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Efficacy of Endovenous Laser Ablation and Ultrasound-Guided Foam Sclerotherapy in Patients with Great Saphenous Vein and Perforating Vein Insufficiency

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Abstract

Aim: In this study, we aimed to investigate the efficacy of endovenous laser ablation (EVLA) and EVLA combined with ultrasound-guided foam sclerotherapy (UGFS) and outcomes of treatments in patients with great saphenous vein (GSV) and perforating vein (PV) insufficiency.

Material and Method: Patients underwent EVLA and EVLA+UGFS at the Interventional Radiology Department of a tertiary referral hospital over a 2-year period were retrospectively analysed. Lower limbs of patients were divided into 2 groups according to the treatment method: lower limbs underwent EVLA (group 1) and EVLA+UGFS (group 2). Before and after the procedures, GSVs and incompetent PVs were assessed by colour Doppler ultrasound. Chronic venous insufficiency symptoms (CVIS): pain, heaviness, night cramps, fatigue, itching, burning sensation, swelling, numbness, tingling and visual analogue scale (VAS) scores were assessed before and at 6 months after treatment.

Results: The study group included 29 female (69.1%) and 13 male (30.9%) patients with a mean age of 49.8±12.5 years (range, 24-73 years). All treated GSVs and IPVs were occluded at 6 months after procedures. Improvement in one or more CVIS was observed in all limbs. Full recovery in CVIS was 11/38 (28.9%) in group 1 and 2/9 (22.2%) in group 2. No significant difference was found between the two groups in the comparison of the percentage reduction in the rate of full recovery of symptoms (p>0.05). The VAS scores were significantly decreased after procedures in group 1 and 2 (p=0.0001 and 0.007, respectively). The difference in the percentage decrease in VAS scores in the 6th month compared to before treatment was not statistically different between the two groups (p>0.05). Conclusion: EVLA and UGFS are highly effective and reliable treatments for GSV and PV insufficiency. EVLA+UGFS treatments provide similar improvements in CVIS in lower limbs with GSV and PV insufficiency. Patients with lower clinical severity, treatment only for GSV insufficiency may be considered instead of concomitant treatment of GSV insufficiency and PVI.

Keywords: Endovenous laser ablation, ultrasound-guided foam sclerotherapy, great saphenous vein, varicose vein, perforating vein insufficiency

INTRODUCTION

Chronic venous insufficiency (CVI) in the lower limbs affects a significant proportion of the world's population. CVI has a wide clinical spectrum. It can be asymptomatic or cause more serious symptoms and signs such as varicose veins, fatigue, heaviness, leg cramps and ulcers (1,2). Recent research has indicated that if patients with varicose veins are not treated, a significant proportion will experience a substantial decline in quality of life. Progressive fasciocutaneous deterioration may result in leg ulcers, superficial venous thrombosis and even

significant bleeding in varicose veins (3).

The symptoms of CVI in the lower extremities may be caused by insufficiency of the saphenous veins, deep veins, perforating veins (PV), or combinations of these venous insufficiencies (4). Previously, surgery was the standard method in the management of CVI. However, this has mostly been replaced by endovenous thermal ablation (EVTA), which has better results and fewer complications. Endovenous laser ablation (EVLA), one of the EVTA procedures, has comparable efficacy to surgery with lower complication rates and shorter recovery times in cases of

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great saphenous vein (GSV) insufficiency (1). Furthermore, conventional surgical procedures have been superseded by minimally invasive techniques in the treatement of perforating vein insufficiency (PVI) (5). Ultrasound-guided foam sclerotherapy (UGFS), as a minimally invasive technique for the treatment of PVI, offers several attractive features. The process is relatively straightforward and can be executed expeditiously (6).

There is no consensus for PVI treatment in patients with GSV and PV insufficiency with low clinical severity, and the question of whether perforator treatment can reduce the incidence of varicose vein recurrence is still controversial. Not enough data reported on improvement in symptoms of CVI after treatment (7).

The objective of the present retrospective study was to evaluate clinical outcomes of the treatment with EVLA and EVLA+UGFS and to determine the changes in chronic venous insufficiency symptoms (CVIS) at 6 months after procedure in patients with GSV and PV insufficiency.

