

## Endovenous Laser Versus Radiofrequency Ablation of Great Saphenous Vein: Early Postoperative Results

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### ABSTRACT

**Background :** Minimally invasive endovenous thermal ablation therapy has revolutionized the treatment of varicose veins. Comparing both techniques (RFA versus EVLA) need to be more elaborated in the context of better management of patients. **Methods:** fifty young 10 patient bilateral and 40 patients unilateral patients were enrolled in this study over the period of 2 years starting from June 2014 in a prospective interventional study. All patients were blinded to the chosen method to achieve a single blinded study, with 2 groups. Exclusion criteria included, DVT, PAD, severe tortuosity of GSV, refusal of consent. All patients were assessed for deep system patency and flow in ablated segment by duplex immediately after procedure and one month later. **Results:** Sixty limbs were equally allocated to 2 groups. There was no significant difference between both groups concerning the demography, and CEAP classification. All patients were blinded to the method of venous ablation. Postoperative duplex shows no failed recanalization nor DVT. Pain, ecchymosis and superficial thrombophlebitis were significantly higher in EVLA group versus RFA group ( $P$  value  $< 0.05$ ) Surprisingly, First degree burn occurred in 2 cases (6.6%) 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 to EVLA, namely postoperative pain, ecchymosis, superficial thrombophlebitis and first degree burn. However such complications were deemed to be benign and managed conservatively.

**Key words:** Endovenous laser, Radiofrequency, Varicose veins ablation, Complications of venous ablation

### INTRODUCTION

Minimally invasive endovenous thermal ablation therapy has revolutionized the treatment of varicose veins. In 2001, endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) were assigned for treating varicose veins by the National Institute for Health and Clinical Excellence in the UK.<sup>(1)</sup> fewer complications, less postoperative pain, early return to work were the main advantages for these techniques if compared to the traditional stripping surgery.<sup>(2-3)</sup>

A reduced groin's neo-vascularization may have an impact over the recurrence rates due to absent dissection in the groin in these techniques.<sup>(4)</sup> The majority of patients with primary varicose veins have an amenable great saphenous vein (GSV) incompetency to endovenous thermal ablation techniques.<sup>(5)</sup> The mostly used endovenous laser wavelength is the 980-nm wavelength with bare fiber in UK.<sup>(6)</sup> The most famous RFA system is the VNUS® Closure FAST™ (VNUS Medical Technologies, San Jose, California, USA) segmental ablation catheter. The RFA catheter delivers radiofrequency energy to achieve heat-

induced venous spasm and collagen shrinkage, whereas EVLA releases thermal energy both to the blood and to the venous wall, causing localized tissue damage. Early reports on endovenous saphenous ablation show high occlusion rates but different patterns of complications related to these two different techniques. Occlusion rates are high with both techniques, but they have been somehow higher after EVLA (98% to 100%) than after RFA (83% to 100%)<sup>(7-8)</sup>

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.

### METHODOLOGY

All young patients presented to our vascular surgery department over the period of study were examined and deemed eligible for one of the ablative thermal techniques, over the period of 2 years in a prospective interventional study. Exclusion criteria included, DVT, PAD, severe tortuosity of GSV, refusal of consent.

Fifty patients with sixty limbs had symptomatic varicose veins with documented GSV incompetence and were classified according to the CEAP (clinical, etiologic, anatomic, 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 2 groups, EVLA & RFA groups.

Venous duplex was done for all cases before , intra-operatively , immediate postoperative and one month later.

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 seconds after calf compression.

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

For both techniques, the GSV was cannulated at, a level below the knee and the catheter tip was positioned 2 cm from the sapheno-femoral junction aided by ultrasonographic guidance. Standard tumescent local anaesthesia (50 ml 1 per cent 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, using a bare tip 980 nm wavelength catheter. While in RFA patients, the first segment was treated with two RFA cycles according to the manufacturer's instructions, and the remainder of the vein was treated with one RFA cycle per 7-cm segment, with half cm overlap between 2 consecutive segments. Extrinsic pressure was applied over the vein during treatment cycles in both techniques.

Ancillary procedures as avulsion phlebectomies , SEPS and injection sclerotherapy were referred to one month after the procedure.

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

After treatment, a crepe bandage was applied for at least 24 hours 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 (400 mg up to three times a day) 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 visual analogue scale (VAS) and a sheet to record the number of analgesic tablets taken every day through the first week post operatively .Data from visual analogue scale were compared to the number of tablets taken per day by the assessors.

Pain is deemed to be mild if the patient had taken 1 tablet per day. As well pain is considered severe if the patient had taken a full dose of analgesic ,i.e 3 tablets per day.

Patients were followed up for one month, using a follow up venous duplex after 1 month , as well as the early postoperative complications, i.e: ecchymosis, first degree burn, superficial thrombophlebitis, severe pain ,hematoma.

#### Statistical analysis

Comparison between the two groups was performed with the Fisher's exact test . $P < 0.05$  was considered statistically significant.

## RESULTS

Sixty limbs were equally allocated to 2 groups, i.e (EVLA group & RFA group). There was no significant difference between both groups concerning the demography, regarding age, sex, CEAP classification, i.e (All patients were C(2-4),E(p),A(gsv),P(r)). (table 1)

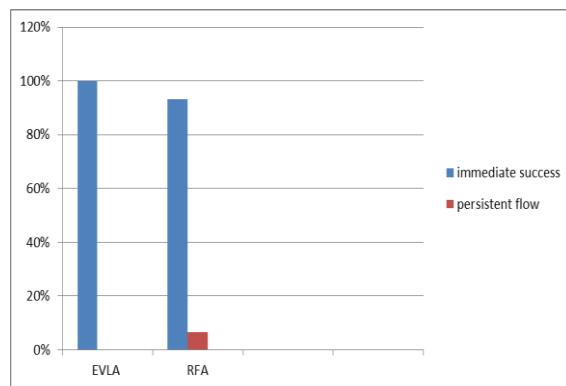
All patients were treated for symptomatic relief, and to stop the progression of the disease.

