Radiofrequency Ablation and Laser Ablation in the Treatment of Varicose Veins

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Chronic venous insufficiency is a major medical disease in the United States. With a total population of 300 million, it is estimated that 25 million persons in this country alone have symptoms of this disease (1 in 12). Great saphenous vein reflux is the most common form of venous insufficiency in symptomatic patients and is most frequently responsible for varicose veins of the lower extremity. Therefore, therapy directed toward correcting superficial venous pathology is beneficial to many patients.

INTRODUCTION

Chronic venous insufficiency (CVI) is a major medical disease in the United States. With a total population of 300 million, it is estimated that 25 million persons in this country alone have symptoms of this disease (1 in 12). Great saphenous vein (GSV) reflux is the most common form of venous insufficiency in symptomatic patients and is most frequently responsible for varicose veins of the lower extremity.[1,2] Therefore, therapy directed toward correcting superficial venous pathology is beneficial to many patients. In the United States, surgical high ligation and stripping is rapidly becoming senescent and will soon be extinct. Endovenous thermal ablation of the GSV is safe and effective with faster recovery and better cosmesis than surgical high ligation and stripping.[3,4] The two methods of thermal ablation presently in comprehensive vein centers are the Closure© procedure, which uses a catheter to direct radiofrequency (RF) energy from a dedicated generator (VNUS Medical Technologies, Sunnyvale, CA), and endovenous laser (EVL) ablation, which employs a laser fiber and generator to produce focused heat (Table I). Both systems use electromagnetic energy to destroy the refluxing GSV. When this energy is delivered at the vein wall (RF or 1,320 nm laser), there is collagen shrinkage and venous spasm with minimal formation of thrombus.[5,6] When focused at the hemoglobin chromophore (810, 940, 980 nm lasers), heat injury of the endothelium by steam bubbles originating from boiling blood is the mechanism of action.[7,8] Sonographic disappearance of the treated vein is the desired end result.

There is a growing body of literature reporting excellent long-term results with RF[9] and laser[10] ablation of the saphenous vein. Interestingly, neovascularization, a principle cause of varicose vein recurrence after surgical high ligation and stripping,[11-14] is rare after thermal ablation.[15]

METHODS

From March 2002 until June 2005, endovenous thermal ablation was performed on 947 refluxing veins in 899 limbs of 694 patients by a single vascular surgeon at Miami Vein Center. A retrospective comparison was made between the EVL (n = 819) and the RF (n = 128) cases. The patient populations were similar in age; gender; clinical,

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Ann Vasc Surg 2006; 20: 547-552
DOI: 10.1007/s10016-006-9098-8

Published online: June 22, 2006

Table I. Available Food and Drug Administration-approved endovenous lasers

Laser wavelength (nm)	Device manufacturer/distributor	Office headquarters
810	Diomed	Andover, MA
	Vascular Solutions	Minneapolis, MN
	Biolitec	East Longmeadow, MA
	Angiodynamics	Queensbury, NY
940	Dornier Medtech	Kennesaw, GA
980	Biolitec	East Longmeadow, MA
	Angiodynamics	Queensbury, NY
1,320	Cooltouch	Roseville, CA

Table II. Distribution of treated veins

Device	GSV	AASV	PTCV	SSV	SVR	Perforator
RF	95	21	-	11	1	-
810 nm laser	17	-	-	-	2	-
940 nm laser	4	-	-	-	-	-
980 nm laser	460	125	7	104	96	2
1,320 nm laser	2	-	-	-	-	-
Total	578	146	7	115	99	2

Dual vein ablations, $n = 46$; triple vein ablations, $n = 2$; quadruple vein ablations, $n = 1$. GSV, great saphenous vein; AASV, anterior accessory saphenous vein; PTCV, posterior thigh circumflex vein; SSV, small saphenous vein; SVR, saphenous vein remnant.

etiological, anatomical, and pathophysiological (CEAP) classification; and comorbidities.

All cases were performed endoluminally, using ultrasound guidance and local anesthesia in the office surgical suite. Successful treatment was defined by the absence of flow in the treated vein segment by duplex ultrasound imaging. Recanalization was defined as the presence of flow in a vein segment >5 cm in length.

Ultrasound follow-up was performed at 2 days, 1 month, 6 months, 12 months, and then annually. The distribution of veins treated and the devices used for treatment are depicted in Table II. Multiple veins, usually the GSV and the anterior accessory saphenous vein, were closed in the same setting in 49 limbs. All saphenous vein remnants, commonly found after high ligation and stripping, were treated with combination thermal ablation and ultrasound-guided sclerotherapy. Table IIIa and b illustrates our treatment protocols for the delivery of laser and RF energy. In the case of laser, energy delivery is based on vein size; in the case of RF, the choice of a 6 or an 8 F catheter is based on vein size. All venous diameter measurements are obtained with the patient in the standing position.

