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INFLUENCE OF DIFFERENT ENERGY DENSITIES OF ENDOVENOUS LASER ABLATION ON THE RESULTS OF VARICOSE VEINS TREATMENT IN PATIENTS WITH DIABETES MELLITUS

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The research material consisted of the results of examination and treatment of 140 patients diagnosed with varicose veins of the lower extremities at the Istanbul NS Clinic and the Yeni Ganja Medical Center during 2017-2020. Among the patients there were 98 men, 42 women, average age 57.1±0.62 years.

The duration of diabetes mellitus was 13.8±0.33 years. At the same time, 98 (70%) patients had a history of diabetes mellitus of 10-14 years, 27 (19.29%) patients – 15-19 years, 13 (9.29%) patients – 20-24 years, and 2 (1.43%) patients had more than 25 years. The concentration of sugar in the blood was 183.9±4.9 mg/dl, and the amount of glycohemoglobin was 9.0±0.09%, varying from 7.5% to 11.9%.

EVLA was performed for all patients after appropriate preoperative preparation.

Depending on the energy density, the patients were divided into control and main groups. In 60 patients included in the control group, the speed limit of the extractor device was set at 1 mm/s, and the power was set at 8-10 Watts to supply 80-100 J/cm of energy to the vein. 80 patients of the main group were divided into 2 subgroups of 40 people each.

Varicose veins of the lower extremities are considered the most obvious clinical sign of chronic venous insufficiency. Varicose veins significantly decreased ($p<0.0001$) in the control group a week after EVLA. Varicose veins were not detected in 57.1% of patients on the right and 25 on the left. In 24 people on the left, the number and volume of varicose veins significantly decreased ($p<0.0001$) and decreased to the level to be assessed at 1 point.

140 patients with diabetes mellitus underwent EVLA. In the control group ($n=60$), energy was applied in 80-100 J/cm; in the main A subgroup ($n=40$) 100-120 J/cm and in the main subgroup ($n=40$) 120-140 J/cm. The results on the VCSS scale were compared a week, 1 month, 6 months and 1 year after EVLA. The analysis proved that EVLA with an energy output of 120-140 J/cm is more effective in patients with diabetes mellitus. The positive effect was confirmed by the VCSS quality of life indicators and a significant reduction in the number of relapses after surgery.

In our study, this effect was confirmed by the best VCSS quality of life indicators and a significant reduction in the number of relapses after surgery in patients with diabetic varicose veins.

Key words: varicose veins, diabetes mellitus, laser ablation, energy, treatment.

Connection of the publication with planned research works.

This work is a fragment of a dissertation for the degree of Doctor of Philosophy in medicine.

Introduction.

Varicose veins of the lower extremities is one of the widespread pathologies among the world's population. For many years, the main positions in the treatment of this pathology have been occupied by conservative treatment with the appointment of venotonics and surgical methods of treatment with the removal of dilated veins. However, in recent decades, minimally invasive methods of treatment have been widely used in most clinics. Minimally invasive procedures include sclerotherapy, radiofrequency ablation, laparoscopic venectomy, cryotherapy, endovenous laser ablation, etc. [1, 2, 3].

Endovenous laser ablation (EVLA) is a minimally invasive treatment method based on coagulation of the vessel wall and subsequent obliteration of the mouth by inserting a special catheter into the mouth of venous vessels and supplying energy. Numerous examples of literature devoted to the results of the effectiveness of EVLA in the treatment of varicose veins can be found in the literature. It is believed that the energy density is in

the range of 80-100 J/cm. is optimal for bringing EVLA [4, 5].

However, the severity of chronic venous insufficiency, large diameter of varicose veins, obesity, diabetes mellitus and in other cases, the effectiveness of EVLA may decrease. In diabetes mellitus, the vessels of the vein walls are sclerosed, and the amount of energy supplied in a standard way does not have the expected effect on the vein wall [6]. In the course of the literature review, no studies were found on the results of treatment of standard energy consumption during EVLA in patients with diabetes mellitus. The high prevalence of diabetes mellitus among patients with varicose veins of the lower extremities, as well as the increase in the effectiveness of EVLA were the initiators for this study.

The aim of the study.

To study the effect of various energy regimes on the results of treatment with EVLA in the treatment of varicose veins in patients with diabetes mellitus.

Object and research methods.

The research material consisted of the results of examination and treatment of 140 patients diagnosed with varicose veins of the lower extremities in the Istanbul NS Clinic and the Yeni Ganja Medical Center during

2017-2020. Among the patients there were 98 men, 42 women, average age 57.1 ± 0.62 years.

The criteria for inclusion in the study were patients suffering from type 2 diabetes mellitus, without cancer, with normal arterial blood supply to the lower extremities. The duration of diabetes mellitus was 13.8 ± 0.33 years. At the same time, 98 (70%) patients had a history of diabetes mellitus of 10-14 years, 27 (19.29%) patients – 15-19 years, 13 (9.29%) patients – 20-24 years, and 2 (1.43%) patients had more than 25 years. The concentration of sugar in the blood was 183.9 ± 4.9 mg/dl, and the amount of glycohemoglobin was $9.0 \pm 0.09\%$, varying from 7.5% to 11.9%.

In addition to anamnestic, objective and subjective examinations, Dopplerography of the lower extremities was performed using a Siemens Acuson P-300 USM device. The clinical picture of varicose veins in patients was determined by the CEAR classification, and the severity of chronic venous insufficiency was assessed by VCSS. If varicose veins are not visible on the VCSS scale = 0 points; dilation of superficial veins in individual areas = 1 point; varicose veins in the basin of the large saphenous vein in only one area of the lower limb (hip or calf) = 2 points; if varicose veins spread to both subcutaneous venous basins and occur throughout the lower limb = 3 points. The intensity of varicose veins according to VCSS at the time of admission to the hospital was 2.77 ± 0.043 on the right limb and 2.7 ± 0.049 on the left.

EVLA was performed for all patients after appropriate preoperative preparation. For this purpose, a diode laser device "Biolitec ELVeS Radial 2 Ring Fiber" (Germany) with a 7.5 mGs linear converter and a catheter with a wavelength of 1470 nm was used. The determination of the energy power at the tip of the optical catheter was carried out using a special detector "Ophir L-150" (Israel), the radiation power was adjusted if necessary.

Depending on the energy density, the patients were divided into control and main groups. In 60 patients included in the control group, the speed limit of the extractor device was set at the level of 1 mm/s, and the power was set at the level of 8-10 Watts to supply 80-100 J/cm of energy to the vein. 80 patients of the main group were divided into 2 subgroups of 40 people each. In subgroup A of the main group, the speed is 1 mm/sec, the power is 10-12 watts due to the energy of 100-120 J/cm; In subgroup B, the speed is 1 mm/sec, the power is 12-14 watts to transfer 120-140 J/cm of energy.

All patients were recommended to use anti-thrombotic prophylaxis and compression knitwear in the postoperative period. Patients were invited for repeated examinations after 1 week, 1 month, 6 months and 1 year after EVLA. The results of the examination and treatment were systematized in an Excel spreadsheet. The results between the groups, as well as between the sub-

groups of the main group, were compared at the specified time after EVLA. The difference between the results was considered statistically significant at $P < 0.05$. Statistical processing of the material was carried out in the IBM SPSS 21 program.

Informed consent: All patients have signed informed consent.

Research results and their discussion.

Varicose veins of the lower extremities are considered the most obvious clinical sign of chronic venous insufficiency. Varicose veins significantly decreased ($p < 0.0001$) in the control group a week after EVLA. Varicose veins were not detected in 57.1% of patients on the right and 25 on the left. In 24 people on the left, the number and volume of varicose veins significantly decreased ($p < 0.0001$) and decreased to the level to be assessed at 1 point.

1 month after the operation, there was a decrease in the number and area of spread of varicose veins. Only 1 person had varicose veins of the right lower limb, 5 people (10.9%) had varicose veins on the left leg. Significant varicose extensions of both lower extremities, which could be estimated at 2 and 3 points, were not observed. It was not possible to achieve 100% results on the right lower limb after 6 months of EVLA. Varicose veins were still observed in 7 people who underwent surgery on the left lower limb, despite 6 months after surgery. Out of 7 people, 1 person had single dilated veins. In 6 people (13.6%), in addition to the appearance of numerous varicose veins, reflux along the large and small subcutaneous veins was observed during Dopplerography, which indicates incomplete closure of the mouth of these veins. **Figure 1** shows the clinical picture of varicose veins of the lower extremities in the control group 6 months after EVLA on the VCSS scale.

In the control group, after 1 year, 5 people (13.9%) developed swelling in the ankles of the right lower limb in the evening. 2 people began to complain of pain in the left lower limb. Due to the formation of varicose veins of the left lower limb, 7 patients (15.4%) developed edema in the evenings.

