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**VARICOSE VEINS OF THE LOWER EXTREMITIES AND
ITS TREATMENT OF RECURRENT ENDOVASCULAR
COAGULATION WITH A HIGH-ENERGY LASER**

Speciality: 3213.01-Surgery

Field of science: Medicine

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ABSTRACT

Of the dissertation for status of Doctor of Philosophy in Medicine

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GENERAL CHARACTERISTICS OF THE SCIENTIFIC WORK

Relevance and development of the topic. The pathology of legs' venous vessels covers a number of systemic diseases (superficial venous thrombosis, phlebitis, narrowing of the main venous vessels, perforated venous insufficiency, etc.). Main reason for chronic venous insufficiency in the leg veins is a varicose enlargement of the venous vessels. Almost lower varicose disease is the most common type of peripheral vein pathologies. Although the history of the disease is ancient, there is not still an ideal solution of problems connected with VIL. [Аверьянов М.Ю., Измайлов С.Г., Измайлов Г.А., 2002¹; Агаев В.А., 2007²; Kantarovsky A, Minerbi A, 2011³]. There is a need for solution of problems on diagnostics and treatment of varicose disease in legs, conducting of scientific research on the There is a need for research on the possibilities of laser technology for raising the level of specialized phlebological care for patients in this category. Many new methods for treatment of varicose disease in legs have been introduced during the last 10 years [Doganci S., Dmirkilic U., 2010⁴; Wong R.J., Ahmed A., 2014⁵]. Currently 45% of all patients with varicose disease in legs are being treated by surgery in general

¹ Аверьянов М.Ю., Измайлов С.Г., Измайлов Г.А. и др. Хронические заболевания вен нижних конечностей. // Нижний Новгород. - ФГУИ1111 «Нижполиграф». -2002.-128 с.

² Агаев В.А Сərrahi xəstəliklər. Bakı 2007, - s. 672-673.

³ Kantarovsky A, Minerbi A. The approach to the treatment of lower-limb varicose veins. Harefuah 2011;150:729-732.

⁴ Doganci S, Dmirkilic U. Comparison of 980 nm Laser and Bare-tip Fibre with 1470 nm Laser and Radial Fibre in the Treatment of Great Saphenous Vein Varicosities: A Prospective Randomised Clinical Trial // Eur J Vasc Endovasc Surg 2010;40: 254-259

⁵ Wong RJ, Ahmed A. Obesity and non-alcoholic fatty liver disease: Disparities among Asian populations // World J Hepatol. 2014 May 27;6(5): 263-73. doi: 10.4254/wjh.v6.i5.263.

surgical hospitals, however, the results of these operations significantly concede to those done in specialized centers and departments.

The surgical treatment of varicose disease is the main treatment method. Standard surgical procedures are preferred during traditional surgical treatment, these operations are insufficient in some cases, and excessive in other cases. They are characterized by high level of traumatism, does not meet aesthetic requirements, causes long-term disability in the postoperative period. Despite certain successes on diagnostics and in indications for various types of surgical treatment of varicose disease, the question of the frequency of cases of recurrence after surgery also remains relevant. Post operative recurrence risk for all available types of surgery is 50% during the first 5 years after operation, depending on management period the frequency of recurrence cases is assessed from 20% to 80% [Schwarz T, von Hodenberg E., 2010⁶; Abışov N.S, Zakirjaye E.J., 2011⁷; Nelson E.A., Harrison M.B. 2014⁸; Kərimov M.M, Həsənov A.B., 2016⁹; Venermo M., Saarinen J., Eskelinen E., 2016¹⁰]. The problem of recurrence of varicose disease is always actual. According to literature content of the concept of recurrence may be different, what leads to contradiction of opinions about recurrence of varicose veins.

⁶ Schwarz T., von Hodenberg E., Furtwangler C., Rastan A., Zeller T., Neumann F.J. Endovenous laser ablation of varicose veins with the 1470-nm diode laser // J Vasc Surg. 2010 Jun. 51(6):1474-1475

⁷ Abışov N.S, Zakirjaye E.J, Kərimov M.M, Abuşova G.N Result of endovenous radiofrequency thermal ablation with and without high ligation in comparison with high ligation and stripping for treatment of great saphenous varicose vein. Vascular without Border: Cite des Congres – Lyon. France 2011

⁸ Nelson EA, Harrison MB. Canadian Bandage Trial Team. Different context, different results: venous ulcer healing and the use of two high-compression technologies. J Clin Nurs 2014;23(5e6):768e73.

⁹ Kərimov M.M, Həsənov A.B. Varikoz xəstəliyinin lazer cərrahiyyəsinin ilk təcrübəsi. Sağlamlıq jurnalı 2016. səh 46-49.

¹⁰ Venermo M, Saarinen J, Eskelinen E, Vahaaho S, Saarinen E, Railo M, et al. Randomized clinical trial comparing surgery, endovenous laser ablation and ultrasound-guided foam sclerotherapy for the treatment of great saphenous varicose veins. Br J Surg 2016;103(11):1438e44.

Analysis of the periodical literature shows that, results of endovenous laser ablation on treatment of varicose disease of surface veins of lower legs are underexplored, prognostic and therapeutic significance of laser surgery at treatment is not studied enough. We believe that surgery is one of the most urgent issues at treatment of varicose disease of veins of lower legs and set a goal to conduct research in this sphere.

Object and subject of research. The study included 126 patients with lower extremity varicose veins. The main group included 86 patients, 86 of whom had endovenous laser ablation. The control group included 40 patients, all of whom underwent traditional open phlebectomy. The number of patients with relapse is 20 in the main group and 14 in the control group.

The purpose of the study. Determination of efficiency of endovasal laser obliteration with 1470 nm radiofrequency and a 2-ring radial laser tip.

Objectives of the study:

1. Assessment of efficiency of endovasal laser obliteration with 1470 nm radiofrequency and a 2-ring radial laser tip at treatment of varicose disease of veins of lower legs and its recurrence.
2. Comparative assessment of effectiveness of traditional surgery methods and endovenous laser ablation on treatment of varicose disease.
3. Assessment of near and far results of endovenous laser ablation.
4. Development of treatment algorithm for varicose disease of veins of lower legs and its recurrence.
5. Determination of the vital activity of patients after endovenous laser ablation of varicose disease of veins of lower legs.

Methods of the study. Surgery under spinal anesthesia – Babcock, Narat et al., Laser coagulation of the environment under tumultuous anesthesia "Biolitec" and endovasal laser obliteration with 1470 nm radiofrequency and a 2-ring radial laser tip was conducted for patients with varicose disease of veins of legs included to the study.

