

COVER STORY



**TAVI: Catheter-based
Aortic Valve Replacement**

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Severe aortic stenosis (AS) is the most common degenerative valvular heart disease in the western world. The most common pathology is degenerative calcification of the aortic leaflets and annulus associated with advanced age.

Severe AS is seen in 2 per cent of the population over 75 years of age. The prognosis is grim. With the onset of symptoms including angina, syncope or congestive heart failure, median survival is limited to 2-3 years, typically with rapidly deteriorating exercise tolerance and quality of life prior to death.

No medical therapy prolongs survival or progression of symptoms. Surgical aortic valve replacement is the only effective treatment to improve prognosis and quality of life. In all valvular heart disease guidelines, it is the recommended treatment for patients with symptomatic severe AS.

However, surgical aortic valve replacement is a major operation. In the elderly population, especially those with multiple co-morbidities, it may have an operative mortality of 10 per cent and can be associated with significant morbidities such as stroke and prolonged rehabilitation. Furthermore, between 30 per cent and 60 per cent of elderly patients with severe AS are either not referred for surgery or are declined by surgeons for valve replacement. There is hence a demand for lesser invasive or percutaneous options to treat this disease.

**WHAT IS TAVI – THE
TECHNOLOGY AND
PROCEDURE?**

Transcatheter aortic valve replacement, commonly abbreviated to TAVR or TAVI, is the new percutaneous option to replace the aortic valve. It was first

performed in 2012, though there are over 250,000 cases done worldwide since. The two most widely used transcatheter valves are the SAPIEN valve (Edwards Lifesciences, Irvine USA) and the CoreValve (Medtronic, Minneapolis USA). They consist of a stent-like metal frame on which are attached tissue leaflet valves (Figures 1a and 1b).

They are mounted on a delivery catheter (in a similar manner to coronary or peripheral stents) and then passed to the aortic annulus (the point of attachment of the native aortic valve leaflets) through an endovascular approach.

Most commonly (80-90 per cent) TAVI procedures are performed via a “transfemoral” approach. It involves typically a 16-18Fr sheath inserted into the common femoral artery for access. The aortic valve is crossed and a stiff wire placed in the left ventricle to facilitate passage of the catheters. A balloon aortic valvuloplasty is performed, which involves dilating the stenosed valve with a balloon. The new transcatheter valve mounted onto the delivery catheter is then passed to the native aortic annulus. The SAPIEN valve is a balloon expandable system with the valve mounted onto a balloon catheter (Figure 1a). The balloon is inflated at the aortic annulus, expanding the transcatheter valve and holding open the native aortic valve leaflets. The transcatheter valve is anchored by the heavily calcified native aortic leaflets and annulus (Figure 2).

The CoreValve is a self-expanding system with a frame made from Nickel Titanium (Figure 1b). This transcatheter valve expands to its

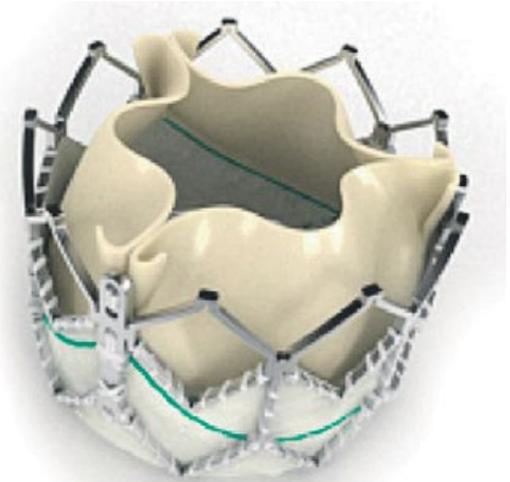


Figure 1a: SAPIEN XT valve – Cobalt-chromium frame onto which is sewn valve leaflets made from bovine pericardial tissue.

original shape as it is deployed from the delivery catheter at the aortic annulus. It also anchors by the calcium at the native aortic leaflets and annulus. The delivery catheter and sheath are then removed by percutaneous closure devices without the need for vascular cutdowns and arteriotomy repair

The transfemoral procedure is a truly percutaneous procedure. Commonly, it is performed under general anaesthesia, which allows the use of transoesophageal echocardiogram to guide positioning of the valve. However it can, and is, increasingly being done under local anaesthesia, with valve positioning guided by fluoroscopy (X-ray) only.

In 10-20 per cent of patients, the transfemoral approach is not technically feasible due to factors such as the size of iliac-femoral vessels not accommodating the large calibre sheath. Options for these patients include tran-subclavian (through a cut-down to the subclavian artery), transaortic (through a puncture at the ascending aorta via a hemisternotomy

COVER STORY

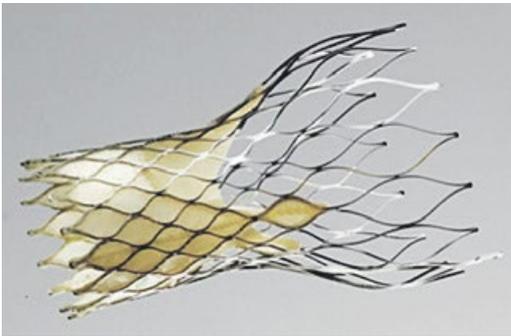


Figure 1b: CoreValve – Nickel-titanium frame onto which is sewn valve leaflets made from porcine tissue.

or thoracotomy) or transapical approach (through a direct puncture in the left ventricular apex via a thoracotomy). These are hybrid procedures performed by a joint team of interventional cardiologists and cardiac surgeons.

