

Higher Energy Endovenous Laser Ablation Impact on Varicose Veins

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ABSTRACT

Background: Varicose veins are most common in the superficial veins of the legs, which are subject to high pressure when standing. Endovenous laser therapy (EVLT) is a popular surgical treatment for varicose veins.

Objective: The aim of the present study was to assess the higher energy endovenous laser occlusion rate in treatment of varicose veins.

Patients and methods: This clinical trial study included 18 patients with lower limb varicose veins presented to the outpatient clinic of the Zagazig University Hospital. All patients were assessed clinically to identify symptoms and signs related to venous diseases and duplex ultrasonography was performed. Patients were instructed to remove all dressings after one week, to shower and then to apply class II full length compression hosiery for 3 months.

Results: the mean age of patient's was 35.58 ± 5.93 and BMI ranged from 18.5 to 32, with a mean of 26.11 ± 2.84 . 27.7% have family history in the first degree relative. The operative time ranged from 35 minutes to 70 minutes, with a mean of 55 minutes. Regarding hospital stay, all patients undergoing GSV were discharged at the same day of the intervention.

Conclusion: Endovenous laser treatment of varicose veins in the great saphenous vein with the 1470 nm diode laser is safe and highly effective. Our study suggests that improved outcomes are associated with higher energy EVLA of varicose veins, 95% of cases were successfully treated.

Keywords: Diode Laser, Endovenous Laser Ablation, Varicose Veins.

INTRODUCTION

Varicose veins are veins that have become enlarged and tortuous. The term commonly refers to the veins on the leg, although varicose veins can occur elsewhere. Veins have leaflet valves to prevent blood from flowing backwards (retrograde flow) ⁽¹⁾. Venous hypertension caused by incompetent valves in the superficial veins is by far the most common cause of this condition. It is expected that approximately 25% of women and 15% of men have lower extremity superficial venous insufficiency ⁽²⁾. Great Saphenous Vein (GSV) reflux is the most common underlying cause of significant varicose veins. When the GSV reflux is the principal underlying problem, treatment should involve eliminating this source of reflux with ablation of any associated incompetent venous segment ⁽³⁾.

Although surgical treatment of varicose veins is the traditional one, it has a 30–60% recurrence rate ⁽⁴⁾. Endovenous laser therapy (EVLT) is a popular treatment for varicose veins ⁽⁵⁾. It was firstly introduced in 1998 by Spanish phlebologist, Carlos Bone. Diode lasers are most commonly used for EVLA ⁽⁶⁾. EVLA is performed with a laser fiber introduced into the lumen of the incompetent superficial vein. By applying different wavelengths, different chromophores are used ⁽⁷⁾. Laser devices with higher wavelengths (1320 nm, 1470 nm) are targeting water and act specifically on the vessel wall. Lower wavelengths (810 nm, 940 nm, and 980 nm) used at the earlier stage of the technical evolution have an indirect heat effect on the venous wall by generating vapor bubbles ⁽⁸⁾.

Commonly energy deliveries of around 20-60 J/cm or equivalent influence calculations have been used, but the current best evidence points to improved

results at energies higher than this and many providers now use 80-100 J/cm. Despite this, 100% success remains an elusive goal. The reluctance to increase energy delivery further is most likely due to concerns that this may result in increased morbidity and complications from the procedure. There is however, no evidence that this is the case, when EVLT is performed using tumescent anesthetic solution ⁽²⁾.

Therefore, this study aimed to assess the higher energy endovenous laser occlusion rate in treatment of varicose veins. Also to demonstrate the outcome after EVLA of GSV or small saphenous vein with a 1470 nm diode laser.

PATIENTS AND METHODS

This clinical trial study included 18 patients with lower limb varicose veins presented to the outpatient clinic of the Zagazig University Hospital.

Inclusion criteria: Patients with varicose vein in age from 25 to 58 years. Patients with primary, symptomatic, varicose veins, patients with saphenofemoral junction (SFJ) incompetence or saphenopopliteal junction incompetence.

Exclusion criteria: Patients with tortuous GSV, deep venous incompetence on duplex, non-palpable distal pulsation and inability to ambulate. Inability to give informed consent to trial participation.

Ethical approval:

The study was approved by the Ethical Committee of Zagazig Faculty of Medicine. An informed consent was obtained from all patients in this research. Every patient received an explanation for the purpose of the study. All given data were used



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for the current medical research only. 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.

The following data were obtained from all the patients including patient's demographics as age, sex, occupation, smoking, body mass index and residence. Family History: Similar condition, hypertension, diabetes, cardiac diseases. Past Medical History: History of superficial thrombophlebitis, deep vein thrombosis (DVT) or major limb trauma and usage of anticoagulants (warfarin) or antiplatelet drugs (aspirin, clopidogrel).

