Transcatheter aortic valve implantation: A review article

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ABSTRACT

Aortic stenosis is a valvular heart disease commonly found in developed and developing countries. The frequency of aortic valve sclerosis is about 25% in people over 65 years of age. In contrast to developing countries, infectious diseases, such as endocarditis or rheumatic fever, contribute greatly to aortic stenosis. Severe aortic stenosis without valve replacement has a poor prognosis and some patients are at high risk for surgery. Transcatheter aortic valve implantation (TAVI) is emerging as an alternative in patients with aortic stenosis who cannot or are at high risk for surgery. TAVI has revolutionized the management of aortic stenosis. This procedure continues to improve yearly and exceeds surgical aortic valve replacement in 2019. Initially, TAVI generated skepticism and criticism, but with many clinical trials and evidence-based investigations, TAVI is now widely accepted. Until now, the development of TAVI continues, starting with better technology, approaches, and new implantation strategies; TAVI is becoming safer for patients. This literature review will discuss more deeply about TAVI and its development.

INTRODUCTION

In developed countries, degenerative calcification is a common cause of aortic stenosis. It occurs in about 5% of the population at age 65, with a prevalence increasing.1 In younger age groups, aortic stenosis is caused by bicuspid aortic valve disease.2 The frequency of aortic valve sclerosis is about 25% at age 65, increasing to 48% after 75 years, while the frequency of aortic stenosis is 4–5% in those younger than 65 years.3,4 During the past few decades, the only effective treatment was aortic valve replacement surgery with satisfactory results but requiring invasive cardiac surgery and extracorporeal circulation. However, the risk of surgery, postoperative complications and death is significantly increased in the very elderly, with either cardiac or noncardiac comorbidities.5,6 Based on the Euro-Heart survey of high-risk patients, one-third of patients cannot have SAVR (Surgical Aortic Valve Replacement) then another alternative is needed. Transcatheter aortic valve implantation (TAVI) was introduced in 2002 as an alternative in inoperable or high-risk patients.7 To date, TAVI has been performed by more than 200,000 patients in 65 countries worldwide and is performed daily in various institutions.8 This procedure has a high success rate of up to 90% in high-risk patients.

Patient risk stratification in TAVI preparation

A preprocedural assessment was performed using the EuroSCORE or STS score. Generally, a high-risk operation is considered when the EuroSCORE exceeds 20%, and the STS is more than 8%. In this case, TAVI is suggested. Recent studies from PARTNER 2, Edwards SAPIEN XT valves with an STS score between 3-8% and SURTAVI (CoreValve) with an STS score between 3-15% showed good TAVI results at moderate risk and have been validated by the FDA.9 Patients should be assessed in detail because this score has several drawbacks which do not take into account certain conditions that can complicate surgery and increase mortality, such as the history of mediastinal radiation, chest wall deformities, porcelain aorta, mediastinitis, liver cirrhosis, history of cardiac bypass surgery, patient susceptibility, severe lung disease, low body mass index, renal impairment, and low transvalvular gradient are associated with poor prognosis.10

Selecting TAVI vs. SAVR

TAVI has a procedural success rate of >90% in high and medium-risk patients. The transfemoral approach is the most preferred technique because it is easier to perform in most patients. Advances in technology, imaging and operator capabilities over the past few years have reduced the 30-day mortality rate from 5-15% to 1–2% using the latest generation of equipment. First-year survival rates range from 60-85% at high risk to 95% at intermediate risk. These results are comparable to those achieved by surgical aortic valve replacement (SAVR) with faster recovery.4,11,12 The first randomized trial compared the balloon-expandable TAVI and SAVR at high risk with a Society of Thoracic Surgeons (STS) score of 11.8. Results showed a non-inferior TAVI for all-cause mortality in the first year with marked functional improvement. In the PARTNER-1 study, in inoperable and high-risk patients, the risk of all-cause mortality was 71.8% on TAVI vs. 93.6% on medication. The median survival rate was 31 months vs. 11.7 months for TAVI vs. medication at a 2-year outcome; TAVI demonstrated superior functional status as assessed by New York Heart
Association (NYHA) symptoms and lower repeat hospital admissions compared with standard therapy. None of the TAVI patients required re-intervention for structural damage to the valve prosthesis. In the high-risk cohort, there was no significant difference in all-cause mortality (67.8 vs. 62.4% for TAVI vs. SAVR) at five years. Rates of readmission to hospital, stroke and functional assessment were relatively similar. The frequency of vascular complications was higher in the TAVI group (11.9 vs. 4.7%), whereas major bleeding was higher in the SAVR (34.4 vs. 26.6%). The durability of both surgical and TAVI valves lasted up to 5 years (TAVI vs. SAVR: mean valve area 1.6 vs. 1.5 cm²; mean transvalvular gradient 10.7 vs. 10.6 mmHg). An increased risk of death occurred in the presence of moderate or severe paravalvular aortic regurgitation when compared with mild or absent AR (72.4 vs. 56.6%).

