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# Outcomes of Cardiac Tamponade Post-Transcatheter Aortic Valve Replacement: Results From a Tertiary Cardiac Center

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ABSTRACT

*Background:* Cardiac tamponade is a rare but potentially lethal complication of transcatheter aortic valve replacement (TAVR). There is paucity of evidence assessing the incidence and outcomes of patients with cardiac tamponade after TAVR.
*Methods:* A retrospective review was performed of all patients who underwent TAVR at our institution from January 2013 to January 2019. The clinical characteristics of patients who developed cardiac tamponade in the periprocedural period were compared to the patients who did not develop tamponade. Qualitative and quantitative assessment of aortic annular calcium distribution on cardiac computerized tomography was analyzed.
*Results:* Twenty out of 2030 patients (0.9%) developed cardiac tamponade post-TAVR. The mean age of the cohort developing cardiac tamponade was 81.7 years, and 50% of them were men. Most of these were intraprocedural (70%) while the remaining were identified in the postprocedural period. The site of injury resulting in pericardial tamponade was thought to be from the injury to aortic annulus (50%), right ventricle (40%), and left ventricle (10%). Tamponade due to annular or left ventricular trauma was mostly identified intraprocedurally (91%; n = 10 of 11), while patients with tamponade due to presumed right ventricular injury were mostly identified in the postprocedural period (62.5%; n = 5 of 8) ($p = 0.009$). Conservative management with supportive therapies was employed in 90% of patients with cardiac tamponade, while two patients had cardiac surgery. There was one in-hospital mortality, and another patient died within 30 days of the TAVR procedure.
*Conclusion:* The incidence of cardiac tamponade after TAVR (0.9%) was low, and this serious complication can be managed successfully in the majority of patients with streamlined processes in high-volume centers.

ABBREVIATIONS

TAVR, transcatheter aortic valve replacement.

## Introduction

Transcatheter aortic valve replacement (TAVR) has revolutionized the way patients with severe aortic stenosis are managed at all surgical risk levels.[1–4] While significant complications like aortic dissection, access site injury, valve embolization, and aortic annular rupture are rare, they present significant risk for morbidity and/or mortality.[5] In this regard, cardiac tamponade is uncommon but carries a high mortality rate,

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especially when it is due to annular trauma.[6,7] Management of cardiac tamponade often requires pericardiocentesis or surgical intervention, which may be challenging due to the high surgical risk of patients undergoing TAVR. There is a paucity of literature regarding the incidence and management of cardiac tamponade after TAVR.[8,9] The aim of this study was to provide a temporal trend of cardiac tamponade post-TAVR and report its incidence and management in the contemporary era.

## Study Design

This was a single-center retrospective observational study performed to evaluate the incidence of tamponade post-TAVR and its management in a tertiary care center. We also aim to provide a procedural case description that may shed some light on this complication and help to identify the etiology of tamponade in these cases. The study was approved by the Cleveland Clinic Institutional Review Board (IRB-181500). The data were deidentified and informed consent was waived. All patients who underwent TAVR from January 2013 to January 2019 after the routine heart team evaluation were identified in the Cleveland Clinic Aortic Valve Center TAVR database. A total of 2030 cases of TAVR were identified. Cardiac tamponade was defined as a life-threatening event that involved slow or rapid compression of the cardiac chambers as a result of pericardial fluid.[10]

Clinical, imaging, procedural features, and follow-up data were collected through review of the electronic medical records. The clinical features collected included age, gender, race, clinical symptoms (angina and syncope), body mass index, diabetes mellitus, smoking, porcelain aorta, hypertension, end-stage renal disease, peripheral vascular disease, stroke, or transient ischemic attack, right/left ventricular size (RV/LV) and function, prior coronary artery bypass graft/percutaneous coronary intervention, and intracardiac devices. Procedural features included type of anesthesia, access site and sheath size, type of temporary pacemaker wire, valve type (balloon-expandable or self-expanding valve), bioprosthetic valve type for valve-in-valve TAVR, guide wires, and pre-/post-dilation. Given the potentially lethal complication, primary endpoint was all-cause death within 30 days of the TAVR procedure. Secondary endpoints included need for cardiac surgery, shock, acute kidney injury, requirement for permanent pacemaker implantation, and in-hospital death. The etiology of tamponade was retrospectively confirmed by A.K. and S.R.K. via review of procedural imaging, the medical chart, and blood gases drawn from the drain when available.

In cases of cardiac tamponade, the preoperative cardiac computed tomography was reviewed again for calcification and its extent.[11] Annular and aortic root measurements were typically performed in systolic (20-30%) phases. Quantitative and qualitative measures were used to assess calcium burden. A volumetric technique was used to assess the extent of calcium, and the mean calcium score was determined using the Agatston method.[12]

## Statistical Analysis

Continuous variables were expressed as mean (standard deviation), and categorical variables were expressed as frequency (percentages). Continuous variables were compared using the Student's t test, while categorical variables were compared using chi-square tests or Fisher exact tests as deemed suitable. The statistical analysis was accomplished using STATA (version 15.1; Statacorp, College Station, Texas).

## Results

### *Baseline Characteristics*

We identified 20 patients (0.9%) with cardiac tamponade from a total cohort of 2030 patients who underwent TAVR for severe aortic stenosis. Baseline characteristics are summarized in Table 1. As expected, patients undergoing TAVR were elderly and had a mean Society of Thoracic Surgeons score of 6.8 ± 3.5. Almost half of the patients had a history of smoking, with more than 80% suffering from hypertension, and diabetes was present in two-third of the cohort.

The average age of the patients suffering from cardiac tamponade was 81.7 years with high rates of comorbidities. Twenty percent (n = 4) of patients suffering from cardiac tamponade were on chronic suppressant steroids. Peripheral arterial disease was present in 20% (n = 4) patients, of whom two had anatomy unsuitable for transfemoral transcatheter aortic valve replacement; one patient underwent subclavian access, and another had transcaval TAVR. Details of anesthesia and equipment including valve type and size and guidewire are provided in Table 2.

### *Radiographic Characteristics*

Echocardiographic parameters are documented and compared in Table 3. All but two patients underwent contrast-enhanced cardiac computed tomography. Cardiac magnetic resonance imaging was used for annular measurement when computed tomography was not available. Aortic valve calcification was severe in 85% and moderate in 15% of cases. All patients had severe leaflet calcification, and 60% of patients (n = 12) also had landing zone calcification. Landing zone calcium was most common in the left coronary cusp (58.3%), followed by a combination of non- and left coronary cusp. The mean aortic valve calcium score was 2566.2 ± 1223.2 Agatston Units and landing zone with a value of 408.3 ± 824.8 Agatston Units (Table 2).

**Table 1**
Baseline characteristics of TAVR recipients who experienced cardiac tamponade

| Characteristics | TAVR complicated by cardiac tamponade (20) | TAVR without cardiac tamponade (2030) | *P* value |
|---|---|---|---|
| Age | 81.7 ± 10.1 | 80.6 ± 9.2 | NS |
| Male | 10 (50) | 1167 (57.4) | NS |
| BMI | 25.8 ± 5.06 | 29.4 ± 13.6 | NS |
| Former smoker | 9 (45) | 1112 (54.7) | NS |
| Hypertension | 16 (80) | 1729 (85.1) | NS |
| Diabetes mellitus | 4 (20) | 729 (35.5) | NS |
| Chronic kidney disease | 10 (50) | 841 (41.4) | NS |
| History of stroke | 4 (20) | 748 (41.9) | NS |
| Percutaneous coronary intervention | 7 (35) | 1379 (67.9) | 0.001 |
| Coronary artery bypass grafting | 1 (5) | 156 (7.6) | NS |
| TAVR | Subclavian/axillary-1 (5%)<br>Transcaval-1 (5%)<br>Transfemoral-18 (90%) | Subclavian/axillary-50 (2.5%)<br>Transaortic-83 (4.1%)<br>Transapical-67 (3.3%),<br>Transfemoral-1830 (90.1%) | |

*Notes.* Measurements in average ± standard deviation or number of patients (percentage).
Abbreviations: BMI, body mass index; NS, nonsignificant; TAVR, transcatheter aortic valve replacement.

**Table 2**
Procedural profiles and details of complications in patients with cardiac tamponade post-TAVR

| Timing of cardiac tamponade | Anesthesia | Type of valve | Prosthesis size | Guidewire | Annular area ($cm^2$) | Annular perimeter (cm) | Aortic valve calcification | Landing zone calcium | Landing zone calcium extent | Sinotubular junction calcium | Type of rupture | Pericardial drain | Open heart surgery | Shock | Stroke | AKI | Permanent pacemaker |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Intraprocedure | MAC | ES3 | 23 mm | Amplatz extrastiff J | 3.6 | 6.8 | Leaflets | NA | 0% | Flat | LV | | + | + | | | |
| | MAC converted to GA | ES3 | 29 mm | Amplatz extrastiff J | 3.5 | 8.7 | Leaflet tips | Nodular; left cusp | 25% | Flat | Annular | + | | | | | |
| | GA | ES-XT + second valve | 23 mm | Amplatz extrastiff J | 3.4 | 6.8 | Leaflet tips | Nodular; left cusp and noncusp | 50% | Nodular | Annular | + | | | | + | |
| | MAC | ES3 | 29 mm | Amplatz extrastiff J | 6.2 | 9 | Leaflets | Nodular; left cusp | 50% | Nodular | Annular | + | | + | | | + |
| | GA | ES3 | 29 mm | Confida wire | na | na | Leaflets | Bulky; left cusp | 50% | NA | Annular | + | | + | | | |
| | GA | Evolute Pro | 29 mm | Amplatz extrastiff J | 4.1 | 7.1 | Leaflets | Bulky; left and noncusp | 75% | Flat | Annular | + | | | | + | |
| | MAC | ES3 | 26 mm | Amplatz extrastiff J | 4.6 | 7.7 | Leaflet tips | Nodular; left cusp | 25% | NA | RV | + | | | | + | + |
| | MAC converted to GA | ES3 | 26 mm | Amplatz extrastiff J | 4.7 | 8 | Leaflet tips | Nodular; left cusp | 25% | Flat | Annular | + | | | | | |
| Postprocedure | MAC | ES-XT | 23 mm | Amplatz extrastiff J | 3.2 | 6.4 | Leaflets | NA | 0% | Flat | Annular | + | | + | | + | |
| | GA | ES-S3 | 26 mm | Amplatz extrastiff J | 4.9 | 7.9 | Leaflets | NA | 0% | Flat | RV | + | | + | | | |
| | MAC | ES-S3 | 23 mm | Amplatz extrastiff J | 4 | 7.6 | Leaflets | Bulky; NA | 0% | Flat | RV | | | | | | + |
| | GA | ES-S3 | 23 mm | Amplatz extrastiff J | 4.2 | 8 | Leaflets | NA | 0% | Flat | LV | | + | + | | | |
| | GA | Medtronic Evolut | 29 | Amplatz extrastiff J | 4.4 | 7.6 | Leaflets | Nodular: NA | 25% | Nodular | Annular | | | | + | | |
| | MAC converted into GA | ES-S3 | 26 | Amplatz extrastiff J | 4.4 | 7.3 | Leaflets | NA; | 25% | Flat | Annular | | | | | + | |
| | GA | ES3 | 23 mm | Amplatz extrastiff J | 3.4 | 6.8 | Leaflets | Bulky; left and noncusp | 25% | Flat | Annular | + | | + | | + | + |
| | MAC | ES3 | 23 mm | Amplatz extrastiff J | 4.2 | 7.3 | Leaflet tips | Nodular; left cusp | 25% | Nodular | RV | + | | + | | | |
| | MAC | Evolut Core | 29 mm | Amplatz extrastiff J | 4.5 | 7.5 | Leaflet tips | Nodular; left cusp | 25% | Nodular | RV | + | | | + | | |
| | MAC | ES3 | 29 mm | Amplatz extrastiff J | 5 | 8.1 | Leaflets | NA | 0% | Bulky | RV | | | + | | | |
| | GA | ES3 | 23 mm | Amplatz extrastiff J | 4.2 | 7.5 | Leaflets | NA | 0% | Nodular | RV | + | | + | | + | |
| | MAC | ES3 | 26 mm | Amplatz extrastiff J | 4.6 | 7.8 | Leaflets | NA | 0% | Nodular | RV | + | | | | | |

