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Bare Tip versus Radial Endovenous Laser Ablation for the Treatment of Primary Varicose Veins

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Abstract

Background: **New modalities in the Endo Venous Laser Ablation (EVLA) include the new design of the laser catheter tip are claimed to distribute more effectively the laser beam to the targeted varicose vein (VV) wall and therefore to achieve better results and produce less complications. These favorable results support the previously suggested better outcome of the EVLA compared to the open procedure.** ***Aim:*** **This study was conducted to confirm this assumption.** ***Patients and Methods:*** **81 patients scheduled for treatment of VV were included and were divided into 3 equal groups. EVLA was used with a bare tip fiber for the first group and compared to a second group treated with a radial fiber. Success rate and post-operative results of both groups were compared to each other, then the mean results of EVLA group as a whole was compared to a third control group treated by surgical stripping.** ***Results:*** **There was no statistical significant difference between both EVLA groups. One patient (3.7%), from the bare tip group, had incomplete ablation that necessitated surgical excision. Fewer complications, shorter hospital stay, early return to work and faster reduction in venous clinical severity score (VCSS) were noted among the EVLA compared to the open group.** ***Conclusion:*** **EVLA using bar tip or radial fibers are effective and safe in treating vv with similar results. Their results are as effective as the open procedure with shorter hospital stay, fewer complications and early return to work.**

Keywords: Endovenous laser ablation, bare tip, radial, Varicose Veins

Introduction

Varicose veins proved to affect the quality of life of a group of relatively young patients[1]. Symptoms include pain, edema, eczema, dermatolipo-sclerosis, and ulceration prevent the usual daily activity and ability to work[2]. The majority of varicose veins (60-80%) are caused by incompetent sapheno-femoral junction (SFJ) or sapheno-popliteal junction (SPJ) with resultant long saphenous vein (LSV) or short saphenous vein (SSV) reflux. For a long period of time, successful treatment was achieved by ligation of the SFJ/SPJ and vein stripping[2,3], under general or spinal anesthesia. This surgery carries considerable peri-operative morbidity, hospitalize

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tion costs and delayed return to normal activities and work[2-4]. In recent years, Ultrasound (US) guided procedures including Endovenous Laser Ablation (EVLA), radio frequency ablation and foam sclera therapy are suggested to have good clinical results and better patient satisfaction[5]. However, other published studies observed no difference between EVLA and open procedure on long term follow up, and doubts regarding the superiority of the open procedure still exist[6,7]. EVLA using Hemoglobin-specific laser wavelengths (HSLW) of 810, 980 and 980 nm, forms steam bubbles within the vein lumen, which destroys the endothelial lining of the vessel[8,9]. Previous studies documented few complications that may result from heat generation, such as: transient bruising and induration along the treated saphenous vein, saphenous nerve paraesthesia, thrombophlebitis, endovenous heat induced thrombus (EHIT) and deep vein thrombosis[5,8,9]. Recent advances were directed to achieve a more specific vein wall ablation and less complication. This was attained by the introduction of water-specific wavelengths (>1000nm) that carries laser beam effect to the water inside the vein wall[10]; therefore produce more ablation effect and less complication[8]. On the other hand, laser fiber tip was changed from bare tip, which claim to have high incidence of perforation and produces a non-uniform vein cauterization[11], to the radial fiber and the Jcket-tip laser fiber[12]. The present study aimed to compare two types of laser fiber ends; the bare tip and the radial fiber and compare their clinical and duplex results to a control group of patients whom open surgery was used to treat primary vv.

