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A randomized prospective long-term (>1 year) clinical trial comparing the efficacy and safety of radiofrequency ablation to 980 nm laser ablation of the great saphenous vein

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Abstract

Purpose: To compare the short- and long-term (>1 year) efficacy and safety of radiofrequency ablation (ClosureFAST™) versus endovenous laser ablation (980 nm diode laser) for the treatment of superficial venous insufficiency of the great saphenous vein.

Materials and methods: Two hundred patients with superficial venous insufficiency of the great saphenous vein were randomized to receive either radiofrequency ablation or endovenous laser ablation (and simultaneous adjunctive therapies for surface varicosities when appropriate). Post-treatment sonographic and clinical assessment was conducted at one week, six weeks, and six months for closure, complications, and patient satisfaction. Clinical assessment of each patient was conducted at one year and then at yearly intervals for patient satisfaction.

Results: Post-procedure pain ($p < 0.0001$) and objective post-procedure bruising ($p = 0.0114$) were significantly lower in the radiofrequency ablation group. Improvements in venous clinical severity score were noted through six months in both groups (endovenous laser ablation 6.6 to 1; radiofrequency ablation 6.2 to 1) with no significant difference in venous clinical severity score ($p = 0.4066$) or measured adverse effects; 89 endovenous laser ablation and 87 radiofrequency patients were interviewed at least 12 months out with a mean long-term follow-up of 44 and 42 months ($p = 0.1096$), respectively. There were four treatment failures in each group, and every case was correctable with further treatment. Overall, there were no significant differences with regard to patient satisfaction between radiofrequency ablation and endovenous laser ablation ($p = 0.3009$). There were no cases of deep venous thrombosis in either group at any time during this study.

Conclusions: Radiofrequency ablation and endovenous laser ablation are highly effective and safe from both anatomic and clinical standpoints over a multi-year period and neither modality achieved superiority over the other.

Keywords

Endovenous laser treatment, endovenous thermal ablation, radiofrequency ablation, varicose veins, venous reflux

Introduction

Chronic venous insufficiency (CVI) is the most prevalent vascular disease in the United States with an estimated 25 million Americans affected by this debilitating condition.[1] Symptoms of CVI include cramping, pain, early fatigue, throbbing, and itching while physical findings include varicose veins, dyspigmentation of the skin, edema, eczema, lipodermatosclerosis, and ulceration. The primary cause of CVI is thought to be poorly functioning venous valves, nearly always at the lower limbs, resulting in prolonged retrograde flow of

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deoxygenated blood. Of the superficial veins in the lower extremity, the great saphenous vein (GSV) is the most common cause of CVI in symptomatic patients.[2,3]

The treatment of CVI has undergone a revolution with the introduction of endovenous thermal ablation (EVTA) as the most preferred method over high surgical ligation and stripping. EVTA is a catheter-based technique utilizing electromagnetic (EM) energy to obliterate the GSV in a minimally invasive, office-based procedure. Indeed, whereas surgical ligation and stripping requires general anesthesia and a prolonged recovery period,[4] EVTA can be performed in an outpatient setting allowing patients to resume normal daily activities with minimal delay. In addition, numerous studies have demonstrated EVTA to have at least equal, and often greater, efficacy than surgical ligation and stripping for the treatment of CVI.[5–9]

The increasing popularity of EVTA has spurred the generation of an array of devices in this rapidly growing arena in phlebology. Variations in devices primarily revolve around fiber tip design and type of EM energy utilized to ablate a vein, the latter of which can be dichotomized into either non-laser radiofrequency (RF) emitting devices or laser-based devices emitting near- to short-wavelength infrared light (810–1500 nm). While initial EVTA procedures were performed with RF devices (denoted as RF ablation, RFA), an abundance of laser devices soon followed, with each device emitting a wavelength primarily targeting either hemoglobin (810, 940, 980, and 1064 nm) or water (1320, 1470, and 1500 nm) as a principle chromophore. The importance of wavelength selection for endovenous laser ablation (EVLA), however, has been called into question as higher power settings, faster catheter pullback velocities, and vein diameter at time of treatment irrespective of wavelength are thought to be the primary determinants for the successful treatment of CVI.[10,11]