All patients were assessed clinically to identify symptoms and signs related to venous disease, Relevant history including the duration and the nature of symptoms (aching, itching, heaviness of leg, ankle swelling). Complete pulse examination was accomplished to exclude peripheral arterial disease. The clinical severity of venous disease was established using CEAP [Clinical, etiological, anatomical and pathological] and Venous Clinical Severity Score (VCSS).

Laboratory investigations :

Complete blood count (CBC), fasting blood sugar (FBS) and (HbA1C) in diabetic patients. Bleeding profile including prothrombin time (PT), international randomized ratio (INR), partial thromboplastin time (PTT), serum urea and creatinine .

Radiological investigations :

Duplex ultrasonography was performed for all patients, the superficial, the deep systems and the perforators were evaluated. The deep system was evaluated for patency, presence of abnormal reflux. The superficial system was evaluated as regarding the SFJ, GSV, SPJ, perforators; measuring reflux time, vein diameter was of great value.

EVLA Procedure:

The procedure was performed under ultrasound guidance. Patients were positioned in reversed Trendelenburg position to permit better GSV and/or small saphenous vein (SSV) visualization. We accessed the GSV and/or SSV via percutaneous technique using the Seldinger method (18-gauge needle) using a 6F, 11-cm-long sheath to introduce the laser fiber. The preferred site access site for the GSV was just below knee. Complementary percutaneous ultrasound guided foam injection sclerotherapy using polidocanol (Aethoxysklerol 1 or 2 %) was done for incompetent perforators and superficial varicosities. Positioning of the laser fiber tip was reconfirmed before starting the procedure. Then, the laser was switched from standby to ready mode and the foot pedal was depressed to deliver energy.

Postoperative and follow up assessments:

All patients received a standard postoperative regimen; dressings were placed over the wounds and crepe bandages wrapped around the treated limbs. Patients were instructed to remove all dressings after one week, to shower and then to apply class II full length

compression hosiery for 3 months. Evaluation was done after one week, one month, 2 months and 3 months following treatment and all limbs were assessed clinically and by using Doppler ultrasound (DUS).

Statistical analysis:

Data were analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) software for analysis. According to the type of data qualitative were represent as number and percentage while quantitative continuous group were represented as mean ± standard deviation (SD) and range.

RESULTS

61.1% of patients were females (Table 1).

Table (1): Age and sex of studied group

Age (years)			35.58±5.93
Sex	Female	N	11
		%	61.1%
	Male	N	7
		%	38.9%
Total			N 18
			% 100.0%

BMI ranged from 18.5 to 32, with a mean of 26.11 ± 2.84 (Table 2).

Table (2): Body mass index (BMI) of studied group

BMI	No. of Patients	%
Less than 18.5	1	5.6
18.5 -24.9	6	33.3
25-29.9	10	55.6
30 or more	1	5.6
Total	18	100

27.8% of the patients had positive family history in the first degree relatives (Table 3).

Table (3): Family history of the studied group

Family history	-VE	N	13
		%	72.2
	+VE	N	5
		%	27.8
Total			N 18
			% 100.0%

Data of CEAP classification are shown in Table 4.

Table (4): CEAP classification of the studied group

CEAP classification	No. of Patients	%
C2	7	38.9
C3	9	50
C4	2	11.1
Total	18	100

Regarding the mean operative time was 55 minutes. Regarding hospital stay, all patients undergoing GSV were discharged at the same day of the intervention. Return to normal activity ranged from 7 to 9 days, with a mean of 7.33 ± 1.46 (Table 5).

Table (5): Operative data of the studied group

Operative data	
Number of studied limb	30
TA	18
Need for adding sedation	12
Amount of energy used: mean (range)	3450 J (2250 to 5000).
The operative time (minutes): mean (range)	55 (35 - 70)
Return to normal activity (days): Mean+SD	7.33 ± 1.46
Hospital stay (days)	1

Regarding clinical outcome, 9 patients had lower limb edema before the procedure, 8 patients showed improvement at the first visit, and 2 patients still showed slower improvement due to prolonged standing (Table 6).

Table (6): Clinical outcome of the studied groups

Symptoms	Preoperative	1 month	3 month	6 month
Pain	13	2	2	0
Edema	9	2	1	1

DISCUSSION

Until the past few years, classic surgical methods of varicose vein removal, mainly vein stripping, were considered as the most radical and effective ways to cope with the pathology. On the contrary, traumatizing nature of these methods yielded several adverse effects, which directed surgeons' attention to less invasive treatment modalities, in particular, endovenous laser ablation (EVLA). Currently, there are two major thermal endovenous treatments available: EVLA, and radiofrequency ablation (RFA) therapy⁽⁹⁾.

