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VENOUS INSIGHTS

PUTTING THEORY TO PRACTICE

New Concepts and Expert Guidance to Optimize Deep Venous Treatment

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How to Set Up a Venous Practice

Advice to successfully create a comprehensive venous center.

BY GERARD O'SULLIVAN, MD

Most vascular specialists initially train in arterial disease, whether it is coronary, peripheral, or carotid arteries. Others begin by performing arteriovenous interventions on patients undergoing dialysis. The common theme for entry into the endovascular specialty is an arterial-based training. It takes time to understand the processes that guide arterial intervention, leaving a dearth of education, training, and understanding when it comes to venous disease.

Deep vein thrombosis (DVT) affects approximately 1 in 1,000 patients in the Western world. Although the majority of these patients do not require endovascular intervention, it is important to have a local specialist available, and there is a substantial deficit in qualified venous specialists around the world. To become the go-to specialist in a hospital or region, physicians must invest time into understanding all aspects of venous diseases, including often-ignored areas. For instance, venous ulceration has, until recently, been relegated to the corner of the vascular world; however, it can be treated in a significant portion of patients through application of compression stockings as well as by ablation of reflux in varicose vein segments and by restoring flow in deep venous obstructive lesions.

In time, increased focus on venous disease from the medical community not only provides more endovascular intervention, but also profound professional and personal satisfaction for venous specialists who treat these patients.

TEAM RELATIONSHIPS

No single endovascular specialist can realistically take on all the tasks that providing a dedicated venous service entails. Therefore, it is essential that the lead team member forms close relationships with the following members of the care team:

- **Imaging expert:** specialized in imaging services including CT venography and MR venography.
- **Vascular ultrasound expert:** able to perform transvaginal ultrasound to identify pelvic vein congestion, which is considered a niche specialty skill and not easily acquired or readily available.
- **Hematology expert:** a resource to help select the best choice of drugs for specific situations and assist with patients who need further investigation.

Ideally, physicians should also form relationships with other doctors performing deep and superficial venous endovascular procedures. Physicians will need help from time to time, and two heads are better than one.

ESSENTIAL SKILLS

A thorough understanding of venous anatomy as well as familiarity with different anatomic variants is essential for physicians looking to provide this important service. Education can be acquired through attendance at workshops as well as virtual training.

The practitioner should be comfortable with vascular access through various routes, including jugular, brachial, basilica, and popliteal. Some access sites are very basic, such as the common femoral or greater saphenous; others are much more difficult to learn, including the posterior tibial vein in the ankle or tiny neck collaterals.

Imaging expertise takes time but can be learned; acquiring transvaginal ultrasound skills takes longer in my opinion; therefore, hiring an expert for this particular imaging type is crucial.

Prior arterial interventional experience can be a blessing and a curse. Those with experience will have little fear gaining access; however, not all learned arterial nuances translate to venous interventions. For example, there is often an assumed belief that pain upon balloon inflation in a vein signals impending rupture, but this is not true in venous interventions. Open surgical skills are an advantage and often help the advancement of a venous program and provide treatment expertise (eg, the ability to perform common femoral vein endophlebectomy and arteriovenous fistula creation).

REFERRAL OUTREACH

Vascular specialists should be available for consultations to explain their work and role to colleagues. This may be difficult if, as a cardiologist, you are expected to attend every cardiology clinic; or as a surgeon, you need to take endless trauma calls; or as a radiologist, you are expected to cover oncology during multidisciplinary team meetings. However, without detailed explanation, colleagues may expect venous disease cases to walk in the door in the same way that peripheral artery disease cases do. Venous disease is often much more dependent on referrals, so these specialists must be more assiduous.

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CREATING A SUCCESSFUL VENOUS PRACTICE

- Attend dedicated venous meetings.
- Spend time in the vascular lab. Request that the lab notify you when a patient with DVT presents.
- Talk with the emergency department and explain what skills you can offer.
- Communicate. Open a discourse with internists and general practitioners to provide them with context about what treatments you can offer—many are unaware of what services you can provide. Keep in mind that the recent results of the ATTRACT trial won't help your cause without an ongoing dialogue.
- Talk within your hospital about referrals and creating a multidisciplinary team for venous disease cases.
- Give grand rounds to further educate other physicians about venous disease.
- Observe other experts in action, preferably close up when possible.
- Participate in mini fellowships at dedicated centers.
- Learn to walk before you run, and start with short stenoses before attempting long-segment occlusions. Remember, these procedures are not the same as doing arterial cases; in fact, they are often more difficult, certainly in the iliacs. More challenging cases will come gradually.
- Consider forming a pulmonary embolus response team.
- Get involved in trials.
- Publish data.

It is also crucial to visit with patients, regardless of whether you are there to offer an intervention. Be sure to write a note or letter to the primary care physician, the referring specialist, and the patient with detailed information about potential disease progression and treatment offerings. I try to include brochures about available options. Also, although I do not use social media for this, others have employed it with success.

REFLECTION

Setting up a venous practice is not hard—but it is hard work. I personally fell into deep venous work by accident. I originally attended Stanford to learn about aortic dissection from Michael Dake, MD, and Charlie Semba, MD, which was a great honor. But in my next job at Rush Presbyterian Chicago, I saw very few aortic dissections and many more DVTs. I fell in love with venous disease and now perform varicose vein therapy, deep venous reconstruction, and varicocele and pelvic vein embolization. I intervene on many acute iliofemoral DVTs and place a large number of venous stents. It is work I very much continue to enjoy. ■

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Disclosures: None.

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CASE REPORT

Single-Session Endovascular Treatment of Acute Iliofemoral DVT

Pharmacomechanical thrombectomy and venous stenting in a patient with phlegmasia secondary to extensive iliofemoral venous thrombosis.

BY ANDREW WIGHAM, BSc, MBBS, MRCS, FRCR

A 39-year-old woman presented to the emergency department with sudden onset of severe left leg swelling and pain. The patient reported some less severe groin and lower back pain over the preceding few days. A sudden deterioration with evolving phlegmasia, significant skin discoloration, and some mottling were observed in the last 24 hours. In addition, she had pronounced shortness of breath but was hemodynamically stable.

There was no previous history of lower limb deep vein thrombosis (DVT); however, there was a significant family history of thrombosis, and the patient had previously suffered a cerebral venous thrombosis. She was not known to our hematology service and was not on anticoagulation therapy at the time of presentation.

Initial ultrasound imaging demonstrated extensive acute venous thrombus extending from the common femoral vein to the popliteal vein with patent below-the-knee veins. Indirect CT venography confirmed acute descending thrombosis extending from the proximal common iliac vein (CIV) with a tight May-Thurner compression and also venous compression by the left internal iliac artery. The CT pulmonary angiogram showed large bilateral main pulmonary artery emboli with no evidence of right heart strain and a right ventricular/left ventricular ratio < 0.9.

TREATMENT OPTIONS

Due to the severity of symptoms, conservative management with anticoagulation was not considered to be a viable option. Catheter-directed thrombolysis was discussed, but the acuity and severity of the symptoms meant rapid restoration of flow was required. There was some initial reticence to perform pharmacomechanical thrombectomy given the large-volume pulmonary emboli. However, given the absence of right heart strain, we believed it was safe to proceed, albeit with the placement of a temporary inferior vena cava (IVC) filter. We do not typically place IVC filters prior to treating DVTs and usually adhere to the theory that the venous compression point effectively acts as a filter. However, in this case, the sheer volume of pulmonary emboli led our decision to place a filter prior to treatment.

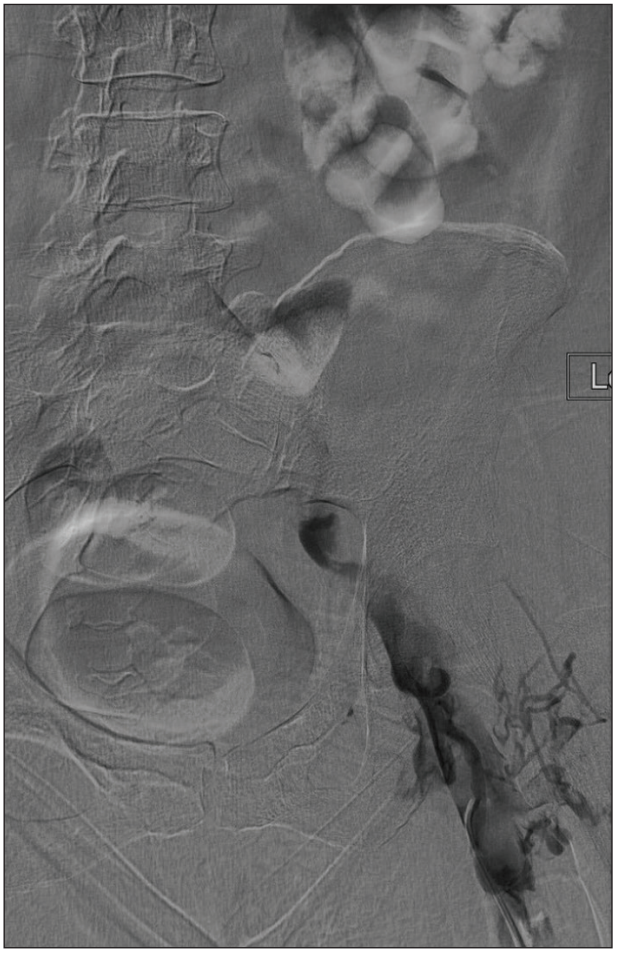

Figure 1. Preintervention venogram demonstrating extensive iliofemoral thrombus and absent flow.

COURSE OF TREATMENT

The procedure was performed in the interventional radiology suite under local anesthetic with conscious

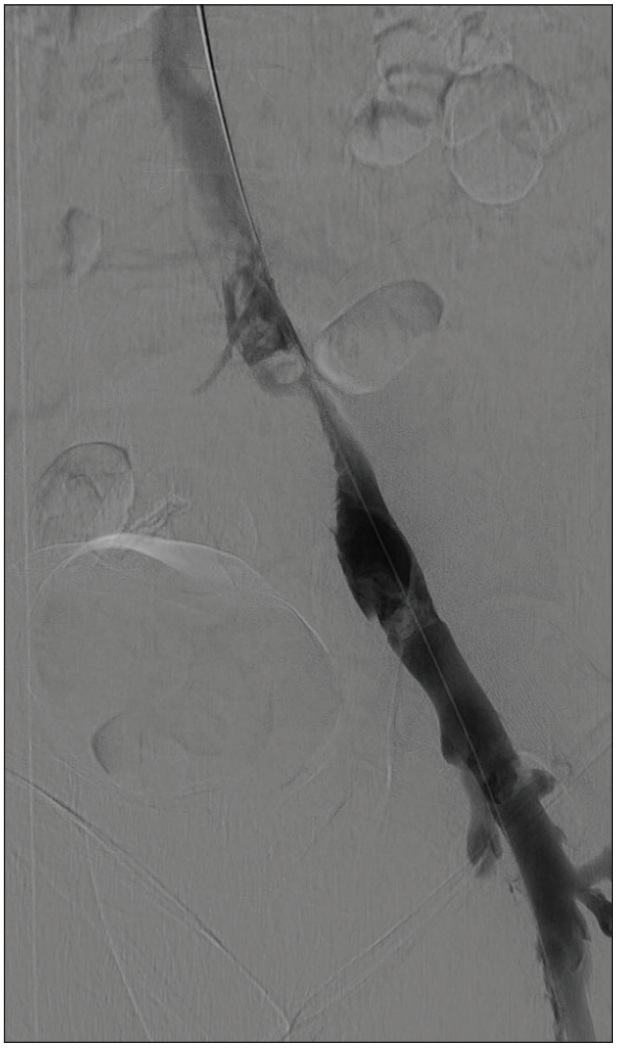

Figure 2. Post-AngioJet venogram demonstrating clearance of a majority of the acute thrombus and the underlying tight CIV stenosis.

sedation. A right internal jugular puncture was used, and an IVC filter was inserted in the infrarenal IVC. The patient was then repositioned prone, and under ultrasound guidance, the popliteal vein was punctured, and a 10-F vascular sheath was inserted. Venography confirmed extensive acute thrombus of the popliteal, femoral, and iliac veins (Figure 1). The occlusion was crossed easily using a catheter and hydrophilic guidewire. Intravascular ultrasound (IVUS) was performed to delineate the extent and volume of the thrombus.

An AngioJet™ ZelanteDVT™ catheter (Boston Scientific Corporation) was inserted, and lytic was instilled using the Power Pulse™ mode throughout the thrombosed segment. The Power Pulse mode drives the lytic deep into the clot, and the device is rotated during delivery to ensure uniform distribution throughout the thrombus.

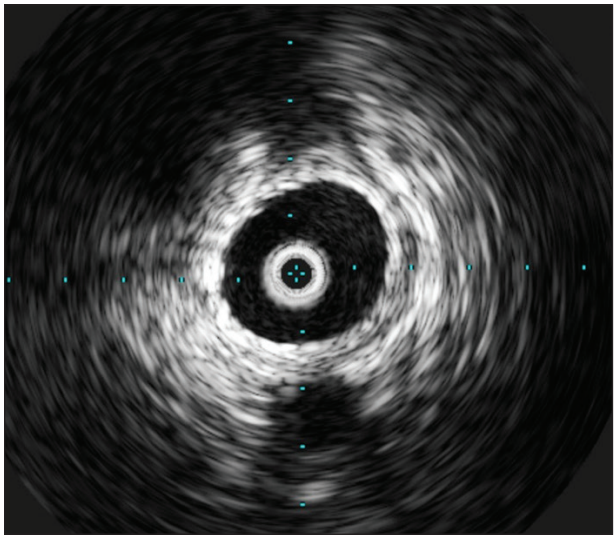

Figure 3. IVUS image of the Vici stent demonstrating complete expansion and circular stent morphology.

For lytic delivery, we dilute 20 mg of alteplase in 100 mL of normal saline. Following administration of the lytic, it is important to pause for at least 15 minutes to allow the lytic to act effectively. The AngioJet was then switched to thrombectomy mode, and the catheter passed slowly through the thrombosed segment to ensure maximal clot clearance. A number of passes through the thrombus were performed with a total run time of 260 seconds.

Venography confirmed excellent clot clearance, with a residual stenotic segment of CIV (Figure 2). IVUS, which has been shown to be more accurate than venography in assessing venous stenosis,[1] was used to identify the compression points, delineate the landing zones, and correctly size the vessel prior to stent selection and placement. Predilatation of the stenotic segment was performed using a 16-mm high-pressure noncompliant balloon. A 16- X 90-mm-diameter Vici Venous Stent® (Veniti, Inc.) was inserted and postdilated following deployment; IVUS was performed to confirm uniform expansion and position (Figure 3). Completion IVUS demonstrated a focal thrombus at the stent inflow that could potentially have jeopardized patency. This was easily treated with another short burst of thrombectomy from the AngioJet. Completion venography demonstrated rapid venous flow (Figure 4). Hemostasis was achieved with manual compression. We planned to remove the filter immediately postprocedure, but the cavogram showed a moderate amount of thrombus within the filter, and retrieval was deferred for 6 weeks.

RESULTS

The patient's symptoms improved rapidly, and our standard posttreatment protocol began. She was

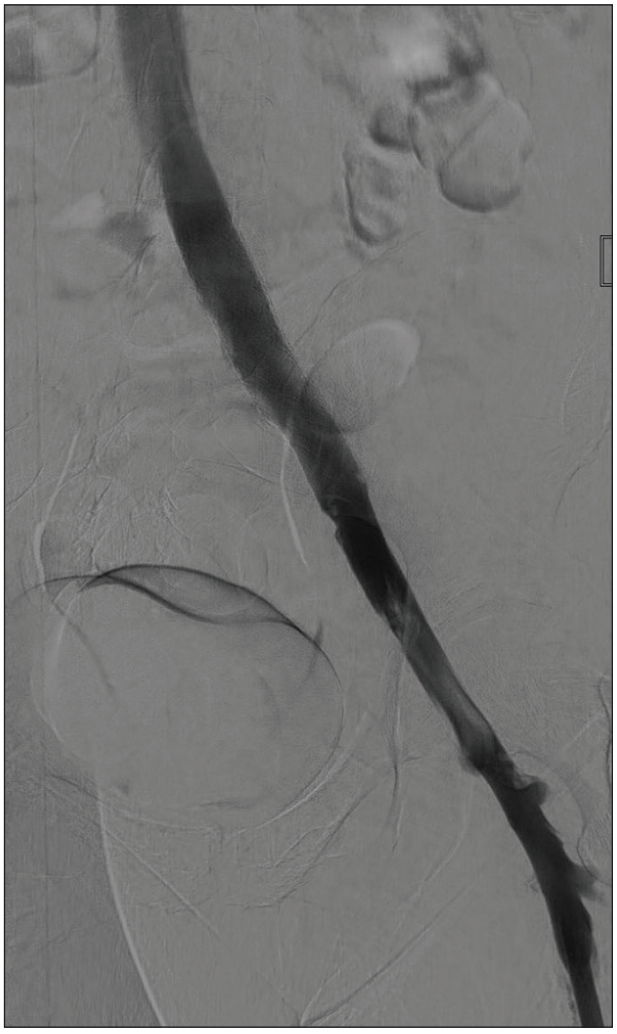

Figure 4. Completion venography demonstrating resolution of thrombus, a uniformly expanded stent, and rapid flow with no collateral filling.

