Efficacy of Endovenous LASER Ablation (EVLA) Versus Conventional Stripping In The Treatment Of Great Saphenous Vein (GSV) Reflux

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Abstract

**Purposes:** Find out advantages & Efficacy of EVLA Versus Conventional Stripping in treatment Of Great Saphenous Vein Reflux.

**Background:** Varicose veins treatment places a considerable strain on the medical system, with long waiting time for operation in the public hospital system. EVLA allows efficient treatment of many patients on out-patient basis.

**Patients and methods:** This prospective study included 44 patients; with primary varicose veins; Patients were randomly allocated into two groups according to the intervention performed; Group A: Conventional surgical stripping of great saphenous vein (N=22 (50%)), Group B: Endovenous Laser Ablation (N=22 (50%)). All patients underwent clinical evaluation, routine hematological tests, Venous duplex of both lower limbs. Follow-up period was for 6-monthes

**Results:** There were satisfactory results in EVLA group (B); about 20 cases (90.8%) of this group were done under tumescent anesthesia with Less mean post-operative (PO) time; 69.1±3; Less PO pain rate; (4.05±1.23); Less 1-week complications limited to Bruising & Ecchymosis in 5 cases (23.8%), Superficial phlebitis in 3 cases (14.28%), DVT in 2 cases (9.52%) or Skin burn in 1 case (4.76%); Rapid return to normal activity (5.8±1.5) and Overall result were better in group (B); 19 (90.47%) than in group (B); 14 (66.66%) with P-Value; 0.001.

**Conclusions:** Endovenous Laser Ablation (EVLA) of GSV being simple to perform and well accepted by patients; is a safe and effective method with low rate of complications, one day hospitalization, short recovery time and quick return to professional activities; For these reasons; this method is considered a very promising techniques especially in female patients for cosmetic reason as compared to surgical stripping.

**Key words:** Great Saphenous Vein Reflux, EVLA, Stripping, Efficacy.
Introduction

There is no universally accepted definition of a varicose vein however, the following definition incorporates the important element a superficial vein of the lower limb, which has permanently its valvular efficiency and as a product of the resultant venous hypertension in the standing position becomes dilated, tortuous and thickened. This definition excludes the muscular veins in thin patients who simply have prominent but normally functioning veins without venous reflux.\(^{(1)}\)

Common symptoms include aching, heaviness, ankle swelling, pruritus and sometimes, muscle cramps. These symptoms are often made worse by prolonged standing or warm weather increase referrals for varicose vein treatment have been noted in summer months.\(^{(2)}\)

Varicose veins are a common problem and cause disfigurement, disability and impairment in the quality of life (QoL). The advent of endovenous ablation techniques has expanded the surgical options for patients requiring treatment.\(^{(3)}\)

Definitive treatment of varicose veins aims at abolishing sources of venous reflux and removing long refluxing segments and varicose reservoirs can be achieved by conventional surgery or by endovenous ablation techniques.\(^{(4)}\)

Fortunately, the pathophysiology of venous disease may lend itself to surgical treatment, which historically has centered on high ligation of the Sapheno-Femoral Junction (SFJ) and/or stripping of the Great Saphenous Vein (GSV). High ligation alone leads to unacceptably high recurrence rates; the addition of GSV stripping decreases recurrence, but with additional morbidity.\(^{(5,6)}\)

The cooperation between Physics and Phlebology has opened doors that one alone never could even have unlocked. If the already proven “fruitful cooperation between doctor and physicist continues, this already good therapy can reach the status of excellence.\(^{(7)}\)

Endovenous laser ablation (EVLA) is a minimally invasive percutaneous technique using laser energy to ablate incompetent superficial veins. EVLA is used primarily to treat venous insufficiency of the axial veins (i.e. great, small or accessory saphenous veins).\(^{(8,9)}\)

Boné, 1999 first reported on delivery of endoluminal laser energy. Since then, an EVLA method for treating the entire incompetent GSV segment has been described. EVLA with a 980-nm diode Laser system is clinically safe, feasible and well-tolerated technique without scar and allows people to return to their normal daily activities rapidly. EVLA which received approval from the United State Food
and Drug administration in January 2002 allows delivery of Laser energy directly into the blood vessel lumen.\textsuperscript{(10-12)}

