Endovenous laser versus radiofrequency ablation of great saphenous vein: early postoperative results

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Background
Minimally invasive endovenous thermal ablation therapy has revolutionized the treatment of varicose veins. Comparison of radiofrequency ablation (RFA) versus Endovenous Laser Ablation (EVLA) needs to be more elaborated in the context of better management of patients.
Patients and methods
A total of 50 young patients (10 patient bilateral and 40 patients unilateral) were enrolled in a prospective interventional study over a period of 2 years starting from June 2014. All patients were blinded to the chosen method to achieve a single-blinded study, with two groups. Exclusion criteria included deep vein thrombosis, peripheral arterial disease, severe tortuosity of Great saphenous Vein (GSV), and refusal of consent. All patients were assessed for deep system patency and flow in ablated segment by duplex immediately after procedure and 1 month later.
Results
Overall, 60 limbs were equally allocated to two groups. There was no significant difference between both groups concerning the demography and clinical, etiologic, anatomic, and pathophysiologic classification. All patients were blinded to the method of venous ablation. Postoperative duplex shows no failed recanalization or deep vein thrombosis. Pain, ecchymosis, and superficial thrombophlebitis were significantly higher in EVLA group versus RFA group ($P<0.05$). Surprisingly, first-degree burn occurred in two (6.6%) cases in EVLA group.
Conclusion
Both thermal ablative techniques performed well concerning high occlusion rates for incompetent GSV. Less postoperative complications were observed with RFA as compared with EVLA, namely, postoperative pain, ecchymosis, superficial thrombophlebitis, and first-degree burn. However, such complications were deemed to be benign and managed conservatively.

Keywords:
complications of venous ablation, endovenous laser, radiofrequency, varicose veins ablation

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Introduction

Minimally invasive endovenous thermal ablation therapy has revolutionized the treatment of varicose veins [1]. Fewer complications, less postoperative pain, and early return to work are the main advantages of these techniques if compared with the traditional stripping surgery [2,3].

A reduced neovascularization in the groin may have an effect over the recurrence rates owing to absent dissection in the groin in these techniques [4].

In this study, we aim to compare the effectiveness of both thermal ablation techniques and to detect the early outcomes of both techniques in a randomized single-blinded study.

Patients and methods

All young patients (<40 years old) presented to our vascular surgery department over the period of study were examined and deemed eligible for one of the ablative thermal technique, over the period of 2 years in a prospective randomized interventional study with blinded randomization of one to one in each group. Exclusion criteria included deep vein thrombosis (DVT), peripheral arterial disease, severe tortuosity of Great saphenous Vein (GSV), and refusal of consent.

Approval from Ethical Committee in Cairo University, Vascular Surgery Division of General Surgery Department was taken before starting the study.

A total of 50 patients with 60 limbs had symptomatic varicose veins with documented GSV incompetence

and were classified according to the clinical, etiologic, anatomic, and pathophysiologic classification. Clinical data, operative details, and postoperative course were recorded (Table 1).

All patients were consented for one of the ablative techniques, and all patients were blinded to the chosen method to achieve a single-blinded study, with two groups, Endovenous Laser Ablation (EVLA) and radiofrequency ablation (RFA) groups.

Venous duplex was done for all cases before, intraoperatively, immediately postoperatively, and 1 and 6 months later to detect failed ablation or thrombophlebitis.

Reflux in the superficial (GSV and small saphenous vein) and deep (femoral vein and popliteal vein) venous systems was assessed with patients in the standing position. Reflux was defined as reversed flow lasting more than 0.5 s after calf compression.

All interventions were carried out under sedation, and DVT prophylaxis consisting of 5000 U of subcutaneous unfractionated heparin sodium and prophylactic antibiotics, flucloxacillin 1 g, was given just before the puncture.

For both techniques, the GSV was cannulated below the knee, and the catheter tip was positioned 2 cm from the saphenofemoral junction aided by ultrasonographic guidance. Standard tumescent local anesthesia [50 ml 1% lidocaine with 1 : 200 000 adrenaline (epinephrine) in 1000 ml normal saline] was infiltrated along the length of the vein using ultrasonographic guidance. In EVLA group, the laser fiber was continually withdrawn aiming at delivery of energy greater than 60 J/cm to the vein wall, with a power setting of 11 W. However, in RFA patients, the first segment was treated with two RFA cycles according to the manufacturer's instructions, [using RFA ClosureFast catheter (VNUS ClosureFAST; VNUS Medical Technologies, San Jose, California, USA)], and the remainder of the vein was treated with one RFA cycle per 7-cm segment, with half a centimeter overlap between two consecutive segments. Extrinsic pressure was applied over the vein during treatment cycles in both techniques.

Table 1 Clinical data for the recruited patients

	EVLA group	RFA group	*P* value
Limbs (*n*)	30	30	
Age (mean) (years)	32 (18–38)	31 (20–39)	0.637
Sex (female) (*n*)	24	26	0.851
CEAP classification			
C2	27	25	0.412
C3	2	3	
C4	1	2	
Mean ablated vein length (cm)	43.5±2	47.5±1	0.354
Mean vein diameter (mm)	6±0.5	6±1.5	0.119

EVLA, endovenous laser ablation; RFA, radiofrequency ablation.

Ancillary procedures such as avulsion phlebectomies, SEPS, and injection sclerotherapy were referred for 1 month after the procedure.

For all patients, deep venous patency was checked by the operating surgeon using duplex ultrasonography in the operating theater immediately after the procedure.

After treatment, a crepe bandage was applied for at least 24 h postoperatively and was replaced with an elastic stocking, class II, thereafter. Patients were instructed to wear the elastic stocking, class II, continuously for 1 week.

All patients were discharged on ibuprofen and instructed to take only if required.

All patients were instructed to start an early ambulation and return back to work and their normal activities as early as possible.

For pain assessment, patients were given a sheet to record the number of analgesic tablets taken every day through the first week postoperatively. Data from visual analogue scale were compared with the number of tablets taken per day by the assessors.

Pain is deemed to be mild if the patient had taken one tablet per day. As well pain is considered severe if the patient had taken a full dose of analgesic, that is, three tablets per day.

Patients were followed after 1, 2 weeks, 1 month, 6 months, and 1 year by clinical examination and follow-up venous duplex after 1, 6, and 12 months to detect early postoperative complications, that is, ecchymosis, first-degree burn, superficial thrombophlebitis, and severe pain.

Statistical analysis

Comparison between the two groups was performed with the Fisher's exact test. *P* value of less than 0.05 was considered statistically significant.

Results

Sixty limbs were equally allocated to two groups, that is, EVLA group and RFA group. There was no significant difference between both the groups regarding demography, age, sex, and clinical, etiologic, anatomic, and pathophysiologic classification.

All patients were C (2-4), E(p), A (GSV), P(r) (Table 1).

All patients were treated for symptomatic relief and to stop the progression of the disease.

All patients were blinded to the method of venous ablation but not the operators.

Immediate success was assigned by immediate closure, noncompressible thickened wall GSV, and absence of common femoral vein thrombus by intraoperative venous duplex. Presence of minimal flow in GSV 2 cm away from SFV upon immediate duplex is deemed to be unsuccessful and mandates extra cycle of ablation. Immediate success was achieved in 100% cases in EVLA group, whereas in RFA group, it was 93 and 7% of cases had persistent minimal flow in GSV, 2 cm away from SFV and mandated an extra cycle of radiofrequency ablation (P=0.491).

After an extra cycle of ablation in RFA group, success rate turned to be 100%. The ablated vein diameter was in these cases 7.5 and 7.4 mm, respectively.

Early postoperative venous duplex was done after 1-month follow-up and showed no recanalization of GSV and no DVT in both groups, which was deemed as a satisfactory result.

Patients in the EVLA group also reported more pain over the first week, 63.33% (n=19), and 23.33% (n=7) for RFA. P value was statistically significant (P=0.0037).

Patients in the EVLA group consumed more analgesic tablets than those in the RFA group, that is, 171 tablets for EVLA group versus 21 tablets for RFA group in the first 3 days postoperatively.

Superficial thrombophlebitis was more dominant in EVLA group (n=8, 26.67%) compared with RFA group (n=1, 3.33%) in the first month postoperatively (P=0.013).

Ecchymosis was more prevalent in EVLA group (n=14, 46.67%) compared with RFA group (n=3, 10%) (P=0.0034).

First-degree burn occurred only in two (6.6%) cases in EVLA group (P=0.49).

At 6-month follow-up, evidence of recanalization was detected using DUS in RFA group (n=1, 3.33%). However, no recanalization was seen in EVLA group at 6-month follow-up (n=0). P value was statistically insignificant (P=1).

At 12-month follow-up, an evidence of recanalization was also detected using DUS, in RFA group (n=2, 6.67%). However, still there was no recanalization detected in EVLA group at 6-month follow-up (n=0). P value was statistically insignificant (P=0.491).

Discussion

Endovenous thermal ablative techniques are recognized as minimally invasive alternatives to open surgical stripping of an incompetent GSV. Traditional stripping technique is also associated with painful and delayed postoperative recovery, as well as the increased risks of infection and hematoma especially in obese patients [5,6].

In this prospective study, we aimed at comparing the two endovenous thermal ablative techniques, namely, EVLA and RFA, regarding the early technical success and the complications of both techniques, especially the postoperative pain.

In our study, we detected a higher need for an extra cycle of RFA in RFA group if compared with EVLA group (6.67 vs. 0%) owing to inadequate closure detected by intraoperative venous duplex after two cycles of RF ablation in RFA group. However, this may be attributed to a larger vein diameter (7.4 and 7.5 mm) in these cases. The findings in literature are scarce regarding the immediate, intraoperative and inadequate closure using RFA, as most data are only linked to the postoperative clinical outcome [7].

