

# The endovenous ASVAL method: principles and preliminary results

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## PURPOSE

We aimed to investigate the feasibility and safety of the endovenous ambulatory selective varicose vein ablation under local anesthesia (eASVAL) method in a selected group of patients with varicose disease and present the short-term results of one-year ultrasonographic follow-up.

## METHODS

Three hundred and ninety-five consecutive patients with varicose veins who had been treated with endovenous laser ablation (EVLA) were retrospectively reviewed over a period of two years. From this group, 41 patients who were treated using the eASVAL technique and had the great saphenous vein (GSV) preserved were included in the study. These patients had only limited segmental GSV reflux accompanied by a competent terminal valve. The eASVAL technique can be defined as EVLA of the proximal straight segments of the major tributaries connecting the symptomatic varicose veins with the GSV, followed by ultrasound-guided foam sclerotherapy of the superficial varicose veins themselves. The patients were assessed before and after the treatment by duplex scan findings and clinical assessment scores.

## RESULTS

The GSVs were successfully preserved in all 41 cases, and all patients showed significant clinical improvement using the eASVAL approach ( $P < 0.001$ ). Segmental reflux was no longer present in 75.3% of patients. The mean diameters of the GSVs were significantly reduced at one-year follow-up (8.5 mm vs. 7.5 mm,  $P < 0.001$ ).

## CONCLUSION

eASVAL is a feasible and safe procedure in selected patients, with promising results at one-year ultrasonographic follow-up. However, prospective studies are required, comparing this approach with the standard techniques.

**A**mbulatory selective varicose vein ablation under local anesthesia (ASVAL) is a surgical treatment for varicose veins based on the ascending hypothesis that venous insufficiency progresses in an ascending manner, from the superficial tributaries to the saphenous vein (SV) and then to the sapheno-femoral junction (SFJ). Recent scientific data based on precise and detailed duplex scanning support this hypothesis (1–6). The ASVAL method recommends preserving the great saphenous vein (GSV), unless there is a serious terminal valve insufficiency, and suggests the surgical removal (phlebectomy) of the superficial varicose reservoir (SVR) as a primary treatment. The major argument in favor of preserving the GSV is the essential physiologic role that the GSV could play in superficial drainage and, to a lesser extent, its availability as revascularization material. Although the original ASVAL method is performed using simple phlebectomies, many patients refuse to have this treatment because they regard it as a surgical operation that would likely yield poor cosmetic results. Thermal endovenous techniques and foam sclerotherapy are less aggressive and are reported to be as effective as traditional surgical treatments (7). The question arises as to whether the ASVAL approach can be performed using endovenous techniques. To the best of our knowledge, this research will be a preliminary study describing the endovenous technique for the ASVAL approach.

The purpose of this study was to investigate the feasibility and safety of endovenous ASVAL (eASVAL) technique and to present the short-term results with one-year ultrasonography (US) follow-up in a selected group of patients.

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## Methods

Three hundred and ninety-five consecutive patients who were treated with endovenous laser ablation (EVLA) were reviewed retrospectively between August 2011 and October 2013. Within this group, 41 patients had been treated with the eASVAL technique and had their GSVs preserved. All patients presenting with varicose veins were evaluated by clinical exam and duplex scanning by a vascular interventional radiologist. General exclusion criteria for EVLA were as follows: patients with severe peripheral arterial disease, active thrombophlebitis, severe deep vein insufficiency, pregnancy, known thrombophilia or coagulation disorders, or a history of deep vein thrombosis. The eASVAL technique can be defined as EVLA of the proximal straight segment(s) of the major tributary or tributaries connecting the symptomatic varicose veins, while sparing the incompetent segment of the GSV, followed by ultrasound-guided foam sclerotherapy (UGFS) of the superficial varicose veins themselves. The purpose of EVLA of the straight proximal segments of major tributaries was to decrease the foam from gaining access to the GSV, since the goal of ASVAL is to preserve the GSV. Patients with any grade of terminal valve reflux were not included in this study group, and they were assigned to a standard GSV ablation treatment.

### Main points

- Ambulatory selective varicose vein ablation under local anesthesia (ASVAL) is a surgical treatment for varicose veins based on the theory that venous insufficiency progresses in an ascending manner, from the superficial tributaries to the saphenous vein and then to the sapheno-femoral junction, which is known as the "ascending hypothesis."
- The ASVAL method recommends preserving the great saphenous vein, unless there is a serious terminal valve insufficiency, and suggests the surgical removal of the superficial varicose reservoir as a primary treatment.
- ASVAL approach can also be performed using endovenous techniques and, to our knowledge, this research will be a preliminary study describing the endovenous technique for the ASVAL.
- The endovenous ASVAL method is feasible and has very good technical success rates and clinical results for treating varicose vein disease in patients with segmental GSV reflux and a competent terminal valve.

The inclusion criteria were competent terminal valve, GSV segment showing reflux  $<10$  cm in length, refluxing GSV diameter  $\leq 10$  mm, GSV without tortuosity, one (or more) large tributary veins with a straight proximal segment, and targeted major tributary vein diameter  $>5$  mm (considered to be large). If all of the above criteria were met, patient was treated with eASVAL. If the patient did not meet one of the first five criteria, standard EVLA procedure was the treatment of choice. If the major tributary vein diameter, which is associated with the superficial varicose veins, was less than 5 mm in diameter, these patients were also excluded from the study. Only eight patients were excluded due to narrowness of the tributary vein. These patients were routinely treated by either standard UGFS or fill and aspirate foam sclerotherapy (FAFS), depending on superficial varicose vein diameters. FAFS is a useful technique for large superficial varicosities (8). US guidance and compression maneuvers were used to prevent the foam from gaining access to the GSV in standard UGFS; these data will be published in a future report. The eASVAL treatment procedure was explained to all patients and written informed consent was obtained. The principles of the Helsinki declaration were strictly followed. Institutional review board approval was not obtained, because it is not required for retrospective studies at our institution.

The demographic information and past medical histories of the patients were recorded. Varicose disease was categorized using the clinical, etiologic, anatomic, and pathologic (CEAP) classification (9), and clinical severity was graded using the revised venous clinical severity score (rVCSS) as recommended by the Society of Interventional Radiology (10). Quality of life changes were assessed using a chronic venous insufficiency quality of life questionnaire (CIVIQ-2) before treatment (11). Each patient underwent laser ablation by the same physician, who also performed the physical examination and duplex US (DUS) examination. The DUS examinations were performed with the patient in standing position, as recommended in the international union of phlebology (UIP) consensus document (12). The same US device with a linear transducer (LA523, 6–13 MHz; Esaote) was used for the diagnosis, treatment, and postprocedural follow-up examination. A venous reflux lasting longer than 0.5 s in the GSV with compression and release or the Valsalva maneuver was diagnostic for venous reflux in that segment (13).

A preoperative reflux map was obtained to allow flow mapping for planning the treatment strategy.

### eASVAL procedure

The procedure was performed under local anesthesia in an office-based treatment facility. A US-guided femoral nerve block was used for analgesia during the eASVAL procedure for 34 patients who were treated after June 2012. Lidocaine 20 mg diluted in 10 mL of saline was injected into the hyperechoic triangle lateral to the common femoral artery under US guidance, using a 22 G needle and a short connection line. This technique is modified from the technique suggested by Yilmaz et al. (14). A cold (4°C) tumescent anesthetic was injected around the incompetent tributary vein under US guidance with a power pump (Klein pump; HK Surgical). A 600  $\mu$ m bare-tipped laser fiber was used at 1,470 nm (Vari-Lase; Vascular Solution) in the continuous mode for the EVLA procedure. The subcutaneous GSV tributary vein insufficiencies were ablated with 80 J/cm (8 s  $\times$  10 Watts) after effective tumescent anesthesia just under the skin. Finally, the energy delivered was decreased to 60 J/cm by the decreased diameter of the vein below the knee. EVLA was performed for the straight segment of the tributary vein, which could be a short or a long segment (Fig. 1). Puncture was performed using a 16 G angiocath for the laser fiber or a 21 G needle to use a micropuncture sheath. If required, the fiber was passed through the large subcutaneous tributary veins with appropriate tumescent anesthesia, even if the veins were just underneath the skin. If there were additional incompetent GSV tributaries, they were ablated during the same session. Incompetent perforator veins were present in six patients, and these veins were not ablated to observe the efficacy of the eASVAL method on its own.

Following EVLA, during the same session, superficial tortuous varicosities were treated by UGFS or FAFS. Polidocanol (Aethoxysklerol 3%; Chemisce Fabrik Kreussler) was used as the sclerosing solution using a modified Tessari technique (1:3; sclerosing agent:air ratio). At the end of the sessions, compression stockings were put on the patients, who were instructed to wear them for two weeks. They were all advised to walk for 20 minutes immediately after the treatment. Nonsteroidal anti-inflammatory drugs were recommended for three days as a standard treatment. Pain medication was allowed after three days, according to patient's requirements.

### Technical and clinical assessment

Technical success in the eASVAL procedure was defined as successful access and delivery of laser energy only to the incompetent major tributary vein, while preserving the GSV.

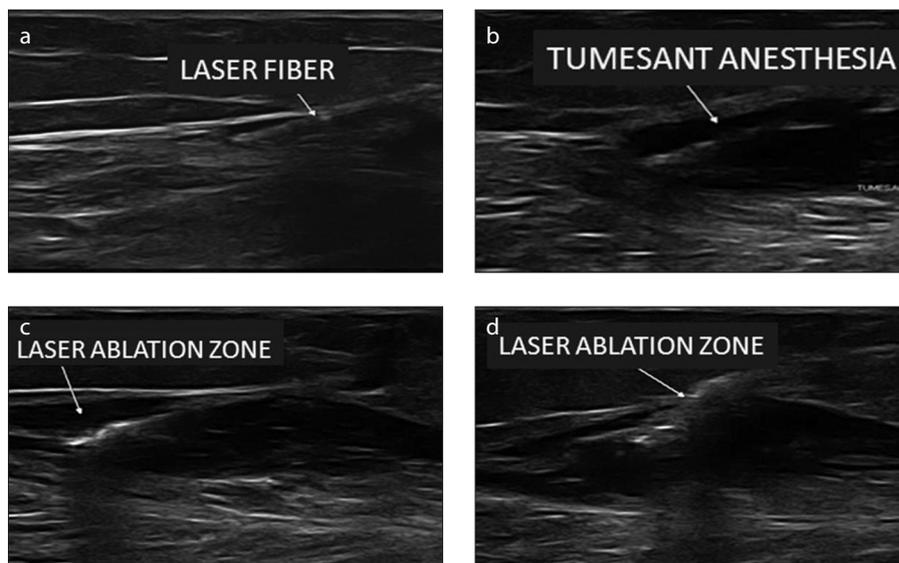
The patients were evaluated clinically and by DUS at one, six, and 12 months after treatment and annually thereafter. Clinical improvements in patients were assessed by the CEAP score and rVCSS; quality of life changes were assessed by the CIVIQ-2 score at six months versus the pretreatment scores, which were available for all patients. The clinical exam and quality of life score assessment were routinely performed at six months on all EVLA patients. Thus, we could not obtain the 12-month scores in this retrospective study. However, the segmental reflux status of the patients and diameters of the GSV were recorded before and at 12 months after treatment. Expected temporary complications, such as pain, bruising, cord-like tightening, superficial vein thrombosis and hyperpigmentation, were recorded if any persisted. Serious side effects that may require treatment, such as large skin sores, allergic reactions, deep vein thrombosis, pulmonary embolism, or paresthesia, were recorded.

### Statistical analysis

The Wilcoxon test was used for statistical analysis to evaluate clinical improvement (CEAP, rVCSS and CIVIQ-2 score) after treatment with the help of SPSS 11.0.4 software (SPSS Inc.). Variables were presented as mean±standard deviation (range) or median (minimum-maximum) values. The null hypotheses of no differences were rejected if the *P* values were less than 0.05.

## Results

The endovenous ASVAL procedure was performed in 41 patients (21 females, 51%; mean age, 42±8 years (range, 20–66 years). The GSV was preserved in all patients, whereas the major incompetent tributary veins were ablated. EVLA was performed for the straight segment of a tributary vein, which ranged from 4 to 36 cm in length, with a mean length of 8.6±2.6 cm (Fig. 2). The mean diameter of the treated major tributary vein was 6±0.5 mm. All treated tributaries were above the knee in origin, except one case. All patients had only one incompetent major tributary vein treated. Additional incompetent truncal veins in



**Figure 1. a–d.** A 29-year-old female patient with varicose disease. After the laser fiber was placed (a), tumescent anesthetic was injected around the incompetent tributary vein under US guidance (b). Laser ablation was performed (c, d) using 80 joule/cm for the straight segment of the tributary vein, which was quite short (4 cm).

**Table 1. Patient characteristics**

Age (years)	42±8 (20–66)
Gender (F/M), n (%)	21 (51)/20 (49)
Targeted major tributary length (cm)	8.6±2.6 (4–36)
Targeted major tributary diameter (mm)	6±0.5 (5–9)
Additional veins with reflux, n	2 AASV, 3 Giacomini veins
Diameter of GSV (mm)	8.5±1.2 (6.1–9.8)
Data are presented as mean±standard deviation (range), unless otherwise noted. F, female; M, male; AASV, anterior accessory saphenous vein; GSV, great saphenous vein.	

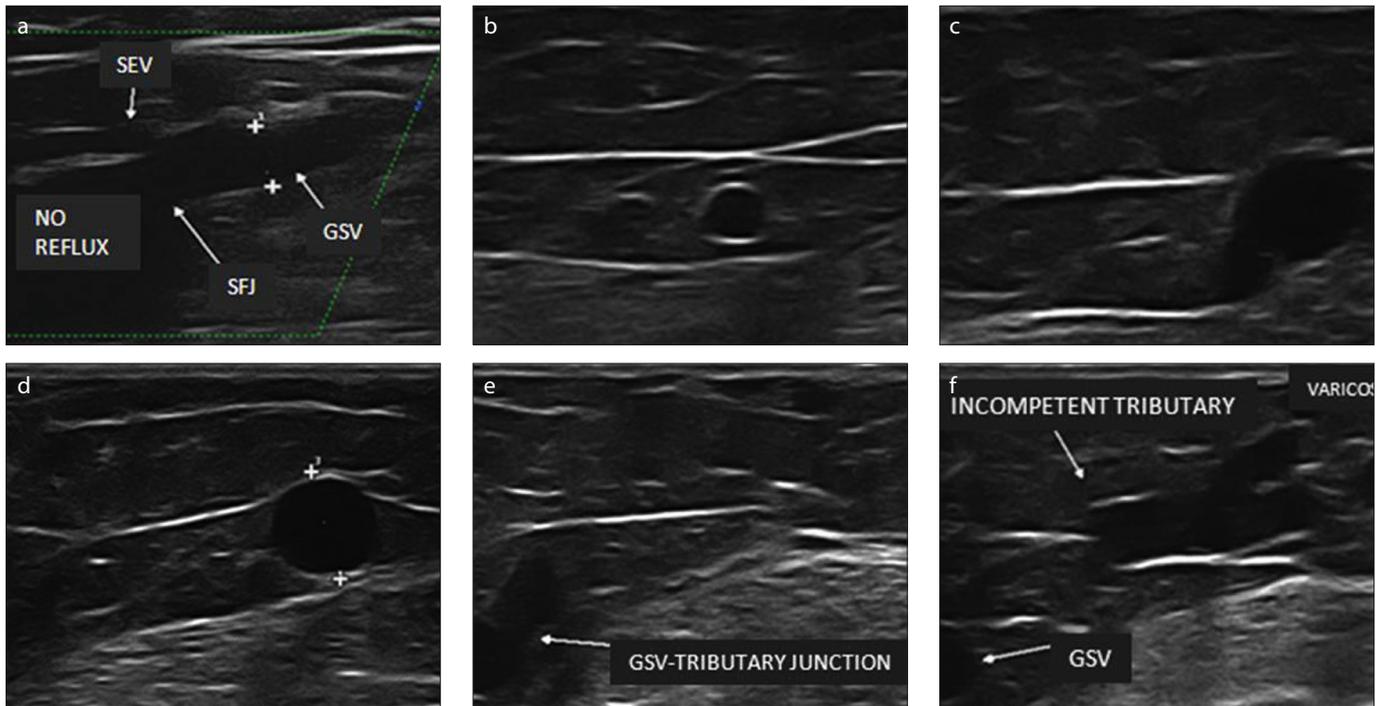
the same extremity, such as two anterior accessory saphenous vein (AASV) and three Giacomini veins, were ablated in the same session. None of the patients had bilateral disease. The patient characteristics are listed in Table 1.

The superficial varicose veins were treated by UGFS. The volume of injected foam ranged from 2 to 10 mL (mean, 4.5±1.1 mL). Three patients required additional UGFS session at one-month visit for persistent varicose veins. Two of these three patients had persistent superficial varicosities at six-month and 12-month follow-ups. These two patients had perforator vein reflux associated with superficial varicose veins. Follow-up was completed in all patients by 12 months (Fig. 3). No residual superficial varicose vein was demonstrated in 95.1% of patients (39/41) at 12-month follow-up.

Technical success was observed in all patients (100%). Undesired obliteration of

the GSV was observed in a single case at one-month visit; however, this vein recanalized by itself, and the terminal valve was still competent at six-month follow-up. The mean diameter of the GSVs at the SFJ was 8.5±1.2 mm (range, 6.1–9.8 mm) before the ablations. The mean diameter decreased to 7.5 mm (range, 5.6–8.9 mm) at 12-month follow-up; the difference in diameter was statistically significant (*P* < 0.001). All patients had segmental reflux <10 cm in length. In 29 patients (70.7%), segmental reflux reached the SFJ; however, the terminal valve remained competent. Segmental reflux was no longer observed in 75.3% of our patients (35/41). One year after treatment, only six patients (14.6%) continued to have segmental reflux. Four of these six patients had GSV-related perforator vein reflux as well.

The patients were classified as CEAP C2 in 36 cases, C3 in three cases, and C4 in two



**Figure 2. a–f.** A 32-year-old female patient with segmental great saphenous vein (GSV) reflux and dilatation as well as a normal sapheno-femoral junction (SFJ) and normal-sized proximal GSV (6.4 mm) (a). A normal-sized GSV could be followed to the mid-femoral level (b). Aneurysmal dilatation of the GSV is observed without perforator vein reflux (c). The GSV diameter was 10.3 mm at the distal femoral level near the tributary vein with reflux (d). The GSV and tributary junction could be observed within the saphenous compartment (e). The incompetent tributary vein and relationship with varicose veins could be observed (f).



**Figure 3. a, b.** A 34-year-old male patient with varicose veins before treatment (a). After endovenous ASVAL treatment, excellent clinical and cosmetic results were achieved by the 12-month follow-up (b).

cases, (median, 2; range, 2–4), and all patients were symptomatic before treatment. Six months after the treatment, 21 patients were classified as CEAP C0 and 20 patients

as C1 (median 0, 0–1 values) (Table 2). The median rVCSS score was 5 (range, 2–9) before the procedure and 2 (range, 0–6) after the procedure. The median value of CIVIQ-2

scores decreased from 42 (24–82) preoperatively to 26 (20–52) postoperatively. rVCSS and CIVIQ-2 scores showed significant improvement at six months after treatment ( $P < 0.001$ ; Table 3).

There were no complications other than the expected postprocedural complaints of pain, bruising and cord-like tightening along the course of the treated vein. Serious side effects were not observed. Two patients had symptomatic thrombophlebitis and recovered with standard nonsteroidal anti-inflammatory drugs in the follow-up examinations. There was mild hyperpigmentation in three patients (3/41, 7%) at one-year follow-up.

## Discussion

In this study, GSVs with short segmental reflux were successfully preserved in all cases by the eASVAL method. Segmental GSV reflux disappeared in 75.3% of patients. The mean diameter of the GSVs was significantly reduced at one-year sonographic follow-up. Segmental GSV reflux remained unchanged in some patients, particularly in those whose reflux was associated with a perforator vein reflux. CEAP “C” classification, rVCSS, and quality of life scores improved after six months of follow-up.

**Table 2. Pretreatment and post-treatment clinical CEAP classification change**

	C0	C1	C2	C3	C4	C5	C6
Pretreatment	0	0	36	3	2	0	0
Post-treatment	21	20	0	0	0	0	0

**Table 3. Pretreatment and post-treatment clinical assessment and quality of life scores**

Total patients (n=41)	Pretreatment	Six months post-treatment
rVCSS scores	5 (2–9)	2 (0–6)
CIVIQ-2 scores	42 (24–82)	26 (20–52)
Data are presented as median (range).		

Traditional surgical treatment for varicose veins is no longer considered the gold standard of treatment. The manifestation of endovenous techniques that preserve the SFJ has created doubts regarding the usefulness of crosssection and has suggested another pathophysiologic theory of varicose veins (the ascending hypothesis) that questions whether SV reflux is initially responsible for the development of insufficiency (15). Supporting this hypothesis, the terminal valve was found to be frequently competent (>50%) when there was truncal reflux (16, 17). The observation that terminal valve reflux was reversible after novel endovenous procedures (18–21) led phlebologists to contemplate whether truncal reflux could be reversed after SVR treatment. At the same time, Zamboni et al. (22) reported that GSV reflux was reversible using simple phlebectomies and that the GSV diameter could be reduced after ablating the refluxing tributary (23). Indeed, the reversibility of the GSV reflux was reported by Quill and Fegan (24) long time ago following compression sclerotherapy. In addition to these studies, several publications have challenged the theory of descending progression, citing the possibility of local or multifocal early distal evolution (ascending) based on detailed duplex scanning (1–5). A recent report based on 2,275 duplex scanning results showed reflux that appeared to progress in an ascending manner from the superficial tributaries to the SV and then to the SFJ (5). The ASVAL approach is based on this novel pathophysiologic theory; only the SVR is treated by simple phlebectomies, and the refluxing GSV is preserved (25). The surgical ASVAL approach is accepted as the method of choice by many phlebologists in cases with segmental GSV reflux accompanied by minimal or no terminal valve reflux (6). Using the classical surgical ASVAL technique (isolated phlebectomy),

GSV reflux was reduced with a significant reduction in reflux duration and peak reflux velocity (26). These results suggest that the hemodynamics and diameter of the GSV can be improved using a treatment focusing on the saphenous tributaries. In a recent study, as an alternative to phlebectomy, SVR was treated by UGFS alone (27). In their study, the authors attempted to block sclerosing foam from gaining access to the GSV by applied pressure. However, this blockade is not simple in our experience, particularly in large incompetent tributaries; thus, we preferred to occlude the major tributary veins using laser ablation at the tributary–GSV junction before the UGFS treatment to the SVR.

This study defines the eASVAL method, in which the ASVAL approach is performed using EVLA for the straight segment of the major incompetent tributary vein and UGFS for superficial varicosities. EVLA of the straight proximal segments of major tributaries was performed to prevent the foam from gaining access to the GSV, since the goal of ASVAL is to preserve the GSV. Excellent results were reported for the surgical ASVAL method. The hemodynamic results were remarkably stable after three years of follow-up, with a significant improvement in GSV hemodynamics in 90% of cases compared with preoperative values. The varicose vein recurrence rate after three years was 15.7%, which was similar to the results obtained after radiofrequency treatment or traditional stripping (28). Although our study presents only short-term results of eASVAL with one-year follow-up, they are similar to the results of surgical ASVAL treatment. Since the recurrence rate for the ASVAL method in the short- and medium-term was not higher than that for techniques that involve ablation of the GSV, a conservative approach could be a better option for patients with

a GSV that is moderately dilated with minimal terminal valve reflux.

As interventional radiologists acquire more technical skills on ultrasound-guided procedures, the role of EVLA is expanding to the targeted treatment of incompetent veins apart from the GSV (29, 30). Image-guided minimally invasive treatments also provide targeted treatment for all reflux sources in addition to the GSV in the same session. These sources could be isolated perforator reflux, AASV, major tributaries, postsurgical recurrent GSV insufficiency, or SSV reflux (31–33). Another advantage of the minimally invasive treatments is the early mobilization of the patients because it may decrease the occurrence of deep vein thrombosis and the anticoagulant drug requirement. Tortuous veins are no longer a big disadvantage for endovenous treatment in experienced hands using multiple punctures.

Physicians must decide when ablation of only the tributary using phlebectomies or endovenous techniques would be feasible. Personalized medicine is very important, and an incompetent SFJ is not the only determinant for the preservation or ablation of the GSV in patients with varicose veins. Older age, a higher body-mass index, presence of trophic skin changes, extension of reflux below the knee and a more damaged GSV trunk must also be considered to decide whether to ablate or preserve the GSV (6).

Routine use of eASVAL approach will lead to the SVR treatment to be the first-line therapy. By this approach ablation of the GSV will be prevented when there is a short segmental saphenous reflux with an intact terminal valve reflux at the SFJ, which has been shown to be potentially reversible. The major argument in favor of this conservative approach is the physiological role that the GSV could play in superficial drainage if it performs its function properly and, to a lesser extent, its availability as a revascularization material in both cardiovascular and oncologic operations.

Our study has some limitations. First, it has a very selective study population, which might have biased the results. Different inclusion criteria were used compared with surgical ASVAL studies. Second, the number of patients and one-year follow-up results were not sufficient to draw precise conclusions regarding eASVAL; however, we hypothesized that this preliminary study would lead to prospective studies with larger series and extensive indications.

In conclusion, the eASVAL method is feasible and has very good technical success rates and clinical results for treating varicose vein disease in patients with segmental GSV reflux and a competent terminal valve. However, prospective studies comparing this technique with surgical ASVAL and EVLA of the GSV in combination with phlebectomy or foam sclerotherapy are required.

#### Conflict of interest disclosure

The authors declared no conflicts of interest.

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