Valve-Related Complications in TAVI Leading to Emergent Cardiac Surgery

Lars Conzelmann[1] Philipp Grotherr[2] Lu Dapeng[3] Alexander Würth[2] Julian Widder[2] Claudius Jacobshagen[3] Uwe Mehlhorn[1]

[1] Department of Cardiac Surgery, HELIOS Clinic for Cardiac Surgery Karlsruhe, Karlsruhe, Germany
[2] Department of Cardiology, Medical Clinic IV, Municipal Hospital Karlsruhe, Karlsruhe, Germany
[3] Department of Cardiology, Intensive Care Medicine and Angiology, Vincentius-Diakonissen Hospital Karlsruhe, Karlsruhe, Germany

Address for correspondence Priv.-Doz. Dr. med. Lars O. Conzelmann, Department of Cardiac Surgery, HELIOS Clinic for Cardiac Surgery Karlsruhe, Franz-Lust-Straße 30, Karlsruhe 76185, Germany (e-mail: lars.conzelmann@helios-gesundheit.de).

Thorac Cardiovasc Surg 2023;71:107–117.

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*

received
May 24, 2022
accepted after revision
September 16, 2022
article published online
November 29, 2022

Georg Thieme Verlag KG,
Rüdigerstraße 14,
70469 Stuttgart, Germany

DOI https://doi.org/10.1055/s-0042-1758073.
ISSN 0171-6425.

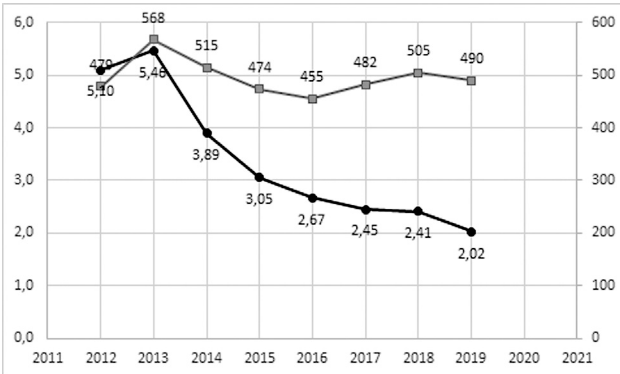

Fig. 1 Rate of intraprocedural complications decreasing over the past years (black line), while the total number remained about 500/year (grey line)—according to the Institut für Qualitätssicherung und Transparenz im Gesundheitswesen quality reports.[1]

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.*"[2] *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.*"[2]

According to the IQTIG, in 2012, device malposition occurred in 2.0% of all TAVI procedures (►**Fig. 2A**).[1] In 2019, this rate came down to a quarter (0.53%).[1]

However, the rates of device embolization based on the IQTIG quality reports are less than 0.38% for all TAVI procedures (►**Fig. 2B**).[1] 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 consecutive 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

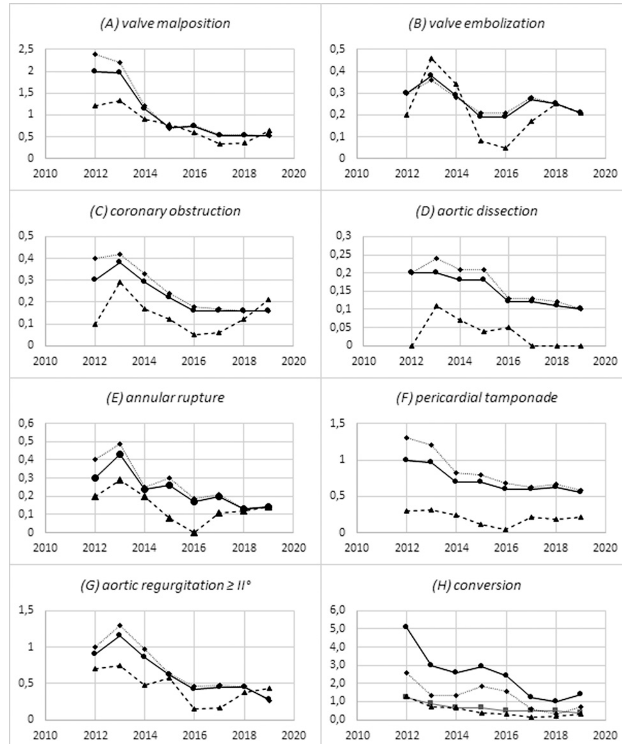

Fig. 2 (A–H) Rates of transcatheter aortic valve implantation–related complications and conversion: all (solid line), endovascular (dotted line), and transapical (broken line) procedures; sternotomy (gray line)—according to the Institut für Qualitätssicherung und Transparenz im Gesundheitswesen quality reports.[1]

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.[8]

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),

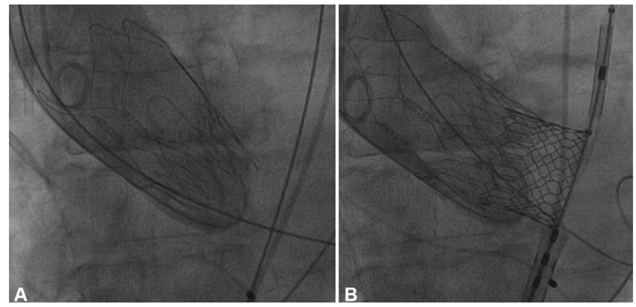

Fig. 3 (**A**) Severe aortic regurgitation after migration of an Acurate Neo (Boston Scientific) prosthesis. (**B**) Instant valve in valve with a SAPIEN S3 (Edwards Lifesciences) as bailout strategy with successful result.

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).[3] 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.[3] Furthermore, multiple resheathing was associated with a higher 1-year mortality of 18.8 versus 10.5%.[3]

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.[4] 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 60.7%, and conversion to open surgery in 13.4 and 41.1%.[4]

Also lately, Zhang et al reported their long-term outcomes of 539 patients with self-expandable THVs, with 11 embolizations into the aorta.[6] Two patients required conversion to surgery. Nine THVs were 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.[6]

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, *Covidien/Medtronic, Dublin, Ireland*). One snare was delivered through the left femoral artery and one through the right femoral artery. The Evolut frame could be captured on both paddles of the frame. Under gentle withdrawal force, the valve was mobilized minimally upward. The arterial pressure curve immediately showed an increase of the diastole, including a dicrotic wave, suggesting a decrease of the aortic regurgitation. Angiography revealed a residual mild aortic regurgitation. Transthoracic echocardiography (TTE) on day 5 showed no regurgitation at all. Success rate for this maneuver is modest and contains the risk of valve migration, embolic stroke, or injury of the surrounding structures.

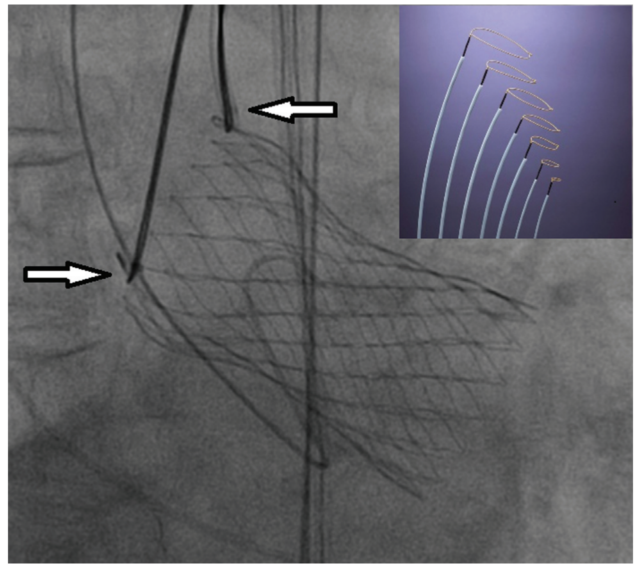

Fig. 4 Migration into left ventricular outflow tract with severe aortic regurgitation. Capture maneuver by snaring (arrows, GooseNeck Snare, femoral artery Covidien/Medtronic, Dublin, Ireland—inset) and withdrawing the self-expanding valve successfully.

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

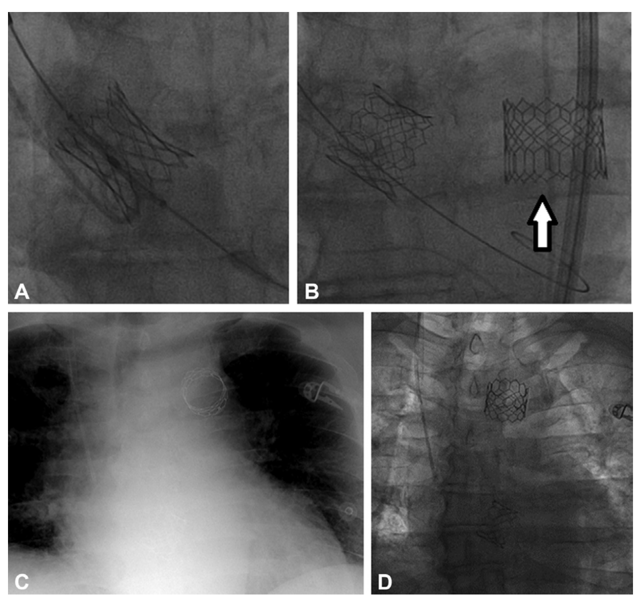

Fig. 5 (**A**) Embolizing SAPIEN S3 (Edwards Lifesciences) valve into ascending aorta due to failure of rapid pacing. (**B**) Retracting and deploying the transcatheter heart valve (THV) into descending aorta (**arrow**). (**C, D**) Chest X-ray 90 minutes after TAVI presenting the retrograde moved THV 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]

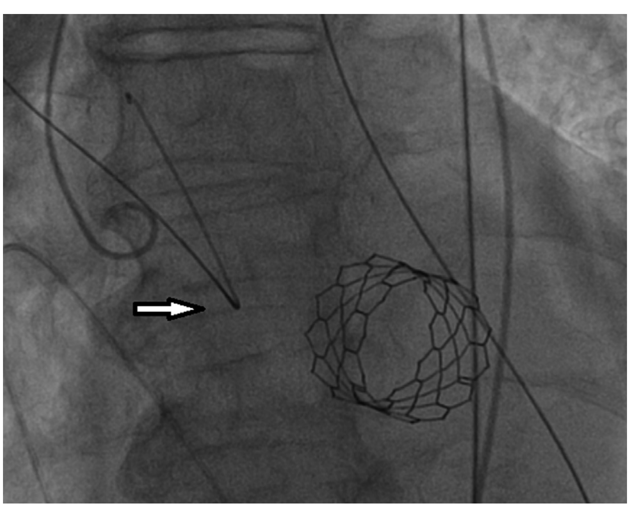

Fig. 6 Embolization of a SAPIEN S3 (Edwards Lifesciences) valve into the left ventricle in a patient with severe aortic valve regurgitation (arrow, guidewire in a coronary cusp marking the annular implanting zone).

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 needed[9,10] (►Fig. 7).

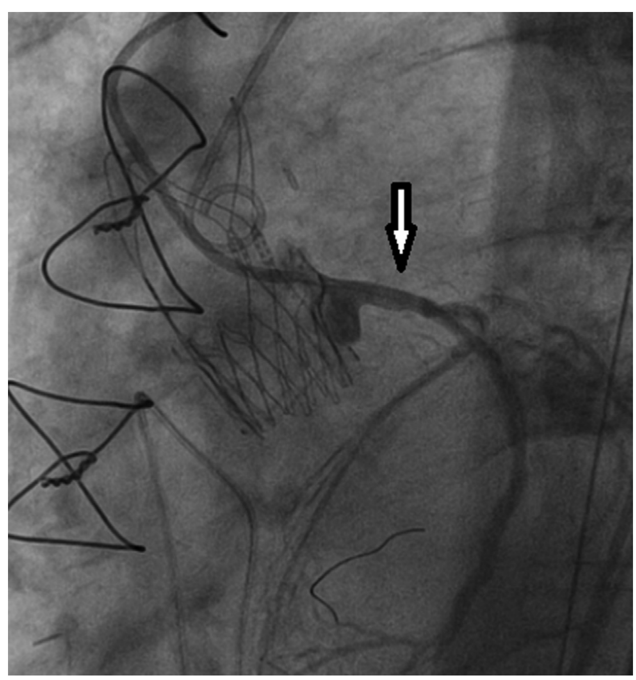

Fig. 7 Undeployed coronary stent (arrow) in routine chest X-ray as preventive strategy at high risk of coronary obstruction.

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.[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%,[10–12,18] which is even higher in valve-in-valve procedures, 22.2 and 57.1%, respectively.[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-replacement was high due to the patient's age, condition, comorbidities, and heavy calcification of the aortic root (►**Fig. 8A**). Risk for coronary occlusion by valve-in-valve TAVI was high due to the low left and right coronary ostia (►**Fig. 8A, B**). Thus, an "open" transoartic 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*) (►**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) (►**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%.[15,25–27] More recent data, for example, from GARY, FRANCE 2, and FRANCE TAVI registries reported rates between 0.2 and 0.4%.[7,28] Data from the IQTIG are even lower (►**Fig. 2D**).[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.[29–32] Ascending aortic dilatation occurs in almost 25% of patients, but it does not automatically increase the risk for iatrogenic aortic dissections.[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.[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.[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%.[33,44] AADA-related mortality in TAVI patients with immediate surgery is excessively high—up to 80%.[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%.[46–48] Over the past years, this has declined to rates between 0.2 and 0.4%.[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% (►**Fig. 2E**).[1]

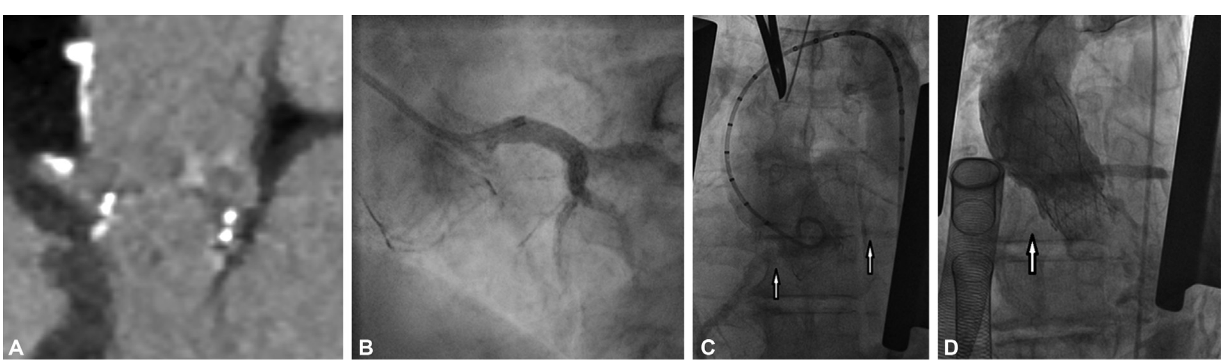

Fig. 8 Severe calcification of the aortic root and very low coronaries ([**A**] RCA; [**B**] LCA) in a degenerated bioprosthesis (Trifecta 21 mm; Abbott). (**C**) Open transaortic "VinV-TAVI"—combination of surgical resection of prosthesis leaflets and TAVI. Before VinV both coronaries are well contrasted 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.

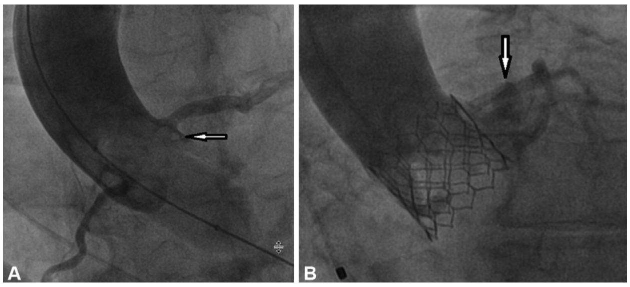

Fig. 9 Rupture of a heavy calcified annulus with a balloon-expandable valve. (**A**) Heavy calcification in area of left coronary artery (arrow). (**B**) Fluoroscopy of annulus rupture—extravasation of contrast due below left coronary artery (arrow).

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 ($\geq$20%) oversizing and/or unfavorable calcification.[46] Calcification of the aortic valve, annulus, and LVOT are predictors of annular injury and rupture.[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.[51]

Annular 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.[52] Others published a mortality rate of 40% (two out of five).[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.[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*."[54]

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**).[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.[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 (frame 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.[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 abovementioned 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.[5] Data from the GARY and the EuRECS registries revealed mortality rates of 40.2 and 35.7% in patients with cardiac tamponade.[7,52] Multivariate analysis has shown that tamponade is an independent predictor of death with an odds ratio of 3.74.[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 $\geq$ II Degrees

Aortic regurgitation after TAVI usually describes transvalvular, paravalvular, or "supraskirtal" leakages. According to the new VARC-3 recommendations, *Doppler echocardiography remains the primary modality for assessing and comparing regurgitation after aortic valve replacement*.[2] 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.[2] Freedom from moderate or severe aortic regurgitation belongs to the composite end point "*early safety (at 30days)*."[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.[63]

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 postprocedural 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 transvalvular 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,[69–72] and identified as independent predictor of mortality.[7,73–75] 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%).[52] 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

Authors	Year of publication	Study/trial	Patients total (*n*)	Patients with ECS (*n*)	ECS (%)	In-hospital/30-day mortality (%)
Arsalan et al[5]	2018	Single center	1,775	32	2.1	43.8
Eggebrecht et al[26]	2013	Meta-analysis from 46 studies	9,251	102	1.1	67.1 ($\pm$37.9)
Eggebrecht et al[79]	2014	SOURCE registry	2,307	27	1.2	51.9
Eggebrecht et al[52]	2018	EuRECS registry	27,760	212	0.76	46.0
Griese et al[86]	2013	Single center	411	20	4.9	35.0
Grube et al[87]	2008	Single center	136	5	3.7	40.0
Hein et al[45]	2013	German Transcatheter Aortic Valve Interventions Registry	1,975	24	1.2	45.8
Laricchia et al[88]	2019	Single center	1,348	17	1.2	41.2
Li et al[80]	2021	Single center	519	20	3.9	35.0
Makkar et al[8]	2013	PARTNER trial	2,542	36	1.4	33.3
Pepe et al[89]	2020	RISPEVA registry	3,507	12	0.3	n.s.
Piazza et al[90]	2008	Multicenter registry	646	3	0.5	n.s.
Seiffert et al[84]	2013	Single center	458	13	2.8	38.5
Walther et al[7]	2015	GARY registry	15,964	201	1.3	42.3

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.[6] Earlier studies from 2013 and 2015 reported higher rates of conversion to surgery due to embolization in 12 of 26 cases (46.2%)[8] and in 20 of 71 cases (28%).[81]

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% (see ►**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*."[82]

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.[83] 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.[5,80,84,85] 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. This combined effort is the guarantee for optimal patient safety, which must not be questioned.

Conflict of Interest
None declared.

References

1 Aortenklappenchirurgie, isoliert (Kathetergestützt): Qualitätsindikatoren und Kennzahlen; Herausgeber IQTIG –Institut für Qualitätssicherung und Transparenz im Gesundheitswesen. 2012–2019. Accessed May 20, 2022, at: www.iqtig.org/veroeffentlichungen/qualitaetsreport/

2 Généreux P, Piazza N, Alu MC, et al; VARC-3 WRITING COMMITTEE. Valve Academic Research Consortium 3: updated endpoint definitions for aortic valve clinical research. Eur Heart J 2021;42 (19):1825–1857

3 Bernardi FLM, Rodés-Cabau J, Tirado-Conte G, et al. Incidence, predictor, and clinical outcomes of multiple resheathing with self-expanding valves during transcatheter aortic valve replacement. J Am Heart Assoc 2021;10(18):e020682

4 Kim WK, Schäfer U, Tchetche D, et al. Incidence and outcome of peri-procedural transcatheter heart valve embolization and migration: the TRAVEL registry (TranscatheteR HeArt Valve EmboLization and Migration). Eur Heart J 2019;40(38):3156–3165

5 Arsalan M, Kim WK, Van Linden A, et al. Predictors and outcome of conversion to cardiac surgery during transcatheter aortic valve implantation. Eur J Cardiothorac Surg 2018;54(02):267–272

6 Zhang P, Li F, Wang Y, et al. Long-term outcomes of patients with self-expandable transcatheter heart valve embolized in the aorta. Int Heart J 2021;62(06):1265–1272

