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EVALUATION OF FLUSH ENDOVENOUS LASER ABLATION OF THE GREAT SAPHENOUS VEIN UP TO THE SAPHENOFEMORAL JUNCTION

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Abstract:

Background: Varicose vein disease is one of the most common health problems faced by vascular surgeons worldwide affecting up to 23% of adult population. The majority of patients with primary varicose veins have great saphenous vein (GSV) insufficiency.**Objective:**To determine the feasibility and safety of flush Endovenous laser ablation (EVLA) of the patients with Great saphenous vein (GSV) up to the saphenofemoral junction.**Patients and Methods:**A prospective study was conducted in Vascular Surgery Department, Faculty of Medicine, at Zagazig University at period from January 2021 to June 2021 including 18 cases. All patients were subjected to detailed history taking, Clinical examination, the clinical severity of venous disease was established using CEAP [Clinical, etiological, anatomical & pathological] and VCSS, the effect of disease specific quality of life was determined using the CIVIQ, Laboratory Investigations and duplex ultrasonography performed for all patients.**Results**:The operative time, it ranged from 20 minutes to 40 minutes, with a mean of 30 minutes. Regarding hospital stay, all patients 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. as regard complications; only Ecchymosis in 2 limbs (7%), Temporary numbness at leg in 3 limbs (11%) and Incomplete occlusion in one patient (4 %).**Conclusions:** That using of high wavelength (1470nm) with modified fiber tip with tumescent solution have a crucial role in achieving best results and minimizing the adverse effects. This allow a homogenous destruction of the vein wall exclusively.

Keywords: Varicose vein , Endovenous Laser Ablation, Great Saphenous Vein,

INTRODUCTION

Varicose vein is considered one of the most common presentations at the vascular clinics; it affects both sex and different age groups, with incidence of up to 40% of the population[(1)].

Traditionally, varicose veins were treated with Trendelenburg and stripping for many decades. Since the start of the 90 in 20 century, new techniques were introduced with subsequent refinement and advance in technology as endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) [(2,3)].

Patients with varicose veins may complain of unsightly appearance, aching, heaviness, pruritus, and early fatigue of the affected leg. These symptoms worsen with prolonged standing and sitting and are relieved by elevation of the leg above the level of the heart. Also, mild edema is often present. More severe signs include thrombophlebitis,hyperpigmentation, lipodermatosclerosis, ulceration, and bleeding[(4)].

A desired consequence of varicose vein therapy is relief from persistent varicose veins. However, current literature indicates that both high ligation and stripping (HL/S) and endovenous laser ablation (EVLA) have a similar high long-term (>5 years) varicose vein recurrence rate[(5,6)].

In approximately one-third of patients, long-term recurrence (> 5 years) after EVLA of the great saphenous vein (GSV) has been documented in practice[(7)]. However, compared to HL/S, where neovisualization tends to be an inept proximal saphenous stump interacting with junctional tributaries at a regular source of reflux (between 8% and 31%)[(8)].

In EVLA, the most common scenario is the propagation of the incompetence from the saphenofemoral junction (SFJ) down the anterior accessory saphenous vein. Not only the GSV, but also all SFJ tributaries were connected during HL/S, specifically for the purpose of reducing recurrence. The GSV is normally ablated up to 1 to 2 cm distal to the confluence of the GSV and common femoral vein (CFV) during EVLA, leaving a GSV stump to mitigate potential thrombotic complications[(3,9)].

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The development of such a postoperative thrombus is called endovenous heat-induced thrombosis (EHIT) at the end of the ablated GSV and is indeed a well-recognized complication following endovenous thermal ablation procedures[10,11].

Compared to first generation front-firing fibers, technological advances, such as the production of radially emitting fibers, could reduce the risk of EHIT during flush EVLA (fEVLA)[11]. This study is aimed todetermine the feasibility and safety of flush Endovenous laser ablation (EVLA) of the patients with Great saphenous vein (GSV) up to the saphenofemoral junction.

PATIENTS AND METHODS

A prospective study was conducted in Vascular Surgery Department, Faculty of Medicine, at Zagazig University at period from January 2021 to June 2021 including 18 with Great saphenous vein (GSV), the duration of the study was from 6 months.Written informed consent was obtained from all participants. The study was approved by the research ethical committee of Faculty of Medicine, Zagazig University. The work has been carried out in accordance with The Code of Ethics of the World Medical Association (declaration of Helsinki) for studies involving humans.

We considered the following Inclusion criteria: Age from 25 – 60 years, both sex. Patients with previous history of deep venous thrombosis (DVT). Patients diagnosed by varicose vein recurrence after ELVA. Patients with symptomatic GSV.Patients with SFJ 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, Pregnant women, Bleeding tendency, Patients have a pacemaker or internal defibrillator, Patients are treated with anticoagulants.

Method:

A comprehensive history was taken from each participant. Clinical examination had been done including a full history especially history of varicose veins disease. Past medical history of hypertension, diabetes, cardiac diseases, superficial thrombophlebitis or deep vein thrombosis (DVT).

General Examination Including cardiovascular, respiratory & abdominal examination. Complete pulse examination was accomplished to exclude peripheral arterial disease. The clinical severity of venous disease was established using CEAP [Clinical, etiological, anatomical & pathological] and VCSS. Further the effect of disease specific quality of life was determined using the CIVIQ.

a) In VCSS, each patient was 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).b) In CIVIQ, each patient completed the 20 question Chronic Venous Insufficiency Questionnaire (CIVIQ) quality of life questionnaire after being translated to Arabic. The CIVIQ comprises 20 questions in four quality of life domains (Physical, psychological, social & 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.

Laboratory Investigations included; Complete blood count (CBC), Fasting blood sugar (FBS) and (HbA1C) in diabetic patients, Bleeding profile, Serum urea and creatinine.

Duplex ultrasonography 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 is of great value. The presence of retrograde flow lasting >0.5s was considered significant. Before surgery, precise mapping (Cartography) was done using duplex-scanning method from the groin to the ankle to highlight tortuous veins, areas of ectasia and incompetent perforators.

Intraoperative performance and techniques used:

The surgical procedure was performed with the patient under spinal anesthesia. Tumescent solution [(5 mL epinephrine + 5 mL bicarbonate) and 35 mL lidocaine 2 % diluted in 500 mL saline solution or Ringer's lactate)] was administered into the perivenous space under US guidance using a syringe or mechanical infusion pump.

EVLA procedure: Venous access was obtained by a puncture with a 6 F. needle under US guidance using the Seldinger method as mentioned before.

The insufficient GSV was entered at knee level or below because of ease of access (i.e. Large diameter and linear course) with the least risk for nerve injury. After the guide wire was in place, the needle was removed & an introducer sheath was passed over the guide wire. After activation, the laser was pulled back continuously with a pull-back speed of 1–3mm/s according to vein diameter. Positioning of the fiber tip was then reconfirmed before starting the procedure. Then, the laser was switched from standby to ready mode and the foot pedal was depressed to deliver energy. Power was set at 10 W; the mean energy delivered was ranged from 70 – 90 J/cm for treatment of

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incompetent GSV. Continuous pullback was used while we watched the real-time energy readout on the generator and gauged speed with the 1 cm marks on the sheath delivering 70– 90 J/cm according to the vein diameter To prevent skin burns or trauma to the entry site, we stopped treatment by removing the foot from the pedal when the tip of the laser fiber was approximately 1–3cm above the entry site, followed by removal of the fiber and sheath. Closure of the vein was visualized with duplex ultrasound to identify an increase in echogenicity of the venous wall to ensure complete ablation. Complementary percutaneous ultrasound guided foam injection sclerotherapy using polidocanol (Aethoxysklerol 1 or 2 %) was done as mentioned in RF procedure. Compressive bandage or long compressive stocking class II was indicated for 1weeks. Patients were discharged at the same day of the procedure.

