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ABSTRACT

of the dissertation for the degree of philosophy doctor
of medicine

OPTIMIZING RESULTS OF ENDOVENOUS LASER ABLATION IN THE TREATMENT OF LOWER PERIPHERAL VEIN VARICOSES IN PATIENTS WITH DIABETES

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INTRODUCTION

The relevance of the subject and the level of elaboration. In the literature samples published in recent years, the increase in the number of patients suffering from chronic venous insufficiency (CVI) and varicose disease (VD) of the lower extremities, the decrease in work capacity and quality of life due to various complications of the disease have been reflected. According to the results of studies conducted by various researchers, VD is found in 10-20% of men and 25-40% of women[1;2;3].

For many decades, in the fight against varicose veins of the lower extremities (VVLE), all the hopes of specialists were in traditional surgical operations. Most of them were proposed at the beginning of the century. Due to the development of science and technology, as a result of the widespread application of more minimally invasive procedures in surgery, new innovative methods have been applied in the treatment of VD. Endovenous laser ablation (EVLA) is chosen for its modernity, ease of implementation and better treatment results, as well as a number of other positive features.[4;5] One of the motivations for the use of minimally invasive methods is the fact that the number of postoperative complications during the application of traditional open surgical methods in patients with comorbidities is high. Among this group of patients, it is especially important to mention those suffering from diabetes mellitus (DM). The traumatism of open phlebectomy was significantly higher in those who

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[5] Qasımov, N.A., Əliyev, M.S. Magistral dərialtı venaların endovazal lazer obliterasiyasına göstərişlər / N.A. Qasımov, M.S. Əliyev // Cərrahiyyə, - Bakı: - 2017. №3, - s. 3-9.

suffered from diabetes at the same time as VVLE. Unsatisfactory post-phlebectomy results of DM patients, even in specialized vascular surgery departments, have been confirmed as one of the important and urgent problems facing phlebologists.[6;7;8]

At the same time, we should note that the frequency of lower extremity wounds developing on the background of diabetic neuropathy and/or angiopathy in DM patients without venous pathology is about 15% in the diabetic population, and 1-2% in the general population. 15% of these wounds are difficult to heal or non-healing wounds. Taking into account the above-mentioned statistical indicators, we can say that the treatment of venous ulcers in DM patients with CVI is one of the most urgent problems of modern medicine.[9;10]

Taking into account the stages of diabetic macroangiopathy and the prognostic criteria of its negative dynamics, we did not find studies on further stricting the indications for surgical treatment of VVLE in this group of patients or keeping them in line with the standard. Currently, the standard amount of laser energy recommended by international clinical protocols (80-100 C/sm) is applied during EVLA in patients with a long history of diabetes, especially uncontrolled DM with a glycemic profile against the background of the phlebosclerosis process. In the local and foreign literatures that we researched, we did not encounter studies on the necessity of performing the procedure

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[6] Abışov N.S, Zakirjayev E.J, Kərimov M.M, Abuşova G.N Result of endovenous radiofrequency thermal ablation with and without high ligation in comparisson with high liqation and stripping for treament of great saphenous varicose vein.Vascular without Borders. Cite des Congres – Lyon. France 2011.

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with different tactics during EVLA in patients with DM, and the comparison of the frequency of side effects of these different tactics in the postoperative period. makes it important.

The object and subject of the research. The subjects of the study were patients suffering from varicose veins of the lower limbs along with DM. Assessment of venous insufficiency in these patients before and after surgery according to CEAP (Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P)) and VCSS (Venous Clinic Severity Score), determination of the optimal amount of energy during EVLA, its near and far evaluation of results is the subject of research.

The purpose of the study. Stratification of the optimal power of laser energy during EVLA in the treatment of VVLE in patients with DM, studying the results in the near and long term.

Tasks of the study:

1. Correvlation evaluation of the severity of VVLE with the history of diabetes and the level of glycemia in patients with DM;
2. Studying the results of the application of standard energy power during EVLA in the near and distant periods on the VCSS system in patients with DM;
3. Comparative assessment of the effect of gradually increasing the amount of energy given in order to achieve complete obliteration in the treatment of VD in patients with DM on the obliteration of the vessel;
4. Comparative characterization of short-term and long-term results of application of standard and higher amounts of energy during EVLA in patients with DM and VVLE.

Research methods: All patients were first subjected to physical and objective examinations, anamnesis was collected, and it was checked whether they met the criteria for inclusion in the research material. Since the patients had DM as a co-morbidity, an endocrinologist's consultation was conducted, and if necessary, the examinations were expanded based on the specialist's advice. Duplex ultrasonography (USG), CEAP classification, VCSS evaluation and diabetic foot examination were performed in all patients.

The necessary examination methods for the diabetic foot questionnaire include: anamnestic and physical examination, pedal pulsation, measurement of the Ankle-Brachial Index and diagnosis of neuropathy.

Additions were also made to the examination plan for the patients included in the material. So, in addition to the main examination methods, electrocardiogram, general blood analysis, fasting plasma glucose, creatinine, glycohemoglobin, INR, fibrinogen, hepatitis B, hepatitis C, HIV, syphilis laboratory analyzes were checked as additional examination methods.

The main provisions submitted to the defense:

1. It was scientifically and practically evaluated how effective the application of the EVLA method with standard energy density was during VVLE in the patients with DM.

2. The results of EVLA performed with standard and revlatively high doses of VVLE energy in DM patients in the near and long term were compared on the basis of VCSS assessment.

