

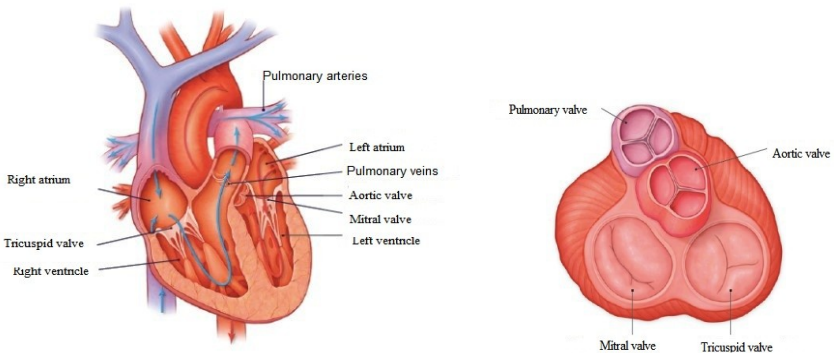


AORTIC STENOSIS AND ITS TREATMENT

INFORMATION FOR PATIENTS

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The heart is a muscle that has the function of pumping blood within the circulatory system. It is divided into four cavities: two atria which receive blood from the main veins, and two ventricles which pump it into the arteries. The right side of the heart is made up of an atrium and a ventricle and pumps blood into the pulmonary circulatory system; the left side is also formed by an atrium and a ventricle and pumps the blood into the circulatory system which oxygenates all the other organs (brain, heart, intestine, muscles, etc.). There are four heart valves (aortic and mitral in the left heart, tricuspid and pulmonary in the right heart) and they have the function of regulating the flow of blood inside the heart. They are often subject to pathologies that can reduce their efficiency. Any valve problem prevents the heart from pumping blood properly.

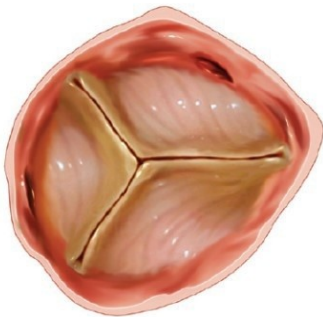


The aortic valve regulates blood flow from the heart to the general circulatory system. Stenosis (narrowing) of the aortic valve occurs when it does not open as it should, straining the heart and preventing it from pumping blood around the body. It is a disease that appears on

average after the age of 65 and is normally related to the body's aging process.

Stenosis is due to various causes: in most cases the accumulation of calcium on the flaps prevents them from moving correctly and narrows the aortic valve when it opens.

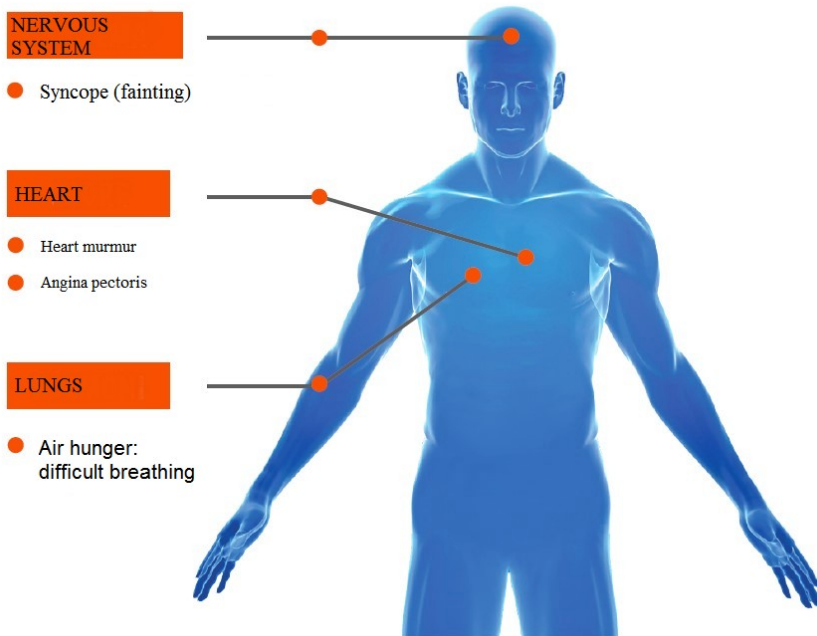
Healthy aortic valve



Stenotic aortic valve



In most cases, aortic stenosis is asymptomatic; when patients complain, the situation is already at a relevant level of severity and it may be necessary to replace the valve or treat it with one of the different approaches available. A first sign is the presence of a characteristic cardiac auscultatory murmur on examination with the stethoscope. Echocardiography is the test that accurately determines the severity of the disease. When the narrowing is severe, three specific symptoms appear: exertional dyspnea (shortness of breath), angina pectoris (chest pain, usually related to effort) and syncope (fainting, most frequently related to physical effort).



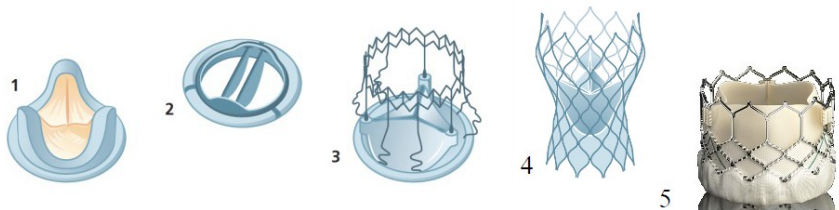
Aortic stenosis is one of the most common diseases among those of the heart valves which in Italy as a whole affect over 1 million people and 10% of the population over 65 years of age, the most affected group. In our country, the percentage of the over-65-year-old population with aortic stenosis is estimated at 3.8%, while that with severe and symptomatic aortic stenosis is around 2% with an indication for valve replacement surgery.

With careful medical care, many patients with heart valve disease have an almost normal life. When symptoms begin to appear, it is time to consider aortic valve surgery, consisting of replacing it with a prosthetic valve.

Different types of valve prostheses are currently available, which can be

divided into two main groups: mechanical and biological ones. Mechanical valve prostheses are usually made of an extremely strong carbon-based metal alloy, which ensures a long service life. These valves can only be applied with a traditional type of surgery and require lifelong oral anticoagulant therapy.

Biological valve prostheses are manufactured from animal tissue (generally from pigs or cattle). To avoid rejection and calcification they are subject to a special chemical process. The animal tissue is mounted on a supporting structure ("stent") which facilitates the implantation. These valves can be implanted either by a catheter, with a minimally invasive intervention, or with an operation. They do not have the same duration as mechanical prostheses, but on the other hand they do not require the intake of anticoagulant medicines.



Different types of valve prostheses: biological heart valve (1), mechanical heart valve (2), «sutureless» heart valve (seamless, 3), biological heart prosthesis for implantation with self-expandable catheter (4) or balloon-expandable (5)

Surgical valve replacement

For more than 50 years, heart valves have been replaced and repaired with conventional surgery. The operation is performed by opening the

sternum ("sternotomy") or in a less invasive way with smaller accesses between the ribs ("thoracotomy"). The defective heart valve is removed and replaced with a biological or mechanical prosthesis, which is fixed to the tissues with surgical stitches. In order to shorten the duration of the operation, it is possible to use so-called «sutureless» valves (i.e. without sutures).

The replacement takes place with a stopped heart, while the function of heart and lungs is performed by a device (extracorporeal circulation pump) which pumps and oxygenates the blood, withdrawing it and subsequently introducing it into the circulatory system. This type of surgery requires general anesthesia with orotracheal intubation.

Minimally invasive transcatheter valve replacement

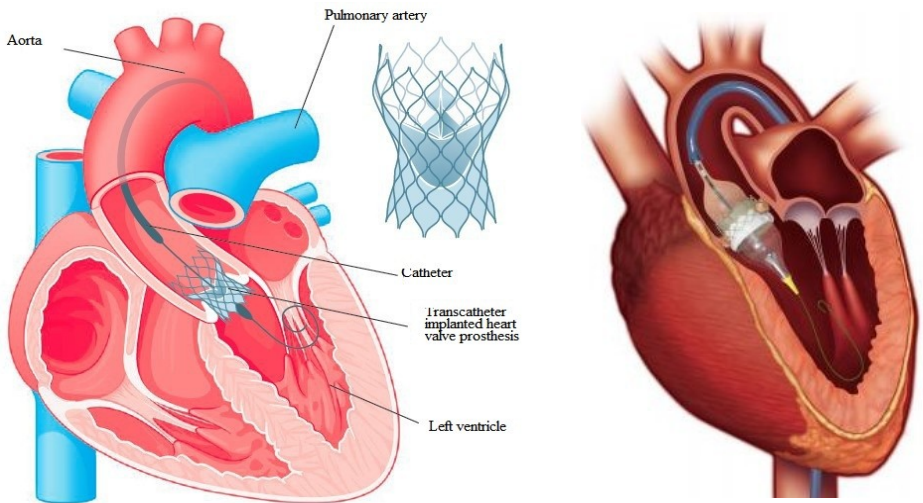
Any intervention on heart valves carried out without open heart surgery (opening of the rib cage) is called "transcatheter". These operations are performed using a probe called a catheter, generally introduced through an access in the area of the inguinal blood vessels (femoral arteries) or, more rarely, also through the tip of the heart – «transapical access» – or by other access routes.

These new transcatheter methods are often used in patients with an increased operative risk, usually over 75 years of age.

With this operation it is not necessary to open the chest, since the valve prosthesis is brought into the correct position by means of the catheter; therefore general anesthesia is not necessary, but only local anesthesia at the insertion site. Furthermore, the use of an extracorporeal circulation pump is not necessary since the procedure takes place with a beating heart.

There are currently two types of transcatheter implantable prostheses:

self-expandable ones, which once correctly positioned resume their original shape, and balloon-expandable ones. The selection of the most suitable bioprosthesis for the case is made on the basis of the clinical, anatomical and technical characteristics.



Which method?

Each method has advantages and disadvantages, especially as regards the duration, the operative procedure and the possible complications. Before each operation, a series of tests are carried out to confirm the need to intervene and establish the best choice for the patient. Usually these are coronary angiography (examination by heart catheterization), echocardiography (examination with ultrasound), and computed tomography (CT) scan of the heart and blood vessels. Depending on the type of intervention planned, further tests may also be necessary, for example a dental check-up to rule out infections in the mouth. The

results of the tests are then discussed in the so-called "Heart Team" (made up of various specialists, including cardiologists and heart surgeons), together establishing the best therapy for the patient, taking into account factors such as age, the type of defect to be corrected, the size of the heart, its willingness to regularly take certain medicines and of course its personal wishes.

Transcatheter implantation surgery is increasingly the most appropriate therapy for aortic valve replacement.

Transcatheter implantation (TAVI)

The patient and his/her family have the right to be extensively informed about the need for the intervention and its procedures in order to promote tranquility and awareness of the most appropriate choice. It is therefore advisable to ask all the necessary questions, for example whether the operation will extend your life expectancy, whether blood transfusions will be necessary, whether the operation will be painful, what the possible complications are, how long the hospital stay will last after the operation, whether you will have to take medication for life and when it will be possible to resume normal activities. Transcatheter procedure is usually less demanding on the body and recovery is faster than surgery.

Hospitalization usually takes place one or two days before the operation, in order to perform the last preliminary tests and the anesthesiological visit.

The intervention is carried out in the Cardiology operating rooms, because high definition radiological equipment is required for the transcatheter procedure. A cardioanesthetist and a dedicated nurse will

be next to the patient during the operation, in order to reduce stress and pain.

After the surgery, the patient will be transported to the Intensive Care Unit of the Cardiology Department, where s/he will generally remain hospitalized for approximately 24 hours in order to check the heart rhythm, the state of the groin wounds and the neurological state. In fact, during this phase the possible appearance of complications related to the TAVI intervention is controlled. The main complications are as follows:

- Cardiac arrhythmias which may require electrical cardioversion or require permanent pacemaker implantation (approximately 20% of cases).
- Vascular complications at the level of the femoral arterial access (approximately 10% of cases) which may require local vascular surgery
- Bleeding requiring blood transfusions
- Alterations of the neurological state correlated to a stroke (about 3% of cases), linked to the migration of thromboembolisms
- Allergic reactions to contrast agents or medicines

Other serious complications, such as perforation of the heart chambers, serious damage to the vascular structures, intraoperative death of the patient, are very rare (less than 1% of cases).

If the course has no complications, the following day the patient can be transferred to the ordinary hospitalization ward, where s/he was initially hospitalized. Also in this phase of hospitalization the activity of the heart will be continuously monitored by means of electrocardiographic telemetry mainly in order to evaluate the cardiac rhythm and the

possible appearance of arrhythmias.

After transcatheter surgery, the further course generally does not create problems. While the first day the patient will already be able to eat normally, the following day s/he will be able to wash himself/herself and move freely. Usually s/he can be discharged from hospital after about 4-5 days.

Discharge from hospital

From the ordinary Cardiology hospitalization, the patient can be discharged directly from hospital to home or to an inpatient rehabilitation facility, based on the level of autonomy achieved by the patient after the operation and on logistical and practical aspects (possibility of family assistance at home, etc.).

After discharge from hospital, a check-up visit with echocardiography is scheduled approximately 30 days after surgery, aimed at verifying the patient's clinical status and the normal functionality of the newly implanted prosthesis. The checkup is scheduled by the doctors who operated on the patient and who followed the patient until discharge from hospital.

Subsequently, the patient can be followed up with annual outpatient check-ups, carried out at the outpatient cardiological facility that have followed the patient previously.

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