Transcatheter Aortic Valve Implantation (TAVI)... & the Radiologist

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Disclosures

• None

TAVR vs. TAVI

• TAVR = Transcatheter Aortic Valve Replacement
• TAVI = Transcatheter Aortic Valve Implantation
• TAVI seems to have won out in the literature

Objectives

• Introduction to TAVR/TAVI
• Familiarization with available and soon to be available valves
• Review measurements performed on preoperative CT scans
• Review potential complications
• Highlight developing applications

Aortic Stenosis

• Slowly develops, but rapidly progresses after symptom onset
  • 50% mortality within 2y of symptom onset
• Severe aortic stenosis defined as any of the Following:
  • Aortic Valve Area < 0.8 cm²
  • Mean Aortic Valve Gradient > 40 mmHg
  • Peak Aortic Jet Velocity > 4 m/sec

Aortic Stenosis

• Surgical replacement typically offers a low mortality cure
  • Up to 30% of patients w/ AS are not surgical candidates
• First transcatheter valve placed using an antigrade transeptal approach by Cribier and co-workers in 2002
• Currently, over 60,000 valves have been placed in over 40 countries
TAVI: how does it work?

Floroscopy

Transapical approach

Edwards SAPIEN Valve

PARTNER

- Cohort A (Non-Surgical Patients → TAVR vs. Valvuloplasty) Oct. 2010
- Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery
- Cohort B (TAVR vs. Surgery in High Risk Patients) June 2011
- Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients

Cohort A (Non-Surgical Patients)

- Multi-Center (21 centers, 17 in US)
  - 358 patients with:
    - Severe Aortic Stenosis:
      - Aortic Valve Area < 0.8 cm²
      - Mean Aortic Valve Gradient > 40 mmHg
    - Peak Aortic Jet Velocity > 4 m/sec
    - Predicted > 50% mortality or severe morbidity at 30 days after potential surgery
  - Exclusion:
    - Bilateral iliac valve: LVEF < 25%, AV annulus < 18 mm or > 25 mm
    - Severe MR or AR; TIACVA within 6 mo; Severe renal insufficiency
  - Randomized:
    - TAVR or Valvuloplasty
  - Follow-up at 30 days and 1 year


Cohort A (Non-Surgical Patients)

- Summary
  - At 1 year, TAVR showed significantly lower risk of death from CV and any cause
    - # needed to treat to prevent 1 death from AS = 5
    - # needed to treat to prevent 1 death or re-hospitalization = 3
  - TAVR had Significantly more:
    - Strokes
    - Major Vascular Complications
    - Major Bleeding
  - TAVR patients experienced significant improvement symptoms
    - Based NYHA class I or II at 30 days, 6 months and 1 year (all P < 0.001)


Cohort B: High-Risk Patients

- Multicenter (25 centers, 22 in US)
- 699 patients with:
  - Severe Aortic Stenosis (same criteria as Cohort A)
  - High-Risk for Operative Complications:
    - Co-Existing conditions associated with > 15% risk of death within 30 days of procedure
  - Randomized into:
    - Standard treatment: Surgical Replacement (N = 351)
    - TAVR (N = 348)
      - Those were further split based on degree of PAD:
        - Transfemoral approach (N = 244)
        - Transapical approach (N = 104)

Cohort B: High-Risk Patients

- Primary endpoint was Death from any cause at 1 year
  - TAVR = 24.2% versus Surgical = 26.8% (P = 0.44)
  - Served to prove “Non-Inferiority” of TAVR in this High-Risk Population (P = 0.001)
  - TAVR again showed increased risk of Stroke at 30 days and 1 year
    - 30 days: 5.5% vs 2.4% (P = 0.04)
    - 1 year: 8.3% vs 4.3% (P = 0.04)
  - Combined risk of Death and Stroke were not different (TAVR vs Surgery)
    - 30 Days: 6.9% vs 8.2%
    - 1 year: 26.5% vs 28.0%


