Diagnostic yield of intravascular ultrasound in patients with clinical signs and symptoms of lower extremity venous disease

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ABSTRACT

Background: Intravascular ultrasound (IVUS) examination has a higher sensitivity compared with venography in the assessment of obstructive venous disease. However, at most venous centers, both modalities continue to be used concomitantly. This study evaluated the diagnostic clinical yield of IVUS examination as a singular intraoperative investigative modality in patients in whom clinical signs and symptoms of venous disease were severe enough to merit such an examination and in whom a venogram was not performed simultaneously.

Methods: From January, 2013, to December, 2018, there were 31 limbs (29 patients) who only had IVUS planimetry without concomitant venogram. Clinical parameters such as pain, swelling and Venous Clinical Severity Score were measured preoperatively and postoperatively. The degree of stenosis noted on intraoperative IVUS was compared with the preoperative duplex. Incidence of complications, technical success, and clinical yield of IVUS examination were noted.

Results: The etiology of venous lesion was post thrombotic in the majority of patients (74%). All patients (100%) were either in Clinical, Etiologic, Anatomic, and Pathologic class C3 or higher. In all patients (100%) taken to the operating room, IVUS examination identified stenosis in at least one of the following three veins: common iliac vein, external iliac vein, and common femoral vein. Intervention was in the form of angioplasty with endovenous stenting. There was significant improvement in pain, swelling and Venous Clinical Severity Score after the intervention.

Conclusions: IVUS is an effective diagnostic tool that displays high quality, real-time cross-sectional anatomy during venous interventions. When used as the sole intraoperative diagnostic modality, it seems to have a high clinical yield in patients in whom signs and symptoms of venous disease are severe enough to merit intervention. (J Vasc Surg: Venous and Lym Dis 2019;■:1-6.)

Keywords: IVUS; Intravascular ultrasound; Iliac vein stent; Chronic venous disease; Endovenous stent

Intravascular ultrasound (IVUS) examination is a sensitive modality to assess stenotic iliofemoral venous lesions compared with multiplanar venography.[1] Previously described sensitivity of IVUS for nonthrombotic iliac vein lesions (eg, May-Thurner syndrome) is greater than 85% to 90%, whereas the sensitivity of venogram for nonthrombotic iliac vein lesions is 66%.[2] The Venogram vs IVUS for Diagnosing Iliac Vein Obstruction (VIDIO) trial demonstrated that IVUS examination can lead to the modification of treatment strategies for patients with venous disease.[1] Also clinical improvement after stenting was better predicted by IVUS measurements of area stenosis compared with venographic measurement of the same parameter.[1]

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Author conflict of interest: S.R. holds stock and receives royalties from Veniti Inc; holds a US Patent for IVUS diagnostics and iliac vein stent design.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

2213-333X

https://doi.org/10.1016/j.jvsv.2019.10.021

In practice, it seems that either venography-guided treatment or combined IVUS- and venography-guided treatment continue to be used at the majority of venous centers. As a modality, venography is more readily accessible and less expensive than IVUS examination.[3] However, IVUS examination is more sensitive than venography. Despite the higher sensitivity of IVUS examination compared with venography, there are very little data about the clinical yield of IVUS as the sole intraoperative diagnostic modality without the concurrent use of venography.

The aim of this report was to ascertain the diagnostic clinical yield of IVUS examination as a singular intraoperative investigative modality in patients in whom the clinical signs and symptoms of venous disease were severe enough to merit such an examination and in whom venogram was not performed concomitantly.

METHODS

Type of research study. This is a single-center study (three surgeons). All data were contemporaneously entered into a time-stamped electronic medical record and analyzed retrospectively. Informed consent was obtained from patients. Institutional review board permission was granted for publication of the study.

Patient selection. From January, 2013, to December, 2018, records of all patients who only had IVUS planimetry without a concomitant venogram were retrospectively analyzed for this study. Intraoperative venography was not used in patients with compromised renal function such as advanced stage renal disease or in patients with a history of severe anaphylaxis or allergy to the contrast dye. These were patients in whom clinical signs and symptoms, clinical history, and preoperative investigative studies were all suggestive of venous disease and for whom the symptoms were significant enough to interfere with work or daily living or both. These patients had failed conservative therapy (including measures such as leg elevation, use of graduated compression stockings [30-40 mm Hg], and local wound care). Conservative therapy was attempted in all patients for at least 6 months before consideration of surgical intervention. All patients with nonvenous causes of limb symptoms were excluded from the study. All patients (100%) were either in Clinical, Etiologic, Anatomic, and Pathologic (CEAP) class C3 or higher.

Clinical parameters. Swelling was assessed by physical examination and was graded from 0 to 3 (grade 0, none; grade 1, pitting, nonobvious; grade 2, ankle edema; and grade 3, obvious swelling involving the limb). Pain was assessed by the visual analog scale (0-10).[4,5] The Venous Clinical Severity Score (VCSS) was also assessed. These clinical parameters were assessed preoperatively, then at 6 weeks after the intervention, and at 3- to 6-month intervals thereafter. Data from the most recent follow-up were used for analysis. Swelling was considered improved if there was an improvement of at least one grade.[4] Pain was considered improved if by visual analog scale, there was an improvement of at least 3 points (3/10).[4] A change in VCSS of at least 4 was considered as indicative of clinical improvement. Ulcer healing was defined as complete epithelization. The etiology of the venous lesions was classified as either post thrombotic or nonthrombotic. The distinctive features of each of these lesions have been outlined in detail in a previous study.[2] This classification was based on the appearance of the lesions on IVUS examination, preoperative investigative studies, and clinical history (eg, previous history of deep venous thrombosis [DVT]). In appropriately selected patients, thrombophilia testing was also performed. The full panel of thrombophilia tests performed at our venous center has been reported previously.[6]

Preoperative evaluation. Duplex technique for examinations performed in our clinic and IVUS technique performed in the operating suite have been described previously in detail.[2,4] Similar to IVUS examination, cross-sectional area is used to measure the percentage stenosis in the vein using duplex ultrasound examination. Although sometimes limited by large body habitus or presence of bowel gas, duplex ultrasound examination seems to be reliable as a noninvasive preoperative investigative modality in delineating iliac vein stenosis. In one prior study, ultrasound examination seemed to have high agreement with IVUS examination for the detection of iliac obstructions of at least 50%.[7] With improvements in current technology, better image resolution and greater depth of penetration with ultrasound examination have proven to be helpful in noninvasive imaging of iliocaval venous segments.[8] Appropriately selected patients underwent a comprehensive preoperative evaluation including duplex scan, ambulatory venous pressure measurements (percent drop, venous filling time, and air plethysmography venous filling index). A valve closure time of more than 0.5 seconds on duplex scan was defined as reflux.[2] All patients in this study had preexisting renal failure. In addition, two of the patients had a history of severe allergy or anaphylaxis to contrast dye. Therefore, they were not subjected to contrast preoperatively in the form of transfemoral venography, computed tomography venography, or magnetic resonance venography.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center, retrospective study
- **Key Findings:** Use of intravascular ultrasound examination in 31 limbs as the sole intraoperative diagnostic modality yielded identification of venous stenosis in at least one venous segment in all patients. Significant improvement in pain, swelling and Venous Clinical Severity Score was noted after the intervention.
- **Take Home Message:** Intravascular ultrasound examination has a high diagnostic yield as a single intraoperative investigative modality in patients with clinical signs and symptoms of chronic venous disease.

Procedural technique. Access was typically obtained at the midthigh or lower thigh femoral vein (second-order vein) followed by the placement of an 11F sheath. This size sheath allows easy introduction and maneuverability of the large IVUS catheter (8.2F, Visions EP .035; Volcano Corp, San Diego, Calif).[3] Access at the midthigh or lower thigh levels is preferred to be able to fully visualize femoral-deep femoral vein confluence. The usual sequence was to perform IVUS examination before balloon dilation and stent placement followed by a completion IVUS examination. The smallest area (greatest stenosis) in the common femoral vein (CFV), external iliac vein (EIV), and common iliac vein (CIV) was captured and stored with the IVUS planimetry.[3] For the performance of stenting, the iliocaval confluence must be identified correctly for two reasons: (a) to prevent the undertreatment of proximal lesions, and (b) to avoid jailing of contralateral iliac vein. Also, the distal landing zone should be carefully selected.[3]

We have previously reported the optimal stent sizes in the CIV, EIV, iliac and CFV segments to be 16 mm (area, 200 mm^2), 14 (area, 150 mm^2), and 12 mm (area, 125 mm^2) in diameter, respectively. These values correspond with the minimal sizes needed for optimal flow calculated from flow equations such as Poiseuille's equation and Young's scaling ratios and IVUS observations of normal iliac vein segments.[4] The adjacent normal segment was not used as a comparator[3]; rather, the IVUS examination was indexed to predetermined caliber for the segment based on measurements in healthy subjects. Presence of long diffuse stenosis (Rokitansky stenosis) in the iliofemoral venous segments pose a unique challenge and can lead to undertreatment of lesions if simply the adjacent venous segment is used as a comparator. A particular vein was considered to be stenosed on preoperative duplex or IVUS examination if the size was smaller than optimal sizes discussed. The goal is to restore the caliber of the diseased venous segments to a level where relatively normal flow and pressure can be expected based on hemodynamic equations and observations in healthy subjects. The grading of venous stenosis is different from arterial stenosis, with venous pressure being a more important component than flow.[9,10] IVUS was used to confirm the position of the wire in the axial vessel. IVUS was used to delineate the iliocaval confluence and the ideal distal landing zone.[3] The location of the iliocaval confluence and the ideal distal landing zone identified by IVUS was also correlated to the adjacent bony landmarks. These bony landmarks included the vertebral body, lower border of the pubic ramus, bottom of the femoral head, ischial crossing, and lesser trochanter.[3] In the majority of the patients, the confluence has been found to be at the level of the L4 vertebral body.[3]

Intervention in this series included stent placement with or without other concomitant procedures such as percutaneous endovenous laser ablation of saphenous vein. The type of stent used was the Wallstent (Boston Scientific, Marlborough, Mass) with the addition of Z stent (Cook Medical, Bloomington, Ind) in some cases where additional radial strength was needed at the iliocaval confluence. Technical success was defined as successful treatment of lesion without intraoperative device complications, establishment or restoration of in-line central venous flow and less than 20% residual stenosis on completion IVUS examination.

Stent surveillance. Our stent surveillance protocol has previously been described in detail.[5] Briefly, stent surveillance was performed at postoperative day 1, at 2 weeks, and at 4 weeks initially. Patients were seen in the clinic at 6 weeks, at 3 months, and at 6 monthly or annual intervals thereafter. Typically, stent surveillance was performed at each of the clinic visits in addition to the first postoperative month. Data from the most recent follow-up were used for analysis purposes. Reinterventions to detect or correct suspected stent malfunction were carried out in patients if symptoms persisted or recurred. The presence of significant in stent stenosis on ultrasound (≥50% area reduction) was used in decision making for reintervention, but was not the sole factor dictating management.[4] The goal of reintervention is to ensure proper stent function and to treat any missed or incompletely treated lesions.[2] Screening for DVT was performed if pattern of symptom recurrence was suggestive of DVT.

Statistical analysis. Statistical analysis was performed using a commercially available statistics program (Prism software; GraphPad Software Inc, La Jolla, Calif). Two-tailed paired and unpaired *t*-tests were used where appropriate. A *P* value of less than .05 was considered significant.

RESULTS

The study included 31 limbs in 29 patients. Demographic details are shown in Table I. The etiology of venous lesion was post thrombotic in 74% and nonthrombotic in 26% of the limbs. Concurrent great saphenous vein ablation was done in one patient (3%). Six limbs (19%) had a venous ulcer preoperatively.

Data for CEAP class are shown in Table II. All patients were either in CEAP class C3 or higher.

Comparison between median area stenosis on preoperative duplex ultrasound and intraoperative IVUS examination is shown in Table III. For the CFV, duplex ultrasound examination measured the stenosis as less compared with the IVUS. For all three veins, the median area stenosis noted on IVUS was higher when compared with the preoperative ultrasound. However, the difference was not statistically significant except for the CFV.

All limbs (31/31) had stenosis noted on intraoperative IVUS measurements in at least one of the following three vessels: CIV, EIV, or CFV. Eighty-six percent had stenosis in at least two of the following vessels: CIV, EIV, or CFV, whereas 53% had stenosis noted in all three vessels. Table IV shows the mean preintervention and postintervention areas in the CFV, EIV, and CIV as noted by IVUS examination.

The median follow-up was 4 months. The mean follow-up for this patient cohort was 3.8 months. Procedural complications were rare; two limbs (6%) had access site hematomas that did not require readmission or intervention. Five patients were noted to have superficial venous reflux in the great saphenous vein. Of them, one underwent endovenous laser ablation performed concomitantly with the IVUS examination. In addition, one other patient had a history of endovenous laser ablation of the

Table I. Demographics of 29 patients (31 limbs)

Age, years, mean (range)	67 (44-87)
Male:female	1:1
Right:left	1:1
Post thrombotic:nonthrombotic	3:1

great saphenous vein on the contralateral leg at a different institution 1 year before presentation to our hospital.

Ulcer healing was seen in 100% of the patients at the time of last follow-up. The mean duration for ulcer healing after intervention was 1.5 months. The mean duration of presence of ulcers before intervention was 9 months. Conservative measures were used for at least 6 months before surgical intervention was considered for nonhealing ulcers.

