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Endovenous Laser Therapy of Great Saphenous Veın: Six Months Follow-Up

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Abstract

Objectives: The aim of this study is to analyze the outcome results and short term follow-up of our Endo Venous Laser Therapy (EVLT) cases operated in a hospital setting.

Patients and Methods: This is a retrospective study. Two hundred patients were enrolled. Of these 200 patients, 124 (62%) were female and the average age of the patients was 37.7 ± 10.8 (ranged, 19 to 64). Reflux duration >0.5 s in ultrasound was considered as significant. The preoperative GSV diameter was measured in the standing position with USG was 12.3 ± 3.9 mm in average (ranged, 4.1 to 27.7 mm). Operations were performed with a 980 nm diode laser system (Gigaa SVLase 30w Surgical Diode Laser System, Wuhan, PRC). Laser energy applied GSV length was 31.1 ± 3.3 cm in average (ranged, 26-39 cm). Total delivered laser energy was 2783.3 ± 426.1 J (ranged, 1992-3464 joules). Follow up controls were performed at 1st week, 1st, 3rd and 6th months after the operation.

Results: Forty-four left, 64 right and 92 bilateral legs were treated. Phlebectomy was performed in 98 (49.0%) cases. The median follow up period for all of the patients was 11 months (range, 6-14 months). Most common complication during follow-up was paresthesia, especially on the first week control (n=8, 4.0%). The rate of symptomatic complications like paresthesia, phlebitis and hematoma gradually disappeared during follow-up as expected. The recanalization rates of ablated GSV were 1.0% in the 1st week and 3.5% recanalization rate was present by 6th month.

Conclusion: EVLT is a comfortable and safe method for treatment of venous insufficiency. It is important not to forget that EVLT is not free of complications and reducing these complications may help to improve the outcome results.

Keywords: Venous insufficiency; Laser ablation; Great saphenous vein

Introduction

Venous insufficiency of the limbs is a common disease which is reported to be seen in 10% to 50% of individuals in various studies [1-3]. The typical symptoms are pain, night cramps of the lower extremities, fatigue, swelling and heaviness [1,4]. The majority of the cases are due to saphenofemoral and great saphenous vein (GSV) incompetence [5]. The well-known treatment *is* surgical ligation and stripping of the GSV [6]. The major problem of the surgical treatment is high recurrence rates and postoperative morbidities such as neurovascular injuries [7,8].

EVLA has become a common minimally invasive therapy to manage leg varicosities. Clinically, scientifically, and commercially, it is a fascinating therapy. Clinically, because EVLA took over surgical stripping as a result of its very high success rate with minimal complications at all laser wavelengths, laser powers, and pullback velocities used [9].

Endovenous ablation has advantages over conventional surgery, including a lower level of postoperative pain, shorter periods of sick leave, an earlier return to normal activities, and a reduction in the overall cost to society [10].In several large case studies, the technical success rate was approximately 100%,and the long-term success rate (up to 5 years) ranged from 90% to 100% [10,11].

The postprocedural duplex US evaluations for the patients in the present study revealed that a total occlusion of the treated GSVs occurred in 88 patients (97%) and that a sub-total occlusion in 2 (2%) patients.

EVLT is being used for about a decade. The rationale of this therapy is delivering heat into the blood vessel by means of laser fiber which results in contraction of collagen and denaturation of endothelium. Eventually the vein is fibrosed [12]. The aim of this study is to analyze the outcome results and short term follow-up of our EVLT cases operated by a single surgeon.

Patients and Methods

Patients

This retrospective study was approved by Institutional Ethics Committee. All patients gave informed consent for the procedure. All procedures were performed in a hospital setting. From April 2010 to

July 2011, 200 patients were operated for varicose veins with EVLT by a single surgeon. The patient characteristics are summarized in Table 1. Of these 200 patients, 124 (62.0%) were female and 76 (38.0%) were male. Patients were 37.7 ± 10.8 years of age in average (ranged, 19 to 64). Ninety eight patients (%49) had a family history of varicose veins. All patients underwent physical and ultrasonographic evaluation. None of the patients were operated for varicose veins before. Saphenofemoral junction (SFJ) incompetence and GSV reflux had been demonstrated with ultrasound examination. Reflux duration >0.5 seconds was considered as significant. The preoperative GSV diameter was measured in the standing position with USG was 12.3 ± 3.9 mm in average (ranged, 4.1 to 27.7 mm). Inclusion criteria for the study were reflux duration >0.5 seconds and preoperative GSV diameter >4 mm. Exclusion criteria for study were as follows: The patients with deep vein thrombosis, presence of acute superficial thrombophlebitis, peripheral vascular disease, significant (Grade 3 or 4) deep venous or small saphenous or perforating vein insufficiency, anatomic problems (tortuous GSV, presence of anterior accessory saphenous vein incompetency) pregnancy, cancer and poor general condition or other systemic disease and patients taking warfarin.

Patient characteristics	**n (%)**
Body mass index:	
Obese (≥ 30 kg/m^2)	61 (30.2%)
Overweight (25-29.9 kg/m^2)	85 (42.6%)
Normal (18.5-24.9 kg/m^2)	54 (24.2%)
Symptoms:	
Pain	190 (95.0%)
Heaviness	148 (74.0%)
Fatigue	180 (90.0%)
Itching	140 (70.0%)
Shooting	120 (60.0%)
Restless leg syndrome	142 (72.0%)
Ankle swelling	132 (66.0%)
Leg cramps	150 (75.0%)
Achy leg at walk	120 (60.0%)
Prolonged standing worsen symptoms	172 (86.0%)
Lowered life quality	148 (74.0%)
Previous treatment:	
Compression stockings	44 (22.0%)
Sclerotherapy	31 (15.5%)
CEAP Classification:	
Clinical	
Class 2	22 (11.0%)
Class 3	95 (47.5%)
Class 4	64 (32.0%)
Class 5	19 (9.5%)
Etiologic	
Primary	200 (100%)
Anatomic	
Superficial	200 (100%)
Above knee GSV	200 (100%)
Pathological	
Reflux	200 (100%)
CEAP Classification: Clinical Anatomic Etiological Pathological Classification; GSV: Great Saphenous Vein; SSV: Small Saphenous Vein	

Table 1: Preoperative data

Operation

The routine preoperative work-up was made. All patients were operated with general anesthesia. The GSV diameters and SFJ positions were determined with ultrasonographic imaging. Percutaneous access points were chosen according to the GSV anatomy; just above or below the knee level. GSV was punctured with the standard Seldinger technique with USG guidance. A guidewire was inserted through the needle and it was advanced a few centimeters inside the femoral vein to make sure that the guidewire passed the SFJ. A 4F introducer sheath was placed over the guidewire. The final position of the sheath introducer was confirmed by USG.

Tumescent local anesthesia was administered with hand-held syringe using ultrasound guidance. The fluid used in the tumescent anesthesia consisted of 100-250 mL isotonic saline solution with lidocain (Aritmal 20 mg/mL, 5 mL amp, Osel, Istanbul, Turkey) and sodium bicarbonate (sodium Bikarbonat Molar 84 mg/mL, 10 mL amp, Galen, Istanbul, Turkey). The solution was applied into the perivenous space along the GSV. Six hundred micrometers thick laser fiber (Angio Dynamix Never Touch Gold-Tip Fiber, Queensbury, NY, USA) was inserted through the sheath introducer. The tip of the fiber was positioned with the help of red aiming beam and the ultrasound guidance. The tip was located just beyond the orifice of superficial epigastric vein distal to the SFJ. A 980 nm diode laser system (Gigaa SVLase 30w Surgical Diode Laser System, Wuhan, PRC) was used. Laser energy was delivered at 14 W in continuous mode. The laser energy was applied after the tip position was confirmed up to 1 cm proximal to the sheath introducer entry point. The average length of ablated GSV was 31.1 ± 3.3 cm (ranged, 26 to 39 cm). The laser fiber was withdrawn manually with 2 to 3 mm increments (approximately 1 cm/5 seconds). The average total delivered laser energy was 2783.3 ± 426.1 J (ranged, 1992 to 3464 joules). Patients were asked to wear 30-40 mmHg pressured stockings for 1 week after the treatment and informed to ambulate immediately and return daily activities.

