Looking Beyond Arteries

Integrating venous disease management into an existing cardiology practice.

BY PAUL KRAMER, MD, FACC, FSCAI

ardiologists are board-certified in cardiovascular disease, but most fellowships include little, if any, training in the demographics, clinical features, diagnosis, and treatment of venous disease and chronic venous insufficiency (CVI). Because most of us receive little training in this disease, we naturally come to believe that it is not very important. Often, vein disease management is promoted in our medical and lay communities in a manner similar to antiaging, weight loss, hair transplantation, and other "paramedical" practices that we comfortably regard as cosmetic and beneath the dignity of a self-respecting cardiologist. However, CVI results in a host of health problems (Figure 1). These range from asymptomatic and largely cosmetic manifestations—such as spider and reticular veins—to mild or moderate impairment (due to lower extremity edema, fatigue, and/or varicose veins) to more advanced problems, such as lipodermatosclerosis, and nonhealing cutaneous ulcers.1

We are taught that peripheral edema is a manifestation of heart, liver, or kidney failure. However, in my clinical experience, I have observed that edema from ambulatory venous hypertension as a result of chronic superficial venous insufficiency is more common than the other causes combined. In the United States, more than 30 million people develop clinical sequelae from CVI.¹ Unfortunately, in most cases, these problems go unrecognized, undiagnosed, and untreated. Some patients eventually undergo limb amputation without a treatable diagnosis. Even milder forms of CVI can produce significant quality-of-life impairments that are often recognized in retrospect after successful treatment.²

WHY VENOUS?

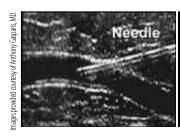
Why would a cardiologist consider adding the management of CVI to his or her practice? The answer is really no different than for any other facet of cardiovascular medicine. Primary care physicians and other specialists care for large numbers of patients with manifestations of venous disease. Many patients in a typical cardiology practice are also afflicted with these problems, but the diagnosis is often not recognized or even considered. Educating ourselves and these potential sources of referrals about the recognition and management of CVI enables diagnosis and treatment, contributing to gratifying improvement in the quality of life for a large number of patients.



Figure 1. Signs and symptoms of CVI include varicose veins (A), leg swelling and skin texture or color changes (B), and venous ulcer (C).

Cardiologists and their staffs often already possess the resources to provide CVI management. Once a diagnosis is suspected, confirmation is typically made with venous duplex ultrasound imaging.3 For those practices with vascular sonographers and imaging apparatuses, learning how to assess venous function and anatomy is an investment in ascending the learning curve. For those without this capability, vascular probes and imaging software can usually be added to existing echocardiography equipment. Understanding the pathophysiology of CVI requires working familiarity with circulatory physiology, hydraulics, and hemodynamics. Treatment involves vascular access, advancing the treatment catheter to the treatment target, employing sterile technique, and performing clinical follow-up. Three-dimensional anatomy is represented in a two-dimensional (ultrasound) image (Figure 2). Catheter positioning is guided by ultrasound imaging during the procedure, which is highly analogous to the handling of cardiac catheters under fluoroscopic guidance. Finally, these diagnostic and treatment procedures are conveniently performed on an outpatient basis in the office setting.

For those cardiologists who are fully secure in their current and future referrals, finances, and range of services they provide (a vanishing breed), read no further. Cardiology practices today struggle to reconcile rising overhead with falling reimbursements. Given the prevalence of venous disease, the need among potential referral sources for a reliable service provider, and the relative ease with which CVI man-



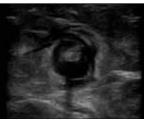


Figure 2. The procedure is performed under ultrasound guidance, from initial vein access using the Seldinger technique (A) to properly locating the catheter in the vein (B).

agement can be incorporated into a cardiology practice, the addition of a venous practice is a win/win decision.

Many cardiologists (and I admit that I was one) regard CVI and varicose veins as a cosmetic problem. I asked myself how I could practice vein medicine and maintain self-respect while my practice was considering offering this service. The answer changed my practice. We built up our referrals the same way cardiologists usually do—by educating potential referrals about the clinical manifestations of venous disease and treatment options. Effective treatment of CVI has such an impact that, ultimately, the greatest factor in increasing referrals is the reaction of treated patients who convey their satisfaction to their physicians, friends, and family.