Based on the analysis of the results, standard energy consumption does not have the expected effect in patients with diabetes mellitus. Thus, out of 60 patients with diabetes mellitus in the control group, 8 people

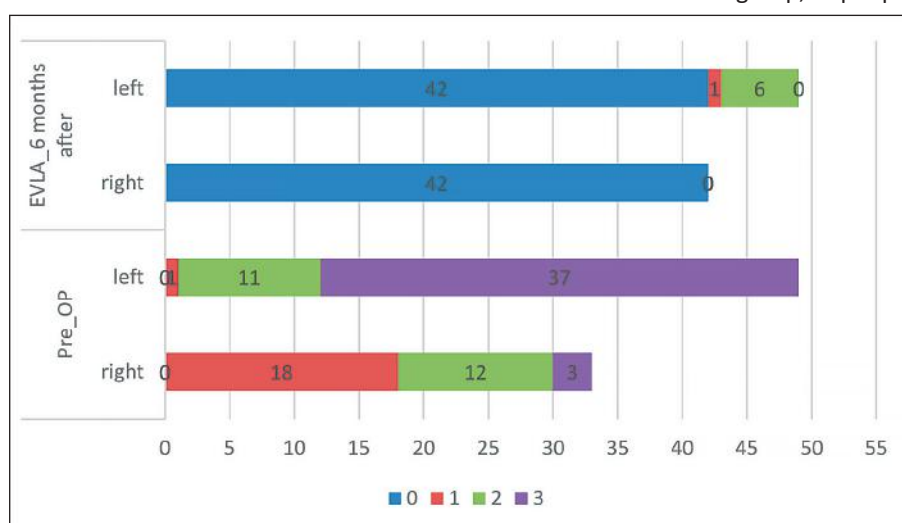


Figure 1 – Evaluation of varicose veins on the VCSS scale 6 months after EVLA.

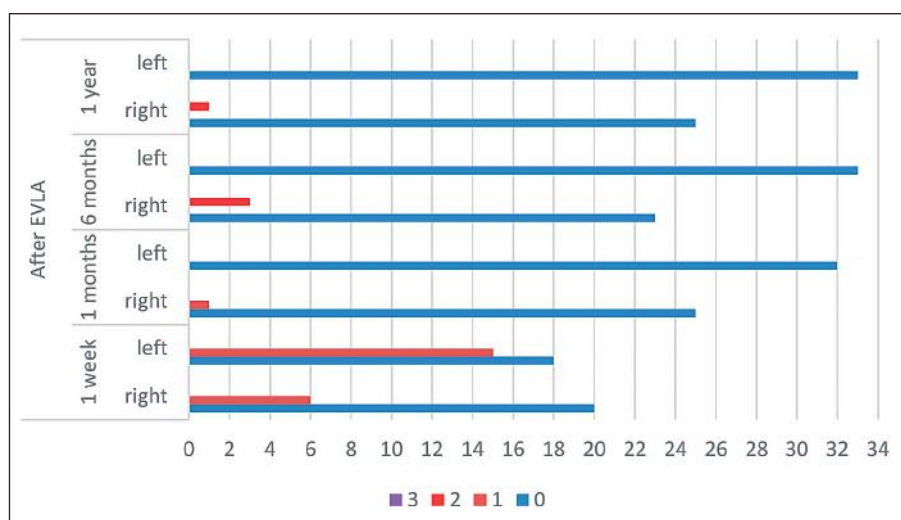


Figure 2 – Evaluation of varicose veins on the VCSS scale in subgroup A.

(13.3%) (1 person after 1 month, 6 patients after 6 months and 1 person after 1 year) had a relapse of the disease.

In subgroup A, after 1 week after surgery, 20 (76.9%) of 26 people who underwent EVLA did not have varicose veins on the right lower limb, and 18 (54.5%) on the left lower limb. During the follow-up 1 month after the intervention, 97% of patients had no varicose veins of the right and left lower extremities. 6 months after EVLA surgery, 3 patients (12%) developed varicose veins with 2 points on the VCSS scale. This indicates relapses of varicose veins in these patients. EVLA was re-recommended to patients. 2 patients agreed to the opera-

tion. EVLA was repeated to both patients, but this time the power was increased to 120-140 J/cm. There were no serious hemodynamic disorders in 1 patient, the operation was refused, since it did not cause significant harm to the patient. Despite the refusal, the patient was left under observation and invited for further examination. So, 1 year after EVLA, varicose folds on the right lower limb were found only in 1 person who refused surgery. **Figure 2** shows the dynamics of the occurrence of varicose veins in subgroup A after EVLA on the VCSS scale.

In subgroup B, the intensity of occurrence of varicose veins of the lower extremities was studied after 1 week, 1 month, 6 months and 1 year after EVLA, both in frequency of occurrence and severity (**table**).

