

## Original Research Article

# Evaluation of healing of varicose ulcers after endovenous laser ablation of great saphenous vein

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## ABSTRACT

**Background:** Varicose veins are permanently swollen, tortuous and elongated while standing due to back flow of blood caused by incompetent valve closure which result in venous congestion .they are of two types primary and secondary varicosities .The main symptoms are tingling, itching, pain, fatigue, a heavy feeling in the legs especially if one has to stand for a long time. Ulcers and thrombophlebitis are possible complications. The aim of this study is to assess the outcome of laser ablation of great saphenous vein on healing of varicose ulcers.

**Methods:** A prospective study conducted at Suez Canal University Hospitals and Nasser Institute Hospital in Cairo on 20 patients complaining varicose ulcers due to incompetent saphenous femoral junction.

**Results:** All patients had improvement in Aberdeen Varicose vein questionnaire after endovenous laser ablation (EVLA) during the first, second and third follow up visits when compared with preoperative scores. The Aberdeen Varicose vein questionnaire ranged from 8 to 18 before the procedure, with a mean of 12.11, ranged from 3 to 11 at the first follow up visit with a mean of 7.07, ranged from 2 to 10 at the second follow up visit with a mean of 4.89 and ranged from 2 to 10 at the third follow up visit with a mean of 3.85, p value is less than 0.001 compared to the pre-operative data. During the assessment of the patients of our study after 6 months of continuous follow up, we found that the healing rate of the patients who underwent laser ablation of great saphenous vein were (91.67) (p=0.769).

**Conclusions:** EVLA of great saphenous vein leads to better wound healing rates in treating patients with varicose ulcers.

**Keywords:** Healing varicose, Endovenous laser ablation, Varicose vein, Ulcers

## INTRODUCTION

Varicose veins affect up to 30% of the population, causing aching, leg heaviness, Itching and cramps. Objective features include edema, eczema, lipodermatosclerosis and ulceration. Patients may seek treatment because of symptoms or cosmetic appearance.<sup>1</sup> The majority of varicose veins (60-80%) arise from incompetence of the saphenofemoral junction saphenofemoral junction (SFJ) with resultant great saphenous vein great saphenous vein (GSV) reflux. Successful long-term treatment of varicose veins aims to

eliminate the highest point of reflux and the incompetent segments of vein for long saphenous varicosities, the procedure of choice to date has been SFJ ligation, GSV stripping to the knee level and multiple avulsions of the varicosities.<sup>1</sup> Requiring general or spinal anesthesia, this surgery carries significant peri-operative morbidity, hospitalization costs and delayed return to normal activities and work.<sup>1-3</sup> In recent years, Ultrasound guided procedures including endovenous laser ablation (EVLA) and Radiofrequency ablation RFA are claimed to have good clinical results and better patient satisfaction. EVLA is a relatively new, minimally invasive technique that was

primarily developed to treat varicose veins due to SFJ and GSV reflux with high success rates 88-100%.<sup>4</sup>

EVLA uses a laser fiber to deliver laser energy to a target area and form steam bubbles within the vein lumen.<sup>5,6</sup> The steam bubbles generate heat within the lumen of the target vessel, which destroys the endothelial lining of the vessel. This causes an inflammatory reaction that eventually leads to fibrosis.<sup>5-8</sup>

Analysis of prospective studies of endovenous treatments for varicose veins showed that incompetence on duplex ultrasound examination was less likely at 5 years after EVLA than following surgery.<sup>9</sup>

Neovascularization has been implicated as the leading cause of surgical recurrence in several studies with rates as high as 52% at 2 years and 79% at 5 years, neovascularization is thought to be the result of angiogenesis following the tissue trauma of surgical dissection, whereas it is speculated that extra venous inflammation does not occur following EVLA. It has also been suggested that the preservation of groin tributaries during EVLA avoids stimulation of angiogenesis.<sup>9</sup>

The aim of this study is to discuss the clinical benefit in healing of varicose ulcers after laser ablation of great saphenous vein.

## METHODS

A prospective study that was conducted at Suez Canal University Hospitals and Nasser Institute Hospital in Cairo on 20 patients from March 2018 till June 2019 complaining varicose ulcer. Patients suitable for EVLA therapy were chosen according to certain criteria.

### *Inclusion criteria*

Inclusion criteria were patients between 18-60 years old, complicated varicose veins affecting the great saphenous vein, patients with incompetent saphenofemoral junction and patent deep venous system confirmed by duplex ultrasound imaging, patients presenting with pigmentation, eczema, ulceration, and patients with informed consent to be included in the study.

### *Exclusion criteria*

Exclusion criteria were younger than 18 years old and older than 60 years old, patients with secondary varicose veins, patients with general debilitating disease, patients with venous ulcers due to only incompetent perforators with competent saphenous femoral junction.

### *Patient assessment*

*Careful history taking:* With special consideration to the complaint of the patient, history of present illness, past

medical history of the patient and previous surgical interventions.

