

Endovenous laser and echo-guided foam ablation in great saphenous vein reflux: one-year follow-up results

Rodrigo Gonzalez-Zeh, MD,^a Ricardo Armisen, MD, PhD,^{a,b} and Sergio Barahona, MD,^a
Santiago, Chile

Background: Great saphenous vein (GSV) reflux is the most frequent form of venous insufficiency in symptomatic patients and is commonly responsible for varicose veins of the lower extremity. This non-randomized prospective controlled study was designed to test the hypothesis that 1) endovenous laser treatment is more effective than foam sclerotherapy in the closure of the refluxing GSV (as measured by degree of great saphenous vein reflux and venous clinical severity score changes) and 2) to record the associated complications of echo-guided endovenous chemical ablation with foam and endovenous laser therapy for the treatment of great saphenous vein reflux and to further identify risk factors associated with treatment failure.

Methods: Between January 1, 2006 and June 25, 2006, patients seeking treatment of varicose veins at a private practice of vascular medicine were assessed for the study. Inclusion criteria were: 1) presence of great saphenous vein reflux and 2) C2-6, Epr, A s, according to the CEAP classification. The selected patients consented into the study and were allowed to choose between foam (53 patients) or laser (45 patients) treatment. Duplex examinations were performed prior to treatment and at seven and 14 days, four weeks, six months, and one year after treatment. Venous clinical severity score was assessed pre-treatment and at one year post-procedure.

Results: The cohorts showed no statistically significant differences in age, sex, clinical and anatomical presentation, great saphenous vein diameter, and venous clinical severity score before the treatments. After one year follow up, occlusion of the great saphenous vein was confirmed in 93.4% (42/45) of limbs studied in the laser group and 77.4% (41/53) of limbs in the foam group ($P < .0465$). Venous clinical severity score significantly improved in both groups ($P < .0001$). Procedure associated pain was higher in the laser group ($P < .0082$). Induration, phlebitis, and ecchymosis were the most common complications. Logistical regression and subgroups analysis shown that a larger great saphenous vein diameter measured before treatment was associated with treatment failure in the foam (odds ratio 1.68, 95% CI 1.24-2.27, $P < .0008$) and in the laser group (odds ratio 1.91, 95% CI 1.02-3.59, $P < .0428$). A 90% treatment success is predicted for veins <6.5 mm in the foam group versus veins <12 mm in the laser group.

Conclusions: Overall, endovenous laser ablation achieved higher occlusion rates than echo-guided chemical ablation with foam after one year follow-up. Matching the patient to the technique based on great saphenous vein diameter measured before treatment may assist in boosting the treatment success rate to $>90\%$. A larger patient cohort followed and compared over a longer period of time would be required to confirm these findings. (J Vasc Surg 2008;48:940-6.)

Lower extremity venous insufficiency is a very common medical condition that affects approximately 25% of women and 15% of men in the western countries¹ and poses a big burden on an individual's quality of life as well on the resources and budgets of many countries' health systems.^{2,3} In particular, great saphenous vein (GSV) reflux is the most frequent form of venous insufficiency and is commonly responsible for varicose veins of the lower extremity and ulterior leg ulcer development.²

The treatment of varicose veins has changed from surgery to minimally invasive techniques. These include radio-

frequency closure of the saphenous vein, endovenous laser obliteration of the saphenous vein, and the use of echo-guided endovenous chemical ablation with foam, also know as foam sclerotherapy.² Besides the satisfactory esthetic and functional results obtained with these treatments and their low rate of complications, most of them are performed in outpatient facilities, under local anesthesia, and with almost no "down time."

Foam sclerotherapy and laser ablation are reported to succeed in the complete closure of the treated vein in around 85% and 95% of the cases, respectively, at two years follow up, and the rate of severe adverse events is under 1%. Thus, they are the favored methods of treatment in several clinical centers.⁴⁻⁶ However, the efficacy and complications of these techniques have not been established in prospective side-by-side studies.⁷

We perform both procedures routinely at the Clínica de Várices Doctor González Folch, and in this article we evaluate the treatment success rate, complications, and indications of GSV reflux treatment with either laser ablation or echo-guided chemical ablation with foam in a

From the Clínica de Várices Doctor González Folch^a and the Programa de Fisiopatología, Instituto de Ciencias Biomédicas, Facultad de Medicina, Universidad de Chile.^b

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Reprint requests to: Rodrigo Gonzalez-Zeh, MD, Clínica de Várices Doctor González Folch, Huérfanos 1022 Of. 1201, Santiago, Chile (e-mail: doctor@varix.cl).

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non-randomized prospective twelve month clinical and hemodynamic follow-up cohort study.

METHODS

Patients and study description

In the period between January 1, 2006 and June 25, 2006, patients seeking varicose vein treatment were interviewed and assessed for the study inclusion/exclusion criteria by a physician using a standard interview and clinical examination protocol. Once patients were found to meet the study criteria, treatment options were explained using a previously defined script. Both treatments were explained as being essentially equivalent and patients were told both treatments were considered among the best options for treating varicose vein disease today. Ninety-eight patients with primary isolated GSV incompetence and C2-6, Ep, A s, presentation were educated about treatment options and allowed to elect into one of two treatment groups: Group 1 was treated with endovenous laser ablation and Group 2 with echo-guided chemical ablation with foam. Only one limb per patient was included and treated during this period of time. A highly experienced surgeon performed the procedures; the physician has performed over 800 endovenous laser therapies and over 2000 foam sclerotherapy therapies over a period of time exceeding five years. This physician was blinded to the initial clinical information of the patients and just followed the treatment protocol as indicated.

Limbs were categorized according to the CEAP classification (as stated by the North American Chapter of the Society for Vascular Surgery and the International Society⁸).

Patients with primary incompetence of the GSV and saphenofemoral junction insufficiency with a reflux time 0.5 seconds measured over a distance of at least 20 cm in the upper leg were included.⁹ Exclusion criteria were pregnancy, active thrombophlebitis, clotting disturbances, known thrombophilia or coagulation disorders, a history of deep vein thrombosis, and malignancies in the patient's medical history.

The clinical and ultrasound follow-ups were done by a physician blinded to the treatment options; the physician followed a protocol to conduct the examination. There was no room for the patient to comment on his/her treatment and patients were scheduled for the follow up visit in such a way they could not get to know each other. No patients were lost or excluded from the study during the study time frame.

Ethics committee approval and informed consent were obtained. The study protocol conformed to the guidelines of the 1975 Declaration of Helsinki.

Color duplex scanning

Pretreatment examination was performed using a color duplex scanner (Medison Pico, Universal Ultrasound Systems Inc, Bedford, NY) with a 6- to 12-MHz transducer, to detect venous reflux in the GSV and other venous pathology such as deep venous insufficiency, obstruction, and venous malformations. Duplex examination was performed

at one and two weeks, one and six months and at one year after treatment to determine reflux (when still present), flow, venous occlusion or opening, compressibility, and vein diameter 2 cm. below the saphenous femoral junction (SFJ). All patients were thoroughly screened for deep venous thrombosis. Physical examination was performed to determine outcomes and side effects, such as induration, echimosys, phlebitis, and others. Venous clinical severity score (VCSS)¹⁰ was assessed pre-treatment and at one year post-procedure.

Endovenous laser ablation (ELA)

The procedure was carried out under local anesthesia in an outpatient treatment facility. The GSV was identified by duplex imaging in the standing position and marked from groin following the path of reflux. While the patient was lying down, the treatment leg was externally rotated and flexed to 40° at the knee. The GSV at the point of the most distal reflux was punctured with a 21-G needle under ultrasonographic control and a guidewire passed up the GSV. A 5-Fr introducer sheath was then passed over the guidewire until the tip reached approximately 1 cm below the SFJ. This position was confirmed by ultrasonography.

Tumescent local anaesthesia (10 ml. per cm. of GSV length, 0.2% lidocaine) was infiltrated under ultrasonographic control into the perivenous space. A 600 µm laser filament was passed through the sheath until the tip was positioned 1 cm below the SFJ. Once in place, the laser sheath was withdrawn, exposing 2 cm of the laser fiber. Protective laser goggles were mandatory for staff and patients. Laser energy was delivered by a 980-nm diode laser (ELVeS; Biolitec, Jena, Germany) set at a power of 15 W. Slow fiber withdrawal at a rate of 1-2 mm per second was employed in continuous mode, delivering 70 to 90 joules/cm.

Echo-guided chemical ablation with foam (ECHA)

The procedure was carried out in an outpatient treatment facility. The GSV was identified by duplex imaging in the standing position and marked from groin following the path of reflux. Sclerosing foams were prepared using the technique described by Tessari, applying a sclerosant to air ratio of 1:4.^{11,12} The treatment with echo-guided foam sclerotherapy consisted of a single injection of 3% foam (Polidocanol, Aet; Kreussler Pharma, Wiesbaden, Germany), with the patient in supine position. The technique involved ultrasound localization of the GSV, access using a 18 G venflon and slow injection of the foamed sclerosing agent. This venflon was placed in the insufficient GSV at the point of the most distal reflux. The volume of foam to be injected was calculated using a ratio of 1 ml per millimeter of diameter of the GSV. The surgeon observing the filling of the GSV decided the final volume. Injection was followed by immediate compression of the SFJ with the ultrasound probe during two minutes.

After endovenous laser and foam sclerotherapy a full-length compression stocking (class II support hosiery; GloriaMed, Menaggio, Italy) was applied 10 minutes post-procedure with the patient lying down. Stockings were

indicated for use for seven days and nights continuously and for seven additional days where usage during the day only was required. Patients were advised to walk immediately post procedure for 30 minutes and then discharged home with written instructions to walk daily for 30 minutes and to take simple, non-prescription analgesics for post-procedural pain, if required.

Follow-up and assessment of outcome measures

At baseline and during follow-up at one month and at one year after inclusion, a history was taken detailing clinical and venous clinical severity score components. The primary outcome measure was presence of reflux, measured with duplex imaging. Success of treatment was defined as complete occlusion of the treated vein. Secondary outcome measures were pain associated with the procedure (analog scale, 1 to 10), VCSS, deep vein thrombosis (DVT), phlebitis, ecchymosis, and paraesthesia.

Statistical analysis

A power analysis, using G*Power3 software¹³ was performed to estimate the chances to test the hypothesis of a 20% difference in success rate between the two groups. We chose to use 20% as the primary outcome effect size for two main reasons; first, it is a clinically significant improvement that would lead us to switch to a different treatment option (about one in every five patients will get an extra benefit from the new treatment) and, second, comparative analysis across many trials looking at foam sclerotherapy and endolaser suggests a difference in efficacy of at most 20%. For a power of 80% with a significant level targeted at 0.05 and using a Fisher's exact test, a group sample sizes of 45 in group one and 45 in group two are necessary to test the hypothesis that endovenous laser treatment performs better than foam sclerotherapy in the closure of the refluxing GSV.

Comparison between the two groups was performed with the Fisher's exact test or χ^2 test for categorical variables and the Wilcoxon tests for continuous variables and differences between pre- and post-procedure outcomes. Statistical analyses were performed using GraphPad Prism version 4.03 (GraphPad Software, San Diego, Cal) statistical package. Logistic regression analysis (on the web <http://statpages.org/logistic.html> by John C. Pezzullo and Kevin M. Sullivan) was used to assess the correlation between outcome and continuous variables. $P < .05$ was considered statistically significant.

RESULTS

Cohorts description

Ninety-eight patients were treated and represent the subjects of this study. Eighty patients were women (81.6%) and 18 were men (18.4%), with a mean age of 52.5 ± 11.9 years (range, 26 to 78 years). Sixty-three patients had symptomatic varicose veins, with or without edema (C2-C3), and thirty-five had a history of skin changes with or without venous ulcers (C4-C6). Etiology was primary superficial valvular incompetence in all patients. Pre-procedure deep venous reflux

Table I. Demographic and clinical data for 98 patients to be treated with great saphenous vein endovenous laser ablation or endovenous chemical ablation with foam

	ELT	ECHA	P value
Number of patients	45	53	
Male:female (n)	7:38	11:42	.6048
Age (years, mean \pm S.D.)	51.1 \pm 11.9	53.7 \pm 12.0	.3063
Clinical presentation (n, %)			≤ 1
C2	15 (33.3)	16 (30.2)	
C3	16 (35.6)	16 (30.2)	
C4	9 (20.0)	10 (18.9)	
C5	3 (6.7)	6 (11.3)	
C6	2 (4.4)	5 (9.4)	
Anatomical classification (n, %)			
Superficial	45 (100.0)	53 (100.0)	
Deep	3 (6.7)	4 (7.5)	≤ 1
Perforator	4 (8.9)	4 (7.5)	≤ 1
Diameter GSV (mm, mean \pm S.D.)	8.2 \pm 3.2	7.6 \pm 3.0	.4288
VCSS (median, IQR)	3, 3-5	3, 3-5	.8112

ECHA, endovenous chemical ablation; ELA, endovenous laser ablation; GSV, great saphenous vein; IQR, interquartile range; VCSS, venous clinical severity score.

Table II. Primary outcomes after endovenous laser ablation or endovenous chemical ablation with foam of the GSV

Outcomes	ELT	ECHA	P value
Number of patients	45	53	
Overall results (n, %)			
Occlusion	42 (93.4)	41 (77.4)	.0465
Flux	3 (6.7)	12 (22.6)	.0465
Reflux	1 (2.2)	8 (15.1)	.0360
Open	1 (2.2)	8 (15.1)	.0360

ECHA, endovenous chemical ablation; ELA, endovenous laser ablation; GSV, great saphenous vein.

and/or perforator reflux was detected in 15 patients (15.3%); the detected deep venous reflux was negligible. Great saphenous vein (GSV) diameter mean was 7.9 ± 3.1 mm (range, 3 to 16 mm). Most patients presented with a low VCSS with a median of 3 and an interquartile range of 3-5 (IQR). The cohorts showed no statistically significant differences in age, sex, clinical and anatomical presentation, GSV diameter, and VCSS before the treatments, as depicted in Table I.

Primary and secondary outcomes

Early postoperative duplex ultrasound scans were performed in all patients seven days after the procedure. These studies revealed incomplete closure (opened, flux, and reflux) in four limbs (7.6%) in the foam group and none (0%) in the laser group. At the six month follow up visit, duplex ultrasound scans were performed in all patients. The analysis showed partial GSV recanalization in two patients (cumulative 11.3% failure) in the foam group and one (2.2%) in the laser group. The cumulative success rates at one year were 93.4% (95% CI 81.5 to 98.4%) for the ELA group and 77.4% (95%

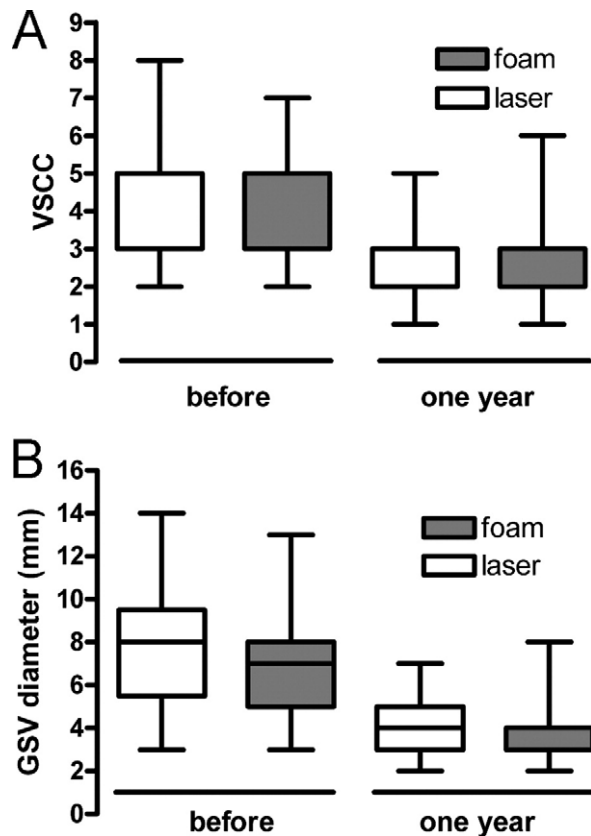


Fig 1. Box and whiskers plots to show, in A, changes in VCSS after treatment with endovenous chemical ablation with foam or laser endovenous GSV ablation and in B, changes in GSV vein diameter after treatment with foam or laser endovenous GSV ablation.

