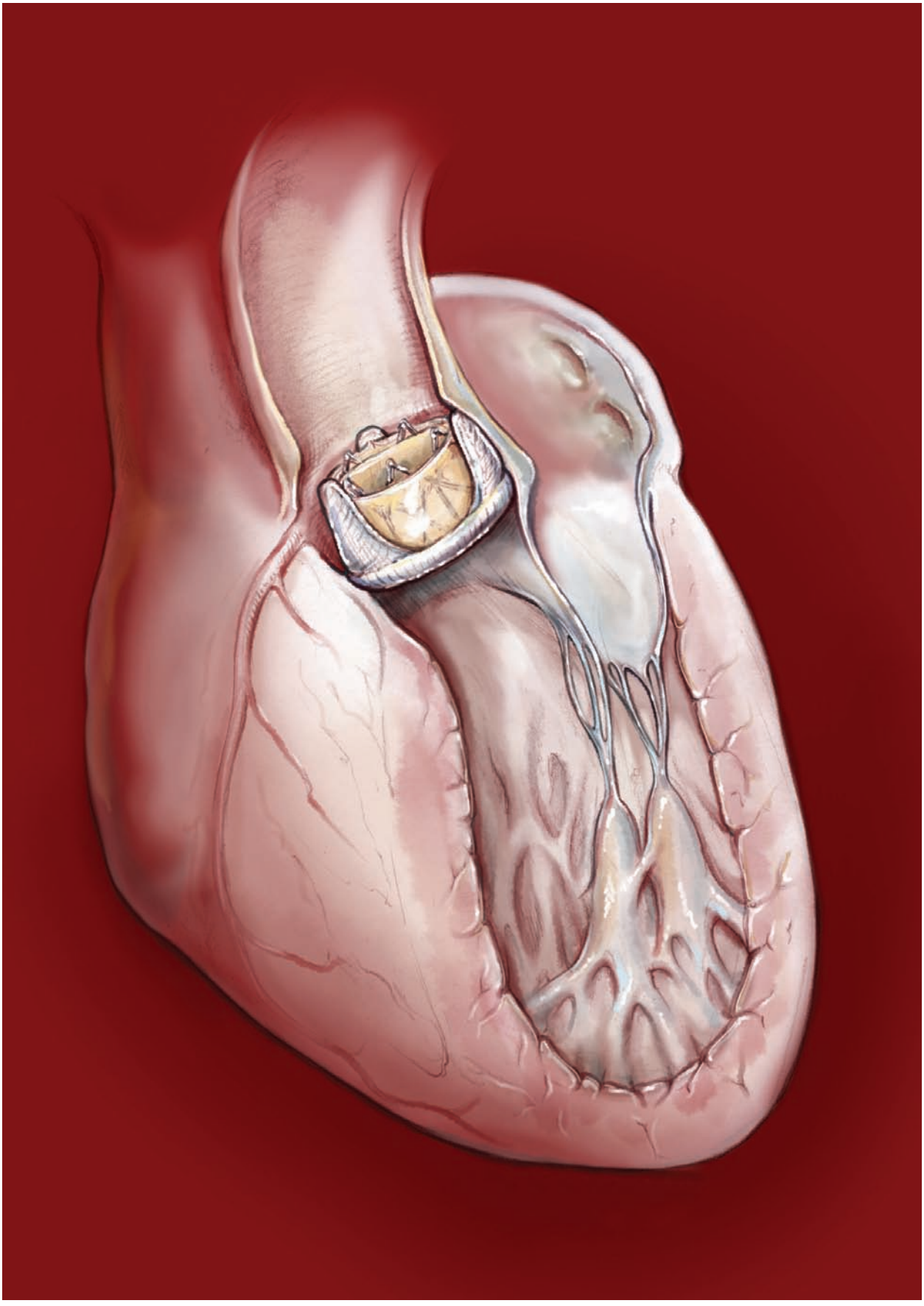

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Transcatheter aortic valve replacement

BY MELODY K. KARYCKI, BSN, RN, CCRN

Abstract: Transcatheter aortic valve replacement (TAVR) is indicated in some patients with severe aortic stenosis for whom surgical intervention is not deemed appropriate. This article explores when TAVR may be the preferred treatment option over surgical aortic valve replacement and discusses various prosthetic valve devices. The TAVR procedure, diagnostic screenings, complications, postoperative management, and nursing considerations are also outlined.

Keywords: aortic stenosis, echocardiography, SAVR, surgical aortic valve replacement, TAVR, transcatheter aortic valve replacement, valvular heart disease

TRANSCATHETER AORTIC valve replacement (TAVR), also known as transcatheter aortic valve implantation, is a minimally invasive procedure that positions a new bioprosthetic valve over the damaged native aortic valve. The first TAVR was completed in 2002 by Alain G. Cribier, MD, FACC, and the procedure has since become an alternative to surgical intervention.[1] TAVR is currently indicated for patients with severe aortic stenosis and high surgical risk.[2]

Clinical manifestations

Recognition of the symptom triad of syncope, heart failure, and angina is crucial to the prompt initiation of appropriate treatment for aortic stenosis, without which mortality nears 50% within 2 years of symptom triad onset.[3]

Clinical manifestations of early aortic stenosis include dyspnea and/or angina on exertion, as well as dizziness. Unfortunately, most patients do not present to healthcare providers with symptoms until aortic stenosis is severe.[3,4] The transition from asymptomatic to symptomatic aortic stenosis leads to irreversible heart damage, such as left ventricular hypertrophy or dysfunction, and dysrhythmias. If left untreated, patients with symptomatic severe aortic stenosis have a poor prognosis.[5]

Diagnosis

The gold standard diagnostic study for aortic stenosis is echocardiography. Severe aortic stenosis is generally defined as an aortic valve area of 1.0 cm^2 or less, a mean transvalvular

pressure gradient of 40 mm Hg or more, or a maximum aortic jet velocity greater than 4.0 m/s.[5]

The stages of aortic stenosis are classified according to patient symptoms, valve hemodynamics, valve anatomy, and the hemodynamic consequences of the aortic stenosis (see *Valvular aortic stenosis stage progression*).

Management

Recommended interventions for aortic stenosis include TAVR, surgical aortic valve replacement (SAVR), percutaneous balloon valvuloplasty, and medical management. The timing of intervention varies but typically occurs when patients approach stage C (asymptomatic severe aortic stenosis) or stage D (symptomatic severe aortic stenosis).

TAVR is recommended for patients in stage D who are either a high surgical risk or are not candidates for SAVR, with a predicted post-TAVR survival of more than 12 months.[2] Several factors are examined to determine the surgical risk, including the Society of Thoracic Surgeons Predicted Risk of Mortality (PROM) score, frailty, postoperative influence on established major organ system dysfunction, and procedural limitations.[5]

Frailty is assessed via the Katz Index of Independence in Activities of Daily Living, which examines six specific activities. These include bathing, dressing, toileting, transferring, bowel and bladder continence, and feeding, plus the associated level of independence or dependence. The seventh factor of the frailty assessment is independence in ambulation.[6]

A candidate is considered a high surgical risk if at least one of the following criteria is met: a PROM score greater than 8%, a frailty index of two or greater, a maximum of two compromised major organ systems that will not improve postoperatively, or possible procedural limitations.[5] Patients with a 50% or greater probability of death or serious complications are deemed an extreme surgical risk and are not considered candidates for SAVR.

Absolute contraindications to SAVR not demonstrated on the PROM score assessment include a highly calcified aorta (extending to the entire ascending aorta and arch), known as "porcelain aorta," and chest cavity limitations due to damage or complications from previous radiation or surgical interventions.[7] Relative contraindications include prior coronary artery bypass grafting (CABG) with susceptible graft injury, severe liver disease or cirrhosis, pulmonary hypertension, and severe right ventricular dysfunction.[7] Factors that influence a patient's treatment choice include surgical risk, patient preference, severity of comorbidities, and frailty.[2]

TAVR vs. SAVR

SAVR, the alternative to TAVR, requires general anesthesia, a surgical incision, and cardiopulmonary bypass. Factors that favor the SAVR approach include presence of coronary artery disease and the need for CABG, the need for mitral valve surgery, age less than 75, need for mechanical valve replacement, and severe left ventricular outflow calcification or calcified bicuspid valve.[7] This procedure requires a greater length of stay and carries an increased risk for infection and other complications.

Not every patient is considered a candidate for SAVR. Those age 75 or older with multiple comorbidities that increase their mortality risk, as well as those with left ventricular dysfunction, should be considered for TAVR. Approximately 50% of individuals with severe aortic stenosis are referred for SAVR, and approximately 40% of those referred undergo the procedure.[8]

According to the 2017 American Heart Association/American College of Cardiology (AHA/ACC) focused update of the 2014 AHA/ACC valvular heart disease guideline, a heart valve team will collaborate and discuss each individual case, reviewing diagnostic information and clinical evaluations, before agreeing on a treatment plan. If the chosen treatment is TAVR, the team decides on access site, type of prosthetic valve and deployment technique, anesthesia, and postoperative management, such as anticoagulation. The heart valve team typically consists of an interventional and noninvasive cardiologist, cardiovascular surgeon,

Valvular aortic stenosis stage progression[4]

The 2014 AHA/ACC guidelines classify progression of valvular aortic stenosis into four stages (A to D), as summarized below.

Stage A: At risk for aortic stenosis

Stage B: Progressive aortic stenosis

Stage C: Asymptomatic severe aortic stenosis, as follows:
- C1: Asymptomatic severe aortic stenosis
- C2: Asymptomatic severe aortic stenosis with left ventricular dysfunction

Stage D: Symptomatic severe aortic stenosis, as follows:
- D1: Symptomatic severe high-gradient aortic stenosis
- D2: Symptomatic severe low-flow/low-gradient aortic stenosis with reduced left ventricular ejection fraction
- D3: Symptomatic severe low-gradient aortic stenosis with normal left ventricular ejection fraction or paradoxical low-flow severe aortic stenosis.

advanced practice nurses, structural valve interventionalists, cardiovascular imaging specialists, a cardiac anesthesiologist, and a valve clinic coordinator.[9]

Several FDA-approved prosthetic valve devices are used in clinical practice, including three categories of valve devices: balloon-expandable devices, self-expanding devices, and mechanically expandable devices. The choice of prosthetic valve for each patient depends on factors such as the aortic annulus size, risk of annular rupture, heart anatomy, and peripheral arterial assessment findings.[10,11]

Preprocedural testing

If TAVR is the intervention of choice, the patient will undergo a series of diagnostic studies to gather relevant clinical data.

Transesophageal echocardiography (TEE) is necessary to determine the severity of aortic stenosis. Additionally, TEE will allow providers to determine if there is concomitant valvular heart disease and evaluate valve anatomy and hemodynamics. As previously mentioned, individuals with coronary artery disease are better candidates for SAVR, so coronary angiography needs to be performed. The patient will need right and left heart catheterization within 1 year to determine hemodynamic measurements.

A critical aspect of TAVR is fitting the patient for the most appropriately sized valve, which is accomplished via computed tomography angiography of the chest, abdomen, and pelvis. This is considered the gold standard for gathering measurements of the aortic annulus. In addition to sizing, this imaging study helps to determine vascular access sites based on tortuosity and calcium deposits.

The patient will need an exam by two cardiothoracic surgeons, an interventional cardiology evaluation, and a meeting with the valve clinic coordinator for further education. A frailty assessment will be conducted. Other evaluations include pulmonary function tests, dobutamine stress echocardiography (particularly for those diagnosed with stage D2 aortic stenosis), depression screening, Mini Mental State Examination, Society of Thoracic Surgery risk score, Kansas City Cardiomyopathy Questionnaire, 5-meter walk test, blood work, and carotid duplex ultrasonography.[9]

TAVR procedure

Depending on the approach chosen by the heart valve team, a small incision is usually made in the groin for bilateral transfemoral access. One access will be used to introduce the prosthetic valve, and the other is used for placement of a right ventricular temporary transvenous pacemaker. Rapid ventricular pacing is used during the procedure to temporarily reduce cardiac output, cardiac motion, and transvalvular flow during balloon valvuloplasty and valve expansion.[12] If the patient does not experience new-onset atrioventricular block, the pacemaker can be removed safely at the completion of the procedure.

Before introducing the new prosthetic valve, preimplantation balloon aortic valvuloplasty is often used to allow for better positioning and movement of the device, to establish optimal valve deployment, and for optimal valve expansion (see *A closer look at TAVR*). Balloon aortic valvuloplasty has demonstrated effectiveness in maintaining hemodynamic stability during valve deployment.[13]

Complications

Complications associated with TAVR include hypotension, which can be managed with I.V. fluids, low-dose inotropes, and vasopressors. Hypotension can occur intraoperatively or postoperatively due to volume depletion, conduction disturbances, and dysrhythmias.[14] Ideally, the patient's systolic BP should be maintained at or above 100 mm Hg.[12]

Vascular complications, such as dissection or perforation, should

Promising results for low-risk patients[34-36]

Currently reserved for patients with severe aortic stenosis who are at increased risk for surgical mortality, TAVR may also be appropriate for similar patients with severe symptoms who are at low surgical risk. In a landmark study, researchers randomly assigned patients with severe symptomatic aortic stenosis to undergo either TAVR with a self-expanding bioprosthetic valve (n = 725) or SAVR (n = 678). The primary endpoint was a composite of death or disabling stroke at 24 months.

