Transcatheter Aortic Valve Replacement

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Aortic stenosis is the most frequently acquired heart disease, and the prevalence is rising because of the aging population. If the disease is left untreated, survival in symptomatic patients averages only 2 to 3 years. Surgical aortic valve replacement is the only definitive treatment, yet 30% of elderly patients are not considered candidates because the presence of comorbidities makes the risk of sternotomy and cardiopulmonary bypass prohibitively high. Transcatheter aortic valve replacement (TAVR) is an innovative, high-tech, less invasive alternative. The procedure is usually performed using general anesthesia and a multidisciplinary team from interventional cardiology and cardiothoracic surgery in a "hybrid" operating environment with advanced imaging capabilities. There are 2 major catheter-based approaches to the aortic valve: retrograde percutaneous through the femoral artery and aorta or direct antegrade through a thoracotomy and the left ventricular apex. Apnea and rapid ventricular pacing are used to interrupt cardiac ejection during balloon valvuloplasty and prosthesis implantation. The most significant complications include vascular damage, stroke, paravalvular aortic insufficiency, and heart block. Outcomes studies comparing TAVR with medical management demonstrate improved patient survival, functional status, and quality of life. Currently TAVR is considered the treatment of choice for patients who are not surgical candidates and is a proven alternative for high-risk surgical candidates.

Keywords: Aortic stenosis, cardiac anesthesia, hybrid operating room, transcatheter aortic valve implantation, transcatheter aortic valve replacement.

Objectives

At the conclusion of this educational activity, the learner should be able to:

1. Outline the general indications and contraindications to TAVR.
2. Describe the TAVR procedure including the retrograde transfemoral and antegrade transapical surgical approaches.
3. Discuss the features of the hybrid operating room environment and explain the anesthetic implications of working in this location.
4. List the risks and complications of the antegrade and retrograde approach to TAVR and discuss the strategies the nurse anesthetist can take to help avoid and manage complications.
5. Develop an evidenced based anesthetic plan for a patient undergoing TAVR.

Introduction

Transcatheter aortic valve replacement (TAVR) has been called "the most exciting recent advancement in interventional cardiology and cardiovascular surgery."[1] Degenerative aortic stenosis (AS) is the most frequent acquired heart disease. If left untreated, AS inevitably leads to physical deterioration, heart failure, and death.[2] Surgical aortic valve replacement (SAVR) is considered the gold-standard treatment, yet 30% of patients are not considered candidates for traditional sternotomy and cardiopulmonary bypass (CPB) by their cardiologists because the presence of advanced age and multiple comorbidities makes the risk prohibitively high.[3] Transcatheter aortic valve replacement, also known as transcatheter aortic valve implantation, offers this population a less invasive treatment option. In 2002, Dr Alain Cribier placed the first transcatheter, transfemoral heart valve in a human.[4] Since then, clinical outcomes have steadily improved and to date, there have been more than 50,000 implants in 60-plus countries.[4,5] On November 2, 2011, the US Food and Drug Administration (FDA) announced the approval of the SAPIEN Transcatheter Heart Valve (THV)

Indications	Contraindications

• Severe, symptomatic, calcific, degenerative aortic stenosis
  • Aortic valve area < 1.0 cm^2
  • Gradient (mean > 40 mm Hg; systolic > 80 mm Hg)
  • Jet velocity > 4.0 m/s
  • Symptoms of angina, syncope, or heart failure
  • Worsening left ventricular function
• Medical factors that preclude surgery or make it very high risk (≥ 15% mortality), as agreed by heart team members, including an interventionalist and 2 cardiothoracic surgeons
  • EuroSCORE ≥ 20%
  • Society of Thoracic Surgeons score ≥ 10%
• Life expectancy > 1 year
	• Acute myocardial infarction or therapeutic intervention ≤ 1 month (6 months for drug-eluting stent)
	• Aortic valve is:
	  • Congenital unicuspid or bicuspid (relative)
	  • Noncalcified, annulus size < 16 mm or > 24 mm
	  • Coexisting aortic regurgitation (> 3+) (relative)
	• Preexisting prosthetic heart valve or ring (relative)
	• Coexisting cardiac disease that requires surgery (coronary artery disease or mitral regurgitation)
	• Blood dyscrasias
	• Hemodynamic instability and/or severe left ventricular dysfunction < 20%, severe pulmonary hypertension, and right ventricular dysfunction
	• Significant aortic, iliofemoral, or renal disease (relative)

Table 1. Indications and Contraindications to Transcatheter Aortic Valve Replacement

for inoperable cases and on October 19, 2012, for high-risk surgical candidates in the United States. Multiple other valves are in varying stages of development, and some pivotal trials are nearing completion. Many experts speculate that in the next 10 years, TAVR will become the dominant therapy for calcific AS.[4,5] Usually, TAVR is performed with the patient under general anesthesia by a multidisciplinary team from interventional cardiology and cardiothoracic surgery in a "hybrid" operating environment that includes advanced imaging capabilities. The potential for life-threatening complications exists in every step of the TAVR procedure. Careful preparation, vigilant monitoring, and treatment of complications by the anesthesia team are keys to successful implantation. Development of an evidenced-based anesthetic plan necessitates a thorough understanding of the patient, the environment, and the procedure.

