Valve-Related Complications in TAVI Leading to Emergent Cardiac Surgery

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Abstract

Transcatheter aortic valve implantation (TAVI) is now a standard procedure for the treatment of symptomatic aortic valve stenosis in many patients. In Germany, according to the annual reports from the German Institute for Quality Assurance and Transparency in Healthcare (Institut für Qualitätssicherung und Transparenz im Gesundheitswesen), the rate of serious intraprocedural complications, such as valve malpositioning or embolization, coronary obstruction, aortic dissection, annular rupture, pericardial tamponade, or severe aortic regurgitation requiring emergency cardiac surgery has decreased markedly in recent years from more than 5.5% in 2012 to 2.0% in 2019. However, with increased use, the total number of adverse events remains about 500 per year, about 100 of which require conversion to sternotomy. These, sometimes, fatal events can occur at any time and are still challenging. Therefore, the interdisciplinary TAVI heart team should be prepared and aware of possible rescue strategies.

Keywords

► transcatheter aortic valve implantation
► complications
► surgery

Introduction

Nowadays, more and more patients with severe symptomatic aortic valve stenosis are suitable for treatment with transcatheter aortic valve implantation (TAVI). Thanks to the further development of TAVI technologies and the many years of experience of the heart teams, TAVI has been established as a safe and well-accepted procedure. Based on the annual reports from the German Institute for Quality Assurance and Transparency in Healthcare (Institut für Qualitätssicherung und Transparenz im Gesundheitswesen [IQTIG]), the number of TAVIs in Germany rose from 9,332 in 2012 to 24,305 in 2019.1 While the rate of intraprocedural complications, summarized by the IQTIG as device malpositioning, coronary obstruction, aortic dissection, annular rupture, pericardial tamponade, left ventricular decompensation, stroke, aortic valve regurgitation ≥II degrees, and device embolization, has decreased markedly from more than 5.5 to 2.0%, the absolute number of complications remained constant with about 500 per year (► Fig. 1).¹

Nevertheless, members of an interdisciplinary heart team should be well informed about these complications and their possible rescue strategies. This article gives an overview over these rare but potentially devastating events with respect to incidence, cause, intraprocedural treatment options, and outcome.

Valve Malposition: Embolization, Migration, and Ectopic Valve Deployment

For a better understanding, the technical terms of valve malpositioning are explained first. According to the new Valve Academic Research Consortium 3 (VARC-3) definitions in May 2021, valve migration means “After initial correct
positioning, the valve prosthesis moves upwards or downwards, within the aortic annulus from its initial position, without valve embolization” and embolization means “The valve prosthesis moves either upward or downward after deployment such that it loses contact with the aortic annulus.”

Ectopic valve deployment is defined as “Irretrievable deployment of a valve prosthesis at a site other than the intended position because of valve embolization or inability to deliver the prosthesis to the desired location.”

According to the IQTIG, in 2012, device malposition occurred in 2.0% of all TAVI procedures (Fig. 2A). In 2019, this rate came down to a quarter (0.53%).

However, the rates of device embolization based on the IQTIG quality reports are less than 0.38% for all TAVI procedures (Fig. 2B). Relevant studies including large collectives present embolization rates between 0.3 and 2.0%.3–7

Embolization—sometimes called “pop out”—of a TAVI prosthesis from the aortic annulus into the ascending aorta or the left ventricle (LV) is a rare but dreaded complication. There are several reasons for an embolization of a transcatheter heart valve (THV), such as valve malpositioning in the annulus, especially when a wrong implantation height was chosen, or when a high implantation is anticipated in order to avoid conduction disturbances requiring permanent pacemaker implantation. Other causes are sizing error, lack of or unfavorable calcification in the landing zone (the prosthesis can slide out of the designated implantation level), loss of rapid pacing with consequent systolic ejection of the valve mostly into the aorta, postdilatation of the implanted prosthesis, accidental release, unexperienced implanter, or after cardiopulmonary resuscitation. According to Kim et al, malpositioning is the most common cause for embolization and migration in 50.2%, either due to wrong angulation, poor visualization, complex anatomy of the aortic root, or absence of calcification.4 The authors could also determine self-expanding or first-generation valve systems and bicuspid aortic valves as independent risk factors for embolization and migration.4 In a matched cohort, they described a significantly increased 1-year mortality of 30.5% in TAVIs with embolization and migration versus 16.6% in successful implantations.4 Another study reported that four out of nine patients (44.4%) died when conversion was necessary after valve embolization.5 In addition, it has been demonstrated that THV embolization is a significant independent predictor of 1-year mortality with a hazard ratio (HR) of 2.68.6