At the 24-month follow-up, the incidence of all-cause mortality or disabling stroke was 5.3% for patients in the TAVR group and 6.7% in the surgical group. Results were also comparable for most of the numerous secondary outcomes analyzed. The authors concluded that TAVR was "noninferior" to SAVR for patients at low surgical risk with respect to the composite endpoint.

Presenting the findings at the American College of Cardiology annual meeting in March 2019, coauthor Michael J. Reardon, MD, FACC, said, "These findings suggest that low surgical risk patients do as well and perhaps even better with TAVR compared with SAVR over 2 years of follow-up." He and his colleagues say that continued follow-up is needed to evaluate long-term performance and assess the risk of complications such as valve leaflet thrombosis and structural valve degeneration.

Additionally, another recent study demonstrated similar results using a balloon-expandable TAVR.

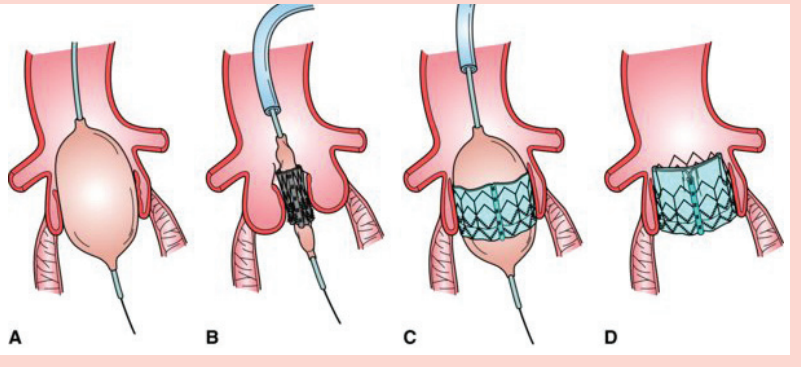
be suspected in the presence of unexplained hypotension after sheath removal. Proper sizing, positioning, and expansion of the prosthetic valve are crucial to prevent complications such as paravalvular regurgitation. Additional complications include atrioventricular (AV) block and stroke.

High-degree AV block requiring permanent pacemaker implantation is the most common complication seen after TAVR.[12] Risk factors for new-onset AV block include a history of right bundle-branch block, as well as AV delay, advanced age, low implant positioning, and an oversized prosthetic valve.[12]

Stroke is another major complication associated with TAVR and can be caused by the embolization of calcified particles from the ascending aorta or native aortic valve. There are three phases of potential stroke following TAVR: early, delayed, and late. The early phase is defined as the immediate postoperative period up to 24 hours. The delayed period is defined as postoperative days 2 through 30. The late phase is defined as a stroke occurring after day 30 and up to 1 year following the procedure. The early phase is typically a direct result of the procedure and is responsible for up to 50% of all cerebrovascular events.[15] Strokes that occur during the late phase can be attributed to preexisting comorbidities, such as asymptomatic carotid artery stenosis or atrial fibrillation.[16]

To combat the risk of stroke, the Protection Against Cerebral Embolism During Transcatheter Aortic Valve Replacement (SENTINEL) trial is examining the use of an embolic filter designed to capture and remove calcified particulates and other debris that may dislodge during TAVR.[17] The device has been able to capture brain-bound debris in 99% of patients included in this study. Debris captured included arterial wall calcification, acute thrombus with tissue elements, valve tissue, and foreign matter found to be polymers used in the TAVR valve delivery system and accessories.[17] Routine use of cerebral protection devices is still under discussion, largely because of cost, as further data are needed to support their role in TAVR procedures.

A closer look at TAVR



Schematic diagram of percutaneous aortic valve replacement. A: Balloon valvuloplasty. B: Balloon catheter with valve in the native diseased valve. C: Balloon inflation to secure the valve. D: Valve in place.

Source: Mulholland MW, Lillemoe KD, Doherty GM, Maier RV, Simeone DM, Upchurch GR. *Greenfield's Surgery: Scientific Principles & Practice.* 5th ed. Philadelphia, PA: Wolters Kluwer Health/Lippincott Williams & Wilkins; 2016.

