

Cardiac Interventions

TODAY

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INTERVENTIONAL TREATMENT OF VENOUS DISEASE

Understanding
and addressing
this unmet need.

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Introduction

As the general population ages and faces an increasing obesity problem, there is an ever-rising demand for venous disease treatments. Although once considered a purely benign, superficial problem, the disease can actually reach a debilitating point and, in some cases, severely dampen patients' quality of life. Most interventional cardiologists routinely refer chronic venous insufficiency patients over to vascular surgeons, but as demand heightens, there is a solid argument for adding peripheral treatments to the cardiology armamentarium. The Venefit™ procedure with the ClosureFast™ radiofrequency catheter (Covidien, Mansfield, MA) has helped meet the needs of patients and physicians alike.

This supplement to *Cardiac Interventions Today* features four articles detailing some of the recent experiences of interventional cardiologists and a cardiovascular nurse who have ventured into the venous arena. The contributing authors detail some of the challenges they face in expanding their practice to this area, as

well as provide helpful tips to make sure the transition to venous goes smoothly.

First, James D. Joye, DO, FACC, explains why it's worth focusing on superficial venous disease and how to become educated on diagnosing and treating the problem.

Next, Paul Kramer, MD, FACC, FSCAI, details the technique he uses for vein access, disease treatment, and optimizing his patients' outcomes.

Ernesto Rivera, MD, provides his firsthand experience with bringing venous disease to his group practice and how he convinced 11 cardiologists that it was a smart addition.

Finally, Michelle Sloan, RN, MSN, APN-BC, shows how to create and sustain a positive venous disease treatment culture in a cardiovascular practice by educating staff, referring physicians, and potential patients.

We hope you find this supplement to be a valuable educational tool in your efforts to provide your patients with venous treatments and increased quality of life. ■

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Why Treat Superficial Venous Disease?

Focusing only on the heart and arteries isn't enough.

BY JAMES D. JOYE, DO, FACC

Why treat superficial venous disease? I would turn this question around for my interventional cardiologist (IC) colleagues and instead ask, "Why NOT treat superficial venous disease?" Granted, most of the training we ICs received focused on the heart and arterial systems and dealt minimally, if at all, with the venous system. Yet the heart, arteries, and veins comprise a system, and as experts on cardiovascular disease, we need to understand that system and treat it when it becomes dysfunctional. Especially for ICs already treating peripheral arterial disease, treating venous disease completes their practice's offerings.

EVOLUTION OF PRACTICE

Caring for patients with venous disease really represents another step in the evolution of interventional cardiology. Until about 2000, most ICs focused primarily on the heart and did little to treat peripheral arterial problems. As awareness of peripheral arterial disease grew, many ICs began treating that condition. Now that we have a better awareness and understanding of the impact of chronic venous insufficiency (CVI), I believe it is time that we add the treatment of CVI to our practices.

In more practical terms, in my experience, many (often the majority) of our patients with cardiac and/or arterial disease also present with venous disease. In my opinion, we owe it to them to provide complete care. Many of these patients can be readily identified by visual inspection of their legs or by simply asking them questions about venous disease symptoms during their visit. Also, you can make sure that the venous disease symptoms are included on the patient ques-

tionnaire. Finally, educational brochures and posters about venous disease can be present in the waiting and examination rooms.

I should add that my "case" for treating venous disease comes with the benefit of hindsight. I have been practicing interventional cardiology since 1995, performing both cardiology and endovascular procedures, including advanced work in limb salvage, claudication, and wound care. I did not start treating venous disease until 2007. Before that, I believed that many physicians who treated vein problems focused on the cosmetic rather than the clinical aspects and were pursuing it more for financial reasons than for patient care. Besides, I had my hands full just treating cardiac and arterial disease, so I would refer out patients with advanced venous disease.

Over time, however, I was increasingly asked to help in cases with large vessel issues (e.g., central vein stenosis, May-Thurner syndrome, and deep vein thrombosis). I also found that, in some patients, arterial treatments did not resolve some problems, such as lingering lower extremity ulcers. Some patients had advanced venous disease, presenting with profound edema, chronic dermatologic changes, recurrent ulcers, and other typical symptoms. I realized I had been missing half of the circulatory picture, the venous system. To provide the care these patients needed, I decided to learn about the venous system and venous disease.

IDENTIFYING VENOUS DISEASE

I realized that there was much about venous disease I did not know, and I believe this probably holds true for many ICs today. First, CVI is fairly common: an estimated 25% of adults in the United States have varicose

veins, and 6% have more advanced chronic venous disease.¹ Risk factors for venous disease include older age, female sex, obesity, family history, prolonged standing (e.g., in an occupation), multiple pregnancies, and frequent heavy lifting.^{2,3}

CVI develops when venous pressure is increased and the return of blood is impaired. This can be due to incompetence of valves in the axial deep, superficial, or perforator veins; venous obstruction; or both. Muscle pump dysfunction in the lower legs can also worsen venous return. Compromised venous return produces venous hypertension, particularly with standing or ambulation. Over time, venous hypertension may result in dermal changes with hyperpigmentation, subcutaneous tissue fibrosis, and possible ulceration.⁴

In my discussions about the development of venous microangiopathy over the last several years, I have encountered several hypotheses about its progression. The “fibrin cuff” hypothesis suggests that fibrin-containing fluid accumulates in the pericapillary space, increasing the diffusion barrier, inhibiting tissue repair, and maintaining inflammation. The “growth factor trapping” hypothesis postulates that fibrin and other macromolecules trap growth factor, preventing it from stimulating healing. In the “white blood cell trapping” hypothesis, white blood cells trapped in the capillaries or postcapillary venules release inflammatory mediators and proteolytic enzymes, resulting in endothelial damage that may increase permeability or impede flow, leading to occlusion. Regardless of the true underlying basic science, the reality is that chronically overpressured superficial veins will dilate, become varicose, and hydrostatically deliver an unhealthy amount of extravascular fluid to the lower extremities.

Symptoms of venous disease include varicose veins; restless legs; heaviness and fatigue; leg or ankle swelling; pain, aching, or cramping; burning or itching of the skin; skin changes; and ulcers on the skin (e.g., on the lower legs). Venous disease is not merely a cosmetic problem; it can be a serious medical condition. Patients with CVI may experience pain, debilitating symptoms, and a reduced quality of life.⁴⁻⁶ In some severe cases, CVI can even require limb amputation.⁵ However, CVI need not be severe to affect quality of life. A study of current and retired employees of the University of California, San Diego, showed that even modest venous disease caused significant pain, reduced individuals’ perception of health, and impaired physical functioning, including at work and in daily activities.¹ Arterial and venous claudication present differently. Venous claudication presents itself as

daily prolonged discomfort and disability.⁴

Obviously, it is important that we treat severe CVI (e.g., CEAP class 4–6), but also selectively treating CEAP class 2 to class 3 patients can improve quality of life. Patients with more moderate CVI may usually feel fine, but by the end of the day, their legs can feel full, heavy, and fatigued. As a result, they are at risk for becoming increasingly sedentary, setting up a path to poor health outcomes over time. Thus, treating even milder forms of CVI can not only prevent progression to more severe disease but can also have a positive impact on overall health.⁴ The opportunity to effectively treat these patients with CVI requires that ICs become educated on the topic, aware of the natural history, and committed to a treatment strategy.

For ICs involved in treating patients with critical limb ischemia (CLI), it is important to know that many patients with CLI have mixed arterial and venous disease. For example, an IC I know well had been treating a patient with arterial disease and recurrent CLI for some time. Despite some very skilled arterial reconstruction, close surveillance, and wound care, the patient’s wound simply would not heal. He referred the patient to me for a second opinion, and within minutes of talking and examining her, it was clearly obvious that her medial malleolar distribution, moist ulcer was perpetuated by CVI. Her problem was not arterial insufficiency, and additional endovascular intervention was not what she needed. A simple venous reflux ultrasound confirmed my suspicion, and subsequent endovenous ablation ultimately led to wound healing. I am embarrassed to admit that earlier in my career, I made the same mistake on a handful of my CLI patients. It was not until I made the commitment to become educated about CVI that I was better able to more comprehensively care for my patients with lower extremity disease.

VENOUS EDUCATION

Resources are increasingly available for those seeking to learn more about venous disease and how to incorporate its treatment into their practice. In addition to satellite programs at most major vascular and endovascular meetings, dedicated vein meetings are now starting to emerge. Dedicated 2- to 3-day seminars are also available for intensive study of CVI, device-specific training, and the ultrasound skills that are necessary. In my opinion, the challenge for the IC really lies in devoting the time and energy to learn the venous system and how it behaves and misbehaves. Compared to most of

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Looking Beyond Arteries

Integrating venous disease management into an existing cardiology practice.

BY PAUL KRAMER, MD, FACC, FSCAI

Cardiologists 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.



Images provided courtesy of Anthony Gasparis, MD.

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-

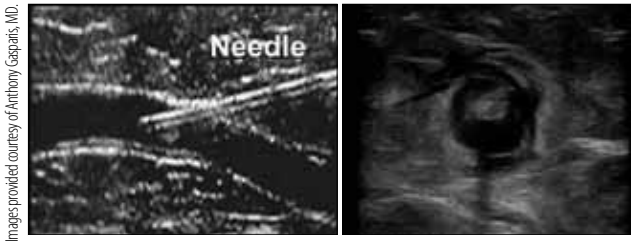


Figure 2. The procedure is performed under ultrasound guidance, from initial vein access using the Seldinger technique (A) to properly locating the catheter in the vein (B).

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.⁴ Inasmuch 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.

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The Case for Treating Venous Disease

Balancing the “red” and “blue” in practice.

BY ERNESTO RIVERA, MD

As an interventional cardiologist who has been practicing for 23 years, I have a good deal of experience across a wide variety of procedures and techniques, from percutaneous transluminal coronary angioplasty and stent placement to pacemaker implantation to peripheral vascular studies and treatment. Most of my training and experience, however, was on the “red” or arterial side of vascular medicine.

Approximately 4 years ago, I noticed that a significant and increasing number of my patients reported leg symptoms, such as heaviness, swelling, and pain, even though their leg arteries were normal, suggesting chronic venous insufficiency (CVI). In the more distant past, I had often referred severe CVI patients to vascular surgeons, who usually performed vein stripping. However, in subsequent years, as far less invasive yet very effective approaches became available and I saw more of my own patients present with venous disease, I decided to learn more about how I could help them. I visited venous practices, observed procedures, and attended courses and symposia on the topic, including one with the surgeons at Methodist Hospital in Houston, Texas, and also the annual International Vein Congress in Miami, Florida. For me, the learning curve was truly an eye-opening experience. I soon realized that venous disease is not only a common and serious medical condition, but I and my practice colleagues and staff already had many of the skills and equipment needed to assess and treat it. Like an ignited match, the cause of including venous disease in our practice quickly caught fire in me.

MAKING THE CASE

As is the process with many group practices, I had to make the case for adding venous disease to ours (a group of 11 cardiologists). At first, there was some resistance from our board of directors (e.g., “We are a cardiology practice”). I pointed out that venous disease is not merely a cosmetic inconvenience, but it can be a serious medical condition—



Figure 1. A look at the waiting room setup at Amarillo Heart Group's vein clinic. A video displays venous disease information to help educate patients and increase their awareness of possible symptoms.

nearly 25% of Americans have varicose veins, and 6% have CVI,^{1,2} which can severely affect quality of life^{1,3,4} and can, in some cases, even result in limb amputation.⁴ I did my homework to specifically describe how we could incorporate it in our practice. For instance, I provided an overview of additional equipment and staffing needs, educational needs, and pro forma costs; how, initially at least, we would have many patients from our existing patient base (and their family members, because venous disease is familial) and current general cardiovascular disease referrals; and therefore, we would not have to solicit or rely on venous disease referrals.

A number of my practice colleagues became interested. As I had done, they made time to visit venous clinics in other practices and observed the procedures, took courses and workshops, and consulted texts and the medical literature. We decided to pursue venous disease treatment. We dedicated a room for venous procedures and acquired

EQUIPMENT LIST

- Venefit targeted endovenous therapy system
- Convertible US
- Klein pump for administration of tumescence anesthesia
- Special vascular table, which offers tilt, height, and back lift
- Vein closure kit tailored to meet supply needs of the procedure
- Temperature control
- Soft music
- TV

and set up all the necessary additional equipment within 2 weeks (see *Equipment List*, above).

GROWING WITHOUT PAINS

Once we started performing venous procedures, it was amazing how rapidly our practice changed and grew. After starting with one room for venous procedures during the first year, we then added a second room. One year later, we created a vein clinic—four treatment rooms and three scanning rooms—by converting to electronic medical records and reallocating space that was previously used for paper records and cardiac rehab. But the demand has continued to grow. We have a patient waiting list time of 6 to 7 months, and that is just from our existing patient base and general cardiovascular referrals (e.g., patients with high blood lipids, hypertension, obesity, type 2 diabetes, etc.). We find that many of these referral patients also have venous disease when they complete our incoming patient questionnaire (see page 11), which captures cardiac, arterial, and venous symptoms. We also have a video about venous disease running in the patient waiting room to increase their awareness and prompt discussions about possible symptoms with their physician (Figure 1).

Of our 11 cardiologists, seven—including four invasive and three interventional cardiologists—now dedicate time each week to venous patients and procedures. I currently allocate about half my time to seeing patients in the office, about 30 to 35 in the morning or afternoon of a day. The other half of my time is fairly evenly divided between “blue” and “red” procedures (i.e., an average of 2 or 3 half days a week for each). That works out to approximately 20 to 30 venous procedures and 15 heart catheterizations and peripheral arterial interventions per week.

Although we have not actively sought venous disease referrals yet, we know that when we do, educating referring physicians about the condition will be important. Indeed, many physicians may not be aware of the signs and symptoms of venous disease and do not realize that patients can



Figure 2. Dr. Rivera performing the Venefit procedure.

have normal healthy arteries and also have venous disease. Educating them about these aspects can help referrals; as in one example, when physicians at a local wound clinic referred patients to us who present with skin problems and ulcers on their legs and requested we open up the patients' arteries. However, after we studied the patients, we often found that their arteries were already open, but ultrasound revealed significant CVI, which we then treated. We have often had to explain to the referrer why we treated the patient for venous rather than arterial disease, as the wound care specialist originally requested.

Equipment manufacturers can help cardiology practices add venous disease treatment to their services. For example, ultrasound companies can provide technical support to teach technicians how to perform and read venous ultrasound studies. The American College of Phlebology provides excellent courses for ultrasound technicians on this topic. Today, we have ultrasound technicians who eat, sleep, and breathe vein studies alone. Generating high-quality ultrasound studies of venous problems is not only a critical diagnostic tool but can be invaluable for patient communications. For example, some patients only want their distal spider veins treated, mainly to address cosmetic issues. I tell them that would only treat the “leaves of the tree” and not the underlying problems of the “trunk” or “larger branches.” A good-quality venous ultrasound image helps me clearly show them what I am talking about, so they understand that they have a medical problem that requires treatment.

For venous procedures, we previously used laser therapy but have changed to radiofrequency ablation (RFA) (Venefit targeted endovenous therapy using the Covidien ClosureFast catheter, Covidien, Mansfield, MA) (Figure 2), because we found it to produce good results, and patients tolerate it well. Less often, we perform phlebectomy or sclerotherapy (each comprising approximately 10% of patients).

