Endovenous Thermal Ablation of the Saphenous Vein

Gerald Niedzwiecki, M.D.¹

ABSTRACT

Endovenous saphenous vein obliteration in the form of radiofrequency or laser therapies has quickly ascended to a position of prime importance in the treatment of reflux within the superficial venous system. The technical aspects of these procedures, as well as their decreased morbidity when compared with saphenous vein stripping, make them highly appealing to both practitioners and patients alike. Less bruising, less pain, and less postoperative recovery are associated with these endovenous techniques than with the historical “gold standard” of saphenous vein stripping. Efficacy exceeds that of sclerotherapy, the other nonsurgical option. These improvements have led to greater acceptance by patients and consequently greater patient demand for endovenous ablation procedures. Practitioners should therefore become well versed in the techniques of performing these procedures safely and effectively for patients.

KEYWORDS: Endovenous, thermal ablation, saphenous vein, reflux, laser, radiofrequency closure

Objectives: Upon completion of this article, the reader should be able to (1) understand the technical considerations in performing endovenous thermal ablation of the saphenous vein whether using laser or radiofrequency closure; (2) understand the importance and role of tumescent anesthetic in the treatment of saphenous vein reflux while using endovenous thermal ablation techniques; and (3) be exposed to the historical treatment options tried for saphenous reflux, and understand their failure rates and complication rates, and how they compare to endovenous ablation techniques.

Accreditation: Tufts University School of Medicine (TUSM) is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Credit: TUSM designates this educational activity for a maximum of 1 Category 1 credit toward the AMA Physicians Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

HISTORICAL PERSPECTIVES

Multiple techniques for treating saphenous reflux have been developed over the years, including high ligation of the saphenous vein, saphenous vein stripping, and ultrasound-guided sclerotherapy, as well as various combinations of these procedures. Most recently, endovenous thermal ablation has also been identified as a viable treatment option for patients with saphenous reflux.

Multiple studies have evaluated the efficacy of sclerotherapy and ultrasound-guided sclerotherapy for saphenous reflux, with some centers using combinations of sclerotherapy alone and sclerotherapy with ligation in an effort to improve outcomes. Follow-up ranged from 2 to 10 years with failure rates in the range of 20–84% being identified.^{1–3} With these very high recurrence rates, these treatments are now considered

Venous Insufficiency; Editors in Chief, Brian Funaki, M.D., Peter R. Mueller, M.D.; Guest Editor, R. Torrance Andrews, M.D. *Seminars in Interventional Radiology*, volume 22, number 3, 2005. Address for correspondence and reprint requests: Gerald Niedzwiecki, M.D., 2655 State Road 580, Suite 202, Clearwater, FL 33761-3167. ¹President of Advanced Vein and Laser Center, Clearwater, Florida. Copyright © 2005 by Thieme Medical Publishers, Inc., 333 Seventh Avenue, New York, NY 10001, USA. Tel: +1(212) 584-4662. 0739-9529,p;2005,22,03,204,208,ftx,en; sir00313x.

to be poor options for patients suffering from saphenous reflux.

Surgical treatments include high ligation of the saphenous vein or high ligation with stripping. High ligation alone demonstrated a 43–71% failure rate at 5 years and ligation and stripping had a 25–60% failure rate, ranging from 5 to 34 years in the available literature.^{4–7} The failures associated with high ligation alone stemmed from neovascularization that occurred in the saphenofemoral surgical bed and was attributed to the process of skeletonization and ligation of all tributaries of the saphenofemoral junction. In the recurrences that occurred after stripping, the etiology may be incomplete removal of the entire vein. It has been noted that only 38% of patients who go to surgery with the intent of undergoing vein stripping have complete stripping; 62% of patients have incomplete stripping because the stripping device passes through tributary veins, rather than the saphenous vein, as the stripper is passed blindly during the surgical procedure.⁷

Vein stripping and ligation are associated with an aggregate 0.5% average incidence of pulmonary embolism, an average 1% incidence of deep venous thrombosis (DVT), an 8% incidence of infection, and an approximately 0.5% incidence of lymphedema.^{8–16} The most common complication associated with vein stripping and ligation is paresthesia in the region of the surgical procedure. Stripping from the saphenofemoral junction through the ankle produces an average paresthesia rate of ~23.4%, and stripping limited to the above the knee saphenous vein has an average paresthesia rate of ~9.9%.^{11,13,17–21} Because of the high failure rates secondary to neovascularization and the relatively high morbidity and recurrences associated with saphenous vein stripping as well as the high failure to strip completely in many patients, there has long been interest in identifying a more effective and less invasive treatment option.

