

RESULTS OF EVLT: RADIAL FIBER VERSUS BARE-TIP FIBER WITH CHEMICAL ASSISTANCE

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Varicose vein disease (VVD) of the lower extremities is one of the most important medical and social issues in the national health care program that significantly reduces the life quality index (LQI) of patients despite of the low impact on the life indicators in general and does not differ with this parameter from cardiovascular illnesses [10]. It is characterized by prevalence (approximately 50% of the employable population of the world suffer from the VVD specter of symptoms that causes serious economic losses at both the individual and the state level), as well as by a steady progress, high frequency and diversity of trophic disorders and varying range of manifestations (from cosmetic lesions in young patients to dystrophic interruptions in elderly ones) [5]. Thus, it results in a serious problem for doctors of general and surgical practice in polyclinic and hospital units. Overlooking numerous long-term studies, a clear gender predisposition has been identified (the female / male ratio is 85/15) [6]; in the age structure there is a direct correlation with age, with a significant portion in patients over the age of 50 years. In addition, patients with compromised heredity are at risk. A wide range of complications of varicose vein disease, caused by a lingering asymptomatic period and a clear underestimation of this problem by medical professionals and patients, as well as pronounced tendency to relapse due to technical or tactical errors during the treatment significantly deteriorates the patients' quality of life [1].

The main tactical rule determines the only correct way to achieve the result by correct wording of tasks and setting achievable goals. Analyzing the many year data of the holistic venous system structure in present allowed us to formulate a terminologically self-defining concept of systemic venous insufficiency of the infra-diaphragmatic segment - infra-diaphragmatic venous disease IDVN [8]. Obviously, this approach eliminates all theories about segmentally damaged venous apparatus, and, accordingly, any ambitions for the definitive recovery in any conservative or radical way. This postulate is fundamental in the practical and educational activities of vascular surgeons and phlebologists, defining the multidisciplinary nature of this process. Correctly set goals and determined prospects of treatment at all stages of patient care increases the compliance between participants of the treatment process and improves the patients' quality of life. The multivector field of technical and tactical treatment approaches of chronic venous insufficiency symptoms in the context of varicose veins disease has been effectively expanded during the foreseeable past by synchronous developments of various phlebological schools. That was a natural consequence of the synthesis of the scientific and technological progress results at the intersection of the medical, biochemical, biophysical, pharmacological and engineering planes. Traditionally, in practice, combinations of mechanical, physical and chemical techniques are used [4]. Each of them has a number of obvious advantages, albeit a rather unsystematic scheme of indications. Within the framework of the minimally invasive phlebology concept, today transcutaneous interference is preferred. At the heart of all methods, there is the constant principle: physical or chemical damage of the endothelium, leading to a temporary occlusion of the vessel, and finally resulting into a constant closure of the venous lumen.

Nowadays endovascular thermal ablation techniques with different physical principles of endothelium destruction are considered the standard method for vertical saphenous trunk

reflux elimination [3,9]. In this context the absence of unambiguous linear formulas and determined recommendations for each CVIcase scenario seems to be dissonant. Along with any other medical discipline, laser surgery is at the stage of formation and searching for optimal treatment regimens, determination of the indications range and application limits. Modern laser equipment used in a high-energy mode has an efficacy of over 95% efficiency achieving the irreversible occlusion superficial subcutaneous veins (SSV) lumen [7,12]. However, as the power increases, the frequency of complications increases proportionally: deep vein thrombosis > 15%, phlebitis > 15%, neuralgia and neuritis > 30%, severe postoperative pain syndrome > 70% (for lasers with radiation power > 50 W and linear energy density 6-8 J/mm) [2,12]. Endovenous laser ablation (EVLA) as a method for technical reasons depends on linear parameters of the affected object, as well as it is incompetent in the case of branched, convoluted or narrow vasculature negative cosmetic effect such as skin pigmentation above the vein restricts the use of EVLT for epifascial vessel location. Violation of these circumstances clearly discredits the method, so there is a need for a comprehensive and individual approach to each patient.

The modern market of medical hardware is ever-growing, so we have a problem of the cost and the variety of equipment for minimally invasive phlebological interventions supply. For the other side there are associated difficulties of rapidly developing methods of work and the slowly accumulating sufficient experience by specialists. These reasons form objectives of economic expediency and maximally efficient use of existing resources to improve the quality of treatment without significantly increasing costs.

These conditions determine the main task of modern domestic phlebology at the individual level of each vascular surgeon with an adequate consideration of reality: the search for the optimal combination of minimally invasive techniques that maximize the occlusion of the vessel lumen with minimally damage effect on surrounding tissues, reducing the frequency of relapses and complications, minimizing the duration of treatment and recovery in the postoperative period and improvement of patient's quality of life.

The purpose of the study - comparative analysis of the results after endovascular bare-tip fiber laser coagulation with simultaneous ultrasound-guided sclerotherapy (btEVLA+USGS) of great saphenous vein (GSV) with the similar technique without sclerotherapy (btEVLA) and endovascular radial fiber laser coagulation (rEVLA) in patients of different age categories with chronic venous insufficiency caused by varicose vein disease of the lower extremities classed C2-C6EpsAsPr.

Material and methods. Statistical analysis of 318 clinical cases of combined surgical treatment in patients with GSV vertical reflux on the base of the University Clinic of Odessa National Medical University for the period 2015-2017 was performed.

The sample Group was formed retrospectively, as far as the efficacy of the EVLT was analyzed, and the combination of btEVLA + USGS as well as rEVLA technique were introduced into the practice of our clinic. Selection criteria: patients with varicose veins classed C2-C6EpsAsPr by CEAP classification with an ostial valve failure, vertical GSV blood reflux, with (M±m) diameter of the subfascial venous segment ranged 11.8±4.1 mm, but with perforator veins and small saphenous vein valves suffi-

Table 1. Distribution of patients by CEAP scale

	Group 1	Group 2	Group 3	Total
C2	14 (30.4%)	45 (31.5%)	51 (39.5%)	110 (34.6%)
C3	21 (45.7%)	68 (47.6%)	54 (41.8%)	143 (45.0%)
C4	6 (13.0%)	24 (16.7%)	18 (13.9%)	48 (15.1%)
C5	3 (6.5%)	3 (2.1%)	4 (3.2%)	10 (3.1%)
C6	2 (4.4%)	3 (2.1%)	2 (1.6%)	7 (2.2%)
Total	46	143	129	318

Table 2. Technical characteristics of the power parameters of the EVLT

Characteristics	I group	II group	III group
Wavelength, nm	1064	1064	1470
Laser radiation power, J/sec	20	20	10
Linear energy density, J/mm	5	5	5
Estimated traction speed, mm/sec	4	4	2
Average length of the coagulation zone, mm	277	283	279
Average total energy, J	1385	1415	1845

ciency. Criteria of excluding patients from the study: pregnancy and lactation, deep vein thrombosis, hypercoagulation conditions and severe systemic diseases.

The sample was standardized by age, sex, and clinical manifestations of CVI, and then divided into 3 groups: I - patients, who was performed the bare-tip fiber EVLA of the GSV insufficient segment - 46 persons, operated in 2015; II - patients who was performed the btEVLA + USGS of the GSV insufficient segment - 143 people operated within 2016-2017; III - patients was performed the rEVLA of the GSV insufficient segment - 129 people operated within 2016-2017.

In every case, the patient did choose a definite method himself after the detailed discussion of the advantages and disadvantages and the acquaintance with world and local statistical indicators of their effectiveness and possible risks.

Average age range ($M \pm m$) of patients: I group - 38.2 ± 13.6 years; II group - 45.1 ± 13.3 years; III group - 41.7 ± 9.6 years.

Gender distribution of patients: I group: women - 34 (74%), men - 12 (26%); II group: women - 114 (79.7%), men - 29 (20.3%); III group: women - 98 (76%), men - 31 (24%).

Average length ($M \pm m$) of the GSV insufficient subfascial segment: I group - 277 ± 12 mm; II group - 283 ± 9 mm; III group is 279 ± 11 mm.

The distribution of patients by CEAP scale is shown in Table 1.