FORMER CVI TREATMENTS

Historically, the treatment of CVI was relegated to the province of vascular surgery. Conservative measures, such as the application of compression stockings, often controlled edema and, in conjunction with other wound care measures, facilitated healing of chronic venous ulcers. Unfortunately, many patients are unable or unwilling to wear compression hose or compressive wraps. Discontinuation of such therapy after successful wound healing immediately restores the original pathophysiology, so the recurrence rate is very high.

Fluid and salt restriction and diuretic therapy probably have no meaningful role in the management of CVI. In the absence of central venous hypertension, lower extremity edema results from severe venous hypertension in the leg (upward of 80 mm Hg) in the setting of a normal right atrial pressure (≤ 7 mm Hg). Minimizing central venous pressure by any of these means exerts minimal impact on lower extremity venous pressure while lowering cardiac filling pressures to the point of reducing cardiac output and arterial blood pressure. In refractory cases of CVI, vein stripping surgery was historically the next step. Unfortunately, due to a combination of trauma, lymphatic disruption, failure to strip the correct insufficient superficial veins, or faulty technique (such as clipping or limited, short-segment treatment), more than 40% of stripping procedures failed

to produce a durable result, and repeat surgery was often required.¹

One of the newer treatment modalities for CVI is radiofrequency ablation (RFA) for incompetent superficial veins, which was cleared by the US Food and Drug Administration in 1998, and which enabled the restoration of nonrefluxing, unidirectional lower extremity superficial venous return without significant trauma or discomfort; the assurance that all refluxing veins could be treated; the absence of lymphatic injury; and the ability to eliminate venous pathophysiology in an outpatient, in-office setting without general anesthesia and provide a highly durable result. In a smuch as this modality is nonsurgical and catheter-based, invasive cardiologists are well-suited to perform these procedures. Interventional experience is helpful but not necessary. Cardiologists who are experienced in cardiac catheterization possess most of the skill required to perform venous RFA. RFA is one of two forms of endovenous thermal ablation, the other being endovenous laser therapy. Both modalities have evolved since their introduction, but there is evidence that, on average, RFA produces less discomfort and bruising with a faster improvement to quality of life when compared to endovenous laser. 5 Both provide durable restoration of normal venous return and an infrequent need for additional treatments.

TECHNIQUE

It is important to learn how to reliably gain access to the vein using the Seldinger technique under vascular ultrasound guidance. This initial step is likely the most important in terms of patient comfort and determining the length of the procedure. The technique is readily learned by attending a teaching conference and/or performing initial procedures under a proctor's guidance. Some operators are assisted by the ultrasound technician throughout the procedure, but I have found that it is simpler and much more efficient to perform the imaging myself—not only when gaining venous access but throughout the procedure. Ensure that the patient is adequately hydrated so that the venous volume is not depleted. The use of a tilting vascular bed enables reverse Trendelenberg patient positioning to enlarge vein caliber while gaining access. Tilt reversal exsanguinates the vein, optimizing catheter contact with the vein wall.

In my practice, we have witnessed outstanding patient outcomes and very rare adverse events with the Venefit procedure using the ClosureFast radiofrequency catheter (Covidien, Mansfield, MA) (Figure 3). This technology heats the vein wall by delivering radiofrequency energy, which is analogous to electrocautery, by direct contact with the vein wall. The result is endothelial denudation, collagen contraction, and rapid occlusion of the vein lumen, with essentially no injury to surrounding tissues. Adjacent tissues (arteries,



Figure 3. The Venefit procedure is delivered by the Covidien ClosureFast radiofrequency ablation catheter.

nerves, fat, lymphatics, and skin) are spared thermal injury by the administration of tumescent anesthesia.

Following successful venous access and catheter positioning, a solution of saline, lidocaine, sodium bicarbonate, and epinephrine is injected along the length of the vein to be ablated. This is performed under ultrasound guidance to ensure a continuous "sleeve" of anesthetic solution, which physically displaces adjacent tissues away from the heat source, acts as a heat sink, and allows for pain management in patients who are awake and alert. RF energy is segmentally delivered during 20-second applications over a 7-cm length. Generally, two applications are performed at the superior end of the treated vein, and the catheter is withdrawn 6.5 cm for each successive application until the heating element reaches the end of the venous introducer sheath, resulting in a 0.5-cm overlap of the heated segments. This overlap ensures the absence of any gaps in ablation that might otherwise occur.