ENDOVENOUS THERMAL ABLATION

Percutaneous endovenous thermal ablation by radiofrequency (RF) (Closure; VNUS Medical) received Food and Drug Administration (FDA) approval in 1999. Laser ablation therapy followed shortly thereafter, with FDA approval in 2002. Many operators now believe that percutaneous endovenous thermal ablation meets the goals of high efficacy and low morbidity and will define a new “gold standard” for the management of saphenous reflux.

Radiofrequency

Endovenous RF ablation (Closure; VNUS Medical) has been in wide use since 1999 and, relative to laser techniques, has the larger collection of published data

and longer follow-up. Three randomized clinical trials studied RF obliteration of the saphenous vein compared with ligation and vein stripping.^{22–24} These three randomized clinical trials demonstrated less postoperative pain, less analgesic use, and shorter sick leave time in the RF closure group than in the ligation and stripping group. The EVOLVeS study (Endovenous Radiofrequency Obliteration [Closure] versus Ligation and Stripping) clearly demonstrated a much lower use of general anesthetic in the RF obliteration group, with extremely well-matched cohorts. The reflux-free clinical status of the patients at 2 years and the recurrence rate for varicosities were similar in both the RF obliteration and stripping ligation groups, and the amount of neovascularization encountered was significantly less (2.9% compared with 16.7%) in the RF ablation group versus the stripping and ligation group. The EVOLVeS study also demonstrated faster recovery time, less postoperative pain, fewer adverse events, and superior quality-of-life scores in the RF obliteration group compared with the group that underwent saphenous vein stripping and ligation.

Single-center data for RF obliteration of the saphenous vein reveal a very high efficacy rate as well as a high durability of the therapy, with efficacy rates in the 90–99% range at 1- and 2-year intervals.^{25–29} Complication rates of RF closure are similar to or less than those of stripping and ligation with the incidence of DVT in the 1% range, infections rates in the 0.2% range, and paresthesia rates above the knee of 4.1% at 24 months. The RF ablation clinical registry now has patients with follow-up of 5 years, with 84% of patients at 5 years continuing to be reflux free and 73% of patients at 5 years continuing to demonstrate absence of varicose veins within the registry. Symptomatic relief remains extremely high through the 5-year interval with fewer than 5% of patients demonstrating return of the pain and fatigue symptoms with which they had presented.

Laser

Laser devices for use in treatment of saphenous reflux are currently available from several manufacturers, and the lasers differ primarily in their wavelengths. Although the initial success rate and short-term durability of laser treatment for saphenous reflux are very promising, the published literature suffers from small numbers of patients and limited long-term follow-up for the different wavelength devices. In addition, there are no available data with which to make any credible distinction among the various wavelengths in terms of efficacy.

Laser data are almost exclusively single-center data.^{30–34} These single-center studies demonstrate a very high initial success rate, in the 97–100% range, with patients demonstrating approximately 90% persistence of occlusion of the great saphenous vein after

24 months. Significant pain was present in 67% of patients for approximately 1 week after laser therapy, and up to 10% of patients were noted to have overt thrombophlebitis for 2 weeks after the procedure.³³ No prospective comparison of the relative safety and efficacy of RF and laser techniques has yet been reported.

TECHNIQUE

As with all procedures, full informed consent should be obtained before beginning the procedure. The most common risks associated with endovenous ablation include transient paresthesias and bruising along the ablation track. DVT has been reported but has a relatively low occurrence rate of 1%. Skin burns have been reported with both RF and laser techniques, although the incidence of these is extremely low with the advent of tumescent anesthesia techniques, which are discussed later.

After informed consent has been obtained, the great saphenous vein, which has previously been identified as having reflux on diagnostic ultrasound examination (discussed separately), is mapped from the saphenofemoral junction through below the knee. At times the great saphenous vein may leave the saphenous sheath and continue as the saphenous vein equivalent outside the saphenous sheath. If this vessel remains relatively straight and allows passage of the catheter, the equivalent saphenous vein may also be treated in the same fashion as the true saphenous vein.