Patients and Methods

This is a prospective comparative clinical trial, performed at Suez Canal University Hospital, Ismailia-Egypt, in the period between October 2014 and February 2016. After approval of the study by the local ethical committee, all patients indicated for varicose vein surgery were included according to the following *inclusion criteria:* 1) Age: adult patients >18 years. 2) Both sexes. 3) Incompetent SFJ >2 seconds. 4) Unilateral or bilateral. While patients with the following *exclusion criteria* were excluded from the study: 1) SPJ and /or SSV incompetence that necessitate treatment in the same setting. 2) Recurrent Varicose veins. 3) Associated deep veins incompetence. 4) Pregnancy. 5) Arterial insufficiency: Ankle Brachial Pressure Index <0.8. Patients were randomly divided into 2 groups. The first group treated with bare tipped laser fiber, the second group treated with a radial laser fiber, with attention to randomized patients for bilateral procedures equally. A third group of patients treated by open surgery were considered as a control group. All procedures were performed by the same surgical team.

The procedures: In both EVLA groups, the target vein was marked preoperatively by duplex. With the patient in reversed Trendelenburg position, a 6F sheath was inserted in the LSV just below the knee, guided by US under local anesthesia, and the laser catheter was advanced up to be positioned 1.5-2 cm distal to the SFJ. After injection of the tumescent fluid around the vein, the amount of energy to be delivered was adjusted aiming a linear endovenous energy density (LEED) of 70 -100 Joules/cm length of the vein. This was achieved by setting the machine at 10 W

while withdrawing the catheter at rate of 1 cm/5-7 seconds. We used VenaCure® 1470 laser (angiodynamics) for the bare tip fiber procedures and the ELVeS (Biolitec AG, Germany) for the radial fiber procedures. Both have laser wave length of 1470 nm. The patient position changed to the Trendelenburg and ablation started in a continuous mode with manual compression. Any marked communicators were avulsed under local anesthesia, then access site was covered with sterile dressing and the limb with compression bandage for 48 hours and the patient was ambulated immediately and discharged in the same day. For the open group; SFJ disconnection + stripping +/- multiple stab avulsions were performed under spinal anesthesia according to the standard technique[13]. All patients received prophylactic antibiotics, instructed to use Diclofenac sodium tablet 50 mg /8 hours for 3 days and to wear graduated elastic stocking for one month. *Follow up:* patients were reviewed after 3 days, 1 week, 1, 3 and 6 months. Duplex ultrasound was used to measure the vein diameter at the mid-thigh segment for the EVLA groups and to search for new-vascularization in the groin for all groups. The following were considered complications: 1) Pain: if the patient required oral or injectable pain killer in addition to the prescribed Diclofenac sodium. 2) Bruising. 3) Hematoma. 4) Infection: at punctures site/ thrombophlebitis /surgical wound. 5) Skin burn. 6) Calf DVT. 7) Endovenous heat induced thrombus. 8) Incomplete ablation: Patent compressible vein segment ≥ 5cm. During the 1, 3 and 6 months follow up visits; Venous clinical severity score (VCSS) [14] was used to assess improvement in symptoms by comparing it to the preoperative results. Data were compared using the Fisher exact probability test and the student t test. Data were considered statistically significant when P value ≤ 0.05.

Results

This study recruited 81 patients. In general, male sex was more prevalent (56.8%), mean age was 40.8 years and mean body mass index (BMI) was 26.2. Patients were distributed equally to the three studied groups and the mentioned characteristics were matched. Male sex was 55.6%, 66.7% and 48.1%, mean age was 42.19, 39.8 and 41.16, and mean BMI was 26.11, 26.31 and 26.19 in the bar tip, radial and the open groups respectively. The two groups, bare tip and radial, were comparable regarding the mean age; 42.2 and 40.9 years, the predominance of the male sex; 55.6% and 66.7% and the mean Body Mass Index (BMI); 26.1 and 26.3 respectively. Most of the patients (77.8% and 70.4% for the bare tip and the radial group respectively) presented with stage C3 according to the clinical etiological anatomical pathological (CEAP) classification, table (1). We ablated the LSV bilaterally during the same session with bare tip in 7 patients and with radial tip in 6 patients. There was no difference between the two groups regarding the mean vein length (41 and 39 cm), the mean operative time (34 and 33 minutes) and the mean LEED was (79 and 78 J/cm) for the bare tip and radial group respectively, table (1). The operative outcome was similar with no statistical significant difference between the two EVLA groups. Hospital stay and return to normal activity were nearly the same in both groups, 8 hours and 3 days respectively. No major complications recorded, minor bruising and increase need for pain killer were more prevalent among the bare tip group, but not statistically significant. Duplex follow up of the ablated vein, figure (1&2), showed reduction in the diameter from 8 and 8.5 mm before the procedure to 4.3 and 4.6 mm after one month, 2.4

