Severe Aortic Stenosis is Life Threatening

Patients may live with aortic stenosis for many years during a latent, asymptomatic period, even before symptoms of the disease develop and present. However, after patients begin experiencing symptoms, it is urgent they receive treatment.
After the onset of symptoms, patients with severe aortic stenosis have a survival rate as low as 50% at 2 years and 20% at 5 years without aortic valve replacement.\textsuperscript{2}
Aortic Stenosis Progression

Healthy  Mild  Moderate  Severe
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 ≥ 40 mmHg

**Symptomatic (stage D1)**
- YES
  - Exercise test demonstrating decreased exercise tolerance or a fall in systolic BP
  - Should be recommended for valve replacement
- NO
  - Reasonable to recommend for valve replacement

**Severe Low Flow/Low Gradient**
- AVA ≤ 1.0 cm² with 
  - resting aortic Vmax < 4 m/s 
  - or ΔP mean < 40 mmHg

**Symptomatic**
- YES
  - Dobutamine stress echo (DSE) with 
  - AVA ≤ 1 cm² and 
  - Vmax ≥ 4 m/s (stage D2)
  - Reasonable to recommend for valve replacement
- NO
  - AVA ≤ 1 cm² and LVEF ≥ 50% (stage D3*)
  - Reasonable to recommend for valve replacement

**At Risk/Progressive**
- AVA Typically > 1.0 cm²
- Vmax < 4 m/s

**Repeat echo every 6 - 12 months**

*AVR should be considered with stage D3 AS 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).*
Transcatheter Aortic Valve Replacement (TAVR)

The TAVR procedure can be performed through multiple access approaches; however, the most common approach is the transfemoral approach. In the transfemoral approach, the valve is delivered via a catheter through the femoral artery.
TAVR Patient Profile

Your patient may be considered a potential TAVR candidate if:

- They have symptomatic heart disease due to severe native calcific aortic stenosis
- The Heart Team determines that the patient has predicted risk of surgical mortality ≥3% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by STS risk calculator
The PARTNER II trial was a robust, rigorous clinical study in more than 3,000 intermediate-risk patients. TAVR with the SAPIEN 3 valve demonstrated 75% lower rates of 30-day mortality and disabling stroke compared to surgery.†

The PARTNER II Trial Intermediate-Risk Data

All-cause Mortality‡

Surgery (PARTNER IIA trial)
TAVR with SAPIEN 3 valve (PARTNER II S3i trial)

<table>
<thead>
<tr>
<th>No. at risk:</th>
<th>Surgery</th>
<th>SAPIEN 3 TAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 days</td>
<td>944</td>
<td>1,077</td>
</tr>
<tr>
<td>6 months</td>
<td>859</td>
<td>1,043</td>
</tr>
<tr>
<td>9 months</td>
<td>836</td>
<td>1,017</td>
</tr>
<tr>
<td>12 months</td>
<td>808</td>
<td>991</td>
</tr>
<tr>
<td></td>
<td></td>
<td>795</td>
</tr>
</tbody>
</table>

† 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).
‡ The PARTNER II trial intermediate-risk cohort unadjusted clinical event rates, AT population.
Disabling Stroke‡

![Graph showing disabling stroke rates over time for surgery (PARTNER IIA trial) and TAVR with SAPIEN 3 valve (PARTNER II S3i trial).]

- Disabling stroke rate:
  - Surgery (PARTNER IIA trial): 1.0% at 30 days, 4.4% at 1 month.
  - TAVR with SAPIEN 3 valve (PARTNER II S3i trial): 2.3% at 1 month.

No. at risk:

<table>
<thead>
<tr>
<th></th>
<th>30 days</th>
<th>3 months</th>
<th>6 months</th>
<th>9 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>944</td>
<td>825</td>
<td>806</td>
<td>778</td>
<td>764</td>
</tr>
<tr>
<td>SAPIEN 3 TAVR</td>
<td>1,077</td>
<td>1,033</td>
<td>1,008</td>
<td>984</td>
<td>953</td>
</tr>
</tbody>
</table>

‡ The PARTNER II trial intermediate-risk cohort unadjusted clinical event rates, AT population.
Understanding Risk Assessment

An evaluation of the possible risks for each individual patient should be performed if intervention is contemplated. Factors such as the risk of operative mortality, patient frailty, major organ system compromise, other major comorbidities and procedure-specific impediments must be taken into consideration.

