DZHK-SOP-K-05

Cardiac Catheterization

Left and right heart examination.
Left ventriculography.
Left and right ventricular myocardial biopsies.

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<table>
<thead>
<tr>
<th>Expert Author</th>
<th>Expert Review</th>
<th>Endorsed by Head of Section</th>
<th>Approved by DZHK</th>
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Date: 26.08.2014

Signature
# CONTENTS

1 Introduction ......................................................................................................................... 4  
1.1 List of Abbreviations ........................................................................................................ 4  
1.2 Purpose .............................................................................................................................. 6  
1.3 Target Group ..................................................................................................................... 6  
  1.3.1 Inclusion Criteria ...................................................................................................... 6  
  1.3.2 Exclusion Criteria .................................................................................................... 6  
1.4 Application and Tasks ...................................................................................................... 6  
1.5 Correlations to Other Examinations ................................................................................ 7  
1.6 Level of Quality ................................................................................................................. 7  
2 Examination Conditions ..................................................................................................... 8  
2.1 Equipment/Hardware ........................................................................................................ 8  
2.2 Special Clinical Consumables ........................................................................................ 8  
2.3 Documents Required ....................................................................................................... 10  
2.4 Information Required ..................................................................................................... 10  
2.5 Personnel ......................................................................................................................... 10  
3 Process of Implementation/Work Process/Work Steps ..................................................... 11  
  3.1 Process Flow Chart ....................................................................................................... 11  
3.2 Preparations for the Examination .................................................................................... 12  
  3.2.1 Preparation of the Work Space ............................................................................... 12  
  3.2.2 Preparation of the Equipment ............................................................................... 12  
  3.2.3 Principles of Preparing the Patient for Examination .............................................. 12  
3.3 Performing the Examination ........................................................................................... 13  
  3.3.1 Local Anaesthesia .................................................................................................. 13  
  3.3.2 Right Heart Catheterization .................................................................................. 13  
  3.3.3 Arterial Puncture and Introduction of the Sheath .................................................. 14  
  3.3.4 Catheterization of the Left Ventricle and Ventriculography .................................. 14  
  3.3.5 Coronary Angiography .......................................................................................... 15  
  3.3.6 Left Ventricular Endomyocardial Biopsy ............................................................... 15  
  3.3.7 Right Ventricular Myocardial Biopsy ..................................................................... 15  
  3.3.8 Number of Biopsies ................................................................................................ 15  
3.4 Post-Processing and Registering the Data ...................................................................... 16  
  3.4.1 Patient Aftercare .................................................................................................... 16
3.4.2 Conservation/Transport/Processing of Samples .................................................... 16

3.4.3 Findings .................................................................................................................. 16

3.5 Handling Deviations ................................................................................................. 19

4 Literature and References ........................................................................................... 20

5 Modifications ................................................................................................................ 20

6 List of Contributors ..................................................................................................... 20

7 Annexes ....................................................................................................................... 21

7.1 Annex 1: Ventriculography Findings ......................................................................... 21

7.2 Annex 2: Coronary Angiography Findings ................................................................. 22

7.3 Annex 3: Right Heart Catheterization Findings ......................................................... 23

7.4 eCRF Modul ............................................................................................................... 24

Die in dieser SOP mit dem Symbol ** unterlegten Textelement sind verpflichtend einzuhalten. Die mit dem Symbol *hinterlegten Textelemente sind nach Möglichkeit einzuhalten.
1 INTRODUCTION