The main provisions submitted to the defense:

1. As the most frequent recurrence reason is the recurrent reflux perforated venous insufficiency we developed the laser coagulation technique of perforated veins in recurrent varicose veins.
2. Optimal techniques for endovasal laser obliteration have been developed.
3. Efficiency of treatment results of patients which don't use compression bandage after endovasal laser obliteration have been proved.
4. Comparative assessment of economic efficiency between endovasal laser obliteration and the alternative method – classic phlebectomy was conducted.

Scientific innovation:

– It has been proven that endovenous laser coagulation is the most effective obliteration for treatment of the most common reason of varicose disease – perforated venous insufficiency and perforated veins, especially in the inflammatory infiltrative region around the trophic ulcer.

– Development of optimal technical parameters of execution of endovasal laser obliteration, selection of optimal patients for laser coagulation is the general condition for effective coagulation.

– Analysis of treatment results at patients which used compression bandages after endovasal laser obliteration in comparison with patients which didn't use compression bandages, comparative clinical, functional and cosmetic indicators of patients let us to tell that, it is not necessary to use a compression bandage.

– Comparative assessment of economic efficiency of endovasal laser obliteration and an alternative method of classical phlebectomy showed that the endovasal laser obliteration is more effective.

Practical significance: According to the scientific and practical results of the scientific research work positive dynamics were identified in prevention and treatment of varicose disease of lower legs. Dissertation results may have practical significance for the daily work of surgeons, especially phlebologists. The practical achievements can be used at treatment of varicose disease of lower legs. It is

proved that EVLO is the most effective and optimal method for treatment of varicose disease of lower legs and its recurrence during comparison with traditional open surgery. Comparison of clinical, functional and cosmetic indications showed that the laser surgery is more effective and less traumatic method. For achievement of more effective results concrete proposals were given about optimal patient selection for endovasal laser obliteration. Indications and contraindications for using of EVLO method at treatment of recurrence of varicose disease have been developed.

Execution of laser surgery is technically easy and economically is effective. Non-significance of using of compression bandage after EVLO was proved, and this is an important step for prophylactics of thrombophlebitis, trophic ulcers, and other diseases, the treatment of which are being postponed to colder seasons in our country with hot climate.

Post-operative management in stationary conditions is unnecessary. Thus, the execution of the procedure saves time during the operation and guarantees more satisfactory results after operation.

Approbation application of study results in practice. The initial discussion of the dissertation was held at the interdepartmental meeting (general surgery with courses of pediatric surgery and plastic surgery, general surgery with courses of cardiovascular surgery and neurosurgery, radiation diagnostics with courses of radiation therapy, anesthesiology and resuscitation). .2020, Protocol №2).

Scientific seminar №1 was held on 22.05.2020 under FD 2.11 dissertation council.

Materials of the dissertation was published as 8 scientific articles and 3 theses.

The traditional open phlebectomy and endovasal laser obliteration methods used at treatment of varicose disease of lower legs' veins are applied at the State Advanced Training Institute for Doctors named after A.Aliyev, Central Hospital of Sailors, Surgery Department of Baku Central Hospital of Sailors, Istanbul NS Clinic. Efficiency of application of achieved results of the study is approved.

Initial discussion of study results: Initial discussion of dissertation was conducted on February 14, 2020 in scientific conference of the State Advanced Training Institute for Doctors named after A. Aliyev (protocole №03).

Name of the organization where the dissertation work is performed. Azerbaijan State Institute for the Improvement of Physicians named after A. Aliyev.

Volume and structure of the dissertation. The dissertation consists of introduction (10922 – symbols), 5 chapters, summary (8154 – symbols), conclusion (989– symbols), practical recommendations (924 – symbols) and the list of literature. I chapter is – literature review (69856 – symbols), II chapter – materials and methods (35710 – symbols), III (13805– symbols), IV (55046 – symbols), V (4988 – symbols) – 206.113 chapters are about achieved results. The dissertation is typed on 142 pages in A4 format in computer, 23 tables, 43 figures and figures are added. The list of literature consists of 171 publications (7 in Azerbaijan, 57 in Russian, 107 in English languages).

MATERIALS AND METHODS OF THE STUDY

General characteristics of clinical part

The study has clinical character. Clinic staff consists of patients who have been treated by means of surgery during 2016-2020 years in in surgery departments of the Central Hospital of Sailors and Istanbul NS Clinics because of varicose disease of veins of legs and its recurrence. Total quantity of patients is 126 person. In correspondence with objectives and purpose of the study the contingent has been divided into two groups and two sub-groups.

The study covered patients with initial varicose expansion, patients on 2nd-4th stage of chronic venous insufficiency according to the CEAP classification and patients with recurrent varicose disease after surgery – 97 women (76,9%) and 29 men (23,1%) [Decision №16 of the Board of the Ministry of Health of the Republic of Azer-

baijan; 2013]¹¹ The vast majority of patients were women. Patients were 20-60 years old and average age was 35,7±8,57.

Patients with arterial venouse pathologies, small thrombosis, even in deep veins, thrombophilia (due to the tendency to thrombus formation), patients with vascular obstruction caused by a residual thrombus, inflammatory changes in areas with venous pathology were not intended by the study.

Initially treatment results of 86 patients undergoing endovasal laser obliteration surgery due to varicose disease of low legs' veins and recurrence in the surgery department of Istanbul NS Clinique during 2016-2018 years. Stationary card information, results and indicators of patients from this group are included to the dissertation materials. Our main goal is to choose an adequate approach method for treatment of varicose disease and its recurrence.

Medical cards of patients from the second focus group have been analyzed. Quality and quantity indicators of surgery methods have been analyzed according to medical cards of 40 patients included to this group, who underwent endovasal laser obliteration surgery due to varicose disease of low legs' veins and recurrence in the surgery department of the Central Hospital of Sailors during 2016-2018 years. We studied the results of surgery operations and justification criteria for diagnose written in medical cards of most of patients, types of executed operation and execution forms.

Patients have been divided into two sub-groups dueto using of compression bandages. 38 patients who used bandages were included to the first sub-group, another 38 patients who didn't use bandages were in the second group. Endovazal laser obliteration has been done for patients from both of groups.

Methods of the study. In patients with suspected varicose veins of the legs initial examination starts from collection of detailed anamneses. Clinical signs of varicose disease usually begin with functional disorders (swelling in the lower legs and ankles, especially

¹¹ Decision №16 of the Board of the Ministry of Health of the Republic of Azerbaijan; 2013

after extended periods of standing, aching or tiredness in the legs, etc.). Formation of first varicose knots after initial functional symptoms takes several years, as usual. Clinic (physical) examination of patients should be conducted vertically and horizontally in well lightening place. During physical examination affected legs of a patient should be naked. It is very important to pay attention to the appearance of the legs, skin, the nature of varicose veins and the localization of trophic ulcers and the violation of the integrity of the skin on the inner surface of the calf during visual examination.

It is also important to pay attention to the anterior wall of the abdomen in the groin area and the intermediate area. They will inform us about post-thrombophlebitic disease and pathological disorders of deep veins. Palpation of venous vessel walls gives the information about the elasticity of the venous vessel and the varicose transformation along the vein, from the solid mass in the vascular bed (thrombus mass). Additional attention should be directed towards fascia defects (especially in the lower 1/3 of the calf, inner and back surfaces). Small subcutaneous vein (2-4 mm norm) is prescribed when the patient's knee joint is slightly bent forward in a vertical position (in norm 2-4 mm). Assessing the edema all the areas of the leg should be symmetrically examined. Different probes can be used if there is a need.

We used Siemens Acuson P-300 (Siemens Medical Solutions USA) ultrasonic device and a transmitter with a frequency of 7.5 MHz for ultrasonic oscillations (linear tip) for study. Studying of venous anatomy and variations of legs using ultrasound dopplerography. Two important characteristic features should be assessed according results of ultrasound examination. The first is the structure and pathomorphological changes of venous vessels. The second is the functional characteristics of venous flow. Based on these, we can tell that the main tasks of ultrasound examination are to study of anatomical features of venous vessels, assessment of vascular permeability, assessment of the structure of the vessel walls and the valve apparatus, determination of pathological reflux.

Ultrasound dopplerography of patients with chronic venous insufficiency was conducted in correspondence with the following rules:

- 1) The examination should be performed by a physician-phlebologist engaged in the treatment of the disease;
- 2) The device used for examination must have a colored doppler image;
- 3) All veins should be assessed at the examination;
- 4) The diameter of the vessel should be measured and the condition of the vessel valves should be indicated for assessment of morphological features;
- 5) Using of colored dopplers is important for determination of pathology reflux;
- 6) Pathology reflux in deep veins should be assessed.

Taking into consideration data collected during clinic and ultrasound examination of patients with varicose disease we thought it made sense to formulate the basic instructions and conditions for conducting EVLO. The main criterion for conducting of laser obliteration is prolonged venous reflux during varicose veins. The optimal condition for large subcutaneous veins is reflux of blood to the upper, middle third of the calf. We considered EVLO expedient even if there is a reflux till the lower third of the calf. We believe that the use of this technique in reflux limited to the proximal region of the subcutaneous vein (upper half of the thigh) is not confirmed. In case of flow damage in small subcutaneous vein when the reflux spreads to the upper and middle thirds of the calf there is indication for EVLO. A main criterion for successful laser obliteration is the linear course of the venous outlet. Development of wavy transformation is considered as contraindication for EVLO, because in this case endovascular manipulations are extremely difficult and are accompanied by the risk of vascular perforation. The most important moment for providing of qualitative thermal effect the inner wall of the main subcutaneous veins is its circular spreading along the lumens. Otherwise, the risk of incomplete obliteration and, accordingly, the risk of vascular recanalization is very high.

Statistical processing of study materials. All figures obtained during the study were statistically analyzed taking into account modern recommendations. Statistical analysis was performed using the methods of variation (average) and discriminant (χ^2 -Pearson). All calculations were performed in EXCEL-2013 spreadsheet and SPSS-20 package program.

RESULTS OF THE STUDY

For determining of the effectiveness of obliteration of the main subcutaneous veins of patients from the first group ultrasound examination was conducted in post-operative period. Examinations were conducted in operation area on 2nd -3rd and 7th days of operation. Special attention was paid to closing of lumens along veins, analysis of vein's lumens before and after operation, to the indurative thrombus boundary at the sapheno-femoral junction and deep veins.

In the group of patients with endavasal laser obliteration, complete occlusion of the vessels subjected to laser intervention was observed in all cases. Obliteration from the sapheno-femoral junction to the venous puncture point was observed in 46 (88.2%) patients. In one patient, repeated blood flow from the safeno-femoral junction to 7 cm proximal was observed. 3 days after operation of 2 legs an unoccluded vascular opening was observed at a distance of 8-10 cm in the lower 1/3 of the thigh of a large subcutaneous vein. Careful analysis of these non-occluded veins revealed that it caused by opening of more than 2 venous branches (2-4mm) close to these parts. No varicose veins were observed in any of these vessels, but activity of spantaneous flow prevents formation of blood clots in the artery where EVLO is performed.

On the 7th day of the post operational period during the Ultrasonic doplerography In 2 patients there was detected occlusion in a large subcutaneous vein with initial permeability in the middle 1/3 of the thigh, and in 1 patient in the upper 1/3 of the thigh. Thus, after an initial examination of patients, it became clear that in 97.1% of cases, we were able to achieve occlusion of the main vessels.

On histological examination of the extracted fragment where endovascular laser obliteration was performed areas of coagulation necrosis were found in the intima of the vessel. In the muscular membrane of the vessel, along with the foci of necrosis, fibrous muscle tissue was detected. After the procedure, the inflammatory process and temperature-related secondary endothelial and muscle damage are observed in the adventitial membrane.

Histological examination of removed vascular fragments showed signs of coagulation necrosis in the vessel walls (Figure 1).

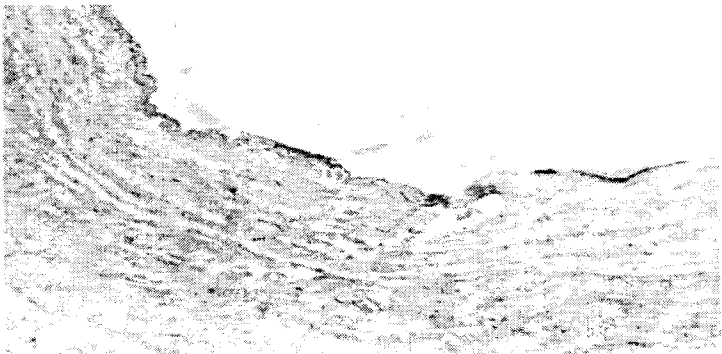


Figure 1. Cross section of a large subcutaneous vein 30 minutes later of laser irradiation. Total damage to the vessel wall (area of coagulation necrosis of the endothelial membrane, part of the inner elastic membrane and muscle cortex).

It is important to wear compression elastic stockings. In this case only during re-examination of the patient, the puncture sites for entering the vein on the skin are visualized. Safeno femoral junction is controlled through Ultrasonic doplerography of patient (Figure 2).

Obliterated veins are almost never identified at 12 weeks after surgery. During this period the possibility of recanalization in obliterated venous branches is relevant. As a rule, this happens in areas with large flows.

Repeated interference for two patients was conducted, what is 2% of patients with conducted EVLO. During 6 months recanaliza-

tion of GSV and SSV was observed. We have conducted sclerobliteration of GSV at one patient under ultrasound examination using 3%

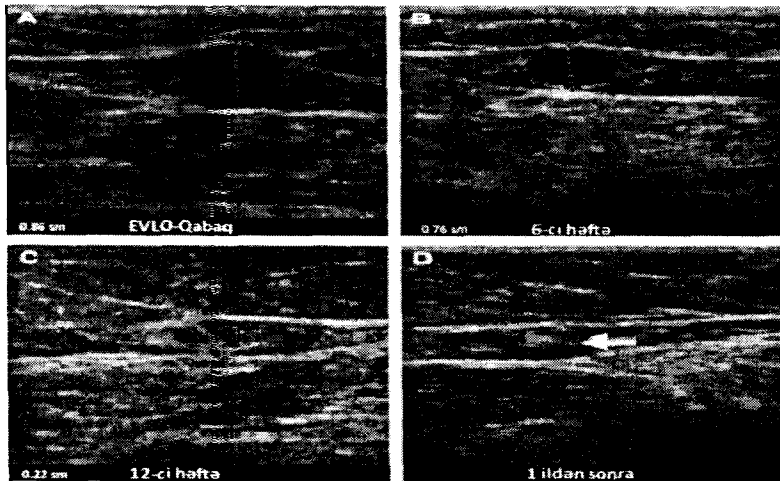


Figure 2. Dynamic observation of venous obliteration in patients with endavasal laser obliteration. Pre- and post-operational results at ultrasound dopler examination.

ethoxychloride or fibro vein with micro foam. In all cases, we were able to achieve a high efficiency.

Temporary edema occurs in 64% of cases before surgery and after 10 days at 57% of patients with similar symptoms edema is observed. In 9,3% of all cases edema in the distal region of the periphery was found to be permanent. Convulsions in the triceps during this period are observed in 6,9 % cases. The varicose eczema, seen in 12,8 % of all cases, disappeared in 8,2 % cases during 10 days. The induration complaints was saved in three patients, but was less intensive than in pre-operation period. In patients with trophic disorders decrease in the area of hyperpigmentation was observed during this period. Quantity of patients with persistent symptoms of CVI consists 27,9 % of all patients.

Results of 34 patients with recurrence were included to the research materials. Patients with recurrence are 20 person in the main

Table 1. Dynamic symptoms of patients with CVI

| Symptomes of CVI | Before operation | | 10 days after operation | | 30 days after operation | |
|-----------------------------------|------------------|------|-------------------------|------|-------------------------|-----|
| | Quantity | | Quantity | | Quantity | |
| Heaviness in the lower legs | 76 | 100 | 12 | 16,2 | 6 | 7 |
| Fatigue feeling in the lower legs | 16 | 21 | 10 | 12,8 | 2 | 3,5 |
| Swelling in legs | 55 | 73,2 | 8 | 10,4 | 5 | 6,9 |
| Pain in venous area | 16 | 22 | 0 | 0 | 0 | 0 |
| Convulsions of the calf muscles | 15 | 21 | 5 | 6,9 | 2 | 3,5 |
| Eczema | 10 | 12,8 | 3 | 4,6 | 0 | 0 |
| Induration | 8 | 10,5 | 2 | 3,5 | 1 | 1,1 |

group and 14 person in the control group. These patients were operated on varicose disease in different hospitals and clinics. As the most spread reason for recurrence of varicose disease is PV enlargement, the study of patients with dilatation and non-closure of perforated veins as a cause of recurrence was included to the study. Operative treatment was conducted on one leg of 32 patients and on two legs of 2 patients.

40 patients with varicose disease of legs (42 legs) were included to the focus group and combined phlebectomy was conducted on these patients by standard method. For assessment of early results of treatment we examined on 10th and 30th day after operation. Technical problems appeared during surgery caused further complications. Technical problems happened as a result of rupture of a vein attached to a Beccocc tube. Rupture of tube was observed at 5 patients (11,2%) and it was conducted with presence of large streams or big number of streams in the main vessels. Such ruptures lead to

bleeding and as a result additional incision is needed, bleeding is stopped from the additional incision, the ruptured vessel is removed by repeated attempts. These additional manipulations take in average 5-10 minutes and it is estimated as a time loss.

Neurological complications during post-operational period were accepted as complaints from patients with paraesthesia and lack of skin sensation caused by trauma to the nerve endings in the skin. Referring to the literature, we can say that paraesthesia is observed in 50-80% of patients as a result of skin trauma during Bebkokk surgery (D117, 203, 205, 271). In our observation, this type of complication was found in 14.7% of cases. This complication was most often observed on the inner surface of the heel and paw.

Table 2. Dynamic symptoms of patinets in 2nd group durin post-operational period

| Lower limbs' CVI symptoms | Before surgery | | 10 days after surgery | | 30 days after surgery | |
|-----------------------------------|----------------|------|-----------------------|------|-----------------------|------|
| | Quantity | % | Quantity | % | Quantity | % |
| Sense of heaviness in lower limbs | 39 | 98,3 | 16 | 40,9 | 9 | 22,9 |
| Sense of fatigue in lower limbs | 28 | 72,1 | 14 | 36 | 5 | 13,1 |
| Edema | 26 | 67,2 | 14 | 36 | 8 | 19,6 |
| Pain around the varicose vein | 14 | 34,4 | 0 | 0 | 0 | 0 |
| Calf muscle cramp | 10 | 26,2 | 5 | 13,1 | 4 | 6,5 |
| Eczema | 5 | 11,5 | 2 | 4,9 | 0 | 0 |
| Induration | 3 | 6,5 | 2 | 4,9 | 1 | 3,2 |

As a result of decreasing of CVI symptoms after surgery general health condition of patients was improved. Dynamics of decreasing

of CVI symptoms of patients included to the 2nd group is described on the Table 2 given below.

Sense of heaviness in lower limbs decreased for 57,4% during 10 days, sense of fatigue- for 36,1%. Proportion of patients with transient edema before surgery was 55,7 %, and patients with permanent edema was 11,5%. On 10th day after surgery decreasing of transient edema was observed in 32,8 % of patients. Edema of the lower 1/3 part of calf observed in patients before surgery decreased for 30% after surgery. Disappearance of calf muscle cramp was observed in 13.1% of cases. Varicose eczema and indurative changes in 4.9% of cases remained unchanged. During the early post-operative period unchanged CVI symptoms was observed in 21 patients (50,8%).

Post-operational complications were observed in both groups during examinations. The main complication is hematoma. Hematomas are mainly visualized on the inner surface of the thigh. Hematomas are observed in a limited area in v.sapheno magna projection in the main group and it covers a relatively large area on the inner surface of the thigh in the control group. Subcutaneous bruising is observed in almost all patients. Complications include paraesthesia (6% in main group, 17% in control group), lymphoedema (not observed in the main group, 2,5% in control group). Secondary wound infection and deep vein thrombosis were not found in any group.

20 patients (16 women and 4 men) with average age 45,8 years (31- 74) treated from March 2016 till September 2018 were included to the study as patients with recurrent varicose disease. All patients were divided into groups with and without enlarged PVs due to the reflux in the main subcutaneous vein, according to the C2-C6 clinical features of the CEAP classification. Results have confirmed by ultrasound dopplerography. EVLO of PVs (EVLO was performed with PV in patients with dilatation of the main subcutaneous vein) with 1470 nm wavelength diode laser (Biolitek. Germany), in order to treat the vertical reflux, have been conducted for all patients. After the EVLO the patients were under our control during 12 months (1 day, 1 week, 1,3,6 and 12 months). Patients with active movement restriction, deep vein thrombosis, or pregnant women were not in-

cluded to the study. All patients underwent a rigorous physical examination, dopplerography of both legs, and a careful anamnesis was collected (Figure 3). Colored Ultrasonic dopplerography with 8 mHS tip (Sonoscape S6 & Sonoscape S8) was used for studying the cause of venous reflux in the vertical position, to mark the PVs on the skin, to measure the diameter of the PVs and the length of the epiphasic segment (Figure 4).

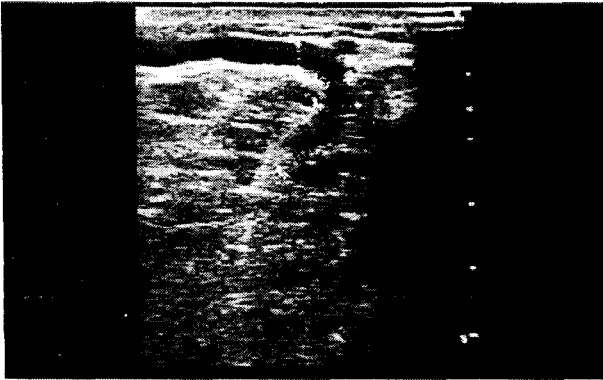


Figure 3. Ultrasonic dopplerography of Perforate Vein (PV)
(reflux up to 0.5 seconds)

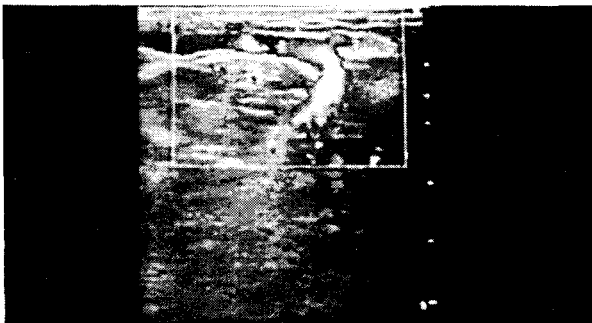


Figure 4. Ultrasonic dopplerography of Perforate Vein (PV)
(with 3,77 mm diameter)

The procedure have been implemented in specialized operation room with careful using of laser. Puncture of the vein is conducted by means of 18 G venous catheter and then "slim" radial laser light tip (Biolitek, Germany) with a diameter of 13 mm is inserted into the vein from the catheter, the distal end is kept in the PV infrafassial part (Figure 5).

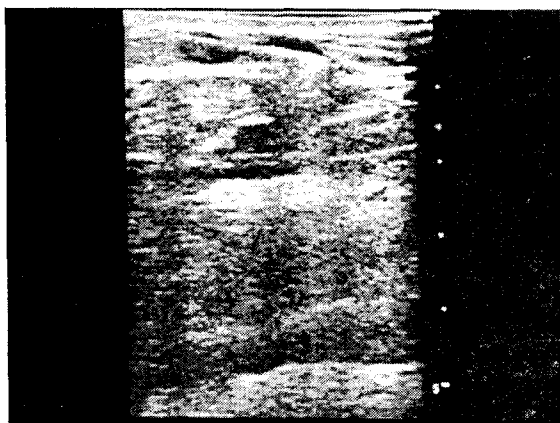


Figure 5. Ultrasound vision of the "Slim" radial laser light in PV.

Tumensent anesthesia is performed under ultrasound control. The standard Klyain liquid is used for anesthesia (physiological solution 1000 ml, lidocaine 1% 100 ml and 8.4% sodium bicarbonate 10 ml). Laser radiation is transmitted in a continuous mode by tracking the fiber regularly back and forth. Average energy consumption in obliteration of PVs is 310 C (between 150 C and 550 C).

The main signs of effective treatment of disease are reduction of symptoms and obliteration of the PV site during ultrasound doplerography. In patients with trophic ulcers and varicose insufficiency, reduction of inflammation, redness around trophic ulcer or epithelialization of the venous wound indicates the effectiveness of the performed operation.

No recurrence of obliterated veins was observed in the US at 6 or 12 months after surgery. Complete absorption or thin fibrous lines are visualized in the projection of the venous lumens. In some cases we assess blood flow resulting from the recanalization of PVs in USD as ineffectiveness of treatment.

Pains after surgery was observed in 4 patients (21,2%), these patients used ibuprofen 1 tablet orally 2 times a day for 4 days for analgesic purposes. Ecchymosis was seen in 9 patients (45,1%) and fully absorbed during 1-3 weeks. 11 patients (66,6%) had complaints of paresthesia during 3-6 months (average period was 3-4 months). It should be noticed that no one patient with ecchymosis, paraesthesia and induration had any medications for solution of problems connected with complaints. During the post-operational period no complaints such as superficial burns, deep vein thrombosis and arteriovenous fistula were found. It should be noticed that, solution of problems connected with enlargement of PVs is distinguished by the improvement of cosmetic parameters and shortening of the rehabilitation period by minimally invasive methods in comparison with the classical surgery, and it is surely reflected in EVLO.

