Percutaneous aortic valve replacement

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New technology – percutaneous aortic valve replacement – offers significant benefit for selected high risk elderly patients who have been rejected for surgical aortic valve replacement. In the past, balloon dilatation of stenosed aortic valves was largely abandoned because benefits were relatively short lived – about 50% developed significant re-narrowing within six months. (This contrasts with mitral valve stenosis, where percutaneous balloon mitral valvotomy produces excellent medium term results in selected patients.) Currently percutaneous aortic valve replacement, thanks to advances in device design, has reached a stage where it is being offered to high risk surgical candidates.

With our ageing population, a significant number of patients have symptomatic severe aortic stenosis (4% of those aged over 65). This is an age-related degenerative process rather than secondary to rheumatic fever. For various reasons, many patients are not suitable candidates for surgical aortic valve replacement, yet the mortality at one year for patients with untreated symptomatic severe aortic valve stenosis is high (62% in one series).

Technical details

The first aortic valve stenting procedure was performed in 2002. Two catheter based devices are currently being used in Australia (and others are being developed). One current device is a self-expanding aortic valve prosthesis (Core Valve™) while the other is a balloon expandable stent (Edwards Sapien™). The bioprostheses are housed in a collapsed form for percutaneous delivery and are implanted within the diseased aortic valve. Both devices are essentially stents with a valve fashioned in the centre of a mesh tube. The frame of the Core Valve™ prosthesis is made of Nitinol (a nickel /titanium alloy which can resume its original shape after distortion) and the Edwards Sapien™ of stainless steel; porcine (Core Valve) or Bovine (Edwards Sapien) pericardium is used to form a tri-leaflet valve that is sutured to the frame.

A balloon catheter is introduced into a femoral artery using a percutaneous technique and passed retrograde to dilate the stenosed aortic valve. The prosthetic device is then loaded into a catheter delivery sheath and introduced the same way.

A temporary transvenous pacing wire is used to pace the right ventricle at 200 beats per minute to effectively produce cardiac standstill for a few seconds, which allows precise positioning of the prosthesis.

The valve is deployed using fluoroscopy, with the correct position being determined by markers on the prosthesis located in relation to the calcification on the native aortic valve leaflets. With the self expanding prosthesis, the position of the device can be adjusted as it is being deployed. With the balloon expandable valve this is not possible. Problems with inappropriate positioning of the prosthesis are uncommon after appropriate training. Sometimes the valve prosthesis can be retrieved and repositioned but on occasion a second prosthesis has had to be deployed.

With the self expanding prosthesis, the native aortic valve leaflets are compressed against the aortic wall. Although the origins of the coronary arteries are covered by the metallic mesh of the stent, coronary flow is not compromised. With the balloon expandable valve, correct sizing is essential as coronary flow can be compromised if the device obstructs the coronary ostia. The stents will not move after deployment if they have been correctly sized because the radial force holds them firmly in position.

Implantation time is currently 50-110 minutes and can be performed under local anaesthesia. Warfarin is not given but clopidogrel and aspirin are recommended from one to six months post procedure, followed by aspirin alone.

Patient selection

At present, the procedure is being limited to highly selected high risk patients who have been rejected for surgical aortic valve replacement because of the high estimated peri-operative mortality (which can approach 50%). Not all elderly high risk patients are suitable for the percutaneous procedure via the femoral artery: peripheral vascular disease, abdominal aortic aneurysm or a tortuous aortic arch are some of the causes for patient rejection. These patients may be able to have the device deployed using a cut-down on the subclavian artery or by direct puncture of the left ventricular apex after a mini thoracotomy.

Outcomes

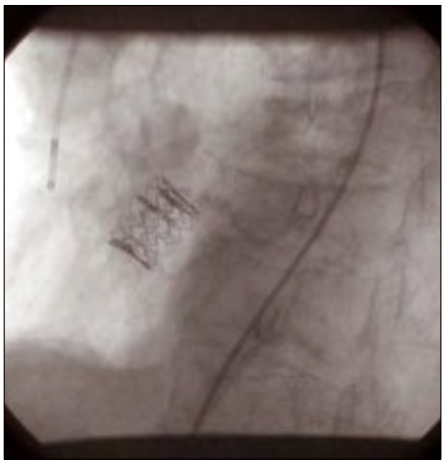
Aortic valve stenting can be performed safely in selected individuals and it results in an improved quality of life and decreased hospital admission. In one series using the Core Valve™ the survival at one year was 74% (non-randomised), with most deaths related to co-morbidities rather than the procedure. This compares favourably with the 38% survival at one year for untreated patients.

Important problems related to the procedure are access site complications (e.g. bleeding or iliac artery dissection which may require surgical repair), the need for a permanent pacemaker, and stroke. Results from the 1,243 patients in the 18F ReValving post marketing registry showed an increase in procedural success from 90 to 98%, with procedural times cut in half. Major complications, such as aortic dissection, major bleeding, cardiac tamponade, conversion to surgery and access site complication rates have also declined dramatically (~2% and lower). Thirty day mortality of 14-15% in earlier studies has reduced to 6.7%, and stroke rates have decreased from 17.3% to 1.4% in the latest series. At the time of hospital discharge most patients in the latest series had no or minimal aortic regurgitation and improved symptoms. A permanent pacemaker was required in 12.2% (not unusual, because the conducting system runs close by the aortic valve). If the device is placed too low in the left ventricular outflow tract it can interfere with the bundle of His and the valve needs to be positioned high enough in the outflow tract to avoid disturbing atrio-ventricular conduction.

Other considerations

The devices cost about A$25,000. In addition to a significant improvement in a patient's quality of life and decreased mortality, percutaneous aortic valve replacement has been shown to result in decreased hospital admissions. Currently, one day in a public hospital in WA costs approximately $1,500. ■

The deployable Edwards SAPIEN™ transcatheter heart valve (THV)



Lateral radiographic view of the Edwards SAPIEN THV, after deployment.