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## STEM RADIOFREQUENCY MONOABLATION IN THE TREATMENT OF DECOMPENSATED FORMS OF VARICOSE VEINS OF THE LOWER EXTREMITIES

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**Ключові слова:** *варикозна хвороба, радіочастотна абляція, венозна гемодинаміка, трофічні виразки, моноабляція*

**Ключевые слова:** *варикозная болезнь, радиочастотная абляция, венозная гемодинамика, трофические язвы, моноабляция*

**Abstract. Stem radiofrequency monoablation in the treatment of decompensated forms of varicose veins of the lower extremities. Kutovyi O.B., Sokolov O.V.** Main recommendations in treatment of decompensated forms of varicose veins of the lower extremities, accompanied with the formation of trophic ulcers (stage C6 according to CEAP classification) are the use of compression therapy and various surgical procedures. In this case, the way of choosing a treatment tactic, taking into account the characteristics of venous circulation in the limbs, remains to be incomplete in every single case. The aim of the work is comparative evaluation of the results of using radiofrequency (RF) ablation of the trunk of the saphenous vein in patients with varicose veins of the lower extremities in stage C6, provided that pathologically altered tributaries are preserved or removed. The study included 59 patients with varicose veins of the lower extremities in stage C6, with reflux in the large saphenous vein pool. The total number of men was 17 (28.8%), women – 52 (71.2%). The age of patients ranged from 44 to 87 years (mean age 59.9±7.9 years). The average area of trophic ulcers was 9.6±5.7 cm<sup>2</sup>. During analysis of postoperative complications on day 7, hematomas and ecchymoses appeared in 29 (96.7%) patients of group I and only in 8 (27.6%) patients of group II. 1 month after the operation, hematoma residues were observed in 3 patients (10%) of I group and were absent in patients of II group. Also, in the postoperative period (day 7 and 1 month), we observed neuropathy phenomena in 3 (10.0%) patients of I group and 1 (3.45%) of a patient of II group. At the end of the follow-up period (6 months), neuropathy phenomena persisted in 2 (6.7%) patients of I group, while they were absent in patients of II group. During the first month after surgery, patients showed a significant decrease in leg swelling by 2.4% in I group and by 3.9% in II group. 1 month after the initial intervention, residual varicose-deformed inflows appeared in 5 patients (16.7%) of I group, and in 12 patients (41.4%) of II group ( $p < 0.005$ ). Relapse of an ulcer 6 months after surgery was detected in 2 (6.7%) patients of I group. Comparative results of stem RF monoablation and combined surgery using miniphlebectomy were comparable in terms of the degree of elimination of vertical reflux, reducing the severity of CVI (chronic vein insufficiency, the number of relapses of varicose veins, the healing speed and the frequency of relapse of trophic ulcers. Moreover, the performance of RF monoablation was accompanied by a significant reduction in the volume of drugs for local anesthesia, leading to a more significant decrease in the intensity of pain after surgery, the number of complications, in particular neuropathy, and to improvement in the quality of life. The number of additional sources of pathological horizontal reflux along incompetent perforating veins and residual varicose-deformed tributaries after surgery requiring corrective interventions were comparable in both groups. Thus, the presence of horizontal reflux is not critical when choosing the method of primary surgical intervention.

**Реферат. Стволовая радиочастотная моноабляция в лечении декомпенсированных форм варикозной болезни вен нижних конечностей. Кутовой А.Б., Соколов А.В.** При декомпенсированных формах варикозной болезни вен нижних конечностей, сопровождающихся образованием трофических язв (стадия С6 по классификации CEAP), главными рекомендациями в лечении являются использование компрессионной терапии и разных вариантов хирургических вмешательств. При этом вопрос выбора тактики с учетом особенностей венозного кровообращения в конечностях в каждом случае остается открытым. Цель работы: сравнительная оценка результатов использования радиочастотной абляции ствола большой подкожной вены у больных варикозной болезнью нижних конечностей в стадии С6 при условии сохранения или удаления патологически измененных притоков. В исследование вошли 59 больных варикозной болезнью вен нижних конечностей в стадии С6, с рефлюксом в бассейне большой подкожной вены. Общее количество мужчин было 17 (28,8%), женщин – 52 (71,2%). Возраст больных колебался от 44 до 87 лет (средний возраст 59,9±7,9 года). Средняя площадь трофических язв составила 9,6±5,7 см<sup>2</sup>. При анализе послеоперационных осложнений на 7 сутки гематомы и экхимозы проявились у 29 (96,7%) больных I группы и только у 8 (27,6%) больных II группы. Через 1 месяц после операции остатки гематом наблюдались у 3 больных (10%) I группы и отсутствовали у больных II группы. Также в послеоперационном периоде (7 день и 1 месяц) мы наблюдали явления нейропатии у 3 (10,0%) больных I группы и 1 (3,45%) больного II группы. В конечный срок наблюдения (6 месяцев) явления нейропатии сохранились у 2 (6,7%) больных I группы, тогда как у больных II группы они отсутствовали. В течение первого месяца после операции у больных было отмечено заметное уменьшение отека голени - на 2,4% в I группе и на 3,9% во II группе. Через 1 месяц после проведения первичного вмешательства остаточные варикозно-деформированные притоки проявились у 5 больных (16,7%) I группы и у 12 больных (41,4%) II группы ( $p < 0,005$ ), хотя при этом наполненность притоков вен и их визуальные проявления стали меньше после проведения абляции ствола. Рецидив язвы через 6 месяцев после операции был констатирован у 2 (6,7%) больных I группы. Сравнительные результаты стволовой РЧ-моноабляции и комбинированной операции с использованием минифлебэктомии были сопоставимы в части степени ликвидации вертикального рефлюкса, снижения тяжести ХВН, количества рецидивов варикозного расширения вен, скорости заживления и частоты рецидивов трофических язв. При этом выполнение РЧ-моноабляции сопровождалось значительным сокращением объема препаратов для местной анестезии, приводило к более значительному снижению интенсивности болевого синдрома после операции, количества осложнений, в частности нейропатии, и к улучшению качества жизни. Количество дополнительных источников патологического горизонтального рефлюкса по несостоятельным перфорантным венам и остаточных варикозно-деформированных притоков после операции, требующих проведения корригирующих вмешательств, были сопоставимы в обеих группах. Таким образом, наличие горизонтального рефлюкса решающего значения при выборе метода первичного хирургического вмешательства не имеет.

In decompensated forms of varicose veins of the lower extremities, which are accompanied by the formation of trophic ulcers (stage C6 according to the CEAP classification), the main treatment recommendations that affect the healing of trophic ulcers are the use of compression therapy and surgery to eliminate reflux [6]. The results of international clinical trials and meta-analyses confirm the advantages of endovenous techniques over open surgical ones, in particular due to the possibilities of more accurate consideration of individual hemodynamic features and intraoperative ultrasound monitoring [9]. Radiofrequency ablation (RFA) of subcutaneous vein trunks is increasingly used as a method alternative to laser ablation (EVLA) [5]. Due to the lower peak temperature load and hardware support of working energy dosing, the RFA method is characterized by less manifestations of pain, ecchymoses, postoperative neuropathies and fewer relapses in the 5-year observation period [2, 10]. The main condition for the treatment of varicose veins of the lower extremities is the correction of vertical reflux in the superficial venous system through the use of various surgical approaches, such as stem monoablation and combined interventions [7, 8]. At the same time the question of a choice of tactics in each case, taking into account features of venous blood circulation in extremities, remains open.

The aim of the study was to compare the results of radiofrequency ablation of the trunk of the great saphenous vein in patients with varicose veins of the lower extremities in stage C6, in the event of the preservation or removal of pathologically altered tributaries.

#### MATERIALS AND METHODS OF RESEARCH

The study included 59 patients with varicose veins of the lower extremities in stage C6, with reflux in the basin of the great saphenous vein, who underwent treatment on the basis of the Department of Vascular Surgery MI "Regional Clinical Hospital named after I.I. Mechnikov" (Dnipro), MI "City Hospital N 16" DRC and MC "JMC". The total number of men was 17 (28.8%), women – 52 (71.2%). The age of patients ranged from 44 to 87 years (mean age  $59.9 \pm 7.9$  years). The average area of trophic ulcers was  $9.6 \pm 5.7$  cm.

Criteria for inclusion in the study were: chronic venous disease confirmed by USR by registered reflux in the great saphenous vein in stage C6 according to the CEAP classification. Exclusion criteria: deep vein thrombosis at the time of examination or in the anamnesis; impairment of arterial blood flow with the disappearance of the pulse in more than one of the arteries of the foot; recurrent erysipelas; malignant ulcers; decompensated arterial

hypertension with average daily blood pressure above 160/100 mmHg.

As a part of preoperative inspection, case-history taking, examination of the patient, photofixation of the general pathological changes on the extremity, an assessment of severity of chronic disease of veins on the VCSS scale (Venous Clinical Severity Score) were carried out. The preoperative risk of thrombotic complications was calculated using the Caprini scale. The intensity of tibial edema was determined by measuring the size of their circumference at the level directly above the medial bone [1, 3, 4, 11]. Each patient underwent screening ultrasound (US) in the vertical and horizontal position in accordance with the requirements of the UIP 2012. The number and parameters of sources of reflux in the superficial venous system, the ways of its spread and re-entry points, that entered into the scheme of venous hemodynamics were identified. The presence of pathological vertical venous reflux of blood was recorded by the duration of retrograde blood flow at standard points under the terminal valve lasting more than 1 sec., in diastole after compression of the calf muscles. Additionally, the diameter of the sapheno-femoral junction was measured in the vertical position of the patient.

Ultrasound screening and intraoperative monitoring were performed using General Electric Logiq E scanners with a 5-7 MHz linear sensor and General Electric Voluson scanners with a 5-7 MHz linear sensor.

To assess the condition of ulcers planimetry and measurement of their depth, as well as the results of microbiological studies were used. The area of the ulcers was measured by photofixing the soft tissue defect, followed by calculating the area of the irregular shape using a specialized application LesionMeter for iOS.

Patients were divided into two groups. Group I included 30 patients who underwent RFA of the GSV trunk with simultaneous removal of varicose deformed tributaries after ultrasound mapping of venous hemodynamics of the limb. Group II included 29 patients who underwent thermal endovenous monoablation, while varicose-deformed tributaries were not removed at once. At the beginning of the survey, groups of patients were comparable according to the main criteria.

For the purpose of anesthesia, local paravenous tumescent anesthesia with Klein's solution was used using an ultrasonic control pump.

All patients were prescribed standard conservative treatment, which included compression therapy (compression class II), Detralex 1000 mg per day for the entire treatment period, change of

dressings for postoperative wounds and ulcers (if available), recommendations on lifestyle and activity in accordance with current clinical and practical recommendations [4].

Postoperative follow-up in the study lasted for 6 months: daily for 1 week, 1 month and 6 months after surgery. Particular attention was paid to the occurrence of recurrences of ulcers and varicose symptom complex in the form of residual varicose-deformed tributaries.

Attention was paid to the intensity of the pain syndrome, which was measured using a 10-point analog visual scale.

After the surgery, patients of both groups underwent ultrasound control of the venous system of the lower extremities in order to determine the effectiveness of ablation using the Valsava test and compression of the tibial muscle pump, detection of recanalization of the trunk, the presence of residual functioning sources of reflux, thermal (EHIT) and venous thrombosis on day 7, 1 month and 6 months after surgery.

Statistical processing of the results was performed using Microsoft Excel software packages (License: Microsoft Office 365 subscription, ID 02984-001-00000), StatPlus: mac (AnalystSoft Inc., StatPlus: mac. Version 6, License: # 12083386).

The mean values  $[M \pm m]$ , the reliability of the mean values according to the Student's t test (t) were determined. The difference between the indicators at  $p < 0.05$  was considered statistically significant. Pearson's linear correlation coefficient and its signi-

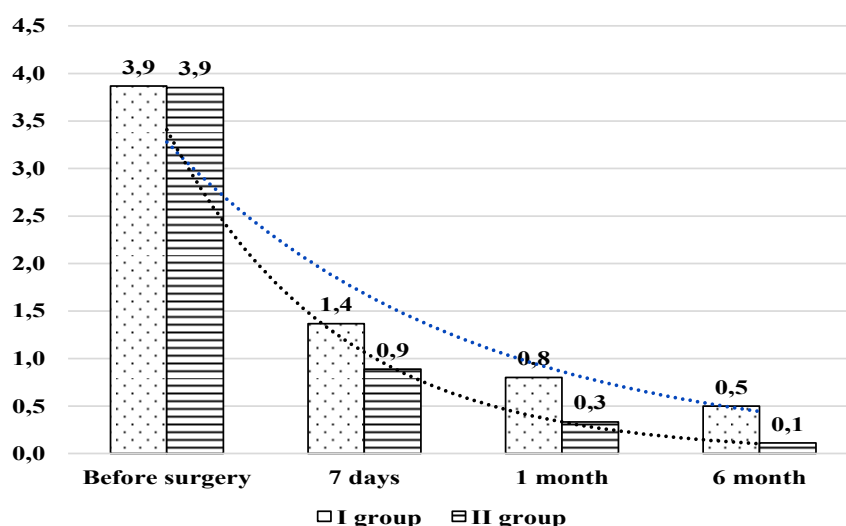
ficance were used to estimate the degree of linear dependence of variables.

## RESULTS AND DISCUSSION

As a result of the study, we obtained the following data. The average duration of surgery in group I was  $1.4 \pm 0.3$  hours, in group II  $0.6 \pm 0.3$  hours. The amount of Klein's solution used in patients of group I was  $1.2 \pm 0.2$  liters against  $0.8 \pm 0.2$  liters in group II.

In the analysis of postoperative complications on day 7, hematomas and ecchymoses appeared in 29 (96.7%) patients of group I and only in 8 (27.6%) patients of group II. One month after surgery, hematoma remnants were observed in 3 patients (10%) of group I and were absent in patients of group II. Also in the postoperative period (7 days and 1 month) we observed neuropathy phenomena, such as burning pain, itching and numbness of the skin in 3 (10.0%) patients of group I and 1 (3.45%) patient of group II. At the end of the observation period (6 months), the phenomena of neuropathy persisted in 2 (6.7%) patients of group I, while in group II they were not observed.

Within 6 months after surgery, thrombotic complications in the form of thrombophlebitis of the unremoved tributary were detected in 3 (10.0%) patients of group I and 2 (6.9%) patients of group II. No cases of EHIT, deep vein thrombosis and pulmonary embolism have been reported. The average intensity of postoperative pain measured using a visual analog scale during the entire observation period was slightly higher in patients of group I, as shown in Figure 1.



Note: Compared data of group I and II  $p < 0.05$

Fig. 1. Intensity of postoperative pain syndrome

At the same time, one week after the surgery, the manifestations of pain decreased by 64.1% in group I and by 76.9% in group II. At the end of the observation period, the manifestations of pain persisted in 2 (6.7%) patients of group I and 1 (3.5%) patient of group II and were associated with incomplete ulcer healing. Some prevalence of pain in the postoperative period among patients of group I is probably due to the greater trauma of the used technique.

During the first month after surgery, patients showed an intensive reduction in leg edema – by 2.4% in group I and by 3.9% in group II. The mean intensity of edema was comparable in both groups during the entire observation period. There were no cases of increased edema due to the development of postoperative complications. The results are presented in Figure 2.

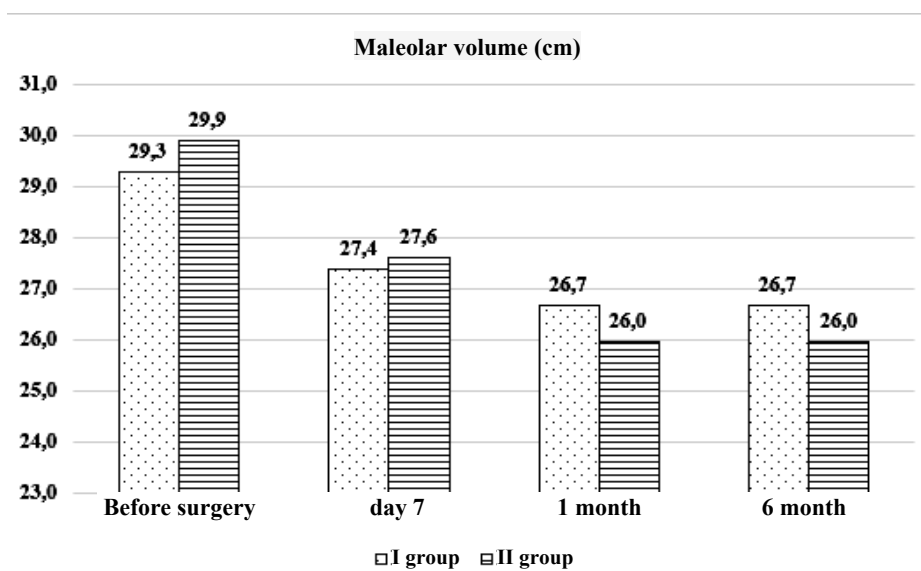


Fig. 2. Intensity of edema in postoperative period

Six months later, the difference between VCSS indicators was  $2.0 \pm 0.3$  in group I against  $0.9 \pm 0.2$  in group II, being equal to 55% (Fig. 3).

When conducting ultrasound examinations after surgery for up to 1 month, no signs of trunk reca-

nalization in both groups were detected, but the phenomenon of horizontal reflux for more than 1 second in the incapable perforating veins that supply tributaries were recorded in 5 patients (16.7%) of group I and in 12 patients (41.4%) of group II.

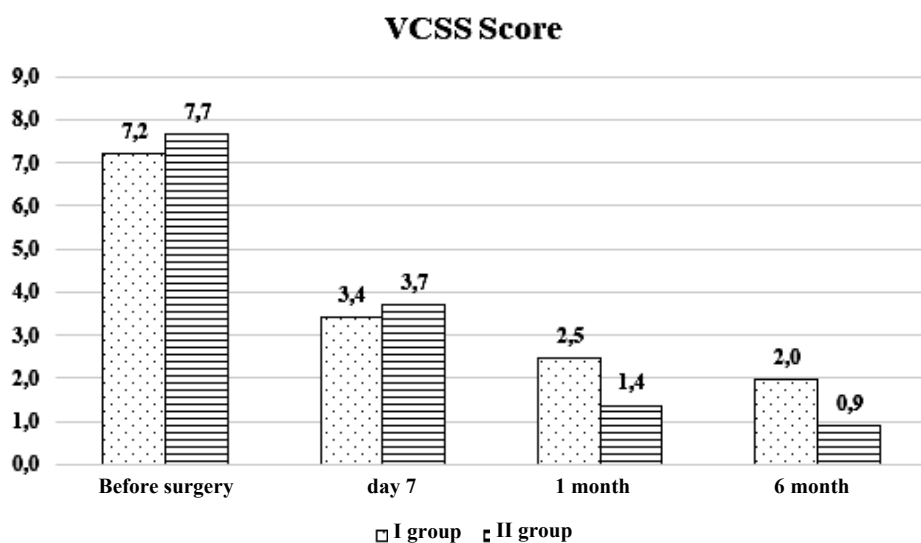


Fig. 3. Severity index of chronic disease of veins in postoperative period

At the stage of preoperative ultrasound scan, in addition to pathological vertical reflux, which was registered in the trunk of the great saphenous vein, reflux along incompetent perforating veins of different groups for more than 1 second was registered in 19 (63.3%) patients of group I and 21 (72.4%) patients of group II.

One month after the primary intervention, residual varicose-deformed tributaries appeared in 5 patients (16.7%) of group I and in 12 patients (41.4%) of group II  $p < 0.005$ , although the fullness of venous tributaries and their visual manifestations became smaller after ablation of the trunk.

It should be noted that in patients of group II unremoved residual inflows appeared only in those patients in whom the screening ultrasound scan had a significant, more than 2 seconds, additional horizontal reflux through the feeding failed perforating veins, which was detected in 5 (16.7%) patients of group I due to the manifestations of recurrent inflows and in 6 (17.2%) patients of group II. In all these patients, corrective foam echo-sclerotherapy of perforating veins and miniphlebectomy of varicose-deformed tributaries were planned and performed.

In areas with indicators of horizontal reflux less than 2 seconds, after the surgery in 14 (46.6%) patients of group I and in 15 (51.7%) patients of group II failure of perforating veins was not further recorded, and inflows visually disappeared.

The rate of epithelialization of ulcers throughout the observation period was comparable in both groups, making up  $44.3 \pm 6.7$  days (group I) and  $45.2 \pm 6.2$  days (group II). Therewith during the first month, the ratio of the area of the ulcer, which characterizes its decrease compared to the state before surgery in patients of group I in  $2.2 \pm 0.3$  cm

( $p > 0.005$ ), in patients of group II in  $2.1 \pm 0.4$  cm ( $p > 0.005$ ). After 6 months, the number of healed ulcers in group I was 19 (63.3%) cases and 20 (69.0%) cases in group II. Incomplete healing of ulcers in patients of both groups was accompanied by the phenomena of early exudation and local inflammation in 4 (13.3%) cases in group I and in 2 (6.9%) cases in group II.

Recurrence of ulcer 6 months after surgery was noted in 2 (6.7%) patients of group I. It should be noted that both patients did not follow the recommendations for wearing compression stockings.

## CONCLUSIONS

1. Comparative results of trunk RF monoablation and combined surgery using miniphlebectomy were comparable in terms of the degree of elimination of vertical reflux, reduction of CVI severity, healing rate and recurrence rate of trophic ulcers, the number of recurrences of varicose veins. At the same time, RF monoablation was accompanied by a significant reduction in the volume of drugs for local anesthesia and led to a more significant reduction in the intensity of pain after surgery, the number of complications, including neuropathy, and better quality of life.

2. The number of additional sources of pathological horizontal reflux through failed perforating veins and residual varicose-deformed inflows after surgery, which required corrective interventions were comparable in both groups. Thus, the presence of horizontal reflux is not crucial when choosing the method of primary surgery.

Conflict of interest. The authors declare no conflict of interest.

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