*Notes.* Details of calcification around the aortic annulus.
Abbreviations: AKI, acute kidney injury; ES3, Edwards SAPIEN 3; ES-XT, Edwards SAPIEN XT; GA, general anesthesia; LV, left ventricle; MAC, monitored anesthesia care; NA, not applicable; RV, right ventricle; TAVR, transcatheter aortic valve replacement.

**Table 3**
Echocardiographic characteristics across patients with and without cardiac tamponade

| Echocardiographic characteristics | TAVR with cardiac tamponade (20) | TAVR without cardiac tamponade (2030) | *p* value |
|---|---|---|---|
| LV EF | 57 ± 13.7 | 54.6 ± 12.9 | NS |
| AV area | 0.6 ± 0.2 | 0.7 ± 0.1 | <0.05 |
| AV cusp calcification | | | |
| Mild | NA | 20 (1.2) | |
| Moderate | 3 (21.4) | 338 (20.5) | |
| Severe | 11 (78.5) | 952 (57.8) | |
| AV | | | |
| Peak gradient | 81.4 ± 26.13 | 69.9 ± 25.1 | NS |
| Mean gradient | 47 ± 17 | 41.5 ± 15.8 | NS |
| AV velocity | 3.2 ± 0.5 | 4.1 ± 0.7 | <0.05 |
| IVS thickness | 1.3 ± 0.3 | 1.3 ± 0.2 | NS |
| RVSP | 39 ± 13.8 | 42.8 ± 14.6 | NS |

*Notes.* Mean ± standard deviation.
Abbreviations: AV, aortic valve; EF, ejection fraction; IVS, inter ventricular septum; LV, left ventricle; NS, nonsignificant; RVSP, right ventricular systolic pressure; TAVR, transcatheter aortic valve replacement.

## *Timing of Cardiac Tamponade*

Cardiac tamponade was observed intraprocedurally (n = 14; 78.5% left heart and 21.4% right heart injuries) in most cases. A smaller number was also noted in the postprocedural period (n = 6; 16.6% left-sided and 83.3% right-sided; Figure 1). All patients with intraprocedural cardiac tamponade not requiring surgical repair were transferred to the coronary intensive care unit with mean length of stay of 3.61 ± 1.5 days and hospital mean length of stay of 9.15 ± 6.3 days.

## *Procedural Details According to the Presumed Location of Injury*

### *Annular trauma*

Intraprocedural tamponade occurred due to annular trauma in 50% (n = 10) of cases. One patient suffered from annular rupture after post-dilatation with the 23-mm Edwards valve balloon. Another patient who underwent subclavian access TAVR with a 29 mm Medtronic Evolut CoreValve required placement of a second Evolut (29 mm) valve due to severe paravalvular regurgitation (requiring postdilatation), after which they became profoundly hypotensive with evidence of cardiac tamponade requiring emergent pericardiocentesis. Despite this, the patient remained hemodynamically unstable and was placed on venoatrial extracorporeal membrane oxygenation and unfortunately passed away. Another patient had superior migration of an Edwards SAPIEN XT (ES-XT) valve resulting in a supra-annular position; a second valve was successfully deployed within and more ventricular to the prior valve, after which hypotension, pulsus paradoxus, and a moderate-sized pericardial effusion with tamponade were observed requiring pericardiocentesis.

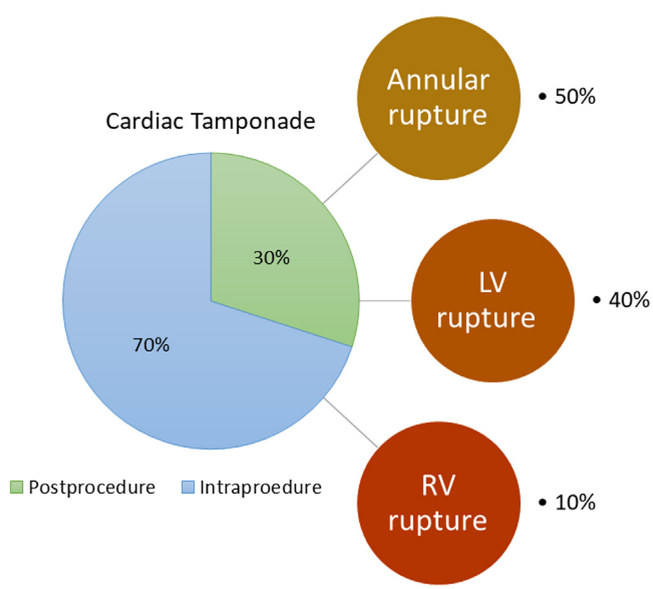


**Figure 1.** Etiologies of cardiac tamponade in TAVR recipients
Abbreviations: LV, left ventricle; RV, right ventricle; TAVR, transcatheter aortic valve replacement.

### *LV trauma*

Two patients had cardiac tamponade due to LV trauma, which occurred after valve deployment (ES-S3 and ES-XT). Both patients underwent emergency sternotomy and repair of a small tear in lateral wall of the left ventricle with an autologous pericardium, along with evacuation of pericardial hematoma.

### *RV trauma*

Right ventricular (RV) tear was often (8; 40%) identified as a cause of tamponade. Three patients suffered RV tear during placement of a temporary pacemaker (a screw in lead temporary pacemaker for procedural complete heart block in one case and temporary active fixation pacemaker lead placement in the other two). In the remaining five cases, cardiac tamponade developed a few hours after the procedure. Pericardial drain fluid assessment revealed venous blood in all patients.

## *Outcomes*

The majority (95%; n = 19) of the patients required pericardial drainage (Figure 2). Pericardiocentesis was performed by subxyphoid approach in all patients and the average volume of blood drained was 260.5 ± 210 ml (Video 1). On average, 3.5 ± 3.2 units of packed red blood cells were transfused, and autotransfusion of the drained pericardial blood via a femoral venous sheath was performed in most patients (65%; n = 13) (Figure 3). The rates of acute kidney injury (30%) and pressor requirements (50%) were high, though only 5% of patients required hemodialysis.

Antiplatelet and anticoagulation post-TAVR were individualized; 31.5% (n = 6) were prescribed single antiplatelet agent (aspirin in 5; clopidogrel in 1), 42.1% (n = 8) received dual antiplatelet agent strategy (aspirin and clopidogrel), 10.5% (n = 2) were placed on anticoagulation (warfarin or apixaban), and 15.7% (n = 3) were discharged on combined antiplatelet and anticoagulant strategy (aspirin and coumadin in 2; aspirin and dabigatran in 1).

All patients except one survived to discharge, and details of cardiac complications are documented in Table 2. At a median follow-up of 1126 (interquartile range-589, 1710) days, 75% of patients survived (n = 15). One patient died in the hospital (5%), another patient died postdischarge within the 30-days of TAVR procedure (5%) and two additional (10%) deaths occurred within 1 year of TAVR procedure.

