Percutaneous Aortic Valve Replacement

By Jacob Green, MD; Vasilis Babaliaros, MD; and Peter Block, MD

Aortic stenosis is the most common valvular heart lesion in the US and Europe. The vast majority of these cases are degenerative in etiology. There is no question that surgical aortic valve replacement remains the treatment of choice for degenerative, symptomatic aortic stenosis, with low operative risk and excellent long-term improvement in symptoms and survival. However, advanced age, severe left ventricular dysfunction, and comorbid conditions substantially increase the risk of this operation. Approximately one third of patients with symptomatic aortic stenosis and isolated valve disease are declined for surgery because of associated comorbid conditions and a short life expectancy. Although this reluctance to operate on high-risk patients is not shared by all institutions, it is a reality that is faced not infrequently by patients and their treating cardiologists. Furthermore, patient preference to avoid open-heart surgery, particularly among elderly patients, also precludes surgical aortic valve replacement, in many cases. These realities have resulted in the natural expansion of the field of interventional cardiology to find innovative percutaneous means of treating this condition.

Early Experience with Percutaneous Valve Replacement

The first attempts to percutaneously treat aortic valve disease began in 1965 when Davies described an experimental device for relieving aortic insufficiency in dogs. Since that time, a number of researchers have continued with animal experiments, with promising results. The earliest attempts in humans began in 1985 when Alain Cribier, MD, introduced balloon aortic valvuloplasty to treat nonoperable candidates with severe aortic stenosis. Despite exciting initial results, this procedure was largely abandoned because the benefits were short-lived. Ultimately, a balloon-expandable, stent-mounted prosthetic valve implanted within the native stenotic valve solved the problem of restenosis. Since the first human implantation in the aortic position by Cribier et al, three phase 1 trials in Europe, Canada, and the US have been completed, proving the feasibility of this technique and further developing the technology.
LESSONS LEARNED AND PRODUCT DEVELOPMENT

Steep Learning Curve: The French Experience

There were obvious limitations with the first-generation valve device (Edwards Lifesciences) and technique. First, the percutaneous heart valve (PHV), which is a stainless steel stent frame with a sutured pericardial valve (Figure 1), was only produced in one size (23 mm diameter). This valve was satisfactory for patients with a 20-mm aortic annulus or smaller but, in those with a larger annulus, the incidence of paravalvular leak was significant (17 of 27 patients with grade 2 or 3 paravalvular leak), and immediate embolization also occurred (two of 27 patients). Second, the original implantation technique was antegrade transseptal (Figure 2A), which was elegant but very complicated and unable to be generalized to other centers. Finally, the optimal placement of the PHV in relation to the level of the native valve leaflets was not initially known. Implantation of the PHV too high resulted in valve embolization. Low implantation prevented adequate sealing of the annulus, precipitating significant paravalvular leak. Despite these adversities, 80% of patients were implanted successfully with no coronary occlusion, secondary migration, or prosthesis dysfunction. Immediate hemodynamic improvement was seen in all patients, and the remaining two patients who survived their comorbidities reached almost 4 years with normal PHV function and continued improved quality of life.15,16

Current Technique and Balloon-Expandable Device

The currently available PHV from Edwards Lifesciences is a bovine pericardial valve sutured to a balloon-expandable stent frame that is either 23 mm or 26 mm in diameter. The skirt of the valve has been increased to allow for lower implantation of the PHV, which is exclusively implanted via a retrograde technique (22-F or 24-F sheath in the femoroiliac arteries) (Figure 2B). A deflectable catheter (Flex Cath, Edwards Lifesciences) can steer the PHV through tortuous aortic anatomy and across the aortic valve without becoming trapped in a commissure. In patients without adequate access (femoral and iliac arteries smaller than 7 mm or 8 mm for a 22-F and 24-F sheath, respectively), a small lateral thoracotomy can be made, and the device can be implanted transapically through the left ventricle. All devices, regardless of access site, are deployed during rapid, right ventricular pacing at 180 bpm to 220 bpm via a temporary pacing lead. Native aortic valves are always predilated with use of a balloon aortic valvuloplasty catheter.

The Vancouver Experience

Although PHV implantation began in France, the technique and newer technology have also been refined in Vancouver, Canada. Currently, more than 100 PHV implantations have been performed there since 2004, and some of the initial results have been published. In the early series, Webb described 14 successful implantations out of 18 attempts, with hemodynamic improvements similar to those observed in Cribier’s series.17 Unlike the French experience, these valves were 23 mm and 26 mm in diameter and were exclusively placed via a retrograde transfemoral approach, thereby demonstrating the feasibility of this less technically challenging technique. Valve areas increased from ≤0.7 cm² to 1.6 cm², with grade 2 paravalvular leak seen in patients implanted with a 23-mm PHV and grade 1 paravalvular leak observed in patients implanted with a 26-mm PHV. Only two patients had vascular complications, including dissection and rupture of the iliac artery. Historically, the prevalence of peripheral vascular disease in patients to whom the technology is most applicable had seemed prohibitive to placement of the large femoral artery sheath and retrograde passage of the balloon-mounted stented valve. The Vancouver experience highlighted the importance of patient selection with careful screening of the femoral and iliac artery size by CT angiography or MR angiography. Also, the importance of oversizing the annulus with the PHV to decrease paravalvular leak and valve embolization was emphasized. In the cumulative