Patients with varicosities that require phlebectomy were examined before the operation after 30 minutes ambulation and preoperative markings were made on the planned phlebectomy areas. Multiple stab wounds were made in patients with a number 11 blade after infiltrating the skin with local anesthetic. The veins were grabbed with a mosquito clamp and avulsed. Dressings were placed along the length of the vein and the avulsed areas. The leg was wrapped with elastic bandages before the patients were transferred to the surgical ward

Postoperative follow-up

Patients were hospitalized on the day of operation and discharged on the 1st postoperative day. Before the patients were discharged, the dressings were changed and the limbs were controlled for hematoma or any postoperative complications. The median follow up period for all of the patients was 11 months (range, 6-14 months). Patients were instructed to keep the elastic compression wrap on for two more days. Except during sleeping and showering, they then were asked to wear custom-made compression stockings until their first follow-up appointment at 1st week. Each patient was given a prescription for 500 mg of calcium dobesilate (bid for 1 week). On the first postoperative visit, all patients underwent a duplex scan of the target vein to confirm thrombotic occlusion and demonstrate evidence of wall thickening. Absence of retrograde flow in a non-compressible vein was accepted as total occlusion. Future visits were scheduled for 1st, 3rd and 6th months after the operation.

Data collection and statistical analysis

Preoperative, intraoperative and postoperative data were collected prospectively. Results are presented as mean ± standard deviation with ranges or frequencies with percentages as appropriate. Data analysis was performed using SPSS 13.0 (Statistical Package for the Social Sciences) program. One-sample Kolmogorov-Smirnov test was used to test the normality of data distribution. The number of patients with a particular symptom before the treatment paired with the number of patients that had the same symptom at each follow-up time and Wilcoxon test was used to evaluate the statistical significance of the change in the number of patients. A probability value less than or equal to 0.05 was considered statistically significant for all comparisons.

Results

The lateralization of the EVLT procedures were as follows: Right leg 64 (32.0%), left leg 44 (22.0%) and bilateral 92 (46.0%). Phlebectomy was performed in 98 (49.0%) cases. None of the patients required conversion to ligation and stripping.

Complications during follow-up were outlined in Table 2. It can be seen that most common complication during follow-up was paresthesia, especially on the first week control. The rate of symptomatic complications like paresthesia, phlebitis and hematoma gradually disappeared during follow-up as expected. None of the patients was observed in the skin and subcutaneous necrosis.

Complication	1 Week	1 Month	3 Months	6 Months
Re-Flow	2 (1.0%)	4 (2.0%)	5 (2.5%)	7 (3.5%)
Phlebitis	8 (4.0%)	0	0	0
Hematoma	5 (2.5%)	0	0	0
Paresthesia	11 (5.5%)	8 (4.0%)*	5 (2.5%)*	5 (2.5%)*
Infection	2 (1.0%)	0	0	0
* Total number of patients with that complication. These cases are not new onset complications				

Table 2: Distribution of Complications during Follow-Up

The recanalization rates of ablated GSV were 1.0% in the 1st week and 3.5% recanalization rate was present by 6th month. The early recanalized patients had 4 mm GSV diameter preoperatively and the first two cases as we started our EVLT treatment in our hospital. These cases were attributed to technical failure. The remaining patients had GSV diameter over 7 mm with many focal excessive dilatations. Only one of these patients had BMI 0ver 30 kg/m2 and the others were either normal or overweight. Compression stockings were recommended to these patients since they refused further procedures at 6th month follow-up.

Significant improvements were observed in the appearance of all extremities. There were significant reductions in the extremity diameters and number of visible varicosities. None of the patients required further procedures for varicosities. There was significant difference between the number of patients that had symptoms before and after the treatment as expected. Patient numbers that had pain, heaviness, fatigue, itching, ankle swelling and leg cramps significantly reduced at each follow-up time (Table 3). Three of the 6 patients with fatigue and pain at 6th month and 4 of the 5 patients with itching also had paresthesia at that time.

