ORIGINAL ARTICLE

MANAGEMENT OF MINIINVASIVE TREATMENT OF PRIMARY VARICOSE SUPERFICIAL VEINS

DOI: 10.36740/WLek202305215

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ABSTRACT

The aim: Determination of the optimal method for surgical correction of stages C2-C6s varicose superficial veins.

Materials and methods: The treatment results of 228 patients with stages C2-C6 of primary varicose according to the CEAP classification using thermal and non-thermal treatment methods were analyzed.

Results: All patients underwent operations under the control of ultrasound scanning. In patients after EVLA, total trunk obliteration was detected in 148 patients (98.7%) after 1 week, and in 100% after a year. In 2 patients, reflux was diagnosed in the PDSV and in the ZDSV after 1 week. In patients after RFA, inflow reflux on the leg was in 1 patient (5.2%), in others - complete obliteration (18 patients - 94.7%). In patients after MOCA, recanalization was performed in 5 patients (19.2%) with a control ultrasound investigation after 1 month. In patients after cyanoacrylate obliteration, inflow reflux on the leg after 1 month was in 2 patients (14.2%). In patients who underwent UGS of the GSV trunk, 5 patients (33.3%) had persistence of pathological reflux after 1 month with control ultrasound. All corrections were performed using Foam form sclerotherapy.

Conclusions: EVLA is the most effective method of treating varicose veins and gives the best long-term results. The advantage of non-thermal methods is the lack of influence on paravenous structures and no need for tumescent anesthesia, which is important in case of an allergic history. After applying cyanoacrylate, there is no need for mandatory compression. The advantage of foam scleroobliteration is its lowest cost among all methods. Foam sclerotherapy was the method of choice for correction of postoperative treatment.

KEY WORDS: primary varicose veins, endovenous laser ablation, mechanochemical ablation, radiofrequency ablation, foam sclerotherapy, injection of bioglue

Wiad Lek. 2023;76(5 p.2):1233-1238

INTRODUCTION

Chronic venous disease is a significant spectrum of morphological and functional disorders of the venous system that last for a considerable duration and are characterized by symptoms or signs that require examination or treatment.

According to various worldwide data, the prevalence of varicose transformation of the lower extremities' superficial veins in certain age groups ranges from 21.8% to 72% of the population in developed countries.

With progression, the disease can significantly worsen the quality of patient's life by causing trophic changes in the skin in the form of pigmentation, lipodermosclerosis, skin atrophy, the formation of ulcers that, in the absence of treatment, recur (stages C4-C6), and complicated forms of varicose transformation (phlebitis and thrombophlebitis, bleeding from varicose varices) [1].

Varicose veins are an economically significant problem, due to the increase in morbidity among able-bodied people, which can cause temporary loss of working capacity or stimulate signs of disability in patients.

The "gold standard" for the diagnosis of varicose disease of the superficial veins today throughout the world is the ultrasound duplex scanning of the venous system, during the last decades [2], thanks to the spread of various techniques of minimally invasive methods, the treatment of primary varicose has gained a high level of development in all developed countries. These methods include two groups: with the use of thermal energy and non-thermal puncture. Thermal methods include endovenous laser ablation (EVLA), endovenous radiofrequency ablation (RFA), and endovenous electrowelding. Non-thermal methods include foam scleroobliteration (UGS), endovenous mechanochemical obliteration (MOCA) and adhesive methods of vein closure [3].

All of the above minimally invasive techniques are puncture-based, which allows for minimizing the need for anesthesia (making it possible to perform under

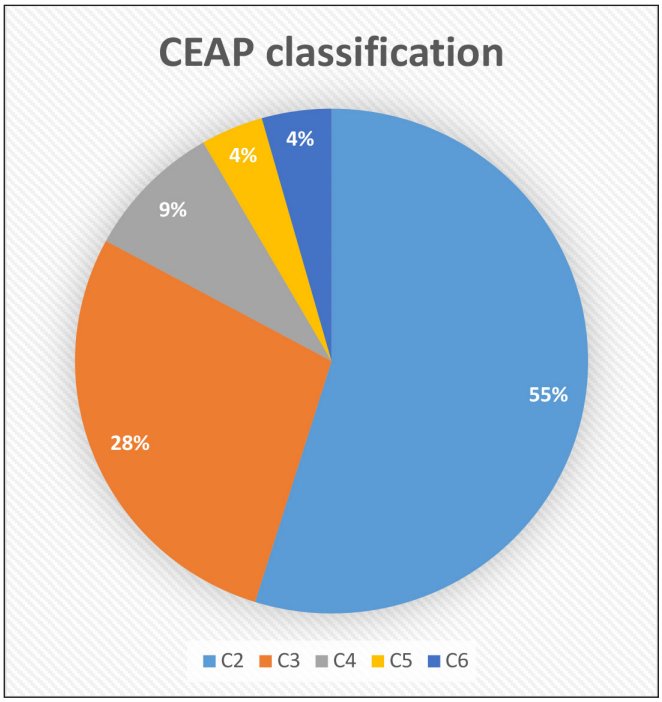

Fig. 1. The distribution of cohorts as to the stage of severity (CEAP classification).

local anesthesia, or without it at all) and for widely implementing them in outpatient settings, taking into account the shorter duration of the surgical intervention itself and the quick recovery period of the patient.

It should be noted that today there are no clear algorithms for choosing a specific minimally invasive technique for this or that case and stage of varicose. Active research is ongoing all over the world to minimize the trauma of treatment, maximize the patient's quality of life, and to optimize the cost of treatment.

THE AIM

The purpose of the work is to determine the optimal method of stages C2-C6s lower extremities varicose veins surgical correction.

MATERIALS AND METHODS

The results of the treatment of 228 patients with primary superficial varicose C2-C6s according to the CEAP classification, operated on using various minimally invasive puncture techniques in the period from 2020 to 2022 on the basis of the surgical department of the State Institution of Science «Research and Practical Center of Preventive and Clinical Medicine» State Administrative Department were analyzed.

The general sample was formed retrospectively, based on the analysis of using one or another minimally invasive method in patients. The authors adhered to the principles contained in the 1964 Declaration of Helsinki and their latest amendments. The permission to conduct the study and the study protocol were approved of by the bioethics committee of the Institution.

Inclusion criteria: patients with symptoms and clinical signs of the lower extremities' varicose, confirmed by ultrasound scanning; patients with stage C2 - C6s. Exclusion criteria: patients with deep vein thrombosis or thrombophlebitis; patients with signs of malformations. By gender, there were 146 (64%) women and 82 (36%) men. The age range was from 20 to 86 years.

The majority of patients complained of optically visible varicose veins and venous networks of the lower extremities, some patients complained of increased leg fatigue, swelling and heaviness that progressed after physical exertion or in the evening, some had changes in the skin of the legs in the form of trophic ulcers . The distribution of cohorts as to the stage of severity (CEAP classification) was as follows: stage C2 - 125 patients (54.8%), C3s - 64 patients (28%), C4s - 20 patients (8.8%), C5s - 9 patients (4%), C6s – 10 patients (4.4%). (Fig. 1).

It can be seen from the Fig. 1, that the largest number of patients belonged to the C2 of the CEAP classification, that is, without the presence of chronic venous insufficiency.

During the initial examination, the patients had to undergo an ultrasound duplex scan of the lower ex-

Table I. Groups of patients were formed depending on the selected and performed minimally invasive method and comparative results are shown.

Method of treatment	Number of patients	Anaesthesia tumescent	Compressive therapy after operation	Recanalization on USDS 1st week after	Other complications
EVLA	150 (65,8%)	Modified cold Klein's solution	Yes, 1 month	2 patients – in the AASV or PASV (1,3%)	No
RFA	19 (8,3%)	Modified cold Klein's solution	Yes, 1 month	1 patient (5,2%)	No
MOCA	26 (11,4%)	None	Yes, 1-1,5 month	5 patients (19,2%)	No
Electrowelding	4 (1,8%)	Modified cold Klein's solution	Yes, 1-1,5 month	Only for patients with the diameter of the proximal area more 20 mm	
Echo-controlled UGS	15 (6,6%)	None	Yes, 1-1,5 month	5 patients (33,3%)	No
Echo-controlled injection of bioglue	14 (6,1%)	None	No	2 patients (14,2%)	Temperature 37,5 degree 3 days after

tremities' venous system, which verified the presence of reflux in different segments of the GSV (188 cases - 82.5%), SSV (25 cases -11%), or in both systems (15 patients – 6.5%). The length of the pathological reflux path was: along the entire length of the GSV in 16 patients (8.5%), up to the level of m/3 leg – in 40 patients (21.3%), up to the level of u/3 leg – in 75 patients (39, 9%), to the l/3 femur – in 36 patients (19.1%), to the m/3 femur – in 21 patients (11.2%).

Pathological reflux path throughout the MPV was detected in 3 patients (12%), up to m/3 tibia - in 19 patients (76%), and up to u/3 tibia - in 3 patients (12%).

The location of the SSV (small saphenous vein) in relation to the superficial fascia of the thigh: i-type in 155 cases (82.5%), h-type in 7 (3.7%), s-type in 26 cases (13.8%). The diameter of the SSV in the area of the saphenofemoral junction was from 4 to 30 mm, and the SSV in the area of the saphenopopliteal junction was from 3.9 to 16 mm. The sizes of ulcer defects in the C6s ranged from 1.7*2.5 cm to 8.0*6.3 cm.

Among the accompanying pathologies, obesity or excess weight (BMI>25) was observed in 23 patients, severe allergic history in 14 patients, coronary heart disease in 23 patients, and endocrinological diseases in 25 patients. When choosing a specific method of operative treatment, we took into account the individual wishes of patients, after discussing with them the advantages, disadvantages, and possible complications of each method according to world data and protocols, as well as the socio-economic component.

Groups of patients were formed depending on the selected and performed minimally invasive method of pathological reflux elimination: 150 patients (65.8%) - EVLA, 19 (8.3%) - RFA, 26 patients (11.4%) - endovenous mechanochemical ablation (MOCA), 14 patients (6.1%) - using the method of echo-controlled injection of bioglue, 15 patients (6.6%) - foam echo-controlled scleroobliteration (UGS), 4 patients (1.8%) - endovenous electrowelding.

Before surgery, each patient underwent repeated ultrasound examination in the standing position to assess vertical and horizontal reflux, as well as to mark deformed saphenous veins and sites of failed perforators.

For EVLA, the "LIKA-KHIRURG" laser device of 1470 nm of continuous laser irradiation with a power of 12 W was used. For tumescent anesthesia, administration with a Nouvag DP-30 dispenser of modified Klein's solution was used.

After the intervention, all patients were fixed with compression bandages in the area of the operation with adhesive bandages of the Peha-haft type and compression knitwear.

For RFA, the COVIDIEN VNUS radio frequency generator and the ClosureFast intravenous catheter were used. A special bipolar electrode and coagulator "Swarmed" were used for electric welding.

For MOCA, the Flebogrif vein closure system was used, which consisted of a special catheter and a sclerosant solution (polidocanol). This technique does not require tumescent anesthesia, as there is no thermal damage to the surrounding paravasal tissues. The basis of the technique is mechanical damage to the inner wall of the vein (endothelium) with sharp microhooks, which open at the end of a special delivery catheter during reverse traction, and subsequently – chemical damage due to the effective action of the injected sclerosant. After this operation, it is mandatory to apply a compression bandage to the projection zone of the treated segment of the vein and wear compression knitwear.

For echo-controlled injection of cyanoacrylate, the VenaSeal and VenaBlock adhesive obliteration system was used, consisting of a special dispenser gun, an echogenic catheter and a device (5 ml) with inert cyanoacrylate glue. No compression was used.

RESULTS

All interventions were performed percutaneously using the puncture technique and monitored intraoperatively using an ultrasound linear sensor and an expert class ultrasound machine. Tumescent anesthesia, if necessary, was applied in the form of injection of modified cold Klein's solution around the trunk of the treated vein. In the presence of varicose vein tributaries, they were isolated and ligated. All patients in the postoperative period underwent scheduled control ultrasound investigations and examinations the day after surgery, after 1 week, after 1, 3, 6, 12 months.

In the group of patients after EVLA, total obliteration of the GSV trunk or SSV was detected in 148 patients (98.7%) after 1 week, and in 100% during the year. In 2 patients, reflux was diagnosed in the PDSV (1 patient) and in the ZDSV (1 patient) at the control after 1 week. In our opinion, this is due to insufficient exposure to laser irradiation in the estuarine section in the area of departure of large tributaries. Clinically, nothing bothered the patients. To correct the detected reflux, a single injection of foam sclerosant Foam form (3%) was used under ultrasound control, successful obliteration after 1 month.

In the group of patients after RFA, inflow reflux was detected on the lower leg in 1 patient (5.2%), in other cases complete obliteration was observed (18 patients - 94.7%). This is due to the fact that monoablation was performed without removing pathological tributaries up to 6 mm in diameter. At the follow-up examination, the reflux was eliminat-

ed by foam sclerotherapy. At the follow-up after 1 month, a significant decrease in the venous diameter and the absence of reflux were noted.

In the group of patients after MOCA, recanalization was noted in 5 patients (19.2%) with control ultrasound after 1 month. It was corrected by carrying out the procedure of foam scleroobliteration (3% polidocanol). Recanalization was again detected in two patients at the examination after a week. Scleroobliteration was performed a second time, successfully. A week after the correction, the degradation of the venous diameter without pathological reflux was visualized.

In the group of patients after cyanoacrylate obliteration, inflow reflux on the leg was detected in 2 patients (14.2%) at examination after 1 month. The correction was carried out by foam sclerotherapy, by single-use, successfully. According to our observations, three patients noted a short-term rise in temperature to 37 - 37.5 degrees during the next 3 days after the operation, which did not require correction.

In the group of patients who underwent echo-controlled UGS of the GSV trunk, 5 patients (33.3%) were diagnosed with the preservation of pathological reflux during the follow-up examination 1 month later with control ultrasound duplex scanning (USDS), and repeated sclerotherapy was performed. At the follow-up examination after 1 month, repeated reflux was detected in 2 patients (13.3%), and corrective sclerotherapy was performed a second time. At the subsequent follow-up, no reflux was detected.

In the group where electrowelding was performed, at the control after 1 month, a recurrence was found of GSV, the diameter of the proximal area being more than 20 mm.

Comparative results are presented in the Table I.

Patients at stage C6s were treated using the main method of EULA or RFA. The control of this patients' group was carried out once every 2 weeks during the first 2 months with modified plasmatherapy of wounds (4 procedures for each case).

Trophic defects healed completely after a month in 8 patients (80%), in 2 – ulcer defects decreased by 3 times in area after a month and completely healed 3 months after the intervention, which is probably related to a deeper skin lesion and the presence of concomitant pathology in the patients - type 2 diabetes mellitus.

Compression therapy after EULA, RFA, electrowelding techniques was used for a period from 14 days to 1 month, and in the presence of trophic ulcers, it was prescribed for the entire healing period; after MOCA and UGS, the compression knitwear was used for a period of 1 to 1.5 months. Compression therapy was not used in patients after the injection of biocyanoacrylate.

DISCUSSION

Over the past 20 years, minimally invasive puncture methods for treating the lower extremities' varicose veins have been increasingly used in the world, becoming an effective alternative to classic open surgery. Taking into account the world data and our experience, endovenous thermal methods have shown the highest efficacy and safety in the treatment of primary varicose veins, as well as the best late long-term results [4].

The purpose of thermal methods is to achieve stable occlusion of the vein lumen by the effect of thermal energy on the venous wall. Technically, each method has its own characteristics regarding the amount of energy absorbed by the vein. If all stages of the surgical intervention are followed, namely, with sufficient high-quality thermal insulation of paravenous structures with tumescent anesthesia and correct calculation of the energy amount, EULA remains the method of choice for the ablation of veins of various diameters.

Literature data indicate that a 1470 nm diode laser requires an energy density of 65-100 J/cm to obtain complete occlusion of the vein lumen within 1 year after ablation. Radiofrequency ablation and thermal ablation have a technically simpler technique due to the operation of the device itself, which, in our opinion, is more comfortable and easier for a novice phlebologist surgeon, since the device in sound mode shows the completed cycle of treating a certain length of vein. At that time, the techniques also require tumescent anesthesia-coupling of paravenous structures and larger puncture access due to the larger working diameter of the optical fiber light guide [5].

EVLA remains the operation of choice for truncal varicose veins in the world. But taking into account the need for tumescent anesthesia and the possibility of complications from thermal energy, non-thermal methods for treating vein pathology are being actively considered. For example, global research on mechanochemical ablation indicates that the technique combines physical (mechanical) damage to the endothelium at the expense of an endovenous device with the chemical effect of a liquid sclerosant. According to various data, the technique has less pronounced postoperative pain and discomfort in patients.

Regarding our data, with the correct protocol of thermal techniques, postoperative pain is practically not pronounced in our patients. But the MOCA technique is faster and required only one injection for access, unlike laser ablation, due to the absence of the need for a tumescent coupling. Therefore, intraoperative MOCA was slightly, but more comfortable for patients,

and was also the method of choice in patients with allergies to the components of the tumescent solution. According to the data of studies in the world, MOCA is the method of choice in patients with various stages of varicose disease in the presence of trunk reflux of at least 10 cm [6].

One of the first comparative studies of thermal techniques, MOCA and UGS showed better results in terms of reduced postoperative pain in patients who underwent non-thermal techniques. But research continues on the possible amount of sclerosant administration per procedure, taking into account the possible side effects of sodium tetradecyl sulfate (the most common are hyperpigmentation, skin necrosis, telangiectasia, mitting, or even venous thrombosis and anaphylaxis or pulmonary embolism). We did not notice these complications in our patients from the MOCA.

And the method of foam sclerotherapy (0.5-1%) was used as a correction method in case of recurrence or detected areas of venous incompetence after other methods, taking into account its availability, ease of use in conditions of manipulation or ligation, and short duration of the procedure. As a monotherapy, foam sclerotherapy had a higher percentage of relapses, so it required more frequent corrections (repeated procedures).

According to a review of 19 primary studies, described in 25 publications, on the comparison of thermal and non-thermal techniques in different variations for the treatment of varicose veins, in most cases mechanochemical ablation had slightly worse technical results in closing veins due to existing recanalizations. At the same time, clinical results, patient satisfaction, and improvement in quality of life were at the same level as in patients after thermal treatment methods. Regarding the technique of using cyanoacrylate glue, neither technically superior quality nor improvement in quality of life was noted in comparison with EVLA or RFA [7].

There was a slightly shorter recovery period after non-thermal methods compared to thermal ones. Regarding the economic significance and costs of the techniques, an analysis was carried out, which revealed the most cost-effective method to be thermal ablation in comparison with open surgical interventions and non-thermal techniques. The analysis showed that open classical vein surgery was the most expensive method.

As for another important factor – the rapid recovery of the patient after the procedure – a slightly shorter rehabilitation period was noted by patients after cyanoacrylate obliteration and mechanochemical ablation [8]. However, these methods required corrections due to a higher percentage of recanalizations.

Taking into account world studies and according to the data of our study, we can recommend minimally invasive techniques as the method of choice during martial law, given the possibility of surgical treatment under local anesthesia or without it at all. This enables outpatient intervention, as it does not require a stationary operating room and a long stay of patients in the ward under the supervision of medical personnel.

Another important factor is rapid rehabilitation due to the patient's activity immediately after the intervention and the possibility to return to the usual rhythm of life. Minimal perioperative pain and improvement in quality of life were noted by patients in all groups of minimally invasive intervention.

CONCLUSIONS

Endovenous laser ablation is the most effective method of treating primary varicose veins, as it gives the best late results in the treatment of varicose veins. The electrowelding technique is more accessible and simpler in the technical aspect than EVLA and RFA, therefore it has quite strong prospects for further wider implementation in the clinical practice of varicose vein management in outpatient settings.

The advantage of non-thermal methods is the absence of thermal influence on paravenous structures and the faster operation technique. Another advantage of non-thermal methods is the absence of the need for tumescent analgesia, since only one puncture is required for the introduction of the drug or device, which is mostly painless. The reduction of the risk of allergic reactions should also be noted, which sometimes occur to the components of the tumescent solution, and therefore the advantage of this method is the possibility of its use in patients with a heavy allergic history.

After using bioglue, according to the recommendations, there is no need for mandatory compression in the intervention area, which makes the technique convenient for the patient and can be used more often in warm seasons. The advantage of echo-guided foam scleroobliteration is its lowest cost per procedure among all minimally invasive methods, which is a significant factor when choosing an intervention for low-income population stratum.

In our study, foam sclerotherapy was the method of choice for treatment correction, if necessary. It is a technically simple method, it is performed in outpatient conditions during a control examination, it is fast in terms of time and the least expensive procedure, which is a significant economic factor.

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The study was conducted as a fragment of complex scientific projects of the Scientific Department of Minimally Invasive Surgery (State Institution of Science «Research and Practical Center of Preventive and Clinical Medicine» State Administrative Department) «Optimization of surgical treatment of patients under a multimodal program of rapid recovery based on the improvement of operative interventions, in particular with the use of nanobiosensor technologies and their anesthetic support» (state registration number 0122U000233; term: 2022-2024).

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Conflict of interest:
The Authors declare no conflict of interest.

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Received: 01.11.2022
Accepted: 29.04.2023

A - Work concept and design, **B** – Data collection and analysis, **C** – Responsibility for statistical analysis, **D** – Writing the article, **E** – Critical review, **F** – Final approval of the article