Transcatheter and Transapical Aortic Valve Replacement

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PRIME POINTS

• Minimally invasive valve replacement is limited to bioprosthetic aortic and pulmonary valves for use in very specific populations of patients.

• Replacement via transcatheter and transapical techniques should be used only in patients in whom traditional surgical replacement is deemed an unacceptable risk.

• Nursing management will focus heavily on care for comorbid conditions because of the high-risk nature of the patients in whom these valves will initially be implanted.

ortic valve replacement (AVR) is a common cardiac surgical procedure. An estimated 106,000 cardiac valve operations were performed in the United States in 2005 (the most recent year for which procedure numbers are available). AVR is the most widely performed valve replacement.

Aortic stenosis affects from 2% to 7% of persons more than 65 years old in the United States and is likely to increase in prevalence as the population ages. The current American Heart Association guidelines for valvular heart disease recommend AVR to improve signs and symptoms and survival rates in patients with symptomatic aortic stenosis or in asymptomatic patients with an ejection fraction less than 50%. In a retrospective cohort study, Pai et al found that asymptomatic patients with severe aortic stenosis had a significant survival improvement with AVR. Therefore, the need for AVR will most likely increase over time, and with people living longer, AVR will be increasingly needed in elderly patients or patients with significant comorbid diseases.

Many larger, experienced centers have an operative mortality of less than 1% for AVR. Mortality data from several large databases are presented.

CE

This article has been designated for CE credit. A closed-book, multiple-choice examination follows this article, which tests your knowledge of the following objectives:

1. List 3 indications and contraindications for performing transcatheter and transapical aortic valve replacement (AVR) on specific patient populations
2. Discuss the advantages of less-invasive insertion techniques for higher risk AVR
3. Identify 4 potential postoperative complications that could occur following transcatheter and transapical AVR and describe nursing interventions for each

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Table 1: Operative mortality for aortic valve replacement (AVR)

<table>
<thead>
<tr>
<th>Source</th>
<th>Mortality, %</th>
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<tbody>
<tr>
<td>Society of Thoracic Surgeons database, 2005</td>
<td>2.8</td>
</tr>
<tr>
<td>All AVR(^1)</td>
<td></td>
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<tr>
<td>Society of Thoracic Surgeons database, 2004(^4)</td>
<td></td>
</tr>
<tr>
<td>AVR with diabetes</td>
<td>6.6</td>
</tr>
<tr>
<td>AVR redo surgery</td>
<td>7.6</td>
</tr>
<tr>
<td>AVR with end-stage renal disease</td>
<td>17.0</td>
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<tr>
<td>EuroHeart Survey, 2001(^1)</td>
<td>2.7</td>
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</table>

Table 1 illustrates the effect of age on mortality. Operative mortality depends on many factors such as the patient’s age, ventricular function, and associated cardiac and noncardiac diseases. Figure 1

Development of Transcatheter Valve Procedures

Many factors have promoted the development of less-invasive valve procedures. AVR that does not require full sternotomy may be more cosmetically attractive to patients. Being able to perform AVR in patients with severe aortic stenosis or calcification without the risk of stroke...
from cross-clamping a calcified aorta is not only beneficial in terms of improved outcomes for patients but also might reduce hospital stays due to complications such as stroke. Conventional AVR must be done with cardiopulmonary bypass with the attendant risks of elevating creatinine level (particularly in patients with renal disease), bleeding, and impaired lung function due to deflation of the lungs during bypass. The avoidance of the use of cardiopulmonary bypass could prevent some of these complications in high-risk patients. In addition, AVR could be extended to patients with conditions previously considered inoperable if the avoidance of cardiopulmonary bypass and sternotomy improved outcomes.

Balloon Aortic Valvuloplasty

Until recently, transcatheter aortic valve interventions have been limited to balloon aortic valvuloplasty, in which a balloon is placed across the stenotic aortic valve and inflated to reduce aortic stenosis. Balloon aortic valvuloplasty has been useful in treating children with aortic stenosis, but it is recommended solely for younger adults without valve calcification. The 2006 American College of Cardiology/American Heart Association (ACC/AHA) guidelines for valvular disease management recommend balloon aortic valvuloplasty in adults solely as a bridge to surgery in patients with aortic stenosis who have unstable hemodynamic status and are at high risk for AVR or for patients with aortic stenosis in whom AVR cannot be performed because of serious comorbid conditions. The ACC/AHA recommendations were based on a review of the literature that cited greater than 10% frequency of serious complications and the fact that restenosis and clinical deterioration typically occur within 6 to 12 months of balloon aortic valvuloplasty. However, the studies cited in the ACC/AHA recommendations are dated, and some technical improvements have occurred since the studies were done that may lead to further study of balloon aortic valvuloplasty, especially in nonagenarians.

Transcatheter Pulmonary Valve Replacement

In 2000, the first valve replacement that became available by catheter delivery was the pulmonary valve replacement (PVR) performed by Bonhoeffer’s group with a bovine jugular vein valve that was intended for use inside surgically placed conduits from the right ventricle to the pulmonary artery. The results of the first North American trial of transcatheter PVR were recently reported; no significant complications or urgent surgical intervention occurred. Transcatheter PVR is intended for patients with congenital heart disease in whom reoperation could be delayed until a future date by the implantation of one of these valves.

Transcatheter AVR

Andersen et al reported the first transcatheter AVR in 1992 in pigs. The first transcatheter AVR in humans was reported by Cribier et al in 2002. Transcatheter and transapical AVR are currently in clinical trials in a few centers in Canada, the United States, and Europe.

