



TRANSCATHETER AORTIC VALVE REPLACEMENT PATIENTGUIDE

INFORMATION FOR PATIENTS AND THEIR FAMILIES





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DEPARTMENT OF CARDIOLOGY

LISIE HEART INSTITUTE

The department of Cardiology at the Lisie Heart institute is one on the largest cardiology facility in the state of Kerala, providing outstanding care for patients with a team of highly qualified, skilled and dedicated professionals from various cardTiac sub-specialities.

The department has a legacy of 25 years, a legacy of excellence in patient care, research and education. Our highly competent team has well qualified doctors in sub-speciality services including Pediatric Cardiology, Electrophysiology, and Adult Coronary, Structural and Vascular Cardiology.

Critical care services are the best, with a fully equipped 24 bedded coronary care unit having the latest equipment in monitoring and therapy. The Non-invasive lab has 8 top of the class echo doppler machines with Stress testing, Holter and Ambulatory monitoring. The Invasive lab has 4 state of the art digital catheterisation labs with dedicated coronary, pediatric electrophysiology and vascular labs.

We are the pioneers of primary angioplasty in acute myocardial infarction in our state. We are also the fore-runners in the field of intra-coronary imaging guided optimal percutaneous transluminal coronary angioplasty across the country. We have dedicated pediatric cardiologists to provide tertiary care for all complex congenital heart diseases. We offer state-of-the art arrhythmia management, with 24X7 on-site facilities for conventional as well as 3D mapping assisted radiofrequency ablation for simple as well as complex arrhythmias. We have a high volume cardiac rhythm management devices implant program with facilities for 24X7 device checks and a global remote monitoring facility for implanted devices.



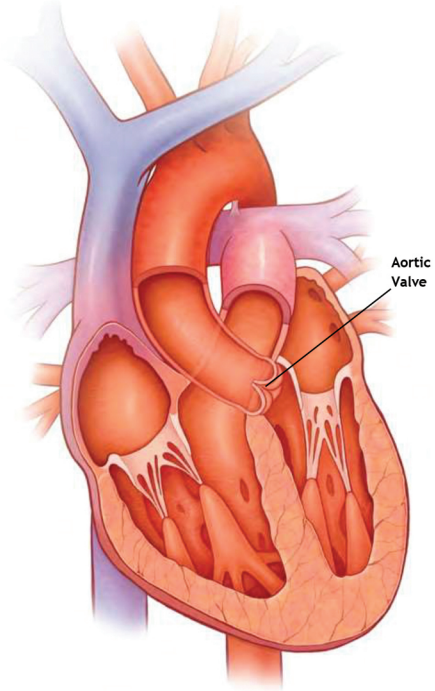
YOUR HEART

The Heart and Its Valves

A healthy heart, which beats about 100,000 times a day, supplies the body with oxygen-rich blood. The heart is a muscular organ that has four chambers. Blood is pumped through the four chambers with the help of four heart valves – the aortic valve, the pulmonic valve, the mitral valve, and the tricuspid valve. During an average lifetime, these valves will open and close over two billion times.

Heart valves open when the heart pumps to allow blood to flow. They close quickly between heart beats to make sure the blood does not flow backward. Any trouble with this normal flow will make it hard for the heart to pump the blood where it needs to go.

The aortic valve controls the flow of blood as it exits the heart and is pumped to the rest of the body.

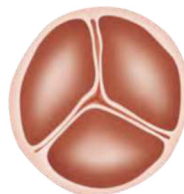


Valve Disorders

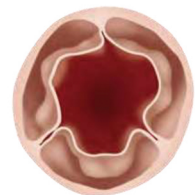
Sometimes, these hardworking valves can run into problems that can cause issues with blood flow and threaten overall health.

Stenosis, more specifically aortic stenosis (AS), is a narrowing of the aortic valve opening. It can be caused by age, genetic predisposition, rheumatic fever, radiation and/or buildup on the leaflets of calcium, cholesterol (fat), etc. This results in stiff valve leaflets that don't move easily or open fully. This reduces the pumping ability of the heart to push blood through the aortic valve to your body. Left untreated, severe AS can lead to heart failure or even sudden death.

Regurgitation happens when the valve has become damaged or worn out and blood is able to leak backwards. This makes the heart work harder to circulate the blood, and, if left untreated, can result in heart failure.



