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ORIGINAL ARTICLE

OUTCOME OF ENDOVENOUS LASER THERAPY FOR GREAT SAPHENOUS VEIN REFLUX. EARLY EXPERIENCE IN UPPER EGYPT

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Abstract

Aim of work: To assess the efficacy and safety of endovenous laser therapy (EVLT) for management of great saphenous veins (GSV) reflux.

Materials and Methods: 25 GSVs in 25 patients (18 females, 7 males) with a mean age of 37.2 years (range from 25 - 60 years) with incompetence at saphenofemoral junction (SFJ) and GSV reflux were treated with EVLT by 980-nm diode laser and evaluated in a prospective study for one year. Patients were evaluated clinically and by duplex ultrasonography at 1 week,1,3,6,9 and 12 months postoperatively to determine efficacy and procedure related complications.

Results: EVLT was technically successful in 24 GSVs (96 %) and remained closed for the whole 12 months clinically and by follow-up duplex ultrasonography. Three patients(12 %) developed pain during the 1-week, Ecchymosis were seen in 18 patients(72%), 2 patients (8%) developed palpable indurations. No one developed paraesthesia or major complications particularly deep venous thrombosis. Complementary foam sclerotherapy was done in 19 patients (76%).

Conclusion: EVLT for GSV reflux appears to be safe, feasible and efficient outpatient technique. With proper patient selection, EVLT can be considered as a successful method for treating superficial vein reflux and may replace the traditional surgical procedure. Long-term follow-up is awaited.

Keywords: Laser, management, saphenous vein

INTRODUCTION

It is expected that approximately 25% of women and 15% of men have lower extremity superficial venous insufficiency.[1] Great saphenous vein (GSV) reflux is the most common underlying cause of significant varicose veins.[1] Although surgical treatment of varicose veins is the traditional one, 30% - 60% recurrence rate is reported, and it is also associated with risk of general or spinal anesthesia and surgical complications e.g. paraesthesia, bleeding, infection, scars or prolonged recovery periods.[2,3]

The possible mechanisms of recurrence after surgical treatment are inadequate procedure as well as neorevascularization at the junctional area.[4] 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.[5]

The main advantages of minimally invasive techniques that have been developed within the last few years are to reduce morbidity and improve recovery time. Endovenous laser therapy (EVLT) is one of the most promising techniques which was firstly introduced in 1998 by Spanish phlebologist, Carlos Bone.[5] Different varieties of wavelengths have been proposed e.g. 810, 940, 980, 1064, and 1320 nm. Wavelengths 810, 940 and 980 nm are the most commonly used with a power energy set between 10-15 W.[6-9] These types of wavelengths induce heating of the venous wall, that is necessary to induce collagen contraction and destruction of endothelium. This leads to luminal contraction, venous thrombosis, and vein fibrosis.[10]

Tumescent anesthesia is a must during the procedure, so patients feel no pain during the procedure. Tumescent anesthesia also has additional two advantages of compressing the vein and minimize its diameter to provide vein wall apposition around the fiber tip as well as acting as a protective barrier to minimize the risk of heat-related damage to adjacent structures.[11]

MATERIAL AND METHODS

This prospective study was carried out in Sohag university hospital from June 2011 to January 2013 on 25 patients (18 females, 7 males) with a mean age of 37.2 years (range from 25 - 60 years). They were presented by varicose vein caused by saphenofemoral junction (SFJ) incompetence with GSV reflux that was confirmed by duplex ultrasound imaging. These patients underwent EVLT with 980-nm diode laser and followed up for a duration of 12 months. All patients were admitted and signed a written informed consent before treatment. The study was approved by ethical committee of our university.

Patients with tortuous GSV that could not allow passage of the sheath, laser fiber, non-palpable distal pulsation, inability to ambulate, patients with previous history of deep venous thrombosis (DVT) and pregnant women were excluded from the study.

All patients were subjected to detailed history, physical examination, and duplex ultrasound imaging. After initial evaluation, patients with appropriate criteria were offered EVLT with its advantages, so all subjects chose EVLT rather than traditional surgical ligation and stripping.