Patient Selection

Aortic valve replacement is typically indicated in patients with severe, echocardiography-documented AS who have 1 or more of the classic symptoms of angina, syncope, and congestive heart failure. Aortic valve replacement may also be recommended for asymptomatic patients with worsening left ventricular (LV) dysfunction. Surgical aortic valve replacement is the only treatment that is considered a class I recommendation by the American College of Cardiology Foundation (ACCF), American Heart Association, and European Society of Cardiology guidelines[6] because it is generally low risk (2.5%-4.0%)[7] and increases 3-year life expectancy by 4.1-fold.[8] However, in the elderly with significant comorbidities, the surgical morbidity can be as high as 25%.[9]

The classic indications and contraindications to TAVR are listed in Table 1. The indications for TAVR are rapidly expanding along with the technology. Both the

Valve Academic Research Consortium and the ACCF/American Association of Thoracic Surgery (AATS) have recently published expert consensus documents that detail risk stratification.[6,10,11] In general, both groups recommend that the patient be evaluated by an expert heart team that consists of interventional cardiologists, cardiovascular surgeons, anesthesiologists, and imaging specialists who can review and interpret individual clinical data to recommend the optimal treatment strategy for each particular patient. The typical TAVR candidate is elderly, often in the eighth or ninth decade of life, with multiple comorbidities such as prior myocardial infarction (MI), prior open heart surgery, LV dysfunction, lung disease, diabetes, prior stroke, peripheral vascular disease, and renal insufficiency.[12] Although the procedure is technically feasible in most patients, there is mounting evidence that placement should be avoided in extremely frail individuals and should be reserved for those in whom the procedure is likely to offer a substantial improvement in quality and duration of life.[5,10,13]

Procedural Environment

Recently the ACCF and the Society of Thoracic Surgeons (STS) recommended that TAVR be restricted to regional centers of excellence because of the high procedural risk and the extensive supportive infrastructure that is required to attain adequate volumes and optimize outcomes.[6] Transcatheter aortic valve replacement is performed in a multidisciplinary, hybrid environment that combines elements of an operating room, cardiac catheterization laboratory, and interventional radiology. Teams from cardiothoracic surgery, interventional and imaging cardiology, anesthesia, perfusion and industry are involved, surrounded by the complex equipment necessary to conduct the procedure. The anesthesia team coordinates the multifaceted care and communication

Valve characteristic	Edwards SAPIEN	Edwards SAPIEN XT	Medtronic CoreValve
Frame	Stainless steel	Cobalt-chromium	Nitinol (nickel-titanium memory shape alloy)
Leaflets	Bovine pericardium	Bovine pericardium	Porcine pericardium
Expansion	Balloon-expanding	Balloon-expanding	Self-expanding
Sizes available in United States (available in some countries)	23, 26 mm	23, 26 mm (20, 29 mm)	26, 29 mm (31 mm)
Sheath internal diameter	22F, 24F	18F, 19F	18F
Repositionable/retrievable	No	No	Yes
Alternate access	Transapical (primary) transaxillary (limited experience), transaortic	Transapical (primary) transaxillary (limited experience), transaortic	Transaxillary, transaortic
Delivery system	RetroFlex 3: transfemoral Ascendra: transapical	NovaFlex: transfemoral Ascendra 3: transapical	AccuTrak delivery catheter
FDA approval	Yes	No	No
Randomized trial	PARTNER I, cohorts A and B; results published in 2010, 2011	PARTNER II, cohorts A and B; estimated completion in 2018	CoreValve US pivotal trial; preliminary results expected in 2013

Table 2. Comparisons of Transcatheter Heart Valves[a]
Abbreviations: FDA, Food and Drug Administration; PARTNER, Placement of AoRtic TraNscathetER valves.
[a] SAPIEN and SAPIEN XT are from Edwards Lifesciences LLC. The CoreValve system (Medtronic CV Luxembourg) is not commercially available in all countries and is an investigational device in some countries such as the United States.

that is essential throughout the perioperative period. Additionally, it is the vigilance of the anesthesia provider that often averts mishaps and helps identify and treat complications. Depending on the location of the hybrid suite in a facility, the anesthesia team may have to deal with all the challenges and safety considerations of providing care in a remote location. Radiation safety is another major concern. A recent report documented that the anesthesia team, located near the patient's head, is exposed to significantly higher levels of radiation than other team members in interventional operating environments.[14] A CPB pump and a perfusionist must also be in the room. Preemptive priming of the CPB circuit is based on surgeon preference. Some centers also use cell salvage.

