

## Innovation Transcatheter Aortic Valve Replacement And Nursing Role

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**Abstract;** *Tran catheter aortic valve replacement (TAVR) is an alternative to surgical aortic valve replacement for patients whom considered an intermediate or high risk for standard valve replacement surgery. This technique is still in its early stages, but rapidly growing evidence has been developed through observational studies, globally more than 30,000 patients undergone treatment by TAVR .This article reviews patient Indications for TAVR, prosthetic valve types, procedural approaches, potential complications, patient education and nursing care.*

**Keywords:** *Transcatheter aortic valve replacement, intensive care unit, severe aortic stenosis, high-risk patients.*

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### Abbreviations

Aortic stenosis; AS, European Association for Cardio-Thoracic Surgery; EACTS, European Society of Cardiology; ESC, transcatheter aortic valve implantation; TAVI, transcatheter aortic valve replacement; TAVR.

### I. Introduction

Aortic stenosis is a common valve disease that limits blood flow from the heart, especially for those over age 65. It is a progressive disease, until recently, the only option was to replace or repair the valve by doing open-heart surgery.<sup>(1)</sup> Transcatheter aortic valve replacement (TAVR) is a minimally invasive procedure to replace a narrowed aortic valve that fails to open properly (aortic valve stenosis).<sup>(2)</sup> It is an innovative and resource-intensive treatment of valvular heart disease.<sup>(3)</sup> This procedure is approved by FDA in 2011 for patient with symptomatic aortic stenosis who are considered an intermediate or high risk patient for standard valve replacement surgery.<sup>(4)</sup> Transcatheter aortic valve implantation can result in sustained and early functional improvement in high-risk aortic stenosis patients.<sup>(5)</sup> It eliminates the need for sternotomy, CPB, and reduces procedural and anesthesia time.<sup>(6)</sup>

#### 1.1 Indications for TAVI according to the ESC/EACTS guidelines:

- TAVI should only be undertaken with a multidisciplinary Heart Team.
- TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR, have a >1-year life expectancy and are likely to gain improvement in quality of life.
- TAVI should be considered in high-risk patients with symptomatic AS who may still be suitable for surgery but in whom TAVI is favored by the Heart Team.<sup>(7)</sup>

#### 1.2. Contraindications to TAVR and exclusion criteria are as follows:

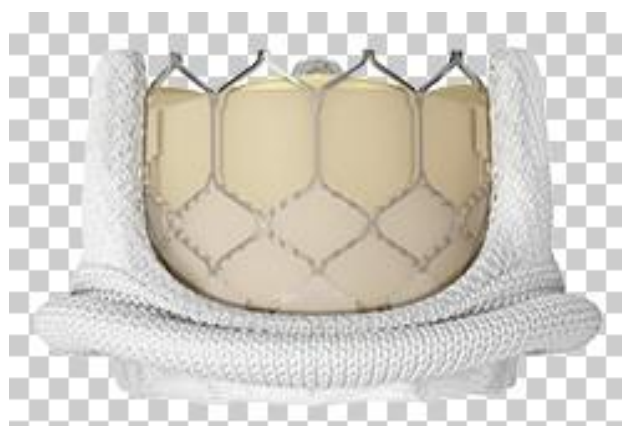
- Occurrence of myocardial infarction (MI) at 1 month (30 days) or less before the intended treatment.
- Congenital Aortic valve unicuspid or congenital bicuspid valve or is noncalcified.
- Another aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation)
- Need for emergency surgery for any reason.
- Severe pulmonary hypertension and right ventricular (RV) dysfunction.
- Echocardiographic evidence of intracardiac mass, thrombus, or vegetation.
- A known contraindication or hypersensitivity to all anticoagulation regimens or an inability to undergo anticoagulation for the study procedure

- Native aortic annulus smaller than 18 mm or larger than 25 mm as measured by echocardiography.
- MRI-confirmed stroke or transient ischemic attack (TIA) within 6 months (180 days) of the procedure. .
- Estimated life expectancy of less than 12 months (365 days) owing to noncardiac comorbid conditions.
- Severe incapacitating dementia.
- Significant aortic disease, including abdominal aortic or thoracic aneurysm defined as a maximal luminal diameter of 5 cm or greater, marked tortuosity (hyperacute bend), aortic arch atheroma
- Severe mitral regurgitation.<sup>(8)</sup>