3. Using an energy density of 120-140 C/sm as the optimal amount of energy to achieve adequate obliteration during EVLA with high laser energy has been confirmed to be more effective.

Scientific innovations:

- It has been established that the long-term co-morbidity of VVLE in the pre-operative period of people with DM infection has a negative effect on the results of EVLA treatment.

– In patients with DM, during EVLA, the standard energy power is not sufficient for adequate obliteration of the venous vessel lumen due to the development of the phlebosclerotic process.

- It has been determined that, despite the fact that the amount of energy of 100-120 C/sm in DM patients gives a certain effect compared to the standard dose, it does not allow to achieve complete obliteration in all patients.

– EVLA with an energy dose of 120-140 C/sm is the optimal energy density for minimally invasive ablation of VD individuals suffering from DM.

Theoretical and practical significance of the study:

1. As a result of our research, it has been proved theoretically and practically that the application of EVLA during VVLE in patients

with DM is an effective method. The EVLA method is characterized by minimal trauma, rapid postoperative rehabilitation, aesthetics, absence of serious complications and fewer complications;

2. In the treatment of VVLE in patients with DM, the near and far results of EVLA are superior to ablation with energy of 120-140 C/sm. The EVLA procedure can also be successfully performed in patients with recurrent and active venous ulcers;

3. The obtained results justify the opinion that the minimally invasive method is more effective in the cases where surgical operation is required in patients with DM who have CVI in the lower extremities;

4. Practical recommendations will be prepared based on the results of our research on the comparison of the use of the EVLA method in patients with DM with different amounts of energy, scientific articles and theses will be written, and reports will be made at conferences and seminars.

Approbation of the work. A number of dissertation results were reported at the scientific-practical conference dedicated to A. Aliyev's birthday (Baku: - 2022), and poster presentations were made at international conferences (Istanbul: - 2022, Antalya: - 2023). The preliminary discussion of the dissertation was carried out at the inter-departmental ASATID meeting named after A. Aliyev ("General and plastic surgery", "Therapy", "Radiography with radiation therapy course") (09.02.2024, protocol № 02). The approval of the dissertation was reported and discussed at the scientific seminar of the FD 2.11 Dissertation Council (03.05.2024, protocol № 03).

Publication. The main results of the research work were published in 7 articles, including two in foreign journals and 4 thesis materials, including two in foreign publishing houses. Published articles and theses correspond to the provisions of the dissertation. Journals in which articles are published correspond to the list approved by the Supreme Attestation Commission.

The obtained results were used for the treatment of patients with DM and VVLE of the "Istanbul NS" and "Yeni Ganja Medical Center" private clinics.

The name of the organization where the dissertation work was performed. The dissertation work was performed at the surgical

profile departments of the Aziz Aliyev ASATID, "Istanbul NS" and "Yeni Ganja Medical Center" medical institutions.

Structure and scope of the dissertation. The thesis is printed on 171 pages and has a total volume of 236,134 characters (excluding spaces, tables, graphics and bibliography). Introduction (12,570 marks), 6 chapters (Chapter I 44,301 marks, Chapter II 28,554 marks, Chapter III 33,427 marks, Chapter IV 52,300 marks, Chapter V 24,113 marks, Chapter VI 38,140 marks), conclusions (1,795 marks), practical recommendations (934 marks), it consists of bibliography and abbreviations. The research work is illustrated with 11 tables and 54 pictures. The bibliography included 162 sources, 10 of them were the works of Russian and other foreign scientists.

MATERIALS AND METHODS OF RESEARCH

The material of the study consisted of the examination results and treatment of 140 patients who suffered from VVLE and also had DM during 2017-2020. Examination and treatment of patients was carried out in "Istanbul NS clinic" and "Yeni Ganja Medical Center" private medical institutions.

Each patient was diagnosed with clinical and instrumental methods, duplex USG, CEAP classification, VCSS assessment and diabetic foot examination were performed.

Most of the patients are women. There were 98 (70%) women and 42 (30%) men in the observations. The average age of the patients was 57.1±0.62, ranging from 41 to 74 years. About 40% of them were older than 60.

In the patients included in the material, the duration of DM disease (disease anamnesis) was 13.8±0.33 years on average, and the longest anamnesis was 25 years. The main specific feature of our research is the development of phlebosclerosis in the wall of the veins due to long-term diabetes, the fact that the vascular wall is rigid and resistant to laser rays, and the effectiveness of laser therapy is reduced. 98 (70%) patients included in the study had a history of diabetes for 10-14 years, 27 (19.28%) patients for 15-19 years, 13 (9.29%) patients for 20-24 years, and 2 (1.43 %) was determined for 25 years in the patient.

In addition to blood glucose determination, glycohemoglobin concentration was also studied in all patients. Fasting blood glucose was 183.9±4.9 mg/dl on average, min. 117 mg/dl with max. It fluctuated between 390 mg/dl. The amount of glycohemoglobin varied between 7.5% and 11.9% with an average of 9±0.09%.

The diameter of the sapheno-femoral joint in the right lower limb is 0.95±0.037 cm; the diameter of the sapheno-popliteal junction was 0.39±0.02 cm. The diameter of the vessels at the same levels on the left side was 1.07±0.037 cm and 0.36±0.015 cm, respectively. As can be seen, the size of the sapheno-popliteal junction on the right side and the sapheno-femoral junction on the left side was not significantly larger than the other side. The average sizes of the subcutaneous veins of the lower limbs in different segments are depicted in figure 1.

