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Original Article

Endovenous laser ablation (EVLA) versus high ligation and striping (HL/S): Two-years follow up

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Abstract. Endovenous laser ablation (EVLA) of the great saphenous vein (GSV) is thought to minimize postoperative morbidity and reduce work loss compared with high ligation and stripping (HL/S). However, the procedures have not previously been compared in a trial with parallel groups where both treatments were performed in tumescent anesthesia on an out-patient basis. Patients with varicose veins due to GSV insufficiency were randomized to either EVLA (980 nm) or HL/S in tumescent anesthesia. Miniphlebectomies were also performed. In our clinics, 87 varicosis patients were treated between September 2006 and December 2009. EVLA was applied in 90 cases and HL/S was applied in 84 cases. Clinical features and demographic characteristics of the patients were summarized. EVLA procedure was done by 980 nm diode laser (Ceralas D 980, Biolitec) at continues mode with 15 W energy. Patient visits were done at post-operative 10th day, 6th month, 1st year and 2nd year. Routine physical examination and Doppler USG assessments were performed at these visits. EVLA and HL/S procedures were done in complete success in all cases at both groups. All cases were invited for control visits. At post-operative 10th day all patients were evaluated, at 1st year control visit number of attended patients was 130 (EVLA: 68, HL/S: 62) and at 2nd year control, visit number of attended patients was 104 (EVLA: 56, HL/S: 48). When complications developed after procedures were evaluated; no infection, hematoma or paresthesis were observed in EVLA group. However in HL/S group; infections, hematomas and paresthesis were observed in 2, 6 and 24 cases respectively. In terms of treatment success there was not significant difference between EVLA procedure and HL/S methods. However, in terms of post-op complication, EVLA method was associated with significantly less paresthesis, hematoma and pain. EVLA method is a method as effective and safe as standard treatment. However, when a long term result of this method is shown completely, its effectiveness will be cleared and its clinical utility will be established.

Key words: Endovenous laser ablation, great saphenous vein, high ligation and stripping

1. Introduction

Venous insufficiency at lower extremities may result with clinical problems from cosmetic issues to ulcerations. When the frequency of venous insufficiency and its related problems are considered besides their diversity, it is encountered as a public health issue. This pathology is reported to affect 40% of the women and 20% of the men (1, 2).

General complaints related to venous insufficiency depends on the severityof the Insufficiency and accompanying pathologies. Discoloration, pain, cramps, itching, edema and ulcerations at legs are symptoms accompanying to venous insufficiency (3). While major risk factors are age and family history for both sexes, pregnancy is an additional risk factor for women (4). Besides, standing for long periods, obesity and female gender are reported as risk factors (5).

Until recently, the standard treatment consisted of ligating vena saphena magna (VSM) at saphenofemoral junction, stripping below knee and mini phlebectomies. Additionally, branches of VSM at junction are ligated and divided and thus, the recurrence is aimed to be prevented (6). With the development of minimal invasive techniques in the past 10 years, the usage of laser energy came to the fore for the endovenous thermal ablation of VSM. Besides, endovenous

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Table 1. Clinical characteristics of patients

	EVLA	Conventional Surgery	p value
Number of patients	90	84	0.961
Age	32.80±8.07	34.45±8.17	0.053
Gender M/F	54/36	50/34	0.964
CEAP			
C_2	64	60	0.974
C_3	12	8	0.575
C_4	8	4	0.442
C_5	2	6	0.349
C_6	4	6	0.591
CEAP Ep	90	84	0.961
CEAP As	90	84	0.961
CEAP Pr	90	84	0.961
Diameter of the knee at the level of VSM	6.55 ±1.39	6.85±0.16	0.205
VSM reflux time	0.71±1.46	0.76±0.18	0.877

EVLA, Endovenous laser ablation; M/F,Male/Female; CEAP, The CEAP classification (Clinical-Etiology-Anatomy-Pathophysiology); C2, varicose veins; C3, edama; C4, Changes in skin and subcutaneous tissue (pigmentation, eczema, lipodermatosclerosis, atrophieblanche); C5, healedvenousulcer; C6, active venous ulcer; Ep, primary; As, superficialveins; Pr, reflux; VSM, Vena saphenamagna.

Table 2. Patient complaints

	EVLA	Conventional Surgery	p value
Pain	90	84	1.000
Cramp	64	68	0.278
Leg edema	12	6	0.336
Skin discoloration	14	16	0.667
Varicose bleeding	2	2	0.961
Varicose ulcer	6	12	0.245

EVLA, Endovenous laser ablation.

Radiofrequency ablation and ultrasound guided foam sclerotherapy methods have emerged. Post-operative follow up results of those 3 techniques are still debating and continued to be evaluated (7-9).

In our study we compared VSM high ligation and stripping (HL/S) to the endovenous laser ablation (EVLA) procedure in cases with varicosis due to VSM insufficiency. We aimed to explore advantages and disadvantages of both procedures for the short term results.

2. Materials and methods

In our clinics, 174 patients with varicose veins were treated between September 2006 and December 2009. EVLA was applied in 90 cases and HL/S was applied in 84 cases. The mean age of participants was 33.6±; 59% were women and 41% were men (Table 1). Diabetes mellitus (DM), hypertension (HT) and obesity were found in 8, 22 and 14 cases respectively. Patients reported they had complaints for more than 3

Table 3. Complication rates

	EVLA	Convantional Surgery	p value
İnfection	-	4	0.147
Thrombophlebitis	6	4	0.701
Hematoma	-	12	0.010
Paresthesia	-	24	0.001
Pigmentation	6	4	0.701
Leg edema	4	2	0.594

EVLA, Endovenous laser ablation.

years. Most frequent complaints were pain (n: 174) and cramps (n: 132). While varicose dilatations were obvious for all cases, skin discolorations were observed in 30 cases. Venous ulceration was also present in 18 cases (Table 2). The study was planned as a retrospective study. Clinical features and demographic characteristics of the patients were summarized at Table1.

Physical examination and venous Doppler USG were performed in outpatient basis for the patients admitted to the outpatient clinics. Deep venous system, duration and degree of reflux at VSM, perforators and vena saphenaparva were evaluated by Doppler USG. Patients with deep venous thrombosis (DVT), perforating venous insufficiency, deep venous insufficiency, thrombophlebitis, peripheral artery disease were excluded.

All procedures were done by 2 experienced surgeons at the operation room. In HL/S procedure the incisional dimensions were 2 cm and 4 cm at ankle level and inguinal region respectively. VSM and its were branches ligated and divided at saphenofemoral junction. It use followed by complete stripping and mini-phlebectomy procedure. HL/S procedure was performed under regional anesthesia.

EVLA procedure was done by 980 nm diode laser (Ceralas D 980, Biolitec) at continues mode with 15 W energy with 80-90 julespr mm. Covered catheter capable of radial emission was used. The catheter was placed in VSM by percutaneous way, but in 5 cases, the catheter placement necessitated cut-down. Catheter was advanced until 2 cm below of the saphenofemoral junction. EVLA procedure was performed under tumescent anesthesia and mild sedation. A homogenous perivenous mantle was formed along VSM by tumescent anesthesia. Tumescent anesthesia was 200 mL and consisted of 4 mg lidocain, 4 mg adrenaline, 0.5 mg dinatrium EDTA, 1.68 g sodium bicarbonate and NaCl.

The leg of the patient was wrapped in pressured bandage following the procedure and the bandage was removed after 2 days and middle pressure varsity socks were worn. All patients were kept under clinical observation for 18 hours. Non-steroidal anti-inflammatory drugs were prescribed for discharged patients and recommended to be used when symptoms occurred. Patient visits were done at post-operative 10th day, 6th month, 1st
year and 2nd year. Routine physical examination and Doppler USG assessments were performed at these visits.

All parameters were evaluated in both groups. Continuous variables were tested with Student's t test and Mann-Whitney U test. The categorical variables were tested with the Z test.

3. Results

EVLA and HL/S procedures were done with complete success in all cases at both groups. All cases were invited for control visits. At post-operative 10th day, all patients were evaluated; at 1st year control, visit number of attended patients was 130 (EVLA: 68, HL/S: 62) and at 2nd year the control visit number of attended patients was 104 (EVLA: 56, HL/S: 48). When the complications developed after procedures were evaluated; no infection, hematoma or paresthesis were observed in EVLA group. However in HL/S group, infections, hematomas and paresthesis were observed in 2, 6 and 12 cases respectively. In contrast, in 1 case in only EVLA group superficial skin burn occurred. Thrombophlebitis, pigmentation and skin blisters were observed in comparable numbers at both groups (Table 3).

When the groups were evaluated for treatment efficacy, VSM was not observed in any case at first control visit (post-op 10^{th} day) and mild leg pain during walking was reported at both groups (EVLA: 38, HL/S: 64). Recanalization of VSM

Table 4. Effectivity of treatment

	EVLA	Conventional Surgery	p value
VSM Stripping	-	84	1.000
VSM Oclusion (Post-op. 10.day)	90	-	
VSM Recanalizations (Post-op 6.month)	-	-	1.000
VSM Recanalizations (Post-op 12.month)	2	1	0.594
VSM Recanalizations (Post-op 24.month)	2	1	0.594

EVLA, Endovenous laser ablation; VSM, Vena saphena magna.

was determined in 2 cases in EVLA group and in 1 case in HL/S group at 2nd control visits of the patients. Recanalization of VSM was determined in 4 cases in EVLA group and in 2 case in HL/S group also at 3rd control visits of patients. At final control visit, recanalization was observed in 2 cases in EVLA group and in 2 cases in HL/S group. When the cases were evaluated for permanent paresthesis and pigmentation at the end of 2 years; in HL/S group, permanent paresthesis was
determined in 8 cases, however there were no cases in EVLA group. Pigmentation ratios were similar in both groups (Table 4).

4. Discussion

HL/S method is most frequently used surgical treatment method worldwide for the treatment of varicosities (6). However, a rapid development was achieved in minimal invasive varicose vein surgery in the recent 10 years. Novel methods such as EVLA, radiofrequency ablation (RFA), foam sclerotherapy became popular as alternatives to this surgical procedure. All of these methods have been compared to each other in various studies. In studies comparing RFA and HL/S methods RFA method has been reported to have significant advantages (10-12). In a study comparing HL/S and EVLA methods, EVLA was reported to result with less edema and blisters but no other significant differences found between (13). In comparison of foam sclerotherapy to HL/S, HL/S procedure was reported to be superior (14).

In our study, recanalization of the EVLA group was determined in 2 cases at post-operative 6th month, in 2 cases at post-op 1st year and in 2 case at post-op 2nd year. In HL/S group recanalization was determined in 2 cases at post-op 1st year and in 4 cases at post-op 2nd year. There was not statistically significant difference between both groups in terms of recanalization. When post-op complications were evaluated, hematoma and paresthesis were significantly higher in HL/S group. Even though early paresthesis decreased with time,it was determined to continue in 8 cases (9%) on HL/S group at the end of 2 years. In literature Hartmann et al. reported pares thesis ratio reached to 40% in complete stripping and Uncu reported in complete stripping, paresthesis healed with time and became permanent in 2% of the patients (15, 16).

Rasmussen et al. compared EVLA and HL/S methods for various parameters in a randomized prospective study. They recorded quite high pain ratios in HL/S group at early period by pain scorings. However they reported that the pain ratios reached lowest limit at 3rd month and coursed at similar ratios in both groups (17). Results of our study are comparable with these data. Pain complaint was determined at quite high ratios in HL/S group. Tumescent anesthesia in the EVLA group was reported to have impact on this difference (17).

VSM stripping and ablation procedures were done in success at post operative early term in all cases. When recanalization ratios were examined there was no significant difference between both groups at post-op 1st and 2nd years. Despite recanalization ratio was observed to be higher in the EVLA group. Various results were reported in literature for recanalization ratios. There are publications reporting 7% recanalization after 24 months follow up besides publications reporting 10% recanalization ratios in 12 months for the cases in whom ablation was performed by the EVLA method (18,19).

Another point of debate for recanalization is impact of VSM branches at saphenofemoral junction on recurrence. These branches are ligated and divided in surgery, however they left open in the EVLA procedure and this causes question marks to raise. In a study performed by Leeds group clinical value and outcome of these branches were investigated in cases in which the EVLA is performed. Recurrence, reflux and ratio of branches to remain open were investigated in 12 months follow up period. In 59% of the cases

with successful ablation one or two open branches were determined. These open branches were reported to have no impact on clinical outcomes. However question marks remain about the long term impact of these open branches (20).

Impact of energy amount and frequency used in the EVLA procedure on remaining open ratios and complications was also investigated. We applied 90 J/CM 15 W energy at 980 nm in our cases. Demirkılıç et al. reported that ablation performed at 1470 nm wavelength resulted with less pain, ecchymosis and need for analgesia at postoperative period (21). Also comparisons were done for various energy densities at EVLA procedure; however similar clinical results were achieved (22).

5. Conclusion

In terms of treatment success there was no significant difference between EVLA procedure and HL/S method. However, in terms of post operative complication, EVLA method was associated with significantly less paresthesis, hematoma and pain. EVLA method is a method as effective and safe as standard treatment. However, when long term results of this method are shown completely, its effectiveness will be cleared and its clinical utility will be established.

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