Percutaneous Aortic Valve Replacement

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CLINICAL POINTS

Aortic valve disease is the 3rd most common cause of cardiovascular disease; however, up to 1/3 of patients are unfit for conventional aortic valve replacement surgery.

Percutaneous aortic valve replacement is a new, less invasive solution for such patients, and possibly for all patients in the future.

Various techniques for percutaneous implantation of prosthetic valves via catheter are being developed and tested.

More high quality studies are needed to confirm the efficacy of PAVR before its use can become a widespread reality.

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Abstract

Aortic valve disease causes significant morbidity and mortality; however, up to one-third of patients are unfit for conventional aortic valve replacement surgery. A new, less invasive technique is percutaneous aortic valve replacement (PAVR). Currently there are two main devices in use for PAVR: CoreValve™ and Edwards SAPIEN™ devices. Both have bioprosthetic valves attached to a stent which is implanted via a catheter transvenously or transarterially. PAVR would be of most benefit to patients who are deemed too high risk for conventional surgery due to co-morbid conditions or advanced age. In the future, it is likely that PAVR will become more common for all patients. However, the efficacy of this treatment has yet to be proven with high quality studies.

Introduction

Aortic valve disease is the third most common cause of cardiovascular disease and is responsible for over 25,000 deaths annually in the US[1,2]. Conventional aortic valve replacement surgery is an effective treatment but is an invasive and expensive operation involving open heart surgery. It is associated with difficulties related to postoperative recovery, chronic anti-coagulation, and late failure of bioprosthetic valves. Procedural morbidity and mortality is significant and may be unacceptably high in a proportion of patients[3].

The presence of co-morbid conditions and excessive risk factors are important in determining the feasibility of surgery. High-risk patients include those with left ventricular failure, coronary artery disease, prior bypass graft surgery, chronic obstructive pulmonary disease, and/or advanced age. In such patient groups, the operative mortality may be as high as 50%[4-6]. Therefore, despite the proven benefits of traditional aortic valve replacement, there are a large number of high-risk patients who do not undergo surgery[7-12].

It has been estimated that a third of patients with a single diseased valve and Heart Failure (New York Heart Association functional class III/IV) were refused conventional surgery by the surgical team[13]. This was reportedly due to associated co-morbid conditions and short life expectancy. In the West, aortic stenosis is mainly due to degenerative changes[14]. This unfortunately means that the typical patient is elderly with multiple co-morbidities, such as cardiovascular or respiratory disease. Since there will be an increase in the elderly population, it is expected that the number of patients requiring valve replacement who are unfit for conventional surgery will rise. Therefore, there is a great need for less invasive therapeutic solutions. Percutaneous valve replacement may be the new treatment option, in particular for those with high surgical risk, but possibly for all patients[15,16].

The purpose of this article is firstly to give a brief summary of the PAVR procedure, including the valve devices currently available, the various percutaneous approaches used for their implantation and the complications of such procedures. Results of studies that investigate the effectiveness of PAVR will also be discussed and the viability of this procedure in the future will be addressed.

Background

In 1992, percutaneous aortic valve replacement (PAVR), using stent-based prostheses, was first proposed[17]. A stent is a collapsible mesh tube, formed from metal wire, which can be expanded and used to prop open an artery in treating heart disease. It was not until 2002 however that the first percutaneous aortic valve implantation was successfully completely by Alain Cribier in Charles Nicolle Hospital, Rouen, France[18]. In recent years, the percutaneous implantation of bioprosthetic heart valves has become a promising new option. The procedure has been performed in various centers worldwide with increasing success[15,19-26].

