A complex minimally invasive approach to the treatment of patients with complicated forms of chronic venous insufficiency

The aim of the work: to determine the effectiveness and results of the clinical application of EVEZ with the local treatment of CVI of complicated TV with the help of PRP; to increase the level of efficiency and safety of treatment of patients with CVI.

Materials and Methods. The results of 112 EVEW operations in 93 patients with CVI C5–C6 were analyzed. EVEW of the GSV was performed in 90 cases, SSV in 22. The diameters of the jugular segments of the veins were 5.7–28.4 mm, the area of the VLU was 8–84 cm². The EVEW device provides electrothermal ablation of veins due to denaturation of the venous wall. The duration and power of EVEW is determined automatically, according to the coefficient of relative resistance. The proposed method of preoperative preparation speeds up the processes of VLU cleaning and regeneration.

Results and Discussion. PP is absent in 74 (66.1%) cases, moderate PP in 38 (33.9 %). After 2 years, fibrosis of target veins in 100 % of cases. Paresthesia lasting up to 14 days in 4.5 %. The proposed algorithm of preoperative preparation led to the clearing of the VLU in (14±7.6) days and healing in (27±4.5) days in 95 % of patients. Automatic EVEW algorithm allows to increase the level of efficiency and safety of surgical treatment of patients with veins of large diameters and their extrafascial location, severe forms of CVI with VLU. The use of a complex of preoperative preparation made it possible to achieve complete clearing of the VLU in 90 % of patients by (14±7.6) days. Injections of PRP in the VLU area and the use of EVEW led to epithelization in (27±4.5) days in 95 % of patients.

Key words: chronic venous insufficiency; endovenous welding; great saphenous vein; trophic ulcer; platelet rich plasma.

Introduction. Chronic venous insufficiency (CVI) is a constantly progressive disease, the basis of which is the weakness of the vascular wall and the failure of the valve apparatus, which leads to stagnation of venous blood in the lower extremities. CVI is manifested by heaviness in the lower extremities, edema, pain, which over time leads to changes in the skin and subcutaneous tissue in the form of hyperpigmentation, lipodermatosclerosis, and venous leg ulcer (VLU). Varicose disease (VD) of the lower extremities occur in 25–40 % of the adult population in the world and are one of the most common pathologies [1]. The presence of irreversible trophic changes against the background of CVI sharply reduces the quality of life and changes the lifestyle of patients. According to 2019 data, VD occurs in 51.9 % of women and 39.4 % of men [2]. The number of patients with CVI increases with age and tends to more severe manifestations in the older age group. VLU of venous etiology occurs in 85 % of all ulcers of the lower extremities [3]. According to financial management data, about $3 billion is spent in the USA every year on the treatment of patients with VLU on the background of CVI, which also leads to temporary disability and loss of 2 million working days [4]. The number of patients with CVI and its complications is constantly increasing every year in light of the aging of the population, which is a serious socio-economic problem and requires the development of new, effective ways to solve it.

Thermal ablation with the use of endovenous laser ablation (EVLA) or radiofrequency ablation (RFA) is currently recognized as a reference method for the elimination of pathological veno-venous reflux in the treatment of patients with CVI [5]. The success of using thermal ablation, as well as the development of possible unwanted effects and complications, primarily depend on the accuracy of the dosage of thermal energy that is absorbed by the venous wall and paravascular tissues [6,7]. In this regard, in order to improve the efficiency and safety of thermal ablation methods, the search for ways to improve the ablation energy management algorithm is of the greatest importance. The optimal solution to this problem can be the use of an automatic algorithm for controlling the thermal ablation process, which is implemented in our proposed endovenous welding (EVEW) method. This method allows to solve the problem of vertical venous reflux along the trunks of the main superficial veins of the lower extremities in a minimally invasive, quick, comfortable and painless way for the patient and to eliminate the manifestations of CVI in the shortest possible time.

The EVEW method is based on the technology of electric welding of living tissues and involves the ablation of incompetent subcutaneous venous trunks under the influence of high-frequency modulated electric current, the parameters of which during the operating cycle (OC) are generated automatically depending on the impedance dynamics and structural changes of the venous wall [8]. Unlike other methods of thermal ablation, EVEW does not require the operator to select, adjust and control exposure parameters,
The aim of our study was to determine the effectiveness and results of the clinical application of the EVEW method in combination with local treatment of VLU using PRP in the early and long-term follow-up in patients with CVI and its complications; to increase the level of efficiency and safety of treatment of patients with CVI.

Materials and methods. In the period from 2018 to 2022, a total of 806 operations were performed on 722 patients with CVI using the EVEW method at the clinical bases of the Department of Surgery and Vascular Surgery of the P. L. Shupyk National Hospital of Ukraine. During the observation period of 3 years, the results of 112 operations performed on 93 patients with CVI C5–C6 (35 men, 58 women aged 31 to 66 years) were studied. In 84 patients, trophic ulcers of venous etiology of various localization were found, in the remaining patients, the ulcers were already healed. Operations on both limbs of the same patient were performed in 26 cases. Due to the fact that operations on both limbs were not performed simultaneously, each operation was considered as a separate clinical case.

EVEW of the great saphenous vein (GSV) was performed in 90 cases. Depending on the spread of pathological reflux, EVEW of the trunk of the GSV was performed within the thigh in 35 cases, up to the upper third of the lower leg – in 38 cases, up to the middle third of the leg – in 17 cases, including: the EVEW method was used in 19 cases of extrafascial location of the GSV trunk on the thigh and lower legs. EVEW of the small saphenous vein (SSV) was performed in 22 cases. The length of the target segments of the veins was from 8.7 to 50.5 cm. The diameters of the jugular segments of the GSV and SSV were from 8.2 to 28.4 mm and from 5.7 to 10 mm, respectively. The area of VLU ranged from 8 cm² to 84 cm². In most patients, the ulcer was located on the medial side of the leg – in 22 cases, with trophic ulcers of venous etiology of various localization were found, in the remaining patients, the ulcers were already healed. Operations on both limbs of the same patient were performed in 26 cases. Due to the fact that operations on both limbs were not performed simultaneously, each operation was considered as a separate clinical case.

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the ablation zone according to a digital rating scale; US data (occlusion, fibrosis, recanalization); complications (burns, deep vein thrombosis, thrombophlebitis in the ablation zone, neurological complications, cosmetic defects); terms of cleaning and healing of a VLU. Recurrences of the disease not related to the result of ablation of the GSV and SSV trunks (horizontal reflux progression) were not taken into account in the study.

Structure of the device for EVEW
The device for EVEW consists of a current generator – a multipurpose device EK 300M "Swarmed" (Ukraine) and a welding endovenous tool (WET) of the original design [11]. The working part of the WET is a bipolar configuration of electrodes with a diameter of 2 to 3 mm and a length of up to 5 cm, which is adapted for puncture import using 9–10 Fr introducers.

Scheme of operation of the automatic mode of EVEW
High-frequency voltage is generated according to the "automatic welding" mode; the potential difference is applied to the electrodes of the working part of the WET. The current that flows between the electrodes and throughout the venous wall causes its heating during RT, which leads to spasm and closure of the vein as a result of dehydration and denaturation of the protein components of the venous wall.

OC is carried out at a voltage from 10 to 100 V, an alternating current frequency from 50 to 500 kHz, with modulation from 0.1 to 250 kHz, with tissue resistance from 0.1 to 1000 Ω, heating of the venous wall preferably within 55–80 °C, heat distribution depth of 1.5–2 mm. The duration of OC in each separate section of the vein is determined by the coefficient of relative resistance according to the formula: 

\[ k = \frac{R(t)}{R_0(t_0)} \]

where \( R(t) \) is the current resistance, \( R_0(t_0) \) is the initial resistance. When the corresponding value of "k" is reached, which is fixed by the data processing and control unit, the device stops the OC.