Anatomical and imaging assessment

Detailed assessment of the aortic valve, aortic root, and descending aorta, including the iliofemoral and subclavian joints, is necessary before performing TAVI. The first thing to assess is to estimate the number and distribution of calcifications in the valves and vessels; assess the location of the coronary artery orifices, which are usually within the two sinuses of Valsalva. The distance between the attachment of the basal valve to the sinuses Valsalva is a matter that must be considered because it is related to the placement of the bioprosthetic. The width of the sinus of Valsalva is also an important parameter because the narrower it is, the higher the risk of coronary obstruction during TAVI. Several crucial parameters that need to be considered are the smallest diameter, tortuosity, calcification, and the degree of atherosclerosis at the iliofemoral level. 3-D reconstruction with Computed Tomography is very useful for assessing valves (distribution and leaflet length); aortic root anatomy (diameter, angulation, calcification, sinus of Valsalva); the distance of the coronary ostium/annulus (assess the risk of coronary artery obstruction), as well as the anatomy of the aorta to the femoral. This modality is the best because it is accurate in evaluating the aortic annulus (diameter, circumferential, calcification, sinus Valsalva) so that it can obtain the correct prosthesis size, thereby reducing the risk of embolism and paravalvular regurgitation or rupture of the annulus. CT without contrast can be used if the patient has renal impairment.

TAVI access, techniques, and procedures

The transfemoral approach is the technique most often used, which is about 70%, followed by transapical (20%), the rest of the other accesses (transapical, transcaval, transactional or subclavian, and transaortic) about 10%. Transactional access is selected when femoral access cannot be performed by insertion through the left axillary artery. The advantage of transfemoral is that it is less invasive and can be performed under local anesthesia. The patient was not intubated, so there was no need for an intensive care unit, less pain and complications, shorter procedure time, and shorter hospitalization. This action will be discussed further in the TAVI techniques and procedures.

Before the procedure, the patient can be given intravenous antibiotics and continued for 48 hours to reduce the risk of infection. Patients were also given aspirin 160 to 325 mg and clopidogrel 300 mg 24 hours before the procedure. Most transfemoral and subclavian procedures are performed in the cardiac catheterization laboratory. In contrast, direct transaortic and transapical procedures should be performed in the hybrid operating room because they are riskier. A heart-lung machine should be available if complications arise. Equipment for treating vascular and coronary complications should be available upon request. Local anesthetics are used more frequently in transfemoral access. This procedure is usually sufficient to use fluoroscopy alone. Still, if complications are found, the patient can be given general anesthesia so that periprocedural TEE can be performed, making it easier for the operator. Invasive hemodynamic monitoring is used during the procedure. After anesthesia is performed, the transapical access is installed using a pre-closing system using Prostar XL or Perclose and then attaching a sheath with a rigid wire. The pre-closing system is useful for making it easier to close the stitches after the action is complete. Access to the contralateral femoral artery was used with a 5–6 Fr pigtail catheter, and the femoral vein was used for pacemaker placement. The pigtail is placed at lumbar level 4 or 5 proximal to the common iliac bifurcation. The panoramic examination was performed to view the aortoiliac bifurcation, iliac artery, left and right common femoral arteries with contrast injection (15-20 ml at 20 ml/sec). Coronary angiography is also recommended as part of the pre-TAVI examination to demonstrate the presence and severity of coronary artery

![Figure 1](image1.jpg)

**Figure 1.** Reconstruction and measurement of the aortic annulus with CT and determining the ideal angle of implantation to assist the aortographic projection covering the three parallel cusps.

![Figure 2](image2.jpg)

**Figure 2.** Various stages of transfemoral TAVI with SAPIEN 3.
disease. Coronary angiography can also demonstrate the height and location of the coronary artery ostia, together with an assessment of sinus Valsalva capacity, which is essential for accurate prosthesis placement.