### **Types of valves**

In June 5, 2017, the FDA approved The Edwards SAPIEN 3 Trans catheter Heart Valve for commercial use in the United States, consists of a catheter-based artificial heart valve and accessories used to implant the valve without open-heart surgery.<sup>(9)</sup> The valve is trileaflet bovine pericardial tissue valve attached to a balloon-expandable, cobalt-chromium frame for support. It is used in patients who previously received a tissue aortic or mitral valve that has become narrowed, leaky, or both, so blood is not able to flow efficiently through the valve.<sup>(9, 10)</sup>

In July of 2017, the FDA approved the Core Valve Evolut platform to use for intermediate risk patients. Self-expandable valve inserted into the heart without open-heart surgery, The valve is squeezed down to roughly the width of a pencil, and then inserted into the body, typically through a femoral vein in the groin or upper chest. It's then guided into the heart and deployed, where it expands to take over for the diseased valve. Secured in situ without sutures .The Medtronic Core Valve is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis<sup>(11)</sup>.



**Figure 1. Edwards SAPIEN 3 Aortic**



**Figure 2. Edwards SAPIEN 3 Mitral**



Figure 5 . CoreValve Evolut Pro system

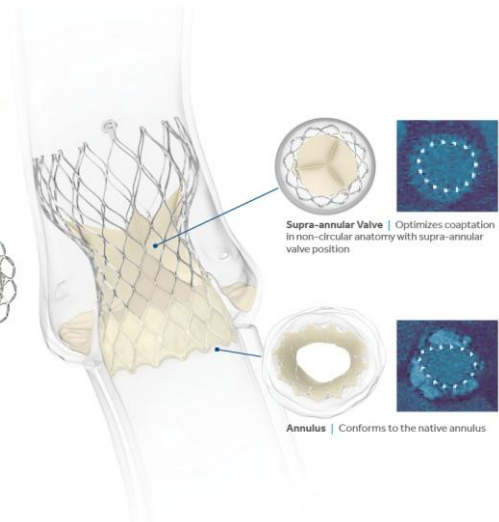


Figure 4. Core Valve Evolut platform

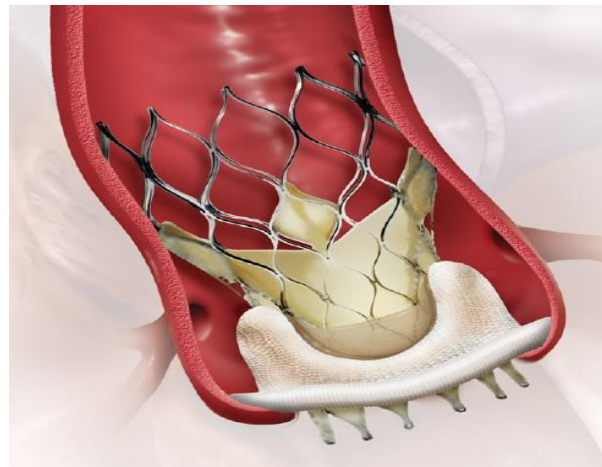
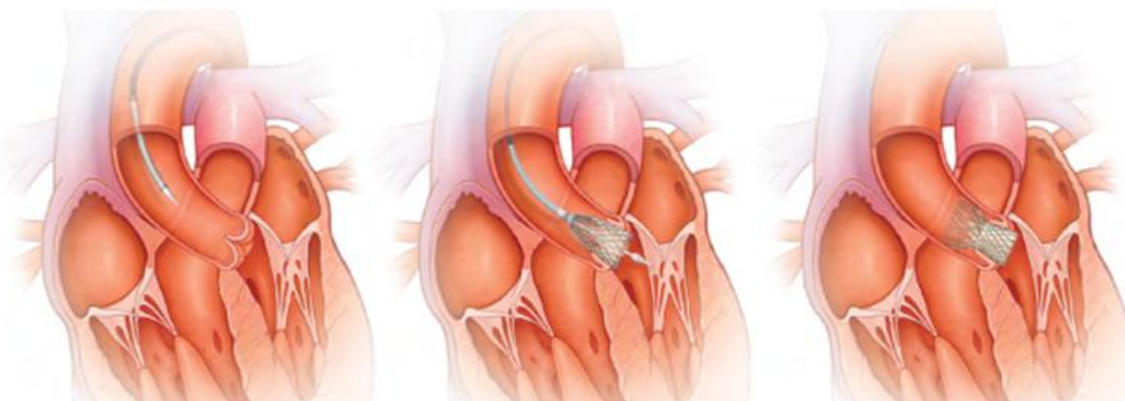