MATERIAL AND METHOD

Study Populations and Design

This study retrospectively analyzed patients who underwent EVLA at the Interventional Radiology Department of a tertiary referral hospital over a 2-year period. Three patients who underwent EVLA for tributary vein insufficiency, venous anomaly and small saphenous vein insufficiency were excluded. Also, patients without PVI accompanying GSV insufficiency (n=48) and patients with incomplete hospital records (n=5) were excluded. In the final analysis, 47 lower limbs with GSV and PV insufficiency in 42 patients were included in the study (Figure 1). EVLA in one lower limb and EVLA+UGFS in the other lower limb was not performed in any of the patients in the study.

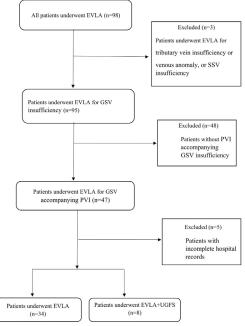


Figure 1. Derivation of the study population; EVLA: endovenous laser ablation, GSV: great saphenous vein, SSV: small saphenous vein, PVI: perforating vein insufficiency, UGFS: ultrasound-guided foam sclerotherapy

The present study has been conducted in accordance with the national regulations and institutional policies that are currently in force and it is consistent with the principles of the Helsinki Declaration. The study was approved by the Ethics Committee of the Faculty of Medicine at Pamukkale University (by decision no. 2013/10 dated 05/08/2013). The lower limbs of patients in the study group were divided into two groups: lower limbs underwent EVLA alone (group 1) and those underwent EVLA with UGFS (group 2). Group 1 consisted of 38 legs in 34 patients and group 2 consisted of 9 legs in 8 patients.

Patients were diagnosed by colour Doppler ultrasound (CDUS) using a 13-5 MHz and a 9-4 MHz multi-frequency linear transducer (Antares, Siemens Medical). All CDUS examinations were carried out by the same experienced radiologist before and after treatment. Clinical and CDUS examinations were performed in the standing position in all patients. Backflow duration ≥500 ms in GSV and the PV during the performance of compression or the Valsalva manoeuvre were considered to be pathological. The number of incompetent perforating veins (IPV), measurements of maximal diameters of IPVs were recorded before and after the treatment. The presence of new IPVs (competent before treatment but incompetent after procedure), partial or total thrombosis of IPVs diagnosed before treatment were also evaluated after the procedures.

EVLA was not performed in pregnant and lactating women and patients with deep venous insufficiency and/or thrombosis, prior varicose vein treatment, severe arterial insufficiency, a history of allergy to local anesthetic substances or sclerosing agents. Before the procedure, the patients were classified according to CEAP (Clinical, Etiologic, Anatomic, and Pathophysiologic) classification (8). The duration of the complaints and body mass index (BMI) were recorded. All patients were asked to rate their pain in their limbs using visual analogue scale (VAS). In the VAS scale, zero denotes the absence of pain, while ten represents the most intense pain imaginable. The VAS scores were assessed before the procedure and at 6 months after the procedure. Prior to all procedures, potential risks and benefits of the EVLA and UGFS was discussed with patients. Each patient gave informed consent. EVLA and UGFS were in accordance with the American Venous Forum Joint Statement reporting standards (8).

EVLA and UGFS Procedures

The EVLA and UGFS procedures were the same for all patients and applied by the same radiologist. The limbs were prepared in a sterile manner in supine position before the procedures and femoral nerve block was performed. All procedures in EVLA and UGFS were performed using 7-12 MHz multifrequency linear array probe (LOGIQ P5, GE Healthcare, Hertfordshire, UK). All EVLA procedures were performed with the same kit (Standard Procedure Kit with 4F 70 cm marked sheath, Vascular Solutions Inc, Sycamore Court, Minneapolis, USA). GSV was punctured either at the level of the knee or below the knee with a 21-gauge needle. A 4F catheter was inserted over

guidewire. A 600 μ m platinum-tipped laser fiber was inserted into the catheter with the wire tip 1 to 2 cm distal to the saphenofemoral junction. Tumescent anesthesia was applied around the GSV using normal saline (1000 cc), 2% prilocaine (20 cc) and 8.4% sodium bicarbonate and 1 mg adrenalin (Figure 2).