Endovenous Laser Ablation can be carried out under local or general anesthesia. EVLA involves delivery of laser energy into the blood vessel lumen. None-thrombotic vein occlusion is achieved by heating the vein wall. Different wavelength, different energies and pulsed or continuous light have been used, there is no feedback control as with RFA, so energy is delivered at predetermined rate with sufficient heating of the vein wall there is endothelial denudation and collagen contraction.\textsuperscript{(13)}

Endovenous procedures allow more efficient management of large numbers of patients with out-patient treatment. EVLA is simple to perform, well accepted by patients and relatively a traumatic and safe.\textsuperscript{(8,9)}

The current prospective selective study aimed to find out safety, efficacy, benefits, advantages and outcomes of Endovenous Laser Ablation as compared to conventional venous stripping of incompetent great saphenous vein.

**Patients and Methods:**

After local ethical committee of Benha university approval and obtaining written fully informed patients consent, The current study was conducted at vascular unit, General surgery Department, Benha University & a private Hospital from September 2015 till January 2017 so as to allow 6 months follow-up period for the last case operated on. This prospective randomized controlled study was conducted on 44 patients with primary varicose veins; Patients were randomly allocated by using a computer generated random number table into two groups according to the intervention performed; Group A: Conventional surgical stripping of great saphenous vein (N=22 (50%)), Group B: Endovenous Laser Ablation (N=22 (50%)).

Patients included in this study were suffering from symptomatic great saphenous vein incompetence; Pain (44 (100%), Visible varicose vein (42 (95.4%), Night cramps (2 (4.5%), Restless leg (38 (86.4%), Bleeding (4 (9.1%) and Skin discoloration (8 (18.2%) and Patients were having GSV with reflux >1 second on duplex ultrasound, GSV incompetence along its whole length with or without active ulcer and CEAP c\textsubscript{2}, c\textsubscript{3}, c\textsubscript{4}, c\textsubscript{5} grade (Clinical, Etiological, Anatomical, Pathological (CEAP) classification). All were fit for regional/general anesthesia. But patients were excluded from this study who were suffering from; Current deep
vein Thrombosis or acute superficial vein thrombosis, Post-thrombotic syndrome, GSV or SSV <3mm or > 15mm in diameter, Tortuous veins that were considered to be unsuitable for EVLA, Coagulation disorder, Peripheral arterial diseases, Pregnant woman, those who were unable to ambulate and extreme obesity.

All patients presenting were admitted at Vascular unit, General Surgery ward for clinical evaluation, routine hematological tests, Venous duplex of both lower limbs; After this, the patient was posted for intervention.

**Interventions:**

In both groups; Patients were operated under general, regional or local anesthesia on a morning list. Preoperative marking of the patient in the standing position with an indelible marker was important in any case in which stab phlebectomy or direct perforator ligation was contemplated in group (A) and foam injection sclerotherapy was done in group (B). Such marking was essential because visualization of varicose tributaries may be impossible once the patient was prepared and the leg elevated. Patients were to be shaved immediately preoperatively with a clipper and the leg was cleansed with an appropriate surgical preparation i.e. aqueous povidone iodine 10% solution and draped with the entire leg exposed from above the groin to just above the ankle. After gaining the great saphenous vein in either in group (A) by veno-stripper or in group (B) by Laser fiber and catheter; tumescent anesthesia was used; (200 to 500 mL) to fully surround the saphenous vein; A combination of 25-40 mL of 1-2% lidocaine with 1 ml epinephrine (1:100000), 10 mL of sodium bicarbonate, and 450 mL of cold (4°C) normal saline in the tumescent mixture, which was administered peri-venously under duplex scanning using an infusion pump until collapse of the GSV and non echogenic halo of fluids were observed around the main trunk of GSV. Most of the interventions in group (B) were performed under local tumescent anesthesia however light intravenous sedation or spinal anesthesia might be used in some of the patients who couldn’t tolerate pain especially in group (A). \(^{14,15}\)

