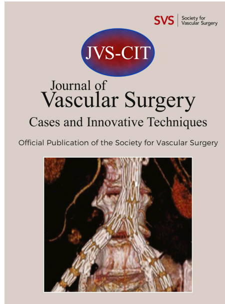
Journal Pre-proof



Safety, feasibility and early efficacy of the water-specific 1940 nm laser wavelength for ablation of saphenous incompetence

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Safety, feasibility and early efficacy of the water-specific 1940 nm laser wavelength for ablation of saphenous incompetence

Short title: Safety, feasibility and efficacy of a 1940 nm laser wavelength

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ARTICLE HIGHLIGHTS

Type of Research: Retrospective study

Key Findings: Endovenous laser ablation of truncal saphenous veins using a water-specific 1940 nm diode laser wavelength showed a 99.6% occlusion rate at six weeks follow-up with minimal side effects and zero EHIT rate.

Take Home Message: Endovenous laser ablation using a water-specific 1940 nm diode laser wavelength with low linear endovenous energy density appears to be feasible, safe and efficient. A larger registry comparing the 1470 nm versus the 1940 nm laser wavelength is warranted to validate our findings.

Table of Contents Summary

Using a water-specific 1940 nm diode laser wavelength to ablate saphenous varicose veins showed zero event rate of EHIT at 2 days and 6 weeks follow-up. Overall, side effects were minimal. These findings call for the need of a larger registry of endovenous laser ablation comparing the 1940 nm versus the 1470 nm diode laser wavelength to ablate saphenous incompetence.

Abstract

Objective: The aim of the study was to evaluate the safety, feasibility, and early efficacy of saphenous vein ablation with a water-specific 1940 nm diode laser wavelength using low linear endovenous energy density.

Methods: Between July 2020 and October 2021 we retrospectively analyzed a series of patients undergoing endovenous laser ablation (EVLA) from the multi-center prospectively maintained VEINOVA Registry (VEIN Occlusion with VArious techniques). EVLA was performed with a water-specific 1940 nm radial laser fiber. In the same session all insufficient tributaries were treated by phlebectomy or sclerotherapy. Tumescent anesthesia was injected into the perivenous space. Vein diameter, energy delivered, linear endovenous density (LEED) were reviewed at baseline. Venous thromboembolism and endovenous heat induced thrombosis (EHIT), burns, phlebitis, paresthesia and occlusion rate were reviewed at 2 days and 6 weeks follow-up. Descriptive statistics were used to describe the results.

Results: Overall, 229 patients were identified. 34 patients were omitted due to treatment of recurrent varicose veins at the previously operated site (residual or neovascularization). Finally, 108 patient with varicose veins and 87 patients with recurrent varicose veins (new varicose veins in untreated area) due to disease progression were included in this analysis. 256 native saphenous veins (163 GSV, 53 SSV, 40 ASV) in 224 legs were treated with EVLA. Mean age was 58.3 ± 16.5 years. 134 (68.7%) patients were female and 61 (31.3%) were male. Nearly half of the patients had a history of saphenous vein operation (44.6%). CEAP C2 was found in 31 legs (13.8%), C3 in 108 (48.2%), C4a-c in 72 (32.1%) and C5-6 in 13 (5.8%). Treatment length was 34.8 ± 18.3 cm. Mean diameter was 5.0 ± 1.2 mm. The average LEED was 34.8 ± 9.2 J/cm.

Concomitant miniphlebectomy was performed in 163 patients (83.6%) and concomitant sclerotherapy was performed in 35 patients (18%).

At two days and six weeks follow-up occlusion rate of treated truncal veins were 99.6% and 99.6%, respectively with only 1 (0.4%) truncal vein with partial recanalization at two days and six weeks follow-up. No proximal DVT, PE or EHIT incidence occurred at follow-up. Only 1 (0.5%) patient had calf DVT at 6 weeks follow-up. Postoperative ecchymosis were rare (1.5%) and resolved at 6 weeks follow-up.

Conclusion: EVLA of incompetent saphenous veins using the water-specific 1940 nm diode laser wavelength is feasible and appears to be safe and efficient with high occlusion rate, minimal side effects and zero rate of EHIT.

Keywords: Varicose vein, 1940 nm diode laser, pain, occlusion, saphenous vein, EHIT, DVT

Funding

No

Conflict of interest

No

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Introduction

Varicose veins arising from chronic venous disorders is a highly prevalent disease that contributes to significant pain, debility, and quality of life reduction.[1] Endovenous thermal ablation is nowadays seen as the gold standard for the treatment of saphenous vein incompetence since 2011.[2-4] The reason for the widespread use of endovenous thermal ablation are the faster recovery time, improvement of quality of life and a lower complication rate when compared with surgical high ligation and stripping.[2] Among endovenous thermal ablation, endovenous laser ablation (EVLA) is currently the method most commonly used worldwide.[5] EVLA uses thermal energy inducing a shrinkage of the vein wall and occlusion of the vein. In the early days, diode laser with shorter wavelengths of 810, 840, 940 or 980 nm were used. These wavelengths had a high absorption coefficient of oxyhemoglobin.[6-8] The currently utilized laser wavelengths have a high absorption coefficient for water and are in the range of 1064, 1320, 1470, 1500 and 1940 nm.[8] The higher the absorption of laser energy in water, the higher is the energy absorbed in the vein wall.[9, 10] Using 1470 nm laser wavelength, excellent results have been achieved mostly at linear endovenous energy density (LEED) of 60-90 J/cm.[11-13] Thus, the focus was set on side effects after EVLA. The most common side effect seen with all laser types are bruising, localized pain, induration and discomfort along the treated vein.[14] Four studies comparing different wavelengths (810- vs. 980-nm,[15] 810- vs, 1,320-nm,[16] 940- vs. 1,320-nm,[17] and 980 vs. 1,500-nm[18]) demonstrated that laser devices with longer wavelength produced fewer side effects at comparable LEED than shorter wavelength. The use of water-specific longer laser wavelengths with a radial fiber tip results in significantly less pain and less ecchymosis during the recovery time.[11, 19, 20] Mathematical remodeling also reveals that the water-specific longer laser wavelength has a better absorption of the laser energy by the vein wall and thus requires less energy to achieve wall damage and consequently reduces the rate of side effects.[21] However clinical data on the 1940 nm laser wavelength are limited.

The aim of the study was to evaluate the safety, feasibility, and early efficacy of saphenous vein ablation with the water-specific 1940 nm diode laser wavelength using low LEED.

Methods

This is a retrospective observational study using data from the ongoing multicenter VEIN Occlusion with VArious technique (VEINOVA) registry. Between July 2020 and October 2021 the medical records of all consecutive patients with truncal saphenous veins treatment with EVLA using the 1940 nm diode laser wavelength in two centers, were reviewed using the venous reporting standard guidelines [22]. This manuscript was prepared in compliance with the STROBE checklist [23]. In accordance with the legal obligations in Switzerland, prior to patients' decision concerning treatment, all of them received detailed written and verbal information about the proposed technique, the benefits and risks, as well as the alternative treatment options. Before we performed the procedure, all patients had to sign a written informed consent form and gave their consent for the investigator to use their data for scientific purposes. The study follows the principles outlined in the Declaration of Helsinki and was approved by the institutional review board (Ethic committee Norwest- und Zentralschweiz, EKNZ) project ID number 2018-00813. Demographic data, vein characteristics, procedural data including concomitant phlebectomies and sclerotherapy and outcome data including ultrasound findings and complications were assessed and extracted from the medical charts. All data were collected prospectively and entered into a database. All patients were diagnosed preoperatively with superficial venous insufficiency according to duplex ultrasound (DUS). Saphenous vein incompetence was assessed with reflux in response to manual calf compression or Valsalva manoeuvre with the patient standing. Reflux was defined as evidence of reverse flow >500 ms in a vein segment.[24]

EVLA was performed by experienced vascular specialists who had experience with treating several hundred patients with EVLA using a 1470 nm diode laser as well as with radiofrequency ablation. Bilateral treatment was allowed. Tumescent anesthesia was used in all cases of EVLA as outpatient procedures. No sedation was routinely given. No limitation was placed on the vein diameter. Details of the procedure were described previously.[25]

In brief, on the day of treatment, the location of the veins being treated was mapped on the patient's leg in standing position under ultrasound guidance (Aplio a, Canon Medical System Europe). Percutaneous cannulation of the GSV or SSV or AASV was performed at the distal point of insufficiency under ultrasound guidance using the Seldinger technique. The access point was mostly infragenual for the GSV , mid tight for the AASV und distal calf for SSV. A 16 gauge angio needle was used for vein puncture without using any separate introducer sheath or guide wire. After insertion of the laser fiber (iMS Diffuse Emission Fiber 400µm, IMS, Germany) through the sheath of the 16 gauge needle sheath, the fiber tip was advanced to the sapheno-femoral junction (SFJ) or sapheno-popliteal junction (SPJ) and then positioned 1-0.5 cm distal of the SFJ/SPJ with ultrasound guidance and connected to a 1940 nm radial diode laser device. The distance of the laser tip to the junction is always measured by ultrasound to ensure safety distance. Local tumescent anesthesia was prepared using 500 ml 0.9% saline, 50 ml of 1% rapidocaine and 5 ml of 8.4% sodium bicarbonate. Local tumescent anesthesia was then infiltrated in the perivenous space under ultrasound guidance using a motor pump. After tumescent anesthesia was administered, the position of the laser tip was again verified and the distance to the junction measured before activating the laser. Laser energy was then released at 3 wattage using a continuous mode, aiming for a linear endovenous energy delivery (LEED) of 20-40 J/cm. The pullback speed per centimeter was set at 10 second and controlled by a ringtone aiming a LEED at 30 J/cm. However, definitive pullback speed was controlled according to the operators discretion based on changes in the diameter, while trying not to exceed a mean LEED of 40 J/cm whenever possible. After the EVLA, refluxing tributaries were removed by phlebectomy or closed with sclerotherapy during the same procedure. After tumescent anesthesia alongside of the tributaries, 1- to 3-mm incisions over varicosities were performed and varicose tributaries were removed using a hook (Oesch; Salzmann AG, St. Gallen, Switzerland). Concomitant foam sclerotherapy was performed alone or in addition to phlebectomy using up to 10 ml of 1% to 3% aethoxysclerol mixed 1:4 with air.

After the treatment, the legs were wrapped in sterile absorbent bandages and covered with a compressive cohesive bandage in those patients who had concomitant phlebectomy. At follow-up at two days, the bandage was removed and a duplex scan was performed looking for truncal occlusion and deep vein thrombosis (DVT) including endovenous heat induced thrombosis (EHIT). The patient was asked for PE symptoms. If there was clinical suspicion for a PE a computer tomography (CT) was done. The patient was then told to wear a class 2 compression stocking during the day for one week. Compliance regarding the use of the stockings was not monitored. At 6 weeks follow-up all side effects were checked and recorded. Efficacy endpoint was total occlusion rate of the treated truncal vein at 2 days and 6 weeks and main safety endpoint was EHIT, DVT, PE or major bleeding at 2 days and 6 weeks. Secondary safety endpoint was the occurrence of phlebitis, paresthesia, burn, infection and minor bleeding. Ecchymosis or minor bleeding Ecchymosis or minor bleeding is defined as clinically apparent bleeding (ie, at least one episode of clinically apparent melena/hematemesis, spontaneous gingival bleeding or epistaxis lasting for >5 minutes) and hemorrhagic wound complications (excessive wound hematoma or wound hematoma leading to an unplanned consultation, hospitalization, or prolonged inability to work).

All patients undergoing EVLA procedures routinely received thromboprophylaxis with doses of 10 mg rivaroxaban (Bayer AG, Zurich, Switzerland) once daily for 3 days routinely. The first dose of the anticoagulant was usually administered 3 hours postoperatively. The 3-day regime of thromboprophylaxis was arbitrary and based on the believe that after 3 days the patient is fully recovered and fully mobilized. Routine mobilization was encouraged for the postoperative period without any limitation.

Statistical analysis

Descriptive statistics with categorical data are presented as frequency and percentage, continuous data are reported as mean and standard deviation (SD). Data analyses were performed using Stata software version 15 (Stata, Inc. Stata Statistical Software Release 10, College Station, TX, USA).

Results

From July 2020 to October 2021 a total of 229 patients with EVLA using the 1940 nm diode laser wavelength were identified in the ongoing VEINOVA register. Among them 34 patients were excluded due to EVLA of recurrent varicose veins at the previously operated site (residual or neovascularization). Finally, 108 patient with varicose veins and 87 patients with recurrent varicose veins (new varicose veins in untreated area) due to disease progression were included in this analysis. Bilateral treatment was performed in 29 patients. Mean age of the total cohort was

58.3 ± 16.5 years. 134 (68.7%) patients were female and 61 (31.3%) were male. Only 7 (3.6%) patients had a history of venous thromboembolism and 3 (1.5%) had thrombophilia. A history of varicose vein surgery was found in 44.6%. Detailed patient characteristics were given in table 1. CEAP (clinical, etiology, anatomy and pathophysiology) clinical score C2 was found in 31 legs (13.8%). The most prevalent CEAP clinical score was C3 in 108 (48.2%) legs and the second most prevalent CEAP clinical score was C4a with pigmentation (n=62, 27.7%) C4b, C4c, C5 and C6 were rare. Detailed numbers are given in table 1.

A total of 256 truncal varicose veins (163 GSV, 53 SSV, 40 AASV) in 224 legs were treated with the 1940 nm diode laser wavelength. Mean treatment length for the total cohort was 34.8 ± 18.3 cm. Mean diameter was 5.0 ± 1.2 mm for the total cohort. Average LEED administered for treating the truncal vein was on average 34.8 J/cm. Concomitant phlebectomy was performed it the same procedure session (83.6%). Detailed procedure variables of the treated veins are given in table 2.

At 2 days follow-up serious side effects such as DVT, PE or EHIT or major bleeding did not occur. At 6 weeks follow-up there was one calf DVT. Postoperative phlebitis, paresthesia, burns and minor bleeding occurred very infrequent. The observed complete occlusion rate of the truncal vein treated was 255 out of 256 (99.6%) at 2 days and at six weeks follow-up. There was one (0.4%) partial recanalization documented at 2 days and 6 weeks follow-up. Detailed outcome variables are given in table 3.

Discussion

This study assessed the safety, feasibility, and early efficacy of saphenous vein ablation with a water-specific 1940 nm diode laser wavelength using low LEED. In the early days, EVLA of shorter wavelength have been used. However, as it becomes evident that absorption of laser energy varies at different chromophores and that postoperative complication depends on wavelength, there was a trend of using a water-specific longer laser wavelength than shorter wavelength.[26] Thus, this study provide important data on the safety and feasibility and early efficacy of varicose vein ablation using a 1940 nm diode laser wavelength. We could demonstrate that early efficacy was high using an average LEED of 35 J/cm. In fact, it has been shown that histological and immunohistochemical changes in the GSV after EVLA with the 1940 nm laser wavelength and LEED values of 50 versus 100 J/cm revealed an excessive destruction to the intima and media layer causing a high-grade thermal damage when using high LEED of 100 J/cm.[27] Based on these results lower LEED with the 1940 nm laser wavelength is suggested to achieve effective occlusion with less high grade thermal damage to the intima and media, as well as to prevent damages to the adventitia and perivenous tissue. It therefore, supports the low LEED we used in this study. Other studies have also shown that water-specific laser wavelengths are significantly more powerful than hemoglobin-specific laser wavelengths and that the direct transfer of energy to the vein enables a lower LEED to achieve adequate vein wall destruction; in other words, despite less energy delivered to the vein wall, significant shrinkage has been seen in veins treated with a water-specific longer laser wavelengths.[13, 28] This findings compares well with our results showing a 99.6% occlusion rate.