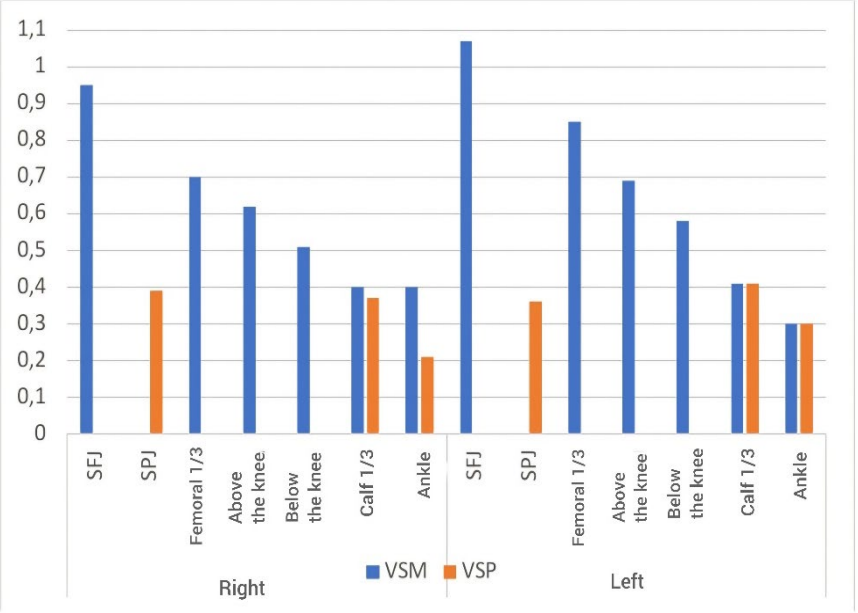

Figure 1. Measurements in cm of the large (VSM) and small (VSP) subcutaneous veins in the right and left lower limbs in different segments

According to the CEAP classification, the clinical picture of VD in DM patients was as follows: in the right lower limb, 21.4% of patients (30 people) had C1 stage, 75% (105 people) had C2-C4 stages; in the left lower extremity in 12.1% (17 people) at the C1 stage, and in 77.1% (108 people) at the C2-C4 stages. In other patients, the C5-C6 stage of the disease was observed (12.1% in the right lower limb (17 people), 13.6% in the left lower limb (19 people)).

During the VCSS evaluation, criteria such as pain, varicose veins, venous edema, skin pigmentation, skin and subcutaneous inflammation, induration, the number of active ulcers, the duration of active ulcers, the diameter of active ulcers, whether or not to use compression stockings were evaluated in the patients.

The total VCSS score for the right lower limb was calculated as 7.82±0.567, varying from 2 to 24, from the summation of the severity levels of the symptoms of VVLE found in the right lower limb. At the same time, the VCSS score was calculated for the left lower limb in the preoperative period. The total VCSS in the left lower limb was equal to 7.37±0.475.

Out of 140 patients with CVI, 22 (15.7%) underwent minimally invasive interventions in the right lower quadrant, 45 (32.1%) in the left lower quadrant, and 73 (52.1%) in both lower quadrants.

In the patients included in the material, VCSS evaluation was performed in the preoperative period, and the obtained results were systematized in the tables. Patients were invited to the clinic for follow-up examinations 1 week, 1 month, 6 months and 1 year after the operation and were re-examined. VCSS assessment was performed separately for each lower limb of the patient. VCSS was not calculated for the legs of patients with C0 according to CEAP classification, and the intervention was performed in limbs marked with C2-C6 clinical stage.

In our studies for EVLA, "Biolitec" 2-loop catheters were used in all patients. The maximum amount of laser beam energy per cm is 80-100 C according to international recommendations. Therefore, application of a 10 W laser beam to the vessel wall at 1 mm per second during extraction is the highest energy level for ablation according to standards. A higher amount of energy results from carbonization.

Taking into account the phlebosclerosis process in DM patients with a long history of diabetes, especially those with an uncontrolled glycemic profile, patients were divided into control and main groups for the purpose of energy stratification. During EVLA, 60 patients included in the control group were applied the standard amount of energy (80-100 C/sm). 80 patients in the main group were divided into 2 subgroups with 40 patients in each. 100-120 C/sm (subgroup A) and 120-140 C/sm (subgroup B) were assigned to 40 of these patients.

Symptoms of varicose veins were asked before the clinical and diagnostic examination of every patient who applied with a complaint of varicose veins. This rule also applies to patients who have previously received conservative or invasive treatment. The patient's occupation, age, genetic factors, operations, pregnancy, number, time, contraceptive use, if a woman, are among the criteria that guide the correct diagnosis and treatment.

Physical examination was carried out in a well-lit room in the supine position. A symmetrical examination of both legs is mandatory. If there are symptoms of severe CVI or secondary varicose veins (for example: post-thrombotic syndrome), the presence of varicose nodes in the lower abdomen and groin area is investigated. These are pathognomonic of iliac or ilio-caval vein obstruction. If there is "coronaphlebectatica", which is an indication of advanced venous stasis, special attention was paid. Skin changes, edema factor were diagnosed, and if necessary, symmetrical measurements were made on both lower extremities.