1.1 LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full form</th>
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<tbody>
<tr>
<td>A.</td>
<td>artery</td>
</tr>
<tr>
<td>ARVC</td>
<td>arrhythmogenic right ventricular cardiomyopathy</td>
</tr>
<tr>
<td>avDO2</td>
<td>arteriovenous difference of O2 content</td>
</tr>
<tr>
<td>BSA</td>
<td>body surface area</td>
</tr>
<tr>
<td>CC</td>
<td>cardiac catheterization</td>
</tr>
<tr>
<td>CFA</td>
<td>common femoral artery</td>
</tr>
<tr>
<td>CI</td>
<td>cardiac index</td>
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<tr>
<td>CO</td>
<td>cardiac output</td>
</tr>
<tr>
<td>CO2art</td>
<td>arterial O2 content</td>
</tr>
<tr>
<td>CO2ven</td>
<td>central venous O2 content</td>
</tr>
<tr>
<td>CVP</td>
<td>central venous pressure = mean pressure right atrium</td>
</tr>
<tr>
<td>ECG</td>
<td>electrocardiogram</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>Hb</td>
<td>haemoglobin</td>
</tr>
<tr>
<td>i.s.</td>
<td>in serum</td>
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<tr>
<td>INR</td>
<td>international normalized ratio</td>
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<tr>
<td>IU</td>
<td>international units</td>
</tr>
<tr>
<td>JL</td>
<td>Judkins left catheter</td>
</tr>
<tr>
<td>JR</td>
<td>Judkins right catheter</td>
</tr>
<tr>
<td>LAO</td>
<td>left anterior oblique</td>
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<tr>
<td>LVEDP</td>
<td>left ventricular end diastolic pressure</td>
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<tr>
<td>mAP</td>
<td>mean arterial pressure</td>
</tr>
<tr>
<td>mPAP</td>
<td>mean pulmonary arterial pressure</td>
</tr>
<tr>
<td>MPC</td>
<td>multipurpose catheter</td>
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<tr>
<td>mPCWP</td>
<td>mean pulmonary capillary wedge pressure</td>
</tr>
<tr>
<td>MRT</td>
<td>magnet resonance tomography</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
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<td>--------------</td>
<td>--------------------------------------</td>
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<tr>
<td>MVO2</td>
<td>mixed venous oxygen saturation</td>
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<tr>
<td>NaCl</td>
<td>natrium chloride</td>
</tr>
<tr>
<td>PAO2</td>
<td>pulmonary arterial oxygen content</td>
</tr>
<tr>
<td>pAOD</td>
<td>peripheral arterial occlusive disease</td>
</tr>
<tr>
<td>PCWP</td>
<td>pulmonary capillary wedge pressure</td>
</tr>
<tr>
<td>PTCA</td>
<td>percutaneous transluminal coronary angioplasty</td>
</tr>
<tr>
<td>PT</td>
<td>parameter of functional performance of the extrinsic blood coagulation pathway</td>
</tr>
<tr>
<td>PTT</td>
<td>partial thromboplastin time</td>
</tr>
<tr>
<td>Q-pulm</td>
<td>cardiac output in the pulmonary circulation</td>
</tr>
<tr>
<td>Q-syst</td>
<td>cardiac output in the systemic circulation</td>
</tr>
<tr>
<td>RA mean</td>
<td>mean right atrial pressure</td>
</tr>
<tr>
<td>RAO</td>
<td>right anterior oblique</td>
</tr>
<tr>
<td>SAO2</td>
<td>systemic arterial oxygen content</td>
</tr>
<tr>
<td>SVR</td>
<td>systemic peripheral vascular resistance</td>
</tr>
<tr>
<td>TSH</td>
<td>thyroid stimulating hormone</td>
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<tr>
<td>V.</td>
<td>Vena</td>
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<tr>
<td>venO2VC1</td>
<td>venous oxygen saturation Vena cava inferior</td>
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<tr>
<td>venO2VCS</td>
<td>venous O2 saturation Vena cava superior</td>
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<tr>
<td>vO2</td>
<td>oxygen consumption</td>
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1.2 **PURPOSE**
The purpose of the cardiac catheter examination dealt with in this SOP is to provide a visual representation and haemodynamic assessment of cardiomyopathies.

Cardiac catheterization is performed for further phenotyping of cardiomyopathies, to assess the degree of severity, and for prognostic purposes.

1.3 **TARGET GROUP**
This SOP is intended for all invasive cardiologists who perform right heart catheterization diagnostics, left heart catheter diagnostics or myocardial biopsies.

1.3.1 **Inclusion Criteria**
An invasive cardiac assessment is indicated according to the current guidelines. In the context of the objective, this applies especially to patients in whom cardiomyopathy has already been verified by other imaging techniques, unexplained reduced left ventricular systolic function and/or corresponding symptoms.

1.3.2 **Exclusion criteria**
All patients without clinical indications for diagnostic left heart catheterization/right heart catheterization.

1.4 **APPLICATION AND TASKS**
The invasive cardiac diagnostic test is intended to determine, in particular, left ventricular systolic function (by ventriculography), clinically relevant coronary stenoses as an expression of heart disease of ischaemic origin (by coronary angiography), as well as the haemodynamic effects of the disease on the systemic and the pulmonary circulation (by right heart catheterization). In the absence of contraindications, standardized removal of myocardial biopsies from the left or right ventricle for further diagnostic specification is also of crucial importance.

Diagnostic cardiac catheterization complements non-invasive imaging methods such as echocardiography and MRT, as well as spirometry/ergometry and the 6-minute walk test. Ideally, these non-invasive preliminary examinations should be available prior to performing cardiac catheterization. To ensure that the cardiac catheter examination is carried out effectively and with few complications, patient preparation and information as well as the methodology, diagnosis and documentation need to be standardized. This SOP deliberately does not deal with details regarding the technical equipment of the catheterization laboratory, staff training, or adherence to radiation protection regulations since it is assumed that generally accepted standards are in place at each site, and because these standards are prescribed by the German X-Ray Regulations and the Guidelines of the German Cardiac Society and can be viewed [here](http://leitlinien.dgk.org/files/2001_Leitlinie_Einrichtung_und_Betreiben_von_Herzkatheterraume_H.pdf). Therefore, the details given essentially serve as examples.

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<tr>
<td>Version: V1.0</td>
<td>Autor: A. Dösch et al.</td>
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Die in dieser SOP mit dem Symbol ** unterlegten Textelement sind verpflichtend einzuhalten. Die mit dem Symbol * hinterlegten Textelemente sind nach Möglichkeit einzuhalten.
1.5 CORRELATIONS TO OTHER EXAMINATIONS

This SOP is closely correlated to the SOP on the Collection, Processing and Handling of Tissue Samples. The non-invasive preliminary examinations are performed in accordance with the current recommendations, clinical standards and local circumstances.

1.6 LEVEL OF QUALITY

The minimum requirements for this SOP correspond to Quality Level 1 of the DZHK.

<table>
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<td>Implementation</td>
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<td>Level 2</td>
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<tr>
<td>Level 3</td>
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2 Examination Conditions

2.1 Equipment/Hardware

The general rules of good practice and asepsis must be observed.

A detailed description of the set-up of a cardiac catheterization laboratory are summarized in the guidelines of the German Cardiac Society: (http://leitlinien.dgk.org/files/2001_Leitlinie_Einrichtung_und_Betreiben_von_Herzkathetererraeumen.pdf):

The cardiac catheterization laboratory should be equipped with at least the following ancillary equipment:

- Pressure transducer (pressure dome with catheter and de-aerator connection)
- Contrast material injector (high-pressure injector)
- Blood gas analyzer
- Pulse oximeter
- Defibrillator (battery-powered)
- Oxygen and compressed air connection (option of invasive ventilation)
- Suction device
- Emergency equipment and medications (see below) including a temporary pacemaker

2.2 Special Clinical Consumables

General requirements:

- 2500 IU unfractionated heparin/5 ml NaCl 0.9%
- 1 mg nitroglycerine/10 ml NaCl 0.9%
- 20 ml NaCl
- 2x 10 ml injections with local anaesthetic and 20-G needles
- Contrast material (ca. 120 ml Imeron®)
- 4 ECG electrodes
- Pressure regulator, valve manifold with rotator with 3 successively switched 3-way valves
- 10 ml contrast material injection syringe
- 1 sterile OP gown
- 1 pair of sterile gloves
- Pressure bandage material
- 2 plastic disposable dishes with heparinized NaCl 0.9%
- 20 sterile dressings 10x10 cm

**Right heart catheterization:**
- Puncture needle (size 1.4 x 7 mm)
- Plastic syringes 1 x 10 ml, 2 x 20 ml and 10 x 2 ml
- J-tip guide wire (0.035 inch, 145 cm in length)
- 7 French multipurpose diagnostic catheter
- 7 French dilatator

**Coronary angiography with LV angiography:**
- Puncture cannula (size 1.4 x 7 mm)
- J-tip guide wire (0.035 inch, 145 cm in length)
- 4 French arterial sheath
- 4 French pigtail catheter (LV angiography)
- 4 French Judkins left catheter (100 cm) (JL) (for men taller than 170 cm, use of a 5 French is preferable)
- 4 French Judkins right catheter (100 cm) (JR)
- Injection piston for high-pressure injection pump
- Injection tube for high-pressure injection pump
- 500 ml NaCl, infusion set and pressure bag
2.3 **DOCUMENTS REQUIRED**
- **Blood collection documentation** (potassium i.S., natrium i.S., creatinine i.S., urea i.S., complete blood count, PT, INR, PTT, TSH basal).
- **Information and consent (signature) using the standard information sheets**: Specific and separate information must be given for left heart catheterization, right heart catheterization and the coronary angiography as well as for the taking of myocardial biopsies. The detailed anamnesis and physical examination should take place in the same context (see corresponding SOPs).
- **Resting ECG (12-lead)** (see corresponding SOPs).

2.4 **INFORMATION REQUIRED**
- **Date of examination**
- **Patient (test subject) ID**
- **Date of birth (DD.MM.YYYY)**
- **Sex**
- **Height (in cm)**
- **Weight (in kg)**
- **Examiner ID and registrant ID**

2.5 **STAFF**
The corresponding legal regulations apply.
3 PROCESS OF IMPLEMENTATION / WORK PROCESS / WORK STEPS

3.1 PROCESS FLOW CHART

Inclusion Criteria
- verified cardiomyopathy
- unexplained reduced left ventricular pump function and/or corresponding symptoms

Preparation of the work space 3.2.1
Preparation of the patient 3.2.3

Implementation
Local anaesthesia 3.3.1
Right heart catheterization 3.3.2
  1) Determination of venous oximetry run
  2) Determination of right cardiac/pulmonary haemodynamics
Arterial puncture and introduction of the sheath 3.3.3
Catheterization of the left ventricle and ventriculography 3.3.4
Coronary angiography 3.3.5

Biopsy Removal
- Left ventricular endomyocardial biopsy 3.3.6
- Right ventricular myocardial biopsy 3.3.7
- Number of biopsies 3.3.8

Post-procedural care
Patient aftercare 3.4.1
Sample conservation/transport/processing 3.4.2
3.2 Preparations for the Examination

The relevant legal regulations apply. Deviations in accordance with local standards and circumstances (e.g. French gauges, closure systems, contrast material pumps) are possible.

3.2.1 Preparation of the Work Space

- 2 disposable plastic dishes with heparinized NaCl 0.9%
- 5 ml syringe with 2500 IU unfractionated heparin in NaCl 0.9%
- 10 ml disposable plastic syringes with 1 mg nitroglycerine in NaCl 0.9%
- 2 x 10 ml disposable syringes with lidocaine (1%) and 27-G injection needles
- 2 x 20 G injection needles
- puncture cannula (size 1.4 x 7 mm)
- 10 x 2 ml disposable plastic syringes
- J-tip guide wire (0.035 inch, 145 cm in length),
- 7 French multipurpose diagnostic catheter
- 7 French dilatator
- 4 French arterial sheath
- 4 French pigtail catheter (LV angiography)
- 4 French Judkins left catheter (100 cm) (JL) (for men taller than 170 cm, use of a 5 French is preferable)
- 4 French Judkins right catheter (100 cm) (JR)
- 8 French arterial sheath
- 7 French MB1 Guiding Launcher (Medtronic®),
- biopsy forceps (e.g. Endo-Flex long®).

3.2.2 Preparation of the Equipment

The cardiac catheterization monitoring station and the examination room are prepared according to local standards.

3.2.3 Principles of Preparing the Patient for Examination

The patient is prepared for examination according to established local standards. First an indwelling catheter is inserted into a peripheral vein, ideally in the proximal left arm (crook of elbow). The patient must undress completely and lie on his/her back on the examination table. Then the patient is connected to a monitoring (3-lead) ECG and a pulse oximeter.
After palpating the pulse, the puncture site is shaved carefully with a disposable razor. Disinfectant is then applied extensively to the puncture site and the patient is covered completely with sterile drapes. The materials required for the examination are provided on a table with a sterile covering.

### 3.3 Performing the Examination

Because the coronary angiography with LV angiography is performed in combination with catheterization of the right side of the heart and removal of an endomyocardial biopsy from the left ventricle, the preferred approach is via the right common femoral artery (CFA) (Judkins technique) and the right femoral vein, if possible. Depending on the study protocol in question, a different approach may be useful (e.g. the radial artery). In principle, myocardial biopsies may be collected from the left and from the right ventricle. Specific requirements regarding the biopsy site should be individually determined in the respective study protocol. Accordingly, there are different venous (e.g. femoral vein, jugular vein) and arterial (femoral artery) approaches.

#### 3.3.1 Local Anaesthesia

After palpating the artery, a local anaesthetic with e.g. 2×10 ml lidocaine (1%) is administered by superficial infiltration of the skin and the subcutaneous tissue in the area of the subsequent puncture channel to the CFA and the femoral vein using a 25 G needle. It takes approx. 3 minutes for the local anaesthetic to take effect.

#### 3.3.2 Right Heart Catheterization

Catheterization of the right side of the heart is performed in accordance with the relevant standards and the respective study protocol. Puncture of the right femoral vein is performed under aspiration approx. 2 cm medial to the arterial puncture site. The guide wire is introduced through the indwelling catheter into the cranial vein until the tip reaches the inferior vena cava. To widen the puncture channel, the 7 French dilator is fully inserted and subsequently exchanged for the 7F multipurpose catheter (MPC). The MPC is positioned above the guide wire in the upper part of the superior vena cava.

After removal of the guide wire, the venous oxygen saturation levels are taken.

1) Determination of venous saturation oximetry run (also for shunt diagnostics):

Following aspiration of approx. 5 ml of blood, for determination of the venous oxygen saturation levels venous blood is taken from the following locations (collection in 2 ml disposable plastic syringes):

- cranial superior vena cava
- caudal superior vena cava (directly above the right atrium)
- right atrium
- cranial inferior vena cava (directly below the right atrium, with the catheter tip pointing away from the hepatic veins)
- caudal inferior vena cava (withdrawal from the last position by approx. 5-10 cm).
- Before collecting blood, after repositioning of the MPC, first aspirate approx. 5 ml of blood (this will be discarded). The oximetry run should be performed quickly without interruption and the oximetric analyses must be carried out directly after collection.

2) Determination of the right cardiac/pulmonary-arterial hemodynamics (right heart catheterization):

The following applies to all registrations: Following zero adjustment of the pressure transducer, the pressure curves are registered in resting respiratory position over 10 cardiac cycles (no ventricular extrasystoles). The quality of the curves must be checked immediately and, if necessary, the manoeuvre must be repeated, e.g. in case of strong artifacts or implausible values. Following collection of the saturation levels, the MPC is initially positioned under fluoroscopy in the trunk of the pulmonary artery. After rinsing the MPC with approx. 5 ml NaCl 0.9% and connecting the catheter to the valve manifold, the pressure curves are registered via the pressure transducer (see above). Then the catheter is repositioned under fluoroscopy in the left pulmonary artery and the pressure curves are registered in the same manner as described above. Then, during deep inspiration, the MPC is carefully advanced into the peripheral pulmonary circulation until an artifact-free pulmonary capillary wedge pressure curve is obtained. The catheter is subsequently withdrawn under continuous registration into the left pulmonary artery where 10 more cardiac cycles are recorded. After repositioning in the right pulmonary artery, the above-described procedure is repeated. Finally, under continuous registration, the catheter is withdrawn from the trunk of the pulmonary artery via the right ventricle into the right atrium (registration over 10 cardiac cycles/localization (see evaluation under 3.3.4.).

3.3.3 Arterial Puncture and Introduction of the Sheath

Employing the single-wall puncture technique, the CFA is punctured approx. 1-2 cm below the inguinal ligament at an angle of approx. 30-45° to the skin surface, following the supposed proximal course of the vessel. The guide wire is advanced through the indwelling cannula into the cranial artery; the puncture needle is withdrawn under compression and the sheath with integrated dilator is inserted through the guide wire. The dilator is subsequently removed. Following aspiration of approx. 5 ml of blood, blood is collected via the sheath using a 2 ml plastic syringe to determine the arterial saturation. This is followed by intra-arterial administration of 2500 IU of fractionated heparin/10 ml NaCl using a 10 ml syringe through the sheath under repeat aspiration.

3.3.4 Catheterization of the Left Ventricle and Ventricularography

Ventriculography is performed according to the relevant standards and the respective study protocol. The pigtail catheter is placed via the indwelling guide wire in the ascending aorta in 30° LAO projection at the level of the sinuses of Valsalva so that it can then be positioned freely in the middle of the left ventricle by means of retrograde catheterization of the aortic valve. After removal of the guide wire, the pigtail catheter is connected to the rotator of the valve manifold. With the patient in resting expiratory position, the ventricular pressure curves are registered over 10 cardiac cycles via the
pressure transducer. After this, the 4 F pigtail catheter is connected to the high-pressure injection pump.

Ventriculography is performed in 2 projection planes with the patient in resting expiratory position over 5 cardiac cycles:

1. 30° RAO, quantity of contrast material according to local standard, flow rate 15 ml/sec.
2. 60° LAO, quantity of contrast material according to local standard, flow rate 15 ml/sec.

After ventriculography, with the patient in resting expiratory position, the ventricular pressure curves are registered again over 10 cardiac cycles and, after withdrawal into the ascending aorta, the aortic pressure curves are registered over 10 cardiac cycles (to determine any possible withdrawal gradient across the aortic valve) (see evaluation in section 3.3.5).

3.3.5 Coronary Angiography

Coronary angiography is performed in accordance with the relevant standards and the respective study protocol (see Coronary Angiography Findings in section 3.3.5). Literature reference: Clinical Research in Cardiology, Vol. 97, No. 8, Clin Res Cardiol 97:475–512 (2008).

3.3.6 Left Ventricular Endomyocardial Biopsy

Removal of endomyocardial biopsies is performed in accordance with the relevant standards and the respective study protocol. After the coronary angiography has been performed the arterial 4F sheath is exchanged for the 8F sheath. This is followed by retrograde catheterization of the aortic valve in 20° RAO projection and placement of a 7F guiding catheter in the left ventricle. Under fluoroscopy, the tip of the catheter is positioned in the target region. Contrast agent is injected to ensure adequate distance to the endomyocard and to avoid injuries of the papillary muscles. The biopsy forceps is inserted through the 7F guiding catheter and biopsies are collected from different parts of the left ventricle. Immediately after collection of the myocardial biopsy, transthoracic echocardiography is performed to exclude the presence of pericardial effusion.