In a position paper, the Society of Thoracic Surgeons, the American Association for Thoracic Surgery, and the Society for Cardiovascular Angiography and Interventions recommended that the initial patients to undergo percutaneous AVR strategies should be at extremely high operative risk (generally >20% operative mortality) as indicated by an established risk scoring system such as the logistic EuroSCORE or the Society of Thoracic Surgeons risk calculator. The guidelines reported by Vassiliades et al state that use of such devices is not acceptable for patients who simply refuse open heart surgery on the basis of personal preference. It was also recommended that initial feasibility studies be conducted in a small number of high-volume cardiology and cardiac surgery programs (minimum 100-150 valve operations per year with each surgeon performing a minimum of 40-50 valve repairs or replacements annually). Some of the indications and contraindications for minimally invasive AVR are indicated in Tables 2 and 3, respectively.

Transcatheter and Transapical Valve Design

Traditional heart valves consist of homografts from another human being, bioprosthetics (valves constructed from bovine pericardium or porcine valves mounted in a metallic stent to preserve their shape or prepared as stentless valves), or mechanical valves mounted in a fabric sewing ring. The valves are sutured into the heart after the diseased valve is excised. Traditional bioprosthetic valves last a mean of 10 to 15 years, and mechanical valves could potentially last a lifetime. In contrast to traditional heart valves, implantation of the transcatheter valve does not require removal of the native heart valve. The transcatheter valves...
are bioprosthetic valves that are crimped or loaded onto a stent or frame. Once in place, the stent or frame containing the valve is expanded to anchor the valve in the aortic annulus. The transcatheter valves are sutureless and are held in place by the stent or frame. The valves currently in clinical trials are the Edwards SAPIEN transcatheter heart valve (Edwards Lifesciences, Irvine, California), also referred to as the Cribier-Edwards valve (Figure 2), and the CoreValve (CoreValve Inc, Irvine, California; Figure 3). A number of other valves are in development.

Table 2  Indications for transcatheter and transapical aortic valve replacement

<table>
<thead>
<tr>
<th>Indication</th>
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<tr>
<td>Severe, symptomatic aortic stenosis</td>
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<tr>
<td>Estimated operative mortality for conventional aortic valve replacement more than 20% according to established risk calculators</td>
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<tr>
<td>Severe ascending aortic calcification such as porcelain aorta that prevents aortic cannulation or cross-clamping</td>
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<tr>
<td>Severe radiation damage to the chest or other severe chest deformities that would preclude a sternotomy (transcatheter approach used because radiation damage may also prevent a transapical approach)</td>
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<tr>
<td>Patients’ willingness to comply with follow-up evaluations to assist with ongoing development of this new technology (will be a requirement of ethics boards that approve studies with these valves)</td>
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Table 3  Contraindications for transcatheter and transapical aortic valve replacement

<table>
<thead>
<tr>
<th>Contraindication</th>
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<tbody>
<tr>
<td>Previously untreated coronary disease (the valve may prevent access for percutaneous coronary interventions although successful stent placement after implantation of a transcatheter valve has been reported)</td>
</tr>
<tr>
<td>No concomitant coronary bypass surgery with transapical aortic valve replacement because the exposure would be inadequate</td>
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<tr>
<td>Infective endocarditis or intracardiac tumor (excision on bypass is the only accepted treatment for intracardiac tumor)</td>
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<tr>
<td>Estimated life span of less than 1 year (would limit follow-up of investigational valves)</td>
</tr>
<tr>
<td>Recent active gastrointestinal bleeding that would prohibit use of heparin or antiplatelet therapies such as aspirin or clopidogrel</td>
</tr>
<tr>
<td>Patients with a contraindication to transesophageal echocardiography (used preoperatively to assess aortic annulus size and to position the valve)</td>
</tr>
<tr>
<td>Aortic annulus size not amenable to use with the currently available valve sizes (valve sizing is critical to avoid paravalvular regurgitation)</td>
</tr>
<tr>
<td>Anomalous coronary ostia (valve could potentially interfere with flow into anomalous coronary ostia) or an unusually bulky coronary leaflet</td>
</tr>
<tr>
<td>Renal failure with creatinine clearance &lt;20 mL/min</td>
</tr>
<tr>
<td>For transcatheter aortic valve replacement only: severely calcified, diseased, small, or tortuous iliac vessels that preclude passage of the delivery catheter or previous aortobifemoral grafting (these patients would qualify for transapical aortic valve replacement) or aortic aneurysm</td>
</tr>
<tr>
<td>For transapical aortic valve replacement only: left apical clot, aneurysm, or scar (these patients would qualify for transcatheter aortic valve replacement; left ventricular clot could be a contraindication for transcatheter aortic valve replacement as well)</td>
</tr>
<tr>
<td>Patient offered conventional aortic valve replacement but refused surgery</td>
</tr>
</tbody>
</table>

The Edwards SAPIEN transcatheter heart valve was an equine available in 23- and 26-mm sizes and is now a bovine trileaflet pericardial valve on a balloon-expandable stainless steel stent. It is currently available in 23- and 26-mm sizes and can be used for transcatheter and transapical AVR. A sewn fabric cuff...
covers the left ventricular part of the prosthesis. The valve is approximately 14 mm in height with cloth covering the proximal 6 mm of the valve. The cloth-covered part of the valve must sit in the annulus to prevent regurgitation through the stent into the left ventricle. In order to use the Edwards valve, a balloon valvuloplasty must be undertaken first to dilate the native valve and allow placement of the new valve.

The CoreValve ReValving System consists of a porcine pericardial valve on a multilevel self-expanding nitinol frame in an hourglass shape (expands with blood temperature), a delivery catheter, and a disposable loading system. The current generation catheter is 18F. The shape of the frame allows secure positioning within the aortic annulus while the valve functions in the supraannular position. Two valve sizes are available for use in aortic annuli between 20 and 27 mm. To date, more than 1800 patients have been treated with the CoreValve device. This system is neither commercially nor investigationally available in the United States at the present time (Rob Michiels, CoreValve Inc, written communication, September 25, 2007).

