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Comparison of Early and Mid-term Outcomes of Endovenous Laser Ablation (EVLA) Treatment Versus Traditional Surgical Treatment in Vena Saphena Magna Insufficiency

Büyük Safen Ven Yetmezliğinde Endovenöz Lazer Ablasyon (EVLA) ve Geleneksel Cerrahi Tedavilerinin Kısa ve Orta Dönem Sonuçlarının Karşılaştırılması

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Abstract

Objective: In this retrospective study, we aimed to compare the short- term and mid- term clinical outcomes of endovenous laser ablation with traditional surgical treatment (high ligation and saphenectomy of Vena Saphena Magna) in patients with isolated unilateral symptomatic Vena Saphena Magna insufficiency.

Materials and Methods: Sixty five patients who underwent traditional surgical treatment (Group 1; n: 35; 16 women, 19 men, mean age; 44.3 ± 12.6 years, range; 20 - 68 years) and endovenous laser ablation treatment (Group 2; n = 30; 20 women, 10 men, mean age; 39.8 ± 11.7 years, range; 20 - 65 years) between May 2013 and December 2013 were included in the study. Groups were compared according to their differences.

Results: Pain scores of EVLA patients were significantly lower at postoperative first week and first month ($p< 0.01$), whereas, there was no significant difference preoperatively. No patient stated to have pain at postoperative 6th month. Frequency of complication development of EVLA patients was found to be lower at postoperative first week follow up but there was no statistically significant difference at 1st month and 6th month controls. CEAP scores of EVLA patients were significantly lower at postoperative follow-ups but there was no significant difference preoperatively.

Conclusion: We observed that endovenous laser ablation is a better treatment modality with better short and mid-term outcomes than traditional surgical treatment in isolated symptomatic unilateral Vena Saphena Magna insufficiencies.

Keywords: Vena Saphena Magna Insufficiency; Saphenectomy; Endovenous Laser Ablation.

Öz

Amaç: Bu retrospektif çalışmada izole ve tek taraflı semptomatik büyük safen ven yetmezliği olan hastalarda, endovenöz lazer ablasyon ve geleneksel cerrahi tedavi (büyük safen vene yüksek ligasyon ve safenektomi) sonrası kısa ve orta dönem klinik sonuçların karşılaştırılması amaçlandı.

Gereç ve Yöntemler: Mart 2013 - Ağustos 2013 tarihleri arasında kliniğimizde geleneksel cerrahi tedavi (Grup 1; 35 hasta: 16 kadın, 19 erkek, ortalama yaş; 44. 3±12. 6 yaş, 20-68 yaş arası) ve endovenöz lazer ablasyon (EVLA) (Grup 2; 30 hasta: 20 kadın, 10 erkek, ortalama yaş; 39. 8±11.7 yaş, 20-65 yaş arası) tedavileri uygulanan 65 hasta bu çalışmaya dahil edildi. Her iki gruptaki hastalar özelliklerine göre karşılaştırıldı.

Bulgular: Postoperatif 1. hafta ve 1. ay ağrı skorları karşılaştırıldığında EVLA yapılan hastalarda, diğer gruba göre istatistiksel olarak ağrı skorlarının daha düşük olduğu saptandı ($p< 0.01$). Buna karşın endovenöz lazer ablasyon uygulanan hastalarda preoperatif ağrı skorları arasında farklılık yoktu. 6. ay kontrolünde her iki grup hastada ağrı gözlenmediği saptandı. Postoperatif 1. hafta takibinde komplikasyon gelişme sıklığı EVLA yapılan hastalarda daha düşük saptandı fakat 1. ay ve 6. ay kontrollerinde istatistiksel farklılık saptanmadı. CEAP skorları EVLA hastalarında postoperatif takiplerinde istatistiksel olarak anlamlı olarak daha düşük iken preoperatif her iki grup arasında farklılık gözlenmedi.