Table 1: Description of the EVLA groups and their operative details

	Bar tip (n=27) No. (%)	Radial (n=27) No. (%)	P value
Male	15 (55.6%)	18 (66.7%)	0.577
Age (Years)	42.19 ± 1.3	40.9 ± 1.3	0.403
BMI	26.11 ± 2.3	26.31 ± 1.9	0.487
CEAP (C)			
– 2	0 (0%)	0 (0%)	1.000
– 3	21 (77.8%)	19 (70.4%)	0.757
– 4	4 (14.8%)	5 (18.5%)	1.000
– 5	1 (3.7%)	3 (11.1%)	0.610
– 6	1 (3.7%)	0 (0%)	1.000
Treated LSV			
– Unilateral	20 (74.1%)	21 (77.8%)	1.000
– Bilateral	7 (25.9%)	6 (22.2%)	1.000
Vein length (cm)	41.2 ± 1.2	39.6 ± 0.7	0.070
Mean operative time (min)	34.1 ± 1.7	33.3 ± 1.6	0.073
LEED (J/cm)	79.0 ± 0.7	78.3 ± 0.8	0.116

Data are presented as mean±SD. BMI: Body mass index. CEAP: clinical etiological anatomical pathological classification. LEED: Linear endovenous energy density

and 2.5 mm after 3 months and 1.3 and 1.2 mm after 6 months for the bare tip and the radial groups respectively, (table 2). Incomplete vein ablation was detected at the one month duplex follow up, in one patient (3.7%) in the radial group. This was managed by open surgery, during which the stripper did not pass through the vein and we had to remove it in segments. This incident was not reflected statistically on the comparison between the two groups, but allowed us to examine part of this partially ablated vein under the microscope, which showed burn effect of the laser in the vein wall, figure (3). Patients treated by EVLA were compared as one group to a control group of open procedure. Patient characteristics; gender, mean age, BMI, CEAP stage and vein length were similarly distributed in both groups with no statistical difference, table (3). EVLA was used in 13 patients to treat the LSV bilaterally in the same session; this advantage was not possible using the open procedure, and therefore, was statistically significant. The operative time was statistically significantly shorter in the EVLA group compared to the open; 33.7 and 45.9 minutes respectively, (table 3). Operative outcome compared in both groups showed that hospital stay was shorter among the EVLA in comparison to the open group: 8 and 29 hours respectively and return to work was faster: 3 and 12.3 days respectively. No major complications were noted in both groups, however, frequencies of pain, bruising and numbness were statistically significantly less among the EVLA compared to the open group: 9% and 30%, 5.6% and 33.3%, 0% and 11% respectively, (table 4). Regarding the VCSS, the mean score was improved irrespective to the type of the procedure. It decreased from 11.80 and 11.93 to 3.26 and 6.33 after one month, to 2.43 and 3.19 after 3 months reaching 1.46 and 2.3 at 6 months for the EVLA and the open group respectively. This faster improvement among the EVLA group was statistically significant compared to the open group, (table 4).