Figure 2. Schematic diagram of the antegrade transseptal approach. The PHV is introduced over a guidewire from the femoral vein and enters the left heart through an atrial septostomy, reaching the aortic valve after making a loop in the left ventricle (A). Schematic diagram of the retrograde approach. The PHV is introduced over a guidewire from the femoral artery and reaches the aortic valve via the ascending aorta (B).
experience, the current mortality risk with the procedure is approximately 5% to 10%, despite a predicted surgical mortality >25%.

Transapical Aortic Valve Implantation

The limitations of the transfemoral approach secondary to arterial access have been addressed by a transapical approach. The initial transapical PHV implantations were done in Leipzig, Germany under general anesthesia and with transesophageal echocardiographic/fluoroscopic guidance.18 A 5-cm to 9-cm, lateral thoracotomy over the apex of the heart allows introduction of the arterial sheath directly into the ventricular apex. The experience in seven patients receiving a transapical 26-mm Cribier-Edwards valve has been reported.19 Again, the results were promising, with 100% procedural success, marked reduction in mean valve gradients, and improvement in valve area. One patient died at 12 days secondary to a complicated postoperative course (pneumonia) despite good valve function. Four of the six patients were alive with markedly improved clinical status at 6 months, and two patients died from noncardiac causes during the follow-up period.20 Since then, more than 100 patients have undergone implantation by this method. The results of this series are awaited with anticipation and should be published in the near future.

THE COREVALVE EXPERIENCE

The CoreValve device is a porcine pericardial tissue valve, mounted in a self-expanding nitinol stent (Figure 3A). The high radial force at the lower pole of the device pushes aside the calcified native leaflets, while the upper pole expands to anchor in the ascending aorta (Figure 3B). This self-expanding design is intended to conform to the dimensions of the aortic valve and aortic root and has the theoretical advantage of less paravalvular leak and decreased risk of dislocation due to its self-positioning properties. The 21-mm inner diameter valve mounted on a 50-mm-long nitinol metal stent design is intended for treatment of aortic stenosis and aortic regurgitation. Results of the largest published series to date, using first- and second-generation CoreValve designs, were similar to those seen with balloon-expandable valves, including reduction in mean transvalvular gradient from 45 mm Hg to 12 mm Hg, with sustained clinical and echocardiographic improvement at 30 days.21 All devices were placed via a retrograde approach under general anesthesia and with extracorporeal circulatory support. As predicted, severe paravalvular aortic regurgitation was not seen in successful implantations, and 81% of patients had only grade 0-1 paravalvular leak. There was no case of secondary valve migration, although two patients had a device placed too high, requiring surgical removal and conventional aortic valve replacement. Complications were not uncommon in the early experience, with periprocedural major adverse cardiovascular and cerebral events occurring in 32% of patients, including one death due to tamponade, one stroke at 11 days after the procedure, one case of disseminated intravascular coagulation, and one death due to progressive hemodynamic failure despite good valve function. Successful device implantation was achieved in 88% of the 25 enrolled patients. Since this report, procedural and 30-day mortality has improved with experience and newer-generation CoreValve devices (from 24-F to 18-F delivery systems). More than 150 implantations have been performed, mostly in Europe, and a US feasibility trial will soon start.

FUTURE DIRECTION AND CONCLUSIONS

More than 10 other companies have started implantations of their aortic devices in animal models and, recently, in humans. These third-generation valves will have the advantage of being retrievable and repositionable, with the added benefit of a lower-profile design for easier delivery and larger patient applicability. With ongoing technical refinements and increasing experience from large randomized trials, percutaneous aortic valve implantation should become an important tool for the treatment of high-risk, nonoperable patients with aortic stenosis. Expansion of this technology to a broader range of lower-risk patients will depend on outcomes from upcoming trials comparing it to surgical aortic valve replacement. ■

(Continued on page 32)
(Continued from page 31)

Jacob Green, MD, is from the Andreas Gruentzig Cardiovascular Center, Emory University, Atlanta, Georgia. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Green may be reached at jgreen@emory.edu.

Vasilis Babaliaros, MD, is from the Andreas Gruentzig Cardiovascular Center, Emory University, Atlanta, Georgia. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Babaliaros may be reached at (404) 712-0131; vasilis.babaliaros@emoryhealthcare.org.

Peter Block, MD, is from the Andreas Gruentzig Cardiovascular Center, Emory University, Atlanta, Georgia. He has disclosed that he is an owner or a shareholder of CoreValve and Direct Flow. Dr. Block may be reached at (404) 778-3204; peter.block@emoryhealthcare.org.