Procedure: Duplex ultrasonography (Sono Ace R3, Medison, Korea) was performed in the upright position to map incompetent sources of venous reflux and mark the skin overlying GSV starting at the SFJ. GSV diameter was measured in upright position in different sites e.g. 2-3 cm below the SFJ, mid-thigh and at the knee level in standing position and recorded. The procedure was done in special operative theatre respecting the safety precautions of using Laser. The target extremity was sterilized and draped. Patient was placed in reversed Trendelenburg position to facilitate cannulation of GSV either directly or under ultrasound guidance. The site of puncture was few centimeters below the knee level with a 18-gauge cannula. Patient was then placed in the Trendelenburg position for starting the technique. J-tip 0.035 inch guidewire was passed under ultrasound guidance up to the SFJ. A 5-F long introducer sheath was placed into the GSV over the guidewire. The introduced length of the sheath ranged from 36 cm -50 cm depending on the length of GSV to be treated. The bare-tipped fiber 600-µm diameter (ARC laser, Nuremberg, Germany) connected to a 980-nm diode laser (Fox III ARC laser, Nuremberg, Germany) was introduced through the sheath. The device was set with 10 W power and pulsed mode manner 2 seconds (on) and one second (off). The distal tip of the laser fiber was positioned 2 cm below the SFJ under duplex sonographic guidance and confirmed by direct visualization of the green aiming beam of the laser fiber tip through the skin.

Perivenous tumescent anesthesia was injected into the fascial space surrounding the GSV under cross sectional sonographic guidance along its length. The amount of tumescent anesthetic solution was about 400-500 cc. The components of tumescent anesthesia was 20-25 ml lidocaine 2% buffered with 1.4 % sodium bicarbonate in 500 cc saline 0.9%.

Then allowing the Laser energy to be fired and then the laser fiber and sheath were slowly pullback till they reached one cm above the site of puncture to avoid skin burn. The mean energy applied was 66 J/cm for GSV diameters ranged between 4-9 mm. Simultaneous complementary foam sclerotherapy to the distal segment of GSV and remaining branch varicosities was done in 19 patients (76 %) using 4-10 ml foam by use of polidocanol 2% - 3% (Aethoxysklerol , Kreussler, Germany)while EVLT alone was done in 6 patients (24 %). Bandage compression was applied postoperatively for 24 hours then patients were asked to wear full-thigh class II compression stockings (30 - 40 mm Hg) for one week. Patients were instructed to walk immediately after the procedure and to continue their normal daily activities. All patients received routinely non-steroidal anti-inflammatory drugs e.g.: diclofenac potassium or piroxicam for one week.

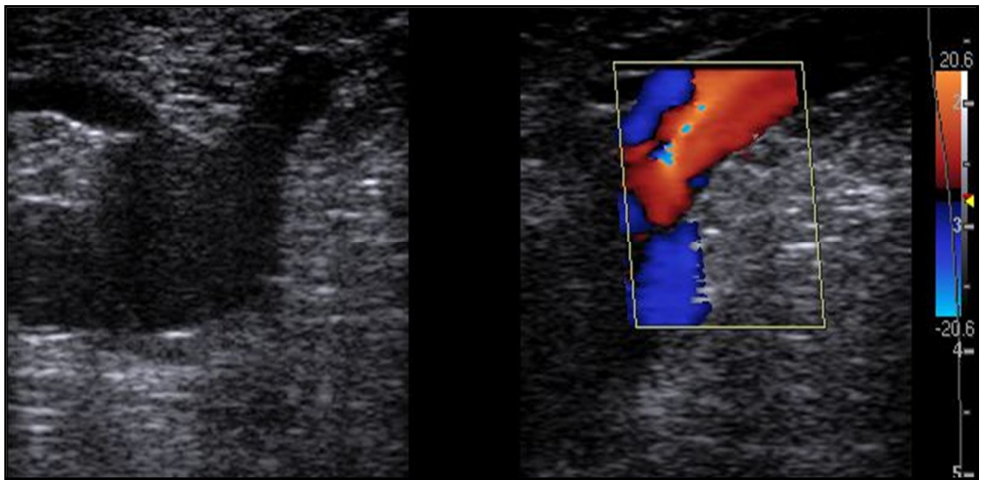


Fig 1. B-mode and duplex US show incompetence of the SFJ with reflux into the GSV before treatment.

