

Update on Endovenous Treatments for Varicose Veins

New data support the trend toward this less-invasive treatment for varicose veins.

BY JOSE I. ALMEIDA, MD, FACS

The treatment of superficial venous disease has undergone dramatic changes over the past 5 years. Led by endovenous treatments, such as radiofrequency and laser ablation of the saphenous vein, we are now able to offer patients alternative solutions to their venous problems. In addition to endovenous thermal ablation, the use of duplex ultrasound has proved invaluable by providing physicians with a better understanding of venous pathology.

Varicose veins are theorized to be caused by incompetent venous valves or inherent defects in the vein wall. As a result, blood fails to return to the right atrium efficiently and, therefore, pools in the legs, causing symptoms of pain, cramping, itching, restlessness and heaviness. In more severe cases, ulceration of the skin occurs. Treatment aims to eliminate the defective vein, so blood is forced to return to the heart through normal deep veins.

PROPER IMAGING IS REQUIRED

It cannot be overstated how duplex ultrasound has changed the landscape of venous disease. One of the most important contributions of endovenous technology came, serendipitously, from its interdependence on ultrasound imaging.

Pre-Duplex Era

Before the introduction of duplex ultrasound imaging, surgeons would diagnose great saphenous vein incompetence solely from the physical exam (ie, a bulging vein in the

calf). The patient would then go to the operating room for surgical stripping of the great saphenous vein and phlebectomy of varicose clusters. In the operating room, after the groin would be opened, a stripping device would be passed "blindly" down the thigh, and retrieved from a remote incision distally in the leg. It should come as no surprise that recurrence rates were unacceptably high, largely because of improper preoperative diagnosis and absent intraoperative imaging.

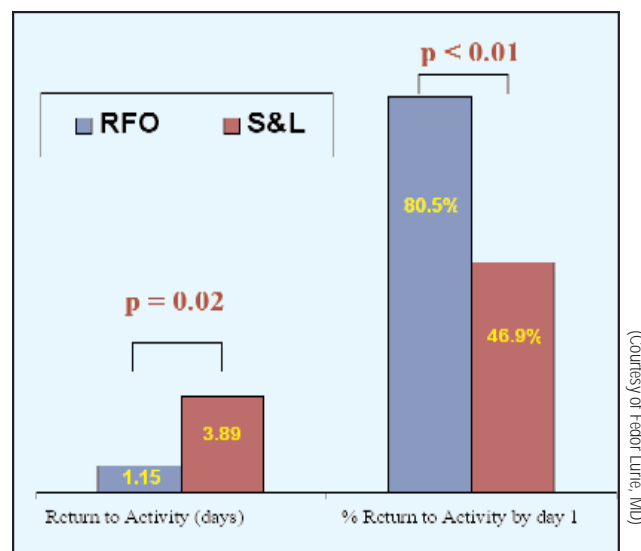


Figure 1. A comparison of the quality-of-life factors between radiofrequency ablation and vein stripping.

Post-Duplex Era

Today, we know from duplex imaging that the great saphenous vein (GSV) is often not the refluxing vessel causing varicosis. Anterolateral tributary veins, posteromedial tributary veins, or even small groin veins, such as epigastric veins, can be the source. If a surgeon identifies the correct vein prior to treatment, be it surgical stripping or endovenous ablation, the immediate recurrence rate is extremely low. Recurrences, in contemporary series, come from neovascularization and/or progression of disease; not from improper diagnosis and treatment.

It should be emphasized that ultrasound technicians are unfamiliar with superficial venous anatomy and its many variations. The treating physician must therefore be self-sufficient with regard to handling an ultrasound probe and recognizing the nuances of venous anatomy.

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ENDOVENOUS TREATMENTS

In the early years of endovenous treatment of varicose veins, many surgeons were loath to embrace the new technology because vein stripping had been proven safe and effective, and data supporting endovenous treatments were sparse. Today, the data demonstrate parity, and in some reports, superiority of endovenous treatments over surgical stripping.

Radiofrequency Ablation Versus Vein Stripping

The VNUS clinical registry (VNUS Medical Technologies, Inc., San Jose, CA) was established in 1998 with more than 30 centers contributing data worldwide. The registry results demonstrate the durability of endovenous radiofrequency ablation. Ninety-four percent of limbs that were free of reflux at 1 year remained reflux free at subsequent follow-up. Absence of reflux by duplex ultrasound was 91.4%, 90.1%, 86.3%, and 86.1% at 1, 2, 3, and 4 years, respectively. In the VNUS registry, 94% of the ablated veins are invisible by ultrasound examination after the second year of treatment. Five-year follow-up on these patients will be available later this year.

Like any new technology, a learning curve invariably has an effect on the treatment outcomes. It is intuitive that the patients with the longest follow-up were those treated early, and endovenous outcome data are therefore, a “moving target.” Procedural modifications (subfascial perivenous tumescent anesthesia, concomitant treatment of multiple reflux-

ing tributary veins) have since taken place, as well as improvements in the equipment and changes in energy delivery. The 10% early treatment failures reflected in the registry have been reduced as operators have gained more experience.

Three randomized trials have compared endovenous radiofrequency obliteration to vein stripping. Rautio et al randomized 28 patients to receive either radiofrequency obliteration or vein stripping and reported significantly less postoperative pain, less postoperative analgesia requirements, and faster recovery in the radiofrequency group.¹ The EVOLVeS study was a multicenter, prospective, randomized study, comparing quality-of-life factors between radiofrequency ablation and vein stripping (Figure 1). In all outcome variables, radiofrequency ablation superceded venous stripping: faster recovery, less postoperative pain, fewer adverse events, and superior quality-of-life score.² Follow-up at 2 years on EVOLVeS patients demonstrated the same treatment efficacy between the radiofrequency ablation and the vein stripping groups with 91.2% versus 91.7% of limbs free of reflux, respectively. In addition, the patient quality-of-life scores and pain scores were significantly better ($P<.05$) at 2 years for radiofrequency ablation over vein stripping, demonstrating lasting benefit for the patients.³ Similar findings were reported by the Stötter group in Germany in their own randomized trial.⁴

Endovenous Laser Ablation

Min et al recently presented 3-year data on 499 limbs treated for incompetent GSVs. At 1-month follow-up, successful endovenous laser treatment, defined as use of 810-nm diode laser energy delivered intraluminally, was observed in 490 of 499 limbs (98%). Posttreatment follow-up demonstrated continued GSV closure in 99.3% (444 of 447 limbs) at 3 months, 98.5% (390 of 396 limbs) at 6 months, 97.8% (351 of 359 limbs) at 9 months, 97.5% (310 of 318 limbs) at 1 year, and 93.4% (113 of 121 limbs) at 2 years. There were no recurrences in the 40 limbs followed out to 3 years. Importantly, all recurrences in this series were noted before 9 months, with the majority seen by 3 months.⁵

Navarro et al reported their 4-year follow-up on 200 limbs treated with endovenous laser at the 2003 UIP World Congress in San Diego and showed success rates approaching 95%. They noted that the recurrences were due to recanalization and not to neovascularization, and occasionally due to progressive involvement and incompetence of saphenofemoral junction branches left untreated.⁶

NEOVASCULARIZATION

One of the main advantages of endovenous procedures is the virtual absence of neovascularization seen after treat-

ment. Neovascularization refers to the growth of new blood vessels in the groin, often after vein stripping, resulting in high recurrence rates. In Fischer's study carried out to 39 years, neovascularization was seen in 60% of groins after surgical ligation and stripping, of which 30% required additional treatment.⁷ Pichot et al reported on clinical and duplex findings on 63 limbs 2 years after great saphenous vein radiofrequency endovenous obliteration. Neovascularity was not identified in any groin.⁸

One theory behind the cause of neovascularization is the concept of "frustrated venous drainage." When performing saphenous ligation and stripping, surgeons are trained to sweep, or eliminate, all vessels in the groin. With the new endovenous techniques, however, small venous tributaries in the groin that drain the lower abdomen are preserved; physiologic tributary flow is relatively undisturbed (does not incite groin neovascularity), and the GSV is eliminated as the refluxing conduit.

"The early literature reports failure rates of approximately 10%, using either radiofrequency or laser ablation."

ENDOVENOUS FAILURE

The early literature reports failure rates of approximately 10%, using either radiofrequency or laser ablation. Failure for endovenous treatments is defined as the reopening (partial or full) of any ablated vein based on examination by ultrasound imaging. In most of the reported series, the failures seem to occur during the first year. The reason for the 10% failure rate is presently unclear. Failure does not appear to be related to vein size, but rather to leaving other large tributaries or perforating veins untreated.

There are recent data from two surgeons, Mark Whitely, MD, from Nuffield Hospital, England and Robert Kistner, Straub Clinic & Hospital, University of Hawaii, who aggressively ablate all perforating and refluxing tributary veins at the time of primary operation with radiofrequency. Both have provided data demonstrating 97% to 99% closure rates at 1 year (personal communication VNUS Medical).

Similarly, at Miami Vein Center, if we observe two or three incompetent axial veins in the leg, all are ablated at the same setting. This has reduced our failure rates to less than 2% at 1 year.

ANESTHESIA

Tumescent Anesthesia

Endovenous procedures are performed using tumescent anesthesia. In the early days of radiofrequency ablation,

patients were sometimes left with skin burns or paresthesias. After the advent of subfascial, perivenous tumescent anesthesia, those complications rarely arise. Using ultrasound guidance, a needle is placed in the saphenous canal and the entire vein is surrounded with tumescent fluid. This accomplishes three things:

1) Creates a reservoir of fluid surrounding the vein that acts as a heat sink. When heat is placed inside the vein during the venous ablation, the heat is quickly dissipated through the wall of the vein precluding any heat-related injury of surrounding tissue. As a result, the rate of skin burns and the paresthesias has been reduced to less than 1% in experienced hands.

2) The tumescent fluid compresses the vein. This allows satisfactory treatment of even the most aneurysmal veins. We have successfully treated 30-mm veins by shrinking the vein with the tumescent solution so that it has adequate contact with the surface of the endovenous device.

3) Effective analgesia. The patient should experience a painless procedure, and postoperatively, most patients are comfortable with a daily nonsteroidal anti-inflammatory.

The tumescent technique eliminates the hemodynamic risks of sympathectomy associated with a conduction block (epidural or spinal anesthetic), and the cardiac and pulmonary risks associated with general endotracheal anesthesia.

ADVERSE EVENTS

Venous stripping has been vexed with postoperative hematomas, paresthesias, and wound complications, especially in the groin. Although most surgeons have reduced these complications by becoming devotees of invagination techniques, the recurrence rates are still high because of neovascularization. The real advantage of endovenous techniques is avoiding the groin altogether and preserving venous drainage from the abdominal wall. Incidentally, if I am faced with a patient who requires surgical crosssectomy (high ligation), I preserve the superficial epigastric, superficial pudendal, and superficial circumflex veins in the groin.

With endovenous thermal ablation of the GSV, mild ecchymosis and a "pulling" sensation in the thigh are seen frequently after treatment. However, complications of paresthesia, hematoma, wound infection, and deep vein thrombosis would be considered rare.

PATIENT SELECTION

There are two anatomical considerations that make endovenous therapy undesirable. Veins located just below the surface of the skin are best removed (stripped). An endothermally treated vein immediately below the skin will result in an unsatisfactory cosmetic result because the patient will experience a stain and palpable cord on the skin

of the medial thigh and leg. Resolution of this problem is spontaneous, however, it may persist for more than 1 year. Second, vein tortuosity can be a challenge because guidewire navigation is difficult. In some cases, using multiple entry sites, these veins can be satisfactorily treated.

ADVANCED TECHNIQUES

Hybrid Procedures

At Miami Vein Center, we routinely use multiple modalities or techniques during a procedure depending on the clinical scenario. For example, we developed a technique referred to as LADS (laser-assisted distal stripping). This hybrid technique is useful when the GSV leaves the saphenous canal in the thigh and courses superficially under the skin down the leg. The thigh GSV is treated in the usual manner, but when the superficial course of the vein is identified by the laser aiming beam, the vein is elevated via a small stab incision, and invagination stripping is performed distally using the 5-F sheath as the stripping device.

AREAS FOR IMPROVEMENT

We will improve results further once standardization of intraoperative energy dosages, pullback rates, and postoperative duplex nomenclature is assigned through further study.

CONCLUSION

During the past 5 years, we have seen dramatic improvements in endovenous techniques for treating varicose veins. Recent data have demonstrated the safety and efficacy of these techniques, as well as their superiority to venous stripping in areas of neovascularization and improved patient comfort. Our efforts should now turn toward standardizing various aspects of these procedures so all patients benefit equally from the experience of those specialists who have found ways to improve these procedures. ■

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