Figure 2. The administration of the tumescent anaesthesia

Laser system parameters (Gigaa 980 nm, Vari-Lase endovenous laser system, Vascular Solutions Inc., Sycamore Court, Minneapolis, USA) were: power, 10–20 W; pulse duration, 4–8 sec; and pulse interval, 1 sec. The amount of applied energy was set according to the diameter, depth, and localization of the vein (120-140 J/cm for the proximal part, 70-90 J/cm for the middle part, and 40-50 J/cm for the distal part of the GSV). Real-time ultrasound was used to visualise intravascular air bubbles during the procedure (Figure 3). The total amount of laser energy and the length of treated GSV were recorded.

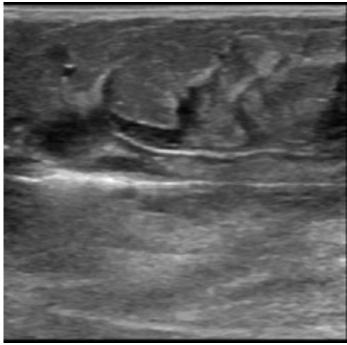


Figure 3. An ultrasound image of intravascular air bubbles

In UGFS procedure, IPVs were accessed under ultrasound guidance with 21G or 22G needles. A thick foam was produced by mixing 1-3% polidocanol solution (Aethoxysklerol, Cem Farma, Ankara, Türkiye) with air 1:4. When IPVs were filled with echogenic foam, before the sclerosing agent reached to the deep venous system, the injection was stopped. A maximum 4 mL sclerosing agent solution was used for each limb.

Follow-up appointments were scheduled for 1st week and on the 1st, 3rd and 6th months post-procedure, and depending on patient complaints thereafter. CDUS was used to evaluate all GSVs and IPVs in treated limbs. Newly developed PV and PVI and the diameters of them were recorded. The patients were again asked to rate their pain using the VAS.

No additional treatment was performed on the patients after procedures. Due to the complication guidelines of the Society of Interventional Radiology Standards of Practice Committee, minor complications were pain, ecchymosis, dysaesthesia, induration, haematoma and superficial thrombophlebitis. Deep vein thrombosis, pulmonary embolism and nerve injury as seen after EVLA were major complications. CVIS (heaviness, night cramp, fatigue, itchiness, burning, swelling, numbness, tingling) were classified as present/absent before the procedure and as full recovery, partial recovery, no change, and worsening at the 6th month after the procedure.

Statistical Analysis

The statistical analyses were conducted utilising SPSS version 18.0 for Windows. The expression of continuous variables is as follows: mean±standard deviation or median (minimum-maximum). Categorical variables were expressed in quantitative terms as frequency and percentage. Comparison between independent groups was performed using the test of significance of difference between two means in parametric conditions and in non-parametric conditions by using the Mann-Whitney U test. For the comparison between dependent groups, Wilcoxon paired two-sample test was used. The comparison of qualitative data was conducted by employing the McNemar and Chi-square and tests. P values less than 0.05 were considered significant.

RESULTS

The study included 29 female (69.1%) and 13 male (30.9%) patients with a mean age of 49.8±12.5 years (range, 24-73 years). The mean BMI of all patients was 29.75±4.55 kg/m2 (range, 23.2-46.1 kg/m²) and the main duration of symptoms in lower limbs was 9.77±5.67 years (range, 2-26 years). There was no significant difference between patients in 2 groups in terms of age and BMI (p>0.05 for each). There was no statistical difference between the two groups in terms of duration of symptoms (p>0.05). Table 1 summarises the characteristics of patients and lower limbs in the study.

The mean length of treated GSV was 54.60±11.15 cm (range, 31-75 cm). The mean energy delivered in all limbs was 5755.34±894.53 J/limb (106.32±11.22 J/cm). There

was no statistical difference between the two groups in terms of treated GSV length, energy delivered/limb and energy/cm (p>0.05, for all) (Table 1).

Table 1. The characteristics of the study population				
	Group 1 (n=38 limbs in 34 patients)	Group 2 (n=9 limbs in 8 patients)	Total (n=47 limbs in 42 patients)	
Age (years), mean±SD, (range)	50.1±12.6 (24-73)	48.5±12.9 (28-65)	49.8±12.5 (24-73)	
Female/male, n (%)	11 (32.4) / 23 (67.6)	2 (25) / 6 (75)	13 (31) / 29 (69)	
BMI (kg/m²) mean±SD, (range)	29.75±4.84 (23.2-46.1)	29.71±3.28 (26.2-34.5)	29.75±4.55 (23.2-46.1)	
Duration of symptoms (years), mean±SD, (range)	10.16±6.00 (2-26)	8.11±3.82 (2-15)	9.77±5.67 (2-26)	
Right/Left limb, n (%)	21 (55.3) / 17 (44.7)	8 (88.9) / 1(11.1)	29 (61.7) / 18 (38.3)	
CEAP, n (%)				
CO	-	-	-	
C1	1 (2.6)	-	1 (2.1)	
C2	9 (23.7)	-	9 (19.2)	
C3	13 (34.2)	6 (66.7)	19 (40.4)	
C4	13 (34.2)	3 (33.3)	16 (34)	
C5	2 (5.3)	-	2 (4.3)	
C6	-	-	-	
Length of ablated GSV (cm), mean±SD	54.84±10.07 (33-75)	53.56±13.56 (31-70)	54.60±11.15 (31-75)	
Total energy (J)/limb, mean±SD	5786.24±902.94 (3960-7672)	5624.89±898.13 (4158-6904)	5755.34±894.53 (3960-7672)	
Energy (J)/cm mean±SD	106.44±10.62 (85.07-137.90)	105.84±14.24 (93.68-134)	106.32±11.22 (85.07-137.90)	

SD: standard deviation, BMI: body mass index, CEAP: clinical, etiologic, anatomic, and pathophysiologic, GSV: great saphenous vein; Continuous variables were presented as mean±standard deviation or median (interquartile range); Absolute variables were presented as number (%)

Before treatment, pain was the most common complaint (100%). Burning sensation (38.3%) was the least common complaint. Frequency of fatigue was higher in group 1 than

group 2 (p=0.003). The frequency of other CVISs were not significantly different in both groups before treatment (p>0.05, for all). The frequency of CVIS is shown in Table 2.

Table 2. The frequency of symptoms in lower limbs before treatment				
Symptom	Group 1 n (%)	Group 2 n (%)	Total n (%)	
Pain	38 (100)	9 (100)	47 (100)	
Heaviness	28 (73.7)	6 (66.7)	34 (72.3)	
Night cramp	23 (60.5)	7 (77.8)	30 (63.8)	
Fatigue	36 (94.7)	8 (88.9)	44 (93.6)	
Itchiness	16 (42.1)	4 (44.4)	20 (42.6)	
Burning sensation	14 (26.8)	4 (44.4)	18 (38.3)	
Swelling	32 (84.2)	7 (77.8)	39 (83)	
Numbness	21 (55.3)	5 (55.6)	26 (55.3)	
Tingling	20 (52.6)	4 (44.4)	24 (51.1)	

Initial technical successes were achieved in all EVLA processes. All concomitant UGFS were also technically successful in group 2. At 6 months after procedures, the

diameter of the treated GSV was significantly reduced in both groups (Table 3) and all treated GSVs and PVIs were completely occluded.

Table 3. The diameters of GSV before treatment and at 6th month after procedure in group 1 and 2				
	Segment of GSV	Before treatment mean (mm)±SD	After procedure (6th month) mean (mm)±SD	P *
EVLA (n=38)	Proximal thigh	8.77±2.91	3.31±0.36	0.0001
	Mid thigh	7.47±2.16	3.08±0.40	0.0001
	Distal thigh	6.95±1.90	2.90±0.50	0.0001
	Proximal kruris	5.26±2.17	2.48±0.42	0.0001
	Distal kruris	3.24±0.95	2.13±0.28	0.0001
	Proximal thigh	7.16±2.57	3.31±0.53	0.008
	Mid thigh	6.97±1.92	3.00±0.27	0.008
EVLA+UGFS (n=9)	Distal thigh	6.88±2.43	2.80±0.34	0.008
	Proximal kruris	5.34±1.98	2.62±0.55	0.008
	Distal kruris	3.96±1.56	2.19±0.40	0.008
All lower limbs (n=47)	Proximal thigh	8.46±2.90	3.31±0.39	0.0001
	Mid thigh	7.37±2.10	3.07±0.38	0.0001
	Distal thigh	6.94±1.98	2.88±0.47	0.0001
	Proximal kruris	5.27±2.12	2.51±0.44	0.0001
	Distal kruris	3.38±1.11	2.14±0.30	0.0001

GSV: great saphenous vein, SD: standard deviation, EVLA: endovenous laser ablation, UGFS: ultrasound-guided foam sclerotherapy, p*: comparison of GSV diameter before treatment and at 6th month after procedure

Before procedures, 110 IPVs were detected in 47 limbs (93 IPVs in group 1 and 17 IPVs in group 2). The mean diameter of IPVs was 4.31±1.24 mm (range, 2.8-8.4 mm in group 1 and 5.32±1.86 mm (range, 3.2-10 mm) in group 2. At the 6th month, the mean diameter of IPVs was 4.70±1.33 mm in group 1 and 3.15±0.95 mm in group 2. The mean diameter of IPVs at 6th after procedure was higher in group 1 and lower in group 2 compared to before treatment (p<0.0001 for each). At 6th months after treatment there was one new IPV in group 1, however no new IPV was observed in group 2. At the 6th month, there were 28 PVs (mean diameter, 2.45±0.32 mm; range, 2.0-3.2 mm) in group 1 and

4 PVs (mean diameter, 2.28±0.17 mm; range, 2.1-2.5 mm) in group 2, which had no insufficiency but became visible compared to before procedure.

Improvement in at least 1 symptom was observed in all limbs in both groups. The proportion of extremities with full recovery in symptoms was 11/38 (28.9%) in group 1 and 2/9 (22.2%) in group 2. No significant difference was found between the two groups in the comparison of the percentage reduction in the rate of full recovery of symptoms (p>0.05). The changes in CVIS at the end of the 6th month is shown in Table 4.

Table 4. Changes in the symptoms at 6th month compared to before procedures					
Symptom		Full Recovery n (%)	Partial recovery n (%)	No Change n (%)	Worsened n (%)
Pain	Group 1 (n=38)	14 (36.8)	22 (57.9)	2 (5.3)	-
	Group 2 (n=9)	6 (66.7)	3 (33.3)	-	-
Heaviness	Group 1 (n=28)	12 (42.9)	14 (50)	2 (7.1)	-
	Group 2 (n=6)	4 (66.6)	1 (16.7)	1 (16.7)	-
Night cramp	Group 1 (n=23)	11 (47.8)	1 (47.8)	1 (4.4)	-
	Group 2 (n=7)	5 (71.4)	2 (28.6)	-	-
Fatigue	Group 1 (n=36)	13 (36.1)	17 (47.2)	5 (13.9)	1 (2.8)
	Group 2 (n=8)	3 (37.5)	4 (50)	1 (12.5)	-
Itchiness	Group 1 (n=16)	6 (37.5)	7 (43.8)	2 (12.5)	1 (6.2)
	Group 2 (n=4)	3 (75)	1 (25)	-	-
Burning sensation	Group 1 (n=14)	7 (50)	3 (21.4)	3 (21.4)	1 (7.2)
	Group 2 (n=4)	2 (50)	1 (25)	1 (25)	-
Swelling	Group 1 (n=32)	14 (43.8)	13 (40.6)	4 (12.5)	1 (3.1)
	Group 2 (n=7)	3 (42.8)	2 (28.6)	1 (14.3)	1 (14.3)
Numbness	Group 1 (n=21)	10 (47.6)	6 (28.6)	3 (14.3)	2 (9.5)
	Group 2 (n=5)	2 (40)	1 (20)	1 (20)	1 (20)
Tingling	Group 1 (n=20)	8 (40)	11 (55)	1 (5)	-
	Group 2 (n=4)	2 (50)	2 (50)	-	-

Table 5 shows the major and minor complications in group 1 and 2. As a major complication, 1 patient in group 2 had thrombus in the popliteal vein. Thrombus was detected 1 week after procedure and popliteal vein was completely recanalized after acetylsalicylic acid

treatment at 1st follow-up. Other major complication was a second-degree skin burn occurred in the anteromedial aspect of the cruris in one limb in group 1. The energy applied to this limb was the highest as 137.9 J/cm.

Table 5. Major and minor complications in Group 1 and 2			
Complication	Group 1 (n=38)	Group 2 (n=9)	
Deep vein thrombosis	-	1 (11.1%)	
Skin burn	1 (2.6%)	-	
Ecchymosis, tenderness	29 (76.3%)	4 (44.4%)	
Increased pigmentation	11 (28.9%)	7 (77.8%)	
Paresthesia	11 (28.9%)	4 (44.4%)	
Thrombophlebitis	2 (5.3%)	1 (11.1%)	

The most common minor symptom in all limbs after procedures was ecchymosis and tenderness (70.2%). Complete regression of ecchymosis was observed at 1st month in all limbs. Local thrombophlebitis developed as a result of thrombosis of varicose veins in three limbs (6.4%). Of the lower limbs with paresthesia (15/47, 31.9%), 10 were ablated to the ankle, 4 to the mid-crural region, and 1 to below the knee. Paresthesia was observed in only one limb (8.3%) where ablation was performed proximal to the cruris. The incidence of paresthesia was 4/12 (33.3%) and 10/23 (43.5%) in patients who underwent ablation to the mid-crural and ankle, respectively. At 6th month after procedures, increased pigmentation was found in 18 (38.3%) limbs. Increased pigmentation was found more in lower limbs that underwent EVLA+UGFS than those underwent EVLA alone (p=0.006). Other complication rates were similar for both groups (p>0.05).

After the treatment, the mean VAS scores improved significantly, falling from 6.13±1.12 (range, 4-8) before procedure to 2.21±1.02 (range, 0-5) at the end of 6th months in group 1 and from 6.33±1.32 (range, 4-8) to 2.11±0.60 (range, 1-3) in group 2 (p=0.0001 and 0.007, respectively). The difference in the percentage decrease in VAS scores at 6th month compared to before treatment was not statistically different between the two groups (p>0.05).

DISCUSSION

In this study, complete occlusion was observed in all veins treated with EVLA or EVLA+UGFS in lower limbs with GSV and PV insufficiency. EVLA and EVLA+UGFS treatments resulted in similar rates of significant improvement in CVISs. There was a significant decrease in VAS scores at 6 months postprocedure compared to before treatment with EVLA and EVLA+UGFS. However, there was no significant difference in the rate of decrease in VAS values between both groups. Major complications were low, and minor complications were high with EVLA and EVLA+UGFS treatments. The increase in pigmentation was found to be higher with EVLA+UGFS than with EVLA alone. Paresthesia was more common in cases where the distal parts of the GSV were also ablated in the crural region.

CVI is a progressive condition that requires public health consideration due to its extensive nature. The following risk factors have been identified as common to CVI: prolonged standing or sitting, venous thrombosis history, increasing age, pregnancy, family history of venous disease, smoking, obesity, history of trauma or surgery to the lower extremities (3,9). While patients with CVI may remain asymptomatic, others may experience localised discomfort. This may include pain, itching or throbbing around the affected veins. Untreated CVI can lead to the advancement of venous disease to a more severe stage, including symptoms such as fatigue, heaviness, and leg cramps. It is estimated that as many as 10% of adults suffering from CVI may eventually have progressive disease. It may include venous ulcers, thrombophlebitis or bleeding from varicosities (1,10). In our study, pain in all lower limbs was the most common symptom. Fatigue was the second most common symptom with a prevalence of 93.6%.

CVISs and varicose veins in limbs may be caused by insufficiency of the saphenous veins, deep veins, PVs, or a combination of these venous insufficiencies (4). PVI has been shown to be a contributing factor to the symptoms of advanced CVI. The majority of patients diagnosed with CVI can be treated with either the ablation of the axial veins or with compression therapy. However, this treatment is sometimes unsuccessful, and patients have been observed to suffer from recurrent varices. In this group, recalcitrant symptoms may be attributed to PVI. In patients with ulcers or a history of ulcers, treatment of PVIs can improve the rate of healing of the ulcer and prevent the recurrence of ulcers. A comprehensive meta-analysis of data derived from 20 trials has concluded that in patients diagnosed with PVI treated in CEAP C6 class, initial cure rates approached 90%, accompanied by a recurrence rate of only 13% (5,11).

The landscape for the treatment of symptomatic varicose veins has changed significantly. This is primarily attributable to the advent of minimally invasive endovascular procedures. Among these procedures, EVTA techniques, particularly EVLA and radiofrequency ablation, have emerged as first-line treatments (1,12). The

EVLA procedure entails the insertion of a laser fiber into the target vein, resulting in the emission of laser energy, which induces thermal damage within the vessel. The consequences include venous constriction, thrombosis and fibrosis (12). The utilisation of radial fibers and lasers characterised by higher wavelengths (1470-1940 nm) has been introduced for the promotion of uniform damage to the vein wall (13). An investigation into the frequently utilised parameters of EVLA (wavelength, administered energy) has demonstrated that these factors exert no influence on the success rates of treatment. The overall success rate of EVLA is found to be high (92%), even in the context of increasing follow-up periods (14). In our study, we used 980 nm wavelength and all GSVs treated with EVLA were thrombosed at the end of the 6th month. The findings of this study are consistent with the extant literature and lend further support to the high success rate of EVLA.

The diameter of GSVs decreases gradually within months following successful treatment with EVLA and the great majority (85%) become invisible on CDUS at the end of the first year (15). In the present study, thigh and crural GSV diameters were significantly reduced 6 months after EVLA compared to preprocedure.

Complications associated with EVLA are generally minor and major complications are uncommon. In the literature, the rate of deep venous thrombosis was reported to be 0-8%, paresthesia was reported to be 0-12%, and skin burn was reported to be 0-12% after EVLA (16). A review focusing on the complications of EVLA reported that the rate of ecchymosis and pain ranged 24-100% and superficial thrombophlebitis ranged 1-22% (17). In the present study, partial thrombus was detected in one patient. Development of thrombus in this patient who underwent EVLA+UGFS was attributed to the sclerosing agent's leaking into the deep venous system through the PV. The other major complication was skin burn in one patient. The energy delivered to this patient was 137.9 J/cm, the highest value in the study. The rate of major complications in the present study was in line with that reported in the literature.

Superficial thrombophlebitis following EVLA was more common in large varicose veins and in the venous structures with impaired drainage due to ablation and it is reported nearly 5% (16). In the present study, superficial thrombophlebitis was detected due to thrombosis of the varicose veins in a total of 3 limbs (6.4%). The most common complication observed in the present study was ecchymosis and tenderness lasting for nearly 1-2 weeks in 70.2% (33/47) of the limbs. The rate of these minor complications in this study were consistent with the literature.

It has been reported that ablation of crural GSV has high risk for saphenous nerve injury and that temporary paresthesia frequently occurs due to the damage of the nerve (which has only sensorial branches in the crural segment) resulting from inserting vascular sheath or catheter, tumescent anesthesia or direct thermal effect. Long lasting paresthesia can be seen by 0-10% (18). As a general agreement on minimizing the risk of postoperative nerve injury, it has been reported that preferably the inferior aspect of the knee joint is convenient for accessing and that accessing from a segment more inferior to the 1/3 proximal aspect of the cruris should be avoided (19). In the present study, paresthesia was observed in a total of 15 lower limbs (31.9%). The rate of paresthesia was higher in limbs exposed to ablation through the middle part of cruris and the ankle. The findings of the present study support the opinion that long-segment GSV ablation enhances the rates of nerve injury and paresthesia.

Current societal recommendations include perforator closure in CEAP C5-6 disease by traditional or minimally invasive techniques (5). However, there is no consensus for the treatment of PVI in patients with lower clinical severity and the question of whether or not perforator treatment can reduce the incidence of varicosity recurrence is still controversial (7). The seven-center retrospective cohort study confirmed that IPVs were important factors for recurrent varicose veins after EVTA (20). However, there are several reasons against definitive perforator transection. Firstly, treatment of GSV alone improves a significant proportion of IPVs; secondly, interruption of IPVs using a variety of techniques is associated with residual or 'missed' IPVs; finally, recurrence is often associated with progression of CVI, not just IPVs (21).

Traditional surgical techniques have been replaced by minimally invasive procedures for the treatment of PVI. UGFS is one of these effective techniques. It is technically simple and can be performed quickly. Also, it is less expensive than thermal ablation. Multiple IPVs and varicose veins can be treated with a single injection. Improvement in symptoms, as measured by venous clinical scores, was seen in patients with successfully treated IPV (6). In contemporary literature, completion rates of between 69% and 96% have been reported with UGFS. Patients with successful IPV thrombosis demonstrated high rates of ulcer healing (11). In the present study, all treated IPVs were occluded at 6 months post-procedure and the success rate of complete occlusion of IPVs was consistent with the literature.