A successful EVLA depends on effective transfer of the laser energy to the vein wall itself. The light energy must be absorbed and converted into heat which result in endothelial denaturation and vein wall shrinkage. LEED is the term used to quantify the amount of energy delivered per centimeter (J/cm) and depends on the wattage used for the laser but not on the wavelength. Longer wavelength have a high absorption coefficient for water and thus, are absorbed by the water molecules in the endothelial cells of the vein wall.[29] Using low power (less wattage) and low LEED, the results of thermal damage to the perivenous tissue also decreases, and faster recovery may be expected with less post-procedural pain and morbidity.

Overall, side effects such as burn and ecchymosis were very low in this study. Insoo and coworkers[5] could demonstrate a consistently low pain score after EVLA using a 1940 nm laser wavelength. Based on our personal experience of using a 1470 nm laser and bare fiber at 10 wattage and mean LEED of 60-90 J/cm to treat incompetent saphenous vein we feel, that post-procedural pain were more present with 1470 nm laser than with the 1940 nm laser wavelength. Unfortunately, we did not monitor the patients' pain scores.

An interesting finding in this study is the zero rate of EHIT. EHIT is the term used to describe thrombotic extension from the treated truncal vein up to the junction or into the deep venous system. The zero rate of EHIT might be explained by the fact that the water-specific laser wavelength transfer the energy directly to the endothelium of the vein wall leading to effective shrinkage of the vein[13] and thus, leads to less thrombus propagation into the deep system. One might argue that the zero EHIT rate is based on the low number of the study population. However, looking at other studies with similar low number of study population and using shorter laser wavelength (810 nm wavelength) EHIT was still high and reported to be 6.4% of 234 laser procedures performed.[30] Whether the longer laser wavelength or the lower LEED was responsible for the zero EHIT rate could not statistically be evaluated due to zero EHIT event rate and no comparison with higher LEED. It is also not clear whether the zero rate of EHIT is due to the administration of thromboprophylaxis. In order to clarify this hypothesis the same study would have to be repeated without prophylactic anticoagulation. It has been shown in a previous multivariate analysis that laser wavelength was an independent risk factor for EHIT incidence, whereas the energy applied was not.[28] In other words, longer laser wavelength may lead to less EHIT incidence. Some possible risk factors such as large GSV diameter (>8.5mm), previous history of venous thromboembolic disease, and male sex have been associated with EHIT.[31] However, the evidence is inconsistent. Also when ablation is started >2.5cm distal to the SFJ or SPJ, there is a trend of decreased EHIT. However, the evidence is low (GRADE - 2; LEVEL OF EVIDENCE – C).[31] In addition these reports have been based on laser wavelength below 1940nm. As precision is presumed to be higher with the 1940nm laser wavelength because the energy delivered is more selectively absorbed by the vein wall, less complication should arise.

This study has several limitations. First, it is limited by its retrospective design which is inherent in observational studies and the lack of a comparison group with lower wavelength. Second, we did not obtain a venous severity score during workup; therefore, we could not include this information in our analysis. Hypercoagulable risk factors such as the Caprini score were not assessed routinely as part of our workup and the effect of these factors on our results could not be determined. Despite these limitations, this study provides valuable information on safety and early efficacy using the water-specific 1940 nm laser wavelength for ablation of incompetent saphenous vein in an ambulatory setting given the limited data currently available. It provides a clear protocol of low power and low LEED for efficient varicose vein ablation. Another advantage of this study is its multicenter aspects of this observational design with prospective data collection. It would be interesting to compare the postoperative morbidity of EVLA with 1470 nm and 1940 nm diode laser. Until such data and longer follow-up will become available this study provides valuable information on practical aspects using a 1940 nm laser wavelength for varicose vein ablation.

In conclusion, EVLA of incompetent saphenous veins using a 1940 nm diode laser wavelength is feasible and appears to be safe and effective with a power at 3 wattage and average LEED of 35 J/cm. Furthermore, occlusion rate is high with low side effects and zero rate of EHIT in patients who routinely receive prophylactic dose of anticoagulation for 3 days post-procedure. A larger registry and longer follow-up comparing the 1940 nm with the 1470 nm diode laser wavelength is clearly warranted, to validate our findings.

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Legend of tables

Table I.

Baseline characteristics of patients treated with the 1940 nm diode laser wavelength.

Table II.

Lesion characteristics and procedural data per truncal vein.

Table III.

Safety and efficacy data of patients treated with the 1940 nm diode laser wavelength.

Table 1

Demographic characteristics	n=195
Female sex, no (%)	134 (68.7)
Age, mean ±SD, year	58.3 ± 16.5
BMI ±SD, kg/cm^2	25.9 ± 3.9
History of phlebitis, no (%)	13(6.7)
History of VTE, no (%)	7 (3.6)
History of varicose vein operation, no (%)	87 (44.6)
Thrombophilia, no (%)	3 (1.5)
CEAP classification per leg (n=224)	
C2	31 (13.8)
C3	108 (48.2)
C4a	62 (27.7)
C4b	3 (1.3)
C4c	7 (3.1)
C5	6 (2.7)
C6	7 (3.1)

n, no, number; SD, standard deviation; BMI, body mass index; VTE, venous thromboembolism; CEAP, clinical, etiology, anatomy, pathophysiology

Table 2

Per treated truncal vein	n= 256
Great saphenous vein, no (%)	163 (63.7)
Small saphenous vein, no (%)	53 (16.8)
Accessory saphenous vein, no (%)	40 (15.6)
Energy applied, mean ± SD, (J)	1199 ± 675
LEED, J/cm	34.8 ± 9.2
Vein length, mean ± SD, (cm)	34.8 ± 18.3
Total diameter, mean ± SD, (cm)	5.0 ± 1.2
GSV diameter, mean ± SD, (cm)	5.3 ± 1.2
SSV diameter, mean ± SD, (cm)	4.5 ± 0.8
ASV diameter, mean ± SD, (cm)	4.5 ± 1.1
Concomittant sclerotherapy of patients (n=195), no (%)	35 (18.0)
Concomittant phlebectomy of patients (n=195), no (%)	163 (83.6)

n, no, number; SD, standard deviation; LEED, linear endovenous energy density; GSV, great saphenous vein; SSV, small saphenous vein; ASV, accessory saphenous vein

Tab. 3

Outcome variable	2 days FU	6 weeks FU
Follow up, mean ± SD (days)	2.1 ± 0.7	40.4 ± 9.3
Total occlusion of truncal vein, no (%)	255 (99.6)	255 (99.6)
Partial recanalization of truncal vein, no (%)	1 (0.4)	1 (0.4)
Complete recanalization of truncal vein, no (%)	0	0
DVT, no (%)	0	1 (0.5)
PE, no (%)	0	0
EHIT class I	0	0
EHIT class ≥II	0	0
VTE + EHIT class ≥II	0	1 (0.5)
Phlebitis, no (%)	1 (0.5)	1 (0.5)
Paresthesia, no (%)	3 (1.5)	6 (3.1)
Burn, no (%)	1 (0.5)	1 (0.5)
Infection, no (%)	0	0
Minor bleeding, no (%)	3 (1.5)	3 (1.5)
Major bleeding, no (%)	0	0

FU, follow-up; no, number; SD, standard deviation; DVT, deep vein thrombosis; PE, pulmonary embolism; EHIT, endovenous heat induced thrombosis; VTE, venous thromboembolism