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ORIGINAL ARTICLE

One-step or step-by-step approaches to varicose veins treatment: timing, method, rationale

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ABSTRACT

BACKGROUND: One of the most contentious issues within the field of phlebology is determining the best approach for correcting varicose tributaries following truncal ablation. Which strategy yields the highest effectiveness remains a subject of debate. Currently, there is a lack of substantial data regarding the selection of treatment strategies based on the diameter of varicose tributaries. Hence, the comparison between staged and one step treatment for varicose veins is a pertinent concern in contemporary phlebology. Conducting research in this area will enable the identification of the benefits and potential drawbacks associated with each proposed tactic.
METHODS: The study involved a prospective analysis of 295 patients with varicose veins who received outpatient treatment as part of a combined therapy approach.
RESULTS: Performing simultaneous endovenous laser ablation (EVLA) of saphenous trunks and ligation (gentle phlebectomy) of visibly large-diameter tributaries (6 mm or more), followed by staged sclerotherapy after a month, offers substantial potential advantages.
CONCLUSIONS: Employing step-by-step treatment for varicose veins helps to reduce the level of traumatic intervention and discomfort experienced by the patient, all the while achieving satisfactory treatment outcomes without compromising the individual's quality of life.

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KEY WORDS: Varicose veins; Laser therapy; Phlebotomy; Sclerotherapy.

Presently, the most effective methods for addressing vertical reflux in the main superficial veins of the lower limbs involve thermal or non-thermal endovenous interventions, as recommended by the latest clinical guidelines.[1, 2] However, a divisive issue within the phlebology community revolves around determining the best approach for managing varicose tributaries following trunk ablation using endovenous interventions.[3] While some specialists favor a one-step treatment, primarily employing phlebectomy (and occasionally sclerotherapy), others advocate for staged treatment: addressing trunk reflux points first and deferring tributary treatment with sclerotherapy.[4] What are the optimal criteria and indications for each of these strategies? Which approach yields better outcomes? These questions remain pertinent and pressing in current practice.

Furthermore, new techniques are developing rapidly, such as endovenous laser ablation (EVLA) of epifascial non-tortuous areas of varicose tributaries, which can be applied with favorable anatomical conditions, or "porcupine" tactics or total EVLA for tortuous tributaries, as well as ASVAL (ambulatory selective varicose vein ablation under local anesthesia) techniques, which also advocate the possibility of surgical interventions only on tributaries without elimination of primary vertical reflux.[5-7] There is currently no clear evidence from high-quality randomized studies to confirm whether eliminating varicose veins in one intervention is more effective than a treatment strategy of ablation of truncal veins and postponing sclerotherapy of residual varicose tributaries.[8] Additionally, there are no established indications for isolated treatment of great

or small saphenous veins in varicose veins treatment.[8, 9] Future research protocols are needed to answer questions about the feasibility of one step phlebectomy or sclerotherapy, and to demonstrate the advantages or disadvantages of a staged approach in the treatment of primary varicose veins.[9, 10] However, there is currently very little data on the choice of tactics for the treatment of varicose tributaries depending on their diameter. Therefore, the comparison of staged and one step methods for the treatment of varicose veins is a relevant problem in modern phlebology, and studying this topic will help to determine the advantages and potential disadvantages of the proposed tactics.

Materials and methods

The study included a prospective analysis of the combined treatment of 295 patients with primary varicose veins who underwent outpatient treatment at one specialized vascular center between May 2017 and September 2021. The study randomized 141 patients over the age of 18 years who had venous reflux caused by insufficiency of the saphenofemoral junction (SFS) and reflux through the great saphenous vein (GSV). All patients had chronic venous disease (CVD) classified as C2-C5 according to the CEAP classification. The patients' ages ranged from 18 to 85 years, with an average age of 53.9±6.1 years, and there were 40 men and 101 women. Patients with muscle diseases, chronic pain syndrome, deep vein reflux, active ulcers, thrombotic complications, and/or post-thrombotic deep veins obstruction were excluded from the study. Patients with reflux through the small saphenous vein (SSV) were also not included in the study. The patients were randomly divided into three groups: the main group (47 patients), comparison group A (47 patients), and comparison group B (47 patients).