CI 64.3 to 86.7%, $P < .0465$) for the ECHA group, as shown in Table II. All the patients with GSV recanalization were further treated with foam with a larger volume, but were excluded from further analysis of this trial.

The successfully treated patient group was further evaluated in terms of VCSS and GSV diameter at the one-year follow up. As shown in Fig 1, A, patients' VCSS significantly improve with treatment, either laser (VCSS before 3 IQR 3-5 to VCSS after 3 IQR 3-2, $P < .0001$) or foam GSV ablation (from VCSS before 3 IQR 3-5 to VCSS after 2 IQR 3-2, $P < .0001$). This improvement is also observed when patients are subdivided into clinical presentation groups (C2-C3 and C4-C5-C6 groups, $P < .005$, not shown). GSV diameter was significantly reduced (Fig 1, B) with both foam (6.9 ± 2.3 to 3.4 ± 1.1 mm, $P < .0001$) and laser (8.0 ± 3.0 to 3.9 ± 1.3 mm, $P < .0001$) treatments.

Variables affecting primary success rate

Patients were classified into arbitrary subgroups according to their clinical presentation (C2-3 vs. C4-5-6) and GSV vein diameter (<8, 8-12, and >12 mm) before treat-

ment. As illustrated in Table III, the cumulative rate of treatment failure at one year was not significantly different in the clinical presentation subgroups; either treated with foam ($P < .5073$) or laser ($P < 1$, Table III). These subgroups had comparable patient age and GSV diameter.

GSV vein diameter subgroups analysis shows an increase in the failure rate from 7% in the <8 mm subgroup to 67% in the >12 mm subgroup treated with foam ($P < .0011$). All the patients who experienced laser treatment failure belong to the >12 mm subgroup ($P < .0070$). In fact, successfully treated patients had an average GSV diameter before treatment smaller than the failed treatment patient groups, either in the foam (6.7 ± 2.3 versus 10.8 ± 3.1 mm, $P < .0002$) or laser (7.8 ± 2.9 versus 13.3 ± 2.3 mm, $P < .0216$) groups.

Logistic regression analysis shows that, indeed, results were worse for greater diameter GSVs compared with smaller diameter GSVs in both the foam (OR 1.68, 95% CI 1.24-2.27, $P < .0008$) and the laser (OR 1.91, 95% CI 1.02-3.59, $P < .0428$) treatment groups. A 90% success rate (logistic regression model calculated probability) is predicted for veins <6.5 mm in the foam group and veins <12 mm in the laser group. Other variables studied (clinical presentation, age, and VCSS) showed no influence on outcome (Table IV).

Postoperative complications and side effects

Deep vein thrombosis (DVT) was detected by routine early postoperative scan after two foam ablation procedures. There was one femoral vein occlusive vein thrombosis and one partially occlusive gastrocnemius vein thrombosis which represented 3.8% of the 53 patients (Table V). All were asymptomatic and resolved within a short period of treatment with subcutaneous low molecular weight heparin therapy follow by oral anticoagulants. No DVT was observed in the laser ablation treatment group. No clinical episodes of pulmonary embolism or other cardiovascular complications were observed. Phlebitis after treatment was present 22.2% in the laser group versus 41.5% in the foam group ($P < .0529$). The incidence of ecchymosis (64.4% in the laser group vs. 47.2% in the foam group, $P < .1051$) and paraesthesia (4.4% in the laser group vs. 1.9% in the foam group, $P < .5923$; Table V) was not statistically different in the treatment groups. Induration (68.9% vs. 39.6% in the foam group, $P < .0047$) and pain associated with the procedure (4.9 ± 1.5 vs. 4.0 ± 1.5 in the foam group, $P < .0082$) were significantly higher in the laser treatment.

DISCUSSION

Endovascular techniques of saphenous vein ablation are minimally invasive alternatives to high ligation and surgical stripping of the incompetent saphenous vein. This non-randomized prospective study compared the early success and complications of two endovenous procedures of GSV ablation performed at a single institution in consecutive patients.

Table III. Variables affecting primary outcome after endovenous laser ablation and endovenous chemical ablation with foam of the GSV: subgroups analysis

Subgroups analysis	ECHA		ELA	
	n, %	Failure (n, %)	n, %	Failure (n, %)
Clinical groups				
C2-C3	32 (68.8)	6 (19.3)	31 (68.9)	2 (6.5)
C4-C5-C6	21 (31.2)	6 (42.9)	14 (31.1)	1 (7.1)
P value		.5073		1
GSV diameter groups				
<8 mm	28 (52.8)	1 (3.6)	21 (46.7)	0 (0.0)
8-12 mm	16 (30.1)	5 (31.2)	13 (28.9)	0 (0.0)
>12 mm	9 (17.0)	6 (66.7)	11 (24.4)	3 (33.4)
P value		.0011		.0070

ECHA, endovenous chemical ablation; ELA, endovenous laser ablation; GSV, great saphenous vein.

Table IV. Variables affecting primary outcome after endovenous laser ablation and endovenous chemical ablation with foam of the GSV: logistic regression analysis

Logistic regression analysis	ECHA			ELA		
	O.R.	95% CI	P value	O.R.	95% CI	P value
Variable						
Clinical groups C1-6	0.89	0.39-2.20	.7890	2.87	0.33-24.77	.3373
VCSS	0.97	0.44-2.15	.9463	0.31	0.03-3.12	.3226
Age	0.99	0.91-1.08	.8519	0.94	0.79-1.09	.4091
GSV diameter	1.68	1.24-2.27	.0008	1.91	1.02-3.59	.0428

CI, confidence interval; ECHA, endovenous chemical ablation; ELA, endovenous laser ablation; GSV, great saphenous vein; IQR, interquartile range; OR, odds ratio; VCSS, venous clinical severity score.

Table V. Complications and side effects after GSV endovenous laser or chemical ablation with foam

Complications (side effects)	ELA (n = 45)	ECHA (n = 53)	P value
Pain (mean \pm SD)	4.9 \pm 1.5	4.0 \pm 1.5	.0082
Induration (n, %)	31 (68.9)	21 (39.6)	.0047
Phlebitis (n, %)	10 (22.2)	22 (41.5)	.0529
Ecchymosis (n, %)	29 (64.4)	25 (47.2)	.1051
Paraesthesia (n, %)	2 (4.4)	1 (1.9)	.5923
DVT (n, %)	0 (0.0)	2 (3.8)	.4982

DVT, deep vein thrombosis; ECHA, endovenous chemical ablation; ELA, endovenous laser ablation; GSV, great saphenous vein; Pain, treatment associated pain.

The occlusion rate of 93.4% at the end of one year after ELA is consistent with other studies. Min et al¹⁴ reported a failure rate of less than 7% at two year follow-up. Proebstle et al¹⁵ reported recanalization in fewer than 10% of treated GSVs at 12 month follow-up after ELA. A recent systemic review of ELA has described 13 case series with encouraging early and mid-term results.¹⁶

On the other hand, the proportion of occluded veins at 12 months after foam sclerotherapy in our study population appears to correspond with data reported by other authors after two to three years of follow-up.^{17,18} Cabrera reported an occlusion rate of 81% in the treatment of 500 GSVs with a follow-up period of three years¹⁹ and Demagny

reported a recanalization of 11% after six months in 300 foam-treated GSVs.²⁰ A recently published systematic review of foam sclerotherapy places its efficacy around 85%.⁵ However, the limitation of the studies described is that most of them did not provide comparative data with which to evaluate the effectiveness of endovenous ablation against other methods of treatment.

Surgical treatment is still considered the 'gold standard' for varicose veins in many centers. Nevertheless, the qualities of conventional surgery have to be judged against the newer minimally invasive techniques. Surgical ligation of the SFJ, with or without GSV stripping, has been associated with high recurrence rates, ranging from 18% to 62% at 10 years.²¹⁻²³

Radiofrequency ablation is another relatively new technique for GSV obliteration, which has been used with respectable success,^{24,25} but some studies reported a high incidence of deep vein thrombosis (16%), paraesthesia (10%), and skin burns (3.3%) with this technique.²⁶

Regarding complications and adverse events, in this study with endovenous ablation, induration, phlebitis, and ecchymosis were the most frequent problems, but paraesthesia and DVT were rare. Surgery is associated with a risk of saphenous nerve injury up to 40% with full-length GSV stripping.²⁷ Moreover, surgical treatment poses a risk of scarring, haematoma formation, and wound infection. It is worth mentioning that studies of foam sclerotherapy have reported a pulmonary embolism rate that ranged between

0.48 and 1.25% and a DVT rate between 0.02% and 1.0% without pulmonary embolism.²⁸ DVT in ELA also has been reported, with rates from 0% to 7.7%, and in agreement with this study, induration, phlebitis, and ecchymosis are the most frequent complications.⁴

Concerning this work, while it is a non-randomized controlled study, major variables such as age, sex, CEAP, GSV diameter, and VCSS before treatment were not statistically different in the two treatment groups (Table I). With respect to the primary outcome, ELA has an advantage over foam sclerotherapy in terms of GSV closure rate at the one year follow-up (93.4% vs. 77.4%, Table II) with a similar profile of minor complications (Table V). Uncomplicated DVT occurred in two patients treated with foam sclerotherapy and in none of the patients treated with ELA. While no significant differences were found in terms of complications (with the exception of pain and induration), we must point out that with a larger sample group some of the secondary outcomes may turn out to be statistically significant.

In both treatment groups, the patients that achieved GSV closure also showed a significant reduction in GSV vein diameter (Fig 1, B). Clinical outcome, measured as a change in the VCSS, also showed a significant improvement in the severity score in both treatment groups (Fig 1, A).

Failed cases were treated with one or more sessions of foam sclerotherapy with a larger volume using the same foam concentration (3%) until a successful outcome (defined as GSV closure, no reflux, compression, or flow) was achieved. The surgeon observing the filling of the GSV decided the final volume; sometimes more than one session was necessary. In the end, all the patients were successfully treated, but because each one required a customized treatment involving variable number of treatment sessions, sclerosant volume, and sites of injection, further analysis of this sub-group was not possible.

To further gain understanding of covariates affecting the primary outcome, a post hoc subgroup analysis and a logistical regression analysis was performed. Both analyses indicated that GSV diameter is a major factor in treatment success rate. But most interestingly, the analyses also indicated that ELA will succeed with a wider range of GSV sizes (larger diameter) than foam sclerotherapy. A conservative extrapolation from the logistical regression analysis data indicates that a 90% treatment success is predicted for veins with a diameter <6.5 mm in the foam group versus veins <12 mm in the laser group. This data agree with a recently published study where a Cox regression analysis of covariates affecting echo-guided sclerotherapy indicated that a vein diameter over 6 mm is associated with treatment failure, and confirm our results that showed that age, gender, and CEAP are not predictive of foam sclerotherapy treatment outcomes (Tables III and IV).²⁹

Considering that the overall total number of failures is low in our study, an alternative explanation of the variables with negative results over the outcome could be explained because of a lack of power of the statistical analysis.

CONCLUSION

In conclusion, ELA gave better results than ECHA with foam in the treatment of GSV reflux at one year. Minor complications were similar in both techniques. GSV diameter before treatment should be considered when choosing the therapeutic approach.

AUTHOR CONTRIBUTIONS

Conception and design: RG, RA
Analysis and interpretation: RG, RA
Data collection: RG, SB
Writing the article: RG, RA
Critical revision of the article: RG, RA, SB
Final approval of the article: RG, RA, SB
Statistical analysis: RA
Obtained funding: N/A
Overall responsibility: RG

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