In case of an embolization, it is important whether there are additional complications, such as coronary occlusion, aortic regurgitation > II degrees, or injury to the surrounding tissue such as an aortic dissection.

Depending on the position of the prosthesis, it may be possible to implant a supplementary THV immediately as a valve-in-valve procedure (Fig. 3). Otherwise, withdrawing the prosthesis with a balloon or a snare can be a successful option (Case 1). In case of a partially inflated balloon, where the balloon-expandable valve is still on the delivery system (e.g., pop out due to loss of rapid pacing),
one might retract the whole system into the descending aorta where the prosthesis can be ectopically implanted (Case 2). However, it is of utmost importance that the designated landing area in the aorta is suitable for adherence, which means a correct diameter, enough calcification, and no obstruction of an important vessel. Finally, open cardiac surgery is the ultimate treatment option. In this way, one can remove the dislocated THV and implant a conventional bioprosthesis (Case 3).

Bernardi et al reported the outcome of 1,026 patients who underwent TAVI with the repositionable self-expanding valves from Medtronic (Evolut R/PRO) and Abbott (Portico). Of these, 9.3% had multiple resheathing with a significantly lower device success rate of 80 versus 89.9%, mainly for two reasons: device embolization and second prosthesis. Furthermore, multiple resheathing was associated with a higher 1-year mortality of 18.8 versus 10.5%.

Recently, the team of the TRAVEL registry investigated a cohort of 29,636 TAVI procedures in which 273 (0.9%) valve embolizations or migrations occurred. In 217 cases, the valve dislocated upward (aorta) and in 56 cases, it moved downward (LV). Salvage maneuvers were repositioning by snares or similar in 46.1% of aortic and 21.4% of left ventricular malpositions, valve-in-valve implantations in 88.9 and 41.1% of aortic and left ventricular implantations, respectively, and valve exchange in 5.7% of aortic and 11.4% of left ventricular implantations. In 9.3% of cases, there was no clinical sequelae, and in 28.4% of cases, it was possible to rescue the THV and implant a conventional bioprosthesis (Case 3). In 5.2%, the prosthesis was retracted into the aortic arch or the thoracic descending aorta. At median follow-up of 40 months, the embolized devices experienced no migration, strut fracture, aortic complication, or thrombosis. However, some embolized valves exhibited leaflet degeneration.

Thorough planning before and during the procedure is therefore inevitable. Once the valve is ready for release, verifying the correct implantation fluoroscopic angulation reduces the risk of malpositioning. Clear and unambiguous commands in the team are essential, particularly when newcomers are present.

**CASE 1: Migration into Left Ventricular Outflow Tract—Snaring Maneuver**

During TAVI with an Evolut PRO 29 mm (Medtronic, Dublin, Ireland), the valve was implanted too deep, leading to a severe valvular regurgitation. Since the patient’s circulation remained stable, an attempt was made to pull the valve higher by using two snares (Fig. 4; GooseNeck Snare, femoral artery Covidien/Medtronic, Dublin, Ireland—inset) and withdrawing the self-expanding valve successfully.

**Fig. 4** Migration into left ventricular outflow tract with severe aortic regurgitation. Capture maneuver by snaring (arrows, GooseNeck Snare, femoral artery Covidien/Medtronic, Dublin, Ireland—inset) and withdrawing the self-expanding valve successfully.

**CASE 2: Embolization: Ectopic Implantation, Migration, and Conversion**

During TAVI with a SAPIEN S3 (Edwards Lifesciences, Irvine, California, United States) valve, the pacemaker was accidentally turned off during the rapid pacing period while the balloon with the bioprosthesis was inflated in the aortic annulus. Thus, with the first systole of the heartbeat, the valve was ejected into the ascending aorta (Fig. 5A). The patient’s circulation remained stable. Therefore, the valve was retracted with the delivery system and implanted further downstream into a

**Fig. 5** (A) Embolizing SAPIEN S3 (Edwards Lifesciences) valve into ascending aorta due to failure of rapid pacing. (B) Retracting and deploying the transcatheter heart valve (THV) into descending aorta (arrow). (C, D) Chest X-ray 90 minutes after TAVI presenting the retrograde moved THV in the aortic arch, which had been implanted in the descending aorta after embolization.
suitable descending aortic segment (ectopic implantation). A second Edwards S3 valve was then implanted through the first one uneventfully (► Fig. 5B). At the end of the procedure, the patient was brought to fast track intensive care unit (ICU). Routine chest X-ray 90 minutes later revealed that the primary valve had moved backward into the aortic arch (► Fig. 5C, D). Most likely, the retrograde valve migration in the descending aorta happened during diastole. The patient was scheduled for open aortic arch surgery. The valve in the aortic arch could be removed via aortotomy under hypothermic circulatory arrest. The patient recovered without incident and was discharged on day 9.

CASE 3: Embolization into Left Ventricle—Open Surgery
An 80-year-old patient presented with a severe aortic valve regurgitation in intermediate risk for cardiac surgery (log EuroSCORE I 17.8%). There was almost no calcification on the large aortic annulus and leaflets, clearly indicating surgical aortic valve replacement (SAVR). Nevertheless, the patient refused the operation for fear of general anesthesia. Thus, a transfemoral TAVI under analgosedation was performed with an Edwards SAPIEN S3 29 mm (Edwards Lifesciences). Despite oversizing, the S3 valve migrated deeper into the left ventricular outflow tract (LVOT) in every diastole, finally, tumbling into the LV (► Fig. 6). In this situation, the patient remained stable and conversion to SAVR with recovery of the THV was performed immediately. The patient recovered well and left the hospital on day 7.

Coronary Obstruction
Coronary obstruction in TAVI most often results from mechanical occlusion of a coronary ostium by shifting the native aortic valve leaflet toward the wall of the aortic root during implantation of a transcatheter prosthesis. Based on the IQTIG data, the incidence of coronary obstruction over the past years declined to 0.16% (► Fig. 2C).1 Several studies described the risk of coronary obstruction to be around 1%—in earlier series, the rate was at 7.7%.9–15
The risk for coronary obstruction in TAVI is higher when the coronary distance to the annulus of the aortic valve is less than 10 mm.11,16–18 The geometry of the aortic root plays an important role in coronary impairment. The diameter of the sinus of Valsalva (SOV), the relation of SOV to annulus, and coronary heights are potential risk factors for coronary obstruction following TAVI.10 In low coronary height, a greater relation of SOV/annulus than 1.27 may prevent coronary obstruction.10,19 However, long frames of the THV across the coronary ostia make access more difficult. Boukantar et al reported challenging coronary procedures in patients with an implanted CoreValve prosthesis.20 There is a higher risk of coronary obstruction in valve-in-valve TAVI procedures, about 2.3 to 3.5%.21,22 Especially, the combination of a small, tubular SOV, low coronary heights and a degenerated surgical prosthesis where the leaflets are sutured “outside” the stent posts, for example, Mitroflow (Sorin Group, Inc., Milan, Italy) or Trifecta (Abbott, Chicago, Illinois, United States) valves, is a risky one.21,23
Patients with coronary obstruction may die when immediate restoration of coronary blood supply fails. Quick removal of the obstructing prosthesis, for example, with a snare maneuver, percutaneous coronary intervention (PCI), or emergent cardiac surgery (ECS), can prevent this.10,11 Aortic root angiography, either during balloon valvuloplasty or during partial release of a retrievable, self-expandable valve, can help rule out potential coronary obstruction. If there is still a high risk for coronary obstruction, one can protect the myocardial perfusion by putting an undeployed coronary balloon or a premounted stent into the coronary artery before valve deployment that can be applied to restore myocardial perfusion if needed9,10 (► Fig. 7).

![Fig. 6](image6.png) Embolization of a SAPIEN S3 (Edwards Lifesciences) valve into the left ventricle in a patient with severe aortic valve regurgitation (arrow, guidewire in a coronary cusp marking the annular implanting zone).

![Fig. 7](image7.png) Undeployed coronary stent (arrow) in routine chest X-ray as preventive strategy at high risk of coronary obstruction.
Another technique is the BASILICA procedure (Bioprosthetic or native Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery obstruction), where a leaflet is lacerated just before THV implantation.\(^\text{24}\) Otherwise, alternative strategies, such as combinations of interventional and surgical approaches can be used (Case 4).

The literature reports increased 30-day mortality rates in patients with coronary obstruction between 8.3 and 40.9%,\(^\text{10–12,18}\) which is even higher in valve-in-valve procedures, 22.2 and 57.1%, respectively.\(^\text{21,22}\)

**CASE 4: Coronary Occlusion—Intended Real Hybrid Approach**

In unusual cases, one has to find unusual solutions. An 82-year-old woman with multiple comorbidities (log EuroSCORE I 83.4%) presented with a degenerated bioprosthesis in aortic position (St. Jude Medical/Abbott Trifecta 21 mm, implanted in 2013) suffering from severe shortness of breath. Risk for surgical aortic valve re-placement was high due to the patient’s age, condition, comorbidities, and heavy calcification of the aortic root (\(\text{Fig. 8A}\)). Risk for coronary occlusion by valve-in-valve TAVI was high due to the low left and right coronary ostia (\(\text{Fig. 8A, B}\)). Thus, an “open” transaortic TAVI was planned with the intention to resect the leaflets of the bioprosthesis and thereafter implant a self-expanding valve with commissural alignment. In addition, a potential coronary malperfusion could have been addressed with instant bypass grafting. After median resternotomy, cardiopulmonary bypass was instituted. The leaflets of the implanted surgical prosthesis were resected while the struts of the frame were left in place because of a heavy calcification of the aortic root. Then, a Medtronic Evolut R 23 mm prosthesis was implanted via the aortotomy under direct vision and fluoroscopy into the frame of the degenerated Trifecta bioprosthesis (Abbott) (\(\text{Fig. 8C}\)). After surgical closing of the aortotomy, the patient was weaned from cardiopulmonary bypass (CPB) leaving the cannulas in place. Control angiography of the aortic root revealed an occluded right coronary artery (RCA) (\(\text{Fig. 8D}\)). Therefore, bypass grafting of the RCA was performed immediately. Eight days later, the patient was discharged in good condition.

**Aortic Dissection**

An aortic dissection during a TAVI procedure is a devastating and life-threatening event with high morbidity and mortality. In the beginning of the TAVI era, incidences were up to 5%,\(^\text{15,25–27}\) More recent data, for example, from GARY, FRANCE 2, and FRANCE TAVI registries reported rates between 0.2 and 0.4%\(^\text{7,28}\). Data from the IQTIG are even lower (\(\text{Fig. 2D}\)).\(^\text{1}\)

There is a hint in literature and several case reports indicating that aortic dissection seems to occur more frequently in bicuspid aortic valves treated with TAVI.\(^\text{29–32}\)

Ascending aortic dilatation occurs in almost 25% of patients, but it does not automatically increase the risk for iatrogenic aortic dissections.\(^\text{33}\) Aortic abnormalities, such as kinks, calcifications, narrow arches, or dilations may aggravate retrograde passage of a TAVI system.

Most likely because of its low incidence, published cases of aortic dissection caused by TAVI are rare.\(^\text{32,34–42}\) It can be assumed that the true number of (fatal) aortic dissections in TAVI procedures remains unknown and might be underestimated, as even delayed mortality has been reported.\(^\text{32,43}\)

In general, overall 30-day mortality of an acute aortic dissection type A despite surgical treatment is around 17% and increases in patients older than 80 years to 35%.\(^\text{33,44}\) AADA-related mortality in TAVI patients with immediate surgery is excessively high—up to 80%.\(^\text{45}\)

Careful evaluation of the aorta is a mandatory part of planning the procedure. In addition, knowledge of technical issues and options of the applied valve delivery system during valve supply and system retrieval are of utmost importance.