Our clinical experience is reflected in several studies. 4.6 Alan Dietzek, MD, showed that Venefit targeted endovenous therapy using the Covidien ClosureFast catheter provided long-term resolution of patient symptoms, such as limb swelling and pain. 6 The ClosureFast catheter is an endovenous RFA catheter designed to heat and close diseased veins. Dietzek reported 3-year follow-up results from patients treated with the ClosureFast catheter at 123 centers in the United States and Europe. In the study, the researchers evaluated 267 greater saphenous veins and demonstrated a 93% occlusion rate. After 3 years, most patients remained symptom-free. 6

Thomas M. Proebstle, MD, MSc, and colleagues, also showed that radiofrequency segmental ablation resolved patient symptoms, such as pain.⁴ Proebstle reported 3-year follow-up results from 256 European patients treated with radiofrequency segmental ablation. The study demonstrated a 93% occlusion rate. After three years, almost 97% of the treated legs remained free of clinically relevant axial reflux.⁴ The researchers found that patients experienced sustained clinical efficacy.⁴

Most patients who stand to benefit from diagnosis and effective treatment of CVI are otherwise healthy. Their

ability to engage in a full, rich, and active lifestyle is often exclusively limited by the consequences of ambulatory venous hypertension. Unlike patients with angina, who so often have multiple comorbidities that independently have an impact on quality of life, otherwise healthy patients with CVI can be restored to vigorous lifestyles and excellent health. At the other end of the spectrum, patients with advanced venous disease present with refractory/recurrent distal lower extremity ulcers. As is too often the case, these are regarded as end-stage manifestations of critical limb ischemia, and amputation is recommended and performed, often with no diagnostic vascular studies having been performed. In this most extreme case, failure to diagnose CVI and perform a simple, fast, and painless office-based procedure and achieve limb salvage is nothing short of tragic.

CONCLUSION

Offering venous disease procedures, with the subsequent comfort with venous manipulation, will allow cardiologists to approach cardiovascular disease with a broader skill set that can translate into enhanced abilities in other areas of cardiovascular medicine. The skills acquired on the arterial side will serve cardiologists well on the venous side and vice versa. With the emergence of innovative minimally invasive endovenous treatment options, the opportunity for invasive and interventional cardiologists to operate in these spheres will only grow.

Patients also benefit from continuity of care when cardiologists add venous disease procedures to their practice offerings. Many patients deeply trust their cardiologist, who has managed their coronary artery disease, and possibly even saved their life after a myocardial infarction. By also managing the patient's CVI, the cardiologist can continue to increase quality of life for their patients by decreasing pain, increasing mobility, and saving their limbs.

Paul Kramer, MD, FACC, FSCAI is an interventional cardiologist based in the Kansas City, Missouri area. He has disclosed that he is a consultant to Covidien. Dr. Kramer may be reached at phkramer41251@gmail.com.

- 1. Gloviczki P, Comerota AJ, Dalsing MC, et al. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg. 2011;5(suppl):2S-48S.
- 2. Kaplan RM, Criqui MH, Denenberg JO, et al. Quality of life in patients with chronic venous disease: San Diego population study. J Vasc Surg. 2003;37:1047-1053.
- 3. Shepherd AC, Gohel MS, Brown LC, et al. Randomized clinical trial of VNUS® ClosureFAST™ radiofrequency ablation versus laser for varicose veins. British Journal of Surgery. 2010;97:810-818.
- 4. Proebstle TM, Alm J, Göckertiz O, et al. Three-year European follow-up of endovenous radiofrequency-powered segmental thermal ablation of the great saphenous vein with or without treatment of calf varicosities. J Vasc Surg. 2011;54:146-152.
- Almeida JI, Kaufman J, Goekeritz, O, et al. Radiofrequency endovenous ClosureFAST versus laser ablation for the treatment of great saphenous reflux: a multicenter, single-blinded, randomized study (RECOVERY study). J Vasc Intery Radiol. 2009;20:757-759
- 6. Dietzek A. Current data on radiofrequency ablation with the ClosureFast catheter. Presented at: the 37th Annual Vein Symposium; November 17, 2010; New York.