Follow-up:

All patients were followed-up on an outpatient basis for physical examination and duplex ultrasound by an experienced vascular physician at day 7, and week 6 after the procedure. A day 7, the eccentric compression dressing was removed, and the presence of possible complications, such as relevant bleeding, hematoma, dysesthesia, and superficial vein thrombosis, were recorded. Duplex ultrasound of the superficial and deep venous system was performed, assessing for successful saphenous vein ablation and deep venous thrombosis. The distance of the occluded GSV of thrombus in relation to the SFJ, named 0-point distance (0-PD), was also recorded. Compression stocking was recommended for another 2 to 3 weeks except during sleep and bathing.Evaluation was done after one week, three month and six months months following treatment and all limbs were assessed clinically.

Statistic analysis

Data were checked, entered and analyzed using SPSS version 23 for data processing. The following statistical methods were used for analysis of results of the present study. Data were expressed as number and percentage for qualitative variables and mean + standard deviation (SD) for quantitative one. The threshold of significance was fixed at 5% level (P-value).

RESULTS:-

Table (1): Age and sex distribution between studied group

Age(years)			35.58±5.93
Sex	**Female**	**N**	14
		%	77.8%
	Male	**N**	4
		%	22.2%
Total		**N**	18
		%	100.0%

Table 1; showed that 77.8% of patients were female and 22.2% male mean age of patient's was35.58±5.93.

Table (2): Body mass index distribution between studied group

BMI	No. of Patients	%
Less than 18.5	1	5.6
18.5 -24.9	6	33.3
25-29.9	2	11.1
30 or more	9	50
Total	18	100

Table 2; showed that body mass index (BMI), ranged from 18.5 to 32, with a mean of 26.11±2.84.

Table (3): Main complaint distribution between patients

Main complaint	**Pain**	**N**	13
		%	72.2%
	cosmetic	**N**	5
		%	27.8
Total		**N**	18
		%	100.0%

The presenting symptoms: pain was in 13 patients (72.2 on the other hand only cosmetic appearance was present in5 patients (27.8%) table 3.

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Table (4): Other complaint associated with pain

Complaint	**Leg ulcer**	**N**	1
		%	5.5
	Oedema	**N**	12
		%	66.6
Total		**N**	13
		%	100.0%

Other complain associated with pain was in 13 patients (72.2%), out of those, 12patients (66.6%) had oedema, out of them leg ulcer in 1 patient (5.5%) table 4.

Table (5):CEAP classification

CEAP classification	No. of Patients	%
C2	7	39
C3	9	50
C4	1	5.5
C5	1	5.5
Total	18	100

Table 5; showed that CEAP classification 7 patients were C2 (38.9), 9 were C3 (50%), while only 1 was C4 (5.5%) and 1was C5 (5.5%).

Table (6): Operative data:

Operative data	
Number of cases	18
Spinal anesthesia with Tumescent solution	18
Need for adding sedation	2
Amount of energy used	3450 J (2250 to 5000) . 3450 +/- 852.9
The operative time (minutes)	30(20- 40) 30 +/-4.85
Return to normal activity (days)	(7-9) 7.33 +/- 1.46
Hospital stay(hours)	(3-4)

This study involved 18 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 2cases , amount of energy used ranged from 2250 to 5000 J with a mean of 3450 J table 6. Regarding the operative time, it ranged from 20 minutes to 40 minutes, with a mean of 30 minutes. Regarding hospital stay, all patients 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 (7): Complication of the procedure

Complication	N . of patients	%
Ecchymosis	2	11,1
Temporary numbness at leg	3	16.6
Incomplete occlusion	1	5.5
Heat induced thrombosis	0	0

Only Ecchymosis in 2 limbs (1.1%), Temporary numbness at leg in 3limbs (16.6%) Incomplete occlusion in one patient (5.5%).and heat induced thrombosis (0%) table 7.

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DISCUSSION:

As regard clinic-demographic characteristics among the patients 77.8% of patients were female and 22.2% male mean age of patient's was 35.58±5.93. Body mass index (BMI), ranged from 18.5 to 32, with a mean of 26.11 ± 2.84.

However, in the study of **Spinedi et al.**[12]the majority of them (77%) were females with mean age 56.7 ± 15.3 years. Their mean BMI was 24.9 ± 4.3.Also, **Zied** [13] demonstrated that the total number of patients in this study was 125 patients, involving 132 limbs. There were 37 (29.6%) male and 88 (70.4%) female patients, with male to female ratio of 1: 2.4. The main age was 40.4±11.8 years.

The present study has some limitations including small sample size, short time of study which is not enough to detect long term complication like recurrent.

On the other hand only cosmetic appearance was present in 5limbs (27.8%). Other complain associated with pain was in 13 patients (72.2%), out of those,12 patients (66.6%) had oedema, out of them leg ulcer in 1 patient (5,5%).

Our results were supported by study of **Zied**[13]as they reported that a total of 18 (94.4%) cases were unilateral, and seven (5.6%) cases were operated for bilateral varicose veins.

However, in the study of **Agena et al.** [14] 43 patients (57.3%) suffered from disfigurement, 21 patients (28.0%) suffered from leg ulcer and 11 (14.7%) suffered from pain.

Our study Showed that as regard CEAP classification; 7 patients were C2 (39%), 9 were C3 (50%), while only 1 was C4 (5.5%) and 1 was C5 (5.5%).

Our results were supported by study of **Zied**[13]as they reported that most of the cases were CEAP classification C2–3 with the collective number of 109 (82.6%) patients of both categories, and C4–6 represent 17.4% (23 patients).

However, in the study of **Shoab et al.**[15] the number of patients in the different CEAP clinical categories were C2, 30 (22.9%); C3, 33 (25.2%); C4, 52 (39.7%); C5, 1 (0.8%); and C6, 15 (11.5%); therefore, more than half of the patients had skin changes or active/healed ulceration.

In the study of **Müller &Alm**[16], there were 22 extremities in CEAP grade C2, 9 with grade C3, 3 with C4 and one with C6. Thrombophlebitis was diagnosed preoperatively in 3/35 (8.6%). The median diameter of the vein to be treated at the upper insufficiency point was 7 mm (range: 5–21).

However, in the study of**Zied**[13], the total operative time was 43±17 and 93±12.7 min for unilateral cases and bilateral cases, respectively; time to establish single sheath was 37±15 s; the treated great saphenous vein segment length was 70.45±3.8 cm; the average amount of tumescent anesthesia was 400±50 ml; per limb, laser energy 5950±730 J with ablation time of 8.7±0.6 min.

According to **Alkhateep et al.**[17], the procedure time was significantly longer in the SHL/ablation group (88.5±9.8 min) than EVLA (66.5±11.76 min). Treated patients resumed their normal daily activities after few days with no significant difference between the two groups.

The current study showed that as regard complications; only Ecchymosis in 2 limbs (11.1%), Temporary numbness at leg in 3 limbs (16.6%) and Incomplete occlusion in one patient (5.5 %).

In our study, no DVT, Pulmonary embolism or any other serious complication related to the procedures recorded.This may be explained by early ambulation to maintain deep vein and SFJ tributary flow and 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

However, in the study of **Spinedi et al.**[12] no local groin complication at day 1, day 10, and week 6, respectively.

CONCLUSION:

In this study we act on Flush EVLA up to saphenofemoral junction and it was noted that using of high wavelength (1470nm) with modified fiber tip with tumescent solution have a crucial role in achieving best results and minimizing the adverse effects. This allow a homogenous destruction of the vein wall exclusively .without any risk of damage to surrounding tissues and also successful ablution of large sized vein diameter.

This study suggest that fEVLA of the GSV using a radial emitting fiber is feasible and safe. And can be suggested as the first option for the management of primary varicose vein based on the lower incidence of complications. Good cosmosis, very short postoperative stay early return to normal activity and can be used for both limbs.

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