Healthy Aortic Valve (closed)



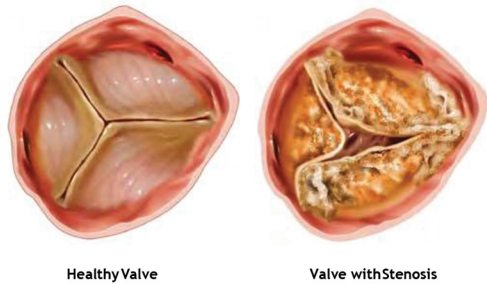
Healthy Aortic Valve (open)

Symptoms of Aortic Stenosis

- Shortness of breath
- Dizziness or fainting
- Chest pain
- Feeling tired or fatigued
- Swelling in your legs

Causes of Aortic Stenosis

- Age
- Genetic Predisposition
- Rheumatic Heart Disease
- Radiation Exposure



Treatment for Severe Aortic Stenosis

Unfortunately, though there are many medications available to treat other heart conditions, there is no drug therapy to cure aortic stenosis.

For severe aortic stenosis, your doctor may prescribe medicine to make you feel better in the short term, but ultimately you will require intervention.

Surgical Aortic Valve Replacement (SAVR)

- Surgical aortic valve replacement has been the standard of treatment for aortic stenosis for many years.
- The procedure may be performed through an open surgery or a minimally invasive approach done using a smaller cut.
- The patient's breathing and circulation are transferred to a heart-lung machine during the surgery.
- Once the site is accessed, the surgeon will remove the diseased valve and implant an artificial valve. There are many valves available on the market. These artificial valves are man-made from synthetic materials (mechanical), constructed from animal tissue (biological), or some combination of the two.
- You may be in the hospital for more than a week.

Transcatheter Aortic Valve Replacement (TAVR)

Transcatheter aortic valve replacement is a relatively new procedure that delivers a replacement valve in much the same way that a cardiac stent is implanted. This procedure does not require stopping the heart or opening the chest cavity. These revolutionary valves, constructed from a combination of metal mesh and animal tissue, are delivered via a thin wire (catheter) and expanded in place over the existing valve. Once in place, the valve immediately begins functioning.

Heart Team Approach

A group of doctors called the “Heart Team” are involved in making a determination if you are a candidate for a TAVR procedure. This includes interventional cardiologists, cardiothoracic surgeons, echocardiographers, anesthesiologists, and valve clinic coordinators.

Candidates for the TAVR Procedure

A series of tests and consultations will be done to see if you can have this procedure. Patients can be admitted to the hospital for the tests or patients can schedule the tests as an outpatient. If the tests show this procedure is right for you, you will return at a later date for the TAVR procedure.



Workup tests include:

Echocardiogram-an ultrasound of your heart chambers and valves.

Chest/Abdomen/Pelvis CT with contrast dye-a view of the size and shape of your blood vessels and aortic valve.

Consultation with an Interventional Cardiologist and a Cardiac Surgeon-You will meet with an interventional cardiologist and a cardiac surgeon. They will explain more about the TAVR procedure and review your treatment options. The test results will be reviewed by the eTAVR Heart Team to determine if you are a candidate. You will then be contacted with the results.

Coronary angiogram check for block in the arteries

Available TAVR Devices

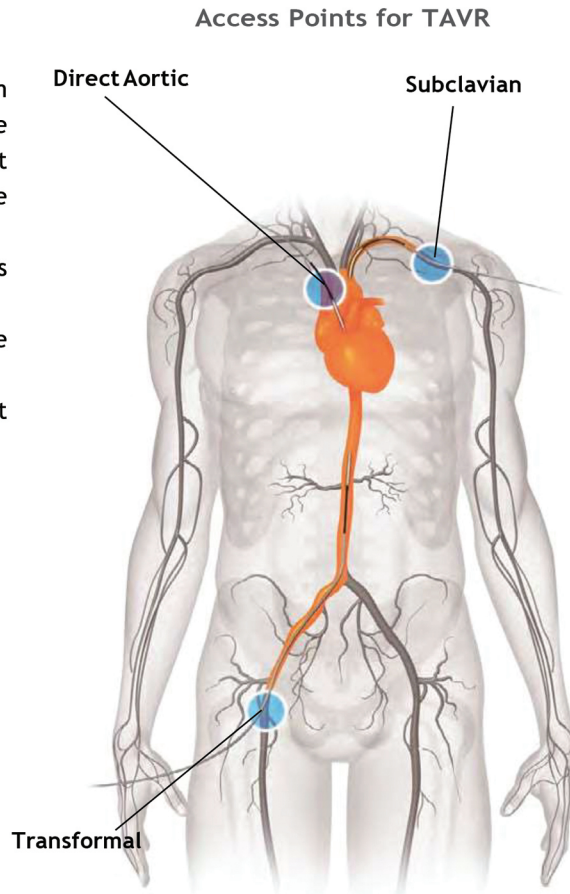
If you are reading this guide, chances are you've been recommended for a transcatheter aortic valve replacement (TAVR) procedure at Lurie Heart Institute. TAVR, also sometimes called TAVI for transcatheter aortic valve implantation, offers options for patients who may not be candidates for surgery due to their overall health, age, or other medical conditions. There are two different valve systems, one is self-expanding valve and other one is balloon-expandable valve. Both devices have been thoroughly researched and tested, and each offers advantages for certain cases. The TAVR Heart Team will determine the device that is appropriate for you.