Transcatheter Heart Valves
Animal experiments using biological heart valves mounted on collapsible metal scaffolds were conducted in the 1990s. The first in-human transfemoral THV was placed in France by Dr Alain Cribier and his team in 2002.[4] In Europe, TAVR has been approved since 2007, and to date there have been more than 50,000 TAVR procedures performed worldwide.[4] The United States lagged behind the Western world in approving TAVR because regulators insisted on waiting for the results of the randomized, controlled Placement of AoRtic TraNscathetER (PARTNER) trial. The findings of the PARTNER trial subsequently

demonstrated that the Edwards SAPIEN THV is "superior" to standard medical therapy in patients who are considered extremely high risk or "inoperable"[15] and that it is "noninferior" or a proven alternative to SAVR in patients who are considered high risk but able to have the operation.[16] In November 2011, the United States became the 43rd country to approve TAVR. As of March 2013, the Edwards SAPIEN THV is the only THV approved for implantation in the aortic position in the United States. However, there are more than 8 such valves in commercial development.[17]

Additionally, there are currently 2 pivotal trials investigating newer valve designs with smaller delivery systems: the SAPIEN XT THV with the NovaFlex transfemoral system and the Ascendra transapical system (Edwards Lifesciences); and the CoreValve ReValving System (Medtronic). The PARTNER II trial is investigating the second-generation SAPIEN XT valve and delivery system as well as comparing TAVR with SAVR in intermediate-risk patients. The CoreValve US pivotal trial has completed enrollment in the extreme high-risk (inoperable) cohort, and initial results are expected later this year. Medtronic reportedly hopes to bring the product to market soon thereafter. Although the SAPIEN XT and CoreValve are in widespread use around the world, at this time, use in the United States is limited to patients enrolled in the clinical trials.[5] Table 2 compares

Figure 1. Transcatheter Heart Valves
Edwards SAPIEN (left, Edwards Lifesciences LLC) and SAPIEN XT (center) and CoreValve (right, Medtronic CV Luxembourg) valves. (Images of SAPIEN and SAPIEN XT valves provided courtesy of Edwards Lifesciences LLC, Irvine, CA. Image of CoreValve courtesy of Medtronic CV Luxembourg Sarl, Luxembourg, Belgium. CoreValve is not commercially available in all countries and is an investigational device in the United States.)
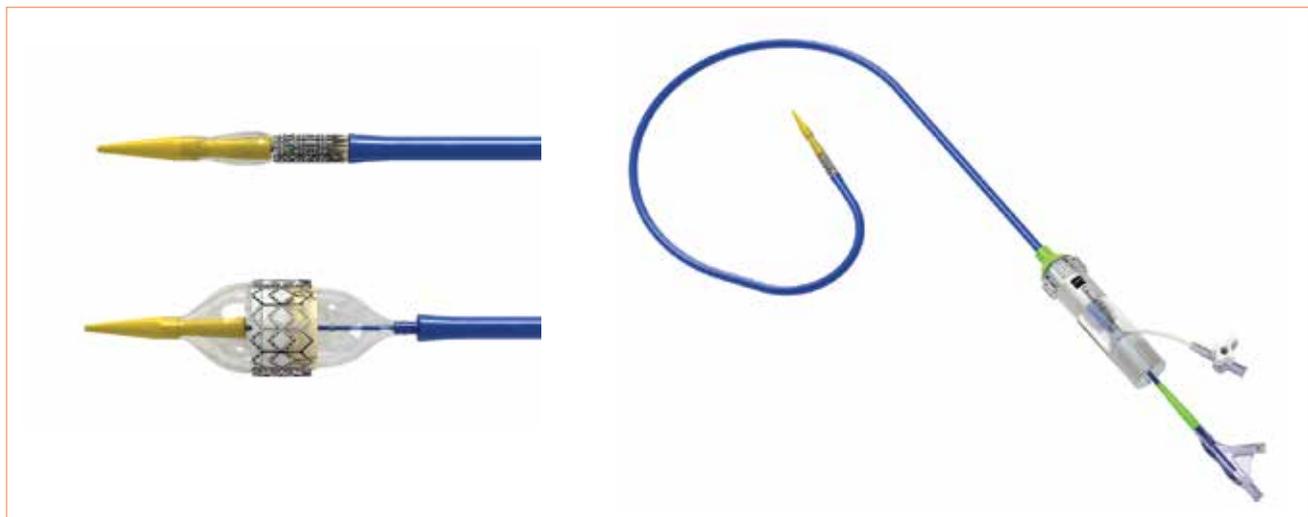

Figure 2. Edwards SAPIEN Transcatheter Heart Valve and RetroFlex 3 Delivery System
(Images provided courtesy of Edwards Lifesciences LLC, Irvine, CA.)

the various valves (shown in Figure 1), and Figure 2 shows the RetroFlex 3 delivery system. Correct sizing of the valve and determination of the approach requires anatomical evaluation of the heart and vasculature using transesophageal echocardiography (TEE), contrast multidetector computed tomography, magnetic resonance imaging, or invasive angiography.