Additional complications to consider after TAVR include bleeding and acute kidney injury (AKI).[18] Complications associated with valve deployment include annular rupture, malpositioning, mitral valve injury, organ damage, and paravalvular and central jets. Paravalvular leak occurs when there is blood flow via a gap between the implanted valve and the native annular tissue due to inadequate sealing, insufficient expansion of the prosthetic valve, or heavy calcium deposits within the native valve preventing proper seal.[19,20] Central jets, or central regurgitation, occur when there is turbulent, high-velocity blood flow within the central aspect of the valve due to improper sizing or deployment.[20] This may warrant delicate manipulation of the valve leaflets with a catheter or deployment of a second TAVR device. Long-term complications following TAVR include paravalvular regurgitation, endocarditis, and valve thrombosis.[14]

Predictors for AKI in patients undergoing TAVR include older age, low ejection fraction, female gender, history of diabetes and/or hypertension, bleeding and blood transfusions, and long durations of hypotension.[18] Three major trials all demonstrated decreased incidence of AKI following TAVR compared with SAVR when evaluated at the 30-day follow-up.[18,21-23] A meta-analysis evaluated the effects of AKI and mortality risk after TAVR and found that AKI increases mortality risk fivefold in 30 days and threefold at 1 year following TAVR.[24]

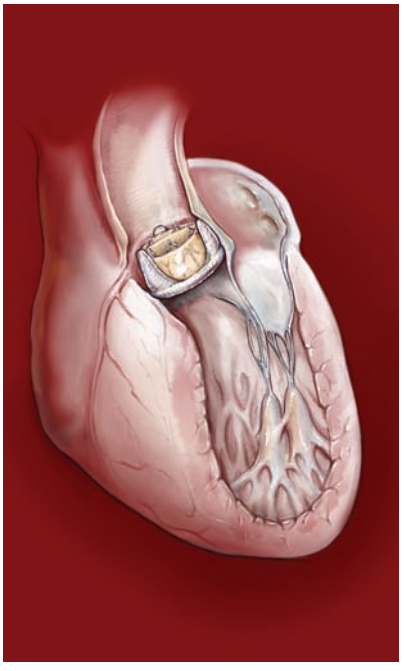
Complications associated with SAVR differ significantly from TAVR. A meta-analysis was conducted to evaluate outcomes associated with TAVR and SAVR in low- and intermediate-risk patients. Two independent reviewers examined the data and classified the effects and quality of evidence

using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system. Four trials that included 3,179 patients with a median follow-up period of 2 years demonstrated that, when compared with SAVR, the transfemoral TAVR approach was associated with decreased mortality, major bleeding, strokes, atrial fibrillation, and AKI.[25] On the other hand, TAVR was associated with a higher incidence of permanent pacemaker implantation, aortic valve reintervention, and moderate-to-severe signs and symptoms of heart failure.[25]

Post-TAVR care

After the procedure, patients are kept overnight in the ICU to monitor for complications and to complete a prophylactic antibiotic regimen. Communication between physicians, anesthesiologists, NPs, nurses, and other healthcare professionals is essential to ensure a smooth transition from the OR to the critical care setting. After approximately 6 hours of bed rest (follow facility protocol), the patient can generally get out of bed and ambulate. Before the patient is discharged from the hospital, follow-up echocardiography should be completed. Because TAVR can be performed using a minimalist approach, such as moderate sedation/analgesia and discontinuation of central venous access devices and pacemakers, patients can usually be discharged the next day if no complications arise.

The Mid-Atlantic Permanente Medical Group TAVR program implemented a fast-track care protocol for patients with a primary goal of next-day discharge. With the use of moderate sedation/analgesia, discontinuation of central venous access devices, admission to non-ICU settings, and ambulation on the same day as the procedure, this TAVR program shortened the average patient's length of stay from 3.2 to 1.9 days.[26]



If TAVR is the intervention of choice, the patient will undergo a series of diagnostic studies to gather relevant clinical data.

Prior to discharge, the patient should begin dual antiplatelet therapy that consists of lifelong daily aspirin and clopidogrel for the first 6 months.[2] Several studies have demonstrated prosthetic valve thrombosis after TAVR, with an incidence ranging from 7% to 40%. Prosthetic valve thrombosis is defined as the presence of reduced leaflet motion, along with hypoattenuating valve lesions on computed tomography.[27-29] Clinical manifestations include exertional dyspnea and increased transvalvular gradients.[30] Current guidelines state that anticoagulation with a vitamin K antagonist to achieve a goal international normalized ratio of 2.5 may be reasonable for at least 3 months following the procedure in patients with a low risk of bleeding. At this time, the use of direct-acting oral anticoagulants has not been determined in this population.

