009 to 2022, 8 patients of 1083 transcatheter aortic valve implantation (0.8%) developed annulus rupture and were treated with the three-step algorithm. The algorithm was composed of a first step (pericardial drainage and protamine neutralization with blood pressure control), second step (manual hemostatic compression via full/partial sternotomy), and a third step (conservative treatment or radical surgical correction).

Results: The median age at the procedure was 85 (78-88) years and 7 female patients were included in this study. Two (25%) patients had end-stage renal failure under hemodialysis, and median Society of Thoracic Surgeons score was 8.9% (2.1%-23.2%). The implanted transcatheter heart valves (THVs) were 7 balloon-expandable THVs and 1 self-expandable THV with balloon postdilatation. Under this strategy, 8 (100%) patients underwent pericardial drainage as first step and 5 patients achieved hemostasis. Of these, patient 1 demonstrated bleeding from left sinus of Valsalva and required a Bentall procedure. Although the etiology of this phenomenon was not investigated by contrast-enhanced computed tomography, it might be derived from pseudoaneurysm rupture or delayed annular rupture. In 2 patients, the second step treatment was needed for hemostasis. Third-step treatment was conducted in 1 patient. Postoperatively, 6 patients could be discharged without critical complications whereas 2 patients died during the hospitalization. There were no other complications during the followed-up (584 [7-1614]) days.

Conclusions: In accordance with the three-step algorithm, 6 patients, including those with high-risk or inoperative status, survived. (JTCVS Techniques 2023;22:169-77)

The safety and efficacy of transcatheter aortic valve replacement (TAVR) have been developed. Nonetheless, certain complications that follow TAVR still remain

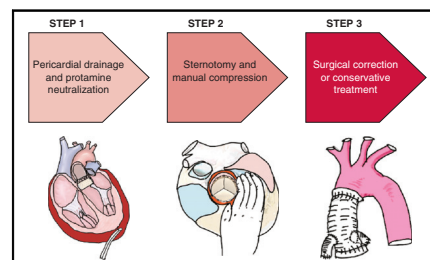
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Three-step algorithm combines with palliative, definite, and conservative treatments.

CENTRAL MESSAGE

The 3-step algorithm is a feasible process to tackle annular rupture with complicated anatomy following transcatheter aortic valve replacement.

PERSPECTIVE

The anatomy of annular rupture following transcatheter aortic valve replacement has been already described. However, the prompt management is not standardized and the lack of the cascading process is associated with its high mortality. Also, the ultimate goal of the treatment varies in each patient depending on their surgical risks. Herein, we report the outcomes of our comprehensive management.

concerns. Of note, annular rupture is a life-threatening disease and results in a devastating postoperative course.¹ Despite the cautious assessment, it is sometimes inevitable that high-risk or inoperable patients requiring aortic stenosis treatment experience this severe complication following TAVR, irrespective of the indication of surgical conversion. The treatment is quite challenging once this has taken place instantaneously. Although a surgical approach, including aortic root replacement, may be conventional, it is too invasive to perform in high-risk patients. Given the situation, we adopted a step algorithm and implemented the treatment for annular rupture. Whereas the etiology, the anatomy of ruptured site, and its treatments including pericardial

Abbreviations and Acronyms

CT	= computed tomography
LVOT	= left ventricle outflow tract
PCPS	= percutaneous cardiopulmonary support
POD	= postoperative day
SV	= sinus of Valsalva
TAVR	= transcatheter aortic valve replacement
THV	= transcatheter heart valve

drainage or surgical correction already are known,¹ the mortality of this disease, which ranges from 33% to 52%,²⁻⁵ is still high reportedly. According to the previous reports,¹⁻⁵ although there are a wide variety of techniques and management, the optimal and prompt treatment has not been determined owing to its emergency status and various types of annular ruptures.¹ Moreover, the ability to endure operation is widely varied in patients, with several risks. As a result, the chaotic surgical management seems to be associated with high mortality of this disease. Herein, we examine the validity and report the outcomes of our strategy for this complicated disease to standardize its management for low- to high-risk patients.

