

Meril

More to Life



Issued in Public Interest and Education by Meril.

www.treatmentzaroorihai.com

The information contained in this Patient Education Booklet (Booklet) is for general information purpose only. Meril Life Sciences Pvt. Ltd. has obtained consent and statutory permissions for this publication and patients whose testimonials printed in this Booklet. Illustrations are artist's representations only and should not be considered as engineering drawings or photographs and are not drawn to scale. Information contained herein is for practicing and trained healthcare professionals only. Even though utmost possible care has been taken in compiling, checking and developing the content to ensure that it is accurate and complete, Meril Life Sciences Pvt. Ltd. as well as its associates are not responsible or in any way liable for any injury or damage to any persons in view of any reliance placed on or action taken on the basis of details and information given in this Booklet or any errors, omissions or inaccuracies and or incompleteness of such details and information in the Booklet, whether arising from negligence or otherwise. The patient testimonials relate to an individual's response to the treatment. The patient accounts are genuine, typical and documented. However, the individual's response does not provide any indication, guide, warranty or guarantee as to the response other persons may have to the treatment. Information outlined herein should not be construed as a promotion or solicitation for any Product or Service or for use of any Product or Service. The content of this Booklet is not intended to be a substitute for professional medical advice, diagnosis or treatment nor does it provide instructions on the appropriate use of the Products. Only qualified medical experts can give you information regarding your individual treatment.

All content related in this Booklet such as text, graphics, logos, icons, images, the trade names and service marks published in this Booklet are the exclusive property of Meril. This Booklet and / or any information contained herein cannot be modified, transmitted, used, distributed, reproduced or reposted without the express written permission of Meril Life Sciences Pvt. Ltd. All rights reserved.

www.merillife.com

Patient Awareness Program
for TAVI/TAVR

Meril

More to Life

TREATMENT ZAROORI HAI.



Transcatheter Aortic Valve Replacement (TAVR) Patient Education Booklet

Learn more about aortic valve stenosis and how the revolutionary
Transcatheter Aortic Valve Replacement therapy can help you *Celebrate Life*.

Welcome

A hearty welcome to TAVR Therapy Information Guide. The booklet will help you understand more about Aortic valve stenosis and its management. It will guide you through the treatment options available and also explain the relevant medical terms, symptoms and risk factors.

The information in this booklet should not be taken as a preference for a given treatment option over another. The information in this booklet is no substitute for medical advice and only qualified medical experts can review your individual condition to guide you regarding your individual treatment.

We wish you a smooth and speedy recovery to Celebrate Life.

HEART HEALTH ZAROORI HAI.

**TREATMENT
ZAROORI HAI.**

CONSULT YOUR CARDIOLOGIST FOR MORE INFORMATION
www.treatmentzaroorihai.com



Contents

- 01 Amazing Human Heart and Heart Valves
- 02 Common Heart Valve Problems
- 03 What Is Aortic Valve Stenosis and its symptoms?
- 04 Causes of Aortic Valve Stenosis
- 05 How to diagnose Aortic Valve Stenosis?
- 06 Treatment Options for Aortic Valve Stenosis: Making a choice
- 07 Benefits of TAVR
- 08 Who is eligible for TAVR procedure?
- 09 THV System
- 10 Back to Celebrate Life
- 11 Who should not have the TAVR Procedure?
- 12 Frequently Asked Questions



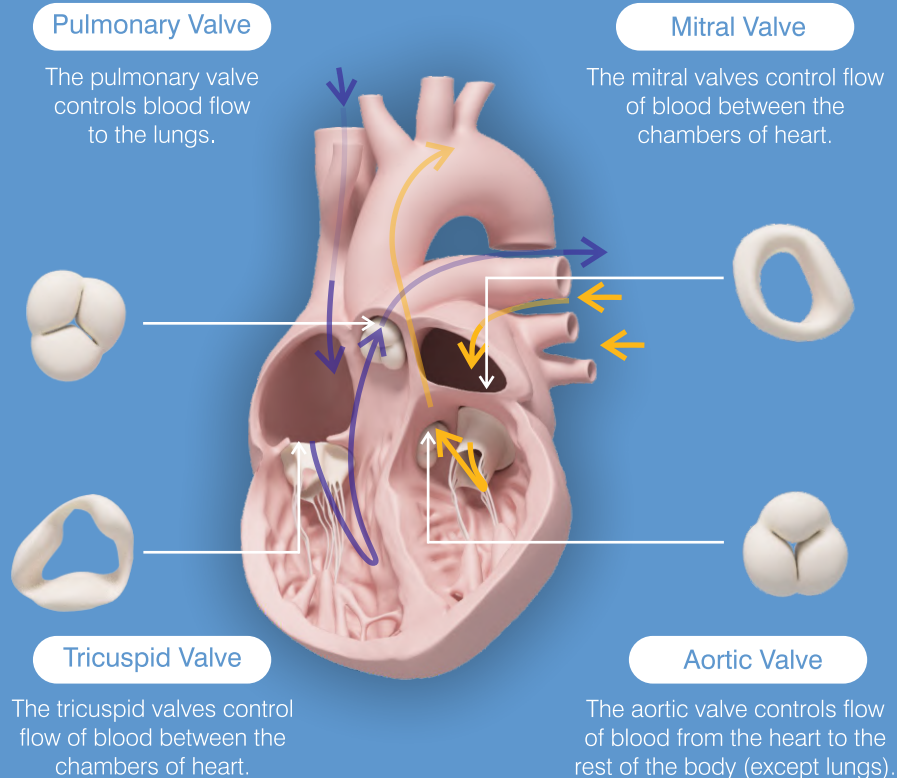
Amazing Human Heart and Heart Valves

Your heart is made of muscles and is about the size of your fist. The primary function of the heart is to provide oxygen-rich blood to the entire body. The heart performs this function by pumping blood through its four chambers along with the corresponding heart valves.