During the past decade, numerous studies have independently confirmed the effectiveness of RFA and EVLA. In particular, clinical studies utilizing RFA reveal excellent short- and long-term results with 4%–17% recanalization rates up to four years after treatment.[6,7,9,16–18] Similarly, EVLA exhibits 0%–10% recanalization rates for up to one year after treatment.[5,14,16–18] Such studies also demonstrate impressive safety profiles for both techniques with a deep venous thrombosis (DVT) rate of $\leq$1% in all but one study[13] and only two pulmonary emboli in over 2500 treated limbs. Minor complications such as skin burns, paresthesias, and phlebitis occur more often with RFA, whereas EVLA is associated with a greater number of vein perforations,[19] post-procedure bruising, and associated pain.[17]

In light of these results, manufacturers of RF devices have aggressively marketed the advantages of less bruising and pain as a basis to prefer RFA over EVLA[20] and, indeed, more recent, albeit small, studies support these claims.[21–26] Yet, despite this mounting body of evidence, there is little data directly comparing RFA and EVLA in a long-term (>1 year) setting. We therefore conducted a prospective randomized single-blinded study to directly compare RFA to EVLA with regards to immediate subjective and objective post-procedure bruising (OPPB) and pain as well as short- and long-term (>1 year) efficacy and complications. It is our hope that the present study will contribute to the existing evidence regarding comparative outcomes between RFA and EVLA in order to assist physicians and patients in choosing the most appropriate modality for the treatment of CVI.

Methods

Patient population

This study was approved by the Institutional Review Board and conducted in accordance with the principles of the Declaration of Helsinki (October 1996 version). Informed consent was obtained from every patient and enrollment occurred from September 2008 through February 2012. Eligible subjects were new patients with symptoms of CVI who underwent a color flow duplex ultrasound examination with a high-resolution linear probe (7 to 12 MHz). All patients were given the opportunity to be included in the study if they satisfied the following criteria: (1) CVI symptoms caused by GSV reflux, defined as reverse flow in the GSV greater than 0.5 s after calf compression in the standing position, (2) a clinical-etiology-anatomy-pathophysiology (CEAP) clinical class of 2 or greater, and (3) prior attempt of at least six weeks of compression stockings for conservative management of CVI. Of note, treatment of CVI with compression stockings was not required if a patient exhibited venous ulcers or bleeding varices.

Exclusion criteria for this study included: (1) previous vein surgery, EVTA, or phlebectomy in the target extremity (excluding sclerosant injections for spider veins or other superficial cosmetic procedures), (2) active or prior DVT in the target extremity, (3) active or prior hypercoagulability disorder, (4) patients who are pregnant or breastfeeding, (5) patients who are non-ambulatory, (6) age less than 18 years, and (7) patients who are prisoners. All patients satisfying these criteria were given the opportunity to enroll in the study prior to undergoing an EVTA procedure. In total, two hundred patients were prospectively enrolled in this trial. All patient charts with photographs

remained in a locked office, and the patient database was kept in a secure password protected format.

Upon inclusion into the study, each participating patient was randomized into either the "LASER Group" (EVLA) or the "RF Group" (RFA) and underwent an EVTA procedure within six months from the time of enrollment. Randomization was performed in blocks of two, four, or six patients in order prevent ascertainment of allocations as well as to assure identical sizes of overall treatment groups. The following variables were collected for each patient after randomization: location of target vein (right or left GSV), gender, race, age, height, weight, body mass index, symptom duration, initial CEAP class, initial venous clinical severity score (VCSS), number of pregnancies, immediate family history of symptomatic varicose veins, and presence or absence of reflux in other saphenous veins (including ipsilateral or contralateral small saphenous vein, contralateral GSV, or ipsilateral-duplicated GSV).

EVTA procedures

Patients were blinded with regard to undergoing either EVLA or RFA. The majority of cases were performed in an office setting without conscious sedation (CS), although CS was commonly administered when adjunctive ambulatory phlebectomy (AP) was performed. Patients were prepped and draped in a sterile manner, and all procedures were performed by one of two attending Interventional Radiologists.

Detailed step-by-step summaries of the procedural aspects of RFA and EVLA of the GSV have been reviewed previously[27] and will not be discussed extensively. In this study, both techniques are nearly identical with regard to accessing the GSV, injecting tumescent anesthesia, and placement of the catheter tip 1 to 2 cm distal to the saphenofemoral junction (SFJ) under ultrasound guidance prior to initiating EVTA treatment.

Briefly, EVLA was performed as follows: the GSV was accessed from a point immediately below the knee or higher as permitted by the patient's venous anatomy, and the LASER tip was positioned 1 to 2 cm distal to the SFJ under ultrasound guidance. Tumescent anesthesia (500 cc normal saline mixed with 40 cc of 1% lidocaine with epinephrine and 4 cc of sodium bicarbonate) was injected liberally in a distal to proximal direction within the saphenous space along the targeted segment of the GSV. Thermal energy was delivered using a 980 nm diode laser system (Angiodynamics, Queensbury, NY) at a fluence range of 50 to 80 J/cm and a power setting of 10 W with a constant continuous pullback velocity. Patients with symptomatic surface varicosities were also offered AP and/or ultrasound-guided foam sclerotherapy (USGFS) as an adjunctive component of the original procedure. After the procedure was completed, steri-strips, sterile dressing, and compression stockings were applied, the latter worn continuously for the first 24 h and then during daytime hours for the next 14 consecutive days. Periprocedural data were immediately recorded including total treatment time (TTT), total tumescent volume, catheter length required, total ablation time (TAT), adjunctive procedures as needed, the use of CS if necessary, and complications.

RFA procedures were performed in an identical manner with regard to vein access, catheter tip positioning, and injection of tumescent anesthesia. Heat energy (120°C) was then delivered segmentally in discrete 20-s cycles spaced 6.5 cm apart via VNUS® ClosureFAST™ technology (VNUS Medical Technologies Inc, Sunnyvale, CA). Of note, two consecutive 20-s cycles were applied at the starting point 1 to 2 cm distal to the SFJ, and all other segments were treated with one cycle. Adjunctive treatments were offered, and identical peri- and post-procedure protocols were followed as described for EVLA previously.

Follow-up

All patients were evaluated post-operatively by interview, physical examination, photographs, and ultrasound examination as per protocol. Every effort was made to conduct this evaluation during the first seven days post-operatively although, in rare cases, this was not possible. During this evaluation, the procedure was judged a primary technical success if ultrasound examination revealed closure of the GSV with no new reflux, neovascularity, or other refluxing truncal veins arising from or near the SFJ and no more than a 2 cm area of patent vein below the SFJ. The following data were collected during this visit (of note, all data recorded on a 10-point scale followed the same graded format: 1 = no sign or symptom and 10 = worst severity of sign or symptom.): post-operative day (POD) of initial evaluation, primary vein closure (yes or no), DVT (yes or no), pain during procedure (1 to 10), post-procedural pain (PPP) during the initial evaluation (1 to 10), subjective post-procedure bruising (1 to 10), OPPB (1 to 10), objective deep ecchymosis/hematoma (yes or no), paresthesia (yes or no), new spider veins (yes or no), thermal injury (yes or no), and overall satisfaction (yes or no). Objective data were interpreted and recorded by a nurse practitioner blinded with regard to the specific EVTA procedure (EVLA or RFA) performed on each patient.

Following the initial post-procedural visit, patients were re-evaluated at six weeks and again at six months after EVTA to further undergo an interview, physical

examination and ultrasound examination as per protocol. During these visits, the following data were collected: POD number, VCSS, sonographic evidence of GSV closure (yes or no), sonographic evidence of neovascularity (yes or no), sonographic evidence of DVT (yes or no), post-procedural infection (yes or no), paresthesia (yes or no), phlebitis (yes or no), presence of recurrent symptoms (yes or no), persistent pain or tenderness at the operative site (yes or no), physical evidence of new spider veins at the operative site (yes or no), physical evidence of hyperpigmentation/erythema (H/E) (yes or no), and physical evidence of cutaneous thermal injury (yes or no). Patients were also asked if they were satisfied with the procedure in terms of resolution of their initial concerns/symptoms (yes or no) and to rate their overall satisfaction with the EVTA procedure on a scale of 1 (completely dissatisfied) to 10 (completely satisfied).

Patients were subsequently contacted via phone at yearly intervals and asked if they were satisfied with the EVTA procedure in terms of resolution of their initial concerns/symptoms (yes or no). If the patient answered "no," then he/she was offered further evaluation with a clinic visit, sonographic evaluation, and adjunctive treatment as needed. Based on their satisfaction regarding resolution of their original complaints, patients were ultimately categorized into one of three following groups from data obtained during the last recorded follow-up: (1) not requiring additional treatments and ultimately satisfied, or (2) requiring further adjunctive treatments and ultimately satisfied, or (3) not satisfied.