## Discussion

This manuscript highlights the outcomes of cardiac tamponade after TAVR performed at a high-volume center. The incidence of cardiac tamponade was rare (0.9%), and only two of these patients required cardiac surgery (both due to a left ventricular tear). Only one in-hospital death was noted in our cohort. Most of these patients were identified in the intraprocedural period, and cardiac tamponade occurred as a result of annular trauma. In the cases of right ventricular trauma leading to cardiac tamponade, these were more often noted in the postprocedural period.

Rezq et al.[8] reported that the rate of cardiac tamponade in TAVR patients examined prior to the year 2012 was 4.3% (17 of 389 subjects). This rate is much higher than the current series, which could be explained by higher rates of transfemoral transcatheter aortic valve replacement and improved procedural technique. An analysis of the Nationwide Inpatient Sample reported a rate of 1.3% pericardial

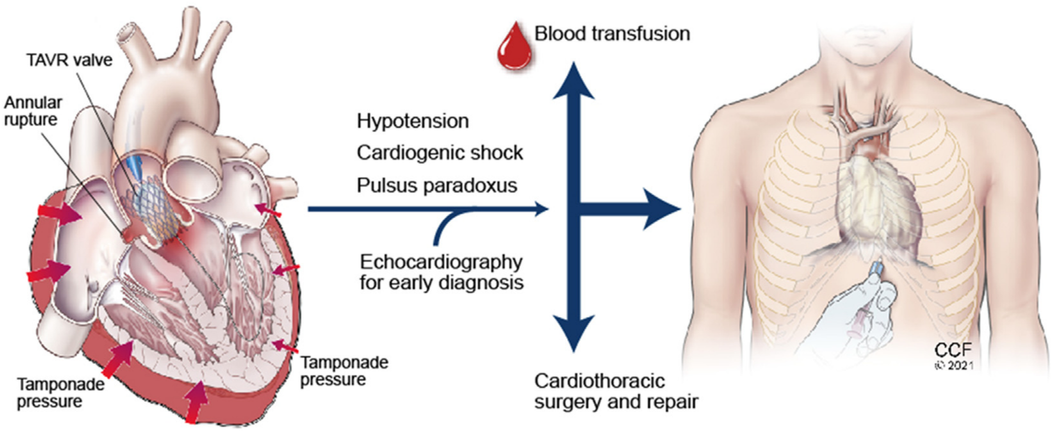


Figure 2. Annular rupture during TAVR (Transcutaneous aortic valve replacement) procedure complicated by cardiac tamponade and its management.

complications (composite of cardiac tamponade, pericardiocentesis, or pericardial window) between the years 2012 and 2014 in the United States.[13] Another report from the Nationwide Readmission Database from January 2012 to September 2015 found an overall incidence of cardiac tamponade of 0.9%.[14]

The impact of center volume on TAVR outcomes is well established.[15] The previously mentioned Nationwide Readmission Database analysis demonstrated lower rates of mortality due to cardiac tamponade in high volume centers when compared with medium and low volume centers (19.1 vs. 36.1% vs. 26.7%, $p < 0.001$).[14] Recognizing tamponade early is crucial during the procedure, and identifying the etiology/site of injury shapes subsequent management. A large proportion of patients in our cohort were managed conservatively with pericardiocentesis alone. This is especially relevant as the outcomes of patients undergoing surgical management, compared to percutaneous or conservative management, are known to be grim as patients (especially during the era studied) are at elevated level of risk for even elective surgery.[16]