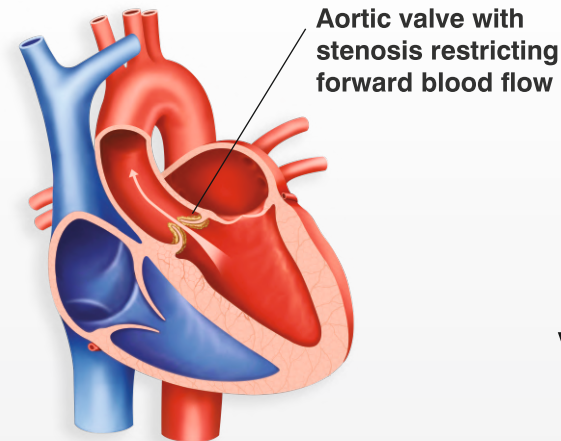
The valves open when the heart pumps to permit blood flow. They quickly close to prevent the blood from flowing backwards. Any problem with the valve will make it difficult for the heart to pump blood in the required direction and in the required quantity.

Common Disorders of the Heart Valves

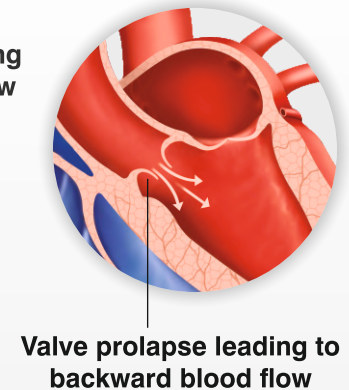
- **Valvular Stenosis:** The valves possess thin tissue leaflets that open and close during heartbeat. Stenosis refers to narrowing of the valve due to thickening, stiffening, or fusion of these leaflets. Hence, the valve isn't able to open completely, which means that not enough blood can flow through the valve. If left untreated, severe stenosis can progress to heart failure or even death.
- **Valvular Regurgitation:** Also known as 'leaky valve', in this condition the valve becomes damaged or worn out and blood begins to leak in the backward direction. This condition makes the heart to work with more effort to maintain normal blood circulation, thus limiting your daily activity.



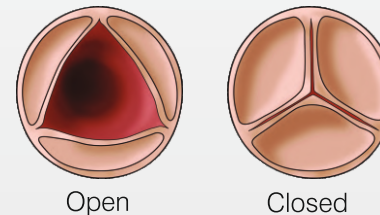
Valvular Stenosis



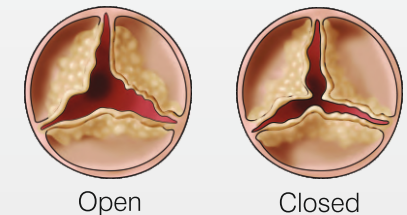
Valvular Regurgitation



Normal Aortic valve



Aortic valve stenosis

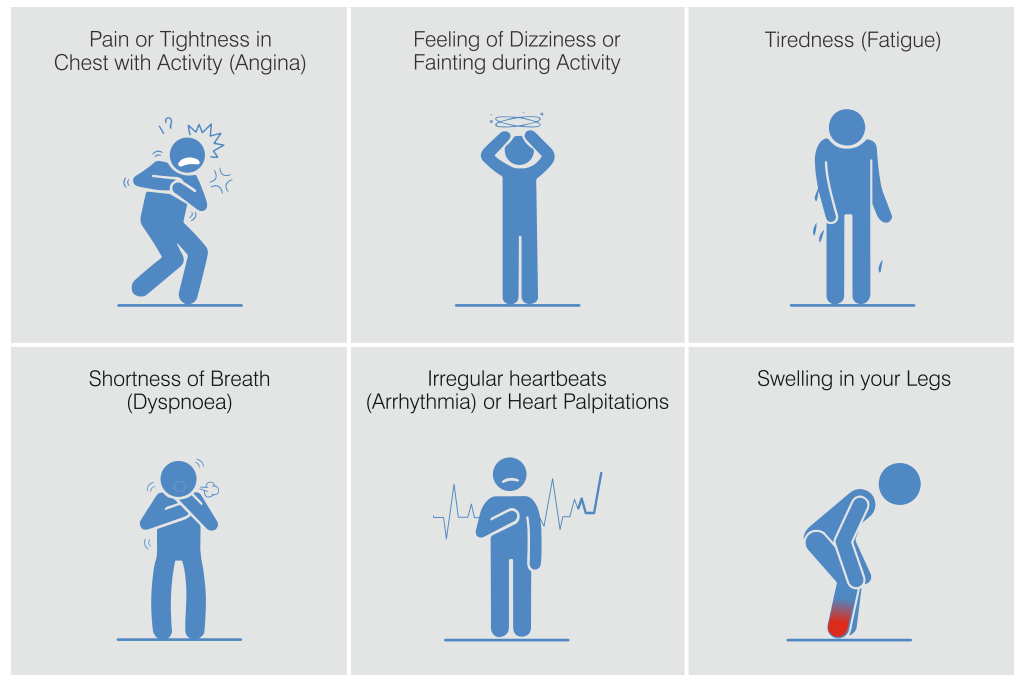


What is Aortic Valve Stenosis and its symptoms?