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

**Table (1):**

<b>Demography</b>	<b>EVLA group</b>	<b>RFA group</b>	<b>P value</b>
<b>Limbs (n)</b>	30	30	
<b>Mean Age(y)</b>	32	31	0.637
<b>Female sex(n)</b>	24	26	0.851
<b>CEAPclassification</b>			
<b>C2</b>	27	25	0.412
<b>C3</b>	2	3	
<b>C4</b>	1	2	
<b>Mean ablated Vein length(cm)</b>	43.5±2	47.5±1	0.354
<b>Mean vein diameter (mm)</b>	6±0.5	6±1.5	0.119

Immediate success was assigned by immediate closure, non compressible thickened wall GSV and absence of common femoral vein thrombus by intraoperative venous duplex. Presence of minimal flow in GSV 2cm away from SFV upon immediate duplex is deemed to be unsuccessful and mandates extra cycle ablation. (fig.1)

**Fig.(1):**

p value =0.491

After an extra cycle ablation in RFA group, success rate turned to be 100%, it's worth mentioning that the ablated vein diameter was in these cases 7.5, 7.4 mm respectively.

Early postoperative venous duplex was done after 1 month follow up and showed no recanalization of GSV, no DVT, in both groups, that 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, i.e (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 to RFA group (n=1,3.33%) in the first week postoperatively. (p=0.013)

Ecchymosis was more prevalent in EVLA group (n=14,46.67%) compared to RFA group(n=3,10%). P value was statistically significant. (p=0.0034)

First degree burn occurred only in 2 cases (6.6%) in EVLA group. P value was statistically insignificant. ( p=0.49)

## 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,delayed postoperative recovery, as well as the increased risks of infection, hematoma, especially in obese patients.<sup>(9)</sup>

Such risks as well including nerve injury are known to be less in incidence in the endovenous thermal ablative techniques.<sup>(10)</sup>

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

In our study, we detected a higher need for an extra cycle RFA in RFA group if compared to EVLA group (6.67% vs 0 %) due to inadequate closure detected by intraoperative venous duplex after 2 cycles RF ablation in RFA group. However, this may be attributed to a larger vein diameter, (7.4 mm &7.5mm ) in these cases . The findings in literature, concerning the immediate, intraoperative, inadequate closure while using RFA are scarce, as most data are only linked to the postoperative clinical outcome.<sup>(11)</sup>

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 PuggioniA.,et al,<sup>(11)</sup> where early recanalization

was infrequent between both groups, EVLA vs RFA, and most patients were asymptomatic and hadn't required a further therapy. Puggioni A., et al,<sup>(11)</sup> believed that non compliance with postoperative compression may be a contributing factor for early recanalization. Though, reports in literature, have shown higher occlusion rates with EVLA (98%-100%) if compared to RFA (83%-100%).<sup>(7-12)</sup> 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 a direct and indirect effects, via laser-induced steam generated by heating of small amounts of blood within the vein leading to an adequate vein wall damage. Some heating may occur via direct absorption of photon energy by the vein wall, as well as through convection from stream bubbles & conduction from heated blood.<sup>(7)</sup> On the other hand, for RFA, there is a heat induced venous spasm, with subsequent collagen shrinkage.<sup>(11)</sup> So, adequate vein emptying via a Trendelenberg position, with the use of generous perisaphenous' tumescent infiltration & adequate probe pressure are crucial with RFA technique.<sup>(11)</sup>

In the current study, patients underwent ancillary procedures like multiple phlebectomies & SEPS to complete the treatment in a single session, & to give amore satisfactory results.

In our study, we focused to observe and assess the post-procedural 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 to EVLA group. ( $p=0.0037$ ) This was consistent with other studies, that have shown an incidence of less postoperative pain after RFA.<sup>(13-14)</sup> 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 and so lessens blood extravasation into tissues.<sup>(15-16)</sup>

It's worth mentioning that in our study, we observed a much less analgesic intake in RFA group if compared to EVLA group which supports the aforementioned data. As all procedures were done using spinal anaesthesia&sedation, it was impossible to assess the adequacy of tumescence intraoperatively.

It was suggested to reduce painful discomforts post EVLA to use recent radial fibers, longer wavelengths i.e 1320 nm, 1470 nm & jacketed laser fibers instead of 980 nm bare tip laser fiber.<sup>(17-18)</sup>

To avoid vein wall perforations, it is advised to use longer wavelengths that aim at targeting the last peak of water absorption; the idea being that hemoglobin absorption is totally bypassed, allowing more robust absorption of laser photons by interstitial water in the vein wall.<sup>(14)</sup> Interestingly, targeting of the vein wall exclusively has always been the goal of RFA.<sup>(14)</sup>

Superficial thrombophlebitis, ecchymosis were more prevalent in EVLA group with statistically significant p values ( $p=0.00138$ ,  $p=0.0034$  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<sup>(14)</sup> In our study, these symptoms were self-limiting and treated conservatively and all recovered in 5 days to 1 week duration.

2 cases of superficial first degree burn had occurred during our study with statistically insignificant p value ( $p=0.49$ ) and may be due to insufficient tumescence or due 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 if compared to the old traditional surgery.

Less postoperative complications were detected with RFA if compared to EVLA, namely postoperative pain, ecchymosis,

superficial thrombophlebitis and first degree burn scars. However such complications were deemed to be benign and managed conservatively.

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