

Original Research Article

Endovenous laser ablation for great saphenous varicose veins

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ABSTRACT

Background: Endovenous laser ablation (EVLA) is one of the most accepted treatment options for great saphenous varicose veins. The aim of this study was to evaluate the efficacy and safety EVLA in a 12 months follow-up.

Methods: Patients with symptomatic great saphenous veins (GSV) reflux were undergo EVLA. The outcome measures the efficacy and safety along the follow up period (12 months). The efficacy assessed by measuring the occlusion rate of the GSV by duplex and by measuring the improvement in the mean venous clinical severity score (VCSS) by clinical examination. The safety assessed by clinical examination to detect the complications.

Results: The rate of complete occlusion in the main trunk of the great saphenous vein was 34/35 (97.1%) at 6 and 12 months. The mean VCSS scores improved significantly after the procedure at 6 and 12 months. Complications detected within 1st week as pigmentation in 3 patients, local hematoma in one patient, and paresthesia in one patient but all complications disappeared within 6 and 12 months.

Conclusions: EVLA is an effective and safe procedure for the treatment of varicose great saphenous.

Keywords: EVLA, Great saphenous varicose veins, Minimally invasive endovenous techniques

INTRODUCTION

Varicose veins affect 25-40 per cent of the adult population.¹⁻³ The majority of varicose veins are due to saphenofemoral and great saphenous vein (GSV) incompetence.⁴ Conventional surgery involves Stripping of the GSV combined with high ligation. This is usually performed as a day-case procedure and with a 2-3 weeks recovery period.⁵ Recently, as alternatives to conventional surgery minimally invasive endovenous techniques have been developed which have a potential advantages in form of low postoperative morbidity and a short recovery period.⁶ Endovenous laser ablation (EVLA) is the most commonly used minimally invasive endovenous procedure.⁷ EVLA acts by releasing thermal energy to the venous wall and to the blood, causing localized tissue damage. High patient satisfaction and relative simplicity have made this procedure popular.⁸

The aim of this study was to assess the efficacy and safety of EVLA for treatment of varicose veins in a 12 months follow-up.

METHODS

This prospective study was carried out in private hospitals between January 2017 and August 2018. All patients gave their formal consent. The study included patients age 21-55 years, with symptomatic primary varicose veins; with Clinical Etiologic Anatomic Pathophysiologic (CEAP) class C2-C4, and reflux (a reflux time of more than 0.5 s on duplex Imaging) in the GSV 5-10 mm in diameter. In this study we excluded patients who have history of previous surgical interventions in the groin area with the exception of inguinal herniotomy or anterior or posterior accessory saphenous vein incompetence or small saphenous vein insufficiency requiring treatment at the same limb.

Technique

All interventions were carried out under general anaesthesia or light sedative before (diazepam) and during (alfentanil, propofol) the procedure in an operating theatre. Access to the great saphenous vein is achieved at the ankle or just below the knee, by either 18-G needle puncture or the stab wound-Mueller hook approach.

Under duplex guidance, J-tip guide wire (diameter of 0.035 inch), a 5F-angio catheter was advanced proximally till reach close to the sapheno-femoral junction (SFJ). Then, perivascular tumescent local anesthesia was infiltrated along the length of the vein using 50 ml 1 per cent lidocaine with 1:200,000 adrenaline (epinephrine) and 8.4 mg bicarbonate in 1000 ml (normal saline) to treat and dissipate the heat. After that, the guide wire was then replaced by a 600-micron laser fiber with an outer diameter of 1.0 mm and the position of the laser fiber tip was confirmed by duplex scanning 1 to 2 cm distal to the SFJ.

Lastly, the laser fiber connected to 810-nm diode laser source (EVL; Diomed, Andover, Massachusetts, USA) and the veins were treated by using pulse mode. The power delivered with 1-s laser pulses and 1-s intervals between pulses. During each interval the laser fiber was withdrawn 2-3 mm.

The energy delivered was 10-14 W at the thigh, reduced to about 6 W at the level of the knee where the vein tends to lie superficially in the subcutaneous tissue, and 4 to 6 W at the lower leg.

