Universitätsspital Basel

Cardiology

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Information and patient consent form
Removal of transvenous probes of pacemakers or implantable defibrillators (ICD)

Dear patient,

Preliminary examinations have shown that one or more probes of your pacemaker or implantable defibrillator (ICD) must be removed. This must be done due to an infection or a malfunction of the probe. Since this process involves certain risks, we want to present this method below in more detail. This document supplements your personal consultation with your doctor.

Examination and treatment method

After opening the pacemaker or the ICD, we will dissect the pacemaker or the ICD and the probes. The probes are removed from the pacemaker/ICD as well as the chest muscles. In case of active fixation probes, the fixation at the tip of the probe is detached. Subsequently, a special wire with barbs (a so-called "locking stylet") is introduced into the probes up to their tip to exert a pull over the entire course of the probe. Depending on the age and degree of coalescence of the probes within the vessels and the heart, a special laser sheath may be necessary to remove the probes. This is threaded through the probes and can dissolve adhesions from the pacemaker box down to the apex so that the probes can then be removed. Depending on the reason for the removal, a new probe can be implanted during the same procedure.

During removal of transvenous probes, various potentially dangerous complications can occur (see below). To be able to monitor you in the best possible way and to be prepared for all eventualities in case of complications, we usually conduct the examination in collaboration with the doctors of the anaesthesia department (anaesthesia) in general anesthesia and intubation, i.e. using a respiratory tube. Please inform your doctor if you have experienced problems during anaesthesia in the past. The monitoring also includes the use of transoesophageal echocardiography (cardiac ultrasound) to detect any changes in the heart as soon as possible. We carry out the intervention in the operating room where a team of cardiac surgery, including heart-lung machine, is always ready to treat complications in standby mode.

For your safety, we will also create access point through the femoral vessels. If your heart is dependent on the pacemaker stimulation, we will insert a temporary pacemaker via a further access point in the groin.

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 3-5% of such 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:

- In rare cases, an injury to the heart wall may occur with subsequent bleeding into the pericardium. If the placement of a drainage tube below the sternum does not help to stop the bleeding, an immediate cardiac surgery through an opening of the sternum may be required in rare cases to stop the bleeding.
- In rare cases, there may be an injury of the blood vessels outside the pericardium. In such a case, an immediate cardiac surgery through an opening of the sternum may be needed to stop the bleeding.
- Rarely there may be a vascular injury in the area of the pacemaker box or access point of the probe into the venous system in the area of the box. This can lead to severe bleeding in this area, for which a vascular surgical procedure may be necessary in some rare cases for correction.
- In the event of the occurrence of the above-mentioned complication, blood transfusions and the administration of other blood products may be necessary.
- In some rare cases, the complete removal of the probe may not be possible. If this is necessary for treating an infection or blood intoxication (sepsis), the remaining probe material must be removed through cardiac surgery by creating an opening of the sternum.
- In some rare cases, the lungs may also be injured. Air may penetrate into the chest cavity ("pneumothorax"), which could make the insertion of a chest tube necessary.
- Formation of blood clots ("thrombosis") may occur rarely, which can also get into the pulmonary circulation ("pulmonary embolism") and make the use of blood thinners necessary.
- Fatal complications associated with the removal of transvenous probes are very rare, but have been described in studies.

After the examination

After the procedure, we will conduct an ultrasound examination of the heart to rule out the late accumulation of blood in the pericardium. We will also perform an X-ray of the chest. If a new pacemaker or ICD is implanted as part of the examination, we will check these on the following day.

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: ……..……..