METHODS

Study Cohort and Data Collection

The institutional surgical database contained a consecutive series of 1083 patients who underwent TAVR for severe aortic stenosis in Osaka University Hospital between September 2009 and December 2021. Of these, 8 patients presented annular rupture of aortic root following TAVR, and they were enrolled in this study. Medical charts, operation reports, and referral letters were reviewed to collect the data, which was further supplemented not only by outpatient service but also by telephone interviews for the patients under the care of distant physicians. All patients were followed up at least once a year. Data collection was performed between September 2009 and January 2023. All patients gave written informed consent for surgery and use of data for diagnostic and research purpose before the surgery. The institutional review board approved the study and waived the need for the patient consent for this retrospective study (No. 16105, approved November 22, 2016).

Operative Details and Diagnosis of Annular Rupture

TAVR was performed using balloon-expandable transcatheter heart valves (THVs), ie, SAPIEN, SAPIEN XT, or SAPIEN 3 heart valve system (Edwards Lifesciences), or self-expandable THVs, ie, Evolut PRO+ (Medtronic). The optimal THV delivery access, such as transfemoral, transapical, transiliac, or direct aortic approach, was determined by using multislice computed tomography (CT) using the 3mensio Structural Heart (Version 10.1; Pie Medical Imaging BV), preoperatively. Further, the prosthetic valve size was also determined by the annulus size measured by multislice CT. To prevent annular rupture, excessive oversizing ($\geq 20\%$),¹ which is a discrepancy between the size of the native annulus and the prosthesis, was not conducted. These decisions, including whether or not TAVR was suitable in each patient, were determined by the institutional heart team discussion.^{6,7} We determined THV type from aspects of aortic complex anatomy including the size of aortic annulus, sinus of Valsalva (SV), sinotubular junction, coronary artery orifice height, volume of calcification, calcification distribution, bicuspid valve, and access site, irrespective

of patients with high Society of Thoracic Surgeons score. The institutional indication for TAVR was changed during the study period. Based on Society of Thoracic Surgeons score, high-risk patients or intermediate-risk patients with inoperative risks underwent TAVR until the early 2010s, whereas low- or intermediate-risk patients without prohibited surgical risks have undergone TAVR recently.⁸

The diagnosis of annular rupture was detected by the intraoperative aortography and echocardiography. After denying the possibility of acute aortic dissection and/or perforation of left or right ventricle by wire-related procedure, the diagnosis and its etiology of cardiac tamponade, which was derived from annular rupture, was given. In all 8 cases, postoperative CT of the heart was performed, and penetration of calcium hematoma around the aortic root was observed.

Surgical Management of Annular Rupture

As the first step, protamine titration and pericardial drainage via subxiphoid pericardiectomy to relieve cardiac tamponade were performed. When hemodynamic instability was observed, percutaneous cardiopulmonary support (PCPS) via femoral artery and vein was established. Systolic blood pressure was controlled under 100 mm Hg. When continuous bleeding and hemodynamic instability was not resolved, the treatment was moved to second step, in which median sternotomy or lower partial sternotomy was made and direct manual compression for ruptured aortic annulus was carried out (Figure 1). Active coagulation substances, such as Tachosil (hemostatic surgical patch; Nycomed), fibrin sealant patch, was used to reinforce hemostasis. The duration of the manual compression was continued for at least an hour. During the compression, the risk of radical surgical repair (root replacement) for each case was discussed by the heart team and the full consideration for patients' themselves was confirmed. When bleeding was controlled in step 1 or step 2 treatment, the patient was directly transferred for electrocardiogram-gated CT to confirm the absence of pseudoaneurysm formation before transfer to the intensive care unit. In case the bleeding was still active or pseudoaneurysm was observed by electrocardiogram-gated CT after step 1/2 treatment, the treatment was moved to third step, in which radical operation (root replacement) or conservative treatment for inoperable case, such as transfusion and gauze packing, was selected (Figure 2).

RESULTS

Baseline Characteristics

Eight patients developed annular rupture following TAVR during the observational period. Patients'

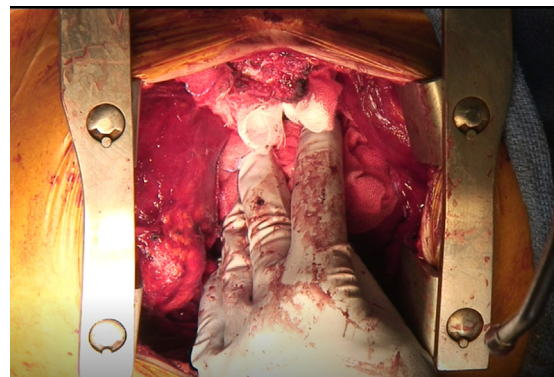


FIGURE 1. Manual compression for annular rupture. Direct manual compression as the second step was conducted by lower partial sternotomy as a result of the failure following the first step (patient 7). Compression with active coagulation substances and gauze for the bleeding site contributed to hemostasis.

