Original article:

Effectiveness and complications of USG guided endovenous laser therapy in patients of varicose veins coming to PRH Loni

Dr Ankit kumar Jain, *Dr D. S. Kulkarni, Dr Y. P. Sachdev

Department of Radio-diagnosis, Rural medical college, Pravara institute of medical sciences Loni , Maharasthtra , India
Corresponding author*

Abstract

Introduction - Endovenous laser ablation of the saphenous vein is a relatively new procedure that involves percutaneous introduction of a laser fiber into the incompetent vein to produce a non-thrombotic occlusion and acute inflammation of the targeted vein. Endovenous laser therapy is a minimally invasive method of treating superficial venous insufficiency; it may be done in an outpatient setting using local anesthesia. This method, being less invasive than surgical stripping, may have fewer adverse effects and better cosmetic outcome, causing less impairment of patients' physical or professional activities, with improved quality of life.

Objectives- To assess the efficacy and safety of endovenous laser ablation as a treatment modality for varicose veins under ultrasonography guidance.

Materials and methods- 56 patients were treated with EVLA. After duplex mapping and seldinger vein access, the laser fibre was placed 2 cm distal to saphenous junction, then withdrawn mechanically. A 1470 nm diode Nd : YAG laser with tumescent anaesthesia was used. With immediate ambulation class 2 compression hose were worn for 1 month. Patients were reexamined one week, 1, 3, 6 and 12 months postprocedure.

Observations & Conclusion: All refluxing veins were closed with no serious adverse outcomes. Most venous symptoms seized within 24 hrs. All junctions reduced in size ; competent or were closed. Success rates at mean follow-up of 12 months were 100 % for great saphenous veins. Ecchymosis was seen in 4 patients (6 %). Superficial burns were observed in 1 patient (2 %) and resolved within two weeks. No paresthesia or DVT was detected.

INTRODUCTION

"Varicose veins" represent a common health problem, the effects of which in terms of disability and health care costs are considerable. Varicose veins are caused by underlying chronic venous insufficiency with ensuing venous hypertension. This venous hypertension leads to a broad spectrum of clinical manifestations, ranging from symptoms like cramps, itching, swelling and leg tiredness to cutaneous findings like reticular veins, telangiectasias, varicose veins, edema, skin pigmentation and ulcerations.

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, it has a 30–60% recurrence rate (2,3). The possible mechanisms of recurrence after surgical treatment are inadequate procedure and 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).

In 1999, the Spanish phlebolologist, Dr. Carlos Boné published his studies about a new method for treating large-caliber varicose veins by applying endovenous laser energy transmitted through an optic fiber.[5] Subsequent studies were performed to evaluate the treatment safety and efficiency on varicose veins with endovenous laser.[6]

Endovenous laser ablation of the saphenous vein is a relatively new procedure that involves percutaneous introduction of a laser fiber into the incompetent vein to produce a non-thrombotic occlusion and acute inflammation of the targeted vein. Endovenous laser therapy is a minimally invasive method of treating refluxing varicose veins; it may be done in an outpatient setting using local anesthesia. This method, being less invasive than surgical stripping, may have fewer adverse effects and better cosmetic outcome, causing less impairment of patients' physical or professional activities, with improved quality of life.

Diode lasers are most commonly used for ELA (7). Different varieties of wavelengths have been proposed. Wavelengths 810, 940 and 980 nm are the most commonly used with a power energy set between 10 and 15W (8–11).

AIMS AND OBJECTIVES

1. To evaluate efficacy of endovenous laser therapy as a treatment modality for symptomatic varicose veins under Ultrasonography guidance.

2. To evaluate safety of endovenous laser therapy in treatment of varicose veins.

MATERIAL AND METHODS

The present prospective study was carried out at pravara rural hospital, for the period of 2 years after approval from the institutional ethical committee. A total of 56 patients (56 limbs) including varicose veins involving great saphenous veins, small saphenous veins and perforators were evaluated and subjected to endovenous laser therapy (EVLT).

Successful treatment of varicose veins with EVLT requires careful preoperative planning. A thorough history and physical examination is the first step. Detailed history regarding previous vein procedures (sclerotherapy, previous ablation, or stripping), prior deep venous thrombosis (DVT), superficial thrombophlebitis, and family history of thrombophilia was taken.

Inclusion criteria:

- Patients with valvular incompetence (i.e. reflux) in superficial lower limb veins documented with Doppler or Duplex Ultrasound scanning.
- Symptomatic patients with CEAP C2 or higher venous disease (according to Clinical, Etiologic, Anatomic and Pathophysiologic classification for varicose veins).

Exclusion criteria:

- Acute deep venous thrombosis.
- Pregnancy or breast-feeding.

www.ijbamr.com P ISSN: 2250-284X , E ISSN : 2250-2858

- Excessive tortuosity of superficial venous system.
- Thrombophlebitis at the time of procedure.
- Severe uncorrectable coagulopathy
- Inability to ambulate

Material:

- **Laser machine:** Lasitronix - Diomed, Wavelength 1470 nm, Optical power 14 Watts, Operating mode: continuous.

Figure 4: Laser Diomed machine.

- **EVLT Procedure Kit:**

Containing- Percutaneous Entry needle (19G, 70 mm length)

- 'J' tip Guide Wire (0.035 J)
- Introducer / Sheath Set (5 Fg, 55 cm length)
- EVLT Fiber (Length 2.5 m, core size 600 micro meter)

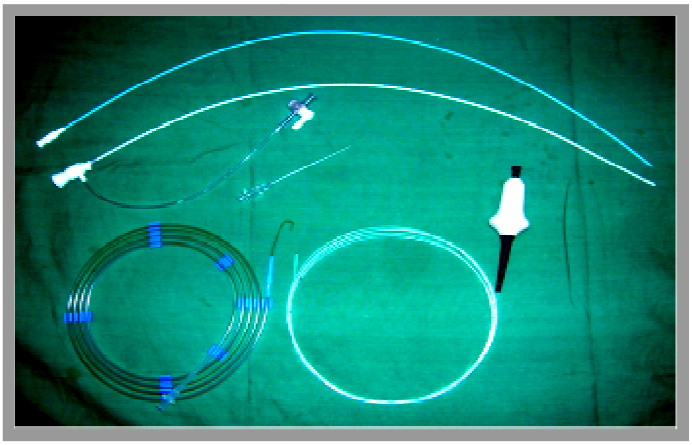


Figure 5: EVLT Procedure Kit:

www.ijbamr.com P ISSN: 2250-284X , E ISSN : 2250-2858

- **Doppler and ultrasound machine:** Toshiba Xario 200 duplex Doppler and color coded imaging ultrasound machine with linear array 7–12 MHz transducer.

Pre operative preparation:

Consent form: The procedure is carried out with prior informed written valid consent.

Clinical history and photographs: we considered certain points in patients' history [varicose veins in family, prior superficial phlebitis or resolved DVT, prolonged standing job]. Patient to describe symptoms and rate the intensity according to CEAP grading and determine the venous disability score (VDS).

Ultrasound - Venous reflux was defined as a reverse flow of more than 0.5 seconds, while perforators were considered incompetent if the diameter was 4 mm or more and/or had an outward directional flow exceeding 0.5 seconds [56]. Mapping of the Junction and superficial vein. (Figure: 6) Access-site is decided. Hard copy documentation of the vein diameters and reflux. The length of the vein to be ablated is noted.

Procedure:

The area of the vein to be ablated is cleaned with betadine and draped. Ultrasound probe is covered with sterile cover. The procedure was carried out in the supine position for GSV ablation and prone for SSV ablation.

Under local anesthesia and ultrasound guidance percutaneous entry into the GSV/SSV is made with 7 cm, 19 gauge thin wall needle. After needle-entry into GSV/SSV is confirmed 0.035"J-tip guide wire is introduced as much as possible. 19 G needle is removed and guide wire is left in position.

A 5- French, 55 cm introducer sheath is inserted over the guide wire (Figure: 8b). Under Ultrasonography guidance position of the SFJ/SPJ is decided and the laser sheath is placed at least 2 cm distal to SFJ/SPJ the junction and the guide wire is removed..

The sterile laser fiber (600 microns) is advanced through the introducer sheath under ultrasound guidance with its tip 2 cm distal to SFJ/SPJ and extending 1 cm out from the introducer sheath. At the saphenofemoral junction, the tip should be just below a competent superficial epigastric vein.

Perivenous local anesthesia , the combination of 250ml of saline and 60ml of 1% Injection Lignocaine, is administered beginning at the access point to the GSV/SSV up to the SFJ/SPJ. Using a micropuncture needle (24G), the solution is injected just above and parallel to the sheath to create a layer of tumescence surrounding the sheath and laser fiber.

The position of the laser fiber and the introducer sheath is reconfirmed by ultrasound. The room light is lowered and the aiming beam is turned on. The position of the tip of the laser fiber is confirmed by red laser aiming beam visible through the skin. After ensuring that the patient and all the staff in the treatment room wear the laser safety glasses, the laser machine is placed in a "ready mode". For treatment using continuous energy delivery, the console is set to 14 W and the laser fiber was slowly withdrawn at a steady rate of approximately 1 mm/s. The laser fiber and the introducer sheath are withdrawn simultaneously.

www.ijbamr.com P ISSN: 2250-284X , E ISSN : 2250-2858

Laser treatment is stopped when the aiming beam is 1 cm from the access site in order to avoid puncture site burn.

Post operative instructions to the patient: To wear stocking continuously for 7 days. To continue with routine activities, to be mobile and to avoid bed rest. To follow up at 1 week, 1 month, 3 months, 6 and 12 months postoperatively.

Post operative follow up evaluation:

At 1 week, 1 month, 3 months, 6 months and 12 months patient is asked to follow up. At each follow up

a. Ultrasonic as well as Doppler screening of the SFJ or SPJ of the operated limb is done to rule out any extension of thrombus into deep venous system.
b. Clinical photograph of the operated limb was taken.
c. Improvement in CEAP grading and VDS was documented.
d. Follow up ultrasound is done and following parameters were recorded:
    i. Reflux at SFJ or SPJ : present or absent.
    ii. Occlusion of the ablated vein: complete(c), near complete(nc) , recanalization (r)
e. In patients with venous ulcers (clinical CEAP grade C6), the approximate area of the healing / non healing ulcer was recorded.

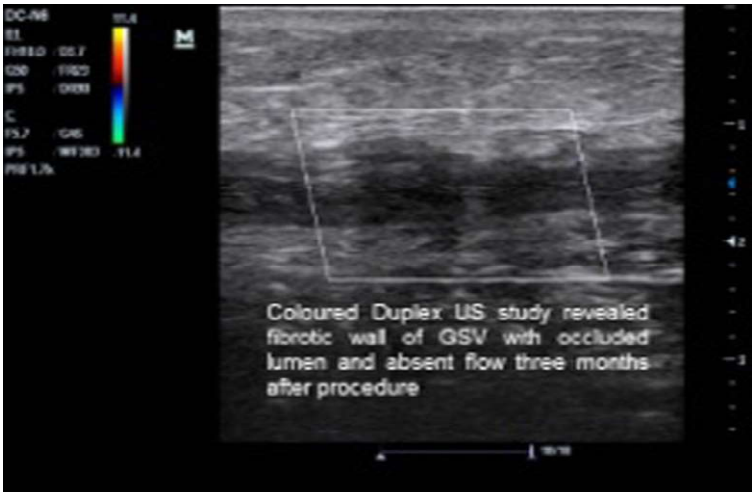
Patient follow-up

– Patients were re-examined one week, 1, 3, 6 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, paresthesia and DVT. Any criteria of these manifestations were recorded.

2.3. Procedure outcome

Treatment success was defined as symptomatic improvement as well as decrease in vein diameter, hyperechoic thickening of vein wall and no flow within the occluded lumen by duplex examination. Further follow-up through 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.

www.ijbamr.com P ISSN: 2250-284X , E ISSN : 2250-2858



RESULTS

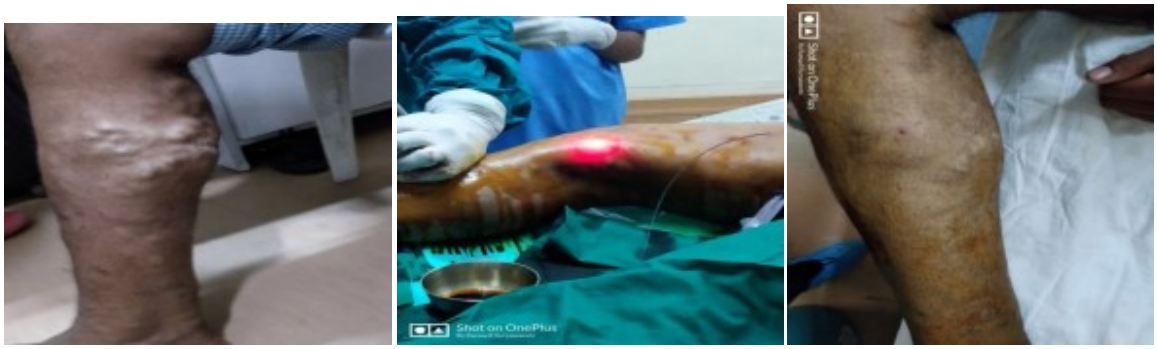
Successful percutaneous access and placement of the sheath with laser fiber were achieved in all patients. The procedure was well tolerated by all patients. The mean GSV diameter measured in upright position, was 7 mm (range from 5 to 9 mm). The mean length of GSV treated was 45 cm (range from 39 to 51 cm).

Immediate postoperative successful occlusion that is defined as absence of flow by duplex ultrasound, was noted in 56 GSVs (100%). 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 8 patients (14%) during the first week and they received analgesics for another one week. Ecchymosis was seen in 4 patients (6 %) and disappeared within 1–2 weeks. Palpable indurations were observed in 2 patients (6%) who resolved within two weeks postoperatively. Superficial burns was observed in 1 patient (2%) No paresthesia, superficial burns or DVT was detected (Table 1).

Post operative pain	14 %
Ecchymosis	6 %
Superficial burns	2 %
Paresthesia	0
DVT	0

www.ijbamr.com P ISSN: 2250-284X , E ISSN : 2250-2858



DISCUSSION

Performing endovenous laser ablation of the GSV / SSV without dissection at SFJ/ SPJ is considered a cardinal rule in saphenous vein surgery that each of the tributaries must be individually divided. Endovenous laser ablation procedures have shown lower recurrence rates than with ligation and stripping. In our study, successful percutaneous access and placement of the sheath with laser fiber were achieved in all patients. Immediate postoperative successful occlusion that is defined as absence of flow by duplex ultrasound, was noted in 56 GSVs (100 %). Less invasive treatment alternatives include ultrasound guided foam sclerotherapy, bipolar radiofrequency as well as EVLT (13). Perhaps minimizing groin dissection and preserving venous drainage in competent tributaries while removing only the abnormal refluxing segments do not stimulate neovascularization (14). EVLT with a 1470-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)

REFERENCES

(1) Callam MJ. Epidemiology of varicose veins. Br J Surg 1994;81: 167–73.

(2) Allegra C, Antignani PL, Carlizza A. Recurrent varicose veins following surgical treatment: our experience with five years follow-up. Eur J Vasc Endovasc Surg 2007;33:751–6.

(3) Sarin S, Scurr JH, Coleridge Smith PD. Assessment of stripping of the long saphenous vein in the treatment of primary varicose veins. Br J Surg 1992;79:889–93.

(5) Min RJ, Khilnani N, Zimmet SE. Endovenous laser treatment of saphenous vein reflux: long-term results. J Vasc Interv Radiol 2003;14:991–6.

6. Navarro L, Min R, Bone' C et al. Endovenous laser a new minimally invasive method of treatment for varicose veins- preliminary observations using an 810 nm diode laser. Dermatol surg 2001; 27:117-122.

(7) Proebstle TM, Lehr HA, Kargl A, Espinola-Klein C, Rother W, Bethge S, et al. Endovenous treatment of the greater saphenous vein with a 940-nm diode laser: thrombotic occlusion after endoluminal thermal damage by laser-generated steam bubbles. J Vasc Surg 2002;35:729–36.

(8) Sadek M, Kabnick LS, Berland T, Cayne NS, Mussa F, Maldonado T, et al. Update on endovenous laser ablation: 2011. Perspect Vasc Surg Endovasc Ther 2011;23(4):233–7.

(9) Goldman MP, Mauricio M, Rao J. Intravascular 1320-nm laser closure of the great saphenous vein: a 6- to 12-

month follow-up study. Dermatol Surg 2004;30:1380–5.

(10) Oh CK, Jung DS, Jang HS, Kwon KS. Endovenous laser surgery of the incompetent greater saphenous vein with a 980-nm diode laser. Dermatol Surg 2003;29:1135–40.

(11) Min RJ, Zimmet SE, Isaacs MN, Forrestal MD. Endovenous laser treatment of the incompetent greater saphenous vein. J Vasc Interv Radiol 2001;12:1167–71.

(12). Van Bemmelen PS, Bedford G, Beach K, Strandness DE et al. Quantitative segmental evaluation of venous valvular reflux with duplex untrasound scanning. J Vasc Surg 1989; 10:425-31.

(13)New Device Approval. http://www.fda.gov/cdrh/pdf/p990021a.pdf. Accessed April 2007.

(14) Robert F. Merchant et al. Endovascular obliteration of saphenous reflux: A multicenter study. J Vasc Surg 2002; 35:1190-1196.

(15). Chang CJ, Chua JJ et al. (2002). Endovenous laser photocoagulation (EVLP)for varicose veins. Lasers Surg Med 31:257–262.