

Research article

Endovenous Laser Ablation & concomitant injection foam Sclerotherapy for Treatment of Great Saphenous or Short Saphenous Varicose Veins

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Abstract

Background: Varicose veins involve at least 20% in the world population. Our study is focusing on the clinical evaluation and management of varicose veins using newly advanced technique Endovenous Laser Ablation (EVLA) to improve the quality of patients care.

Purpose: To study the Endovenous Laser Ablation & concomitant injection foam Sclerotherapy for Treatment of Great Saphenous or Short Saphenous Varicose Veins.

Patients & Methods: A total 30 patients with primary varicose veins. Most of them were unilateral on right side 67%, GSV involved in 78.13% along its whole length, investigated, operated using diode laser 980 nm, under LA and injection sclerotherapy, their Final outcome evaluated. **Results:** In this study we include varicose veins patients GSV reflux; 93.75%, SSV reflux; 6.25% and injection sclerotherapy 15.63%, no recurrence in follows up. **Interpretation & conclusion:** EVLT with a 980-nm diode Laser system and concomitant injection foam Sclerotherapy of tributaries of Great Saphenous or Short Saphenous Varicose Veins is clinically safe, feasible, simple to perform, well accepted by patients and relatively atraumatic and well-tolerated technique without scar.

Key words: Endovenous Laser, Ablation, Varicose Veins

Introduction

Three newer techniques have been developed as alternatives to open surgery to treat GSV incompetence. They have been advocated to offer benefits over open surgical stripping of the above knee portion of the GSV in eliminating sapheno-femoral reflux^{1,2,3} and in reducing complication rates, patient discomfort and the length of time before return to work^{4,3}. These three techniques are foam injection sclerotherapy, Endovenous laser therapy and radio-frequency ablation.

Endovenous laser therapy and RFA require duplex ultrasound localization of the GSV for Endovenous insertion of the device, identification of the device at the sapheno-femoral junction and direct visualization of the device during treatment. Foam sclerotherapy is also carried out under ultrasound visualization. Foam sclerotherapy relies on the basic principle of inducing fibrosis of the vein and obliteration

of the lumen by causing inflammation in the endothelial and sub-endothelial layers of the vein wall. The foam replaces blood in the vein, which enhances the efficacy of the sclerosing agent by reducing the volume of sclerosant required for treatment and increasing the effective surface area of the sclerosant in contact with the vein wall^{5,6,7}.

Patients and Methods

This is a prospective study, enrolled 30 selected patients at Minia University, Complaining of GSV and/ or SSV varicosity with or without SFJ and /or SPJ reflux. The principle examination included detailed medical history of the disease, careful physical examination and venous duplex ultra-sound imaging.

Inclusion criteria:

- Adult patients with primary varicose veins which were symptomatic.
- GSV and SSV with reflux > 1 second on duplex ultrasound

- Primary varicose veins with GSV incompetence with or without SFJ reflux with or without active ulcer.
- Primary varicose veins with SSV incompetence with or without SPJ reflux with or without active ulcer.

Exclusion criteria:

- Current deep-vein Thrombosis or acute superficial-vein thrombosis; Post-thrombotic

syndrome or occlusion of the femoral or iliac vein.

- GSV or SSV <3mm or > 15mm in diameter; Tortuous veins that were considered to be unsuitable for EVLA.
- Contra-indications to foam or to general/regional anesthesia which may be required for interventional surgery.
- Coagulation disorder, Peripheral arterial diseases; pregnant woman, those who were unable to ambulate.

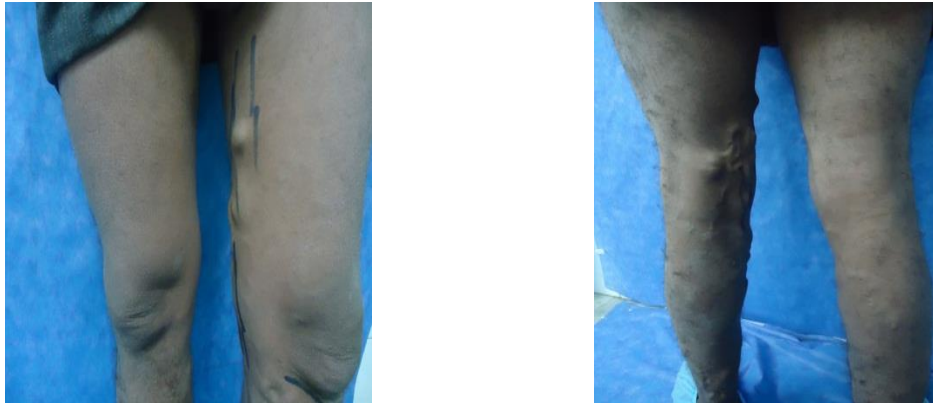


Figure (1) showing GSV , SSV marked enlargement in 2 different patients

DUS examination was performed using color coded duplex **Mindray system™**. The purpose was to measure the diameter of the superficial venous system, determine venous reflux and previous DVT or deep venous insufficiency.

Technique: The patient lie supine on the operative table and pre-operative duplex ultrasound is performed and the GSV, SSV is marked on the skin every 6 to 8 cm along its course from the proposed access site to

the sapheno-femoral junction using skin marker. The patients were placed in anti-trendelenburg position on the table in order to minimize shrinkage of the vein, EVLT with 980 nm diode Laser (**Fox™, Cherolase™** of ARC Laser Systems, Germany) was performed under tumescent anesthesia for all 30 patients. The GSV was cannulated at knee level via percutaneous needle puncture under ultra-sound guidance in 10 patients in other patients it had been cannulated at the ankle level.



Figure (2) clinical and duplex diagnosis of SSV varicosity and SPJ reflux

Once the device is appropriately placed for ablation, the patient is placed in Trendelenburg position to facilitate vein emptying and peri-venous tumescent

anesthesia is then delivered .Optimal delivery of this fluid into the saphenous space is accomplished under DUS examination.

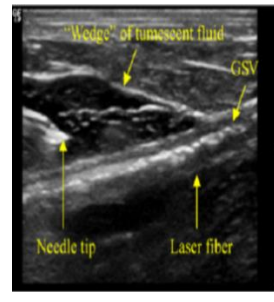


Fig (3): Under DUX scans guide-wire and sheath advancement till below SPJ.

Fig (4): Longitudinal and cross-sectional views of DUS during tumescence.

The tumescent local anesthetic solution consists of 20 ml 1% lidocaine and 1 ml adrenaline (1:100000) diluted in 500 ml of cold (4°C) saline was applied peri-venously.

mL syringe, the 10-mL syringe is connected to a 3-way cannula with a 10-mL syringe containing 7 mL of air; the syringes are rapidly depressed sequentially to create the foam (1:3) sclerosant to air volume ratio, or usually performed 1-3 weeks after EVLT; this was done in the out-patient clinic. The sclerosant used in this study was Aethoxysklerol™.

Further treatment by ultra –sound guided sclerotherapy for the residual tributaries was required after 30% of procedure, the sclerosing agent solution is prepared for foam sclerotherapy, it is aspirated in a 10-



Figure (5):step by step concomitant injection foam sclerotherapy with EVLA using tessari technique

DUS criteria for successful treatment: At 1-week follow-up, an enlarged non-compressible GSV, with echogenic, thickened vein walls and no flow seen. At 3 and 6

months follow-up, an occluded GSV with substantial (50%) reduction in diameter. relief at follow-up visits, particularly improvement or resolution of lower-extremity pain associated with venous insufficiency.

Clinical evaluation was performed on all subjects at 1 week, 1, 3 and 6 months. Patients were asked about symptomatic

Results

The treatment was in the form of Endovenous Laser Ablation with or without injection sclerotherapy in the same session or in follow up visits.

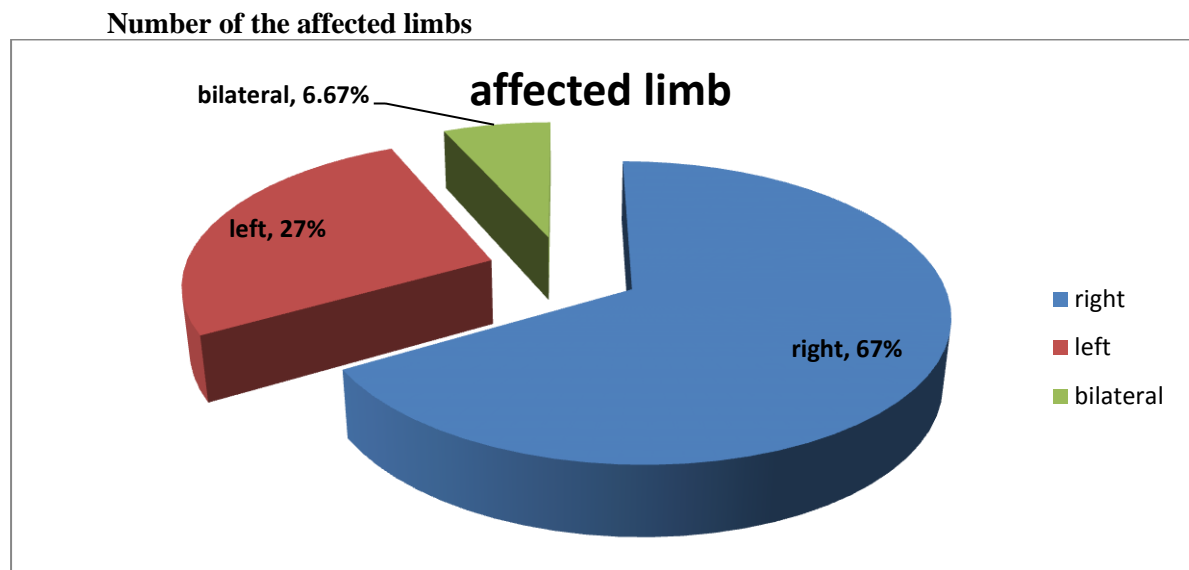


Fig (7): Pie chart showing percent of the affected limb. (N=32 limbs in 30 patients)

The anatomical classification of varicose vein of the studied 30 patients is shown in and demonstrated in fig (8):

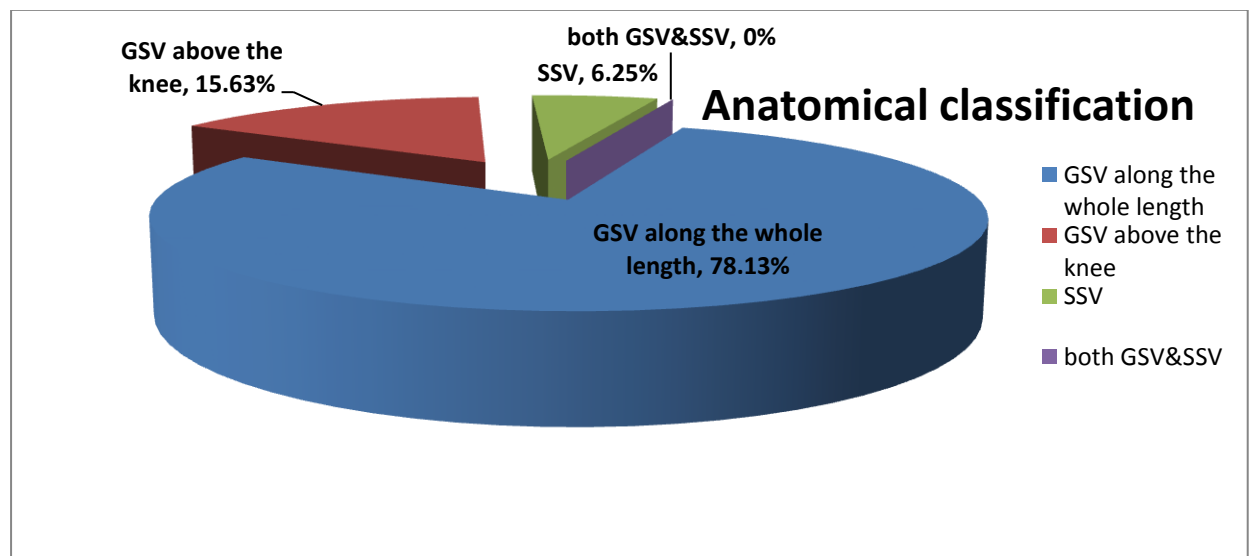


Fig (8): Pie chart showing anatomical classification of V.V in the studied patients.

On the colored duplex examination all the patients were found to have incompetent saphenous veins in one or both limbs, in this examination significant reflux was seen in the great saphenous veins and /or small

saphenous vein. The colored duplex ultrasound determine the site of puncture the GSV either at the level of the knee or at the ankle according to the diameter of the vein as demonstrated in the bar chart of fig (9).

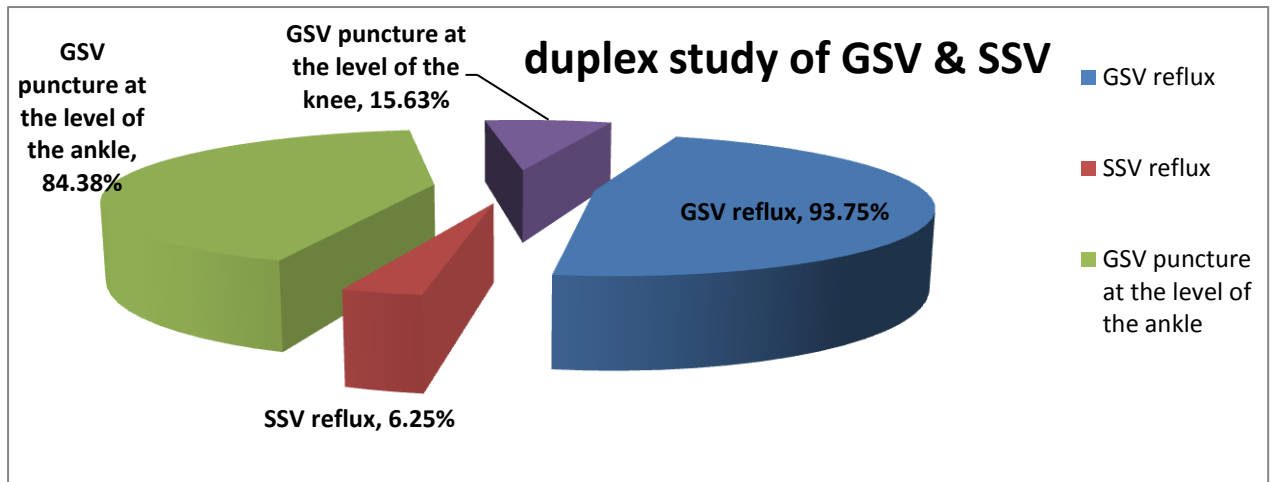


Fig (9): pie chart showing duplex study of the studied patients.

Chemical sclerotherapy was performed for some of our cases with residual dilated tributary after EVLT. This was usually

performed in the same session of EVLT the following table show the rate of injection in our patients.

