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Full Length Research Paper

Comparative Study between Endovenous Laser Ablation and Foam Sclerotherapy in Treatment of Lower Limb Primary Varicose Veins

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Abstract
Varicose veins represented a challenging surgical problem. The ideal surgical intervention for eradication of varicose veins is not yet established. The search continues to compare between endovenous laser ablation (EVLA) and ultrasonic guided foam sclerotherapy (USGFS) in treatment of primary varicose veins. The present study included 70 patients who were presented by uni- or bi-lateral varicose veins and scheduled for operative treatment. Patients were randomly assigned to either endovenous laser ablation (35 patients) or ultrasound guided foam sclerotherapy (35 patients). Patients were assessed at the end of postoperative, one week, one month and three months by clinical examination and Doppler ultrasound. Side effects and complications of the treatment were also documented. Both groups were comparable as regard to patient age, sex; the majority of cases were presented by unilateral varicose veins (94.3% vs 91.4% of EVLA and USGFS groups respectively). There was statistically significant decrease of operative time in USGFS group when compared to EVLA group (22.52±1.98 vs 26.45±3.20 minutes respectively). VCSS score was significantly lower in EVLA when compared to USGFS at 3 months postoperative (1.89±0.87 vs 2.49±0.96 respectively). VDS was significantly reduced in EVLA when compared to USGFS groups at 1 and 3 months postoperatively (0.78±0.51, 0.69±0.46 vs 0.98±0.28, and 0.93±0.24 respectively). Finally, both groups were comparable as regard to ecchymosis, tenderness or local thrombophlebitis. All were transient and managed conservatively (no need for further intervention). Laser ablation found to be superior to foam sclerotherapy guided by ultrasound for treatment of primary varicose veins.

Keywords: *varicose veins, endovenous laser ablation, foam sclerotherapy, lower limb.*

Introduction

Varicose veins affect up to 40% of industrialized countries' citizens in the age between 30 and 70 (Bradbury et al., 1999). Etiology involves weakness of the vein wall and venous dilatation (Pfisterer et al., 2014). Patients with varicose veins complain from multiple complications such as skin discoloration, ulceration, thrombotic disorders, and hemorrhage (Gloviczki et al., 2011). There are two ways for varicose vein management: lifestyle modifications and medical procedures. Lifestyle-related treatment includes avoidance of a prolonged standing and sitting, an increase of physical exercise, and losing weight by obese people (Jones and Carek, 2008). Medical treatments include the use of venoactive drugs, compression treatment, sclerotherapy, phlebectomy, open venous surgery with ligation and stripping, and endovenous ablation techniques (Gloviczki et al., 2011). The treatment of varicose veins has directed away from old invasive surgery to minimally invasive methods and in particular endovenous thermal and chemical ablation.

The foam sclerosants were firstly introduced in 1999, and since that time, the ultrasound guided sclerotherapy (UGS) has obtained wide acceptance in the treatment of venous diseases. In United Kingdom, at 2013, it was considered as an effective treatment for varicose veins as traditional as endothermal ablation methods (National Institute for Health and Care Excellence, 2013). The advantages of foam sclerosants over liquid agents included: 1) increased echogenicity which permits readily tracing by ultrasound and allows precise injections into selected veins. In addition, any fault entry into deep veins or arteries is easily diagnosed (Wollmann, 2010); 2) high potency of foam sclerosants is up to three to four times more than the same amount of liquid substances, and thus, can be used to ablate larger veins (Duffy, 2010).

The physicochemical properties responsible for high potency include increased viscosity, immiscibility and cohesiveness. These properties enable the foam to escape both excessive mixing with intravascular blood and removal from target vessels (Wong et al., 2014). However, the main disadvantages of foam sclerotherapy include high rate of recurrence and adverse effects like air embolism, and deep venous thrombosis (Jia et al., 2007). Endovascular ablation techniques, like laser and radiofrequency ablation, are widely used and prove as effective treatments modalities. The results are nearly similar, and both achieve nearly 90% long-term success rates (Rasmussen et al., 2011). However, the need for tumescent anesthesia and the occurrence of adverse events such as burns, pigmentation and paresthesia are unavoidable downsides (Almeida et al., 2014). The present study was designed as a comparative study between endovenous laser ablation and foam sclerotherapy in treatment of varicose veins, in a trial to establish the ideal therapy in our hospital.