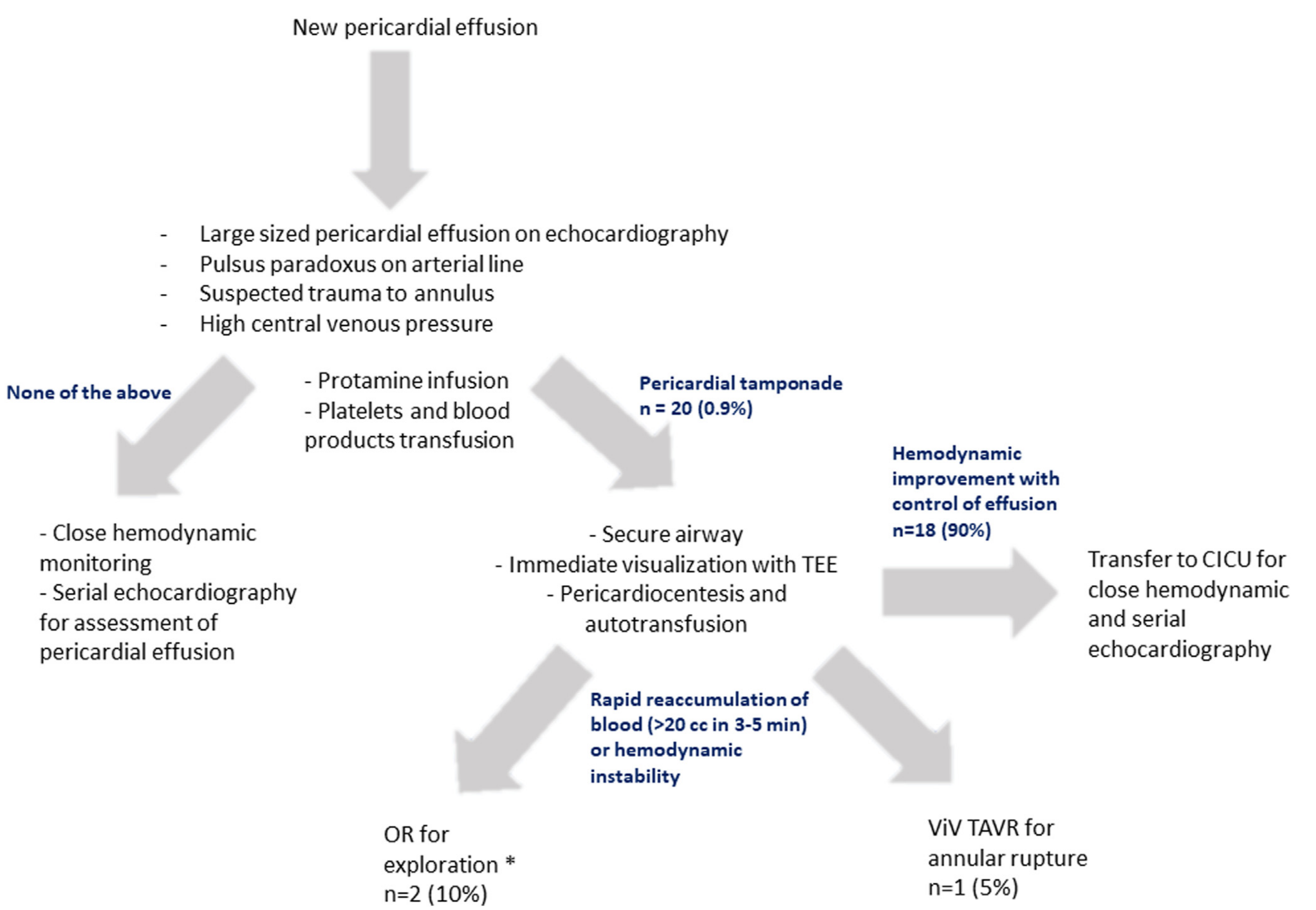


Figure 3. Proposed mechanism for managing pericardial effusion during transcatheter aortic valve replacement. * One patient was taken directly to the operating room as pericardial effusion with rapid hemodynamic compromise postvalve deployment
Abbreviations: CICU, cardiac intensive care unit; OR, operating room; TEE, transesophageal echocardiography; ViV TAVR, valve in valve transcatheter aortic valve replacement.

