Valvular Heart Disease

Percutaneous Aortic Valve Implantation Retrograde From the Femoral Artery

John G. Webb, MD; Mann Chandavimol, MD; Christopher R. Thompson, MD; Donald R. Ricci, MD; Ronald G. Carere, MD; Brad I. Munt; Christopher E. Buller, MD; Sanjeevan Pasupati, MD; Samuel Lichtenstein, MD

Background—Percutaneous aortic valve implantation by an antegrade transvenous approach has been described but is problematic. Retrograde prosthetic aortic valve implantation via the femoral artery has potential advantages. Percutaneous prosthetic aortic valve implantation via the femoral arterial approach is described and the initial experience reported.

Methods and Results—The valve prosthesis is constructed from a stainless steel stent with an attached trileaflet equine pericardial valve and a fabric cuff. After routine aortic balloon valvuloplasty, a 22F or 24F sheath is advanced from the femoral artery to the aorta. A steerable, deflectable catheter facilitates manipulation of the prosthesis around the aortic arch and through the stenotic valve. Rapid ventricular pacing is used to reduce cardiac output while the delivery balloon is inflated to deploy the prosthesis within the annulus. Percutaneous aortic prosthetic valve implantation was attempted in 18 patients (aged 81 ± 6 years) in whom surgical risk was deemed excessive because of comorbidities. Iliac arterial injury, seen in the first 2 patients, did not recur after improvement in screening and access site management. Implantation was successful in 14 patients. After successful implantation, the aortic valve area increased from 0.6 ± 0.2 to 1.6 ± 0.4 cm². There were no inprocedural deaths. At follow-up of 75 ± 55 days, 16 patients (89%) remained alive.

Conclusions—This initial experience suggests that percutaneous transarterial aortic valve implantation is feasible in selected high-risk patients with satisfactory short-term outcomes. (Circulation. 2006;113:842-850.)

Key Words: aorta ■ stenosis ■ catheters ■ stents ■ valvuloplasty

Symptomatic aortic stenosis is an accepted indication for surgery, in which valve replacement can both reduce symptoms and extend life. Despite this, many patients with severe aortic stenosis do not undergo surgery because of excessive risk, advanced age, or preference. Prognosis with medical management is poor, and percutaneous alternatives to surgery have been limited to balloon valvuloplasty with palliation that is modest and short-lived.

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Percutaneous valve implantation has been under active investigation by a number of groups. Cribier et al recently described successful percutaneous aortic valve implantation using the antegrade, transvenous approach; however, the technical complexity and associated risks of the antegrade approach appear likely to limit its widespread application. Although a retrograde femoral arterial approach is an intuitive extension of aortic valvuloplasty technique, initial experiences were disappointing. Antegrade femoral access problems relate not only to positioning the prosthesis across the stenotic, calcified aortic valve but also to delivery of the large-profile device and sheath through frequently diseased and tortuous femoral and iliac arteries and the abdominal and thoracic aorta. We describe our experience with the development of this procedure and the techniques and equipment designed to allow percutaneous retrograde transarterial implantation of aortic prosthetic valves.

Methods

Patients

The procedure was approved by the Therapeutic Products Directorate, Department of Health and Welfare, Ottawa, Canada, for compassionate clinical use in patients unsuitable for surgery. Patients with severe symptomatic aortic stenosis were referred for a percutaneous procedure because of multiple comorbidities and excessive surgical risk. A team of senior cardiologists, cardiac surgeons, and nursing representatives formally reviewed patients with a consensus that patients did not have a reasonable surgical option. Patient preference alone for a percutaneous procedure was not considered adequate if surgery was an option. Informed consent was obtained. We reviewed our initial 6-month experience from January to July 2005 with this procedure.

Patients underwent transthoracic echocardiography, iliofemoral contrast angiography, and coronary angiography. Computed tomographic angiography was performed if arterial access was considered marginal. Clinical follow-up and echocardiograms were obtained.

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within 24 hours of the procedure and at 1, 6, and 12 months after the procedure.

Prosthetic Valve System
The Cribier valve (Edwards Lifesciences Inc) is constructed from a tubular, slotted, stainless steel stent with an attached equine pericardial trileaflet valve. A sewn fabric cuff covers the left ventricular portion of the prosthesis (Figure 1). Valves are supplied sterile in glutaraldehyde and require onsite preparation. A mechanical crimping device is used to attach the prosthesis onto a specially constructed valvuloplasty balloon catheter. For the transarterial approach, the occlusive fabric skirt must be mounted distally on the balloon catheter. The opposite orientation would be required for a transvenous antegrade approach.

The previously described stent has an expanded external diameter of 23 mm and measures 14.5 mm in height. In later patients, a new large-annulus valve became available, which measured 26 mm in diameter and 16 mm in height. The diameter of the aortic annulus was measured from the transthoracic echocardiographic parasternal long-axis view immediately below the insertion point of the valve leaflets. An annulus diameter of 18 to 22 mm was considered appropriate for a 23-mm-diameter prosthesis and 21 to 25 mm for a 26-mm prosthesis. Femoral arterial sheaths (Edwards Lifesciences Inc) had an internal diameter of 22F (8 mm external diameter) to accommodate the 23-mm prosthetic valve and 24F (9 mm external diameter) for the 26-mm valve. An iliofemoral arterial diameter of 8 mm was considered adequate for a 22F sheath and 9 mm for a 24F sheath, although short segments of noncalcified focal stenosis were not considered exclusions (Table 2). The working length of the hydrophilic sheath was increased from 18 cm early in the series to 25 cm in later patients.

A deflectable guiding catheter (Edwards Lifesciences Inc) was used to facilitate passage of the prosthesis through the arterial system and aortic valve. Active deflection is accomplished by rotation of an external handle. This guiding catheter has a diameter of 18F, although the distal tip expands to 22F to provide support for the crimped prosthesis (Figure 2). The prosthesis, balloon, and deflection catheter are introduced into the femoral sheath as a unit through a hemostatic loader catheter.

Procedure
Patients were premedicated with clopidogrel and aspirin and received vancomycin or cefazolin 1 g IV immediately before the procedure. The procedure was performed in a catheterization laboratory with operating room–like sterile precautions. Percutaneous sheaths were placed in both femoral arteries and 1 femoral vein. Heparin 50 U/kg IV was administered. Aortic root angiography was performed and displayed during the procedure to facilitate subsequent positioning of the prosthesis. Balloon valvuloplasty was performed in a standard manner with a balloon slightly smaller than the diameter of the planned prosthesis (Z-Med, Numed Inc).

After valvuloplasty, the femoral access site was sequentially dilated to allow introduction of the large sheath to a position beyond the iliac arteries into the aorta. The steerable deflection catheter was used to actively direct the prosthesis through the tortuous aorta. The left anterior oblique view was helpful to avoid foreshortening of the aortic arch (Figure 3). Further manipulation and axial support with

Figure 1. Cribier-Edwards percutaneous valve. An equine pericardial valve is sewn within a stainless steel frame. A fabric skirt covers the bottom third of the stent.

Figure 2. A, Femoral sheath and dilator. B, The deflection catheter facilitates delivery of the prosthetic valve to the aortic annulus.

Figure 3. A, The prosthesis could not be advanced around the aortic arch. B, Active deflection allowed redirection around the arch and access to the ascending aorta. Fluoroscopy in the left anterior oblique projection may aid in negotiating the aortic arch.
the deflection catheter was required to cross the stenotic native valve (Figure 4). The prosthesis was positioned such that it was coaxial within the calcified native valve leaflets.

During prosthesis implantation, rapid right ventricular pacing was used to minimize pulsatile transaortic flow, which would otherwise act to eject the inflated device-deployment balloon. Test pacing was performed at 220 bpm, and if necessary, the rate was reduced sequentially until reliable capture was achieved and a reduction in systolic arterial pressure to below 50 mm Hg was observed (Figure 5). A coordinated approach was developed wherein one individual observed the fluoroscopic image and maintained ideal valve position, a second individual initiated pacing, and a third confirmed reliable pacemaker capture and effective reduction in arterial pressure before rapidly inflating and then deflating the stent-deployment balloon (Figure 6). Dilute (10%) contrast was used to facilitate rapid inflation and deflation. Only when the balloon was fully deflated was pacing terminated and the catheter system withdrawn. Coaxial wire position was maintained. A pigtail was advanced to the left ventricle and transvalvular gradient measured. The pigtail was removed carefully over a straight guidewire.