Patients and methods

The present study included 70 patients who were presented by uni - or bi-lateral varicose veins and scheduled for operative treatment. They were selected from Al-Azhar university hospital new Damietta during the period from June 2013 to july 2015. All patients had significant reflux in a segment of great saphenous vein (GSV) and/or saphenofemoral junction (SFG) on duplex ultrasound. Patients were randomly assigned to either endovenous laser ablation (EVLA; 35 patient) or ultrasound guided foam sclerotherapy (USGFS; 35 patient). Randomization was done by generation of randomized numbers and each was inserted in an envelope and closed till the time of operation (then opened by a surgical nurse before operative intervention). *In assessment and statistical analysis, in patients with bilateral varicose veins, each limb will be treated as a separate patient.*

The **exclusion criteria** included history of previous arterial insufficiency, previous deep vein thrombosis, marked GSV tortuosity, pulmonary embolism, coagulopathy, immobility, malignancy, ankle brachial pressure index (ABPI) < 0.9, locoregional infection and pregnancy.

Preoperative ultrasound assessment

Duplex ultrasound of superficial, deep, perforating, and communicating veins of the lower extremities was performed before treatment for all patients. The insufficiency of the saphenofemoral junction (SFJ) and saphenopopliteal junction (SPJ), diameter of GSV at the terminal portion (5 cm from the SFJ), the presence of pathological reflux, its duration and the prevalence in the GSV, its tributaries, and deep veins were assessed. All veins were assessed for patency and compressibility. Reflux was defined as reserved flow for >0.5 seconds.

Endovenous laser ablation

It was done as described by Koroglu et al. (2011). Briefly, the patient's hip on the same side of the operated limb was rotated externally. Then, the lower extremity was prepared by betadine antiseptic solution and draped. US-guided EVLA of veins was performed. Ultrasound was used to guide the puncture of the vein, for the placement of the ablation catheter, and to confirm the position of the tip of the laser probe. After the entry of puncture set, a 0.035-inch, 260cm J guide wire was advanced into the vein. A laser sheath was placed over the 0.035-inch guide wire. A laser kit containing a 5-French, 70-cm sheath having calibrated markings useful during the laser pullback, and laser fiber was used. A 980 nm diode laser system was used fig.(1). The laser fiber was advanced through the laser sheath. The laser fiber tip was projected approximately 1 cm beyond the tip of the sheath. The tip adjusted 2-3 cm from SFJ using US. Subcutaneous injection of tumescent anesthesia was done to increase the distance between GSV and skin (fig. 2). The laser fiber was then linked to the laser source. Laser protective wear for eyes was dressed by all staff in the room as well as the patient. Power was set at 10 to 15 Watts. The energy was administrated endovenously in a pulsed fashion. The fiber pullback rate was 10 mm in every 6–8 seconds. The energy density (in J/cm) was approximately 100 J/cm to the treated vein.