All patients underwent ultrasound duplex scanning of the deep and superficial venous systems of the limbs and pelvis before treatment. The GE Logiq E ultrasound scanner using a 7-14 MHz linear sensor was used during the ultrasound examination. During the ultrasound examination, the anatomical cause of varicose veins was verified, the diameters of the trunk of the GSV, the anterior accessory saphenous vein (AASV) in the presence of reflux, the diameters of visible non-saphenous veins and visible tributary varicose veins (their location relative to the knee), the lowest point of venous reflux was also evaluated, as well as incompetent perforators. Attention was paid to the anatomical variations of the GSV, especially at the hip level – aplasia, hypoplasia with developed collateral segments, and their diameters. The diameter of the GSV was assessed in a transverse view (including the vein wall) 3 cm below the SFJ, in the middle third of the thigh and at the level of the knee. The diameters of the visible tributaries were also evaluated in a transverse view in the maximally proximal area from the great saphenous vein in the standing position of the patient. Venous reflux was assessed using a distal compression test (squeezing the leg muscles) as a retrograde blood flow lasting more than 0.5 seconds, according to the UIP recommendations.[11]

TABLE I.—*The number and location of visible varicose tributaries relative to their associated superficial truncal veins.*

Group	GSV tributaries above the knee	GSV tributaries below the knee	AASV tributaries	Non-saphenous tributaries
Main study group	12	25	13	-
Group A	16	23	10	1
Group B	14	21	9	2

The number and location of visible tributaries relative to their associated subcutaneous veins are shown in Table I.

After analyzing the table data, it was found that in most patients in each group, the main cause of visible tributaries was pathological below-the-knee GSV reflux and AASV reflux. The mean diameters of the subcutaneous veins and their associated visible tributaries are presented in Figure 1. The diameter of the GSV in the SFJ area varied highly from 7 to 21 mm. The average diameter of the GSV in the main group was 8.2±5.1 mm, in group A it was 7.9±4.7 mm, and in group B it was 7.9±6.1mm. The diameters of visible varicose tributaries ranged from 3-12 mm, and the average diameter of tributaries in the main group was 5.7±3.8 mm. In group A, it was 5.5±4.1, and in group B it was 5.3±2.2 mm.

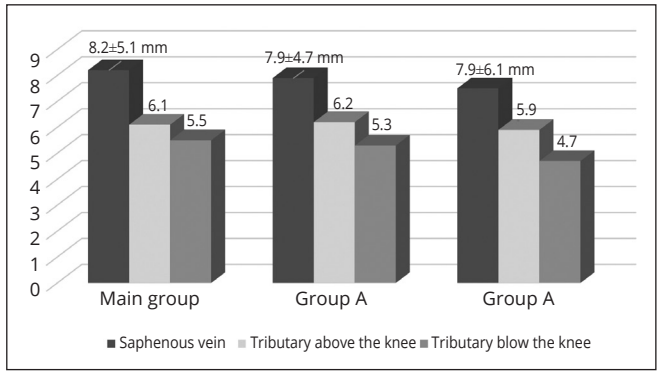

Figure 1.—Mean diameters of superficial saphenous (GSV and AASV) veins and associated visible tributaries.

There were no statistically significant differences in the diameter of the tributaries between the groups.

After analyzing the ultrasound results and the data in Figure 1, the visible varicose tributaries were divided into two categories: large and small. Large tributaries had a diameter greater than 6mm and small tributaries less than 6mm when the patient was in a vertical position. The outflow level of the tributary into the main saphenous trunk was also taken into consideration, as well as the diameter of the latter and their ratio.

All patients underwent photo documentation of their lower extremities before and after treatment in three projections. Visible varicose veins after various types of treatment were evaluated, along with any undesired consequences and complications of surgical interventions (such as hematomas or hyperpigmentation).

Each patient had a detailed conversation regarding the choice of treatment method to obtain the desired result. Clear explanations were given about each treatment stage and possible consequences.

Endovenous laser ablation (EVLA) of the GSV was performed using a 1470 nm diode laser under ultrasound control and tumescent anesthesia. Thermal ablation of the GSV was supplemented with EVLA of the non-tortuous subfascial segment of AASV in the presence of pathological reflux on the latter. EVLA was performed using a radial laser fiber e with automatic traction using a pull-back device. Phlebectomy of visible tributaries was performed through skin punctures up to 2 mm using special phlebological hooks. Sclerotherapy of varicose tributaries was performed using a 1-2% solution of Polidocanol in the form of foam (Foam microbubbles) in a ratio of 1 to 2 with air. After the procedure, patients are recommended to wear individually selected compression stockings of the second class (27-32 mmHg) for 1-3 months. Wearing compression underwear for more than 1 month is recommended in case of discomfort or swelling after treatment.

The efficacy of the combined treatment was assessed at different intervals, including 1, 15, and 90 days after treatment, as well as 6 months later. The evaluation was based on various clinical data such as pain intensity after the procedure, which was assessed using a standard 10-point Visual Analogue Scale (VAS) on the next day, and after 7- and 15-days post-treatment. The presence of ecchymoses and hematomas was also evaluated on the next day, as well as 7 and 15 days after the procedure. Reduction of external manifestations, such as visible varicose veins, and the need for additional treatment and reinterventions 6 months after the procedure, were also considered. Additionally, the patient's subjective impression of the treatment and the dynamics of changes in the patient's quality of life were evaluated using the CIVIQ-20 and VCSS scales. The assessment was carried out before treatment and after 1 month and 6 months.

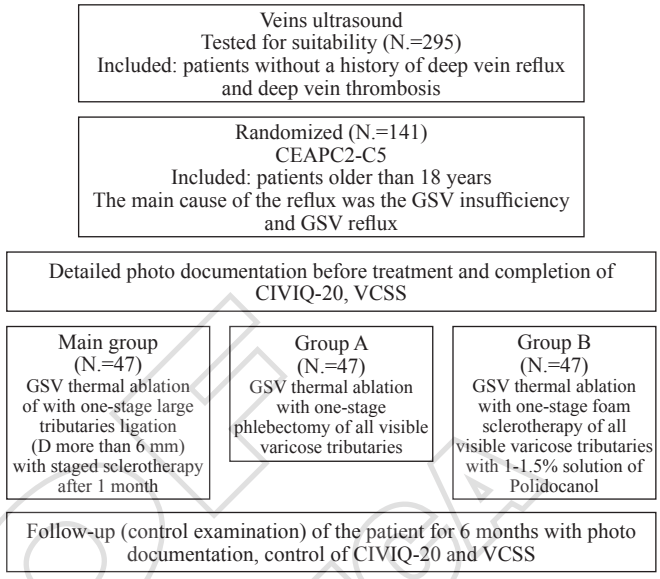

Figure 2.—Study design.

The study design structure is presented below in Figure 2.

In the main group (N.=47), during the endovenous ablation of vertical reflux, only the visible large varicose tributaries (with a diameter of more than 6 mm) were ligated in the maximal-proximal area from the saphenous vein (through one puncture). The second stage, which involved staged sclerotherapy of residual visible varicose veins, was performed after 32±2.1 days, if necessary.

In comparison group A (N.=47), all visible varicose tributaries were removed immediately after the elimination of vertical reflux through phlebectomy.

In comparison group B (N.=47), the sclerotherapy of varicose tributaries was performed immediately after the elimination of vertical reflux.

Statistical analysis

The results obtained were presented as the mean (M) and standard error of the mean (m). In order to assess differences within groups, the two-sample $\chi 2$ test was used based on the type of data, using the StatPlus 2012 program. If the null hypothesis was rejected at a significance level of $P<0.05$, differences between indicators were considered statistically significant.

Results

In the analysis of the results of various types of combined treatment for varicose tributaries of subcutaneous veins in the lower extremities, no serious complications were recorded that required patient hospitalization or follow-up termination.

In the main study group that underwent staged treatment, the average duration of the GSV thermal ablation was 19±9.2 minutes. After one month of follow-up, 26 patients (55.3%) in this group, who had undergone EVLA of the GSV and isolated ligation of large tributaries more than 6 mm in diameter, reported that all visible varicose veins had disappeared without the need for staged sclerotherapy of residual veins. Among these patients, four cases (8.5%) underwent isolated ablation of the GSV on the thigh since the diameter of the visible tributaries was small (less than 6 mm), and all visible tributaries disappeared after 1 month of observation.

Out of the main group, only 21 patients (44.6%) needed to undergo staged sclerotherapy to treat residual visible tributaries, one month after the elimination of vertical reflux in GSV. Among these 21 patients, 17 required only one sclerotherapy session, three needed two sessions, and one patient had 3 residual vein sclerotherapy sessions spaced 14-20 days apart.

In group A with GSV thermal and one-stage phlebectomy of all visible tributaries on the limb, the average duration of the surgery was 36±10.5 minutes. Additional interventions (one session of staged sclerotherapy in 3 months of follow-up) was required in 1 patient.