Nursing considerations

Preprocedure nursing considerations include but are not limited to performing comprehensive baseline neurologic and cardiovascular assessments to identify new neurologic deficits or alterations in cardiovascular status post-TAVR. Nurses should also assess patients for kidney disease, bleeding disorders, and chronic lung disease. Nurses are responsible for providing patient education before the procedure and ensuring all preoperative imaging studies and lab work are completed.[31]

Postprocedure nursing considerations include frequent monitoring for complications, such as neurologic deficits, bleeding, and dysrhythmias. Neurovascular assessments of the extremities used for vascular access should also be performed. Patients who have undergone a percutaneous approach are to remain on bed rest per facility protocol. Once this protocol is completed, nurses may advance the diet as tolerated.[31]

Nurses should also ensure that transcutaneous pacing pads remain on the patient, even if they are not currently in use, for 24 hours after the procedure in case cardiac conduction abnormalities develop. Additionally, they are responsible for assessing and documenting fluid status; collecting routine lab specimens, including specimens for complete blood cell count, renal function tests, and a basic metabolic panel and coagulation profile; and reporting any abnormal values.[31]

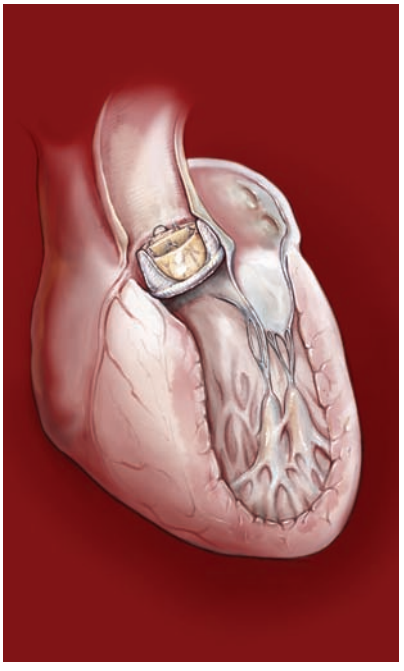
Early mobilization is important to combat potential complications, such as venous thromboembolism. After

the bed rest period is completed, patients should be assisted to a chair and establish a daily walking regimen. Ensure fall risk assessments have been completed and that appropriate interventions are in place to promote patient safety.[31]

Patient education

After discharge, patients may slowly resume their normal activities. Patient education should include incision care and signs of infection, signs and symptoms of fluid overload (such as weight gain), recognizing progressive activity intolerance, how to take vital signs (including BP and heart rate), and warning signs such as chest pain or shortness of breath. They should also be educated on infective endocarditis prophylaxis because patients with prosthetic heart valves, including those who have undergone TAVR, are at increased risk. Prophylaxis for infective endocarditis is suggested for high-risk procedures, such as dental procedures that involve manipulation of gingival tissue, the periapical region of teeth, or perforation of the oral mucosa.[2,32]

For the first 2 weeks after TAVR, advise patients to avoid activities that involve pushing, pulling, or lifting anything weighing more than 10 lb (4.5 kg). During this time, patients should also avoid driving, excessive straining, and activities such as gardening or lawn mowing. For the first 4 weeks after the procedure, patients should avoid taking a bath or soaking in water until the incisions completely heal to avoid risk of infection.[33] Patients can shower the day of discharge using gentle bathing motions and a mild, unscented soap at the incision site, taking care to avoid rubbing the incisions. They can also cover the incision site with an adhesive bandage until the skin has healed or leave the site open to air.



Communication between physicians, NPs, nurses, and other healthcare professionals is essential for a smooth transition from the OR to the critical care setting.

Follow-up care

The patient will follow up with the structural heart clinic 30 days after the procedure. At this appointment, the patient will undergo a 12-lead ECG, the Kansas City Cardiomyopathy Questionnaire, and echocardiography to assess the prosthetic valve position, determine paravalvular leak, access site follow-up, and blood work to assess kidney function and signs of anemia. Patients will be transitioned back to their primary care provider and primary cardiologist 6 weeks after the procedure. Patients will follow up again with the structural heart provider at 1 year for the same diagnostic procedures, but they will also complete a 5-meter walk test.

Promising option

Patients with severe aortic stenosis who are considered a high surgical risk now have an option for intervention. With the introduction of TAVR, patients can be discharged from the hospital faster and avoid the complications associated with SAVR. This minimally invasive procedure has the potential to improve overall health and quality of life for many individuals. ■

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