Our data showed that all cases had no recanalization of GSV, as evidenced by a postoperative venous duplex done at 1 month. This was consistent with a study conducted by Puggioni *et al.* [7], where early recanalization was infrequent between both groups (EVLA vs. RFA), and most patients were asymptomatic and had not required further therapy. Puggioni *et al.* [7] believed that noncompliance with postoperative compression may be a contributing factor for early recanalization. However, reports in literature have shown higher occlusion rates with EVLA (98–100%) when compared with RFA (83–100%)

[5–12]. In a study recently performed by Bozoglan *et al.* [13], higher occlusion rates were detected in EVLA group in contrast to RFA group (100 vs. 93.2%), which was consistent with our results. The variability in occlusion rates between both techniques may be attributed to a different mechanism of action for each. For both techniques, the underlying goal to induce an irreversible occlusion is to deliver enough thermal energy to the wall of incompetent vein resulting in a subsequent fibrosis. For EVLA, it has been stated that there is are direct and indirect effects via laser-induced steam generated by heating of small amounts of blood within the vein leading to adequate vein wall damage. Some heating may occur via direct absorption of photon energy by the vein wall, as well as through convection from steam bubbles and conduction from heated blood [8]. On the contrary, RFA causes heat-induced venous spasm, with subsequent collagen shrinkage [7]. So, adequate vein emptying via a Trendlenberg position, with the use of generous perisaphenous tumescent infiltration and adequate probe pressure are crucial with RFA technique [7].

Recanalization was detected in RFA group in contrast to EVLA group at 6-month follow-up using DUS in one case (n=1, 3.33%) (P=1) which was statistically insignificant. While reviewing our later results at 12 months follow-up between both groups, recanalization was obvious in RFA group in two cases, (n=2, 6.67%) (P=0.491), which was also still statistically insignificant. In a study conducted by Almeida and Raines [12], recanalization rates were 5.5% for RFA in contrast to EVLA which was 1.7%. It seems to our knowledge, as the evidence is scarce in literature, that still we have to conduct more studies in the future to assess the remote results for recanalization of the ablated venous segments for both techniques.

In our study, we focused to observe and assess the postprocedural pain following both techniques. It is difficult to assess a subjective symptom, like postoperative pain in patients without a method for accurate quantification. So, we tried to make all the selected patients blinded to the allocated treatment chosen for them. As well, we depended on the number of analgesic tablets received by them in the first week postoperative to quantify a subjective finding with correlation to a visual analogue for pain assessment given to the patients.

Interestingly, we found less postoperative pain in RFA group, compared with EVLA group (P=0.0037). This was consistent with other studies that have shown an incidence of less postoperative pain after RFA [14,15]. A possible explanation for the reduced incidence of postoperative pain after RFA may be the controlled heating and segmental ablation technique of VNUS ClosureFAST that results in a less number of vein wall perforations, so lessens blood extravasation into tissues [16,17].

In our study, we observed a much less analgesic intake in RFA group if compared with EVLA group, which supports the aforementioned data. It was suggested to reduce painful discomforts after EVLA by using recent radial fibers, with shorter wavelengths, that is, 1320 and 1470 nm, and jacketed laser fibers instead of 980-nm bare tip laser fiber [18,19].

To avoid vein wall perforations, it is advised to use shorter wavelengths that aim at targeting the last peak of water absorption; the idea behind is that hemoglobin absorption is totally bypassed, allowing more robust absorption of laser photons by interstitial water in the vein wall [15]. Interestingly, targeting of the vein wall exclusively has always been the goal of RFA [15].

Superficial thrombophlebitis and ecchymosis were more prevalent in EVLA group, with statistically significant P values (P=0.00138 and 0.0034, respectively), which was consistent with RECOVERY trial, and may be attributed to the high treatment temperatures and vein wall perforation with extravasation of boiled blood into surrounding tissues [15]. In our study, these symptoms were self-limiting and treated conservatively and all recovered in 5 days to 1 week duration.

Overall, two cases of superficial first-degree burn had occurred during our study with statistically insignificant P value (P=0.49) and may be owing to insufficient tumescence or owing to a closely lying GSV to the skin in thin patients. As well, both cases were managed conservatively thereafter.

Conclusion

As stated in this prospective interventional study, both thermal ablative techniques performed well concerning high occlusion rates for incompetent GSV.

Less postoperative complications were detected with RFA if compared with EVLA, namely postoperative pain, ecchymosis, superficial thrombophlebitis, and

first-degree burn scars. However, such complications were not statistically significant and it deemed to be benign and managed conservatively.

Limitation of study

The results of the present study were derived from a single-center experience where certain techniques have been routinely used. It is consequently likely that the selection of techniques with its own limitations may differ largely from centers with another experience.

Additionally, a larger number of patients are needed to make a firm conclusion with both treatment modalities, and surgery may be compared with them.

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Conflicts of interest

There are no conflicts of interest.

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