The two important etiologies of cardiac tamponade are ventricular perforation (left or right) and annular trauma.[17] Ventricular perforation is often due either to the stiff LV wire or the RV temporary pacing wire. Lower rates of RV perforation are expected in future reports with the advent of pacing using LV stiff guidewires and balloon-tipped RV pacing wire. Annular trauma was the most common etiology for tamponade in our cohort, closely followed by right ventricular injury from a nonballoon-tipped pacing wire and, in one instance, screw in lead. We have subsequently used balloon-tipped RV pacing wire with no further complications. The mortality reported in the literature for annular rupture is high: 25% for contained rupture and 67% for frank rupture.[18] Known risk factors for annular rupture include aortoventricular annular diameter <20 mm, left ventricular hypertrophy, significant valve oversizing, and severe annular calcification.[19–21]

Careful evaluation of annular dimensions and appropriate valve selection is critical in preventing annular trauma. All patients developing cardiac tamponade due to annular rupture in our cohort had moderate to severe calcifications at the level of valve, sinotubular junction, and landing zone. (Video) Left ventricular outflow tract calcification below the noncoronary cusp is often a weak spot and annular rupture can occur.[21] Annular trauma often occurs either during balloon-expandable valve deployment or while postdilating a self-expanding valve. Oversizing of the valve by 20% or more compared with the annulus on pre-TAVR is an important risk factor for trauma when using a balloon-expandable valve.[22] The majority (85%; Table 2) of patients in our cohort underwent treatment with a balloon expandable valve. One consideration is to undersize the prosthesis relative to the annular dimension in cases of severely calcified valves.[23] A technique of underfilling the deployment balloon by 1 or more milliliter may be beneficial. Further, assessment of the pressure exerted on the annulus during deployment may be helpful with an eye toward not exceeding 6 atmosphere irrespective of inflation volume left in the syringe.[24] Appropriately, some operators prefer the use of a self-expanding valve in cases of extensive valve calcifications to reduce the risk of annular rupture, though when necessary, paravaluvlar leak closure is more complicated with the taller valve frame, and tamponade can still occur when valve postdilation is required, as demonstrated in the current series (Table 2).[25] In addition, the postdilatation of self-expanding valves is often performed with conservative balloon diameter size. However, the decision for valve type is contingent on several factors including coronary height from the annulus, risk of complete heart block postprocedure, and risk of paravalvular leak. Some operators also choose to perform cases with high risk of annular trauma under general anesthesia with transesophageal echocardiography guidance to “visualize” the calcium at the annular plane during valve expansion with cessation of inflation if the calcium appears to extend too close to the border of the annulus.[20,26]

Regarding ventricular trauma, using a preshaped wire may prevent trauma to the left ventricle. Nevertheless, one patient who developed tamponade due to laceration of the LV had undergone treatment with a self-expanding valve using the preformed Confida wire (Medtronic, Minneapolis, MN). Another opportunity for safety and preventing potential RV perforation is the use of on-wire pacing either with a typical stiff guidewire or one of the wires designed specifically for this purpose (OpSens SavvyWire).[26] We acknowledge the limitations of this study, with inherent limitations of its retrospective single-center design and possible bias of underreporting with restricted generalizability. Future studies in the form of prospective registries are necessary for reporting complication rates in the contemporary TAVR era.

## Conclusions

As evident from our institutional experience, postprocedural survival after cardiac tamponade, even when due to annular trauma, demonstrates conservative management with pericardial drainage as a reasonable therapeutic option in most patients. Streamlining care for the management of cardiac tamponade is essential. A dedicated protocol review on a regular basis (given the infrequency of this complication) by the institutional heart valve team is recommended for the management of these life-threatening complications.

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The authors report no conflict of interest. The research has adhered to relevant ethical guidelines, as detailed in the Study Design section.

## Supplementary Material

Supplemental data for this article can be accessed on the publisher’s website

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