After the vessel has been mapped, the saphenous vein is accessed utilizing direct ultrasound guidance and micropuncture technique. The ideal point of entry is caudal to the most caudal point of reflux but not more than 10–15 cm below the knee (below which point the saphenous nerve lies in close proximity to the vein). After the vessel has been accessed utilizing transverse or sagittal imaging, a vascular sheath is introduced with antegrade orientation. Here the techniques for endovenous laser and RF closure diverge slightly. The sheath for the endovenous laser is a 40- to 65-cm-long device that is intended to extend from the venotomy site to the saphenofemoral junction, whereas the RF closure sheath is a short device used simply to maintain access and allow hemostatic introduction of the RF closure catheter, which is then advanced over the wire to the saphenofemoral junction. After the sheath is introduced, either the long sheath (for laser) or the probe itself (for RF) is advanced under ultrasound guidance to the saphenofemoral junction. A 0.025 guidewire may be used to aid the passage of the closure catheter through tortuous areas of the saphenous vein. Similarly, standard guidewires may be used to aid in the passage of the sheath for the laser fiber. When marked tortuosity or segmental aneurismal dilatation is present, fluoroscopy may also be helpful.

To minimize the risk of DVT or injury to the central veins, it is of critical importance that the tip of the closure catheter or the laser fiber be definitively identified with ultrasound and positioned just caudal to the epigastric vein prior to activation. This position also decreases the risk for future neovascularization around the saphenofemoral junction. For greatest accuracy, the saphenofemoral junction, the epigastric vein, and the RF or laser tip should be identified simultaneously with longitudinal imaging. If the epigastric vein can be identified, the tip is positioned within the saphenous vein just caudal to the epigastric vein confluence. If not, the tip should be positioned 1–2 cm caudal to the saphenofemoral junction.

Tumescent anesthetic is then administered along the entire length of the great saphenous vein within the perivenous space. In addition to providing local analgesia, this dilute mixture of lidocaine and saline (0.15–0.20%) acts as a thermal heat sink as well as compresses the saphenous vein to improve the transfer of thermal energy to the vein wall. Typically, tumescent anesthetic administration is begun at the level of the knee with longitudinal imaging. The needle is slowly advanced toward the outer wall of the saphenous vein under direct ultrasound guidance as the tumescent anesthetic is gently injected. Once the perivenous space is entered, the fluid begins to flow freely up the perivenous potential space along the saphenous vein. The resulting “cuff” of perivenous fluid is followed cephalad until its progress begins to slow (a variable distance), at which time the needle is reinserted at the cephalad edge of the cuff and more tumescent anesthetic is administered in a similar fashion until the saphenofemoral junction has been reached. At this level, additional anesthetic agent should be administered in the soft tissues deep and superficial to the catheter-fiber tip and saphenous vein because of slightly greater innervation in this region.

After tumescent anesthetic has been administered, the entire course of the saphenous vein is evaluated with ultrasound to confirm that it is completely surrounded by anesthetic fluid at all levels. Transverse orientation is useful in this determination. One should additionally confirm that the superficial aspect of the saphenous vein is at least 1.0 cm deep to the skin surface along its entire length. The purpose of this gap (which can be achieved by use of additional perivenous fluid if necessary) is to reduce the likelihood of skin burns.

The RF and laser procedures again diverge at this point. For the closure procedure, a bloodless field is desirable, as the closure catheter works by conducting RF energy through the vein wall. Blood within the field can coagulate on the tines of the closure catheter, increasing the impedance and diminishing the effectiveness of the heat deposition. In contrast, it is desirable and necessary with laser treatment to maintain a small volume of blood within the lumen of the vein, as blood

is the chromophore for the absorption of the laser energy to transfer heat to the vein wall and cause injury to the vein wall. Reflecting these differences, the RF system uses a heparin drip to exsanguinate the saphenous vein, but no such drip is used for laser ablation. In both techniques, Trendelenburg positioning is useful during device activation to reduce (or, for RF, eliminate) the volume of endoluminal blood.

After the patient is placed in Trendelenburg position and, if appropriate, the heparin infusion begun, correct positioning of the RF or laser fiber tip is again verified and adjusted as necessary. The catheter-fiber is then energized and withdrawn through the vein. The rate of pullback with the laser technique is adjusted to maintain an energy transfer of 80–100 joules/cm within the vein. Most centers use continuous energy production of 12–14 watts. Some operators recommend applying manual pressure to the vein over the fiber tip (as identified by transcutaneous visualization of an “aiming beam” that projects from it). For the RF procedure, the standard technique is an 85°C treatment in which the first 5.0 cm of saphenous vein is treated at 1.0 cm per minute, followed by the remainder of the great saphenous vein being treated at 2–3 cm per minute. Some centers have begun treating with a modified technique in which the first 5.0 cm of saphenous vein is treated at 1.0 cm per minute with the generator set at 90°C, after which the catheter is slowly and continuously pulled back at a rate that maintains a vein wall temperature of 90°C. This does speed the closure procedure when compared with the 85°C technique. Successful energy transfer is monitored by the closure generator. If the tines become fouled, impedance rises above acceptable levels and the generator automatically shuts off. In such cases, the closure catheter can be withdrawn over a guidewire, cleaned, and reinserted to complete the procedure.