Cohort B: High-Risk Patients

- TAVR had higher rates of Major Vascular Complications:
  - 11.0% vs 3.2% (P<0.001)
- Surgery had higher rates of Major Bleeding and New-Onset A-Fib
  - 9.3% vs 19.5% (P<0.001) and 4.6% vs 16.0% (P<0.001)
- TAVR had shorter ICU stay (3d vs 5d) & index hospitalization (8d vs 12d)
  - At 30 days, TAVR showed a significant reduction in NYHA symptoms
    - (Grades I or II), but this difference equalized at 1 year follow up
  - At 1 year, TAVR had better valve function (Gradient and Valve Area)
    - Significantly more aortic regurgitation after TAVR:
      - 30 Days: 12.2% vs 0.8%
      - 1 Year: 6.0% vs 1.3%

### Valve comparison

<table>
<thead>
<tr>
<th>Sapien valve</th>
<th>CoreValve</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Balloon expandable</td>
<td>- Self-expanding</td>
</tr>
<tr>
<td>- Round annulus</td>
<td>- Oval annulus</td>
</tr>
<tr>
<td>- Annular valve</td>
<td>- Supraannular valve</td>
</tr>
<tr>
<td>- Lower pacemaker risk (5.9%)</td>
<td>- Higher pacemaker risk (22.5%)</td>
</tr>
</tbody>
</table>

### Preoperative imaging

- Cardiac Catheterization
- Transthoracic and/or transesophageal echo
- Cardiac CT
  - Gated, with systolic and diastolic phases
  - No β blockade
- Chest/Abdomen/Pelvis CT
  - Aortic runoff—with fast scanner can be performed with same bolus as cardiac CT

### Anatomy: how do we size valves?

- Sinutubular junction
- Anatomical ring
- Virtual ring formed by joining basal attachments of aortic valve leaflets

### Schultz et al. (Euro Heart Journal)

- **Three Dimensional Evaluation of the Aortic Annulus Using Multiphasic CT: Are Manufacturer’s Guidelines for Sizing for Percutaneous Aortic Valve Replacement Helpful?**

- 75 pts being evaluated for TAVR including a CT for pre-op planning
  - Only 50 received the valve (25 were too small / large for valve)
  - Cardiologist picked valve based on:
    - Gender, body height, weight
    - LVOT and Aortic root on TTE and Aortography
  - CT was performed and various measurements were obtained to find:
    - What was the best match between the cardiologist choice and manufacturer
Measurements

Radiologists

Cardiologists


How Did Schultz et al. Measure?

Step 1
- Establish sagittal (A) and coronal (B) planes to determine the oblique sagittal and coronal planes

Step 2
- Using oblique sagittal and coronal planes to establish coaptation plane through the coronary cusps (C)

Step 3
- Using the coaptation plane (C), scroll towards the heart in this plane to find the nadir of the cusps (D)

Step 4
- Using plane D, measure the maximum and minimum diameter of the aortic annulus

What did Shultz et al. Find?

- $D_{max}$
- $D_{min}$
- $D_{mean}$
- Assessed Adverse Outcomes
- Trend when disagreement between cardiologist & manufacturer
- Chose too Small
  - Para-valvular aortic regurgitation
- Chose too Large
  - Device embolization
  - Aortic root rupture

Cardiac CTA: what to report?

Sapien valves:
- Annular diameters
- Annular area
- Valve plane to coronary ostia distances
- Agatston calcium score of the valve
- LA or LV thrombus
- IMA graft crossing midline (in case of SAVR)

Measurements

Annular cross-sectional area (CSA)

- Area = 379 mm²
- $D_{CSA} = 22.0$ mm

**Long and short axes**

- \( D_{\text{max}} = 25.9 \)
- \( D_{\text{min}} = 20.1 \)
- \( D_{\text{mean}} = 23.0 \)

**Annular perimeter**

- Perimeter = 71.9 mm
- \( D_{\text{circ}} = 22.9 \) mm

**Coronary sinus heights**

**Agatston calcium score of valve**

- Orange = central valve calcification
- A score of \( \geq 1650 \) is highly correlated with severe stenosis in cases where Echo is equivocal

**CoreValve: what to measure?**

- Aortic annulus perimeter
- Sinus of Valsalva diameters
- Sinus of Valsalva perimeter
- Sinus of Valsalva heights
- Sinotubular junction diameters

**Sinus of valsalva diameters and perimeter**
Sinus of Valsalva heights

Sinotubular junction diameters

CoreValve: what to measure?

