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Research Article

The multimodal treatment approaches to varicose veins: Preservation versus thermal ablation of the incompetent great saphenous vein

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Abstract

Objective: To compare the clinical efficacy of Ambulatory Selective Varices Ablation under Local Anesthesia (ASVAL) and Endovenous Laser Ablation (EVLA) with concomitant phlebectomy in patients with the incompetent Great Saphenous Vein (GSV).

Design: "Prospective Case Series study (C2-C3 patients) with 2 and 5 years follow-up.

Methods: This was a prospective observational cohort study in a single center. Seventy-six patients (59 females) with GSV incompetence and C2-C3 were included in the prospective consecutive case study. The diameter of GSV at the 15-cm below the SFJ level was the main criterion to identify two groups of patients. Thirty-three patients (25 females, mean age 37.03) with the GSV diameter ≤6 mm were treated with ASVAL. Forty-three patients (34 females, mean age 46.19) with the GSV diameter >6 mm were treated by EVLA with concomitant phlebectomy. Clinical and functional outcomes measured by Venous Clinical Severity Score (VCSS) and clinical recurrence-free rate according to the classification of recurrent varicose veins after treatment (PREVAIT) were analyzed in 2 years follow-up. The clinical recurrence-free rate was analyzed in 5 years follow-up.

Results: 2-year follow-up was detected a significant decrease in the postoperative VCSS in the ASVAL and the EVLA group (p< 0.001). There was no statistically significant difference between both groups in VCCS in 2 years post-operation (p= 0.681). Frequency of recurrence did not differ between ASVAL (18.8%) and EVLA (21.4%) groups 2 years after treatment (p= 0.776) and the diameter of the GSV significantly decreased in the ASVAL group (5.48 vs 5.13, p= 0.008). The 5-year follow-up was detected recurrences in 40.0% of patients ASVAL group and 45.6% EVLA group (p = 0.668).

Conclusions: Both ASVAL and EVLA effectively improve the disease severity in the groups of patients, selected according to the GSV diameter (≤ 6 mm or > 6 mm).

Introduction

In the last decade, endovenous methods of thermal ablation for treating varicose veins of lower extremities have been widely recognized, and the efficacy and safety of these methods have been demonstrated in large randomized trials [1-4]. However, the evidence suggests that neither endovenous thermal ablation, nor surgical removal of Great Saphenous Vein (GSV) guarantee long-term clinical efficacy: for both methods, there are no differences in the recurrence rates in 2- and 5-year periods [5-8]. In light of these observations, removal/ablation of the GSV trunks as a standard treatment for all patients with varicose veins is in question.

According to the concept of ascending or multifocal evolution of varicose veins, preservation of an inconsistent

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GSV trunk may be justified, since its reflux is associated with hypervolemia in varicose tributaries. Selective phlebectomy of dilated tributaries can help reduce hypervolemia and, ultimately, eliminate reflux in the GSV trunk. It is considered to be less traumatic and is associated with a lower complication rate compared to other treatment approaches. Modern guidelines acknowledge the potential of this method to effectively treat chronic diseases of the veins [9-11].

The severity of the clinical course of varicose veins is associated with ambulatory venous pressure (AMVP). This pressure, which leads to an increase in the diameter of the incompetent vein, is associated with the volume and duration of venous blood reflux. However, the pathological volume of refluxing venous blood can be directed into the physiological flow (eliminated) by the work of the calf pump. As a result, venous pressure decreases. A study by S. Raju, et al. [12] found that if a diameter of GSV is less than 5.5 mm, the volume of reflux in it can be eliminated by work of the calf pump in 94% of cases. Although if GSV diameter measuring more than 5.5 mm, refluxing volume in it can be eliminated by the calf pump in 51% of cases. These data allowed us to formulate a hypothesis of the possibility of preserving an incompetent GSV if its diameter is less than 6 mm. The level of measuring the diameter of GSV at a distance of 15 cm from the SFJ was determined based on the results of a study by Mendoza, et al. [13], which showed that GSV diameter measured at this level demonstrated a good correlation (r = 0.77) with the CEAP clinical class.

This prospective study compares 2-years clinical outcomes, a number of complications, and relapses in two groups of patients (as defined by the GSV diameter) that underwent Ambulatory Selective Varices Ablation under Local Anesthesia (ASVAL) and Endovenous Laser Ablation (EVLA) with concomitant phlebectomy.

Methods

This was a prospective observational cohort study (ClinicalTrials.gov ID: NCT04034329). Patients at a single center (University Hospital No. 10, Minsk, Belarus) were included onwards and all data were entered into a database. The study protocol was approved by the University ethics committee (No. 20140451) and all patients signed a written consent to participate in the study. Patients with GSV incompetence and C2-C3 were included in the prospective consecutive case study if they satisfied the selection criteria outlined in Table 1.

Full venous duplex ultrasonography was performed using B-K Medical REF ZV0071 colour-coded duplex scanner fitted with a 7.5-MHz linear probe. Cognizant of the negative consequences of standing and sitting for long periods of time (e.g. venous hypertension, venous reflux), we scheduled investigations for early morning, thus ensuring examination of the physiological status of the venous system in each patient. Ultrasound examinations of reflux at the Saphenofemoral Junction (SFJ) were performed using the Valsalva maneuver. Ultrasound examination of GSV reflux was performed by manually compressing the calf followed by sudden release.

Table 1: Inclusion/ exclusion criteria.

Inclusion criteria	Exclusion criteria
Great saphenous vein (GSV) incompetence with reflux at least down to the knee level	Previous surgical groin exploration, except herniotomy
Primary symptomatic varicose veins, CEAP clinical class C2-C3	The small saphenous vein, anterior or posterior accessory saphenous vein incompetence at the same limb
Physical status according to the American Society of Anesthesiologists (ASA) I-II	Deep venous thrombosis, thrombophilia associated with a high risk of deep venous thrombosis or postthrombotic syndrome
	Arterial occlusive disease > Fontaine IIA and/or the ankle-brachial index below 0.8
	Osteoarthropathy of the legs, which limited the motion activity
	Active malignancy (diagnosed in the past 5 years)

Reverse flow that lasted more than 0.5 seconds was considered pathological. Preoperative venous duplex mapping was done in the upright position [14].

Duplicate measurements GSV diameter were measured holding the probe transversely with no pressure and were taken 15 cm below the SFJ. This result was the main criterion to identify two groups of patients. Those with the GSV diameter ≤ 6 mm were treated with ASVAL. If the diameter of GSV was > 6 mm, EVLA with concomitant phlebectomy was performed.

All surgical procedures were accomplished by the same surgeon, using tumescent local anesthesia (i.e. 0.1% lidocaine and sodium bicarbonate solution without epinephrine). The EVLA was done under duplex guidance with a 1560-nm diode laser (Mediola Endo model «Fotek LK-50-4», Belarus) using bare fibers via a Seldinger wire technique. The GSV was cannulated at the lowest point of the reflux. The laser fiber was advanced below the SFJ at the level after which the GSV was ablated during gradual withdrawal of the fiber. The 15W laser power was delivered in continuous pull-back traction. The average applied linear endovenous energy dose (LEED) was 75.3, CD=9.2 J/cm. Peripheral side branches were removed by multiple stab avulsions using Várady hook in both groups. After the treatment, the leg was wrapped in sterile absorbent bandages, and compression stockings class II (23-32 mm Hg) were put on and recommended to wear for two weeks.

All patients were discharged on the day of the treatment and were invited to a follow-up duplex ultrasonography (DUS) on the 1st postoperative day and 2 years after the operation. DUS at the 2 years follow-up visits were carried out by an independent specialist who was not involved in the initial treatment of the patients. To report clinical recurrence after EVLA we have used Groupe d' Évaluation des Lasers et de l'Échographie Vasculaire (GELEV) score [15]. VCSS was registered before, 2 years, and 5 years after the treatment.

The objectives of the study were the following: 1) to determine the 2 years clinical and functional outcomes while

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taking into account the severity of the disease (as measured by VCSS) and the degree to which patients were affected by it; 2) to establish the 2 years and 5 years clinical recurrence-free rate according to the classification of recurrent varicose veins after treatment (PREVAIT) [16,17]. PREVAIT is defined as the presence of any new visible or palpable varicosities on the studied leg that had been noticed through the clinical examination. The criterion of a recurrent varicose vein was a visible or palpable varicosity with a diameter of more than 3 mm.

Statistical analysis

We used descriptive statistics to report baseline characteristics of the sample and pre-and postoperative scores. Dependent t-test and Wilcoxon signed-rank test were used to analyze changes in VCSS pre-and post-operation. Differences in frequencies of categorical variables between groups were analyzed using Fisher's exact test. The multivariable regression model was used to establish the relationship between a dependent variable (recurrence rate) and independent variables (treatment method, category C, side, age. The level of statistical significance was set at an alpha level of 0.05. IBM SPSS 22 was used to conduct all statistical analyses.

Results

The sample in this study included 76 patients / 88 legs. However, to achieve higher homogeneity of the two groups, a leg with a more severe varicose disease was included in the study, hence the final sample included 76 patients/76 legs. The flowchart (Figure 1) shows the number of patients excluded from and included in the analysis.

Baseline patient characteristics are presented in Table 2.

2 years follow-up. Evolution of signs and symptoms

In the ASVAL group, VCSS before operation (Me=3.0, IQR 2.0-3.0) was higher than VCSS post-operation (Me=0.0, IQR 0.0-1.75), p< 0.001. Statistically significant decrease in the VCSS post-operation was also detected in the EVLA group: the mean VCSS pre-surgery (Me=5.0, IQR 3.0-6.0) was substantially higher than the mean VCSS post-operation (Me=0.0, IQR 0.0-1.0), p<0.001. There was no statistically significant difference between both groups in VCCS 2 years post-operation (p= 0.681) (Figure 2).

2 years follow-up. Clinical recurrence according to PREVAIT

Overall, frequency of clinical recurrence, irrespective of extent and source, did not differ between ASVAL (18.8%) and EVLA (21.4%) groups 2 years after treatment (p=0.776).

Table 3 summarizes the detailed PREVAIT data.

A small number of observations did not allow for comparisons of two groups by sections of PREVAIT. Phlebectomy was recommended for treatment of PREVAIT in 3

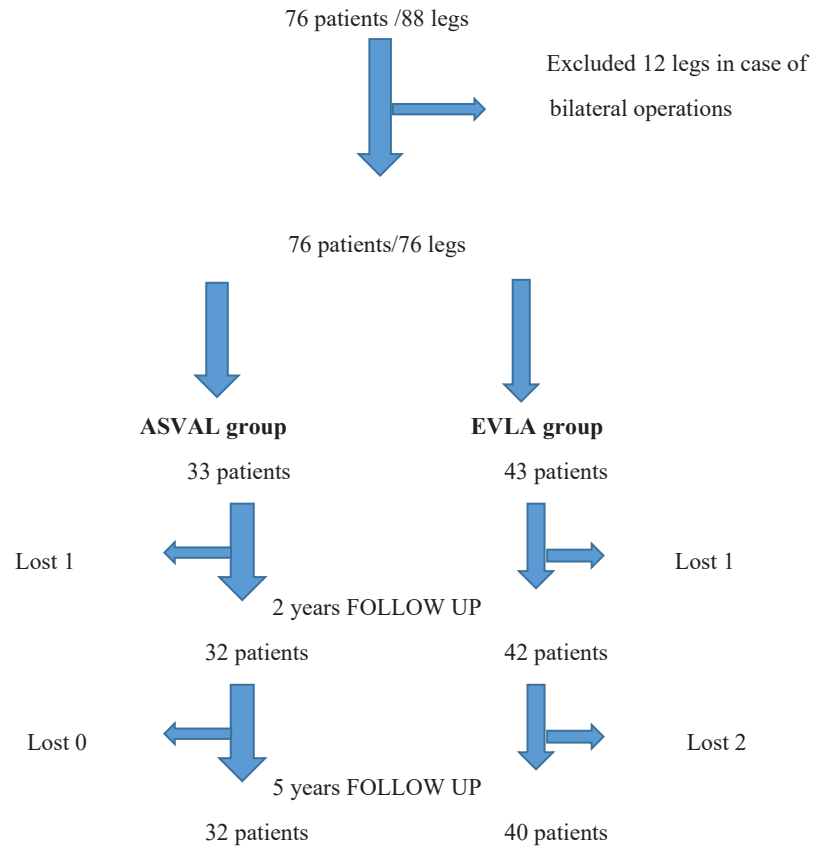

Figure 1: Chart is showing the flow of patients through the prospective consecutive case study.

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Table 2: Baseline patient characteristics.

Characteristic	ASVAL group (n=33)	EVLA group (n=43)	p
Age (M, SD)	37.03 (11.4)	46.19 (10.76)	<.001
Sex: Female (N, %) Male (N, %)	 25 (76) 8 (24)	 34 (79) 9 (21)	.731
The severity of the varicose disease (CEAP stage): C2 stage C3 stage	 27 (82) 6 (18)	 17 (40) 26 (60)	<.001
Side: Right Left	 22 (67) 11 (33)	 17 (40) 26 (60)	.019
Diameter	5.5 (0.74)	7.53 (0.92)	<.001
VCSS (prior to the surgery), Me	3.0	5.0	<.001

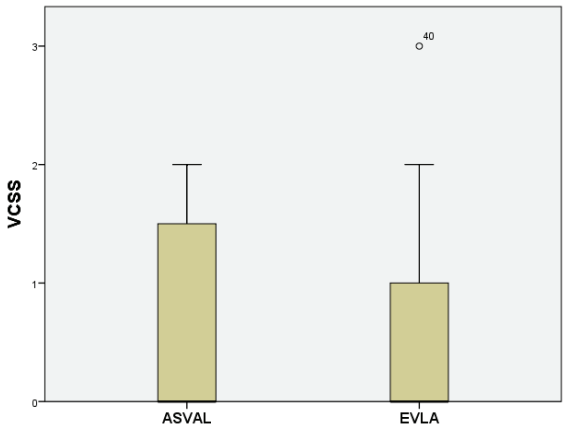

Figure 2: VCCS 2 years post-operation.

ASVAL patients and 5 EVLA patients. Two patients in the ASVAL group required repeated surgery of extensive recurrence due to SFJ reflux. One EVLA patient underwent Anterior Accessory Saphenous Vein (AASV) surgery. All re-operations were for cosmetic indications.

2 years follow-up. Duplex reflux and GSV incompetence

Reflux was not significant in the GSV (reflux duration <0.5 seconds) after 2 years in 15 (46.9%) ASVAL patients. The diameter of the GSV, as measured at 15 cm below the SFJ level, significantly decreased in the ASVAL group (5.48 vs 5.13, p=0.008). There was no statistically significant association between refluxing GSV and observed recurrence in the ASVAL group (p=0.659). The results of the GSV examination 2 years after EVLA are presented in Table 4.

GELEV-score: Lev 0: no occlusion, refluxing vein, unchanged vein. Lev 1a: partial occlusion with proximal reflux. Lev 1b: partial occlusion without reflux. Lev 2a: complete occlusion with unchanged or larger diameter. Lev 2b: complete occlusion with diameter reduction >30%. Lev 3: complete occlusion with diameter reduction >50%. Lev 4: fibrotic cord, vein not visible. This scoring was introduced by GELEV (Groupe d' Évaluation des Lasers et de l'Échographie Vasculaire, part of the " Société Française d'Angéiologie") - information is in accordance to M.E. Vuylsteke, et al. [15].

Recurrences connected with GSV recanalization were detected only in 4 out of 9 patients of the EVLA group.

2 years follow-up. Copmplications

We observed postoperative thrombosis of the GSV in 1 patient in the ASVAL group. Endothermal Heat Induced Thrombosis (EHIT) was not observed in the EVLA group. A lymphocele developed on the phlebectomy side in 3 patients in the ASVAL group and 4 patients in the EVLA group. One puncture and additional compression were sufficient for rapid

Table 3: Clinical recurrences by PREVAIT classification and management.

Group	ASVAL	EVLA
Overall PREVAIT, n (%)	6 (18.8)	9 (21.4)
Topographical sites of PREVAIT		
Groin		
Thigh	3	1
Popliteal fossa		
Lower leg	3	8
Other		
Source of recurrence		
Pelvic or abdominal	1	
SFJ	2	4[c]
Thigh perforator	1	
SPJ		
Lower leg perforator	2	5
Nature of source		
Same site		
Persisting or recurrent reflux	3	4
Neovascularization		
Uncertain		
Different site		
Persistent		
New	3	5
Uncertain		
Contribution from persistent incompetent GSV		
Reflux not detectable [a]\GSV not detectable	3	5
Reflux above knee	3	3
Reflux below knee		1
Management of PREVAIT		
Wait and see	1	2
Sclerotherapy		
Phlebectomy	3	5
SFJ and/or GSV or AASV redo treatment[b]	2	2
SSV surgery		

ASVAL= Ambulatory Selective Varices Ablation Under Local Anaesthesia
EVLA= Endovenous Laser Ablation; GSV= Great Saphenous Vein; PREVAIT= Recurrent Varicosities After Treatment; SFJ= Saphenofemoral Junction; SPJ= Saphenopopliteal Junction; SSV= Small Saphenous Vein.
[a]We added the option *Reflux not detectable* for characteristics of ASVAL group.
[b]Comprises *EVLA* in ASVAL group.
[c]Comprises refluxing SFJ with recanalization of treated GSV as well as refluxing SFJ with AASV reflux.

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Table 4: Two years follow up GSV occlusion rates in EVLA group.

GELEV-score	n (%)
Lev 0	0
Lev 1a	4 (9.3%)
Lev 1b	5 (11.6%)
Lev 2a	0
Lev 2b	1 (2.3%)
Lev 3	9 (20.9%)
Lev 4	23 (53.5%)
Not-controlled	1 (2.3%)
Total	43

treatment of lymphocele. Transient paresthesia was detected in 2 patients of the ASVAL group and 3 patients of the EVLA group.

5 years follow-up

The 5-year follow-up also showed no significant differences in treatment outcomes in both groups. Recurrences were detected in 40.0% of patients ASVAL group and 45.6% EVLA group (p = 0.668). Repeated interventions were performed in 5 patients ASVAL group and 9 patients EVLA group (p = 0.933). The multivariate regression model was unable to establish a relationship between the dependent variable (recurrence rate) and independent variables, such as the treatment method used in the form EVLA or ASVAL (0.867), category C (0.785), side (0.953), age (0.073).

Discussion

This study supports the need to implement a cost-effective individualized approach for the treatment of varicose disease that is different from ones widely accepted worldwide (i.e. removal of the GSV). Based on the overall health status, the clinical manifestation of varicose veins, and the venous hemodynamics detected by DUS, this approach allows treatment alternatives for a specific patient. This paper is an attempt to correct the prevailing view on the destruction of the GSV as a core component of the varicose veins treatment. As our findings showed, there should be a shift in the understanding of varicose disease treatment from "one size fits all" to an individualized approach.

We suggest using a less traumatic ASVAL technique, with saphenous vein preservation, in patients with a mild course of varicose disease and the GSV diameter ≤ 6 mm. Securing the GSV as a potential shunt is recommended by 2017 ESC Guidelines on the diagnosis and treatment of peripheral arterial diseases: "limit vein harvesting if lower extremity artery disease (class recommendation IIa)" [18].

In addition, preservation of the GSV and selective phlebectomy in the treatment of varices in nullipara patients may lead to a reduction in the severity of signs and symptoms in the case of varicose vein recurrence after pregnancy [19].

Reduction in diameter of the main saphenous vein after the selective removal of its incompetent side branches is illustrated in several investigations. In 1999 D. Creton revealed the diameter reduction of the proximal GSV after ablation of a distal incompetent tributary [20]. The same tendency was observed by N.S.Theivacumar, et al. and P.Pittaluga. et al. [21,22]. Nevertheless, the reflux and incompetence of the saphenous veins in some patients persisted even after the selective removal of the insolvent tributaries. This fact rises interest in terms of the possible relapses and VCSS in the long run.

In the present study, VCSS and the number of varicose vein recurrences did not differ significantly among the patients of the two groups, despite the fact that the ASVAL group maintained reflux in 43.1% of patients. The recurrence rate was slightly higher in our patients who had undergone ASVAL than in the trial by P.Pittaluga [23] (5.4%) and did not differ significantly from the I.Zolotukhin [24] results (13.5%). The amount of the relapses after EVLA in our study is equal to L.Rasmussen, et al. [5], who notes 26% of relapses in 2 years follow up. We have a slightly higher recurrence rate after EVLA than N.S.Theivacumar, et al. [25] (7%) and K. Rass, et al. [6] (16.2%).

However, the data presented by K. Rass [6] indicates recurrence in 32 out of 185 patients in the EVLA group revealed on a duplex scan, but 26 of them (81%) were clinically silent. There were partial GSV recanalizations observed in 24 patients (75%), but GSV surgery was performed only in 1 case.

A good clinical and cosmetic result, despite the recanalization of GSV, confirms the evidence that it is possible to keep an incompetent GSV without worsening the clinical outcome of varicose veins treatment in a selective group of patients. Similar data was given by N.S. Theivacumar, et al. [26], noting the absence of clinical manifestations during the recanalization of GSV even in the presence of reflux. GSV recanalization without clinical manifestations was demonstrated in a trial by J.T.Christenson [27]. This being said, the recurrence of varicose veins in our patients was minor, in many cases not noticed by the patient, and was not associated with a significant increase in mean VCSS. LEED that was used in the EVLA group was at par with other studies [25-28].

Two major limitations of the study include its study design (i.e. non-randomized nature) and small sample size (derived from a single center). Moreover, group allocation based on the GSV diameter does not take into account other characteristics of reflux and the state of the muscular pump of the calf. Nonetheless, we have not noted any reflux below the knee in patients with GSV≤6. The results obtained in a prospective study of the GSV preservation concept in real clinical practice are encouraging. Further follow-up with an increased number of patients will probably provide more evidence on this topic.

Conclusion

Patients suffering from varicose disease with GSV incompetence have certain differences in severity and the course of the disease, therefore treatment should be individualized. We found similar good results using the following treatment

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options: selective phlebectomy with GSV preservation for patients with diameter ≤ 6 mm and mild clinical course of the disease and/or with mostly cosmetic concerns; and GSV ablation with concomitant phlebectomy in more severe clinical cases and GSV diameter > 6 mm. Both ASVAL and EVLA effectively improve the disease severity in the groups of patients, selected according to the GSV diameter.

The results obtained in a prospective study of GSV preservation in real clinical practice are quite encouraging. Further large randomized trials will probably provide more evidence on this topic.

Declaration

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Ethical approval: The ethics committee of Belarusian State Medical University approved this study (registration number 20140451).

Guarantor: II

Contributorship: II and KI researched literature and conceived the study. II, GK, JD, and NN were involved in protocol development, gaining ethical approval, patient recruitment, and data analysis. KI and II wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

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