7 Walther T, Hamm CW, Schuler G, et al; GARY Executive Board. Perioperative results and complications in 15,964 transcatheter aortic valve replacements: prospective data from the GARY registry. J Am Coll Cardiol 2015;65(20):2173–2180

8 Makkar RR, Jilaihawi H, Chakravarty T, et al. Determinants and outcomes of acute transcatheter valve-in-valve therapy or embolization: a study of multiple valve implants in the U.S. PARTNER trial (Placement of AoRTic TraNscathetER Valve Trial Edwards SAPIEN Transcatheter Heart Valve). J Am Coll Cardiol 2013;62 (05):418–430

9 Abramowitz Y, Chakravarty T, Jilaihawi H, et al. Clinical impact of coronary protection during transcatheter aortic valve implantation: first reported series of patients. EuroIntervention 2015;11 (05):572–581

10 Ribeiro HB, Webb JG, Makkar RR, et al. Predictive factors, management, and clinical outcomes of coronary obstruction following transcatheter aortic valve implantation: insights from a large multicenter registry. J Am Coll Cardiol 2013;62 (17):1552–1562

11 Ribeiro HB, Nombela-Franco L, Urena M, et al. Coronary obstruction following transcatheter aortic valve implantation: a systematic review. JACC Cardiovasc Interv 2013;6(05):452–461

12 Arai T, Lefèvre T, Hovasse T, et al. Incidence and predictors of coronary obstruction following transcatheter aortic valve implantation in the real world. Catheter Cardiovasc Interv 2017; 90(07):1192–1197

13 Seipelt RG, Hanekop GG, Schoendube FA, Schillinger W. Heart team approach for transcatheter aortic valve implantation procedures complicated by coronary artery occlusion. Interact Cardiovasc Thorac Surg 2012;14(04):431–433

14 Rodés-Cabau J, Webb JG, Cheung A, et al. Transcatheter aortic valve implantation for the treatment of severe symptomatic aortic stenosis in patients at very high or prohibitive surgical risk: acute and late outcomes of the multicenter Canadian experience. J Am Coll Cardiol 2010;55(11):1080–1090

15 Zierer A, Wimmer-Greinecker G, Martens S, Moritz A, Doss M. The transapical approach for aortic valve implantation. J Thorac Cardiovasc Surg 2008;136(04):948–953

16 Holmes DR Jr, Mack MJ, Kaul S, et al. 2012 ACCF/AATS/SCAI/STS expert consensus document on transcatheter aortic valve replacement. J Am Coll Cardiol 2012;59(13):1200–1254

17 Masson JB, Kovac J, Schuler G, et al. Transcatheter aortic valve implantation: review of the nature, management, and avoidance of procedural complications. JACC Cardiovasc Interv 2009;2(09): 811–820

18 Akinseye OA, Jha SK, Ibebuogu UN. Clinical outcomes of coronary occlusion following transcatheter aortic valve replacement: a systematic review. Cardiovasc Revasc Med 2018;19(02):229–236

19 Conzelmann LO, Würth A, Schymik G, et al. Feasibility of transcatheter aortic valve implantation in patients with coronary heights $\leq$7 mm: insights from the transcatheter aortic valve implantation Karlsruhe (TAVIK) registry. Eur J Cardiothorac Surg 2018;54(04):752–761

20 Boukantar M, Gallet R, Mouillet G, et al. Coronary procedures after TAVI with the self-expanding aortic bioprosthesis Medtronic CoreValve™, not an easy matter. J Interv Cardiol 2017;30(01): 56–62

21 Dvir D, Webb J, Brecker S, et al. Transcatheter aortic valve replacement for degenerative bioprosthetic surgical valves: results from the global valve-in-valve registry. Circulation 2012;126(19):2335–2344

22 Ribeiro HB, Rodés-Cabau J, Blanke P, et al. Incidence, predictors, and clinical outcomes of coronary obstruction following transcatheter aortic valve replacement for degenerative bioprosthetic surgical valves: insights from the VIVID registry. Eur Heart J 2018; 39(08):687–695

23 Dvir D, Leipsic J, Blanke P, et al. Coronary obstruction in transcatheter aortic valve-in-valve implantation: preprocedural evaluation, device selection, protection, and treatment. Circ Cardiovasc Interv 2015;8(01):e002079

24 Khan JM, Greenbaum AB, Babaliaros VC, et al. The BASILICA trial: prospective multicenter investigation of intentional leaflet laceration to prevent TAVR coronary obstruction. JACC Cardiovasc Interv 2019;12(13):1240–1252

25 Smith CR, Leon MB, Mack MJ, et al; PARTNER Trial Investigators. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med 2011;364(23):2187–2198

26 Eggebrecht H, Schmermund A, Kahlert P, Erbel R, Voigtländer T, Mehta RH. Emergent cardiac surgery during transcatheter aortic valve implantation (TAVI): a weighted meta-analysis of 9,251 patients from 46 studies. EuroIntervention 2013;8(09): 1072–1080

27 Thomas M, Schymik G, Walther T, et al. Thirty-day results of the SAPIEN aortic Bioprosthesis European Outcome (SOURCE) registry: a European registry of transcatheter aortic valve implantation using the Edwards SAPIEN valve. Circulation 2010;122(01): 62–69

