Treatment of Chronic Venous Insufficiency

How current technology is changing our approach.

BY JENNIFER HELLER, MD, FACS

n the United States, an estimated 23% of adults have varicose veins, and 6% have more advanced chronic venous disease (CVD).^{1,2} Although varicose veins are still considered by many laypeople and health care practitioners to be a benign condition, varicose veins can be a harbinger of future CVD, which is associated with debilitating symptoms, chronic skin changes, phlebitis, and ultimately, venous stasis ulceration.^{1,3,4} Further, severe CVD can result in the loss of a limb and death.⁵ The direct medical cost of CVD (or chronic venous insufficiency [CVI]) in the United States has been estimated to be between \$150 million and \$1 billion per year.^{4,5}

In an effort to improve these statistics and ultimately decrease the prevalence of venous stasis ulceration, the Pacific Vascular Symposium was developed. This group identified a number of research priorities in the categories of clinical practice, basic science research, and education. These priorities still hold and, ideally, should be fulfilled as we strive toward improving comprehensive care of venous insufficiency.

In May 2011, however, the Society for Vascular Surgery and the American Venous Forum shifted the focus from research to the development of clinical practice guidelines for the evaluation and treatment of patients with CVI.² The authors clearly state that the guidelines should not be construed as the standard of care, which must be determined by the individual patient's condition, treatment setting, and other factors. They further note that the approach to treatment and management is driven largely by proper diagnosis along with a thorough understanding of the patient's medical history, clinical presentation, and diagnostic imaging studies.

The practice guidelines are required reading for any physician treating venous disease. In this article, I describe an algorithmic approach used to determine treatment decisions for CVI that focuses not only on the great saphenous vein (GSV) and small saphenous vein (SSV) but also on the anterior and posterior accessory veins. I have included two case studies to show how I apply this approach.

CVI ALGORITHM

There are many factors that contribute to the complexity of treatment for venous insufficiency. First, the lower extremity venous anatomy is variable. Duplicate systems are commonly encountered, and the perforator veins vary in function, size, and location. Patients may present with a chronic course of venous disease and not be aware of postthrombotic or secondary venous insufficiency as the predominant cause of their problems. Therefore, the importance of taking a thorough patient history and performing a comprehensive physical examination cannot be overemphasized, and the findings can dramatically alter the treatment approach.

My initial evaluation concludes with a determination of the severity of the patient's venous disease. I group patients into one of two categories: uncomplicated and complicated. Uncomplicated venous disease is a stage of venous insufficiency composed of mild-to-moderate symptoms devoid of complications or advanced stigmata on physical examination. I consider complicated venous disease to be > C4 (CEAP classification) or when patients report symptoms that are debilitating, disabling, and are not improved with conservative management.

CONSERVATIVE TREATMENT

The cornerstone of conservative treatment for CVI is compression stocking use, and it is the responsibility of the physician to communicate the advantages and role of compression care in treatment. Stockings are noninvasive, safe, and in patients who manifest mild or uncomplicated venous disease, compliant compression stocking use may be sufficient. Compression stockings are a required treatment component during travel in patients who require surgical intervention and in those with advanced CVI > C4 disease. Patients who demonstrate resolution of symptoms with compliant compression stocking use are instructed to return to the office every 6 months for surveillance. If the patient develops breakthrough symptoms or if physical examination findings deteriorate, the patient is counseled for intervention. In my practice, patients who demonstrate mild disease and are compliant with stocking use

require delayed operative intervention approximately 15% of the time.

Although I am an advocate of conservative management, there are many patients for whom stockings alone do not suffice. This is when the comprehensive history becomes so important, as it can reveal factors that suggest when a more aggressive intervention is warranted. These include: multiparity with deteriorating symptoms with progressing pregnancies, bleeding varicosities, superficial phlebitis, and a standing occupation.

During the physical examination, it is important to evaluate CVI symptoms, their location, history of onset, and factors associated with their exacerbation and alleviation. After a clinical evaluation is performed, a reflux examination is indicated. Duplex examination is the gold standard for evaluating superficial venous reflux. Further, this examination provides information on the presence of reflux in the deep venous system and whether stigmata are present that are consistent with postthrombotic disease, such as recanalized flow, thickened walls, or atrophic nonvisualized vein segments. Treatment cannot be performed until the reflux examination results are obtained and evaluated. Further, intervention is contraindicated when acute deep venous thrombosis (DVT) is present. The presence of chronic deep venous disease is a relative contraindication to treatment. In my practice, I will intervene on these patients if they manifest severe C4b, C5, or C6 disease. I use my duplex findings to help tailor an approach that is as localized as possible.

Patients with postthrombotic syndrome rely on their superficial systems, so removal can precipitate edema, as outflow can be further compromised. In these circumstances, I may ablate a single perforator or attempt to elucidate an accessory segment that can be localized. A staged approach can provide local control in the gaiter distribution while maintaining reasonable venous outflow in the lower extremity. These patients are carefully monitored during follow-up office visits, which are scheduled every 3 months, and are instructed to wear level III grade compression stockings. These evaluations can help to determine how reflux in the saphenous veins contributes to reflux elsewhere in the venous anatomy (eg, anterior, posterior, and lateral accessory saphenous veins, SSV, their terminal anatomy along with perforators) and their clinical impact on CVI overall.

TREATMENT APPROACHES

Perhaps most importantly, duplex scanning helps me decide which veins to treat and which not to treat. Again, using a conservative approach, my goal is to target veins that, if treated, stand a good chance of

improving or alleviating other possible problems "downstream." For example, I have found that in patients with incompetence in both the GSV and SSV, oftentimes I do not need to treat the SSV because ablating the GSV alone resolves the SSV insufficiency approximately 80% of the time.

For venous ablation, I have had excellent treatment success with the Closure device (Covidien, Mansfield, MA). Postoperatively, patients experience less pain and bruising compared to traditional vein stripping surgery or endovenous laser treatment. I have used ClosureFast (Covidien), which ablates in 7-cm segments and ClosureRFS (Covidien) for treating incompetent perforator veins. The ClosureFast 3-cm catheter is expected to be available in late 2011 for ablation of shorter refluxing vein segments.

Because it uses segmental ablation technology, ClosureFast provides controlled, consistent energy delivery—no gradual pullback, no subjective determination of adequate energy delivery—resulting in controlled, even heating for more consistent and reliable vein ablation.⁶ With the 7-cm catheter and the soonavailable 3-cm catheter, the procedure is versatile enough to treat shorter veins (eg, the anterior and posterior accessory saphenous veins, SSV, and intersaphenous) and longer veins simultaneously.

ClosureFast has a reported efficacy rate of 93% at 3 years.⁷ In addition to long-term efficacy, I also am finding that, overall, patients are very satisfied with their quick recovery and ability to return to work soon after the procedure. This is also supported by clinical study findings. In the RECOVERY trial, 8 a multicenter, head-to-head, comparative randomized trial, the Closure procedure resulted in patients experiencing less pain and bruising than those treated with endovenous laser, leading to faster recovery and return to normal activities. Other randomized comparative studies have also shown that patients who underwent the Closure procedure returned to normal activity and work significantly faster than those who underwent vein stripping.^{9,10}

Finally, regardless of whether the treatment approach is conservative or more aggressive, it is important to communicate clearly with patients about their disease, how best to manage it, and that the disease can progress over time. Those initially managed conservatively (eg, with a compression stocking) need to understand that although this can stabilize the progression of the disease, if their symptoms remain uncontrolled or worsen, radiofrequency ablation (RFA) or surgery will likely be required.

The following cases illustrate how I make treatment decisions based on such factors as those previously described.

CASE 1

Overview: A 57-year-old man with a left lower extremity ulcer that was present for several months.

History and Examination

The patient denied any history of trauma to the site. He had a history of DVT in the right lower extremity. He had no history of thrombophilia and no family history of clotting disorders. He works as an architectural designer and stands on his feet for only approximately 2 hours a day. The patient described symptoms of aching pain, fatigue, and swelling.

The physical examination revealed a 2.2- X 2-cm, laterally based ulcer with a thin layer of fibrinous exudates. He also had a 2/2+ dorsalis pedal pulse/posterior tibial pulse in both lower extremities. The arteries appeared normal.

A duplex scan of the left lower extremity revealed significant reflux of the GSV > 6 seconds through the distal thigh. There was no evidence of SSV reflux and no DVT.

Diagnosis

The patient had varicosity of the anterolateral thigh with extension to the lateral proximal calf and transverse branch communication across the mid aspect of the anterior calf, with distal extension into the 11 o'clock aspect of the ulcer bed.

My first clinical impression was GSV reflux with the refluxing branch being a predominant source for venous hypertension, thereby causing the ulcer. However, I was surprised by the lack of SSV reflux, so I reimaged the patient and carefully explained his presentation to my

registered vascular technician. The clinical presentation (ulcer) made me suspicious of additional underlying disease that was not initially discovered.

The follow-up duplex examination revealed reflux of the SSV proximal and mid portions and a small saphenous branch that appeared to course toward the ulcer, but no definitive communication was evident.

Treatment

Based on these findings, I decided to proceed with RFA of the GSV and the anterior branch of the GSV. Following the procedure, the patient was placed in Unna boots and was assessed weekly.

Postoperative Observation and Follow-up

The postoperative course was uneventful, and the postoperative duplex scan was normal. For the first 4 weeks, although the ulcer depth decreased, the size remained unchanged. At postoperative week 5, he developed a second ulcer that was shallow and inferior to the first. This new ulcer appeared to be in direct communication with the SSV branch previously seen on duplex imaging.

SSV ablation with branch phlebectomy was planned. This case is a good example of the importance of closely examining the complex terminal anatomy and having an experienced registered vascular technician help to uncover the true culprit vessel.

CASE 2

Overview: A 61-year-old man presented for evaluation of a right lower extremity venous stasis ulcer disease that he had for several decades.

History and Examination

The patient's first problems occurred at age 19 when he sustained a DVT in the right lower extremity and pulmonary emboli. His workup after this episode revealed heterozygosity for factor V Leiden. He was placed on lifelong warfarin maintenance and, over time, not only developed chronic edema, controlled only with level II grade compression, but also venous stasis ulceration. In 1998, he underwent perforator ligation for C6 disease, which healed the ulcer but experienced a recurrence 9 years later that was treated at various centers with various dressings and compression devices. This resulted in multiple healings and recurrences. At

presentation, he had a 5-month history of the chronic ulcer.

Physical examination revealed two ulcers—one on the left medial malleolus and the other on the right lateral malleous—both measured at 1 X 2 mm.

A duplex scan of the right lower extremity revealed significant reflux of an anterior branch of the GSV into the distal thigh, with reflux also in one focus in the mid calf. The GSV was atrophied in its infrapopliteal segment. Significant SSV reflux was also demonstrated. There was no acute DVT, but chronic recanalization in the common femoral and femoral veins was seen, which was consistent with the patient's history.









Diagnosis

The patient had CVI with recurrent venous stasis ulcers (C6 disease) against a backdrop of heterozygosity for factor V Leiden, conferring an increased risk of thrombus formation and a need for ongoing warfarin therapy.

Treatment

The patient underwent RFA of the SSV with concomitant phlebectomy. Intraoperative duplex imaging was also used to locate additional branches that communicated with the distal calf and were subsequently phlebectomized under ultrasound guidance. The patient remained on warfarin during the procedure, with international normalized ratio closely monitored and maintained between 2.5 and 3.

Postoperative Observation and Follow-up

The postoperative duplex scan was normal, and both ulcers healed at 4 weeks follow-up. Via verbal communication, the patient continued to have C5 disease at 5-month follow-up.

Teaching Points

This case involved a number of important lessons learned for me:

- Even though the patient manifested anterior branch reflux, it did not require treatment.
- Never take a thrombophilic patient off their anticoagulation therapy for treatment. That is one of

the advantages of endovenous therapy.

Use intraoperative ultrasound to ensure comprehensive care of an area that may not have been adequately imaged in the vascular laboratory.

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