Original Research Article

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EVLT with foam sclerotherapy for varicose veins: a single unit study

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ABSTRACT

Background: The true incidence of varicose veins in our country is not known as majority of patients with mild to moderate varicosities do not report to the physicians and only patients with complication like eczema, ulceration and bleeding are seen in clinics and hospitals. The search for a more effective means of prevention and for the perfect cure for this common condition continues. The aim of this study was to assess feasibility of Endovenous laser therapy with foam sclerotherapy for varicose veins with SFJ/SPJ incompetence.

Methods: Out of two hundred and fifty (n = 250), the most common age group was between 31-40 years. 68% were females. Left limb was more affected. The patients presented with varied symptoms, out of which painless dilated and tortuous veins was most common. Long Saphenous system was the most common venous system affected by varicosity. The median operating time for one system was 35 mins. Visual analog scale for pain (VAS) was median 1 at 24 hours. 25 patients had pain for 2 weeks, 30 patients had ecchymosis, 45 patients had neuralgia, 35 patients had pain, none of the patients had skin burns and one (1) patient developed DVT. Mean hospital stay was 1 day. Follow up at 3 months showed, no pain and no scar.

Results: In this retrospective study, we found that incidence of colorectal carcinoma is more between 40-60 years of age with male predominance; lymph node metastasis is more than metastasis in any other sites. CT scan can diagnose lymphatic metastasis and infiltration in surrounding tissue more accurately. Percentage of sphincter saving procedure were low in rectal malignancies in our study.

Conclusions: At present, endovenous laser ablation with Foam Sclerotherapy of both the GSV and SSV shows considerable promise in the treatment of varicose veins. Avulsion is not required. The advantages of this procedure include ease, safety, cosmesis and durability.

Keywords: Endovenous laser therapy, Foam sclerotherapy, Varicose veins

INTRODUCTION

The true incidence of varicose veins in our country is not known as majority of patients with mild to moderate varicosities do not report to the physicians and only patients with complications like eczema, ulceration and bleeding are seen in clinics and hospitals. These complications are a major cause of morbidity.^{1,2} Varicose veins have an estimated prevalence between 5% and 30% in the adult population, with a female: male predominance of $3:1.^3$ Varicose veins can cause significant disability and affect the quality of life.

Awareness and health education has helped in patients reporting early particularly in urban areas. The search for a more effective means of prevention and for the perfect cure for this common condition continues. There has been a paradigm shift in past decade in treatment of varicose veins. Since the 1990s, new techniques for the treatment of varicose veins have emerged, including laser treatment. Carlos Bone was the first to introduce Endovenous Laser Therapy (EVLT).⁴

The various techniques available to treat varicose veins include Compression stockings, Ligation and stripping, Avulsion of perforators, Endovenous Laser ablation, Radiofrequency ablation, Foam Sclerotherapy, Liquid Sclerotheray, Glue, TIPP and SEPS.

There is no single gold standard method for all the cases. Studies have shown that combination of various methods give better results. We report our experience (2012-2016) with treatment of 250 consecutive cases of varicose veins, with Laser ablation combined with Foam Sclerotherapy.

The aim of this study was to assess feasibility of Endovenous laser therapy with foam sclerotherapy for varicose veins with SFJ/SPJ incompetence

METHODS

A total of two hundred and fifty (n=250) patients underwent Endovenous Laser Therapy with Foam Sclerotherapy by a single Unit of Department of Vascular surgery, Manipal Hospitals from May 2012 to April 2016.

All consecutive patients were included having either unilateral or bilateral lower limb varicose veins and with or without venous ulcer. All included patients had SFJ incompetence. The patients excluded from the study had competent SFJ / SPJ and Varicose veins with DVT.



Figure 1: A) and B) Pre-operative SFJ incompetence (reflux).

Detailed history with thorough clinical examination was done in all the patients. Venous Doppler of the affected limbs was carried out in all the patients, and Sapheno-Femoral Junction/Sapheno-Popliteal Junction incompetence confirmed (Figures 1A and 1B). The routine pre-operative investigations and pre-anesthetic check was done. Informed written consent was taken from each patient and the technique explained in detail to all.



Figure 2: Cannulation of GSV at ankle (Ultrasound guided).



Figure 3: Introduction of cannula and laser fiber (980nm diode).

Proper marking of the side of the surgery with all the incompetent perforators was done with a permanent marker before shifting the patients to elective theatres. All the patients underwent the procedures under spinal anesthesia and supine position.



Figure 4: Cannulation at ankle for radial fiber (1470nm).

The affected limbs were prepared with povidine-iodine solution and sterile, disposable drapes were used. For GSV ablation, the leg to be treated was flexed and externally rotated at the hip, and the knee slightly flexed. Using ultrasound guided marking, the GSV was cannulated just above ankle or below the knee (Figure 2).

For SSV ablation, the affected leg was flexed, and cannulation done posterior to the lateral malleolus.



Figure 5: Introducing radial fiber into the sheath.



Figure 6: Marking of the LSV along the fiber tip till SFJ.

In first 150 cases, a guide wire was passed beyond the SFJ or SPJ. 5-Fr catheter is then passed over the guidewire (Figure 3). The laser fiber (bare tip 980 nm diode) was inserted as far as the tip of the catheter following which the latter was withdrawn by 2 cm so that the laser fiber protrudes beyond the catheter. In next 100 cases, radial fiber (1470 nm) was used (Figure 4). After cannulation, a smaller guide wire and sheath (6-Fr) were introduced into the vein and the fiber was passed till the SFJ/SPJ (Figure 5). The vein was marked along the light of the fiber tip (Figure 6).



Figure 7: Ultrasound confirmation of SFJ.

The SFJ / SPJ junctions confirmed with ultrasound and laser tip positioned about 2 cm distal to them (Figures 7 and 8). Up to 200 ml of tumescent anesthetic solution infiltration was given along the length of the GSV/SSV to be ablated.^{5,6}



Figure 8: Confirming the position of laser tip (2 cms below SFJ).



Figure 9: Firing of the laser.

The laser fiber was fired during stepwise withdrawal (Figure 9). Delivery of 80 J/cm and 8 Watts energies was used. During treatment, manual pressure was exerted over the vein. The Laser firing and vein occlusion confirmed with ultrasound (Figure 10).



Figure 10: Ultrasound confirmation of laser firing and vein occlusion.



Figure 11: Foam preparation (Tessari method).

The laser was fired till just below knee. The laser is the removed and sheath left in the vein. Foam was the prepared with sodium tetradecyl sulfate injection using Tessari method (Figure 11) and injected below knee into to GSV.⁷ Foam was also injected in all the dilated veins and incompetent perforators (Figure 12). No avulsions were done in all the cases.



Figure 12: Injecting foam into incompetent perforators.

Following sheath removal, the exit wound closed with a suture-strip and a compression bandage was applied. Patients were mobilized on the same day and encouraged to resume normal activity as soon as possible and are discharged either same day or early next day (within 23 hours).

All the patients with cellulitis were first treated conservatively for cellulitis and then subsequently underwent EVLT with Foam Sclerotherapy.

All patients were followed up in outpatient clinic at 1 week (for removal of compression bandage and advised class II below knee stockings), 3 months and 24 months. Post-operative complications were noted.

RESULTS

Out of Two hundred and fifty (n = 250), 170 (68%) were females and 80 (32%) were males. The age of the patients

ranged from 20-68 years, the most common age group was between 31-40 years (Table 1).

Table 1: Demographic data.

Parameter	Values		
Gender			
Male	80 (32%)		
Female	170 (68%)		
Age groups			
20-30 years	20		
31-40 years	118		
41-50 years	46		
51-60 years	44		
61-70 years	32		

Twenty four percent (24%) patients (60) had family history of similar complaints.

Left limb was more affected, 150 cases (42%) than right limb, 70 cases (28%) and bilateral limbs in 30 cases (12%) (Graph 1).



Figure 13: Limbs involved.

The patients presented with varied symptoms, out of which painless dilated and tortuous veins was most common, 200 (80%) patients, followed by aching pain 50 patients (20%), 63 (25%) cases had limb edema and Venous ulcer was present in 50 (20%) of cases.

Table 2: Symptomology.

Symptoms	No. of cases (n=250) (%)
Dilated tortuous veins	250 (100%)
Painless veins	200 (80%)
Pain	50 (20%)
Limb edema	63 (25%)
Venous ulcer	50 (20%)
Venous eczema	150 (60%)
Lipodermatosclerosis	100 (40%)
Cellulitis	50 (20%)

60% patients had venous eczema (itchy and dry skin), 40% patients had lipodermatosclerosis (tender, tight and hardened skin) and 20% presented with cellulitis of lower limbs secondary to venous insufficiency (Table 2 and 3).^{5,6}

Table 3: The CEAP Clinical classification for our
study was done.

