Management of primary uncomplicated varicose veins, endovenous laser ablation with sclerotherapy versus traditional surgery: which is the best option?

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Aim
To compare between endovenous laser treatment (EVLT) with ambulatory phlebectomy, EVLT with injection sclerotherapy, and the standard surgical procedure.
Patients and methods
A randomized prospective study was conducted on 60 (72 limbs) patients having primary uncomplicated varicose veins and was carried out at Minia University Hospital. Patients were divided into three groups (20 patients each), each with a different intervention for varicose veins. Group A underwent endovenous laser with injection sclerotherapy, group B underwent endovenous laser with ambulatory phlebotomy, whereas group C underwent traditional surgery.
Results
Operative time and hospital stay were significantly lower in group A. There was a significant decrease in complications in patients in group A (12.5%) compared with group C (37.5%). The most common complication in groups A and B was superficial thrombophlebitis, represented by 8.3 and 12.5%, respectively, and in group C was hematoma at 12.5%. After 1-month follow-up, residual varicose veins (VV) was 4.2, 16.7, and 8.3% in groups A, B, and C, respectively. Approximately 96% of patients in group A, 83.3% of patients in group B, and 66.7% of patients in group C were satisfied.
Conclusion
The combination technique of EVLT and injection sclerotherapy appears to be a safe and an efficient treatment method for the treatment of the great saphenous vein and small saphenous vein, achieving good short-term and long-term results.

Keywords:
endovenous laser treatment, injection sclerotherapy, varicose veins

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Introduction

Varicose veins belong to the most frequent lifestyle diseases, as they affect up to 40% of industrialized countries' citizens in the age between 30 and 70 years [1]. Etiology of the disease involves weakness of the vein wall and venous dilatation, elicited by abnormal venous wall remodeling. Patients with varicosity have multiple complications resulting from hemodynamic vein malfunction, such as skin discoloration, ulceration, thrombotic disorders, and hemorrhage [2].

Early monographs of venous disease and their surgical treatment date back to 1550 BC. Celcus, in first century Rome, proposed the concept of ligation and division of bleeding varicosities, whereas Galen, in the second century, introduced ligation and vein avulsion using specialized hooks [3].

Approximately 2400 years ago, Hippocrates performed the first phlebotomy to treat a varix. Since that time, modifications to the removal of varicose vein have evolved. It was Dr Muller, a Swiss dermatologist, who reinvented and refined the technique of ambulatory phlebectomy. Although this technique was adopted slowly, it is now considered the standard method for treating varicose veins [3].

Currently, there are two ways for varicose vein management: lifestyle modifications and medical procedures. Lifestyle-related recommendations include the avoidance of a prolonged standing and sitting, an intensification of physical exercise, a loosening of restrictive clothes, and losing weight by obese people. Medical methods include the use of venoactive drugs, compression treatment, sclerotherapy, phlebectomy,

open venous surgery with ligation and stripping, endovenous ablation techniques, and radiofrequency ablation (RFA) therapy [4].

Until the past few years, classic surgical methods of varicose vein removal mainly vein stripping were considered as the most radical and effective ways to cope with the pathology. On the contrary, traumatizing nature of these methods yielded several adverse effects, which directed surgeons' attention to less invasive treatment modalities, in particular endovenous laser ablation (EVLA). The development of minimally invasive procedures for the treatment of varicose veins has been led by a desire to reduce operative trauma and bruising associated with standard surgical techniques. Currently, there are two major thermal endovenous treatments available: EVLA and RFA [1].

The National Institute of Health and Clinical Excellence guidelines (United Kingdom) on the management of varicose veins already recommend endothermal ablation as the first option to consider, relegating surgery only to a third-line alternative [5].

The ultimate goal of any treatment regimen is to eliminate sources of reflux to control symptoms and progression of disease, improve cosmesis, promote ulcer healing, and prevent recurrence or a combination of these. The best therapeutic results are based on two hemodynamic principles: the abolishment of the highest point of reflux and the elimination of the incompetent and dilated venous segments. Endovenous laser treatment (EVLT) allows delivery of laser energy directly into the vein lumen. Published reports confirm that EVLA of an incompetent great saphenous vein (GSV) or small saphenous vein (SSV) is safe and can provide outcomes equal to or better than traditional surgical ligation and stripping [6].

At the time of designing our study, the comparison of EVLA with a 980-nm laser combined with injection sclerotherapy or ambulatory phlebectomy and traditional surgery had been assessed.

Patients and methods

Study design

A randomized prospective study was conducted on 60 (72 limbs) patients having primary uncomplicated varicose veins over the period started between May 2017 and February 2018 and was carried out at Minia University Hospital. The cases were followed up for 3 months.

Study population

This a prospective comparative study among three groups that were randomly selected.

Group A included 20 patients (24 limbs) who underwent endovenous laser with injection sclerotherapy management.

Group B included 20 (24 limbs) patients with primary uncomplicated varicose veins who underwent endovenous laser with ambulatory phlebotomy.

Group C included 20 patients (24 limbs) with primary uncomplicated varicose veins who underwent traditional surgery (high ligation and GSV stripping with or without ligation of saphenofemoral junction plus or minus phlebectomy.

Inclusion criteria included age between 15 and 50 years, patients with primary unilateral or bilateral uncomplicated varicose veins (Comprehensive Classification System for Chronic Venous Disorders (CEAP) C2, 3, and 4), duplex ultrasound scanning demonstrated reflux at the saphenofemoral junction with dilated GSV more than 5 mm and SSV more than 3.5 mm and truncal reflux, and accepted operative risk.

Exclusion criteria included age less than 15 years and more than 50 years; patients with reticular veins (C1 CEAP classification); patients who were treated with medical or injection sclerotherapy; patient with secondary varicose veins contraindicated for stripping and EVLA for preservation of superficial system to compensate deep system insufficiency; pregnant women to avoid any hazards of anesthesia and operative risks; and recurrent cases, in which GSV has been stripped; and patients unfit for surgery.

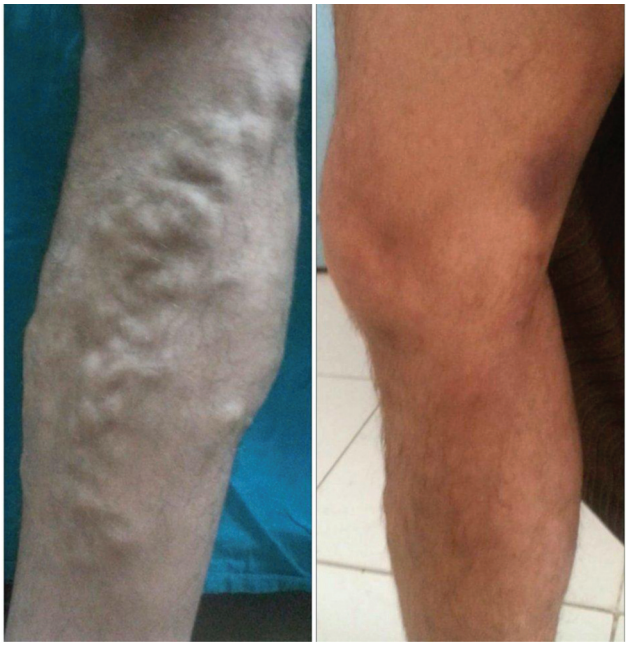
Patients who were included in this study were subjected to the following:

(1) History taking, including name; age; sex; medical history; presence of predisposing factors such as hereditary; occupational prolonged standing; surgical history of any pervious surgical operation; gynecological and obstetric history in women, including the number of pregnancies, any plan for future pregnancies, or history of contraceptive pills; history of any prior treatment for venous disease, including medication, injections, surgery, laser therapy or compression therapy; history of superficial thrombophlebitis or DVT or venous ulcers unilateral lower limb swelling; and history of any vascular disease including peripheral arterial disease.

(2) Physical examination (general, abdominal, and local examination which included inspection for any swelling, scar, edema, or skin complication) and inspection of the superficial system (GSV and SSV) to detect dilatation and saphena varix at the groin. Moreover, palpation for detection of thrill on cough at saphena varix at the groin, fascial defect at the site of perforator (Fegan's sign), firm tender nodule or cord-like structure at the site of vein (superficial thrombophlebitis), and check patency of deep venous system (lax calf muscle, no edema, no tenderness, and peripheral arterial pulsation to exclude associated arterial disease).
(3) Investigation: laboratory investigation (complete blood count, coagulation profile, random blood sugar, liver and renal function tests, HBV, and HCV) and venous duplex ultrasonography examination were performed on each patient before and after their therapy.

Deep, superficial, and perforating venous systems were evaluated, with the patient in the upright position (venous mapping). Intraoperative use of Duplex ultrasonography (DUS) was done to mark incompetent perforators and during injection of tumescent local anesthesia. The use of postoperative colored duplex ultrasound concerned about the outcome of our procedure either ablated vein for venous reflux, thrombus, and recanalization or absence of Saphenofemoral junction (SFJ) and GSV or presence of accessory saphenous vein in selected patients (Figs 1–4).

Figure 1



Incompetent GSV and dilated tributaries at the leg before and after combined EVLA and injection. EVLA, endovenous laser ablation; GSV, great saphenous vein.

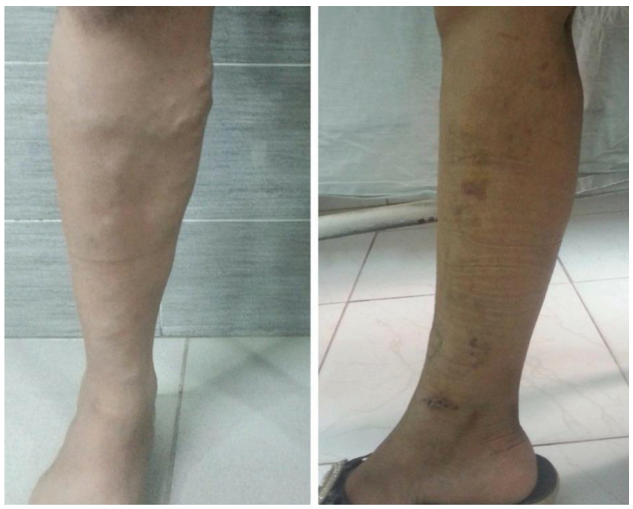
Postoperative follow-up

In early postoperative follow-up (1–2 weeks), after discharge, the patient was given instructions regarding activity level, pain control, the use of a compression stocking, and follow-up. The patients were encouraged to ambulate after the procedure. When stationary, it was recommended to elevate the leg. Pain control after the procedure was accomplished with a nonsteroidal anti-inflammatory medication. The compression stocking was applied for 48 h. After this, the compression dressing (ACE wrap) was removed.

Ultrasound was performed at that time to assess the GSV and deep venous system. Criteria for technical success of surgical stripping were absent GSV and SFJ with lack of flow. Criteria for technical success of EVLA were decrease in the diameter of GSV.

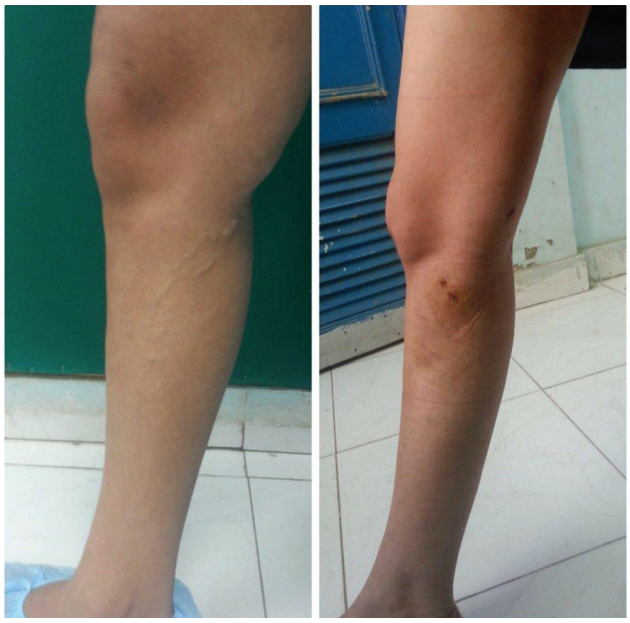
Regarding late postoperative follow-up (1–3 months), evaluation was performed on all patients at 1 and 3 months. Patients were asked about symptomatic relief at follow-up visits, particularly improvement or resolution of lower-extremity pain in three groups. Improvements in the appearance of the leg included reduction in visible varicosities and swelling as assessed by the patient and with direct comparison with pretreatment photographs obtained from all patients who underwent treatment.

Figure 2



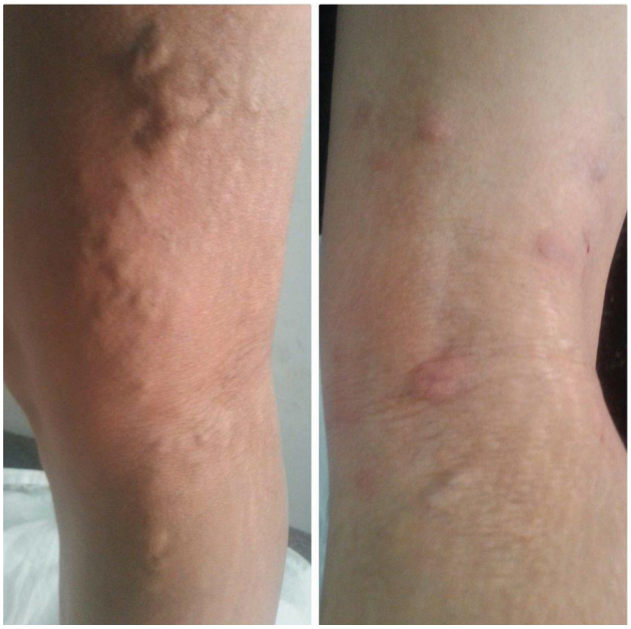
Incompetent GSV with dilated tributaries at the leg before and after combined EVLA and injection. EVLA, endovenous laser ablation; GSV, great saphenous vein.

Figure 3



Incompetent GSV and dilated tributaries at the knee before and after EVLA and ambulatory phlebectomy. EVLA, endovenous laser ablation; GSV, great saphenous vein.

Figure 4



Residual dilated tributaries at the knee before and after injection.

Patients were evaluated for possible adverse reactions at each follow-up visit. Complications were defined as those that had no significant clinical sequelae, such as superficial thrombophlebitis, ecchymosis, deep venous thrombosis (DVT), residual varicosities, skin pigmentation, ulcers at the site of injection, infection, healing, tract hematoma, seroma and bruising, and any residual dilated veins.

Duplex ultrasound criteria for successful treatment in cases managed by EVLA were as follows:

(1) At 1-month follow-up, an enlarged noncompressible GSV minimally decreased in diameter, with echogenic, thickened vein walls and no flow seen within the occluded vein lumen.
(2) At 3-month follow-up, an occluded GSV with substantial (50%) reduction in diameter.

The vein lumen was usually obliterated by the thickened wall, which had low level echoes and is incompressible. This wall thickening should be differentiated from acute GSV thrombosis where the vein is also incompressible but the lumen is filled with an echoic acute thrombus. Several weeks after successful EVLT, resolution of the acute inflammation in the vein wall should result in reduction.

Ethical approval

The title, aim, and plan of the study were discussed with the staff members, and approval regarding conduction of the study was obtained from ethics committee of research in General Surgical Department, Minia Faculty of Medicine. Full written, informed consent was obtained from all participants.

Statistical analysis

The Statistical Package for the Social Sciences Version 19 (SPSS Inc., Chicago, IL, USA), was used for data entry and analysis. Graphics were done by Excel Microsoft office 2010. Quantitative data were presented by mean and SD. Analysis of variance test was used to compare differences between the groups. Qualitative data were presented by number and %. χ^2 test was used to compare differences between the independent groups. The lowest accepted level of significance was 0.05 or less.

Results

Table 1 shows that the mean age in group A was 33.20 ±6.429 years, in group B was 34.90±9.744 years, and in group C was 32.85±7.365 years. Sex distribution was equal groups A and C, but in group B, females were more common (60%) than males (40%). The main predisposing factor in the three groups was occupational, and the second common factor was pregnancy, whereas hereditary and obesity factors affecting less than others. There is no significant difference among the three groups regarding age, sex, and predisposing factors.

Table 1 The demographic data of the studied patients

	EVLA and injection [20 (100%)]	EVLA and phlebotomy [20 (100%)]	Stripping GSV and phlebectomy of tributaries [20 (100%)]	*P* value
Age				
Range	22–45	18–50	19–45	0.6
Mean±SD	33.20±6.429	34.90±9.744	32.85±7.365	
Sex [*n* (%)]				
Male	10 (50)	8 (40)	10 (50)	0.7
Female	10 (50)	12 (60)	10 (50)	
Predisposing factors [*n* (%)]				
Hereditary	3 (15)	2 (10)	2 (10)	0.9
Obesity	4 (20)	5 (25)	3 (15)	
Occupational	8 (40)	8 (40)	10 (50)	
Pregnancy	5 (25)	5 (25)	5 (25)	

EVLA, endovenous laser ablation; GSV, great saphenous vein.

Table 2 Comparison among the three groups regarding laterality and distribution of dilated veins

	EVLA and injection [*n* (%)]	EVLA and phlebotomy [*n* (%)]	Stripping GSV and phlebectomy of tributaries [*n* (%)]	*P* value
Laterality [20 (100%)]				
Bilateral	4 (20)	4 (20)	4 (20)	1
Unilateral	16 (80)	16 (80)	16 (80)	
Distribution [24 (100%)]				
GSV, dilated tributaries	15 (62.5)	11 (45.8)	16 (66.7)	0.1
GSV, SSV	7 (29.1)	6 (25)	5 (20.8)	
GSV, SSV, dilated tributaries	2 (8.4)	7 (29.2)	3 (12.5)	

EVLA, endovenous laser ablation; GSV, great saphenous vein; SSV, small saphenous vein.

Table 3 Comparison among the three groups regarding anesthesia, operative time, and hospital stay

	EVLA and injection [20 (100%)] [*n* (%)]	EVLA and phlebotomy [20 (100%)] [*n* (%)]	Stripping GSV and phlebectomy of tributaries [20 (100%)] [*n* (%)]	*P* value
Anesthesia				
Local	2 (10)	1 (5)	0	0.3
Spinal	18 (90)	19 (95)	20 (100)	
Operative time(min)				
Range	30–90	70–120	50–120	≤0.001*
Mean±SD	59.00±17.815	91.25±16.049	92.00±20.545	
Hospital stay (h)				
Range	5–10	6–12	6–24	≤0.001*
Mean±SD	6.90±1.447	9.30±1.455	12.05±4.359	

EVLA, endovenous laser ablation; GSV, great saphenous vein. *Statistically significant.

Table 2 shows that varicose veins affected 80% unilateral lower limb in all groups, and the common distribution of dilated veins was GSV and dilated tributaries in all groups.

Table 3 shows that spinal was the common type of anesthesia in the three groups and local anesthesia was used in selected patients in group A (10%) and group B (5%). Operative time and hospital stay were significantly low in group A, with mean±SD of 59.00±17.815 min and 6.90±1.447 h, respectively. Operative time and hospital stay were increased in group C, with mean±SD of 92.00±20.545 min and 12.05±4.359 h, respectively.

Table 4 shows significant decrease of complications in patients in group A (12.5%) than group C 37.5%. The most common complication in groups A and B was superficial thrombophlebitis, representing 8.3 and 12.5%, respectively, and in group C was hematoma (12.5%).

Table 5 shows the follow-up of all patients at 2 weeks, 1 months and 3 months, which revealed decreased ecchymosis, resolved hematoma, and healed wounds and ulcers in all groups within 2 weeks. Residual varicose veins (VV) within 1-month follow-up appeared in seven patients, and in all groups, they were treated with injection sclerotherapy. Superficial

Table 4 Complication in the three groups

Complications	EVLA and injection [24 (100%)] [*n* (%)]	EVLA and phlebotomy [24(100%)] [*n* (%)]	Stripping GSV and phlebectomy of tributaries [24(100%)] [*n* (%)]	*P* value
Overall complication rate	3 (12.5)	6 (25)	9 (37.5)	0.049*
Superficial thrombophlebitis	2 (8.3)	3 (12.5)	0	0.4
Ecchymosis	1 (4.1)	2 (8.3)	2 (8.3)	
Hematoma	0	0	3 (12.5)	
Ulcer	0	0	1 (4.1)	
Wound infection	0	1 (4.1)	1 (4.1)	
Residual VV	0	0	1 (4.1)	
Bleeding intraoperative at SFJ	0	0	1 (4.1)	

EVLA, endovenous laser ablation; GSV, great saphenous vein; VV, varicose veins. *Statistically significant.

Table 5 Postoperative follow up complications after 2 weeks, 1 and 3 months

	EVLA and injection [24 (100%)] [*n* (%)]	EVLA and phlebotomy [24 (100%)] [*n* (%)]	Stripping GSV and phlebectomy of tributaries [24 (100%)] [*n* (%)]	*P* value
2 weeks				
Decreased ecchymosis	2 (8.3)	2 (8.3)	2 (8.3)	0.07
Resolved hematoma	0	0	3 (12.5)	
Residual tributaries	0	2 (8.3)	1 (4.2)	
Discoloration of skin	1 (4.2)	0	0	
Resistant superficial thrombophlebitis	1 (4.2)	2 (8.3)	0	
Healed wounds	0	1 (4.2)	1 (4.2)	
Healed ulcer	0	0	1 (4.2)	
Subsided thrombophlebitis	0	1 (4.2)	0	
After 1 month				
Residual VV	1 (4.2)	4 (16.7)	2 (8.3)	0.5
Improved thrombophlebitis	1 (4.2)	1 (4.2)	0	
After 3 month				
Not satisfied	1 (4.2)	3 (12.5)	8 (33.3)	0.03*
Recurrent VV	0	1 (4.2)	0	
Satisfied	23 (95.8)	20 (83.3)	16 (66.7)	

EVLA, endovenous laser ablation; GSV, great saphenous vein; VV, varicose veins. *Statistically significant.

thrombophlebitis improved within 1 month. There was only one recurrent VV case reported in our study after 3 months of follow-up. There was significant increase in satisfaction in patients of group A (95.8%). After 1-month follow-up, residual VV was 4.2, 16.7, and 8.3% in groups A, B, and C, respectively, and sclerotherapy was performed for our patients with residual dilated tributary. Improved thrombophlebitis was seen in 4.2% of cases in groups A and B. Approximately 96% of patients in group A, 83.3% of patients in group B, and 66.7% of patients in group C were satisfied according to time of hospital stay, time of recovery, postoperative pain, wound scar, and residual VV.

Discussion

The treatment of varicose veins and its complications consumes a relatively large proportion of the limited health care resources [7]. For many years, stripping of the saphenous vein has been a standard treatment. However, the operation has a traumatic experience for patients. Surgical treatment may also be associated with serious complications such as bleeding, groin infection, thrombophlebitis, saphenous nerve injury, or even life-threatening conditions [8].

In the past decade, minimally invasive techniques such as EVLA, RFA, and ultrasound-guided foam sclerotherapy have challenged the position of Conventional surgery (CS) for primary varicose veins [9]. Although EVLA has been demonstrated to effectively occlude incompetent saphenous veins, it does not treat branch varicosities directly, thus requiring an ambulatory phlebectomy or follow-up sclerotherapy. For the treatment of leg veins smaller than 4 mm in diameter, sclerotherapy has been considered to be the criterion standard [10].

In the current study, EVLA is combined with either injection sclerotherapy or phlebectomy to treat branch varicosities to achieve better results. These two groups are compared with conventional surgery in which stripping of GSV was done with phlebectomy of tributaries.

Common complications with group A (EVLA +injection sclerotherapy) were superficial thrombophlebitis (8.3%) followed by ecchymosis (4.1%). No cases of hyperpigmentation was reported in this group. Ecchymosis resolved within 2 weeks, and superficial thrombophlebitis resolved within 1 month.

Lee and colleagues studied EVLA combined with fluoroscopy-guided endovenous foam sclerotherapy. They found that bruising was noted in 79.0%, but this was asymptomatic and resolved completely in all followed-up limbs by 1-month follow-up. Pain or tightness over the treatment site was complained of in 68.4% at 1-month follow-up. These symptoms were greatly improved or resolved by 3 or 6 months [11].

Although rare, EVLT with sclerotherapy was not free of significant complication. Mozes and colleagues reported three cases of thrombus extension into the common femoral vein following EVLT. All of the thrombus resolved in these cases by 1 month without adverse sequelae; in our study, the follow-up of patients was free from any thrombus in the deep venous system [12].

In group B, complications were superficial thrombophlebitis (12.5%), ecchymosis (8.3), and wound infection (4.1%). Ecchymosis resolved within 2 weeks, and superficial thrombophlebitis resolved within 1 month. Fernández and colleagues have evaluated the safety and clinical and anatomic effectiveness of EVLT and microphlebectomy (1559 patients), and the complications were in the form of superficial phlebitis of associated tributary varicose veins, which was noted in 58 (2.9%) patients and resolved with compression therapy and nonsteroidal anti-inflammatory medication in all cases [13]. Local transient paresthesia at the ankle and midcalf level occurred in 38 (2.43%) patients and resolved spontaneously after 2 weeks. Hyperpigmentation occurred in 62 (4%) patients and cellulitis in 16 (1%). Only two (0.13%) cases of DVT were found.

EVLT induced more pain in a higher percentage of patients compared with HLS in the early postoperative phase, confirming the data of a recent randomized controlled trial (RCT) [14]. Use of Tumescent anesthesia (TA) and more analog-sedatives in the High ligation stripping (HLS) group (data not shown) as well as phlebitic reactions of the GSV after EVLT might both account for this. Of additional importance is the fact that in this study EVLT was performed using a bare fiber 400 μm and 980-nm wavelength. Novel laser devices (e.g., radial fiber and devices with 1320 and 1470-nm wavelength) probably warrant less adverse effects [14].

In this study, mean energy applied was 70 J/cm. This was comparable to the amount of energy applied in the studies of Theivacumar *et al*. [15], Timperman *et al*. [16] and Proebstle *et al*. [17], which reported 60–70, 63.4, and 63 J/cm, respectively. Timperman and colleagues had published in his study that the use of high energy of approximately 63.4 J/cm had lower failure rate. However, Kim and Paxton [18] reported successful rate equal to that obtained by Timperman and colleagues, in spite of using lower energy of approximately 32.5 J/cm. Discrepancy in the energy delivered during EVLT reflects the hypothesis of Proebstle and colleagues that to achieve reliable ablation of GSV, we required two factors: quantity of energy delivered as well as vein diameter. On the contrary, Kim and Paxton had reported that there was no significant difference in success rate or failure rate between higher and lower amount of laser energy, so higher energy was not necessary as it theoretically led to more adverse effects, for example, superficial burns and palpable induration.

Regarding group C in the present study (HLS with phlebectomy), complications were ecchymosis (8.3%), hematoma (12.5%), ulcer (4.1%), wound infection (4.1%), residual VV (4.1%), bleeding intraoperative at SFJ (injury of GSV near to SFJ) (4.1%). Three-month follow-up revealed ecchymosis, hematoma, ulcer, and wound healing improved within 2 weeks and at 1-month follow-up. After 3-month follow-up, 8.3% of the patients experienced residual VV.

In a randomized clinical trial reviewing conventional high ligation and stripping for great saphenous varicose veins, the commonest complication was paresthesia and tingling sensation. Groin wound problems were noted after conventional surgery, which included mild inflammation (7.5%), serous wound discharge (4.9%), hematoma (2.5%), and wound breakdown (2.5%), all of which resolved spontaneously. Clinically evident hematomas in the thigh and leg were slightly more common after conventional surgery [19].

In their comparative RCT, Rasmussen et al recorded one incidence of DVT, five cases of paresthesia, and six

cases of hyperpigmentation in patients having surgery. The rate of these latter two complications was similar to those reported for the endovenous procedures; however, there was a significantly higher incidence of phlebitis in the endovenous ablation methods [20].

Christenson and colleagues noted significantly more cases of bruising in their surgical group compared with the EVLA group (15 vs. 2). No cases of wound infection or DVT were reported, and it matched with this study regarding bruising in surgical group compared with EVLA groups (5 vs. 2), but only one case of wound infection was reported [21].

In the MAGNA study, a significantly higher number of patients undergoing surgery experienced wound infection requiring systemic antibiotics. The overall rate of complications was also higher with surgery, but this was not significant (P=0.64) [22]. However, in this study, there was significant decrease in complication rate with EVLA (P=0.049).

In the CLASS trial, the surgery group had a comparable overall complication rate to ultrasound-guided foam sclerotherapy and EVLA (3.5, 3.8, and 3.3%, respectively) and similar serious adverse events related to treatment with the endovenous procedures (1.4%). A rather high incidence of numbness (15.6%) and persistent bruising (17.0%) was found to be still present at 6 months [23].

In this study, 95% of patients in group A, 80% of patients in group B, and 60% of patients in group C were satisfied according to time of hospital stay, time of recovery, postoperative pain, wound scar, and residual VV.

Regarding patient satisfaction, in RELACS trial, they asked all patients to evaluate their satisfaction with each treatment and with the cosmetic results by VAS-based questionnaires (scale, 1–5). Cosmetic outcome was rated significantly better by the EVLT group at the 2-year follow-up (1.5 vs. 1.7; P=0.02). They detected no other differences between the treatments. At the 2-year follow-up, 98% of all patients stated that they would undergo each treatment again if medically necessary.

Furthermore, the patients were asked to indicate how long the recovery took until they could resume basic physical activities (e.g., walking around without discomfort and doing housework) and capacity to work. Basic activity was achieved after 4.8 days (EVLT group) and 4.0 days (HLS group) (P=0.13), and the ability to work or to perform comparable tasks was achieved after 10.4 and 11.8 days (P=0.02) [24].

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Conflicts of interest

There are no conflicts of interest.

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