Percutaneous Aortic Valve Replacement Will Become a Common Treatment for Aortic Valve Disease

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Percutaneous valve replacement is developing into an effective and reproducible therapy for aortic valve stenosis. Initial experience suggests that outcomes compare favorably with conventional valve surgery in selected patients with comorbidities, such as advanced age. Caution is prudent, however, in the future a more mature procedure might represent a viable alternative for a much broader range of patients. (J Am Coll Cardiol Intv 2008;1:122–6) © 2008 by the American College of Cardiology Foundation

The advent of percutaneous aortic valve replacement (PAVR) can be considered to have begun in 1992 when Andersen et al. (1) demonstrated the feasibility of intravascular implantation of a catheter-mounted valved stent in an animal model. Several groups pursued the goal of aortic valve implantation, but it was not until 10 years later that the first successful percutaneous valve implantation in a patient with aortic stenosis was reported by Cribier et al. (2). Despite initial stumbles, PAVR is becoming a clinical reality, with over 500 procedures performed to date and commercial release in many countries.

Why Percutaneous Valve Implantation?

Severe aortic stenosis is common and, when symptomatic, is associated with a predictably high mortality (3,4). Aortic valve surgery can be performed at very low risk with marked benefit in terms of survival and symptoms (4). However, the risk of mortality and morbidity with sternotomy, cardio- pulmonary bypass, aortotomy, and valve replacement is not always low, particularly in the elderly patient with comorbidities (4–6). Despite the potential benefit of valve replacement, many patients with aortic stenosis are not offered or do not accept surgical therapy (3,7).

Transcatheter Valves

The 2 most widely evaluated catheter implantable valves, the balloon-expandable Edwards SAPIEN valve (successor to the Cribier-Edwards valve; Edwards Lifesciences, Irvine, California) and the self-expanding CoreValve device (CoreValve Inc., Irvine, California), are shown in Figure 1. As the procedure has evolved, standard off-the-shelf balloon catheters have been replaced by more complex integrated valve and valve delivery catheter systems. Whereas first-generation delivery systems were large, requiring 24-F sheaths (external diameter 9 mm), newer systems are being progressively reduced in profile, moving toward the likely limits of current technology at around 16- to 20-F. Multiple other valves and delivery systems with potential advantages in terms of the ability to deliver, deploy, or reposition the prosthesis are under development or in early clinical evaluation (8,9). It will be important to assure that implant performance is not compromised in the quest for ease of implantation.

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The Procedure

The PAVR is typically performed in a cardiac catheterization laboratory or hybrid operating room. General anesthesia is optional. Femoral artery access and hemostasis might require cutdown but is increasingly accomplished with percutaneous closure (Fig. 2). Conventional balloon valvuloplasty is initially performed. The valved stent is typically introduced into a femoral sheath and passed through the aorta. Positioning of the prosthesis within the native valve is confirmed with fluoroscopy, aortography, and often transesophageal echocardiography. Burst pacing might be used to transiently reduce transvalvular flow during deployment of balloon-expandable valves. The valved stent is expanded within the native aortic valve, displacing and excluding the diseased leaflets and substituting a new functional valve in place of the old. Discharge occurs as early as day 2, although median discharge might average 5 days as a consequence of delayed mobilization and disposition of elderly patients (10).

Transapical Procedure

A discussion of percutaneous valve implantation would not be complete without acknowledging the open chest equivalent, which allows extension of the “transcatheter” technology to patients with vascular disease. This approach uses a mini-thoracotomy and needle puncture of the apical left ventricle without cardiopulmonary bypass (11,12). Reported experience is favorable but limited (13,14), although as of late 2007 approximately 200 transapical valve implantations have been performed worldwide.

Early Outcomes

Initial procedures were performed with a transvenous technique with puncture of the femoral vein and inter-atrial septum allowing antegrade access to the left heart and aortic valve (15,16). In a report of the initial 36, primarily transvenous, patients from France, valve implantation was successful in 75% (17). Although problematic, this early transvenous experience did document the feasibility of the procedure and the potential for durable benefit.

Subsequently we described a transarterial procedure using femoral arterial access, which seemed more reproducible and has supplanted the earlier transvenous procedure (18). Initial transarterial experience in “high-risk” or “inoperable” patients was favorable, with successful implantation increasing from 76% to 96% with experience (10). Intra-procedural mortality was low at 2%. Mortality at 30 days after the procedure was 12%, comparing favorably to a logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) (19) estimate of 28% in this high-risk group (Fig. 3). As the Vancouver transcatheter experience exceeds 150 patients, transarterial success rates continue to improve and 30-day mortality has fallen well into the single digits in high-risk patients (20). As of late 2007, approximately 300 PAVR procedures have been performed with balloon expandable valves. Early, as yet unpublished analysis of this global experience, including the multicenter REVIVE and REVIVE-II (21) trials, confirms similar outcomes.