- Ascending aortic diameters
  - 3 cm above valve plane
    - For 23 mm valve, must be less than 34 mm
  - 4 cm above valve plane
    - For 26 mm valve, must be less than 40 mm
    - For 29 and 31 mm valves, must be less than 43 mm

CoreValve: what to measure?

- Aortic angulation
  - Coronal view
    - For femoral/subclavian access, must be <70°
    - For transaortic access, must be >30°

Aortic angulation
Chest/abd/pelvis CT: what to report?

- Porcelain aorta
- Aneurysms
- Minimal diameters
  - Aorta
  - Common iliacs
  - External iliacs
  - Common femorals
- Comorbid disease
  - Tumors

What is a porcelain aorta?

- Severely calcified ascending aorta and arch, precluding cross clamping or replacement
- Generally, dense circumferential or near-circumferential calcification of all or most of the ascending aorta

Porcelain aorta

Common iliac measurement

External iliac measurement

Common femoral measurement
Comorbid disease: PE

What are we doing at Columbia
- Standard here is to use TEE to obtain annulus measurements
- CTA Cardiac
  - To assess aortic annulus size (End Diastole and Systole)
  - To assess annulus to coronary ostia distance (locking the artery)
  - To assess degree of valve calcification
- CTA Chest/Abdomen/Pelvis
  - To assess Aorta calcification
  - Assess the iliac and femoral artery anatomy
  - Best to have a ≥8 mm vascular access to accommodate the loading system

Complications
- Stroke
- Para-valvular aortic regurgitation
- Heart block
- Vascular injury
- Device migration

Next Generation valves

<table>
<thead>
<tr>
<th>Valve</th>
<th>Company</th>
<th>Innovations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sapien 3</td>
<td>Edwards</td>
<td>14 fr introducer Cuff to reduce paravalvular leak</td>
</tr>
<tr>
<td>Centera</td>
<td>Edwards</td>
<td>14 fr introducer, repositionable</td>
</tr>
<tr>
<td>Sadra Medical Lotus</td>
<td>Boston Scientific</td>
<td>Repositionable/retrievable prior to deployment, Reduce paravalvular leak</td>
</tr>
<tr>
<td>Direct Flow</td>
<td>Direct Flow</td>
<td>Repositionable/retrievable prior to deployment, Reduce paravalvular leak</td>
</tr>
<tr>
<td>Acurate TA</td>
<td>Symetis</td>
<td>Reduce paravalvular leak. Stabilization arched</td>
</tr>
<tr>
<td>Portico</td>
<td>St. Jude</td>
<td>Repositionable. Anti-calcification, Decreased conduction system abnl.</td>
</tr>
<tr>
<td>Engager</td>
<td>Medronic</td>
<td>Transapical only. Low implant height to prevent interference with coronary ostia.</td>
</tr>
<tr>
<td>JenaValve</td>
<td>JenaValve</td>
<td>Transapical only. Repositionable/ retrievable prior to deployment.</td>
</tr>
</tbody>
</table>

Centera valve
- Self-expanding nitinol
- Waist designed to anchor in the annulus

Sapien 3 Valve
- Balloon expandable
- External sealing ring
- 14 fr introducer
Direct Flow valve

- Repositionable/retrievable
- Cuff inflatable with polymer to conform to irregular annulus

Developing applications

- Valve-in-valve aortic and mitral valve replacements
- Pulmonic valve
- Antiembolization devices

Valve in valve TAVI and TMVI

TMVR in mitral annuloplasty ring

Melody transcatheter pulmonic valve
MRI safety

- Edwards Sapien conditional 6
- Edwards Sapien XT conditional 5
- Medtronic Core Valve conditional 5
- Direct Flow conditional 5

“the list”, MRISafety.com

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