

Your Guide to TAVI:

Transcatheter Aortic Valve Implantation



*A guide for people with severe aortic stenosis
who need treatment.*



Edwards

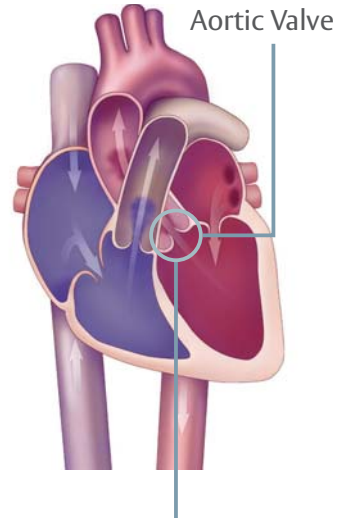
Know the Facts About Aortic Stenosis

Your heart works hard every second of the day, pumping blood throughout the body. Your aortic valve is located inside your heart. The valve has thin leaflets that open and close like gates and control blood flow to the rest of your body.

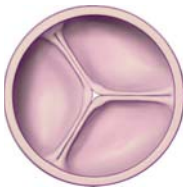
Aortic stenosis is a disease of the aortic valve. The disease makes the valves leaflets stiff, which means that the valve cannot fully open and close as it should. As the opening becomes smaller, it makes it harder for the heart to pump blood to the rest of your body, which can cause you to feel tired and out of breath.

Aortic stenosis is a serious condition that weakens the heart, damages your health, and makes it hard to do the things you want and need to do. **Aortic stenosis can be mild, moderate, or severe and may worsen over time.**

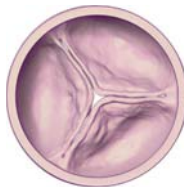
Your Heart



Disease Progression in the Valve Leaflets in Aortic Stenosis



Healthy



Mild



Moderate



Severe

Most often, aortic stenosis affects older adults and is caused by a build-up of calcium, a substance normally found in the blood. The disease can also be caused by:

- **birth defect**
- **rheumatic fever**
- **radiation therapy**

Aortic Stenosis Gets Worse Over Time

To protect your health, your heart will be monitored on a regular basis. If the aortic stenosis is “mild,” your doctor may recommend “watching and waiting” and not prescribe treatment. For people who have “moderate aortic stenosis,” medicine may be prescribed.



It's important to know that medicine cannot stop or cure aortic stenosis – it can only treat the symptoms.

As the disease progresses and becomes “severe,” you may need to have your aortic valve replaced.

With this disease it is important to be aware of possible symptoms. Your doctor will listen to your heart and ask about your activity level. People who have severe aortic stenosis may find it hard to take part in regular activities such as walking to get the mail or going up the stairs. They may also have an increased risk for heart failure.

“*All was fine. I was active. I didn't know anything was wrong. I have a cardiologist, and one day he said, 'You have a heart murmur.' And here I am now.*”
– Patient

Not every heart murmur is heart valve disease.




Monitoring Aortic Stenosis

You will have an echocardiogram, or “echo” test, which is a noninvasive test that takes a picture of your heart. This test shows the size of the aortic valve and measures the speed of the blood that flows through the valve and the pressure on either side of it.

The test will show whether you have mild, moderate, or severe aortic stenosis. Follow-up echo tests will show whether the disease is progressing.*

Severity of Aortic Stenosis	How Often Should an Echocardiogram Be Performed?
Mild Aortic Stenosis	Every 3 to 5 years
Moderate Aortic Stenosis	Every 1 to 2 years
Severe Aortic Stenosis	Seek treatment options

It’s important to stay in touch with your doctor between tests. Report any new symptoms or any changes in current symptoms you may have even if they do not seem significant. Ask how often you should have an echocardiogram to monitor the progression of aortic stenosis.

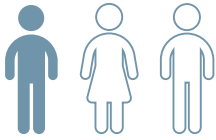


If you are 70 years or older and have not had an echocardiogram, ask your doctor whether you should have one.

