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Endovenous laser ablation of incompetent saphenous veins with a 1940 nm laser

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Abstract

Background: Endovenous laser ablation (EVLA) performed with wavelengths of high water absorption decrease postoperative pain and bruising. The aim of this study is to show the mid-term outcome after EVLA of incompetent saphenous veins with radial fibers and a 1940 nm diode laser.

Methods: 95 incompetent saphenous veins were treated. The gravity of venous disease was determined according to the CEAP classification and to the revised Venous Clinical Severity Score (VCSS).

Results: The average linear endovenous energy density was 101 J/cm vein. The VCSS improved drastically from a mean of 5.2 (SD: 2.4) pre-interventional to 0.18 at six months and 0.30 at twelve months. During the follow-up period all the veins were occluded.

Conclusion: EVLA of saphenous veins with a 1940 nm diode laser is a safe and efficient therapy option, with a high success rate in the mid-term period, low postoperative pain and rapid convalescence.

Introduction

In the western adult population, the prevalence of varicose veins is >20% and about 5% of it have venous edema, skin changes or venous ulcerations [1,2]. According to the current international guidelines [3-5], for the treatment of saphenous vein reflux in patients with symptoms and sign of chronic venous disease (CVD) thermal ablation technique are recommended in preference to surgery and foam sclerotherapy, with strong evidence.

Currently, the endothermal method most commonly used worldwide is endovenous laser ablation (EVLA); it has a high success rate of over 90% after several years of follow-up studies and a minimal complication rate compared with traditional venous stripping [6,7]. For Example, wound complications and nerve injury occur in 3-10% and 2-39% of patients, respectively, after surgical stripping, while wound complications are rare and nerve injury occur in only 3% of the patients after thermal ablation [4].

Laser technology has evolved over time. After 2011, the introduction of the so-called Water-Specific Laser Wavelengths (WSLWs) with the radial fiber has significantly improved the post-operative course, compared to the previous technology, resulting in less pain and less ecchymosis [8-19].

Although there are several explanations about the mechanism of EVLA, these have not been clearly identified yet. Theoretically, the higher the water absorption of laser, the higher is the vein wall absorption of laser achieved [16-19]. After the introduction of 1470 nm laser that has a higher water absorption than Hb absorption rate, effective treatment with lower laser power (W) and linear endovenous energy density (LEED; J/cm) than earlier methods has become possible, reducing the complications associated with thermal damage. Using 1470 nm, satisfactory outcomes have been achieved mostly at LEED <100 J/cm [20-22]. However, there are few studies on the effective power or LEED at a longer wavelength of 1940 nm [23-26].

The aim of this study was to evaluate the outcome and side effects after EVLA of saphenous veins with a 1940 nm diode laser at 6W for treating incompetent great (GSV), short (SSV) and anterior accessory saphenous vein (AASV) by using the HF Ring Fibers (Eufoton®, Trieste, Italy), especially designed probes that shoot for 360 degrees radially from the tip with a ring spot sized only 200 microns, allowing to concentrate energy, as well as a better energy diffusion for a safer EVLA (Figure 1).

Methods

Patients

This is a prospective observational study.

Between February 2018 and March 2020, all sequential patients who underwent EVLA for saphenous veins' insufficiency with functional and/or aesthetic problem in outpatient cabinets of two surgeons (CA, FRS), experts in venous disease and with years of experience in endovascular venous treatment, were retrospectively included into a database. The chronic venous disease's gravity was determined in each leg according to the Clinical-Etiology-Anatomy-Pathophysiology classification (CEAP)27. The symptoms' gravity was scored according to the revised VCSS (Venous Clinical Severity Score)28. Color flow duplex ultrasound examination with a high-resolution linear probe (7 to 12 MHz) was performed on all patients. Saphenofemoral or saphenopopliteal reflux was diagnosed in all patients. Duplex was