Figure 6. Core Valve Evolut platform implanted by TAVR

### Pre-Procedure Planning

#### Preparation for Patients who are considered for TAVR

- Routing laboratory tests prior to the procedure include complete blood cell (CBC) count, international normalized ratio (INR), partial thromboplastin time (PTT), albumin and transaminase levels, renal function testing, and 12-lead electrocardiography (ECG). Cardiac biomarker levels (ie, CK and CK-MB) are also tested within 48 hours of the procedure.<sup>(12)</sup>
- Echocardiography is used to confirm the aortic valve anatomy, severity of aortic stenosis, and extent of calcification and to evaluate the diameter of the aortic annulus, ascending aorta, the presence of concomitant severe other valvular disease, and the LVEF.
- CT angiography of the aortic root is used to determine the optimal image orientation for valve positioning.
- Right and left cardiac catheterization is used to evaluate for concomitant pulmonary hypertension or coronary artery disease that may require treatment before to TAVR.
- CT angiography of the thoracoabdominal and iliofemoral arteries is used to evaluate the diameter, tortuosity of the vessels, and calcifications and to plan for the access site.<sup>(13)</sup>
- Aspirin & clopidogrel are loaded pre- Apical TAVR procedure and patient will continue these 6 months post.<sup>(14)</sup>



**Figure 7. CoreValvePlacement**

### **Patient Education & Consent**

For obtaining informed consent, it is critical to appropriately inform patients and their family about the benefits and risks of the procedure so the patient is ultimately able to make a voluntary decision.<sup>(15)</sup>

- Teach the patients and his family about the procedure and the benefits and risks of TAVR.
- Need to teach patients about incentive spirometry, cough and deep breathing, and the need for early ambulation after the procedure.
- Inform the patient to report any signs or symptoms of infection (such as fever, purulent drainage, pain, or redness) at the access site.
- For patients with a prosthetic heart valve these, prophylaxis is reasonable for all dental procedures that involve manipulation of gingival tissue or the periapical region of teeth or perforation of the oral mucosa.
- Teach the patients about adherence to medication specifically antiplatelet therapy to prevent stroke after the procedure and signs and symptoms of stroke.

### **Multidisciplinary team**

TAVI is usually performed in a hybrid cardiac catheterization laboratory. Designed and equipped to accommodate personnel and tools required for performing both interventional and open surgical procedures. procedures of TAVI are best performed by a multi-disciplinary team including cardiovascular disease specialists-such as interventional cardiologists and noninvasive cardiologists-work with cardiac surgeons, radiologists, anesthesiologists, a surgical scrub nurse trained in transcatheter procedures, a circulating nurse and others to provide coordinated, comprehensive care for people undergoing transcatheter aortic valve replacement (TAVR).<sup>(16,17)</sup> Before that the multi-disciplinary team evaluate if patient suitable for SAVR or TAVR. The team assesses surgical risk, cardiovascular disease and health status, valve anatomy and function, signs and symptoms, physical and cognitive function. Overall comorbidities, and life expectancy.<sup>(18)</sup> Recently, increased operator experience and enhanced transcatheter valve systems have led to a worldwide trend to use TAVR in patients who are at low or intermediate risk.<sup>(19)</sup>

One study done revealed that hospital staff may find it economically favorable to opt for the use of a catheterization laboratory as opposed to a hybrid room regardless of the approach chosen.<sup>(20)</sup>



**Figure 8 .Hybrid operating room**



**Figure 9. Tableside monitors in a hybrid operating room**

### **TAVR approaches**

Different access routes have been proposed for TAVI including trans apical, trans Subclavian and trans femoral, with percutaneous trans femoral being the preferred because least invasive and nonsurgical.

### **Transapical approach**

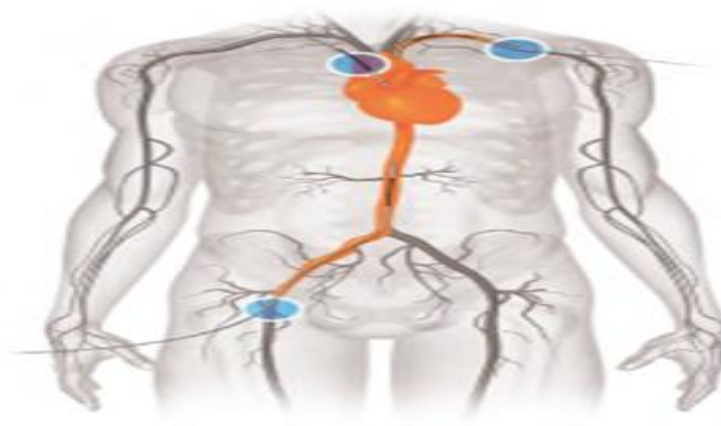
TA-TAVI should only be undertaken in a hybrid operating room or catheterization laboratory with high-definition fluoroscopic equipments and multiple monitors. As well, it is imperative that transesophageal echocardiography (TEE) or intracardiac echocardiography (ICE) be available to access ventricular, valvular functions and the annular size. Sixth intercostal space (ICS) is the most common access site, followed by 5<sup>th</sup> ICS. Over the previously determined location of the apex, a 3 cm incision is made. The incision is made over the top of the rib to avoid trauma to the neurovascular bundle. The valve is delivered via a catheter through the apex of the heart. <sup>(16, 25)</sup>

