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Comparative Study between Using of Radio Frequency Ablation and Endovenous Laser Ablation in the treatment Of Primary Lower Limb Varicose Veins

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ORIGINAL ARTICLE

Comparative Study Between Using of Radiofrequency Ablation and Endovenous Laser Ablation in the Treatment of Primary Lower Limb Varicose Veins

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Abstract

Background: **Varicose veins are a frequent vascular issue. Radiofrequency ablation (RFA) and endovenous laser ablation (EVLA) are endovenous treatments for varicose veins. Endovenous therapy demonstrated superior outcomes than standard high ligation and stripping regarding pain, quality of life, healing, and recurrence. The RFA and ELA surpass vein stripping in morbidity, outcome, and neovascularization (recurrence), which is attributed to greater recurrence rates.**

Aim: **The authors aimed to compare between using of RFA and EVLA in the treatment of primary lower limb varicose veins regarding complications, treatment failure, and recurrence.**

Patients and methods: **This prospective randomized controlled study was carried out at the Vascular Surgery Department of Al-Azhar University Hospitals (Al-Hussein and Sayed Galal) between June 2021 and June 2022 (12 months). The study included 50 patients who presented with primary varicose veins; males represented 22 (44%) cases, whereas females represented 28 (56%) cases.**

Results: **In the EVLA group, recanalization of short-segment occlusion was done in four patients, recanalization of long-segment occlusion was done in two patients, and recurrent varicose veins happened in five patients. In the RFA group, recanalization of short-segment occlusion was done in three patients, recanalization of long-segment occlusion was done in three patients, and recurrent varicose veins happened in six patients.**

Conclusion: **Overall, 94% of inadequate great saphenous vein (GSVs) were successfully blocked by endovenous ablation procedures after one month. Although postoperative problems were more common with EVLT than after RFA in the experience, EVLT was linked with somewhat greater occlusion rates.**

Keywords: Endovenous laser ablation, Primary, Radiofrequency ablation, Varicose veins

1. Introduction

One of the most prevalent vascular issues that affect a large section of the population is varicose veins. Approximately 10−40% of adults aged 30−70 years are affected by the condition.

According to most research studies, women are more likely than males to develop varicose veins, with a 3: 1 female to male ratio.

One of the most important studies for assessing and detecting venous deficiency and thrombosis is duplex ultrasonography of the extremities; at the moment, this imaging technique is the 'gold standard' for superficial venous imaging. The evaluation of reflux and blockage in the deep, superficial, tributary, and perforating veins is a necessary component of a proper assessment.

For many years, surgical ligation and vein stripping were the go-to treatments for varicose veins.

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Although results have improved recently owing to a better knowledge of the lower leg venous architecture, it is usually stated that this method has a recurrence rate of 20–30%.

The most important improvements in endovenous medicine concern the newly popular radiofrequency ablation (RFA) and endovenous laser ablation (EVLA) procedures. These techniques may have therapeutic advantages over surgical ligation and stripping, as well as much reduced postoperative discomfort and healing time.

The target vessel's endothelium lining is destroyed by heat and steam bubbles produced by the thermal energy inside the vessel's lumen. This results in an inflammatory response that leads to occlusion, which finally results in fibrosis by essentially blocking the vein[1].

Endovenous treatments for varicose veins, such RFA and EVLA, have been accessible since the late 1990s. In terms of decreased pain, improved quality of life, quicker recovery, and a lower likelihood of recurrence, endovenous therapy outperformed conventional high ligation and stripping, according to recent randomized controlled studies.[2]

RFA and ELA not only perform better in terms of morbidity and result but also lessen the development of neovascularization (recurrence), which is commonly cited as the cause of the higher recurrence rates seen after vein stripping.

We aimed to compare between using RFA and EVLA in the treatment of primary lower limb varicose veins regarding complications, treatment failure, and recurrence.

2. Patients and methods

Between June 2021 and June 2022 (12 months), this prospective randomized controlled trial was carried out in the Vascular Surgery Department of Al-Azhar University Hospitals (Al-Hussein and Sayed Galal). The study included 50 patients who presented with primary varicose veins; males represented 22 (44%) cases. whereas females represented 28 (56%) cases.

According to the CEAP (clinically, etiologically, anatomically, and pathophysiological) categorization, all patients exhibited symptomatic varicose veins with proven GSV incompetence.

