TAVR: It’s a Career, Not Just a Procedure!

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Cardiology
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Transcatheter Aortic Valve Replacement

UCDMC Team
- Administration
- Cardiology
- CT Surgery
- Anesthesia
- Nurses
- Cath Lab Techs
- Perfusionists
- Echo staff
- Ancillary support

- Team
- Approach to
- Valve
- Replacement

[Image of a transcatheter aortic valve replacement device]
Before You Start

- Do you have a hybrid OR?
- Do you have the necessary equipment?
- Do you have the necessary staff?
- Are you sure you want to do this?
- Novelty wears off very fast!
- These patients are very old, very needy and have lots of concerned family!
Aortic Stenosis

• Symptomatic Aortic Stenosis - Surgical Aortic Valve Replacement is the standard of care

• Surgical Aortic Valve Replacement - Mortality Risk
  - Isolated AVR - 3.3 to 5.7%
  - AVR with CABG - 6.8 to 7.3%

• Percutaneous Aortic Valve Implantation in high risk aortic stenosis patients - feasible and safe
Aortic Stenosis

– Etiology

- Calcific degenerative
  - Degenerative process with proliferative & inflammatory changes, lipid accumulation, up regulation ACE, infiltration with macrophages & T lymphocytes. Bone formation (vascular calcification)

- Congenital - Bicuspid
  - Turbulent flow - traumatizes leaflet fibrosis, rigidity, calcification & narrowed orifice

- Rheumatic
  - Adhesion & fusion of commissures & cusps retraction & stiffening cusps borders.
  - Calcific nodules both surfaces - small round or triangular opening
Prolonged latent period - morbidity & mortality very low

Symptomatic aortic stenosis - Cardinal symptoms
- Angina
- Syncope
- Heart failure

Onset of symptoms - Outlook changes dramatically

Average survival 2 - 3 years - High risk of sudden death

Management decisions based on these data
- Asymptomatic - Conservative treatment
- Symptomatic - Aortic Valve Replacement
PARTNER Study Design

**Symptomatic Severe Aortic Stenosis**

**ASSESSMENT:** High Risk AVR Candidate
3105 Total Patients Screened

Total = 1058 patients

**n= 700**

**High Risk**

- **ASSESSMENT:** Transfemoral Access

  - **High Risk TF**
    - 1:1 Randomization
      - TAVI Transfemoral VS Surgical AVR
  
  - **High Risk TA**
    - 1:1 Randomization
      - TAVI Transfemoral VS Surgical AVR

**Primary Endpoint:** All Cause Mortality (1 yr) (Non-inferiority)

**n= 358**

**Inoperable**

- **ASSESSMENT:** Transfemoral Access

  - 1:1 Randomization
    - TAVI Transfemoral VS Standard Therapy (usually BAV)

**Primary Endpoint:** All Cause Mortality over length of trial (Superiority)

2 Parallel Trials: Individually Powered
Absolute Reduction in Mortality Continues to Diverge at 2 Years

HR [95% CI] = 0.56 [0.43, 0.73]  
P (log rank) < .0001

Δ at 1 yr = 20.0%  
NNT = 5.0 pts

Δ at 2 yrs = 24.7%  
NNT = 4.0 pts

Counts at Risk

<table>
<thead>
<tr>
<th></th>
<th>Edwards SAPIEN THV</th>
<th>Standard Therapy</th>
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</thead>
<tbody>
<tr>
<td>1 yr</td>
<td>138</td>
<td>121</td>
</tr>
<tr>
<td>2 yrs</td>
<td>124</td>
<td>85</td>
</tr>
<tr>
<td>3 yrs</td>
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<td>62</td>
</tr>
<tr>
<td>4 yrs</td>
<td>83</td>
<td>42</td>
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</table>
> 30% Absolute Reduction in Cardiovascular Mortality

Cardiovascular Mortality at 1 Year and 2 Years

HR [95% CI] = 0.44 [0.32, 0.60]
P (log rank) < .0001

Δ at 1 yr = 24.1%
NNT = 4.1 pts

Δ at 2 yrs = 31.4%
NNT = 3.2 pts

Numbers at Risk

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Valve Clinic

- Must have a dedicated valve clinic
- Must have a dedicated valve nurse
- Must have CT surgeons with you in clinic
- Should have multiple screening exams done before patients are seen in clinic
- Janine will go over screening exams
- All data must be submitted online to Edwards for approval
• The SAPIEN valve is intended to be implanted in a native annulus size range comparable to the following TEE measurements:

<table>
<thead>
<tr>
<th>Valve Size</th>
<th>Annulus Diameter</th>
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<td>26 mm valve</td>
<td>23 mm</td>
</tr>
<tr>
<td>18 mm</td>
<td>21 mm</td>
</tr>
<tr>
<td>19 mm</td>
<td>22 mm</td>
</tr>
<tr>
<td>20 mm</td>
<td>23 mm</td>
</tr>
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<td>21 mm</td>
<td>24 mm</td>
</tr>
<tr>
<td>22 mm</td>
<td>25 mm</td>
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Valve Size Selection

- In annulus diameters 21 mm and 22 mm, either a 23 mm or 26 mm valve may be implanted.

Valve Size to Annulus Diameter
The primary goal of aortic valve implantation is to maximize the effective orifice area and reduce the mean and peak pressure gradients.

- When possible a 26 mm valve should be implanted in annulus diameters 21 mm and 22 mm.

**Effective Orifice Area**

![Effective Orifice Area Graph](image)
Members of the Heart Team present in the TAVR procedure:
• IP: Implanting physician (Room-setup shown for transfemoral procedure)
• PA: Physician’s Assistant
• CTS: Cardiothoracic Surgeon
• A: Anesthesiologist

• E: Echocardiographer
• P: Perfusionist
• DPL: Device Prep Lead
• OR/CCL Staff: Operating Room/Cardiac Cath Lab Staff

Ideal room size is >800ft²
Prepare the Patient

- RIJ large sheath and PA catheter
- Radial arterial line
- General Anesthesia
- Oral Gastric Tube
- Foley catheter
- Full surgical prep
- TEE probe in place
- Defibrillator pads in place
- IABP leads on the patient
Puncture Site
RetroFlex 3 Transfemoral System

23 mm RetroFlex 3 Transfemoral System

9000TFX
Edwards SAPIEN Transcatheter Heart Valve

9120FS23
RetroFlex 3 Transfemoral Delivery System

9100CR23
Crimper

9120BC20 (20 mm x 3 cm)
RetroFlex Balloon Catheter

9100DKS7
RetroFlex Dilator Kit

9120S23 (22F)
RetroFlex Introducer Sheath Set

96402 (25 mL)
Two Atrion QL2530 Inflation Devices
RetroFlex 3 Transfemoral System

26 mm RetroFlex 3 Transfemoral System

9000TFX
Edwards SAPIEN Transcatheter Heart Valve

9100CR26
Crimper

9120BC23 (23 mm x 3 cm)
RetroFlex Balloon Catheter

9120FS26
RetroFlex 3 Transfemoral Delivery System

9120S26 (24F)
RetroFlex Introducer Sheath Set

96402 (25 mL)
Two Atrion QL2530 Inflation Devices

9100DKS7
RetroFlex Dilator Kit
Edwards SAPIEN Valve
Model 9000TFX

Edwards SAPIEN Valve
• 23 mm and 26 mm valve sizes
• Stainless steel frame
• Bovine pericardial tissue
• Carpentier-Edwards ThermaFix process*

*No clinical data are available which evaluate the long-term impact of the Edwards Lifesciences tissue treatment in patients.
Edwards Crimper
Models 9100CR23 and 9100CR26

Uniquely designed to crimp transcatheter heart valves
RetroFlex 3 Delivery System