PATIENT QUESTIONNAIRE

Ernesto Rivera, MD**Assessment of Venous Insufficiency**

Name _____ DOB _____

Date _____

Assessment: Varicose Veins Spider Veins

CEAP Classification: 1 2 3 4 5 6

Does the pt have any symptoms due to venous insufficiency?

YES NO

If yes, what symptoms does the pt have?

Pain Swelling Cramping Aching Heaviness
Burning Itching Color change

Do symptoms interfere with activities of daily living?

YES NO

If yes, what activities?

Does the pt take OTC or prescription medication to relieve symptoms?

YES NO

If yes, what medication and dose?

How many days did the pt have to use medications within 2 weeks?

Do the pt's daily activities require prolonged periods of standing?

YES NO

If yes, how many times during the day does the pt take a break or sit due to sx?

Has the pt experienced intractable ulceration due to venous stasis?

YES NOHas the pt had more than 1 episode of minor hemorrhage from
a ruptured superficial varicosity?**YES NO**

Has the pt had a hemorrhage requiring a blood transfusion?

YES NO

A PATIENT CASE

One of our more interesting cases involved a woman in her late 20s. She had a history of venous insufficiency on both sides of her family (her two grandmothers) and began noticing spider veins on her ankles when she was 14 years old. Around 2007, she began experiencing common symptoms of CVI: leg and ankle swelling, a feeling of heaviness in the legs, and general fatigue at the end of the day. Although she was a nurse by training, she did not consider CVI and thought her symptoms were merely a normal response to the long periods of standing at her job. She began wearing over-the-counter compression stockings, which initially helped, but over time, her symptoms worsened. In 2009, both of her legs became acutely swollen for more than a week, so she consulted her primary care physician. After ultrasound yielded negative findings for deep vein thrombosis, he prescribed anti-inflammatory medication and recommended she continue wearing the over-the-counter compression stockings; he never raised the possibility of CVI. Her symptoms improved somewhat but then worsened again a year later, at which point, her (new) primary care provider referred her to our practice.

Ultrasound revealed significant reflux in the greater saphenous veins of both legs (10 and 12 seconds in the right and left legs, respectively), although she reported worse symptoms in the right leg. I prescribed compression stockings and asked her to return in 3 months. On her return, it was clear that her symptoms remained, so we decided to proceed with laser ablation of the greater saphenous vein in her right leg in August 2011. By 2 weeks after the procedure, her CVI symptoms resolved, and she was able to stop wearing compression stockings, although she experienced a “rope-like” feeling of discomfort in her leg for about a week. A few weeks later, we treated her left leg, this time with RFA (Venefit targeted endovenous therapy using the Covidien ClosureFast catheter). We achieved the same results in resolving the CVI symptoms but with almost no discomfort after the procedure, which has generally been our experience with RFA versus laser.

Soon after the RFA procedure, the patient came to work as a nurse in our practice and has become an “ambassador” for CVI treatment, educating patients about the condition and treatment options, discussing their ultrasound findings with them, and assisting in the procedures. As she told me, “The treatment changed my life—I have more energy and no longer feel fatigued at the end of the day. I feel passionate about educating patients on CVI; so many have it but don’t know it and don’t realize there are very effective treatments for it. I wish more primary care practitioners knew about CVI. In my case, and likely for many other people, it would have meant being treated earlier and avoiding years of needless suffering.”

SUMMARY

Why should a cardiology practice consider adding “blue” to its current “red” services? Based on our experience, I think it boils down to the following:

Medically, it’s the right thing to do. Venous disease can have serious, even life-threatening consequences, and we owe our patients the best care possible.

It usually requires only a minimal investment in education and equipment. Both invasive and interventional cardiologists know “wire techniques,” so they can easily learn RFA. Also, most practices already have a good deal of the necessary equipment; the additional equipment needed for venous disease procedures can be obtained and set up quickly.

It can be added to the practice in a very controlled way. Many cardiologists say to me, “I’m already busy enough—how can I incorporate veins?” We all know time allocation is a key consideration in any interventional cardiology practice. If an interventional cardiologist wants to spend all day, every day in the cath lab, he or she can do so. Venous disease does not generally require urgent treatment, and procedures can be scheduled on days and times that the interventional cardiologist and the practice determines.

It is scalable. Practices can decide how much time they want to devote to venous disease, because there are many patients with the condition. Most practices will find many patients in their existing patient and referral base. More patients can be identified by pursuing venous disease referrals from other providers (e.g., primary care, podiatrists, and obstetricians/gynecologists) and from community outreach.

It is exciting and fast-paced, yet less worrisome. The physician can perform most procedures fairly rapidly in the practice setting (as opposed to in a hospital cath lab), without the need to wear lead shielding. And unlike many cardiac and peripheral arterial procedures, the risk of complications with venous procedures is very low. ■

Ernesto Rivera, MD, is a practicing interventional cardiologist and the Medical Director of Clinical Research at the Amarillo Heart Group in Texas. He is also the founder and codirector of the Amarillo Heart Group Vein Center. He has disclosed that he is a consultant to Covidien. Dr. Rivera may be reached at riverastent@yahoo.com.

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Rethinking Your Peripheral Practice

Incorporating treatment of venous disease.

