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CURRENT GUIDELINES FOR TREATMENT OF VENOUS INSUFFICIENCY

AT THE ALLURE VEIN CENTER, AUGUST 2017

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To give a very brief overview of how the practice of managing varicose veins in venous insufficiency has evolved, I'll tell you a story.

I first started treating varicose veins with ultrasound-guided sclerotherapy. This is something that came over from Europe as a solution for or an alternative to the conventional surgical stripping of saphenous veins and varicosities. French and other European doctors had noted that if they treated the saphenous reflux with liquid sclerotherapy, it wasn't as effective as surgical stripping. If these sclerotherapy solutions were turned into a foam, however, they were about as effective as surgery for long-term resolution of saphenous reflux. Numerous papers (that I won't review here) showed almost even effectiveness; in some cases, these European methods were superior as far as patient satisfaction went.

I then decided to start treating patients with venous insufficiency. In 2004, when I started this practice, lasers and radiofrequency weren't approved for insurance coverage, so I did pretty extensive research and became an expert at foam sclerotherapy for the treatment of varicose veins. I had the only practice in the Midwest that offered this novel, amazing alternative to surgery.

We grew extremely rapidly because we had no competition. Yes, at the time, there were certainly surgeons who were cutting out veins, but I was standing at a table by myself saying "I'm different!" When people can see that you're doing something different, they get an opportunity to investigate what exactly you're doing and find out that you're offering a better service. You have to show them why—just saying that you're better is not a differentiating factor. This is a secret to our success.

I started attending various venous disease meetings where the new lasers and radiofrequency devices were being presented. At that point, the manufacturers had gotten FDA approval; then, insurers started paying for the procedure since the laser- and radiofrequency-based methods were found to be superior to surgery. Interestingly, I treated 10 patients who had bilateral venous insufficiency by using foam on one leg with a catheter and tumescent—in other words, it was chemical ablation, but treated the exact same way as we do now with laser. In the other leg, I treated those 10 patients with a 1320 nm CoolTouch laser, which was the best laser available at the time.

At the one-year mark, both the laser-treated leg and the foam-treated leg had the same outcome. The foam was less much less expensive, but Blue Cross and other carriers had approved paying for the laser treatments—which were expensive and cost insurers a lot of money—and then decided that foam sclerotherapy was "experimental" and that they therefore wouldn't cover foam treatments for saphenous reflux. They still cover for foam treatments for varicose veins, but not for saphenous reflux.

We switched over to CoolTouch for ablation of the saphenous reflux and did sclerotherapy for associated varicosities. At that time, I never did any microphlebectomies, because I was differentiating us as a nonsurgical vein practice, and although the surgical removal of the varicosities is a reasonable option, my patients were coming to me because they did not want to be cut.

I did a study comparing the radiofrequency device to the laser device: I treated one hundred patients with bilateral disease using laser on one leg and radiofrequency on the other. The outcomes were pretty much the same. They had the same postoperative comfort or discomfort and the same procedural comfort or discomfort. Neither leg had any significant complications. In the end, performing the procedure with the laser was a little easier—plus I already had the laser machine, whereas I had to purchase/rent the radiofrequency generators—so I stuck with laser.

About two or three years ago, the radiofrequency device company came to me and offered us the radiofrequency generators at no charge if we would use their product instead of lasers. Since there was no ethical concern because I knew that scientifically, the two procedures had the same outcome, I decided to start using the radiofrequency devices so that I didn't have to buy more generators as we grew our offices.

What we observed years after our first study was that radiofrequency patients had less postoperative pain than our laser patients typically did. Both were very minimal, but in that regard, the radiofrequency is superior. And after doing the radiofrequency procedures consistently, we've been able to see that the outcomes are identical, so from time to time, we may change between laser treatments and radiofrequency treatments. I consider them to be equally highly effective. Certainly, either is superior to traditional old-fashioned surgery.

Early on, we were a "varicose vein" practice. We saw some patients with significant disease, as in the case of Jerry (whom we highlight in our promotional material). Jerry had extensive blood clots with some outflow obstructions and extremely ugly legs: one of his legs was about two times or three times as big as the other leg, and he had ulcerations and skin changes. He was pretty much incapacitated and got around in a wheelchair or with a walker. He had had prior stripping of the saphenous system in 2006. Over a period of about a year, I treated 16 of his perforators. He brought his daughter in to see me in 2016, and while he was in my office with her, I took a look at his legs. They're now both the exact same size and free of ulcerations. He has no more pain. His wife was telling me that now he can walk around the yard, do chores, and is very active, none of which he never thought he would be able to do again.

Jerry's case led me to hyperfocus on "ugly legs." This group of "ugly leg" patients is a group of patients nobody in our market is paying any attention to. They are left to suffer with venous insufficiency, and because their legs are ugly and they have comorbidities, doctors are telling them to "just live with it" so that the doctors can focus on patients with "pretty legs"—that is, patients who have a normal appearance and some varicose veins.

Our business is a business. It is a medical practice, yes, but we have to run it like a business in order to stay in business. One uncommon business move that is hyper-effective is to focus on treating a select group of people rather than being "everything to everybody." Since everybody else is treating all cases of venous disease, it makes business sense to focus on treating people with more advanced disease—although it's a smaller segment of the market, they have no alternatives. We really are their beacon of hope. Again, a classic example of this is Jerry. He told me he had been to several vascular surgeons and that they all turned him away because his legs were so bad. He said, "They all told me they could do nothing for me."

UGLY LEGS AND VENOUS ULCERATION

Chronic venous insufficiency is commonly associated with ulcers. The diagnosis of venous insufficiency with ulceration is based on a patient's history or physical exam. For example, a person who has a healed ulceration may be CEAP Class 5 but for diagnosis coding, the CEAP classification system is not used. This is simply for the history. In this case, the diagnosis would be "venous insufficiency or varicose veins with ulceration."

Even if the ulceration is completely healed, we know that historically, ulcerations are a recurrent condition, so they are considered varicose veins with ulceration or venous insufficiency with ulceration. During the physical examination, you may see signs of prior low-grade ulceration, such as atrophie blanche. This would still be venous insufficiency with ulceration.

The significance of this has to do somewhat with medical coding procedures. A history of ulceration or ulceration associated with the perforator vein is considered to be a medical necessity for a standalone procedure—it does not have to be done as an add-on procedure. There is a specific catheter for radiofrequency that is separate from the one we use for the saphenous vein, so when the CMS made its guidelines, they built this in as a separate standalone procedure rather than assigned it the reduced rate of an add-on procedure. The same thing is true for laser.

If there is no ulceration or no signs of a pending ulceration, the medical necessity should be questioned. To put this into historical perspective, since having mostly done foam sclerotherapy for varicose veins, it was observed that sclerotherapy varicosities associated with the perforator vein would likely recur in time if the perforator vein was not ablated. Now that we are doing more microphlebectomies, the actual avulsion of the vein from the perforator vein may be sufficient.

However, if there is a refluxing perforator associated with skin changes, I treat these like varicose veins with ulceration. The skin changes either proceed ulceration or follow ulceration—these are part of a continuum of progression of venous disease from minor to more major.

Numerous studies have shown that venous insufficiency with ulceration is a chronic disease with significant public health implications. An article from the Journal of Medical Economics titled "Burden of Venous Leg Ulcers in the United States" did a thorough review of almost 100,000 Medicare records. What it found was that the annual US taxpayer burden for untreated venous ulceration is approximately $14.9 billion. Let me repeat that: $14.9 billion.

The annual cost of managing leg ulcers is astounding. According to the FDA, numerous bandages, creams, dressings, and sterile solutions are used to treat leg ulcers, and approvals for more and more treatments are being sought every day. Currently, the annual expenditure for these creams, dressings, and bandages exceeds $6 billion annually. That is staggering.

On Wall Street, this is a very hot topic because of the potential additional billions of dollars that will likely be consumed as baby boomers age. The majority of people with venous insufficiency and ulceration are little bit older and typically have Medicare insurance. The costs of treating these conditions are expected to rise from $14.9 billion a year to over $20 billion a year. This is getting the attention of pharmaceutical companies and medical supply companies. The beauty of the situation for drug manufacturers and medical supply companies is that typically doctors are not treating the primary source of the venous insufficiency and the ulceration—instead, they're just putting a bandage on it. It seems absurd, but this is what is happening.

I read an interesting position paper titled "Challenges and Current Best Practices" that was in a supplement of the Journal of Wound Care in April 2016. The paper came from a major wound care medical society. The authors stated that wounds resulting from venous insufficiency should be treated with various types of compression. They evaluated different compression methods, the best dressing methods, and the best topical and ointment medications. The authors also stated that this is going be a lifelong, chronic condition for patients and recommended considering performing surgical treatments such as subfascial endoscopic perforator surgery (also known as SEPS) along with ligation and surgical stripping. They also acknowledged that many of these patients are little old to undergo these kinds of aggressive procedures and noted that new ablation techniques may be considered. They called these procedures "new" even though the referenced ablation techniques been FDA-approved for over 12 years and are now considered to be standard care in the industry for the management of venous insufficiency. As a group, wound care specialists have a vested interest to maintain the status quo, because again, this is a $14.9 billion-a-year money-making machine.

I want to put this in perspective. There were about 683,000 venous ablations in 2016. That comes to a little over $2 billion in insurance expenditures for treatment of all venous disease done by nonsurgical techniques (i.e., ablations). And the vast majority those ablations were done for patients with "pretty legs." I've even seen the bias in our own market, with providers reluctant to treat ugly legs because the appeal to treat pretty legs was more significant. Let's face it—we have all kinds of competitors going after the pretty leg market. Nobody is considering treating the ugly leg patients even though these patients with venous insufficiency are the most in need of treatment and the obvious public health impact is enormous, with well over $10 billion annually in costs…and growing.

I want to make it crystal clear that from a purely financial standpoint, the cost-benefit ratio for Americans strongly favors treating venous insufficiency with methods that result in permanent resolution. I'll talk more about this later. Then there are also the significant quality-of-life interruptions that leg ulcers cause. Another study (listed in the reference section at the end of this booklet) found that about 600,000 productive workdays are lost per year because of venous insufficiency. If you add that to the healthcare costs, the overall cost of untreated

leg ulcers is quite staggering. If we want to fix healthcare, maybe we should be treating the cause of the ulceration and not just putting a bandage on it.

I heard recently that some of our providers have started offering patients Unna Boots. Let's put this in perspective: Unna Boots were developed by a German dermatologist, Dr. Paul Gerson Unna, in 1910. That's over 100 years ago.

In a study published in 2014, "A Comparative Clinical Study of Five Types of Compression Therapy in Patients with Venous Leg Ulcers," the authors evaluated the use of Unna Boots and compared them to different types of compression. Basically, the Unna Boots were the least likely to be effective in healing leg ulceration. The most effective is the inelastic compression that has been around the last 20 or so years. Should we still be using something that worked great in 1910 but by today's standards doesn't come close to modern compression? Note that inelastic compression is 400% more effective than the Unna Boots. No, we obviously should not be using Unna Boots.

What about the timing of treatment for venous ulceration patients? I've heard that some providers want their patients to heal their leg ulcers prior to treatment with endovenous ablation and that to achieve this, the providers were telling their patients to use Unna Boots or some other form of compression. Numerous studies (again listed in the reference section) show that this is inappropriate practice of medicine—using Unna Boots leads to a very low resolution rate or takes a very long time to achieve resolution of ulceration.

However, contemporaneous treatment of axial venous reflux (i.e., a great or lesser saphenous vein and its major tributaries along with associated perforator veins, which are virtually always present in the face of ulceration) rapidly speeds up resolution of venous ulcers. More importantly, traditional wound care treatment of venous ulcers has a very high rate of recurrence: about 50% at the two-year mark. Only 50% after two years using standard but old-fashioned treatments for venous ulceration! Whereas studies following patients over long periods of time found that when patients were treated with any type of compression as well as ablation when appropriate, the recurrence rates were less than 5%. So with traditional wound care, the condition is 10 times less likely to reoccur, and this is a condition that costs billions of dollars a year in healthcare costs and interrupts hundreds of thousands of workdays! Not to mention puts obvious stress on patients when they have unhealthy legs and a poor quality of life.

"The Impact of Ablation of Incompetent Superficial and Perforator Veins on Ulcer Healing Rates" published by the Society of Vascular Surgery cited a study involving people who had venous ulceration for an average of five years who were treated with ablation of the saphenous reflux as well as the perforators. Over 75% of them were completely healed in six months…and again, that's after having had nonhealing ulcerations for over five years. And keep in mind people who have open ulcerations for five years are relatively sick people with very ugly legs. If the

majority of them healed in as few as six months (most healed in three months or fewer), there is no reason to withhold this treatment for people regardless of comorbid conditions. Not even if they live in a nursing home.

A paper titled "Endovenous Laser Ablation of the Great Saphenous Vein and Perforator Veins Improves Venous Stasis Ulcer Healing" in the Annals of Vascular Surgery in 2013 retrospectively looked at charts of patients who had venous ulceration and underwent ablation. What the authors found was that when perforator veins were identified, they were ablated along with the great saphenous vein (and of course, when perforator veins were not identified, they were not treated). Again, this was a retrospective review of what they observed: that the patients who had both great saphenous veins (and their tributaries of veins) treated along with perforator veins had a significantly greater degree of complete resolution of ulceration. The highlight of this paper was to look for perforator veins when venous stasis signs are present. If your technician does not find perforator veins, do the procedure again—perhaps with a more experienced technician—or take a look yourself and perhaps have the patient stand for a longer period of time. If there are significant findings of venous stasis, the perforator veins are there.

A paper titled "Endovenous Ablation of Incompetent Perforating Veins is Effective Treatment for Recalcitrant Venous Ulcers" published in the Journal of Vascular Surgery in September 2011 evaluated patients with venous ulcers who were treated with ablation of their perforators along with any actual reflux. At about three months, the authors found that 90% of ulcers healed when at least one perforating vein was closed and that no ulcer healed unless at least one perforator vein was closed. There is a clear pattern here: if you don't close the perforating veins, the procedure doesn't really work. That means that if you evaluate a patient who has ulceration that's either current or remote, they're going to require an ablation of the perforating vein. If the technician doesn't find one, the patient hasn't been adequately evaluated. We are treating the patient, not the technician's findings.

There's actually no reason to wait until the ulcers have resolved to treat the reflux. Don't put a bandage on it and "wait and see"—solve the problem. This is we are meant to do. Our patients come to us from other doctors' offices or on their own because they have a problem that nobody will deal with. They are not to be turned away, because we do not want to practice old-fashioned medicine.