Results

Pre-procedure data

EVLA and RFA groups were compared in terms of basic demographic information, VCSS, and CEAP scores. Initial descriptive statistics of patients from both groups can be found in Table 1. Medians for continuous variables were compared using the nonparametric Wilcoxon rank-sum (Mann–Whitney U) test, and proportions were compared using Fisher's exact test. No statistically significant differences were found between groups.

EVTA procedure

Table 2 compares procedural data between groups. Variables were compared using the Wilcoxon rank-sum or Fisher's exact test. Statistically significant differences between groups included longer required catheter length and shorter TAT in the RFA group. However, there was no statistically significant difference in TTT, total tumescence volume, the use of

Table 1. Demographic comparisons.

	EVLA ($n = 100$)	RFA ($n = 100$)	p value
Age (years) (median (range))	48.5 (23–86)	47 (19–86)	0.5476[a]
BMI (kg/m^2) (median (range))	27.3 (18.3–45.6)	27.9 (19.0–44.7)	0.9441[a]
Number of pregnancies (median (range))	2 (0–9)	2 (0–8)	0.7600[a]
Symptom duration (months) (median (range))	98 (4–480)	67 (2–444)	0.2009[a]
Initial CEAP clinical class (median (range))	3 (2–11)	2 (2–8)	0.2095[a]
Initial VCSS (median (range))	5 (2–26)	5 (1–20)	0.7463[a]
Right leg vein involvement	53%	47%	0.4796[b]
Female gender	77%	80%	0.7310[b]
Race/ethnicity			0.5357[b]
Caucasian	70%	78%	
African American	18%	16%	
Hispanic	7%	3%	
Asian	3%	1%	
Other	2%	2%	
Immediate family history of saphenous reflux	70%	71%	1.0000[b]
Reflux in other saphenous veins	57%	58%	1.0000[b]

EVLA: endovenous laser ablation; RFA: radiofrequency ablation; BMI: body-mass index; CEAP: clinical-etiology-anatomy-pathophysiology; VCSS: venous clinical severity score.
[a]Wilcoxon rank-sum test.
[b]Fisher's Exact test.

Table 2. Procedural Data.

	EVLA ($n = 100$)	RFA ($n = 100$)	p value
Total treatment time (minutes per case) (median (range))	23.5 (8–95)	21 (6–64)	0.1772[a]
Total tumescence volume (mL per case) (median (range))	450 (50–800)	475 (100–850)	0.2578[a]
Catheter length required (cm per case) (median (range))	31 (11–52)	37 (9–69)	<0.0001[a]
Total ablation time (minutes per case) (median (range))	5 (1–18)	4 (1–14)	0.0009[a]
Ambulatory phlebectomy or ultrasound-guided foam sclerotherapy	53%	45%	0.3221[b]
Patients requiring conscious sedation	16%	15%	1.0000[b]
Procedural complications	0%	0%	–

EVLA: endovenous laser ablation; RFA: radiofrequency ablation.
[a]Wilcoxon rank-sum test.
[b]Fisher's Exact test.

Table 3. Initial post-procedural outcomes.

	EVLA ($n = 100$)	RFA ($n = 100$)	p value
Post-operative day of initial evaluation (median (range))	5 (1–29)	6 (1–9)	0.1922[a]
Pain during procedure (scale 1–10) (median (range))	4 (1–10)	3 (1–10)	0.1163[a]
Post-procedural pain (scale 1–10) (median (range))	5 (1–10)	2 (1–10)	<0.0001[a]
Subjective post-procedural bruising (scale 1–10) (median (range))	3 (1–10)	3 (1–8)	0.0847[a]
Objective post-procedural bruising (scale 1–10) (median (range))	3 (1–8)	2 (1–9)	0.0114[a]
Objective deep ecchymosis/hematoma	5%	2%	0.4448[b]
Paresthesia	16%	23%	0.2842[b]
New spider veins	1%	1%	1.0000[b]
Thermal injury	0%	0%	–
Satisfaction	93%	92%	1.0000[b]

EVLA: endovenous laser ablation; RFA: radiofrequency ablation.
[a]Wilcoxon rank-sum test.
[b]Fisher's exact test.

adjunctive treatments for surface varicosities, or the use of CS between groups. There were no peri-procedural complications in either group.

Initial post-procedural evaluation

One-hundred patients in each group completed an initial post-procedural evaluation. All saphenous veins were closed, and there was no sonographic evidence of DVT or endovenous heat-induced thrombosis in either group. Table 3 compares initial post-procedural outcomes between groups. Overall, PPP ($p < 0.0001$) and OPPB ($p = 0.0114$) were significantly lower in the RFA group, by a median difference of 3 and 1, respectively.

Six-week post-procedural evaluation

Table 4 compares the subjective and objective data between groups at the six-week post-procedural evaluation. Overall, 96 and 97 patients completed a six-week post-procedural evaluation in the EVLA and RFA groups, respectively. Sonographic evaluation revealed two cases of partial GSV recanalization in the EVLA group and one case of partial GSV recanalization in the RFA group. There were no cases of DVT. There were no significant differences in minor complications between groups.

Six-month post-procedural evaluation

Table 5 compares the subjective and objective data between groups at a six-month post-procedural evaluation. Overall, 79 and 74 patients completed a full six-month post-procedural evaluation with ultrasound in the EVLA and RFA groups, respectively. Sonographic evaluation revealed two additional cases of truncal superficial reflux in the RFA group (partial GSV recanalization in one patient and central GSV recanalization supplying a new refluxing anterior

Table 4. Six-week follow-up evaluation.

	EVLA ($n = 96$)	RFA ($n = 97$)	p value
Post-operative day (median (range))	47.5 (28–311)	43 (23–520)	0.2854[a]
VCSS (median (range))	2 (0–8)	2 (0–15)	0.9734[a]
Patient satisfaction (scale 1–10) (median (range))	9 (5–10)	9 (1–10)	0.3983[a]
Neovascularization	0%	0%	–
AP or USGF (number administered post-procedurally)			0.1806[b]
0	62.50%	50%	
1	32.29%	44.79%	
2	4.17%	5.21%	
3	1.04%	0%	
Infection	3.13%	2.08%	1.0000[b]
New spider veins	7.29%	3.13%	0.3306[b]
Thermal injury	0%	0%	–
Great saphenous vein closure	97.92%	98.96%	1.0000[b]
Deep venous thrombosis	0%	0%	–
Recurrent symptoms	5.21%	6.19%	1.0000[b]
Persistent pain or tenderness at operative site	17.71%	18.56%	1.0000[b]
Phlebitis	1.04%	1.03%	1.0000[b]
Hyperpigmentation/erythema	3.16%	3.13%	1.0000[b]
Paresthesia	9.38%	13.68%	0.3744[b]

EVLA: endovenous laser ablation; RFA: radiofrequency ablation; VCSS: venous clinical severity score; AP: ambulatory phlebectomy; USGF: ultrasound-guided foam sclerotherapy.
[a]Wilcoxon rank-sum test.
[b]Fisher's exact test.

tributary pathway in another patient) and no cases of reflux in the EVLA group. There were no cases of DVT in either group. There were no significant differences in minor complications. Improvements in VCSS were noted over time in both groups. There was no significant difference in median VCSS between groups at the initial, six-week, or six-month follow-up time points ($p = 0.7705$ by repeated measures analysis of variance analysis with a Bonferroni adjustment).

Technical long-term follow-up

During the long-term follow-up period (>1 year), 17 (19.1%) patients from the EVLA group and 10 (11.5%) patients from the RFA group ($p = 0.2099$ Fisher's Exact Test) underwent additional ultrasound examinations for concerning clinical findings. Of these patients, recurrent truncal reflux originating from a recanalized central GSV at the SFJ supplying a new refluxing anterior tributary pathway was noted in two patients from the EVLA group (at 28 months and 33 months). One patient from the RFA group had a recurrent refluxing GSV at 35 months.

Overall, throughout all time points evaluated in this study, there were a total of four distinct patients in each group with sonographically confirmed recurrent truncal reflux originating at the SFJ (eight total cases of recurrent reflux—see Table 6). Primary assisted closure was achieved for 100% of these patients after additional treatments. There were no DVTs or other major complications identified in any patient throughout the entire study period.

