Aortic Stenosis

- Occurs when the heart's aortic valve narrows.
- The narrowing prevents the valve from opening fully, which obstructs blood flow from your heart into your aorta and onward to the rest of his/her body.
- Usually when aortic valve stenosis becomes severe and symptomatic, per ACC/AHA guidelines, the native valve should be replaced.
- Left untreated, aortic valve stenosis may lead to sudden death.
Aortic Stenosis

Gross specimen of minimally diseased aortic valve (left) and severely stenotic aortic valve (right)

Images courtesy of Renu Virmani MD at the CVPath Institute
Prevalence of Aortic Stenosis

- Aortic stenosis is estimated to be prevalent in up to 7% of the population over the age of 65\textsuperscript{1}

- It is more likely to affect men than women; 80% of adults with symptomatic aortic stenosis are male\textsuperscript{3}
What Causes Aortic Stenosis in Adults?

More Common

- **Age-Related Calcific Aortic Stenosis**: Aortic stenosis in patients over the age of 65 is usually caused by calcific (calcium) deposits associated with aging.

- **Infection**: Aortic stenosis can be caused by various infections.

- **Rheumatic Fever**: Adults who have had rheumatic fever may also be at risk for aortic stenosis.

Less Common

- **Congenital Abnormality**: In some cases adults may develop aortic stenosis resulting from a congenital abnormality.
Independent clinical factors associated with degenerative aortic valve disease include the following:\(^4\)

- Increasing age
- Male gender
- Hypertension
- Smoking
- Elevated lipoprotein A
- Elevated LDL cholesterol
Symptoms of Aortic Stenosis

What are the symptoms of aortic stenosis?

- Angina - A sensation of aching, burning, discomfort, fullness, pain, or squeezing in the chest. It may also be felt in the arms, back, jaw, neck, shoulders and throat.

- Syncope - A sudden and brief loss of consciousness.

- Shortness of breath - Feeling winded and tired when walking or lying down.

- Dizziness (after periods of inactivity).

- Rapid or irregular heartbeat.

- Palpitations – An uncomfortable awareness of the heart beating rapidly or irregularly.
Multiple Modalities May Be Used to Diagnose Severe Aortic Stenosis\textsuperscript{6}
Survival after onset of symptoms is 50% at 2 years\(^1\) and 20% at 5yrs.

Surgical intervention for severe aortic stenosis should be performed promptly once even minor symptoms occur\(^1\).
In the absence of serious comorbid conditions indicated in the majority of symptomatic patients with severe aortic stenosis, consultation with or referral to a Heart Valve Center is reasonable when discussing treatment options for:

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

Because of the risk of sudden death, replacing the aortic valve should be performed promptly after the onset of symptoms.

Age is not a contraindication to surgery.

Timely intervention is critical for patients with symptoms.
Severe aortic stenosis has a worse prognosis than many metastatic cancers

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

*Using constant hazard ratio. Data on file, Edwards Lifesciences LLC. Analysis courtesy of Murat Tuczu, MD, Cleveland Clinic
AHA/ACC guidelines for aortic valve replacement in patients with aortic stenosis

Aortic stenosis

Severe high gradient
- AVA typically ≤ 1.0 cm²
- Vmax ≥ 4 m/s or Δp mean ≥ 10 mmHg
  - Symptomatic (stage D1)

Severe low flow / low gradient
- AVA typically ≤ 1.0 cm²
- Resting aortic Vmax < 4 m/s or Δp mean < 40 mmHg
  - Symptomatic
  - LVEF < 50%

At risk / progressive
- AVA typically ≥ 1.0 cm²
- Vmax < 4 m/s
  - Repeat echo every 6-12 month

Yes
- Exercise test demonstrating decreased exercise tolerance or a fall in systolic BP
  - Should be recommended for valve replacement

No
- Dobutamine stress echo (DSE) with AVA ≤ 1 cm² and Vmax ≥ 4 m/s (stage D2)
  - Reasonable to recommend for valve replacement

Yes
- AVA ≤ 1 cm² and LVEF ≥ 50% (stage D3*)
  - Reasonable to recommend for valve replacement

No
- Worsening signs or symptoms
- Increased flow restrictions AVA < 1.0 cm² and or Vmax ≥ 4 m/s
  - Consider for severe aortic stenosis evaluation

*AVR should be considered with stage D3 A8 only if valve obstruction is the most likely cause of symptoms, stroke volume index is < 35 mL/m², indexed AVA is ≤ 0.6 cm²/m² and data are recorded when the patient is normotensive (systolic BP < 140 mmHg).
Options for Aortic Valve Replacement

- Intermediate Risk Patients (STS 3-8%)
- High Risk Patients (STS >8%)
  - Transcatheter Aortic Valve Replacement (TAVR)

- Low Risk Patients (STS <3%)
  - Surgical Aortic Valve Replacement (SAVR)
  - Minimal Incision Valve Surgery (MIVS)
  - PARTNER Research: Continued Access for Low Risk Enrollment for TAVR
What is in the STS score?

