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Endovenous laser ablation vs phlebectomy of foot varicose veins

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ABSTRACT

Objective: The aim of this study was to compare the outcomes and complications of selected patients treated with endovenous laser ablation (EVLA) or ambulatory phlebectomy for foot varicose veins.

Methods: From October 2016 to February 2022, selected patients undergoing EVLA (using 1470-nm with radial-slim or bare-tip fibers) or phlebectomy of foot varicose veins for cosmetic indications were analyzed, and the outcomes were compared. Patients were classified according to the Clinical, Etiologic, Anatomical, and Pathophysiological (CEAP) classification. Anatomic criteria provided the basis for the decision to perform EVLA or phlebectomy. Clinical and ultrasound assessments were performed on postoperative days 7, 30, and 90 for visualization of the sapheno-femoral and sapheno-popliteal junctions and the deep venous system. Disease severity was graded with the Venous Clinical Severity Score (VCSS), and quality of life was measured with the Aberdeen Varicose Vein Questionnaire (AVVQ) before and after treatment. Treatment outcomes were evaluated based on changes in VCSS and AVVQ scores. The groups were also compared for procedure-related complications. Data were statistically analyzed in SPSS v. 20.0 using the χ^2 , Student *t* test, Mann-Whitney test, Wilcoxon test, and analysis of variance. The results were presented as mean (standard deviation or median (interquartile range).

Results: The study included 270 feet of 171 patients. Mean patient age was 52.3 (standard deviation, 13.1) years, ranging from 21 to 84 years; 133 (77.8%) were women. Of 270 feet, 113 (41.9%) were treated with EVLA and 157 (58.1%) with phlebectomy. The median preoperative CEAP class was 2 (interquartile range, 2-3) in the phlebectomy and EVLA groups, with no statistically significant difference between the groups (P = .507). Dysesthesia was the most common complication in both groups. Only transient induration was significantly different between EVLA (7.1%) and phlebectomy (0.0%) (P = .001). The two approaches had an equal impact on quality of life and disease severity.

Conclusions: Treatment complications were similar in phlebectomy and EVLA and to those previously described in the literature. (J Vasc Surg Venous Lymphat Disord 2024;12:101703.)

Keywords: Ablation techniques; Foot; Minimally invasive surgical procedures; Postoperative complications; Varicose veins

Treatment of varicose veins of the foot poses an increased risk of complications¹ due to the anatomic particularities of this site, including minimal if any subcutaneous fat,² peculiar presence of lymphatic vessels,³ and innervation.⁴ Indications for treatment of foot varicose veins should consider the particular physiologic characteristics⁵⁻⁷ that differentiate them from varicose veins in the legs, such as inversion of the physiologic flow direction in perforating veins compared with leg

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veins and presence of valveless perforating veins.⁸ Although the treatment of foot varicose veins with ambulatory phlebectomy was described by Muller in 1990,⁹ indications for this approach remain controversial for some authors.² Previous studies^{1,7,10,11} have reported the outcomes and complications of ambulatory phlebectomy of the foot, thus helping to demystify this issue (Fig 1).

Described by Carlos Boné in 2001,¹² endovenous laser ablation (EVLA) currently has a good level of evidence that has led it to assume a prominent place among treatment options for saphenous vein reflux.¹³ The level of safety achieved by mastering this method has prompted researchers to evaluate its use for other indications. Currently, there are reports of the use of EVLA for saphenous vein tributaries,^{14,15} veins in the hands,¹⁶ in the face,¹⁷ and in congenital extra-truncular venous malformations.¹⁸ In varicose veins of the foot, however, current data on the use of EVLA is limited to isolated experiences, with only occasional reports in the literature.^{19,20}

The aim of this study was to compare the outcomes and complications of ambulatory phlebectomy vs EVLA for the treatment of foot varicose veins.

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METHODS

The study was approved by the Research Ethics Committee of Universidade Feevale (protocol no. 5.800.985, CAAE 64,371,422.5.0000.5348) and followed the tenets of the Declaration of Helsinki. Each study participant provided written informed consent.

Between October 2016 and February 2022, patients treated for foot varicose veins with phlebectomy or EVLA for cosmetic indications were screened for eligibility. The inclusion criteria were patients with varicose veins of the foot willing to undergo treatment due to clinical discomfort and/or for cosmetic purposes. We excluded patients with poor clinical conditions, such as thromboembolic events, with moderate to severe heart failure, ischemic heart disease, or degenerative diseases, and with infection or hostile skin conditions.

Anatomic criteria provided the basis for the decision to perform EVLA or phlebectomy: patients whose foot vessels were very tortuous and/or adherent to the skin were assigned to phlebectomy, and the others to EVLA. Patients with tortuous and straight segments in the same foot were subjected to only phlebectomy (Fig 2). According to our protocol, all patients were subjected to clinical examination at each follow-up visit (postoperative days 7, 30, and 90) and, if necessary, to evaluation with venous duplex ultrasound (My lab gold 25 -ESAOTE) for patency and occurrence of thrombophlebitis. If saphenous vein treatment was required, adjuvant therapy was performed with polidocanol foam and EVLA.

Patients were classified according to the Clinical, Etiologic, Anatomical, and Pathophysiological (CEAP) classification.²¹ The Fitzpatrick skin phototype classification was parameterized according to the color bar tool for skin type self-identification.²²

Disease severity was graded with the Venous Clinical Severity Score (VCSS),^{23,24} and quality of life was measured with the Aberdeen Varicose Vein Questionnaire $(AVVQ)^{25}$ before and after treatment to analyze lower-limb overall outcomes.

ARTICLE HIGHLIGHTS

- Type of Research: Observational study
- **Key Findings:** Comparison between endovenous laser ablation and phlebectomy for the treatment of varicose veins in 270 feet resulted in the same complication rates, except for transient induration. Both techniques promoted the improvement of quality of life and appeared to be safe and effective for foot varicose vein treatment.
- **Take Home Message:** This is a pioneering study which presents a new option for the treatment of foot varicose veins by using an endovenous laser ablation technique. Compared with phlebectomy of the foot, it showed the expected complication rate and quality-of-life improvements.

EVLA technique. The best position to approach the foot depends on the location of the vein. With the patient in supine position with external rotation of the thigh and slight knee flexion (frog-leg position), the medial vessels were accessed. The veins on the lateral aspect of the foot and superficial dorsal arch were best punctured with the patient supine and with the sole of the foot resting on the operating table. An anesthetic solution was prepared with 0.25% to 1% lidocaine and 1M sodium bicarbonate (1:10) for local anesthesia. After identifying the ideal entry point, an anesthetic button was made at the puncture site. Straight veins >3 mm in diameter were punctured using a 16-gauge angiocath, advanced under ultrasound guidance just beyond the site of the anesthetic button as soon as the vein was visible on ultrasound. Ultrasound-guided puncture was often used, but, in some cases, puncture was performed under direct visualization. During puncture, even if visible blood reflux was observed in the angiocath, advancing it for a few more millimeters was recommended because the needle was longer than the introducer.



Fig 1. Preoperative (A) and postoperative (B) photographs of varicose veins of the foot treated with ambulatory phlebectomy.



Fig 2. Preoperative marking of varicose veins of the foot. Note the straight appearance of the veins making them suitable for endovenous laser ablation (*EVLA*). The indication for treatment is based on the presence of symptoms, cosmetic complaints, and dilation. Due to the bidirectional flow in the feet, reflux cannot be used as an indication criterion.

Once the vein had been safely punctured, a 1470-nm radial-slim 400 μ laser fiber (Biolitec) or a 1470-nm bare-tip 400 μ laser fiber (ORLight) was introduced to the desired point and radial fiber. If a bare-tip fiber was chosen, a 40 \times 16 mm needle (16G, 1 1/2) for puncture was recommended, with the fiber already partially inserted in it.

Once blood reflux had been identified, the laser fiber was advanced carefully as long as there was no resistance, given the risk of vein perforation (Fig 3). With the laser fiber in place, tumescent anesthesia was administered with a 27×7 mm needle (22G, 1 1/4) under ultrasound guidance. Sometimes, to achieve a cleavage plane or a better contact surface for the ultrasound probe, the tumescent anesthetic was initially injected under direct visualization and then under ultrasound guidance. The ultrasound device was required to demonstrate adequate image definition (zoom up) and



Fig 3. Treatment of superficial dorsal varicose veins with endovenous laser ablation (*EVLA*).

identification of proper distance between the tissues and the vein to be ablated. Ablation was performed immediately after tumescence due to the small volume of tumescent infiltration required, and the injected fluid spread quickly as its protective effect diminished rapidly. According to our protocol, cold tumescence was used only with lactated Ringer's solution and lidocaine at a concentration of 0.25%, without epinephrine.

Starting from a predetermined power set between 6 and 8 W, the necessary energy intensity was calculated by direct visualization of vein ablation (formation of a pearl necklace), compensating the greater or lesser need for energy with a traction speed that ranges from 1 to 3 mm per second. Extra care must be taken to observe the fiber tip-due to its natural stiffness, the fiber tip may protrude toward the skin at some curved point on the foot. Also important was the ablation endpoint. Because the skin was usually very close to the vein puncture site, it was not always possible to "cauterize" the vein entry hole, in which case extra local compression was needed to avoid hematoma at the puncture site. Whenever getting too close to the skin, a little more tumescent solution should be added to the site. After removing the laser fiber, slight compression was applied locally for a few seconds. Cotton rolls were placed locally, and class 2 compression stockings were worn for 7 days.

Phlebectomy technique. Our operative technique was based on the approach developed by Muller.¹⁹ In the presence of thin subcutaneous tissue, the skin should be pinched with the fingers as a maneuver to move it away from other structures. After the incision was made, the vein was separated from the adjacent tissues using the

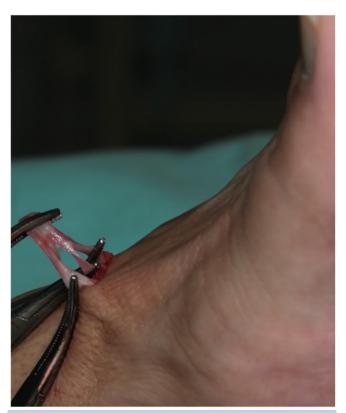


Fig 4. Detail of ligation of perforating veins of the first metatarsal treated with ambulatory phlebectomy.

tip of the crochet hook as a dissection instrument, with "sweeping" movements of the vein toward the subcutaneous tissue. An advantage was the wide mobility of the feet in several axes, which facilitated removal of the vein segments. Once the varicose vein was exposed, the exposed vessel was observed to avoid inadvertent manipulation of the superficial nerve. After resection of the varicose veins, the remaining vein stumps were ligated with 5.0 absorbable monofilament suture (Fig 4). For stumps <1 mm, the vein tips may be cauterized with a bipolar cautery, taking care to maintain a safe distance from the edges of the incision. Incisions were closed with adhesive strips or by suturing the edges with 5.0 mono-filament suture.

Statistical analysis. All data were analyzed in SPSS, version 20.0. Categorical data were presented as number (%), and quantitative data as mean (standard deviation [SD]) if normally distributed and as median (interquartile range [IQR]) if not normally distributed. The χ^2 test or Fisher exact test was used to compare categorical variables. Normally distributed quantitative variables were compared between groups with the Student *t*-test for independent samples and within groups with the Student *t*-test for paired samples. For non-normally distributed quantitative variables, the Mann-Whitney test was used

for between-group comparisons and the Wilcoxon test for within-group comparisons. Before-and-after data were compared between the groups by repeated measures analysis of variance. The significance level was set at 5% for all analyses.

RESULTS

The study included 270 feet of 171 patients. Mean patient age was 52.3 years (SD, 13.1 years), ranging from 21 to 84 years; 133 (77.8%) were women. Of 270 feet, 113 (41.9%) were treated with EVLA and 157 (58.1%) with phlebectomy.

The median preoperative CEAP class was 2 (IQR, 2-3) in the phlebectomy and EVLA groups, with no statistically significant difference between them (P = .507; Mann-Whitney test).

Table I shows procedure-related complications in both groups. Dysesthesia was the most common complication in the EVLA (11.5%) and phlebectomy (5.7%) groups, with no statistically significant difference between them (P = .138). Most dysesthesias were observed in the first 90 days of follow-up, and only two cases persisted for 6 months; one in the EVLA group and one in the phlebectomy group, and both resolved within 6 months. Patients in the EVLA group more frequently had a palpable indurated fibrous cord along the treated vein (induration) than those in the phlebectomy group (7.1% vs 0.0%; P = .001) (Fig 5), but induration was transient and lasted no more than 3 months.

Procedure-related complications were subdivided into two study phases for analysis: cases treated from October 2016 to November 2018 (phase 1) and from December 2018 to February 2022 (phase 2). The results of this analysis are shown in Table II. Induration occurred more frequently in feet treated with EVLA only in phase 1 (8.2% vs 0.0%; P = .001). There were no other significant differences in the techniques between the two phases.

The overall median AVVQ score decreased significantly from 16.0 (IQR, 11.4-24.1) preoperatively to 8.1 (IQR, 4.5-13.2) postoperatively (P < .001; Wilcoxon test). In the EVLA group, the median AVVQ score decreased significantly from 15.0 (IQR, 11.4-21.3) to 9.0 (IQR, 4.1-14.0) (P < .001; Wilcoxon test), resulting mainly from the reported reduction in aesthetic concern and disease extent. This reduction was also statistically significant in the phlebectomy group (median of 16.8 [IQR, 11.5-26.0] preoperatively vs 8.1 [IQR, 5.0-12.0] postoperatively; P < .001; Wilcoxon test) (Fig 6).

The overall median VCSS decreased significantly from 3 (IQR, 2-5) preoperatively to 1 (IQR, 0-1) postoperatively (P < .001; Wilcoxon test). In the EVLA group, the median VCSS decreased significantly from 3 (IQR, 2-4.3) to 1 (IQR, 0-2) (P < .001; Wilcoxon test). This reduction was also statistically significant in the phlebectomy group (median of 4 [IQR, 2-5] preoperatively vs 0 [IQR, 0-1] postoperatively; P < .001; Wilcoxon test) (Fig 7).

Table I. Comparison of procedure-related complications between endovenous laser ablation (*EVLA*) and phlebectomy (n = 270 feet)

Complication	EVLA, n = 113	Phlebectomy, $n = 157$	P
Dysesthesia/paresthesia	13 (11.5)	9 (5.7)	.138
Induration	8 (7.1)	-	.001
Pigmentation	5 (4.4)	4 (2.6)	.499
Persistent pain	3 (2.7)	3 (1.9)	.697
Edema	3 (2.7)	6 (3.8)	.739
Lymphocele/lymphatic	-	-	1.000
Infection	2 (1.8)	-	.174
Deep/superficial venous thrombosis	-	-	1.000
Ulcer	2 (1.8)	-	.174
Hematoma	_	_	1.000
Data presented as number (%).			

Boldface P values indicate statistical significance.

 $^{a}\chi^{2}$ test with Yates correction or Fisher exact test.

Analysis of complications

EVLA group. Of 113 feet treated with EVLA, 84 (74.3%) had no complications, 23 (20.4%) had only one complication, five (4.4%) had two complications, and one (0.9%) had three complications.

Complications occurred in 17 feet (23.9%) classified as CEAP 2, in 10 (32.3%) classified as CEAP 3, and in two (25.0%) classified as CEAP 4. There was no significant association between preoperative CEAP class and occurrence of any complications (P = .763).

Median preoperative VCSS was 3 (IQR, 2-5) in feet with complications and 3 (IQR, 2-5) in feet without complications, with no significant difference between them (P = .513).

A total of 515 segments were treated in the 113 feet included in the EVLA group, and the mean laser energy used for ablation was 45.4 J/cm (SD, 24.5 J/cm). There was no significant difference in mean laser energy between feet with and without complications (P = .295).

Pigmentation was observed in one patient (5.3%) with skin phototype I, in two (3.8%) with phototype II, in one (4.8%) with phototype III, and in none (0.0%) with phototype IV. There was no significant association between skin phototype and occurrence of pigmentation (P = .981).

Comparing study phases 1 and 2, the mean laser energy used for ablation increased significantly from 47.4 J/cm (SD, 14.9 J/cm) in phase 1 to 55.6 J/cm (SD, 19.4 J/cm) in phase 2 (P = .060; Student' *t*-test).

Phlebectomy group. Of 157 feet treated with phlebectomy, 140 (89.2%) had no complications, 13 (8.3%) had only one complication, three (1.9%) had two complications, and one (0.6%) had three complications.

Complications occurred in eight feet (8.6%) classified as CEAP 2, in six (11.5%) classified as CEAP 3, in two (22.2%) classified as CEAP 4, and in one (100%) classified as CEAP 5. There was no significant association between preoperative CEAP class and occurrence of any complications (P = .599).

Preoperative VCSS was significantly higher in feet with complications (median, 5; IQR, 3-7) than in feet without complications (median, 3; IQR, 2-5) (P = .015).

DISCUSSION

Despite the lack of randomized controlled trials, previous studies have considered the outcomes of ambulatory phlebectomy for foot varicose veins safe and effective based on surrogate outcomes.17,10,11 On the other hand, there are only isolated reports of the use of EVLA for veins other than the saphenous veins, including congenital venous malformations,¹⁸ veins in the hands,¹⁶ saphenous vein tributaries,^{14,15} forehead veins,¹⁷ and veins in the feet.^{19,20} In the absence of more robust evidence, the use of EVLA for varicose veins of the foot has been based on individual experiences and sparse literature.^{19,20}

To our knowledge, the current study is the first series using EVLA as an alternative to phlebectomy in the treatment of foot varicose veins. We used 400µ bare-tip fiber (ORLight) and radial fiber (Biolitec) laser systems, but, as the purpose of the study was to evaluate the performance of EVLA for foot varicose veins; we did not compare individual performance between bare-tip and radial fibers. However, some issues were observed during the study. As an advantage, bare-tip fibers can be introduced with a 40 \times 16 mm needle into smaller vessels, such as superficial dorsal vessels, which facilitates puncture and saves time during activation. As a disadvantage, there seemed to be a greater risk of vein perforation upon introduction of bare-tip than radial fibers. Despite the lower risk of perforation, radial fibers needed to be introduced through a 16-gauge angiocath, making puncture more difficult, and are best suited for larger vessels, such as the dorsal venous arch. We used a concentration



Fig 5. Induration as a complication of endovenous laser ablation (*EVLA*) of superficial dorsal varicose veins.

of 0.25% due to the small volume of tumescent infiltration required. In procedures with local anesthesia, we corrected the anesthetic solution pH with 1M sodium bicarbonate to reduce sensitivity to the anesthetic.^{26,27} The indication of EVLA followed a consecutive but nonrandom sampling based on anatomic criteria. Limitations to the indication of EVLA included veins that could not be separated from the skin and very tortuous foot vessels that prevented us from introducing and advancing the fiber through the veins. Conversely, larger straight veins with reasonable space for tumescence were best suited for the procedure, potentially reducing bleeding, requiring fewer cuts, and reducing procedure time as the phlebologist became more experienced (Fig 8). For these reasons, we did not use random sampling in this study.

Regarding complications, only the occurrence of induration was significantly different between the EVLA and phlebectomy groups. Induration occurred in 7.1% of cases, appearing as a palpable indurated fibrous cord along the treated vein. Lower energy may lead to incomplete ablation and increased inflammatory reaction, thus leading to granuloma formation in the region. Due to the long study period, we divided it into two phases for didactic purposes. At the end of phase 1, we identified a possible relationship between low energy dose and the occurrence of induration, and then we started to use higher energy doses. This change was likely the reason for the reduction in induration rates in phase 2 (Table II), when there was an increase in the mean laser energy used for ablation. Further studies are needed to confirm this assumption. In our series, this complication was self-limiting and resolved without sequelae within 3 months.

Dysesthesia was also observed in the EVLA group (11.5% vs 5.7% in the phlebectomy group; P = .138). Greater

Table II. Comparison of procedure-related complications between endovascular laser ablation (*EVLA*) and phlebectomy for the total sample and per study phase

	All N = 270			Phase 1 ^a n = 228			Phase $2^{b} n = 42$		
Complication	EVLA, n = 113	Phlebectomy, n = 157	P°	EVLA, n = 85	Phlebectomy, n = 143	P ^c	EVLA, n = 28	Phlebectomy n = 157	/, P ^e
Dysesthesia/paresthesia	13 (11.5)	9 (5.7)	.138	11 (12.9)	8 (5.6)	.090	2 (7.1)	1 (7.1)	1.000
Induration	8 (7.1)	-	.001	7 (8.2)	-	.001	1 (3.6)	-	.999
Pigmentation	5 (4.4)	4 (2.6)	.499	5 (5.9)	3 (2.1)	.154	5 (17.9)	1 (7.1)	.645
Persistent pain	3 (2.7)	3 (1.9)	.697	3 (3.5)	3 (2.1)	.673	-	-	1.000
Edema	3 (2.7)	6 (3.8)	.739	1 (1.2)	3 (2.1)	.999	2 (7.1)	3 (21.4)	.313
Lymphocele/lymphatic	-	-	1.000	—	-	1.000	-	-	1.000
Infection	2 (1.8)	-	.174	1 (1.2)	-	.373	1 (3.6)	-	.999
Deep/superficial venous thrombosis	-	-	1.000	-	-	1.000	-	-	1.000
Ulcer	2 (1.8)	-	.174	—	-	1.000	2 (7.1)	-	.545
Hematoma	_	_	1.000	_	_	1.000	_	_	1.000

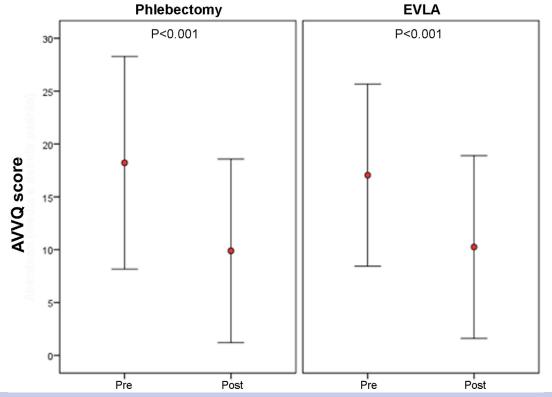
Data presented as n (%).

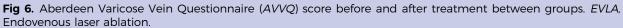
Boldface *P* values indicate statistical significance.

^aCases treated from October 2016 to November 2018.

^bCases treated from December 2018 to February 2022.

 $^{c}\chi^{2}$ test with Yates correction or Fisher exact test.





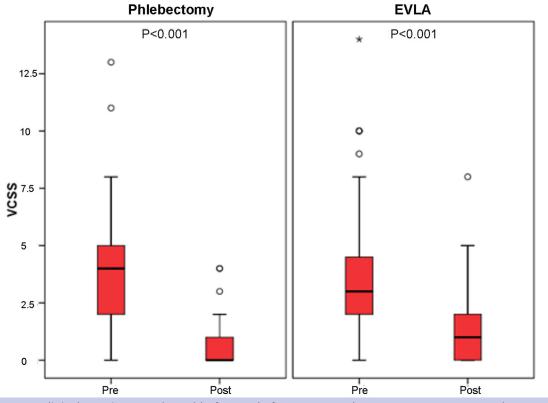


Fig 7. Venous clinical severity score (VCSS) before and after treatment between groups. EVLA, Endovenous laser ablation.



Fig 8. Photograph of straight varicose veins suitable for endovenous laser ablation (*EVLA*).

occurrence of transient dysesthesia with the use of EVLA may be explained by the proximity of nerve endings in larger veins, where we preferentially performed ablation. Adequate ultrasound visualization during tumescence played a key role in preventing this complication. We must introduce the tumescent anesthesia needle gently, avoiding excessive movement of the needle next to the vessel-because the needle itself could damage the adjacent nerve endings. Dissection performed by the tumescence itself (hydro-dissection) allowed the creation of a virtual space to advance the needle, thus minimizing this complication. Direct visualization also allowed us to observe the infiltration of the tumescent solution and adequate separation between the segment to be ablated and the adjacent structures, such as nerve endings. Also, due to the small volume of tumescent infiltration required, the injected fluid spread rapidly. Therefore, to perform the ablation immediately after injecting the tumescent solution was important, while the surrounding tissues were away from the vein, thus providing more adequate thermal protection.

Other complications included persistent pain, hyperpigmentation, and edema, all of which had similar incidence in the EVLA and phlebectomy groups. We defined persistent pain as pain that required the use of anti-inflammatory or analgesic agents after 7 days. This study was limited to only observe the quantitative relationship of analgesics and anti-inflammatory drugs with duration of use. It would be interesting, however, if future studies assessing pain also qualitatively measure the intensity of pain. The findings of persistent pain in the EVLA (2.7%) and phlebectomy (1.9%) groups did not interfere with quality of life, and symptom severity improved significantly from pre-to post-treatment.

As a limitation of the study, it is important to note that, to find a statistical difference in dysesthesias of 8.3 percentage points (from 6.2% to 14.5%), considering a power of 80% and an alpha of 0.05, a sample size of 234 patients per group would be necessary. Therefore, regarding dysesthesias, we have no evidence that the differences are statistically significant or whether they are a type 2 error, requiring further studies with a larger sample size of feet for clarification.

It is our opinion that, in clinical practice, EVLA and ambulatory phlebectomy are not competitive but synergistic techniques. Therefore, knowing their strengths and limitations, indications and contraindications, and potential complications is crucial to select which procedure to both safely and effectively perform in each patient to optimize patient outcomes.

CONCLUSIONS

In this series, foot varicose vein intervention was relatively safe and effective, leading to improved quality of life. Treatment complications were similar in phlebectomy and EVLA and to those previously described in the literature. Granuloma (induration) along the treated vein appeared as a complication only in EVLA. The reduction in this complication after increasing the mean laser energy used for ablation in phase 2 study suggested a possible relationship between the occurrence of induration and lower energy densities. Dysesthesias were more common in EVLA, but we found no statistical evidence to confirm this trend. The lack of previous comparative studies with EVLA for treatment of foot varicose veins makes this a pioneering study in the field. Further studies are required to consolidate EVLA as an option for the treatment of foot varicose veins, whether performed alone or in combination with phlebectomy.

AUTHOR CONTRIBUTIONS

Conception and design: LA Analysis and interpretation: LA, DA Data collection: LA, AS, DA, FZ, FS, YC Writing the article: LA, DA Critical revision of the article: LA, AS, DA, FZ, FS, YC Final approval of the article: LA, AS, DA, FZ, FS, YC Statistical analysis: LA, DA Obtained funding: LA Overall responsibility: DA

DISCLOSURES

None.

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