Table 2: Outcome of the EVLA procedures

	Bare tip	Radial	P value
Hospital stay (hours)	7.8±0.8	8.1±0.7	0.110
Return to normal activity (days)	2.9±0.5	3.1±0.6	0.093
Complication, number (%)			
– Pain	4 (14.8)	1(3.7)	0.351
– Bruising	2 (7.4)	1(3.7)	1.000
– Hematoma	0 (0)	0 (0)	1.000
– Numbness	0 (0)	0 (0)	1.000
– Skin burn	0 (0)	0 (0)	1.000
– Calf DVT	0 (0)	0 (0)	1.000
– Infection	0 (0)	0 (0)	1.000
– EHIT	0 (0)	0 (0)	1.000
– Incomplete ablation	0 (0)	1 (3.7)	1.000
Mean VCSS			
– Pre-op	11.63± 0.84	12.0±0.94	0.175
– 1 month	3.30± 1.47	3.22±0.70	0.714
– 3 months	2.37±0.79	2.48±0.75	0.599
– 6 months	1.52±0.51	1.41±0.51	0.423
Vein diameter (mm)			
– Preoperative	8.0±0.9	8.5±0.7	0.182
– 1 month	4.3±0.5	4.6±0.5	0.104
– 3 months	1.4±0.2	1.3±0.4	0.111
– 6 months	1.3±0.1	1.2±0.2	0.111

Data are presented as mean±SD. EHIT: Endovenous heat induced thrombosis.
VCSS: Vascular clinical severity score.

Discussion

The present study aimed at comparing results of two types of catheter tip while fixing the other energy production parameters during EVLA of primary vv. The EVLA results up to 6 months were compared to the open procedure. The advantage of this design should improve the basis on which type of treatment would be suggested to the patient. The mean age was 41 years, other studies reported higher mean age (50–52 years)[15,16]. This observation is most probably due to prolonged exposure of our population to risk factors as standing or setting and lack of physical exercises. The mean BMI in this study was 26.11 which is similar to previous studies[17,18]. These characteristics were equally distributed among the three studied groups. Most of the treated patients were in class 3 based on the CEAP classification. This is the same finding in researches conducted in a similar communities[16,19], but more early presentation was noted in developed countries[10,20]. Also, socioeconomic level for those patients was not addressed; this observation may reflect the better orientation and more developed medical system that can bring patients earlier to the medical attention in the western countries. Using the EVLA enables us to treat the LSV bilaterally in the same cession in 16.7% of EVLA group, which is a strong advantage not available in the open procedure. Vein length was similar to previous studies[10,19,20], with no difference between groups in our study. Previously, HSWL was used and resulted in suboptimal vein obliteration rate of 92-94%[12,16,21].

Table3: Characteristics of the EVLA compared to the open group

	EVLA (N = 54)	Open (N = 27)	P Value
Male: No. (%)	33 (61.1%)	13 (48.1%)	0.343
Age (yrs)	41.0 ± 1.3	41.16	0.402
BMI	26.21 ± 13	26.19±1.7	0.684
CEAP (C) No. (%)			
– 2	0 (0)	0 (0%)	1.000
– 3	40 (74.1)	18 (66.7%)	0.602
– 4	9 (16.7)	5 (18.5%)	1.000
– 5	4 (7.4)	2 (7%)	1.000
– 6	1 (1.9)	2 (7%)	0.256
Bilaterally Treated LSV No. (%)	13 (24.1)	0 (0%)	0.004*
Vein length (cm)	40.39 ± 1.0	39.67 ± 1.3	0.230
Operative time (min)	33.7 ± 1.7	45.9 ± 201	0.001*

Data are presented as mean±SD BMI: Body mass index. SD: standard deviation. CEAP: clinical etiological anatomical pathological classification. * Statistically significant difference.

Table 4: Procedure outcome of the EVLA compared to the open group

	EVLA (N = 54)	Open (n = 27)	P value
Hospital stay (hours)	8.0 ± 0.8	29.0 ± 0.7	0.001*
Return to normal activity (days)	3.0 ± 0.6	12.3 ± 0.5	0.001*
Complication No. (%)			
– Pain	5 (9.3)	8 (30)	0.026*
– Bruising	3 (5.6)	9 (33.3)	0.002*
– Hematoma	0 (0)	2 (7.4)	0.108
– Numbness	0 (0)	3 (11.1)	0.034*
– Skin burn		NA	
– Calf DVT	0 (0)	0 (0)	1.000
– Infection	0 (0)	0 (0)	1.000
– Incomplete ablation	1 (1.9)	0 (0)	1.000
VCSS			
– Pre-op	11.80 ± 0.90	11.93 ± 0.73	0.518
– 1 month	3.26 ± 0.73	6.33 ± 0.83	0.001*
– 3 months	2.43 ± 0.77	3.19 ± 0.88	0.001*
– 6 months	1.46 ± 0.50	2.30 ± 0.47	0.001*

Data are presented as mean±SD. EHIT: Endovenous heat induced thrombosis. VCSS: Vascular clinical severity score. * Statistically significant difference.

In the present study we used a WSLW of 1470 nm, which is suggested to be more effective with fewer complications[22-24]. Indeed, successful vein obliteration is related to the LEED, as well as, to the wave length[25]. LEED levels as low as 35-58 J/cm were used previously with lower success rate[20,25-27], and levels >60 J/cm are advised to achieve ablation[20] where levels <100 J/cm are advised to prevent complications[28]. The mean LEED used in this study was 79 and 78.3 J/cm for the bare tip and radial respectively. This <85 J/cm level was suggested to be effective when used with WSLW, theoretically producing a maximum effect at the vein

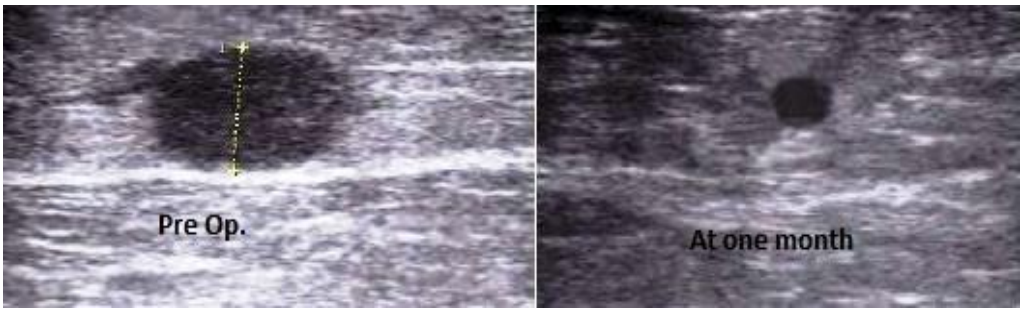

Figure 1: Long Saphenous Vein, Pre-operative and at 1 month follow up visit

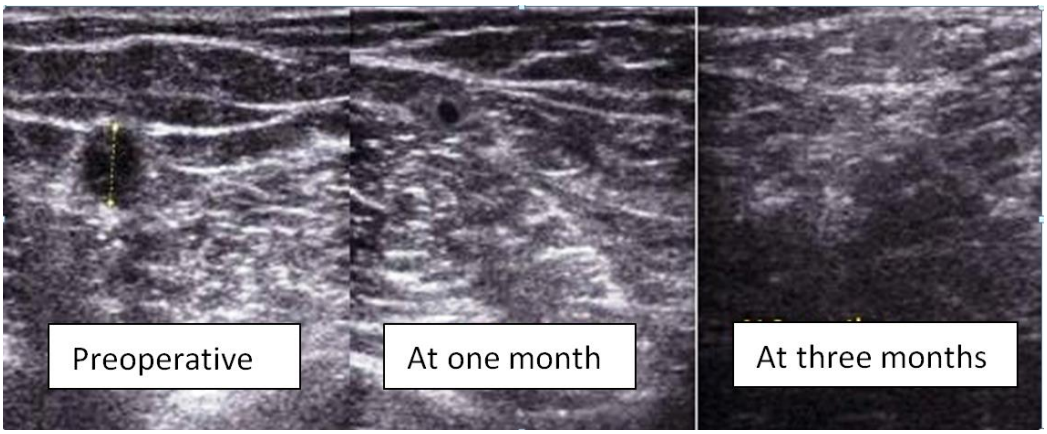

Figure 2: Long Saphenous Vein, Pre-operative, at 1and 3 months follow up visits

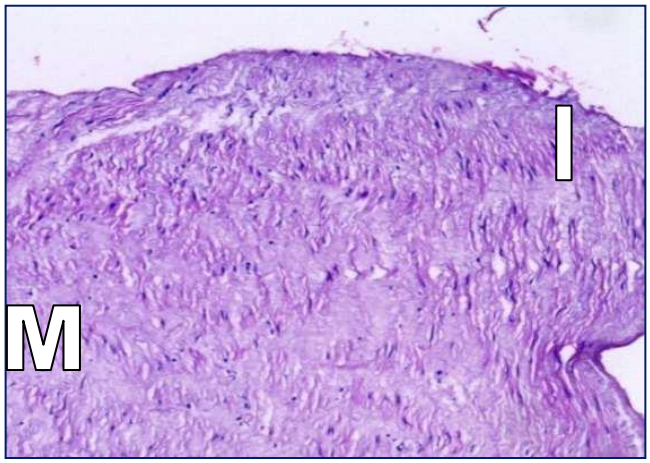

Figure 3: Microscopic study of vein segment removed surgically after recanalization, showing coagulation of media (M), Necrosis and loss of tissue in the intima (I).

wall, while reducing the chance of surrounding tissue injury[29]. When the bare tip and the radial groups were compared, no statistical difference was found regarding the studied parameters. In contrary to the suggestion by Doganci and his college, who suggested better effect and less complications of the radial fiber[1], but he selected a lower wave form for the bare tip group that may affect this group results and his conclusion. It was thought that using the radial laser beam may produce uniform vein wall effect; however, this was proved by Yamamoto and his col-

leagues not to affect the shrinkage ratio or the resulted microscopical changes[30], which agrees with our results. Among the bare tip treated group, one patient had incomplete vein ablation. This was not statistically significant finding compared to the radial group. The pre-operative vein diameter of this patient was 9.2 mm, which may explain the incomplete ablation, as vein trunk diameter >8 mm was suggested to be a cause of failure[31]. Microscopic study of this partially ablated vein showed damaging effect of the laser. This damaging effect is a progressive process, as onset of complete vein closure has been reported to delay up to 12 months after the EVLA[19], during which duplex evidence of patency was present without clinical effect. Therefore, open surgery for this single patient in our study could be avoided if we increased the LEED, on the basis of the increased diameter, or following the asymptomatic patient up to 12 months waiting for delayed closure. Mean operative time was statistically significantly shorter when EVLA was used compared to the open procedure. As expected there was no difference noted in the operative time between the used two EVLA catheter tips, and was similar to previous studies[10]. Parameters reflecting better early results when using the EVLA were noted, as statistically significant shorter hospital stay, fewer post-operative pain and bruising, early return to work and faster reduction in the VCSS, when compared to the open procedure. There were no cases of neovascularization in the groin detected during the follow up ultrasound visits. This may be due to the short period follow up, as previous studies found neovascularization at the SFJ in 1% of EVLA compared to 18% in a matched control group undergoing conventional surgery when patients followed up to 18 months[7].

Conclusion

When the energy production parameters were fixed, no difference was found when the bare tip or radial fibers were used regarding the rate of ablation and complications. EVLA is as effective as open surgery in treating primary varicose vein up to 6 months and superior to it in terms of shorter hospital stay, fewer minor complications and faster recovery.

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