The aortic valve is located between the left chamber of the heart and the aorta which is a principal artery delivering blood from the heart to the body. Aortic valve stenosis (AS) develops when aortic valve gets narrowed or doesn't open properly. If this occurs, the heart needs to work more against this narrowed valve to pump required quantity of blood into the aorta. This situation can lead to thickening and enlargement of the heart eventually leading to heart failure.

The severity of the Aortic valve stenosis can range from mild to severe. Many patients might not experience any symptoms of Aortic valve stenosis until the disease reaches a high severity.

Patients with severe Aortic valve stenosis may experience the following symptoms:



Causes of Aortic Valve Stenosis

- Advancing Age
- Calcium Build-up
- Genetic Predisposition
- Rheumatic Heart Disease
- Radiation Exposure

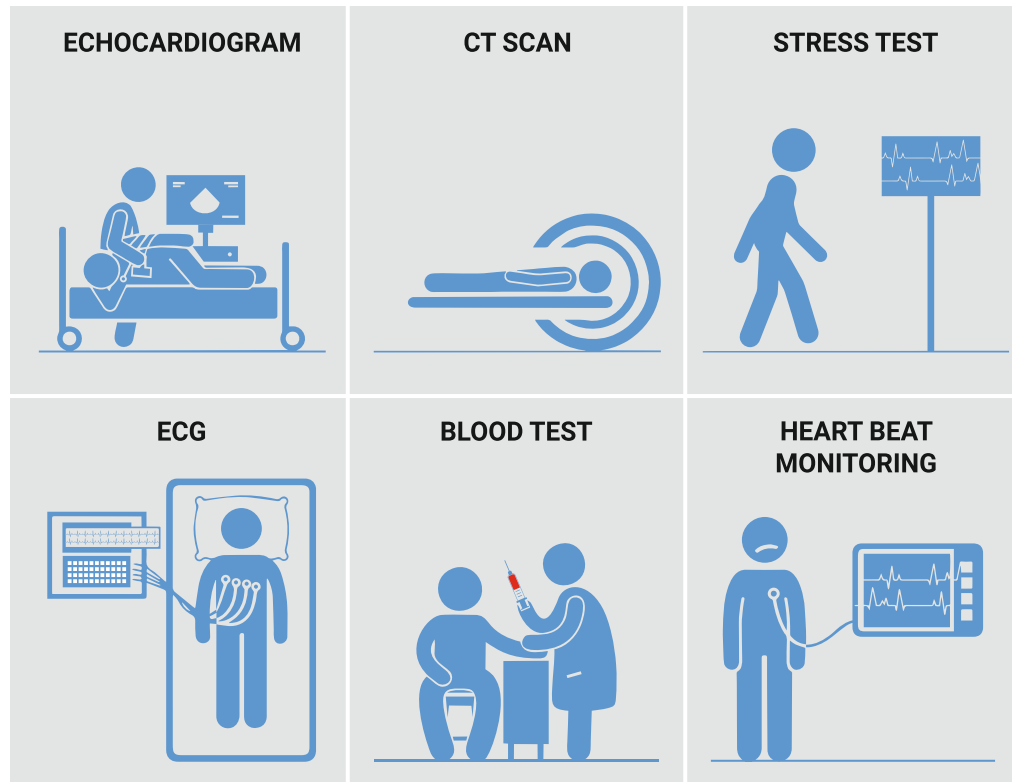
**Degenerative Aortic valve disease affects over 25% of all patients over the age of 65 years.*

*Ref.: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5351823/>

How to Diagnose Aortic Valve Stenosis?

A disorder of the heart valve usually leads to an abnormal heart sound (murmur). In case your doctor hears such a murmur during physical examination, he/she will recommend tests such as ECG, Echocardiography and a six-minute walk test. To confirm further, a CT scan and few other blood tests will be done.

Once confirmed the further management of Aortic valve stenosis will depend on its severity and associated symptoms.



Treatment Options for Aortic Valve Stenosis: Making a Choice

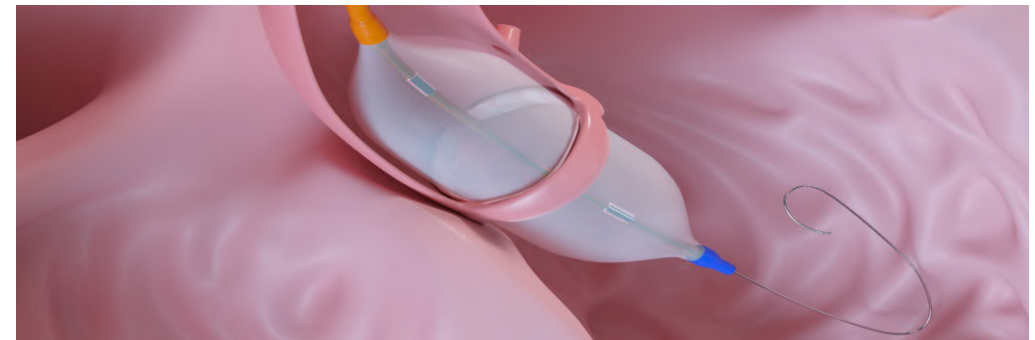
1. Medications

If you are having no or mild symptoms, your doctor may prescribe you medications along with periodic check-up. The medicines will make you feel better in the short term, but ultimately you will require further evaluation and possible intervention.



