

Comparison of Endovenous Laser and Radiofrequency Ablation in Treating Varicose Veins in the Same Patient

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Abstract

Purpose: To compare endovenous laser ablation (EVLA) and radiofrequency venous ablation (RFA) in different legs in the same patients with venous insufficiency. **Methods:** Sixty patients with bilateral saphenous vein insufficiency were included. Endovenous laser ablation or RFA was applied to one of the patient's legs and the remaining procedure, RFA or EVLA, to the other leg. **Results:** Minor complications in EVLA and RFA were hyperemia at 20.7% and 31.0%, ecchymosis at 31.0% and 51.7% and edema at 27.6% and 65.5%, respectively. The rate of recanalization was 6.8% in the RFA group. No recanalization was observed in the EVLA group. The level of patients satisfied with EVLA was 51.7%, compared to 31.0% for RFA, while 17.2% of patients were satisfied with both the procedures. Times to return to daily activity were 0.9 days in the EVLA group and 1.3 days in the RFA group. **Conclusion:** The EVLA procedure may be superior to RFA in certain respects.

Keywords

varicose veins, endovascular laser ablation, radiofrequency ablation

Introduction

Ligation and stripping was for years the most frequently employed therapeutic option in the treatment of great saphenous vein insufficiency. However, in association with technological advances, there has been ongoing research into treating the disease using endovenous methods. Research into sclerosing the venous wall using thermal methods in particular has recorded considerable progress, and in 2001, Navarro et al published the first application of thermal endovenous ablation using a 810 nm diode laser.¹ Since then, there has been steady progress in laser technology, and numerous studies have been performed using different wavelengths and types of laser.²⁻⁷ The Food and Drug Administration (FDA)-approved lasers today are 810, 940, 980 and 1470 nm diode lasers and 1319 and 1320 nm neodymium-doped yttrium aluminium garnet (Nd:YAG) lasers. In parallel to advances in laser technology, studies were performed concerning thermal ablation of the saphenous vein using radiofrequency energy, and permission for the use of radiofrequency energy in endovenous ablation was granted by the FDA in 1999. In 2002, Weiss et al reported the first patients receiving thermal ablation using radiofrequency energy.⁸ Numerous studies using radiofrequency ablation (RFA) subsequently appeared.⁹⁻¹¹ Studies comparing endovenous laser ablation (EVLA) and RFA then began being published. These studies generally reported equal success

between EVLA and RFA, albeit with fewer side effects and greater patient satisfaction with RFA.^{12,13} All these studies compared laser energy at low wavelengths (810, 940, and 980 nm) with radiofrequency. However, high wavelength laser energy and radial fiber have been shown to produce better patient satisfaction and fewer side effects compared to low wavelength laser energy and bare fiber.¹⁴ There are no clinical studies in the literature comparing laser energy at a wavelength of 1470 nm or more with RFA. We therefore planned this study in order to compare patients receiving EVLA with laser energy at a wavelength of 1470 nm and radial fiber with patients receiving RFA in terms of procedure success, complications, and patient satisfaction. In order to eliminate patient-related

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variables, EVLA was applied to 1 leg in cases of bilateral saphenous vein insufficiency and RFA to the other leg.

Methods

Sixty patients, 28 men and 32 women, with symptomatic great saphenous vein insufficiency in both lower extremities and presenting to the cardiovascular surgery clinic between January and December 2013 were enrolled. In this study, the EVLA and RFA procedures were performed in a single center, and all procedures were performed by 2 experienced surgeons. Patients' ages ranged between 29 and 64 (mean 42.8 ± 10.0 years). Sixty EVLA and 60 RFA procedures were applied to the saphenous veins in the lower extremities of the 60 patients. Ethical committee approval was obtained before the study began. Patients with unilateral vena saphena magna (VSM) insufficiency, patients receiving the same technique in both legs, and patients not permitting intervention on both legs in different sessions were excluded. Patients with a saphenous vein diameter less than 5.5 mm at the saphenofemoral junction (SFJ) were also excluded. Patients were classified on the basis of Clinical Severity, Etiology, Anatomy and Pathophysiology (CEAP) before the procedure began. Venous clinical severity score (VCSS) values based on scoring of preprocedural clinical symptoms and findings were recorded. The EVLA and RFA procedures were decided on in the light of insufficiency in both existing VSM at colored Doppler ultrasonography (CDUSG) performed for diagnostic purposes. No advanced insufficiency or obstruction was determined in the deep veins of any extremity. Patients were randomized for EVLA and RFA. The EVLA was first performed on 1 patient and RFA first on the next. No patient was aware which procedure would be performed on which leg.

A 12W diode laser source with a wavelength of 1470 nm (Biolas-15D; Del YCHI GMBH, Duisburg, Germany) and radial fiber (EVLAS Circular-2; FG Group, Ankara, Turkey) were used for EVLA, and an EVRF: Endo Venous Radio Frequency CR45i device and catheter (F-Care Systems NV, Antwerp, Belgium) were used for RFA. Percutaneous entry was performed with a 21-G needle accompanied by caudal section USG appropriate for treatment of saphenous vein with reflux determined in all patients under local anesthesia. Tumescent local anesthesia consisting of 20 mL 2% prilocaine, 500 mL 0.9% isotonic solution ($+4^{\circ}\text{C}$), 20 mL 8.4% sodium bicarbonate, and 0.5 mg adrenalin was administered to the area surrounding the saphenous vein with 19- to 21-G needles guided by USG.

Endovenous Laser Ablation Procedure

Laser energy was applied by adjusting the laser parameters (12W, 1.2-1.8 mm/sec withdrawal speed) in pulse mode (0.2-second interval) depending on the vein diameter and depth from the skin of the saphenous vein, such as to be greater in those areas close to the SFJ.

Radiofrequency Ablation Procedure

Radiofrequency energy was applied to the saphenous vein in the form of 25 W every 0.5 cm from the distal aspect of the SFJ (50 W/cm). Analgesic (paracetamol) was prescribed for all patients after both procedures.

Pain during and after the procedure was assessed using a pain scale. Patients indicated the pain felt on a scale of 1 to 5, in which 1: no pain, 2: mild pain, 3: moderate pain, 4: severe pain, and 5: very severe pain. The analgesic requirements of patients were recorded. An elastic bandage was applied for 2 days to the leg receiving the procedure. Compression socks were subsequently recommended for 3 months. Patients were encouraged to return to their daily activities as early as possible. Time to return to daily activities were recorded. Follow-ups were performed clinically on the second day postprocedure and both clinically and using CDUSG on the first week and at the first, third, and sixth months. Saphenous vein occlusion, recanalization, perforating veins, and residual varicosities were recorded at CDUSG. Major and minor complications were investigated.

Statistical Analysis

Data were expressed as mean \pm standard deviation or as median and range. Demographic and clinical data were tested using the paired samples *t* test for parametric variables and the Wilcoxon Signed Ranks test for nonnormally distributed data. McNemar test was used to analyze quantitative data. All calculations were performed using SPSS version 17.0 (SPSS Inc, Chicago, Illinois). $P < .05$ was considered statistically significant.

Results

All patients had primary etiology, and pathophysiology was associated with reflux in the entire extremity. All patients receiving EVLA and RFA were symptomatic in both legs. No statistically significant difference was determined between legs in terms of CEAP and VCSS classification at preoperative assessment. Mean duration of reflux in the SFJ was 3.4 seconds in the EVLA group and 3.8 seconds in the RFA group. Both EVLA and RFA procedures were performed on 120 saphenous veins. Mean diameters of saphenous veins receiving EVLA were 9.6 mm at the level of the SFJ and 8.2 mm at the knee level. The equivalent values in patients receiving RFA were 10.3 mm at the level of the SFJ and 8.4 mm at knee level. The length of the saphenous vein undergoing the procedure was 27.4 cm in patients receiving EVLA and 26.5 cm in those receiving RFA. Depth of the saphenous vein beneath the skin was 15.3 mm in the EVLA group and 14.7 mm in the RFA group. Duration of procedures was 31.2 minutes for EVLA and 32.7 minutes for RFA. No significant difference was determined between the groups in these respects. Demographic and clinical findings are shown in detail in Table 1. Preoperative pain score was 1.4 in the EVLA group and 1.7 in the RFA group, and the difference was not significant. Postoperative pain score was 1.2 in the EVLA group and 1.4 in the RFA group, the difference being statistically

Table 1. Demographic and Clinical Data.

	EVLA (min–med–max), n = 60	RFA (min–med–max), n = 60	P Value
Age	42.2 ± 10.2	42.2 ± 10.2	–
Gender, M/F	28/32	28/32	–
VCSS	9.7 ± 2.5 (4.0–10.0–14.0)	9.9 ± 2.5 (4.0–11.0–14)	>.05
CEAP	3.2 ± 0.4 (3.0–3.0–4.0)	3.2 ± 0.4 (3.0–3.0–4.0)	>.05
VSM diameter (SFJ), mm	9.6 ± 1.7 (5.6–6.7–12.0)	10.3 ± 2.8 (5.6–10.9–16.0)	>.05
VSM diameter (knee), mm	8.2 ± 1.4 (5.0–6.2–11.0)	8.4 ± 2.3 (5.0–9.0–13.0)	>.05
Mean SFJ reflux time, sec	3.4 ± 1.4 (2.0–3.0–5.0)	3.8 ± 1.3 (2.0–3.0–5.0)	>.05
Distance from skin, mm	15.3 ± 7.3 (6.0–16.0–29.0)	14.5 ± 7.3 (5.0–14.0–28.0)	>.05
Length of saphenous vein, cm	27.4 ± 3.4 (16.0–29.0–31.0)	26.5 ± 6.5 (19.0–27.0–32.0)	>.05
Duration of procedure, min	31.2 ± 4.7 (22.0–30.0–45.0)	32.7 ± 6.5 (24.0–32.0–50.0)	>.05

Abbreviations: EVLA, endovenous laser ablation; RFA, radiofrequency ablation; VCSS, venous clinical severity score; CEAP, Clinical Severity, Etiology, Anatomy, and Pathophysiology; VSM, vena saphena magna; SFJ, saphenofemoral junction; M, male; F, female; min, minimum; med, medium; max, maximum.

Table 2. Postoperative Data.

	EVLA (min–med–max), n = 60	RFA (min–med–max), n = 60	P Value
Pain score (intraoperative)/d	1.4 ± 0.6 (1.0–1.0–3.0)	1.7 ± 0.8 (1.0–2.0–3.0)	>.05
Pain score (postoperative)/d	1.2 ± 0.4 (1.0–1.0–2.0)	1.4 ± 0.5 (1.0–1.0–2.0)	<.05
Analgesic requirement, mg/d	850 ± 300	950 ± 200	>.05
Time to return to activity/d	0.9 ± 0.8	1.3 ± 1.1	<.05
Time to return to work/d	1.8 ± 0.8	2.1 ± 1.2	>.05

Abbreviations: EVLA, endovenous laser ablation; RFA, radiofrequency ablation; min, minimum; med, medium; max, maximum.

Bold p value are statistically significant

Table 3. Complications After Endovenous Laser Therapy and Radiofrequency Ablation.

	EVLA, n = 60	RFA, n = 60	P Value
Induration	20.7%	31.0%	>.05
Ecchymosis	31.0%	27.6%	>.05
Edema	27.6%	65.5%	<.05
Paresthesia	0.0	0.0	–
Deep vein thrombosis	0.0	0.0	–
Pulmonary embolism	0.0	0.0	–

Abbreviations: EVLA, endovenous laser ablation; RFA, radiofrequency ablation. Bold p value are statistically significant

significant ($P < .035$). Postoperative analgesic requirement (paracetamol) was 850 mg/d in the EVLA group and 950 mg/d in the RFA group. The difference was not significant. Length of time to start of postoperative activity was 0.9 days in the EVLA group and 1.3 days in the RFA group, the difference being significant ($P < .001$). Time to return to work was 1.8 days in the EVLA group and 2.1 days in the RFA group, and the difference was not significant. Postoperative data are shown in Table 2. Postoperative minor complications were determined in the form of induration, ecchymosis, and edema. Induration developed in 69.0% of patients in the EVLA group and 79.3% of those in the RFA group. The difference was not significant. Ecchymosis developed in 31.0% of the patients in the EVLA group and in 51.7% of those in the RFA group. This difference was also not significant. Edema developed in 27.6% of the patients in the EVLA group and 65.5% of those in the RFA group. This

difference was statistically significant ($P < .007$). Induration, ecchymosis, and edema resolved entirely at the end of 2 weeks. No major complication (such as deep venous thrombosis [DVT], pulmonary embolism, or skin burn) was observed in any patient. Complications after EVLA and RFA are shown in Table 3. When asked after both procedures had been performed which they were more satisfied with, 31% of patients responded to RFA, 51.7% favored EVLA, and 17.2% were pleased with both. Recanalization developed in 4 saphenous veins in the RFA group during monitoring, a rate of 6.8%. Complete occlusion was determined in 60 (100%) saphenous veins at sixth month follow-up after EVLA in the EVLA group.