RISK SCORES

Procedure: Isolated AVR

- Risk of Mortality: 2.570%
- Renal Failure: 1.398%
- Permanent Stroke: 1.691%
- Prolonged Ventilation: 7.597%
- DSW Infection: 0.194%
- Reoperation: 4.099%
- Morbidity or Mortality: 11.705%
- Short Length of Stay: 48.712%
- Long Length of Stay: 4.320%

PRINT CLEAR
TAVR is indicated for intermediate-risk patients

For relief of aortic stenosis in patients with:

- Aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis
- Evaluated by a Heart Team, including a cardiac surgeon, to be at intermediate or greater risk for open heart surgery

Predicted risk of surgical mortality \( \geq 3\% \) at 30 days, based on the STS risk score and other clinical co-morbidities unmeasured by the STS risk calculator
The Safety and Effectiveness of the SAPIEN 3 Transcatheter Heart Valve in Low Risk Patients With Aortic Stenosis (PARTNER 3)

This study is currently recruiting participants. (see Contacts and Locations)
Verified May 2016 by Edwards Lifesciences

Sponsor:
Edwards Lifesciences

Information provided by (Responsible Party):
Edwards Lifesciences

ClinicalTrials.gov Identifier:
NCT02675114

First received: January 22, 2016
Last updated: May 26, 2016
Last verified: May 2016

Purpose

To establish the safety and effectiveness of the Edwards SAPIEN 3 Transcatheter Heart Valve in patients with severe, symptomatic aortic stenosis who are at low operative risk for standard aortic valve replacement (AVR).

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic Stenosis</td>
<td>Procedure: Surgical aortic valve replacement (SAVR)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device: Transcatheter Aortic Valve Replacement (TAVR)</td>
<td></td>
</tr>
</tbody>
</table>

Full Text View  Tabular View  No Study Results Posted  Disclaimer  How to Read a Study Record
History of Edwards’ transcatheter heart valve technology in the United States

- **2010**: Landmark PARTNER clinical trials begin
- **2011**: Edwards SAPIEN valve
- **2012**: Edwards SAPIEN XT valve
- **2014**: SAPIEN XT valve approved for high or greater-risk patients
- **2015**: Edwards SAPIEN 3 valve
- **2016**: SAPIEN 3 and SAPIEN XT valves approved for intermediate or greater-risk patients
VIV TAVR & TMVR is an option to treat patients with failed surgical valves in high risk patients

For use in patients with:

- Symptomatic heart disease due to either severe native calcific aortic stenosis or failure (stenosed, insufficient, or combined) of surgical bioprosthetic aortic or mitral valves.

- Evaluated by a Heart Team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy

- Ongoing trial for intermediate-low risk MVIV patients
The PARTNER II Trial: Intermediate-risk cohort

Intermediate-risk symptomatic severe aortic stenosis

Intermediate-risk assessment by Heart Valve Team

PARTNER II S3i
(n = 1078)

Assessment for optimal valve delivery access

- Transfemoral (TF)
- Transapical (TA)/ Transaortic (T Ao)

- TF TAVR SAPIEN 3 valve

PARTNER IIA
(n = 2032)

Assessment transfemoral access

Yes

- Transfemoral (TF)

1:1 Randomization

- TATAVR SAPIEN XT valve vs Surgical AVR

No

- Transapical (TA)/ Transaortic (TAo)

1:1 Randomization

- TA/T Ao TAVR SAPIEN XT valve vs Surgical AVR

The most robust, rigorous study in more than 3,000 intermediate-risk patients
Mortality rates continue to decline

- **PARTNER IB trial**
  - Inoperable: 6.3%
  - High-risk or greater: 5.2%
  - Intermediate-risk: 4.5%
  - SAPIEN valve
  - Participants: 175

- **PARTNER IA trial**
  - Inoperable: 5.2%
  - High-risk or greater: 3.6%
  - Intermediate-risk: 3.4%
  - SAPIEN XT valve
  - Participants: 344

- **PARTNER IIB trial**
  - Inoperable: 4.5%
  - High-risk or greater: 3.4%
  - Intermediate-risk: 2.2%
  - SAPIEN 3 valve
  - Participants: 271

- **PARTNER II trial**
  - High-risk or greater: 2.2%
  - Intermediate-risk: 1.1%
  - SAPIEN 3 valve
  - Participants: 1,011

- **PARTNER II HR trial**
  - High-risk or greater: 3.6%
  - Intermediate-risk: 3.4%
  - SAPIEN XT valve
  - Participants: 167

- **PARTNER II S3i trial**
  - High-risk or greater: 2.2%
  - Intermediate-risk: 1.1%
  - SAPIEN 3 valve
  - Participants: 583
Intermediate Risk Patients

Superior to medical management for inoperable patients*

Unprecedented clinical outcomes in high risk Patients*

Transforming the therapy of aortic valve replacement

Better than surgery for intermediate-risk patients*

---

*The PARTNER II trial intermediate-risk cohort VI population (n=2,005); the difference in the primary endpoint (composite of all-cause mortality, all stroke, and a moderate aortic regurgitation at one year) event rate between TAVR with the SAPIEN 3 valve and surgery appeared to be clinically significant. The PARTNER II trial intermediate-risk cohort 30-day unadjusted clinical event rates for TAVR with the SAPIEN 3 valve, AT population (n=1,077).
All-cause mortality*

- Surgery (PilA)
- TAVR with SAPIEN 3 valve

Number at risk:
- Surgery: 944 859 836 808 795
- SAPIEN 3 TAVR: 1077 1043 1017 991 963

*The PARTNER II trial intermediate-risk cohort unadjusted clinical event rates.
Disabling Stroke*

*The PARTNER II trial intermediate-risk cohort unadjusted clinical event rates.
Better than surgery for intermediate-risk patients*

1.1% All-cause mortality†

1.0% Disabling stroke†

75% Lower than surgery†

*The PARTNER II trial intermediate-risk cohort VI population (n=2,005); the difference in the primary endpoint (composite of all-cause mortality, all stroke, and ≥ moderate aortic regurgitation at one year) event rate between TAVR with the SAPIEN 3 valve and surgery appeared to be clinically significant.

†The PARTNER II Trial intermediate-risk cohort 30-day unadjusted clinical event rates for TAVR with the SAPIEN 3 valve, AT population (n=1,077).
Identifying Potential Candidates for TAVR
Characteristics of a TAVR Patient\textsuperscript{17}

TAVR patients may present with some of the following:

- Severe, symptomatic native aortic valve stenosis
- Old age
- Frailty
- History of stroke/CVA
- History of syncope
- Reduced EF
- Heavily calcified aorta
- Prior CABG
- Prior chest radiation
- History of AFib
- History of CAD
- Prior open chest surgery
- History of COPD
- Fatigue, slow gait
- History of renal insufficiency
- Peripheral vascular disease
- Diabetes and hypertension
Cohesive, multi-disciplinary approach embodies

- Optimal patient centric care
- Dedication across medical specialties
- Collaborative treatment decision

National coverage determination

The patient (preoperatively and postoperatively) is under the care of a Heart Team

Complete TAVR Workup Includes:

- Qualifying gradients (either by TTE or Cath)
- TAVR CT- both Heart/coronaries & Chest/abd/pelvis
- Coronary Angiogram
- Pulmonary Function Test
- 2 CV surgery visits
Following Patient Referral, the TAVR Team will Perform Further Evaluation

1. Confirm the patient is diagnosed with severe symptomatic native aortic stenosis
2. Confirm the patient has been evaluated by two cardiac surgeons and meets the indication for TAVR
3. Evaluate the aortic valvular complex using echocardiography
4. Evaluate the aortic valvular complex and peripheral vasculature using CT
5. Evaluate the aortic valvular complex and peripheral vasculature using catheterization
6. Determine access route for transcatheter aortic valve replacement

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.
A collaborative treatment decision

1. Patient with severe aortic stenosis identified by referring physician
2. Patient referred to valve clinic
3. Additional testing completed
4. Multidisciplinary review and treatment decision by Heart Team
5. Treatment recommendations reviewed with referring physician, patient and patient's family

Devising a treatment plan is a collaborative process. Ultimate treatment choice is a collaborative decision between the physicians, patient and patient's family.
According to the 2008 ACC/AHA guidelines, severe aortic stenosis is defined as:

- Aortic valve area (AVA) less than 1.0 cm$^2$ or index AVA <0.6 cm$^2$/m$^2$
- Mean gradient greater than 40 mmHg OR jet velocity greater than 4.0 m/s

### Grading the Severity of Aortic Stenosis per the ACC/AHA Guidelines *

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
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<td>Jet velocity (m/s)</td>
<td>&lt; 3.0</td>
<td>3.0 - 4.0</td>
<td>&gt; 4.0</td>
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<tr>
<td>Mean gradient (mmHg)</td>
<td>&lt; 25</td>
<td>25 - 40</td>
<td>&gt; 40</td>
</tr>
<tr>
<td>Valve area (cm$^2$)</td>
<td>&gt; 1.5</td>
<td>1.0 – 1.5</td>
<td>&lt; 1.0</td>
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<tr>
<td>Valve area index (cm$^2$/m$^2$)</td>
<td>N/A</td>
<td>N/A</td>
<td>&lt; 0.6</td>
</tr>
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</table>

*Doppler-Echocardiographic measurements*
Dobutamine stress echocardiography can be used to differentiate between true and pseudo severe aortic stenosis

- Better define the severity of the aortic stenosis
- Accurately assess contractile/pump reserve

Some patients with severe aortic stenosis based on valve area have a lower than expected gradient (e.g. mean gradient < 30 mmHg) despite preserved LV ejection fraction (e.g. EF > 50%)

- Up to 35% of patients with severe aortic stenosis present with low flow, low gradient
- These low gradients often lead to an underestimation of the severity of the disease, so many of these patients do not undergo surgical aortic valve replacement
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
- Chest radiation
- Oxygen-dependent respiratory insufficiency
- Frailty
Frailty is an important parameter in assessing operative risk.

Transcatheter aortic valve replacement is a best therapy for intermediate and high risk inoperable patients with severe aortic stenosis.

Prevalence of frailty increases with aging; old does not necessarily equal frail.

Rehab potential post procedure.

Elderly patients achieve measurable benefit from cardiac surgery, particularly in terms of:
- Quality of life
- Increased survival
- Prevention of adverse cardiovascular events
Vessel diameters must be a minimum of:

- $\geq 5.5\text{mm}$ for a 20, 23 & 26mm valve (requires a 14F eSheath)
- $\geq 6.0\text{mm}$ for a 29mm valve (requires a 16F eSheath)
Clinical outcomes improves as therapy evolves

**Low mortality and stroke rates**
Patient selection, procedural techniques, device evolution

- RetroFlex 3 delivery system
- NovaFlex+ delivery system
- Edwards Commander delivery system

**Improved vascular access**
Lower profile devices expands treatment possibilities

- 22F RetroFlex 3 introducer sheath
- 16F Edwards eSheath introducer set
- 14F Edwards eSheath introducer set*

**Increased treatment range**
Larger and smaller valves

- SAPIEN valve 23 mm and 26 mm
- SAPIEN XT valve 23 mm, 26 mm, 29 mm
- SAPIEN 3 valve 20 mm, 23 mm, 26 mm, 29 mm

*Only used with 20 mm, 23 mm, 26 mm valve sizes
### 3mensio CT report

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<td>44980401</td>
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<td>HALF 30% 1.16s Axial Sys...</td>
<td>HALF 70% 1.16s Axial Sys...</td>
</tr>
<tr>
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<td>2/20/2019</td>
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<tr>
<td>Phase: 30.0%</td>
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Series: 10
Slices: 1-640
Slice Spacing: 0.3 mm
### Perpendicular Plane

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<td>Polygon Min. Ø</td>
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</tr>
<tr>
<td></td>
<td>Max. Ø</td>
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<tr>
<td></td>
<td>Avg. Ø</td>
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### LVOT

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### Perpendicular Plane 70%

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<td>2</td>
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### LVOT 70%

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<td>Avg. Ø</td>
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<td></td>
<td>Area derived Ø</td>
<td>24.4 mm</td>
</tr>
<tr>
<td></td>
<td>Perimeter derived Ø</td>
<td>25.1 mm</td>
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<tr>
<td></td>
<td>Area</td>
<td>466.9 mm²</td>
</tr>
<tr>
<td></td>
<td>Perimeter</td>
<td>78.5 mm</td>
</tr>
</tbody>
</table>
**Device Selection**

**SAPIEN 3 Valve**

1. **Outer sealing skirt**
   - Designed to minimize paravalvular (PV) leak

2. **Frame design**
   - Enhanced frame geometry for low delivery profile
   - Cobalt-chromium

3. **Bovine pericardial tissue**

**Edwards CENTERA**

Self expanding (in trial)

---

**Supra-annular valve design**
Unsurpassed hemodynamics

**Self-expanding frame**
Provides the foundation for controlled delivery

**Porcine pericardial tissue**
Thin and strong for low profile delivery and durability

**Evolut PRO System**

---

**J-VALVE™ AORTIC VALVE BIOPROSTHESIS**

The J-Valve™ aortic valve bioprosthesis positions itself according to the anatomy of the native aortic annulus. It naturally slides into place, allowing doctors to rely on tactile feedback to achieve optimal positioning.

*This system has not yet been approved by the FDA and is currently not for sale.*

**KEY DESIGN FEATURES:**

- U-shaped "closers" facilitate accurate self-positioning of the replacement aortic valve bioprosthesis
- Low profile design minimizes risk of coronary blockage
- With six different valve sizes, the system ensures a perfect fit for each patient
Complete range of valve sizes expands the treatable patient population

<table>
<thead>
<tr>
<th>Valve size</th>
<th>20 mm</th>
<th>23 mm</th>
<th>26 mm</th>
<th>29 mm</th>
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</thead>
<tbody>
<tr>
<td>Native annulus size by TEE</td>
<td>16 – 19 mm</td>
<td>18 – 22 mm</td>
<td>21 – 25 mm</td>
<td>24 – 28 mm</td>
</tr>
<tr>
<td>Native annulus area (CT)</td>
<td>273 – 345 mm²</td>
<td>338 – 430 mm²</td>
<td>430 – 546 mm²</td>
<td>540 – 683 mm²</td>
</tr>
<tr>
<td>Area-derived diameter (CT)</td>
<td>18.6 – 21 mm</td>
<td>20.7 – 23.4 mm</td>
<td>23.4 – 26.4 mm</td>
<td>26.2 – 29.5 mm</td>
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</tbody>
</table>
**TAVR Committee:**
CMS requires a multi-disciplinary approach; patients are worked up and presented to our in-house TAVR Committee for approval – committee includes cardiologists, CV surgeons, research staff, Cath lab, OR, CCU/HFICU, HVI administration, etc.; meets weekly

**Slides include:**
Patient demographics; pertinent medical history; STS score; diagnostic testing results & anatomical measurements; proposed treatment plan

### Patient Name

<table>
<thead>
<tr>
<th><strong>Age</strong>:</th>
<th><strong>Coronary Angio (date)</strong>:</th>
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</thead>
<tbody>
<tr>
<td>Gender:</td>
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<tr>
<td>PMHx:</td>
<td>LAD:</td>
</tr>
<tr>
<td>STS: %</td>
<td>LCX:</td>
</tr>
<tr>
<td>Sx: DOE (NYHA, CCS):</td>
<td>RCA:</td>
</tr>
<tr>
<td>Frailty: Katz, Walk ( ), Grip ( ), Alb ( )</td>
<td></td>
</tr>
<tr>
<td>Operability: Operable ( )</td>
<td></td>
</tr>
<tr>
<td>BMI: kg/m²</td>
<td><strong>BSA</strong>: m²</td>
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<tr>
<td>CT (date):</td>
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</tr>
<tr>
<td>R CI mm</td>
<td>R CI min mm</td>
</tr>
<tr>
<td>R EI mm</td>
<td>L CI mm</td>
</tr>
<tr>
<td>R CF mm</td>
<td>LEI mm</td>
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<tr>
<td>AoAnn x mm (~ mm); Area mm²</td>
<td>L CF mm</td>
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<tr>
<td>Perimeter</td>
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</tr>
<tr>
<td>AoAnn-LM mm; AoAnn-RC mm</td>
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<tr>
<td>Co-Planar Angle: LAO CAU</td>
<td>AA: °</td>
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<td>STJ- mm</td>
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**Proposed Plan:**
Operable _____ Risk
Transcatheter Aortic Valve Replacement (TAVR)

TAVR Pre-Procedure Overview
Pre-Procedure Nursing Implications

- Patients will be admitted to the hospital the day before the procedure or will report to the Cath Lab/OR the morning of the procedure depending on facility
- Hibiclens scrub
- Patient education and discharge expectations
- Shaving
- Possibility of a Foley Catheter or Condom Catheter
  - MD Preference
  - MAC vs. General Anesthesia
Inpatients should be ready for transport by 7am
♥ Labs drawn, consents obtained, anesthesia assessment done
♥ Consent should read: “Transcatheter aortic valve replacement”

Procedural needs:
♥ NPO per anesthesia guidelines
♥ Current type and screen with products available
♥ Blood products are to be available in room during procedure
♥ Pre-procedure hydration to prevent kidney injury
♥ CHG bath completed
♥ Clip hair from neck to knees
♥ Arm/blood bands preferably on left arm (anesthesia uses right wrist for arterial line)
The TAVR procedure can be performed through multiple access approaches

- Some patients may not have adequate vascular access to accommodate the sheath used during transfemoral procedures
- For these patients, alternative access approaches are available*
Access Sites

- Arterial
  - 14Fr/16Fr Sheath for Transcatheter Valve
  - 5Fr/6Fr Sheath Pigtail Catheter (contralateral to THV)
  - Radial Line

- Venous
  - 5Fr/6Fr Sheath Temporary Pacemaker (contralateral to THV)
  - 5Fr/6Fr Sheath Secondary venous access (possible)
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 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 transcatheter heart valve is delivered through an incision in the front of the chest.
Trans-axillary approach
Access: Femoral (primary method), trans-aortic, trans-subclavian, trans-apical or trans-axillary

Done under MAC anesthesia or general (if necessary)

Valve is advanced via the aorta (over a delivery catheter) to the aortic valve

Valve is positioned and inflated with a balloon (similar to a coronary stent)

Rapid pacing is performed during balloon inflation

This minimizes cardiac motion and prevents dislodgement of the valve during deployment

Balloon is deflated and removed

Valve positioning is confirmed using angiography and echo
Edwards SAPIEN Transcatheter Heart Valve Deployment
Angiogram Images

Pre valve deployment angiogram

Post valve deployment angiogram
Post-Operative Care and Length of Stay
Post-Op Nursing Implications

Two Post-Op Pathways

- Transfemoral
- Transapical, Transaortic & Trans-axillary
Post-Op Nursing Implications Transfemoral

Transfemoral TAVR Fast Track Clinical Pathway
Post op 0-12 Hours

<table>
<thead>
<tr>
<th>Site ID</th>
<th>Patient Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admission Date</td>
<td>Procedure Date</td>
</tr>
</tbody>
</table>

### 0-4 Hours

<table>
<thead>
<tr>
<th>Goal Met (yes)</th>
<th>Goal</th>
<th>Deviation/Explanation (Goal not met)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>1. Extubate within 1 hour if not extubated in OR.</td>
<td>☐</td>
</tr>
<tr>
<td>☐</td>
<td>2. Wean off all drips within 1 hour of arrival. Saline lock all IVs except renal protection protocol fluids. Continue for 6H post op (if ordered).</td>
<td>☐</td>
</tr>
<tr>
<td>☐</td>
<td>3. Remove PA catheter within 1 hour if present. Continue central line.</td>
<td>☐</td>
</tr>
<tr>
<td>☐</td>
<td>4. Remove arterial line within 2 hours.</td>
<td>☐</td>
</tr>
<tr>
<td>☐</td>
<td>5. OOB to chair after 4 hours of bed rest.</td>
<td>☐</td>
</tr>
<tr>
<td>☐</td>
<td>6. Discontinue foley catheter once patient has been OOB.</td>
<td>☐</td>
</tr>
<tr>
<td>☐</td>
<td>7. Discontinue oxygen within 4 hours if O2 sat &gt; 90%.</td>
<td>☐</td>
</tr>
</tbody>
</table>

### 4-12 Hours

<table>
<thead>
<tr>
<th>Goal Met (yes)</th>
<th>Goal</th>
<th>Deviation/Explanation (Goal not met)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>1. Restart oral antihypertensive medications in 4 hours and if able to take p.o. Hold if SBP &lt;100. Do not give beta blockers if bradycardia and heart rate &lt;60.</td>
<td>☐</td>
</tr>
<tr>
<td>☐</td>
<td>2. Restart BPH medications in 4-6 hours. Double dose for 1st dose.</td>
<td>☐</td>
</tr>
<tr>
<td>☐</td>
<td>3. Begin incentive spirometry, cough &amp; deep breathe Q2H.</td>
<td>☐</td>
</tr>
<tr>
<td>☐</td>
<td>4. RN bedside evaluation for dysphagia. ST consult on POD #1 if fails.</td>
<td>☐</td>
</tr>
<tr>
<td>☐</td>
<td>5. Begin ice chips, advance to clear liquids, and then advance to regular diet if passed bedside evaluation.</td>
<td>☐</td>
</tr>
<tr>
<td>☐</td>
<td>6. Walk within 8 hours by RN.</td>
<td>☐</td>
</tr>
<tr>
<td>☐</td>
<td>7. Reinforce early ambulation with family. Educate family how to mobilize patient.</td>
<td>☐</td>
</tr>
</tbody>
</table>
### Transfemoral TAVR Fast Track Clinical Pathway

**Post Op Day 1 to Discharge**

<table>
<thead>
<tr>
<th>Post op Day 1</th>
<th>Goal Met (yes)</th>
<th>Goal</th>
<th>Deviation/Explanation (Goal not Met)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1.</td>
<td>Aggressive blood sugar control per individual hospital policy.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.</td>
<td>Anticoagulants: Begin ASA 325mg/day if not started preop. Begin Plavix 75mg/day unless contraindicated.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.</td>
<td>Anticoagulation: Begin Coumadin at 1700 if pt was taking preop.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.</td>
<td>Insert peripheral IV and remove central line POD #1.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.</td>
<td>PT consult. Ambulate X 6. Encourage all meals OOB.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6.</td>
<td>Social work consult if indicated.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7.</td>
<td>Discharge if discharge criteria met on POD #1-3.</td>
</tr>
</tbody>
</table>

**Discharge Criteria**

1. Baseline neurological function.
2. Stable heart rhythm and has not required pacing within 24 hours.
3. VSS: HR 60-90, SBP 90-140 (or at baseline).
4. Voiding without difficulty, emptying bladder.
5. If discharged with foley cath, urology follow up appointment with urologist is scheduled.
7. Creatinine at or below baseline.
8. O2 weaned off with O2 saturation >90%, with effective cough and airway clearance.
9. Effective pain control on oral medications.
10. Independent in ADLs and ambulation, or has appropriate assistance and devices.
11. Able to ambulate 200 feet, or baseline.
12. Groins without bleed or hematoma.
13. Patient and family voice appropriate understanding of post TAVR discharge instructions.
14. Discharge studies completed: TTE, CXR, EKG, BMP, BNP, PT, PTT.

**Discharge and Follow up**

1. Discharge to designated hotel for 1-2 days prior to returning home (if OOT).
2. Return to Valve Clinic the first Friday after discharge for office visit. Provide patient with date and time.
3. Return to Valve Clinic for 30 day studies. Provide patient with date and time.

**Discharge Date:**

**Discharge Status:**
- Alive
- Expired

**Discharge Location:**
- Home
- Extended care/Rehab
- Nursing Home
- Other

**Discharge Date:** ________

**Discharge Location:** ________
## Transapical and Transaortic TAVR Fast Track Clinical Pathway

**Post op 0-12 Hours**

<table>
<thead>
<tr>
<th>Site ID</th>
<th>Patient Number</th>
<th>Admission Date</th>
<th>Procedure Date</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>0-4 Hours</th>
<th>Met Goal (yes)</th>
<th>Goal</th>
<th>Deviation/Explanation (Goal not Met)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1. Extubate within 1 hour if not extubated in OR.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Wean off all drips within 1 hour of arrival. Saline lock all IVs except renal protection protocol fluids. Continue for 6 hours post (if ordered).</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Remove PA catheter within 1 hour if present. Continue central line.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Continue IV TYLENOL initiated in OR.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4-12 Hours</th>
<th>Met Goal (yes)</th>
<th>Goal</th>
<th>Deviation/Explanation (Goal not met)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1. Remove arterial line within 4 hours.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Restart oral antihypertensive medications in 4 hours and if able to take p.o. Hold if SBP ≤100. Avoid beta blockers.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Restart BPH medications within 4 hours. Double dose for 1st dose.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Begin incentive spirometry, cough &amp; deep breathe Q2H.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. Discontinue oxygen within 4-6 hours if O2 sat &gt; 90%.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>6. OOB to chair 4-6 hours after arrival.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>7. Discontinue Foley catheter once patient has been OOB.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>8. RN bedside evaluation for dysphagia. ST consult on POD #1 if fails.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>9. Begin ice chips, advance to clear liquids, and then advance to regular diet if passed bedside evaluation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>10. Walk within 6 hours by RN.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>11. Reinforce early ambulation with family. Educate family how to mobilize patient.</td>
<td></td>
</tr>
</tbody>
</table>
# Transapical and Transaortic TAVR Fast Track Clinical Pathway

## POD 1 to Discharge

<table>
<thead>
<tr>
<th>Post op Day 1</th>
<th>Met Goal (yes)</th>
<th>Goal</th>
<th>Deviation/Explanation (Goal not met)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐</td>
<td>1. Aggressive blood sugar control per individual hospital policy.</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>2. Antiplatelets: Begin ASA 325mg/day if not started preop. Begin Plavix 75mg/day unless contraindicated.</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>3. Anticoagulation: Begin Coumadin POD #2 if pt was taking preop. May DC home before INR therapeutic.</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>4. Insert peripheral IV. Remove central line POD #1. Place PICC if central line is required.</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>5. Remove CTs/drainage POD #1 if no air leak, no PTX, and drainage &lt;300cc.</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>6. If drains remain on POD #2, remove if drainage &lt;300cc or trending down and &lt;100cc for the last 8 hours.</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>7. Remove EPVs POD #2 if pt has not required pacing X 24 hours.</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>8. PT consult. Ambulate X 6. Family to participate in rehab activities.</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>9. Social work consult if indicated.</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☐</td>
<td>10. Discharge if discharge criteria met on POD #3-5.</td>
<td>☐</td>
</tr>
</tbody>
</table>

**Discharge Date:**

**Discharge Status:** [ ] Alive  [ ] Expired  **Date:**

**Discharge Location:** [ ] Home  [ ] Extended care/Rehab  [ ] Nursing Home  [ ] Other

**Discharge and Follow up**

1. Discharge to designated hotel for 1-2 days prior to returning home (if OOT).
2. Return to Valve Clinic the first Friday after discharge for office visit. Provide patient with date and time.
3. Return to Valve Clinic for 30 day studies. Provide patient with date and time.
How to reduce Length of Stay (LOS)

Pre-procedure
- Patient evaluation and selection
- Set patient and family expectations
  - Early discharge

Procedure
- Procedural brief
- Perioperative Protocols
  - Foley, MAC vs. GA, Swan-Ganz

Post-Procedure
- Extubation
- Ambulation
  - Transfemoral and Transaortic: 4 hours
  - Transapical: 6-8 hours
- Foley removal
- Swan-Ganz removal
- Discharge Communication to family, MD, NP, Charge Nurse
# TVT Registry Info

## TAVR Quality Metrics

**Memorial Hermann TMC**  
**Summary by Discharge Date**  
**October 2018**

<table>
<thead>
<tr>
<th></th>
<th>My Hospital</th>
<th>Rolling 4 Qtr Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2018Q1</td>
<td>2018Q2</td>
</tr>
<tr>
<td></td>
<td>Num</td>
<td>Den</td>
</tr>
<tr>
<td>Total # patients with TVT procedures</td>
<td>142</td>
<td>151</td>
</tr>
<tr>
<td>Outcome Metrics (In-Hospital)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In Hospital Observed Mortality (L-Indexed)</td>
<td>4</td>
<td>142</td>
</tr>
<tr>
<td>Significant Cardiac Event (Procedure Related)</td>
<td>0</td>
<td>142</td>
</tr>
<tr>
<td>Stroke (any)</td>
<td>2</td>
<td>142</td>
</tr>
<tr>
<td>Acute Kidney Injury (Stage 3)</td>
<td>3</td>
<td>142</td>
</tr>
<tr>
<td>Bleeding - Disabling or Life Threatening</td>
<td>0</td>
<td>142</td>
</tr>
<tr>
<td>Vascular Access Site Complication (any)</td>
<td>2</td>
<td>142</td>
</tr>
<tr>
<td>Value Metrics (In-Hospital)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Success</td>
<td>133</td>
<td>135</td>
</tr>
<tr>
<td>Device Complications (any)</td>
<td>1</td>
<td>142</td>
</tr>
<tr>
<td>Aortic Regurgitation (moderate to severe)**</td>
<td>0</td>
<td>142</td>
</tr>
<tr>
<td>Other Metrics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of Stay - Post Procedure (Median)</td>
<td>2.00</td>
<td>2.00</td>
</tr>
<tr>
<td>Pacer Disturbance Req Pacer (Count)</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>D/C Location</td>
<td></td>
<td></td>
</tr>
<tr>
<td>home</td>
<td>117</td>
<td>138</td>
</tr>
<tr>
<td>extended care, transitional or rehab</td>
<td>18</td>
<td>138</td>
</tr>
<tr>
<td>other acute care hospital</td>
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<td>138</td>
</tr>
<tr>
<td>nursing home</td>
<td>0</td>
<td>138</td>
</tr>
<tr>
<td>hospice</td>
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<td>138</td>
</tr>
<tr>
<td>other</td>
<td>2</td>
<td>138</td>
</tr>
<tr>
<td>left against medical advice</td>
<td>0</td>
<td>138</td>
</tr>
</tbody>
</table>

*US Hospital Benchmark, from most recent published Outcomes Report [D/C Location, from Site Level Reports]  
**Denominator = Count of patients with Aortic Regurgitation assessed

---

*This document is the product of a hospital committee or a peer review committee and is exempt from discovery. Tex. R.S. Code § 141.002 and Tex. Govt. Code § 151.003 et seq. & 160.007. The Health Care Quality Improvement Act, 42 U.S.C. 11102 et seq. also provides for immunity related to healthcare quality and peer review proceedings.*
Common Complications

♥ Vascular issues – damage to iliac/femoral arteries – sometimes requires surgical repair
♥ Ventricular wall perforation by wire – resulting in tamponade (may be seen after leaving the procedural area)
♥ Valvular complications - annular rupture, malpositioning, leaking around the valve
♥ Arrhythmias – heart block related to AV node disruption – sometimes resolves, sometimes requires permanent pacer insertion
♥ Most patients develop a BBB during deployment – this usually resolves over a few minutes or hours, however, some remain and ultimately require pacing intervention
♥ Temporary pacers maybe left overnight to monitor
♥ Coronary artery occlusion by TAVR valve resulting in MI
♥ Stroke
♥ Death
Post Procedure Management

- Observe access site for complications
- Observe for signs/symptoms of stroke, MI, chest pain
- Observe for conduction disruptions – bradycardia, bundle branch block, heart block
- Monitor hemodynamics – address hyper or hypotension
- Remember – these are not surgical patients – early ambulation is preferred (within 2-4 hours)
- Up, out of bed, eating as soon as tolerated
- Begin discharge planning immediately post-procedure
- Consult social work/ case management
- Goal for length of stay is no more than 1-2 days post-procedure
- Cardiac Rehab consult
Post Procedure Management

- **Access sites:** Primary access site is whichever side the valve delivery sheath is inserted – it could be right or left femoral artery depending on vessel size - the valve sheath is usually 14F – for a 29mm valve it is 16F
- **Smalling/Dhoble/Balan:** Valve sheath & 7F venous (for temp pacer) to primary side; 6F arterial & 5F venous to contralateral side (opposite side)
- **Kar/Jumean/Kumar/Loyalka:** Valve sheath to primary side; 5F arterial & 7F venous (for temp pacer) to contralateral side
- Valve sheaths & 6F arterial sheaths are closed with Proglide/Prostar – 5F arterial sheaths are closed with Mynx
- Venous sheaths are closed with manual pressure
- **Lines left in place:** Radial arterial line and peripheral IV – generally these are the only lines left in
- If there are AV conduction issues (bradycardia, BBB, other heart block) the temporary pacing wire will be left in place
- If carotid protection (Sentinel) was used, there will be a TR band to the associated radial site
Carotid Protection

Stroke is a concern during TAVR due to calcification of aortic valve – debris can travel to the cerebral arteries during valve deployment causing stroke.

Cerebral protection devices: *(inserted during procedure and removed at end of procedure)*

- Sentinel – 6F via radial access (FDA approved)
- TriGuard – 9F via femoral access (current trial in enrollment)
Claret Sentinel
Cerebral Protection System (CPS)

Proximal Filter
(innominate Artery)
9–15 mm

Distal Filter
(LCC Artery)
6.5–10 mm

Figure 3: Example of Debris Captured by Sentinel

Source: Claret Medical, 2017.
AV Conduction Delays

♥ Some patients experience new BBB or AV block due to swelling/irritation or compression around the AV node

♥ Monitor for heart block, BBB or bradycardia in the post-procedure period – this can be a late occurrence

♥ Avoid use of beta-blockers that may potentiate heart block

TAVR Valve placement

1 Sinoatrial node (Pacemaker)
2 Atrioventricular node
3 Atrioventricular Bundle (Bundle of His)
4 Left & Right Bundle branches
5 Bundle Branches
Patients may experience post TAVR hypertension

♥ Due to the decrease in afterload by relieving LV outflow obstruction (the heart is used to working hard, but no longer needs to)

♥ For transapical or transaortic access – keep SBP no more than 120 mmHg to prevent suture line tears

♥ Commonly treated with Cardene gtt – Dr. Smalling prefers his MAPs to be 75-85 for all TAVR patients
Post Procedure Hypotension

♥ Hyperdynamic ventricle – some patients develop an enlarged LV with diastolic dysfunction due to chronic high afterload

♥ Rapid relief of the obstruction results in severe hypotension/shock – dubbed “suicide ventricle”

♥ Generally have small LV cavity, enlarged septum and high EF (>70%) – “little old ladies” are particularly at risk

♥ LV is unable to fill adequately (preload), decreasing CO; tachycardia decreases LV filling time even more, creating a downward spiral

♥ Use of Dopamine, Epi, Norepi increases contractility & heart rate even more – this makes it worse!

♥ Treatment involves decreasing contractility using beta-blockers and ensuring adequate preload by increasing volume

♥ **Beta-blockers & Volume**
Resources Available for You and Your Patients

- Resources for healthcare providers to access information about aortic stenosis and TAVR
- Patients can learn about the disease and locate a local TAVR Center
- Symptom checklist to help patients discuss their treatment options with their healthcare provider
9,000+ people clicked on the Symptom Checklist & Doctor Discussion Guide

Let's Get Started

Use this tool to help you make the most of your doctor visit. Create this personalized guide to aid in having a productive discussion with your doctor.

It will take less than 2 minutes to complete.

Have you been diagnosed with Severe Aortic Stenosis by your doctor?

No.
I have not been diagnosed with Aortic Stenosis

Yes.
I have been diagnosed with Aortic Stenosis by my doctor

Skip this step and print generic version

NOTE: This questionnaire is a resource, but is not meant to be a diagnostic tool. All of the symptoms listed are common symptoms of aortic stenosis. However, they are also symptoms of other diseases or conditions. Please talk to your doctor about your symptoms.

Step 1  Step 2  Step 3  Step 4
NewHeartValve.com Resource Library

- Severe Aortic Stenosis Brochure
- Patient Brochure
- TAVR Patient Screening Fact Sheet
- Patient Screening Supplement
- Heart Tablets
- SAS Kit
- SAS Poster
- TF & TA Posters
- SAS Brochure Stand
- Rubber Valve Display Stands
Edwards Heart Master Apps on iTunes

- Educational Resource that can be used to help educate patients
- Dedicated to AS with 3D immersion in heart anatomy and pathophysiology
- Free iPad and iPhone Apps

3/6/2019 TAVR Nursing Implications
Questions?
References


(Continues on next page)


19. Dumesnil et al, Paradoxical low flow and/or low gradient severe aortic stenosis despite preserved left ventricular ejection fraction: implications for diagnosis and treatment European Heart Journal 2010; 31, 281-289.


