TAVR

Indications, Techniques, Outcomes and Results

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What Causes Aortic Stenosis in Adults

Less Common
- Congenital Abnormality

More Common
- Rheumatic Fever
- Age-Related Calcific Aortic Stenosis

Images courtesy of John Webb, MD at St. Paul’s Hospital and Renu Virmani, MD at the CVPath Institute
In the absence of serious comorbid conditions, aortic valve replacement (AVR) is indicated in the majority of symptomatic patients with severe aortic stenosis.

Because of the risk of sudden death, AVR should be performed promptly after the onset of symptoms.

Consultation with or referral to a Heart Valve Center of Excellence is reasonable when discussing treatment options for:

- Asymptomatic patients with severe valvular heart disease
- Patients with multiple comorbidities for whom valve intervention is considered.

Age is not a contraindication to surgery.
Studies show at least 40% of severe aortic stenosis (SAS) patients are not treated with an AVR^{11-17}
Despite frequent BAV, standard therapy did not alter the dismal course of disease for inoperable patients in The PARTNER Trial:

- 50% died within 1 year
- 68% died within 2 years
Worse Prognosis than Many Metastatic Cancers

- 5 year survival of breast cancer, lung cancer, prostate cancer, ovarian cancer and severe inoperable aortic stenosis
Surgical AVR

- Standardized, reproducible procedure via sternotomy
- Operation has low risk in most referred patients
- Use of CPB allows stable hemodynamics throughout procedure
- After aortic cross-clamping and cardioplegic arrest, aorta is opened and all leaflets resected and all calcium debrided.
- Modern fourth generation xenograft or mechanical prosthesis implanted with sutures
- Very low incidence of paravalvular leak
Surgical AVR

Figure: Traditional heart surgery incision: median sternotomy
Mini-Sternotomy for Aortic Valve Procedures

Procedure Advantages
- Smaller incision
- Less tissue damage
- Allows for central cannulation

Procedure Disadvantages
- More concern for sternal healing
- Sternal infections not eliminated
- May be challenging for redo patients
Surgical AVR

Right Anterior Thoracotomy for Aortic Valve Procedures

Procedure Advantages
- No sternal disruption
- Significantly less wound burden
- Comparable valve exposure
- Cosmesis

Procedure Disadvantages
- Challenging for root procedures
- Possibly more painful for muscular patients
- Extrathoracic cannulation
Alain Cribier: First Human Transcatheter Valve Replacement (2002)
Transfemoral Procedural Animation
A New Era Begins

• There has been tremendous interest in transcatheter aortic valve replacement (TAVR) since the first procedure via the transfemoral approach in 2002

• Since then, patient selection, operator skills, and technology have improved

• There continues to be a regulatory requirement for clinical data to evaluate TAVR compared with current standard therapies
TAVR: HISTORY OF EVIDENCE
Evolution of TAVR with SAPIEN Valves

Edwards SAPIEN valve is superior to medical management in inoperable patients.

Edwards SAPIEN valve is a reasonable alternative to surgery in high-risk patients.

Edwards SAPIEN XT valve mirrors SAPIEN valve with added benefits in an expanded patient population.
Absolute Reduction in Mortality in Inoperable Patients

The Edwards SAPIEN valve significantly improves survival

24.7% absolute reduction in mortality

Despite expert care and frequent BAV, standard therapy failed to alter the dismal natural course of disease
In patients with severe symptomatic native aortic valve stenosis who were not suitable candidates for surgery:

- Treatment with the Edwards SAPIEN valve remained superior to standard therapy, reducing the rates of mortality and repeat hospitalization.
- Treatment with the Edwards SAPIEN valve improved NYHA functional status and decreased class III/IV symptoms compared to standard therapy.
- There were significantly more strokes, major vascular complications, and major bleeding in patients treated with the Edwards SAPIEN valve than in patients who received standard therapy.
Evolution of TAVR with Edwards SAPIEN Valves

Edwards SAPIEN valve is superior to medical management in inoperable patients.

Edwards SAPIEN valve is a reasonable alternative to surgery in high-risk patients.

With the Benefits of a Less Invasive Procedure.

