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ORIGINAL ARTICLE / ÖZGÜN ARAŞTIRMA

Laser saphenous ablation results with at least one year of follow-up

En az bir yıl takipleriyle birlikte lazer safen ablasyon sonuçlarımız

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ABSTRACT

Objectives: This retrospective study aimed to evaluate the efficacy and durability of endovenous laser ablation with 940 nanometer wavelength with at least one-year follow-up.

Materials and methods: Between December 2009 and February 2012, a total of 68 incompetent great saphenous veins and 4 small saphenous veins were treated by endovenous laser ablation, using 940 nanometer wavelengths.

Patients underwent standard clinical and duplex follow-up examinations with a mean of 18 months (range 12 to 26 months) after endovenous laser ablation. Patient satisfaction regarding the procedure was assessed with the use of a visual analog scale (range 1 to 100).

Results: Post-procedural duplex scans showed total occlusion of the treated great saphenous veins in 56 patients (97%) and sub-total occlusion in 2 (3%) patients. For small saphenous veins, post-procedural duplex scans showed total occlusion in 4 (100%) patients.

The average pre-procedure modified clinical picture, etiology, anatomic distribution and pathophysiology clinical score improved significantly after 12 months. Complications from our series included swelling and induration in 3 patients (5%), skin pigmentation in 3 patients (5%). Patient satisfaction with the surgical outcome was 83.17 % (±11.79, n=58).

Conclusions: Our results have been satisfying, and this study has reaffirmed the effectiveness and durability of endovenous laser ablation with 940 wavelength in the treatment of great saphenous vein insufficiency.

Key words: Duplex ultrasound, endovenous technique, saphenous vein, venous insufficiency

ÖZET

Amaç: Bu retrospektif çalışma, 940 nanometre dalga boyu ile endovenöz lazer ablasyonun etkinlik ve kalıcılığını, en az 1 yıllık takibiyle birlikte değerlendirmeyi amaçlamıştır.

Gereç ve yöntem: Aralık 2009 ve Şubat 2012 arasında, inkompetan 68 büyük safen ven ve 4 küçük safen ven, 940 nanometre dalga boyu kullanarak, endovenöz lazer ablasyonla tedavi edildi. Hastaların, endovenöz lazer ablasyonu sonrası ortalama 18 ay (aralığı 12 ile 26 ay) ile standart klinik ve dupleks muayeneleri yapıldı. Prosedür ile ilgili hasta memnuniyeti, görsel analog skala kullanımı (aralığı 1 ila 100) ile değerlendirildi.

Bulgular: İşlem sonrası dupleks taramalarda, büyük safen veninin 56 (%97) hastada total okluzyonu ve 2 (%3) hastada sub-total okluzyonu tespit edildi. İşlem sonrası dupleks taramalarla, küçük safen ven için 4 (100%) hastada total okluzyon tespit edildi. İşlem öncesi ortalama modifiye klinik tablo, etyoloji, anatomik dağılım ve patofizyoloji klinik skor, 12 ay sonra önemli ölçüde düzeldi. Serimizin komplikasyonları olarak, 3 (%5) hastada şişme ve endurasyon; 3 (%5) hastada cilt pigmentasyonu görüldü. Cerrahi sonuçla ilgili hasta memnuniyeti 83,17 % (±11,79, n=58) bulundu.

Sonuç: Sonuçlarımız tatmin edicidir ve bu çalışma, büyük safen ven yetmezliği tedavisinde 940 dalga boyu ile endovenöz lazer ablasyon etkinliğini ve kalıcılığını teyit etmiştir.