There was significant improvement in mean pain score (as assessed by visual analog scale), swelling and VCSS (Table V) after the intervention. Data from last recorded follow-up were used for this analysis, which was at least 6 weeks or more after the intervention. For VCSS, 42% patients had a change in the VCSS of at least 4. For swelling, 53% patients had a change of at least 1 grade in their swelling. For pain, 81% patients had an improvement in their pain score by at least 3.

No reinterventions were performed in this patient group. The median maximal in-stent restenosis noted on follow-up ultrasound in CFV, EIV, and CIV was 0%, 18.5%, and 10%, respectively.

DISCUSSION

This study showed that IVUS examination had a high clinical yield when used without concomitant venography. All interventions were technically successful. There was a significant improvement in clinical parameters from before to after the intervention. Also, no reintervention was needed at follow-up, suggesting that there was adequate treatment of the venous lesion with the use of IVUS examination. The use of IVUS examination and associated interventions had an overall excellent safety profile. We had two access site hematomas that did not require readmission or intervention.

For the optimal treatment of a venous lesion, several important factors require recognition. In particular, measurement of degree of stenosis and proper landing zones for stent placement are important.[3] IVUS has several advantages when compared with venography. It provides fine intraluminal and mural details (eg, trabeculations, frozen valves, mural thickness, and outside compression), data about the degree of venous stenosis presenting, the apposition of the stent to venous wall, presence of shelving in case of overlapping stents, and the proximal and distal landing zones for more precise stent placement, as well as visualization of collaterals or branches.[11-13] IVUS can be used with less fluoroscopic exposure when compared with multiplanar venography.[3] Additionally, during recanalization of chronic total venous obstructions, IVUS can be used to confirm the position of the wire in the true venous lumen. IVUS can also demonstrate the degree of in-stent restenosis.[4] Duplex ultrasound examination has been often seen to underestimate the degree of in-stent restenosis when compared with IVUS examination.[4] In our particular subset of patients, the preoperative ultrasound examination underestimated the degree of stenosis in the CFV when compared with intraoperative IVUS measurements.

Both IVUS examination and venography continue to be used in venous procedures. The use of both modalities adds to the overall procedural time. Venography has inherent risks, including allergic reactions to contrast dye, renal toxicity from contrast dye, and increased radiation exposure particularly with multiplanar imaging. Additional findings on venogram such as presence of collaterals, iliac contrast stagnation, or contralateral cross-filling either lack sensitivity or are of uncertain clinical significance. Also, these findings may occur only at greater degrees of stenosis and may not necessarily occur at levels that produce symptoms of swelling or

Table II. Clinical, Etiologic, Anatomic, and Pathologic (*CEAP*) classification distribution

CEAP class	Distribution(%) (N = 31)
C3	9 (29)
C4	14 (45)
C5	3 (10)
C6	5 (16)

Table III. Comparison of median stenosis noted on preoperative ultrasound and intraoperative intravenous ultrasound (*IVUS*) examination

Vein	IVUS	Duplex	*P* value
CFV[a]	9.32%	−8.33%[b]	.04[a]
EIV	30.97%	25.00%	.50
CIV	29.50%	28.75%	.52

CIV, Common iliac vein; *CFV,* common femoral vein; *EIV,* external iliac vein.
[a]Significant.
[b]Negative value indicates measurement was less than IVUS examination.

Table IV. Preintervention and postintervention areas noted by intravascular ultrasound (IVUS) examination

Vein	Preintervention area, mm^2	Postintervention area, mm^2	*P* value
CFV	113 (40-197)	161 (81-234)	<.001[a]
EIV	109 (25-206)	176 (91-259)	<.001[a]
CIV	140 (22 -214)	217 (116-261)	<.001[a]

CIV, Common iliac vein; *CFV,* common femoral vein; *EIV,* external iliac vein.
Values are mean (range).
[a]Significant.

Table V. Comparison of pain, swelling and Venous Clinical Severity Score (*VCSS*) before and after intervention in 31 limbs

Clinical parameter	Preintervention	Postintervention	*P* value
VAS pain	6.5 ± 3.5	1.7 ± 2.7	.0005
Swelling	2.9 ± 0.57	2.1 ± 1.0	.0001
VCSS	7.2 ± 2.8	4.9 ± 2.5	<.0001

VAS, Visual analog scale.
Values are mean ± standard deviation.
[a] Significant.

pain that most patients find disabling or life-style limiting.[2] For example, hemodynamically significant obstruction can exist even without collateral formation.[12] Venography-guided treatment, therefore, has the risk of undertreating patients with venous disease, sometimes in up to one-third of cases.[1] The timing of contrast in venography is also an important consideration.[3] Improperly timed contrast can mask lesions. However, it should be acknowledged that venography may still have a role in patients where IVUS examination cannot clearly delineate venous anatomy; for example, in patients with complex anatomic venous variants or pelvic venous disorders or during recanalization of chronic total occlusions. In our study, we did not encounter any unusual venous anatomy. IVUS examination, with the use of fluoroscopy, was able to provide an adequate road map for intervention based on correlation to adjacent bony landmarks.