Regardless of which device your doctor chooses for your case, you will be treated by an experienced multidisciplinary team that includes interventional cardiologists, cardiac surgeons, an echo cardiographer, anesthesia, intensivists, clinical nurses, and other support staff.

Delivery of the TAVR Device

The arteries in the body are like a system of roads that branch out from the heart. There are different "routes" to get to the heart to deliver the valve. These include:

- An artery in your leg (femoral) – this is the most common approach.
- An artery near your collarbone (subclavian)
- A space between your ribs (direct aortic)



Medtronic CoreValve

The Self expanding supra annular transcatheter aortic heart valve consists of a frame made from a flexible nickel-titanium alloy and a valve made of porcine (pig) heart tissue. The Self expanding aortic heart valve is available in different sizes and diameters. The TAVR team will choose one that's best for you.

The device is delivered to your heart through a catheter. The frame of the device is self-expanding, springing into place over the existing valve.

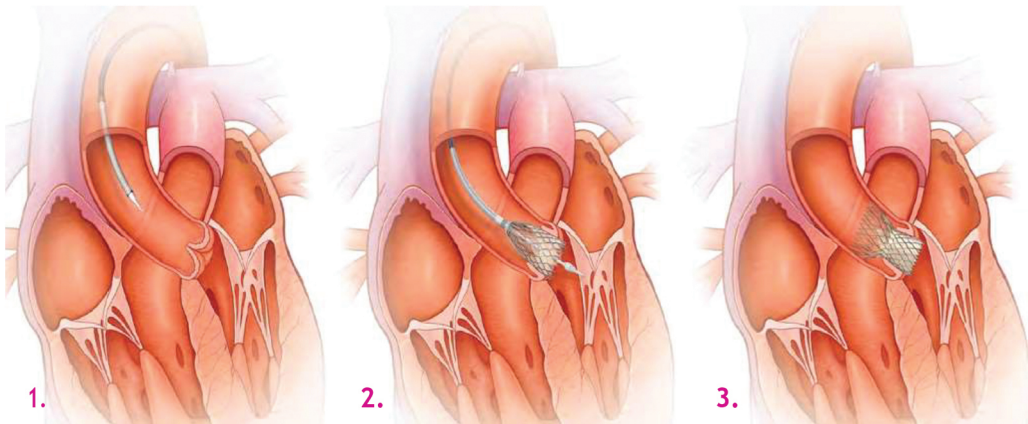


Self Expanding Valve

Placement

The Self expandable valve may be delivered through three approaches:

- An artery in your leg (femoral or iliac)—this is the most common approach.
- An artery near your collarbone (subclavian)
- A space between your ribs (direct aortic)



Self Expanding valve deployment

Placement of Your Valve

X-ray imaging, called fluoroscopy, will be used during the procedure.

1. The doctor will make a cut and insert a sheath into your artery. A balloon-tipped catheter will be guided to the aortic valve and opened in place, forcing open and preparing the diseased valve for the self-expandable device. The valve on the delivery system will be inserted into the sheath to reach the heart.
2. The doctor will place the self-expandable device in place over your diseased valve. When in place, the device expands to replace the diseased valve. The self-expandable valve will start functioning immediately at 80% of the deployment, easily retrievable and safe.
3. The catheter and sheath will be removed, the cut will be closed, and the operation will be complete.



Balloon Expandable Valve

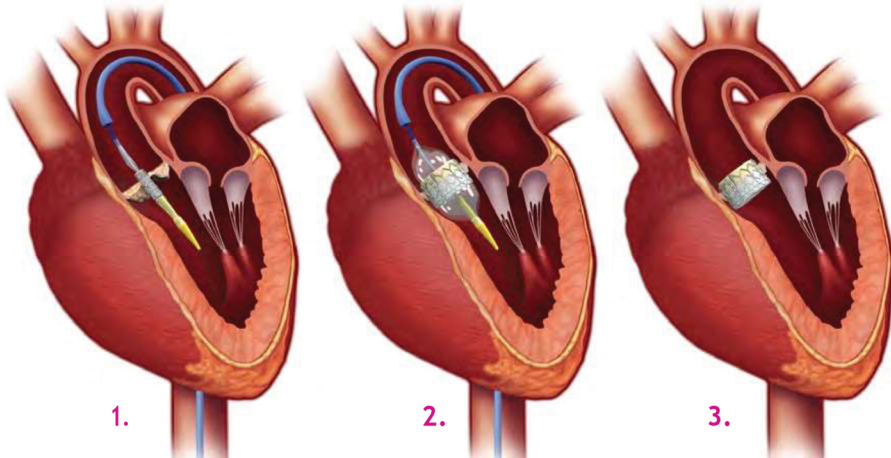
This consists of a valve made from bovine (cow) heart tissue supported by a frame of chromium cobalt. The device is available in four sizes, and if you are a candidate for this device, the TAVR team will choose one that's best for you.

The device will be guided to your heart via catheter and expanded in place with the help of an aortic balloon.

Placement

This valve can be placed using two approaches:

- An artery in your leg (femoral) - this is the most common approach.
- A space between your ribs (direct aortic)



Balloon Expandable valve deployment

Placement of Your Valve

X-ray imaging, called fluoroscopy, will be used during the procedure.

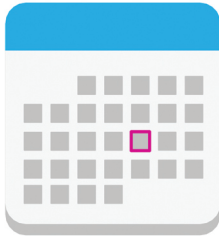
1. The New Balloon expandable valve will be compressed on a balloon to make it small. The delivery system is a tube with a balloon at the end. The valve on the delivery system will be inserted into the sheath to reach the heart.
2. When the delivery system reaches your diseased valve, the balloon will be inflated to open the device. The new valve will push your diseased valve, crushing it against the wall and the new valve will start functioning immediately. The frame of the new valve uses your diseased valve leaflets to anchor itself in place.
3. The deflated balloon will now be removed. Your doctor will make sure that the new valve is working properly.



YOUR PROCEDURE STEP-BY-STEP

1 Week Before Procedure

You will receive a call to confirm your appointment and give you instructions, including when to arrive at the Hospital. You will be informed which medications to continue or discontinue and any restrictions. He/she will answer any questions you may have.



2 Pre-Procedure

Patients will be admitted to a room in the cardiac unit after registration, where they will stay overnight before their procedure, and an IV line will be inserted into your arm, you will receive blood work, chest X-ray and ECG. The instruction for whole body preparation will be given to you.

Consent will be obtained and an antiseptic scrub will be used to prepare the access site.



3 Day of Your Procedure (1-3 hours)

You will be wheeled into the cardiac catheterization laboratory holding area. Here you will wait for evaluation by a nurse and anesthesiologist. Then you will be wheeled to the procedure room.



4 Procedure Room (3-5 hours)

You will be wheeled into the Procedure Room, where you will be attached to monitoring equipment. IV infusion will be given, delivering medication for sedation and anesthesia. You will be asleep when the procedure is performed. The procedure will be performed on conscious sedation or General Anesthesia depending on heart team discussion.

5 Cardiac Intensive Care Unit (24-48 hours)

After your procedure you will be brought to the intensive care unit (ICU). You will be monitored closely and given a thorough physical exam that involves blood tests, a chest x-ray, an ECG, and an ultrasound to be certain that you are recovering properly. You will remain in the ICU until you are stable and then you will be transferred to

a hospital room. Your stay will generally be one to two days. While in the ICU you will have several sensor and lines in place to monitor our heart and internal blood pressure.



6 Monitoring in Hospital Room (2-3 days)

You will be monitored closely in a hospital room until your doctor feels you are ready for discharge.



IV

WHEN YOU ARE DISCHARGED

The average hospital stay after a TAVR procedure is 3-6 days.

Follow-Up

You will be asked to return to Hospital for an evaluation with the TAVR Heart Team roughly 15-30 days post-procedure and receive an echocardiogram. You will be given this follow-up appointment prior to your discharge from the hospital. You will continue to see the TAVR Heart Team on a regular basis depending on clinical status of the patient.

Care for the Procedure Site:

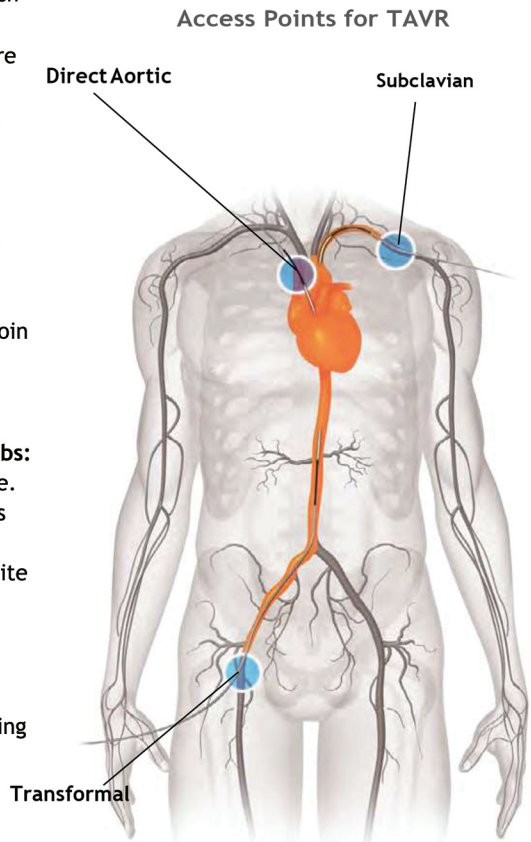
- Carefully inspect the site daily, being sure to first wash your hands.
- Do not leave the bandage dressing on the site for more than 24 hours.
- Once you are discharged, you may take a shower and softly wash the site with plain soap and water
- Keep the site clean and dry. Do not apply lotions, powders, or ointments

If the access site was the groin (transfemoral): There may be some bruising of the access site, which is expected and normal. After surgery, the area will be tender to touch. You may notice a small lump in the groin if the doctors used this site to place the valve. This will dissolve on its own in about 4-6 weeks.

If the access site required an incision in the lower abdomen/ groin under the clavicle or between the ribs: Expect a small amount of firm tissue at the incision site. There may be some bruising of the access site, which is expected and normal. After surgery, the area will be tender to touch. You may have sutures at the incision site and will be instructed when to return to have them removed.

Immediately call your doctor or go to the closest emergency room if you notice:

- Bleeding at the site that does not resolve after applying pressure for five minutes
- Discharge or drainage at the site
- Unusual or excessive swelling, pain, or redness
- A temperature greater than 100 degrees



Activity

Once you are discharged, it is okay to return to your normal daily activities with the following precautions:

- Avoid heavy lifting, excessive bending, stretching, pushing, or pulling for two weeks after your procedure.
- It's okay to climb stairs, but take your time, go slow, and pause to rest if you feel tired.
- If your procedure was done through the groin percutaneously (without making an incision), you may drive after days.
- If your procedure was done through an incision (through the groin, under the clavicle or in the chest), you should not drive until you have your follow-up appointment with your cardiologist and they clear you to drive.
- Avoid sexual activity until your follow-up appointment with your cardiologist.
- Your cardiologist will recommend a time frame for when you can return to work.

Medications

Your doctor may prescribe medications after your TAVR procedure. These will most likely include aspirin and Clopidogrel, and you may also be prescribed a blood thinner (anticoagulant).

General guidelines for taking your medications:

- Never discontinue any medication unless your cardiologist instructs you to do so.
- Stopping some medications, especially aspirin and Clopidogrel or other blood thinners, may result in serious medical problems including stroke, heart attack, and death.
- If you forget a dose, take it as soon as you remember. If it is almost time for your next dose, skip the one you missed and go back to the regular schedule. Do not take a double dose.
- If your medication is in tablet form, do not split, crush, or chew it. Swallow the tablet whole. If it is in capsule form, do not open it and sprinkle the content on food. Swallow the capsule whole.

If you have any questions or concerns, or any medication side effects develop, call your cardiologist.

Complications

Most medical procedures have risks, the TAVR procedure's most serious risks, which occur less than 2 percent (2 out of 100) of the time are:

- Stroke
- Arterial damage
- Bleeding complications
- Need for permanent pacemaker
- Kidney injury
- Heart attack
- Need for additional valve surgery
- Valve infection
- Death



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