In order to assess the state of the venous network in the lower extremities, a Siemens Acuson P300 Doppler ultrasound device was used during the study. With duplex USG, the venous system can be evaluated anatomically and hemodynamically. This examination is safe, non-invasive, economical and reliable. It can be repeated pre-operatively, intra-operatively and post-operatively. The image provides anatomical and morphological information in "B" mode, and hemodynamic information in "C" mode. In this way, primary or secondary VVLE, assessment of the condition of trunk superficial veins, deep veins and perforating veins and their associated tributary branches or communicating veins, differentiation of acute venous thrombosis or chronic venous changes, correlation of existing clinical

symptoms with venous pathology, treatment to be carried out The tactics and strategy of the methods are defined.

Duplex USG was started below the inguinal ligament and the examination was continued at 3-5 cm intervals. All deep and superficial trunk venous structures, including perforating veins, were examined. Attention was paid to 4 main components: 1) visualization; 2) compressibility of the vessel; 3) venous flow, if there is reflux, its continuation; 4) augmentation maneuver.

Reflux was considered if the venous return in all lower extremity superficial veins was more than 0.5 seconds, and in the subknee and femoral veins was more than 1.0 seconds.

Perforating veins lasting more than 0.5 seconds or measuring more than 3.5 mm in healed or active ulcer localization were considered pathological. In repeated examinations 1 week and 1 month after EVLA, the relation of the obliterated superficial main vein to the deep vein in terms of the risk of Endo-Thermal Heat Induced Thrombosis (EHIT) was evaluated. In addition, the size of the sapheno-femoral and sapheno-popliteal joints, the middle 1/3 of the thigh, above the knee, below the knee, the middle 1/3 of the calf and the ankle, as well as the diameter of the small subcutaneous vein in the middle 1/3 of the calf and the ankle dynamic observation was carried out.

Statistical processing of the material. During the course of the research, the results of examinations were collected in Excel tables. Indicators were analyzed according to the parameters that can be calculated in this table. Parametric and non-parametric methods were used to find the difference between groups. Statistical processing was performed on a personal computer using the IBM SPSS-21 statistical program.

Results of preoperative CEAP and VCSS assessment of patients in the control group

During the examination of 3 people in the control group, there were no signs of varicose disease in the right leg (stage C0). In all other patients, one or several symptoms of clinical signs of varicose veins were recorded together. Thus, C1 stage – in 12 people (20%); C1 and C2 together – in 12 people (20%); C1, 2, 3 – in 13 people

(21.7%); C1, 2, 3, 4 – 7 people (11.7%); C1,2,3,4,5 – in 1 person (1.7%); C1,2,3,4,5,6 – in 1 person (1.7%); C1,2,3,5 – in 1 person (1.7%); C2,3,4 – in 2 people (3.3%); C2,3,4,6 – 7 people (11.7%); C3,4,6 – in 1 person (1.7%).

In the same manner, the results of the CEAP evaluation of the left lower extremity were as follows: C0 stage - 1 person (1.7%), C1 stage - 7 people (11.7%); C1 and C2 together – in 20 people (33.3%); C1, 2, 3 – in 16 people (26.7%); C1, 2, 3, 4 – in 1 person (1.7%); C 1,2,3,4,6 – in 3 people (5%); C 1,3,4,6 – in 1 person (1.7%); C2,3,4 – in 1 person (1.7%); C2,3,4,6 – in 2 people (3.3%); C3,4,5 – in 1 person (1.7%).

The total VCSS value in the right lower extremity was equal to 9.17±0.94, and varied from a minimum of 2 to a maximum of 24 during individual evaluations for patients. Regarding the details of VCSS, pain in the legs is 1.21±0.134; varicose veins 2.79±0.064; leg edema 1.39±0.16; skin pigmentation 0.83±0.16; skin inflammation 0.48±0.14; induration 0.74±0.156; number of ulcers 0.26±0.077; ulcer duration 0.48±0.146; ulcer diameter 0.38±0.118; and the use of compression knitwear was calculated equal to 0.62±0.136 (table 1)..

Table 1. VCSS assessment in the preoperative period for both sides in the control group

	Pain	Varicose vein	Edema	Hyperpigment.	İnflammation	İnduration	Number of ulcers	Ulcer duration	Ulcer diameter	Komp. knitting
right										
M	1,21	2,79	1,39	0,83	0,48	0,74	0,26	0,48	0,38	0,62
m	0,13	0,064	0,160	0,160	0,141	0,156	0,08	0,146	0,12	0,136
min	0	2	0	0	0	0	0	0	0	0
max	3	3	3	3	3	3	2	3	3	3
left										
M	1,08	2,73	1,04	0,59	0,24	0,41	0,14	0,22	0,16	0,63
m	0,11	0,070	0,137	0,130	0,090	0,113	0,07	0,102	0,07	0,126
min	0	1	0	0	0	0	0	0	0	0
max	3	3	3	3	3	3	2	3	2	3

The total value of VCSS in the left lower extremity was equal to 7.33±0.7 and varied from a minimum of 2 to a maximum of 23. The various indicators that make up the VCSS were as follows: pain in the legs 1.08±0.112; varicose veins 2.73±0.07; leg edema 1.04±0.137; skin pigmentation 0.59±0.13; skin inflammation 0.24±0.09; induration 0.41±0.113; number of ulcers 0.14±0.065; duration of ulcer 0.22±0.102; ulcer diameter 0.16±0.073; and the use of compression knitwear was equal to 0.63±0.126 (table 1).

VCSS assessment values were re-studied 1 week, 1 month, 6 months, and 1 year postoperatively and compared with preoperative values.

Comparative analysis of results in the immediate and long periods after EVLA in the control group

During the examinations carried out 1 week after the operation, a decrease in total VCSS values was recorded in both lower limbs, it decreased to 7.19±0.954 in the right lower limb, and 5.49±0.722 in the left lower limb. A statistically significant decrease in VCSS score in both lower extremities was observed when compared with preoperative numbers ($p<0.001$).

During the examinations conducted 1 week after EVLA, an important point is the evaluation of the so-called EHIT condition revlated to intravenous heat. So, in the control group, 19 patients (31.7%) had EHIT detected during duplex USG. Among these patients, 4 people (6.7%) had the 1st class severity level of EHIT, and 15 people (25%) had the 2nd class severity level.

There have been changes in the VCSS criteria at different time intervals. Finally, at the end of 1 year, the current situation of patients who participated in repeated examinations is shown in the following table (table 2).

As can be seen from the table, in the control group, although certain positive effects were obtained in patients who underwent EVLA with the standard amount of energy, some patients continued to have symptoms such as pain, edema, skin inflammation, and subcutaneous induration.

Table 2. VCSS assessment 1 year after EVLA in control group patients

	Pain	Varicose veins	Edema	Hyperpigment	İnflammation	Induration	Ulcer number	Ulcer duration	Ulcer diameter	Komp. knitting
Right										
M	0	0	0,14	0,50	0	0,28	0	0	0	0
m	0	0	0,058	0,129	0	0,094	0	0	0	0
min	0	0	0	0	0	0	0	0	0	0
max	0	0	1	3	0	2	0	0	0	0
Left										
M	0,05	0,1	0,15	0,21	0	0,13	0	0	0	0
m	0,04	0,072	0,06	0,066	0	0,054	0	0	0	0
min	0	0	0	0	0	0	0	0	0	0
max	1	2	1	2	0	1	0	0	0	0

Summing up the analysis of the results of the treatment in the control group, it can be said that the standard intake of energy does not have the expected effect in patients suffering from DM. Thus, 8 out of 60 DM patients in the control group (13.3%) had VD revlapse at different times after EVLA. Among these patients, 1 patient had residual VD due to recanalization of the ablated segment of the right great saphenous vein 1 month after EVLA. It is believed that this is mostly due to the fact that the patient is overweight (Body-Mass Index 36.8) and the presence of paroxysmal dry cough on the background of chronic bronchitis. In 6 patients, recurrent varicosities were revealed during examinations conducted 6 months after EVLA. As we can see from these patients, 5 patients developed new varicose veins due to recanalization of the large subcutaneous vein, and 1 patient developed new varicose veins due to the recurrence of the ablated perforating vein.

In the observations conducted 1 year after EVLA, incomplete recanalization was recorded in the knee segment of the left large subcutaneous vein in 1 person. Echo-sclerotherapy procedure was assigned to that patient, EVLA was repeated to all other patients. During EVLA, higher (120-140 C/sm) energy was used instead of the

standard amount of energy. After EVLA, patients recovered at a higher rate, clinical signs of the disease did not recur. At the same time, faster sonographic absorption and resolution of the ablated vein segment, rapid involution of the vascular port were observed in patients who underwent EVLA with high energy, and there were no aesthetic or clinical discomforts in the lower limbs.

It should be noted that in all patients, when starting EVLA, the maximum amount of energy was given in the proximal part of the corresponding trunk superficial vein, and the minimum amount of energy was given in the middle 1/3 of the calf and in the distal part. Our goal is to prevent thermal damage to the saphenous and sural nerves.

General characteristics and CEAP assessment of patients treated with EVLA at 100-120 C/sm energy (Subgroup A)

Among 40 people included in this group, the CEAP classification of the right and left sides is given separately. Varicose veins in the legs of 2 people happened on the left side, while the right leg was evaluated as VD C0. Consequently, 9 people (22.5%) had tevlangiectasias and reticular veins; only isolated varicose veins were found in 1 patient (stage C2), 9 people (22.5%) with both tevlangiectasias and varicose veins (C1 and C2 together) in the lower right area were observed. Tevlangiectasias, edema in the right lower limb together with varicose veins (C1,2,3) were observed in 8 people (20%). In addition to the presence of varicose dilated veins in the leg, which developed venous edema, skin changes (pigmentation, venous eczema, lipodermatosclerosis) occurred in 6 patients (15%). Along with all the mentioned clinical signs, a healed ulcer scar on the right lower limb (C 1,2,3,4,5) – in 1 person (2.5%); varicose veins, changes in the skin and the presence of an active ulcer (C2,3,4,6) were found in 4 people (10%).

CEAP evaluation of left lower extremity was performed and the results were as follows: C0 stage – 2 people (5%), C1 stage in 6 people (15%); C1 and C2 together in 14 people (35%); C1,2,3 - in 10 people (25%); C1,2,3,4 – in 2 people (5%); C2,3,4,6 – in 1 person (2.5%); C2,3,4,6 – 5 people (12.5%).

In the preoperative period, VCSS assessment was performed for both sides of the patients. The total VCSS value in the right lower limb was equal to 7.77±1.151. The preoperative VCSS value of patients in the control group was not statistically significantly different. Based on the individual parameters of VCSS determined in the right lower limb, the situation in the pre-operative period was as follows: the average assessment of pain in the legs was 0.96±0.152; varicose veins 2.77±0.084; leg edema 1.15±0.173; skin pigmentation 0.65±0.192; skin inflammation 0.23±0.115; induration 0.5±0.194; number of ulcers 0.27±0.131; ulcer duration 0.38±0.185; ulcer diameter 0.19±0.096; and the use of compression knitwear was calculated equal to 0.58±0.177.