Anahtar kelimeler: Dupleks ultrason, endovenöz teknik, safen ven, venöz yetmezlik

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INTRODUCTION

Varicose vein disease is an important cause of morbidity and a substantial public health burden. The disease affects up to 20% of the population in the developed countries and the occurrence increases with age to exceed 65% in women and 50% in men over the age of 45. Common symptoms include leg pain, swelling and skin changes.[1]

The traditional, most common treatment for varicose vein disease is surgical vein stripping and removal of affected veins.[2] However, research has shown that the clinical results are not always as expected and that severe side effects, such as infection or nerve damage, are not uncommon.[3]

Recurrence occurs in approximately one-third to two-thirds of patients after five years. Other disadvantages of surgery are the necessity for general anesthesia and the development of scars and postoperative pain.[4]

Endovenous laser ablation (EVLA) of the great saphenous vein (GSV) and small saphenous vein (SSV) is an alternative, minimally invasive technique for the treatment of the venous insufficiency. EVLA avoids the need for surgical incisions, and the complications of surgical exploration of the groin or popliteal fossa, and stripping. The procedure is commonly performed under local anesthesia, with immediate mobilization and rapid return to normal activity.[5] EVLA produces a transmural vein wall injury, typically associated with perforations and carbonization. The pattern of injury is eccentrically distributed, with maximum injury occurring along the path of laser contact.[6]

Our purpose is to report 940 nm laser saphenous ablation results from the safety and effectiveness point of view with at least 1 year of duplex follow-up.

MATERIALS AND METHODS

Study population

There were 58 patients treated for varicose veins with saphenous reflux consisting of 38 (65%) females and 20 (35%) males. The patients' mean age was 43.71± 16.53. Mean age for the males was 45.8 ± 16.07 and for the females was 42.61 ± 16.88. The mean body mass index for the patients was 24,6 kg/m2. Premorbid conditions in our patients included hypertension in 3 (5%) patients and diabetes mellitus in 3 (3%) patients (Table 1).

The most common symptoms were cramping and pain in the lower limbs in 28 (48%) of the patients. Other symptoms included lower limb swelling in 12 (21%) of the patients, skin pigmentation in 3 (5%) of the patients (Table 1). Fifteen (26%) of our patients chose to undergo to surgery for cosmetic reasons.

Table 1. Preoperative clinical presentations and characteristics of the patients

Presentation/ Characteristics	Number of patients (%)
Total number of patients	58
Unilateral limbs	48 (83%)
Bilateral limbs	10 (17%)
Total number of limbs	68
Age (range) (years)	48 (17-70)
Gender	
Female	38 (65%)
Male	20 (35%)
Premorbid conditions	
Hypertension	3 (5%)
Diabetes mellitus	3 (5%)
CEAP[a] clinical class	
II	48 (83%)
III	7 (12%)
IV	3 (5%)
V/VI	0
Varicose vein	
Few	12 (21%)
Calf	24 (41%)
Calf and thigh	12 (21%)
Pain/ Cramping	
Occasional	38 (65%)
Daily	20 (35%)
Oedema	7 (12%)
Pigmentation	
Small area	2 (3%)
Large area	1 (2%)

aCEAP denotes Clinical, Etiology, Anatomical and Pathology

Patients with documented saphenous vein insufficiency through duplex venous examination, and in modified clinical picture, etiology, anatomic distribution and pathophysiology (CEAP) clinical class II or above were studied (Table 1). Duplex scanning was performed by a radiologist using an Acuson 120XP10 (Aspen, California, USA) device to document the patency of the deep veins and to evaluate the extent and severity of the reflux in the superficial venous system (GSV, SSV and perforators) of patients in the standing position. The competence of the leg perforators was also assessed during the examination. Venous reflux is defined as a reverse flow of more than 0.5 seconds, while perforators are considered incompetent if the diameter is 4 mm or more and/or have an outward directional flow exceeding 0.5 seconds.[7]

Great saphenous vein diameter was measured at a location that was 3 cm below the sapheno-femoral junction, and SSV diameter was measured at a location that was 1.5 cm below the sapheno-popliteal junction while the patient was standing.

Patients were excluded if there was any evidence of deep venous thrombosis (DVT), superficial thrombophlebitis, non-healing ulcers or non-palpable pedal pulses. Patients with very superficial or tortuous GSV, and patients with ancillary procedures included (phlebectomy/sclerotherapy) after EVLA were also excluded. A written consent was obtained from all patients, and our local ethical committee approved the study.