Sonuç: İzole, semptomatik ve tek taraflı büyük safen ven yetmezliklerinde, endovenöz lazer ablasyon tedavisinin kısa ve orta vadedeki daha iyi sonuçlarla geleneksel cerrahi tedaviye göre daha iyi tedavi metodu olduğunu gözlemledik.

Anahtar Kelimeler: Büyük Safen Ven Yetmezliği; Safenektomi; Endovenöz Lazer Ablasyon.

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INTRODUCTION

Chronic venous disorder (CVD) has a considerable socio-economic impact due to its high prevalence, investigations and treatment costs, and loss of working days (1). Varicose veins are present in 25 - 33% of female and 10 - 20% of male adults, while its incidence is 2.6% per year and 1.9% per year in men (1). The classical or traditional surgical strategy for incompetence of the Vena Saphena Magna (VSM), in other words, Great Saphenous Vein (GSV) is a high ligation and stripping (saphenectomy) at the saphenofemoral junction (SFJ) (2). In the last decade, several new minimally invasive treatment options like as foam sclerotherapy accompanied with ultrasound, endovenous laser ablation (EVLA) and radiofrequency ablation have been introduced as alternatives to classical surgical treatment for improving the efficacy and quality of life of patients, minimizing side effects, costs, and postoperative pain of treatment (2). Of these new therapies, EVLA therapy is one of the most widely accepted and used treatment options for incompetent VSM (2). However, traditional surgical treatment is the most frequent treatment modality in varicosity of VSM at present (3).

The CEAP classification for CVD was developed in 1994 by an international ad hoc committee of the American Venous Forum and clinical signs (C), etiology (E), anatomy (A), and pathophysiology (P) were defined in this classification (4). Rutherford et al. reported that the CEAP classification system is an excellent classification scheme for the evaluation of chronic venous insufficiency (5). Venous clinical severity scores (VCSS) is based on scoring of clinical complaints, symptoms and signs. VCSS is important for the evaluation of patients with CVD.

Some patients want to undergo EVLA treatment to avoid the disadvantages associated with the traditional surgery, like cosmetic reasons and possible complications. Also, some surgeons prefer the EVLA treatment for the same reasons. On the other hand, other surgeons prefer the traditional surgery because there is a risk for recanalization of VSM after the EVLA treatment.

In this retrospective study, we aimed to compare the short-term and mid-term clinical outcomes of endovenous laser ablation with those of traditional surgical treatment (high ligation and saphenectomy of Vena Saphena Magna) in patients with isolated unilateral symptomatic Vena Saphena Magna insufficiency.

MATERIALS and METHODS

The study includes sixty five patients who underwent traditional surgical treatment (Group 1; total 35 patients; 16 women, 19 men, mean age; 44.3 ± 12.6 years, range; 20 - 68 years) or EVLA treatment (Group 2; total 30 patients; 20 women, 10 men, mean age; 39.8 ± 11.7 years, range; 20 - 65 years) in our clinic for VSM insufficiency between May 2013 and December 2013. This study was approved by the local Institutional Review Board. Written informed consents were obtained from all subjects before the operations. All of the patients were symptomatic at the onset. Main complaints of the patients with VSM insufficiency were swelling of the legs, pain in the extremities, cramping and burning.

All patients underwent venous Doppler ultrasound examinations, and their source and level of the venous reflux were obtained in preoperative period. Patients demonstrating backflow lasting more than 1.5 seconds during Valsalva maneuvers and those with a VSM diameter more than 5 mm were included in the study and considered for operations.

Patients with deep venous insufficiency, history of deep vein thrombosis, acute deep vein thrombosis, high risk of pulmonary thromboembolism, acute superficial phlebitis, lymphedema, active malignancy, peripheral arterial occlusive disease (ankle / brachial indices < 0.8), diabetes mellitus, pregnancy, lactation and immobility were excluded from the study. Inclusion criteria and exclusion criteria are shown in Table 1. VSM reflux was confirmed with color flow Doppler ultrasound by the surgeon before the operation while the patients were on the table.