When summing the VCSS in the left lower extremity, it was equal to 7.42±1.049 and varied from a minimum of 2 to a maximum of 23. The indicators that make up the VCSS were as follows: pain in the legs 0.91±0.165; varicose veins 2.67±0.083; leg edema 0.94±0.168; skin pigmentation 0.45±0.151; skin inflammation 0.33±0.135; induration 0.48±0.164; number of ulcers 0.21±0.01; duration of ulcer 0.36±0.156; ulcer diameter 0.3±0.134; and the use of compression knitwear was equal to 0.79±0.188.

Most of the preoperative parameters of patients in subgroup A of the main group were close to those of the control group and did not differ statistically.

VCSS results after energy application of 100–120 C/sm during EVLA

In the preoperative period, the total value of VCSS was calculated as 7.77±1.151, and the total value of VCSS in the left lower extremity was calculated as 7.42±1.049 in 26 people with right VVLE. VCSS was 5.85±1.151 on the right side and 5.97±1.027 on the left side during the measurements made 1 week after the operation. We witnessed a significant ($p<0.05$) reduction in VCSS value compared to preoperative values. However, when comparing the results obtained 1 week after the operation in the control group (7.19±0.954 on the right side and 5.49±0.722 on the left side), there was no statistically significant difference between the results ($p>0.05$).

In subgroup A, EHIT was detected in 8 patients (20%) during the control duplex sonographic examination 1 week after laser ablation. In all patients, the 1st class severity degree of EHIT was determined. Therefore, the routine anticoagulant appointment was limited to 1 week. This shows that adequate energy intake also reduces the risk of EHIT.

In the main group, the results of post-operative observation of patients with 100-120 C/sm energy amount EVLA gave us the reason to say the following. After EVLA, it was possible to observe significant positive dynamics in parameters such as pain, number of varicose veins, and edema in patients, which can be evaluated as an indicator of the effectiveness of EVLA. In some patients with edema, the lack of regression rate to any degree was also noticed. However, when comparing hyperpigmentation, induration, skin and subcutaneous inflammation parameters, it was not possible to obtain statistically significant results. Positive changes in these parameters were observed in distant periods after the operation, in 6-month follow-up observations, and in some cases, even 1 year later (Figure 2).

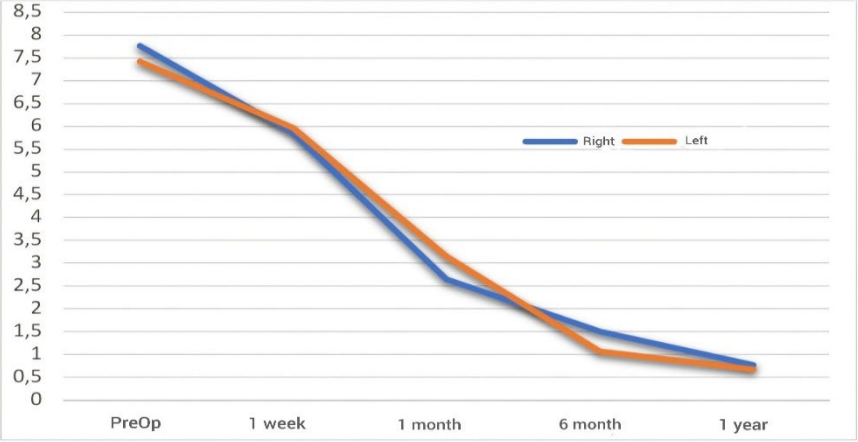

Figure 2. Dynamic change of the total indicator of VCSS in the preoperative period and after EVLA in patients in subgroup A

In subgroup A, 6 months after surgery, 3 patients had recurrence of VD, and 1 year later, 2 more patients had recurrence of VD. After 6 months, in 1 of 3 patients, despite obliteration of the right great saphenous vein, recanalization involved the saphenous-femoral junction and was confirmed by the development of new reflux in the anterior appendicular branch. Recurrence was found in the left great saphenous vein in 2 other people. The relapses noted in the left lower limb were observed in the sapheno-femoral junction and thigh segments, although the vessel sizes decreased, reflux was observed. Thus, partial obliteration took place. At the same time, new varicose folds were found on the front surface of the thigh on the right side.

During the observations carried out 1 year after the operation, the presence of blood flow again in the distal projections of the right and left small subcutaneous veins in 1 person was confirmed by USG doppler. However, there was no clinical and hemodynamic significance.

What has been mentioned suggests that adequate coagulation cannot be achieved in all patients due to sclerosing of the vein wall in patients with DM. This indicates recanalization and recurrence of the disease in the future.

General characteristics and results of CEAP assessment of patients treated with EVLA with an energy content of 120-140 C/sm (subgroup B)

The results of CEAP assessment in subgroup B were as follows. No signs of VD were observed during the examination of 3 people in the right lower limb (stage C0). C1 stage in 9 people (22.5%); C1 and C2 together in 12 people (30%); C1,2,3 - in 9 people (22.5%); C1,2,3,4 – in 4 people (10%); C1,2,3,4,6 – in 1 person (2.5%).

In the left lower extremity, the results of the CEAP evaluation of the CVI were as follows: C0 stage - 1 person (4%), C1 stage in 4 people (10%); C2 stage – in 1 person (2.5%); C1 and C2 together in 7 people (17.5%); C1,2,3 - in 19 people (47.5%); C1,2,3,4 – in 3 people (7.5%); C1,2,3,4,5 – in 1 person (2.5%); C1,2,3,4,6 – in 1 person (2.5%).