28 Auffret V, Lefevre T, Van Belle E, et al; FRANCE TAVI Investigators. Temporal trends in transcatheter aortic valve replacement in France: FRANCE 2 to FRANCE TAVI. J Am Coll Cardiol 2017;70(01): 42–55

29 Zhao ZG, Jilaihawi H, Feng Y, Chen M. Transcatheter aortic valve implantation in bicuspid anatomy. Nat Rev Cardiol 2015;12(02): 123–128

30 Conzelmann LO, Würth A, Balthasar V, et al. Transcatheter aortic valve implantation in severe calcified annulus using the Lotus valve system: increased incidence of fatal major vascular complications. Catheter Cardiovasc Interv 2020;95(01):E21–E29

31 Himbert D, Pontnau F, Messika-Zeitoun D, et al. Feasibility and outcomes of transcatheter aortic valve implantation in high-risk patients with stenotic bicuspid aortic valves. Am J Cardiol 2012; 110(06):877–883

32 Al-Attar N, Himbert D, Barbier F, Vahanian A, Nataf P. Delayed aortic dissection after transcatheter aortic valve implantation. J Heart Valve Dis 2013;22(05):701–703
33 Rylski B, Suedkamp M, Beyersdorf F, et al. Outcome after surgery for acute aortic dissection type A in patients over 70 years: data analysis from the German Registry for Acute Aortic Dissection Type A (GERAADA). Eur J Cardiothorac Surg 2011;40(02):435–440
34 Cigala E, Monteforte I, Piro O, Monda V, Capozzolo C, Bonzani G. [Lotus Sadra valve implantation complicated by type B aortic dissection: diagnosis and treatment]. G Ital Cardiol (Rome) 2017; 18(04):325–328
35 Conzelmann LO, Yousef M, Schnelle N, et al. How should I treat a DeBakey type I acute aortic dissection four weeks after transcatheter aortic valve implantation in an old, fragile patient? EuroIntervention 2015;10(12):e1–e6
36 Dachille A, Iacovelli F, Giardinelli F, et al. [Acute aortic dissection during ineffective attempt of transcatheter implant of a fully resheathable, respositionable and retrievable aortic valve]. G Ital Cardiol (Rome) 2017;18(2, suppl 1):31S–34S
37 Yashima F, Hayashida K, Fukuda K. Delivery balloon-induced ascending aortic dissection: an unusual complication during transcatheter aortic valve implantation. Catheter Cardiovasc Interv 2016;87(07):1338–1341
38 Ong SH, Mueller R, Gerckens U. Iatrogenic dissection of the ascending aorta during TAVI sealed with the CoreValve revalving prosthesis. Catheter Cardiovasc Interv 2011;77(06):910–914
39 Mwipatayi BP, Picardo A, Masilonyane-Jones TV, et al. Incidence and prognosis of vascular complications after transcatheter aortic valve implantation. J Vasc Surg 2013;58(04):1028–36.e1
40 Rezq A, Basavarajaiah S, Latib A, et al. Incidence, management, and outcomes of cardiac tamponade during transcatheter aortic valve implantation: a single-center study. JACC Cardiovasc Interv 2012;5(12):1264–1272
41 Baikoussis NG, Argiriou M, Kratimenos T, Karameri V, Dedeilias P. Iatrogenic dissection of the descending aorta: conservative or endovascular treatment? Ann Card Anaesth 2016;19(03): 554–556
42 Nagasawa A, Shirai S, Hanyu M, Arai Y, Kamioka N, Hayashi M. Descending aortic dissection injured by tip of the sheath during transcatheter aortic valve implantation. Cardiovasc Interv Ther 2016;31(02):122–127
43 Gerber RT, Osborn M, Mikhail GW. Delayed mortality from aortic dissection post transcatheter aortic valve implantation (TAVI): the tip of the iceberg. Catheter Cardiovasc Interv 2010;76(02): 202–204
44 Conzelmann LO, Weigang E, Mehlhorn U, et al; GERAADA Investigators. Mortality in patients with acute aortic dissection type A: analysis of pre- and intraoperative risk factors from the German Registry for Acute Aortic Dissection Type A (GERAADA). Eur J Cardiothorac Surg 2016;49(02):e44–e52
45 Hein R, Abdel-Wahab M, Sievert H, et al; German Transcatheter Aortic Valve Interventions Registry Investigators. Outcome of patients after emergency conversion from transcatheter aortic valve implantation to surgery. EuroIntervention 2013;9(04): 446–451
46 Barbanti M, Yang TH, Rodès Cabau J, et al. Anatomical and procedural features associated with aortic root rupture during balloon-expandable transcatheter aortic valve replacement. Circulation 2013;128(03):244–253