Despite different complications after surgery, endovasal laser obliteration remains the most effective and safe method in treatment of varicose disease of the lower limbs. Most of complications can be removed after repeated minor manipulations, unlike traditional open phlebectomy. Outpatient treatment conditions, local anesthesia, early activation of patients and short rehabilitation period show the indispensability of this method.

In order to clarify the role of compression bandage in the rehabilitation of the disease in the postoperative period, patients underwent EVLO have been divided into two sub-groups. Both sub-groups consist of 38 patients (50%). Patients included to the first sub-group used the compression bandage, but patients in the second sub-group didn't use bandage. Achieved results of patients with implemented EVLO divided into above mentioned sub-groups have been assessed on 3rd, 5th, 7th and 12th day after surgery. But the main subject of comparison among patients included to these sub-groups is to reveal

signs of recanalization that may occur in the early postoperative period.

Ultrasonic doplerography examination was conducted for all patients in post-operational period. Analysis of achieve results showed that no signs of recanalization were observed in any of the patients using the compression bandage. Recurrent recanalization signs also have not been founded among patients (who didn't use compression bandage) from the second sub-group after analysis of ultrasound examination results. Main complaints of patients using compression bandages are skin reactions in hot weather and local allergic reactions. These complaints lead to postponing of operation date and conducting of surgery in cold seasons. Sometimes this break caused complications such as thrombophlebitis, trophic ulcers, etc. Treatment results of patients who use and do not use compression bandages are given on Table 3.

Table 3. Treatment results of patients depending on using of compression bandages

| Complaints | Patients who used compression bandages | Patients who didn't use compression bandages |
|--|--|--|
| Sense of heaviness in lower limbs | 6 (15.7%) | 6 (15.7%) |
| Sense of fatigue in lower limbs | 2 (5.2%) | 1 (3.8%) |
| Edema | 1 (3.8%) | 2 (5.2%) |
| Pain around the varicose vein | 0 | 0 |
| Allergic reactions on the skin surface | 7 (18.4%) | 0 |
| Recanalization | 0 | 0 |

In our time, the development and modernity of medicine is constantly improving. The demand of the modern age is to treat the

disease using less traumatic, less costly and less toxic methods for patients. Thus we devoted a part of our study to economic aspects of the problem. For calculation of costs and economic lost we used indications for inpatient and outpatient treatment implemented in the Central Hospital of Sailors' on date 25.12.2018. During analysis of personal data we calculated the following indications for comparison of costs for surgical treatment and endovasal laser coagulation (Table 4).

Table 4. Comparative indications for calculation of costs for treatment

| | Surgical treatment | EVLO |
|---|---|---|
| Duration of the operation | 50-80 minutes | 10-15 minutes |
| Number of doctors | 3 | 2 |
| Used equipment | Anesthesia machine, diathermocoagulator (price is not included in the price of shock absorbers) | Ultrasound device (shock absorber cost for 1 procedure = 500 AZN), diode laser (cost for 1 procedure 500 AZN) |
| Medications | Medications for intubation anesthesia. Total: 258 azn | 0.9% - with NaCl 600-1.5 azn. 2.0 Lidacaine 10 ampoules- 0.92 azn, 8.4% Sodium bicarbonate Total: 6.17 AZN |
| The average length of stay in the hospital | 5 | 0 |
| Average number of days of incapacity for work | 21 | 1 |

Surgery costs connected with salary of medical staff was calculated according to the annual salary fund of the Central Hospital of Sailors'. In correspondence with obtained indicators during surgery operations due to varicose disease of lower limbs the following costs have been calculated related salaries of medical staff (Table 5).

Table 5. Calculation of surgery costs related to salaries of medical staff

| Staff members | Annual budget of working time (minute) | Annual salary fund for the position (AZN) | Coefficient of use of working time | Price per minute (AZN) | Time spent for service (minute) | The number of participants of the operation | Total salary (AZN) |
|-------------------------|--|---|------------------------------------|------------------------|---------------------------------|---|--------------------|
| Doctor-surgeon | 101862 | 49806 | 0,935 | 0,52 | 80 | 3 | 139,2 |
| Operating room nurse | 101862 | 36245 | 0,935 | 0,38 | 80 | 1 | 30,4 |
| Doctor-anesthesiologist | 101862 | 49806 | 0,935 | 0,52 | 90 | 1 | 64,8 |
| Anesthesiologist nurse | 101862 | 36245 | 0,935 | 0,38 | 90 | 1 | 34,2 |
| Total | | | | | | 6 | 268,6 |

Working time spent to one operation:

- The main time spent for surgery - 50-80 minutes.
- Doctor-surgeon, operating room nurse (additional time - 30 minutes);
- Changing of clothes, washing (shower), hand scrubbing - 15 minutes;
- Medical documentation - 15 minutes.
- The total time spent for surgery - 80-110 minutes.
- Doctor-anesthesiologist - resuscitator, anesthesiologist nurse (additional time - 40 minutes);

- Changing of clothes - 5 minutes; pre-operational examination - 15 minutes, total time spent for operation - 90-130 minutes. Coefficient of use of working time – $C = 1 - 30/462 = 0,935$, Here - 30 minutes shift personal time, 462 minutes shift suretion.
- Depreciation of operating unit equipment: Use of operating block equipment per minute, depreciation - 0,65 AZN.
- Depreciation of operating unit equipment used for operation - $0,65 \times 50 \text{ min.} = 32,5 \text{ AZN}$

Soft inventory wear (special clothing for key personnel) $0,005 \text{ AZN} \times 50 \times 6 = 1,5 \text{ AZN}$: 6 – number of staff participating in surgery. Average duration of hospital stay after surgery is 5 days. Dayly price for hospital room (without taking into account profitability) is 50 AZN. Suration of staying in the hospital after surgery is 8 days $\times 50 \text{ azn} = 400 \text{ azn}$. The following indicators were used for calculation of the cost for treatment using the EVLO method (Table 6).