Using duplex scanning, the degree and scope of GSV reflux were assessed before surgery. With patients standing, the degree of reflux in the superficial (GSV and small saphenous vein) and deep (femoral vein and popliteal vein) venous systems was evaluated. The existence of ineffective perforators was not frequently assessed.

Inclusion criteria were as follows: patients with primary uncomplicated varicose veins, age from 18 to 60 years old, men and women, incompetent great saphenous vein, intact deep venous vein system, vein diameter at the GSV greater than or equal to 5.5 mm and less than or equal to 15 mm, reflux in GSV greater than 0.5 s, and CEAP categorization between C2 and C5.

Exclusion criteria were as follows: secondary lower limb varicose veins, lower limb lymphedema, recurrent varicose veins of lower limb, convoluted GSV making it unsuitable for endovenous therapy, acute superficial thrombophlebitis of lower limb, congenital anomalies of venous system of lower limb, lower limb ischemia, and lower limb malignancy.

Patient evaluation: after informed written consent, patients were subjected to the following: clinical evaluation and duplex assessment. Clinical evaluation was carried out for all patients according to the following scheme: detailed history, detailed general examinations, lower limb examination to detect varicose veins, distribution of veins affected, and incompetent perforators and shape (spider, serpentine, or saccular). Duplex was done as a routine to all patients to detect patency of the deep venous system, saphenofemoral or saphenopopliteal reflux, presence and number of perforators, diameter of GSV and distance from the skin, exclude any venous anomalies of lower limb (LL), exclude accessory GSV and mapping of it if present, and mapping of superficial venous system of LL.

2.1. Treatment

2.1.1. Endovenous laser ablation procedure

After the patient received local tumescent anesthetic, EVLA was done. The patient was placed in supine position. Sterilization was performed by cleaning of the affected limb with povidone iodine and then putting of sterilized towels. Vein access was acquired while under local anesthetic by puncturing the vein with a 16-F needle while under ultrasound (US) supervision. Because it is easier to enter the inadequate GSV immediately distal to the popliteal region (because of its wide diameter and linear course) and because the danger of nerve damage is lower, this is the most typical location (Figs. 1–3).

2.2. Radiofrequency ablation procedure

During therapy, a bandage was used to compress the limb. The generator was programmed to produce 23 W of electricity. Using aural input from the RFiTT system, the RFA catheter was removed

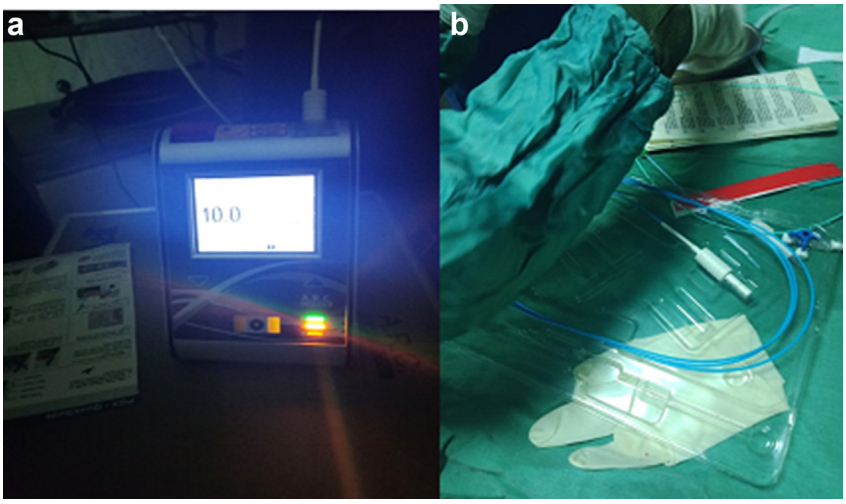

Fig. 1. (a) Laser device for endovenous ablation. (b) Laser fiber.

during treatment at a rate of around 0.8 cm per second. The vein carrying the sheath was not treated since treatment ceased when the catheter reached the sheath.

Medical treatment: low-molecular-weight heparin (enoxaparin sodium 40 mg) injected for 7 days in selected high-risk cases and grade 2 postoperative compression treatment that continued for 8 weeks were routinely utilized as a part of thrombosis prevention in both groups. Anti-inflammatory medications were recommended postoperatively for 3 days (EVLA and RFA).

Follow-up and assessments: using routine ultrasound scans on the day of surgery (day 0), 1 week, 1 month, and then every 6 months after the procedure, the patients were tracked postoperatively. Over the course of 5 years, the patients had routine clinical tests and ultrasound scans to monitor them.

3. Results

Table 1 shows demographic details about the group under study. Patients aged from 20 to 52 years old, with an average age of 30.60 ± 7.559 years. Males were 22 (44%), whereas females were 28 (56%).

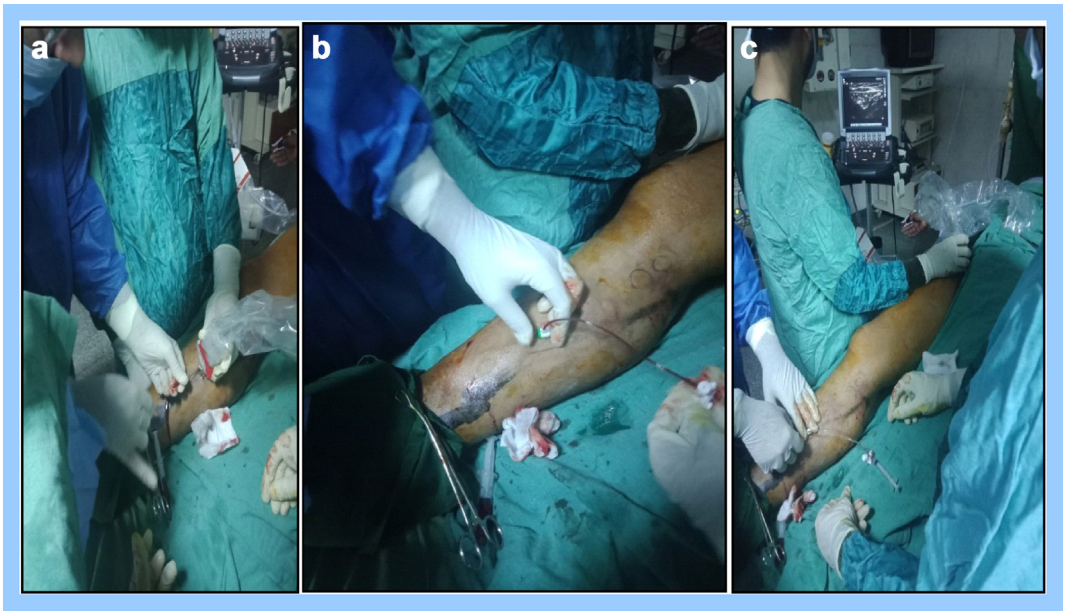

Fig. 2. (a) Puncture of GSV duplex guided and introducing of the guide wire. (b After introducing of the sheath. (c) Duplex ultrasound during introducing of laser catheter.

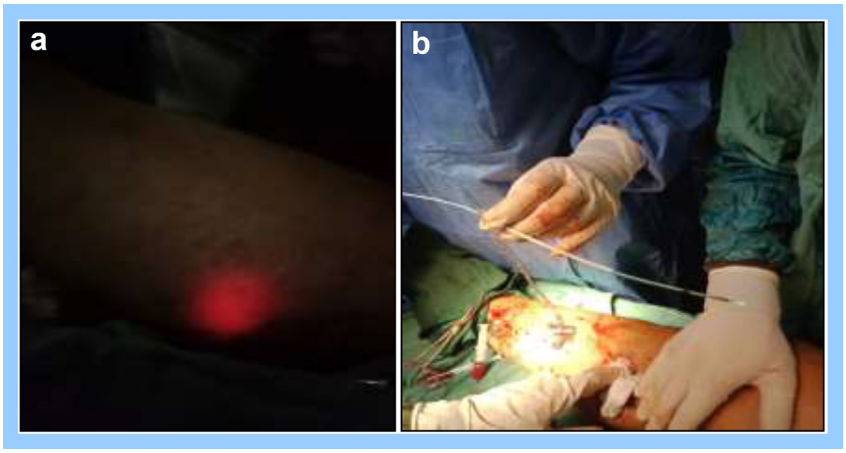

Fig. 3. (a) Laser beam while in truncal varicosity. (b) Laser beam after removal of the sheath.

In this study, there are four (8%) diabetic patients, 10 (20%) dyslipidemic patients, and one patient had HTN, as presented in Table 2.