In group B with GSV thermal ablation and one-step sclerotherapy, the average duration of the surgery was 29±16.2 minutes. After 3 month of observation, two patients required correction and elimination of residual visible tributaries with additional staged sclerotherapy session.

It was observed that there were significant differences in the intensity of pain among the three groups. The main group reported 3 points on the VAS scale during the procedure, while group A reported 6 points and group B reported 4 points. Additionally, the pain indicators continued to differ 7 days after the treatment. The main group reported 1 point, group A reported 3 points, and group B reported 5 points (Figure 3).

The pain severity in group A was higher during the main stage of treatment and the following day compared to other groups. This was likely due to more injections for tumescence of the subcutaneous fat around the varicose veins, significantly more punctures for phlebectomy of visible tributaries, and a longer procedure. On the other hand, in group B, which underwent one-step sclerotherapy of visible tributaries after GSV thermal ablation, the most pronounced pain syndrome was noted on the seventh day of observation. This is most likely associated with inflammatory processes and phlebitis in sclerosed tributaries.

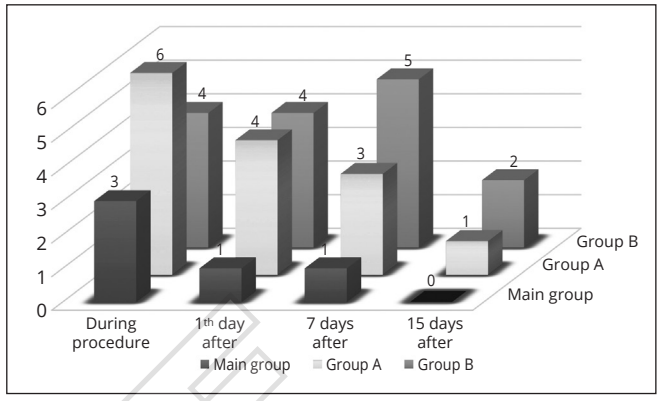

Figure 3.—Intensity of pain during and after treatment.

The main group with staged treatment had the least pain syndrome during the entire observation period, and after 15 days, the pain syndrome was completely absent in all patients. This was due to the minimum number of injections during tumescence and 1-2 punctures for access to GSV or AASV trunk.

The severity of bruising, hematomas, phlebitis, hyperpigmentation, and residual veins are presented in Table II.

The highest number of hematomas was observed in patients from group A, who underwent EVLA and one-step phlebectomy. Conversely, the number of hyperpigmentation cases was greater in group B, where patients received EVLA and one-stage sclerotherapy.

It is highly probable that the greater number of bruises and hematomas observed in group A during the first two weeks of follow-up was a result of the higher number of injections during tumescent anesthesia and phlebectomy. These procedures can cause damage or even rupture of small tributaries, leading to the aforementioned indicators.

At the same time, in group B, in the second week of observation, a greater number of phlebitis and hyperpigmentation is noted, as a predicted consequence of varicose veins sclerotherapy with GSV thermal ablation.

During the third month follow-up analysis of treatment results, no serious complications were recorded. However, the number of patients with residual skin changes (pigmentations) in the area of the treated veins was higher in group B, which significantly affected their satisfaction with

TABLE II.—*Number of complications and predicted complications after various types of combined treatment of varicose veins.*

Complications	Main group N.=47	Group A EVLA+ phlebectomy N.=47	Group B EVLA+ sclerotherapy N.=47	P value
Mean age (years)	54.2±5.2	53.1±7.1	54.5±6.1	0.09
Surgery duration (minutes)	19±9.2	36±10.5	29±16.2	0.41
1 day				
Ecchymoses	7 (14.9%)	26 (55.3%)	8 (17%)	0.12
Hematomas	4 (8.5%)	21 (44.7%)	5 (10.6%)	0.06
Superficial vein thrombosis	2 (4.2%)	1 (2.1%)	4 (8.5%)	0.07
Skin inflammation in the access site area	1 (2.1%)	3 (6.4%)	1 (2.1%)	0.05
15 days				
Residual ecchymosis	3 (6.4%)	15 (31.9%)	4 (8.5%)	0.54
Residual hematoma	1 (2.1%)	11 (23.4%)	1 (2.1%)	0.32
Persistent symptomatic superficial veins thrombosis	1 (2.1%)	1 (2.1%)	7 (14.9%)	0.09
Hyperpigmentation	2 (4.2%)	1 (2.1%)	29 (61.7%)	0.14
3 months				
Change in skin color	2 (4.2%)	1 (2.1%)	3 (6.4%)	0.05
Residual veins	1 (2.1%)	1 (2.1%)	2 (4.2%)	0.06
100% satisfied with the result	45 (95.7%)	40 (85.1%)	42 (89.4%)	0.08
Dissatisfied with the result	0	1 (2.1%)	2 (4.2%)	0.09