Transcatheter Aortic Valve Replacement Procedure

• *Surgical Access.* Figure 3 anatomically illustrates the various surgical approaches for placement of THVs. The *transfemoral retrograde* approach is preferred (Figure 4C). The main steps of the procedure and possible complications are outlined in Table 3. When TAVR was first performed, the femoral artery was accessed by means of a surgical cutdown. Current practice typically involves percutaneous puncture for arterial access and the use of a vascular closure device.[18] Access begins with a wire, then a series of dilators are placed, and finally the large sheath for the delivery catheter is introduced. Heparin is admin-

istered before sheath placement. The right femoral artery is most often used for the valve delivery system, but this can vary depending on the patient's anatomy. The left femoral artery is also accessed for contrast dye injection through a pigtail catheter, right ventricular pacing, and cannulation if necessary for urgent CPB.

Vascular injury is the most common complication of TAVR and is often associated with morbidity and mortality. Bleeding can be insidious (hidden in the surgical drapes or retroperitoneum) or massive (requiring urgent CPB). Delivery systems that require larger sheaths have reported vascular complication rates between 11% and 17%, but newer generation devices that require smaller diameter sheaths seem to be reducing the vascular complication rate to as low as 1% to 3%.[18]

• *Alternate Access.* When vascular access is limited because of peripheral vascular disease or a severely calcified "porcelain aorta," the *antegrade transapical* route is used with the SAPIEN THV. In addition to achieving femoral venous and femoral arterial access for the transapical approach, a left anterior minithoracotomy incision
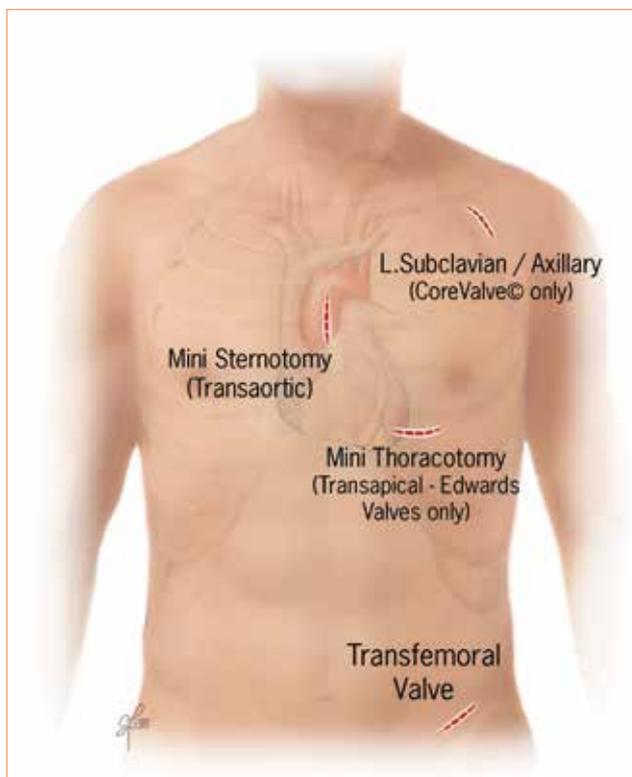
Figure 3. Anatomical Areas Showing Surgical Approaches for Transcatheter Aortic Valve Replacement
Abbreviation: L., left.

is made through the fifth or sixth intercostal space over the LV apex (see Figures 3, 4A, and 4B). The surgeon opens the pericardium and places purse-string sutures in the LV apex. Next, the apex is punctured to allow the bioprosthetic valve to be delivered (under TEE and fluoroscopic guidance) through the LV into the aortic valve annulus in an antegrade fashion. The main disadvantages to the transapical approach is the need for a thoracotomy, which is associated with greater postoperative pain, lung dysfunction, myocardial injury and the potential for life-threatening bleeding associated with the apical puncture.[19]

Another alternative approach that is becoming increasingly common is *retrograde transaortic*. This approach requires a small right or midsternotomy and allows the surgeon to approach the valve from the same direction that is used for standard surgical replacement. Both the SAPIEN and CoreValve can be placed transaortic.[19] The media has coined this approach "valve-on-a-stick."[20] The CoreValve can also be placed using a transaxillary or subclavian retrograde approach.