In this study and according to CEAP classification, we had a variety of patients from C2 to C6 (Tables 3 and 4).

Evaluation of effect on healing of venous ulcer with EVLA and RFA with time at 1, 2, and 3 months (Table 5).

Saphenous nerve neuralgia was close in EVLA and RFA. By the third month, only one patient in RFA group was suffering from saphenous nerve neuralgia.

Patient could return to daily activities post-operatively from 4 to 10 days as Table 6.

Table 7 shows that GSV diameter ranged between 4.50 and 9.50, with a mean value of 6.52 ± 1.271, and it was decreased significantly at postoperative time to reach after 6 months of follow-up to be at mean value of 0.52 ± 0.252.

Table 8 shows that GSV diameter was ranged between 5.50 and 10.0, with a mean value of 7.12 ± 1.271, and it was decreased significantly at postoperative time to reach after 6 months of follow-up to be at a mean value of 0.82 ± 0.252 (Table 9).

In the EVLA group, two patients were complicated with persistent skin hyperpigmentation, three with transient skin hyperpigmentation, two with transient saphenous nerve damage, and only one with persistent saphenous nerve damage. In the RFA group, three patients were complicated with persistent skin hyperpigmentation, two with transient skin hyperpigmentation, one with skin burns, two with transient saphenous nerve damage, and two with persistent saphenous nerve damage (Table 10).

In the EVLA group, recanalization of short-segment occlusion was done in four patients, recanalization of long-segment occlusion was done in two patients, and recurrent varicose veins happened in five patients. In the EVLA group, recanalization of short-segment occlusion was done in three patients, recanalization of long-segment occlusion was done in three patients, and recurrent varicose veins happened in six patients.

Table 1. Distribution of the study population based on the patients' demographic information.

	N (%)
Age (years)	
≤30	20 (40.0)
>30	30 (60.0)
Range	20–52
Mean ± SD	30.60 ± 7.559
Sex	
Male	28 (56.0)
Female	22 (44.0)

4. Discussion

No direct comparisons between RF ablation and laser ablation have been reported. The published studies, however, point to significantly greater laser ablation occlusion rates. Long-term follow-up and measurement of 5-year to 10-year recurrence rates will be crucial for both therapies. Both procedures depart from conventional surgical training in that the sapheno femoral junction (SFJ) tributaries are left untreated and may serve as a catalyst for recurrence.[3]

Table 2. Distribution of investigated sample according to comorbidities of the patient.

Comorbidity	*N* (%)
DM	4 (8.0)
HTN	1 (2.0)
Dyslipidemia	10 (20.0)

DM, diabetes mellitus; HTN, hypertension.

Table 3. Distribution of investigated sample according to CEAP classification of patient limbs.

CEAP classification of patient limbs	*N* (%)
C2	6 (12.0)
C3	25 (50.0)
C4	12 (24.0)
C5	7 (14.0)
Total	50 (100)

CEAP, clinically, etiologically, anatomically, and pathophysiological categorization.

We decided to distinguish between the short-segment (<5 cm) and long-segment (5 cm) recanalization for the study. Varicose vein recurrence was often linked to long-segment recanalization, which was detected in individuals with proven active blood flow along a 5-cm or longer portion of the destroyed channel.

This was verified in individuals who had EVLA (3.6%) and RFA (8.6%) procedures. Therefore, with EVLA and RFA, effective obliteration was accomplished in 96.4 and 91.4%, respectively,.[4]

In our EVLA group, type 3 anatomical failure was discovered in four of five people with varicose vein recurrence, which was linked to insufficiency of the anterior (two patients) or posterior (two patients) accessory great saphenous vein. Varicose vein recurrence in one patient was linked to type 2 anatomical failures in the great saphenous vein recanalization. Four instances of type 3 anatomical failure, involving the insufficiency of the anterior (three patients) and posterior (one patient) accessory great saphenous veins, were verified in the RFA group. Two occurrences of type 2 anatomical failures were noted. None of our patients had type 1 anatomical failure, as far as we could tell.

A somewhat frequent consequence following GSV striping is impaired superficial feeling caused by saphenous nerve injury, which has been shown to occur in 23–40% of patients having whole saphenectomy and 7–19% of those having partial saphenectomy (above the knee).

Limiting stripping helps the saphenous nerve heal and minimizes irreversible harm. In our research sample, 3.7% of individuals in the RFA group and 1.8% of participants in the EVLA group had persistent dysesthesia (altered feeling). The rates of neuropathy have been dramatically lowered by tumescent anesthesia. Neuropathies tended to afflict 25% of treated individuals during the early phases of RFA when it was carried out without tumescent anesthesia. Following EVLA, patients had less abnormal sensations than after RFA.[5]

Table 4. Healing was close in EVLA and RFA.

	Follow-up	EVLA	RFA
Effect on healing of venous ulcer	At 1 month	0	0
	At 2 months	1	1
	At 3 months	2	1

EVLA, endovenous laser ablation; RFA, radiofrequency ablation.

Table 5. Evaluation of saphenous nerve neuralgia with EVLA and RFA with 1, 2, and 3 months.

	Follow-up	EVLA	RFA
Saphenous nerve neuralgia	1 month	2	2
	2 months	1	1
	3 months	0	1

EVLA, endovenous laser ablation; RFA, radiofrequency ablation.

Skin darkening is a common side effect after sclerotherapy; it may occur in up to 30% of patients. Rarely, it happens following traditional varicose vein surgery, and it can be brought on by the absorption of hematoma after striping. The reason for hyperpigmentation in patients after EVLA and RFA is thrombophlebitis.[6]

In this research, the EVLA and RFA groups had hyperpigmentation in as low as 3.6 and 6.8% of patients, respectively.

Burns in individuals who had endovenous thermal ablation have been documented in isolated case reports. A thin patient receiving RFA was the victim of our instance of a skin burn.

Due to duplex evidence of patency after the first pass of the closure catheter, this research revealed that the RFA group needed to treat the saphenous vein twice during the same procedure more often than the EVLT group did (17 vs. 0%). This discovery was more than the typical intraoperative residual flow and was deemed to be insufficiently closed, requiring repeated obliteration under the same anesthetic.

RFA and GSV stripping were compared in the Endovenous Radiofrequency Obliteration (Closure) Versus Ligation and Stripping in a Selected Patient Population (EVOLVeS) trial. On the day of therapy, 95% (42/44) of patients reported immediate success. In 16.3% (7/44) of the limbs on a scan taken 72 h after the surgery, the proximal GSV was showing flow. Reflux was seen in the open portion of five of these segments.

Two of these segments ended after 1 week, whereas a third ended after 3 weeks.[7]

Table 6. Distribution of the sample based on the patient's return to everyday activities.

Return to daily activity	*N* (%)
≤5	20 (40.0)
>5	30 (60.0)
Range	4–10
Mean ± SD	6.10 ± 1.876

Table 7. Evaluation of GSV diameter preoperatively and postoperatively after LASER ablation.

GSV diameter	Preoperative	Follow-up			
		1 week	1 month	3 months	6 months
Minimum–maximum	4.50–9.50	3.20–8.50	1.30–6.40	0.60–4.30	0.10–0.90
Mean ± S.D	6.52 ± 1.271	5.31 ± 1.273	3.50 ± 1.070	1.88 ± 0.731	0.52 ± 0.252

There was no discernible connection between the existence of modest GSV flow at the conclusion of the surgery and recanalization when we examined the results of intraoperative and postoperative duplex ultrasonography.

One of the reasons for early recanalization might have been noncompliance with postoperative compression, although we were unable to monitor this.

Additionally, earlier studies have shown that EVLT has somewhat greater occlusion rates (98–100%) than RFA (83–100%).[8]

Because of the intraluminal thrombus and accompanying inflammation, there is a greater incidence of painful thrombophlebitis and cellulitis when using the EVLT procedure.

After EVLT, similar issues have been noted by other writers. The presence of thrombotic material that accumulates in the stump of the GSV above the treated region is most likely the cause of the absence of flow close to the inferior epigastric vein during postoperative duplex scans.[9]

Only after recent reports of thrombotic problems after RFA was routine postoperative duplex scanning started. It is believed that the current rates of DVT for EVLT, RFA (0.3% vs. 0.4–2.1%), and stripping (5.7%) are comparable when pooled from large series. It is likely that GSV thrombi brought on by laser energy varies from those brought on by RFA. In contrast to RFA, which results in collagen shrinkage and fibrosis, EVLT produces homogenous thrombotic blockage of the artery owing to the formation of steam bubbles.[10]

Patients with grade C2 illness were more prevalent in the majority of recent research, according to a systematic literature analysis published in 2018, with the exception of two studies where the majority of patients had grade C4 disease.

The assessment of postoperative improvement of venous symptoms was assessed by CEAP postoperatively which showed dramatic improvement in EVLA group as all patients turned to C1EpAsPr (100%), whereas in RFA group, only 88.9% turned to C 1 EpAsPr.

Regardless of the therapies used, there was a substantial improvement in quality of life from baseline and resolution of venous symptoms in all studies that provided pertinent data; however, Gale and colleagues found no substantial distinction in improvement in quality of life between RFA and laser treatment.[11]

Regarding the length of the treated vein, there was no statistically significant difference between EVLA and radiofrequency-powered segmental ablation (cm). According to GSV with incompetent terminal valve, there was no statistically significant difference between radiofrequency driven segmental ablation and EVLA. In both the groups, that is, EVLA and the radiofrequency-powered segmental ablation, the severity score had decreased over time in an extremely statistically substantial manner.

There was good correction of venous reflux-related parameters, particularly venous hypertension attributable to GSV incompetence, regardless of the treatment method utilized, when comparing closure FAST RF catheter therapy with 980-nm EVLA. There was no difference between RF ablation and EVLA in any of the indicators assessing post-inflammatory sequelae. According to reports, patients tolerate the RF technique better because regulated heating prevents vein perforations common to EVLA.[12]

This study failed to show any significant difference between the two groups regarding patient satisfaction, and ease of use of RFA versus EVLA was not significantly different. As yet, there has not been any standardization in energy dosage delivered with EVL, but future studies are likely to focus on these technical issues.

Table 8. Evaluation of GSV diameter preoperatively and postoperatively after RFA ablation.

GSV diameter	Preoperative	Follow-up			
		1 week	1 month	3 months	6 months
Minimum–maximum	5.50–10.0	3.20–8.50	1.30–6.40	0.90–5.60	0.30–1.20
Mean ± SD	7.12 ± 1.271	5.31 ± 1.273	3.50 ± 1.070	2.28 ± 0.731	0.82 ± 0.252

RFA, radiofrequency ablation.

Table 9. Evaluation of complications following both EVLA and RFA ablations.

Complication type	EVLA group [*N* (%)]	RFA group [*N* (%)]
Venous thromboembolism	0	0
Pulmonary embolism	0	0
Persistent skin hyperpigmentation	2 (3.6)	3 (5.6)
Transient skin hyperpigmentation	3 (5.4)	2 (3.7)
Skin burns	0	1 (1.8)
Persistent saphenous nerve damage	1 (1.8)	2 (3.7)
Transient saphenous nerve damage	2 (3.6)	2 (3.7)

EVLA, endovenous laser ablation; RFA, radiofrequency ablation.

Table 10. Evaluation of treatment failure in both EVLA and RFA ablations.

	EVLA group [*N* (%)]	RFA group [*N* (%)]
Recanalization of short-segment (below 5 cm) occlusion	4 (7.1)	3 (5.6)
Recanalization of long-segment (below 5 cm) occlusion	2 (3.6)	3 (5.6)
Recurrent varicose veins	5 (8.9)	6 (11.1)

EVLA, endovenous laser ablation; RFA, radiofrequency ablation.

Comparing the two techniques in this study in the term of successful ablation, minor complication, and improvement of symptoms, EVLA was superior to RFA.

The pullback treatment time is shorter, the saphenous obliteration rates are likely greater, and the EVLT laser fiber is more costly than the RFA catheter.

4.1. Conclusion

Overall, 94% of incompetent GSVs were successfully treated by endovenous ablation procedures after 1 month. Although postoperative problems were more common with EVLT than after RFA in this study, EVLT was linked with somewhat greater occlusion rates. Complications of endovenous ablation included the following: deep vein thrombosis, pulmonary embolism, pain, abscess, seroma, hyperpigmentation, and burn of the skin. After endovenous saphenous ablation, compression therapy may be crucial. To rule out proximal thrombus extension, confirm occlusion, and eliminate more distant DVT, early postoperative duplex scanning should be performed on all patients who get endovenous operations. We find that older patients have a tendency to acquire more proximal GSV thrombi following ablation, as a result, individuals older than 50 years may want to consider DVT prevention.

Conflicts of interest

None declared.

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