Procedure

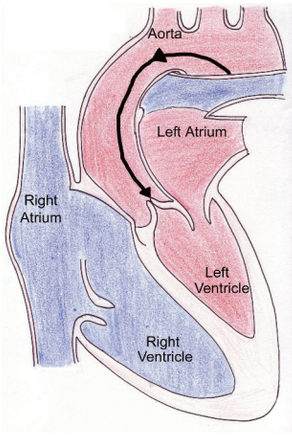
The procedure can usually be performed in a catheterization laboratory. The patient is under general anaesthetic although the operation can also be carried out using local anaesthetic and sedatives. Two prosthetic devices are currently available: the CoreValve and the Edwards SAPIEN. Before either of the valves is implanted, balloon valvuloplasty can be performed[27,28].

A deflated balloon at the tip of a catheter is inserted through the blood vessels. The balloon is then inflated to stretch the narrowed aortic valve before implanting the replacement valve. Bioprosthetic valve devices can be implanted using a retrograde, antegrade or trans-apical approach[29]. With both the retrograde and antegrade approaches, extracorporeal circulatory support, i.e. cardiopulmonary bypass, is used.

Retrograde Approach

In the retrograde or trans-arterial approach, a percutaneous incision is made to access the common femoral artery, common iliac artery, or rarely, the subclavian artery[30]. Using a stiff guidewire, the prosthesis is passed through the aorta to the aortic valve (see Fig. 1). The device is implanted within the aortic annulus, which is a fibrous structure that attaches the root of the aorta to the left ventricle[26]. Transoesophageal echocardiography, fluoroscopy and aortography can be used for guidance and to confirm that the valve has been positioned correctly before the prosthesis is expanded (by balloon for the Edwards Sapien, or by self-expansion once the sheath from CoreValve is removed)[31].

Paravalvular regurgitation, in which there is a backflow of blood, can be checked for using aortography and transoesophageal echocardiography. Depending on the grade of aortic regurgitation and position of the device, further dilatation of the CoreValve prosthesis can be performed, even after it has been implanted. Closure of any area ➔



▲ ***Fig. 1.Retrograde approach.***

contributing to paravalvular leak is done either surgically or, more recently, with a percutaneous suture device[32].
A percutaneous suture device consists of a needle that can be inserted percutaneously and suture tissue portions within a body cavity. The patient recovers from general anaesthesia in the intensive care unit.

Antegrade Approach
An alternative to the retrograde approach is the antegrade or trans-venous approach (see Fig. 2)[29]. The femoral vein is accessed percutaneously, and the native valve is approached from the inferior vena cava and the right atrium. A puncture is made in the inter-atrial septum, and a wire is subsequently passed through the heart into the aorta and snared by another wire from the femoral artery in order to form a loop. This is done in order to provide support in the introduction of the necessary catheters. The bioprosthesis is introduced through the femoral vein, inferior vena cava, right atrium, trans-septally into the left atrium, and finally through the mitral valve into the left ventricle. The antegrade approach is technically more difficult than the retrograde approach[33].

Trans-apical approach
A more recent method is the trans-apical approach[29]. The prosthesis and delivery catheter are introduced into the left ventricle via a mini-thoracotomy. Fluoroscopic guidance is used to help position the new valve. Cardiopulmonary bypass is not used. The trans-apical approach removes the problem of narrow or calcified femoral vessels. Animal experiments showed the viability of this technique and it has been used successfully in patients[34].

Complications
Complications of percutaneous aortic valve replacement may be associated with the device itself or the technique of implantation. Complications relating to the antegrade approach include mitral valve leaflet trauma, while the retrograde approach is mainly associated with vascular complications. Since the trans-apical approach is a relatively new technique, specific complications of this procedure remain to be seen[35].
Embolization of the device, paravalvular aortic regurgitation and possibly coronary ostia obstruction are associated with both antegrade and retrograde techniques[36]. Paravalvular aortic regurgitation is an important complication seen in many patients. Heavy calcification of the aortic cusps can prevent the stent from opposing the native commissures properly. Aortic regurgitation has been reported in up to one-third of patients. Severe acute aortic regurgitation may not be well tolerated and may cause or worsen heart failure in patients.
In addition, since balloon aortic valvuloplasty is performed before implantation of the device, this can be the cause of some of the related complications, such as stroke and can contribute to morbidity[36]. The antegrade approach is technically more challenging, and it is possible for the mitral valve to become tethered in the process, resulting in trauma to the mitral valve. Most patients are already in the high-risk category and are unable to tolerate acute severe mitral regurgitation. Rapid decompensation can ensue, resulting in haemodynamic collapse. It is also possible for the guidewire to lacerate the mitral leaflet, which can lead to permanent mitral regurgitation, with death from cardiogenic shock[37].

The retrograde approach is expected to become the standard practice for a variety of reasons. It is similar to the technique used for retrograde balloon aortic valvuloplasty and is less technically demanding. Also, it does not require trans-septal puncture. Unlike the antegrade approach, there is no risk of a mitral leaflet complication.

However, in patients with narrow, calcified, stenotic or tortuous ilio-femoral vessels, the retrograde approach is more difficult or may be impossible. In such patients, there is an increased risk of vessel trauma and transection and atheroembolism. As a result, the retrograde approach is not used in patients with arteries less than 8 mm in diameter or calcified arteries. For such patients, the antegrade approach is favourable[38-41].

Currently there is insufficient evidence and use of the trans-apical approach to justify regular use of this technique.

Bioprosthetic valve devices

Currently the two main devices available and in use in Europe are the CoreValve™ device and the Edwards SAPIEN™ (formerly known as the Cribier-Edwards) device[42]. Both have received the CE Mark, indicating that the devices have conformed to the essential health and safety requirements set out in European Directives.
The CoreValve (CoreValve Inc, Irvine, CA and Paris, France) is a self-expanding aortic valve prosthesis[43]. It is a porcine pericardial tissue valve with three leaflets sutured to an approximately 50 mm long self-expanding nitinol stent. The stent has a tubular 'hour glass' shape and can be deployed in the aortic root. The nitinol is compliant and soft at low temperature, which allows compression within a restraining sheath until its release. It assumes its predetermined shape without a need for dilation by a balloon. This has the advantage of allowing the delivery system to have a smaller diameter[44].
On the other hand, the Edwards SAPIEN prosthesis, produced by Edwards Lifesciences has a straight-tube steel stent that is 14-16 mm long. The leaflet cusps of the SAPIEN prosthesis are constructed from bovine pericardial tissue material. A balloon is used to inflate and deploy the prosthetic valve[43].

Unlike the CoreValve prosthesis, it can only be deployed within the aortic annulus. It is positioned below the coronary ostia. Sizes come in diameters of 23 and 26 mm, and a 29 mm prosthesis is currently being developed. 22F and 24F sheath diameters for trans-femoral implantation are currently available, with smaller versions soon to be on offer.

Work is currently being done to develop improved valve designs[45]. New valves that have been implanted, or will soon be, include the Direct Flow, Panigua, 3F, Sadra and AorTx. Qualities being targeted to improve prosthetic devices include durability, retrievability and paravalvular sealing. Efforts are also being made to develop devices that are easier to use and position. It has yet to be seen how successful they will be.

Results of PAVR to date

In 2006, Cribier[46] et al gave a midterm follow-up of 33 patients who underwent percutaneous valve replacement surgery. In 22 of 26 patients, the antegrade method was used successfully. Of the other four patients, two could not hemodynamically tolerate the guidewire across the mitral valve, and in the other two patients, the prosthetic valve migrated immediately after implantation. The retrograde approach was used in 7 cases, with 4 valves ➔

successfully implanted. Two were unsuccessful because of extensively calcified vessels, and in the other patient, the aortic valve could not be reached because the catheter was too short.