• *Ventricular Pacing.* After achieving vascular access, a pacemaker wire is inserted into the right ventricle and tested at a rate of 200 ± 20/min to ensure capture. Rapid ventricular pacing (RVP) is used to reliably create a state of low blood flow. Pacing the ventricles at this rapid rate is clinically equivalent to artificially creating a state of "pulseless ventricular tachycardia" in which the
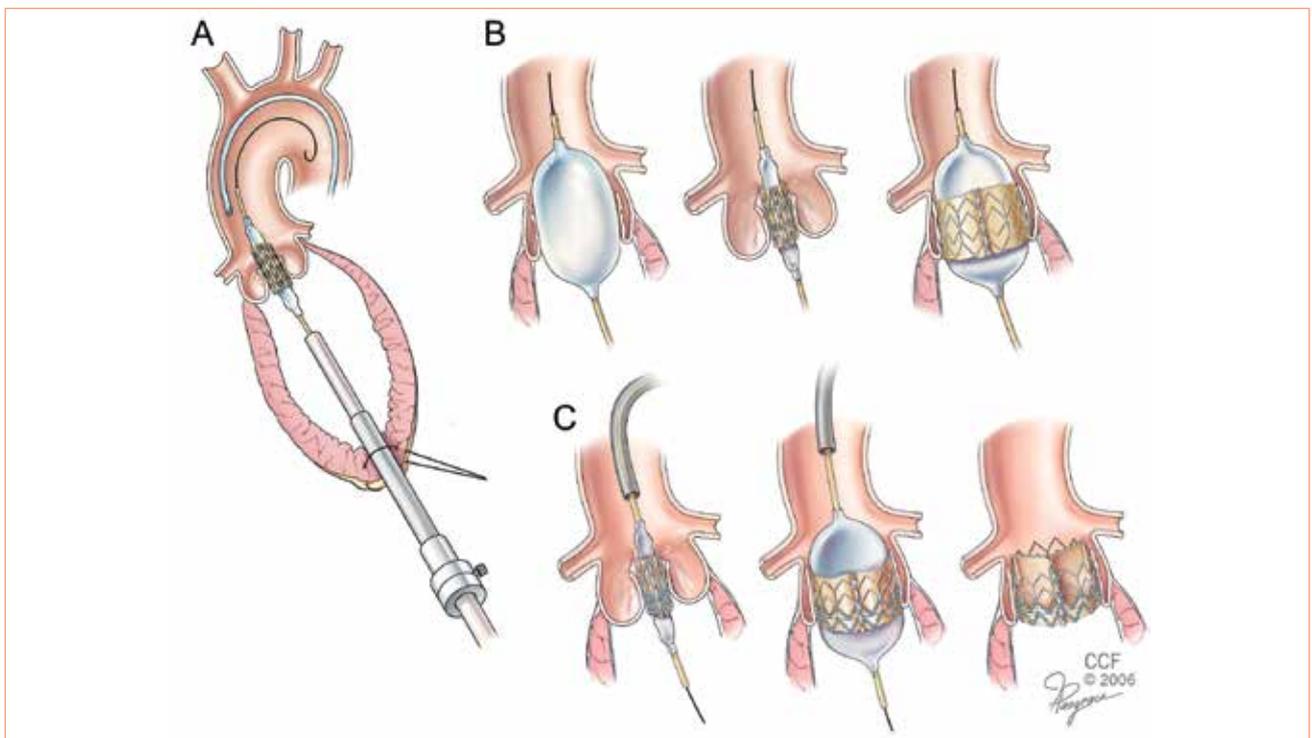

Figure 4. Surgical Approaches for Transcatheter Aortic Valve Replacement
(A) Antegrade transapical approach. (B) Transapical balloon valvuloplasty followed by valve deployment. (C) Retrograde transfemoral valve deployment.

Key steps in TAVR procedure	Potential complications

1. Vascular or thoracic access
  • 20- to 23-mm balloon-tipped valvuloplasty wire advanced across aortic annulus
  • Catheters and guidewires for dye injection and CPB
	• Vascular complications are the most common
	• Dissection or perforation of femoral vessels or aorta, hemorrhage, retroperitoneal hematoma
	• Perforation of left ventricle or damage to left lung with transapical approach

2. Right ventricle pacemaker placed • Tested at rate of 200 ± 20/min with ventilation held to achieve low cardiac output state and motionless field	• Perforation of the right atrium or ventricle with wires • Dysrhythmias leading to hemodynamic deterioration or sustained VT/VF
3. Balloon valvuloplasty (rapid V-pace and apnea) to dilate the calcified aortic annulus	• Displacement of small calcified particles increasing the risk of stroke or MI, occlusion of the coronaries by the native valve leaflet, hemodynamic deterioration or sustained VT or VF, rupture of aortic annulus
4. Femoral artery dilated, device introduced via sheath and carefully positioned using fluoroscopy and TEE	• Displacement of small calcified particles increasing the risk of stroke or MI • Vascular damage, aortic dissection
5. Valve deployed under rapid V-pace and apnea to achieve low cardiac output state and motionless field	• Occlusion of the coronaries by the native valve leaflet, valve embolization, rupture of aortic annulus, aortic dissection, displacement of small calcified particles increasing the risk of stroke or MI, hemodynamic deterioration, new left bundle branch block or complete heart block, sustained VT/ VF
6. Position and function of valve evaluated with TEE and fluoroscopy before surgical closure	• Paravalvular insufficiency, intravalvular insufficiency, reaction to dye injection, acute kidney injury, hemorrhage

