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Prospective evaluation of endo venous laser therapy for varicose vein; early efficacy and complications. The first report from Iran

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Background: In recent years, the endovenous laser therapy (EVLT) has been proposed to treat the incompetent greater saphenous veins (GSV) to increase patient comfort,and to reduce cost as well as risk. EVLT causes vein wall thickening, luminal contraction and vein fibrosis. The purpose of this article, as the first report from Iran, is to review our experience and outline the early results and complication of EVLT. ***Materials and Methods:*** 22 patients (13 females and 9 males, mean age: 40.6±11 years, range: 25-64) underwent EVLT of incompetent GSV segments with 810-nm diode laser with an average energy of 89.2 J/cm (range, 50-123 J/cm). Success rate was defined as absence of reflux throughout the entire treated segment on follow-up doppler ultrasound (DUS) and clinical resolution of symptoms. ***Results:*** Short-term results in the EVLT of 22 GSV indicate a 100% rate of closure. Self-limiting complication were occurred in 18% of patients and included moderate ecchymosis and paresthesias in 3 (13.5%), and 1 (4.5%) patients, respectively. No major complications such as deep vein thrombosis and pulmonary embolism were occurred. DUS demonstrated 21 (95%) and 19 (90.9%) occluded GSVs at 12 weeks, and 24 weeks respectively. ***Conclusion:*** The early results of our experiences are excellent. EVLT of the incompetent GSV with an 810 nm diode laser appears to be an extremely safe technique. EVLT is a very effective and safe with best cosmetic results and rare side effects. **Iran. J. Radiat. Res., 2006; 4 (2): 87-91**

Keywords: *Endo venous laser therapy ,varicose vein-, diode laser.*

INTRODUCTION

Lower limb varicose veins are common, with a prevalence of %15 in men, and %25 in women in the United States [1]. Many patients are a symptomatic, but their complaints may vary from subjective symptoms such as aching, leg heaviness, pruritus, and muscle cramps, to more objective features of edema, eczema, lipodermatosclerosis and ulceration [2]. Several treatment options are available when there is no reflux, including sclerotherapy, hand-held lasers applied externally and ambulatory phlebectomy for varicose veins [3]. The vast majority (60-80%) of varicose veins arise from incompetence of the sapheno-femoral junction (SFJ) and great saphenous vein (GSV) reflux [4]. When reflux is present, the standard intervention is SFJ ligation with GSV stripping. Surgery usually requires general anesthesia, and it is associated with significant perioperative morbidity, increased cost of hospitalization and delayed return to normal activities and work [5].

Endovenous laser therapy (EVLT) is a new and minimally invasive therapeutic option for treating primary varicose veins which provides an effective and safe alternative to conventional surgical management and it may be done in an outpatient setting using local anesthesia [2, 6]. Several wavelengths have been proposed, 810, 940, and 980 respectively. At these wavelengths, the power is usually set between 10 and 15 Watts. The energy is administered endovenously, either in a pulsed fashion or continuously with a constant pullback of the laser fiber. At all the mentioned parameters, doses applied will range from 20 J/cm to 140 J/cm. These doses induce a heating of the vein wall which is necessary to cause collagen contraction and destruction of endothelium. Blood vaporization was found to be the main vehicle for vein wall damage [7, 8].

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The changes produced on the venous wall by laser thermal action have been described as follows: shrinking by myoglobin contraction, collagen retraction, thrombosis, and fibrosis .They are apparently fluence dependent. Fluence (F) represents the result of the power expressed in Watts (W) multiplied by time (T) of exposure and divided by irradiated surface (S) ratio as follows: $F = W \times T/S$. The practical results of the endovenous laser selective thermal action also seem to be dependant on other factors such as the venous diameter and thickness of the venous wall, the retraction velocity, the physical condition of the optical fibers, the venous tone, the immediate venous spasm, blood and vaporization volume [8].

Short-term and intermediate-term outcome is comparable to surgical stripping in terms of elimination of venous reflux (90%-98%), resolution of visible varices (85%), and improvement of subjective complaints such as sensations of heaviness and tension (96%) [9]. There have not been any previous publications on EVLT from Iran. In an effort to demonstrate the effectiveness of EVLT as an alternative to conventional surgery, we reviewed the records of the patients treated by EVLT in Milad hospital, Tehran.