Improvements in valve performance were noted. On average the trans-valvular gradient was reduced from 37 to 9 mm Hg. The gradient represents the degree of aortic stenosis and is calculated using Bernoulli's equation:

Gradient = 4(velocity)² mmHg

where velocity is the flow velocity through the valve measured by echocardiography. There should be no gradient in a normal aortic valve, and a gradient of more than 25 mm Hg indicates moderate stenosis. The valve area, which should normally be greater than 2 square centimeters increased from 0.60 to 1.70 square centimeters, and the left ventricular function improved from 45% to 53%. Post-PAVR paravalvular aortic regurgitation varied from grade 0 to grade 3 in five patients. Aortic regurgitation is graded using a combination of 2D echocardiography, color-flow imaging, pulsed and CW Doppler techniques[47].

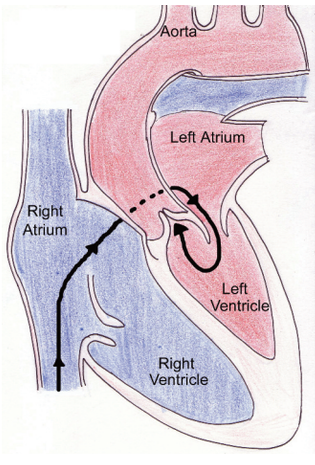
26% of patients at 30 days had complications of stroke, pericardial tamponade, arrhythmia or urosepsis. None of the complications were related to the device but there was one unexplained death. Provided a patient survived their co-morbid conditions, long-standing clinical improvement was observed in all. During follow-up, no mitral regurgitation, coronary occlusion, prosthesis dysfunction or valve migration was reported.

Webb et al used only the retrograde method[26]. Implantation of the bioprosthesis was successful in 14 of 18 patients. The valve area increased from 0.6 to 1.6 square centimeters. 16 of the patients were alive on follow-up at 75 ± 55 days.

Grube et al implanted the CoreValve in 21 of 25 patients (25). Death occurred in 20 % (5 patients), and overall, 8 patients had major complications within the hospital. 18 patients were discharged with no complications reported at 30 days. In this study there was no change in the mean aortic regurgitation grade but the aortic valve gradient was reduced.

Another smaller study by Berry et al used the 21F CoreValve device in 11 high-risk patients[32]. They have reported a 30-day mortality of 18%.

A post-marketing registry for the CoreValve18F showed a 98% success rate. This included 1243 patients from more than 100 centres in 18 countries with an average EUROSCORE (European System for Cardiac Operative Risk Evaluation) of 22%. Major complications, such as cardiac tamponade, aortic dissection, severe bleeding or conversion to open heart surgery were 2% or less. This registry reported a 6.7% rate of 30-day mortality and a 70% one-year survival rate. There was a 1.4% rate of stroke, and 12.2% rate of pacemaker implantation also reported[48].



▲ ***Fig. 2. Antegrade approach.***

Conclusion

At present it is difficult to determine the clinical value of percutaneous aortic valve replacement. Randomised controlled trials are needed in order to compare PAVR with conventional aortic valve replacement.

One such trial currently underway is the PARTNER-US trial (Placement of AoRticTraNscathetER Valves Trial). In this study, percutaneous balloon expandable valve implantation and surgical valve replacement in high-risk patients are being compared with medical treatment in patients with contraindications to surgery. The trial is enrolling high-risk patients with severe symptomatic aortic stenosis, who are then randomly assigned treatment. They are either managed with conventional surgical or medical treatment, or are implanted with the Edwards SAPIEN device in this trial. It is hoped that the safety and effectiveness of the device and delivery systems will be determined by this trial, which is due to be completed in September 2014.

Until the results of this and other such studies are available, PAVR cannot become the gold standard treatment. At present, the excellent long-term results of conventional aortic valve replacement cannot be disputed. Uncertainty remains about outcomes, implications, durability, and the appropriate role for this new therapy. Patients that are not in the high-risk category should still undergo the standard surgery.

However, it is probable that percutaneous valve implantation will become a more widely available and accepted therapeutic option. In the future, it looks likely that the surgical treatment for aortic valve disease, particularly for high-risk patients but perhaps for all patients, will change to less invasive percutaneous techniques. ■

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