The technique of EVEW
The import of the WET is performed under ultrasound control using Klein's solution or 0.125 % bupivacaine hydrochloride solution in a volume of up to 10 ml per 1 cm of vein. Thus, in addition to anesthesia, extravasal compression of the vein is carried out and optimal contact of the venous wall and the working part of the WET is ensured. In elderly patients and patients with corresponding concomitant diseases (hypertensive disease, chronic lung diseases, diabetes, etc.), surgical interventions, in addition to tumescent anesthesia, were performed under superficial sedation with the use of propofol under the supervision of an anesthesiologist.

After ultrasound control of the position of the working part of the WET, the operator activates the device, which is accompanied by a sound signal that continues until the end of the OC. The ablation takes place in the area of the vein, the length of which is equal to the length of the working part of the WET and is 5 cm. The process is monitored with the help of an ultrasound sensor, which is located above the welding zone. After completion of the OC, the tool is moved to the next section at a distance of 5 cm, where the process is repeated along the entire length of the target segment of the vein. The operation can be supplemented with miniphlebectomy or phlebosclerosis and ends with elastic compression of the limb.

Preoperative preparation of VLU
In order to clean a trophic ulcer, an individual selection of wound coverings was applied to each patient, depending on the volume of exudation and the stage of the wound process. In patients with trophic ulcers that were without proper care and the presence of necrotic masses in the wound, mechanical debridement was first performed using a povidone-iodine+ethanol+glycerol+laurate 9 solution. After that, the wound surface was cleaned with an antiseptic with proteolytic enzymes 0.1 % polyanaminopropyl biguanide + 0.1% surfactant, which allows you to significantly reduce the bacterial load of the container and eliminate biofilm. After that, treatment was carried out with the use of occlusive hydrogel dressings for a period of 2 to 4 days. Replacement of occlusive dressings was repeated until the wound was cleaned and its water balance was restored. After that, atraumatic primary wound dressings made of hydrophobic polyester material and hydroactive colloidal gel in combination with PRP were used to preserve and stimulate granulation.

Algorithm of preparation and application of PRP
After cleaning the VLU from necrotic masses and the appearance of signs of granulation, PRP was obtained from the patient's autologous blood by double centrifugation. In order to rule out thrombocytopenia, the level of platelets in the blood was determined before preparing PRP. With a two-sided butterfly needle 0.8×19 mm, whole venous blood was collected in a volume of 8 ml into a vacuum glass tube with the an-
ticoagulant Sodium Citrate 3.8%. After mixing the blood with citrate in the test tube, the first centrifugation was performed with an acceleration of 186G for 10 minutes. After centrifugation with an anticoagulant, the sedimented plasma with platelets was collected and transferred to a test tube without an anticoagulant, and repeated centrifugation was performed with an acceleration of 744G for 15 minutes to obtain a platelet concentrate. From the second test tube, we took the upper 2/3 of the plasma, which was pure platelet plasma. Concentrated platelets settled in the lower part of the test tube, where they were collected from a small part of the plasma, after which they were thoroughly mixed. After double centrifugation, we obtained about 1 ml of PRP with a platelet concentration of 1.45–1.58×10^9 ml. Compliance with all requirements for the preparation of PRP and the correct selection of centrifuge acceleration and centrifugation duration allow you to achieve the target level of platelets in the final volume of plasma and the predicted result of VLU treatment. PRP injections were performed along the edge of the VLU to a depth of up to 5 mm with a G20 needle on the 7th and 14th day of treatment.

The main biologically active component of PRP is a platelet, which contains three main types of granules: lysosomes, dense granules and α-granules [12,13]. Such a multicomponent composition explains all other physiological effects of the platelet and not only as one of the factors of aggregation, as we used to think.

Three-dimensional ultrastructural studies of the location of the grain in the platelet revealed that dense granules are formed faster, but α-granules are released more slowly [14,15]. The rapid formation and release of dense granules is due to their morphological location near the plasma membrane, while α-granules are located in the center of the platelet, in groups at a short distance from each other [14,15]. The main role and functional activity in platelets is played by α-granules, and the result of PRP application depends on their number and activity. Therefore, even under the standardized conditions of PRP preparation and the same concentration of platelets in the produced plasma, we get different treatment results.