Table 6. Salary expenses for EVLO

| Staff members | Annual budget of working time (minute) | Annual salary fund for the position (AZN) | Coefficient of use of working time | Price per minute (AZN) | Time spent for service (minute) | The number of participants of the operation | Total salary (AZN) |
|----------------|--|---|------------------------------------|------------------------|---------------------------------|---|--------------------|
| Doctor-surgeon | 101862 | 49806 | 0,935 | 0,52 | 30 | 2 | 31,2 |
| Total | | | | | | 2 | 31,2 |

The main time - 10 minutes; additional time - 20 minutes:

- Preparation for surgery - 15 minutes;
- Preparation of medical documents - 5 minutes.
- Total time spends for EVLO - 30 min.
- Coefficient of use of working time - $C = 1 - 30/462 = 0,935$;
Here: 30 min.- shift personal time, 462 min. – shift duration;

- Depreciation of operating unit equipment: depreciation of 1 diod-laser - 500 azn. Cost of consumed laser diode inventory which we use in our research was calculated according the price of Biolitek laser with 2 ring light transmitter. Taking into account that the price varies depending on the country of manufacture and modification, the difference in the price index will be even higher when using a cheaper laser tip.
- Depreciation of laser thermal equipment - $(500 + 50) \times \text{min.} = 550$ azn.
- Depreciation of soft inventory (special clothing for key personnel) $0,005 \text{ azn} \times 30 \times 3 = 0,9$ azn. Here - 3 is staff members participated in EVLO prosedure.

Table 7. Comparative calculation of costs spent for “Phlebectomy of the dilated superficial veins of the lower limbs” surgery and EVLO treatment method

| № | Costs' item | Surgery (azn) | Laser ablation (azn) |
|---|---------------------------------------|---------------|----------------------|
| | Salary of key staff | 268,6 | 31,2 |
| | Total fixed costs 18,2% | 48,89 | 5,68 |
| | Total salary fund | 317,49 | 36,88 |
| | Salary calculations 35,8% | 113,66 | 13,20 |
| | Total | 431,15 | 50,08 |
| | Additional costs 71% | 306,12 | 35,56 |
| | Costs for medicines | 258,00 | 0,5 |
| | Costs for soft inventory | 1,50 | 0,30 |
| | Depreciation of equipment | 32,5 | 500 |
| | Total operation costs: | 1029,27 | 637,06 |
| | Costs for hospital stay after surgery | 1329,00 | 0 |
| | Total: | 1329,27 | 637,06 |

We have conducted comparative assessment of costs for surgery summarizing the obtained indicators of patients receiving inpatient treatment in the surgery department of Central Hospital of Sailors and the results of the calculations and costs of EVLO treatment method conducted in private Istanbul NS Clinic (Table 7).

So, according to our calculations the economic effect of the treatment of varicose disease of veins of the lower limbs in the out-patient setting of the Central Seamen's Hospital for 1 patient was as following:

$$DU_1 = (1029,27 - 637,06) + (150 - 0) = 542,21 \text{ azn.}$$

Indicators given in the Table 7 show that costs spent for surgery operation is two times higher than costs for EVLO treatment method.

Rehabilitation of restoration of patients' labor activity after endovenous laser ablation of lower limbs is faster than in patients which underwent surgery operation and is more effective because of faster returning of these patients to a normal work schedule. Especially considering that the age group is between 20-60 years, we should notice that, hospital costs also intended in addition to the inpatient costs for patients older than 50 years. For example, examination methods such as echocardiography, contrast computed tomography of the arteries requiring additional costs was used for 7 patients at age over 60 years.

CONCLUSION

1. Endovenous laser ablation is an effective method for treatment of varicose disease of lower limbs due to cosmetic indications and low traumatism.
2. Endovenous laser ablation operation is not a universal method for treatment of varicose disease of lower limbs. Its effectiveness depends on correct selection of patients for the laser procedure.

Proper assessment of the trunk vein means to obtain a reliable occlusion.

3. During obliteration of trunk veins there is no need to close vessels at the safeno femoral junction, it's just a waste of time and extra trauma.
4. Use of minimally invasive methods makes the postoperative rehabilitation period of patients shorter.
5. EVLO is considered as an effective method for obliteration of performant veins (especially in the perforated veins around the trophic ulcer), which are main reasons for recurrence of varicose disease.
6. Taking into consideration the location of Azerbaijan in the hot climate zone implementation of EVLO is possible in all seasons of a year. Using of compression bandage after surgery is not necessary.

PRACTICAL RECOMMENDATIONS

1. The doctor executing surgery for treatment of varicose disease of lower limbs should have a perfect knowledge on ultrasound indications of veins of lower limbs.
2. Using of EVLO is appropriate for treatment of the vertical reflux of large subcutaneous veins.
3. Careful determination of ultrasound dopplerography of pathology of perforated veins as the main reason of recurrence of varicose disease makes laser ablation more effective.
4. Large subcutaneous vein is more efficient at patients with lineal progression of disease regardless of the diameter of the lumens. In patients with arterial vessel pathology, infected skin surface the endovasal laser obliteration is not considered as an alternative method.
5. After the endovasal laser obliteration, surgery operation has no adverse effect on the patient's quality of life, especially in summer months, because we did not use compression bandage on a group of patients in our study. We didn't detect any difference

between which didn't use and which used the bandage after operation after analysis of condition of patients.

The list of published scientific works on the dissertation subject

1. Əliyev, M.S., Qasımov, N.S. Mağıstral dərialtı venaların endovazal lazer obliterasiyası // - Bakı: Azərbaycan Təbabətinin Müasir nailiyyətləri jurnalı, -2016. №4, - s.127-131
2. Алиев, М.С., Касимов, Н.А. Сравнительный анализ мини инвазивных и традиционных методов хирургического лечения больных с варикозной болезни нижних конечностей // - Баку: Биомедицина, - 2017. № 3, с.57-62
3. Əliyev, M.S. Aşağı ətrafların residiv varikoz xəstəliyinin müalicəsində endovenoz lazer obliterasiyasının effektivliyi. / M.S. Əliyev, N.A Qasımov, V.A. Fəttahpur, İ.M. Əsgərov, Ü.Z. İsmayılov // - Bakı: Metabolizm jurnalı – 2017. №3, - s. 25-30.
4. Əliyev, M.S., Qasımov N.A, Mağıstral dərialtı venaların endovazal lazer obliterasiyasına göstərişlər // - Bakı: Sağlamlıq jurnalı. – 2018. №1, - s.18-27
5. Əliyev, M.S. Magistral dərialtı venaların endovazal lazer obliterasiyası əməliyyatsonrakı dövrün nəticələri və qiymətləndirilməsi / M.S. Əliyev, N.A Qasımov, V.A. Fəttahpur, İ.M. Əsgərov, Ü.Z. İsmayılov // Sağlamlıq - Bakı: 2018. №3, - s. 7
6. Алиев, М.С. Касимов, Н.А., Фаттах-Пур В.А. Эндовенозная лазерная абляция перфорантных вен: наш опыт применения // - Москва: РМЖ. Медицинское образование - 2018. № 2, - с. 50-56
7. Əliyev, M.S. Aşağı ətraf venalarının varikoz xəstəliyində cərrahi müalicənin inkişaf mərhələləri və müasir aspektləri / M.S. Əliyev, N.A Qasımov, V.A. Fəttahpur, Əsgərov İ.M, İsmayılov Ü.Z // Cərrahiyyə jurnalı -Bakı: - 2018. №3, - s.86-90.
8. Əliyev, M.S Endovenoz lazer ablasianın iqtisadi hesablamaları və açıq cərrahiyyənin iqtisadi göstəriciləri ilə müqayisəsi // - Bakı: Azərbaycan Təbabətinin Müasir nailiyyətləri, -2019. №3, - s.170-173.