Recently energy density utilized since the advent of EVLT has been increased and deliveries of >100 J/cm are now the norm. Studies now need to focus upon the optimal energy required to result in 100% outcome rates and achieve durable one-stop treatment, first time and every time⁽¹⁰⁾.

Therefore, the current study aimed to improve the occlusion rate in the treatment of patients with varicose veins. Additionally, the objective of this study was to demonstrate the outcome and side-effects after EVLA of GSV or small saphenous vein (SSV) with a 1470 nm diode laser,

In our study 18 patients presented in the 25 – 58 years age. This age distribution correlates well with other studies conducted by **Samane et al.**⁽¹¹⁾, who showed the commonest age at presentation to be 31-50 years. However, other study done by **Campbell**⁽¹²⁾ showed the commonest age at presentation to be 30-40 years. The mean \pm SD age of the study population was to be

35.58 ± 5.93 years. This finding was in agreement with a study by **Aly et al.**⁽¹³⁾ who conducted 231 participants with a mean age of 34.6 years. The majority of the patients in the study were less than 58 years. So, it is the disease, which affects the youth and the bread-earning members of the society. The age range in the present study is almost similar to the study done by **Khan et al.**⁽¹⁴⁾ and **Singh et al.**⁽¹⁵⁾ in their study.

Out of a total of 18 patients in the present study, 11 (61.1%) were female as compared to males. This probably has a lot of similarities to other studies. **Mirji et al.**⁽¹⁶⁾ found 25% of the total patients in their study were females as compared to males who were 75% of total cases.

The current study observed 10 (55.5%) overweight patients with mean body mass index (BMI) (\pm SD) to be 26.11 ± 2.84 Kg/m² (range, 18.5 - 32 Kg/m²). These findings go with the study conducted by **Samane et al.**⁽¹¹⁾. Moreover, the study of **Aly et al.**⁽¹³⁾ observed more than two-fifths of the participants (43.3%) were overweight (BMI 25- 29.9)

Additionally, the majority of 27.7% patients in our study were having family history. This finding is consistent with those of previous studies showing that family history is a risk factor for varicose veins^(17,18).

According to the presenting symptoms, the current study revealed that pain was found in 72.2% of patients, and cosmetic appearance was found in 27.7% of patients. This result agreed with the study of **Aly et al.**⁽¹³⁾. This finding also correlates well with other study done by **Chen et al.**⁽¹⁹⁾ with cosmetic symptoms being 90% and aching pain 57%.

On the other hand, **Samane et al.**⁽¹¹⁾ found the commonest symptom in 60 (100%) cases was that of dilated, tortuous veins, 26 (43.3%) cases had complaints of pain in the affected limb and 24 (40%) cases had limb edema, and venous ulcer was present in 4 (6.7%) of cases.

The C of the CEAP classification was used to score the clinical severity of each affected limb⁽²⁰⁾. The current study shows 7 patients (38.9%) classified as C2 (varicose veins), 9 patients (50.0%) classified as C3 (varicose vein and edema), and 2 patients (11.1%) classified as C4 (varicose vein, edema, and skin lesions). **Labropoulos et al.**⁽²¹⁾ carried out a longitudinal study comprising 116 limbs from 90 patients presenting with symptomatic chronic venous disease, they found 43.8% had C2 disease, 23.3% had C3 disease, and 13.8% had C4 disease, respectively.

The operative time of EVLA ranged from 35 minutes to 70 minutes, with a mean of 55 minutes. However, regarding the hospital stay, all patients were discharged on the same day of the intervention. Return to normal activity ranged from 7 to 9 days, with the mean \pm SD of hospital stay was 7.33 ± 1.46 says. These findings are in accordance with the study of **Osman et al.**⁽¹⁰⁾ who reported, the operative time and hospital stay between their studied groups were significantly low in group A, ranged from 30-90 min with mean \pm SD of 59.00 ± 17.815 min and the hospital stay ranged from 5-

10 hours with mean \pm SD of 6.90 ± 1.447 hours, respectively.

Al-Saeed and Saleh ⁽²²⁾ concluded that, EVLA of the saphenous veins is safe and has excellent early and mid-term outcomes for treatment of superficial venous insufficiency with or without ulceration of the lower extremities.

CONCLUSION

Endovenous laser treatment of varicose veins in the great saphenous vein with the 1470 nm diode laser is safe and highly effective. Our study suggests that improved outcomes are associated with higher energy EVLA of varicose veins, 95% of cases were successfully treated and 91% of treated veins were completely eradicated.

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Conflict of interest: Nil.

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