Valve Insertion Procedure
Transcatheter AVR is performed with either local or spinal anesthesia with sedation or with general anesthesia in a cardiac catheterization laboratory or an operating room equipped with fluoroscopy and transesophageal echocardiography. Transcatheter AVR may require surgical cutdown and may require placement of femoral grafts in order to insert the large transcatheter delivery systems. The large size of the delivery catheters limits the transcatheter approach to patients with vessels large enough to accommodate the catheters. An angiogram or a computed tomographic angiogram (and probably femoral Doppler imaging) is required before transcatheter AVR to ensure that the femoral and iliac vessels are not tortuous and are large enough to accommodate the valve delivery catheters.

Transcatheter AVR: Deployment
Two approaches have been described for deployment in transcatheter AVR. In the antegrade,
transeptal approach, access is via the femoral vein; the catheter is passed into the right ventricle and then punctures the septum to be placed antegrade across the aortic valve. This approach is technically difficult and may cause mitral valve damage, including acute mitral regurgitation, if not carefully performed. In the retrograde approach, a femoral artery puncture is used. The catheter is advanced retrograde through the aorta to cross the aortic valve. Limitations of the retrograde approach include the small size of the femoral artery compared with the femoral vein, a situation that makes the approach difficult to use in older patients with peripheral vascular disease or small patients whose vessels cannot accommodate the 18F to 24F sheath sizes. With the retrograde technique, atherosclerotic material can be embolized from the aorta into the distal circulation. Gupta et al compared 52 antegrade vs 111 retrograde AVRs and found no difference in outcomes except that antegrade deployment avoided vascular complications (7% in retrograde vs 0% in antegrade approach, \(P < .05\)). Contrast medium is used to ensure correct positioning of the catheter valve across the aortic annulus. Transcatheter AVR with the Edwards valve requires rapid pacing of the heart (rate, 150-220/min) to decrease cardiac output to place the valve. Failure to stop the cardiac output with pacing while the valve is placed could result in ejection of the valve into the aorta. The alternative would be brief femoral-femoral cardiopulmonary bypass to place the valve. In some centers, the femoral vessels are cannulated for possible emergent cardiopulmonary bypass in case of problems such as valve embolization into the aorta. Great care must be used in positioning the valve to ensure that the coronary ostia are not blocked or that a bulky native aortic valve leaflet does not block the ostia when pushed back by the stent.

The CoreValve ReValving system uses a suture-mediated closure device (Prostar, Abbot Vascular Devices, Redwood City, California) for femoral percutaneous closure (Rob Michiels, CoreValve Inc, written communication, September 25, 2007). The Edwards SAPIEN transcatheter heart valve system uses a femoral graft closure.

activated clotting time at greater than 250 seconds and prevent clot formation during catheter and valve positioning. The transapical incision is depicted in Figure 4. One chest drain was placed for 24 hours to drain blood from the surgical site.

After the procedure, Ms L. was admitted to the cardiovascular intensive care unit for 24 hours and was extubated within 2.5 hours of arrival in the unit. An intercostal nerve block was performed soon after the procedure for pain control, and then intravenous narcotic analgesia and then oral narcotic analgesia were used several days later. Intravenous nitroglycerin was administered for 6 hours for hypertension. An intravenous insulin infusion was used for 24 hours to maintain optimal glycemic control until a full diabetic diet was possible. Ms L. was transferred to the cardiovascular surgery unit on the day after surgery.

Ms L. was taking clopidogrel 75 mg daily, to continue for at least 6 months, and aspirin 81 mg daily, to continue indefinitely, for the aortic valve, previous bypass grafts, and carotid stenosis. She had a brief postoperative episode of atrial fibrillation that was treated with oral amiodarone and metoprolol with conversion to sinus rhythm. Her postoperative echocardiogram revealed an aortic valve area of 0.97 cm\(^2\) with peak and mean aortic valve gradients of 34 and 12 mm Hg, respectively. Two small jets of paravalvular aortic insufficiency were noted, as is common with this type of valve. The aortic insufficiency evident on the echocardiogram done on postoperative day 4 was unchanged from that revealed on the intraoperative transesophageal echocardiogram. Ms L. was discharged home on postoperative day 5.
Transapical AVR

Because of the possible vascular complications of transfemoral catheter approaches, the transapical approach has been developed. The transapical approach can be used in persons who have small or tortuous femoral or iliac vessels or severe peripheral vascular disease such as persons with previous aortobifemoral grafting. It would be a preferential approach if a porcelain (heavily calcified) aorta prevented cannulation for cardiopulmonary bypass or aortic cross-clamping or if aortic atheroma was marked. The transapical approach is quicker and less technically difficult than the transcatheter technique. The transapical approach could be a problem, however, if a left ventricular apical thrombus, a left ventricular aneurysm, or apical scarring from previous surgery or chest radiation was present.