OUTCOMES

Currently TAVIs are typically performed in high-risk patients. In these patient cohorts, the 30-day mortality in most contemporary series is 3-7 per cent, stroke 3-5 per cent, major vascular complications of 10 per cent, bleeding 10-15 per cent. In these typically elderly patients, one-year mortality ranges from 15-30 per cent.

In one randomised controlled study, TAVI has an absolute reduction in one-year mortality of 20 per cent compared to medical therapy for aortic stenosis (30.7 per cent vs. 50.7 per cent).

Two randomised trials have compared TAVI to surgical valve replacement in high risk patients, with one showing similar 30-day and one-year mortality (24.2 per cent vs. 26.8 per cent) while another demonstrating lower one year mortality compared to surgery (14.2 per cent vs. 19.1 per cent). TAVI is associated with a higher risk of vascular complications but lower risk of bleeding and renal dysfunction. There is significantly shorter hospitalisation, with average lengths of stay of three to seven days.

There are a number of limitations to TAVI that need to be addressed. Firstly, the durability of transcatheter valves is unknown due to its novel nature, although the most recent data

suggest similar functionality to surgical bioprosthesis at least to five years.

Second is the issue of paravalvular regurgitation, which is the most significant ‘Achilles’ heel’ of the technology. Due to the fact that the transcatheter valve is not sutured onto the aortic annulus (unlike surgical

valve), regurgitation around the transcatheter valve prosthesis occurs. With the current generation of valves, mild regurgitation or worse occurs in over 50 per cent cases. Paravalvular regurgitation is associated with worse outcomes, including an almost doubling of one-year mortality.

Finally improvements need to be made to reduce the stroke and vascular complication risks, mainly by reducing the profile of the delivery systems.

IS TAVI FOR EVERYONE? – PATIENT SELECTION AND ASSESSMENT

Due to the above limitations, current guidelines suggest the role of TAVI is in treatment of patients with symptomatic severe AS at high risk for cardiac surgery. Currently it is not recommended to generalise to low or even moderate surgical risk patients, although studies are underway evaluating its utility in a “moderate risk” cohort. It is recommended that the patients be assessed by a ‘Heart Team’ comprising of cardiologists, cardiac surgeons, imaging specialist,

and other multidisciplinary professionals.

In Western Australia, this procedure and service is currently offered by the High Risk Aortic Stenosis Service, which is a state program based at Fiona Stanley Hospital (formerly at Royal Perth Hospital). It offers to review patients with symptomatic severe AS in whom the referrers feel may be at high risk for surgery due to advanced age or co-morbidities. The patients are reviewed by both cardiologists and cardiac surgeons. They are assessed for their cardiac and general co-morbidities which affect the risk of TAVI, their surgical risks, and their overall prognosis. Due to the typical advanced age, there is a formal frailty assessment. They are also evaluated for technical feasibility of the TAVI procedure, including size of the iliac-femoral vessels (currently a minimum diameter of 6mm is needed), anatomy of the aortic annulus and aortic root, and the shape of the aorta.

Typically the investigations the patients would undergo include an echocardiography, coronary angiography and CT aortography. The Heart Team will then make a recommendation to offer surgical valve replacement, TAVI or medical therapy.

Of note, currently the only approved transcatheter valve by the TGA in Australia is the first generation SAPIEN valve which utilises a 22-24Fr sheath. There are no re-imburement codes yet. Most cases in Australia,

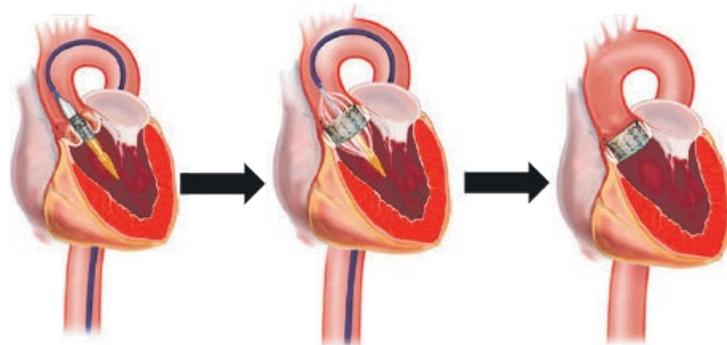


Figure 2: Transpercutaneous TAVI using Edwards SAPIEN XT Valve – The transcatheter valve is crimped onto a balloon catheter. It is passed to the aortic annulus via a femoral arterial puncture. The balloon is inflated deploying the valve. The balloon catheter is then removed leaving behind the transcatheter valve held by the native diseased valve. The new valve leaflets function as the new aortic valve.

Continued on page 29



Continued from page 27

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however, use second or third generation devices under a Special Access Scheme or as part of a clinical trial.

CONCLUSION AND THE FUTURE...

TAVI represents one of the most exciting developments in interventional cardiology, offering a viable alternative to surgery in severe AS. Limitations such as paravalvular regurgitation restrict its use in high-risk patients currently.

There are newer valve systems that

attempt to address the limitations. The sheath sizes for transfemoral access are now lowered to 14Fr. Paravalvular regurgitation is reduced by innovations such as a “skirt” around the valve inflow. Most new generation valves are also repositionable. There is also improved understanding of imaging and valve type / size selection to reduce regurgitation.

With these improvements, together with more proof of durability, it may be appropriate to expand the indication

to patients at lower risk. Finally other niche indications are also emerging such as ‘valve-in-valve’ treatment of degenerating bioprosthetic valves (i.e. position the transcatheter valve within a degenerating bioprosthetic valve as an alternative to redo cardiac surgery). ■

References will be available on request.

For referral to the High Risk Aortic Stenosis Service, please fax referral to (08) 9463 6260 or contact Dr Yong on 0408 004 282.