**Annular Rupture**

Annular rupture during TAVI occurred in 0.5 to 1.0% of cases and remained a fatal complication with mortality rates up to 50%.\(^\text{46–48}\) Over the past years, this has declined to rates between 0.2 and 0.4%.\(^\text{4,6}\) According to the IQTIG database, the rate of this complication in Germany was less than 0.5% in 2013, and until 2019, it has decreased to about 0.1% (\(\text{Fig. 2E}\)).\(^\text{1}\)

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**Fig. 8** Severe calcification of the aortic root and very low coronaries ([A] RCA; [B] LCA) in a degenerated bioprosthesis (Trifecta 21 mm; Abbott). (C) Open transaortic “VinV-TAVI”—combination of surgical resection of prosthesis leaflets and TAVI. Before VinV both coronaries are well contrasted during root angiography (arrows). (D) After VinV with an Evolut R 23 mm (Medtronic) angiography revealed an occluded RCA (arrow). LCA, left coronary artery; RCA, right coronary artery; TAVI, transcatheter aortic valve implantation.
Rupture of the aortic annulus is a consequence of excessive force to the tissue transduced by balloon valvuloplasty during predilatation, by implantation of a balloon-expandable valve (Fig. 9), or by postdilatation of a prosthesis—especially in excessive (>20%) oversizing and/or unfavorable calcification.\textsuperscript{46} Calcification of the aortic valve, annulus, and LVOT are predictors of annular injury and rupture.\textsuperscript{46,49,50} Furthermore, a meta-analysis revealed that bicuspid versus tricuspid anatomy has an increased incidence of annular rupture (0.3 vs. 0.02%; \( p = 0.014 \)) in matched subjects.\textsuperscript{51}

Anular rupture in TAVI is devastating and mostly leads to cardiac tamponade, shock, and death. Usually, ECS is required to save the patient’s life (for further details, see heading “Conversion to Open Surgery”).

The European Registry on Emergent Cardiac Surgery (EuRECS)-TAVI showed an in-hospital mortality of 62.2% for emergency cardiac surgery in 45 cases with annular rupture.\textsuperscript{52} Others published a mortality rate of 40% (two out of five).\textsuperscript{5}

In rare cases, annular injury leads to an iatrogenic Gerbode defect with a shunt from the LV to the right atrium (RA) due to a direct lesion of the membranous septum. It is notable that patients can remain clinically unremarkable in the beginning, but then deteriorate over time. Clinically, right heart overload leads to cardiac decompensation. Echocardiography helps identify the LV/RA shunt. Surgery or percutaneous closure, for example, with an Amplatzer Muscular VSD Occluder (Abbott), are the therapies of choice.\textsuperscript{53}

**Pericardial Tamponade**

Per definition, a cardiac tamponade following a THV implantation is “Evidence of a new pericardial effusion associated with hemodynamic instability and clearly related to the TAVI procedure.”\textsuperscript{5,46}

According to the IQTIG database, the incidence of a cardiac tamponade in TAVI has slightly decreased over the past few years, from 0.69 to 0.56% (Fig. 2F).\textsuperscript{1} Others observed a tamponade in 15 out of 1,775 procedures (0.8%) or in the GARY registry in 164 of 15,964 cases (1.0%) requiring intervention.\textsuperscript{5,7}

Reasons for TAVI-related cardiac tamponade are perforation of right ventricle (RV) or LV, aortic root, ascending aorta, rupture of annulus, or aortic dissection. Perforation can happen with the guidewire, the (tip of the) prosthesis, the (tip of a) delivery device, or with the electrode of the pacemaker, during balloon valvuloplasty, or during a concomitant PCI.

