

EFFICIENCY OF THE COMBINED APPLICATION OF RADIOFREQUENCY AND ENDOVENOUS LASER ABLATION OF VEINS IN THE TREATMENT OF VARICOSE DISEASE OF THE LOWER EXTREMITIES

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SUMMARY. Radiofrequency ablation (RFA) and endovenous laser coagulation of veins (EVLC) are of priority in the treatment of varicose veins of the lower extremities in outpatient settings. Although the indications for these operations and the technology of their application are defined, the issue of improving their functional results, in particular the involution of collateral veins on the lower leg after ablation of the great saphenous vein, is relevant.

The aim – to improve the results of the treatment of varicose veins in an outpatient setting by using a combination of radiofrequency and laser vein ablation.

Material and Methods. Under observation were 154 patients who were operated on with the help of RFA and 111 patients who underwent combined thermal ablation GSV RFA (on the thigh) and EVLC (on the leg).

To compare the effectiveness of RFA and the combination of RFA with EVLC (hybrid thermoablation of veins), a quantitative and qualitative assessment of their results was carried out. In particular, the quantitative assessment was performed using a number of scales VCSS, VDS, VSDS, VSS. Questionnaires: MOS SF-36 and CIVIQ-20 were used for qualitative assessment. The results of operations were evaluated after 3, 6 months and a year after their implementation.

Results. The analysis of the results of operations shows that, according to quantitative and qualitative indicators, combined operations with the simultaneous use of RFA and EVLC are more effective than RFA. These indicators were directly influenced by the number of residual veins after 6 months of observation (33.1 % after RFA and 5.4 % after hybrid thermoablation).

Conclusion. The use of hybrid thermal ablation for the treatment of varicose veins of the lower extremities, in outpatient conditions, is qualitatively and quantitatively more effective than RFA.

KEY WORDS: varicose disease; radiofrequency ablation; combination of radiofrequency ablation with endovenous laser coagulation of veins; quantitative and qualitative assessment of operations.

Introduction. Endovenous laser coagulation (EVLC) and radiofrequency ablation (RFA) are the most common minimally invasive methods of treating varicose veins of the lower extremities in the world, which have been sufficiently experimentally and clinically confirmed [1, 2]. In connection with a significant reduction in the number of such complications as wound suppuration, lymphorrhea, hematomas, isolated distal thrombosis, blood loss, as well as a reduction in pain syndrome, the duration of antibiotic therapy, and a reduction in the duration of surgery, EVLC and RFA outperform classical saphenectomy in terms of functional efficiency and quality of life in the postoperative period [2, 3, 4, 5, 6].

It should be noted that when comparing the results of EVLC and RFA, especially when using a laser with a range of 1940 nm, a number of authors did not notice a fundamental difference in the use of these methods, both in terms of complications specific to thermal ablation and in the percentage of complete obliteration of veins [7, 8, 9].

The widespread use of thermal methods of ablation of incompetent trunk superficial veins prompted phlebologists to seek answers to a number of actual questions. Thus, in the scientific literature, the issue of one-time RFA or EVLC on incompetent venous subcutaneous trunks with subsequent postponement of

operations on dilated collateral veins of the leg using miniphlebectomy or foam sclerotherapy is discussed [10, 11]. At the same time, in modern scientific works you can find information about the involution of collateral veins after performing only RFA, within 3–6 months [11, 12, 13, 14, 15, 16, 17]. According to our data, involution of collateral veins after RFA occurs in 66 % of patients, both on the thigh and in 21 % on the lower leg [19]. Our data coincide with similar data of other authors – after removal of axial reflux, collateral varicose veins above the knee disappear in 42 % of cases and 25 % below [11, 12].

It should be noted that the peculiarity of using RFA is the puncture insertion of the ClosureFast™ catheter through the introducer into the large subcutaneous vein, 15 cm distal to the knee joint. In this way, it is possible to avoid damage to the subcutaneous nerve under the influence of heating.

At the same time, there remains a section (lower third – upper third of the lower leg) of the large subcutaneous vein that is not subject to thermal ablation. This can explain the significant percentage of absence of involution of collateral veins after RFA on the lower leg.

In our opinion, it is possible to improve the functional results of the operation by additional thermal ablation of the great saphenous vein (GSV) on the lower leg by using EVLC.

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The aim of the study – to improve the results of the treatment of varicose veins in an outpatient setting by using a combination of radiofrequency and laser vein ablation.

Material and Methods. Under observation were 154 patients, who were operated on with the help of RFA for EVLC and 111 patients, who underwent combined thermal ablation of GSV RFA (on the thigh) and EVLC (on the leg). The condition for performing mono RFA and EVLC was the absence of failure of the perforating veins of the Cocketta and Boida groups. All patients had C2–C4 according to the clinical classification of CEAP. The age of patients in both groups was 41–54 years, men – 98, women – 159.