In our analysis of vein closure, we used two methods. The first method, %Recanalization, quotes the absolute number of recanalized veins divided by the absolute number of veins at risk for recanalization. %Recanalization is not statistically linked to mean follow-up or recanalization at a specific point in time. This less than rigorous statistic has been quoted extensively in the endovenous literature and is the reason we include it here. We report primary vein closure using the Kaplan-Meier life-table method since, in the arterial literature, that approach has a long and successful history. With this method we can link vein closure to mean follow-up, a measure of the strength of the series, and time after the procedure. This method also allows determination of assisted primary vein closure and secondary vein closure. The log rank test was used to determine if closure by RF and EVL differed on a statistical basis.

RESULTS

Cessation of retrograde flow in the target vein was observed in all patients at the completion of the procedure. Recanalization was observed in 21 veins. Ninety percent (19 of 21) of the recanalizations occurred within the first 12 months after treatment. The primary closure rate was 85% for RF (%Recanalization = 5.5%) and 92% for EVL (%Recanalization = 1.7%) at 500 days. These figures are depicted in Figure 1 and Table IVa. This suggests a statistically significant difference in favor of EVL. The mean follow-up time for RF and EVL

Table IIIa. Laser energy protocol

Vein size (mm)	Laser energy delivery (J/cm)
0-10	50
10-15	50-60
15-20	60-70
20-25	70-80
25-30	80-90
>30	90-100

Table IIIb. RF treatment protocol

Treatment period	RF temperature (°C)
March 2002-March 2004	85
March 2004-March 2005	90
March 2005-present	95
Vein size (mm)	Catheter size (French)
<15	6
>15	8

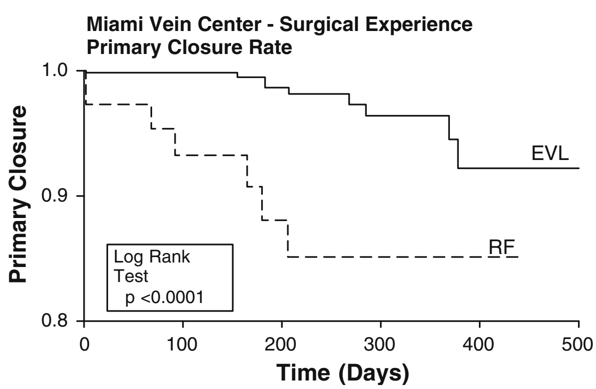

Fig. 1. Kaplan-Meier Primary Closure Rate.

subjects was 198 days (range 1-1,036) and 160 days (range 1-890), respectively. When recanalization was present in the GSV, it usually occurred proximal to the posterior thigh circumflex vein; in the small saphenous vein, recanalization occurred proximal to May's perforator. The distribution of veins associated with recanalization is presented in Table IVb.

Concomitant phlebectomy was performed in 795 of 899 limbs (88%), while adjunctive ultrasound-guided sclerotherapy was performed in 142 of 899 limbs (16%).

Adverse events associated with endothermal venous ablation were minimal and transient. Two limbs in the RF group and two limbs in the EVL group developed transient paresthesias. Thrombus extension into the common femoral vein requiring anticoagulation occurred in two cases after EVL (2/819 = 0.2%). Our incidence of DVT with RF was zero. Ambulatory phlebectomy was associated with the development of six small seromas, which resolved without further treatment.

Table IVa. %Recanalization

Catheter type	*n*	Recanalized veins (*n*)	% Recanalization
EVL	819	14	1.7
RF	128	7	5.5
Totals	947	21	2.2

Table IVb. Sites of recanalization

	Recanalization site		
Catheter type	GSV proximal to PTCV	Entire length GSV	SSV proximal to May's perforator
EVL	6	3	5
RF	6	1	0

GSV, great saphenous vein; PTCV, posterior thigh circumflex vein; SSV, small saphenous vein.

DISCUSSION

Catheter delivery of thermal energy is an effective means of saphenous ablation and can be used safely in the office with local anesthesia. In our series, %Recanalization was 1.7% with EVL and 5.5% with RF. These statistics are improved when compared to a report from our center published last year. In that study, %Recanalization was 2.3% for EVL and 7.5% for RF.[16] Both studies demonstrated statistically significant higher efficacy in favor of EVL. It is not yet known if laser wavelength influences outcome.

Recanalization is less frequent with our current practice protocols. We now deliver more energy to the treated segment and close multiple refluxing veins at the same setting. In our earlier EVL experience, we delivered 30-50 J/cm along the treatment length; our current protocol calls for 50-80 J/cm. With RF, we used an 85°C temperature for catheter pullback early in our series, while currently we use 95°C. Adventitial (outer vein wall) temperatures have been shown in animal models to remain relatively cool during EVL[17] and RF[18] ablation, supporting the safe use of higher energy delivery with both technologies. Further, the addition of perivenous fluid (local anesthesia), which we add in all of our cases, acts as a heat sink and prevents radiation of heat to nontarget tissues.