Pericardial tamponade requires immediate therapy, either by interventional or surgical approach. Intervention means catheter pericardiocentesis by subxiphoid puncture of the pericardium using Seldinger’s technique. Briefly, under fluoroscopy, a soft tip guidewire is carefully inserted through a hollow needle into the pericardium. Over this wire, a 7F (or bigger) pigtail catheter is introduced into the pericardium. This allows aspiration and drainage of the blood. Additionally, improvement of coagulation, such as antagonizing of heparin, can lead to closure of small lacerations with good results (e.g., perforation of RV with pacemaker electrode). If bleeding decreases and circulatory stability can be achieved, a drainage system can be attached to the catheter. Further monitoring on the ICU is mandatory. On one hand, this minimally invasive technique is quick, requires no general anesthesia, and is effective in small lesions. On the other hand, the inserted catheter can occlude because of coagulating blood, cardiac injury may occur, and larger defects cannot be treated that way. In case of remaining instability of circulation, persistent blood loss, or cardiopulmonary resuscitation, the next step should be surgical exploration. Surgically, there are two options addressing a pericardial tamponade depending on the status of the patient—subxiphoid pericardial drainage and pericardiotomy by sternotomy.\textsuperscript{55} If the patient’s circulation is stable, subxiphoid pericardial drainage might be first choice. This might be eligible in small injuries (e.g., the above-mentioned perforation of RV). In critical situations and when serious complications are to be expected, a median sternotomy with the possibility of an extracorporeal circulation may be more reliable.

In our department, the interdisciplinary heart team, which performs the procedure together, decides upon the treatment modality. Sometimes, institution of an extracorporeal life support system via femoral access can be a fast and safe way to allow for diagnosis, decision, and further therapy.

Current literature shows that survival after conversion to surgery is limited in patients with pericardial tamponade. There is a report about a mortality rate of 53.3% (\( n = 8/15 \)) within 30 days.\textsuperscript{5} Data from the GARY and the EuRECS registries revealed mortality rates of 40.2 and 35.7% in patients with cardiac tamponade.\textsuperscript{7,52} Multivariate analysis has shown that tamponade is an independent predictor of death with an odds ratio of 3.74.\textsuperscript{7}

As safety in daily TAVI business, TTE after each intervention with the focus on pericardial effusion and valve function should be routine. For example, the first TTE could be done before the patient leaves the hybrid operating room (OR), a second TTE on the fast track ICU, and a last one on the day before discharge.

**Aortic Regurgitation ≥ II Degrees**

Aortic regurgitation after TAVI usually describes transvalvular, paravalvular, or “supraskirtal” leakages. According to

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Fig. 9 Rupture of a heavy calcified annulus with a balloon-expandable valve. (A) Heavy calcification in area of left coronary artery (arrow). (B) Fluoroscopy of annulus rupture—extravasation of contrast due below left coronary artery (arrow).
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the new VARC-3 recommendations, Doppler echocardiography remains the primary modality for assessing and comparing regurgitation after aortic valve replacement.\(^5\) It is suggested to divide aortic regurgitation into either a five-class (mild, mild−moderate, moderate, moderate−severe, and severe) or a three-class (mild, moderate, and severe) grading scheme.\(^6\) Freedom from moderate or severe aortic regurgitation belongs to the composite end point “early safety (at 30 days).”\(^2\)

Over the past years, the incidence of residual aortic regurgitation ≥ II degrees in TAVI has declined. In 2013, the German IQTIG documented the highest rate of 1.15%, whereas in 2019, only 0.28% of TAVIs had an aortic regurgitation ≥ II degrees (→ Fig. 2G).\(^1\)

Paravalvular regurgitation (PVR) depends not only on the anatomy (e.g., bicuspid valve), geometry (e.g., size, shape), and morphology (e.g., calcification) of the aortic valve complex but also on the prosthesis type and its position in the aortic annulus. Important predictors of PVR are implantation depth, valve undersizing, and the Agatston calcium score.\(^56\) Extent, location, and distribution of calcification are influencing parameters for PVR.\(^57\) Optimal valve sizing and lower degree of valve calcification have been associated with lower degrees of regurgitation.\(^58\) An oval shape of the annulus and annular eccentricity are further predictors of PVR.\(^57\) Furthermore, there is a direct correlation between undersizing of the THV and severity of PVR.\(^57\) Malpositioning of the THV including very low implantation is an important cause for PVR.\(^57\)