Table 3. Steps and Potential Complications of Transcatheter Aortic Valve Replacement Procedure
Abbreviations: CPB, cardiopulmonary bypass; MI, myocardial infarction; TEE, transesophageal echocardiography; TAVR, transcatheter aortic valve replacement; V, ventricular; VF, ventricular fibrillation; VT, ventricular tachycardia.

heart does not have time to repolarize completely and is consequently unable to adequately fill or eject blood. Rapid ventricular pacing is more reliable and controllable than injecting adenosine in hopes of causing a short period of asystole. Ventilation is suspended during RVP to achieve a motionless field. This state of low blood flow and motionless field is used to decrease the risk of improper placement of the valvuloplasty balloon and THV. Hemodynamic instability and serious dysrhythmias may develop in the peripacing period. Additionally, the right atrium or ventricle could be damaged or perforated by pacemaker wires.

Balloon valvuloplasty of the native aortic valve is performed using RVP and apnea before prosthetic valve implantation. During the procedure, small calcified particles may be displaced increasing the risk of stroke or MI. It is also possible to rupture the aortic annulus or the aorta.

• *Valve Deployment.* The valve is loaded on a balloon-expanding catheter that is introduced using a large 18F to 24F sheath. Placement of the sheath requires progressive dilation of the femoral and iliac arteries. Fluoroscopy, angiography, and TEE are used to ensure optimal positioning of the insertion device across the native aortic valve. Correct placement in the aortic annulus is critical for proper function. Before valve deployment, RVP is instituted and ventilation is held to achieve a low-flow state and motionless field to prevent valve embolization into the left ventricle or distal aorta. Deployment is ini-
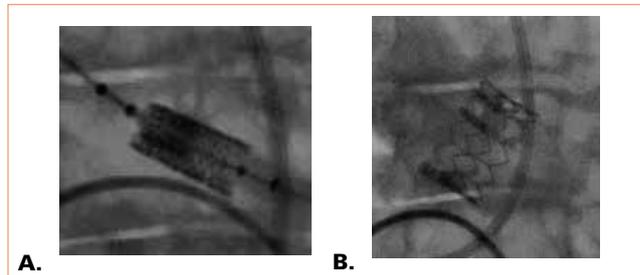

Figure 5. Fluoroscopy Images of Transcatheter Aortic Valve Replacement Using Edwards Valves
(A) Crimped valve on a balloon-expanding catheter. (B) Fully expanded, deployed valve.

tiated when optimal positioning has been attained and the TEE and arterial line indicate a loss of ventricular ejection. The Edwards valves are placed using a balloon-expanding catheter.[21] See Figures 4 and 5 and watch an animation of the placement at the Edwards website.[22] The CoreValve is made of a self-expanding nickel-titanium memory-shape alloy (Nitinol) that is malleable at low temperatures but relatively rigid at body temperature. The valve is deployed by retracting the outer sheath and does not require RVP. This feature also makes the CoreValve somewhat repositionable and retrievable.[19]

Hemodynamic instability is relatively common following valve deployment, especially in patients with LV dysfunction. Valve deployment carries all the risks discussed

with balloon valvuloplasty. Once the THV is deployed, it is important to assess patency of the coronary arteries using TEE because it is possible for one of the native aortic valve leaflets to physically occlude the coronary ostia, causing acute ischemia or MI. Coronary artery occlusion is a rare complication of TAVR. Dysrhythmias, including new left bundle branch block or complete heart block, are more common. The atrioventricular bundle passes through the intraventricular septum immediately below the aortic valve. Conduction disturbances are most likely due to direct mechanical injury and inflammation of the conduction system from the valve and procedure. Dysrhythmias can lead to the need for placement of a permanent pacemaker. A recent meta-analysis comparing the 2 valves showed that permanent pacemakers are needed significantly more often with the Medtronic CoreValve than with the Edwards SAPIEN (24.5% vs 5.9%).[23]

• *Assessment of Valve Function and Surgical Closure.* Following valve implantation, TEE and angiography are used to assess for paravalvular and intravalvular leaks (aortic insufficiency), and to rule out hemopericardium and aortic dissection.[12] Severe intravalvular regurgitation (in the prosthetic valve itself) is rare after TAVR, but paravalvular regurgitation (between the native and prosthetic valve) is common. Paravalvular insufficiency is thought to be caused by prosthesis undersizing or incomplete expansion, positioning of the prosthesis too high or low so that the sealing ring does not approximate the native aortic annulus, or residual calcium deposits prohibiting the prosthesis from forming a complete seal.[24] Severe AI can sometimes be treated by reexpanding the balloon in the orifice or rarely by reimplanting a second prosthesis. The CoreValve can be repositioned to some extent. These maneuvers, however, are associated with an increased risk of embolic stroke. Often, AI that is present initially will improve in 24 to 48 hours.[2,5,24]

After proper positioning and functioning of the valve is confirmed, all items used for vascular access will be removed. Pacemaker wires are usually removed, but may be left temporarily in place in patients who develop bundle branch block or complete heart block. These dysrhythmias sometimes resolve over time, but up to 25% of patients may need a permanent pacemaker inserted later. Heparin therapy is reversed with protamine, and pressure is applied to the vascular insertion sites. Postoperatively about 5% to 28% of patients will experience a mild, reversible rise in creatinine levels, most likely related to the contrast dye that is injected for the procedure.[23] In summary, the most frequent complications from TAVR are vascular injury, stroke, paravalvular aortic insufficiency, and conduction disturbances.