3.3.7 Right Ventricular Myocardial Biopsy

A standard biotome (e.g. B-18110; Medizintechnik Meiners, Mannheim, Germany) is advanced through the sheath under X-ray control. The right ventricle is reached through the right atrium and a small biopsy is taken from various septal sites. Before obtaining a biopsy, it should be verified by X-ray control that the biotome is in the correct position in the right ventricle. Another common approach is through the the jugular vein.

3.3.8 Number of Biopsies

The recommended number of biopsies depends on the clinical question under consideration and whether material is to be collected for the purpose of addressing research questions. The latter is only possible if an application for ethical approval exists.

For the clinical clarification of, e.g. storage diseases, experience has shown that 1-2 samples are needed for histological analyses, 1 sample for immune-histological analysis and, where applicable, 1-3
samples for molecular biology questions. For questions related to inflammatory responses and/or virus identification, experience has shown that 6 additional samples are required. It is important to note that the quality/size of each biopsy obtained also determines the number of samples taken. We recommend to collect at least 5 samples per procedure and up to 10 to guarantee reliable results. Samples for histology and immunohistochemical analysis should be at least 1-2 mm in size.

3.4 POST-PROCESSING AND REGISTERING THE DATA

3.4.1 Patient Aftercare

Patient aftercare is given in accordance with the relevant standards and the respective study protocol. After excluding the presence of post-procedural pericardial effusion, the venous and arterial sheaths are withdrawn. First, manual compression is applied to the puncture site(s) until bleeding stops. Then, a compression dressing is applied in circular fashion around the hip using elastic bandages. This dressing remains in place for 6 hours during which time the patient is confined to bed. The patient is then transferred to the ward where the compression dressing is monitored closely. On the following day, elective patients can be discharged once pericardial effusion has once again been excluded by echocardiography.

3.4.2 Conservation/Transport/Processing of Samples

Samples are processed in accordance with the SOP on the Collection, Processing and Handling of Tissue Samples. Samples intended for histological studies should be fixed in 4-5% formalin immediately after removal. Samples intended for immune-histological and molecular biology studies should be placed in so-called RNAlater tubes for fixation. The biopsies must be placed in the pre-prepared tubes immediately after removal for subsequent transport of the samples in RNAlater; the tube must be well sealed and immediately inverted so that the biopsy is submerged in the liquid and the material is conserved for all further analyses.

Afterwards the samples must be shipped without delay or stored in the refrigerator at +4°C until shipment takes place. Samples may be dispatched to the laboratory at room temperature in a padded envelope.

The RNAlater tubes should be stored at room temperature prior to use. Slight formation of crystals does not impair fixation of the samples. For parallel detection of systemic viral infection in blood, please send an additional EDTA tube from the patient. Shipment also takes place at room temperature.

Biopsy analysis should be performed in a laboratory that specializes in myocardial biopsy analyses. A simultaneous biopsy work-up for histology, immune-histology and molecular-histology analyses is desirable. The use of laboratories with additional FDA approval is preferred.

3.4.3 Findings

Examples of acceptable documentation of findings (see Annexes).
1. **Ventriculography (see Annex 1):**
   Assessment of left ventricular (pump) function is qualitative:
   
   1. Evaluation of wall motion abnormalities according to the nomenclature defined by Herman et al.
   2. The classification and evaluation of specific wall regions are to be documented according to the Coronary Artery Disease Reporting System of the AHA.

   Haemodynamics of the left ventricle (in mmHg):
   
   1. End-systolic and end-diastolic ventricular pressure prior to angiography.
   2. End-systolic and end-diastolic ventricular pressure following angiography.
   3. Following catheter withdrawal into the aortic bulb, systolic, diastolic and mean aortic pressure (if necessary, “peak-to-peak” withdrawal gradient).
   4. Classification of mitral regurgitation according to Sellers.

<table>
<thead>
<tr>
<th>Grade I</th>
<th>Contrast material reflux with only minimal dye in the left atrium</th>
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<tbody>
<tr>
<td>Grade II</td>
<td>Contrast material regurgitation jet with moderate dyeing of the left atrium</td>
</tr>
<tr>
<td>Grade III</td>
<td>Complete dyeing of the left atrium corresponding to the contrast material density of the left ventricle</td>
</tr>
<tr>
<td>Grade IV</td>
<td>Enlarged left atrium with high contrast material density compared to the left ventricle and reflux into the pulmonary veins</td>
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</tbody>
</table>

2. **Coronary angiography (see Annex 2):**
   Assessment of the coronary angiography findings is semi-quantitative in accordance with the guidelines of the AHA.
   
   - coronary artery dominance type
   - stenosis localization according to the AHA classification segments (see Annex 2),
   - collateralization
   - suitable for PTCA and/or bypass surgery
   - the diagnosis is documented (as well as the type of vascular disease).
3. **Right heart catheterization (see Annex 3):**
General haemodynamics:

**Cardiac output (CO) (l/min):**
- Calculation according to Fick’s equation: \( vO_2 \times \text{avDO}_2 \)
  \[
  vO_2 = \text{BSA} \times (161-\text{age} \times 0.54) \text{ ml/min}^{-1} \quad (\text{empiric})
  \]
  \[
  vO_2 \text{ Women} = \text{BSA} \times (147.5-\text{age} \times 0.47) \text{ ml/min}^{-1} \quad (\text{empiric})
  \]
  \[
  \text{avDO}_2 = \text{CO arteria-vena}
  \]
  \[
  \text{CO arteria}=O_2 \text{ saturation (femoral artery)} \times \text{Hb} \times 1.34
  \]
  \[
  \text{CO ven} = O_2 \text{ saturation (pulmonary artery)} \times \text{Hb} \times 1.34
  \]

**Cardiac index (CI) (l/min/m²):**
- Calculation: CO/BSA

**Pulmonary vascular resistance (PVR) (dyn/sec*cm⁻⁵):**
- Calculation: 80*(mPAP-mPCWP)*CO⁻¹

**Systemic (peripheral) vascular resistance (SVR) (dyn/sec*cm⁻⁵):**
- Calculation: 80*(mAP-CVP)*CO⁻¹
Mixed venous oxygen saturation (MVO₂) (%):
- Calculation: \(3 \times \text{venO₂(VCS)} + \text{venO₂(VCI)} \) / 4

Shunt calculation (Fick’s principle): A shunt calculation should be performed when there is a significant (more than 5%) difference in oxygen saturation between two sampling sites:

**Left-to-Right Shunt** (l/min)
Calculation: \((Q_{\text{pulm}} - Q_{\text{sys}})\)

**Right-to-Left Shunt** (l/min)
Calculation: \((Q_{\text{sys}} - Q_{\text{pulm}})\)
- \(Q_{\text{sys}} = \frac{\text{VO₂}(\text{arterial saturation} \times \text{Hb} \times 1.34 \times \text{ml}^{\text{100 ml}^{-1}})}{(\text{SAO₂} - \text{MVO₂}) \times 10^{-1}}\)
- \(Q_{\text{pulm}} = \frac{\text{VO₂}(\text{arterial saturation} \times \text{Hb} \times 1.34 \times \text{ml}^{\text{100 ml}^{-1}})}{(\text{SAO₂} - \text{PAO₂}) \times 10^{-1}}\)

3.5 Handling Deviations
This SOP describes a standard procedure under optimal examination conditions from which it is necessary to deviate when problems occur. For instance, ventriculography must be omitted in patients who have undergone mechanical aortic valve replacement because retrograde catheterization of the prosthetic aortic valve should be avoided. If the right common femoral artery approach is problematic (e.g. in case of severe pAOD, status post stent implantation or bypass operation, severe kinking of the artery etc.) alternative approaches must be selected. Likewise, in case of severe renal insufficiency, a reduction in the amount of contrast material applied must be considered.

The value of right ventricular angiography for diagnosis of ARVC is unclear, because a standardized diagnostic assessment is not established. Nevertheless, it can be considered in individual cases.
4 LITERATURE AND REFERENCES


5 MODIFICATIONS

Modifications to the previous version.

<table>
<thead>
<tr>
<th>Section</th>
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6 LIST OF CONTRIBUTORS

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<tr>
<th>Name</th>
<th>Function</th>
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<tbody>
<tr>
<td>PD Dr. Andreas Dösch</td>
<td>First author</td>
<td>Drafted the SOP</td>
</tr>
<tr>
<td>Dr. Ralf Bauer</td>
<td>Author</td>
<td>Drafted the SOP</td>
</tr>
<tr>
<td>Prof. Dr. Carsten Tschöpe</td>
<td>Author</td>
<td>Drafted the SOP</td>
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Gültig ab: 01.09.2014
Version: V1.0
Autor: A. Dösch et al.
Seite 20 von 29

Die in dieser SOP mit dem Symbol ** unterlegten Textelement sind verpflichtend einzuhalten. Die mit dem Symbol *hinterlegten Textelemente sind nach Möglichkeit einzuhalten.
7 ANNEXES