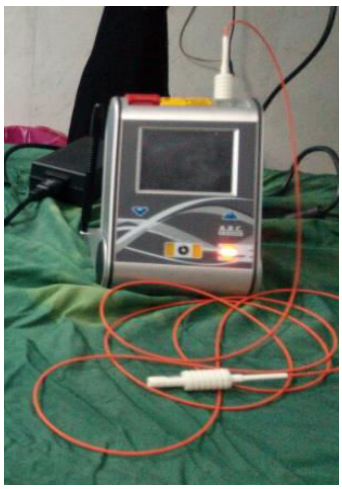

Fig (1): A 980 nm diode laser system

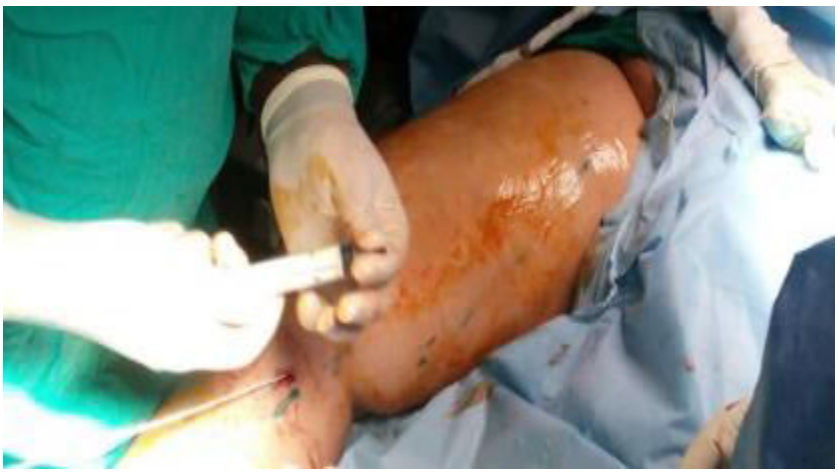

Fig (2): Subcutaneous injection of tumescent anesthesia

Ultrasound guided foam sclerotherapy: The GSV was cannulated with a 6-Fr sheath in front of medial malleolus fig. (3) Either directly or under ultrasound guidance. pern catheter is introduced through the sheath over 0.035 wire up to 3 cm below the SFJ, guided by ultrasound (fig. 4) while the patient was in horizontal position. After cannulation, the patient was put in reverse Trendelenburg position with the limb raised. A pressure was applied at the SFJ either by thumb or using ultrasound probe, foam was injected slowly, and simultaneously, a catheter was steadily pulled out. An average volume of foam solution used was 8–10 ml. A maximum of 10 ml of solution was used at a time. External compression was applied over the treated segment manually. After injection, cotton wool was wrapped over thigh and compression bandage was applied. Compression therapy was recommended for a period of 1 week.

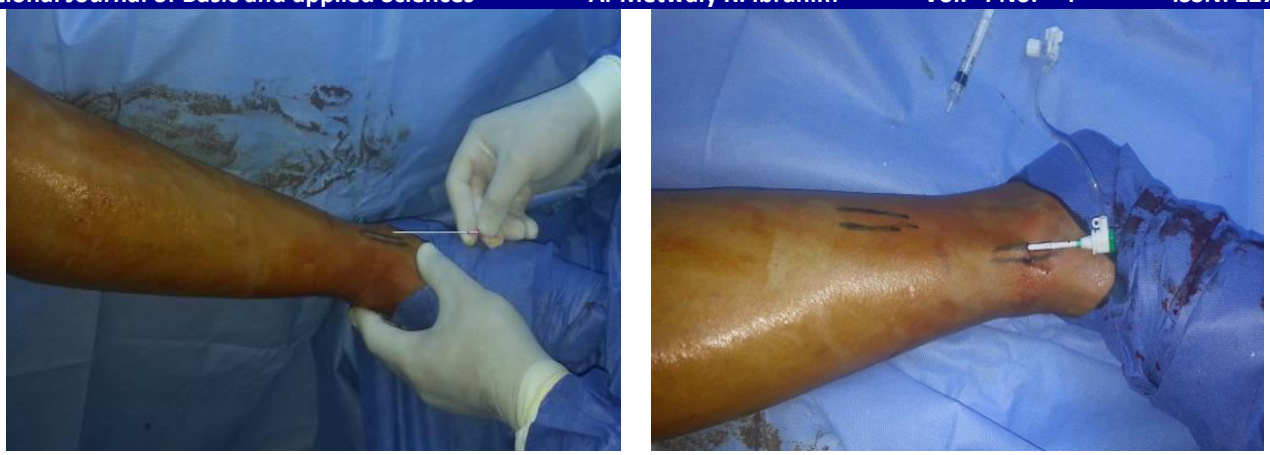

Fig (3): The GSV cannulated with a 6-Fr sheath

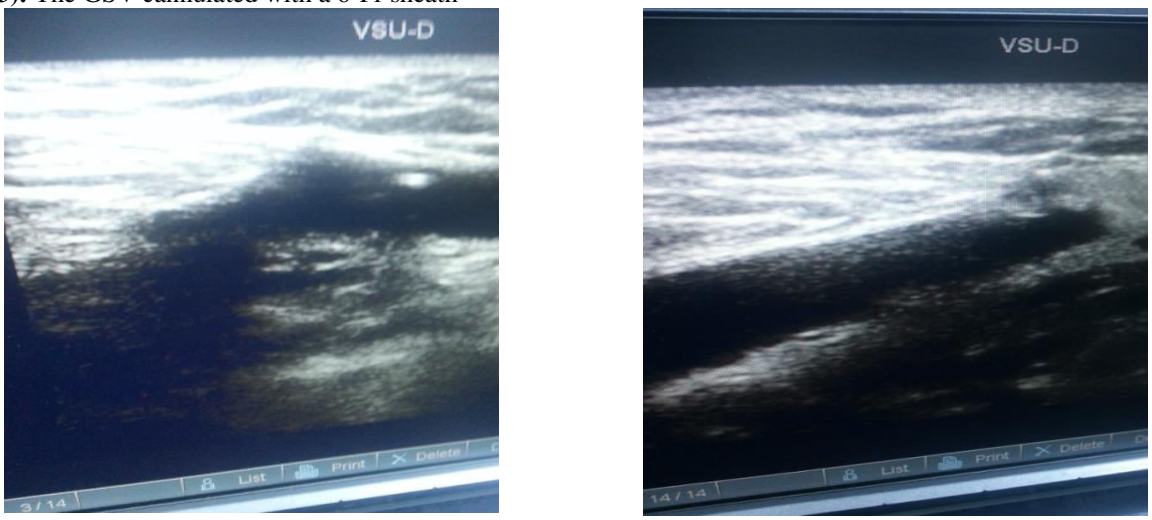

Fig (4): Ultrasound showing Tip of cath. at SFJ, and pulsed injected saline

Postoperative assessment

Patients were assessed at the end of postoperative, one week, one month and three months by clinical examination and Doppler ultrasound. Clinical assessment was based on the Venous Clinical Severity Score (VCSS) and Venous Disability Score (VDS), taking into consideration the presence of pain, residual varicosity, edema, inflammation, pigmentation, induration, need of compression therapy, and ability to carry out usual activities. Side effects and complications of the treatment were also documented. Duplex ultrasound of the treated GSV trunk was used for sonographical assessment. End points were vein occlusion (no blood flow in the treated segment of the great saphenous vein) and absence of reflux. Flow in the GSV stump up to 3 cm below the SFJ was considered normal.

Statistical analysis of data: Categorical variables were presented as numbers & percentages, and continuous data was presented as mean ± standard deviation as appropriate. The comparison between qualitative data was determined by applying chi-square or Fischer's exact test. The continuous data was compared by Student's t test/Mann-Whitney U test wherever required. P value less than 0.05 was considered significant.

Results

The patient characteristics were presented in table (1). The patient age ranged from 20 to 63 years and there was no significant difference between EVLA and USGFS groups (43.60±10.15 vs 42.37±8.41 respectively). Males represented 45.7% of EVLA group, compared to 45.7% in USGFS group, with no significant difference. The majority of cases were presented by unilateral varicose veins (94.3% vs 91.4% of EVLA and USGFS groups respectively). Finally, the varicose were on right side in 54.1% in EVLA group and 55.3% in USGFS groups.

The mean GSV diameter was 8.04±1.14 and 7.71±0.92 mm in EVLA and USGFS groups respectively, and both groups were comparable. In addition, both groups were comparable as regard to VCSS before treatment, at 1 week and 1 month postoperatively; and VDS before treatment and 1 week postoperatively. However, there was statistically significant decrease of operative time in USGFS group when compared to EVLA group (22.52±1.98 vs 26.45±3.20 minutes respectively). On the other hand, VCSS score was

significantly lower in EVLA when compared to USGFS at 3 months postoperative (1.89±0.87 vs 2.49±0.96 respectively). In addition, VDS was significantly reduced in EVLA when compared to USGFS groups at 1 and 3 months postoperatively (0.78±0.51, 0.69±0.46 vs 0.98±0.28, and 0.93±0.24 respectively). Furthermore, in both groups, VCSS and VDS was significantly reduced at the end of follow up period when compared to previous values (i.e., both scores in each group progressively reduced after treatment with advancement of time) (Table 2).

Regarding side effects (complications), both groups were comparable as regard to ecchymosis, tenderness or local thrombophlebitis. All were transient and managed conservatively (no need for further intervention) (Table 3).

Table (1): Comparison between both groups as regard to patient characteristics

		EVLA (n=35 pts; 37 limb)	USGFS (n=35pts; 38 limb)	Test	p
Age (mean±SD); Range		43.60±10.15; 20-63	42.37±8.41; 22 – 57	0.55	0.58(ns)
Sex (n,%)	Male	19(54.3%)	16(45.7%)	0.51	0.47(ns)
	Female	16(45.7%)	19(54.3%)		
Laterality	Unilateral	33(94.3%)	32(91.4%)	0.21	0.64
	Bilateral	2(5.7%)	3(8.6%)		
Side	Right	20(54.1%)	21(55.3%)	0.01	0.91
	Left	17(45.9%)	17(44.7%)		

Table (2): Comparison between both groups as regard to outcome

		EVLA (n=35 pts; 37 limb)	USGFS (n=35pts; 38 limb)	Test	p
GSV diameter (mm)		8.04±1.14	7.71±0.92	1.80	0.07(ns)
Operative time (min)		26.45±3.20	22.52±1.98	***8.32***	***<0.001****
VCSS	End of post-operative	8.24±0.96	8.01±1.21	1.17	0.24(ns)
	1 week postop.	4.51±1.02	4.73±0.70	1.38	0.16(ns)
	1 month postop.	2.83±0.93	3.03±0.73	1.33	0.19(ns)
	3 months postop.	1.89±0.87	2.49±0.96	***3.68***	***<0.001****
VDS	End of post-operative	2.77±0.42	2.73±0.44	0.55	0.59(ns)
	1 week postop.	1.95±20	1.90±0.34	0.99	0.32(ns)
	1 month postop.	0.78±0.51	0.98±0.28	***2.67***	***0.008****
	3 months postop.	0.69±0.46	0.93±0.24	***3.64***	***<0.001****

Table (3): Comparison between both groups as regard to complications

	EVLA (n=37 limb)	USGFS (n=38 limb)	Test	p
Ecchymosis 1 week postop.	6(16.2%)	9(23.7%)	0.65	0.41(ns)
Ecchymosis 1 month postop.	0(0.0%)	0(0.0%)	-	-
Ecchymosis 3 months postop.	0(0.0%)	0(0.0%)	-	-
Tenderness (pain) 1 week postop.	16(43.2%)	15(39.5%)	0.11	0.74(ns)
Tenderness (pain) 1 month postop.	2(5.4%)	1(2.6%)	0.37	0.54(ns)
Tenderness (pain) 3 months postop.	1(2.7%)	3(7.9%)	1.00	0.31(ns)
Local thrombophlebitis 1 week postop.	1(2.7%)	2(5.3%)	0.32	0.57(ns)
Local thrombophlebitis 1 month postop.	0(0.0%)	0(0.0%)	-	-
Local thrombophlebitis) 3 months postop.	0(0.0%)	0(0.0%)	-	-
Recanalization at 3 months postop.	2(5.4%)	6(15.8%)	2.12	0.14

