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# Safety and efficacy of endovenous laser therapy with microphlebectomy or foam sclerotherapy for varicose vein patients in outpatient clinic

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## ABSTRACT

Varicose vein of the lower extremity are common problems which is commonly the result of reflux in one or more of the saphenous veins and their primary tributaries. The new treatment modalities including endovenous laser therapy for truncal refluxing vein with microphebectomy or foam sclerotherapy for tributeries are highly effective and safe in outpatient clinic.

Method**:**From Jan , 2015, to Jan , 2022, 1500 EVLT procedures were performed in 1500 patients with a mean age of 42.6 years (range, 15-75 years). A 1470-nm diode laser (Venacure laser device ,Angiodynamics and Wolf device by ARC Laser ) and microphlebectomy or foam sclerotherapy were used for tributaries and perforators. All refluxing truncal veins above knee were ablated . Symptoms of venous insufficiency were present in 67%, and 90 patients (2.85%) had an open ulcer when they underwent operation. Patients had clinical follow-up visits, including duplex ultrasound examination, at 1 week, 1 month, 3 months ,6 months and were assessed for deep venous thrombosis (DVT), recanalization of the ablated vein, nerve injury, ulcer healing, and resolution of symptoms.

Results**:**A total of 1300 great saphenous veins (86.66%), 120 small saphenous veins (8%), 42 combined great and short saphenous veins (2.8) were ablated by endovenous laser therapy . Combined microphlebectomies or foam sclerotherapy were performed at the same session . The primary ablation rate at 1 and 6 months was 99.2% . Recanalization occurred in 12 veins (0.85%) who successfully closed with a second EVLT. Postoperatively, the 90 ulcers showed healing at a mean of 5.2 weeks (range, 2-10 weeks), and only 1 failure of healing . a few major complications occurred. 6 cases of DVT (0.28%) occurred, 10 mild pulmonary emboli ,one (0.28%) skin burns had occurred. Local transient paresthesia at the ankle and midcalf level occurred in 9 patients (0.6 %).

Conclusions**:**Endovenous laser therapy for superfacial refluxing truncal veins together with microphlebectomy or foam sclerotherapy for tributeries highly effective and safe in treating varicose vein in an outpatient clinic.

**Keywords:** *major, safety, efficiency, clinic*

## INTRODUCTION

Varicose veins are common ,often leading to significant impact on patient quality of life .varicose vein are usually due to superfacial venous reflux affecting the great saphenous vein (GSV),small saphenous vein (SSV) or nontruncal veins .whether the valve failure is primary phenomenon or secondary to vein wall dilatation remains unknown . The ultimate goal of any treatment regimen is to eliminate sources of reflux in order to control symptoms and progression of disease, improve cosmetics, promote ulcer healing, and prevent recurrence or a combination of all these. The best therapeutic results are based on two hemodynamic principles: the abolishment of the highest point of reflux and the elimination of the incompetent and dilated venous segments.

Endovenous laser treatment (EVLT) is thought to obliterate saphenous vein by producing heat at varying wavelengths ,which inducec a photothermolytics process between catheter and vein wall that is responsible for closure a lower wavelengths between 810-10064 nm are absorbed by haemoglobin which results in bubbling steam that are transferred to denature the vein wall,whereas higher wavelength between 1,320-1470 are absorbed by the water molecules within plasma and transfere to heat energy to the vein wall.tumescence anesthesia is used to both decrease the distance between the vein wall and ablation catheter as well as to act as heat sink to prevent thermal injury to the surrounding structures such as saphenous nerve or subcutanous fat.1

While endovenous laser ablation is safe with low risk but still associated with the complication of postprocedural thrombus ,termed endothermal heat induced thrombosis (EHIT).Kabnick et al developed classification system for EHIT which defines postprocedural thrombosis depending on the level of protrusion of clot from superfacial into deep systemat saphenofemoral junction. 2 Current literature supports the assertion that most instance of EHIT are clinically insignificant ;however,the propagation into the deep venous system can lead to a deep venou thrombosis (DVT) with potential risk for pulmonary embolism .3,4

Published reports confirm that endovenous laser ablation of an incompetent great saphenous vein (GSV)5,6,7 , or small saphenous vein (SSV)8,9 is safe and can provide outcomes equal to or better than traditional surgical ligation and stripping .10

Some practitioners advocate ablating the thigh segment of the GSV and treating the remaining visible varicosities with sclerotherapy during subsequent follow-up visits. Our chosen protocol at first is to perform EVLT of all the refluxing truncal veins above knee and to remove all varicose veins with microphlebectomies (MPs) at the same time until october 2019. This approach mirrors past protocols in which the incompetent GSV was stripped in combination with stab avulsion of varicosities. Then we replaced to EVLT with foam sclerotherapy for tributaries since October 2019 till now. Several larger series have included GSV, SSV, EVLT ablations, but studies specifically of the success rate and risks associated with EVLT combined with MP or Foam sclerotherapy have included only a small number of patients .11,12 The purpose of this study is to report the safety and clinical and anatomic effectiveness of the combined application of EVLT and MP or FS for a large number of patients in an outpatients clinic.

## MATERIALS AND METHODS

### *Patient selection criteria*

This retrospective study included 1500 patients with varicose vein who presented for routine evaluation at our clinic and underwent EVLT ablations from Jan.2015 until Jan 2022. Directed history and physical examination was performed to document varicosities and symptoms according to CEAP classification. All patients had preoperative documentation of axial venous reflux using a sonoscape duplex ultrasound (DUS) unit.

### *Inclusion criteria*

Inclusion criteria included primary varicose veins caused by saphenous reflux (GSV and SSV) and their tributaries in patients aged (15 – 75) years.

### *Exclusion criteria*

Exclusion criteria included nonpalpable pedal pulses, inability to ambulate, deep vein thrombosis (DVT), secondary varicose vein , general poor health and pregnancy. After an initial examination and consultation, patients

who met the selection criteria were offered the choice of surgery or EVLT. Nearly all patients choose EVLT rather than surgical ligation and stripping.

***Technique***

All patients were treated as an ambulatory procedure day clinic under local anesthesia. DUS imaging was done with the patient standing. All refluxing truncal veins were identified and marked on the skin, and a percutaneous entry point was chosen where reflux was no longer seen or where the vein became too small to access for ablation figure (1).

**FIGURE 1:** patient with RT lower limb varicose vein

With the use of local anesthesia and sonographic guidance, the vein was punctured using Seldinger technique (6F) introducer femoral sheath was used. The intraluminal position within the vein was confirmed by aspiration of nonpulsatile venous blood and visualization with ultrasound. A 600-µm laser fiber was introduced into the sheath and advanced to 1 – 2cm distal to saphenofemoral junction in case of GSV ablation fig(2), fig(3), and 2cm distal to saphenopopliteal junction in the SSV cases sometimes we ablate also anterior or posterior accessory varicose vein in the same manner.

**FIGURE 2:** multiple sheaths and laser fiberoptics insertion

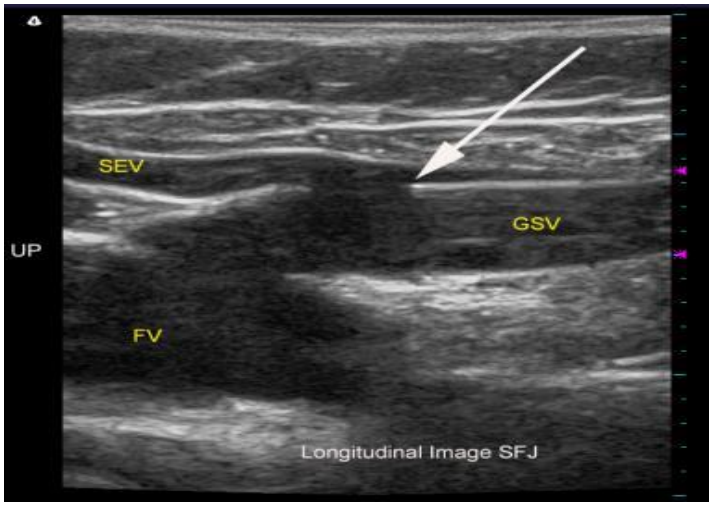


**FIGURE 3:** positioning of fiberoptic laser catheter 2cm distal to saphenvarix junction

neutralized with sodium bicarbonate, was administered along the perivenous space under ultrasound guidance. The tip of the laser fiber was repositioned within the GSV or SSV 1-2 cm distal to the SFJ or SPJ, respectively. Laser energy was delivered using an 1470-nm diode laser (venacure 1470, angiodynamic. Wolf ARC laser) at 8-10 W in continuous mode. The vein was treated from 1-2 cm below the SFJ or SPJ to approximately 1 cm above the skin entry site. The laser fiber was withdrawn at an average rate of 6-8 sec/ cm for GSV and SSV. These rates of withdrawal represent about 60-70 J/cm energy delivered. These steps were repeated as needed to treat all refluxing truncal veins.

All patients underwent concomitant microphlebectomy MP by 11 scalpel was used to make a 2-mm skin incision, and a hook device was used to remove the refluxing tributaries immediately after the laser ablation this maneuver used until October 2019 the we replaced to foam sclerotherapy for all tributaries and near perforators.

Once the procedure was completed, compression pads were applied over the treated area, and a low- stretch elastic compression bandage was placed on the treated limb. In the open ulcer cases confeel dressing was used and changed weekly until complete healing was achieved.

All patients were encouraged to ambulate the day of the procedure, to resume their normal daily activities in 2 to 3 days, and to wear the elastic bandage 24 hours a day for 10 days and then to replace it with a 15 to 20 mm Hg, full-thigh support stocking for at least 1 month at all times, except to sleep or shower. Low molecular heparin (clexane) in dose of 4000 IU were routinely used as prophylaxis daily for 4 days. Nonsteroidal anti-inflammatory drugs and an oral second-generation cephalosporin were ordered for the first week after therapy.

***Follow-up Protocol***

Patients had clinical follow-up visits, including DUS examination at 1 week, 1 month, 3 months, and 6 months. At the time of the visit, patients were asked about the severity of immediate postprocedural pain, timing to resume daily activities, work and exercise; complaints of nerve injury, and about changes in their extremity symptoms compared with those before the procedure. The presence of residual varicosities, edema, thrombophlebitis, skin changes and ulceration was recorded. The DUS scans assessed for the presence of DVT and for accuracy of saphenous ablation or recanalization in a previously ablated vein. At the 3-month visit, patients were asked to complete a patient satisfaction questionnaire, a nonvalidated instrument that we created, asking about relief of symptoms of chronic venous insufficiency, cosmetic results and overall satisfaction.

Statistical analysis of data was carried out by using SPSS-25.data were presented in simple measures of mean,standerd deviation,frequency and perstange.

## RESULTS

Endovenous laser ablations in 1500 patients who also underwent MP and or FS for treatment of varicose veins during 9 y period at our day clinic.Most of studied patient was between (20-40) with mean age (42.8),female were much more affaected than male(60.85%) .Most of patient (52.4%) were overweight in range of 20-24.9BMI .family history presented in 60% of studied group .

Symptoms were present in 67% of patients, who had a median CEAP clinical class of C 3.6 (range, 2-6). Open ulcers were present in 90 patients (6%) at operation. The LT lower limb involved in 62%while the Right 31%and 7% were bilateral . great saphenous vein was the most commonly involved (86%) while short saphenous was just in( 8%),bilateral in( 2.8%) .Demographic and CEAP clinical classification of studied population are summarized in table (1) and table (2). Ablation was performed in 1300 GSVs (86.66%), 120 SSVs (8%), 42 patients combined GSV and SSV ablation (2.8%), 26 patients combined GSV and AASV (1.7), 12 patients with GSV and PASV (0.8%). Of the GSVs treated, 70.2% were ablated to the above knee level, 20.4% to the knee, 8.82% below the knee, and0.57% to the ankle level. Pretreatment vein diameter, measured in the upright position 1-2cm below the SFJ and SPJ, was a mean of 10,5 mm (range, 5-22mm) and a mean of 6.8 mm (range, 4-12mm) for the GSV and SSV cases, respectively.