There are no absolute contraindications to venous ablation. (I'll get to that in another section.) Many patients have concomitant low-grade cellulitis. If patients appear to have chronic cellulitis, still treat the problem—it won't go away on its own. I've done this in the past or have had to go right to the ulceration. I use antiseptic on the skin and a little clear covering like we might use on an IV. This way, I pierce only a very small area of the skin. After having done over 60,000 vein procedures, I cannot recall a single infection. However, I guarantee you these patients were turned away by other providers simply because they had ugly legs. These patients would have wound up eventually developing recurrent and chronic infections.

Another study published in US Pharmacist, February 16, 2017 reviewed the significant incidents of ulceration in the US population. But one or 2% of US population and is more common in elderly less common in younger people. Venous insufficiency was a significant cause of all extremity ulcerations, with over 80% of all ulcerations being related to venous insufficiency. The authors also note that about 2% of patients admitted to long-term care facilities have ulcerations related to chronic venous insufficiency. Their angle was how to offer these patients various drugs or dressings or topicals to manage these conditions, of course benefitting in the process. They talk about different types of dressings and different kinds of agents, and they keep noting that these ulcers do not go away and that the patient will be on them long-term or forever. In the same paper, the authors identify a subgroup with severe ulcerations for whom surgery may be warranted. They note that surgery of perforator veins markedly improves healing and results in reduced recurrence, but nonetheless, the authors recommend this only when the patients are severe cases, and for this subgroup, the authors recommend doing standard endoscopic perforator surgery and stripping. The article didn't take into consideration that in the past 12 years, management of vein ulceration has experienced tremendous breakthroughs: there is now a very low-cost, safe, outpatient, well-tolerated, extremely effective, and permanent solution.

I have an article from 2002, before we were using ablation for reflux. The authors were addressing the fact that insurance companies would pay for compression stockings in many cases, pointing out that if stockings were used by people with chronic venous stasis, insurance companies would save $17,000 during the patient's lifetime even after paying for the stockings. (Keep in mind this was before ablation procedures were FDA-approved.) The authors acknowledged that patients would still have chronic ulceration, but they figured that even while paying tens of thousands of dollars to manage these chronic conditions, insurance companies would save about $17,000 per patient by paying for stockings.

More contemporaneous evidence suggests that if we treat reflux with ablation, the cost savings during the patient's lifetime would be upwards of $100,000 per individual. You may not be aware of how much money is being paid to wound care centers. It's about 5% of the national healthcare budget. Not just wound care centers—that's the most obvious—but wound care in general. And venous ulcerations account for about 50% of chronic wound care in the US (which is about $30 billion a year). Again, the annual cost to manage chronic venous ulcers is $14.9 billion. It'll keep growing if we don't take action.

It's long been known that using traditional surgical methods such as SEPS and surgical stripping to treat saphenous reflux and its tributaries (as well as perforating veins) improves outcomes in patients with venous insufficiency and ulceration. Those methods have been approved to treat and manage this condition for years. But that was then and this is now.

Surgical management of venous disease in the face of ulceration hasn't really caught a lot of traction because the surgical procedures that were historically used prior to 2005 involved general anesthesia, potentially prolonged immobility that increased the risk of DVT, and significant morbidity. Additionally, these procedures involved managing ulceration while simultaneously managing a fresh surgical wound that could become infected. Also note that compared to age-matched controls, studies show that patients with venous insufficiency and associated ulcerations are typically sicker people. They have higher rates of heart failure, peripheral vascular disease, lung disease, obesity, hypertension, diabetes, and other comorbid conditions.

Currently, however, we have an extremely safe and minimally invasive outpatient procedure to treat venous insufficiency. Endovenous ablation involves local anesthesia only, patients can immediately return to normal mobility, and patients do not experience any negative impact on their immediate quality of life. It doesn't matter if they have other comorbid diseases—none of those diseases are contraindications. Patients with comorbidities can be treated. There may be some rare circumstances—and those circumstances are extremely rare—where patients cannot be immediately treated because of an impending problem such as acute arterial occlusion. In such a case, the inflow should be managed before the outflow. But cases of peripheral vascular disease that are otherwise stable and are not intended for surgery do provide certain indications, so if a patient has comorbidities such as diabetic neuropathy, intermittent claudication that is not surgical at the time, intermittent cellulitis, or other conditions that may be comorbid to venous insufficiency, it is appropriate to tell the patient that they will still have some other symptoms. However, once you release them from having venous insufficiency, their will leg will start to heal and they will feel better. They will have a better quality of life and less recurrence of their leg ulcer.