Discussion

Varicose veins represent a major health problem as it affects 30 to 40% of adult populations, and during sometime of their life, up to 6% of patients with varicose veins will develop ulcers (Nelzen, 2008). Varicose veins can cause pain, function impairment and decreasing quality of life (Vlajinac et al., 2013). Clinical treatment of varicose veins usually started by rest and compressive socks. However, compressive therapy does not eradicate varicose veins and does not affect anatomic basis of venous hypertension (Samuel et al., 2013). Surgical stripping usually used for eradication of varicose veins. However, patients with surgical treatment had more pain and postoperative discomfort, delaying resuming the usual activities and return to work (Nesbitt et al., 2011). Less invasive methods

of therapy were developed to avoid post-surgical complications (e.g., DVT, recurrence, saphenous nerve lesions and hematoma). These methods included ultra-sound guided foam sclerotherapy and thermal ablation using radiofrequency or laser. These methods seem to be effective as surgical stripping or even more effective with less frequent complications (National Clinical Guideline Centre (UK), 2013). However, these minimally invasive methods were not compared as regard to their effectiveness and safety.

The present study was designed to compare between foam sclerotherapy and laser ablation for treatment of varicose veins. Results of the present work revealed that, foam sclerotherapy had significant shorter duration of operative time. However, laser ablation was significantly associated with better outcome especially at the end of third month of follow up and lower rate of recanalization when compared to foam sclerotherapy. Both groups were statistically comparable as regard to side effects (complications). The occlusion rate in foam group was 84.2% compared to 94.6% of laser group. These results reflect the superiority of EVLA when compared to foam sclerotherapy.

Confirming the superiority of EVLA in treatment of varicose veins, Hirokawa et al. (2014) in their study for treatment methods of varicose veins in Japan, reported that, the EVLA treatment for varicose vein is a safe and minimally invasive treatment procedure
For foam group, the occlusion rate in the present work lies within that of previous literature reported that, rate of occlusion of treated veins by foam sclerotherapy varied from 53 to 85% (Rabe et al., 2008; van den Bos et al., 2009; Brittenden et al., 2015). In addition, results of the present work are comparable to previous literature, reported that, frequent side effects following ultrasound guided foam sclerotherapy are phlebitis and cutaneous pigmentation. There are a few reports of severe complications such as DVT, pulmonary thromboembolism, stroke and cerebral embolization in patients with patent foramen oval. Severe complications are rare (<0.1%) (Jia et al., 2007; Guex, 2009). Jia et al. in a systematic review included more than 9000 foam sclerotherapies reported that, the most frequent complications were as the following: 4.7% of phlebitis, 17.8% of cutaneous pigmentation and 25.6% of local pain. He also detected less than 1% of deep venous thrombosis and pulmonary embolism, and 1.4% of visual disturbances.

For EVLA group, the occlusion rate was 94.6%, and this is comparable to those reported by Mozafar et al. (2014) who reported that, EVLA occlusion rates were 93.6%. In addition, literature showed that, the venous occlusion rate after EVLA with the 1470 nm laser and radial fiber has been reported elsewhere to be 99.6-100% (Pannier et al., 2011; von Hodenberg et al., 2015). One sure thing is that the tendency in surgical units is the decreasing incidence of EVLA complications e.g (deep vein thrombosis) which can be attributed to both the increasing experience of surgeons in using the technique and technological advancements in surgical appliances (Marsh et al., 2010).

Going with the results of the present study, it was reported that, there was higher recurrence rate of varicose veins and lower occlusion rate of treated veins with ultrasound guided foam sclerotherapy when compared to (Pang et al., 2010) which reported a success rate of 100%. However, Koroglu et al. (2011) combined laser ablation with ultrasound guided foam sclerotherapy, starting by laser and confined foam for residual varices and concluded that, EVLA and concomitant US-guided foam sclerotherapy is an effective, safe, minimally invasive treatment option with good cosmetic and clinical results in both isolated truncal and truncal with perforating vein insufficiency groups.

Conclusion

In conclusion, Laser ablation found to be superior to foam sclerotherapy guided by ultrasound for treatment of varicose veins. However, this study has some limitations like small sample size and short duration of follow-up. However, the results are very encouraging especially with laser ablation. A longer duration of follow-up with a larger sample size will definitely help in establishing the ideal method of treatment in our institution.

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