Ultrasound color duplex scanning of veins was performed on a Vivid 3 device (General Electric, USA) and a Mindray Z5 device (Mindray Bio-Medical Electronics, CO, China) with a 5–10 MHz frequency sensor and the corresponding standard software package of the indicated companies for examination of the venous system.

Patients were examined in the afternoon, in a vertical and horizontal position. The research began with the inguinal area – in the projection of the saphenofemoral joint using compression tests and the Valsalva breathing test.

The functional state of the mouth valve was evaluated, the size of the mouth and the mouth part was determined. Subsequently, the functioning of the valvular apparatus of the great saphenous vein, the diameter of the great saphenous vein, the presence of tributaries, their drainage sites, and the condition of the small saphenous vein and perforating veins were determined.

To eliminate vertical discharge, RFA was used according to the VNUS Closure FAST method, using the Medtronic COVIDIEN device. Sensors are built into the catheter, which determine the effectiveness and completeness of the effect on the venous wall, which automatically ensures an accurate and controlled effect. Such a precise and standardized technique of VNUS Closure Fast, which is performed on fully automated equipment of the latest generation of the company "Covidien" (Medtronic, USA), practically excludes the influence of the "human factor" and the possibility of a doctor's error. Ultrasound guidance of the catheter allowed us to bring it directly under the ostial valve and thus leave a minimal short stump of the GSV. Ablation was performed in 20-second cycles from 40 W (120°C) to 10 W. For the initial segment of GSV with its diameter of 7 cm, two cycles were used, and then one cycle per segment.

When the diameter of the GSV under the sapheno-femoral junction is from 12–16 mm, 3–4 cycles were used. The catheter was withdrawn 7 cm accord-

ing to the markings after each ablation cycle to ensure segment overlap according to the manufacturer's recommendations.

EVLC was performed with a Ukrainian portable high-intensity semiconductor (diode) laser device "Lika-surgeon", produced by the Cherkasy MPP "Fotonika Plus" with a wavelength of 1470 nm, a power of 7–10 W, and a radial catheter. EVLC was carried out simultaneously with RFA, two brigades.

In order to study the effectiveness of surgical treatment of varicose disease, using RFA and RFA in combination with EVLC, a quantitative assessment of the results of surgical treatment was applied using a number of scales developed by the American Forum of Phlebologists, in particular, VCSS (C), VDS (D), VSDS (A), VSS (sum of A+C+D).

Quality of life (QoL) was assessed using two questionnaires: MOS SF-36 and a special CIVIQ-20 questionnaire. The SF-36 questionnaire (The Short Form-36) is a non-specific questionnaire for assessing the patient's quality of life (QoL-quality of life).

The questionnaire reflects the general well-being and the degree of satisfaction with those aspects of a person's life activities that affect the state of health. The CIVIQ-20 questionnaire (Chronic Venous Insufficiency Questionnaire) allows you to get an idea of the respondent's physical condition, presence of pain syndrome, social activity, and psychological comfort. The expediency of using CIVIQ-20 is determined by its maximum specificity in relation to patients with chronic venous diseases. Due to which, the symptoms of venous insufficiency are most fully evaluated, the problem of long stay of the patient in a static position (standing, sitting, etc.) is well reflected.

The results of surgical treatment were assessed on the basis of objective and subjective indicators before surgery, after 3 months, after 6 months and after 1 year.

Statistical data processing was performed using the STATISTICA application program package (Stat-Soft Inc., USA, version 6.0). All received data were processed by the Microsoft Excel program. The obtained database and software automatic processing of the research results made it possible to compare the results according to various criteria and use the obtained parameters in the statistical processing of the material. Statistical processing of the research results was carried out using computer programs for comparing average values and relative indicators in groups using Student's criteria, Pearson's parametric correlation analysis, and the Mann-Whitney U-test. In the absence of normality of distribution of characteristics, non-parametric Wilcoxon tests were applied. Coefficients with 95 % confidence were taken into account ($p < 0.05$).

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Results and Discussion. 6 months after RF monoablation alone, we established that involution of the tributaries of dilated collateral veins on the leg was noted in 103 (66.9 %) patients. In the other 51 (33.1 %) patients, in whom the involution of the tributaries of the GSV on the leg did not occur, delayed mini-interventions were used to eliminate the expanded collaterals. In the other 51 (33.1 %) patients, in whom the involution of the tributaries of the GSV on the leg did not occur, delayed mini-interventions were used to eliminate the expanded collaterals. In particular, miniphlebectomy was performed in 32 patients according to the standard technology, without suturing the skin punctures and using wound dressings of the Steril Strip type. In 19 patients, a combination of miniphlebectomy with obliteration of their lumen with the help of puncture sclerotherapy was used to eliminate varicosely al-

tered inflows of the saphenous veins. At the same time, after performing a combination of RFA with EVLK, after 6 months, we noted the disappearance of extended VPV tributaries on the lower leg in 105 (94.6 %) patients.