Endovenous laser ablation procedure and postoperative course

The anaesthetic solution for tumescent anaesthesia included 500 mL saline, 5 mL 10% lidocaine, 10 mL 8.4% sodium bicarbonate, and 1 mL adrenaline. After the sapheneous veins were punctured and the laser fibers were inserted to proper location, 250 to 500 mL of tumescent anaesthesia solution was administered under duplex ultrasonography (US) guidelines. We used a 300-600-µm bare-tip laser fiber for each procedure, and the fibers were not used again. During the EVLA, we preferred 10-12 W power, 1 s duration, and 1 s interval using the pulse mode. After administering the tumescent anaesthesia, we performed EVLA (940 nm/ delivering 70-100 joules/cm energy).

After each vein was ablated, the fiber and the sheath/catheter were removed, and the puncture area was covered with sterile tape. Tinzaparin 100 anti-Xa IU/kg administered subcutaneously. An elastic bandage was then wrapped around the leg and patients were immediately requested to walk for 20-30 minutes.

Patients were given a non-steroidal anti-inflammatory drug (diclofenac 100 mg/daily) for three days postoperatively. They wore elastic bandages for three days and class II (30-40 mmHg) stockings or eccentric compression bandages for at least one month. They were also advised to walk at least one hour/day, warned to avoid intense exercise and standing for a long period of time.

Patients were followed up with duplex US by the same radiologist and clinically assessed for at least one-year postoperatively. Tibial and popliteal veins of treated legs were also checked for duplex evidence of DVT. All the patients attended post-procedural duplex examination and clinical follow-ups. To assess treatment satisfaction after 1-year, patients were asked to express their overall appreciation by using of a visual analog scale between 0 and 100, 0 (the extreme left side) indicated not satisfied to 100 (the extreme right side) indicated entirely satisfied.

Statistical analysis

For statistical analysis, non-normally distributed data were analyzed with Mann-Whitney U-test (for two-group comparison). Mann Whitney U Test was used in the analysis of age and satisfaction scores between males and females. Spearman correlation test was applied for the correlation between satisfaction score and age variable. P values smaller than 0,05 were accepted significant statistically. Analyses were done by using SPSS 18.00 packet program.

RESULTS

Between December 2009 and February 2012, we performed EVLA in 58 patients. 10 patients had EVLA for both of their legs. GSVs and SSVs of the same limb were treated in 4 (7%) patients by EVLA. In total, 68 GSVs were treated with EVLA.

The mean follow-up period for all patients was 18 months (range, 12-26 months).

The lengths of GSVs and SSVs treated ranged from 24 to 50 cm (mean, 35 cm) for GSVs and 12 to 20 cm (mean, 15.2 cm) for SSVs. The diameters of the GSVs and SSVs shrunk from 18 to 8 mm (mean, 12 mm) for GSV, and 16 to 6 mm (mean, 8.25 mm) for SSV. The mean tumescent anesthesia solution was 402 mL (range 250-500). The mean operating time, and mean energy delivered per unit of length were 38 minutes (range 25-60), and 80 joules/cm (range 70-100) respectively.

After 1-year, post-procedural duplex scans showed total occlusion of the treated GSVs for 56 patients (97%) and sub-total occlusion for 2 (3%) patients, respectively. For SSVs, postprocedural duplex scans showed total occlusion in 4 (100%) patients. At the duplex examination, the patients treated with EVLA but still having visible GSVs, there was a diameter reduction of about 50% and these were the patients in whom sub-total occlusion of the GSV was determined. At the duplex examination of GSVs treated with EVLA, in 56 of patients (97%), there were no longer GSVs detectable by US. The commonest duplex finding in the groin was an open, competent, SFJ with a < or =4-cm patent terminal GSV segment (97%). Two GSV trunks had sub-total occlusion, but only one refluxed. Neovascularity was not identified in any groin. Recurrent varicosities including telangiectasias and isolated small tributary branches were observed in 3 patients, and 2 patients of recurrent varicosities group had sub-total occluded GSVs post-procedurally.