47 Pasic M, Unbehaun A, Dreysse S, et al. Rupture of the device landing zone during transcatheter aortic valve implantation: a life-threatening but treatable complication. Circ Cardiovasc Interv 2012;5(03):424–432
48 Pasic M, Unbehaun A, Buz S, Drews T, Hetzer R. Annular rupture during transcatheter aortic valve replacement: classification, pathophysiology, diagnostics, treatment approaches, and prevention. JACC Cardiovasc Interv 2015;8(1 Pt A):1–9
49 Hansson NC, Nørgaard BL, Barbanti M, et al. The impact of calcium volume and distribution in aortic root injury related to balloon-expandable transcatheter aortic valve replacement. J Cardiovasc Comput Tomogr 2015;9(05):382–392
50 Sá MP, Van den Eynde J, Malin JH, Torregrossa G, Sicouri S, Ramlawi B. Impact of left ventricle outflow tract calcification on the outcomes of transcatheter aortic valve implantation: a study-level meta-analysis. J Card Surg 2022;37(05):1379–1390
51 Montalto C, Sticchi A, Crimi G, et al. Outcomes after transcatheter aortic valve replacement in bicuspid versus tricuspid anatomy: a systematic review and meta-analysis. JACC Cardiovasc Interv 2021;14(19):2144–2155
52 Eggebrecht H, Vaquerizo B, Moris C, et al; European Registry on Emergent Cardiac Surgery during TAVI (EuRECS-TAVI) Incidence and outcomes of emergent cardiac surgery during transfemoral transcatheter aortic valve implantation (TAVI): insights from the European Registry on Emergent Cardiac Surgery during TAVI (EuRECS-TAVI). Eur Heart J 2018;39(08):676–684
53 Deleanu D, Platon P, Chioncel O, Iliescu VA, Parasca CA. Percutaneous closure of Gerbode defect type II post-TAVR with Amplatzer Muscular VSD Occluder. JACC Cardiovasc Interv 2021;14(17): e229–e230
54 Kappetein AP, Head SJ, Généreux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. J Am Coll Cardiol 2012;60(15):1438–1454
55 Moores DW, Allen KB, Faber LP, et al. Subxiphoid pericardial drainage for pericardial tamponade. J Thorac Cardiovasc Surg 1995;109(03):546–551, discussion 551–552
56 Athappan G, Patvardhan E, Tuzcu EM, et al. Incidence, predictors, and outcomes of aortic regurgitation after transcatheter aortic valve replacement: meta-analysis and systematic review of literature. J Am Coll Cardiol 2013;61(15):1585–1595
57 Hahn RT, Kodali S, Généreux P, Leon M. Paravalvular regurgitation following transcutaneous aortic valve replacement: predictors and clinical significance. Curr Cardiol Rep 2014;16(05):475
58 Kaneko H, Hoelschermann F, Tambor G, Yoon SH, Neuss M, Butter C. Predictors of paravalvular regurgitation after transcatheter aortic valve implantation for aortic stenosis using new-generation balloon-expandable SAPIEN 3. Am J Cardiol 2017;119(04): 618–622
59 Webb JG, Doshi D, Mack MJ, et al. A randomized evaluation of the SAPIEN XT transcatheter heart valve system in patients with aortic stenosis who are not candidates for surgery. JACC Cardiovasc Interv 2015;8(14):1797–1806
60 Meredith Am IT, Walters DL, Dumonteil N, et al. Transcatheter aortic valve replacement for severe symptomatic aortic stenosis using a repositionable valve system: 30-day primary endpoint results from the REPRISE II study. J Am Coll Cardiol 2014;64(13): 1339–1348
61 Yang TH, Webb JG, Blanke P, et al. Incidence and severity of paravalvular aortic regurgitation with multidetector computed tomography nominal area oversizing or undersizing after transcatheter heart valve replacement with the SAPIEN 3: a comparison with the SAPIEN XT. JACC Cardiovasc Interv 2015;8(03):462–471
62 Kalogeras K, Ruparelia N, Kabir T, et al. Comparison of the self-expanding Evolut-PRO transcatheter aortic valve to its predecessor Evolut-R in the real world multicenter ATLAS registry. Int J Cardiol 2020;310:120–125
63 Rück A, Kim WK, Kawashima H, et al. Paravalvular aortic regurgitation severity assessed by quantitative aortography: ACURATE *neo*2 versus ACURATE *neo* transcatheter aortic valve implantation. J Clin Med 2021;10(20):4627
64 Schymik G, Herzberger V, Bergmann J, et al. Evolution of transcatheter aortic valve implantation over 7 years: results of a prospective single-centre registry of 2000 patients in a large municipal hospital (TAVIK Registry). BMJ Open 2018;8(10):e022574