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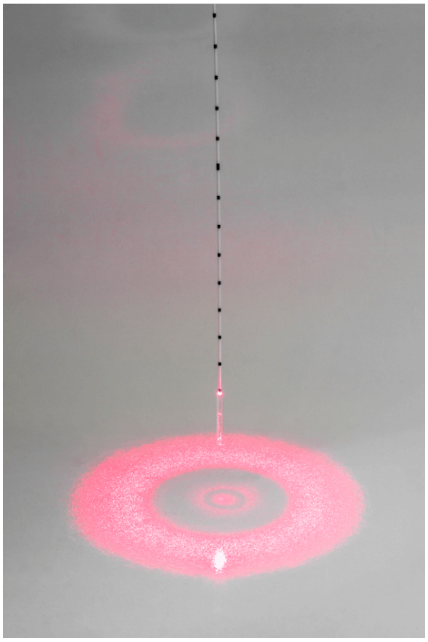

Figure 1. The HF Ring Fibers (Eufoton®, Trieste, Italy)

performed in upright position. Normal flow is defined as anterograde. Reflux was defined as retrograde flow of >0.5 second duration after a Valsalva maneuver and manual compression and decompression of the distal limb. The vein diameter was measured at least in 3 points: at 2-5 cm distal to the SFJ or SPJ, at 10-15 cm distal to the crosse, near the knee for the great saphenous vein (GSV) or distal to the calf for the SSV.

A total of 95 incompetent saphenous veins in 82 consecutive patients (60 female) were treated by EVLA: 80 GSVs, 7 SSVs and 8 AASVs incompetence. All patients agreed their data, already collected for clinical evaluation, to be included in an observational retrospective study, in accordance with the Declaration of Helsinki.

Patients' characteristics are presented in Tables 1

EVLA procedure

EVLA was performed with a 1940 nm diode laser (LASEmaR® 2000) and a 600 µm HF Ring Fibers (Eufoton®, Trieste, Italy), according to the procedure already previously described [16].

Patients' refluxing GSVs, SSVs, and AASVs were mapped before surgery. All EVLA procedures were performed with tumescent local anesthesia and, for the GSVs, with the femoral nerve block29-33. EVLA was carried out in a continuous mode with a power of 6 W and the pullback speed on the fiber was calculated to achieve a standard energy rate of about 100 J/cm. In this manner, the laser treatment of the entire saphenous vein lasted 2 to 5 minutes. Closure of the saphenous veins was confirmed by US. In the same session all insufficient tributaries were treated by phlebectomy and/or sclerofoam.

Main parameters treatment are presented in Table 1.

Compression with 20-30 mmHg elastic stocking for one month was prescribed. Furthermore, as a precaution without any further rationale, low-molecular-weight heparin for seven days was administered at prophylactic dosage to all patients. Patients were mobilized immediately after the intervention and were advised to walk regularly during recovery from treatment. Diclofenac 75 mg was prescribed to be taken in case of postoperative pain.

Follow-up

Patients were re-examined clinically and with duplex on the 7th post-operative day and at months one, six, one year ant two years after the treatment by the same phlebologist who performed the procedure. The entire deep venous system was checked for signs of deep venous thrombosis. VCSS, post-operative pain, patient satisfaction, side effects, adverse events and recurrence rates have been assessed and recorded at each visit.

Ecchymosis and paresthesia were reported in regions of the limb adjacent to the treated vein segments. The areas of ecchymosis and paresthesia were not measured: were listed as present or absent. Pain was valued on a ten-point scale ranging from no pain at all (0) to very painful (10).

Patient's satisfaction was assessed by asking them: 'Are you satisfied with the method being used?' (0=very satisfied, 1=satisfied, 2=fairly satisfied), 'would you choose endovenous laser therapy again?' (0=definitely, 1=probably, 2=don't know, 3=probably not).

Statistics

According to the exploratory purposes of the study only descriptive statistics were involved.

Mean values and standard deviations were calculated using the statistics tool provided by the Microsoft Excel 2007 version.

Results

The results are shown in Tables 2 and 3.

No patient was lost during the follow-up period (mean 7 months, range: 1-24 months). Mean age was 52.2 years; 59 Patients (62%) were classified as C2, 25 Patients (26%) were classified as C3, 9 (10%) as C4, 1 (1%) as C5 and 1 (1%) as C6 according to CEAP classification. Terminal valve was incompetent in 82 cases (86%). 84% of Patients

Table 1. Patients' characteristics analysis

Variables	
Patients (n)	82
Age (years), mean (SD)	55.2 (10.4)
Female gender, n (%)	60 (73%)
CEAP (highest classification per limb)	
C2, n (%)	59 (62%)
C3, n (%)	25 (26%)
C4, n (%)	9 (10%)
C5, n (%)	1 (1%)
C6, n (%)	1 (1%)
Veins treated, n	95
GSV, n (%)	80 (84%)
SSV, n (%)	7 (7%)
AASV, n (%)	8 (9%)
VCSS, mean (SD)	5.2 (2.4)
Terminal valve incompetence, n (%)	82 (86%)
Length of treated vein, mean (SD)	25.5 (10.6)
LEED (J/cm), mean (SD)	101 (26.4)
OP time (min) (EVLA + phlebectomies), mean (SD)	40 (11.4)

(BMI, body mass index; CEAP, clinical, aetiological, anatomical and pathological elements; GSV, great saphenous vein; SSV, short saphenous vein; AASV, anterior accessory saphenous vein; VCSS, venous clinical severity score; LEED, linear endovenous energy density; OP, operation; SD: standard deviation; EVLA: EndoVenous Laser Ablation)

Table 2. Pain, ecchymoses, paresthesia and return to daily activities after EVLA

Variables	Outcome
Postoperative pain	
Patients with pain after the procedure n (%)	29 (35%)
Pain score at day one, mean (SD), n of patients	2.0 (1.3), 25
Pain score at days 2–10, mean (SD), n of patients	0.6 (1.4), 13
Pain score days at 11–30 mean (SD), n of patients	0.0 (0.0), 0
Patients without analgesics after the procedure, n (%)	69 (84%)
Return to daily activities (days), mean (SD)	1.6 (1.4)
Ecchymoses	
Limbs with ecchymoses at day one, n (%)	37 (39%)
Limbs with ecchymoses at day 10, n (%)	32 (34%)
Limbs with ecchymoses at day 30, n (%)	13 (14%)
Paresthesia	
Limbs with paresthesia at day 7	1 (1%)
Limbs with paresthesia at day 10	1 (1%)
Limbs with paresthesia at day 30	0 (0%)

Table 3. Patient's outcome after EVLA

Variables	One month	Six months	One year	Two years
Patients at follow-up (n)	82	73	51	19
Patients lost to follow-up (n)	0	0	0	0
Occlusion rate, n (%)	82 (100%)	73 (100%)	51 (100%)	19 (100%)
Satisfaction patients n (%)				
Very satisfied	69 (84%)	64 (88%)	43 (84%)	16 (84%)
Satisfied	13 (16%)	8 (11%)	7 (14%)	3 (16%)
Fairly satisfied	0 (0%)	1 (1%)	1 (2%)	0 (0%)
Willing to choose EVLA again, n (%)				
Definitely Yes	71 (87%)	67 (91%)	46 (90%)	18 (95%)
Probably Yes	11 (13%)	5 (7%)	4 (8%)	1 (5%)
Did not know	0 (0%)	1 (2%)	1 (2%)	0 (0%)
Probably Not	0 (0%)	0 (0%)	0 (0%)	0 (0%)

have had symptoms; the most common was heaviness (44%), followed by pain and itching.

The average diameter of treated saphenous veins, measured at 3-5 cm distal to the SFJ or SPJ, with patient in orthostatic position, was 8 mm (min: 4 mm; max: 15 mm); the presence of segmental vein dilatations was not an exclusion criteria from EVLA.

The average length of treated saphenous veins was 25.5 cm with a mean operative time of 40 minutes. The average LEED was 101 J/cm.

Patients return to daily activities after a mean of 1.6 days; no evidence of residual flow or venous reflux was found on US imaging at any time during follow-up. No recurrent varicose veins occurred so far.

Treatment effects on the VCSS–related signs or symptoms

The VCSS improved drastically from a mean of 5.2 (SD: 2.4) pre-interventional to 0.18 at day 30; it was still 0.18 at six months and 0.30 at twelve months.

The EVLA substantially reduced signs and symptoms.

Complications and side-effects

We did not observe any clinically-apparent pulmonary emboli or motor nerve lesions. No complications such as deep venous thrombosis, skin burns or the formation of arterio-venous fistula occurred in any treated legs. Phlebitic reactions, which were defined by painful indurations with erythema at any location on the treated leg, were never observed in the treated limbs.

Paresthesia: in one patient (1%; GSV), mild paresthesia occurred in the region of EVLA.

Pain: 29 patients (35%) have had pain with a mean intensity of 2.0 in a scale of intensity from 0 to 10; 13 Patients required analgesic therapy.

Ecchymoses: Post-operative ecchymoses in the track of the treated saphenous veins were present in 39% of cases and in 14% of cases were still present after 30 days.

Patients' satisfaction

After 30 days, 69 (84%) patients were very satisfied and 13 (16%) were satisfied; at six months, 64 patients (88%) were very satisfied, 8 (11%) were satisfied and one patient not satisfied with the method. At one year 43 (84%) patients were very satisfied ad 7 (14%) satisfied, 1 patient not satisfied and also at two years 16 (84%) patients were still very satisfied a 3 (16%) satisfied.

At day 30 the response to the question 'Would you choose endovenous laser therapy again?' was 'definitely' in 71 patients (87%), 'probably yes' in 11 (13%), 'do not know' in 0 and 'probably would not' in 0 patients.

At six months, 67 (91%) patients definitely and 5 (7%) patients probably would chose EVLA again; 1 patient (1%) was uncertain and 0 probably not. After 1 year 46 (90%) patients definitely and 4 (8%) patients probably would chose EVLA again; 1 patients (2%) was uncertain and none probably not. After 2 years all patients were very satisfied (18) or satisfied (1) and would definitely chose EVLA again.

Discussion

EVLA is an efficient technique to treat insufficient saphenous veins with an occlusion rate that reaches about 95%7-8. Now that all users of EVLA consistently report excellent closure rates, the focus shifted to the reduction of the complication rate after treatment.

WSLWs have a specificity to the vein wall at least five times that of the lower hemoglobin-specific wavelengths (Figure 2). Additionally, water as a chromophore is 40 times more efficient for energy absorption as compared to hemoglobin34-36.34 This allow effective treatment with lower laser power (W) and linear endovenous energy density (LEED; J/cm) than earlier methods, reducing the complications associated with thermal damage.

Optimal wavelength and LEED and W settings would be able to provide the best balance between a high anatomical success rate and a low procedure-related complication rate. Some notions in EVLA

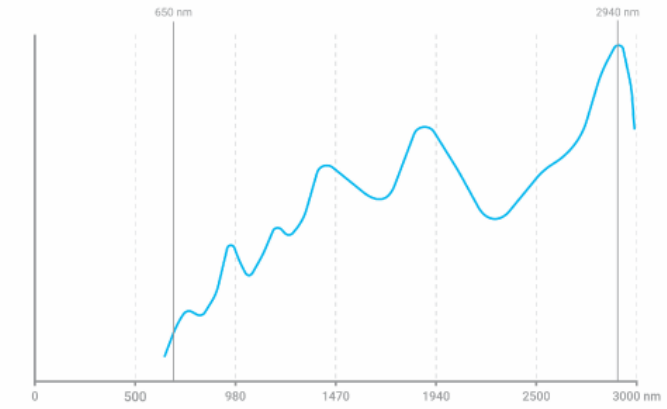

Figure 2. The absorption coefficient of water

with WSLWs (like 1320, 1470 and 1540 nm) are now acquired: a) not to exceed 100 J/cm to avoid post-operative paresthesia37; b) not to increase the laser power (W) too much because it didn't influence the occlusion rate when a high LEED with comparable values was used, but a lower power level significantly reduced use of analgesic tablets 38; c) to perform a cold, good quality tumescent anesthesia, especially if EVLA is performed with WSLW, since the biological target is vessel wall and not hemoglobin, the vein must be drained of its blood in order to avoid important attenuation of light by the blood "layer" [39-41]; d) post-operative pain and bruising may be reduced by the use of radial or jacket-tip fibers if compared to bare-tip fibers [17,42]; e) the incidence of endothermal heat-induced thrombosis (EHIT) remains low and has declined with increasing experience and WSLW reduces the risk of EHIT compared with a hemoglobin-specific wavelength [42,43].

The absorption coefficient of the vein wall for a 1940 nm laser is more than four times higher than that for 1470 nm and more than 200 times higher than that for 980 nm [23,44,45] (Figure 2).

The few published clinical paper are discordant regarding the parameters used and the findings, resulting in a lack of standardization of the method [23-26].

A histological study has highlighted the great potential of this wavelength even with respect to 1470 nm46; these findings corroborate the possibility of using lower LEEDs and laser power (W) with 1940 nm devices to achieve effective occlusion, as well as to prevent damages to the adventitia and perivenous tissues. However, the results published by some authors who used excessively low LEED and laser power (W) led to unsatisfactory results in the short term regarding to occlusion rates of the treated saphenous veins [24]. Other Authors23 confirmed that there was no recanalization in veins treated with a LEED greater than 30 J/cm. 2 other papers25,26 confirmed that with an average LEED between 50 and 60 J/cm the occlusion rate reaches 100%; however, Sroka, *et al.* 26 reported a significant percentage of paresthesias (13.9%), similar to that reported by Pannier, *et al.* in 200937 with the 1470 wavelength when more than 100 J/cm were delivered. The 1940 is therefore very effective to treat saphenous veins but it is necessary to be cautious, as the extinction coefficient of the laser energy is greater in the vein wall and also in the perivenous tissue (where the nerves are allocated)47. Although we have delivered much more energy (100 J/cm) we have had only one case of paresthesia because we have limited the treatment to the saphenous tract of the thigh (with a mean length of treated vein of 25.5 cm), avoiding treating the risk area of the leg and eventually completing the treatment with sclerosing foam, as done by Park [25] who reported a percentage of paresthesias of 3.8%.

In our experience 65% of the patients had no postoperative pain vs 44% of a previous study with 1470 nm wavelength laser and radial fiber [14], when the Authors used a LEED 90.8 J/cm (SD: 35.3); furthermore there are also differences in length of treated segments (45.4 cm versus 25.5 cm), age of the patients (48 vs 55 years) and CEAP score. These results are also more satisfying than our previous experience with a 1540 nm diode laser associated with a ball-tipped fiber16, when 55% of patient had no post-operative pain.

When present, the pain was very mild, a mean of 2 on a scale of 0 to 10, defined as "discomfort" and resolved within a few days; most of the patients (84%) did not take painkillers and rapidly return to daily activities (Table 2).

In earlier studies using instead a lower wavelength and bare fibers, the majority of patients developed postoperative pain for a few days [9] but also with the 1470 nm diode laser associated with the bare fiber 35% of patients have had pain despite painkillers assumption [47].

In our series, ecchymosis occurred in 39% of cases. We reported the presence of bruising when these were present, without quantifying them or specifying if they were located along the course of the saphenous vein or phlebectomy (always present in this last case). We think that bruising or ecchymoses are probably related to the tumescent anesthesia (ecchymoses can be noted all along the needle sticks), phlebectomy and intake of low molecular weight heparin after the procedure rather than to the laser technique.

Patients' satisfaction regarding the procedure is very high (84% very satisfied after one month) and remained high throughout the follow-up (Table 3), also in the group of patients who reported pain and all patients would still choose EVLA again except 1 (who experienced post-treatment telangiectasias).

Conclusion

EVLA of saphenous vein with a radial emitting laser fiber using a 1940 nm diode laser appears to be a safe and efficient treatment option; patients are satisfied with the outcome of the procedure and would gladly undergo further treatment using this laser. In fact, postoperative pain is reported in low percentage, it is generally of short duration and well tolerated. A limitation of this study is that we cannot identify whether these results are attributable solely to the laser wavelenght, the radial fiber or a combination of both factors; furthermore, associated phlebectomies and/or sclerofoam might have an impact on postoperative pain and quality of life that we were not able to analyze.

Future randomized blinded study is still required to assess the durability of treatment at lower power and energy settings.

Author contribution

- Conception and design: CA
- Analysis and interpretation: CA, MD
- Data collection: CA, MD
- Writing the article: CA, MD
- Critical revision of the article: CA, FRS, MD
- Final approval of the article: CA, FRS, MD
- Statistical analysis: CA, MD
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Conflict of Interest

None.

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Contributorship

None.

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