7.1 ANNEX 1: VENTRICULOGRAPHY FINDINGS
7.2 ANNEX 2: CORONARY ANGIOGRAPHY FINDINGS
Anlage 3

Klinikum der Universität Heidelberg
Medizinische Klinik
Abteilung Innere Medizin III (Kardiologie)
Direktor: Prof. Dr. H. A. Katus
Vitiumbogen

Name: 
Vorname: 
geb. am: 
Anschrift: 

Große (cm): 
Gewicht (kg): 
Station: 

Oberweisernder Arzt: 
Untersucher: 
Registrierer: 
Befunder: 

Untersuchungsdatum: 
Letzte Änderung: 
Endbefund: 

O₂ Verbrauch: ml/min

HZV
Gr.: limin
KL.: limin
Eff.: limin

Li-Re Shunt: ml/min
Re-Li Shunt: ml/min

Pulm Art.-R.: dyn.sec.cm⁻⁵
syst.Art.-R.: dyn.sec.cm⁻⁵

Bemerkungen:

Maßnahmen:

Diagnosen:

DZH-K-SOP Herzkatheter (ii/re), li. ventrik.
Ventrikulographie, Entnahme linksventrik.
Myokardbiopsien

Gültig ab: 01.09.2014

Version: V1.0
Autor: A. Dösch et al.
Seite 23 von 29

### 7.4 eCRF Modul

**Cardiac catheter**

#### Examination details

1. **Quality level**
   - Bitte auswählen

#### Right heart catheterisation

1.1. Was the right heart catheterisation performed?
   - yes
   - no
   - unknown
   - not assessed

1.2. Date of examination

1.3. Left ventricular end-diastolic pressure (LVEDP)

1.4. Heart time volume

1.5. Systolic pulmonary artery pressure

1.6. Diastolic pulmonary artery pressure

1.7. Mean pulmonary artery pressure

1.8. Pulmonary capillary pressure (PCWP)

1.9. Mean RA

1.10. Central venous oxygen saturation

1.11. Arterial oxygen saturation

1.12. Transpulmonary gradient

1.13. Pulmonary vascular resistance

1.14. Systemic vascular resistance (SVR)

1.15. Body height

1.16. Weight

1.17. Haemoglobin

#### Left heart catheterisation

2.1. Was the left heart catheterisation performed?
   - yes
   - no
   - unknown
   - not assessed

2.2. Date of recording

2.3. Coronary heart disease (CHD)
   - none
   - 1-vessel CHD
   - 2-vessel CHD
   - 3-vessel CHD
   - unknown
   - not assessed

2.4. Pump function
   - good
   - mildly impaired
   - moderately impaired
   - severely impaired
   - unknown
   - not assessed
### Myocardial biopsy

3.1. Was the myocardial biopsy performed?  
- yes  
- no  
- unknown  
- not assessed

3.1.2. Date of recording  
- [ ]

3.1.3. Ventricles  
- LV  
- RV  
- LV and RV  
- unknown  
- not assessed

3.1.4. Institution performing the assessment

---

3.2. Previous biopsies available  
- yes  
- no  
- unknown  
- not assessed

3.2.1. Date of previous biopsy  
- [ ]

3.2.2. Previous diagnosis

3.2.3. Number of biopsies  
- [ ]

3.2.4. Ventricles  
- LV  
- RV  
- LV and RV  
- unknown  
- not assessed

3.2.5. Institution performing the assessment

---

4. Storage diseases

4.1. Storage diseases  
- yes  
- no  
- unknown  
- not assessed

4.2. Amyloidosis  
- yes  
- no  
- unknown  
- not assessed

4.3. Other storage disease  
- yes  
- no  
- unknown  
- not assessed

Please specify
### Histological/Immunohistological/Viral Findings Report

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<td>5.1.6. Myocyte hypertrophy*</td>
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<td>5.2. Immunohistological findings report available*</td>
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<td>5.2.1. Positive for inflammation*</td>
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### 6. Procedural complications

#### 6.1. Procedural complications

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DZHK-SOP-K-05
Herzkatheter
Links- und Rechtsherzkatheteruntersuchung.
Linksventrikuläre Ventrikulographie.
Entnahme von links-/ rechtsventrikulären Myokardbiopsien.

Version: V1.0
Gültig ab: 01.09.2014

Ersetzte Version: Vom:

Änderungshinweis:

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<th>Zustimmung Bereichsleitung</th>
<th>Freigabe DZHK</th>
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<tbody>
<tr>
<td>Name</td>
<td>Ralf Bauer</td>
<td>Matthias Nauck</td>
<td>Thomas Eschenhagen</td>
</tr>
<tr>
<td></td>
<td>(Heidelberg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Andreas Dösch</td>
<td></td>
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<td>Carsten Tschöpe</td>
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