



# Complications After Transcatheter Aortic Valve Implantation: an Updated Umbrella Review

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## Abstract

**Purpose of Review** We conducted a comprehensive and updated overview on complications occurring after transcatheter aortic valve implantation (TAVI) for severe aortic stenosis.

**Recent Findings** Despite remarkable improvements in patient selection, devices, procedures, and ancillary management, complications may still occur in patients undergoing TAVI. On top of most commonly described adverse events such as death, myocardial infarction, stroke, bleeding, vascular complication, renal failure, pacemaker implantation and residual valve regurgitation, other less common but similarly severe complications may still occur. These may include events ranging from acute delirium to valve compression during cardiopulmonary resuscitation. Meticulous care should be applied to all screening and procedural steps for TAVI, and attentive follow-up should be implemented afterwards, especially in suboptimal TAVI candidates or those otherwise at high operative risk.

**Summary** Despite recent remarkable improvements, additional research is warranted in order to further improve early and late outlook of TAVI, identify predictors of complications, and the best way to handle them.

**Keywords** Aortic stenosis · Complication · Transcatheter aortic valve implantation · Transcatheter aortic valve replacement

An expert is a man who has made all the mistakes which can be made, in a narrow field  
Niels Bohr

## Introduction

Transcatheter aortic valve implantation (TAVI) represents an appealing alternative for patients with severe symptomatic

aortic stenosis and high surgical risk score. Indeed, surgical risk is typically appraised quantitatively with the EuroSCORE II, logistic EuroSCORE, or Society of Thoracic Surgery instruments. Otherwise, unsuitability for surgery is based on adverse features such as porcelain aorta, sequelae of chest radiation, or frailty [1, 2–4].

Since the first pioneering cases, techniques and devices for TAVI have dramatically improved, and now, percutaneous transfemoral approach is considered the best option over

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transapical approach to minimize the risk of local as well as peripheral complications of TAVI procedures, even if other approaches are possible [5–10]. Indeed, several landmark randomized clinical trials have established the safety and efficacy of first and then current-generation TAVI devices, even in intermediate risk patients [10, 11••]. Most recent data are likely to expand indications for TAVI to include also subjects at low risk and those with pure aortic regurgitation [12].

While TAVI has provided favorable early and mid-term results in selected patients, comparing favorably to surgery whenever risk was moderate, high, or prohibitive, there is uncertainty on the potential risk of adverse events associated acutely or chronically with TAVI, and this appraisal is further complicated by the ever increasing success of this procedure, and ensuing increase in the number of TAVI cases worldwide. Our primary objective was thus a systematic review of the TAVI literature focusing on potential complications (Fig. 1).

## Methods

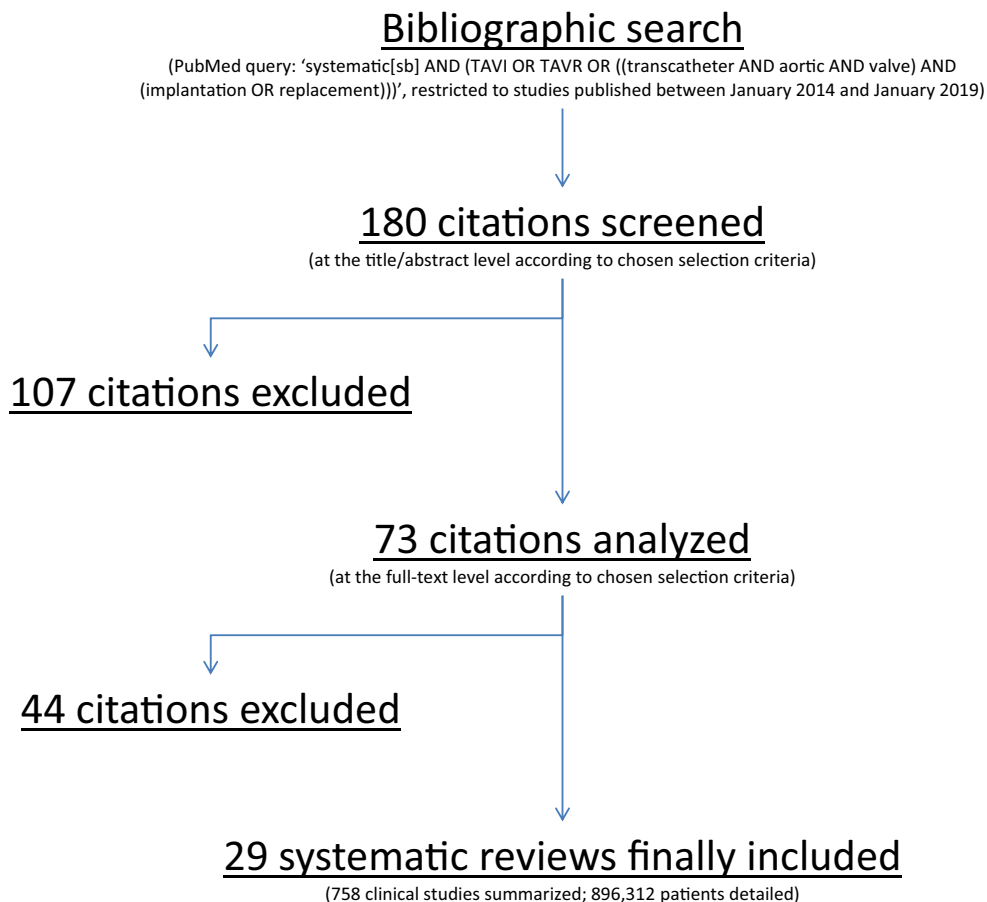
This work was designed as an umbrella review (i.e., overview of systematic reviews) in keeping with established recommendations for evidence synthesis [13]. Specifically, we searched

PubMed in order to find pertinent systematic reviews or meta-analyses on of TAVI using the following string: systematic[sb] AND (TAVI OR TAVR OR ((transcatheter AND aortic AND valve) AND (implantation OR replacement))), restricting our search to studies published between January 2014 and January 2019 in order to inform on complications of currently available devices. Citations were first screened at the title/abstract level. Then, full texts were sought if potentially pertinent. We extracted salient features of included reviews, and then on type, timing, incidence and outlook of described complications, eventually summarizing the results in tabular form. Pragmatically, we differentiated complications in early and late ones. Specifically, in keeping with the Valve Academic Research Consortium (VARC)-2 recommendations, procedural and peri-procedural complications were defined as early, and the same applied to events occurring within 72 h after the procedure [14•]. Conversely, all other events were considered as late. Given the design of this work as a scoping review, we did not explicitly appraised methods or internal validity of included studies.

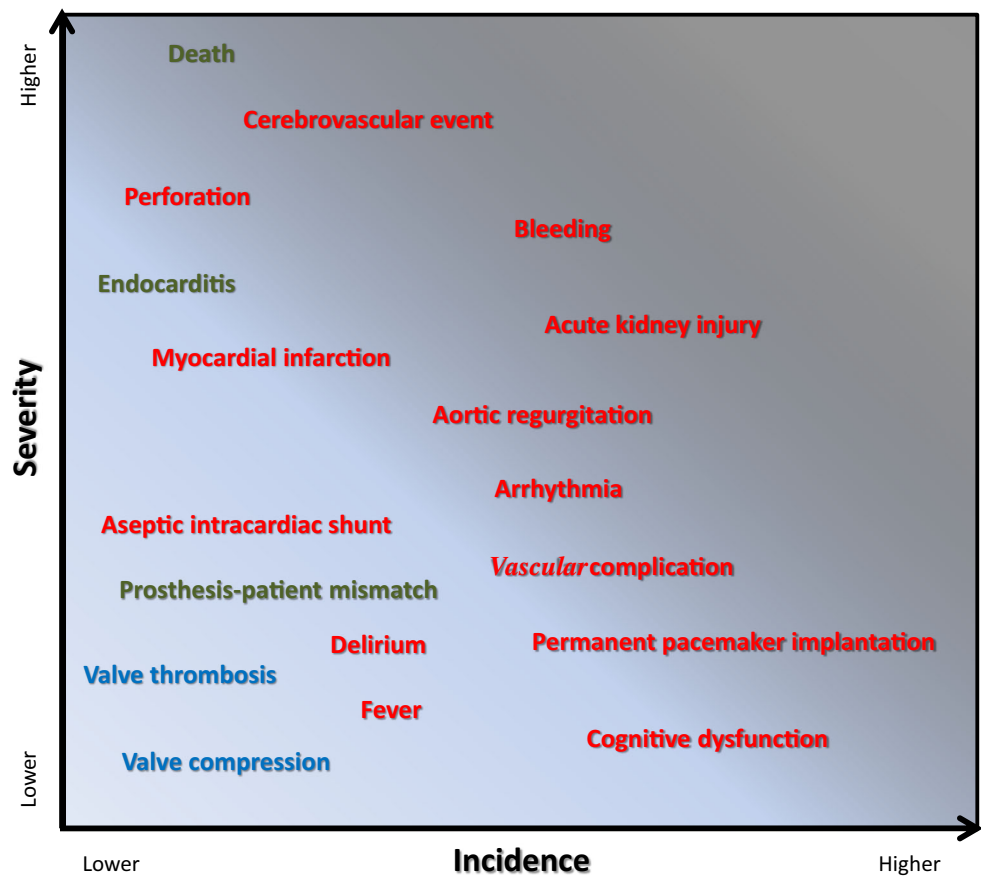
## Results

The selection process is summarized in Fig. 1.

Fig. 1 Review profile



**Fig. 2** Main complications following transcatheter aortic valve implantation, distinguished according to incidence (horizontal axis), severity (vertical axis), and timing (color code, distinguished as follows: red: early; blue: late; green: both)



**Early Complications**

TAVI may be associated with several types of early complications, ranging, for instance, from arrhythmia to bleeding, dissection, myocardial infarction, perforation, or stroke, including fatal ones. Most can be easily anticipated and explained pathophysiologically given the need to gain vascular access, reach the aortic valve, and safely deliver there a bulky device (Fig. 2) [1]. Further acute adverse events can be easily anticipated given that TAVI is most often performed in elderly or otherwise at intermediate to high-risk patients [10, 11••]. Incidence of such events varies, and it may also depend on individualized device choice, operator experience, institution volume, and proactive multidisciplinary care (Table 1; Table 2). Briefly, death, myocardial infarction, stroke, bleeding, vascular complication, renal failure, permanent pacemaker implantation, and aortic regurgitation with or without paravalvular regurgitation should always be considered as potential early complications of TAVI [1, 11••, 15–19]. In addition, other less common acute complications of TAVI have been described, ranging from delirium, cognitive dysfunction, liver failure, endocarditis, and aseptic intracardiac shunt [20–23]. Similarly to more common events, these are more frequent or more worrisome in higher risk patients or when procedures entail more aggressive or time consuming approaches.

Proactive surveillance is thus required shortly after TAVI, possibly in an intensively monitored setting, with frequent checks of vital signs, and repeat measurements of laboratory tests capable of eliciting early signs of complications. In addition, periodic echocardiograms are useful to verify valve morphology and function, as well as other cardiac details. A low index of suspicion should be applied also to order magnetic resonance imaging for neurologic complications, computed tomography imaging for chest, abdominal, or access site complications, as well as duplex ultrasound imaging.

**Late Complications**

There are some clearly uniquely late adverse events that can occur after TAVI (Table 1; Table 2) [1]. As pertinent for acute complications, most late adverse events in patients with prior TAVI depend of course on baseline risk, which is typically high, and even when low or intermediate, is dominated by advanced age. Important albeit uncommon late events after TAVI include valve thrombosis, compression, or embolization caused by manual chest compression during cardiopulmonary resuscitation, valve deterioration, endocarditis, and coronary occlusion due to neointimal hyperplasia on valve struts [15, 16, 24•].

**Table 1** Recent systematic reviews on complications after transcatheter aortic valve implantation (TAVI)

First author (year)	PubMed ID	Studies	Patients	Main findings
Abawi (2018)	30296342	31	32,389	Delirium occurred frequently after TAVI and is more common after non-TF procedures.
Akinseye (2018)	29102344	40	96	Coronary occlusion complicating TAVI was a rare event.
Amat-Sandos (2015)	25700757	28	32	Most cases of PVE involved male patients with a very high-risk profile.
Amat-Sandos (2017)	26775197	5	5	High temperature and positive blood cultures for typical micro-organisms were present early on in all cases of early infective endocarditis.
Ando (2016)	27157312	18	20	VSD were seen more frequently with balloon-expandable valves and with pre-dilation or post-dilation.
Ando (2017)	28963761	25	21,018	PVR decreased with latest-generation TAVI devices.
Athappan (2013)	23500308	45	12,926	Moderate or severe AR was common after TAVI and predicted mortality. Mild AR is variably linked with mortality.
Auffret (2016)	27515325	64	72,318	Female gender, CKD, enrolment date, and new-onset AF predict post-TAVI CVE.
Chandrasekhar (2015)	26319968	28	17,020	TF TAVI was associated with more vascular complications but less surgical conversions than non-TF TAVI.
Córdoba-Soriano (2015)	25667117	11	16	Dyspnea and increasing gradient after TAVI indicated valve thrombosis. While thrombus visualization appeared difficult, oral anticoagulation therapy might restore valve function.
Gorla (2018)	29656120	9	1059	Large TAVI device valve surface was associated with decline in platelet count.
Lai (2015)	25785192	6	349	Global cognition improved or remained unaltered over a 3-month period after TAVI, while individual cognitive domains remained preserved over time.
Liao (2017)	27890858	35	13,256	There were multi-factorial causes of AKI following TAVI.
Liao (2017)	29118326	30	4691	The incidence of prosthesis-patient mismatch was lower with TAVI than with SAVR.
Ma (2019)	30173298	43	544,112	AKI after TAVI was linked to increased post-operative mortality and morbidity.
Mohananey (2018)	29437037	5	5414	Incidence of major stroke, any stroke and CVE were similar with TAVI and SAVR.
Mojoli (2017)	28938965	11	11,033	AF was associated with adverse events after TAVI, including mortality, stroke and (limited to new-onset AF) major bleeding.
Mylotte (2015)	25265974	70	18	MCC during CPR might lead to late valve embolization or compression.
O'Sullivan (2015)	25756746	10	1736	There were no significant differences noted between TAo and TA TAVI in procedural success rate, stroke, TIA, major bleeding or PPI.
Pagnesi (2016)	27400304	25	1225	Silent cerebral injury occurred in the majority of patients subjected to TAVI and DW-MRI enabled accurate characterization of new ischemic brain lesions.
Pavasini (2018)	28586413	6	2329	After TAVI, mortality was higher in those with moderate-severe TR only in case of EF > 40%.
Regueiro (2016)	27169577	19	11,788	New-onset LBBB post-TAVI predicted cardiac death and need for PPI. The need for early post-TAVI PPI did not increase the risk of death.
Ren (2018)	29422266	21	5725	RV systolic function was unchanged after TAVI up to 12 months, while it significantly worsened following SAVR.
Rojas (2016)	27889349		31	Post-TAVI AICS were not frequent yet increased 30-day mortality, unless treated, especially in symptomatic patients.
Siontis (2018)	29275399	64	43,506	Identification of new-onset arrhythmias after TAVI impacted on subsequent management and prognosis.
Sterling (2015)	26001285	8	1598	Major stroke occurred in up to 6% of patients undergoing TAVI and DAPT does not seem superior or inferior to SAPT.
Sun (2017)	28668263	47	65,209	Age, gender, CKD, TA access, sheath diameter, vascular complication, and circulatory support predicted post-TAVI bleeding.
Van Rosendaal (2018)	29420704	40	17,139	Pre-existent conduction abnormalities, LVOT calcification, balloon valvuloplasty and implantation depth predicted increased risk of PPI.
Zhang (2017)	28910289	20	12,583	Peri-TAVI MI was best defined as combination of clinical criteria and cardiac biomarkers changes.

AF atrial fibrillation, AICS aseptic intracardiac shunt, AKI acute kidney injury, AR aortic regurgitation, CKD chronic kidney disease, CPR cardiopulmonary resuscitation, CVE cerebro-vascular events, DAPT dual antiplatelet therapy, DW-MRI diffusion-weighted magnetic resonance imaging, EF ejection fraction, LBBB left bundle branch block, LVOT left ventricular outflow tract, MCC manual chest compression, MI myocardial infarction, PPI permanent pacemaker implantation, PVE prosthetic valve endocarditis, PVR paravalvular leak, RV right ventricular, SAPT single antiplatelet therapy, SAVR surgical aortic valve replacement, TA transapical, TAo transaortic, TF transfemoral, TIA transient ischemic attack, TR tricuspid regurgitation, VSD ventricular septal defect

Periodic patient assessment with a detailed cardiac exam is mandatory after TAVI and should include transthoracic echocardiogram every 3 to 12 months, depending on timing since TAVI

and clinical stability. A low index of suspicion should be applied to order transesophageal echocardiography or computed tomography imaging, whose greater diagnostic and prognostic

**Table 2** Key complications after transcatheter aortic valve implantation (TAVI)

Complication	Timing	Incidence	Impact
AKI	D to W	5–60%	Increasing severity of AKI is associated with higher risk of short and long-term all-cause mortality.
Aortic regurgitation	H to M	5–30%	Moderate or severe aortic regurgitation is common following TAVR and represents an adverse prognostic factor at short and long term.
Arrhythmia	D to W	5–30%	Arrhythmias impact variably on patient morbidity and mortality.
AICS	D to M	0–2%	AICS increase 30-day mortality if left untreated, especially in symptomatic patients, depending on location and size.
Atrial fibrillation	H to D	10–25%	Atrial fibrillation post-TAVI is associated with increased rates of death and cerebrovascular events.
Atrioventricular block	H to W	10–25%	Atrioventricular blocks confer an increased risk of PPI.
Bleeding	H to W	5–15%	Bleeding (related or unrelated to access) may impact on morbidity and mortality depending on severity, cause, and management strategy.
Bradycardia	H to D	1–5%	Bradycardia confers an increased risk of PPI.
Cardiac perforation	H	< 1%	While uncommon, cardiac perforation carries a high risk of in-hospital death.
CVE	H to D	1–5%	CVE impact differently on mortality and morbidity, including cognitive function.
Chronic renal failure	H to W	1–10%	Renal function may decline shortly after TAVI, but typically stabilizes afterwards.
Cognitive dysfunction	H to W	1–10%	The link between TAVI and cognition remains unclear due to methodological limitations of available studies.
Coronary obstruction/occlusion	H	0–2%	Coronary obstruction following TAVI is linked to a high procedural and 30-day mortality rate.
Delirium	H to D	1–10%	Delirium has significant morbidity implications following TAVI, while its mortality impact remains uncertain.
Aortic dissection	H	< 0.1%	Aortic dissection complicating TAVI has a major mortality impact.
Endocarditis	D to M	0–3%	Endocarditis has a major morbidity and mortality impact.
Fever	H to D	20–60%	Patients with fever after TAVI may have adverse clinical complications, especially if fever represents a sign of endocarditis.
LBBB	H to D	10–40%	New-onset LBBB is a marker of an increased risk of cardiac death and need for PPI at 1-year follow-up.
Low platelet count	H to D	40–70%	Low platelet count is linked with increased risk of life-threatening or major bleeding and death.
Mitral leaflet perforation	H	< 0.1%	Mitral leaflet perforation has a major mortality impact especially if associated with endocarditis.
Mitral regurgitation	H	0–5%	Aortic regurgitation may impact on morbidity and mortality depending on severity.
Myocardial Infarction	H to D	0–2%	Myocardial infarction has major morbidity and mortality implications, with varying impact depending on timing and extent.
PVR	H to D	5–20%	PVR is associated with increased all-cause and cardiovascular mortality following TAVI.
PPI	H to D	5–30%	Early PPI is not significantly associated with death, whereas subsequent PPI has been linked with a significant decrease in the cardiac systolic function, which could impact on survival.
Prosthesis-patient mismatch	Hours	10–30%	PPIM is common following TAVI, with no significant differences in short and mid-term all-cause mortality between patients with and without PPIM.
RBBB	Hours	0–2%	New-onset RBBB is a significant predictor of PPI.
Right ventricular systolic dysfunction	H to D	0–5%	RV systolic dysfunction is associated with significant increase in all-cause mortality 1 year after TAVI.
Silent cerebral injury	H to D	40–80%	Silent cerebral injury is common after TAVI but its implications on cognitive or neurologic function are unclear.
Stroke	H to D	1–5%	Stroke has a major impact on morbidity and mortality depending on extent and location.
Surgical conversion	H	< 1%	Surgical conversion is typically requested for left ventricular guidewire perforation or annular rupture.
SIRS	H	< 1%	SIRS has significant morbidity implications on liver and renal function, as well as cognition.
TIA	H to D	1–10%	TIA have morbidity implications and may correlate with cognitive dysfunction.
Tricuspid regurgitation	H to D	1–10%	Moderate-severe TR is a significant predictor of all-cause mortality after TAVI.
Valve compression	H to Y	< 0.1%	Valve embolization may occur during cardiopulmonary resuscitation with manual chest compression with serious consequences on valve function.
Valve embolization	H to Y	< 0.1%	Valve embolization may occur during cardiopulmonary resuscitation with manual chest compression with serious consequences.
Valve thrombosis	H to Y	0–5%	Leaflet and valve thrombosis may have adverse consequences on valve function and cause systemic embolization. Leaflet or valve thrombosis may lead to valve dysfunction, with recurrent stenosis, regurgitation, or peripheral embolization. Treatment may include thrombectomy, valvuloplasty, repeat TAVI, or surgical aortic valve replacement, but prolonged systemic anticoagulation may often improve valve function and anatomy.
Vascular complication	H to D	1–15%	Vascular complications occur with variable frequency during TAVI, having a variable impact of prognosis depending on severity.

*AICS* aseptically intracardiac shunt, *AKI* acute kidney injury, *CVE* cerebrovascular event, *D* days, *H* hours, *LBBB* left bundle branch block, *M* months, *PPI* permanent pacemaker implantation, *PVR* paravalvular regurgitation, *RBBB* right bundle branch block, *SIRS* systemic inflammatory response syndrome, *TIA* transient ischemic attack, *W* weeks, *Y* years



accuracy result crucial for decision making (e.g., when considering repeat TAVI or surgical aortic valve replacement) in case of valve deterioration or compression.

## Conclusions

Despite ongoing improvements in patient selection, procedural details, device features, and operator skill, complications may still occur in patients undergoing TAVI. On top of most commonly described events such as death, myocardial infarction, stroke, bleeding, vascular complication, renal failure, pacemaker implantation, and residual valve regurgitation, other less common but similarly dreadful conditions may impact on patient morbidity and mortality after TAVI. These may include heterogeneous events ranging from acute delirium to valve compression during cardiopulmonary resuscitation. Meticulous care should be applied to all the screening and procedural steps, and attentive follow-up with periodic clinical and imaging assessments should be implemented. This appears even truer given that TAVI to date is mostly offered to elderly patients at prohibitive, high or intermediate surgical risk, who by definition have an increased risk of complications, and may also have difficulties in facing clinical complications which would be less than life-threatening in fitter subjects.

Limitations of our work include those inherent to any umbrella review with scoping goals, thus avoiding accurate assessment of review validity and methods. In addition, most included reviews focused on first-generation devices, which are now considered outdated for TAVI.

In conclusion, despite ongoing improvements in early and long-term outcomes after TAVI, complications still occur. Thus, additional research is warranted in order to further improve early and late outlook of TAVI, better identify predictors of complications, and define the most effective way to handle them.

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## Compliance with Ethical Standards

**Conflict of Interest** Prof. Biondi-Zoccai has consulted for Abbott Vascular and Bayer. Alberto Morello, Nicola Corcione, Paolo Farraro, Sirio Conte, Giacomo Frati, Barbara Antonazzo, Mariangela Peruzzi, Elena Cavarretta, Leonardo Roever, Antonio Popolo Rubbio, Magdalena Cuman, and Arturo Giordano declare interest.

**Human and Animal Rights and Informed Consent** This article does not contain any studies with human or animal subjects performed by any of the authors.

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- Of importance
  - Of major importance
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