The transapical AVR is placed via a 5- to 8-cm anterolateral left thoracotomy usually in the sixth intercostal space (Figure 4). The pericardium is opened, and a small transapical stab incision of the left ventricle is made to accommodate the delivery catheter. A total of 1 bipolar or 2 unipolar epicardial pacing wires are placed on the left ventricle to pace the heart during valve placement. A balloon aortic valvuloplasty is performed to dilate the native aortic valve before placement of the new valve. A balloon aortic valvuloplasty is performed to dilate the native aortic valve before placement of the new valve. The new valve is then placed on a catheter across the native aortic valve (Figure 5) and uncrimped by balloon expansion of the stent (Figure 6). Cardiac output must be momentarily stopped by the use of high-rate pacing of the heart (rate, 150-220/min) until the valve is positioned. Transapical placement of an AVR requires a collaborative team approach between cardiology and cardiovascular surgery to ensure that imaging and pacing capabilities merge to allow the surgeon to place the valve precisely and at exactly the appropriate time to prevent valve embolization. At the end of the procedure, the pacing wires are removed, the pericardium is closed to prevent herniation of the heart through the pericardium, and the mini-thoracotomy is closed, with a chest tube left in situ for overnight drainage. An example of a stented aortic valve placed via a transapical approach is seen on a chest radiograph in Figure 7.

Important Points About Transcatheter and Transapical AVR

Valves used for transcatheter and transapical AVR must be oversized to ensure stability within the aortic valve annulus without perivalvular regurgitation. Paravalvular insufficiency can be caused by undersizing or inadequate dilatation of the valve stent. Therefore, the aortic annulus is measured, and a valve size is selected that is slightly larger than the patient’s own annulus. Because of the current limitation in sizes available in these new valves, patients with larger annuli cannot currently receive the valve. Lichtenstein et al.23
stated that an unusually bulky coronary leaflet could be displaced by the valve stent or frame and would therefore be a contraindication.

Anomalous coronary ostia might be a contraindication to the use of these valves. The valve stent or frame may interfere with introducing catheters into the coronary arteries. Such interference could be an issue if catheterization or stenting of coronary arteries should be required at a later date. Therefore, before these valves are placed surgeons must ensure that patients have no marked coronary disease. Open bypass grafts would provide a safety margin in the situation of a short distance between the annulus and the coronary ostia.

If the valve is placed via the femoral vessels, the vessels must not have a tortuous course or be severely calcified. The catheters used to deliver the valves are relatively stiff and large. Therefore, vessel rupture, dissection, formation of a pseudoaneurysm, bleeding, and thrombus formation can be problems, as can myocardial perforation and cardiac tamponade. Embolization of calcified material could also occur during the balloon valvuloplasty, or atheromatous material in the aorta could be embolized during retrograde valve placement.

Early Results of Transcatheter and Transapical AVR

Early outcomes for humans after transcatheter and transapical AVR have been reported by a number of investigators (Table 4). In general, valve implantation is successful in most patients, who have symptomatic improvement after the implant. Because these valves are secured in place by the valve stent or frame, perivalvular regurgitation may occur. Morbidity and mortality are currently higher than with conventional valve implantation and will most likely decrease as experience with transcatheter valves increases and design is improved. Long-term follow-up is limited with these newer valves.

Long-term follow-up is needed to determine the durability of transcatheter valves and to assess what other problems may arise. For those who had SAPIEN equine valves, equine valves have not been tested for durability beyond a few years in humans. It is not clear if crimping the valve for delivery will affect long-term function of the valve.

A number of long-term problems have been reported with percutaneous PVR, and it is unclear whether these problems will occur with the newer AVR techniques.
### Table 4  Early published results of studies of transcatheter and transapical aortic valve replacement in humans

