Aortic Stenosis Fact Sheet

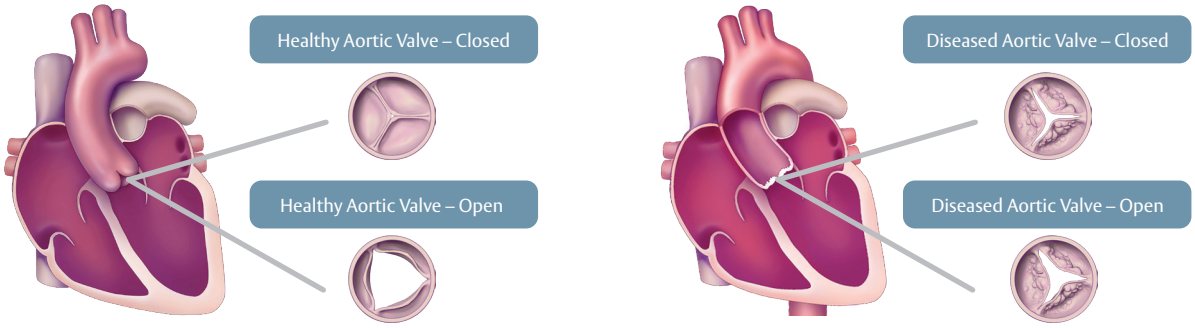
Introduction

Aortic stenosis is a progressive disease that occurs with a narrowing of the patient's aortic valve opening. Aortic stenosis primarily happens over time as we age but can also be caused by a birth defect, previous chest radiation, or rheumatic fever. The prevalence of aortic stenosis increases with age. It is estimated that approximately 2.5 million people, or 12.4% of the population, in the United States over the age of 75 suffer from aortic stenosis.

Overview of the Disease

Human heart valves are remarkable structures. Normal heart valves have two or three flaps of tissue called leaflets. These tissue-paper thin membranes attached to the heart wall constantly open and close to regulate blood flow (making the sound of a heartbeat).

In elderly patients, aortic stenosis is sometimes caused by the buildup of calcium (mineral deposits) on the aortic valve's leaflets. Over time, the leaflets become stiff, reducing their ability to fully open and close. When the leaflets don't fully open, a person's heart must work harder to push blood through the aortic valve to the rest of the body. Eventually, the heart gets weaker, increasing the risk of heart failure (when the heart cannot supply enough blood to the body).



Severe Aortic Stenosis

Aortic stenosis is a progressive disease which means it gets worse over time. It's typically measured as mild, moderate, or severe aortic stenosis. As a result of the reduced blood flow, the body does not get the oxygen it needs, which may cause symptoms. If a patient has been diagnosed with severe aortic stenosis and is experiencing symptoms, it can be life-threatening and may progress rapidly.

However, it's important to know that Severe Aortic Stenosis may occur with no obvious symptoms

Many patients initially appear asymptomatic, but on closer examination, up to 32% exhibit symptoms. The symptoms listed below are typically associated with severe aortic stenosis but are commonly misunderstood by patients as "normal" signs of aging.

Signs of Severe Aortic Stenosis

You may notice symptoms like:

- Chest pain
- Rapid, fluttering heartbeat
- Trouble breathing or feeling short of breath
- Feeling dizzy or light-headed, even fainting
- Difficulty walking short distances
- Swollen ankles or feet
- Not doing activities you used to enjoy
- Difficulty sleeping or the need to sleep sitting up

Major Risk Factors
Factors associated with aortic valve disease include the following:

- Increasing age
- High blood pressure
- High cholesterol
- Smoking

Severe aortic stenosis is life-threatening, and treatment for this condition is critical. Patients who have developed symptoms from severe aortic stenosis have about a 50% chance of living at 2 years without aortic valve replacement.

Diagnosis
In addition to a physical exam, severe aortic stenosis is diagnosed in several ways, the most common being an echocardiogram, electrocardiogram (EKG), chest X-ray of the patient's heart, and cardiac catheterization (angiography).

Aortic Valve Replacement Options

Transcatheter Aortic Valve Replacement (TAVR)
TAVR (sometimes called transcatheter aortic valve implantation, or TAVI) is a less invasive procedure than open-heart surgery which allows a new valve to be inserted within the native, diseased aortic valve.

The TAVR procedure can be performed using one of many approaches, the most common being the transfemoral approach (through a small incision in the leg). Only a Heart Team can decide which approach is best, based on the patient's medical condition and other factors.

In preparation for the patient's transfemoral procedure (or through the upper leg), the patient may be placed under anesthesia. The doctor will make an incision in the leg and insert a short, hollow tube called a sheath. This will allow the doctor to put various devices through the sheath to access the patient's heart. The new heart valve is placed on the delivery system and compressed onto a balloon to make it small enough to fit through the sheath. Once the delivery system reaches the patient's diseased valve, the balloon will be inflated with fluid, expanding the new valve into place. The new valve pushes the leaflets of the patient's diseased valve aside, and the frame of the new valve uses the diseased valve's leaflets to secure itself into place. The balloon is then deflated and removed. The patient's doctor will ensure the new valve is working properly before closing up the incision.