MATERIALS AND METHODS

Patients

Patients with varicose vain, incompetent SFJ and GSV reflux on Doppler ultrasonographic (DUS) were selected for the treatment. Exclusion criteria included nonpalpable pedal pulses, inability to ambulate, deep-venous thrombosis, general poor health, pregnancy, and extremely tortuous GSVs identified on pretreatment DUS that could not allow the passage of the laser fiber [9]. Institutional review board approval and informed consent was obtained and all patients signed an informed consent form before undergoing EVLT. .

Technique

Access to the GSV vein was achieved by open cannulation just below the knee under DUS guidance [2, 3]. A vascular 5F catheter was introduced into the vein and maneuvered upward. A sterile bare-tipped laser fiber, 600 µm in diameter was inserted into the catheter to approximately 1-2 cm below the saphenofemoral junction. Laser energy was delivered endovenously using an 810 nm diode laser generator (12 W, 3 s Pulse Length) with perivascular tumescent infiltration of local anesthetic along the length of the vein. Thermal laser energy was applied by withdrawing the laser fiber in 8-10mm increments over time. Once the laser fiber and catheter were removed, gauze dressings were applied to stab wounds. A 1-week course of non-steroidal anti-inflammatory drugs was prescribed for all patients.

Follow-Up

Follow-up was performed at 1 week, 3 months, and 6 months. Patients were assessed clinically, and DUS were performed for GSV occlusion rates. Success was defined as the stability or the reduction in the size and extent of the varicose veins attributed to the reflux and the absence of reflux throughout the entire treated segment on each follow-up US. After 4 weeks, any patient with residual varicosities was offered sclerotherapy.

RESULTS

The study population included 22 patients (13 women and 9 men); mean age was 40 years (range, 25-64 years; SD ± 11 years). Average patient body mass index (BMI) was 30 (range, 20-36 BMI; SD ± 4). Fourteen veins were on the right and 8 on the left. The energy dose and the treated vein length data were available for all veins (table 1). The total mean laser energy used was 89.2 J/cm (range, 50-123 J/cm). Mean vein length treated was 29 cm (range, 16-42 cm). There were no adverse effects related to the local anesthesia with mild pain. No work stoppage was required, and all the patients had normal occupational

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Table 1. Demographic and treatment data for 22 patients treated with Endo venous laser therapy (EVLT) for greater saphenous vein (GSV) ablation.

Patient	Sex	Age (year)	Weight (kg)	Height (cm)	Vein Length (cm)	Total Energy (Joule)	Mean Laser Energy (J/cm)	Complication	Sclero-therapy	EVLT Failure
1	M	40	108	178	32	3100	97	No	No	No
2	M	54	80	178	30	2700	90	Paresthesia	Yes	No
3	F	25	70	140	36	3700	102	No	No	No
4	M	40	108	178	30	2700	90	No	No	No
5	F	52	68	160	42	4830	115	No	Yes	No
6	F	27	69	162	20	1100	55	Ecchymosis	No	Yes
7	F	39	54	164	38	3170	83	No	No	No
8	M	32	68	170	30	2700	90	Ecchymosis	No	No
9	F	25	57	158	32	1593	50	No	Yes	Yes
10	M	43	90	180	20	1800	90	No	No	No
11	M	31	80	175	20	1800	90	No	Yes	No
12	M	30	60	175	25	2400	96	Ecchymosis	Yes	No
13	F	34	63	163	25	2400	96	No	Yes	No
14	M	64	76	170	16	1400	87	No	Yes	No
15	M	44	84	185	30	3145	104	No	Yes	No
16	F	50	57	165	30	3705	123	No	No	No
17	F	31	71	165	30	1600	53	No	Yes	No
18	F	42	68	155	24	1700	71	No	No	No
19	F	50	75	160	32	2500	78	No	Yes	No
20	F	62	62	170	36	2800	78	No	No	No
21	F	45	62	165	30	3700	123	No	No	No
22	F	33	62	169	30	3052	101	No	No	No

activity days following the procedure. Four minor complications occurred. One paresthesia occurred in the superior calf distal to the skin exit site, which continued for 1 month, but it improved after 2 months. In other patients, moderate ecchymosis developed in the medial thigh along perivascular tumescent infiltration of local anesthetic line. The one week follow-up was clinically successful, and was and DUS 100%. All patients had symptomatic relief on interview. Three and six months follow-ups were 100% (22 of 22 veins) and complete vein ablation on DUS was 95% (n=21), and 90.9% (n=20) at three and six months, respectively. There were two treatment failures in two patients. The first one was discovered at three months, and the other one at six months by

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DUS. They were both clinically asymptomatic and complete relief of pain with itching related to their varicose veins. As far the first one incomplete ablations were GSVs in which a 8-centimeter segment was very narrow but persistently patent in the distal thigh (at 6 months DUS), and another in the other one reflux of saphenofemoral junction was observed (at 3 month DUS). All treatment successes including the two incomplete ablation patients, experienced regression in size and extent of their varicose veins .Ten patients underwent injection sclerotherapy after 4 weeks for residual varicosities. Two treatment failures went for surgery.

