

Evaluation of Efficacy of Foam Sclerotherapy in Treating Truncal and Perforator Reflex: A One Year Prospective Hospital Based Study

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Abstract

Background: Veins varicose are the most common condition which affects the 30% of the adult population. This can be seen more in males than females. The present study aim is to see the efficacy of foam sclerotherapy in treating truncal and perforator reflex in varicose patients. *Materials and Methods:* This study was conducted in the Department of surgery, 2008-2010 for the period of 2 years. Patients came to the surgery OPD with veins varicose was included based on the inclusion and exclusion criteria. The entire patient's demographic and clinical data was collected. A total of 56 patients were included in the study. All the patients subjected to the foam sclerotherapy and observed for 1 year. This study was ethically cleared from Institutional Human Ethics Committee (IHEC). All patients were explained detailed procedure and informed consent was obtained from each patient. *Results:* In this study males were more than females. 50 patients were in the primary treatment and 6 patients showed recurrent/residual varicose. In primary treatment maximum number of patients showed SFJ incompetence. 7 patients showed pain along the injected site. Thrombophlebitis is the major complication after the surgery. *Conclusion:* Foam sclerotherapy has its own advantages compared to the other procedures patients with veins varicose. It reduced the economic burden and patients in abolishing the truncal reflex as well the waiting list for surgery.

Keywords: Foam Sclerotherapy; Truncal; Perforator Reflex; Varicose; Vein.

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Introduction

Varicose veins are dilated, tortuous superficial veins which affect the lower extremities. 20-30% of adult population has varicose veins. Many treatment modalities are available and each has its own advantages and disadvantages. First one is the surgical management. In the surgical management of long saphenous vein varices has traditionally consisted of saphenofemoral ligation and stripping of GSV to the knee. Visible truncal and non saphenous varices in calf as well as varicosed GSV branches in the thigh are treated with hook phlebectomies or sclerotherapy [1,2]. This procedure must be performed under general and anaesthesia and is associated with several complications. The recurrence rate following saphenofemoral junction ligation and stripping at five years is reported between 20% and 28% and in the absence of GSV stripping (saphenofemoral ligation only) recurrence rate is doubled for primary GSV surgery, the overall complication rate is between 17% and 20% while that for recurrent varicose veins is 40% [3-5]. Following conventional surgery, groin haematoma and disrupted superficial pudendal venous drainage are stimulants for neovasclarisation in the groin which is the source of venous reflux recurrence [6].

Radiofrequency ablation (RFA) involves the use of high frequency alternating current delivered via a bipolar catheter, placed intraluminally under duplex guidance, to obliterate the vein lumen. The current causes ionic agitation and local heating resulting in venous spasm and irreversible denaturation of collagen with intimal destruction. This produces a fibrotic luminal seal with minimal thrombus formation. The procedure is performed under general, regional or tumescent local anaesthesia. The recurrence after 2 years is between 10-15% and Nicolini reported that this incidence remained

unchanged after three years. By avoiding a groin dissection, RFA provides no stimulus for neovascularisation and may potentially reduce recurrence [7-9].

In EVLASER uses laser energy delivered laser fibre to obliterate the vein. Steam bubbles generated from boiling blood in the lumen cause heat injury to the vein wall. Laser is available in various wavelengths and types 810-, 940-, 980-nm diode and 1064- or 1320-nm Nd:Yag. Recently 1470 nm diode laser has been introduced. The GSV or small saphenous vein (SSV) is cannulated at the ankle or just below the knee either by needle puncture or via a cut down. Vein closure at the end of follow-up of up to 2 years varies from 90-100%. Re-treatment for recanalisation is seen in less than 10% of cases. Failure of EVLASER or early recanalisation appears to be related to lower laser fluence and lower doses of energy delivered per length of treated vein. A higher body mass index is linked to a greater risk of failure. Results after EVLA with 1320 nm showed good occlusion rates, and less bruising and less pain. The recent article on one year follow up with 1470 nm diode laser claims occlusion rate of 100% with less complication rates [10].

Sclerotherapy

Sclerosing agents have been employed for treating varicose veins for over 100 years. Liquid sclerosing agents have their greatest effect in the smallest incompetent veins, usually non truncal varicosities below the knee (macro sclerotherapy) and telangiectasias (microsclerotherapy). The technique is not useful however, if proximal venous hypertension exists and any proximal venous reflux should be corrected first.

Foam sclerotherapy method injection of sclerosing agent such as sodium tetradecyl sulphate, polidoconal in a foam vehicle, the sclerosing agent having been mixed forcibly with air. Several techniques have been proposed to produce sclerosant foam and Tessari and Frullini techniques appear to give the most favourable results.

The foam replaces blood in the vein, which enhances the efficacy of the sclerosing agent by reducing the volume of sclerosant required for the treatment and increasing the effective surface area of the sclerosant in contact with the vein wall [11,12]. Duplex monitoring during the procedure is necessary to prevent spread of foam into femoral vein. The present study conducted to evaluate the efficacy of foam sclerotherapy in treating truncal and perforator reflux.

Materials and Methods

Study Settings and Time Period

The study is prospective hospital based study conducted in the department of surgery. It was done for 2 years (May 2008 to May 2010).

Inclusion Criteria

- Study participants will be patients of any age with varicose veins affecting long or short saphenous system or isolated perforators or the combinations
- Truncal / perforator reflux proven by duplex
- C4, C5 and C6 patients (according to CEAP classification)
- Patients who have undergone previous surgery for varicose veins were included in the study.

Exclusion Criteria

- The patients who are classified as C1, C2 and C3 degree on CEAP classification are excluded from the study
- All patients with venous malformation
- Acute deep venous thrombosis
- Post phlebitis legs
- Associated arterial disease or ABI of less than 0.9
- Cardiac patients and neurological diseases are excluded from the study
- Patients who are not turning up for follow up

Procedure

A total of 56 patients are enrolled as inpatients after clinical examination is in the standard protocol. In patients with C6 varicose veins, the size of ulcer was measured during the first clinical examination and followed up during subsequent reviews and photographed. They are subjected to duplex study. Study of IVC, iliac veins, femoral veins, popliteal vein and tibial are examined to rule out venous thrombosis and any reflux in deep venous system. The superficial system is assessed for reflux in the SFJ, SPJ and all the perforators. In all the veins any reflux more than 0.5 sec inferred as positive. All the incompetent perforators are assessed and their levels from the heel given in cms, the amount of reflux, size of veins at the junction and at various levels are assessed.

Type of Intervention

The sclerosant used was 3% pilodoconol. Shown strength agent foamed as per Tessari double syringe method using room air, the ratio of air to liquid are 4:1. The volume of foam injected depends on the diameter and length of the vein to be sclerosed. The maximum amount of foam used in this study is 20 ml in single sitting. Vascular access for foam injection is usually under duplex guidance with direct puncture of GSV/SSV/Perforators followed by limb elevation alone. The deep veins are assessed for evidence of foam. If any present they are cleared by ankle flexion and extension maneuvers, follow up assessment was done to rule out DVT. Then compression bandage are applied with focal compression over larger veins and saphenous vein post treatment bandage are replaced with class 2 compression after 24 hrs for 14 days. If the patient was not fully relieved or any residual varicosities found during follow up further sitting of sclerotherapy was given. Surveillance was be done by inspection, palpation and duplex study after 1 year. The primary outcome is gaining of reflex and the secondary outcomes are recurrence of canalization, neovascularisation and post procedure complications [13].

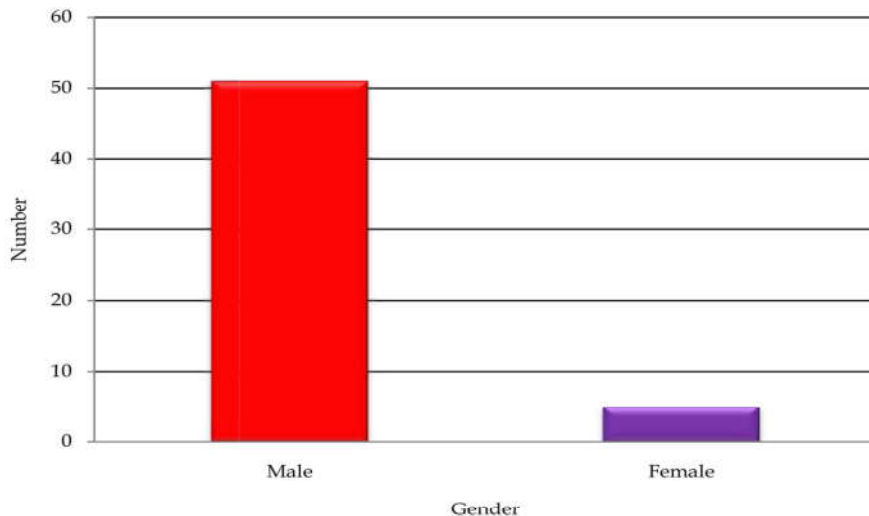
Statistical Analysis

The data was expressed in number and percentage. Microsoft excel 2017 used to calculate the percentage.