65 Nombela-Franco L, Rodés-Cabau J, DeLarochellière R, et al. Predictive factors, efficacy, and safety of balloon post-dilation after transcatheter aortic valve implantation with a balloon-expandable valve. JACC Cardiovasc Interv 2012;5(05):499–512

66 Eggebrecht H, Doss M, Schmermund A, Nowak B, Krissel J, Voigtländer T. Interventional options for severe aortic regurgitation after transcatheter aortic valve implantation: balloons, snares, valve-in-valve. Clin Res Cardiol 2012;101(06):503–507

67 McInerney A, Vera-Urquiza R, Tirado-Conte G, et al. Predilation and post-dilation in transcatheter aortic valve replacement: indications, benefits and risks. Interv Cardiol 2021;16:e28

68 Wunderlich NC, Honold J, Swaans MJ, Siegel RJ. How to image and manage prosthesis-related complications after transcatheter aortic valve replacement. Curr Cardiol Rep 2021;23(08):94

69 Abdel-Wahab M, Zahn R, Horack M, et al; German transcatheter aortic valve interventions registry investigators. Aortic regurgitation after transcatheter aortic valve implantation: incidence and early outcome. Results from the German transcatheter aortic valve interventions registry. Heart 2011;97(11):899–906

70 Zahn R, Gerckens U, Grube E, et al; German Transcatheter Aortic Valve Interventions-Registry Investigators. Transcatheter aortic valve implantation: first results from a multi-centre real-world registry. Eur Heart J 2011;32(02):198–204

71 Sinning JM, Hammerstingl C, Vasa-Nicotera M, et al. Aortic regurgitation index defines severity of peri-prosthetic regurgitation and predicts outcome in patients after transcatheter aortic valve implantation. J Am Coll Cardiol 2012;59(13):1134–1141

72 Gotzmann M, Korten M, Bojara W, et al. Long-term outcome of patients with moderate and severe prosthetic aortic valve regurgitation after transcatheter aortic valve implantation. Am J Cardiol 2012;110(10):1500–1506

73 Adams DH, Popma JJ, Reardon MJ, et al; U.S. CoreValve Clinical Investigators. Transcatheter aortic-valve replacement with a self-expanding prosthesis. N Engl J Med 2014;370(19):1790–1798

74 Kodali SK, Williams MR, Smith CR, et al; PARTNER Trial Investigators. Two-year outcomes after transcatheter or surgical aortic-valve replacement. N Engl J Med 2012;366(18):1686–1695

75 Hahn RT, Pibarot P, Stewart WJ, et al. Comparison of transcatheter and surgical aortic valve replacement in severe aortic stenosis: a longitudinal study of echocardiography parameters in cohort A of the PARTNER trial (placement of aortic transcatheter valves). J Am Coll Cardiol 2013;61(25):2514–2521

76 Ando T, Briasoulis A, Telila T, Afonso L, Grines CL, Takagi H. Does mild paravalvular regurgitation post transcatheter aortic valve implantation affect survival? A meta-analysis. Catheter Cardiovasc Interv 2018;91(01):135–147

77 Pibarot P, Hahn RT, Weissman NJ, Monaghan MJ. Assessment of paravalvular regurgitation following TAVR: a proposal of unifying grading scheme. JACC Cardiovasc Imaging 2015;8(03):340–360

78 Pibarot P, Hahn RT, Weissman NJ, et al. Association of paravalvular regurgitation with 1-year outcomes after transcatheter aortic valve replacement with the SAPIEN 3 valve. JAMA Cardiol 2017;2(11):1208–1216

79 Eggebrecht H, Mehta RH, Kahlert P, et al. Emergent cardiac surgery during transcatheter aortic valve implantation (TAVI): insights from the Edwards SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) registry. EuroIntervention 2014;10(08):975–981

80 Li F, Wang X, Wang Y, et al. Short- and long-term outcome after emergent cardiac surgery during transcatheter aortic valve implantation. Ann Thorac Cardiovasc Surg 2021;27(02):112–118

81 Ibebuogu UN, Giri S, Bolorunduro O, et al. Review of reported causes of device embolization following trans-catheter aortic valve implantation. Am J Cardiol 2015;115(12):1767–1772

82 Kobo O, Saada M, Roguin A. Can transcatheter aortic valve implantation [TAVI] be performed at institutions without on-site cardiac surgery department? Cardiovasc Revasc Med 2022;41:159–165

83 Minimum volumes for TAVI: Better prospects of success with larger case volumes. (July 28, 2021). Accessed on May 24, 2022 at: www.iqwig.de/en/presse/press-releases/press-releases-detail-page_43840.html

84 Seiffert M, Conradi L, Baldus S, et al. Severe intraprocedural complications after transcatheter aortic valve implantation: calling for a heart team approach. Eur J Cardiothorac Surg 2013;44(03):478–484, discussion 484

85 Smith CR. Emergency cardiac surgery following TAVI: implications for the future. Eur Heart J 2018;39(08):685–686

86 Griese DP, Reents W, Kerber S, Diegeler A, Babin-Ebell J. Emergency cardiac surgery during transfemoral and transapical transcatheter aortic valve implantation: incidence, reasons, management, and outcome of 411 patients from a single center. Catheter Cardiovasc Interv 2013;82(05):E726–E733

87 Grube E, Buellesfeld L, Mueller R, et al. Progress and current status of percutaneous aortic valve replacement: results of three device generations of the CoreValve Revalving system. Circ Cardiovasc Interv 2008;1(03):167–175

88 Laricchia A, Mangieri A, Latib A, et al. Temporal trends in procedural death and need for urgent open surgery during transcatheter aortic valve replacement: a single, high-volume center 10-year experience. Int J Cardiol 2019;293:80–83

89 Pepe M, Corcione N, Biondi-Zoccai G, et al. Comparison of outcomes of transcatheter aortic valve implantation in patients $\geq$85 years versus those $<$85 years. Am J Cardiol 2020;129:60–70

90 Piazza N, Grube E, Gerckens U, et al. Procedural and 30-day outcomes following transcatheter aortic valve implantation using the third generation (18 Fr) CoreValve revalving system: results from the multicentre, expanded evaluation registry 1-year following CE mark approval. EuroIntervention 2008;4(02):242–249

