Universitätsspital Basel

Cardiology

Declaration of consent for the catheter treatment of mitral valve stenosis (Mitral valvuloplasty)

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Declaration of consent

for the catheter treatment of mitral valve stenosis (Mitral valvuloplasty)

I was informed about the planned intervention and agree to it.
I have been informed about the purpose, the chances of success, the risk and other treatment options. I have been informed that in order to carry the balloon dilation
a catheter must be inserted through the right side of the heart and the atrium wall into the left ventricle. This catheter insertion can be associated with complications, the worst of which is a bruise in the pericardium. The same complication can also result from the dilatation of the mitral valve. Overall, bleeding in the pericardium, which must be drained by catheter or surgery, is expected in 1-3 percent of treatments. I have been informed that an emergency heart operation may have to be performed if the valve is injured in rare cases (about 2 percent) and due to an excessive backflow of the blood through
the valve an operation may also be required at a later stage. In rare cases, you can also die because of the treatment (1 percent). Other serious but rare side effects include stroke, a severe allergy to the medication used, circulatory problems in the legs or clotting in the arteries. They occur in 1-2 percent of patients.

I have been informed that it is not uncommon for the valve to become constricted again after years and that further treatment might be necessary.

I was also informed about the general risks of cardiac catheter examination. I know that bleeding, e.g. at the injection site, and disturbances of the heart rhythm or kidneys can rarely occur and must be treated.

As there is a small risk of bacterial infection, I will get an antibiotic and take it as prophylaxis for the rest of my life if I have a dental or other form of intervention or any febrile illness.

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.

I have understood the information passed on to me. My questions were satisfactorily answered.

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: _____