Results

This study included 56 patients. 50 patients had primary treatment and 6 are recurrent/ residual group. Maximum number of patients (n=19) had SFJ incompetence followed by perforator (n=13) and

SFJ+perforator incompetence (n=13). 3 patients had SPJ incompetence and 1 patient had SFJ+SPJ+perforator incompetence and SPJ+perforator incompetence. 7 patients showed complete ulcer healing in SFJ incompetence category. One patient had superficial thrombophlebitis it settled with oral antibiotics. One patient had transient visual loss one hour after the procedure, he was evaluated in ophthalmology department. Fundus examination - normal. Cardiac evaluation done - ECHO - normal. Out of 19 cases treated for SFJ incompetence, 5 patients had residual reflux of SFJ with patent GSV thigh segment (26%). This occurred in vein size more than 7 mm. In perforator incompetence all veins remained sclerosed. Patients treated with SFJ incompetence with perforator incompetence 11 cases veins were completely sclerosed at 1 year follow up. 1 patient had recanalised GSV in 3 months follow up another had recanalised GSV in 1 year follow up (for those the 2 vein size was 9 mm). Both had repeat foam following which symptoms are relieved. 3 patients for all 3 veins remained sclerosed at the end of one year in SPJ incompetence. SPJ incompetence with perforator incompetence We have treated one patient (C4) for whom the vein remained sclerosed at the end of one year. SFJ & SPJ incompetence with perforator incompetence we have treated one patient (C6) for whom GSV was patent at the end of one year. Vein size 8 mm. Total number of SFJ Reflux Treated (SFJ IC, SFJ + Perf, SFJ with combination of other Reflux) with 1 year follow up group - 33 Total number of GSV that are sclerosed at the end of 1 year - 25 Recanalisation seen in 8 patients all had vein diameter more than 7 mm. 3 patients developed thrombophlebitis, 2 breathlessness and pain along the injected site. 6 patients developed recurrent/residual varicose veins. 2 SFJ incompetence, 1 SFJ + Perf incompetence and 3 Perf incompetence.



Graph 1: Distribution of patients based on gender

Table 1: Number and percentage of patients based on primary treatment

Anatomical distribution of Reflux	No of cases	Percentage (%)
SFJ Incompetence	19	38.00
SPJ Incompetence	3	6.00
Perforator	13	26.00
SFJ +Perforator Incompetence	13	26.00
SFJ + SPJ + Perforator Incompetence	1	2.00
SFJ + SPJ Incompetence	0	0.00
SPJ + Perforator Incompetence	1	2.00
Total	50	100.00

Table 2: Distribution of patients based on category treated

Anatomical distribution of Reflux	C6	C5	C4	Total
SFJ Incompetence	9	5	5	19
SPJ Incompetence	2	0	1	3
Perforator	7	3	3	13
SFJ +Perforator Incompetence	5	3	5	13
SFJ + SPJ + Perforator Incompetence	0	0	1	1
SFJ + SPJ Incompetence	0	0	0	0
SPJ + Perforator Incompetence	0	0	1	1
Total	23	11	16	50

Table 3: Number and percentage of patients with complications

Type of complication	Number	Percentage (%)
Thrombophlebitis	3	20.00
Breathlessness/Dyspnoea	2	13.33
Transient visual loss	1	6.67
Extravasation/Skin necrosis	1	6.67
Skin allergy	1	6.67
Pain along the injected site	7	46.67
Total	15	100.00

Table 4: Number and percentage of patients with recurrent/residual varicose in different category

Anatomical distribution of Reflux	C4	C5	C6	Total
SFJ Incompetence	1	0	1	2
SFJ +Perf Incompetence	0	0	1	1
Perf Incompetence	1	1	1	3
Total	2	1	3	6

**Image 1:** SFJ reflux with ulcer 6x4 in the foot

Discussion

Larger veins can be successfully treated with the foam technique compared to liquid sclerotherapy. Sclerotherapy and newer techniques preserve the pudendal and lower abdominal wall venous drainage and prevent haematoma formation in the groin thus potentially removing stimulus for neovascularisation [14]. Cebrera et. al published a study on a clinical series of 500 legs treated with foam sclerotherapy. He reported that after 3 or 1 more years 81% are remained occluded and 97% of superficial vertices had disappeared [15]. A number of studies are published on problems in the management of varicose veins. It was explained that recurrent verocises had poor outcome compared to new one. Creton et.al have reported a combined surgical and foam sclerotherapy for patients with recurrent varices. 93% had developed verices at 40 days study [16].Thrombophebitis is the most important complication was observed in this study. The success rate varies between 88-93% depending on the technique employed to produce foam. Foam sclerotherapy has the advantages like treating truncal reflux as well as repeatability of the procedure. As more than 60% out patients come for treatment of varicose veins it will be beneficial for the patients in abolishing the truncal reflux as well the long waiting list for conventional surgery and the expenditure incurred can be cut short [17,18]. Foam sclerotherapy plays important role in the treatment of vericosis. Use of this method will reduce the complications and facilitates surgical treatment of non recurrent and recurrent varicose veins.

Conclusion

The present study shows the feasibility of using foam sclerotherapy in the management of varicose veins. It can use in the obliteration of major and minor varicose veins. It has a limitation of development of thrombosis it can be prevented by using prophylactic anticoagulant therapy.

Conflict of Interest: No conflict of interest.

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