**TABLE 1:** demographic distribution of varicose vein .

| Variable | | NO. | % | P value |
|---|---|---|---|---|
| Age(year) | <20 | 30 | 2 | 0.222 |
| | 20---29 | 327 | 21.8 | |
| | 30---39 | 436 | 29 | |
| | 40---49 | 163 | 10.8 | |
| | 50-59 | 217 | 14.4 | |
| | 60-70 | 237 | 15.8 | |
| | >70 | 90 | 6 | |
| | Mean+SD | 42.8+12.6 | | |
| Gender | Male | 588 | 39.14 | 0.690 |
| | Female | 912 | 60.85 | |
| BMI(Kg/m2) | Normal(18.524.9) | 252 | 16.8 | 0.194 |
| | Overweight(25-29.9) | 787 | 52.4 | |
| | Obese(30-34.9) | 351 | 23.4 | |
| | Morbidobesity>35 | 109 | 7.3 | |
| | Mean+SD | 26.5+4.6 | | |
| Family history of varicose vein | Yes | 900 | 60 | 0.176 |
| | No | 600 | 40 | |

**TABLE 2:** clinical classification of varicose vein patient

| Variable | | No. | % | P value |
|---|---|---|---|---|
| CEAP | C2 | 495 | 33% | 0.125 |
| | C3 | 270 | 18% | |
| | C4 | 525 | 35% | |
| | C5 | 120 | 8% | |
| | C6 | 90 | 6% | |
| Side of limb involved | Left side | 930 | 62% | 0.543 |
| | Right side | 465 | 31% | |
| | Bilateral | 105 | 7% | |

| | | | | |
|---|---|---|---|---|
| The vein involved with varicose | Great saphenous | 1300 | 86 % | 0.175 |
| | Short saphenous | 120 | 8 % | |
| | GSV+SSV | 42 | 2.8 % | |
| | GSV and AASV | 26 | 1.7 % | |
| | GSV and PASV | 12 | 0.8 % | |

CEAP (clinical ,etiological,anatomical ,pathological ).GSV, great saphenous vein; SSV, small saphenous vein; AASV anterior accessory saphenous vein; PASV, posterior accessory saphenous vein

Vein characteristics of entire series are reported in Table (3).

218 patient need just EVLT, 800 patients underwent microphlebectomy with EVLT, 482 foam sclerotherapy for tributaries with EVLT.

**TABLE 3:** vein details and laser energy density

| Characteristics | GSV | SSV | AASV | PASV |
|---|---|---|---|---|
| No | 1300 | 120 | 26 | 12 |
| Diameter mm (mean) | 12,5 | 5,4 | 5.2 | 6,2 |
| Treated length | 42.55(12,7) | 17,6(5.2) | 13,2 | 14.6 |
| Total energy, J | 1540 | 630 | 460 | 490 |
| Laser energyJule/cm | 80,6 | 58,2 | 60,5 | 60,8 |

GSV, great saphenous vein; SSV, small saphenous vein; AASV anterior accessory saphenous vein; PASV, posterior accessory saphenous vein

Continuous data are presented as means (standard deviation).

The primary ablation rate for the veins treated during the study period was (99.22%) at 1 months and (98.2%) at 6 months, during the study period, 12 veins recanallized (0.85%) of these, symptoms of venous insufficiency (anatomic and clinical failure) developed and they were successfully treated with a second EVLT.

The 90 limbs with an open ulcer that were operated on showed healing at a mean of 6.4 weeks (range,4-8 weeks) after the procedure, three of them reopened again during the study period caused by morbid obesity and recurrence of varicose vein treated by redo EVLT and multiple Foam sclerotherapy for large perforators.

Mild to moderate pain along the course of the treated vein during the first week and ecchymosis along the area of the tumescent anesthesia administration and at phlebectomy sites were noted in most patients, as well as indurations. Superficial phlebitis of associated tributary varicose veins was noted in 43 patients (2.7%) and resolved with compression therapy and nonsteroidal anti-inflammatory medication in all cases. Local transient parasthesia at the ankle and midcalf level occurred in 9 patients (0.6%) and resolved spontaneously after 2 weeks. Most of these patients underwent extensive MP below the knee. Hyperpigmentation occurred in 60 patients (4%) and cellulitis in 15 (1%) mainly in group patient who treated with FS with EVLT.

Endovenous heat induced thrombosis at saphenofemoral junction seen in 50 (3.3%) majority was mild stage 1 just at the junction, 8 patient (0.53%) with stage 2,5 (0.33%) patient with stage 3 only 2 (0.13%) with stage 4 total localized common femoral vein thrombosis all of them treated successfully with anticoagulant drugs for minimum of three months .

Deep venous thrombosis (DVT) was found in 6 (0.4%) patients 1 with iliofemoral DVT.two cases with popliteal vein DVT. Three patients with posterior vein vena commitments, all of them after using FS for tributaries. The patient

had ileofemoral involvement and was successfully treated after a 6-month course of oral anticoagulation, with the GSV remaining occluded. 10 patients (0.6%) presented with the signs of pulmonary embolism, felt chest tightness and chest pain during first-third day postoperatively just two cases need hospital admission to CCU and treated with heavy course of anticoagulant with rapid recovery. Only one patient (0.06%) with mild skin burn.as shown in table (4).No death being recognized in our study .

**TABLE 4:** incidence of early complications of EVLT .

| Parameters | | Number | Percentage |
|---|---|---|---|
| Phlebitis | | 43 | 2.9% |
| Paresthesia | | 9 | 0.6% |
| Hyperpigmentation | | 60 | 4% |
| Cellulitis | | 15 | 1% |
| EHIT endovenous heat induced thrombosis at SV junction | Total | 50 | 3.3% |
| | Stage 1 | 35 | 2.3% |
| | Stage 2 | 8 | 0.53% |
| | Stage 3 | 5 | 0.33% |
| | Stage 4 | 2 | 0.13% |
| Deep vein thrombosis | Total | 6 | 0.4% |
| | Iliofemoral | 1 | 0.06% |
| | Poplitial | 2 | 0.13% |
| | Poaterior tibial vena commitant | 3 | 0.2% |
| Pulmonary embolism | | 10 | 0.6% |
| Skin burn | | 1 | 0.06% |

## DISCUSSION

Varicose vein were more common in female (60.08%) than male,this is acceptable rate may be explained by hormonal effects or by multiple pregnancies or by more obesity in female than male .with mean age of 20-29 y being most affected age group ,GSV were much more to be affected by reflux 86.66% while SSV just in 8% this compariable for most studies . Improved understanding of the mechanism of action of EVLT and its high degree of safety and effectiveness in the treatment of GSV reflux has led to the exploration of treatment of non-GSV sources of superficial reflux, with excellent results.5 Therefore, by targeting all the sources and length of axial reflux, above and below the knee, we can provide patients with a safe and superior alternative to ablating just the proximal portion of a refluxing saphenous vein, and this is the rationale behind our approach .Recently we use Foam sclerotherapy for obliterating GSV below knee especially for patient with multiple perforators . still there is great debate about the concentration ,the full dose that can be use which depend mainly about experience .

Until October 2019 we combining MP with EVLT offers the additional advantage of resolving the varicose veins in just one visit, leading to immediate better cosmetic results. Both procedures can be done simultaneously, under local anesthesia and conscious sedation, without a significant increase of complications. Our rate of postoperative pain, cellulitis or paresthesias is not very different from series where EVLT was the only procedure performed. None of our patients found the paresthesias or numbness to be significant concern. Since October 2019 onword we replaced MP with FS for tributaries and perforators. It improves our work, reduce the duration of procedure, less pain, less, need for local anesthesia make it more appropriate for more elderly patient, but we saw more pain postoperatively with more pigmentation more duration needed for recovery. We did have a smaller number of patients with postoperative phlebitis compared with those

series. Ulcer healing occurred at a mean of 6.4 weeks after treatment in the 90 patients who underwent the procedure with an open ulcer. The ulcer reopened in only 3 patients who underwent a second EVLT due to recanalization of the ablated vein.

The primary ablation rate for the veins treated during the study period was 98.23% at 1 month and 97.5% at 6 months, during the study period, 12 veins recanalized (0.79%). Of these, symptoms of venous insufficiency (anatomic and clinical failure) developed, and they were successfully treated with a second EVLT. These results are very similar to published reports. Desmyttere et al 15 reported a primary ablation rate of 97% at 4 years in 511 GSVs treated with a 980-nm endovenous laser.

Nine patients with recanalized veins representing an anatomic failure; however, these veins were noticeably smaller, symptom-free, without recurrent tributaries veins. As a possible explanation, it is likely that shrinking a refluxing vein to a smaller diameter allowed the valves to completely or partially close, thus decreasing or eliminating reflux. 2 patients in this group presented with symptoms of venous insufficiency, indicating anatomic and clinical failure, and they were successfully treated with a second EVLT. Only one patient, with BMI of 31 kg/m2, presented with an anatomic failure after his second EVLT, reflecting the importance of obesity as an independent risk factor for recanalization.

We observed that a BMI more than 30 kg/m2 and a vein diameter more than 8.5 mm were independent risk factors for recanalization. Timperman16 has also found that obesity was common among patients in whom recanalization occurred. It is known that obese patients have increased abdominal and femoral venous pressure17. In this latter group of failures, it is possible that the fibrosis caused by the EVLT was overcome by the increased femoral venous pressure, with the saphenous vein reopening in a proximal to distal fashion, sometimes into a varicose tributary close to the SFJ that functions similarly to a relief valve. MP of these varicose tributary at the time of EVLT and ligation of the SFJ to isolate the GSV from increased venous pressure may improve the success of endovenous ablation. These findings have relevance in counseling patients before the procedure about their risk of recanalization and also may suggest which patients should have a prophylactic ligation of the saphenous vein to reduce this undesired outcome.

The incidence EHIT in this study was low 3.3% ,the majorty were in satge 1 and Stage 2 who treated just by mild course of anticoagulant for 4 weeks and observation by repeated US examination .all of the resolved spontenously just two patient with stage 4 with total CFV occlusion at junction who needs tratement and follow up for 3 months ,this was comparable with other studies like Shekeeb et al study who find 2.9% incidence of EHIT with EVLA or EVRA.the risk factors that were associated with EHIT were large vein size ,male gender,old age .19 The incidence of DVT was very low just one case with iliofemoral DVT , who need treatement with full course of anticoagulation for 6 months ,two case with pop vein thrombosis also need treatment with full course of anticoagulation three patient with just tibial vein thrombosis who presented with leg swelling and persistence leg edema .we observe those case mainly after we swiched to use foam sclerotherapy for treatement of leg tributieries espacialy with large perforators

## CONCLUSION

Endovenous laser therapy for all refluxing superfacial vein with microphlebectomy or foam sclerotherapy for tributeries above or below knee are safe and highly effective in treating varicose vein and can be done on outpatient clinic under local anesthesia. Further investigations may ascertain whether ligating the saphenous vein at the SFJ or SPJ in patients with vein diameters more than 8.5 mm or with BMIs more than 30 kg/m2, will reduce the rate of recanalization, decrease the risk of DVT and EHIT thus improving the long-term results of EVLT.

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