The 5F graded pigtail was placed into the noncoronary cusp, and an aortogram was performed (20 ml contrast at 20 ml/sec). Aortograms are used to demonstrate aortic tortuosity, calcification, aneurysmal dilatation, and obstructive atherosclerosis, which contraindicate TAVI. It can also indicate the size of the aortic ring, calcification of the aortic valve and the presence of aortic regurgitation. Through the femoral vein, a pacemaker is inserted into the right ventricle. Rapid ventricular pacing at a rate of 180-220 beats per minute is performed during balloon angioplasty so that the heart can stop and the installation is safe and precise. A temporary pacemaker is inserted before the procedure and is usually removed after 48 hours.16

The next step is to enter the delivery sheath. The valve is stenotic through a straight wire (crossing) of which the most commonly used is the Amplatz Left (AL) 1 size 5 Fr for diagnostics with projections from RAO 30° to LAO 30°. Then AL1 was replaced with a 0.035-inch pigtail catheter to allow the other pigtail to enter the ascending aorta. A pigtail catheter was placed, and a valve gradient was then obtained. The main concern in valve crossing is the increased risk of embolic stroke from manipulating the catheter in the vicinity of a calcified aortic valve. Therefore, a time limit was set for the aortic valve crossing to be achieved in less than 10 minutes.

Once the pigtail has passed through the valve into the left ventricle, measurements of left ventricular and femoral artery pressures can now be performed. After performing a ventriculogram, careful retraction of the pigtail into the aorta was performed to measure the transaortic gradient and ensure that the aortic pressure and the femoral artery pressure were the same. Next, BAV (Balloon Aortic Valvuloplasty) is performed using a pacemaker at 180-200 bpm. The valve prosthesis should be ready for insertion shortly before the completion of BAV to prevent the possibility of severe insufficiency and hemodynamic instability in 1-2% of cases. The bioprosthetic valve is then inserted on a very rigid cable into the sheath. After reaching the aortic arch, the delivery catheter is advanced until it reaches the ascending aorta, and the valve is placed in the aortic position. After confirmation of appropriate location by angiography (and TEE if available), rapid ventricular pacing (RVP) is activated, and when systemic blood pressure reaches its nadir, a prosthetic valve is placed. Balloon inflation is held 3 to 5 seconds before deflation, and the RVP is stopped to avoid traction on the prosthesis when the balloon catheter is withdrawn. RVP runs generally take no more than 15 seconds. Immediately after removal of the bioprosthesis, regurgitation and hemodynamic assessments was performed, which included measurement of the transaortic gradient, left ventricular end-diastolic pressure, and systemic diastolic pressure.24,25

The procedure is completed by closing the vascular access site. The sheath is withdrawn with close blood pressure monitoring, especially when the catheter passes through the level of the iliac branch or in the iliac artery, for which contrast injection is required. A steep drop in blood pressure or extravasation of contrast media indicates a vascular rupture and should be treated promptly and appropriately with a covered stent or surgery. A large sheath or balloon can be used as a tampon before the artery is repaired.9,16 If there are no puncture site complications, after 12 hours, the patient can mobilize. After the procedure was completed, antiplatelet agents were administered, namely clopidogrel 75 mg daily for one month and aspirin 75 mg daily for life. If there is an indication for oral anticoagulation, dual antiplatelet therapy can be replaced or combined with one type of antiplatelet.26-29

**COMPLICATION**

It should be noted that only major
vascular complications are associated with increased mortality at 30 days. Newer generation valves also reduce the incidence of paravalvular regurgitation. Moderate to severe regurgitation is consistently associated with increased first-year mortality. AV block and the need for a pacemaker may occur in post-TAVI patients. Conduction abnormalities usually occur because of the proximity of the aortic ring to the left bundle branch and atrioventricular node. In the PARTNER trial, the total incidence of av heart block requiring a pacemaker was 4.7% (cohort B) and 5.7% (cohort A), 9% (moderate risk SAPIEN 3), left bundle branch block 12%, and first-degree block 15%. The lower the implant into the LVOT, the higher the risk of AV conduction disorders and the need for a permanent pacemaker. Stroke is a dreaded complication because it significantly affects survival and quality of life. Most of the causes of stroke are due to embolism. In the PARTNER trial, stroke significantly increased mortality in both TAVI and SAVR. According to Eggebrecht’s meta-analysis involving more than 10,000 TAVI, the 30-day mortality rate increased 3.5-fold in patients with stroke. Acute renal failure after TAVI is quite common with an incidence of 12% to 28% and sometimes requires renal replacement therapy of 1.4% and is associated with higher mortality. The incidence of acute renal failure on TAVI was lower than SAVR at 9.2% vs. 25%, and dialysis requirements at 2.5% vs. 8.7%. Coronary obstruction occurs in 0.6% of cases and is seen in patients with thin sinotubular, which causes the coronary Ostia to shift. Although severe procedural complications such as annular rupture, coronary obstruction, valve embolization, or ventricular perforation are extremely rare, approximately 1-2% of TAVI patients still require urgent cardiac surgery for life-threatening complications.

Recent Updates and Developments in TAVI

In the United States, the STS-ACC TVT Registry (Society of Thoracic Surgeons – American College of Cardiology Transcatheter Valve Therapy Registry) 2011 to 2019 has collected data on 276,316 patients undergoing TAVI in all states of America. The number of TAVIs continues to increase yearly, surpassing surgical aortic valve replacement in 2019. TAVI measures now extend from extreme risk to low-risk patients. This is the first registry of 8,395 low-risk patients since 2019. The average length of stay for high- and medium-risk TAVI patients was only two days, while for low-risk patients, it was only one day. In-hospital mortality decreased from 5.4% to 1.3%, and mortality within 30 days decreased from 7.2% to 2.5%.

On the other hand, the use of TAVI in Asia is still slow, mainly due to the high cost of the device, the need for specialized training programs and the lack of specialized cardiac care and structures. Asians also have a smaller body surface area, smaller annulus dimensions, and a lower coronary ostia position confirmed in the international Asia TAVI registry, the OCEAN-TAVI study (Optimized transcatheter vAlvular iNtervention), and PREVAIL (Transfemoral and transapical Placement of Aortic Balloon Expandable Transcatheter Valves). These considerations raise concerns of complications and indicate the need for smaller devices than those produced by western brands. The Asia Pacific medical community and Chinese manufacturers are trying to meet this unmet need with different strategies. On the one hand, Japan, Hong Kong, Taiwan, Singapore, and South Korea use tools developed by western countries. On the other hand, China favors developing
By 2020, decisions about TAVI candidates will no longer be based solely on the patient’s surgical risk level. Instead, age becomes the basis for initial decision-making. The ACC/AHA 2020 Guidelines for the Management of Patients with Valvular Heart disease recommend mechanical valves for patients <55 years and tissue valves for patients >65 years with shared decision making based on patient preference for ages between 55 and 65 years. Antithrombotic therapy in TAVI is still a special concern. Although thromboembolic complications and post-TAVI bleeding have decreased over time, side effects are still common. The ESC/EACTS 2017 Guidelines for antithrombotic therapy in patients undergoing TAVI are largely based on expert opinion. However, based on the “Consensus document of the ESC Working Group on Thrombosis and the European Association of Percutaneous Cardiovascular Interventions (EAPCI)” in 2021, it has updated antithrombotic therapy on TAVI. The same recommendation was made for the POPULAR-TAVI (Antiplatelet Therapy for Patients Undergoing Transcatheter Aortic-Valve Implantation) trial, a parallel design trial involving two groups. Cohort A compared patients without an indication for anticoagulation and DAPT (clopidogrel) versus single antiplatelet therapy (low-dose aspirin), which was recently published in The New England Journal of Medicine in October 2020. Cohort B, published first, compared patients with an indication for anticoagulation. Who underwent TAVI to receive oral anticoagulation alone or anticoagulation plus clopidogrel for three months. POPULAR-TAVI concludes that three possible clinical scenarios will be encountered in the table below:

**Table 1. Summary of Antithrombotic Therapy Recommendations for Patients Undergoing TAVI**

<table>
<thead>
<tr>
<th></th>
<th>Single antiplatelet therapy</th>
<th>DAPT</th>
<th>VKA or DOAC</th>
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<tbody>
<tr>
<td>No recent intervention and no indication of anticoagulation</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recent PCI or other independent indication for DAPT</td>
<td></td>
<td>+</td>
<td></td>
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<tr>
<td>There are independent indications for anticoagulation</td>
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</tr>
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</table>

*In patients at high ischemic risk due to acute coronary syndrome or other anatomic/procedural characteristics also indicated for anticoagulation, triple therapy may be considered individually after carefully considering the bleeding risk; DAPT: Dual antiplatelet therapy; DOAC: Direct oral anticoagulants.

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**Conclusion**

TAVI has revolutionarily changed the way in which patients with severe AS and bioprosthetic valve dysfunction were previously treated because of the high risk of surgery. In preparation for TAVI, a solid team is needed to avoid the outcome and the risk of complications. With the development of TAVI technology, complications such as conduction disorders and paravalvular insufficiency are expected to be lower. Currently,
research on the use of TAVI in low-risk, asymptomatic patients continues to grow, and TAVI’s future development will be wider. Although, until now, patients undergoing TAVI were assessed based on the surgical risk level, the action will also be assessed individually in the future.

CONFLICT OF INTEREST
All authors declared that there is no conflict of interest regarding this article

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