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Early and Mid-Term Results of Treatment of Superficial Venous Insufficiency of the Lower Extremity Using Endovenous Laser Therapy

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Abstract

Background and aim of the study: Endovenous laser ablation (ELA) has become an important procedure to treat saphenous vein reflux. In this study the early and mid-term results of endovenous laser ablation of the long or/and short saphenous veins (ELAS) will be evaluated.

Patients and methods: This prospective study was conducted from March 2010 to December 2016. The study enrolled 35 symptomatic patients with unilateral or bilateral superficial venous insufficiency (CEAP; 2-6) with documented reflux in long saphenous, short saphenous, or both veins by duplex ultrasound.

Results: Thirty five patients were enrolled in this study, 30 women with mean age 35.5± 8.2 years and 5 men with mean age of 32.2± 7.8 years. ELAS was performed in 52 limbs 9 of them had ulcers. Early postoperative clinical and ultrasound examination revealed complete ablation of the targeted veins (100%) with no reflux. Great saphenous alone was ablated in 76.9% of limbs, short saphenous in 13.5%, and both 9.6%. Postoperative complications were minimal, well tolerated, and completely resolved within 3-27weeks with treatment. In 88.9% of limbs with active ulceration, healing occurred after a mean of 6.6±1.6 months. Only 61.5% of legs (including all ulcer patients) were followed up for 49.5±11.3 months; recorded recanalization by duplex ultra sound was 0%, 10.3%, and 20.8% after 1, 3, and 5 years respectively. Recanalization was insignificantly higher in long than short saphenous veins. The recorded recurrence of ulcers after 1, 3, and 5 years of follow up was 0%, 12.5%, and 40% respectively. **Conclusion:** endovenous laser ablation of the saphenous veins is safe and has excellent early and mid-term outcomes for treatment of superficial venous insufficiency with or without ulceration of the lower extremities.

Keywords: Endovenous laser ablation, saphenous veins, venous insufficiency, varicose veins, , venous ulcer.

Introduction

Chronic venous insufficiency (CVI) of the lower limbs is usually the result of incompetent valves in one or more of the saphenous veins and their primary tributaries [1]. Symptoms of CVI can be ameliorated by compression therapy but it does not cure it [2]. For long time high ligation and stripping of the saphenous vein(s) was the main curative procedure to eliminate incompetence and reflux [3].The first report about the use of endovenous laser to ablate varicose veins was introduced by Boné which is followed by the approval of US Food and Drug Administration in January 2002 to allow endoluminal delivery of laser energy directly into the blood vessels [4-6]. The thermal effect on the venous wall leads to collagen contraction with eventual fibrosis, thickening of its wall and luminal obliteration [5]. The procedure can be performed on an ambulatory basis with the use of tumescent local anesthesia, even though, the results of this minimally invasive techniques have been shown to be at least equal to that of high ligation and stripping with minimal complications and shorter recovery [7-9]. In this study the early and long term results of endovenous laser ablation of the long or/and short saphenous veins (ELAS) will be evaluated.

Patients and methods: This prospective study was conducted in Taif tertiary hospital and enrolled 35 patients from March 2010 to December 2016. The study was conducted after approval from the Ethics Committee of the Hospitals and written informed consents were obtained from all participants. All

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patients were subjected to full history taking, clinical examination, and complete work up including duplex ultrasound for full assessment. The patients were categorized using the comprehensive classification system for chronic venous disorders; CEAP (clinical, etiological, anatomical and pathological). The inclusion criteria were: ambulatory symptomatic patients with unilateral or bilateral superficial venous insufficiency (CEAP; 2-6) with reflux in long saphenous, short saphenous, or both veins documented by duplex ultrasound. Exclusion criteria included; patients below 18 and above 65 years, patients with marked venous tortuousity, patient with deep venous insufficiency, patients with major comorbidities, patients with peripheral arterial disease, patients allergic to the local anesthetic, and pregnant females.

Preoperative mapping of the veins was done with duplex ultrasound and the course of vein was marked with determination of the saphenofemoral or saphenopopliteal junctions and the puncture site or sites. The varicosities of the saphenous tributaries were marked to be removed by hook phlebectomy, marking maximum 3 sites to access these veins.

After light sedation and analgesia the patient was put in reverse Trendelenburg position for ablation of long saphenous vein and in prone position for ablation of short saphenous vein. After preparing the limb, the long saphenous vein is cannulated below the knee using an eighteen gauge cannula under ultrasound guidance and a guide-wire was passed proximally into the femoral vein followed by insertion of a 5F introducer sheath which was positioned under ultrasound imaging and advanced to SFJ. The short saphenous is cannulated in the lower third of leg and a guide wire is inserted and passed to the saphenopopliteal junction followed by advancement of 5F introducer sheath to saphenopopliteal junction. Local tumescent anesthesia was used and injected around the vein under guidance of ultrasound. Tumescent anesthesia contained; 0.1% lidocaine, one per million adrenaline in 900 ml normal saline and 100 ml of 8.4% sodium bicarbonate. The temperature of tumescent fluid was set at 4°C. The fluid was injected around the vein under ultrasound guidance and the amount of injected solution was variable wherein in long saphenous vein 500-1000 ml was injected and in short saphenous vein the injected amount was 250-500 ml. After injection of tumescent anaesthesia the guide wire was replaced by the optical fiber connected to a 980-nm diode laser source and its tip was positioned always 2 to 3 mm below the saphenofemoral or saphenopopliteal junction and the sheath was then withdrawn exposing the last 2 cm of the laser fiber. The energy source was activated setting the continuous mode to be 16 watts in the thigh and decreasing gradually to be 12 watts in the leg. The rate of delivery of the energy depended also on the speed of withdrawal of the laser fiber and sheath (3-5 mm/second) to deliver uniformly the required amount of energy. For the long saphenous vein, the energy used was 140 J/cm for the first 10 cm to ensure closure of the proximal segment of the vein just distal to the saphenofemoral junction and decreased gradually to be 100 J/cm at the knee and 70 J/cm below to decrease the risk of nerve injuries lower in the leg. For the short saphenous vein 110-115 J/cm was delivered for the first 5 cm, then 100 J/cm for the next 5 cm, and then 70 J/cm for the remaining vein. The delivery of was stopped when the distal aspect of the vein was ablated and the entire optic fiber and the sheath were removed.

After the laser procedure, hook phlebectomies were done through tiny stabs. No skin sutures were used and hemostasis was achieved by applying pressure to the entry sites. To minimize the risk of bruising, pain, and DVT; the procedure is followed by application of an elastic bandage for about one week and replaced by graduated compression stockings for 1-3 months and the patients were advised for early ambulation.

Regular clinical and sonographic follow up was done in outpatient clinic after one week, 1 & 3 months, and then every 6 months for a mean of 79.5±18.3 months (range from 60-104 months). The early outcomes were; ablation of the targeted veins, absence of reflux, healing of ulcers, early postoperative complications, and long term outcomes included; recanalization, reflux, and recurrence of ulceration. The collected data were tabulated, analyzed and SPSS program version 22.0 (SPSS inc., Chicago, IL, USA)

was used for description of quantitative variables in the form of means, standard-deviation and range. The qualitative data were expressed in number and percentage. Data were analyzed on an intention-to-treat basis. Differences between groups were determined using analysis of variance with $P < .05$ considered significant.

Results: Table 1 shows Demographic data and preoperative patient characteristics. The table shows that; the number of females was significantly higher than that of female with no significant difference in their ages; there was no significant difference in ethnicity of patients, and no significant difference in number of patients with family history of CVI vs. patient with absent family history. The table shows also that patients suffering from CVI and lower limb ulceration was significantly lower than those without ulcers, ulceration was significantly associated with incompetent LSV than with SSV, in addition the total number of ablated LSV was significantly higher than that of SSV. Early postoperative clinical and ultrasound examination revealed complete ablation of the targeted veins (100%) with no reflux. Postoperative complications were minimal, well tolerated, and completely resolved within 3-27weeks with treatment. Table 2 shows the results of the operations and early post operative complications.After 6 months of the procedure 33/35 patients (94.3%) were satisfied with their treatment results and they claimed their symptoms had diminished to none or minimal. Only 32/52 legs (including all ulcer patients) were followed up for a mean of 49.5±11.3 months (61.5%). The followed up patients were 26 great saphenous, 4 for great and short, and 2 short saphenous alone. After one year no recanalization was recorded by duplex ultrasound documenting vein atresia without blood flow signals and thickened wall. Recoded recanalization and reflux after 3 years was 3/29 legs (10.3%) all in great saphenous, and in 5/24 who completed 5 years of follow up (20.8%, of all legs; 4/20 "25%" of long saphenous, 1/4 "16.7%" short saphenous with no combined recurrence) after 5 years. The recanalization in long saphenous veins was significantly higher than in short saphenous ($P<0.05$). The recorded recurrence of ulcers after 1, 3, and 5 years of follow up was in 0/8 limbs (0%), in 1/8 limbs (12.5%), and in 3/8 limbs (37.5%) respectively. Figure 1 shows the results of ablation of short saphenous vein and long saphenous vein using ELAS in 2 different patients.

Table 1: Demographic data and preoperative patient characteristics

Parameters			P-value
Gender	**Females**30/35 (85.7%)	**Males**5/35 (14.3%)	**<0.05 (S)**
Mean age	Females 35.5± 8.2 years	**Males** 32.2± 7.8 years	**>0.05 (IS)**
Family history of CVI	**Present**17/35 (48.6%)	**Absent**18/35 (51.4%)	**>0.05 (IS)**
Ethnicity	**Saudi**19/35 (54.3%)	**Non Saudi**16/35 (45.7%)	**>0.05 (IS)**
Ulcers	**Present** 9/52 (17.3%)	**No ulcer** 42/52 (82.7%)	**<0.05 (S)**
	Only with LSV; 6/9 (6.7%)	**Only with SSV;** 1/9 (1.1%)	**<0.05 (S)**
	With both L&SSVs2/9 (2.2%)		----------
Incompetent veins	**Total number of incompetent veins 57 veins**		----------
	Ablated LSV 45/57 (78.9%)	**Ablated SSV 12/57 (21.1%)**	**<0.05 (S)**

S; Significant, IS; Insignificant, LSV; long saphenous vein, SSV; short saphenous vein

Table 2: Primary outcomes and early postoperative complications

Parameter	Number	Per cent
Ablated veins with no reflux	57/57	100%
Healed ulcers	8/9	88.9%

After 1-12 months (mean of 6.6±1.6 months)		
Post operative complications		
Moderate ecchymosis and swellings	14/52 limbs	26.9%
Induration	13/52 limbs	25%
Para-esthesia		
– **All limbs**	– 3/52 limbs	– 5.8%
– **With ablated long saphenous veins**	– 2/45 veins	– 4.4%
– **With ablated short saphenous veins**	– 1/12 veins	– 8.3%
Skin burns	1/52	1.9%
Thromboembolic complications	0/52	0%
More than one complication.	21/52	(40.4%)

Figure 1: Shows the results of ablation of short saphenous vein (left) and long saphenous vein (right) using ELAS

Discussion:

Endovenous laser therapy of chronic venous insufficiency of the lower limb is fast and safe and can be performed in outpatient setting and its results are comparable to the traditional surgical approach [6]. In accordance with the inclusion criteria of the current study investigators found that ELA is a suitable therapy of ambulant symptomatic patients having CVI with significant reflux documented on duplex ultrasound examination [1]. Contraindications of the ELA procedure include; pregnancy to avoid the hazards of local anesthetic or/and the passage of heated blood through placenta on the fetus, too tortuous veins interfering with insertion of the laser probe, marked deep venous insufficiency to avoid post-procedural impaired venous return, presence of allergy to the local anesthetic used, presence of non correctable major comorbidity, non ambulatory patient, and those who can't wear compression stockings, as presence of peripheral arterial disease [3, 7].

The procedure is performed under local tumescent anesthesia to provide anesthesia, compression and emptying of the vein which maximizes the thermal effect of the laser on the venous wall [1-3, 10]. It was found that cold tumescent solution would increase the anesthetic effect, induce spasm of the vein and the peri-venous vessels, in addition it also acts as a thermal sink reducing the risk of complications specially burns, ecchymosis, and nerve insult [10]. The tumescent solution contains lidocaine (0.1%) in normal saline with or without epinephrine [11]. **Thompson *et al*** found that addition of sodium bicarbonate would synergize the anesthetic effect of lidocaine and increase its antibacterial action [12]. In the present study tumescent solution used was similar to that used in the previous studies.

Using the pulsed mode laser source more energy would be delivered; however, the majority of recent studies used continuous mode energy source because it is more practical and has standardized delivery of

total energy given per unit of length or surface area [13]. **Sichlau *et al.*** verified in their study that calculation of the delivered energy is more difficult if pulsed mode is used and its use was associated with a higher risk of adverse events such as venous perforation and thermal injury of the skin [14]. In Investigators found a direct correlation between the amount of thermal energy delivered and the success of endovenous laser therapy and documented that the ranges of energies used to achieve durable ablation included 50 J/cm for veins ≤4.5 mm and 120 J/cm for veins >10 mm in diameter [13]. The previous findings are concordant with that of our study where a 100% ablation of the targeted veins was achieved with no recorded major complications and no recanalization was recorded during the first year of follow up.

Kheirelseid *et al*. found in their study that reflux was recorded in 33.6% of legs after 5 years of follow up and there was no statically significant difference in recurrence rate in comparing EVLT with conventional surgery or radiofrequency ablation [15]. The limited number of patients and the difference in methodology might explain the lower incidence of recanalization after 5 years in the current study (20.8%) if compared with that reported in the previous study.

Boersma *et al.* documented the efficacy and safety of endovenous in treatment of incompetence of short saphenous veins and its success rate was 97.7-99.2% [16]. Similar results were verified in this study.

Neurological injuries as transient para-esthesia or dys-esthesia are recorded to be less than 5% after ELA and the most commonly affected nerves are the distal part of saphenous nerve after ablation of LSV and the sural nerve after SSV ablation [16-17]. The previous findings are similar to that in the current study, yet, it was relatively higher after ablation of short saphenous veins.

Bruising and ecchymosis over the treated veins are frequent and can be minimized by elastic bandages and stockings [1-3]. Transient discomfort which occurs due to thermal inflammation of the ablated veins is self limited and can be reduced by the aid of non steroidal anti-inflammatory drugs [2].

Skin burns are rare following ELA and the recorded rate in different studies varies from 0-4% and its incidence was negatively correlated with amount of the injected tumescent anaesthesia [10, 14, 16]. In the present study cold tumescent was used in sufficient amount and only one patient developed minor skin burn.

Previous studies reported that DVT following ELA varies from 0.3 to less than1% in and it can be diagnosed by duplex ultrasound as it is typically asymptomatic [15, 16]. Data about the treatment of such a condition are scarce; however, heparin was used by investigators and they documented thrombus regression. No DVT was recorded in the current study.

Teo *et al.* reported in their study on value of ELA in the treatment of lower-limb venous ulcers a 100% success rate in ablation of targeted veins and a 97.4% healing rate of the of the ulcers with no ulcer recurrence in the first year, but, 33.3% of the ulcers recurred after 14-52 months.[18] In this study slightly inferior results were obtained where 88.9% of the ulcers healed after a mean of 6.6±1.6 months following ELAS and the recorded recurrence of ulcers during 1, 3, and 5 years of follow up was 0%, 12.5%, and 40% respectively.

Though the previous studies found that greater energy delivery improves treatment success of endovenous laser treatment of incompetent saphenous veins, the results of **Navarro *et al.*** in one of the earliest trials conducted at the beginning of this century using an 810 nm Diode Laser verified a high success rate of the use of low energy laser and they emphasized that; proper selection of patients, the feasibility and success of the procedure, and the reduced risk would make endovenous laser therapy a reasonable alternative to ligation and stripping [5]. Similar results were reported by **Kim *et al.*** and they advocated the use of lower energy ELA [19]. To conclude; our results support the findings of the previous studies that endovenous laser ablation of the saphenous veins is safe and has excellent early and mid-term outcomes for treatment of superficial venous insufficiency with or without ulceration of the lower extremities.

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