BY MICHELLE SLOAN, RN, MSN, APN-BC

"Do you feel your legs limit you?" Incorporating this simple-yet-open question in your practice can unveil valuable patient information. It can assess your patient's functional level, which is essential to know in a cardiology practice. Their perceived functional limitations can help you risk stratify them by potentially identifying "dormant" peripheral arterial disease (PAD) or chronic venous insufficiency (CVI) as the culprit of this limitation. However, is your practice prepared to address the answer to this question?

Vascular diseases of the lower extremities are a growing problem in our aging, overweight society. Both PAD and CVI can cause functional decline and can be associated with significant debility.¹ Disability and/or a sedentary lifestyle brought on by both of these disease processes can worsen comorbid conditions, affecting overall health. Both of these disease states can carry cardiovascular implications, yet these conditions are not foremost in the minds of many cardiology practices.

Early identification and awareness of these diseases can provide patients better outcomes. Conservative management has long served as a "bandage" for both PAD and CVI, addressing symptoms rather than the underlying cause. Recent advances in research and technology are challenging and changing our treatment and practice patterns. Guidelines are being generated and updated to follow suit. Where there were once few options, there now exists an opportunity to give function, activity, and life back to our patients who have vascular disease. According to Delos M. Cosgrove, MD, CEO and President of the Cleveland Clinic, "The future belongs to those who seize the opportunities created by innovation."²

At Eastlake Cardiovascular (St. Clair Shores, MI), we seized this opportunity to provide our patients with innovative vascular treatments. The desire to offer complete cardiovascular care was an enlightening and rewarding journey. It originally began with PAD and evolved with the incorporation of venous disease. Our experience may provide pearls in creat-

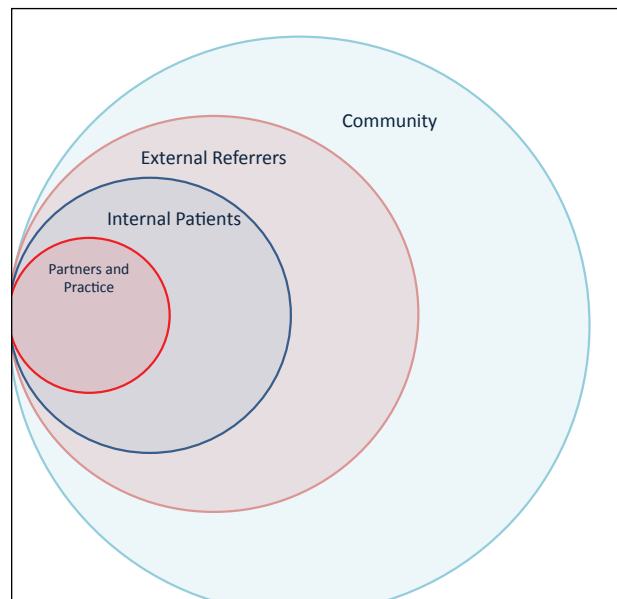


Figure 1. The circles of success: key audiences and environments to consider when branding and expanding your peripheral practice.

ing and refining your own complete vascular practice.

Physical limitations brought on by venous disease are not fully appreciated in the healthcare community and carry many preconceived notions.^{3,4} A majority of our society recommends being more active and follow a heart-healthy lifestyle. For some patients, this is simply not an option; they are "peripherally challenged." As we ventured into the peripheral space addressing the circulatory limitations of our patients, we unexpectedly found our diagnosis had migrated more often than not from arterial to venous pathology. Lifestyle-limiting claudication and nighttime symptoms requiring analgesics were, and could be assumed to be, atypical PAD symptoms. This was the genesis of respect for venous disease within our practice.

By inquiring about our patients' overall leg health and

function, we found that venous disease was abundant and that several patients had both arterial and venous disease. We met the biases and myths of venous disease head on. It is not a benign cosmetic annoyance; it carries medical implications and can be debilitating. CVI was embraced as part of our vascular efforts to offer full circulatory care to our patients. We incorporated venous treatment and complementary services into our practice including the Venefit procedure (RF ablation) (Covidien, Mansfield, MA), superficial venous reflux studies, and compression stockings, which added another dimension and further differentiated us from other practices. We took our key learnings from incorporating PAD and applied them to CVI for our vascular transformation. Our peripheral culture, which had matured over the years, led to a level of comfort among the office staff when expanding this vascular focus. Speaking to patients about their complete leg health (now including venous disease) seemed only natural and was a nearly seamless transition. I attribute this progression to our physicians seeking and recognizing the disparity of patients who have functional limitation and physical lifestyle changes due to circulatory problems and their lack of awareness of options and treatments.

I also consult with other cardiology practices around the country, and I have begun to see a similar adoption curve. New technology is contributing to the emergence of a new specialist: a circulatory care physician, expanding on medical and endovascular intervention.

Each practice, patient, geographical location, and payer mix is different. These variables present their own unique challenges; however, to build a successful, sustainable vascular program, all practices require the same critical elements. These elements, although they may seem basic, are often taken for granted and overlooked. They include the creation of an internal culture adopted by the entire practice and office, capturing existing patients, educating your referral physicians, and finding new patients through community outreach.

No matter how good the intentions are, change in any form can be challenging. We found taking a stepped approach and building a strong internal foundation can help transform your vascular practice into a sustainable entity. These steps should be initiated internally first and then branch out to your referrals and the community.

CREATION OF AN INTERNAL CULTURE: ENGAGE AND EDUCATE INTERNALLY

To truly brand your practice as a vascular center of excellence, you must first establish the culture in your office. Everyone in the office, from receptionists to medical assistants to your partners, must know the mission, understand the passion in this direction, and believe in it. Success is syn-

ergistic. There is power in numbers. Incorporating arterial and venous disease treatment into a practice is not an easy process. It takes time, education, and dedication to achieve a mission of providing complete cardiovascular care. We had to change our physicians' existing practice paradigm by having them engage and inquire about their patients' vascular symptoms. This new process needs to be seamless and mindful of time. Trial and error with proactive revisions were paramount to our success.

We engaged our office through education. Several meetings with the partners were held to address recent technological advances and patient success stories. We went back to the basics and discussed risk factors, symptoms, and treatment algorithms. It is a misconception to assume that this information is known and mastered by those who do not practice it or see it daily. We devised a mission and a goal in implementing guidelines. This initiative was then carried to our staff, and a vascular champion was sought out to help manage the program. This "champion" can be anyone in the office that is driven and motivated by the vascular mission. It can be a nurse practitioner, nurse, MA, office manager, or a vascular tech, but is typically not a physician as they are usually too busy with the day-to-day logistics of the practice. This champion owns the program and seeks ways to implement and sustain it and is always open to improvements to the program. The champion is the liaison between the staff, physicians and the patient, and represents each perspective.

When your staff is knowledgeable about the goals and reasons behind the vascular endeavor in your office, they are empowered. They will feel ownership and are apt to play an integral role in establishing the culture. Several meetings outlined our mission with staff, and we welcomed their input. To identify these patients, complete vascular awareness must be part of the entire practice's mindset every day. The staff needs to be educated about venous disease and its signs and symptoms, as well as the solutions we can offer to lessen their burden. We created a culture in our office: "Be the expert, be proud, motivate, support, and create a complete cardiovascular experience for the patient."

CAPTURING EXISTING PATIENTS

Your waiting room may have patients who already have venous disease. Many have lifestyles and occupations that contribute to this condition. Reach out to these established and engaged patients and educate them.

Given the role heredity plays in one's risk of developing CVI, a patient may have watched a parent or relative deal with the disease and assume they are destined the same fate. Patients tend to self-diagnose, or make assumptions about their symptoms and treatment options. They may believe their achy legs are a benign condition and a result

PATIENT SCREENING LETTER



Eastlake Cardiovascular, PC

Dear Patient,

Your *Complete Cardiovascular Health* is very important to us. The arteries and veins in your body work together with your heart and make up your Cardiovascular System. Healthy legs can be a sign of a healthy heart. Abnormalities in the arterial or venous system in the legs can cause discomfort and limit your activity or cause you to “slow down.” Many myths surround these ailments, and symptoms may be gradual and subtle, making Peripheral Arterial Disease (PAD) and Chronic Venous Insufficiency (CVI) or varicose veins difficult to identify. Both are a growing problem in our society and often go under treated and even unrecognized. There have been many advances in the research and treatment of PAD and CVI, which can make you more active, feel better, and improve your quality of life.

Please take a moment to answer the questions below so that we may briefly assess your *Circulatory or Cardiovascular Health*.

Comments:

1.) Do you have discomfort, fatigue or heaviness in your legs

with activity that is relieved by rest? and/or YES / NO
at the end of the day or with standing? YES / NO*

2.) Most nights do your legs or feet bother you or awaken you with burning, pain or coldness while laying in bed?

YES / NO
Do your legs spasm or feel restless at night? YES / NO*
Do your legs feel better with elevation? YES / NO*

3.) Do you ever need to stop and rest when walking or have difficulty keeping up with others? Why? _____

YES / NO

4.) Do you feel your legs limit you? If yes, please explain.

YES / NO

5.) Please indicate if you have experienced any of the following in your feet or legs (circle all that apply):

Presence of:	Swelling*	Ulcers/Poor healing	Itchiness*
Changes in:	Temperature	Texture	Color
		(leathery or dry skin)	(red, brown, or blue/purple)

6.) Do you have a history of any of the following?

- | | |
|--|---|
| ☐ Diabetes or “borderline” diabetes | ☐ Family or ☐ Personal history of varicose/spider veins* |
| ☐ Smoking or history of smoking | ☐ Family or ☐ Personal history AAA (aneurysm) |
| ☐ Age > 65 years | ☐ Family or ☐ Personal history of blood clotting disorder |
| ☐ Occupation requiring you to be on your feet or sitting for the day* | or blood clot in the legs (DVT) or lungs (PE)* |

Name _____ Date _____ Reviewed by _____

If you have any questions, concerns, or would like more information please do not hesitate to let us know.

*More indicative of Venous disease vs. Arterial

Sloan, 2012

of being on their feet all day or aging. Increasing patient awareness and education about CVI with in-office materials, such as posters and brochures in the waiting or examination rooms, can prompt patients to discuss their symptoms or concerns with their doctor. Educational materials are an effective way to convey important messages to patients about their risk factors, signs, symptoms, and treatment options. Patients might recognize themselves or family members through the use of photos displaying CVI progression with chronic skin changes. Our experience is that patients are more likely to make a connection to their leg symptoms after seeing educational posters in the waiting room.