Several investigations over the past could determine various PVR rates of the established TAVI systems. Including all valve generations, PVR ≥ II degrees after TAVI occurred in 0.6% (Lotus in REPRISE II) up to 24.2% (SAPIEN XT in PARTNER IIB).\(^59,60\)

A milestone in reducing PVR rates appeared in 2013 with the coating of the lower part of the THV frames with external seal cuffs or pericardial skirts/wraps. By this, mild and higher PVR rates dropped from 54.3% (SAPIEN XT) to 19.7% (SAPIEN 3) using the Edwards valve,\(^61\) from 48.8% (Evolut R) to 43.2% (Evolut PRO) using the Medtronic CoreValve valve,\(^62\) and from 63.9% (Neo) to 32.5% (Neo2) using the Boston Scientific Acurate valve.\(^53\)

A monocentric analysis of 2,000 patients treated with TAVI in a high-volume center between 2008 and 2015 presented evidence that moderate or severe aortic valve regurgitation after TAVI declined significantly in this interval from 3.3% for the first 500 patients to 0% for the last 500 patients (p < 0.001).\(^64\)

Patients with aortic regurgitation after TAVI may suffer from congestive heart failure or arrhythmias and have a limited long-term prognosis—therefore, PVL ≥ II degrees needs a therapy right after implantation. A post procedural balloon valvuloplasty of the THV also called “postdilation” is an effective method to reduce a relevant PVR—observed for more than 1 degree in 70% of patients.\(^65,66\) However, postdilation has advantages, such as reduction of PVR, optimized frame expansion, and optimized valvular gradient, and disadvantages, such as risk of valve embolization, conduction disorders, leaflet damage, cerebrovascular embolism, and annular rupture.\(^57,67\) If postdilation is no option and transcatheter or PVR remains ≥ II degrees, an additional THV prosthesis can be implanted as valve-in-valve procedure (→ Fig. 3). Wunderlich et al described the use of this strategy in 1.7 to 3.9%.\(^68\) Patients requiring a rescue valve-in-valve implantation seem to have a higher 1-year mortality (HR 1.86).\(^8\)

Finally, but very rarely when the above strategies fail, conversion to open cardiac surgery is the last treatment option. Then, the THV is explanted and replaced with a surgical bioprosthesis.

Moderate and severe aortic valve regurgitation after TAVI have been associated with increased in-hospital and 1-year mortality, 28 and 57 to 63.6%, respectively,\(^59–72\) and identified as independent predictor of mortality.\(^73–75\) There is evidence that also mild regurgitation is associated with higher long-term mortality,\(^76\) whereas no or trace PVR has no impact on mortality.\(^77,78\)

Conversion to Open Surgery

Conversion to open surgery or ECS is the ultimate bailout treatment option in severe acute procedural and technical valve-related complications.

Since 2012, the overall conversion rates to sternotomy, transapical, or endovascular approach reported by the IQTIG dropped from 5.1 to around 1.4% (→ Fig. 2H).\(^1\) Decline for conversion to sternotomy over time has been reported from 1.2% in 2013 to 0.4% in 2019,\(^1\) whereas the total number of conversions to sternotomy remains quite stable between 85 and 109 per year in Germany (96.3 ± 6.8).\(^1\) Relevant publications report emergency cardiac surgery rates between 0.3 and 4.9% (→ Table 1).

Reasons for conversion to surgery are valve embolization (Cases 1 and 3), severe aortic regurgitation, annular rupture/perforation, pericardial tamponade, or aortic dissection. The EuREC-TAVI registry has shown that major reasons for ECS were perforation of the LV with a guidewire (28.3%) and annular rupture (21.2%).\(^5\) The three most common causes in a single-center study were pericardial tamponade (46.9%), device embolization (28.1%), and annular rupture (15.6%).\(^5\) Data from a meta-analysis of 46 studies including 9,251 TAVI patients showed that embolization was the main reason for emergency cardiac surgery (36/88 patients = 40.9%) followed by aortic dissection or injury (each n = 14), tamponade by myocardial injury (n = 12), severe aortic regurgitation (n = 10), annular rupture (n = 6), and coronary obstruction (n = 5).\(^26\) Similar results were observed in the SOURCE registry including 2,307 Edwards SAPIEN implantations.\(^79\) Two major causes for emergency cardiac surgery were embolization/migration (9/27; 33%) and aortic injury (7/27; 26%).\(^79\) Recently, it was published that the most common reason for conversion was left ventricular perforation (7/20, 35.0%).\(^80\)