the treatment. The main group had a lower number of hyperpigmentation because after GSV thermal ablation and ligation of large tributaries (greater than 6 mm), the visible varicose veins significantly reduced in size, requiring a smaller volume and lower concentration of Polidocanol for staged sclerotherapy compared to group B. Additionally, according to the study data, tributary veins disappeared completely after the main stage of treatment in 55.3% of cases.

The results of the patient's quality of life and the severity of CVI (VSSS) of patients with various types of combined treatment of varicose veins are shown in Figure 4.

In all observation groups, patients with obesity had worse VCSS severity of varicose veins and CIVIQ-20 quality of life compared to those with normal weight. However, there was no significant difference in disease severity or quality of life between the observation groups after the treatment phase. In the first month of observation, the quality of life improved by almost 50% from the initial indicators before treatment in all observation groups. This is likely due to the correction of venous reflux and prolonged compression therapy. After the treatment procedures, patients in all groups were recommended to wear compression stockings of the 2nd compression class for approximately three months. One month later, the assessment showed that about 80% of patients in each group were regularly using compression stockings. During this period, patients who used stockings reported an improvement in their well-being, with fewer complaints of pain and swelling. However, about 20% reported that they did not use compression stockings regularly because they found them annoying.

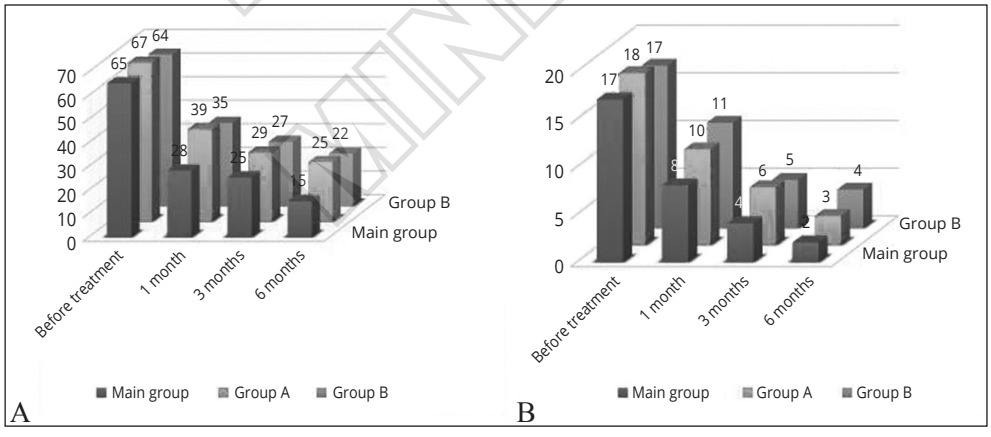

Figure 4.—Assessment of patient's quality of life according to the CIVIQ-20 scale (A) and severity of venous diseases according to the VCSS (B).

A case study (clinical example)

The patient of the main group is male 54 years old with the diagnosis: Varicose veins. CEAP C4s. The view of the lower extremities before treatment is shown in Figure 5. According to the US data, insufficiency of SFG, reflux along the GSV to the middle of the calf (Figure 6). It was technically feasible to remove all varicose veins by performing a phlebectomy, considering the location of the varicose tributaries. However, in order to minimize trauma, the patient was offered a staged treatment. At the first stage, GSV endovenous laser ablation with ligation

Figure 5.—Appearance of the limb in 3 projections. The arrow indicates the place of measurement of the diameter of the visible GSV tributary and the place of "future" ligation of that tributary with one puncture site.