Predictive Risk of Operative Mortality

The STS risk model calculator predicts the risk of operative mortality and morbidity after adult cardiac surgery on the basis of patient demographics and clinical variables.

Frailty

The standard assessment of frailty includes the following four components:

- Activities of Daily Living, independence in
  - feeding
  - bathing
  - dressing
  - ambulating
  - toileting
  - hygiene
- Serum Albumin Level
- Grip Strength
- Gait Speed

Major Organ System Compromise

- Cardiac severe LV systolic or diastolic dysfunction or RV dysfunction, fixed pulmonary hypertension
- CKD stage 3 or worse (≥ 45 GFR)
- Pulmonary dysfunction with FEV1 < 50% or DLCO2 < 50% of predicted
- CNS dysfunction
- GI dysfunction
- Cancer – active malignancy
- Liver – any history of cirrhosis, variceal bleeding, or elevated INR in the absence of VKA therapy
Intermediate or Greater Risk TAVR Patients May Present with Some of the Following

<table>
<thead>
<tr>
<th>Reduced EF</th>
<th>History of renal insufficiency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior CABG</td>
<td>History of syncope</td>
</tr>
<tr>
<td>Prior open chest surgery</td>
<td>History of CAD</td>
</tr>
<tr>
<td>History of AFib</td>
<td>Prior chest radiation</td>
</tr>
<tr>
<td>History of stroke/CVA</td>
<td>History of COPD</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>Diabetes and hypertension</td>
</tr>
<tr>
<td>Old age</td>
<td>Heavily calcified aorta</td>
</tr>
<tr>
<td>Fatigue, slow gait</td>
<td>Frailty</td>
</tr>
</tbody>
</table>
Logistics of Patient Assessment for TAVR

The Heart Team confirms the patient meets the treatment indication by conducting a series of additional tests.

Patient with severe aortic stenosis is identified by referring physician. Patient is referred to TAVR Center.

An evaluation of the cardiac morphology and function of the valve is completed using transthoracic echocardiography.

The aortic valvular complex and peripheral vasculature are evaluated using MDCT.
Cardiac catheterization is performed in order to assess if coronary intervention is needed. If the Heart Team determines that the patient meets the indication for TAVR, devising a treatment plan is a collaborative decision between the referring physician, Heart Team, patient and patient’s family. Multidisciplinary review is conducted and treatment plan is recommended by the Heart Team.

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.
The Specialized Heart Team Approach at a TAVR Center

The Heart Team at a TAVR Center is composed of a multidisciplinary, collaborative group of physicians and caregivers, including interventional cardiologists, cardiothoracic surgeons, imaging specialists, anesthesiologists and valve clinic coordinators. This cohesive, multi-disciplinary approach embodies optimal patient-centric care, dedication across medical specialties and a collaborative treatment decision.
Devising the Treatment Plan

The Heart Team will conduct a comprehensive evaluation to determine whether the TAVR procedure is appropriate.

- Obtain information required to make a recommendation for the best plan of care
- All potential treatment options are discussed with the patient and caregivers
- Treatment choice is a collaborative decision between the physicians, patient, and patient’s family
Visit NewHeartValve.com/hcp to download or order educational materials at no charge.

References
1. Lester S, Heibron B, Dodek A, Gin K, Jue J. The Natural History and Rate of Progression of Aortic Stenosis. Chest. 1998; 113(4): 1109

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician.
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Warning: Observation of the pacing lead throughout the procedure is essential to avoid perforation, inaccuracy of lead positioning, and fractures. Obtain a detailed history of any allergy to contrast media or device materials. Do not resterilize or reuse the devices.

Precautions: For special considerations associated with the use of the Edwards Crimper prior to valve implantation, refer to the Edwards SAPIEN 3 transcatheter heart valve Instructions for Use.

Potential Adverse Events: There are no known potential adverse events associated with the Edwards Crimper.

Indications: The Edwards Crimper is indicated for use in preparing the Edwards SAPIEN 3 transcatheter heart valve for implantation.

Contraindications: There are no known contraindications associated with the use of the Edwards Crimper.