2. Balloon Valvuloplasty (BAV)

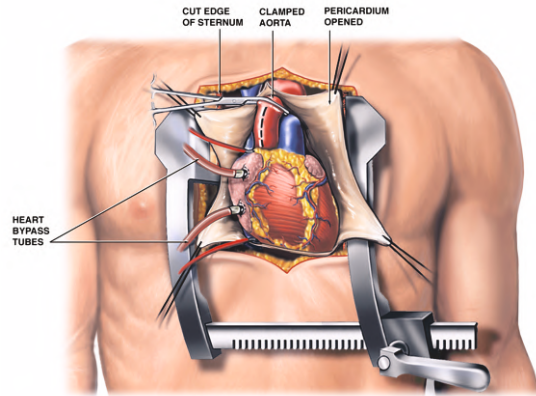
A long, thin tube (catheter) with a little balloon on its tip is inserted by the doctor into an artery. This balloon is guided to the aortic valve and then inflated to expand the valve opening. The balloon is then deflated, and the catheter and balloon are finally removed. However, this approach can only provide temporary relief. Normally, this method is performed in patients who are severely ill for surgery or are awaiting valve replacement.



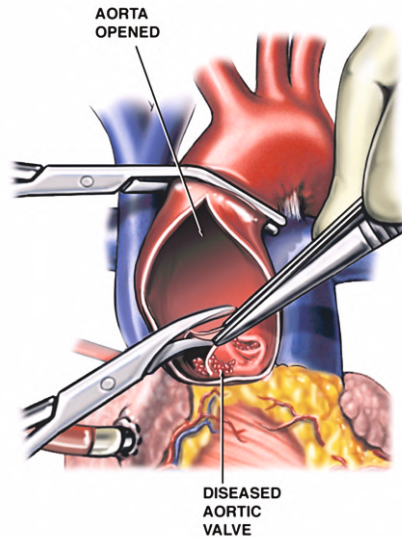
If the Aortic valve stenosis is severe, your doctor may advise either open heart surgery (SAVR) or Transcatheter Aortic Valve Replacement (TAVR).

3. Surgical Aortic Valve Replacement (SAVR)/Open Heart Surgery

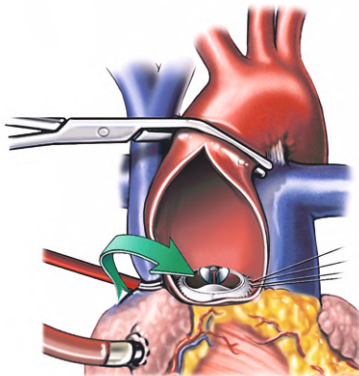
Most open heart surgeries are performed through sternotomy. The patient is placed under general anaesthesia and the breast bone is cut open. The heart is stopped and a heart lung machine takes over the function of the heart temporarily. The surgeon will then completely remove the diseased aortic valve and place a new valve. The heart is then restarted and the chest incision is closed.



A The sternum and pericardial sac are opened exposing the heart.



B The aorta is opened and old diseased valve excised.



C The new prosthetic valve is secured with sutures.

There are two different types of surgical valves:

- Mechanical (man-made material)
- Biological (animal or human tissue)

Biological valves get degraded over time and may require another replacement. On the other hand, mechanical valves will require lifelong blood thinning medicines. Hence, discuss with your doctor to determine which valve may be best suited for you.

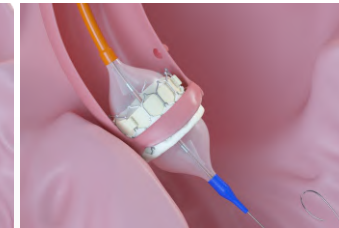
SAVR can also be a challenge in elderly patients with multiple co-morbidities as it may increase the risk of death in such patients.

4. Transcatheter Aortic Valve Replacement (TAVR)

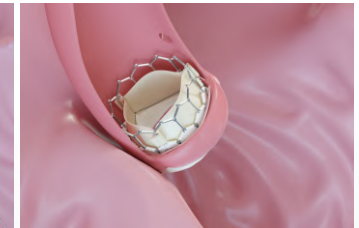
TAVR procedure can be done without general anesthesia and does not require stopping the heart or opening the chest cavity. It is a minimally invasive, catheter based technique during which the doctor replaces the patient's diseased valve with a bioprosthetic valve. Once in place, the valve immediately begins functioning. You will be discharged from the hospital within a few days and will have a much shorter recovery period compared to open heart surgery. This novel, interventional technique is somewhat similar to angioplasty and is done in the Cardiac Catheterization Lab (Cath-lab).



Crimped THV placed across aortic annulus



THV placement and expansion



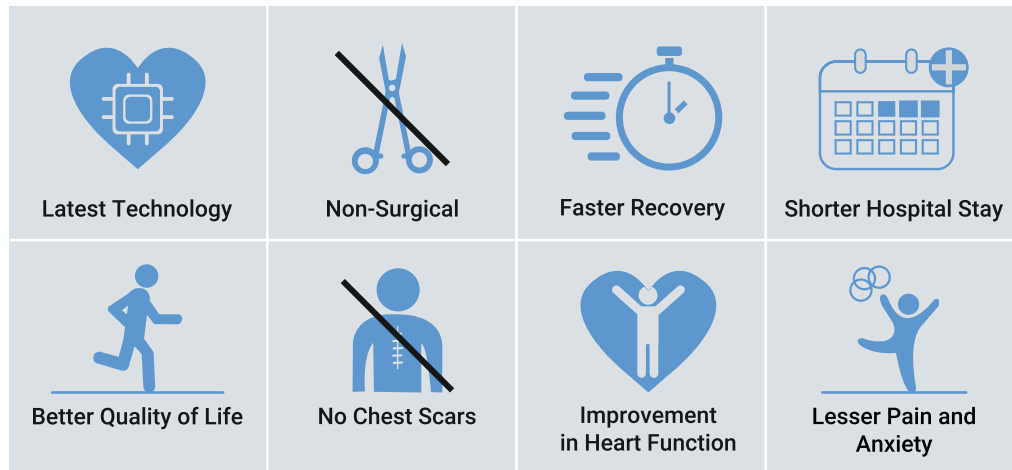
THV after being deployed across aortic annulus

If you have been diagnosed with severe aortic stenosis and your doctor has evaluated you to be at a high risk for surgery, TAVR may be a better alternative for you. However only a specialized Heart Team can determine which treatment option is best for you.

TREAT YOUR HEART WITH LOVE.

TAVR/TAVI has revolutionised the treatment of aortic valve disease. It's a minimally invasive procedure, with shorter recovery time.

Benefits of Transcatheter Aortic Valve replacement



HEART HEALTH ZAROORI HAI.

TREATMENT
ZAROORI HAI.

CONSULT YOUR CARDIOLOGIST FOR MORE INFORMATION

www.treatmentzaroorihai.com

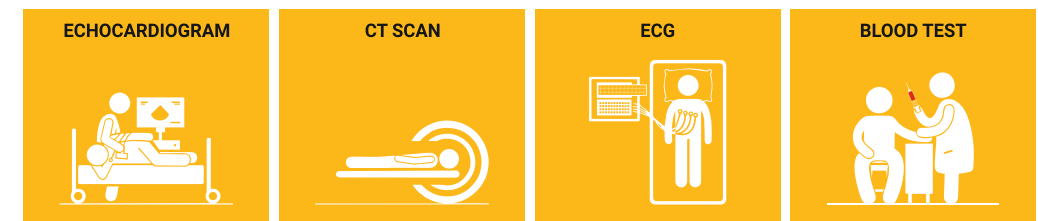


Who is eligible for TAVR procedure?

Your doctor would need to evaluate and plan for your TAVR case by conducting few medical and clinical tests. You could be admitted to a hospital for carrying out these tests or you can get these tests done in day care. If the tests confirm that you can go for TAVR, the doctors will give you a definite time for getting this procedure done at the hospital.

The tests required include:

- Echocardiogram:**
This test uses sound waves to produce visible images of the moving heart. This will help in analyzing the condition of the heart and its valves.
- CT scans of Chest/Abdomen/Pelvis:**
This test helps the doctors to see the size and shape of the blood vessels and the heart.
- Catheterization/Angiogram of the Heart:**
This test is performed to check the flow of blood in the blood vessels around the heart and also to determine the pressures in the heart chambers.
- Pulmonary Function Test:**
To check the functioning of the lungs.
- Doppler Ultrasound of the Carotid Artery:**
A test to check the flow of blood through the carotid arteries in the neck.
- Other Tests might also include some Blood Tests, Aortogram, a detailed Physical Examination and Frailty Testing :**
The results of your tests will be reviewed by a Heart Team to decide if you are suitable for the TAVR procedure.



HEART HEALTH ZAROORI HAI.

TREATMENT
ZAROORI HAI.



THV System

THV (Heart Valve) is a biological tissue valve designed to work like one's own heart valve. It is available in multiple sizes and the specialized Heart Team will determine which size is right for the patient.

Various clinical studies have shown TAVR procedure to have a lower incidence of death and stroke compared to open heart surgery. TAVR may shorten recovery time to allow patients to get back to everyday activities. Patients have reported quality of life improvements within 30 days including the ability to take care of themselves.

Celebrate life

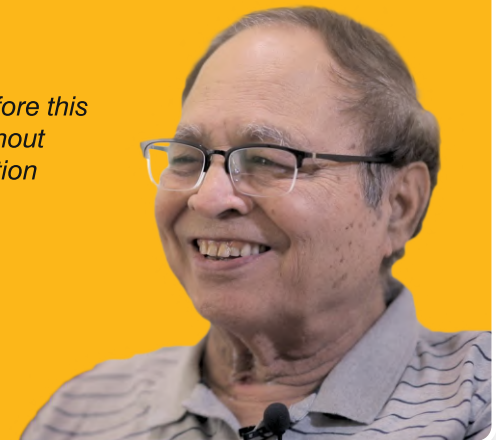
TAVR: Non Surgical Valve Replacement

“

I don't feel tired the way I used to feel before this treatment. I can walk and climb stairs without anyone's support. Now I can plan a vacation with my family.

”

Mr. V. K. Anand
Age - 79



Before TAVR Procedure

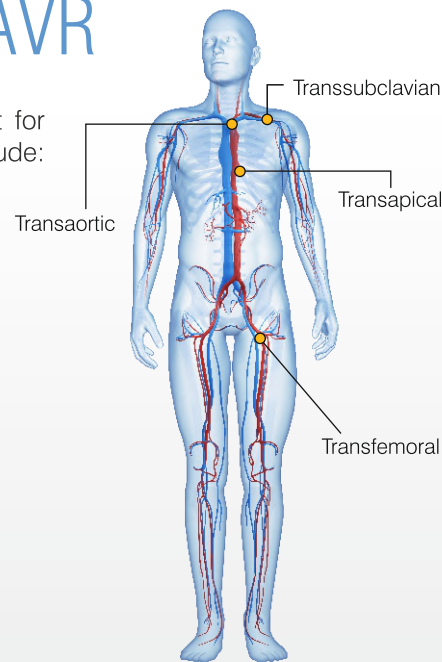
You will be treated by an expert 'Heart team' of specialists which includes an interventional cardiologist, cardiac surgeon, radiologist, anesthesiologist, intensive care expert, nurses and some others.

- **Exercise:** Ask your doctor about the maximum amount of physical activity that you can perform and what activity you should avoid before some days of your TAVR.
- **Medicines:** Your Heart team might advise you to stop taking certain medication up to one week prior to the procedure.
- **Diet:** Consult your doctor about any diet recommendations that you have to follow. Your doctor may tell you not to eat or drink anything after midnight of the day prior to the procedure.
- **Dental Health:** As bacteria in the mouth can cause valve infection, it is important that you visit your dentist before your TAVR to check that you have good dental health.
- **Recovery Plan:** It is important to make prior arrangement on a ride to and from the hospital, and arrange for help at home after the procedure.

Access Points for TAVR

There are a number of ways to enter the heart for placing the artificial valve. The possible ways include:

- A blood vessel (artery) present in your leg (femoral artery) which is the most common route used (Transfemoral route).
- An artery present near your collarbone (Subclavian Artery route)
- A space present between your ribs in your chest (Transapical route)
- Through an incision in the upper chest (Transaortic route)



TAVR

PROCEDURE STEPS

1. **Week before TAVR:** You might receive a call for confirmation of your appointment and provide you brief information on when to reach the hospital. You will be advised about discontinuing or continuing your current medicines and diet restrictions.
2. **Day of TAVR:** You will be admitted to the hospital on the day or the day prior to your procedure.



3. **Pre-procedural Care:** An intravenous instead of IV line will be introduced into your arm. You will go through some blood tests, ECG/EKG, and an X-ray of the chest. Consent will be obtained and an antiseptic scrub will be used to prepare the access site.
4. **Day of Your Procedure:** You will be wheeled into the cardiac catheterization laboratory (Cath Lab) holding area where you will be evaluated by a nurse and anesthesiologist. Then, you will be taken to the procedure room. In procedure room, you will be attached to the monitoring equipment. Permission will be taken and the access site will be shaved and prepared using an antiseptic scrub. You will be given sleep medicines (anesthesia) through the IV line.
5. **TAVR Procedure using a Balloon-Expandable Valve (Transfemoral route):** Imaging techniques will be used to help the doctors during the TAVR procedure. A small incision will be made in your groin where your doctor will insert a short, hollow tube called a sheath. Your new valve will be placed on a Navigator delivery system and compressed on the balloon to make it small enough to fit through the sheath. When the delivery system reaches the diseased valve, balloon will be inflated to open the new valve within the diseased valve. The balloon will then be deflated and removed. Immediately after this, the new valve will start working. The sheath will be removed and the incision in your leg will be closed.

After TAVR Procedure

Intensive Care Unit (ICU) after the Procedure:

You will be shifted to the ICU after your procedure. You will remain here for 24-48 hours or until you become stable. You will be closely monitored here and will undergo a detailed physical examination involving some blood tests, a chest X-ray, an ECG, and an echocardiogram (24 hours after procedure) to ensure that your recovery is proper. Once you are stable, you will be transferred to the patient room where you will be kept for another 1-2 days.



Recovery Period after Discharge

Care for the Procedure Site:

- Carefully inspect the site daily, being sure to first wash your hands.
- Once discharged, you may take a shower and softly wash the site with plain soap and water, but do not take a bath, soak in water, or swim for two weeks after the procedure
- Keep the site clean and dry. Do not apply lotions, powders, or ointments
- Do not leave the bandage dressing for more than a day on the site

If the access site was the groin (transfemoral):

There may be some bruising and tenderness at the access site, which is expected and normal. You may notice a small lump in the groin which will dissolve on its own in about 4-6 weeks.