The paper "The Care of Patients with Varicose Veins and Associated Chronic Venous Disease: Clinical Practice Guidelines of the Society for Vascular Surgery and the American Venous Forum" published in 2011 made specific recommendations for most all aspects of care of the venous insufficiency patient. In the guidelines, the authors recommend ablation of the saphenous reflux and its tributaries as well as perforator veins in the face of ulceration. They recommended using compression as an adjuvant treatment. They also recommend against using surgery and instead recommend endovenous ablation because of the substantial reduction in complications, pain, and convalescence. They also specifically recommend against conservative management in patients with venous insufficiency, from insufficiency that is associated with symptomatic varicose veins all the way to venous ulcerations. This may conflict with certain insurers' guidelines that conservative management should be considered where appropriate. Keep in mind that you are an advocate of the patient, not the insurance companies, and that

there are guidelines in place that recommend against conservative management. This means that conservative management is inappropriate. So you are following certain insurance carriers' recommendations if you do not recommend conservative therapy. An expert panel has said that conservative therapy is inappropriate. "Three months of conservative therapy were appropriate" is the proper documentation. If you feel it is appropriate for the patient to pursue conservative therapy in spite of the recommendations made by the society, you can recommend it, and if you feel that it is inappropriate because there is no evidence of any benefit to the patient, just document that they had conservative therapy where appropriate. That may have been just simple walking, or perhaps the patient used compression stockings. The point is that patient pursued conservative therapy and it didn't work. That's good enough. It is absurd to treat symptomatically venous insufficiency with additional nonbeneficial conservative therapy, particularly when venous insufficiency also involves something as severe as ulceration.

In summary, venous ulceration is a significant public health threat. It is an enormous economic burden on the US healthcare system, and for the most part it is currently being mismanaged. Drug companies, bandage manufacturers, and large wound care management groups would prefer we keep the status quo—they only briefly mention that there is an intervention available that essentially cures what has become a huge money-making chronic disease.

The cost of venous ulceration to the US healthcare system is almost $15 billion annually and is expected to increase as baby boomers continue to age. We will see more cases of venous ulceration and more unnecessary expenditures for a totally treatable disease. Hundreds of thousands of workdays are interrupted in the name of managing this chronic disease every year. This is on top of the economic burden of direct healthcare expenses. Also, these numbers don't take into consideration the cost of the patient losing their quality of life.

Traditional therapies invented over hundred years ago (i.e., Unna Boots) have no role in the management of venous insufficiency or venous ulceration today. Compression therapy—particularly inelastic compression devices—can be used along with our management of the incompetent reflux. However, given the complexity of modern medical devices, the rapid resolution after ablation of perforating veins, and the simplicity of standard compression, this may be overkill. Again, no more Unna Boots. They don't work and they are outdated.

Patients with current or previous ulceration—even those with "pre-ulceration" such as significant chronic skin changes—should be treated exactly the same way. Diagnose them as venous insufficiency with ulceration, find the perforator vein even if it is missed during the first pass, and treat the saphenous reflux and its tributaries. Bring the patient back in for a perforator procedure. This is consid-

ered a standalone procedure in the face of ulceration and it is not an add-on. In the rare circumstances where the patient's insurance doesn't allow them to have a sufficient number of standalone procedures, use your own judgment.

We are really moving from a "pretty leg" practice to an "ugly leg" practice. Mainly, this is an element of our strategy. There are three components to our strategy that are easy to explain.

First is the "who": People who want an easy way to look and feel better with less risk.

Second is the "what": Our accommodating staff make it easy for you to experience the evolution in healthcare.

Third is the "how": By continually adapting, we make it easy for you to look and feel better with less risk.

DVT, DEEP VENOUS INSUFFICIENCY, AND OUTFLOW OBSTRUCTION

I am writing this to clarify what is involved in the management of chronic venous insufficiency for the past 10 or 15 years. We will continually be adding providers to our team who arrive with various experiences. Some providers will have been trained in traditional vascular surgery or will have had general surgery residencies and fellowships, where their mentors were training them to carry out classic management methods of chronic venous insufficiency on their patients. That meant either leaving them alone, doing long-term conservative management, or doing surgery. With the advent of modern vein treatments, this type of classic management is no longer the proper standard of care. The public health costs associated with not treating venous insufficiency are enormous.

One of the concerns I have heard from providers is that some patients may be at increased risk for developing DVT. They may even have had DVT in the past. The reality is that because we are treating more CEAP classifications 4 through 6, we will see more people who had DVT in the past or who are at increased risk.

In the paper "Primary Venous Insufficiency Increases Risk of Deep Vein Thrombosis" published in April 2016 in the Journal of Vascular Surgery, the authors evaluated this risk factor. They found that patients diagnosed with acute DVT were about five times more likely to have venous insufficiency compared to controls. This was primary venous insufficiency, not that which may be caused by a blood clot. Five times as likely. So yes, we are going to encounter patients who have had DVT or who may be at risk. However, when we treat the venous reflux as well as varicosities, we have just neutralized that risk factor.

In the Journal of Vascular Surgery in 2008, a paper was published that evaluated patients with concomitant deep and superficial venous insufficiency. Prior to that time, there had been some degree of bias towards not treating superficial insufficiency when deep venous insufficiency was present. However, physicians observed that when patients with mild to moderate venous insufficiency were treated for their superficial symptoms and disease, their deep venous insufficiency improved or resolved entirely. In the paper, the authors sought to evaluate the factors that would lead to predictability of resolution reflux of the deep venous system after treatment of the superficial venous system.

What they found was that regardless of the duration of the reflux of the deep venous system, treatment of the superficial venous system tended to improve the deep venous reflux. In patients with more severe deep venous insufficiency who had a relatively high velocity of reflux, they were less likely to see improvements. Yet, this is in no way a contraindication—it means having a discussion with the patient who has severe deep venous insufficiency as well as superficial venous insufficiency about the fact that the patient would likely benefit from compression stockings long-term and that they might have some degree of persistent symptoms. But this is in no way to be considered an "outflow obstruction" or contraindication for treatment.

The clinical practice guidelines from the Society of Vascular Surgery and the American Venous Forum that were published in 2011 in the Journal of Vascular Surgery are still intact today. Once again, these guidelines identify that there are no absolute contraindications to venous ablation. Patients with extensive venous occlusion and outflow obstruction can be treated with superficial ablation, however selectively. Here's a case I heard about that illustrates this point. The patient had outflow obstruction mechanical from prior DVT. Had some flow-through various tributaries of the femoral vein, but did have some degree of outflow obstruction. The patient was treated with saphenous ablation and had persistence of venous ulcers at the ankles. They were perforating veins associated with the ankle ulcerations, and the doctor was reluctant to treat them because the doctor felt that perhaps the perforator veins were required for collateral flow. This is not the case. Perforating veins do not account for majority of blood flow in patients. When they are pathologic—that is, greater than 3.5 millimeters and greater than 500 ms of reflux—and associated with ulcerations, the society of experts recommends that they be treated.

What about patients who have had prior DVT and the DVT is still visible? If it's fenestrated and there's flow, there's no need for unusual caution. You should indeed tell the patient that they are at an increased risk for blood clots since they had them in the past, and mobility is appropriate as recommended. This may be an area where you consider medical prevention therapy; however, this is not clearly elucidated in the literature.

Prophylaxis for DVT in the face of venous ablation is something that is practiced with various protocols, but there are no generally accepted criteria. In the clinical practice guidelines, the Society for Vascular Surgery and the American Venous Forum acknowledge that there is no data available but that it is reasonable, however, to treat such patients with a single dose of low-molecular-weight heparin before or at the beginning of the procedure. The societies also note that since this is performed as an outpatient procedure with early ambulation, the overall risk is not substantial, making this purely a clinical judgment—there is no standard of care.

PERIPHERAL ARTERIAL DISEASE

Peripheral arterial disease is an inflow problem and venous insufficiency is an outflow problem. Both conditions may concur concomitantly. There may be considerations for withholding venous insufficiency treatment until the peripheral vascular disease is managed. Patients with an ABI of less than 0.7 should have a clearly defined relationship with a vascular surgeon to determine if the inflow obstruction should be managed prior to pursuing treatment of the outflow problem. Patients with known peripheral vascular disease and no intent of or plan for surgery are not contraindicated for venous ablation. In the cases where it is not clear, the patient's prior records should be obtained. If they not had a vascular evaluation in some time, an evaluation should be done before initiating venous insufficiency. Again, this applies to patients with severe peripheral vascular disease who may have an impending problem. After over 10 years and tens of thousands of procedures, I've seen very, very few of these cases. Typically, they come in thinking they have leg pain from their veins, and they are trying to see somebody for their leg pain…and then it turns out they have previously undiagnosed arterial disease. This is going to happen, yes, but it is uncommon in our practice.

Patients with peripheral arterial disease have a relative counter indication for compression therapy. I talk about this in the compression therapy section, but in general, patients with mild to moderate peripheral artery disease should be treated with minimal or no compression after ablation. There's very little evidence to support routine use of compression after ablation other than "That's how we've always done it." The use of compression after treating veins with ablation is based on the legacy of using compression after surgical stripping. What was valid then is not valid now.

RESTLESS LEG SYNDROME

This is a condition first diagnosed in 1944 where patients have unexplained leg symptoms (most commonly at night) and an urge to move them, sometimes uncontrollably. The cause was unknown. Until now.

Physicians like me started noticing that the patients we treated for varicose veins with reflux by venous ablation who also had restless leg syndrome started reporting elimination of their restless leg syndrome. At the American College of Phlebology, a few papers had been orally presented by doctors who explained that their restless legs patients had experienced resolution of their restless legs after ablation. The theory is that the continued stasis and inflammation leads to injury to the neural circulatory system in the skin.

Early studies done in the 90s specifically reported improvement of restless leg syndrome after patients had sclerotherapy for varicose veins. (Sclerotherapy had been an option for treatment of saphenous reflux for decades before the advent of venous ablation with radiofrequency or laser.) In "The Effect of Sclerotherapy on Restless Leg Syndrome" in Dermatologic Surgery in 1995, the authors recommended screening patients who presented for restless leg syndrome for venous insufficiency. They found that 98% of the patients had at least some degree of improvement of the restless leg syndrome, with the majority of them seeing significant improvement.

A study published in 2008 in Phlebology evaluated the International Restless Leg Score (IRLS) for 35 patients who were diagnosed with venous insufficiency and then underwent ablation of venous insufficiency. After treatment, the average discomfort score decreased by 80% in very short order. Fifty percent of the patients had absolutely no symptoms of restless leg syndrome after treatment. Virtually all patients had at least some improvement, and about 90% had near complete resolution. In this study, the authors also recommend screening patients with restless leg syndrome for venous insufficiency because of the substantial benefit that is received using a noninvasive procedure that is safer than the long-term use of drugs currently being prescribed for restless leg syndrome.

COMPRESSION THERAPY

Compression therapy has been a mainstay of the treatment of venous insufficiency for decades. Prior to 2005, insurance companies did not reimburse for venous ablation as it was too new. Then, however, insurance carriers started taking notice, realized the reduced costs compared to surgery, and began covering this procedure. Now reimbursement is pretty much universal.

Initially, insurers were recommending that conservative management be tried prior to initiating therapy. Some insurance carriers were vague and recommended the use of some form of conservative therapy, including stockings, walking, weight loss, narcotics, and other chronic management interventions. Other carriers were very specific and required patients to wear a specific type of compression for a finite amount of time even though there was absolutely no evidence to support this recommendation.

In addition to the legacy of having patients wear stockings when they do not resolve chronic disease, physicians are making patients wear stockings after the procedures. Sometimes for months! When I started going to the phlebology meetings, there were two different groups. Group 1 was the surgical section and group 2 was the nonsurgical section (which was of course ablations). The groups were split about 50/50, with the traditionalists balking at a new effective and noninvasive procedure that would undermine everything they been doing for decades and the people who had open minds interested in learning about advances in healthcare. That was in 2004. Now if you go to the same meeting, there is only one section: the nonsurgical group. Nobody's lecturing about or doing studies on surgical stripping, high ligation, or SEPS procedures anymore. There is even a procedure called TRIVEX that arrived on the scene around the same time as venous ablation. This was a procedure that made stripping easier, but was very expensive. In addition, although it was a very effective procedure, it had the same issues as surgical stripping did: it's a surgery, the patient needs be knocked out, there's a lot of recurrence, and there's a convalescence period.

Still, even though we differentiated between surgical and nonsurgical approaches, we applied the same logic to venous ablation as we did to surgical stripping: we made patients wear stockings. I heard some guys talking about having the patients wear stockings for two weeks and others saying three months.

When I started doing the procedure, I told some patients to wear stockings for about a week and some for about two weeks. I observed there was no difference in outcomes, so I changed my recommendation to a week. I starting asking patients "Did you wear the stockings?" In reality, only about half of them actually wore the stockings for a week. I noticed that the weeklong-wearers and the non-weeklong-wearers had no difference in outcomes. The latter would typically wear them for about two days, get sick of them, and take them off. They had the same outcomes as people who wore the stockings for a whole week, so I changed my recommendation to two days. We did that for about 10 years.

Let's review the science and a little bit of history. The first endovenous laser ablation procedure used a laser that had a wavelength of 810 nm. It worked by attacking the red color in the red blood cells, hemoglobin. Because the laser heated up the red blood cells and caused little holes in the saphenous vein, however, this led to considerable bruising and discomfort. Then came the laser with a wavelength of 980 nm, which caused less pain and discomfort. And then came the 1320 and 1470 nm lasers we use today. These attack the water in the blood vessel wall and are not fraught with the kind of discomfort caused by 810 nm lasers. There's also radiofrequency, which heats up the vein wall. There is far less discomfort with the newer lasers and with radiofrequency than what the original 810 nm laser caused.

That being said, a paper was written that evaluated the use of compression therapy after vein ablation with an 810 nm laser. The study was on 400 patients. Half of them used compression stockings and the other half did not use compression after an ablation. The authors found no difference in outcomes, but they did note a decrease in patient discomfort in the week following the ablation for the patients that wore stockings.

But let's talk about ablation done with more modern devices (i.e., radiofrequency and newer lasers). "Compression Versus No Compression After End of Venous Ablation of the Great Saphenous Vein: A Randomized Controlled Trial" was published in 2017 in the Annals of Vascular Surgery. The authors studied compression stockings after radiofrequency, the device we most commonly use. There were 80 patients in the study, with half of them using compression stockings for week and the other half not using compression. The authors found no differences between the groups in terms of success or postoperative symptoms.

A paper published in the British Journal of Surgery in 2015 titled "Systematic Review of Compression Following Treatment for Varicose Veins" pulled together seven randomized controlled trials evaluating the use of stockings or the lack of compression after endovenous ablation. The results were interesting. The studies that looked at compliance found it wasn't that good. We can probably suspect that our patients are not following directions exactly, especially in regards to something as inconvenient as wearing compression stockings (particularly when we're talking about working adults). But the authors found that in some cases, the use of compression stockings led to slightly longer recovery time compared to not using compression. Other studies showed a slight decrease in postoperative symptoms with compression stockings. In summary, they found no evidence to support or detract from the use compression stockings after endovenous ablation. We can surely offer stockings to our patients, but using them is not mandatory, and there is no scientific reason to use them.

With respect to sclerotherapy, there have been longstanding recommendations to use grid compression stockings after the procedure. There's plenty of evidence showing that patient may have some decreased pain or discomfort or discoloration if they wear compression stockings from anywhere from one to three weeks. But the data for this is not very strong. A few papers looked at the amount of compression, the length of compression, and other factors, and there is some correlation that using high-grade compression for a long time may give a slight benefit to people with spider veins or varicose veins who use sclerotherapy. However, statistically, you would have to treat several post-sclerotherapy patients with long-term compression stockings to see a single person derive any benefit from them. We recommend that patients may choose to wear compression stockings but that the stockings don't have to be very high-compression, nor do they have to be worn at night. If patients can do this, there may be some potential for improved cosmetic outcome, but not much. Patients can weigh their options.

SPECIAL CIRCUMSTANCES

Patients may be on medications that give us concern, such as aspirin, Plavix, Coumadin, or the newer all-oral alternatives to low-molecular-weight heparin. For certain surgeries, there's a resistance or reluctance to perform the procedure in patients taking these blood thinners. However, like other physicians with large-scale vein practices, I have observed in my practice that when it comes to side effects and outcomes, we see no difference in results between patients who are on blood thinners and those who are not.

A paper in the Annals of Vascular Surgery in 2012 titled "Success of Endovenous Saphenous and Perforator Ablation in Patients with Symptomatic Venous Insufficiency Receiving Long-Term Warfarin Therapy" reported an observational study where patients on Coumadin had the same outcomes, side effects, and consequences after ablation as compared to those who were not on Coumadin. The fact that a patient is on blood thinners is no reason to withhold treatment.

Some patients have numerous medical conditions—they may be immobile, be of advanced age, and/or be under care for multiple different conditions. There are no absolute contraindications to venous ablation in the face of chronic venous insufficiency. If patients have quality-of-life issues, there is no reason withhold treatment. Since the vast majority of symptom improvement will occur from ablation alone—whereas microfoam sclerotherapy results in more of a cosmetic improvement—then patients with other comorbidities and/or immobility should be treated with ablation alone. The addition of microfoam sclerotherapy does give them an inherent increased risk of developing a complication of DVT, making the therapy unnecessary.

In patients with ulceration related to venous insufficiency, is not necessary to wait for the ulceration to be treated, managed, or resolved. Even if you put the patient in some type of aggressive compression for six months and the ulcer resolves, the majority of the time, they will come back, so it is inappropriate to wait.

The Society for Vascular Surgery and the American Venous Forum recommend against the use of compression therapy for the primary treatment of symptomatic varicose veins in patients who are candidates for saphenous vein ablation. While compression stockings cause a great deal confusion because they don't really work when compared to ablation of reflux, some doctors are still requiring their patients to wear them. The societies that issue the guidelines as well as their own clinical practices recommend against this. It is inappropriate.

As we treat more and more patients who have advanced diseased "ugly legs," we are going to see more complicated cases. A natural response is to want to have the good old days back, the time when we were the only ones treating varicose veins in the region and we could stick to patients with "pretty legs." But our strategy has changed.

We are adapting a new strategy. We are the leading provider for venous disease in our region, and we are probably the largest non-chain provider in America who treats varicose veins. Therefore, we can intercommunicate and collectively have more experience in treating this condition than anyone else in America. That means we should be treating more complicated cases, because with our thorough base of experience, we can give our patients the best outcomes with the lowest risk.

There are no absolute contraindications to venous ablation. There may be circumstances where another medical condition is more pressing and is easily managed, but in over 10 years of performing tens of thousands of vein procedures, I have rarely encountered a type of condition that precluded proper management of venous insufficiency.

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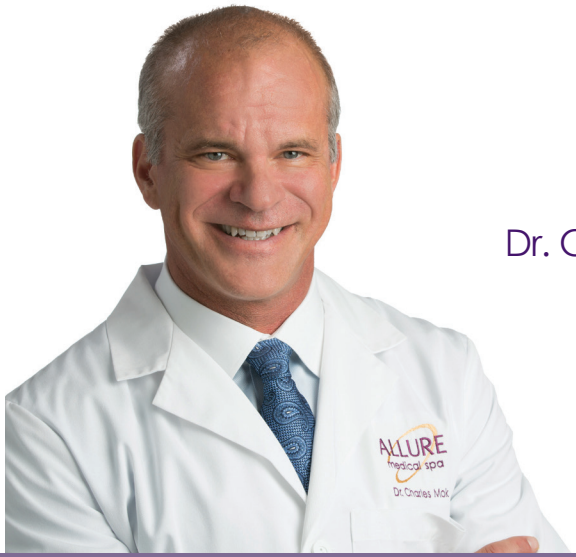

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