Universitätsspital Basel

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 left 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.

As an alternative to surgery (open heart), a technique has been developed which enables percutaneous implantation of your heart valve (TAVI). 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 (frame). 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.

Due to the risk profile the heart team has now decided to perform an interventional aortic valve replacement (TAVI).

If, following the aortic valve replacement performed via catheterisation, your attending physician would determine that there is a restriction of electrical conduction in the heart, whereby the so-called left bundle branch is blocked, i.e. the electrical conduction in the heart only takes place via the right bundle branch, a brief electrophysiologic cardiac catheterisation would become necessary.

After a local anesthetic is applied in the groin, a cardiac catheter is advanced under X-ray control into the heart. The electrical activity of the heart is measured. These measurements are made via the computer and are not associated with stress or pain for you. Immediately after that we can inform you of the examination findings. The examination will take 15 - 20 mins.

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 at the injection site
- 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
- Vascular damage
- 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

The procedure or examination is performed under X-ray radiation. Consequently there is a certain radiation exposure, that however is kept as low as possible. Based on general considerations, in case of pregnancy this kind of examination should only be performed in emergency cases.

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.

Consent to data collection and transfer to the SwissCaRe National Quality Register

I agree that personal data relating to my procedure and my medical history, including my surname, first name, gender and date of birth, may be collected for quality assurance and transmitted to the SwissCaRe National Quality Register. I have been informed of the scope and purpose of the data transmission by means of the patient information document on the SwissCaRe quality register, version 1/2022. Any questions were answered. I was explained that my decision whether or not to consent to the data transfer to the registry has no influence on my treatment. I know that I can revoke this consent at any time, without giving reasons.

☐ YES, I agree that my personal data will be transmitted to SwissCaRe

☐ NO, I do not want my personal data to be transmitted

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: _____