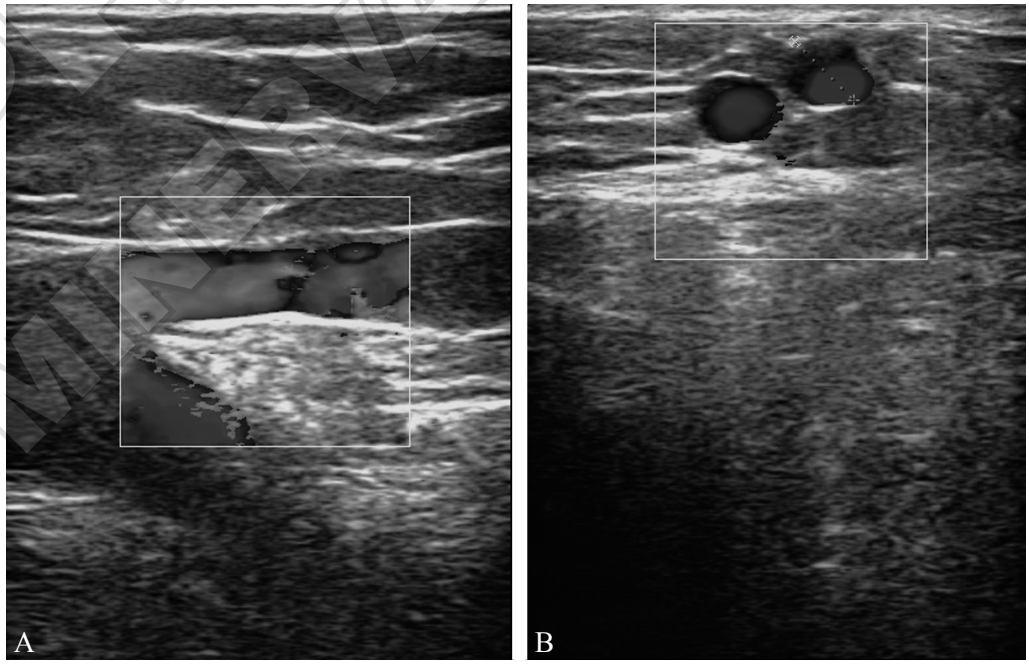

Figure 6.—Data of ultrasound examination. A- Insufficient SFJ, and GSV reflux during a distal compression test. B – The method of measuring the diameter of a large visible inflow in the maximally-proximal area from the GSV (diameter 7.4 mm).

of a large varicose tributary was performed (Figure 7) and patient was monitored at day 7 (Figure 8) and at day 30 after remnant tributaries reduction foam sclerotherapy was performed. At day 45 was observed slight pigmentation (Figure 9) which resolved significantly by day 95 (Figure 10). Throughout the entire observation period, the patient wore 2nd class compression stockings. Three months after undergoing the staged treatment, which involved foam sclerotherapy of residual veins, the patient showed no signs of CVI, residual veins, or edema. Additionally, there was a significant reduction in the induration of the skin on the lower leg.

Discussion

An essential consideration in deciding the optimal approach for treating varicose tributaries, whether it involves simultaneous or delayed intervention, and the choice be-

Figure 7.—Stage of GSV endovenous laser ablation with ligation of a large varicose tributary (diameter 7.4 mm) through one puncture in the maximum-proximal area from the saphenous vein. The total duration of the intervention is 17 minutes.

Figure 8.—Appearance of the limb on the 7th day after the first stage of treatment. Significant reduction of varicose veins on the leg.

Figure 9.—The appearance of the limb 45 days after the first stage of treatment and staged sclerotherapy (1% foam-form polidocanol) of the residual leg veins after 30 days.

Figure 10.—The appearance of the limb 95 days after staged treatment: GSV EVLA with major tributary ligation.

tween sclerotherapy or phlebectomy, is the diameter of the affected vein.

According to a study, the most effective diameter for sclerotherapy is 5-6 mm. This reduces the risk of recanalization and long-term side effects. Tributary ligation is also highly effective in reducing the distal part of the varicose tributary. After a month of observation, the tributary disappeared completely in 55.3% of cases. Eric Mowatt-Larssen's publication in 2010 supports the same criterion. It indicates that sclerotherapy can be used for any type of varicose tributaries but is less effective and carries a greater number of complications in treating large-diameter tributaries. Ambulatory phlebectomy is the best option for visibly apparent and palpable tributaries and is particularly effective for those with a large diameter.[3] A study conducted by Myers in 2006 demonstrated that US-guided sclero-

therapy for varicose veins with a diameter of more than 6 mm is less effective due to the foam not making contact with all areas of the target vein wall. This increases the risk of complications such as deep vein thrombosis, especially when using large concentrations and volumes of sclerosant, which is necessary for adequate obliteration of the vein in such cases.[12] It is possible to perform phlebectomy even on smaller visible veins that are closer to the surface. However, after vertical reflux has been eliminated, a significant number of these smaller tributaries tend to disappear. This has been demonstrated in various studies on isolated ablation of saphenous trunks. On the other hand, larger tributaries tend to remain and may require delayed interventions.[13]

Many studies have been conducted on the treatment of varicose veins after ablation of superficial truncal veins. Most of these studies refer to a technique called phlebectomy.[4] A meta-analysis published in the European Journal of Vascular and Endovascular Surgery in 2021 showed that a single-step approach may have potential advantages, such as a better quality of life for patients early after the procedure (less than 3 months) and a lower frequency of reinterventions.[4] However, this fact was not confirmed after statistical analysis, due to the studies' heterogeneity.[8] Recently, a safe and effective method called single-stage sclerotherapy of tributaries after ablation has gained popularity.[14] However, the main argument in favor of a delayed approach is that most of the tributaries will disappear or decrease in diameter after the elimination of main reflux.[15] The Kawai study, which included 954 patients, found no significant differences between the need for additional sclerotherapy in patients who underwent isolated saphenous ablation compared to a group of patients who underwent ablation with phlebectomy of the tributaries.[15]

One crucial factor that indicates the pros and cons of different approaches in treating tributaries is the level of pain, which can affect the quality of life during the early postoperative period. For example, a more severe pain condition is observed during the first few weeks after total phlebectomy of all visible tributaries, which aligns with the findings of other studies that state a considerable number of hematomas and pain syndrome after this procedure, especially when implementing a one-stage approach.[4] The pain condition following the sclerotherapy of all visible tributaries may also be linked to phlebitis in large-diameter varicose tributaries due to inadequate interaction of the sclerosant with all the vein walls, causing obliteration not only due to phlebosclerosis but also phlebothrombosis with a simultaneous inflammatory reaction (periphlebitis), which can trigger pain within one week to one month after the intervention. As per the latest clinical recommendations, it is best to use a 1-1.5% solution of Polidocanol for treating small and medium-sized varicose veins.[16]

In terms of quality of life, after a follow-up period, there was no significant difference observed between different treatment methods for varicose veins. This indicates that both one-stage sclerotherapy or phlebectomy, as well as the staged approach, are highly effective in treating varicose veins. However, the main difference is seen in the first few weeks after the procedure. Therefore, clinicians should focus on improving the quality of life for patients during this period by reducing pain, hematomas, phlebitis, and other adverse effects. A new survey called the Venous Treatment Satisfaction Questionnaire (VenousTSQ) is being developed and tested, which may show higher patient satisfaction with all varicose vein treatment procedures.[17] Hence, future studies should include similar questionnaires to analyze the effectiveness of treatment not just from the physician's perspective but also from the patient's point of view. This is important as quality of life and satisfaction are crucial factors in determining the most suitable technique for each clinical case.

The proposed approach entails conducting endovenous laser ablation (EVLA) of the saphenous trunks simultaneously with the ligation (gentle phlebectomy) of visibly large-diameter tributaries (measuring 6mm or more). Following this, staged sclerotherapy is administered one month after the procedure. This method offers notable advantages, as the majority of tributaries tend to diminish and become nearly imperceptible within a month. Additionally, it reduces procedural duration and minimizes patient discomfort, thus positively impacting long-term quality of life.

Conclusions

Treatment for varicose veins can be approached in two ways: either by addressing the affected tributaries simultaneously or in step-by-step following treatment of the saphenous trunk. Each approach comes with its own set of pros and cons. Step-by-step treatment entails utilizing endovenous laser ablation (EVLA) to treat the saphenous trunks and ligating visible large tributaries (those measuring over 6mm in diameter). This is followed by sclerotherapy a month later. This method aims to reduce the level of trauma and discomfort experienced by the patient while still achieving satisfactory treatment outcomes without compromising their quality of life.

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Conflicts of interest
The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Authors' contributions
Larisa Chernukha, Olexandr Voloshyn, Olexandr Suzdalenko: conception and study design, interpretation of data. Viktor Gubka: assistance with study design and data statistical analysis. Serhii Machuskui. Viktor Pavlychenko: data collection, analysis and manuscript preparation. All authors read and approved the final version of the manuscript.

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