CEAP Classification	No. of limbs (%)	
C2 - Varicose veins	250 (100%)	
C3 - Edema	63 (25%)	
C4		
Pigmentation / eczema	150 (60%)	
Lipodermatosclerosis /atrophie blanche	100 (40%)	
C5-Healed ulcer	25 (10%)	
C6-Active venous ulcer	50 (20%)	

Long Saphenous system was the most common venous system affected by varicosity (72%), Short saphenous system was involved in 6% patients and in 22 % patients both the systems were involved (Table 4).

Table 4: Venous System involved.

Venous system involved	No. of cases (n=250) (%)
Long saphenous system	180 (72%)
Short saphenous system	15 (6%)
Both systems	55 (22%)

The median operating time for one limb and one system was 35 mins (range 30-45 mins) and for bilateral GSV the median time was 55 mins (range 45-60 mins). Visual analog scale for pain (VAS) was median 1 (range 0-2) at 24 hours. 25 patients had pain for 2 weeks, 30 patients had ecchymosis, 45 patients had neuralgia, none of the patients had skin burns and only one patient developed DVT.

Mean hospital stay was one day. Patients were discharged with pressure dressing, removed after 1 week and advised below knee compression stockings (Table 5).⁸

Table 5: Intraoperative and post-operative data.

Parameters	N=100	Range	
Operating time			
Unilateral	All	30-45 mins	
Bilateral	All	45-60 mins	
Hospital stay post op.	All	01-02 days	
Post-operative complications			
Immediate Pain (VAS)	All	0-2	
Pain	25	0-2 week	
Ecchymosis	30	-	
Neuralgia	45	-	
Recurrence	01	2 years	
DVT	01	2 years	

Follow up at 3 months showed, 92% of patients (230) had collapsed cord like vein and 8% (20) patients) showed thrombosed vein with patchy recanalization.

All the patients had no pain and no scar. Venous ulcer patients had healing of ulcer without skin grafting in 12 (40%) cases (Figure 14).



Figure 14: Follow-up Doppler after 3 months.

Follow up at 24 months, one patient has flow in GSV and hence recurrence.

DISCUSSION

The aim of minimal access treatments like EVLT and foam sclerotherapy is to reduce complications and lead to acceptable short and long-term results.^{8,9}

Although saphenous vein surgery is accepted as a standard treatment option, studies have suggested a high recurrent rate of up to 71% after high ligation alone in long follow-up.^{10,11}

Studies have shown that EVLA of GSV and SSV is minimally invasive, safe and efficient treatment option.¹²

The American College of Phlebology Guidelines Committee and The Society for Vascular Surgery, using an accepted process for guideline developments, developed a consensus to recommend thermal ablation (EVLA and RFA) as safe and effective methods for treatment of incompetent saphenous veins. And EVLT being one of the most common procedures performed on an outpatient basis.^{13,14}

Most studies of EVLT have used either 980 nm or 1470 nm diode lasers. The heat generated by the laser is believed to produce steam bubbles that cause thermal damage to the endothelium and sub-endothelial layer resulting in focal coagulative necrosis and shrinkage leading to thrombotic occlusion of the vein.

Histological studies at 3 and 6 months following EVLT indicate failure of endothelial regeneration and

progressive damage to the muscle layers of the vein wall resulting in further shrinkage.^{15,16}

In our study, two different types of fibers were used. For first 150 cases, bare tip fiber was used (980 nm). In this the laser is irradiated only forward and hence the chances of perforation of the vessel wall are high. Radial fiber was used in next 150 cases and now routinely used in our center, irradiates in entire circumference via prism and hence prevent the perforation of the vein wall.

Foam Sclerotherapy is widely applicable in treating venous diseases. Foam Sclerotherapy has significantly inferior occlusion rates compared with open surgery or EVLA, and results in additional treatments.^{17,18}

Authors recommend use of EVLT along with Foam Sclerotherapy (below the knee) to avoid nerve injury. Avulsion of perforators can be avoided by using Foam injections separately into the previous marked perforators. Authors prescribe graduated compression stockings to be worn for at least 6 weeks after operation. Class II below knee compression stockings may be designed to apply graduated or uniform compression. The occlusion rates reported in literature after EVLT are around 97%.^{19,20} Varicose veins do need a treatment for better quality of life and to reduce disability.²¹

CONCLUSION

At present, endovenous laser ablation with Foam Sclerotherapy of both the GSV and SSV shows considerable promise in the treatment of varicose veins. Avulsion is not required. The advantages of this procedure include ease, safety, cosmesis and durability.

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