

Cardiology

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Information and patient consent form

Interventional mitral valve reconstruction with MitraClip® in case of severe mitral insufficiency

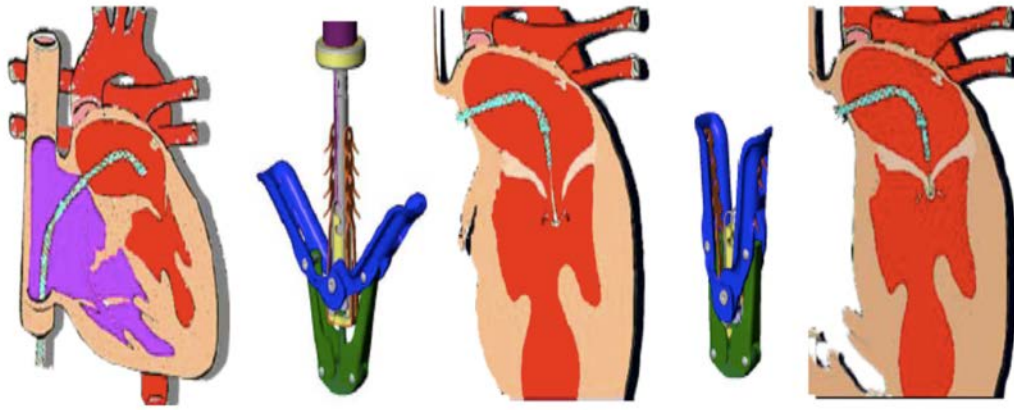
Dear patient,

Explanation of the heart defect and the standard therapy

You were diagnosed with an inability of the valve between the left atrium and left ventricle - the so-called mitral valve - to close. This leads to the accumulation of blood in the lungs. Typical symptoms include shortness of breath and inefficiency. Valvular defect of a high degree may lead to a cardiac insufficiency or an existing cardiac insufficiency may deteriorate as a result. The standard treatment of this valvular defect is the surgical reconstruction or replacement of the mitral valve. This surgical procedure has good results. However, it is always involved with the opening of the chest cavity and connection to the heart-lung-machine-. In your case, the risk of this type of heart surgery was considered to be too high. Reasons for this are follows:

Explanation of the alternative method proposed for you

As an alternative procedure to cardiac surgery, a method was proposed for you, which is based on catheter technique and does not require the opening of the chest cavity and the connection to the heart-lung-machine-. The procedure is performed under general anesthesia due to the need for a prolonged swallowing ultrasound examination (transoesophageal echocardiography, echo through the oesophagus). A catheter (stable hollow plastic tube) is placed over the groin by puncturing the atrial septum into the left atrium. Between the two left heart chambers, the mitral valve is present, which is to be treated. About the catheter, a kind of clip - the MitraClip (s drawing.) is guided towards the mitral valve directly above the site of the leak.



After accurately positioning the clip, it is attached to both leaflets of the mitral valve at the exact spot of dehiscence. This two leaflets are firmly connected at this point and the closing ability of the valve is improved. If the result is not satisfactory, the clip can be opened again and the leaflets may be connected at another point, or a second clip can be implanted. If the result is good, i.e. a sufficient improvement in valve function is achieved; the clip is released from the catheter. The clip then remains fixed to the valve. The catheter is then removed. If no satisfactory result can be achieved, the clip can be removed as long as it is connected to the catheter. To perform the procedure, X-ray fluoroscopy and transoesophageal echocardiography are required (ultrasound through the oesophagus). To check the results of the procedure, an injecting catheter may be introduced into the lungs (right heart catheterisation). These tests may have been performed for you already. To the extent known, the intervention described above can be carried out very gently. The system has already been used in more than ten thousand patients worldwide. However, long-term results are not available yet.

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.

Possible complications of the intervention

Bleeding: A vascular injury may lead to bleeding. This bleeding could make it necessary to perform an emergency operation. The administration of allogeneic blood transfusions may be necessary. Bleeding may also result also from gastric ulcers or other existing sources of bleeding because certain blood thinners may be required after the intervention to prevent clot deposits at the valve. An additional source of bleeding may be the insertion of the ultrasonic probe into the oesophagus for too long.

Pericardial effusion/tamponade: Through the necessary puncture of the atrial septum, an injury to the heart walls may occur. Bleeding into the pericardium may occur. This pericardial effusion would have to be drained or released by surgery (possible on an acute basis). As with any bleeding, the administration of foreign blood with the associated risks (e.g. allergic reaction, acquiring an infectious disease) may become necessary.

Clip separation and migration: Despite a close examination of clip position in the ultrasound, it is not possible to completely rule out the possibility that the clip might get partially or completely detached from the valve acutely or later. The migrated clip could occlude arteries and thus cause a stroke. The removal of the clip by catheter or surgery

would be necessary in such a case. In case of continuing deterioration of dehiscence, a cardiac surgery may have to be performed.

Infection: Through the bacteria present in the blood, infection in the area of the clip may occur. Therefore, a heart disease record card is handed over to you. In situations where bacteria can enter the bloodstream in significant numbers, antibiotics should be given on a short-term basis at least. An infection of the clip could possibly make the surgical removal and a valve replacement necessary.

Air embolism: The insertion of the catheter could cause the carryover of air, leading to the blockage of the vessels and thus a stroke, a heart attack or a shock for example.

Cardiac arrhythmias: Through the insertion of catheters into the cavities of the heart, arrhythmias can be triggered, which could make drug or electrical therapy necessary.

Defect of the atrial septum: After the puncture of the atrial septum, a small defect may remain in the septum, which generally does not require treatment. One could however consider the closure of the defect by means of cardiac catheterisation or cardiac surgery.

Other possible complications include injury to the cutaneous nerves, an allergic reaction or deterioration of cardiac insufficiency. In extreme cases, these complications could lead to death.

Other significant complications (to be completed by the physician):

The following questions will help us to reduce the risk of the intervention even further:

- Do you take anticoagulants (e.g. aspirin, marcoumar etc.)?

- Is a malfunctioning of the kidneys or thyroid gland known to you?

- Do you have allergies?

- Do you take tablets for diabetes?

- Have you ever had a thrombosis or embolisation?

- Do you have a disease of the stomach or oesophagus?

- Do you have an X-ray log?

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: