

Options for Treating the Saphenous Vein

A discussion of radiofrequency versus laser versus chemical ablation.

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During the last 5 years, traditional surgical ligation and stripping for treating saphenous vein incompetence has been replaced by endovenous thermal ablation. Thermal endoablation of the saphenous vein has proven to be safe, durable, and widely accepted by patients.¹⁻³ At Miami Vein Center, surgical ligation and stripping is limited to saphenous veins that are adherent to the skin. Furthermore, although endovenous techniques are less costly overall when compared to surgical ligation and stripping, there are patients who do not have insurance coverage for the newer technology and who do not have the financial resources to absorb the out-of-pocket expense.

Radiofrequency ablation (RF) was the first technology to gain a foothold in the venous market. Currently, endovenous laser (EVL) ablation is seemingly beginning to gain more market share. RF and EVL are forms of thermal ablation. Until recently, results of sclerotherapy (chemical ablation) to control saphenous vein reflux have been disappointing. Foam sclerotherapy has proven to be a more effective chemoablative method of vein closure than its liquid counterpart in contemporary clinical trials.⁴ Catheter-directed sclerotherapy (CDS) with an occlusive balloon at the saphenofemoral junction is now available to isolate the foamed sclerosant to the desired treatment segment.

The Miami Vein Center is one of the few facilities in the country with experience using all of these endovenous methods. This article provides a summary of our results and perspectives.

METHODS AND MATERIALS

From March 2002 to September 2005, endovenous ablation (thermal or chemical) was performed on 1,148

refluxing veins in 1,083 limbs by a single vascular surgeon at Miami Vein Center. All cases were performed endoluminally, using ultrasound guidance and local anesthesia in the office setting. Adjunctive ambulatory phlebectomy was used selectively in the majority of legs treated with thermal ablation. Successful treatment was defined as the absence of flow in the treated vein segment by duplex ultrasound. Follow-up with ultrasonography was performed at 2 days, 1 month, 6 months, 12 months, and annually thereafter. All treated veins met standard criteria for surgical treatment, which included reflux on standing ultrasound examination. Kaplan-Meier life-table statistics were used to determine primary closure, primary-assisted closure, and secondary closure associated with the treated veins.

RESULTS

There were 155 veins treated with RF (VNUS Medical Technologies, San Jose, CA), with a mean follow-up of 173 days (range, 1-1,036 days). There were 958 veins treated with EVL (Biolitec, Inc., East Longmeadow, MA),

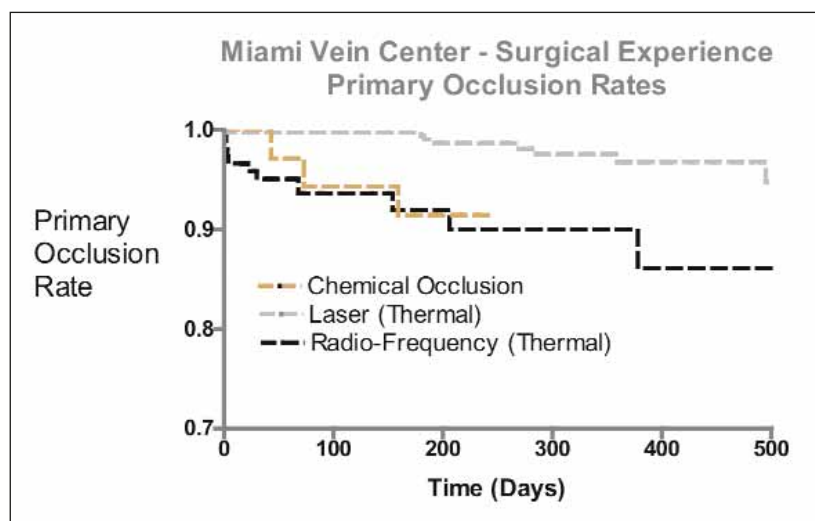


Figure 1. Primary closure rates for RF, EVL, and CDS.

with a mean follow-up of 159 days (range, 1-890 days). In the CDS (VeinRx, Inc., Miami, FL) group, all 35 veins were followed for 180 days.

In this aggregate group during follow-up, 28 veins demonstrated recanalization of at least a 5-cm segment (7.1% RF, 1.6% EVL, 5.7% CDS).

The primary closure rates by life-table analysis were greater than 85% for all three devices; however, after 500 days, there was loss of statistical validity in the data because of limited follow-up (Figure 1). During the initial 500 days, the primary closure rate for EVL was significantly better when compared to RF or CDS (log rank, $P < .002$).

Twenty symptomatic recanalized veins underwent a single reintervention in the form of ultrasound-guided sclerotherapy, or rarely, repeated thermal ablation. To date, the remaining eight veins have not been re-treated. The primary-assisted and secondary closures were grouped together for simplification (Figure 2). The assisted/secondary closure rates approached 98% for all three methods of treatment.

Asymptomatic deep venous thrombosis requiring anticoagulation was present in two limbs after EVL (0.2%), in one limb in the CDS patient group (2.9%), and not present in the RF group.

DISCUSSION

To fully appreciate this subject, it is important to note the advantages of endovenous techniques over traditional surgery, and the advantages and disadvantages that separate RF, EVL, and CDS.

Closure Rates

It is critical to understand the analogy between arterial graft patency and venous closure when evaluating the durability of a procedure. When evaluating longevity of an arterial bypass graft, patients and surgeons are interested in primary patency, primary-assisted patency, and secondary patency. Primary patency refers to the situation in which the graft remains patent without additional intervention after the original operation. Primary-assisted patency includes a single intervention to salvage a graft prior to closure. Secondary patency refers to intervention to re-establish flow after graft occlusion.

In a similar fashion, the durability of endovenous ablation can be discussed in the light of primary closure, primary-assisted closure, and secondary closure. Primary clo-

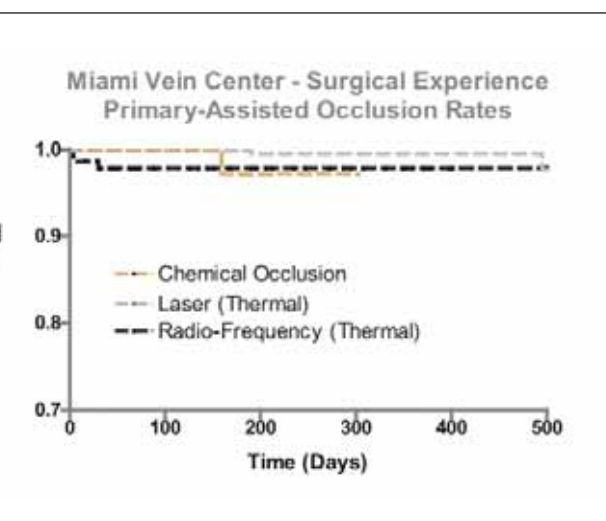


Figure 2. Primary-assisted/secondary closure rates for RF, EVL, and CDS.

sure refers to continued venous ablation of the treated vein without intervention after the original operation. Primary-assisted closure includes intervention prior to complete recanalization of the treated venous segment. Secondary closure refers to intervention to close a completely recanalized vein.

Ultrasound Guidance

High levels of efficacy for RF and EVL have been firmly established in published medical literature. Our current results are in close accord with this literature. Improved precision in diagnosis and treatment are partly due to the use of duplex ultrasound in these endovenous procedures. In contrast to stripping and ligation, endovenous techniques always include image guidance. We suspect that surgical stripping would have better outcomes if image guidance were routinely employed because, currently, surgeons "blindly" pass devices into target veins. This practice may result in treatment of the incorrect vein.

Neovascularization

An important issue that affects long-term recurrence is neovascularization. We know from longitudinal clinical studies that neovascularization is responsible for more than 50% of recurrences after surgical stripping.⁵⁻⁷ Although early studies suggested that neovascularization was absent after thermal ablation,⁸ recent studies demonstrate that it does occur in a small percentage of cases.⁹

Rescue

The most important advantage of thermal and chemical ablation over surgical stripping is the ease associat-

ed with assisted closure. Specifically, failed (ie, recanalized) treatment segments are easily rescued (ie, closed) with a single session of ultrasound-guided sclerotherapy. Failures after surgical stripping require a more complex combination of therapy, which includes EVL, ultrasound-guided sclerotherapy, and phlebectomy. In this regard, patients need to be counseled preoperatively, which will provide them with realistic expectations. Furthermore, with the knowledge that “touch-ups” may be required after thermal or chemical ablation to treat failed segments or progression of disease, patients will have a better understanding of their disease process.

Point of Service

We inform all of our patients presenting with superficial venous disease that initial management, therapy, follow-up, and procedures to treat recurrences are managed in the office. Hospitalization no longer plays a role in the treatment of superficial venous insufficiency.

RF

When compared to EVL, RF is less painful in the recovery period and patients present with fewer ecchymoses postoperatively. Intraoperatively, residue build-up at the catheter tip can prompt a delay in the procedure because of catheter cleaning and re-entry into the vein. RF catheters require infusion of intraluminal, heparinized saline to minimize residue build-up at the catheter tip, but if heparinized saline is infused too vigorously, the treated vein segment adjacent to the catheter tip will cool excessively and may retard closure. Finally, RF catheters are more expensive than EVL fibers.

EVL

EVL is the most versatile of the devices because the smaller-profile fibers readily enter smaller target veins, including perforating veins. The 600- μ m-diameter fibers can enter micropuncture sheaths, thus facilitating the treatment of small tributaries and perforators in the same setting. Newer 400- μ m fibers can readily enter a 21-gauge needle. EVL includes an aiming beam for improved transdermal identification of the tip during placement and pullback. Pullback rates are rapid, fiber removal for cleaning during treatment is never required, and infusion of heparinized saline solution is also not required. The closure rates, regardless of laser wavelength, are higher than the closure rates of RF or CDS. This difference reaches statistical significance. The method is easily used in conjunction with sclerotherapy. It should be acknowledged that postoperative discomfort, generally minimal, and bruising is expected.

In our hands, treating complex superficial venous dis-

ease presenting with multiple refluxing axial veins and multiple perforating veins is more readily done with EVL in conjunction with ultrasound-guided sclerotherapy. Furthermore, for veins greater than 20 mm in diameter, EVL offers a more aggressive and secure ablation.

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CDS

Initial investigators produced poor closure rates with injection liquid sclerotherapy; however, chemoablation has been resurrected for the treatment of saphenous vein incompetence with the development of a catheter with CDS. CDS has several attractive features over thermal ablation. It requires no generator (ie, minimal capital investment), requires no tumescent anesthesia along the treatment length (ie, less patient discomfort), and the sclerosant can enter incompetent venous tributaries, which may lead to less subsequent treatment of varicose venous tributaries. Some sclerosant does enter the deep system with unknown effects, and if the sclerosant is foamed, there is potential for migration into the left-sided circulation through a patent foramen ovale. Sotradecol liquid is currently the only FDA-approved medication for venous sclerotherapy. However, when Sotradecol is “foamed,” it is an off-label use. Currently, CDS catheters are 2 mm in diameter (6 F) and cannot enter smaller vein targets.

CONCLUSION

Overall, compared to surgical stripping, endoablation of the saphenous vein offers rapid recovery, durable closure, minimal recurrence, excellent patient acceptance, minimal morbidity, and decreased cost when performed in-office. The technical details continue to improve, and adjunctive procedures allow eradication of all bulging varicose veins by means of a 1-hour procedure in the comfort of a physician's office.

Rescue of failed segments or disease progression usually requires only one or two injections of a foamed sclerosant under ultrasound control. Careful ultrasound follow-up should be performed lifelong; however, in our practice, many patients are lost to follow-up after 1-year after the procedure. Presumably, they do not return because they are doing well. We know from our experience, and that of others, that successfully treated veins

disappear sonographically between 6 and 12 months postprocedure. Absent veins are unlikely to recanalize.


In our practice, RF is reserved for the straightforward, medium-sized great saphenous vein not associated with other refluxing accessory veins. In addition, if we sense that the patient is anxious, with a low tolerance for pain, we prefer RF. EVL is our preference for complex anatomy and large saphenous trunks, which are the majority of our cases. CDS until now has only been used as part of a clinical trial, but we anticipate it will have a larger role in our practice in the future. ■

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