started on split treatment dose low-molecular-weight heparin for 2 weeks, with the first dose given 2 hours postprocedure. A duplex ultrasound performed on day 1 confirmed stent patency. A second ultrasound was performed at 2 weeks and showed a widely patent stent with good flow; the patient was then transitioned to warfarin. At 6 months, the patient was converted to a direct oral anticoagulant, which will be continued indefinitely, given the multiple episodes of venous thrombosis.

The filter was easily removed 6 weeks after the procedure with complete resolution of the thrombosis. At 1-year follow-up, the stents were patent with no in-stent stenosis, and the patient remained symptom free (Villalta score < 5).

DISCUSSION

Acute iliofemoral DVT is a potentially life-changing event, and severe cases with phlegmasia can be limb threatening. The long-term sequelae and high incidence of postthrombotic change are now well recognized. Almost half of patients with an iliofemoral DVT will develop a degree of postthrombotic syndrome (PTS), and up to 10% will develop severe PTS with ulceration and skin changes.[2] In cases such as ours with a potentially threatened limb, rapid restoration of flow is vital. Prevention of PTS relies on thrombus removal and restoration of flow to prevent vessel and valvular damage, which ultimately leads to venous hypertension and PTS.

One of the most common problems with delivering catheter-directed lysis treatment is the availability and cost of high dependency beds for the period of lytic treatment. For this reason, therapies that enable effective "single-session" thrombus removal are attractive. Additionally, avoiding patient exposure to lysis infusions reduces bleeding risk. The AngioJet device utilizes rheolytic technology with high-pressure jets disrupting thrombus and creating a vacuum behind that entrails thrombus into the in-flow window. The Zelante catheter is specifically designed for treatment of large-vessel veins with a single large in-flow window for torqueable and directional thrombectomy, combined with a more powerful jet. In our experience, this significantly increases the rate and volume of thrombus clearance.

Maintaining venous patency after venous intervention is key to achieving good long-term results when treating DVT. In the majority of cases, this requires treating any underlying stenosis with a dedicated venous stent. A venous stent must have sufficient crush resistance and radial force to maintain luminal shape, in combination with flexibility to accommodate movement in the pelvis and groin. Early data have suggested that attaining a circular lumen may have more impact on clinical outcomes than area change.[3] The Vici stent is a closed-cell nitinol stent that provides uniform end-to-end strength balanced with flexibility. Preliminary data from the VIRTUS clinical trial investigating the use of the Vici stent in the treatment of chronic venous outflow obstruction have confirmed excellent technical results: 0% mean residual stenosis; primary, assisted primary, and secondary patency of 93%, 96%, and 100%, respectively.[4]

The recently published ATTRACT trial, and its headline finding of no significant difference in the presence of PTS between patients treated with catheter-directed therapies and those receiving standard anticoagulation,[5] has inevitably led some to question whether this will affect contemporary DVT treatment practices. However, the limitations of the trial must be considered when interpreting the findings. The use of a binary endpoint of PTS or no PTS, the inclusion of patients with femoropopliteal thrombosis, the low incidence of stenting, and absence of a standardized postprocedure follow-up

are significant weaknesses and do not reflect current best practice. As our understanding of venous disease has evolved, we now know that by selecting the correct patient for intervention (descending iliofemoral DVT, thrombus age < 14 days, and patients with low bleeding risk), effectively clearing the clot, addressing any underlying venous stenosis, and adopting a rigorous post-procedure anticoagulation and ultrasound surveillance protocol, we are able to achieve excellent results for our patients. ■

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Lumen Shape: A New Measurement to Consider in the Treatment of Iliofemoral Venous Outflow Obstruction

Exploring the role of pre- and postprocedure lumen shape in predicting patient outcomes.

BY MICHAEL K.W. LICHTENBERG, MD, FESC

With the advent of dedicated venous stents, physicians no longer have to rely on the use of repurposed arterial or general utility stents in the treatment of venous outflow obstruction (VOO). This is significant because of the differences in the anatomy of veins versus arteries as well as the etiology of the disease addressed in the treatment of VOO. To a far greater degree than ever before, the external compression of the nonthrombotic iliac vein lesion is recognized in cases of deep vein thrombosis and chronic venous disease with clinical, etiology, anatomy, and pathophysiology (CEAP) classification clinical scores C4 to C6.[1] Additionally, the restriction of the elastic collagen bands found in the postthrombotic iliofemoral vein segments present unique challenges for balloon angioplasty and stenting.[2]

The ideal dedicated venous stent will comprise a balance of design features that address the needs of physicians treating VOO. These design features will include open- versus closed-cell architecture, radial strength, coverage, flexibility, ease of use, and accuracy of placement. There are currently six dedicated venous stents with CE Mark approval and four with US Food and Drug Administration investigational device exemptions (IDEs) for clinical studies being conducted at centers in the United States, Europe, and Australia.

The question remains, how do we measure the performance of these stents in the treatment of venous disorders? Clinical trials present data on safety and efficacy, but efficacy is generally limited to stent patency. Ongoing debate about the degree of stenosis and severity of venous disease at which patients should be treated for VOO calls into question patency as a singular measure of stent performance. It is important to know what performance characteristics of dedicated venous stents contribute to improved clinical success.