Univariate analysis reveals subjects with recurrent reflux ($n = 8$) were younger on average than the remaining subjects ($n = 192$) (32.0 years [range: 19–66] vs. 48.5 years [range: 23–86], respectively; Wicoxon rank-sum test). Step-wise logistic regression reveals decreasing age and increasing symptom duration as statistically significant predictors of failure.

Clinical long-term follow-up

Of the 100 patients in each group, 89 EVLA patients and 87 RFA patients were interviewed at least 12 months after EVTA. The mean long-term follow-up in the EVLA group was 44 (12–64) months, and the mean long-term follow-up in the RFA group was 42 (12–75) months ($p = 0.1096$ Wilcoxon rank-sum test). Sixty-nine patients in each group (77.5% EVLA and 79.3% RFA) were satisfied with the treatment results and did not require further evaluation or treatment (Group 1). Fifteen patients in the EVLA group

Table 5. Six-month follow-up evaluation.

	EVLA ($n=79$)	RFA ($n=74$)	p value
Post-operative day (median (range))	188.5 (99–330)	187.5 (129–352)	0.6945[a]
VCSS (median (range))	1 (0–18)	1 (0–6)	0.3338[a]
Patient satisfaction (score 1–10) (median (range))	9 (4–10)	9 (1–10)	0.6698[a]
Neovascularization	0%	0%	–
AP or UGFS (number administered post-procedurally)			0.5485[b]
0	44.30%	44.59%	
1	43.04%	48.65%	
2	7.59%	6.76%	
3	2.53%	0%	
4	2.53%	0%	
Infection	0%	0%	–
New spider veins	15.19%	13.51%	0.8207[b]
Thermal injury	0%	0%	–
Great saphenous vein closure	98.73%	97.30%	0.6105[b]
Deep vein thrombosis	0%	0%	–
Recurrent symptoms	7.59%	6.76%	1.0000[b]
Persistent pain or tenderness at operative site	11.39%	13.51%	0.8076[b]
Phlebitis	0%	2.70%	0.2323[b]
Hyperpigmentation/erythema	12.66%	8.11%	0.4334[b]
Paresthesia	10.26%	8.33%	0.7827[b]

EVLA: endovenous laser ablation; RFA: radiofrequency ablation; VCSS: venous clinical severity score; AP: ambulatory phlebectomy; USGF: ultrasound-guided foam sclerotherapy.
[a]Wilcoxon rank-sum test.
[b]Fisher's exact test.

Table 6. Primary treatment failures.

Treatment group	Time identified	New reflux	Treatment	Final result
EVLA	Six weeks	GSV	EVLA	Vein closure
EVLA	Six weeks	Partial GSV	USGFS	Vein closure
EVLA	28 months	Central GSV	USGFS	Vein closure
EVLA	33 months	Central GSV	EVLA	Vein closure
RFA	Six weeks	Partial GSV	USGFS	Vein closure
RFA	Six months	Partial GSV	USGFS	Vein closure
RFA	Six months	Central GSV	RFA	Vein closure
RFA	35 months	GSV	RFA	Vein closure

EVLA: endovenous laser ablation; GSV: great saphenous vein; RFA: radiofrequency ablation; USGFS: ultrasound-guided foam sclerotherapy; partial GSV: partial GSV recannulization; central GSV: proximal GSV supplying a new refluxing anterior tributary.

(16.9%) and nine patients in the RFA group (10.3%) were ultimately satisfied but required additional adjunctive treatments after the first six weeks (Group 2). Finally, five patients in the EVLA group (5.6%) and nine patients in the RFA group (10.3%) reported at last follow-up that they were not happy with the treatment results relative to their original complaints (Group 3). Overall, there were no significant differences with regard to patient satisfaction between RFA and EVLA ($p=0.3009$).

Discussion

This prospective randomized single-blinded comparison trial between EVLA and RFA demonstrates both modalities are highly effective from both anatomical and clinical standpoints. In both treatment groups, EVTA was highly successful from both a technical standpoint (96% primary GSV closure and 100% primary assisted closure in each group) and in terms of safety (no cases of DVT in either group) to treat GSV-mediated CVI. Clinically, nearly 80% of patients in both groups who had long-term follow-up were satisfied with their results without requiring adjunctive treatments beyond the first six weeks.

While there was increased immediate post-operative pain and bruising for EVLA relative to RFA, there was no difference in patient satisfaction parameters between modalities at any of the subsequent pre-specified time points in our study, and both groups demonstrated a substantial reduction in VCSS through six months.

When our study was initiated, there were no prospective randomized comparisons between EVLA and RFA. Since that time, several studies have been published directly comparing EVLA and RFA for GSV-mediated CVI. The first single-blinded study (the RECOVERY trial) was published by Almeida et al.[21] involving 46 veins treated with ClosureFast™ RFA and 41 veins treated with EVLA (980 nm). Patients were followed for one month, and they found that RFA led to reduced post-operative pain, tenderness, and ecchymosis at 48 h, one week, and two weeks. RFA also led to a reduced incidence of phlebitis at 48 h, and VCSS and quality-of-life (QOL) measures improved for RFA relative to EVLA at 48 h, one week, and two weeks. Major complications did not occur with either modality.

Similar results were reported in a slightly larger single-blinded study by Shepherd et al.[26] comparing 64 EVLA (980 nm) and 67 RFA (VNUS® ClosureFast™) patients over a six week period. Median pain scores were significantly lower for RFA patients at 3- and 10-days post-procedurally although both modalities had similar outcomes in terms of clinical and QOL improvements at six weeks.

Gale et al.[22] conducted a comparative study in 118 patients and reported RFA and EVLA (810 nm) groups had similar perioperative results. However, at one year, GSV closure failure occurred in 11 out of 46 RFA patients and in only 2 of 48 EVLA patients. Of note, unlike Almeida et al., Gale utilized an older version of RFA technology requiring continuous pullback of the catheter. This technology was subsequently replaced in 2007 after demonstration of inferiority[23] relative to segmental pullback RFA technology commonly used by other investigators and in our study. Therefore, the conclusion by Gale et al. that LASER ''may provide a more secure closure over the long-term than RFA'' must be interpreted with caution.

Nordon et al.[25] compared 80 EVLA (810 nm) and 79 RFA (VNUS® ClosureFast™) patients and demonstrated nearly identical GSV occlusion rates at three-months for both modalities (96% and 97%, respectively). Post-operative pain and bruising within the first week of treatment was worse for EVLA although improvements in QOL were statistically similar for both modalities at three months.

In the largest similar study to date, Rasmussen et al.[28] recruited 500 patients to compare EVLA (980 or 1470 nm bare tip fibers), RFA (VNUS® ClosureFast™), surgical stripping, and USGFS (125 patients per group) and reported one-year failure rates (i.e., return of GSV reflux) of 5.8%, 4.8%, 4.8%, and 16.3%, respectively. RFA was associated with the least pain throughout the first 10-days post-procedurally followed by USGFS, surgery, and lastly, EVLA. Of note, greater than 80% of patients in the EVLA group were treated with the 1470 nm device. In addition, RFA and USGFS were associated with the shortest time for patients to resume to normal daily activities and return to work. Overall, all four treatment modalities led to comparable improvements in QOL at one year after treatment.

Prior to our study, the longest direct-comparison trials of EVLA and RFA were conducted over a one-year timeframe. The present study was performed in a randomized controlled prospective single-blinded fashion with a patient population of 200 over a multi-year period. Consistent with studies mentioned previously, we observed RFA leads to less PPP and bruising relative to EVLA (980 nm bare tip laser). There was no difference in these modalities at six weeks after treatment and both remained effective after three-and-a-half years.

The use of bare tip lower wavelength LASER fibers is a potential drawback for this study. At the time of study initiation, only bare-tipped fibers were in use, and thereafter, the development of jacketed fibers has been marketed as a means to prevent direct contact of the vein wall with the energy emitting tip, which may decrease the risk of vein perforation among other complications. To date studies have shown a decrease in immediate PPP with jacketed LASER fibers relative to bare-tipped fibers,[29] and a pilot study comparing RFA (ClosureFastT™) to EVLA (980 nm jacket-tipped fiber) demonstrated no difference in pain and bruising scores at one week after ablation.[30,31] While promising, these results must be replicated in larger studies.

Overall, this prospective randomized study demonstrates that both EVTA modalities can be technically successful with no major complications over a period of years. Perhaps more importantly, this study demonstrates that both modalities result in high clinical satisfaction at three-and-a-half year follow-up. As these technologies continue to improve and new technologies including non-tumescent ablation continue to emerge, further longitudinal direct-comparison studies will be needed.

Declaration of Conflicting Interests

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