**Study Specific SOP**

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# Purpose / Scope

The purpose of this standard operating procedure (SOP) is to describe the standards for performing a transthoracic echocardiography (TTE) as part of the EPOCH-ASO study. The SOP is valid for all clinical research functions participating at EPOCH-ASO and aims to improve the comparability of echocardiography exams performed at different investigating sites. The SOP shall set a common standard for the performing of an echocardiographic study in compliance with GCP, other SOP and regulatory requirement(s).

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# Abbreviations

|  |  |
| --- | --- |
| PW | Pulsed wave Doppler |
| CW | Continuous wave Doppler |
| PR | Pulmonary regurgitation |
| RV | Right ventricle |
| LVOT | Left ventricular outflow tract |
| TAPSE | Tricuspid annular plane systolic excursion |

# Procedure

Transthoracic echocardiography

## Requirements / Responsibilities

|  |  |
| --- | --- |
| **Responsibility** | **Procedure** |
| Study physician / echo technician(dedicated by the study site) | Performing a full echocardiographic study following the protocol outlined in detail in this SOP |
| Core lab | Not determined |

## Detailed echocardiography protocol

|  |  |
| --- | --- |
| **Responsibility** | **Procedure** |
| General requirements | * For each view: Record at least 2 consecutive loops (beware of extra-systole)
* Gain and depth settings must be optimized for each view
* All echocardiographic studies must be recorded with ECG
* For images for strain analysis a framerate of 50-90 should be obtained
 |
| Detailed echocardiography protocol | **Parasternal views:**1. **Parasternal long-axis**
* Overview
* Parasternal long axis view optimized for neo-aortic valve and aortic root, with and without color
* Parasternal long axis with detailed recording of the neo-aorta (including measurement LVOT)
* Parasternal long axis optimized for mitral valve, with and without color
1. **Parasternal short-axis**
* Parasternal short axis view optimized for neo-aortic valve, with and without color
* Parasternal short axis view optimized for pulmonic valve, with and without color, if possible.
* High parasternal short axis view optimized for pulmonary artery including the branches, with,without color and cw.
* Short axis view at mid-ventricular level (please ensure that the entire RV-wall is within the scanning sector) with frame rate 50-90/sec
* Parasternal short axis view optimized for tricuspid valve regurgitation jet, with and without color
1. **RV-inflow view with and without color**

**Apical views:**1. **Apical views**
* 4-chamber view overview: at least 2 recordings
* 2-chamber view overview
* 3-chamber (apical long axis) overview
* 4-chamber view focused on left atrium
* Measurement of LVef and LV volumes
* Measurement of left and right atrium volume

**Additional apical assessment of left ventricle** * LV-optimized 4CV-view (frame rate: 50-90/sec) At least 2 recordings
* 2-chamber view (frame rate: 50-90/sec): at least 2 recordings
* 3-chamber view (frame rate: 50-90/sec): at least 2 recordings
* Tissue Doppler lateral mitral valve annulus– optimized for systolic and diastolic flow velocities (S’, E’, A’)
* PW at tips of mitral valve leaflets (to obtain E and A velocity)

**Apical assessment of LVOT, mitral regurgitation, pulmonary regurgitation*** Mitral valve with color 4,2 and 3 chamber view (including attempt for PISA in case of > minor MR)
* CW mitral valve to record mitral regurgitation max. velocity (optimized gain settings) if there is mitral regurgitation
* LVOT with and without color
* LVOT CW and PW
* Pulmonic valve from 5CV with and without color Doppler, if possible
* Pulmonic valve regurgitation CW (to obtain diastolic pulmonary artery pressure)

**Apical 4-chamber view RV-assessment*** RV-optimized view (frame rate: 50-90/sec): At least 2 recordings
* M-Mode lateral tricuspid valve annulus, maximal sweep speed (2 recordings)
* Tissue-Doppler lateral tricuspid valve annulus – optimized for systolic and diastolic flow velocities (S’, E’, A’)
* PW at tips of tricuspid valve leaflets (to obtain E and A velocity)
* Tricuspid valve annulus maximal diameter

**Apical 4-chamber view tricuspid regurgitation assessment:** * With normal color baseline including zoom modality (for Vena contracta)

**CW measurements:*** TR with optimized scale settings for measurement
* TR with optimized scale settings for measurement of PISA (entire TR-spectrum, optimized gain settings

**Subcostal view*** Inferior vena cava with inspiration (5 loops)
* Hepatic vein velocities (PW)

**Suprasternal view*** Aortic arch with and without color Doppler and PW & cw in descendens
* PA branches if possible
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## Results / Report

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| --- | --- |
| **Responsibility** | **Procedure** |
| PI of each center | Standard-measurements as outlined in the detailed protocol

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| --- | --- | --- |
| **Measurement**  | **Result** | **Unit** |
| Weight |  | kg |
| Height |  | cm |
| BP systolicBP diastolic |  | mmHgmmHg |
| HR |  | Beats/min |
| Estimated left ventricular function- Visual estimation0: NoneI: Mild dysfunctionII: Moderate dysfunctionIII: Severe dysfunction- LV volumes systolic- LV volumes diastolic ml- LV EF %- LV-GLS % |  | -mlml%% |
| LVEDDLVESDLA-M-ModePosterior wall thicknessSeptal wall thickness |  | mmmmmmmmmm |
| Right ventricular enddiastolic areaRight ventricular endsystolic area FAC (score)TAPSETAPSE S’ |  | cm2cm2%mmcm/s |
| Tricuspid valve regurgitation0: NoneI: MildII: ModerateIII: Severe |  | Grade: 0: NoneI: MildII: ModerateIII: Severe |
| Peak systolic RA-RV gradient |  | mmHg |
| Inferior vena cava width – maximum |  | mm |
| Inferior vena cava width – minimum |  | mm |
| Estimated enddiastolic pulmonary pressure (pressure gradient PA/RV – as measured from PR-signal) |  | mmHg |
| Maximal / mean pressure gradient across the Pulmonic valve  | Max.Mean | mmHgmmHg |
| Neo-aortic valve regurgitation0: NoneI: MildII: ModerateIII: Severeguidelines |  | 0: NoneI: MildII: ModerateIII: Severeguidelines |
| Diameter of neo-aortic root:(all measurements inner-to-inner edge, enddiatolic)Sinus ValsalvaSinotubular junctionAorta ascendens |  | mmmmmm |

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