Table 1. Inclusion and exlusion criteria.

Inclusion criteria	Age; 20 to 68 years
	Insufficiency of VSM and SFJ with reflux (backflow lasting more than 1.5 seconds and those with a VSM diameter more than 5 mm)
	Symptoms of VSM insufficiency
	C2 in according to CEAP
Exclusion criteria	Pregnancy
	Active malignancy
	Arterial occlusive disease (ankle/brachial indices <0. 8)
	Acute deep vein thrombosis
	History of deep vein thrombosis
	High risk of pulmonary thromboembolism
	Deep venous insufficiency
	Diabetes mellitus
	Lactation
	Acute superficial phlebitis
	Lymphedema

VSM: Vena saphena magna, SFJ: Safeno femoral junction, CEAP: clinical (C), etiological (E), anatomical (A) and pathological (P) classification

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Groups were compared in terms of differences between clinical characteristics, age and gender, CEAP classification, VCSS and development of complications were recorded and compared at the preoperative, postoperative 1st week, 1st month, and 6th month.

Gender, clinical characteristics, CEAP classification and age were not statistically significant variables in the preoperative control. Clinically, all patients in both groups were classified in C_2 at the preoperative control. We mainly evaluated VCSS through pain scores of patients.

Surgical Technique

When the patients' files were investigated, we detected that the patients underwent EVLA at knee medial to SFJ with a wavelength of 1470 nm diode laser using laser catheter with fiber optic radial tip under spinal anesthesia in all EVLA patients. Tumescent anesthesia which containing 5 mg bupivacaine, 0.5 mg adrenaline, 6 ampules of 8.4% sodium bicarbonate, 500 ml and 4°C isotonic saline solution was applied before the EVLA application. Dependent on the diameter of the vein, we used laser energy with the mean value of total energy, power, and interval at 70 J/cm (range 60 to 75 J/cm), respectively. In traditional surgical operation, approximately 4 cm oblique and 3 cm transverse incisions were performed in inguinal region and knee region of the patient, respectively, and then VSM high ligation and partial stripping (saphenectomy) were performed as usual.

Also, we detected that both groups of patients were discharged after the intervention on the postoperative first day. Follow-up examinations were done at 1st week, 1st month and 6th months.

Data were analyzed using the Statistical Package for Social Sciences 15.0 for Windows (SPSS Inc., Chicago, IL) in our study. Parametric tests were applied to data of normal distribution, and non-parametric tests were applied to data of questionably normal distribution. Repeated-measure analysis of variance was used to compare variable parameters. The distribution of categorical variables in both groups was compared using Pearson's chi-square test. Spearman correlation coefficient followed by the Tukey post-hoc test was used to determine correlations between different variables. All differences associated with a chance probability value (p value) is less than 0.05 were considered statistically significant.

RESULTS

Preoperative pain scores of VCSS were not statistically significant, and these values were mean 2±0 in group 2 and mean 2±1 in the other group, respectively. Mean pain scores of group 1 patients were 2 ± 1, 1 ± 1 and 0 at postoperative 1st week, postoperative 1st and 6th months, respectively (Table 2). Pain scores of patients who underwent EVLA were statistically significantly lower than other group at postoperative 1st week and 1st month ($p < 0.01$). No patient stated to have pain within postoperative 6th months.

Table 2. Pain scores of the patients before and after the operation.