For the two GSVs where sub-total occlusion was observed, the diameter was greater than 12 mm. During follow-up, all patients had resolution of their varicosities and improvement in their symptoms postoperatively. The modified CEAP clinical score improved from 3 to 0.8 (mean value). The complications of EVLA experienced by our patients after one year postprocedurally included swelling and induration in 3 patients (5%) and skin pigmentation in 3 patients (5%) (Table 2). The mean body mass index in patients with skin pigmentation following EVLA was 18. The mean body mass index in patients without skin pigmentation was 25 kg/m2. Patient satisfaction with the surgical outcome was 83.17 % (±11.79, n=58). In statistical analyses, no significant difference was observed between the ages of males and females (p=0.461) and between the satisfaction scored (p=0.993). No patient underwent a secondary surgical procedure. None developed pulmonary embolism.

Table 2. List of complications of all endovenous laser ablation performed after 1 year of postprocedural

Complications	Number (%) of patients
Pigmentation	3 (5%)
Swelling and induration	3 (5%)
Recurrent varicosities	3 (5%)
Neovascularization	0
Deep vein thrombosis	0

DISCUSSION

Recent studies show that EVLA has a high success rate of over 90% after several years of follow-up studies and a minimal complication rate compared with traditional ligation plus stripping.[8] EVLA for saphenous vein insufficiency treatment is proven to be successful for over 10 years.

The prospective randomised study of endovenous radiofrequency obliteration (closure) versus ligation and vein stripping (EVOLVeS) study showed a better quality-of-life score for the endovenous group compared with conventional treatment for varicose veins at the one- and two-year assessments.[9]

Endovenous ablation had advantages over conventional surgery in terms of less postoperative pain, shorter periods of sick leave, earlier return to normal activities, and reduced overall costs to society.[10] In a number of large case series the technical success rate was close to 100%, and the long-term success rate (up to 5 years) ranged from 90% to 100%.[10-12]

Laser energies of various wavelengths including 810 nm,[13] 940 nm,[7] 980 nm,[14] 1320 nm [15] and 1470 nm [16] have been applied to obliterate the GSV. A prospective randomised study [17] comparing the use of 980 nm and 810 nm laser for endovenous obliteration procedures and another one [18] comparing the use of 810, 940, and 980 nm diode lasers showed no significant difference in their effectiveness and complication rate. We used laser energy of 940 nm in our study, as it was readily available in our hospital Ecchymoses and pain are frequently reported side effects of endovenous laser ablation. Nerve injury, skin burns, deep vein thrombosis and

pulmonary embolism seldom occur. An exceptional complication is a material or device that by accident remains inside the body after the procedure. Ecchymosis, pain, induration, skin burns, dysesthesia, superficial thrombophlebitis, and hematoma were classified as minor complications. Deep vein thrombosis and nerve injury were classified as major complications.[19]

Incidence of hypoaesthesia, swelling, bruising and discomfort following EVLA are not rare, but these impairments are usually self-limited and often improve within months.[10,20] Hyperpigmentation along the course of the treated vein can also be seen at times, especially if the vein is above the fascial level and in thin individuals, but this complication also gradually fades over time.[10] The mean body mass index for our patients with hyperpigmentation following EVLA was significantly low and they were thin individuals. We think that this factor might contribute to the skin discoloration following EVLA.

Our results are comparable with those of other studies.[12,20] However, only a few studies have reported late results, especially late recanalization.[11,12] Ravi and et al.[12] have reported recanalization with a ratio of 0.007 as the most frequent complication in the long term follow up of a 3000-leg study. We haven't come across with a recanalization in our study. After one year post-procedurally, most of the our postprocedure complications were transient and self limiting; the most common complications were swelling, induration, and hyperpigmentation in our study. No major complications, such as deep vein thrombosis, occurred. In conclusion, our EVLA study is satisfactory from the point of 1-year results and major complications observed. However, for the enlightenment of possible major complications, long term results of large scale patient studies are important.

We think that EVLA with 940 nm wavelength is safe and effective in all suitable patients especially from the point of satisfaction factor regardless of age and gender differences.

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