Edwards SAPIEN XT valve mirrors SAPIEN valve with added benefits in an expanded patient population.
At 2 years, in patients with symptomatic severe aortic stenosis who were high-risk candidates for surgical AVR:

- Edwards SAPIEN valve was non-inferior to surgical AVR with similar rates of all-cause and cardiovascular mortality
- Hemodynamic performance of the Edwards SAPIEN THV was maintained with similar valve gradients and effective orifice areas compared with surgical AVR
- TAVR is a reasonable alternative to surgical AVR in patients who meet an indication for AVR and who have high surgical risk for surgical AVR

### Key Takeaways

<table>
<thead>
<tr>
<th>Complication</th>
<th>TAVR Similar to Surgical AVR?</th>
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<tbody>
<tr>
<td>All-Cause Mortality</td>
<td>Yes</td>
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<tr>
<td>Stroke</td>
<td>Yes</td>
</tr>
<tr>
<td>Major Bleed</td>
<td>Yes</td>
</tr>
<tr>
<td>Major Vascular Complication</td>
<td>Yes</td>
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</table>
30 day STS/ACC TVT Registry Data (Nov 2011 - May 2013):

- 7,710 patients treated at 224 centers
- Median Age of 84
- Patient Risk Profile
  - 20% Inoperable / 80% High-Risk

### Real World SAPIEN Valve Outcomes

<table>
<thead>
<tr>
<th>Outcomes (In Hospital)</th>
<th>Overall (n=7,710)</th>
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<tbody>
<tr>
<td>Death (Any Cause)</td>
<td>5.5%</td>
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<tr>
<td>Stroke</td>
<td>2.0%</td>
</tr>
<tr>
<td>Moderate or Severe Aortic Insufficiency</td>
<td>8.5%</td>
</tr>
<tr>
<td>Major Bleeding (VARC)</td>
<td>3.5%</td>
</tr>
<tr>
<td>New Permanent Pacemaker</td>
<td>6.6%</td>
</tr>
<tr>
<td>Hospital Duration, Median Days</td>
<td>6</td>
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Real World SAPIEN Valve Outcomes

- One year STS/ACC TVT Registry
- 5,980 Patients
- Median Age of 85

This represents the largest TAVR Data Set and is a testament to predictable and reproducible outcomes with the SAPIEN valve
Edwards SAPIEN valve is superior to medical management in inoperable patients.

Edwards SAPIEN valve is a reasonable alternative to surgery in high-risk patients.

Edwards SAPIEN XT valve mirrors SAPIEN valve with added benefits in an expanded patient population.

Reduced Complications with Next Generation Device.
Clinical Outcomes Improve as Therapy Evolves

Low Stroke Rates – Patient selection, procedural techniques, device evolution

- RetroFlex Delivery System
- RetroFlex 3 Delivery System
- NovaFlex+ Delivery System

Improved Vascular Access – Alternative access, lower profile devices

- 22F RetroFlex 3 Introducer Sheath
- 16F eSheath

Increased Treatment Range – Advanced imaging, larger size devices

- 23 mm SAPIEN XT
- 26 mm SAPIEN XT
- 29 mm SAPIEN XT
First randomized comparison of Edwards SAPIEN XT valve and Medtronic CoreValve in patients at high-risk for surgery

- 241 patients treated at 5 centers (Mar 2012 – Dec 2013)
- Although death (any cause) and stroke were not statistically different, results demonstrated that **SAPIEN XT valve delivered better outcomes**:
  - Higher rate of device success (p < 0.001)
  - Lower rate of mod/severe AR (p < 0.001)
  - Lower rate of rehospitalization for heart failure (p = 0.02)
  - Lower permanent pacemaker implantation (p = 0.001)
  - Higher mean quality of life score (p = 0.02)
Options for Aortic Valve Replacement

<table>
<thead>
<tr>
<th>Surgery</th>
<th>Low- to Moderate-Risk</th>
<th>High Risk</th>
<th>Greater Risk</th>
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<tbody>
<tr>
<td>TAVR</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Open-Heart Surgery (AVR)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Minimal Incision Valve Surgery (MIVS)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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High Risk Patients Defined by Risk of Mortality ≥ 15%
IDENTIFYING POTENTIAL CANDIDATES FOR TAVR
Symptoms include: Dyspnea or decreased exercise tolerance, heart failure, angina, syncope and presyncope

Patients with severe aortic stenosis typically have an aortic valve area ≤ 1.0 cm²

<table>
<thead>
<tr>
<th>Stage</th>
<th>Definition</th>
<th>Valve Hemodynamics</th>
<th>Hemodynamic Consequences</th>
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<tbody>
<tr>
<td>D1</td>
<td>High-gradient</td>
<td>Aortic jet velocity ≥ 4m/s or mean gradient ≥ 40 mmHg Or aortic valve area index ≤ 0.6 cm²/m²</td>
<td>Left ventricular diastolic dysfunction Left ventricular hypertrophy Pulmonary hypertension may be present</td>
</tr>
<tr>
<td>D2</td>
<td>Low-flow/low-gradient with reduced left ventricular ejection fraction</td>
<td>Resting aortic jet velocity &lt; 4m/s or mean gradient &lt; 40 mmHg Dobutamine stress echocardiography shows aortic valve area ≤ 1.0 cm² with aortic jet velocity ≥ 4m/s at any flow rate</td>
<td>Left ventricular diastolic dysfunction Left ventricular hypertrophy Left ventricular ejection fraction &lt; 50%</td>
</tr>
<tr>
<td>D3</td>
<td>Low-gradient with normal left ventricular ejection fraction or paradoxical low-flow</td>
<td>Aortic jet velocity &lt; 4m/s or mean gradient &lt; 40 mmHg Indexed aortic valve area ≤ 0.6 cm²/m² Stroke volume index &lt; 35 mL/m² measured when patient is normotensive (systolic blood pressure &lt; 140 mmHg)</td>
<td>Increased left ventricular relative wall thickness Small left ventricular chamber with low stroke volume Restrictive diastolic filling Left ventricular ejection fraction ≥ 50%</td>
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Characteristics of a TAVR Patient