Table Va. RF literature review

Author, year	Limbs (n)	Skin burn	Paresthesia	Phlebitis	DVT	PE	%Recanalization	Mean follow-up
Weiss and Weiss, 2002[23]	140	0	4%	0	0	0	10%	9 months
Merchant et al., 2002[24]	318	4%	15%	2%	1%	1	15%	24 months
Rautio et al., 2002[25]	30	3%	10%	6%	0	0	17%	10 months
Lurie et al., 2003[4]	44	2%	23%	4%	0	0	10%	4 months
Hingorani et al., 2004[21]	73	0	0	0.3%	16%	0	4%	10 days
Almeida,2004[16]	106	0	2%	NA	0	0	8%	3 months
Merchant et al., 2005[9]	1,078	2%	12%	3%	0.5%	1	11%	4 years*

Table Vb. Laser literature review

Author, year	Limbs (n)	Skin burns	Paresthesia	Phlebitis	DVT	PE	%Recanalization	Mean Follow-up
Navarro et al.,2001[26]	40	0	0	0	0	0	0	4 months
Proebstle et al.,2003[27]	109	0	0	10%	0	0	10%	12 months
Min et al., 2003[10]	504	0	0	5%	0	0	2%	6 months
Perkowski et al., 2004[28]	154	0	0	0	0	0	3%	0.5 months
Almeida, 2004[16]	429	0	0.2%	NA	0.5%	0	2%	3 months

NA, not applicable.
*There were 87/836 (10%) limbs followed to 4 years; mean follow-up not reported.

Higher delivered energy has also been reported as an advantage by other authors.[19,20] Most recanalizations occurred in the first 12 months and developed in the GSV proximal to the posterior thigh circumflex vein or in the small saphenous vein proximal to May's perforator. Aggressively treating posterior thigh circumflex veins is supported by this study. The posterior thigh circumflex vein, when large, drains cooler blood into the treatment segment and does not allow proper heat-induced closure of the saphenofemoral junction. When the posterior thigh circumflex vein is >4 mm in diameter, we now access it and close it concomitantly with the primary procedure.

We also recommend that future publications adopt the Kaplan-Meier life-table method to report vein closure. The closure rate was 92% for EVL and 85% for RF at 500 days in this series. A weakness of this study, and most endovenous reports published to date, is the number of patients who failed to return for ultrasound follow-up after 1 year. The life-table method accounts for the significant number of patients lost to follow-up.

Our incidence of DVT was 0.2% and falls within the standard of care for the treatment of superficial venous disease. With the exception of one RF study by Hingorani et al.,[21] DVT has been infrequent in most clinical reports of thermal ablation to date, with a range of 0-1% (Table Va and b). It is important to note that the anesthetic technique of Hingorani et al. (general anesthesia 44%, regional femoral block 45%, and conscious sedation in 11% of cases) produces venodilatation and stasis followed by delayed ambulation; this encourages thrombosis. Performing thermal ablation in the hospital adds many steps before, during, and after the procedure, thus removing much of the benefit of minimally invasive technology. Most contemporary vein centers perform these cases with tumescent local anesthesia only (no sedation) and immediate ambulation, thus eliminating 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. Thrombosis is discouraged using local anesthesia because venous tone is maintained intraoperatively and the calf muscle pump is engaged immediately after the procedure. Furthermore, infections are a rare occurrence in the office.

We recently completed a literature review of RF and EVL. We recorded important clinical parameters such as number of limbs treated, complications including DVT, closure rates, and mean follow-up. This tabulation is found in Table Va and b. Comparative highlights include more effective ablation with EVL. With RF, there was a lower incidence of postoperative superficial phlebitis. More skin burns and paresthesias are documented in the earlier reports using RF ablation; these complications have been mostly eliminated since the advent of perivenous local anesthesia.

We feel ambulatory phlebectomy remains a useful adjunct to saphenous ablation and should be used liberally. Performing ambulatory phlebectomy in conjunction with saphenous ablation cures the patient of axial venous reflux and bulging varicosities with one procedure. However, varicosities in continuity with a refluxing truncal vein, and not in continuity with any perforating veins, will diminish in size after endovenous ablation only. Therefore, 12% of patients in our series did not require adjunctive ambulatory phlebectomy. In addition, ultrasound-guided sclerotherapy, particularly with foam, is another valuable tool in the armamentarium of venous surgeons.[22]

In closing, thermal ablation has become the new standard of care for the treatment of superficial axial vein reflux. Compared to conventional surgery, it has the advantage of minimal invasion, quicker recovery, lower recurrence, and fewer complications. It is well accepted by patients. When thermal ablation is used in conjunction with other adjunctive procedures (phlebectomy, sclerotherapy, ligation, etc.), all cases can be treated in the office setting, thus eliminating the role of the hospital.

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