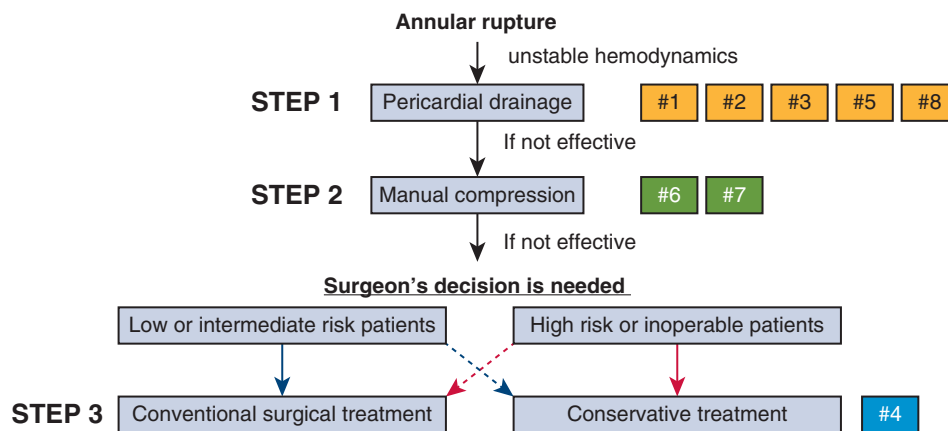


FIGURE 2. Three-step algorithm against annular rupture. Once annular rupture occurred, protamine neutralization and pericardial drainage via subxiphoid pericardiectomy was performed as first step. If not effective, the treatment proceeded to second step and direct manual compression was carried out. Nonetheless, when annular rupture was not resolved, surgeons had to make decisions to select conventional surgical correction or conservative treatment under the consideration of patients' risk and feasibility after the heart team discussion.

characteristics are shown in [Table 1](#). The median age at the procedure was 85 (78-88) years, and 7 patients were female. There were 2 patients requiring hemodialysis preoperatively. The median Society of Thoracic Surgeons score was 8.9% (2.1%-23.2%). According to preoperative CT assessment, median calcium volume, annular size at aortic valve, and SV were 966 mm³ (305-2947 mm³), 22.9 mm (20.7-27.1 mm), and 29.5 mm (27.3-34.8 mm), respectively. The preoperative echocardiographic findings and the year distribution of overall TAVR implementation are described in [Table 1](#).

Valvular Demographics and THV Selection in Each Patient

The details of the aortic valve anatomy and THV selection are shown in [Table 2](#). Except for 1 type 0 bicuspid case (patient 1), 7 patients' aortic valve was tricuspid. Regarding calcium volume, whereas the volume in patient 8 demonstrated 305 mm³, the figures of the other patients were approximately 700 or greater. As for THV selection, the self-expandable THVs were chosen in patient 7 and balloon postdilatation was performed. Balloon-expandable THVs were used in the others. Annular size, SV size, THV size, and its oversize ratio in each patient are described in [Table 2](#).

Surgical Outcomes

As shown in [Table 3](#), there were 5 patients treated by the first step and 2 patients proceeded to the second step. Ultimately, 1 patient required the third step. Patients 1 and 2 underwent TAVR via the transapical approach and TAVR via transfemoral approach was conducted in the other 6 patients. To detect the ruptured site and the occurrence of pseudoaneurysm around the annular rupture, we conducted postoperative multislice CT on the same day of TAVR as

early as possible. Seven patients underwent the CT examination, except for patient 1 ([Figure 3](#)). As for the patient (patient 1) of the first step, she initially underwent pericardial drainage for annular after TAVR and it was controllable on the day of TAVR. However, she developed blow-out rupture of aortic annulus despite the cautious postoperative care on postoperative day (POD) 1. Therefore, an additional Bentall procedure was implemented immediately and PCPS was also initiated on the same day. Thereafter, coronary bypass grafting was carried out for low-output syndrome on POD 5; nonetheless, she died eventually. Turning to the patient 4 in the third step, even though she underwent pericardial drainage followed by manual compression and PCPS establishment, the bleeding from aortic annulus could not be controlled. Owing to her poor preoperative status, the decision of the conventional surgical correction for annular rupture was avoided, and she died on POD 7. The other patients were discharged from our hospital, whereas patient 2 underwent permanent pacemaker implantation, patient 6 developed mediastinitis and needed antibacterial treatment, and patient 7 required tracheotomy after prolonged ventilation and the induction of permanent dialysis for preoperative chronic kidney disease. Pseudoaneurysm around aortic annulus was formed in patients 4 and 7 postoperatively. The location of annular rupture in each patient is shown in [Figure 3](#). As for left ventricle outflow tract (LVOT) calcification,⁹ patients 1, 3, and 7 had mild LVOT calcification, whereas LVOTs of patients 7 and 8 displayed moderate and severe calcification, respectively. No patients demonstrated annular rupture at the subannular portion ([Figure 3](#)).

The median followed-up period was 584 days (range, 7-1614 days). Except for 2 deaths in the hospital, the other patients have survived for more than 1 year ([Table 3](#)). As for the long-term outcomes, there were 2 deaths caused by

TABLE 1. Patients' characteristics

Baseline variables	Annular rupture (n = 8)
Age, y (median)	85.5 (78-88)
Sex (female), no. patients (%)	7 (87.5)
BSA, kg/m ² (median)	1.25 (1.22-1.78)
STS score, % (median)	8.9 (2.1-23.2)
Bicuspid valve, no. patients (%)	1 (12.5)
Hypertension, no. patients (%)	5 (62.5)
Dyslipidemia, no. patients (%)	0
Diabetes mellitus, no. patients (%)	1 (12.5)
Chronic lung disease, no. patients (%)	2 (25.0)
Peripheral vascular disease, no. patients (%)	1 (12.5)
Previous cerebrovascular event, no. patients (%)	0
Previous cardiac surgery, no. patients (%)	1 (12.5)
Estimated glomerular filtration rate, mL/min	33.9 (5.2-58.8)
Hemodialysis, no. patients	2 (25.0)
CT measurement	
Calcium volume, mm ³ (median)	966 (305-2947)
Annulus size, mm (median)	22.9 (20.7-27.1)
SV size, mm (median)	29.5 (27.3-34.8)
Preoperative echocardiographic measurement	
Left ventricular end-diastolic dimension, mm (median)	49 (40-66)
Left ventricular end-systolic dimension, mm (median)	36 (20-53)
Mean pressure gradient of aortic valve, mm Hg (median)	71 (40-116)
LVEF, % (median)	52.5 (29-81)
Year distribution of overall TAVR, no. patients	
2009	2
2010	18
2011	21
2012	40
2013	46
2014	104
2015	96
2016	96
2017	143
2018	123
2019	105
2020	115
2021	174

Data are expressed as medians with interquartile range or number (%). BSA, Body surface area; STS, Society of Thoracic Surgeons; CT, computed tomography; SV, sinus of Valsalva; LVEF, left ventricular ejection fraction; TAVR, transcatheter aortic valve replacement.

prosthetic valve endocarditis (patient 2) and unknown origin (patient 3) during the observation. A patient (patient 7) developing pseudoaneurysm has survived without any problems related to the complication for more than 500 days so far. The other 3 patients are surviving without adverse cardiac events.

DISCUSSION

Annular rupture is a life-threatening disease following TAVR that requires a precise diagnosis and emergent management. Although the etiology, classification of the ruptured site in aortic complex, and surgical correction have been described previously,¹⁻⁵ the precise diagnosis and the identification of ruptured site in the limited time and investigation tools in operation rooms are difficult. Furthermore, there are diverse patients with distinct surgical risks, such as inoperable or endurable patients surgically. The high mortality of annular rupture derives not only from the surgical failure but also from the individualized management of this complicated disease. Hence, we need to standardize the management and set the ultimate goal of the treatment in each patient. Thus, we present the three-step algorithm for annular rupture following TAVR.

Treatment of Annular Rupture

Pasic and colleagues¹ have already described the anatomical classification of annular rupture and its treatment. However, the prompt and on-site decision including surgical repair without CT investigation is required once symptomatic annular rupture occurs. Given the circumstances, fluorographic and echocardiographic assessment used in a hybrid operation room, such as transesophageal echocardiography or transthoracic echocardiography, are essential for diagnosis instead of contrast-enhanced CT. In addition, the standard method to repair annular rupture has not established yet, although various treatments have been reported.¹⁻⁵ The anatomical complexity of ruptured site and excessive therapeutical options may contribute to high mortality. When the optimal treatments by conventional surgery have not performed, palliative treatments underlying the precise strategy to control bleeding from aortic annulus are essential. The bailout procedures, valve-in-valve and catheter intervention, may be alternatives^{5,10,11}; however, the consecutive decision is needed if certain treatment is inadequate. In particular, low- or intermediate-risk patients, who are also candidates for surgical aortic valve replacement, can undergo TAVR these days.^{8,12-14} The heart team must consider the eligibility to perform treatments including conventional surgical approach for annular rupture beforehand when low- or intermediate-risk patients

TABLE 2. Valvular demographics and THV selection

Case	Age, y	Sex	STS score, %	Native valve	Calcium volume, mm ³	Annulus size, mm	SV size, mm	THV	THV size, mm	THV oversize, %
1	83	Female	7.1	Bicuspid (type 0)	2947	24	34.8	SAPIEN	26	8
2	85	Female	7.2	Tricuspid	2103	22.5	27.7	SAPIEN XT	23	2
3	86	Female	23.2	Tricuspid	1368	21.3	29.5	SAPIEN XT	23	7
4	88	Female	18.6	Tricuspid	860	23.2	29.4	SAPIEN 3	23	-1
5	78	Male	2.1	Tricuspid	840	27.1	30.9	SAPIEN 3	29	7
6	87	Female	10.6	Tricuspid	1072	25.8	31.8	SAPIEN 3	26	0.7
7	86	Female	16	Tricuspid	743	22.6	28	Evolut PRO+	26	15
8	80	Female	3.5	Tricuspid	305	20.7	27.3	SAPIEN 3	23	10

STS, Society of Thoracic Surgeons; SV, sinus of Valsalva; THV, transcatheter heart valve.

without severe comorbidity develop annular rupture after TAVR. Thus, the uniformized approach with cascading process is needed and we demonstrated the 3-step algorithm for annular rupture.

By contrast, palliative treatments comprising pericardial drainage and manual compression may be an adequate option in high-risk individuals, such as patients on dialysis.¹⁵ After this process, if the bleeding is constant, conservative treatment and watchful waiting may be an ultimate resolution for those groups, even though the robust experience is needed to validate its efficacy.

Reviewing the patients treated by this algorithm in this article, 6 patients were discharged from the hospital and 2 died during long-term observation, not relevant to annular rupture. The mortality rate related to annular rupture accounted for 25% and this was relatively lower than previous reports.²⁻⁵ Thus, our data suggest that the three-step algorithm is feasible and might be effective for the treatment of annular rupture.

In contrast, there is a potential risk of the inadequate treatment by the first and second step for annular rupture in the case of large annular ruptures. In such cases, however, it is quite difficult to diagnose correctly in the operation room. Therefore, we need to recognize the possibility of the ineffective treatment by first and second step and move to the next step systematically through the 3-step algorithm if necessary.

In addition, we need to consider an exception of the three-step algorithm in patients with severe adhesion around the heart due to previous cardiac surgery. Pericardial drainage and manual compression in the first and second step of our strategy may be time-consuming and harmful in such cases. To save the patients faced with hemodynamic instability, we may need to skip first and second step after VA-ECMO establishment. Then, surgical correction or conservative treatment should be considered, whereas we did not experience the exception in this study.

Also, partial sternotomy for annular rupture in second step can minimize the wound, which may help the

postoperative recovery and is enough to conduct manual compression postoperatively. In addition, the minimized wound is beneficial in terms of prevention of surgical-site infection. In particular, lower partial sternotomy enables us to perform a tracheotomy immediately. However, full sternotomy is a standard method and is able to expose aortic root maximally. Even though we performed partial sternotomy in patient 7, who had excessive high risk, partial sternotomy should be optional. In high-risk and inoperable cases aiming for conservative treatment in the final step, partial sternotomy is a useful alternative.

Short- and Long-Term Outcomes After Annular Rupture

Whereas the mortality of annular rupture was reported to be still high, contained aortic annular rupture was reported as the better outcome compared with the noncontained rupture.^{2,16,17} In contrast, the outcomes of surgically repaired annulus with the noncontained rupture showed good short-term outcomes.¹⁸⁻²⁰ However, long-term outcomes have not been clarified, and the further investigation is needed.¹ Considering the prognosis, the formation of pseudoaneurysm stemming from the ruptured site may become a significant contributor not only in short-term but also in long-term outcomes since it caused sudden deaths.^{21,22} Indeed, the catheter intervention for pseudoaneurysm prevents the potential risk of late-onset noncontained annular rupture.¹⁷ On the contrary, looking back in our cohort, patient 7, who was a high-risk patient, has survived for more than 1 year regardless of the existence of pseudoaneurysm. Based on our experience, in high-risk or inoperative patients demonstrating symptomatic annular rupture, palliative treatment based on the strategy is crucial and may be acceptable. More importantly, the regular assessment using the postoperative instant contrast-enhanced CT after the occurrence of annular rupture is vital to search pseudoaneurysm surrounding the ruptured site. In fact, in our case series, patient 1, without the prompt CT evaluation, developed blowout of annular rupture on the

TABLE 3. Surgical outcomes

Case	Year of TAVR	Approach	Treatment	PCPS support	Operation time, min	Bleeding, mL	Algorithm step	Postoperative hospital stay, d	Complication	Formation of pseudoaneurysm	Status at discharge	Status at last follow-up	Follow-up period after TAVR, d
1	2012	TA	Drainage + ad-hoc Bentall (POD1) +CABG (POD5)	Yes (POD1)	122	630	1	23	LOS	-	Dead	Dead	23
2	2013	TA	Drainage	No	169	830	1	26	PMI	No	Alive	Dead	1614
3	2015	TF	Drainage	No	213	1230	1	37	None	No	Alive	Dead	571
4	2017	TF	Conservative treatment	No	325	3700	3	7	LOS	Yes	Dead	Dead	7
5	2019	TF	Drainage	Yes	102	1060	1	40	None	No	Alive	Alive	1421
6	2020	TF	Manual compression	No	114	500	2	106	Mediastinitis	No	Alive	Alive	744
7	2021	TF	Manual compression	Yes	255	3585	2	31	Tracheotomy Permanent dialysis	Yes	Alive	Alive	597
8	2021	TF	Drainage	No	84	180	1	10	None	No	Alive	Alive	542

TAVR, transcatheter aortic valve replacement; PCPS, percutaneous cardiopulmonary support; TA, transapical; POD, postoperative day; CABG, coronary artery bypass grafting; LOS, low-output syndrome; PMI, pacemaker implantation; TF, transfemoral.

Classification of annulus rupture

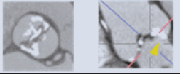


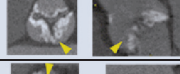
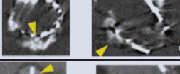





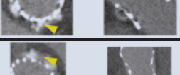


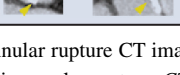
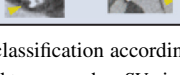
Case	Preoperative CT image	Post-rupture CT image	Ruptured site	Classification of annular rupture
1		No CT image	SV (L)	Supra-annular
2			SV (R)	Supra-annular
3			AVJ (N-L commissure)	Intra-annular
4			SV (R)	Supra-annular
5			SV (L)	Supra-annular
6			SV (N-L commissure)	Supra-annular
7			SV (R)	Supra-annular
8			AVJ (N-L commissure)	Intra-annular

FIGURE 3. Pre- and postannular rupture CT image and its classification according to anatomy. *Yellow arrow* indicates the projection of the calcium of aortic annulus and it resulted in annular rupture. *CT*, Computed tomography; *SV*, sinus of Valsalva; *L*, left; *R*, right; *AVJ*, arterioventricular junction; *N*, non.

next day of TAVR, and we lost the case. The CT examination may be beneficial to evaluate its enlargement or shrinkage in the long-term period when the patients suffered from symptomatic annular rupture have survived through the three-step algorithm. In contrast, the immediate CT scan in high-risk or inoperable patients undergoing the conservative treatment as the final step may be dangerous and less meaningful due to hemodynamic instability and no options to treat if a pseudoaneurysm exists. It is latently advantageous to estimate the therapeutic efficacy in these patients, whereas there is no need to conduct prompt contrast-enhanced CT.

