

Preliminary experience with a 1470 nm diode ring laser with echosclerotherapy in lower limb varicose veins

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Abstract

Objective : To study the effect of endovenous laser ablation (EVLA) of lower limb varicose veins using a 1470 nm diode ring laser with ultrasound-guided foam sclerotherapy (UGFS), also known as echosclerotherapy.

Methods : From January 2020 to December 2022, 236 patients with primary lower limb varicose veins were enrolled in the study. All patients were treated with 1470 nm diode ring laser with echosclerotherapy in our center. Under tumescent anesthesia, venipuncture of the great saphenous vein (GSV) trunk was performed, followed by 1470 nm laser therapy (80-100J/10W). Before the procedure, 1% polidocanol foam was injected into the insufficient collateral veins extending from the main trunk of the GSV. During the 3 days after surgery, self-adhesive elastic bandage was used for compression therapy. After 3 days of surgery, grade II compression stockings was used for 1 month. All patients underwent a follow-up duplex Doppler ultrasound 1, 30 days after the procedure. Hospital stay time, postoperative pain, GSV occlusion rate, recurrence rate and complications, such as ecchymosis, edema, paresthesia and endovenous heat-induced thrombosis (EHIT).

Results: Four patients were lost to follow up. The average hospitalization time was 2.8 days, the average admission time after operation was 1-2 days. The average operating time was 45.79 ± 8.57 min. At the one month follow up all treated GSV remained occluded. There were 2 patients were treated with echosclerotherapy in outpatient because of new reflux in the treated collateral veins. Seventy-five percent of patients did not have any pain after the treatment and ninety-one point eight percent of ones did not take any analgesic tablets at any time after the procedure. No severe complications such as deep venous thrombosis could be detected. And there was no patient developed EHIT after treatment. Minor complications were ecchymosis at 15.1%, edema at 44.8%, and paresthesia around ankle at 0, respectively. All patients expressed satisfaction with the operative curative effects and cosmetic effects.

Conclusion: EVLA with 1470-nm diode ring laser with echosclerotherapy in lower limb varicose veins is comfortable with less incision, hospitalization procedure and is a safe and efficient treatment option.

Keywords: Endovenous Laser Ablation, Ultrasound-Guided Foam Sclerotherapy, Varicose Veins, Compress Therapy

Introduction

Lower limb varicose vein is one of the most common diseases in vascular surgery. This disease is also a common problem that affect approximately 60% of the adult population, particular in the developed countries [1]. In early phase, varicose veins are benign and may be asymptomatic. People would not pay enough attention to this problem. But as the development of the disease, varicose veins may lead to hyper pigmentation, leg ulcers and thrombosis [2]. The most common cause of varicose veins is chronic venous insufficiency (CVI), especially great saphenous vein (GSV)

insufficiency. Although classic intervention of high ligation with or without stripping (HL/S) has been shown to have an excellent outcome, improving general quality of life of the patients [3-5]. However, in some cases, the operation was associated with significant bleeding, postoperative pain and bruising, occasionally, severe complications such as groin infection, thrombosis, and nerve damage may occur [6].

In the last decade, minimally invasive techniques, such as endovenous laser ablation (EVLA), radiofrequency ablation

(RFA), and ultrasound guided foam sclerotherapy (UGFS), has been developed and accepted by clinicians for excellent cosmetic results. In particular, EVLA technology is a highly effective treatment for lower limb varicose veins in Europe and North American for safety and preferable occlusion rates [7-9]. It has been found moderate postoperative pain and bruising are frequent in clinical trials using 8810, 940 or 980nm diode lasers and a bare fiber [10]. And higher wavelength lasers like 1320, 1470-lasers have a higher absorption in water (water-specific laser wavelength, WSLW) and have equal occlusion rates and less postoperative pain and bruising [11].

The basis of sclerotherapy is irreversible damage to the venous endothelium by injection of agent [12]. The cellular membranes of the endothelium are disrupted creating vasospasm, in which the thrombus is deposited, leading to gradual fibrous obliteration of the vessel lumen and achieving venous ablation [13,14]. Sclerotherapy is usually used in dilated reticular veins, isolated varicose lesions and dilatation of incompetent branches with competent main trunks of the GSV [15].

In recent years, more and more combined procedure are used in clinic works for increasing effectiveness and reducing complications and recurrence. The purpose of the study was to evaluate its safety and effectiveness of the combined therapies with 1470-nm diode ring laser with echosclerotherapy in lower limb varicose veins.

Patients and Methods

This study was approved by the Committee for the Protection of Human Subjects at PKUcare Luzhong Hospital (Shanghai, China). Informed consent was obtained from each patient involved in this study. This single-center historical cohort study included all sequential patients from January 2020 to December 2021 who received an overall treatment program of EVLA with 1470-nm diode ring laser combining foam sclerotherapy. Each patient underwent physical examination and color duplex ultrasonography examination by experienced phlebologist.

Inclusion Criteria and Exclusion Criteria

Inclusion criteria were as follows: (1) age 18-80 years; (2) unilateral limbs with the clinical symptom of varicose veins (C3-C5); (3) GSV incompetence as defined with reflux/retrograde flow time >0.5s after a Valsalva maneuver in the proximal part of the vein (Philip, M-Turbo, 5-12MHz linear probe).

Exclusion criteria were as follows: (1) previous surgery or sclerotherapy treatment for lower limb varicose veins; (2) previous venous thrombosis; (3) history of arterial insufficiency or ankle-brachial index 0.9, or both; (4) serious systematic diseases unsuitable for treatment and (5) coagulation disorder.

Treatment

Before operation, all the varicose veins were marked in the standing position. And the perforating vein was marked under ultrasound if existing.

GSV at the Medial malleolus level was punctured after local anesthesia with 1% lidocaine under ultrasound (US) guidance. A guide wire with 0.035" was inserted and a 6F introducer sheath (TERUMO) was inserted through the guide wire. A disposable sterile laser fiber for 1470-nm diode ring laser (YYGX600R, L.H.H.MEDICAL, China) was inserted through the introducer sheath. Under US location, the fiber was placed around 2cm under the saphenofemoral junction (SFJ).

Sclerosing foam was prepared using the Tessari method [16]. Two 5-mL syringes were filled with 1 mL of 1% polidocanol injection (Chemische Fabrik Kreussler & Co. GmbH, approval number H20160033) and 4 mL of air. The reagent should be used immediately after preparation. Through a three-way stopcock, 5 mL of sclerosing foam (SFT) was prepared in the ratio of 1:4, which appeared to be Ivory micro-foam (Figure 1). Foam was injected into the marked branch varicosities and insufficiency perforator vein under US guidance using 18-gauge butterfly needles. The total administered volume did not exceed 10 ml.

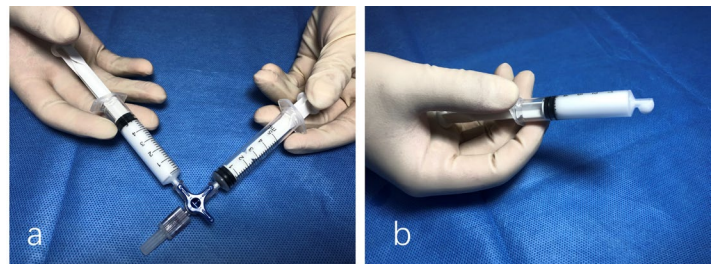


Figure 1: a) The three-way tap and the formed foam in both the syringes; b) The sclerosing foam prepared using Tessari's method.

Then the tumescent local anesthesia solution, which consists of 0.9% saline 500 ml, 2% lidocaine 20 mL, Ropivacaine hydrochloride 10ml, adrenaline 0.4 mL, and 8.4% sodium bicarbonate 475 mL, was applied in all the patients under US guidance [17]. A 10 ml syringe with 19-gauge needle under US guidance was used for the infusion to ensure a homogenous layer of tumescent fluid around the GSV trunk. The 1470 nm diode laser device was set under continuous power using 8W of power. The tip of fiber was positioned at the 2-3cm distal to SFJ and was drawback at the speed of 10mm/s manually achieves a linear endovenous energy density (LEED) of 70 to 85J cm. During the process of EVLA, the limb along GSV was compressed with ice water gauzes to avoid the damage of superficial tissue. At last, the US equipment was used to confirm that there's no remaining GSVs and thrombosis in the SFJ.

After laser ablation of the GSV, eccentric compression with self-adhesive elastic bandage for 72 hours and class II graduated compression stocking (30-40 mmHg) for 1 month were applied. In addition, a prophylactic dosage of rivaroxaban (20 mg/d) was given to all patients for 3 days. The patients were instructed to pace immediately after the intervention. Aeccuven forte or diosmin tablets was administered for at least 1 month.

Postinterventional checkups took place 3, 30 days after surgery. During the follow-up, the patients were asked about the pain on the visual analog scale (VAS), recovery status and complications such as bruising, edema and paresthesia. Doppler US examination was performed in all patients at 30 days after EVLA.

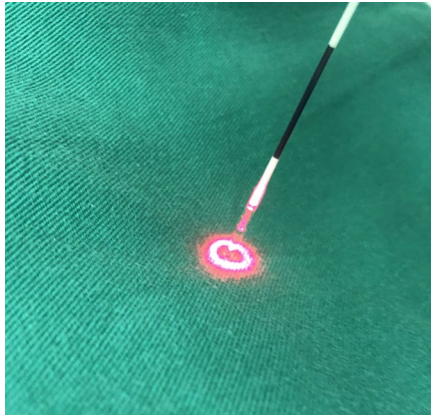


Figure 2: A 1470 nm diode ring fiber (L.H.H.MEDICAL, China.)

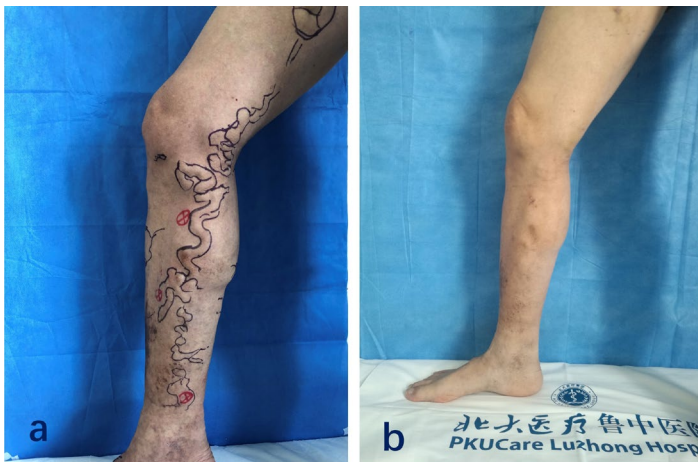


Figure 3: a) Black marked varicose veins: enlarged tortuous superficial veins and pigmentation; red marker site: the perforating veins positioned under US (before operation); b) status post treatment: varicose veins disappeared and pigmentation faded (1 month after operation).

Results

From January 2020 to December 2021, 110 male and 126 female patients (male to female ratio 1:1.15) aged 23 to 75 (mean age 46.8 years). At the end of follow up, complete data were available from 232 patients (98.3%). Four patients moved to other cities. The average operating time was 45.79 ± 8.57 min. The average hospitalization time was 2.8 days (1-5 days), the average admission time after operation was 1-2 days. At one month after operation, all patients were under Doppler US examination. All treated GSV trunks remained occluded. The new reflux in the treated collateral veins presented in two patients. They were treated with echosclerotherapy in outpatient. 75% patients did not feel any pain after the treatment and 91.8% ones did not take any analgesic tablets at any time after the procedure. During the following up,

no deep venous thrombosis happened. And there's no patient having EHIT. Ecchymosis was seen in 35 patients (15.1%). Edema occurred in 104 patients (44.8%). The paresthesia around ankle did not emerge in all patients. All patients expressed satisfaction with the operative curative effects and cosmetic effects.

Discussion

Varicose vein of lower extremity is one of the most common disorders of the vascular system, affecting approximately 60% of adults. If left untreated it can lead to numerous complications, such as sore sensation of lower limb, ankle edema, eczema, skin pigmentation, and ulcers. Clinically, varicose veins are accurately called as chronic venous insufficiency (CVI) [2]. The various stages of the condition are classified in the clinical severity, etiology, anatomy and pathophysiology (CEAP) classification system [18]. The goal in treating varicosis is to eliminate pathological reflux by blocking recirculation. These goals can be achieved in a conservative manner by compression therapy or by classical surgery (ligation of perforating veins and stripping, saphenectomy, crossectomy) [19,20]. The standard surgical treatment of GSV insufficiency has been high ligation and stripping at the saphenopopliteal junction (SPJ) first described by William Wayne Babcock, which is still used with some modification. However, the operation may be the high recurrence, postoperative pain, prolonged sick leave, and occasionally, morbidities such as groin infection, phlebitis and saphenous nerve injury. The hematoma formation is also common in the stripping track after removal of GSV. And the operation is performed with general anesthesia.

As the development of the technique and the patients' requirement of safety, effectiveness, less trauma, better cosmetic results and fast recovery, the strategies in treatment of varicose veins had changed from traditional open operation to minimally invasive endoluminal procedures, such as UGFS, RFA and EVLT. Since the EVLA technique being introduced to the treatment of lower limb varicose veins by Dr. Carlos Bone in 1999, it has been used widely in clinic as an alternative to conventional therapies and become increasingly popular, because of the advantage of being performed under local anesthesia, safety, minimal invasion and short convalesce duration. The effective rate of the occlusion of GSV was demonstrated to reach about 87.2% to 95.3% in 3-year-period [21]. EVLA uses the laser to destroy the vascular wall and endothelial cells and make the vein contraction, blood thrombosis, vascular wall fibrosis and closure permanently. However, moderate postoperative pain, bruising, pulling sensation, induration, skin burn, pigmentation and EHIT often found. The studies found that wavelength, energy density, mode of wave and types of had significant effects on occlusion rates and complications.

According to the wavelength, the lasers (810 to 2000 nm) were classified into two types: water-specific laser wavelengths (WSLW: 1000nm or greater) and hemoglobin-specific laser wavelength (HSLW) [22]. As its name implies, the laser was specially absorbed in water or hemoglobin. Higher wavelength lasers have been reported to have equal occlusion rates and less postoperative pain, incision and hospitalization than lower wavelength lasers [23,24].

Furthermore, various types of optical fiber including jacket-tip, bare tip, diffusion and radial fibers have been developed. The radial fibers can reflect the laser beam by means of a prism and emit the laser energy 360° radially around the tip directly into the venous wall. It is thought to have more homogeneous effect on the vein wall and make it possible to prevent perforation leading less pain and bruising. The ring used in our center actually is the type of radial laser, which emit the laser in loop around the tip. So in our center, we adopted the 1470-nm diode ring laser to make the patients more comfortable and produce fewer complications. The result did demonstrate the effectiveness and patients' satisfaction. 75% patients did not have any pain after the treatment and 92% ones did not take any analgesic tablets at any time after the procedure.

The proper tumescent infusion technique is essential to ensure that the EVLA procedure is safe and less complications. The tumescent anesthesia was injected into the perivenous space under US guidance providing a margin of safety and prevents thermal injury to adjacent structures. Meanwhile, the tumescent infusion created a halo around the GSV to compress the vein to benefit closing dilating veins. In our center, the tumescent anesthesia was injected by hand injection during the first six months of the study and then by the peristaltic pump (PreFluid BT600L YZ15, Changzhou PreFluid Technology Co. Ltd. China.) for the remainder of the study period. Injection by pump can supply the adequate pressure and have indeed effect of protection. Meanwhile, lidocaine added in the solution was not for anesthetic purposes but for analgesia in the post-operative period, as described by Nisar and colleagues [25]. This technique has contributed to the lack of skin burn or saphenous nerve damage in our patients.

The EVLT depends on effective transfer of the laser energy into heat to thermal injury to the vein. Fluence (J/cm^2) is the single most important parameter to quantify the amount of energy given. The amount of Joules can be calculated by wattage (w) and duration of the treatment (pull back speed or pulse duration). However, it is difficult to determine the surface area of dilated saphenous veins. Therefore, the linear endovenous energy density (LEED, J/cm) was applied to measure the energy delivered. The pullback rate determined the LEED to each centimetre of vein at a given power and wave mode. The LEED in EVLA has been reported from 20J/cm to 100J/cm. A higher LEED is associated with higher vein closure rates, but a higher occurrence of complications [26]. And the EVLA studies propose an LEED of more than 60J/cm to sufficiently occluded GSV.

Though the EVLA has high occlusion rate of GSV or small saphenous vein (SSV) trunk, the effectiveness is not satisfactory in reticular varicose veins, isolated varicose lesions and dilatation of incompetent branches with competent main trunks of the GSV and/or SSV [27]. And the foam sclerotherapy (FS), which was defined at the 2003 European Consensus Meeting on Foam Sclerotherapy [28], also referred to as echosclerotherapy, is appropriate in treatment of collateral veins, reticular varicose veins,

spider veins, telangiectasia, recurrent varicose veins and varicose veins surrounding ulcers. When performed correctly, FS does not have much more side effects and have high occlusion rate. It is important to monitor the progress of the foam with US. However, some studies demonstrated the UGFS has high GSV recanalization ranged 16.3%-51%. So the UGFS was not recommended to treat significant dilated varicose veins, SFJ or SFJ reflux.

Taking advantages of VELA and UGFS, we combined both techniques as hybrid method for the comprehensive treatment of lower extremities varicose veins. The result revealed this hybrid method is effective as Joanna Rosinczuk reported [29]. There are few minor complications happened. And the patients were satisfactory with the procedure for convenience, less pain and medical cost.

In addition, compression treatment with elastic bandages or compression stockings after ELVA and/or UGFS can reduce pain, bruising and other effects [30,31]. Generally, the compression stockings were used in daytime for 1 month after compressing for 3 days with self-adhesive elastic bandages. However, in recent days, the studies demonstrated that long-term compression, even beyond 2 days, may be not necessary [32,33]. If so, this will significantly improve the comfort level of patient after discharge.

Conclusion

Combining the EVLA with a 1470 nm diode ring laser with intraoperative echosclerotherapy as hybrid method with tumescent anesthesia in treatment of lower limb varicose veins is safe, minimally invasive and efficient method to make patients comfortable. And we think this could be done as day-case surgery in few days.

Disclosure Statement

The authors have nothing to disclose and there is no conflict of interest.

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