Venous Clinical Severity Scope (VCSS) [12] was used to quantify the patients state dynamics in groups 1, 2 and 3. According to the protocol, patients were asked to assess the pain syndrome, the degree of active life restriction and the need for compression therapy with the analog scale ranged [0-3]: 0 - no signs, 1 - slight manifestation of symptoms, no limitations of active life and the compression therapy during exercises is periodically required, 2 - medium daily pain syndrome, restriction of active life and the compression therapy is required during the period of body verticalization, 3 - severe daily pain syndrome, significant limitation of active life, and the patient requires the constant use of compression knitwear. Remaining parameters are objective indicators, the dynamics of them are determined by the physician, however, by the same analog scale: 0 - the sign is absent, 1 - moderate manifestation of the sign, 2 - average manifestation of the trait; 3 - maximum manifestation of the characteristic (Table 2).

The EVLA in groups 1 and 2 was performed with the bare-tip fiber with a quartz core sized 600 μ m using Dornier MediLasFibertom 4060 Nd: YAG Surgical Laser with a wavelength of 1064

nm and a laser radiation power of 20 W as a source of laser energy. For patients in group 3, the laser-radiation source with a wavelength of 1470 nm and a laser radiation power of 10 W and with radial fiber was offered. The energy characteristics of the EVLA are given in Table 2.

Generalized procedure record.

During the operation the subfascial GSV segment was punctured, then the introducer (6 Fr for bare-tip and 7 Fr for radial optics) was installed, and the laser fiber was applied through it to the sapheno-femoral junction. The positioning of the fiber tip was performed with the dynamic ultrasound control. For the tunnel tumescental anesthesia by Klein solution was injected along the GSV trunk [11]. For all groups the lineal power density of 5 J/mm was chosen as a stable parameter of comparable analysis. The traction velocity of the fiber is always to be determined intraoperatively, considering ultrasound signs of vein obliteration: the GSV spasm and the appearance of hyperechogenic heterogeneous content inside it: for groups 1 and 2 - minimal in the sapheno-femoral junction region (2 mm/sec), with the average value along the GSV trunk of 4 mm/sec; for group 3 minimal in the sapheno-femoral junction region (1 mm/sec), with the average value along the GSV trunk of 2 mm / section the second group, 1 ml of 1% foam-form solution of aethoxysclerol was injected through the port of the introducer before the EVLA procedure. After that, the methodology of the EVLA was similar to the same in group 1. The epifascial GSV segment and its branches was neutralized with the USGS or miniflebectomy.

Compression therapy (class 2 compression stockings) in the postoperative period was obligate: 24h mode - 7 days, then daytime mode - 10 days.

All patients received a 3-day course of NSAIDs and a 60-day course of phlebotonics (micronised purified flavonoid fraction - 500 mg twice a day) in the postoperative period.

Results and ther discussion. Treatment quality control was performed by interviewing of patients and the duplex ultrasound investigation (equipped with Toshiba Nemio XG SSA 580A) intraoperatively and during re-examinations in terms of 7 days, 1, 2, 6 months after the intervention. As a criterion, the completeness of the insufficient GSV segment obliteration parameter was selected. The results were analyzed and grouped in 6 months next way: "excellent" - recanalization was not observed, "satisfactory" - there was segmental recanalization without hemodynamically significant blood reflux along GSV trunk, and "unsatisfactory" - hemodynamically significant blood reflux along the GSV trunk.

Table 3: Objective treatment outcomes

Outcomes	Group 1	Group 2	Group 3
Excellent	33 (72%)	138 (96.5%)	129 (100%)
Satisfactory	11 (24%)	5 (3.5%)	–
Unsatisfactory	2 (4%)	–	–
Total	46	143	129

Table 4. Treatment results on the VCSS scale.

