Introduction to Trans-Catheter Cardiac Valves

William S. Whitley MD
Assistant Professor
Clinical Chief of Service, Cardiothoracic Anesthesiology
Emory University Hospital, Atlanta, Georgia

Learning Objectives

1. Indications and implantation of Trans-catheter Pulmonic valves
2. Indications and selection process of Trans-catheter Aortic Valves Insertion (TAVI)
3. Surgical approaches to TAVI
4. Anesthetic challenges associated with each stage of the procedure
5. Intra-operative assessment with TEE

Objective 1: Indications and Selection: Pulmonic Valve

The Melody valve (Medtronic Inc, Minneapolis, Minn) is the first FDA approved transcatheter valve device. It is a bovine jugular vein sewn within a balloon-expandable stent. It was formally approved in January of 2010, on a humanitarian device exemption, for patients with the Melody valve for placement in high risk patients with right ventricular outflow tract (RVOT) obstruction.

The data is limited to a published prospective, non randomized short-term case series of 124 patients with stenosis and/or regurgitation within the RVOT.

Short term success and results were good. The procedure was performed in 124 of 150 catheterized patients. A major limitation is the circumferential coronary artery anatomy, due to risk of compression.

The RVOT pressure gradient dropped from a mean of 40 mmHG to a median of 12 mm Hg. 8/124 (6%) had short term events necessitating re-intervention. 7/8 went home. Pulmonic valve regurgitation was trivial to mild in all successful placements.

This device can be placed under sedation, but general anesthesia(GA) is typically performed. TEE is often helpful and much more feasible in the intubated patient. The GA is typically straight forward, with limited hemodynamic instability from the procedure.
Objective 2: Indications and Selection: TAVI
Aortic stenosis (AS) affects from 2% to 7% of Americans more than 65 years old. AS is a consistently progressive disease and is often associated with advanced, comorbid risk factors and previous bypass surgery. Because of advanced age and co-morbidities, up to 33% of symptomatic, AS patients are denied surgery. It is primarily for these patients a less invasive option for valve replacement is being sought. (2)

There are currently 2 Trans-Catheter AV devices available in other countries: the Edwards Sapien prosthesis and the CoreValve prosthesis.

Edwards Sapien Valve

Medtronic’s CoreValve

The Edwards SAPIEN Transcatheter Heart Valve is a pericardial xenograft with 3 tissue cusps mounted on a stainless steel vascular stent (Edwards Lifesciences, Irvine, CA). U.S. utilization has been limited to the prospective, randomized PARTNER (Placement of Aortic Transcatheter Valve) trial: 2 cohorts arms were studied.
  • Cohort A patients are randomized to TC AVR or conventional surgical AVR.
  • Cohort B patients are randomized to TC AVR or optimal medical management, including balloon aortic valvuloplasty.
Enrollment was limited to high-risk patients with significant risk of the poor outcomes typically associated with cardiac surgery. Specifics of the study criteria can be seen online:

  http://www.clinicaltrials.gov/ct/show/NCT00530894?order=4’;

Nation-wide enrollment in the Partner Trial has recently concluded and the device is now under consideration for FDA approval.

The CoreValve Revalving system is a self-expanding, nitinol frame with porcine pericardial leaflets and a sealing cuff. The valve extends from the left ventricular outflow tract to the aortic root. The valve is in the supra-annular position and thus does not interfere with the coronary ostia. Nearly 3000 patients in 25 countries have been treated worldwide. The Medtronic Corp acquired rights to the Corevalve system in 2009. FDA Trials are planned, but not yet underway. Wide spread use in the U.S. is several years away.
Objective 2: Surgical Approaches (3,4)
TC AVR is the implantation of a prosthetic AV via a catheter delivery system. Sophisticated fluoroscopy capabilities are required, and the procedure is done in the cardiac catheterization laboratory or a hybrid operating room.

The PARTNER trial:
The Edwards Sapien valve is crimped onto a balloon tipped catheter which is inserted via a 24F or 26F vascular introducer. 2 sizes are available; 23mm or 26 mm. Deployment requires balloon inflation of the stainless steel frame. Once deployed, the valve measures 14 or 16 mm in length

There are 2 approaches of the catheter delivery system to the aortic valve:
1. Trans-apical: anterograde through the left ventricular apex via mini thoracotomy
2. Trans-femoral: retrograde from the aorta via cannulation of the femoral artery.

The transfemoral approach is less invasive, but requires adequate femoral artery diameter for the introduced to be inserted. The primary indication for the trans-apical approach is inadequate femoral artery diameter, high grade aortic atheroma, and a tortuous aortic arch.

Excellent video animations of the 2 procedures are available on-line:

Objective 3: Anesthetic Challenges:
The anesthetic plan is determined by the TC approach and the use of TEE. It is critical that all vital support systems of the cardiac operating room (such as anesthesia supplies and cardiopulmonary bypass) be immediately available in the cardiac catheterization laboratory if no “hybrid room,” fluoroscopy capability is located in the operating rooms. Arterial and pulmonary artery catheter monitoring are standard in the PARTNER trial. Access to the patient is limited by the continuous use of a fluoroscopy arm. Placement of the lines and orientation of the equipment must anticipate the imaging boom’s position at the head of the head.

The transfemoral approach has been successfully completed under sedation and regional anesthesia, but general anesthesia (GA) is more comfortable and feasible in cases were prolonged TEE placement is planned. GA is required for the transapical approach due to the left, mini-thoracotomy. A single lumen, oral endotracheal tube is adequate with the apical incision.

Common stages of device delivery include:
1. Venous and Arterial access sheath placement: The most significant differences between the 2 TC AVR approaches are associated with the challenges and risks of the introducer insertion for device placement. With either approach, femoral artery and femoral vein access is required for the fluoroscopic aortogram, balloon valvuloplasty, and ventricular pacing.
With the retrograde trans-femoral approach, a 24 or 26 French introducer must be inserted and removed with significant risk of arterial injury and bleeding. The current introducer requires a cut down, but the next phase of the PARTNER trial will compare a newly designed 18 French delivery system to the larger systems.

Placement and withdrawal of the arterial cannula and the device introducer has been associated sudden volume loss and / or tissue injury. Rarely arterial/ventricular bleeding is poorly controlled and hypotension can occur.

The apical approach requires a 33 French introducer to be placed into the left ventricle apex. Apical left ventricular injury has been described and conversion to cardiopulmonary bypass seems to have a higher incidence in the limited published series.

Packed RBCs should be immediately available and conversion to cardiopulmonary bypass is a possibility.

2. **Balloon Valvuloplasty with rapid ventricular pacing:** Balloon valvuloplasty of the aortic valve is done during rapid ventricular pacing to minimize systolic pulse pressure. Mean blood pressures of 80-90 mmHg are the goal prior to the pacing. Blood pressure recovery is dependent on rhythm, LV function and preload filling after the brief overpacing. Valuloplasty is commonly associated with sudden onset or worsening of aortic regurgitation. Treatment should be supportive until TC AV is placed.

Aortic dissection and atheroembolism into the aortic arch have occurred secondary to retrograde catheter manipulation and device embolization. Neurologic deficits can occur. There are no specific mechanisms to limit embolic debris. It is recommended to utilize the transapical approach for patients with high-grade aortic atheroma and tortuous aortas. The complication rates of stroke and cognitive dysfunction are probably significant but require further data to be conclusively established.

3. **TC AV Stent Expansion:** The positioning and appropriate sizing of the stent is critical prior to balloon expansion. The valve comes in only 2 sizes 23mm or 26 mm. Direct sizing is not available and TEE typically does not visualize the calcified annulus very well. If the annulus is too large, stent embolization can occur into the LV or the ascending aorta. Over expansion of the annulus during the valvuloplasty and stent placement can cause root rupture and calcium embolization.

EKG changes are common after TC AVR. Up to 20% of patients demonstrated transient S-T elevation in one study. New onset regional wall abnormalities suggest ischemia. A serious concern would be malpositioning of the valve with occlusion of coronary ostia. Aortic root catheterization is typically done.
immediately after implantation to confirm patency of the coronary vasculature. Interventions include coronary stenting and coronary bypass grafting.

**Objective 4:** Role of TEE in the Procedure: (3,5)

TEE is an optional, but powerful adjuvant to placement of the TC AVR. Pre-implantation assessment with TEE allows for AV annular sizing and assessment of ascending aortic atheroma. Pre-and post-implantation TEE examination can improve prosthetic positioning and confirm parallel orientation of the valve to the aortic root. Aortic regurgitation can be rapidly assessed and possibly fixed in the OR. Hemodynamic management can be optimized and aortic dissection can be ruled out.

Some aortic insufficiency (AI) occurs in almost all patients after balloon valvuloplasty. Severe AI could cause a precipitous rise in capillary wedge pressure and pulmonary edema. Hemodynamic support should be initiated immediately, but definitive therapy would be placement of the TC AVR and resolution of the AI.

Some degree of para-valvular AI is seen after deployment of most Sapien valves. Typically AI is trivial to mild. Assessment should include imaging of the aortic valve in midesophageal long and short axis to determine the source and severity of the aortic valve insufficiency (AI). Moderate or severe AI often can be improved with balloon re-expansion of the stainless steel frame. (3,5) Hemodynamically significant central jets are less common, but have been reported. There are isolated reports of successful deployment of a second TC AVR into a defective Edwards Sapien valve and even reports of “off label” use of the Sapien valve in a calcified standard bioprosthetic ring. (6) While this sounds promising, concerns of patient prosthesis mismatch are a concern of “stacking” devices.

Clavel et al. did a comparative study 50 TC AVR patients to 2 groups of case matched stented and stentless bioprosthetic AVRs. Despite the retention of calcified AV tissue, the TC AVR demonstrated superior hemodynamics and larger effective orifice area than standard bioprosthetic techniques. A higher incidence of aortic regurgitation was found with the TC AVR. Previous studies suggest that incomplete and irregular expansion of the stainless ring can occur because of the retained calcified tissue in the annulus. (7)

**References**