Investigators from the current multicenter TRAVEL registry observed a conversion in 52 of 273 patients (19%) with transcatheter valve embolization and migration.\(^4\) Another
Table 1  ECS and in-hospital/30-day mortality in TAVI—summary of relevant studies

<table>
<thead>
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<th>Authors</th>
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<th>Study/trial</th>
<th>Patients total (n)</th>
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<td>Grube et al.187</td>
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<td>136</td>
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<td>3.7</td>
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<td>Hein et al.45</td>
<td>2013</td>
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<td>1,975</td>
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<td>201</td>
<td>1.3</td>
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Abbreviations: ECS, emergent cardiac surgery; EuRECS, European Registry on Emergent Cardiac Surgery; n.s., not specified; TAVI, transcatheter aortic valve implantation.

Recent study comes to a similar conclusion: 2 out of 11 patients (18.2%) underwent open-heart surgery to retrieve an embolized THV. Earlier studies from 2013 and 2015 reported higher rates of conversion to surgery due to embolization in 12 of 26 cases (46.2%) and in 20 of 71 cases (28%).

Based on the publications already mentioned, the 30-day mortality in emergency cardiac surgery ranges between 33.3 and 67.1% (Table 1).

Summary

Currently, the vast majority of TAVI interventions are performed without major complications. The reasons for the improvement in TAVIs are the dedicated and experienced heart teams, the meticulous patient screening with careful risk stratification, the advanced quality of imaging, the sophisticated implantation techniques, and the technological progress of the latest generation of THV systems.

In Germany, the rate of intraprocedural complications, including valve malpositioning or embolization, coronary obstruction, aortic dissection, annular rupture, pericardial tamponade, or severe aortic regurgitation requiring ECS has decreased significantly over the past years, but the total number of these events remains stable at around 500 cases per year. Every year almost 100 patients undergoing THV implantations require conversion to sternotomy. Essential publications report conversion rates to open heart surgery between 0.3 and 4.9% (Table 1). Thus, an active implanting heart team—including both interventional cardiologist and cardiac surgeon—is of utmost importance. However, the pressure to consider TAVI in institutions without on-site cardiac surgery is growing, not just because of an increasing demand with extended waiting times but also due to the opinion that “… the outcomes of patients treated with salvage surgery are grim, no matter where the procedure is done.”

In our opinion, this interpretation ignores the available data and its conclusion is simply not correct. In accordance with relevant publications, the average 30-day survival rate in emergency cardiac surgery during TAVI procedures is around 56.7% (see Table 1). In addition, the independent Institute for Quality and Efficiency in Health Care recently stated that in hospitals where TAVIs are performed more frequently, patients requiring surgery have higher survival rates, fewer bleeding events, less long-term ventilation after the procedure, and lower rehospitalization rate. This underlines the importance of heart valve centers that provide hybrid OR, on-site cardiac surgery, and perfusionists with CPB in the OR. Due to the novel guidelines, the percentage of low–intermediate-risk patients which can safely be operated on will rise significantly, and therefore, the risk of acute operation after failed TAVI will probably further decline, but the number of acute surgeries will rise.

Like others, we firmly believe that an experienced and well-rehearsed heart team is of crucial importance for the prevention of life-threatening complications and for providing immediate interventional or surgical solutions if needed. The different perspectives and skills of the interventional cardiologist and the cardiac surgeon provide the perfect armamentarium and environment for optimal planning and performance of TAVI procedures, specifically, in high-risk situations.
combined effort is the guarantee for optimal patient safety, which must not be questioned.

Conflict of Interest
None declared.

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Valve-Related Complications in TAVI Leading to Emergent Cardiac Surgery

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