<table>
<thead>
<tr>
<th>Study and year</th>
<th>Sample size and route</th>
<th>Valve type</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cribier et al, 27 2006</td>
<td>36 (33 implants attempted, 26 successful), 22 antegrade and 4 retrograde transcatheter aortic valve replacements</td>
<td>Edwards SAPIEN transcatheter heart valve</td>
<td>Aortic valve area (AVA) increased from 0.60 (SD, 0.09) cm² to 1.70 (SD, 0.11) cm² ($P &lt; .001$) and increase remained stable at up to 24 months of follow-up. Ejection fraction improved significantly in successful implants (45% [SD, 18%] preimplantation and 53% [SD, 14%] 1 week after implantation, $P = .02$). Procedure-related complications occurred in 6 patients (2 deaths due to cardiac tamponade, 1 death due to sepsis, 1 case of complete heart block with temporary loss of pacing lead contact with prolonged resuscitation leading to irreversible brain damage, 1 stroke during retrograde catheterization, and 1 death unexplainable at autopsy); the remaining patients experienced symptomatic improvement. Survival was limited by comorbid conditions.</td>
</tr>
<tr>
<td>Pasupati et al, 30 2006</td>
<td>50, 43 transcatheter and 7 transapical aortic valve replacements</td>
<td>Edwards SAPIEN transcatheter heart valve</td>
<td>Valve implantation was successful in 86%; AVA increased from 0.6 (SD, 0.2) cm² to 1.8 (SD, 0.4) cm², $P &lt; .001$; improvements were maintained at 1 month. No late structural valve deterioration detected with the longest follow-up of 14 months. Paravalvular regurgitation was common but generally mild with no hemolysis reported. The periprocedural stroke rate was 2% with no long-term sequelae. Baseline New York Heart Association functional class was III or IV and by 1 month after the procedure 84% had improved by 1 or more classes ($P &lt; .001$). Overall 30-day mortality was 12% and decreased to 8% in the final 25 patients.</td>
</tr>
<tr>
<td>Walther et al, 7 2006</td>
<td>30 transapical aortic valve replacements Cardiopulmonary bypass was used in 13 patients; 9 patients had femoral cannulation for possible cardiopulmonary bypass but bypass was not needed; 8 more recent patients had replacement completed off cardiopulmonary bypass with only a venous wire inserted in the femoral vein in case of emergent need for cardiopulmonary bypass</td>
<td>Edwards SAPIEN transcatheter heart valve</td>
<td>Implantation was successful in 96.7%. One patient had severe eccentric calcification of 1 of the cusps and was converted to conventional aortic valve replacement because the valve slipped into the left ventricular outflow tract and caused severe mitral regurgitation. No neurological events occurred. Three patients (10%) died in the hospital: 1 on postoperative day (POD) 86, 1 on POD 18 due to acute abdomen with multisystem organ failure, and 1 due to biventricular failure during induction in a patient who subsequently had a traditional aortic valve replacement as a salvage procedure; this patient died of low-output syndrome on POD 3. Repeat thoracotomy was undertaken in 1 patient because of bleeding, and 2 patients had atrioventricular block requiring resuscitation; 1 operation was repeated on POD 37 for new onset of annular dehiscence. AVA had increased from 0.60 (SD, 0.14) cm² to 1.83 (SD, 0.68) cm², and the mean gradient decreased from 38.7 (SD, 12.7) mm Hg to 10.2 (SD, 5.8) mm Hg at 1-month follow-up. Mild aortic regurgitation occurred in 4 patients; no perioperative deaths or complications occurred. Thirty-day mortality was 10%; 1 patient died of pneumonia on POD 12. During 6-month follow-up of the initial 7 patients, 2 patients died of noncardiac causes. AVA was further increased at 6-month follow-up; valvular regurgitation occurred in 3 patients (2 mild and 1 moderate).</td>
</tr>
<tr>
<td>Ye et al, 31 2006</td>
<td>10 transapical aortic valve replacements (including the 7 patients reported by Pasupati et al 30)</td>
<td>Edwards SAPIEN transcatheter heart valve</td>
<td>AVA had increased from 0.60 (SD, 0.14) cm² to 1.83 (SD, 0.68) cm², and the mean gradient decreased from 38.7 (SD, 12.7) mm Hg to 10.2 (SD, 5.8) mm Hg at 1-month follow-up. Mild aortic regurgitation occurred in 4 patients; no perioperative deaths or complications occurred. Thirty-day mortality was 10%; 1 patient died of pneumonia on POD 12. During 6-month follow-up of the initial 7 patients, 2 patients died of noncardiac causes. AVA was further increased at 6-month follow-up; valvular regurgitation occurred in 3 patients (2 mild and 1 moderate).</td>
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Stent fractures occurred in 19.5% of the series of 123 percutaneous PVRs reported by Nordmeyer et al\textsuperscript{33} from 8 to 843 days after insertion of the valve. A total of 4 patients required insertion of a second percutaneous PVR, and 1 required surgical explantation. Endocarditis and hemolysis have also been documented with percutaneous PVR,\textsuperscript{33} and it is unclear what the incidence of these problems will be with transcatheter and transapical AVR.

Other outcomes that should be monitored include death, stroke, myocardial infarction, paravalvular leaks, device migration, changes in signs and symptoms after implantation of the device, angiographic gradients, and rehospitalization.\textsuperscript{16} Until it can be determined that the newer AVR technologies are as durable as conventional AVR, it would be unethical to offer this new technology to patients who are at low surgical risk for conventional AVR. For most patients, conventional AVR will remain the gold standard of treatment for the foreseeable future. As more experience is gained with less-invasive valve technology, outcomes most likely will improve.