Aortic root angiography and echocardiography were performed to reassess valve competency and coronary patency. Angiographic aortic regurgitation severity was the consensus grade of 2 senior angiographers using standard criteria. Echocardiographic aortic regurgitation severity was the consensus grade of 2 senior echocardiographers using the ratio of regurgitation jet height to left ventricular outflow tract height and regurgitation pressure half-time determination.16–18 “Trivial” was used to denote very narrow regurgitant jets.

At the completion of the procedure, the femoral arterial access site was repaired surgically in the catheterization laboratory. Patients continued taking aspirin indefinitely and clopidogrel for 3 months.

Results

Patient Outcome

Percutaneous valve implantation was attempted in 18 patients between January and July 2005. Baseline characteristics are shown in Table 1. Initial procedures were performed with conscious sedation. Later patients (n=12) received a general anesthetic to facilitate sheath placement and removal, airway management, and transesophageal echocardiography. Percutaneous placement of a 22F or 24F sheath was successful in all patients selected for the procedure on the basis of screening femoral angiography. All patients underwent planned open surgical access site closure.

The initial 2 patients had iliac arterial complications. In the first patient, a short sheath was used to access the internal iliac artery. During passage of the prosthesis through the atherosclerotic artery, a localized dissection resulted in iliac occlusion that required surgical repair. Subsequent cases were performed with a longer sheath designed to deliver the prosthesis beyond the iliac artery directly to the aorta. The second patient, having had prior coronary bypass surgery, had recently undergone repeat thoracotomy during which aortic valve replacement was aborted because of an unsuspected porcelain aorta. A 22F sheath was advanced with considerable difficulty through a very heavily calcified common iliac artery. Prosthesis implantation was uneventful. Surgical removal of the sheath 1 hour later was associated with sudden hemorrhage from the common iliac artery. Although the artery was repaired successfully, and excellent prosthetic valve function was documented repeatedly, death occurred due to multisystem failure 2 weeks later. There were no major femoral access site complications or hematomas in the subsequent 16 patients.

One patient developed a visual deficit that had resolved at the time of 1-month follow-up (Table 3). There were no intra-procedural deaths. At 30 days, there were 2 deaths: one the result of iliac perforation, as described above, and a second likely due to left coronary obstruction by a displaced native aortic valve leaflet excrescence, as described below. At follow-up of 73±49 days, 16 (89%) of 18 patients remained alive. Details are shown in Table 4.

Prosthesis Positioning

The prosthesis typically enters the ascending aorta along its greater curvature, with the guidewire lying within the aortic valve commissure. Crossing the native valve with the prosthesis generally requires active manipulation of the deflection catheter. It is helpful to advance the deflection catheter into a backup position in direct contact with the prosthesis, steer the prosthesis into the central orifice, and apply force to cross the native valve. Further manipulation may be necessary to orient the prosthesis coaxially within the annulus. This approach was successful in all but 1 patient, in whom the prosthesis would not cross the stenotic calcified valve but was uneventfully removed.

Patients generally tolerated placement of the prosthesis across the valve well, which allowed time for positioning. The prosthesis was positioned such that its midpoint was adjacent to fluoroscopically visible native leaflet calcification. Aortography that used hand injections through a pigtail catheter placed immediately above the valve was often helpful. The posteroanterior view was used most commonly; however, at times, other angulations were useful to visualize the valve plane. Transesophageal echocardiography was used in 5 patients but was sometimes limited in its ability to clearly distinguish the prosthesis while mounted on the balloon catheter. Echocardiographic visualization of the native valve leaflets was of particular value when valve calcification was mild and fluoroscopic positioning difficult. Echocardiogra-
phy was useful in assessing postprocedural paravalvular leaks and the need for further dilation.

In no patient did the stent appear to extend above the ostium of the coronary arteries (Figure 7). Aortography reliably visualized the left coronary ostium and coronary flow. In one 87-year-old individual with preprocedural cardiogenic shock, the stent remained below the coronary ostium; however, an unusually bulky calcified native leaflet was displaced over the left coronary ostium. Initial clinical improvement was followed by subsequent deterioration due to pneumonia, followed by withdrawal of active treatment 5 days later. Postmortem examination confirmed pneumonia but also showed the calcified valvular nodule obstructing the left main coronary artery (Figure 8). On subsequent review of both the baseline aortogram and balloon valvuloplasty, displacement of the native leaflet excrescence might have been anticipated, which suggests a cautionary role for close inspection of these recorded images before prosthetic valve implantation.