Immediately after the procedure in the operating theatre, the patency of the deep veins was checked in all patients by the operating surgeon using duplex ultrasonography. After treatment non-stretch compression bandage applied for 1 week, followed by a grade II compression stocking for a further week day and night.

On the day of surgery and the first postoperative day, all patients received thromboprophylaxis consisting of 20 to 40 mg of enoxaparin. At time of discharge all patients instructed to take analgesia only if required in form of paracetamol (1 g up to four times a day) and ibuprofen (400 mg up to three times a day) and to mobilize as much as possible

Assessments and follow up

The patients attended follow-up at 7 days, 1, 3, 6 and 12 months postoperatively. At every follow-up visit, clinical examination and duplex ultrasonography were done for every patient to assess the effectiveness and safety of EVLA.

The effectiveness outcome of EVLA assessed by duplex ultrasonography and clinical examination. Duplex ultrasonography detects the abolition of reflux (reflux

was defined as a retrograde flow lasting more than 0.5 s) after calf compression in the saphenous vein, and detect the degree of GSV occlusion either complete or partial or no occlusion. (Treatment failure is defined as an open part of the treated vein segment ≥ 5 cm in length). Clinical examination evaluates the patients by VCSS to detect symptom severity before treatment, and after 6 and 12 months.⁹

The safety of EVLA assessed by clinical examination to detect its complications at 7 days, 1, 3, 6 and 12 months.

Statistical analysis

We calculated mean values using the Excel 2003 statistics part.

RESULTS

Between January 2017 and August 2018, 27 patients (35 limbs) with varicose vein met the inclusion criteria and were enrolled in the current series (Table 1).

Table 1: Baseline characteristics of the study patients.

Patients (no.)	27
Legs (no.)	35
Patient demographics	
Age	39.1*(21-55)
Sex	17 ♀ (77.1%)
Limb characteristics	
Rt side	15 (42.8)
C class (CEAP classification)	
C2	20 (57.1)
C3	9 (25.7)
C4	6 (17.1)

*Value is the mean. ♀-Female.

The treatment effectiveness

Duplex ultrasonography during the follow-ups, at 1 week after the operation revealed the abolish of reflux and complete occlusion in the main trunk of the great saphenous vein was 33/35 (94.3%). At 1, 3, 6, 12 month after the operation, abolish of reflux and complete occlusion in the main trunk of the great saphenous vein was 34/35 (97.1%) (Table 2).

Table 2: Postoperative duplex follow up results.

	Trunk blood flow signal
1 week	2
1 month	1
3 months	1
6 months	1
12 months	1

Clinical examination evaluating the patients by VCSS at 6 and 12 months revealed improvement of the mean

VCSS scores significantly after the procedure where the mean VCSS scores declined from 7.76±1.49 at the baseline to 2.67±1.32 at 6 month (p<0.001) and to 2.59±1.03 at 12 month (p<0.001) (Table 3).

Table 3: Improvement of the mean VCSS scores.

	At baseline	At 6 months	At 12 months	P value
Mean VCSS	7.76±1.49	2.67±1.32	2.59±1.03	<0.001

The treatment safety

During follow up, pigmentation recorded within 1 week and 1 month after the operation in 3 patients. At 3 months after the operation, pigmentation was still present in one patient only but disappeared at 6 months. At 1 week after the operation, local hematoma occurred in one patient but, it disappeared at 1 month. Paresthesia was observed within 1st week, 1 month and 3 months in one patient but resolved within 6 months. None of the patients developed skin burn, lower extremity deep vein thrombosis (DVT), or pulmonary embolism (PE) during follow up (Table 4).

Table 4: Postoperative complication results.

	Pigmentation	Local hematoma	Paresthesia	Skin burn	DVT	PE
1 week	3	1	1	0	0	0
1 month	3	0	1	0	0	0
3 months	1	0	1	0	0	0
6 months	0	0	0	0	0	0
12 months	0	0	0	0	0	0

DISCUSSION

The role of minimally invasive varicose vein treatments increase due to increase the patients demands.¹⁰ EVLA has been established as a minimally invasive varicose vein treatment alternative to saphenous vein stripping surgery.¹¹ Many studies reported that EVLA is a safe and effective means of treating GSV reflux.^{6,12-14} This article describes our experience on treating GSV reflux using EVLA. In the present study, the occlusion rate of GSV using EVLA was 97% at 6 and 12 months that confirm the results which reported in other studies.^{6,15-19}