THV Types Related to Annular Rupture

Focusing on THV types, balloon-expandable THV is more associated with annular rupture than self-expandable THV reportedly.^{1,2,5,9,23} The mechanism of annular rupture by using self-expandable THV stems from overdilatation of the prosthesis. Likewise, we experienced 1 patient who developed annular rupture after TAVR using self-expandable THV who underwent postdilatation to reduce paravalvular leakage. This phenomenon had been demonstrated by Pasic and colleagues¹ previously. Whereas there were diverse causes of annular rupture, the prudent consideration of aortic complex and selection of THV type is

crucial to avoid rupture. If patients have various factors for annular rupture and have been identified as being in the high-risk group of annular rupture, we may need to reconsider the indication of surgical aortic valve replacement, especially in low- to intermediate-surgical risk patients.

Study Limitations

This study is limited by the retrospective nature of the study design. During the study period, we encountered only 8 patients who developed annular rupture following TAVR. This was too small a number to analyze the significant factor leading this disease statistically and to conclude that the three-step algorithm is effective enough to treat annular rupture.

CONCLUSIONS

As annular rupture is extremely dangerous and needs instantaneous cure, the establishment of consecutive treatments is required for this pathology. The three-step algorithm and its management combined with palliative treatments for annular rupture may improve the prognosis, especially in high-risk or inoperative patients, whereas there are still controversies in low- or intermediate-risk patients in terms of their optimal treatment (Figure 4).

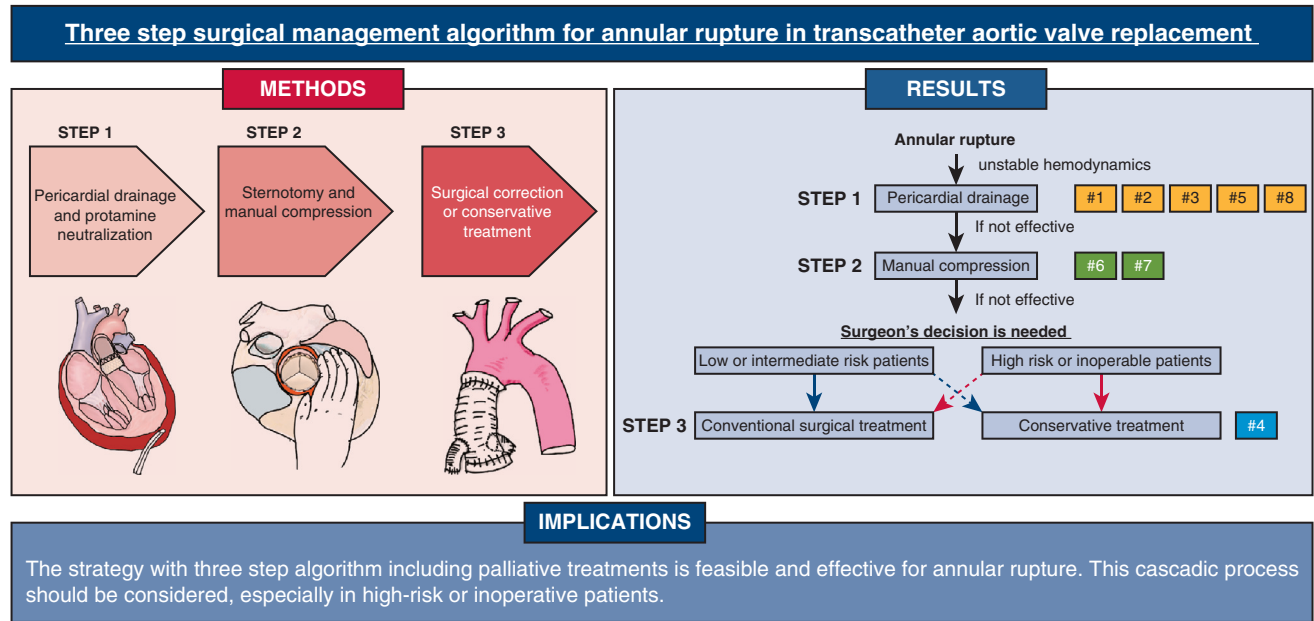


FIGURE 4. Three-step algorithm. Three step algorithm combined with a surgical correction and palliative treatments is a supportive strategy for annular rupture in the emergent situation following TAVR. TAVR, Transcatheter aortic valve replacement.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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