Prosthesis Sizing
Annulus diameter as determined by the echocardiographic long-axis view was 23.0±1.5 mm. Initially, only the previously described 23-mm outer-diameter valve was available. Later, a large-annulus 26-mm prosthesis was available intermittently. The larger valve was implanted successfully in 7 patients. Compared with 8 patients who received the smaller valve, these patients had a similar echocardiographic native valve area (0.7±0.2 versus 0.6±0.1 mm) but a slightly larger annulus (23.7±1.5 versus 22.0±1.4 mm). Valve area achieved with the larger prosthesis was greater (1.6±0.2 versus 1.3±0.5 mm), paravalvular regurgitation was less (median 1+ versus 2+/4), and valve embolization did not occur (0 versus 2).

Unsuccessful Deployment
Prosthetic valve embolization occurred in 2 patients immediately after deflation of the deployment balloon. Both patients received the smaller 23-mm-diameter prosthesis, with echo-
cardiographic annulus diameters of 20 and 22 mm, respectively. Potential contributors to embolization included native annulus/prosthesis mismatch, aggressive predilation of the native valve, and excessively high positioning. In 1 patient, termination of rapid pacing while the deployment balloon remained inflated, slow balloon deflation, and a hyperdynamic left ventricle contributed to forceful ejection of the balloon, which carried the prosthesis with it.

In both cases, the deployment balloon was readvanced through the prosthesis, partially inflated, and used to withdraw the prosthesis to a relatively safe position remote from important side branches that might be compromised (the descending aorta in 1 patient and the transverse aorta in a second). One of these patients, who responded well to balloon valvuloplasty, subsequently underwent uneventful colectomy for malignancy and impending bowel obstruction. Four months after implantation, elective surgical aortic valve replacement was performed, at which time avulsion of 1 native valve leaflet was noted, which suggests this may have predisposed to embolism. The embolized prosthesis was easily removed, and the patient remains well. The second patient remains stable at 5 months. Delayed valve migration or embolization has not been observed. In total, prosthesis deployment was unsuccessful in 4 patients. Prosthesis embolization resulted in final positioning in the transverse or descending aorta in 2 patients. Inability to negotiate a diseased iliac artery and inability to cross the native aortic valve led to removal from the femoral artery in 2 patients.

**Valve Function**

Valve function as assessed by echocardiography within 24 hours after implantation and at 1 month remained essentially unchanged (Table 5). Prosthetic valve insufficiency was generally mild, ranging from none to moderate. Paravalvular insufficiency was common, as assessed by transesophageal echocardiography. In 3 patients, severe paravalvular insufficiency appeared to be associated with an underexpanded prosthesis. In 2 of these patients, redilation at the time of the initial procedure with a slightly oversized balloon during rapid pacing reduced severe paravalvular insufficiency to moderate without causing any apparent damage to the valve leaflets. Late valve failure was not observed.

Contrast aortography was available for analysis in 13 of 14 patients before and after successful prosthetic valve implantation. One patient, with mild echocardiographic paravalvular insufficiency, did not undergo postprocedural aortography owing to renal dysfunction. All patients had some degree of preprocedural aortic valvular insufficiency. Immediately after prosthetic valve implantation, all but 1 patient had some degree of paravalvular aortic insufficiency. Immediately after prosthetic valve implantation, all but 1 patient had some degree of paravalvular aortic insufficiency. Patients undergoing successful valve implantation had an angiographic aortic insufficiency grade of 1.6±0.5 before the procedure and 1.8±0.6 after the procedure.