The major complications associated with UGFS were reported to include anaphylactic reactions (although these were rare), deep venous thrombosis (1-3%), and stroke (0.01%). Other complications reported were superficial venous thrombosis (4.4%), tissue necrosis, oedema (0.5%), and nerve injury (0.2%). Among the cosmetic complications, newly developed telangiectasia was reported to be 15-24% (22). In this study, increased pigmentation was detected in 18 lower limbs (38.3%) after 6 months after treatment. Of these lower limbs, 7 (77.8%) were in group 2 and 11 were (28.9%) in group 1. A systematic review showed that the incidence of hyperpigmentation with sclerotherapy increased with higher concentrations of polidocanol. In addition, at polidocanol concentrations greater than 0.25%, more pigmentation was observed after sclerotherapy

of epifacial veins than intrafacial truncal veins (23). We believe that the relatively high concentration of polidocanol used in our study and the fact that polidocanol injected into the perforating veins passes into the superficial venous structures may explain why more pigmentation was observed in the second group.

In the present study, the decrease in VAS scores at 6 months post procedure was statistically significant for patients underwent EVLA alone and EVLA+UGFS (p=0.0001 and 0.007, respectively). In the literature, it is reported that the maximum clinical benefit is seen in the first three to six months after EVTA. In addition, it is indicated that no clinical improvement has been seen after 6 months of treatment (24). Therefore, 6 months after treatment seemed to be the best time to assess clinical benefit after treatment. In this study, all limbs were clinically evaluated and CDUS examinations were performed at the end of 6th month following treatment. For this reason, we are of the opinion that there is sufficient data in our study to determine the changes in CVIS after the treatment.

Previous studies have compared the anatomic success rate and improvement in quality of life according to the type of EVTA. Not enough data has been reported for the improvement of CVIS and the rate of full recovery of CVIS is uncertain (25,26). In a study (27), involving a total of 174 patients, the changes in CVIS in patients underwent cyanoacrylate ablation+UGFS and EVLA+UGFS were evaluated. The most significant improvements reported were night cramps (94.7%), itching (93.8%), heaviness (85.2%), numbness (77.8%) and pain (60.9%). Also, the improvement rates for all symptoms were found to be similar in both groups. In our series, there was no statistically significant difference in the frequency of limbs with improvement in 1 or more symptoms and full recovery from all symptoms between the EVLA and EVLA+UGFS groups (p>0.05 for each). Also, there was no significant difference in the percentage decrease in VAS scores between the two groups after the procedure (p>0.05). For these reasons, we are in the opinion that there is no significant difference between EVLA and EVLA+UGFS treatment in terms of improvement of CVIS in limbs with GSV and PV insufficiency.

Thrombosis (blood clots) in the saphenous and varicose veins, as well as inflammation in the vessel wall and the structures around it, may cause an increase in CVIS in the early period after treatment of the saphenous vein (1). These complaints are mostly transient, and they can even be reduced by compression stockings and anti-inflammatory medications (27). In our study, the incidence of deterioration in symptoms post-treatment was found to be minimal (in 0 to 2 limbs with EVLA and 0-1 limbs with EVLA+UGFS). Our results are in line with the literature, but further research is needed to determine the cause of the worsening of symptoms.

Limitations of Study

There are some limitations of this study. It has a retrospective and single-center design. This methodological framework may be susceptible to selection bias, thereby restricting the external validity of the findings. The 6th month postprocedure data may result in a relative lack of outcome measures. Moreover, the study's sample size is limited, which has the potential to compromise the statistical power and precision of the results.

CONCLUSION

EVLA and UGFS are highly effective and reliable treatments for GSV and PV insufficiency. They are associated with high patient satisfaction and low complication rates. EVLA alone and EVLA+UGFS treatments provide similar improvements in symptoms in patients with GSV and PV insufficiency. In this patient group with lower clinical severity, treatment only for GSV insufficiency may be considered instead of concomitant treatment of GSV insufficiency and PVI. However, large randomised trials comparing EVLA and EVLA+UGFS are needed in these patients.

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Ethical approval: The present study was approved by the Ethics Committee of the Faculty of Medicine at Pamukkale University (approval number: 2013/10; date of approval: 05/08/2013). The study was conducted in accordance with the Declaration of Helsinki. Informed consent was obtained from all patients during their period of hospitalisation.

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