After the catheter or fiber has been withdrawn to the venotomy site, the saphenous vein is again evaluated with ultrasound. Typically, one identifies vessel wall thickening, concentric narrowing, and absence of flow, indicating a successful endovenous saphenous vein obliteration procedure. The common femoral vein is also evaluated for compressibility and the absence of thrombus. The sheath is then removed and hemostasis is obtained with manual compression. The patient is observed for approximately 1/2 hour and thigh-high class II compression stockings are then applied to the treated leg or legs. The exact regimen for compression stocking use varies from center to center, but most recommend at least 1 week of compression therapy following an endovenous saphenous vein obliteration procedure. A follow-up ultrasound examination is performed in 2–3 days to confirm a successful obliteration procedure and to rule out any potential DVT or extension of thrombus from the saphenous vein into the femoral vein.

CONCLUSIONS

Previous techniques for controlling saphenous reflux, including sclerotherapy, ligation, and even stripping of the saphenous vein, are morbid procedures and, because of neovascularization at the saphenofemoral junction, have high recurrence rates. Endovenous techniques, by comparison, have low rates of complication and have not been shown to generate the same degree of neovascularization. The use of ultrasound-guided tumescent anesthesia has dramatically improved the effectiveness of endovenous techniques by collapsing the saphenous vein and allowing better wall contact by the laser fibers and the RF closure catheters. This technique has also markedly diminished complication rates associated with the procedures, making them an extremely desirable treatment option for patients suffering from venous reflux. It would therefore appear that endovenous obliteration of the saphenous vein has established itself as a new gold standard for the treatment of symptomatic saphenous reflux.

REFERENCES

1. Neglen P, Einarsson E, Eklof B. The functional long-term value of different types of treatment for saphenous vein incompetence. *J Cardiovasc Surg (Torino)* 1993;34:295–301
2. Kanter A, Thibault P. Saphenofemoral incompetence treated by ultrasound-guided sclerotherapy. *Dermatol Surg* 1996;22:648–652
3. Belcaro G, Nicolaides AN, Ricci A. Endovascular sclerotherapy, surgery and surgery plus sclerotherapy in superficial venous incompetence: a randomized 10 year follow-up trial: final results. *Angiology* 2000;51:529–534
4. Jones L, Braithwaite BD, Selwyn D, Cooke S, Earnshaw JJ. Neovascularization is the principle cause of varicose vein recurrence: results of a randomized trial of stripping the long saphenous vein. *Eur J Vasc Endovasc Surg* 1996;12:442–445
5. Dwerryhouse S, Davies B, Harradine K, Earnshaw JJ. Stripping the long saphenous vein reduces the rate of reoperation for recurrence varicose veins: five year results of a randomized trial. *J Vasc Surg* 1999;29:589–592
6. Fischer R, Linde N, Duff C, Jeanneret C, Chandler JG, Seeber P. Late recurrent saphenofemoral junction reflux after ligation and stripping of the greater saphenous vein. *J Vasc Surg* 2001;34:236–240
7. Mackenzie RK, Paisley A, Allan PL, Lee AJ, Ruckley CV, Bradbury AW. The effect of long saphenous vein stripping on quality of life. *J Vasc Surg* 2002;35:1197–1203
8. Hagmuller GW. Complications in surgery of varicose veins. *Langenbecks Arch Chir Suppl Kongressbd* 1992:470–474
9. Lofgren EP, Coates HL, O'Brien PC. Clinically suspected pulmonary embolism after vein stripping. *Mayo Clin Proc* 1976;51:77–80
10. Miller GV, Lewis WG, Sainsbury JR, Macdonald RC. Morbidity of varicose vein surgery: auditing the benefit of changing clinical practice. *Ann R Coll Surg Engl* 1996;78:345–349

