

Endovenous laser ablation gold standard for varicose veins of lower limbs

Bhosale Dattatray^{1*}, Sawant Sharad²

¹Assistant Professor, Department of General Surgery, Government Medical College, Miraj, Sangali, Maharashtra, INDIA.

²Associate Professor, Department of General Surgery, BVMC, Sangali, Maharashtra, INDIA.

Email: drbhosaledn@gmail.com

Abstract

Endovenous laser ablation (EVLA) of the great saphenous vein (GSV) is thought to minimize postoperative morbidity and reduce work loss compared with high ligation and stripping (HL/S). Patients with varicose veins due to GSV insufficiency were randomized to either EVLA (980 nm) or HL/S in tumescent anesthesia. In our clinics, 50 varicose patients were treated between August 2013 and September 2016. EVLA was applied in 25 cases and HL/S was applied in 25 cases. Clinical features and demographic characteristics of the patients were summarized. EVLA procedure was done by 980 nm diode laser (Ceralas D 980, Biolitec) at continuous mode with 15 W energy. Patient visits were done at post-operative 10th day, 6th month, 1st year and 2nd year. Routine physical examination and Doppler USG assessments were performed at these visits. EVLA and HL/S procedures were done in complete success in all cases at both groups. All cases were invited for control visits. When complications developed after procedures were evaluated; no infection, hematoma or paresthesia were observed in EVLA group. However in HL/S group; infections, hematomas and paresthesia were observed in 6, 4 and 2 cases respectively. In terms of treatment success, there was no recurrence in EVLA procedure while recurrence rate after conventional surgery found in 3 cases. In terms of post-op complication, EVLA method was associated with significantly less paresthesia, hematoma and pain. EVLA method is a method as effective and safe as standard treatment. However, when a long term result of this method is shown completely, its effectiveness will be cleared and its clinical utility will be established.

Keywords: Glimepiride, Metformin, Malondialdehyde level (MDA), Glycemic Control, Lipid Profile.

*Address for Correspondence:

Dr. Bhosale Dattatray, Assistant Professor, Department of General Surgery, Government Medical College, Miraj, Sangali, Maharashtra, INDIA.

Email: drbhosaledn@gmail.com

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INTRODUCTION

Venous insufficiency at lower extremities may result with clinical problems from cosmetic issues to ulcerations. When the frequency of venous insufficiency and its related problems are considered besides their diversity, it is encountered as a public health issue. This pathology is reported to affect 40% of the women and 20% of the men^{1,2}. General complaints related to venous insufficiency depends on the severity of the Insufficiency

and accompanying pathologies. Discoloration, pain, cramps, itching, edema and ulcerations at legs are symptoms accompanying to venous insufficiency³. While major risk factors are age and family history for both sexes, pregnancy is an additional risk factor for women⁴. Besides, standing for long periods, obesity and female gender are reported as risk factors⁵. Until recently, the standard treatment consisted of ligating vena saphena magna (VSM) at saphenofemoral junction, stripping below knee and mini phlebectomies. Additionally, branches of VSM at junction are ligated and divided and thus, the recurrence is aimed to be prevented⁶. With the development of minimal invasive techniques in the past 10 years, the usage of laser energy came to the fore for the endovenous thermal ablation of VSM. Radiofrequency ablation and ultrasound guided foam sclerotherapy methods have emerged. Postoperative follow up results of those 3 techniques are still debating and continued to be evaluated⁷⁻⁹. In our study we compared VSM high ligation and stripping (HL/S) to the

endovenous laser ablation (EVLA) procedure in cases with varicosis due to VSM insufficiency. We aimed to explore advantages and disadvantages of both procedures for the short term results.

What does the procedure involve?

An ultrasound scan is performed and the veins to be treated are marked with a pen. You lie on a couch and your leg is cleaned and covered with drapes. Depending on which veins are to be treated, you may be on your back or your front. All these steps are guided by ultrasound scanning. Endovenous means inside the vein, so the next thing the doctor has to do is to get inside your vein. A small amount of local anaesthetic is injected into the skin over the vein and a needle inserted into it. A wire is passed through the needle and up the vein. The needle is removed and a catheter (thin plastic tubing) is passed over the wire, up the vein and the wire removed. A laser fibre is passed up the catheter so its tip lies at the highest point to be heated (usually your groin crease). A large quantity of local anaesthetic solution is then injected around the vein through multiple tiny needle pricks. All staff and the patient put on laser safety specs as a precaution. The laser is then fired up and pulled down the vein over about 5 minutes. You will hear a warning buzzer ringing and may smell or taste burning but won't feel any pain. If you're having both legs treated the process is repeated on the other leg. The laser and catheter are removed and the needle puncture covered with a small dressing.

Target veins

ELA has been successfully and safely used to ablate the great and small saphenous veins, the anterior and posterior accessory great saphenous vein, the superficial accessory saphenous vein, the anterior and posterior circumflex veins of the thigh as well as the thigh extension of the small saphenous vein, including the vein of Giacomini. ELA has been used to treat long straight competent tributary veins outside the superficial fascia, particularly in patients who are obese and who either sclerotherapy or microphlebectomy would be difficult, time consuming, or prone to side effects.³

ELA mechanism of action

The underlying goal for all thermal ablation procedures is to deliver sufficient thermal energy to the wall of an incompetent vein segment to produce irreversible occlusion, fibrosis, and ultimately disappearance of the vein. The mechanism of vein wall injury after ELA is controversial. It has been postulated to be mediated both by direct effect and indirectly via laser-induced steam generated by the heating of small amounts of blood within the vein.¹ Adequately damaging the vein wall with thermal energy is imperative to obtain effective ablation. Some heating may occur by direct absorption of photon

energy (radiation) by the vein wall, as well as by convection from steam bubbles and conduction from heated blood. However, these later mechanisms are unlikely to account for most of the impact on the vein. Diode lasers are most commonly used for ELA. Laser generators exist with multiple different wavelengths, including lower wavelengths that are considered hemoglobin specific and include 810 nm, 940 nm, 980 nm, and 1064 nm. Higher wavelengths are considered water specific and include 1320 nm and 1470 nm. Although it is still not definitively established in the literature, some authors suggest that the higher wavelength lasers produce similar efficacy at lower power settings with less postprocedure symptoms.² It can be performed with multiple different laser fiber designs (ie, bare-tip fibers, jacket-tip fibers [see image below], radial fibers) and diameters available from a variety of vendors. Each of the fiber designs has been demonstrated to be effective in closing the saphenous vein. At this point, there are no conclusive data demonstrating a superiority of a given fiber, wavelength and energy deposition combination, efficacy, significant adverse effects, or complications as metrics for comparison. EVLA should be performed under local anesthesia using large volumes of a dilute solution of lidocaine and epinephrine (average volume of 200-400 mL of 0.1% lidocaine with 1:1,000,000 epinephrine) that is buffered with sodium bicarbonate. This solution should be delivered either manually or with an infusion pump under ultrasound guidance so the vein is surrounded with the anesthetic fluid along the entire length of the segment to be treated. The benefits of tumescent anesthesia for endovenous ablation include: anesthesia, separation of vein to be treated from surrounding structures, thermal sink, which reduces peak temperatures in perivenous tissues, vein compression, which maximizes the effect of treatment on the vein wall. Contraindications to EVLA technique are summarized below.

- Allergy to local anesthetic
- Hypercoagulable states
- Infection of the leg to be treated
- Lymphedema
- Nonambulatory patient
- Peripheral arterial insufficiency
- Poor general health
- Pregnancy
- Recent/active venous thromboembolism
- Thrombus or synechiae in the vein to be treated
- The treatment takes about 20-30 minutes per leg. You may also have some foam sclerotherapy or some avulsions undertaken and a compression stocking is then put on.