The total VCSS calculated for the right lower limb in the pre-operative period was equal to 5.86±0.705 in patients included in

subgroup B. According to individual parameters, the situation was as follows: pain in legs 0.82±0.146; varicose veins 2.75±0.083; leg edema 0.86±0.16; skin pigmentation 0.39±0.139; skin inflammation 0.11±0.79; induration 0.36±0.138; number of ulcers 0.04±0.036; ulcer duration 0.07±0.71; ulcer diameter 0.04±0.36; and the use of compression knitwear was equal to 0.43±0.140.

The total value of VCSS in the left lower limb was equal to 7.37±0.792. Separate values of the parameters are pain in the legs 1.17±0.104; varicose veins 2.69±0.107; leg edema 1.23±0.148; skin pigmentation 0.51±0.155; skin inflammation 0.23±0.101; induration 0.34±0.108; number of ulcers 0.17±0.096; duration of ulcer 0.26±0.125; ulcer diameter 0.2±0.099; the use of compression knitwear was calculated as 0.54±0.138.

The difference between the indicators of the VCSS parameters determined in the preoperative period for both the right and left lower limbs in the control group and the preoperative indicators in subgroup B of the main group was not statistically significant ($p>0.05$).

Comparative results of changes in VCSS among patients after EVLA performed with an energy amount of 120-140 C/sm

As mentioned, patients were invited to the clinic at different times after EVLA, 1 week, 1 month, 6 months, and 1 year. Complaints of all patients were heard, objective examinations and doppler USG were performed. After calculating the VCSS parameters for the right and left sides separately for the recorded times in each patient, the total VCSS score was calculated. This was the dynamic change of the total indicator of VCSS. For right lower extremity: 4.75±0.725 1 week after EVLA; 1 month later 1.93±0.547; 0.79±0.306 after 6 months; 0.36±0.138 after 1 year; For the left lower limb, 5.37±0.806 after 1 week respectively; 2.6±0.643 after 1 month; 1.06±0.351 after 6 months; After 1 year, it was equal to 0.62±0.240.

When tracking the dynamic change of various parameters of VCSS, we witnessed better results in this subgroup. At the same time, it was noted that the positive dynamics occurred earlier than subgroup B.

In subgroup B, 1 week after EVLA, repeated duplex USG EHIT was monitored as follows. In 4 patients (10%) EHIT-1 and in 1 patient

(2.5%) EHIT-2 were detected. For this reason, the duration of "enoxaparin" treatment was extended for another 7 days in only 1 patient. When comparing the respective indicator with the control and subgroup A, there was a statistically significant difference ($p<0.05$). Thus, the optimal amount of energy ensures effective obliteration while minimizing the risk of heat-revlated thrombosis.

Patients in subgroup B of the main group received 120-140 C/sm of energy during EVLA. This amount of energy was higher than the standard guidelines recommended in the control group (80-100 C/sm) and revlatively higher than the regime applied in subgroup A (100-120 C/sm). During our study, we observed that the results in subgroup B were better than both the control group and subgroup A. Thus, in subgroup B patients, an earlier decrease of average indicators on VCSS assessment was observed. Along with the decrease in the number of ulcers, it was revealed that the size of the ulcers decreased in a shorter period of time. Patients included in this subgroup, in the post-EVLA observations, there were fewer complaints, and milder clinical symptoms of CVI were noteworthy points. During the next re-examination of the patients, most of them noted that they had practically no worries, and emphasized that they were able to fully function in their daily life and work routine.

Among 40 diabetic patients in subgroup B, recurrence of varicose veins was observed in 1 patient (2.5%) 6 months after EVLA. This case of revlapse was discovered during our own examinations in our clinic and did not cause any discomfort to the patient. The recurrent VD in the respective patient was caused by branches returning from the pelvic veins. The issue was resolved after repeated EVLA performed on the patient.

Treatment outcomes in this subgroup were better in the short-term and long-term compared to the control group as well as subgroup A of the main group. Figure 3 shows the frequency of revlapses at different time points after EVLA by subgroups of the control group and the main group.

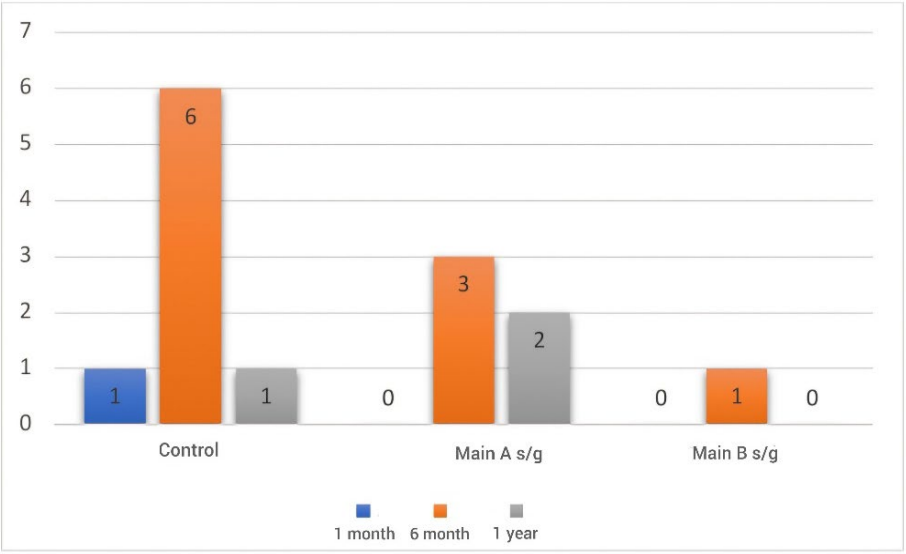

Figure 3. Incidence of rEVLApses at different time points after EVLA in the control group and subgroups A and B of the main group

As can be seen from the picture, among 60 people in the control group, revlapse was recorded in 8 patients in general. Among the 40 people in subgroup A, revlapses occurred in 3 patients (7.5%) 6 months after EVLA and in 2 patients (5%) after 1 year, while the complication rate in subgroup B is different, was minimized and statistically significant compared to the number of revlapses in subgroup A.