**Technique of Surgical Stripping:**

The GSV was most easily approached through an oblique incision 1 cm above and parallel to the groin crease. This location provided the best cosmetic results and the most reliable access to the saphenofemoral junction. The incision started over the palpable femoral artery and extended medially to balance the better cosmesis of limited incisions with the necessity to ensure appropriate visualization
of the saphenofemoral junction and its tributaries to be ligated. High double ligation of the GSV was performed close to the femoral vein with the second ligation being a suture ligature. Care was taken to avoid narrowing the femoral vein and to avoid leaving a long stump with a risk for thrombus formation and potential embolism.\(^{(16,17)}\)

Then GSV stripping using wire strippers or disposable plastic strippers to strip the vein from knee to groin by another incision was done; this standard stripping was the central component of the classic operation for varicose veins. Recurrence rates were markedly reduced when the GSV was stripped as opposed to when high ligation was performed alone. Associated varicosities if present were removed by multiple phlebectomies through small incisions. All legs were dressed postoperatively with cotton padding applied externally over the length of the GSV track which was secured using a crepe bandage.\(^{(18,19)}\)

**Technique of Endovenous Laser Ablation (EVLA):**

The patients were placed in anti-trendelenburg position in order to minimize shrinkage of the vein; EVLA was done with Fox Diode ARC Laser system and protective eye glasses; Laser 980 nm bare fiber was performed under tumescent anesthesia for all 22 patients. Mapping of GSV was mandatory by preoperative duplex U/S examination from saphenofemoral junction till below knee. Then GSV was accessed utilizing direct ultrasound guidance and micropuncture technique; If vasospasm occurred before successful cannulation, application of tourniquet proximal to the access site in conjunction with dependent positioning of the leg could be helpful or Finally direct cut-down over GSV could present itself; in these technique; lidocaine 1% was infiltrated over the site and make 1 cm small skin incision over the GSV then cannulation was proceeded under direct visualization. The ideal point of entry was caudal to most caudal point of reflux but not more than 10-15 cm below the knee (below which point saphenous nerve lies in close proximity to the vein). \(^{(20,21)}\)

Then calibrated 40cm long vascular sheath 6 F was introduced to extend from venotomy site to 5cm below SFJ over the 0.35 j-tip 55cm guide wire; This calibrated marking on the sheath was useful during Laser fiber pullback under ultrasound guidance and was used to aid the passage of the bare tipped laser fiber inside A 4 FR guide catheter over the wire; The distal tip of the Laser fiber was positioned 2-3 cm below SFJ, before inserting the Laser fiber and catheter into the
vein the optimal Laser fiber length was determined outside the body, the Laser fiber was introduced into the catheter and positioned so as to protrude 2.5 cm from the distal end of the catheter, the stopper at the proximal end of the catheter was firmly tightened onto the fiber, the fiber (with properly positioned and secured stopper) was removed from the catheter, this step ensure that the fiber protrude correctly from the catheter inside the vein. the laser fiber tip was positioned caudal to the saphenofemoral junction just caudal to the epigastric vein prior to activation to minimize the risk of DVT or injury to the central veins. (22)

Once the device is appropriately placed for ablation, the patient is placed in Trendelenburg position to facilitate vein emptying and peri-venous tumescent anesthesia that was administered along the entire length of the great saphenous vein as described before. After tumescent anesthetic had been administered, the entire course of the GSV was evaluated with ultrasound to confirm that it was completely surrounded by anesthetic fluid at all levels but was not occluded completely as it is desirable and necessary with laser treatment to maintain a small volume of blood within the lumen of the vein, as blood is the chromophore for the absorption of the laser energy to transfer heat to the vein wall and cause injury to the vein wall. Then correct positioning of laser fiber tip was again verified and adjusted as necessary. The catheter-fiber was then energized in a continuous manner and was slowly withdrawn in wide sections of the vein at a velocity of 1mm/second and faster in narrow sections at a velocity of 3mm/second under ultrasound guidance until it reach a distance of 2/2.5 cm from the puncture site of GSV this is done with manual pressure which assist vein wall apposition, the pullback rate is adjusted to maintain an energy transfer of 60–90 joules/cm2 at 12-14 watts within the vein. The Linear Endovenous Energy Denisty (LEED) values were used to calculate the Laser energy based on the GSV diameter 1.5-2 cm distal to SFJ; For GSV diameters between 4.5-6.9mm 60/70 j/cm2 of energy was used and For GSV diameter between 7-10mm 80/90 j/cm2 energy was used. (23)