## Discussion

### Antegrade Versus Retrograde Approach

The first percutaneous valve procedures reported by Cribier et al.\(^{12,13}\) used an antegrade approach to the aortic valve. This approach requires femoral venous access, a transseptal puncture, dilation of the interatrial septum, passage of a flotation balloon through the mitral valve, antegrade cannulation of the stenotic aortic valve, and snaring of a guidewire from opposite the femoral artery with exteriorization of an arteriovenous wire loop. Transseptal puncture and dilation carries an

### TABLE 1. Baseline Characteristics

<table>
<thead>
<tr>
<th>Age, y, mean±SD (range)</th>
<th>81±6 (69–92)</th>
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<tbody>
<tr>
<td>Angina, n (%)</td>
<td>6 (33.3)</td>
</tr>
<tr>
<td>Heart failure, n (%)</td>
<td>14 (77.8)</td>
</tr>
<tr>
<td>NYHA failure class, median (range)</td>
<td>3 (2–4)</td>
</tr>
<tr>
<td>Syncope, n (%)</td>
<td>3 (16.7)</td>
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<td>Male gender, n (%)</td>
<td>13 (72.2)</td>
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<tr>
<td>Diabetes mellitus, n (%)</td>
<td>3 (16.7)</td>
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<tr>
<td>Prior and current smoking, n (%)</td>
<td>11 (61.1)</td>
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<tr>
<td>Coronary heart disease, n (%)</td>
<td>11 (61.1)</td>
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<tr>
<td>Peripheral vascular disease, n (%)</td>
<td>5 (27.7)</td>
</tr>
<tr>
<td>Porcelain aorta, n (%)</td>
<td>3 (16.7)</td>
</tr>
<tr>
<td>Prior cardiac surgery, n (%)</td>
<td>6 (33.3)</td>
</tr>
<tr>
<td>Prior noncardiothoracic surgery, n (%)</td>
<td>1 (5.6)</td>
</tr>
<tr>
<td>Prior angioplasty, n (%)</td>
<td>3 (16.7)</td>
</tr>
<tr>
<td>Prior malignancy, n (%)</td>
<td>6 (33.3)</td>
</tr>
<tr>
<td>Prior cerebral ischemic event, n (%)</td>
<td>1 (5.6)</td>
</tr>
<tr>
<td>Chronic pulmonary disease, n (%)</td>
<td>4 (22.2)</td>
</tr>
<tr>
<td>Renal dysfunction,* n (%)</td>
<td>10 (55.6)</td>
</tr>
<tr>
<td>Recent cardiogenic shock, n (%)</td>
<td>1 (5.6)</td>
</tr>
<tr>
<td>Other severe comorbidities, n (%)</td>
<td>1 (5.6)†</td>
</tr>
<tr>
<td>EuroSCORE(\text{II})</td>
<td>11.3±2.0</td>
</tr>
<tr>
<td>Logistic EuroSCORE predicted mortality, mean±SD, %</td>
<td>26.2±13.1</td>
</tr>
<tr>
<td>Logistic EuroSCORE &gt;20%, n (%)</td>
<td>12 (66.7)</td>
</tr>
</tbody>
</table>

\(\text{NYHA}\) indicates New York Heart Association.

\(n=18.\)

*Estimated glomerular filtration rate <60 mL/min.

†Recent pulmonary emboli.

### TABLE 2. Iliofemoral Arterial Access

<table>
<thead>
<tr>
<th>Access (n=18)</th>
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<tbody>
<tr>
<td>Right femoral access</td>
<td>10 (55.6)</td>
</tr>
<tr>
<td>Left femoral access</td>
<td>8 (44.4)</td>
</tr>
<tr>
<td>Percutaneous puncture</td>
<td>18 (100)</td>
</tr>
<tr>
<td>Surgical closure</td>
<td>18 (100)</td>
</tr>
</tbody>
</table>

CT indicates computed tomography.

Values are n (%) unless otherwise indicated.

*Sheaths of 22F or 24F internal diameter have external diameters of 8 or 9 mm, respectively.
attendant risk of pericardial tamponade. Passage of large-diameter catheters through the mitral valve produces temporary mitral incompetence, and mitral injury may occur. Atrial and ventricular arrhythmias are common. Hemodynamic instability has been characteristic of the antegrade technique, and acute procedural mortality remains a concern. Refinements of this approach may minimize these concerns, particularly in skilled hands, but the technical complexity of the antegrade approach appears likely to limit widespread application.14

A femoral transarterial, retrograde approach to prosthetic valve implantation shares much in common with other cardiac interventions and thus may be both more intuitive and more generalizable. Initial attempts at transarterial implantation with standard balloon valvuloplasty equipment were, however, compromised by difficulties negotiating the aortic arch and reaching and crossing the stenotic native valve, ultimately leading to abandonment of this approach (A. Cribier, MD, unpublished data, 2005). Recently, Hanzel et al15 reported an antegrade procedure, which, when unsuccessful, was converted to a retrograde approach; however, mitral valve injury as a consequence of the antegrade component of the procedure led to cardiovascular collapse and death. Our experience suggests that with the use of equipment and techniques specifically designed for a transarterial approach, percutaneous aortic valve implantation can be accomplished routinely.