Open-Heart Surgery
Most open-heart surgeries are performed through an incision across the full length of the breast bone, or sternum. This incision is called a median sternotomy. Occasionally, open-heart surgeries can be performed through smaller incisions. Open-heart surgeries, including those performed through smaller incisions, require the use of a heart-lung machine which temporarily takes over the function of the heart. During the procedure, the surgeon will completely remove the diseased aortic valve and insert a new valve. There are two different types of surgical valves:

- Mechanical (artificial material)
- Biological (animal or human tissue)

Additional Information
More information about the TAVR procedure can be found at www.NewHeartValve.com.

Important Risk Information

Edwards SAPIEN 3 THV System and Edwards SAPIEN 3 Ultra THV System

Indications:
The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System are indicated for patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic or mitral valve who are judged by a Heart Team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the STS risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

Contraindications (Who should not use):
The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System should not be used in patients who:

- Cannot tolerate medications that thin the blood or prevent blood clots from forming.
- Have an active infection in the heart or elsewhere.

Warnings:

- There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, compared to other standard treatments for aortic stenosis in the high or greater risk population.
- If an incorrect valve size for your anatomy is used, it may lead to heart injury, valve leakage, movement, or dislodgement.
- Patients should talk to their doctor if they have significant heart disease, a mitral valve device or are sensitive to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials.
- The SAPIEN 3 Ultra and SAPIEN 3 valves may not last as long in younger patients, or patients with a disease that results in more calcium in their blood.
- During the procedure, your doctors should monitor the dye used in the body; if used in excess it could lead to kidney damage. X-ray guidance used during the procedure may cause injury to the skin, which may be painful, damaging, and long-lasting.
- Patient's creatinine level should be measured prior to the procedure.
- Patients who have already had a valve replaced should be carefully assessed by their physician prior to receiving a new valve to ensure proper placement of the new valve.
- Injury can occur if the delivery system is not used properly.
- Transcatheter heart valve patients should talk to their physicians about the potential need for medications that thin the blood or prevent blood clots from forming.

Precautions:
The long-term durability of the Edwards SAPIEN 3 Ultra and SAPIEN 3 transcatheter heart valves are not known at this time. Regular medical follow-up is recommended to evaluate how well a patient's heart valve is performing. Safety, performance, and durability of the SAPIEN 3 Ultra and SAPIEN 3 valves have not been established for placement inside a previously implanted transcatheter valve.

The safety and effectiveness of the transcatheter heart valves are also not known for patients who have:

- An aortic heart valve that is not calcified, contains only one leaflet, two leaflets in low surgical risk patients, has leaflets with large pieces of calcium that may block the vessels that supply blood to the heart or in which the main problem is that the valve leaks.
- Previous prosthetic ring in any position.
- Previous atrial septal occlude.
- A heart that does not pump well, has thickening of the heart muscle, with or without blockage, unusual ultrasound images of the heart that could represent irregularities such as a blood clot, a diseased mitral valve that is calcified or leaking, or Gorlin syndrome, a condition that affects many areas of the body and increases the risk of developing various cancers and tumors.
- Low white, red or platelet blood cell counts, or history of bleeding because the blood does not clot properly.
- Diseased, abnormal or irregularly shaped vessels leading to the heart. Vessels which are heavily diseased or too small for associated delivery devices, or a large amount of calcification at the point of entry.
- Allergies to blood-thinning medications or dye injected during the procedure.
- For a valve in valve procedure, there is a risk of leakage if the previously implanted tissue valve is not securely in place or if it is damaged. There is also the possibility that a partially detached valve leaflet from the previously implanted valve could block a blood vessel.
- Additional pre-procedure imaging will be completed to evaluate proper sizing.

Potential risks associated with the procedure include:

- Death, stroke, paralysis (loss of muscle function), permanent disability, or severe bleeding.
- Risks to the heart, including heart attack or heart failure, a heart that does not pump well, irregular heartbeat that may result in a need for a permanent pacemaker, chest pain, heart murmur, false aneurysm, recurring aortic stenosis (narrowing), too much fluid around the heart, injury to the structure of the heart.
- Risks to your lungs or breathing, including difficulty breathing, fainting, buildup of fluid in or around the lungs, weakness or inability to exercise.
- Risks involving bleeding or your blood supply, including formation of a blood clot, high or low blood pressure, limited blood supply, a decrease in red blood cells, or abnormal lab values, bleeding in the abdominal cavity, collection of blood under the skin.
- Additional risks, including life-threatening infection, dislodgement of calcified material, air embolism (air bubbles in the blood vessels), poor kidney function or failure, nerve injury, fever, allergic reaction to anesthesia or dye, reoperation, pain, infection or bleeding at incision sites, or swelling.

Additional potential risks specifically associated with the use of the heart valves include:

- Valve movement after deployment, blockage or disruption of blood flow through the heart, need for additional heart surgery and possible removal of the SAPIEN 3 Ultra and SAPIEN 3 valve, a blood clot that requires treatment, damage to the valve (e.g., wear, breakage, recurring aortic stenosis), nonstructural valve dysfunction (e.g., leakage, inappropriate sizing or positioning, blockage, excess tissue in growth, blood cell damage, etc.) or mechanical failure of the delivery system and/or accessories.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician.

Edwards Lifesciences • One Edwards Way, Irvine CA 92614 USA • edwards.com

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