Darwood et al reported that GSV reflux at 3 months was abolished in 41 of 42 (97.6%) legs treated with EVLA in randomized clinical trial comparing endovenous laser ablation with surgery for the treatment of primary great saphenous varicose veins.⁶

Koramaz et al reported in retrospective nonrandomized study evaluated treatment of GSV of 339 patients with either nontumescent n-butyl cyanoacrylate versus endovenous laser therapy that the occlusion rate of GSV which treated with EVLA was 97.3% at one year.¹⁵

Rasmussen et al reported that the occlusion rate of GSV using EVLA was (93% (95-92)) at one year, in randomized clinical trial including 500 patients (580 legs) comparing endovenous laser ablation, radiofrequency, foam sclerotherapy, and surgical stripping.¹⁶

Hamann et al reported in randomized clinical trial including 450 patients with GSV varicosities which were treated with either RFLA or RFA that the occlusion rate of patients who treated with EVLA was 95% at one year.¹⁷

Hodenberg et al reported that the occlusion rate of varicose vein at one year was 99.6% of the treated 308 limbs with endovenous laser ablation using 1470 nm diode laser with a radial fiber.¹⁸

Liu et al reported in study evaluated the efficacy of endovenous laser treatment combined with sclerosing foam in treating 186 lower limbs with varicose veins that the occlusion rate of GSV was 100% at 6 months.¹⁹

In the present study the mean VCSS scores improved significantly after the procedure, similar to that reported in other trials.^{15,16} The VCSS score improvement confirms that the treatment is efficacious.

In the present study, no skin burn, DVT, or PE were detected during follow up. Pigmentation was detected in 3 patients at 1 week and 1 month follow up, but at 3 months, pigmentation was still present in one patient only which disappeared at 6 months. Local hematoma was detected in one patient at 1 week follow up but it disappeared in the following follow up. Paresthesia was observed in one patient during follow up at 1st week, 1 month and 3 months but it disappeared at 6 months. The complications in our study are comparable to that reported by some authors¹⁹ and also, are different than that reported by some others.^{15,18}

Liu et al reported that pigmentation occurred in 30 patients, within 1 week and 1 month after the operation, while at 3 months after the operation, pigmentation was found in 15 patients. Within 6 months after the operation, pigmentation in the surgical site had not completely disappeared in six patients. Local hematoma occurred in two patients at 1 week after the operation, saphenous nerve injury occurred in five patients Within 3 months after the operation, however, these disappeared at 6

months after the operation. None of the patients developed deep vein thrombosis and pulmonary embolism. The complications of EVLA in Liu et al study are comparable to that observed in our study taking in mind the difference in number of study patients in each of 2 studies.¹⁹

Hodenberg et al reported that no DVT or PE were detected during follow up. Local hematoma was detected in 18 patients, paresthesia in one patient, phlebitis in 3 patients at 1 week follow up but all these complications disappeared at one year follow up. The difference between our study and hodenberg study in the complication of EVLA which may be explained by the difference in the type of laser where, in our study we used 810-nm laser, which targets the blood in the vein because laser light of this wavelength is predominantly absorbed by hemoglobin that make this type of laser has a good hemostatic effect but Hodengerg used 1470 nm laser which acts directly on the vessel wall through absorption of interstitial water but not hemoglobin.¹⁸

Koramaz et al reported that the patients experienced burning, pigmentation, and bruising, 2.12%, 5.82%, and 2.65% respectively in the first week, but these conditions resolved by the 6-month follow-up. In 1.59% of the patients, paresthesia was observed and resolved within 6 months. Phlebitis was observed in 7.94% of the patients. DVT was diagnosed in 1.59% of the patients. There is a difference between our study and Koramaz et al study in the complication of EVLA which may be explained by the difference in the type of laser where Koramaz used 1470 nm laser and also, he did not give us details on the amount and the constituent of the tumescent anesthesia that he used.¹⁵

CONCLUSION

EVLA is an effective and safe procedure for the treatment of varicose great saphenous veins. It is considered a new armamentarium that is added to the treatment modalities of great saphenous varicose veins.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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