

Developments in Endovascular and Endoscopic Surgery

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 RF⁹ and laser¹⁰ 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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Table I. Available Food and Drug Administration-approved endovenous lasers

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

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