9. Aliyev, M.S The role and efficacy of lazer ablation in the conduct of phlebectomy of incompetent perforating veins // - Алматы: Вестник Хирургии Казахстана, - 2019. №3, - с. 61-66
10. Алиев, М.С., Касимов, Н.А., Фаттах-Пур, В.А. Эндовенная лазерная абляция перфорантных вен: наш опыт применения // First Kazakhstan Venous Forum, - Almata: - 2018, - с. 36
11. Əliyev, M.S, Qasımov, N.A. Yaşlı qrup xəstələrdə endovazal lazer koagulyasiyasının // Əziz Məmmədkərim oğlu Əliyevin doğum gününə həsr olunmuş elmi-praktik konfrans,-Bakı: 2019, - s.62
12. Əliyev M.S Varikoz xəstəliyi və residivlərinə səbəb olan venaların müalicəsinə müəssir yanaşma // Somatik xəstəliklər və komorbid vəziyyətlər mövzusunda elmi-praktik konfransın tezislər toplusu, - Bakı: - 2019, - s.8

ВАРИКОЗНОЕ РАСШИРЕНИЕ ВЕН НИЖНИХ КОНЕЧНОСТЕЙ И ПРИ ЕГО ЛЕЧЕНИИ РЕЦИДИВОВ ВЫСОКОЭНЕРГЕТИЧЕСКОЙ ЛАЗЕРНОЙ ЭНДОВАСКУЛЯРНОЙ КОАГУЛЯЦИИ

МАХИР САФАР ОГЛЫ АЛИЕВ

РЕЗЮМЕ

Патология венозных сосудов нижних конечностей включает ряд системных заболеваний (варикозное расширение вен, тромбофлебит, сужение магистральных венозных сосудов и др.). Самая частая причина хронического венозного недостаточности нижних конечностях является варикозное расширение вен. Несмотря на достижения современной медицины в диагностике этого заболевания, проблема рецидивов, которые могут возникнуть после операции, остается актуальной.

Целью нашего исследования является разработка принципов лечения варикозного расширения вен нижних конечностей. Для этого необходимо разработать алгоритм клинической инструментальной оценки инструкций по выполнению ЭВЛО, поврежденных сосудистых отверстий. Цель перед нами для исполнения EVLO заключается в выборе оптимальных пациентов.

Для определения преимуществ и недостатков эндовазальной лазерной облитерации, радикальной флебэктомии мы изучили ближний и дальний результаты методов. Установлено, что ЭВЛО, несомненно, незаменим во время операции и на период послеоперационной реабилитации. Болевой синдром не наблюдался у подавляющего большинства пациентов, однако почти у всех пациентов, перенесших радикальную флебэктомию, боль наблюдалась в проекции вены, а также на внутренней поверхности бедра и голени. Подкожные кровоизлияния наблюдались в очень немногих случаях по сравнению с операцией Бэбкока. Неврологические расстройства встречались вдвое реже (парестезия и, др). Все эти показатели показывают, что восстановле-

ние жизненных и социальных факторов пациентов происходило в 3 раза быстрее, чем в другой группе.

Одна из основных целей исследования - отличить лазерную облитерацию от других хирургических методов лечения варикозного расширения вен. Мы считаем, что при варикозном расширении вен нельзя допускать операционный разрез и его использование в хирургической практике следует ограничить. Косметические показания к операции при минифлебэктомии оценили ЭВЛО как оптимальный метод завершения.

Полученные нами результаты и литература позволили нам предложить алгоритм лечения варикозного расширения вен нижних конечностей.

VARICOSE VEINS OF THE LOWER EXTREMITIES AND ITS TREATMENT OF RECURRENT ENDOVASCULAR COAGULATION WITH A HIGH-ENERGY LASER

MAHIR SAFAR ALIYEV

SUMMARY

The pathology of the venous vessels of the lower extremities includes a number of systemic diseases (varicose veins, thrombophlebitis, narrowing of the main venous vessels, etc.). The most common cause of chronic venous insufficiency of the lower extremities is varicose veins. Despite the achievements of modern medicine in the diagnosis of this disease, the problem of relapses that may occur after surgery remains relevant.

The aim of our research is to develop the principles of treatment of varicose veins of the lower extremities. To do this, it is necessary to develop an algorithm for the clinical instrumental assessment of instructions for performing EVLO, damaged vascular holes. The goal for us to perform EVLO is to select the optimal patients.

To determine the advantages and disadvantages of endovasal laser obliteration, radical phlebectomy, we studied the near and far results of the methods. It has been established that EVLO is undoubtedly irreplaceable in surgical operations and in postoperative rehabilitation. Pain syndrome was not observed in the vast majority of patients, however, in almost all patients who underwent radical phlebectomy, pain was observed in the projection of the vein, as well as on the inner surface of the thigh and lower leg. Subcutaneous hemorrhages have been observed in very few cases compared with Babcock's operation. Neurological disorders met half as often. All these indicators show that the recovery of vital and social factors in patients was 3 times faster than in the other group.

One of the main goals of the research is to distinguish laser obliteration from other surgical methods for the treatment of varicose veins. We believe that with varicose veins, a preoperative incision should not be allowed and its use in surgical practice should be lim-

ited. Cosmetic indications for miniflebectomy surgery evaluated EVLO as the best completion method.

Our results and literature allowed us to propose an algorithm for the treatment of varicose veins of the lower endpoints.

Dissertation defence will be conducted on 30 March 2021 at the meeting of the FD 2.11 Dissertation Council operating under the Azerbaijan State Institute for the Improvement of Physicians named after A.Aliyev.

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