After the catheter or fiber has been withdrawn to the venotomy site, the saphenous vein is again evaluated with ultrasound. Typically, one identifies vessel wall thickening, concentric narrowing, and absence of flow, indicating a successful endovenous saphenous vein obliteration procedure. The common femoral vein is also evaluated for compressibility and the absence of thrombus. The Laser unit was turned off and sheath and Laser fiber was then removed and hemostasis is obtained with manual compression over the access site. Simultaneously, the leg is elevated...
to achieve 90° of hip flexion. Thigh and knee were wrapped with an elastic compression bandage for 3 days then thigh high class II graduated compression stocking was applied for 2 weeks to facilitate GSV closure and minimize post procedure bruising. (24, 25)

**Post-intervention follow up:**

Post-operative pain was assisted for both group by using "The 0-10 Numeric Pain Rating Scale" and relating doses of analgesic drug. The patient was asked to make three pain ratings, corresponding to current, best and worst pain experienced over the past 24 hours. The average of the 3 ratings was used to represent the patient’s level of pain over the previous 24 hours (0 = No pain, 1-3 =Mild pain, 4-6 =Moderate pain and 7-10 =Sever pain).

Patients were discharged 1-3 day post-operatively. Both groups were followed up 1-week for (Bleeding, Hematoma in the subcutaneous along the stripped vein or in the groin, Bruising & Ecchymosis, Wound infection, Nerve injury (manifesting as numbness, decreased or altered sensation or paraesthesia), Superficial thrombophlebitis, DVT and Skin burn) and at 3- and 6-months for (Skin discolouration or pigmentation, residual varicosities, Scarring and Recanalization); to assess postoperative outcome. Duplex ultrasound examination was performed to confirm a successful obliteration procedure and to rule out any potential DVT or extension of thrombus from the saphenous vein into the femoral vein especially in group (B). Bruising was assessed in the thigh along the stripping or ablation line and not in the calf where any bruising would be related to the avulsions. (Fig. 1A-F)

**Statistical analysis:** Analysis of data was done by using SPSS version 16 (Bristol university; in United Kingdom). Quantitative data were presented as mean and standard deviation and were analyzed by using one way Unpaired t-test to compare quantitative variables, in parametric data (SD<50% mean). Qualitative data was presented as numbers and percentages and were analyzed by using Chi-square and Fisher exact tests. (P-value <0.05) was considered significant while (P-value <0.01) was considered highly significant. But (P-value >0.05) was considered insignificant.

These all data were shown in the following pictures: (Fig. 1A-F)
<table>
<thead>
<tr>
<th>Group (A); Stripping</th>
<th>Group (B); EVLA</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.jpg" alt="Image 1" /></td>
<td><img src="image2.jpg" alt="Image 2" /></td>
</tr>
</tbody>
</table>

A-Rt thigh GSV incompetence

**B₁** - Hig ligation of GSV

**B₂** - U/S guided Cannulation of the great saphenous vein below knee

**C₁** - Stripping of GSV

**C₂** - Laser fiber inside dilator placed through the sheath.
D₁-Stripper used with stripped vein

D²-FOX laser apparatus 980 nm (ARC laser systems – Germany) in use 12 watt

E-Tumescent anesthesia injected via spinal needle under DUX scan.

F₁-1-week Post-operative bruising

F₂-1-week Post-EVLA photo of Rt thigh

Fig. (1): Steps of GSV stripping and EVLA for RT lower limb GSV incompetence
Results:

This prospective study included 44 patients with duplex U/S features of GSV reflux >1 second along its whole length; who were divided into two groups according to the intervention performed; Group A: Conventional surgical stripping of GSV (N=22 (50%)), Group B: Endovenous Laser Ablation (N=22 (50%)); The age of studied cases ranged from 24 to 59 years, mean age in group (A) was 32.6 ys and in the group (B) was 34.2 ys. There were 13 female patients and 9 male patients in group (A) where in group (B) 14 female and 8 male patients. there was no statistical difference between both groups in demographic data; Tab. (1), Graph. (1)

Tab. (1): Patients' demographic data:

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A</th>
<th>Group B</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=22 (50%)</td>
<td>N=22 (50%)</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>32.6±3</td>
<td>34.2±2.5</td>
<td>0.44 Non Significant (NS)</td>
</tr>
<tr>
<td>Gender</td>
<td>Male ♂</td>
<td>9 (40.9%)</td>
<td>8 (36.4%)</td>
</tr>
<tr>
<td></td>
<td>Female ♀</td>
<td>13 (59.1%)</td>
<td>14 (63.6%)</td>
</tr>
</tbody>
</table>

Data are presented as numbers & mean ± SD; percentages & ranges are in parenthesis.

Graph. (1): Patients' demographic data:

The Presenting symptoms of GSV reflux were; Pain (44 (100%)), Visible varicose vein (42 (95.4%)), Night cramps (2 (4.5%)), Restless leg (38 (86.4%)), Bleeding (4 (9.1%)) and Skin discoloration (8 (18.2%)). Tab. (2), Graph. (2).
Tab. (2): Patients' Presenting symptoms:

<table>
<thead>
<tr>
<th>Variables</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number (%)</td>
</tr>
<tr>
<td>Presenting symptoms</td>
<td>44 (100%)</td>
</tr>
<tr>
<td>Pain</td>
<td>42 (95.4%)</td>
</tr>
<tr>
<td>Visible varicose vein</td>
<td>2 (4.5%)</td>
</tr>
<tr>
<td>Night cramps</td>
<td>38 (86.4%)</td>
</tr>
<tr>
<td>Restless leg</td>
<td>4 (9.1%)</td>
</tr>
<tr>
<td>Skin discoloration</td>
<td>8 (18.2%)</td>
</tr>
</tbody>
</table>

Data are presented as numbers & mean ± SD; percentages & ranges are in parenthesis.

Graph. (2): Patients' Presenting symptoms:

As regard the type of anesthesia used in this study; In surgical group; spinal and general anesthesia were used in 15 (68.1%) & 5 (22.7%) respectively and tumescent anesthesia combined with spinal or general anesthesia was tried in 2 cases (9.2%) where in EVLA group; tumescent anesthesia was used in all cases (100%) beside general or spinal anesthesia. There was statistically difference between both groups; P-Value: 0.001 (Highly Significant); Tab. (3), Graph. (3).

Tab. (3): Type of anesthesia:

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A (N=22 (50%))</th>
<th>Group B (N=22 (50%))</th>
<th>X²</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spinal</td>
<td>15 (68.1%)</td>
<td>0</td>
<td>25</td>
<td>0.001</td>
</tr>
<tr>
<td>General</td>
<td>5 (22.7%)</td>
<td>0</td>
<td></td>
<td>Highly Significant (HS)</td>
</tr>
<tr>
<td>Tumescent and spinal</td>
<td>1 (4.6%)</td>
<td>6 (27.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tumescent and general</td>
<td>1 (4.6%)</td>
<td>5 (22.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tumescent alone</td>
<td>0</td>
<td>11 (50%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Data are presented as percentages and by using chi-square test
All patients passed uneventful intra-operative course without complications except one case with femoral vein injury & bleeding. Mean operative time was 76.8±4; range: 60-91 minutes in group (A) and 69.1±3 range: 53-79 minutes in group (B). Mean intra-operative blood loss was 56±5.5; range: 50-60ml in group (A) and 47.2±5.1 range: 40-50ml in group (B). Patients in group (A) were discharged 1-3 days Post-Operative (PO); But in group (B) were discharged 1-2 days PO;  

**Tab. (4), Graph. (4).**

**Tab. (4): Operative and immediate Post-Operative (PO) data:**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A</th>
<th>Group B</th>
<th>t</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative time (minutes)</td>
<td>Mean ± SD</td>
<td>76.8±4</td>
<td>69.1±3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>60-91</td>
<td>53-79</td>
<td></td>
</tr>
<tr>
<td>Intra-operative blood loss (ml)</td>
<td>Mean ± SD</td>
<td>56±5.5</td>
<td>47.2±5.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>50-60</td>
<td>40-50</td>
<td></td>
</tr>
<tr>
<td>Duration of PO hospital stay (days)</td>
<td>Mean ± SD</td>
<td>1.8±0.5</td>
<td>1.2±0.4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>1-3</td>
<td>1-2</td>
<td></td>
</tr>
</tbody>
</table>

Data are presented as numbers & mean ± SD; ranges are in parenthesis and statistically significant difference by using unpaired t-test

**Graph. (3): Type of anesthesia:**

**Graph. (4): Operative and immediate Post-Operative (PO) data:**
Upon review of the results in this study post-operative pain was assisted for both group by using The (0-10) Numeric Pain Rating Scale and relating doses of analgesic drugs; high significant difference between both groups was noticed; Group (A) average doses was (12.3±1.9) and pain rate was (6.05±1.099) Vs (5.4±2.1) for group (B) and pain rate was (4.05±1.23); t =10.9  &  t =4.5 P-value: 0.001; surgical stripping had moderate to sever pain and received more analgesic drugs than EVLA patients who had mild to moderate pain. Tab. (5), Graph. (5).

Tab. (5): Post-operative pain assessment using "0-10 Numeric Pain Rate":

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A</th>
<th>Group B</th>
<th>t</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doses of pain analgesic (mean ±SD)</td>
<td>12.3±1.9</td>
<td>5.4±2.1</td>
<td>10.9</td>
<td>0.001 HS</td>
</tr>
<tr>
<td>PO Numeric Pain Rate (mean ±SD)</td>
<td>6.05±1.099</td>
<td>4.05±1.23</td>
<td>5.4</td>
<td>0.001 HS</td>
</tr>
</tbody>
</table>

Data are presented as numbers & mean ± SD; ranges are in parenthesis and statistically significant difference by using unpaired t-test

Graph. (5): Post-operative pain assessment using "0-10 Numeric Pain Rate":

No mortality was recorded but two patients did not come for follow-up, and data collection was applied on 42/44 patients only; 21/22 in each group; At 1-week PO, in group (A); There were Bleeding due to femoral vein injury at the saphenofemoral junction during surgery which was due to slipped ligature by retractor and discovered intraoperative in one case (4.76%); the vein was repaired by continuous prolene 6/0, Hematoma that was noticed in the subcutaneous along the stripped vein and in the groin in 6 cases (28.57%); Bruising & Ecchymosis in 7 cases (33.33%), Wound infection and Nerve injury in 2 cases (9.52%) but there were no Superficial thrombophlebitis, DVT or Skin burn). In group (B); There
were complications limited to Bruising & Ecchymosis in 5 cases (23.8%), Superficial thrombophlebitis in 3 cases (14.28%), DVT in 2 cases (9.52%) or Skin burn in 1 case (4.76%). Residual varicosities appeared in both groups were treated by foam sclerotherapy. **Tab. (6), Graph (6).**

**Tab. (6): Distribution of Post-operative 1-week complications:**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A N=21 (50%)</th>
<th>Group B N=21 (50%)</th>
<th>$X^2$</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bleeding by Femoral vein injury</strong></td>
<td>1 (4.76%)</td>
<td>0</td>
<td>23</td>
<td>0.01</td>
</tr>
<tr>
<td><strong>Hematoma</strong></td>
<td>6 (28.57%)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bruising &amp; Ecchymosis</strong></td>
<td>7 (33.33%)</td>
<td>5 (23.8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Wound infection</strong></td>
<td>2 (9.52%)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Nerve injury (Paraesthesia)</strong></td>
<td>2 (9.52%)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Superficial thrombophlebitis</strong></td>
<td>0</td>
<td>3 (14.28%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DVT</strong></td>
<td>0</td>
<td>2 (9.52%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Skin burn</strong></td>
<td>0</td>
<td>1 (4.76%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>No complications</strong></td>
<td>14 (66.66%)</td>
<td>15 (71.42%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Data are presented as percentages and by using chi-square test

**Graph. (6): Distribution of Post-operative 1-week complications:**

As regard to return back to normal activity; The mean time to return to normal activity in surgical group was 8.5±2.4; this is higher than in EVLA group was the mean time to return to normal activity 5.8±1.5; so there is statistically significant difference between both groups; P-Value =0.001. **Tab. (7), Graph (7).**
Tab. (7): Return back to normal activity:

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A N=21 (50%)</th>
<th>Group B N=21 (50%)</th>
<th>t</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SD</td>
<td>8.5±2.4</td>
<td>5.8±1.5</td>
<td>5.2</td>
<td>0.001 HS</td>
</tr>
<tr>
<td>Range</td>
<td>7-14</td>
<td>4-7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Data are presented as numbers & mean ± SD; ranges are in parenthesis and statistically significant difference by using unpaired t-test.