<table>
<thead>
<tr>
<th>Study and year</th>
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<th>Outcomes</th>
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<tr>
<td>Grube et al,\textsuperscript{19} 2007</td>
<td>86 transcatheter aortic valve replacements at 3 sites (North America and Europe), 50 patients with the 21F device and 36 patients with the 18F device</td>
<td>CoreValve ReValving system</td>
<td>Mean valve area before the procedure was 0.60 (SD, 0.16) cm\textsuperscript{2}; AVA after the procedure was not reported. Patients treated with the 18F system had significantly more surgical cutdowns for access than did the 21F group. Twenty-five percent of the 18F group had procedures performed with local anesthesia of the groin vs none in the 21F group. Extracorporeal support was used in all of the 21F group, but 64% of the 18F group were treated with no hemodynamic support. Six patients (6%) had misplacement of the valve with urgent conversion to conventional aortic valve replacement. In 2 patients (2%), the device could not cross the calcified native valve despite valvuloplasty, and the procedure was abandoned. In 2 patients (2%), suboptimal placement of the valve with aortic regurgitation was corrected by implantation of a second valve inside the first valve. Dilatation to fully expand the prosthesis was needed in 24% of the patients. Five patients (6%) died, 3 of cardiac tamponade, 1 after conversion to balloon aortic valvuloplasty only, and 1 after conversion to surgical aortic valve replacement. Nine patients (10%) had a periprocedural stroke; none had myocardial infarctions. Overall 30-day mortality was 12%; in patients with device and procedural success, the mortality rates were 9% and 5%, respectively. New York Heart Association functional class improved significantly from 2.85 (SD, 0.73) to 1.85 (SD, 0.60; \textit{P} &lt; .001). The stiff delivery wire was modified because of cardiac tamponade from wire perforations. The aortic regurgitation grade was unchanged or reduced in 66% of patients. Aortic regurgitation increased to grade 2+ in 20% of patients and from 0 to grade 1+ in 14% (all paravalvular). No severe aortic regurgitation occurred. After 30 days, the regurgitation decreased from 2+ to 1+ or 0 in 6 patients and increased from 1+ to 2+ in 5 patients.</td>
</tr>
<tr>
<td>Problem</td>
<td>Expected Outcome</td>
<td>Nursing Interventions</td>
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<tr>
<td>Paravalvular leak and hemolysis resulting in anemia</td>
<td>No paravalvular or minimal paravalvular leak (the valve is not sutured in situ and held in place by the stent); an oversize valve must be selected to prevent paravalvular leak</td>
<td>A transesophageal echocardiogram is obtained during the procedure to confirm absence of a significant paravalvular leak or that any such leak is minimal. A transthoracic echocardiogram is obtained several days after the procedure to ensure that no paravalvular leak is present. Patients with more than a mild paravalvular leak should have serial measurements of hemoglobin, lactate dehydrogenase, and elevated lactate dehydrogenase, haptoglobin, and bilirubin levels. Patients with significant hemolysis may require transfusion of packed red blood cells to treat anemia.</td>
<td>Table 5: Nursing Care for Patients Undergoing Transcatheter and Transapical Aortic Valve Replacement</td>
</tr>
<tr>
<td>Diminished renal perfusion due to intravenous contrast material used to verify correct positioning of the valve, and possible preoperative renal insufficiency or renal failure</td>
<td>Maintenance of baseline hemoglobin levels</td>
<td>Monitor patients for signs of allergic reaction including dyspnea, rash, pruritus, and hypotension and intervene rapidly with further antihistamines, steroids, and airway protection measures if any signs of reaction occur.</td>
<td></td>
</tr>
<tr>
<td>Allergic reaction due to allergy to contrast material</td>
<td>No allergic reaction will occur with administration of intravenous contrast material</td>
<td>Baseline creatinine and electrolyte levels are assessed before the procedure. Patients with renal insufficiency will ... creatinine and electrolyte levels after the procedure; continued monitoring of electrolyte and creatinine levels after any postprocedural increase in creatinine level has started to decline.</td>
<td></td>
</tr>
<tr>
<td>Bleeding due to possible allergies to intravenous contrast material</td>
<td>No significant bleeding noted immediately</td>
<td>Baseline creatinine and electrolyte levels are assessed before the procedure. Patients with renal insufficiency will ... creatinine and electrolyte levels after the procedure; continued monitoring of electrolyte and creatinine levels after any postprocedural increase in creatinine level has started to decline.</td>
<td></td>
</tr>
<tr>
<td>Patients will require intravenous hydration with normal saline before the procedure</td>
<td>No significant bleeding noted immediately</td>
<td>Perform baseline complete blood cell count, noting in particular the hemoglobin level and platelet count.</td>
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<td>Patients with a history of preprocedural clopidogrel (Plavix) and aspirin loading to prevent thrombosis of the stent or frame on which the valve is loaded. With transcatheter aortic valve replacement, bleeding may be initiated by the long sheath used to deploy the valve</td>
<td>Significant bleeding is treated immediately</td>
<td>Patients should be screened for prior allergic reaction to intravenous contrast material before the procedure; patients with iodine or shellfish allergies should be considered at risk for allergic reactions. Patients with possible allergies to intravenous contrast material should be premedicated with steroids (eg, prednisone or methylprednisolone) and antihistamines (eg, diphenhydramine) per institutional protocol.</td>
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<tr>
<td>Patients with significant hemolysis may require transfusion of packed red blood cells to treat anemia</td>
<td>No significant bleeding noted immediately</td>
<td>Patients with elevated potassium levels (eg, prednisone or methylprednisolone) and antihistamines (eg, diphenhydramine) per institutional protocol.</td>
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<td>Condition</td>
<td>Description</td>
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<tr>
<td>Hematoma</td>
<td>No hematoma</td>
<td>For patients with transcatheter aortic valve replacement, inspect the catheter insertion site (may be a cutdown) every 30 minutes for 2 hours, then every hour for 4 hours, and then every 4 hours for 24 hours for bleeding; apply direct pressure to actively bleeding site; observe the catheter insertion site for the development of ecchymoses and hematoma. Patients stay on bed rest with no flexion of the leg on the side where the catheter was inserted for at least 4 to 6 hours after the procedure.</td>
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<tr>
<td>Impaired cerebral perfusion due to embolization of calcified material to the cerebral circulation from balloon valvuloplasty before valve placement</td>
<td>No changes in baseline cognitive function</td>
<td>Baseline neurological vital signs are assessed by a nurse before the procedure; the Mini-Mental State Examination™ is also helpful preoperatively and if any alteration in cognitive function is apparent after the procedure. Neurological vital signs should be assessed until patients are fully awake after the procedure; any alterations in neurological functioning should be investigated immediately with a computed tomography scan (magnetic resonance imaging is relatively contraindicated because of the sutureless stent valve that could be malpositioned by the magnetic forces; refer to specific manufacturer's recommendations).</td>
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<tr>
<td>Pain due to incisions, catheter insertion sites, aortic dissection</td>
<td>Adequate pain control will facilitate chest physiotherapy (especially after transapical aortic valve replacement)</td>
<td>Monitor pain scores every hour for 4 hours and then every 2 to 4 hours. Monitor patients who have undergone transcatheter aortic valve replacement for groin or back pain (could indicate an aortic dissection caused by the stiff catheters used); aortic dissection is an emergency, and patients should be assessed by a physician or nurse practitioner immediately. With transapical aortic valve replacement, intravenous analgesia is used until the chest drain is removed, and then oral analgesia may be instituted.</td>
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<tr>
<td>Atelectasis due to the incision for transapical aortic valve replacement</td>
<td>Prevention of atelectasis due to the incision for transapical aortic valve replacement</td>
<td>Teach patients before the procedure about use of the incentive spirometer and effective deep breathing and coughing. Assess baseline lung function with pulmonary function tests and oximetry if the patient has any respiratory comorbid diseases. Postprocedural incentive spirometry, deep breathing, and coughing exercises every hour while the patient is awake. Monitor oximetry continuously while patients are in the intensive care unit and then every 4 hours and as needed after transfer to the intermediate care unit; titrate oxygen to achieve oxygen saturations &gt;94% if oxygen saturations are normal before the procedure (if a patient has chronic obstructive pulmonary disease, individual goals for the patient's oxygen saturation should be established). Ensure that pain is sufficiently controlled to facilitate adequate lung expansion. Auscultate the lungs every 6 hours and as needed to assess air entry.</td>
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<tr>
<td>Decreased peripheral perfusion due to calcium embolization to the peripheral vasculature from balloon valvuloplasty in order to place valve</td>
<td>No change from baseline peripheral perfusion, as evidenced by no change in peripheral pulses, limb color, or limb temperature</td>
<td>Complete baseline vascular assessment before the procedure, and note position and strength of leg pulses. Doppler images of leg arteries and angiographic assessment of iliac artery size and patency completed before procedure. Do a peripheral vascular assessment (pulses, color, temperature of all extremities) every 30 minutes for 1 hour, then every hour for 4 hours, and then every 4 hours for 48 hours after the procedure. Any alteration in peripheral vascular perfusion should be assessed immediately by a vascular surgeon.</td>
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<tr>
<td>Myocardial infarction due to embolization of calcified material from balloon valvuloplasty before valve placement or obstruction of the coronary arteries by the stent or frame of the valve</td>
<td>No changes from baseline electrocardiogram</td>
<td>Obtain a baseline 12-lead electrocardiogram before the procedure, immediately after the procedure, and 24 hours after the procedure. Cardiac monitoring should be continuous for at least 24 hours after the procedure and if the patient has any chest pain. If any chest pain or electrocardiographic changes suggestive of myocardial ischemia or infarction occur (inverted T waves, ST-segment elevation or depression, new Q waves), obtain serial measurements of the serum level of troponin and 12-lead electrocardiograms.</td>
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Continued
### Table 5  Continued

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<tr>
<th>Problem</th>
<th>Expected outcome</th>
<th>Nursing interventions</th>
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<tbody>
<tr>
<td>Decreased cardiac output due to iliac/femoral artery or ventricular perforation resulting in cardiac tamponade</td>
<td>No iliac/femoral artery dissection or perforation (with transcatheter aortic valve replacement) or ventricular perforation</td>
<td>With transcatheter aortic valve replacement, monitor the patient for aortic dissection, cardiac tamponade, or iliac/femoral artery perforation due to the wires/catheter system used to position the valve. Signs and symptoms of aortic dissection or iliac/femoral artery perforation include acute onset of back pain, flank pain, or groin pain and hypotension. With transapical aortic valve replacement, monitor for signs of pericardial effusion and cardiac tamponade after the procedure. Signs of pericardial tamponade include hypotension, tachycardia, orthopnea, elevated central venous pressure, equalization of intracardiac diastolic pressures (ie, central venous pressure, pulmonary artery diastolic pressure). With transapical aortic valve replacement, the chest drain is left in situ until drainage is minimal (&lt;100 mL in 12 hours) and the drainage is no longer sanguineous. Patients should be placed upright before drain removal to ensure that all pericardial fluid has been drained. If a pericardial effusion is present, serial transthoracic echocardiograms are obtained to monitor the size of the effusion and whether tamponade is present. A transthoracic echocardiogram is done several days after the procedure to ensure that no significant pericardial effusion has occurred. Pericardial effusion can be treated with high doses of anti-inflammatories such as aspirin.</td>
</tr>
<tr>
<td>Pericardial effusion resulting from transapical aortic valve replacement</td>
<td>Signs of aortic dissection or iliac/ femoral artery perforation are detected and treated immediately. Minimal pericardial effusion and no cardiac tamponade.</td>
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</table>
| Infection (incisional, infective endocarditis)                         | No incisional infection. No infective endocarditis.                               | Screen patients for any recent fever or signs of infection before the procedure. Note patient's last dental visit and dental condition. Any infections, including dental infections, should be dealt with before the procedure. Measure patient's temperature before the procedure, immediately after the procedure, and every 4 hours for 12 hours and then 4 times daily until hospital discharge. Inspect the incisional sites twice daily for any signs or symptoms of infection (purulent drainage, pain, redness). Cleanse the incisions daily and as needed with chlorhexidine and apply a dry dressing until the drainage has ceased. Obtain a blood sample for a white blood cell count before the procedure and daily thereafter while the patient is in the hospital and monitor for elevated counts. Obtain samples for blood and urine cultures if patient's temperature is greater than 38.5°C. Obtain samples for sputum cultures if patient's temperature is greater than 38.5°C if the cough is productive. Instruct the patient to report any significant fevers or incisional discharge that occurs after discharge, because fevers could indicate infection. Before discharge, teach patients about use of infective endocarditis prophylaxis for life as per the 2007 American Heart Association Infective Endocarditis Guidelines.
|
Future Directions

Removal and ablation of the native aortic valve in situ might be possible in the future with lasers to facilitate positioning of a new valve. This procedure would need a filtering mechanism to prevent embolization of valve remnants. Tissue-engineered heart valves may be placed by transcatheter or transapical routes in the future. These grafts consist of a scaffold seeded with host cells that eventually cover the scaffold. The valve can then be conditioned to function under normal intracardiac pressures before implantation.

Nursing Implications of Transcatheter and Transapical AVR

Table 5 presents the nursing care required by patients undergoing transcatheter and transapical AVR. Because multiple comorbid diseases may have made a patient a candidate for transcatheter and transapical AVR, much of the focus of nursing care is on preventing complications due to these comorbid conditions. The case study highlights key concepts of the nursing care.

Summary

Transcatheter and transapical AVR are new technologies that could benefit many patients who are considered high-risk candidates for traditional surgical AVR. Although experiences with transcatheter and transapical AVR are limited, preliminary results indicate that these techniques are feasible in selected high-risk patients and have satisfactory short-term outcomes. Long-term follow-up in a larger population of patients is needed to determine if transcatheter and transapical AVR reduce surgical risk, lower complication rates, and produce satisfactory longer term outcomes.

Financial Disclosures

None reported.

References


Transcatheter and Transapical Aortic Valve Replacement

Facts

- Minimally invasive valve replacement is now clinically available in a few centers and is currently limited to bioprosthetic aortic and pulmonary valves for use in very specific populations of patients.
- Because of the good outcomes with traditional aortic valve replacement, replacement via transcatheter and transapical techniques should be used only in patients in whom traditional surgical replacement of the aortic valve is deemed an unacceptable risk.
- Only short-term follow-up data on outcomes with these new valves are available.
- Nursing management with transcatheter and transapical aortic valve replacement will focus heavily on care for comorbid conditions because of the high-risk nature of the patients in whom these valves will initially be implanted.

Table

<table>
<thead>
<tr>
<th>Indications for transcatheter and transapical aortic valve replacement</th>
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<td>Severe, symptomatic aortic stenosis</td>
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<tr>
<td>Estimated operative mortality for conventional aortic valve replacement &gt;20% according to established risk calculators</td>
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<tr>
<td>Severe ascending aortic calcification such as porcelain aorta that prevents aortic cannulation or cross-clamping</td>
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<td>Severe radiation damage to the chest or other severe chest deformities that would preclude a sternotomy (transcatheter approach used because radiation damage may also prevent a transapical approach)</td>
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<tr>
<td>Patients’ willingness to comply with follow-up evaluations to assist with ongoing development of this new technology (will be a requirement of ethics boards that approve studies with these valves)</td>
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This article and an online version of the CE test may be found online at www.ccnonline.org.
Learning objectives: 1. List 3 indications and contraindications for performing transcatheter and transapical aortic valve replacement (AVR) on specific patient populations. 2. Discuss the advantages of less-invasive insertion techniques for higher risk AVR patients. 3. Identify 4 potential postoperative complications that could occur following transcatheter and transapical AVR and describe nursing interventions for each.

1. An advantage of not cross-clamping the aorta during minimally invasive valve replacement would include which of the following?
   a. Decreases the risk of bleeding
   b. Decreases the risk of stroke
   c. Decreases creatinine levels
   d. Decreases risk of infection

2. What was the first transcatheter valve replacement?
   a. Bovine jugular vein valve replacement of a pulmonary valve
   b. Porcine jugular vein valve replacement of aortic valve
   c. Bovine jugular vein valve replacement of an aortic valve
   d. Porcine jugular vein valve replacement of a pulmonary valve

3. Which of the following are contraindications for transcatheter and transapical valve replacement?
   a. Severe, symptomatic aortic stenosis
   b. Estimated patient lifespan of less than 1 year
   c. Severe aortic valve calcification
   d. Renal failure with creatinine clearance > 20 mL/min

4. Which of the following tests may be ordered to ensure the femoral and iliac vessels are large enough to accommodate transcatheter aortic valve replacement (AVR)?
   a. Computed tomographic angiogram and echocardiogram
   b. Angiogram and transesophageal echocardiographic imaging
   c. Computed tomographic angiogram and femoral doppler imaging
   d. Computed tomographic angiogram and transcranial doppler imaging

5. Why does transcatheter AVR with the Edwards valve require rapid cardiac pacing?
   a. To increase cardiac output during placement
   b. To decrease cardiac afterload during placement
   c. To increase cardiac contractility during placement
   d. To decrease cardiac output during placement

6. What is an advantage of using the transapical approach instead of the transcatheter approach?
   a. The transcatheter approach is quicker but more technically difficult than the transapical approach.
   b. The transapical approach is less technically difficult and quicker than the transcatheter approach.
   c. The transapical approach is safer in cases of left ventricular scarring than the transcatheter approach.
   d. The transapical approach is safer in cases of ventricular aneurysms than the transcatheter approach.

7. If a patient complains of back and flank pain and is hypotensive after a transcatheter AVR, what would the nurse suspect the patient may be experiencing?
   a. Pericardial effusion
   b. Cardiac tamponade
   c. Aortic dissection
   d. Valve embolization

8. Because of the use of intravenous contrast material during placement verification for transcatheter and transapical AVR, what nursing interventions should be performed preoperatively for all patients undergoing transcatheter and transapical AVR?
   a. Obtaining baseline serum urea nitrogen and creatinine levels
   b. Hydrating the patient with D5.45NS
   c. Treating potassium levels >3.5 mmol/L
   d. Obtaining baseline clotting studies

9. Which of the following tests is indicated for patients experiencing hemiplegia after a transcatheter or transapical AVR?
   a. Magnetic resonance imaging of the brain
   b. Computed tomography scan of the brain
   c. Mini-Mental State Exam
   d. Arterial doppler images of the leg

10. What is the most recent version of the Edwards SAPIEN valve?
    a. A bovine trileaflet valve
    b. A porcine trileaflet valve
    c. An equine trileaflet valve
    d. A mechanical valve

11. According to data collected between 1994 and 2003 by the Society of Thoracic Surgeons, what was the most common complication of valve surgery?
    a. Prolonged mechanical ventilation
    b. Atrial fibrillation
    c. Stroke
    d. Pneumonia

12. Which type of valve is the most recent version of the Edwards SAPIEN valve?
    a. A bovine trileaflet valve
    b. A porcine trileaflet valve
    c. An equine trileaflet valve
    d. A mechanical valve

Test answers: Mark only one box for your answer to each question. You may photocopy this form.

1. □ a □ b □ c □ d
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Transcatheter and Transapical Aortic Valve Replacement
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