Discussion

Chronic venous insufficiency and lower extremity varicose veins that develop in association with this are an important clinical condition that significantly affect quality of life and have socioeconomic consequences.¹⁵ Significant progress has been made in the treatment of varicose veins in the last 10 years. Endovenous ablation techniques have to a large extent replaced surgery. Thermal endovenous procedures such as RFA and EVLA are now the most commonly used techniques. Several studies have compared these 2 different forms of ablation. There is no general consensus on which method is superior. Publications generally report that both methods have the same levels of successful ablation but that pain levels and rates of complications following RFA are lower compared to EVLA.^{12,16–20} However, these studies have generally used low

wavelength laser. Several recent studies suggest that better results can be achieved with higher laser wavelengths. One recent study compared radial laser fiber at a wavelength of 1470 nm and bare fiber at a wavelength of 980 nm and reported better patient comfort with 1470 nm radial fiber.¹⁴ Therefore, in order to compare the 2 methods, it is 1470 nm radial laser and RFA that require investigation. The most important factor determining patient comfort is perception of pain. This may vary from person to person, and when the two techniques are compared in different patients, it may be impossible to make a completely objective assessment due to variations in different individuals' pain thresholds. Our purpose was therefore to compare the effectiveness and side effects of these methods by applying the 2 different ablation techniques to different legs in the same patient. No previous studies have compared these 2 techniques applied to different extremities in the same patient. We determined ablation rates of 100% in the EVLA group and 93.2% in the RFA group. The difference was not statistically significant. In their meta-analysis, Van Den Bos et al evaluated 119 studies and determined success rates of 94% for EVLA and 84% for RFA on the basis of results for 12 320 legs.²¹ Almeida and Raines reported recanalization rates of 5.5% for RFA and 1.7% for EVLA.¹⁶ Puggioni et al reported success rates at 1-month follow-up of 100% for EVLA and 96% for RFA.¹⁷ In performing ablation with RF, the catheter has to touch the vein wall, while thermal ablation is possible without laser energy making contact. All previous studies have reported that the greatest superiority of RFA over EVLA lies in superior patient satisfaction.^{12,17-19} In our study, patient satisfaction was higher in the EVLA group, while better results for criteria such as intraoperative and postoperative pain, postoperative analgesic requirement, return to activity, and return to work were obtained in the EVLA group. Of these, differences in postoperative pain and time to return to activity were statistically significant ($P < .035$ and $P < .001$, respectively). We attribute this both to the low wavelengths in previous studies and to the use of bare tip laser catheters. Since high-wavelength laser rays use water as a chromophore, they are better able to penetrate the vein wall. In addition, the radial dissemination of rays permits a more homogeneous contact with the vein wall and reduces the incidence of perforation. No procedure-related major complication (DVT, pulmonary embolism, and skin burn) were observed in this study. Minor complication levels were lower in the EVLA group. It must not be forgotten that the majority of minor complications (hematoma and ecchymosis) occur not in association with the procedure but with the application of tumescent anesthesia. Careful application of tumescent anesthesia will reduce these complications to a minimum. In that event, the most important differences between the 2 techniques will be perception of pain and occlusion rates. Perception of pain is lower with EVLA (with a 1470 nm wavelength and radial fiber).

Conclusion

Comparing the 2 techniques in the same patient in this study reduced subject-dependent factors to a minimum. This made

it possible to assess patient satisfaction more objectively. In conclusion, EVLA and RFA have similar success rates. However, in terms of pain and patient satisfaction, EVLA at a wavelength of 1470 nm and using radial fiber is superior to RFA.

Authors' Note

The ethics committee of Kahramanmaraş Sütçü İmam University approved this study (REC number: 2013/14-05).

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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