If the access site required an incision under the clavicle or between the ribs:

Expect a small amount of firm tissue, tenderness, and bruising at the incision site, which is normal. You may have staples 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 or discharge at the site
- Unusual or excessive swelling, pain, or redness
- A temperature greater than 101 degrees

Post Procedure Activity:

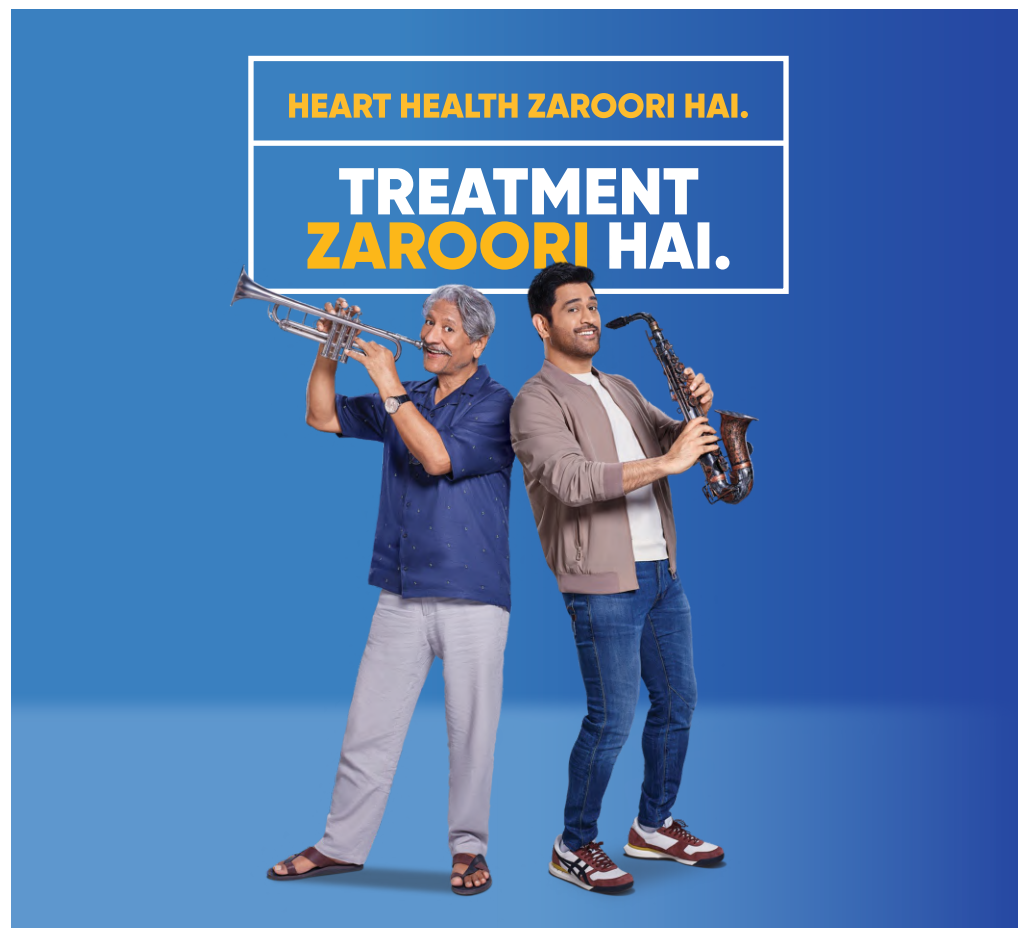
- Avoid lifting heavy objects, excess bending, stretches, push or pull activities for two weeks.
- Walking: Begin by trying to walk for 5 minutes daily after discharge. Then, gradually increase the duration as per your convenience. Ask someone to accompany you during the first few walks.
- Sit-to-stand Exercise: Try performing 10 sit-to-stand repetitions daily without hand assistance. Increase to performing this activity 2-3 times per day.
- It is all-right to slowly climb stairs.
- If your TAVR was performed through the groin without any incision, you can drive after 5 days.
- Avoid sexual activity until a follow up appointment with your cardiologist.
- Your doctor will provide a time frame for when you can return to work.

Medicines:

- Your cardiologist may recommend some blood thinners after your TAVR procedure. These will most likely include aspirin and clopidogrel, and you may also be prescribed a blood thinner (anticoagulant).
- Never stop taking any medicine unless the doctor advises to do so as it may cause serious medical problems.

Follow up visit:

- You may be advised for a follow-up visit to the hospital at 1 month, 3 months, and 1 year after your TAVR procedure. If in between you develop any health concerns, kindly inform your doctor immediately.



Back to *Celebrate Life*

What benefits to expect after TAVR procedure:

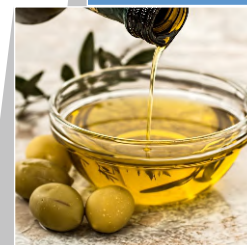
- More energy and active daily routine
- Regaining ability to take care of self
- Normal breathing and reduced anxiety

Dietary adjustments for Healthy Heart:

A diet rich in fresh fruits and vegetables or fish and seafood (for non-vegetarians) are preferred



Use salt (sodium) as little as possible

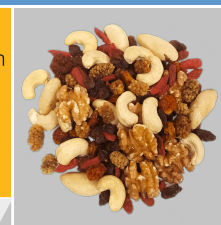


Olive oil is a preferred cooking oil as compared to other oils.



