

Cardiology

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Information and patient consent form

Interventional aortic valve replacement (TAVI) with severe symptomatic aortic stenosis

The doctor diagnosed me with a severe narrowing of a heart valve (aortic stenosis).

The aortic heart valve is one of the four heart valves that control blood flow to the heart and from the heart. Oxygenated blood from the left ventricle is pumped into the aorta through the aortic valve. In case a narrowing of a valve (aortic stenosis), the heart muscle is overstrained, since now it has to pump the same amount of blood through a narrowed valve. When the heart valve does not close tightly (aortic insufficiency), then a portion of the pumped blood flows back into the left ventricle. In both cases, the load exerted on the ventricle increases. As a result, the heart muscle becomes thicker (hypertrophy) and the ventricle increases in size abnormally.

Besides a markedly reduced efficiency, common symptoms of aortic stenosis include: breathlessness or chest pain because the body and the heart muscle can no longer be supplied with sufficient blood due to the narrowed valve. The reduced supply of the brain with oxygen can also lead to dizziness or fainting spells.

The only long-term effective treatment for aortic stenosis and aortic insufficiency is to replace the stenotic heart valve. If not treated, there is a risk of a rapid development of severe impaired function of the heart (heart failure), and thus a lower life expectancy.

Surgical heart valve replacement is an open-heart surgery, which is connected with a long recovery period. On average, after a cardiac valve surgery, patients need 3 to 6 weeks to recover. In some cases, it may take several months.

Taking into account your health condition, the treating cardiac surgeons do not consider the surgical replacement of the aortic valve to be useful because this intervention presents high risk.

As an alternative to surgery (open heart), a technique has been developed which enables percutaneous implantation of your heart valve. Percutaneous means that the blood vessel is accessed through the skin. After puncturing the blood vessel in the groin, the heart valve, which is mounted on a catheter, advances to the heart and is placed there, just like in angiography.

An interventional aortic valve prosthesis is designed to replace a diseased aortic valve without having to perform an open-heart surgery. The valve portions of the prosthesis are made from animal pericardial tissue (pericardium), which is applied to a metal support (tubes). The prosthesis is advanced through the artery to the area of the diseased heart valve, and is then unfolded or dilated, the original valve is pressed by the metal grill into the wall of the aorta. Once placed, the prosthesis immediately takes over the function of the original aortic valve.

Worldwide tens of thousands of patients have already been treated with this method and the safety of the method is documented. For this reason, the prostheses were certified in Europe and the USA and may be used for the treatment of aortic stenosis now.

Advantages

The advantages are evident from the fact that no open heart surgery needs to be performed, thus eliminating the risks involved (usually a short-term deterioration of cardiac function, infections, lung, kidney or liver problems) and the symptoms. Furthermore, a shorter recovery time and an improvement in your symptoms and your overall condition are expected.

Potential risks

Potential risks and symptoms are similar to those that may occur as a result of percutaneous implantation and heart valve surgery:

- Bleeding
- Hematoma (bruising)
- Heart Attack
- Pain and / or infection in the surgical area
- Cardiac arrhythmias with possible need for implantation of a cardiac pacemaker.
- Abnormal blood coagulation that can lead to the release of blood clots into the bloodstream and cause clogging, which in turn can lead to heart attack and stroke
- Blood vessel breaks
- improper positioning of the aortic valve prosthesis
- Malfunction of the aortic valve prosthesis
- Need for a repeat surgery
- Allergy against anesthetics or drugs
- Apoplexy
- Death

In very rare cases, serious complications such as tearing of the heart muscle or the aorta may be caused, which cannot be brought under control by an emergency operation, and can thus lead to death. In this case, a surgical treatment is deliberately avoided. For other complications with good prospects of improvement and preservation of quality of life after surgery, surgical intervention may be performed at any time.

Alternative methods of treatment

I am aware that an open heart surgery with aortic valve replacement for the treatment of aortic stenosis would be possible as an alternative method of treatment at the expense of an increased operational risk.

Space for a sketch / personal notes:

Please contact us,

if you do not understand something or if something seems to be important that was not mentioned in this document or in the personal consultation with your doctor.

Declaration of consent

Dr. med.

held an informed consent discussion with me. I have understood the information provided to me and could make all the pertinent questions. After sufficient time to think and answering of all my questions I hereby declare myself ready for the proposed therapy. I express my consent for any follow-up procedures that may become necessary.

Signature of patient: _____

Signature of doctor: _____

Place and date: _____

Consent to data collection and evaluation

I agree with the collection and analysis of scientific data of my treatment in an encrypted, electronic form. If necessary, the traceability of data for quality assurance is ensured. We assure you with an unrestricted right of access to inspect the data archived about you.

Signature of patient:

Place and date: