

Cardiology

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Information and patient consent form **Catheter ablation of atrial fibrillation**

Dear patient,

You suffer from atrial fibrillation that is difficult to treat and can be treated with catheter ablation. Since this process involves certain risks, we want to present this method in more detail. This document supplements your personal consultation with your doctor.

Preliminary examinations

Typically, your doctor will perform transoesophageal echocardiography (ultrasound through oesophagus) before the catheter ablation. For this, a probe is inserted into the oesophagus to ensure that there is no blood clot in the left atrium. Sometimes, an additional imaging procedure, such as a magnetic resonance scan or a CT scan may be necessary.

Examination and treatment method

The treatment is performed on fasting patients. After applying local anesthesia to the groin, various catheters are advanced through the veins into the heart under x-ray control. To reach the left atrium, the septum must be pierced with a thin needle (transseptal puncture). The structures responsible for the tachycardia are "sclerotized" with radiofrequency energy (a high frequency alternating current) through local tissue heating. The energy is delivered (ablation) through a catheter with a small metal cap. The electrophysiological examination with simultaneous ablation takes several hours. To ensure that the intervention is not too unpleasant, sleeping aids and sedatives are administered. During surgery, the blood must be extensively diluted. If you suffer from an increased risk of bleeding or thrombosis, please inform your doctor before the procedure is started. If you have respiratory problems, inform your doctor about them.

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.

Potential complications:

Although these treatments can usually be performed without a problem, complications may occur in a few cases. "Rare" complications are those, which are expected to occur in approximately one of a hundred interventions and "very rare" are those which occur approximately once per thousand interventions. Serious complications are described in a total of about 6 % of these interventions. "Serious" complications are those, which lead to a prolongation of

hospital stay or additional treatment. However, this category also includes the rare complications that can lead to some permanent damage or very rarely even to death.

Risks specifically associated with this therapeutic procedure include:

- A bleeding in the pericardium ("cardiac tamponade") is rare. If this results in an impairment of the heart function, the blood has to be removed. An emergency surgery is very rarely required for this.
- The influx of a blood clot or air into the circulatory system rarely occurs. If blood vessel in the brain becomes occluded, temporary or permanent damage to the brain may result, a condition also referred to as transient ischemic attack or a stroke (cerebrovascular accident).
- As in all procedures, in which a blood vessel has to be punctured, complications such as bruises, vascular lesions, clogged blood vessels (thromboses), mobilization of blood clots (embolism) or very rarely infections may occur in the puncture sites.
- The procedure rarely leads to the constriction of the pulmonary veins and very rarely a follow-up intervention is required.
- Through the release of energy, the oesophagus could get injured resulting in a fistula connecting with the atrium. This dangerous complication is very rare. Other rare complications are injuries to the left or right phrenic nerve, catching a catheter in a heart valve, or the injury of a coronary artery.
- Administration of strong pain relieving and sleeping drugs may rarely lead to inadequate breathing. Allergies or hypersensitivity against medications may rarely occur.
- The examination may involve a high exposure to radiation. Therefore, it should not be performed in pregnant women. Long-term damage cannot be excluded, but are usually very rare.

In your situation, the benefits of this intervention outweigh the risks by far.

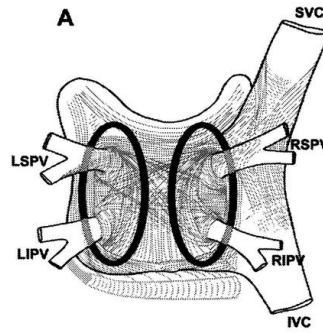
After treatment

After the treatment, you must stay in bed to rest according to the doctor's orders. The legs must be kept straight, and the pressure bandage on the groin may not be removed. If swelling occurs on the puncture site, please contact us immediately, especially if this occurs after you are discharged from the hospital.

After ablation, it is necessary for you to take blood thinners (marcoumar or Sintrom) for least two months to prevent the formation of a blood clot. Whether you will need the long-term use of blood thinners depends on your individual risk of stroke.

Whether the treatment was successful can be evaluated at the earliest after three months since arrhythmias can initially occur as a result of sclerosis as well. A second ablation, which is often necessary for overall therapeutic success, is therefore usually carried out three months after the first intervention.

Diagram of the left atrium



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: