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Endovenous Laser Ablation (EVLA) Below the Knee with and without Chemical Ablation below Knee in Great Saphenous Vein Varicosity

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ABSTRACT

Background: For many years, varicose veins have been one of the most frequently treated venous issues. In the treatment of superficial venous insufficiency, endovenous laser ablation (EVLA) and concurrent ultrasound-guided foam sclerotherapy have recently emerged as viable alternatives to surgery.

Aim: This study aimed to compare between outcome of EVLA below the knee with and without foam sclerotherapy in great saphenous vein (GSV) varicosity.

Patients and methods: This study involved 160 patients presented by primary GSV varicosities of the lower limb (LL). Patients were split evenly between two groups; Patients in group (A) received EVLA only below the knee. However, Patients in group (B) had combined full EVLA and sclerotherapy (chemical ablation) below the knee. In the present investigation, the Venous Clinical Severity Score (VCSS) and Visual Analogue Scales (VAS) were used both before and after the therapy.

Results: After one week of interventions, combined EVLA and chemical ablation group has a higher occlusion rate (100%) compared to (97.5%) for EVLA only group where complete occlusion was more prominent than partial occlusion, however, two patients (2.5%) have a recanalization in EVLA only group with significant difference between both groups regarding complete and partial occlusion ($p=0.015$ and 0.038). Also, after six months of interventions, percent of complete occlusion increased with one patient has a recanalization in EVLA only group with significant difference between both groups regarding complete and partial occlusion ($p<0.001$ and 0.028). **Conclusion:** Combining EVLA and sclerotherapy (chemical ablation) for below-the-knee long saphenous varicosities offers a very successful method to extend the treatment down to the foot, decrease the prevalence of saphenous nerve injury, and reduce the number of treatment session and recurrence.

Keywords: Endovenous laser ablation, Sclerotherapy, Great saphenous vein varicosity.

INTRODUCTION

Lower limb varicose veins are enlarged, protruding, and convoluted veins. Lower limb superficial varicosities were thought to be one of the chronic, frequent venous issues that disproportionately affected women. In addition to ankle edema, chronic eczema, deformity, incapacity, ulceration, bleeding, foot deformities, and a reduction in quality of life. Patients with varicose veins may also present with other symptoms [1, 2].

The goal of treating lower limb superficial varicosities is to repair the anatomical and hemodynamic abnormalities that led to their formation, enhancing the health and quality of life of the patient [3]. Trendelenburg and stripping have been the standard treatments for varicose veins for many years. Since the beginning of the 1990s in the previous century, a new approach has been launched with subsequent improvement and technological advancement [4].

The first-line therapy for truncal varicose veins is now universally established and recognized as endovenous laser ablation (EVLA). When compared to surgical ligation with stripping and better effectiveness when compared to the injection of foam sclerotherapy, this strategy improved recovery, with less discomfort, leading to an improvement in life events. However, there is a chance that EVLA might harm nerves or soft tissues. Therefore, tumescent anesthesia, which requires many injections throughout the length of the target vein, is needed for individuals receiving EVLA treatment. Some individuals continue to feel discomfort weeks after surgery [5].

Sclerotherapy injections, surgical treatment, and hybrid methods make up the rest of the interventional management options. By damaging the venous endothelium, injection of sclerotherapy causes thrombosis and finally fibrosis [6].

Endovenous chemical ablation (also called Foam sclerotherapy) allows elevated contact with the vein wall on injection. Effective interaction with the vein wall may be encumbered by blood flow within larger veins that dissipates the agent [7].

Recently, the treatment of superficial venous insufficiency and varicose veins has undergone a revolution, thanks to EVLA and ultrasonography (US)-guided foam sclerotherapy [8]. The aim of this research was to compare between outcome of EVLA below the knee with and without foam sclerotherapy in great saphenous vein varicosity.

PATIENTS AND METHODS

A prospective study involved 160 patients presented by primary GSV varicosities of the lower limb (LL) at AL-Azhar University Hospital during the period from January 2020 to May 2022.

Inclusion criteria: Patients were enrolled in the study if they had primary GSV varicosities (dilatation >5 mm in diameter) associated with reflux. In addition, they

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were eligible for the study if they had GSV varicosities plus SFJ incompetence.

Exclusion criteria:

Patients with secondary VV, recurrent VV, lymphedema, acute superficial thrombophlebitis, Congenital abnormalities of the venous system, arterio-venous fistula (congenital or acquired), and general comorbidities, skin infection or ischemia.

Patients were split evenly between two groups: Group (A) where patients received EVLA below the knee only and group (B) where patients received combined complete EVLA and sclerotherapy (chemical ablation) below the knee. All patients were subjected to history taking, laboratory, and radiological investigations (Evaluation of the great saphenous vein, small saphenous vein, and extra-axial varicosities using a duplex ultrasound of the lower limb's venous system (patency and diameters). In the present investigation, the VCSS and VAS were used both before and after the therapy. To quantify venous results in clinical trials. The VCSS is helpful tool for evaluating venous outcome [(9)].

Rutherford *et al.* [(10)] have provided a thorough table for VCSS. Before the operation and throughout the follow-up period, all patients used a VAS (range 0–10, 0 = no symptoms, 10 = the worst possible symptoms) to rate the severity of their symptoms.

Endovenous laser ablation (EVLA):

In the upright posture, duplex ultrasonography was used to identify ineffective sources of venous reflux and indicate the skin that covered the GSV beginning at the SFJ. The diameter of the GSV was measured when it was erect and noted. The affected extremity was covered and sterilized. A 980 nm diode laser (Diode laser Ceralas D25 with ELVeS^{TM} Endolaser Vein System from Jena, Germany) was utilized.

The patient was positioned in an antitrendelenburg posture to enable either direct or ultrasound-guided cannulation of the GSV. Using an 18-gauge cannula, the puncture was made a few millimeters below the knee. Under ultrasound guidance, a J-tip, 0.035-inch guidewire was advanced up to the SFJ. Over the guidewire, a 5-F long introducer sheath was inserted into the GSV. Depending on the length of GSV to be treated, the inserted length of the sheath varied from 36 cm to 50 cm. Through the sheath, a bare-tipped fiber with a 600-lm diameter and a 980-nm diode laser attached was inserted. The appliance was programmed to pulse for 10 seconds (on) and 1 second using 10W of electricity (off). Under the direction of duplex sonography, the distal laser fiber tip was positioned 2 cm below the SFJ, and its location was verified by direct viewing of the red laser fiber tip targeting beam through the skin. Under cross-sectional sonographic guidance, peri-venous tumescent anesthetic was administered into the fascial region around the GSV. About 400 to 500 cc of tumescent anesthetic solution were used. 20–25 ml of 2% lidocaine buffered with 1.4% sodium bicarbonate in 500 cc of 0.9% saline made up the tumescent anesthetic component. The laser fiber and sheath were then gradually pulled back until they reached one centimeter above the point of penetration in order to prevent skin burn. Patients were instructed to wear full-thigh class II compression stockings (30-40 mmHg) for one week after postoperative bandage compression of 24 hours.

Endovenous chemical ablation:

Air foam 1:4 polidocanol to air ratio by volume, 0.5 ml polidocanol at syringe 3 ml + 2 ml air at syringe 3 ml are making foam, and inject 2.5 ml foam for every 15 cm length of GSV, withdrawal of the catheter at speed of 15 cm/min for the complete distribution of foam to vein endothelium. The Injection was repeated again during catheter withdrawal with maximum volume of 15 ml. at the limb till the removal of the catheter and the sheath. Complete bed rest for the first 6 hours postoperatively. Return to daily activity on the 2nd day. The crepe bandage was left in place for one week (Figures 2 & 3).

All patients had clinical follow-up to check for subcutaneous hematomas, recurrences, ecchymosis, infections, skin ulcerations, burns, nerve injuries, skin pigmentation, and the degree of healing of venous ulcers or chronic discomfort. After one week and six months, duplex ultrasound checks for early and late surgical problems and GSV for (diameter, recanalization). Both the VCSS and VAS were used.

Statistical analysis

On an IBM compatible computer, the acquired data were tabulated and analyzed utilizing SPSS (statistical software for social research), version 25 (IBM, Armonk, NY, USA). Frequency and percent distributions were computed for qualitative data. The mean and standard deviation (SD) for quantitative data were computed. To compare the two groups, the student t-test, Mann-Test Whitney's (U test), and Chi Square Test (X^2-value) were applied. Statistics were deemed significant when $P \leq 0.05$.

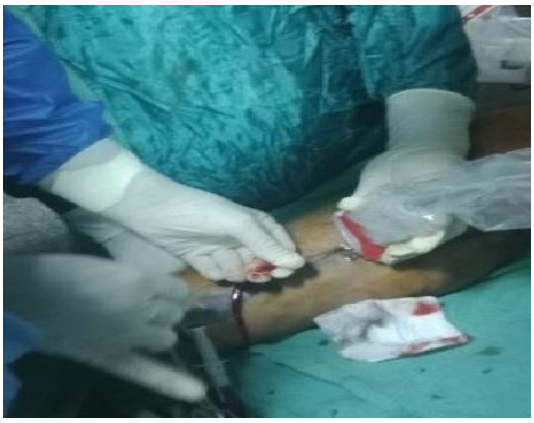

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Figure 1: (A) Puncture of G.S.V duplex guided and introducing of the guide. (B) Duplex ultrasound during introducing of laser catheter.

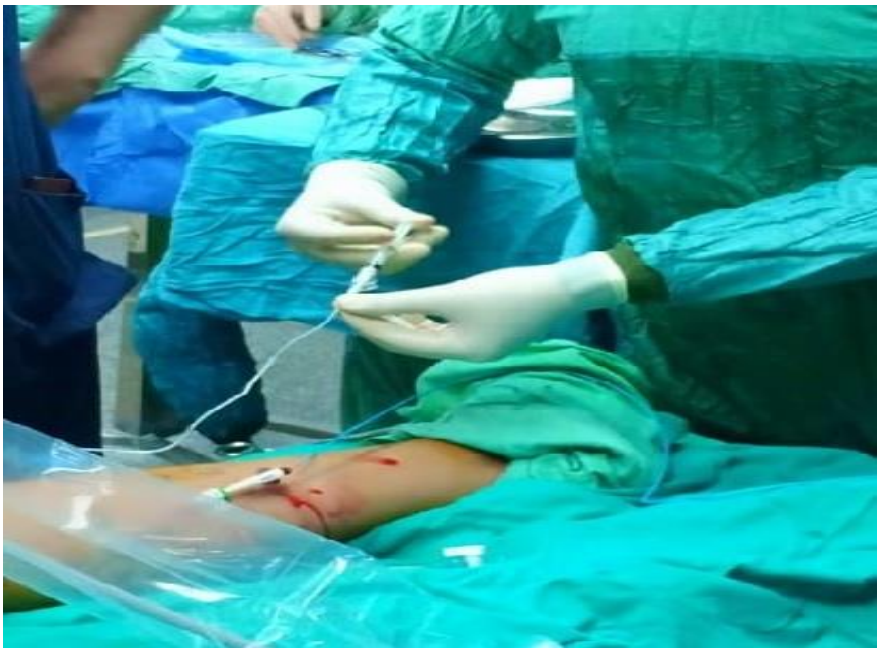

Figure 2: Injection of foam sclerotherapy in varicosities below the knee via butterfly cannula (27G).

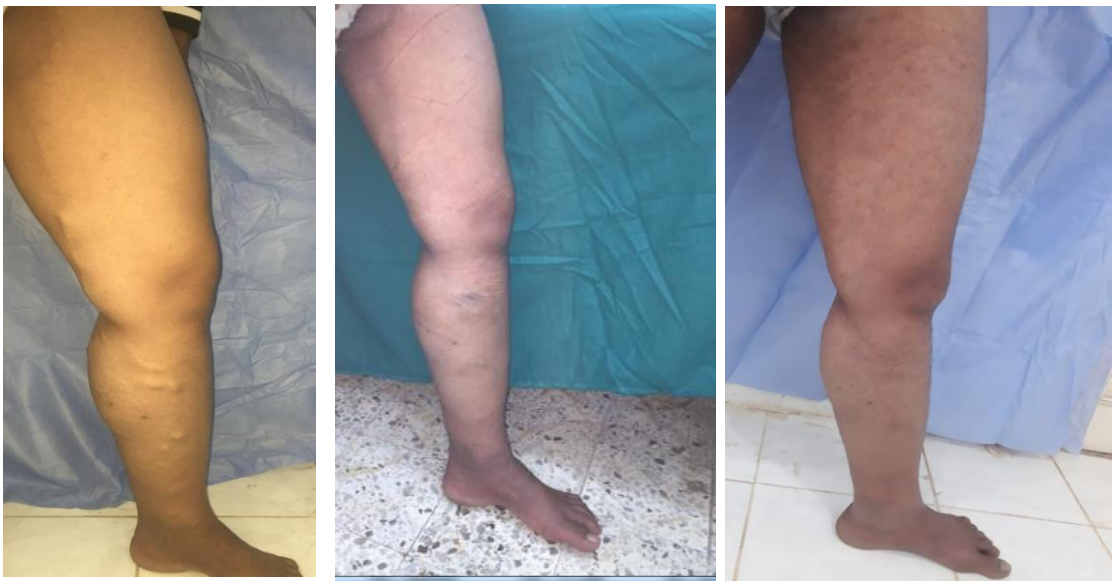

Figure 3: (A) GSV varicosities before operation (B) one week after operation (c) 3 months after operation

Ethical Approval:

The study was approved by the Ethics Board of Al-Azhar University and an informed written consent was taken from each participant in the study. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

RESULTS

A total of 160 patients involved in this research, median age of group A was 37.55 ± 11.46 years and group B was 39.27 ± 8.31 years. Regarding age, sex, and standing patients, there was no substantial variation between the two groups (Table 1).

Table 1: Comparative analysis of the demographics of the two groups

		Group (A) (n=80)	Group (B) (n=80)	*P* value
Age (year)	Mean ±SD	37.55 ±11.46	39.27 ±8.31	0.278
	Range	31 - 46	34 - 48	
Sex	Male	54 (67.5%)	63 (78.8%)	0.108
	Female	26 (32.5%)	17 (21.2%)	
Standing	Yes	63 (78.8%)	55 (68.8%)	0.151
	No	17 (21.2%)	25 (39.2%)	

There was no substantial variation between both groups regarding GSV Caliber 10 cm above Knee (Table 2).

Table 2: Comparison between both groups regarding GSV Caliber 10cm above Knee

	Group (A) (n=80)	Group (B) (n=80)	*P* value
Mean ± SD	11.02 ±2.14	9.92 ±4.57	0.053
Range	7 - 13	8 -11	

After one week of interventions, combined EVLA and chemical ablation group had a higher occlusion rate (100%) compared to (97.5%) for EVLA only group where complete occlusion was more prominent than partial occlusion, however, two patients (2.5%) had a recanalization in EVLA only group with significant difference between both groups regarding complete and partial occlusion (p=0.015 and 0.038). Also, after six months of interventions, percent of complete occlusion increased with one patient has a recanalization in EVLA only group with significant difference between both groups regarding complete and partial occlusion (p<0.001 and 0.028) (Table 3).

Table 3: Comparison between both groups regarding outcome after One week and 6 months of interventions

	Group (A) (n=80)	Group (B) (n=80)	*P* value
After one week			
Complete Occlusion	59 (73.8%)	71 (88.8%)	**0.015***
Partially occlusion	19 (23.7%)	9 (11.2%)	**0.038***
Recanalization	2 (2.5%)	0 (0%)	0.156
After 6 months			
Complete Occlusion	62 (77.5%)	73 (91.2%)	**< 0.001***
Partially occlusion	17 (21.3%)	7 (8.8%)	**0.028***
Recanalization	1 (1.2%)	0 (0%)	0.327

*p value was significant

Regarding VCSS, there was no substantial variation between both groups as regard VCSS before intervention, however, combined EVLA and chemical ablation group has a better significant VCSS after 6 months of intervention. Also, there was a substantial variation between VCSS before and 6 months after intervention in both groups. According to visual analogue scales (VAS), there was no substantial variation between both groups as regard VCSS before and 6 months after intervention. However, there was a substantial variation between VCSS before and 6 months after intervention in both groups (Table 4).

Table 4: Comparison between both groups regarding VCSS and VAS score before and after 6 months of interventions

		Group (A) (n=80)	Group (B) (n=80)	*P* value
VCSS	**Before**	6.48 ± 3.15	7.11 ±3.47	0.231
	After 6 months	3.63 ± 1.29	1.92 ± 1.05	**< 0.001***
	***P* value**	**< 0.001***	**< 0.001***	
VAS	**Before**	7.12 ± 1.82	6.81 ± 1.66	0.262
	After 6 months	2.42 ± 1.25	2.19 ± 1.14	0.225
	***P* value**	**< 0.001***	**< 0.001***	

*p value was significant

Regarding post intervention complications, ELVA only group has a higher significant minor complication in the form of infection in 3 (3.8%) patients, hematoma in 7 (8.8%), ecchymosis in 5 (6.3%) and pigmentation in 2 (2.5%) patients (p=0.002) (Table 5).

Table 5: Comparison between both groups regarding post intervention complication

	Group (A) (n=80)	Group (B) (n=80)	*P* value
Infection	3 (3.8%)	1 (1.3%)	**0.002***
Hematoma	7 (8.8%)	1 (1.3%)	
Ecchymosis	5 (6.3%)	2 (2.5%)	
Pigmentation	2 (2.5%)	0 (0%)	
Total	17 (21.3%)	4 (5%)	

*p value was significant

DISCUSSION

Surgery was regarded as the best method for treating varicose veins (VV) for a very long time. For the treatment of varicose veins, less intrusive techniques have recently gained in popularity (such as EVLA, RFA). Additionally, patients nowadays choose less intrusive treatments than traditional ones since they promote quicker recovery and return to regular activities [(11)].

EVLA of varicose veins is a well-recognized treatment nowadays, with high efficacy and excellent results. Multiple refinements in the laser technology, type, and wavelength and laser fiber design have led to a widespread use of this type of treatment [(12)]. The standard technique of EVLA includes treatment of the above-knee vein segment starting 1.5–2 cm away from the saphenofemoral junction (SFJ) to avoid thermal injury of the common femoral vein with subsequent risk of deep vein thrombosis (DVT). On the other hand, extending laser treatment to below the-knee segment frequently results in saphenous nerve thermal injury with postoperative paresthesia or anesthesia of the medial aspect of the leg and foot, with too many patients failing to improve on long-term follow-up [(13)].

Most of the non-improvement after laser treatment is owing to leaving dilated refluxing leg vein segment with multiple refluxing perforators on one hand, and on the other hand, recanalization of proximal great saphenous with subsequent recurrence after laser treatment referring to insufficient treatment or missing large vein joins the great saphenous proximally. With most of the recurrence after laser ablation occurs at the groin due to recanalization, the concept of missing big refluxing tributary at the proximal segment necessitates the evaluation of the more proximal thermal ablation [(14)].

Sclerotherapy is a medical procedure that involves injecting a solution directly into the vein to eliminate varicose and spider veins. The remedy harms and irritates the blood vessel's lining [(15)]. Foam sclerotherapy provides a number of benefits over liquid sclerotherapy, including the requirement for just a little quantity of sclerosing agent to be injected, the absence of blood dilution, and the homogeneous impact assures along the injected vein [(16)].

It remains undefined whether EVLA alone is better than EVLA plus ultrasound guided foam sclerotherapy (UFS). The best that we can tell that our investigation is a unique one where we combined EVLA with sclerotherapy at the same time for the below-knee vein segment versus EVLA alone below the knee. Additionally popular, UFS with EVLA is less intrusive and more tolerable for both the patient and the operator. In contrast to tributary EVLA with truncal EVLA, **Wang *et al.*** [(17)] showed that simultaneous tributary UFS with truncal EVLA is a promising, practical, and secure therapeutic strategy. **Theivacumar *et al.*** [(18)] revealed that the majority of the varicose veins shrank after EVLA down to the lowest

degree of GSV reflux, negating the need for delayed sclerotherapy.

In the current study, combined EVLA and chemical ablation group has a higher significant occlusion (100%) compared to (97.5%) for EVLA only group where complete occlusion was more prominent than partial occlusion with two (2.5%) patients have a recanalization in EVLA only group. In the study of **Köroğlu *et al.*** [19] 60 lower extremities had concurrent US-guided foam sclerotherapy and 73 EVLA (58 GSV, 15 LSV). The complete occlusion rate for the saphenous veins was 98.64% (72/73) at the six-month follow-up, and the re-canalization rate was 1.36%, which was consistent with the literature. In our trial, no significant problems like deep vein thrombosis, paresthesia, or pulmonary emboli appeared.

Another study by **Yilmaz *et al.*** [20] 504 out of 610 patients who received EVLA for GSV varicosity also underwent concurrent UFS of the varicose veins. Even though a second venous puncture was required in 29 legs. They discovered that EVLA was technically effective in every instance. Concomitant UFS was likewise technically effective in every instance, but in 203 legs with residual varicosities, further sclerotherapy treatments ranged from one to three. Recanalization of the refluxing veins that had been laser-ablated developed in 16 legs (1.7%) during the follow-up and was treated with further EVLA or UFS.

The VCSS is regarded as a superb tool for assessing changes in the clinical severity of varicose illness and superficial venous impairment [23]. With the use of the VCSS and VAS scores, we were able to anticipate and monitor the clinical severity of the condition. Each patient's VCSS values and VAS ratings were compared before treatment and at the sixth month follow-up. Group A (combined EVLA and chemical ablation group) showed a more pronounced drop in VCSS values and VAS scores than did Group B. (EVLA only). In the same line, study of **Köroğlu *et al.*** [19] found that prior to and six-months after receiving EVLA and sclerotherapy, the mean values of the VCSS were 7.01 ± 2.76 and 2.48 ± 1.49, respectively. The mean VCSS decreased in a statistically significant way. 55 individuals had mean VAS scores of 7.51 ± 1.3 before therapy and 2.36 ± 1.84 six months afterwards. It was statistically significant that the VAS score dropped in this way.

Regarding post intervention complications in our study, ELVA only group had a higher significant minor complication in the form of infection in 3 (3.8%) patients, hematoma in 7 (8.8%), ecchymosis in 5 (6.3%) and pigmentation in 2 (2.5%) patients. No one in both groups recorded DVT or nerve injury. **Itoga *et al.*** [21] reported an incidence of DVT after endothermal ablation of around 1.9 and 3.2% at 7 and 30 days after the procedure, respectively. **Shutze *et al.*** [22] found a higher incidence of 5.1% of DVT in their study, whereas in our study, no DVT occurred in all cases. The use of laser for the below-the-knee vein segment with the recommended LEED (60–80 J/cm) is usually associated with the high incidence of saphenous nerve injury [23].

This research contained a number of restrictions: it was (1) prospective but uncontrolled and random, (2) constrained by the single center structure and the paltry patient population, and (3) Long-term monitoring is required for additional research.

CONCLUSION

Combining EVLA and sclerotherapy (chemical ablation) for the below-the-knee long saphenous varicosities offers a very successful method to extend the treatment down to the foot, decrease the incidence of saphenous nerve injury, and decrease the number of treatment session and recurrence, with promising short-term and mid-term follow-up results.

DECLARATIONS

- **Consent for Publication:** I confirm that all authors accepted the manuscript for submission
- **Availability of data and material:** Available
- **Competing interests:** None
- **Funding:** No fund
- **Conflicts of Interest:** The authors declared no conflicts of interest regarding the publication of this paper.

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