It should be emphasized that the patients included in the material of our study are specific. That is, in contrast to people with ordinary varicose veins, these patients have suffered from DM for a long time. As it is known, the sclerosing of the vein wall during DM creates a certain difficulty for laser coagulation. Although we achieved improvement in the control group, a high frequency of disease recurrence is observed in the long postoperative period. Despite the fact that increasing the amount of energy in a dosed manner in subgroup A was manifested with certain positive results, it was not

possible to achieve complete obliteration of the vascular orifice in all patients due to phlebosclerosis. This has paved the way for relapses in the future.

In subgroup B, the process of intravascular coagulation of varicose veins during EVLA was more effective, obliteration of the vascular orifice was more reliable due to the increase in the amount of energy. In some patients, a part of the large and small subcutaneous veins located extrafascially is also removed during the miniphlebectomy procedure. In subgroup B, it was macroscopically observed that the exit of the removed subcutaneous veins was completely obliterated due to successful coagulation. Also, in the postoperative period, subjective negative feelings occurred less often in the patients, and the quality of life of the patients increased to higher levels compared to the control group.

RESULTS

1. According to the CEAP classification, the clinical picture of VD in DM patients was as follows: in the right lower limb, 21.4% of patients were at C1 stage, 75% were at C2-C4 stages; in the left lower extremity, 12.1% at C1 stage, and 77.2% at C2-C4 stages. In the remaining patients, the C5-C6 stage of the disease was observed (12.14% in the right lower limb, 13.57% in the left lower limb). Complicated forms of varicose veins are more common in DM patients.

2. In the control group, in the immediate period after EVLA, the disappearance of clinical signs of VD went at a slow pace. 1 week later, during examinations, EHIT was found in 19 patients (31.7%). After EVLA, recurrent varicose veins appeared in 8 people (13.3%) at different times, with repeat EVLA performed in 5 patients due to clinical and hemodynamic significance.

3. After EVLA with an energy of 100-120 C/sm, significant positive dynamics were observed in parameters such as pain, number of varicose veins, edema, but statistically honest results were not obtained in the parameters of induration, hyperpigmentation, and inflammation ($p>0.05$). In this subgroup, VD relapse was observed in

3 patients after 6 months, and in 2 patients after 1 year (total 12.5%). 8 patients (20%) were diagnosed with EHIT in duplex USG during the first postoperative week. EVLA with revlatively high energy failed to significantly improve outcomes and reduce revlapses. The improvement of EVLA results and reduction in recurrences with 100-120 C/sm energy have not shown significant impact.

4. The process of intravascular coagulation of varicose veins during EVLA with the amount of energy of 120-140 C/sm was more effective, obliteration of the vascular orifice was more reliable. When comparing the results of VCSS evaluation in the near and long term, it was honestly different compared to other patients ($p<0.05$). 5 patients (12.5%) had EHIT 1 week after EVLA. After 6 months, 1 patient (2.5%) underwent repeated EVLA due to revlapse of VD and achieved complete recovery. Quality of life indicators and rehabilitation rate in patients with high-energy EVLA were honestly ($p<0.05$) better compared to other patients.

PRACTICAL RECOMMENDATIONS

1. The occurrence of aggravated forms of VVLE (edema; hyperpigmentation on the skin, eczema, induration), including venous ulceration, without the need for preoperative special preparation in DM patients, cannot be considered a contraindication for minimally invasive intervention.
2. During EVLA, the standard intake of energy in DM patients does not have the expected effect. As a result of DM, the process of sclerosis formed in the vein wall prevents the effective obliteration of the vessel by the effect of standard energy.
3. The use of energy amount of 120-140 C/sm in clinical practice is useful in the direction of improving the treatment with the EVLA method as an optimal regime in varicose veins patients suffering from DM.
4. Pre-operative duplex USG examination by the doctor performing EVLA is important, as well as periodic control examinations with doppler to make sure the complete involution of the vascular orifice during the first 1 year after the operation.

This creates the basis for early detection of revlapses and their hemodynamic assessment.

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1. Qasımov, N.A., Əliyev, M.S., Fəttah-Pur, V.Ə., Əsgərov. İ.M. Aşağı ətraf venalarının varikoz xəstəliyində cərrahi müalicənin inkişaf mərhələləri və müasir aspektləri // - Bakı: Cərrahiyyə jurnalı - 2018. №3, - s.86-90
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ABBREVIATIONS

VVLE – Varicose veins disease of the lower extremities;
CEAP – Clinical Etiology Anatomy Pathology;
EHIT – Endovenous heat induced thrombosis;
EVLA – Endovenous laser ablation;
CVİ – Chronic venous insufficiency;
DM – Diabetes mellitus;
USG – Ultrasonography;
VCSS – Venous Clinical Severity Score;
VD – Varicose disease;

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