Aortic Stenosis: When Will Surgery ALWAYS Be a Better Option in 2016

September 17, 2016
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Associate Professor of Surgery

Educational Objectives

At the conclusion of this activity, learners should be able to:

1. To describe the role of surgery in patients with aortic stenosis.
2. To describe the role of transcatheter aortic valve replacement in patients with aortic stenosis.
3. To delineate the risks and benefits of when surgical valve replacement is better than transcatheter aortic valve replacement.
**Isolated Aortic Valve Replacement**

**When to intervene?**

**Aortic Stenosis:**
- Symptomatic (angina, syncope, dyspnea, heart failure)
- Asymptomatic
  - Severe (mean $\geq 50$ mm Hg, $\text{AVA} \leq 1.0$ cm²)

**Aortic Regurgitation:**
- Severe (3+ to 4+) aortic insufficiency in the presence of symptoms, left ventricular dilation, or impaired left ventricular function.
Aortic Stenosis
Symptomatic - Survival

<table>
<thead>
<tr>
<th>Severity of aortic stenosis&lt;sup&gt;25&lt;/sup&gt;</th>
<th>Degree of aortic stenosis</th>
<th>Mean gradient (mmHg)</th>
<th>Aortic valve area (cm&lt;sup&gt;2&lt;/sup&gt;)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mid aortic stenosis</td>
<td>&lt;25</td>
<td>&gt;1.5</td>
<td></td>
</tr>
<tr>
<td>Moderate aortic stenosis</td>
<td>25 - 40</td>
<td>1.0 - 1.5</td>
<td></td>
</tr>
<tr>
<td>Severe aortic stenosis</td>
<td>&gt;40</td>
<td>&lt;1.0</td>
<td></td>
</tr>
<tr>
<td>Critical aortic stenosis</td>
<td>&gt;70</td>
<td>&lt;0.6</td>
<td></td>
</tr>
</tbody>
</table>

Aortic Stenosis
ACC / AHA Classification

Angina and Syncope – 3 years
Dyspnea – 2 years
Heart Failure – 1.5 years

Aortic Valve Replacement
Options

Access
- Full sternotomy
- Hemisternotomy
- Transapical
- Groin incision
- True percutaneous

Support
- CPB
- Left-sided heart support
- CPB standby

Invasiveness
- Most
- Least

Support
- CPB

Invasiveness
- Most
- Least
Patient Selection

- Open Surgical AVR
  - Full Sternotomy
  - Mini Sternotomy

- TAVR
  - Transileofemoral
  - Transapical
  - Left subclavian
  - Direct aortic
  - "Alternative alternative"
    - Carotid
    - Cavo-aortic

Aortic Stenosis: TAVR vs (s)AVR

Operable AS patients

- Surgery (AVR): ~65%
- TAVR or AVR: ~25%
- TAVR: ~10%
- Full: Too Sick
So why not TAVR everyone?
Conversely, why not surgery for everyone?

"OK, pay up, Roy. I did the entire procedure left-handed and with only two minor goof-ups."

**COMMON SENSE**
Just because you can, doesn’t mean you should.

**Anatomy**

- Left Atrium and Ventricle
- Right pulmonary artery
- Left pulmonary artery
- Atrioventricular valves
- Opening of left coronary artery
- Right coronary artery
- Aortic valve
- Nodal area of sinuatrial node
- Nodal area of atrioventricular node

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**THE OHIO STATE UNIVERSITY MEDICAL CENTER**
Anatomy: Bicuspid valve

- Less Common
  - Congenital Abnormality
  - Rheumatic Fever
- More Common
  - Age-Related Calcific Aortic Stenosis

Images courtesy of John Reed, MD at St. Paul’s Hospital and Nars Tuinen, MD at the CVPath Institute.

Anatomy: Annulus

- Too large annulus
  - Aortic aneurysm

- Too small annulus
  - Need for root enlargement

Surgical techniques of posterior aortic root enlargement reported so far (Nick’s white arrow, Nuñez’s black arrow, Manouquian’s black plus black dotted arrows). NCC, noncoronary cusp; LCC, left coronary cusp; RCC, right coronary cusp; AML, anterior mitral leaflet.
Anatomy: Coronary obstruction

- Height of coronary to annulus
- Inappropriate Sinus reserve
  - Heavy calcifications
  - Aortic root rupture

Anatomy: Transcatheter access route

- Inappropriate access vessels
  - Transfemoral
  - Direct aortic
  - Subclavian
# Anatomy: Access

## Edwards SAPIEN vs. Medtronic CoreValve

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Edwards SAPIEN</th>
<th>Medtronic CoreValve</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>23mm</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delivery Catheter Diameter</td>
<td>22F</td>
<td>18F</td>
</tr>
<tr>
<td>Sheath External Diameter</td>
<td>7.7</td>
<td>5.3</td>
</tr>
<tr>
<td>Minimum Arterial Diameter</td>
<td>5.9</td>
<td>5.1</td>
</tr>
<tr>
<td>Aortic Valve Prosthesis Height</td>
<td>14.3</td>
<td>16.1</td>
</tr>
<tr>
<td><strong>26mm</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delivery Catheter Diameter</td>
<td>24F</td>
<td></td>
</tr>
<tr>
<td>Sheath External Diameter</td>
<td>9.0</td>
<td></td>
</tr>
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<td>Minimum Arterial Diameter</td>
<td>6.1</td>
<td></td>
</tr>
<tr>
<td>Aortic Valve Prosthesis Height</td>
<td>16.1</td>
<td></td>
</tr>
<tr>
<td>Available Access Approaches</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transcaval, Transapical</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Transcaval, Left Subclavian, Direct Aortic</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Other Measurements

- **Annulus Size CTA (mm)**
- **Annulus Perimeter CTA (mm)**
  - Edwards: N/A, Medtronic: 66.5-68.2, 62.8-72.3, 72.3-84.8, 81.8-91.3
- **Annulus Area CTA (mm²)**
  - Edwards: >25, >28, Medtronic: ≥34, <40, <43, <43
- **SOV (mm)**
  - Edwards: N/A, Medtronic: ≥15, >15, >15, >15
- **Ascending Aorta Max Diameter (mm)**
  - Edwards: >10, >10, Medtronic: N/A, N/A, N/A, N/A
- **SOV Height (mm)**
  - Edwards: >10, >10, Medtronic: N/A, N/A, N/A, N/A
- **Annulus to Right Coronary Height (mm)**
  - Edwards: >10, >10, Medtronic: N/A, N/A, N/A, N/A
- **Annulus to Left Coronary Height (mm)**
  - Edwards: >10, >10, Medtronic: N/A, N/A, N/A, N/A

## Expanded Annulus Size Coverage and Reduced Minimum Access Vessel Diameters

- **Edwards SAPIEN**
  - Edwards SAPIEN Introducer Set (Transfemoral)
  - Minimum Access Vessel Diameter: 6.0 mm
  - Edwards SAPIEN Steent (Transapical)
  - Native Annulus Size by TEE: 16.7±2 mm
  - Native Annulus Area: 230-462 mm²
  - Area-Shortest Diameter: 20.7-25.4 mm

- **Medtronic CoreValve**
  - Edwards SAPIEN Introducer Set (Transfemoral)
  - Minimum Access Vessel Diameter: 6.0 mm
  - Edwards SAPIEN Steent (Transapical)
  - Native Annulus Size by TEE: 16.7±2 mm
  - Native Annulus Area: 230-462 mm²
  - Area-Shortest Diameter: 20.7-25.4 mm
Anatomy: Access

**Illofemoral vessels < 6 mm**

Anatomy: Access – tortuosity
Anatomy: Borderline and Tortuous

Anatomy: No ileofemoral access
Anatomy: Aortic Angulation

Abdominal Aorta Angulation

Long sheath to avoid perforating the aorta

Anatomy: Aortic Angulation

Ao Root angulation 62° - site
Ao Root angulation 61° - CA
Anatomy: Aortic Angulation

Whole Aorta and Iliacs Tortuosity

Anatomy: Aortic Pathology
Subclavian Access

Transapical Approach
Anatomy: Pre-operative planning

- Computed tomography
  - Anatomy
    - Length of ascending aorta
      - Aortic annulus to brachiocephalic trunk
    - Sternomanubrium to right rib cage
    - Calcified plaques
    - Lung lesions, pleura, pericardium, mediastinum, supra-aortic valves
  - Size of aortic annulus


Patient Prosthesis Mismatch
Concomitant Procedures

• Mitral valve
• Tricuspid valve
• Anti-arrhythmia
• Coronary revascularization

Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Prior Coronary Artery Bypass Graft Operation: A PARTNER Trial Subgroup Analysis

Kevin L. Greason, MD, Verghese Mathew, MD, Rakesh M. Suri, MD, David R. Holmes, MD, Charanjit S. Rihal, MD, Tom Mcelwain, MS, Ke Xu, PhD, Michael Mack, MD, John G. Webb, MD, Augusto Pichard, MD, Mathew Williams, MD, Martin B. Leon, MD, Lars Svensson, MD, Vinod Thourani, MD, and Craig R. Smith, MD

Mayo Clinic, Rochester, Minnesota; Cardiovascular Research Foundation, New York, New York; Medical City, Dallas, Texas; University of British Columbia and St. Paul's Hospital, Vancouver, British Columbia, Canada; Washington Hospital Center, Washington, District of Columbia; Columbia University Medical Center and New York Presbyterian Hospital, New York, New York; Cleveland Clinic Foundation, Cleveland, Ohio, and Trinity University, Atlanta, Georgia

Background. The Placement of Aortic Transcatheter Valves (PARTNER) trial reported a reduced rate of mortality in patients with previous coronary bypass surgery (CABG) operation who received surgical aortic valve replacement (SAVR) in comparison with transcatheter aortic valve replacement (TAVR). We sought to further evaluate these groups.

Methods. We reviewed the database of the 699 patients enrolled in the PARTNER trial. The cohort for this study consisted of 288 patients (41.3%) who had a history of CABG operation before enrollment in the PARTNER trial. All patients were followed up for 2 years.

Results. The mean age was 81.5 ± 6.4 years, and 231 patients (66.2%) were men. The preoperative characteristics were similar in the 100 patients (32.4%) who received SAVR and the 188 (58.6%) who received TAVR. There were no differences between the two groups with respect to the operative outcomes of death, stroke, and myocardial infarction, but the TAVR patients experienced more paravascular regurgitation (p=0.0001). At 2 years, there was a trend toward greater all-cause mortality in the TAVR patients (hazard ratio [HR] 1.35; 95% confidence interval [CI] 0.89, 2.03; p=0.22). Furthermore, the TAVR patients had more repeated hospitalization (HR 1.75; 95% CI 1.09, 2.75; p=0.03), death at any cause or repeated hospitalization (HR 1.32; 95% CI 1.06, 1.69; p=0.02), and death of any cause or stroke (HR 1.50; 95% CI 1.00, 2.27; p=0.05).

Conclusions. The 2-year follow-up of patients with a history of previous CABG operation in the PARTNER trial demonstrated improved outcomes with SAVR in comparison with TAVR. Further longitudinal assessment is necessary to corroborate these findings and to understand the possible causes.

(Am Thorac Surg 2014;108:4-8) © 2014 by The Society of Thoracic Surgeons
Infection

- Need to debride all infected tissue in endocarditis
  - Aortic root abscess

- Prosthetic valve endocarditis

Risk-adjusted estimates of explant for structural valve dysfunction (SVD) by competing risk analysis. For this figure, the patient was assumed to be a man in New York Heart functional class III, undergoing first valve replacement, and not undergoing con...

Michael K Banbury, Delos M Cosgrove III, Jennifer A White, Eugene H Blackstone, Robert W M. Frater, J.Edward Okies

Age: Case Example

<table>
<thead>
<tr>
<th>Procedure Type</th>
<th>Cardiac Valve Replacement (AVR)</th>
<th>CABG only</th>
<th>AVR Replacement only</th>
<th>AVR Repair</th>
<th>AVR Replacement + CABG</th>
<th>AVR Replacement + CABG only</th>
<th>AVR Repair + CABG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Age</td>
<td></td>
<td></td>
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<tr>
<td>Sex</td>
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<td>Height (inc)</td>
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<td>Weight (lbs)</td>
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<td>Hemato Stat?</td>
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<td>Hemato Data?</td>
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</tbody>
</table>

**RISK SCORES**

- Risk of Mortality: 0.492%
- Risk of Stroke: 0.644%
- Length of Stay: 7.90%
- Risk of Embolic Event: 2.55%
- CABG Indicators: 0.800%
- Transplant: 0.75%
- Infection: 0.99%

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"This is TAVR Today: Better Than Surgery"

See the Clinical Difference →

The PARTNER trial randomized 1,211 patients to TAVR (n=601) or surgery (n=610). The difference in survival was statistically significant (1.1% lower mortality in the TAVR group) and the difference in stroke rate was clinically significant (1.0% lower stroke rate in the TAVR group).
What’s the long view: Long term follow-up

Bileaflet mechanical valve replacement: an assessment of outcomes with 30 years of follow-up.

TAVR Candidacy

PARTNER I TRIAL

Symptomatic Severe Aortic Stenosis
1057 Total Patients Enrolled

n = 358

High-Risk

Inoperable

STS ≥ 10; Predicted Mortality > 15%
Predicted death, serious morbidity > 50%

TAVR vs SAVR

CoreValve US Pivotal Trial

Symptomatic Severe Aortic Stenosis
1381 Total Patients Enrolled

n = 487

High-Risk

Extreme Risk

Predicted Mortality > 15%
Predicted death, serious morbidity > 50%

TAVR vs SAVR

TAVR vs Standard Tx

TAVR v Performance Goal
Aortic Stenosis: TAVR vs (s)AVR

- Surgery (PARTNER IIA trial)
- TAVR with CoreValve 3 valve (PARTNER II S trial)

Graph showing outcomes:
- All-cause Mortality, %
- No. at risk:
  - Surgery: 141, 50%, 356, 208, 795
  - TAVR: 1,077, 1,043, 1,017, 981, 963

Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis
Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis
Financial Burden: Aortic Valves

<table>
<thead>
<tr>
<th>TABLE 1 Index Admission Resource Use and Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td>Procedure duration, min*</td>
</tr>
<tr>
<td>Room time, min</td>
</tr>
<tr>
<td>Hospital LOS, days</td>
</tr>
<tr>
<td>Non-ICU</td>
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<tr>
<td>Post procedure</td>
</tr>
<tr>
<td>Total</td>
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<tr>
<td>Total ventilator time, h</td>
</tr>
<tr>
<td>Costs, U.S.$</td>
</tr>
<tr>
<td>Nonprocedural</td>
</tr>
<tr>
<td>Physician fees</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

Values are mean ± SD (median); *Procedure duration defined as interval from insertion to removal of introducer sheath, room time defined as interval from when patient entered the procedural area (anesthesia/delivery room) to when they left the room.


The Association of Transcatheter Aortic Valve Replacement Availability and Hospital Aortic Valve Replacement Volume and Mortality in the United States

J. Matthew Brennan, MD, MPH, David R. Holmes, MD, Matthew W. Sherwood, MD, Fred H. Edwards, MD, John D. Carroll, MD, Fred L. Grover, MD, E. Murat Tuzcu, MD, Vincen Theurani, MD, Ralph G. Brindis, MD, David M. Shahian, MD, Lian C. Seneviratne, MD, Susan M. O'Brien, MD, Cynthia S. Schoenwaelder, PhD, Kathleen Hewitt, James S. Gammie, MD, John S. Rumsfeld, MD, PhD, Eric D. Peterson, MD, MPH, and Michael I. Mack, MD

![Graph 1: Temporal trends in aortic valve replacement (AVR) procedure volume show a modest increase in surgical AVR volume (solid gray line), with significant increases in transcatheter aortic valve replacement (TAVR) volume (short-dashed gray line) and total AVR procedure volumes (solid black line), during the study period.]

![Graph 2: Temporal trends in aortic valve replacement (AVR) procedure case volumes at transcatheter aortic valve replacement (TAVR) centers and no-TAVR centers display substantial increases in procedural volume at TAVR centers (solid line) versus surgical aortic valve replacement (SAVR) dashed line = overall SAVR and modert increases in procedural volume at no-TAVR centers (solid line).]
Inpatient Mortality after aortic valve replacement

<table>
<thead>
<tr>
<th>Procedure</th>
<th>2008 to 2009</th>
<th>2010 to 2011 Q3</th>
<th>2011 Q4 to 2013 Q2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall AVR (SAVR + TAVR)</td>
<td>0.82 (0.79-0.85)</td>
<td>0.79 (0.76-0.83)</td>
<td>0.75 (0.71-0.80)</td>
</tr>
<tr>
<td>Overall AVR at TAVR centers</td>
<td>0.79 (0.71-0.87)</td>
<td>0.64 (0.60-0.69)</td>
<td>0.60 (0.55-0.66)</td>
</tr>
<tr>
<td>Overall AVR at no-TAVR centers</td>
<td>0.90 (0.85-0.94)</td>
<td>0.88 (0.84-0.93)</td>
<td>0.84 (0.80-0.88)</td>
</tr>
<tr>
<td>Overall high-risk AVR</td>
<td>0.83 (0.78-0.88)</td>
<td>0.79 (0.76-0.83)</td>
<td>0.75 (0.71-0.80)</td>
</tr>
<tr>
<td>Overall TAVR</td>
<td>0.82 (0.79-0.88)</td>
<td>0.81 (0.76-0.86)</td>
<td>0.75 (0.70-0.82)</td>
</tr>
<tr>
<td>Overall TAVR at established centers</td>
<td>0.62 (0.56-0.68)</td>
<td>0.61 (0.56-0.67)</td>
<td>0.58 (0.53-0.63)</td>
</tr>
<tr>
<td>Overall TAVR at new centers</td>
<td>--</td>
<td>--</td>
<td>0.60 (0.55-0.65)</td>
</tr>
<tr>
<td>High-risk SAVR</td>
<td>0.84 (0.79-0.89)</td>
<td>0.78 (0.73-0.84)</td>
<td>0.71 (0.66-0.78)</td>
</tr>
<tr>
<td>Intermediate-risk SAVR</td>
<td>0.55 (0.48-0.63)</td>
<td>0.70 (0.62-0.82)</td>
<td>0.71 (0.66-0.78)</td>
</tr>
<tr>
<td>Low-risk SAVR</td>
<td>0.75 (0.70-0.81)</td>
<td>0.65 (0.58-0.74)</td>
<td>0.60 (0.55-0.65)</td>
</tr>
</tbody>
</table>

* The expected risk was calculated using The Society of Thoracic Surgeons predicted risk of mortality score for isolated aortic valve replacement (SAVR) and adjusted for 2007 data for consistency across the study.  
  * p < 0.05 for all comparisons of observed to expected values across each of the three intervals (early premarket, late premarket, early postcommercialization), with the exception of those specifically listed.  
  * High-risk surgical aortic valve replacement (SAVR) plus any transcatheter aortic valve replacement (TAVR).  
  * p = 0.65.  
  * p = 0.5.

Values are observed to expected ratio (95% confidence interval).

Q = quarter.

Heart Valve Team

Increasing referral of patients for TAVR that are too well

Increasing referral of patients for TAVR that are too sick

Appropriate Case Selection – Risk Assessment
  Predicted risk of mortality AND morbidity
  Frailty Assessments
  Clinical Futility
  Technical Challenges

Integral involvement of the Heart valve team
Heart Valve Team

Appropriate Patient – Intervention Matching

Importance of Clinical Trials

PARTNER II Trial
SURTAVI Trial
What do surgeons really think of TAVR……

Valve bad ……Me Surgeon ….. Me replace with new one……
Fig 1. Valve design features: button holes. Button holes allow correct axial-rotational positioning in the native aortic root. (LC = left coronary; NC = noncoronary; RC = right coronary.)
Conclusions for Aortic Stenosis: When Will Surgery ALWAYS Be a Better Option in 2016

- Low risk patients
- Intermediate risk patients – Need longer term follow-up
- Infective endocarditis
- Adverse anatomy
  - Bicuspid
  - Annulus
  - Coronary height / blood flow
  - Sinus reserve
- Concomitant
  - Valvular
  - Coronary revascularization

Bioprosthetic valve performance and durability will improve.
- Mechanical valves have excellent long term outcomes.
- There will always be clinical scenarios when surgery will outperform transcatheter therapies.
- Surgical valve replacement, just like TAVR, will continue to evolve and adapt
- Our understanding for the role of appropriate patient selection for BOTH transcatheter and surgical aortic valve replacement will continue to evolve
- The structural heart disease – team based approach will improve patient outcomes.
Thank You