Experience with the self-expanding CoreValve device demonstrates similar trends in outcomes. Grube et al. (22) reported a single-center, 25-patient experience in which valve implantation was successful in 84% of patients with an in-hospital mortality of 20% in a high-risk group. A later multicenter report described 86 cases using newer lower profile devices with valve implantation successful in 88% and a 30-day mortality falling to 12% (logistic EuroSCORE 22%) (23). As of late 2007, approximately 300

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**Figure 1. Transcatheter Valves**

(A) The balloon-expandable Edwards SAPIEN valve incorporates a stainless steel stent, bovine pericardial leaflets, and a fabric sealing cuff. (B) The self-expanding CoreValve device incorporates a nitinol (nickel titanium) alloy stent with leaflets and a sealing cuff constructed of porcine pericardial tissue.
CoreValve procedures have been performed. As yet unpublished, global analysis of 175 procedures using the newer generation devices demonstrate procedural success in 92% with a 30-day mortality of 15% (logistic EuroSCORE 24%).

**Valve Function**

In vitro and clinical evaluations of currently available transcatheter valves demonstrate excellent valve function (Fig. 4). Orifice areas are typically larger than comparable surgical prostheses, owing to the absence of a bulky sewing ring and the ability to implant oversized prostheses after balloon dilation. Echocardiographic evaluation of both currently available valves typically documents gradients of under 10 mm Hg and effective orifice areas of over $1.5 \text{ cm}^2$ (10).

Initial experience with transcatheter valves suggested that paravalvular regurgitation was often severe (2,17,24). With various modifications of the procedure, such severe leaks are infrequent. Although paravalvular regurgitation remains ubiquitous, such leaks are generally mild (10,25) and hemothysis has not been observed (26). For the most part clinical
Late Outcomes

Consequences are not apparent, although further improvements are certainly desirable (10,27).

In vitro valve testing predicts durability comparable to that seen with surgical bioprostheses. In vivo valve failure must be expected eventually, although this has not been reported with the currently available valves. Admittedly, follow-up of reasonable numbers of implants is limited to 2 years (10,20,23), with only a few patients followed out to 4 years. Importantly, early experience with implantation of transcatheter valves within failed surgically implanted bioprostheses sets the scene for a "valve in valve" procedure that might be, at least in a limited sense, repeatable when percutaneous valves do fail (28–30).

Complications of Percutaneous Valves

Of great concern is the possibility of arterial dissection or perforation while manipulating very large catheters through the vasculature (10,31). As with any procedure in a patient with aortic stenosis, myocardial ischemia and cardiogenic shock might occur (31). A unique concern with transcatheter valves is the possibility of coronary obstruction by the prosthetic or native valve, although this seems infrequent (18,23). As with aortic valve surgery, PAVR is associated with a finite risk of atrio-ventricular block and pacemaker dependence (32). Reported rates of stroke with transcatheter valve implantation vary from 3% to as high as 9% in 1 report (10,14,18,22,23,33). Hopefully these risks will diminish as the procedure improves and is applied to patients with fewer comorbidities.

Late Outcomes

Acute and sustained improvements in left ventricular systolic function, functional mitral insufficiency, and functional class have been demonstrated after PAVR (10,20,23,34). In our initial experience left ventricular ejection fraction increased from 53% to 57% and mitral insufficiency from grade 2 to grade 1 within days, and this improvement was sustained at 1 year (10). In the high-risk candidates currently undergoing these procedures, 1-year survival seems limited by comorbidities rather than valvular or coronary disease (10,14).

Which Patients Are Candidates?

In our experience most patients with aortic stenosis are, from a purely technical standpoint, candidates for PAVR. Nevertheless, conventional valve surgery remains the proven therapy of choice for the majority of patients with symptomatic aortic stenosis, at this time. Percutaneous aortic valve replacement should only be considered in patients in whom comorbidities greatly increase the risk of conventional surgery but have a lesser impact on the risk of a transcatheter procedure. To date PAVR has been performed only in patients at high surgical risk. Objective estimates of surgical mortality have been used to help define “high-risk” (35). A logistic EuroSCORE >20 or Society of Thoracic Surgeons (STS) score >10 might be of some value in decision-making (19).

The major specific contraindication to PAVR via the femoral artery is the presence of severe ilio-femoral stenosis (10). Some patients might have an aortic annulus that is too small or too large (current prostheses are suitable for an echocardiographic annulus diameter between 18 and 26 mm) (25). Others might have an unusually bulky valve at risk of obstructing a coronary ostium (18). Mitral insufficiency and non-revascularized coronary disease are not necessarily contraindications; both are often well-tolerated in elderly patients, once aortic stenosis is relieved (10). However severe left ventricular dysfunction, severe mitral valve disease or non-revascularized coronary disease can predispose to hemodynamic instability during PAVR.

Conclusions

Percutaneous aortic valve replacement offers the potential for significant benefit but is not without risk. Optimal outcomes will require cautious application, technological and procedural improvements, formal training, centers of expertise, further trials, and ongoing surveillance. Currently this procedure can be considered for symptomatic patients who are poor candidates for conventional surgery. A more mature procedure might soon offer a viable alternative to a much broader range of patients.

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