A review of the complications associated with Transcatheter Aortic Valve Implantation.

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Transcatheter Aortic Valve Implantation (TAVI) has become the standard of care for treating elderly, high risk patients with severe aortic stenosis.\textsuperscript{1} Early trials demonstrated the superiority of TAVI over medical therapy in very high risk patients and the superiority of TAVI to surgical aortic valve replacement (SAVR) in high risk patients.\textsuperscript{2} More recently, publication of the PARTNER 2 trial highlighted the role of TAVI in intermediate risk patients, being non-inferior to SAVR overall and even superior to SAVR in patients undergoing the transfemoral approach.\textsuperscript{3} As such, TAVI has now become cemented with a ‘class I’ indication for treating high risk patients in the latest European Society of Cardiology (ESC) guidelines.\textsuperscript{1} Technology has continued to develop alongside increased operator experience. The 4th generation TAVI valves along with smaller and easier to use delivery systems have led to a considerable decline in the incidence of complications associated with TAVI. However, there is still a significant rate of serious complications. This editorial aims to describe the mechanism and frequency of common and serious complications associated with TAVI.\textsuperscript{4}

**Permanent pacemaker implantation**

Conduction disturbances requiring permanent pacemaker (PPM) implantation post TAVI are one of the most common periprocedural complications. The German Aortic valve RegistrY (GARY) demonstrated PPM implantation to be in the region of 15-33.7\% following TAVI.\textsuperscript{5} Compression of the adjacent conduction tissue is the speculated mechanism of action which appears to be particularly vulnerable to self-expanding valves (for example; Medtronic CoreValve, St Jude Portico and Boston Scientific Lotus valves), deep valve implant depth in the LVOT, balloon aortic valvuloplasty pre TAVI, post dilatation of the valve and extensive valvular calcification.\textsuperscript{4,5} Patients who develop RBBB and LBBB have a higher incidence of PPM implantation than patients with a narrow QRS complex. However, PPM implantation is not associated with increased 30 day or two-year mortality.
**Stroke**
Although one of the most severe complications of TAVI, prevalence of stroke is relatively uncommon at 1.8% in hospital and 3% at 30 days. Indeed this is comparable to surgical aortic valve replacement (SAVR) with an estimated stroke rate of 1.9%. Transcatheter Embolic Protection during TAVI could potentially decrease periprocedural stroke. However, while the SENTINEL trial demonstrated that embolic debris (including thrombus, calcification, valve tissue and artery wall) was captured in 99% patients, this failed to improve clinical outcomes.

**Vascular access complications**
Despite improved technology and reduction in size of delivery systems, vascular access complications including bleeding, dissection and vessel occlusion still occur in up to 16% transfemoral cases and are associated with increased mortality. Sheath to artery ratio, vessel tortuosity and calcification increase the risk of vascular complications. A sheath to femoral artery ratio of >1.05 predicated a higher rate of major vascular complications (30.9% vs 6.9%) and is a predictor of increased 30-day mortality (18.2% vs 4.2%).

**Cardiac tamponade**
Cardiac tamponade during TAVI may occur due to aortic rupture, right ventricular perforation during placement of a temporary pacing wire or left ventricular perforation with a super stiff wire after crossing the valve. The incidence ranged from 0.2-4.3%. Right ventricular perforations can often be managed conservatively, however left ventricular perforation requires urgent surgical intervention. Aortic root rupture is a rare complication during TAVI and is more common in cases with heavily calcified valves and oversized transcatheter implants.

**Coronary obstruction**
Coronary ostia occlusion during TAVI is life threatening. It is seen in 0.2-0.4% cases. Low set coronary ostia close to the annular level and extensively calcified valves are the major risk factors for ostial occlusion. This often results in significant haemodynamic compromise. The ability to re-sheathe some valves prior to final deployment can rapidly correct coronary malperfusion.
**Aortic regurgitation**
A degree of paravalvular leak (PVL) following TAVI is common, much more common than SAVR. This is due to the eccentric nature of the annulus and calcification encountered on degenerative valves. Central transvalvular aortic regurgitation (AR) is rare but may be due to leaflet malfunction secondary to damage during the crimping process or post dilatation. Moderate and severe PVL are prognostically unfavorable.\(^1\) The PARTNER trial reported moderate AR in 11.8% patients and severe AR in 12.2%. The GARY registry however, observed 7% and 0.3% respectively. The lack of a standardised reporting system for describing AR in transcatheter valves undoubtedly contributes to the disparity observed between these two large trials. Mild PVL was noted in 62% patients but was not correlated with increased morbidity.

![Severe AR following TAVI due to presumed leaflet malfunction during crimping.](image1a)

![Treated with emergency valve-in-valve.](image1b)

**Valvular thrombosis**
Increased use of multidetector computed tomography (MDCT) has led to the detection of subclinical valvular thrombosis in TAVI. Transcatheter heart valve thrombosis is in the region of 7%, although most cases are incidental.\(^2\) Patients with obstructive valvular thrombosis typically present with heart failure symptoms. The presence of subclinical valvular thrombosis does not appear to be associated with an
increased risk of stroke. The optimal antithrombotic strategy following TAVI is yet to be established, however most patients undertake a period of dual antiplatelet therapy. The Global Study Comparing a Rivaroxaban-based Antithrombotic Strategy to an Antiplatelet Strategy After Transcatheter Aortic Valve Replacement to Optimize Clinical Outcomes (GALILEO: NCT02556203) study will provide additional valuable evidence in this area.

**Endocarditis**

Incidence of infective endocarditis following TAVI is low at 0.5%. It is a severe complication with an in-hospital death rate approaching 50%. Coagulase-negative staphylococci (24%), Staphylococcus aureus (21%) and enterococci (21%) are among the most frequently encountered organisms. The infection may be indolent initially, however many patients present with established complications of endocarditis. Surgical options are limited as many patients underwent a transcatheter approach as they were deemed to have excessive surgical risk or were inoperable.

Figure 2a: Transoesophageal echocardiography demonstrating a small echo dense mass adherent to a TAVI prosthesis in a patient with Enterococcus *Faecalis* endocarditis. Figure 2b: 3-D reconstruction during TOE demonstrating the exact location of the mass on the TAVI prosthesis.
<table>
<thead>
<tr>
<th>Complications</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>Coronary occlusion</td>
<td>0.3%</td>
</tr>
<tr>
<td>Cardiac tamponade</td>
<td>1.4%</td>
</tr>
<tr>
<td>Device embolization</td>
<td>0.6%</td>
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<tr>
<td>Left ventricular failure</td>
<td>0.9%</td>
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<tr>
<td>Vascular complications</td>
<td>15.9%</td>
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<tr>
<td>Conversion to sternotomy</td>
<td>1.4%</td>
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<tr>
<td>Pacemaker</td>
<td>23.7%</td>
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<tr>
<td>Stroke</td>
<td>1.7%</td>
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<tr>
<td>Blood transfusion (0-2 units)</td>
<td>88.5%</td>
</tr>
<tr>
<td>Blood transfusion &gt;2 units</td>
<td>11.5%</td>
</tr>
<tr>
<td>Severe AR</td>
<td>0.3%</td>
</tr>
<tr>
<td>Moderate AR</td>
<td>7%</td>
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<tr>
<td>In-hospital mortality</td>
<td>5.1%</td>
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Table 1: Synopsis of complications associated with TAVI as observed in the German Aortic valve RegistrY.\(^6\)

**Conclusion**

TAVI is now well established as the optimal interventional strategy for treating elderly and high risk patients with severe aortic stenosis, and is no doubt superior to medical therapy. It is however still associated with a considerable complication rate. While industry continues to improve the valves and delivery systems and medical staff acquire expertise, complication rates have fallen significantly from the initial TAVI procedures. Nevertheless, the Heart Team remains central to making informed collaborative decisions on what is the best way to treat patients. As technology continues to improve it is likely that the indication for TAVI will expand with it. We await the outcome from the PARTNER 3 trial comparing the safety and efficacy of the SAPIEN 3 heart valve to SAVR in low risk patients which may further widen the patient group suitable for TAVI.
References