“ I stopped being able to walk the dog and work in my garden.... I guess it was gradual, but I could feel it happening to me. ”
– Patient (Tennessee)

*The frequency of testing is based on guidelines from the American College of Cardiology Foundation and American Heart Association. Nishimura RA, Otto CM, Bonow RO, et al; ACC/AHA Task Force Members. 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2014;129(23):2440-2492. <http://circ.ahajournals.org/content/circulationaha/early/2014/02/27/CIR.000000000000029.full.pdf>.

Symptoms of Aortic Stenosis or Signs of Getting Older?



About 1 out of every 3 people with aortic stenosis realize they have symptoms only when further evaluated.

Many people simply confuse the symptoms of aortic stenosis with “normal” signs of aging. People who have aortic stenosis may report no symptoms, but after closer examination, they realize in fact they have symptoms. This is why it’s so important to talk with your doctor about your symptoms and changes in your daily activity. **Many times people do not know they have symptoms until they discuss their daily activity with a doctor.**



Know the Symptoms of Severe Aortic Stenosis

Listen to your body. Tell your doctor about changes in your health and any new or worsening symptoms. Once aortic stenosis becomes severe, people usually have symptoms but not always. The symptoms can appear suddenly, worsen quickly, and become life-threatening.

You may notice one or more of these symptoms:



Fatigue (extreme tiredness)



Swollen ankles and feet



Shortness of breath



Not engaging in activities you used to enjoy



Chest pain (tightness in the chest that often gets worse with exercise)



Feeling dizzy or lightheaded



Difficulty walking short distances



Difficulty sleeping (or need to sleep sitting up)



Rapid heartbeat (feels like your heart is fluttering in your chest)



Fainting

Other Signs:

- Rapid weight gain
- Irregular heartbeat (heart murmur)
- Dry cough



Tip for Family Members

Your role is an important one. Keep an eye on any changes and new or worsening symptoms your loved one may experience. If you see changes, contact the doctor right away.

Know Your Treatment Options

Taking the next step to find out about treatment options for severe aortic stenosis may feel overwhelming, but you should not wait. It's important that you talk with your doctor about all available treatment options. Aortic stenosis can progress quickly, and you should understand what your options are before treatment becomes urgent. Early treatment for this progressive disease can make a significant difference in your long-term health.

The only effective way to treat severe aortic stenosis is by replacing your aortic valve. This can be done through transcatheter aortic valve implantation (TAVI) or open heart surgery. TAVI may be available for all aortic stenosis patients and is a less invasive option for replacing the aortic valve. Your risk for complications and your overall health will determine which treatment option is best for you.



Tip for Family Members

Seek treatment early so that you and your loved one can get back to life and all the things you like to do.



Benefits of TAVI for Severe Aortic Stenosis



More than 400,000 people worldwide have received the TAVI procedure.

TAVI is a procedure that replaces the diseased aortic valve in people who have severe aortic stenosis. It is a less invasive procedure than open heart surgery that may help you get back on your feet faster.

Benefits of TAVI may include:



Improved quality of life



Relief of symptoms



Shorter recovery time to getting back to everyday activities



Less pain and anxiety



Shorter hospital stay



Better clinical outcomes

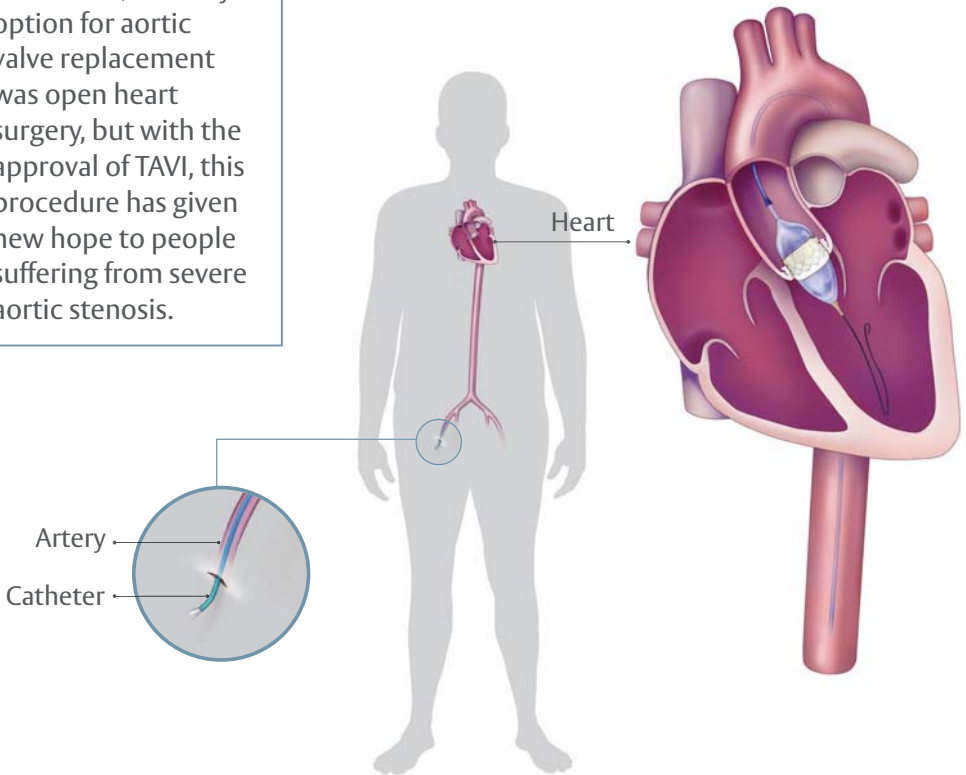


Less invasive with minimal scarring

“Having mom healthy again means that she can resume her life. I guess that also means that I can resume mine, now that she is back to her old self.”
– Caregiver (Nashville)

Learn How TAVI Is Different

Until 2011, the only option for aortic valve replacement was open heart surgery, but with the approval of TAVI, this procedure has given new hope to people suffering from severe aortic stenosis.



- Compared with open heart surgery, TAVI is a less invasive procedure that involves making a small incision in the leg versus opening up the chest
- TAVI uses a small catheter, or tube, that is pushed through an artery to the heart to place a new valve within a diseased aortic valve
- The recovery time after TAVI and the length of hospital stay is shorter than that with open heart surgery. On average, the TAVI procedure lasts approximately 1 hour

Is TAVI Right for You?

TAVI may be recommended for people who have been diagnosed with severe aortic stenosis and need their valve replaced.

A specialized doctor at a TAVI Hospital will consider all factors about your health to decide whether TAVI is a treatment option for you.

Your doctor will consider these factors:



Your medical history



Your age



Your current health status



The condition of your heart

Your doctor should review with you all the options available. If not, find a doctor trained in the TAVI procedure who will provide this information. TAVI may be the preferred option compared to open heart surgery for people who have severe aortic stenosis and have been told they are eligible for the procedure by a TAVI Team.



Remember, only a TAVI doctor can determine whether TAVI is an option for you.

The TAVI Evaluation

Once the patient is confirmed to have severe symptomatic aortic stenosis, he or she should be evaluated to determine whether TAVI is an option. A team trained in TAVI assesses aortic valve disease in patients who are referred for evaluation. The team includes cardiologists, cardiac surgeons, and imaging specialists. Together, this team looks at each patient and based on a number of factors, decides whether TAVI is an option for aortic valve replacement.

The evaluation may include these tests:



Echocardiography (echotest) – a noninvasive test that takes pictures of your heart



Stress test – involves walking on a treadmill or riding a stationary bike while your heart is being monitored to show how your heart works during physical activity



Chest x-ray scan – shows the size and shape of your lungs and heart



Cardiac catheterization – shows the blood pressure and blood flow within your heart

In some cases, you may have already had some of these tests. These assessments help the TAVI Doctor create a treatment plan based on your current images and measurements. They're important because your TAVI Doctor wants to make sure he or she is recommending the best treatment for you.

What to Expect With the TAVI Procedure

Before the procedure

You may need to get a dental clearance. Any infection that may be present in your mouth or teeth can spread and cause an infection in your heart valve. Therefore, it is important for your dentist to examine you and provide dental clearance before any valve procedure.

Your Valve Clinic Coordinator will give you information and instructions to get ready for the procedure. It is normal to be nervous. Your TAVI Doctor will be sure to review the risks and benefits of TAVI with you and answer any questions.

During the procedure

TAVI is performed in a hospital. Before the procedure, you will be given anesthesia. During a common TAVI procedure, the doctor will make a small incision in the leg and insert a thin tube called a catheter into the artery. The doctor will then guide the catheter, which is carrying the new valve on a balloon, up to the heart. The balloon is inflated to expand the new valve and push the leaflets aside. The new valve attaches to the calcification of the old diseased valve's leaflets and is anchored in place. It begins working right away.



On average, the TAVI procedure lasts about 1 hour, versus 4 hours with open heart surgery.

It is important to discuss your particular situation with your doctor to understand the possible risks, benefits, and complications associated with TAVI.

After the procedure

The recovery time and length of hospital stay may be different for each person. However, patients who receive TAVI usually have a shorter hospital stay than those who receive open heart surgery. Your TAVI Doctor can tell you how long you can expect to stay in the hospital after the TAVI procedure.



Your quality of life may improve as early as 30 days after the TAVI procedure.

Helpful Resources

Taking control of your health can help you get the care you need. Free resources are available below to help you and your loved ones better understand aortic stenosis and the TAVI procedure.



Aortic Stenosis and TAVI Website

For more information, visit NewHeartValve.asia



TAVI Patient Stories

Visit the Patient Resources tab at NewHeartValve.asia



Frequently Asked Questions

Q If I am 70 years of age or older, how often should I get an echocardiogram or heart health evaluation?

Different factors contribute to heart disease, and age can be one of them. It's important to be aware of your risk and talk with your doctor about your heart health. Aortic stenosis is an age related disease, so make sure to ask your doctor about whether you should get an echocardiogram.

Q How serious is severe aortic stenosis (also known as severe aortic valve stenosis)?

Approximately 50% of people who develop symptoms from severe aortic stenosis will die within an average of two years if they do not have their aortic valve replaced.¹ If you have been diagnosed with severe aortic stenosis and have symptoms, talk to your doctor right away about your treatment options.

Q How long will it be before my aortic stenosis becomes so severe that I will need my valve replaced?

The progression of aortic stenosis is different for everyone, so it may take years or months before a valve replacement is necessary. Your doctor will be better able to assess the severity of aortic stenosis according to your physical symptoms and the results of your echo tests.

Q What are the treatment options for aortic valve stenosis?

Depending on how far your aortic stenosis has progressed, your doctor may prescribe medication to help control your symptoms. However, it's important to know the only effective way to treat aortic stenosis is by replacing your valve. TAVI is now the preferred treatment option for patients with severe aortic stenosis and may have symptoms.

Frequently Asked Questions

Q What if my doctor doesn't specialize in the TAVI procedure?

Ask your doctor to refer you to a TAVI Doctor. TAVI Doctors are experts in valve disease and valve replacement and can determine the appropriate treatment option for you.

Q How could I benefit from transcatheter aortic valve implantation?

With the less invasive TAVI procedure, people may return to daily activities sooner than with open heart surgery. People who undergo TAVI report improved quality of life following the procedure. Other TAVI benefits include shorter hospital stay, relief of symptoms (sometimes immediately), improved heart function, and reduced pain and anxiety.

Q How long has the TAVI procedure been performed and for how many people?

TAVI has been commercially available in Europe since 2007, in Southeast Asia countries since 2009, and in the United States since 2011, for more than 400,000 people worldwide.

Q What can I expect after the TAVI procedure?

Research has shown that patients who undergo the TAVI procedure have improved health within 30 days of their procedure.

Q What are the risks of the TAVI procedure?

Serious complications that could be associated with the TAVI procedure may be death, stroke, serious damage to the arteries, or serious bleeding. It is important to discuss your particular situation with your doctor to understand all the possible risks, benefits, and complications.

Q How long does a TAVI valve last?

The TAVI was approved in 2011 and long-term clinical data are still being reviewed. The Edwards TAVI valve is made from cow tissue, and it has been shown to last at least 5 years, according to US clinical data. Less than 1% of patients have their valve replaced due to valve deterioration after 5 years.



References

1. Otto CM. Timing of aortic valve surgery. *Heart*. 2000;84:211-218.

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