	Group 1			Group 2			Group 3		
Pain syndrome	2.1	1.1	0.2	2.2	1.1	0.2	2.1	0.5	0.1
Varicose veins	2.5	0	0.4	2.6	0	0.3	2.5	0	0.3
Venous edema	2.0	1.1	0.3	2.1	0.9	0.2	2.1	0.6	0.2
Stasis dermatitis	1.4	0.9	0.4	1.2	0.4	0.2	1.3	0.3	0.1
Skin discoloration	0.4	0.4	0.4	0.4	0.4	0.4	0.3	0.3	0.3
Skin induration	1.1	1.0	0.8	1.1	1.0	0.8	1.1	1.1	0.7
Number of ulcers	0.02	0.02	-	0.03	0.03	-	0.02	0.03	-
Duration of ulcers	0.02	0.02	-	0.02	0.02	-	0.02	0.02	-
Diameter of ulcers	0.01	0.01	-	0.01	0.01	-	0.01	0.01	-
Compression therapy	1.3	3.0	0.03	1.1	3.0	-	1.1	3.0	-
TotalVCSS	10.45	7.55	2.53	10.66	6.86	2.1	10.35	5.86	1.7

In the postoperative period (1 month), the incidence of partial GSV trunk recanalization in the group 1 was 24%, in the second - 3.5%, in the third 0%. As a benchmark, only “excellent” results were selected.

For the results of groups 1 and 2, the Pearson X2 calculated criterion was 6.635, and the actual - 29.527 ($p < 0.001$), which allows us confidently constating the statistically significant difference in favor of the results of group 2. For the results of groups 1 and 3, the calculated criterion X2 was 6.635, the actual - 44.045 ($p < 0.001$), which confirms the statistical significance of the difference in favor of the results of group 3. For the results of groups 2 and 3, the actual value of the Pearson criterion was 4.595 ($p = 0.033$), which, compared to the calculated 3.841, has a statistical advantage for the 3rd group at a level of significance of $p < 0.05$.

The change in the clinical status of patients according to the VCSS scale is shown in Table 4. For all groups, the time series of each VCSS parameter are presented in three control points of the study: before the manipulation, 7 days and 6 months after the operation.

First of all, it is important to note the positive clinical dynamics of skin ulcers in patients of all groups. Only one of 7 patients with active trophic skin lesions did not reach self-recovery of the defect with scar tissue for 3 months. After repeated consultations with the oncologist and the plastic surgeon, the patient was advised to undergo skin transplantation procedure. This outcome indicates the sufficient efficacy of all the methods to eliminate the trophic significant microcirculatory changes and bring them back to critical limits.

For the comprehensive evaluation of the data in Table 4, the statistics of time series to the indicator of the total score of VCSS was used. In the first group, in 1 week after the operation, the clinical status improved from 10.45 points to 7.55, which corresponds to 28%, and in 6 months - to 2.53, that is another 34%, and 76% in total since the beginning of treatment. Some better results were achieved in group 2: after 7 days the patient's assessment changed from 10.66 points to 6.86 (decreased in 36%), and in 6 months - to 2.1 (decreased in 31% since the previous stage and in 80% since the beginning). The best results in comparison with the first group were demonstrated by the EVLA

method using radial optics: the advantage of the method in group 3 with changes of the overall score from 10.35 to 5.86 (in 43%) was determined in a 1 week and to 1.7 (one more 29%) in 6 months meaning 84% positive outcome. The same proportions correspond to each individual parameter in the comparison.

In addition to the criteria of the VCSS scale in the postoperative period, during a re-examination for 7 days after the intervention, patients were separately offered evaluating the pain syndrome with a linear analog scale of pain with a range of values from 1 to 10: no pain - 0 points, weak pain - 1-3 points, moderate pain - 4-6 points, severe pain - 7-9 points, very strong pain - 10 points. The necessity and the duration of the additional course of analgesics also was considered. The survey was conducted under the condition of clear terminological differentiation and confidence in the patient's understanding of the difference between the characteristics of postoperative, inflammatory and congestive pain syndromes in case of their addition or succession. While the interviewing the attention was paid to the actual level of pain and its dynamics. Good result was the absence of pain or its weak intensity, bad - the pain of middle, strong and very strong intensity. In group 1, the expressed pain syndrome and / or the need for analgesics were observed in 32 (70%) patients, in the second group - in 95 (66.4%), in the third - in 40 (31%). There is no statistically significant difference between the results of groups 1 and 2 (the actual X2 criterion is 0.155 ($p = 0.694$)). But while comparison of pairs “1st and 3rd groups” and “2nd and 3rd groups”, the corresponding actual figures were 20.818 ($p < 0.001$) and 34.047 ($p < 0.001$), which is significantly more than the critical 6.635 and indicates a significant advantage of the EVLA method using radial optics according to this indicator.