A high-fiber breakfast with fresh fruits, low fat milk, or yoghurt can be a perfect healthy start for a day

Walnuts, cocoa, and berries contain anti-oxidants and are known to promote heart health



- Avoid smoking, alcohol and tobacco consumption in any form

Activity and exercise after complete recovery:

- Begin with regular walking, cycling, or swimming.
- Ideally, 30-minutes of exercise 3-5 times per week is good for heart.
- Overhead Press Exercise and Wood Chop Exercise. The precise technique of the last two exercises can be known through a Gym Trainer or a Physiotherapist.
- Talk to your healthcare provider to know more.

Who should not have the TAVR Procedure?

Patients who:

- Have an active infection
- Cannot take or are allergic to blood thinners
- Are allergic to metals or radio-imaging agents
- Please visit your nearby trained healthcare practitioner for thorough evaluation and further management of Aortic stenosis.



“My kids and their kids keep wanting grandma’s hand made oven fresh cakes. Celebrating life is being able to serve my love with food to all on every occasion.”

HEART HEALTH ZAROORI HAI.

TREATMENT
ZAROORI HAI.

CONSULT YOUR CARDIOLOGIST FOR MORE INFORMATION
www.treatmentzaroorihai.com



FREQUENTLY ASKED QUESTIONS

Q. Will I feel pain during the TAVR operating procedure?

A. You will be given medicines before the procedure due to which you will remain asleep throughout the procedure and ideally won't feel any pain or discomfort. However, you might feel little pain or tenderness at IV line insertion sites. Inform the staff if it bothers you.

Q. How can a TAVR procedure benefit me?

A. As the TAVR procedure is less invasive, you may be able to return to routine activity more quickly than an open heart surgery. Patients who have undergone a TAVR procedure report an improvement in their quality of life soon after. Other advantages of TAVR include shorter stay at hospital, no chest scars, immediate relief of symptoms, improvement of heart function, and decreased pain and anxiety.

Q. How long will my valve last?

- A.** The life of your TAVR valve depends on numerous factors and differs for each person. However, its functioning can be checked from time to time through the regular follow-up with your doctor.

Q. What is a Heart Team?

- A.** A Heart Team is a group of specialists including interventional cardiologists, cardiac surgeons, radiologists, anesthesiologists, and cathlab staff. All these experts will collectively decide if the TAVR procedure is suited for you or not.

Q. What are the specifications for MRI post TAVR procedure?

- A.** The TAVR Valve is MRI Conditional. It can be safely scanned under the following specifications:
- Static magnetic fields of 1.5 and 3 Tesla.
 - 2500 gauss/cm spatial gradient field.
 - Normal operating mode with a maximal whole-body SAR of 2.0 W/Kg for 15 minutes as stated on the equipment monitor.
 - MRI is not recommended in case you have undergone a TAVR inside an old surgically replaced valve.

Q. Are there any risks involved with TAVR procedure?

- A.** As with any other operating procedure, TAVR is also associated with several risks. The most severe risks with the TAVR procedure include:
- Death
 - Major Stroke
 - Major Blood Vessel Complications such as a large clot formation under the skin
 - Major bleeding events that may prove dangerous to life and need a blood transfusion
- Other risks include (but not limited to):
- Heart Attack
 - Heart Failure
 - Disturbances in your heart's electrical activity, requiring a pacemaker implantation
 - Edema formation
 - Infection
 - Injury to the blood vessel

- Inability or difficulty in Breathing
- Anemia
- Abnormal BP
- Problems at the incision site such as pain or change in skin colour
- Valve dysfunctioning
- Blood leak around the valve
- Additional heart or blood vessel surgery requirement

Q. Can the valves get rust?

- A.** No. the metallic portions of the valve are made from corrosion-resistant metals such as cobalt-nickel alloy which do not react with the body or rust over time.

Q. Will I feel the valve after the procedure?

- A.** No, the valve will not be felt after placement.

Q. Can I have an X-Ray after the TAVR is in place?

- A.** Yes. It is safe to have X-Ray tests done after the TAVR device is in place.

Q. What are the warnings for a TAVR procedure?

- A.**
- The implanted valve may not last long in patients who have problems with calcium metabolism in their body.
 - Talk to your doctor if you have allergies of any of the components involved with the TAVR device or procedure.
 - X-ray exposure may lead to radiation injury on the skin.
 - Confirm with your doctor in advance whether the device is suitable for your condition.

Q. What precautions must be taken once a TAVR heart valve is implanted?

- A.**
- Patients should stay on blood-thinning and other medications after the procedure as instructed. Patients who do not follow this are more likely to get a stroke.
 - TAVR patients who are going for a dental procedure should take antibiotics to decrease the chance of getting an infection.

Q. How do I take care of my valve?

- A.** Be sure your dentist and doctors know that you have had heart valve replacement. Ask your dentist and doctor about taking antibiotics before dental or surgical procedures or endoscopy to help prevent valve infection. Always follow your doctor's instructions carefully.

More to Life

TREATMENT ZAROORI HAI.



#TreatmentZarooriHai

www.treatmentzaroorihai.com

**FOR MORE INFORMATION
ABOUT THERAPY SCAN**



Note: