Criteria for defining significant central vein stenosis with duplex ultrasound

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Objective: **To determine criteria for a clinically significant vein stenosis with duplex ultrasound (DU) in patients with signs and symptoms of central venous outflow obstruction.**

Methods: **Patients referred with swelling with or without pain to the vascular laboratory to detect vein obstruction were evaluated. These were mostly patients who had liver transplant, dialysis access, and tumors. All patients had DU prior to any other imaging. Only patients who subsequently underwent phlebography with intention to treat the vein stenosis were included in the study. A phlebogram with two views, pressure measurements across the stenosis, and intravascular ultrasound in selected cases were performed in all patients with suspected stenosis on DU. Adjacent ipsilateral normal vein segments were utilized as controls. The invasive tests were performed within 2 weeks of the DU. Follow-up was performed with DU at discharge and within 6 months of the procedure. A pressure gradient of =3 mm Hg across the stenosis was used to define a >50% diameter reduction, which was also determined by phlebographic measurement.**

Results: **Thirty-seven patients, 20 males and 17 females, mean age 54 years, range 27 to 79, were evaluated. Forty-one stenotic venous sites were detected with DU; inferior vena cava 14, superior vena cava 2, portal 2, iliac 11, common femoral 3, brachiocephalic 3, subclavian 5, and axillary vein 1. Phlebography identified 37 of these stenoses and demonstrated two more not seen by DU. Pressure measurements confirmed 39 of those detected by DU. The best criterion by DU to detect a >50% stenosis was a poststenotic to prestenotic peak vein velocity ratio of 2.5. The presence of poststenotic turbulence and planimetric calculations of the diameter reduction increased the diagnostic confidence but not the accuracy. Using the pressure gradient of ≥3 mm Hg as a reference test, there were two false positive and two false negative exams with DU, while phlebography had two false negative exams. The overall agreement of DU alone was 90% of phlebography >95% and when combined 100%. Intravascular ultrasound identified correctly all 11 lesions in 11 patients. After angioplasty and stenting, there was a dramatic reduction in the edema in most patients particularly in those that had a caval stenosis. Restenosis was identified by DU in 5/29 (17%) patients at 6 months that were confirmed by phlebography and pressure measurements. Reintervention was performed in four and it was successful in three.**

Conclusions: **DU is a sensitive method to identify a clinically significant vein stenosis. A peak vein velocity ratio of >2.5 across the stenosis is the best criterion to use for the presence of a pressure gradient of =3 mm Hg. DU can be used to select patients for intervention and also to monitor the success of the treatment during follow-up. (J Vasc Surg 2007;46: 101-7.)**

Treatment of chronic venous disease (CVD) is based on relief of reflux and obstruction.[1] Detection and treatment of venous stenosis that may contribute to signs and symptoms of CVD has only recently been investigated.[2,3] Vein stenosis is diagnosed by phlebography, or intravascular ultrasound and being confirmed by the pressure gradient across the stenosis.[2,3] Currently, it has not been determined what degree of vein stenosis is hemodynamically significant. Also there are no criteria for determining vein stenosis with duplex ultrasound (DU). DU offers a significant advantage on being noninvasive, cheap, and easily repeatable test compared with the other techniques. Therefore, the aim of this study was to develop criteria to detect central vein stenosis by DU in patients with signs and symptoms of venous outflow obstruction.

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Competition of interest: none.

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0741-5214/$32.00

doi:10.1016/j.jvs.2007.02.062

PATIENTS AND METHODS

Patients referred with swelling with or without pain to the vascular laboratory to detect stenosis or occlusion of their veins were evaluated. These were mostly patients who had liver transplant, dialysis access, and tumors. The location of the vein stenosis and the reasons associated with its cause and investigation are seen in Tables I and II. All patients had the DU prior to any other venous imaging. Only patients who subsequently underwent phlebography with intention to treat the vein stenosis were included in the study. A phlebogram with two views, pressure measurements across the stenosis, and intravascular ultrasound in selected cases were performed in all patients with suspected stenosis on DU. Adjacent ipsilateral and also contralateral normal vein segments were utilized as controls. The invasive tests were performed within 2 weeks of the DU. Follow-up was performed with DU at discharge and within 6 months of the procedure.

Thus, patients selected for this study were limited to those with the following criteria: presence of limb swelling and vein stenosis identified by ultrasound subsequently

Table I. Location of vein stenosis

Vein	*Number of patients*	*Number of stenoses*	*%*
Inferior vena cava	13	14	34
Superior vena cava	2	2	5
Portal	2	2	5
Common iliac	7	9	22
External iliac	2	2	5
Common femoral	3	3	7.3
Brachiocephalic	2	3	7.3
Subclavian	5	5	12
Axillary	1	1	2.4
Total	37	41	100

undergoing a two plane phlebography with pressure measurement of a gradient ≥3 mm Hg.

Duplex ultrasound. The veins were imaged with different transducers based on their location and depth. Compression of the vein by the transducer was avoided by applying very low pressure in the skin or by using an ultrasonic window through which vein compression did not occur. Velocity measurements were taken before and after the area of stenosis. Velocities were also obtained from normal venous segments. The peak vein velocity (PVV) was measured three times. The PVV ratio of the poststenotic (V2) to prestenotic (V1) PVV was used to calculate the significance of the stenosis.

The angle of insonation was set at <60° and parallel to the flow channel in the lumen. The sample size was kept small and placed at the area with the brightest color. The color gain was adjusted to a level where flow was shown into the lumen without saturating the vein wall and the surrounding tissues. The color box was set in the best possible angle and was kept very small to allow the best frame rate. The pulse repetition frequency was kept at low levels <1500 Hz in normal vein segments and was increased at areas with stenosis to allow flow to be seen only in the flow channel. The B-mode was set to show an anechoic lumen with the focus placed in the far wall.

Mosaic color indicating poststenotic turbulence, abnormal Doppler signal at the area of stenosis, slow flow, spontaneous contrast, poor augmentation, contralateral asymmetry in the absence of inferior vena cava (IVC) or superior vena cava (SVC) obstruction, and vein dilatation prior to the stenosis were also used for the detection of stenosis. The vein diameter reduction was also measured by planimetry by comparing the smallest lumen with the normal lumen. The luminal reduction was measured on B-mode, color, and power Doppler in the longitudinal and transverse view. A >50% stenosis was calculated by the diameter reduction and also by an area reduction of >75%. The PVV ratio was >2.0.

The common femoral vein was imaged using a 4 to 7 MHz linear array transducer without applying any pressure in the skin as a slight compression can reduce the femoral vein diameter. The external iliac, common iliac, IVC, and portal vein were assessed with a 2 to 4 MHz curvilinear transducer. The iliac veins and IVC were imaged along their course using different views at the paraumbilical area, midline and both lateral sides from the line that connects the superior iliac spine with the umbilicus. The suprarenal IVC was visualized through the liver and the subxyphoid space. The entrance of IVC into the right atrium was imaged with a phased array transducer when the window obtained with the curvilinear transducer was not adequate. The portal vein was imaged directly through the liver.

The SVC and brachiocephalic veins were assessed through the supraclavicular space next to the suprasternal notch. A 5 to 8 MHz phased array with a very small foot print was used to allow for optimal imaging of these vessels. The subclavian vein was imaged with a 4 to 7 MHz linear array transducer by placing it obliquely over the clavicle. This window allows seeing the subclavian vein before and after the clavicle at the same view. The only part that is not seen is the segment directly under the clavicle. Stenosis at this level is easily detected with ultrasound because the velocity is always higher at the exit of the stenosis, which on this occasion is proximal to the clavicle. The axillary vein was evaluated through the infraclavicular space and the axilla.

Phlebography. Large vein anatomy was evaluated angiographically with digital subtraction angiography using multiple oblique projections. Whenever possible, orthogonal imaging was obtained simultaneously (biplane) in order to conserve total administered IV contrast load. Contrast was power injected in a robust fashion (ie, inferior vena cava was usually evaluated with injection of 20 cc per second for 2 seconds). Image acquisition rate was at least two frames per second. A stenosis of >50% was determined by phlebography when both average of the two views exceeded this number.

Intravascular ultrasound. Intravascular ultrasound (IVUS) was used to evaluate venous anatomy when questionable finding was present on phlebography (reduced contrast intensity, local jet flow, irregular luminal pattern without being certain for the presence of significant stenosis), on cases with disagreement between phlebography and pressure gradient or when renal insufficiency limited the use of iodinated contrast. It was mostly used in the IVC and iliac veins to evaluate residual thrombosis, lesion anatomy, stent size and perfecting the apposition of the stent placement. A 12.5 or 20 MHz IVUS transducer (Sonicath Ultra; Boston Scientific, Maple Grove, Minn) was inserted into the venous segment through the appropriate size sheath. Images were obtained with catheter pullback to assess for venous size, degree of stenosis, and intraluminal thrombosis. The morphology of the stenosis, wall thickening, and the presence of intraluminal webs were recorded. Both the area and the diameter reduction were measured. The precise percent stenosis and are reduction were calculated. An area reduction of >75% was considered to be >50% stenosis in diameter.

Intravenous pressure measurements. Pressure measurements were obtained across all stenotic segments. When possible, pressures were obtained simultaneously

Table II. Associated procedure and pathology

Vein	*Liver transplant*	*Tumor*	*Dialysis access*	*Cardiac catheter*	*Compression syndrome*	*Portal hypertension*
Inferior vena cava	12	1	0	0	0	0
Superior vena cava	0	1	1	0	0	0
Portal	0	1	0	0	0	1
Common iliac	0	1	0	0	6	0
External iliac	0	1	0	1	0	0
Common femoral	0	0	0	3	0	0
Brachiocephalic	0	0	2	0	0	0
Subclavian	0	0	3	0	2	0
Axillary	0	0	1	0	0	0
Total	12	5	7	4	8	1

with a coaxial sheath/catheter system proximal and distal to a stenosis with two pressure transducers. More commonly a single pressure transducer was used to record pressure measured with pull back of the intravascular catheter across the region of stenosis. Mean pressures were recorded and read for comparison at leach location. A pressure gradient of ≥3.0 mm Hg across the stenosis was set to determine a >50% diameter stenosis.

Statistical analysis. Analysis of the data was performed with a two-sided *t* test for the difference of the means of the PVV and ratios in the normal and the stenotic vein segments. The imaging tests were compared with the pressure gradient across the stenosis. However, since the patients were selected and no patients with normal veins were studied no testing was performed for positive and negative predictive values. Also the selection of the patients would have biased significantly these values. Patients with a gradient of <3 mm Hg were not included, although in some occasions they had significant stenosis on imaging tests. Life tables were not used due to the short follow-up and the valid or invalid exit of patients at 6 months and later.

RESULTS

Thirty-seven patients with 41 stenotic venous sites were assessed. There were 20 males and 17 females with a mean age of 54 years ranging from 27 to 79 years. All patients had swelling in at least one extremity and 29 of them had also pain. All 13 patients with IVC stenosis, the two patients with SVC stenosis, and one patient with bilateral brachiocephalic vein stenosis presented with bilateral edema. The edema in these patients was significant extending almost throughout the extremities. Three patients with previous thrombosis had skin changes. Three patients that had all tests were excluded because they had a PPV ratio of 2.7, 2.9, and 3.2 but a pressure gradient of 1, 1, and 2 mm Hg, respectively.

Forty-one lesions were detected by DU and their location and number are seen in Table I. Most stenoses were found in the IVC and iliac veins. The associated pathology and procedures performed in the patients that were responsible for the veins stenosis are displayed in Table II. Stenosis of the inferior vena cava after liver transplant, compression of the iliac veins, dialysis access procedures, and tumors were the most common (Fig 1). The mean ±SD value for the PVV at the exit of the stenosis was 112 ± 22 (median value 91) and ranged from 55 to 294 cm/s whereas in the normal vein segments was 28 ± 8 (median value 25), range 14 to 49 cm/s ($P < .0001$). The PVV distal to the stenosis was lower than the normal vein segments 12 ± 7 (median value 10), range 5 to 26 cm/s ($P < .0001$). The V2/V1 was 5.3, ranging from 2.5 to 15 and in the normal segments was 0.98, range 0.83 to 1.17 ($P < .0001$). The values for the PVV velocity ratios and pressure measurements are seen in Table III.

The comparison of imaging techniques with the pressure gradient across the stenosis is shown in Table IV. A V2/V1 >2.5 yield the best results for the DU having only two false positive and two false negative tests. A V2/V1 >2.0 did not increased the sensitivity because two lesions were completely missed by DU. Also this cut-off value had two more false positive tests. The two stenoses that were missed by ultrasound were detected by phlebography. There were two false negative cases with phlebography that were classified as 35% and 40% diameter stenosis but IVUS demonstrated a 65% and 70%, which was also confirmed by the pressure gradients of 4 and 5 mm Hg, respectively.

Eleven stenoses in 11 patients were evaluated by IVUS and were in complete agreement with the pressure gradients as all had a ≥3 mm Hg. In four patients, the stenosis shape was circular matching the size of the transducer in two was irregular and in five was a flattened eclipse (Fig 2). Intraluminal webs were detected in four. In two patients, the webs were found by DU but phlebography did not depict any. Wall thickening was seen in three cases one of which was identified by DU but none were detected by phlebography.

Planimetric 2D evaluation of the stenosis by DU was accurate in the femoral, axillary and subclavian veins but it overestimated the degree of stenosis in two patients with iliac, two patients with IVC, and it was not possible to be performed in three cases. The mosaic color at the stenotic area was not well seen in four cases where the depth of imaging was >13 cm and it was present in three other patients who had a <50% stenosis. In 17 patients with unilateral femoral, iliac, brachiocephalic, subclavian, and axillary vein stenosis the contralateral signal had a significant asymmetry in 14.

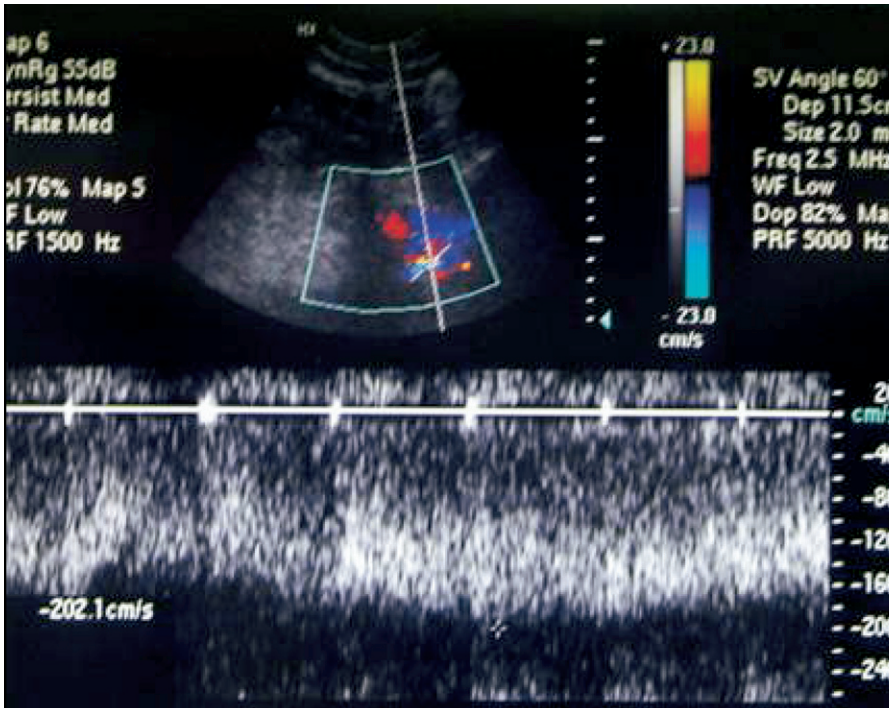

Fig 1. Color ultrasound picture of the common iliac vessels in a patient who presented with swelling and pain. The left common iliac was compressed by the right common iliac artery. The vein had a narrow lumen at the compression site 1.2 mm where distally its diameter measured 14 mm. There was mosaic color flow at the exit of the stenosis, which was much brighter than the color of the iliac artery. The peak vein velocity at the exit of the stenosis was 202 cm/c and 18 cm/s in distally giving a velocity ratio of 11. The waveform in the common femoral vein was continuous with small flow augmentation on distal limb compression and asymmetrical to the normal waveform of the right common femoral vein.

Table III. Pressure gradient, velocity measurements and ratios across the stenosis

	Mean	*Median*	*IQR*	*Range*
Δ*P*	7	6	4-9	3-22
V2/V1	5.2	4.9	3-8	2.5-15
V2/V1 normal	0.98	0.95	0.87-1.05	0.83-1.17
PVV after stenosis	112	91	79-173	55-294
PVV before stenosis	12	10	7-15	5 to 26
PVV control	28	25	19-36	14-49

Δ*P*, Pressure difference across the stenosis; *V2/V1*, velocity ratio across the stenosis; *V2*, poststenotic velocity; *V1*, prestenotic velocity; *PVV*, peak vein velocity; *IQR*, interquartile range.

Table IV. Comparison of imaging techniques with pressure gradients across the stenosis

	Δ*P*	*False negative*	*False positive*
Duplex ultrasound	37	2	2
Phlebography	39	2	0
Intravascular ultrasound	11	0	0

Using a cut-off value of 3 mm Hg for the pressure gradient across the vein stenosis, the overall agreement with DU alone was 90%, for phlebography 95% and when combined 100%. Four stenoses were present for part of the venous cycle as there was an interchange with high and lower velocities. These were affected by the respiration and the change in the right atrial pressure where the affected vein was intermittently compressed and decompressed. The lower velocities measured were always significantly greater than the control measurements at the prestenotic vein segment and were found only in areas with extrinsic compression. However, the pressure gradient in all four cases was ≥3 mm Hg.

Within a few hours from the intervention (angioplasty and stenting) and in the next few days, there was a dramatic reduction in the edema. The edema resolved completely only in five patients since other reasons were also responsi-

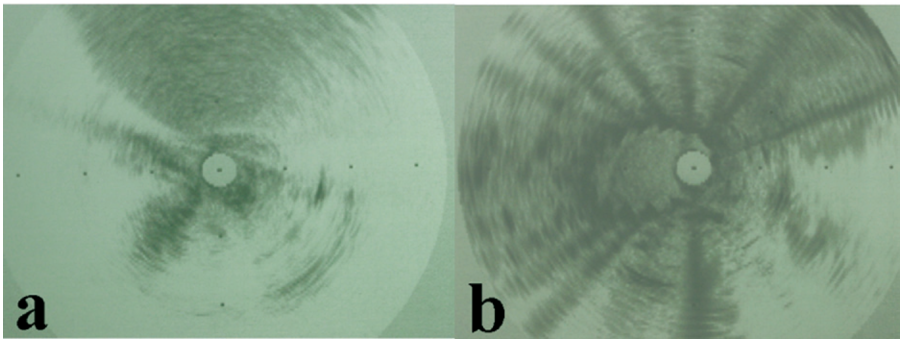

Fig 2. Assessment of the left common iliac vein stenosis with intravascular ultrasound. **a,** At the site of the stenosis the vein diameter matches the size of the catheter. **b,** After angioplasty and stent deployment the vein lumen is near normal size. The pressure in the inferior vena cava was 9 mm Hg and in the left external iliac vein 31 mm Hg giving a gradient of 22 mm Hg. After the angioplasty the venous pressure gradient was 8 mm Hg and following the stent placement it dropped at 2 mm Hg.

ble for the edema. Of the 37 patients, 29 had a follow-up at 6 months. Three patients had died, two were admitted in a local hospital for other reasons, and three did not come. Restenosis was identified by DU in 5/29 (17%) patients at 6 months that were confirmed by phlebography and pressure measurements. Reintervention was performed in four, and it was successful in three. One patient with iliac and one with brachiocephalic vein stenosis developed thrombosis within 2 months of the procedure.

DISCUSSION

Currently, there are no criteria for determining clinically or hemodynamically significant vein stenosis by DU. The main reasons for this are the wide unrecognized clinical importance of vein stenosis as even many specialists often do not look for it and because most areas at which the stenosis occur are technically challenging to investigate and training for this is lacking. Also, the complexity of the venous lesions and the lack of definition for a significant stenosis have made its evaluation harder. Our group has a long standing interest on this topic, and we often deal with patients having vein stenosis. The recent publications on the treatment of significant vein stenosis that have demonstrated relief of the patients' symptoms emphasized the need for its detection. The patient population in the current study was typical of a University hospital, and therefore, it was possible to evaluate patients from many disciplines.

The best DU criterion for detecting significant vein stenosis was a V2/V1 >2.5. Previous work on arteries and has shown that a V2/V1 >2 has a great sensitivity in detecting a >50% stenosis, but it may be not as good in detecting subcritical lesions.[4-6] In most patients, provocation tests were not used, and therefore, it is possible that some subcritical lesions have been missed. According to the equation of continuity (A1V1 = A2V2) that relates flow in two adjacent points in a tube the V2/V1 ratio seems appropriate.[7] This ratio has also been used for detecting stenosis in the dialysis access and in the portal vein.[8,9] A V2/V1 >3.0 has been used for detecting a significant stenosis in the portosystemic stents and the anastomosis of the dialysis access and a V2/V1 >2 for the vein proximal to the anastomosis.[8-11] The hemodynamics of stenosis in the arteries and arteriovenous fistulae are different form those in the veins, and they may be not comparable. However, there is a similarity across the stenosis regarding the V2/V1 ratio as seen in our data. In the current study using a V2/V1 >2 there were four false positive tests compared with only two using a ratio of >2.5, and therefore, the latter was chosen as a better cut-off value. Two stenoses in two different patients were missed by DU but were identified by phlebography. One of these was early in our study in a patient with cavo-atrial stenosis after liver transplant and the second was in a brachiocephalic vein that had multiple collaterals.

Using a venous pressure gradient of ≥3 mm Hg to detect a >50% may be not ideal as this has never been determined. In fact, significant stenosis detected by intravascular ultrasound may have a lesser gradient. However, the value was selected using our experience. In the presence of such gradient, there was always significant stenosis. We asked many experts in the field who also thought similarly. Such a pressure gradient in the venous system may select a higher degree of diameter stenosis. Definitely, more work is needed to determine the best cut-off value for vein stenosis using the pressure gradient. The gradient was measured by pull back of the catheter across the stenosis. The simultaneous two catheter technique is better, and it was used in a few occasions and the difference was <2 mm Hg between the two techniques. We do not have any reproducibility data, and this is a limitation of our study. However, the mean pressure gradient was 7 mm Hg. Most patients had a pressure, which was >3 mm Hg so this would not be much of a problem.

Patients with a pressure gradient of <3 mm Hg were excluded because we wanted to include patients that had a clinical relevance. A gradient of <3 mm Hg often did not produce significant symptoms. This is pilot study, and we wanted to make sure that a "significant" stenosis can be detected by ultrasound in experienced hands. Extrinsic compression and intrinsic problems gave similar waveforms and velocity changes. What mattered the most was the degree of luminal narrowing. In several cases, what appeared to be a significant stenosis on DU or phlebography the DP was <3 mm Hg. Evaluation of vein stenosis is not simple as many other factors may play role. The length of the stenosis, vein compliance, flow rate, and the number and size of vein collaterals can affect the pressure gradient across the stenosis. Clearly, this is a pilot study and the first attempt in the literature to define vein stenosis by DU. A larger study using the current experience is necessary to evaluate the different degrees of vein stenosis, their role in the development of signs and symptoms, and the effect of treatment on the quality of life of the patients.

Contralateral asymmetry of the Doppler waveform in unilateral stenosis, low amplitude signals, which are symmetrical during IVC, SVC, or bilateral vein stenosis, mosaic color at the exit of the stenosis, and poor flow augmentation are good indicators for suspecting vein stenosis. In the presence of any of those signs, the threshold for looking for vein stenosis should be very low. If the investigator has no experience in detecting significant vein stenosis with DU then another imaging modality should be performed to detect a possible stenosis or occlusion.

The morphology of the stenosis was best described by IVUS. This method has the highest resolution as a very high frequency transducer is used at the shortest possible distance from the stenosis. This is in contrast to DU where a low frequency transducer is used because of the large distance. Despite of these limitations, wall thickening and intraluminal webs were detected by DU in some patients but none of them were seen on phlebography. This is expected as phlebography depicts only the contrast in the lumen. The luminal webs are completely covered by the contrast and thus, are not depicted. Because of its high resolution IVUS is superior to both DU and phlebography in estimating the degree of stenosis, in describing the wall and luminal characteristics and allow stent deployment with the best possible wall apposition. However, because of its added costs and the unproven advantage for routine use is applied in most centers selectively. The combination of DU and multiplanar phlebography offers near excellent imaging for vein stenosis. Both these methods are operator dependent and the results are far from being optimal when there is small experience.

Other methods applied for detecting vein stenosis is magnetic resonance venography (MRV) and computer tomographic venography (CTV). These methods have been used mostly in the venous thromboembolism. However, there are recent reports with MRV showing great results for detecting stenosis in patients with common iliac vein compression. MRV, though, is not currently used to guide interventional treatment; this is not the method of choice. Recently, angioplasties were performed in the lower extremity arteries with MRA guidance,[12] and it is possible that in the future MRV could be used to guide endovenous procedures.

The clinical significance of the stenosis was very clear in our study as the patients had swelling and/or pain, which were relieved after angioplasty and stenting. The results were very impressive particularly in the patients with IVC and SVC stenosis. Other studies have shown significant relief of the patients' signs and symptoms after the endovenous treatment of the stenosis.[3,13,14] Good results have also been reported in treating IVC stenosis.[15,16]

DU is a great method for following up venous interventions since restenosis, thrombosis, and reflux can be detected. In the current study, restenosis and thrombosis were found during the follow-up. Such patients can be treated appropriately so that their symptoms could be relieved and possibly prevent sequellae that may occur later. It should be noted that this work has determined significant stenosis by DU only in the presence of a pressure gradient ≥3 mm Hg. Further work is needed to evaluate the best parameters for a hemodynamically and/or clinically significant stenosis.

AUTHOR CONTRIBUTIONS

Conception and design: NL, MB
Analysis and interpretation: NL, MB, PP
Data collection: NL, MB, KP
Writing the article: NL
Critical revision of the article: NL, MB, KP, PP
Final approval of the article: NL, MB, KP, PP
Statistical analysis: NL
Obtained funding: Not applicable
Overall responsibility: NL

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Submitted Sep 26, 2006; accepted Dec 5, 2006.