As can be seen from the **table**, in the observations conducted 1 week after EVLA, 11 patients (39.3%) had minor varicose veins on the right. When measured 1 month after surgery, the intensity of varicose veins decreased to 0.14 ± 0.067 , and after 6 months to 0.07 ± 0.051 , varicose veins were observed only in 1 patient. Varicose veins 1 year after EVLA were not detected. On the left lower limb, 1 week after EVLA, varicose veins were estimated at 1 point in 14 people.

With catamnestic observation after 1 and 6 months the number and volume of varicose veins began to decrease rapidly, and during a catamnestic examination after 1 year, only 1 person had superficial vasodilation. In all cases, the intensity of varicose veins in the preoperative period, as well as in comparison with the previous observation, was significantly less ($p < 0.05$).

In subgroup B, in 1 patient 6 months after the operation developed a relapse of varicose veins with the formation of reflux in a certain segment of the small subcutaneous vein. In the course of a detailed analysis, it was found that varicose veins originate from the anterior accessory subcutaneous vein. Varicose veins in this patient did not cause significant discomfort and did not cause a serious pathological violation of the venous circulation of the lower limb. However, in order to avoid any cosmetic defects, EVLA was repeated to the patient with the same amount of energy. At the observations carried out after 1 year, the patient had no discomfort and no signs of varicose veins.

Patients of subgroup B of the main group received 120-140 J/cm of energy with EVLA, and the results were better

Table – Dynamics of signs of varicose veins in subgroup B according to VCSS

Points for VCSS		Before EVLA	The week after EVLA	1 month after EVLA	6 months after EVLA	1 year after EVLA
Right lower limb	Point	0	0	0	0	0
	Number	0	17	24	27	25
	%	0,0	60,7	85,7	96,4	100,0
	Point	1	1	1	1	1
	Number	0	11	4	0	0
	%	0,0	39,3	14,3	0,0	0,0
	Point	2	2	2	2	2
	Number	7	0	0	1	0
	%	25,0	0,0	0,0	3,6	0,0
	Point	3	3	3	3	3
	Number	21	0	0	0	0
	%	75,0	0,0	0,0	0,0	0,0
M±m		2,75±0,083	0,39±0,094	0,14±0,067	0,07±0,05	0
Left lower limb	Point	0	0	0	0	0
	Number	1	21	34	32	29
	%	2,9	60,0	97,1	97,1	100,0
	Point	1	1	1	1	1
	Number	0	14	1	0	0
	%	0,0	40,0	2,9	0,0	0,0
	Point	2	2	2	2	2
	Number	8	0	0	1	0
	%	22,9	0,0	0,0	2,9	0,0
	Point	3	3	3	3	3
	Number	26	0	0	0	0
	%	74,3	0,0	0,0	0,0	0,0
M±m		2,69±0,107	0,4±0,084	0,03±0,029	0,06±0,057	0

than in both the control group and subgroup A. These patients had fewer complaints, and the clinical symptoms of chronic venous insufficiency were milder. Of 40 patients suffering from diabetes mellitus, relapse of varicose veins was observed in 1 patient (2.5%) 6 months after EVLA. It should be noted that in the control group, 8 patients (13.3%) had a relapse. Relapses occurred in 3 patients (7.5%) 6 months after EVLA and in 2 patients (5%) 1 year later out of 40 people in subgroup A.

It should be emphasized that the patients included in the material of our study are specific. That is, unlike patients with ordinary varicose veins, these patients suffered from diabetes mellitus for a long time. As is known, sclerosing of the vein wall in diabetes mellitus creates certain difficulties for laser coagulation. Although we have made improvements in most patients, there is a high frequency of relapses of the disease in

the long-term period after surgery. Despite the positive results of the dosed increase in the amount of energy in subgroup A, complete obliteration of the vessel mouth due to phleboscrosis was not achieved in all patients. This set the stage for relapses in the future.

Conclusions.

EVLA with an energy density of 120-140 J/cm is more effective in patients with diabetes mellitus compared with ablation in both the control group and subgroup A. In our study, this effect was confirmed by the best quality of life indicators according to VCSS and a significant reduction in the number of relapses after surgery in patients with diabetic varicose veins.

Prospects for further research.

It is planned to further study the possibilities of treating varicose veins of the lower extremities in patients with type 2 diabetes mellitus.

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ВПЛИВ РІЗНИХ ЩІЛЬНОСТЕЙ ЕНЕРГІЇ ПРИ ЕНДОВЕНОЗНІЙ ЛАЗЕРНІЙ АБЛЯЦІЇ НА РЕЗУЛЬТАТИ ЛІКУВАННЯ ВАРИКОЗНОЇ ХВОРОБИ У ХВОРИХ НА ЦУКРОВИЙ ДІАБЕТ

Асгаров І. М., Гасимов Н. А., Фаттах-Пур В. А., Бабаєв Р. М.

Резюме. Мета. Визначити вплив різних енергетичних режимів на результати лікування при ЕВЛА при лікуванні варикозної хвороби у пацієнтів з цукровим діабетом.

Об'єкт і методи дослідження. Об'єктом дослідження були результати обстеження та лікування 140 пацієнтів з діагнозом варикозне розширення вен нижніх кінцівок у клініці Стамбул НС та «Медичному центрі Йені Гянджа» протягом 2017-2020 рр. Серед пацієнтів було 98 чоловіків та 42 жінки, середній вік 57,1±0,62 роки.

Тривалість цукрового діабету становила 13,8±0,33 роки. При цьому 98 (70%) хворих мали анамнез цукрового діабету 10-14 років, 27 (19,29%) хворих – 15-19 років, 13 (9,29%) хворих – 20-24 роки, у 2 (1,43%) хворих більше 25 років. Рівень глюкози крові – 183,9±4,9 мг/дл, а рівень глікогемоглобіну – 9,0±0,09%, коливаючись від 7,5% до 11,9%.

Всім хворим після відповідної передопераційної підготовки було проведено ЕВЛА.

Залежно від щільності енергії пацієнтів було розділено на контрольну та основну групу. У 60 пацієнтів контрольної групи, межа швидкості роботи екстракторного апарату була встановлена на рівні 1 мм/с, а потужність – на рівні 8-10 Вт для подачі у вену 80-100 Дж/см. 80 пацієнтів основної групи були розділені на 2 підгрупи по 40 осіб у кожній.

Результати дослідження та їх обговорення. Варикозне розширення вен нижніх кінцівок вважається найвираженішою клінічною ознакою хронічної венозної недостатності. Варикозне розширення вен значно зменшилось (p<0,0001) у контрольній групі через тиждень після ЕВЛА. Варикозне розширення вен не було виявлено у 57,1% пацієнтів справа та у 25 зліва. У 24 осіб зліва кількість і об'єм варикозно розширених вен значно зменшилися (p<0,0001) та знизилася до рівня, що оцінюється в 1 бал.

140 пацієнтам з цукровим діабетом було проведено ЕВЛА. У контрольній групі (n=60) було застосовано енергію 80-100 Дж/см; у основній А підгрупі (n=40) 100-120 Дж/см та у основній В підгрупі (n=40) 120-140 Дж/см. Результати за VCSS порівнювали тиждень, 1 міс., 6 міс. та 1 рік після ЕВЛА. Аналіз довів, що ЕВЛА з подачею енергії 120-140 Дж/см більш ефективна у пацієнтів з цукровим діабетом.

У нашому дослідженні позитивний ефект був підтверджений кращими показниками якості життя за оцінкою VCSS та достовірним зниженням кількості рецидивів після операції у хворих з діабетичним варикозом.

Ключові слова: варикоз, цукровий діабет, лазерна абляція, енергія, лікування.

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Key words: varicose veins, diabetes mellitus, laser ablation, energy density, treatment.

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Conflict of interest:

The Authors declare no conflict of interest.

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THE EFFECT OF LIPOIC ACID, ZINC SULFATE AND SODIUM THIOSULFATE ON H_2S METABOLISM IN CARDIOVASCULAR SYSTEM OF RATS IN EXPERIMENTAL OBESITY

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The article is devoted to the study of the peculiarities of hydrogen sulfide (H_2S) exchange in the heart and blood vessels during experimental obesity induced by a high-calorie, high-fat diet and to the justification of approaches to the correction of detected violations by modulators of various ways of sulfide exchange. It is known that a decrease in the level of endogenous H_2S is a factor in the development of arterial hypertension, coronary heart disease, left ventricular dysfunction, myocardial fibrosis, and heart failure. The primary source of H_2S in the heart and blood vessels is PLP-dependent L-cysteine desulfurization reactions, an alternative source can be sulfur transferase reactions of thiosulfate exchange. The role of different pathways of H_2S metabolism in the mechanisms of damage to the cardiovascular system due to obesity is unclear, and the search for effective and safe correctors of sulfide metabolism is urgent. The work aimed to find out the effect of lipoic acid, zinc sulfate and sodium thiosulfate on H_2S exchange in the cardiovascular system of rats with experimental obesity (EO) and to compare it with the effect of reference modula-