*Careful clinical examination:* Including general and local examination of the lower limb duplex study was done for all patients the procedures were done under spinal and tumescent anesthesia in all patients, but with proper sedation in irritable patients. The patient was initially positioned in the lateral decubitus position (anti-Trendelenburg) to facilitate cannulation of the GSV. Subsequently, EVLA was performed on the patient lying in the horizontal position without inclination.

Using perivenous tumescent administered subcutaneously and inducing tumescence along the segment of vein undergoing EVLA. EVLA was performed with percutaneous access to the GSV using a diode laser (vena cure laser1470®). An FDA-approved endovenous laser kit was employed, consisting in a 21 G needle, a 6 Fr sheath, a centimeter-scale catheter, and a 45 cm 0.035 steel wire. During the procedure, using a continuous retraction protocol, the energy dose (in joules) was recorded as the probe passed from one segment to the next. As guided by the centimeter scale or the acoustic signal, the operator was able to accurately adjust the pull-back speed.

Under our protocol, 100 J/cm are delivered empirically to the first 3 cm distal to the saphenous femoral junction (to be sure that collapse is locally very effective), thus providing 300 J in this first segment. In the underlying segments, the dose is diminished empirically to (50-70) J/cm.

Following EVLA, compressive stocking 20-25 mmHg was prescribed for 4 weeks. The recommended analgesic therapy was paracetamol 1 g as needed (up to 3 g per day). Technical success is defined as great saphenous vein obliteration assessed by duplex.

### *Follow up*

*All patients were followed up in regards to*

Technical post-operative clinical and diagnostic assessment was scheduled at 1 week, 2 weeks, 1 month, 2 months, 6 months on the following. Healing of venous ulcer and formation of granulation tissue with decrease in the size of the ulcer till complete healing. Post-operative complications minor (pain and ecchymosis) and major (deep venous thrombosis, phlebitis, skin hyperpigmentation, erythema, and infection) complications.

### *Ethical consideration*

The data were collected after permission of the responsible authorities. Written consent was obtained from all patients after full explanation of hazards and benefits of the management procedures that will be performed for each patient before getting them involved

in the study. Introducing myself to the patients and explaining the aim and the benefits of the study to them. Patients will be informed about any complications. Patients have the right to refuse participation without affecting the medical care expected to be offered to them. Patients have the right to withdraw from the study at any time without giving reasons, and this was not affecting the medical care expected to be offered to them. Confidentiality of all data and test results of all the study population will be preserved. All taken photos will be used in research and educational purposes.

**Statistical methods**

Data was recorded in a database sheet which was verified before data entry. SPSS program version 17 was used for data analysis. Comparisons were performed with ANOVA test followed by Tukey’s test for multiple comparison. P value: to find significant relation between two or more percentages for qualitative data, statistical significance if p value <0.05, statistical high significance if p value <0.01, statistical not significant if p value >0.05.

**RESULTS**

All patients had improvement in Aberdeen Varicose vein questionnaire after EVLA during the first, second and third follow up visits when compared with preoperative scores.

The Aberdeen Varicose vein questionnaire ranged from 8 to 18 before the procedure, with a mean of 12.11, ranged from 3 to 11 at the first follow up visit with a mean of 7.07, ranged from 2 to 10 at the second follow up visit with a mean of 4.89 and ranged from 2 to 10 at the third follow up visit with a mean of 3.85, p value is less than

0.001 compared to the pre-operative data statistically significant in (Table 3 and Figure 1).

Baseline characteristics of the patient of the total population and occupation are reported in (Table 1). Regarding body mass index (BMI), it ranged from 19 to 32, with a mean of 26.11±2.84 in (Table 2).

**Table 1: Demographic data of the patients.**

Variables	No.	%	
Gender	Male	15	75
	Female	5	25
Occupation	Workers	10	50
	House wives	2	10
	Drivers	3	15
	Retired from Office work	3	15
	Employee	2	10

**Table 2: Body mass index (BMI).**

Body mass index	Number of patients	%
Less than 18.5	1	5
18.5-24.9	15	75
25-29.9	3	15
30 or more	2	10
Total	20	100

Follow up of all patients table comparison of vein diameter at pre-operative, 1 month, 3 months and 6 months follow up. In Table 4, 18 patients (90%) were satisfied with the procedure; two patients (10%) was unsatisfied due to persistence of symptoms, duplex revealed incomplete occlusion (Table 4 and Figure 1).