	VCSS	Pretreatment		1-week follow-up ($p < 0.01$)		1-month follow-up ($p < 0.01$)		6-months follow-up	
		n	(%)	n	(%)	n	(%)	n	(%)
EVLA TREATMENT (Group 2)	Absent (0)	0	(0%)	12	(40%)	30	(100%)	30	(100%)
	Mild (1)	6	(20%)	18	(60%)	0	(0%)	0	(0%)
	Moderate (2)	14	(47%)	0	(0%)	0	(0%)	0	(0%)
	Severe (3)	10	(33%)	0	(0%)	0	(0%)	0	(0%)
TRADITIONAL SURGICAL TREATMENT (Group 1)	Absent (0)	0	(0%)	0	(0%)	15	(42. 8%)	35	(100%)
	Mild (1)	8	(22. 8%)	23	(65. 7%)	20	(57. 2%)	0	(0%)
	Moderate (2)	15	(42. 8%)	12	(34. 3%)	0	(0%)	0	(0%)
	Severe (3)	12	(34. 3%)	0	(0%)	0	(0%)	0	(0%)

EVLA: Endovenous laser ablation; n: number of patients; p values < 0.05 were considered statistically significant.

In postoperative 1st week control; hematoma, in other words, ecchymosis, wound infection, induration and paresthesia were seen in nine, three, six and three patients in group 1, respectively. Ecchymosis, thrombophlebitis, induration and paresthesia were seen in three, three, five and two patient in group 2, respectively. On the other hand, thrombophlebitis wasn't seen in group 1 and wound infection wasn't seen in group 2. In addition to this, we detected that wound infection, ecchymosis and thrombophlebitis were found to be statistically significant between the two groups ($p < 0.05$). However, induration and paresthesia were not statistically significant difference between two groups; even they were found at higher frequency in group 1 in the 1st week control. Complications at 1st week control were shown in Table 3. Ecchymosis, wound infections, thrombophlebitis, induration and paresthesia were recovered with medical treatment in the 1st month

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control. During these controls, we detected 100% ablation of veins in EVLA patients. On the other hand, there was no statistically significant difference between the two groups by means of frequency of complication development at 1st month and 6th month controls. In the 6th month control; recanalization was detected in two (6.6%) patients in EVLA group but there was no recanalization in stripping group.

Table 3. Complications detected in the first week control.

	Ecchymosis ($p < 0.05$) n	Wound infection ($p < 0.05$) n	Thrombophlebitis ($p < 0.05$) n	Induration n	Paresthesia n
EVLA TREATMENT (Group 2)	3	0	3	5	2
TRADITIONAL SURGICAL TREATMENT (Group 1)	9	3	0	6	3

p values < 0.05 were considered statistically significant; n: number of patients, EVLA: Endovenous laser ablation.

Patients were analyzed in accordance with CEAP classification in the postoperative 1st week, 1st month and 6th month controls. In the postoperative 1st week control; 13 patients were at C_2 (varicose veins) and 22 patients were at C_1 (telangiectasia) in group 1 while 6 patients were at C_2 and 20 patients were at C_1, 4 patients were at C_0 in EVLA group though there was no patient at C_0 in group 1. In the postoperative 1st month control; 34 patients were at C_2 and 1 patient was at C_0 in group 1 and 22 patients were at C_1 and 8 patients at C_0 in EVLA group. In the postoperative 6th month control; 20 patients were at C_0 and 8 patients were at C_1 and 2 patients were at C_2 in EVLA group, on the other hand, 15 patients were at C_0 and 11 patients were at C_1 and 9 patients were at C_2 in group 1. Both groups were compared with each other statistically; there was no statistically significant difference between the two groups preoperatively. However, CEAP scores of the patients who underwent EVLA were significantly lower in the postoperative 1st week, 1st month and 6th month follow-ups ($p< 0.01$). Detailed clinical findings of the patients according to CEAP classification are shown in Table 4. There was no mortality in either group at the perioperative period and follow-ups.

Table 4. CEAP scores of the patients before and after the operation.

