**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

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| --- | --- |
| **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 |

## Results / Report

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| --- | --- |
| **Responsibility** | **Procedure** |
| PI of each center | Standard-measurements as outlined in the detailed protocol   |  |  |  | | --- | --- | --- | | **Measurement** | **Result** | **Unit** | | Weight |  | kg | | Height |  | cm | | BP systolic  BP diastolic |  | mmHg  mmHg | | HR |  | Beats/min | | Estimated left ventricular function  - Visual estimation  0: None  I: Mild dysfunction  II: Moderate dysfunction  III: Severe dysfunction  - LV volumes systolic  - LV volumes diastolic ml  - LV EF %  - LV-GLS % |  | -  ml  ml  %  % | | LVEDD  LVESD  LA-M-Mode  Posterior wall thickness  Septal wall thickness |  | mm  mm  mm  mm  mm | | Right ventricular enddiastolic area  Right ventricular endsystolic area  FAC (score)  TAPSE  TAPSE S’ |  | cm2  cm2  %  mm  cm/s | | Tricuspid valve regurgitation  0: None  I: Mild  II: Moderate  III: Severe |  | Grade:  0: None  I: Mild  II: Moderate  III: 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 | mmHg  mmHg | | Neo-aortic valve regurgitation  0: None  I: Mild  II: Moderate  III: Severe  guidelines |  | 0: None  I: Mild  II: Moderate  III: Severe  guidelines | | Diameter of neo-aortic root:  (all measurements inner-to-inner edge, enddiatolic)  Sinus Valsalva  Sinotubular junction  Aorta ascendens |  | mm  mm  mm | |