Symptoms	*Before Treatment	*1st week	p	*1st Month	p	*3rd Month	P	*6th Month	p
Pain	190 (95.0%)	14 (7.0%)	0,000	6 (3.0%)	0,000	5 (2.5%)	0,000	6 (3.0%)	0,000
Heaviness	148 (74.0%)	11 (5.5%)	0,000	5 (1.5%)	0,000	0	0,000	0	0,000
Fatigue	180 (90.0%)	8 (4.0%)	0,000	4 (2.0%)	0,000	6 (3.0%)	0,000	6 (3.0%)	0,000
Itching	140 (70.0%)	5 (2.5%)	0,000	5 (2.5%)	0,000	5 (2.5%)	0,000	5 (2.5%)	0,000
Ankle Swelling	132 (66.0%)	12 (6.0%)	0,000	7 (3.5%)	0,000	1 (0.5%)	0,000	2 (1.0%)	0,000
Cramps	150 (75.0%)	8 (4.0%)	0,000	6 (3.0%)	0,000	6 (3.0%)	0,000	6 (3.0%)	0,000
* Frequencies and percentages									

Table 3: Comparison of Preoperative Symptoms with Controls at 1st Week, 1st Month, 3rd Month and 6th Month after Treatment

Discussion

Endovenous laser treatment is a less invasive procedure for venous insufficiency which has gained a considerable popularity among surgeons and patients [13]. The current technique of EVLT was first used in 1999 and many reports are being published since then [12,14,15]. Patients prefer endovenous treatment modalities for the advantages like less pain and quicker recovery [14,16]. The follow-up results of EVLT are therefore important to guide surgeons and patients in choice of treatment modalities.

The first studies demonstrating the efficacy of EVLA were published in 2001 [9,14]. A success rate of 100% one week after EVLA and a success rate of >90% on one-year and three-year follow-up have been reported in most series since then [17,18]. Freedom from recurrent varicose veins was achieved in 79% of patients after a five year follow-up in a randomized trial [19]. There are few studies comparing EVLA with other treatment modalities, mainly surgery. These studies showed comparable or superior outcomes with EVLA in terms of technical success, recurrence rates and HRQOL when compared to surgery [19,20].

The main goal in EVLT is to selectively ablate incompetent GSV and eliminate the reflux in both GSV and SFJ [21]. Our re-flow rates and other complication rates were similar to the literature [22,23]. In our study there were 2 (1.0%) patients with early recanalization in GSV at first postoperative week which was ascribed to technical failure. Excluding these cases, recanalization was present in 5 patients at 6th month follow-up (about 2.5%) which is compatible with the reported results. Recanalization was thought to be secondary to focal dilatations and excessively dilated varicosities of GSV. The low amount of energy applied may be objected in this sense. Different EVLT protocols were compared in a randomized study by Darwood and colleagues [24]. They reported that use of different EVLT protocols did not differ in terms of outcome results. The abolition of reflux was comparable to surgery with a more comfortable postoperative recovery for the patient [24]. Rasmussen and colleagues reported 3 cases of recanalization out of 54 cases at 6 month follow-up [25] in their randomized study. We prefer apply the laser energy at 5 seconds per every centimeter of GSV in order to avoid thermal complications. Despite this protocol, we had patients with paresthesia and phlebitis at 4% and 5.5% incidences. These complications gradually disappeared in most of the cases and we believe that use of higher energy levels will cause higher complication rates. The mean value of energy we applied was 71.3 J/cm of GSV and the fiber is pulled out 1 cm in 5 seconds. Theivacumar et al. reported to use similar levels of energy at similar speed of withdrawal and reported higher complication rates [26]. In contrast to these arguments, Kim et.al reported 100% technical success in 34 patients using a 980 nm diode laser at 11 W power with application of 35.16 J/cm [26]. Although the patient number is limited, it must be a word of caution for the surgeon to consider lower energy levels and spare the higher energy applications for the selected cases like excessive dilatations.

Most striking findings were achieved with symptomatic improvement in our patient cohort (Table 3). The relief of symptoms was dramatic and in the 6 months of follow-up, the improvement seemed to be durable. As was pointed out earlier, most of the patients with symptoms had some complications that could be ascribed to EVLT. So, reducing these complications will improve the results and probably the patient satisfaction.

In conclusion we think that EVLT with 980 nm diode laser is a comfortable and safe method for treatment of chronic venous insufficiency. The complication rates and satisfactory outcomes will be more improved with increasing experience. It is important not to forget that EVLT is not free of complications and reducing these complications may help to improve the outcome results.

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