TAVR patients may present with some of the following:

- Severe, symptomatic native aortic valve stenosis
- Old age
- Frailty
- History of stroke/CVA
- Reduced EF
- History of syncope
- Prior CABG
- Heavily calcified aorta
- Prior chest radiation
- History of AFib
- Prior chest radiation
- History of CAD
- Prior open chest surgery
- History of COPD
- Fatigue, slow gait
- History of renal insufficiency
- Peripheral vascular disease
- Diabetes and hypertension
Frailty: An Important Parameter in Assessing Operative Risk

- Prevalence of frailty increases with aging; old does not necessarily equal frail
- Elderly patients achieve measurable benefit from cardiac surgery, particularly in terms of:
  - Quality of life
  - Increased survival
  - Prevention of adverse cardiovascular events
- The “Eyeball Test”

Same age (90) and predicted risk (12%)
One passes the “eyeball test,” one does not

Slide provided courtesy of Todd Dewey, MD, Medical City Dallas
Multiple Modalities for Assessing Frailty

- PARTNER II Trial Frailty Index Assessment
  - 15-Foot Walk
  - Grip strength
  - Serum albumin
  - Katz ADLs - (Independence in dressing, bathing, toileting, transferring, feeding, continence)
While some patients may have low STS scores, certain conditions may preclude them from being suitable candidates for surgery, for example:

- Extensively calcified (porcelain) aorta
- Chest wall deformity
- Oxygen-dependent respiratory insufficiency
- Frailty
Multidisciplinary approach ensures:

- Patient centric care
- Thorough assessment by a team of specialists
- Collaborative treatment decision
Pre-screening Review of Records

Clinical Evaluation

Gated CTA (Chest/Abdomen/Pelvis)

RHC/LHC Coronary Angiography

Functional Status Assessment (Cognitive Function, Frailty, etc.)

STS Score Calculation

Treatment Plan

Note: The above is a suggested flow for the patient screening process, however, the order in which screening tests are conducted varies depending on the patient’s profile and should be at the discretion of the Heart Team.
An Alternative Option for Patients Without Vascular Access

- Some patients may not have adequate vascular access to accommodate the sheath used during transfemoral procedures
- For these patients, alternative access approaches are available, such as transapical and transaortic

**During the transapical approach**, the Edwards SAPIEN XT transcatheter heart valve is delivered through the apex of the heart by making a small incision between the ribs.

**During the transaortic approach**, the Edwards SAPIEN XT transcatheter heart valve is delivered through an incision in the front of the chest.
A Collaborative Treatment Decision

Devising a Treatment Plan is a Collaborative Process
Ultimate treatment choice is a collaborative decision between the physicians, patient and patient’s family.

1. **Patient with Severe Aortic Stenosis Identified by Referring Physician**

2. **Patient Referred to TAVR Valve Clinic**

3. **Additional Testing Completed**

4. **Multidisciplinary Review and Treatment Decision by TAVR Heart Team**

5. **Treatment Decision Discussed with Referring Physician**
Immediate Goals of AS Treatment

- Aortic valve replacement is intended to relieve the stress on the left ventricle by:
  - Maximizing area
  - Maximizing laminar flow
The Principles of Aortic Valve Replacement Have Not Changed Since 1962

Principles

- Predictable procedure
- Optimal hemodynamics
- Low rate of complications
- Durability
Cardiac surgeons originally were “non-believers” or “slow-adapters” of this new approach to the aortic valve.... How can this ever work when you leave the diseased, stenotic valve in place?.....Well, it can and does work in carefully selected patients.....
Cardiologists and Cardiac Surgeons have come together as a multidisciplinary heart team to jointly develop different, novel therapeutic options for the undertreated patient with critical aortic stenosis.
Paradigm Shift

Cardiologists now suturing on the heart’s LV apex ??
and
Cardiac surgeons pushing heart valves on a stick up a six foot long wire from the groin ???