MATERIALS AND METHODS

In our study, 50 patients with varicose veins were treated between August 2013 and September 2016. EVLA was applied in 25 cases and HL/S was applied in 25 cases. Patients reported they had complaints for more than 3 years. Most frequent complaints were pain (n: 45) and cramps (n: 43). While varicose dilatations were obvious for all cases, skin discolorations were observed in 5 cases. Venous ulceration was also present in 3 cases. The study was planned as a retrospective study. Physical examination and venous Doppler USG were performed in outpatient basis for the patients admitted to the outpatient clinics. Deep venous system, duration and degree of reflux at VSM, perforators and vena saphenaparva were evaluated by Doppler USG. Patients with deep venous thrombosis (DVT), perforating venous insufficiency, deep venous insufficiency, thrombophlebitis, peripheral artery disease were excluded. All procedures were done by 2 experienced surgeons at the operation room. In HL/S procedure the incisional dimensions were 2 cm and 4 cm at ankle level and inguinal region respectively. VSM and its were branches ligated and divided at saphenofemoral junction. It use followed by complete stripping and mini-phlebectomy procedure. HL/S procedure was performed under regional anesthesia. EVLA procedure was done by 980 nm diode laser (Ceralas D 980, Biolitec) at continues mode with 15 W energy with 80-90 julespr mm. Covered catheter capable of radial emission was used. The catheter was placed in VSM by percutaneous way, but in 5 cases, the catheter placement necessitated cut-down. Catheter was advanced until 2 cm below of the saphenofemoral junction. EVLA procedure was performed under tumescent anesthesia and mild sedation. A homogenous perivenous mantle was formed along VSM by tumescent anesthesia. Tumescent anesthesia was 200 mL and consisted of 4 mg lidocain, 4 mg adrenaline, 0.5 mg dinatrium EDTA, 1.68 g sodium bicarbonate and NaCl. The leg of the patient was wrapped in pressured bandage following the procedure and the bandage was removed after 2 days and middle pressure varsity socks were worn. All patients were kept under clinical observation for 18 hours. Nonsteroidal anti-inflammatory drugs were prescribed for discharged patients and recommended to be used when symptoms occurred. Patient visits were done at post-operative 10th day, 6th month, 1st year and 2nd year. Routine physical examination and Doppler USG assessments were performed at these visits. All parameters were evaluated in both groups. Continuous variables were tested with Student's t test and Mann-Whitney U test. The categorical variables were tested with the Z test.

RESULTS

Table 1

	EVLA	HL/S	p value
Infection	1	6	0.042
Hematoma	0	4	0.037
Paresthesia	0	2	0.148
Recurrence	0	3	0.074

EVLA, Endoveinous laser ablation. HL/S: High ligation and stripping

EVLA and HL/S procedures were done with complete success in all cases at both groups. All cases were invited for control visits. At postoperative 10th day, all patients were evaluated; When the complications developed after procedures were evaluated; no infection, hematoma or paresthesia were observed in EVLA group. However in HL/S group, infections, hematomas and paresthesia were observed in 6, 4 and 2 cases respectively. In contrast, only 1 case found to be infected in EVLA group. When the groups were evaluated for treatment efficacy, there was no recurrence in EVLA procedure while recurrence after conventional surgery found in 3 cases.

DISCUSSION

HL/S method is most frequently used surgical treatment method worldwide for the treatment of varicosities⁶. However, a rapid development was achieved in minimal invasive varicose vein surgery in the recent 10 years. Novel methods such as EVLA, radiofrequency ablation (RFA), foam sclerotherapy became popular as alternatives to this surgical procedure. All of these methods have been compared to each other in various studies. In studies comparing RFA and HL/S methods RFA method has been reported to have significant advantages¹⁰⁻¹². In a study comparing HL/S and EVLA methods, EVLA was reported to result with less edema and blisters but no other significant differences found between¹³. In comparison of foam sclerotherapy to HL/S, HL/S procedure was reported to be superior¹⁴. In our study, When the groups were evaluated for treatment efficacy, there was no recurrence in EVLA procedure while recurrence after conventional surgery found in 3 cases. When post-op complications were evaluated, hematoma and paresthesia were significantly higher in HL/S group. In literature Hartmann *et al.* reported pares thesis ratio reached to 40% in complete stripping and Uncu reported in complete stripping, paresthesia healed with time and became permanent in 2% of the patients^{15,16}. Rasmussen *et al.* compared EVLA and HL/S methods for various parameters in a randomized prospective study. They recorded quite high pain ratios in HL/S group at early period by pain scorings. However they reported that the pain ratios reached lowest limit at 3rd month and coursed at similar ratios in both groups¹⁷.

Results of our study are comparable with these data. Pain complaint was determined at quite high ratios in HL/S group. Tumescence anesthesia in the EVLA group was reported to have impact on this difference¹⁷. When recurrence rates were examined there was significant difference between both groups at post-op 1st and 2nd years. Recurrence rate was observed to be higher in the HL/S group. Various results were reported in literature for recurrence rate. There are publications reporting 7% recurrence after 24 months follow up besides publications reporting 10% recurrence rate in 12 months for the cases in whom ablation was performed by the EVLA method^{18,19}.

CONCLUSION

According to obtained results this endovenous laser ablation (EVLA) enables patients after treatment of varicose veins with better recovery in terms of significantly lower post treatment pain, faster return to everyday activities. In terms of treatment success, EVLA procedure is better than HL/S method. In terms of post operative complication, EVLA method was associated with significantly less infection, paresthesia, hematoma and pain. EVLA method is more effective and safe HL/S method. When long term results of this method are shown completely, its effectiveness will be cleared and its clinical utility will be established.

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