**Procedural Issues**

Optimal positioning of the prosthetic valve is critical if embolization, paravalvular insufficiency, and coronary obstruction are to be avoided; however, the precise methods and location of positioning remain to be established. Dependence on fluoroscopic visualization of the native valve is problematic owing to variability in the amount and location of calcification. Aortography and transesophageal echocardiographic assessment may be helpful. Additional imaging modalities and design features that assist in optimal positioning are needed. Both native valve leaflet and aortic annulus-prosthesis apposition appear to play a role in secure valve seating and prevention of paravalvular regurgitation. In 1 patient, the presence of an avulsed leaflet subsequent to aggressive balloon valvuloplasty may have predisposed to prosthesis embolization, which suggests that in the absence of good prosthesis/native valve apposition, prosthesis/native annulus apposition may increase in importance. Early in our experience, we attempted to center the prosthesis adjacent to leaflet calcification; however, it may be desirable to center the prosthesis slightly lower to ensure more secure seating within the annulus and avoid interference with the coronary ostia.

![Figure 7. Ascending aortograms obtained in the posteroanterior projection. A, Before prosthetic valve implantation. B, After prosthetic valve implantation. The prosthesis is positioned below the ostia of the coronary arteries. There is no aortic insufficiency.](image)
The diameter of the aortic annulus was routinely measured immediately below the insertion of the native valve leaflets by echocardiography. Initially, only a 23-mm-diameter prosthesis was available and thought suitable for diameters between 18 and 22 mm. Later, when available, a new 26-mm prosthesis was used preferentially for annulus diameters between 19 and 25 mm. It is notable that in none of the implants with a large prosthesis did embolization occur, and significant paravalvular insufficiency was infrequent. Our favorable experience with this larger prosthesis suggests that some patients receiving the smaller prosthesis might have benefited from a larger prosthesis. Variation in the reported annulus diameter with various imaging modalities (angiography, transthoracic and transesophageal echocardiography, and computed tomography) suggests that further study of the factors involved in prosthesis sizing is needed.

Important factors in secure deployment include correct sizing, positioning, coaxial alignment, timely reduction of cardiac output, and operator technique. Prosthesis embolization appears to be an early, rather than late, risk. In our experience, embolization was manageable by deploying the valve in the transverse or descending aorta. Nevertheless, the potential for adverse consequences is a concern, which suggests that the potential for surgical bailout should be determined in advance of the procedure.

In 1 patient, inadequate predilation, poor guiding catheter support, and inadequate catheter length resulted in an inability to pass the prosthesis across the stenotic native aortic valve. Although it was possible to remove the prosthesis through the femoral sheath, this is not likely to be possible routinely. Currently, this would require surgical removal or deployment in a relatively benign location. Future design enhancements are planned to enhance deliverability and retrievability.

Stroke is a known risk of routine balloon valvuloplasty,19,20 and 1 of our patients experienced a possibly embolic cerebrovascular event. Atheroembolism resulting from manipulation of the native valve or aortic arch may have played a role. Our initial approach was to advance the prosthesis through the aorta until an obstruction was encountered, at which point the steerable deflection catheter was utilized; however, it would seem preferable to more actively manipulate the deflectable catheter so as to avoid contact with the atherosclerotic wall of the aorta. It is possible that with this more active approach, our single, possibly atheroembolic event might have been avoided.