A separate parameter for the objective evaluation is the fact of ecchymosis occurring along the GSV trunk in the postoperative period. For the first and second groups, these indicators were close for obvious reasons (29 cases (63%) and 98 cases (68.5%) respectively). Pearson's criterion was 0.476 at $p = 0.491$, which does not represent a statistically significant difference between these parameters. In the third group, the damage to the vessel wall, and consequently the hemorrhage, occurred in 35 people, which is 27%, and by this parameter, working with radial fibers

far surpasses the practice of using bare-tip ones ($X_2 = 18.852$ at $p < 0.001$) and the combined EVLA ($X_2 = 46.518$ at $p < 0.001$).

For certain reasons, there were no dynamics in skin pigmentation and skin induration. The absence of cases of burns and deep vein thrombosis is associated with the correct implementation of the international protocols recommendations.

Economic feasibility made bare-tip fibers predominant in the medical equipment market, thus this research became current. Their main disadvantage is their structure. Due to small area of the fiber tip, the surface quartz layer fragmentation with an exponential increase of energy dissipation rate is rather soon. It leads to its overheating and carbonization, which reduces the transfer of energy from the fiber to the endothelium and causes significantly different energy levels on the generator and on the effector part. So, the procedure of laser obliteration transforms into the procedure of thermal ablation with uneven excessive damage of the venous wall, its carbonization and perforation, which results into increased frequency of infiltration and pain syndrome incidences in the postoperative period.

For the study, patients with a subfascial hip segment of GSV diameter ranged 8-16 mm were chosen. The indicated reference values were dictated by the world recommendations, the experience of phlebologists of our clinic, as well as theoretical considerations on the technical parameters of the bare-tip fiber laser equipment and schematic modeling of the extremely uneven distribution of energy along the trunk of the saphenous vein. The choice of the combination of EVLK + ECO is due to our ideas about improving the contact of the venous wall with the effective part of the fiber and improving the quality of the manipulation as a result of extravasal tumescent compression and venous spasm induced by intravasal chemical damage to the endothelium.

The important and unresolved problem in bare-tip fiber using is the laser radiation parameters determination and normalization. Significant energy losses in the mentioned ways require increasing of power (J/s) or density of radiation (J/mm²). However, as the power increases, the frequency of complications increases proportionally, which limits the wide variation of this index and keeps it within 30-Watts range. The second parameter does not have sufficient theoretical substantiation, since an area of the acceptor surface is used for the calculation and the determination of it is complex due to a number of technical reasons. At the same time, the equivalent linear density (J/mm) is only an indirect parameter, forcing practitioners to focus on approximate empirical data in their practice. Therefore, any techniques that maximize the contact of the vascular wall with the energy source, including EVLA + ESO, contribute accumulating of information about low-energy modes of laser surgery.

Analyzing the technical component of surgical intervention focusing on the parameter of convenience, the absence of significant differences in the technique labor intensity was noted: using the 6 Fr diameter introducer allows positioning and manipulating the laser fiber without difficulty. At the same time, the introducer structure such as the presence of an additional port makes possible the insertion of sclerosant solution into the vein without the need for additional venous puncture.

Conclusions. The use of combined (physicochemical) methods of exposure to the venous wall increases the efficacy of bare-tip fiber endovascular laser coagulation that allows effective eliminating vertical reflux in larger trunks with less relapse probability compared to isolated laser thermal ablation.

The given technique allows bare-tip fiber EVLA (without reducing its accessibility and aggravation of its defects) to be

comparable to radial results for the efficiency parameter without any excessive costs.

The emergence and application of new techniques based on existing ones allows accumulating experience of using different treatment approaches of chronic venous insufficiency and developing the most optimal ones for the price and quality parameter.

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SUMMARY

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Purpose of the study - comparison of the effectiveness of various methods of endovenous laser coagulation of the great saphenous vein, searching the optimal scheme for the treatment of chronic venous insufficiency. Retrospective analyze of 318 clinical cases of combined surgical treatment using various methods

of thermoablation (bare-tip fiber, radial fiber, simultaneous thermoablation and echosclerobliteration) of a great saphenous vein.

By the parameter of the great saphenous vein occlusion, the results in the group of simultaneous thermoablation and echosclerobliteration surpassed the bare-tip thermoablation group results and were comparable with the results of radial thermoablation.

The combination of methods of subcutaneous veins occlusion allows to use lower-energy modes of bare-tip endovenous laser coagulation to achieve the effective vein obliteration comparable to the results of radial thermoablation.

Keywords: endovenous laser coagulation, bare-tip fiber, radial fiber, echosclerobliteration, chronic venous insufficiency.

РЕЗЮМЕ

РЕЗУЛЬТАТЫ ЭНДОВЕНОЗНОЙ ЛАЗЕРНОЙ КООГУЛЯЦИИ: ОЦЕНКА ЭФФЕКТИВНОСТИ ИСПОЛЬЗОВАНИЯ РАДИАЛЬНОГО СВЕТОВОДА В СРАВНЕНИИ С ТОРЦЕВЫМ СВЕТОВОДОМ В КОМБИНАЦИИ С ХИМИЧЕСКИМ ПОСОБИЕМ

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Целью исследования явилось сравнение эффективности различных методик эндовенозной лазерной коагуляции большой подкожной вены, поиск оптимальной по цене и качеству схемы лечения хронической венозной недостаточности.

Проведен ретроспективный анализ 318 клинических случаев комбинированного хирургического лечения с применением различных методик термоабляции (торцевой световод, радиальный световод, симультанная термоабляция и экосклерооблитерация) большой подкожной вены. По параметру окклюзии большой подкожной вены результаты

в группе симультанной термоабляции и экосклерооблитерации превзошли результаты группы с торцевой термоабляцией и оказались сопоставимы с результатами радиальной термоабляции.

Результаты исследования позволяют заключить, что применение комбинированных методик окклюзии вен позволяет использовать более низкоэнергетические режимы торцевой эндовенозной лазерной коагуляции для достижения эффективной облитерации вен, сопоставимой с результатами радиальной термоабляции.

რეზიუმე

ენდოვენური ლაზერული კოაგულაციის შედეგები: რადიალური შუქსხივის და ქიმიურ საშუალებასთან კომბინირებული ტორსიული შუქსხივის გამოყენების ეფექტურობის შეფასება

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კვლევის მიზანს წარმოადგენდა დიდი კანქვეშა ვენის ენდოვენოზური ლაზერული კოაგულაციის სხვადასხვა მეთოდის ეფექტურობის შედარება, ქრონიკული ვენური უკმარისობის მკურნალობის ოპტიმალური ფასის და ხარისხის სქემის ძიება.

ჩატარდა დიდი კანქვეშა ვენის თერმოაბლაციის სხვადასხვა მეთოდის გამოყენებით (ტორსიული შუქსხივი, რადიალური შუქსხივი, სიმულტანური თერმოაბლაცია და ექსკლეროობლიტერაცია) განხორციელებული კომბინირებული ქირურგიული მკურნალობის 318 კლინიკური შემთხვევის რექტროსპექტული ანალიზი.

დიდი კანქვეშა ვენის ოკლუზიის პარამეტრის მიხედვით, შედეგები სიმულტანური თერმოაბლაციის და ექსკლეროობლიტერაციის ჯგუფებში აღემატებოდა ტორსიული თერმოაბლაციის ჯგუფის მონაცემებს.

კვლევის შედეგების საფუძველზე ავტორები დაასკვნინან, რომ ვენების ოკლუზიის კომბინირებული მეთოდების გამოყენება იძლევა ტორსიული ენდოვენური ლაზერული კოაგულაციის უფრო დაბალ-ენერგეტიკული რეჟიმების გამოყენების საშუალებას ვენების ეფექტური ობლიტერაციის მიღწევისათვის, რადიალური თერმოაბლაციის შედეგებთან შედარებით.