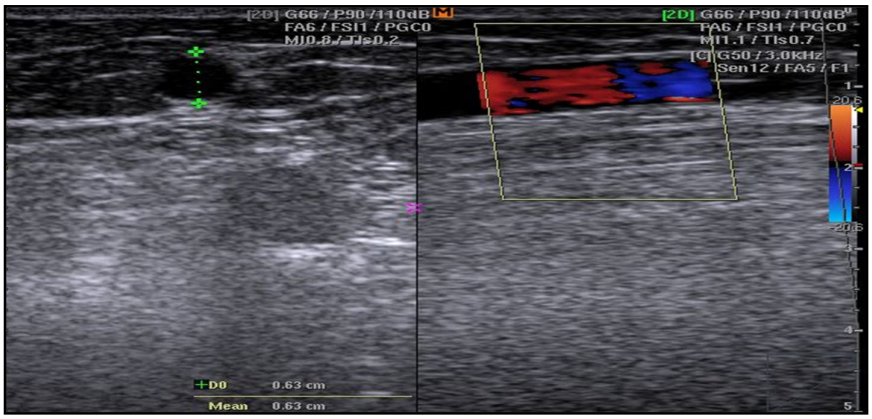
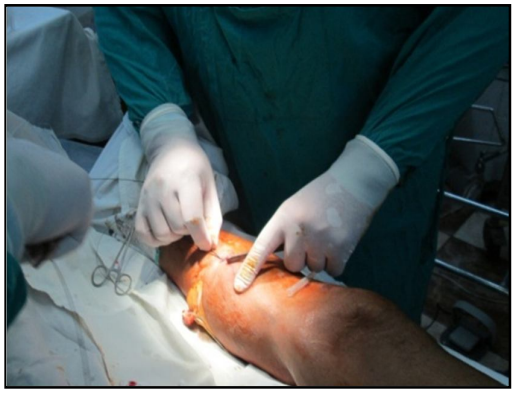
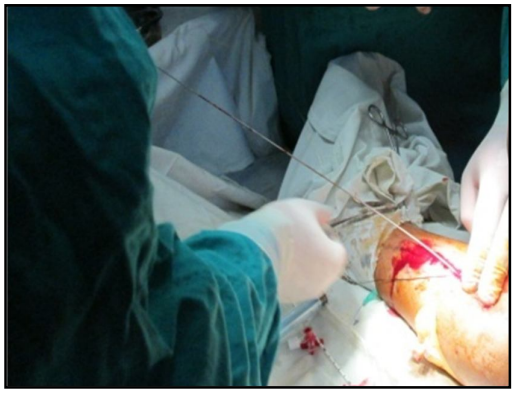


Fig 2. Pretreatment duplex US shows enlarged GSV measuring 6.3 mm in cross section and longitudinal dimension.





A **B**

Fig 3a. Shows passage of the guide wire after cannulation of GSV.
3b. Shows advancement of vascular sheath over guide wire.

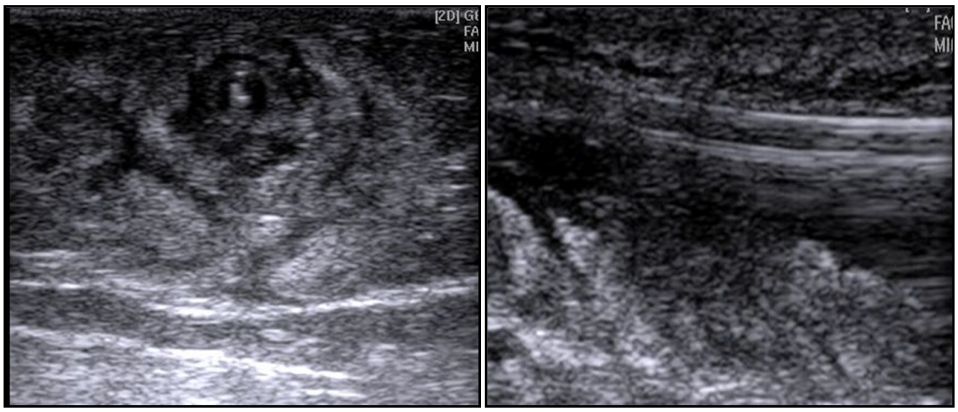


Fig 4. GSV surrounded by tumescent anaesthesia cross section and longitudinal view.

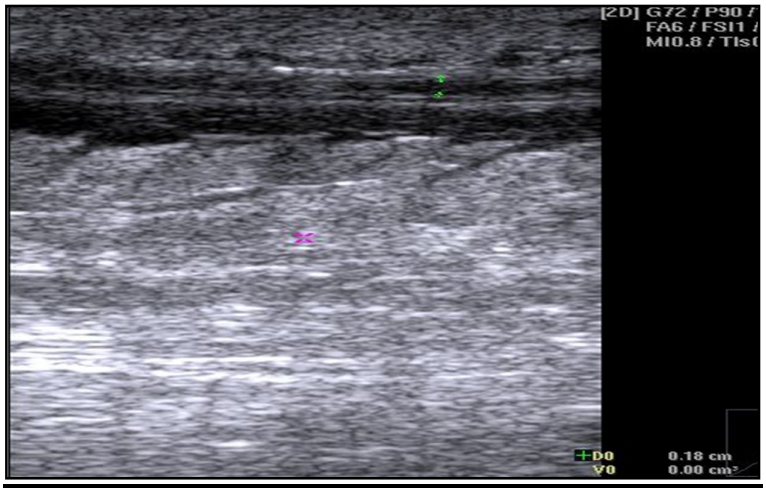


Fig 5. Shrinkage of GSV diameter immediately after the procedure to be 1.8 mm in diameter.

Follow-up examinations:- Patients were re-examined one week, 1, 6, 9 and 12 months postoperatively. Patients were evaluated each visit clinically and by duplex ultrasound to assess symptomatic improvement, patient satisfaction, saphenofemoral incompetence and observe any procedure related side effects. Manifestations of interest were postoperative pain, ecchymosis, palpable induration, paraethesia and DVT. Any criteria of these manifestations were recorded.

Management outcome

Treatment success was defined as symptomatic improvement as well as decrease in vein diameter, echogenic thickening of vein wall and no flow within the occluded lumen by duplex examination. Further follow up duplex ultrasound by time revealed complete disappearance of the GSV or minimal residual fibrous cord with no detectable flow. Treatment failure was defined as persistent patency or recanalization of the treated segment of GSV with no clinical improvement.

RESULTS

Table 1. Postoperative complications.

Postoperative pain	3 (12%)
Ecchymosis	18 (72%)
Induration	2 (8%)
Paraethesia	0 (0%)
DVT	0 (0%)

Successful percutaneous access and placement of the sheath with laser fiber was achieved in all patients. The

procedure was well tolerated by all patients with only tumescent anesthesia.

The mean GSV diameter measured in upright position, was 6.5 mm (range from 4 -9 mm). The mean length of GSV treated was 44.2 cm (range from 38 - 50 cm). Immediately postoperative successful occlusion that defined as absence of flow by duplex ultrasound, was noted in 24 GSVs (96%). Failure occurred only in one case with large vein (GSV diameter > 0.8 cm). Minimal residual cord was noted in 20% of patients at the 1-month follow-up followed by complete disappearance of the GSV few months later. Mean energy applied was 66 J/cm.

Postoperative pain was reported in 3 patients (12 %) during the first week and they received analgesics for another one week. Ecchymosis were seen in 18 patients (72%) and disappeared within 1-2 weeks. Palpable indurations were observed in 2 patients (8%) who resolved within two weeks postoperatively. No paraesthesia, superficial burns or DVT were detected.

DISCUSSION

In addition to the potential risks of surgery and anaesthesia needed for ligation and stripping, surgical treatment for the GSV is not free from recurrence. Sarin et al[3] reported 18 % rate of recurrent GSV reflux after ligation and stripping while 45% recurrence rate after high ligation alone which appeared as early as 3 months after treatment.[3] Similarly , Dwerryhouse et al[12] found a recurrence rate of 29% after ligation and stripping of the GSV while 71% after high ligation alone.[12]

Less invasive treatment alternatives aim to reduce risk, morbidity, and cost while leading to acceptable short and long-term results. Less invasive treatment alternatives include ultrasound guided foam sclerotherapy, bipolar radiofrequency as well as EVLT.[13]

Performing endovenous ablation of the GSV without dissection at SFJ which is considered a cardinal rule in saphenous vein surgery that each of the tributaries must be individually divided. Surprisingly, endovenous ablation procedures have shown lower recurrence rates than with ligation and stripping. Perhaps minimizing groin dissection and preserving venous drainage in competent tributaries while removing only the abnormal refluxing segments does not stimulate neovascularization.[14]

EVLT with a 980-nm diode laser system is clinically safe, feasible, well-tolerable technique without scar and allows people to return to their normal daily activities immediately.[15]

Although the number of patients treated with EVLT in this study was relatively small with a short-term follow-up duration, it was noted that other studies were also similar in the small number of patients or short term follow up duration, such as Navarro et al,[15] who performed his study on 40 patients for a duration of 14 month, Kim et al,[16] who studied 48 patients for 6 month duration, Oh Chang-Keun et al,[17] who followed12 patients for 3 months. Also both Sharif et al,[18] and Proebstle et al,[19] had followed their patients for 12 months only similar to the duration of that study.

Our early results with EVLT have been similar to Duran et al.,[20] who treated 517 GSV and reported closure rate of 98% after follow-up period of 24 months. Other similar results were obtained from Min et al,[21] and Sadick et al,[22] who reported similar closure rate around 98%.

Comparing results of EVLT with that of other less invasive techniques, Kanter et al,[23] had reported ultrasound guided foam sclerotherapy efficacy rate of 75%-80% in expert hands after one year follow-up while Manfrini et al,[24] had demonestrated recanalization rate of 10 % at a mean follow-up of 4.7 months by the use of radiofrequency.

Trendelenburg positioning of the treated limb as well as adequate tumescent anaesthetic solution are very important to empty the vein from blood because the presence of blood reduces the light transmitted to the vein wall. In such circumstances vein closure will occur by thrombosis and then thrombus dissolution leads to recanalization.[25]

Tumescent anaesthesia is essential for EVLT making this procedure safe and painless. About 400 -500 cc of fluid was required to be injected perivenously to be a barrier for surrounding structures from heat as well as its role in vein compression.[26]

In this study, mean energy applied was 66 J/cm. Similar amount of energy was applied in the studies of Theivacumar et al,[27] Timperman et al,[28] and Proebstle et al,[19] that reported 60-70 J/cm, 63.4 J/cm and 63 J/cm respectively. Timperman et al,[28] had published in his study that the use of high energy about 63.4 J/cm had lower failure rate, however Kim et al,[16] reported successful rate equal to that obtained by Timperman et al, in spite of using lower energy about 32.5 J/cm. Discrepancy in the energy delivered during EVLT reflects the hypothesis of Proebstle et al,[19] that to achieve reliable ablation of GSV , we required two factors; quantity of energy delivered as well as vein diameter. On the contrary, Kim et al,[16] had reported that there was no significant difference in success rate or failure rate between higher and lower amount of laser energy, so higher energy was not necessary as it theoretically led to more side effects e.g. superficial burns and palpable indurations.

We used the pulsed mode as it was our early experience. As pulsed mode of endovenous laser had induced bruising in most of patients, Proebstle et al.[31] suggested

the use of continuous pullback mode of the laser fiber with proper speed. In spite continuous pullback of laser fiber could avoid perforation of the vein wall and produced more destruction of the venous wall, however too slow pullback could produce a longitudinal cut in the venous wall and too rapid pullback could produce incomplete occlusion.[31]

Postoperative pain varied from being sore, discomfort to mild pain. Sharif et al,[18] 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 perivenous tissue. Gibson et al,[32] reported pain in 97% of treated patients, and also Proebstle et al,[33] confirmed that 72% of patients complained of pain. In their series, pain was treated with analgesics twice daily for 1-2 weeks. In our study, analgesics were routinely given to patients for one week before feeling of pain, that can explain why postoperative pain occurred only in 12% of patients and they required another one week duration of analgesics.

Ecchymosis occurred in our study in 18 patients (72%), which was similar to Sadick et al,[28] who reported 61.7% and Proebstle et al,[29] that reported 73.2%. Ecchymosis may be attributed to various causes but mostly due to laser induced micro vessel perforation, extravasation of blood into surrounding tissues, multiple subcutaneous injections of tumescent anesthetic solution.[30]

Indurations occurred in our study in 2 patients (8%) and it was similar to that occurred with Min et al, 2003[21] who reported (5%) incidence. These results hypothesize that delivered energy should be calculated according to the GSV diameter to obtain high rate of GSV closure with minimal thermal side effects.

Failure of the procedure was defined as persistent patency or recanalization of the treated segment with no clinical improvement. Failure was observed in our study in one case when GSV diameter was > 0.8 cm. It was discovered during follow up visits after first week, 1 month and considered failed procedure after 3 months. This patient refused repeating the technique and was treated by ligation and stripping.

We await longer-term follow-up results from our patients already treated with EVLT and evaluation of other new cases. This may offer a good alternative technique to ligation and stripping for those patients wishing to avoid or afraid of surgery.

In conclusion EVLT for GSV reflux appears to be safe, feasible and efficient outpatient technique. With proper patient selection, EVLT can be considered as a successful method for treating superficial vein reflux and may replace the traditional surgical treatment. Long-term follow-up is awaited.

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