Tapered Distal End

Articulating Delivery System

Flex Catheter
Valve Crossing and Wire Exchange

- Cross native valve with straight wire (suggestion: AL1 or AL2)
- Can measure pressure gradients prior to wire exchange
- Exchange 0.035” Amplatz extra-stiff wire with pre-shaped distal end in left ventricle
  - Ensure guidecath is advanced upon wire exchange to ensure exchange wire does not get caught in the mitral chordae.
Rapid Ventricular Pacing: Test Run

- Set output to high setting to ensure proper capture
- Note that there can be a delay between pacing onset and effective reduction of cardiac output
Tracking Over Aortic Arch

- Rotate flex wheel to track over aortic arch
- Use LAO 30 to 40 to provide view of aortic arch
- Catheter flexes away from the flush port
- Five rotations of the flex wheel for full flex
Crossing Native Valve

- Flex catheter should be fully flexed to pull wire out of commissure
- Always keep delivery system and SAPIEN valve directly adjacent to support crossing the native valve
- DO NOT FORCE THE VALVE
- Use short movements to prevent “jumping” of the valve into the ventricle
- Use RAO or AP projection for crossing to visualize the wire in the ventricle

NOTE: Tip extends 4.5 cm past crimped valve
Final Positioning

• Fluoroscopy should be the primary method of visualization for positioning and deployment

• Use of TEE will assist with positioning

• Position the Edwards SAPIEN valve:
  – 50% to 60% ventricular
  – Valve positioning should be coaxial
Valve Foreshortening

<table>
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<th>Edwards SAPIEN Valve</th>
<th>Crimped Height</th>
<th>Expanded Height</th>
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<tr>
<td>23 mm</td>
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NOTE:
The Edwards SAPIEN valve foreshortens approximately 2 mm for both size 23 mm and 26 mm.
Assessing Aortic Regurgitation: TEE

- 2D TEE provides better visualization than TTE
- 3D TEE
  - Biplane Imaging allows real-time evaluation of both short and long axis
Sheath Removal

- Reinsert introducer into sheath over guidewire
- Carefully withdraw sheath into common femoral artery
- Contrast can be injected contralateral or through the sheath to detect vascular damage
- Withdraw sheath
- Leave guidewire and contralateral pigtail in place
Post Procedure Care

- Monitor patients in ICU or CCU for 24 hours
- Monitor closely for potential post-op complications
  - Bleeding
  - Late AV block (ECG monitoring)
  - CHF
  - Renal dysfunction
  - CVA
CCU/CTICU

• Systolic blood pressure control
  ▪ Manage between 110 and 130 mmHg for the first 24 hours

• Antiplatelet therapy
  ▪ 81-325 mg aspirin PO QD
  ▪ Optional: Clopidogrel 75 mg PO QD for six months (or 250 mg ticlodipine PO BID for patients who are allergic to aspirin or clopidogrel)
Reimbursement?

- CMS released a statement on May 1st: They will pay for TAVR in properly selected patients and appropriately selected sites.
- Patients with severe symptomatic AS in whom 2 CT surgeons have deemed the patient not to be a candidate for standard surgery
- Certain number of PCIs, AVR experience etc.
• Mandatory reporting of every case and follow up for at least one year.
• Database is not cheap
• Follow for complications and redo procedures as well as quality of life assessment.
Boston Scientific - Lotus™ Valve

- Braided nitinol stent structure
  - Radial expansion as it shortens
- Bovine pericardial valve
- Valve leaflets function during deployment
- Repositionable
- Retrievable at any point prior to release
- Adaptive Seal
- 23 mm, 27 mm - 18 French

First in Man 18 French
European Trial

First in Man 21 French
European Trial

2007  2008  2009  2010  2011  2012

European Trial
European Trial
CE Mark
Final Thoughts

• The greatest new technology since stents- without question
• Don’t rush into this, it is a career choice not a hobby
• The patients aren’t going anywhere fast
• Don’t do patients just to do patients!
• They better be able to recover or the procedure is not worth doing.
Thanks