Transcatheter Aortic Valve Replacement (TAVR)

Melissa Mattimore, MS, ACNP-BC, AACC

Mount Sinai Heart TAVR Program
Mount Sinai Medical Center,
New York, NY
TAVR

- Aortic valve replacement via catheter approach
- Native aortic valve remains and is displaced by the new valve implantation
- Once in place the new prosthetic valve begins to function
- Indicated for use in severe, symptomatic AS due to degenerative calcification of the aortic valve
Etiology: Calcific Aortic Stenosis (AS)

Mechanism of Stenosis is Similar to Atherosclerosis

• Mainly solid calcium deposits within the valve cusps
• Progressive calcification and thickening results in stiff valve leaflets that do not move easily or open fully
• Similar risk factors to Coronary Artery Disease (CAD)
• High coincidence of CAD and AS in same individual
• 6th, 7th, and 8th decades of life

Normal 3-4 cm²
mild >1.5 cm²
moderate 1.0-1.5 cm²
severe <1.0 cm²
critical <0.7 cm²
Aortic Stenosis Prevalence

• Aortic Stenosis (AS) is the most prevalent native valve disease

• Prevalence:
  – 2% of people over 65
  – 3% of people over 75
  – 4% of people over 85

• Over 100,000 people in the U.S. are diagnosed with severe aortic stenosis each year
Aortic Stenosis and Symptoms

Onset of Severe Symptoms

Onset of dyspnea and other heart failure symptoms foretell the worst outlook for aortic stenosis patients

Classic symptoms of aortic stenosis:

• Angina
• Syncope
• Heart failure


Rationale for Transcatheter Aortic Valve Replacement

• Surgical Aortic Valve Replacement (SAVR) is the gold standard treatment for AS, it reduces symptoms and improves survival
• A large number of patients present a prohibitive risk for SAVR
• (In clinical practice, at least 30% of patients with severe symptomatic aortic stenosis do not undergo surgery for replacement of the aortic valve)
• Mortality is ~50% in the first 2 years after symptoms appear. Treating this group of patients with a safe and effective minimally-invasive catheter-based approach is a promising alternative for treating these patients
TAVR: Benefits

• Reduction in:
  – all-cause mortality
  – cardiovascular mortality
  – repeat hospitalizations

• Improvement in:
  – mean gradient and valve area
  – NYHA Functional Class
  – 6-Minute Walk Test
  – QOL
Medtronic CoreValve
Edwards Sapien Valves
TAVR: Potential Adverse Events

- Stroke
- Valve dysfunction, Paravalvular leak
- Conduction disturbance/Need for PPM
- Vascular/Bleeding Complication
- Annular rupture, LV perforation, tamponade
- Urgent need for Surgery
- Acute MI
- Thrombosis
- Infection
- Death
The Sapien 3 Trial:

Edwards SAPIEN 3
Transcatheter Heart Valve

Enhanced frame geometry for ultra-low delivery profile

Bovine pericardial tissue

Outer skirt minimizes paravalvular leak
CoreValve EVOLUT Study
CoreValve EVOLUT

Valve positioned too deep
Recapture begins
Partially recaptured
Valve fully recaptured
SENTINEL Cerebral Protection Device
TAVR Evaluation

- TTE/TEE/DSE (qualifies the patient, AVA < 1cm², MG > 40mmHg and/or PV > 4m/sec)
- CTA
- Cardiac Catheterization
- PFTs
- Carotid Doppler studies
- NYHA Functional Class
- Consult with interventional cardiologist
Surgical Risk Assessment

- Surgical risk assessment
  - Low Risk-STS <3%, surgical AVR
  - Intermediate Risk-operative mortality risk 3-8%. Surgical AVR. Sapien 3 Trial, SURTAVI.
  - High Risk-predicted operative mortality or serious, irreversible morbidity > 8% <50% @ 30 days, TAVR
  - Extreme Risk-predicted operative mortality or serious, irreversible morbidity > 50% @ 30 days, TAVR
Surgical Risk Assessment

- STS risk-The Society of Thoracic Surgeons’ risk model calculates the risk of operative mortality and morbidity of adult cardiac surgery on the basis of patient demographic and clinical variables.

- Incremental Risk Factors-evaluation of other clinical risk factors to improve the prediction of mortality and major morbidity in elderly patients undergoing cardiac surgery.
STS and Incremental Risk Score

**STS Risk**
- Age, Ht, Wt, Race
- Prior CTS
- Prior MI, CAD, PCI
- Valvular abnormalities
- EF, NYHA class
- Arrhythmia
- CKD, DM, chronic lung disease
- PAD, CVD

**Incremental Risk**
- Home O2,
- OSA, nocturnal BiPap
- Liver disease
- Anemia requiring transfusion
- Hostile mediastinum, porcelain aorta
- Frailty, Significant mobility impairment
Case Study: YK, 86 yr. M

- **Presentation:** Progressive exertional dyspnea and fatigue – NYHA class III for last 3 months.
- **PMH:** Atrial fibrillation, PPM, s/p WATCHMAN device 4/2015, CAD s/p PCI LAD 2/2015, TIA, DVT, Pulmonary embolism, PHTN, anemia, BPH, Osteoarthritis, Seizure disorder.
- **Medications:** Clopidogrel, Aspirin, Rosuvastatin, Coreg, Lisinopril, Finasteride
- **TTE:** Severe valvular aortic stenosis; Doppler valve area = 0.6 cm², Mean Gradient 42 mmHg, Ao peak CW velocity = 4.1 m/sec, LVEF = 68%
- **EKG:** Paced rhythm
- **R/L Cath 02/08/15 and course:** I vessel CAD, normal systolic LV function, mod pulmonary hypertension, severe AS and mild AI. Pt was considered high risk for SAVR and underwent PCI – successful intervention of LAD-Mid (DES – Xience Alpine) and LAD branch D1 (PTCA and CB PTCA).
• **CT Angiography:** Aortic annulus 22 X 30mm. Right CFA 8X 8mm, Left CFA 8 X 9mm. No anatomical contraindications.

• **STS risk mortality:** 4.63%
• **EuroScore risk:** 1.6%
• **Logistic Euroscore mortality:** 16.6%

• **Course:** Patient is determined to be high risk for surgical AVR due to advanced age, frailty, anemia and pulmonary hypertension.

• **Plan:** Patient is planned for CoreValve TAVR (31mm) via percutaneous femoral access
severe valvular aortic stenosis; mean gradient = 41 mmHg, Doppler valve area = 0.6 sqcm, Ao peak CW velocity = 4.1 m/sec, LVEF = 68%
CT Scan

**Annulus**

Max: 31.4 mm  
Min: 26.5 mm  
Mean: 28.9 mm

Perimeter = 90mm

Area = 6.4cm²
Ascending aortic diameter = 32 mm

Annular angle = 45 degrees
Sinus of Valsalva
Diameter = 38.6 mm

NCC 41/LCC 38/RCC 37 mm

Sino-tubular junction height
(above annulus)
= 26.2 mm and 23 mm
Coronary Ostia Height

RCA: 13.9 mm  
LM: 15.5 mm
Access

RCFA: 9 mm

LCFA: 9.2 mm
Summary of Case

- 86 year old male
- NYHA Class III
- TTE: AS – AVA 0.6cm², MG 42 mmHg

STS mortality: 4.63%
EuroScore: 1.67
Logistic Euroscore mortality: 16.6

Patient was determined to be high risk for surgical AVR
Case Study

Procedure:
CoreValve 31mm THV implant via percutaneous femoral access.

Post implant aortogram and TEE revealed severe paravalvular leak.

Post dilation with 28mm balloon with reduction in PVL to moderate and stable hemodynamics.

Post procedure course uncomplicated and discharged the following day.
Improving Outcomes and Reducing Complications

- Established TAVR team
- Patient-selection criteria
- Improved operator skills
- Improvement in valve sizing and positioning
- Judicious use of post implant dilation
- Subsequent device generations
- Reduction in sheath size
- Distal protection devices
- Better standardization of antiplatelet and anticoagulation therapy
- Established Pre and Post-procedure Protocols
Conclusion

- TAVR is an alternative treatment for aortic stenosis in those considered to have high or prohibitive surgical risk.

- The results of the Sapien 3 and SURTAVI trial may shift the guidelines if determined the TAVR is an appropriate course of treatment in those with an intermediate surgical risk.

- The TAVR results in marked valvular function improvement, immediate hemodynamic and clinical improvement.

- Results of the diagnostic work-up and the surgical risk assessment determines if TAVR appropriate