11. Einarsson E, et al. Sclerotherapy or surgery as treatment for varicose veins: a prospective randomized study. *Phlebology* 1993;8:22-26
12. Dale WA, et al. Symposium: management of varicose veins. *Contemp Surg* 1975;6:86
13. Mackay DC, Summerton DJ, Walker AJ. The early morbidities of varicose vein surgery. *J R Nav Med Serv* 1995;81:42-46
14. Durkin RC. PIN vs. conventional stripping. 1999
15. Corder AP, Schache DJ, Farquharson SM, Tristram S. Wound infection following high saphenous ligation—a trial comparing two skin closure techniques: subcuticular polyglycolic acid and interrupted monofilament nylon sutures. *J R Coll Surg Edinb* 1991;36:100-102
16. Ouvry PA, Guenneguez H, Ouvry PA. Complications lymphatiques de la chirurgie des varices. *Phlebologie* 1993;46:563-568
17. Ramasastry S, Dick GO, Futrell JW. Anatomy of the saphenous nerve: relevance to saphenous vein stripping. *Am Surg* 1987;53:274-277
18. Rutgers PH, Kitslaar PJ. Randomized trial of stripping versus high ligation combined with sclerotherapy in the treatment of the incompetent greater saphenous vein. *Am J Surg* 1994;168:311-315
19. Holme JB, Skajaa K, Holme K. Incidence of lesions of the saphenous nerve after partial or complete stripping of the long saphenous vein. *Acta Chir Scand* 1990;156:145-148
20. Munn SR, Morton JB, Macbeth WA, Mcleish AR. To strip or not to strip the long saphenous vein? A varicose veins trial. *Br J Surg* 1981;68:426-428
21. Jones L, Braithwaite BD, Selwyn D, Cooke S, Earnshaw JJ. Neovascularization is the principal cause of varicose vein recurrence: results of a randomized trial of stripping the long saphenous vein. *Eur J Vasc Endovasc Surg* 1996;12:442-445
22. Lurie F, Creton D, Eklof B, et al. Prospective randomized study of endovenous radiofrequency obliteration (closure) vs. ligation and stripping in a selected patient population (EVOLVE study). *J Vasc Surg* 2003;38:207-214
23. Lurie F, Creton D, Eklof B, et al. Prospective randomized study of endovenous radiofrequency obliteration (closure) vs. ligation and vein stripping (EVOLVEs): two year follow-up. *Eur J Vasc Endovasc Surg* 2005;29:67-73
24. Rautio T, Ohinmaa A, Perala J, et al. Endovenous obliteration vs. conventional stripping operation in the treatment of primary varicose veins: a randomized controlled trial with comparison of the costs. *J Vasc Surg* 2002;35:958-965
25. Stotter L, et al. Presentation at German Phlebology Society, September 2003
26. Weiss RA, Weiss MA. Controlled radiofrequency endovenous occlusion using a unique radiofrequency catheter under duplex guidance to eliminate saphenous varicose vein reflux: a two year follow-up. *Dermatol Surg* 2002;28:38-42
27. Rosenblatt M. Treatment of venous insufficiency due to greater saphenous vein reflux with endovenous radiofrequency ablation. Abstract presentation. Society of Interventional Radiology, March 27-April 1, 2003, Salt Lake City, Utah
28. Kistner RL. Endovascular obliteration of the greater saphenous vein: the closure procedure. *Jpn J Phlebol* 2002;13:325-333
29. Whiteley MS, et al. Radiofrequency ablation of reflux in great saphenous systems, Giacomini vein and incompetent perforating veins using VNUS closure and TRLOP technique [abstract]. *J Endovasc Ther* 2003;10:1-51
30. Min RJ, Zimmet SE, Isaacs MN, Forrestal MD. Endovenous laser treatment of the incompetent greater saphenous vein. *J Vasc Interv Radiol* 2001;12:1167-1171
31. Min RJ, Khilnani N, Zimmet SE. Endovenous laser treatment of saphenous vein reflux: long term results. *J Vasc Interv Radiol* 2003;14:991-996
32. Proebstle TM, Gul D, Lehr HA, Kargl A, Knop J. Infrequent early recanalization of greater saphenous vein after endovenous laser treatment. *J Vasc Surg* 2003;38:511-516
33. Proebstle TM, Lehr HA, Kargl A, et al. Endovenous treatment of the greater saphenous vein with a 940-nm diode laser: thrombotic occlusion after endoluminal thermal damage by laser-generated steam bubbles. *J Vasc Surg* 2002;35:729-736
34. Proebstle TM, Krummenauer F, Gul D, Knop J. Non-occlusion and early reopening of the great saphenous vein after endovenous laser treatment is fluence dependent. *Dermatol Surg* 2004;30:174-178