**Table 3: Comparison of Aberdeen Varicose vein questionnaire at pre-operative, 1 month, 2 months, and 6 months follow up.**

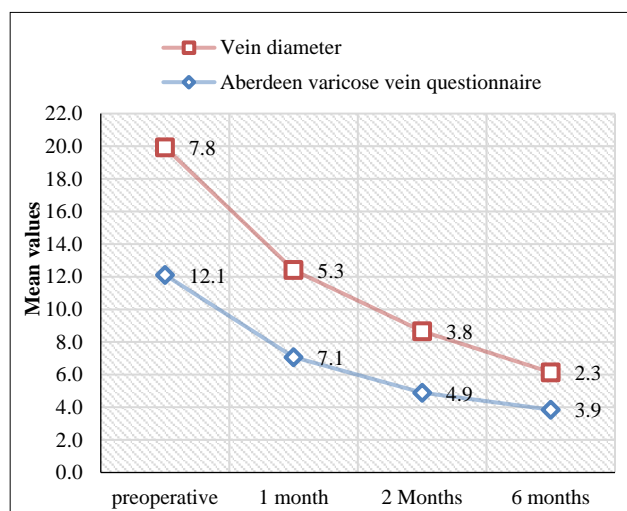
Aberdeen varicose vein questionnaire	Pre-operative	1 month	2 Months	6 months
Mean±SD	12.11±3.04	7.07±2.23	4.89±2.15	3.85±1.83
P value		0.001 <sup>a*</sup>	0.001 <sup>a*</sup>	0.001 <sup>a*</sup>
			0.005 <sup>b</sup>	0.001 <sup>b*</sup>
				0.374 <sup>c</sup>

Data are presented as mean ±SD. Comparisons were performed with ANOVA test followed by Tukey’s test for multiple comparison. <sup>a</sup> vs pre-operative, <sup>b</sup> vs 1 month, <sup>c</sup> vs 2 months. \* Significantly different from normal control, p value >0.05 NS; \*p value <0.05 S.

**Table 4: Comparison of vein diameter at pre-operative, 1 month, 2 months, and 6 months follow up.**

Vein diameter	Preoperative	1 month	2 Months	6 months
Mean±SD	7.82±0.88	5.34±1.16	3.77±1.02	2.29±1.05
P value		0.001 <sup>a*</sup>	0.001 <sup>a*</sup>	0.001 <sup>a*</sup>
			0.001 <sup>b*</sup>	0.001 <sup>b*</sup>
				0.001 <sup>c*</sup>

Data are presented as mean ±SD. Comparisons were performed with ANOVA test followed by Tukey’s test for multiple comparison. <sup>a</sup> vs pre-operative, <sup>b</sup> vs 1 month, <sup>c</sup> vs 2 months. \*Significantly different from normal control, p value >0.05 NS; \*p value <0.05 S.



**Figure 1: Distribution of Aberdeen Varicose vein questionnaire and vein diameter at pre-operative, 1 month, 2 months, and 6 months follow up.**

## DISCUSSION

The objectives of treatment in varicose veins of the lower limbs are to relieve symptoms, improve appearance and to stop deterioration and spread of disease to other connected veins. These objectives can be achieved by addressing the SF reflux and the varicosities.<sup>10</sup> Over the last few decades, there has been a tendency to change from various kinds of in-hospital surgery to ambulatory out-patient settings. The advancements in minimally invasive technology have been the main reasons for this trend.<sup>11,12</sup> The mean age in the present study was 39 years, other studies reported higher mean age (50 years by Carradice et al 52 years by Desmyttere et al, this younger mean age is most probably due to prolonged exposure to risk factors as standing or sitting without rest and lack of physical exercises which let the condition appears earlier.<sup>13,14</sup>

In this study, the family history was positive for varicose veins in 20% of patients, Chang et al reported positive family history in 58.5% of patients, Ergenoglu et al reported positive family history in 43% of patients, lower percent of family history reflecting that most of patients included in the study were affected mainly by the acquired risk factors.<sup>15,16</sup> Doganci et al found that treatment of the GSV by EVLA using a 1470nm laser and a radial fibre resulted in less postoperative pain and better VCSS scores in the first month than treatment with a 980 nm laser and a bare-tip fibre.<sup>17</sup>

However, Duman et al failed to confirm difference in technical success or occurrence of complications between patients treated with 980nm laser and others treated with 1470nm laser, therefore in our study we used diode laser 1470nm, as noted from the previous studies, higher wavelengths is linked to better postoperative outcome.<sup>18</sup>

## CONCLUSION

Twenty lower limbs with varicose ulcers and superficial venous insufficiency due to SFJ incompetence and reflux along GSV were treated with EVLA using 1470 nm diode laser. of them were male and 25% were female, the family history of varicose ulcers was positive in 20%, The BMI ranged from 19 to 32, the patients were 13 limbs were right (65%) while 7 limbs were left (35%). Patients experienced symptom relief after the procedure with decrease in both the venous clinical severity score and Aberdeen Varicose vein. Duplex examination was done for all patients before the procedure and at 1, 2 to 6 months post-operative which showed obliteration of the ablated vein with no flow. Also, it showed progressive decrease in the diameter of the treated vein over the 6 months follow up. Spinal anesthesia or tumescent anesthesia were used in all cases, sedation anesthesia (dormicum or fentanyl) was added in 15 patients (75%), tumescent anesthesia was found sufficient with early postoperative mobilization. Adjunctive procedure in the form of stab was done to eliminate superficial varicosities to obtain the utmost benefit of the procedure.

## Recommendations

EVLA of great saphenous vein with regular dressing can be suggested as the first option for the management of varicose ulcers and primary varicose veins. EVLA of great saphenous vein provides low incidence of complications, and very short post-operative stay and early return to normal activity.

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