### **Transfemoral approach**

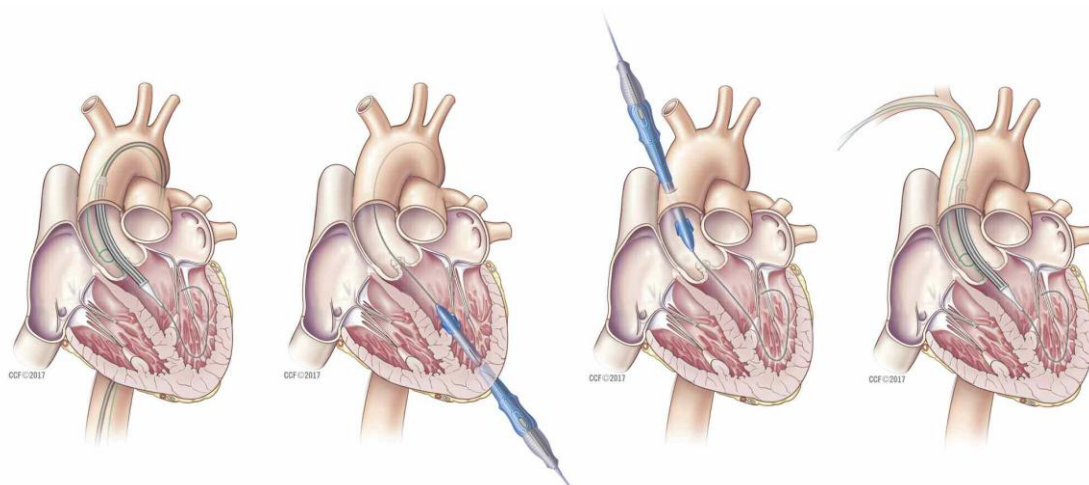
Femoral access cannulated percutaneously or via surgical cut down, the access is obtained on the contralateral side for aortic angiography using a 5F-6F pigtail catheter. A 6F venous access is obtained for a temporary pacemaker lead, which is used for rapid ventricular pacing. Vascular access is obtained percutaneously for the valve delivery sheath; it can be preclosed with 2 sutures-mediated closure devices. The TF approach may not be suitable for patients with peripheral vascular disease because of potential issues with vessel size. <sup>(26)</sup>

### **Transaxillary/subclavian [TAX]**

In the TAX approach, access is gained through the subclavian artery, with a sheath catheter fed into the aortic arch to the aortic valve. Although this approach offers a shorter catheter-insertion route, it's done by utilizing only local anesthesia. <sup>(27)</sup>



**Figure 10. Access Points for TAVR**



**Post procedure .Figure 11. Transfemoral Transapical Transaorti Transaxillary/subclavian complications**

Some complications are often fatal. Prevention, early recognition, and effective treatment of these complications will significantly improve the outcome of this procedure. Conduction abnormalities such as AV or bundle-branch block are known complications of TAVI even in the absence of surgical excision of valve or annulus tissue. <sup>(28, 29)</sup> Vascular complications are common after TAVR and occurred in 32%, and 10% required surgical repair, it include retroperitoneal hemorrhage, femoral or iliac artery dissection, and development of a femoral pseudoaneurysm. <sup>(30)</sup> The vascular access complication is often detected in the ICU postoperatively. Proper techniques must be ensured with removal of any femoral arterial sheath. Pressure at the puncture site must be held for an adequate length of time in order to achieve hemostasis. <sup>(31)</sup> The risk of stroke or TIA was greatest in the first 24 hours after surgery. Neurologic events occurring in the first 24 hours are likely related to embolization of calcium and debris, or thrombi that may form on wires and surgical devices intraoperatively. <sup>(32)</sup> Valve leaks: Sometimes blood leaks around the new valve because the replacement is not big enough, did not fully expand, or has interference from calcium buildup. <sup>(33)</sup> Complications that may occur or be detected after the procedure include acute kidney injury, myocardial injury, tamponade after removal of temporary wire, valve migration or embolization, mitral valve dysfunction, and death<sup>(34)</sup> pain after TAVR may be substantial, particularly after TA-TAVR. <sup>(32)</sup>

### **Nursing care**

One-third of patients experience complications after TAVR, so the nursing care focuses mainly on patient monitoring and assessment and on educating patients about activity, diet, medications, and pain management. <sup>(35)</sup>

### **Post procedure monitoring**

The patient will be transferred to CSICU (Cardiac Surgical Intensive Care Unit) or the CCU (Coronary Care Unit). The patient will be carefully monitored for the first 24 hours after TAVI procedure, and the care begins with the handoff report. <sup>(36)</sup> Obtain pertinent information, including vital signs, medications administered during the procedure, current level of consciousness, access difficulties and overall procedure events, such as complications, arrhythmias or other cardiac events, or difficulties with placement. <sup>(35)</sup>

the patient place on continuous telemetry monitoring and observe for heart rate and rhythm changes. Auscultate heart sounds to detect changes from baseline, and monitor vital signs frequently per protocol, or orders. <sup>(35)</sup>

If percutaneous access was performed, observe the site distal to the puncture for adequate circulation. When checking vital signs perform a neurovascular assessment of the affected extremity, including color, temperature, pulse, numbness, tingling, and swelling. Assess the insertion site for signs of bleeding, hematoma, and infection. Keep dressings clean, dry, and intact and look for bleeding. Promptly report the need for dressing changes due to bleeding. Dressings may typically be removed 24 to 48 hours after the procedure and conduct routine blood work .The TAVR Heart Team will see client every day. <sup>(37)</sup>

Continuous ECG monitoring should be undertaken for at least 48 hours in every patient who develops a new LBBB before discharge. <sup>(38)</sup> Generally the patient spends the night in the intensive care unit for monitoring after the procedure and about two to five days recovering in the hospital. <sup>(39)</sup>

### **Activity**

The nurse informs the patient that for the first four hours after the implant procedure, to keep both legs straight. This is very important to prevent bleeding from the insertion sites in groin. Activity will begin gradually and increase depending on patient progress. It begins with sitting up in bed, and then sitting in a chair and then walk in and patient gradually increase his level of activity with assistance. Every day he will be able to do more activity and walk further. After 1-2 weeks return to usual activities, back to work 1-4 weeks for sedentary work. For manual labor 2-4 weeks and is dependent of whether TAVR was placed via leg (femoral) artery or another location that may take longer to heal. Return to driving 1-4 weeks. The timing depends first on whether there are other limitations to driving present pre-TAVR. In addition, post TAVR there is a need to be an assessment of a stable heart rhythm and no potential need for a pacemaker. <sup>(36, 40)</sup>

### **Diet**

The nurse informs the patient that the diet will be clear fluids at first and increased gradually to his regular diet over the first few days after his implant procedure. <sup>(36)</sup>

The nurse tells the patient that it is a normal groin area to be tender for a few days after the angiogram. It is also normal for a bruise to develop. If procedure made by incision in the chest, pain killers will be described for two up to six weeks. <sup>(41)</sup>

### **Follow-up**

First appointment is at 3–4 days after discharge to follow up with the nurse practitioner / cardiac surgeon / interventional cardiologist in the Valve Clinic, after 30 days post-procedure for an evaluation by the TAVR Heart Team, and then continue to see the TAVR Heart Team on an annual basis. <sup>(41)</sup>

### **Cardiac Rehabilitation**

During follow up visits with the cardiologist, they may recommend cardiac rehabilitation. Focusing on exercise, physical therapy, and adopting healthier lifestyle habits. <sup>(41)</sup>

Now a day valve positioning accuracy has improved dramatically due to both design enhancements, which have improved valve stability during deployment, and the availability of retrievable and repositionable delivery systems with newer versions of self-expanding TAVR devices. Based on initial results from ongoing clinical trials, it reveals in finding that the indication for TAVR may expand to lower-risk patients in the future; one can predict that by 2020, the majority of patients with severe symptomatic AS will undergo TAVI as first line therapy, regardless of surgical risk.

Globally, the modern-day medical adventure of TAVR has transformed clinical practice and will remain an important contribution in the management of patients with AS. In the current era Transcatheter devices for the different valves are meanwhile in development. <sup>(42, 43)</sup>

## **II. Conclusion**

TAVR has become the standard treatment for high-risk or inoperable older adult patients with severe aortic stenosis. As more patients undergo this procedure, nurses will need to understand TAVR, its potential complications, and the nursing strategies necessary to provide optimal care to these high-risk patients.

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