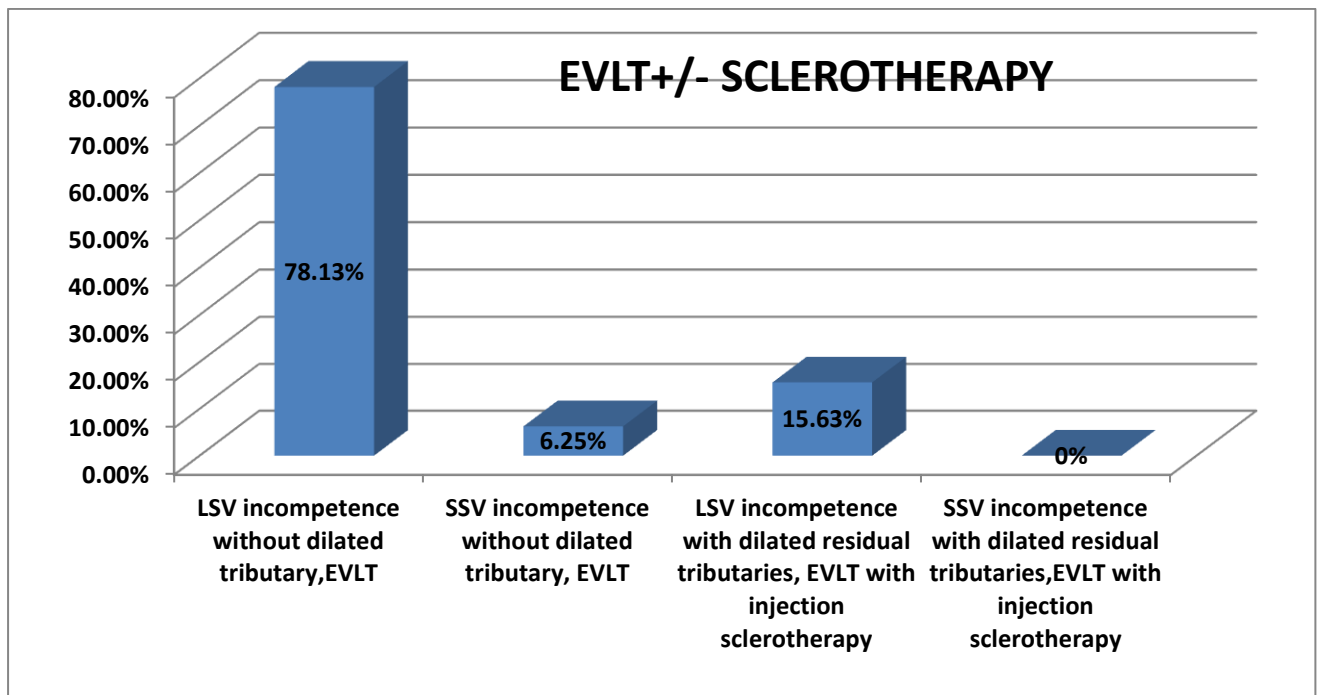


Figure (10) Bar chart Sclerotherapy in the studied patients

Discussion

The Laser system used in this study was Fox™, Chrolase™ diode Laser 980 nm (A.R.C, German) which is one of the highest qualities Laser, mean energy applied was 70 J/cm. The choice of pulsed laser for EVLA was based on the description of the technique and the results reported by Min et al., the principle benefit of continuous withdrawal is a reduction in treatment time with no increase in complications⁸. The basis of classification of varicose veins was according to CEAP classification¹⁰, and Revision of the CEAP classification¹¹.

In this study we use terms of volume of sclerosant, 5 patients received 1%, 2%, 3% polidocanol, Branch varicosities can have liquid or foam sclerosant placed into them appropriately, Volume is now based on diameter and length; different concentrations of sclerosant may be used according to vein size. Chemical sclerotherapy was performed in 5 limbs (15.625%) of our patients with residual tributaries in the same session of EVLT, P Ho et al., similarly performed sclerotherapy in 3 patients (12.5%) of his 24 patients at 8th weeks follow up and in 1 patient (4.1%) at 6th month¹².

Our early results 97% success with EVLT has been similar to Duran Mario¹³.most patients needed additional complementary procedures such as sclerotherapy or phlebectomy as was published in a study by Robert J et al.,¹⁴.

Brittenden J et al., Considered that both the 6-month clinical outcomes and the estimated 5-year cost-effectiveness suggest EVLA to be the treatment of choice for suitable patients¹⁵.

In this study superficial thrombophlebitis was preserved in 5 patient (16.6%) topical anti-inflammatory was prescribed and rapid improvement was noticed in the follow up, this was reported in several studies^{16,17}. Hyper-pigmentation developed in one patient over the thrombosed occluded GSV.

Conclusion

Endovenous procedures allow more efficient management of large numbers of out-patient treatment. EVLT with a 980-nm diode Laser system concomitant injection foam Sclerotherapy is clinically safe, feasible, simple to perform, well accepted by patients and relatively atraumatic and well-tolerated technique without scar and allows people to return to their normal daily activities rapidly.

References

1. Bergan JJ (2002): Saphenous vein stripping by inversion: Current technique. *Surg Rounds*; 7: 451-459.
2. Navarro L, Min R, Boné C. (2001) Endovenous laser: a new minimally invasive method of treatment for varicose veins-preliminary observations using an 810 nm diode laser. *Dermatol Surg*; 27:117-122.
3. Rautio T, Ohinmaa A, Pera" la" J, et al., (2002) Endovenous obliteration versus conventional stripping operation in the treatment of primary varicose veins: a randomized controlled trial with comparison of the costs. *J Vasc Surg* ;35: 958-965.
4. EVOLVEs Study :Lurie F, Creton D, Eklof B et al., (2003) Prospective randomised study of endovenous radiofrequency obliteration (closure) versus ligation and stripping (evolves study): early results and one year followup. *European Society for Vascular Surgery, Programme and Abstract Book, XVII Annual Meeting and Course on Vascular Surgical Techniques*: 74-5.
5. Baccaglini U, Spreafico G, Castoro C et al., (1997) Consensus conference on sclerotherapy or varicose veins of the lower limbs. *Phlebology*. 1997; 12 (1):2-16.
6. Tessari L, Cavezzi A, Frullini A. (2001) Preliminary experience with new sclerosing foam in the treatment of varicose veins. *Dermatologic Surgery*; 27(1):58-60.

7. Nesbitt C, Bedenis R, Bhattacharya V et al., (2014) Endovenous ablation (radiofrequency and laser) and foam sclerotherapy versus open surgery for great saphenous vein varices. *Cochrane Database of Systematic Reviews*, Issue 7. Art. No.: CD005624.DOI: 10.1002/14651858.CD005624.pub3.
8. Theivacumar NS, Dellgrammaticas D, Beale RJ et al., (2008) Factors influencing the effectiveness of endovenous laser ablation (EVLA) in the treatment of great saphenous vein reflux. *Eur J Vasc Endovasc Surg* 35:119-123.
9. Min R, Zimmet S, Isaacs M, Forrestal M. (2001) Endovenous laser treatment of the incompetent greater saphenous vein. *J Vasc Interv Radiol*; 12:1167–1171.
10. Bergan JJ, Eklof B, Kistner RL et al., and the International ad hoc committee of the American Venous Forum(1996) Classification and grading of chronic venous disease in the lower limbs. A consensus statement, *Vasc. Surg.* 30: 5–11.
11. Eklöf B., Rutherford R.B., Bergan J.J.et al., for the American Venous Forum International ad hoc committee for the revision of the CEAP classification (2004) Revision of the CEAP classification for chronic venous disorders: Consensus statement. *Journal of Vascular Surgery*. 40(no.6). Pp 1248-1252.
12. P Ho, Jensen TC Poon, SY Cho et al., (2009) Day surgery varicose vein treatment using endovenous laser. *Hong Kong Med J*; 15:39-43.
13. Duran Mario (2005) Endovenous laser treatment with 980 diode laser: follow up in two years in 670 procedures. Presented at the 15th World Congress of UIP; Rio, Brazil.
14. Robert J, Neil Khilnani and Steven E. Zimmet (2003) Endovenous Laser Treatment of Saphenous Vein Reflux: Long-Term Results. *J Vasc Interv Radiol* 14:991-996.
15. Brittenden J, Cotton SC, Elders A et al., (2015) Clinical effectiveness and cost-effectiveness of foam sclerotherapy, endovenous laser ablation and surgery for varicose veins: results from the Comparison of LAser, Surgery and foam Sclerotherapy (CLASS) randomised controlled trial. *Health Technol Assess*; 19(27).
16. Min RJ, Khilnani NM, Zimmet SE. (2003) Endovenous laser treatment of saphenous vein reflux: long-term results. *J Vasc Interv Radiol*; 14:991-996.
17. Proebstle TM, Gul D, Lehr HA, et al., (2003) Infrequent early recanalization of greater saphenous vein after endovenous laser treatment. *J Vasc Surg. Sep*; 38(3):511-6.