Anesthetic Considerations
• *General Considerations.* The TAVR procedure is fraught with potentially serious complications. Additionally, the patients who qualify for TAVR will have severe AS and multiple comorbidities such as chronic obstructive pulmonary disease, elevated pulmonary pressures, heart failure, LV dysfunction, and acute or chronic kidney disease that may predispose them to hemodynamic instability. Preoperatively, the patient's medical condition should be stabilized and optimized as much as possible. Intravenous preoperative hydration should be considered, especially in patients with chronic renal dysfunction. Laboratory evaluation should be similar to all patients undergoing valve replacement, and 2 U of cross-matched blood should be available. Serious complications necessitating the urgent use of CPB are rare (< 5%)[6]; however, the anesthetist must always be prepared for the possibility. Antibiotic prophylaxis with a cephalosporin (vancomycin and ciprofloxacin if the patient is allergic to penicillin) is used to prevent postoperative surgical infection and endocarditis. Most patients will be on an antiplatelet regimen of aspirin and clopidogrel preoperatively and for 3 to 6 months postoperatively. Clear communication, radiation safety, and possibly preparing to administer anesthesia in a remote location are additional considerations.

• *Choice of Anesthetic Technique.* In North America, TAVR is performed using a balanced general anesthetic technique, with the goal of early emergence and extubation 95% of the time.[25] The transapical and transaortic approaches require the use of general anesthesia because a thoracotomy or ministernotomy is needed. General endotracheal anesthesia offers several advantages, including a protected airway, full utilization of TEE, ventilation control during valve deployment, and the ability to urgently institute CPB if needed. Only small doses of standard narcotics are usually required because the population is generally elderly and frail. Additionally, postoperative pain is usually minimal. A direct intercostal nerve block by the surgeon helps reduce the pain associated with the thoracotomy that is used for the transapical approach. Since the slightest patient movement (even ventilation) can be disastrous during valve deployment, muscle relaxants are usually administered. Patients are generally extubated at the end of the procedure. One-lung ventilation may be used for the transapical approach if the surgeon prefers, but it is not absolutely necessary for ventricular apical exposure.[26]

In Europe, the use of local or regional anesthesia with sedation as an alternative anesthetic technique for transfemoral TAVR procedures is much more common. Only 3 centers in North America routinely use sedation, but more institutions are trying this technique as they gain experience with the procedure.[25] Reported advantages of local anesthesia with sedation include continuous neurologic assessment, avoidance of complications associated with general anesthesia in high-risk patients who have severe AS, quicker recovery, improved hemodynamic stability, and decreased hospital length of stay.[27,28] The inability

to use TEE fully to guide valve placement and detect complications is an important disadvantage of selecting local anesthesia with sedation. Other disadvantages may include patient agitation or movement due to decreased cerebral blood flow during RVP, potential worsening of pulmonary artery hypertension secondary to hypercapnia and depressed ventilation, and the need to rapidly obtain a secure airway if hemodynamic instability ensues.

    • *Room Preparation and Intraoperative Management.* In addition to standard ASA monitors, a large-bore peripheral intravenous catheter, arterial line (A-line), and central venous access are generally preferred for TAVR.[6,12,28] Procedures that are done as part of the PARTNER trial require the use of a pulmonary artery catheter (PAC) for measuring cardiac output and pulmonary pressures before and after valve deployment. The PAC may also be valuable postoperatively to help differentiate causes of hemodynamic deterioration. The A-line is most often radial, but the femoral artery may also be used. All lines should have the appropriate amount of extension tubing to facilitate safe use of any fluoroscopic device. Hypothermia must be avoided to facilitate rapid extubation, and measures such as fluid warmers, an underbody-heating system, and maintenance of room temperature are helpful.

    The anesthetist must be prepared to treat sudden dysrhythmias such as ventricular fibrillation or AV block that can occur because of RVP and/or manipulation of catheters within the heart.[6] The surgical suite should be equipped with a defibrillator and pacemaker. Radiolucent defibrillator pads should be placed on the patient before induction of anesthesia. A transvenous pacing wire is inserted during the procedure and can be left in place for patients who are at high risk for heart block or exhibit intraventricular conduction abnormalities during or after the procedure. Patients are positioned supine for all TAVR procedures, but the transapical approach requires a slight tilt to the right for surgical exposure of the left hemithorax. Vasoactive medications, such as phenylephrine, norepinephrine, and epinephrine need to be immediately available for administration to promptly treat hemodynamic instability. Hypotension should be anticipated when RVP is induced. In patients with limited hemodynamic reserve, the frequency and duration of RVP may need to be reduced. Additionally, a preemptive bolus of a vasopressor often helps maintain vascular tone and coronary perfusion, and facilitates successful return to the baseline rhythm and blood pressure. Crystalloid or colloid, 1 to 1.5 L, is usually sufficient to meet a patient's intraoperative intravascular fluid requirement during a TAVR procedure. Volume status can be further assessed using echocardiography, pulmonary artery, and central venous pressures.

    Most blood loss occurs with the initial placement and final removal of the deployment device sheath from the femoral artery or LV apex or both. Blood loss is usually minimal during a TAVR procedure using the transfemoral, transapical, or transaortic approach. However, the subclavian approach has the potential for major intrathoracic bleeding if the subclavian artery is injured. Typed and cross-matched blood should be available regardless of the approach in the event that a major complication such as an aortic dissection or pericardial tamponade were to occur. The anesthetist should be prepared to administer heparin before insertion of the large sheath into the vasculature. An activated clotting time longer than 300 seconds is desired, and heparin anticoagulation is usually reversed with the administration of protamine sulfate on a milligram-to-milligram dose.[2,12,26]

Outcomes

The PARTNER trial is the multicenter, randomized, controlled pivotal trial whose results allowed the Edwards SAPIEN THV to receive FDA approval. The trial demonstrated that TAVR is unequivocally superior to standard medical therapy in patients with symptomatic severe AS that is considered inoperable (cohort B). At 2 years, the rate of cardiac death was reduced by half (31% vs 62.4%), although the presence of extensive coexisting conditions may attenuate the survival benefit. The rate of rehospitalization also decreased by more than 50% (35% vs 72.5). The patients improved in vitality, physical functioning, and general and mental health scores. Valve hemodynamics were sustained for 2 years.[29] At 30 days, the TAVR patients had more major vascular injuries (16% vs 1%) and major stroke (6.7% vs 1.7%).[15] Additionally, TAVR showed a trend toward less deterioration in renal function compared with medical management or SAVR, but the differences were not statistically significant.[15,29]

    Transcatheter aortic valve replacement was also found to be a "noninferior" or acceptable alternative to SAVR in patients who are high-risk surgical candidates (cohort A).[16,30,31] Mortality rates were similar for TAVR and SAVR. The improvement in the valve area and gradient was similar and trended toward improvement for TAVR. Residual paravalvular AI occurs in approximately 12% of patients undergoing TAVR and is associated with a higher long-term mortality.[15,16,30] Patients undergoing TAVR had more strokes in the first 30 days, but there was no difference at 1 or 2 years.[16,30] There was significantly less major bleeding found in TAVR (14.7% vs 25.7%) as well as a decrease in the onset of atrial fibrillation (12.1% vs 17.1%). However, results favored SAVR in occurrence of vascular complications (11.5% vs 3.5%).[17,30] Results of the PARTNER II trial have not been officially published, but the preliminary results that were presented at the American College of Cardiology's 62nd Annual Scientific Session in San Francisco in March of 2013 indicate that there are fewer vascular events with the lower profile Sapien XT valve and delivery system.[32]

Conclusion

Transcatheter aortic valve replacement is a less invasive alternative to SAVR for the treatment of severe, symptomatic calcific AS. Currently, TAVR is considered the treatment of choice for patients whose cases are considered inoperable and is a proven alternative for high-risk surgical candidates, according to the ACCF, AATS, SCAI, and STS.[5,6] Transfemoral retrograde is the primary catheter-based approach, and transapical antegrade may be used in patients with limited vascular access. The hemodynamic results of TAVR are usually excellent, and the patient's functional status and quality of life most often improve markedly. The most significant complications include moderate paravalvular aortic insufficiency, conduction disturbances, vascular damage, and stroke.

Close collaboration between the TAVR multidisciplinary team of cardiologists, cardiac surgeons, and anesthesia providers is essential to ensure patient safety and a successful outcome. Currently in the United States, the patients selected for TAVR are usually elderly with multiple comorbidities. Careful anesthetic management is required to mitigate risk. Although the SAPIEN valve is the only THV currently approved for implantation in the United States, there are more than 8 valves in commercial development and 2 ongoing pivotal trials in the United States.[17] Transcatheter valves are being placed inside of failed bioprosthetic valves and bicuspid native valves, with promising results. Newer generations of the valves and insertion devices appear to significantly lower the complication rate, especially for vascular injury, paravalvular leak, and stroke.[23] Transcatheter heart valves will likely play a dominant role in aortic valve replacement, and the anesthetic management will continue to be key in the successful implementation of this exciting technology.

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