Significant prosthetic valvular insufficiency was not observed; however, some degree of paravalvular insufficiency was common and appeared to result from 1 of 2 mechanisms. Transesophageal echocardiography demonstrated that paravalvular regurgitation was most often due to inadequate apposition of the prosthesis and the aortic annulus. This appeared to be associated with an undersized prosthesis, inadequate expansion of the stent, or dense calcification with a noncylindrical aortic annulus. Although the fabric cuff presents a fixed constraint to dilation of the stent, further

<table>
<thead>
<tr>
<th>TABLE 5. Echocardiographic Characteristics</th>
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<tr>
<td>Characteristic</td>
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<tr>
<td>Gradient, mm Hg, mean±SD</td>
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<tr>
<td>Valve area, cm²‡, mean±SD</td>
</tr>
<tr>
<td>Calcification, grade</td>
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<tr>
<td>Annulus diameter, mm, mean±SD</td>
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<tr>
<td>Ejection fraction, %, mean±SD</td>
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<tr>
<td>Mitral insufficiency, grade (range)</td>
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<tr>
<td>Prosthetic-mitral valve contact</td>
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<tr>
<td>Mitral injury</td>
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<tr>
<td>Aortic valvular insufficiency, grade (range)</td>
</tr>
<tr>
<td>Aortic paravalvular insufficiency, grade (range)</td>
</tr>
<tr>
<td>Valve failure</td>
</tr>
</tbody>
</table>

N/A indicates not applicable.
*Does not include 4 patients in whom valve implantation was unsuccessful.
‡Does not include 4 patients who had not yet reached 1-month follow-up.
‡Derived from continuity equation.
dilation of the prosthesis was commonly helpful. A second mechanism of paravalvular insufficiency relates to the fabric cuff lining the distal one third of the stent. The proximal two thirds of the stent is uncovered to allow for coronary perfusion should the prosthesis be implanted so as to overlap the coronary ostia; however, if the prosthesis is implanted too low within the annulus, then regurgitant blood flow can occur around the prosthetic leaflets, through the open stent, and into the left ventricle. Minimizing paravalvular insufficiency by appropriate sizing, positioning, and complete expansion is important to optimize patient outcome. Design modifications are anticipated to reduce this concern.

Coronary obstruction could conceivably occur due to embolization of friable valvular debris, although this has not been a limitation of balloon valvuloplasty. Obstruction might also occur should the fabric cuff lining the lower portion of the stent be placed above the annulus so as to cover the coronary ostia. This risk is likely low, because the diameter of the stent is less than that of the sinuses of Valsalva. However, coronary obstruction by a displaced native valve was observed in a single patient. Until this is better understood, the presence of an unusually bulky left coronary leaflet appears to be a relative contraindication to percutaneous valve implantation.

Alternative Therapies

For many patients with severe aortic stenosis and comorbidities, particularly advanced age, therapy remains medical, a strategy associated with poor outcome. Although balloon valvuloplasty may result in temporary relief of symptoms, benefit is modest and restenosis certain. In-hospital mortality reportedly ranges from 8% to 14% and 1-year survival from 54% to 75%. Complications can occur, including stroke, aortic dissection and rupture, and access-related complications. These risks reflect those that might occur with percutaneous valve implantation without the potential of greater benefit.

According to the Society of Thoracic Surgeons Database (1998–2001), surgical aortic valve replacement carries a rate of serious complication or mortality of 16.8%. Operative risk is increased in the setting of comorbidities, such as advanced age. A prior publication from our institution reported aortic valve surgery carried a risk of early mortality of 15.1% for patients 80 to 84 years of age and 17.8% for patients 85 years of age. Mortality at 30 days in this initial percutaneous series of patients with a mean age of 82 years was 11%, which was favorable compared with the Logistic EuroSCORE-predicted surgical mortality rate of 26%. These predicted surgical mortality estimates are derived from coronary disease patients actually accepted for surgery. As such, they may underestimate mortality in patients with valve disease or patients not considered surgical candidates for reasons that may not be fully accounted for by modeling.

Conclusions

Percutaneous heart valves are a new but immature technology with the potential to benefit many patients. Device and procedural enhancements are required to assure reliable and safe prosthesis delivery, positioning, deployment, anchoring, function, and durability. Transarterial, retrograde prosthesis implantation represents a significant enhancement with respect to delivery and procedural simplicity. Although our results are promising, current application of this procedure should be limited to patients who are poor candidates for surgical valve replacement.

Disclosures

Drs Munt and Webb are consultants to Edwards Lifesciences, Irvine, Calif.

References


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