It should be noted that the sensitivity of the IVUS is not 100%, particularly at areas of confluence or bifurcation. At these locations, lesions may not be picked up even with the use of IVUS examination because the lesion can cause the tip of the IVUS catheter to angulate toward one side and miss the lesion. In these cases, balloon sizing (a 14- to 16-mm balloon inflated to 1 atm pressure to detect waisting) can be helpful in providing a clue to the presence of an obstructive lesion. Also, the IVUS catheter is not always in the center of the venous lumen or channel and the presence of the wire biases it toward one of the walls. This may lead to underestimation or overestimation of diameters.

Venous hypertension forms the basis of symptoms seen in patients with chronic venous insufficiency. The goal of treating venous stenosis with venous stenting is to reduce the venous pressure by restoration of normal lumen. A 50% threshold has been mentioned in some venous literature as the basis for a critical venous stenosis; however, there is not much evidence in support of how this number was derived. The median amount of stenosis reported in most prominent series is actually greater than 50%. This may be a prevalence statistic likely influenced to some extent by selection bias of the 50% concept in some venous literature; however, it is not proof of a hemodynamic threshold. In our own series of highly symptomatic venous patients, the median stenosis was noted to be about 60%.[14] A 70% threshold is used in the arterial system because perfusion is seen to diminish beyond this critical threshold. A well-known example is the carotid bed, where a 70% stenosis is considered as limiting to flow. Tissue autoregulation is able to compensate to this level of stenosis; beyond this critical threshold, there is a decrease in perfusion.[9] On the venous side, a similar mechanism does not exist.[10] In experimental simulations, stenotic grading in venous models has been shown to be best indexed to normal caliber, which is associated with normal peripheral venous pressure and not to relative stenosis using adjacent caliber.[15] The teleological and intuitive argument to consider normal caliber as the indexing standard can be corroborated by proof of hemodynamic flow equations. In the clinical context, restoration of normal caliber is associated with reduced peripheral venous pressure and improvement in clinical symptoms.[16]

Cross-sectional area was used for the calculation of median stenosis with the IVUS examination. The median value was calculated from multiple same vein segment measurements in different patients. In our experience, the caliber of iliac veins has been uniform in average-sized adults with a variation that rarely exceeds 10%. Iliac veins have a high collagen content and are thin walled. This factor causes them to expand at smaller pressures; assuming an almost circular shape from a more ovoid shape. Hence, the calculation of cross-sectional area using IVUS examination seems to be a reliable venous parameter.[17]

Carbon dioxide venography may decrease some of the risks of traditional venography and has been described in literature along with carbon dioxide angiography.[18] However, we have found the technique to be of limited value in actual venous practice. The delivery system has often been cumbersome and it is difficult to precisely visualize branches and collaterals. Visualization of any lesion on carbon dioxide venography would, in many instances, still require subsequent confirmation by a contrast injection. Last, it still does not obviate radiation exposure to the operator and patient.

Study limitations. The main limitations of the study include retrospective nature, small sample size, single-center location, and relatively short median follow-up. The study was performed in a highly selected group of patients in whom the use of contrast was prohibitive (renal failure or severe contrast allergy). In the future, other patient subsets should be studied to see if similar clinical outcomes are obtained. Stenosis was predicated on criteria that have been calculated based on hemodynamic equations studied in normal, healthy individuals.

CONCLUSIONS

IVUS examination is an effective and feasible diagnostic tool that displays high-quality, real-time cross sectional anatomy during venous interventions. The diagnostic information provided by IVUS examination is superior to venography. When used as the sole intraoperative diagnostic modality, it seems to have a high clinical yield in patients in whom signs and symptoms of venous disease are severe enough to merit intervention.

AUTHOR CONTRIBUTIONS

Conception and design: TS, SR
Analysis and interpretation: TS, AK, SR
Data collection: TS, AK, SR
Writing the article: TS, AK, SR
Critical revision of the article: TS, SR
Final approval of the article: TS, AK, SR
Statistical analysis: TS, AK, SR
Obtained funding: Not applicable
Overall responsibility: TS

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Submitted Jul 31, 2019; accepted Oct 15, 2019.