FLUID DYNAMICS AND LUMEN SHAPE

Raju et al have provided significant insight into area as a proxy for determining success in venous stenting in the iliofemoral veins. Stents implanted in the iliofemoral veins are subjected to both external compressions at anatomic choke points and/or recurrent postthrombotic stenosis. Increases in area should result in greater flow volume and reduced peripheral venous pressure.[3]

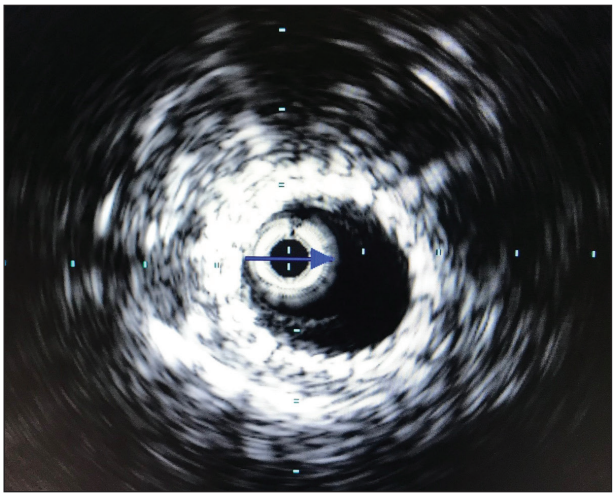

Figure 1. Postprocedure IVUS image of a 41-year-old woman with postthrombotic obstruction. The round lumen shape suggests a lower and improved aspect ratio.

The ability to predict patient outcomes through assessment of stenosis using different imaging modalities has also been recently published. Gagne et al found that a threshold stenosis of 54% was optimal to indicate stenting in VOO and correlated with future clinical improvement. The threshold was higher in the subset of nonthrombotic patients (61%).[4]

Can the theoretical science of fluid dynamics on flow rate, volume, and pressure be applied to stenting of VOO in the treatment of venous disease? There may be other technical performance characteristics of venous stents that require investigation as we seek to better understand the relationship between stent performance and patient outcomes.

Lumen shape is defined by aspect ratio. For a vein, this is expressed as a ratio of maximum diameter to minimum

diameter. A perfect circle has an aspect ratio of 1. Figure 1 shows an IVUS image of a vein poststenting with a round lumen, suggesting a lower and improved aspect ratio. As the ovality of the vein increases, so does the aspect ratio.

When a perimeter is held constant, the area is dramatically different for various shapes, from a perfect circle to a dramatic oval. Figure 2 demonstrates the theoretical changes in flow as a shape with the same perimeter increases in aspect ratio and ovality.[5] Flow volume is dramatically reduced with an increase in ovality. The science also demonstrates that, in order to maintain the same flow rate, an increase in pressure would be required to overcome the resistance in flow due to the flatter shape.

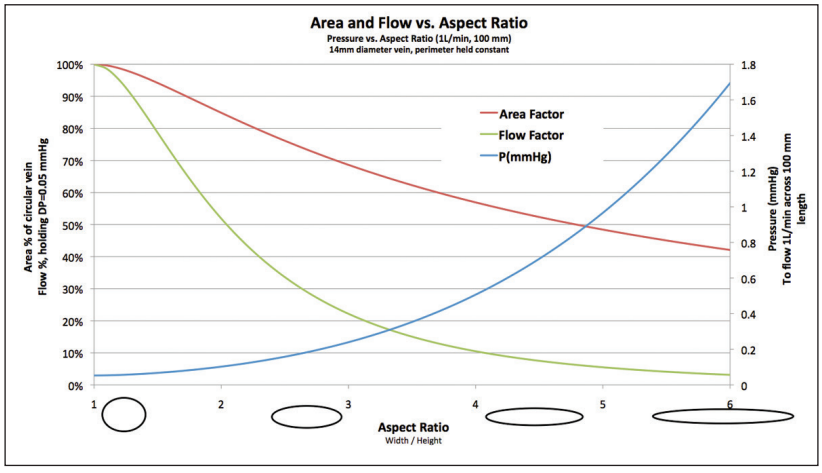

Figure 2. Holding perimeter constant, as the aspect ratio (ovality) increases, the area decreases. To maintain the same flow rate, pressure must increase.

Fluid dynamics suggest that shape matters, as it directly affects the area for a given perimeter. Furthermore, the theory of hydraulic diameter implies that shape will have an effect on the cross-sectional flow area (hydraulic diameter is the effective flow diameter for a nonround shape; for a circle, it is the diameter). This will then have an impact on flow and pressure. Applying these concepts in clinical practice and analyzing the outcomes may provide clinicians with valuable information that could have an impact on long-term clinical success. This research is intended to explore the relationship of changes in venous cross-sectional area (CSA) and lumen shape postindex procedure to patient outcomes at 12-month follow-up.

METHODS

The VIRTUS investigational device exemption trial (NCT02112877) of the Vici Venous Stent® System (Veniti, Inc.) included a 30-subject feasibility cohort that was conducted at nine centers in the United States and Europe. Patients aged 18 years and older with clinically significant venous obstruction (eg, luminal diameter reduction ≥ 50%) were eligible. Included patients presented with a CEAP classification clinical score ≥ 3 or Venous Clinical Severity Score (VCSS) pain score ≥ 2. Major exclusion criteria were pulmonary emboli within 6 months of enrollment, contralateral venous disease, obstruction extending into the inferior vena cava, active coagulopathy, and intended concurrent venous procedure within 30 days of index procedure.

Notably, the VIRTUS trial included the use of duplex ultrasound, multiplanar venography, and intravascular ultrasound (IVUS); all were reviewed in a core lab. For the purpose of this analysis, the focus was on eight IVUS measurements of the common iliac vein (proximal, central, and distal), external iliac vein (proximal, central, and distal), and common femoral vein (proximal and distal) made at both baseline and postprocedure. From these measurements, median changes in CSA and lumen shape, as defined by aspect ratio, resulting from stent implantation were calculated.

VCSS scores were used as the clinical assessment metric in the lumen shape analysis. VCSS scores were captured in the VIRTUS trial at baseline, 6, and 12 months. Specifically, the change in VCSS from baseline assessment to 12 months was used in the analysis of the relationship of changes in CSA and lumen shape to clinical outcomes.

Pearson correlation coefficients (r) measured the strength of the relationship between the following pairs of variables: poststent change in CSA and 12-month VCSS score and poststent change in aspect ratio and 12-month VCSS score.

RESULTS

The 30-patient feasibility cohort was composed of 24 women and six men with a median age of 43 years. The mix of lesion etiology was 19 (63%) postthrombotic and 11 (36%) nonthrombotic; 25 (83%) were left leg lesions. Fifteen patients had lesions involving more than one vein, including nine with involvement of the common iliac, exter-

TABLE 1. ANATOMIC CHANGES IN CSA AND ASPECT RATIO

	Prestent	Poststent	Pre- to poststent change
CSA, cm^2 (range)	43 (20 to 76)	130 (73 to 286)	74% (-18% to 48%)
Aspect ratio (range)	2.8 (1.2 to 5.3)	1.3 (1.1 to 2.2)	-45% (-77% to -0.2%)

Abbreviations: CSA, cross-sectional area.

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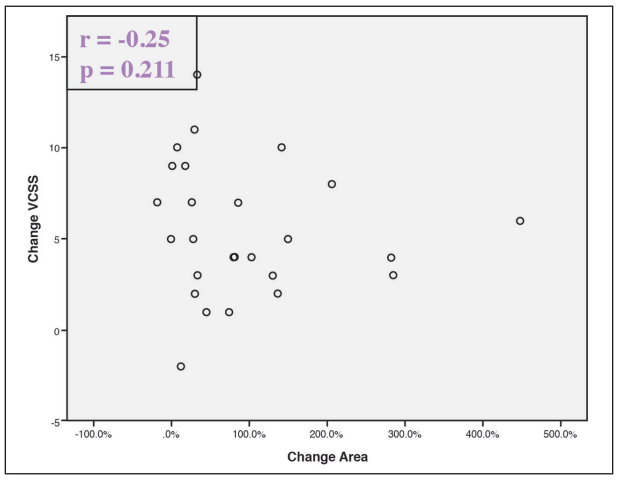

Figure 3. Postprocedure CSA increases from left to right on the x-axis. There was no relationship between increase in postprocedure CSA and clinical improvement.

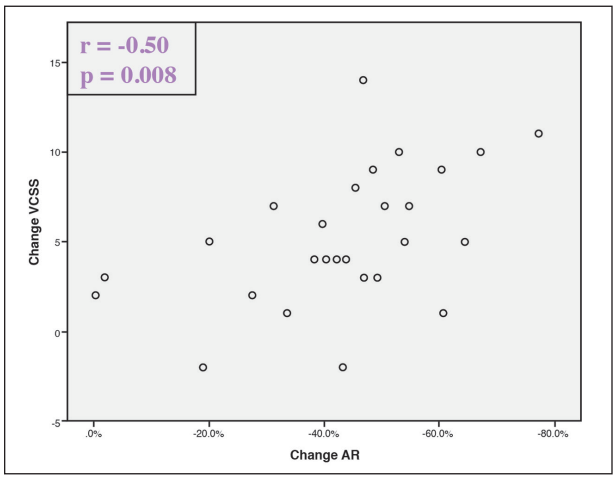

Figure 4. Postprocedure aspect ratio improves (lower value) from left to right on the x-axis. A moderately positive relationship between lower aspect ratio and clinical improvement is seen and is statistically significant.

nal iliac, and common femoral veins. Median baseline stenosis was 91% (range, 50%–100%).

The anatomic changes in CSA and aspect ratio, pre- and poststenting, are presented in Table 1. Twenty-seven patients with available 12-month VCSS scores were utilized for this analysis. Three patients were outside the 12-month follow-up window 365 ± 60 days. Median VCSS score declined by 5 points from baseline to 12 months, and 23 (85%) patients experienced symptomatic improvement (≥ 2-point score improvement).

The change in area from pre- to postprocedure was calculated for each patient, using the formula: (postprocedure area - baseline area)/baseline area. Looking at patients' changes in vessel area from baseline to postprocedure, one would expect to see a positive correlation between area change and clinical improvement; that is, the greater the relative increase in luminal area, the greater the clinical improvement. However, as Figure 3 shows, this was not observed. The correlation coefficient between these variables (r = -.25) indicates a negative relationship between the variables, which is surprising but should not be attributed any significance considering the strength of the relationship. At -.25, this correlation coefficient does not even meet the threshold of a weak relationship. This is a negligible relationship, and as shown in Figure 3, there is no clear pattern. This is also confirmed by the P value of .211.

Conversely, in Figure 4, there is a clearer relationship in the correlation between postprocedural change in lumen shape and clinical improvement. Analysis showed a moderately positive relationship (r = .50) between the decreased ellipticity of the stented vessel and clinical improvement. Patients undergoing the greatest luminal change in the direction of oval to round are most likely to exhibit clinical improvement, which is a statistically significant finding (P = .008).

CONCLUSION

This research suggests that increased poststenting CSA is desirable, and change in lumen shape, as defined by aspect ratio, may contribute further to positive patient outcomes. Additionally, with further research, aspect ratio may be important as a predictive factor of clinical improvement in patients treated for VOO. Further research is necessary and forthcoming. Validation of this analysis with the VIRTUS trial 170-patient pivotal cohort is required. ■

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CASE REPORT

Patient-Centered Discussion on Treating Chronic Vein Obstruction

Recanalization with both the Wallstent™ and Vici Venous Stent® to treat iliofemoral vein chronic occlusion.

BY OLIVIER HARTUNG, MD, MSc

A 39-year-old woman had a left iliofemoral acute deep venous thrombosis (DVT) 38 months before intervention. This DVT occurred 2 days after lumbar spine surgery and was medically treated by elastic stockings and low-molecular-weight heparin followed by warfarin, because the surgical procedure precluded interventional treatment of the DVT. Despite elastic stockings, the patient experienced venous claudication and thigh edema (> 3 cm in diameter) without skin lesions.

Duplex ultrasound showed a normal popliteal vein (PV), severe postthrombotic obstructive lesions of the femoral vein (FV), and a normal deep femoral and common FV (CFV) between the confluence and the saphenofemoral junction with an occluded cephalad CFV. Additionally, it also showed an external iliac vein (EIV) and common iliac vein (CIV) occlusion without deep axial reflux or contralateral and inferior vena cava lesions. CT venography confirmed these findings.

Based on this assessment, the patient was classified as having symptomatic edema (C3s), postthrombotic (Es), deep veins (Ad), and obstruction only (Po). The patient's venous disability score and Villalta score were 3 and 11, respectively. No thrombophilia was found.

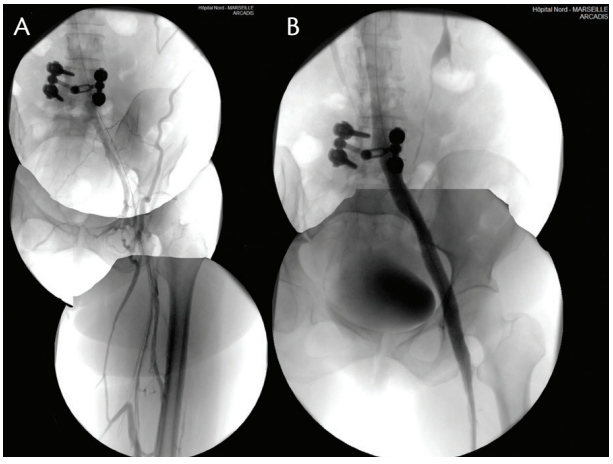

Figure 1. Before recanalization of an occluded left iliofemoral venous axis (A). After recanalization and stenting with a combination of a caudal Wallstent and a cephalad Vici Stent (B).

TREATMENT OPTIONS

Medical therapy alone was insufficient. According to the European Society for Vascular Surgery guidelines, surgery is not recommended as a standard primary treatment, and recanalization and stenting is recognized as the first-line option to treat such lesions.[1] PV access was chosen because of the presence of FV obstructive lesions, but a jugular approach could have been used, too.

It must be highlighted that preoperative evaluation of the inflow and of the CFV lesions, postoperative care, and oral anticoagulation are essential to ensure good long-term results.

COURSE OF THE PROCEDURE

The procedure was performed under local anesthesia with sedation. Access was achieved with echo-guided puncture of the left PV, and a 6-F sheath was inserted. Iliocavography confirmed preoperative findings with a severely diseased FV (Figure 1A), a good landing zone in the caudal part of the CFV, and a totally occluded left iliofemoral axis. Recanalization was performed using a 0.035-inch guidewire and a 5-F vertebral catheter. Then, the patient received 50 IU/kg of unfractionated heparin (UFH) and 250 mg of aspirin.

Predilatation was performed with a 16-mm-diameter Atlas percutaneous transluminal angioplasty dilation balloon (BD Interventional), followed by the deployment of three stents: one 16- X 120-mm Vici Venous Stent (Veniti, Inc.) in the left CIV and cephalad part of the EIV, one 16- X 90-mm Wallstent Endoprosthesis (Boston Scientific Corporation) in the CFV above the femoral confluence up to the caudal part of the EIV, and one 16- X 60-mm Wallstent to fill the gap between the two previous stents. All stents were postdilated using a

16-mm Atlas percutaneous transluminal angioplasty balloon before completion phlebography (Figure 1B) and sheath retrieval. Intermittent compression devices were used, and the patient received an intravenous perfusion of 20,000 IU per day of UFH.

RESULTS

The patient was able to walk as soon as she returned to the ward (2 hours after the end of the procedure), and UFH was stopped that evening, then she had 14,000 units a day of tinzaparin in combination with warfarin and clopidogrel (goal international normalized ratio of 2.8–3.2). The patient was discharged on day 2.

Duplex ultrasounds were performed on day 1, then at 1, 3, 12 months, and annually thereafter. Venous claudication disappeared, and at 1 year, venous disability score and Villalta scores were 0 and 3, respectively. Oral anticoagulation was discontinued because it was a first and provoked DVT and because the result was excellent according to clinical and duplex criteria.

DISCUSSION

A variety of stents are available for use in venous stenting. The Wallstent has been used for decades, and despite limitations in deployment accuracy, size, and the need to deploy the stent over the right CIV ostium when treating CIV obstructive lesions, the stent continues to offer several advantages. These advantages include good flexibility and resistance to compression, reconstrainability, absence of fracture, and positive results in the treatment of iliofemoral vein obstructive lesions as reported in numerous publications.[2-4] For more than 20 years, we have stented totally occluded veins, and in our experience treating 162 patients admitted for recanalization, the overall secondary patency rates were 88.3% at 90 months. However, when considering only patients who had a percutaneous procedure without endophlebectomy, patency rates were 90.9%.[5]

Laser-cut self-expanding nitinol stents have limited shortening during deployment, which allow precise positioning but can suffer from fractures; long-term results are also sparse.[6,7] These stents are increasingly used in Europe (none have US Food and Drug Administration approval), and the main criteria for their use is precision. The Vici Venous Stent has a closed-cell design that gives it uniform crush resistance without compromising its flexibility. The delivery system is coaxial over-the-wire compatible with a 9-F sheath. It is under evaluation in the VIRTUS clinical trial, and feasibility cohort results were reported with 96% secondary patency for post-DVT patients.[8]

Our concept is to leverage the advantages of both types of stents for iliofemoral venous stenting while avoiding their limitations: a long nitinol stent into the cephalad part to avoid stent protrusion over the right CIV ostium and to stent down into the EIV and a Wallstent in the caudal part to avoid the risk of fracture under the inguinal ligament. ■

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Cost Considerations: Is a Venous Practice Financially Feasible?