DEAR PATIENT...

We found the most effective and efficient way to assess our patients, without disrupting the primary visit concern (for example, heart failure) was to institute a "Dear Patient" letter (see page 15). Whatever assessment method is chosen, it cannot interfere with existing office workflow. If it does, adoption, success, and sustainability will be more difficult to achieve.

The "Dear Patient" letter is given to patients annually and has been a key step in our vascular program. It is intended to briefly educate the patient with an opening paragraph explaining arterial and venous vascular disease, its implications, and prevalence. It also contains six simple questions focusing on different aspects of potential leg symptoms and functional limitations. The questions are pertinent in differentiating PAD and CVI and address risk factors and medical history.

Upon entering the examination room, patients are asked to remove their socks and shoes making their lower extremities more easily accessible for examination. The physician couples this with the responses given on their "Dear Patient" letter, and a treatment plan is formulated, if need be. At the very least, we are creating awareness of vascular disease among the community.

Do not underestimate the influence each patient can have in the success of your practice. Providing patients with a pleasant, inviting, and well-organized experience can speak volumes in terms of referrals. Each patient can become ambassadors for your practice.

YOUR REFERRAL BASE: EDUCATION AND EXTERNAL EXPANSION

Once your internal platform is established, a more formal focus can be placed outside your office to drive in new patients and increase awareness. Begin with established referral streams and build upon these existing relationships. This is best done with small personal meetings, dinners, lunches, or "curbside consults." Educate them on evolving

technologies, prevalence, symptoms, and etiology. Most importantly, abolish the ingrained cosmetic misconceptions revolving around venous disease. Help them understand that disability caused by venous hypertension and reflux is a progressive disease that can be effectively treated. As health care professionals, we share the responsibility to increase the awareness and identification of CVI as part of the vascular disease continuum. Commit to the circulatory health of mutual patients by being on the forefront of technology.

Remember, you are presenting yourself as the expert in this space. Anticipate the questions your referral base will have and provide them with the information they will need to refer patients. This includes questions the patient may ask regarding RF ablation, conservative therapy, what to expect before and after RF ablation, what is normal, and when patients should be referred back. Extend an invitation to these referring clinicians to visit your lab and observe cases. You also need to convey that appropriate and timely care of patients is a priority. Communication with your referring community with prompt feedback is key. Know the best way to keep them abreast of their patients' treatment plan. Again, as with your staff, involvement and engagement ignites empowerment and builds trust and loyalty. Apply the 80/20 rule of business: 80% of your success comes from 20% of your efforts. The key however, is learning where to focus those efforts.

Once you feel you have successfully built a support system internally and among your referral base, it is appropriate to branch out and develop new, targeted referral streams. Seek out those health care providers who may have patients who could benefit from your relationship. To find these resources and relationships, revisit the risk factors and complaints of CVI patients (the key patient attributes being female sex, history of pregnancy or obesity, standing or sitting occupation, and wounds and skin alterations). Primary care physicians are obviously important for referrals; however, we have found that we also need to target the specialists who are most likely to see these at-risk patients, such as podiatrists, obstetricians, and gynecologists.

We are also active with local medical group chapters and we make presentations at their meetings. Some of our partners include SALSAL (Save a Leg, Save a Life Foundation), Michigan Podiatric Society, and the Second Chance Heart Club. Grand rounds at your local hospital and speaking at seminars for residents all support your reputation and dedication, as well as foster awareness.

COMMUNITY OUTREACH: BRANDING AND EXPANDING

Community outreach serves two purposes. It establishes your practice with patients in your community as a vascular

or circulatory center of excellence, and it also breeds awareness. Considering the scope of CVI, awareness and education are paramount in the improvement of outcomes, prevention, identification, and treatment. In the United States, more than 30 million people have varicose veins or CVI, yet only 1.9 million seek treatment.^{5,6} This underdiagnosis and undertreatment of CVI is not all related to the health care community's biases and lack of awareness. Patients may be unaware of their options with recent technological advancements and research. Varicose veins are, erroneously, often not viewed as a true medical condition that interventions (1) could successfully treat, and (2) would be covered by insurance.

Outreach can take many forms, including educational seminars or screening events. We have held evening lectures in our office focusing on leg symptoms and have an open forum addressing concerns and options. In these forums, patients see they are not alone and can take hope from this event that they could potentially regain a more active, pain-free lifestyle. Regardless of the platform, advertising and promotion of these events are essential. Also, keeping in mind the target audience of this disease, you should make these events convenient and accessible for your target patient to attend. This may require evenings or weekends to reach a working population. Keep in mind the risk factors and demographics of this population. Then, "go to the disease." By this, I mean go to the environment where patients with the risk factors for CVI can be found—mothers, nurses, teachers, assembly line workers, etc. Given the prevalence and target audience of patients with varicose veins or CVI (women/mothers between the ages of 35–60 years who have a standing occupation), a great place to conduct your initial educational event might be at the hospital itself. This can be promoted to the nursing staff and other employees. New patients can be generated and should be sought in your marketing efforts as well. Contact the local media to run a news story. They can be a catalyst to driving conversation and questions.

The nurses and physicians in our practice also speak at various locations covering CVI and other topics to educate and make a presence in the community. Some of these venues we put together and run, others we piggyback onto. These sessions may be at senior centers, health expos, church gatherings, diabetic education classes, places of employment (such as the hospital or assembly line workers), community events, and in our office. Spring and summer are great times for a patient seminar on CVI because people tend to be more active and their symptoms (such as heaviness and swelling) become more apparent. Also, people start thinking about shorts and exposing their legs.

Our next endeavor will be to conduct an event focusing on general leg health, which may also include a podiatrist,

to allow us to address both PAD and CVI at one event. Such value-added services—referral physician education and support, patient screening and education, and community outreach—enhance your reputation. It brands your practice and gives you name recognition among the community you serve and other health care providers.

INGREDIENTS FOR SUCCESS

There are a number of important ingredients for successfully integrating venous disease and its treatment into a cardiovascular practice. I believe three of the most important are passion, dedication, and persistence. It can take a great deal of time and energy to become established among your peers, patients, and the community as a respected leader. It is not enough to just say you are a peripheral center of excellence. You and your practice need to showcase a united culture internally and externally, with a common philosophy shared throughout the office. A physician with the ability and passion needs to lead others in the office who can assist in promoting the awareness, outreach, and logistics of an internal and external action plan. It is growth through enlightenment and alignment. A champion of venous offerings must want to learn about varicose veins and CVI, educate practice physicians and staff, institute venous disease screening tools and protocols and other procedural changes, develop or identify relevant materials—such as patient education posters and brochures—and spearhead approaches to identify patients.

Tracking the path a patient takes in finding your practice, and their movement through your office, is important. A simple question from the receptionist or on a new patient questionnaire can provide insight as to which avenues are most effective in treating your patients. Tracking this information can help you channel your efforts toward the appropriate programs.

Finally, cardiology practices seeking to add venous disease treatment to their practice can be comforted in knowing you do not have to recreate the wheel to expand opportunities for your patients. Many industry leaders and coalitions in the peripheral space have a variety of marketing and educational resources to assist with practice development and community outreach.

To treat venous reflux or CVI, our practice offers Venefit targeted endovenous therapy using the Covidien ClosureFast catheter. It delivers energy using radiofrequency to ablate the refluxing superficial vein. Covidien provides a wealth of excellent information and materials on its website to help customers with market development, including educational modules for both treating and referring physicians, and in-office materials including templates for newsletters, posters, and patient education brochures.

Educational materials are also available from the Society

for Vascular Nursing, the Vascular Disease Foundation, the American Venous Forum, and Rethink Varicose Veins—an educational campaign sponsored by Covidien that aims to raise community awareness of the health implications of varicose veins and CVI.

SUMMARY

Many cardiology practices have successfully integrated PAD treatment into their offerings. Now, they are beginning to add the treatment of venous disease. CVI is a serious, often debilitating condition, and early treatment can make an immense difference in the quality of life of our patients. Offering complete circulatory care can accomplish this.

Patients with CVI include a large portion of those already seen in most cardiology practices. In addition, referrals from other providers, patients, and the broader community can help bridge the gap between presence of symptoms to diagnosis and from diagnosis to treatment.

Many excellent resources are readily available that can help smooth the integration and create the internal culture for your practice. Having a venous disease champion in a practice is invaluable for facilitating educating, organizing, marketing and making structural and procedural modifications to the program, and ensuring sustainability can often be an overlooked and underappreciated responsibility. One individual or a focused and dedicated team of people can carry out these responsibilities. You will go further and be stronger with the energy this person can bring to your mission.

If you are thinking of expanding your practice to include venous disease treatment, have a vision, set goals, create a plan, and develop a team. Working this plan will help you successfully expand your practice's peripheral vision. ■

Michelle Sloan, RN, MSN, APN-BC, is with Eastlake Cardiovascular in St. Clair Shores, Michigan. She has disclosed that she is a consultant to Covidien. She may be reached at michellesloan.np@gmail.com.

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(Continued from page 5)

the interventional procedural work that we perform, the technical aspects of endovenous ablation are not difficult to learn or apply. Many of the catheter and wire skills used for coronary and endovascular procedures readily translate to endovenous procedural work. The reverse is also true, as I feel that the unique skill sets learned to perform venous procedures has made me better on the arterial side of my practice. Endovenous procedures intimately require a dedication to transcutaneous, hand-held ultrasound to identify pathology, gain access, and guide therapy. Now that I am comfortable with ultrasound guidance, and in the interest of patient safety, I encourage the routine use of ultrasound for all vascular access.

CONCLUSION

Given that CVI is a widely prevalent condition among cardiovascular patients, ICs can determine the amount of time they want to devote to it in their practice. In my case, treatment of CVI and its sequelae comprises approximately 5% of my consultative and procedural work. For others, it may be significantly more. I find this work to be professionally satisfying on many levels. I perform radiofrequency ablation (my preference) in my office and must confess that after a long week of intense cardiac and vascular interventions, I look forward to "lead-free" Fridays! ■

James D. Joye, DO, FACC, is Medical Director of Research & Education at the Heart & Vascular Institute of El Camino Hospital in Mountain View, California. He also serves as Chief Medical Officer of the Fogarty Institute for Innovation in Mountain View, California. He has disclosed that he is a founding board member of VIVA (Vascular Interventional Advances) and a consultant to Covidien. Dr. Joye may be reached at jimjoye@aol.com.

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