The assessment of clinical severity before surgery – VCSS (C) in all patients was equal to (6.1 ± 0.2) points, the indicator of venous segmental diseases VS DS (A) – (1.09 ± 0.12) points, physical activity VDS (D) – (1.05 ± 0.10) points. On average, the severity of chronic venous disease VSS (C+A+D) was (8.47 ± 0.40) points. 3 months after the operation, in the group of patients in whom RFA was combined with EVLK, the above-mentioned indicators were slightly higher than after RFA was transferred. Thus, VCSS was (2.75 ± 0.21) points, VS DS – (0.61 ± 0.19) points, VDS and VSS were (0.76 ± 0.12) and (4.3 ± 0.34) , respectively) points.

Table 1. Quantitative assessment of the effectiveness of operations on clinical scales

Clinical scales	Before the operation	3 months		6 months		1 year	
		RFA	RFA+EVLC	RFA	RFA+EVLC	RFA	RFA+EVLC
Anatomic score VS DS (A)	1.09±0.12	0.58±0.21 p<0.001	0.61±0.19 p<0.001	0.83±0.13* (p*=0.001)	0.33±0.15* (p*=0.001)	0.09±0.01* (p*=0.001)	0.06±0.15* (p*=0.001)
Venous clinical severity score VCSS (C)	6.1±0.2	2.23±0.38 p<0.001	2.75±0.21 p<0.001	1.04±0.54* (p*=0.001)	0.67±0.23* (p*=0.001)	0.63±0.13* (p*=0.001)	0.59±0.18* (p*=0.001)
Physical activity VDS (D)	1.05±0.1	0.61±0.53 p<0.001	0.76±0.12 p<0.001	0.25±0.1* (p*=0.001)	0.19±0.42* (p*=0.001)	0.1±0.01* (p*=0.001)	0.09±0.02* (p*=0.001)
The average disease severity VSS (C+A+D)	8.24±0.82	3.53±0.71 p<0.001	4.3±0.34 p<0.001	2.12±0.22* (p*=0.001)	1.25±0.17* (p*=0.001)	0.82±0.2* (p*=0.001)	0.74±0.15* (p*=0.001)

* – non-parametric Wilcoxon test for dependent samples.

At the same time, 6 months after the operations, we noted a difference in the VS DS, VCSS, VDS, VDS indicators between RFA and RFA with EVLK in favor of the latter combination. This can be explained by the presence of a certain number of collateral veins, the involution of which did not occur on the lower leg after RFA. It should be noted that after

the use of delayed mini-interventions on collateral veins (6 months after RFA), and a year after observation of the two categories of patients, we did not notice a significant difference in the above-mentioned indicators.

In addition, we performed an analysis of the quality of life (QoL) in patients after RFA and RFA+EVLC.

Table 2. Quality of life of patients after the use of various methods of operations for varicose veins (SF-36 questionnaire)

Scales	Before the operation	RFA		RFA+EVLC	
		1 months	3 months	1 months	3 months
Physical Functioning (PF)	79.6±0.8	95.6±0.4**	96.4±0.6**	89.8±0.6**	95.3±0.12**
Role-Physical Functioning (RP)	75.2±0.7	86.7±0.6**	89.2±0.3**	82.4±0.7**	91.2±0.23**
Bodily pain (BP)	84.7±0.3	98.5±0.7**	99.6±0.7**	89.4±0.9**	95.1±0.3**
General Health (GH)	74.3±0.6	93.7±0.3*	95.0±0.23*	92.5±0.7*	96.3±0.4*
Vitality (VT)	82.5±0.4	95.6±0.5*	95.0±0.23*	90.05±0.4*	95.9±0.33*
Social Functioning (ST)	81.7±0.6	98.7±0.8*	96.4±0.15*	92.08±0.1*	90.8±0.2*
Role-Emotional (RE)	77.6±0.8	98.3±0.7*	98.7±0.21*	89.8±0.7*	99.1±0.1*
Mental Health (MH)	75.9±0.5	94.8±0.1*	95.1±0.2*	90.1±0.6*	91.2±0.3*

A significant difference was established between the parameters of the patients before and after the operation: * – p<0.05; ** – p<0.01.

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Thus, the quality of life of all operated patients significantly improved compared to before the operation. However, 3 months after performing RFA alone, patients have better quality of life on all scales than after a combination of thermoablation methods. At the same time, after 3 months, the dynamics of recovery of physical, psychological and social functioning of patients after RFA and RFA and EVLK is practically the same. This indicates that the use of hybrid thermal ablation operations does not significantly affect the main life indicators of patients.

In addition, we used the CIVIQ-20 questionnaire (Chronic Venous Insufficiency Questionnaire) to subjectively evaluate the effectiveness of the transferred operations. This questionnaire allows you to get an idea of the respondent's physical condition, presence of pain syndrome, social activity, and psychological comfort. Compared to the SF-36 questionnaire, the CIVIQ-20 questionnaire specifies and more accurately reflects the typical symptoms of venous pathology, including pain.

Table 3. Quality of life of patients after the use of various methods of operations for varicose veins (CIVIQ-20 questionnaire)

Scales	Before the operation	RFA		RFA+EVLC		P
		1 months	3 months	1 months	3 months	
Pain factor	5.4±1.3	1.75±0.98	0.8±0.2	1.92±0.45	0.89±0.39	<0.05
Physical factor	15.6±2.4	8.18±1.26	5.4±0.7	9.04±0.92	4.1±0.2	<0.05
Psychological factor	16.1±1.9	9.1±0.58	4.3±0.2	9.9±0.71	3.9±0.4	<0.05
Social factor	8.47±2.1	3.84±0.31	3.3±0.1	4.2±0.77	2.7±0.22	<0.05

According to the data of the CIVIQ-20 questionnaire, patients feel better physically, psychologically and socially 3 months after performing hybrid thermoablation operations than after RFA. This is explained by the residual phenomena of varicose veins in the form of enlarged collateral veins on the leg after RFA.

Thus, hybrid thermal ablation operations (RFA in combination with EVLK) are superior to RFA in terms of quantitative and qualitative indicators.

Conclusions: 1. A comprehensive visual and sonographic assessment of the condition of the GSV

and its collaterals is necessary to choose the use of RFA or hybrid thermoablation in outpatient conditions.

2. The use of hybrid thermal ablation for the treatment of varicose veins of the lower extremities, in outpatient conditions, is more effective than RFA in terms of qualitative and quantitative indicators.

Prospects for further research. Taking into account the performance of thermal ablation operations in outpatient (office) conditions, there is a need to substantiate the indications and methods of minimally invasive operations on perforating veins.

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ЕФЕКТИВНІСТЬ КОМБІНОВАНОГО ЗАСТОСУВАННЯ РАДІОЧАСТОТНОЇ ТА ЕНДОВЕНОЗНОЇ ЛАЗЕРНОЇ АБЛЯЦІЇ ВЕН У ЛІКУВАННІ ВАРИКОЗНОЇ ХВОРОБИ НИЖНІХ КІНЦІВОК

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РЕЗЮМЕ. Радіочастотна абляція (РЧА) та ендовенозна лазерна коагуляція вен (ЕВЛК) мають пріоритетне значення у лікуванні варикозної хвороби нижніх кінцівок (ВХНК) в амбулаторних умовах. Хоча показання до цих операцій та технологія їх застосування визначені, актуальним є питання покращення їх функціональних результатів, зокрема інволюція колатеральних вен на гомілці після абляції великої підшкірної вени.

Мета – покращити результати лікування варикозної хвороби в амбулаторних умовах шляхом застосування комбінації радіочастотної та ендовенозної лазерної абляції вен.

Матеріал і методи. Під спостереженням знаходились 154 хворих, які були прооперовані за допомогою РЧА з приводу ВХНК, та 111 пацієнтів, яким була виконана комбінована термоабляція великої підшкірної вени РЧА (на стегні) та ЕВЛК (на гомілці).

Для порівняння ефективності РЧА та комбінації РЧА з ЕВЛК (гібридна термоабляція вен) проведена кількісна та якісна оцінка їх результатів. Зокрема, кількісна оцінка виконана з використанням ряду шкал VCSS, VDS, VSDS, VSS. Для якісної оцінки були застосовані опитувальники: MOS SF-36 та CIVIQ-20. Результати операцій оцінювались через 3, 6 місяців та через рік після їх виконання.

Результати. Аналіз результатів операцій свідчить, що за кількісними та якісними показниками комбіновані операції з одночасним застосуванням РЧА та ЕВЛК ефективніші, ніж РЧА. На ці показники безпосередньо впливала кількість залишкових вен через 6 місяців спостереження (33,1 % після РЧА та 5,4 % після гібридної термоабляції).

КЛЮЧОВІ СЛОВА: варикозна хвороба; радіочастотна абляція; комбінація радіочастотної абляції з ендовенозною лазерною коагуляцією вен; кількісна та якісна оцінка операцій.

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