Results Discussion. The duration of OC in different areas of the GSV and SSV during operations ranged from 5 to 12 seconds. During this time, the development of ultrasound signs of occlusion was observed (spasm, thickening of the venous wall and the formation of hyperechoic masses that block the lumen of the vein). In addition, the presence of spasm and vein overlap was evidenced by the feeling of resistance when extracting the WET from the welding area after completion of the OC, as well as the feeling of obstruction when trying to move the WET in the opposite direction.

After the operations, there was no violation of the general condition and function of active gait in any case. Absence of PP in the ablation zone was registered in 74 cases (66.1%). The intensity of PP in the remaining 38 cases (33.9%) was (3.14±1.23) points (moderate pain), including in all patients after ablation of the extrafascial part of the GSV. The period of regression of PP in all cases did not exceed 12 hours.

During the first month of observation, ultrasound signs of stable occlusion of the target segments of the GSV and SSV were determined in all patients. Fibrosis of individual areas of veins was determined after 1 month in 26 (28.9%) cases. Within 3 to 6 months, fibrosis of the target segments of the veins was determined in all cases of EVEW application. At the same time, all patients had a characteristic US picture of "thermal crossectomy".

Ultrasound signs of fibrosis of the target segments of the GSV and SSV remained in all (100%) patients 1 year after surgery. Along with successful ultrasound results, satisfactory cosmetic results and regression of clinical symptoms of CVI were noted in all patients.

3 years after surgery, a successful ablation result was maintained in all (100%) cases of SSV welding and in 87 (96.7%) cases of GSV welding. Recanalization with the restoration of segmental reflux on the esophageal segments of the GSV and the associated recurrence of CVI were determined in 3 (3.3%) cases.

Severe complications in the form of burns, deep vein thrombosis, and thrombophlebitis of the target segments of the GSV and SSV were not noted in any case. All patients experienced ecchymosis of the skin in the projection of the target veins of the GSV within 5 to 10 days. These specific effects of tumescent anesthesia regressed independently and had no effect on the intensity of PP, active gait function, and treatment outcomes.

Neurological complications in the form of paresis, neuralgia and long-term paraesthesiae were not observed in any case. Temporary paraesthesiae lasting up to 14 days were observed in 5 (4.5%) cases – 3 after GSV welding and 2 after SSV welding. Hyperpigmentation of the skin over the welding areas occurred in 3 out of 19 cases of EVEW application in relation to the extrafascial segments of the GSV. These cosmetic defects were limited in nature and regressed on their own during the first 2 months after surgery.

It is important to note the positive dynamics of regression of clinical symptoms in patients with C5-C6 class of CVI. The use of a complex of preoperative preparation of VLU, pretreated with an antiseptic with surface-active substances that destroy the biofilm
and maintain the water balance and the installation of occlusive hydrogel dressings, has shown its high efficiency with EVEW.

It is important to use PRP, which significantly accelerates the processes of granulation tissue formation and TV regeneration. With the use of the proposed technique of preoperative preparation of the VLU, it was possible to achieve its cleaning and stabilization of wound processes in (8±2.4) days. Complete clearing of VLU was noted in 90 % of patients by (14±7.6) days of treatment. Healing of the trophic ulcer occurred in (27±4.5) days in 95 % of patients in combination with EVEW of target segments of veins. Only one patient with a VLU area of 78 cm² required additional autodermoplasty to accelerate its closure.

Thus, the use of PRP in patients with long-term non-healing ulcers significantly accelerates the processes of regeneration and neoangiogenesis, which, in combination with EVEW, allows to achieve positive treatment results in a short period of time.

According to the results of our research, it was established that the EVEW method allows creating a controlled zone of high-frequency modulated current flow in the vein lumen, which initiates heating and denaturation of the protein components of the venous wall and leads to vein ablation [9]. It was demonstrated for the first time that, unlike other methods of process control, ablation occurs automatically through a feedback loop. The duration and power of OC welding is determined automatically in accordance with the dynamics of the resistance value, as an objective indicator of structural changes in the venous wall. At the same time, the maximum power of EVEW develops at the moment of minimal resistance of the venous wall and subsequently decreases as the resistance increases. In the conditions of optimal contact of the working part of the WET and the vein, the completion of the OC welding always occurs at the moment of the development of denaturation of the venous wall, regardless of the diameter of the vein [9,10]. Thus, the influence of subjective factors on the result of ablation is limited by the choice of the access point and the position of the working part of the tool and the technique of performing tumescent anesthesia. The results of thermometry and morphological studies showed that the heating of the venous wall in the welding area mostly does not exceed the temperature of protein denaturation [9]. The maximum values of the temperature of the venous wall during OC welding were very short intervals of time (0.02–0.6 s), which did not exceed the values of the time of thermal relaxation of veins according to J. Bergan [16], which, together with the small depth of heat propagation, did not lead to damage of paravasal tissues.

An effective element of CVI treatment is the use of compression knitwear of the second compression class with a pressure of 23–32 mm Hg, which significantly helps in the treatment of trophic ulcers. It is worth noting that in some cases its use is significantly limited, especially in patients with an ankle-brachial index <0.8. The use of compression knitwear as a monotherapy allows to accelerate ulcer healing, but the recurrence rate is 50 % higher compared to surgical elimination of vertical reflux [17]. Since the reduction of venous hypertension in the veins of the lower extremities occurs only with the use of knitwear, the patient’s level of adherence to treatment is important. Often, patients over 70 years of age violate the doctor’s recommendations due to the fact that the process of putting on the jersey is not easy and stop using it. After EVEW, all patients wore a compression garment for 1 month, after which no change in condition was noted and a stable positive effect was achieved.

The level of postoperative pain 1 year after RFA was (5.35±2.47) [18]. We did not observe a significant manifestation of postoperative pain in our patients, and within 12 hours after the operation it was (3.14±1.23) points. The day after the surgery, the patients did not notice any pain in the EVEW area.

The percentage of paresthesias 6 months after RFA was 55.6 % [18]. The use of EVEW reduces the risk of paresthesias in the long-term results, which amounted to 4.5 % within 14 days and were not noted in the future.

According to the results of the meta-analysis, the percentage of confirmed occlusion in the trunk of the target vein after RFA after 3 months is from 93–100 %, on average about 98 % according to the data of various authors [19]. After 6 months, in most studies, the percentage of occlusion was 98.6–100 % [19–23].

During the ultrasound examination of the state of target segments of veins after RFA, 1 year after surgery, recanalization was found in 16.7 %, and in 60 % of cases, technical errors during RFA were the cause, and neovascularization was observed in 30% [18]. In two cases, complete recanalization was detected, and in 3 cases, local recanalization of the distal segments of the GSV and SSV, in one case, local recanalization in the area of the saphenofemoral junction [18]. The results of follow-up of patients after EVEW after 1 year indicate the absence of recanalization in the treated vein segments.

In the studies of Park and Pisano, after one year of observation, the percentage of occlusion after RFA was 76.7–100 % [18, 24].

While the long-term results of obliteration of the target segment of veins vary between studies and at a follow-up period of 36 months is 92.6 % [25], while
another group of researchers found the percentage of persistent vein occlusion to be 100 % [24] at a follow-up period of 5 years. According to the results of the conducted meta-analysis, persistent occlusion of the vein was 87.9 % during the observation period of 2 years [26]. The use of EVEW proved its effectiveness, which is evidenced by the presence of occlusion and fibrosis of the target segment of the vein after 3 years in 96.7 %, only in 3.3 % of cases was the presence of oropharyngeal reflux observed.

We consider the results of the clinical application of the EVEW method to be successful. Compared with other methods, the automatic algorithm of EVEW management showed a low level of PP intensity, the maximum frequency of successful ablation in different periods of observation, and the absence of complications regardless of the diameters of the target vein segments. We did not observe a single case of recanalization in patients with veins larger than 20 mm in diameter. Also, no complications were noted in cases of welding of extranodal segments of the GSV. Along with this, in the opinion of many authors, the possibility of using EVLA and RFA in this contingent of patients is questionable and should cause caution regarding the possibility of developing severe complications [7].

The use of PRP in combination with EVEW made it possible to achieve ulcer healing in 95 % of patients in (27±4.5) days. Treatment of trophic ulcers by means of "classical" dressings and planned surgical intervention to eliminate vertical reflux with the use of stripping of the failed trunk of the subcutaneous veins significantly extends the period of preoperative preparation, rehabilitation and, accordingly, healing of the ulcer, which takes (41±10.3) days.

**Conclusion.** 1. The automatic algorithm in the EVEW method allows to increase the level of efficiency and safety of surgical treatment of patients with severe forms of CVI, to expand the possibilities of using thermal ablation in patients with veins of large diameters and their extranodal location, the presence of trophic ulcers.

2. The use of a complex of preoperative preparation made it possible to achieve cleaning and stabilization of wound processes in the VLU in (8±2.4) days and complete cleaning of the VLU in 90 % of patients by (14±7.6) days of treatment.

3. Injections of PRP in the zone of a trophic ulcer and the use of EVEW of target segments of veins allowed to achieve its epithelization in (27±4.5) days in 95 % of patients.

Declaration of conflicting interests
The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

**LITERATURE**

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КОМПЛЕКСНИЙ МІНІ-ІНВАЗИВНИЙ ПІДХІД ДО ЛІКУВАННЯ ПАЦІЄНТІВ З УСКЛАДНЕНИМИ ФОРМАМИ ХРОНІЧНОЇ ВЕНОЗНОЇ НЕДОСТАТНОСТІ

Мета роботи: визначити ефективність та результати клінічного застосування ЕВЕЗ із місцевим лікуванням ХВН ускладненої ТВ за допомогою PRP; підвищити рівень ефективності та безпеки лікування пацієнтів з ХВН.

Матеріали і методи. Проаналізовано результати 112 операцій ЕВЕЗ у 93 пацієнтів з ХВН С5 – С6. ЕВЕЗ ВПВ виконано у 90 випадках, МПВ у 22. Діаметри пригирлових сегментів вен 5,7–28,4 мм, площа ТВ 8–84 см². Апарат для ЕВЕЗ забезпечує електротермічну абляцію вен за рахунок денатурації венозної стінки. Тривалість і потужність ЕВЕЗ визначається автоматично, відповідно до коефіцієнта відносного супротиву. Запропонований метод передопераційної підготовки пришвидшує процеси очищення та регенерації ТВ.

Результати досліджень та їх обговорення. ПБ відсутній у 74 (66,1 %) випадках, помірний ПБ у 38 (33,9 %). Через 2 роки фіброз цільніх вен у 100 % випадків. Пасента́лії з тривалістю до 14 діб у 4,5 %. Запропонований алгоритм передоперапійної підготовки призвів до очищення ТВ на (14±7,6) день та загостні на (27±4,5) день у 95 % пацієнтів. Автоматичний алгоритм ЕВЕЗ дозволяє підвищити рівень ефективності та безпеки хірургічного лікування пацієнтів із венами великих діаметрів та їх екстрафасціальною локалізацією, тяжкими формами ХВН із ТВ. Застосування комплексу передоперапійної підготовки дозволило досягти повного очищення ТВ у 90 % пацієнтів до (14±7,6) дня. Ін’єкції PRP у зоні ТВ та застосування ЕВЕЗ призвело до епітелізації на (27±4,5) день у 95 % пацієнтів.

Ключові слова: хронічна венозна недостатність; ендовенозне зварювання; велика підшкірна вена; трофічна виразка; Platelet rich plasma.