European experts comment on the economic challenges they face with venous reimbursement within their countries.

WITH STEPHEN BLACK, MD, FRCS(Ed), FEBVS; MARC SAPOVAL, MD, PhD; AND CHRISTIAN ERBEL, MD

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This question, as ever, is a chicken-and-the-egg conundrum. Treatments inevitably start from a position of patient need and require refinement before the question of economic viability is addressed. Financial feasibility, in its barest essence, comes down to the question: is the cost of the treatment delivered exceeded by the cost of withholding the treatment from the patient?

To truly understand this question, we need to understand the cost of no treatment (eg, best medical therapy). ATTRACT has demonstrated that 50% of patients with acute deep vein thrombosis (DVT) will develop postthrombotic syndrome (PTS), and no reliable data exist to outline how expensive this condition may be. Until we understand this and stop focusing only on the cost of treatment, we will not make progress. Significant complications of PTS take years to manifest (in particular, ulcers), and it is well established that the cost of treating ulcers is high. However, the cost of work days lost, lifelong analgesia, destruction of quality of life, and other associated health burdens are not as well understood.

The cost of treatment is expensive to start with, and payment structures, funding bodies, and commissioners have not yet caught up with the economic demands. Cost-effective treatment is delivered by improving results, minimizing reintervention, and ultimately, ensuring that we keep the intervention as short and simple as possible. The demands are different for the treatment of patients with acute and chronic disease.

Acute therapy is compounded by a more unpredictable length of stay, the need for lytic (which is expensive), and in many centers, requirements for high-dependency beds as routine. To improve financial feasibility in patients with acute disease, we have increased the use of mechanical thrombectomy to reduce the length and dose of lytic and actively worked to reduce in-hospital stay with the ultimate goal of moving to an outpatient/office-based delivery of therapy. Additionally, we have made strides to remove the need for high-dependency bed support based on evidence that suggests venous patients have little need for it. We have also dedicated effort toward improving technical outcomes to mitigate the cost of reintervention.

In patients with chronic disease, the pathway has been easier because many patients can be managed through a day-case pathway. The procedural fees for these stents sustain the practice, which is built around the ability to do multiple procedures in an operating session. Lists need to be optimized, and as with acute patients, we have actively worked to improve primary patency.

Returning to the question at hand, at this stage, we probably do not know the answer, but if we drive data to understand the cost of no treatment in these patients, ensure that we continue to improve our delivery of intervention, and collect robust data to support emerging therapies, we should be able to answer the question fully.

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The indication of acute thrombus removal using pharmacomechanical thrombectomy (PMT) is still open for debate. Despite several randomized trials showing

positive results in favor of this approach (eg, open vein theory), the recent ATTRACT trial failed to confirm the benefit of interventional treatment compared with conventional anticoagulation.

Because of these results, in France, where there is already a deficit of teams performing PMT, the referring clinicians are now more reluctant to send patients. The issue of reimbursement for the device further complicates the adoption of PMT and increased utilization.

However, in a few dedicated centers that are trained to use the AngioJet™ thrombectomy system (Boston Scientific Corporation) and have a multidisciplinary approach to the disease, there is still significant activity. There is a need to persuade the local payers (eg, the hospital administration) that the cost is acceptable, given the benefit for the patient and the attraction of new patients to the health care structure.

Still, there is a need for more clinical evidence. A properly designed prospective trial evaluating the benefit of a single session of PMT is needed to assess the clinical value in appropriately selected patients. We anticipate that focusing on proximal ascending acute DVT in younger patients and absence of underlying prothrombogenic disease (eg, cancer) in a relatively small number of patients with total stenting, would yield enough positive results to allow the design of the next ATTRACT trial.

Upon availability of a larger data set, a macroeconomic study would be of great value to help in aiming at reimbursement of the technique in France.

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Health care economics may limit interventional treatment of chronic venous occlusions for the vast population of venous patients. One retrospective review calculated that the economic burden of DVT, pulmonary embolism, and PTS is about $20,569 per year for United States health care plan enrollees,[1] which is a significant financial cost for any health system. Expenses are high for specific high-pressure balloons and dedicated venous stents worldwide, whereas the billing system for these devices is based on those used for arterial interventions, which have significantly lower material costs. Conversely, in Germany, adequate reimbursement is possible for catheter-directed lysis and thrombectomy of patients with an acute thrombotic occlusion.

Based on these factors, whether a venous practice is financially feasible depends on many factors:

- Having a balance of patients with acute and chronic venous occlusions will help optimize the budget for your venous practice.
- The type of intervention used for a chronic occlusion affects the cost structure of the venous center. The longer the venous occlusion, the higher the amount of dedicated venous stents needed, and the higher the expenses for the center.
- In the acute thrombosis setting, reimbursement depends on the type of intervention—local lysis alone or with thrombectomy, as well as whether rotational or nonrotational thrombectomy is used.
- The costs for a dedicated venous stent vary significantly; the stent selection has a major impact on the expenses of the venous center.

Another important aspect is the negotiations of the purchasing groups to reduce material costs. ■

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