	CEAP	Pretreatment n (%)	1-week follow-up ($p < 0.01$) n (%)	1-month follow-up ($p < 0.01$) n (%)	6-months follow-up ($p < 0.01$) n (%)
EVLA TREATMENT (Group 2)	C_0	0 (0%)	4 (13. 3%)	8 (26. 6%)	20 (66. 6%)
	C_1	0 (0%)	20 (66. 6%)	22 (73. 4%)	8 (26. 6%)
	C_2	30 (100%)	6 (20. 1%)	0 (0%)	2 (6. 8%)
	C_3	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	C_4	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	C_5	0 (0%)	0 (0%)	0 (0%)	0 (0%)
TRADITIONAL SURGICAL TREATMENT (Group 1)	C_0	0 (0%)	0 (0 %)	1 (2. 8%)	15 (42. 8%)
	C_1	0 (0%)	22 (62. 8%)	0 (0%)	11 (31. 4%)
	C_2	35 (100%)	13 (37. 1%)	34 (97. 2%)	9 (25. 8%)
	C_3	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	C_4	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	C_5	0 (0%)	0 (0%)	0 (0%)	0 (0%)

n: number of patients, EVLA: Endovenous laser ablation, p values < 0.05 were accepted as statistically significant; n: number of patients; CEAP: clinical (C), etiological (E), anatomical (A) and pathological (P) classifications.

DISCUSSION

Nowadays, it is known that number of patients treated with methods alternative to stripping treatment is rapidly increasing. Radiofrequency ablation and endovenous laser ablation treatment have been introduced as important new endovenous ablative techniques for the minimally invasive treatment of superficial venous reflux and varicose veins (6). Minimally invasive techniques such as endovenous laser therapy, radiofrequency ablation, and ultrasound guided foam sclerotherapy are widely used in the treatment of varicosity of VSM (7). Furthermore, there are some studies in the literature that compare short and mid-term results and patient satisfaction in patients with VSM insufficiency treated with open surgery with saphenectomy or minimally invasive techniques; hence, such minimally invasive techniques appear to be at least

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as effective as open surgery (3, 7-11). Stirling and Shortel report that results of minimally invasive therapies are equal to or may even surpass conventional surgery and offer dramatically reduced recovery time and complication rates (6). On the other hand, we observed that EVLA is superior to surgery with respect to early term complication rates. Furthermore, both groups were compared statistically and the frequency of development of complication were found to be lower while clinical recovery of the patients was also found to be better in the EVLA group in the postoperative first week follow up. However, there was no statistically significant difference between the two groups in the 1st month and 6th month controls. Pain scores were estimated during the first week and first month controls and were statistically lower in the EVLA group ($p < 0.01$). We detected that recovery after treatment was significantly quicker in the EVLA group than the surgery group in the early postoperative period; yet both groups were similar in the latter follow ups. Moreover, EVLA procedure doesn't need surgical incision.

Doganci and Demirkilic (12) report that they found 100% ablation in the veins of both treatment groups during the six months controls with duplex ultrasound assessment. in their study performed with 980 nm laser, Bare-tip fibre 1470 nm laser, and radial fibre in the treartment of GSV varicosities. Etlik et al. (13) report 100% technical success and a 99% closure rate after six, and then twelve months. Also, it is known that one drawback of EVLA is recanalization. Proebstle et al. (14) report that early recanalization is observed in less than 10% of VSM after EVLA treatment. On the other hand, we detected 100% ablation of veins after the 1st month while we observed recanalization in two (6.6%) patients within 6th month after the EVLA treatment. There was no recanalization in the saphenectomy group. Due to some mild complaints, these patients were suggested to receive medical treatment and use elastic compression stockings.

Our study has three major limitations; limited sample size of the groups, lack of long-term follow-up data, and its retrospective nature. We think that prospective, randomized and multicenter studies with more participants and the long-term follow-up data may affect the results.

CONCLUSION

In VSM vein insufficiencies, EVLA is a treatment method that can be preferred by surgeons as well as patients since it offers a short recovery period with low pain scores, postoperative complication ratios, and no surgical scars. As a result, we conclude that EVLA treatment has better early and mid-term results in comparison to traditional surgical treatment and, thus, it is an efficient and safe alternative modality.

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