

C-TRACT: Venous Compression Sonogram Requirements Baseline and 6-month Visit

Introduction:

All C-TRACT Study patients (EVT Arm and Control Arm) will undergo detailed venous duplex ultrasound examination of the iliac and lower extremity veins of the index limb at baseline (before randomization) and at 6month follow-up to evaluate for venous obstruction and valvular reflux. The sonographers will be blinded to the patient's treatment group allocation. The venous compression sonogram includes evaluation from the ilio caval confluence through femoral and popliteal vein to the tibial vein confluence.

Venous Compression Sonogram Goals:

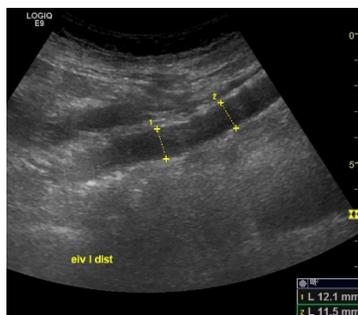
- **BASELINE SONOGRAM**
 - Document status of iliac veins from ilio caval confluence to the saphenofemoral junction
 - Lower extremity venous compression exam; document absence or presence of venous disease from the tibial popliteal confluence up through the saphenofemoral junction
 - If the vein is not fully compressible (common femoral vein and/or popliteal vein) measure the anterior to posterior residual diameter during compression. Complete the corresponding baseline worksheet. If not fully compressible, enter the residual diameter in mm.
 - Submit de-identified images with corresponding worksheet to VasCore promptly
 - Refer to baseline worksheet for a review of exam requirements.

- **6 – MONTH SONOGRAM**
 - Document patency of the iliac veins post treatment; stented or endovascular treatment
 - If the vein is not fully compressible (common femoral vein and/or popliteal vein) measure the anterior to posterior residual diameter during compression. Complete the corresponding 6-month worksheet. If not fully compressible, enter the residual diameter in mm.
 - Document any changes from the baseline exam
 - Submit de-identified images with corresponding worksheet to VasCore promptly
 - Refer to baseline worksheet for a review of exam requirements.

Iliac Veins – Gray Scale and Color Doppler:

Examination of the iliac veins should be conducted in a warm room after an 8-hour fast to minimize overlying bowel gas. Place the patient supine with head slightly elevated to minimize muscular rigidity. Transducer frequency is selected based upon the depth of the vessel. Place the transducer at the level of the umbilicus to identify the ilio caval confluence in a transverse view. Document images and spectral Doppler waveforms from the proximal, mid, distal common iliac vein (CIV) and external iliac vein (EIV). Examine the CIV and EIV for vessel wall motion, compressibility when possible, (some segments of EIV) and respiratory variation. Images must clearly document the absence or presence of any venous disease. If stent present document stent patency and apposition to vein. If the stent is not widely patent obtain measurements of the minimal lumen (flow) diameter, measure the corresponding stent diameter at the same location. (fig. 1). After completing gray scale evaluation of the iliac veins, the spectral Doppler and color Doppler evaluation should commence, from a longitudinal view. The Doppler evaluation of the iliac veins is critical to determine patency since compressibility is limited. Document spectral waveforms from the CIV and EIV. Assess waveforms for spontaneity and respiratory phasicity. Use breath holding techniques to enhance the respiratory variation. Optimize color Doppler to visualize flow patterns and respiratory variation within the iliac veins. If possible, document the respiratory variation with a cine loop clip. Optimize color Doppler to display vein lumen, avoid color over-write outside vein walls and or the any intraluminal echoes. Document abnormal findings from two views; longitudinal and transverse. Not required to measure the Doppler angle but remember use angles less than 60 degrees to maximize the returning Doppler signal.

Fig. 1: a) stent diameter



b) minimal lumen(flow) diameter



Lower Extremity Veins - Compression:

Examine from the saphenofemoral junction to the confluence of the popliteal tibial veins. Document the absence or presence of venous disease at all levels. Veins must fully compress in the transverse view. Use cineclip clips to document compression and release/opening of compressed vein or side by side split screen pre and post compression. This confirms the sonographer did not roll off the vein during the compression maneuver. Continue compressions moving inferiorly at 1-2 cm increments from the saphenofemoral junction to femoral vein and into the popliteal vein. The entire course of each segment should be compressed. If probe pressure does not completely collapse the vein, increased pressure should be used – if the accompanying artery begins to deform then adequate pressure is confirmed. Any area that does not compress must be evaluated from both sagittal and transverse views to determine the reason for lack of compression. If a vein segment does not compress, the gray scale image should be enhanced to identify the absence or presence of low level echoes. If echoes are present where the vein is not compressible, the location and extent of the thrombus, the vessel size, and the absence or presence of flow should be documented (fig.1)

Common femoral and popliteal vein perform residual diameter measurements, in a transverse view (fig. 2). Optimize settings to detect any low-level echoes (fig. 2). Document spectral Doppler waveforms from all segments. Document respiratory variation at all levels (fig.3). If occluded segment, include one spectral Doppler image to document absence of flow. The transducer frequency should be selected based upon the depth of the vessel. Attention should be paid to ensuring patient comfort to minimize muscular rigidity during external compression with the probe.

Fig. 2: Non-compressible segment; how to measure the residual diameter and set gain level to display intraluminal echoes

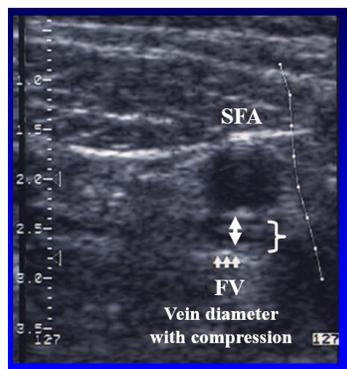


Fig. 2

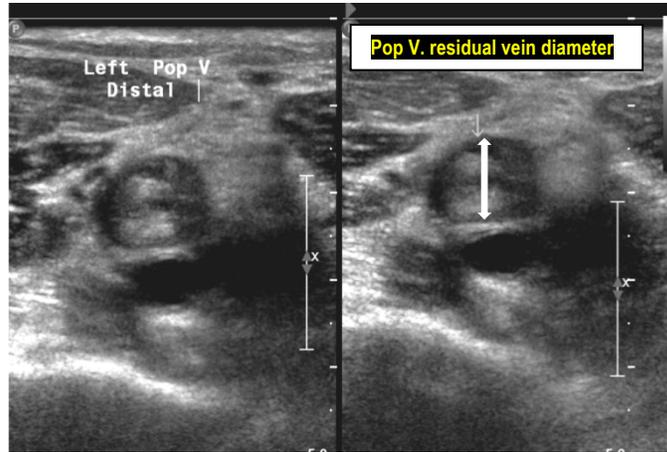
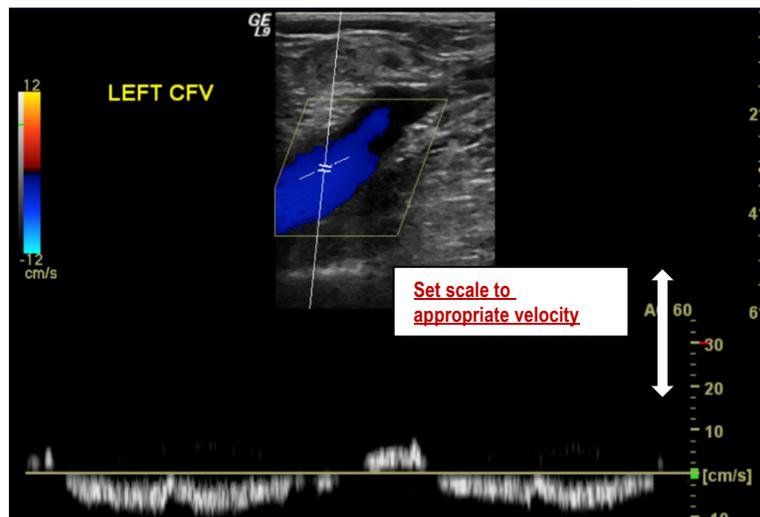


Fig. 3: Phasicity documented with Spectral Doppler



Lower Extremity Veins – Pulsed and Color Doppler

From a longitudinal view, place the Doppler sample within the lumen of the vein. Not necessary to measure the Doppler angle however angles over 60 degrees are not acceptable. Assess venous flow for spontaneity, respiratory phasicity and if necessary, use augmentation to document variation.

Characteristics of a normal venous Doppler signal are:

- 1) Spontaneous: Blood flow present without augmentation maneuvers
- 2) Respiratory phasicity: Blood flow velocity changes with respiration or Valsalva
- 3) Augmentation: Blood flow velocity increases with distal limb compression or with release proximal limb compression

Interpretation of Ultrasound Exams:

Exam interpretation will be based on the following criteria: 1) compression unequivocally excludes the presence of thrombus; 2) when compression is limited, such as in the iliac veins, the diagnosis is weighted more heavily on the Doppler waveform findings, the gray scale b-mode image, symmetry of both common femoral vein waveforms, and the presence of color flow (the absence of color flow by itself does not necessarily indicate DVT or vein occlusion) and comparison between baseline and 6-month sonogram. A test is negative when the vein compresses (the vein walls coapt) when extrinsic pressure is applied; the lumen of the vein is echo-free; and the venous spectral Doppler waveforms and color Doppler document normal flow patterns and normal color filling.