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Assessment of Higher Energy Endovenous Laser Ablation of Varicose Veins

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Abstract

Background: Varicose veins are veins that have become enlarged and tortuous. The term commonly refers to the veins on the leg. Endovenous laser therapy (EVLT) is a popular treatment for varicose veins. The study aimed to assess improvement the occlusion rate in the treatment of patients with varicose veins. Patients and methods: this study involved 18 patients with lower limb varicose veins presented at Zagazig University Hospital. All patients were examined clinically to identify symptoms and signs related to venous diseases and duplex ultrasonography were performed. Evaluation was done after one week, one month, 2 months and 3 months following treatment. Results: All patients had improvement in VCSS after EVLA during the first, second and third follow up visits when compared with preoperative scores. The VCSS ranged from 5 to 15 before the procedure, with a mean of 8.89, ranged from 1 to 6 at the first follow up visit with a mean of 3.4, ranged from 1 to 5 at the second follow up visit with a mean of 2.5 and ranged from 0 to 4 at the third follow up visit with a mean of 1.6. CIVIQ in the legs of studied group: Pre-operative was14.42 ± 7.29 while after 6 month was 7.64 ± 4.62. Only Ecchymosis in 2 limbs (6%), Paresthesia at leg in 3 limbs (9%), Phlebitis 4 limbs (12%),Skin burn in one limb (3%)and Incomplete occlusion in one patient(4%). Conclusion: Higher energy EVLA of varicose veins showed faster recovery attributable to the decreased pain, immediate ambulation and faster return to everyday activities. Patients experienced symptom relief after the procedure with decrease the VCSS and CIVIQ in both.

Keywords: Varicose Veins; Endovenous Laser Ablation; Diode Laser

INTRODUCTION

Venous hypertension caused by incompetent valves in the superficial veins is by far the most common cause of this condition **(1).** 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 **(6).** 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%) **(7).** Diode lasers are most commonly used for EVLA **(8).**

EVLA is performed with a laser fiber introduced into the lumen of the incompetent superficial vein. By applying different wavelengths, different chromophores are used **(9).** 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 **(10).**

Therefore, the aim of the present study was to assess the higher energy endovenous laser occlusion rate in treatment of varicose veins and to demonstrate the outcome and side-effects after EVLA of GSV or small saphenous vein with a 1470 nm diode laser.

ISSN 2515-8260 Volume 08, Issue 04, 2021

PATIENTS AND METHODS:

A Clinical trial study included 18 patients with lower limb varicose veins presented to theoutpatient clinic of the Zagazig University Hospital. After obtaining approval by the Research Ethics Committee, patients undergoing management of lower limb varicose veins at Zagazig University Hospital were involved in the study.

Inclusion criteria:

Patients diagnosed by varicose vein aged from 25 to 58 years. Patients with primary, symptomatic, varicose veins, with sapheno-femoral junction (SFJ) incompetence. Patients with sapheno-popliteal junction incompetence.

Exclusion criteria:

Patients with tortuous GSV, deep venous incompetence on duplex, inability to give informed consent to trial participation, non-palpable distal pulsation, inability to ambulate, patients with previous history of deep venous thrombosis (dvt) and pregnant women**.**

Clinical assessment:

All patients were assessed clinically to identify symptoms and signs relatedto venous disease, Relevant history including the duration and the nature of symptoms (aching, itching, heaviness of leg, ankle swelling).

The clinical severity of venous disease was established using CEAP [Clinical, etiological, anatomical and pathological] and Venous Clinical Severity Score(VCSS). Further the effect of disease specific quality of life was determined using the Chronic Venous Insufficiency Questionnaire(CIVIQ).

In VCSS, each patient is given a score between 0 and 30 according to 10 parameters (pain, varicose veins, edema, pigmentation, inflammation, induration, number of ulcers, duration of ulcers, size of ulcers, compressive therapy) which are graded 0 to 3 (absent, mild, moderate, severe).

In CIVIQ, each patient completed the 20-question CIVIQ quality of life questionnaire after being translated to Arabic. The CIVIQ comprises 20 questions in four quality-of-life domains: physical, psychological, social, and pain. All questions have a 5-point response category, with higher scores reflecting more severe impairment, and the global scores, were transformed into a scale of 0–100.

EVLA Procedure:

The procedure is performed under ultrasound guidance. Patients are positioned in reversed Trendelenburg position to permit better GSV and/or 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 is just below knee

Post-operative evaluation:

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.

Follow up:

Evaluation was done after one week, one month, 2 months and 3 months following treatment and all limbs were assessed clinically and by using DUS. Primary end points were the technical success rate, complication rate (bruising, hematoma, phlebitis, skin burn, pigmentation and DVT), time to return to normal activity, Pain scores and quality of life (QOL) were recorded using visual analog scale,VCSS andCIVIQ.

Statistical analysis

Data analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0). According to the type of data qualitative represent as number and percentage, quantitative continues group represent by mean ± SD, the following tests were used to test differences for significance, difference and association of

ISSN 2515-8260 Volume 08, Issue 04, 2021

qualitative variable by Chi square test (X2). Differences between quantitative independent groups by t test. P value was set at <0.05 for significant results &<0.001 for high significant result.

RESULTS:

The obtained results showed 12 patients had bilateral limbs affected (66.6%), out of total limbs and 6 cases were unilateral (4 limbs were right while 2limbs were left) **(Table 1)**. The presenting symptoms: pain was in 13 patients (72.3%) on the other hand only cosmetic appearance was present in5 patients (27.7%) **(Table 2)**.

All patients had improvement in VCSS after EVLA during the first, second and third follow up visits when compared with preoperative scores. The VCSS ranged from 5 to 15 before the procedure, with a mean of 8.89, ranged from 1 to 6 at the first follow up visit with a mean of 3.4, ranged from 1 to 5 at the second follow up visit with a mean of 2.5 and ranged from 0 to 4 at the third follow up visit with a mean of 1.6 **(Table 3)**. CIVIQ in the legs of studied group: Pre-operative was14.42 ± 7.29 while after 6 month was 7.64 ± 4.62 **(Table 4)**.

Only Ecchymosis in 2 limbs (6%), Paresthesia at leg in 3 limbs (9%), Phlebitis 4 limbs (12%),Skin burn in one limb (3%)and Incomplete occlusion in one patient(4%) **(Table 5)**. About 17 patients (96 %) were satisfied with the procedure; one patient (4%) was unsatisfied due to persistence of symptoms, duplex revealed incomplete occlusion **(Table 6)**.

Regarding radiological outcome, second duplex follow up showed decreased caliber of GSV as compared with the first duplex and with the preoperative measurements. The diameter of the vein in the upper thigh ranged from 2.7 to 5.7 with a mean of 3.77 with no flow in the GSV **(Figure 1)**.

Table (1): Distribution of cases according to bilaterality

Bilateral	**N**	12
	%	66.6
Unilateral	**N**	6
	%	33.4
Total	**N**	18
	%	100

Table (2): Main complain distribution between studied group

Pain	**N**	13
	%	72.3%
Cosmotic	**N**	5
	%	27.7
Total	**N**	18
	%	100.0%

Table (3): Comparison of VCSS at pre-operative, month, 3 and 6 months follow up

ISSN 2515-8260 Volume 08, Issue 04, 2021

Venous clinical severity score (VCSS)	Preoperative	1month	3month	6month
Mean ± SD	8.89 ± 2.98	3.41±1.47	2.52±1.40	1.63±1.15
P Value		0.001[*a]	0.001[*a]	0.001[*a]
			0.313[b]	0.004[*b]
				0.313[c]

[a]vs Pre Op, [b] vs 1 month, [c] vs 3 months.* Significantly different from pre-operative .

Table (4): CIVIQ in the legs of studied group

CVIQ: Pre-operative	
Mean ± SD	14.42 ± 7.29
Range	37 – 58
CVIQ: after 6 months	
Mean ± SD	7.64 ± 4.62
Range	14– 32

Table (5): Complication of the procedure

Complication	N. of patients	%
Ecchymosis	2	6
Paresthesia	3	9
Incomplete occlusion	1	3
Phlebitis	2	12
Skin burn	1	3
DVT	0	0

Table (6): Patients satisfaction

	N. of patients	%
patients satisfied	17	96
patients unsatisfied	1	4

Figure (1): Long Saphenous Vein, Pre-operative, at first and second follow up visits

DISCUSSION

Varicosity of the lower limb is a common clinical problem. Varicosities often start early in life but assume a silent course for a variable length of time, before they develop complications due to venous hypertension **(11)**. Varicose veins belong to the most frequent

lifestyle diseases, as they affect up to 40% of industrialized countries' citizens in the age between 30 and 60 years (**12**).

Although EVLA has been demonstrated to effectively occlude incompetent saphenous veins, it does not treat branch varicosities directly, thus requiring an ambulatory phlebectomy or follow-up sclerotherapy. For the treatment of leg veins smaller than 4 mm in diameter, sclerotherapy has been considered to be the criterion standard **(13)**.

This study involved 30 limbs, had bilateral limbs affection while the rest had only one limb affected; GSV was refluxing in all limbs, TA was used in all cases while sedation was added in 15 cases (83.6%), amount of energy used ranged from 2250 to 5000 J with a mean of 3650 J.

The current study showed that, the majority of 12 (66.6%) patients had bilateral limbs affected, and 6 (33.4%) of patients were 2 unilateral limbs, out of these limbs there were 4 veins were on the right limb and were on the lift limb.

In a study of **Samane et al.(12)** revealed a right limb involvement of 36.7% (22 patients) and the left limb involvement of 45.0% (27 patients), favourably compares with the study conducted by **Das et al.** (**14**). The cause for the increased incidence of left side is not known. This is probably because that the loaded left colon constantly compresses the left iliac veins, the left common iliac artery crossing over the left common iliac vein and the longer course traversed by the left iliac veins.

Ultrasound was performed at that time to assess the GSV and deep venous system. Criteria for the technical success of EVLA were a decrease in the diameter of GSV (**15**).Moreover, the current study in pre-treatment shows the mean ± SD of vein diameter was 9.82 mm and ranged from (6.6 - 12.6 mm).

The present study involved 30 limbs, had bilateral limbs affection while the rest had only one limb affected; GSV was refluxing in all limbs, all patients using spinal anesthesia with tumescent anesthesia (TA) in EVLA, while sedation was added in 12 cases (66.6%), amount of energy used ranged from 2250 to 5000 J with a mean ±SD of 3450 J. In the study of **Osman et al**. (**15**) revealed the spinal anesthesia was the common type of anesthesia in their studied groups and local anesthesia was used in selected patients in group A 2 (10%) and group B 1 (5%).

The current study suggested that the mean average LEED (J/cm) was 108.8 ± 13.35, ranged from (100-120J/cm) in EVLA group. **Pannier et al.(16)** showed that using a 1470 nm diode laser with a radial fiber EVLA has a very high occlusion rate after six months.

In comparison of VAS between pre-treatment and post-treatment follow-up 1st month, 3rd month, and 6th month, the results of pain score from all patients can be seen in the chart. The current study shows the pain score in 13 (72.2%) of patients had lower limb pain pre-treatment, compared with 2 (11.1%) patients in the 1st and 3rd-month post-treatment. While there were 9 (50%) of patients had lower limb edema pre-treatment, compared with 2 (11.1%) patients at the 1st month and one patient (0.55%) at 3rd and 6th month still showed slower improvement due to prolonged standing. These findings were in concordance with the result of **Chen et al.** (**17**).

In the current study, all patients had improvement in VCSS post-treatment shows with a significantly lower VCSS were reported in higher energy EVLA after six months post-operative than pre-operative, P= 0.001.

The results of pain score in a study of **Chen et al.**(**17**) from all the 31 patients can be seen in the chart; the score of one-month post-operation was 1.32 ± 0.64, significantly different from that of one week pre-operative (4.56 ± 1.89). So they considered that the patients recovered well and the operation did not increase magnificent complications, especially the pains. Paired t-test showed that the *t*-value was 8.048 ($P < 0.05$), showing significant differences.

As regard to phlebitis in our study; it was significantly higher in EVLA in 6 limbs (12%) due to foam injection of superficial varicosities; with no phlebitis detected due to vein ablation. The present study shows no DVT, pulmonary embolism or any other serious complications related to the procedure recorded. This may be explained by early ambulation to maintain deep vein and SFJ tributary flow and the use of the correct distance for the fiber optic

catheter and recent radial fiber during the ablation which prevented thrombi from extending into the deep venous system.

Insufficient energy delivery into the vessel wall can be caused by several factors, including excessively rapid or inconsistent pullback rates, insufficient tumescent anesthesia, variations in vein diameter, and inconsistent tissue heat resistance (**18**).

The CIVIQ was applied to assess the patients' QOL one week before varicose vein surgery (defined as CIVIQ-1) and at least 1 month after treatment (defined as CIVIQ-2). The scale contained four dimensions (20 questions), namely pain, physical dimension, social function, and psychological dimension. There are five grades to each question using 10 cm visual-analog scale (from 1 to 5 points accompany with the serious situation). CIVIQ scores vary from 20 (refer to very poor QOL) to 100 points (very good QOL) (**19 ; 20**).

In the present study, all patients had improvement in CIVIQ after procedure with a significant improvement in higher energy EVLA after six months post-operative, P<0.0001. This finding in concordant with the study of **Chen et al**. (**2013**) who demonstrated that, the life quality has significantly improved after operation of EVLA. Paired t-test showed that t value was 12.71 with significant differences (P< 0.05).

Our findings suggest that greater energy delivered per unit of vein length can result in improved procedural success rates.

Boersma et al. (**21**) documented the efficacy and safety of endovenous in treatment of incompetence of short saphenous veins and its success rate was 97.7-99.2%. Similar results were verified in this study.

In the current study no major complications occurred at these higher energy doses. The 9% parenthesis, Phlebitis 4 limbs (12%), skin burn in one limb (3%) and incomplete occlusion in one patient (4%) incidence is consistent with other published studies.

Skin burns are rare following EVLA and the recorded rate in different studies varies from 0-4% and its incidence was negativelycorrelated with amount of the injected tumescent anaesthesia (**21 ; 22**).

Chen et al. (17) reported the major complications such as deep vein thrombosis and skin burns were not found. Most of the complications were minor and improved quickly.

CONCLUSION

Higher energy EVLA of varicose veins showed faster recovery attributable to the decreased pain, immediate ambulation and faster return to everyday activities. Patients experienced symptom relief after the procedure with decrease the VCSS and CIVIQ in both.

Using of high wavelength laser (1470 nm) with modified fiber tip (radial emission) with tumescent solution has a crucial role in achieving best results and minimizing the adverse effects. This allows a homogeneous destruction of the vein wall exclusively, without any risk of damage to surrounding tissues, and also successful ablation of large sized vein diameter.

No conflict of interest

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