Radiofrequency vs Laser Ablation for Great Saphenous Reflux Under Regional Femoral Nerve Block

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ABSTRACT

Aim of the Study: *To evaluate our centers results of both techniques, radiofrequency and endo-venous laser ablation of varicose veins as regard the efficacy and rate of complications.* ***Material & Methods:*** *This study was designed as a prospective analysis of the two techniques for varicose veins treatment that was done from January 2012 to December 2015. This study included two groups of patients, one Group A (151 patients) who were exposed to endo-venous laser ablation (EVLA) and Group B (167 patients) in whom radiofrequency ablation was done. We studied both techniques with regards post-operative pain degree, post-operative thrombophlebitis & DVT and the rate of recurrence within one year.* ***Results:*** *The primary closure of both techniques was 100%. The postoperative pain in the first two weeks were significantly higher in group A (33/151= 21.8%) than in group B (12/167 = 7.1%), however this difference is not significant after those two weeks. Also three weeks post-operative, thrombophlebitis rate was significantly higher at group A (17/151 = 11.2%) than group B (4/167 = 2.3%). No DVT was detected in both groups, while the rate of recurrence of SFJ reflux within one year follow up was 1.3% (2/151) & 4.1% (6/167) in groups A & B respectively.* ***Conclusion:*** *RFA using VNUS® Closure FAST™ was associated with less post procedural pain & thrombophlebitis than EVLA. However, clinical and quality-of-life improvements were similar after 2 weeks for the two treatments. The efficacy of both techniques was the same as regard the vein closure without recanalization within one month follow up. The regional nerve block technique for anesthesia is effective & safe method for endo-venous ablation.*

Key Words: *Radiofrequency, Laser albation, Saphenous reflux*

INTRODUCTION

In the past decade the introduction of minimally invasive endo-venous ablation therapy has introduced as an alternative treatment of varicose veins. Since then surveys and venous registries have shown that their use has been increasing steadily [1,2].

Perceived advantages over traditional surgery include fewer complications, minimal post procedural pain [3,4] and faster recovery times [5,6]. Theoretically, the reduced incidence of neovascularization in the groin may also result in lower recurrence rates in years to come [7]. With evidence to suggest that patients are concerned about recovery times and recurrence rates 13, the appeal of endo-venous interventions is understandable

The majority of patients with primary varicose veins have great saphenous vein (GSV) incompetence that is amenable to endo-venous thermal ablation. Unfortunately, ablation is not suitable for each patient with saphenous reflux as introduction of the catheters is usually not feasible in highly tortuous or in thrombosed vein, [8]. The aim of the present study was to compare early outcomes following Endo-venous laser ablation 980 nm and segmental Radiofrequency ablation in a prospective randomized study.

MATERIAL & METHODS

From January 2012 to December 2015, 318 patients were treated from primary SFJ reflux by endo-venous ablation technique.

All candidate Patients were divided into two Groups A and B. In Group A, 151 patients were treated by laser photocoagulation (EVLA) using Bioletec laser machine with 980 nm wave length (Bioletec, Germany) while in group B, 167

Patients were treated by radiofrequency ablation (RFA) by using VNUS closure Fast machine (Covidien, Medtronic USA).

This study is a prospective randomized one; the clinical inclusion criteria in both groups were patients' age more than 18 years old and de novo (no history of previous intervention) while the ultrsongraphic inclusion criteria included straight great saphenous vein (GSV) and the diameter of less than 10 mm with presence of grade II & III sapheno-femoral junction (SFJ) reflux. Exclusion criteria included Secondary or recurrent Varicose veins and the presence of thrombophlebitis.

The diagnosis of venous incompetence with reflux was made with clinical evaluation and color duplex Doppler studies in all patients. We performed color duplex studies in cross-sections and longitudinal sections with the patient standing. Maximum and mean diameters of GSV were measured. We tested flow on color duplex images by manual compression–release of the calf to provoke reflux. Reflux was defined as >0.5 sec of reverse flow. The common femoral vein, superficial femoral vein, and popliteal veins were also evaluated by duplex Doppler, and patients with thrombus in deep veins were excluded from endo-venous laser ablation therapy.

Techniques

After informed consent was obtained, the patient's medial lower thigh was prepared and draped in the usual sterile fashion. Regional anesthesia by femoral block technique, Ultrasound and Peripheral Nerve Stimulator guided, all patients were premedicated by 1-2 mg midazolam IV before starting the procedure. All patients were in the supine position with extended both legs. In obese patients, pillow was placed underneath the hips to facilitate the palpation of the femoral artery. The femoral artery and nerve were visualized using a high resolution ultrasound device. These structures were marked on the skin. A 22-gauge B-bevel shaped insulated stimulating needle was advanced. The end-point used for injection was an ipsilateral quadriceps contraction and patella movement. At this point, 10-15mL of lidocaine 1% was injected slowly after negative aspiration. Needle advancement and the injection of local anesthetic were visualized with ultrasound. A sensory level to cold temperature in the femoral nerve distribution was established within 10-15 min.

After regional anesthesia, clexan 40 mg s.c was given as our protocol, prophylaxis for DVT for all patients. The most distal GSV at a knee level was accessed using the Seldinger technique with a 7 Fr sheath, under hand-held ultrasound guidance. Tumescent anesthesia was performed over the entire length of the GSV under hand-held ultrasound guidance. Attention was given to injecting tumescent anesthesia in the peri-venous area, around the wall of the GSV, via a 25G needle under real-time sonographic guidance to produce the so-called saphenous eye appearance on ultrasound examination. This was performed to compress the GSV for circumferential displacement of laser energy and to dissect and separate the GSV from peri-venous tissue to prevent skin burn or nerve damage. Tumescent anesthetic was made by mixing 250 ml of 0.9 cold (iced) normal saline and 30 ml of 1% Xylocaine with. Subsequently, the laser fiber or RFA catheter positioned about 2 cm below the sapheno-femoral junction, as confirmed by ultrasound. Subsequently, the entire length of GSV was ablated with a 980 nm diode laser or by heat energy generated by closure Fast machine. For all patients, the power was set at 12 W at beginning till mid-thigh than changed to 10 W till the site of entry of GSV, and the laser was run in continuous mode. The laser fiber pull-back speed was kept at about 0.25 cm/sec. Achieving the nearly constant pull-back speed was helped by measurement marks on the 45 cm sheath. For the group B the machine is seated with temperature 120 dc all over the course of the ablation and to start at energy 40 watt at the beginning of the cycle and to drop to about 20 Watt at the mid of the cycle. The RFA ablation catheter withdrawal was done for each 7.5 cm at 20 seconds. Our technique in RFA, the first cycle was repeated three times and the second cycle was repeated twice. Manual compression over the treated site was applied during the catheter or fiber pull-back to help increase the vessel wall contact with the laser heat. After the treatment, hemostasis at the venous access site was achieved by manual compression. Constant pressure was applied to the treated leg by immediately wrapping the leg with class II (30–40 mmHg) graduated compression stockings. Patients were kept in the day case department for 4 hours in accordance with the hospital protocol as regard regional anesthesia. After discharge, patients were encouraged to

ambulate immediately and kept the treated leg above waist level when sitting or lying. No pain killer prescription was given. The patient kept the class II graduated compression stocking on, except when sleeping and showering, until the follow up visit (mean 7 days). Postoperative clexan 40 mg s.c for 5 days was given as routine DVT prophylaxis

Clinical Outcomes and Data Analysis

Postoperative evaluations assessing clinical outcomes and duplex ultrasound of the GSV were performed within one year follow up. The endpoints of the study were the measurement of clinical outcomes and complications. The presence and intensity of postoperative pain was measured by Visual analogue score VAS test. Ecchymosis was measured clinically as mild, moderate & severe according to the extent of the ecchymosis over the area of treated vein. Clinical success was defined as occlusion of the GSV by duplex ultrasound and disappearance of clinical symptoms in one month follow up. Clinical failure was defined as patency or recanalization of the treated GSV or any significant residual symptoms at the same time interval. Complications were listed as minor and major. Minor complications were defined as temporary and self-limiting symptoms without any clinical sequelae, and major complications were defined as those involving further intervention or permanent sequelae. . These adverse procedural sequelae included deep vein thrombosis, paresthesia, phlebitis, hyperpigmentation, and infection. The patients were followed up to 18.5 months (mean 12.19 months).

RESULTS

The demographic features in both groups were the same as shown in **table I**.

Table I:- Patient demographics

Demographic features	Group A	Group B
Age (mean)	29 years	33 years
Gender		
Male	26.4% (40/151)	22.7% (38/167)
Female	73.6% (111/151)	77.3% (129/167)
Among women		
HRT use	58.2% (88/151)	60.4% (101/167)
Parous	47.6% (72/151)	49.1% (82/167)
History of:		
Varicose veins in family	75.4% (114/151)	72.4% (121/167)
Prior superficial phlebitis or resolved DVT	9.9% (15/151)	10.1% (17/151)
Prolonged standing job	65.5% (99/151)	68.4% (116/167)
Mean length of treated segment(cm)	42	37
Diameter 2 cm from SFJ (mm)	0.66	0.64

The presenting symptom for both groups are demonstrated in **table II** and showed no difference.

Table II: - Presenting symptoms

Presenting symptoms	Group A	Group B
Spider veins	90%	82%
Varicose veins	78%	73%
Leg pain	70%	66%
Leg edema	55%	72%
Venous stasis: dermatitis	45%	32%
Venous stasis: ulceration	8%	6%

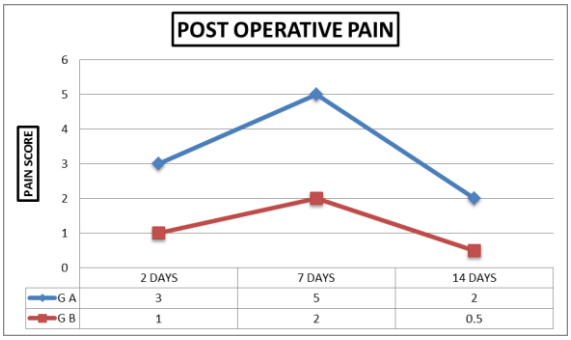
The CEAP classifications of the patients were recorded (**table III**).

Table III:- CEAP classification

CEAP	Characteristics	Group A	Group B
Clinical classification			
Class 0	Lacks visual or palpable signs of venous disease	0%	0%
Class 1	Telangiectasia, reticular veins, malleolar flare	2%	3%
Class 2	Varicose veins	77%	82%
Class 3	Edema without skin changes	13%	6%
Class 4	Venous disease and skin changes	4%	3%
Class 5	Venous disease with healed ulceration	2%	3%
Class 6	Skin changes with active ulceration	2%	3%

Approximately 80% of subjects fell into CEAP classification C2 (i.e., varicose veins); however, classes C3–C6 were also represented in the study. Approximately 80% of subjects were treated for symptom relief.

Postoperative pain, in the Closure FAST group reported significantly lower pain levels than the EVL group during visits at 48 hours (1 vs 3), 1 week (2 vs 5), and 2 weeks (0.5 vs 2) as shown in **figure 1**.



Postoperative ecchymosis was is much higher in group A than group B. Nearly more than half of the patients of group A (54%) developed severe type of ecchymosis while only 12% of group B had this severe type of ecchymosis. The development of superficial phlebitis was the only complication in which a statistical difference could be demonstrated at 48 hours as it is higher in group A more than group B.

No major complication was observed. No deep venous thrombosis or pulmonary embolism was noted. No skin burn or permanent nerve injury was noted. The following minor complications were observed as showed in (**Table IV**). Six patients of group A & 3 patients of group B developed in the same day, decrease in motor power with standing and failure of support during standing that returned to normal after 6-8 hours. These patients required one day admission in hospital. At follow-up times up to 18.5 months (mean 12.19 months) for all patients, 0% recanalization was noted in first month. 91% & 93% of both groups A & B improved clinically.

Table IV:- complications related to the technique and femoral nerve block

Complications	GROUP A	GROUP B
DVT & PE	0	0
Skin burn	0	0
Nerve damage	0	0
Groin hematoma post nerve block	0	0
Infection	0	0
Thrombophlebitis	19.2% (29/151)	2.9% (5/167)
Skin ecchymosis	53.6% (81/151)	11.9% (20/167)
Extension of hospitalization to one day	3.9% (6/151)	1.7% (3/167)

DISCUSSION

According to many studies, the RFA procedure is better tolerated by patients because controlled heating avoids the vein perforations often seen with EVLA; this is the case even with high dosing of thermal energy. The linear endo-venous energy density, is frequently used to compare energy dosing in endo-venous procedures [9,10]. As in cases of Radiofrequency ablation, with the first- generation (i.e., bipolar) RF device, the catheter pullback velocity had to be slow enough to allow resistive heating of the vein wall to a target temperature of 85°C. Now with the Closure FAST catheter, the temperature is kept stable at 120°C during a 20-second treatment cycle, [11].

In addition, in our study, RF treatment showed better results than EVL treatment in the post-operative sequelae in first 2 weeks. RF treatment produced significantly less pain & bruising.

At the SFJ, second & third cycles of energy are delivered, averaging a linear endo-venous energy density of 116.2 J/cm ± 11.6 for the first 7 cm of vein juxtaposed to the SFJ to ensure good vein closure at this critical site [12]. Distal to the SFJ, 68.2 J/cm ± 17.5 is delivered to each 7-cm treatment site. This aggressive "three energy cycle" at the zone of the SFJ is supported by a study performed by Almeida and Raines [13] in which most recanalization occurred in the first 12 months and developed in the GSV proximal to the posterior thigh circumflex vein at the SFJ. The posterior thigh circumflex vein, when large, drains cooler blood (37°C) into the treatment segment, and does not allow proper heat-induced closure of the SFJ; therefore, the SFJ requires more energy to close [14].

In our study, no recorded recurrence rates at one month post-operative follow-up in our patients at both groups demonstrate the favorable clinical outcome of the endo-venous laser as well as the radio frequency ablation. Our clinical success rate is higher than or comparable to the rates in previously published studies using lasers and other studies for RFA. This may be explained by our usage of the iced saline during the tumescent anesthesia (instead of the normal one) that causes vein wall contraction over the catheter so increasing the closure effect of the laser and radiofrequency. We also repeated the first ablation cycle for three times instated of one time as in other studies.

Almeida et al[15] published a retrospective comparison of RF and laser vein ablation with 1-year follow-up in which 50 patients were randomized to undergo treatment with bipolar RF or 810-nm pulsed laser vein ablation. Post procedural bruising and pain were greater with laser treatment, and primary GSV occlusion rates were better with RF (80%) than with laser (66%; P <.0500). This matches our study which showed similar results but with equal efficacy in both techniques.

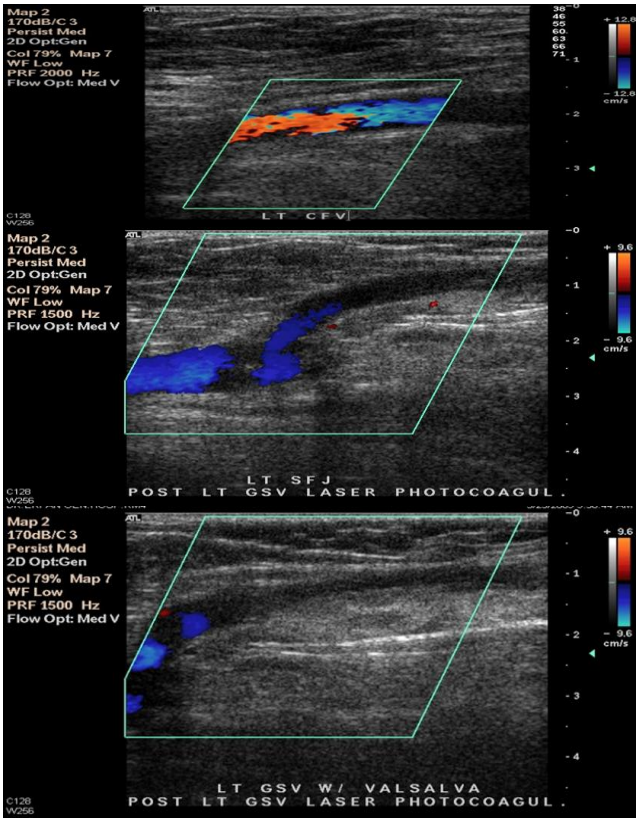
To reduce the post-procedural discomfort associated with EVLA, newer radial fibers, longer wavelengths and jacketed laser fibers have been developed. These newer techniques have been shown to be associated with low post-intervention pain scores and are likely to replace the 980-nm bare-tip laser fiber. Data from randomized trials supporting the use of these newer devices are awaited, [16].

In this study, an important arm should be considered as well, which is the type of anesthesia. Here the regional femoral nerve block was used which proves to be an effective and safe method that allowed the technique to be as a day case & also with limited complications.

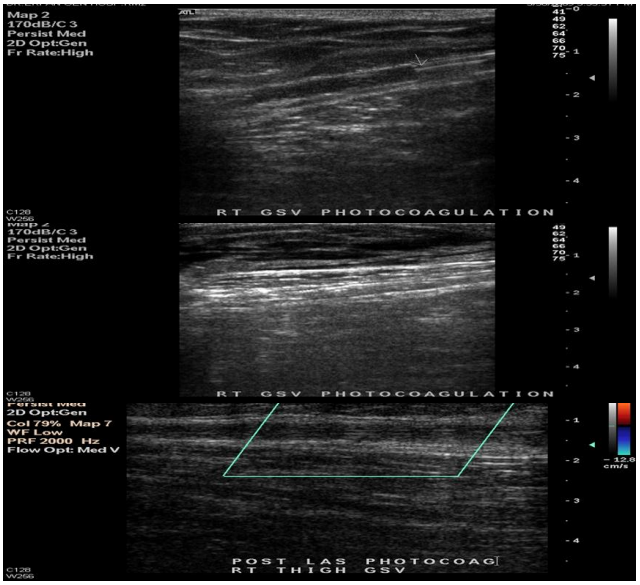
We believe the main limitations of our study were the retrospective analysis and the one month only duplex follow-up. Also the cost– benefit analysis was not performed.

CONCLUSION

RFA using VNUS® Closure FAST™ was associated with less post procedural pain & thrombophlebitis than EVLA. However, clinical and quality-of-life improvements were similar after 2 weeks for the two treatments. The efficacy of both techniques was the same as regard the vein closure without recanalization within one month follow up. The regional nerve block technique for anesthesia is effective & safe method for endo-venous ablation.



A case of EVLA for LT GSV reflux



Case of EVLT for RT GSV Reflux

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