DISCUSSION

SFJ ligation, GSV stripping and multiple stab avulsions remain the gold standard for treatment of varicose veins with SFJ incompetence and GSV reflux; however, in the quest for a less invasive treatment for this common yet non-life-threatening condition several alternatives emerged [10, 11].

During the recent years, minimally invasive alternatives to surgical treatment of SFJ's incompetence have been developed with promising results [10]. The most promising of these is minimally invasive treatment with EVLT, which can be performed as an outpatient procedure under local anesthesia [11]. About 50% of patients returned to normal activity within 48 h of treatment. Since the first report on delivery of endoluminal laser energy in 1999, a method for treating the entire incompetent GSV segment has been developed [10]. Endovenous laser treatment, or EVLT which, has received FDA approval in January 2002, involves intraluminal delivery of laser energy [10, 12]. The goal is to cause nonthrombotic vein occlusion by heating the vein wall and collagen contraction and denudation of endothelium resulting in vein-wall thickening with eventual fibrosis of the vein [10].

In a recent study, Chang and Chua reported the use of 1,064-nm laser energy delivered endovenously for treatment of GSV reflux. Although this study reported a success rate of 96.8% in 244 legs followed up to 28 months, significant complications were noted, including paresthesias (36.5%) and skin burns (4.8%) [13]. In a report published by Min and colleagues, after treatment of more than 500 limbs with 810-nm diode laser endovenously, there have been no heat-related complications despite the high temperatures attained at the laser fiber tip [13]. This may be explained by selective, homogeneous, and circumferential heating of the inner vein wall by absorption of 810-nm laser energy by blood lining of the vein wall, rather than deeper penetration of laser energy and less-homogeneous heating from endovenous laser performed with wavelengths such as 1,064 nm, which are less absorbed by blood and more by water [13].

Although EVLT has been used in clinical practice for GSV laser ablation since 7 years ago, no report has been published from Iran to date. We performed EVLT with 810-nm diode laser of average energy of 89.2 J/cm (range, 50-123 J/cm), combined with sclerotherapy for 22 patients. Early studies demonstrated an overall failure rate of 10% at a mean follow-up of 4.7 months and recent studies have reported success rates of 73% to 90% with follow-up to 24 months [10]. In our experience, the failure rate was 5% and 9.1% at 12 and 24 weeks, respectively. These 2 cases were performed early in the series, and were associated with total laser energy delivery below the recommended 80 J/cm for technical and clinical success.

Pain, transient paresthesias, ecchymosis, induration and skin burns, haematoma and phlebitis are common adverse events associated with EVLT, but in most cases they are self-limiting. The most serious adverse events are deep vein thrombosis and incorrect positioning of laser within the wrong vessel. Deep vein thrombosis was observed in only one patient. Despite DUS guidance, incorrect laser placement occurred in two patients, representing serious operator error [11]. The patients in our study reported minimal pain and only four minor complications occurred. Moderate ecchymosis

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was developed in three patients, and one paresthesia occurred which was comparable to those reported by others studies [2, 3]. No major complications such as deep vein thrombosis and pulmonary embolism occurred. At follow up, 10 patients had several small residual varices such as reticular dermis and telangiectasia, and none of them had DUS evidence of treatment failure. These patients underwent successful treatment with compression sclerotherapy.

We conclude that EVLT is a safe procedure for the treatment of GSV reflux and SFJ incompetence with low morbidity and as outpatient procedure. We evaluated EVLT of the GSV, and the results proved that 95% of the treatments were successful and 91% of treated veins were completely ablated without an increase in complications. We have found the EVLT to be a feasible option, acceptable to patients with cosmetic appearance and not associated with the kind of pain that limits immediate return to normal activities. It is associated with high levels of patient satisfaction with an overall treatment. Desirable results can be expected with adequate patient selection, intraopravtive DUS, and concomitant sclerotherapy. This relatively new technique can be performed with safety and a success rate similar to those reports in other studies. It should be considered that as the first experience in the field in Iran, the present study had certain flaws with regard to the number of cases and the length of follow-ups.

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