**Graph. (7): Return back to normal activity:**

At 3- and 6-monthes post-operative follow-up; there were Skin discoloration (pigmentation) noticed in 7 cases (33.33%) of group (A) and in only in one case (4.76%) of group (B), Scarring was noticed only in group (A); 6 cases (28.57%) and Recurrence (Recanalization) was noticed only in group (B); 2 cases (9.52%). The overall results were better in group (B); 19 (90.47%). Tab. (8), Graph (8).

Tab. (8): Distribution of Post-operative 3- and 6-monthes outcomes:

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A N=21 (50%)</th>
<th>Group B N=21 (50%)</th>
<th>X²</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin pigmentation</td>
<td>7 (33.33%)</td>
<td>1 (4.76%)</td>
<td>26</td>
<td>0.001 Highly Significant (HS)</td>
</tr>
<tr>
<td>Scarring</td>
<td>6 (28.57%)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recurrence</td>
<td>0</td>
<td>2 (9.52%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No complications</td>
<td>14 (66.66%)</td>
<td>19 (90.47%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Data are presented as percentages and by using chi-square test.

**Graph. (8): Distribution of Post-operative 3- and 6-monthes outcomes:**
Discussion:

Vein stripping and high ligation has been the standard of care for superficial venous insufficiency for many decades. Efficacy assessment of stripping and ligation was often performed by using varicose vein recurrence as the primary endpoint. Because of the wide availability of duplex ultrasound scanning, has the significance of recurrent reflux been recognized. The prevalence of recurrent reflux increases over time, with a 28.8% incidence at 5 years and 60% at a mean follow-up of 34 years. (26)

During the last decade new less invasive methods have been developed as alternatives to conventional High Ligation/Excision (HL/S) in the treatment of Greater Saphenous Vein (GSV) incompetence, including radiofrequency ablation (RFA), Endo-Venous Laser Ablation (EVLA) and foam sclerotherapy (FS). In the not so distant past, physicians did not perceive venous disease as a serious health risk. Typically; a patient would be treated with extremity elevation and compression for long periods, remaining severely debilitated. (6)

This study was on the utilization of "FOX" 980-nm diode Laser system EVLA in the treatment of primary varicose veins group (B) compared to stripping group (A), it included 44 patients and the mean follow up period was 6 months, as regard to EVLA group (B) that included 22 patients; this was smaller than recent studies done by "Shi et al., 2015" who studied 132 patients (156 limbs) with EVLA among a total of 311 patients (376 limbs) for a duration of 12 months, and "Brittenden et al., 2015" who treated 212 out of 798 patients in along term follow up 5 years duration. (3,9)

The Presenting symptoms of GSV reflux were; Pain (44 (100%)), Visible varicose vein (42 (95.4%)), Night cramps (2 (4.5%)), Restless leg (38 (86.4%)), Bleeding (4 (9.1%)) and Skin discoloration (8 (18.2%)). This was comparable to "Campbell et al., 2003", who performed a study on 151 limbs of 100 patients, the main presenting symptom was aching pain; it was present in 97 limbs (64%); other symptoms included skin changes in 40 limbs (26%), disfigurement in 32 limbs (21%), heaviness in 18 limbs (12%), phlebitis in 10 limbs (7%) and bleeding in 1 limb (7%), Noting that many patients reported more than one main symptom, so the total percentage exceeds 100%. (27)

In this study; tumescent local anesthetical solution was used in all cases (100%) beside general or spinal anesthesia in group (B) and tried in combination with spinal or general anesthesia in 2 cases of group (A); This technique provided excellent anesthesia and allowed in group (A); Vein stripping to be performed...
under straight local anesthesia. In addition, the vasoconstriction from the epinephrine and the direct compressive effects of the instilled volume resulted in rapid hemostasis from the avulsed tributaries and a marked decrease in postoperative ecchymosis and pain and allowed in group (B) separation of the superficial aspect of the GSV by at least 1.0 cm deep to the skin surface along its entire length to reduce the likelihood of skin burns and collapse of GSV to improve the transfer of thermal energy to the vein wall and the vasoconstriction from the epinephrine reduced incidence of hematoma and hyper pigmentation. The ability to perform the procedure under tumescent local anesthesia allows for an immediate return to daily activities with optimal medical and cosmetic results, as well as high patient satisfaction (14,15).

In the present study; Mean operative time was 76.8±4; range: 60-91 minutes in group (A) and 69.1±3 range: 53-79 minutes in group (B). This against "De Maeseneer, et al., 2006", who mentioned that; The total theatre time (between entry into and exit from the theatre suite) was significantly longer for EVLA than for conventional surgery; due to time consumed during marking the course of the GSV under duplex guidance in EVLA. (28)

Upon review of the results in this study post-operative pain; surgical stripping patients had moderate to severe pain and received more doses of analgesic drugs than EVLA patients who had mild to moderate pain; P- value: 0.001; as in EVLA patients there were no multiple skin incision. "Sharif, et al., 2006" had reported that pain felt by patients occurred 5 to 8 days after the procedure and was related to the inflammation resulting from successful endovenous ablation but not related to ecchymosis nor damage to peri-venous tissue. (28, 29)

At 1-week PO, in group (A); there were Bleeding due to femoral vein injury during surgery in one case (4.76%); the vein was repaired by prolene 6/0, Hematoma that was noticed in the subcutaneous along the stripped vein and in the groin in 6 cases (28.57%); Bruising & Ecchymosis in 7 cases (33.33%), Wound infection (due to skin incision) and Nerve injury (especially in cases with reflux of GSV >15cm below knee stripping) in 2 cases (9.52%) but there were no Superficial thrombophlebitis, DVT or Skin burn. (28) In group (B); there were complications limited to Bruising (occurred at the sites where the tumescent anesthesia has been instilled) & Ecchymosis (most likely caused by laser-induced perforation of the vein wall, could be observed in every patient at the inner thigh and knee region from the next day to approximately 2 weeks later) in 5 cases (23.8%); which improve spontaneously in the follow up, There were 3 cases
(14.28%) of superficial thrombophlebitis in the form of skin redness (topical anti-inflammatory was prescribed and rapid improvement was noticed in one case in the follow up for this phlebitis) and the other 2 cases (9.52%) developed Thrombosis (DVT) which were due to extension from superficial thrombophlebitis; one case was due to late ambulation and the other case was due to laser fiber was too close to deep vein; this 2 cases were managed conservatively without sequelae or Skin burn (most probably from inadequate administration of tumescent anesthesia), in 1 case (4.76%). This was similar to "Proebstle et al., 2004 & Gibson et al., 2007" (25,30)

The mean time to return to normal activity in surgical group was 8.5days; this is higher than in EVLA group was the mean time to return to normal activity 5.8days; similar results were mentioned by (28); Who mentioned that; Patients returned to their full level of normal household activities, for driving and for work significantly more quickly following EVLA than after conventional surgery.

At 3- and 6-monthes post-operative follow-up; there were Skin discoloration (pigmentation) noticed in 7 cases (33.33%) of group (A) and in only in one case (4.76%) of group (B) due to still present thrombotically occluded GSV, Scarring was noticed only in group (A) due to skin incision; 6 cases (28.57%) and Recurrence (Recanalization) was noticed only in group (B); 2 cases (9.52%); Recurrence of reflux at the SFJ is often blamed on operator failure during the first intervention but it cannot always be explained by such technical inadequacy. Its development can be attributed to neovascularization in the granulation tissue around the ligated saphenous stump as mentioned by.(25,28).

The overall results were better in group (B); 19 (90.47%) which is similar to promising results published by "Shi et al., 2015" as the technical success rate of EVLA was 100% in their evaluation of the Effect of Endovenous Laser Ablation of Incompetent GSV in Patients with Primary Venous Disease. (3)

**Conclusions:** Endovenous Laser Ablation (EVLA) of GSV being simple to perform and well accepted by patients; is a safe and effective method with low rate of complications, one day hospitalization, short recovery time and quick return to professional activities; So this method is very promising techniques especially in female patients for cosmetic reason as compared to surgical stripping.
References:


